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REFINE

CE

SWAN

CURING LIGHT

Instruction Manual



Please read this manual before operating

RF-SWA-M001-1.1 20210506

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⚠Safety Precautions

1. This product is intended for use in hospitals and dental clinics only. The use of the product must comply with the requirements of the relevant operating specifications and relevant regulations of the medical department. Users must be professionally trained and qualified as dentists or technicians. Do not look directly into the light output. Patient, clinician and assistants are always suggested wearing protectors (safety goggle, face shield…) to avoid crossing infection.
2. The products are reusable:
Prior to each use, place a new barrier sleeve over the curing light Swan. The hygienic barrier sleeve is customs fitted to the curing light and keeps the surface of the curing light clean. The barrier sleeve helps prevent cross contamination, helps keep dental composite material from adhering to the surface of the lens and curing light, and prevent discoloration and corrosion from cleaning solutions. The curing lights must be cleaned and sanitized with appropriate cleaning and/or sanitizing agents after each patient. The sleeve is not equipped with the curing light. Please note that the sleeve must meet the requirements of relevant medical device regulation and it's disposable.
3. During the operation, the light should be aimed straightly at the composite resin to ensure the effect of solidification.
4. Please use the original light hood and follow the right installation ways to avoid the damage of blue light to the eyes.
5. Please do not use other than the specified voltage to recharge the battery. 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. Please recharge the battery at least 4 hours before first time usage. It's forbidden to connect the charger to the base for long time while not charging and it's not allowed to use the curing light while charging.
7. It is forbidden to touch the charging connector with metal or other conductor, to avoiding damage the circuit of charge or the battery.
8. Please recharge the battery in cool and ventilated room. Please press the main unit to the buckle of charging base, in order to avoid the poor connection.
9. It is forbidden to self-taking-apart the battery, in order not to result in short-circuit or leakage.
10. It is forbidden to extrude, shake or rock the battery. The Lithium battery is forbidden to be in short-circuiting situation and it is forbidden to put the battery with metal or other conductors.
11. The instrument has electromagnetic interference. Do not use it around electronic surgery, and use the instrument with caution in an environment with strong electromagnetic interference.
12. This product does not contain toxic or hazardous substances and it is discarded in accordance with the relevant laws and regulations on waste medical devices. Please deal with the replaced battery according to national regulations
13. 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.

Product contraindications:
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
	Warning, Caution and Important! Check the Instruction Manual		Consult the accompanying documents
	Date of manufacture		Manufacturer
	According to the type of protection against electric shock: CLASS II EQUIPMENT		According to the degree of protection against electric shock:Type B applied part
	Screw inside/ outside		Used indoor only
	Recovery		Keep dry
	Handle with care		Atmospheric pressure for storage
	Temperature limitation for storage		Humidity limitation for storage
	Appliance compliance WEEE directive, Dispose as required by the law.		CE Mark

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⏻	Turn on/off	M	Mode
EC REP	Authorised Representative in the EUROPEAN COMMUNITY	T	Time setting

1 Product introduction

The curing light manufactured by Guilin Refine Medical Instrument Co., Ltd. uses the principle of light radiation to irradiate photosensitive resin in order to quickly cure it. This product is intended for use in hospitals and dental clinics and it's used for prevention and treatment of dental complications of adults or children.

Scope of application: suitable for dentistry, used to cure light-curing materials.

Product composition: main unit, LED light, light hood, charging base, battery and power adapter, etc.

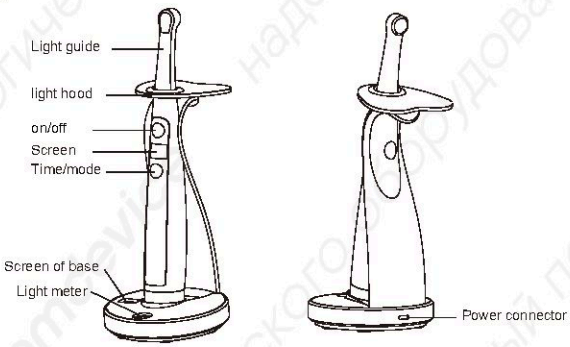
The features of this product are:

1.1 A variety of different working modes and working hours can be set.

1.2 Constant light power output, the decrease of battery power will not affect the curing effect.

1. 3 Large-capacity battery. While full charged, under 10 seconds of light per time, it can be used continuously for more than 500 times.

1. 4 Product schematic



2 Replacement instructions for accessories

Accessories	Period of replacement	Method of replacement
Power adapter	Damaged	Replace directly according to the requirements of the manual.
Charging base	Damaged	Replace directly according to the requirements of the manual.
Battery	Damaged	Take out the damaged battery and replace it with a new one.
Light hood	Damaged	Replace directly according to the requirements of the manual.

3 Technical parameters

3.1 Technical Parameters of each model (table 1)

Dimensions	Φ86mm*223mm
Net weight	265g
Classified by power supply	Powered by rechargeable lithium battery
Input	Charging: DC5V 1A Working: 3.6V lithium battery(ICR 18650)
Rechargeable lithium battery	Battery model: ICR 18650 Battery voltage and capacity: 3.6V/2600mAh The battery has overvoltage, overcurrent and short circuit protection.
Power supply (Adapter)	Input : 100-240V AC 50Hz/60Hz 0.4A Max Output: DC 5V/1A Built-in fuse: T1A 250V
Performance of led lamp	a) 10W high power blue and purple LED lamp. b) Wave length: 385nm-515nm c) Category: class I.d)Shoot limit(AEL): 3.9*10—³J
Light Intensity	1000mW/cm²-2500mW/cm²
Inspection method of LED lamp	When operating correctly, the LED lamp lights up, indicating that the lamp is in good condition. Dental resin materials commonly used in clinic can match the wavelength of this curing light, such as 3M, Dentsply and other resins.

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Modes and time setting	TURBO mode: Blue and purple light, 2500mW/cm2 for 1s, 3s NORMAL mode: Blue and purple light, 1200mW/cm2 for 5s, 10s, 15s, 20s ORTHO mode: Blue and purple light, 2500mW/cm2 for 3s to work 10 times every cycle, or 5s to work 10 times every cycle, interval 1s CHECK mode: purple light, 900mW/cm2 for 30s, 60s
Effective area of irradiation light	66.4mm²

3.2 Environmental factors

3.2.1 Operation: +5°C - +40°C

3.2.2 Relative humidity: 10% - 93%

3.2.3 Atmospheric pressure: 70kPa-106kPa

3.3 Equipment safety classification

3.3.1 Classified by type of protection against electric shock: **Class II**

3.3.2 Classified by degree of protection against electric shock: Type B application part

3.3.3 Classified according to the degree of protection against incoming liquid: Ordinary equipment (IPXO), non-waterproof

3.3.4 Classified by operation mode: Short-term operation equipment

3.3.5 Classification of safety degree when using flammable anesthetic gas mixed with air or oxygen or nitrous oxide: Equipment that cannot be used with flammable anesthetic gas mixed with air or oxygen or nitrous oxide.

4 Installation and demounting

Insert the large end of the light guide (front connector) into the mounting hole at the upper end of the curing light (please insert it into the bottom in a rotating way, do not be obliquely).

Clamp and install the light hood at the root of the light guide (front joint).

When removing or replacing the light guide, proceed in the opposite direction above.

5 Operation

5.1 When the machine is under stand-by mode, press the time/mode key to light up the screen.

5.2 Mode setting: press the time/mode key for more than 2 seconds to select the mode; during mode switching, the display screen has a transition picture (the picture shows the full English name of the mode to be switched to), and every time the key is pressed, there's a beep. Without operating within 1 minute, the screen will turn off and the main unit enters the sleep state.

5.3 Time setting: press the time/mode key to select time, see table 1 for settable curing time.

5.4 Point the light guide rod (front connector) light source at the right position, press the switch button and there's a beep. The curing light will start to work as the mode setting. The display screen starts counting down from the selected time, and after the timing ends, the display screen displays the setting time.

5.5 Before the end of setting time, at any time pressing the on/off key can finish the work.

5.6 After the end of an irradiation cycle, you can immediately press the switch to start the next irradiation cycle. If the handle starts to become hot, please stop working until the handle is completely cooled down. It is recommended that the number of consecutive irradiations should not exceed 10 times.

5.7 If the transparent cover is stained with resin after use, please wipe it with a cotton cloth to avoid affecting the light intensity.

5.8 The effective light intensity of this machine is many times higher than that of the halogen lamp curing light, and the curing depth of the light-curing composite resin is not less than 4mm for 10 seconds.

5.9 The front connector at the front end can be removed, but high temperature and high-pressure sterilization is not allowed, otherwise it will cause damage.

6 Low battery prompt and charging

6.1 Low voltage indication: The battery symbol on the display starts to flicker, accompanied by a sound prompt;

6.2 When charging, insert the charging cable into the TYPE-C socket at the back of the base, the blue light at the bottom of the base will light up, and the brightness will be changing;

6.3 Correctly put the main unit into the charging base, the base display will automatically light up and display the power;

6.4 The charging base has a light meter function. When the base is in standby mode, the display is off. Only when the main unit is charged or when testing light intensity that the display will automatically light up.If it is not charged or measured, the base display will automatically turn off.

7 Transportation, storage and maintenance

7.1 Transportation

7.1.1 During transportation, avoid shocking and vibration, handle with care and avoid inversion.

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7.1.2 Do not mix with dangerous goods during transportation.

7.1.3 Avoid sunlight, rain or snow during transportation

7.2 Storage

7.2.1 Do not mix with toxic, corrosive, flammable and explosive materials during storage.

7.2.2 The product should be stored in an environment where the relative humidity does not exceed 10% - 93%, the atmospheric pressure is 70kPa - 106kPa, and the temperature is -20°C - +40°C.

7.3 Maintenance

7.3.1 This equipment should be handled with care, far away from the source of the earthquake, and should be installed or stored in a cool, dry and ventilated place.

7.3.2 When the device is not in use, turn off the power switch and unplug the power plug; when not in use for a long time, charge the main unit every 3 months.

7.3.3 To clean or disinfect, wipe the surface with clean water or disinfectant, do not soak.

7.3.4 After use, check if there is any resin remaining on the surface of lamp, so as not to affect the life of the front joint or affect the curing effect.

8. Troubleshooting

Faulty	Possible cause	solutions
No reaction	1. Out of battery 2. Faulty of battery 3. Battery protection	1. Charge/Change a new battery 2. Change a new battery 3. Activate it by putting it on the base
Insufficient Light intensity	There is resin remaining on the surface of the transparent cover of light guide.	1. Remove the resin 2. Change the transparent cover
Not charging when connecting with the adapter	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. Clean the inner connector of charging base by the alcohol
Less working life after fully charge	Capacity of battery decreased	Change a new battery
The mode indicator twinkles when charging	Low voltage	Back to normal after 15-minute charging.

If the fault still cannot be resolved, please contact your local dealer or our company.

9. Electromagnetic compatibility

Attention:

•This Curing Light meets the relevant requirements of YY 0505 standard electromagnetic compatibility. The basic performance of the light curing machine is: the front LED light can emit blue (UV) when working.

•The user should install and use it according to the electromagnetic compatibility information provided by the accompanying documents.

•Portable and mobile radio frequency communication equipment may affect the performance of the curing light, avoid strong electromagnetic interference when using it, such as close to mobile phones, microwave ovens, etc.;

•The guidelines and manufacturer's declaration are detailed in the attachment.

•Without the express consent of Guilin Refine Medical Instrument Co., Ltd., unauthorized changes or modifications to the equipment may cause damage to the equipment or other

The electromagnetic compatibility of the equipment.

Alert:

•This light curing machine should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed and verified that it can be used in the configuration used.

Normal operation.

• Except for the cables sold by the manufacturer of the curing light as spare parts of internal components, the use of accessories and cables other than those specified may cause the curing light

Increase in emission or decrease in immunity.

• The following cables must be used to comply with electromagnetic emission and anti-interference requirements:

Cable Name	Cable Type	Cable Length
Power Line (Output end)	Unshielded Parallel Lines	1.2 m

• Key components of electromagnetic compatibility

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The key components of electromagnetic compatibility of this product are IC chip, main PCB, lithium battery, power adapter and LED lamp. Use or replace the accessories and cables that are not designed to match, will cause the electromagnetic compatibility emission and anti-interference performance to be significantly reduced. Do not change machine parts without authorization.

Enclosure:

Guidance and manufacturer's declaration - electromagnetic emissions		
The models Curing Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models Curing Light should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissionsGB 4824	Group 1	The models Curing Light use 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 emissionsGB 4824	Class B	The models Curing Light are 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 17625.1	Unapplicable	
Voltage fluctuations / flicker emissions 17625.1	Complies	

Guidance & Declaration — electromagnetic immunity			
The models Curing Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models Curing Light should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) GB/T 17626.2	±8 kV contact ±15 kV air	±8 kV contact ±15 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 GB/T 17626.4	±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 GB/T 17626.5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	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 GB/T 17626.11	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Curing Light requires continued operation during power mains interruptions, it is recommended that the models Curing Light be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field GB/T 17626.8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The models Curing Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models Curing Light should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

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Conducted RF GB/T 17626.6 Radiated RF GB/T 17626.3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models Curing Light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V1]\times P^{1/2}$ $d=[1.2/E1]\times P^{1/2}$ 80 MHz to 800 MHz $d=[2.3/E1]\times P^{1/2}$ 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 Interference may occur In the vicinity of equipment marked with the following symbol: 
NOTE: 1 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 models Curing Light are used exceeds the applicable RF compliance level above, the model Curing Light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Curing Light. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

The Rated maximum output power of the transmitter W	The distance between different frequencies of the transmitter		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,5GHz d=2.3×P1/2
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.22.3	2.3
10	3.8	3.8	7.3
100	12	12	23
For the maximum rated output power of the transmitter not listed in the above table, the recommended separation distance (d) which in meters (m) that can be determined by the formula in the frequency column of the corresponding transmitter. The P is the maximum rated output power of the transmitter provided by the transmitter manufacturer which in watts (W).			
Note 1: At 80MHz and 800MHz frequency points, the higher frequency band formula is used.			
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.			

10. Environmental protection

Components	hazardous substance or element					
	(Pb)	(Hg)	(Cd)	(Cr6+)	(PBB)	(PBDE)
Main units	o	o	o	o	o	o
Charging base	o	o	o	o	o	o
Adaptor	o	o	o	o	o	o
Mechanical element (Including screws, nuts, joint rings, etc.)	o	o	o	o	o	o

○: Indicates that the content of this toxic and hazardous substance in all homogeneous materials of this component is below the limit requirement in SJ/T-11363-2006 "Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products".

×: It means that the content of this toxic and hazardous substance in at least one of the homogeneous materials of the part exceeds the limit requirement of SJ/T11363-2006. (This product complies with EU RoHS environmental protection requirements; currently there is no mature technology in the world that can replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys)

According to the "Administrative Measures for Restricting the Use of Hazardous Substances in Electrical and Electronic Products", "Regulations for Recycling and Disposal of Waste Electrical and Electronic Products" and relevant standards, please comply with the safety and use precautions of the products, and recycle or dispose of the products in appropriate ways according to local laws and regulations after the use of the products.

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11. After sales service

11.1 If this equipment cannot work normally due to quality problems from the date of sale, please show the warranty card and our company will be responsible for the maintenance. Please refer to the product warranty card for the warranty period and warranty scope.

11.2 This product does not contain replaceable parts. All maintenance, adjustment, calibration and modification of technical parameters of the product can only be carried out by our company's technicians or special repair shops. If customers need to repair themselves, our company can provide them on request Circuit diagrams, component lists, legends, calibration specifications, or other materials needed to help qualified technical personnel repair the equipment parts designated by our company, but we will not bear any consequences.

11.3 The user must use the original parts, purchase please contact with the local dealer or the manufaturer. Do not use the related accessories of other brands, so as not to cause damage to the light curing machine or other dangers.

11.4 After the power adapter, charging base and other accessories are damaged, users should not repair by themselves. Please buy new parts and replace them by yourself. If you need relevant information, please contact the manufacturer.

12. Special instructions

The company reserves the right to modify the machine design, product technology or accessories, operation manual and machine packaging content at any time without prior notice. The product is subject to the real object, and the picture is for reference only. The final interpretation right belongs to

Guilin Refine Medical Instrument CO., LTD.

After service and Warranty Instruction

1 Period validity: two year's free repair for the main unit, charging base, power adapter from the date of purchase. One year's free repair for lithium battery. Warranty card is necessary while submitting the repairing request.

2 Range of warranty: Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

3 The followings are beyond our warranty:

1) The damage caused by disobeying the operation instruction or lack of the needed condition.

2) The damage caused by unsuitable operation or disassembly without authorization.

3) The damage caused by unadvisable transportation or preservation.

4) There isn't the seal of distributor or the warranty card isn't filled in completed.

5) Light tip and protective light shield.

After service card

Name of Customer			
Address			
Post Code		Tel	
E-mail			
Purchase Date		Production Date	
Distributor			
Model		Product No.	

Guilin Refine Medical Instrument Co., Ltd.
No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China
Tel: +86-773-7796686 Email:refine@refine-med.com Website: http://www.refine-med.com

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

Product life: 5 years

Production date: please refer to packaging label.

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