



CURING LIGHT LED.B USER'S MANUAL

(Please read this manual before operating)



Industrial design patent No.: CN 200730092316.9



- Certified Management System
- EN ISO 9001
- EN ISO 13485

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 LED.B 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 and solidify material for whitening teeth.



Picture 1

3. Structure and components

LED.B (dental) is composed mainly of high power LED, optical fiber and the main unit. (Picture 1)

4. Technical specifications

4.1 Power supply: rechargeable Lithium battery

Battery model: ICR18650

Battery voltage and capacity: 3.7V/2000mAh

Input of adapter: 100V to 240V~ 50Hz/60Hz

4.2 Applied part: Optical fiber

4.3 Light source: Blue light

Wave length: 420nm to 480nm

Light intensity: 850mW/cm²~1000mW/cm²

4.4 Working condition:

Environment temperature: 5°C to 40°C

Relative humidity: ≤80%

4.5 Dimensions: 31mm×34mm×260mm

4.6 Net weight: 145g

4.7 Consumption power: ≤8W

4.8 Protection type against electrical shock: class II equipment

4.9 Protection against electrical shock: type B applied part

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

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

5. Operation

5.1 Take off the red cap from the optical fiber and then insert the metal part into the front of LED.B (Make sure to screw the fiber to the end).

5.2 To install the light hood on as show in picture 1.

5.3 Press the time button to choose the solidification time. 4 working time modes are available: 5, 10, 15 and 20 seconds.

5.4 During the operation, aim blue light at the position needing solidification. There is a "Di" sound and the LED starts working. Then it counts down to "0" to end the solidification.

5.5 After the operation, please clean the fiber with calico in order not to affect the light intensity.

5.6 The depth of solidification of composite is no less than 4mm per 10 seconds.

5.7 The optical fiber can be spined off by 360° and autoclaved to the high temperature of 135°C and pressure of 0.22MPa.

5.8 During operation, if the indicator light of capacity is on, it means low volume. Recharge it at once.

6. Instruction of recharging

6.1 Recharging by UDS-M scaler: press the recharging button, insert the LED.B into the recharging hole and the light shines, which means that the recharging is on. When the light turns off, it means the recharging is over.

6.2 Recharging by pedestal: connect the plug of the adapter into the AC 100V~240V power supply. Then connect the output plug of the adapter to the input plug of the pedestal, and the indicator turn to green, that means the pedestal is standby. Put the main unit to the charging point of the pedestal, the indicator turn to yellow, and the curing lights starts charging. When charging finished, the indicator turn to green.

6.3 The battery has no memory and can be recharged any time.

6.4 The main unit should be in a full charge when it's used for the first time, the ordinary charge time for a full charge is 4 to 6 hours.

7. Precaution

7.1 Notice when using equipment

7.1.1 During operation, the light should be aimed straightly on the resin, to ensure solidification effectively.

7.1.2 Avoid aiming light at eyes directly.

7.2 Only the original pedestal charger, adapter and Lithium

battery could be used, because other brand pedestal charger, adapter and Lithium battery are likely to damage the circuit.

- ① **WARNING: If the curing light works for 40s continuously, the temperature of the top of optical fiber may reach 56°C.”**
- ② **WARNING: Do not modify this equipment without authorization of the manufacturer.**

8. Maintenance

8.1 Only the optical fiber can be autoclaved to the high temperature and pressure.

8.2 After operation each time, please shut off the power source and clean the optical fiber.

9. Contraindication

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

10. Notice

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

11. Trouble shooting

Fault	Cause	Solution
Light intensity insufficient	<ol style="list-style-type: none"> 1. The optical fiber is not inserted till the bottom. 2. The optical fiber has cracked. 3. There is resin remained on the surface of optical fiber. 4. Low battery. 	<ol style="list-style-type: none"> 1. Insert again correctly. 2. Change the optical fiber. 3. Wipe off the resin. 4. Charge the LED.B.
Non-indication Non-acts	<ol style="list-style-type: none"> 1. The battery is used up. 2. The LED B works continuously too long and the heat protection system works. 3. Short circuit of charge connector makes the battery enter self-protection. 4. LED is damaged. 	<ol style="list-style-type: none"> 1. Charge the LED.B. 2. Stop the operation for several minutes. 3. Please put the curing light into the pedestal for charging, then the battery works again. 4. Contact the local distributor or us.

<p>The equipment is not charging when the adapter is connected.</p>	<ol style="list-style-type: none"> 1. The adapter is not connected well. 2. Faulty of adapter or incompatible. 3. The charging point is impurity. 	<ol style="list-style-type: none"> 1. Reconnect. 2. Change the adapter. 3. Cleaned by the alcohol.
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If any malfunction case was found, please contact with the dealer the unit was purchased 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 $\leq 80\%$, the atmosphere pressure is 75kPa to 106kPa and the temperature is -10°C to $+55^{\circ}\text{C}$.

13.4 Excessive 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. Packing list

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

Note: When the LED acts as one part of UDS-M, the charger and pedestal are optional.

15. Symbol instruction



Trademark



Type B applied part



Consult the accompanying documents

IPX0

Ordinary equipment



Date of manufacture



Manufacturer



Used indoor only



Screw inside/outside



Class II equipment



CE marked product



FDA marked product



Authorised Representative in the EUROPEAN
COMMUNITY



• Certified Management
System
• EN ISO 9001
• EN ISO 13485

Got the quality management system
certification and CE certification issued by
TüV Rheinland

16. Environmental protection

There is any harmful element in our product. It can be disposed according to the local law.

17. For technical data, please contact



Wellkang Ltd (www.CE-Marking.eu)
29 Harley St., LONDON, W1G 9QR, UK

18. 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.

19. Declaration of conformity

19.1 Product conforms to the following standards

EN 60601-1:2006	EN 1041:2008
EN 60601-1-2:2007	EN ISO 14971:2009
EN 61000-3-2:2006	EN ISO 7405:2008
EN 61000-3-3:2008	EN ISO 17664:2004
EN 60601-1-4:1996	EN ISO 17665-1:2006
EN 60825-1:2007	EN ISO 10993-1:2009
EN 980:2008	EN ISO 10993-5:2009
ISO 9687:1993	EN ISO 10993-10:2010

19.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions

The model LED.B is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.B should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model LED.B 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.
RF emissions CISPR11	Class B	The model LED.B is 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	Not applicable	

Guidance & Declaration — electromagnetic immunity


The model LED.B is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.B 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	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	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	±2 kV line to earth	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 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model LED.B requires continued operation during power mains interruptions, it is recommended that the model LED.B be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable

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

Guidance & Declaration - Electromagnetic immunity

The model LED.B is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.B 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the model LED.B, 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>3V</p> <p>$d=1.2 \times P^{1/2}$ 80 MHz to 800 MHz $d=2.3 \times P^{1/2}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz end 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 model LED.B is used exceeds the applicable RF compliance level above, the model LED.B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model LED.B.

^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 model LED.B

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

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.

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