Please carefully read this Manual before first use.

Instruction Manual of Dental Diode Laser Device

CE 0197

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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Thank you for selecting LX 16 Plus Diode Laser Device manufactured by Guilin Woodpecker Medical Instrument Co., Ltd. Woodpecker is an enterprise developing, producing and selling dental instruments. We have complete quality control system. To ensure correct and safe use of device, please carefully read this Instruction Manual before use.

1 Product Introduction

1.1 Introduction

The LX 16 Plus Diode Laser Device realizes oral soft tissue surgery, periodontal disease, endodontic disease, pain treatment, soft laser therapy and other oral diseases by vaporizing, carbonizing and solidifying the tissue by laser.

Features:

a) Using a capacitive touch screen which has clear display and is easy to operate;

b) Built-in large-capacity rechargeable lithium battery with longer time of endurance;

c) The handpiece sleeve and the fiber tip can be autoclaved to prevent cross infection;

d) Preset more than 20 treatment procedures to reduce the difficulty of use.

e) A secure protection mechanism that automatically shuts down the device after 5 minutes of inactivity;

1.2 Model

LX 16 Plus

1.3 Configuration

Please refer to the Packing List.

1.4 Structures and components

This device consists of a main unit, a laser transmission system, and a power adapter. The main unit includes a semiconductor laser, a power supply system and a control device, a safety protection device, a display device, etc.

Detachable parts:handpiece sleeve,tips.

1.5 Scope of application

The device realizes oral soft tissue surgery, periodontal disease, pulp disease, pain treatment, soft laser therapy and other oral diseases by vaporizing, carbonizing and solidifying the tissue.

1.6 Contraindications

Patients with hemophilia are not allowed to use.

Patients with pacemakers are not allowed to use.

Doctors with a pacemaker are not allowed to use.

Patients with heart disease, pregnant women and young children should be cautious to use.

1.7 Target group

The dental Diode Laser Device is applicable to the person who needs treatment with diode laser in the dental clinical.

1.8 Device safety classification

Classified by operation mode: Continuous operation

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.

Degree of protection against electric shock: B type applied part (Applied part:fiber tip ,physiotherapy tip, whitening tip and biostimulation tip).

Degree of protection against harmful ingress of water: Ordinary equipment (IPX0), not waterproof

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

Power adapter input：100-240Vac， 50/60Hz， 2.5A

Main unit input：15V 6.0A

Wavelength and power:

a）976± 20nm ：

0.2W-4W(CW), Peak Power 5W；

chopped 1Hz to 20KHz

chopped mode:5us – 0.9S

b）650± 20nm ：

25mW-200mW(CW)；

c）450± 20nm：

0.2W-3W(CW)；

chopped 1Hz to 20KHz

chopped mode:5us – 0.9S

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)

Aiming beam:

650 ± 20 nm /Pmax<5mW

Divergence:12.7°

(According to IEC 60825-1: 2014)

Rechargeable battery:

11.1V/2600mAh x2 (57.7Wh)

Time consumption for charging: about 4h (5 hours for first charging)

Diverging half angle: 0.22 mad/ 12.6 °

size: 22 cm x 20cm x 23cm

Weight: 1.5kg

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

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

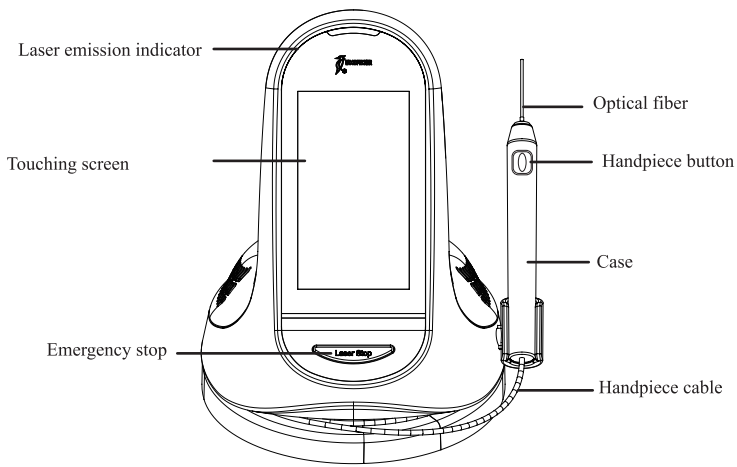


Figure 1 Front view of device

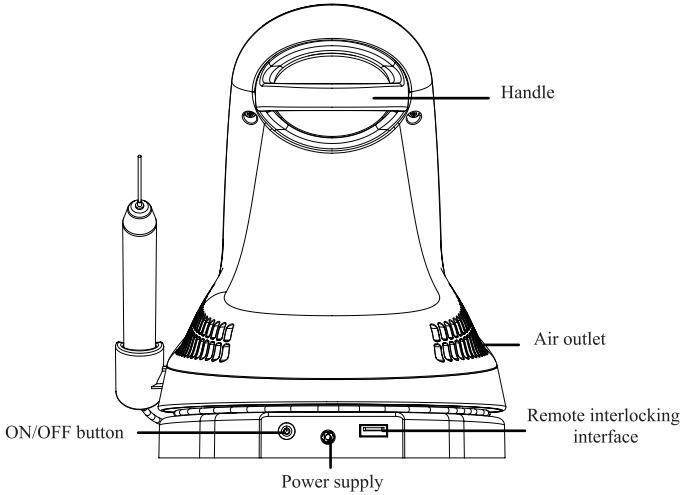


Figure 2 Rear view of the device

2.1 Installation of accessories

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.

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.

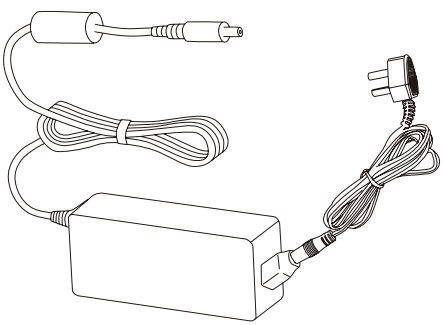


Figure 3 Assembly diagram of power adapter and power supply cable

Installation and removal of dustproof 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.

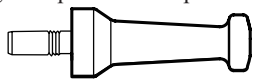


Figure 4 Dustproof plug

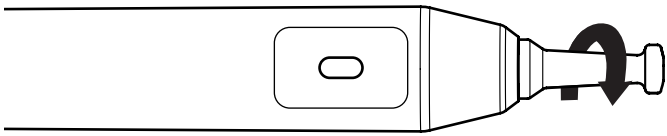


Figure 5 Dustproof plug removal diagram

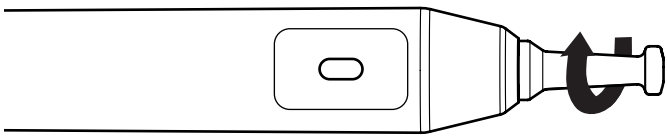


Figure 6 Dustproof plug assembly diagram

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.

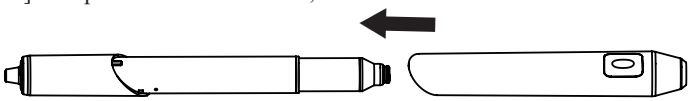


Figure 7 Installation diagram of handpiece sleeve

Handpiece switch

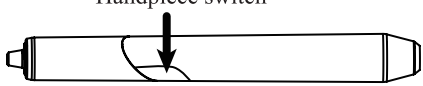


Figure 8 Removal diagram of handpiece sleeve

Assembly and removal of fiber tip

Remove the fiber tip and screw it in the clockwise direction after inserting it into the handpiece. As shown in Figure 9, remove the fiber tip and put it into the tip box to prevent the fiber from breaking. Rotate counterclockwise when disassembling, as shown in Figure 10.

After removing the fiber tip, install the dustproof plug according to the method in section 2.2.3.

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

[Note] When installing and removing the fiber tip, keep the tip surface clean and please do not touch the surface of fiber tip.

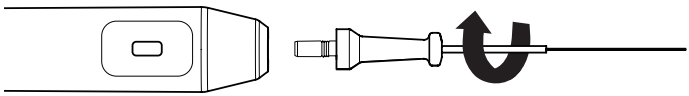


Figure 9 Fiber tip assembly diagram

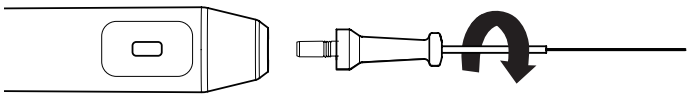


Figure 10 Fiber tip removal diagram

Installation and removal of physiotherapy tip, whitening tip and biostimulation tip.

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 disassembling the physiotherapy tip, whitening tip, and bio-stimulating tip, keep the working tip surface clean and do not touch the tip surface.

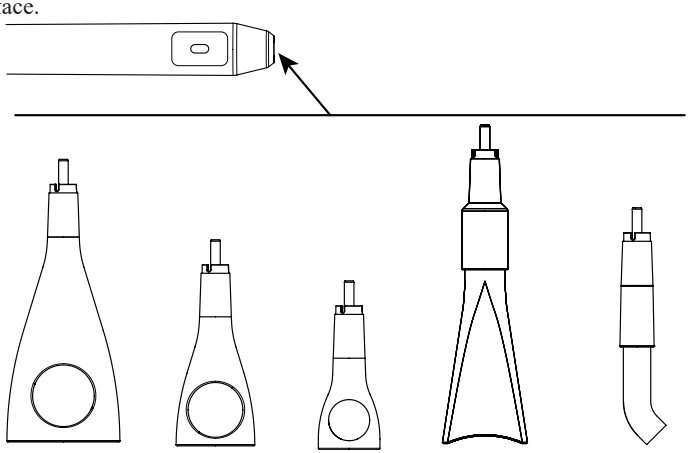


Figure 11 Installation diagram of physiotherapy tip, whitening tip and biostimulation tip

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.

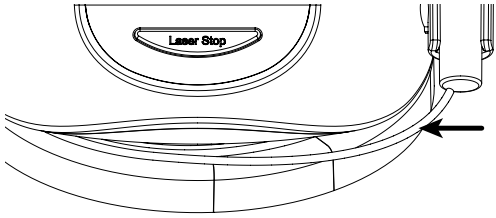
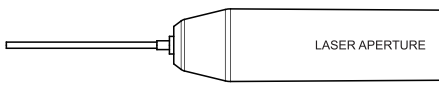


Figure 12 Diagram of handpiece tail cord storage

Note: There is a laser apertures in the handpiece.



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.

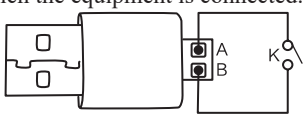


Figure 13 Wiring diagram of remote control interlock

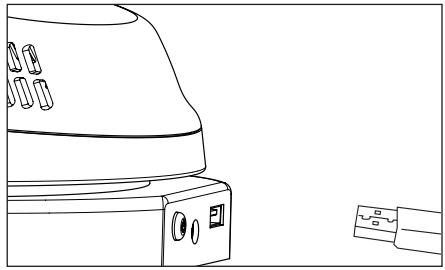


Figure 14 Installation diagram of remote control interlock

3 Operation

3.1 Touching screen

As shown in Figure 15, press the "ON/OFF" button on the back of the device to turn it on, then enter the user password on the display screen (the initial user password is "8888") and press OK to enter the desktop menu of the device as shown in Figure 16.

Press the “ON/OFF” button directly when powering off the device.

Note

The administrator password "6363" and the initial user password "8888" can be used to open the device. The user password can be modified in the setting interface, but the administrator password cannot be modified.

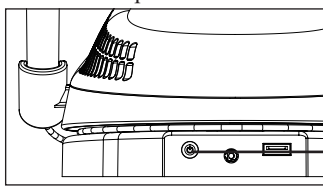


Figure 15 Schematic diagram of ON/OFF button

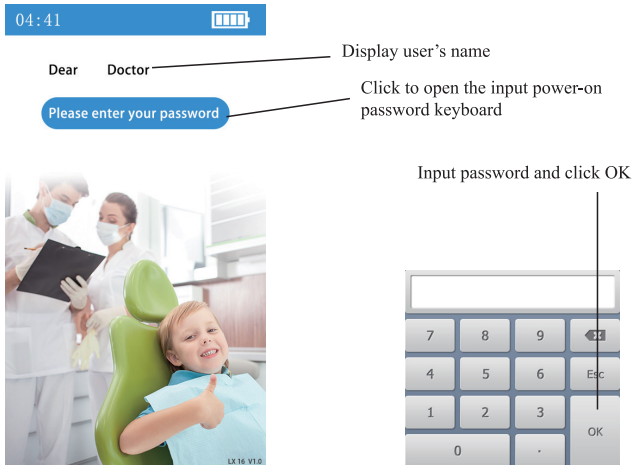


Figure 16 The greeting interface and password inputting interface

Select a preset program

As shown in Figure 17, there are 4 desktop menus, among which the first three are the preset treatment programs with preset parameters. They can be used according to the default parameters. The fourth is the user-defined program menu (refer to section 3.1.9-3.1.10 for more details)..

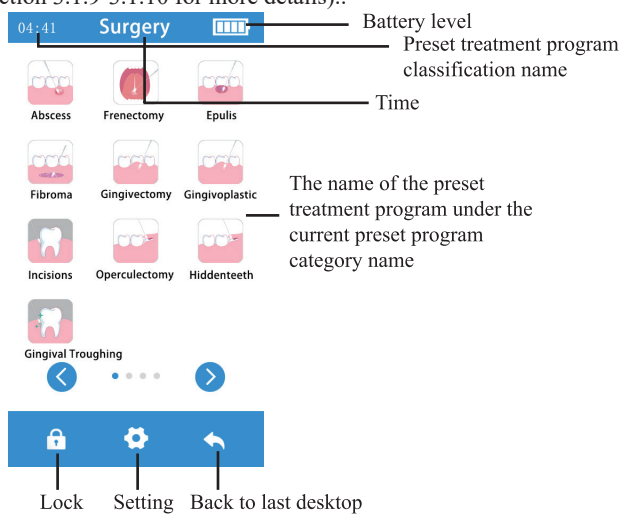


Figure 17 Preset treatment program interface

Treatment parameter adjustment

The device can set the peak power, frequency, duty cycle, time by keyboard

input, and automatically calculate the effective power and energy (there is a numerical range limit, and there will be a corresponding prompt when the value excesses the limit).

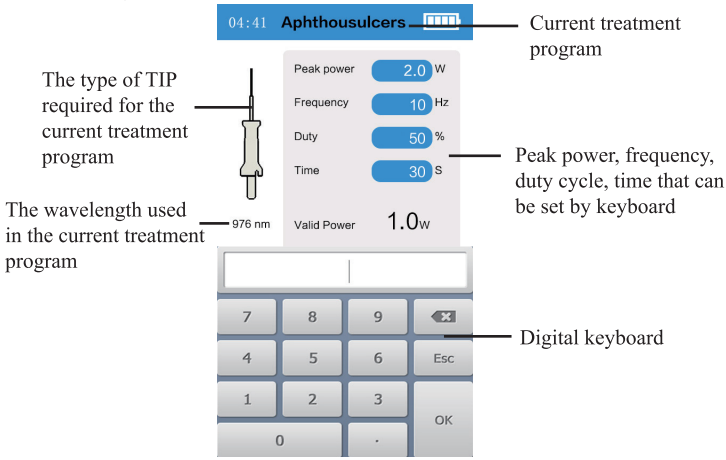


Figure 18 Treatment parameter adjustment interface

Treatment instructions and aiming beam adjustment

After selecting the treatment procedure, there are instructions for the corresponding treatment procedure, and display of the effective power and energy. There are 3 levels of aiming beam, which can be adjusted as needed as shown in Figure 19.

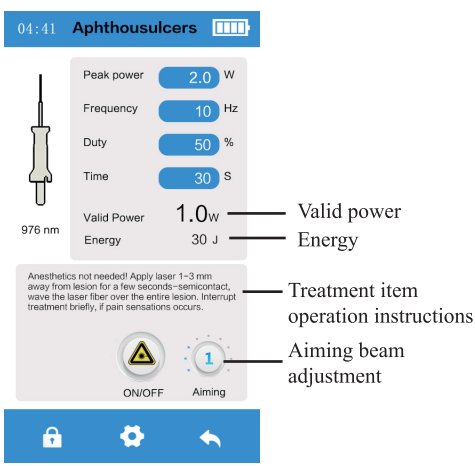


Figure 19 Schematic diagram of treatment instructions and aiming beam adjustment

Laser emission ready

Click the “Switch” button on the screen to prepare for laser emission. The device will prompt to wear the protective glasses. Click “Yes” button after wearing the glasses, enter the laser emission ready state after 2s countdown, and the “Switch” button will display “Ready”, and the indicator at the top of the screen is green as shown in Figure 20;

Figure 20 Schematic diagram of prompt of wearing glasses, Ready state, and green indicator

Check of laser emission aiming beam

In the laser emission ready state, the top end of the fiber tip emits a red aiming aura as shown in Figure 21. The method can be used to detect whether the optical path transmission system works well. It is recommended to check before each treatment.

[Note] Please use the new fiber optic tip. If the red aiming aura is an evenly rounded circle when it is about 8cm away from the white paper surface, the optical path transmission system of this device works well. Otherwise, check out the troubleshooting section in Chapter 5.

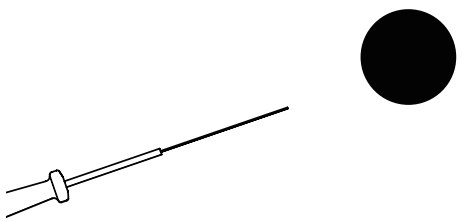


Figure 21 Schematic diagram of red aiming aura

Wireless Footswitch

If the product is equipped with foot switch, please read the following about foot switch carefully.

(a). Check before use

Before use, please check the footswitch for defects.The wireless footswitch consists of a protective cover (①),a pedal (②), a charging interface (③), an indicator light (④)and a pair button (⑤), as shown in Figure 22.

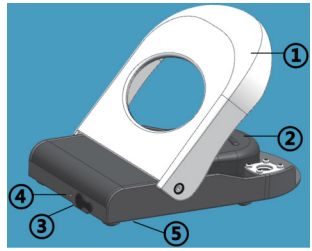


Figure 22

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

Fast flashing green: indicates that the footswitch is pressed down.

Slow flashing green: indicates that the footswitch is in standby.

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

(b). Charging

The main unit and footswitch share a power adapter. When charging, you first need to pull out the waterproof silicone plug of the charging interface (next to the indicator light), and then charge.

Observe the indicator light:

Steady yellow: indicates that the battery is charging.

Steady green: indicates that the battery is fully charged.

Alternative flashing yellow and green: indicates that the battery is damaged and needs to be replaced in time.

(c). Switch footswitch control mode

The main unit can be controlled by 2 methods: footswitch control mode and handpiece control mode. The machine control mode can be identified by observing the icon on the screen. Figure 23 shows the footswitch control mode.

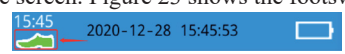


Figure 23

In the main unit function interface, click the “Setting” button, and then click “More”. The icon  indicates that the machine is currently controlled by the handpiece, and the icon  indicates that the machine is currently controlled by the footswitch. The control mode can be switched by the click of icons.

(Note: The icon  in the upper left corner of the screen shows the remaining battery power of the footswitch. When the footswitch is fully charged, the icon shows 3 bars of remaining battery power.The icon  indicates that the footswitch is in low battery and needs to be charged.)

(d). Footswitch pairing

If the footswitch has enough power but fails to control the main unit, you need to pair the footswitch and the machine again. First switch the control mode

to footswitch control mode, and then click the “Pair” button in the footswitch setting interface, as shown in Figure 24.

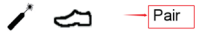


Figure 24

After the screen shows that it is pairing, press the “Pair” button at the bottom of the footswitch once. If the screen displays the “Successful pairing”, then the pairing is successful, otherwise there will be a message that the pairing fails.

Laser emission

When the laser emission is in the ready state, press the laser emission button on handpiece or footswitch to emit laser. When emitting laser, there will be audible sound prompt, and the top of the screen would alternately flash green and blue as shown in Figure 25. There will also be countdown. The laser emission will automatically stop as soon as the countdown ends. After it stops emitting laser, release the button to return to normal.

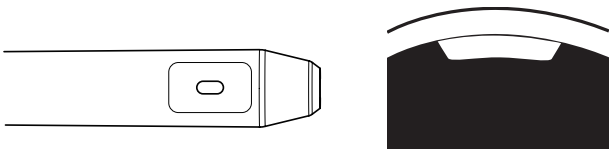


Figure 25 Laser emission button on handpiece and blue indicator light during laser emission

Stop emitting laser

As shown in Figure 26, the laser emission can be stopped by releasing the laser emission button or pressing the emergency stop button or pressing the laser emission "switch" button or pressing the machine lock button or the end of countdown,.

In addition, in order to prevent high temperature damage to the laser emission device, the device will automatically stop emitting laser when the internal temperature of the laser is higher than 60 °C. During the laser emission process, it is necessary to monitor whether the aiming beam is normally output at any time to verify whether the entire optical path system is working properly. If the aiming beam is found to be abnormal, stop the laser emission immediately.

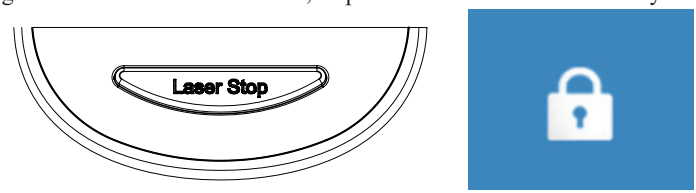


Figure 26 Emergency stop button "Laser Stop" and lock machine button

Modification of name of user-defined program

As shown in Figure 27, click on the system default program name in the

middle of the top of the screen, and the system would automatically pop up the input keyboard. After the input is completed, click the "Enter" button.

[Note] Only the name of user-defined program name be modified.

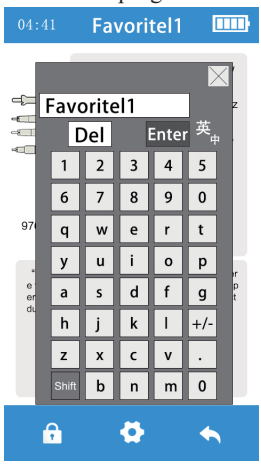


Figure 27 Schematic diagram of user-defined program name modification

User-defined program parameter settings and saving

As shown in Figure 28, click the parameter you want to modify, the system will pop up the numeric keypad; after entering the required parameters, click the save button, the system prompts "Save", click "Yes" to save the parameters, click "No" to return without saving. Click on the wavelength section to select the desired wavelength.

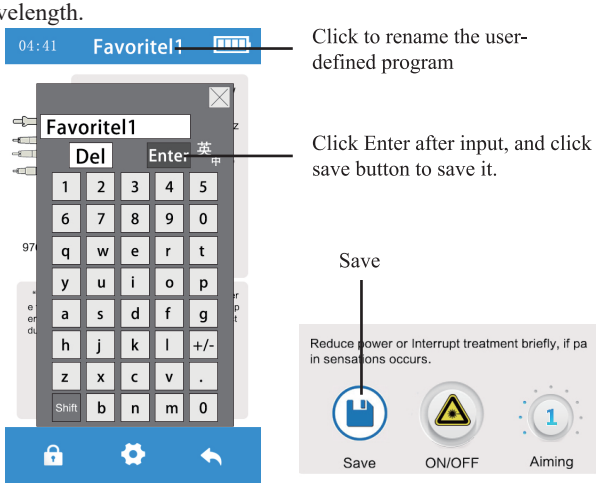


Figure 28 Schematic diagram of setting and saving of user-defined program parameters

Setting interface function description

As shown in Figure 29, enter the setup menu to perform system property settings.

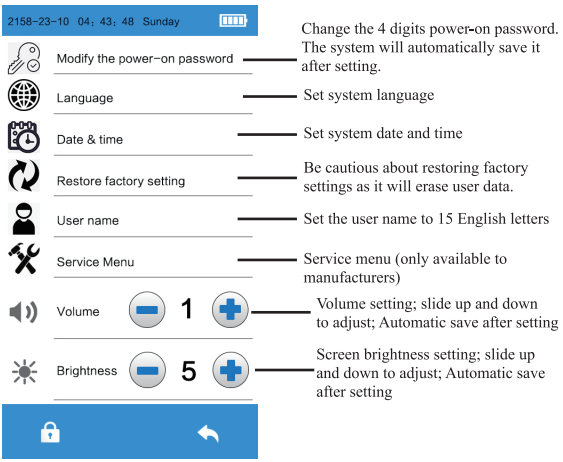


Figure 29 Setting interface function description

Charging

After plugging in the power adapter (original adapter only):

a) As shown in Figure 30, when the power is off, the charging icon will display the charging; when it is fully charged, it will display the full grid.

b) As shown in Figure 31, after booting up, a yellow prompt icon will appear in the upper right corner of the device screen, and green will appear when it is full charged.

Figure 30 The prompting icon of charging under power-off state

Figure 31 The prompting icon of charging under power-on state

Wearing laser goggles

As shown in Figure 32, during the use of this equipment, all personnel in the room (such as doctors, assistants, and patients. Other non-related personnel need to leave the treatment room.) need to wear the laser goggles provided by the

manufacturer. The laser goggles that were not provided by manufacturer cannot be used.

For doctors or assistants For doctors or assistants For patients

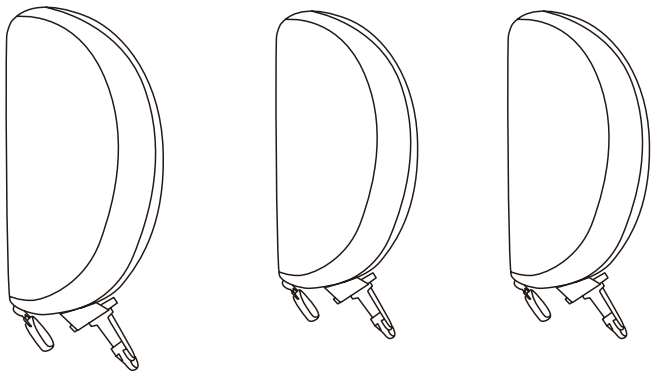


Figure 32 Laser goggles wearing instruction

Cutting fiber

During soft tissue surgery, proteins may cover the fiber end face and affect cutting efficiency. At this point, the protein should be removed or the part of the fiber should be cut off; the end face of the fiber should be cut before the irradiation treatment is needed; as shown in Figure 33, when cutting, use the fiber-cutting pen to gently traverse the fiber, and then break it with the appropriate force at the lined position. A neat fiber tip can be obtained. Discard the removed fiber in a container that is specially filled with sharp waste. Also check the aiming beam spot (Please refer to section 3.1.6 for more details of operation).

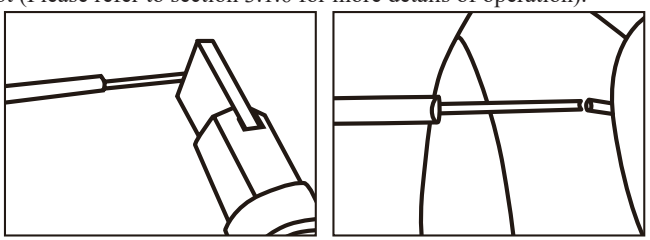


Figure 33 Schematic diagram of cutting the fiber

Fiber optic tip activation

Before the soft tissue operation, the fiber tip surface needs to be activated; as shown in Figure 34, take out a piece of articulating paper, use 976nm wavelength and 3W continuous power, after emitting the laser, gently stroke the articulating paper for 3-5 times.

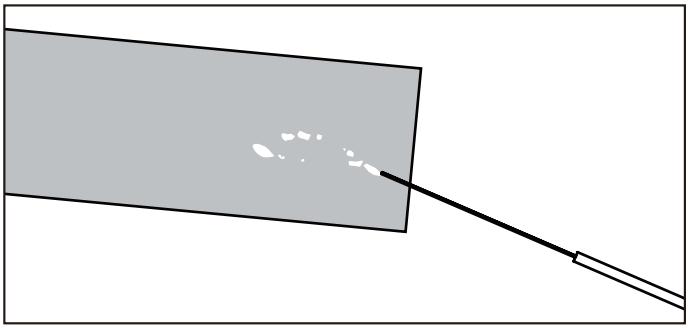


Figure 34 Schematic diagram of fiber tip activation

4 Precautions

4.1 Precautions for operation

1) The device should be kept clean before and after use.

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 .

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) Product operation must comply with the relevant medical and operational regulations and relevant regulations, and should only be used by trained doctors or technicians.

5) Do not pull or sharply bend the tail wire during the use of the device to avoid damage to the tail wire.

6) Do not hit or scratch the handpiece.

7) After operation, turn off the power and unplug the power cord.

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 manual, we are responsible for the security.

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.

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.

5 Troubleshooting

Fault	Cause	Solution
Without visible aiming beam	Aiming beam setting is too low / optical fiber tip is damaged	Press the "Aim at Beam" button to increase the setting of the aiming beam / replace the new fiber optic tip.
Working beam cannot be cut	The set power is too low	Increase power. If the power is set above 3 W, the working beam still does not work, please replace the optical fiber tip. If it still does not work properly, please contact the dealer.
The Foot Switch does not control the laser	The Foot Switch lacks power or is not paired	Use the Foot Switch after it is fully charged or repaired

If the above method cannot eliminate the fault, please contact the dealer and return the equipment to the dealer for returning it to the factory for processing. Do not attempt to open the casing of the machine and repair it yourself, which may result in electric shock or laser leakage.

6 Indications

6.1 Abscess

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Abscess	establish a drainage Path	450nm	Uninitiated	2.0W	2.0W	CW

Determine the status of the lesion, chronic or acute, and select a site to enter the parulis of the infection.

*Based on the lesion status, enter the lesion by placing the fiber tip at the most coronal spot on the parulis and with short strokes, make an incision to establish a drainage path.

*Using high volume suction, irrigate the area with saline solution as the exudate appears.

*Insert the fiber tip into the incision site without emitting energy and lightly probe the area inside the parulis as you advance the fiber apically.

*Once you have established the base of the parulis, back the fiber out approximately 2 mm and activate the laser as you slowly withdraw the fiber.

*Remove the fiber briefly and allow any exudate to drain.

*After the draining is slowed, re-enter the parulis and insert the fiber just short of the base and then withdraw the fiber as the laser is activated.

*Repeat the process until you have established a clear path for completing the remaining drainage.

*Cleave the fiber tip and do not initiate the fiber and re-enter the parulis while activating the laser at 2.0 Watts in the pulsed mode Pulse length is 200us and pulse interval is 200us.

Note: This process will "flood" the area with laser energy and reduce the number of pathogens remaining within the parulis.

*Administer oral antibiotics as needed and give the patient instructions on using warm saline to cleanse and irrigate the oral environment.

*If you are not able to complete the drainage procedure without pain. review basic protocols before administering a local anesthetic into the infected area.

6.2 Frenectomy

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Frene-ctomy	Removal of labial or sublingual tissue	450nm	Uninitiated	2.0W	2.0W	CW

The procedures to relieve the frenum will differ for three basic areas:

1. Mandibular frenum- labial or buccal
2. Mandibular frenum- lingual (tongue-tied relief)
3. Maxillary frenum- labial and buccal

Mandibular Labial frenum Attachments

Place tension on the frenum by retracting the lip or cheek. Begin at the base of the attachment to the gingival tissue and make an incision that is perpendicular to the length of the frenum.

*Using continued tension, extend the incision until you are nearing the periosteum.

Note: Do not cut into or damage the periosteum.

*You may need to extend your incision laterally when you have a wide attachment.

*Wipe the debris from the hard and soft tissues using hydrogen peroxide or warm saline solution.

*Sutures are usually not required.

Lingual Frenum:

Lingual frenum relief must be approached with caution to insure that you do not inadvertently rupture or incise the rich vascular beds in the floor of the mouth and the inferior border of the tonque.

*Though techniques are a matter of personal preference, many operators will grasp the frenum with a hemostat near the attachment to the tongue and use a hemostat to protect the vascular complex as the incision is made and the frenum released.

Maxillary Labial Frenum:

Grasping the lip, place tension on the frenum and begin to make a perpendicular incision at the most coronal aspect of the attachment to the gingiva.

*With continued tension, release the frenum fibers as you are moving apically. Note: Do not perforate or incise the periosteum.

*Release all fibers down to the frenum attachment to the periosteum.

*A diamond shaped surgical area will indicate that you have released the attachment.

*Use warm saline rinses to clean the area.

6.3 Epulis

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Epulis	Removal of epulis tissue	450nm	Uninitiated	2.0W	2.0W	CW

Stretch the tissue and use laser tip like an scalpel to excise the tissue.

6.4 Fibroma

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Fibroma	Removal of fibroma tissue	450nm	Uninitiated	2.0W	2.0W	CW

Stretch the tissue and use laser tip like an scalpel to excise the tissue. Depending on the size of the fibroma energy can be adjusted until desired cutting is achieved.

6.5 Gingivectomy

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Gingiv-ectomy	Gingiv-ectomy	450nm	Uninitiated	2.0W	2.0W	CW

*With an initiated fiber proceed to cleanly remove the tissue from the labial surface of the cuspid by lifting a flap, as in this case, or cutting a window to expose the tooth.

The Denlase diode laser may also be used for hemorrhage control prior to bonding the bracket to the tooth.

*Prior to acid etching, remove excess blood from the area.

*et the power to 0.8 watts, the mode to continuous wave and do not initiate the fiber tip.

*Place the fiber tip near the target wound (non-contact), lasing the bleeding area in a constant sweeping motion.

*Laser hemostatic control may require several passes of the tip over the target tissue, depending upon the extent of hemorrhage.

*Once the hemorrhage is controlled, you can proceed with predictable placement of the bracket within the same appointment.

*Finally clean any remaining tissue tags with hydrogen peroxide.

Note: There are many situations where soft tissue modification is an asset to the efficiency and effectiveness of orthodontic treatment-accelerating treatment time or simply providing an opportunity to achieve true occlusal and soft tissue balance.

6.6 Gingivoplastic

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Gingivo-plastic	Gingive-ctomy	450nm	Uninitiated	2.0W	2.0W	CW

Gently shape the gingival tissue in contact with the fiber. Caution: Work parallel to the tooth surface.

6.7 Incision

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Incision	Gentle removal of soft tissues for biopsy	450nm	Uninitiated	2.0W	2.0W	CW

Depending on the location of the lesion, you will want to establish a perimeter around the lesion that is 2mm+ outside its border

*Grasp the lesion with the beaks of a hemostat or tissue forceps and pull the lesion away from its base.

*With the tip contacting the tissue at the base of the lesion, activate the laser as you make an incision to remove the lesion.

*Limit the amount of power you use and move in quick strokes of 2-3 mm each so that you do not accumulate excessive energy.

*Place the lesion in a specimen bottle and send it to a diagnostic lab.

Note: If you have maintained the 2mm boundary around the lesion, the pathologist should be able to compare the healthy tissue with the diseased specimen.

6.8 Operculectomy

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Opercu-lectomy	Soft tissue crown Lengthening	450nm	Uninitiated	2.0W	2.0W	CW

Go into the pocket and push the footswitch the laser. If possible move the tip from right to left, to prevent that the tip will lose from the handpiece. Normally go not deeper than 3mm. If you have to go deeper, prevent to touch the bone. To be sure not to touch the bone, go into the pocket lift the tip approximately 1mm and activate the Laser.

6.9 Hidden teeth

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Hidden teeth	Soft tissue crown Lengthening	450nm	Uninitiated	2.0W	2.0W	CW

Stretch the tissue and use laser tip like an scalpel to excise the tissue.

6.10 Gingival Troughing

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Gingival Troughing	Gingival troughing for crown impressions	450nm	Uninitiated	2.0W	2.0W	CW

Following preparation of the tooth, cleanse the area with H2O2 and then rinse with alight spray of water.

Air dry with low volume flow of air.

Lightly contact the sulcus lining just inside the crest of the gingiva while resting the side of fiber against the tooth.

Using very light pressure, begin lasing as you make small paint brush strokes around the circumference of the tooth.

Create a small trough between the tooth and gingiva.

Note: Larger capillary damage may also require additional hemostasis by using chemical hemostatic agents. Hemostasis may improve by using an uninitiated tip.

6.11 Perio Germ

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Perio Germ	Starilization of pocket	976nm	Uninitiated	1.5W	0.8W	10Hz

Irradiate the whole pocket starting from the deepest position using a meandering courseto cover all contaminate regions. Reduce power, if pain sensations appear.

6.12 Implant Uncovery

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Implant Uncovery	Exposure of implant during second stage	450nm	Uninitiated	2.0W	2.0W	CW

Using a perio-probe or explorer, locate the cover screw for the submerged implant.

*Remove gingival tissue above the implant, using a 400um initiated fiber and continuous wave energy to remove tissue without charring.

*Impressions can usually be taken the day of recovering the implant.

*When an implant is covered with excessive tissue, inspect the area to determine how much tissue should be removed.

*Begin laser vaporization of tissue at 3.0 watt power an increase as necessary to obtain the treatment objectives and develop a tapered channel to reproduce anatomic contour and a good emergence profile for insertion of the final restoration procedure, it is important to direct the laser energy towards the tissue and away from the implant.

6.13 Periimplantitis

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Periimp-lantitis	Starilization of implant	976nm	Uninitiated	1.5W	0.8W	12Hz

“Move the fiber tip around the implant gently up and down with a sinuous movement, covering the wall of the tissue. Caution: Keep the laser tip always in motion!”

6.14 Endo. Germ

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency

Endo. Germ	Canal Starilization	976nm	Uninitiated	1.5W	0.8W	15Hz

*Root canal: Use fiber 200um.

*At first you have to go with a root canal instrument ISO 15 into the rootcanal. Make the measurement of the root canal length. Transfer this length to the fiber tip by coloring the side of the fiber at the correct length.

*To be sure not to touch the bone at the end of the root canal, go into the root canal lift the tip approximately 1mm and activate the Laser. Make a rotating move while still keeping on moving outside. Do this four to eight times for each canal. The pulp material will glue at the tipend.

*Recommendation for the root canal:

*Make your regular root canal treatment as usual and do only root canal disinfection in the way as described above.

6.15 Pulpotomy

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Pulpotomy	adjunct to root canal therapy	976nm	Uninitiated	1.5W	0.8W	15Hz

Pulp chamber: Use fiber 400um

Go into the chamber and push the footswitch of the laser Come close to the tissue without touching it. Than push the footswitch and stroke soft over the tissue you want remove.

Root canal: Use fiber 200um

At first you have to go with a root canal instrument ISO 15 into the rootcanal. Make the measurement of the root canal length. Transfer this length to the fiber tip by coloring the side of the fiber at the correct length.

To be sure not to touch the bone at the end of the root canal, go into the root canal lift the tip approximately 1mm and activate the Laser. Make a rotating move while still keeping on moving outside. Do this four to eight times for each canal. The pulp material will glue at the tipend. Recommendation for the root canal:

Make your regular root canal treatment as usual and do only root canal disinfection in the way as described above.

6.16 Gangrene Germ

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Gangrene Germ	Starilization of gangrene tissue	976nm	Uninitiated	3.0W	2.0W	20Hz

Carefully insert the fiber into the root canal, directly to the apex, start laser and

after maximum 2 seconds at the apex, retract fiber slowly in circular motion from the canal(1-2mm/s). Repeat procedure 4times in 5-seconds-intervals. Caution: Stay maximum 2seconds at the apex after laser activation.

6.17 Germ Pain Therapy

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Pain Therapy	Relief the pain in Perio tissue	976nm	DT15-Tip/ DT20Tip/ DT30-Tip	4.0W	4.0W	CW

Connect the Therapy handpiece. Lasing the Perio tissue for 1 minute before injection and after Curettage.

6.18 Aphthous Ulcer Care

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Aphthous Ulcer	Aphthous Ulcer	976nm	Initiated	2.0W	1.0W	10Hz

With a newly cleaved un-initiated fiber tip and power at 0.5 watts, start lasing about 10mm above the lesion and make circles from the outside edge of the lesions and move toward the center.

*The first pass, set the power to 1.5 watts. Use the laser for 10-20 seconds and stop to check if the patient feels pain or excessive heat.

*If not, increase the laser power to 1.8 watts and repeat the circling procedure for up to 30 seconds.

*Again, check with the patient and if okay, increase the power to 2.0 watts.

*Repeat the process a third time while moving closer to the lesion. Usually, the lesion will begin to display a milky appearance. If it does, you have completed the care for that day.

*If there is no milky appearance, you can repeat the circling motion until you are down to about 2 mm from the lesion.

Note: Do not exceed 2 minutes of total treatment per session. Keep the fiber tip moving at all times as you move closer.

*Repeat the procedure in 3 days if the condition doesn't improve and the pain is diminished.

*Record powers used and treatment times in the patients chart.

6.19 Hemostasis

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Hemo-stasis	Hemostasis	450nm	Uninitiated	2.0W	2.0W	CW

Place the fiber tip 2 mm above the gingival sulcus non-contact with tissue, direct energy into sulcus and away from the dentin and cementum.

*Activate the energy as you make a series of 2-3 mm strokes while circling the tooth. This should take 30-40 seconds.

*Note: Do not stop the movement of the fiber tip until you have reached the starting point again and do not contact the tissue.

*Examine the sulcus and see if you have hemostasis or if the "oozing has slowed.

*Repeat again for 30 seconds if hemorrhage persists.

*If bleeding continues after the second attempt, clean any excessive hemorrhage and lase for a third time. Do not exceed 11/2 minutes of lasing care.

*Note: Continued bleeding will indicate that you may have a larger arteriole that requires other hemostatic assistance in order to control.

6.20 Wound healing

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Wound healing	Promote wound healing	650nm	BT8-Tip	25mW	25mW	CW

Move the light guide back and forth over the area being treated so that the entire affected region is covered. Use the power setting provided for this application.

6.21 Dentin Hypersensitivity

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Dentin Hypersensitivity	Desensitization to Hot and Cold teeth	650nm	BT8-Tip	25mW	25mW	CW

Move the light guide back and forth over the area being treated so that the entire affected region is covered. Use the power setting provided for this application.

6.22 Desensitization

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Desensitization	Tooh desensitization	650nm	BT8-Tip	25mW	25mW	CW

“Apply tin fluoride solution as described in scientific diode-laser studied on the sensitive tooth areas, apply laser 2-4 mm away from these regions-semicontact, total time per area: 60seconds. Caution: Avoid contact to dentine, keep laser tip always in motion!”.

6.23 Herpes

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Herpes	Elimination of herpes	976nm	Initiated	2.0W	1.0W	10Hz

“Anesthetics not needed! Apply laser 1-3mm away from lesion for a few seconds-semicontact, wave the laser fiber over the entire lesion. Interrupt treatment briefly, if pain sensations occurs”.

6.24 Burning Mouth

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Burning Mouth	Relieve the Burning Mouth	650nm	BT8-Tip	50mW	50mW	CW

Move the light guide back and forth over the area being treated so that the entire affected region is covered. Use the power setting provided for this application.

6.25 Teeth Whitening

Pre-set NAME	Indications	Wavelength	Tip	Power	Average Power	Frequency
Teeth Whitening	Whitening Tooth	450nm	Whitening-Tip	3.0W	3.0W	CW

*Connecting the Bleaching Handpiece (Quadrant), radiate the tooth surface covered with TiO2 gel for 30seconds, wait 1minute to impact and check if the patient feels pain or excessive heat. Repeat above procedure four times for each tooth. Generally do not exceed 6 minutes of total treatment.

*To do a single tooth whitening, the biostimulation handpiece can be used.

*Please contact your supplier for the information of the laser bleaching gel.

Pain Therapy- Adverse Effects

Some reddening of the skin at the treatment site is normal due to increased circulation: however. in very rare cases burning or blistering of the skin may occur. Immediately stop treatment, rinse the area with cool water or place a cold pack to the affected area for at least 5 minutes, then apply a burn ointment or spray. DO NOT USE ICE.

Patients should be monitored for discomfort and visual skin changes. Redness has been associated with increased temperature at the site of application and increased absorption properties of the skin. If discomfort or redness of the skin occurs at any time during the treatment, you have the following options:

*Move the handpiece relative to the affected anatomy

*Defocus the energy by moving the Handpiece further away from the skin

*Decrease the power setting

*Stop treatment

*Pain Therapy -Warnings and Precautions

*Scar tissue has been associated with poor circulation and reduced cooling through heat transport by blood; power settings may have to be reduced to avoid overheating.

*Patients with tender or sensitive skin may be hypersensitive to heat; reduce power as necessary to ensure comfort during treatment.

*Patients with swelling and/or inflammation may be sensitive to heat reduce power as necessary to ensure comfort during treatment.

*Do not treat open wounds.

*Muscle tissue closer to the skin surface may experience a higher absorption of heat; carefully monitor skin temperature and reduce power as necessary.

*Excessive fatty tissue is known to transmit heat without much attenuation:; reduce power.

*Different implant materials will respond differently to laser energy and heat, be aware of any implants and their location, avoid direct exposure to laser energy or heat at the site of the implant.

*Avoid treatment of sites that have tattoos.

*Do not apply ointment, creams, lotions or heating lotion patches at, or in close proximity to, the treatment area.

*Do not apply therapies prior to treatment that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches.

*Do not apply treatment over articles of clothing.

*Recommended Use.

*There are four main variables that impact the safety and effectiveness of pain therapy procedures:

*Power output

*Distance from the skin surface

*Range of movement of the Handpiece

*Patient skin type

Safety and effectiveness are described by elevating the skin temperature in the treatment area utilizing the settings recommended below. Use personal clinical judgment with consideration of the Fitzpatrick Skin Type Scale when selecting procedure parameters; monitor the patient and adjust the settings as necessary for effectiveness and patient comfort.

NOTE: To avoid potential patient discomfort and/or skin damage, it is advisable to use a test prior to the initial treatment to assess the suitability of the selected settings for the individual patient.

Using the Deep Tissue Handpiece

If holding the Handpiece in a constant location, adjust the settings on the

screen to the recommended initial power settings for therapeutic effect, 4. 0W, delivered over 10 minutes(600 seconds)of continuous treatment(CW), with the spacer set at a 30mm spot size. Always monitor patient response, adjust power and/or distance as needed for patient comfort.

7 Cleaning, disinfection and sterilization

7.1 Scope

Unless otherwise stated, BT8-Tip,Whhitening-Tip,DT15-Tip,DT20-Tip,DT30-Tip will be here in after referred to as “reusable tips”. MF2-14,MF2-20,MF3-4,MF3-9,MF4-4 and MF4-9 refer to as single-use only tips. Reusable tips and single-use only tips refer to as “tips”. Reusable tips and Handpiece shell refer to as “products”.

Those can be sterilized are as follows:

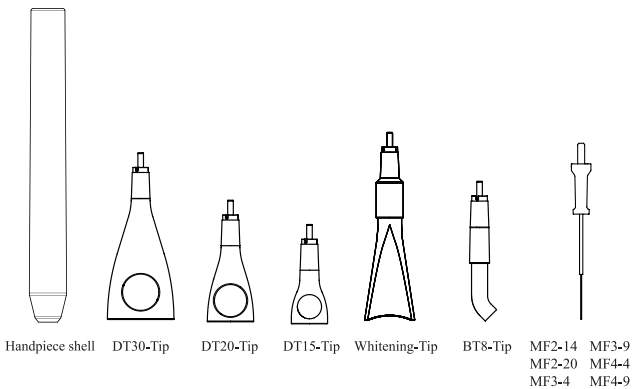


Figure 33 parts can be sterilized

Warnings:

The use of ultrasound cleaning device and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH <5) can reduce the life span of products. The manufacturer takes no responsibility in such cases.

The products may not be exposed to temperature above 138℃. This device shall not be exposed to high temperature above 138℃.

7.2 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 allowed maximum times of sterilization for handpiece shell and Bending Tools are 250 times, other reusable tips are 200

times. Single- use only tips should not be reused. Single- use only tips should not be reused.

Warnings:

1) Before the product is used for the first time, it needs to be cleaned and sterilized in accordance with the reprocessing requirements.

2) It is forbidden to reuse the single-use only tips, otherwise it may cause cross-infection.

7.3 Initial processing

7.3.1 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.

7.3.2 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 handpiece shell from the Dental Diode Laser Device handpiece,and rinse away the dirt on the surface of handpiece shell with pure water.

2.Dry the handpiece shell with a clean, soft cloth and place it in a clean tray.

3.Clean the tips with a clean, soft cloth with medical alcohol, dry the tips with a clean, soft cloth and place it in a clean tray.

7.3.3 Transportation

Safe storage and transportation the uesd device to the reprocessing area to avoid any damage and contamination to the environment.

7.3.4 Preparation before cleaning

Steps:

Tools: tray, soft brush, clean and dry soft cloth

1. Remove the physiotherapy tip, whitening tip , biostimulation tip and Handiece Shell refer to 2.1.

2. Unscrew the tip from handpiece and put it into the tray.

3. Push the switch on the handpiece. Remove the handpiece shell of handpiece.

4. Use a clean soft brush to carefully brush the handpiece and accessories until the dirt on surface is not visible. Then use soft cloth to dry the handpiece shell and accessories and put them into a clean tray. The pre cleaning agent can be pure water .

Note:

a)In the washing stage, the water temperature should not exceed 45 ℃,

otherwise the protein will solidify and it is difficult to remove.

b)The Fiber tip is a disposable item. After removing the Tiber tip from the factory packaging bag, cleaned the Fiber tip as soon as possible to prevent contamination.

c)When taking the Fiber tip out of the factory packaging, do not touch the two ends to prevent the fiber from being damaged.

7.4 Cleaning

The cleaning should be performed no later than 24 hours after the operation. The cleaning adopt automated cleaning

The cleaning procedure are as follows.

1) Pre-wash with pure water at 25 ℃ for 3 minutes.

2) Clean with the condition recommended by the cleaning agent manufacturer for 5 minutes. For example the detergent use RUHOF 11 ENDOZIME AW PLUS WITH APA, Dilution Ratio1: 270, temperature 25℃ Clean for 5minutes.

3) Rinse twice with pure water at 25 ℃ for 1 minute each.

Notes:

a) The solution used the pure water and only freshly prepared solutions can be used.

b) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed.

c) The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

d) The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

7.5 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

For the thermal disinfection here, the temperature is 93 ° C, the time is 5 min, and A0>3000.

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 handpiece shells and tips in the disinfection basket. Fastening of the handpiece shells and tips if only permissible of they are freely moveable in the fixture. The handpiece shells and tips are not permitted to make contact with one another.

2.Start the program.

3.After the program is finished, remove the handpiece shells and tips from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the handpiece shell repeatedly if necessary (refer to section "Drying").

The intrinsic suitability of the product for effective cleaning and disinfection using the above automated cleaning and disinfection procedures was verified by a certified facility.

Notes:

a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and Notes.

With this equipment, cleaning, disinfection and drying will be carried out together.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Only pure 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).

d) The air used for drying must be filtered by HEPA.

e) Regularly repair and inspect the disinfector

7.6 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1. Put a clean white paper (white cloth) on the flat table, point the handpiece shell against the white paper (white cloth), and then dry the handpiece shell with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the handpiece shell drying are completed.

2. The handpiece shell and tips can be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃ ~ 120℃ and the time should be 15 ~ 40 minutes.

Notes:

1. The drying of product must be performed in a clean place.

2. The drying temperature should not exceed 138 °C;

3. The equipment used should be inspected and maintained regularly.

7.7 Inspection and maintenance

In this chapter, we only check the appearance of the handle shell and tips. After inspection, ensure that there is no problem.

7.7.1 Check the handpiece shell and tips. If there is still visible stain on the handpiece shell and tips after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

7.7.2 Check the handpiece shell and tips. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

7.7.3 Check the handpiece shell and tips. 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.

7.7.4 If the service time (number of times) of the handpiece shell and tips reaches the specified service life (number of times), please replace it in time.

7.8 Packaging

The disinfected and dried handpiece shells and tips are quickly packaged in a medical sterilization bag (or special holder, sterile box).

Notes:

1.When picking the Fiber tip , do not touch the two ends and place the optical fiber to be damaged.

2. The package used conforms to ISO 11607;

3.It can withstand high temperature of 138 °C and has sufficient steam permeability;

4.The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

5. Avoid contact with parts of different metals when packaging.

7.9 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 EN285 to comply with EN ISO 17665;

2. The sterilization time is at least 5 minutes at a temperature of 134°C and a pressure of 2.0 bar ~ 2.3 bars.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Notes:

1. Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

2. Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

3. Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

4. 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.

7.10 Storage

7.10.1 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;

7.10.2 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:

1. The storage environment should be clean and must be disinfected regularly;
2. Product storage must be batched and marked and recorded.

7.11 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.

7.12 The cleaning and disinfection of main unit and other accessories are as follows

7.12.1 Before each use, wipe the surface of the main unit and charging base with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.

7.12.2 After each use, wipe the surface of the main unit with a soft cloth soaked in clean water (pure water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

Warning:

1. Do not clean the main unit with Ultrasound cleaning machine;
2. Goggles can be wiped with a soft cloth or soaked in a normal temperature disinfectant solution. Do not sterilize it under high temperature.
3. The handpiece contains precise optical lens which cannot be cleaned (except the handpiece sleeve); therefore, it should be protected from water ingress.
4. Do not use volatile and diffluent solvents for cleaning, which can damage the surface of the device or cause the markings on the device to fade.

8 Storage, maintenance, and transport

8.1 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 is10%

~ 93%, atmospheric pressure is 70kPa ~ 106kPa, and the temperature is -20℃ ~ +55℃.

8.2 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.

9 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

10 Safety Information

In make sure safety, please do as follows.

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;

2. Can not be used under maintenance;

3. When using an adapter, the product must be placed where it is easy to disconnect the power supply;

4. Do not modify this equipment without authorization of the manufacturer.

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.

6. Under working mode, goggles should be equipped to protect eyes.

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.

8. Attention is also drawn to the danger of ignition of endogenous gases. laser equipment should be protected against unauthorized use.

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.

10. Make sure to check the integrity of the delivery system.

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.

12. When the device is applied to the patient, the device cannot be maintained.

13. At ambient temperature of 40℃, the maximum temperature of the application part of the device can reach approximately 52℃.

14. The time for the device to emit a single laser continuously should be less than one minute.

15. When replacing the lithium battery, it should be replaced by an authorized professional or dealer.

11 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 Field MaxII- To with detector PM10 is suitable. They are access from Coherent of the USA.

2. Download the user manual through the link above and setuo power meter under the guide of its user manual 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 manual.

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. For aiming beam, set the aiming beam to full power.

8. The reference value of laser power is from 2.4W to 3.6W. For aiming beam, t is from 0. 8mw to 1. 2mw.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 manual when operating the laser during the calibration to avoid any hazardous radiation exposure.

12 After-sales service

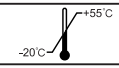
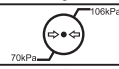
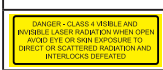
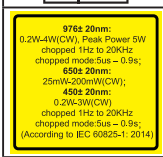
Since the date of sales, for the device what has quality problem, with Warranty Card, our company is responsible for the repair. Please refer to the Warranty Card for the warranty period and scope. This product does not contain any accessories that can be repaired by users. The device can only be repaired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

13 European authorized representative

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

14 Symbols

WOODPECKER ®	Trademark		Follow Instructions for Use
	Manufacturer		Date of manufacture
	B type applied part		Use indoor only
SN	Product serial number		Products comply with WEEE directive

IPX0	Ordinary equipment	DC 15V	15V Direct current input
	Power switch		Avoid exposed to rain
	Temperature limitation for storage		Humidity limitation for storage
	Atmospheric pressure for storage		Sterilization under high temperature
	Caution! Avoid scalding		Fragile items, handle with care
	Laser radiation warning		Safety warning sign
CE 0197	CE marked product	INTERLOCKS	Connect remote control interlock
LASER APERTURE	LASER APERTURE		Connection socket for interlock
	When using the device, 4 types of laser radiation can be generated.		
	“Laser Stop” button; if there is emergency situation, press this button.		
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		
	Specification of laser output power and wavelength		

15 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.

15.1 Requirements for cable installation

No.	Cable	Length	Whether to shield?
1	Handpiece tail cord	2m	No
2	Power supply cord	1.5m	No
3	Output cable of power adapter	2.0m	No

15.2 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.

15.3 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 lEC 61000-3-2	Class A	
lEC 61000-3-2	Compliance	

15.4 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) lEC 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 lEC 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 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) 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 lEC 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 a.c. mains voltage prior to application of the test level.			

15.5 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 lEC 61000-4-6 Conducted RF lEC 61000-4-6 Radiated RF lEC 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×P1/2 d=2×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 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 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 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.

15.6 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.

16 Statement

Woodpecker reserves the right to change the design of the equipment, the technique, fittings, instruction manual 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: 5 years)

Scan and Login website
for more information

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