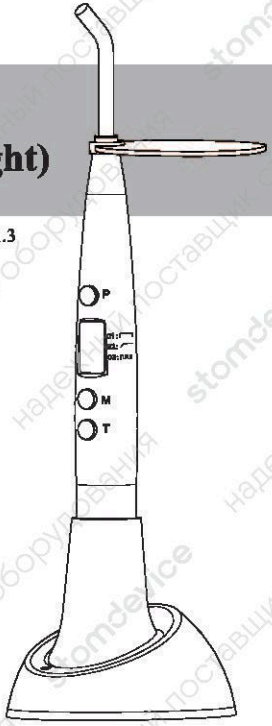
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WOODPECKER

Instruction Manual for LED.H (curing light)



Industrial design patent No.: CN 201130176281.3

FDA CE

Please read this manual before operating

Guilin Woodpecker Medical Instrument Co., Ltd.

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1 Principle and usage

1.1 LED.H 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 to restore teeth.

2 Structure and component

LED.H (dental) is composed mainly of high power LED, optical fiber and main unit.

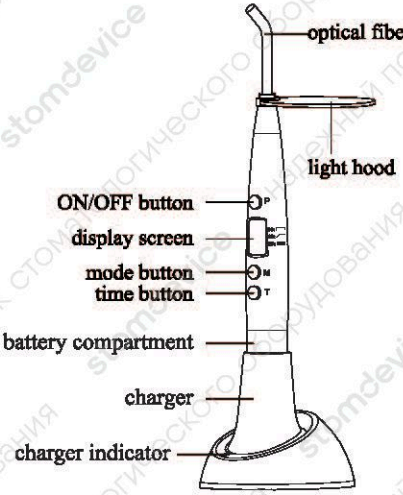


Figure 1- I

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Figure 1- II

3 Technical specifications

3.1 Power supply: rechargeable Lithium battery

Battery model: ICR18650

Battery voltage and capacity: 3.7V/2200mAh

Input of adapter: AC100V to 240V, 50Hz/60Hz

Output of adapter: DC5V/1A

3.2 Applied part: optical fiber

3.3 Light source:

a) 5W high power blue LED

b) Wave length: 420nm-480nm

c) Light intensity: 1000mW/cm^2~1200mW/cm^2

3.4 Working condition:

a) Environment temperature: 5℃ to 40℃

b) Relative humidity: ≤80%

c) Atmosphere pressure: 70kPa to 106kPa

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3.5 Dimensions: Φ25mm×252mm

3.6 Net weight: 178g

3.7 Consumption power: ≤8W

3.8 Protection type against electrical shock: class II

3.9 Protection against electrical shock: type B

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

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

4 Installment and dismantlement

4.1 Take off the red cap from the optical fiber and then insert the metal part into the front of LED.H, make sure to screw the fiber to the end.

4.2 To install the light hood on the top of the optical fiber.

4.3 For dismantlement, taking the instruction of istallment above reversely.

4.4 When finishing using or when the battery needs to be charged, plug the output port of the adapter into the charge port, than connect the adapter to the power supply. After that, place the device into the socket on the charger.

5 Operation

5.1 Lightly press the mode key. Following three modes are available.

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5.1.1 Full power mode: screen shows 01, LED works in full power.

5.1.2 Ramping mode: screen shows 02, LED turns from weak to stronger, and reaches the highest power in 5 seconds.

5.1.3 Pulse mode: screen shows 03, LED works in the mode of pulse.

5.2 Lightly press the time button to choose the solidification time. 9 working time modes are available: 3,5,10,15,20,25,30,35,40 seconds.

5.3 During the operation, aim blue light at the position needing solidification. Press the ON/OFF switch, a "beep" sound will appear, the LED starts to work under the selected mode. Then it counts down to "0" second to end the solidification.

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

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

5.6 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 input plug of the pedestal, and then 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.

5.7 After the operation, please clean the fiber with calico in order not to

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affect the light intensity.

5.8 This equipment will turn off automatically if no any action within 2 minutes, turn it on by press any button.

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

5.10 The optical fiber can be sterilized in the condition of 135℃ and 0.22MPa.

5.11 The curing light is equipped with over-heat protection system. It can continuously work 200s, For example, continuously operate the curing light for 10 times under 20s working mode (even the curing light works less than 20s, it is counted as a full operation), then it will come into over-heat protection status. And only after 2-minute sleep, it can restart working 200s continuously.

6 Cautions

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

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

6.3 Avoid aiming at eyes directly.

6.4 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.

6.5 It is forbidden to touch the charging connector with metal or other

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conductor, to avoiding damage the circuit of charge or the battery.

6.6 Please recharge the battery in cool and ventilated room.

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

6.8 It is forbidden to extrude, shake or rock the battery. The Lithium battery is forbidden to be in short-circuit situation and it is forbidden to put the battery with metal or other conductors.

6.9 If you don't use this equipment for a long time, please take the battery out and preserve separately.

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

【WARNING】Do not modify this equipment without authorization of the manufacturer.

7 Contraindication

The heart disease patient, pregnant woman and children should be cautious to use this equipment.

8 Maintenance

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

8.2 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

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water. Do not clean by volatile or soluble liquid, otherwise the marks of the control panel will fade.

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

9 Troubleshooting

Faulty	Possible cause	Solutions
No indication, no response.	1. Battery is out of power. 2. Faulty of battery. 3. The main unit battery protection system works.	1. Charge the equipment/ Change a new batter. 2. Change a new battery. 3. Place the main unit into the socket on the charger for activation.
"Er" shown on the screen.	Faulty of main unit.	Send to after service for repair.
Wink shown on the screen.	Low battery.	Reconnect the charger, if "Er" show again after 15 minutes please change the battery.
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.

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Faulty	Possible cause	Solutions
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 alcohol.
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 such handlings are completed, the equipment still cannot work normally, please contact with the special maintenance shop or our company.

10 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.

11 Storage and transportation

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

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

11.3 This equipment should be stored in the environment where the relative humidity is ≤ 80%, the atmosphere pressure is 70kPa to 106kPa and the temperature is -10℃ to +55℃.

11.4 Excess impact or shake should be avoided during transportation.

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

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

12 Environmental protection

There is not any harmful element in this equipment. It can be disposed of according to the local laws. We reserve the rights to alter the design, the technology and fitting parts, instruction manual and packaging without further notice. If there is any discrepancy between the picture and the real product, please refer to the real product.

13 Representative in Europe

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

14 Symbol instructions

WOODPECKER Trademark

CE marked product

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Type B applied part



FDA marked product



Ordinary equipment


Class II equipment


Date of manufacture


Manufacturer

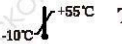

Recovery


Used indoor only


Keep dry


Screw inside/ outside


Handle with care



Temperature limitation



Humidity limitation



Atmospheric pressure for storage


Appliance compliance WEEE directive


Consult the accompanying documents

EC REP Authorised Representative in the EUROPEAN COMMUNITY

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15 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.

16 Declaration of conformity

16.1 Product conforms to the following standards

EN 60601-1:2006	EN 60601-1-2:2007
EN 60601-1-6:2010	EN 62366:2008
EN 60825-1:2007	EN 980:2008
ISO 9687:1993	EN 1041:2008
ISO 15223-1-2012	EN ISO 14971:2012
EN ISO 17664:2004	EN ISO 17665-1:2006
EN ISO 7405:2008 +A1:2003	EN ISO 10993-1:2009
EN ISO 10993-5:2009	EN ISO 10993-10:2010

16.2 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.

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Guidance and manufacturer's declaration - electromagnetic emissions		
The model LED.H is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.H 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.H 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.H 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.H is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.H 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.H requires continued operation during power mains interruptions, it is recommended that the model LED.H 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.			

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Guidance & Declaration - Electromagnetic Immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the model LED.H, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
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*	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 I 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 model LED.H is used exceeds the applicable RF compliance level above, the model LED.H 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.H.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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Recommended separation distances between portable and mobile RF communications equipment and the model LED.H

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

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