

VALO™ X

Curing Light

USE DIRECTIONS

For all references to the Product Specification, see PS# for this product.
Those headers with “(UD Only)” indicate that they do not need to be copied to the IFU.

1. User Profile (UD Only)

- ☒ **Licensed Dental Professional Use Only** – If marked, the Rx symbol is all that is required on IFU.
- ☐ **Licensed Dental Professional & Patient Use** – If marked, the following verbiage must be included in IFU:
“Consult healthcare professional for any device related questions.”
- ☐ **Patient Use Only** – If marked, the following verbiage must be included in IFU: “Consult healthcare professional for any device related questions.”

2. Product Description

With its broadband spectrum, VALO™ X curing light is designed to polymerize all light-cured products in the wavelength range of 380–515 nm per ISO 10650.

The VALO X curing light can be used in a corded or cordless configuration using the Ultradent VALO rechargeable batteries or provided VALO X cord adapter. The curing light is designed to rest in a standard dental unit bracket or can be custom-mounted using the VALO surface mounting bracket included with the kit.

VALO X Product Components:

- 1 – VALO X curing light
- 1 – VALO X cord adapter
- 2 – Ultradent VALO Li-ion 15/740
- 1 – Ultradent VALO battery charging cradle with medical grade 12VDC AC power adapter
- 1 – VALO X barrier sleeve sample pack
- 1 – VALO hand-held light shield
- 1 – VALO surface mounting bracket with double stick adhesive tape
- 1 – VALO X Instructions for Use
- 1 – VALO X Interproximal accessory lens
- 1 – VALO X TransLume accessory lens
- 1 – VALO X White/Black light diffuser accessory lens
- 1 – VALO X ProxiCure accessory lens

- 1 - VALO X PointCure accessory lens
- 1 - VALO X Accessory Lens Use brochure

Overview of Controls:



Quick Start Guide:

Indicator on VALO X	State or function
Blue	Curing modes
White and Violet	Diagnostic aid modes
Red Flashing	Low battery
Red Steady	Dead battery
Amber	Device over temperature
Flashing Red and Green	AF lock out
Indicator on charger	State
Solid Amber	Pre-Charge
Solid Amber	Bulk Charge
Solid Green	Charge Complete
Both off	Standby
Cord Adapter - Remove cap at the base of the curing light with a counter-clockwise turn. Remove battery/cell. Insert cord adapter into battery/cell compartment, fully seat adapter and turn clockwise to lock into place.	

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

3. Delivery Form(s) (N/A - handheld dental instrument)

- Add delivery form(s) here.

4. Composition (N/A – the device is not intended to be absorbed or locally dispersed within the body)

List primary and risk-related composition elements here in their general form without including concentration or ranges.

5. Indications for Use/Intended Purpose

Source of illumination for curing photo-activated dental restorative materials and adhesives and light source for visual aid.

6. Contraindications

Universal (UD Only)

- No known contraindications have been identified for this product.

Chemical (UD Only)

- For patients or users with allergy concerns, refer to product allergen document available at www.ultradent.com. If allergic reaction is observed, rinse exposed area thoroughly with water and have the patient consult their physician.

Country-/Region-Specific (UD Only)

Enter Country/Region (UD Only)

- Add contraindications here.

7. Warnings and Precautions

Universal (UD Only)

- CAUTION Possibly hazardous optical radiation emitted from this product. DO NOT look directly into the curing 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, charger, batteries, 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:
 - DO NOT autoclave or spray battery, battery contacts, charger, or AC power adapter with liquid of any kind. If corrosion appears on the contacts of the smart charger, call Ultradent Customer Service to order a replacement.
 - DO NOT charge batteries around flammable materials
 - DO NOT keep charger in clinical operatory
 - DO NOT charge non-rechargeable batteries/cells
 - DO NOT recharge Ultradent batteries with a non-Ultradent charger
- 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/cells.
- 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 Standard Power mode or 5 seconds in Xtra Power - Triple Pulse 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/cell compartment of the curing light.
- To avoid damaging the equipment, DO NOT attempt to clean the gold contacts, or any part of the battery/cell compartment. Call Ultradent Customer Service if there is a concern.
- To help prevent cross contamination and help keep dental composite material from adhering to the surface of the lens and wand body, a barrier sleeve must be used over the VALO X curing light with each use. Barrier sleeves are intended for 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.
- To prevent the risk of product damage, do not autoclave or dry heat sterilize the VALO X Accessories.
- DO NOT use any VALO X Accessories for complete cure.
- DO NOT use illumination/visualization accessories for curing dental restorative materials and adhesives.

Country-/Region-Specific (UD Only)

Enter Country/Region (CA)

- **WARNING:** This product can expose you to substances which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

8. Stepwise Instructions

NOTE: Prior to each use, place a new barrier sleeve over the curing light, minimizing wrinkles over the lens for best results.

Curing Modes

Curing Mode	Power (mW)	Irradiance (mW/cm ²)	Total Exposure Time (Seconds)	Energy (Joules)	Button Indicator
Standard Power	1,350	1,100	10	13.5	Steady Blue
Xtra Power - Triple Pulse	2,700	2,200	5	13.5	Pulsing Blue

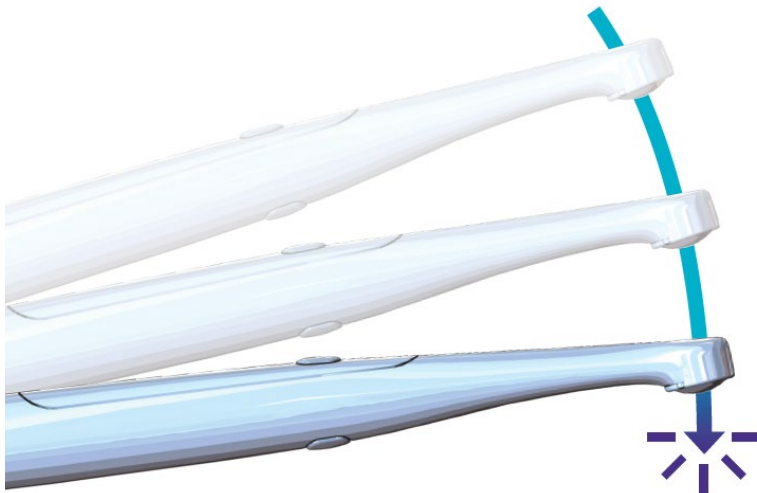
NOTE: Xtra Power - Triple Pulse: 0.5 second auto rest between pulses with 2 second cooling period after completion of the triple pulse.

NOTE: For optimal results, position curing light centered over and as close to resin as possible without contacting surface.

Changing between modes:

Drum Tap (AF = accelerometer function) air forward to change through 2 curing modes:

- Pulsing Blue - Xtra Power - Triple Pulse
- Steady Blue - Standard Power



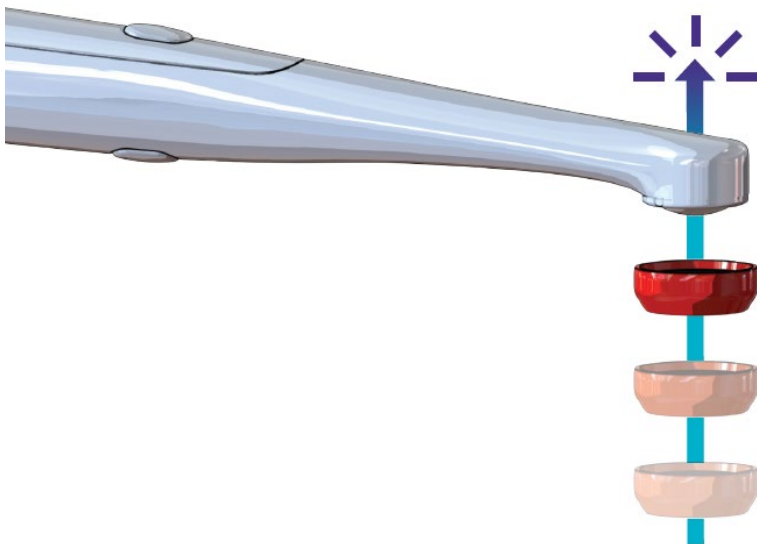
Button Push – hold top button for 1 second to cycle through 2 curing modes

To cycle to Diagnostic Aid Mode from Curing Mode, press and hold the bottom button for 1 second.

Diagnostic Aid Modes - Use with Diffuser Lens

Attaching accessory/diffuser lens:

Accessory/ **diffuser** lenses are attached magnetically over the curing light lens. Place barrier sleeve prior to attaching lens.



Changing between modes:

Drum Tap (AF = accelerometer function): Mid-air side-ways to change through 2 diagnostic aid modes:

- Violet Indication - Black Light Diagnostic Aid Mode
- White Indication - White Light Diagnostic Aid Mode



Button Push - Push and hold bottom button for 1 second to cycle through 2 diagnostic aid modes.

Violet Indication - Black Light Diagnostic Aid Mode – 1 cycle at 1 minute - Turn off with either button press or AF

White Indication - White Light Diagnostic Aid Mode – 1 cycle at 1 minute - Turn off with either button press or AF

To cycle back to Curing Mode from Diagnostic Aid Mode, press and hold the top button for 1 second.

Additional Modes with Button Pressing

- 1) Push and hold both buttons for 1 second to put in sleep mode.
- 2) Push and hold either button for 10 seconds to enable/disable accelerometer function. This mode will persist even after removing/reinserting the battery or cord.
- 3) Upon holding a button, you will get an audible indication at 1 seconds and 10 seconds.
- 4) Upon holding both top and bottom buttons you will get an audible indication when entering sleep. When entering sleep state, you must continue holding until the audible tone is complete. When you enter the sleep state by pressing button press, the VALO X curing light will not wake until either button is pressed.

Accessory	Mode	Indications for Use
PointCure Lens	Curing Mode	Intended to aid the VALO X curing light to polymerize composite through a translucent prosthetic.
ProxiCure Ball	Curing Mode	Intended to aid the VALO X curing light to polymerize composite and help shape contact area matrix of an interproximal restoration.
Diffuser Lens	Diagnostic Aid Mode - White 5000 k	Intended to aid the VALO X curing light to provide for accurate color/shade comparison or whenever natural light is needed.
	Diagnostic Aid Mode - Black < 420 nm	Intended to aid the VALO X curing light to provide visualization of fluorescing chemicals in dental resins.
Interproximal Lens	Diagnostic Aid Mode - White	Intended to aid the VALO X curing light in visualization of teeth and dental prostheses.

Translume	Curing or Diagnostic Aid Modes	Intended to aid the VALO X curing light in visualization by providing longer wavelength light to transilluminate teeth and dental prostheses.
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VALO X Accessories

Preparation

- Position accessory lens near the VALO X curing light lens allowing the magnet to snap the accessory lens into place.

Use – PointCure Lens

- NOTE: The PointCure Lens concentrates the light into a 2.5 mm aperture. This is ideal for point curing (tacking) veneers and all porcelain crowns.
- Point curing (tacking) translucent prosthesis: Point cure prosthesis according to manufacturer guidelines of the luting material, material thickness, shade, and opacity of material, and professional judgement. Clean up the uncured excess luting material around the margins, remove the accessory, then cure the entire restoration. Recommendation: Veneer - point cure the facial/buccal center of prosthesis. Crown - point cure facial/buccal and lingual center of prosthesis.

Use – ProxiCure Ball Lens

- Supports the matrix and aids in convex proximal contact before and during partial light polymerization. Avoid entrapping lens in polymerized material. Remove accessory and cure the entire restoration. Recommendation: Determine mode and time as per composite manufacturer's instructions.

Use – TransLume Lens

- Neon colored lens, which looks like the PointCure Lens, provides longer wavelength light to transilluminate the teeth to aid in visualization of cracks, fractures, defects, etc. Recommendation: Use the Diagnostic Aid Mode - White, which gives 60 seconds of illumination.

Use – Diffuser Lens - Diagnostic Aid mode

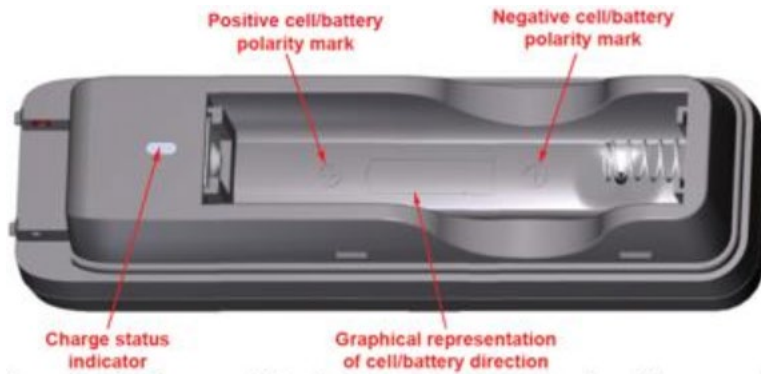
- Black Light Mode - Use to aid in visualization of fluorescent particles in various dental resins. Gives 60 seconds of illumination.
- White Light Mode - Visual aid for whenever the dental professional may need a source of natural light, e.g., determining shade. Gives 60 seconds of illumination.

Use – Interproximal Lens

- Transillumination of teeth: use to aid in visualization of fractures, cracks, or defects in teeth by illuminating the teeth from the lingual and observing shadows. Recommendation: Use the Diagnostic Aid Mode - White, which gives 60 seconds of illumination.

Powering the VALO X Curing Light

- **Charging Batteries/Cells** - Remove cap at the base of the curing light with a counter-clockwise turn. Insert dead battery/cells in the provide Ultradent VALO Battery Charging Cradle with medical grade 12VDC AC power adapter in the orientation shown in the cradle. Battery/cells will be fully charged in 1–2 hours.



Charge State Description	Charge Status Indicator	Voltage Condition	Charge Current
Pre-Charge	Solid Amber	2.86 Vdc to 3.15 Vdc	95 mA
Bulk Charge	Solid Amber	3.15 Vdc to 4.20 Vdc	950 mA
Charge Complete	Solid Green	>4.20 Vdc	N/A
Standby	Both off	N/A	N/A

- **Cord Adapter** - Remove cap at the base of the curing light with a counter-clockwise turn. Remove battery/cell. Insert cord adapter into battery/cell compartment, fully seat adapter and turn clockwise to lock into place.

Warning Indicators for VALO X Curing Light

- Red Flashing = Low Battery – Should have about 10 curing cycles after indication.
- Red Steady = Dead Battery
- Amber indicates an over temperature state of the device.
- Flashing Red and Green indicate AF lock out.

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.
- 5) If running the curing light on battery/cell power, the curing light should be oriented downward in the bracket. If running the curing light on the VALO X Cord Adapter power, the curing light should be oriented upward in the bracket.

9. Maintenance

User-Performed Maintenance

- 1) End of life is determined by wear and damage due to use. Inspect all components for damage prior to use and contact authorized service personnel to repair damage.
- 2) Routinely check the lens for cured dental resins. If necessary, use a plastic or stainless steel dental instrument to carefully remove any adhered resin.
- 3) Routinely check the output in Standard Power mode. Light meters differ greatly and are designed for specific light guide tips and lenses. NOTE: the true numeric output will be skewed due the inaccuracy of common light meters and the custom LED pack in the curing light; however, contact authorized service personnel if a decrease in output is observed when measuring with the same meter.

10. Repair

Manufacturer Repair

- 1) Repairs are only to be performed by authorized service personnel. Ultradent to provide service personnel with documentation to perform repairs.

Warranty

Ultradent hereby warrants that this instrument shall, for a period of 5 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/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 curing light system. Tampering with the VALO curing light will void its warranty.

The VALO curing light warranty does not cover customer damage. For example, if a VALO curing light is misused or dropped and the lens breaks, the customer will be responsible to pay for any necessary repairs.

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

11. Processing

If the product is reusable or requires processing before use, use the following language (if applicable) or fill out the below table to be compliant with ISO 17664. (UD Only)

To avoid cross-contamination, wipe syringe with an intermediate level disinfectant between uses and use a disposable barrier sleeve. If a barrier sleeve is not used, syringe should be treated as single-use.

VALO Curing Light Processing Instructions

Disinfection Reprocessing Instructions		
Initial treatment at the time of use	Can be disinfected in the event the device becomes contaminated during use. A new disposable barrier sleeve must be used for each patient.	
Preparation before disinfection	Use a 70% isopropyl alcohol (IPA) wipe to thoroughly wipe the entire surface and remove any debris. Discard soiled wipe.	
Rinsing	None	
Drying	Allow to completely air dry at ambient temperature.	
Maintenance, inspection, and testing	Visually inspect that the device is not damaged and is free of debris. If debris is present, repeat preparation step with a new wipe.	
Packaging	No packaging required for disinfection.	
Disinfection	Wipe the entire surface and keep wet for the exposure time while paying special attention to cracks, crevices, seams, and hard-to-reach areas. Use additional wipes as necessary to keep the surface wet.	
	Disinfectant	Exposure Time
	70% IPA wipe	4 minutes
Storage	Store in a clean and dry location. To prevent moisture buildup, do not store in a barrier sleeve.	

Additional information	This procedure was validated by an independent and accredited laboratory.
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VALO Accessories Processing Instructions

Disinfection Reprocessing Instructions		
Initial treatment at the time of use	Disinfection is required between each use.	
Preparation before disinfection	Remove any cured dental composites from accessory lenses prior to cleaning.	
Cleaning	Place in an ultrasonic cleaner with the detergent listed below:	
	Detergent	Cleaning Time
	Henry Schein General Purpose Cleaner or equivalent product	2–10 minutes
Rinsing	Rinse accessory with warm water to remove detergent for 1–2 minutes.	
Drying	Dry with gauze. Air dry 30 minutes.	
Maintenance, inspection, and testing	Visually inspect that the accessory is not damaged and free of debris. If cracked or damaged, discontinue use. If debris is present, repeat cleaning process.	
Packaging	No packaging required for disinfection (sterilization packages can be used for storage after disinfection).	
Disinfection	Remove from storage packaging (if applicable). Submerge accessory in disinfection solution as per manufacturer’s instructions listed below:	
	Disinfectant	Exposure Time
	Cidex® OPA Solution or equivalent product	12 minutes
Rinsing	<p>Rinse per disinfectant manufacturer’s instructions listed below:</p> <p>1. Following removal from CIDEX® OPA Solution, thoroughly rinse the accessory by immersing it completely in a large volume (e.g., 2 gallons) of water.</p> <p>2. Keep the accessory totally immersed for a minimum of 1 minute in duration.</p> <p>3. Remove the accessory and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.</p> <p>4. Repeat the procedure two (2) additional times, for a total of three (3) rinses, with large volumes of fresh water to remove CIDEX® OPA Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED.</p>	

	Additionally, rinse in water in ultrasonic cleaner for 5 minutes.
Storage	Store in a clean and dry location.
Additional information	This procedure was validated by an independent and accredited laboratory.

12. Storage and Disposal

Storage (UD Only)

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 unchargeable. 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

Disposal (UD Only)

Dispose of waste (e.g., barrier sleeves) according to local rules, guidelines, and regulations.

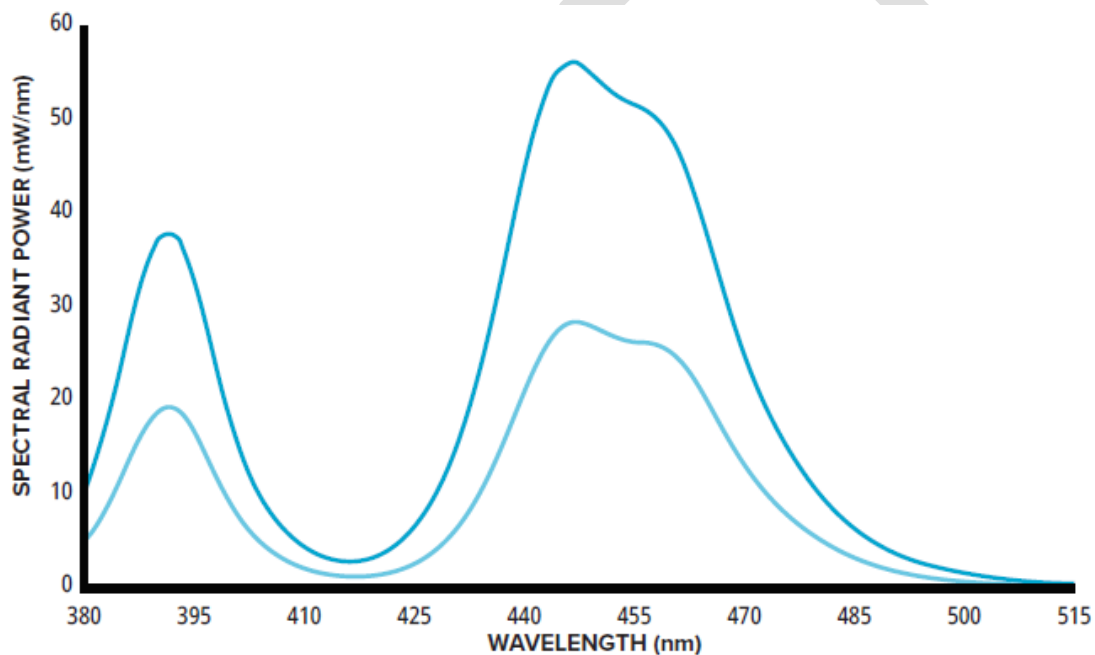
13. Technical Considerations

Accessories

Item	CE Information		
VALO Barrier Sleeves	  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			
VALO Charger			
VALO Batteries			
VALO X Interproximal Accessory Lens			
VALO X Translume Accessory Lens			

VALO X White/Black Light Diffuser Accessory Lens	
VALO X ProxiCure Accessory Lens	
VALO X PointCure Accessory Lens	

Technical Information/Data



Attribute	Information/Specification
Lens	Diameter 12.5 mm = 1.2271 cm ² (122.71 mm ²) PointCure Lens: Diameter 2.5 mm ProxiCure Lens: Diameter 2.1 mm
Wavelength range	Utilizable wavelength range: 380 – 515 nm Peak wavelengths: 380 – 420 nm and 420 – 515 nm
Light Intensity Table	Standard Power - 1,100 mW/cm ² (±10%) Xtra Power - 2,200 mW/cm ² (±10%) (Conforms to ISO 10650 when measured with a Gigahertz spectrum analyzer) Black Light - 260-590 mW/cm ² White Light - 160-300 mW/cm ²

	NOTE: PointCure and ProxiCure lenses focus the light energy into a smaller aperture, thus increasing the light intensity above calibrated values.	
VALO X Curing Light	Ratings: IEC 60601-1 (Safety), IEC 60601-1-2 (EMC)	Weight: With battery: 4.6 oz. (137 grams) Without battery: 3.6 oz. (103 grams) With cord adapter: 5.6 oz. (158 grams) Dimension (battery configuration): 8.64 x 0.83 x 0.83 inches, (219 x 21 x 21 millimeters)
Power Supply	Output - 9VDC at 2A Input - 100VAC to 240VAC, 50-60 Hz Ultradent P/N 4952 - VALO X Power Supply with international plug inserts	Ratings: IEC 60601-1 (Safety) Cord Length - 6 feet (1.8 meters) VALO Power Supply is a Medical Grade Class II power supply and provides isolation from MAINS power
VALO Smart Charger	VALO X 3.7VDC Lithium Ion (Li-Ion) smart charger: Automatic shut off when fully charged Auto-detection of defective cell Protections: Overcharge, Short-circuit, Reverse polarity Yellow LED - Charging Green LED - Empty or Fully Charged Charging time: 1–3 hours Rating: CE, WEEE	
VALO cells	Rechargeable: Li-ion 15/740 <ul style="list-style-type: none"> Working Voltage: 3.7VDC Ratings: WEEE, IEC 62133-2	
Operating Conditions	Temperature: +10°C to +32°C (+50°F to +90°F) Relative Humidity: 10% to 95% Ambient Pressure: 700 hPa to 1060 hPa	
Duty Cycle:	At maximum ambient temperature (32°C) 10 seconds ON and 60 seconds OFF.	

Trouble 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	<ul style="list-style-type: none"> Press the Power Button to wake from Power Save Mode Confirm battery/cell is fully charged Check that cell is correctly inserted into the unit If amber Warning LED is 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.

	<ul style="list-style-type: none"> • If red or amber Warning LED flashes continuously, call Ultradent Customer Service for repair
Light does not stay on for desired time	<ul style="list-style-type: none"> • Check Mode lights for correct input • Check the Low power indicator for cell charge status • Check that a fresh cell is properly inserted into the unit
Light is not curing resins properly	<ul style="list-style-type: none"> • Check lens for residual cured resins/composites • Using proper amber UV eye protection, verify the LED lights are working • Check power level with light meter. If using a light meter, Ultradent recommends checking the curing light in Standard Power mode. <p>NOTE: Check the light before initial use to establish a baseline for future readings. 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.</p> <ul style="list-style-type: none"> • Check expiration date on curing resin • Ensure proper technique is being followed according to manufacturer recommendations
Battery will not charge	<ul style="list-style-type: none"> • Make sure the cell is inserted into the charger in the correct orientation and allow cell to fully charge for about 1 hour • If yellow lights on the charger do not change to green, call Ultradent Customer Service to order replacement cells and/or charger • If neither green nor yellow lights on the charger are visible, call Ultradent Customer Service to order or replace charger and/or AC adapter
Charger does not charge battery	<ul style="list-style-type: none"> • Make sure charger is plugged in and AC adapter is plugged into a working power outlet • If green or yellow lights on the charger are not visible, call Ultradent Customer Service for a new charger and/or AC adapter
Cannot change modes with gestures.	Hold either single Power button down until a series of beeps indicates the curing light is unlocked (approximately 9–10 seconds)

State	LED indicator
Low battery	Flashing red
Sleep mode	
AF lock out	
Diagnostic aid mode	White/violet
Curing mode	Pulsing blue


14. 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 a cell and is not affected by EMI, RF, or surge suppression.
RF emission CISPR 11	Class B	The curing light uses electrical and electromagnetic energy only for their internal functions. However, any RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	N/A	Harmonic emission and voltage fluctuation testing are not applicable to the curing light because it is cell/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	± 2 kV for power supply lines	± 2 kV for power supply lines	

IEC 61000-4-4	± 1 kV for input/output lines	Note 1: The curing light has no I/O ports	The curing light is battery/cell powered and is not capable of connection to AC MAINS power.
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	Because the curing light is battery/cell powered, it is not subject to electric transients, surges, voltage dips, shorts, interruptions, or variations on AC MAINS power.
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	The accessory battery charger may be subject to the above but it is separate from and not critical to the operation of the VALO X curing light. If battery voltage of the curing light drops to 4VDC the unit will not allow operation. The VALO X 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.
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.

IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	<p>Recommended separation distance:</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>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).</p>
Radiated RF	3 V/m	3 V/m	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p>
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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 X 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 X 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	80 MHz – 800 MHz	800 MHz – 2.5 GHz

	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01			
0.1			
1			
10			
100			
0.01			

(English ONLY)

FCC Regulatory Statement

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference, and
- 2) This device must accept any interference received, including interference that may cause undesired operation.

Warning

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Interference

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Re-orient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

(English and French ONLY)

ISED Regulatory Statement

This radio transmitter has been approved by Industry Canada to operate with the antenna types listed with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

- 1) This device may not cause interference, and
- 2) This device must accept any interference, including interference that may cause undesired operation of the device.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to ICES-003. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Re-orient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

French

PRUDENCE: Changements ou modifications pourraient annuler le droit de l'utilisateur à utiliser l'équipement non autorisées. Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'expLe présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils oitation est autorisée aux deux conditions suivantes:

1. L'appareil ne doit pas produire de brouillage, et
2. L'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

Ces limites sont conçues pour fournir une protection raisonnable contre les interférences nuisibles dans une installation résidentielle. Cet équipement génère, utilise et peut émettre une énergie de radiofréquence et, s'il n'est pas installé et utilisé conformément a ux instructions, il peut causer des interférences nuisibles aux communications radio. Cependant, il n'existe aucune garantie que des interférences no se produiront pas dans une installation particulière.

Si cet équipement provoque des interférences nuisibles à la réception radio ou télévision, ce qui peut être déterminé en mettant l'équipement hors et sous tension, l'utilisateur est encouragé à essayer de corriger l'interférence par une ou plusieurs des mesures suivantes:

- Réorienter ou déplacer l'antenne de réception.
- Augmentez la distance entre l'équipement et le récepteur.
- Connecter l'équipement à une sortie sur un circuit différent de celui sur lequel le récepteur est branché.
- Consulter le revendeur ou un technicien radio / télévision expérimenté pour de l'aide

Report any serious incident to the manufacturer and the competent authority.
www.ultradent.com / 1.800.552.5512 / 801.572.4200

15. Symbols (UD Only)

See Product Specification for regulatory symbols. (UD Only)

Manufacturer Information (UD Only)

Paste from Product Specification the manufacturer information here.

Authorized Representative (UD Only)

Paste from Product Specification the name and address for authorized representative here.

Country-/Region-Specific (UD Only)

Australia (UD Only)

Australian Sponsor:

Ultradent Australia Pty Ltd

P.O. Box 111 Coogee, NSW 2034 1800 29 09 29 | www.ultradent.com.au