

Please read this manual before operating

MiniS Curing light Instruction Manual



GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.
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1. Instruction

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 including ultrasonic scaler, curing light, micro motor, apex locator and ultrasurgery, etc.

1.2 Principle and Usage

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

1.2.2 This product is used to restore teeth.

1.3 Features

1.3.1 The solidification effect is not affected by the consumption of remaining power.

1.3.2 A full charge can be continuously used for more than 300 times under 10s working time mode.

1.3.3 Ergonomic design, small and convenient.

1.3.4 Special light hood and holder design with high efficiency in filtering light.

2. Structure and Components

MiniS curing light (dentistry) is mainly composed by high power LED, optical fiber, and main unit.

3. Technical Specifications

3.1 Size: 230mm×26mm×30mm

3.2 Net weight: 105g

3.3 Configuration:

Main unit *1

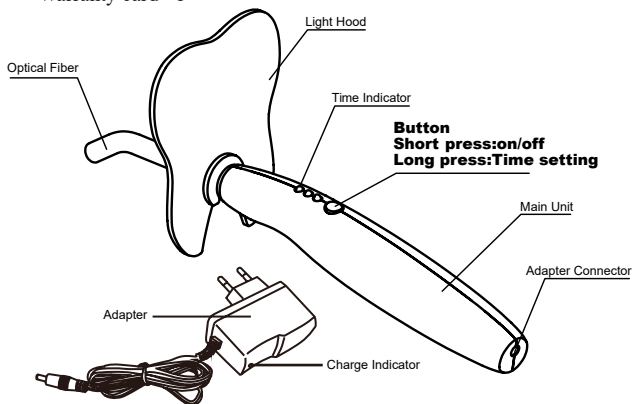
Adapter *1

Optical fiber *1

Light hood *1
Warranty card *1

Instruction book *1

Product certificate *1



Picture 1

Button:

“Short Press” means let go of the button immediately after pressing it, while “Long Press” means keep pressing the button.

3.4 Power Source

3.4.1 Power supply: rechargeable Lithium battery.

3.4.2 Rechargeable Lithium battery.

Battery mode: ICR 18490

Battery voltage and capacity: 3.7V/1400mAh

Battery has protection against Over-voltage, over-current and short circuit.

3.4.3 Adapter (charger)

Power Input: AC100V - 240V, 50Hz/60 Hz

Power Output: DC4.2V/1A

Built-in Fuse: F2AL250V

3.5 LED Light Performance

3.5.1 3W high power blue light LED.

3.5.2 Classes: Class I

3.5.3 AEL: $3.9 \times 10^{-3} \text{J}$

3.5.4 Checking method: the LED light is fine when the light is on during correct operation.

3.5.5 The wave length of this product can match with the clinical dental resin solidification, such as 3M, Dentsply, etc.

3.5.6 Wave length: 440nm-490nm

3.6 Light intensity: 1000mW/cm^2 - 1200mW/cm^2

3.7 Light effective acreage: 50mm^2

3.8 Working condition:

3.8.1 Environment temperature: $+5^\circ\text{C} \sim +40^\circ\text{C}$

3.8.2 Relative humidity: 30%~75%

3.8.3 Atmospheric pressure: 70kPa~106kPa

3.9 Equipment Safety

3.9.1 Operating mode: intermittent operation.

3.9.2 Protection type against electrical shock: class II .

3.9.3 Protection degree against electrical shock: type B.

3.9.4 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0).

3.9.5 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

4. Installation and Uninstallation Method

4.1 Fix the light hood on the bottom of the optical fiber.

4.2 Take off the red cap from the optical fiber, and then insert the straight end into the front part of main unit (make sure to screw the fiber to the end).

4.3 Please do the opposite way when uninstall or change the optical fiber.

5. Operation

5.1 Short press the button to start the curing light.

5.2 Long press the button, then the time indicator will flash in cycles and three time modes are available: 5s, 10s, and 20s.

5.3 During the operation, please aim the light at the solidification-needed point, short press the button and the main unit will produce "Bi" sound, the curing light radiates blue light and starts working according to the set modes. Meanwhile, it starts counting down and it stops working when counting down to "0".

5.4 During the operation, the blue light can be stopped by short pressing the button at any time.

5.5 After a working cycle, operator can short press the button switch to start another working cycle. Stop operating if the equipment began to heat obviously, do not restart until the equipment cool down. Suggest continuous working cycle less than 10 times.

5.6 Low power detect circuit is fixed inside of the main unit, when low power is detected, the display screen of main unit will wink or the buzzer will ring 3 times, please charge in time.

5.7 When the battery needs charging, connect the plug of the adapter into the AC100V-240V power supply. Then connect the output plug of the adapter to the input plug of the main unit. Adapter charge indicator turns yellow means it is charging. When charging is finished, the indicator will turn green.

5.8 When operation is finished, please clean the optical fiber with calico in order not to affect the light intensity.

5.9 This equipment will turn off automatically if there is no action within 2 minutes, turn it on by pressing any button.

5.10 The depth of solidification of composite is no less than 4mm per 10 seconds.

5.11 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 (even the curing light works less than 20s, it is counted as a full operation), then it will come into over-heat protection status. And only after 2-minute sleep, it can restart working 200s continuously.

Notice: Before operation, the optical fiber must be rotated and stuck into the bottom, in case the optical fiber falls down.

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 ENISO 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 $\geq 90^{\circ}\text{C}$, time ≥ 5 min or $A0 \geq 3000$.

(d2) Sterilize it after disinfection and use: temperature $\geq 90^{\circ}\text{C}$, time ≥ 1 min or $A0 \geq 600$.

(d3) For the disinfection here, the temperature is 93°C , the time is 2.5 min, and $A0 > 3000$.

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 Please charge the battery at least 4 hours before first time usage.

7.2 When fixing the optical fiber, revolve it to the bottom to avoid the decline of light intensity.

7.3 Optical fiber is fragile, so it is forbidden to beat, crush or drop.

7.4 During operation, the blue light should be aimed straightly at the composite resin to ensure the effect of solidification.

7.5 Avoid aiming the blue light at eyes directly. Please use the original light hood or special curing light glasses to protect eyes.

7.6 Please use the power adapter and lithium battery which is designed and supplied by our company. It may cause dangers to operator and patient by using the power adapter and lithium battery which is designed and supplied by other manufacturers.

7.7 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 battery short circuit.

7.8 Please recharge the battery in cool and ventilated room.

7.9 It is forbidden to personally take apart the battery, in order not to cause short- circuit or leakage.

7.10 It is forbidden to extrude, shake or rock the battery. The Li-ion battery is forbidden to be in short circuit situation and it is forbidden to place the battery with metal or other conductors.

8. Contraindication

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

9. Daily Maintenance

9.1 This equipment does not include the self-maintenance parts, so it should be performed by professional or special maintenance shop.

9.2 Users can change the light hood and optical fiber on-site. Please use accessory which is designed and supplied by our company, contact 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.

9.3 The optical fiber should be sterilized for 4 minutes with 134℃ and 2.0bar~2.3bar (0.20MPa~0.23MPa) before each use, other parts should be cleaned by clean water or neutral sterilized liquid, but do not soak the equipment in the water. Do not clean by volatile or soluble liquid, otherwise the marks of the control panel will fade.

9.4 Please clean the optical fiber to avoid remaining resin left on the surface and affecting solidification effectiveness and lifespan.

10. Troubleshooting

Faulty	Possible cause	Solutions
No indication, no response	1. Battery is out of power 2. Faulty of battery 3. Short circuit of charging port, battery enters the state of protection	1. Charge the equipment 2. Send to after-service to change a new battery 3. Plug the adapter to activate the battery
Indicator flickers	1. Low battery 2. Faulty of the main unit	1. Charge the battery 2. Send to the after-service

Faulty	Possible cause	Solutions
Light intensity is weak	1. Optical fiber is not fixed to the bottom 2. There is resin on the top of the optical fiber. 3. Low battery 4. Faulty of the main unit	1. Fix the optical fiber to the bottom 2. Clean the resin 3. Charge the battery 4. Send to the after-service
Not charging when the adapter is connected	1. The adapter is not connected well 2. Faulty of adapter or incompatible	1. Reconnect 2. Change the adapter
Effective duration of the battery become short	The capacity of the battery decreased	Send to after-sales Service for change a new battery

If the problem still can't be solved, please contact the local dealer or manufacturer.

11. Storage and Transportation

11.1 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.

11.2 Don't store the machine together with the 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 Excessive impact or shake should be prevented during

transportation, lay it carefully and do not invert it.

11.5 Don't put it together with dangerous goods during transportation.

11.6 Avoid solarization and getting wet in rain or snow during transportation.

12. After-sales 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.

13. Environment Protection

Please dispose according to the local laws.

14. Symbol Instruction



Caution! Consult the accompanying documents

5S

5-second time symbol

10S

10-second time symbol

20S

20-second time symbol



Short press: on/off

Long press: time setting



Date of manufacture



Manufacturer



Class II equipment



Type B applied part

IPX0

Ordinary equipment



Used indoor only



Appliance compliance WEEE directive



Atmospheric pressure for storage



Temperature limitation for storage



Humidity limitation for storage

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

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