iPALM-9B
Medical Diode Laser Systems
Operating Manual
<table>
<thead>
<tr>
<th>1. Model</th>
<th>iPALM -9B, 980nm, 9W</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Serial number</td>
<td></td>
</tr>
<tr>
<td>3. Software version</td>
<td></td>
</tr>
<tr>
<td>4. Date of sale</td>
<td></td>
</tr>
<tr>
<td>5. Manufacturer</td>
<td>Wuhan Gigaa Optronics Technology Co., Ltd.</td>
</tr>
<tr>
<td></td>
<td>Add.: 5, 6/F, Unit A, B, Building B8, Hi-Tech Medical Device Industrial Park, #818 Gaoxin Avenue, East Lake Development Zone, Wuhan 430206, China</td>
</tr>
<tr>
<td></td>
<td>TEL.: +86-27-6784 8871</td>
</tr>
<tr>
<td></td>
<td>FAX: +86-27-6784 8873</td>
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<tr>
<td></td>
<td>EMAIL: <a href="mailto:info@gigaalaser.com">info@gigaalaser.com</a></td>
</tr>
<tr>
<td></td>
<td><a href="http://www.gigaalaser.com">www.gigaalaser.com</a></td>
</tr>
<tr>
<td>6. European Representative</td>
<td>Company: Lotus Global Co., Ltd</td>
</tr>
<tr>
<td></td>
<td>Add: 1 Four Seasons Terrace, West Drayton, Middlesex, London, UB7 9GG, United Kingdom</td>
</tr>
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<td>Tel: +0044-20-75868010, +0044-20-70961611</td>
</tr>
<tr>
<td></td>
<td>Fax: +0044-20-79006187</td>
</tr>
</tbody>
</table>
Medical Laser Professional

Medical Device: iPALM-9B, 980nm+-10nm/ 9W, 400µm

We herewith declare that the above mentioned product meet the essential requirements of the Annex II of the Directive 93/42/EEC and is classified subject to Annex IX rule 9 as a medical device of Class IIb.

The product is designed in conjunction with the following safety standards:


EN 60601-1:2006 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.


EN 60601-1-6: 2010 Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability


This declaration is based upon a Quality System meeting the requirements of EN ISO 13485:2012, EN ISO 13485:2012/AC: 2012.

Notified Body: TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431, Nürnberg, Germany

CE 0197

Our expected sales countries are the European Union. This manual is only for EU-English speaking countries. We will prepare the local language for the non-English speaking countries.

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GA/QRCE-M-iPALM-9B
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GA/QRCE-M-iPALM-9B
1 Introduction

Thank you for using the iPALM-9B Medical Diode Laser Systems.

“iPALM-9B” is class 4 laser. Care is required to avoid hazards or injuries. Please read the operation manual carefully before operating. If you have further questions which are not answered by this manual regarding safety, application or operating of the device please get in touch with GIGAA (See sales and service information, paragraph 13) or your local distributor.

The intended use of Medical Diode Laser Systems “iPALM-9B” is to adjust blood circulation, improve nutrition metabolism, improve immune function, regulate the nervous system function, promote tissue repair, thus eliminating pathogenic factors and improving the pathological process to achieve the effect of treatment. This device can be specifically used for the treatment of bone pain, muscle pain, soft tissue pain, neuralgia, pain and wound incision pain, frozen shoulder, soft tissue sports injuries, acute lumbar sprain, rheumatoid arthritis, knee disease, skin ulcers, cervical spondylosis, acute and chronic pain, tissue repair and other diseases which need physiotherapeutic rehabilitation.

1.1 Copyright

The appearance, the fiber-coupled technology, control software and other related parts are parts of the GIGAA’s copyright with all rights reserved. Any person or company will bear legal liability for counterfeit.

Under the copyright laws, this manual cannot be copied in whole or in part without the express written permission of GIGAA. Permitted copies must carry the same proprietary and copyright notices as were affixed to the original.

The manual will be updated with the continuous modifications and upgrade for the device.

1.2 Warnings and safety precautions

Visible and Invisible Laser Radiation
Avoid Eye or Skin Exposure to Direct or Scattered Radiation
CLASS 4 LASER PRODUCT

DIODE LASER 980 +/-10nm cw 9W
DIODE LASER 650 +/-10nm PWM 4mW (max)

WARNING: Always wear protective eyewear when using this unit.

The optical power output from this system can cause severe eye damage or other injuries. Always wear protective eyewear when using this unit. Exercise extreme caution to prevent injury.

This equipment is intended for use by trained physicians or scientists only, and should only
be operated by qualified personnel who have familiarized themselves with the operating parameters of this product prior to use.

The “iPALM-9B” is a class 4 laser according to Directives EN 60825:2007.

A class 4 laser is hazardous to the eye from both direct beam and diffuse reflection of the beam. It also represents significant skin and fire hazards.

⚠️ Danger!

Do not use the unit near flammable anesthetics or other flammable substances.

Avoid eye or skin exposure to direct or scattered radiation. Take all necessary precautions in areas in which the laser is being used.

Near infrared light (980nm) from the “iPALM-9B” passes through the transparent components of the eye and is focused on the retina at the back of the eye. This can cause an accidental retinal burn.

Only protective glasses designed for protection from cw-diode laser radiation at a wavelength of 980nm +/-10nm with an optical density of OD ≥ 4 should be used. Glasses not designed to this specification are not suitable for eye protection. Suitable glasses are available from your Gigaa Laser representative.

⚠️ Attention!

Do not stare into the aiming beam or view the aiming beam directly through optical instruments. Avoid direct exposure to the aiming beam.

Avoid placing reflective material, such as metal and glass, into the beam.

⚠️ Attention!

Accidental irradiation to other than the target tissue may result in laser burn.

⚠️ Attention!

The “iPALM-9B” is only to be used in combination with specified application and light delivery systems appendant to the device.

⚠️ NOTE:

A minimum distance of 25 cm should be maintained between the ventilation slots and the walls.

To prevent the risk of electrical shock, do not remove the cover. All servicing should be done by Gigaa Laser or by qualified personnel authorized by Gigaa Laser. After the end of
guarantee period servicing can also be done by sufficiently qualified persons.

The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual.

Separate the unit from power supply before cleaning and disinfecting.

**Caution!**

*Use controls or adjustments or performing procedures other than those specified in this manual may result in hazardous radiation exposure.*

1.3 Vigilance

*Gigaa Laser* maintains a procedure to review the experience gained from devices in the post-production phase and to implement any necessary corrective action. This medical device vigilance system is designed to improve the protection of the health and safety of patients, users, and others by reducing the likelihood of the same type of adverse incident recurring. This will be achieved by the evaluation of reported incidents, and where appropriate, the dissemination of information to prevent repetitions, and/or alleviate the consequences.

Organizations and individuals involved in the purchasing of medical devices and in the provision of health-care should be aware that their co-operation is vital in providing the first link in the Vigilance chain. This includes organizations and individuals responsible for providing calibration and maintenance of medical devices.

The following incidents should be reported to *Gigaa Laser* immediately upon them becoming known:

Any malfunction or deterioration in the characteristics and/or performance of a device, or inadequacy in the labeling or instructions for use, which led to or might have led to:

- Death of a patient or user
- Serious deterioration in the state of health of a patient or user

Reports should be made to the following:

5, 6/F, Unit A, B, Building B8, Hi-Tech Medical Device Industrial Park, #818 Gaoxin Avenue, East Lake Development Zone, Wuhan 430206, China

Tel.: +86-27-6784 8871
Fax: +86-27-6784 8873
Email: info@gigaalaser.com
2 Theory and technical information

Diode laser is a kind of laser with semiconductor as working material. It consists of working material, cavity resonator and power source.

The diode laser for this unit is GaAlAs diode bar, and the wavelength is 980nm. It features impact structure, high efficiency and long lifetime. Generally the beam shall be shamed as the big beam divergence of the laser from the diode. With the GIGAA’S unique fiber-coupling technology, the laser beam can be coupled efficiently into the fiber.
3 Transportation and Storage

3.1 Information on the packaging

**NOTE:**
Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Up Arrow]</td>
<td>This end up.</td>
</tr>
<tr>
<td>![Umbrella]</td>
<td>Keep away from moisture.</td>
</tr>
<tr>
<td>![Not Turning]</td>
<td>Don’t turn over.</td>
</tr>
<tr>
<td>![Temperature]</td>
<td>Temperature extremes.</td>
</tr>
<tr>
<td>![Glass]</td>
<td>Fragile – handle with care.</td>
</tr>
<tr>
<td>![Cross]</td>
<td>Not to be stowed under other cargo.</td>
</tr>
</tbody>
</table>

The “iPALM-9B” should only be transported and stored in its original container to prevent damage. The drastic shaking during the transportation should be prohibited. Also please don’t throw or beat the device.

The device should avoid any contamination of acid, alkali or caustic material. Protect it from direct exposure under the sun or the rain.

3.2 Transportation and storage conditions

The ambient air has to be dry (less than 80%) and clean. The temperature ranges from 0°C to 55°C, and the atmospheric pressure ranges from 500hPa to 1060hPa.
4 Installation

4.1 Unpacking and installation

In most of the cases the device should be unpacked and installed by GIGAA or one of the representatives who is responsible for the tests and inspections on the spot.

The product is well packed before transportation. Please do check carefully whether there’s any damage to the package after you receive it.

When unpacking, please check whether all the items are inside according to the packing list and save them with care, for them will be in demand when you return the product to GIGAA. If you have any questions, please contact GIGAA or authorized distributor immediately.

4.2 Requirements to the Room

The use of a medical Class 4 laser requires warning logos on the unit itself and clear markings at the entrances to the room. Please refer to the information below for further instruction.

4.2.1 Labelling of the Entrance

Each entrance door has to be marked clearly so that from the outside the laser room can be recognized immediately.

- A laser warning logo with laser wavelength information must be put up on all entrance doors.
- Each entrance door has to be equipped with a warning light. Every time the laser is switched on the warning light has to come on and be illuminated to the outside.
- Entering the room is strictly prohibited while the laser is in use.

4.2.2 Laser protection at windows

During treatment, it is important that no laser light can escape from the room. All openings to the exterior of the laser room including windows must be properly secured to prohibit the escape of laser beams. If you need information or help in designing the room please get in touch with GIGAA or your local distributor.

4.2.3 Protection against high reflective Surface

To avoid any direct or indirect scattered radiation from the laser beam, no highly reflective material should be found in the treat room. This includes mirrors, picture frames, polished chromium surfaces and windows. All such surfaces have to be removed or protected by non-reflective material.
4.3 Safety indicators

Safety indicators must be affixed to all entrances, exits and places, including windows, from where the laser or laser radiation could escape.
5 Safety Tips and Technical Acceptance

5.1 General

The “iPALM-9B” is a precise medical laser device and can only be used for medical application. The system has been thoroughly developed and will be thoroughly tested before shipment. To enjoy your product through the lifetime and to protect you and your personal from laser radiation we recommend reading this chapter very carefully. In addition, the person to operate the unit should get relative professional training before using.

The “iPALM-9B” is classified as class 4.

Class 4 describes only high energy lasers and therefore needs certain precautions before switching on the system to allow a safe and trouble free operation. Additional we high recommend not using any flammable close to the laser.

⚠️ Caution!

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

5.2 Eye Protections

⚠️ Attention!

Do not look into the laser beam or reflected or scattered light of the laser beam. Never look directly into the output of the laser aperture. Otherwise damages of the retina could occur.

To avoid any eye injuries, in the treat room where safety goggles placed has to be clearly marked. All the people including patients have to wear safety goggles as soon as the laser is turned on.

Different safety goggles for corresponding wavelengths are available to protect the eyes. If you have further questions about safety goggles please get in contact with GIGAA or your local distributor.

5.3 Electrical Protection

- Opening the device to repair or maintain should only be carried out by certified person from GIGAA or the distributors. GIGAA will not take any responsibility if any other person opens the device without the approval of GIGAA or the distributors.

- “iPALM-9B” Medical Diode Laser Systems has already been set limitation of current before shipment so as to prevent the dangerous output in a non-normal condition.

- The room where the device will be used should be clean and dry. Please make sure
that there is no water drop or water vapor when the device is turned on.

![Attention!]

Do never attempt to work with the laser when a failure code is displayed and please get in contact with GIGAA or the distributors.

5.4 Fire Hazards

![Danger!]

Do not work with the device and the laser beam close to flammable, anesthetic or any other solvents which are easily flammable. Remove the paper and plastics from the laser working area. Within a certain distance, these materials absorb considerable energy can be ignited.

When the laser is not in use or patients are changed or a break in the treatment occurs please turn the device into “stand-by” status. At this mode the laser cannot be activated by the laser output button.

5.5 Main Switch

The main switch of the unit is a power switch at the top of the device. Turning the main switch to “\(\bigcirc\)” position then release the switch, the system will boot. Then the system will perform a self-check. After inputting the password, you can enter into the main operate interface.

5.6 Manual Reset

Any improper function of the system will immediately cut the voltage supply to the laser and the complete unit is switched off. To restart the unit just turn the main switch to “\(\bigcirc\)” position and release the switch. If the failure shows up repeatedly, please contact GiGAA or the distributor at once.

5.7 Safety Signs

Danger for laser

Laser output window

External interlock connector on
Laser Touch detector B type device Refer to operate manual

Manufacturer Product nameplate Safety mark

European Representative
6 Environmental protection

“iPALM-9B” will not generate any wastes during the normal use. When scrapping, the host can be disposed as the conventional electric products.
7 Clinic indications

The intended use of Medical Diode Laser Systems “iPALM-9B” is to adjust blood circulation, improve nutrition metabolism, improve immune function, regulate the nervous system function, promote tissue repair, thus eliminating pathogenic factors and improving the pathological process to achieve the effect of treatment. This device can be specifically used for the treatment of bone pain, muscle pain, soft tissue pain, neuralgia, pain and wound incision pain, frozen shoulder, soft tissue sports injuries, acute lumbar sprain, rheumatoid arthritis, knee disease, skin ulcers, cervical spondylosis, acute and chronic pain, tissue repair and other diseases which need physiotherapeutic rehabilitation.

The physician should be aware of the clinical applications for the laser when the exact therapy of the diode laser in each clinical case cannot be known clearly.

Prohibited to be applied in:

The patients who have heart trouble, psychosis, hypertensive diseases or any patient who has been proved are not suitable for the therapy of laser.
8 Product description

8.1 General Overview

The “iPalm-9B” consists of four main components:

(1) Laser system
(2) Color touch screen
(3) Dock
(4) Power adapter

The laser system consists of the fiber-coupled diode laser module, power supply, control panel, safety shutter and the embedded computer control system.

8.2 Top

At the top of the unit you will find:

(1) Laser emission and alarm indicator
(2) Power indicator
(3) Emergency stop
(4) Dock
(5) Power outlet
(6)Laser output button
(7) Main switch
(8) Color touch screen

8.2.1 Laser emission and alarm indicator

The Laser emission and alarm indicator will be red when the laser is emitting or when a system failure occurs. The action of the indicator synchronizes with the laser or system malfunction.

The laser emission and alarm indicator will still be on if the system is in an emergent or a non-normal status. At that time the system will stop all the output and the touch screen will show the error information, meanwhile the system alarms.

⚠️ **Attention!**

Press the emergency stop to terminate laser emission if the laser emission and alarm indicator constant light.

8.2.2 Power Indicator

The power indicator will be blue if the power supply of the laser is normal.

8.2.3 Emergency Stop

The emergency stop connects to the system's power supply. In the event of an emergency, pressing the emergency stop will immediately stop laser emission.

8.2.4 Dock

In order to protect the laser aperture, the device should be placed on the dock when not in use.

8.2.5 Power outlet

Power outlet must be connected with an external power supply through an adapter when in use.

8.2.6 Laser Output Button

When you press down the laser output button, the laser will emit.

⚠️ **Attention!**

The operator must wear the safety goggles (protect wavelength from 800nm to 1100nm) before laser emitting.
8.2.7 Main Switch

Turn the main switch right to position then release the main switch, the laser unit will start up.

8.2.8 Color Touch Screen

⚠️ Attention!

Do not put heavy objects or apply excessive pressure on the touch screen to prevent distorting the touch screen display. Also avoid touching the screen with sharp materials in case there’s any scratch to the surface.

Cautions have to be taken that don’t sprinkle any liquid directly on the surface of the touch screen.

The LCD touch screen of the unit features high sensitivity and high resolution. It is the man-machine interface. You can touch the icons on the screen with finger or professional pen to open the corresponding program.

8.3 Bottom

(1) Laser Aperture
(2) Touch detector
(3) Spot size adjuster
(4) FAN
9 Specifications

(Temperature is 5°C～40°C, relative humidity is less than 80%, and atmospheric pressure is 860hPa～1060hPa.)

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser type</td>
<td>GaAlAs diode laser</td>
</tr>
<tr>
<td>Model</td>
<td>iPALM-9B</td>
</tr>
<tr>
<td>Wavelength</td>
<td>980nm±10nm</td>
</tr>
<tr>
<td>Output power</td>
<td>1-9W</td>
</tr>
<tr>
<td>Operation mode</td>
<td>CW, pulse</td>
</tr>
<tr>
<td>Pulse width</td>
<td>1ms-1s</td>
</tr>
<tr>
<td>Pulse repetition rate</td>
<td>1Hz-500Hz</td>
</tr>
<tr>
<td>Aiming beam</td>
<td>Red diode laser of 650nm, power&lt;5mW, adjustable brightness.</td>
</tr>
<tr>
<td>Operation interface</td>
<td>Color LCD touch screen, 3.5”</td>
</tr>
<tr>
<td>Power supply</td>
<td>100V-240V, 47-63Hz, 2.0A</td>
</tr>
<tr>
<td>Laser Class</td>
<td>4</td>
</tr>
<tr>
<td>Safety classification</td>
<td>Class I Type B</td>
</tr>
<tr>
<td>Cooling</td>
<td>Air</td>
</tr>
<tr>
<td>Dimensions</td>
<td>120(W)*280(L)*102(H)mm</td>
</tr>
<tr>
<td>Weight</td>
<td>700g</td>
</tr>
<tr>
<td>Waterproof level</td>
<td>IPX1</td>
</tr>
<tr>
<td>Safety Compliance</td>
<td>CE 0197</td>
</tr>
</tbody>
</table>
10 Operating the Instrument

⚠️ Attention!

The “iPALM-9B” should only be operated by a physician who has been instructed in the use of the instrument during installation.

This part of the manual only describes the technical use of the instrument without detailing the medical use.

10.1 Introduction

To guarantee a faultless operation of the device during treatment the following requirements have to be met:

- The device has already been plugged into electricity.
- The safety goggles are available for the people in the room.
- The emergency stop has already been popped out.

10.2 Starting of the Unit

To start the laser unit, turn the main switch right to position then release the switch. Immediately the power indicator will be blue with the system fans working. At the same time, the LCD screen lights up as the picture shows below.
10.3 Password inputting

After showing the information, the system will turn into the password input interface. You must input password before entering into the system, the password is 4 numbers from 0 to 9 and the initial password is “0000”. (You can modify password on Device Setting interface which will be explained later). If you forget your password, hold on the laser emission button for about 5 seconds, the unit will directly enter the self-check interface.

10.4 Self-check

After inputting the right password, the system will perform a self-check. If there are problems during startup, the system will inform you at the display about the problems. System needs several seconds to setup.
10.5 Therapy settings and programs

10.5.1 Main menu

When finished setting the protocols parameter, press “OK” button (in Picture 9), the system turns into the main menu.

(1) Laser output sign. When there is laser output, the icon turns to red.

(2) Touch detector

(3) Timer on

(4) Sound on

(5) Aiming beam on

(6) Battery power (optional)

(7) The display of laser emission mode

(8) Frequency

(9) Reset the energy

(10) The remaining treat time

(10) The selected proposals

(11) Standby/Ready

(12) Parameter settings

(13) Device settings
(14) Laser power
(15) The selected proposals
(16) Total energy
(17) Aiming beam intensity
(18) Menu-turning to the human menu page
(19) Help message or alarm message

10.5.5.1 Reset the total energy

When laser working, the energy is summated. The total energy ranges from 0 to 99999J. If you want reset the total energy please press the reset button. When the total energy is more than 99999J, it will back to 0 automatically.

10.5.5.2 Adjust aiming beam

Adjust density of the aiming beam. [+ ] is increase and [-] is decrease.
There are 7 levels of the aiming beam from 0 to 6. When the level is selected, it turns blue, otherwise it is gray. If the aiming beam level is 0, it means that the aiming beam is closed.
At the main menu, the item 5 (aiming beam on icon) is active only when the value is more than 0.

⚠️ Attention!

Only in Ready status, you can see the density of the aiming beam. In standby status you can adjust the density, but can’t see it.

10.5.5.3 Standby and Ready

When you press the Ready/Standby button, it changes from a status to another status.
Standby: in this status, the laser power supply is disabled. When you press the laser output button, it can’t send out laser.

Ready: in this status, the laser power supply is enabled. When you press the laser output button, it can send out laser.

10.5.2 Proposal Menu

In this interface there are Head/Upper Limb/Upper Body/Lower Body/Lower Limb/Foot 6 items can be chosen. Each item correspond to a series of pre-set proposals. When selected, the icon will turn light and you will enter into the corresponding interface.

: Back icon--back to the main menu.

: Info icon--turn into info page as below:
Corresponding proposal page:

<table>
<thead>
<tr>
<th>Head</th>
<th>Upper Limb</th>
<th>Upper Body</th>
<th>Lower Limb</th>
<th>Foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine</td>
<td>Lateral Epicondylitis</td>
<td>Myofascitis</td>
<td>Trochanteric Bursitis</td>
<td>Arthritis</td>
</tr>
<tr>
<td>Tension Headache</td>
<td>Soft Tissue Strains/Strains</td>
<td>Degenerative Osteoarthritis</td>
<td>Degenerative Osteoarthritis</td>
<td>Hallux Valgus</td>
</tr>
<tr>
<td>Trigeminal Neuralgia</td>
<td>Facet Joint Syndrome</td>
<td>Compression Fractures</td>
<td>Capsulitis / Synovitis</td>
<td>Turf Toe</td>
</tr>
<tr>
<td>Bell's Palsy</td>
<td>Neuropathic Pain</td>
<td>Kyphosis</td>
<td>Trauma / Sprains &amp; Strains</td>
<td>Metatarsalgia</td>
</tr>
<tr>
<td>TMJ</td>
<td>Cervical Spondylosis</td>
<td>Neuropathic Pain</td>
<td>Pinformis Syndrome</td>
<td>Plantar Fasciitis</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>User Defined</td>
<td>Muscle Strains/Sprains</td>
<td>Fractures</td>
<td>Plantar Strain</td>
</tr>
</tbody>
</table>

- **Head**: Migraine, Tension Headache, Trigeminal Neuralgia, Bell's Palsy, TMJ, Sinusitis
- **Upper Limb**: Lateral Epicondylitis, Soft Tissue Strains/Strains, Facet Joint Syndrome, Fibromyalgia, Neuropathic Pain, Cervical Spondylosis, User Defined
- **Upper Body**: Myofascitis, Degenerative Osteoarthritis, Compression Fractures, Kyphosis, Neuropathic Pain, Muscle Strains/Sprains
- **Lower Limb**: Spinal/Foraminal Stenosis, Disc Herniation With Radiculopathy, Facet Joint Syndrome, Sacroiliac Joint, Lumbar, Spondylosis, User Defined
- **Lower Limb**: Trochanteric Bursitis, Degenerative Osteoarthritis, Capsulitis / Synovitis, Trauma / Sprains & Strains, Pinformis Syndrome, Fractures
- **Foot**: Arthritis, Sprained Or Strained Ankle, Degenerative Osteoarthritis, Tarsal Tunnel Syndrome, Morton's Neuroma, Fractures/ Stress Fractures

Version: V2.0
10.5.3 Device settings

In main menu interface pressing “Device Settings” icon 🔄, you will go into device setting interface. In this interface, you can set the speaker sound, LCD back light, select options you need, reset factory settings and modify your password. In this interface by pressing back icon, you can back to the main menu.

🔄: Reset factory setting

กด: Modify password.

←: Back icon--back to the main menu with parameters unchanged.

✅: OK icon--confirm the parameters and go to the main menu.
10.5.4 Parameter settings

In main menu interface pressing “Device Settings” icon, you will go into parameter setting interface. In this interface, you can set the power value, frequency value and select emission mode.

CW - continuous laser output
Pulse: press the footswitch, multiple pulses laser out

Back icon--back to the main menu with parameters unchanged.
OK icon--confirm the parameters and go to the main menu.
Timer icon--turn into timer setting page as below:
10.6 Laser Emission

After finishing setting the parameters, press the “Ready” button in main menu and then the system will remind you to wear the safety goggles (protect wavelength from 800nm to 1100nm). At this time when you press down the laser output button, the laser will emit.

10.7 Turning off the unit

To turn off the laser unit, turn the main switch right to position then release the switch, meanwhile the screen will show the warning as the following:

Press “OK” button to insure turning off the unit, at the same time the LCD screen lights off.
11 Warnings

If there are problems during your using of the unit, the system will inform you by appearing warning interface on the screen, and also give some advice against the problem. Basically there may be 3 kinds of problems:

1) “Window temperature is high!”
   At this time you can wait for the temperature cooling down, the system will be back to normal. Or you can just turn off the power and reboot the unit.

2) “LD temperature is high!”
   At this time you can wait for the temperature cooling down, the system will be back to normal. Or you can just turn off the power and reboot the unit.

3) “Power supply error!”
   When this warning appears on LCD screen, you should turn off the power immediately, and then check the power supply.
WARNING

Power supply error!

Please turn off the power!
# 12 Failure Detection

<table>
<thead>
<tr>
<th>Problem</th>
<th>Eventually Cause</th>
<th>Problem Solving</th>
</tr>
</thead>
<tbody>
<tr>
<td>When put on the main switch, the unit does not start, and the power indicator is off</td>
<td>1) “Emergency Stop” button is pressed 2) The fuse is burned</td>
<td>1) Turn the “Emergency Stop” button back to the normal position 2) Take off the power line to cut off the power, and check the fuse.</td>
</tr>
<tr>
<td>Alarm information on the screen</td>
<td>See Chapter 11</td>
<td>See Chapter 11</td>
</tr>
<tr>
<td>TEMPERATURE is HIGH</td>
<td>Temperature more than 35℃</td>
<td>Stop the laser and wait for a few minutes</td>
</tr>
<tr>
<td>TEMPERATURE is LOW</td>
<td>Temperature less than 10℃</td>
<td>Make room temperature more high</td>
</tr>
<tr>
<td>POWERSUPPLY ERROR</td>
<td>Laser current too high</td>
<td>The Laser current is high</td>
</tr>
<tr>
<td>Remote INTERLOCK</td>
<td>Not connect the interlock</td>
<td>Connect the interlock</td>
</tr>
<tr>
<td>MOSFET temperature is high</td>
<td>MOSFET temperature is high</td>
<td>Stop the laser output</td>
</tr>
<tr>
<td>no electricity when opening the laser</td>
<td>not plug in the external power</td>
<td>plug in the external power</td>
</tr>
<tr>
<td>no electricity when opening the laser</td>
<td>Press down the emergency stop switch</td>
<td>Turn around clockwise, pop-up the emergency stop switch</td>
</tr>
<tr>
<td>no electricity when opening the laser</td>
<td>The inner power supply has no output</td>
<td>Check the supplied pressure and the required pressure</td>
</tr>
<tr>
<td>no electricity when opening the laser</td>
<td>The inner power supply has no output</td>
<td>The power supply have already destroy, must sent back the system to GIGAA</td>
</tr>
<tr>
<td>can not start up, no display</td>
<td>the screen wire break off or the data wire fall off</td>
<td>take apart the machine to check the the screen wire and the data wire</td>
</tr>
<tr>
<td>can not start up, no display</td>
<td>The control board cannot output</td>
<td>The control board broken, send back to GIGAA</td>
</tr>
<tr>
<td>no aiming beam</td>
<td>The intensity is too low</td>
<td>The take aim light broken, send back to GIGAA</td>
</tr>
<tr>
<td>no aiming beam</td>
<td>The laser keeps standby situation</td>
<td>Only the laser is in the preparative situation, people could see the light</td>
</tr>
<tr>
<td>no aiming beam</td>
<td>The diode laser problem</td>
<td>Contact GIGAA</td>
</tr>
<tr>
<td>no aiming beam</td>
<td>The aim beam status is “OFF”</td>
<td>Set aim beam status to “ON”</td>
</tr>
<tr>
<td>no aiming beam</td>
<td>The diode laser output lens in the SMA connector is destroyed</td>
<td>Contact GIGAA</td>
</tr>
<tr>
<td>has take aim light, no laser light</td>
<td>Foot switch didn't insert in</td>
<td>Check if the switch connected well</td>
</tr>
<tr>
<td>Condition</td>
<td>Possible Cause</td>
<td>Action</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Has take aim light, no laser light</td>
<td>Something wrong with the laser output button</td>
<td>Check the laser output button</td>
</tr>
<tr>
<td>No aiming beam, no laser light</td>
<td>Something wrong with the fiber part</td>
<td>Contact with GIGAA</td>
</tr>
<tr>
<td>No aiming beam, no laser light</td>
<td>Something wrong with the laser output button</td>
<td>Check the laser output button</td>
</tr>
<tr>
<td>Have aiming beam, but no laser light</td>
<td>Something wrong with the foot switch</td>
<td>Replace the foot switch of the same model</td>
</tr>
<tr>
<td>Have aiming beam, but no laser light</td>
<td>Diode laser module is destroyed</td>
<td>Contact with GIGAA</td>
</tr>
<tr>
<td>The alarm info. appears</td>
<td>Checked the temporary failures</td>
<td>Restart the laser to see if still failure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If still failure, to read the info.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Description, analyse the reason or contact GIGAA</td>
</tr>
</tbody>
</table>
13 Maintenance

“iPALM-9B” is precise medical instrument and should only be maintained by professional engineer authorized by GIGAA.

(1) When the fiber is removed, please cover the aperture with protective hat. The protective hat should be cleaned by alcohol in advance.

(2) Don’t touch the screen with hard or sharp materials. Don’t scrub the screen with reagent. You can clean it softly with soft tissue.

(3) The unit should avoid drastic shaking and hitting during movement.

(4) The laser output power is yearly calibrated by professional engineer from GIGAA.
14 Service

➢ Provide professional training about laser and clinic.
➢ Quick response within 24 hours, readily available accessories and equipments.
➢ Regular maintenance and technique support on the spot.

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