WOODPECKER®

CURING LIGHT LED.G USER'S MANUAL

(Please read this manual before operating)

CE

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

www.glwoodpecker.com

Content

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.G 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.

3. Structure and components

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

4. Technical specifications

4.1 Power supply: 24V~ 50Hz/60Hz
4.2 Applied part: optical fiber
4.3 Light source:
Blue light
Wave length: 385nm-515nm

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

4.4 Working condition:

Environment temperature: 5℃ to 40℃

Relative humidity: 30%~75%

Atmosphere pressure: 70kPa to 106kPa

4.5 Dimensions: 26mm×25mm×260mm

4.6 Net weight: 135g

4.7 Consumption power: ≤8W

4.8 Protection type against electrical shock: class Ⅱ

4.9 Protection against electrical shock: type B

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.

4.12 Intermittent operation instrument: after work 200 seconds, stop 20 seconds, and then work 20 seconds, stop 20 seconds, work in the rule as above circularly.

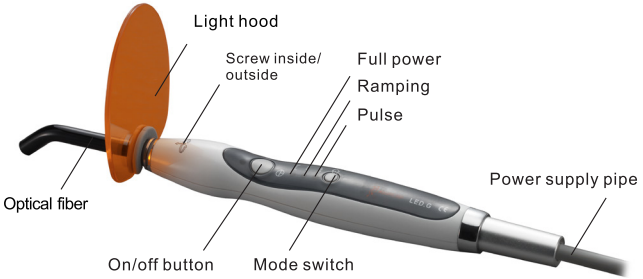
5. Install and uninstall way

5.1 Connect the LED power supply line with the power (24V~) of dental unit. Tight the nylon thread to the fixation of the dental unit, then it will be available for operation.

Notice:When installing the LED, be sure the power is cut off.

The two power wire should be a little longer than the nylon thread to keep the power wire safe.

5.2 Take off the red cap from the optical fiber and insert the metal part into the front of the built-in LED.G (Make sure to screw the fiber to the end by rotation).
5.3 Install the light hood as showed in picture 1.
5.4 Uninstall the LED, just reverse the procedure above.



Picture 1

6. Operation

You can choose one of three operation modes by pressing the mode switch button on the curing light.
6.1 Full power: the blue light radiates in full power.

6.2 Ramping: The blue light power increases stronger continually, after five seconds reaches to the highest power.
6.3 Pulse: The blue light works on the pulse condition. During the operation, aim blue solidification. The working time of all modes is ten seconds.
6.4 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.

7. Cleaning , Disinfection and Sterilization

The cleaning, disinfection and sterilization of optical fiber is as follow.
Unless otherwise stated, they will be hereinafter referred to as “products”.

⚠ Warnings
The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no

responsibility.
This device shall not be exposed to high temperature above 138℃.
Processing limit
The products have been designed for a large number of sterilization cycles.
The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for optical fiber is 500 times.

7.1 Initial processing
7.1.1 Processing principles
It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.
Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic,especially with regard to the additional

requirements for the inactivation of prions.

7.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Remove the optical fiber from the Curing light Device,and rinse away the dirt on the surface of product with pure water (or distilled water/deionized water);

2. Dry the product with a clean, soft cloth and place it in a clean tray.

Notes

a) The water used here must be pure water, distilled water or deionized water.

7.2 Preparation before cleaning

Steps

Tools: tray, soft brush, clean and dry soft cloth Remove optical fiber from main unit and put it into the clean tray. Use a clean soft brush to carefully brush the optical fiber until the dirt on surface is not visible. Then use soft cloth to dry the optical fiber and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

7.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

7.3.1 Automated cleaning

•The cleaner is proved to be valid by CE certificationin accordance with ENISO 15883.

▪There should be a flushing connector connected to the inner cavity of the product.

▪The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

It is recommended to use a washer-disinfector in accordance with EN ISO15883. For the specific procedure, please refer to the automated disinfection section in the next section “Disinfection”.

Notes

a) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.

b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it

would be difficult to remove.
c) After cleaning, the chemical residue should be less than 10mg / L.
7.4 Disinfection
Disinfection must be performed no later than 2 hours after the cleaning phase.
Automated disinfection is preferred if conditions permit.
7.4.1 Automated disinfection-Washer-disinfector
·The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883..
·Use high temperature disinfection function. The temperature does not exceed 134 ℃, and the disinfection under the temperature cannot exceed 20 minutes.
·The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.
Cleaning and disinfecting steps by using Washer-disinfector
1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.
2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.
4. After the program is finished, remove the product from the washer-disinfector,
inspect (refer to section “Inspection and Maintenance”) and packaging (refer to chapter “Packaging”). Dry the product repeatedly if necessary (refer to section “Drying”).

Notes
a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
b) With this equipment, cleaning, disinfection and drying will be carried out together.
c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4)

During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed.
The used cleaner is neodisher MediZym (Dr. Weigert).
d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000.
(d2)Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600.
(d3) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and A0>3000.
e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).
f) After cleaning, the chemical residue should be less than 10mg / L.
g)The air used for drying must be filtered by HEPA.
h) Regularly repair and inspect the disinfector.
7.5 Drying
If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.
Methods
1. Spread a clean white paper (white cloth) on the

flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time should be 15~40 minutes.

Notes

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

7.6 Inspection and maintenance

In this chapter, we only check the appearance of the product. After inspection, if there is no problem, the optical fiber can only be used.

7.6.1 Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

7.6.2 Check the product. If it is obviously damaged,

smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

7.6.3 Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

7.6.4 If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

7.7 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

Notes

a) The package used conforms to ISO 11607;

b) It can withstand high temperature of 138 °C and has sufficient steam permeability;

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.

7.8 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.

7.9 Storage

7.9.1 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;

7.9.2 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 goodsduring 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.

8. Precaution

8.1 During operation the light should be aimed straightly on the resin, to ensure solidification effectively.
8.2 Avoid aiming light at eyes directly.

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.

9. Contraindication

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

10. Maintenance

10.1 The optical fiber should be sterilized for 4 minutes with 134℃ and 2.0bar~2.3bar (0.20MPa~0.23MPa) before each use. Other parts should be cleaned by clean water or neutral sterilized liquid, but do not soak the equipment in the water.
10.2 After operation each time, please shut off the power source and clean the optical fiber.

11. 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 for units and parts.

12. Troubleshooting

Faulty	Possible cause	Solution
Non-indication Non-act.	1. The LED is not connected well with the power. 2. The power is off.	1. Check the connection of the LED and the power. 2. Make sure the power is on.
Light intensity insufficient.	1. Optical fiber isn't inserted well to the bottom. 2. The optical fiber has cracked. 3. There is resin remain on the surface of the optical fiber.	1. Install the optical fiber well. 2. Change the optical fiber. 3. Remove the resin.

If all the above solutions have been completed, the machine still can not work normally. Please contact our special repair shop or us.

13. Packing List

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

14. Storage and transportation

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

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

14.3 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℃.

14.4 Excess impact or shake should be avoided during transportation.

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

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

15. Environmental protection

Please dispose according to the local laws.

16. Manufacturer's right

We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

17. European authorized representative

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

18. Symbol instruction

Trademark

CE marked product

Type B applied part

Screw inside/ outside

Ordinary equipment

Class II equipment

Date of manufacture

Manufacturer

Recovery

Used indoor only

Keep dry

Handle with care

Temperature limitation for storage

Humidity limitation for storage

Atmospheric pressure for storage

Appliance compliance WEEE directive

Sterilizable up to the temperature specified

Follow Instructions for Use

EC REP Authorised Representative in the EUROPEAN COMMUNITY

19. 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.

20. 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 model LED.G is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.G 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.G 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.G is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance & Declaration — electromagnetic immunity			
The model LED.G is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.G 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	Not applicable	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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model LED.G require continued operation during power mains interruptions, it is recommended that the model LED.G be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/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 model LED.G is intended for use in.the electromagnetic environment specified below. The customer or the user of the model LED.G 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* *3V/m*	Portable and mobile RF communications equipment should be used no closer to any part of the model LED.G, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 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,[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 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.G is used exceeds the applicable RF compliance level above, the models LED.G 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.G.

[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.G

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

Scan and Login website
for more information

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ZMN-SM-160 V1.2-20200319