WOODPECKER®

LED.D Curing light Instruction Manual

Please read this manual before operating

Industrial design patent No.: CN 200930300230.X

Guilin Woodpecker Medical Instrument Co., Ltd.

Instruction Manual for LED.D (curing light)

1.Principle and usage

1.1 LED.D adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.

1.2 This product is used for dentistry. It has the function of accelerating dental restoration and solidifying the material of dental whitening.

2. Structure and components

LED.D curing light (dentistry) is mainly composed by high power LED, optical fiber, and main unit. Figure 1 shows the main components of LED.D.

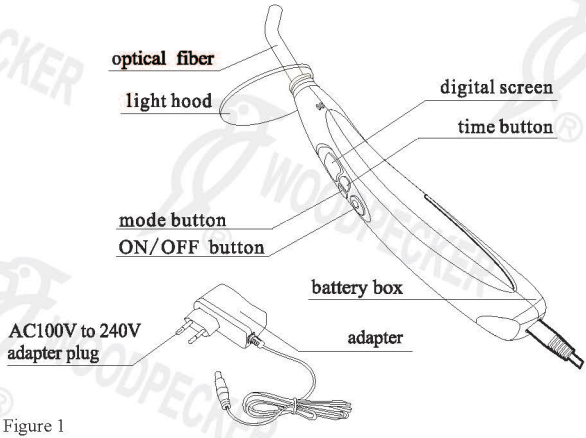

Figure 1

3. Pictures of components

Optical fiber	Light hood	Bracket	Power adapter
			
Material: Glass fibre Size: ¢8.0mm	Material: PS Colour: Salmon pink	Material: PMMA Colour: Navy blue	Input: AC100V~240V 50Hz/60Hz Output:DC5.0V/1A

4. Technical specifications

4.1 Power supply:

4.1.1 Rechargeable Lithium battery:

Battery model: ICR18490

Battery voltage and capacity: 3.7V, 1400mAh

The battery includes over-voltage protection, over-current protection and short circuit protection.

4.1.2 Adapter:

Input: AC100V-240V 50Hz/60Hz

Output: DC5.0V/1A

4.2 Applied part: Optical fiber

4.3 Light source:

4.3.1 5W high power blue light LED

4.3.2 Wave length: 420nm-480nm

4.3.3 Light intensity: 650mW/cm^2~800mW/cm^2

4.4 Work condition:

4.4.1 Environment temperature: +5℃~+40℃

4.4.2 Relative humidity: ≤80%

4.4.3Atmosphere pressure: 70kPa to106kPa

4.5 Size: 202mm×32mm×38mm

4.6 Net weight: 143g

4.7 Consume power: ≤8W

4.8 Protection type against electrical shock: class II

4.9 Protection degree against electrical shock: type B

4.10 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0), not water protected.

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

4.12 Equipment for operation in the room

4.13 Non-continuously work instrument: after work 200 seconds, stop 60 seconds, and then work 40 seconds, stop 60 seconds, work in the rule as above circularly.

5. Contraindication

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

6. Cautions

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

6.2 Before operation, please read this instruction carefully. Please make sure the user has the general knowledge of dental restoration, dental treatment and dental

whitening. The basic operate technique is also needed for user.

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

6.4 Avoid direct irradiation to the eye with the blue light.

6.5 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.

6.6 In order to avoid damaging the circuit of charge or the battery, it is forbidden to touch the charging connector with metal or other conductor.

6.7 Please charge the battery in the condition of cool and ventilated.

6.8 Do not disassemble the battery, it will lead to a circuit short and the electrolyte leakage.

6.9 Do not squeeze or shake the battery, do not store the battery with metal material.

6.10 If this equipment is not going to be used for a long time, please take the battery out and preserve separately.

6.11 This equipment may cause the electromagnetic interference. Please don't use it on the patients with pacemaker or on an E-Surgery. Please be caution to use this equipment under the condition of strong electromagnetic interference.

6.12 It is forbidden to disassemble the equipment. We shall not assume any responsibility for any malfunction, damage or accident caused by disassembling the equipment.

6.13 It is forbidden to modify the equipment. We shall not assume any

responsibility for any malfunction, damage or accident caused by improper removal, modification, maintenance, or repair with device components not supplied by the manufacture or our authorized representative.

6.14 The optical fiber is reusable. Please make sure they are autoclaved under high pressure and high temperature before each operation.

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

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

7. Installation

7.1 Take off the red cap from the optical fiber, and then insert the metal part into the front of main unit (make sure to screw the fiber to the end).

7.2 Fix the light hood on the bottom of the optical fi

7.3 Battery replacement method: open the battery cover of the main unit, take the battery out, and disconnect the plug slightly. Connect the plug of the new battery correctly (Figure 2), put the new battery in, and then fix the battery cover.

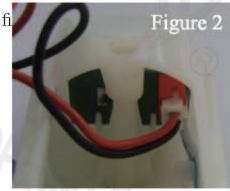
Figure 2

7.4 Charge method: For Charging, please pull out the charge port protector of the main unit slightly, plug the output port of the adapter into the charge port of the main unit, and then connect the adapter to the power supply. When charging is finished, pull out the adapter and plug the protector back into the charge port of the main unit.

Notice: Don't fix the adapter at where the operation can't be taken place easily.

8. Operation

8.1 Press the mode button to set the working mode, the corresponding indicator will be on when a mode is set.

8.1.1 Full power: the blue light radiates in full power.

8.1.2 Ramping mode: the blue light power increase stronger continually and gets to the highest power 5 seconds later.

8.1.3 Pulse mode: the blue light works on the pulse condition.

8.2 Press the time button to set the solidifying time, 8 working times are available: 5, 10, 15, 20, 25, 30, 35, 40 seconds.

8.3 When operating, aim the optical fiber at the correct position, press the power button to start or stop emitting of the blue light.

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

8.5 A battery detect circuit is fixed inside the main unit, when low power is detected, the indicator of the main unit will wink, please charge in time.

8.6 The mode indictor will be enlightened one by one when charging. They will all be enlightened if charging has finished. If a battery error is detected, the indicator of the mode will wink.

8.7 When the equipment is charging, it is possible to turn the equipment into the normal work state by pressing any button. If the button is not pressed within 10 seconds, the equipment will turn back into charge state.

8.8 If the charge is not finished, when the working condition changes from normal

mode to sleep mode, the equipment will turn into charge state automatically.

8.9 The equipment still can be used for a while after a low power alarm, but with a lower light intensity. And then the equipment will turn into the protect mode that all functions will be locked until the machine is connected to the power supply or the battery is replaced.

8.10 When operation is finished, please clean the optical fiber with calico in order not to affect the light intensity.

8.11 This equipment will be off automatically if no action occurred within 2 minutes. Turn it on by pressing any button.

8.12 The effective light intensity of this equipment is much higher than halogen lamp curing light. The solidified depth of the composite resin is no less than 4mm if irradiated by this equipment for 10 seconds.

8.13 The optical fiber can be sterilized in the condition of 135℃ and 0.22MPa for 20 minutes.

9. Maintenance

9.1 This equipment does not include the self-maintenance parts, so it should be performed by professional or special maintenance shop.

9.2 Only the optical fiber of this equipment can be autoclaved under high temperature and high pressure, other parts should be cleaned by clean water or neutral sterilized liquid, but do not soak the equipment in the water. Do not clean by volatile or soluble liquid, otherwise the marks of the control panel will fade.

9.3 Please clean the optical fiber to avoid the remaining resin on the surface and infect the life-span and the effectiveness of solidification.

10. Transportation

10.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

10.2 Don't put it together with dangerous goods during transportation.

10.3 Avoid solarization and getting wet in rain or snow during transportation.

11. Storage and transportation

11.1 The equipment should be handled carefully and lightly, kept away from the shaking source, installed or stored at shadowy, dry, cool and ventilated places.

11.2 Don't store the equipment together with articles that are combustible, poisonous, caustic, and explosive.

11.3 This equipment should be stored in the environment where the humidity is ≤80%, the atmosphere pressure is 75kPa~106kPa and the temperature is -10℃~55℃.

11.4 Excess impact or shake should be prevented during transportation. Handle with care. Do not place upside down.

11.5 Don't put it together with dangerous articles during transportation.

11.6 Keep it away from the sun, rain or snow during transportation.

12. After service

12.1 We offer one year warranty of quality problems, counting from the sales date.

12.2 We will not responsible for any damage caused by the non-professional person.

13. Trouble shooting

Faulty	Possible cause	Solutions
No indication, no response.	1. Battery is out of power. 2. Faulty of battery.	1. Charge the equipment/ Change a new batter. 2. Change a new battery
"E1" shown on the screen.	Low battery.	Reconnect the charger, if "E1" show again after 15 minutes please change the battery.
"Er" shown on the screen.	Faulty of main unit.	Send to after service for repair.
The equipment is not charging when the adapter is connected.	1. The adapter is not connected well. 2. Faulty of adapter or incompatible. 3.The charging point is impurity.	1. Reconnect. 2. Change the adapter. 3. Cleaned by the alcoho.
Light intensity is weak.	1. The optical fiber is not installed well. 2. There is crevice on the optical fiber. 3. There is resin on the tip of the optical fiber.	1. Reinstall the optical fiber. 2. Change a new optical fiber. 3. Clear the resin.

Faulty	Possible cause	Solutions
Effective duration of the battery become short.	The capacity of the battery decreased.	Change a new battery.
The mode indicator twinkles when charging.	1. Low voltage. 2. Short-circuit of the battery.	1. Back to normal after 15 minuets charging. 2. Change a new battery.

If the problem still can't be solved, please contact with local dealer or manufacurer.

14. Storage and transportation

14.1 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry and ventilated place.

14.2 Don't store the machine together with the articles that are combustible, poisonous, caustic, and explosive.

14.3 This equipment should be stored in a room where the relative humidity is ≤80%, atmospheric pressure is 50kPa to106kPa, and the temperature is -10℃ to +50℃.

14.4 Excess impact or shake should be prevented during transportation, lay it carefully and do not invert it.

14.5 Don't put it together with dangerous goods during transportation.

14.6 Avoid solarization and getting wet in rain or snow during transportation.

15. Packing list

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

16. Environment protection

There is no harmful factor in this product. It can be dealt based on the local law.

17. After service

From the date this equipment has been sold, we offer two year free repair to the equipment if it has quality problems, please refer to the warranty card for the warranty period.

18. Representative in Europe

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

19. Symbol instructions

WOODPECKER Trademark

Used indoor only

Type B applied part

Screw inside/ outside

Consult the accompanying documents

CE marked product

FDA marked product

IPX0 Ordinary equipment

Class II equipment

Date of manufacture

Manufacturer

EC REP Authorised Representative in the EUROPEAN COMMUNITY

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

20.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.

21. Declaration of conformity

21.1 Product conforms to the following standards

IEC 60601-1:2005	EN 1041:2008
EN 60601-1:2006	EN ISO 14971:2009
EN 60601-1-2:2007	EN ISO 7405:2008
EN 61000-3-2:2006	EN ISO 17664:2004
EN 61000-3-3:2008	EN ISO 17665-1:2006
EN 60601-1-4:1996	EN ISO 10993-1:2009
EN 60825-1:2007	EN ISO 10993-5:2009
EN 980:2008	EN ISO 10993-10:2010
EN ISO 9687:1995	

21.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model LED. is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.D 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.D 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.D 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.D is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.D 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.D requires continued operation during power mains interruptions, it is recommended that the model LED.D 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.D is intended for use in.the electromagnetic environment specified below. The customer or the user of the model LED.D 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	Portable and mobile RF communications equipment should be used no closer to any part of the model LED.D, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 3V $d=1.2\times P^{1/2}$ 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, [a] 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: 

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) telephon es 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, a n electromagnetic site survey should be considered. I f the measured field strength in the location in wh ich the model LED.D is used exceeds the applicable RF compliance level above, the model LED.D 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.D.

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