ANSI/ADA Specification No. 48
Reaffirmed by ANSI: October 26, 2015

American National Standard/
American Dental Association

Specification No. 48

Visible Light Curing Units

Modified adoption of *ISO 10650-1:2004, Powered polymerization activators — Part 1: Quartz tungsten halogen lamps*

ADA American Dental Association®
Council on Scientific Affairs

2004

SPECIFICATION NO. 48 FOR VISIBLE LIGHT CURING UNITS

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Specification No. 48 for Visible Light Curing 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. 48 as an American National Standard on August 25, 2004.

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

P. L. Fan (chair), American Dental Association, Chicago, IL; Joseph B. Dennison, Univeristy of Michigan School of Dentistry, Ann Arbor, MI; William J. Dunn, United States Air Force, San Antonio, TX; Scott Erickson, 3M ESPE, St. Paul, MN; Paul D. Hammesfahr, L.D. Caulk, Milford, DE; Frank Lentine, Lentine Enterprises, Taylor, MI; Daniel L. Leonard, Ashville NC; Keith B. Moore, Indiana University School of Dentistry, Indianapolis, IN; Howard Roberts, United States Air Force, Great Lakes, IL; Frederick A. Ruggeberg, Medical College of Georgia School of Dentistry, Augusta, GA; and Jeff Zawada, A-Dec, Newberg, OR.

SPECIFICATION NO. 48 FOR VISIBLE LIGHT CURING UNITS

FOREWORD

(This Foreword does not form a part of ANSI/ADA Specification No. 48).

This proposed specification is based on ISO 10650 – 1: 2004, Powered visible light curing units – Part 1: Quartz tungsten halogen lamps, with the exception that a requirement value is defined for radiant exitance for the 400-515 nm (blue light) region.

This specification specifies requirements for the 190 –385 nm wavelength region, the 400-515 nm wavelength region and the wavelength region above 515 nm and test methods for powered visible light curing units. This specification refers to IEC 60601-1:1988, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:1988. This specification uses wavelength regions based on cut-off filters. Thus the 190 nm to 385 nm region includes not only the ultraviolet region but also the near blue wavelength region of around 380 nm. The 400 nm to 515 nm region is taken as the blue region for blue light curing (powered polymerization activation). The region above 515 nm expands to approximately 1 100 nm, which is the detection limit of the detector specified in this specification. The test methods described in the specification do not give absolute values nor do they reflect energy emitted as black body radiation. Nevertheless, the values obtained using these test methods are used in conjunction with this specification.

Addendum to the Foreword for this Reaffirmation:

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

SPECIFICATION NO. 48 FOR VISIBLE LIGHT CURING UNITS

CONTENTS

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 48 FOR VISIBLE LIGHT CURING UNITS

1 SCOPE

This specification gives requirements and test methods for visible light curing units with powered tungsten-halogen lamps in the blue wavelength region intended for chairside use in polymerization of dental resin-based materials. This specification is also applicable to rechargeable battery-powered visible light curing units. It does not cover powered visible light curing units used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances. This specification takes priority over IEC 60601-1:1988 where specified in the individual clauses of this specification.

2 CONFORMANCE

Not applicable.

3 NORMATIVE REFERENCES

The following normative documents contain provisions, which through reference in this text constitute provisions of this specification. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942-4, Dental vocabulary — Part 4: Dental equipment.

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

IEC 60601-1-2:1993, Medical electrical equipment — Part 1: General requirements for safety — 2. Collateral Standard: Electromagnetic compatibility — Requirements and test.

4 TERM(S) AND DEFINITIONS(S)

4.1 For the purposes of this specification, the terms and definitions given in ISO 1942-4 and in clause 2 of EC 60601-1:1988 apply.

5 CLASSIFICATION

5.1 Type 1: Visible light curing units powered with mains supply.

5.2 Type 2: Visible light curing units powered with rechargeable battery supply.

6 REQUIREMENTS

6.1 General

6.1.1 Design

The construction of powered visible light curing units shall provide for safe and reliable operation. If field-repairable, the visible light curing unit should be capable of being easily disassembled and reassembled