SUMMUS™
MEDICAL LASER

Platinum Series™ P4H Operator's Manual

Operating Instructions Manual

Instructions Before Use

Platinum Series P4H Diode Laser Systems are for Professional Use Only according to the Indications for Use in this manual. The laser is to be used under the supervision of a trained medical professional.

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

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

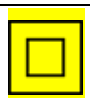
It is strongly recommended that users receive related training before use, contact your Sales Representative and make sure your training is scheduled. Carefully read the instructions and do the relevant security measures in the course of use to avoid risks to the human body and damage to equipment that may be caused by the possible harmful laser radiation.

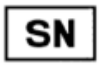
The company will not be liable for any personal injury or damage to equipment caused by the failure to follow instructions during use.

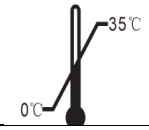
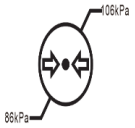
Product identification and packaging instructions in accordance with IEC60825-1: 2014, EN ISO 15223-1: 2016 and other related requirements. Graphic symbols used for product identification and packaging are as follows:

SYMBOL	DESCRIPTION
	Laser Danger

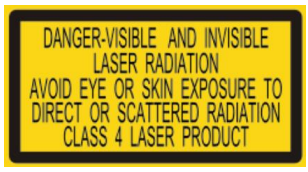
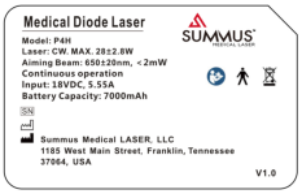
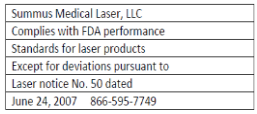
SYMBOL	DESCRIPTION
	Optical Fiber

	Laser Stop
	Class II medical equipment
	B-Type Device
	Date of Manufacture
	Lithium Battery Hazard Symbol
	Indicates the manufacturers catalog number
	Both direct and alternating current
	Do not use if package is damaged

	Warning or precaution associated with the device which are not found on the label
	Serial Number
 and or 	Refer to the Instruction Manual
	Manufacturer
	Recycle Lithium-Ion Battery. Do not dispose with common waste
	Indicating separate collection for WEEE- Waste of electrical and electronic equipment
	Keep Dry
	Keep away from sunlight

	Transport Upright			Fragile - Handle with Care
	Indicates the temperature limits to which the medical device can be safely exposed.			Indicates the medical device is not made with latex
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.			Indicates the range of humidity to which the medical device can be safely exposed.
IPX0	Indicates the level of enclosure protection			Indicates the connection for a finger switch
	Prescription Use Only			European Representative
	Indicates conformity to European standards and requirements of accreditation and market surveillance relating to marketing Compliance			Restriction of Hazardous Substances
	Non-sterile: Indicates a medical device that has not been subjected to a sterilization			An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

	Indicates a medical device that is non-pyrogenic		Intentionally left blank	Intentionally left blank

Label / Symbol	Title	Description / Explanatory Text
	Laser Danger	Safety warning
	Optical Fiber	Safety warning
	Laser Output Port	Safety warning
	Class 4 Laser Product Explanatory	Safety warning
	Safety Interlock	Indicates the presence of interlock to prevent human access to Class 3 or Class 4 laser radiation when that portion of the housing is removed.
	Product Nameplate Specific per model	Summus Medical Laser Product Information
	Performance Standard Compliance	Indicates FDA Performance Standards Compliance to Laser Notice No.50

CONTENTS

1 INTRODUCTIONS

This manual applies to Platinum Series™ P4H model.

The Platinum Series P4H is a portable laser product designed for medical laser therapy. This device is for Professional Use Only and its therapy uses shall only be administered by or under the supervision of a trained professional. The product is dedicated to clinicians and patients with a safe and effective treatment experience.

1.1 Device Description

The Platinum Series P4H uses Gallium Aluminum Arsenide (GaAlAs) semiconductor diode as the lasers source. The laser energy is delivered to the therapy area by an optical path transmission system consisting of a flexible quartz fiber connecting the laser source and hand piece. Activation occurs when the operator enables the laser and presses the finger switch on the distal end of the probe. When the switch is activated, the message “LASER EMITTING” appears on the LCD screen. When the finger switch is pressed a second time and released, the laser is deactivated. The laser light is applied to the target area on the patient with the hand piece either in contact or slightly off contact with the patient’s skin.

The light is an invisible non-ionizing thermal radiation that does not create changes in cellular DNA. The P4H’s continuous output power is 28W and 30W with intense super pulse (ISP) mode . The output spot size and the power density of the applied laser light is achieved with the 25mm and the 50mm broad beam open end and curved contact hand piece tips respectively. In addition, the P4H has been preset with a variety of reasonable and effective treatments in the system for clinicians as a reference.

⚠ The user needs to carry out appropriate clinical and technical training before using this product and should strictly follow the operation instruction manual during the operation of the device. Before treatment, professional users should choose the reasonable treatment parameters for the treatment according to the patient's condition and treatment.

Note

The manufacturer assumes no responsibility for the direct effects or side effects that arise from therapeutic or use of the system. The sole responsibility lies with the

medical personnel.

Note

Every clinic and hospital utilizing this device is encouraged to adopt a Laser Training and Safety Program.

1.2 Indication

Platinum Series P4H is indicated for temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.

1.3 Intended User

Professional users under prescription use only.

1.4 Intended Population

Male and Female patients' adolescence through adult.

1.5 Contraindications

There are currently no known adverse effects for the use of laser devices of the same power and wavelength as the P4H laser device. Professional users shall be fully aware of the patient's condition and medical history prior to treatment.

1.5.1 Absolute Contraindications

- ⚠ Do not shine laser light directly into the eyes, with or without eyewear protection
- ⚠ Do not apply the laser to pregnant females.
- ⚠ Do not apply the laser over the mammary gland of breastfeeding mothers
- ⚠ Do not apply the laser directly over the thyroid gland.

-  Do not apply the laser on patients with active cancer.
-  Do not apply the laser to patients with a compromised immune system
-  Do not apply the laser to patients with concerns of anticoagulation or thromboembolic disorders
-  Do not apply the laser to patients with herpes simplex

1.5.2 Relative Contraindications

-  Do not apply the laser over a working spinal cord stimulator (SCS)
-  Do not apply the laser directly over a pacemaker or implanted electronic device. It is safe to laser distant to a pacemaker.
-  Do not apply the laser to patients who are taking drugs that have heat or photosensitivity contraindications.
-  Do not apply the laser over areas recently injected with corticosteroids.
-  Do not apply the laser when individual intolerance of the treatment is noted.
-  Do not apply the laser to patients over an area with an active infection
-  Do not apply the laser over a hemorrhage or active bleeding.
-  Do not apply the laser to patients with keloid or hypertrophic scar formation
-  Do not apply the laser over tattoos.

- ⚠Do not use the laser on patients with meningitis or encephalitis.

1.6 Warnings and Precautions

For medico-legal reasons, the practitioner should know the patients' medical history and must weigh the benefit versus risk when providing laser therapy.

- ⚠Use caution when applying the laser over areas where sensory perception is absent or diminished.
- ⚠Use caution when applying the laser to patients who are sensitive to light exposure.
- ⚠Use caution when applying the laser to patients who have heart or pulmonary disease.
- ⚠Use caution when applying the laser to patients taking blood thinners or who have hemorrhagic disorders.

1.7 Features

In the course of use, users will find that Platinum Series lasers are best-in-class in the following ways:

Precise

The Platinum Series is designed to provide the most precise therapy protocols, reducing time for the user and also patient.

Safe

Designed power ranges for various types of pain and inflammation. At the same time, there are a variety of security alarm systems to facilitate security of the operation.

Simple operation

With the intelligent human-computer interaction system and the internal self-teaching video screen, the interface is clearer. It provides a variety of mature treatment options for clinicians as reference, largely saving the time and steps for setting the treatment parameters, and largely bringing convenience to clinicians.

Portable

The device is lightweight, easy to carry and can be used with power adapter or rechargeable battery.

1.8 Usage Prerequisites

Every clinic and hospital utilizing this device is encouraged to adopt a Laser Training and Safety Program.

If there are any questions or needed assistance during the use, please contact the designated dealer or our company.

2 SAFETY PRECAUTION

⚠ WARNING: Before using this product, please read this section carefully and strictly observe the safety information. This device is for Professional Use Only and its therapy uses shall only be administered by or under the supervision of a trained professional.

2.1 Safety Instruction

Platinum Series P4H is a Class 4 laser product. Before use, users must read and familiarize the instruction manual, and strictly follow the instructions in the manual to operate and maintain the device. Operation and setup beyond the scope of this manual can potentially harm the operator and or patient.

Before treatment, clinicians need to determine the clinical symptoms of patients and make an analysis for appropriate treatment. They must take full account for the treatment and obtain the patient's permission before treatment.

Clinicians need to be fully aware of the patient's medical history prior to treatment. Coagulation dysfunction, melanoma, cancer and precancerous lesions, acute hemorrhagic disease, cardiopulmonary and renal failure, pre-stroke symptoms, acute inflammation associated with sepsis symptoms, pregnancy response, skin wound healing with a tendency to form keloids, wound healing ability disorder, suffering from systemic diseases and other people banned; anesthesia allergy, heart disease, lung disease, bleeding disorders, sleep breathing suspension and other groups, and immunodeficiency patients should be treated with caution.

2.2 Requirements for the Therapy Room

Follow these safety requirements to arrange the therapy room:

- Each entrance door must have a laser safety warning sign (Warning label) to warn others of the existence of laser radiation hazards.
- 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 cannot emit laser, preventing anyone from entering the room when the laser is emitted and being exposed to laser radiation.
- AVOID any reflected radiation from the laser beam causing laser radiation

hazard. No highly reflective material should be found in the therapy room, such as mirrors and chrome-plated glass.

⚠ WARNING: Avoid contact of the laser and laser beam with flammable, explosive, anesthetic or other flammable solvents. Do not put paper or plastic products in the area of laser treatment to prevent fire.

2.3 Safety Requirements for Patients, Operators and Other Personnel

Follow ALL safety instructions before and during treatment:

⚠ WARNING: Invisible laser radiation - avoid eye or skin exposure to direct or scattered radiation!

⚠ WARNING: Nominal Ocular Hazard Distance (NOHD) is 3.30m from the distal end of the fiber.

- ⚠ Unauthorized persons or those who do not obtain a clinical qualification certificate shall not use the product for clinical treatment.
- ⚠ 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 shall wear protective eyewear containing specific protection for an optical density of 7.0 or greater for the infrared (810, 915, 980nm) wavelengths and 2.0 or greater for the visible red (650nm) wavelength emitted by the P4H device.
- ⚠ WARNING: Non-specified protective goggles may cause damage to eyes.
- ⚠ WARNING: Inspect your goggles regularly for damage or breakage. Do not look into the laser beam or the indicator light to avoid eyes exposing to direct or scattered radiation of laser.

NOTE: Please contact the designated dealer or visit the company product web site to purchase replacement goggles.

- ⚠ NEVER attempt to view the laser beam or the indicator light along an optical path with eyes or with optical equipment. Direct contact may cause irreparable damage to the eyes.

- ⚠ DO NOT remove the protective goggles until the operator returns to the "Standby" mode.
- ⚠ DO NOT leave the laser in READY mode.
- ⚠ DO NOT allow non-personnel to enter the therapy area during laser treatment.
- ⚠ DO NOT wear any reflective jewelry or items during treatment. Avoid scattering or reflecting laser energy that may cause damage to eyes or skin.
- ⚠ Turn the power switch to off when not using the laser device. The secure login password should not be shared and should be kept by designated and authorized personnel only. Unauthorized persons are prohibited from obtaining the login password to avoid personal injury and equipment damage.
- ⚠ When the device is powered on and operating, if there is an abnormal function (such as no display, light abnormality, etc.), immediately press the emergency stop switch to stop the laser output. Do not use this unit if you suspect it is functioning improperly. Identify and correct the cause prior to resuming use. Reference Alarm Function and Fault Diagnosis and Analysis sections. If necessary, please notify the designated dealer or the company for help.
- ⚠ AVOID strong pull force and extreme bending of handle or optical fiber. NEVER bend the fiber cable or apply stress. Keep the bending curvature radius larger than 50mm and at an angle of 90 degrees or greater
- ⚠ It is strongly recommended that the equipment be inspected and maintained regularly by a Summus Medical Laser authorized service representative or users under the guidance of the companies authorized representative. Reference Daily Maintenance, Routine Inspection, Laser Calibration, and Service sections.

- ⚠ WARNING: If the device does not work normally, please contact the designated dealer or the company immediately for consultation. Unauthorized users are not allowed to open the device without permission. Unauthorized opening of the device presents a risk of electric shock, as well as severe or irreversible injury or damage to user or device.

2.4 Safety Requirements Related to the Running of the Equipment

Observe the following safety instructions to ensure safe and efficient operation of the equipment:

- ⚠ Choose a safe, well-ventilated location to install and use the equipment. A minimum distance of 20 cm should be maintained between the ventilation slots and the walls to ensure smooth ventilation during work.
- ⚠ Strong electromagnetic environment may affect the normal operation of equipment, it should also be avoided that the device is together used with other easily interfered devices. Reference Electromagnetic Compatibility section.
- ⚠ Only use the designated accessories. Contact the designated dealer or company to purchase replacement accessories. Non-specified accessories may cause the equipment to malfunction or cause damage to the equipment.
- ⚠ Turn the equipment off before moving or lifting the laser equipment. Protect the hand piece, fiber and the laser window with a dust cap to protect them from dust or other foreign material.
- ⚠ 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. Consult with the designated dealer or our company.
- ⚠ The use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N2O) and oxygen must be avoided. Certain materials, such as cotton wool, are oxygen-rich and will be ignited by the high temperature

generated by the laser equipment being used. Solvents and flammable solutions used for cleaning and disinfection should be volatilized before using the equipment. There is a risk the internal gas may be ignited.

- ⚠ WARNING: Diode lasers are attracted to melanin and hemoglobin. Power levels are inversely related to the amount of pigmentation and vascular of the targeted tissue. As pigmentation varies from patient to patient, start with the lowest power setting and increase as needed to accomplish the procedure in tissues which have lower melanin and vascular content; Use anesthetic as needed for patient comfort.

⚠ WARNING: To avoid risk of electrical shock, AC/DC adapter must only be connected to a properly grounded power source!

2.5 Safety Classifications

The following safety classification applies to the P4H:

Laser radiation: Class 4 laser products

Type of Electric shock protection: Class 1

Degree of Electric shock protection: Type B

Indication of enclosure protection: IPX0

2.6 Security Issues

Inform Summus Medical Laser or the designated dealer directly about the safety problems discovered during the use of this product.

2.7 Security Features

The P4H provides a range of safety monitoring and safety functions for monitoring the operating status of the system and emergency interruption of laser output. The purpose and operation of these safety devices should be familiarized when using the diode laser equipment.

Power Switch

Used as a line switch for separating the device from the main power supply:

O = OFF, | = ON.

Login Password

The login interface is prompted after the equipment is powered on requesting

the user's 4-digit security PIN identification for permissions.

Emergency Stop

The emergency stop switch is used to immediately stop the laser emitting output. When the device is powered on and operating, if an abnormal function (such as no display, and light abnormality, etc.) occurs during the course of treatment, immediately press the emergency stop switch to stop the laser output. Identify and correct the cause prior to resuming use. The user can reset the EMERGENCY STOP switch by pulling the switch out and away from the equipment.

Remote Interlock

If the interlock is not inserted into the connector on the device, all electrical power to the controls and laser components is terminated. The safety interlock MUST be inserted before the device can power on. Interlock should be installed at each designated therapy room entrance and connected to the remote interlocking connector on the rear panel of the device.

The remote interlock should normally be connected to an interlock (closed switch) on the entrance door of the therapy room. The remote-control interlock head should be connected to the remote-control interlock interface. When the therapy room door is opened, the equipment can no longer emit. An auxiliary connector should be used to access the equipment if the room does not have an interlock.

System Monitoring

The P4H is equipped with an emergency stop switch, remote interlock, foot/finger switch, fiber, laser temperature and other system status functions. If the system detects any associated anomalies or errors, the laser emitting output will be stopped and an audible, visual alarm will alert the user device to an error.

Start Treatment (Standby/Ready) Button

The power or program selection settings can only be made in the standby mode. When the system is in all normal conditions, press the START TREATMENT (Standby/Ready) button to switch the device from Standby to Ready mode. Activation of the finger switch will allow the equipment to enter the laser emission state. Users are informed the equipment is emitting laser through a beeping sound and a yellow light.

Indicator Lights

Used to indicate power, laser output and alarms.

- When the device is turned on, the power indicator light is green.
- When the laser is outputting, the corresponding indicator light is yellow.
- When the alarm state occurs, the corresponding indicator light is red.

Alarm Prompt

When the system detects an abnormal or a non-normal working state, the equipment will provide alarm notifications by sound, light, graphic text alerts on the LCD screen that would inform the user the system is in an abnormal state. Users can view the interface information to understand the operation of the device.

⚠ WARNING: Failure to follow the above safety information may result in electric shock and laser radiation hazards. Please observe all safety instructions, requirements, and warnings.

3 INSTALLATION

⚠ WARNING: The acceptance and set up of the P4H medical laser device should be done with the assistance and guidance of our authorized technicians or agents.

3.1 Check the Appearance and Packing Items

Platinum Series P4H is packed and inspected strictly at the factory. After you receive the product, please check the box for damage. After unpacking, please check the boxing items are complete according to the packing list. Note: Please check carefully whether the contents of the packing list are complete, missing or damaged. Please contact the designated dealer or the company for replacement if the items are found missing or damaged, or the packaging has obvious damage, crashes and so on. Reference Section 5, Contents of the laser device.

3.2 Preservation of Packaging Materials

Save all packaging material. It is recommended to use these materials when you store the equipment or return equipment to our company for repair.

Laser will arrive in this secure box. Remove laser & accessories. Do not throw away the box. Keep box for future use!

带格式的: 字体: (默认) Arial

3.3 Device Installation

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

	
Laser is designed to fit perfectly in the left portion of the foam. All accessories fit on the right.	Remove the foam on the right to access the accessories.

Installation Site and Platform Selection

The Platinum Series P4H has an air cooling design system. The system consists of a closed loop, liquid filled, heat pipe thermal transfer system with fan and air assistance. Heat is transferred to the system and dissipated across a framework of fins where it is released to the ambient atmosphere. Please choose a well-ventilated location for equipment installation. The placement platform requires a hard texture and 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.

Fiber and Finger Switch Connection

The foot/finger switch connector is located directly above the device. Align the red portion of the finger switch connector to the red portion of the device connector and insert the connector horizontally into the device.

		
Unscrew and remove cap.	**Do not let dirt or debris enter this port.**	Place and store the cap on the chain of the fiber.

		
Do not touch end of the fiber. Place immediately into the laser port, and when removing the fiber place screw cap back on without touching end.	Insert fiber into laser port and screw it until fastened tight.	Insert the black cable into the finger switch by aligning red dots. Push in and **Do not twist.**

⚠ WARNING: In order to avoid dust contamination, do not touch the laser port and the handle port by hand when connecting the handle. Dust cap should be placed and stored on the chain of the fiber. The hand piece and coupler face need to be protected from dust and foreign material after the separation of the handle and laser port with dust caps.

⚠ WARNING: Do not bend the fiber tail cover during connection or disconnection to prevent damage or breakage of the fiber. Failure to follow these procedures will lead to optical fiber and optical transmission system damage, resulting in laser radiation hazards. NEVER bend the fiber cable or apply stress. Keep the bending curvature radius larger than 50mm and at an angle of 90 degrees or greater

Remote Interlock Installation

The remote interlock interface is located directly above the device. Place the red part of the remote interlock switch connector at the red part of the device interface and insert the connector into the device. The remote interlock should be connected to the interlocking device on the door of the therapy room while the equipment is in operation. When the door is opened, the equipment cannot emit laser, preventing anyone from entering the room and being exposed to laser radiation.

		
Insert the plastic protrusion into the handle fiber optic cap to prevent dust contamination.	Fiber and black cable inserted correctly.	Insert interlock on the other side of the laser.

		
Complete view. **Do not twist to tighten.**	Attach the base to the laser.	Insert fiber below coupler into fiber clip on pedestal of laser. This will secure the fiber.

	
Wrap fiber counterclockwise leaving enough slack to move the hand piece to the cradle.	Complete view with the hand piece in the cradle

⚠ WARNING: The door should be closed entirely and shouldn't be opened when the equipment is in use.

Hand Piece Connection

The hand piece connector is located directly above the device. Remove the handle and laser port dust cap before installing the handle. Gently insert the handle connector into the laser port and tighten it by turning the fastening nut clockwise. Remove the black protective cap and place into case. Select the treating head and screw it to the base of the hand piece.

Insert fiber into laser port and screw it until fastened tight.

Remove black protective cap and place into case.

Select the treating head, and connect to base of hand piece.

Power Requirements

Platinum Series P4H Diode Laser has two power supplies: external adapter power supply and internal battery. Keep the device at least 20cm away from the wall to ensure smooth ventilation during work and facilitate the operation of the power switch. Press the power switch to the ON position to start the device.

External power supply: Directly insert the adapter plug specified by our company into the DC jack of the rear panel of the device.

	
External adapter	Internal battery

Internal power supply: When using the internal power supply, the power switch can be turned directly to the ON position. When the battery power is less than 1%, the laser stops working, and users will be informed of the sound and light that they should charge the device. When connecting an external power supply, use the provided power adapter.

⚠ WARNING: Only use the rechargeable battery specified by our company to supply power. Non-specified accessories may cause the equipment to malfunction or cause damage to the equipment.

Turn on laser with switch in flank of device, and if a red light is showing check to make sure all connections are secure.

If still red, check to see if Emergency Stop button has been pushed inward.

If so, press down and blue light will illuminate.

The Use of Hand Piece

After setting the treatment, open the indicator light and click the "START TREATMENT" (Standby) button in the interface to enter the "READY" state. In the "READY" state, align the handle head with the treatment site and press the foot/finger switch. The laser will be emitted for corresponding Medical Therapy.

Use case to place

To wind fiber back up, place metal coupler at the depicted

Wind fiber until complete.

accessories neatly in position. When putting fiber away unscrew tips and place black cap back on hand piece.

edge of the cutout, and wind counterclockwise.

4 PRODUCT SPECIFICATION

4.1 Technical Parameters

Feature	Platinum P4H
Laser Source	Diode GaAlAs
Number of Diode	4
Housing Color	Black
Wavelength	650nm±20nm, 810nm±10nm, 915nm±10nm, 980nm±10nm
Average Energy Output (Don't turn on ISP in pulse mode）	14 W ± 1.4 W
Average Energy Output (Turn on ISP in pulse mode）	20W±2W
CW Power (W)	28W±2.8W
Intense Super Pulse (ISP) Max Output power	30W±3W
NOHD (*)	3.30 m
Isolation Class	Class II, type B
Laser System	Class IV
Aiming Beam	650 nm ± 20 nm
Aiming Beam Power	< 2mW

Transmission System	600um
Timer	0-3600s
Fiber	Quartz
Emission	CW or chopped (0 – 20000 Hz)
Operating Voltage	100 – 240V 50-60HZ
Cooling Method	Closed loop, liquid filled, heat pipe thermal transfer system with fan/air assist.
Current	1.2-0.5A
Operating Parameters	10.8V
User Interface	7-inch touch screen color display
Laser Activation	Finger switch, optional Foot pedal
Laser Stop	Yes
Fiber Detection	Yes
Interlock	Yes
Power Supply	Input 100-240VAC, 50/60Hz Output 18 VDC, 5.55A
Battery Pack	Rechargeable Battery 18650-7000mAh-10.8V 3S2P
Weight (Battery Pack Included)	approx. 5.4 pounds (incl. hand piece and rechargeable battery)
Dimension (H x W x D)	258.65mm x 238.43mm x 88.86mm
Device IP Protection	IPX0
Power Density Range **Minimum to Maximum Wattage power**	

Model	Average Power in CW and ISP (W)	251 25mm tip* (W/cm2)	253 25mm tip* (W/cm2)	501 50mm tip (W/cm^2)	502 50mm tip (W/cm^2)	8S 8mm tip (W/cm^2)
P4H	**0.5**	0.10	0.10	0.03	0.03	0.248
	7	1.43	1.43	0.36	0.36	/
	15	3.06	3.06	0.77	0.77	/
	28	5.70	5.70	1.43	1.43	/

* The laser device limits the 25mm tip to a maximum of 15W.

* The laser device limits the 8mm tip to a maximum of 3W.

Note Reference Operation Instructions section, Custom Treatments of this manual for recommended musculoskeletal dosing guidelines.

4.2 Storage and Use of Environment

The following 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 atmospheric pressure: 86~106kPa
- Avoid direct sunlight, rain is strictly prohibited
- Well ventilated
- Avoid storing in strong electromagnetic environment
- Avoid severe vibration
- Programmed electrical medical system

- Avoid storing in explosive, corrosive gases, excessive dust or salt of the environment

The battery may be stored within an environmental range of -10^{0}C to 45^{0}C for short term storage.

Should the battery need to be stored for an extended period of time (over 3-months), provide battery with a full charge and the environmental condition shall be 23±5^{0}C and 65±20% RH.

Battery shall be charged every three-months when in long term storage. Please charge the battery with standard charging current for approximately 0.5 to 1-hour to maintain 40-60% state of charge.

5 CONTENTS OF PLATINUM SERIES P4H laser

#	ITEM	DESCRIPTION	NUMBER
1	Diode Laser	Therapeutic laser device	1
2	Hand Piece	Treatment Hand Piece	1
3	Hand Piece Tips	25mm Open 25mm Curved Contact 50mm Curved Contact 50mm Broad Beam Open	4
4	Fiber	Laser energy is transported through the fiber	1
5	DC Power Connector	Connects Power Supply to the Unit Power supply - Input 100-240VAC, 50/60Hz Output 18 VDC, 5.55A	1
6	Lithium Ion Battery	The local reserve power supply	1
7	Safety Goggles	Laser protective glasses	3
8	Diode Laser Operation Manual	Instructions for use	1
9	Certificate	Product Inspection Certificate	1
10	Packing list	Packing List	1

Contents of Platinum Series P4H laser

Component	Description
	Platinum P4H is Black 
	Side view showing hand piece in cradle and emergency shut off
	Hand piece in cradle and the zoom distal part
	Sinmpro external AC power adapter for all the models

	Battery pack (included in the main unit)
	Protective goggle

6 SET - UP INFORMATION

6.1 Platinum Series P4H Set-up

Reference Contents and Accessories section of the Platinum Series P4H for identification of components and Installation section for pictured diagrams for assembly.

- Place unit in a clean, dry, and well-ventilated area
- Verify power is in OFF position
- Verify Emergency Stop button is disengaged (pull out)
- Connect hand piece
- Connect remote interlock
- Connect power cord to power connector on unit and plug into grounded wall outlet
- Insert fiber into Fiber Connection Port by first removing small stainless-steel protective cap from the connector end of the fiber. Save the protective cap for future use and take care not to touch the end of the fiber. Next, attach the fiber to the Fiber Connection Port by screwing the aluminum collar onto the Fiber Connection Port until the connection is “finger-tight”. If using strippable fiber, refer to the instructions provided with the fiber.
- Set up delivery system hand piece and fiber. Attach the therapy tip to the distal end of the hand piece.

6.2 Operation Instructions

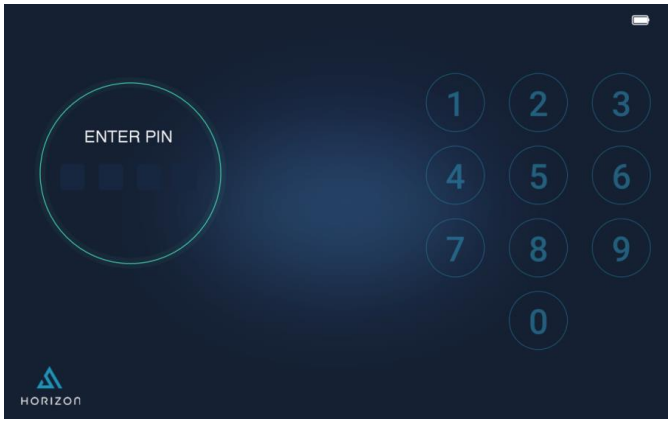
(Images are shown as a reference only and may appear differently between devices)

Turn on P4H laser device

- Verify red emergency button is disengaged and pulled out

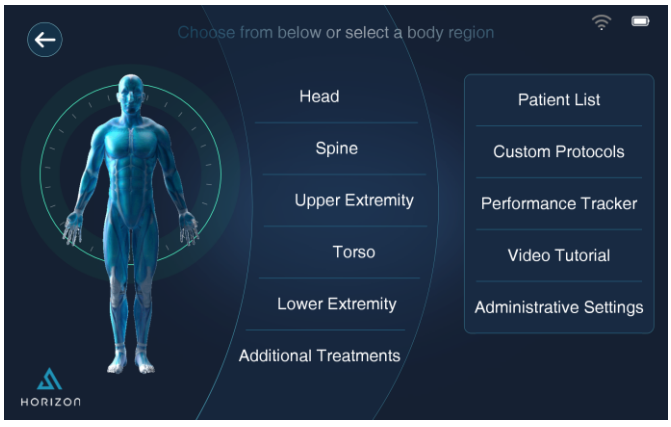
- Turn power switch to the ON position
- User interface login system to enter 4-digit security PIN enter the main interface
- Enter 1111 for super administrative privileges

  i. Summus Medical Laser highly recommends changing the super administrative password to a unique 4-digit PIN applicable to your establishment.



Entering a wrong security PIN will elicit a temporary “PIN error” message requiring the user to re-enter the correct secure PIN.

- Select a PRESET from the Home Interface administrative options

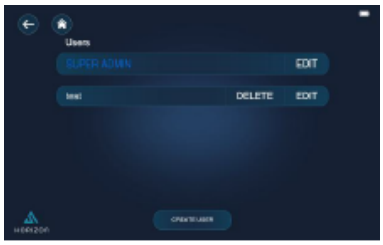


- Navigate through the Home Interface settings for appropriate protocol selections.

Administrative Settings

- The user can change the parameters for adding and removing users, volume, LCD brightness, language, date, time (standard or military), Wi-Fi connection, etc., for desired setting.

Add New User



Add, Edit or Remove User

Adjust Volume, Brightness, Date, and Time

Select Wi-Fi Settings

Select Language

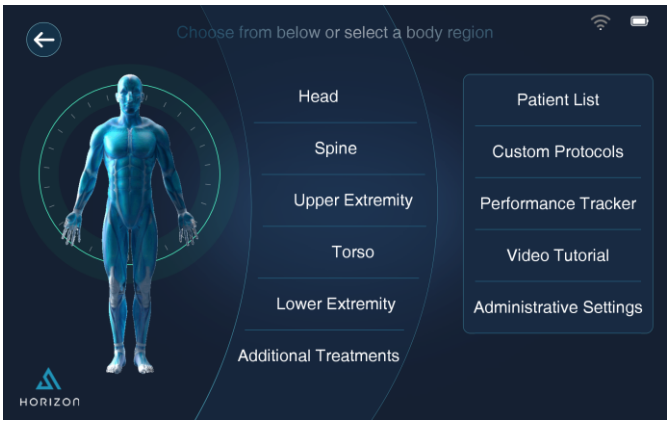
Device Information

Device Information

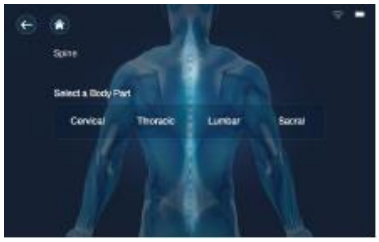
New Treatment

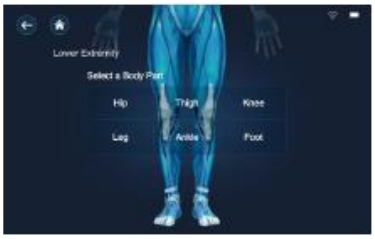
- The user can choose and program the parameters for initial treatment according to the needs of the patient.

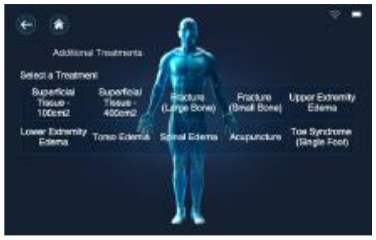
Select a Body Region: The user can choose between 5 body regions (Head, Spine, Upper Extremity, Torso and Lower Extremity) and Additional Treatments.



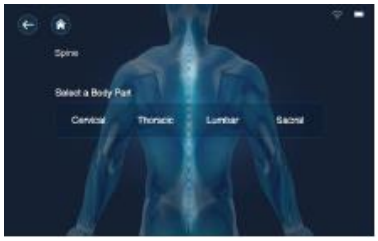
Select a Body Part: The user can choose body parts for each body region previously chosen.

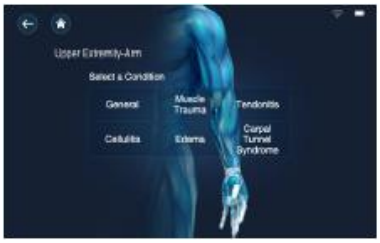


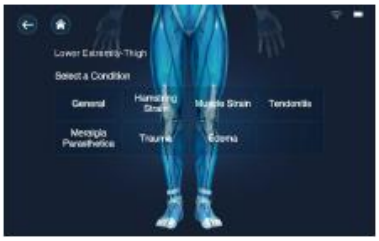




Select a Condition: The user can choose a general treatment or a specific condition to be treated for the body part previously chosen.

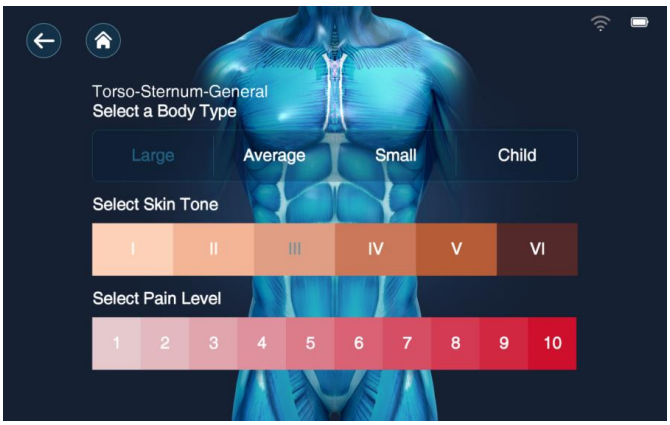




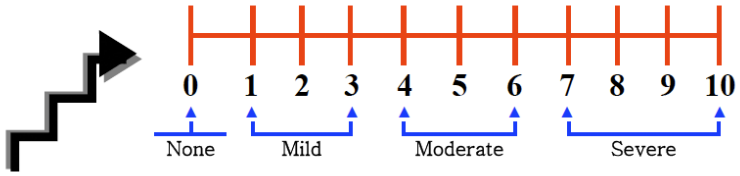


Customize Treatment by: The user can customize the treatment by the following variable.

Body Type **Skin Tone** **Pain Level**



Pain may be assessed by the numerical rating scale which is one of the most used pain scales in health care. The patient has the option to verbally rate their pain from 0 to 10. Zero indicates the absence of pain while ten represents the most intense pain possible.



Skin tone of the patient is based upon the Fitzpatrick scale. A recognized tool for dermatological assessment to skin pigmentation and how the skin responds to light. The scale is a numerical classification scheme for human skin color by six types. Type I indicates light skin color and Type IV indicates dark skin color.

Thermal effects vary with skin pigmentation – darker absorbs more. If you get a withdrawal response, increase distance and/or move the beam more rapidly and/or reduce power. You may need to increase power or time (Dosage) with darker skin being cautious of superficial thermal effects.

The user may manage selected parameters

Power	Automatically calculated by the laser device
Average Power	Calculated from the power values and the time of emission
Wavelength	May be selected individually
Frequency	Adjustable between 0-20,000Hz
Phase	Adjustable between 0-3600s
Treatment Time	Automatically calculated by the laser device

Units can only accept one input at a time. Laser settings will reflect the last input from the user.

Treatment Techniques

Direct Contact

This is the technique used when treating most patients. The laser has a 25 mm and a 50 mm treatment tip. The use of mild pressure allows for deeper penetration in some areas. Treat in a scanning pattern for most cases and especially when using higher power and Continuous Wave (CW). Scan in a slow methodical pattern at a rate of approximately 3 cm/second. Another treatment technique is to administer the therapy using a grid pattern or point-to-point. This is done only with lower power lasers and/or when the laser power is reduced and/or pulsing or modulating. Treat in a grid pattern at 1-3 seconds per point or the recommended timeframe to deliver the prescribed dose. Always treat the area of interest as well as including a border of surrounding healthy tissue and any other parts of the kinetic chain that are involved in; compensating for; or affected by the injured body part. You can perform laser therapy in conjunction with (simultaneously) stretching or ROM in patients.

Non-Contact

Non-contact treatments are almost always done in a scanning mode. Scan 1-2 cm from the surface with slow passage (about 3 cm/second) over the affected area and 1-2 inches of surrounding healthy tissue. Used over an injured area or where any other inflamed condition may be present. Also used on very painful/sensitive areas. Again, it can be done in conjunction with stretching or ROM.

Keep in mind your “Line of Drive”. Make sure the laser beam is being directed towards the target tissue.

Direct the beam perpendicular to muscle tissue.

Direct the beam parallel to joint surfaces.

Treat connecting muscles, tendons, bursas.

Patient List

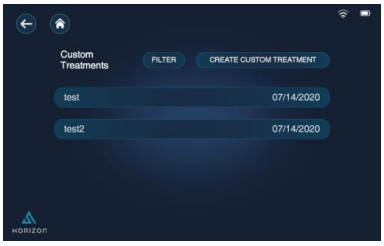
- The user can create and edit a patient profile, view and choose previous treatment settings according to the needs of the patient.

Custom Treatment

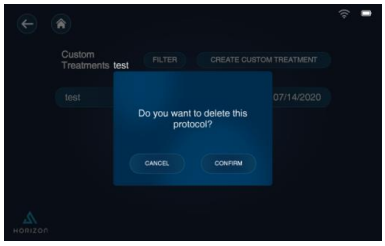
- The user can create custom treatments for general use of the device

Modify Treatment Time, Power, Frequency, Wavelength, and Continuous Wave (CW) or Intense Super Pulse (ISP)

Modify Treatment Power



Custom treatment List



Delete

Note ISP peak power is delivered only in pulsed mode. The laser delivers the following average power in pulse mode:

Platinum P4H Max avg. output = 0.1 to 20 W ± 2 W

Note The frequency in Continuous Wave (CW) is automatically converted into 0 Hz. The frequency in ISP modality is defined between 1–20000 Hz.

Note A 25 mm tips diameter is is 2.5 cm and has a 1.25 cm radius. Its area is 4.9 cm^2.
A 50 mm tips diameter is 5.0 cm and has a 2.5 cm radius. Its area is 19.6 cm^2.

Recommended Musculoskeletal Dosing Guidelines	
Energy	
Pain	2-20 J/cm2
Optimum Beam Frequency	
Pain/Neuralgia	2-20 Hz or CW
Edema/Swelling	1,000 Hz
General Stimulation	2,500 Hz

Inflammation	>5,000 Hz

Average power remains constant during emission in CW or Pulse respectively. Refer to Recommended Treatment Protocol tables for light or dark skin below for average power.

Recommended Treatment Protocol for Light Skin

Fitzpatrick scale 0 through 3

Intended Body part	Average Power, Watts	Power Density, Watts/cm2	Treatment time, seconds	Total Dose delivered, J	Treatment Area size, cm2	Dosage, J/cm2	Wavelength
Cervical	7	0.36	360	2520	400	6.3	*
Thoracic	8.5	0.43	420	3570	500	7.14	*
Lumbar	12	0.61	420	5040	500	10.08	*
Shoulder	8	0.41	360	2880	400	7.2	*
Elbow	6	0.31	180	1080	200	5.4	*
Forearm	5	0.25	240	1200	300	4	*
Wrist	4	0.20	120	480	100	4.8	*
Hand	4	0.20	90	360	100	3.6	*
Finger	2	0.10	45	90	25	3.6	*
Hip	10	0.51	420	4200	500	8.4	*
Thigh	9	0.46	420	3780	450	8.4	*
Knee	8	0.41	360	2880	400	7.2	*
Leg	7	0.36	300	2100	300	7	*
Ankle	6	0.31	240	1440	200	7.2	*
Foot	5	0.25	150	750	100	7.5	*
Toe	2	0.10	45	90	25	3.6	*

* Depending on laser device model (P1 = 650, 810, 980nm or P4 = 650, 810, 915, 980nm)

Recommended Treatment Protocol for Dark Skin

Fitzpatrick scale 4 through 10

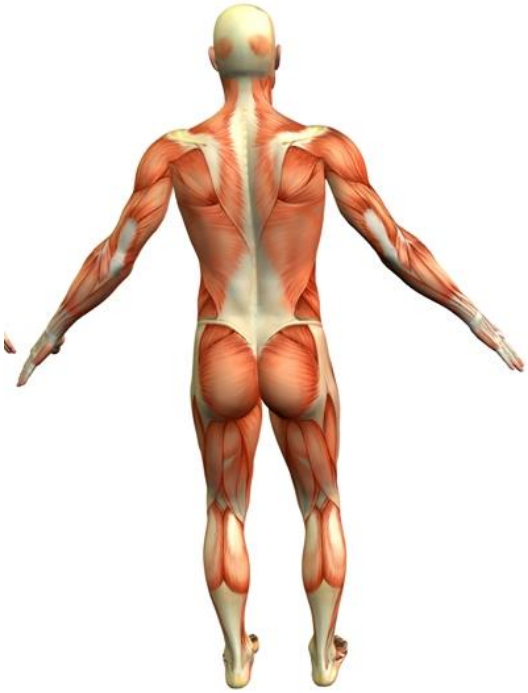
Intended Body part	Average Power, Watts	Power Density, Watts/cm2	Treatment time, seconds	Total Dose delivered, J	Treatment Area size, cm2	Dosage, J/cm2	Wavelength
Cervical	3.5	0.18	720	2520	400	6.3	*
Thoracic	4	0.20	840	3570	500	7.14	*
Lumbar	6	0.31	840	5040	500	10.08	*
Shoulder	4	0.20	720	2880	400	7.2	*
Elbow	3	0.15	360	1080	200	5.4	*
Forearm	2.5	0.13	480	1200	300	4	*
Wrist	2	0.10	240	480	100	4.8	*
Hand	2	0.10	180	360	100	3.6	*
Finger	1	0.05	90	90	25	3.6	*
Hip	5	0.25	840	4200	500	8.4	*
Thigh	4.5	0.23	840	3780	450	8.4	*
Knee	4	0.20	720	2880	400	7.2	*
Leg	3.5	0.18	600	2100	300	7	*
Ankle	3	0.15	480	1440	200	7.2	*
Foot	2.5	0.13	300	750	100	7.5	*
Toe	1	0.05	90	90	25	3.6	*

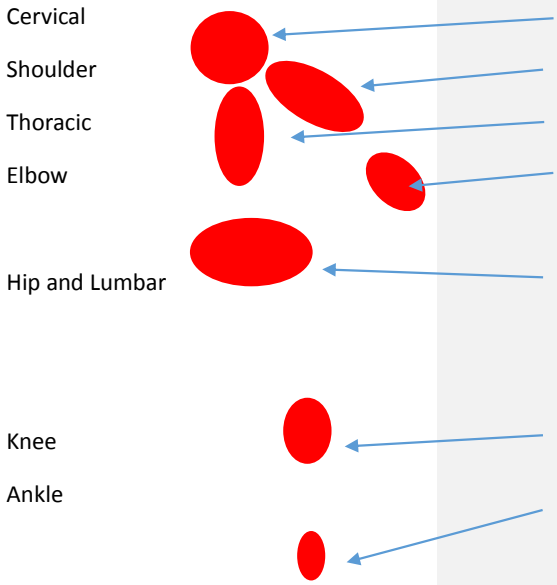
* Depending on laser device model (P1 = 650, 810, 980nm or P4 = 650, 810, 915, 980nm)

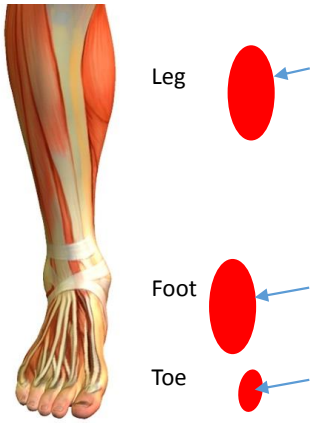
Note The 25mm or the 50mm treatment tip can be used with the P4H model on all listed body parts.

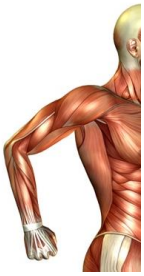
Treatment areas

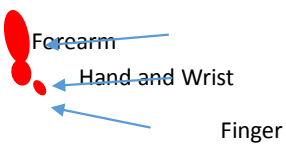
The shaded areas on the figures below indicate the area to be treated for the listed body parts in the recommended values table above. The shaded areas represent the proper area to treat, to deliver the proper laser dosage.











Acute injuries use shorter times and/or lower power (Lower Total Dosage/Joules). Some injuries may respond to a graduated treatment from lower to higher frequencies. Example: Start with CW then go to 20 Hertz followed by 500 Hertz followed by 2500-5000 Hertz.

The protocols programmed into the Summus lasers will do this for you automatically. However, if the user wants to adjust the set protocols then following these guidelines would assist them in safely doing so.

If noticing any discomfort, aversion reactions, or other hypersensitivity reactions, decrease power, increase hand speed, increase distance to tissue, or switch to a Pulse or Modulating (Hertz) delivery mode.

A slow, constant, scanning or rocking motion over the target area is optimal. Always include a border of healthy tissue surrounding the area of concern. Laser any other structures in the kinetic chain that may be contributing to the mechanical support and therefore may be injured or adding stress to the injured area. It is always recommended when treating large areas to treat from proximal to distal (musculoskeletal) or central to peripheral (neurologic). When treating for edema/swelling always start with the major draining lymph nodes and associated lymphatics proximally then work down the affected area.

Laser therapy effects are cumulative-Response should improve with each treatment and duration of response should increase with each treatment until a plateau is reached. Plan on a minimum package of 6-10 treatments (Similar to 10-14 days of Ab) in most cases.

Acute injuries can be treated 2-3 days in a row then every other day or twice weekly.
Chronic injuries should be treated 2-3 times a week initially until a response is observed.

A good starting protocol could be 3 times week one, then twice the following week, then once or twice the week after. Then re-evaluate.
If needed, continue treatments twice weekly (or weekly if better for client compliance) until the condition is resolved or plateaus. This is often achieved in 6-10 treatments on average.

For those conditions which will not establish a ‘cure’, once a maximum response is reached, you can then lengthen the time between treatments

gradually until acceptable patient comfort is maintained. Treatments every 3-4 weeks may be adequate for maintenance in many patients.

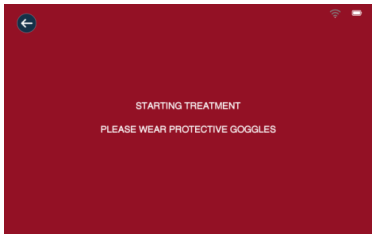
Most patients will show at least a mild positive response in 1-2 treatments. If positive response is not noticed in 3-4 treatments, re-evaluate condition/treatment or protocol/diagnosis. If diagnosis is correct, you may need to increase dosage (Time and/or Power). Increase dosage by 25%-50% per treatment episode until a positive response is observed. You can also expand your treatment area to include more of the potentially involved tissue/structures.

Some patients may experience a 'flare' after laser treatment due to the stimulation of the healing response. This may be manifested in increased soreness or fatigue. If this is noted, consider decreasing the dosage by 25%.

Video Tutorial Library

- The user can view uploaded educational content, teaching videos, and find related documents specific to certain treatments
- Select the appropriate educational tutorial. Volume may then be adjusted by sliding your finger up or down on the pictured screen. Video play may be adjusted by sliding your finger left or right on the pictured screen and may be stopped by pressing once on the screen
- Remove the hand piece from the cradle
- Aim the hand piece perpendicular to the surface you are treating

Press START TREATMENT to put the device in standby



Optical Density (OD) 7.0 or greater for the infrared (810, 915, 980nm) wavelengths and 2.0 or greater for the visible red (650nm) wavelength

- Press finger switch to emit laser.

- Press and release finger switch a second time stop the laser from emitting during treatment if needed.
- Laser emission will automatically stop at the end of the selected protocol treatment time.

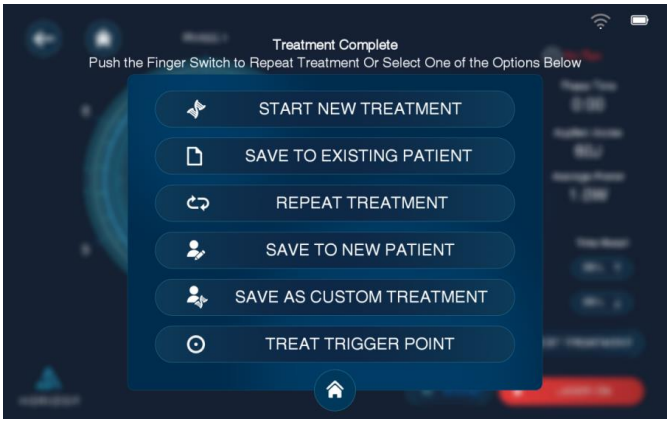
Performance Tracker

The user can review the online Performance Tracker for usage history, treatments provided by day, treatments by body part, and revenue generation.

Turn Off P4H laser device

Finished Treatment with Leaving Device Power On

- Place hand piece back on hand piece cradle
- Navigate through the settings for other appropriate selections
- Or Press the Go Home button 



- From the Go Home button you return to the Home screen

Finished Treatment Turning Device Power Off

- Wrap fiber clockwise leaving enough slack to move hand piece to cradle.
- Place hand piece on hand piece cradle
- Turn the power switch to the OFF position
- Unplug the power adapter
- If applicable, relocate to a secure storage area

⚠ WARNING: Verify that the fiber optic assembly is not twisted when returning the hand piece to the cradle. Fiber may break if it is twisted or crimped.

⚠ WARNING: Do not leave the system in an uncontrolled environment where the temperature or humidity is too low or too high. Environmental conditions too low or too high will affect the stability of laser output power.

6.3 Control Panel of P4H

⚠ WARNING: Please read the control panel information carefully to understand the P4H panel definition of buttons, product settings and operating procedures to avoid misuse caused by graphic button misunderstanding.

Note: The display screens in the manual are examples, which may be slightly different from the actual display of the diode laser you purchased. Please refer to the actual display of the device.

⚠ WARNING: The login 4-digit security PIN is owned by authorized personnel. Unauthorized personnel are not allowed to use the device without permission.

Interface button meaning:		
NO.	ITEM	DESCRIPTION
1		Previous screen
2		Users can click on the button to return to the home screen
3		Wi-Fi connection
4		Battery icon: Display real-time battery power; when the battery is less than 1% and internal battery power supply is used, the system will stop the laser output.

5	2017/06/19 09:44	Date and time display found in customizations: Users can set the date and time in the settings interface.
6	LED Operational Color	Color indicates current status of the equipment Green - LED on when the device is in “Laser ready” Yellow - LED on when the device is in “Laser active” Red - LED on when device is in “Laser alarm”
7	CW	Continuous Wave - the mode of emission delivery
8	ISP	Intense Super Pulse - the mode of emission delivery
9	650nm	650nm ±20 wavelength button
10	810nm	810nm ±10 wavelength button
11	915nm	915nm ±10 wavelength button
12	980nm	980nm ±10 wavelength button
13	Volume	Adjusts audible
14	Go to Treatment	After protocol modifications you return to the treatment screen
15	ISP On/ Off	Allows ISP setting for customized protocol treatments
16	↑25%	Time Boost and/or Power Boost to increase treatment time and or power for customized protocol treatments
17	↓25%	Time Bump and/or Power Bump to decrease treatment time and or power for customized protocol treatments

Note：

1) The display screens in the manual are examples and may differ slightly from the actual display of the purchased medical diode laser. Refer to the actual display of the device.

2) Read the button table in detail to understand the definition and use of the button.

3) The user is only able to set the parameters in the Standby state

⚠ WARNING: After completion of treatment, release the finger switch to return the system from the READY state to the STANDBY state to avoid laser radiation

due to misuse.

6.4 Emergency Troubleshooting

When the device is powered on and operating, if there is abnormal function (such as no display, light abnormal, etc.), immediately press the emergency stop switch to stop the laser output. Identify and correct the cause prior to resuming use. Reference Alarm Function and Fault Diagnosis and Analysis sections. If necessary, please notify the dealer or the company for help.

Emergency stop switch reset method: Pull the emergency stop switch out and away from the device to reset the emergency stop switch.

ON – Power On

OFF – Power interruption

7 Control Instruction for Use

7.1 Finger Switch

- Connect the connector of the finger switch cable to the device.
- Place the finger switch on the platform floor.
- Set up appropriate parameters according to patient needs.
- Apply pressure to enclosed finger switch with your foot. The yellow LED Indicator light glows to indicate that the finger switch is operating when pressure is applied on the pedal to emit laser.

		
Insert the black cable into the finger switch by aligning red dots. Push in and **Do not twist.**	Complete view. **Do not twist to tighten.**	Fiber and black cable inserted correctly.

⚠ WARNINGS：

1） Do not re-use disposable or single-use items，such as tips and fiber. Failure to comply may result in reinfection or cross-infection and is a hazard to the patient.

7.2 Goggles

Post warnings in therapy areas where the lasers are to be used, so that appropriate goggles can be donned before entry into the area. The user, patient, assistant, and any other persons in the therapy area during laser procedures

MUST wear the appropriate laser goggles for protection of emitting diode lasers with an optical density (OD) of 7.0 or greater for the infrared (810, 915, 980nm) wavelengths and 2.0 or greater for the visible red (650nm) wavelength emitted by the Platinum Series P4H device. Class IV laser radiation is hazardous to the eye from the direct beam and diffuse reflections. Laser radiation also represents a significant skin and fire hazard. Safety goggles not designed to this specification are not suitable for use with Platinum Series P4H lasers.

Laser protective goggles can be purchased by contacting our company.

Goggles

7.3 Training

Only licensed professionals who are certified in Class 4 laser use and have read and understood the Operating Instructions Manual shall use this device. Summus Medical Laser assumes no responsibility for parameters, techniques, methods, treatments, or results. Clinicians and/or operators must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

If there is any operation or technical problems during the process, please refrain from use and contact the authorized representative or our company for consultation.

8 ALARM FUNCTION DESCRIPTION

8.1 Alarm Type

The system provides five alarm prompts, namely:

- High temperature alarm
- Remote interlock alarm
- Hand piece switch alarm
- Laser alarm
- Fiber alarm

All of the above alarms are technical alarms. When the alarm occurs, the user should follow the appropriate safety precaution procedures defined in Alarm Function section according to the priority of the alarm to prevent personnel and device damage.

8.2 Alarm Mode

Platinum Series P4H provides sound and graphical warning signs in the alarm indicator alarm mode. Abnormal system state will lead to alarm and interrupt the laser output to ensure the safety of personnel and device. The alarm delay is less than 1s.

Sound Alarm

When the system status is abnormal, the sound alarm will be triggered. When the alarm is released, the audible alarm stops.

Graphical Warning Signs

In the interaction interface, different types of alarms correspond to different graphical warning signs. When the alarm is released, the screen returns to normal.

Indicating Light Alarm

When the alarm prompt appears, the red light of the alarm indicator will be on. When the alarm is released, the red LED light turns off and resumes to green LED laser ready state.

8.3 Alarm Function

The Platinum Series P4H Laser monitors the operating status of the system in real time. Sounds, indicators, and graphical warning signs alert the system to unusual events with different priorities while interrupting the laser outputting.

Alarm Types	Triggering conditions	Alarm release method
High Temperature Alarm	1.Laser temperature exceeds 45 ° C 2. Fiber coupler temperature exceeds 60 ℃; 3. Temperature sensor failure	1. If the alarm is caused by high temperature, power off the device. Air cooling device for ~10 minutes will return to normal after the reboot. Do not cover the opening of the air flux. 2. Please contact the company after-sales maintenance.
Remote Interlock Alarm	The remote interlock is not inserted correctly or is not plugged 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 alarm condition is still unresolved, please contact the company for after-sales maintenance.
Hand Piece Switch Alarm	The hand piece switch is not properly inserted or is not inserted into the device.	1. Check the front panel and whether the hand piece switch is correctly inserted into the device. 2. If the handle switch is properly inserted into the device, and the alarm status is still unresolved, please check the handle switch button is pressed or not. 3. Check the above operation, if there is still alarm status, please contact the company after-sales maintenance.
Laser Alarm	Safety interlock failure	1. Please contact the company for after-sales maintenance.
Fiber Alarm	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 alarm condition, please contact the company after-sales maintenance.

8.4 Alarm System Detection

The device will determine the alarm status. When the device detects an alarm, the system will emit a sound, the alarm red LED indicator will illuminate, and graphical warning signs will appear on the LCD screen.

8.5 Fault Diagnosis and Analysis

⚠ WARNING: Do not use the device for treatment when the device is malfunctioning or in other abnormal conditions. Promptly follow in accordance with the instructions for troubleshooting and contact the company for after-sales advice.

Failure Phenomenon	**Cause Analysis**	**Exclusion Method**
Turn on the power switch, the system indicator does not light and the system does not start	1. Emergency stop switch is not turned on 2. The power switch is not turned 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. ⚠ WARNING: Use only use the 1a 250v fuse
The screen displays an alarm	1. Remote control interlock is not connected 2. The hand piece switch is not connected 3. The Optical fiber is not connected 4. Laser failure	1. Check whether the remote interlock is connected properly. 2. Check the handle switch is connected properly. 3. Check whether the fiber is connected properly. 4. Check whether the hand piece switch is pressed in standby mode. 5. Contact the company for after-sales maintenance.
There is no sound indication when the laser is outputting	1. Buzzer malfunction	Contact the company for after-sales maintenance.
Laser power attenuation	1. The glass lens of hand piece is with dust or other dirt	1. Clean the glass lens with lens paper or paper towel. 2. Calibrate the laser power according to

	2. Laser attenuation	the instructions. 3. Contact the company for after-sales maintenance.
No power outputting	1.The coupler is damaged 2. Optical fiber is damaged 3.Laser is damaged 4. System failure	Contact the company for after-sales maintenance.

⚠ WARNING: Users can perform general troubleshooting according to the above scenarios. If you cannot solve the problem, Do Not disassemble the device to check and contact the designated dealer or company for maintenance.

9 POST TREATMENT CLEANING

Appropriate steps shall be taken by the operator between treatments of the laser device and components to ensure the distal parts coming into direct or indirect contact with the patient such as the applicator treating head/ hand piece tips receive a thorough cleaning process.

Thorough manual cleaning shall be completed by the operator for all reusable components to assure all surfaces are completely free of any organic or inorganic material to prevent transmission of potential bioburden.

Wear appropriate Personal Protective Equipment (PPE) when performing cleaning and disinfecting procedures.

⚠ WARNING: Following treatment, switch off the device and disconnect the power cable from the power supply.

⚠ WARNING: Unit and accessories are not sterilizable.

9.1 Cleaning of the Distal Hand Piece Tip

⚠ WARNING: The applicator treating head/ hand piece tips may be warm immediately after treatment. Allow to air cool.

⚠ Do not twist the hand piece for possible damage to the optic fiber.

Remove the zoom distal part from the hand piece by gently pulling the tip from the hand piece for cleaning.

⚠ Make sure that no dust or dirt enter the optical fiber socket or the hand piece optical system as these may permanently damage the unit.

Clean the applicator treating head/ hand piece tips between uses with products that are commonly used to disinfect medical electrical equipment, e.g. high purity alcohol, lens paper and/or Caviwipes ™. Observe the directions for intended use provided by the manufacturers of these products.

⚠ Do not overly saturate the area being cleaned and wipe off any excess liquid to prevent the liquid from penetrating the optical fiber. Allow the liquid to volatize before reattaching the tip to the hand piece.

⚠ Use only disinfectants that comply with the requirements of your national authorities and have been tested and properly certified.

⚠ Be careful not to scratch and damage the foil on the lens.

9.2 Cleaning of the Hand Piece

Clean the hand piece between uses with products that are commonly used to disinfect medical electrical equipment, e.g. high purity alcohol, lens paper and/or Caviwipes ™. Observe the directions for intended use provided by the manufacturers of these products.

⚠ Do not overly saturate the area being cleaned and wipe off any excess liquid. Allow the liquid to volatize before use.

9.3 Cleaning of the Main Unit

Use a soft cloth or lens paper to clean the main unit and the LCD touch screen. Reference Daily Maintenance in section 11.1.

⚠ WARNING: Solvents and flammable solutions used for cleaning and disinfection should be volatilized before using the equipment. There is a risk the internal gas may be ignited.

10 MAINTENANCE

⚠ WARNING: This product 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. It is strongly recommended that users carefully read the instructions to avoid injury to the patient and damage to the device caused by possible harmful laser radiation.

10.1 Daily Maintenance

1) Check the optical fiber before each treatment to ensure the fiber is not bent or broken. Protect the fiber of hand piece from rigid bending, so as not to break the fiber.

   ⚠ AVOID strong pull force and extreme bending of handle or optical fiber. NEVER bend the fiber cable or apply stress. Keep the bending curvature radius larger than 50mm and at an angle of 90 degrees or greater

2) After removing the hand piece, immediately cover the dust cap to prevent dust pollution; dust cap must be cleaned with alcohol before use.

3) DO NOT use hard or sharp objects which will scratch the touch screen. Do not use chemical reagents on the touch screen. Please wipe carefully with lens paper or paper towel to avoid scratching or damage to the touch screen.

4) Clean the surface of the device regularly to prevent the accumulation of dust. We recommend the use of CaviWipes™.

   ⚠ AVOID spraying or splashing cleaning and disinfectant liquid into the interior of the device. Spraying or splashing may allow liquids to penetrate into the device.

   ⚠ The medical device and accessories are not sterilizable

5) Vibrations or collisions with other objects should be avoided in the process of moving the device.

6) 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 of Summus Medical Laser personnel or designated dealers to avoid injury to the patient and damage to the device caused by possible harmful laser radiation.

7) Summus Medical Laser recommends carrying out routine inspection and maintenance and power calibration every year under the guidance and operation of authorized company personnel or designated dealers to avoid possible injury or damage to the device from harmful laser radiation.

10.2 Routine Inspection

Clinicians can routinely check the device under the guidance of the dealer or on their own to ensure that the device is working properly. The general check contents are as follows:

1) Whether the safety device is normal: Safety interlock, finger switch, optical switch, emergency stop switch

2) Whether the finger switch signal is normal: Emit the laser in the READY state

3) Whether the sound or Indicator light is normal

4) Whether the operation of touch screen is normal

5) Whether the label is affixed firmly

6) Whether the laser power is within the normal range

7) Whether the optical fiber is normal (i.e. bent, broken) before each treatment)

⚠ If national or local legal regulations require additional safety checks for the laser unit, these regulations must be complied with and the corresponding checks shall be performed by the user.

10.3 Laser Power Calibration

⚠ Warning: When the power output has changed and the speed exceeds ± 10% of the set power, please contact a Summus Medical Laser designated representative for required power calibration. Calibrations must be under the direction of our companies authorized personnel to avoid possible injury or

damage to the device from harmful laser radiation.

We recommend that you have your P4H laser calibrated every 24 months. Contact the Summus Medical Laser Service Center to schedule the calibration.

11 WASTE DISPOSAL

Medical equipment is considered for disposal because of its natural obsolescence and failure to meet current treatment standards, uneconomic or poor serviceability, lack of spare parts, etc.

Fibers, batteries and other discarded items, should be disposed of in accordance with Waste Disposal Policies and local laws and regulations for processing.

⚠ The end user has an obligation to ensure the safe and responsible disposition of the medical laser device and battery. Under no circumstances should lasers be abandoned, disposed as common regular trash or put out for sale to the general public. Observe all legal provisions. This has been expressed using the icon of the crossed-out receptacle container 

⚠ All lasers designated for disposal must be decommissioned and made inoperable to ensure an unqualified person does not use the device and expose themselves or others to potential hazards. Disposal is an option when lasers are of no value and only after the laser is rendered inoperable. Contact Summus Medical Laser at 866-595-7749 or an authorized service center.

12 ELECTROMAGNETIC COMPATIBILITY

Platinum Series P4H™ semiconductor laser treatment instrument is the basic performance of the laser output power accuracy.

Note:

1) The purchaser or user of the P4H semiconductor laser treatment instrument should use the instrument in the electromagnetic environment specified in this section. Otherwise, the Platinum Series semiconductor laser treatment instrument may not work properly.

2) Portable and mobile radio frequency communication equipment may affect the normal use of the P4H semiconductor laser treatment device. Please use the recommended electromagnetic environment during use of the P4H semiconductor laser treatment instrument.

⚠ WARNING:

1) In addition to the accessories and cables provided by the manufacturer of the P4H laser device, the use of non-specified accessories and cables may result in an increase in the emission or immunity of the semiconductor laser treatment instrument.

2) P4H therapy lasers should not be close to or stacked with other equipment.

12.1 RF Transmitting

Guidance and manufacturer's declaration - Electromagnetic emission		
The Therapy laser is intended for use in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment.		
Emission Tests	Compliance	Electromagnetic environment - guidance
RF Emissions EN 55011	Group 1	The Therapy laser uses RF energy only for its internal functions. As a result, its RF emissions are low and may not cause any interference to nearby electronic equipment.
RF Emissions EN 55011	Class A	The Therapy laser is not suitable for use in a power supply facility that is directly connected to a public low voltage power supply network that powered by a civil power supply or for a civil building.
Harmonic emissions EN 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions EN 61000-3-3	Complies	

12.2 Electromagnetic Immunity

Guidance and Manufacturer's statement - Electromagnetic Immunity			
The Therapy laser is intended for use in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment.			
Immunity Test	GB9706 Test Level	Match Level	Electromagnetic Environment Guidance
Electrostatic discharge(ESD) EN 61000-4-2	± 8kV contact ± 15kV air	± 8kV Contact ± 15kV Air	The semiconductor laser treatment device should not be affected by the electrostatic discharge that may occur under normal use conditions.
Electrical transient/ burst EN 61000-4-4	± 2kV for power cord ± 1kV for input / output lines	Applicable Applicable	The network power supply should have a typical commercial or hospital environmental quality.
Surge EN 61000-4-5	± 1kV line to line ± 2kV line to ground	Applicable Applicable	

Power dips, short interruption and voltage variations on power supply input lines EN 61000-4-11	<5% U_T for 0.5 cycles (On U_T ,> 95% of the sag) 40% U_T for 5 cycles (On U_T , 60% of the sag) 70% U_T for 25 cycles (On U_T , 30% of the sag) <5% U_T for 5s (On U_T ,> 95% of the sag)	Applicable Applicable Applicable Applicable	The network power supply should have a typical commercial or hospital environmental quality. If the user needs to run continuously during power interruption, it is recommended that the Therapy laser be powered by uninterruptible power supply.
Power frequency （ 50Hz/60Hz ） magnetic field EN 61000-4-8	3A/m	3A/m	The magnetic field caused by the power frequency should be at the characteristic level in the commercial or hospital environment
Note: U_T is the AC power supply voltage before applying the test level.			

12.3 Electromagnetic Immunity

Guidance and Manufacturer's statement - Electromagnetic Immunity			
The Therapy laser is intended for use in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment.			
Immunity Test	GB9706 Test	Match Level	Electromagnetic Environment Guidance

<table>
<tr><td></td><td>Level</td><td></td><td></td></tr>
<tr><td>Conduction RF
EN 61000-4-6

Radiation RF
EN 61000-4-3</td><td>3V(Valid values)
150KHz~80MHz

3V/m(Valid values)
80MHz ~2.5GHz</td><td>Not Applicable

3V/m

3V/m</td><td>Portable and mobile RF communication equipment shall not be used within the recommended distance (unit: m) of any part of The Therapy laser (including cable). The recommended separation distance is calculated using the equation for the frequency of the transmitter. Recommended Interval Distance
$d=\left(\frac{3.5}{V1}\right)\sqrt{P}$
150KHz ~80MHz
$d=\left(\frac{3.5}{E1}\right)\sqrt{P}$
80 MHz ~800MHz
$d=\left(\frac{7}{E1}\right)\sqrt{P}$
800MHz ~2.5GHz
P4H is based on the transmitter manufacturer's description of the output power rating of the transmitter in watts (W), and d is the recommended separation distance in meters (m). In accordance with the electromagnetic field survey a, fixed RF transmitter field strength "should be less than the accuracy of each frequency range" b.
Interference may occur in the vicinity of equipment marked with the following symbols：</td></tr>
<tr><td colspan="4">Note: Within 80 MHz and 800 MHz, the higher frequency range is applicable.
Note: These guidelines are not applicable to all situations. Electromagnetic transmission is affected by buildings, objects, body absorption and reflection.</td></tr>
<tr><td colspan="4">A fixed transmitters, such as radiotelephone base stations and mobile radio communications, amateur radio, AM and FM radio and television broadcasts, which cannot be accurately predicted in principle. IN order to approach the electromagnetic environment generated by the fixed transmitter, electromagnetic field measurements should be considered. If the field strength in the site where the Therapy laser is used exceeds the applicable RF compliance level, observe whether the semiconductor laser treatment instrument verifies its normal operation. If abnormal operation is observed, other measures may have to be taken, such as adjusting the position and orientation of the</td></tr>
</table>

semiconductor laser treatment instrument.

b In the frequency range of 150KHz ~ 80MHz, the field strength should be less than [V1] V / m.

12.4 The Spacing Distance Between RF Communication Equipment and The Therapy laser

Portable and mobile is the recommended distance between RF communication equipment

And the Therapy laser

The Therapy laser is intended to be used in radioactive radiation harassment in controlled electromagnetic environments. Depending on the maximum rated output power of the communication device, the purchaser or user may prevent the electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment and the semiconductor laser treatment device by the following recommendation.

The rated output power of the transmitter（W）	According to the distance of the transmitter frequency		
	150kHz~80MHz $d=\left(\frac{3.5}{V1}\right)\sqrt{P}$	80MHz~800MGHz $d=\left(\frac{3.5}{E1}\right)\sqrt{P}$	800MHz~2.5GHz $d=\left(\frac{7}{E1}\right)\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

The above recommended isolation distance is calculated from the equation used with the transmitter, where P is the maximum output rating (unit: W) of the transmitter.

Note: Within 80 MHz and 800 MHz, the higher frequency range is applicable.

Note: These guidelines are not applicable to all situations. Electromagnetic transmission is affected by buildings, objects, body absorption and reflection.

13 SERVICE

13.1 Quality Commitment

Summus Medical Laser guarantees the factory technical parameters of Platinum Series P4H semiconductor laser device is in line with the product standard requirements of the medical device, is regulatory approved, and provides a lifetime diode warranty and a 3-year manufacturer warranty.

1) To provide laser training and clinical guidance

2) To provide parts or machine spare parts

3) Product maintenance and technical advice

13.2 Disclaimer Clause

Damage to the product caused by the following will not be covered by the warranty:

1) Improper use by the user

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 of unapproved accessories that do not match the device

5) Failure to follow the recommended maintenance schedule

6) Turn on the chassis of the laser system

The forgoing warranty is exclusive and in lieu of all other warranties, whether written, oral, or implied, and shall be the purchaser's sole remedy and Summus Medical Laser's sole liability under contract or warranty or otherwise for the product.

14 FCC STATEMENT

This equipment has been tested and found to comply with the limits for a Class A digital device requirement of 47 CFR, pursuant to Part 15 of the FCC Rules.

The device contains 20 and 40 MHz signal band width. The device must be placed at a minimum separation distance of at least 20cm from all persons and must not be located or operating in conjunction with any other antenna or transmitter.

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

15 CONTACT INFORMATION

If you have any difficulties in the use of your P4H therapy laser, or have any questions and suggestions, please visit www.summuslaser.com, call or write to us.

Manufacturer:

Summus Medical Laser, LLC	1185 West Main St. Franklin TN 37064
Tel:	866-595-7749
Fax:	-261-3535
Email:	service@summuslaser.com

Any serious incident occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

European Authorized Representative:

EC REP

Name: Emergo Europe Address: Prinsessegracht 20, 2514 AP The Hague, The Netherlands

CE 0297

The device is manufactured in compliance with the provisions of Council Directive 93/42/EEC and 2007/47/CE concerning medical devices (MDD). Its compliance is based on the following standards: EN ISO 60601-1, EN ISO 60601-1-2, EN ISO 60825-1, EN ISO 60601-2-22, EN ISO 14971, EN ISO 15223-1, EN ISO 62366-1, EN ISO 10993-4, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-11, EN 55011, EN 61000-3, EN 61000-4, EN 62133-2, EN 1041, EN ISO 62304 and IEC TR

60878.