ANSI/ADA Specification No. 48-2-2010/ISO 10650-2:2007
Reaffirmed by ANSI: October 26, 2015

American National Standard/American Dental Association

Specification No. 48-2

LED Curing Lights

Identical adoption of ISO 10650-2:2007, *Dentistry – Powered polymerization activators – Part 2: Light – emitting diode (LED) lamps.*

ADA American Dental Association®
Council on Scientific Affairs

2010

LED CURING LIGHTS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 48-2 for LED Curing Lights. 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. 48-2 as an American National Standard on January 8, 2010.

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 (Chairman), American Dental Association, Chicago, IL;

Joseph Dennison, University of Michigan, Ann Arbor;

William Dunn, U.S. Air Force;

Scott Erickson, 3M ESPE, St. Paul, MN;

Paul Hammesfahr, Dentsply Caulk, Milford, DE;

Frank Lentine, Lentine Enterprises, Ltd., Taylor, MI;

Daniel Leonard, Asheville, NC;

B. Keith Moore, Indiana University, Indianapolis;

Frederick Rueggeberg, Medical College of Georgia, Augusta; and

Jeff Zawada, A-Dec, Inc., Newberg, OR.

LED CURING LIGHTS

FOREWORD

(This Foreword does not form a part of ANSI/ADA Specification No. 48-2 for LED Curing Lights).

This specification is an identical adoption of ISO 10650-2:2007, *Dentistry – Powered polymerization activators – Part 2: Light-emitting diode (LED) lamps*. ADA SCDP Working Group No. 6.33 on Activator Lights examined the international standard and found it acceptable for identical adoption as ANSI/ADA Specification No. 48-2.

This specification sets forth requirements and test methods for light emitting diodes (LED) type powered polymerization activators in the 190 nm to 385 nm wavelength region and the wavelength region above 515 nm. No requirements are given for the 400 nm to 515 nm wavelength region.

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 around 380 nm. The 400 nm to 515 nm region is taken as the blue region for powered polymerization activation. The region above 515 nm extends to approximately 1 100 nm, which is the detection limit of the detector specified in this document.

The test methods described do not give absolute values nor do they reflect energy emitted as black body radiation. The measured values are not true radiant exitance but are values obtained using the methods described in this document. Nevertheless, the values obtained using these test methods are used in conjunction with this document.

This specification refers to IEC 60601-1:2005, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:2005.

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.

LED CURING LIGHTS

1 SCOPE

This specification details requirements and test methods for powered polymerization activators with light-emitting diodes (LED) in the blue wavelength region intended for chair-side use in polymerization of dental polymer-based restorative materials.

This specification is not applicable to powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances.

This specification takes priority over IEC 60601-1:2005 where specified in the individual clauses of this document.

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 10650-1:2004, *Dentistry — Powered polymerization activators — Part 1: Quartz tungsten halogen lamps*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

(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. 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 ISO 1942, ISO 10650-1, IEC 60601-1 and the following apply.

3.1 Light-emitting diode (LED) lamp – semiconductor-based light emitting source.

3.2 Fully charged battery – battery which has at the beginning a charge of 80 % to 100 % of the first full charge.

4 CLASSIFICATION

For the purposes of this document, powered polymerization activators with light emitting diodes are classified as specified in ANSI/ADA Specification No. 48-2004, *Visible Light Curing Units*.

5 REQUIREMENTS

5.1 General

ANSI/ADA Specification No. 48-2004, 6.1 applies.

Test the LED lamps at each continuous irradiation mode or pulse mode of 10 s or longer stated by the manufacturer.

5.2 Radiant exitance