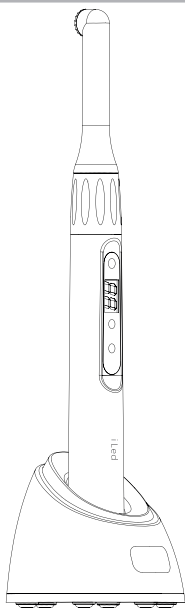


Please read this manual before operating

# i Led Curing Light Instruction Manual



**FDA CE**

**Guilin Woodpecker Medical Instrument Co., Ltd.**

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## **1. Introduction**

Guilin Woodpecker Medical Instrument Co., Ltd. is a high-tech enterprise in researching, developing, and producing dental equipment, and has a perfect quality assurance system, main products including ultrasonic scaler, curing light, micro motor, apex locator and ultrasurgery etc.

## **2. Principle and usage**

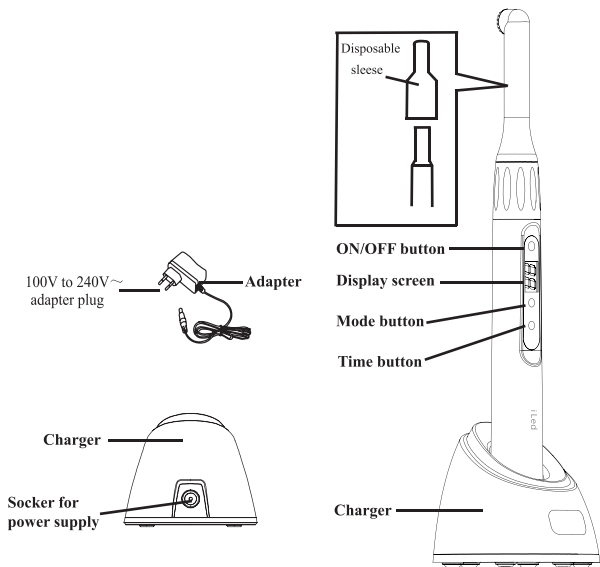
2.1 i Led adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.

2.2 This product is used to restore teeth.

2.3 The device can only be used by the dentist who is qualified and well-trained. This product is used on dental patient in the place of hospital or professional medical site.

## **3. Structure and components**

i Led curing light (dental) is composed mainly of high power LED and main unit



#### **4. Technical specifications**

4.1 Dimensions: 25mm×25mm×240mm.

4.2 Net weight: 278g.

4.3 Power source

4.3.1 Power supply: rechargeable Lithium battery

4.3.2 Battery mode: ICR 18490

4.3.3 Battery voltage and capacity: 3.7V/ 1400mAh

Battery has protection against Over-voltage, over-current and short circuit.

4.3.4 Adapter

Power Input: 100V to 240V, 50Hz/60 Hz

Input Power: 10VA

Power Output: DC5V/1A

4.4 Light source:

4.4.1 5W high power blue light LED

4.4.2 Checking method: the LED light is fine when the light is on during operating correctly.

4.4.3 The wave length of this product can match with the clinical dental resin solidification, such as 3M, Dentsply etc.

4.4.4 Wave length: 420nm-480nm

4.5 Light intensity: 1000 mW/cm<sup>2</sup>~2500mW/cm<sup>2</sup>

4.6 Working condition

4.6.1 Environment temperature: +5°C to +40°C

4.6.2 Relative humidity: 30%~75%

4.6.3 Atmosphere pressure: 70kPa to106kPa

4.7 Equipment safety

4.7.1 Operating mode: intermittent operation

4.7.2 Protection type against electrical shock: class II .

4.7.3 Protection degree against electrical shock: type B.

4.7.4 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0).

4.7.5 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

## **5. Install and uninstall way**

5.1 The top of the unit can be turned 360 degrees to both left and right while it is forbidden to remove.

5.2 When the battery needs to be charged, connect the plug of the adapter into the AC100V~240V power supply. Then connect the output plug of the adapter to the DC 5.0V input plug of the pedestal, then put the main unit into the pedestal.

## **6. Operation**

6.1 Press the mode button. Following two modes are available.

6.1.1 TURBO Mode: screen shows P1, Press the time button to select of time which could be 1 and 3 seconds. Its output light intensity is about  $2300 \text{ mW/cm}^2$ - $2500 \text{ mW/cm}^2$ .

6.1.2 NORMAL Mode: screen shows P2, Press the time button to select of time

which could be 5,10 ,15and 20 seconds. Its output light intensity is about  $1000 \text{ mW/cm}^2$ - $1200 \text{ mW/cm}^2$ .

6.2 During the operation, put the disposable sleeve on the top of the main unit, aim the top at the correct position, press the ON/OFF button and the main unit will produce "Bi" sound, the curing light radiates blue light and starts working according to the set modes. Meanwhile, it starts counting down and will produce tone at every 5 seconds, it stops working when counting down to "0".

6.3 During operation, the blue light can be stopped by press the power button at any time.

6.4 After a working cycle, operator can press the ON/OFF switch to start another working cycle. Stop operating if the equipment began to heat obviously, do not restart until the equipment cool down. Suggest continues working cycle less than 10 times.

6.5 Low power detective circuit is fixed inside of the main unit, when low power is detected, the display screen of main unit will wink, please charge in time.

6.6 When the battery needs to be charged, connect the plug of the adapter into the AC100V~240V power supply. Then connect the output plug of the adapter to the DC 5.0V input plug of the pedestal, and then the logo turn to blue. Put the main unit to the charging point of the pedestal, the display screen turn to scrolling display, and the curing lights starts charging. When charging finished, the display screen display "1111".

6.7 After operating, take off the disposable sleeve and throw away, forbidden to reuse.

6.8 This equipment will turn off automatically if don't any action within 2 minutes, turn it on by press any button.

6.9 The depth of solidification of composite is no less than 2mm per 1 second.

## **7. Precaution**

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

7.2 In order to prevent cross-infection, it is forbidden to reuse the disposable sleeve.

7.3 The top of the main unit can be turned 360 degrees to both left and right while it is forbidden to remove.

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

7.5 Avoid aiming the blue light at eyes directly.

7.6 Please use the power adapter and lithium battery which is designed and supplied by our company. It may cause potential dangers to operator and patient by using the power adapter and lithium battery which is designed and supplied by other manufacturers.

7.7 It is forbidden to use metal or other conductors to touch the main unit and the charging point of pedestal because it may burn the internal circuit or make the lithium battery short circuit.

7.8 Please recharge the battery in cool and ventilated room.

7.9 It is forbidden to self-taking apart the battery, in order not to result in short-circuit or leakage.

7.10 It is forbidden to extrude, shake or rock the battery. The Li-ion battery is

forbidden to be in short-circuit situation and it is forbidden to put the battery with metal or other conductors.

7.11 To invoid electromagnetic interference, the device should be installed at the medical site which meet the requirement of EMC.

**①WARNING: If the curing light works for 40s continously, the temperature of the top of optical fiber may reach 56℃.**

**②WARNING: Do not modify this equipment without authorization of the manufacturer.**

**③WARNING: The adapter should be connected to the socket which is easy**

for operator to touch.

④ **WARNING: over-heat scorching: the device cannot be used for 20s continuously; interval time should be no less than 10s for each usage.**

## **8. Contraindication**

The heart disease patients, pregnant women and children should be cautious to use this equipment.

## **9. Daily maintenance**

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

9.2 Users can change the disposable sleeve and lithium battery. Please use accessory which is designed and supplied by our company, contract with the local dealer or our company if you want to buy. It may cause potential dangers to curing light or other damages which is designed and supplied by other manufacturers.

9.3 The accessory of the product should be cleaned by clean water or neutral sterilized liquid. Do not soak. Do not use highly volatile and diffluent solvent to clean this equipment, which can cause the signs on the control panel to fade.

9.4 Please clean the resin remained on the top of the main unit after using to avoid infecting the life-span or solidified effect.

9.5 The device cannot be maintained during operation. And it is suggested to maintain it once a month. But sleeve is for one-time usage and no need for maintenance.

## **10. Packing List**

The components of the equipment are listed in the packing list.



## 11. Trouble shooting

Faulty	Possible cause	Solutions
No indication, no response.	<ol style="list-style-type: none"> <li>1. Battery is out of power.</li> <li>2. Faulty of battery.</li> <li>3. The main unit battery protection system works.</li> </ol>	<ol style="list-style-type: none"> <li>1. Charge the equipment/ Send to after service for repair.</li> <li>2. Send to after service for repair.</li> <li>3. Place the main unit into the socket on the charger for activation.</li> </ol>
"Er" shown on the screen.	<ol style="list-style-type: none"> <li>1. System error.</li> <li>2. Faulty of main unit.</li> </ol>	<ol style="list-style-type: none"> <li>1. Send to after service for repair.</li> <li>2. Send to after service for repair.</li> </ol>
Wink shown on the screen.	Low battery.	Reconnect the charger, if "Er" show again after 15 minutes please send to after service for repair.
Light intensity is weak.	There is resin on the top of the main unit.	Clear the resin.
The equipment is not charging when the adapter is connected.	<ol style="list-style-type: none"> <li>1. The adapter is not connected well.</li> <li>2. Faulty of adapter or incompatible.</li> <li>3. The charging point is impurity.</li> </ol>	<ol style="list-style-type: none"> <li>1. Reconnect.</li> <li>2. Change the adapter.</li> <li>3. Cleaned by the alcohol.</li> </ol>
The mode indicator twinkles when charging.	<ol style="list-style-type: none"> <li>1. Low voltage.</li> <li>2. Short-circuit of the battery.</li> </ol>	<ol style="list-style-type: none"> <li>1. Back to normal after 15 minuets charging.</li> <li>2. Send to after service for repair.</li> </ol>

If such handlings are completed, the equipment still cannot work normally, please contact with the special maintenance shop or our company.

## 12. After service

From the date this equipment has been sold, base on the warranty card, we will repair this equipment free of charge if it has quality problems, please refer to the warranty card for the warranty period.

## 13. Storage and transportation

13.1 This equipment should be handled carefully, kept away from shaking point, installed or stored at shadowy, dry, cool and ventilated places.

13.2 Don't store it together with articles that are combustible, poisonous, caustic and explosive.

13.3 This equipment should be stored in the environment where the relative humidity is 10%~93%, the atmosphere pressure is 70kPa to 106kPa and the temperature is -20℃ to +55℃.

13.4 Excess impact or shake should be avoided during transportation.

13.5 Don't mix it with dangerous articles during transportation.

13.6 Keep it away from sun or snow or rain during transportation.

## 14. Environmental protection

Please dispose according to the local laws.

## 15. Symbol instruction



Date of manufacture



Manufacturer



Class II equipment



Type B applied part

**IPX0**

Ordinary equipment



Used indoor only



Screw inside/outside



Appliance compliance  
WEEE directive



Handle with care



Keep dry



Humidity limitation  
for storage



Recovery



Temperature  
limitation for storage



Atmospheric pressure  
for storage



CE mark product



FDA marked product



Consult the  
accompanying  
documents



Refer to instruction  
manual/ booklet



Authorised Representative in the EUROPEAN  
COMMUNITY

## 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 models i LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models i LED should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models i LED 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 models i LED are suitable for used 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 models i LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models i LED 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	±8 kV contact ±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 IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	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 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 models i LED require continued operation during power mains interruptions, it is recommended that the models i LED be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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 models i LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models i LED should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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<p>Conducted R F I E C 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms in ISM bands</p> <p>3 V/m 80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms in ISM bands</p> <p>3 V/m 80 MHz to 2.7 GHz</p> <p>3 8 5 M H z - 5785MHz Test specification s for ENCLOSUR E P O R T IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the models i LED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p><math>d = [3,5/\sqrt{V}] \times P^{1/2}</math></p> <p><math>d = 1.2 \times P^{1/2}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \times P^{1/2}</math> 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter</p> <p>In watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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></p> <p>Interference may occur In the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz end 800 MHz. the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

<sup>a</sup> 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 models i LED are used exceeds the applicable RF compliance level above, the model i LED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models i LED.

<sup>b</sup> 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 models i LED**

The models i LED are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models i LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models i LED 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
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) accordable 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.

## 17. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

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