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DentLight

Setting New Standards through Innovation




# FUSION

## INSTRUCTIONS FOR USE

℞

LED Curing Light System

Powered by Patented Focus Beam Technology

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## Product Information

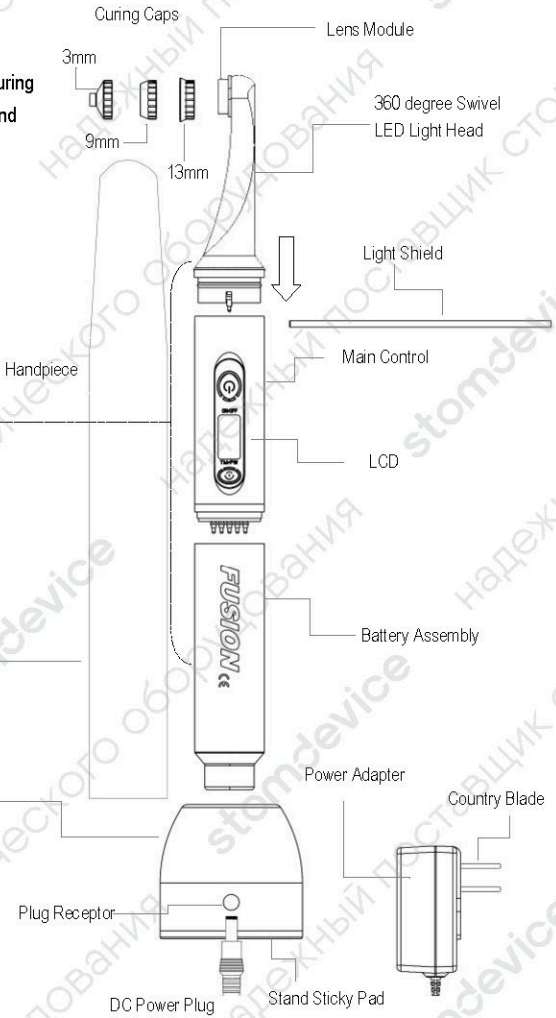
### Description and Indications for Use

Fusion Curing Light System is a source of illumination for curing photo-activated dental restorative materials and adhesives. The system has an interchangeable LED light head that preconfigures as: 1) FUSION with a peak wavelength of 440 – 480 nm; 2) FUSION Plus with center wavelengths of 395-480 nm. These operating instructions provide recommendations and guidelines for the intended use of the light. Please read them carefully.

### System Components

FUSION Curing Light System consists of a curing Handpiece (LED Light Head, Main Control, and Battery Assembly), Charging Stand, Curing Caps①②, Power Adapter, Light Shield, 100 Barrier Sleeves, Stand Sticky Pad, and Instructions for Use.

| Quantity | Description |
|---|---|
| 1 | Standard Head① |
| 1 | Plus Head② |
| 1 | Main Control |
| 1 | Battery Assembly |
| 3 | Curing Caps①② (3mm, 9mm, 13mm/each) |
| 1 | Barrier Sleeves (1 pack of 100) |
| 1 | Power Adapter |
| 1 | Light shield |
| 1 | Charging Stand |
| 1 | Stand Sticky Pad |
| 1 | Instructions for Use |




Marked components included in:

①: FUSION Standard Kit
②: FUSION Plus Kit
③: FUSION Grand Kit

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**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 lights produce 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.
2. ⚠ CAUTION! Do not look directly at light emitted from the device. Do not use FUSION lights 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! ② FUSION must be used with "Single Use" Barrier Sleeves to avoid cross contamination. ⚠ ice Barrier Sleeve after each patient treatment is completed. This sleeve also prevents composite/residue 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. 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 the 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. Caution: Federal law restricts this device to sale by or the order of a licensed dentist.

**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 | EC REP EMERGO EUROPE | European Authorized Representative |
| | Date of Manufacturing | | Atmospheric Pressure Limitation |

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| | | | |
|---|---|---|---|
| ⎓ | DC Voltage | | Humidity Limitation |
| | Single Use Only | | Keep Dry |
| | Temperature Limitation | | 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.

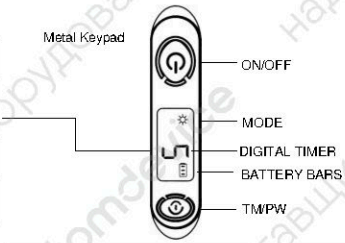
Attach the Battery Assembly to the Main Control by screwing the Battery Assembly clockwise into the Main Control. A short beep upon connection indicates that the light is battery powered and the LCD display should automatically power on. Adjust the 360° swivel LED Light Head to a comfortable curing position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

**Operation and Setting**

FUSIONs use 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.

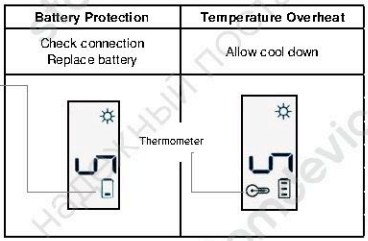
Plasma Power Mode allows the fastest curing. Pulse Power Mode maintains the peak power and generates the minimum heat by lowering the average power in half with a 50/50 on and off duty cycle. Built-in settings are shown in the table below. After starting, Digital Timer counts down and the light makes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

| MODE | Plasma Power | Pulse Power | | | | |
|---|---|---|---|---|---|---|
| Digital Timer (seconds) | 3 | 3* | 5 | 10 | 20 | 60 |
| Backlit LCD | White | Green | | | | |
| To Change Power Mode | Press/hold TM/PW Key for 2 seconds then release | | | | | |




* Sequential 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 (above 50°C at the light tip) is indicated with a flashing Thermometer symbol, an audible warning beep together with a red backlit LCD. Light shuts off when overheat is triggered. The light will be deactivated until the temperature is restored back below 38°C.



**Curing Recommendations**

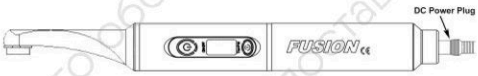
Please follow the method below to check the performance of the device. For specific resin, sealants and bonding materials, perform a timed curing test outside the mouth using a 3mm washer or hardness disk. Cure from the top for the recommended time and reverse the disk. Using a sharp instrument, compare the hardness of the disk to the hardness of the top composite - it should feel exactly the same if well cured. For general guidance, use recommended curing times below. The time required to cure can then be determined. It is highly recommended to test the device using radiometer periodically to track the performance of the device. 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.

**Recommended Cure Times (seconds) - Plasma Power Mode**

| *Manufacturer* | | *3M* | | *Ivoclar* | | *Dentsply* | | *Kerr* | |
|---|---|---|---|---|---|---|---|---|---|
| Resin Brand | | Filtek Supreme Plus | | Heliomolar | Tetric EvoCeram | TPH3 | | XRV Herculite | |
| Color/Shade | | A3E | C6D | A3 | A2 | A3 | DY | A3 | YB |
| Cure Times | Per layer | 3 | 3x3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | Final layer | 3x2 | 3x4 | 3x2 | 3x2 | 3x2 | 3x2 | 3x2 | 3x2 |

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**

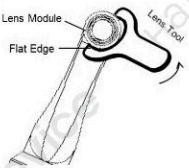



Keep FUSION on the Charging Stand when not in use. Connect DC Power Plug to Plug Receptor on the Charging Base. Peel off Stand Sticky Pad and secure Charging Stand on a table counter for easy one-handed pick up. Alternatively connect DC Power Plug directly to the back end of the Handpiece to charge and 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. It is completely safe to have the light stand on the Charging Stand all the times. 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 the end of its life, recycle or dispose it according to national, state and local regulations.

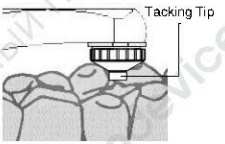
**Techniques**




**Lens Module:** Always use disposable Barrier Sleeves to protect lenses from liquid and composite damages. Replace Lens Module immediately if it: a) has cured resin or residue; 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.

**Light Shield or curing cap:** Slide in Light Shield from the LED Light Head to the Handpiece into proper position. Snap on curing cap before barrier sleeve. Light shield and curing cap functions as protective filter to decrease the blue light exposure for the operator for safe operation as explained in the precautions paragraph.

**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. Curing Caps are for single use only.




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**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.

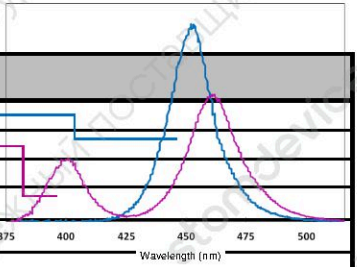
**Configuration/Add-ons**

FUSION has interchangeable LED light head allowing users to customize composite curing to their commonly used dental materials by switching its modular light head. To interchange the LED light head, simply twist and pull out the modular light head with its quick connect/tight fit connection between the light head and main control module. Optical performances of both light heads are preset by the main control ensuring consistent performance for either light head per product specification. The system can be preconfigured or later add-on using any one of the light heads:

**Standard Head** - providing center wavelengths coverage from 440 to 480nm

**Plus Head** – providing wavelength coverage from 395nm to 480nm.

**Product Specification**




| Type of information | | Specifications |
|---|---|---|
| Peak Wavelength | Standard Light Head | 440-480nm |
| | Plus/Grand Light Head | 395-480nm |
| | Violet Light Head | 395-420nm |
| | White Light Head | 5000- 6500K |
| | | |
| Tip Size (mm) | Standard/Plus Head<br>Grand Head | 10<br>12 |
| Light Intensity at light tip (±10% mW/cm2 or lux)* | Standard/Plus/Grand | 4000 (Plasma Mode); 2000 (Pulse Mode) |
| | Violet Light Head | 1200 (Plasma Mode) |
| | White Light Head | 110,000 lux (Plasma Mode with Tacking/Exam 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 Mode) and 140 minutes (Pulse Mode); 90 minutes full recharging time. Expected life: 1000 full charge/discharge cycles. |
| 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. ⧈ |

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| | |
|---|---|
| Safety | IEC 60601-1 |
| EMC Compliance | IEC 60601-1-2 |
| Protection from Electric shock | Type BF |
| Protection from ingress of liquids | IPX0 |
| Shelf Life | 5 years |
| 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: 50ºF to 86ºF (10ºC to 30ºC) Relative humidity: 10%-80%, non-condensing, Atmospheric pressure:0.5-atm to 1.0-atm(500hPa-1060hPa) |
| Storage environment | Ambient temperature: 14ºF to 104ºF (-10ºC to 40ºC) 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 with cosine corrector.

**Limited Two-Year WARRANTY**

Register your FUSION curing light at 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, Charging Stand, and Power Adapter (one-year warranty). This warranty does not cover accessory components such as curing caps, barrier sleeves and light shield, which are disposable items. 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. Buzzing noise when charging. 2. LCD is blank. | 1) Charge Battery Assembly alone by directly plugging DC Power Plug (bypassing Charging Stand) for 2+ hours. 2) Push any Key.   |
| | 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.<br>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.<br>2. Bad connection or contacts.<br>3. Battery out-of-capacity | 1) Charge Handpiece directly (bypass Charging Stand) for 2 hours; 2) Check connection pins to make sure that they are not damaged; 3) Replace battery. |
| Battery will not charge | 1. Broken pins in Charging Stand.<br>2. Electronic defect in Battery Assembly. | 1. Bypass, replace or service Charging Stand.<br>2. Replace or service Battery Assembly. |

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**Reorder and Optional Item Codes**

| REF | Description | REF | Description |
|---|---|---|---|
| 7800080 | FUSION Standard Curing Light Kit | 7800060 | Standard Light Head |
| 7820080 | FUSION Plus Curing Light Kit | 7820060 | Plus head |
| 7500082 | Barrier Sleeves (100/pack) | 7800060U | Violet Head |
| 7600081 | Curing Caps – 9mm (10/pack) | 7800060W | White Light Head |
| 7620081 | Curing Caps – 3mm (10/pack) | 7610081 | Curing Caps – 13mm (10/pack) |
| 7500084-08 | Battery Assembly | 7500083 | Charging Stand |
| 7500093 | Standard Lens Module (10mm) | 7500085 | Power Adapter |
| 7500193 | Plus Lens Module (10mm) | 7500095 | Lens Tool |
| 7500293 | Grand Lens Module (12mm) | 7500088 | Orange Goggle |
| 7500085 | Power Adapter | 7500092 | Light Shield |

**DentLight Inc.**
1825 Summit Ave. #210
Plano, TX 75074, US
Tel: (800) 763 6901
Outside US: 1-972-889-8857
www.dentlight.com

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EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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