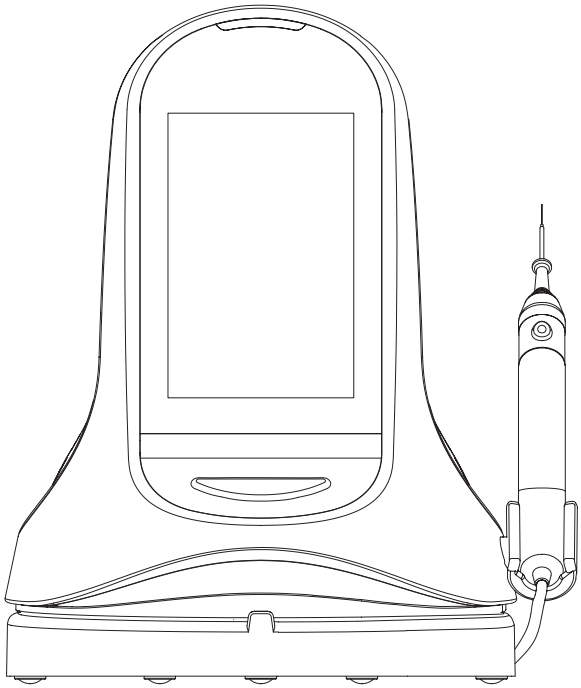
CE 0197

INSTRUCTIONS FOR USE

Dental Diode Laser Device

Please read this IFU carefully before using the device for the first time
ZMN-SM-227 V2.8-20251107



Guilin Woodpecker Medical Instrument Co., Ltd.

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Dear Customer:

Thank you for choosing LX 16 Plus Diode Laser Device manufactured by Guilin Woodpecker Medical Instrument Co., Ltd.
Woodpecker is a company specializing in the development, production, and sales of dental devices. We have established a comprehensive quality control system. To ensure the correct and safe use of the device, please read this IFU carefully before use.

1 Product Introduction

1.1 Introduction

The LX 16 Plus Diode Laser Therapy Device is intended for use in medical institutions for the vaporization of oral mucosa and gingiva, as well as for soft tissue incision and gingivectomy in the oral cavity.
Features:
a) Equipped with a capacitive touch screen which has clear display and is easy to operate.
b) Built-in high-capacity rechargeable lithium battery with long-lasting of endurance.
c) The fiber tip can be autoclaved.
d) Preset more than 35 treatment procedures to reduce the difficulty of use.
e) Auto-standby and auto-shutdown functions: The device enters standby mode after 10 minutes of inactivity, and powers off automatically after an additional 10 minutes without operation.

1.2 Model

LX 16 Plus

1.3 Configuration

Please refer to the Packing List.

1.4 Structures and components

The Dental Diode Laser Device primarily consists of the following components:
Main unit, Handpiece(including handpiece sleeve), Fiber tips, Physiotherapy stick, Power adapter and a Foot pedal, etc.

1.5 Scope of application

1.5.1 Intended use
The Dental Diode Laser Device is developed as a table top laser device for:
• (976nm and 450nm) : Intra-oral and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue.
• (650nm and 976nm): Low level laser therapy (LLLT): To emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and

joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

1.5.2 Indications

The Dental Diode Laser Device is developed as a table top laser device for the following Indications:

• (976nm and 450nm) : All situations that require intraoral and extraoral soft tissue cutting, including: Marginal and inter-dental and epithelial lining of free gingiva (frenectomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

• (650nm and 976nm):Low Level Laser Therapy: Muscle spasms and joint pain.

1.5.3 Intended user: Professional dentists.

1.5.4 Benefit

Based on the information of the state of the art, The Dental Diode Laser Device have the following benefit:

- Used in oral soft tissue treatment to promote healing, control bleeding, stimulate dentin formation and protect pulp vitality.
- Laser treatment is safe and good for soft tissue removal, incision or ablation.
- It effectively assists in the treatment of periodontitis and has excellent ability to sterilize and prevent infection.
- Reduction of dental pulp bacteria.
- Reduces swelling, pain.

1.5.5 Intended patients

All patients coming to a dental office or clinic and needing a treatment that can be done or supported by the use of a diode laser can be treated with the Dental Diode Laser Device except for Contraindication.

1.6 Contraindications

All clinical procedures performed with Dental Diode Laser Device must be subjected to the same clinical judgment and care used with traditional

techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment and exercise caution for general medical conditions that might contraindicate a local procedure; such conditions may include, but are not limited to, allergy to local or topical anesthetics, heart disease (including pacemakers and implantable defibrillators), lung disease, bleeding disorders, sleep apnea, an immune system deficiency, or any medical conditions or medications that may contraindicate the use of certain light/laser-type sources associated with this device, including general neurovascular conditions which can reduce a patient's pain sensitivity while undergoing pain therapy procedures (e.g., patients with neurodegeneration associated with Type II diabetes). Medical clearance from the patient's physician is advisable when doubt exists regarding treatment. Moreover, patients suffering from photodermatoses must not be treated as well as photosensitized patients (Photoallergy).

1.7 Side-effect

High power settings can possibly lead to pronounced carbonization of the tissue margins, Burns caused during laser treatment.

1.8 Device safety classification

1.8.1 Classified by operation mode: Continuous operation
1.8.2 Type of protection against electric shock: For charging, it is Class I device;
For working, the dental diode Laser Device is internally powered ME equipment.
1.8.3 Degree of protection against electric shock: B type applied part (Applied part:fiber tip ,Physiotherapy stick).
1.8.4 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0), not waterproof
1.8.5 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.9 Main technical parameters

1.9.1 Power adapter input: 100-240VAC, 50/60Hz, 2.5A Max
1.9.2 Main unit input: 15V 6.0A Max
1.9.3 Wavelength and power:
a) 976± 20nm:
0.2W-4W(CW), Peak Power 7W;
chopped 1Hz to 20kHz
chopped mode: 5μs – 0.9s
b) 650± 20nm:
25mW-200mW(CW);
c) 450± 20nm:

0.2W-3W(CW), Peak Power 4W;
chopped 1Hz to 20kHz
chopped mode: 5μs – 0.9s
1.9.4 Laser classification:
a) 976 nm: Class 4;
b) 650 nm: Class 2;
c) 450 nm: Class 4;
Aiming beam: 650 ± 20 nm / Pmax<5mW (class 1)
1.9.5 Aiming beam:
650 ± 20 nm /Pmax<5mW
1.9.6 Divergence:12.7°
(According to IEC 60825-1: 2014)
1.9.7 Rechargeable battery:11.1V/2600mAh × 2 (57.7Wh)
1.9.8 Time consumption for charging: about 4h (5 hours for first charging)
1.9.9 Diverging half angle: 0.22 rad/ 12.6 °
1.9.10 Size (length × width × height): 19cm × 21cm × 23cm
1.9.11 Weight(Main Unit): 1.6kg

1.10 Operation circumstance

1.10.1 Temperature: +5℃ ~ +40℃
1.10.2 Humidity: 30% ~ 75%
1.10.3 Air pressure: 70kPa ~ 106kPa

2 Installation and functions

2.1 Schematic diagram of the whole machine, components and control buttons.

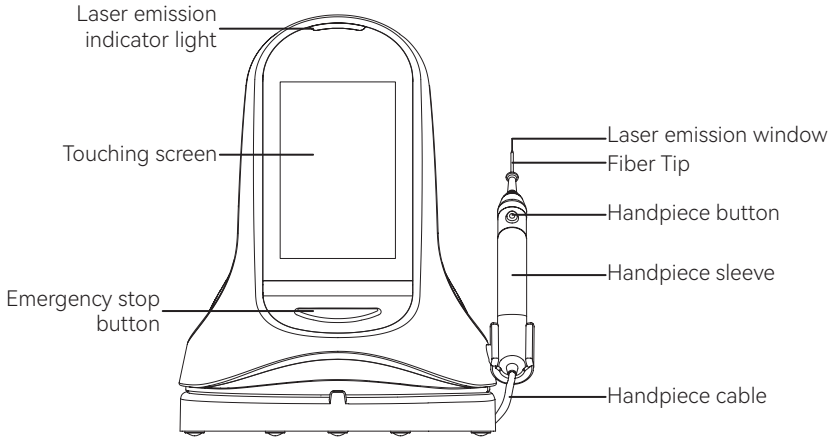


Figure 1: Front view of device

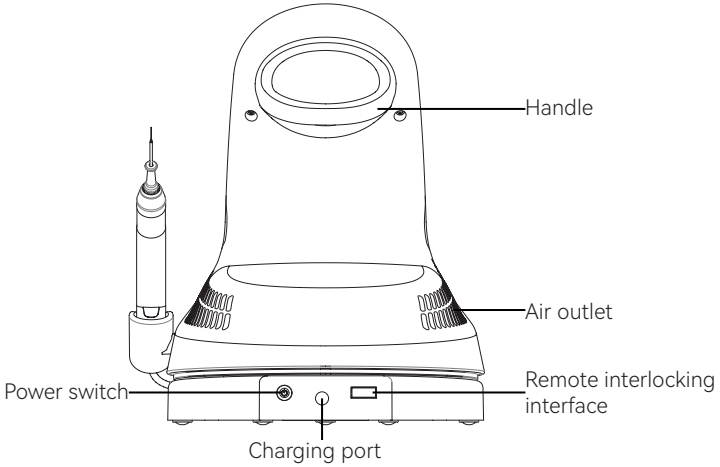


Figure 2: Rear view of the device

2.2 Installation of accessories

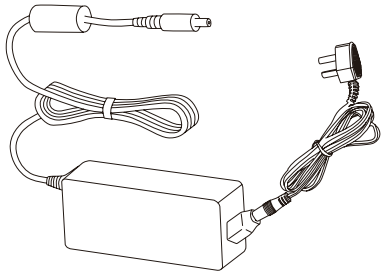
2.2.1 Installation area

Remove all parts from the box, taking care not to drop or damage the unit. Install the device in the area to be used. Note that there should be enough space around the device to make the fiber handpiece wire have a large bending diameter to prevent breakage. At the same time, do not have other items to block the air outlet on the side of the device.

2.2.2 Installation of power adapter

Take out the power adapter and power supply cable from package and connect them as shown in the picture.

[Note] Only the power adapter and power supply cable coming with the device can be used.


Figure 3: Assembly diagram of power adapter and power supply cable

2.2.3 Installation and removal of dust proof plug

Remove the dustproof plug on the handpiece counterclockwise as shown in Figure 5.

Tighten the dustproof plug clockwise as shown in Figure 6.

[Note] When the device is not in use, the dustproof plug should be tightened to prevent dust from entering the tip of the handpiece to contaminate the lens.

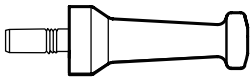


Figure 4: Dustproof plug

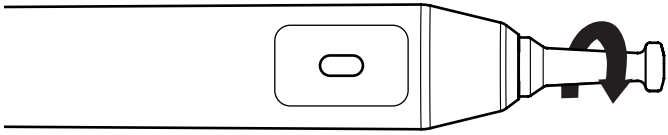


Figure 5: Dustproof plug removal diagram

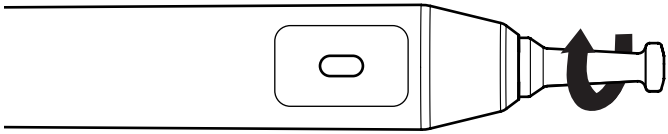


Figure 6: Dustproof plug assembly diagram

2.2.4 Installation and removal of handpiece sleeve

The handpiece sleeve of the device is replaceable. The installation can be completed by carefully inserting the sleeve into the handpiece as shown in Figure 7; when disassembling, please press the handpiece switch to pull out the sleeve as shown in Figure 8.

[Note] handpiece sleeve be cleaned, disinfected and sterilized before use.

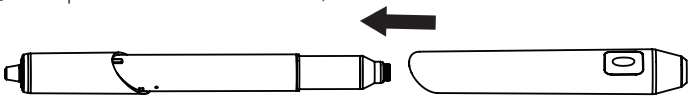


Figure 7: Installation diagram of handpiece sleeve

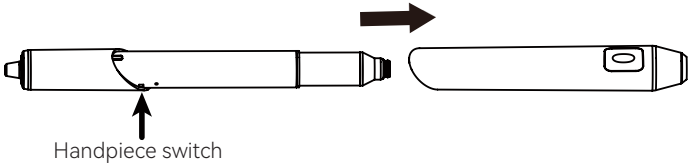


Figure 8: Removal diagram of handpiece sleeve

2.2.5 Assembly and removal of fiber tip

Take out the required fiber tip, remove the dust cap on the fiber tip, and then install it on the handpiece. When installing, insert the threaded end of the fiber tip into the handpiece, and then tighten it by rotating it clockwise, as shown in Figure 9. When removing, just rotate it counterclockwise, as shown in Figure 10. After removing the fiber tip, please install the dustproof plug according to the method in Section 2.2.3.

[Note] The fiber tip must be cleaned, disinfected and sterilized before use. When installing and removing the fiber tip, keep the end face of the threaded end clean, and do not touch the fiber end face of the threaded end of the fiber tip.
[Note] Before installing the fiber tip on the handpiece, use a clean and dry soft cloth to wipe the outer surface of the threaded connection end and the incident light end face of the fiber. Make sure that the section inserted into the handpiece is clean, dry and free of dirt, otherwise it may contaminate the optical lens inside the handpiece and affect its transmission efficiency.

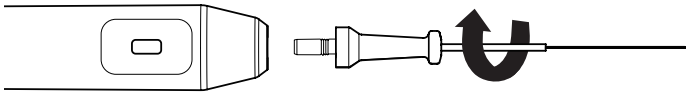


Figure 9: Fiber tip assembly diagram

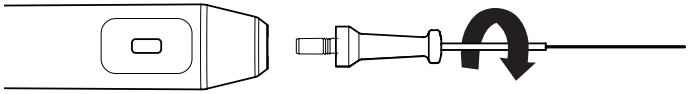


Figure 10: Fiber tip removal diagram

2.2.6 Installation and removal of tips
Select the appropriate tip, rotate it in a clockwise direction to install, and rotate it in a counterclockwise direction to remove as shown in Figure 11. Please remove the tip and place it properly after the treatment is completed. After removing the tip, install the dustproof plug according to the method in section 2.2.3.
[Note] When installing and removing the physiotherapy tip and the biostimulation tip, please keep the outer surface of the threaded end of the work tip clean. And before each installation and use, use a clean soft cloth to wipe the incident light end face and the outer surface of the threaded end to avoid dust, water stains, etc. from entering the handpiece hole to contaminate the internal optical lens.

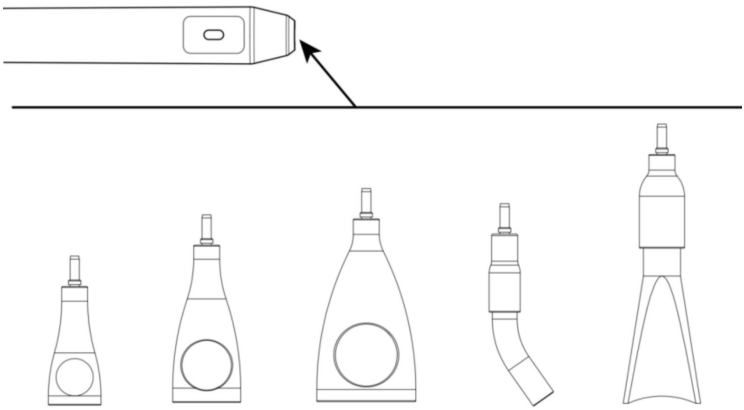


Figure 11: Installation diagram of work tip

2.2.7 Storage of handpiece tail cord

The handpiece tail cord of this device contains extremely fine glass fiber which is easy to break. Do not bend the cord greatly during use and avoid it from being squeezed by other objects. Therefore, please be careful to store the cord as shown in Figure 12 when the device is not in use.

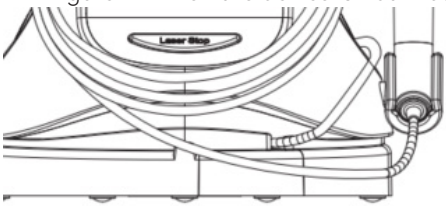


Figure 12: Diagram of handpiece tail cord storage

2.2.8 Installation of remote control interlock

Remote interlocking is a safety device that terminates laser radiation whenever the door of the treatment room is opened. This device must be used with the remote interlock, install the corresponding control switch K on the door of the room, and connect the two control cables of the control switch to the "A" and "B" ports of the remote control interlock. As shown in Figure 13, when the control switch K is short-circuited, this device works normally, and this device will be prohibited from emitting laser light when the control switch K is open. Remote interlocking can work when plugging the USB into the USB port of this device as shown in Figure 14.

[Note] The installation of the remote control interlock must be completed by a qualified electrician who is responsible for the installation and maintenance of the electrical system to which the equipment is connected.

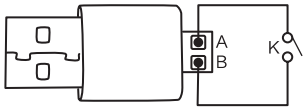


Figure 13: Wiring diagram of remote control interlock

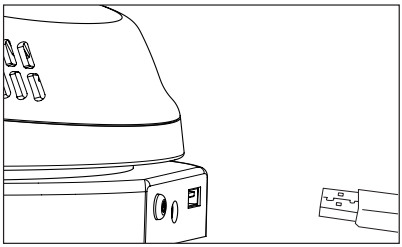


Figure 14: Installation diagram of remote control interlock

3 Operation

3.1 Power on and off

As shown in Figure 15, long press the "⏻" button on the back of the device to turn it on, then enter the power-on password (the initial power-on password is "8888") on the display screen, and click OK to enter the operation interface of the device, as shown in Figure 16.

To turn off the device, short press the "⏻" button.

[Note] Both the fixed power-on password "6363" and the initial power-on password "8888" can turn on the device, and the initial power-on password can be modified in the setting interface; the fixed power-on password cannot be modified.

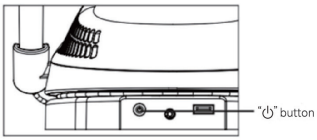


Figure 15: Standby button diagram

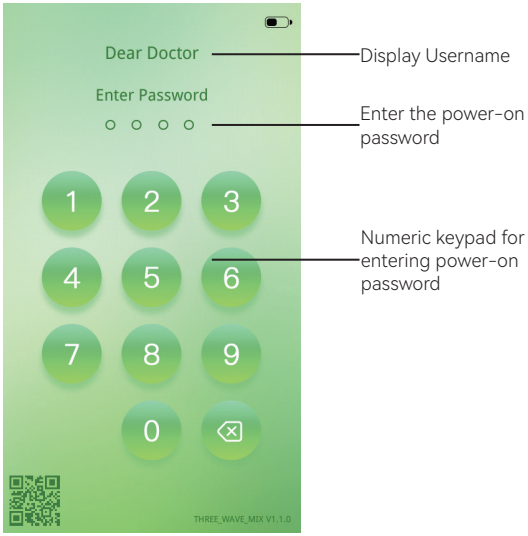


Figure 16: Diagram of the password input interface after powering on

3.2 Parameter adjustment

This device can adjust and set Peak power, Frequency, Duty cycle, Time parameters, and automatically calculate the effective power, as shown in Figure 17.

The adjustable range of machine parameters is shown in the table below:

Wavelength	Waveform	Peak power	Duty cycle	Frequency
450nm	Continuous output (CW)	0.2-3W	100%	0
	Repeated pulse output (QCW)	0.2-4W	10-90%	1-20000Hz
650nm	Continuous output (CW)	25-200mW	100%	0
976nm	Continuous output (CW)	0.2-4W	100%	0
	Repeated pulse output (QCW)	0.2-7W	10-90%	1-20000Hz

[Note] Continuous output (CW) mode is continuous mode. In this mode, the Frequency and Duty cycle are fixed values, and only the “Peak power” and “Time” parameters can be adjusted.

[Note] Repeated pulse output (QCW) mode is pulse mode. In this mode, the “Peak power”, “Frequency”, “Duty cycle” and “Time” parameters can be adjusted.

[Note] The switching method between continuous output (CW) mode and repeated pulse output (QCW) mode is as follows:

When the “CW” button in the parameter interface is selected, it is continuous output (CW) mode; when the “QCW” button in the parameter interface is selected, it is repeated pulse output (QCW) mode.

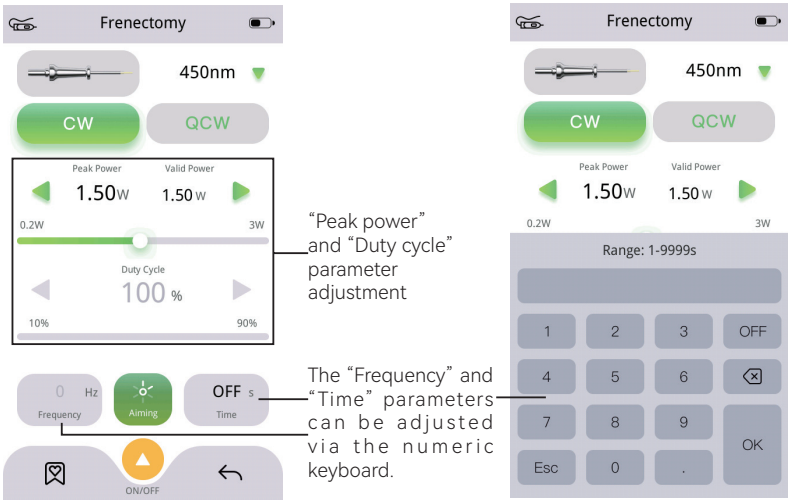


Figure 17: Schematic diagram of parameter adjustment interface

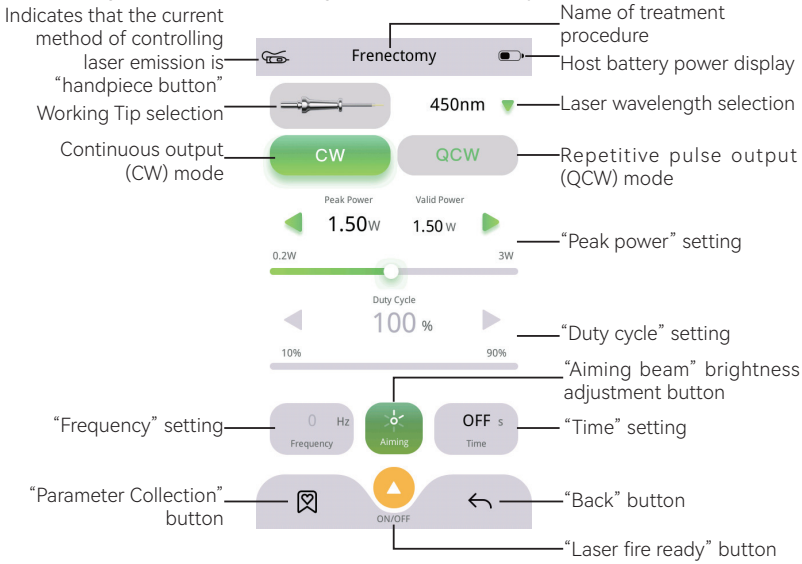


Figure 18: Schematic diagram of treatment operation interface and aiming light adjustment

3.3 Aiming beam adjustment

The aiming beam is a red beam with a wavelength of 650nm and a maximum power of less than 5mW. Its brightness is adjusted by the aiming beam button. Each click of the aiming beam button switches to a brightness

level. The brightness of the aiming beam can be adjusted as needed, as shown in Figure 18.

3.4 Laser emission preparation

Click the “ON/OFF” button on the screen to prepare for laser emission. The device will prompt you to put on protective glasses. After putting them on, please click the “Yes” button; then enter the laser emission preparation state. At this time, the “ON/OFF” button displays green, and the indicator light at the top of the host screen displays green, as shown in Figure 19.
[Note] The laser emission can only be controlled by the handpiece button or foot switch when the laser is ready to be emitted.
[Note] The laser parameters cannot be adjusted when the laser is ready to be emitted, but the brightness of the aiming beam can be adjusted.
[Note] The aiming beam will emit red light only when the laser is ready to be emitted;

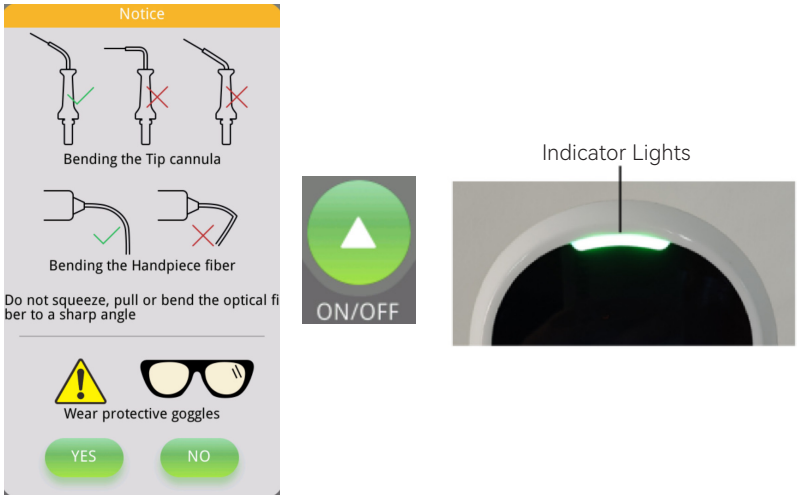


Figure 19: Schematic diagram of reminder to wear protective glasses, laser emission preparation status, and green indicator light

3.5 Check of laser emission aiming beam

When the laser is ready to be emitted, the tip of the optical fiber working tip will emit a red aiming spot, as shown in Figure 20. This method can be used to detect whether the optical path transmission system is normal. It is recommended to perform this check before each treatment.
[Note] Please use a brand new fiber optic working tip. When the red aiming spot is a uniform circle at a distance of about 8cm from the white paper, it means that the optical transmission system of this device is normal. Otherwise, please refer to Chapter 5 “Troubleshooting” of the IFU to find the cause.

[Note] When performing the aiming light inspection, please wear laser protective glasses according to the method in Chapter 3.13 to prevent laser emission from damaging the eyes due to misoperation. It is strictly forbidden to aim the laser at the human eye.

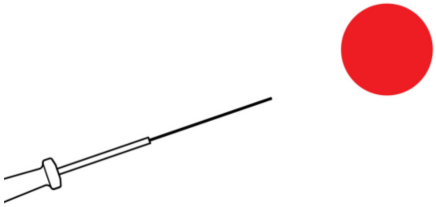


Figure 20: Schematic diagram of red aiming aura

3.6 Wireless Footswitch

If the product you purchased is equipped with a foot switch, please read the following content about the use of the foot switch carefully.

(a). Check before use

Before use, please take out the host and foot switch to check for defects. The foot switch of this product is a wireless foot pedal, as shown in Figure 21. The wireless foot pedal consists of a protective cover ①, a foot pedal ②, a charging port ③, an indicator light ④ and a pair button ⑤.



Figure 21: Schematic diagram of foot switch

Turning on the pedal: Press the pedal once to turn it on.

Turning off the pedal: The pedal will automatically turn off after 10 minutes of inactivity.

Press the protective cover to uncover it and then press the pedal to observe the indicator light:

(1) Fast flashing green: indicates that the footswitch is pressed down;

(2) Slow flashing green: indicates that the footswitch is in standby;

(3) Not on: indicates that the footswitch needs to be charged.

(b). Foot Switch Charging

The main unit and the foot switch share a single power adapter. When charging, first remove the waterproof silicone plug from the charging port (located next to the indicator light), then connect the charger.

(1) Steady Orange: The battery is charging.

(2) Steady Green: The battery is fully charged.

(3) Orange-green alternating indicator light: The battery is damaged and

should be replaced promptly.
(c). Switching to Foot Switch Control Mode
The main unit supports two control modes: foot switch control and handpiece button control. You can identify the current control mode by checking the icon displayed at the top of the main unit screen:



Figure 22: Indicates the unit is in handpiece button control mode



Figure 23: Indicates the unit is in foot switch control mode

On the main unit operation interface, tap the handpiece or foot switch icon located at the top-left corner of the screen, or go to “Settings” button ( )---Control Mode Switching to access the control mode interface (see Figure 24).
The icon ( ) indicates handpiece button control mode.
The icon ( ) indicates foot switch control mode.
Tap the icon to switch control modes.
[Note] When the main unit is in foot switch control mode, a battery icon ( )appears under the foot switch icon in the top-left corner of the screen, the battery icon shows the battery level of the foot switch. If the battery icon appears as ( ), it indicates a low battery level in the foot switch and charging is required.
(d). Foot Switch Pairing
If the foot switch icon appears as ( ), it indicates that the foot switch is not successfully connected to the main unit. Possible reasons include:

- The foot switch is not powered on
- The battery level is too low.

If the foot switch is turned on but still fails to connect automatically (i.e., the icon remains as ( ), manual pairing with the main unit is required. The steps are as follows:
(1) Switch the control mode of the main unit to foot switch control.
(2) On the foot switch settings interface, tap the “Pair” button (see Figure 24).

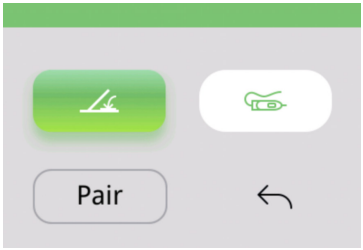


Figure 24: Foot Switch Pairing Interface

(3) Once the screen displays “Pairing…”, press the pedal once to ensure the foot switch is powered on. Then press the “Pair” button located at the bottom of the foot switch.

• If the screen shows “Pairing Successful”, the foot switch has been successfully paired with the main unit.

• If not, a “Pairing Failed” message will appear.

[Note] For optimal performance, keep the wireless foot switch within 2m of the main unit and avoid any obstructions between them during use.

3.7 Laser Emission

When the laser is in ready mode, pressing and holding the laser emission button on the handpiece or stepping on the foot switch pedal will initiate laser emission. During emission, the main unit will emit an audible signal, and the indicator light at the top of the screen will flash alternately green and blue, as shown in Figure 25. At the same time, the “Time” field in the parameter interface will begin a countdown display. Once the countdown finishes, the laser emission will automatically stop.

[Note] When the “Time” field is set to and displays “OFF”, the countdown function is disabled.



Figure 25: Laser Emission Button on Handpiece and Indicator Light on Main Unit

3.8 Stopping Laser Emission

Laser emission can be stopped through any of the following actions (see Figure 26):

• Releasing the laser emission button on the handpiece;
• Releasing the foot switch;
• Pressing the red Emergency Stop button on the main unit;
• Pressing the laser ready “ON/OFF” button on the main interface;
• The countdown of “Time” on the parameter interface ends.

To prevent overheating damage to the laser system, the device will

automatically stop laser emission if the internal temperature of the laser module exceeds 55℃. During laser emission, the aiming beam should be continuously monitored to ensure proper functioning of the optical path. If any abnormality in the aiming beam is detected, laser emission should be stopped immediately.
[Note]When the internal temperature of the laser exceeds 55℃, a pop-up warning will appear indicating high temperature, and laser emission will be automatically stopped.



Figure 26: Emergency Stop Button

3.9 Renaming a Custom Program

To rename a custom program, tap the system default program name displayed at the center top of the screen. An on-screen keyboard will automatically appear. After entering the desired name, tap the “Enter” key to confirm, as shown in Figure 27.

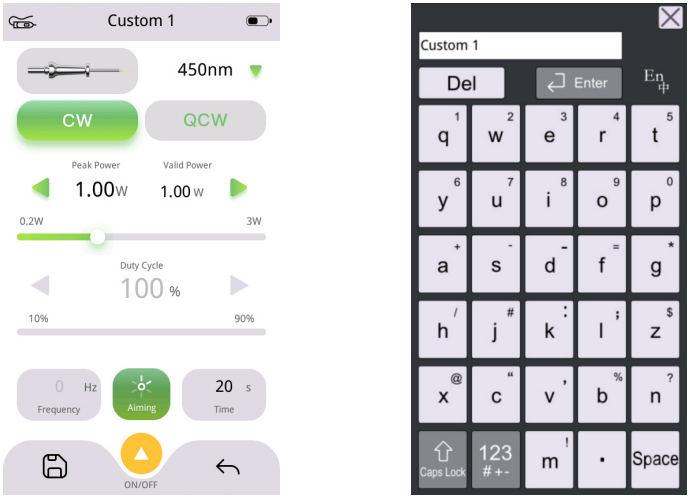


Figure 27: Custom Program Renaming Interface

3.10 Parameter Setting and Saving for Custom Programs

To modify and save parameters for a custom program, tap the parameter to be adjusted. After setting the desired values, tap the “Parameter saving” button. A confirmation message will appear:
“Whether to save?”

Tap “Yes” to confirm and save the parameters or tap “No” to cancel and return without saving (see Figure 28).

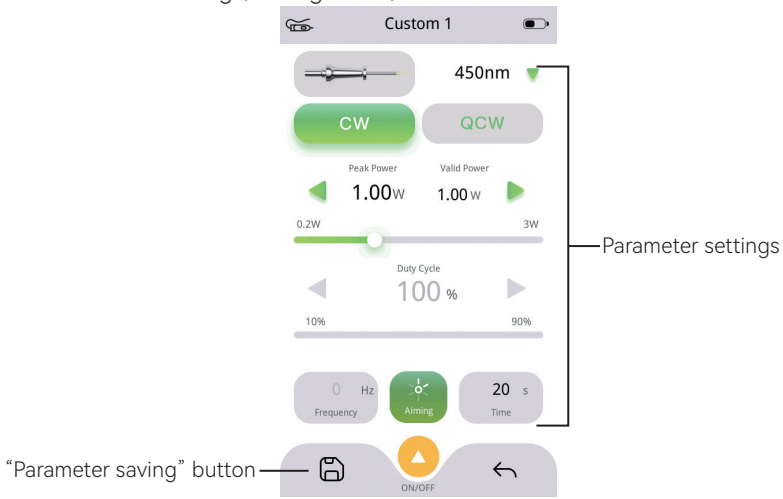


Figure 28: Parameter Setting and Saving for Custom Programs

3.11 Settings Menu Functions

Tap the Settings icon ( ) on the screen to enter the system settings menu, as shown in Figure 29.

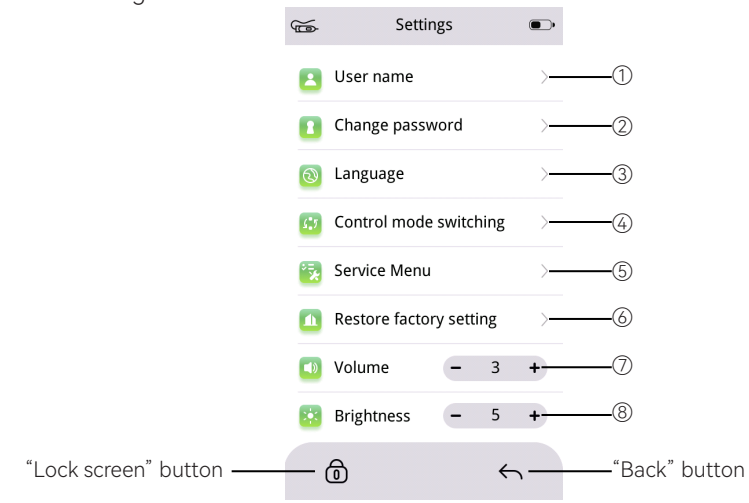


Figure 29: Settings Menu Interface

Descriptions of each setting item are listed below:

No.	Items	Descriptions
①	User name	Set the name or designation of the device user.
②	Change Password	Change the power-on password. It must be a 4-digit number not starting with “0”. The system saves the new password automatically.
③	Language	Set the system menu language.
④	Control Mode Switching	Switch the laser emission control mode between handpiece and foot switch.
⑤	Maintenance Menu	Accessible only by the manufacturer. A 6-digit password is required to prevent accidental access.
⑥	Restore Factory Settings	Restore factory default settings. All user data will be erased. Use with caution.
⑦	Volume	Adjust the volume by pressing “+” or “−”. The system saves changes automatically.
⑧	Brightness	Adjust the screen brightness using “+” or “−”. The system saves changes automatically.

3.12 Charging

Connect the original power adapter to charge the device.
a) When the device is powered off:
A battery icon will appear at the center of the screen (see Figure 30). When charging is complete, the icon will display a full charge level.
b) When the device is powered on:
A battery icon is shown at the top-right corner of the screen (see Figure 31). When fully charged, the icon turns solid green and displays “100” inside.



Figure 30: Charging Display When Powered Off



Figure 31: Charging Display When Powered On

3.13 Wearing Laser Protective Goggles

During operation, all personnel in the treatment room (including the dentist, assistant, and patient) must wear the manufacturer-provided protective goggles. Unauthorized personnel must leave the treatment room (see Figure 32). The use of non-manufacturer goggles is strictly prohibited.
[Note] The 450 nm and 650 nm lasers are visible; 976 nm is invisible. All

personnel in the treatment room must wear protective goggles regardless of the laser wavelength being used. Additionally, treatment room doors and windows must be kept closed to prevent accidental laser leakage.
[Note] Protective goggles only protect against diffuse reflection. Even while wearing protective goggles, never point the fiber tip or handpiece directly at the eyes.
[Note] Do not observe along the laser optical path or place the protective goggles in the laser optical path.
[Note] Do not clean lenses with alcohol, alkaline solutions, or other organic solvents, otherwise the protective ability will be reduced. Only use a clean soft cloth or clean water to clean them.
[Note] When properly maintained, the protective goggles can be used for up to 3 years. It depends on the user's maintenance, such as cleaning, storage method, etc. Please replace laser protective goggles regularly.
[Note] Always inspect protective goggles before use. If lenses are damaged, scratched, or discolored, immediately discontinue use and replace them with new manufacturer-provided protective goggles (identical to the original goggles).
[Note] These protective goggles are intended only for protection against the laser emitted by this device. They are not suitable for protection from other lasers or for use as sunglasses.

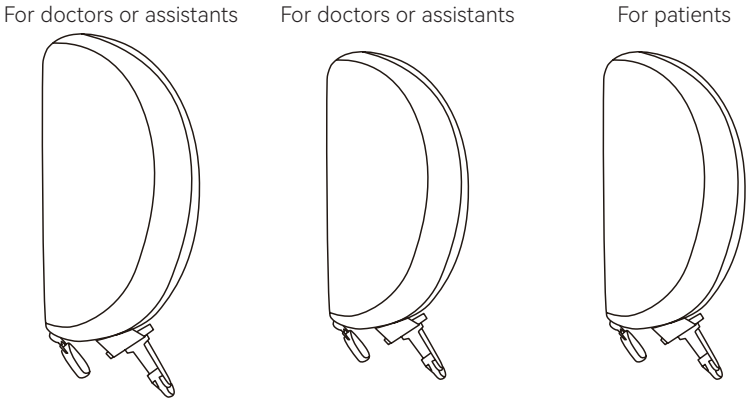


Figure 32: Proper Wearing Protective Goggles

3.14 Cutting the Fiber

Fiber cutting is required in the following cases:
① During soft tissue cutting, tissue may cover the fiber end, reducing cutting efficiency. In such cases, the contaminants should be removed using saline-soaked gauze. If cleaning fails, cut off the contaminated portion of the fiber.
② Before irradiation treatment, the fiber should be trimmed to ensure that

the end surface is clean and flat, confirming that the fiber end has not been activated.

③ If the fiber end is heavily charred, the charred section must be removed to maintain laser emission efficiency.

Fiber Cutting Method:

Use the fiber cutting pen to gently score the fiber surface. Then apply moderate force to break it at the scored line, creating a clean, flat fiber end (see Figure 33). Dispose of the removed fiber segment in a designated sharps container. Check the aiming beam for light spot (see section 3.5 for details).

[Note] Do not cut the fiber directly using the fiber cutting pen or scissors, as it may damage the fiber cutting surface and reduce laser emission efficiency.

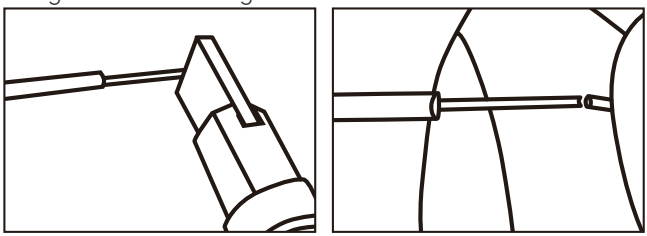


Figure 33: Fiber Cutting Process

3.15 Fiber Tip Activation

Before soft tissue cutting using 976 nm wavelength, the fiber tip must be activated (see Figure 34). Use a dark fiber optic activation paper (or dark articulating paper). Set the device to: Wavelength: 976 nm, Mode: Continuous, Peak Power: 1W.

Wear laser protective goggles, emit laser, and gently slide the fiber tip on the activation paper 3-5 times to carbonize (turn black) the fiber tip before use.

[Note] Activation is required only for soft tissue cutting using 976 nm wavelength.

[Note] When using the 976 nm wavelength for irradiation treatments, the fiber tip must not be activated. The tip end surface should be kept clean and flat at all times. If any contaminants are observed on the fiber tip during use, they should be removed promptly using saline-soaked gauze. If the contaminants cannot be removed or if the tip has already been activated, the contaminated portion should be cut off following the procedure in Section 3.14, or the tip should be replaced with a new, non-activated one.

[Note] When using the 450nm wavelength for treatment, it is not necessary to activate the fiber tip.

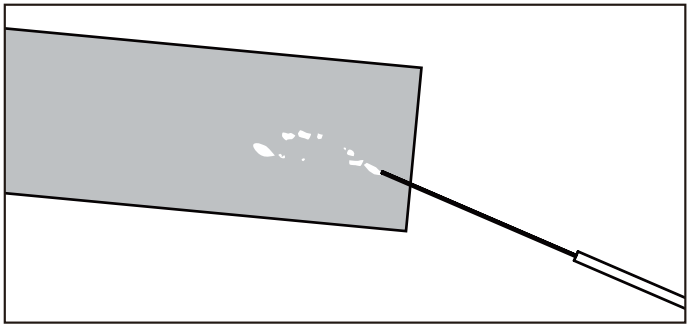


Figure 34: Fiber Tip Activation Process

4 Precautions

4.1 The device should be kept clean before and after use.
4.2 Please check whether the aiming beam output of this device is normal before each clinical operation, As the AIMING BEAM passes down the same delivery system as the WORKING BEAM, it provides a good means of checking the integrity of the delivery system. If the AIMING BEAM is not present at the distal end of the BEAM DELIVERY SYSTEM, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning BEAM DELIVERY SYSTEM.
4.3 All personnel in the treatment room such as doctors, assistants, and patients must wear laser goggles. Do not look directly into the laser during use; lasers may cause harm when human skin or other objects are exposed to it at close range.
4.4 Product operation must comply with the relevant medical and operational regulations and relevant regulations, and should only be used by trained doctors or technicians.
4.5 Do not pull or sharply bend the tail wire during the use of the device to avoid damage to the tail wire.
4.6 Do not hit or scratch the handpiece.
4.7 After operation, turn off the power and unplug the power cord.
4.8 Our company is specialized in the production of medical devices, only when the maintenance, repair and modification of this equipment is operated by our company or our authorized dealers, and the replacement parts are woodpecker brand accessories and the replacement is operated according to the instruction IFU, we are responsible for the security.
4.9 When laser treatment is performed, it may cause surgical damage, minor burns and minor pain. With the correct use of Semiconductor laser therapy device, the comprehensive benefits outweigh the risks, and the risks are acceptable.
4.10 Do not use the Semiconductor Laser Therapy device in an environment that is not conducive to the operation of electrical equipment, such as near

heat sources, near magnetic fields, near precision instruments, and unstable voltage environments.

4.11 During soft tissue cutting, the temperature at the fiber tip may exceed several hundred degrees Celsius. Therefore, the fiber should be moved swiftly and continuously during the cutting process, and should never be held stationary. Cooling measures should be applied to the cutting area, such as intermittently spraying physiological saline, to prevent thermal damage to surrounding soft tissue.

4.12 During laser treatment, adjacent tissues may be irradiated unintentionally. Excessive irradiation can lead to tissue damage. Doctors should set the radiation dose to the lowest possible level and the laser treatment time to the shortest possible duration. They should also move the optical fiber to prevent heat accumulation and heat transfer, thus avoiding damage or even necrosis to bone tissue, dental pulp, etc.

4.13 Optimal laser surgical parameters should be adjusted gradually from low to higher values based on treatment requirements. The energy output directly affects the cutting speed, precision, and potential thermal damage to surrounding tissue.

4.14 The laser beam should be directed only at the intended treatment area during use. Avoid irradiating non-target tissues.

4.15 The laser must not be directed at reflective surfaces, such as mirrors or the smooth surfaces of metal instruments.

4.16 Avoid performing maintenance or inspection while the device is in Laser Ready mode.

If necessary, always wear the provided laser protective goggles. Regardless of whether protective goggles are worn, never look directly into the laser emission port during operation.

5 Troubleshooting

Issue	Possible Cause	Solution
No aiming beam	(1) Aiming beam brightness is set too low (2) Damaged fiber tip	(1) Increase the brightness level (see Section 3.3 of the manual) (2) Replace the fiber tip
Laser cutting failure	(1) Power is set too low (2) Not in standby mode (3) Damaged fiber tip (4) The fiber tip is not activated (for 976nm)	(1) Increase the power (2) Set the laser to the emission standby state. (see Section 3.4 of the manual) (3) Replace the fiber tip (4) Activate the fiber tip (see Section 3.15 of the manual)
Foot switch cannot control the laser	(1) Control mode is not set to foot switch (2) Foot switch is not connected to the main unit	(1) Switch to foot switch control mode (see Section 3.6 of the manual) (2) Re-pair foot switch and main unit (see Section 3.6 of the manual)

If the above troubleshooting steps do not resolve the issue, please contact

your authorized distributor. Do not attempt to open or repair the device yourself, as this may result in electric shock or laser radiation leakage.

6 Cleaning, disinfection and sterilization

The handpiece sleeve(also called handpiece shell), fiber tip, physiotherapy stick of this Dental Diode Laser Device can be reprocessed. The reprocessing steps are as follows:

Product name	Product model
Handpiece Sleeve	LASER APERTURE
Physiotherapy Stick	DT15-Tip, DT20-Tip, DT30-Tip, BT8-Tip
Fiber Tip	MF2-14, MF2-20, MF3-4, MF3-9, MF4-4, MF4-9
Whitening-Tip	Whitening-Tip

Advice:	Reprocessing procedures have only limited implications to this handpiece sleeve, fiber tip, physiotherapy stick. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. It is recommended that you overhaul or replace it after reaching the corresponding number of sterilizations. In case of damage the device should be reprocessed before sending back to the manufacturer for repair or scrapped. handpiece sleeve:500 times; Physiotherapy Stick: 500 times; Fiber Tips: 20 times;
Reprocessing Instructions	
Preparation at the Point of Use:	Disconnect the handpiece sleeve, Physiotherapy Stick . Remove gross soiling of the instrument with cold water (<45℃) immediately after use. Don't use a fixating detergent or hot water (>45℃) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state.
Pre-Cleaning:	Do a IFU pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristol brush.

Cleaning/ Disinfecting and Drying	-Put the handpiece sleeve, Physiotherapy Stick and Fiber Tips in the cleaning basket, and the put into the washer-disinfectors (According to EN ISO 15883-1), and star the automated cleaning and disinfection program: - 4 min pre-washing with cold water (<40℃) - emptying - 5 min washing with a mild cleaner at 55 ℃(0.5% Neodisher MediClean forte as the cleaner) -emptying - 3 min rinsing with warm water (40 ℃) -emptying -5 min intermediate ringing with warm water (40 ℃) -emptying - 5 min disinfection at 93 ℃ - drying Note Acc. to EN ISO 17664 no IFU reprocessing methods are required for these devices. If a IFU reprocessing method has to be used, please validate it prior to use.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Before packaging , make sure that the reusable components has been maintained acc. to manufacturer's instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Steam sterilization parameters: - 3 times pre-vacuum - sterilization temperature : 134 ℃ - holding time: 5 min - drying time: 8min Note :The drying time depends on the actual load in the sterilizer chamber. During the validation study, the drying time was set for 8 minutes. This is sufficient for the test, as the chamber was empty except the test items. In typical loads in hospital, a drying time of 20-40 minutes maybe necessary to get the devices dry after the sterilization.The dry time actually needed will be determined in the validation study performed by the operator.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

[Note] The plastic dustproof cap included with the fiber tip is not

autoclavable and must be removed before sterilization.
[Note] During fiber tip sterilization, ensure the fiber is not bent or crushed by other instruments.

7 Storage, Maintenance, and Transport

7.1 Storage and Maintenance

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.
Do not store the machine together with articles that is poisonous, combustible, caustic, or explosive.
This machine should be stored in a room where the relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa ~ 106kPa, and the temperature is -20℃ ~ +55℃ .
[Note] Do not spray liquid directly onto the device body, as fluid infiltration may cause internal damage.
Clean the surface with a soft cloth dampened with a neutral detergent or non-corrosive disinfectant.
It is recommended to use 75% medical alcohol as the disinfectant.
After cleaning, wipe the surface with a clean and dry soft cloth to keep it dry.
[Note] Do not use alcohol, alkaline solutions, or other organic solvents to clean the lenses of the laser protective goggles.
Lenses must only be cleaned with a lens cloth or clean water. Contact with alcohol or alkaline solvents is strictly prohibited.
The temples and frame of the laser protective goggles may be disinfected with 75% medical alcohol. After wiping, dry immediately with a clean, soft cloth to maintain a dry surface.

7.2 Transport

Excessive impact and shake should be prevented during transport. Lay it carefully and lightly. Avoid placing it upside down.
Do not put it together with dangerous goods during transport.
Avoid being exposed to sun, rain, and snow during transport.

8 Environment protection

The device does not contain any harmful ingredients. It can be disposed or destroyed in accordance with the relevant local regulations.

Part	Toxic or harmful substances or elements					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
Handpiece	○	○	○	○	○	○
Main unit	○	○	○	○	○	○
Power adapter	○	○	○	○	○	○

Tip	○	○	○	○	○	○
Mechanical elements, including bolts, nuts, washers, etc.	○	○	○	○	○	○

○: Indicates that the content of the toxic substance in all homogeneous materials of the part is below the limit requirement stipulated in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.
×: indicates that the content of the toxic substance in at least one of the homogeneous materials of the part exceeds the limit requirement specified in SJ/T-11363-2006.
(This product meets EU RoHS environmental protection requirements; there is currently no mature technology in the world to replace or reduce the content of lead in electronic ceramics, optical glass, steel and copper alloy.)
According to the Administrative Measures on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products and the Regulations on the Management of the Recycling of Waste Electrical and Electronic Products and related standards, please observe the safety and precautions of the products, and after use, please recycle or dispose this product after according to the methods in local laws and regulations

9 Safety Information

In make sure safety, please do as follows.
9.1 In order to avoid the possible danger of overheating/fire or explosion, it is necessary to replace the batteries with trained personnel when maintenance personnel are required to replace batteries;
9.2 Can not be used under maintenance;
9.3 When using an adapter, the product must be placed where it is easy to disconnect the power supply;
9.4 Do not modify this equipment without authorization of the manufacturer.
9.5 There may be fume during the treatment, so it is necessary to prepare dental suction tubes to absorb the produced fume.Laser fume and/or plume may contain viable tissue particulates.
9.6 Under working mode, goggles should be equipped to protect eyes.
9.7 High temperatures produced in normal use of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
9.8 Attention is also drawn to the danger of ignition of endogenous gases. laser equipment should be protected against unauthorized use.
9.9 Information on potential hazards when inserting, sharply bending, or improperly securing the fiber optics, indicating failure to follow manufacturer's recommendations may lead to damage to the fiber or

delivery system and/or harm to the patient or user.Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
9.10 Make sure to check the integrity of the delivery system.
9.11 When the laser wavelength is used, it will increase with the increase of power and ambient temperature, but they are within the range of marked parameters.
9.12 When the device is applied to the patient, the device cannot be maintained.
9.13 At ambient temperature of 40℃, the maximum temperature of the application part of the device can reach approximately 52℃ .
9.14 The time for the device to emit a single laser continuously should be less than one minute.
9.15 When replacing the lithium battery, it should be replaced by an authorized professional or dealer.
9.16 Close the doors and windows of the treatment room during use to prevent accidental laser leakage.
9.17 Clearly mark the laser operation area. Unauthorized personnel must not enter the area during operation. Authorized personnel must wear laser protective goggles before entry.
9.18 Only use the manufacturer-provided power adapter for charging. Using other adapters may damage the lithium battery or control circuitry.
9.19 Do not insert any metal objects or other conductors into the charging port, as this may cause a short circuit and result in severe damage to internal circuits or the lithium battery.
9.20 This device may be affected by electromagnetic interference. Do not use it near electronic surgical equipment, and exercise caution when operating in environments with strong electromagnetic interference.
9.21 To avoid electromagnetic interference, the device must be operated in a medical environment that complies with EMC standards.
9.22 If any abnormal performance is observed during use, immediately stop using the device, power it off, and contact the local distributor or manufacturer for assistance.
9.23 When the battery level falls below the threshold required for normal operation, a pop-up message will appear: “Low battery, please charge.”
At this time, connect the power adapter promptly to ensure normal operation.

10 Calibration

Calibration procedure is recommended to be performed each year so as to maintain the required accuracy of the output power versus displayed power. Annual calibration can be done at a certified depot repair facility. Contact your Authorized Service Representative to schedule an appointment. For calibration the Dental Diode Laser Device ,you can just follow the guidance

below.
Devices: an optical power meter and a detector.
1. To calibrate the Dental Diode Laser Device, an optical power meter is needed. The FieldMaxII-TO with detector PM10 is suitable. They are access from Coherent of the USA.
2. Download the user IFU through the link above and setuo power meter under the guide of its user IFU and place a layout. The distance between fiber end and detector active surface shall be less than 25mm.
3. Detector PM10 shall be used for measurement range from 0-10W.
4. Turn on power meter and set wavelength corresponded to that to be calibrated(650nm for aiming beam, 450nm, 810nm or 980nm for laser working beam), AUTO mode as per its user IFU.
5. To calibrate laser working beam, turn on laser and set the power at 3W, CW mode. Press the switch on the handle to let the laser energy out.
6. Be sure that all red beam is contained into the aperture of detector. Wait for 5 seconds get a steady read and record the data.
7. The reference value of laser power is from 2.4W to 3.6W. If the value read is not in reference range, please clean the fiber. If the read value remains call your distributor or manufacturer.
[Note] Please follow this IFU when operating the laser during the calibration to avoid any hazardous radiation exposure.

11 After-sales service

Since the date of sales, for the device what has quality problem, with Warranty Card, our company is responsible for the repair. Please refer to the Warranty Card for the warranty period and scope. This product does not contain any accessories that can be repaired by users. The device can only be repaired by authorized professional personnel or in authorized repair shop.

12 European authorized representative

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

13 Symbols

	Follow Instructions for Use	LASER APERTURE	LASER APERTURE
	Manufacturer		Date of manufacture
	B type applied part		Use indoor only

SN	Product serial number		Products comply with WEEE directive
IPX0	Ordinary equipment	15.0V ⎓ 6.0A	15V 6A Direct current input
	Power switch		Avoid exposed to rain
	“ON”/“OFF” (push button)	93% 10%	Humidity limitation for storage
+55℃ -20℃	Temperature limitation for storage	134°C	Sterilization under high temperature
106kPa 70kPa	Atmospheric pressure for storage		Fragile items, handle with care
	Class II equipment		Recyclable
	Laser radiation warning		Safety warning sign
CE 0197	CE marked product		Connection socket for interlock
	Optical fiber output laser warning	PAIR	Pedal pairing button
DANGER • CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION AND INTERLOCKS DEFEATED	When using the device, 4 types of laser radiation can be generated.	STOP	“Laser Stop” button; if there is emergency situation, press this button.
EC REP	Authorised Representative in the EUROPEAN COMMUNITY	**976± 20nm:** 0.2W-4W(CW), Peak Power 7W; chopped 1Hz to 20kHz chopped mode:5μs – 0.9s **650± 20nm:** 25mW-200mW(CW); **450± 20nm:** 0.2W-3W(CW), Peak Power 4W; chopped 1Hz to 20kHz chopped mode:5μs – 0.9s (According to IEC 60825-1: 2014)	Specification of laser output power and wavelength
MD	Medical device	UDI	Unique deivce identifer

14 Electromagnetic compatibility

Note

a) LX 16 Plus type Diode Laser Device meets the requirements of electromagnetic compatibility in IEC 60601-1-2 :2014 standard.

b) The user should install and use the device according to the electromagnetic compatibility information provided in the accompanying file.

c) Portable and mobile RF communications equipment may affect the performance of the LX 16 Plus Diode Laser Device. During operation, avoid

strong electromagnetic interference such as being close to cell phones, microwave ovens, etc. Please refer to following table for the details of guidelines and manufacturer's declarations.

⚠ Warnings

a) LX 16 Plus Diode Laser Device should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed to be able to operate normally in its configuration. Except the cables of LX 16 Plus sold by the manufacturer as spare parts for internal components, the use of other accessories and cables may result in increased emissions or reduced immunity of the LX 16 Plus Diode Laser Device.
b) Use of accessories, tips or cables that were not provided by LX 16 Plus manufacturer with LX 16 Plus and systems may result in increased emissions or reduced immunity of the LX 16 Plus Diode Laser Device.
c) The cables specified below must be used to comply with the requirements of electromagnetic emissions and immunity.

14.1 Requirements for cable installation

No.	Cable	Length	Whether to shield?
1	Handpiece tail cord	2m	No
2	Power supply cord	1.2m	No
3	Output cable of power adapter	1.5m	No

14.2 Key components of electromagnetic compatibility

The key components of electromagnetic compatibility of this product are power supply cord, main circuit board, fuse, IC chip. The use or replacement of non-conformed accessories, cables, transducers, etc. will result in significantly reduced electromagnetic compatibility emission and immunity performance. Do not replace the parts of this equipment without authorization.

14.3 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
LX 16 Plus is intended for being used in the electromagnetic environment specified below. The customers or users of LX 16 Plus should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	LX 16 Plus 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 device.

RF emissions CISPR 11	Class B	LX 16 Plus is suitable for being used in domestic establishment and in establishment that is directly connected to a low voltage power supply network which is for domestic power supply.
Harmonic emissions IEC 61000-3-2	Class A	
IEC 61000-3-2	Compliance	

14.4 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model LX 16 Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the model LX 16 Plus should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV 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 ±1kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	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 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T.) for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 250 cycles	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T.) for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models LX 16 Plus requires continued operation during power mains interruptions, it is recommended that the models LX 16 Plus 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 U_T is the a.c. mains voltage prior to application of the test level.

14.5 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance & Declaration - Electromagnetic immunity			
The model LX 16 Plus is intended for use in.the electromagnetic environment specified below. The customer or the user of the models LX 16 Plus should assure 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 Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models LX 16 Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\times P^{1/2}$ $d=2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.7 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.b 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 model LX 16 Plus is used exceeds the applicable RF compliance level above, the model LX 16 Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model LX 16 Plus.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

14.6 Recommended separation distance between portable and mobile RF communications equipment and the LX 16 Plus

Recommended separation distance between portable and mobile RF communications equipment and the LX 16 Plus

The model LX 16 Plus is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model LX 16 Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model LX 16 Plus as recommended below.

Maximum rated power output of transmitter/ W	Separation distance according to frequency of transmitter/ m		
	150kHz ~ 80MHz	80MHz ~ 800MHz	800MHz ~ 2.5GHz
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) according to the transmitter manufacturer.
Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all solutions. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.

Note

a) Without the consent of Guilin Woodpecker Medical Instrument Co., Ltd., unauthorized modification of the device may result in electromagnetic compatibility problems of this device or other device.
b) The design and testing of Diode Laser Devices are in compliance with

related operating procedures of electromagnetic compatibility.

15 Statement

Woodpecker reserves the right to change the design of the equipment, the technique, fittings, instruction IFU and the content of the original packing list at any time without further notice. The pictures are only for reference. The final interpretation rights belong to Guilin Woodpecker Medical Instrument Co., Ltd.
(Please refer to the packaging label for the date of manufacture. Service life: 10 years)

Scan and Login website
for more information

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Cut along the dashed line

Warranty Card

Name of Customer		(Ⅰ) For Distributor
Address Details		
Postal Code		
Tel		
Model		
Unit No.		
Handpiece No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

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E-mail: woodpecker4@glwoodpecker.com
Website: http://www.glwoodpecker.com

Distributor:

Seal

Warranty Card

Name of Customer		(Ⅱ) Return to Manufacturer
Address Details		
Postal Code		
Tel		
Model		
Unit No.		
Handpiece No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

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Distributor:

Seal

Warranty Instruction

Ⅰ Period validity:

Since the date of sale, with a warranty card, this product enjoys a 2 years warranty for the main unit , a 18 months warranty for power adapter, and a 12 months warranty for handpiece (excluding fiber optics).

Ⅱ Range of warranty:

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

Ⅲ The following 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.

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Harm of fake products

and are two brands of Guilin woodpecker medical instrument company. Recently, growing fake ultrasonic scaler handpieces, tips curing lights are produced and sold on the market, which do harm to users' interest.On this issue, We Woodpecker will crack down fake products and provide safe and secure medical instrument products.

1. Harm of fake ultrasonic scaler handpieces.

1.1 Fake handpieces with poor-designed inner structure can lead to frequent power leakage, which may cause medical accidents.
1.2 Material used on fake handpieces don' t pass biocompatible test, which can easily lead to irritability and poisoning.
1.3 Fake handpieces have quality problems of overheating, non-vibration and cracking, which cause ultrasonic scalers out of order.
1.4 Fake handpieces can' t be compatible with ultrasonic scalers, thus leading to circuit burn out.

2. Harm of fake scaler tips.

2.1 Fake tips are low in toughness, poor in resistance and easy to crack, thus easily cause medical accident.
2.2 Fake tips' screw threads are roughly processed, which can cause handpiece' s screw loosing and cracking.
2.3 Material used on fake tips is inferior and easily rusting, which can cause infection of patient.
2.4 Fake tips have used problem of poor water-spraying, bad screw-thread fit and water leaking, which leads ultrasonic scalers work wrongly.

3. Harm of fake curing light.

3.1 Fake curing light' s batteries can cause self-ignite, even explosion with poor-quality material and no complete charging management.
3.2 Light intensity of fake curing light is not constant, when battery level goes down under 60%, it would lead to incomplete solidification of resin, causing secondary dental caries.

