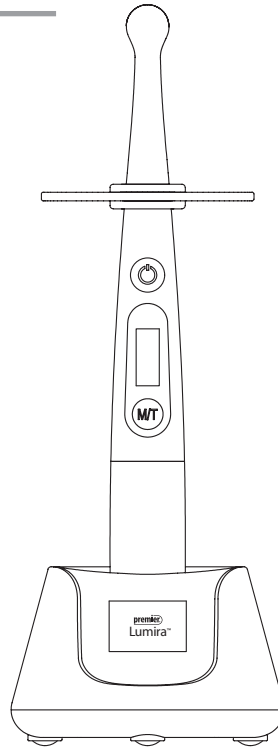
premier®

# Lumira™

## LED Curing Light System

## Instructions For Use

*Please read carefully and completely before operating unit.*




premierdentalco.com

# Catalog

# 1. Indications for Use

1.1 Lumira™ is a device which generates high intensity light for polymerization of light-curing materials used for dental curing purpose. Unlike Halogen light generating full light spectrum, it only emits light with wavelength primarily in the range of 440 to 490 nm. This is the applicable range for dental curing of camphor quinine (CPQ) containing products.

# 2. Introduction

2.1 Features:

2.1.1 Seven working modes: Normal, High, Turbo, Ortho, Soft, Pulse and Check.

2.1.2 Optimally collimated beam output, effectively reduce the optical loss.

2.1.3 Light source design providing excellent intra-oral access.

2.1.4 Constant light intensity. The solidification effect is not affected by the consumption of remaining power.

2.1.5 Charging station with integrated radiometer.

2.2 Principle and Application

2.2.1 Adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.

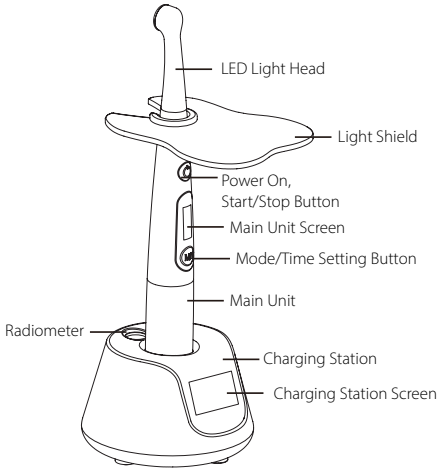
2.2.2 This product is used for dentistry. It has the function of accelerating the material of dental restoration curing.

2.2.3 The Check mode uses violet light to irradiate the teeth, and the fluorescence reaction is produced to detect dental caries or plaque.

2.2.4 The user must be professionally trained and licensed dentists.

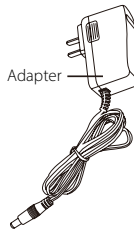
# 3. Product Performance Structure and Components

The Lumira™ LED curing light is composed of the main unit, LED light head, light shield, charging station, battery, point cure lens, and adapter.





Point Cure Lens




## 4. Basic Technical Specifications

4.1 Size of main unit: 23mm×23mm×204mm

4.2 Net weight of main unit: 108g

4.3 Applied parts of the equipment: Top of main unit, point cure lens

4.4 Duty cycle of the equipment: 20 Sec on/20 Sec off

4.5 Adapter:

4.5.1 Classified by power supply:

The power supply by the rechargeable battery.

4.5.2 Rechargeable Lithium battery:

Battery model: 18500, Battery capacity: 2000mAh

Battery has over-voltage, over current and short circuit protection

4.5.3 Adapter

Input: 100-240V~ 50/60Hz 0.4A Max. Output: 5.0V 1A

The adapter must comply with IEC 60601-1 and IEC 60601-1-2.

4.6 Light source:

4.6.1 10W high power

4.6.2 Emitted Wavelength Range: 440nm-490nm

4.6.3 Typical wavelength peaks: 460±15nm and 400±15nm

4.6.4 Class: Class II

4.6.5 AEL: $3.9\times10^{-3}$J

4.6.6 Intensity:

Not less than 250 mw/cm2.

4.6.7 Operating Conditions:

Environment temperature: 41°F (5°C) to 104°F (40°C) Relative humidity: 30%~75% Atmosphere pressure: 70kPa to 106kPa

4.6.10 Irradiance tolerance range: ±10%

4.7 Safety classification

4.7.1 Protection type against electrical shock: Class II

4.7.2 Protection degree against electrical shock: Type B

4.7.3 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0), can't be waterproof.

4.7.4 Operation mode: short time run equipment.

4.7.5 Not suitable for use in environments containing flammable anesthetic mixtures with air, oxygen, or nitrous oxide.

## 5. Installation

5.1 Insert the LED light head into the main unit, until it locks in with a click. The LED light head can rotate 360 degrees.

5.2 Using a disposable sleeve, place it over the entire unit. .

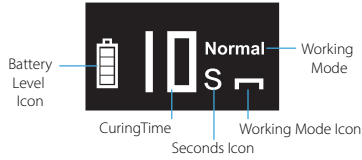
***WARNING: Use only disposable sleeves that are single patient use only. Discard used disposable sleeves in standard waste after each patient.***

5.3 Clip the notch of the light shield into the head of the top of main unit and then clamp the light shield down on the main unit.

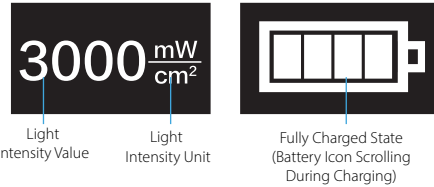
5.4 When charging is required, take out the charging station and power adapter, connect the adapter to the AC100V-240V power supply, and insert the output plug of adapter into the charging jack marked as "DC 5.0V" on the charging base. The system is designed with wireless charging technology, and the main unit can be charged wirelessly by placing it onto the charging base. Please unplug the adapter after charging.

# 6. Operation

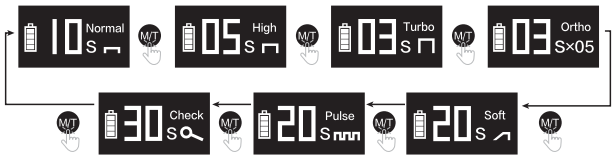
## 6.1 Main unit screen display




## 6.2 Charging station screen display




## 6.3 Working mode setting:




Quickly press the "M/T" button to select the working mode. Seven working modes can be selected: Normal, High, Turbo, Ortho, Soft, Pulse and Check. Because the curing time of different modes is different, when switching modes, the curing time will automatically follow the switching.

## 6.4 Curing time setting

Long press "M/T" button:


Press and hold the "M/T" button to change the curing time.
Different working modes have different curing times.

### 6.5 Quick mode guide

| Mode | Curing time (Seconds) | Light intensity (mW/cm2) |
|---|---|---|
| Normal | 5, 10, 15, 20 | 1000-1200 |
| High | 3, 5 | 1800-2000 |
| Turbo | 1, 3 | 2700-3000 |
| Ortho | 3*5, 3*10 | 2700-3000 |
| Soft | 5, 10, 15, 20 | 1000-1200 |
| Pulse | 5, 10, 15, 20 | 1000-1200 |
| Check | 30, 60 | — |
| Working mode setting | Press and release "M/T" button quickly to cycle to next working mode. | |
| Curing time setting | Press and hold "M/T" button 1 second and release. Curing light will cycle to next curing time. | |

6.6 Quick Curing Guide: Recommended curing times for optimal results exposure times may need to be adjusted due to composite reactivity, shade, distance from the light lens to the composite, and depth of composite layer if it is over 2mm.

| Mode | Normal, Soft, Pulse | High | Turbo | Ortho |
|---|---|---|---|---|
| Per 2mm Layer | 1×10 Seconds | 2×3 Seconds | 1×3 Seconds | — |
| Final Cure | 2×10 Seconds | 2×3 Seconds | 2×3 Seconds | — |
| Ortho Metal & Ceramic Brackets | — | 2×5 Seconds | 2×3 Seconds | 2×3 Seconds |

**6.7 Use Point Cure Lens:** The magnetic point Cure Lens provides pinpoint curing of small composites and is helpful for tack curing veneers and all porcelain crowns.

For veneers, the Turbo mode with a 1-second curing time allows for point curing the center of a veneer with the ability to then clean up the uncured excess around the margins, then cure the entire restoration using the full-sized curing lens.

For all porcelain crowns, place the curing light on the buccal and lingual surfaces and point cure using Turbo mode for approximately 2 seconds each, clean up the uncured resin around the margins, then cure the entire restoration using the full-sized lens.

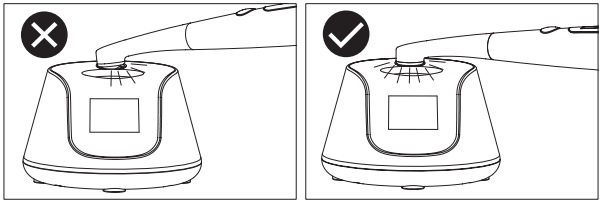
### 6.8 Caries detection using Check mode

Select the Check mode, when purple light irradiates caries or dental plaque, it will produce orange red fluorescence reaction to detect surface caries or dental plaque.

*WARNING: Check mode is prohibited for curing resin-based materials.*

6.9 Measuring the light intensity

The integrated radiometer allows the light intensity (mW/cm2) to be measured easily and quickly while the charging station is connected. To measure the light intensity, place the lens of the LED light head, without disposable sleeve, flush into the marked recess on the upper side of the charging station. Then activate the light and read the value displayed on the screen. Measurement accuracy is in the range of +/–10%.



*CAUTION: If the lens of the light head is placed obliquely to measure the light intensity, there will be obvious deviation in the measured light intensity value. The effective measurement of the integrated radiometer is the diameter of the light source is 10mm, if the measured light source diameter is not 10 mm (As common 8mm), it will lead to the obvious difference in the measured light intensity. At the same time, different manufacturers have different standards for measuring the light intensity value. It is suggested that it should only be used for measuring the Lumira™ LED curing light. If it is not the Lumira™ LED curing light, the measured light intensity value may have obvious differences.*

6.10 When operating, put a disposable sleeve on the main unit, clip the notch of the light shield into the head of the top of main unit, and then clamp the light shield down on the main unit. Aim the top of main unit at the correct position, press the power button, a beeping sound will occur starting the working cycle of the mode selected. The screen will begin to display the countdown time. When the countdown is back to 0 the working cycle is completed. The screen will return to setting time.

6.11 While in operation, pressing the power button at any time will stop the working cycle.

6.12 At the end of a working cycle , the next working cycle can be started immediately by pressing the power button. If the main unit gets hot, turn off the device until the main unit becomes cool. Please don't make it continuously illuminate more than 10 times.

6.13 When the battery is low, the main screen displays "Low Battery".

6.14 When charging, connect the adapter with the charging station: Put the main unit into the charging cradle for wireless inductive charging. At this time, the battery icon on the charging station screen will scroll to show that it is charging. When the battery icon on the charging station screen stops scrolling and displays full charge, it means that the battery is fully charged.

6.15 When the procedure is complete, please clean the LED light head lens with a clean cloth to avoid infecting the light intensity.

6.16 This equipment will turn off automatically if no action is implemented within 2 minutes. Turn it back on by pressing the power button.

*WARNING: Place a disposable sleeve over the curing light before using on the patient.*

## 7. Contraindication

The curing light is contraindicated for use in patients prone to photobiological reactions (including patients with solar urticaria or erythropoietic protoporphyria) or those currently undergoing treatment with photosensitizing pharmaceuticals.

Heart disease patients, pregnant women and children should be cautious to use the curing light.

## 8. Precaution

8.1 Please recharge the battery at least 4 hours before first time usage.

8.2 When charging the battery, please place the charging station within reach to be able to easily unplug the unit.

8.3 As is the case with all high-performance lights, the high light intensity results in a certain heat development. Prolonged exposure of areas near the pulp and soft tissues may result in irreversible damage. Therefore, this high-performance curing light must only be operated by licensed dental professionals.

8.4 Do not expose soft oral tissues at close proximity for more than 10 seconds in any mode. If longer curing time is required, use multiple shorter curing cycles to avoid heating soft tissue, or use a dual-cure product.

8.5 If the light emission window cannot be optimally placed in relation to the composite restoration, the restoration must be polymerized using a conventional method. If soft tissue exposure to the curing light cannot be avoided, the High mode and Turbo mode must not be used, as exposure may result in damage of the soft tissues.

8.6 Never aim the light directly at unprotected soft tissues, as this may cause injury or irritation. Do not aim the light at eyes. Light reflected from the tooth surface may also injure eyes. Use the eye protection light shield supplied with the unit or suitable, light filtering safety glasses. The curing light is classified as a Risk Group 2 device according to IEC 62471.

8.7 Check mode is prohibited for curing resin-based materials.

8.8 During operation, the light should be aimed straightly at the resin to ensure the effect of solidification.

8.9 Be sure to use the original light shield to avoid the blue light injuring eyes. DO NOT aim light directly into eyes.

8.10 Only the original adapter should be used. Other brands of adapters may cause damage to the curing light's circuit.

8.11 Charge the unit in a cool, well-ventilated area. Make sure there is no debris inside the charging station well, otherwise the battery charging might fail because of poor induction contact.

8.12 Do not disassemble the lithium battery, it will lead to the circuit short or the electrolyte leakage.

8.13 Do not squeeze or shake the battery. Do not store the battery with metal material.

8.14 The instrument has electromagnetic interference. Do not use around the electronic operation, at the same time have a strong electromagnetic interference environment should be careful to use the instrument.

8.15 This product should be used by trained, licensed dental professionals.

8.16 To avoid electromagnetic interference, the device should be installed at the medical site which meets EMC requirements.

*WARNING: The adapter should be connected to the socket that is easy for the operator to reach.*

*WARNING: over-heat scorching: The duty cycle of the equipment is 20 Sec on/20 Sec off. If the curing light works for 40s continuously, the temperature of the top of main unit may reach 132°F (56°C).*

## 9. Cleaning, Disinfection and Sterilization

9.1 Reprocessing Summary

| Component | Clean & Sterilize | Disinfect |
|---|---|---|
| Point Cure Lens | Yes | — |
| LED Light Head | No | Yes |
| Main Unit | No | Yes |
| Light Shield | No | Yes |
| Charging Station / Power Adapter | No | Yes |

### 9.2 Infection Control Methods

#### 9.2.1 During Patient Use:

- Use single-use disposable barrier sleeves over the main unit and LED light head.

#### 9.2.2 After Each Patient:

1. Remove and discard barrier sleeve.
2. Clean visible debris if present.
3. Wipe-disinfect only using an EPA-registered intermediate-level disinfectant.
4. Allow to air dry per disinfectant instructions.

#### 9.2.3 Prohibited Actions:

- Do not autoclave the Main Unit, LED Light Head, Light Shield or Charging Station.
- Do not soak any components in liquid.
- Do not spray disinfectant directly into seams on the Main Unit or onto the LED Light Head.

The cleaning, disinfection and sterilization of point cure lens is as follow. Unless otherwise stated, they will be hereinafter referred to as "products".

*Warnings*

***The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. In such cases, the manufacturer takes no responsibility.***

***This device shall not be exposed to high temperature above 280°F (138°C). Processing limit.***

***The products have been designed for a large number of sterilization cycles.***

***The materials used in manufacturing were selected accordingly. However, with every reprocessing preparation, thermal and chemical stresses may result in degradation of the products. The maximum number of sterilizations for point cure lens is 500 times.***

### 9.3 Initial processing

#### 9.3.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.

Cleaning and Disinfection Prior to Use - Main Unit

- Before each use, wipe the surface of the machine with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.
- After each use, wipe the surface of the device with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe.
- Repeat the wipe for at least 3 times.

### 9.3.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Remove the point cure lens from the Curing light Device,and rinse away the dirt on the surface of product with pure water (or distilled water/deionized water);
2. Dry the product with a clean, soft cloth and place it in a clean tray.

*Notes*

a.) The water used here must be pure water, distilled water or deionized water.

### 9.4 Preparation before cleaning

*Steps*

Remove point cure lens from main unit.

Use a clean soft brush to carefully brush the point cure lens until the dirt on surface is not visible. Then use soft cloth to dry the point cure lens and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

### 9.5 Cleaning

### 9.5.1 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Wipe down with FDA approved disinfectant the components as listed in Reprocessing Summary chart.

### 9.5.2 Automated Washer-disinfector

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

- Use high temperature disinfection function. The temperature does not exceed 273.2°F (134 °C), and the disinfection under the temperature cannot exceed 20 minutes.
- Cleaning and disinfecting steps by using Washer-disinfector:
  1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.

2. Run the washer/disinfector according to the manufacturer's instructions.
3. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

*Notes*

a.) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b.) With this equipment, cleaning, disinfection and drying will be carried out together.

c.) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 113°F (45 °C), otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed.

d.) Disinfection: (d1) Direct use after disinfection: temperature ≥ 194°F (90 °C), time ≥ 5 min or A0 ≥ 3000. (d2) Sterilize it after disinfection and use: temperature ≥ 194°F (90 °C), time ≥ 1 min or A0 ≥ 600. (d3) For the disinfection here, the temperature is 199°F (93 °C), the time is 2.5 min, and A0>3000.

e.) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f.) After cleaning, the chemical residue should be less than 10mg / L.

g.) The air used for drying must be filtered by HEPA.

h.) Regularly repair and inspect the disinfector.

### 9.6 Drying

If the cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

*Methods*

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered

dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 176°F~248°F (80°C~120°C) and the time should be 15~40 minutes.

*Notes*

a.) The drying of product must be performed in a clean place.

b.) The drying temperature should not exceed 280°F (138°C).

c.) The equipment used should be inspected and maintained regularly.

### 9.7 Inspection and maintenance

9.7.1 Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

9.7.2 Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

9.7.3 Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

9.7.4 If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

### 9.8 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

*Notes*

a.) The package used conforms to ISO 11607;

b.) It can withstand high temperature of 280°F (138°C) and has sufficient steam permeability.

c.) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants.

d.) Avoid contact with parts of different metals when packaging.

### 9.9 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665.
2. The highest sterilization temperature is 280°F (138°C).

3. The sterilization time is at least 4 minutes at a temperature of (270°F/273°F) 132°C/134°C and a pressure of 2.0 bar ~ 2.3 bars.
4. Allow a maximum sterilization time of 20 minutes at 273°F (134°C).
5. Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

*Notes*

a.) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

b.) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

c.) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

d.) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

*Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

## 10. Daily Maintenance

10.1 A disposable sleeve helps prevent cross contamination and helps keep dental composite material from adhering to the surface of the lens and main unit.

10.2 Cleaning the housing: wipe the housing surfaces with a cloth lightly moistened with ethanol for disinfection (ethanol 70 to 80 vol%). Do not clean with highly aggressive disinfecting solutions (e.g. solutions based on orange oil or with an ethanol content of more than 40%), solvents (e.g. acetone), or pointed instruments, which may damage or scratch the housing surfaces.

10.3 Routinely check the lens for cured dental resins. If necessary, use a non-diamond dental instrument to carefully remove any adhered resin.

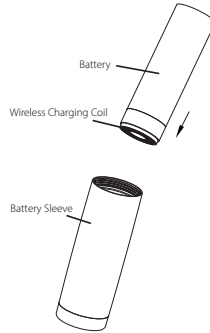
10.4 This unit does not include the self-maintainable spare parts. The maintenance of this unit should be taken by the appointed professional or special repair shop.

10.5 Please use only accessories designed and supplied by our company or your dental dealer.

10.6 Please clean the resin remained on the light head or the main unit immediately after using.

10.7 If the main unit is not used for a long time, be sure to charge the lithium battery every six months to prevent damage to the lithium battery.

10.8 If you need to replace the lithium battery, first unscrew the battery sleeve on the main unit counterclockwise to take out the battery. Then put the wireless charging coil end of the new lithium battery into the battery sleeve (as shown in the figure below) and push battery into place. Finally tighten the battery sleeve clockwise.




## 11. Troubleshooting

| Faults | Possible causes | Solutions |
|---|---|---|
| No Display.<br>No response. | 1. Battery is out of power.<br>2. Battery is protected.<br>3. Faulty battery. | 1. Charging.<br>2. Place the curing light into the charging station well, check if the battery is working.<br>3. Please contact dental dealer or Premier. |
| The main unit can't be charged. | 1. The adapter is not fully plugged into outlet.<br>2. The charging well is dirty or blocked by debris.<br>3. Using the wrong adapter.<br>4. Faulty adapter. | 1. Reconnect the adapter.<br>2. Clean by the alcohol.<br>3. Use the original adapter.<br>4. Please contact dental dealer or Premier. |
| Main unit screen displays "Low battery!" | Battery is out of power. | Charging. |
| Main unit screen displays "LED Error!" | LED light source is damaged or broken. | Replace the light head unit with a new one. Please contact your dental dealer or Premier. |
| Light intensity is weak. | 1. Check for resin on the lens.<br>2. Lens damaged. | 1. Clean the resin.<br>2. Replace the lens assembly with a new one, please contact your dental dealer or Premier. |
| Effective duration of the battery becomes short. | The capacity of the battery decreased. | Replace the battery with a new one, please contact your dental dealer or Premier. |

If all the above solutions have been completed, the machine still cannot work normally. Please contact a special repair shop or Premier.

## 12. Storage and Transportation

12.1 Storage

12.1.1 Store in a clean, dry, ventilated, non-corrosive atmosphere; kept away from any shaking source, with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -4°F (-20°C) to 131°F (55°C).

12.1.2 After sterilization, the product should be packaged in a medical sterilization bag or a clean sealing container and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

*Notes:*

a.) The storage environment should be clean and must be disinfected regularly.

b.) Product storage must be batched and marked and recorded.

12.1.3 Don't store the unit with articles that are combustible, poisonous, caustic, and explosive.

12.1 Transportation

12.4 Prevent excessive shock and vibration during transportation, and handle with care.

12.5 It should not be mixed with dangerous goods during transportation.

12.6 Avoid exposure to sun or rain or snow during transportation. The cleaning and disinfection of main unit are as follows.

## 13. After Service

From the purchased date of this unit to the end of the warranty period, Premier will repair or replace this unit free of charge if it has quality problems. Please refer to the warranty for details.

## 14. Environmental Protection

There are no harmful factors in the product. Please refer to the local law for guidance.

## 15. Symbol Instruction

| | |
|---|---|
|  | Type B Applied Part |
|  | Date of Manufacture |
|  | Class II equipment |
|  | Follow instructions for use |
|  | Atmospheric pressure for storage |
|  | Humidity limitation for storage |
|  | Manufacturer |
|  | Do not autoclave |
| UDI | Unique Device Identifier |
|  | Consult instructions for use |

| | |
|---|---|
| **Rx ONLY** | Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner. |
| MD | Medical Device |
|  | Keep dry |
|  | Fragile; handle with care |
|  | Used indoor only |
|  | Appliance compliance<br>WEEE directive |
|  | Temperature limitation for storage |
| REF | Reference Number |
| SN | Serial number |
| IPX0 | Ordinary equipment |

# 16. EMC - Declaration of Conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The device are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The device use 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 CISPR11 | Class B | The device is suitable for use in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

**Guidance & Declaration — electromagnetic immunity**

The device are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that It is used in such an environment.

| Immunity test | IEC 60601 | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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<br>IEC 61000-4-4 | ±2kV for power supply lines ±1 kV for Input/ output lines | ±2kV for power supply lines ±1kV for interconnecting cable | Main power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 kV line to line<br>±2 kV line to earth | ±1 kV line to line | Main power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5 % $U_T$<br>(>95% dip in $U_T$.) for 0.5 cycle<br>40 % $U_T$<br>(60% dip in $U_T$) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$) for 25 cycles<br><5% $U_T$<br>(>95 % dip in $U_T$) for 5 sec | <5 % $U_T$<br>(>95% dip in $U_T$.) for 0.5 cycle<br>40 % $U_T$<br>(60% dip in $U_T$) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$) for 25 cycles<br><5% $U_T$<br>(>95 % dip in $U_T$) for 5 sec | Main power quality should be that of a typical commercial or hospital environment. If the user of the device require continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

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

**Guidance & Declaration — electromagnetic immunity**

The device are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that It is used in such an environment.

| Immunity test | IEC 60601 | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6<br>Radiated RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM bands<br>3 V/m<br>80 MHz to 2.7 GHz<br>385MHz-5785MHz<br>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014) | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM bands<br>3 V/m<br>80 MHz to 2.7 GHz<br>385MHz-5785MHz<br>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014) | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d=[3,5/V1]\times P^{1/2}$<br>$d=1.2\times P^{1/2}$ 80 MHz to 800 MHz<br>$d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz<br>where 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).<br>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]<br>Interference may occur In the vicinity of equipment marked with the following symbol:  |

1. At 80 MHz end 800 MHz. the higher frequency range applies. / 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 device are used exceeds the applicable RF compliance level above, the model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. / b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

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

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter /m | | |
|---|---|---|---|
| | 150kHz to 80MHz $d=1.2\times P^{1/2}$ | 80MHz to 800MHz $d=1.2\times P^{1/2}$ | 800MHz to 2,5GHz $d=2.3\times P^{1/2}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| .1 | .38 | .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) accordable to the transmitter manufacturer. 1. At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies. / 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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## 17. Limited Warranty

The Premier® Lumira™ LED Curing Light is designed exclusively for use by licensed dental professionals. This warranty extends to Lumira systems purchased from an authorized Premier® dealer and is available only to the original purchaser of the unit who is able to provide proof of purchase from an authorized Premier® dealer.

Premier® warrants all components* of the Lumira™ LED Curing Light System, including a limited warranty of the lithium battery as set forth below, against defects arising from faulty materials and workmanship for two (2) years from the date of purchase. With regard to the lithium battery, if Premier® determines that the lithium battery is defective and that the defects are not caused by misuse, abuse or accident by the user, Premier will provide a one-time replacement of the main unit within one (1) year from the date of purchase. The use of an AC adapter other than the one provided with the Lumira™ LED Curing Light System, and the use of any other unauthorized parts or an unauthorized repair facility, will void in its entirety the foregoing warranty.

Parts will be repaired or replaced at the discretion of Premier® provided that the system has been operated and maintained as prescribed in these instructions and has not been subjected to apparent misuse, abuse or accident. Claims covered by this warranty will be honored when presented to Premier® within thirty (30) days from discovery of defect within the applicable warranty period.

There are no warranties, express or implied, which extend beyond the description on the terms described above. Premier® neither assumes, nor authorizes any person to assume for it, any other liability in connection with the sale or use of the Lumira™ LED Curing Light System. Damages are limited strictly to repair or replacement of parts. Premier® expressly disclaims liability for incidental, indirect and consequential damages resulting from the use of the Lumira™ LED Curing Light System

* Exclusions: Optical fiber and light shield are not covered.