K110582

SPECIAL 510(K) PREMARKET SUMMARY

VALO® Cordless

APR 2 8 2011

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for VALO® Cordless.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	April 1, 2011

Name of the Device

Trade Name:	VALO® Cordless
Common Name:	Activator, ultraviolet for polymerization
Device Classification:	II
Classification Product Code:	EBZ

Legally Marketed Predicate Device to Which Equivalence is Claimed

The predicate device is VALO® (K083647). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

Product Description: Valo® Cordless is a visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials. The VALO Cordless is shipped as a system with the VALO Cordless wand, 4 rechargeable batteries, 2 for initial use and 2 for later use, a battery charger and 50 VALO Cordless Barrier Sleeves. An Instruction for Use is also included inside the packaging. The Instructions for Use details the function of the device and describes the modes for the VALO Cordless. VALO Cordless has three operating modes. They are Standard Power Mode: 1000mW/cm^2, High Power Mode: 1400mW/cm^2 and Xtra Power Mode: 3200mW/cm^2.

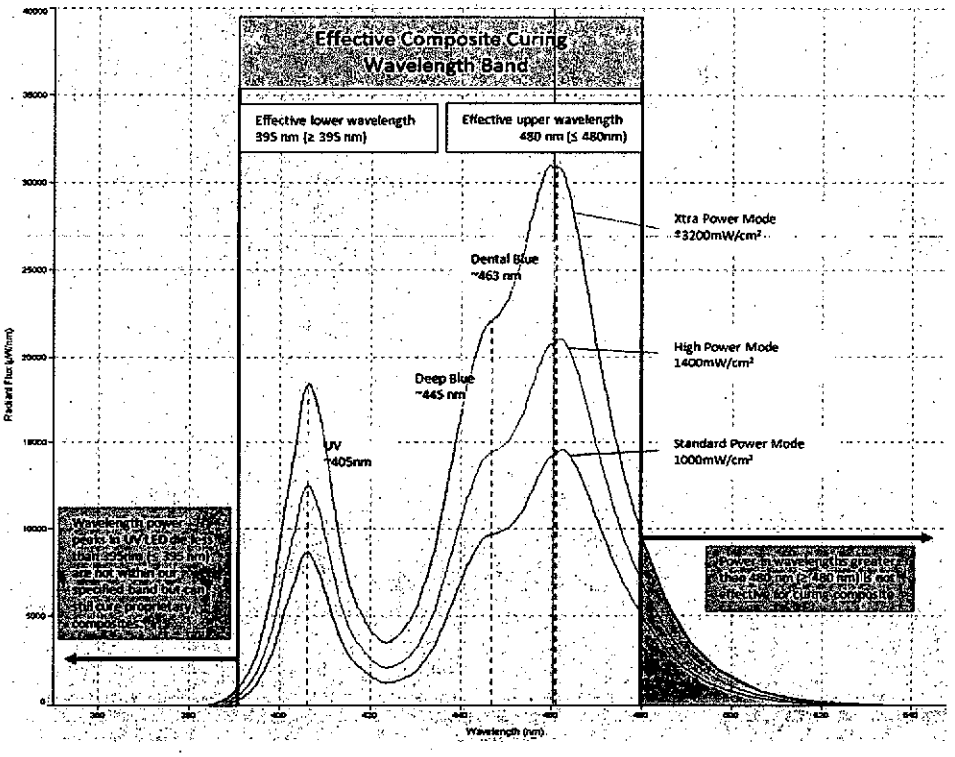
K110582

Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Technological Summary: The VALO CORDLESS curing light uses a custom, multi-wavelength Light Emitting Diode (LED) for producing the high intensity light (395 - 480 nm) capable of polymerizing all light cure dental materials. This intensity will also penetrate porcelain and is capable of curing underlying resin cements similarly to a quality halogen light.

The VALO CORDLESS curing light uses safe Ultradent VALO rechargeable batteries and battery charger.

Performance Data:

	VALO CORDLESS Curing Light
Wavelength range	395nm – 480nm (see qualification below) Effective output Power of VALO CORDLESS falls within the following wavelength range: • 395nm <= EP <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48 
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10%

K110582

	† Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation') • ** As measured by a Demetron® L.E.D, Radiometer* *† As measured by a spectrum analyzer* *Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer*

The following three tests were conducted along with bench tests described in the 510(k); depth of cure, software verification and validation and IEC 60601-1 Electrical Safety.

Conclusion:

Comparison Table

	VALO® (K083647)	VALO® Cordless
Power Supply	Wall powered, 12VDC, medical grade with adapters for International capability UL Approved	Same
Indications For Use	Source of illumination for curing photo-activated dental restorative materials and adhesives.	Same
Structure	Ergonomic wand	Same
Light	Blue and UV wavelengths	Same
Current control	Regulates current in the light source	Same
Buttons	Two buttons that function the light	Same
Power ON button	Located on handle of wand	Same
Power cord	8' length	Same
Time	Device indicates time and time selection	Same
Power Rating	Plasma Emulation Mode is 4500mW/cm²	Xtra Power mode is 3200mW/cm²
Operation	110VAC	110VAC

K110582

Substantial Equivalence:

The VALO™ SCOUT is substantially equivalent to the VALO™ which is also manufactured by Ultradent Products, Inc. These two products are manufactured from the same materials, utilize many of the same components, are calibrated to the same levels and parameters, are used in the same manner and fashion, and are designed to operate and function in a near identical manner. The VALO™ SCOUT was designed to be the VALO™ but without the cord. The programming code is near identical, save micro-controller variations and enhanced safety features. Both products have the same intended use and technological characteristics. Both products are safe and effective when used for as intended and for the purposes described.
The following three tests were conducted along with bench tests described in the 510(k); depth of cure, software verification and validation and IEC 60601 Electrical Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

APR 2 8 2011

Re: K110582
Trade/Device Name: VALO® Cordless
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: April 1, 2011
Received: April 5, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K110582

Device Name: VALO® Cordless

Indications for Use:

Source of illumination for curing photo-activated dental restorative materials and adhesives.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110582

Page 1 of 1

(Posted November 13, 2003)

 K110582/A1

April 18, 2011

K-51

Lauren Giles

Food and Drug Administration CDRH

Document Mail Center (HFZ-401)

10903 New Hampshire Drive

Silver Spring, MD 20850

Reference VALO Cordless Special 510(k) K110582

Dear Lauren,

Thank you for your quick review of the changes to our submission. I made all the changes you requested during our phone call on April 18, 2011. (detailed in emails dated April 14, 2011 and April 15, 2011).

- Added Form FDA 3654 for ADA Specification No. 27
- 510(k) Summary: Added new Summary which includes a statement : The following three tests were conducted along with bench tests described in the 510(k): depth of cure, software verification and validation and IEC 60601-1 Electrical Safety testing"
- 510(k) Summary: Provided a bold heading for Product Description
- Provided a statement that the Instructions for Use will be modified to include the correct trade name of the device, VALO Cordless.
- Included a complete copy of the 510(k) Summary
-

Please review these changes and feel free to contact me if you have any further questions. Thanks again for your quick review.

Kind regards,

Diane Rogers

Diane Rogers

Regulatory Affairs Manager

Ultradent Products, Inc.

ULTRADENT PRODUCTS, INC.
Questions?
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

SPECIAL 510(K) PREMARKET SUMMARY

VALO® Cordless

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Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

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Telephone:	800-552-5512 x4491, 801-553-4491
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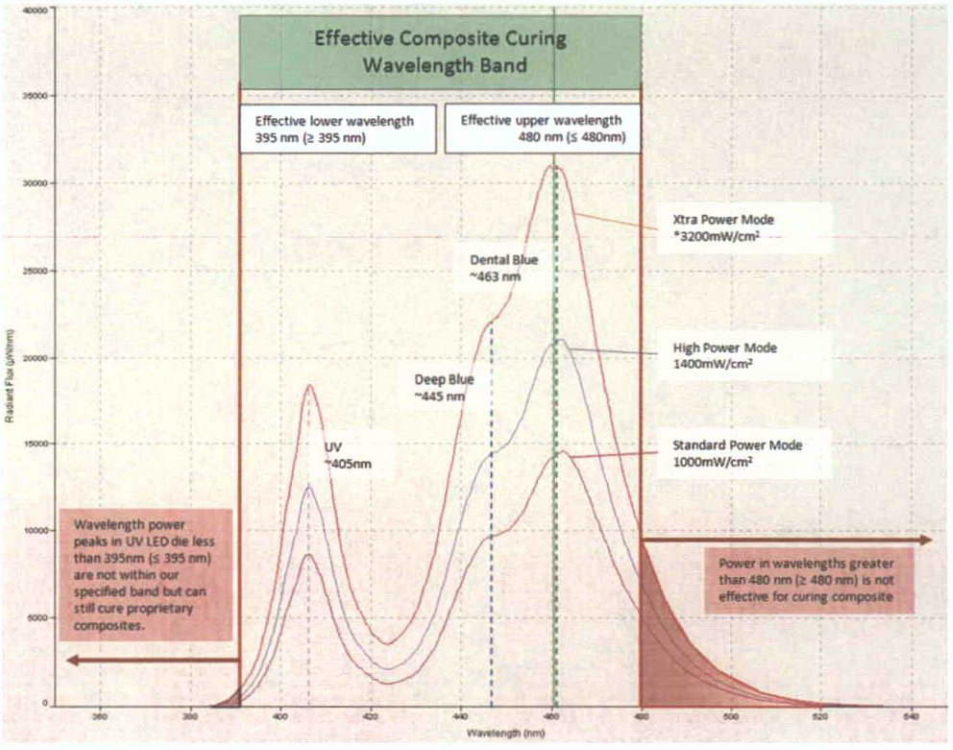
Wavelength range	395nm – 480nm (see qualification below) Effective output Power of VALO CORDLESS falls within the following wavelength range: • 395nm <= EP <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48 
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The following three tests were conducted along with bench tests described in the 510(k); depth of cure, software verification and validation and IEC 60601 Electrical Safety.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

ADA Specification No. 27 Resin Based Filling Materials (Section 7.7 only) (Depth of Cure test)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301) 443-1090 EF

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ADA Specification No. 27 Resin Based Filling Materials (Section 7.7 only) (Depth of Cure test)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.7	Depth of Cure, type 2 materials	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

7.7.1.1. Mold modified from 4 mm deep stainless steel to 6 mm deep natural Teflon/ Delron.*

DESCRIPTION

Mold modification to accommodate deeper cures and reflect in-vivo environment.

JUSTIFICATION

* to accommodate deeper cures and reflect in-vivo environment.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

April 18, 2011

Re: 510(k) K110582 Valo Cordless

The Instructions for Use will be modified to include the correct trade name of the device, VALO Cordless.

Diane Rogers — April 18, 2011

Diane Rogers

April 18, 2011

ULTRADENT PRODUCTS, INC.
Questions?
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

APR 2 8 2011

Re: K110582
Trade/Device Name: VALO® Cordless
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: April 1, 2011
Received: April 5, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K110582

Device Name: VALO® Cordless

Indications for Use:

Source of illumination for curing photo-activated dental restorative materials and adhesives.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110582

Page 1 of 1

(Posted November 13, 2003)

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 25, 2011

ULTRADENT PRODUCTS, INC.
505 WEST 10200 SOUTH
SOUTH JORDAN, UTAH 84095
ATTN: DIANE ROGERS

510k Number: K110582
Product: VALO CORDLESS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 02, 2011

ULTRADENT PRODUCTS, INC.
505 WEST 10200 SOUTH
SOUTH JORDAN, UTAH 84095
ATTN: DIANE ROGERS

510k Number: K110582
Received: 3/1/2011
Product: VALO CORDLESS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K111

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ULTRADENT PRODUCTS INC 505 West 10200 South South Jordan UT 84095 US	Diane Rogers 2.1 E-MAIL ADDRESS diane.rogers@ultradent.com 2.2 TELEPHONE NUMBER (include Area code) 801-553-4491
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 801-553-4609

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4)

15-Feb-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

101

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	✓	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.	✓	
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	✓	
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer:_____
Concurrence by Review Branch:_____

Date:_____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/ADA Specification #48

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1 Medical electrical ewuipment - Part 1: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire document	Visible Light Curing Units	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616. Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Ultradent Products, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
February 1, 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
505 West 10200 South
South Jordan, UT 84095

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (801) 553-4491
(Fax) (801) 553-4609

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B), of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Diane Rogers

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Diane Rogers
(Title) Regulatory Affairs Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
505 West 10200 South
South Jordan, Utah 84095

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (801) 553-4491
(Fax) (801) 553-4609

15. DATE OF CERTIFICATION
February 1, 2011
2/23/11

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
February 1, 2011	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Ultradent Products Inc.	1718912		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(801) 553-4491		
Street Address	FAX Number *(including area code)*		
505 West 10200 South	(801) 553-4609		
City	State / Province	ZIP/Postal Code	Country
South Jordan	Utah	84095	USA
Contact Name			
Diane Rogers			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	diane.rogers@ultradent.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Graphics (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	EBZ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K083647	Valo	Ultradent Products Inc.
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

VALO Cordless

	Trade or Proprietary or Model Name for This Device	Model Number
1	VALO Cordless	
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K083647	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
EBZ	872-6070	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Dental

Indications *(from labeling)*

Source of illumination for curing photo-activated dental restorative materials and adhesives

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 60601-1	IEC	Medical Electrical Equipment - Part 1 General requirements for basic safety and essential performance.	Third edition	12/15/2005
2	ANSI/ADA Specification #48	ANSI/ADA	Visible Curing Lights	2004	08/25/2004
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SPECIAL 510(k) Premarket Notification

VALO® Cordless

Ultraviolet activator for polymerization

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Establishment Registration Number 1718912

K110582

February 21, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
10903 New Hampshire Avenue
Silver Spring, MD 20850

RE: Special 510(k) for VALO™ Cordless

Dear Sir or Madam,

In compliance with the Code of Federal Regulations, Section 807, subpart E, regarding Premarket Notification (510(k), Ultradent Products, Inc., hereby notifies the FDA of its intent to market a revised ultraviolet activator for polymerization, similar to our VALO (K083647). The enclosed Special 510(k) submission is considered proprietary and falls within the confidentiality of information as stipulated by Section 807.95 of the Code of Federal Regulations.

The new product is classified as follows:

Device:	Ultraviolet activator for polymerization
Trade/Device Name:	VALO® Cordless
Regulation Number:	CFR 872.6070
Device Class:	Class II
Product Code:	EBZ

The enclosed information is true and correct to the best of my knowledge and no material facts have been omitted. A check for $4348.00 for the submission fee has been sent under separate cover (payment identification number MD6054282-956733). Please do not hesitate to contact me if you require any clarification or information.

Sincerely,

Diane Rogers

Diane Rogers
Regulatory Affairs Manager
TEL: 800-552-5512 x4491, 801-553-4491
FAX: 801-553-4609
Email: Diane.Rogers@Ultradent.com

Table of Contents

Section 1

Introduction

Introduction
Description
Indications for Use
Substantial Equivalence
Truthful and Accurate Statement
Special 510(k) Premarket Summary
Statement of Indications for Use

Description: Valo® Cordless is a visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials.

Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Substantial equivalence: VALO® Cordless and VALO® (K083647) are similar in that they are dental curing lights.

Comparison Table

	VALO® (K083647)	VALO® Cordless
Power Supply	Wall powered, 9VDC, medical grade with adapters for International capability UL Approved	Same
Indications For Use	Source of illumination for curing photo-activated dental restorative materials and adhesives.	Same
Structure	Ergonomic wand	Same
Light	Blue and UV wavelengths	Same
Current control	Regulates current in the light source	Same
Buttons	Two buttons that function the light	Same
Power ON button	Located on handle of wand	Same
Power cord	8' length	Same
Time	Device indicates time and time selection	Same

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

I certify in my capacity as a Regulatory Affairs Manager of Ultradent Products, Inc., I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Diane Rogers
Regulatory Affairs Manager

February 23, 2011
Date

State of Utah, County of Salt Lake
Subscribed and sworn to before me
this 23rd day of February 2011

Andrea Smith
Andrea Smith, Notary Public

ANDREA J. SMITH
NOTARY PUBLIC - STATE OF UTAH
Commission No. 575044
My Comm. Exp. 06/18/2012

ULTRADENT PRODUCTS, INC.
505 West 10200 South
South Jordan, Utah 84095, USA
www.ultradent.com
800.552.5512

SPECIAL 510(K) PREMARKET SUMMARY

VALO® Cordless

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for VALO® Cordless.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	February 21, 2011

Name of the Device

Trade Name:	VALO® Cordless
Common Name:	Activator, ultraviolet for polymerization
Device Classification:	II
Classification Product Code:	EBZ

Legally Marketed Predicate Device to Which Equivalence is Claimed

The predicate device is VALO® (K083647). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

Product Description: Valo® Cordless is a visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials.

Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: VALO® Cordless

Indications for Use:

Source of illumination for curing photo-activated dental restorative materials and adhesives.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

Section II

Labeling for VALO® Cordless

Primary labeling
Instructions for Use

Notice of names used in VALO® Cordless 510(k)

Valo, VALO Cordless, VALO® Cordless, VALO CORDLESS, and VALO SCOUT are all names used during development of the VALO® Cordless. Some documents use these names, but all documents in this 510(k) refer to Ultradent's VALO® Cordless product.

Diane Rogers

Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Inc.

February 23, 2011
Date

INSTRUCTIONS FOR USE

WARNING

Read all instructions before operating this unit.

The VALO® Cordless curing light emits extremely high intensity light waves and must only be used as indicated in this manual.

- **DO NOT look directly into the light output. Patient, clinician and assistants should wear UV orange eye protection when this device is in use.**
- **DO NOT expose soft oral tissues at close proximity. Maintain a minimum of 2mm between the lens and the soft tissue.**
- **If using the VALO CORDLESS Curing Light in the Standard Power mode and in close proximity of the gingival tissue, DO NOT expose tissue for more than 20 seconds. If a 40-second cure is needed, allow 2 minutes between two 20 second cures. If longer curing time is required, consider a dual-cure product (composite or adhesive).**
- **In Xtra Power Mode, DO NOT expose soft oral tissue for more than 10 seconds. The Xtra Power Mode has a 2 second safety delay to limit oral tissue heating during consecutive curing. If a longer cure is needed, allow 2 minutes between consecutive cures or consider a dual-cure product (composite or adhesive).**

Product Information:

Indications for Use: The source of illumination for curing photo-activated dental restorative materials and adhesives.

The VALO CORDLESS curing light uses a custom, multi-wavelength Light Emitting Diode (LED) for producing the high intensity light (395 - 480 nm) capable of polymerizing all light cure dental materials. This intensity will also penetrate porcelain and is capable of curing underlying resin cements similarly to a quality halogen light.

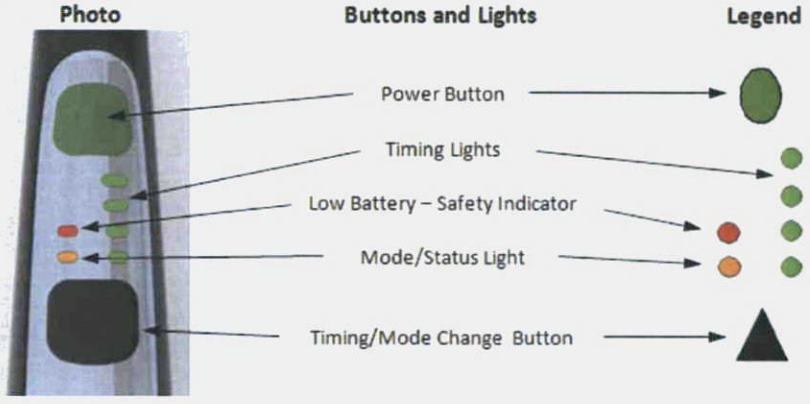
The VALO CORDLESS curing light uses safe Ultradent VALO rechargeable batteries and battery charger.

Contact Information	**Ultradent Products Inc.** 505 West 10200 South South Jordan, Utah 84095 USA Customer Service Phone: 801-571-4000 Ext. 4100 Web site: http://www.ultradent.com/

Product Components:

- 1 – VALO CORDLESS curing light
- 4 – Ultradent VALO rechargeable batteries
- 1 – Ultradent VALO Battery recharger with medical grade S/B 12VDC AC power adaptor
- 50 – VALO CORDLESS Barrier Sleeves

Overview of Controls:



Instructions for Use:

1- Remove all components from the packaging and examine them.
2- See section **How to Charge Batteries**. Place 2 of the batteries in the Ultradent VALO charger. The light on the charger will change from red to green when the batteries are fully charged (approximately 1 hour).
3- See section **How to Change Batteries**. Remove the battery compartment cap at the base of the VAL O Cordless by twisting the silver metal cover counterclockwise 1/8 to 1/4 of a turn.
4- Insert two fully charged batteries plus (+) end first. 5- Replace the battery cover
6- The VALO CORDLESS hand piece beeps when powering on.
7- Selecting the desired mode: The VALO CORDLESS curing light has 3 modes: Standard Power, High Power, and Xtra Power. Each mode is identified by the Mode/Status light (green = Standard Power, orange = High Power, and flashing orange = Xtra Power). To change modes hold the Time Change button for 2 seconds and release. The Mode/Status light will change to the next mode.
NOTE: The VALO CORDLESS curing light is programmed to cycle from the Standard Power to the High Power to the Xtra Power mode in sequence. For example, to change from the Standard Power mode to the Xtra Power mode, it is necessary to cycle into the High Power mode and then to the Xtra Power mode.
The VALO CORDLESS curing light always stores its last used timing interval in each mode and will default back to that timing interval whenever the modes are changed or if the batteries are removed.
SLEEP MODE: The VALO CORDLESS curing light will go into POWER SAVE mode after 30 seconds of inactivity, as indicated by a slow flashing of the mode/status light. Picking up or touching the unit will wake-up VALO CORDLESS and automatically return it to the last setting used.
WARNING: Storage and Travel: If storing the VALO CORDLESS for periods longer than 2 weeks, packing it for travel, or traveling with it, always remove the batteries. If batteries are left in for long periods of time without recharging they may become non-functional and be unable to be recharged or to retain charge.

Charging and Changing Batteries

The VALO Cordless comes with 4 rechargeable safe lithium rechargeable batteries.

LOW BATTERIES: The VALO CORDLESS signals the user that it is time to change the batteries when the Low Battery Indicator Light is flashing red. If the battery charge becomes too low, an audible 3 beep warning sound will occur and the VALO will not allow further operation until batteries recover or new batteries are inserted.

Battery Charge Expantancy: Battery charge life in the VALO Cordless is dependent on the MODE, TIME interval, battery type, amount of use, and LED efficiency. Different battery types will last longer than others. In general, rechargble batteries should last 1 -2 weeks. Non-rechargeable batteries may last 2- 3 time longer.

- **Recommended Recharge Interval:** To avoid low battery warnings or shut off during a proceedure, recharge batteries every 1 – 2 weeks.
- **Extra Batteries:** To avoid possible VALO CORDLESS down time, keep an extra set of non-rechargeable batteries on hand in case batteries get lost or have not been charged. You can order extra rechargeable batteries as needed.

Battery Life Expectancy: Rechargeable Lithium Iron Phosphate batteries can be recharged approximately 1000 to 2000 times before wearing out. However, in everyday use, batteries may be dropped, scratched, scuffed, lost and misplaced. Keep a spare set of non-rechargeable CR123 batteries available.

How to change batteries

1. Remove back cap by twisting counter clockwise a quarter turn.
2. Remove batteries
3. Insert fresh batteries positive (+) side first
4. Reattach back cap by aligning and gently pushing while twisting clock wise. The cab will click when fully attached.
5. The unit is ready for use

WARNING – CAUTION

- VALO CORDLESS will not operate if batteries are put in backwards. If the VALO CORDLESS does not turn on when fresh batteries are inserted, remove the batteries and check to see that they are inserted correctly with the positive (+) battery ends pointed forward as shown below.
- If VALO CORDLESS warning indicator LED flashes red when batteries are inserted, remove batteries and insert freshly charged batteries.
- Do not insert fingers, instruments, or objects into the battery compartment of the VALO Cordless .
- Do not attempt to clean the gold contacts of the battery compartment or anywhere in the battery compartment. Call Ultradent Customer Service if there is a concern.

How to charge batteries

1. Insert batteries into charger with plus (+) end pointed towards the lights on authorized charger.
2. The charger LEDs will show red indicating that the batteries are charging.
3. When the charger LEDs show green, the batteries are ready for use.
4. Batteries will take about 1 hour to charge. Leave batteries in charger until ready for use.

WARNING - CAUTION

- Make sure batteries are inserted into the charger in the correct orientation.
- If the red LED on the charger doesn't turn to green, this means a battery may have gone bad and cannot be charged. Try a new battery or call Ultradent Customer Service to order a new set of batteries.
- If batteries appear to bubble or smell bad, remove batteries from the charger immediately and call Ultradent Customer Service.
- Do not use batteries if the battery wrapping has become torn or removed from the battery. Replace with a new battery immediately and recycle old battery.

If necessary, Ultradent authorizes the following alternative batteries and chargers for the VALO Cordless. Other battery brands will work but they have not been tested and operation life has not been verified.

Authorized Alternate Batteries	Authorized Alternate Chargers
Tenergy® 3.6V rechargeable RCR123A, 750mAh $LiFePO_4$ Powerizer® 3.6V rechargeable RCR123A, 450mAh $LiFePO_4$ Energizer® 123: 3.0V non-rechargeable CR123A Duracell® Ultra: 3.0V non-rechargeable CR123A	Tenergy® 3.6V RCR123 $LiFePO_4$ charger Powerizer® 3.6 RCR123 $LiFePO_4$ charger

WARNING - CAUTION

- Do not mix rechargeable batteries with non-rechargeable batteries.
- Do not charge non-rechargeable batteries.
- Use only safe rechargeable Lithium Iron Phosphate batteries or non-rechargeable batteries.
- Do not store batteries in temperatures over 60°C or in direct sunlight.
- **DO NOT autoclave batteries, charger, AC power adaptor, or VALO Cordless .**

Note: Ultradent does not recommend or authorize any other battery chemistry types or chargers at this time. While other battery types and chargers will operate with the VALO Cordless, they have not been tested and may not have safe battery chemistry or approved safety ratings.

Note: Always recycle spent non-rechargeable batteries.

Quick Mode Guide

Mode Power Level	Standard Power Mode 1000mW				High Power Mode 1400mW				Xtra 3200mW
Power Button									
Mode/Timing LEDs									
Time Button									
Time Options	5s	10s	15s	20s	1s	2s	3s	4s	3s Only
To Change Time	Press and release Time Button quickley to cycle through time options.								
To Change Modes	Press and hold the Time Button for 2 seconds and release. VALO will cycle to next Mode								
Legend	Solid LEDs				Blinking LEDs				

Quick Curing Guide: Recommended Curing Times for Optimal Results with VALO Cordless

Power Level - Layer	Standard Mode **1000mW/cm²**	High Power Mode **1400mW/cm²**	Xtra Power Mode **3200mW/cm²**
Per Layer	One 10 second cure	One 4 second cure	One 3 second cure
Final Cure	One 20 second cure	Two 4 second cures	Two 3 second cures

Quick Warning Guide

Power level warning	**Temperature warning**	**Calibration Warning**	**LED warning**
Replace batteries	Allow cool down	**Send in for repair**	**Send in for repair**
Low battery: quiet flashing Shut off : 3 beeps, flashing Prohibits operations	3 beeps Quiet flashing Prohibits operation	No sound, Flashing, 2 seconds Allows operation	Continuous 3 beeps Flashing Prohibits operations

CURING MODE: Standard Power mode - 1000mW/cm2

USES: Curing of restorative materials with photo initiators.

TIMING INTERVALS: 5, 10, 15, 20 seconds

VALO CORDLESS defaults to this mode when it is INITIALLY powered on. The green Status light is on and the green Timing Lights are solidly illuminated.

To change timing intervals quickly press the Time Change Button
- One light = 5 seconds
- Two lights=10 seconds
- Three lights=15 seconds
- Four lights=20 seconds

Press the Power Button to cure. To stop curing prior to completion of a timing interval, press the Power Button again.

CURING MODE: High Power mode - 1400mW/cm2

USES: Initial curing of restorative materials with photo initiators. Tacking of veneers, brackets, and restorative materials.

TIMING INTERVALS: 1, 2, 3, 4 seconds.

From Standard Power mode, press and hold the Time Button for 2 seconds. The green Timing Lights will illuminate and flash. The Status Light will illuminate as a steady orange light, indicating High Power mode. A two-second power tack is the most commonly used timing interval in this mode.

To change timing intervals quickly, press the Time Change Button
- One flashing light = 1 second
- Two flashing lights = 2 seconds
- Three flashing lights = 3 seconds
- Four flashing lights = 4 seconds

Press the Power Button to cure. To stop curing prior to the completion of a timing interval, press the Power Button again.

To return to Standard Power mode, press and hold the Time Change Button for 2 seconds, release, hold for 2 seconds, and release. The green Status light is on and all 4 timing lights are illuminated.

CURING MODE: †Xtra Power mode - 3200mW/cm2

USES: The Xtra Power mode is **useful for all dental curing**. It is especially valuable for deep curing of restorative materials, placing thin veneers, attaching orthodontic brackets, and fast curing in pediatric settings.

TIMING INTERVAL: 3 seconds only *(Note: there is a 2 second safety delay at the end of each curing cycle)*

From the Standard Power mode, press the Time Button for 2 seconds, release, press again for 2 seconds, and release. Three of the green Timing Lights and the orange Status Light will illuminate *and flash* indicating Xtra Power mode.

Three green flashing lights = 3 seconds

Press the Power Button to cure. To stop curing prior to completion of a timing interval, press the Power Button again.

To return to the Standard Power mode, press and hold the Time Button for 2 seconds

NOTE: The VALO CORDLESS curing light is programmed to cycle from the Standard Power mode to the High Power mode to the Xtra Power mode in sequence. For example, to change from the Standard Power mode to the Xtra Power mode, it is necessary to cycle into the Power mode and then to the Xtra Power mode.

WARNING - CAUTION

In Xtra Power mode, VALO CORDLESS emits extremely high intensity light in a controlled 3 second burst. The VALO CORDLESS curing light must only be used as indicated in this manual.

- **DO NOT look directly into the light output. Patient, clinician and assistants should wear UV orange eye protection when this device is in use.**
- **DO NOT expose soft oral tissues at close proximity. Maintain a minimum of 2mm between the lens and the soft tissue.**
- **DO NOT expose soft oral tissue for more than 10 seconds. The Xtra Power mode has a 2 second safety delay to limit oral tissue heating during consecutive curing. If a longer cure is needed, allow 2 minutes between consecutive cures or consider a dual-cure product (composite or adhesive).**

† Note: 'Xtra Power' equals Plasma Power levels in the Corded VALO. In this context Plasma refers to 'plasma-like' due to intense optical output and curing capacity. Actual plasma arc lights generate broad optical output that must be filtered to reduce harmful short wave ultraviolet radiation.

Maintenance and Cleaning

The VALO CORDLESS curing light is a sealed unit with a sapphire-like hard surface and a scratch resistant glass lens. After each use, moisten a gauze or soft cloth with an anti-microbial surface disinfectant and wipe the surface and lens.

Periodically check the lens for cured dental resins.
CAUTION: Ensure the VALO CORDLESS lens efficacy and curing effectiveness by using VALO CORDLESS brand Barrier Sleeves. These sleeves have been designed and optimized specifically for use with the VALO CORDLESS curing light. In the event that dental resin adheres to the VALO CORDLESS lens, use a non-diamond dental instrument to carefully remove the resin.
Light meters differ greatly and are designed for specific light guide tips and lens. Ultradent recommends checking VALO CORDLESS in Standard Power mode. NOTE: the true numeric output will be skewed due the inaccuracy of common light meters and the custom LED pack VALO CORDLESS uses.

WARNING - CAUTION

- DO NOT autoclave batteries, charger, power adaptor, or VALO Cordless.
- DO NOT insert fingers, instruments, or objects into the battery compartment of the VALO Cordless..
- DO NOT attempt to clean the gold contacts of the battery compartment or anywhere in the battery compartment. Call Ultradent Customer Service if there is a concern.
- DO NOT immerse in any kind of ultrasonic bath or any liquids.
- DO NOT wipe down the VALO CORDLESS curing light with caustic or abrasive cleaners. See lists of acceptable cleaners below:

ACCEPTABLE CLEANERS:

- Cavicide™ products
- Isopropyl alcohol-based cleaners
- Ethyl alcohol-based cleaners
- Lysol® disinfectant
- Other *non-bleach* and *non-abrasive* disinfectants or cleaners

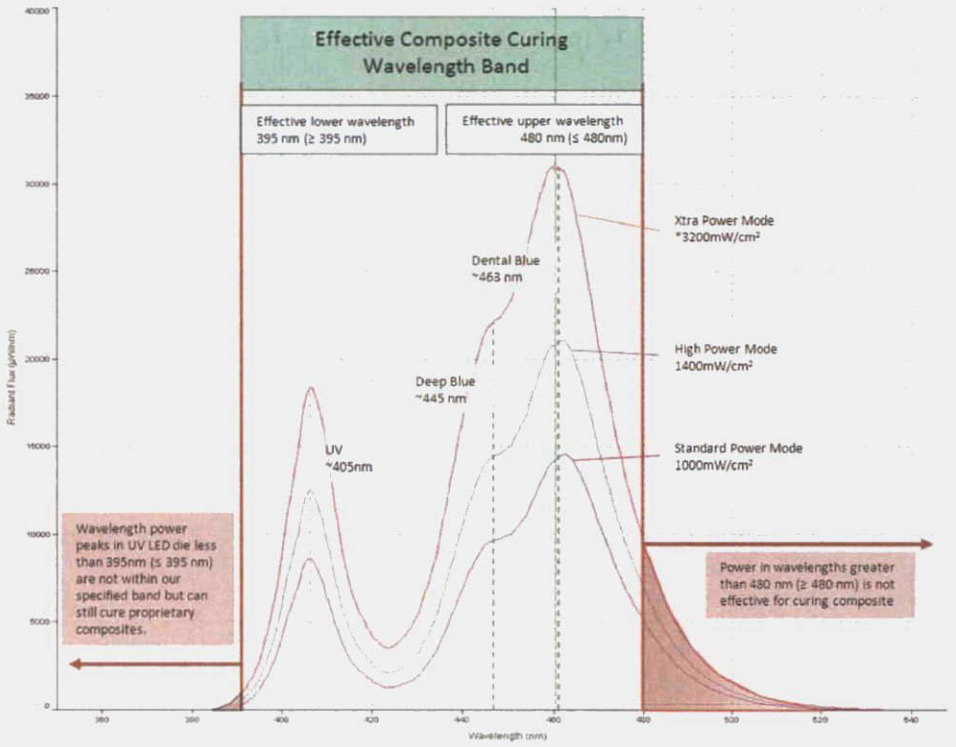
DO NOT USE:

- Formula 409® based cleaners
- Bleach-based cleaners (e.g. - Clorox™, Sterilox™)
- Hydrogen Peroxide based cleaners
- Abrasive Cleansers (e.g. – Comet Cleanser™)
- Acetone-based cleaners (e.g. – nail polish remover, Goo-off™)
- MEK

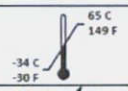
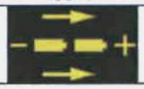
Troubleshooting Guide

If the solutions suggested below do not rectify the problem, please call Ultradent at 800.552.5512. Unauthorized service will invalidate warranty.

Problem	Possible solutions
Light will not turn on	1. Wiggle VALO CORDLESS to see if unit wakes up. 2. Press the Time or Power Button to wake from Power Save Mode. 3. Check the red Low Battery Indicator for battery charge status. 4. Check that fresh batteries are correctly inserted into the unit. 5. If red and yellow Warning LEDs are flashing this means the VALO CORDLESS has reached its internal temperature safety limit. Allow the VALO CORDLESS to cool down for 10 minutes or use a cool moist towel to cool the unit down quickly. 6. If red Warning LED flashes and beeps continuously, call Ultradent Customer Service for repair.
Light does not stay on amount of time desired	1. Check that the unit is set to desired Mode. 2. Check the Low Battery Indicator for battery charge status. 3. Check that fresh batteries are properly inserted into the unit.
Light is not curing resins properly	1. Check lens for residual cured resins/composites (see "Maintenance and Cleaning"). 2. Using proper orange UV eye protection, verify the LED die lights are working. 3. Check power level with light meter. 4. Check expiration date on curing resin.
Batteries won't charge	1. Make sure batteries are inserted in the charger in the correct orientation and allow batteries to charge for 1 hour. 2. If red LEDs on the charger do not change to green, call Ultradent Customer Service to order replacement batteries and/or charger. 3. If neither green nor red LEDs on the charger are visible, call Ultradent Customer Service to order or replace charger and/or AC adaptor.
Batteries bubble and smell bad	1. Remove batteries from the charger immediately 2. Do not insert these batteries into the VALO Cordless. 3. Call Ultradent Customer Service for new batteries and/or charger. 4. Recycle batteries.
Charger does not charge batteries	1. Make sure charger is plugged in and AC adapter is plugged into power outlet. 2. If green or red LEDs on the charger are not visible, call Ultradent Customer Service for new charger and/or AC adaptor. 3. If charger smells as though it is burning, unplug charger immediately and call Ultradent Customer Service for replacement.
Wrapping comes off of battery	1. Do not use these batteries in the VALO Cordless. 2. Recycle batteries. 3. Call Ultradent Customer Service to order replacement batteries.

Technical Information	**VALO CORDLESS Curing Light**
Wavelength range	395nm – 480nm (see qualification below) Effective output Power of VALO CORDLESS falls within the following wavelength range: • 395nm <= EP <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48 
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10% † Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation') † Xtra Power Pulse – 3200mw/cm2 +/- 20 at 50% duty cycle (formerly called 'Plasma Pulse') **** As measured by a Demetron® L.E.D, Radiometer*** ***† As measured by a spectrum analyzer*** ***Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer***

AC Power Adapter	Globtek Medical Grade with international plug inserts Output: 12VDC, 500mA Input: 100VAC – 240VAC Ratings: Medical Grade, (UL, CE, RoHS, WEEE) Includes: International plug adapter kit Cord: 6 ft (1.8m), 2.5mm DC connector Weight: 152 grams w/o plug Dimensions: (75 x 43 x 34) mm
VALO Charger	VALO 3.6VDC Lithium Iron Phosphate smart battery charger: • Peak Voltage: 3.6VDC • Automatic shut off when fully charged • Auto-detection of defective batteries • Protections: Thermal, Overcharge, Short-circuit, reverse polarity o Red LED – Charging o Green LED – Empty or Fully Charged o LED off – short circuit • Charging time: 1 – 3 hours Rating: CE, WEEE Weight: 1.27 troy oz. (39.5 grams) Dimensions: (2.5 x 4 x 1) inches, (63.5 x 101 x 25.4) mm
VALO Batteries	Rechargeable: Safe chemistry Lithium Iron Phosphate ($LiFePO_4$) RCR123A • Working Voltage: 3.2VDC • Peak Voltage: 3.65VDC • Cut-off Voltage: 2VDC • mAh rating: greater than 400mAh Ratings: CE, RoHS, WEEE Weight: 17 grams each Dimensions: 34.5mm x 17mm Alternate use Non-rechargeable: Lithium CR-123A 3VDC (rating greater than 1400mAh for long operation)
VALO Cordless:	Current draw from batteries: • Sleep Mode – 230uA (wake up on button press and movement) • Ready Mode – 30mA (maximum) • Power LED: (dependent on MODE of use and state of charge on batteries) o Minimum – 250mA o Maximum – 2000mA Battery Input Voltage: 4VDC – 10.5VDC • Minimum – 3.95VDC (lock out activated to prevent use) • Maximum – 10.5VDC (lock out activated to prevent use) LED Current Source: Micro-processor controlled, precision regulated LED current and time. Calibrated Power Modes: Standard Power, High Power, Xtra Power. See Instruction Manual. Protections: Low Battery, Over Voltage, Over Temperature, LED Failure, Calibration Failure Limitations for Use: VALO Cordless will not allow operation if temperatures exceed 50°C. • Standard Power: 3 curing cycles, 15 minute off, after 60 minutes of use allow 30 minutes off. • High Power and Xtra Power: 5 curing cycles, 10 minutes off. Ratings: Medical Grade, CE, RoHS, WEEE Weight: • With batteries: 5.5 troy oz. (170 grams) • Without batteries: 4.4 troy oz. (136 grams) Dimension: (8 x 1.28 x 1.06) inches, (203 x 32.5 x 27) m

Marks and Symbols	Meaning
	Warning to read and following instructions and pay attention to specific use warnings and cautions. This symbol is on the VALO CORDLESS and on the packaging
	VALO CORDLESS complies with Medical Class B electrical safety This symbol is on the VALO CORDLESS and on the packaging
	VALO CORDLESS complies with EU regulations for safety, electrical and electronic interference and immunity. This symbol is on the VALO CORDLESS and on the packaging.
	WEEE compliant: Recycle, Do Not discard improperly. This symbol is on the VALO CORDLESS packaging box.
	RoHS compliant: VALO CORDLESS contains no restricted or hazardous components or substances. The symbol also means recycle. This symbol is on the VALO CORDLESS followed by the date of manufacture, and on the packaging.
	VALO CORDLESS is manufactured by Ultradent in accordance with GMP and ISO 9000 practices This symbol is on the VALO CORDLESS on the top panel followed by the date of manufacture, and on the packaging.
	Upper and lower temperature limitations: Do not store or transport VALO CORDLESS in areas above 65°C (149°F) or below -34°C (-30°C). This symbol is on the packaging box.
	Keep Dry: Cargoes bearing this symbol must be protected from excessive humidity and must be stored under cover. This symbol is on the packaging box.
	VALO CORDLESS must be stored in areas where the humidity is less than 95% and greater than 15%. This symbol is located on the VALO CORDLESS packaging box.
	VALO CORDLESS is to be used by trained dental or medical professionals. This symbol is on the packaging box.
EC REP UP Dental GmbH Am Westhover Berg 30 51149 Koln-Porz Germany	Authorized representative This symbol and address is inside the back cap of the VALO SCOUT
Ultradent Products Inc. 505W. 10200S. South Jordan, Ut 84095	Manufacturer – Manufacturing address This address is on the inside of the back cap of the VALO SCOUT
SN:	Serial number of VALO Cordless. This mark and number is on the top panel of VALO Cordless
	This marking shows the correct method of inserting batteries. This mark is located on the top inside of the battery compartment in large yellow print.

Warranty

Ultradent hereby warrants that this instrument shall, for a period of 2 years from the date of purchase, conform in all material respects to the specifications therefore as set forth in Ultradent's documentation accompanying the product and be free from any defects in materials and/or workmanship. This warranty applies solely to the original purchaser and is not transferable. This warranty applies solely to the VALO CORDLESS and does not cover any accessory components such as batteries, chargers, adapters, and adaptive lenses. Other warranties periods and service conditions apply to all accessory parts. All defective products are to be returned to Ultradent. There are no user service components of the VALO CORDLESS system. Tampering with VALO CORDLESS will void its warranty. **WARNING:** When sending units in for repair, service, or calibrations, **always remove the batteries** from the VALO CORDLESS and charger. Wrap batteries, charger, adapter, and VALO CORDLESS separately in the return box.

WARNINGS and PRECAUTIONS

Read all instructions before operating this unit.

The manufacturer accepts no liability for any damage resulting from the improper use of this unit and/or for any purpose other than those covered by these instructions.

USER - PATIENT SAFETY WARNINGS:

- **The VALO CORDLESS curing light emits extremely high intensity light very similar to high intensity quartz halogen lights and must only be used as indicated in this manual.**
- **DO NOT look directly into the light output. Patient, clinician and assistants should wear UV orange eye protection when this device is in use.**
- **DO NOT expose soft oral tissues at close proximity. Maintain a minimum of 2mm between the lens and the soft tissue.**
- **If using the VALO CORDLESS curing light in close proximity of the gingival, DO NOT exposes tissue for more than 20 seconds. If a 40-second cure is needed, allow 2 minutes between two 20 second cures. If longer curing time is required, consider a dual-cure.**
- **In Xtra Power mode, DO NOT expose soft oral tissue for more than 10 seconds. The Xtra Power mode has a 2 second safety delay to limit heating during consecutive curing. If a longer cure is needed, allow 2 minutes between consecutive cures or consider a dual-cure product (composite or adhesive).**

PRODUCT SAFETY WARNINGS:

- **DO NOT autoclave.**
- **DO NOT immerse in disinfectant, cleaning solutions, or any kind of liquid.**
- **DO NOT immerse in any kind of ultrasonic bath.**
- **PRECAUTION: Static Electricity – This unit may be susceptible to strong magnetic or static electric fields which could disrupt the programming. If you suspect this has occurred, remove the batteries from the unit momentarily and then re-insert them.**

Section III

Marketing

Marketing Strategy/Advertising

Marketing and Sales Strategy for VALO® Cordless

VALO's go-to-market plan includes the development of sales tools, press releases, case studies, reviewer reports, promotional pieces, tradeshow presence, and sales force incentives. Detailed deliverables:

- Sales Sheet in May 2011
- Prototypes at Trade Shows
- Landing Page/micro site on Ultradent.com when launched
- Training to TAMs and IRMs prior to launch (competitor at-a-glance, video presentation)
- Press Release at product launch
- CRA and Reality to be given product at launch for their review and comments
- Direct Mailer to all current VALO® customers
- Direct Mailer to Non-TAM covered accounts
- TAM incentive program

Section IV

Labeling for Predicate Device

Primary Labeling
Instructions for Use

ULTRADENT PRODUCTS, INC.

EN

VALO® Curing Light

General Information:

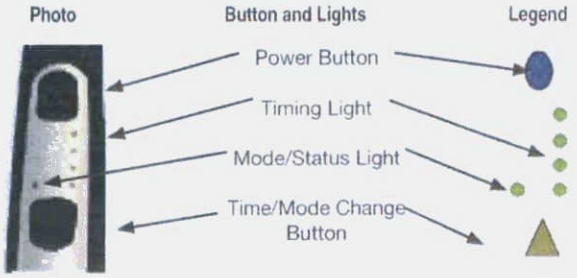
VALO is an LED curing light for the polymerization of light cured dental materials. With its broadband spectrum, VALO is designed to polymerize all light cured products in the wavelength range of 395-480nm.

VALO has a medical grade, international power supply and is suitable for power outlets from 100 to 240 volts. The handpiece is designed to rest in a standard dental unit bracket or can be custom mounted using the bracket included with the kit.

Product Components:

- 1 – VALO curing light with 7 foot / 2.1 meter cord
- 1 – 9 volt, medical grade, international power supply with 6 foot / 1.8 meter cord and universal plugs
- 1 – Handpiece surface mounting bracket with double stick adhesive tape
- 50 – VALO Barrier Sleeves

Overview of Controls:



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Instructions for Use:

1 - Connect the 9-volt power cord to the handpiece cord.

2 - Plug the power cord into any electrical outlet (100 -240 VAC). The timing lights will illuminate indicating the light is ready for use. The VALO handpiece beeps twice when powering on.

3 - Place the VALO handpiece into a standard dental unit mounting bracket or accessory mounting bracket until ready to use.

4 - Select the desired mode: VALO has 3 modes: Standard Power, High Power, and Plasma Emulation. Each mode is identified by the Mode/Status Light (green = Standard Power, orange = High Power, flashing orange = Plasma Emulation). To change modes, hold the Time/Mode Change button for 2 seconds and release. The Mode/Status light will change to the next mode.

NOTE: VALO is programmed to cycle from the Standard Power to the High Power to the Plasma Emulation mode in sequence. For example, to change from the Standard Power mode to the Plasma Emulation mode, it is necessary to cycle into the High Power mode and then to the Plasma Emulation mode.

VALO always stores its last used timing interval in each mode and will default back to that timing interval whenever the modes are changed, or if the unit is unplugged and loses power.

CURING MODE: Standard Power mode - 1000mW/cm²

Mode Power Level	Standard Power Mode 1000mW/cm²
Power Button	
Mode/Timing LEDs	
Time Button	
Time Options	5s 10s 15s 20s
To Change Time	Press and release Time Button quickly to cycle through time options.
To Change Modes	Press and hold the Time Button for 2 seconds and release. VALO will cycle to the next Mode.
Legend	Solid LEDs ● ● Blinking LEDs ● ●

TIMING INTERVALS: 5, 10, 15, 20 seconds

VALO defaults to this mode when it is INITIALLY powered on. The green Mode/Status light is on and the green Timing Lights are solidly illuminated.

To change timing intervals quickly press the Time/Mode Change Button.

Press the Power Button to cure. To stop curing prior to completion of a timing interval, press the Power Button again.

CURING MODE: High Power mode - 1400mW/cm²

Mode Power Level	High Power Mode 1400mW/cm²
Power Button	
Mode/Timing LEDs	
Time Button	
Time Options	1s 2s 3s 4s
To Change Time	Press and release Time Button quickly to cycle through time options.
To Change Modes	Press and hold the Time Button for 2 seconds and release. VALO will cycle to the next Mode.
Legend	Solid LEDs ● ● Blinking LEDs ● ●

TIMING INTERVALS: 1, 2, 3, 4 seconds

From Standard Power mode, press and hold the Time/Mode Change Button for 2 seconds. The green Timing Lights will illuminate and flash. The Status Light will illuminate as a steady orange light, indicating High Power mode.

To change timing intervals quickly, press the Time/Mode Change Button.

Press the Power Button to cure. To stop curing prior to the completion of a timing interval, press the Power Button again.

To return to Standard Power mode, press and hold the Time/Mode Change Button for 2 seconds, release, hold for 2 seconds, and release. The green Status light is on and one light is illuminated.

CURING MODE: Plasma Emulation mode 3200mW/cm²

WARNINGS AND PRECAUTIONS

In Plasma Emulation mode, DO NOT expose soft tissue for more than 10 seconds. The Plasma Emulation mode has a 2-second safety delay to limit heating during consecutive curing. At the end of the delay, beeping indicates the unit is ready for continued use. If a longer cure is needed, allow 10 seconds between consecutive cures or consider a dual-cure product (composite or adhesive).

DO NOT look directly into the light output. Patient, clinician, and assistants should wear UV orange eye protection when this device is in use.

DO NOT expose soft oral tissues at close proximity. Maintain a safe distance between the lens and the soft tissue.

Mode Power Level	Plasma Emulation Mode 3200mW/cm²
Power Button	
Mode/Timing LEDs	
Time Button	
Time Options	3s Only
To Change Modes	Press and hold the Time Button for 2 seconds and release. VALO will cycle to the next Mode.
Legend	Solid LEDs ● ● Blinking LEDs ● ●

TIMING INTERVAL: 3 seconds only (Note: there is a 2-second safety delay at the end of each curing cycle).

From the Standard Power Mode, press the Time/Mode Change Button for 2 seconds, release, press again for 2 seconds, and release. Three of the green Timing Lights and the orange Status Light will illuminate and flash, indicating Plasma Emulation mode.

Press the Power Button to cure. To stop curing prior to completion of a timing interval, press the Power Button again.

To return to the Standard Power mode, press and hold the Time/Mode Change Button for 2 seconds.

SLEEP MODE: VALO will go into POWER SAVE mode after 1 hour of inactivity, as indicated by the green mode light blinking slowly. Press any button to wake VALO and begin curing. VALO will automatically return to the last setting used.

Follow the guidance of the manufacturer of the light curing material you use in your office re: curing times and intensity of light needed (See Suggested Curing Program)

WARNINGS AND PRECAUTIONS

Read all instructions before operating this unit. The manufacturer accepts no liability for any damage resulting from the improper use of this unit and/or for any purpose other than those covered by these instructions.

USER/PATIENT SAFETY WARNINGS:

VALO emits extremely high intensity light very similar to high intensity quartz halogen lights and must only be used as indicated in this manual.

DO NOT look directly into the light output. Patient, clinician, and assistants should wear UV orange eye protection when this device is in use.

DO NOT expose soft oral tissues at close proximity. Maintain a safe distance between the lens and the soft tissue.

If using VALO in close proximity to the gingiva, DO NOT expose tissue for more than 20 seconds. If a 40-second cure is needed, allow 10 seconds between two 20-second cures. If longer curing is required, consider a dual-cure product.

In Plasma Emulation mode, DO NOT expose soft tissue for more than 10 seconds. The Plasma Emulation mode has a 2-second safety delay to limit heating during consecutive curing. At the end of the delay, beeping indicates unit is ready for continued used. If a longer cure is needed, allow 10 seconds between consecutive cures or consider a dual-cure product (composite or adhesive).

PRODUCT SAFETY WARNINGS:

DO NOT autoclave.
DO NOT immerse in disinfectant, cleaning solutions, or any kind of liquid.
DO NOT immerse in any kind of ultrasonic bath.
PRECAUTION: This unit may be susceptible to strong magnetic or static electric fields, which could disrupt the programming. If you suspect this has occurred, unplug the unit momentarily and then replug it into the outlet.

Accessory Bracket Instructions

1- Bracket should be mounted to a flat, oil-free surface.
2- Clean surface with rubbing alcohol.
3- Peel backing off of the bracket's adhesive tape.
4- Position bracket so the handpiece lifts upward when removed. Press firmly into place.

Maintenance and Cleaning

VALO is a sealed unit with a sapphire-like hard surface and a scratch reistant glass lens. After each use, moisten a gauze or soft cloth with an anti-microbial surface disinfectant and wipe the surface and lens. Periodically check the lens for cured dental resins.

CAUTION: Ensure the VALO lens asepsis by using VALO Barrier Sleeves. These sleeves have been designed and optimized specifically for use with VALO. In the event that dental resin adheres to the VALO lens, use a non-diamond dental instrument to carefully remove the resin.

If using a light meter, Ultradent recommends checking VALO in Standard Power mode. NOTE: The true numeric output will be skewed due to the inaccuracy of common light meters and the custom LED pack VALO uses. Light meters differ greatly and are designed for specific light guide tips and lenses. Their main purpose is not to find an absolute value, but to test consistency in repeated measurements.

ACCEPTABLE CLEANERS:

- Cavicide products
- Isopropyl alcohol-based cleaners
- Ethyl alcohol-based cleaners
- Lysol disinfectant
- Other non-bleach and non-abrasive disinfectants or cleaners

DO NOT USE

- Strong alkali detergent of any type, including hand soaps and dish soaps.
- Bleach-based cleaners (e.g. - Clorox™, Sterilox™)
- Abrasive Cleaners (e.g. - Comet Cleanser™)
- Acetone-based cleaners (e.g. - nail polish remover, Goo-off™)
- Methyl Ethyl Ketone

Troubleshooting Guide

If the solutions suggested below do not rectify the problem, please call Ultradent at 800.552.5512.

Problem	Possible Solutions
Light will not turn on	1. Press the Time/Mode Change Button or Power Button to wake from Power Save Mode. 2. Check that both cords are firmly connected together and to the electrical outlet. 3. Confirm power to the wall outlet.
Light does not stay on for desired time	1. Check Mode and Timing lights for correct time input. 2. Confirm all cord connections are fully seated. 3. Unplug and re-plug power cord into the electrical receptacle.
Light is not curing resins properly	1. Check lens for residual cured resins/composites. (see "Maintenance and Cleaning") 2. Using proper orange UV eye protection, verify the LED lights are working. 3. Check power level with light meter. (See "Maintenance and Cleaning," page 7) 4. Check expiration date on curing resin.

Technical Information	VALO LED Curing Light
Valo Lens	Diameter 9.6 mm
Wavelength	395nm - 480nm
Light Intensity	Standard Power - 1000mW/cm²* High Power - 1400mW/cm²* Plasma Emulation - 3200mW/cm²†
Wand	Weight - 8 ounces/226 grams (with cord) Length - 9.26 inches/23.5 cm Breadth -.74 inches/1.9 cm Width - .79 inches/ 2 cm Cord length - 7 feet/2.1 meters Ratings - CE, IEC 60601
Power Supply	Output - 9VDC at 2A Input - 100VAC to 240VAC Rating - Medical Grade (UL, CE, RoHS, WEEE) Cord length - 6 feet/1.8 meters

*As measured by a properly calibrated Demitron Light Meter
†As measured by an Integrating Sphere
(Den-Mat Sapphire Plasma Arc Curing Light – irradiance measured at 2,600mW/cm² with Integrating Sphere)

Warranty for VALO units:

Ultradent hereby warrants that this instrument shall, for a period of 2 years**, conform in all material respects to the specifications therefore as set forth in Ultradent's documentation accompanying the product and be free from any defects in materials/or workmanship. This warranty applies solely to the original purchaser and is not transferable. All defective products are to be returned to Ultradent. There are no user service components of the VALO system. Tampering with VALO will void its warranty. Removal of the serial label from the cable cord will void Valo's warranty.

**With sales receipt indicating the date of sale to the dentist.

Section V

Design Control Summary

Summary of Design Control Activities
Design Requirements
Risk Analysis Methods
Testing and Test methods
Declaration of Conformity with Design Controls
60601 Testing and Certifications
Software Requirement Specifications
ADA 48 Compliance

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-CONFIDENTIAL-

SUMMARY OF DESIGN CONTROL ACTIVITIES

This document intends to:

1) Demonstrate substantial equivalence to the existing, legally-marketed product, VALO® (K083647).

The following information is being submitted in accordance with the requirements of 21 CFR 807.87. The document, "How to Prepare a Special 510(k)" was used to identify the process necessary to evaluate safety and efficacy of the device and to provide a format to summarize information as necessary for demonstration of substantial equivalence, safety and efficacy.

Product Identification

Trade Name:	VALO® Cordless
Common Name:	Dental Curing Light
Device Classification:	II
Classification Product Code:	EBZ

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is VALO® (K083647). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

Product Description: VALO® Cordless is an activator, ultraviolet for polymerization. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials.

Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Device Design Requirements

Risk analysis method

The risk analysis methods used to assess the impact of the modification on the device and its components, as well as the results of the analysis, are as follows:

- Review of testing data for comparison of new product to legally-marketed product
- Review of Design History File and identification of the verification and validation activities required, including methods or tests used and the acceptance criteria applied
- Review of legally-marketed product history including complaints
- Performance, documentation and review of risk assessment per the requirements of ISO 14971:2007, using FMECA as a tool
- No major risks were identified during the risk analysis. (b) (4) [redacted]

Brief Description of Testing Performed

ANSI/ADA Specification No. 48 Visible Light Curing Units

Testing was conducted for ANSI/ADA Specification No. 48 and VALO® Cordless passed all tests.
ANSI/ADA Specification No. 48 approval requires the VALO® Cordless to pass the following parameters:

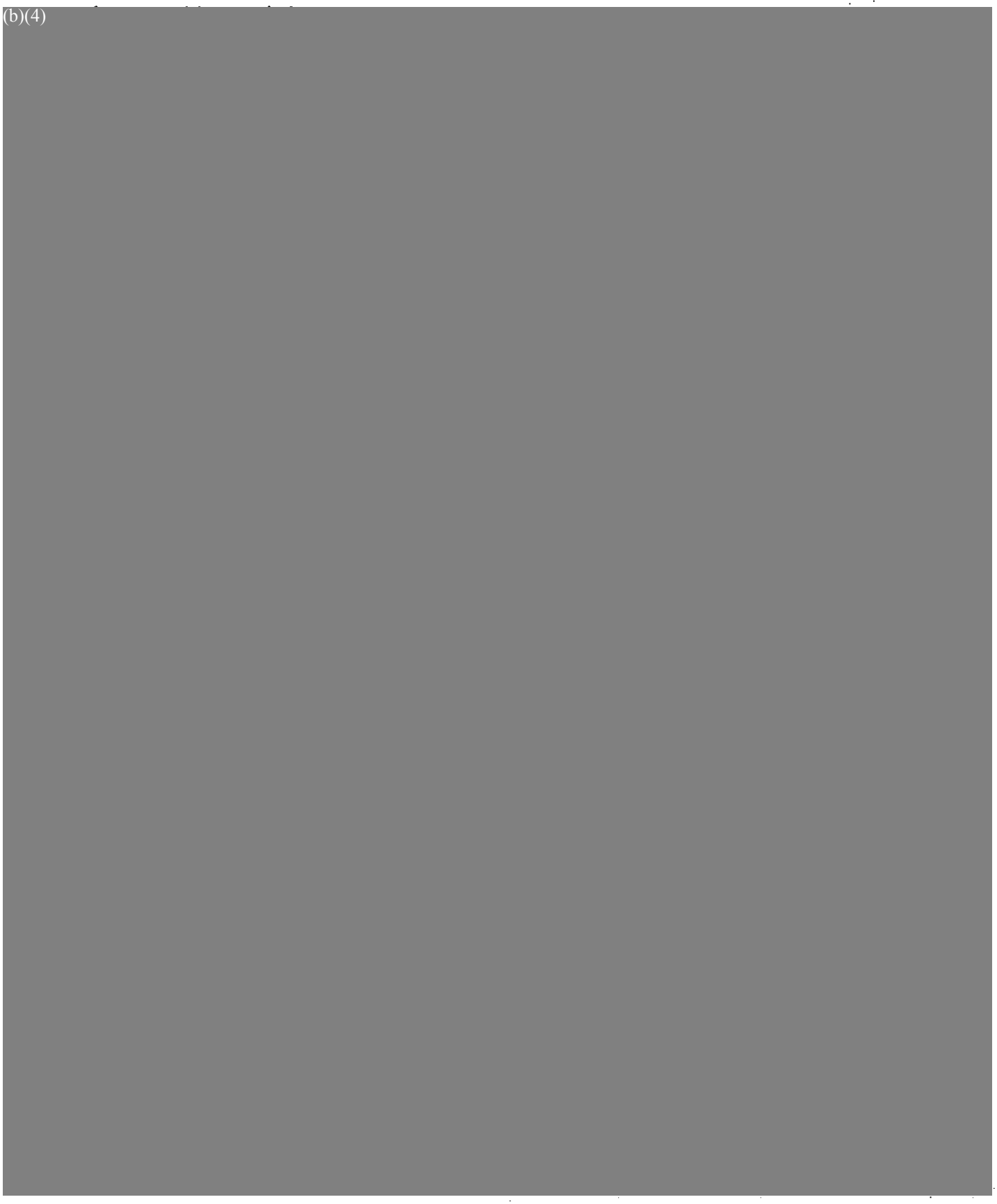
- Cleaning and disinfection
- Excessive temperatures
- Radiant Exitance
    - Measurement of the optical cross-sectional area of the optic tip
    - Measurement of irradiance
    - Measurements using filters

- Electrical requirements
    - Power input
    - Single fault conditions
    - Protection against electric shock hazards
    - Enclosures and protective covers
    - Leakage
    - Protective earthing

- Continuous leakage currents
- Dielectric strength
- Interruption of the power supply
- Abnormal operating and fault conditions
- Components and general assembly
- Main parts, components and assembly
- Electromagnetic compatibility
- Atmospheric conditions
- Supply and test voltages, type of current, nature of supply, frequency
- Preconditioning
- Conditioning
- Repairs and Modifications

Software Verification and Validation Documentation:

(b)(4)



Conclusion and Substantial Equivalence

In conclusion, VALO® Cordless is to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, UT 84095, and is substantially equivalent to VALO® (K083647), also manufactured by Ultradent Products, Inc. The two products are composed of similar materials, have the same intended use and technological characteristics, and both are safe and effective when used for the indications described.

Verification and Validation

In-house and outside testing facilities were utilized to complete testing for ANSI/ADA 48, and

EN 60601-1. Test protocols were written and pre-approved.
Test data, Inputs and Outputs of the Design Control Process were verified and validated by our in-house QA department, Marketing, R & D Engineering and Regulatory Affairs.

ADA 48 Compliance Testing with Exceptions

Device: Ultradent VALO® Cordless multi-wavelength dental curing light

Compiled by: Dee Jessop
February 8, 2011

The Ultradent VALO® Cordless multi-wavelength dental curing light has been tested and shown to be in compliance with ADA 48 (American National Standard/American Dental Association Specification No. 48)

Document Contents:

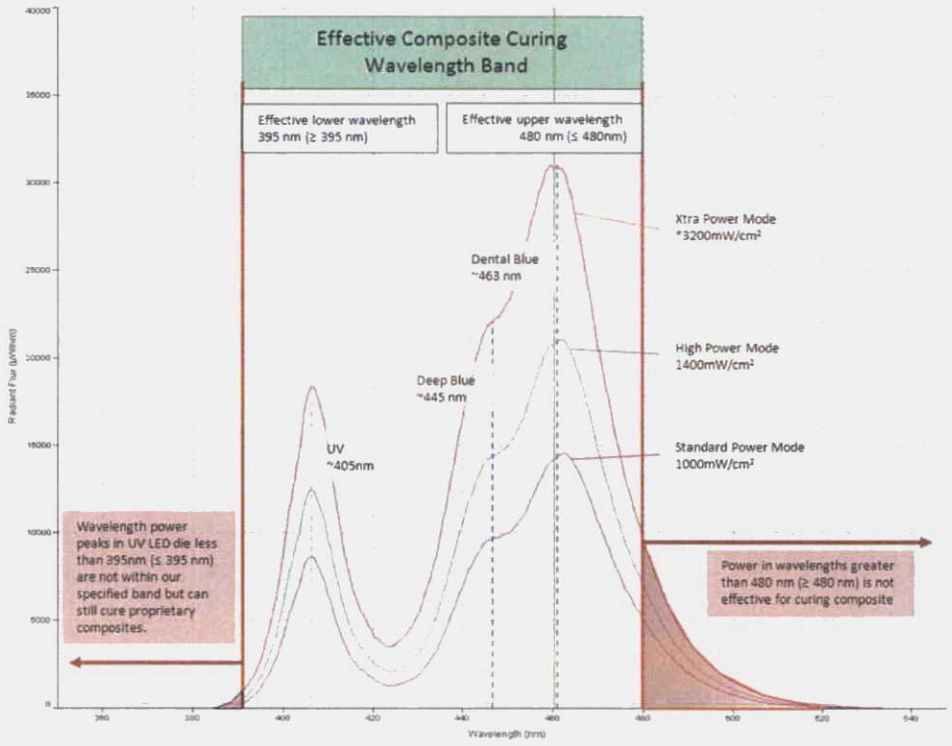
1. Contacts and Address – Measurement Instruments
2. Table 1: Measured and calculated values in compliance with ADA 48
3. Table 2: Exceptions pertaining to methods of measurement
4. Graph 1: 350nm – 550nm spectrum response of the VALO CORDLESS with noise filtering on spectrum edges. Measurements compliant with ADA 48 are taken from this spectrum.
5. Graph 2: Full broad band spectrum of VALO Cordless
6. Graph 3: Full broad band dark spectrum response of the analyzer. Dark spectrum means there is no light input to the analyzer. Note the saturation noise in the deep UV range (190nm – 280nm) and the slight noise in the high IR region (850nm – 900nm). These are the edges of range for the USB4000 spectrum analyzer.
7. Passing requirements for IEC 60601-1 Medical Electrical Equipment
8. Nemko-CCL Certifications
9. Troubleshooting Guide
10. Technical Information
11. Marks and Symbols descriptions

Contacts and Addresses	Measurement Instruments
Ultradent Products Inc., **Research and Development** 505 West 10200 South South Jordan, UT 84095 USA R&D Phone: 801-553-4351 Dee Jessop: Test Engineer Email: dee.jessop@ultradent.com Neil Jessop: Senior R&D Manager Email: neil.jessop@ultradent.com Richard Tuttle: DDS, R&D Clinical Division Manager Email: rich.tuttle@ultradent.com Diane Rogers: Regulatory Affairs Manager Email: diane.rogers@ultradent.com	(b)(4) Test Data

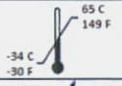
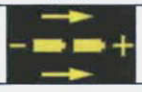
Troubleshooting Guide

If the solutions suggested below do not rectify the problem, please call Ultradent at 800.552.5512. Unauthorized service will invalidate warranty.

Problem	Possible solutions
Light will not turn on	7. Wiggle VALO CORDLESS to see if unit wakes up. 8. Press the Time or Power Button to wake from Power Save Mode. 9. Check the red Low Battery Indicator for battery charge status. 10. Check that fresh batteries are correctly inserted into the unit. 11. If red and yellow Warning LEDs are flashing this means the VALO CORDLESS has reached its internal temperature safety limit. Allow the VALO CORDLESS to cool down for 10 minutes or use a cool moist towel to cool the unit down quickly. 12. If red Warning LED flashes and beeps continuously, call Ultradent Customer Service for repair.
Light does not stay on amount of time desired	4. Check that the unit is set to desired Mode. 5. Check the Low Battery Indicator for battery charge status. 6. Check that fresh batteries are properly inserted into the unit.
Light is not curing resins properly	5. Check lens for residual cured resins/composites (see "Maintenance and Cleaning"). 6. Using proper orange UV eye protection, verify the LED die lights are working. 7. Check power level with light meter. 8. Check expiration date on curing resin.
Batteries won't charge	4. Make sure batteries are inserted in the charger in the correct orientation and allow batteries to charge for 1 hour. 5. If red LEDs on the charger do not change to green, call Ultradent Customer Service to order replacement batteries and/or charger. 6. If neither green nor red LEDs on the charger are visible, call Ultradent Customer Service to order or replace charger and/or AC adaptor.
Batteries bubble and smell bad	5. Remove batteries from the charger immediately 6. Do not insert these batteries into the VALO Cordless. 7. Call Ultradent Customer Service for new batteries and/or charger. 8. Recycle batteries.
Charger does not charge batteries	4. Make sure charger is plugged in and AC adapter is plugged into power outlet. 5. If green or red LEDs on the charger are not visible, call Ultradent Customer Service for new charger and/or AC adaptor. 6. If charger smells as though it is burning, unplug charger immediately and call Ultradent Customer Service for replacement.
Wrapping comes off of battery	4. Do not use these batteries in the VALO Cordless. 5. Recycle batteries. 6. Call Ultradent Customer Service to order replacement batteries.

Technical Information	VALO CORDLESS Curing Light
Wavelength range	395nm – 480nm (see qualification below) Effective output power of VALO CORDLESS falls within the following wavelength range: • 395nm <= P <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48 
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10% † Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation') † Xtra Power Pulse – 3200mw/cm2 +/- 20 at 50% duty cycle (formerly called 'Plasma Pulse') **** As measured by a Demetron® L.E.D, Radiometer*** ***† As measured by a spectrum analyzer*** ***Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer***

AC Power Adapter	Globtek Medical Grade with international plug inserts Output: 12VDC, 500mA Input: 100VAC – 240VAC Ratings: Medical Grade, (UL, CE, RoHS, WEEE) Includes: International plug adapter kit Cord: 6 ft (1.8m), 2.5mm DC connector Weight: 152 grams w/o plug Dimensions: (75 x 43 x 34) mm
VALO Charger	VALO 3.6VDC Lithium Iron Phosphate smart battery charger: • Peak Voltage: 3.6VDC • Automatic shut off when fully charged • Auto-detection of defective batteries • Protections: Thermal, Overcharge, Short-circuit, reverse polarity o Red LED – Charging o Green LED – Empty or Fully Charged o LED off – short circuit • Charging time: 1 – 3 hours Rating: CE, WEEE Weight: 1.27 troy oz. (39.5 grams) Dimensions: (2.5 x 4 x 1) inches, (63.5 x 101 x 25.4) mm
VALO Batteries	Rechargeable: Safe chemistry Lithium Iron Phosphate ($LiFePO_4$) RCR123A • Working Voltage: 3.2VDC • Peak Voltage: 3.65VDC • Cut-off Voltage: 2VDC • mAh rating: greater than 400mAh Ratings: CE, RoHS, WEEE Weight: 17 grams each Dimensions: 34.5mm x 17mm Alternate use Non-rechargeable: Lithium CR-123A 3VDC (rating greater than 1400mAh for long operation)
VALO SCOUT:	Current draw from batteries: • Sleep Mode – 230uA (wake up on button press and movement) • Ready Mode – 30mA (maximum) • Power LED: (dependent on MODE of use and state of charge on batteries) o Minimum – 250mA o Maximum – 2000mA Battery Input Voltage: 4VDC – 10VDC • Minimum – 3.95VDC (lock out activated to prevent use) • Maximum – 10.5VDC (lock out activated to prevent use) LED Current Source: Micro-processor controlled, precision regulated LED current and time. Calibrated Power Modes: Standard Power, High Power, Xtra Power. See Instruction Manual. Protections: Low Battery, Over Voltage, Over Temperature, LED Failure, Calibration Failure Ratings: Medical Grade, CE, RoHS, WEEE Weight: • With batteries: 5.5 troy oz. (170 grams) • Without batteries: 4.4 troy oz. (136 grams) Dimension: (8 x 1.28 x 1.06) inches, (203 x 32.5 x 27) mm

Marks and Symbols	Meaning
	Warning to read and following instructions and pay attention to specific use warnings and cautions. This symbol is on the VALO CORDLESS and on the packaging
	VALO CORDLESS complies with Medical Class B electrical safety This symbol is on the VALO CORDLESS and on the packaging
	VALO CORDLESS complies with EU regulations for safety, electrical and electronic interference and immunity. This symbol is on the VALO CORDLESS and on the packaging.
	WEEE compliant: Recycle, Do Not discard improperly. This symbol is on the VALO CORDLESS packaging box.
	RoHS compliant: VALO CORDLESS contains no restricted or hazardous components or substances. The symbol also means recycle. This symbol is on the VALO CORDLESS followed by the date of manufacture, and on the packaging.
	VALO CORDLESS is manufactured by Ultradent in accordance with GMP and ISO 9000 practices This symbol is on the VALO CORDLESS on the top panel followed by the date of manufacture, and on the packaging.
	Upper and lower temperature limitations: Do not store or transport VALO CORDLESS in areas above 65°C (149°F) or below -34°C (-30°C). This symbol is on the packaging box.
	Keep Dry: Cargoes bearing this symbol must be protected from excessive humidity and must be stored under cover. This symbol is on the packaging box.
	VALO CORDLESS must be stored in areas where the humidity is less than 95% and greater than 15%. This symbol is located on the VALO CORDLESS packaging box.
	VALO CORDLESS is to be used by trained dental or medical professionals. This symbol is on the packaging box.
EC REP UP Dental GmbH Am Westhover Berg 30 51149 Koln-Porz Germany	Authorized representative This symbol and address is inside the back cap of the VALO Cordless
Ultradent Products Inc. 505W. 10200S. South Jordan, Ut 84095	Manufacturer – Manufacturing address This address is on the inside of the back cap of the VALO Cordless
SN:	Serial number of VALO Cordless. This mark and number is on the top panel of VALO Cordless
	This marking shows the correct method of inserting batteries. This mark is located on the top inside of the battery compartment in large yellow print.

Declaration of Conformity with Design Controls

Ultradent Products Inc. certifies that VALO® Cordless was designed according to our written SOPs for Design Control. All inputs to the design, and all outputs were carefully evaluated and approved by the Design team at intervals during the design process. The final design was evaluated by numerous dentists all over the world. Their inputs helped the Design team to assure that VALO® Cordless performs according to user requirements.

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

1. As required for VALO® Cordless, Risk Analysis, and all verification and validation activities were performed and the results demonstrated that the predetermined acceptance criteria were met; and
2. The Ultradent Products, Inc., manufacturing facility is in conformance with Design Control requirements as specified in 21 CFR 820.30 and the records are available for review.

Diane Rogers

Diane Rogers
Regulatory Affairs Manager

February 23, 2011
Date

(b)(4) Test Data

(b)(4) Specifications

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(b)(4) Test Data

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Contacts and Addresses	Measurement Instruments
Ultradent Products Inc., **Research and Development** 505 West 10200 South South Jordan, UT 84095 USA R&D Phone: 801-553-4351 Dee Jessop: Test Engineer Email: dee.jessop@ultradent.com Neil Jessop: Senior R&D Manager Email: neil.jessop@ultradent.com Richard Tuttle: DDS, R&D Clinical Division Manager Email: rich.tuttle@ultradent.com	(b)(4) Test Data

(b)(4) Test Data

Marks and Symbols	Meaning
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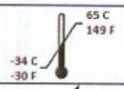
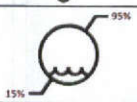
	Upper and lower temperature limitations: Do not store or transport VALO CORDLESS in areas above 65°C (149°F) or below -34°C (-30°C). This symbol is on the packaging box.
	Keep Dry: Cargoes bearing this symbol must be protected from excessive humidity and must be stored under cover. This symbol is on the packaging box.
	VALO CORDLESS must be stored in areas where the humidity is less than 95% and greater than 15%. This symbol is located on the VALO CORDLESS packaging box.
Rx	VALO CORDLESS is to be used by trained dental or medical professionals. This symbol is on the packaging box.
EC REP UP Dental GmbH Am Westhover Berg 30 51149 Koln-Porz Germany	Authorized representative This symbol and address is inside the back cap of the VALO Cordless
Ultradent Products Inc. 505W. 10200S. South Jordan, Ut 84095	Manufacturer – Manufacturing address This address is on the inside of the back cap of the VALO Cordless
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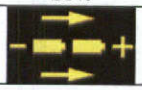	This marking shows the correct method of inserting batteries. This mark is located on the top inside of the battery compartment in large yellow print.

Section VI

Biocompatibility, Clinical Summary, Literature Review

Biocompatibility and Clinical Summary Literature Review

BIOCOMPATIBILITY SUMMARY

VALO®
Curing Light

During our effort to document and prepare a 510(k) and Technical File for VALO®, it was determined that biocompatibility testing is not necessary for the device. The device does not come in contact with oral tissue as it is strictly used as a curing light.

CLINICAL SUMMARY

Valo® Cordless

I. **Introduction:** The following summary provides a documented review of clinical data collected with respect to the involved device as part of the conformity assessment procedure required by the Medical Device Directive (93/42/EEC), using the 'literature route.' The following documentation demonstrates safety and efficacy of the device, and provides a basis for clinical evaluation and assessment of the risk to benefit for the intended use and claims as required.

A keyword search was performed in PubMed on "(LED Curing Light) AND Safety", "(LED Dental Curing Light) AND Safety", "(Safe Use) AND LED Curing Light", "(Dental Curing Light) AND Battery Powered", and "(Cordless) AND Dental Curing Light", returning 17 articles. Six were omitted, four are redundant, one was not available in English, and one was not relevant to curing dental restoratives and adhesive materials. Eleven relevant articles are listed to the safety and efficacy of the product.

II. **Product Description:** Valo® Cordless is a visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials.

III. **Product Indications:** Source of illumination for curing photo-activated dental restorative materials and adhesives.

IV. **Background:** The process of light curing is one of the most frequent tasks that are performed daily in dental practice. Photo-polymerization is used in various aspects of virtually every dental discipline. A technique that was initially introduced as a convenience factor to speed up the polymerization of composite restorations has now become a basic tool for restorative, aesthetic, orthodontic, endodontic, and other branches of the profession. The light-curing techniques, as well as the hundreds of different curing lights, have been an integral part of dentistry for almost 25 years.

There are several major advantages to photo-polymerizing composites:

- Unlimited, dentist-controlled working time
- Greatly improved material properties
- Microhybrids, hybrids, microfills, macrofills, nanofills, packables, flowables, resin cements, and now resin-based endodontic sealers are all specifically designed to make dentistry better, easier, and faster.

With such a wide range of composite categories, materials, and manufacturers to choose from, predictable polymerization is an important clinical parameter. First and foremost, there are several major categories of curing lights to choose from: conventional halogen, fast halogen,

plasma arc, argon laser, and most recently, the light-emitting-diode (LED). In selecting an appropriate curing light, it is important to remember that not all composite materials will fully polymerize with all curing lights. The 2 most common photo-initiators used in dental materials are camphoroquinone (CQ) and phenyl-propamedione
(PPD). Each photo-initiator cures at a somewhat different wavelength of light. The CQ is initiated at approximately 468nm, while PPD is activated in the <430nm range. However, the newer-generation LED curing lights have an extended output range that encompasses all the commonly used dental composite photo-initiators. Prior to purchase, the curing range of the intended light should be examined; at the minimum, the range should extend adequately over both the CQ (-468nm) and the PPD (-429 nm) polymerization wavelengths.

V. Safety:

1. Baysal A, Uysal T, Ulker M, Usumez S. Effects of high-intensity curing lights on microleakage under bonded lingual retainers. Angle Orthod. 2008 Nov:78(6):1084-8.

   OBJECTIVE: To evaluate the effects of high-intensity light curing units (light-emitting diode [LED] and plasma arc curing [PAC]) on the microleakage of flexible spiral wire retainers (FSWRs) at the composite/enamel and composite/wire interfaces.
   MATERIALS AND METHODS: Forty-five human mandibular incisor teeth were separated into three groups of 15 teeth. Multistranded PentaOne wire of .0215 inch diameter was bonded to enamel and was cured with three different light curing units: a quartz-tungsten-halogen (QTH) unit and two high-intensity units (ie, LED and PAC). A conventional halogen light served as the control. Samples were sealed with nail varnish, stained with 0.5% basic fuchsine, and sectioned. Transverse sections were evaluated under a stereomicroscope and were scored for microleakage for the composite/enamel and composite/wire interfaces. Statistical analysis was performed by Kruskal-Wallis and Mann-Whitney U-tests with Bonferroni correction.
   RESULTS: Little or no microleakage was detected at the composite/enamel interface of the FSWR cured with three different light sources. However, at the composite/wire interface, statistically significant differences were found between the QTH (mean, 1.10 +/- 1.05 mm) and high-intensity curing units. The PAC resulted in the greatest amount of microleakage (mean, 2.63 +/- 1.49 mm), whereas no statistically significant difference was noted between the PAC and the LED (mean, 2.35 +/- 1.28 mm).
   CONCLUSION: High-intensity light curing units show statistically significant microleakage at the composite/wire interface and therefore may not be safe for use in bonding FSWRs

2. Schattenberg A, Lichtenberg D, Stender E, Willershausen B, Ernst CP. Minimal exposure time of different LED-curing devices. Dent Mater 2008 Aug:24(8):1043-9.

   OBJECTIVES: The purpose of the study was to investigate the shortest possible exposure time of different LED-curing devices for five different resin composites in a clinically relevant

in vitro-model, where a 7 mm distance from the light guide tip to the bottom side of the cavity was compiled.
METHODS: Resin composite samples (Tetric EvoCeram A3, Filtek Supreme XT A3B, Premise A3, CeramX Mono M5, QuiXfil) were filled in three increments of 2mm thickness each in stainless steel moulds (Ø=5 mm, h=6 mm, n=9). The samples were incrementally exposed to different blue LED-curing devices (Bluephase, Bluephase C8, Bluephase 16i/Ivoclar Vivadent, L.E. Demetron II/sds Kerr, Elipar FreeLight 2/3M ESPE, Smartlite PS/DENTSPLY, Translux Power Blue/Heraeus) according to the manufacturer's recommendations at a distance of 7 mm from the bottom of the cavity to simulate a class II-curing situation. Surface hardness was measured (Zwick Z2.5/TS1S) 10 min post-exposure at the bottom surfaces of the resin sample. A bottom/top-surface hardness ratio of 80% of a reference sample (2mm thickness, 40s), was defined as clinically acceptable for safe curing. A descriptive statistical analysis was carried out.
RESULTS: The curing devices Bluephase, Bluephase C8, Smartlite PS and Translux Power Blue could cure all composite resins investigated sufficiently in the exposure time recommended by the manufacturers (10-20s). The curing device Bluephase 16i and L.E. Demetron II only cured the composite Quixfil sufficiently in the exposure time recommended by the manufacturer. FreeLight 2+ allowed a 10s exposure time for all materials except Ceram X Mono (20s).
SIGNIFICANCE: When incrementally exposed, all resin composites investigated were polymerized sufficiently at a maximum of 20s exposure time.

3. Ernst CP, Meyer GR, Müller J, Stender E, Ahlers MO, Willershausern B. Depth of cure of LED vs QTH light-curing devices at a distance of 7mm.J Adhes Dent. 2004 Summer:6(2):141-150.

PURPOSE: To determine the depth of cure of 5 blue LED curing devices compared to that obtained with 3 QTH curing devices.
MATERIALS AND METHODS: The LED curing devices tested were 1) e-Light: 40 s; 2) Elipar FreeLight: 40 s; 3) Elipar FreeLight 2: 20 s and 40 s; 4) Ultra-Lume LED 2: 20 s and 40 s; 5) LEDemetron 1: 20 s and 40 s. The QTH curing devices tested were 1) Optilux 501: standard light guide 20 s and 40 s, turbo light guide 20 s; 2) Elipar TriLight: 40 s; 3) Astralis 10: 20 s. Surface hardness was measured (Zwick Z2.5/TS1S) 10 min after exposure on the top and bottom surface of resin samples (Tetric Ceram A3, 1 to 5 mm; 0.5 mm increment, diameter 5 mm, n = 9) which were cured at a distance of 7 mm from the bottom of the sample to the light-guide tip to simulate a Class II curing situation. A reference sample was cured under direct contact with the light guide. The reference sample with the greatest top surface hardness of all devices measured served as the overall control. A bottom/top surface hardness ratio of > or = 80% of the reference sample cured at zero distance was defined as clinically acceptable for safe curing. A descriptive statistical analysis was carried out.
RESULTS: With QTH lamps, the mean maximum resin composite sample thickness which cured sufficiently (relative surface ratio > or = 80%) was: 3 mm for Optilux 501, standard light guide, 40 s; 2.5 mm for Trilight, 40 s; and 1.5 mm for Astralis 10, 20 s. The first-

generation LED curing devices FreeLight and GC e-Light, both applied for 40 s, and the Optilux 501 operated for 20 s with the standard and the turbo light guide could not sufficiently cure a 1-mm-thick sample at a distance of 7 mm. The new FreeLight 2 and the Ultra-Lume LED 2 cured resin samples up to 2.5 mm thick in 40 s with a relative surface ratio > or = 80%, while no sufficient depth of cure was found after 20 s exposure time for the FreeLight 2. However, a 1.5-mm depth of cure with the Ultra-Lume LED 2 and the LEDemetron 1 with the 13/11 mm light guide was obtained after 20 s. The LEDemetron 1 equipped with a 13/8 mm light guide reached a depth of cure of 2.0 mm. No significant difference was found between the Elipar FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1 in their overall curing potential (linear statistical model, 5% level, Bonferroni-correction) given 40 s or 20 s of exposure time.
CONCLUSION: Application of the first-generation LED curing devices FreeLight and e-Light did not ensure clinically sufficient depths of cure, while the new high-power LED curing devices FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1 showed a curing potential equal to the Optilux 501, given 40 s of exposure time.

4. YAP AU, Soh MS. Thermal Emission by different light-curing units. Oper Dent. 2003 May-June:28(3):260-6.

   This study quantified and compared the thermal emission of different light curing units (LCU). Three LED (Elipar Freelight [3M]; GC e-light [GC]; Coolblu [Dentalsystems.com]) and three halogen (Max [Dentsply-Caulk]; Elipar Trilight [3M]; Astralis 10 [Ivoclar-Vivadent]) lights were selected for the study. Thermal emission of the LCUs, when used in various curing modes, was assessed using a K-type thermocouple and a digital thermometer at distances of 3 mm and 6 mm compared to the conventional halogen LCU (Max). The temperature profiles and mean maximum temperature change (n = 7) generated by each LCU were obtained. Data was subjected to ANOVA/Scheffe's post-hoc test and Independent Samples t-test at significance level 0.05. At 3 mm, temperature rise observed with LED lights ranged from 4.1 degrees C to 12.9 degrees C, while halogen lights ranged from 17.4 degrees C to 46.4 degrees C. At 6 mm, temperature rise ranged from 2.4 degrees C to 7.5 degrees C and 12.7 degrees C to 25.5 degrees C for LED and halogen lights, respectively. Thermal emission of LED lights was significantly lower than halogen lights. Significant differences in temperature rise were observed between different curing modes for the same light and between different LED/halogen lights.

5. Hubbezoglu I, Dogan A, Dogan OM, Bolayir G, Bek B. Effects of light curing modes and resin composites on temperature rise under human dentin: an in vitro study. Dent Mater J. 2008 Jul:27(4):581-9.

   The influence of three curing modes of a high-powered LED curing unit on temperature rise under 2-mm-thick dentin was investigated during the polymerization of resin composite samples of Admira, Filtek P60, Premise, Tetric Flow, Tetric Ceram, and Filtek Z250. Ninety standard specimens were prepared. The bonding agents and resin composites were cured

with standard, pulse, or soft-start mode (n=5 for each curing mode). Temperature rise was measured using a type L thermocouple. Data were analyzed by two-way ANOVA and Tukey's test. Soft-start curing led to statistically higher temperature rises compared than the other two modes. The highest temperature rise was observed for Admira and Tetric Flow cured with soft-start mode. The lowest temperature rise was observed for Premise cured with pulse mode. However, temperature rise did not reach the critical value that can cause pulpal damage by virtue of a prominent safety feature of the high-powered LED LCU, which ensures that no excessive heat is produced by all the three curing modes.

VI. Efficacy

6. Judy RH, Dunn WJ, Patel AB, Swanson T. Effects single-charge end point of cordless light-emitting diode light curing unit. Am J Orthod Dentofacial Orthop. 2006 Sep:130(3):378-84

   INTRODUCTION: The purpose of this study was to evaluate the battery lives of cordless light-emitting diodes (LEDs) and their effect on orthodontic bracket bond strength.
   METHODS: One hundred eighty-six metal orthodontic brackets were bonded to extracted molars. Two LED light-curing units (L. E. Demetron [SDS/Kerr, Orange, Calif] and Ortholux [3M Unitek, Monrovia, Calif]) were evaluated. Each light was used to bond 93 specimens. One bracket was bonded every 5 minutes until the battery ran out. The lights were activated for 20 seconds, then automatically turned off for 40 seconds every minute (33% duty cycle) without recharging. Bonded specimens were stored in water at 37 degrees C for 24 hours and then subjected to shear force with a universal testing machine until bracket failure.
   RESULTS: Repeated measures ANOVA detected significantly weaker mean shear bond strength and fewer consecutive cures with the Ortholux compared with the L. E. Demetron light-curing unit. However, when the first 5 time points were excluded, there were no differences between the 2 lights, demonstrating that the lights performed similarly after the first 20 minutes of operation Just before battery failure, both lights still provided the same power density as at the beginning.
   CONCLUSIONS: Both light-curing units provided adequate power density for up to 2 hours without recharging at a 33% duty cycle. There was no significant decrease in power in cordless LED light-curing units as the battery life approached its end point.

7. Platt JA, Clark H, Moore BK. Curing of pit & fissure sealants using Light Emitting Diode curing units. Oper Dent 2005 Nov-Dec:30(6):764-71.

   Light Emitting Diode (LED) curing units are attractive to clinicians, because most are cordless and should create less heat within tooth structure. However, questions about polymerization efficacy have surrounded this technology. This research evaluated the adequacy of the depth of cure of pit & fissure sealants provided by LED curing units. Optilux (OP) and Elipar Highlight (HL) high intensity halogen and Astralis 5 (A5) conventional halogen lights were used for comparison. The Light Emitting Diode (LED) curing units were Allegro

(AL), LE Demetron I (DM), FreeLight (FL), UltraLume 2(UL), UltraLume 5 (UL5) and VersaLux (VX). Sealants used in the study were UltraSeal XT plus Clear (Uclr), Opaque (Uopq) and Teethmate F-1 Natural (Kclr) and Opaque (Kopq). Specimens were fabricated in a brass mold (2 mm thick x 6 mm diameter) and placed between two glass slides (n=5). Each specimen was cured from the top surface only. One hour after curing, four Knoop Hardness readings were made for each top and bottom surface at least 1 mm from the edge. The bottom to top (B/T) KHN ratio was calculated. Groups were fabricated with 20 and 40-second exposure times. In addition, a group using a 1 mm-thick mold was fabricated using an exposure time of 20 seconds. Differences between lights for each material at each testing condition were determined using one-way ANOVA and Student-Newman-Keuls Post-hoc test (alpha=0.05). There was no statistical difference between light curing units for Uclr cured in a 1-mm thickness for 20 seconds or cured in a 2 mm-thickness for 40 seconds. All other materials and conditions showed differences between light curing units. Both opaque materials showed significant variations in B/T KHN ratios dependent upon the light-curing unit.

8. Peris AR, Mitsiu FH, Amaral CM, Ambrosano GM, Pimenta LA. The effect of composite on microhardness when using quart-tungsten-halogen (QTH) or LED lights. Oper Dent 2005 Sep-Oct:30(5):649-54

   This study evaluates the Knoop microhardness of resin composites cured with different light-emitting diode (LED) based light curing units (LCU) or with a conventional quartz-tungsten-halogen light (QTH). Ten experimental groups with 10 specimens each were used. The specimens were prepared by placing two light-cured resin composites with similar VITA shade A2-microhybrid Filtek Z250/3M ESPE and microfill Durafil VS/Heraeus Kulzer--in a 2.0 mm-thick disc shaped mold. The specimens were polymerized for 40 seconds with the use of one QTH LCU (Optilux 501/Kerr-Demetron) and four LED LCUs: Elipar FreeLight 1 Cordless LED (3M ESPE), Ultrablue II LED with cord (DMC), Ultrablue III LED cordless (DMC) and LEC 470 I (MM Optics). Knoop microhardness was determined at the top and bottom surfaces of the specimens 24 hours following curing. Microhardness values in the microhybrid resin composite group showed no statistically significant differences when cured with LED FreeLight 1 LCU and QTH LCU ($p<0.05$). The other LED devices evaluated in the study presented lower microhardness values in both surfaces ($p<0.05$) when compared to QTH. In the microfill resin composite group, no statistically significant differences were observed among all LCUs evaluated on the bottom surfaces ($p<0.05$). However, on the top surfaces, QTH presented the highest KHN values, and the LED devices presented similar results when compared with KHN values relative to each other ($p<0.05$).

9. Wiggins KM, Hartung M, Althoff O, Wastian C, Mitra SB. Curing performance of a new-generation light-emitting diode dental curing unit. J Am Dent Assoc. 2004 Oct:135(10):147-9

   BACKGROUND; Recent technological advances have resulted in the marketing of high-powered, or HP, battery-operated light-emitting diode, or LED, dental curing lights. The

authors examine the curing efficiency and peak polymerization temperature, or Tp, of a new HP LED curing light.

METHODS: The authors studied four visible light-curing, or VLC, units: HP LED (A), first-generation LED (B), conventional halogen (C) and high-intensity halogen (D). They determined the depth of cure, or DOC; adhesion; and Tp of three types of VLC resin-based composites after exposure to each light. The exposure times for units A and D were one-half those for units B and C.

RESULTS: The power density of unit A was 1,000 milliwatts per square centimeter, which was comparable to that of unit D with turbo charge. The DOC and adhesion attained for all three resin-based composites after being light cured by unit A for a 10-second exposure time were equivalent to those after being light cured by unit D for a 10-second exposure time and to those after being light cured by units B and C for 20-second exposure times. The resin-based composites light cured by unit A attained significantly lower Tps than did those light cured by unit D at equivalent cure, or exposure, times and by unit C at twice the cure time.

CONCLUSIONS: The authors found that Unit A effectively cured the resin-based composites at one-half the cure time of units B and C and at the same time as unit D, while maintaining low Tp.

CLINICAL IMPLICATIONS: The battery-operated HP LED curing light might be an effective, time-saving alternative for clinicians to use in light curing resin-based composites.

10. Althoff O, Hartung M. Advances in light curing. Am J Dent. 2000 Nov:13(Spec No): 77D-81D.

PURPOSE: To review and connect the scientific background of light curing with clinical requirements and new technical opportunities in order to conclude the best technology for next generation light curing units. RESULTS: Three conclusions are drawn for proper light curing: (1) A minimum dose of light is needed (wavelength dependent); (2) Internal stress can be reduced by giving the sample time to flow before gel point is reached; (3) An upper intensity limit has to be respected to limit temperature increase as well as light intensity dependent deactivation of activated photoinitiators. These conclusions can best be realized by using the softstart approach. A comparison of different light generation technologies shows that LEDs are most likely to shape the next generations of curing lights. Due to their superior power conversion rate as well as to their optimum spectral emission small and handy devices can be realized that work battery-powered and totally silent. The benefits for the dentist are improved reliability, handling, and hygiene.

11. Shortall AC, Harrington E. Effectiveness of battery powered light activation units. Br Dent J. 1997 Aug9:183(3):95-100.

OBJECTIVE: To investigate the effectiveness of chargeable light curing units and their ability to sustain a high radiant output following successive discharge cycles.

SETTING: University based research investigation assessing the output intensity of three battery powered light activation units and the effect of successive discharge cycles, without intervening periods of recharging, on light output and depth of cure of resin composite.
MATERIALS AND METHODS: Mean light intensity (mW/cm2), through a 4 mm aperture, was measured with a computer based radiometer. Two commercially available resin composites (one hybrid and one microfilled resin) were used for the depth of cure determinations using a digital penetrometer.
RESULTS: Depths of cure were significantly greater for the hybrid resin composite. Output intensity diminished over the period of battery discharge for two of the three units and this finding was paralleled in the depth of cure results. The battery light units tested varied significantly with regard to their length of discharge cycle and recharge times from complete discharge.
CONCLUSIONS: Output intensity diminishes over the period of battery discharge for some makes of battery light units. However, many other factors including handpiece size and weight and unit cost and reliability are important considerations when choosing a unit.

VII. Summary and Conclusion:

Considering the intended clinical applications, as well as many years of clinical evidence of safety in a significant patient population, it is concluded that the evidence for the safety and efficacy of Valo® Cordless is adequate and there are no significant risks associated with this product when it is used following the manufacturer's instructions.

Per the review described above, Ultradent Products, Inc. states that there are no new or existing safety and/or efficacy issues that require action prior to the release of Valo® Cordless. Labeling for intended use, warnings, precautions, etc., have been reviewed and deemed comprehensive and sufficient for safe and accurate use of the modified product.

VIII. Signature and Date:

Report prepared by:

Matt Buck
Regulatory Affairs Specialist

2/22/11
Date

Report reviewed by:

Rich Tuttle, DDS

22 FEB 11
Date

Original Article

Effects of High-Intensity Curing Lights on Microleakage under Bonded Lingual Retainers

Asli Baysal[a]; Tancan Uysal[b]; Mustafa Ulker[c]; Serdar Usumez[d]

ABSTRACT

Objective: To evaluate the effects of high-intensity light curing units (light-emitting diode [LED] and plasma arc curing [PAC]) on the microleakage of flexible spiral wire retainers (FSWRs) at the composite/enamel and composite/wire interfaces.

Materials and Methods: Forty-five human mandibular incisor teeth were separated into three groups of 15 teeth. Multistranded PentaOne wire of .0215 inch diameter was bonded to enamel and was cured with three different light curing units: a quartz-tungsten-halogen (QTH) unit and two high-intensity units (ie, LED and PAC). A conventional halogen light served as the control. Samples were sealed with nail varnish, stained with 0.5% basic fuchsine, and sectioned. Transverse sections were evaluated under a stereomicroscope and were scored for microleakage for the composite/enamel and composite/wire interfaces. Statistical analysis was performed by Kruskal-Wallis and Mann-Whitney *U*-tests with Bonferroni correction.

Results: Little or no microleakage was detected at the composite/enamel interface of the FSWR cured with three different light sources. However, at the composite/wire interface, statistically significant differences were found between the QTH (mean, 1.10 ± 1.05 mm) and high-intensity curing units. The PAC resulted in the greatest amount of microleakage (mean, 2.63 ± 1.49 mm), whereas no statistically significant difference was noted between the PAC and the LED (mean, 2.35 ± 1.28 mm).

Conclusion: High-intensity light curing units show statistically significant microleakage at the composite/wire interface and therefore may not be safe for use in bonding FSWRs.

KEY WORDS: Microleakage; High intensity; Photopolymerization

INTRODUCTION

Lingual retainer fabrication requires meticulous work; therefore, orthodontists prefer to use visible light cured composites over chemically cured ones. In addition to the advantages of extended working time, ease of use, and better physical properties,[1-3] one of the most important tasks involved with the use of light cured composites is the choice of curing units and related curing times.

The most popular light curing unit (LCU) in dentistry has been the quartz tungsten halogen (QTH) light.[4] Manufacturers have recently presented plasma arc curing (PAC) lights,[5,6] argon lasers,[7,8] and solid-state light-emitting diodes (LEDs)[9-11] as alternatives to QTH curing units. The use of these high-intensity units has been recommended because they can enhance monomer conversion while decreasing curing time.[12]

According to the manufacturer instructions, these devices reduce polymerization time to 3 to 10 seconds, and they minimize polymerization shrinkage.[13] Although reduced curing times offer advantages for the orthodontist and for the patient,[14] rapid curing of composites may cause excessive shrinkage and gap formation along the resin/preparation interface.[15,16] These gaps may cause seeping and leakage of oral fluids and bacteria between the tooth and restoration

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surface, an event that defines microleakage in dentistry.[17]

In restorative dentistry, microleakage may result from many factors, such as polymerization shrinkage of materials used, degradation of the particular bonding or restorative material, dissolution of linear or smear layers, and varying coefficients of thermal expansion for restorations.[18] During bracket bonding in orthodontics, the composite is very thin and the composite at the edges of the bracket may absorb some shrinkage.[14] Moreover, Oesterle et al[14] indicated that, because the brackets are free floating, shrinkage can pull the brackets closer to the enamel. Therefore, it is believed that polymerization shrinkage and concomitant microleakage are matters of minimal concern in orthodontic applications.[19] However, the composite material is used commonly in orthodontics during fabrication of the flexible spiral wire retainer (FSWR). The amount of this composite present over the retainer wire may be inversely affected by high-intensity light curing and potential gaps at the composite/enamel and composite/wire interfaces and may cause failure of FSWRs.

In operative dentistry, clinical symptoms associated with the occurrence of microleakage include breakdown and discoloration of margins, secondary caries, increased postoperative sensitivity, and pulp pathology.[20] From the orthodontic point of view, microleakage between composite and enamel can cause white spot lesions, which could cause lingual retainer failure or could result in their removal. On the other hand, polymerization shrinkage and concomitant microleakage can trigger the most common lingual retainer failure type, that is, detachment at the composite/wire interface.[21] This is said to be the result of insufficient composite over the wire and material loss due to abrasion.[22,23]

As a result, the microleakage beneath the composite is particularly important in orthodontics, especially for lingual retainer adhesives, because they are exposed to the oral cavity and are intended to serve in the mouth for a long time. LCUs differ in radiance, and it has been shown that radiant exposure has a significant effect on microleakage.[15] So far, no research has reported on the effects of high-intensity LCUs on microleakage of FSWRs.

Therefore, the aim of this in vitro study was to measure and compare the microleakage between the composite/enamel and composite/wire interfaces of FSWRs that are bonded with two high-intensity LCUs (LED and PAC) and a conventional QTH light. For the purposes of this study, the null hypothesis assumed that the type of LCU used would not affect the microleakage that occurs at the composite/enamel and composite/wire interfaces.

MATERIALS AND METHODS

Sample Preparation

A total of 45 human mandibular incisor teeth, extracted for periodontal reasons, were collected over a 1-month period. Exclusion criteria included caries, cracks, developmental defects, and restorations. Soft tissue remnants were removed with a scaler, and teeth were stored in distilled water before they were randomly divided into three groups of 15 teeth.

Multistranded PentaOne wire (Masel Orthodontics, Bristol, Pa, USA) of 0.0215 inch diameter was used in all groups. Wires were cut into 20 mm lengths to ensure standardization, and the wires were bent to fit the lingual curvature of incisor teeth.

Before composite was placed, teeth were prepared according to the protocol suggested by the manufacturer (ie, cleaned with nonfluoridated pumice and rubber cups, acid etched [3M Dental Products, St Paul, Minn, USA] for 15 seconds, rinsed with water, and air dried). Transbond-XT primer (3M Unitek, Monrovia, Calif, USA) was applied to the etched surface as a thin uniform coat and was not cured.

To ensure stability during placement and contouring, the composite teeth were placed over silicone putty compound, and care was taken to thoroughly inspect the bonding area. Wires that were 20 millimeters in length were bonded to the lingual surfaces from the middle portion. While samples were prepared, care was taken to shape the bulk of the composite 4 mm in diameter and to ensure 1 mm of composite thickness over the wire.[24] However, for ethical concerns, smaller and larger samples were included in the study.

Transbond-LR (3M Unitek) composite was applied and cured with one of the following LCUs at the following curing times, as suggested by manufacturers:

- Group 1 (Control): QTH (Hilux 350; Express Dental Products, Toronto, Ontario, Canada) for 10 seconds
- Group 2: LED (Elipar FreeLight 2; 3M ESPE, Seefeld, Germany) for 5 seconds
- Group 3: PAC (Power Pac; American Medical Technologies, Hannover, Germany) for 3 seconds

Microleakage Evaluation

Prior to dye penetration, the apices were sealed with sticky wax, rinsed in tap water, and air dried, and nail varnish was applied to the entire surface of the tooth, except for the area approximately 1 mm away from the composite bulk. To minimize dehydration of the bulk, the teeth were put into water as soon as the nail polish had dried. The specimens were immersed in 0.5% solution of basic fuchsine for 24 hours at room temperature. After they had been removed from the solution,

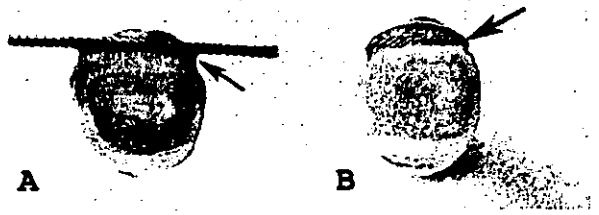

Figure 1. Microleakage between (A) composite/enamel and (B) composite/wire interfaces.

the teeth were rinsed in tap water, and the superficial dye was removed with a brush and dried.

The composite bulk was sectioned in a transverse plane (parallel to the lingual retainer wire) just above the wire with a low-speed water-cooled diamond. First, specimens were evaluated under a stereomicroscope (20× magnification) (SZ 40; Olympus, Tokyo, Japan) for dye penetration along the composite/enamel interface at the mesial and distal borders. Then, lingual retainers were gently removed from the restoration, and dye penetration at the composite/wire interface to the mesial and distal borders was evaluated under a stereomicroscope (Figure 1). Microleakage was assessed by direct measurement with an electronic digital caliper to the nearest value as a range between 0.5 and 5 millimeters, and the data were recorded.

Statistical Analysis

For each composite interface (composite/enamel or composite/wire), the microleakage score was obtained by calculating the mesial and distal microleakage scores. After the mesial and distal leakage was statistically evaluated, the score for each composite and interface was obtained by calculating the mean of the mesial and distal microleakage scores. The Shapiro-Wilks normality test and the Levene variance homogeneity test were applied to the microleakage data. The data did not show normal distribution, and no homogeneity of variances was observed between groups. Thus, statistical evaluation of microleakage values between test groups was performed with Kruskal-Wallis and Mann-Whitney *U*-tests with Bonferroni correction. Intraexaminer and interexaminer method error was evaluated by the kappa test. The level of significance was set at $P < .05$.

RESULTS

Intraexaminer and interexaminer kappa scores for assessment of microleakage were high, with all values exceeding 0.8.

Comparison of the mesial and distal microleakage scores for all specimens showed no statistically significant side differences ($P > .05$). Thus, the mesial and distal microleakage scores for each specimen were pooled, and the microleakage scores for each LCU and interface were obtained by calculating the mean of the mesial and distal microleakage scores.

Table 1. Microleakage Scores at the Composite/Enamel Interface*

Groups	N	X	SD	Min	Max	Statistical Evaluation
Group 1	15	0.22	0.39	0.00	1.00	
Group 2	15	0.22	0.28	0.00	0.75	NS
Group 3	15	0.33	0.48	0.00	1.75	

* N indicates sample size; X, mean; SD, standard deviation; Min, minimum; Max, maximum; NS, not significant; Group 1, quartz tungsten halogen (QTH); Group 2, light-emitting diode (LED); and Group 3, plasma arc curing (PAC).

Table 2. Microleakage Scores at the Composite/Wire Interface*

						Multiple Comparison	
Group	N	X	SD	Min	Max	Group 2	Group 3
Group 1	15	1.10	1.05	0.00	4.50	*	**
Group 2	15	2.35	1.28	1.00	4.50		NS
Group 3	15	2.63	1.49	0.75	5.00		

* N indicates sample size; X, mean; SD, standard deviation; Min, minimum; Max, maximum; NS, not significant; Group 1, quartz tungsten halogen (QTH); Group 2, light-emitting diode (LED); and Group 3, plasma arc curing (PAC). * $P < .05$; ** $P < .01$.

Composite/Enamel Interface

Descriptive statistics and comparisons of microleakage between the enamel and adhesive interfaces of the three LCU groups are shown in Table 1. Little or no microleakage was observed for the three LCUs, and the differences were not statistically significant ($P > .05$). Therefore, the first portion of the null hypothesis failed to be rejected.

Composite/Wire Interface

Descriptive statistics and the results of statistical tests for microleakage at the composite/wire interface are shown in Table 2. Statistically significant differences were noted between Groups 1 and 2 ($P < .05$) and Groups 1 and 3 ($P < .01$). However, no statistically significant difference was detected between Groups 2 and 3 ($P > .05$). Comparison of the results showed the least microleakage with QTH (mean, 1.10 ± 1.05 mm) and the greatest microleakage with PAC (mean, 2.63 ± 1.49 mm). Therefore, the second portion of the null hypothesis was rejected.

DISCUSSION

Light-activated composites are now the material of choice for most orthodontists, and selection of these

materials is important.[25] Until recently, QTH LCUs were the most popular LCUs[4] in dentistry, but these units have drawbacks such as limited light power output when compared with consumed electric power, degradation of components, and a short lifetime.[26] Moreover, it has been shown that halogen curing lights deliver an inadequate light density.[27] With the introduction of LEDs in 1995,[4] these drawbacks were thought to be overcome. The longer lifetimes and more consistent light output with LEDs compared with halogens show promise for their use in orthodontics.[26] According to Usumez et al,[28] another concern is the reduced curing time. Curing for 20 seconds with an LED yields similar results to curing for 40 seconds with a QTH. The advantages and disadvantages of these LCUs over others have led to a research focus on their in vitro performance. In this study, investigators aimed to evaluate microleakage in and around bonded lingual retainers, while using the same orthodontic composite cured with different light sources.

Several techniques have been introduced to assess microleakage around dental restorations. The easiest and most commonly used method involves exposure of the samples to a dye solution before cross sections are viewed under a light microscope.[29] If the relevance of a leakage test is to be evaluated, the effective size of oral bacteria must be considered. Because of the range of bacteria sizes, dyes such as methylene blue and fuchsine are realistic agents to use for identifying the presence of a clinically relevant gap.[30,31] Dye penetration was chosen for this study because it provided a simple, relatively cheap quantitative and comparable method of evaluating the microleakage of lingual retainer composite through the use of various LCUs. In the present study, all specimens were evaluated by two operators at two different times so measurement error could be evaluated. Interexaminer and intraexaminer kappa scores for assessment of microleakage were high, with all values greater than 0.80. However, it is important to note that assessment was performed only at the mesial and distal aspects of each tooth. These sites were selected because they were readily identifiable on each specimen.

The wire of choice for this testing procedure was 0.0215 inch PentaOne. Today, this wire is most commonly used in orthodontics for lingual retainer fabrication,[32] and a study by Bearn et al[21] showed that a diameter increase from 0.0175 inch to 0.0215 inch increased the force required to pull out the wire from the composite.

The match between the wavelength of the LCU and the required wavelength for polymerization of adhesives is another consideration for light-activated adhesives.[33] In orthodontics, this was not thought to be a major concern because the common photoinitiator, camphorquinone, whose initiation wavelength is 470 to 480 nm, is the most common filter for most lights.[14] Therefore, Transbond-LR, which is a specially manufactured composite for lingual retainers, was thought to polymerize in these wavelengths with all LCUs used in this study. All specimens were prepared by the same investigator, and care was taken to get 1 mm adhesive thickness over the wire.

In this study, curing times were chosen according to the manufacturer's instructions. Usumez et al[34] showed that curing Transbond-LR for 6 to 9 seconds with PAC and for 40 seconds with an LED yielded statistically similar results when the degree of conversion was taken into account. Besides these results, curing for 3 seconds with a PAC produced statistically similar direct cure (DC) values compared with conventional halogen lights used for 40 seconds. Investigators thought that, in keeping with the results of previous studies,[34] increased curing times achieved with the PAC may promote microleakage.

From this perspective, lingual retainer composites can be used as restorative materials more often than composites under a bracket, and this bulk of composite is more prone to polymerization shrinkage and gaps between the teeth and the adhesive. At the same time, these gaps may be the reason for microleakage. However, results of this study showed no statistically significant microleakage between enamel and adhesive with either of the LCUs used; thus, the total null hypothesis of this study failed to be rejected. This finding is consistent with restorative dentistry studies that showed no significant difference in microleakage between the enamel and composite interfaces when different LCUs were used.[29,35]

From another perspective, according to the results of this investigation, statistically significant differences for microleakage at the composite/wire interface were noted among QTH and the other two high-intensity LCUs. Thus, the null hypothesis that assumed that the type of LCU used would not affect the microleakage between composite/wire interfaces was rejected.

In the literature, it is clearly stated that the most common failure type for lingual retainers is detachment at the wire/adhesive interface.[21,24] According to the results of this study, statistically significant microleakage at this interface may be interpreted as a factor for failure. Higher scores were recorded for the PAC light source, and PAC results were comparable with those of LED LCUs.

CONCLUSIONS

- Little or no microleakage occurs at the composite/enamel interface with high-intensity LCUs.
- High-intensity LCUs allow more microleakage at the

composite/wire interface and may not be safe for bonding of lingual retainers.

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Minimal exposure time of different LED-curing devices

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ABSTRACT

Objectives. The purpose of the study was to investigate the shortest possible exposure time of different LED-curing devices for five different resin composites in a clinically relevant in vitro-model, where a 7 mm distance from the light guide tip to the bottom side of the cavity was compiled.

Methods. Resin composite samples (Tetric EvoCeram A3, Filtek Supreme XT A3B, Premise A3, CeramX Mono M5, QuiXfil) were filled in three increments of 2 mm thickness each in stainless steel moulds (Ø = 5 mm, $h = 6$ mm, $n = 9$). The samples were incrementally exposed to different blue LED-curing devices (Bluephase, Bluephase C8, Bluephase 16i/Ivoclar Vivadent, L.E.Demetron II/sds Kerr, Elipar FreeLight 2/3M ESPE, Smartlite PS/DENTSPLY, Translux Power Blue/Heraeus) according to the manufacturer's recommendations at a distance of 7 mm from the bottom of the cavity to simulate a class II-curing situation.

Surface hardness was measured (Zwick Z2.5/TS1S) 10 min post-exposure at the bottom surfaces of the resin sample. A bottom/top-surface hardness ratio of 80% of a reference sample (2 mm thickness, 40 s), was defined as clinically acceptable for safe curing. A descriptive statistical analysis was carried out.

Results. The curing devices Bluephase, Bluephase C8, Smartlite PS and Translux Power Blue could cure all composite resins investigated sufficiently in the exposure time recommended by the manufacturers (10–20 s). The curing device Bluephase 16i and L.E.Demetron II only cured the composite Quixfil sufficiently in the exposure time recommended by the manufacturer. FreeLight 2+ allowed a 10 s exposure time for all materials except Ceram X Mono (20 s).

Significance. When incrementally exposed, all resin composites investigated were polymerized sufficiently at a maximum of 20 s exposure time.

1. Introduction

High power blue LED (light emitting diode) curing devices are known for their curing potential. Although previously LED devices were to some extent inferior to high power QTH curing devices, current blue LED visible light curing units (VCL) are comparable or even superior to high power QTH curing devices, due to an enormous increase of power output of high power blue LEDs [1].

The depth of cure of composite resins is mainly dependent on exposure time and the distance of the light guide tip of the light source from the composite resin. Furthermore layer thickness, shade and the translucency of the composite resin have an influence on the depth of cure. It is unknown, if the established determination of depth of cure according to ISO 4049:2000 is in accordance with the clinical setting, since a distinct distance between the light guide tip and the bottom side of the resin composite sample is commonly found.

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Hansen and Asmussen [2] described, that a class II cavity in upper molars can exhibit cavity depths of up to 7 mm. Therefore, this distance has to be considered in an investigation on depth of cure. In accordance with this data, Felix and Price [3] asked for power measurement of curing devices at a distance of 0–10 mm to simulate clinical relevant conditions, since the measurement with zero-distance cannot conclude to measurements in a 10 mm distance. With increasing distance between light guide tip and radiometer, Meyer et al. [4] reported significantly reduced data.

In accordance to these informations the depth of cure of different composite resins was investigated in contrast to ISO 4049:2000, where a light guide tip is placed on top of the resin composite sample to be investigated but in a distance of 7 mm [5]. However in these investigations it was not taken into account that a single increment, as it was investigated in the mentioned study, does not represent a clinical situation except for bulk fill-restoration. In clinical reality, this increment is mostly covered by two more increments of almost the same volume. Therefore, the exposure of a second layer of resin composite placed incrementally on top of the previous one might positively influence the overall polymerization of the first increment.

Since power output of curing devices increased constantly in recent years [1,6], nearly all high power LED-curing devices available nowadays provide the necessary light emission spectrum and power density to ensure a sufficiently cured resin composite [5,7]. The question arose, if exposure time can be reduced from 40 s as recommended as a standard exposure time to cure a 2.0 mm increment sufficiently over years [3]. To achieve an equal degree of curing with shorter exposure times the manufacturers increased the power output of the curing devices. But it was reported, that there is no linear correlation existing between the power output and depth of cure of resin composites [5]. And thus the increased power output might result only in a negligent improvement in depth of cure, while a significant rise of temperature occurs [8].

To determine the depth of cure, the degree of conversion can be measured [9,10] using FTIR spectroscopy [11] or a penetrometer [12,13]. In the present study surface hardness was determined to assess the depth of cure of different curing devices with different composite resins.

The aim of this study was to determine a minimum exposure time for different resin composite/blue LED-curing device-combinations with a clinical relevant distance of 7 mm between the light guide tip and the cavity floor (bottom side of test sample) when an incremental layering of a total of three individually exposed increments was compiled.

A hypothesis was set, that the minimum exposure time can be reduced to a 10 or 20 s with respect to the individual combination of light curing device/resin composite when an incremental curing is taken into account.

2. Materials and methods

For this study on minimal exposure time, stainless steel moulds of 5 mm in diameter with a height of 6 mm were filled in three increments of 2 mm thickness each. Five different state of the art resin composites (Tetric EvoCeram A3, Supreme XT A3B, Premise A3, CeramX Mono M5, QuiXfil, $n=6$, Table 1) and seven different high power blue LED-curing devices (Elipar FreeLight 2+, Bluephase, Bluephase 16i, Bluephase C8, L.E.Demetron II, Smartlite PS, Translux Power Blue; Table 2) were selected for the investigation. With the curing devices Bluephase, Bluephase 16i and Bluephase C8, the high power-curing mode (HIP) was employed since these curing devices are equipped with three different curing programs. All other curing devices were used in the standard modus.

The experimental setup was selected to simulate a clinically relevant setting for restoring a Class II cavity in three increments of 2 mm thickness each. In coincidence with previous studies [14], the light guide tip was placed at a distance of 7 mm to the simulated cavity floor, resulting in a 1 mm space between the light guide tip and the top resin composite layer.

Both resin sample surfaces were covered with a cellophane strip (Frasaco, Tettnang, Germany) to avoid an influence of the oxygen inhibition layer. The steel moulds were placed on a dentin colored base socket (Venus OA 3, Heraeus, Hanau, Germany) to obtain light reflection and absorption phenomena as it occurs in patients.

In a first approach, the exposure times used were as recommended by the manufacturers for the different curing devices. While some manufacturers (DENTSPLY) provided very detailed informations on individual resin composites even from other manufacturers, most manufactures (i.e. 3M ESPE) provided only vague information on exposure time as i.e. to reduce the exposure time recommended from the resin composite manufacturers to 50%. Therefore initial exposure time investigated varied from 5 to 20 s, depending on the individual resin composite/curing device combination (Table 3).

Ten minutes after light exposure, the surface hardness (universal hardness) of the resin composite samples was measured using a load of 4.9 Newton (Zwick Z2.5/TS1S, Zwick GmbH, Ulm, Germany, loading speed 1 mm/min) employed from the bottom surfaces of the test samples at three different spots, to consider an unequal light exposure of the resin composite sample surface. The mean value of those three individual measurements was taken as the overall surface hardness value for this individual sample. In contrast to

Table 1 – Resin composites investigated in the present study

Resin composite	Manufacturer	Shade	Lot number
Tetric EvoCeram	Ivoclar/Vivadent, Schaan, Liechtenstein	A3	J09968
Filtek Supreme XT	3M ESPE, St. Paul, MN, USA	A3B	20060601
Premise	Sds Kerr, Orange, CA, USA	A3	05-135501
Ceram-X Mono	DENTSPLY, Konstanz, Germany	M5	0607000965
QuiXfil	DENTSPLY, Konstanz, Germany	Universal	0604000608

Table 2 – LED curing devices investigated in the present study

LED curing device	Manufacturer	Radiometer data (Ulbricht sphere)	Serial number
Elipar Free Light 2+	3M ESPE	975 mW/cm²	939820016379
Bluephase	Ivoclar/Vivadent	1083 mW/cm²	1543203
Bluephase 16i	Ivoclar/Vivadent	1370 mW/cm²	1587039
Bluephase C8	Ivoclar/Vivadent	730 mW/cm²	1565534
L.E.Demetron II	Sds Kerr	1091–1247 mW/cm²	782004849
Smartlite PS	DENTSPLY	879 mW/cm²	BA 01514
Translux PowerBlue	Heraeus Kulzer	852 mW/cm²	060HG654

Radiometer data were obtained from the Ulbricht-sphere.

the measurement of the original "Vickers" hardness, where the diameter of the impression, generated by the Vickers-diamond (136°), is measured optically through the diamond itself, this device, using a comparable diamond under load, measures the depth of impression, from which the diameter and there from the hardness can be calculated. Hardness was defined as "universal hardness", determined under load, in contrast to "Vickers"-hardness, originally not determined under load.

In addition, six reference samples (2 mm thickness) were made of each resin composite and were exposed for 40 s under direct contact to the light guide tip. According to that, a maximally cured reference surface could be expected. Those reference samples were generated for all curing devices. The mean surface hardness of all reference samples from a single resin composite, obtained from exposure with all the different curing devices, was taken as the reference hardness value for the individual resin composites (Table 4). The mean bottom surface hardness values from the reference samples bottom side, exposed from a distance of 7 mm and thereafter incrementally recurred, were correlated to this reference surface hardness (Fig. 1).

A bottom (test sample) to top (reference sample) relative surface hardness ratio ≥80% was defined as sufficiently cured. When the calculated surface hardness ratio between the bottom of the test sample, that was cured three times (3 mm × 2 mm) and the top of the reference sample, cured under direct contact to the light guide tip, was 100% or more, exposure time was reduced by 10 s (5 s with L.E.Demetron II). With a surface hardness ratio <80%, the exposure time for each sample's increment was increased by 10 s (5 s with L.E.Demetron II). If the relative surface hardness ratio was then <80% again, another trial was performed, where the resin composite increments were exposed with an exposure time increased by a further 10 s (5 s with the L.E.Demetron II).

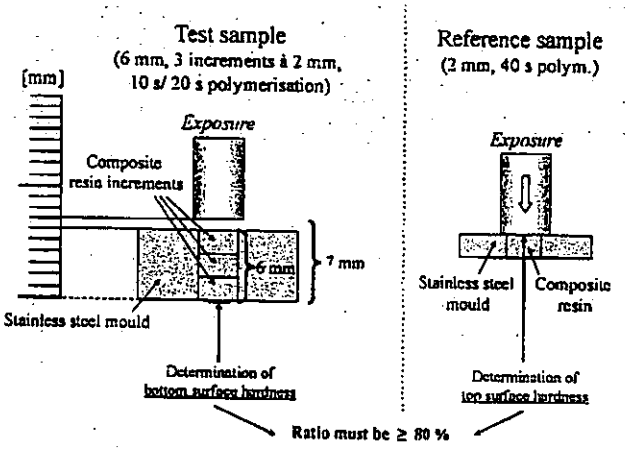

Fig. 1 – Schematic drawing of the test setup to investigate the depth of cure. Each test samples of 2 mm thickness (three increments, each 2 mm) was exposed within a distance of 7 mm between the light guide tip and the bottom of the resin sample, while the reference sample (2 mm thickness) was cured under direct contact to the lightguide tip. A ratio ≥80% of test samples bottom sides to reference samples top surfaces was defined as sufficient curing.

The power output of all curing devices was determined after the investigation with an Ulbricht sphere (Gigahertz Optik GmbH, Puchheim, Germany). A descriptive statistical analysis (Excel) was carried out.

Table 3 – Mean exposure time needed to cure composite increments sufficiently

	Bluephase	Bluephase 16i	Bluephase C8	LEDemetron II	FreeLight 2+	Smartlite PS	Power Blue
EvoCeram	10 (10 s)	20 (10 s)	20 (20 s)	15 (5 s)	10 (10 s)	20 (20 s)	10 (20 s)
Supreme XT	15 (15 s)	20 (10 s)	20 (20 s)	10 (5 s)	10 (10 s)	20 (20 s)	20 (20 s)
Premise	15 (15 s)	20 (10 s)	20 (20 s)	10 (5 s)	10 (10 s)	20 (20 s)	20 (20 s)
CeramX	15 (15 s)	20 (10 s)	20 (20 s)	15 (5 s)	20 (10 s)	20 (20 s)	20 (20 s)
QuiXfil	5 (15 s)	10 (10 s)	5 (20 s)	5 (5 s)	10 (10 s)	10 (10 s)	20 (20 s)

The number in parentheses in each box represents the recommendation of the manufacturer on exposure time per increment of resin composite.

Table 4 – Mean top surface hardness (±S.D.) of the reference-samples of all curing devices investigated (N/mm²)

	Bluephase (HIP)	Bluephase 16i (HIP)	Bluephase C8 (HIP)	LEDemetron II	FreeLight 2+	Smartlite PS	Power Blue	Mean reference surface hardness
Tetric EvoCeram	230.1 (20.3)	249.6 (27.6)	230.8 (2.7)	214.2 (23.3)	225.8 (11.4)	241.0 (13.9)	212.8 (20.2)	229.2 (13.3)
Supreme XT	316.1 (36.4)	352.0 (30.4)	298.7 (44.8)	327.1 (32.0)	317.7 (30.0)	324.1 (54.9)	276.4 (39.1)	316.0 (23.6)
Premise	203.1 (37.7)	261.9 (20.8)	227.9 (58.7)	219.9 (47.0)	223.8 (24.7)	204.1 (70.0)	198.3 (38.2)	219.9 (21.8)
CeramX Mono	210.9 (37.8)	250.7 (23.2)	236.8 (61.1)	249.8 (62.7)	230.4 (50.2)	233.0 (38.3)	197.7 (34.5)	229.9 (19.5)
QuiXfil	346.4 (93.7)	401.8 (40.8)	300.4 (75.8)	354.9 (81.4)	362.4 (85.2)	384.1 (59.6)	397.8 (65.9)	364.0 (35.1)

The mean reference hardness in the right column represents the mean reference hardness of each material, determined with all curing devices investigated. This was the final reference hardness used for the particular resin restorative in this investigation.

3. Results

The power output data obtained from the measurements with the Ulbricht sphere are shown in Table 2. The mean surface hardness reference values are shown in Table 4. The mean top surface hardness of each composite resin sample was used as the overall reference sample for the further investigation of depth of cure within the 7 mm distance to the light guide tip. Based on the surface hardness ratio determined, a minimal exposure time for every light guide tip with every composite resin could be acquired. The resulting minimal exposure times were a relative surface hardness ratio ≥80% was achieved and the exposure times as recommended by the manufacturers are shown in Table 3. In 23 test approaches the exposure time recommended by the particular manufacturer was appropriate (Table 3). Nine of 35 recommended exposure times of the manufactures for an appropriate exposure were too short and sufficient surface hardness were not achieved: this was the case for all the composites exposed with the Bluephase 16i and the L.E.Demetron II except for QuiXfil (10 and 5 s) as well as for CeramX when cured with the FreeLight 2+. In three cases, even a reduced exposure time could be obtained: as there was no individual recommendation for the QuiXfil from the manufacturers except from DENTSPLY, this material could be sufficiently cured in 5 s when incrementally applied and exposed with the Bluephase and the Bluephase C8. A 10 second exposure time was sufficient for Tetric EvoCeram, when exposed with the Translux Power Blue.

4. Discussion

The depth of cure of different composite resins was assessed by the determination of the surface hardness in this study. The determination of the surface hardness is still the most frequently used method [15,16]. Even though other methods like the determination of the degree of conversion [9,10] appears to be the most sensitive and reliable method to evaluate the depth of cure [17,18], surface hardness measurements seem to come relatively close to the results obtained with these methods [11]. By means of the determination of surface hardness, different exposure techniques and procedures can be compared [15,16,19,20] and data thus obtained can be related to the degree of conversion to a certain extent [21,22].

The testing of material properties such as flexural strength and modulus [13] are also suitable methods to compare differently exposed resin composite samples. An 80% ratio in relative surface hardness as the defined limit for sufficient depth of cure was commonly used in the literature [21–23].

Since increased distance between the light guide tip and the composite results in a decrease in power density [24] and curing efficiency [25,26], a clinically relevant distance of 7 mm between the light guide tip and the bottom side of the simulated cavity was used in this investigation to obtain an experimental setup, which came as close as possible to a clinically relevant experimental setup [2,14,27].

As the shade and opacity of a composite resin has an impact on the depth of cure [28], the shade A3 was used for Tetric EvoCeram, Filtek Supreme XT and Premise, as it was done in

previous studies [29,30]. According to manufacturer's recommendations, CeramX Mono M5 is equivalent to a Vita A3. On the other hand, QuiXfil is only available in a very translucent universal shade, especially designed to allow short exposure time and an improved depth of cure. Due to the fact that only the determination of the minimal exposure time for a defined increment of 2 mm thickness was the subject of this investigation, no conclusion can be drawn with regard to the maximum bulk thickness possible, which might result in a sufficient polymerization. One has to keep in mind that a lighter shade like a Vita A2 probably results in better outcomes concerning relative surface hardness.

The determination of the surface hardness was done 10 min after light exposure. This time was needed to mount the composite samples into the measuring device. Even though a post-cure-polymerisation over the following 24 h has been described in literature [31], the current study measured the surface hardnesses only immediately following light exposure. That was due to the fact that the operator should expect that the restoration has to be sufficiently cured to allow a masticatory loading immediately. If there would be a time interval with restricted loading, additional information on that had to be delivered by the manufacturers. Due to the fact that not a single instruction manual addresses this point, we came to the conclusion, that immediate loading testing were appropriate for the present study.

The composite surfaces were both covered by a cellophane strip. It has to be taken into account that this layer is enriched with monomers and the hardness values might be lower compared to a finished and polished surface. But since relative surface hardness between bottom and top-surface was determined and both surfaces were covered with a cellophane strip, no interference was expected.

In contrast to previous investigations [5,14], the present study was designed to evaluate the influence of a second and third layer of resin composite, placed on top of the previously applied one. With this approach the former increment might be post-cured and the remaining exposure light might pass through the second (or third) increment. This was particularly addressed in this study. A 40 s exposure time was selected to ensure a maximum hardness of the reference samples at the surface top. It is known from the literature that an exposure time of 60 s achieves a further increase of the polymerization and the surface hardness [32]. However, this approach seems to be far from clinical practice.

Therefore with doubling of the exposure time of the reference samples, a sufficient cure of those samples could be expected. While the exposure time of the reference samples was 40 s in all the cases, in some approaches, the test samples were exposed in an overall shorter time. A 10 s exposure time per increment resulted in an overall exposure time of the entire restoration of 30 s, which is 25% less than the exposure time of the reference sample. This was in accordance with the manufacturer's description to cure a resin composite restoration sufficiently when such a number of increments are used.

In an earlier investigation [5], the Bluephase cured a 2.0 mm increment of Tetric Ceram at 40 s sufficiently; in the present investigation only 10 s were needed for sufficient cure of Tetric EvoCeram. But it has to be taken into account that Tetric EvoCeram is a different material than Tetric Ceram. The same was observed for QuiXfil that was previously tested polymerized sufficiently after 20 s of exposure, but in the current study only a 5 s exposure time was necessary in most of the cases. For the SmartLite PS, 40 s were needed to sufficiently cure the QuiXfil in the cited study. However, in the present study 10 s exposure time was enough to cure a 2 mm increment. It has to be kept in mind that these investigations are not directly comparable since in the previous one, only a single increment of 2 mm was cured out of a distance of 7 mm.

So far, an exposure time of 40 s was considered to be a standard to cure a composite increment of 2.0 mm sufficiently over years [3]. However, after critically reviewing the recent data, recommendations should be changed. In comparison to the recent investigation [5], incremental exposure seems to have a positive influence on the time needed for sufficient cure. There was a reduced time needed to cure composite increments sufficiently when multiple exposures were taken into consideration, depending on which combination of curing device and composite was tested. All composites could be cured sufficiently within 20 s of exposure time with incremental layering. The present data supports the observation that the investigated composites are a determining factor and influence the polymerization time needed for sufficient cure to the same extent as the curing device [5,33]. Therefore, the exposure time necessary to polymerize an increment sufficiently mainly depends on the individual combination of a particular curing device and a particular resin composite. This assumption is supported by the investigations from Price et al. [3,34]. Therefore it can be concluded that the polymerisation time can be reduced, if a multiple exposures for composite increments are taken into consideration.

The exposure times recommended by manufactures could be verified in 23 cases (Table 3). This resulted in two groups of similar power output. One group cured composite increments with a mean exposure time of 11/12 s per increment from the resin composites investigated—including the QuiXfil (Bluephase, LEDemetron II, Free Light2+) while the other group cured composite increments in a mean of 17/18 s per increment (Smartlite PS, PowerBlue, and Bluephase C8). Comparing the obtained results to the acquired radiometer data derived from the Ulbricht-sphere, no linear correlation between power and the curing potential was observed. Even though the Bluephase 16i showed the highest top surface hardness (Table 4), the curing device showed an unexpected curing performance compared to the other curing devices tested that cannot be explained by this investigation. Although Radiometer data obtained from the Ulbricht-sphere are appropriate to compare different light sources, the curing performance of the different devices cannot be compared in the same ratio. Therefore recommendations on exposure time should not only be based on measurements of the power output.

It is known that the new generation of blue LED-curing devices develops more heat than devices of the first generation [9]. The high power LED-curing devices provide the necessary energy spectrum to cure composite resins sufficiently [7], a further increase of power density does not seem to be necessary and practicable due to the significant rise of temperature [8] while at the same time the depth of cure cannot be improved to the same extent. Besides that Knezevic et al. [35] found,

that the highest rise in temperature occurred during the first 20 s, due to the additional exothermic heat production from the polymerizing resin composite. The increase in temperature during the first 20 s depends on the light density of the emitted light [35]. Thus with a certain power output available, it does not seem appropriate to increase the power output of blue LED-curing devices further on. Nevertheless, the application of blue LED-curing devices can be considered as efficient and save [10].

5. Conclusion

All the blue LED-curing devices investigated in this study had the potential to cure composites sufficiently, but it could be verified that the different composites required different exposure times. All composites tested were cured sufficiently in an exposure time of 20 s when a multiple exposure of composite increments was taken into consideration. The post-curing through a second and third layer of resin composite might positively influence the polymerization of the first increment on the interproximal cavity floor. The minimum exposure time can be reduced to 20 or 10 s with respect to the individual light curing device/resin composite combination.

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Depth of Cure of LED vs QTH Light-curing Devices at a Distance of 7 mm

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Purpose: To determine the depth of cure of 5 blue LED curing devices compared to that obtained with 3 QTH curing devices.

Materials and Methods: The LED curing devices tested were 1) e-Light: 40 s; 2) Elipar FreeLight: 40 s; 3) Elipar FreeLight 2: 20 s and 40 s; 4) Ultra-Lume LED 2: 20 s and 40 s; 5) LEDemetron 1: 20 s and 40 s. The QTH curing devices tested were 1) Optilux 501: standard light guide 20 s and 40 s, turbo light guide 20 s; 2) Elipar TriLight: 40 s; 3) Astralis 10: 20 s. Surface hardness was measured (Zwick Z2.5/TS1S) 10 min after exposure on the top and bottom surface of resin samples (Tetric Ceram A3, 1 to 5 mm; 0.5 mm increment, diameter 5 mm, n = 9) which were cured at a distance of 7 mm from the bottom of the sample to the light-guide tip to simulate a Class II curing situation. A reference sample was cured under direct contact with the light guide. The reference sample with the greatest top surface hardness of all devices measured served as the overall control. A bottom/top surface hardness ratio of ≥ 80% of the reference sample cured at zero distance was defined as clinically acceptable for safe curing. A descriptive statistical analysis was carried out.

Results: With QTH lamps, the mean maximum resin composite sample thickness which cured sufficiently (relative surface ratio ≥ 80%) was: 3 mm for Optilux 501, standard light guide, 40 s; 2.5 mm for Trilight, 40 s; and 1.5 mm for Astralis 10, 20 s. The first-generation LED curing devices FreeLight and GC e-Light, both applied for 40 s, and the Optilux 501 operated for 20 s with the standard and the turbo light guide could not sufficiently cure a 1-mm-thick sample at a distance of 7 mm. The new FreeLight 2 and the Ultra-Lume LED 2 cured resin samples up to 2.5 mm thick in 40 s with a relative surface ratio ≥ 80%, while no sufficient depth of cure was found after 20 s exposure time for the FreeLight 2. However, a 1.5-mm depth of cure with the Ultra-Lume LED 2 and the LEDemetron 1 with the 13/11 mm light guide was obtained after 20 s. The LEDemetron 1 equipped with a 13/8 mm light guide reached a depth of cure of 2.0 mm. No significant difference was found between the Elipar FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1 in their overall curing potential (linear statistical model, 5% level, Bonferroni-correction) given 40 s or 20 s of exposure time.

Conclusion: Application of the first-generation LED curing devices FreeLight and e-Light did not ensure clinically sufficient depths of cure, while the new high-power LED curing devices FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1 showed a curing potential equal to the Optilux 501, given 40 s of exposure time.

Key words: blue LED curing devices, QTH curing devices, depth of cure, clinically relevant distance, posterior teeth

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When resin composite restorations in posterior teeth became a standard procedure in most dental offices, different issues regarding depth of cure arose compared to those pertinent to anterior teeth. In anterior resin composite restorations, the layer thickness exposed at once rarely exceeded 1 to 2 mm, and the light-guide tip

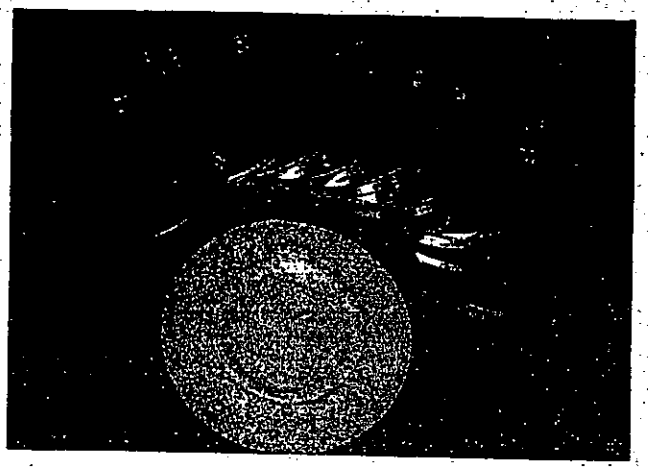


Fig 1 Stainless steel molds 5 mm in diameter and height varying from 1 to 5 mm in 0.5 steps. The steel molds were placed on a dentin-colored base socket to obtain light reflection and sorption phenomena comparable to a clinical cavity preparation. Each steel ring contains 5 holes which will be filled with composite,

could be placed very close to the resin composite. When the use of resin composites was extended to posterior cavity preparations, the thickness of incremental layers was not as easy to control as in anterior restorations, and frequently reached 2 to 3 mm. Therefore, demands arose to obtain sufficient depths of cure by more powerful curing devices, even when the light-guide tip could not be placed as close to the composite as is possible in anterior cavities.[20]

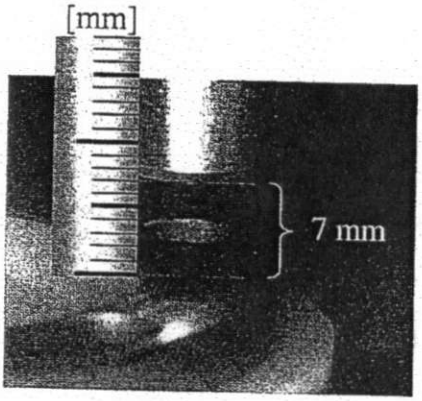
The literature shows that a distance of 7 mm from the light-guide tip to the gingival floor must be assumed in a typical Class II preparation.[9,18,24] Due to the fact that a light-guide tip mostly rests on the occlusal edge of the cavity,[20] these 7 mm must be taken as a clinically relevant distance between the light-guide tip and the lower surface of a resin composite increment in the approximal box of a Class II cavity preparation. In this context, it is important to recognize that increasing the distance between the light-guide tip and the resin composite surface to more than 6 mm can cause a significant difference in the polymerization of the resin composite 2 mm below the resin surface, although there is little change in the light intensity determined on the surface.[20] Pires et al[16] reported a remaining power density of 78% at a distance of 2 mm and of 47% at a distance of 6 mm. Similarly, Prati et al[17] found that the mean power output had fallen to 61% at a distance of 2 mm and to 23% at 6 mm. As shown recently,[12] the light intensity of conventional QTH curing devices decreased 56% to 76% at a distance of 10 mm compared to a 100% power output at zero distance to a radiometer. In that particular study, the blue LED[13] curing devices showed a significantly greater decrease in power output with increasing distance between light-guide tip and radiometer compared to the QTH devices. As a consequence of these findings, there was a strong need for further investigations on the depth of cure in contrast to ISO 4049:2000, where the light-guide tip is placed directly on top of the resin sample. A clinically relevant distance of 7 mm between the light-guide tip and the bottom side of the resin composite increment should be maintained, as this represents an average maximum of approximal box depth.

Therefore, the aim of this study was to compare the maximum depth of cure obtained at a distance of 7 mm using first-generation and recently introduced high-power blue LED curing devices to that of conventional QTH curing devices. Sufficient cure was defined as a surface hardness ratio of ≥ 80% between the bottom and top sides of resin composite samples.

MATERIALS AND METHODS

Stainless steel molds 5 mm in diameter and with heights ranging from 1 to 5 mm in 0.5-mm steps were bulk filled with a standard hybrid resin composite (Tetric Ceram A3, Vivadent, Schaan, Liechtenstein, lot D 63754, n = 3 per thickness and light-curing device; 3 measurments were take per sample: 3 x 3 = 9). Both resin sample surfaces were covered with a cellophane strip (Frasaco, Tettnang, Germany) to avoid oxygen inhibition. The steel molds were placed on a dentin-colored base socket (Charisma OB 3, Heraeus-Kulzer, Hanau, Germany) (Fig 1) to ensure light reflection and sorption phenomena comparable to a clinical cavity preparation. The light-guide tip was placed 7 mm from the bottom side of the resin sample to simulate a clinical situation involving a Class II approximal box. A metal matrix system (Automatrix, Dentsply, Konstanz, Germany) was wrapped around the light-guide tip, reaching up to the top surface of the resin composite sample (Fig 2). This experiment was carried out to simulate reflection phenomena of a metal matrix system used in a Class II cavity restoration process. The resin composite was exposed for 20 s or 40 s according to recommendations by the manufacturers of the curing devices or the resin composite.

Five blue LED curing devices (Table 1) were investigated mainly using a 40-s standard exposure mode. Due to the fact that the manufacturers of the FreeLight 2, UltraLume LED 2, and LEDemetron 1 claim that a 20-s exposure time is enough to cure Tetric Ceram sufficiently, these devices were additionally tested in a 20-s exposure trial. The LEDemetron 1, equipped with a 13/11-mm focusing light guide was investigated in a separate trial using the 13/8-mm focusing light guide recommended for the Optilux 501. Three QTH curing devices (Table 1) served as control. While the Elipar TriLight and the Optilux 501, both using a standard light guide, were operated in the 40-s standard exposure mode, the depth of cure obtained with Optilux 501 was also investigated after a 20 s exposure time using the standard light guide, as well as a 13/8 focusing light guide ("Turbo" light guide). As recommended by the manufacturer for curing resin composite fillings, the Astralis 10, equipped with a 13/8 light guide comparable to that of the Optilux 501, was operated in the 20-s pulsed mode, where intensity increases



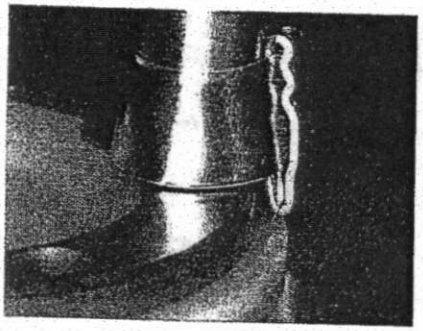


Fig 2 Experimental setup with the light-guide tip placed 7 mm from the bottom side of the resin sample to simulate the clinical situation of a Class II approximal box. A metal matrix system was wrapped around the light-guide tip, reaching up to the top surface of the resin composite sample.

Table 1 Visible light curing devices tested in this study. Conventional QTH curing devices are shown with a white background; first-generation LED curing devices are marked with a light grey background, high-power blue LED curing devices with a dark grey background. The ticks in the right columns mark the exposure times investigated with the particular curing devices

Visible light curing device	Light guide	Light intensity [mW/cm²]	Manufacturer	Serialnumber	20 s exposure time	40 s exposure time
Elipar TriLight	8 mm standard	0 mm: ~ 500 7 mm: ~ 300	3M ESPE, Seefeld, Germany	3900402		❑
Optilux 501	11 mm standard	0 mm: ~ 500 7 mm: ~ 300	SDS Kerr Demetron, Danbury, CT, USA	53100227	❑	❑
Optilux 501	13/8 mm focusing	0 mm: ~ 800 7 mm: ~ 200	SDS Kerr Demetron, Danbury, CT, USA	53100227	❑	
Astralis 10, "Pulse"-mode	13/8 mm focusing	0 mm: altern. ~ 500–900 7 mm: altern. ~ 100–200	Vivadent, Schaan, Liechtenstein	010072	❑	
GC e-Light	8 mm standard	0 mm: ~ 200 7 mm: ~ 60	GC Europe N.V., Leuven, Belgium	01/29/00474G		❑
Elipar FreeLight	10/8 mm focusing	0 mm: ~ 250 7 mm: ~ 100	3M ESPE, Seefeld, Germany	939800000047		❑
Elipar FreeLight 2	10/8 mm focusing	0 mm: ~ 680 7 mm: ~ 200	3M ESPE, Seefeld, Germany	34 (Prototype)	❑	❑
Ultra-Lume LED 2	13 x 6 mm light emitting surface	0 mm: ~ 420 7 mm: ~ 200	Ultradent Products Inc., South Jordan, UH, USA	000839	❑	❑
LEDemetron 1	13/11 mm focusing	0 mm: ~ 750 7 mm: ~ 420	SDS Kerr Demetron, Danbury, CT, USA	921544	❑	❑
LEDemetron 1	13/8 mm focusing	0 mm: ~ 1000 7 mm: ~ 380	SDS Kerr Demetron, Danbury, CT, USA	921544	❑	

from 150 mW/cm² to 650 mW/cm² within the first 10 s und then alternately pulses between 650 mW/cm² and 1200 mW/cm² every 2 s (information obtained from the instruction manual) for another 10 s.

Ten minutes after light exposure, the surface hardness (universal hardness) of the resin composite samples was measured under a load of 4.9 N (Zwick Z2.5/TS1S, Ulm, Germany, loading speed 1 mm/min) on the top and bottom surface at three different spots, in order to take possibly unequal light exposure into consideration. Thus, nine measurements for each sample thickness and for every exposure variation were obtained from the total of three samples exposed (3 samples x 3 measurements/surface each: n = 9). In contrast to the measurement of the original "Vickers" hardness – where the diameter of the impression generated by the Vickers diamond (136 degrees) is measured optically through the diamond itself which is connected to an optical system – this device, using a comparable diamond under load, measures the depth of the impression, from which the diameter and thus the hardness can be calculated mathematically. This hardness is then defined as "universal hardness", determined under loading, in contrast to "Vickers" hardness, originally not determined under loading; this marks the different modes of generating data from the same diamond penetration corpus.

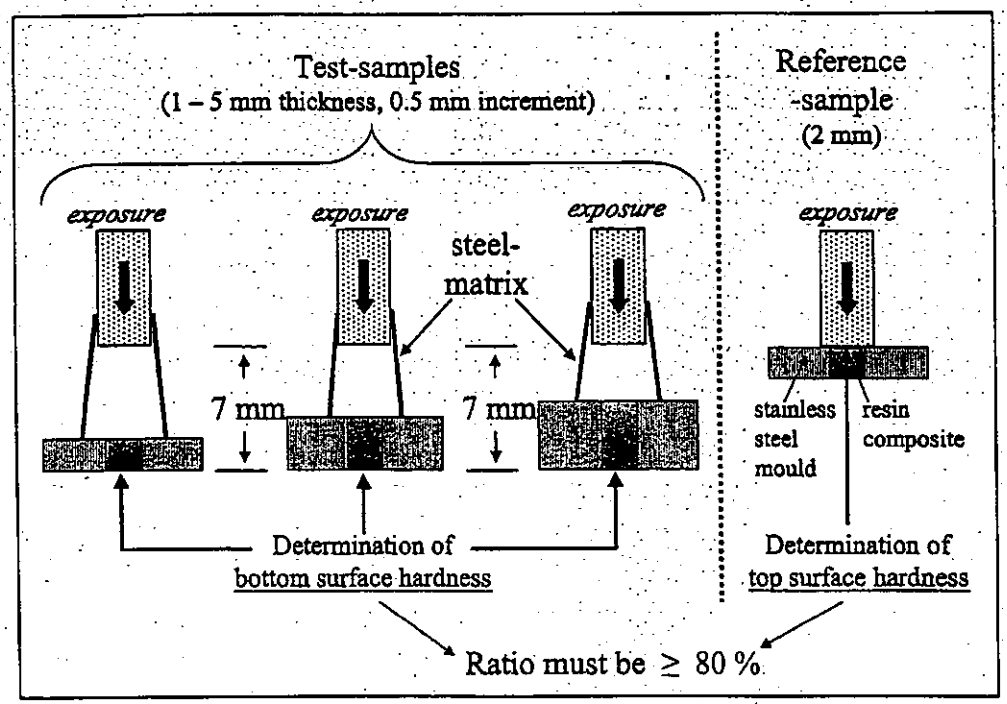


Fig 3 Schematic representation of the test setup to investigate the depth of cure of Tetric Ceram resin composite samples (shade A3). The test samples were exposed at a distance of 7 mm from the light-guide tip to the bottom of the resin sample, while the reference sample (2 mm thickness) was cured under direct contact to the light-guide tip. A ratio of ≥ 80% of test sample bottom to reference sample top surfaces was defined as sufficient curing.

In addition, three reference samples (2 mm thickness, 3 measurements each on bottom and top, n = 9) were exposed to each of the curing devices under direct contact to the light-guide tip to obtain an optimally polymerized resin composite sample. Of these 2-mm-thick reference samples, the sample with the highest surface hardness was selected as the overall reference sample to represent the best polymerized surface that could be expected. The bottom surface hardness data obtained from all samples cured 7 mm from the light-guide tip were compared to this (Fig 3). A bottom (test sample) to top (reference sample) relative surface hardness ratio ≥ 80% was defined as sufficiently cured.

According to the manufacturer of Astralis 10, the "esthetic cementation system" (ECS) – delivering 1200 mW/cm² for 30 s – in direct light-guide contact could be expected to result in the highest surface hardness; thus, three additional reference samples were exposed in this curing mode.

The light intensity of all curing devices was determined by means of a Demetron 100 Curing Radiometer (Kerr-Demetron, Danbury, CT, USA) at 0 and 7 mm from the light-guide tip with a metal matrix wrapped around the light guide as it was performed in the depth-of-cure experiments.

For statistical analysis, the difference in bottom hardness between different light-curing devices was assessed in a linear model which included "thickness" as a covariate in addition to the factor "device". Because a total of 105 comparisons was carried out, a Bonferroni correction was used to adjust for multiple testing. Therefore, only p-values below 0.0005 could be considered significant at the global 5% level.

RESULTS

The results of the radiometer measurements at 0 and 7 mm are shown in Table 1. In Fig 4, the mean surface hardness data from the bottom and top surfaces of all the reference samples are shown. The highest mean surface hardness (290.8 ± 19.1 N/mm²) of the reference sample was obtained with the Elipar FreeLight 2 after 40 s of exposure. Therefore, the mean top surface hardness of these samples was used as the overall reference sample for the further investigation of depth of cure at 7 mm from the light-guide tip. In addition, Elipar FreeLight 2 produced the highest bottom surface hardness of the 2-mm reference samples, 324.6 ± 10.9 N/mm². Thus, the 2-mm reference samples cured with the Elipar FreeLight reached the highest cure rate of all samples investigated, followed by the QTH curing devices, in which 40 s of exposure time was used (Optilux 501: 284.9 ± 26.9 N/mm² top surface hardness, 295.3 ± 22.0 N/mm² bottom surface hardness; and Elipar TriLight: 273.9 ± 12.7 N/mm² top surface hardness, 286.4 ± 14.70 N/mm² bottom surface hardness). The reference sample surface hardness obtained with the Astralis 10 operated in 20-s pulsed mode was comparable to that of the QTH curing devices using 40 s of exposure time: the mean top surface hardness was 274.3 ± 20.3 N/mm² and the mean bottom surface hardness 262.6 ± 1.1 N/mm². The 30-s ECS mode of the Astralis 10 was originally integrated in the investigation to obtain a maximally cured resin composite surface. Surprisingly, this mode did not show better results than the 20-s pulsed mode. However, it should be mentioned that before starting to expose the reference samples to the Astralis 10 ECS mode, the halogen bulb had to be changed.

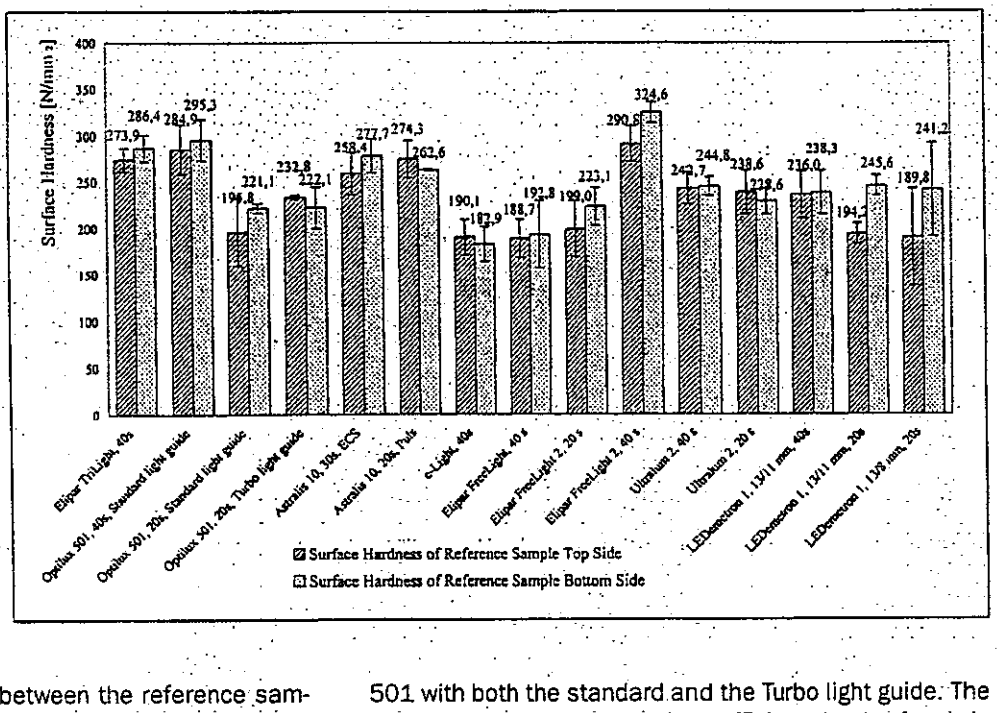


Fig 4 Surface hardness of reference samples, top and bottom surfaces, by device and exposure time.

so that a direct comparison between the reference samples exposed with the different modes of the Astralis 10 was not possible. The mean surface hardness data of the other reference samples were far below the reference samples mentioned above, as can be seen from Fig 4.

Table 2 shows the mean (± SD) values for surface hardness measured at the top and bottom surfaces of the resin composite samples cured with the light-guide tip 7 mm from the bottom surface of the sample. As expected, the mean bottom surface hardness decreased with increasing resin sample thickness, while the mean top surface hardness increased with increasing sample thickness due to a shorter distance to the light-guide tip.

Table 3 shows the ratios of the mean bottom surface hardness of test samples to the overall reference sample, defined as the best-cured resin composite surface from this investigation (Elipar FreeLight, 40-s exposure time, 290.8 N/mm²). In some cases, a relative bottom:top surface hardness ratio of > 100% was found. The limit for sufficient cure the sample thickness was defined as the value after which the relative surface hardness ratio dropped below 80% the first time. A later, higher relative surface ratio was not included in maximum depth of cure. As can be seen from Table 3, the mean maximum resin composite sample thickness which cured sufficiently (relative surface ratio ≥ 80%) was: 3 mm for Optilux 501 with standard light guide, 40 s; 2.5 mm for Trilight, 40 s; and 1.5 mm for Astralis 10, 20 s. The first-generation LED curing devices FreeLight and the GC e-Light, both applied for 40 s, as well as the Optilux 501 operated for 20 s with the standard and the Turbo light guide were not able to cure a 1-mm-thick sample sufficiently at 7 mm. The high-power blue LED curing device FreeLight 2 cured resin samples up to 2.5 mm thick with a relative surface ratio of 80% in 40 s, but 20 s of exposure did not produce a sufficient depth of cure. The FreeLight 2, applied for 20 s, showed comparable results to 20 s of the Optilux 501 with both the standard and the Turbo light guide. The Ultra-Lume LED 2 produced a sufficient depth of cure in samples up to 2.5 mm thick when the samples were exposed for 40 s, and sufficient depth of cure in up to 1.5-mm-thick samples when a 20 s exposure time was used. The LEDemetron 1, equipped with the 13/11-mm light guide and operated for 20 s, reached the same depth of cure in 1.5 mm samples as the Ultra-Lume LED 2, when a 80% relative surface hardness was taken as the limit. When equipped with the 13/8-mm light guide taken from the Optilux 501, the LEDemetron 1 reached a sufficient depth of cure up to a sample thickness of 2 mm.

A mean relative surface hardness ratio of > 80% was found with the Elipar FreeLight 2 for the 3.5-mm sample thickness and with the LEDemetron 1 for the 3.0-mm sample thickness, even when the 0.5-mm thinner sample showed a relative surface hardness ratio below 80% (Table 3). However, due to the fact that the maximum sample thickness with sufficient depth of cure was defined as the sample thickness after which the relative surface hardness was below 80%, these data were not taken into consideration for the definite determination of depth of cure.

Statistical analyses are shown in Table 4. Due to the Bonferroni correction, only differences resulting in a respective p-value of < 0.0005 could be defined as statistically significant. The QTH curing devices, given 40 s of exposure time (Elipar TriLight and Optilux 501), are not significantly different from the global 5% level ($p = 0.09$). Twenty seconds of exposure time (Optilux 501, Astralis 10) showed a statistically significantly lower curing potential ($p < 0.0005$) than a 40-s exposure time (Optilux 501). The Astralis 10 applied for 20 s resulted in a significantly superior curing potential compared to the Optilux 501, both using a comparable 13/8-mm focusing light guide.

First-generation blue LED curing devices showed a significantly lower curing potential ($p < 0.0005$) than the

Table 2 Mean bottom and top surface hardness data (± SD, N/mm²) of the different sample thicknesses (1.0 to 5.0 mm, in 0.5-mm steps, n = 9) exposed at a clinically relevant distance of 7 mm between the light-guide tip and the bottom side of the resin composite sample

		Sample thickness [mm]								
Curing device		1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0
TriLight	Top	236.9 ± 17.1	247.8 ± 23.5	268.9 ± 29.8	276.8 ± 24.8	235.7 ± 18.4	255.7 ± 10.8	305.6 ± 14.5	298.8 ± 12.2	296.7 ± 15.6
	Bottom	237.3 ± 35.8	251.6 ± 24.2	255.3 ± 15.8	232.7 ± 22.0	164.4 ± 18.0	167.3 ± 21.3	187.7 ± 10.4	123.7 ± 6.3	76.6 ± 6.7
Optilux 501 40 s	Top	240.6 ± 11.8	177.2 ± 35.1	244.6 ± 4.5	241.4 ± 45.4	285.2 ± 47.6	272.8 ± 24.5	276.1 ± 41.8	294.6 ± 13.4	290.1 ± 20.4
	Bottom	230.4 ± 48.3	214.4 ± 26.1	278.8 ± 14.5	279.6 ± 19.8	235.0 ± 39.0	219.1 ± 4.6	195.8 ± 13.5	132.1 ± 8.5	72.0 ± 10.4
501 20 s, Standard	Top	187.4 ± 28.9	204.3 ± 25.8	244.4 ± 15.0	274.9 ± 16.5	200.1 ± 54.3	158.7 ± 42.8	155.7 ± 64.2	274.2 ± 29.3	255.0 ± 14.4
	Bottom	169.6 ± 25.4	230.3 ± 24.9	190.7 ± 40.1	198.8 ± 34.9	122.1 ± 40.2	118.8 ± 6.7	78.2 ± 14.8	37.2 ± 10.5	24.3 ± 18.5
501 20 s, Turbo	Top	188.6 ± 12.0	214.0 ± 5.8	219.0 ± 40.1	234.0 ± 2.3	247.0 ± 5.4	251.6 ± 31.4	283.8 ± 7.4	293.3 ± 6.4	289.0 ± 3.5
	Bottom	171.1 ± 18.7	188.3 ± 44.2	144.1 ± 8.3	148.6 ± 11.3	128.9 ± 5.3	104.0 ± 8.6	82.9 ± 5.4	68.6 ± 10.2	32.3 ± 7.8
Astralis 10, Pulsed mode	Top	227.2 ± 34.2	286.2 ± 17.2	280.6 ± 15.8	289.7 ± 17.0	283.3 ± 25.9	303.6 ± 24.4	318.7 ± 16.7	306.4 ± 15.2	306.0 ± 30.7
	Bottom	235.2 ± 15.4	274.2 ± 21.4	227.8 ± 6.6	198.8 ± 16.8	162.1 ± 14.9	128.9 ± 8.3	96.4 ± 10.1	57.2 ± 9.4	27.2 ± 12.1
e-Light	Top	161.3 ± 12.7	154.1 ± 20.2	190.1 ± 19.1	209.9 ± 21.7	221.9 ± 15.8	238.6 ± 20.7	244.0 ± 18.4	289.4 ± 17.5	281.7 ± 15.5
	Bottom	162.4 ± 62.5	153.2 ± 69.3	182.3 ± 19.2	149.8 ± 15.5	123.2 ± 14.7	93.3 ± 15.0	57.1 ± 11.5	26.0 ± 13.5	*
FreeLight	Top	165.8 ± 15.1	196.9 ± 14.3	173.8 ± 36.0	274.4 ± 8.4	240.3 ± 29.2	276.9 ± 23.7	289.8 ± 15.2	308.1 ± 24.8	229.7 ± 9.6
	Bottom	161.6 ± 31.5	189.0 ± 29.1	148.9 ± 61.1	220.2 ± 14.8	165.1 ± 8.0	147.9 ± 43.4	108.9 ± 25.3	74.6 ± 11.1	39.0 ± 12.5
FreeLight 2, 20s	Top	189.8 ± 23.7	191.9 ± 21.1	254.1 ± 20.8	241.3 ± 18.2	236.2 ± 34.6	304.1 ± 14.9	307.7 ± 11.0	303.8 ± 13.4	317.6 ± 16.9
	Bottom	189.0 ± 22.8	214.7 ± 30.1	228.9 ± 13.8	220.6 ± 9.8	203.4 ± 21.2	179.2 ± 13.9	125.9 ± 11.4	69.8 ± 5.2	31.6 ± 8.6
FreeLight 2, 40s	Top	205.0 ± 20.1	222.3 ± 55.1	310.9 ± 11.4	262.8 ± 10.6	239.0 ± 22.8	303.1 ± 5.6	305.4 ± 5.7	324.8 ± 8.4	303.8 ± 50.0
	Bottom	241.7 ± 33.8	234.4 ± 18.7	262.1 ± 29.7	253.7 ± 13.9	207.1 ± 34.3	240.7 ± 11.2	216.1 ± 15.5	156.6 ± 33.7	113.2 ± 18.6
Ultra-Lume LED 2, 20s	Top	253.4 ± 19.2	296.1 ± 19.4	278.9 ± 12.9	278.8 ± 27.7	286.4 ± 7.6	266.6 ± 8.9	274.6 ± 15.0	217.4 ± 12.3	260.6 ± 57.4
	Bottom	268.7 ± 16.4	249.7 ± 25.1	219.9 ± 19.1	183.3 ± 14.9	110.9 ± 23.6	80.9 ± 12.6	43.7 ± 17.5	19.2 ± 14.4	*
Ultra-Lume LED 2, 40s	Top	264.3 ± 32.9	255.7 ± 22.3	291.2 ± 19.7	290.0 ± 27.4	309.7 ± 15.3	307.2 ± 13.6	308.9 ± 6.6	269.0 ± 37.8	255.6 ± 14.2
	Bottom	288.1 ± 6.8	298.4 ± 18.7	274.2 ± 18.9	235.6 ± 30.3	215.6 ± 10.1	173.3 ± 11.8	135.1 ± 16.9	64.9 ± 89.0	43.4 ± 61.1
LEDemetron 13/11 mm, 20s	Top	175.6 ± 54.2	240.1 ± 57.2	219.8 ± 43.5	232.7 ± 20.5	258.0 ± 24.1	225.8 ± 64.6	241.6 ± 74.8	286.2 ± 19.7	284.9 ± 15.0
	Bottom	255.2 ± 19.5	243.4 ± 38.6	227.7 ± 47.1	199.3 ± 13.7	171.6 ± 26.6	169.7 ± 10.6	103.0 ± 20.7	52.9 ± 8.3	23.7 ± 26.8
LEDemetron 13/11 mm, 40s	Top	240.7 ± 23.9	270.8 ± 14.9	273.6 ± 26.9	234.4 ± 44.3	261.3 ± 19.9	279.6 ± 41.4	300.8 ± 30.4	248.4 ± 25.7	256.4 ± 10.8
	Bottom	227.7 ± 20.7	273.7 ± 20.0	263.5 ± 18.5	236.4 ± 25.7	217.3 ± 18.9	229.7 ± 14.7	209.8 ± 29.2	115.4 ± 8.7	65.3 ± 8.1
LEDemetron 13/8 mm, 20s	Top	225.4 ± 28.2	244.8 ± 25.4	254.0 ± 26.2	212.3 ± 39.9	286.8 ± 32.4	305.9 ± 19.7	303.7 ± 42.4	315.8 ± 31.0	310.4 ± 17.9
	Bottom	225.7 ± 31.1	266.4 ± 23.0	256.9 ± 17.6	188.6 ± 26.5	242.6 ± 14.4	201.1 ± 8.9	136.9 ± 29.4	77.7 ± 17.1	30.9 ± 7.5

Table 3 Mean ratio [%] of bottom:top surface hardness of the reference sample with the overall highest surface hardness of all reference samples investigated. Dark grey background indicates sample thicknesses with relative surface ratios ≥ 80%. Light grey background indicates sample thicknesses with a relative surface ratio < 80%, but which were followed by a thicker sample, resulting in a relative surface ratio ≥ 80% again

Mean ratio of bottom surface hardness to top surface hardness of reference sample with the overall highest surface hardness (= 290.8 N/mm², Elipar FreeLight 2, 40 s)	Sample thickness [mm]								
Curing device	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0
TriLight	82	87	88	80	57	58	65	43	26
Optilux 501, 40 s, 11 mm standard	79	74	96	96	81	75	67	45	25
Optilux 501 20 s, 11 mm standard	58	79	66	68	42	41	27	13	8
Optilux 501 20 s, 13/8 mm focusing	59	65	50	51	44	36	29	24	11
Astralis 10, 20 s, "Pulse"-mode	81	94	78	68	56	44	33	20	9
e-Light, 40s	55	52	62	51	42	32	19	9	–
FreeLight, 40s	55	64	51	75	56	50	37	25	13
FreeLight 2, 20s	60	73	78	75	69	61	43	24	11
FreeLight 2, 40s	82	80	89	86	71	82	74	53	39
Ultra-Lume LED 2, 20s	92	86	76	63	38	28	15	7	–
Ultra-Lume LED 2, 40s	99	103	94	81	74	59	46	22	15
LEDemetron 1, 20s 13/11 mm focusing	88	84	78	69	59	58	35	18	8
LEDemetron 1, 40s 13/11 mm focusing	78	94	90	81	74	78	72	39	22
LEDemetron 1, 20s 13/8 mm focusing	78	92	88	65	84	69	47	27	11

QTH curing devices at 40 s of exposure time. With the same exposure time of 40 s, statistically significant differences were no longer found between the QTH control group and the high-power blue LED curing devices Elipar FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1. No statistically significant difference exists within the group of the high-power blue LED curing devices for either 40-s or 20-s exposure times ($p = 0.01$ to 1.0). The use of the 13/8-mm focusing light guide in the LEDemetron 1 resulted in a greater depth of cure (2 mm vs 1.5 mm) compared to the 13/11-mm standard light guide, but this did not prove to be statistically significant ($p = 0.1$) when the overall performance of the light-curing device was taken into consideration. In contrast, no improvements in depth of cure at 7 mm were found with the Optilux 501 when the 13/8-mm light guide was used instead of the 11/11-mm standard light guide. The group of the high-power blue LED curing devices showed a significantly higher ($p < 0.0005$) curing potential than the first-generation curing devices Elipar FreeLight and GC e-Light.

DISCUSSION

The determination of surface hardness was used to assess the depth of cure of different curing devices in this study. While the determination of the degree of conversion[11,22] appears to be the most sensitive and reliable method to evaluate depth of cure,[2,8] surface hardness measurements seem to come relatively close to the results obtained with FTIR spectroscopy.[19] Besides the use of a penetrometer,[13] the testing of material properties such as flexural strength and modulus[21] are suitable methods to compare resin composite samples exposed according to different protocols. However, the determination of surface hardness is still the most frequently employed method to compare different exposure techniques and procedures.[4,14,15,23] An 80% ratio in relative surface hardness as the defined limit for sufficient depth of cure has been used by other authors[25] and in other studies,[5,7] as has a 7-mm distance from the light tip to the sample base.[3] Daronch et al[1] discussed that the distance between the light tip and the composite may be responsible for lower surface hardness at greater depths.

In some cases, a relative bottom:top surface hardness ratio of > 100% was found. This can be explained by reflection phenomena of the steel mold into which the resin composite samples were inserted. This effect has also been observed in several studies on depth of cure[6,7] in which stainless steel rings were also used. It is possible that comparable reflection phenomena may occur in Class II approximal boxes, if they are bordered by a metal matrix system. In the present study, this kind of reflection was taken into consideration by wrapping a metal matrix system around the light-guide tip, which came closer to the real clinical situation. This effect of metal reflection made it more difficult to evaluate absolute depths of cure; nevertheless, the experimental setup was appropriate for evaluating comparative depths of cure. The determination of the surface hardness was done 10 min after curing directly on the composite surface, which was covered by a cellophane strip. It must be borne in mind that

Table 4 Statistical analysis using a linear model. Due to Bonferroni correction, only p-values < 0.0005 can be considered statistically significant

	Elipar TriLight 40 s	Optilux 501, 11 mm, 40 s	Optilux 501, 11 mm, 20 s	Optilux 501, 13/8 mm, 20 s	Astralis 10, 20 s	GC e-Light, 40 s	Elipar FreeLight, 40 s	Elipar FreeLight 2, 20 s	Ultra-Lume LED 2, 40 s	Ultra-Lume LED, 20 s	LEDemetron 1, 13/11, 40 s	LEDemetron 1, 13/11, 20 s	LEDemetron 1, 13/8, 20 s
Elipar TriLight 40 s		0.09	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.002	0.002	0.9	< 0.0005	0.3	0.002	0.3
Optilux 501, 11 mm, 40 s	0.09		< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.006	0.1	< 0.0005	0.5	< 0.0005	0.2
Optilux 501, 11 mm, 20 s	< 0.0005	< 0.0005		< 0.0005	0.002	0.03	0.6	< 0.0005	< 0.0005	0.7	< 0.0005	0.003	< 0.0005
Optilux 501, 13/8 mm, 20 s	< 0.0005	< 0.0005	< 0.0005		< 0.0005	0.5	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.006	< 0.0005
Astralis 10, 20 s	< 0.0005	< 0.0005	0.002	< 0.0005		< 0.0005	0.04	< 0.0005	0.9	0.003	0.007	< 0.0005	0.8	0.06
GC e-Light, 40 s	< 0.0005	< 0.0005	0.03	0.5	< 0.0005		0.02	< 0.0005	< 0.0005	< 0.0005	0.01	< 0.0005	< 0.0005	< 0.0005
FreeLight, 40 s	< 0.0005	< 0.0005	0.6	< 0.0005	0.04	0.02		< 0.0005	0.04	< 0.0005	0.9	< 0.0005	0.03	0.001
FreeLight 2, 40 s	0.002	0.3	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005		< 0.0005	0.01	< 0.0005	0.08	< 0.0005	0.001
FreeLight 2, 20 s	0.002	< 0.0005	0.006	< 0.0005	0.9	< 0.0005	0.04	< 0.0005		0.02	0.04	0.001	1.0	0.1
Ultra-Lume LED 2, 40 s	0.9	0.1	< 0.0005	< 0.0005	0.003	< 0.0005	< 0.0005	0.01	0.02		< 0.0005	0.4	0.01	0.4
Ultra-Lume LED, 20 s	< 0.0005	< 0.0005	0.7	< 0.0005	0.007	0.01	0.9	< 0.0005	0.04	< 0.0005		< 0.0005	0.01	0.001
LEDemetron 1, 13/11, 40 s	0.3	0.5	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.08	0.001	0.4	< 0.0005		0.001	0.09
LEDemetron 1, 13/11, 20 s	0.002	< 0.0005	0.003	0.008	0.8	< 0.0005	0.03	< 0.0005	1.0	0.01	0.01	0.001		0.1
LEDemetron 1, 13/8, 20 s	0.3	0.2	< 0.0005	< 0.0005	0.06	< 0.0005	0.001	0.001	0.1	0.4	0.001	0.09	0.1	

this layer is enriched with monomer and the hardness values might be lower compared to a finished and polished surface. However, because the relative bottom:top surface hardness was determined and both surfaces were covered with the cellophane strip, this factor should not influence the outcome of this study. To remove the first ca. 100 microns, the samples had to be removed from the sample holder. After finishing, it would not have been possible to replace them into the stainless steel molds in a way that the system could have measured the hardness afterwards. Yet finishing and polishing might, in fact, reduce the standard deviation of the results. A measurement after 24 h would have taken the post-curing process into account, but in terms of clinical relevance, a resin composite should have a distinct hardness right after placement, when the patient leaves the dental office. Therefore, although the post-curing process was not taken into account here, the study design should allow proper comparison of light-curing devices. It is also of clinical relevance that curing a second layer of resin composite placed on another, already cured increment might positively influence the overall polymerization of the increment cured first. This should be the subject of further investigations on depth of cure, especially for Class II cavity preparations.

As expected, the conventional QTH curing devices Elipar TriLight and Optilux 501 proved their ability to sufficiently cure a resin composite sample of at least 2.5 mm thickness with an exposure time of 40 s. In contrast, the results of this study show clearly that first-generation blue LED curing devices were not capable of providing a sufficient depth of cure at a clinically relevant distance. Not even a 1-mm increment of Tetric Ceram resin composite (color A3) was cured with a resulting surface hardness ratio > 80%. These findings thus support the supposition of Meyer et al,[12] which arose after their radiometer measurements, which showed a tremendous drop in power output with increasing distance to the radiometer. The results obtained by maintaining a distance between the light-guide tip and resin composite differ from those of an earlier investigation on depth of cure with the same curing devices, Elipar FreeLight and Elipar TriLight:[6] the light-guide tip was placed on top of the resin composite samples, yielding comparable depths of cure with the Elipar TriLight and the Elipar FreeLight. A big step forward seems to be the second-generation blue LED curing devices, which consist of only one high-power LED. When operated in a 40 s exposure mode, the Elipar FreeLight 2 and the Ultra-Lume LED 2 showed comparable results to that of the Optilux 501 regarding depth of cure. In contrast, the Elipar FreeLight 2 was not able to produce a sufficient depth of cure in 20 s (as claimed by the manufacturer); the same happened with the Optilux 501 as well, when operated for only 20 s. The LEDemetron 1, equipped with the 13/11-mm light guide, and the Ultra- Lume LED 2 were at least able to cure a 1.5-mm increment sufficiently, while the LEDemetron 1, equipped with the 13/8-mm light guide, was the only curing device investigated to reach a 2-mm depth of cure within 20 s. Therefore, the Elipar FreeLight 2 and the Ultra-Lume LED 2 seem to possess a curing potential comparable to the Optilux 501, while the curing potential of the LEDemetron 1 tended to be slightly higher, although this was not statistically significant. Taking into account that the Astralis 10 is also equipped with a 13/8-mm focusing light guide, which is similar to that used with the Optilux 501 and LEDemetron 1, the LEDemetron 1 showed obvious, but not significantly better results than the Astralis 10 given 20 s exposure time.

In contrast to first-generation blue LED curing devices,[4,12-14,22] high-power blue LED curing devices combine the advantages of LED technology – such as constant power output and longevity of the LEDs[10] – with the curing potential of high-power QTH curing devices.[14] This can be seen from the radiometer measurements in this study as well. Nevertheless, it is not admissible to compare radiometer data between LED and QTH curing devices; these data were reported only to obtain some rough information on power output within LED and QTH groups. The quality of polymerization, of course, does not automatically correlate with the light intensity measured with a radiometer. The absorption curve of the photoinitiator camphoroquinone ranges from 360 nm to 520 nm, with a maximum at 468 nm. For this reason, the optimal emission spectrum of a curing device should be in the range of 440 nm to 480 nm. In conventional QTH devices, 95% of the emission spectrum is in the range of about 400 to 510 nm. The emission spectrum maximum of a blue LED is 465 nm, which is relatively close to that of the photoinitiator camphoroquinone; thus, the probability that a photon emitted by a blue LED curing device will be absorbed by camphoroquinone is obviously higher than in the case of a halogen device. Hence, LED curing devices have a lower measurable power output than conventional QTH curing devices, but the emitted blue light is nevertheless capable of starting a polymerization process.[12] The Demetron radiometer used here is a good device to follow up the power output of a single curing device but not to compare different devices. As discussed in a previous paper,[12] it was necessary to use a more complex measurement system.

The results of this study show that the use of the Optilux 501's "turbo" (focusing) light guide compared to the standard light guide had no positive influence on depths of cure when a distance of 7 mm to the bottom surface of the resin composite was maintained, while the surface hardness of the reference sample, exposed under direct contact to the light-guide tip, showed a significantly higher surface hardness when the 13/8-mm focusing light guide was used instead of the standard one (232.8 ± 2.5 N/mm^2 compared to 195.8 ± 36.0 N/mm^2). As known from the literature,[12,18] the use of a turbo light guide results only in a higher power output when the light guide is placed very close to the radiometer. In both studies,[12,18] due to the focusing effect of the turbo light guide, the light energy diffuses at a much greater rate than from the standard light guide with increasing distance to the surface. Just the opposite was observed with the LEDe-

metron 1 using the minimal focusing standard light guide (13/11 mm) vs the 13/8 mm focusing light guide.

The mean ratios of surface hardness between bottom and top were comparable in the Elipar FreeLight and the GC e-Light. As the Elipar FreeLight consisted of 19 LEDs and the e-Light of 64 LEDs, a higher power output at zero distance was expected for the e-Light. The reverse results might be explained by a focusing effect as well: while the FreeLight has a distinct focusing light-guide tip (not as strong as the turbo light guide of the Optilux 501, which focuses 1:1.6 vs 1:1.3 of the FreeLight) which seems to be able to compensate for the scattering of the emitting light, the e-Light is equipped with a parallel light guide without any kind of focusing. Therefore, distinct focusing light guides seem to be able to compensate the scattering of the light emitted by a blue LED curing device. The LEDemetron 1 is equipped with a 13/11-mm focusing light guide, with a resulting compression ratio of 1:1.2. This comes close to the focusing ratio of the FreeLight (1:1.3). The 13/8-mm focusing light guide from the Optilux 501 improved the depth of cure of the LEDemetron 1, in contrast to its use in the Optilux 501, where it caused almost a reverse effect, as described by Price et al.[18] Hence, focusing light guides must be rated differently in blue LED curing devices than in conventional QTH curing devices.

CONCLUSION

The new high-power blue LED curing devices showed promising depths of cure at clinically relevant distances between light-guide tip and the resin composite. Their curing potential is comparable to or even better than that obtained with high-power QTH curing devices. Except for the LEDemetron 1, which was the only device (if equipped with the 13/8-mm light guide) that cured a 2-mm resin composite increment of Tetric Ceram A3 sufficiently within 20 s, all the other devices investigated (QTH as well as blue LED) should be operated at an exposure time of 40 s when this type of medium-shade conventional hybrid resin composite is used. To increase the depths of cure, the use of distinct focusing light guides seems only to be of advantage in blue LED but not in QTH curing devices.

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Clinical relevance: The newest generation of blue LED curing devices are capable of curing resin composites comparable to or even better than high-power QTH curing devices, but a significant reduction in exposure time has not yet been reached. The exposure time required to cure a resin composite might be determined more by the type of resin composite than by the light source.

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Thermal Emission by Different Light-Curing Units

AUJ Yap • MS Soh

Clinical Relevance

LED (Light-Emitting Diodes) light curing units produce significantly less heat than halogen lights. High-intensity halogen lights are potentially hazardous to pulp.

SUMMARY

This study quantified and compared the thermal emission of different light curing units (LCU). Three LED (Elipar Freelight [3M]; GC e-light [GC]; Coolblu [Dentalsystems.com]) and three halogen (Max [Dentsply-Caulk]; Elipar Trilight [3M]; Astralis 10 [Ivoclar-Vivadent]) lights were selected for the study. Thermal emission of the LCUs, when used in various curing modes, was assessed using a K-type thermocouple and a digital thermometer at distances of 3 mm and 6 mm compared to the conventional halogen LCU (Max). The temperature profiles and mean maximum temperature change (n=7) generated by each LCU were obtained. Data was subjected to ANOVA/Scheffe's post-hoc test and Independent Samples *t*-test at significance level 0.05. At 3 mm, temperature rise observed with LED lights ranged from 4.1°C to 12.9°C, while halogen lights ranged from 17.4°C to 46.4°C. At 6 mm, temperature rise ranged from 2.4°C to 7.5°C and 12.7°C to 25.5°C for LED and halogen lights, respectively. Thermal emission of LED lights was significantly lower than halogen lights. Significant differences in temperature rise were observed between different curing modes for the same light and between different LED/halogen lights.

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INTRODUCTION

The potential damaging effects of temperature increase on pulp tissue during restorative treatment has been a matter of concern to dentistry for many years. Light curing units (LCUs) can cause a temperature increase that could damage the pulp (Hussey, Biagioni & Lamey, 1995; Hannig & Bott, 1999). Thermal transfer to pulp is affected by material shade, thickness, composition, porosity, curing time and residual dentin thickness (McCabe, 1985; Goodis & others, 1989; Shortall & Harrington, 1998). It also varies with the type of curing unit, quality of light filter, output intensity and irradiation time (Goodis & others, 1997; Shortall & Harrington, 1998; Hannig & Bott, 1999). Temperature rise during the curing of restorative materials is, however, mainly contributed by the light source (Lloyd, Joshi & McGlynn, 1986).

LED (Light-Emitting Diodes) LCUs were recently introduced to the dental profession. They are solid-

Table 1: *Details of the Light Curing Units (LCU) and the Various Curing Modes Evaluated*

LCU	Curing Modes	Curing Profiles
Elipar Freelight (LED) 3M-ESPE, St Paul, MN, USA	Standard (FL1)	400 mW/cm² (20 seconds)
	Standard (FL2)	400 mW/cm² (40 seconds)
	Exponential (FL3)	0-400 mW/cm² (12 seconds) → 400 mW/cm² (28 seconds)
GC e-Light (LED) GC Europe, Leuven, Belgium	Pulse Curing (EL1)	750 mW/cm² (10 pulses x 2 seconds)
	Standard (EL2) (40 seconds)	350 mW/cm²
	Turbo (EL3)	600 mW/cm² (20 seconds)
	Soft-Start Curing A (EL4)	0-600 mW/cm² (20 seconds) → 0-600 mW/cm² (20 seconds)
	Soft-Start Curing B (EL5)	0-300 mW/cm² (20 seconds) → 0-300 mW/cm² (20 seconds)
CoolBlu (LED) Dental Systems.Com, Tokyo, Japan	Mode 3 (CB1)	350 mW/cm² (20 seconds)
	Mode 6 (CB2)	140 mW/cm² (6 seconds) → 350 mW/cm² (15 seconds)
Max (Halogen) Dentsply-Caulk, Milford, DE, USA	Standard (MX)	400 mW/cm² (20 seconds)
Elipar Trilight (Halogen) 3M-ESPE, St Paul, MN, USA	Standard (TL1)	800 mW/cm² (40 seconds)
	Exponential (TL2)	100-800 mW/cm² (40 seconds)
Astralis 10 (Halogen) Ivoclar-Vivadent, Liechtenstein, Austria	High Power (AS1)	1200 mW/cm² (10 seconds)
	Adhesive Program (AS2)	650 mW/cm² (20 seconds)
	Pulse Program (AS3)	150 to 650mW/cm² (10 seconds) → Pulsating between 650 and 1200 mW/cm²
	ECS-Program (AS4)	1200mW/cm² (30 seconds)

Curing profiles are based on manufacturers' information.

state semiconductor devices that convert electrical energy directly to heat. Thermal light sources (halogen and plasma lights) emit light by electrical heating. The generation of light produced by LEDs results in high efficacy as most of the energy radiated falls within the absorption spectrum of camphorquinone photoinitiators (Mills, Jandt & Ashworth, 1999). Cited advantages of LED lights include: (a) cost-efficiency with a longer-lasting light source compared to halogen or other devices, (b) clinician friendliness with cordless features and a more slim-line construction, (c) equivalent or improved physical properties of polymerized resin composite, (d) battery operation with no bulb aging, (e) no decrease in output as bulb ages, (f) less heat production during routine and extended use of the polymerization device and (g) no fan necessary (Duke, 2001). Although some research has been conducted on the use of LED lights on composite hardness, modulus, depth of cure, compressive and flexural strengths (Mills & others, 1999; Stahl & others, 2000; Jandt & others, 2000; Kurachi & others, 2001), the thermal emission of LED lights has not been investigated.

This study quantified the thermal emission of three LED and halogen lights. Temperatures changes associated with various curing modes of each LCU were also compared.

METHODS AND MATERIALS

The light curing units selected for this study included three LED lights (Elipar Freelight [3M-ESPE, St Paul, MN, USA]; GC e-light [GC]; Coolblu [Dental Systems.com]) and three halogen lights (Max [Dentsply-Caulk, Milford, DE, USA]; Elipar Trilight [3M-ESPE]; Astralis 10 [Ivoclar-Vivadent]). Details of the LCUs and curing modes evaluated are shown in Table 1. Thermal emission of the LCUs was measured

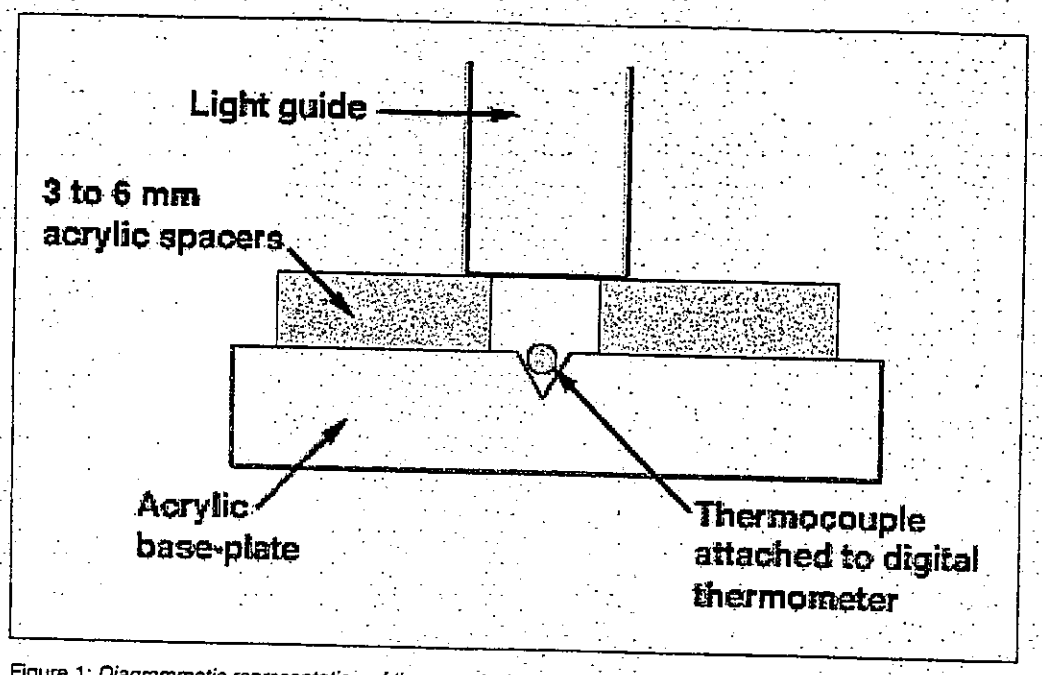

Figure 1: *Diagrammatic representation of the experimental set-up.*

Table 2: *Mean Maximum Temperature Rise Observed with the Various LCUs/Curing Modes*

Light-Curing Units	Light-Curing Modes	At 3 mm [°C]	At 6 mm [°C]
Elipar Freelight	FL1	11.0 (0.22)	7.5 (0.21)
	FL2	12.9 (0.17)	6.6 (0.18)
	FL3	10.9 (0.31)	7.2 (0.24)
GC e-Light	EL1	8.1 (0.16)	4.9 (0.20)
	EL2	5.5 (0.10)	3.4 (0.23)
	EL3	7.5 (0.20)	4.1 (0.24)
	EL4	8.4 (0.16)	4.5 (0.13)
	EL5	4.1 (0.29)	2.4 (0.11)
CoolBlu	CB1	5.8 (0.21)	3.9 (0.11)
	CB2	5.5 (0.23)	3.9 (0.17)
Max	MX	17.4 (0.70)	12.7 (0.28)
Elipar Trilight	TL1	26.7 (0.39)	19.8 (0.32)
	TL2	22.6 (0.16)	18.3 (0.41)
Astralis 10	AS1	36.0 (0.88)	20.2 (0.20)
	AS2	24.4 (0.42)	14.6 (0.23)
	AS3	34.6 (0.31)	17.9 (0.15)
	AS4	46.4 (0.55)	25.5 (0.22)

Standard deviations in parentheses.
See Table 1 for times and intensities of light-curing modes.

by a K-type thermocouple and a digital thermometer (305, Peacock Precision Instruments, Singapore). The thermocouple was secured onto a groove in an acrylic base-plate so that the surface of the thermocouple was flushed against the top surface of the base-plate (Figure 1). Two clear acrylic plates 3 mm and 6 mm in thickness with a 7 mm diameter hole served as spacers to control the thermocouple-light guide exit window distance. The experimental set-up allowed the thermocouple to be positioned at the center of the 7-mm hole. The light guide exit windows of the LCUs were placed over the 7-mm hole of the upper acrylic plates and activated. Temperature rise during irradiation can, therefore, be measured at distances of 3 mm and 6 mm away from the thermocouple.

A pilot study was first conducted to determine the effects of environmental temperature on temperature rise during light irradiation using the Max polymerization unit. The experiment was conducted in a controlled and enclosed environment (Concept 300 Workstation; Ruskin Technology Limited, Yorkshire, UK) at preset temperatures of 25°C and 37°C. Temperature rise associated with the Max polymerization unit at both preset environmental temperatures was measured at distances of 3 mm and 6 mm. Five readings were taken at five-minute intervals for each preset temperature and distance. Results were analyzed with paired sample *t*-test at significance level 0.05. At 3 mm, temperature rise was 15.2 ± 0.1 and 15.3 ± 0.2°C for environmental temperatures of 37°C and 25°C, respectively. At 6 mm temperature rise was 10.8 ± 0.2 and 10.8 ± 0.3°C for environmental temperatures of 37°C and 25°C, respectively. As no significant difference in temperature rise was observed between the two environmental temperatures at both distances, the main experiment was conducted under ambient room temperature.

The ambient room temperature was recorded and maximum temperature rise during light activation was obtained for the different LCUs and curing modes. Seven readings were obtained for each light-curing mode combination. To minimize the effects of heating, a five-minute hiatus was implemented between each

le 3: *Comparison of Mean Maximum Temperature Rise of the Various Curing Modes for the Same LCU*

Light Guide Exit Window Distance	Light Curing Unit	Differences
3 mm	Elipar Freelight	FL2>FL1, FL3
	GC e-light	EL1; EL4>EL3>EL2>EL5
	CoolBlu	NS
	Elipar Trilight	TL1>TL2
	Astralis 10	AS4>AS1>AS3>AS2
6 mm	Elipar Freelight	FL1, FL3>FL2
	GC e-light	EL1>EL4>EL3>EL2>EL5
	CoolBlu	NS
	Elipar Trilight	TL1>TL2
	Astralis 10	AS4>AS1>AS3>AS2

Results of one-way ANOVA/Scheffe's post-hoc test or independent sample t-test ($p<0.05$). > indicates statistical significance while NS denotes no statistical significance.

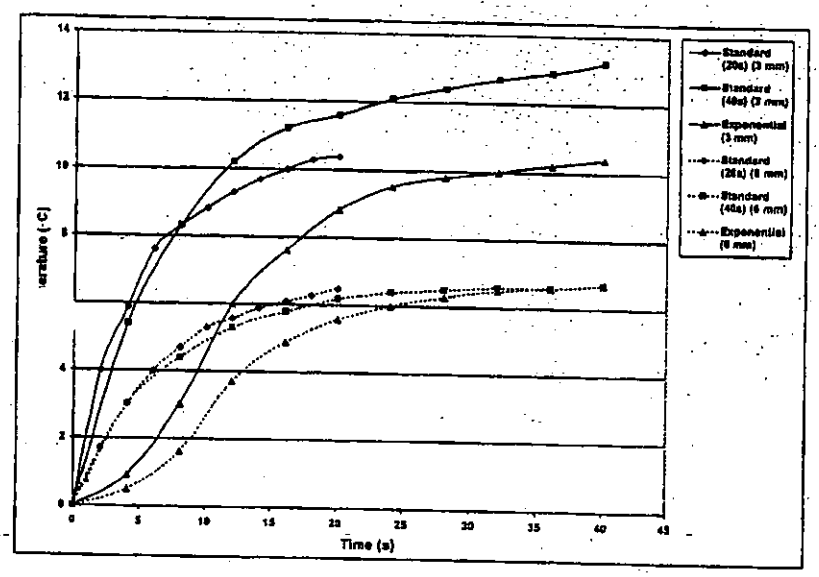

Figure 2: *Temperature rise profile of Elipar Freelight.*

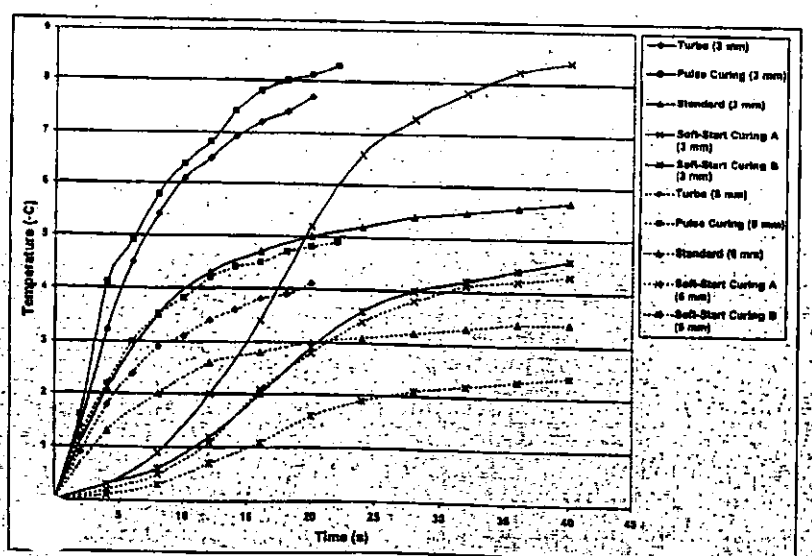

Figure 3: *Temperature rise profile of GC e-light.*

curing cycle. The temperature rise profiles of the various lights and their different curing modes were also determined by obtaining 10 temperature readings at equal time intervals over the light curing period. Data was subjected to one-way ANOVA/ Scheffe's post-hoc test and Independent Samples *t*-test at significance level 0.05. The mean maximum temperature rise of the different LCUs/curing modes was compared to the conventional halogen LCU (Max). In addition, differences between the curing modes for the same light and different LED/halogen lights were also compared. Temperature changes at 3 mm and 6 mm were also contrasted.

RESULTS

Table 2 shows the mean maximum temperature rise observed with the various LCUs/curing modes. The temperature rise profiles of the various LCUs/curing modes are reflected in Figures 2 through 7.

The temperature rise observed at 3 mm was significantly higher than at 6 mm. At 3 mm the temperature rise observed with LED lights ranged from 4.1°C to 12.9°C, while the halogen lights showed a range of 17.4°C to 46.4°C. At 6 mm, temperature rise ranged from 2.4°C to 7.5°C and 12.7°C to 25.5°C for LED and halogen lights, respectively. Thermal emission of LED lights was significantly lower than halogen lights at both distances. Table 3 reflects the significant differences in temperature rise among different curing modes of the same curing light. For Freelight and e-light, minor variations in significant differences between curing modes were observed between 3 mm and 6 mm. No significant difference in temperature rise was observed between the two curing modes for Coolblu. At both distances, the thermal emission of Freelight, with its various curing modes, was significantly higher than the other LED lights. Among the halogen lights, curing with the ECS mode (designed for curing of resin cements through ceramic restorations) for 30 seconds resulted in the most heat generation. Maximum or peak temperatures were consistently observed toward the end of the curing cycles and duration lasted no more than 15 seconds (Figure 2 through 7).

DISCUSSION

Light guide exit window distances of 3 mm and 6 mm were used to mimic distances encoun-

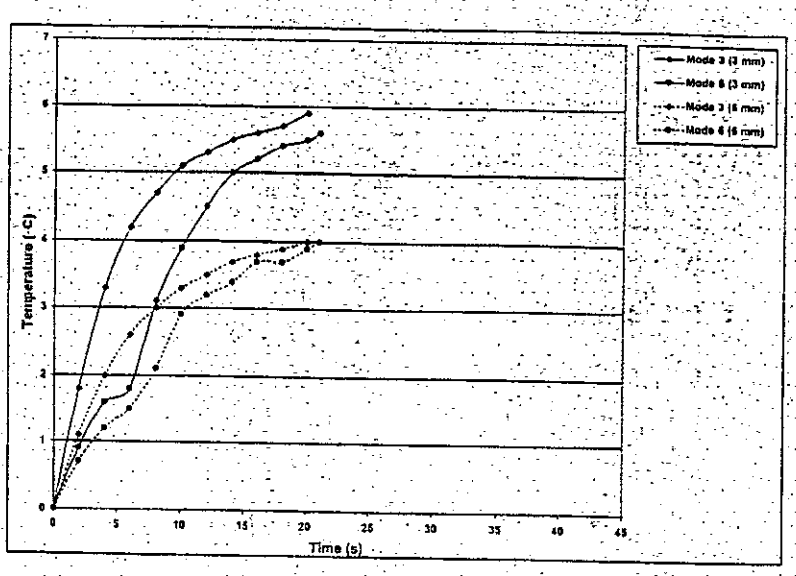

Figure 4: *Temperature rise profile of CoolBlu.*

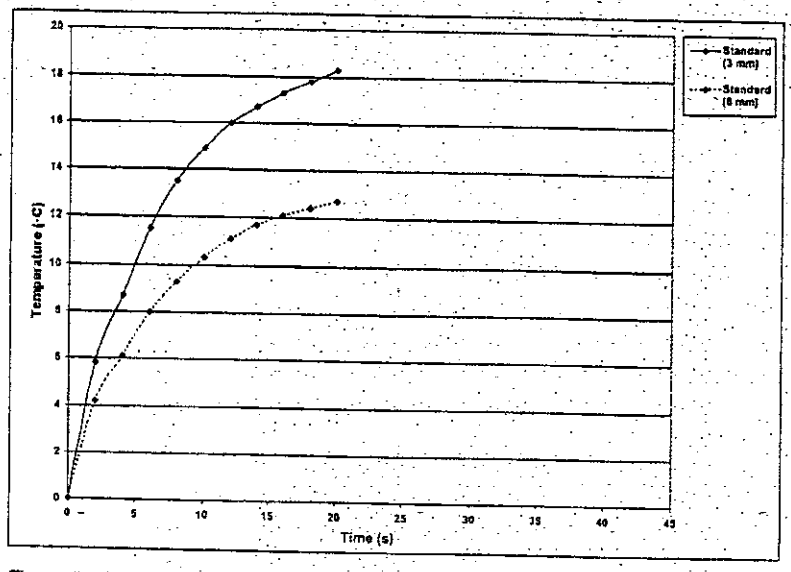

Figure 5: *Temperature rise profile of Max.*

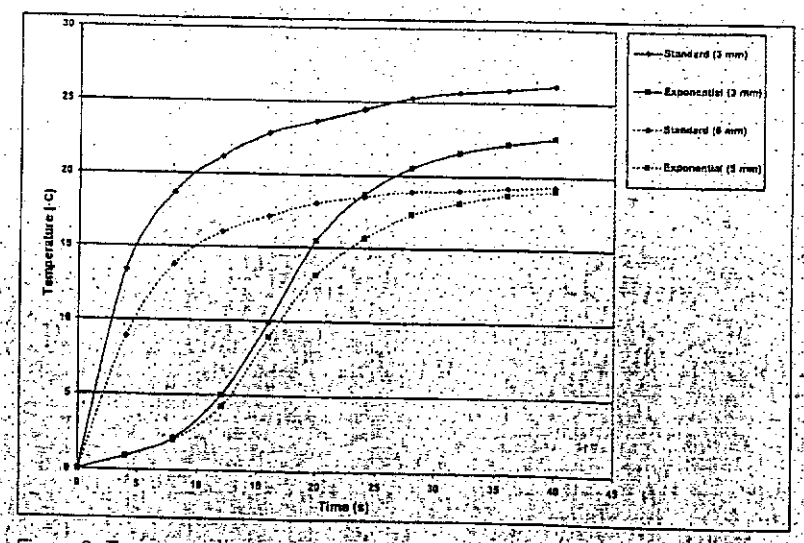

Figure 6: *Temperature rise profile of Elipar Trilight.*

tered when curing deep Class I and Class II cavities. The experimental set-up also allowed for the simulation of a confined cavity as in the case of a Class II cavity with matrix and rubber dam placement. In addition, the 3 mm distance approximates the proximity of the light guide exit window to the top layer of restorative materials during clinical restorative procedures. Since the acrylic spacers used have a low thermal conductivity, the maximum temperature rise observed represents the worst case scenario. Restorative materials and teeth were excluded from the experiment design to minimize the number of variables involved. By doing so, the data obtained can also be applied to light-(heat) enhanced bleaching procedures and thermal expansion of composites during curing.

In this study, temperature rise decreased significantly with increased light guide exit window distance. Results concur with those of Shortall and Harrington (1998), who investigated temperature rise due to radiation energy at various cavity depths. Although the light output of LCUs (350 and 710 mW/cm²) used by the latter group were similar to that of Max and Trilight (400 and 800 mW/cm², respectively) in this study, maximum temperature rise observed at 6 mm distance was considerably lower (2.0°C and 3.7°C, compared to 12.7°C and 19.8°C). This may be partially attributed to using black nylon spacers that may absorb part of the heat emitted, instead of clear acrylic ones.

The thermal emission of LED lights was significantly lower than halogen lights at both distances. Rather than a hot filament (as used in halogen bulbs), LEDs use junctions of doped semiconductors (p-n junctions) for the generation of light (Nakamura, Mukai & Senoh, 1994). Under proper forward biased conditions, electrons and holes recombine at the LED's p-n junctions, leading to the emission of blue light in the case of gallium nitride LEDs. As the spectral output of gallium nitride blue LEDs falls within the absorption spectrum of the camphoroquinone photoinitiators, no light filters are required. The latter (light filters), however, serve as partial thermal buffers in curing lights (Shortall & Harrington, 1998). From Table 2, it is apparent that LED LCUs still emit heat and the thermal emission from different LED lights varies significantly. The temperature rise observed with Freelight was significantly higher than e-light and Coolblu despite the same or a lesser number of LEDs used (Freelight and

Coolblu 19 LEDs; e-light 64 LEDs). The maximum temperature observed with Freelight is expected to be even higher if not for the aluminum casing cum handle used. This serves to conduct heat and cool the unit. Reasons for the higher thermal emission of Freelight are not known. Possible hypotheses include LED size and inter-LED spacing.

Among the halogen lights, curing modes utilizing high light outputs generally resulted in significantly greater thermal emission. The lowest temperature rise was observed with the Max polymerization unit that had the lowest light output among the three halogen lights evaluated. The clinical experience with conventional halogen LCUs (<500 mW/cm²) indicates that pulp appears able to recover from transient heating from light-curing. Zach and Cohen (1965) reported that 15% of teeth in rhesus monkeys developed necrosis when healthy pulps were exposed to a temperature increase of only 5.5°C. These findings and those of Pohto and Scheinin (1958) suggest that the critical temperature for irreversible damage to the pulp begins at between 42°C and 42.5°C. Hannig and Bott (1999) measured the pulp chamber temperature increase induced during resin composite polymerization with various LCUs using a tooth model (Class II cavity with 1 mm dentin layer between the pulp chamber and proximal cavity wall), K-type thermocouple positioned at the pulp-dentin junction and 2 mm composite layers. They found that LCUs with outputs greater than 670 mW/cm² generated temperature increases of more than 5.5°C when used for 40 seconds. Taking this into consideration, the maximum temperature rise detected in Trilight (800 mW/cm² for 40 seconds) should be viewed as critical, especially where residual dentin thickness is limited. In spite of the very high value observed with Astralis High Power mode (AS1—designed for curing composite restorations), the very short-term temperature peak may not be relevant to pulpal damage (Figure 7). The Astralis ECS mode should, however, never be used for curing composites and bonding agents.

For an individual tooth, it is nearly impossible for a clinician to predict the temperature rise that may occur when curing a restoration. In general, the thicker the dentin and the shorter the curing time, the smaller the temperature increase (Loney & Price, 2001). Clinicians should be aware of the potential thermal hazard associated with using high intensity lights when curing composites in deep cavities. Minimum irradiation times should also be used when curing bonding agents with these lights in view of the absence of a composite thermal buffer. A simple and effective way to protect the pulp is to apply a cement base or lining material to the cavity floor (Hansen & Asmussen, 1993).

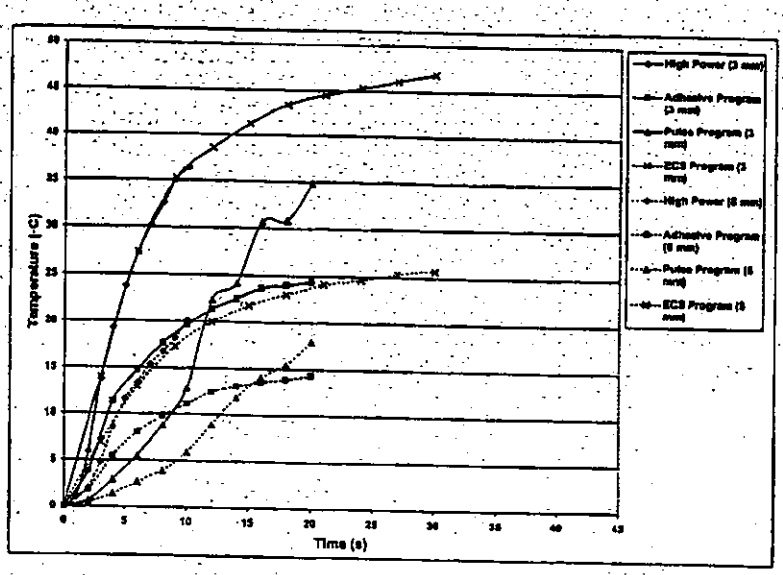

Figure 7: *Temperature rise profile of Astralis 10.*

CONCLUSIONS

Under the conditions of this *in-vitro* study:

1. LED lights emit significantly less heat than halogen lights.
2. The heat emitted by individual curing lights depends on the curing mode used.
3. The heat emitted by different LED/halogen lights varies significantly.

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Original Paper

Effects of Light Curing Modes and Resin Composites on Temperature Rise under Human Dentin: An *in vitro* Study

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The influence of three curing modes of a high-powered LED curing unit on temperature rise under 2-mm-thick dentin was investigated during the polymerization of resin composite samples of Admira, Filtek P60, Premise, Tetric Flow, Tetric Ceram, and Filtek Z250. Ninety standard specimens were prepared. The bonding agents and resin composites were cured with standard, pulse, or soft-start mode (n=5 for each curing mode). Temperature rise was measured using a type L thermocouple. Data were analyzed by two-way ANOVA and Tukey's test. Soft-start curing led to statistically higher temperature rises compared than the other two modes. The highest temperature rise was observed for Admira and Tetric Flow cured with soft-start mode. The lowest temperature rise was observed for Premise cured with pulse mode. However, temperature rise did not reach the critical value that can cause pulpal damage by virtue of a prominent safety feature of the high-powered LED LCU, which ensures that no excessive heat is produced by all the three curing modes.

Key words: Temperature rise, Composites, Polymerization

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INTRODUCTION

An important milestone in the history of modern restorative dentistry is the development of light-cured resin composites for direct procedures[1]. The majority of them are based on conventional monomer systems such as 2,2-bis [4-(2-hydroxy-3-methacryloyloxy-propoxy)-phenyl] propane (Bis-GMA), urethane-ethoxydimethacrylate (UEDMA), and triethylene glycol dimethacrylate (TEGDMA), with camphorquinone (CQ) typically as the photosensitizer for free radical polymerization[2]. These resin composites include inorganic fillers in varying degrees, of varying sizes and types. Recently, a new type of organic-inorganic hybrid dental material, known as Ormocers, was introduced as an alternative to conventional dental composites. It has been stated that the combination of organic-inorganic matrix and filler particles in high concentrations (up to 67%) in ormocers provided an improvement in some mechanical and physical properties, thereby rendering them superior to those of conventional composites[3-5].

An increase in demand for esthetic dental restorations has also led to a tandem increase in the use of light sources to photocure resin composites[6]. Whereas the output of first-generation LED LCUs is limited[7], manufacturers have recently turned their attention to high-powered LED LCUs for the polymerization of dental resins. With a high-powered light source, more photons are available per given period of absorption by the photoinitiators. As a result, more CQ molecules are raised to an excited state. The excited CQ molecules then collide with amine molecules to form free radicals. The latter, in turn, react with the carbon-carbon double bond of a monomer molecule and initiate the polymerization process[8,9]. These LED LCUs generally have higher power densities, thereby producing potentially higher thermal emissions and depths of cure[9].

Regardless of the amount of infrared energy transmitted from the curing source, polymerization of resin composites always results in a temperature increase in the material caused by both the exothermic polymerization and the light energy absorbed during irradiation[7,10,11-17]. When using high-powered LCUs, the issue of temperature increase is of particular interest. This is because the increased energy of these LCUs may also increase the potential of generating injurious temperatures in the pulp — especially when they are used in deep cavities with minimal remaining dentin thickness[10,12]. Moreover, the concept of total adhesive bonding precludes the use of a protective cement base or cavity lining, which also means a higher potential for thermal injury to the pulp[12].

It has been stated that the released energy and maximum polymerization temperature depend on the curing mode and polymerization characteristics of the dental composite[13]. Traditionally, continuous cure at constant irradiance is used for the polymerization of resin composites. However, Feilzer *et al.*[18]

pointed out that the use of high-intensity curing light negatively affected the restoration-cavity interface. To solve this problem, several curing protocols have been suggested. The so-called "soft-start polymerization" characterized by using an initial low-power intensity of the curing light followed by higher-power intensity has been suggested to minimize internal stresses in composites and improving their marginal adaptation[11,19]. On the other hand, Kanca and Suh[20] proposed "pulse-curing or pulse-delay curing". In this curing mode, the most occlusal increment of the resin composite is activated with a short pulse of light at rather low irradiance. They have shown that the use of this curing mode provided a reduction in enamel fractures and a general improvement of marginal adaptation, especially for Class I composite restorations when compared to those cured at constant irradiance.

However, few studies have been performed for the purpose of measuring temperature changes under the dentin in situations where the resin composites were cured with different curing protocols. When a high-powered LCU is used, it is important to determine the correct curing mode so as not to lead to a temperature rise which is potentially hazardous for the tooth. In light of this concern, the objective of this *in vitro* study was to evaluate the influence of different curing modes of a high-powered LED LCU on temperature rise under the dentin during the polymerization of six different composites.

MATERIALS AND METHODS

Composites

In this *in vitro* study, six different dental resin composites of shade A2 were tested for temperature rise. These composites were Admira (Voco GmbH, Cuxhaven, Germany), Filtek P60 (3M ESPE, St. Paul, MN, USA), Tetric Flow (Ivoclar Vivadent, Schaan, Liechtenstein), Tetric Ceram (Ivoclar Vivadent, Schaan, Liechtenstein), Filtek Z250 (3M ESPE, St. Paul, MN, USA), and Premise (Kerr Corp., Orange, CA, USA). The Admira composite is an ormocer consisting of additive aliphatic and aromatic dimethacrylates and Ba-Al-B-silicate glass and SiO_2 inorganic filler particles loaded in 56% by volume. Filtek P60 is a packable resin composite and Filtek Z250 is a microhybrid resin composite, whereby both are based on Bis-GMA, urethane dimethacrylate (UDMA), and bisphenol A polyethylene glycol diether dimethacrylate (Bis-EMA) resin matrix. The filler is zirconia-silica and inorganic filler loading is 61% and 60% by volume for Filtek P60 and Filtek Z250 respectively. Tetric Flow is a flowable resin composite and Tetric Ceram is a microfilled hybrid resin composite, whereby both have similar resin matrices composed of Bis-GMA, UDMA, and TEGDMA. Their inorganic fillers are composed of barium glass, ytterbium trifluoride, Ba-Al-fluorosilicate glass, highly dispersed silicone dioxide, and spheroid mixed oxide in 39.7% and 60% by volume for Tetric Flow and Tetric Ceram respectively. Premise is a nanofilled hybrid composite, which has an organic resin matrix composed of ethoxylated Bis-EMA and TEGDMA. Premise incorporates a trimodal filler system consisting of prepolymerized, barium glass, and silica nano fillers. The inorganic filler loading is 69% by volume.

The bonding systems recommended by each composite manufacturer were used. Three of them were total-etching single bottle systems (Admira Bond, Adper Single Bond 2, and Optibond Solo Plus), and the other was a self-etching adhesive system (AdheSE). Table 1 shows the detailed information of the resin composites and their manufacturers, as well as information on the conditioning system and bond matrix composition of each adhesive system.

Light curing units

The composites were cured with a high-powered LED LCU (Mini LED, Satelec, Merignac, France). Output of the LED unit stated by the LED manufacturer was accepted as accurate (1100 mW/cm^2), and five specimens of each composite were polymerized using one of the three curing protocols: standard (10-second exposure at full power), pulse mode (10 consecutive one-second exposures at full power), and soft-start mode (progressive cycle lasting 20 seconds). The energy produced by each polymerization mode was dependent on both the polymerization time and light intensity (total energy=light intensity×exposure time)[11,17,21-23]. In this study, total energy was 22 J/cm^2 for soft-start polymerization, while it was 11 J/cm^2 for the other two modes. The LED unit's battery was recharged according to manufacturer's recommendation and placed in its charger following the polymerization of each specimen. Table 2 shows the details pertaining to the LED unit and its polymerization modes and profiles.

Preparation of dentin disks

Ninety noncarious, extracted human premolars were stored in physiological saline solution in an incubator. The occlusal enamel portions of the premolars were removed using a low-speed saw (Isomet, Buehler Ltd., Lake Bluff, IL, USA) to expose the dentin by sectioning the tooth perpendicular to its long axis. Dentin disks, 2 mm thick, were then sectioned perpendicular to the long axis of the tooth, and 90 dentin disks were obtained as a result. These dentin disks were placed at the bottom of a Teflon mold cylinder of a temperature test apparatus as explained below.

Table 1 Restorative materials used in this study

Material	Admira	Filtek P60	Tetric Flow	Tetric Ceram	Filtek Z250	Premise
Manufacturer	Voco GmbH Cuxhaven, Germany	3M ESPE, St. Paul, MN, USA	Ivoclar Vivadent Schaan / Liechtenstein	Ivoclar Vivadent Schaan / Liechtenstein	3M ESPE, St. Paul MN, USA	Kerr Corporation, Orange, CA, USA
Type	Ormocer based packable	Composite-based packable	Composite-based flowable	Hybrid	Microhybrid	Nano-filled hybrid
Resin matrix	Ormocers / additive aliphatic and aromatic dimethacrylates	Bis-GMA, UDMA Bis-EMA	Bis-GMA, UDMA TEGDMA	Bis-GMA, UDMA, TEGDMA	Bis-GMA, UDMA Bis-EMA	ethoxylated Bis-EMA, TEGDMA
Filler type	Ba-Al-B-silicate glass, SiO_2,	zirconia / silica	barium glass, ytterbium trifluoride, Ba-Al-fluorsilicate glass, highlydispersed silicon dioxide spheroid mixed oxide	barium glass, ytterbium trifluoride Ba-Al-fluorsilicate glass highly dispersed silicon dioxide spheroid mixed oxide	zirconia / silica	Barium glass, non-agglomerated silica nano particles, prepolymerized filler
Average particle size	0.7 μm	0.01-3.5 μm the mean particle 0.6 μm	0.04-3.0 μm the mean particle 0.7 μm	0.04-3.0 μm the mean particle 0.7 μm	0.01-3.5 μm	barium glass: 0.4 μm, silica nano particles: 0.02 μm
Filler volume %	56	61	39.7	60	60	69
Filler weight %	78	80	64.6	79	82	84
Co-initiators absorption within<410 nm	no	no	unknown	unknown	no	unknown
Bonding Systems	Admira Bond	Adper Single Bond 2	AdheSE		Adper Single Bond 2	Optibond Solo Plus
Conditioning	Vococid (35% ortho-phosphoric acid gel)	Scotchbond etchant (35% phosphoric acid gel)	AdheSE Primer: Dimethacrylate phosphonic acid acrylate		Scotchbond etchant (35% phosphoric acid gel)	Kerr gel etchant (37.5% phosphoric acid gel)
Bond matrix	Bis-GMA, HEMA, organic acids complex, acetone three-dimensionally curing anorganic-organic copolymers	Bis-GMA, HEMA, water dimethacrylates, ethanol methacrylate functional copolymer of polyacrylic and polyitaconic acids, silica photoinitiators	AdheSE Bond: HEMA, dimethacrylate silicone dioxide		Bis-GMA, HEMA, water dimethacrylates, ethanol methacrylate functional copolymer of polyacrylic and polyitaconic acid, silica photoinitiators	Bis-GMA, HEMA, GPDM ethanol, fumed silica, barium, sodium hexa-fluorosilicate, glass, camphorquinone

*Data as disclosed by the manufacturers
Bis-GMA: Bisphenol A diglycidylmethacrylate; Bis-EMA: Bisphenol A polyethylene glycol diether dimethacrylate; UDMA: Urethane dimethacrylate; TEGDMA: Triethyleneglycoldimethacrylate; HEMA: 2-Hydroxyethyl methacrylate; GPDM: Glycerophosphate dimethacrylate; GDM: Glycerol dimethacrylate

Table 2 Details of the light polymerization unit and its polymerization modes and profiles

Unit	Light type and diameter	Wavelength of emission	Mode	Output and total time	Profile
Mini LED	LED (7.5 mm)	420-480nm	Standard	1100 mW/cm² (10 seconds)	Continuous energy output for 10 seconds
			Pulse	1100 mW/cm² (10 seconds)	10 successive 1-second flashes, at full power pulse activation mode, with a rest period of 250 ms between flashes.
			Soft start	0 to 1100 mW/cm² +1100mW/cm² (20 seconds)	Exponential energy output automatically increased to full energy within 10 seconds +10 seconds full energy

*Light intensity purported by manufacturer

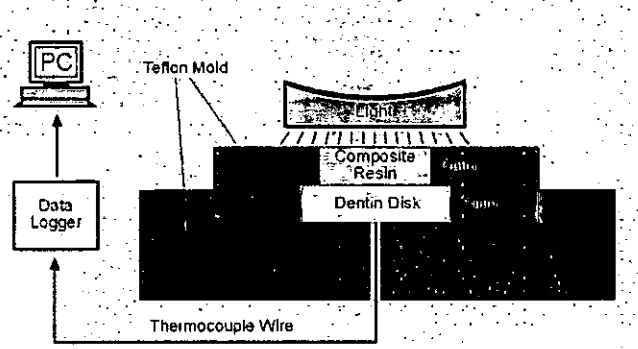

Fig. 1 Apparatus for measuring temperature changes.

Temperature test apparatus

To standardize temperature rise measurements, an apparatus was modified from that developed by Smail *et al.*[28] (Fig. 1). It comprised two concentric Teflon mold cylinders constructed from polyetrafluoroethylene. The top Teflon mold cylinder had a central aperture (6 mm diameter, 2 mm depth). The resin composite bulk was directly placed in this aperture onto the dentin disk treated with bonding agent. The bottom Teflon mold cylinder then formed the lateral walls of the dentin disk (8 mm diameter, 2 mm depth). The bottom portion of the apparatus had a hole (1 mm diameter) just beneath the center of the dentin disk for thermocouple wire insertion. To achieve an accurate positioning of all the dentin disks, their thicknesses were standardized at 2 mm between the tip of the thermocouple and the resin composite in each experiment.

Temperature measurement

Fifteen specimens were prepared for each resin composite, whereby five specimens (n=5) were polymerized using one of the three curing modes. All measurements were taken in a temperature controlled room with a constant temperature of 20±1°C. A type L Fe-constantan thermocouple (Fe-Const, Elimko Co., Turkey) connected to a data logger (E-680, Elimko Co., Turkey) was used to record temperature rise during the light-curing of bonding and resin composites. E-680 series of universal data loggers/scanners are advanced, new-generation microcontroller-based industrial instruments compatible with IEC 668 standards. Universal inputs and outputs of the device could be programmed easily by the user, and data were collected and stored in a centrally located PC loaded with software (Data Logger, ver. 5.1, Elimko Co., Turkey).

Temperature rises were recorded at the following three levels:

1. Temperature rise beneath the dentin disk without any restoration to detect whether histochemical and/or structural variables of the dentin disk affected temperature change. Temperature rise beneath all dentin disks was effected by using LED LCU for 10 seconds. The mean temperature rise was 0.24±0.04°C. Thus, it was concluded that the temperature change was not affected by any histochemical and/or structural dentin variables.
2. Temperature rise during polymerization of the visible light-cured bonding systems.
3. Temperature rise during polymerization of the resin composites. The central cylinder aperture was filled with the selected material and then covered with a Mylar strip and digitally pressed. For light curing, the LCU tip was positioned against the Teflon mold/composite.

During each measurement, the initial temperature was recorded following temperature stabilization (20±1°C) and then the peak temperature was registered. To obtain the temperature change, the initial temperature was deducted from the final

one.

Statistical analysis

Using a SPSS statistical software program (Version 10.0, SPSS Inc., Chicago, USA), temperature change data were subjected to statistical analysis between the composites as well as among LED curing modes using two-way analysis of variance (ANOVA). Where significant differences were present, Tukey's *post hoc* test was applied to examine pairwise differences at a significance level of 0.05.

RESULTS

Table 3 lists the means and standard deviations of temperature rise measured during the polymerization of six different composites with three different modes of LED LCU. Data analysis by two-way ANOVA showed significant temperature rise differences among the curing modes both during application of bonding agent (F=18.84) and polymerization of resin composites (F=119.54).

During the application of all bonding systems, the highest temperature rise was observed with the soft-start mode and this increase was statistically different from the other two modes ($p<0.05$). Temperature rises observed with the standard and pulse-mode curing of the bonding systems showed no statistical differences ($p>0.05$). Admira and Tetric Flow resin composites showed the highest temperature increase when they were cured with soft-start mode (1.50±0.11°C and 1.46±0.05°C respectively), whereas pulse-mode curing of Premise resin composite led to the lowest temperature increase among the materials and curing modes tested (0.22±0.04°C).

With soft-start curing, significantly higher temperature increase was recorded for Admira, Filtek P60, Tetric Ceram, and Premise resin composites as compared to the other two curing modes ($p<0.05$). No statistically significant differences were observed for these specimens when they were cured with the standard and pulse modes ($p>0.05$). For Tetric Flow and Filtek Z250 resin composites, temperature

Table 3 Mean temperature rise values and standard deviations (SD) for the resin composite systems and light curing modes evaluated

Composite	Curing mode	Bonding Agent Application Mean ± SD	Resin Composite Polymerization Mean ± SD
Admira	Standard	0.26 ± 0.05	0.54 ± 0.11^{a}
	Pulse	0.28 ± 0.04	0.42 ± 0.08^{b}
	Soft start	0.46 ± 0.05*	1.50 ± 0.07*^{i,j,k,l}
Filtek P60	Standard	0.24 ± 0.05	0.38 ± 0.08^{b,c}
	Pulse	0.22 ± 0.04	0.34 ± 0.05
	Soft start	0.46 ± 0.05*	0.90 ± 0.10*^{i,j,m}
Tetric Flow	Standard	0.26 ± 0.05	0.62 ± 0.08^{b,d,f}
	Pulse	0.28 ± 0.04	0.38 ± 0.04
	Soft start	0.46 ± 0.05*	1.46 ± 0.05*^{m,n,o,p}
Tetric Ceram	Standard	0.26 ± 0.05	0.40 ± 0.07^{f,g}
	Pulse	0.28 ± 0.04	0.30 ± 0.07
	Soft start	0.46 ± 0.05*	1.08 ± 0.13*^{j,n,r}
Filtek Z 250	Standard	0.26 ± 0.05	0.62 ± 0.08^{b,c,g}
	Pulse	0.28 ± 0.04	0.24 ± 0.05
	Soft start	0.46 ± 0.05*	0.98 ± 0.13*^{k,o,s}
Premise	Standard	0.24 ± 0.05	0.34 ± 0.05^{a,b,c}
	Pulse	0.22 ± 0.04	0.22 ± 0.04^{b}
	Soft start	0.46 ± 0.05*	0.76 ± 0.05*^{l,p,q,s}

n=5 specimens per experimental condition.

By two-way ANOVA: F=18.84, P=0.000, $p<0.05$ for bonding agent application; F=119.54, P=0.000, $p<0.05$ for resin composite polymerization.

Means labelled with the same small letters in the columns are for the comparison of different resin composites cured with the same light curing mode. * denotes the highest temperature rise values among three light curing modes of a given material. They are significantly different by Tukey's test ($p<0.05$).

change with each of the three curing modes differed ($p<0.05$).

Tukey's test results showed that the standard mode curing led to statistically significant differences in temperature rise between Admira and Premise, Filtek P60 and Tetric Flow, Filtek P60 and Filtek Z250, Tetric Flow and Tetric Ceram, Tetric Flow and Premise, Tetric Ceram and Filtek Z250, and Premise and Filtek Z250 ($p<0.05$). Pulse-mode curing of composites did not lead to statistically different temperature variations among all the resin composites, except between Admira and Premise which were found to be statistically different from each other at $p<0.05$. The comparison of temperature changes of all resin composites cured with soft-start mode showed no statistically significant differences between Admira and Tetric Flow, Filtek P60 and Tetric Ceram, Filtek P60 and Filtek Z250, Filtek P60 and Premise, and Tetric Ceram and Filtek Z250 ($p>0.05$); the others were found to be statistically different from each other ($p<0.05$).

DISCUSSION

Temperature rise during polymerization is a consequence of both the exothermic reaction process and the radiant heat from the light curing unit. The contribution from the material depends on material composition, material depth, and ambient temperature, whereas contribution from the light depends on exposure time and characteristics of the light source[1]. This *in vitro* study sought to evaluate the effect of three different polymerization modes of a latest high-powered LED LCU on temperature rise under human dentin during the polymerization of different resin composite systems. A stringently standardized dentin thickness (2 mm) was used with a view to eliminating any possible variation in thermal transfer. Further, a composite specimen size of 2 mm thickness was selected as it was considered to be clinically realistic[16]. Many manufacturers quote 2-mm-thick specimens when recommending radiation times. On the shade of resin composite specimens, shade A2 was selected to minimize the effects of colorant on light polymerization[21].

Temperature increases up to 20°C have been measured during light-induced polymerization of composite resins[19,25]. According to Zach and Cohen[26], a temperature rise of 5.5°C in the pulp is the limit that permits the pulp to recover from thermal damage. In the current study, temperature changes were measured during the operation of a high-powered LED LCU with a starting temperature of 20±1°C as previously suggested[7,27]. Temperature increases under dentin were continuously measured up to the point where the temperature began to fall. The peak values registered during the curing of all the tested materials with each of the three modes were lower than this previously reported critical value. This below-critical-value temperature rise could be attributed to a prominent feature of this high-powered LED LCU, in that there was basically no infrared light transmission to the tooth — and hence no excessive heat was produced[27]. Based on the data obtained in this study, it may be suggested that this LED light source could be used safely in similar clinical situations.

Resin composites were used with their own bonding agents in order to simulate clinical use. The same curing mode made no statistically significant differences among the bonding agents, which was probably due to the same irradiation time. Ozturk *et al.*[28] have compared the temperature changes under 1-mm-thick dentin using total-etch and self-etch adhesive systems and polymerization using a LED LCU. They obtained a higher temperature rise (1.61°C) for both types of adhesives systems than those found in the current study. The use of different dentin thicknesses might explain this. Knezevic *et al.*[29] have reported higher temperature increases with increased irradiation time and decreased material thickness. During the application of all the bonding systems in this study, the highest temperature rise was observed with the soft-start mode of LED LCU at a value of 0.46±0.05°C. The reason for this result could stem from the irradiation time of soft-start mode being approximately two times longer than the other curing modes. Furthermore, the absence of remarkable temperature changes in this study supported the suggestion by Shortall and Harrington[16] that greater thermal insult might occur when polymerizing bonding resins prior to restorative resins.

The soft-start mode was introduced to reduce shrinkage stress of dental composites, to achieve smaller marginal gaps, and to increase marginal integrity[30-32]. However this technique requires long cure times and consequently increases the energy produced, raising the temperature of resin composites and the surrounding dentin[1]. In the current study, the temperature rise induced by each curing mode did not exceed a previously reported critical value. In this respect, the thermal insulation provided by a relatively thick dentin[7] might be effective. However, in deep cavities where the residual dentin thickness is smaller and the tubular surface area increases[17], soft-start mode should be used cautiously to avoid excessively heating the pulp. This is because during the polymerization of all the tested resin composites, the highest temperature increase under dentin was consistently recorded with soft-start mode. Conversely, the pulse mode yielded the lowest temperature rise for all the tested resin composites.

These data were in agreement with those of

Aguiar *et al.*[1], who evaluated the effect of five polymerization modes and the presence of resin composite on temperature rise in human dentin of different thicknesses. They found that conventional and high-intensity polymerization modes presented lower temperature rise than soft-start mode in all conditions. However, the values obtained were higher than those of the current study, which could be due to the test conditions and light source used. According to Loney and Price[33], the difference in energy produced by the light curing units was an important factor for different temperature rises in different polymerization modes. Therefore, the differences in energy produced by the three curing modes might be responsible for the differences in the observed temperature changes.

With regard to material composition, Shortall and Harrington[16] have concluded that temperature rise is also related to the light transmission characteristics of resin composition. Masutani *et al.*[31] suggested that the exothermic reaction of the resin during polymerization had a greater influence on temperature rise *vis-à-vis* the light source. This suggestion was supported by our results where the temperature rise was very specific to a given composite due to its unique combination of filler, resin characteristics and formulation. While the highest temperature increase was observed for ormocer (Admira) and flowable (Tetric Flow) resin composites with soft-start curing, the lowest temperature rise was observed for nanofilled hybrid resin material (Premise) with pulse curing. It should be highlighted that all the composites tested had different volume fractions of the organic resin matrix. This appeared to be effective in influencing the extent of exothermic reaction during the polymerization process, and thus the differences in temperature change.

Under the same light-curing conditions, the different thermal conductivity values of composites and the different patterns of energy density distribution along time[27] could help explain the results in this study. The ormocer material possessed a modified organic matrix, formed by monomers with a single polymerizable end. The other end was formed by an alkoxy group, resulting in an inorganic area, bonded to other monomers by a chemical reaction of condensation, converting the monomer precursors in a polymeric inorganic condensate — via sol-gel processing — to create a complex structure with the formation of the Si-O-Si chain in the inorganic area of the polymer[1,5,15]. The significantly greater temperature rise with the ormocer compared to the other products presumably resulted from the different monomer compositions, given the relatively low light transmittance of this product.

Although Filtek Z250 and Filtek P60, and Tetric Ceram and Tetric Flow had the same molecules in their organic matrices and the same types of fillers, they showed different temperature rises. According to the data given by the manufacturers, the majority of TEGDMA was replaced with a blend of UDMA and BisEMA in Filtek Z250 when compared to Filtek P60. On the other hand, Tetric Ceram had a higher amount of inorganic filler than Tetric Flow. Taking these differences into consideration, they could have thus led to a decrease in temperature rise during polymerization. Tarle *et al.*[36] found higher temperature rises with standard-mode curing of hybrid composite Tetric Ceram (2.2°C) and microhybrid composite Filtek Z250 (1.5°C) than those found in the current study for the same materials (0.40°C and 0.62°C respectively). It should be highlighted that in their experiment[36], they used one of the early commercial blue LED LCUs giving an exposure profile of 10 seconds at 50 mW/cm², then 30 seconds at 150 mW/cm². Differences in the curing protocol might help to explain the differences in results between the two studies using the same products.

Premise, which is a nanofilled resin composite, has been highly rated for handling, polishability, esthetics, and shade matching by clinical evaluators[17]. Its manufacturer claimed that this resin demonstrated only moderate polymerization shrinkage caused by changes in dimensions as the resin was being cured. The temperature measurements under all conditions revealed the lowest temperature rise with this product and affirmed its safe use in clinical situations.

In this study, final temperature increases during polymerization with the high-powered LED LCU appeared to be below the critical value that can cause pulpal damage, thereby indicating its safety. In the current study, temperature change was evaluated under human dentin of 2 mm thickness. At this juncture, it should be put into perspective that for heat-related pulpal injury, the remaining dentin thickness is a critical factor that influences the amount of heat reaching the pulp. Therefore, further studies should be performed to confirm the effects of different curing modes on temperature change during the polymerization of composites placed over a thinner dentin. This would then mimic a more realistic clinical situation.

CONCLUSIONS

Within the limitations of this *in vitro* study, the following conclusions were drawn:

(1) The high-powered LED LCU caused minimal temperature rise under dentin during the polymerization of all resin composite systems.

(2) Soft-start curing led to significantly higher

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Effective single-charge end point of cordless light-emitting diode light-curing units

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Introduction: The purpose of this study was to evaluate the battery lives of cordless light-emitting diodes (LEDs) and their effect on orthodontic bracket bond strength. **Methods:** One hundred eighty-six metal orthodontic brackets were bonded to extracted molars. Two LED light-curing units (L. E. Demetron [SDS/Kerr, Orange, Calif] and Ortholux [3M Unitek, Monrovia, Calif]) were evaluated. Each light was used to bond 93 specimens. One bracket was bonded every 5 minutes until the battery ran out. The lights were activated for 20 seconds, then automatically turned off for 40 seconds every minute (33% duty cycle) without recharging. Bonded specimens were stored in water at 37°C for 24 hours and then subjected to shear force with a universal testing machine until bracket failure. **Results:** Repeated measures ANOVA detected significantly weaker mean shear bond strength and fewer consecutive cures with the Ortholux compared with the L. E. Demetron light-curing unit. However, when the first 5 time points were excluded, there were no differences between the 2 lights, demonstrating that the lights performed similarly after the first 20 minutes of operation Just before battery failure, both lights still provided the same power density as at the beginning. **Conclusions:** Both light-curing units provided adequate power density for up to 2 hours without recharging at a 33% duty cycle. There was no significant decrease in power in cordless LED light-curing units as the battery life approached its end point. (Am J Orthod Dentofacial Orthop 2006;130:378-84)

Visible light-curing units (LCUs) play an important role in the practice of modern clinical orthodontics by providing rapid resin-based composite polymerization on command. Resin polymerization occurs when carbon double bonds in methacrylate monomers are selectively converted into single bonds, propagating polymer growth, by free radicals created by the activation of diketone photoinitiators by light in the blue range of the visible spectrum at approximately 468 nanometers (nm).[1] Currently, most sources of visible blue light used in orthodontic practice are quartz-tungsten-halogen (QTH) LCUs. Despite their popularity, QTH lights have several drawbacks. Conventional units operate by heating a tungsten filament, similar to an incandescent light bulb, to generate light; they also generate a significant amount of heat, and the process in inherently inefficient because only 1% of the initial energy input is actually converted into blue light for composite polymerization.[2] The heat generated from QTH light systems can cause blistering of sensitive light filters and discoloration of the reflectors, and the cooling fan can be noisy and disperse any bacterial aerosol in the patient's mouth.[3] In addition, halogen bulbs last approximately 50 hours[4] and should be replaced every 6 months.[5] Studies have shown that private dental offices do not routinely service their QTH LCUs, and many LCUs have an output that is inadequate for polymerization.[6,7] Other methods for curing dental composite resins use xenon plasma arc lights and argon lasers. Although these lights dramatically reduce the curing time for dental composite resins, they are substantially more expensive and bulky.

In 1995, after improvements in blue light-emitting diode (LED) semiconductor technology, LEDs were proposed as a light source for the polymerization of light-cured resins.[8,9] LEDs are solid-state light sources that convert electrical energy directly into light.[10] Because they are solid-state devices, they can be manufactured to extremely small dimensions and withstand mechanical shock and vibration with low failure rates. LEDs are in everyday household appliances such as indicator lights and sensors, and in the dashboard instrument panels of automobiles, and they can have a lifetime of up to 10,000 hours.[11] LEDs are manufactured by metal-organic chemical vapor deposition of different semiconductor materials in films that are

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layered on top each other. The most recent blue LEDs use indium-gallium-nitride technology to generate high-energy photons in the blue region of the visible light spectrum.[12] As electrical current flows through the semiconductor chip in an LED, electrical energy is converted directly into light with little energy lost as heat. The result is a stable, efficient, long-lasting output of blue light in the range of 440 to 480 nm with no need for a cooling fan.[3] The narrow spectral emission band of LEDs closely overlaps the spectral absorption peak of the common dental photoinitiator, camphoroquinone, at 468 nm; this means that the LED is very efficient at polymerization.[8] The efficient energy conversion of LEDs has allowed the development of cordless LCU units that operate silently and have a long bulb life.[10]

Composite resins cured with LEDs appear to have physical properties equivalent to resins cured with QTH units.[12-14] Initial studies demonstrated that increased curing time or decreased composite resin material thickness was necessary to obtain equivalent mechanical properties in the composite with the first generation of LED LCUs.[15,16] Although depth of cure is an important consideration for the restorative dentist, it is much less of a concern for the orthodontist because the layer of composite that bonds brackets to tooth structure is significantly thinner. The first generation LED LCUs could cure a 0.7-mm-thick increment of composite in 40 seconds.[15] Although this rate of cure might be unfavorable for restorative dentistry,[17] LEDs can provide an efficient method for bonding orthodontic brackets to tooth enamel. It has been reported that bond strengths from 3 to 7.85 MPa might be adequate to withstand orthodontic forces.[18,19] Recent studies demonstrated acceptable shear bond strengths of brackets bonded with commercially available LEDs[20,21]; however, no studies have evaluated the shear bond strength of orthodontic brackets to teeth with cordless LEDs when teeth are consecutively polymerized without recharging. Orthodontists often bond an entire arch, up to 10 brackets, with no pause between teeth. With the manufacturer's usual recommendation of a 20-second curing time per bracket, this could mean that an LCU would operate for at least 200 seconds. It is also possible that, if a multiple-chair office shares an LCU, the light might have to perform many bonding procedures on several patients before recharging. The purpose of this study was to evaluate the ability of commercially available LEDs to consecutively bond orthodontic brackets to teeth on a single charge.

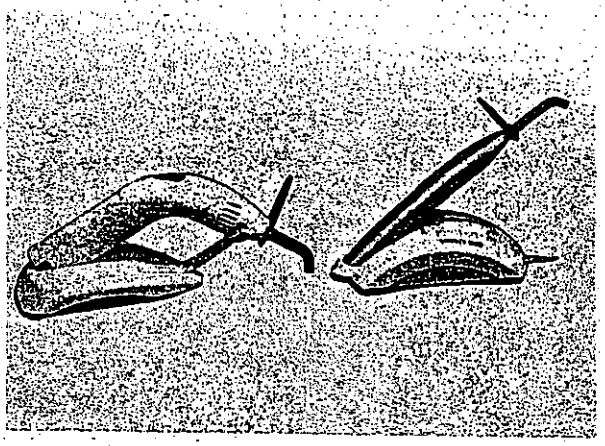

Fig 1. LED LCUs used in study: *left*, L. E. Demetron; *right*, Ortholux.

MATERIAL AND METHODS

One hundred eighty-six extracted human molars were collected and stored in 0.5% chloramine-t solution for no longer than 6 months before the start of the study. Teeth with caries, cracks, hypocalcification, peculiar morphology, or other visible defects were excluded. The roots of the teeth were notched and embedded in laboratory stone (Whip Mix, Louisville, Ky) in an acrylic ring (Mark V Laboratory, East Granby, Conn). A placement guide was used to align their buccal surfaces so that they were perpendicular to the bottom of the acrylic mold. The buccal tooth surface was cleaned with nonfluoridated flour of pumice (Moyco Industries, Philadelphia, Pa) for 10 seconds and rinsed with sterile water from an air/water syringe for 10 seconds. Transbond self-etching primer (3M Unitek, Monrovia, Calif) was used to condition the buccal surface of each tooth according to the manufacturer's recommendations. APC (Adhesive Pre-Coated) II Victory Series Twin premolar brackets (3M Unitek) were pressed to place on either the mesiobuccal or the distobuccal surface of each tooth, depending on which surface provided better adaptation with the premolar bracket. A plastic instrument was used to remove excess adhesive. The same operator (R.J.) placed all orthodontic brackets to minimize operator variability. Brackets were positioned so that the bracket/tooth interface would be parallel to the direction of the dislodging force. Orthodontic brackets were photopolymerized with 1 of 2 LED LCUs (Fig 1): L. E. Demetron (SDS/Kerr, Orange, CA) and Ortholux LED (3M Unitek). The teeth were randomly divided into 2 groups of 93 teeth each.

The first group of teeth and brackets was cured with the L. E. Demetron for 20 seconds. The second group was cured with the Ortholux LED for 20 seconds. Each

LCU was fully charged according to the manufacturers' recommendations. At the start time (0 seconds), the light was activated for 20 seconds. The light guide tip was placed on the mesial surface of the first specimen's bracket/tooth interface for 10 seconds and on the distal surface of the bracket/tooth interface for the remaining 10 seconds. The light automatically timed itself off, and 40 seconds were allowed to elapse without recharging (33% duty cycle). The 40 seconds simulated the time required to accurately place the next orthodontic bracket in the direct bonding method. This simulation of curing and waiting was continued until the total elapsed time was 5 minutes. Then the light source was placed on the mesial surface of the second specimen's bracket/tooth interface for 10 seconds and on the distal surface of the bracket/tooth interface for another 10 seconds. This cycle of activating the LCU for 20 seconds every minute and photopolymerizing a specimen every 5 minutes was performed for a total of 155 minutes without recharging to simulate consecutively bonding 155 brackets (6-7 full-mouth patients) without recharging the light. Bonding a specimen every 5 minutes produced 32 bracket/tooth specimens over the 155-minute time span. The battery was then fully recharged for 24 hours between testing, and the 155-minute process was repeated twice more for each unit. The specimens were stored in distilled water at 37° C for 24 hours and then loaded to failure on a universal testing machine (Instron model 1541s, Canton, Mass) at a crosshead speed of 1.0 mm per minute. A chisel-shaped rod was placed as close as possible to the bracket-tooth interface during the shear test. The order of polymerization of each bracket was identified, and the force in newtons was recorded. The force was divided by the surface area of the bracket base pad to obtain the shear stress value in megapascals (MPa). The manufacturer reported the surface area to be 9.81 mm^2. The 3 data points for each time point were averaged and recorded on a time–bond-strength graph. A within-groups analysis of variance (ANOVA) was performed to identify any differences across the 3 trials. The shear bond strength for each group (L. E. Demetron and Ortholux) was analyzed by using repeated measures ANOVA at $\alpha = .05$.

RESULTS

Shear bond strength data for specimens photopolymerized with the L. E. Demetron and the Ortholux LCUs are reported in Tables I and II. A within-groups ANOVA detected no differences across the 3 trials ($P > .05$). Repeated measures ANOVAs between subjects detected a significant difference ($P < .003$) between specimens bonded with the Ortholux and the L. E. Demetron. Because the Ortholux shut down earlier and zero values were recorded for the last 5 time points, another repeated measures ANOVA was run excluding the zero values to determine whether a difference could be detected. Significant differences were still observed ($P < .015$). The profile plots of the 2 lights (Fig 2) show that the difference was largely due to differences in the earlier time points. As time elapsed, the lines began to approach each other. When the ANOVA was run excluding the data from the first 5 and last 5 time points, the difference between light groups was no longer significant ($P > .05$).

DISCUSSION

Since the 1970s, the halogen LCU has been the instrument of choice to cure visible-light polymerized adhesive.[22,23] Halogen LCUs operate by superheating a tungsten filament in the presence of halogen gas in the bulb. Energy is then released mostly as heat, but white light is also created. The white light is filtered to isolate wavelengths of 400 to 500 nm in the blue region of the visible spectrum and directed down a light guide that concentrates the light beam. In contrast, the LED produces blue light via a quantum mechanical process in a semiconductor chip, and little energy is wasted in the process.[3,8]

The halogen LCU market was challenged in 2001 with the first commercially available LED LCUs, which promised equivalent polymerization in a much smaller, cordless unit. Today, there are at least 74 commercially available LCUs on the dental market. Still, the most popular kind of LCU is the halogen light, with over 40% of users using a specific one—Optilux, manufactured by SDS/Kerr.[24] Kerr's introduction to the LED market was the L. E. Demetron, the most popular LED LCU among dentists, capturing about 10% of the entire visible LCU market share. 3M/ESPE's Elipar Freelight LED, which is very similar to the Ortholux LED (3M Unitek), had 1.2% of the visible LCU market in 2004.[24] Recent studies demonstrated that, with 2-mm-thick specimens of resin-based composite, the first generation of commercially available LED LCUs provided inferior polymerization compared with QTH lights.[21,25] Maximum conversion of monomer to polymer is necessary to achieve optimal physical properties of adhesive cements.[26] Incomplete polymerization has been associated with bonding failures and inferior physical properties of light-cured composite materials.[27,28] Depth-of-cure studies have limited relevance in orthodontics because of the thickness of the specimens. Because the adhesive layer between orthodontic brackets and tooth enamel is considerably thinner than 2 mm, adequate photopolymerization can still occur with the

Table I. Shear bond strength results of L. E. Demetron

Time (minutes)	Stress at auto break run 1 (MPa)	Stress at auto break run 2 (MPa)	Stress at auto break run 3 (MPa)	Stress at auto break mean (MPa)
1. T = 0	13.93	20.82	14.66	16.47
2. T = 5	14.51	14.66	9.47	12.88
3. T = 10	12.30	14.62	16.58	14.50
4. T = 15	12.17	10.38	18.13	13.56
5. T = 20	9.81	12.85	17.48	13.38
6. T = 25	15.26	20.33	10.88	15.49
7. T = 30	20.28	12.81	3.72	12.27
8. T = 35	16.06	15.60	6.45	12.70
9. T = 40	10.77	17.13	10.39	12.76
10. T = 45	18.94	6.60	9.94	11.83
11. T = 50	10.64	8.18	10.19	9.67
12. T = 55	9.92	18.12	11.45	13.16
13. T = 60	12.12	9.99	16.79	12.97
14. T = 65	14.13	8.56	16.54	13.08
15. T = 70	10.84	15.05	12.06	12.65
16. T = 75	16.04	9.20	14.83	13.36
17. T = 80	12.76	15.98	9.91	12.88
18. T = 85	9.94	5.60	15.60	10.38
19. T = 90	8.95	22.24	17.24	16.14
20. T = 95	17.07	17.08	8.67	14.27
21. T = 100	10.26	10.89	9.65	10.27
22. T = 105	19.12	10.59	9.51	13.07
23. T = 110	12.16	11.06	16.69	13.30
24. T = 115	20.63	14.24	11.77	15.55
25. T = 120	8.21	9.18	7.91	8.43
26. T = 125	14.20	10.96	10.78	11.98
27. T = 130	14.92	14.60	13.31	14.28
28. T = 135	19.04	13.95	6.63	13.21
29. T = 140	14.59	10.33	15.74	13.55
30. T = 145	12.71	0	15.82	9.51
31. T = 150	10.90	0	12.95	7.95
32. T = 155	0	0	0	0

currently available commercial LEDs. Tavas and Watts[23] demonstrated that, for bonding metal orthodontic brackets to teeth, sufficient light is transilluminated by the teeth to effect adequate photopolymerization of the thin layer of resin-based material.

LEDs often have irradiance levels that are much lower than traditional halogen lamps when measured on curing radiometers, yet still cure composite because the emission spectrum of the blue LED is similar to the absorption spectrum of the camphoroquinone photoinitiator.[10] Curing radiometers report total irradiance intensity, which includes wavelengths outside the usable spectrum of camphoroquinone.[14,15] This would only be important if the composite being used contains a different photoinitiator that is activated outside the spectrum of most LEDs. Phenylpropanedione, a photoinitiator, is sensitive to light in the near-ultraviolet range at 410 nm. Several resin systems use this photoiniator in restorative dentistry. It is not known whether any orthodontic resin cements contain phenylpropanedione Operators are urged to contact their product representatives for further information on which photoinitiators are contained in the resin if the office uses LED LCUs.

Our results show that both LED LCUs provided sufficient power density to bond orthodontic brackets to teeth for a minimum of 2 hours without recharging, assuming that the lights are fully charged and used with a duty cycle of 33% (20 seconds on and 40 seconds off). An interesting observation of the data plots (Fig 2) showed that the lights did not lose intensity before they shut down. Laboratory data on LED battery-life tests conducted by Clinical Research Associates (CRA)[24] also noted a rapid, sharp, drop-off in intensity when the light was about to fail. However, CRA's results demonstrated shutdown earlier than our results. CRA reported the L. E. Demetron failing at 55 minutes and the Elipar Freelight-2 at 50 minutes. Our study demonstrated acceptable battery life up to 115 minutes. The battery life in the CRA study ranged from 17 minutes

Table II. Shear bond strength results of Ortholux

Time (minutes)	Stress at auto break run 1 (MPa)	Stress at auto break run 2 (MPa)	Stress at auto break run 3 (MPa)	Stress at auto break mean (MPa)
1. T = 0	8.05	5.07	10.27	7.80
2. T = 5	5.50	11.96	12.97	10.14
3. T = 10	8.02	9.99	13.22	10.41
4. T = 15	8.95	8.69	9.46	9.03
5. T = 20	11.37	9.88	9.77	10.34
6. T = 25	6.19	10.43	14.49	10.37
7. T = 30	9.9	8.50	11.19	9.85
8. T = 35	11.38	16.42	5.78	11.19
9. T = 40	7.57	10.07	10.82	9.49
10. T = 45	7.47	8.76	10.66	8.96
11. T = 50	13.96	6.50	12.33	10.93
12. T = 55	9.68	9.01	9.73	9.47
13. T = 60	10.54	10.03	7.34	9.30
14. T = 65	14.13	3.98	13.31	10.47
15. T = 70	8.41	10.52	9.65	9.53
16. T = 75	9.79	17.26	13.86	13.64
17. T = 80	9.28	8.56	8.28	8.71
18. T = 85	12.70	5.12	18.51	12.11
19. T = 90	8.29	14.16	9.51	10.65
20. T = 95	11.96	8.04	16.76	12.25
21. T = 100	10.24	11.63	15.54	12.47
22. T = 105	6.63	12.71	8.69	9.34
23. T = 110	10.48	12.85	8.92	10.75
24. T = 115	10.19	12.66	15.72	12.86
25. T = 120	11.15	9.54	17.10	12.60
26. T = 125	7.66	16.02	0	7.89
27. T = 130	0	0	0	0
28. T = 135	0	0	0	0
29. T = 140	0	0	0	0
30. T = 145	0	0	0	0
31. T = 150	0	0	0	0
32. T = 155	0	0	0	0

(Advance LED1, TPC Advanced Technology, City of Industry, Calif) to 125 minutes (Smartlite IQ, Dentsply/Caulk, Milford, Del). However, the CRA study tested the bond strength of composite rods to teeth and not orthodontic brackets. Also, the power densities ranged from 225 mW (Smartlite PS, Dentsply/Caulk) to 680 mW (Allegro, Den Mat, Santa Maria, Calif). It is serendipitous that LEDs perform at acceptable intensities until they fail. If the battery slowly died, and power intensity fell off gradually, many subclinical bracket failures would occur after the patient left the office.

Repeated measures ANOVAs performed on all 32 time points detected a significant difference in bond strength between the 2 lights ($P < .003$). Because the Ortholux discharged earlier and therefore recorded zero values for the last 5 time points, another ANOVA was performed on just the first 26 time points to determine whether a difference would still exist. Again, a significant difference between groups was detected ($P < .015$). Figure 2 suggests that the main difference between the lights occurred primarily at the earliest time points. When another repeated measures ANOVA was performed excluding the 5 earliest time points, the difference between lights was no longer significant ($P > .05$). This demonstrates that the differences between the 2 lights are significant for only the first 20 minutes of operation after full recharging, but not for the rest of operation up to discharge.

The data of this in-vitro study should be compared only with groups within the study, and the laboratory findings should not be extrapolated to the clinical situation.[29] Statistically significant differences have been found between in-vivo and in-vitro mean shear bond strengths.[30] Laboratory studies are a valuable screening tool, but clinical validation is necessary before any product or technique is universally accepted. Clinical studies are needed to validate the preliminary

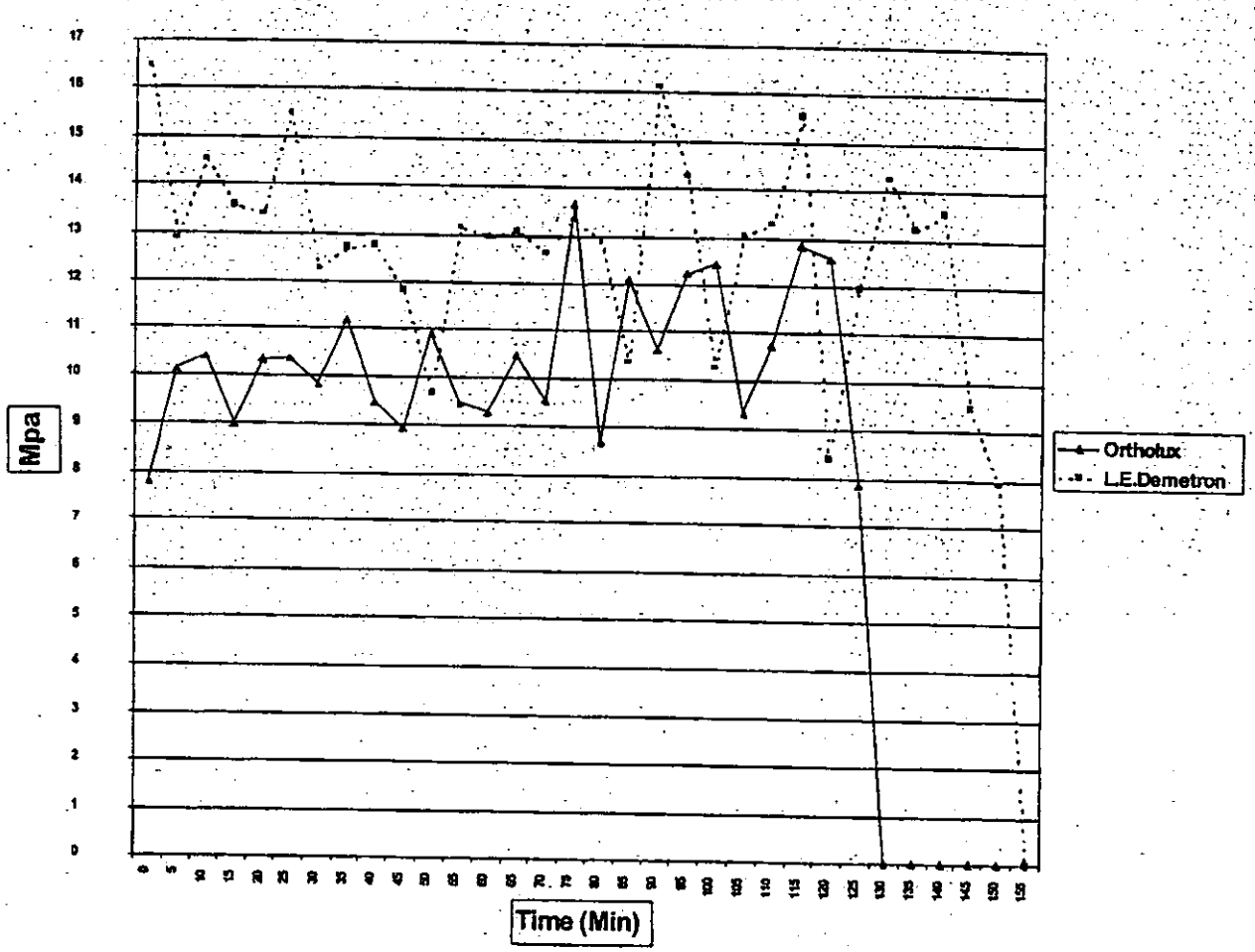

Fig 2. Stress (MPa) vs time (min) of Ortholux and L. E. Demetron LCUs. L. E. Demetron had higher mean shear bond strength and longer battery life than Ortholux.

in-vitro performance of brackets bonded with the LEDs in vivo.

CONCLUSIONS

Under the conditions of this in-vitro study, brackets bonded to teeth with the L. E. Demetron had significantly higher mean shear bond strength for the first 20 minutes of operation compared with the Ortholux LED LCU. For the rest of light operation, there was no statistical difference in bond strength between the 2 lights; however, the L. E. Demetron had a longer battery life. Both LCUs provided adequate power density for up to 2 hours without recharging at a 33% duty cycle. Furthermore, it was shown that, just before battery failure, both lights could cure brackets to teeth at acceptable bond strengths. There was no significant decrease in power in cordless LED LCUs as the battery life approaches its end point.

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Curing of Pit & Fissure Sealants Using Light Emitting Diode Curing Units

JA Platt • H Clark • BK Moore

Clinical Relevance

Adequate polymerization of opaque light-activated sealants should not be assumed and is dependent upon the material and light-curing unit.

SUMMARY

Light Emitting Diode (LED) curing units are attractive to clinicians, because most are cordless and should create less heat within tooth structure. However, questions about polymerization efficacy have surrounded this technology. This research evaluated the adequacy of the depth of cure of pit & fissure sealants provided by LED curing units. Optilux (OP) and Elipar Highlight (HL) high intensity halogen and Astralis 5 (A5) conventional halogen lights were used for comparison. The Light Emitting Diode (LED) curing units were Allegro (AL), LE Demetron I (DM), FreeLight (FL), UltraLume 2(UL), UltraLume 5 (UL5) and VersaLux (VX). Sealants used in the study were UltraSeal XT plus Clear (Uclr), Opaque (Uopq) and Teethmate F-1 Natural (Kclr) and Opaque (Kopq). Specimens were fabricated in a brass mold (2 mm thick x 6 mm diameter) and placed between two glass slides (n=5). Each specimen was cured from the top surface only. One hour after curing, four Knoop Hardness readings were made for each top and bottom surface at least 1 mm from the edge. The bottom to top (B/T) KHN ratio was calculated. Groups were fabricated with 20 and 40-second exposure times. In addition, a group using a 1 mm-thick mold was fabricated using an exposure time of 20 seconds. Differences between lights for each material at each testing condition were determined using one-way ANOVA and Student-Newman-Keuls Post-hoc test (α=0.05). There was no statistical difference between light curing units for Uclr cured in a 1-mm thickness for 20 seconds or cured in a 2 mm-thickness for 40 seconds. All other materials and conditions showed differences between light curing units. Both opaque materials showed significant variations in B/T KHN ratios dependent upon the light-curing unit.

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INTRODUCTION

The use of pit & fissure sealants is recognized as an important component of preventive dentistry (Weintraub, 1989; Wendt, Koch & Birkhed, 2001). These sealants are also utilized as part of preventive resin restorations (Simonsen, 1978) and, as such, are an important material for the dental practitioner. The presence of an intact sealant or sealed restoration may decrease the need for, or delay the onset of, a more invasive restoration (Mertz-Fairhurst & others, 1998). This effect is dependent upon the presence of the sealant. Therefore, issues that impact the retention of resin-based sealants are important when selecting a sealant for use.

Table 1: *Light-activating Units Used*

Curing Units	Manufacturer	Type	Power Density (mW/cm²)
Highlight (HL)	3M ESPE, St Paul, MN, USA	QTH	764
Optilux (OP)	SDS Kerr, Danbury, CT, USA	QTH	894
Astralis 5 (A5)	Ivoclar-Vivadent, Liechtenstein	QTH	504
LE Demetron I (DM)	SDS Kerr, Danbury, CT, USA	LED	740
Allegro (AL)	Den-Mat, Santa Maria, CA, USA	LED	1033
UltraLume 5 (UL5)	Ultradent Products, South Jordan, UT, USA	LED	793
UltraLume 2 (UL)	Ultradent Products, South Jordan, UT, USA	LED	589
FreeLight (FL)	3M ESPE, St Paul, MN, USA	LED	273
Versalux (VX)	Centrix, Shelton, CT, USA	LED	142

Table 2: *Sealant Materials Tested*

Sealant	Manufacturer	Lot #
UltraSeal XT Clear (Uclr)	Ultradent	4W44
UltraSeal XT Opaque (Uopq)	Ultradent	4VYC
Teethmate F-1 Natural (Kclr)	Kuraray	067BA
Teethmate F-1 Opaque (Kopq)	Kuraray	187BA

Partial loss of the sealant may be associated with decreased effectiveness (Weintraub, 1989). Because visualizing a partial loss with clear resins can be difficult, opaque materials have been developed in an effort to enhance detection (Rock & others, 1989). These materials have opacifiers, such as titanium oxide, added to the resin-matrix. Also, clinicians seem to favor light-activated materials that provide a rapid initiation of polymerization. This rapid initiation may aid ease of placement, particularly in the pediatric population. It has long been recognized that the shade of a resin has a significant impact on the polymerization of a resin composite (Kanca, 1986; Shortall, Wilson & Harrington, 1995). By their nature, opacifiers would be expected to cause significant amounts of light reflection, scattering and absorption. They should decrease the amount of light energy that penetrates through the bulk of the resin. Therefore, the opacity of

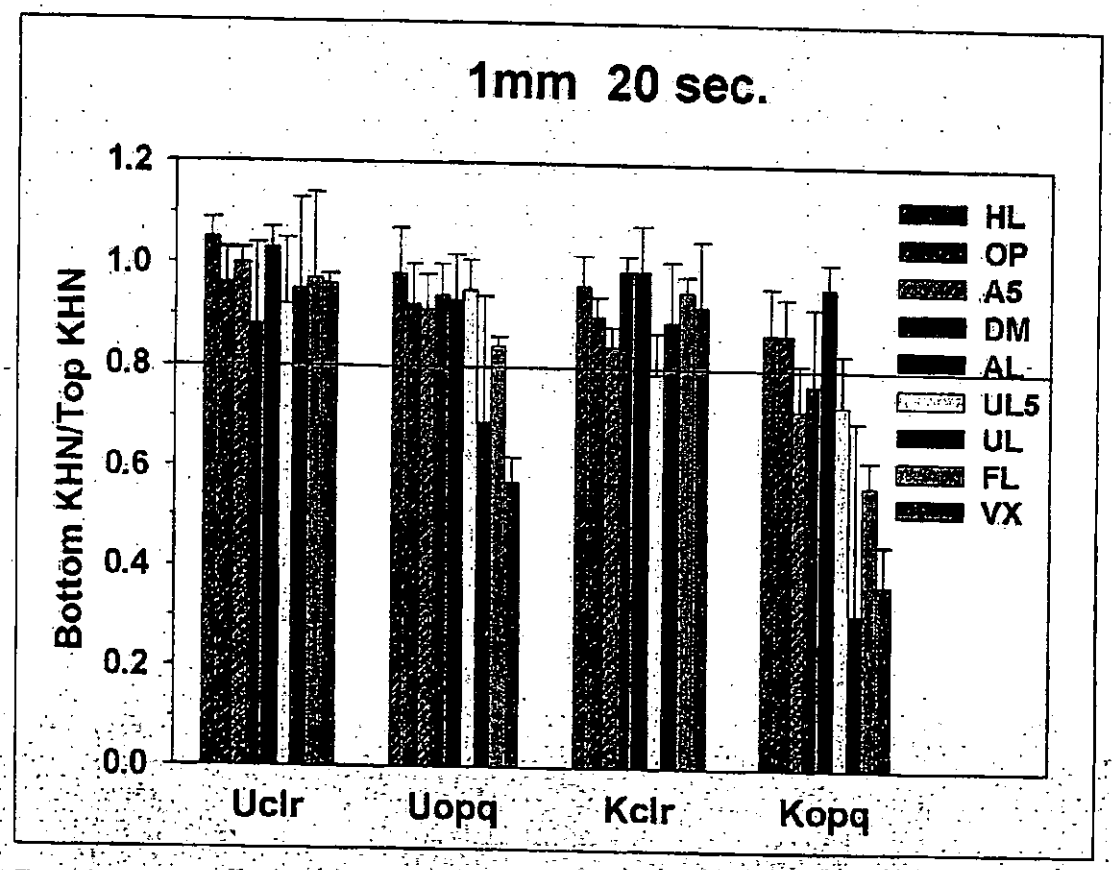


Figure 1: *1-mm thick—20 second cure: bottom/top KHN. (n=5)*

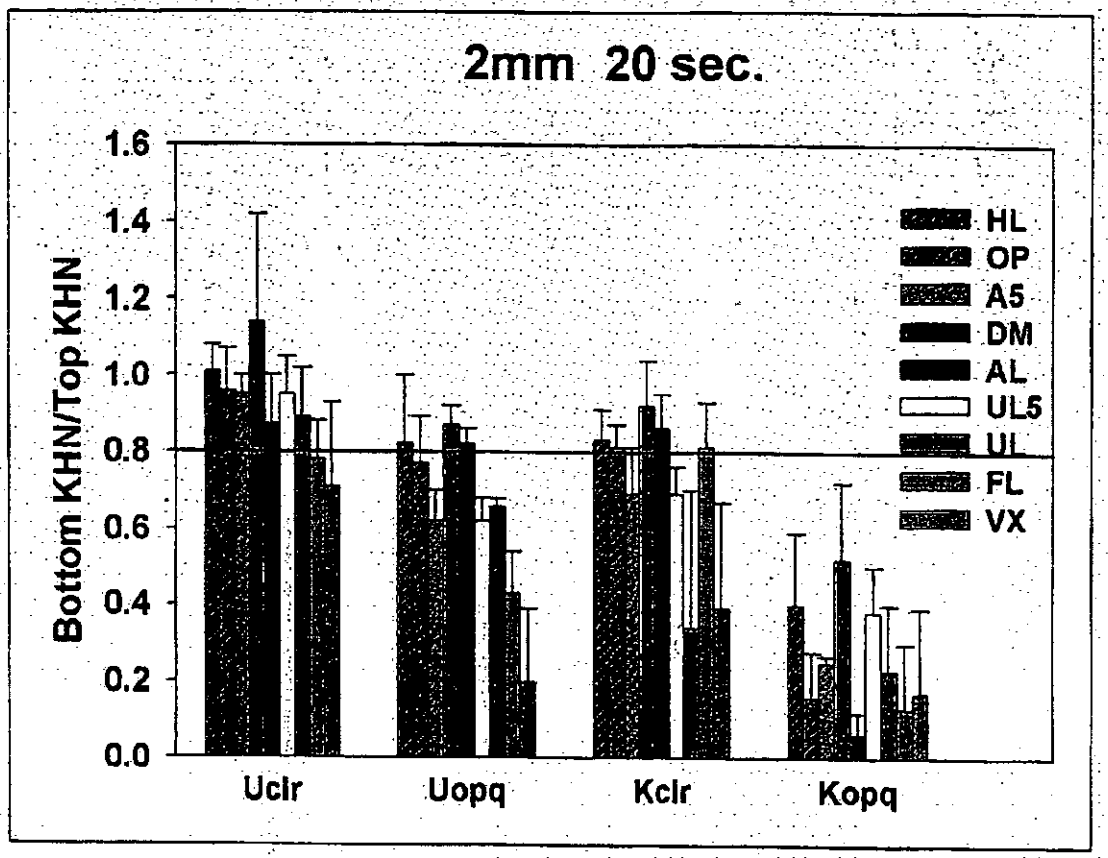


Figure 2: *2-mm thick—20 second cure: bottom/top KHN. (n=5)*

some currently marketed pit & fissure sealants should be expected to have a similar impact on the polymerization process.

The clinician has the choice of several light sources for the activation of light-activated sealants, including quartz-tungsten-halogen (QTH), Light-Emitting Diode (LED), plasma arc and laser units. There have been reports on the impact of LED light-activation units on the polymerization of restorative resin composites (Besnault & others, 2003; Price & others, 2003; Uhl, Sigusch & Jandt, 2004). Higher degrees of conversion in a resin system provide increased mechanical properties that, in turn, should provide increased longevity of the restoration. Ferracane (1985) demonstrated that Knoop Hardness Numbers (KHN) predict the relative degree of conversion for a specific resin under variable conditions. Because the impact of the light source on the sealant's degree of conversion is less well known, this study investigated this relationship using bottom/top KHN ratios (B/T KHN). The hypothesis tested was that B/T KHN for light-activated pit & fissure sealants is not affected by the light-curing unit used.

METHODS AND MATERIALS

Nine different light curing units (Table 1) were used. Irradiance for the activation lights was measured using a USB2000 Spectrometer with a FOIS-1 integrating sphere (Ocean Optics Inc, Dunedin, FL, USA). Calibration of the spectrophotometer in absolute spectral irradiance units was conducted with an LS-1-CAL-INT NIST traceable light source using OOIIrrad-C software, also from Ocean Optics. The power spectrum was integrated from 380-520 nm to obtain intensity values in mW/cm². Four different sealant materials (Table 2) were investigated using three curing conditions for each combination of light/material: 1-mm thickness—20-second cure, 2-mm thickness—20-second cure and 2-mm thickness—40-second cure.

Each specimen was fabricated in a brass mold of appropriate thickness, with a 6 mm internal diameter. The mold was placed between two glass slides and on top of a white background. Each specimen was cured for the appropriate amount of time from the top surface only. The specimens were stored in the dark under 100% relative humidity and 37°C for one hour. Four Knoop Hardness readings were made at least 1 mm from the edge of each top and bottom surface after an indenter dwell time of 15 seconds and a load of either 10 or 25 grams (M-400 Hardness Tester, LECO Corp, St Joseph, MI, USA). A B/T KHN ratio was calculated for each specimen. Top surface and B/T KHN means were determined for each group (n=5). Statistical analysis was performed using one-way ANOVA and Student-Newman-Keuls Post-hoc tests (α=0.05) for each material in each of the three testing conditions. The independent variable was the light-curing unit. In addition, a linear regression followed by an ANOVA for the regression was performed for each material in each testing condition (α=0.05).

RESULTS

The B/T KHN ratios are given in Tables 3, 4, 5 and Figures 1, 2 and 3. Uclr showed no significant difference between lights when curing 1 mm for 20 seconds or 2 mm for 40 seconds. There were differences when curing

Table 3: *1-mm Thick—20 Second Cure: Bottom/Top KHN. Vertical Means with the Same Letters Are Not Significantly Different (n=5)*

Curing Units	Uclr (sd)	Uopq (sd)	Kclr (sd)	Kopq (sd)
HL	1.05 (0.04)a	0.98 (0.09)a	0.96 (0.06)a	0.87 (0.09)a
OP	0.98 (0.07)a	0.92 (0.08)a	0.90 (0.04)ab	0.87 (0.07)a
A5	1.00 (0.03)a	0.91 (0.07)a	0.84 (0.04)ab	0.72 (0.09)ab
DM	0.88 (0.16)a	0.94 (0.06)a	0.99 (0.03)a	0.77 (0.15)ab
AL	1.03 (0.04)a	0.93 (0.09)a	0.99 (0.09)a	0.96 (0.05)a
UL5	0.92 (0.13)a	0.95 (0.06)a	0.79 (0.08)b	0.73 (0.10)ab
UL	0.95 (0.18)a	0.69 (0.25)b	0.89 (0.12)ab	0.31 (0.39) d
FL	0.97 (0.17)a	0.84 (0.02)a	0.95 (0.03)a	0.57 (0.05) b,c
VX	0.96 (0.02)a	0.57 (0.05)b	0.92 (0.13)ab	0.37 (0.08) cd

Table 4: *2-mm Thick—20 Second Cure: Bottom/Top KHN. Vertical Means with the Same Letters Are Not Significantly Different (n=5)*

Curing Units	Uclr (sd)	Uopq (sd)	Kclr (sd)	Kopq (sd)
HL	1.01 (0.07)ab	0.82 (0.18)ab	0.83 (0.08)a	0.40 (0.19)ab
OP	0.96 (0.11)abc	0.77 (0.12)ab	0.81 (0.06)a	0.16 (0.12) bc
A5	0.95 (0.05)abc	0.62 (0.08) b	0.69 (0.12)a	0.25 (0.02) bc
DM	1.14 (0.28)a	0.87 (0.05)a	0.92 (0.12)a	0.52 (0.20)a
AL	0.87 (0.13)abc	0.82 (0.04)ab	0.86 (0.09)a	0.06 (0.06) c
UL5	0.95 (0.10)abc	0.62 (0.06) b	0.69 (0.07)a	0.38 (0.12)ab
UL	0.89 (0.13)abc	0.66 (0.02) b	0.34 (0.36) b	0.23 (0.17) bc
FL	0.78 (0.10) bc	0.43 (0.11) c	0.81 (0.12)a	0.13 (0.17) bc
VX	0.71 (0.22) c	0.20 (0.19) d	0.39 (0.28) b	0.17 (0.22) bc

Table 5: *2-mm Thick—40 Second Cure: Bottom/Top KHN. Vertical Means with the Same Letters Are Not Significantly Different (n=5)*

Curing Units	Uclr (sd)	Uopq (sd)	Kclr (sd)	Kopq (sd)
HL	1.04 (0.06)a	0.88 (0.08)a	0.81 (0.05) c	0.59 (0.06)ab
OP	0.97 (0.06)a	0.87 (0.12)a	0.88 (0.08) bc	0.59 (0.06)ab
A5	0.98 (0.06)a	0.81 (0.09)a	0.77 (0.05) c	0.41 (0.10)ab
DM	0.93 (0.04)a	0.93 (0.07)a	0.96 (0.06)ab	0.65 (0.11)a
AL	0.88 (0.27)a	0.95 (0.05)a	1.00 (0.05)a	0.45 (0.35)ab
UL5	0.87 (0.12)a	0.78 (0.12)a	0.77 (0.06) c	0.64 (0.07)a
UL	1.01 (0.03)a	0.79 (0.10)a	0.84 (0.11) c	0.50 (0.16)ab
FL	0.83 (0.14)a	0.57 (0.06) b	0.80 (0.09) c	0.31 (0.04) b
VX	0.84 (0.07)a	0.24 (0.10) c	0.81 (0.05) c	0.31 (0.07) b

Table 6: *1-mm Thick—20 Second Cure: Top KHN. Vertical Means with the Same Letters Are Not Significantly Different (n=5)*

Curing Units	Uclr (sd)	Uopq (sd)	Kclr (sd)	Kopq (sd)
HL	29.9 (2.0)ab	27.6 (1.9) bc	17.9 (0.4)a	18.3 (0.6)a
OP	30.9 (0.9)a	29.4 (1.0)ab	17.4 (0.7)a	17.9 (0.7)a
A5	31.7 (1.0)a	29.4 (1.8)ab	18.8 (0.1)a	18.3 (0.6)a
DM	29.3 (3.2)ab	26.8 (1.2) bc	14.1 (0.6) b	14.0 (1.0) b
AL	28.8 (2.6)ab	26.8 (1.8) bc	14.5 (1.1) b	14.3 (1.2) b
UL5	31.6 (1.3)a	30.6 (1.7)a	17.9 (1.0)a	17.5 (0.5)a
UL	28.3 (2.3)ab	27.5 (1.9) bc	14.3 (2.1) b	14.9 (0.9) b
FL	26.2 (2.7) b	26.2 (1.3) c	13.1 (0.7) b	13.6 (0.9) b
VX	21.4 (2.1) c	23.9 (1.5) d	9.9 (2.5) c	10.4 (1.0) c

2 mm for 20 seconds, although the differences appear to be related to the brand of curing unit and were not related to the use of QTH versus LED. Uopq, Kclr and Kopq showed significant differences for all curing conditions that were dependent upon the brand of light used.

The top KHN values are given in Tables 6, 7 and 8 and Figures 3, 4 and 5. There were differences for all materials dependent upon the light-curing unit used to activate the polymerization.

The results of the linear regression are provided in Table 9. The predicted required power density for each material to produce a B/T KHN of 0.80 is included.

DISCUSSION

Currently, ANSI/ADA Specification 39 for Pit & Fissure Sealants (1992) requires a 0.75-mm depth of cure determined by wiping the bottom surface after polymerizing. ISO Specification 6874 (1988) requires a 1.5-mm depth of cure. Although many areas of sealants would fall within these thickness requirements, a pilot study indicated that areas greater than 2 mm in thickness were commonly present in molar sealants. Covey, Johnson and Hopper (2004) supported this finding. Though most fissures have signifi-

cant portions that result in thin areas of sealant, inadequate cure of the thicker areas may be associated with partial sealant loss and failure of the preventive therapy or restoration. Therefore, 2-mm thick specimens were used in this study.

A B/T KHN ratio of 0.80 has been used to identify an acceptable level of conversion in resin-matrix systems (Pilo & Cardash, 1992; Shortall & Harrington, 1996; Yap & Seneviratne, 2001). Only Uclr met this requirement with all of the lights when curing 1 mm for 20 seconds and 2 mm for 40 seconds. No material consistently reached this level when curing 2 mm for 20 seconds. It should be noted that the times tested were not necessarily those recommended by the manufacturers. However, the results support activation, with QTH or LED units being most predicable when accomplished, for 40 seconds.

All but one of the test conditions demonstrated the presence of LED and QTH lights in the same statistical groups. In the 2-mm thickness-40 seconds Kclr group, the LED AL provided the highest B/T KHN. This provides evidence that current LED light curing units are capable of initiating polymerization of these materials.

Table 7: *2-mm Thick—20 Second Cure: Top KHN. Vertical Means with the Same Letters Are Not Significantly Different (n=5)*

Curing Units	Uclr (sd)	Uopq (sd)	Kclr (sd)	Kopq (sd)
HL	30.2 (1.1)a	28.7 (1.8)abc	18.2 (0.3)a	16.8 (0.5) b
OP	31.0 (2.1)a	28.5 (2.7)abc	17.8 (1.1)a	17.6 (1.0)ab
A5	31.3 (0.9)a	30.4 (1.5)a	19.0 (1.6)a	18.5 (0.4)a
DM	25.0 (5.2) bc	26.2 (2.3) bc	14.1 (0.8) b	13.6 (0.9) c
AL	28.9 (2.5)a	25.6 (2.5) c	14.8 (0.7) b	13.8 (0.7) c
UL5	30.6 (0.9)a	30.0 (1.1)ab	19.0 (0.4)a	17.6 (0.4)ab
UL	27.6 (1.4)ab	28.0 (2.9)abc	13.9 (0.5) b	14.1 (0.7) c
FL	27.0 (0.5)ab	26.7 (0.6)abc	12.2 (0.9) c	14.3 (1.9) c
VX	22.2 (1.9) c	24.8 (1.5) c	9.1 (0.7) d	11.4 (0.8) d

Table 8: *2-mm Thick—40 Second Cure: Top KHN. Vertical Means with the Same Letters Are Not Significantly Different (n=5)*

Curing Units	Uclr (sd)	Uopq (sd)	Kclr (sd)	Kopq (sd)
HL	30.0 (2.4)ab	28.8 (1.0)ab	18.3 (0.4)ab	18.4 (0.6)a
OP	30.5 (1.4)ab	29.4 (2.0)ab	17.7 (2.2) b	18.3 (0.8)a
A5	33.0 (1.1)a	31.6 (0.9)a	19.8 (0.3)a	18.6 (0.3)a
DM	28.8 (1.1) b	27.0 (2.5) bc	15.8 (1.1) c	14.0 (1.0) c
AL	28.1 (2.1) b	29.0 (0.8)ab	14.7 (0.6) c	14.1 (0.4) c
UL5	32.1 (1.4)a	29.5 (2.0)ab	19.2 (0.7)ab	18.4 (0.6)a
UL	30.1 (1.6)ab	28.2 (2.4) bc	14.6 (1.0) c	15.8 (0.9) b
FL	28.0 (2.5) b	27.7 (0.7) bc	14.1 (1.3) c	14.0 (0.6) c
VX	25.4 (1.4) c	25.4 (1.5) c	11.5 (0.7) d	13.7 (1.4) c

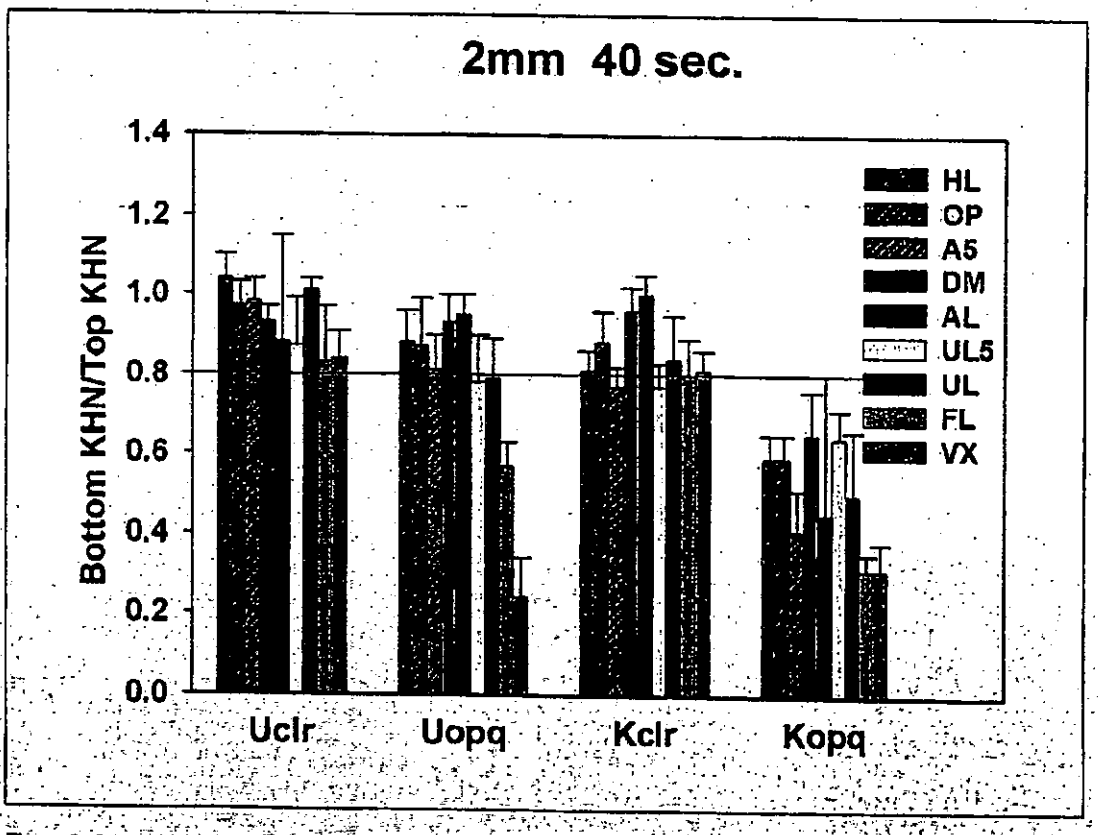


Figure 3: *2-mm thick—40 second cure: bottom/top KHN. (n=5)*

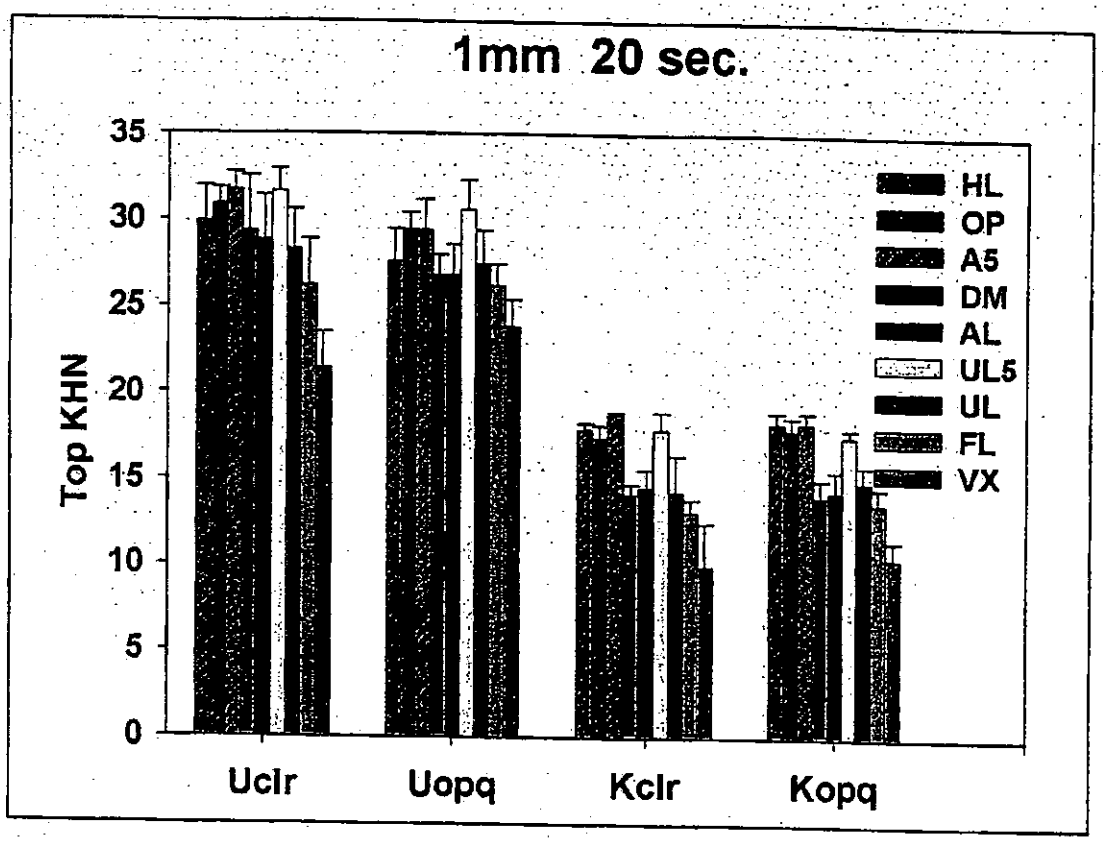
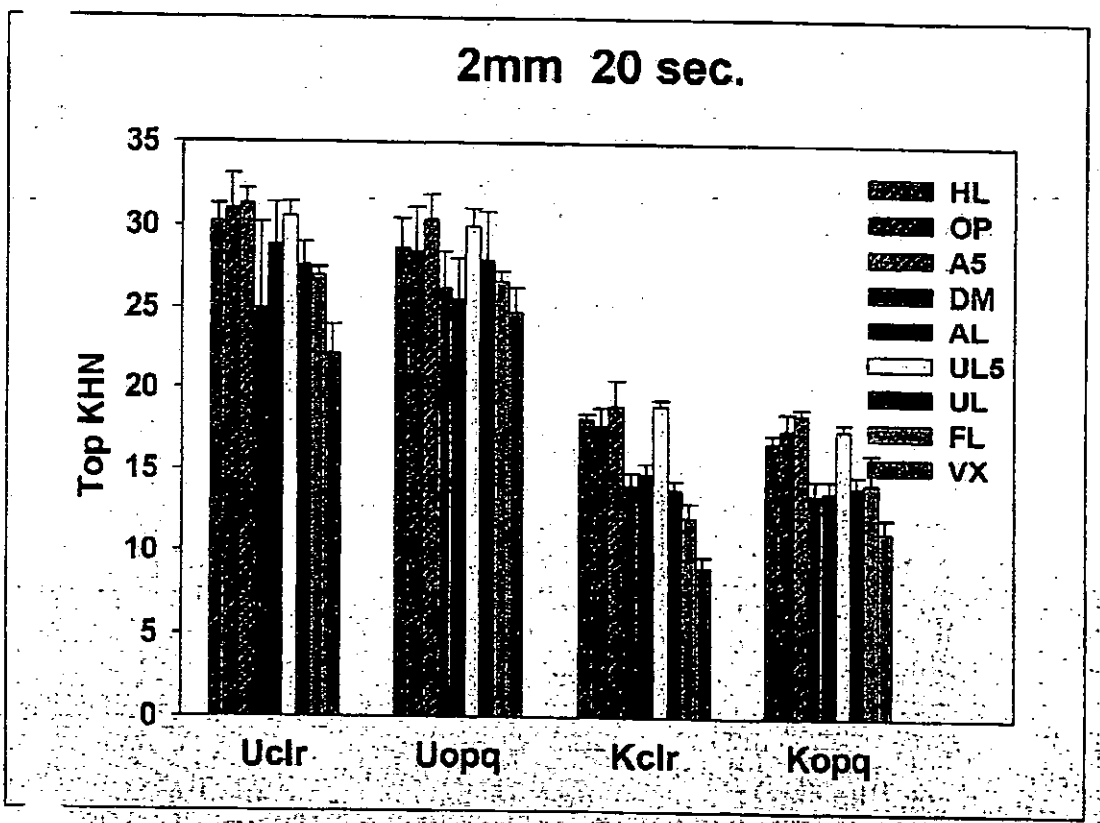


Figure 4: *1-mm thick—20 second cure: top KHN. (n=5)*



F. 5: 2-mm thick—20 second cure: top KHN. (n=5)

The power density produced by a light-curing unit is one factor that influences the monomer conversion in methacrylate resin systems. Five of the six opaque material groups in this study exhibited at least modest correlation between the hardness ratios and power density. The fact that the correlation for the clear materials was quite low would indicate that other factors may be more important in influencing the polymerization of these materials.

Another important factor in the polymerization process is the spectrum of light output as it relates to the absorption of the photoinitiator/s of the resin. A camphoroquinone-amine system is used for photoinitiation in the Kclr and Kopq materials. The Uclr and Uopq materials also contain a second proprietary initiator. This may account for some of the apparent differences noted between materials, particularly with the UltraLume 5 light, which contains a second diode with an intensity peak at approximately 410 nm likely activating the proprietary initiator. However, this study did not pursue a comparison between materials.

It seems apparent that the opaque materials were more difficult to polymerize in

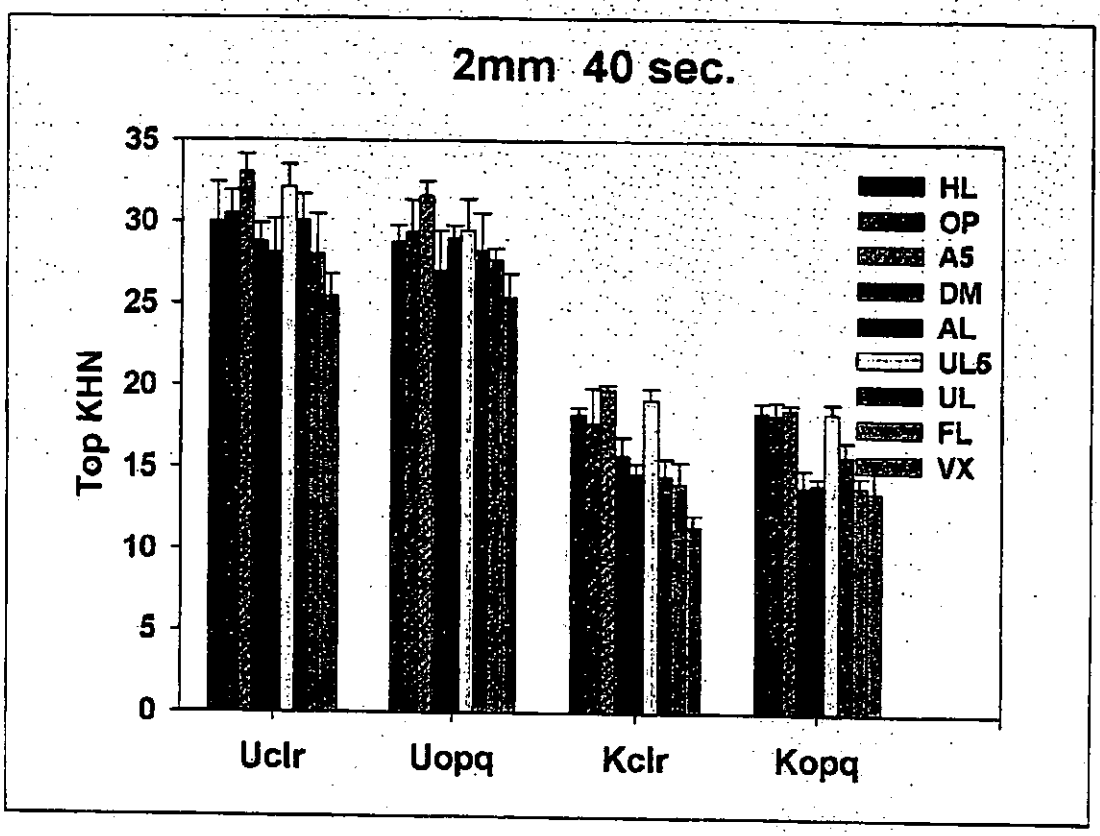


Figure 6: *2-mm thick—40 second cure: top KHN. (n=5)*

Table 9: *Linear Regression Analysis of Testing Condition Versus Power Density (r^2 reported), Analysis of Variance of the Regression (p-value reported) and Power Density Predicted by the Regression to Obtain a B/T KHN of 0.80 (reported as PD)*

	1 mm – 20 seconds	2 mm – 20 seconds	2 mm – 40 seconds
Uclr	r^2=0.018 p=0.733 PD=513.034	r^2=0.387 p=0.074 PD=468.409	r^2=0.333 p=0.104 PD=537.465
Uopq	r^2=0.527 p=0.027* PD=547.378	r^2=0.787 p=0.001* PD=820.649	r^2=0.777 p=0.002* PD=685.006
Kclr	r^2=0.010 p=0.874 PD=587.687	r^2=0.298 p=0.128 PD=710.138	r^2=0.137 p=0.327 PD=457.754
Kopq	r^2=0.605 p=0.014* PD=751.116	r^2=0.024 p=0.693 PD=799.574	r^2=0.546 p=0.023* PD=1129.919

general. This could have significant clinical implications. The 2-mm 20-second group provides some indication of what might occur in any area of compromised light access. Cusp tips increasing the distance between the curing wand and the sealant surface and patients with limited opening would challenge sealant polymerization. It should be expected that most light curing units would not perform adequately with opaque sealants in these situations. The results of this study support the use of a clear light-activated sealant, a chemically-activated sealant or prolonged curing times for opaque light-activated sealants with a high output light-curing unit to overcome this concern.

CONCLUSIONS

The ability to initiate polymerization of resin-matrix pit & fissure sealants was dependent upon the light-curing unit used. Differences were not related to the energy source being QTH or LED. Under the conditions of this study, clear light-activated resin-matrix sealants are more predictable than opaque materials when light exposure may be compromised.

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The Effect of Composite Type on Microhardness When Using Quartz-tungsten-halogen (QTH) or LED Lights

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Clinical Relevance

Resin composite surface microhardness is affected by the selection of different LCUs, with some LEDs providing similar performance to the QTH source. However, results vary greatly with composite brand and type (microhybrid and microfill).

JMMARY

This study evaluates the Knoop microhardness of resin composites cured with different light-emitting diode (LED) based light curing units (LCU) or with a conventional quartz-tungsten-halogen light (QTH). Ten experimental groups with 10 specimens each were used. The specimens were prepared by placing two light-cured resin composites with similar VITA shade A2–microhybrid Filtek Z250/3M ESPE and microfill Durafil VS/Heraeus Kulzer—in a 2.0 mm-thick disc shaped mold. The specimens were polymerized for 40 seconds with the use of one QTH LCU (Optilux 501/Kerr-Demetron) and four LED LCUs: Elipar FreeLight 1 Cordless LED (3M ESPE), Ultrablue II LED with cord (DMC), Ultrablue III LED cordless (DMC) and LEC 470 I (MM Optics). Knoop microhardness was determined at the top and bottom surfaces of the specimens 24 hours following curing. Microhardness values in the microhybrid resin composite group showed no statistically significant differences when cured with LED FreeLight 1 LCU and QTH LCU ($p<0.05$). The other LED devices evaluated in the study presented lower microhardness values in both surfaces ($p<0.05$) when compared to QTH. In the microfill resin composite group, no statistically significant differences were observed among all LCUs evaluated on the bottom surfaces ($p<0.05$). However, on the top surfaces, QTH presented the highest KHN values, and the LED devices presented similar results when com-

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pared with KHN values relative to each other ($p<0.05$).

INTRODUCTION

Light-cured resin composites were introduced into the market in the 1970s. The early products were cured by UV light, while the later versions by visible light (Rueggeberg, 2002). A halogen lamp is routinely used as a dental light activation unit. These lamps produce light by incandescence, where a filament is heated and causes the excitation of atoms over a wide range of energy levels, producing a very broad spectrum of light (Fujibayashi & others, 1998). Filters are therefore needed to restrict the emitted light to the blue region of the spectrum for the polymerization of resin composites (Rueggeberg, 2002). However, halogen based light-curing units (LCU) used to polymerize dental material have several drawbacks (Yoon & others, 2002). Some examples include overheating of the incandescent lamp (Fujibayashi & others, 1998), limited effective lifetime (approximately 40-100h) of the halogen bulbs (Rueggeberg & others, 1996; Jandt & others, 2000; Stahl & others, 2000) and degradation of internal components over time (bulb, reflector, filter) due to the high operating temperatures and large quantity of heat produced during duty cycles (Mills, Jandt & Ashworth, 1999; Jandt & others, 2000). It has also been shown that many halogen LCUs do not reach the minimum power output specified by the manufacturers (Barghi, Berry & Hatton, 1994; Martin, 1998; Miyazaki & others, 1998; Mills & others, 1999; Jandt & others, 2000; Stahl & others, 2000). These shortcomings could result in inadequate curing, which could negatively affect restoration prognosis (Mills & others, 1999; Jandt & others, 2000; Stahl & others, 2000).

To overcome the problems inherent with halogen LCU, solid-state light-emitting diode (LED) technology has been proposed for curing light-activated dental materials (Mills, 1995). Rather than a hot filament, as used in halogen lamps, LED use junctions of doped semiconductor (p-n junctions) to generate blue light (Nakamura, Mukai & Sengh, 1994; Haitz, Craford & Weissman, 1995; Kurachi & others, 2001). These junctions are partially collimated by a small polymer lens positioned in front of the p-n junctions (Jandt & others, 2000; Stahl & others, 2000). LEDs operate around 470 nm, which falls conveniently within the camphorquinone absorption spectrum (Mills & others, 1999; Jandt & others, 2000; Stahl & others, 2000). Blue LEDs present spectral purity for the highly efficient curing of dental resins. Moreover, LEDs have an effective lifetime of more than 10,000 hours and do not present significant degradation of light emission over time (Haitz & others, 1995; Stahl & others, 2000).

An adequate curing of resin composites may influence the mechanical properties and clinical optimization of these materials (Ferracane, 1993; Bayne, Heymann & Swift Jr, 1994). Microhardness is a typical parameter for indicating the degree of polymerization of resin composites (Ferracane, 1985). However, adequate surface hardness does not ensure proper polymerization throughout the restoration (Asmussen, 1982). Thus, hardness analysis must also be performed on the bottom surface of the specimens, since insufficient polymerization of this area may increase the risk of bulk and marginal fracture (Quance & others, 2001). Other possible complications associated with the inadequate curing of resin composites include secondary caries and adverse tissue reactions (Shortall, Wilson & Harrington, 1995). These factors could highly contribute to an early failure of the restorative procedure (Blankenau & others, 1991; Ferracane, 1993).

Several methodologies have been proposed in order to evaluate the polymerization of light curing units. Yearn (1985) has presented a review on the three main methods for evaluating resin composite curing depth: scrape test, hardness test (Barcol, Vickers and Knoop) and degree of conversion (Multiple Internal Reflection spectroscopy and Laser Raman spectroscopy). The author concluded that the hardness test provides a convenient and efficient method for evaluating curing depth.

A composite material has been defined as a "three-dimensional" combination of at least two chemically different materials with a distinct interface separating the components (Peutzfeldt, 1997). Dental resin composites usually encompass three main components: 1) resin matrix, 2) inorganic fillers and 3) coupling agents (Peutzfeldt, 1997). The amount and size of filler particles incorporated in the resin matrix determine the type, and ultimately, the most advantageous clinical application of each composite (Wakefield & Kofford, 2001). Early materials incorporated large ground quartz particles which resulted in rough surfaces that were difficult to polish (Rueggeberg, 2002). Due to the modification of fillers to extremely small particles, microfill composites have been developed (Rueggeberg, 2002). These materials usually consist of silica particles with 0.01-0.1 μm (Wakefield & Kofford, 2001). In general, microfill composites have the advantage of high polish, which lasts, in addition to excellent esthetics (Wakefield & Kofford, 2001).

Microhybrid composites are a combination of microfill and larger filler particles. The main drawback of this group, as determined by larger particle size, is the difficulty in long-term maintenance of a high polish (Wakefield & Kofford, 2001). The advantages of these materials are strength, high percent fill (75% to 80% by weight) and a wide array of shades, opacities and translucencies that are important when considering function and esthetics in restoration (Wakefield & Kofford, 2001).

Therefore, due to the increasing use of resin composites in daily practice and the availability of different light curing devices in the dental market, this study evaluated the efficacy of polymerization of two resin composites cured with four LED and one QTH LCUs at two depths.

The research hypothesis tested was that there is no difference between the light-curing units (LED or QTH) for the Knoop microhardness of resin composites (microhybrid or microfilled).

Table 1: *Restorative Materials Used in This Study*

	Filtek Z250	Durafil VS
Manufacturer	3M ESPE Dental Products St Paul, MN, USA	Heraeus Kulzer Inc Armonk, NY, USA
Batch #	1LC	020131
Classification	Microhybrid	Microfill
Shade	A2	A2
Type of filler	Zircon/silica	Highly disperse silicon dioxide
Filler particle size (μm)	0.01-3.5	0.02-0.07
Pre-polymerized particles	—	Splinter polymer (10-20 μm)
Filler loading	60 vol%	Unknown
Photoinitiator system	Camphoroquinone	Camphoroquinone

METHODS AND MATERIALS

Specimens were prepared with microhybrid Filtek Z250 (3M ESPE Dental Products, St Paul, MN, USA) and microfill Durafil VS (Heraeus Kulzer Inc, Armonk, NY, USA) resin composites (Table 1). The four light-curing units (LCU), based on blue LED technology with a different number of LEDs and the quartz-tungsten-halogen (QTH) light LCU, are presented below:

- FreeLight 1 LED (3M ESPE Dental Products)
- Ultrablue II corded LED (DMC Equipamentos, Sao Carlos, SP, Brazil);
- Ultrablue III cordless LED (DMC Equipamentos)
- LEC 470 I (MM Optics, Sao Carlos, SP, Brazil)
- Optilux 501 (Kerr Dentistry/Demetron, Orange, CA, USA)

Specimens were prepared at random by placing a single increment of resin composite in a cylindrical metallic mold (4.0 mm in diameter and 2.0 mm in height). The mold was then positioned over a polyester strip fixed on a glass plaque. After resin insertion, a second polyester strip was placed on the top of the mold. In order to ensure a level plane on the top and bottom surfaces, a glass lamina with a 500g weight was laid on the top polyester strip for 30 seconds. Light curing was performed by touching the LCU guide on the top polyester strip for 40 seconds. The power output of the light sources was measured by the use of a radiometer attached to the Optilux 501 LCU to verify whether they were properly working. Thus, 10 experimental groups (n=10) were prepared according to the resin composite and LCU that was applied.

The specimens were stored in distilled water in a light-proof container for 24 hours and microhardness was determined by a Microhardness Tester FM (Future-Tech Corp, Tokyo, Japan). Microhardness measurements were performed by applying a 10g load for 10 seconds at five points, 1 mm apart on the specimens' top and bottom surfaces. The five measurements obtained were converted into a Knoop Hardness Number (KHN) and the average was calculated.

Statistical analysis was performed by three-way analysis of variance (ANOVA) with split-plot at a significance level of α=5%. The plots were represented by factors LCU and resin composite, and sub-plots were represented by factor surface (top and bottom). Tukey test was applied when significant differences were detected by ANOVA (α=5%).

RESULTS

The results showed statistically significant differences between the LCUs (p=0.00001), resin composites (p=0.00001) and depths (p=0.00001) evaluated. It also verified a significant interaction among LCU vs resin composites vs depths (p=0.00148).

Mean hardness values and standard deviations (SDs) at top and bottom depths for each resin composite and the LCUs are shown in Table 2. Analyzing the bottom surface of the microhybrid resin composite group, the FreeLight 1 LED LCU was the only device that presented no statistically significant difference when compared with QTH LCU (LED-53.1 ± 6.5^A, QTH LCU-57.7 ± 4.2^A). In addition, there was no statistically significant difference between Ultrablue II corded LED LCU (46.9 ± 5.4^C) and Ultrablue III cordless LED LCU (48.45 ± 2.5^C). Also, LEC 470 I LED LCU presented the lowest values of KHN (40.4 ± 11.5^D). However, for the microfill group, no statistically significant difference was found among all evaluated LCUs.

On the top surface of the microhybrid group, FreeLight 1 LED LCU also presented no statistically significant difference when compared to QTH LCU (LED-57.1 ± 3.7^A, QTH LCU-60.1 ± 6.5^A). In addition, no statistical difference was observed between Ultrablue II corded LED (51.2 ± 5.2^B) and Ultrablue III cordless LED LCU (53.21 ± 4.8^B). In the microfill group, QTH LCU presented the highest values of KHN.

Comparing Knoop hardness values at the top and bottom surfaces, it was verified that the top surface of the microhybrid resin presented the highest KHN

values. However, when the microhybrid resin was cured by QTH lamp, no statistically significant difference could be noted between the two surfaces. As for the microfill group, no statistically significant difference was observed between the two surfaces for all LED devices. Nevertheless, KHN values for QTH LCU on the bottom surface were lower (16.46 ± 1.1[b]) than the top surface values (25.1 ± 2.4[a]).

DISCUSSION

By analyzing the data obtained in this study, it could be verified that the research hypotheses tested in this study were rejected.

The microhybrid resin composite presented the highest KHN values (Table 2) regardless of the light source (QTH or LEDs) or surface (top or bottom). The size and content of filling particles in the organic matrix of microhybrid resin composites might have accounted for the highest KHN values reported (Ruyter & Oysæd, 1982; Pilo & Cardash, 1992; Rueggeberg & others, 1993).

The polymerization of microhybrid resin composite with FreeLight 1 LED LCU resulted in similar microhardness values when compared to QTH LCU (Table 2). Although LED LCU presents a 32% smaller light intensity (282 mW/cm²) than QTH LCU (866 mW/cm²), an adequate polymerization of microhybrid could be verified in the current investigation. A possible explanation for these results may be the fact that LED LCUs present a specific pattern of light emission, which is similar to the absorption spectrum of the camphorquinone photoinitiator of resin composites (Mills & others, 1999; Jandt & others, 2000; Stahl & others, 2000). This spectral purity allows total usage of the emitted light by LED, which does not happen with QTH (Whitters, Girkin & Carey, 1999; Althoff & Hartung, 2000). Hofmann, Hugo and Klaiber (2002) also evaluated the microhardness of Filtek Z250 microhybrid resin cured with QTH (800mW/cm² for 40 seconds) and LED (320mW/cm² for 40 seconds). These authors observed no statistically significant differences between these two light sources, which is in agreement with the results of this study.

The remaining LED-based LCUs evaluated in this study showed lower hardness values when compared with QTH LCU (Table 2). Some authors report that LED-based LCUs have a narrow spectral range, with a peak around 470 nm, which matches the optimum absorption wavelength for the activation of the camphorquinone photoinitiator (Jandt & others, 2000; Uhl & others, 2004a; Uhl, Sigusch & Jandt, 2004b; Bennett & Watts, 2004). This study did not evaluate the wavelength of the LCUs. However, it was verified that both Ultrablue LED LCUs presented low power output of 130 mW/cm² (15% of QTH intensity) and LEC 470I LED LCU presented 91 mW/cm² (14% of the QTH power output). Thus, the low light intensity presented by both Ultrablue LED LCUs and LEC 470I LED LCU could explain these results. Other studies have also shown that LED LCUs with relatively low irradiance sold on the market may result in insufficiently cured composites and, therefore, inferior mechanical properties of the restorations (Hofmann & others, 2002; Uhl & others, 2002; Mills, Uhl & Jandt, 2002).

An alternative way to improve LED-based LCUs curing effectiveness could be to increase the light exposure time during polymerization (Leonard & others, 2002; Kurachi & others, 2001). However, this could result in a longer clinical restorative procedure. Thus, the use of argon laser and plasma arc based LCUs could be suggested, since these devices are capable of curing dental composites in a shorter period of time (Vargas, Cobb & Schmidt, 1998; Hasegawa & others, 2001). Recently, new LEDs, so-called second generation LEDs, were

Table 2: *Mean Hardness Values and Standard Deviations (SD) at Top and Bottom Surfaces for Each Resin Composite and LCUs Evaluated by the Tukey's Test (p<0.05)*

Resin Composites	LCUs	Top Surface		Bottom Surface		Surface Hardness Ratio
		Mean	SD	Mean	SD	
Microhybrid	FreeLight 1	57.1 ^{Aa}	3.7	53.1 ^{Ab}	6.5	0.92
	Ultrablue II Corded	51.2 ^{BCa}		46.9 ^{Cb}	5.4	0.91
	Ultrablue III Cordless	53.2 ^{BCa}	4.8	48.5 ^{BCb}	2.5	0.91
	LEC 470 I	49.7 ^{Ca}	11.0	40.4 ^{Db}	11.9	0.81
	Optilux 501	60.1 ^{Aa}	6.5	57.7 ^{Aa}	4.2	0.95
Microfill	FreeLight 1	16.4 ^{Ba}	1.5	14.9 ^{Aa}	1.2	0.90
	Ultrablue II Corded	14.9 ^{Ba}	0.8	12.8 ^{Aa}	1.2	0.85
	Ultrablue III Cordless	14.9 ^{Ba}	1.4	13.4 ^{Aa}	1.2	0.89
	LEC 470 I	14.1 ^{Ba}	1.6	12.3 ^{Aa}	1.7	0.87
	Optilux 501	25.1 ^{Aa}	2.4	16.4 ^{Ab}	1.1	0.65

Statistically significant differences are expressed by upper case letters in columns and by lower case letters in rows (p<0.05). n=10 specimens per experimental condition.

introduced to the market and will be used in several LED LCUs. These single InGaN LEDs consist of multiple emitters on the same substrate. The new prototype achieved a higher irradiance and depth of cure than the QTH LCU, which indicates that the new LED may lead to enhanced mechanical properties of composites (Uhl & others, 2004). On the other hand, this might lead to higher temperatures within the restoration (Uhl, Mills & Jandt, 2003), because of its high power output.

Comparing the microhardness performed on the top and bottom surfaces, the microhybrid resin showed a hardness reduction on the opposite surface from the light exposure (bottom surface) for all LED LCUs evaluated (Table 2). These results indicate that the curing degree decreases as a function of depth, as demonstrated previously by other studies (Hansen & Asmussen, 1993; Kurachi & others, 2001). However, when the QTH device was evaluated, no statistically significant difference was found between these two surfaces. According to Leonard and others (2001), the minimum required irradiance of a halogen lamp for proper polymerization of a 2.0 mm-thick microhybrid resin composite is 300 mW/cm². However, the halogen light Optilux 501 used in this study has a high irradiance level (866 mW/cm²), which could explain the previous results.

The QTH resulted in the greatest hardness mean value (25.17) on the top surfaces of the microfill resin group. This could be due to the high intensity of the halogen light emitted on this surface (866 mW/cm²). However, when evaluating the bottom surfaces, no statistically significant differences were found among the groups cured with LED and QTH. It is thought that microfill resin based composites are more difficult to cure, because their small filler particles cause light to scatter, decreasing the effectiveness of the curing light (Nomoto, Uchida & Hirasawa, 1994; Kawaguchi, Fukushima & Miyazaki, 1994; Leonard & others, 2001). This could explain the poor results for hardness at the bottom surfaces of the microfill resin, regardless of the light source.

Yap and Severante (2001) and Yap, Soh and Siow (2002) suggested a bottom/top surface hardness ratio to verify the efficiency of cure in deep surfaces when compared to the surfaces located closest to the light sources. Theoretically, the hardness of the cured resin composite at the bottom surface has to present 80% (0.80) of the hardness at the top surface. In this study, for the microhybrid resin composite, it was observed that all LCUs tested reached ratios of more than 0.80; however, for the microfill resin composite, the surface hardness ratio bottom/top presented a value of 0.65, which was lower than that considered the minimum, when the QTH unit was used (Table 2). This lower value can suggest that this QTH device was not efficient, though it is important to observe the highest microhardness values were observed at the top surface for this type of unit, which contributed to reducing this ratio.

According to the methodology proposed by this investigation, it can be concluded that the microhardness of resin composites vary according to the type of resin (mycrohybrid and microfill), the light curing unit and the depth at which hardness is measured. However, further investigation is necessary to verify the performance of LED based LCUs in cavities deeper than 2.0 mm, such as clinical in-depth Class II cavities.

CONCLUSIONS

Within the limitations of this study, the authors conclude:

1. For the microhybrid composite, Freelight 1 was the only LED light providing equivalent hardness values as those from a conventional QTH light.
2. For the microfill composite, all LED lights provided similar performance, while the QTH provided the hardest surfaces.
3. The microhardness of resin composites vary according to the type of resin (mycrohybrid and microfill), the light curing unit and the depth at which hardness is measured.

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Curing performance of a new-generation light-emitting diode dental curing unit

KIM M. WIGGINS, MARTIN HARTUNG, OLAF ALTHOFF, CHRISTINE WASTIAN and SUMITA B. MITRA

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Curing performance of a new-generation light-emitting diode dental curing unit

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ABSTRACT

Background. Recent technological advances have resulted in the marketing of high-powered, or HP, battery-operated light-emitting diode, or LED, dental curing lights. The authors examine the curing efficiency and peak polymerization temperature, or T_p, of a new HP LED curing light.

Methods. The authors studied four visible light-curing, or VLC, units: HP LED (A), first-generation LED (B), conventional halogen (C) and high-intensity halogen (D). They determined the depth of cure, or DOC; adhesion; and T_p of three types of VLC resin-based composites after exposure to each light. The exposure times for units A and D were one-half those for units B and C.

Results. The power density of unit A was 1,000 milliwatts per square centimeter, which was comparable to that of unit D with turbo charge. The DOC and adhesion attained for all three resin-based composites after being light cured by unit A for a 10-second exposure time were equivalent to those after being light cured by unit D for a 10-second exposure time and to those after being light cured by units B and C for 20-second exposure times. The resin-based composites light cured by unit A attained significantly lower T_ps than did those light cured by unit D at equivalent cure, or exposure, times and by unit C at twice the cure time.

Conclusions. The authors found that Unit A effectively cured the resin-based composites at one-half the cure time of units B and C and at the same time as unit D, while maintaining low T_p.

Clinical Implications. The battery-operated HP LED curing light might be an effective, time-saving alternative for clinicians to use in light curing resin-based composites.

The use of visible light-curing, or VLC, units for the polymerization of dental materials is an essential part of a contemporary dental practice. In recent years, many types of VLC lights have been marketed with a view toward making the polymerization process more efficient for dental practitioners. Dental VLC materials generally contain a diketone-type photoinitiator that absorbs light in the 400- to 500-nanometer range covered by blue light from the visible spectrum. The most common photoinitiator used is camphorquinone, or CPQ, which has a peak absorption maximum at 465 nm.

The battery-operated high-powered light-emitting diode curing light might be an effective alternative in light curing resin-based composites.

Tungsten halogen curing lights (often referred to simply as "halogen curing lights") are the most frequently used polymerization source in dental offices.[1] The advantage of halogen curing lights is that they are derived from relatively low-cost technology. However, they have low efficiency and present several drawbacks. The light from a halogen curing light is produced by an electric current flowing through a thin tungsten filament.[2] The filament functions as a resistor, and when it is heated by the current to temperatures of about 3,000 Kelvin, it becomes incandescent and emits electromagnetic radiation in the form of visible light, as well as a large amount of infrared radiation. The light emitted is not selective; therefore, when blue light is given off, the rest of the spectrum is unused and has to be filtered out.[3] Because the filament generates high temperatures, the curing light has to be cooled by a ventilating fan that forces airflow through slots in the casing. This

DISCLOSURE
The authors are employees of 3M ESPE Dental Products, St. Paul, Minn., and 3M ESPE AG, Seefeld, Germany. The study described here was conducted at both 3M ESPE locations.

feature causes the handpiece to become cumbersome and noisy, and the slots can make it difficult to disinfect the handpiece completely. The high temperatures attained also can cause the bulb components to have limited lifetimes and requires frequent monitoring and replacement of the curing light's bulb.[4]

Newer types of curing lights have been introduced to photopolymerize dental materials. Plasma arc curing, or PAC, lights have been introduced with the claim that they can decrease curing times significantly without a concomitant reduction in mechanical properties and performance of the cured materials.[5] Scientific data, however, do not support this claim unequivocally.[6] Typically, adequate curing results can be obtained only if the cure, or exposure, times are extended beyond those recommended by the devices' manufacturers. In PAC lights, a high voltage is applied between two electrodes, resulting in a light arc between them. Like halogen curing lights, PAC lights also have low efficiency, and their power consumption is higher than that of halogen curing lights. PAC lights have high operating temperatures, which makes the use of ventilating fans necessary. In addition, the bulbs of PAC curing lights are located inside a tabletop base that uses rigid light-guiding cables. The lights' spectral output is continuous and must be filtered to provide the useful blue light. The use of these high-intensity PAC lights can present a danger of increased heat generation in the cured dental materials, which may lead to pulpal damage.[7,8]

Laser lights also have been introduced. They have the advantage of having narrow spectral emission characteristics that may be well-adapted to dental photoinitiators. Because of their low energy conversion, they require a larger base for power supplies and cooling.

More recently, the use of light-emitting diodes, or LEDs, that produce blue light have been mentioned in conjunction with curing dental materials.[9-11] LED technology is not new, and different versions of it have been used in many common applications, such as indicators in common electronic devices (for example, computer keyboards) and red or green laser pointers. Highly bright blue LEDs have been available only since the mid-1990s. A new semiconductor material system—the gallium nitride—forms the basis for the blue emission, as well as for the high efficiency of devices that use it. Both characteristics are essential requirements for their use in the dental curing application. In LEDs, a voltage is applied across the junctions of two doped semiconductors (n-doped and p-doped), resulting in the generation and emission of light in a specific wavelength range. By controlling the chemical composition of the semiconductor combination, one can control the wavelength range.[12] The dental LED curing lights use LEDs that produce a narrow spectrum of blue light in the 400- to 500-nm range (with a peak wavelength of about 460 nm), which is the useful energy range for activating the CPQ molecule most commonly used to initiate the photopolymerization of dental monomers.

Light-emitting diode curing lights are lightweight, portable and highly efficient and have long life spans.

LED curing lights are lightweight, portable and highly efficient and have long life spans. Since a narrow band of light is emitted, there is no need for filter systems. Because there is no infrared emission, the curing lights have low amounts of wasted energy, leading to minimum heat generation, which obviates the need for cooling fans. The LED curing light's power consumption is low, so batteries can be used to power it. The light output is consistent, there is no bulb to change and the service life is long. Studies have been conducted to demonstrate the potential of the blue LED technology for curing of dental materials. The earlier versions of blue LEDs were low in intensity and required the use of a large number of LEDs to provide adequate performance. In 1996, Fujibayashi and colleagues[9] reported using 61 LEDs to achieve adequate cure of dental composites. Mills and colleagues[11] needed 26 LEDs to do the same in their 1999 study. In their 2002 report on polymerization of a hybrid and a microfill resin-based composite using two commercial LED light-curing units (LumaCure, LumaLite, Spring Valley, Calif., and Versalux, Centrix, Shelton, Conn.), Dunn and Bush[13] concluded that the light output of commercially available LEDs for resin-based composite polymerization still required improvement to be able to provide the same adequacy of cure as halogen light-curing units.

Since then, marked improvements in LED technology have resulted in the development of

several types of commercial LED light-curing units that have improved intensity output, which results in a depth of cure, or DOC, equivalent to that of conventional halogen lights at about the same length of light exposure.[14] Uhl and colleagues[15] demonstrated that an LED light-curing unit—Elipar FreeLight (3M ESPE, St. Paul, Minn.)—that had an array of 19 LEDs in its first version represented a viable alternative to halogen light-curing units for light polymerization of dental composites because it generated a generally lower temperature increase within the composite. These older versions of LED light-curing units had intensities of up to 400 milliwatts per square centimeter.

Further advancements in technology have made it possible for manufacturers to produce high-powered, or HP, LED lights. A number of HP LED lights have been marketed recently that claim to reduce curing times.[16,17] To achieve this reduction in curing times, this newer generation of curing lights have incorporated the latest advancements in HP LEDs so that they are capable of delivering a power density of about 1,000 mW/cm^2. Since all of the spectral output of the LEDs is concentrated in the blue wavelength range, more efficient curing should be possible with the HP LED lights, resulting in reduced curing time compared with the first LED lights and conventional halogen lamps. Thus, they would be comparable to HP or high-intensity halogen curing lights. At the same time, they are lightweight and portable and have long life spans, like the first-generation LED curing lights.

We conducted a study to assess the effectiveness of a new HP LED curing light (unit A) and compare it with a first-generation LED curing light (unit B), a conventional halogen curing light (unit C) and a high-intensity halogen curing light (unit D). We measured the DOC of three VLC dental filling materials and the interfacial adhesion of these materials to dental hard tissue using a common bonding agent and each of the four curing lights. We also compared the temperature rise caused by the curing of a composite by the HP LED curing light with those generated by the other three VLC units. We tested the following hypotheses:

- The curing efficiency of the HP LED curing light (unit A) would be equivalent to those of the conventional LED curing light (unit B) and the conventional halogen curing light (unit C) at one-half the cure time.
- The curing efficiency of unit A would be equivalent to that of the high-intensity curing light (unit D).
- The peak polymerization temperature, or T_p, reached by the composites cured by units A and B would be lower than that of units D and C, respectively.

We measured the depth of cure of three visible light-cured dental filling materials and the interfacial adhesion of these materials to dental hard tissue using a common bonding agent and each of the four curing lights studied.

MATERIALS AND METHODS

Light-curing units. Table 1 lists the VLC units we used in this study, their power densities and their exposure times. Unit A, Elipar FreeLight 2 (3M ESPE, St. Paul, Minn.), has a single HP LED, and unit B, Elipar FreeLight, has an array of 19 LEDs. Unit C is a conventional halogen light-curing unit (Elipar TriLight, 3M ESPE), and unit D is an HP halogen lamp (Optilux 501, KerrLab, Orange, Calif.) with turbo tip and boost mode. We obtained the units' power densities (Table 1) and the spectral emission characteristics (Figure 1) using a calibrated fiber-optic spectrally resolving radiometer system (S2000 Miniature Fiber Optic Spectrometer, Ocean Optics, Dunedin, Fla., coupled to an integrating sphere).

Resin-based composites. We used representative examples of three dental filling composites—a microfill (Filtek A110, 3M ESPE), a hybrid (Filtek Z250 Universal Restorative, 3M ESPE) and a nanocomposite (Filtek Supreme, 3M ESPE)—in this study (Table 2, page 1475).

DOC measurement. We measured DOC according to the procedure defined by the International Organization for Standardization 4049:2000 (E) for resin-based filling materials.[18] We packed the filling material into a metal cylinder (4 millimeters diameter, 6 mm length) and cured it for the exposure time recommended by the manufacturer with units B and C or for one-half the recommended time with units A and D. After exposing the resin-based composite with the light-curing units for the times specified in Table 1, we removed it from the mold and scraped

TABLE 1

LIGHT-CURING UNITS STUDIED, POWER DENSITIES AND EXPOSURE TIMES.

LIGHT-CURING UNIT	NAME AND MANUFACTURER	TYPE*	ELECTRICAL POWER CONSUMPTION (WATTS)	POWER DENSITY BY SPECTRAL-RADIOMETER (mW/cm²†)	EXPOSURE TIME (SECONDS)
Unit A	Elipar FreeLight 2, 3M ESPE, St. Paul, Minn.	Light-emitting diode (1)	5	1,000	10
Unit B	Elipar FreeLight, 3M ESPE	Light-emitting diode (19)	5	400	20
Unit C	Elipar TriLight, 3M ESPE	Conventional halogen	75	700	20
Unit D	Optilux 501, KerrLab, Orange, Calif.	High-energy halogen	80	1,500	10

* The number in parentheses is the number of light-emitting diodes in the head of the light-curing unit.
† mW/cm²: Milliwatts per square centimeter.

away any uncured material using a plastic instrument. The DOC value we recorded was one-half the height of cured material after scraping back. We used a sample size of five for each resin-based composite for each of the light-curing units.

Adhesion measurement. We determined the resin-based composites' adhesion to bovine enamel by measuring shear bond strength using a total etch technique. We ground bovine teeth to enamel with a final 320-grit finish. We applied Scotchbond Etchant Gel (batch 2YR, 3M ESPE) for 15 seconds, and then rinsed the teeth with water and dried them. We applied Single Bond adhesive (batch 2HB, 3M ESPE) to the teeth as recommended by the manufacturer and dried and light cured the teeth for the times shown in Table 3. We placed each resin-based composite to 2 mm depth in the mold and cured it for the times shown in Table 3. Thus, the light-curing time for unit A was only one-half that of unit C. We stored the specimens in distilled water at 37 C for 24 hours. We measured bond strength in the shear mode using a wire loop with an Instron Universal testing machine (model 1123, Instron, Canton, Mass.) at a shear rate of 2 mm/minute. We used a sample size of six for each resin-based composite for each of the light-curing units. We conducted statistical analysis using analysis of variance, or ANOVA, at $P < .05$.

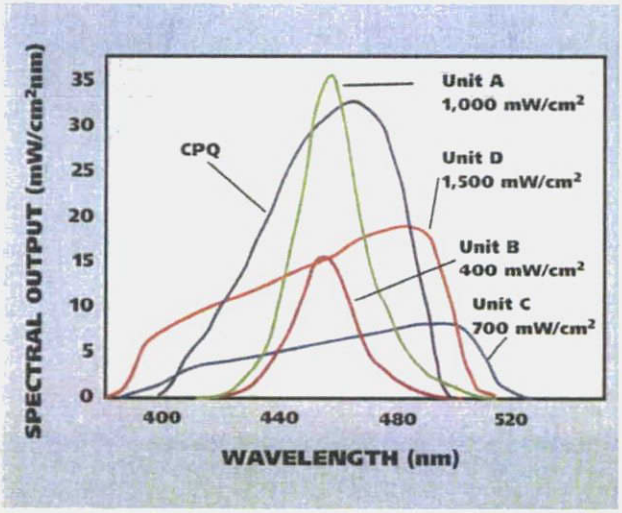

Figure 1. Absorption spectrum of the photoinitiator camphorquinone, or CPQ, and emission spectra of the curing lights. Total light intensity is equivalent to area under the emission curve for each light. Total useful light is the extent of overlap of the emitted light of a curing light with the absorption spectrum of the photoinitiator. The values given with the light-curing units are the units' total power densities. mW/cm²: Milliwatts per square centimeter. nm: Nanometer.

T_p measurement. We measured T_p in vitro with a cavity consisting of an aluminum cylinder (2 mm height, 6 mm diameter) filled with resin-based composite material. We incorporated a thermocouple into the bottom of the cavity, and we recorded the temperature increase during the irradiation from the curing lights with a computer-based data acquisition system. We considered the maximum of the temperature rise to be the peak temperature. We light cured five samples of each material with each of the four

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curing lights, and we conducted statistical analyses (ANOVA, $P < .05$) to determine significant differences in T_p among the curing lights used. This setup allowed us to measure the amount of relative heat that was produced owing to the polymerization reaction of the resin-based composite sample, as well as the thermal effect due to the radiation from the curing lights. We did not interpret the absolute temperature values in terms of the real temperatures present during a clinical procedure, as the thermal capacity, heat transport and dissipation of a vital tooth may be completely different. The evaluation, however, allowed us to make relative comparisons of the amount of heat that a tooth, and in turn the pulp, had to handle with the different treatments.

RESULTS

DOC. Figure 2 shows the DOC results for units C and B at 20-second cure times for the three resin-based composites. Figure 2 also shows the results of curing using unit A at 10-second cure times, as well as that of unit D at 10-second cure times. We performed statistical analysis using ANOVA for equality of medians at $P < .05$. We found no significant difference in DOC for all three types of resin-based composites tested using units A and D both at 10-second cure times. In all cases, there was no sig-

TABLE 2

RESIN-BASED COMPOSITE MATERIALS USED.

RESIN-BASED COMPOSITE (NAME AND MANUFACTURER)	LOT NO.	RESIN	FILLER TYPE
Microfill (Filtek A110, 3M ESPE, St. Paul, Minn.) Shade A3E	3BY	Bis-GMA* TEGDMA†	Prepolymerized filler and pyrogenic silica
Hybrid (Filtek Z250 Universal Restorative, 3M ESPE) Shade A3	3AR	Bis-GMA UDMA‡ Bis-EMA6§ TEGDMA	Zirconia-silica Average particle size 0.6 micrometers
Nanocomposite (Filtek Supreme, 3M ESPE) Shade A3B	3BB	Bis-GMA UDMA Bis-EMA6 TEGDMA	Zironia-silica nanocluster and silica nanoparticles Effective particle size 20 nanometers

* Bis-GMA: Bisphenol A glycidyl dimethacrylate.
† TEGDMA: Triethylene glycol dimethacrylate.
‡ UDMA: Urethane dimethacrylate.
§ Bis-EMA6: Bisphenol A polyethylene glycol diether dimethacrylate.

TABLE 3

CURING TIMES FOR ADHESION STRENGTH MEASUREMENT.

LIGHT SOURCE*	CURE TIME FOR SINGLE BOND ADHESIVE (3M ESPE, ST. PAUL, MINN.) (SECONDS)	CURE TIME FOR RESIN-BASED COMPOSITE (SECONDS)
Unit A	5	10
Unit B	10	20
Unit C	10	20
Unit D	5	10

* Unit names and manufacturers are listed in Table 1.

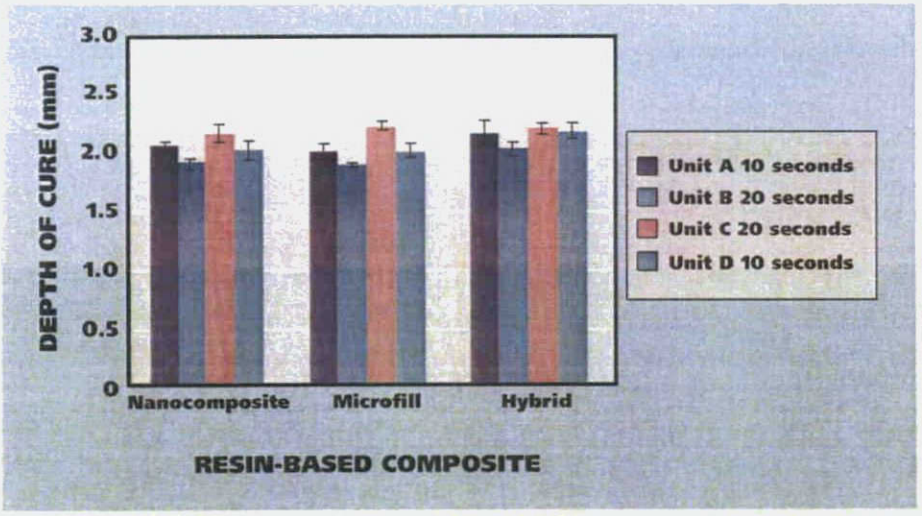

Figure 2. Depth of cure of composites using the curing lights. mm: Millimeters.

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TABLE 4

ADHESION VALUES OF LIGHT-CURED RESIN-BASED COMPOSITES TO ENAMEL.

RESIN-BASED COMPOSITE*	UNIT A 10-SECOND CURE (MPa ± SD†)‡	UNIT B 20-SECOND CURE (MPa ± SD)	UNIT C 20-SECOND CURE (MPa ± SD)	UNIT D 10-SECOND CURE (MPa ± SD)
Nanocomposite	28.0 (5.3)[a]	25.6 (4.3)[a]	25.6 (4.8)[a]	26.8 (3.1)[a]
Microfill	26.9 (4.9)[a]	22.1 (2.2)[a]	26.7 (2.8)[a]	22.7 (6.0)[a]
Hybrid	32.5 (2.5)[b]	28.5 (2.8)[a,b]	24.9 (2.6)[a]	29.3 (3.1)[a,b]

* Resin-based composite names and manufacturers are listed in Table 2.
† MPa: Megapascals; SD: standard deviation.
‡ Within each resin-based composite group, the numbers with same superscript letter are not significantly different from each other (analysis of variance, $P < .05$).

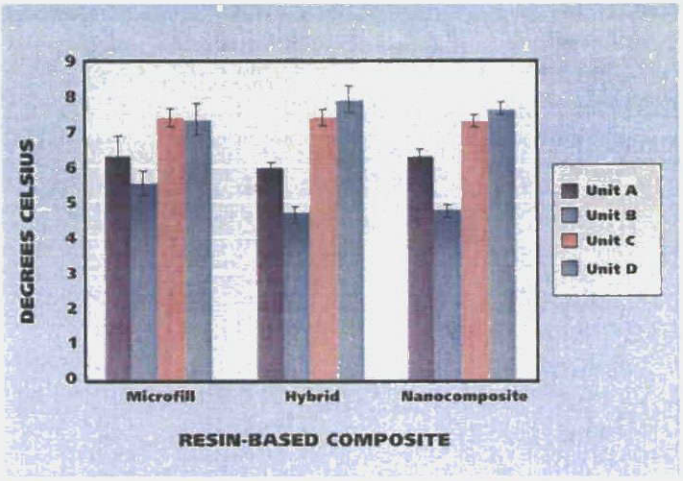

Figure 3. Peak polymerization temperatures.

nificant difference in the DOC obtained from unit A at 10 seconds and unit C at 20 seconds, while that obtained from unit B at 20 seconds was significantly lower than that of unit A.

Adhesion. Table 4 shows the results of adhesion to enamel testing using the adhesive in the total etch technique and each of the three composites cured with the four lights. We recorded the cure time of the resin-based composites for each light. The adhesion values for all three resin-based composites showed no significant difference or greater results between samples cured with unit A and samples cured with each of the other three curing lights (ANOVA, $P < .05$).

T_p. Figure 3 shows the results of T_p measurements. Table 5 shows the mean temperature and standard deviation. For each resin-based composite, the numbers with same superscript letters have mean values that are not significantly different from each other (ANOVA, $P < .05$). We found that the T_p for the nanocomposite and the hybrid were the highest when unit D was used at the 10-second cure time, though the average value was not significantly different from that obtained from unit C at the 20-second cure time. For the microfill, these T_p values were essentially the same. The resin-based composites cured by unit A attained a significantly lower ($P < .05$) T_p than that reached by unit D at an equivalent 10-second cure time. At the 20-second cure time, unit B produced a T_p that was 65 to 75 percent lower than that of unit C at the same cure time.

DISCUSSION

LED technology has advanced significantly since the original use of blue LEDs for curing dental composites.[8-10] Unit A is one of the newest curing lights. In contrast to previous generations of LED lights, which used an array of LEDs (for example, there are 19 LEDs in unit B), it uses a single high-intensity blue LED that has a larger semiconductor crystal, which increases both the illuminated area and light intensity with an output of 1,000 mW/cm^2. An efficient optical arrangement is required for the delivery of the high-intensity light to the light guide to ensure optimum polymerization. For this, a conical reflector consisting of a highly reflective mirror film (3M Radiant Light Film, 3M) is used at the base of the light guide to ensure maximum light flux.[17] This mirror film consists of multilayer polymer film technology, which serves as a perfectly reflective mirror that is only a few micrometers thick.[19] Using this film allows for integration of unit A into a slender, ergonomically optimized handpiece that weighs only 220 grams (one-half pound), while providing high optical efficiency. Unit B's handpiece weighs 320 g, unit C's

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TABLE 5

PEAK POLYMERIZATION TEMPERATURES OF LIGHT-CURED RESIN-BASED COMPOSITES.

RESIN-BASED COMPOSITE*	UNIT A 10-SECOND CURE (DEGREES C ± SD†)‡	UNIT B 20-SECOND CURE (DEGREES C ± SD)	UNIT C 20-SECOND CURE (DEGREES C ± SD)	UNIT D 10-SECOND CURE (DEGREES C ± SD)
Nanocomposite	6.32 (0.23)[b]	4.80 (0.16)[a]	7.30 (0.20)[c]	7.62 (0.23)[c]
Microfill	6.32 (0.58)[b]	5.50 (0.41)[a]	7.40 (0.24)[c]	7.32 (0.45)[c]
Hybrid	6.04 (0.11)[b]	4.70 (0.19)[a]	7.42 (0.23)[c]	7.88 (0.38)[c]

* Resin-based composite names and manufacturers are listed in Table 2.
† SD: Standard deviation.
‡ Within each resin-based composite group, the numbers with same superscript letter are not significantly different from each other (analysis of variance, $P < .05$).

weighs 270 g, and unit D's weighs 280 g.

We used three types of resin-based composites—microfill, hybrid, nanocomposite—to study the efficiency of light curing using unit A, which uses a single high-intensity LED as its energy source. All three resin-based composites use CPQ as the photosensitizer component, as well as a tertiary amine. We found that though there were small differences in curing between the three resin-based composite groups, the overall differences we observed when comparing the four light sources were independent of the type of composite used.

The guiding principle that dictates the efficiency of a photopolymerization reaction is how much light energy is absorbed by the photoinitiator in the system. The efficiency of a photopolymerizing device can be described by the total energy concept.[3] This means that while light intensity is important, the more important factor is how much of the emitted light effectively matches the absorption spectrum of the photoinitiator (total useful light). Figure 1 shows the light output from all four curing lights. It also shows the absorption spectrum of CPQ. Although the CPQ absorption curve constitutes the total range of light that can initiate a polymerization reaction, the highest probability of light absorption is at the peak maximum of 465 nm. Light at this wavelength is much more likely to start a photopolymerization reaction and, therefore, is more efficient than light at all other wavelengths. The spectral output curves for units C and D (halogen curing lights) were broad and a substantial portion of them were outside the CPQ curve. In contrast, both the spectral output curves for units A and B (LED curing lights) had sharp emission peaks centered around the CPQ absorption maximum of 465 nm, with 95 percent of the photons being emitted between 440 and 480 nm. This is why unit B, which has an intensity of 400 mW/cm^2, provided DOC and adhesion values at 20-second cure time for the three resin-based composites comparable with those obtained from unit C, which has an intensity of 700 mW/cm^2.

The guiding principle that dictates the efficiency of a photopolymerization reaction is how much light energy is absorbed by the photoinitiator in the system.

A recent survey showed that while the convenience of LED curing lights such as unit B was appreciated by clinicians, 60 percent said they preferred shorter cure times.[16] Manufacturers have moved toward higher-intensity LED curing lights that have shorter curing times. Unit A, with its HP LED light source, has a light intensity of 1,000 mW/cm^2, which is more than twice that of unit B (400 mW/cm^2). The recommended cure time of unit A is one-half that of units B and C. Uhl and colleagues[20] recently demonstrated that the DOC of a resin-based composite correlates with the curing efficiency of the light unit. In our study, we used DOC and adhesion of resin-based composite as measures of curing efficiency. The results of the DOC and adhesion testing indicated that the values for unit A at a 10-second cure time are equivalent to or exceed those obtained from units C or B at 20-second cure times. This supports our first hypothesis for all three resin-based composites. Our second hypothesis also was supported, since we found no significant difference in the DOC values

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and adhesion results for all three resin-based composites when we used units A and D at 10-second exposure times.

According to the total energy concept, a certain dose (intensity × time) of light is needed to adequately cure a specific material. Thus, if one wants to reduce the curing time of a standard halogen lamp (for example, unit C at intensity of approximately 700 mW/cm²), one would need to use a high-energy halogen light with an intensity of about 1,400 mW/cm². This is what we saw for unit D, which has an intensity of 1,500 mW/cm² and cures the resin-based composites in 10 seconds as efficiently as unit C does in 20 seconds. Unit B, which is a first-generation LED curing light with an intensity of 400 mW/cm² at 20 seconds, provided DOC and equivalent adhesion results comparable with those of unit C at 20 seconds. Hence, to cut down unit B's cure time by one-half, unit A (a HP LED curing light) would need to have an intensity of about 800 mW/cm². The measured intensity for unit A was 1,000 mW/cm², which was slightly higher than the required value, providing an added safeguard against undercuring.

An important factor to consider in regard to increased light intensity of the curing source is the heat generated in the resin-based composite being cured. If excessive heat is generated during the curing of the composite, it could be transmitted to the surrounding tissues and pulp, causing them damage. A low T_p is desirable. As we expected, in all cases, the lowest T_p value was that for unit B; it was significantly less in all instances from those of unit C, even though we used equivalent curing times and obtained similar DOC and adhesion values from both units. The total energy concept we described previously also explains why T_ps for unit A were significantly lower than those of unit D at the same light 10-second exposure, even though the DOC and adhesion values were statistically equivalent in all cases. Thus, our third hypothesis also was upheld.

One might have expected that the higher-intensity LED used in unit A would cause substantial heat generation in the handpiece, requiring external cooling. However, a design feature of this unit obviates the need for external cooling fans. Heat generated by the LED is dissipated by a heat sink made of highly thermal conductive aluminum that is integrated in the housing of the unit. The high conductivity of this material ensures that a low LED temperature is maintained when the unit is operating for several minutes, which protects the LED's longevity. When the unit is turned off, heat temporarily stored in the heat sink dissipates into the environment via interaction with the aluminum composite housing. This design means that fans or other means of air-cooling the device are not needed, which means that the HP LED curing unit (unit A) is lighter weight than the other light-curing units.

CONCLUSIONS

We found that unit A effectively cured three representative resin-based composites at 10-second cure times comparable with unit D with turbo charge, while maintaining lower T_p. All three null hypotheses we proposed were upheld by the results of our study. The design features of unit A provided us the option of using a lightweight, battery-powered portable curing light that combines time savings and curing efficiency without excessive heat generation. ■

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Special Issue Article

Advances in light curing

OLAF ALTHOFF, PHD & MARTIN HARTUNG, PHD

ABSTRACT: ***Purpose:*** To review and connect the scientific background of light curing with clinical requirements and new technical opportunities in order to conclude the best technology for next generation light curing units. ***Results:*** Three conclusions are drawn for proper light curing: (1) A minimum dose of light is needed (wavelength dependent); (2) Internal stress can be reduced by giving the sample time to flow before gel point is reached; (3) An upper intensity limit has to be respected to limit temperature increase as well as light intensity dependent deactivation of activated photoinitiators. These conclusions can best be realized by using the softstart approach. A comparison of different light generation technologies shows that LEDs are most likely to shape the next generations of curing lights. Due to their superior power conversion rate as well as to their optimum spectral emission small and handy devices can be realized that work battery-powered and totally silent. The benefits for the dentist are improved reliability, handling, and hygiene. (*Am J Dent* 2000;13:77D-81D).

CLINICAL SIGNIFICANCE: New light curing units based on LED technology will offer the dentist improved reliability, handling, and hygiene.

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Introduction

There is an ongoing interest in new curing lights for composite restorations due to the need for a curing light that works reliably and conveniently in the general practitioner's office for many years. It should help the dentist to place restorations of better mechanical stability in less time under clinical conditions.

This longing for the ultimate polymerization light leads quite a few dentists to invest money in more exotic and expensive curing lights like lasers or plasma arc lamps. While a confusing discussion about the opportunities in time savings as well as special effects on the restorative materials is ongoing, new technology like LEDs or laser diodes are already emerging on the horizon and will add to this discussion.

This article presents a review of the scientific background of light curing and about the opportunities different light sources open up for future developments.

Scientific background of light curing

For best results in light curing, the development of the right curing strategy is as important as the design of the used light source. This section is about the relevant issues concerning the properties of light, the polymerization process and its correlation with clinical factors.

In light curing light is used to activate the photoinitiator system in the restorative material. The activated photoinitiator will then start the polymerization reaction. In a first approximation each activated photoinitiator will stay active for a certain time and can integrate a certain number of monomers into the polymer network. This efficacious time is limited by deactivation mechanisms inside the sample. The final mechanical properties of the composite restoration are a result of the whole process including its time dependence. The desired effects are an increase in surface hardness, compressive strength, flexural strength, and bonding capability. Unfortunately, there are also undesired side effects like shrinkage induced internal stress, residual monomers, and temperature rise. A good light curing strategy aims to realize the specified material properties under clinical conditions while keeping undesired side effects down.

Activation of photoinitiator by light - A photoinitiator molecule gets activated by absorbing a photon. The absorbed energy of the photon is used to change the molecular structure, forming a radical. Activating a photoinitiator is nothing else but light absorption by a photoinitiator. The number of activated photoinitiators during light curing depends on the amount of photoinitiator contained in the sample,[1] the number of photons the sample is exposed to and on the energy of the photons. The amount of photoinitiator in the sample is a material property defined by the manufacturer, while number and energy of photons can be adjusted by the design of the light curing unit. Activation of a photoinitiator works better the closer the photon energy (wavelength) matches the needed activation energy. In this case we have optimum light absorption. For camphorquinone, which most dental photoinitiator systems are based on, this absorption maximum is at a wavelength of 470 nm.

These reflections show that the relevant properties of light for activating photoinitiators are wavelength and number of photons. The equation for the correlation between number of photons (*i.e.* light dose) and light intensity is as follows:

$$\text{dose} \sim \text{intensity} \cdot \text{time} \quad (1)$$

Other more exotic properties of light like coherence or polarization, which are typical for light generated by lasers, play no role at all, because they describe a certain orientation or correlation among the photons which gets lost immediately due to the multiscattering processes inside the composite sample.

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Radical polymerization and deactivation mechanisms - The activated photoinitiator is in chemical terms nothing other than a radical. This radical can attach to a monomer and in addition will activate the monomer. In the same way further monomers can be attached resulting in a growing polymer chain. In theory this process can go on forever, in practice however, there are termination reactions, *i.e.* there are other chemicals and radicals that are able to stop the chain growth after a certain period of time. Usually a radical in a radical polymerization stays active for about 0.1 to 1.0 s. The exact value for dental materials still has to be worked out which is difficult for high viscous materials. During the efficacious time of an activated photoinitiator about 50 monomers will be integrated into the polymer network.

The efficacious time of photoinitiators is limited by deactivation mechanisms. While the influence of oxygen and stabilizers on the polymerization process is independent from light intensity, the amount of activated photoinitiator is of course a function of intensity. It is important to know that an activated photoinitiator cannot only start a polymerization reaction, but can also stop chain growth by recombination with another activated photoinitiator or by reaction with an activated end of a polymer chain. This dependence of light intensity on the deactivation mechanism will influence the polymerization process. At higher light intensities every activated photoinitiator will integrate less monomers into the polymerization network, *i.e.* a higher light dose is needed to get the same degree of polymerization.

The information provided here with respect to radical polymerization with its activation and deactivation mechanisms can be found in general polymer science textbooks like that by Elias.[2]

Bulk properties and curing strategies - The desired properties of a composite restoration are high mechanical strength and good bonding capability. The mechanical strength mainly depends on the degree of polymerization.[3] For a high degree of polymerization a minimum amount of activated photoinitiator is needed which can be guaranteed by a minimum amount of photons or a minimum light dose.

Conclusion I

For an optimized wavelength a minimum dose of light is needed for proper curing which only depends on material properties. High degree of polymerization means high mechanical strength, low amount of residual monomers and, unfortunately, large polymerization shrinkage. The amount of shrinkage of a fully cured sample is a purely material dependent property with a value of about 2.5% (volume shrinkage) for dental materials. The shrinkage induced internal stress reduces the bonding strength of the composite restorations. This effect can be reduced by giving the material time to flow and in this way to compensate for the volume shrinkage. This has to happen before the gel point is reached, afterwards the polymer network is already too strong to allow stress free flow of material. This soft start concept first proposed by Feilzer *et al.*[4] and Uno *et al.*[5] was introduced by ESPE to the dental market and has become a standard today.[6] Published data show less microleakage and lower curing stress for samples cured with the soft start approach.[7-9]

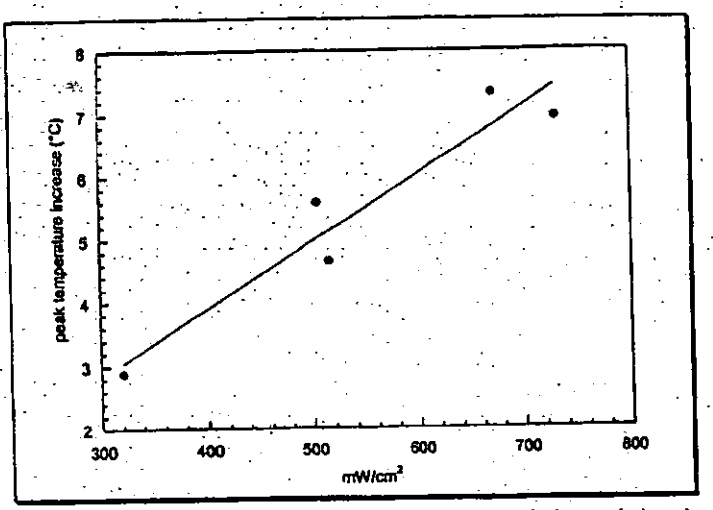

Fig 1. The maximum pulp chamber temperature rise during resin-based composite polymerization shows a linear increase with increasing light intensity for given polymerization time of 40 s. The *in vitro* data points were found by Hannig *et al.*[11] The different light-intensity values represent different light curing units. With today's high power curing lights with light intensities of about 800 mW/cm², a maximum acceptable thermal exposure seems almost to be reached. Also the clinical relevance of such *in vitro* data is under discussion, any further intensity increase should be assessed with great care.

Conclusion II

Internal stress can be reduced by giving the sample time to flow before gel point is reached. Besides shrinkage induced internal stress and residual monomers, temperature increase during polymerization is another side effect which has to be taken into account. Heat will be generated by the absorbed light as well as by chemical reaction of the polymerization process.[10,11] Figure 1 shows that for a defined curing time the *in vitro* pulp chamber temperature increases with light intensity.

Conclusion III

Respect an upper intensity limit. In terms of economics as well as convenience there is a demand in reducing curing time. This section about the scientific background shows that in order to realize a fast cure strategy, compromises have to be made. Due to Conclusion I and equation (1) intensity has to double for cutting curing time in half. Otherwise residual monomers will be left in the sample and the mechanical strength is weakened. This intensity increase comes quickly into conflict with (III), because increase of intensity has a stronger influence as reduction of time. Furthermore, when using high levels of light intensity no time is left for reducing internal stress (II). The result is a weakened bonding strength and an increase in microleakage.[12] Increased light intensity will increase temperature during the curing process in the restoration. Under really fast curing conditions even an autocatalytic speed up of the reaction may be possible for some materials with additional increase in temperature. At higher levels of light intensity, a higher light dose is required to get the same high degree of polymerization, because light-intensity dependent deactivation mechanisms have to be compensated. Although for some of the boundary conditions more research is needed to give hard numbers, it is obvious that any fast curing strategy is a difficult optimization problem for which compromises have to be made anyway.

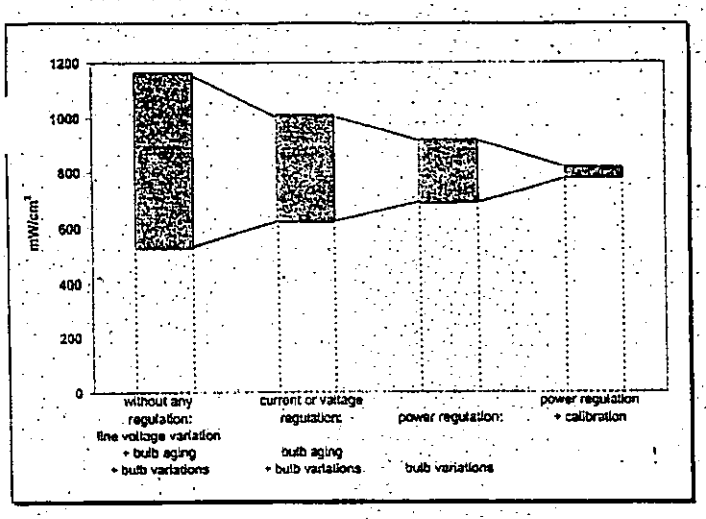

Fig. 2. The different electronic control means, realized in today's curing lights result in dramatically different tolerances of the actual light intensity. Also all techniques show the same mean value for the light intensity, line voltage variation, bulb aging and variations between normally identical bulbs cause deviations from the mean value. Especially, in unregulated devices these variations lead to minimum (maximum) light-intensities more than 1/3 lower (higher) than the mean value (left bar). Only with advanced control electronics (power regulation + calibration) can any individual sources of intensity fluctuation be minimized (right bar).

The soft start strategy takes an opposite approach. Conclusions I - III show that best results can be obtained by using this approach: starting with a low level of light intensity gives the material time to react to the shrinkage by material flow, resulting in lower internal stress. After reaching the gel point light intensity is increased observing a safe intensity limit; curing time is chosen such that the minimum dose for all composite restorative materials is reached. This approach sets safety and reliability first.

Reliability of light curing units today

The main requirements for adequate, modern curing processes of composite restorative materials are reliability and safety as well as fulfillment of specified material properties under clinical conditions. A state-of-the-art curing light has to bring out the best of composite materials in terms of mechanical stability and longevity under clinical conditions.

It is surprising that even with toady's state-of-the-art curing lights, it is still a challenge to keep them running in the dentist's office in a reliable way for years. Meniga *et al*[13] analyzed 83 light curing units that were in use in dental offices. The astonishing result was that only 58% of the light curing units in use were in acceptable conditions (see also Pilo *et al.*[14]). However, taking into account all the facts we have concerning light curing, the results do not look as incomprehensible as they may on first sight. Light intensity is still a crucial parameter concerning reliability, because numerous factors are able to change light intensity.[15] Even a simple exchange of a light bulb can significantly change the light intensity output of the unit, to say nothing of the effects caused by aging or dirt. Obviously, we cannot make concessions in terms of reliability and safety.

ESPE's answer to this situation is the new Elipar TriLight. This patent pending system measures its light output with full respect to the complete optical system including bulb, filter and light guide. This means that all possible sources of failure are taken into account. Based on this measured data a microprocessor changes the electric power control of the bulb in such a way that the light intensity is kept constant even after changing parts of the optical system. With the help of said microprocessor, the dentist can not only monitor his system, the calibration feature helps him to eliminate deviations. The strong impact of this technology on the variations in light intensity output is shown in Fig. 2.[15]

Next generation of curing lights

Before talking about new opportunities for the future let us recall some of the dental needs concerning light curing units. Shorter curing times and reliability of curing units have already been mentioned in this context. Since light curing units are not easy to clean, another issue is the improvement of hygiene. Furthermore, a small and wireless light curing unit would definitely improve handling properties.

Can new technology help to meet these needs? It was worked out in the first part of this article that reducing curing time is limited by a temperature increase in the composite restorations and by an increase of internal stress. Therefore, progress in this field is not as much a question of choosing the right light source, but more that of having the right curing strategy and optimizing the composite materials. Especially, the development of low shrinking materials would be most helpful.

The only properties of light sources that are relevant for light curing are light output and wavelength, both of course in a reliable and defined way. There is no doubt about the fact that these parameters are already optimized considerably in state-of-the-art light curing units. From a technical point of view, further development has to focus on efficiency. This means the efficient generation of light at the absorption maximum of the photoinitiator (470 nm).

To see what kind of advantages this might offer, it is helpful to define the optimal light source. This ideal light source would convert all the consumed electrical power into light of the desired wavelength. The better the power conversion, the less heat will be generated by the curing device, which means easier thermomanagement with no need of fans for cooling. If less energy is wasted in heating up the environment, less electrical energy is needed for the same optical power output. Therefore, battery-powered devices might become practical. It is obvious that this kind of an ideal light source would lead to a smaller wireless unit with improved hygiene. The better the wavelength is confined to the optimum value of 470 nm, the more efficient the light is used for activation of the photoinitiator, which in turn leads to a lower temperature increase in the restorative material due to light absorption. This might a quicker curing process without hitting the upper intensity limit, but only in combination with a low shrinkage material that maintains low internal stress.

In order to value different lightening technologies in respect to better efficiency, one has to revert to the physical principles of light generation on which the particular light source is based. These principles have a strong impact on electrical-to-optical power conversion rate as well as on the wavelength range.

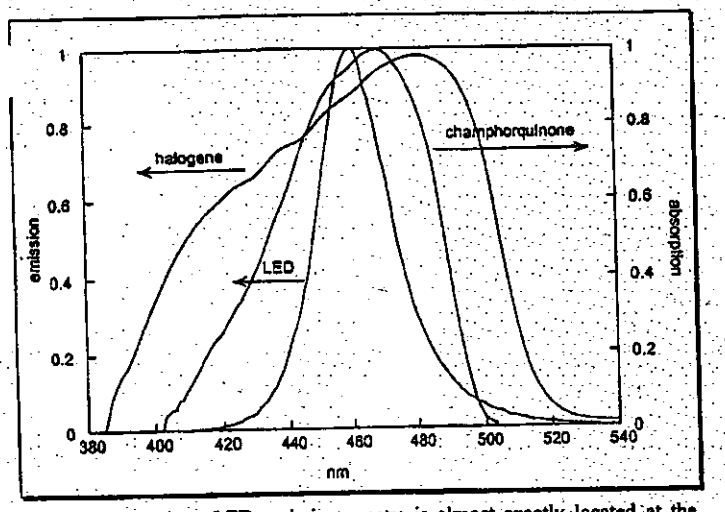

Fig. 3. The narrow LED emission spectra is almost exactly located at the maximum of the camphorquinone absorption maximum. This is the reason for the much higher polymerization efficiency of LED based light sources in comparison to conventional halogen lights. When comparing the camphorquinone absorption spectrum with the emission characteristics of the halogen lights it can clearly be seen that a lot of power at the lower as well as at the higher end of the emission spectrum is not or only to a very small extent used for activation of the photoinitiator molecules.

Halogen light bulbs generate light just by electrically heating a small tungsten thread to temperatures of some thousands of degrees centigrade. So mostly heat radiation is generated, which is in the infrared range of the electromagnetic spectrum. Only a few percent of the light output is in the visible part, including the blue range, desired for polymerization. This wavelength range used for curing is usually selected by filters. The light power output is less than 1% of the consumed electrical power. Nevertheless, this technique has become well established in light curing units and reached a high reliability level in the latest devices. But because of the principle of light generation used there is only little room for further improvement, power conversion cannot be improved and further wavelength adjustment would result in an even lower power conversion.

Plasma-light consists of two electrodes in a Xenon filled bulb. Started by a high voltage pulse, extremely high current densities generate a hot plasma of several thousands of degrees centigrade. This plasma irradiates light with an emission spectrum that strongly corresponds to that of halogen bulbs (once again, mostly heat radiation is generated). In other words less than 1% conversion efficiency can be achieved. In comparison to a halogen bulb the absolute value of power that can be realized is up to four times larger. Even with the optical losses of the waveguide, necessary because of the high voltage present at the bulb, higher light intensities can be obtained. As for the halogen technique, however, filters have to be used to select the desired wavelength and for the same reasons there is only little room for improvement.

Polymerization-lasers, known as exotics in the dental office, offer the advantage of narrow band light emission, as the process of radiation generation is no longer thermal. The electrons of suitable gas atoms are excited to well-defined energy levels by strong electric fields. The stimulated light emission laser principle forces the emission of those excited atoms into one or few discrete lines of the desired wavelength. Therefore, the demand of wavelength adjustment is fulfilled almost ideally. However, the power conversion is even worse compared to the halogen or plasma technology, resulting in very bulky units, despite the high price of such devices.

Light emitting diodes (LED) have been known for decades as indicators for consumer products. Only since the very recent development of the past few years, also lighting applications came into view as with the invention of high efficiency, high brightness LEDs. As for lasers, light is generated not by a thermal process but by a well-defined relaxation of excited electrons. It takes place inside a microscopic semiconductor crystal. The wavelength of light generated by this process is given by the so-called band gap and is defined by the chemical composition of such devices. By means of so-called band-gap-engineering the demand of wavelength adjustment is nowadays only a task of the right material design. And indeed, LEDs with the right emission spectrum, perfectly matching the needs of dental materials, have been available only very recently.[16]

Figure 3 shows how well the LED emission spectrum fits the maximum absorption of camphorquinone. In comparison, the emission spectrum of a halogen light is considerably broader, although the wavelength range is already adjusted by filters. The power converting factor has still not reached its theoretical limit, but with the latest devices it has already beaten conventional lighting techniques by one order of magnitude. This development is still going on, following the well known speed of the whole semiconductor and microelectronics industry.

Laser diodes probably will offer further advantages in the years to come. They are based on the same technology as LEDs and will reach power conversion rates that will be without any competition.

Conclusion

The comparison of the different light generation technologies, presented above, shows a strong advantage of the semiconductor-based techniques of LEDs and laser diodes. Due to their superior power conversion rate as well as due to their defined wavelength range, it is very likely that they will shape the next generations of curing lights.[17]

Closest to realization are LEDs which are already available with the right wavelength range.

To make these new devices happen the light output of diodes still must be improved and experience under clinical conditions has to be collected. It will, however, be only a question of time until a new technical standard for light curing will be established in the dental practice. Small and handy light curing units that work battery-powered and totally silent will be available. These devices will very likely offer new opportunities in handling, hygiene, and in connection with new material, might even be able to push technology to the limits in reducing curing time one day in the near future.

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Refereed paper

Effectiveness of battery powered light activation units

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Objective To investigate the effectiveness of chargeable light curing units and their ability to sustain a high radiant output following successive discharge cycles.

Setting University based research investigation assessing the output intensity of three battery powered light activation units and the effect of successive discharge cycles, without intervening periods of recharging, on light output and depth of cure of resin composite.

Materials and methods Mean light intensity (mW/cm^2), through a 4 mm aperture, was measured with a computer based radiometer. Two commercially available resin composites (one hybrid and one microfilled resin) were used for the depth of cure determinations using a digital penetrometer.

Results Depths of cure were significantly greater for the hybrid resin composite. Output intensity diminished over the period of battery discharge for two of the three units and this finding was paralleled in the depth of cure results. The battery light units tested varied significantly with regard to their length of discharge cycle and recharge times from complete discharge.

Conclusions Output intensity diminishes over the period of battery discharge for some makes of battery light units. However, many other factors including handpiece size and weight and unit cost and reliability are important considerations when choosing a unit.

Visible light cured composites have come to dominate the dental market because of their advantages over chemically cured composites. However, light activated composites require adequate light intensity at the effective bandwidth to initiate polymerisation, unlike chemically cured composites where mixing the two components together brings about polymerisation, in bulk.[1] Thus cure at the surface of a light activated composite is near maximal compared with the deepest part of the restoration where light intensity is greatly attenuated.[2] This property of light activated composites has been termed as 'depth of cure', and this has been found to increase in proportion to the logarithm of the product of the radiation output and the exposure time.[3] In order to ensure long-term clinical success, photo-cured composites depend directly on the degree of polymerisation initiated by the light curing unit.[3] Filler size, resin shade, light source intensity and exposure duration all influence the depth of cure.[4]

Modern visible light activation units are mostly mains powered, and this has limited their versatility and convenience. Accordingly, a number of manufacturers have marketed cordless or battery powered units. Little information is available about the effect that sequential irradiation without recharging has on the output intensity and depth of cure produced by these units. A considerable reduction in radiant excitance has been reported for successive illuminations with one make of chargeable light curing unit.[5] The aim of the current investigation was firstly to assess the effect of successive discharge cycles, without intervening recharging, on light output from three makes of battery powered units and the influence of any reduction in light intensity on depth of cure. A second objective was to assess the effect of increasing

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light guide tip/composite surface distance on light intensity and depth of cure. The total discharge and recharge times for the battery light units were also recorded.

Materials and methods

Three battery light units and a mains powered control light activation unit were tested (Table I). All units were tested new as supplied from the manufacturers (fig. 1). The light activated composites used in the depth of cure evaluations are listed in Table II.

Light intensity

Light output from the light activation units was measured using a computer based radiometer.[6] This equipment has the advantage over commercially available hand held radiometers in that it allows constant monitoring of the radiation energy output over the entire irradiation period. As this device is interfaced to a computer, comparison between different light activation units can easily be made and the mean light output over the entire irradiation period is calculated using the computer program.

Radiation energy from the light activation units was recorded through a 4 mm aperture in order to standardise test conditions for different light activation units and to relate light intensity to depth of cure.[7] Depth of cure determinations were made on composite specimens cured in 4 mm diameter cavities in stainless steel moulds. A 400–500 nm filter was interposed between the light guide tip and the light sensing device to allow recording of useful curing energy only. Light guide alignment rings were used to ensure accurate positioning relative to the aperture. Mean light output (expressed in mW/cm^2) was established as described previously.[6]

Table I The three battery-powered light activation units and the mains powered control used in this study

Name	Manufacturer
Arcus Mk 1	Litema Dental, Baden-Baden, Germany
Vivalux	Ivoclar-Vivadent, Schaan, Liechtenstein
Prolite	Dentsply, Weybridge, Surrey, UK
Heliolux GTE (Mains powered)	Ivoclar-Vivadent, Schaan, Liechtenstein

Table II The light-activated tetramicrohybrid and microfilled resin composites used in this study

Material	Batch number	Manufacturer
Heliomolar RO	560028	Ivoclar-Vivadent, Schaan, Liechtenstein
Tetric	560017	Ivoclar-Vivadent, Schaan, Liechtenstein

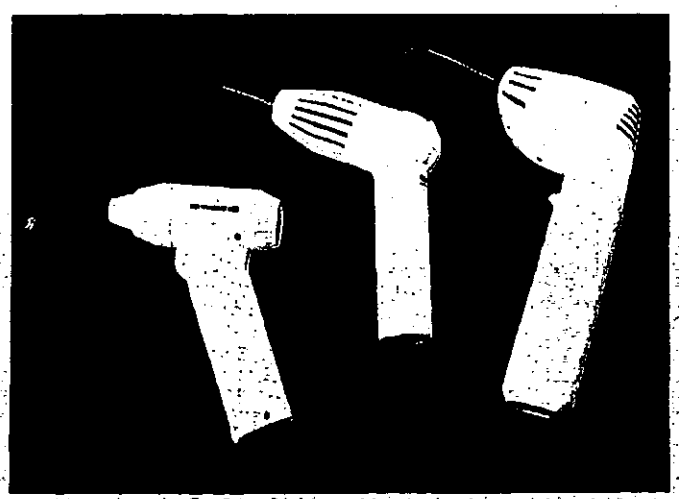

Fig. 1 The Vivalux, Arcus and Prolite battery light handpieces are shown from left to right.

Depth of cure

Depth of cure of the composites was measured using a penetrometer technique.[8] This method is similar to the scrape test described in standards, in that they both measure the height of the cylinder of hardened material. The penetrometer applies a constant force of 62 MPa thus favouring consistency of results. The values presented for depth of cure are half the height of hardened cylinder in line with the ISO recommendation (ISO 4049: 1993). The composite was placed in 4 mm diameter cylindrical mould cavities in stainless steel moulds. The material was irradiated from the upper surface for 40 s and light guide alignment rings were used to ensure that the light guides were applied centrally and reproducibly. After removing the matrix strips the mould was inverted and positioned centrally beneath the indentor of the digital penetrometer to assess the height of the cured cylinder 45 s after composite irradiation. Five determinations were made in each case and means and standard deviations obtained.

Measurement of radiation energy

SERIES 1: EFFECT OF REPEATED DISCHARGE ON LIGHT INTENSITY

Light output for the three cordless units and the mains powered control unit was monitored against time until all the battery units were completely discharged. Battery units were discharged using serial 40 s discharge cycles with one minute intervals between each activation period. The same timing was applied to the control unit and tests were repeated to allow the mean of five complete battery discharge cycles to be determined.

SERIES 2: EFFECT OF DISTANCE ON LIGHT INTENSITY

In addition to monitoring light output intensity at zero distance, spacer rings of 1, 2, 3, 4, and 6 mm thickness were used to assess the effect on output intensity of increasing distance between the light

guide proximal to the measuring device corresponding to the surface of the material to be cured. For this series of tests the handpieces were replaced in their charger units to maintain full charge between light activations. Five determinations were made in each case and means and standard deviations obtained.

Measurement of depth of cure

SERIES 3: EFFECT OF REPEATED DISCHARGE ON DEPTH OF CURE

Depths of cure, at zero distance, were repeated at 40 s successive discharge cycle intervals, without intervening recharging for those battery powered units whose output intensity diminished during battery discharge. As output intensity did not vary significantly over the entire period of battery discharge for this unit depth of cure was only measured at the two extremes of time. The sequence of light intensity readings and depth of cure evaluations was rotated to allow for any possible deterioration of light output over the period of the investigation. The material used for this series of tests was a microfilled composite (Heliomolar RO, Vivadent, Schaan, Liechtenstein). Tetramicrohybrid composite (Tetric, Vivadent, Schaan, Liechtenstein) was also tested for depth of cure at the initial firing from the fully charged condition.

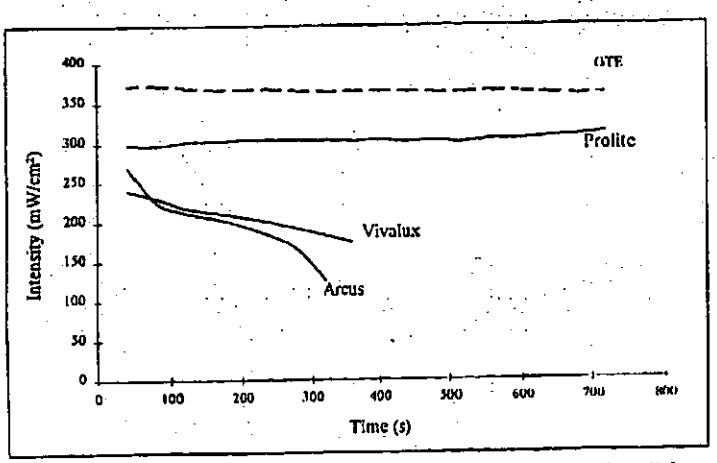

Fig. 2 Graphical display of mean output intensity versus time for all four light activation units. Battery lights fired without recharging until completely discharged. Intensity monitored over 40 s activation intervals with one minute rest periods between each activation. Five replications of each complete discharge cycle made for all light units.

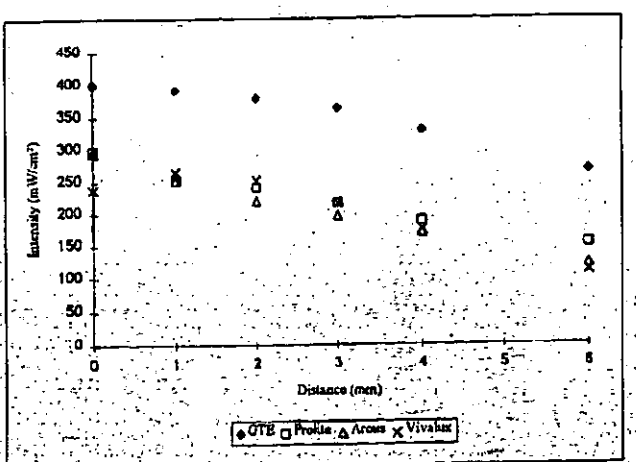

Fig. 3 Graphical display of mean output intensity at increasing distances (up to 6 mm) from the measuring device for the four light activation units. Five determinations made for each unit at every distance.

SERIES 4: EFFECT OF DISTANCE ON DEPTH OF CURE

Depths of cure values were obtained at increased light guide/composite surface distances of 1, 2, 3, 4, and 6 mm. Five determinations were made in each case and means and standard deviations obtained. The battery light handpieces were replaced in their charger base units between light activations to maintain the full charge condition for this series of tests.

Measurement of discharge and recharge times

The total discharge time as well as the time taken for each battery powered light unit to recharge fully after complete discharge was recorded and means and standard deviations calculated (n = 10 and 5).

Statistical analysis

Depth of cure data were analysed by one and two-way analysis of variance (ANOVA). Paired group comparisons were made with Tukey tests at the 5% level of significance. Linear regression analysis was used to correlate light intensity findings to depth of cure results.

Results

Series 1 Effect of repeated discharge on light intensity

Two of the three battery units displayed significant reductions in light intensity over the period of battery discharge (fig. 2). The third unit (the Prolite) remained stable until complete battery discharge whereas light output for the mains powered unit showed a slight reduction on repeated light activation for an equal time (fig. 2).

Series 2 Effect of distance on light intensity

In general, light output decreased at increasing distances from the measuring device (fig. 3) Three of the lights showed the greatest output intensity at zero distance with progressive reduction with increasing distance. However the intensity for the Vivalux was greatest at the 1 mm distance and only became significantly less ($P < 0.05$; one-way ANOVA) at distances of greater than 3 mm (fig. 3).

Series 3 Effect of repeated discharge on depth of cure

Depth of cure of the microfilled composite followed the reduction in light intensity (at increasing discharge times) of the Vivalux and Arcus units

(Table III). The percentage reduction in depth of cure was, however much less than the corresponding intensity decrease (fig. 2). The depth of cure of the tetramicrohybrid composite (at first 40 s activation from full charge) was approximately 40% greater than the microfilled material with all lights (fig. 4) and this difference was statistically significant ($P < 0.001$; two-way ANOVA).

Table III Depth of cure (mm) for the microfilled composite (Heliomolar RO) at successive discharge times for the three battery powered units and the mains powered control

Discharge time (s)GTE	Heliolux	Arcus	Vivalux	Prolite
0–40	2.28 (0.02)	2.15 (0.02)	2.09 (0.02)	2.17 (0.02)
41–80		2.10 (0.02)	2.05 (0.02)	
81–120		2.08 (0.04)	1.99 (0.01)	
121–160		2.03 (0.03)	1.98 (0.04)	
161–200		2.03 (0.02)	1.98 (0.02)	
201–240		2.00 (0.02)	1.97 (0.03)	
241–280		1.96 (0.03)	1.96 (0.02)	
281–320		1.88 (0.01)	1.95 (0.03)	
321–360			1.90 (0.03)	
601–640				2.17 (0.01)

n = five replicate determinations.
Figures in parentheses are standard deviations.
Only two sets of determinations were made for the Prolite as output intensity did not diminish over the entire period of the discharge cycle.

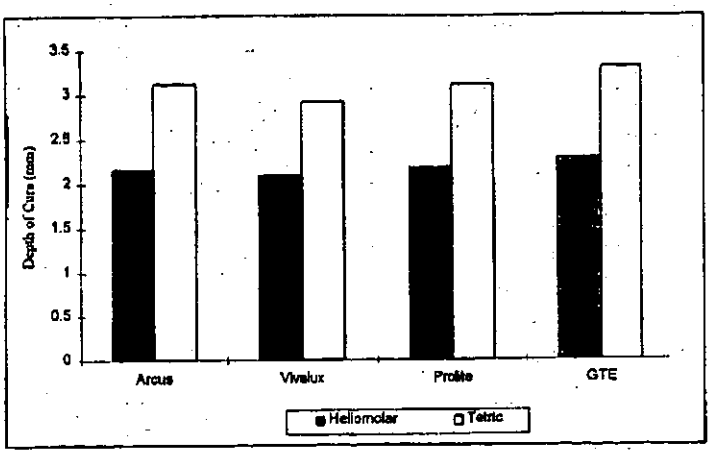

Fig. 4 Depth of cure (mm) for the microfilled and hybrid composite materials (40 s irradiation from full charge) with each of the four light units. Values are the mean of five determinations in each case.

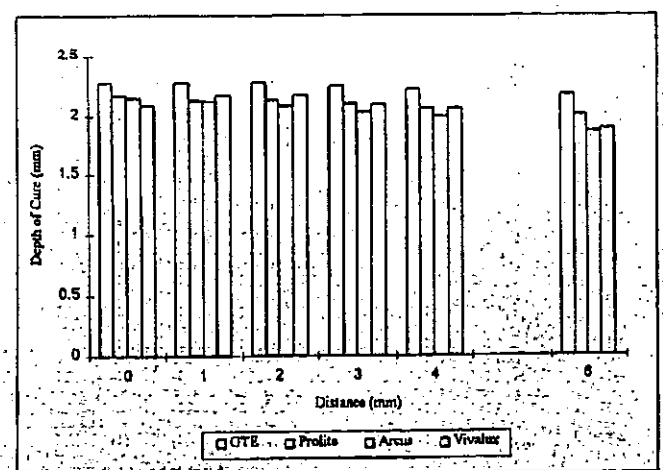

Fig. 5 Depth of cure (mm) for the microfilled composite at increasing light guide distances (up to 6 mm) with each of the four light activation units. Values are the mean of five determinations in each case.

Series 4 Effect of distance on depth of cure

Depths of cure (fig. 5) followed the pattern of output intensity (fig. 3). Two-way ANOVA revealed that composite and light unit type were highly significant factors ($P < 0.001$) in regard to depth of cure and their interaction was also highly significant ($P < 0.001$). Linear regression analysis was used to relate depth of cure findings at increasing distances to $\log_{10}$ of the mean light intensity readings. Coefficients of determination (R^2 adjusted for degrees of freedom) for the four light activation units ranged from 93.3% for the Vivalux to 98.7% for the Prolite unit.

Discharge and recharge times

Mean discharge and recharge times, and standard deviations, for the three battery powered units are presented in Table IV. Total discharge time was greatest for the Prolite and least for the Arcus unit. While one of the three battery lights tested maintained its output intensity throughout the full battery discharge cycle (the Prolite), this unit took the greatest time to recharge fully.

Discussion

Battery powered units offer the operator portability and convenience and are not subject to mains voltage fluctuation.[9,10] Optimal output intensity for a light unit in a given situation has not yet been determined and many factors are involved including material composition, increment thickness, irradiation time, and tip/material distance. Inadequate depth of cure will adversely effect restoration longevity.[11] The relationship of light intensity to the depth of cure of the composite is not direct. However a linear relationship exists between depth of cure and the $\log_{10}$ of the product of light intensity and irradiation time.[12] Light intensity may vary with time as some units have a slow build-up of intensity whereas other units reach their peak output almost instantaneously with a gradual decline in output thereafter.[6] The computer based radiometer used in this study allows light output to be constantly monitored against time. Significant changes in output intensity versus time

Table IV Results of the discharge and recharge times (minutes) for the battery light units evaluated

Light unit	Discharge time (min)	Recharge time (min)
Arcus	6.3 (0.1)	24.3 (1.1)
Vivalux	6.9 (0.2)	9.1 (0.9)
Prolite	12.2 (0.5)	57.2 (2.5)

n = 10 replicate determinations for discharge and n = 5 for recharge times.
Figures in parentheses are standard deviations.

In Brief

Key messages:

- Battery powered light activation units offer the operator increased convenience.
- They are ideal for domiciliary visits.
- Output intensity and curing potential may reduce on repeat activations without intervening recharging.
- Many factors should be taken into consideration when choosing a light curing unit including handpiece weight.

were noted over the first 40 s discharge cycle for two of the three battery units tested (fig. 6). A spike or peak in output intensity was noted for the Vivalux unit during the first discharge cycle period. According to the manufacturer, this unit has a current regulator and once the power to the bulb stabilises, a relay closes and an additional surge of approximately 5% is supplied to the bulb. Current commercially available light meters (curing radiometers) are limited in that they can only make instant recordings of light output and are unable to monitor output continuously against time.[7]

The tetramicrohybrid composite (Tetric) cured to a much greater depth than the microfilled composite (Heliomolar RO). Light attenuation and scattering is greater for microfilled than hybrid composites because the filler particles are closer in size to half the wavelength of the light (470 nm) which is optimal for camphorquinone activation.[13,14] Material composition is therefore an important factor in regard to depth of cure. Light intensity has always been found to diminish as the light guide tip is positioned at greater distances from the composite surface[15–18] and close approximation between the light guide tip and the material surface is frequently impossible.

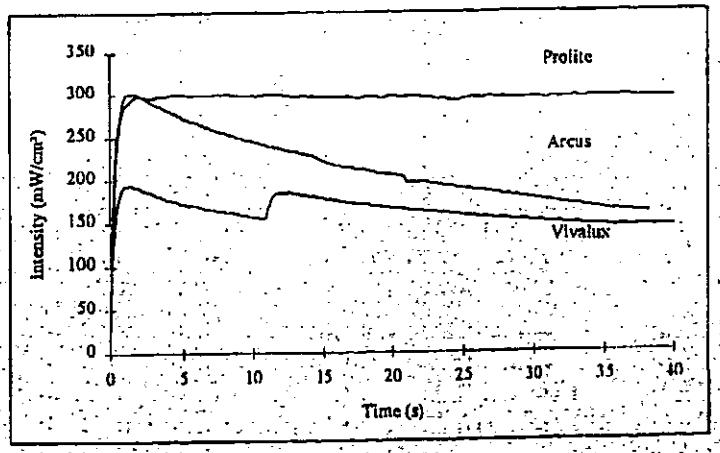

Fig. 6 Graphical display of light intensity versus time for a single irradiation period (from full charge) for each of the three battery light units.

Three of the lights tested yielded maximum intensity at zero distance as expected. Output intensity for the Vivalux unit, however, reached a maximum at 1 mm tip distance and did not fall below the zero distance baseline value until 3 mm distance was reached, which could be argued as being important clinically. This is different from the normal pattern of reducing depth of cure at increasing light guide distances as intensity progressively reduces. This output pattern may relate to the convex profile of the light guide tip which is unique to this unit. The design presumably alters the focussing characteristics of this guide's light output. It is interesting to note that the manufacturer has reverted to a conventional flat ended design of light guide tip in the mark II version of this unit which has just been marketed.

It has previously been reported that light intensity decreases with increasing distance from the source in an approximately linear log distance/intensity relationship[8] and this conclusion is supported by the findings of the current investigation for the three light units with conventional flat ended light guide tips. Many factors are involved in choosing a light curing unit. Cost, convenience, reliability, light intensity, portability, discharge and recharge times, handpiece size (fig. 1). and weight are all important.[19] A knowledge of the importance of these factors allows the individual practitioner to make an informed choice.

Conclusions

Battery powered lights vary significantly in respect to their length of discharge and recharge times. Output intensity diminished over the period of discharge for two of the three units tested. Material composition is a more important factor in regard to depth of cure than intensity reduction over the manufacturer's recommended discharge cycle for the units tested. The relationship between $\log_{10}$ intensity and depth of cure is linear in agreement with the findings of previous investigations.[7,14,20]

Acknowledgements

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Gilespi

Subject: 510(k) Number K110582

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?		✓	
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	--
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21		✓	
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.* ✓

Regulation Number	Class*	Product Code
872.6070	II	EBZ

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Susan Runner (Branch Chief) | JED3 (Branch Code) | 4/28/11 (Date)

Final Review: _____ (Division Director) | 4/29/11 (Date)

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K110582

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for see attached memo .
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and see attached memo .
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the

design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

(Reviewer's Signature) 04/27/2011 (Date)

Comments

see attached memo

revised:8/1/03

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Special

K110582/S1

Date: April 27, 2011

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineer Division: DAGID

510(k) Holder: Ultradent Products Inc., of South Jordan, Utah

Device Name: *VALO Cordless* (K110582)

Contact: Ms. Diane Rogers

Phone: 1-801-553-4491

Fax: 1-801-553-4609

Email: diane.rogers@ultradent.com

I. Purpose and Submission Summary

Ultradent Products Inc., of South Jordan, Utah, has submitted a Premarket Notification (Special 510(k)) to modify a device currently in U.S. interstate commerce. *VALO Cordless* is a modified version of *VALO (K083647)*. *VALO Cordless* is a prescription Class II medical device regulated under 21 CFR 872.6070 as an "Ultraviolet Activator for Polymerization." The *VALO Cordless* is listed under product code EBZ.

The submission for *VALO Cordless* consists of an Introduction, Description, Indications for Use, Substantial Equivalence, Truth and Accurate Statement, Special 510(k) Premarket Summary, Statement of Indications for Use, Primary Labeling, Instructions for Use, Marketing Strategy/Advertising, Primary Labeling and Instructions for Use for Predicate Device, Summary of Design Control Activities, Design Requirements, Risk Analysis Methods, Testing and test Methods, Declaration of Conformity with Design Controls, 60601 Testing and Certifications, Software Requirement Specifications, ADA 48 Compliance, Biocompatibility and Clinical Summary, and Literature Review. Supplement 1 (S1) dated April 1, 2011 contains the applicant's response to the previous deficiencies, revised 510(k) Summary, revised package labeling, revised Instructions for Use, complete Form FDA 3654, and revised Software Documentation. Amendment 1 dated April 18, 2011 contains the applicant's response previous deficiencies, revised 510(k) Summary, Form FDA 3654 for ADA No. 27, and a statement the IFU will be revised to reflect the correct Trade Name. The primary mode of action for this device is emittance of LED light for the polymerization of light cured materials. The submission claims substantial equivalence to *VALO (K083647)*.

The information submitted by Ultradent Products Inc., demonstrates that *VALO Cordless* has the same indications and performance characteristics as a legally marketed device. *VALO Cordless* is substantially equivalent (SE) to predicate LED light curing units.

The submission references the following standards or guidance documents and has provided the appropriate Standards Data Report Form. In S1, the applicant provided both pages of the form for IEC 60601-1 and ADA #48. In A1, the applicant provided Form FDA 3654 for ADA #27.

Standard	Standard Title	Version	Date
IEC 60601-1	Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance	2004	12/15/2005
ANSI/ADA Specification #48	Visible Curing Lights	2004	08/25/2004
ANSI/ADA Specification #27	Resin Based Filling Materials (Section 7.7 only) (Depth of Cure test)	1993	

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
510(k) Statement			X
Standards Form	X		
Risk analysis predetermined acceptance criteria met	X		
Manufacturing facility design control conformance	X		

	YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)			
Clearly labeled "510(k) Summary"	X		
Submitter' s name, address, phone #, a contact person	X		
Date the summary was prepared	X		
The name of the device/trade name/common name/classification name	X		
An identification of the legally marketed Predicate	X		
Description of the subject device	X		
Statement of intended use(identical to indications for use)	X		

			YES	NO	N/A
	Technological	if same, a summary of comparison of technological characters			X
		If different, a summary of how do they compare to the Predicate	X		
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	X		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			X
		Conclusion that data demonstrate SE	X		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				X

The submission provides a 510(k) Summary titled "Special 510(k) Premarket Summary". The 510(k) Summary is missing three section required under 21 CFR 807.92 to include the technological summary, performance data discussion and a conclusion that the data demonstrates SE. In addition, the description of the device is vague and non-descriptive.

In S1 dated April 1, 2011, the applicant provided a revised 510(k) Summary to include a technological summary, performance data discussion and a conclusion that the data demonstrates SE. In addition, the device description was expanded to include a description of the curing modes and a list of the product components.

In A1 dated April 18, 2011, the applicant provided a revised 510(k) Summary to include a bold heading for the Product Description and a list of non-clinical data submitted in the Performance Data section of the 510(k) Summary.

III. Device Description and Changes

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?	X		

The submission for the *VALO Cordless* unit contains two major design changes from its predicate *VALO* (K083647).

1. The *VALO Cordless* unit is provided cordless and is powered by two 3.2VDC lithium iron phosphate (LiFePO4) batteries and uses the *VALO* Charger to recharge the batteries. The *VALO* (K083647) is powered using a 9V power cord connection to a 90-240VAC wall outlet.
2. The *VALO Cordless* unit utilizes a curing mode called Xtra Power Mode. Xtra Power Mode operates at a light intensity of 3200mW/cm² and has only one time selection of 3 seconds. This replaces the Plasma Pulse Power Cure mode described in *VALO* (K083647). The Plasma Pulse Cure mode operates at a light intensity of 4500mW/cm² and has two time selections of 5/10 seconds. Both the *VALO Cordless* and *VALO* have two other curing modes, the Standard Mode and High Power mode with identical time selection and light intensity.

The submission describes the *VALO Cordless* as a dental light curing for the polymerization of light cured dental restoration materials and adhesives. The *VALO Cordless* contains four components 1) one *VALO Cordless* curing light, 2) four Ultradent *VALO* rechargeable batteries, 3) one Ultradent *VALO* battery recharger with S/B medical grade 12VDC AC power adaptor, and 4) fifty *VALO Cordless* Barrier Sleeves.

1) The *VALO Cordless* unit contains eleven modes but only three operating modes are universally accessible. All curing modes operate at a wavelength range of 395nm-480nm. Pressing and holding the Time Button for 2 seconds and releasing cycles through the curing modes. Quickly pressing and releasing the Time Button cycles through the time selection. Once the time and curing mode have been selected, quickly pressing the Power Button begins the curing process
   a. The default curing mode is Standard Mode. Standard Mode is indicated by a solid green LED. Standard Mode operates at a light intensity of 1000mW/cm² and has a time selection of 5/10/15/20 seconds indicated by solid green LEDs.
   b. The next mode is High Power Mode which is indicated by a solid orange LED. High Power Mode operates at a light intensity of 1400mW/cm² and has a time selection mode of 1/2/3/4 seconds indicated by flashing green LEDs.
   c. The final mode is Xtra Power Mode which is indicated by a flashing orange LED. Xtra Power Mode operates at a light intensity of 3200mW/cm² and has only one time selection of 3 seconds indicated by flashing green LEDs.
2) The *VALO Cordless* unit utilizes two rechargeable, VALO 3.2VDC lithium iron phosphate (LiFePO4) batteries. The batteries are placed positive side first into the distal end of the *VALO Cordless* unit. The batteries should be recharged every 1-2 weeks, however a flashing red LED on the *VALO Cordless* unit indicates low batteries and the need for charging. If the batteries become too low in the *VALO Cordless* unit, three audible beeps warning will sound and the unit will not operate. The batteries can be recharged approximately 1000-2000 times before wearing out. The submission list authorized alternative batteries that can be used in the *VALO Cordless* unit.
3) The *VALO* Charger is a 3.6VDC lithium iron phosphate battery charger and comes with a 12VDC, AC Power Adaptor. The charger can independently charge two VALO batteries. A green LED indicates if the when there in no battery in the slot and also indicates if the battery is fully charged. A red LED indicates the battery is charging. The battery should be placed in the charger with the positive end towards the LED and takes approximately an hour to charge. The submission list authorized alternative

chargers that can be used with the authorized rechargeable batteries.

4) The submission states that the *VALO Cordless* unit includes fifty *VALO Cordless* Barrier Sleeves. In S1 dated April 1, 2011, the applicant stated the barrier sleeves are comprised of polyethylene-low density (CAS #: 9002-88-4).

IV. Indications for Use

VALO Cordless is source of illumination for curing photo-activated dental restorative materials and adhesives.

The Indications for Use is identical to its predicate, *VALO* (K083647).

V. Labeling

Included in the submission is primary labeling and instruction for use. The primary labeling contains the "Rx" symbol required by 21 CFR 801.109 and additional symbols defined in the instructions for use.

The Instructions for Use contains sections for Product Information, Product Components, Overview of Controls, Instructions for Use, Changing and Charging Batteries, Quick Mode Guide, Quick Cure Guide, Quick Warning Guide, Maintenance and Cleaning, Troubleshooting Guide, Technical Information, and Warranty. The Instructions for Use contains appropriate Warnings and Cautions regarding the high intensity, use of the batteries, and cleaning.

In S1 dated April 1, 2011, the applicant provided revised Instructions for Use. The revisions include instruction for proper placement of the barrier sleeves with appropriate warning statements and removal of references to Xtra Power Pulse.

In A1 dated April 18, 2011 the applicant provided a signed statement stating the Instructions for Use will be revised to include the correct trade name, *VALO Cordless*.

VI. Sterilization/Shelf Life/Reuse

The *VALO Cordless* is provided non-sterile and is not intended to be sterilized. A *VALO Cordless* brand barrier sleeve is intended to be place in the *VALO Cordless* prior to use. The *VALO Cordless* should be wiped down using gauze or soft cloth with an anti-microbial surface disinfectant. The Instructions for Use provides a list of acceptable and non-acceptable cleaners.

VII. Biocompatibility

The submission states that biocompatibility testing is not necessary for this device because it does not come in direct or indirect contact with oral tissue.

(b)(4) Test Data

12

VIII. Software

Version: Version 2.6		
Level of Concern: **MINOR**		
	Yes	**No**
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:	X	
Development:		
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:		

All software documentation required for a device of minor level of concern is included in the submission. The software for the VALO Cordless used a microprocessor (Microchip 40pin QFP PIC16F887). The device hazard analysis was determined to be low or none. Software verification and validation testing was conducted on each of the curing modes using an identical criterion utilized in the predicate. The software passed all verification and validation testing. As of 2/15/2011 the software is on version 2.6, Code UltraBV28.

In S1 dated April 1, 2011, the applicant provided revised software documentation. The applicant added a note to the Traceability Analysis that the desired radiant exitance for each curing mode was measured and achieved with the barrier sleeve on. In addition, the applicant software version (2.6) and Firmware Code (UltraBV28) used for software verification and validation testing.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Testing was conducted on the VALO Cordless by Nemko-CCL Testing Laboratories in accordance with IEC 60601-1. The submission states the VALO Cordless passed all electrical, mechanical and safety requirements of IEC 60601-1. Test Reports are included in the submission. The VALO Cordless has a thermometer and will not allow operation if temperatures exceed 50°C. Temperature must cool down to 45°C before operation is allowed to continue.

X. Performance Testing – Bench

Testing was conducted on the *VALO Cordless* for ANSI/ADA Specification No. 48. ADA 48 is FDA recognized (recognition number 4-139). This standard requires that the *VALO Cordless* pass the following parameters: 1) cleaning and disinfection, 2) excessive temperatures, 3) radiant exitance, and 4) electrical requirements.

1) IEC 60601-1 standard for cleaning and disinfection was unitized in fulfilling the cleaning and disinfection requirement of ADA 48. The IEC 60601-1 requirement states

that the equipment must be capable of withstanding cleaning, sterilization, or disinfection without deterioration of safety provisions. Test report provided in the submission states this test was passed.

2) IEC 60601-1 standard for excessive temperatures was unitized in fulfilling the excessive temperatures requirement of ADA 48. IEC 60601-1 requirement that the equipment does not exceed a given value over a range of ambient temperature specified in the standard. Test report provided in the submission states this test was passed.
3) Radiant Exitance is defined as radiant power (W) divided by optical area (m^2). The ADA 48 Standard specifies the allowable exitance and a given range of wavelength band. Radiant Exitance for the *VALO Cordless* was measure and calculated in compliance with ADA 48. Test report provided in the submission states this test was passed.
4) IEC 60601-1 standards for electrical requirements was unitized in fulfilling electrical requirements of ADA 48. IEC 60601-1 test reports included in the submission state the VALO Cordless passed all electrical requirements for IEC 60601-1.

The submission states the *VALO Cordless* passed all ANSI/ADA Specification No. 48 testing.

In S1 dated April 1, 2011, the applicant provided depth of cure testing is comparison to *VALO (K083647)*. Testing was conducted on standard mode for 20 seconds. Depth of cure testing was conducted in accordance to ADA Specification No. 27.

The chart below details the results:

VALO (K083647)		*VALO Cordless*	
Total Depth	Total Depth/2	Total Depth	Total Depth/2
11.23	5.615	11.14	5.570
12.07	6.035	11.72	5.860
11.62	5.810	11.99	5.995
Mean Depth	5.82	Mean Depth	5.81
Reference Depth	5.82	Depth Tolerance ±2% (±0.1mm)	PASS

The EMC testing conducted above demonstrates that the *VALO Cordless* would most like perform according to the design specification under conditions of electric and/or magnetic disturbance. In addition, thermal safety testing demonstrates the device helps prevent overheating with thermostat protection encoded into the firmware, thus decreasing the potential for burns. The software verification and validation testing verified inputs and outputs of the device meet the specifications of the Design Controls. To demonstrate equivalent curing performance, the applicant provided depth of cure testing that verified the light intensity output of the *VALO Cordless* is equivalent to that of *VALO*. The bench testing demonstrates that *VALO Cordless* has equivalent performance standards to *VALO* despite the changes in the technological characteristics.

XI. Performance Testing – Animal

The submission does not contain any animal testing. The intended use, device design, and bench testing demonstrate *VALO Cordless* is equivalent to predicate *VALO* (K083647). Therefore, animal testing is not applicable.

XII. Performance Testing – Clinical

The submission does not contain any clinical testing. The intended use, device design, and bench testing demonstrate *VALO Cordless* is equivalent to predicate *VALO* (K083647). In addition, the submission provides eleven literature articles to demonstrate the clinical evaluation of the safety and effectiveness of LED curing lights. Therefore, clinical testing is not applicable.

XIII. Predicate Device Comparison

The submission claims the *VALO Cordless* is substantially equivalent to its predicate, *VALO* (K083647). The chart below compares the two devices (for this chart VALO Scout = VALO Cordless)

Characteristic – Aspect	VALO™	VALO™ SCOUT	Equivalence
Purpose	(b) (4)		quivalent
Ergonomics			ubstantial Equivalence
Standard Power Mode 1. Power Output 2. Spectrum 3. Timing Intervals			quivalent ee Technical Information below
High Power Mode 1. Power Output 2. Spectrum 3. Timing Intervals			quivalent ee Technical Information below
Xtra (Plasma) Power Mode 1. Power Output 2. Spectrum 3. Timing Intervals			quivalent ee Technical Information below
Main Power LED			quivalent ED Irradiance is calibrated to the ame output levels using the same ED from the same manufacturer
Curing head structure 1. Optical lensing (same) 2. Light focusing (same) 3. Mechanical (same) 4. Power LED (same)			quivalent ptical lensing, focus, power LED, nd mechanical retention of the ower LED are identical. Parts are nterchangeable.
Button - Switch placement			quivalent
Timing Indicator LED placement			quivalent
Mode Indicator LED placement			quivalent
Body Materials: wand and panel			quivalent
Circuit Board: Precision current control 1. Microprocessor 2. DC-DC booster 3. Inductor 4. Regulator 5. Current sensing mechanism 6. Current feed-back loop 7. Amplifiers 8. DAC 9. Indicator LEDs 10. Sonalert 11. Switches 12. IR communication chip 13. Temperature sensing 14. Motion sensing			Substantial Equivalence VALO™ SCOUT circuit board includes all aspect of its predicate VALO™ plus the capacity to sense temperature and motion. Feedback current loops and sensing circuitry are the same. Power circuitry has been strengthened to handle lower voltages and heavier current draws from batteries.
Firmware Code Version 1. Function 2. Modes 3. Timing intervals 4. ADC/DAC data use 5. IR communication data 6. Serial communication data 7. Low power warning 8. Power safety shut down 9. Calibration method			Substantial Equivalence VALO™ SCOUT firmware includes all aspects of the predicate VALO™ firmware plus new capacity to sense temperature and motion and to give more informative warnings.

Input Power 1. Range 2. Power source 3. Power delivery 4. Fusing	(b) (4)	Substantial Equivalence VALO™ SCOUT power circuitry was enhanced for higher current and is capable of using the 9VDC medical grade power supply of the VALO™ with an accessory adaptor.

Technical information	VALO™ and VALO™ SCOUT LED Curing Light
Wavelength range	(b) (4)

(b) (4)

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics: see paragraph below.
4. Explain how new characteristics could or could not affect safety or effectiveness: see paragraph below
5. Explain how descriptive characteristics are not precise enough: see paragraph below
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: see paragraph below
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: see paragraph below

The IFUS for *VALO Cordless* is identical to *VALO* (K083647) as required for a special 510(k) submission. However, the technological characteristics of the *VALO Cordless* differ to that of *VALO*. The primary technological differences are the power source of the handpiece and firmware modifications. The *VALO Cordless* utilizes 2 VALO 3.2VDC lithium iron phosphate (LiFePO4) batteries and contains additional firmware coding to prevent overheating of the handpiece as well as motion detection for power saving mode[3]. The batteries could affect the EMC susceptibility of the device, generate extra heat to the device, and require appropriate warning and instructions. If the firmware is defective, there is a potential for burns and inadequate performance of the device[4]. No new questions of safety or effectiveness are raised and are concerns that have been addressed in predicate light curing devices[6]. Since the *VALO Cordless* operates using a battery source and the Xtra Power Mode operates at a light intensity

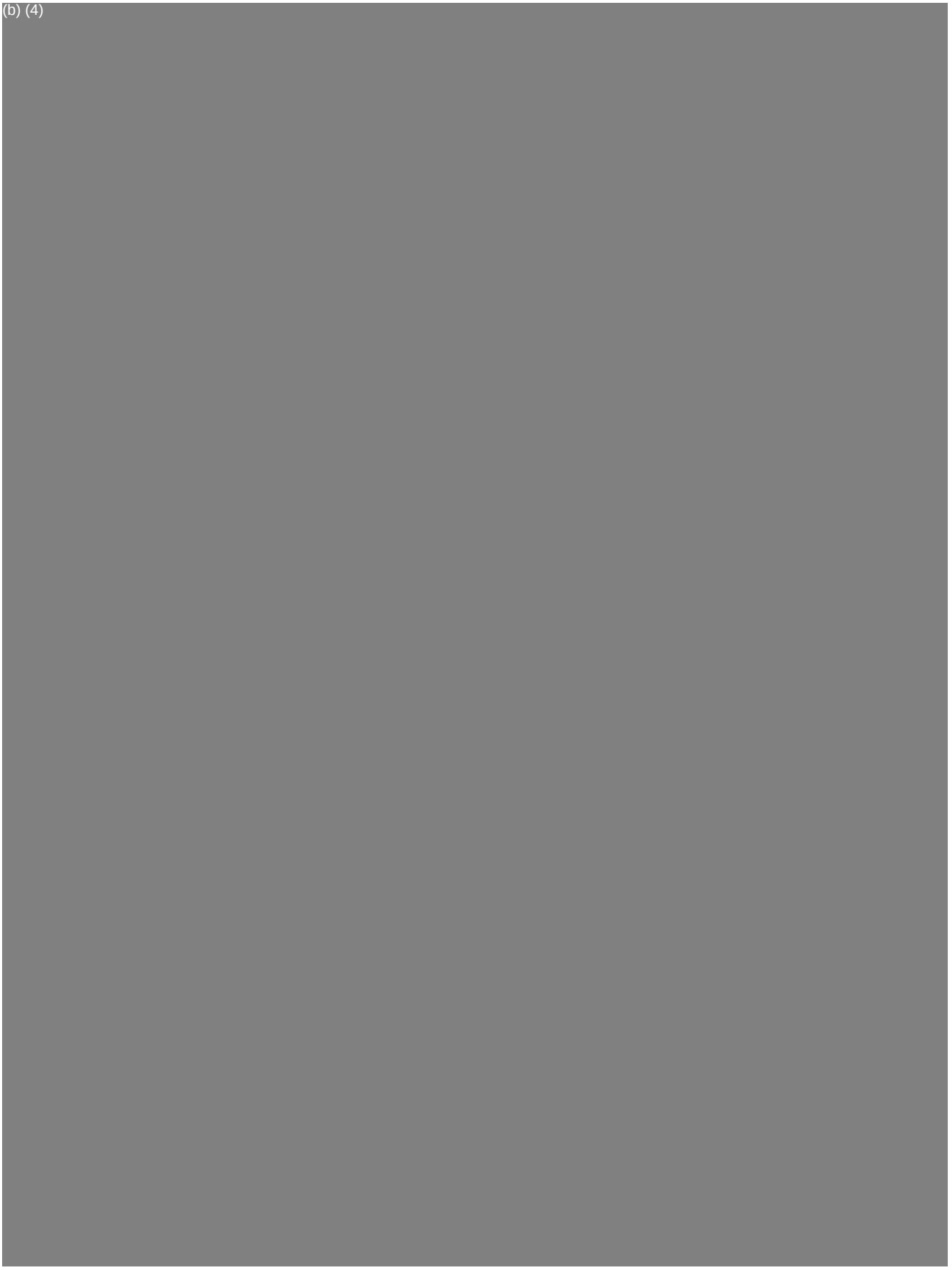
of 3200mW/cm², the following performance data is needed and was provided by the applicant to determine substantial equivalence to *VALO*: EMC testing according to IEC 60601-1, software verification and validation documentation, and comparative depth of cure testing[8]. The performance data demonstrates the EMC safety of the *VALO Cordless*, the firmware operates according to the design specification, and the curing ability of the *VALO Cordless* is equivalent to the *VALO*[9]. The information contained in this submission demonstrates the substantial equivalence of this device to predicate ultraviolet activator for polymerization.

XV. Contact History

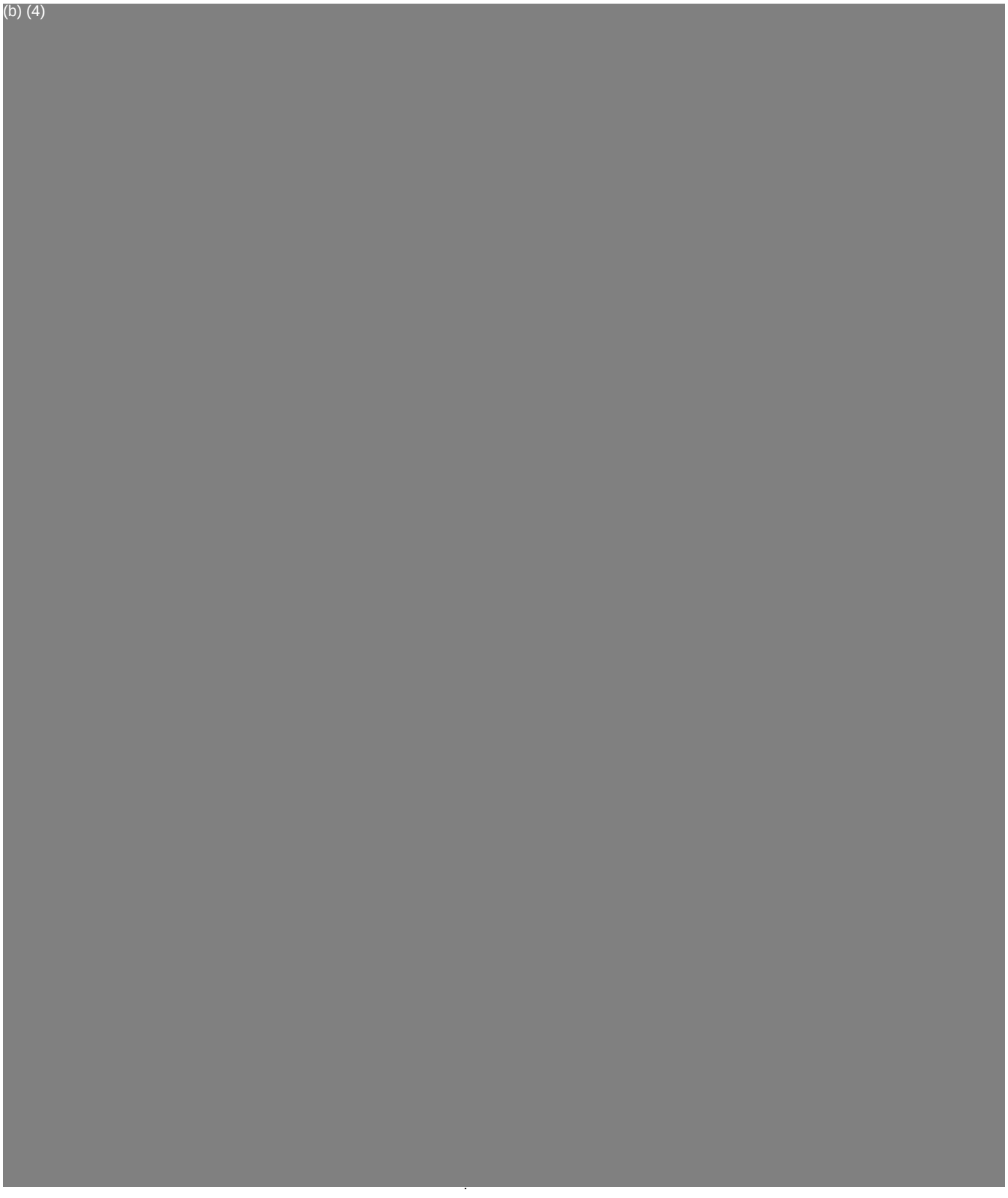
(b) (4)

[redacted]

(b) (4)



(b) (4)



XVI. Recommendation

Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: Class II
Product Code: EBZ

Reviewer
Lauren M. Giles, B.S. B.M.E
Biomedical Engineer

04/27/2011
Date

Branch Review
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

4/27/11
Date

Giles, Lauren

From: Diane Rogers [Diane.Rogers@ultradent.com]
Sent: Monday, April 18, 2011 2:57 PM
To: Giles, Lauren
Subject: RE: VALO Cordless K110582
Attachments: Response to FDA VALO Cordless.pdf

Dear Lauren,

(b) (4)

[redacted]

Thanks very much,
Kind regards,
Diane...

ULTRADENT PRODUCTS, INC.
"Improving Oral Health Globally"

Diane Rogers
Regulatory Affairs Manager
P: 801.553-4491
M: 801-201-7144
F: 801-553-4609

From: Giles, Lauren [mailto:Lauren.Giles@fda.hhs.gov]
Sent: Friday, April 15, 2011 9:29 AM
To: Diane Rogers
Subject: RE: VALO Cordless K110582

Ms Rogers,

(b) (4)

[redacted]

Please contact me with questions or concerns.

Sincerely,

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

From: Giles, Lauren
Sent: Thursday, April 14, 2011 4:27 PM
To: 'Diane Rogers'

Subject: RE: VALO Cordless K110582

Ms Rogers,

(b) (4)

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

From: Diane Rogers [mailto:Diane.Rogers@ultradent.com]
Sent: Wednesday, April 06, 2011 3:25 PM
To: Giles, Lauren
Subject: RE: VALO Cordless K110582

Dear Lauren,
Thanks for the update and your review.
Kind regards,
Diane...

ULTRADENT PRODUCTS, INC.
"Improving Oral Health Globally"

Diane Rogers
Regulatory Affairs Manager
P: 801.553-4491
M: 801-201-7144
F: 801-553-4609

From: Giles, Lauren [mailto:Lauren.Giles@fda.hhs.gov]
Sent: Wednesday, April 06, 2011 1:19 PM
To: Diane Rogers
Subject: RE: VALO Cordless K110582

Ms. Rogers,

I have recieved the supplement information. The information is currently under review. I will contact you if any concerns arise during my review.

Sincerely,

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

From: Diane Rogers [mailto:Diane.Rogers@ultradent.com]
Sent: Wednesday, April 06, 2011 12:47 PM
To: Giles, Lauren
Subject: RE: VALO Cordless K110582

Dear Lauren,
I just wanted to get in touch with you to see how your review of K110582 is going along. Do you expect we'll have clearance on it this week?
Thanks,
Kind regard,
Diane...

ULTRADENT PRODUCTS, INC.
"Improving Oral Health Globally"

Diane Rogers
Regulatory Affairs Manager
P: 801.553-4491
M: 801-201-7144
F: 801-553-4609

From: Giles, Lauren [mailto:Lauren.Giles@fda.hhs.gov]
Sent: Thursday, March 31, 2011 10:42 AM
To: Diane Rogers
Subject: RE: VALO Cordless K110582

Ms. Rogers,

The documents are under review. I will response as soon as possible.

Sincerely,

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

From: Diane Rogers [mailto:Diane.Rogers@ultradent.com]
Sent: Wednesday, March 30, 2011 6:37 PM
To: Giles, Lauren
Subject: VALO Cordless K110582

Dear Lauren,
(b) (4)

(b) (4) [redacted]

Thanks very much,
Kind regards,
Diane..

ULTRADENT PRODUCTS, INC.
"Improving Oral Health Globally"

Diane Rogers
Regulatory Affairs Manager
P: 801.553-4491
M: 801-201-7144
F: 801-553-4609

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Giles, Lauren

From: Diane Rogers [Diane.Rogers@ultradent.com]
Sent: Tuesday, April 26, 2011 2:04 PM
To: Giles, Lauren
Subject: RE: VALO Cordless K110582

Thanks Lauren!

ULTRADENT PRODUCTS, INC.
"Improving Oral Health Globally"

Diane Rogers
Regulatory Affairs Manager
P: 801.553-4491
M: 801-201-7144
F: 801-553-4609

From: Giles, Lauren [mailto:Lauren.Giles@fda.hhs.gov]
Sent: Tuesday, April 26, 2011 11:59 AM
To: Diane Rogers
Subject: RE: VALO Cordless K110582

Ms. Rogers,

The response appears to be fine.

Thanks,

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

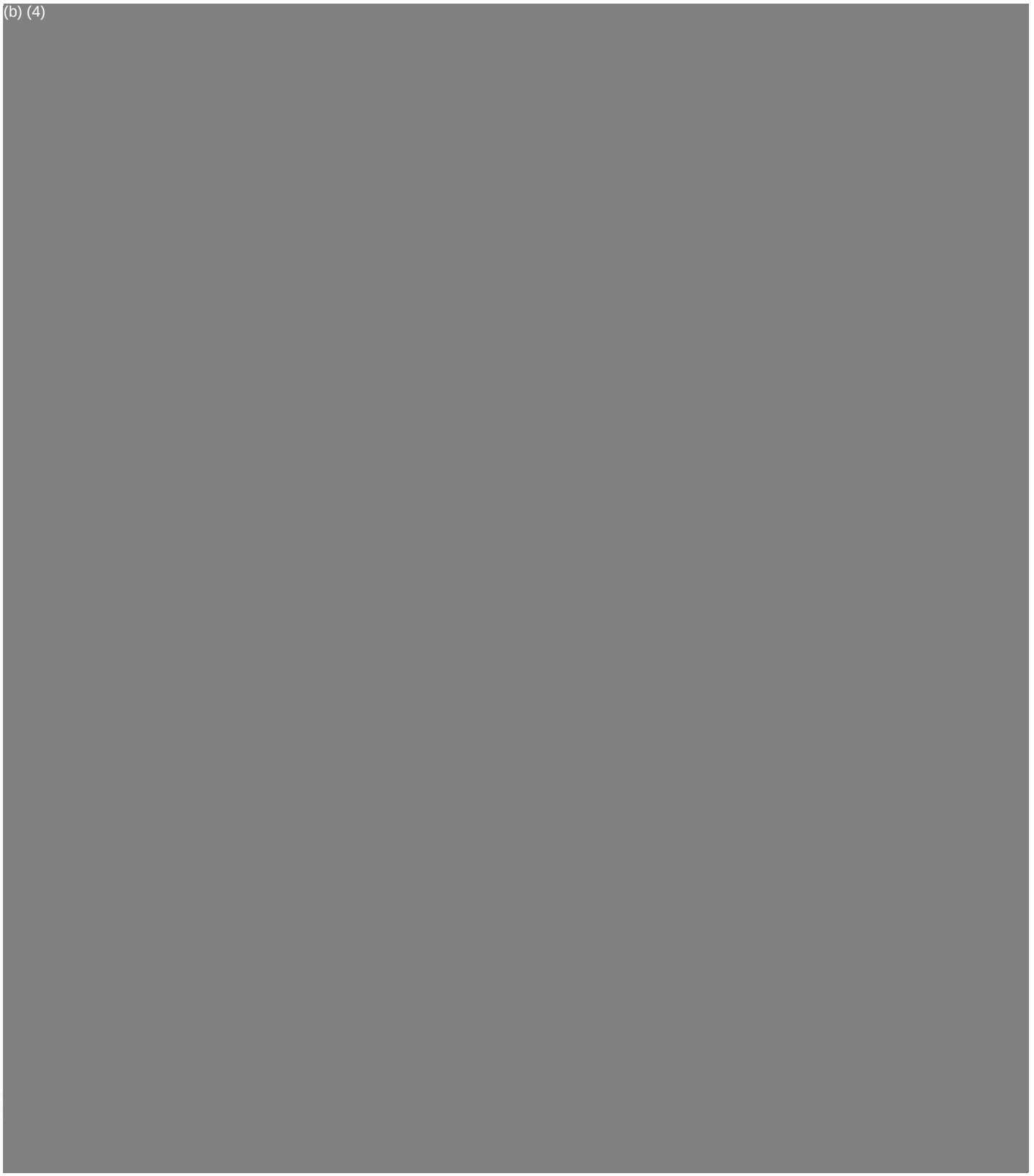
From: Diane Rogers [mailto:Diane.Rogers@ultradent.com]
Sent: Tuesday, April 26, 2011 12:09 PM
To: Giles, Lauren
Subject: RE: VALO Cordless K110582

Dear Lauren,
(b) (4)
[redacted]

Thanks very much for the explanation.
Kind regards,
Diane…

Installing Hygienic Barrier Sleeves

(b) (4)



ULTRADENT PRODUCTS, INC.
"Improving Oral Health Globally"

Diane Rogers
Regulatory Affairs Manager

P: 801.553-4491
M: 801-201-7144
F: 801-553-4609

From: Giles, Lauren [mailto:Lauren.Giles@fda.hhs.gov]
Sent: Tuesday, April 26, 2011 9:53 AM
To: Diane Rogers
Subject: VALO Cordless K110582

Ms. Rogers,

(b) (4)

[redacted]

Sincerely,

Lauren Giles
Biomedical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
10903 New Hampshire Avenue
WO66 - Rm. 2546
Silver Spring, MD 20993
phone: 301-796-9552
fax: 301-847-8109
Lauren.Giles@fda.hhs.gov

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Giles

Subject: 510(k) Number K110582

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

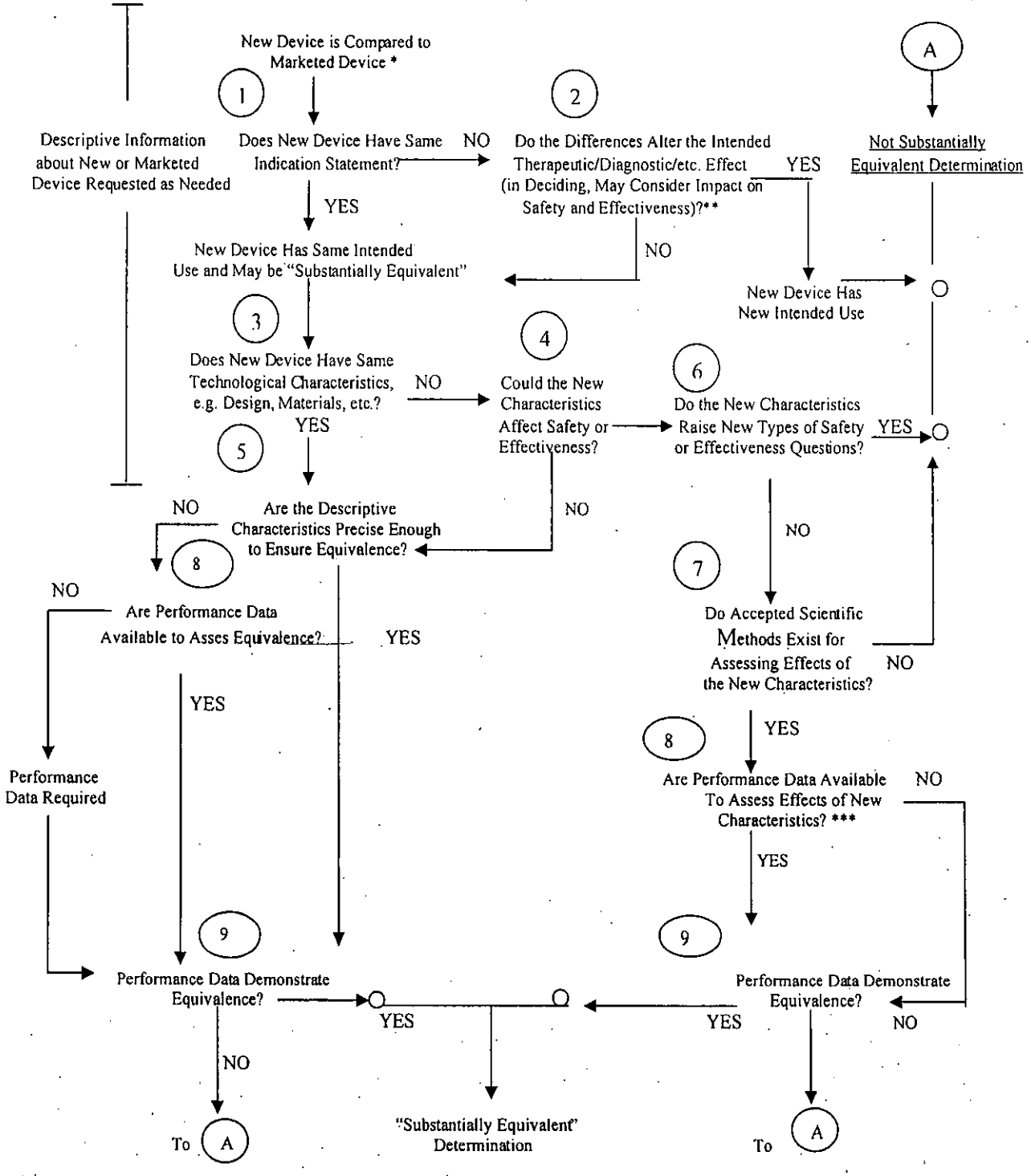
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Susan Runco (Branch Chief) DEN B (Branch Code) 3/24/11 (Date)

Final Review: Susan Runco (Division Director) 3/24/11 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Special

Telephone Hold

K110582

Date: 23 March 2011

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineer Division: DAGID

510(k) Holder: Ultradent Products Inc., of South Jordan, Utah

Device Name: *VALO Cordless* (K110582)

Contact: Ms. Diane Rogers

Phone: 1-801-553-4491

Fax: 1-801-553-4609

Email: diane.rogers@ultradent.com

I. Purpose and Submission Summary

Ultradent Products Inc., of South Jordan, Utah, has submitted a Premarket Notification (Special 510(k)) to modify a device currently in U.S. interstate commerce. *VALO Cordless* is a modified version of *VALO (K083647). VALO Cordless* is a prescription Class II medical device regulated under 21 CFR 872.6070 as an "Ultraviolet Activator for Polymerization." The *VALO Cordless* is listed under product code EBZ.

The submission for *VALO Cordless* consists of an Introduction, Description, Indications for Use, Substantial Equivalence, Truth and Accurate Statement, Special 510(k) Premarket Summary, Statement of Indications for Use, Primary Labeling, Instructions for Use, Marketing Strategy/Advertising, Primary Labeling and Instructions for Use for Predicate Device, Summary of Design Control Activities, Design Requirements, Risk Analysis Methods, Testing and test Methods, Declaration of Conformity with Design Controls, 60601 Testing and Certifications, Software Requirement Specifications, ADA 48 Compliance, Biocompatibility and Clinical Summary, and Literature Review. The primary mode of action for this device is emittance of LED light for the polymerization of light cured materials. The submission claims substantial equivalence to *VALO (K083647).*

The submission references the following standards or guidance documents.

Standard	Standard Title	Version	Date
IEC 60601-1	Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance	2004	12/15/2005
ANSI/ADA Specification #48	Visible Curing Lights	2004	08/25/2004

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
510(k) Statement			
Standards Form	X		
Risk analysis predetermined acceptance criteria met	X		
Manufacturing facility design control conformance	X		

		YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)				
Clearly labeled "510(k) Summary"		X		
Submitter' s name, address, phone #, a contact person		X		
Date the summary was prepared		X		
The name of the device/trade name/common name/classification name		X		
An identification of the legally marketed Predicate		X		
Description of the subject device		X		
Statement of intended use(identical to indications for use)		X		
Technological	if same, a summary of comparison of technological characters		X	
Technological	If different, a summary of how do they compare to the Predicate		X	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
Performance Data	Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and		X	

			YES	NO	N/A
		especially: ▪ Adverse events and complications ▪ Other information for SE determination			
		Conclusion that data demonstrate SE		X	
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				

The submission provides a 510(k) Summary titled "Special 510(k) Premarket Summary". The 510(k) Summary is missing three section required under 21 CFR 807.92 to include the technological summary, performance data discussion and a conclusion that the data demonstrates SE. In addition, the description of the device is vague and non-descriptive.

III. Device Description and Changes

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?	X		

The submission for the *VALO Cordless* unit contains two major design changes from its predicate *VALO* (K083647).

1. The *VALO Cordless* unit is provided cordless and is powered by two 3.2VDC lithium iron phosphate (LiFePO4) batteries and uses the *VALO* Charger to recharge the batteries. The *VALO* (K083647) is powered using a 9V power cord connection to a 90-240VAC wall outlet.
2. The *VALO Cordless* unit utilizes a curing mode called Xtra Power Mode. Xtra Power Mode operates at a light intensity of 3200mW/cm^2 and has only one time selection of 3 seconds. This replaces the Plasma Pulse Power Cure mode described in *VALO* (K083647). The Plasma Pulse Cure mode operates at a light intensity of 4500mW/cm^2 and has two time selections of 5/10 seconds. Both the *VALO Cordless* and *VALO* have two other curing modes, the Standard Mode and High Power mode with identical time selection and light intensity.

The submission describes the *VALO Cordless* as a dental light curing for the polymerization of light cured dental restoration materials and adhesives. The *VALO Cordless* contains four components 1) one *VALO Cordless* curing light, 2) four Ultradent *VALO* rechargeable batteries, 3) one Ultradent *VALO* battery recharger with S/B medical grade 12VDC AC power adaptor, and 4) fifty *VALO Cordless* Barrier Sleeves.

1) The *VALO Cordless* unit contains eleven modes but only three operating modes are universally acessible. All curing modes operate at a wavelength range of 395nm-480nm. Pressing and holding the Time Button for 2 seconds and releasing cycles

through the curing modes. Quickly pressing and releasing the Time Button cycles through the time selection. Once the time and curing mode have been selected, quickly pressing the Power Button begins the curing process

a. The default curing mode is Standard Mode. Standard Mode is indicated by a solid green LED. Standard Mode operates at a light intensity of 1000mW/cm^2 and has a time selection of 5/10/15/20 seconds indicated by solid green LEDs.
b. The next mode is High Power Mode which is indicated by a solid orange LED. High Power Mode operates at a light intensity of 1400mW/cm^2 and has a time selection mode of 1/2/3/4 seconds indicated by flashing green LEDs.
c. The final mode is Xtra Power Mode which is indicated by a flashing orange LED. Xtra Power Mode operates at a light intensity of 3200mW/cm^2 and has only one time selection of 3 seconds indicated by flashing green LEDs.

2) The *VALO Cordless* unit utilizes two rechargeable, VALO 3.2VDC lithium iron phosphate (LiFePO4) batteries. The batteries are placed positive side first into the distal end of the *VALO Cordless* unit. The batteries should be recharged every 1-2 weeks, however a flashing red LED on the *VALO Cordless* unit indicates low batteries and the need for charging. If the batteries become too low in the *VALO Cordless* unit, three audible beeps warning will sound and the unit will not operate. The batteries can be recharged approximately 1000-2000 times before wearing out. The submission list authorized alternative batteries that can be used in the *VALO Cordless* unit.
3) The *VALO* Charger is a 3.6VDC lithium iron phosphate battery charger and comes with a 12VDC, AC Power Adaptor. The charger can independently charge two VALO batteries. A green LED indicates if the when there in no battery in the slot and also indicates if the battery is fully charged. A red LED indicates the battery is charging. The battery should be placed in the charger with the positive end towards the LED and takes approximately an hour to charge. The submission list authorized alternative chargers that can be used with the authorized rechargeable batteries.
4) The submission states that the *VALO Cordless* unit includes fifty *VALO Cordless* Barrier Sleeves.

IV. Indications for Use

VALO Cordless is source of illumination for curing photo-activated dental restorative materials and adhesives.

The Indications for Use is identical to its predicate, *VALO* (K083647).

V. Labeling

Included in the submission is primary labeling and instruction for use. The primary labeling contains the "Rx" symbol required by CFR 21.801.109 and additional symbols defined in the instructions for use.

The Instructions for Use contains sections for Product Information, Product Components, Overview of Controls, Instructions for Use, Changing and Charging Batteries, Quick Mode Guide, Quick Cure Guide, Quick Warning Guide, Maintenance and Cleaning, Troubleshooting Guide, Technical Information, and Warranty. The Instructions for Use contains appropriate Warnings and Cautions regarding the high intensity, use of the batteries, and cleaning.

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VI. Sterilization/Shelf Life/Reuse

The *VALO Cordless* is provided non-sterile and is not intended to be sterilized. A *VALO Cordless* brand barrier sleeve is intended to be place in the *VALO Cordless* prior to use. The *VALO Cordless* should be wiped down using gauze or soft cloth with an anti-microbial surface disinfectant. The Instructions for Use provides a list of acceptable and non-acceptable cleaners.

VII. Biocompatibility

The submission states that biocompatibility testing is not necessary for this device because it does not come in contact with oral tissue.

VIII. Software

Version: Version 2.6

Level of Concern: **MINOR**

	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:	X	
Development:		
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:		

All software documentation required for a device of minor level of concern is included in the submission. The software for the VALO Cordless used a microprocessor (Microchip 40pin QFP PIC16F887). The device hazard analysis was determined to be low or none. Software verification and validation testing was conducted on each of the curing modes using a identical criterion utilized in the predicate. The software passed all verification and validation testing. As of 2/15/2011 the software is on version 2.6, Code UltraBV28.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Testing was conducted on the VALO Cordless by Nemko-CCL Testing Laboratories in accordance with IEC 60601-1. The submission states the VALO Cordless passed all electrical, mechanical and safety requirements of IEC 60601-1. Test Reports are included in the submission. The VALO Cordless has a thermometer and will not allow operation if temperatures exceed 50°C. Temperature must cool down to 45°C before operation is allowed to continue.

X. Performance Testing – Bench

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Testing was conducted on the *VALO Cordless* for ANSI/ADA Specification No. 48. ADA 48 is not FDA recognized. This standard requires that the *VALO Cordless* pass the following parameters: 1) cleaning and disinfection, 2) excessive temperatures, 3) radiant exitance, and 4) electrical requirements.

1) IEC 60601-1 standard for cleaning and disinfection was unitized in fulfilling the cleaning and disinfection requirement of ADA 48. The IEC 60601-1 requirement states that the equipment must be capable of withstanding cleaning, sterilization, or disinfection without deterioration of safety provisions. Test report provided in the submission states this test was passed.
2) IEC 60601-1 standard for excessive temperatures was unitized in fulfilling the excessive temperatures requirement of ADA 48. IEC 60601-1 requirement that the equipment does not exceed a given value over a range of ambient temperature specified in the standard. Test report provided in the submission states this test was passed.
3) Radiant Exitance is defined as radiant power (W) divided by optical area (m^2). The ADA 48 Standard specifies the allowable exitance and a given range of wavelength band. Radiant Exitance for the *VALO Cordless* was measure and calculated in compliance with ADA 48. Test report provided in the submission states this test was passed.
4) IEC 60601-1 standards for electrical requirements was unitized in fulfilling electrical requirements of ADA 48. IEC 60601-1 test reports included in the submission state the VALO Cordless passed all electrical requirements for IEC 60601-1.

The submission states the *VALO Cordless* passed all ANSI/ADA Specification No. 48 testing.

XI. Performance Testing – Animal

The submission does not contain any animal testing. The intended use, device design, and bench testing demonstrate *VALO Cordless* is equivalent to predicate *VALO* (K083647). Therefore, animal testing is not applicable.

XII. Performance Testing – Clinical

The submission does not contain any clinical testing. The intended use, device design, and bench testing demonstrate *VALO Cordless* is equivalent to predicate *VALO* (K083647). In addition the submission provides eleven literature articles that demonstrate a clinical evaluation of the safety and effectiveness of LED curing lights. Therefore, clinical testing is not applicable.

XIII. Predicate Device Comparison

The submission claims the *VALO Cordless* is substantially equivalent to its predicate, *VALO* (K083647). The chart below compares the two devices

	VALO Cordless	**VALO**
Indications For Use	Source of illumination for curing photo-activated dental restorative materials and adhesives.	Source of illumination for curing photo-activated dental restorative materials and adhesives.
Light Source	Blue LED	Blue LED
Optical Cross-Section Diameter	9.75mm	9.75mm
Wavelength	395nm - 480nm	395nm - 480nm
Light Intensity	standard power - 1000mw/cm^2 high power - 1400mw/cm^2 xtra power - 3200mw/cm^2	standard power - 1000mw/cm^2 high power - 1400mw/cm^2 plasma pulse - 4500mw/cm^2

		(approx.) at 50% duty cycle
Power Supply	Battery Input Voltage: 4VDC-10.5VDC	Output - 9VDC at 2A Input - 90VAC to 240VAC
Maintenance/Cleaning	Moisten a gauze or soft cloth with an anti-microbial surface disinfectant and wipe the surface and lens.	Moisten a gauze or soft cloth with an anti-microbial surface disinfectant and wipe the surface and lens.

XIV. Substantial Equivalence Discussion

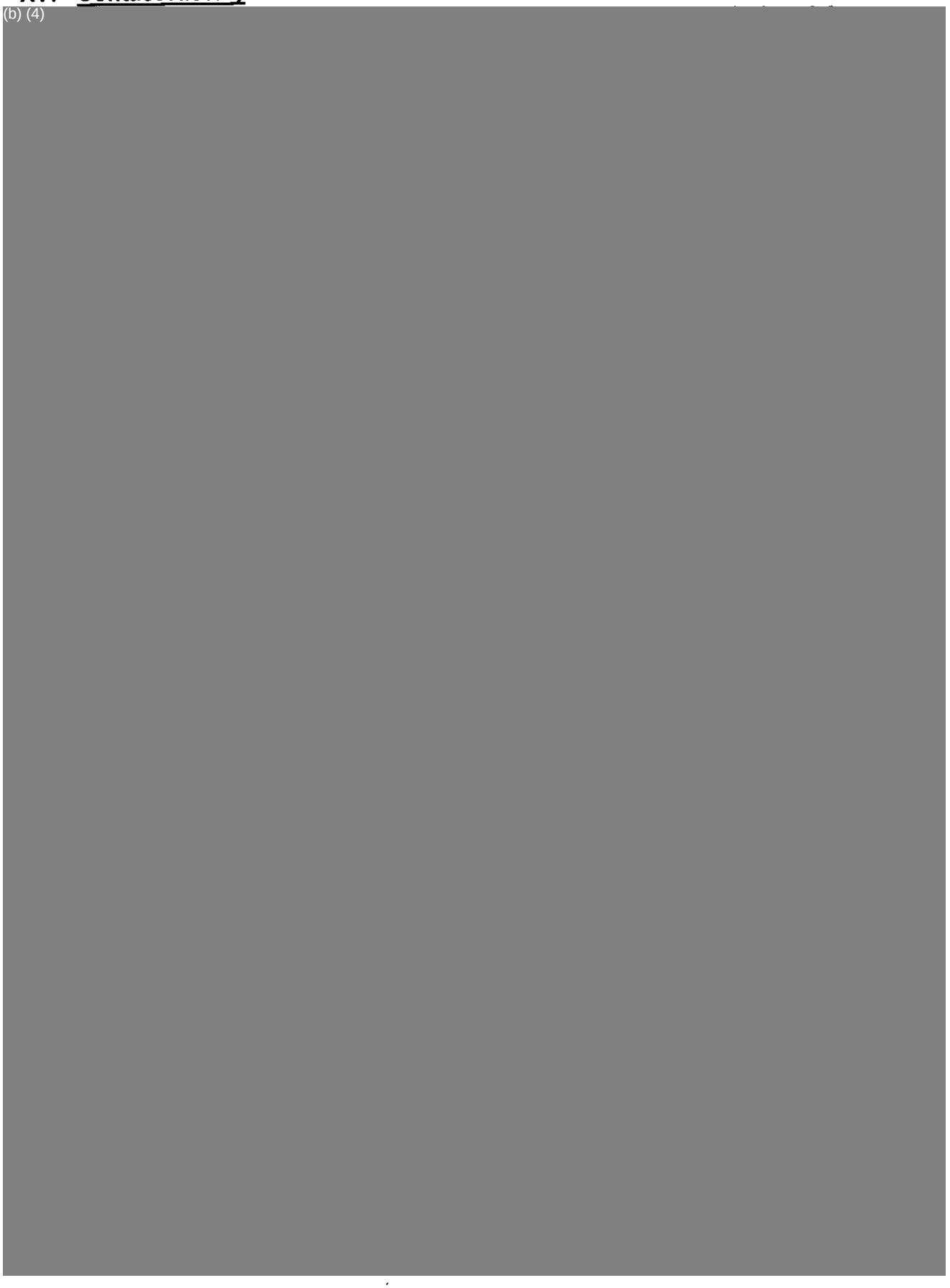
	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Contact History

(b) (4)



XVI. Recommendation

Telephone Hold.

Reviewer
Lauren M. Giles, B.S. B.M.E
Biomedical ~~Engineer~~

03/23/2011
Date

Branch Review
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

3/24/11
Date

Giles, Lauren

From: Giles, Lauren
Sent: Wednesday, March 23, 2011 4:22 PM
To: 'diane.rogers@ultradent.com'
Subject: VALO Cordless , 510(k)# K110582 Additional Information Request and Telephone Hold

Ms. Rogers,

(b) (4)

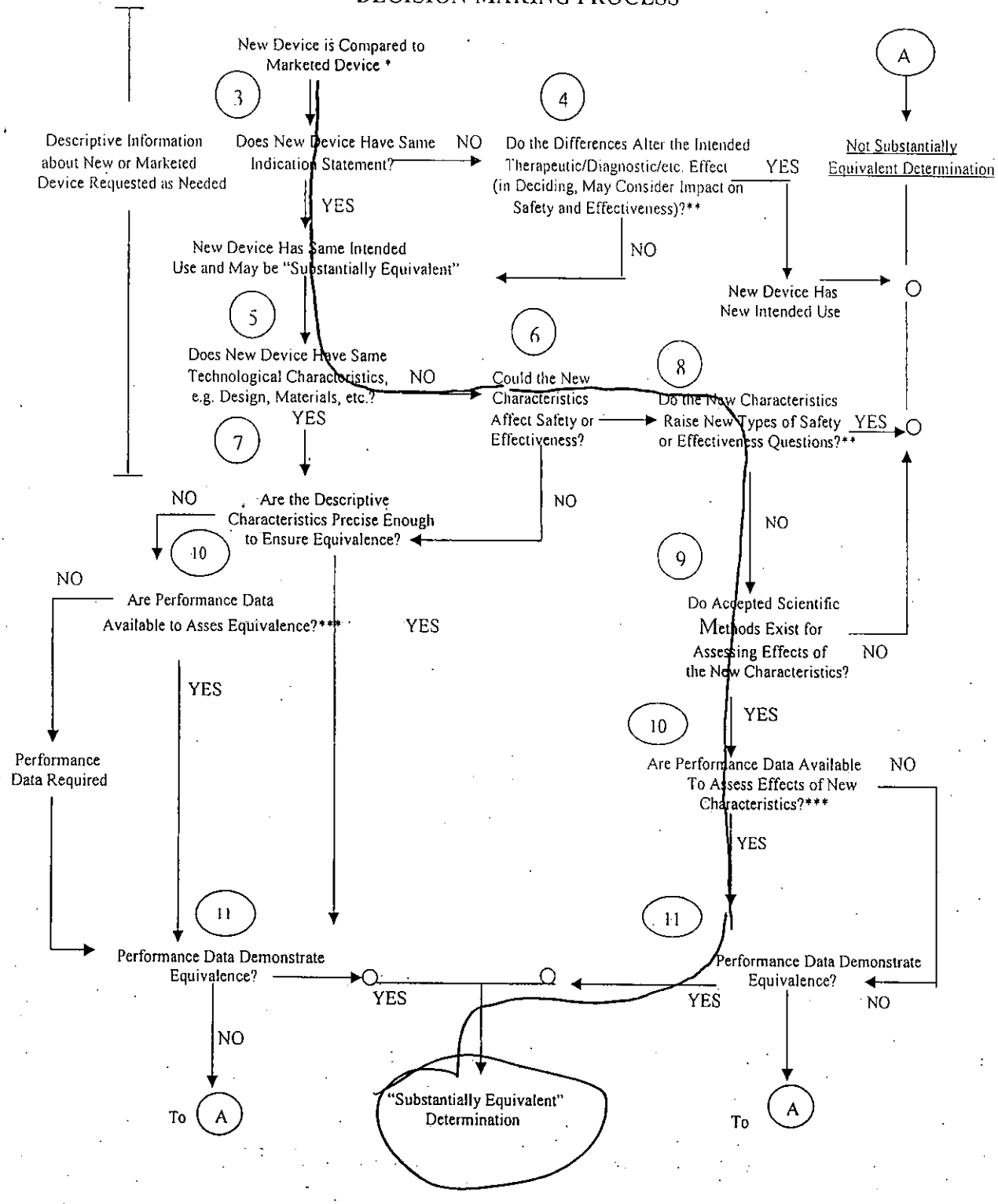
[redacted]

Please contact me with questions or concerns.

Sincerely,

Lauren Giles
Biomedical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
10903 New Hampshire Avenue
WO66 - Rm. 2546
Silver Spring, MD 20993
Phone: 301-796-9552
Fax: 301-847-8109
Lauren.Giles@fda.hhs.gov

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 05, 2011

ULTRADENT PRODUCTS, INC.
505 WEST 10200 SOUTH
SOUTH JORDAN, UTAH 84095
ATTN: DIANE ROGERS

510k Number: K110582

Product: VALO CORDLESS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K110582/51

April 1, 2011

Lauren Giles

Food and Drug Administration CDRH

Document Mail Center (HFZ-401)

10903 New Hampshire Drive

Silver Spring, MD 20850

FDA CDRH DMC

APR 5 2011

Received

Reference VALO Cordless Special 510(k) K110582

Dear Lauren,

Thank you for your quick review of the changes to our submission. I made all the changes you requested during our phone call on April1, 2011.

(b)(4)

Please review these changes and feel free to contact me if you have any further questions. Thanks again for your quick review.

Kind regards,

Diane...

Diane Rogers 4/1/11

K18

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Traceability Analysis:

Product Design Requirements: General	Acceptance
1. Design a curing light for use on restorative materials with photo-initiators	Achieved
2. Design a battery powered curing light with the same operational functionality modeled from and off of the Ultradent VALO corded dental curing light.	Achieved
Design Specifications: Design Inputs for Design Control	
1. Multiple wavelength high power, high efficiency LED with dental blue, deep blue, and UV (395nm - 480nm) and capable of polymerizing all light cure dental materials.	Achieved
2. Power Modes, Times, and Power Levels: LED will light up each time cycled a. Standard Power restorative curing mode with 5, 10, 15, and 20 second intervals, and capable of a minimum radiant exitance of 1000mW/cm^2 b. High Power restorative tacking mode with 1, 2, 3, and 4 second intervals, and capable of a minimum radiant exitance of 1400mW/cm^2 c. Xtra Power restorative tacking mode with 3 seconds only, and capable of a minimum radiant exitance of 3200mW/cm^2 *Note: Measurement with barrier sleeve.	Achieved
3. Provide a unit that maintains the same ergonomic usability, elegance, functionality, and overall 'look and feel' of Ultradent's corded Valo	Achieved
4. A dental curing light that is able to operate from 2 ea. CR123A batteries a. Ultradent will make available safe rechargeable $LiFePO_4$ batteries that are CE, RoHS, and WEEE compliant. b. Safe rechargeable battery will bare Ultradent label/logo c. Alternate batteries will be easily obtainable from local sources.	Achieved
5. Provide a safe 3.6VDC battery charger with Ultradent labeling that is CE certified.	Achieved
6. Provide a medical grade charger adapter with full international compliance and adaptability	Achieved
7. Curing light circuit voltage input from 3.95VDC – 10.5VDC	Achieved
8. Provide the following safety and warning protections a. Unit has a sounder to indicate warnings and change of state b. Unit has LEDs to indicate time intervals, modes, and warnings c. Low battery voltage detect d. Unit Shuts down under the following circumstances: i. Battery voltage is too low ii. Input voltage too high iii. Unit detects LED overcurrent, undercurrent, and overvoltage e. Radiate power levels are calibrated in Standard Power, High Power, and Xtra Power modes f. Provide battery polarity protection g. Provide overcurrent fusing	Achieved
9. Provide a thermometer inside the unit to monitor temperature to warn and shut down operation if temperatures reach 50°C	Achieved
10. Battery life will provide a minimum of 200 Xtra Power 3 second cycles	Achieved
11. Provide a unit that will sleep to conserve battery life by going to sleep quickly and waking up easily	Achieved

and without having to push buttons and extra time.	

March 29, 2011

Lauren Giles

Food and Drug Administration CDRH

Document Mail Center (HFZ-401)

10903 New Hampshire Drive

Silver Spring, MD 20850

Reference VALO Cordless Special 510(k) K110582

Dear Lauren,

(b) (4)

[redacted]

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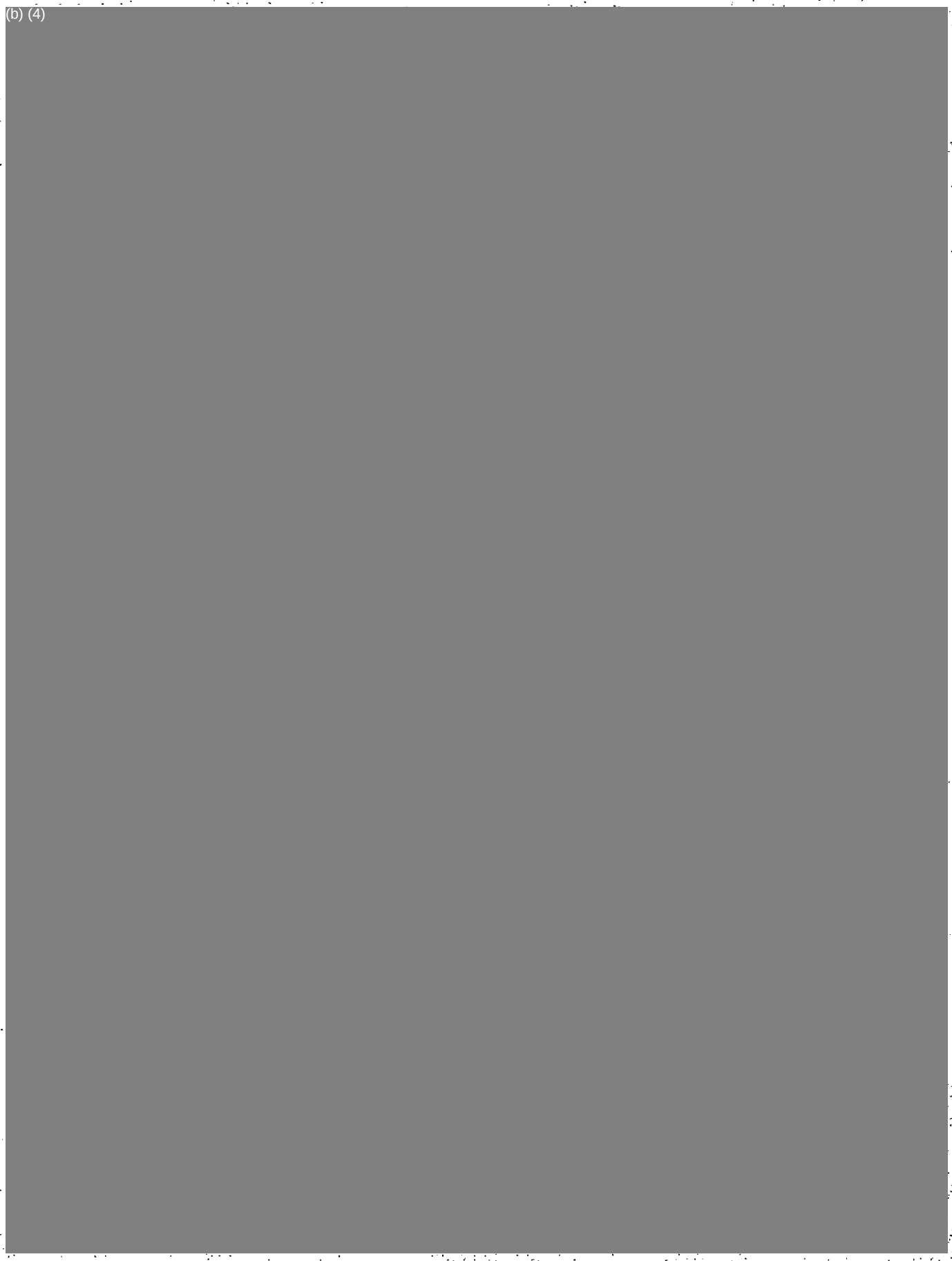

Lauren,

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[redacted]

Thanks again for your time and review,

Kind regards,

Diane Rogers

Diane Rogers

Description: Valo® Cordless is a battery operated, visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials. The cordless version functions the same as the corded version. VALO (K083647).

Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Substantial Equivalence:

The VALO™ SCOUT is to be manufactured and marketed by:	**Ultradent Products, Inc.** 505 West 10200 South South Jordan, Utah 84095, USA

The VALO™ SCOUT is substantially equivalent to the VALO™ which is also manufactured by Ultradent Products, Inc. These two products are manufactured from the same materials, utilize many of the same components, are calibrated to the same levels and parameters, are used in the same manner and fashion, and are designed to operate and function in a near identical manner. The VALO™ SCOUT was designed to be the VALO™ but without the cord. The programming code is near identical, save micro-controller variations and enhanced safety features. Both products have the same intended use and technological characteristics. Both products are safe and effective when used for as intended and for the purposes described.

Overview of Purpose

The VALO™ and VALO™ SCOUT are designed to cure all known dental composites in the market. There are a wide variety of dental composites available, each having unique properties. Dental composites vary in shade, chemical composition, behavior, viscosity, cured hardness, nature of curing, rate of curing, and purpose of use. Dental composites can also vary due to their age from the date of manufacture and how they are stored. Many have expiration dates. Dentists and dental assistants are trained to operate curing lights to achieve proper curing of dental composites during restorations, and to check for proper curing, but due to the wide range of techniques, skill levels, and states of composite, curing light manufactures will often deliver extra curing time and/or light output power to ensure proper composite curing during a dental restoration.

The VALO™ and VALO™ SCOUT both utilize the same high intensity LED calibrated to identical output power levels, with lensing and focusing that are also identical. Each have the same LED consisting of 2 dental blue die, 1 deep blue die, and 1 UV die. Each wavelength color is present to stimulate the photo-reactions of various types of chemistry present in different dental composites. Not all dental composites can be cured with the same frequency of light. This is the reason for the different colors and wavelengths present in the LED.

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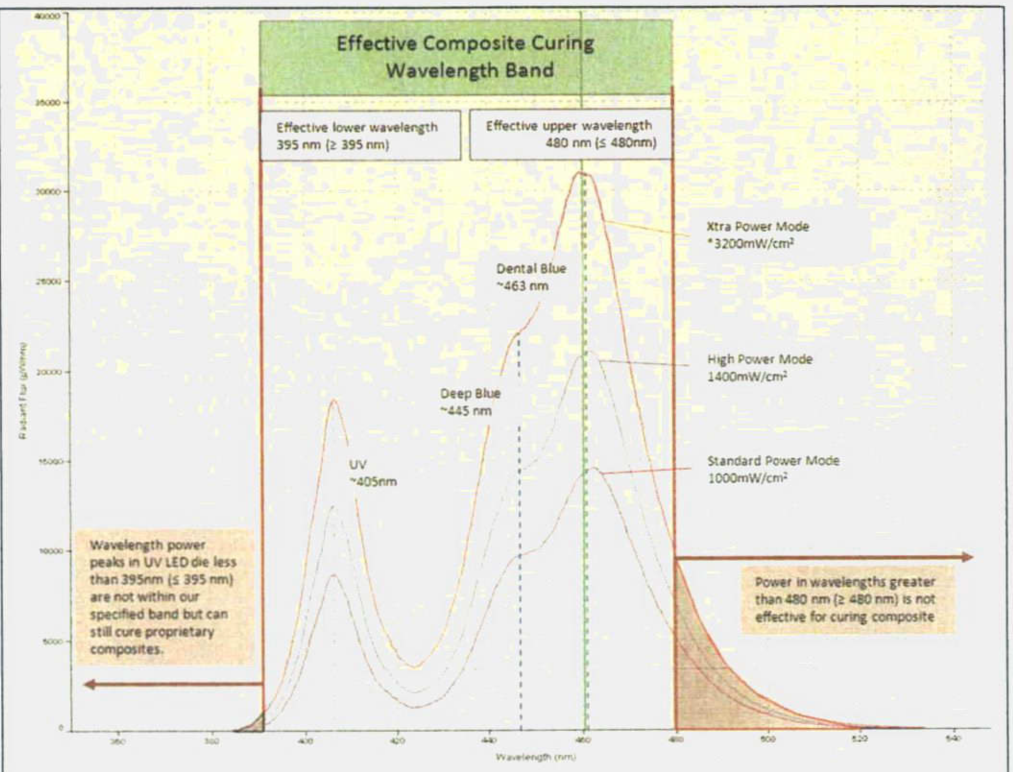
Characteristic – Aspect	VALO™	VALO™ SCOUT	Equivalence
Purpose	(b) (4)		Equivalent
Ergonomics			Substantial Equivalence
Standard Power Mode 1. Power Output 2. Spectrum 3. Timing Intervals			Equivalent See Technical Information below
High Power Mode 1. Power Output 2. Spectrum 3. Timing Intervals			Equivalent See Technical Information below
Xtra (Plasma) Power Mode 1. Power Output 2. Spectrum 3. Timing Intervals			Equivalent See Technical Information below
Main Power LED			Equivalent LED Irradiance is calibrated to the same output levels using the same LED from the same manufacturer
Curing head structure 1. Optical lensing (same) 2. Light focusing (same) 3. Mechanical (same) 4. Power LED (same)			Equivalent Optical lensing, focus, power LED, and mechanical retention of the power LED are identical. Parts are interchangeable.
Button - Switch placement			Equivalent
Timing Indicator LED placement			Equivalent
Mode Indicator LED placement			Equivalent
Body Materials: wand and panel			Equivalent
Circuit Board: Precision current control 1. Microprocessor 2. DC-DC booster 3. Inductor 4. Regulator 5. Current sensing mechanism 6. Current feed-back loop 7. Amplifiers 8. DAC 9. Indicator LEDs 10. Sonalert 11. Switches 12. IR communication chip 13. Temperature sensing 14. Motion sensing			Substantial Equivalence VALO™ SCOUT circuit board includes all aspect of its predicate VALO™ plus the capacity to sense temperature and motion. Feedback current loops and sensing circuitry are the same. Power circuitry has been strengthened to handle lower voltages and heavier current draws from batteries.
Firmware Code Version 1. Function 2. Modes 3. Timing intervals 4. ADC/DAC data use 5. IR communication data 6. Serial communication data 7. Low power warning 8. Power safety shut down 9. Calibration method			Substantial Equivalence VALO™ SCOUT firmware includes all aspects of the predicate VALO™ firmware plus new capacity to sense temperature and motion and to give more informative warnings.

Button - Switch placement	(b) (4)	Equivalent
Timing Indicator LED placement		Equivalent
Mode Indicator LED placement		Equivalent
Body Materials: wand and panel		Equivalent
Circuit Board: Precision current control 1. Microprocessor 2. DC-DC booster 3. Inductor 4. Regulator 5. Current sensing mechanism 6. Current feed-back loop 7. Amplifiers 8. DAC 9. Indicator LEDs 10. Sonalert 11. Switches 12. IR communication chip 13. Temperature sensing 14. Motion sensing		Substantial Equivalence VALO™ SCOUT circuit board includes all aspect of its predicate VALO™ plus the capacity to sense temperature and motion. Feedback current loops and sensing circuitry are the same. Power circuitry has been strengthened to handle lower voltages and heavier current draws from batteries.
Firmware Code Version 1. Function 2. Modes 3. Timing intervals 4. ADC/DAC data use 5. IR communication data 6. Serial communication data 7. Low power warning 8. Power safety shut down 9. Calibration method		Substantial Equivalence VALO™ SCOUT firmware includes all aspects of the predicate VALO™ firmware plus new capacity to sense temperature and motion and to give more informative warnings.
Input Power 1. Range 2. Power source 3. Power delivery 4. Fusing		Substantial Equivalence VALO™ SCOUT power circuitry was enhanced for higher current and is capable of using the 9VDC medical grade power supply of the VALO™ with an accessory adaptor.

Technical Information	VALO™ and VALO™ SCOUT LED Curing Light
Wavelength range	(b) (4)

(b) (4)

	
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10% † Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma' or 'Plasma Emulation') ***As measured by a Demetron® L.E.D, Radiometer*** *† As measured by a spectrum analyzer* ***Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer***

(b) (4) [redacted]

Diane Rogers

To: Diane Rogers
ubject: FW: Valo Scout: FDA depth of cure testing

Depth of Cure

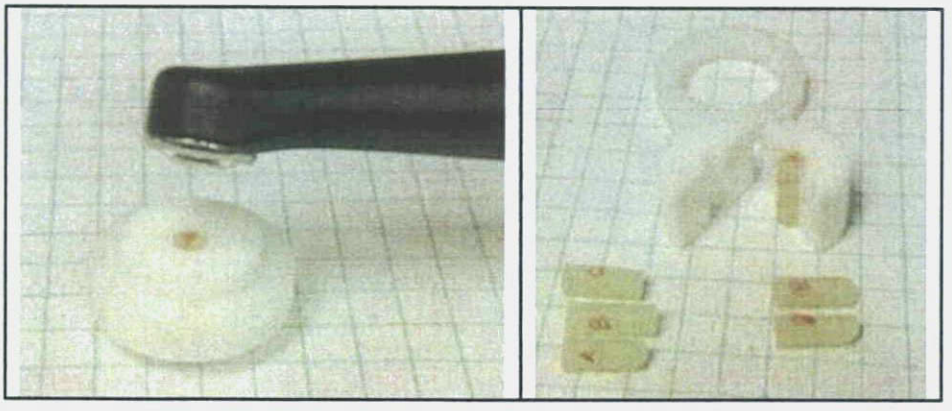
VALO SN: 11364		VALO SCOUT SN: 00037	
Total Depth	**Total Depth/2**	**Total Depth**	**Total Depth/2**
11.23	5.615 mm	11.14 mm	5.570 mm
12.07	6.035 mm	11.72 mm	5.860 mm
11.62	5.810 mm	11.99 mm	5.995 mm
Mean Depth	**5.82 mm**	**Mean Depth**	**5.81 mm**
Reference Depth	5.82 mm	Depth Tolerance +/- 2% (+/- 0.1 mm)	PASS

Test Date: 03-28-2011
Test Temperature: 22° C
Test Technician: Josh Jessop

Device Test Conditions: VALO and VALO SCOUT in Standard Power Mode, 20 second cure time.

Reference Dental Composite: 3M Z-100, Shade A2, Expiration date 02-23-2012

Regulatory References:
1. ISO 4049 -1998 (Equivalent to ADA 27)
2. ADA Specification No. 27 - 1993 Resin Based Filling Materials
   a. Section 7.7 Depth of Cure, type 2 materials
   b. Section 7.7.11 Modifications
      i. Mold modified from 4mm deep stainless steel to 6mm deep natural Teflon/Delron to accommodate deeper cures and reflect in-vivo environment.



Note 1: Depth-of-cure tests are dependent on the chemistry of the composite resin, shade, age of composite, temperature. Ideal dental curing attempts to activate/cure the entire sample of the composite to its full final hardness. Cure hardness at various depths is not entirely consistent and is ensured by the dentist by extending the duration of exposure to the curing light, performing multiple cure cycles, and/or by increasing the power output of the curing light.

Note 2: Due to chemical mixing limitations, uniformity within batches dental composite varies. Not every area of the composite will have identical hardness or depth of cure.

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(b) (4)

WARNING

Read all instructions before operating this unit.

The VALO SCOUT LED curing light emits extremely high intensity light waves and must only be used as indicated in this manual.

- **DO NOT look directly into the light output. Patient, clinician and assistants should wear UV orange eye protection when this device is in use.**
- **DO NOT expose soft oral tissues at close proximity. Maintain a minimum of 2mm between the lens and the soft tissue.**
- **If using the VALO SCOUT LED Curing Light in the Standard Power mode and in close proximity of the gingival tissue, DO NOT expose tissue for more than 20 seconds. If a 40-second cure is needed, allow 2 minutes between two 20 second cures. If longer curing time is required, consider a dual-cure product (composite or adhesive).**
- **In Xtra Power Mode, DO NOT expose soft oral tissue for more than 10 seconds. The Xtra Power Mode has a 2 second safety delay to limit oral tissue heating during consecutive curing. If a longer cure is needed, allow 2 minutes between consecutive cures or consider a dual-cure product (composite or adhesive).**

Product Information:

Indications for Use: The source of illumination for curing photo-activated dental restorative materials and adhesives.

The VALO SCOUT curing light uses a custom, multi-wavelength Light Emitting Diode (LED) for producing the high intensity light (395 - 480 nm) capable of polymerizing all light cure dental materials. This intensity will also penetrate porcelain and is capable of curing underlying resin cements similarly to a quality halogen light..

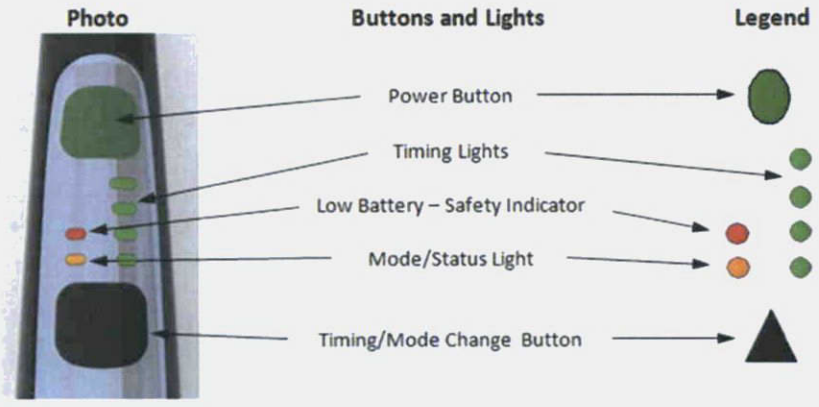
The VALO SCOUT curing light uses safe Ultradent VALO rechargeable batteries and battery charger.

Contact Information	**Ultradent Products Inc.** 505 West 10200 South South Jordan, Utah 84095 USA Customer Service Phone: 801-571-4000 Ext. 4100 Web site: http://www.ultradent.com/

Product Components:

- 1 – VALO SCOUT curing light
- 4 – Ultradent VALO rechargeable batteries
- 1 – Ultradent VALO Battery recharger with medical grade S/B 12VDC AC power adaptor
- 50 – VALO SCOUT Barrier Sleeves

Overview of Controls:



Instructions for Use:

1- Remove all components from the packaging and examine them.

2- See section **How to Charge Batteries**. Place 2 of the batteries in the Ultradent VALO charger. The light on the charger will change from red to green when the batteries are fully charged (approximately 1 hour).

3- See section **How to Change Batteries**. Remove the battery compartment cap at the base of the VAL O SCOUT by twisting the silver metal cover counterclockwise 1/8 to 1/4 of a turn.

4- Insert two fully charged batteries plus (+) end first. 5- Replace the battery cover

6- The VALO SCOUT hand piece beeps when powering on.

7- Selecting the desired mode: The VALO SCOUT curing light has 3 modes: Standard Power, High Power, and Xtra Power. Each mode is identified by the Mode/Status light (green = Standard Power, orange = High Power, and flashing orange = Xtra Power). To change modes hold the Time Change button for 2 seconds and release. The Mode/Status light will change to the next mode.

NOTE: The VALO SCOUT curing light is programmed to cycle from the Standard Power to the High Power to the Xtra Power mode in sequence. For example, to change from the Standard Power mode to the Xtra Power mode, it is necessary to cycle into the High Power mode and then to the Xtra Power mode.

The VALO SCOUT curing light always stores its last used timing interval in each mode and will default back to that timing interval whenever the modes are changed or if the batteries are removed.

SLEEP MODE: The VALO SCOUT curing light will go into POWER SAVE mode after 30 seconds of inactivity, as indicated by a slow flashing of the mode/status light. Picking up or touching the unit will wake-up VALO SCOUT and automatically return it to the last setting used.

WARNING: Storage and Travel: If storing the VALO SCOUT for periods longer than 2 weeks, packing it for travel, or traveling with it, always remove the batteries. If batteries are left in for long periods of time without recharging they may become non-functional and be unable to be recharged or to retain charge.

Charging and Changing Batteries

The Valo Scout comes with 4 rechargeable safe lithium rechargeable batteries.

LOW BATTERIES: The VALO SCOUT signals the user that it is time to change the batteries when the Low Battery Indicator Light is flashing red. If the battery charge becomes too low, an audible 3 beep warning sound will occur and the Valo will not allow further operation until batteries recover or new batteries are inserted.

Battery Charge Expantancy: Battery charge life in the Valo Scout is dependent on the MODE, TIME interval, battery type, amount of use, and LED efficiency. Different battery types will last longer than others. In general, rechargble batteries should last 1 -2 weeks. Non-rechargeable batteries may last 2- 3 time longer.

- **Recommended Recharge Interval:** To avoid low battery warnings or shut off during a proceedure, recharge batteries every 1 – 2 weeks.
- **Extra Batteries:** To avoid possible VALO SCOUT down time, keep an extra set of non-rechargeable batteries on hand in case batteries get lost or have not been charged. See list of authorized batteries. You can also order extra rechargeable batteries as needed.

Battery Life Expectancy: Rechargeable Lithium Iron Phosphate batteries can be recharged approximately 1000 to 2000 times before wearing out. However, in everyday use, batteries may be dropped, scratched, scuffed, lost and misplaced. Keep a spare set of non-rechargeable CR123 batteries available.

How to change batteries

1. Remove back cap by twisting counter clockwise a quarter turn.
2. Remove batteries
3. Insert fresh batteries positive (+) side first
4. Reattach back cap by aligning and gently pushing while twisting clock wise. The cab will click when fully attached.
5. The unit is ready for use



WARNING – CAUTION

- VALO SCOUT will not operate if batteries are put in backwards. If the VALO SCOUT does not turn on when fresh batteries are inserted, remove the batteries and check to see that they are inserted correctly with the positive (+) battery ends pointed forward as shown below.
- If VALO SCOUT warning indicator LED flashes red when batteries are inserted, remove batteries and insert freshly charged batteries.
- Do not insert fingers, instruments, or objects into the battery compartment of the VALO SCOUT.
- Do not attempt to clean the gold contacts of the battery compartment or anywhere in the battery compartment. Call Ultradent Customer Service if there is a concern.

How to charge batteries

1. Insert batteries into charger with plus (+) end pointed towards the lights on authorized charger.
2. The charger LEDs will show red indicating that the batteries are charging.
3. When the charger LEDs show green, the batteries are ready for use.
4. Batteries will take about 1 hour to charge. Leave batteries in charger until ready for use.

WARNING - CAUTION

- Make sure batteries are inserted into the charger in the correct orientation.
- If the red LED on the charger doesn't turn to green, this means a battery may have gone bad and cannot be charged. Try a new battery or call Ultradent Customer Service to order a new set of batteries.
- If batteries appear to bubble or smell bad, remove batteries from the charger immediately and call Ultradent Customer Service.
- Do not use batteries if the battery wrapping has become torn or removed from the battery. Replace with a new battery immediately and recycle old battery.

WARNING - CAUTION

- Do not mix rechargeable batteries with non-rechargeable batteries.
- Do not charge non-rechargeable batteries.
- Use only safe rechargeable Lithium Iron Phosphate batteries or non-rechargeable batteries.
- Do not store batteries in temperatures over 60°C or in direct sunlight.
- **DO NOT autoclave batteries, charger, AC power adaptor, or VALO SCOUT**

If necessary, Ultradent authorizes the following alternative batteries and chargers for the VALO SCOUT.

Note: Ultradent does not recommend or authorize other batteries or chargers at this time. While other battery types and chargers will operate with the VALO SCOUT, they have not been tested and may not have safe battery chemistry or approved safety ratings.

Note: Always recycle spent non-rechargeable batteries.

Authorized Alternate Batteries	Authorized Alternate Chargers
Rechargeable $LiFePO_4$ batteries 1. Tenergy® 3.6V RCR123A, 750mAh 2. Powerizer® 3.6V RCR123A, 450mAh 3. Mottcell® 3.6V IFR16340 series **Non-rechargeable, primary, batteries** 1. Tenergy Propel Photo Lithium: (safe, long lasting, recommended) 2. Titanium Innovations CR123A: (safe, long lasting, recommended) 3. Energizer® 123 4. Duracell® Ultra CR123A 5. Sanyo® CR123A 6. Rayovac® CR123A 7. SureFire® SF123A 8. Panasonic® CR123A	Tenergy® 3.6V RCR123 $LiFePO_4$ charger Powerizer® 3.6 RCR123 $LiFePO_4$ charger

Installing Hygienic Barrier Sleeves

The hygienic barrier sleeve serves keeps the surface of the VALO SCOUT clean and aseptic. It prevents the transfer of pathogenic micro-organisms from one patient to another. It also helps keeps dental composite materials from adhering to the surface of the lens and wand body. A new hygienic barrier sleeve is to be inserted onto the VALO SCOUT with each new patient.

WARNING – CAUTION

- Do not re-use barrier sleeves. Use a new barrier sleeve for each patient.
- Discarded used barrier sleeves appropriately after each patient.
- Do not leave barrier sleeves on the wand for extended periods.
- Do not store the VALO SCOUT with the barrier sleeve on.
- If barrier sleeves are not used, VALO SCOUT must be cleaned and sanitized with appropriate cleaning and/or sanitizing agents after each patient. See section titled **Maintenance and Cleaning.**

Quick Mode Guide

Mode Power Level	Standard Power Mode 1000mW				High Power Mode 1400mW				Xtra 3200mW
Power Button									
Mode/Timing LEDs									
Time Button									
Time Options	5s	10s	15s	20s	1s	2s	3s	4s	3s Only
To Change Time	Press and release Time Button quickley to cycle through time options.								
To Change Modes	Press and hold the Time Button for 2 seconds and release. VALO will cycle to next Mode								
Legend	Solid LEDs				Blinking LEDs				

Quick Curing Guide: Recommended Curing Times for Optimal Results with VALO SCOUT

Power Level - Layer	Standard Mode **1000mW/cm^2**	High Power Mode **1400mW/cm^2**	Xtra Power Mode **3200mW/cm^2**
Per Layer	One 10 second cure	One 4 second cure	One 3 second cure
Final Cure	One 20 second cure	Two 4 second cures	Two 3 second cures

Quick Warning Guide

Power level warning	Temperature warning	Calibration Warning	LED warning
Replace batteries	Allow cool down	Send in for repair	Send in for repair
Low battery: quiet flashing Shut off : 3 beeps, flashing Prohibits operations	3 beeps Quiet flashing Prohibits operation	No sound, Flashing, 2 seconds Allows operation	Continuous 3 beeps Flashing Prohibits operations

CURING MODE: Standard Power mode - 1000mW/cm2

USES: Curing of restorative materials with photo initiators.

TIMING INTERVALS: 5, 10, 15, 20 seconds

VALO SCOUT defaults to this mode when it is INITIALLY powered on. The green Status light is on and the green Timing Lights are solidly illuminated.

To change timing intervals quickly press the Time Change Button

- One light = 5 seconds
- Two lights=10 seconds
- Three lights=15 seconds
- Four lights=20 seconds

Press the Power Button to cure. To stop curing prior to completion of a timing interval, press the Power Button again.

CURING MODE: High Power mode - 1400mW/cm2

USES: Initial curing of restorative materials with photo initiators. Tacking of veneers, brackets, and restorative materials.

TIMING INTERVALS: 1, 2, 3, 4 seconds.

From Standard Power mode, press and hold the Time Button for 2 seconds. The green Timing Lights will illuminate and flash. The Status Light will illuminate as a steady orange light, indicating High Power mode. A two-second power tack is the most commonly used timing interval in this mode.

To change timing intervals quickly, press the Time Change Button

- One flashing light = 1 second
- Two flashing lights = 2 seconds
- Three flashing lights = 3 seconds
- Four flashing lights = 4 seconds

Press the Power Button to cure. To stop curing prior to the completion of a timing interval, press the Power Button again.

To return to Standard Power mode, press and hold the Time Change Button for 2 seconds, release, hold for 2 seconds, and release. The green Status light is on and all 4 timing lights are illuminated.

CURING MODE: †Xtra Power mode - 3200mW/cm2

USES: The Xtra Power mode is **useful for all dental curing**. It is especially valuable for deep curing of restorative materials, placing thin veneers, attaching orthodontic brackets, and fast curing in pediatric settings.

TIMING INTERVAL: 3 seconds only *(Note: there is a 2 second safety delay at the end of each curing cycle)*

From the Standard Power mode, press the Time Button for 2 seconds, release, press again for 2 seconds, and release. Three of the green Timing Lights and the orange Status Light will illuminate *and flash* indicating Xtra Power mode.

Three green flashing lights = 3 seconds

Press the Power Button to cure. To stop curing prior to completion of a timing interval, press the Power Button again.

To return to the Standard Power mode, press and hold the Time Button for 2 seconds

NOTE: The VALO SCOUT curing light is programmed to cycle from the Standard Power mode to the High Power mode to the Xtra Power mode in sequence. For example, to change from the Standard Power mode to the Xtra Power mode, it is necessary to cycle into the Power mode and then to the Xtra Power mode.

WARNING - CAUTION

In Xtra Power mode, VALO SCOUT emits extremely high intensity light in a controlled 3 second burst. The VALO SCOUT curing light must only be used as indicated in this manual.

- **DO NOT look directly into the light output. Patient, clinician and assistants should wear UV orange eye protection when this device is in use.**
- **DO NOT expose soft oral tissues at close proximity. Maintain a minimum of 2mm between the lens and the soft tissue.**
- **DO NOT expose soft oral tissue for more than 10 seconds. The Xtra Power mode has a 2 second safety delay to limit oral tissue heating during consecutive curing. If a longer cure is needed, allow 2 minutes between consecutive cures or consider a dual-cure product (composite or adhesive).**

† Note: 'Xtra Power' equal Plasma Power levels in the Corded VALO. In this context Plasma refers to 'plasma-like' due to intense optical output and curing capacity. Actual plasma arc lights generate broad optical output that must be filtered to reduce harmful short wave ultraviolet radiation.

Maintenance and Cleaning

The VALO SCOUT curing light is a sealed unit with a sapphire-like hard surface and a scratch resistant glass lens. After each use, moisten a gauze or soft cloth with an anti-microbial surface disinfectant and wipe the surface and lens.

Periodically check the lens for cured dental resins.

CAUTION: Ensure the VALO SCOUT lens efficacy and curing effectiveness by using VALO SCOUT brand Barrier Sleeves. These sleeves have been designed and optimized specifically for use with the VALO SCOUT curing light. In the event that dental resin adheres to the VALO SCOUT lens, use a non-diamond dental instrument to carefully remove the resin.

Light meters differ greatly and are designed for specific light guide tips and lens. Ultradent recommends checking VALO SCOUT in Standard Power mode. NOTE: the true numeric output will be skewed due the inaccuracy of common light meters and the custom LED pack VALO SCOUT uses.

WARNING - CAUTION

- DO NOT autoclave batteries, charger, power adaptor, or VALO SCOUT.
- DO NOT insert fingers, instruments, or objects into the battery compartment of the VALO SCOUT.
- DO NOT attempt to clean the gold contacts of the battery compartment or anywhere in the battery compartment. Call Ultradent Customer Service if there is a concern.
- DO NOT immerse in any kind of ultrasonic bath or any liquids.
- DO NOT wipe down the VALO SCOUT curing light with caustic or abrasive cleaners. See lists of acceptable cleaners below:

ACCEPTABLE CLEANERS:

- Cavicide™ products
- Isopropyl alcohol-based cleaners
- Ethyl alcohol-based cleaners
- Lysol® disinfectant
- Other *non-bleach* and *non-abrasive* disinfectants or cleaners

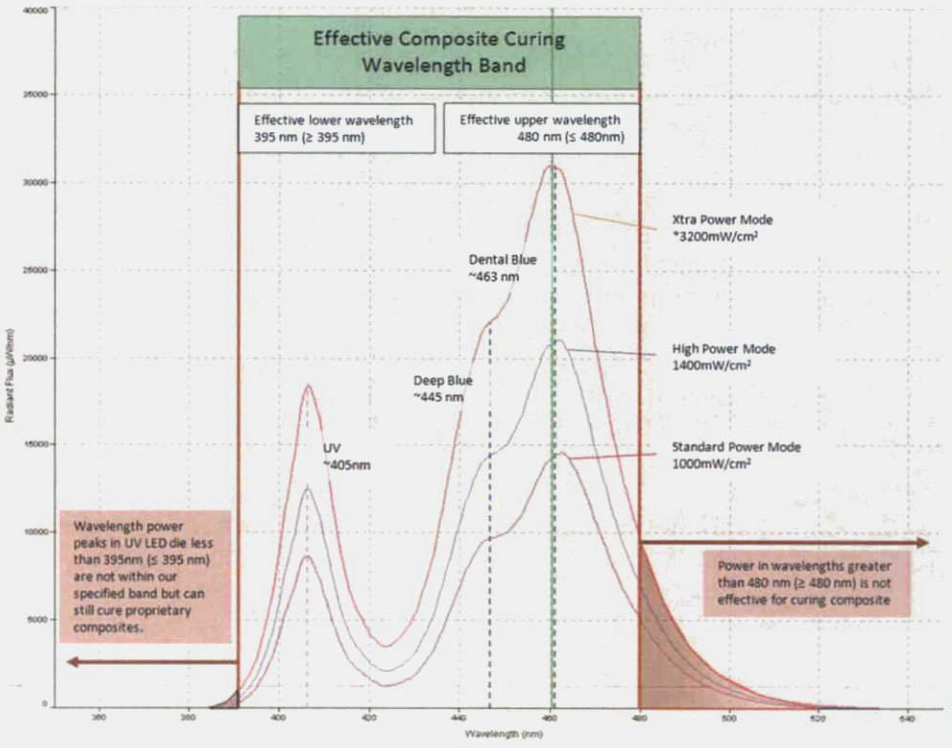
DO NOT USE:

- Formula 409® based cleaners
- Bleach-based cleaners (e.g. - Clorox™, Sterilox™)
- Hydrogen Peroxide based cleaners
- Abrasive Cleansers (e.g. – Comet Cleanser™)
- Acetone-based cleaners (e.g. – nail polish remover, Goo-off™)
- MEK

Troubleshooting Guide

If the solutions suggested below do not rectify the problem, please call Ultradent at 800.552.5512. Unauthorized service will invalidate warranty.

Problem	Possible solutions
Light will not turn on	1. Wiggle VALO SCOUT to see if unit wakes up. 2. Press the Time or Power Button to wake from Power Save Mode. 3. Check the red Low Battery Indicator for battery charge status. 4. Check that fresh batteries are correctly inserted into the unit. 5. If red and yellow Warning LEDs are flashing this means the VALO SCOUT has reached its internal temperature safety limit. Allow the VALO SCOUT to cool down for 10 minutes or use a cool moist towel to cool the unit down quickly. 6. If red Warning LED flashes and beeps continuously, call Ultradent Customer Service for repair.
Light does not stay on amount of time desired	1. Check that the unit is set to desired Mode. 2. Check the Low Battery Indicator for battery charge status. 3. Check that fresh batteries are properly inserted into the unit.
Light is not curing resins properly	1. Check lens for residual cured resins/composites (see "Maintenance and Cleaning"). 2. Using proper orange UV eye protection, verify the LED die lights are working. 3. Check power level with light meter. 4. Check expiration date on curing resin.
Batteries won't charge	1. Make sure batteries are inserted in the charger in the correct orientation and allow batteries to charge for 1 hour. 2. If red LEDs on the charger do not change to green, call Ultradent Customer Service to order replacement batteries and/or charger. 3. If neither green nor red LEDs on the charger are visible, call Ultradent Customer Service to order or replace charger and/or AC adaptor.
Batteries bubble and smell bad	1. Remove batteries from the charger immediately 2. Do not insert these batteries into the VALO SCOUT. 3. Call Ultradent Customer Service for new batteries and/or charger. 4. Recycle batteries.
Charger does not charge batteries	1. Make sure charger is plugged in and AC adapter is plugged into power outlet. 2. If green or red LEDs on the charger are not visible, call Ultradent Customer Service for new charger and/or AC adaptor. 3. If charger smells as though it is burning, unplug charger immediately and call Ultradent Customer Service for replacement.
Wrapping comes off of battery	1. Do not use these batteries in the VALO SCOUT. 2. Recycle batteries. 3. Call Ultradent Customer Service to order replacement batteries.

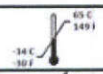
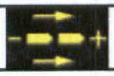
Technical Information	VALO SCOUT LED Curing Light
Wavelength range	395nm – 480nm (see qualification below) Effective Output Power (EOP) of VALO SCOUT falls within the following wavelength range: • 395nm <= EOP <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power minimums within specific wavelength bands. The VALO SCOUT complies with ADA 48 
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10% † Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation') **** As measured by a Demetron® L.E.D, Radiometer*** ***† As measured by a spectrum analyzer*** ***Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer***

AC Power Adapter	Globtek Medical Grade with international plug inserts Output: 12VDC, 500mA Input: 100VAC – 240VAC Ratings: Medical Grade, (UL, CE, RoHS, WEEE) Includes: International plug adapter kit Cord: 6 ft (1.8m), 2.5mm DC connector Weight: 152 grams w/o plug Dimensions: (75 x 43 x 34) mm
VALO Charger	VALO 3.6VDC Lithium Iron Phosphate smart battery charger: • Peak Voltage: 3.6VDC • Automatic shut off when fully charged • Auto-detection of defective batteries • Protections: Thermal, Overcharge, Short-circuit, reverse polarity o Red LED – Charging o Green LED – Empty or Fully Charged o LED off – short circuit • Charging time: 1 – 3 hours Rating: CE, WEEE Weight: 1.27 troy oz. (39.5 grams) Dimensions: (2.5 x 4 x 1) inches, (63.5 x 101 x 25.4) mm
VALO Batteries	Rechargeable: Safe chemistry Lithium Iron Phosphate ($LiFePO_4$) RCR123A • Working Voltage: 3.2VDC • Peak Voltage: 3.65VDC • Cut-off Voltage: 2VDC • mAh rating: greater than 400mAh Ratings: CE, RoHS, WEEE Weight: 17 grams each Dimensions: 34.5mm x 17mm Alternate use Non-rechargeable: Lithium CR-123A 3VDC (rating greater than 1400mAh for long operation)
VALO SCOUT:	Current draw from batteries: • Sleep Mode – 230uA (wake up on button press and movement) • Ready Mode – 30mA (maximum) • Power LED: (dependent on MODE of use and state of charge on batteries) o Minimum – 250mA o Maximum – 2000mA Battery Input Voltage: 4VDC – 10.5VDC • Minimum – 3.95VDC (lock out activated to prevent use) • Maximum – 10.5VDC (lock out activated to prevent use) LED Current Source: Micro-processor controlled, precision regulated LED current and time. Calibrated Power Modes: Standard Power, High Power, Xtra Power. See Instruction Manual. Protections: Low Battery, Over Voltage, Over Temperature, LED Failure, Calibration Failure Limitations for Use: VALO Scout will not allow operation if temperatures exceed 50°C. • Standard Power: 3 curing cycles, 15 minute off, after 60 minutes of use allow 30 minutes off. • High Power and Xtra Power: 5 curing cycles, 10 minutes off. Ratings: Medical Grade, CE, RoHS, WEEE Weight: • With batteries: 5.5 troy oz. (170 grams) • Without batteries: 4.4 troy oz. (136 grams) Dimension: (8 x 1.28 x 1.06) inches, (203 x 32.5 x 27) mm

Diane Rogers

From: Dee Jessop
Sent: Tuesday, March 29, 2011 10:01 AM
To: Diane Rogers
Subject: FDA submission symbols
Attachments: Marks and Symbols for FDA submission only.docx

See if this works...

Marks and Symbols	Meaning
	Warning to read and following instructions and pay attention to specific use warnings and cautions. This symbol is on the VALO SCOUT and on the packaging
	VALO SCOUT complies with Medical Class B electrical safety This symbol is on the VALO SCOUT and on the packaging
	WEEE compliant: Recycle, Do Not discard improperly. This symbol is on the VALO SCOUT packaging box.
	Upper and lower temperature limitations: Do not store or transport VALO SCOUT in areas above 65°C (149°F) or below -34°C (-30°C). This symbol is on the packaging box.
	Keep Dry: Cargoes bearing this symbol must be protected from excessive humidity and must be stored under cover. This symbol is on the packaging box.
	VALO SCOUT is to be used by trained dental or medical professionals. This symbol is on the packaging box.
	This marking shows the correct method of inserting batteries. This mark is located on the top inside of the battery compartment in large yellow print.

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Warranty

Ultradent hereby warrants that this instrument shall, for a period of 2 years from the date of purchase, conform in all material respects to the specifications therefore as set forth in Ultradent's documentation accompanying the product and be free from any defects in materials and/or workmanship. This warranty applies solely to the original purchaser and is not transferable. This warranty applies solely to the VALO SCOUT and does not cover any accessory components such as batteries, chargers, adapters, and adaptive lenses. Other warranties periods and service conditions apply to all accessory parts. All defective products are to be returned to Ultradent. There are no user service components of the VALO SCOUT system. Tampering with VALO SCOUT will void its warranty.

WARNING: When sending units in for repair, service, or calibrations, **always remove the batteries** from the VALO SCOUT and charger. Wrap batteries, charger, adapter, and VALO SCOUT separately in the return box.

WARNINGS and PRECAUTIONS

Read all instructions before operating this unit.

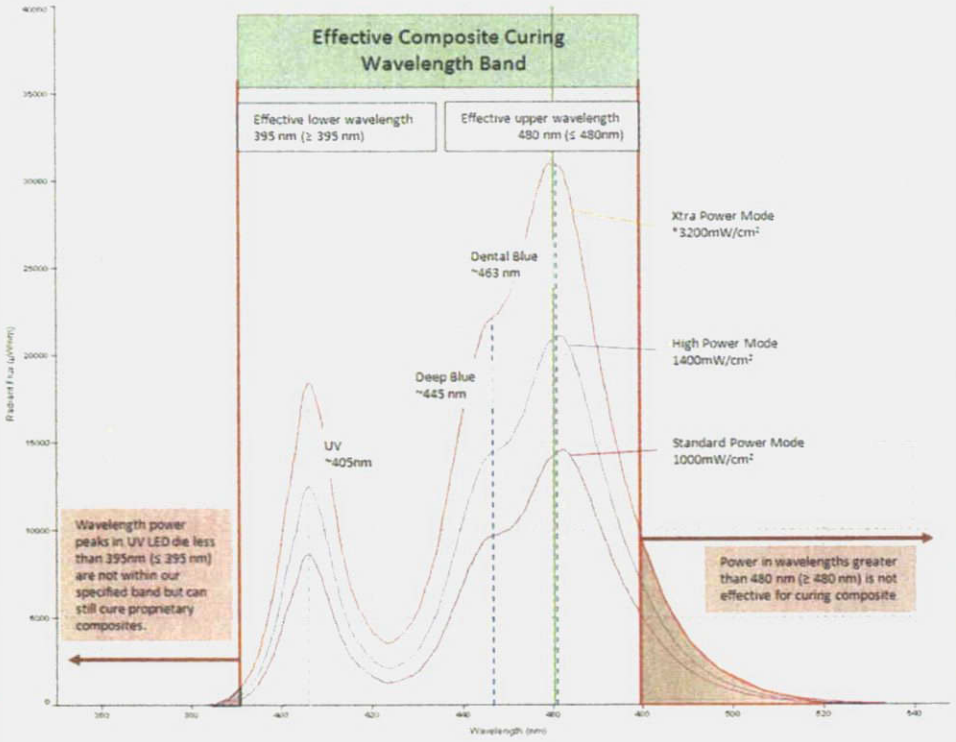
The manufacturer accepts no liability for any damage resulting from the improper use of this unit and/or for any purpose other than those covered by these instructions.

USER - PATIENT SAFETY WARNINGS:

- **The VALO SCOUT curing light emits extremely high intensity light very similar to high intensity quartz halogen lights and must only be used as indicated in this manual.**
- **DO NOT look directly into the light output. Patient, clinician and assistants should wear UV orange eye protection when this device is in use.**
- **DO NOT expose soft oral tissues at close proximity. Maintain a minimum of 2mm between the lens and the soft tissue.**
- **If using the VALO SCOUT curing light in close proximity of the gingival, DO NOT exposes tissue for more than 20 seconds. If a 40-second cure is needed, allow 2 minutes between two 20 second cures. If longer curing time is required, consider a dual-cure.**
- **In Xtra Power mode, DO NOT expose soft oral tissue for more than 10 seconds. The Xtra Power mode has a 2 second safety delay to limit heating during consecutive curing. If a longer cure is needed, allow 2 minutes between consecutive cures or consider a dual-cure product (composite or adhesive).**

PRODUCT SAFETY WARNINGS:

- **DO NOT autoclave.**
- **DO NOT immerse in disinfectant, cleaning solutions, or any kind of liquid.**
- **DO NOT immerse in any kind of ultrasonic bath.**
- **PRECAUTION: Static Electricity – This unit may be susceptible to strong magnetic or static electric fields which could disrupt the programming. If you suspect this has occurred, remove the batteries from the unit momentarily and then re-insert them.**

Technical Information	VALO CORDLESS Curing Light
Wavelength range	395nm – 480nm (see qualification below) Effective output Power of VALO CORDLESS falls within the following wavelength range: • 395nm <= EP <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48 
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10% † Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation') **** As measured by a Demetron® L.E.D, Radiometer*** ***† As measured by a spectrum analyzer*** ***Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer***

answer for question #6

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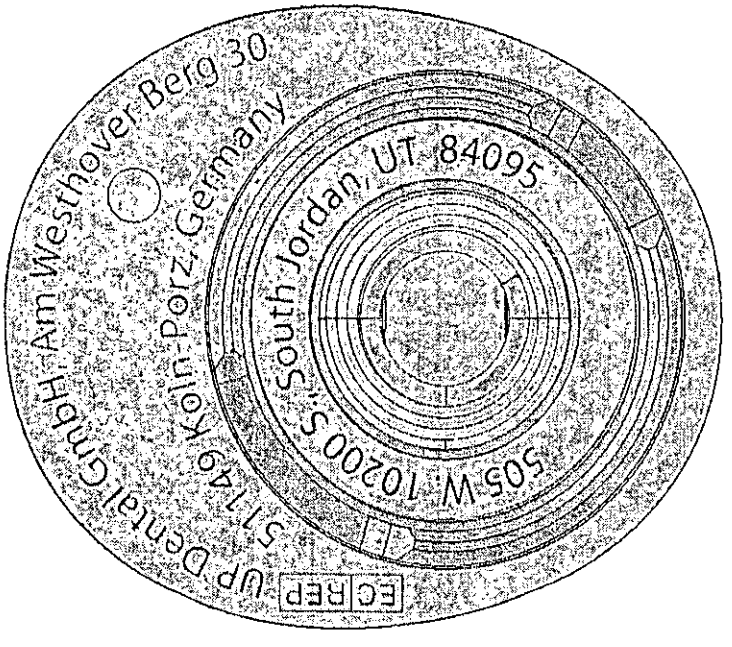
(b) (4)

Black
pms 312 blue
pms 356 green
pms 877 metallic silver (if not silver material)

88935.1 022811

(b) (4)



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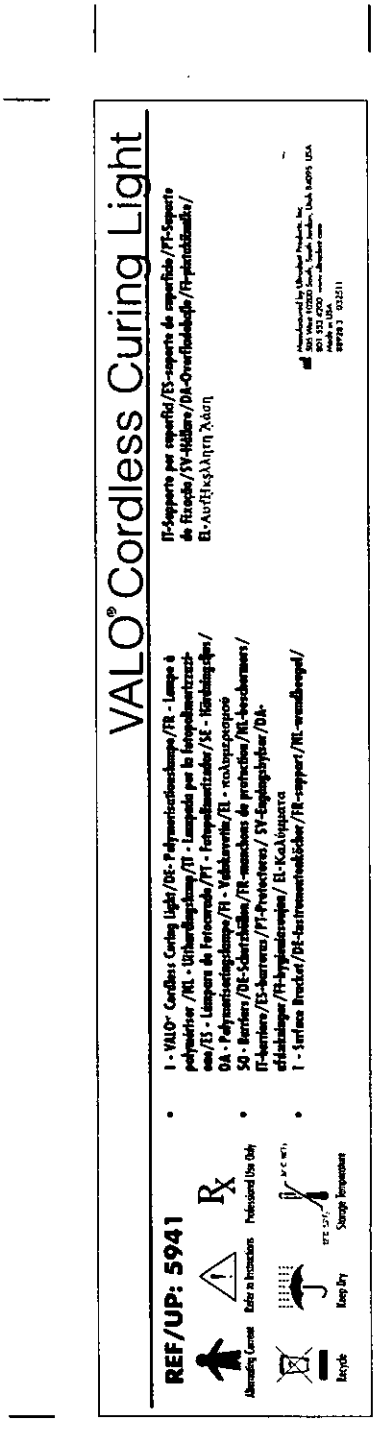


(b) (4)

SPECIAL 510(K) PREMARKET SUMMARY

VALO® Cordless

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for VALO® Cordless.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	April 1, 2011

Name of the Device

Trade Name:	VALO® Cordless
Common Name:	Activator, ultraviolet for polymerization
Device Classification:	II
Classification Product Code:	EBZ

Legally Marketed Predicate Device to Which Equivalence is Claimed

The predicate device is VALO® (K083647). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

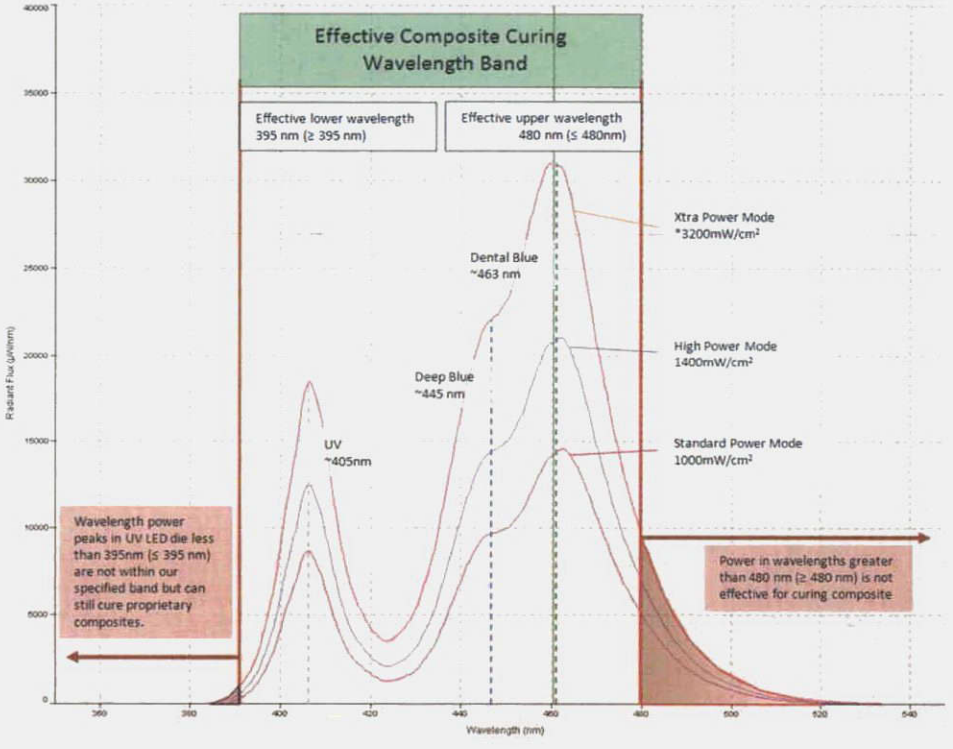
Product Description: Valo® Cordless is a visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials. The VALO Cordless is shipped as a system with the VALO Cordless wand, 4 rechargeable batteries, 2 for initial use and 2 for later use, a battery charger and 50 VALO Cordless Barrier Sleeves. An Instruction for Use is also included inside the packaging. The Instructions for Use details the function of the device and describes the modes for the VALO Cordless. VALO Cordless has three operating modes. They are Standard Power Mode: 1000mW/cm^2, High Power Mode: 1400mW/cm^2 and Xtra Power Mode: 3200mW/cm^2.

Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Technological Summary: The VALO CORDLESS curing light uses a custom, multi-wavelength Light Emitting Diode (LED) for producing the high intensity light (395 - 480 nm) capable of polymerizing all light cure dental materials. This intensity will also penetrate porcelain and is capable of curing underlying resin cements similarly to a quality halogen light.

The VALO CORDLESS curing light uses safe Ultradent VALO rechargeable batteries and battery charger.

Performance Data:

	VALO CORDLESS Curing Light
Wavelength range	395nm – 480nm (see qualification below) Effective output Power of VALO CORDLESS falls within the following wavelength range: • 395nm <= EP <= 480nm. Minimal and insignificant power can be found in wavelength ranges from: • 380nm – 395nm and 480nm – 510nm ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48 
Light intensity	* Standard power – 1000mw/cm2 +/-10% * High power – 1400mw/cm2 +/-10%

	† Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation') ** As measured by a Demetron® L.E.D, Radiometer* *† As measured by a spectrum analyzer* *Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer*

Conclusion:

Comparison Table

	VALO® (K083647)	VALO® Cordless
Power Supply	Wall powered, 12VDC, medical grade with adapters for International capability UL Approved	Same
Indications For Use	Source of illumination for curing photo-activated dental restorative materials and adhesives.	Same
Structure	Ergonomic wand	Same
Light	Blue and UV wavelengths	Same
Current control	Regulates current in the light source	Same
Buttons	Two buttons that function the light	Same
Power ON button	Located on handle of wand	Same
Power cord	8' length	Same
Time	Device indicates time and time selection	Same
Power Rating	Plasma Emulation Mode is 4500mW/cm²	Xtra Power mode is 3200mW/cm²
Operation	110VAC	110VAC

Substantial Equivalence:

The VALO™ SCOUT is substantially equivalent to the VALO™ which is also manufactured by Ultradent Products, Inc. These two products are manufactured from the same materials, utilize many of the same components, are calibrated to the same levels and parameters, are used in the same manner and fashion, and are designed to operate and function in a near identical manner. The VALO™ SCOUT was designed to be the VALO™ but without the cord. The programming code is near identical, save micro-controller variations and enhanced safety features. Both products have the same intended use and technological characteristics. Both products are safe and effective when used for as intended and for the purposes described.
The following three tests were conducted along with bench tests described in the 510(k); depth of cure, software verification and validation and IEC 60601 Electrical Safety.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/ADA Specification # 48 Visible light Curing Units

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b) (4)

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/ADA Specification # 48 Visible Light Curing Units

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire document	Visible Light Curing Units	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(b) (4)

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601 medical electrical equipment General requirements for basic safety and essential performance

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☑
FDA Recognition number [3]	#: _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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 (b) (4) PSC Graphics (301) 443-1090 EF

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1 Medical Electrical Equipment General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Entire document	General requirements for basic safety and essential performance	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Rockville, MD 20850

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(b) (4)