VALO™

CORDLESS

ULTRADENT PRODUCTS, INC.

Improving Oral Health Globally

VALO™ Cordless
Curing Light

EN

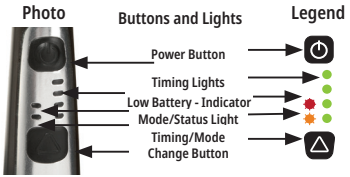
1. Product Description

With its broadband spectrum, VALO Cordless is designed to polymerize all light cured products in the wavelength range of 385-515nm per ISO 10650. The VALO Cordless curing light uses Ultradent VALO rechargeable batteries and battery charger. The curing light is designed to rest in a standard dental unit bracket or can be custom mounted using the bracket included with the kit.

VALO Cordless Product Components:

- 1 – VALO Cordless curing light
- 4 – Ultradent VALO rechargeable batteries
- 1 – Ultradent VALO battery charger with medical grade 12VDC AC power adapter
- 1 – VALO Barrier Sleeve sample pack
- 1 – VALO Cordless Light Shield
- 1 – Curing light surface mounting bracket with double stick adhesive tape

Overview of Controls:



For all products described, carefully read and understand all instructions and SDS information prior to use.

2. Indications for Use/Intended Purpose

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

3. Warnings and Precautions

Risk Group 2
CAUTION UV emitted from this product. Eye or skin irritation may result from exposure. Use appropriate shielding.
CAUTION Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes.

- DO NOT look directly into the light output. Patient, clinician, and assistants should always wear amber colored UV eye protection when curing light is in use.
- To prevent the risk of electric shock, no modification of this equipment is allowed. Use only the included Ultradent VALO power supply and plug adapters. If these components are damaged, do not use and call Ultradent Customer Service to order a replacement.
- Portable RF communications equipment may degrade performance if used closer than 30 cm (12 in").
- Use only authorized accessories, cables, and power supplies to prevent improper operation, increased electromagnetic emissions or decreased electromagnetic immunity (refer to Electromagnetic Emissions section).
- To avoid the risk of electrical fire associated with handling of batteries:
    - o DO NOT mix rechargeable batteries with non-rechargeable batteries or other battery types.
    - o DO NOT attempt to charge non-rechargeable batteries.
    - o DO NOT autoclave or spray batteries, battery contacts, charger, or AC power adapter with liquid of any kind. If corrosion appears on the contacts of the battery charger, call Ultradent Customer Service to order a replacement.
    - o DO NOT charge batteries around flammable materials.
    - o DO NOT keep charger in clinical operatory.
- To avoid the risk of injury, DO NOT use batteries that are corroded (rust), dented, emit an odor or fluids, have a torn or missing wrapping, or are otherwise damaged. Call Ultradent Customer Service to order replacement batteries.
- To prevent the risk of thermal irritation or injury, avoid back-to-back curing cycles and do not expose oral soft tissues at close proximity for more than 10 seconds in any mode. If

longer curing times are required, use multiple shorter curing cycles or use a dual-cure product to avoid heating soft tissue.

- Use caution when treating patients who suffer from adverse photobiological reactions or sensitivities, patients who are undergoing chemotherapy treatment, or patients being treated with photosensitizing medication.
- 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 re-plug it into the outlet.
- DO NOT wipe down the curing light with caustic or abrasive cleaners, autoclave, or immerse in any kind of ultrasonic bath, disinfectant, cleaning solution, or liquid. Failure to follow included processing instructions may render curing light inoperable.
- To avoid damaging the equipment, DO NOT insert fingers, instruments, or other objects into the battery compartment of the curing light.
- To avoid damaging the equipment, DO NOT attempt to clean the gold contacts, or any part of the battery compartment. Call Ultradent Customer Service if there is a concern.
- To prevent the risk of cross-contamination, barrier sleeves are single patient use.
- To reduce the risk of corrosion, remove barrier sleeve after use.
- To reduce the risk of under-cured resins, do not use curing light if lens is damaged.

4. Stepwise Instructions

Preparation

1. Charge batteries before using the curing light (See section Battery Maintenance).
2. Place the curing light into a standard dental unit mounting bracket or accessory mounting bracket until ready for use.
3. Prior to each use, place a new barrier sleeve over the curing light.

Installing Hygienic Barrier Sleeves:

The hygienic barrier sleeve is custom fitted to the curing light and keeps the surface of the curing light clean. The barrier sleeve helps prevent cross contamination, helps keep dental composite material from adhering to the surface of the lens and curing light, and prevents discoloration and corrosion from cleaning solutions.

Note:

- Using the hygienic barrier sleeve will reduce the light output by 5-10%. Due to the high output power of the curing light, curing has been shown to be substantially equivalent.
- The curing light must be cleaned and sanitized with appropriate cleaning and/or sanitizing agents after each patient. See section titled Processing.

VALO Cordless Light Shield:

The VALO Cordless Light Shield is oval-shaped, can be rotated for maximum use, and can be used with a transparent barrier sleeve.

Use

1. Each power mode is used for the curing of dental materials with photo initiators. See Quick Mode Guide for recommended curing times.
   NOTE: The 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.
2. The curing light stores the most recently used timing interval and mode, and it will default back to this whenever the modes are changed or if the batteries are removed.

Operation

CURING MODE: Standard Power mode

TIMING INTERVALS: 5, 10, 15, 20 seconds.

- The curing light defaults to this mode when it is INITIALLY powered on. The Mode/Status Light will be green and the four green Timing Lights are illuminated, indicating Standard Power mode.
- To change timing intervals, quickly press the Time/Mode 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

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

- From Standard Power mode, press and hold the Time/Mode Change Button for 2 seconds and release. The Mode/Status Light will be orange, and the four green Timing Lights will illuminate and flash, indicating High Power mode.
- To change timing intervals, quickly press the Time/Mode 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 and release, this will cycle to Xtra Power mode. Press and hold again for 2 seconds, and release. The Mode/Status Light will be green and the four green Timing Lights are illuminated, indicating Standard mode.

CURING MODE: Xtra Power mode

TIMING INTERVAL: 3 seconds only (Note: The Xtra Power mode has a 2 second safety delay at the end of each curing cycle to limit heating during consecutive curing. At the end of the

delay, beeping indicates unit is ready for continued use).

- From Standard Power mode, press the Time/Mode Change Button for 2 seconds, release, press and hold again for 2 seconds, and release. The Mode/Status Light will be orange and flash, and three of the green Timing Lights will illuminate and flash, indicating Xtra Power mode.
- 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 the Standard Power mode, press and hold the Time/Mode Button for 2 seconds and release. The Mode/Status Light will be green and the green Timing Lights are illuminated, indicating Standard Power mode.

Sleep Mode: The curing light will go into Sleep Mode after 60 seconds of inactivity, as indicated by a slow flashing of the mode/status light. Picking up or touching the unit will wake-up the curing light and automatically return it to the last setting used. To maximize battery life, leave the curing light undisturbed when not in use.

Cleanup

1. Discard used barrier sleeves in standard waste after each patient.
2. See Processing Section.

Mounting Bracket Instructions

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

Quick Mode Guide

Mode	Standard Power				High Power				Xtra Power
Power Button									
Mode/Timing LEDs									
Time Buttons									
Time Options	5s	10s	15s	20s	1s	2s	3s	4s	3s Only
To Change Time	Press and release Time Button quickly to cycle through time options.								
To Change Modes	Press and hold 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			
Mode	Standard Mode	High Power Mode	Xtra Power Mode
Per Layer	One 10 second cure	Two 4 second cures	One 3 second cure
Final Cure	Two 10 second cures	Three 4 second cures	Two 3 second cures
Note: Exposure settings and times may need to be adjusted due to composite reactivity, shade, distance from the light lens to the composite, and depth of composite layer. It is up to the dental professional to know the requirement for the material they are using to determine the adequate time and settings.			

Quick Warning Guide:

Power Level Warning	Temperature Warning	Service Warning	LED Warning
Replace batteries	Allow for cool down	Call Customer Service for Repair	Call Customer Service for Repair
• Low battery: slow flashing • Shut off: 3 beeps, flashing • Prohibits operation	• 3 beeps • Slow flashing • Prohibits operation	• No sound • Flashing, 2 seconds • Allows operation	• Continuous 3 beeps • Single rapid flash • Prohibits operations
			

5. Maintenance

Repair

User-Performed Repair

1. Routinely check the lens for cured dental resins. If necessary, use a non-diamond dental instrument to carefully remove any adhered resin.
2. Light meters differ greatly and are designed for specific light guide tips and lenses. Ultradent recommends routinely checking the output in Standard Power mode. NOTE: the true numeric output will be skewed due the inaccuracy of common light meters and the custom LED pack in the curing light.

Manufacturer Repair

1. Repairs are only to be performed by authorized service personnel. Ultradent to provide service personnel with documentation to perform repairs.
2. When sending units in for repair, service, or calibrations, always remove the batteries from the curing light and charger. Wrap batteries, charger, adapter, and the curing light separately in the return box.
3. Ship batteries in accordance with local regulations.

Battery Maintenance

Charging and Changing Batteries

The curing light comes with 4 rechargeable lithium iron phosphate batteries.

How to charge batteries:

1. Plug charger into electrical outlet.
2. Insert batteries into charger with positive (+) end pointed towards the indicator lights on charger.
3. Green Lights indicate batteries are ready for use.
4. Batteries will take 1-3 hours to charge. Leave batteries in charger until ready for use.

NOTE: If the red light on the charger does not turn green when the batteries have been charging longer than three hours, the battery may be degraded (corrupted) and cannot be charged. Try a new battery or call Ultradent Customer Service to order a new set of rechargeable batteries.

How to change/insert batteries:

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

If necessary, Ultradent authorizes the following NON-RECHARGEABLE batteries for the curing light:
NOTE: DO NOT attempt to charge non-rechargeable batteries.

1. Tenergy Propel Photo Lithium
2. Titanium Innovations CR123A
3. Energizer® 123

4. Duracell® Ultra CR123A
5. SureFire® SF123A
6. Panasonic® CR123A

Low Batteries: The curing light 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 curing light will not allow further operation until batteries are recharged or new batteries are inserted. (See Quick Warning Guide)

Charging Time and Battery Life: Fully charged battery life in the curing light is dependent on the Mode/Time interval, battery type, amount of use, and LED efficiency. In general, rechargeable batteries should last 1 - 2 weeks. Non-rechargeable batteries may last 2 - 3 times longer.

- Recommended Recharge Interval: When low battery indicator comes on, or approximately every 1 – 2 weeks, depending on use.
- Extra Batteries: The curing light comes with 4 rechargeable batteries. We also recommend keeping a spare set of non-rechargeable CR123A Batteries on hand in the event of a problem or loss of the rechargeable batteries.
- Battery Life Expectancy: Rechargeable Lithium Iron Phosphate batteries can be recharged approximately 1000 to 2000 times. Based on normal use and proper care, batteries should last up to five years, but should be replaced as necessary.

Warranty

Ultradent hereby warrants that this instrument shall, for a period of 5 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 Cordless curing light system. Tampering with the VALO Cordless curing light will void its warranty. The VALO Cordless curing light warranty does not cover customer damage. For example; if a VALO Cordless is misused or dropped and the lens breaks, the customer would be responsible to pay for any necessary repairs.

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

6. Processing

After each use, moisten a gauze or soft cloth with an approved surface disinfectant and wipe the surface and lens.

ACCEPTABLE CLEANERS:

- Lysol Brand III Disinfectant Spray (Recommended)
- Isopropyl alcohol
- Ethyl alcohol-based cleaners
- Lysol®* Concentrate (alcohol-based only)
- Cavicide™* products (Non-Bleach)**

UNACCEPTABLE CLEARNERS - DO NOT USE:

- Strong alkali detergent of any type, including hand soaps and dish soaps
- Bleach-based cleaners (e.g. Clorox™*, Sterilox™*)
- Hydrogen Peroxide based cleaners
- Abrasive Cleansers (e.g. Comet Cleanser™*)
- Acetone or hydrocarbon-based cleaners
- MEK (Methyl Ethyl Ketone)
- Birex®*
- Gluteraldehyde
- Quaternary Ammonium Chloride salt-based cleaners (except Cavicide™*)
- Cavicide1™* solution or wipes

*Trademark of a company other than Ultradent

** If used, it may fade the color

BATTERY CHARGER:

If cleaning becomes necessary then unplug charger, dampen a cloth with isopropyl alcohol, and gently wipe the surface of the charger or batteries. Let the charger dry completely before resuming use.

CLEANING THE LIGHT SHIELD:

Cold disinfect the VALO Cordless Light Shield using any surface disinfectant. DO NOT autoclave.

7. Storage and Disposal

If storing the curing light for periods longer than 2 weeks, or packing it for travel, always remove the batteries. If batteries are left in the unit for long periods of time without recharging they may become nonfunctional or un-chargeable. Do not store batteries in temperatures over 60°C (140°F) or in direct sunlight.

Curing light Storage and Transport:

- Temperature: +10°C to +40°C (+50°F to +104°F)
- Relative Humidity: 10% to 95%
- Ambient Pressure: 500 hPa to 1060 hPa

When disposing of electronic waste, (i.e. devices, chargers, batteries and power supplies), follow local waste and recycling guidelines.

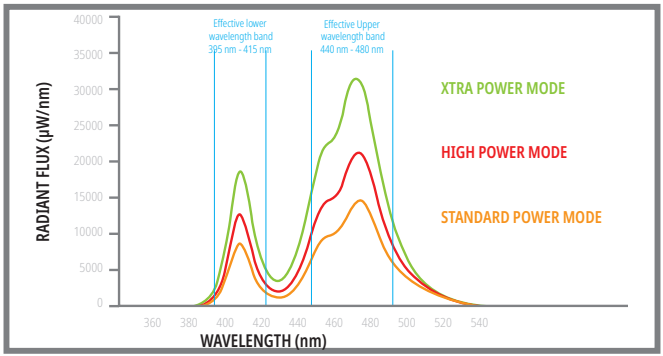
8. Technical Considerations

Accessories

Item	CE Information		
VALO Barrier Sleeves	CE EC REP MDSS GmbH Schiffgraben 41 30175 Hanover Germany	Manufactured by: TIDI Products, LLC. 570 Enterprise Drive Neenah, WI 54956 Made in USA	Distributed by: Ultradent Products Inc 505 West Ultradent Drive (10200 South) South Jordan, UT 84095 USA
VALO Cordless Light Shield	CE		
VALO Charger	CE		
VALO Batteries	CE		

Technical information/Data

Effective Composite Curing Wavelength Bands:



<table>
<tr><th>Attribute</th><th colspan="6">Information/Specification</th></tr>
<tr><td>Lens</td><td colspan="6">Diameter 9.75 mm</td></tr>
<tr><td>Wavelength range</td><td colspan="6">• Utilizable wavelength range: 385 – 515nm
• Peak wavelengths: 395 – 415nm and 440 – 480nm</td></tr>
<tr><td rowspan="6">Light Intensity Table</td><td colspan="5">Nominal Radiant Exitance Comparison Chart</td><td rowspan="6">Radiant Exitance will vary based on instrument capability, measurement method and light placement.
† Demetron radiometers and MARC spectrum analyzers should be used as reference only due to having smaller apertures than VALO curing lights.
* Demetron radiometers should be used as reference only due to limitations in power and spectral response.
‡ Radiant Exitance conforms to ISO 10650 when measured with a Gigahertz spectrum analyzer.</td></tr>
<tr><td>Measurement Instrument</td><td>†* Demetron L.E.D. Radiometer</td><td>† MARC spectrum analyzer</td><td colspan="2">‡ Gigahertz spectrum analyzer</td></tr>
<tr><td></td><td></td><td></td><td>Exitance</td><td>Total Power</td></tr>
<tr><td>Aperture of Meter</td><td>7 mm</td><td>3.9 mm</td><td>15 mm</td><td>15 mm</td></tr>
<tr><td>Standard Power (±10%)</td><td>1000 mW/cm^2</td><td></td><td>900 mW/ cm^2</td><td>670 mW</td></tr>
<tr><td>High Power (±10%)</td><td>1400 mW/cm^2</td><td></td><td>1300 mW/ cm^2</td><td>970 mW</td></tr>
<tr><td>Xtra Power (±10%)</td><td></td><td>3200 mW/cm^2 (+/-20%)</td><td>2100 mW/ cm^2</td><td>1570 mW</td></tr>
<tr><td>VALO Cordless Curing Light</td><td colspan="3">Ratings: IEC 60601-1 (Safety), IEC 60601-1-2 (EMC)</td><td colspan="3">Weight:
• With batteries: 6 oz. (190 grams)
• Without batteries: 5 oz. (150 grams)
Dimension: (8 x 1.28 x 1.06) inches, (203 x 32.5 x 27) mm</td></tr>
<tr><td>Charger Power Supply</td><td colspan="3">Output - 12VDC at 500mA
Input - 100VAC to 240VAC
Ultradent P/N 5930 VALO Charger Power Supply with international plug inserts</td><td colspan="3">Ratings: IEC 60601-1 (Safety)
Cord Length - 6 feet (1.8 meters)
VALO Charger Power Supply is a Medical Grade Class II power supply and provides isolation from MAINS power</td></tr>
<tr><td>VALO Charger</td><td colspan="6">VALO 3.6VDC Lithium Iron Phosphate smart battery charger:
• 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</td></tr>
<tr><td>VALO Batteries</td><td colspan="6">Rechargeable: Safe chemistry Lithium Iron Phosphate (LiFePO4) RCR123A
• Working Voltage: 3.2VDC
Ratings: UL, CE, RoHS, WEEE</td></tr>
<tr><td>Operating Conditions</td><td colspan="6">Temperature: +10°C to +32°C (+50°F to +90°F)
Relative Humidity: 10% to 95%
Ambient Pressure: 700 hPa to 1060 hPa</td></tr>
<tr><td>Duty Cycle:</td><td colspan="6">The curing light is designed for short-term operation. At maximum ambient temperature (32°C) 1 minute ON back-to-back cycling, 30 minutes OFF (cooling-off period).</td></tr>
</table>

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rouble Shooting

If the solutions suggested below do not rectify the problem, please call Ultradent at 800.552.5512. Outside the United States, call your Ultradent distributor or dental dealer.	
Problem	Possible Solutions
Light will not turn on	1) Press the Time/Mode or Power Button to wake from Power Save Mode. 2) Check the red Low Battery Indicator for battery charge status. 3) Check that fresh batteries are correctly inserted into the unit. 4) If red and yellow Warning LEDs are flashing this means the curing light has reached its internal temperature safety limit. Allow the curing light to cool down for 10 minutes or use a cool moist towel to cool the unit down quickly. 5) If red Warning LED flashes and beeps continuously, call Ultradent Customer Service for repair.
Light does not stay on for desired time	1) Check Mode and Timing lights for correct time input. 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. 2) Using proper amber UV eye protection, verify the LED lights are working. 3) Check power level with light meter. If using a light meter, Ultradent recommends checking the curing light 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 the curing light uses. Light meters differ greatly and are designed for specific light guide tips and lenses. 4) Check expiration date on curing resin. 5) Ensure proper technique is being followed according to manufacturer recommendations.
Batteries will not charge	1) Make sure batteries are inserted into the charger in the correct orientation and allow batteries to charge for 1-3 hours. 2) If red lights 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 lights on the charger are visible, call Ultradent Customer Service to order or replace charger and/or AC adapter.
Charger does not charge batteries	1) Make sure charger is plugged in and AC adapter is plugged into a working power outlet. 2) If green or red lights on the charger are not visible, call Ultradent Customer Service for new charger and/or AC adapter.
Cannot change mode or time intervals	1) Hold both Time/Mode and Power buttons down until a series of beeps indicates the curing light is unlocked.

9. Miscellaneous Information

Guidance and Manufacture's Declaration for Electromagnetic Emissions		
The curing light is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The curing light uses batteries and is not affected by EMI, RF, or surge suppression. The curing light uses electrical and electromagnetic energy only for their internal functions. Therefore, any RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	N/A	Harmonic emission and voltage fluctuation testing are not applicable to the curing light because it is battery powered.
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	The curing light is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.

Guidance and Manufacture's Declaration for Electromagnetic Immunity			
The curing light is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Physical environment should be restricted to the following: 1. IP Code: IP20 2. Do not immerse in liquid. 3. Do not use around flammable gas. Unit is Non-APG and Non-AP. 4. Storage humidity range: 10% - 95% 5.Storage temperatures range: 10° C - 40° C
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Note 1: The curing light has no I/O ports	The curing light is battery powered and is not capable of connection to AC MAINS power. Because the curing light is battery powered, it is not subject to electric transients, surges, voltage dips, shorts, interruptions, or variations on AC MAINS power. The accessory battery charger may be subject to the above but it is separate from and not critical to the operation of the VALO Cordless curing light. If battery voltage of the curing light drops to 4VDC the unit will not allow operation. The VALO Cordless curing light will turn off. When new batteries are put in and the proper power levels are restored, the curing light will restart and return to the same state before power loss. The curing light will self-recover in the event of power loss.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	
Voltage, dips, shorts, interruptions and variations on the power supply input lines IEC 61000-4-11	<5% U (>95% dip in U for 0.5 cycle) 40% U (60% dip in U for 5 cycles) 70% U (30% dip in U for 25 cycles) <5% U (>95% dip in U for 5 s)	<5% U (>95% dip in U for 0.5 cycle) 40% U (60% dip in U for 5 cycles) 70% U (30% dip in U for 25 cycles) <5% U (>95% dip in U for 5 s) Note 2: Self recovers	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical, residential, home health care, commercial, hospital, or military environment.
Note 1: The curing light is not equipped with any ports or any accessible I/O lines.			

Guidance and Manufacture's Declaration for Electromagnetic Immunity for non-life support systems			
The curing light is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conduction RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the curing light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF	3 V/m	3 V/m	
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the curing light is used exceeds the applicable RF compliance level above, the VALO Cordless curing light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the curing light.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacture's Declaration for recommended separation distances between portable and mobile RF communications equipment and the VALO Cordless curing light			
The curing light is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the curing light can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the curing light as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (P in Watts)	Separation distance according to frequency of transmitter (meters)		
	150 kHz – 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz – 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz – 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12 meters	0.035 meters	0.07 meters
0.1	0.37 meters	0.11 meters	0.22 meters
1	1.7 meters	0.35 meters	0.7 meters
10	3.7 meters	1.11 meters	2.22 meters
100	11.7 meters	3.5 meters	7.0 meters

The curing light has been tested according to IEC 60601-1-2:2014 and passed under radiated field strengths of 10 V/m between 80-MHz to 2.5 GHz. The value of 3Vrms corresponds to V1 and the value 10 V/m corresponds to E1 in the formulas above.
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

VALO™ 无线光固化机

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1. 产品描述

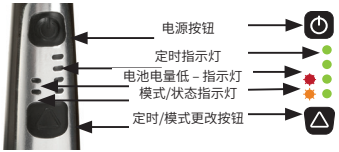
VALO无线光固化机使用定制、多波长的发光二极管产生400-515nm的高强度光，可固化所有光固化牙科材料。使用VALO充电电池和电池充电器进行充电。机头的设计适合在标准牙科综合治疗台支架上使用，或放在配套的支架上。

结构组成：

- 1台--无线光固化机
- 4节--Ultradent VALO充电电池
- 1个--Ultradent VALO电池充电器并配备医用级的12V 交直流适配器
- 1包--一次性使用保护套
- 1个--VALO遮光罩
- 1个--固定支架

控制按钮概述：

照片　　按钮和指示灯　　图例



对于所描述的产品，使用前请仔细阅读并理解所有说明和 SDS 信息。

2. 适用范围

本产品用于牙科光动力材料和粘合剂的固化。
禁忌症
无。

3. 警告和注意事项

风险组 2
请注意，本产品发射紫外线。暴露可能会导致眼睛或皮肤刺激。进行适当的遮蔽。
请注意，本产品可能会发射危险光射线。请勿直视手术灯。可能对眼睛有害。

- 切勿直视固化光。使用该设备时患者、医生和助手必须佩戴防紫外线橙色护目镜。
- 为了预防电击危险，不得对本设备进行任何改动。只准使用随带的Ultradent VALO电源适配器和转换插头。如果这些组件损坏，请不要再使用并致电Ultradent客户服务部订购更换件。。
- 如果使用距离小于30厘米（12英寸），便携式射频通信设备可能会降低性能。
- 只准使用经授权的附件、电缆和电源，以防止操作不当、电磁辐射加大或电磁抗扰性下降（请参见电磁辐射章节）。
- 为避免与处理电池相关的电气火灾风险：
  - o 请勿将充电电池与非充电电池或其他类型的电池混用。
  - o 请勿尝试为非充电电池充电。
  - o 请勿使用任何类型的液体对电池、电池触点、充电器或交流电源适配器进行高压灭菌或冲洗。如果电池充电器的触点出现腐蚀，请致电Ultradent客户服务部订购更换电池。
  - o 请勿在易燃物料周围给电池充电。
  - o 请勿在临床操作中使用充电器。
- 为避免伤害风险，请勿使用腐蚀（生锈）、凹陷、散发异味或液体、包装破损或丢失或其他损坏的电池。致电Ultradent客户服务部可订购更换电池。
- 为了防止热刺激或伤害风险，请避免连续循环固化，并且在任何模式下都不要将口腔软组织在近处暴露 10 秒以上。如果需要更长的固化时间，请使用多个较短的固化循环或使用双固化产品以避免加热软组织。
- 当治疗患有不良光生物反应或过敏症的患者、接受化学治疗的患者或接受光敏药物治疗的患者时，请格外谨慎。
- 本装置可能会受强磁场或静电场的影响，从而干扰编程。如果您怀疑已发生这种情况，请立即拔掉装置的电源，然后再将其插入插座。
- 请勿用腐蚀性或研磨性清洁剂、蒸汽灭菌器或浸入任何类型的超声波浴、消毒剂、清洁溶液或液体擦拭光固化机。不遵循随带的处理说明可能会导致光固化机无法操作。
- 为避免损坏设备，请勿将手指、设备或其他物体放入光固化机的电池盒内。
- 为避免损坏设备，请勿尝试清洁金触点或电池盒的任何部件。如有疑虑，请致电Ultradent客户服务部。
- 为了预防交叉污染，保护套仅限单个患者使用。
- 为降低腐蚀风险，使用后请取下保护套。
- 为了降低未完全固化树脂的风险，如果镜头损坏，请勿使用固化灯。

4. 分步说明

准备

1. 使用光固化机前请为电池充电（请参见电池维护章节）。
2. 将光固化放入标准牙科综合治疗台安装支架或安装支架附件上，直到做好使用准备。
3. 在每次使用之前，在光固化上放置一个新的一次性保护套。

使用一次性保护套：
使用专门为VALO光固化机设计的一次性保护套能保持光固化机的表面清洁。一次性保护套有助于预防交叉感染，有助于保持牙科复合材料不粘附到镜头和光固化机的表面上，并且预防因清洁溶液而变色和腐蚀。
注：

- 使用一次性保护套将减少光输出 5-10%。由于光固化机的高输出功率，固化效果已被证明是基本相当的。
- 光固化机必须在每位患者使用后使用适当的清洁和/或消毒剂进行清洁和消毒。请参见清洁与保养的章节。

无线VALO遮光罩：
无线VALO遮光罩为椭圆形，可旋转以实现最大化的使用，而且可以与透明的一次性保护套配套使用。
使用

1. 每种功率模式均用于固化含光引发剂的牙科材料。请参见快速操作指南了解建议固化时间。
   注：按照程序设定，本型号的光固化机需要完成从标准模式到强光模式再到超强模式的顺序切换。比方说要从标准模式切换到超强模式，必须先切换到强光模式，再切换到超强模式。
2. 光固化机总是存储最近一次使用过的光照时间和模式。在切换模式或取下电池时默认切换到该光照时间和模式。

操作
固化模式：标准模式——1000mW/cm2
固化时间：5、10、15、20 秒。

- 光固化机初次通电时默认这一模式。状态灯为绿色，且绿色指示灯常亮。
- 要更改定时间隔，请快速按定时/模式按钮。
- 按电源按钮可进行固化。要在完成设定固化时间之前停止固化，请再次按电源按钮。

固化模式：强光模式——1400mW/cm2
固化时间：1、2、3、4 秒。

- 在标准功率模式下，按下并保持住定时/模式更改按钮 2 秒，此时绿色指示灯亮起并闪烁。状态灯为橙色常亮，表明进入强光模式。
- 迅速按下定时/模式按钮切换固化时间。
- 按电源按钮可进行固化。要在完成设定固化时间之前停止固化，请再次按电源按钮。
- 若要返回标准模式，按住定时/模式按钮2秒后松开，这将切换到超强模式，然后再按2秒松开，切换到标准模式。

固化模式：+超强模式——3200mW/cm2
固化时间：仅 3 秒（注超强模式在每次固化循环结束时都有一段 2 秒的安全延时，以限制在连续固化期间进行加热。延时结束时，笛音将响起，表示装置可以继续使用）。

- 从标准模式持续按下定时/模式按钮2秒后松开，再按2秒，再松开，三盏绿色指示灯和橙色状态灯亮起并闪烁，表示进入超强模式。
- 按电源按钮可进行固化。要在完成设定固化时间之前停止固化，请再次按电源按钮。
- 若要返回标准模式，按住定时/模式按钮2秒，然后松开。模式/状态指示灯将为绿色，绿色指示灯将亮起，表示标准功率模式。

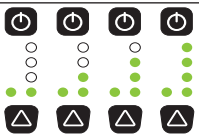
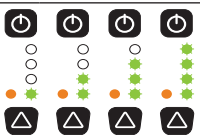
睡眠模式：光固化机将在60秒钟无动作后自动进入“睡眠”状态，此时，模式/状态灯将会慢闪。拿起或触碰机身则会“唤醒”光固化机，并自动返回到最近一次使用时的设置。为了最大限度地延长电池寿命，请在不使用时保持光固化机不受干扰。
清理

1. 每次患者使用之后，将使用过的一次性保护套弃置在普通垃圾中。
2. 参见清洁与保养章节。

安装支架说明

1. 支架应安装在平整、无油的表面上。
2. 用医用酒精清洁表面。
3. 撕掉支架的胶带。
4. 定位支架，以使取出光固化机时的方向朝上。牢固地按压到位。

快速操作指南

模式	标准模式				强光模式				超强模式
电源按钮 定时/模式LED灯 定时/模式按钮									
固化时间	5秒	10秒	15秒	20秒	1秒	2秒	3秒	4秒	3 秒
更改定时	快速按下然后释放定时按钮可切换固化时间。								
切换模式	快速按住定时/模式按钮2秒，然后释放。光固化机会切换至下一个模式。								
图例	LED灯常亮 ● ●				LED灯闪烁 ✸ ✸				

快速固化指南：

VALO光固化机实现最佳效果的建议固化时间			
模式	标准模式	强光模式	超强模式
每层	一次 10 秒固化	两次 4 秒固化	一次 3 秒固化
最后固化	两次 10 秒固化	三次 4 秒固化	两次 3 秒固化
注：固化模式和固化时间可能因复合材料反应活性、色度、光镜头到复合材料的距离以及复合层的深度而需要调节。牙科专业人员需要了解他们所用材料的要求，以确定适当的固化模式和固化时间。			

快速警示指南：

功率水平警示	温度警示	校准警示	LED 警示
更换电池	允许降温	致电客户服务部进行维修	致电客户服务部进行维修
· 电池电量低：慢闪 · 关闭：3 声笛音，闪烁 · 禁止操作	· 3 声笛音 · 慢闪 · 禁止操作	· 无声音 · 闪烁，每 2 秒一次 · 允许操作	· 连续 3 声笛音 · 单快闪 · 禁止操作
			

5. 维护

维修

用户日常维护

1. 例行检查镜头上是否存在固化的牙科树脂。如必要，使用非金刚砂类的牙科器械小心翼翼地清除任何粘附的树脂。
2. 测光表各不相同，需针对特定的导光棒和镜头进行设计。Ultradent建议例行检查标准功率模式下的输出功率。注：实际数值可能与测量值存在偏差。

厂家维修

1. 维修只准由经授权的服务人员进行。Ultradent提供服务人员及相关文件，以执行维修。
2. 将设备返厂进行维修、保养或校准时，请务必取出光固化机和充电器中的电池。在返厂包装箱中分别对电池、充电器、适配器和光固化机进行单独包装。
3. 按当地法规装运电池。

电池维护

充电和更换电池

光固化机配有4节可充电磷酸锂铁电池。

如何给电池充电

1. 将充电器插入电源插座。

2. 将电池插入充电器，正极 (+) 一端指向充电器上的指示灯。
3. 绿灯表明电池充电完毕，可以使用。
4. 电池充满电需要 1-3 小时。将电池留在充电器内，使用时再从中取出。

注：当电池的充电时间超过三小时时，如果充电器上的红色指示灯未变为绿色，电池可能已老化（损坏），无法充电。尝试使用新电池或致电Ultradent客户服务部订购一组新的可充电电池。

如何更换/插入电池：
1. 通过逆时针扭转四分之一圈取下后盖。
2. 取出电池。
3. 插入新电池，正极 (+) 一端先插入。
4. 顺时针旋转的同时，通过对齐并轻轻推压重新装入后盖。完全连接时，后盖将卡入就位。
5. 设备可以使用了。

如必要，Ultradent对光固化机授权使用下列非充电电池：
注：请勿尝试为非充电电池充电。

1. Tenergy Propel Photo Lithium
2. Titanium Innovations CR123A
3. Energizer® 123
4. Duracell® Ultra CR123A
5. SureFire® SF123A
6. Panasonic® CR123A

电池电量低：低电量指示灯呈红色并不停闪烁时，光固化机提醒用户电池需要更换。电量过低时会听到3声笛音，光固化机在电池被充足电或更换新电池前将不允许任何操作（详见"快速警示指南"部分）。

充电时间和电池寿命：光固化机的电池寿命取决于模式、光照时间、电池种类、使用频率和LED效率等因素。一般来说，充电电池可以使用约400次固化周期或1-2周。非充电电池的使用时间是充电电池的 2-3 倍。
- 建议充电间隔：当电池电量低指示灯亮起时或大约每隔 1-2 周，具体取决于使用情况。
- 备用电池：光固化机配4节可充电电池。我们还建议预备一组备用的非充电 CR123A 电池，以防可充电电池发生问题或丢失。
- 电池使用寿命：充电磷酸铁锂电池可以重复充电约1000到2000次。在正常使用和护理得当的情况下，电池的使用寿命可达5 年，但必要时应更换。

质保
Ultradent特此保证，本器械在 5 年*的期限内，在所有重大方面均符合本产品所附带的Ultradent文件所规定的各项规格，并且不存在任何材料和/或工艺缺陷。本质保仅适用于原始购买者，且不可转让。所有问题产品均须退回Ultradent。
VALO 无线光固化机无任何用户可维修的组件。擅自改动 VALO 无线光固化机将导致本质保作废。
VALO 无线光固化机的质保不涵盖因客户造成的人为损坏。例如，VALO 无线光固化机被误用或跌落以及镜头破裂，客户将负责支付任何必要的维修费用。
*在销售发票上注明销售日期。

6. 清洁与保养

每次使用后，用纱布或软布蘸取获准的表面消毒剂擦拭表面和镜头

认可的清洁剂：
- Lysol 品牌 III 消毒剂喷液（推荐使用）
- 异丙醇
- 乙醇清洁剂
- Lysol®* 浓缩液（仅限酒精基）
- Cavicide™* 产品（非漂白剂）**

切勿使用：
- 任何种类的强碱清洁剂，包括洗手皂和肥皂
- 有漂白功能的清洁剂（如 Clorox™*、Sterilox™*）
- 过氧化氢基清洁剂
- 研磨类清洁剂（如 Comet Cleanser™*）
- 丙酮或碳氢化合物基清洁剂
- MEK（甲基乙基酮）
- Birex®*
- 戊二醛
- 氯化季铵盐型清洁剂（Cavicide™* 除外）
- Cavicide1™* 溶液或纸巾

*非Ultradent的其他公司商标
** 如使用，可能会使颜色退化

电池充电器：

如需要清洁，请拔下充电器，用异丙醇浸湿一块布轻轻擦拭充电器或电池的表面。在恢复使用之前，让充电器完全干燥。

清洁遮光罩：
使用任何表面消毒剂冷消毒 VALO 无线光固化机遮光罩。请勿高压灭菌。

7. 储存和处置

如果保存光固化机超过2星期，或者携带外出，请务必取出电池。如果电池长时间留在光固化机内部不充电可能导致失灵或无法充电。请勿将电池储存在温度超过 60°C (140°F) 或受阳光直射的地方。
光固化机储存和运输：
- 温度：+10°C 至 +40°C (+50°F 至 +104°F)
- 相对湿度：10% 至 95%
- 环境压力：500 hPa至 1060 hPa

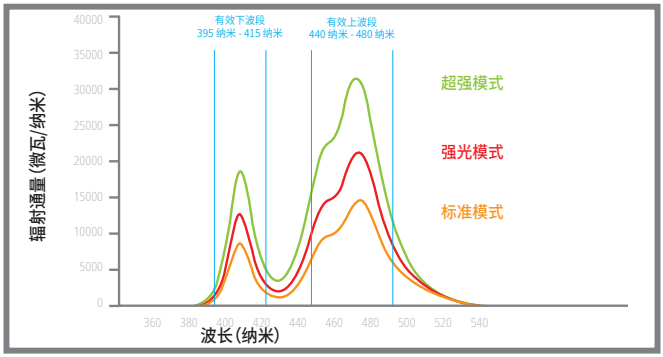
处置电子废弃物（即光固化机、充电器、电池和电源系统）时，请遵守当地废弃物及回收准则。

8. 技术考虑因素

附件

产品	CE 信息		
VALO 一次性保护套	CE EC REP MDSS GmbH Schiffgraben 41 30175 Hanover Germany	制造商： TIDI Products, LLC. 570 Enterprise Drive Neenah, WI 54956 美国制造	经销商： Ultradent Products Inc 505 West Ultradent Drive (10200 South) South Jordan, UT 84095 USA
VALO遮光罩	CE		
VALO 充电器	CE		
VALO 电池	CE		

技术信息/数据
有效的复合材料固化波段



<table>
<tr><th>技术资料</th><th colspan="6">光固化机</th></tr>
<tr><td>镜头</td><td colspan="6">直径 9.75 毫米</td></tr>
<tr><td>波长范围</td><td colspan="6">· 可用波长范围：400nm- 515nm（参见以下条件）
VALO光固化机的有效输出功率在以下波长范围内：
400nm<=有效功率<=515nm
以下波长范围可见最低及无效功率：
· 380nm-400nm和>=515nm</td></tr>
<tr><td rowspan="6">光强度表</td><td colspan="5">公称辐射密度比较图表</td><td rowspan="6">辐射发散度将依仪器能力、测量方法和光照位置不同而有所不同。
† Demetron辐射计和 MARC 光谱分析仪应仅用作参考，因为其孔径小于 VALO 光固化机。
* 由于功率和光谱响应的限制，Demetron 辐射计应仅用作参考。
‡ 使用Gigahertz光谱分析仪测量时，辐射密度符合 ISO 10650 标准。</td></tr>
<tr><td>测量仪器</td><td>† * Demetron L.E.D. 辐射计</td><td>† MARC 光谱分析仪</td><td colspan="2">‡ Gigahertz光谱分析仪</td></tr>
<tr><td></td><td></td><td></td><td>辐射密度</td><td>总功率</td></tr>
<tr><td>仪表孔径</td><td>7 mm</td><td>3.9 mm</td><td>15 mm</td><td>15 mm</td></tr>
<tr><td>标准功率（±10%）</td><td>1000 mW/cm²</td><td></td><td>900 mW/cm²</td><td>670 mW</td></tr>
<tr><td>强光功率（±10%）</td><td>1400 mW/cm²</td><td></td><td>1300 mW/cm²</td><td>970 mW</td></tr>
<tr><td>超强功率（±10%）</td><td></td><td>3200 mW/cm² (+/- 20%)</td><td>2100 mW/cm²</td><td>1570 mW</td></tr>
<tr><td>VALO 无线光固化机</td><td colspan="3">使用限制：光固化机在温度超过50摄氏度时不允许操作。
评级：IEC 60601-1（安全）、IEC 60601-1-2（电磁兼容性）</td><td colspan="3">重量：
· 含电池：6 盎司（190 克）
· 不含电池：5 盎司（150 克）
尺寸：（8 x 1.28 x 1.06）英寸（203 x 32.5 x 27）毫米</td></tr>
<tr><td>交直流电源适配器</td><td colspan="3">输出：12V DC，500mA
输入：100V AC-240V AC
Ultradent P/N 5930 VALO 充电器电源系统，带国际通用插头。</td><td colspan="3">评级：IEC 60601-1（安全）
电源线长：6英尺（1.8米）
VALO 充电器电源系统为医用级 II 类电源系统，提供与电网电源的隔离。</td></tr>
<tr><td>VALO 充电器</td><td colspan="6">VALO3.6V DC磷酸铁锂智能电池充电器：
· 充满电后自动关闭
· 自动检测有缺陷的电池
· 保护：热、过充、短路、反接
o红色 LED – 充电
o绿色 LED – 空电量或充满电
o LED 熄灭 – 短路
· 充电时间：1 – 3 小时
等级：CE、WEEE</td></tr>
<tr><td>VALO 电池</td><td colspan="6">可充电：磷酸铁锂(LiFePO4)安全化学电池RCR123A
· 工作电压：3.2伏直流
评级：UL、CE、RoHS、WEEE</td></tr>
<tr><td>操作条件</td><td colspan="6">温度：10°C-32°C
相对湿度：10% 至 95%
环境压力：700 hPa -1060 hPa</td></tr>
<tr><td>工作循环：</td><td colspan="6">光固化机用于短时操作。在最高环境温度（32°C）下，连续循环工作1分钟，需停机30分钟（冷却期）。</td></tr>
</table>

故障排除指南

如果以下所建议的方法未能排除故障，请致电Ultradent，电话：800.552.5512。在美国境外，请致电您的Ultradent经销商或牙科经销商。	
问题	可能解决方案
灯不亮	1)按下定时/模式或电源按钮，从节电模式中唤醒。 2)检查红色低电量指示灯，以了解电池充电状况。 3)检查新电池安装是否正确。 4)红色及黄色LED灯闪烁表明光固化机达到内部温度安全警戒线。让光固化机冷却10分钟，或用凉爽的湿毛巾辅助设备冷却。 5)如果红色LED警示灯持续闪烁并发出笛音，请致电Ultradent客户服务部以进行维修。
灯在固化时间前熄灭	1)检查模式和定时指示灯的时间输入是否正确。 2)检查电量低指示灯，以了解电池电量状态。 3)检查新电池是否正确插入本装置。
树脂固化效果不佳	1)检查镜头上是否有残留的固化树脂/复合材料。 2)选用合适的防紫外线橙色护目镜，确保LED指示灯正在工作。 3)用照度计检查功率情况。如果使用测光表，Ultradent建议在标准功率模式下检查光固化机。 4)检查固化树脂的有效期。 5) 确保在按制造商的建议遵守正确的技术。
电池无法充电	1)确保将电池正确放入充电器，并充电1-3小时。 2)如果充电器上的红色指示灯不变为绿色，请致电Ultradent客户服务部，以订购更换电池和/或充电器。 3)如果充电器上绿色指示灯或红色指示灯均不亮起，请致电Ultradent客户服务部，以订购或更换充电器和/或交流适配器。
充电器不充电	1)确保充电器接通电源，且交流适配器插入有电的电源插座。 2)如果充电器绿色或红色指示灯都不亮，请致电Ultradent客户服务部，以订购新充电器和/或交流适配器。
无法更改模式或固化时间	1) 同时按住时间/模式和电源按钮，直到发出一连串笛音，表示光固化机已解锁。

9. 其他信息
产品的安全分类：
防电击类型分类：内部电源类；
按防电击的程度分类：B型应用部分；
按对进液的防护程度分类：IPX0设备；
按在与空气混合的易燃麻醉气或与氧或氧化亚氮混合的易燃麻醉气情况下使用时的安全程度分类：属于不能在此两种情况下使用的设备；
按运行模式分类：间歇运行；
无信号输出和信号输入部分；
设备的额定电压：DC 6.4V。
设备是否具有对除颤放电效应防护的应用部分：无；
永久性安装设备或非永久性安装设备：非永久性安装设备。

生产日期
请参见产品标签。

使用期限
见外标签

符号解释：


B型应用部分


请查阅随机文件

电磁兼容

光固化机符合YY0505标准电磁兼容有关要求。
用户应根据随机文件提供的电磁兼容信息进行安装和使用。
便携式和移动式RF通信设备可能影响光固化机性能，使用时避免强电磁干扰，如靠近手机、微波炉等；
指南和制造商的声明详见附件。

光固化机不应与其他设备接近或叠放使用，如果必须接近或叠放使用，则应观察验证在其使用的配置下能正常运行。
除光固化机的制造商作为内部元器件的备件出售的电缆外，使用规定外的附件和电缆可能导致设备或系统发射的增加或抗扰度的降低。

电缆信息

序号	名称	电缆长度（m）	是否屏蔽	备注
1	适配器电缆	1.8	否	/

指南和制造商的声明–电磁发射		
光固化机预期使用在下列规定的电磁环境中，光固化机的购买者或使用者应该保证它在这种电磁环境下使用：		
发射试验	符合性	电磁环境 - 指导意见
GB4824 RF发射	1组	光固化机仅为其内部功能而使用RF能量。因此，它的RF发射很低，并且可能不会对附近电子设备产生任何干扰。 光固化机适于使用在家用和直接连到供家用的住宅公共低压供电网的所有设施中。 谐波辐射和电压波动测试不适用于光固化机，因为它由电池供电。
GB4824 RF发射	B类	
GB17625.1 谐波发射	不适用	
GB17625.2 电压波动/闪烁发射	不适用	

指南和制造商的声明–电磁抗扰度			
光固化机预期使用在下列规定的电磁环境中，光固化机的购买者或使用者应该保证它在这种电磁环境下使用：			
抗扰度试验	GB9706测试电平	符合电平	电磁环境–指南
静电放电（ESD） GB/T 17626.2	±6 kV 接触放电 ±8 kV 空气放电	±6 kV 接触放电 ±8 kV空气放电	物理环境应局限于以下规定： IP代码：IP20 请勿浸入液体。 请勿在易燃气体周围使用。装置不含烷基糖苷和烷基酚。 储存湿度范围：10%-95% 储存温度范围：10°C-40°C
电快速瞬变脉冲群 GB/T 17626.4	±2kV 对电源线 ±1kV 对输入/输出线	±2kV 对电源线	光固化机由电池供电，不能连接到交流电网电源上。 因为光固化机由电池供电，因此不受电瞬变、浪涌、电压骤降、短路、中断或交流电网电源变化的影响。 附件电池充电器可能会受上述各项的影响，但它与 VALO 无线光固化机的操作是分开的，而且对于它的操作并不重要。 如果光固化机的电池电压降至直流 4 伏，则本装置将不允许操作。VALO 无线光固化机将关闭。 当放入新电池并恢复适当的功率等级时，光固化机将重新启动并恢复到与断电前相同的状态。在断电的情况下，光固化机将自动恢复。
浪涌 GB/T 17626.5	±1 kV 差模电压 ±2 kV 共模电压	±1 kV 差模电压	
电源输入线上电压暂降、短时中断和电压变化 GB/T 17626.11	<5 % UT,持续0.5周 （在UT上,>95%的暂降） 40 % UT,持续5周 （在UT上,60%的暂降） 70 % UT, 持续25周 （在UT上,30%的暂降） <5 % UT,持续5s （在UT上,>95%的暂降）	<5 % UT,持续0.5周（在UT上,>95%的暂降） 40 % UT,持续5周（在UT上,60%的暂降） 70 % UT，持续25周（在UT上,30%的暂降） <5 % UT,持续5s（在UT上,>95%的暂降）	
工频磁场（50/60Hz） GB/T 17626.8	30 A/m	30 A/m	工频磁场应具有在典型的商业或医院环境中典型场所的工频磁场水平特性
注 1：UT指施加试验电压前的交流网电压			

指南和制造商的声明–电磁抗扰度-对非生命支持设备和系统

光固化机预期使用在下列规定的电磁环境中，光固化机的购买者或使用者应该保证它在这种电磁环境下使用：

抗扰度试验	GB9706测试电平	符合电平	电磁环境–指南
RF传导 GB/T 17625.6	3 Vrms 150 kHz to 80 MHz	3 Vrms	便携式和移动式RF通信设备不应比推荐的隔离距离更靠近光固化机的任何部分使用，包括电缆。该距离应由与发射机频率相应的公式计算。 推荐的隔离距离 $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
RF辐射 GB/T 17626.3	3 V/m 80 MHz to 2.5 GHz	3 V/m	其中，P是根据发射机制造商提供的发射机最大输出额定功率，以瓦特（W）为单位，d是推荐的隔离距离，以米（m）为单位。b 固定式RF发射机的场强通过对电磁场所勘测a来确定，在每个频率范围b 都应比符合电平低。 在标记下列符号的设备附近可能出现干扰。

注1：在80MHz和800MHz频率上，采用较高频段的公式。
注2：这些指南可能不适合所有的情况，电磁传播受建筑物、物体和人体的吸收和反射的影响。

a 固定发射机场强，诸如：无线（蜂窝/无线）电话和地面移动式无线电的基站、业余无线电、AM（调幅）和FM（调频）无线电广播以及电视广播等，其场强在理论上都不能准确预知。为评定固定式RF发射机的电磁环境，应该考虑电磁场所的勘测。如果测得光固化机所处场所的场强高于上述应用的RF符合电平，则应观测光固化机以验证其能正常运行。如果观测到不正常性能，则补充措施可能是必需的，如重新对光固化机定向或定位。
b 在150KHz～80MHz整个频率范围，场强应该低于3 V/m。

便携式及移动式射频通信设备和光固化机之间的推荐隔离距离

便携式及移动式射频通信设备和光固化机之间的推荐隔离距离

光固化机预期在辐射RF骚扰受控的电磁环境下使用。依据通信设备最大输出功率，光固化机的购买者或使用者可通过下面推荐的维持便携式及移动式RF通信设备（发射机）和光固化机之间最小距离来防止电磁干扰。

发射机的额定最大输出功率/W	对应发射机不同频率的隔离距离/m		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ～ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.37	0.11	0.22
1	1.7	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

对于上表未列出的发射机额定最大输出功率，推荐隔离距离d，以米（m）为单位，能用相应发射机频率栏中的公式来确定，这里P是由发射机制造商提供的发射机最大输出额定功率，以瓦特（W）为单位。
注1：在 80 MHz 和 800 MHz频率上，采用较高频范围的公式。
注2：这些指南可能不适合所有的情况，电磁传播受建筑物、物体和人体的吸收和反射的影响

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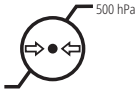
住所：广州市海珠区工业大道北路67号34号楼首层自编102房
联系方式：020-84156506
医疗器械注册证编号/产品技术要求编号：国械注进20152173536
产品名称：光固化机
型号规格：VALO CORDLESS, VALO ORTHO CORDLESS

说明书校准或修订日期：2020-07-20



EN - For professional use only
ZH - 仅供专业人士使用

EN - Importer
ZH - 进口商

EN - Medical Device
ZH - 医疗器械

VALO™
CORDLESS

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Report any serious incident to the manufacturer and the competent authority.

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