

Setting New Standards through Innovation



FUSION

INSTRUCTIONS FOR USE

LED Curing Light System (Rev 5)

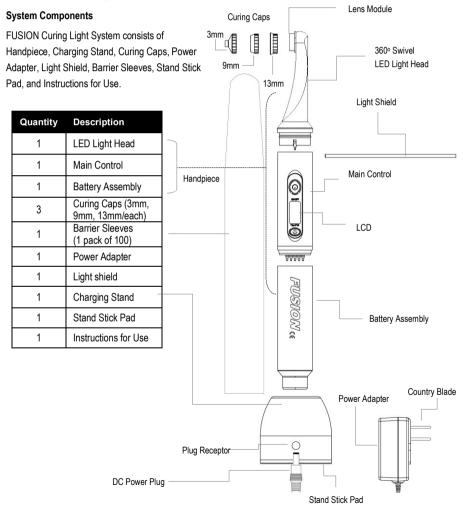


Powered by Patented Focus Beam Technology

Product Information

Description and Indications for Use

Fusion Curing Light System (Rev 5) is a high power curing light device for polymerization of light-cured materials by dental professionals. It cures the wavelength range of 420 – 490 nm, with the option to go down to 390nm. These operating instructions provide recommendations and guidelines for the intended use of the light. Please read them carefully.



Product Safety Warnings and Cautions



Prior to installation and activation of the light, please read these instructions carefully and follow safety procedures as well as the specific safety comments and recommendations presented throughout the instructions for use. 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.

- 1. CAUTION! FUSION produces high intensity light. Prolonged exposure to the skin, oral mucosa, or pulp can result in irritation or injury.
 - Do not place light in direct contact with unprotected gingival, oral mucous membrane or skin.
 - Do not place light directly on the same tooth segment for more than 6 seconds in Plasma Power Mode.
 - If long exposure cannot be avoided, direct a stream of air over the tooth surface from an air syringe or high-speed vacuum tip, adjust to Pulse Power Mode or adjust curing distance.
- CAUTION! Do not look directly at light emitted from the device. Do not use FUSION without suitable eye
 protection for the operator, assistant and patient. Use Light Shield, Protective Goggles, and/or Curing Caps.
 Exposure must be restricted to the area of the oral cavity for which the clinical treatment is intended.
- CAUTION! FUSION must be used with "Single Use" Barrier Sleeves to avoid cross contamination. Replace Barrier Sleeve after each patient treatment is completed. This sleeve also prevents composite material from adhering to the surface of the lens and degrading the curing performance.
- 4. Products marked "Single Use" on the labeling are intended for single use only. Discard properly after each use.
- DO NOT operate the unit in the proximity of flammable mixtures; FUSION is not suitable for uses in the presence of a flammable anesthetic mixture with air or nitrous oxide. Use in well-ventilated area.
- 6. Keep solvents, flammable liquids, and sources of intense heat away from FUSION as they may damage internal and external parts, the seals or the buttons on the control panel.
- 7. DO NOT autoclave or immerse unit in any kind of ultrasonic bath, disinfectant, cleaning solution or any kind of liquid. Do not spray liquids directly onto the light and prevent liquids from entering FUSION open area such as Keypad, Charging Stand and its connectors as this may damage or short-circuit the device and can cause potential hazard for operator and/or patient.

Glossary of Symbols

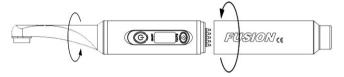
A number of symbols are used on the device, accessories and throughout this manual, it is important that the user/operator of FUSION understands the meaning of each symbol to avoid possible injury to the operator or/and patient.

	Symbol is used to alert you to consult instructions for use. Understand all safety messages that follow this symbol to avoid injury to the operator and/or patient.					
Â	Attention, consult accompanying documents					
X	Waste Electrical and Electronics Equipment (WEEE)					
Ŕ	Type BF Applied Medical Equipment Protection Class II- Double insulated					
	Manufacturer Ec REP European Authorized Representative					

М	Date of Manufacturing		Atmospheric Pressure Limitation
	DC Voltage	(F)	Humidity Limitation
2	Single Use Only	Ť	Keep Dry
-05C	Temperature Limitation	R	For Licensed Dental Professional Use Only!
SN	Serial Number	REF	Product Number

Start Up

Assemble Handpiece



Upon receiving your FUSION, remove all components from the package and examine

them. If damage is apparent, please contact your authorized DentLight distributor from whom your light was purchased.

Attach the Battery Assembly to the Main Control by screwing the Battery Assembly clockwise into the Main Control. A short beep upon connection indicates that the light is battery powered and the LCD display should automatically power on. Adjust the 360° swivel LED Light Head to a comfortable curing position and ensure good connection with the Main Control. Light is now ready for use.

Operation and Setting

FUSION uses advanced Metal Keypad and LCD interface. ON/OFF Key starts and stops the light.TM/PW Key sets the Operation Time and Power Mode. FUSION defaults in Pulse Power Mode (green backlit LCD and flash MODE symbol) with 5 second timer. Press TM/PW Key to select a Digital Timer of your choice. Press and hold TM/PW Key for 2 seconds and release to change power to Plasma Power Mode (white backlit LCD with steady MODE symbol) and vice versa.

Plasma Power Mode allows the fastest curing with plasma-like energy dosage. Pulse Power Mode maintains the peak power and generates the minimum heat by lowering the average power in half with a 50/50 on and off duty cycle. Built-in settings are shown in the table below. After starting, Digital Timer counts down and the light makes an audible beep every 5 seconds. Press ON/OFF Key anytime to stop.

Select 60 seconds timer for optional applications including: a) Violet Light Head (optional) for early cancer screening; b) White Light Head (optional) for caries and fracture detection; c) fPad Head (optional) for TMJ photodynamic pain therapy or photoactivated disinfection.

						\sim			
MODE	Plasma Power	Pulse Power			Matal Kausad —				
Digital Timer (seconds)	3	3*	5	10	20	60	Metal Keypad	ON/OFF	
Backlit LCD	White	Green				* 5	MODE DIGITAL TIMER		
To Change Power Mode	Press/hold TM/PW	Key for 2 seconds then release				TM/PW	BATTERY BARS TM/PW		
							-	((①))	

* Sequantial curing 6 times (3s cure, 5s period) for brackets/veneers.

Built-in Self-Protection

FUSION has built in self-protection on low battery and overheats. Low battery is indicated with low Battery Bars (one or no bars). Low battery triggers one beep a minute ahead of self-protection shutdown. Light then goes to sleep mode.

Overheating is indicated with a flashing Thermometer symbol, an audible warning beep together with a red backlit LCD. Light shuts off when overheat is triggered.

Curing Recommendations

For specific resin, sealants and bonding materials perform a timed curing test outside the mouth using a 3mm washer or hardness disk. Cure from the top for the recommended time, and reverse the disk. Using a sharp instrument, compare the hardness of the disk to the hardness of the composite - it should feel exactly the same if well cured. For general guidance, use recommended curing times below. For reduced heat or shrinkage, use Pulse Power Mode and replace 3sec with 5sec curing times below.

Thermometer

Manufacturer		3М		lve	Dentsply		Kerr		
Resin Brand			k Supreme Heliomolar		Tetric	TPH3		XRV	
		Plus			EvoCeram			Herculite	
Color/S	hade	A3E	C6D	A3	A2	A3	DY	A3	YB
Cure	Per layer	3	3x3	3	3	3	3	3	3
Times	Final layer	3x2	3x4	3x2	3x2	3x2	3x2	3x2	3x2

Recommended Cure Times (seconds) - Plasma Power Mode

To bond brackets, use 1) 3 seconds in Plasma Mode for single bracket; 2) 3x2 seconds in Plasma Mode for band or tube; 3) 3 seconds in Pulse Mode for a quadrant.

Battery Care

Keep FUSION charged at all times in the office.



Connect DC Power Plug to Plug Receptor on

the Charging Base. Place Handpiece onto Charging Stand. Secure Charging Stand on a table counter with Stand Stick Pad for ease of operation. Alternatively connect DC Power Plug directly to the back end of Handpiece to charge and power on the unit. Separate Battery Assembly from Main Control in case of long-term storage (>2 months).

LCD screen lights green while charging. LCD backlight turns off when fully charged. Battery Bar displays three full bars when the battery is fully charged. In normal operation, Battery Bar drops from three to two bars while running and returns to full bar upon completion of a cycle.

BATTERY DISPOSAL: The Battery Assembly contains a Lithium ion (Li-ion) battery.

When the battery is at

DC Po

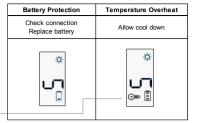
Techniques

Lens Module: Use disposable Barrier Sleeves and Curing Caps to protect lenses from liquid and composite damages. Replace Lens Module immediately if it: a) has cured resin; b) is scratched or cloudy. Align and lock flat edge of Lens Tool (optional accessary) to flat edge of Lens Module. Turn Lens Tool counter-clockwise and unscrew Lens Module. Replace damaged lens with a new Lens Module by reversing the steps. Do not overtight the thread and O-rings underneath.

Barrier Sleeves: Slide sleeve into Handpiece. Twist body relative to sleeve for tight fit.

Light Shield: Slide in Light Shield from the LED Light Head to the Handpiece into proper position for best access.





Tip Size: Tip and beam size can be adjusted by selecting the proper size Curing Caps. For small cavity treatment, snap on 9mm Curing Cap and anchor light on occlusal or bonding surface. For temporary bonding, snap on 3mm Curing Cap (Tacking Tip) at the end of the Lens Module and apply pressure at the center of crown/veneer for best contact. Tack for 1 second then remove excess adhesives before final bonding. For veneer bonding and molar cavity treatment, snap on 13mm Curing Cap and place light in direct contact.

Cleaning and Disinfecting

- Clean and disinfect Handpiece and Charging Stand with a soft cloth or tissue dampened with cleaning solution including: Cavicide, Lysol, Isopropyl or Ethyl alcohol and equivalent. <u>Do not spray, soak, or autoclave.</u>
- Use Q-tips to clean lens and electrical contacts by slightly dampening the tip (do not soak) with Isopropyl alcohol.
- Safeguard Handpiece opening area, Metal Keypad, Charging Plug, and Lens Module against liquid and sharp objects as this may cause electrical short-circuit, permanent optical damage or malfunction.

Optional Add-ons

FUSION is the most versatile LED light system allowing users to implement multiple functionalities from its advanced modular base kit. In addition to the Standard LED Light Head that comes with the kit (wavelengths from 420-490nm), optional add-on functions can be achieved with:

Violet Light Head - providing violet light (390 – 430 nm) for (a) oral lesion/cancer screening; (b) curing of lower wavelength initiator adhesives (e.g. Lucirin TPO and Ivocerin) and (c) composite visualization/removal. Oral screening enables early cancer detection using fluorescence generated from tissue and viewed through Fluorescence Viewer that comes with FUSION-to-DOE starter kit. <u>Provide the starter wavelength</u> <u>Be sure to position the light 1-3 inches (2.5 – 7.5cm) distance away from examined tissue.</u>

White Light Head - offering an exam probe light that outputs super high power transillumination (best used with Tacking/Exam Tip) for detection of dental caries, cracks and location of root canal.

fPad Light Head - providing red light (620 – 650 nm) for 1) TMJ photodynamic pain therapy for pain relief; 2) photo-activated disinfection.

Full-arch Bleaching Attachment - converting the light into a full–arch bleaching light. Bleaching Upgrade Kit will allow the operator to use the dental chair's head rest to fix the light. To operate in Bleaching Mode, first select Pulse Power mode, press and hold ON/OFF Key for 3 seconds to select Bleaching Mode (15 minute Pulse Power Mode) then press ON/OFF to start. CAUTION: Be sure to use Mouth Guard and Bleaching Attachment during bleaching.

Product Specification

Type of information		Specifications	
	LED Light Head	420-490nm	
Wavelength	Violet Light Head	390-430nm	
Ŭ	White Light Head	5000- 6500K	
	fPad Head	620-650nm	
Light Intensity	LED Light Head	Plasma Mode: 4000; Pulse Mode: 2000 (avg.); Bleaching Mode:1600 (avg.)	
at light tip	Violet Light Head	1000 (at light tip)	
(±10% mW/cm2	White Light Head	Plasma Mode: 110,000 lux (with Tacking/Exam Tip)	
or lux)*	fPad Head	Plasma Mode: 1600; Pulse Mode: 800 (average)	





Tacking Tip

Power Adapter	Input: 100-240V - 50/60Hz; Output: 5V 1-2A			
Battery performance	Output: 3.7V nominal and 1.4AH. Total light exposure time 70 minutes (Plasma Power); 90 minutes full recharging time. Expected life: 500 full charge/discharge cycles.			
Operation	Continuous operation patient application, curing: duty cycle 6sec (Plasma Mode) 10sec (Pulse Power Mode) ON/30sec OFF; exam (place 1inch [2.5cm] away from soft tissue): 60sec (Pulse Power Mode) ON/1 minute OFF.			
Shutoff	Timer auto shutoff; User shut off anytime by pressing ON/OFF Key; Low battery auto shutoff; Overheat auto shutoff (50°C at Light Head). Self-protection shutoff is accompanied by warning backlight, audible beep and flashing THERMOMETER or BATTERY BAR symbols.			
Overcurrent Protection	Auto			
Light Dimension (mm)	Length: 204; Width: 22; Height: 22			
Charging Dock Dimensions (mm)	Height: 45; Diameter:44			
Weight (grams):	Handpiece: 114; Charging Stand: 89			
Equipment Class	Symbol for class II equipment.			
Safety	IEC 60601-1			
EMC Compliance	IEC 60601-1-2			
Protection from Electric shock	Type BF			
Protection from ingress of liquids	IPX0			
Service Lifetime	Lifetime of the device is approximately 150,000 curing cycles based on battery life or typically 5 service years in normal office use.			
Operating environment	Ambient temperature: 50°F to 86°F (10°C to 30°C) Relative humidity: 10%-80%, non-condensing, Atmospheric pressure:0.5-atm to 1.0-atm(500hPa-1060hPa)			
Storage environment	Ambient temperature: 14°F to 104°F (-10°C to 40°C) Relative humidity: 10%-80%, non-condensing, Atmospheric pressure:0.5-atm to 1.0-atm(500hPa-1060hPa)			

* Irradiance (mW/cm²) is absolute irradiance measured using calibrated optical spectrometer.

Limited Two-Year WARRANTY

Register your FUSION curing light at <u>www.dentlight.com</u>. DentLight Inc. extends a two-year warranty against defects in material and workmanship to the original purchaser of this product from an Authorized dealer, except the Battery Assembly and Charging Stand (one-year warranty) and disposable items (curing caps, barrier sleeves and light shield). This warranty is valid providing factory inspection indicates that any such defect was developed during normal and proper use. DentLight shall under no circumstances be liable for incidental, special, consequential damages and damage from misuse including the following expressed or implied:

- Improper operation, accident or neglect, misuse or abuse, such as physical damage (dents, scratches, etc.);
- Liquid, water, rain, extreme humidity, ultrasonic, autoclaving;
- Tampering, improper repairs or modifications that have not been carried out by a certified Service Center;
- Use of other spare parts and accessories other than from the manufacturer such as incorrect power adapter;
- Other acts which are not the faults of DentLight.

For service, call 1-800-763-6901 (in US) to obtain RMA number. Fill out RMA form online and return as instructed. In case of a warranty claim, the complete apparatus must be returned. Alternatively, contact your dealer for service return.

Troubleshooting Guide

Problem	Error Indication	Possible Solutions				
Light will not	1. Buzzing noise when charging. 2. LCD is blank.	1) Charge Battery Assembly alone by directly plugging DC Power Plug (bypassing Charging Stand) for 5 hours. 2) Push any Key.				
turn on	Handpiece is overheated. LED Light Head gets hot.	Direct an air stream from an air syringe or high-speed vacuum tip to the light tip, or wait for cool down.				
	 Light does not activate with Key. Timer counts down yet no output light. 	Contact manufacturer or your local dealer for service.				
Light does not stay on for desired time	 One or no Battery Bars. Bad connection or contacts. Out-of-capacity or battery at the end of its life. 	1) Charge Handpiece directly (bypass Charging Stand) for 1 hour; 2) Check connection pins to make sure that they are not damaged; 3) Replace battery.				
Light generates too much heat	Patient feeling discomfort	 Cure 3 seconds at plasma power or 5 seconds at pulse mode per layer. 2) Direct an air stream from an air syringe or high-speed vacuum tip. 3) Adjust to Pulse Power Mode; Adjust curing distance. 				
Battery will not charge	 Broken pins in Charging Stand. Electronic defect in Battery Assembly. 	 Bypass, replace or service Charging Stand. Replace or service Battery Assembly. 				

Reorder and Optional Item Codes

REF	Description	REF	Description
7800080	FUSION ⁵ Curing Light Kit	7800060	LED Light Head
7500082	Barrier Sleeves (100/pack)	7800060U	Violet Light Head
7600081	Curing Caps – 9mm (10/pack)	7800060W	White Light Head
7610081	Curing Caps – 13mm (10/pack)	7800060R	fPad Head
7620081	Curing Caps – 3mm (10/pack)	7800093	Lens Module
7500083	Charging Stand	7500095	Lens Tool
7500084-08	Battery Assembly	7500092	Light Shield
7800050	Main Control	7511511	FUSION Bleaching Starter Kit
7500088	Eye Safety Goggle	7500152	FUSION-DOE Starter Kit
7500085-Y	Power Adapter (Y: country code)**	7700512	FUSION-DOE Kit

** Y: US, EU, AU (Australia)



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