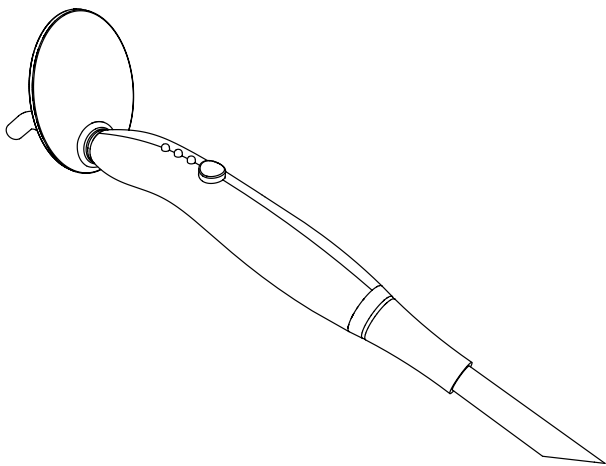


CURING LIGHT LED.Q USER'S MANUAL

(Please read this manual before operating)



GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.
www.glwoodpecker.com

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1. Introduction

1.1 Foreword

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 include periodontal treatment device, ultrasonic scaler, curing light, high speed turbine handpiece, apex locator and ultrasurgery etc.

1.2 Feature:

- A) Sealed, connect to dental unit.
- B) Time setting: 10s, 20s, 30s.
- C) Working mode: Full.

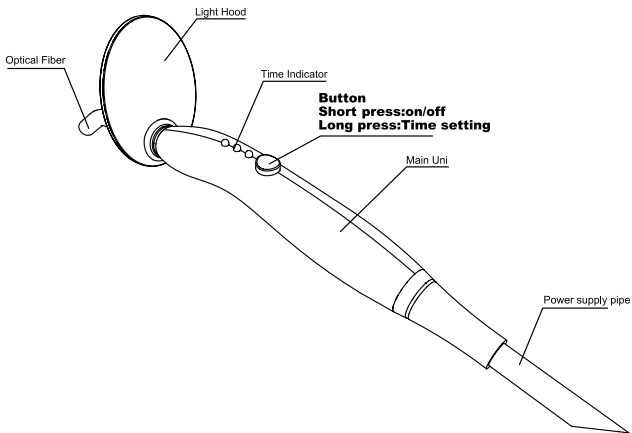
1.3 Principle and usage

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

1.3.2 This product is used to restore teeth and solidify material for whitening teeth.

2. Structure and components

LED.Q is composed mainly of main unit, optical fiber, light hood, high power LED and cable. (Picture 1)



3. Technical specifications

3.1 Dimensions: 248mm×26mm×26.5mm

3.2 Net weight: 127g

3.3 Configuration:

Main unit *1

Optical fiber *1

Light hood *1

Instruction book *1

Product certificate *1

Warranty card *1

3.4 Power supply

3.4.1 According to the classification of power supply

Connect to dental unit ~24V

3.4.2 Power input: ~24V 50Hz/60Hz 0.4A Max

3.5 Light source

3.5.1 3W high power blue LED light

3.5.2 Wave length: 420nm-480nm

3.5.3 Light intensity: $1000\text{mW}/\text{cm}^2 \sim 1200\text{mW}/\text{cm}^2$

3.5.4 Category: 1

3.5.5 Launch limit(AEL): $3.9 \times 10^{-3}\text{J}$

3.5.6 Inspection method: If the LED light shines when operate correctly, it's in good condition.

3.5.7 Clinical commonly used resin can match with the wavelength, such as 3M, Dentsply etc.

3.6 Radiation during 400nm~515nm(blue light):

$\cong 250\text{mW}/\text{cm}^2$

3.7 Optical active area: 50mm^2

3.8 Working condition:

3.8.1 Environment temperature: 5°C to 40°C

3.8.2 Relative humidity: 30%~75%

3.8.3 Atmosphere pressure: 70kPa to 106kPa

- 3.9 Protection type against electrical shock: class II
- 3.10 Protection against electrical shock: type B
- 3.11 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0)
- 3.12 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

4. Install and uninstall way

4.1 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 wires should be a little longer than the nylon thread to keep the power wire safe.

4.2 Take off the red cap from the optical fiber and insert the metal part into the front of the built-in LED.Q (Make sure to screw the fiber to the end by rotating it).

4.3 Install the light hood as shown in picture 1.

5. Operation

5.1 Press the button to turn on the device.

5.2 After turning on the device, keep pressing the button in 1second, then the indicator light scroll shines. Now you can choose 10s, 20s, and 30sworking time.

5.3 While operating, put the light source alignment the position where needs to be solid, press the button in a short time, then with a “Di” voice, the main unit shines blue light and starts the countdown. When countdown back to 0, the main unit stops working, and with a long “Di” voice, the indicator light comes back to the setting time.

5.4 It can be stopped working at any time by short pressing the button while operating.

5.5 At the end of a working cycle, the next working cycle can be started immediately by short pressing the button. If the main unit gets hot obviously, please turn off the device until the main unit becomes cool.

Please don't make it continuously illuminate more than 10times.

5.6 If there is resin on the fiber after using, please clear it by cotton cloth to make sure the power intensity is good.

5.7 The device will turn off after 2 minutes idle.

5.8 This device can cure composite resin not less than 4mm in 10 seconds.

6. 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°C.

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.

6.1 Initial processing

6.1.1 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.

6.1.2 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.

6.2 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.

6.3 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.

6.3.1 Automated cleaning

- The cleaner is proved to be valid by CE certification in accordance with EN ISO 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.

6.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase.

Automated disinfection is preferred if conditions permit.

6.4.1 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 ° C, 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 3 minutes, 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 $A_0 \geq 3000$.

(d2) Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or $A_0 \geq 600$.

(d3) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and $A_0 > 3000$.

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 disinfectant.

6.5 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°C~120°C 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.

6.6 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.

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

6.6.2 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.

6.6.3 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.

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

6.7 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.

6.8 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.

6.9 Storage

6.9.1 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;

6.9.2 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.

6.10 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.

7. Precaution

- 7.1 Optical fiber is fragile glass, do not knock, collide it or let it fall.
- 7.2 During operation the light should be aimed straightly on the resin, to ensure solidification effectively.
- 7.3 Be sure to use the original light hood, and make sure to install it in correct way to avoid the blue light hurt eyes. Strictly prohibit aiming light at eyes directly.

8. Contraindication

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

9. Maintenance

9.1 This product does include repair part, machine maintenance and repair shall be made by the designated professional or repaired at a repair shop.

9.2 Users can replace light hood and optical fiber on hand. Besure to use the original accessories. Please contact with the local dealer or the company. Banning the use of other related accessories, lest cause curing light damage or other dangerous.

9.3The optical fiber should be sterilized for 4 minutes with 134℃ and 2.0bar~2.3bar (0.20MPa~0.23MPa) before each use.

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

10. Trouble shooting

Faulty	Possible cause	Solution
No-indication Non-act.	1, Continuous use time is too long, thermal protection circuit working. 2, The device is not connected well with power. 3, main unit broken.	1, Wait for a few minutes, it will be back to normal. 2, Check the connection of the device and the power. 3, Contact the local dealer or us.
Light intensity insufficient.	1, Optical fiber isn't inserted well to the bottom. 2, The optical fiber is 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.

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.

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

11.3 This equipment should be stored in a room where the relative humidity is 10%~93%, atmospheric pressure is 70kPa to 106kPa, and the temperature is -20°C to +55°C.

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. After-sale service

From the date of this equipment sold, if the equipment can't work normally because of the quality problems, our company will be responsible for the maintenance base on the warranty card. Please refer the warranty scope and period from warranty card.

13. Environmental protection

Please dispose according to the local laws.

14. Symbol instruction



Class II equipment



Type B applied part

IPX0

Ordinary equipment



Used indoor only



Date of manufacture



Manufacturer



Recovery



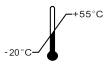
Screw inside/ outside



Keep dry



Handle with care



Temperature limitation for storage



Humidity limitation for storage



Atmospheric pressure for storage



Appliance compliance WEEE directive



Follow Instructions for Use

15. 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.

Scan and Login website
for more information



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