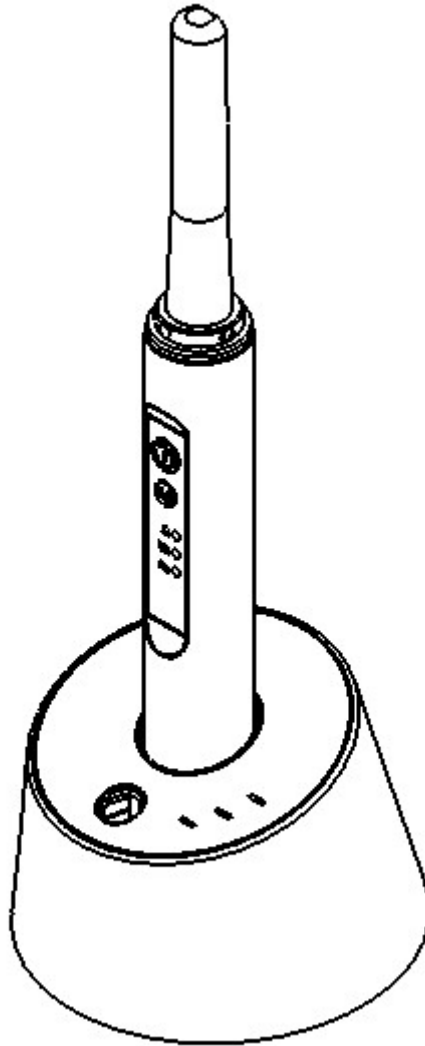


*User Manual*

***Rolence LED Curing Light***

# ***ELITEDENT<sup>®</sup> Q6-NLG***



## ***Instructions For Use***

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**Caution: For dental use only.**

# 1. PRECAUTIONS AND SAFETY NOTES

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## PLEASE NOTE!

Prior to installation and start-up of the unit, carefully read the instructions provided herein!

As with all technical devices, the proper function and safe operation of this unit depend on the user's compliance with the safety recommendations presented in these operating instructions.



**CAUTION:** This curing unit produces high curing energy output! A significant increase in curing energy is possible compared with conventional Halogen equipment you have previously used. Do not place light directly on or toward unprotected gingiva or skin. Exposure of the soft tissues (gingiva, oral mucosa and skin) to high-intensity light may cause damage or irritation.

Adjust your curing techniques in accordance with the increase in curing energy. Some examples are; decrease curing time, increase composite thickness, increase distance between light guide exit and light cured materials e.g.



**CAUTION:** Do not look directly into the light emitted from this curing unit. It may be harmful to the eyes. Exposure must be restricted to the area of the oral cavity in which clinical treatment is intended. Do not use this device without suitable protective eye shield for the operator, assistant and patient. Suitable protective eye shield should blocks most energy below 550nm wavelength.



**CAUTION:** Do not touch the charger and the patient at the same time while operating.



**CAUTION:** Persons having a history of photosensitive reactions or who are using photosensitizing drugs should not be exposed to the light from this unit.



**CAUTION:** Equipment is not suitable for use in the presence of flammable anesthetic mixture with air, nitrous oxide or environment full of flammable material. Use in well ventilated area.



**CAUTION:** DO NOT IMMERS UNIT IN WATER OR DISINFECTANT. Do not spray liquids directly onto the light. Spray a towel, then wipe the light. Prevent liquids from entering openings on unit, especially the socket for re-charging. Refer to Section 10, Cleaning / Disinfecting / Sterilizing for sterilizing instructions.



**CAUTION:** Always unplug the base/charger before disinfecting.



**CAUTION:** Don't dispose of the battery into fire or take battery apart.










**CAUTION:** The system need a 10 minutes cooling down after 2 minutes of continuous operating.




1. This product is intended to be used only as specifically outlined in these Directions for Use. Any use

of this product inconsistent with the Directions for Use is at the discretion and is the sole responsibility of the practitioner.

2. Keep solvents, flammable liquids, and sources of intense heat away from the unit as they may damage the plastic housing of the charger, the seals, or the cover on the operating buttons.
3. To protect the no light guide, after each curing procedure is completed, the handpiece should always be placed back into its holder.
4. To obtain a safety operation, we suggest that check your local AC power supply voltage before you buy and use this product from oversea.
5. The adaptor is served to disconnect the device, not to position the equipment to make it difficult to operate the disconnection device.
6. Check unit for adequate light output before each procedure. Failure to verify output may allow inadequate curing.
7. On the applied part, no light guide, the temperature may up to 43°C/110°F at the atmosphere temperature of 40°C/104°F.
8. In order to avoid electric shock do not introduce any objects into the unit with the exception of replacement parts handled in accordance with the Operating Instructions. Do not attempt to change the Curing LED, open or alter the unit in any way
9. Use only genuine Rolence parts when replacing defective components as directed in these Operating Instructions. The product’s warranty does not cover any damage resulting from the use of third-party replacement parts.
10. A warning that other cables and accessories may negatively affect EMC performance.
11. A warning regarding stacking and location close to other equipment.
- 12.** A warning that use of other accessories results in non-compliance.

## 2. Glossary of Symbols

	Caution, Consult accompanying Documents
	Read usage instructions
	Alternating Current
	Manufacturer
	Date of manufacture
	Catalogue number
	Type BF Applied Part; Type BF Equipment - Protection against electric shock

	Equipment class: Class II (IEC601-1) - double insulated
	The equipment complies with the requirements in the Medical Device Directive 93/42 EEC.
	Icon to identify electric and electronic devices. The unit must be collected and disposed of separately.

### **3. PRODUCT DESCRIPTION & FIELDS OF APPLICATION**

---

The ELITEDENT Q6-NLG curing light is a pen style, cordless, high-performance LED light source curing unit intended for polymerization of resin-based light cured dental materials by dental professionals. ELITEDENT Q6-NLG incorporates two types of LEDs to achieve broad wavelength with range of 390 to 480nm output to polymerize virtually all the resins in the market and a high power mode to produce super fast curing effect. The relevant range both for camphorquinine (CPQ) and phenyl propanedione (PPD) containing product. Though the majority of light-curing dental materials are responsive in this range of wavelengths, it is suggested you should contact the filling material maker to make sure it before use.

The ELITEDENT Q6-NLG is a fast-curing LED curing light. It emits typical light energy output at about 2,000~2,200mW/cm<sup>2</sup>. 3 seconds to cure most composite in the market with 2mm thickness. It also features:

- ▶ Multiple mode selection: High (fast curing), low and ramp up.
- ▶ All aluminum handpiece housing for improved durability. No more plastic to stain or crack.
- ▶ Two button easy operation.
- ▶ Quiet operation, fan-free design.
- ▶ Can be used both cordless and corded.
- ▶ Low battery warning; for urgent use, just insert power cord connector into Handpiece directly.
- ▶ Rechargeable lithium battery inside, capable of 200 x 10 sec curing cycles prior to recharging.
- ▶ Slim handpiece for most comfortable hand holding
- ▶ Curing tip rotates 270° for curing at any position of mouth.

### **4. PACKAGE CONTENT**

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· Charging Base Assembly	X 1 PCE
· Hand piece Assembly	X 1 PCE
· eye shield	X 1 PCE
· Wall Plug-in Power Adaptor	X 1 PCE
· Instructions For Use	X 1 PCE

## 5. TECHNICAL DATA

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### 5.1 Charging Base

Operating voltage:	INPUT: 100~240VAC, 0.5A , 50/60HZ
	OUTPUT(Adaptor) : 5V DC , 3A
	OUTPUT(Charging Base) : 4.2V DC , 1A
Dimensions	
Diameter:	93 mm
Height:	66 mm
Weight:	Roughly 202 g

### 5.2 Handpiece

Power supply:	Lithium battery – 3.6V DC, 2040mAh
Wavelength range:	390-480 nm
Typical light intensity	2,000~2,200 mW/cm <sup>2</sup>
Total exposure time with new fully charged battery	Typically 30 minutes
Dimensions	
Diameter:	25 mm
Length	235 mm
Weight (with light guide and battery):	Roughly 140 g

### 5.3 Charging Base and Handpiece

Time to charge empty battery:	Approximate 3 hours
Protection from electric shock:	Type BF (IEC601-1)
Equipment class:	Class II (IEC601-1)
Protection from ingress of liquids:	None
Operation temperature	+10°C ~ +35°C
Relative humidity range	30% ~ 75%
Atmospheric pressure	700hPa ~ 1060hPa

### 5.4 Transportation and Storage Environment

Ambient temperature	-10°C ~ +70°C
Relative humidity range	10% ~ 90%
Atmospheric pressure	500hPa ~ 1060hPa

## 6. INSTALLATION OF THE UNIT

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### 6.1 Initial set-up

**NOTE:** Upon receiving the LED Curing Light, check the packaging and parts for any possible damage that may have occurred in transit. If damage is apparent, please contact your authorized Rolence distributor from which the light was purchased.

1. Remove the contents from the shipping package. Be careful not to drop or impact the curing light. Choose a flat, level, sturdy surface to place the charging base on. The light is shipped in a “sleep” mode, and no timer display. To wake the unit, press the On/Off button.
2. Before using for the first time, the light must be fully charged. For the first charge, this process will take about 6 hours. Use only the power supply furnished with the light system. Attempting to use another power supply source may cause injury or damage and will void the warranty.
3. Charging indicator on charging base illuminates orange light during recharging. It will turn off automatically after battery is fully charged.

**NOTE:** Power indicator on charge base illuminates blue light, which indicates the charging base is well connected to power supply. If power indicator is not lit when connecting power plug to charging base, please check the outlet plug is firmly connected or not.

4. Plug the connector of the power supply into the back of the charging base as shown in Figure 3. Plug the other end of the power supply into the appropriate electrical outlet. As mentioned above, wait for at least 6 hours to completely charge the light before the first use.

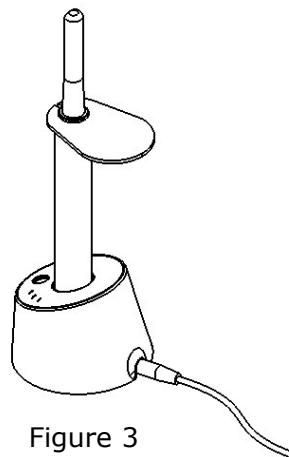


Figure 3

**NOTE:** Verify the line plug of the power supply plug is properly rated for your facility, and that all connections comply with safe practices and all local requirements. Always use unit in conjunction with a properly grounded outlet.

## 6.2 Keypad and modes

There are 2 buttons on the key pad for the mode/timer selection, and the on/off button. (Fig. 4) The on/off button is used to activate and deactivate the light. Push once to turn on the light and push it again if you need to turn it off at any time during the curing cycle.

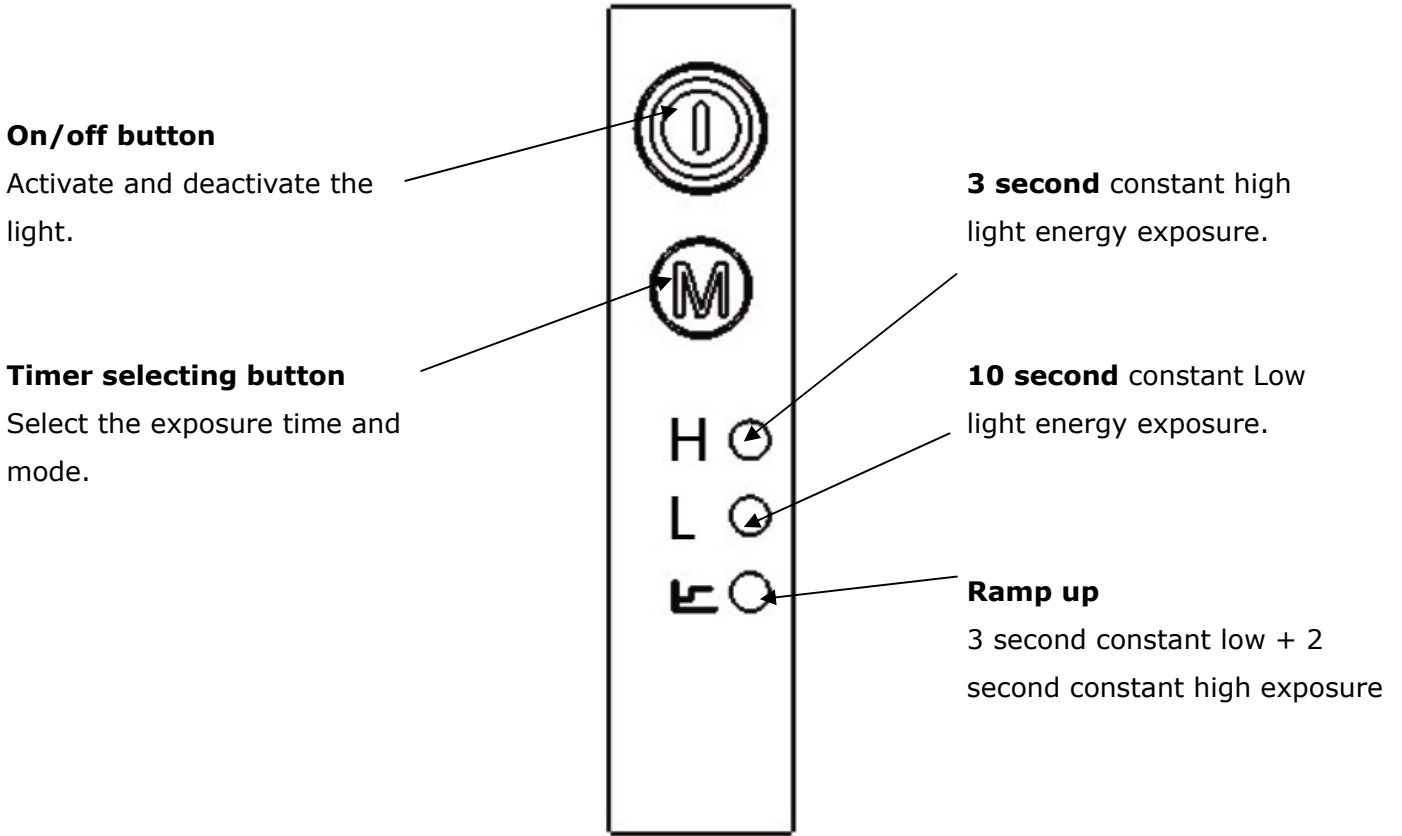


Figure 4

There are 2 different modes to select from based on the procedure and the requirement. (Fig. 4)

- Select the exposure time by pressing the mode button briefly.
- While exposure is ongoing, the button for selection of the exposure time is inactive.

**(3s or H)** – This setting provides high power to the LEDs, helping them generate a higher power output up to 2,000mW/cm<sup>2</sup>. Since the LEDs function at such high power level, only the 3 second curing cycle is provided to avoid premature LED failure. You can use multiple boost cycles in succession to obtain longer Boost curing.

**(10s or L)** – Provides low light energy exposure at 10 seconds exposure. Choose this setting for special lighter or darker shade curing requirement or when light energy declines after long time use.

**(Ramp Up)** - An initial 45~60% energy of high intensity and then switch to high intensity 2,000mW/cm<sup>2</sup> constant. Total **5** seconds (3 seconds low intensity + 2 seconds high intensity)



### 6.3 Charging Base

#### Light Checker

Place light probe onto the window and turn on the light to check light intensity. (Refer to Section 9)

#### Intensity indicator

Illuminates only when light intensity is over 600mW/cm<sup>2</sup> (this is an appropriate read, for reference only.)

#### Power Indicator

Illuminates when charging base is connected to power supply.

#### Charging indicator

Illuminates during charging, turn off after fully charged.

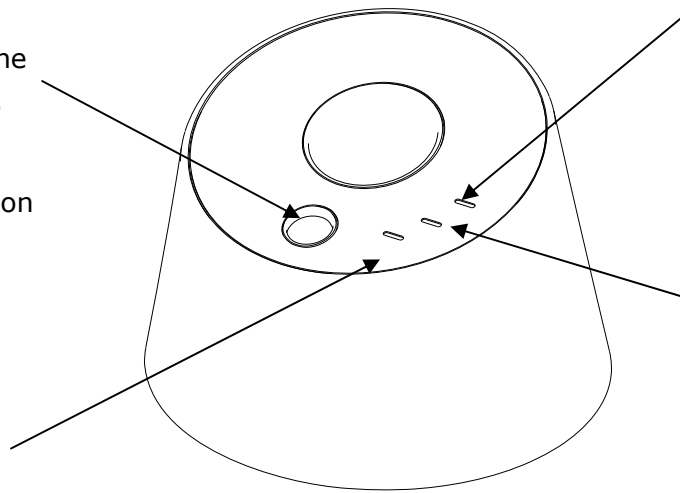


Figure 5

### 6.4 Battery Charging

To charge the battery, place the handpiece in the charging base, with the power supply attached to the charging base. When this is done, the POWER INDICATOR will illuminate. (Figure 5)

The light may be used with the power supply attached to the handpiece handle, even if the battery is low. While in this configuration, the battery will charge while the unit is not being used. When the handle is removed from the charger, or the power disconnected, none of the battery indicators will illuminate.

## 7. OPERATION INSTRUCTION

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### Activating and Deactivating the Light:

- ▶ The light will enter "sleep" mode if the unit has not been used for more than 2 minute, the panel display will turn off to conserve power. If the panel display is not illuminated, simply press on/off button to bring it out of the sleep mode.
- ▶ Activate the light by pressing the on/off button on the keypad.
- ▶ Press the on/off button again to turn off (interrupt) the light before the exposure time is over.

### Adjust mode and curing time for the Light:

- ▶ Always use the settings recommended by the manufacturer of the dental material when selecting the settings
- ▶ Please refer to Chapter 6.2 for more information of mode selection and curing time setting.
- ▶ Make sure everyone is wearing the appropriate eye protection.

### Warning signal:

- ▶ If the temperature on hand piece is over 40°C, the "H" and "L" indicator will illuminate at the same time and buzzer continuously beep 5 tones and cannot turn on curing LEDs.
- ▶ If the temperature on hand piece is over 35°C, the all indicator will illuminate at the same time and buzzer continuously beep a long tone for high temperature warning.
- ▶ If the battery voltage runs low, the "L" and "Ramp up" indicator will illuminate at the same time and buzzer beep continuously 3 tones. Please place handpiece back into charger for recharging.

### Note:

- ▶ Follow manufacturer's directions for curing times on various materials. It is better to over cure rather than insufficient cure. Over curing should not harm the restoration.
- ▶ If the LED remains activated for an extended period, a safety thermostat will cut off the LED to protect curing gun from overheating. Normal usage may then be resumed if the handpiece is idled for an extended period for cooling.

## 8. OPERATING ERRORS AND TROUBLE SHOOTING

Problem	Cause ▶ Solution
1. No timer display on handpiece.	The unit is in sleep mode. ▶ Press the on/off button to wake the unit.
2. Can not activate/wake the light.	Battery is drained. ▶ Please recharge battery, and try again. Handpiece is out of order. ▶ If not sure what happen, contact the dealer for further inspection.
3. All illuminate at the same time and buzzer beeps a long tones	Handpiece is almost overheat ▶ It will be reaching the limit of high temperature. Then it will be limited counts for LEDs curing.
4. "H" and "L" indicator illuminate at the same time and buzzer beeps 5 short tones.	Handpiece is overheat ▶ Please wait for to have handpiece cooled down. ▶ Waiting time can be shortened if handpiece is cooled by compressor air.
5. "L" and "Ramp up" indicator illuminate at the same time and buzzer beeps 3 short tones.	Low battery voltage ▶ Battery is drained. Please place handpiece back to charging base for recharging.
6. Charging indicator on handpiece is not on when placing handpiece on the charging base.	Check the power plug connects to power outlet socket firmly. ▶ If not sure what happen, contact the dealer.
7. Battery working time is significantly shortened.	▶ Battery is exhausted after period use (generally 2 years). Please contact the dealer to replace with a new battery. ▶ If not sure what happen, contact the dealer for further information.
8. Whenever press the on/off button or mode button on keypad, there is no response in timer display, nor light.	The light program is crashing. ▶ Insert adaptor connector (not powered) into the hole on the back of handpiece to reset the light program.

**If the above steps do not solve the problem, contact the dealer or point of purchase.**

**Note:** We and our authorized distributors will make available on request circuit diagram, component part lists and other information to assist user's appropriate technical personnel to repair the light cure units which are designated by us as repairable.

## 9. SERVICE AND REPLACEMENT PARTS

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For product service please contact your nearest Rolence authorized dealer you purchased product.

### **Replacement Accessories**

<b>Part #</b>	<b>Description</b>	<b>Contents</b>
<b>1133B80</b>	ELITEDENT <sup>®</sup> Q6-NLG Wall Plug-In Power Supply	1x Power Supply
<b>1133B90</b>	ELITEDENT <sup>®</sup> Q6-NLG eye shield	1x eye shield
<b>1133A10</b>	ELITEDENT <sup>®</sup> Q6-NLG Charging Base Assembly	1x Charging Base
<b>1133A20</b>	ELITEDENT <sup>®</sup> Q6-NLG Handpiece Assembly	1x Handpiece

### **Optional accessories**

<b>Part #</b>	<b>Description</b>	<b>Contents</b>
<b>LM200</b>	Digital Light Meter 200	1x Light meter 200
<b>LM105</b>	Analog Light Meter 105	1x Light meter 105

### **Check light intensity with light checker on charging base**

The Elitedent Q6-NLG consists of a light intensity checker on charging base. Place the probe of light tip onto the window (See Figure 6) to ensure sufficient light energy provided for treatment prior to each curing.

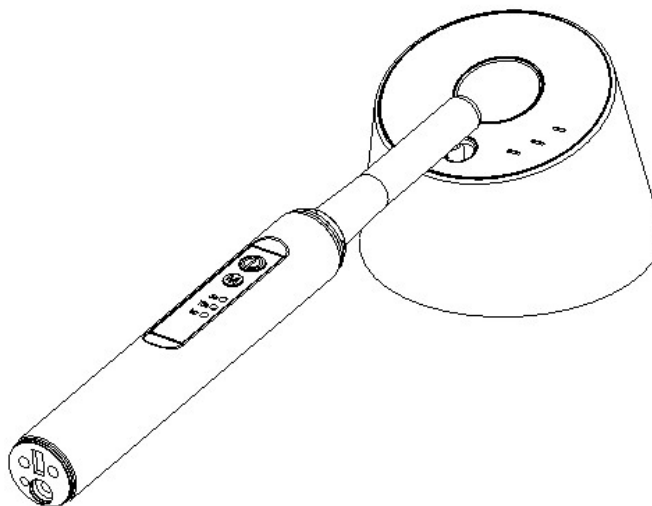


Figure 6

## **10. Cleaning / Disinfecting / Sterilizing**

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### **10.1 Cleaning and Disinfection of Fiber**

- ▶ Please check the manufacturer's information about the cleaning and disinfecting agents.
- ▶ Make sure that the cleaning and disinfectant agents you have chosen do not contain any of the following materials:
  - Organic, mineral, and oxidizing acids (minimum acceptable pH value 5.5)
  - Bases (maximum acceptable pH value 8.5)
  - Oxidation agents (e. g., hydrogen peroxide)
  - Halogens (chlorine, iodine, bromide)
  - Aromatic/halogenated hydrocarbons
- ▶ Use a soft brush or a soft cloth to manually remove gross contaminations. Adhering polymerized composite should be removed with alcohol, a plastic spatula may help in removing the material. Do not use any sharp or pointed tools to protect the surface of the light guide from scratching.

**CAUTION:** The charging base shall be unplugged before cleaning and disinfection of the charging base to prevent from electric shock.

**CAUTION:** To immerse or spray the out surface of charging base and handpiece with water, cleanser and chemical disinfectant is not allowed as it may result in electric shock and damage of inner circuit board.

### **10.2 Clean Charging Base, Handpiece, and eye shield**

- ▶ To disinfect all components, spray the disinfectant on a towel and use it to disinfect the unit. Do not spray the disinfectant directly on the handpiece or the charging base.
- ▶ Clean the keypad of the handpiece with a soft and fluff-free cloth.
- ▶ Dry residual disinfectants on the charger, the handpiece and the anti-glare cone with a soft and fluff-free cloth, as they damage the plastic components.
  
- ▶ Clean the charging base, the handpiece and the eye shield with a soft cloth and, if required, a mild cleaning agent.
- ▶ Solvents or abrasive cleaners may not be used in any case, as they damage the plastic components!
- ▶ Make sure that charge connector remains dry and is not contacted by metallic or greasy parts. Do not bend the charge connector during drying. Wet charge connector will cause an operating error.

## ***11. Disposal***

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**Follow the national requirement and regulation to dispose of the unit.**

As a mean of protection of the environment, your new device is equipped with lithium battery. This kind of battery is free from toxic heavy metal ions. Dispose of battery and units in accordance with local legal regulations.

## ***12. Disclaimer***

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ROLENCE considers itself responsible for the effects on safety, reliability and performance of this product only if:

- ▶ Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by ROLENCE.
- ▶ The electrical installation of the relevant room complies with the requirements.
- ▶ The equipment is used in accordance with this instruction for use.

## 13. Warranty

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### 13.1 Malfunction

Rolence hereby warrants that for a period of one year from the delivery date, this device shall be free from defects in material and workmanship. In case the machine is found malfunctioned under normal use, Rolence will offer service of free maintenance and parts for replacement.

### 13.2 Repair

Repairs must be only carried out by an authorized Rolence engineer/dealer. If repairs during warranty period are not carried out by an authorized engineer/dealer, warranty will expire immediately.

### 13.3 Warranty Exception

The warranty stated herein is the sole warranty applicable to Rolence products. Rolence expressly disclaims the liability for warranty even within warranty period, if

- (1) Damages caused by natural disaster.
- (2) Operator's fault or wrong operation.
- (3) Application use other than field specified in this instruction.
- (4) A malfunction or damage caused by repair, adjustment, modification which is not carried out by Rolence authorized technicians/dealers.
- (5) A malfunction caused by abnormal power source or voltage.
- (6) It is a consumption part.

(This instruction subjects to change without pre-notice.)

**The equipment complies with the requirements in the Medical Device Directive 93/42 EEC.**

#### **Rolence Enterprise Inc.**



No. 18-3, Lane 231, Pu Chung Rd.,  
Chungli, Taoyuan 32083, Taiwan.

#### **EU authorized representative name and address**



CMC Medical Devices & Drugs S.L.  
C/ Horacio Lengo n18, C.P 29006, Málaga-Spain



REM: Please contact our authorized dealer if users require user manual in other European language.

# Declaration of Conformity

## For EN 60601-1-2

Company Name : Rolence Enterprise Inc.  
 Company Address : 18-3 Lane 231 Pu Chung Rd., Chunli, Taoyuan 320, Taiwan R.O.C.  
 Trade Name : LITEIDENT ®  
 Report Number : ETC 13-09-RBO-023(URL: http://www.etc.org.tw Tel: +886-2-26023052)  
 Power Supply : AC Power: 100-240Vac .50 / 60Hz

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment			
The Rolence LED Curing Light is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Rolence LED Curing Light can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Rolence LED Curing Light as 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		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[ \frac{3.5}{P_1} \right] \sqrt{P}$	$d = \left[ \frac{2.5}{E_1} \right] \sqrt{P}$	$d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.67	11.67	23.33

### Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and are specified for use only in a shielded location

The Rolence LED Curing Light declaration – electromagnetic immunity			
The Rolence LED Curing Light system is intended for use in the electromagnetic environment specified below. The customer or the user of the Rolence LED Curing Light system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	

Declaration – electromagnetic immunity			
The Rolence LED Curing Light system is intended for use in the electromagnetic environment specified below. The customer or the user of the Rolence LED Curing Light system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±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	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 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 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic emissions		
The Rolence LED Curing Light is intended for use in the electromagnetic environment specified below. The customer or the user of the Rolence LED Curing Light should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
CE emissions CISPR11	Group 1	The Rolence LED Curing Light 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.
RE emissions CISPR11	Class B	The Rolence LED Curing Light is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	