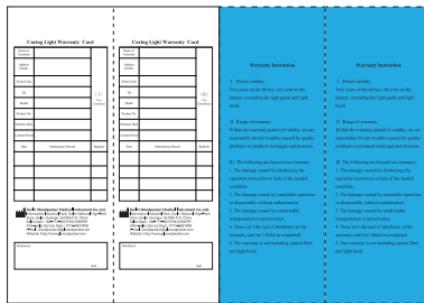


文件名/NAME	光固化机英文说明书 Led II 聚光宽幅版 无LOGO 1.4版240419 14.02.02.186	代码/CODE	14.02.02.186
尺寸/SIZE	100×140mm, 出血6mm	版本/REV.	V1.4
材质/MATERIAL	120g 铜版纸		
装订&注释/ bind (books etc) &NOTES	折叠; 保修卡正反面印刷需对应。	印刷颜色/COLORS	4X4 CMYK
修订日期/DATE	2024.04.19		

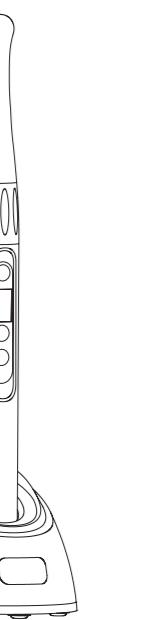
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保修卡正反面





Guilin Woodpecker Medical Instrument Co., Ltd.



i Led II Curing Light Instruction Manual

ZMN-SM-406 V1.4-20240419
Please read this manual before operating

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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 II 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

The curing light (dentistry) is mainly composed by LED, light hood, charging base, battery, adapter, main unit.



4. Technical specifications

4.1 Dimensions: 25mm×25mm×240mm.
4.2 Net weight: 278g.
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 The components of machine(Packing list):

- 1. Main unit *1
- 2. Top of main unit *1
- 3. Light hood *1
- 4. Instruction manual *1
- 5. Adapter *1
- 6. Charging base *1
- 7. Point cure lens *1
- 8. Disposable sleeve *100
- 9. Qualified certificate *1

4.6 Power source

4.6.1 Power supply: rechargeable Lithium battery

4.6.2 Battery mode: 18500

4.6.3 Battery capacity: 2000mAh

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

4.6.4 Adapter(charge)

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

Output: 5.0V---1A

The adapter must be complies with IEC 60601-1 and IEC 60601-1-2.

4.7 Light source:

4.7.1 10W high power blue light LED

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

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

4.7.4 Emitted Wavelength Range: 380nm-515nm

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

4.7.6 Irradiance tolerance range: ±10%

4.8 Light intensity: 1000-3000mW/cm²

4.9 Working condition

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

4.9.2 Relative humidity: 30%-75%

4.9.3 Atmosphere pressure: 70kPa to 106kPa

4.10 Equipment safety

4.10.1 Operating mode: intermittent operation

4.10.2 Protection type against electrical shock: class II.

4.10.3 Protection degree against electrical shock: type B.

4.10.4 Protection against harmful ingress of water or particulate matter: ordinary equipment (IPX0).

4.10.5 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.

5.3 Quick Curing Guide: Recommended Curing times for Optimal Results with i Led II curing light

Exposure times may need to be adjusted due to composite reactivity, shade, distance from the lightens to the composite, and depth of composite layer if it is over 2mm.

Mode	Standard Power	High Power	Turbo Power
Per 2m Layer	1×10 Seconds	2×3 Seconds	1×3 Seconds
Final Cure	2×10 Seconds	3×3 Seconds	2×3 Seconds
Ortho	2×10 Seconds	2×5 Seconds	2×3 Seconds
Metal & Ceramic Brackets	2×10 Seconds	2×5 Seconds	2×3 Seconds

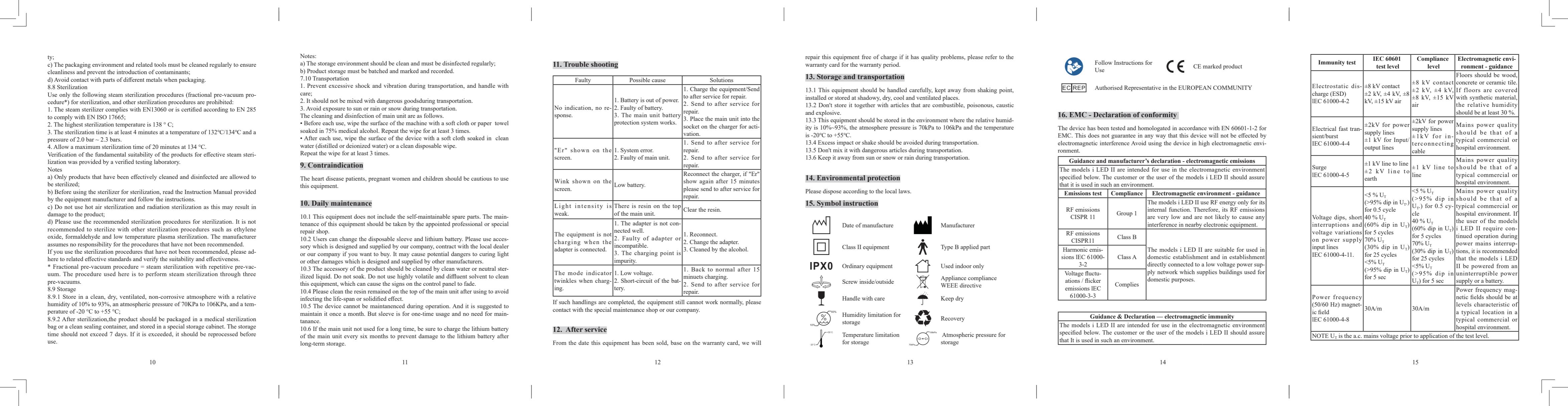
6.4 Use Point Cure Lens: hemispheric Point Cure Lens provides pinpoint curing of small composites and is helpful to pack curing veneers and all porcelain crowns. For veneers, the Turbo Power mode with a 1-second timing interval works for pinpoint curing the center of a veneer with the ability to then clamp 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 Power mode for approximately 2 seconds each, then clean up the uncured resin around the margins, then cure the entire restoration using the full-sized lens.

6.5 During the operation, the top of main unit should be positioned as closely as possible to the restoration. Press the ON/OFF button and the main unit will produce "Bi" sound, the curing light starts 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".

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

6.7 After a working cycle, operator can press the ON/OFF switch to start another working cycle. Stop operating if the equipment begin to heat obviously, do not start until the equipment cool down. Suggest continues working cycle less than 1



ty;
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.
8.8 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 138 °C;
3. The sterilization time is at least 4 minutes at a temperature of 132°C/134°C and a pressure of 2.0 bar ~ 2.3 bars.
4. Allow a maximum sterilization time of 20 minutes at 134 °C.
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.
8.9 Storage
8.9.1 Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;
8.9.2 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.

7.10 Transportation

- 1. Prevent excessive shock and vibration during transportation, and handle with care;
- 2. It should not be mixed with dangerous goods during transportation.
- 3. Avoid exposure to sun or rain or snow during transportation.

The cleaning and disinfection of main unit are as follows.

- 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. Contraindication

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

10. Daily maintenance

- 10.1 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.
- 10.2 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.
- 10.3 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.
- 10.4 Please clean the resin remained on the top of the main unit after using to avoid infecting the life-span or solidified effect.

10.5 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.

10.6 If the main unit not used for a long time, be sure to charge the lithium battery of the main unit every six months to prevent damage to the lithium battery after long-term storage.

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.

12. After service

13. Storage and transportation

14. Environmental protection

15. Symbol instruction

16. EMC - Declaration of conformity

17. Guidance and manufacturer's declaration - electromagnetic emissions

18. Guidance & Declaration — electromagnetic immunity

19. Immunity test

20. Compliance level

21. Electromagnetic environment - guidance

22. Follow Instructions for Use

23. CE marked product

24. EC REP Authorised Representative in the EUROPEAN COMMUNITY

25. Guidance and manufacturer's declaration - electromagnetic emissions

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100. Compliance level

101. Electromagnetic environment - guidance

102. Follow Instructions for Use

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Guidance & Declaration - Electromagnetic immunity			
The models i LED II are intended for use in the electromagnetic environment specified below. The customer or the user of the models i LED II should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the models i LED II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: ^a Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.
Conducted RF IEC 61000-4-6	6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz	6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz	$d=[3.5/V]^1/2$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models i LED II are used exceeds the applicable RF compliance level above, the model i LED II 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 II.
^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 models i LED II

The models i LED II are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models i LED II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models i LED II 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	80MHz to 800MHz	800MHz to 2,5GHz
0.01	$d=1.2\times P^{1/2}$	0.12	0.12	0.23
0.1	$d=1.2\times P^{1/2}$	0.38	0.38	0.73
1	$d=1.2\times P^{1/2}$	1.2	1.2	2.3
10	$d=1.2\times P^{1/2}$	3.8	3.8	7.3
100	$d=1.2\times P^{1/2}$	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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Harm of fake products

 and  are two brands of Guilin woodpecker medical instrument company. Recently, growing fake ultrasonic scalers and curing lights are produced and sold on the market, which do harm to users' interest. On this issue, We Woodpecker will crackdown fake products and provide safe and secure medical instrument products.

1. Harm of fake ultrasonic scaler handpieces.

- 1.1 Fake handpieces with poor-designed inner structure can lead to frequent power leakage, which may cause medical accidents.
- 1.2 Material used on fake handpieces don't pass biocompatible test, which can easily lead to irritation and poisoning.
- 1.3 Fake handpieces have quality problems of overheating, non-vibration and cracking, which causes ultrasonic scalers out of order.
- 1.4 Fake handpieces can't be compatible with ultrasonic scalers, thus leading to circuit burnout.

2. Harm of fake scaler tips.

- 2.1 Fake tips are low in toughness, poor in resistance and easy to crack, thus easily cause medical accidents.
- 2.2 Fake tips' screw threads are roughly processed, which can cause handpiece's screw loosening and cracking.
- 2.3 Material used on fake tips is inferior and easily rusting, which can cause infection of patient.
- 2.4 Fake tips have used problem of poor water-spraying, bad screw-thread and water leakage, which leads ultrasonic scalers work wrongly.

3. Harm of fake curing light.

- 3.1 Fake curing light's batteries can cause self-ignite, even explosion with poor-quality material and incomplete charging management.
- 3.2 Light intensity of fake curing light is not constant, when battery level goes down under 30%, it would lead to incomplete solidification of resin, causing secondary dental caries.

 The following are beyond our warranty:
1. The damage caused by disobeying the operation instruction or lack of the needed condition.
2. The damage caused by unsuitable operation or disassembly without authorization.
3. The damage caused by unadvisable transportation or preservation.
4. There is no seal of distributor or the warranty card isn't filled in completed.
5. The warranty is not including optical fiber and light hood.

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Scan and Login website for more information
