Platinum Laser System
User Manual

K-laser USA, LLC

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Instructions Before Use

Thank you for using the Platinum Laser System！

When receiving this product, please check the integrity of the packaging. Refer to the packing list and check the product components and their quantity. If there are any packing damage, equipment damage or component missing, please contact our sales personnel or dealer for replacement.

In order to serve you better, please confirm the packaging in good condition and check the product set, fill out the product receipt, the user file form and training records, and return to the company promptly.

It is recommended that users receive train before use, and read the instructions, and have the relevant security measures to avoid the damage on the human body and equipment that caused by the possible harmful laser radiation in the course of use.

The company will not be liable for any personal injury or damage to equipment caused by the failure to follow instructions in the course of use.

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1 Introductions

The Platinum Laser System is a therapeutic laser product for relieving mild muscle pain and joint pain.The product uses intelligent human-computer interaction system, which is committed to clinicians and patients to bring a safe and effective treatment experience.

1.1 Model / Specifications and Divide Instructions

P4

1.2 Device Description

The Platinum Laser System is a Class IV laser product that uses GaAlAs semiconductor lasers as energy sources to deliver laser energy to the treatment area by an optical path transmission system. The optical transmission system is composed of a flexible fiber connected to the laser source and handle switch, SAM905 coupler. Clinicians set reasonable treatment parameters according to the patient's condition and treatment, click the hand-held switch to start treatment.

Platinum Laser System has the following characteristics in the alleviation and treatment of pain:

- To provide a non-invasive treatment for patients with tissue pain, muscle strain using laser irradiation.
- With a stronger tissue penetration, 980nm diode laser can be more in-depth role in the patient's tissue, significantly alleviate and improve local pain, muscle strain and other symptoms.
- There are continuous output mode and pulse output mode. With continuous mode, the maximum output power is 24W which can provide doctors a variety of effective treatment options.
- With intelligent human-computer interaction system and the internal tutorial video screen, the interface is more clear and the operation is more simple to facilitate medical operations.
- Provide a variety of security reminding function, to facilitate the safe and effective use of this product.

2 Indications

The Platinum Laser System as laser devices for medical application intended to alleviate musculoskeletal pain, osteoarticular diseases and laser acupuncture.

3 Contraindications

People with the following symptoms are disabled:

- Melanoma, precancerous lesions
- Pregnancy response of the crowd
- Patients with acute hemorrhagic disease
- Thyroid disease
- Cutaneous tuberculosis
- Active bleeding
- Cardiopulmonary and renal failure
- Pre - stroke symptoms
- Acute inflammation associated with sepsis symptoms

4 People with caution

- Light sensitive populations
- Patients with local or major anesthesia, heart disease, pulmonary disease, hemorrhagic disorder, sleep apnea, immunocompromised patients
- Do not accept laser treatment psychologically, do not meet the doctor's treatment

5 Adverse Reactions

In the course of treatment, doctors should pay attention to the treatment of patients with the treatment site and treatment of skin conditions, adjust the corresponding parameters or move the handpiece to adjust the energy convergence according to treatment.

- In the course of treatment, due to laser irradiation tissue, the treatment site of the blood circulation will accelerate, there may be skin redness phenomenon. In conventional treatment, reddening of the skin is normal reaction.
- In the course of treatment, when laser irradiation site appears hot phenomenon, appropriately move the laser treatment handpiece away from the treatment site to reduce the energy convergence; or by setting the treatment parameters to reduce the laser output power.
- In the course of treatment, treatment should be immediately stopped and thermal burns treatment must be done when the treatment site of skin burns, blisters ,etc.

WARNING: The treatment parameters should be set according to the patient's condition and clinical diagnosis. And in the course of use, make the appropriate protective measures, operating the device safely and effectively in strict accordance with the contents of the instructions. Otherwise, injury or damage to persons or device may be caused.

6 Specifications

Model	P4
Laser Classification	Class 4
Laser type	GaAlAs
Operation mode	CW/Pulsed
Wavelength(Working)	650±20nm,810±10nm,915±10nm,980±10 nm
Max Output power	200mW,8W,8W,8W
Wavelength(Indication)	650±20 nm
Max Indication power	＜2mW
Uncertainty for output power	≤±10%
Magnitudes of the cumulative measurement uncertainty	≤±20%
Expected increase in the measured quantities	≤±10%
Positive pulse width	0ms– 999 ms
Negative pulse width	0ms–999 ms
Transmission system	200um,400um,600um
Timer	0-3600s
Adapter input parameters	100-240VAC,50/60Hz
Main Unit input parameters	19VDC，5.8A
Battery capacity	3350mAh
Cooling Method	Air cooling
Weight	≤3KG NW
Dimensions	300 × 220 × 200 mm
Date of manufacture	See product nameplate
Validity Period	5 years
Divergence Angle	25°

7 Safety Warnings

Platinum Laser System is a Class 4 laser product. During use and maintenance, do not look into the laser or direct beam to avoid irreversible damage to the eyes. For this reason, some safety precautions must be observed when using this product as follows. Otherwise, it may cause personal injury or damage to equipment.

7.1 Requirements to the Room

7.1.1Requirements to the entrance

Platinum Laser System is a Class 4 laser product. Each entrance door has to be marked clearly with a laser warning logo.

- A laser warning logo with laser wavelength information must be put up on all entrance doors, preventing anyone from entering the room when the laser is emitted and being exposed to laser radiation.
- 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.
- Interlock shall be installed at each entrance and connected to the remote interlocking connector on the rear panel of the device. When the door is opened, the device can not emit laser.

7.1.2 Laser radiation protection at windows

All openings to the exterior of the laser room including windows must be properly secured to prohibit the escape of laser beams, resulting in danger.

7.1.3 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 treatment room. This includes mirrors, picture frames, polished chromium surfaces and windows. All such surfaces have to be removed or protected by non-reflective material.

7.1.4 Warning Labels of the Entrance

A laser warning label must be put up on all openings to the exterior of the laser room including windows.

7.1.5 Fire Hazards

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 “Standby” status or just switch off the device.

7.2 Warnings for patients, operators and other personnel

It is strongly recommended that users receive related training and carefully read the instructions to be familiar with the basic operation and safety regulations before use.

- Nominal Ocular Hazard Distance (NOHD)： NOHD identifies the beam irradiance or the amount of irradiation is equal to the distance of the maximum permissible exposure (MPE) of the cornea. The product has a NOHD of 3.43Km. In other words, in the absence of any defensive situation, the distance between the human eye and the laser emission point must exceed 3.43Km.
- Laser direct radiation or scattered radiation can cause irreversible damage to the cornea, retina, and skin tissue. All Individuals present during the operation of this device must wear protective goggle with an optical density of 5.0 or greater at 980nm wavelength.
- Never attempt to view the laser beam or the indicator light along an optical path with eyes or with optical device, which may cause irreparable damage to the eyes.
- Do not remove the protective goggles until the operator returns to the standby mode.
- In the course of use, do not move the laser irradiation area to an unspecified treatment site.
- In the course of treatment, a minimum distance of 3cm should be maintained between the laser output handpiece window and the patient's skin. And the treatment time is generally 3-5 minutes. In the course of treatment, the doctors must always pay attention to the treatment of patients to avoid skin redness, burning and other adverse reactions.
- When connecting or removing the handpiece, make sure that the device is in standby mode or switched off.
- Do not place the laser in READY mode to avoid unnecessary hazards in standby mode.
- Do not allow non-personnel to enter the treatment area during laser treatment to avoid any laser radiation.
- Do not wear any reflex jewelry or items during treatment. Avoid scattering or reflecting laser energy that may cause damage to eyes or skin.
- The handpiece must be placed in the working area of the medical personnel who is responsible for the treatment and only can be operated by full-time personnel.
- Users should wear medical plastic gloves, use alcohol (or lens paper) to clean the probe end and handpiece until the alcohol is completely evaporated before using the device.
- When the laser device is not being used, please turn off the power switch and remove the key to prevent non-designated personnel or unauthorized persons from operating the device.
- When the device is working, if there is any abnormality (such as crash, no display, light abnormality, etc.), press the emergency stop switch immediately

and turn off the device. To identify the reasons before deciding whether to operate. If necessary, please contact the designated dealer or K-Laser for help.

- If the device does not work properly, please contact the company or dealer for consultation immediately. Do not disassemble the device without guidance or permission by unauthorized persons to avoid the serious, irreversible harm on human body and device that caused by the possible electric shock.
- No strong pull, extreme bending fiber in the course of the use. Failure to do so may cause a loss of laser transmission efficiency, which may result in a decrease in the therapeutic effect. In severe cases, fiber breakage may damage the optical transmission system or cause unknowable damage to the user (or patient).
- It is strongly recommended that the device be inspected and maintained regularly.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

7.3 Safety warnings pertaining to the operation of the equipment

7.3.1 Warnings

- Please choose a well-ventilated location for device installation. A minimum distance of 20 cm should be maintained between the ventilation slots and the walls to avoid the temperature rise. Otherwise, the treatment instrument could not work, or even damage to the laser would be caused.
- Strong electromagnetic environment may affect the normal operation of device. It should also be avoided that the device is together used with other easily interfered devices.
- Unauthorized accessories (e.g handpiece, protective goggles, key switches, interlock, etc.) may cause laser radiation hazards and damage to device. Please use the related accessories specified by our company.
- Before moving or lifting the laser device, please turn off the device and protect the handpiece, fiber and the laser window with a dust cap from dust.
- Check the integrity of the beam transmission system before use： A good way to check the integrity of the transmission system is to have the aiming beam pass through the same transmission system as the working beam. If the light spot of the aiming beam is not at the end of the transmission system, or its intensity is reduced or does not appear to converge, this may indicate that the transmission system is damaged or not working properly.
- The use of flammable anesthetics or oxidizing gases must be avoided, such as nitrous oxide (N2O) and oxygen. Certain materials, such as cotton wool, are oxygen-rich and will be ignited by the high temperature generated by the laser device being use. Solvents and flammable solutions used for cleaning and disinfection should be volatilized before using the device. It should be noted that there is a risk that the internal gas may be ignited.

7.3.2 Storage and use of the environment

- The followings are the environmental conditions for the storage and use of the device.
- Storage Temperature: 0~35℃ (With packaging)
- Operating Temperature: 10~30℃
- Storage humidity: ＜80% (With packaging)
- Use ambient humidity: 30%~75%
- Operating environment：86~106kPa
- Altitude：≤2000m
- Avoid direct sunlight, rain is strictly prohibited
- Well ventilated
- Avoid storing in strong electromagnetic environment
- Avoid severe vibration
- Avoid storing in explosive, corrosive gases, excessive dust or salt of the environment

7.4 Safety Signs

The device has the following label affixed at the relevant location informing the user of the safety-related information of the device and to warn the user that the laser has a radiation hazard to avoid direct exposure or scattering of laser light to the eyes and skin.

See 14 parts of product identification and packaging instructions.

7.5 Safety functions

The Platinum Laser System provides some special safety function devices such as key switch, emergency stop switch and remote interlock. These devices are used for identification or emergency interruption, etc. All users of this product should be familiar with the purpose of these safety devices and methods of operation.

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

7.5.1 Emergency Stop

ON

OFF

As shown, the switch is located on the front panel of the SAT-G30 for emergency interruption of the laser output. When the device is working, if there is abnormal working (such as crash, no display, light abnormal, etc.), immediately press the emergency stop switch to stop the laser output. Reset the emergency stop switch to restore power to the system, at which point the laser can not emit the laser. Please reset the parameter and press the handpiece to emit the laser.

Follow the direction of the arrow on the emergency stop switch, turn the emergency stop switch or pull up the emergency stop switch to reset the emergency stop switch.

7.5.2 Remote Interlock

As shown, the remote interlock is located below the rear panel of the device. The remote interlock should normally be connected to an interlock (normally closed switch) on the entrance door of the room. And its head should be connected to the remote control interlock interface. When the door is opened, the device can not emit laser, preventing anyone from entering the room when the laser is emitted and being exposed to laser radiation.

Note: There is a red dot on the connector. Insert the interlock with the red dot facing upward as the picture shows above.

7.5.3 Indicator lights

The indicator lights are located on the right of the LCD panel for power, remingding, laser output prompts.

1) When the device is turned on, the power indicator light is green;
2) When the laser is emitting, the corresponding indicator light is yellow；
3) When the warning state occurs, the corresponding indicator light is red.

8 Installation

8.1 Check the appearance and packing items

Platinum Laser System is packed and inspected at the factory. After you receive the product, please check the box whether damage. After unpacking, please check the packing items whether complete.

#	Items	Number
1	Platinum Laser System	1
2	HandPiece	1
3	Protection Goggles	2
4	Remote Interlock	1
5	Adapter	1
6	Lithium battery	1
7	User Manual	1
8	Product Inspection Certificate	1
9	Packing List	1

Note: Please check the contents of the packing list whether complete, missing or damaged. Please contact the designated dealer or the company for replacement if the above items are found missing or damaged, or the packaging has obvious damage, crashes and so on.
WARNING: Use of non-specified accessories may cause laser radiation hazards and device damage. If the Handpiece, Fiber, Adapter, Lithium battery and other accessories are damaged or lost during use, and if you need to purchase the accessories again, please contact your designated dealer or K-Laser to purchase.

8.2 Preservation of packaging materials

Carefully save all packaging material. It is your best choice to pack these materials when you store or return them to our company for repair.

8.3 Device Installation

Note: Please install the equipment under the guidance of our authorized technician or the designated dealer.

8.3.1 Installation site and platform selection

Platinum Laser System adopts air cooling design. Please choose a well-ventilated location for equipment installation; placement platform requires a hard texture, shall not impede the air flow of the bottom of the equipment. Keep the device at least 20cm away from the wall to facilitate the operation of the power switch.

8.3.2 Remote interlock installation

The interlock (normally closed switch) shall be installed at each entrance and connected to the remote interlock connector on the rear panel of the device while the device is in operation.When the door is opened, the device can not emit laser, preventing anyone from entering the room when the laser is emitting and being exposed To laser radiation.

Remote interlock interface located above the device, the port has anti-plug design. Align the red part of the remote interlock connector with the red part of the device connector and insert the connector horizontally into the device.

Note: We recommend that the door should be closed entirely and can’t be opened from outside when the unit is in use, or it’ll terminate the therapy at once.

8.3.3 Handpiece Connection

The handpiece connection is divided into the connection of signal side and the connection of laser side:

1) The handpiece signal port is located on the front panel of the device, which has an anti-mis-insertion design. Please align the red port of the connector to the red port of the device connector and insert the connector horizontally into the device.

2) The handpiece laser port is located on the front panel of the device, when installing the handpiece, first turn the dust cap on the laser port and the dust cap on the handpiece counterclockwise, remove it and place it in the accessory bag; Gently insert the laser port and tighten the fastening nut clockwise. The port is a laser window, when connecting the laser handpiece, please turn off the device to prevent exposure to Class 4 laser radiation.

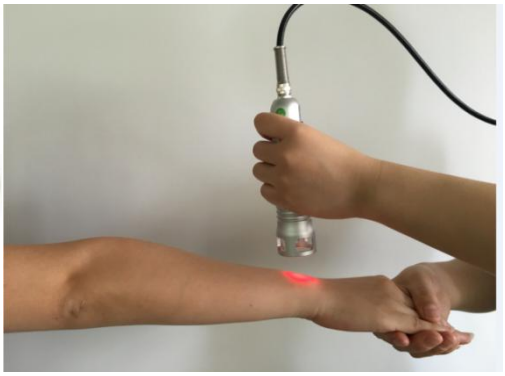
After the laser handpiece is connected with the device, try not to separate the handpiece and the laser port to prevent equipment from being damaged by dust. If separation is necessary, protect it with a dust cap as soon as possible after the separation, and do not bend the fiber tail cover during separation to prevent damage or breakage of the fiber.

WARNING: In order to avoid dust contamination, do not touch the laser port and the handpiece port by hand when connecting the handpiece, otherwise it will lead to decreased output power, burned fiber head or coupler and other issues; When connecting the handpiece or fiber into the laser port, try not to bend or improper fixation to prevent the fiber break, burn fiber and coupler. Failure to follow these procedures will lead to optical fiber and optical transmission system damage, resulting in laser radiation hazards.

8.3.4 The use of handpiece

After setting the treatment, open the indicator light and click the "STANDBY" button in the interface to enter the "READY" state. In the "READY" state, align the handpiece head with the treatment site and press the handpiece button switch to fire the laser.

In the course of treatment, the laser output handpiece window and the patient's skin should maintain a minimum distance of 3cm, and the treatment time is generally 3-5 minutes. At the same time, the treatment staff should always pay attention to treatment to avoid the patient's skin redness, burning and other adverse reactions.



During the course of treatment, please wear protective goggles. Do not look into the laser beam or reflected or scattered light of the laser beam, otherwise irreversible damage to the eyes could occur. In the course of treatment, do not remove the handpiece head to prevents the laser energy from over-irradiating the skin; Do not use the handpiece to illuminate the non-treated area.
Note: If the accessories(such as handpiece) are damaged, lost, or need to be purchased, please contact the designated dealer or K-Laser. The use of non-designated accessories will result in device not working, or damage and injury to personnel.

9 The appearance of the medical device

#	ITEM	DESCRIPTION
1	Display	Display all the operation information
2	Handpiece	Treatment Handpiece
3	Indicator	Power(Green)/Reminding(red)/Laser(Yellow)
4	Fiber Spool	Stores Fiber
5	Holder	Handpiece holder
6	Handle	For Transporting the Unit
7	Foot switch Connector Port	Connects Wired Foot switch to the Unit
8	Remote Interlock Port	Connects Interlock to the Unit
9	Circuit Breaker	Master ON/OFF Switch
10	DC Power Connector	Connects Power Supply to the Unit
11	Lithium ion battery	Back-up power
12	Fiber Port	SMA 905
13	USB Port	Software Update
14	Emergency Stop Button	Disables the device In the Event of an Emergency
15	Safety Goggles	Laser protective glasses

10 Operation Guide

There are continuous and pulse output modes in Platinum Laser System, the operator should select a reasonable treatment based on the patient's condition and treatment options.

1) When using continuous mode for treatment, it is recommended that the power setting does not exceed 3W. In the course of treatment, we recommend the use of scan treatment methods and observe the treatment at any time to prevent a long time exposure to a site, causing skin and soft tissue burns.

2) When using pulse mode, it is recommended that the operator limit the average power to within 3W with positive and negative pulse width settings.

WARNING: If the control device, regulating device or operation does not follow the prescribed method, the hazardous radiation exposure may result in injury or damage to personnel and equipment. And the control device, regulating devices include: LCD, emergency stop, key switch, remote interlock, handpiece switch, etc.

10.1 Preparations

Before starting the systems, make sure to complete the following:

- The protective goggles are available for the people in the room;
- The device has already been plugged into electricity, and the socket has a good grounding;
- The handpiece has already been connected to the laser aperture;
- The remote interlock connector has been used.

10.2 Starting of the device

1) Turn on the system main power, power indicator will be green with the system fans working. At the same time, the LCD screen lights up.

2) The system will perform a self-check.

3) After the self-test, the system enters the standby main interface.

Note: After the system is powered on, it will enter the self-test program, and the welcome interface will be showed after the completion of self-test, please be patient.

10.3 Custom treatments operation instructions

1） After the self-test completed, enter Figure 1: standby interface.

Figure 1: Standby interface

2）Click on the standby interface, enter to the power-on password input interface (Figure 2), enter the power-on PIN code.

Figure 2: PIN code input interface

3）After entering the PIN code, enter the user selection interface (Figure 3), click on "CUSTOM TREATMENT" to enter the custom treatments interface.

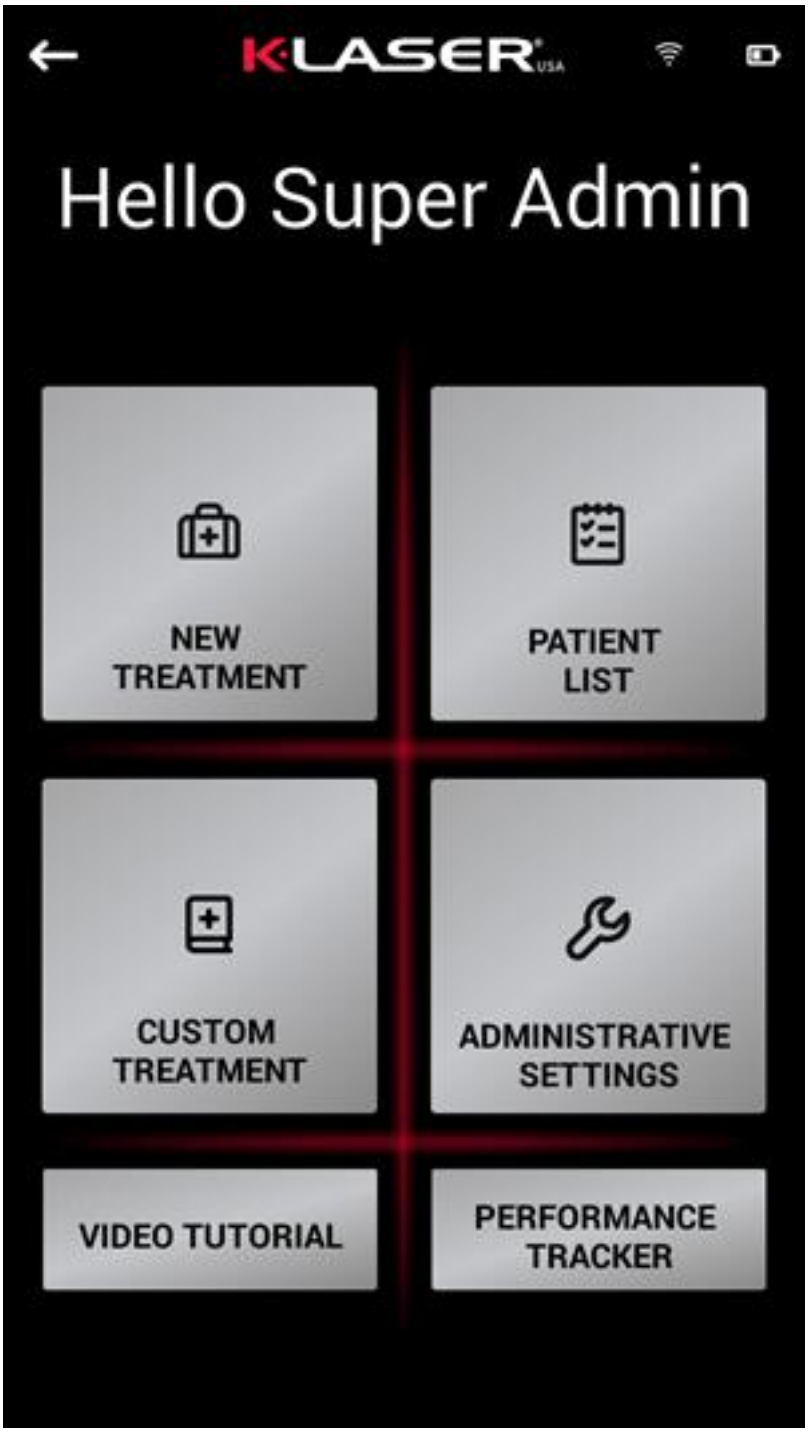


Figure 3: User Selection Interface

4）Click "CREATE CUSTOM TREATMENT" in the Custom treatments Interface (Figure 4) , create a new treatment plan.

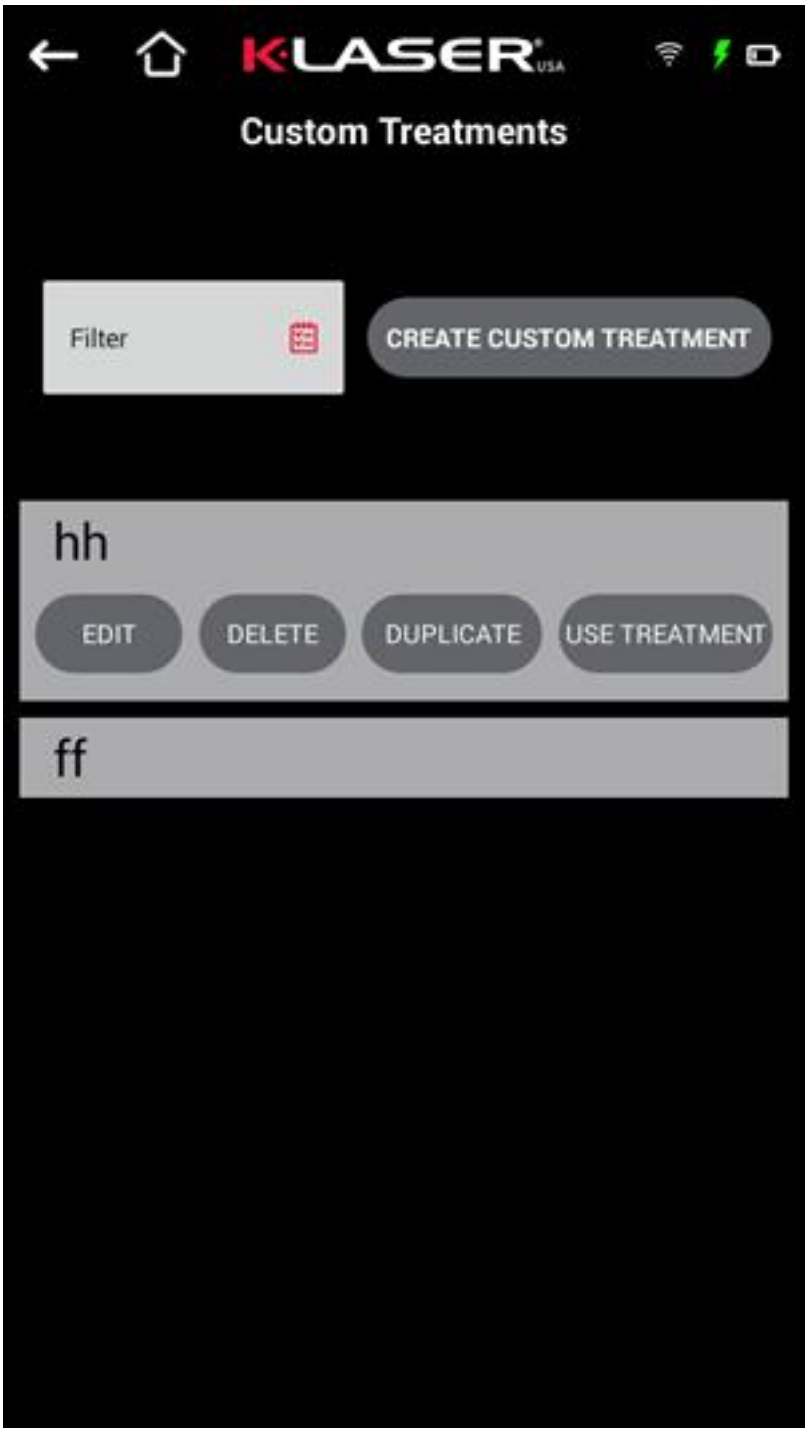


Figure 4: Custom Treatments Interface

5）Into the treatment parameter selection interface (Figure 5), the treatment is divided into six phases (PHASE 1 ~ PHASE 6), the user can change the treatment time, treatment power, pulse frequency, wavelength selection and other parameters according to the actual needs of each stage. When setting completed, click "SAVE AS", select the category, enter the name of the treatment plan, such as "hh", click

"SAVE" to save.

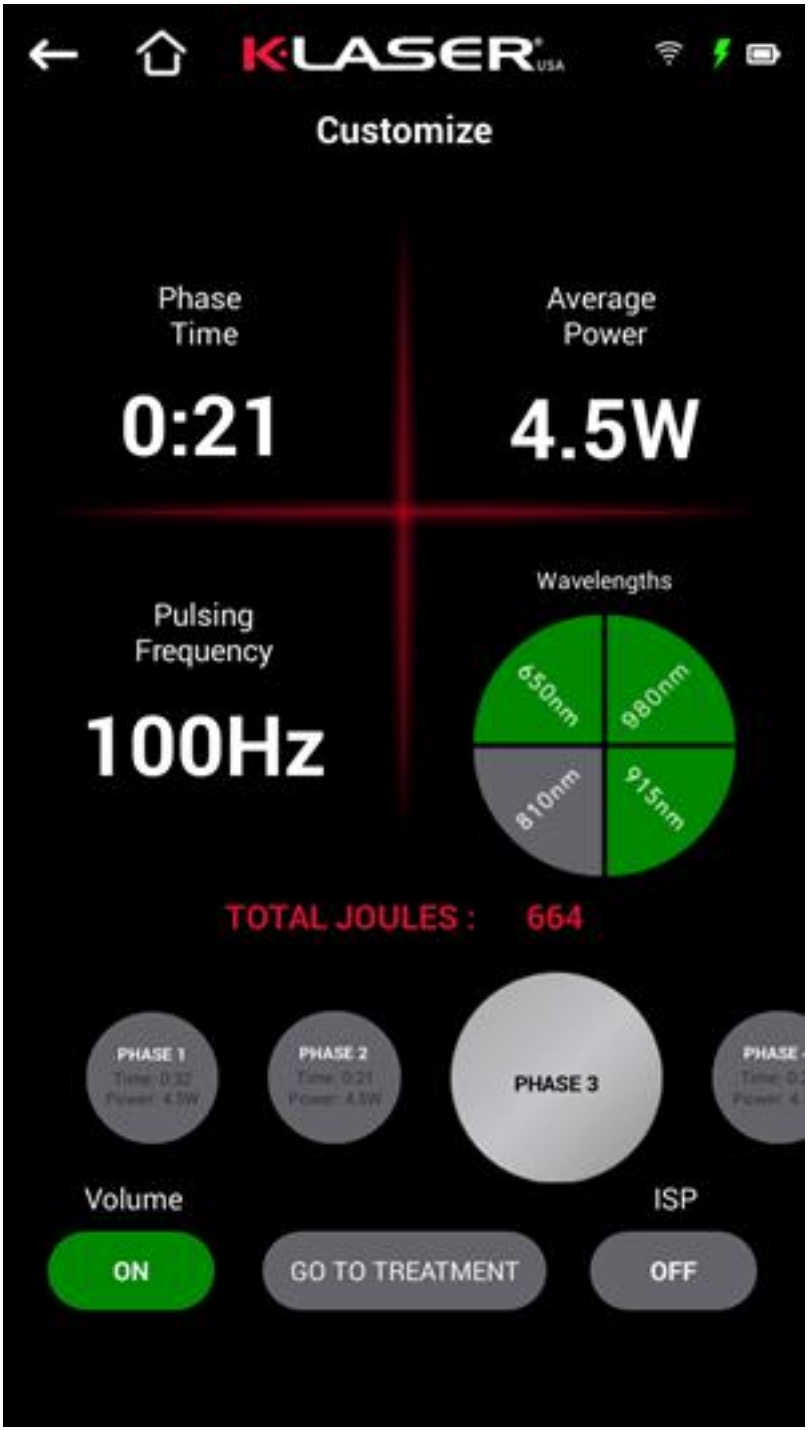


Figure 5: Treatment parameter setting interface

6）Go back to the "Custom Treatments" interface (Figure 6) and select the treatment plan you just created. If you want to edit it again, click "EDIT"; if you want to delete it, click "DELETE"; if you want to copy the treatment, click "DUPLICATE" , Enter the new program name; if you want to directly treat, click on "USE TREATMENT" to

enter the start treatment interface, it shows the parameters of the treatment plan, you can increase or decrease the time and energy by 25%, after the confirmation, click "START TREATMENT".

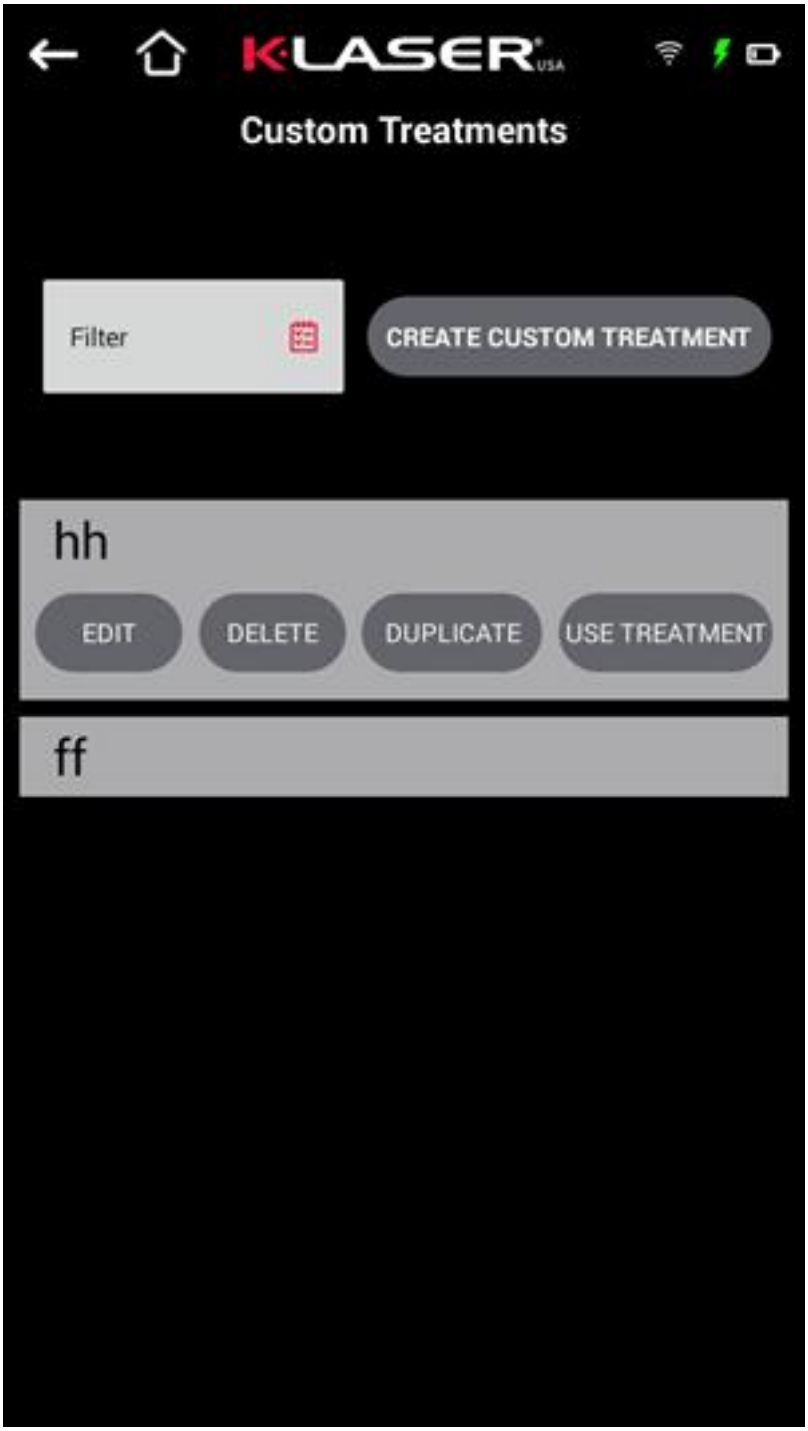


Figure 6: Custom Treatments Interface

7）Enter the protective goggles warning interface (figure 7). Please make sure the user has put on protective goggles to avoid the laser radiation.

Figure 7: Protective Goggles Warning Interface

8）After confirming that the protective goggles are worn, press the finger switch to enter the start treatment interface, and “LASER ON” (Figure 8) is displayed in the lower right corner. The device starts the treatment with accompanying sounds and indicators.

Figure 8: Treatment interface

9.4 Administrative settings instructions

1） Click “ADMINISTRATIVE SETTINGS” in the interface of Figure 1 to enter the administrative setting interface, see Figure 9.

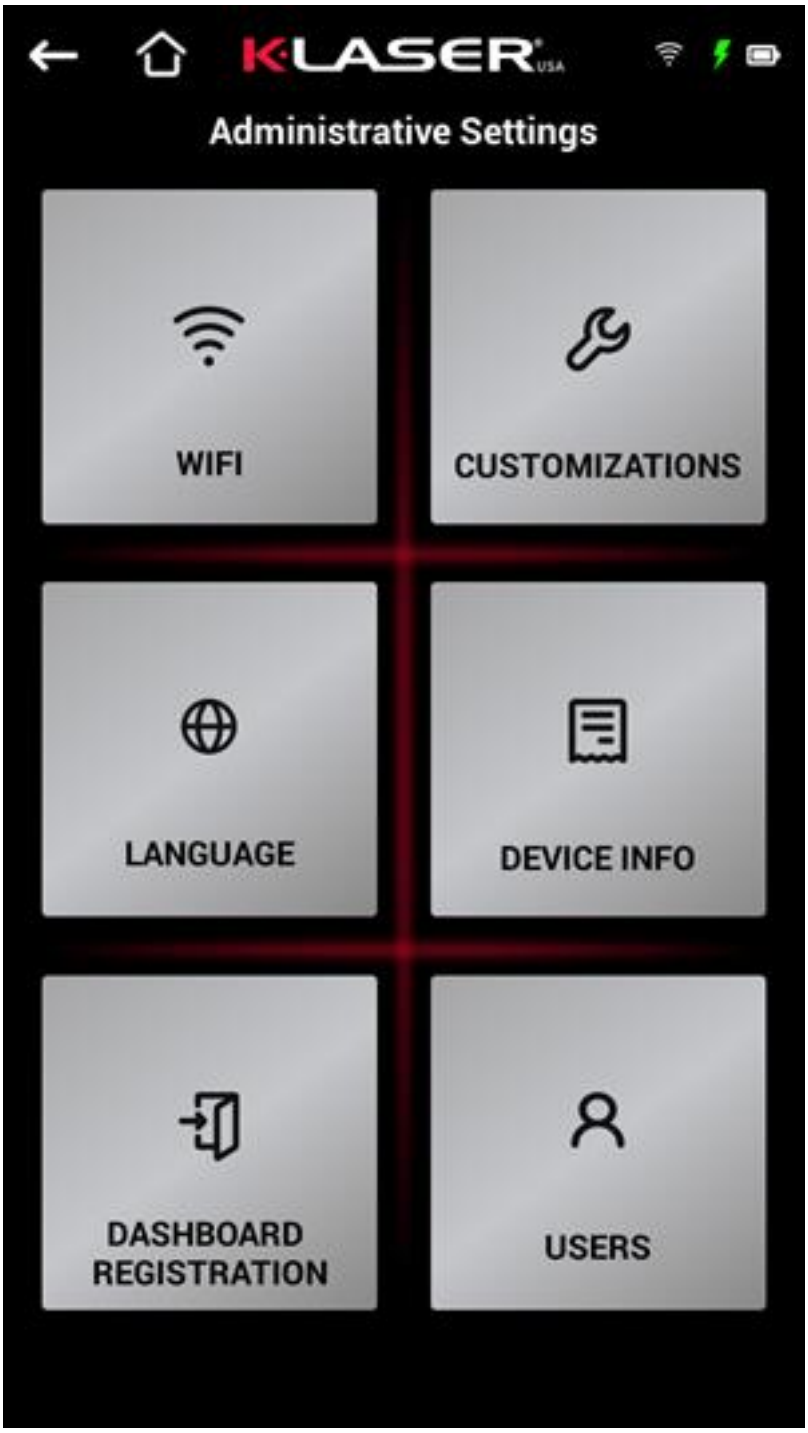


Figure 9: Administrative Settings interface

2） Click "WIFI" and click "ON" to connect to the wireless network.

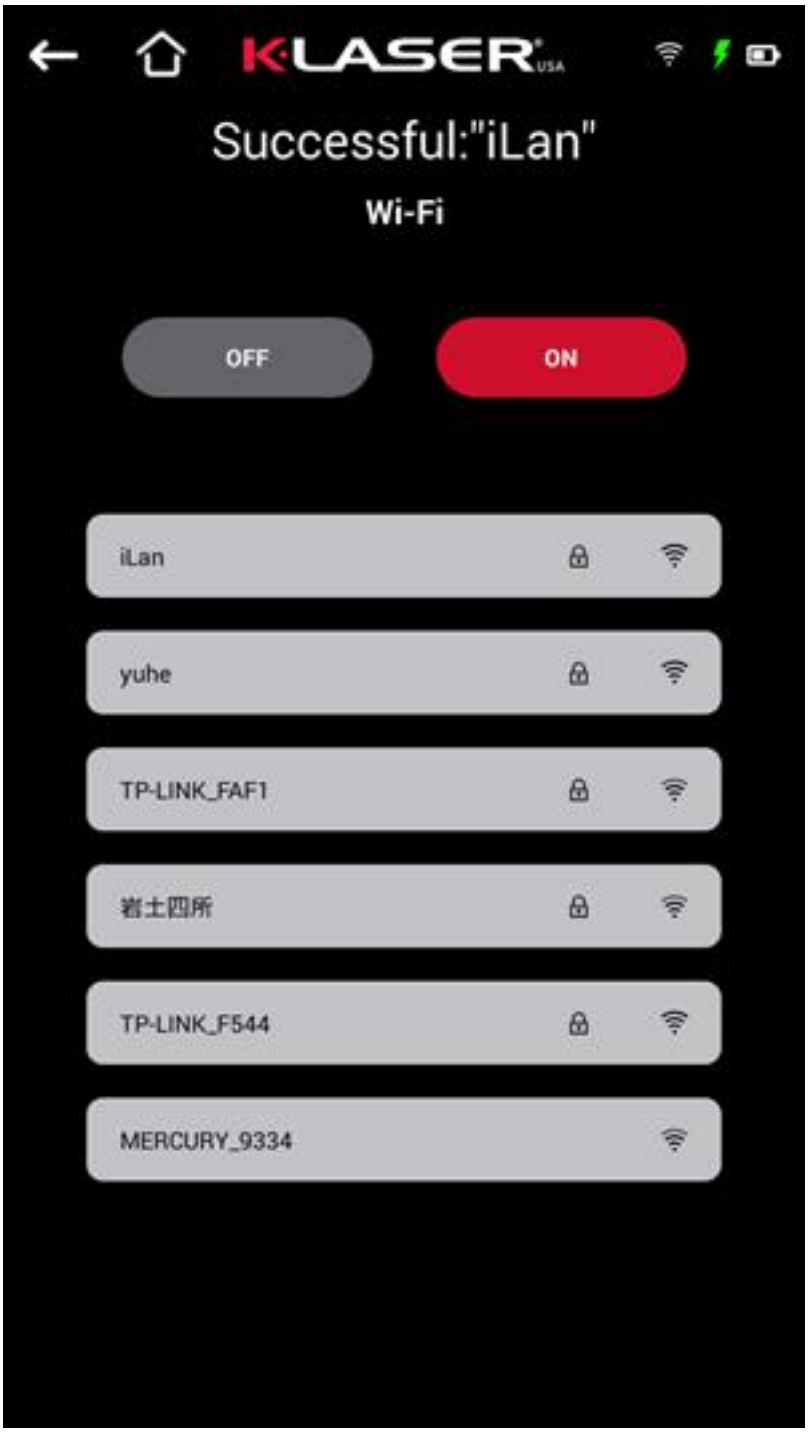


Figure 10: WIFI connection interface

3） Click “CUSTOMIZATIONS” to enter the customizations parameter settings interface (Figure 11). You can set the device's sound size, brightness, date, time, unit of measure and other parameter settings.

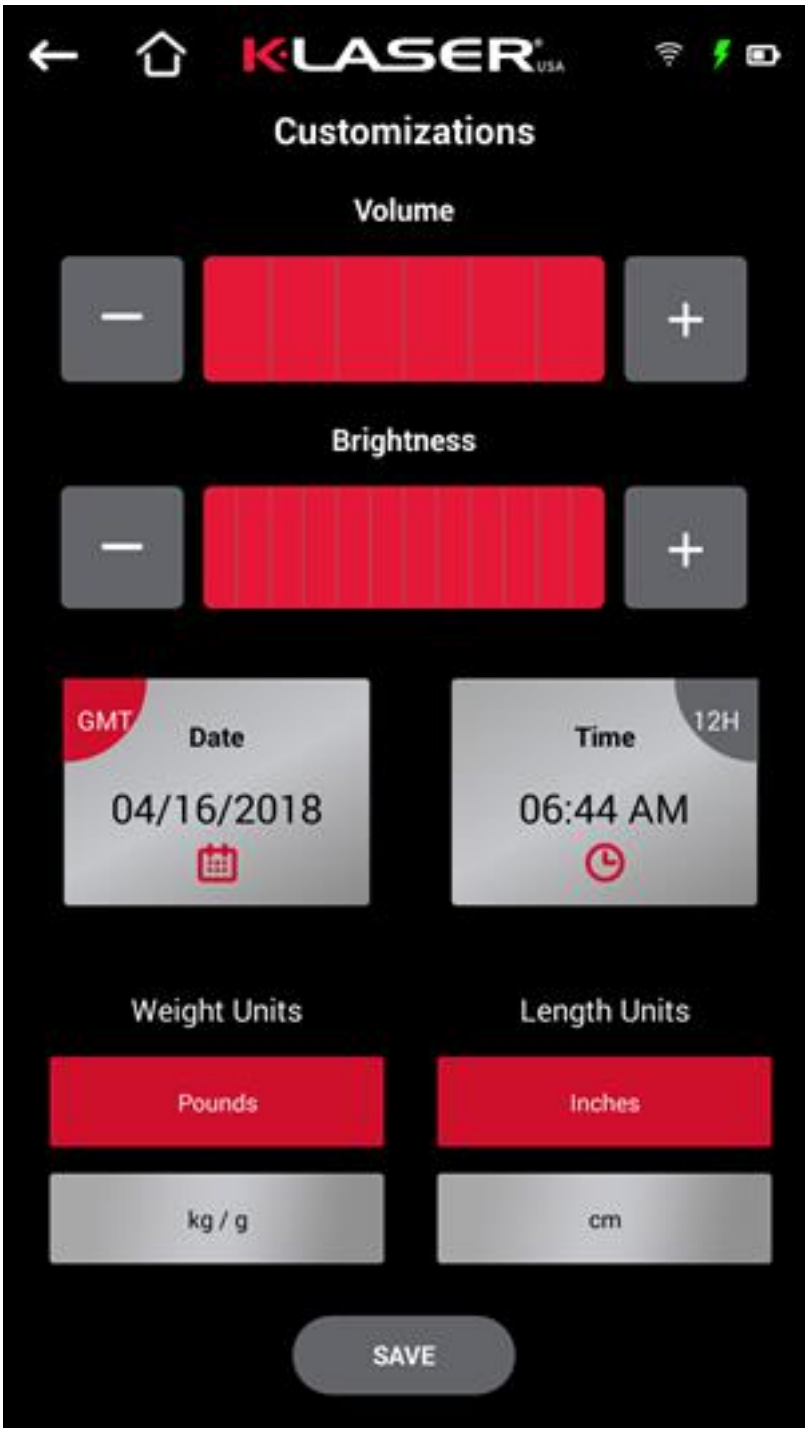


Figure 11: Customizations Parameter Settings interface

4） Click on "LANGUAGE" to enter the language settings interface (Figure 12) to set the user's language.

Figure 12: Language Settings interface

5） Click "DEVICE INFO" to enter the device parameter information interface, you can view the device information.

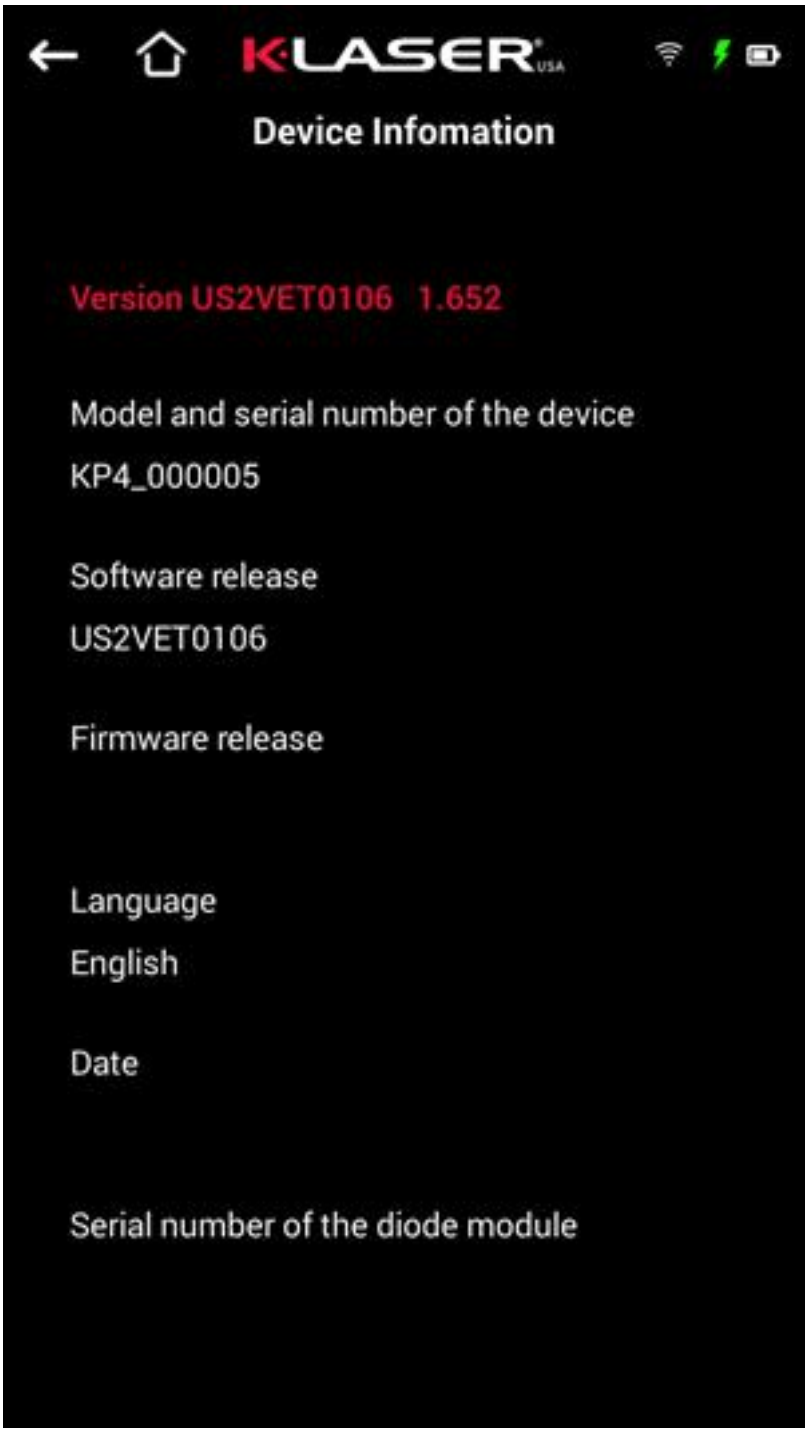


Figure 13: Device Parameter Information Interface

6）Click "DASHBOARD REGISTRATION" to enter the user registration interface (Figure 14), you can fill in user-related information and change the password and other operations.

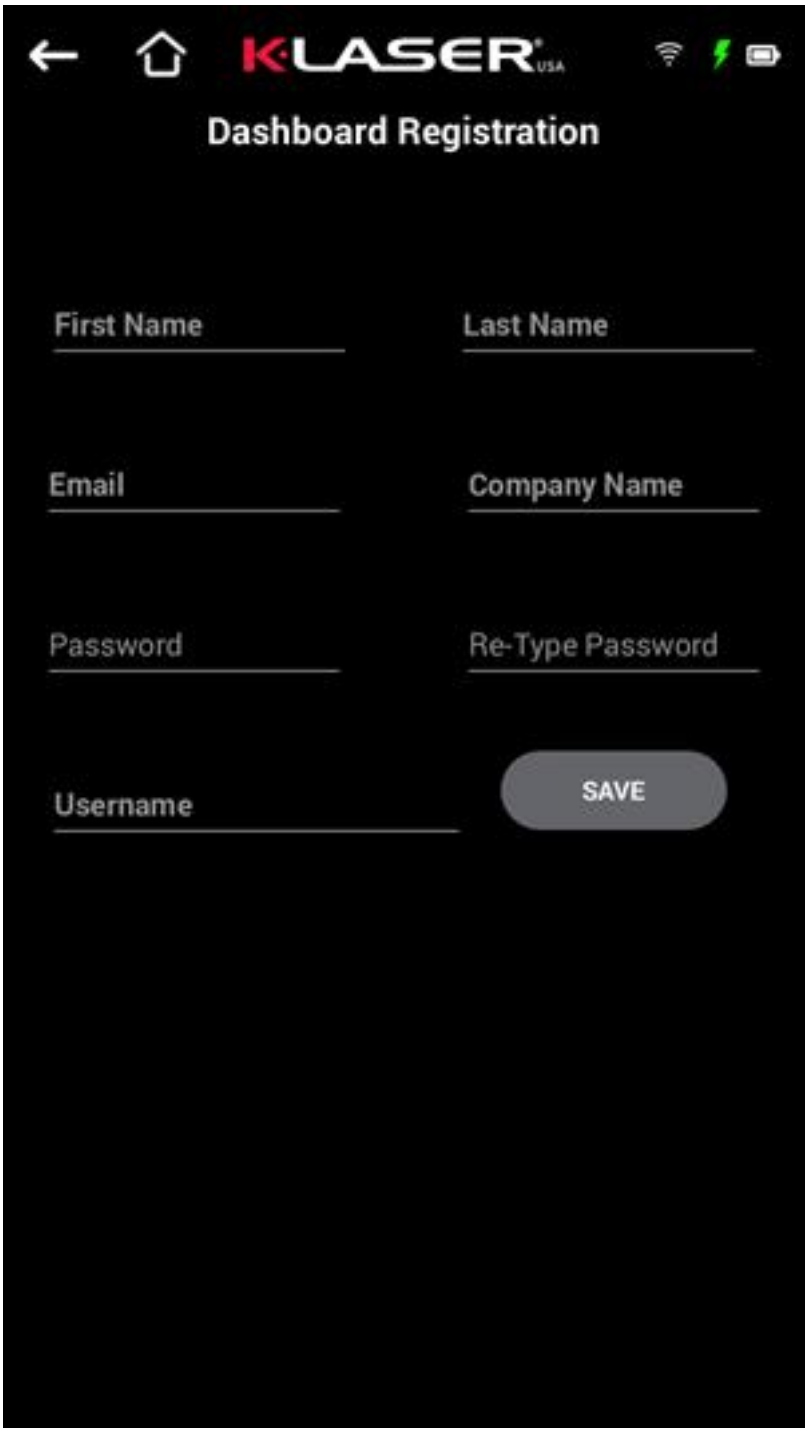


Figure 14: User Registration infterface

7） Click "USERS" to enter the user management interface (Figure 16), you can change the administrator name, password, add users and other operations.

Figure 15: User Management Interface

11 Reminding Function Description

11.1 Reminding Types

The system provides five reminding prompts, namely:

- High temperature reminding
- Remote interlock reminding
- Handpiece switch reminding
- Laser reminding
- Fiber reminding

All of the above remindings are technical remindings. When the reminding occurs, the user must do the appropriate treatment according to the priority of the reminding to prevent the harm to personnel or device.

11.2 Reminding Mode

The Platinum Laser System provide three kinds of reminding modes. They are sound, graphical reminding signs, reminding indicator. Abnormal system state will lead to reminding and interrupt the laser outputting to ensure the safety of personnel and device. Moreover, the reminding delay is less than 1s.

11.3 Reminding Function

The Platinum Laser System monitors the operating status of the system in real time. Sounds, indicator lights, and graphical reminding signs alert the system to abnormal events while interrupting the laser laser outputting.

The following table details the reminding types, reminding priority, reason and reminding fix methods for this device:

Reminding Types	Reason	Exclusion Methods
High Temperature reminding	1.Laser temperature exceeds 45℃; 2. Fiber coupler temperature exceeds 60 ℃; 3. Temperature sensor failure;	1. Turn off the power, if the temperature reminding caused by the high temperature, air cooling device for 10 minutes and it will return to normal after the boot; 2. Please contact the company for after-sales maintenance.
Remote Interlock reminding	The remote interlock is not properly inserted or is not inserted into the device;	Check the rear panel of the device and whether the remote interlock is correctly inserted into the device; If the remote interlock is inserted into the device and the reminding condition is still unresolved, please contact the company for after-sales maintenance.
Handpiece Switch reminding	The handpiece switch is not properly inserted or is not inserted into the device; Press the handpiece switch button when it's not into the "Ready" state;	1,Check the front panel and whether the handpiece switch is correctly inserted into the device; 2, If the handpiece is properly inserted into the device, the reminding status is still unresolved, please check the handpiece switch button is pressed or not; 3, Check the above operation, if there is still reminding status, please contact the company for after-sales maintenance.

Laser reminding	Emergency interlock failures	Please contact the company for after-sales maintenance.
Fiber reminding	Fiber connector is not inserted into the laser window; Micro - switch of laser window fails;	Insert the fiber connector into the laser window of the device; If there is still an reminding, please contact the company for after-sales maintenance.

Based on the above, the user can perform general troubleshooting. If the fault can not be solved, please do not disassemble inspection and contact the company for after-sales maintenance.

11.4 Reminding System Test

The user can determine whether the reminding system is functional by self-test: For example, if the user unplug the remote interlock, the system will appears sound, reminding indicator, graphical reminding signs and other reminding messages. After verifying the reminding system is functional, please restore the remote interlock.

11.5 Fault Diagnosis and Analysis

Do not use the device for treatment when the device is malfunctioning or in other abnormal conditions. Please promptly in accordance with the instructions for the troubleshooting and contact the company for customer service advice.

Failure Phenomenon	Cause Analysis	Exclusion Methods
Turn on the power switch, the system indicator does not light and the system does not start	1, Emergency stop is not turned on; 2, The power switch is not turned on; 3, Fuse blown.	1, Release of emergency stop switch; 2, Turn on the power switch; 3, Remove the fuse holder and check the internal fuse with professional tools. If the fuse is damaged, replace the two 1A 250V quick-blow fuses and insert the fuse holder into the filter switch.
The screen displays an reminding	1, Remote interlock is not connected; 2, The handpiece switch is not connected; 3, The handpiece fiber is not connected; 4, Laser failure.	1,Check whether the remote interlock is connected properly; 2,Check the handpiece switch is connected properly; 3, Check whether the fiber is connected properly; 4, Check whether the handpiece switch is pressed in standby mode; 5,Contact the company for after-sales maintenance;
There is no sound indication when the laser is outputting	Buzzer malfunction	Contact the company for after-sales maintenance;
Laser power attenuation	1, The glass lens of handpiece is with dust or other dirt; 2, Laser attenuation;	1, Clean the glass lens with a paper towel; 2,Calibrate the laser power according to the instructions; 3,Contact the company for after-sales maintenance;
No laser emission	1, The coupler is damaged;	Contact the company for after-sales maintenance

	2, Optical fiber is damaged; 3, Laser is damaged; 4, System failure.	

Note: Users can perform general troubleshooting according to the above. If you can not solve the problem, do not disassemble to check, please contact the company after-sales staff for maintenance.

12 Maintenance

12.1 Daily maintenance

1) Protect the fiber of handpiece from rigid bending, so as not to break the fiber.
2) After removing the handpiece, immediately cover the dust cap to prevent dust pollution, dust cap must be cleaned with alcohol before use.
3) Do not use a hard or sharp things scratch the touch screen, can not use chemical reagents rub the touch screen. Please wipe carefully with lens paper.
4) Before using the device, please wear medical plastic gloves and check whether the end of the handpiece probe is clean. Otherwise, use alcohol (or lens paper) to clean the probe end and handpiece until the alcohol is completely evaporated before using the device.
5) Clean the surface of the device regularly to prevent the accumulation of dust. We recommend the use of alcohol, but should avoid splashing liquid into the interior of the device.
6) The vibration or collision should be tried to avoid in the process of moving the device.
7) Please contact the company or the designated dealer to repair and maintain the device when the power is reduced. Do not disassemble the device without guidance to avoid the damage on the human body and device that caused by the possible harmful laser radiation.
8) It is advisable to carry out a routine inspection and maintenance and power calibration every year under the guidance and operation of our authorized personnel or designated dealers to avoid possible damage to the device and harmful laser radiation on personnel.

12.2 The maintenance for long-term storage

Please pack the device in accordance with the factory packaging for long-term storage and then place it in a well-ventilated, dry, cool environment.
1) Turn the power switch to the "OFF" position and unplug the power adapter;
2) Turn the power switch to the "O" position and unplug the power cord;
3) Rotate the fastening nut at the laser port of the handpiece counterclockwise and gently unplug the handpiece fiber. Then protect the handpiece with the dust cap and optical fiber laser port;
4) Gently unplug the handpiece signal connector and the remote interlock connector, then place them into the accessory bag with the key switch.
5) Place the main device, accessory bag, handpiece, power cord, protective goggles in the packing box.
6) After being packed, place the device in a well-ventilated, dry, cool environment.

12.3 Power Calibration

Note: When the outputting power is found to be more than ± 10% of the setting power, please contact our company or a designated dealer for power calibration.

The suggested frequency for calibriation is once per year.When it expires and needs to be calibrated, the user can send it to our company for calibration or our company engineer to go to the scene for calibration. Users are not allowed to calibrate themselves in order to avoid the risk of laser radiation.
WARNING: Please carry out the calibration of the device under the guidance of the authorized personnel of the company or the designated dealer. During the calibration process, please wear eye protection to avoid possible harmful laser radiation damage to personnel and device.

CALIBRATION SCHEDULE

Authorized by:

Purchase Date ____//____// _____ _____

Calibration 1 ____//____// _____ _____
(12 months after purchase date)

Calibration 2 ____//____// _____ _____(24 months after purchase date)

Calibration 3 ____//____// _____ _____
(36 months after purchase date)

Calibration 4____//____// _____ _____(48 months after purchase date)

Calibration 5 ____//____// _____ _____
(60 months after purchase date)

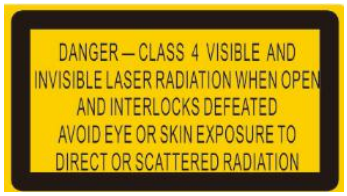
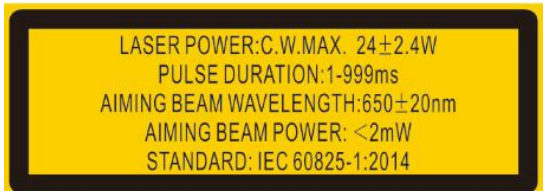
Calibration 6 ____//____// _____ _____
(72 months after purchase date)
Contact PIOOM to be connected to the repair center closest to the laser location. Repair and maintenance centers are located worldwide.

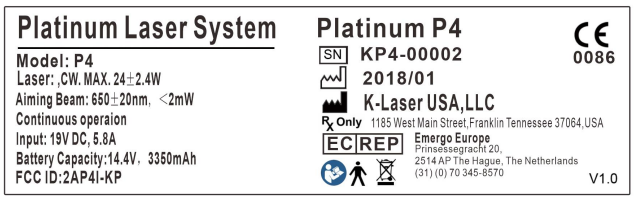
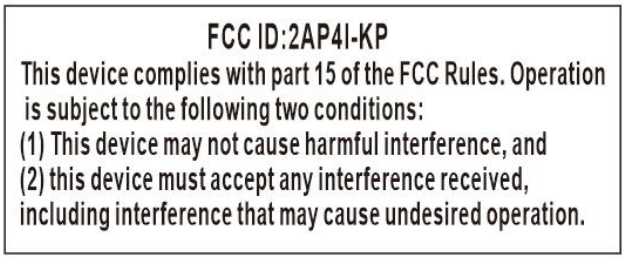
13 The Waste Dispose

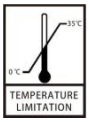
Scrapped device and loss parts (such as Battery， etc.)should be strictly in accordance with the local laws and regulations for processing rather than could be discarded optionally.

14 Product Identification And Packing Instructions

Product identification and packaging instruction are in line with EN ISO 15223-1: 2012 and other related requirements. Product identification and packaging used in graphics, symbols are as follows:

Graphics / symbols	Meaning	Position
	Laser Danger & Optical Fiber	The window of the fiber connection on the top of the devi ce
	Class 4 laser product explanatory Laser output and standard information	The position of the back panel near the top of the device
	remoteinterlock	The position of the back panel near the top of the device
	Laser aperture	Laser output window on the top panel of the device
	Panel	The position of the back panel near the top of the device
	Laser output and standard informatioin	The position of the back panel near the top of the device

	Emergency Power Off	The position of the emergency stop switch at the side panel of the device
	Product nameplate	The position of the rear base of the device
	FCC Note	The position of the rear base of the device
	Serials number	The position is on the nameplate
	Instruction manual	The position is on the nameplate
	Manufacture date	The position is on the nameplate
	Manufacturer	The position is on the nameplate
	Non-recyclable	The position is on the nameplate
	BF Type	The position is on the nameplate
IPX1	Water proof level	The position is on the outer package
	Fragile, be careful	The position is on the outer package
	Keep Dry	The position is on the outer package

	Transport should be upright	The position is on the outer package
	Temperature Limitation	The position is on the nameplate
FCC ID:2AP4I-P4	FCC ID	The position is on the nameplate

15 Electromagnetic Compatibility

Platinum Laser System conforms to the EMC requirements of IEC 60601-1-2: 2015 and has been tested in accordance with IEC 60601-1-2: 2015.

Warning: Keep away from strong radiation sources and electromagnetic interference environment. External RFI and electromagnetic interference will affect the normal operation! Such as cardiac pacemakers and other device sensitive to electromagnetic environment, please try to avoid using together.

16 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

§ 15.21 Information to user.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The antenna must be installed complying with the requirements of manufacturer or supplier, and it must be at least 20cm from human body.

17 Services

17.1 Quality commitment

The company guarantees the factory technical parameters of Platinum Laser System is in line with the product standard requirements of the EU medical device regulatory approved, and promises the sale of products for free maintenance within 12 months.

1) Provide laser training and clinical guidance;

2) Provide parts or machine spare parts;

3) Product maintenance and technical advice.

When it expires and needs to be calibrated, the user can send it to our company for calibration or our company engineer to go to the scene for calibration. Users are not allowed to calibrate themselves in order to avoid the risk of laser radiation.

17.2 Disclaimer Clause

Damage to the product caused by the following will not be covered by the warranty:
1) The customer is incorrect, improper use.
2) operate and store in an environment other than those specified in the product specification;
3) Unauthorized removal of the shell, modified device.
4) Use accessories that do not match the device.
5) Incorrect maintenance.
6) Turn on the chassis of the laser system.

18 Contact information

If there’s any difficulty in using the medical laser systems, or any questions and suggestions, please visit our website, call or write to the company.We will provide you and the company's products for a comprehensive long-term service!

K-laser USA, LLC
Add: 1185 West Main Street Franklin,Tennessee 37064 U.S.A.
Tel:866-595-7749
Email:info@k-laser.com

EU Authorised Representative Information:

EU Authorised Representative: Emergo
EU Representative Address: Prinsessegracht 20, 2514 AP, The Hague, The Netherlands