



# Instruction Manual for MaxCureH(Curing Light)

Please read this manual before operating

# **≜**Safety Precautions

**WARNING:** If you neglect these safety precautions, you may cause personal injury such as electric shock, fire or damage to the product.

- 1. Use a separate, grounded power outlet. Never use wet hands to unplug the power cord.
- 2. Please do not use other than the specified voltage. Before connecting the built-in curing light without transformer to power supply, please check the output voltage is 24VAC, in case of connecting to wrong power supply and that may break the unit.
- 3. Keep the Curing Light clean before and after operation. The optical fiber must be sterilized before each treatment.
- 4. During the operation, the light should be aimed straightly at the composite resin to ensure the effect of solidification.

**MARNING:** Avoid aiming at eyes directly.

- 5. Don't knock or rub the Curing Light.
- 6. This product is intended for use in hospitals and dental clinics only. The user must be professionally trained and qualified dentists.
- 7. As a professional manufacturer of medical instruments, we are only responsible for the safety on the following conditions:
- The maintenance, repair and modification are made by the manufacturer or the authorized dealer.
- The changed components are original of our company and operated correctly according to instruction manual.
- 8. The device must not be used in MRI environment for the device is easily affected by the electromagnetic emission and would not work or work normally.

Guilin Refine Medical Instrument Co., LTD. RF-MCH-M001 Version: 1.6 20240617

9. When you meet circumstances where the main unit expires, the misuses lead to the short circuit of the circuit board or accidentally dropping the device results in the damage of components, the device should no longer be reused.

**MARNING:** No modification of this equipment is allowed.

<u>↑</u>WARNING: If the curing light works for 40s continously, the temperature of the top of optical fiber may reach 56 °C.

⚠WARNING: Do not modify this equipment without authorization of the manufacturer.

#### **!** Contraindication :

The heart disease patient, pregnant woman, children and the person who are allergic to blue light should be cautious to use this equipment.

## Symbol instruction

Symbol	Instruction	Symbol	Instruction
<u> </u>	Caution	<b>(3)</b>	Refer to instruction manual/booklet
₩	Date of manufacture	***	Manufacturer
	Class II equipment	★	Type B applied part
d>	Screw inside/ outside	台	For indoor use only
<b>E</b>	Recovery	<b>Ť</b>	Keep dry
Ţ	Fragile, handle with care	70kPa - 106kPa	Atmospheric pressure limitation: 70kPa- 106kPa
-20°C	Temperature limit: -20°C- +55°C	10%	Humidity limitation: 10%-93%
泫	Waste electrical and electronic equipment	C€	CE Mark

EC REP	Authorized representative in the European Community	SN	Serial number
MD	Medical device	UDI	Unique device identifier

## 1 Product introduction

The product suppose to be used in hospital and dental clinic, should be used by trained qualified dentist. This Curing Light is used for the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time, This curing light is intended for use by trained dental professionals for the purpose of light curing dental resins and composites and used to restore teeth.

Patient target groups: adults and pediatrics.

Applied part: optical fiber.

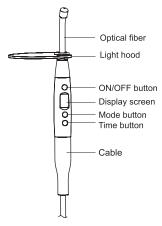


Figure 1

**Note:** The button labeled 'Time' indicates the time setting, and the button labeled 'Mode' indicates the mode setting.

Safety classification	Working condition
1. Protection type against electrical shock: Class II 2. Protection degree against electrical shock: Type B 3. Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0), can't be waterproof. 4. operation mode: non-continuous operation, the maximum working time 100 seconds, the minimum deactivation time 30 minutes 5. Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.	a) Environment temperature: 5°C-+40°C b) Relative humidity: 30%-75% c) Atmosphere pressure: 70kPa-106kPa

#### 2 Technical Parameters

- 2.1 Power supply:
- 2.1.1 Input: 24V AC, 50Hz/60Hz
- 2.2 Light intensity: 1000mW/cm<sup>2</sup> 1800mW/cm<sup>2</sup>
- 2.3 Applied part: Optical fiber
- 2.4 Modes setting:
- 2.4.1 TURBO mode: Display P1, Illumination 1600mW/cm<sup>2</sup> 1800mW/cm<sup>2</sup>
- 2.4.2 NORMAL mode: Display P2, Illumination 1000mW/cm<sup>2</sup> 1200mW/cm<sup>2</sup>
- 2.5 Time setting:
- 2.5.1 TURBO mode: 3S, 5S
- 2.5.2 NORMAL mode: 5S, 10S, 15S, 20S
- 2.5.3 Lightly press the time button to choose the solidification time.
- 2.6 Dimensions: Φ25mm\*267mm
- 2.7 Net weight: 191g
- 2.8 Light source:
- a) 5W high power blue LED
- b) Wave length: 420nm-480nm
- 2.9 Consumption power: ≤5W
- 2.10 Composed mainly: main unit, optical fiber, light hood, LED lamp, cable.
- 2.11 Software version : 1.0.0

#### 3 Installation and demounting

a) Connect the Curing Light power supply line with the power (24VAC)

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 Curing Light, 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.

- b) Take off the red cap from the optical fiber and insert the metal part into the front of the built-in Curing Light (Make sure to screw the fiber to the end by rotation).
- c) Install the light hood as showed in figure 1.
- d) Uninstall the Curing Light, just reverse the procedure above.

## 4 Operation

- 4.1 Modes setting: Lightly press the mode key to change the running modes. The Curing Light will shine the diffrent Illuminated blue light. The available modes see the Technical Parameters.
- 4.2 Time setting: Lightly press the time button to choose the solidification time. The available time setting see the Technical Parameters.
- 4.3 During the operation, aim blue light at the position needing solidification. Press the power button "ON/OFF" switch, a "beep" sound will appear, the Curing Light starts to work under the selected mode. Then it counts down to "0" second to end the solidification.
- 4.4 During operation, the blue light can be stopped by press the power button "ON/OFF" at any time.
- 4.5 After the operation, please clean the fiber with calico in order not to affect the light intensity.
- 4.6 This equipment will turn off automatically if no any action within 2 minutes, turn it on by press "ON/OFF" button.
- 4.7 The depth of solidification of composite is no less than 4mm per 10 seconds.
- 4.8 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, then it will come into over-heat protection status. And only after 2 minutes sleep, it can restart working 200s continuously.

## 5 Cleaning, disinfecting and sterilizing

- 5.1 Please conform to the recommendations of the manual "Reprocessing Instructions of Cleaning, Disinfecting And Sterilizing" delivered with your product regarding the procedure of cleaning, disinfecting, sterilizing and packing of the components. Follow present-day regulations enforced in the country about reprocessing. The use of scouring powder or an abrasive sponge will damage its surface.
- 5.2 The optical fiber can be sterilized. The light hood, LED lamp cannot be sterilized.

#### ∕!\Notice:

- a) Clean in the handpiece (detachable) with compressed air before sterilization.
- b) Be sure that the optical fiber has been unscrewed from the handpiece and it cannot be sterilized with others.
- c) Please notice whether the outer of the optical fiber is damaged during the treatment and sterilization. Change a new one once it is damaged or worn excessively.
- d) Don't smear any protective oil on the surface of optical fiber.

### 6 Transportation, storage and maintenance

- 6.1 Transportation
- 6.1.1 Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.
- 6.1.2 Don't put it together with dangerous goods during transportation.
- 6.1.3 Avoid solarization and getting wet in rain or snow during transportation.
- 6.2 Storage
- 6.2.1 Don't store the machine together with the articles that is combustible, poisonous, caustic, or explosive.
- 6.2.2 This equipment should be stored in a room where the relative humidity is 10%-93%, atmospheric pressure is 70kPa-106kPa, and the temperature is -20°C-+55°C.
- 6.3 Maintenance
- 6.3.1 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.

- 6.3.2 Please turn off the electrical source if not use it, if not use for a long time, please make the machine get through to the power once 3 months for five minutes.
- 6.3.3 Please clean the resin remained on the top of the main unit after using to avoid infecting the life-span or solidified effect.

# 7 Troubleshooting

Faulty	Possible cause	Solutions
Non- indication Non-act.	The LED is not connected well with the power.     The power is off.	Check the connection of the LED and the power.     Make sure the power is on.
Light intensity insufficient.	Optical fiber isn't inserted well to the bottom.     The optical fiber has cracked.     There is resin remain on the surface of the optical fiber.	Install the optical fiber well.     Change the optical fiber.     Remove the resin.
No indication, no response.	1. The connection between the device and the dental unit is loose 2. the cable connector with the dental unit is broken.	Pull out the device and connect with the dental unit again.     Send it to our company to repair.
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.	Reinstall the optical fiber.     Change a new optical fiber.     Clear the resin.

If such handlings are completed, the equipment still cannot work normally, please contact with the local dealer or the manufacturer.

## 8 Environmental protection

After the device is out of its service life, please dispose it in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive and the medical waste disposal regulations of your country.

#### 9 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 REFINE MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by REFINE, any copy or fake product must take legal responsibilities.



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EC REP

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Shelf life: 10 years

Production date: please refer to packaging label.

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