

Guilin Woodpecker Medical Instrument Co., Ltd.

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Preface

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, apex locator and ultrasurgery etc.

1. Introduction

1.1 Features:

1.1.1 Two working modes: High, Norm

1.1.2 Time setting:

High: 1S, 3S

Norm: 5S, 10S, 15S, 20S

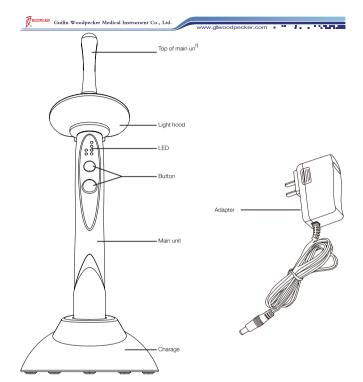
- 1.1.3 Constant light intensity. The solidification effect is not affected by the consumption of remaining power.
- 1.1.4 Large capacity battery. A full charge can be used for more than 400 times continuously under 10s working time mode.

1.2 Principle and Application

- 1.2.1 O-Light adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.
- 1.2.2 This product is used for dentistry. It has the function of accelerating the material of dental restoration curing.

2. Product Performance Structure and Components

O-Light curing light (dentistry) is mainly composed by LED, light hood, charging cradle, battery, adapter, main unit.



3. Basic Technical Specifications

3.1 Size: 268.8mm×26.1mm×31.8mm

3.2 Net weight: 259g

3.3 The components of machine: see the packing list.

3.4 Adapter:

3.4.1 classified by power supply

The power supply by the rechargeable battery.



3.4.2 Rechargeable Lithium battery:

Battery model: ICR18490, Battery capacity: 1400mAh

Battery has over-voltage, over current and short circuit protection

3.4.3 Adapter(charge)

Adapter input: AC100~240V 50Hz/60Hz

Output: DC5V 1A Built-in fuse: T1A250V

3.5 Light source:

3.5.1 5W high power blue light LED 3.5.2 Wave length: 385nm~515nm

3.5.3 Class: class I 3.5.4 AEL: 3.9×10-3J

- 3.5.5 Check method: When operate machine properly, LED luminous means LED is in good condition.
- 3.5.6 The wavelength of our curing light machine can match with dental resin material which are commonly used on clinical, such as 3M and Dentsply.
- 3.5.7 440 nm to 490 nm (blue light) wavelength range of radiation: not less than 250 mw/cm2.
 - 3.5.8 Work condition:

Environment temperature: +5°C to +40°C

Relative humidity: 30%~75%

Atmosphere pressure: 70kPa to106kPa

3.6 Safety classification

- 3.6.1 Protection type against electrical shock: Class II
- 3.6.2 Protection degree against electrical shock: Type B
- 3.6.3 Protection against harmful ingress of water or particular matter: ordinary equipment (IPXO),can't be waterproof.
 - 3.6.4 operation mode: short time run equipment.
- 3.6.5 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.



4. Installation and Demounting

- 4.1Aim the mounting holes which on the upper of machine ,and make the long side of top of the main unit inserted to it (must screw the top of the main unit to the end, don't inclined inserted).
- 4.2When the battery needs to be charged, connect the plug of the adapter into the AC100V~240V power supply. Then connect the output plug of the adapter to the DC 5V input plug of the pedestal, then put the main unit into the pedestal. Please pull out the adapter after charging.

5. Operation

- 5.1 Press the mode button to set the working mode, the corresponding indicator will on when a mode set.
 - 5.2 High:2300~2500 mw/cm²
 - 5.3 Norm:1000~1200 mw/cm²
 - 5.4 Press the time button to set the solidifying time:

High: 1S, 3S

Norm:5S, 10S, 15S, 20S the solidifying time

- 5.5 When operating, aim the top of the main unit at the correct position, press the power button, a "di"sound will appear, the LED shine the blue light and start to work under the selected mode. Screen began to display the countdown time. When the countdown back to 0 the work finished .Then the screen will return to setting time.
- 5.6 While operation, press the power switch button can stop work at any time.
- 5.7 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 10 times.
- 5.8 Low power detect circuit is fixed inside of the main unit, when low power is detected, the battery symbol display LED flashing, please

charge in time.

- 5.9 Connect the adapter well when charge. Inserted the main unit into the charging seat and pressing out the buckle between the main unit. Then the Charge LED become red.
- 5.10 When operating finish, please clean the top of the main unit with calico to avoid infecting the light intensity.
- 5.11 This equipment will turn off automatically if don't any action within 2 minutes, turn it on by press power button.
- 5.12 The effective light intensity of this equipment is much more higher than Halogen Lamp, The solidified depth of the curing light composites resin for 10 seconds will not less than 4mm.

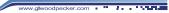
WARNING:

Wear a disposable isolation cover before using the machine.

6. Precaution

- 6.1 The top of the main unit should be autoclaved under the high temperature of 134°C and pressure 0.22 Mpa.
- 6.2 Please recharge the battery at least 4 hours before first time usage.
- 6.3 During operation, the light should be aimed straightly at the resin to ensure the effect of solidification.
- 6.4 Be sure to use the original light hood to avoid the blue light hurt eyes. Prohibit aiming light at eyes directly.
- 6.5 Only the original adapter could be used, because other brand adapters are likely to damage the circuit.
- 6.6 It is forbidden to use metal or other conductors to touch the charging point of main unit, because it may burn the internal circuit or make the lithium short circuit.
- 6.7 Charging the battery in the condition of cool and ventilated. Please make sure of pressing out the buckle between the main unit and the pedestal, otherwise the battery charging might be failed because of the poor contact.





- 6.8 Do not disassemble the Lithium battery, it will lead to the circuit short or the electrolyte leakage.
- 6.9 Do not squeeze, shake and short the battery, do not store the battery with metal material.
- 6.10 The instrument has electromagnetic interference. Do not use around the electronic operation, at the same time have a strong electromagnetic interference environment should be careful to use the instrument.
 - 6.11 It is forbidden to use when charging or operation.
- 6.12 This product should be used by trained, qualified dentists. And this product is suitable for dental patients. Must be use in hospital or professional medical site.
- 6.13 To avoid electromagnetic interference, the device should be installed at the medical site which meet the requirement of EMC.

WARNING: The adapter should be connected to the socket which is easy for operator to touch.

WARNING: over-heat scorching: the deivce cannot be used for 20s continuously.

WARNING: High temperature burn, The machine can not direct shining to the skin tissue like lips and mucosa.

7. Contraindication

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

8. Daily maintenance

- 8.1 This equipment does not include the self-maintainable spare parts. The maintenance of this equipment should be taken by the appointed professional or special repair shop.
- 8.2 Please use accessory which is designed and supplied by our company, contract with the local dealer or our company if you want to buy. It may cause potential dangers to curing light or other damages

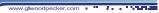
which is designed and supplied by other manufacturers.

- 8.3 The accessory of the product should be cleaned by clean water or sterilized liquid. Do not soak.
- 8.4 Please clean the resin remained on the top of the main unit after using to avoid infecting the life-span or solidified effect.

9. Troubleshooting

Faults	Possible causes	Solutions
No indication No response.	Battery is out of power. Battery is protected. Faulty of battery.	Charging. Please put the curing light into the pedestal for charging, then the battery works again. Please contact our special repair shop or us.
Light intensity is weak.	There is resin on the top of the top of the main unit.	 Clean the resin. Change a new top of the main unit.
The equipment doesn't charge when the adapter is connected.	The adapter is not connected well The charging point is impurity. Faulty of adapter or incompatible.	Reconnect. Clean by the alcohol. Please contact our special repair shop or us.
Effective duration of the battery become short.	The capacity of the battery decreased.	Please contact our special repair shop or us.
The Display LED twinkles when charging.	low voltage.	Back to normal after 15 minuets charging.

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



10. Storage and transportation

- 10.1 The equipment should be handled carefully and lightly, kept away from the shaking source, installed or stored at shadowy, dry, cool and ventilated places.
- 10.2 Don't store the equipment together with articles that are combustible, poisonous, caustic, and explosive.
- 10.3 This equipment should be stored in the environment where the humidity is 10%~93%, the atmosphere pressure is 70kPa~106kPa and the temperature is -20°C~+55°C.
- 10.4 Excess impact or shake should be prevented during transportation. Handle with care.
- 10.5 Don't put it together with dangerous articles during transportation.

10.6 Keep it away form the sun, rain or snow during transportation.

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.

12. Environmental protection

There are no harmful factors in our product. You can deal with it based on the local law.

13. Symbol instruction



Class II equipment

Used indoor only



Appliance compliance WFEE directive



High temperature sterilization



Atmospheric pressure for storage



Temperature limitation for storage



Humidity limitation for storage



Follow Instructions for Use

14. 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 models O-Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models O-Light should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models O-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 emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The models O-Light are suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	network which supplies buildings used for domestic purposes.





Guidance & Declaration — electromagnetic immunity

The models O-Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models O-Light should assure that It is used in such an environment.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/ output lines	±2kV for power supply lines ±1kV for interconnecting cable	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	±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 IEC 61000-4- 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 O-Light require continued operation during power mains interruptions, it is recommended that the models O-Light be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/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	e a.c. mains voltag	ge prior to application	on of the test level.



Guidance & Declaration - Electromagnetic immunity

The models O-Light are intended for use in the electromagnetic environment specified below. The customer or the user of the models O-Light should assure that it is used in such an environment

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 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1- 2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz- 5785MHz Test specification s for ENCLOSUR E PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1- 2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the models O-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]×P ^{1/2} d=1.2×P ^{1/2} 80 MHz to 800 MHz d=2.3×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 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 models O-Light are used exceeds the applicable RF compliance level above, the model O-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 O-Light.

^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 models O-Light

The models O-Light are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models O-Light can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models O-Light are recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter /m		
output power	150kHz to 80MHz	80MHz to	800MHz to 2,5GHz
of transmitter	d=1.2×P1/2	800MHz	d=2.3×P1/2
W		d=1.2×P1/2	
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.

15. Statement

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ZMN/WI-09-420 V1.0-20190413