Instruction Manual
for MaxCureG(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.
4. During the operation, the light should be aimed straightly at the composite resin to ensure the effect of solidification.

⚠**WARNING:** 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.
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.

⚠**WARNING:** No modification of this equipment is allowed.

⚠**WARNING:** If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

⚠**WARNING:** If the curing light works for 40s continously,the temperature of the top of light guide 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.

Guilin Refine Medical Instrument Co., LTD.
RF-MCG-M002 Version: 1.6 20240617

Symbol instruction

Symbol	Instruction	Symbol	Instruction
	Caution		Refer to instruction manual/booklet
	Date of manufacture		Manufacturer
	Class II equipment		Type B applied part
	Screw inside/ outside		For indoor use only
	Recovery		Keep dry
	Fragile, handle with care	70kPa 106kPa	Atmospheric pressure limitation: 70kPa-106kPa
-20°C +55°C	Temperature limit: -20℃- +55℃	10% 93%	Humidity limitation: 10%-93%
	Waste electrical and electronic equipment	CE	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, it is used to restore teeth and solidify material for whitening teeth.
Patient target groups: adults and pediatrics.
Applied part: light guide.

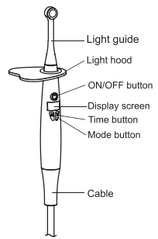

Figure 1

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^2 - 2500mW/cm^2
2.3 Applied part: Light guide
2.4 Modes setting：
2.4.1 TURBO mode: Display P1, Light Intensity 2300mW/cm^2 - 2500mW/cm^2
2.4.2 NORMAL mode: Display P2, Illumination 1000mW/cm^2 - 1200mW/cm^2
2.5 Time setting：
2.5.1 TURBO mode: 1S, 3S
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*240mm
2.7 Net weight：171g
2.8 Light source：
a) 5W high power blue LED
b) Wave length: 385nm-515nm
2.9 Consumption power：≤5W
2.10 Composed mainly：main unit, LED lamp, light hood, 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 light guide and insert the metal part into the front of the built-in Curing Light (Make sure to screw the light guide 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, put disposable isolation sleeve on the main unit, 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 light guide 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

5.3.1 Please notice that this equipment is not allowed to carry out steam sterilization process otherwise it will cause damage.
5.3.2 Before using this equipment, users need to put disposable isolation sleeve which is supplied by our company on the light guide of Curing Light to avoid contact between the main unit or other components and the patient's skin or oral mucosa and avoid cross infection. After use, remove the disposable isolation sleeve and dispose of it in accordance with applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.
5.3.3 The disposable isolation sleeve purchased by the user should meet the requirements of medical device regulations.
5.3.4 The accessory of the equipment should be cleaned by clean water or neutral sterilized liquid. Do not soak. Do not use highly volatile and diffluent solvent to clean this equipment, which can cause the signs on the control panel to fade.
5.3.5 Disposable isolation sleeves are not allowed to be reused to prevent cross-infection.
5.3.6 Please clean the resin remained on the top of the main unit after using to avoid infecting the life-span or solidified effect.

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.

7 Troubleshooting

Faulty	Possible cause	Solutions
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.	1. Pull out the device and connect with the dental unit again. 2. Send it to our company to repair.

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

8 EMC-Declaration of conformity

8.1 Instructions for use
The ME EQUIPMENT or ME SYSTEM use in hospitals or dental clinics.
Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

List of all cables

No	Name	Length	Shielded or not	Detachable or not	Note
1	Power supply cable	2 m	No	Yes	It should be connected with the power (AC 24V) of dental unit.

Replaceable accessories
None
Essential performance
The curing light has neither life sustaining functions nor diagnostic of life supporting functions.
The following functions are observed:
- Curing of dental resins and composites
- Continuous light on handpiece
When the product is invalid or degraded due to electromagnetic disturbance, the user should stop using it immediately to ensure that there is no error caused by the product's performance failure or degradation. In this case, the user should remove the disturbance source or adjust the direction or position of the product, so that the product can work normally.

8.2 Technical description
8.2.1 Portable and mobile RF communications equipment may affect the performance of equipment , use of equipment should be avoided strong electromagnetic interference, and do not closer to mobile phone, microwave oven, etc.
8.2.2 Use of equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
8.2.3 Except for the cables sold by manufacturers of as spare parts of internal components, the use of accessories and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
8.2.4 Use of accessories, transducers and cables other than those specified or provided by the manufacturer together with equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
8.2.5 Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/ burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency

Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45° , 90° 135° , 180° 225° , 270° and 315° . 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45° , 90°, 135°, 180° 225° , 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30A/m 50Hz/60Hz	30A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance & Declaration - Electromagnetic immunity						
	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
	Test Frequency	**Modulation**	**IEC 60601-1-2 Test Level(A/m)**	**Compliance level (A/m)**
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 MHz	Pulse modulation 50 kHz	7,5	7,5

9 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.

10 Statement

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Shelf life: 10 years
Production date: please refer to packaging label.

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