



American National Standard/American Dental Association Specification 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
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Council on
Scientific Affairs

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

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 47 for Dental Units. 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. 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 specification 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.

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FOREWORD

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

This revised specification 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 Specification 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.

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1 SCOPE

ANSI/ADA Specification 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 disconnect 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

for the use of authorized persons in the practice of dentistry and/or its associated procedures.

- 3.8 Dental unit – item of dental equipment through which electrical power and/or various fluids or gasses are supplied to a number of dental instruments and devices. It is usually fitted with conveniently oriented instrument holders and controls, and consists of interconnected sub-units of dental equipment and instruments providing a functional unit for dental use.
- 3.9 Incoming air – compressed air supplied to the dental unit.
- 3.10 Incoming solution – solution of substances defined by the manufacturer and introduced in combination with, or in place of, the incoming water in order to improve or maintain the quality of the procedural water or for other reasons.
NOTE: Other reasons may be as coolant for cutting burs, medicament for oral cavity, etc.
- 3.11 Incoming water – water supplied to the dental unit for procedural or non-procedural use.
- 3.12 Incoming-air connection point – any port on the dental unit for connection to a compressor.
- 3.13 Incoming-water connection point – any port on the dental unit for connection to a municipal water supply.
- 3.14 Non-procedural water – water supplied by the dental unit for purposes other than use in the oral cavity.
EXAMPLE: Cuspidor bowl rinse water or water venturi supply water.
- 3.15 Outgoing solution – solution of substances, defined by the manufacturer, emerging from the dental unit in combination with, or in place of, the outgoing water.
- 3.16 Outgoing water – water emerging from the dental unit.
- 3.17 Procedural water – water supplied by the dental unit for use in the oral cavity.
EXAMPLE: Handpiece coolant water, syringe water, scaler coolant water or rinse cup water.
- 3.18 Retraction – re-entry of water, air and/or other medium into the dental unit or the dental instruments due to flow reversal.
NOTE: Retraction may be caused e.g. by momentary dynamic pressure variations during turning off the instruments.
- 3.19 Rinse water – water for cleaning.
- 3.20 Spill-over level – highest possible level of water or solution in a device above which the fluid spills over the edge.
- 3.21 Wastewater – any solution that is discharged into the drainage system from the dental operatory. NOTE: Wastewater may be discharged from e.g. the cuspidor, saliva ejector, air-water separator, amalgam separator.
- 3.22 Wastewater connection point – port for the connection through which wastewater flows and is discharged into the drains.
- 3.23 Water venturi – device using water flow to produce a vacuum.
- 3.24 Water-disinfection system – system intended to reduce the number of colony-forming units of bacteria per milliliter of water or solution.

4 CLASSIFICATION

4.1 According to type of protection against electric shock

Dental units may be classified as follows.

A Class I equipment

Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of accessible conductive parts to the protective (earth) conductor in the fixed wiring of the installation so that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

B Class II equipment

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

4.2 According to degree of protection against electric shock

Dental units may be grouped by type as follows.

A Type B equipment

Class I or II equipment with an internal electrical power source providing an adequate degree of protection against electric shock, particularly regarding:

- Allowable leakage currents;
- Reliability of the protective earth connection (if present).

Type B equipment is, for example, suitable for intentional external and internal application to the patient, excluding direct cardiac application.

B Type BF equipment

Type B equipment with an F-type isolated (floating) applied part.

4.3 According to mode of operation

Dental units are a type of equipment with intermittent operation.

5 REQUIREMENTS AND RECOMMENDATIONS

5.1 General requirements

5.1.1 Design

5.1.1.1 Electrical requirements given in 5.3 are only applicable to electrically powered dental units. The general requirements referred to in IEC 60601-1:1988, are applicable to non-electrical dental units as well.

If the dental unit is an integral part of the dental patient chair, then ISO 6875 applies in addition.

5.1.1.2 Dental units shall be designed, constructed and manufactured so that when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they cause no reasonably foreseeable danger to the patient, to the operating personnel or to the surroundings in normal use and in single-fault condition.

These requirements cannot be objectively assessed. They are considered as fulfilled if all the tests specified in Section 7 are passed.