Instruction Manual of Semiconductor Laser Therapy Device



GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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Forward

Thank you for selecting LX 16 Plus Diode Laser System 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 System 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.

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 Device safety classification

Classified by operation mode: Continuous operation

Type of protection against electric shock: For charging, it is Class I device; For working, it is Class II internal power supply device.

Degree of protection against electric shock: B type applied part

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.

1.8 Main technical parameters

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

Main unit input: 15V 6.0A

Wavelength and power:

a) $450 \pm 20 \text{nm}$: Pmax = 3W;

b) 650 ± 20 nm : Pmax = 200mW;

c) $976 \pm 20 \text{nm}$: Pmax = 5W;

Laser classification:

a) 976 nm: Class IV;

b) 650 nm: Class II;

c) 450 nm: Class IV; (According to IEC 60825-1)

Aiming beam: $650 \pm 20 \text{ nm /Pmax} < 5 \text{mW}$

Rechargeable battery: 11.1V/2600mAh x2 (57.7Wh)

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

size: 22cm x 20cm x 23cm

Weight: 1.5kg

1.9 Operation circumstance

1.9.1 Temperature: +5°C $\sim +40$ °C

1.9.2 Humidity: $30\% \sim 75\%$

1.9.3 Air pressure: 70kPa ~ 106kPa

2 Installation and functions

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

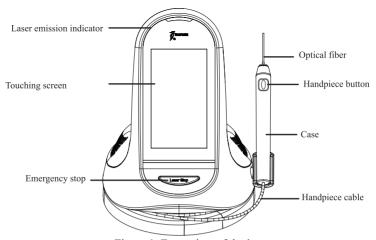


Figure 1 Front view of device

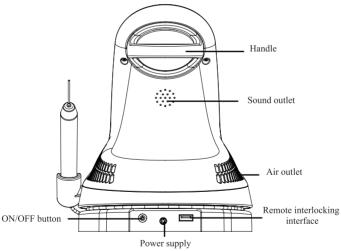


Figure 2 Rear view of the device

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.

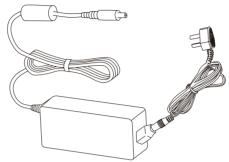


Figure 3 Assembly diagram of power adapter and power supply cable

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.

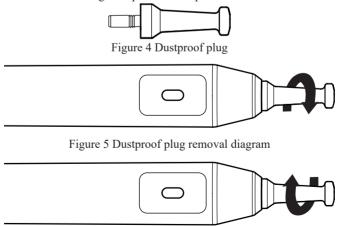


Figure 6 Dustproof plug assembly diagram

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

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

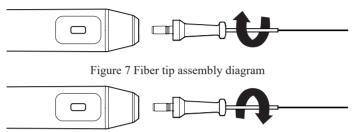


Figure 8 Fiber tip removal diagram

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 9. 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.

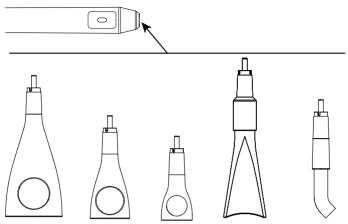


Figure 9 Installation diagram of physiotherapy tip, whitening tip and biostimulation tip

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 10; when disassembling, please press the handpiece switch to pull out the sleeve as shown in Figure 11.

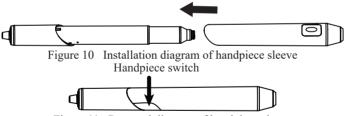


Figure 11 Removal diagram of handpiece sleeve

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.

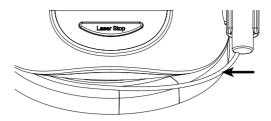


Figure 12 Diagram of handpiece tail cord storage

Installation of remote control interlock (optional)

Remote interlocking is a safety device that terminates laser radiation whenever the door of the treatment room is opened. This device can also be used normally without the remote interlock. When this function is required, 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

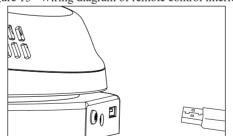


Figure 14 Installation diagram of remote control interlock

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.

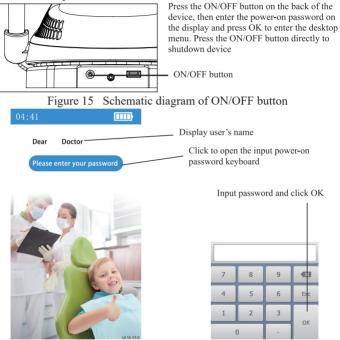


Figure 16 The greeting interface and password inputting interface

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)..

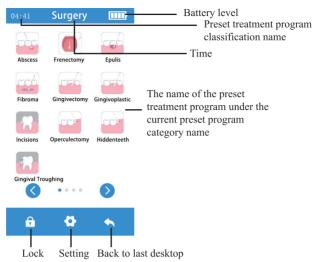


Figure 17 Preset treatment program interface

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).

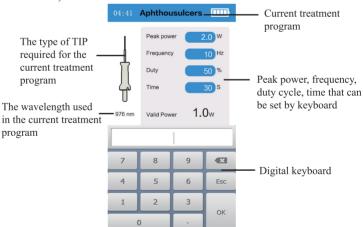


Figure 18 Treatment parameter adjustment interface

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.

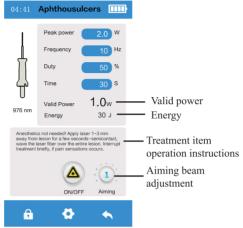


Figure 19 Schematic diagram of treatment instructions and aiming beam adjustment

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

Laser emission

When the laser emission is in the ready state, press the laser emission button on handpiece 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 22. 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.

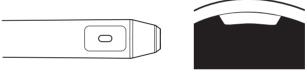


Figure 22 Laser emission button on handpiece and blue indicator light during laser emission

Stop emitting laser

As shown in Figure 23, 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.

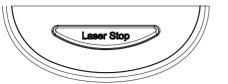




Figure 23 Emergency stop button "Laser Stop" and lock machine button **Modification of name of user-defined program**

As shown in Figure 24, 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 24 Schematic diagram of user-defined program name modification User-defined program parameter settings and saving

As shown in Figure 25, 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.

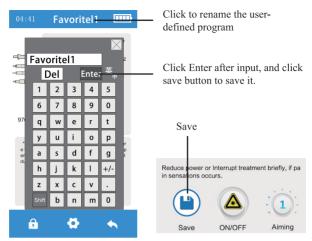


Figure 25 Schematic diagram of setting and saving of user-defined program parameters

Setting interface function description

As shown in Figure 26, enter the setup menu to perform system property settings.

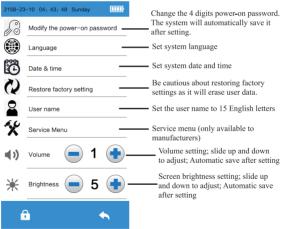


Figure 26 Setting interface function description

Charging

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

a) As shown in Figure 27, 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 28, 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 27 The prompting icon of charging under power-off state



Figure 28 The prompting icon of charging under power-on state **Wearing laser goggles**

As shown in Figure 29, 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.

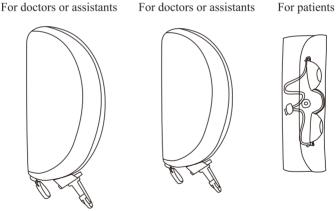


Figure 29 Laser goggles wearing instruction

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 31, 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).

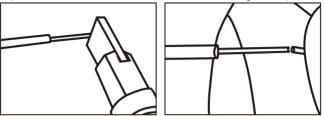


Figure 31 Schematic diagram of cutting the fiber

4 Precautions

4.1 Precautions for operation

The device should be kept clean before and after use.

Please check whether the aiming beam output of this device is normal before each clinical operation (Please refer to section 3.1.6 for more details of operation).

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.

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

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

Do not hit or scratch the handpiece.

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

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.

5 Troubleshooting

| Fault | Cause | Solution |
|----------------|-------------------------|---|
| Without | Aiming beam setting is | Press the "Aim at Beam" button to |
| visible aiming | too low / optical fiber | increase the setting of the aiming beam / |
| beam | tip is damaged | replace the new fiber optic tip. |
| Working | The set power is too | Increase power. If the power is set above |
| beam cannot | low | 3 W, the working beam still does not |
| be cut | | work, please replace the optical fiber tip. |
| | | If it still does not work properly, please |
| | | contact the dealer. |

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 Cleaning, disinfection and sterilization

The touch panel and handpiece tail cord can be cleaned with a soft cloth dampened with a water-based cleaner or disinfectant. The recommended disinfectant is 70% isopropyl alcohol. To avoid wear, do not use a hard tool to clean it.

The laser handpiece sleeve, fiber tip and physiotherapy tip can be autoclaved and placed in a box than can be sterilized under high temperature. The temperature, pressure, and consuming time of sterilization should be: $134 \,^{\circ}$ C, $2.0 \,^{\circ}$ bar $\sim 2.3 \,^{\circ}$ bar $(0.20 \,^{\circ}$ MPa), 4min.

Goggles can be wiped with a soft cloth or soaked in a normal temperature disinfectant solution. Do not sterilize it under high temperature.

The handpiece contains precise optical lens which cannot be cleaned (except the handpiece sleeve); therefore, it should be protected from water ingress.

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.

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 $10\% \sim 93\%$, atmospheric pressure is $70\text{kPa} \sim 106\text{kPa}$, and the temperature is $-20^{\circ}\text{C} \sim +55^{\circ}\text{C}$.

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

12.6 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 | 0 | 0 | 0 | 0 | 0 | 0 |
| Main unit | 0 | 0 | 0 | 0 | 0 | 0 |
| Power adapter | 0 | 0 | 0 | 0 | 0 | 0 |
| Tip | 0 | 0 | 0 | 0 | 0 | 0 |
| Mechanical elements, including bolts, nuts, washers, etc. | | 0 | 0 | 0 | 0 | 0 |

o: 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 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.

10 Electromagnetic compatibility



- a) LX 16 Plus type Diode Laser System meets the requirements of electromagnetic compatibility in YY0505-2012 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 System. 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.



- a) LX 16 Plus Diode Laser System 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 System.
- 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 System.
- c) The cables specified below must be used to comply with the requirements of electromagnetic emissions and immunity.

10.1 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 |

10.2 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.

10.3 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 environn | nent. | | | |
| Emission test | Compliance | Electromagnetic environment – | | |
| | | guidance | | |
| RF emissions | Group 1 | LX 16 Plus use RF energy only for | | |
| GB 4824 | | its internal function. Therefore, its | | |
| | | RF emissions are very low and are | | |
| | | not likely to cause any interference | | |
| | | in nearby electronic device. | | |
| RF emissions | Class B | LX 16 Plus is suitable for being | | |
| GB 4824 | | used in domestic establishment and | | |
| 17625.1 | Class A | in establishment that is directly | | |
| Voltage fluctuations/ | Compliance | connected to a low voltage power | | |
| flicker emissions | | supply network which is for | | |
| GB 17625.2 | | domestic power supply. | | |
| | | | | |

10.4 Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity

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 environment.

| Immunity test | IEC 60601 | Compliance | Electromagnetic environment – |
|------------------|----------------|----------------|------------------------------------|
| | test level | level | guidance |
| Electrostatic | ±6kV Contact | ±6kV Contact | Floors should be made of wood, |
| discharge | discharge | discharge | concrete or ceramic tile. If |
| GB/T 17626.2 | ±8kV Air | ±8kV Air | floors are covered with synthetic |
| | discharge | discharge | material, the relative humidity |
| | | | should at least reach 30%. |
| GB/T 17626.4 | ±2kV For | ±2kV For | Mains power should be of the |
| Electrical fast | power supply | power supply | quality to be used in commercial |
| transient bursts | lines | lines | or hospital environment. |
| GB/T 17626.4 | | | _ |
| Surge | ±1kV Line to | ±1kV Line to | Mains power should be of the |
| GB/T 17626.5 | line | line | quality to be used in commercial |
| | ±2kV Line to | | or hospital environment. |
| | earth | | |
| Voltage | <5%UT, (> | <5%UT, (> | Mains power should be of the |
| dips, short | 95% dip in | 95% dip in | quality to be used in commercial |
| interruption | UT) for 0.5 | UT) for 0.5 | or hospital environment. If the |
| and voltage | circle | circle | user of LX 16 Plus requires |
| variations on | 40%UT, (60% | 40%UT, (60% | continued operation during |
| power supply | dip in UT) for | dip in UT) for | power mains interruptions, it |
| input lines. | 5 circles | 5 circles | is recommended that the LX |
| GB/T 17626.11 | 70%UT, (30% | 70%UT, (30% | 16 Plus be powered from an |
| | dip in UT) for | dip in UT) for | uninterruptable power supply or |
| | 25 circles | 25 circles | a battery. |
| | <5%UT, (> | <5%UT, (> | |
| | 95% dip in | 95% dip in | |
| | UT) for 5s | UT) for 5s | |
| Power | 3A/m | 3A/m | Power frequency magnetic field |
| frequency | | (50Hz) | should be at levels characteristic |
| magnetic field | | | of a typical location in a |
| (50/60Hz) | | | typical commercial or hospital |
| GB/T 17626.8 | | | environment. |
| | . 14 4 | 4 14 | a maior to amplication of the test |

Note: U_T is the alternative current mains voltage prior to application of the test level.

10.5 Guidance and manufacturer's declaration – electromagnetic immunity

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 environment.

| used III such | environinent. | | |
|---|---|-----------------------------------|--|
| Immunity | | _ | e e |
| test | | level | guidance |
| Immunity test G B / T 17626.3 Conducted | IEC 60601 test le vel 3 V r m s 150kHz~80MHz 3V/m 80MHz~2.5GHz | Compliance level 3Vrms 3V/m | Electromagnetic environment - guidance Portable and mobile RF communications equipment should not be used closer than the recommended separation distance to any part of LX 16 Plus, including cables. The separation distance should be calculated from the corresponding formula of transmitter frequency. Recommended separation distance: 80MHz~800MHz 800MHz~2.5GHz P is the maximum rated power output of the transmitter in Watts (W) provided by transmitter manufacturer. d is the recommended separation distance in meters (m). As field strength from fixed RF transmitters is determined by an electromagnetic site survey a, therefore it should be less than the compliance level in each frequency range. Interference may occur near the |
| | | | therefore it should be less than the compliance level in each frequency range. Interference may occur near the device marked by the following |
| | | | symbols. |

Note 1: At 80MHz and 800MHz frequency, adopt formula of higher frequency range.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.

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 taken into consideration. If the measured field strength in the location where LX 16 Plus is used exceeds the applicable RF compliance level above, the 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 LX 16 Plus.

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

10.6 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

LX 16 Plus is intended for being used in electromagnetic environment where radiated RF disturbances is controlled. As per the maximum power output of communication device, the customer or user of LX 16 Plus can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication device (transmitter) and LX 16 Plus recommended below.

| Maximum rated power output of | Separation distance according to frequency of transmitter/ | | | |
|-------------------------------|--|--------------|---------------|--|
| transmitter/ W | | 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.



- 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 Systems are in compliance with related operating procedures of electromagnetic compatibility.

11 Symbols

| WOODPECKER | Trademark | ③ | Follow Instructions for Use |
|--------------|------------------------------------|---------------------|--------------------------------------|
| | Manufacturer | M | Date of manufacture |
| † | B type applied part | | Use indoor only |
| SN | Product serial number | X | Products comply with WEEE directive |
| IPX0 | Ordinary equipment | DC 15V | 15V Direct current input |
| (1) | Power switch | | Avoid exposed to rain |
| -20°C | Temperature limitation for storage | 93% | Humidity limitation for storage |
| 70kPa 106kPa | Atmospheric pressure for storage | 134℃ ∫ ∫∫ | Sterilization under high temperature |
| | Caution! Avoid scalding | | Fragile items, handle with care |
| | Laser radiation warning | 1 | Safety warning sign |

| 1 | Connect remote control interlock | <u> </u> | Tip of handpiece emits laser |
|--|--|----------|------------------------------|
| CAUTION VIBBLE AND RVISBLE LASER RADIATION. AVOID BYE OR BAIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT | When using the device, 4 types of laser radiation can be generated. | | |
| Laser Stop | "Laser Stop" button; if there is emergency situation, press this button. | | |

12 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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