

# DentLight

Setting New Standards through Innovation



## FUSION

## INSTRUCTIONS FOR USE

Ortho LED Curing Light System (Rev 4)



Powered by Patented Focus Beam Technology

## Product Information

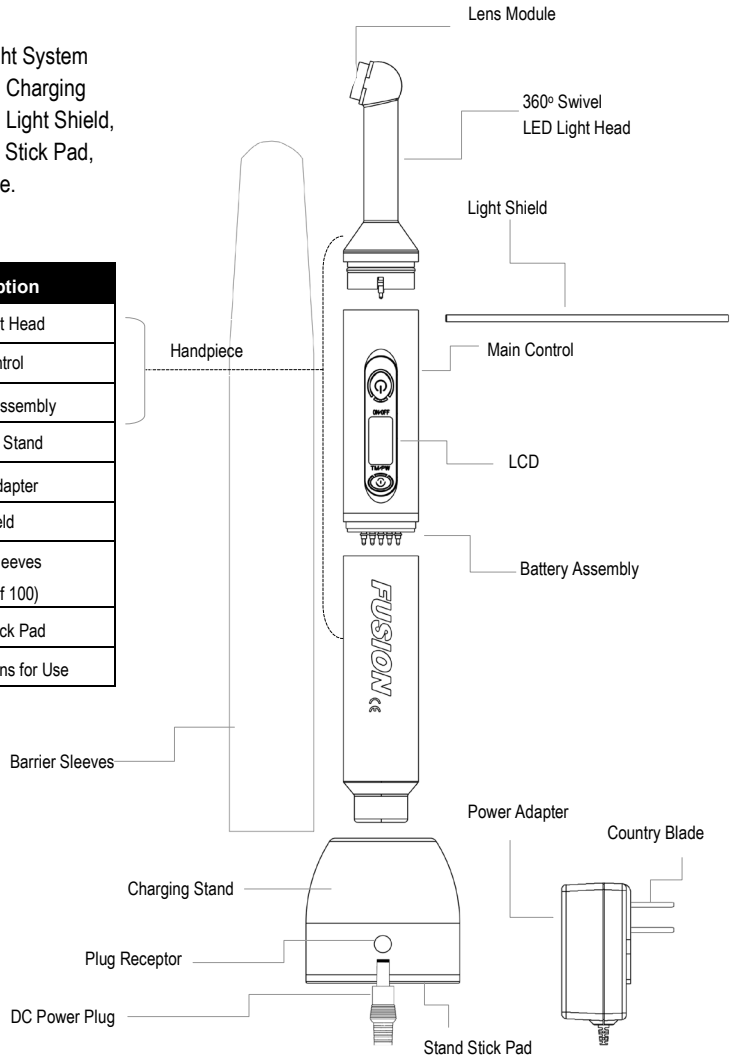
### Description and Indications for Use

Fusion<sup>Ortho 4</sup> Curing Light System 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.

### System Components

Fusion<sup>Ortho 4</sup> Curing Light System consists of Handpiece, Charging Stand, Power Adapter, Light Shield, Barrier Sleeves, Stand Stick Pad, and Instructions for Use.




Quantity	Description
1	LED Light Head
1	Main Control
1	Battery Assembly
1	Charging Stand
1	Power Adapter
1	Light shield
1	Barrier Sleeves (1 pack of 100)
1	Stand Stick Pad
1	Instructions for Use



## 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 10 seconds in High 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.
2.  **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.
3.  **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.
5. 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.
8. User must regard EMC, please install and put in service FUSION according to the EMC information provided in the accompanying documents.
9. Portable and mobile RF communications equipment can affect medical electrical equipment.

10. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by DentLight as replacement parts for internal components, may result in increased Emissions or decreased Immunity of FUSION.
11. FUSION should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, FUSION should be observed to verify normal operation in the configuration in which it will be used.

## Glossary of Symbols

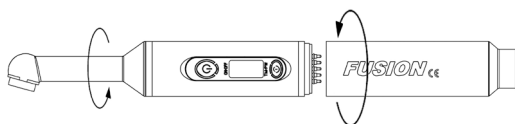
A number of symbols are used on the device, accessories and throughout this manual, it is important that the user/operator of FUSION understands the meaning of each symbol to avoid possible injury to the operator or/and patient.

	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.		
	Attention, consult accompanying documents		
	Waste Electrical and Electronics Equipment (WEEE)		
	Type BF Applied Medical Equipment		Protection Class II- Double insulated
	Manufacturer		European Authorized Representative
	Date of Manufacturing		Atmospheric Pressure Limitation
	DC Voltage		Humidity Limitation
	Single Use Only		Keep Dry
	Temperature Limitation		For Licensed Dental Professional Use Only!
<b>SN</b>	Serial Number	<b>REF</b>	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

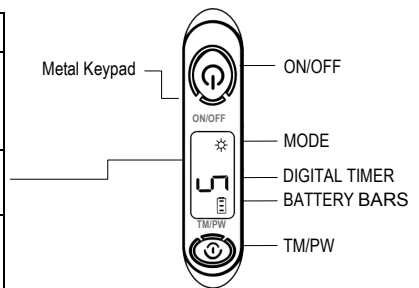


purchased. Attach the Battery Assembly to the Main Control by screwing the Battery Assembly clockwise into the Main Control. A short beep upon connection indicates that the light is battery powered and the LCD display should automatically power on. Adjust the 360° swivel LED Light Head to a comfortable 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 High Power Mode (white backlit LCD with steady MODE symbol). Press TM/PW Key to select a Digital Timer. Press and hold TM/PW Key for 2 seconds and release to change power to Pulse Power Mode (green backlit LCD and flash MODE symbol) and vice versa. Press and hold ON/OFF Key together with TW/PW Key to go to sleep mode. Built-in settings are shown in the table below.

MODE	High Power			Pulse Power			
<b>Digital Timer (seconds)</b>	4	5	10	4	5	10	20
<b>Backlit LCD</b>	White			Green			
<b>To Change Power Mode</b>	Press and hold TM/PW Key for 2 seconds and release						



After starting, Digital Timer counts down and the light makes an audible beep every 5 seconds. Press ON/OFF Key anytime to stop. High 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. **4 second timer is used for bonding 16 brackets in a row when the light turns on 4 seconds and idles 1 second to move to the next bracket/position.**

## Curing Recommendations

For specific resin, sealants and bonding materials perform a timed curing test outside the mouth. For general guidance, use recommended curing times below. Cure posterior teeth from the occlusal side and anterior teeth from both mesial and distal side. For reduced heat or shrinkage, use Pulse Power Mode while doubling the recommended curing times below.



### Recommended Cure Times (seconds) - High Power Mode

SETTINGS	CURING TIMES (seconds)	PER UNIT CURE (seconds)
Single Bracket	1x5	5
Band/tube/Two Brackets	1x10	5+5
Four Plus Brackets	1x4	4
Indirect Bracket	1x4	4+4

## 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 warning 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.

Battery Protection	Temperature Overheat
Check connection Replace battery	Allow cool down
	

Thermometer

## 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. For storage, separate Battery Assembly from Main Control to extend lifetime.

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.  Recycle or dispose of batteries according to national, state and local regulations.

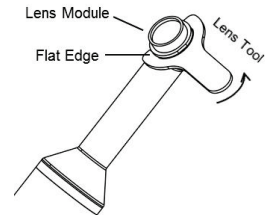


## Techniques

**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 accessory) to flat edge of Lens Module. Turn Lens Tool counter-clockwise and unscrew Lens Module. Clean mounting thread. Replace damaged lens with a new Lens Module by reversing the steps.

**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.



## Cleaning and Disinfecting

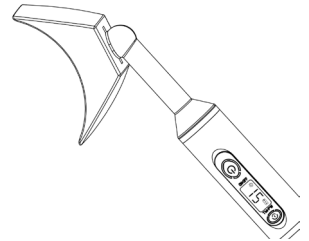
- Clean and disinfect Handpiece and Charging Stand with a soft cloth or tissue dampened with cleaning solution including: Cavicide, Lysol, Isopropyl or Ethyl alcohol and equivalent. ⚠ Do not spray, soak, or autoclave.
- Use Q-tips to clean lens and electrical contacts by slightly dampening the tip (do 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) curing of lower wavelength initiator adhesives (e.g. TPO) and (b) composite visualization/removal.

**Full-arch Bleaching Attachment** - converting the light into a full-arch bleaching light. Bleaching Upgrade Kit includes the Full-arch Bleaching Attachment, and a Flex-arm that holds the Handpiece on the one side and clamps on the other side of the dental chair's head rest. To operate in Bleaching 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.



## Product Specification

Type of information		Specifications
Wavelength	LED Light Head	420-490nm
	Violet Light Head	390-430nm
Light Intensity ( $\pm 20\%$ ; mW/cm <sup>2</sup> )*	LED Light Head	High Power Mode: 2700; Pulse Power Mode: 2700 (peak);1300 (average)
	Violet Light Head	1000 (at light 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 35-45 minutes (High Power); 90 minutes full recharging time. Expected life: 500 full charge/discharge cycles.

Operation	Continuous operation patient application, curing: duty cycle 10sec (High Power Mode) ON/10sec OFF.
Shutoff	Timer auto shutoff; User shut off anytime by pressing ON/OFF Key; Low battery auto shutoff; Overheat auto shutoff. Self-protection shutoff is accompanied by warning backlight and audible beep as well as flashing THERMOMETER or BATTERY BAR symbols; Automatic overcurrent protection.
Light Dimension (mm)	Length: 200; Width: 22; Height: 22
Charging Dock Dimensions (mm)	Height: 45; Diameter:44
Weight (grams):	Handpiece: 111; 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
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)

\* Measured absolute irradiance using calibrated optical spectrometer.

### Limited Two-Year WARRANTY

Register your FUSION curing light at [www.dentlight.com](http://www.dentlight.com). 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). 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:

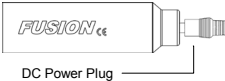
- Improper operation, accident or neglect, misuse or abuse, such as physical damage (dents, scratches, etc.);
- Liquid, water, rain, extreme humidity, ultrasonic, autoclaving;
- Tampering, improper repairs or modifications that have not been carried out by a certified Service Center;
- Use of other spare 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 turn on	1. LCD is blank. 2. Buzzing noise when charging.	1) Push any Key. 2) Charge Battery Assembly alone by directly plugging DC Power Plug (bypassing Charging Stand) for 5 hours. 
	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.
	1. Light does not activate with Key. 2. Timer counts down yet no output light.	Contact manufacturer or your local dealer for service.
Light does not stay on for desired time	1. One or no Battery Bars. 2. Bad connection or contacts.	1) Charge Handpiece directly (bypass Charging Stand) for 1 hour. 2) Check connection pins to make sure that they are not damaged. If problems persist, contact your dealer or Manufacturer for Service.
Light generates too much heat	Patient feeling discomfort	1) Cure $\leq 10$ seconds per layer. 2) Direct an air stream from an air syringe or high-speed vacuum tip. 3) Adjust to Half Power Mode; 4) Adjust curing distance.
Battery will not charge	1. Broken pins in Charging Stand. 2. Electronic defect in Battery Assembly.	1. Bypass, replace or service Charging Stand. 2. Replace or service Battery Assembly.

### Reorder and Optional Item Codes

REF	Description	REF	Description
7600080-OX	Fusion <sup>Ortho 4</sup> Curing Light Kit	7500060-X	LED Light Head
7500082	Barrier Sleeves (100/pack)	7500060U	Violet Light Head
7500083-X	Charging Stand	7500093	Lens Module (Focus)
7600084-X	Battery Assembly	7500095	Lens Tool

7500085-Y	Power Adapter	7511011	FUSION Bleaching Starter Kit
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\* X: blank (Silver), B (Blue), P (Pink), G (Gold); \*\* Y: US, EU, AU (Australia)

The FUSION<sup>Ortho4</sup> is intended for use in the electromagnetic environment specified below. The customer or the user of the FUSION should assure that it is used in such an environment.

#### Guidance and manufacturer's declaration – electromagnetic emissions


Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The FUSION uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The FUSION 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 used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

#### Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)  IEC 61000-4-2	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FUSION requires continued operation during power mains interruptions, it is recommended that the FUSION be powered from an uninterruptible power supply or a battery.

	70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	
Power frequency (50/60 Hz) magnetic field  IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Conducted RF IEC 61000-4-6  Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz  3 V/m 80 MHz to 2,5 GHz	3 Vrms  3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the FUSION, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>    Interference may occur in the vicinity of equipment marked with the following symbol:
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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 FUSION is used exceeds the applicable RF compliance level above, the FUSION should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FUSION.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The FUSION is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FUSION can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FUSION as recommended below, according to the maximum output power of the communications equipment.

**Recommended separation distances between portable and mobile RF communications equipment and the FUSION**

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

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