Platinum Series™ H1 User Manual

Summus Medical Laser, LLC

Document H1-M-301-EU

(Model Number: SL*H1)*

Instructions Before Use

Platinum Series 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 for multiple patients and multiple use.

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.

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.

CONTENTS

1 GENERAL

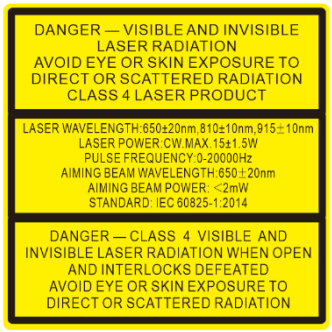
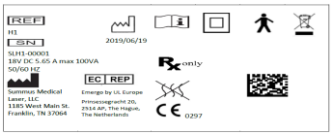
1.1 User Guide

Requirement: Read these instructions before the initial start-up to prevent misuse and damage.

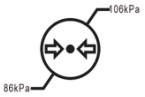
1.1.1 LABELS AND SYMBOLS

Product identification and packaging instruction are in line with IEC60825-1:2014, EN ISO 15223-1: 2021 and other related requirements. Product identification and packaging used in graphics symbols are as follows:

Graphics / Symbols	Meaning	Position
	Warning and informational signs	Operators Manual
	Important information for users and technicians	Operators Manual
IPX	Level of Waterproofing	Operators Manual
	Optical fiber, laser aperture and laser danger	Back side of the main unit

Graphics / Symbols	Meaning	Position
	Class 4 laser product explanatory, remote interlock and laser output and standard information	Back side of the main unit
	Emergency power off	Right side of the main unit
	Product nameplate	Left back side of the main unit
Summus Medical Laser, LLC Complies with FDA performance Standards for laser products Except for deviations pursuant to Laser notice No. 50 dated June 24, 2007 866-595-7749	Performance Standard Compliance	Indicates FDA Performance Standards Compliance to Laser Notice No.50
	Prescription Use Only	Nameplate
	Serials number	Nameplate
	Refer to instruction manual	Nameplate
	Manufacture date	Nameplate

Graphics / Symbols	Meaning	Position
	Manufacturer	Nameplate
	Type B applied part	Nameplate
	Non-recyclable	Nameplate
FCC ID:2AP4I-HS This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.	FCC label	Back side of the main unit
 or Foot Switch	Indicates the usage of a foot switch or the connection for a foot switch	Back side of the main unit
	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 outer package
	Keep away from direct sunlight	The position is on the outer package

Graphics / Symbols	Meaning	Position
	Restriction of Hazardous Substances	The position is on the: • Base of unit • User manual • Shipping box
	The medical device is not made with latex	The position is on the outer package
	The range of humidity to which the medical device can be safely exposed	The position is on the outer package
	The range of atmospheric pressure to which the medical device can be safely exposed	The position is on the outer package
	Do not use if package is damaged	The position is on the outer package
	Lithium battery hazard symbol	The position is on the outer package
	Recycle Lithium-Ion Battery. Do not dispose with common waste.	Battery
	Indicates the medical device is non-sterile	Shipping box

Graphics / Symbols	Meaning	Position
	Both direct and alternating current	Battery
	Class II medical equipment	Nameplate
	Indicates the manufacturers catalog number	Nameplate
	European Representative	Nameplate
	Indicates conformity to European standards and requirements of accreditation and market surveillance relating to marketing Compliance with RoHS and other EU directives; European Conformity Mark	Nameplate
	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	Nameplate
	Indicates a medical device that is non-pyrogenic	Nameplate

Graphics / Symbols	Meaning	Position
MD	Medical Device	Nameplate
#	Device Model	Nameplate
UDI	Unique Device Identification	Nameplate

1.1.2 Target Group

This document is for clinicians and the clinicians trained associates under medical supervision.

1.2 Introduction

The ***H1*** 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.

The Medical Diode Laser uses Gallium Aluminum Arsenide GaAlAs diode lasers as energy 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 or the optional foot switch. When the switch is activated, the message “LASER EMITTING” appears on the LCD screen. When the foot switch or 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 therapy diode laser produces wavelengths at approximately 650nm, 810nm, 915 nanometers (nm) in pulse, continuous (15 Watts), and intense super pulse mode (16 Watt peak). The light is both a visible aiming and an invisible, non-ionizing thermal radiation that does not create changes in cellular DNA. The laser radiation is absorbed by the tissue under management and is converted to heat. The rise in temperature of

the treated area, promotes an increase in circulation, resulting in temporary pain relief and muscle relaxation.

The ***H1*** unit is an air-cooled device consisting 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 or other equipment to facilitate the operation of the power switch.

For safety, the diode features several ways to stop energy flow if the operator wants to deactivate the laser. The safety system includes a choice of an emergency shutdown button, a hand piece finger switch, a foot switch, a power switch on the main unit, and a remote door interlock. Any of these features can be used to shut down the laser.

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. Protective eye wear provided by Summus Medical Laser includes:

- Shield protection 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 Platinum Series devices.
- Glasses/ Goggles protection containing specific protection for an optical density of 5.0 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 devices.

The user needs to carry out appropriate clinical and technical training before using this product and shall follow the instruction manual during the operation of the device. Before use, professional users should choose the reasonable treatment parameters 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. Summus Medical laser assumes no liability for any damage caused by improper use or non-compliance with the instructions for use provided in this manual. The sole responsibility lies with the medical personnel.

1.3 Indication

The H1 indicated for medical application intended to alleviate musculoskeltal pain, osteoarticular diseases and laser acupuncture.

Note

It is not recommended to use the product for a purpose for which it was not intended.

1.4 Intended User

Professional users under prescription use only.

Note

The H1 medical laser device is to be used by clinicians and trained associates under medical supervision. Clinical decisions regarding the suitability of the device and the selection of the corresponding treatment methods are exclusively the responsibility of the clinician.

1.4.1 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 for after-sales support.

1.5 Intended Population

Male and Female patients, adolescence through adult.

1.6 Adverse Events

There are currently no known adverse effects for the use of laser devices with equivalent power and wavelength as the H1 laser device. Professional users shall be fully aware of the patient's condition and medical history prior to treatment.

All clinical procedures performed with ***H1*** must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical management. The clinician must completely understand the patient's medical history prior to the procedure. Exercise caution for general medical conditions that might contraindicate procedure.

Note

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

Note

Medical clearance shall be sought from patient's physician when doubt exists regarding the procedure.

1.6.1 Absolute Contraindications

DO NOT shine laser light directly into the eyes, with or without eyewear protection.

Do not apply the laser directly over the developing fetus/ over the abdomen of pregnant females.

DO NOT apply the laser directly over the thyroid gland.

DO NOT apply the laser on patients over active cancer. If the patient presents with malign tumours or obligate precancerous, carefully consider the specific therapy for the situation.

DO NOT apply to patients who suffer from photodermatoses as well as photosensitised patients (photoallergies).

1.6.2 Relative Contraindications

DO NOT apply the laser over a working spinal cord stimulator (SCS).

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 procedure is noted.

DO NOT apply the laser over a hemorrhage or active bleeding.

DO NOT apply the laser over tattoos.

1.6.3 Warnings and Precautions

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

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.

1.6.4 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

2.1 Proper Use

The diode laser is a **Class 4** laser system. The user must ensure that the device works properly and is in a satisfactory condition before each use.

"Proper use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.

Apply and meet the underlying guidelines and/or national laws, national regulations, and the rules of technology for medical devices applicable for start-up and use of the Summus Medical Laser products for the intended purpose.

The user shall observe the following:

- Only use properly operating equipment
- Protect him/herself and third parties from danger

During use, national legal regulations must be observed, in particular:

- The applicable health and safety regulations
- The applicable accident prevention regulations

To guarantee constant readiness for use and maintenance of value of the Summus Medical Laser product, the recommended servicing and safety inspections shall be adhered to:

Authorized to repair and service the Summus Medical Laser product:

- Technicians from Summus Medical Laser or its branches who are trained to deal with the product.
- The technicians of Summus Medical Laser franchised dealers specifically trained by Summus Medical Laser.

The person responsible for the device and the user of the device must operate their devices in accordance with the provisions of Medical Device Regulations.

Note

The product must be cleaned and serviced according to instructions found in the Maintenance and Service Sections of this manual if it is not to be used for a long period of time.

Note

Only those accessories may be used that are approved for the device.

Information on electromagnetic compatibility

Note

Based on IEC 60601-1-2 concerning the electromagnetic compatibility of electromedical devices:

- Medical electrical devices are subject to special measures regarding electromagnetic compatibility and must be operated in accordance with Summus Medical Laser assembly instructions.
- Portable and mobile high-frequency communications devices can influence medical electronics.

Damage from unsuitable accessories

CAUTION

The use of other accessories, transformers and lines than those indicated (with the exception of transformers and lines that Summus Medical Laser sells as replacement parts for internal components) can increase transmission or reduce the electromagnetic immunity of the product.

- Only use accessories recommended by Summus Medical Laser.

Note

Summus Medical Laser cannot guarantee accessories, lines and transformers that are not delivered by Summus Medical Laser.

- Summus Medical Laser will correspond with EMC requirements of IEC 60601-1-2.

Disposal of electronics

Note

According to the **Directives 2012/19/EC and 2002/96 /EC** concerning electrical and electronic used devices, this product is subject to the cited directive and must be disposed of accordingly.

Before disassembling and disposing of the product, it must be completely processed according to the section "Disinfection ". Additional information can be obtained from Summus Medical Laser.

2.2 Safety Instructions

2.2.1 General Information

CAUTION

Become thoroughly familiar with the instructions for use. This device is for Professional Use Only and its therapy uses shall only be administered by or under the supervision of a trained professional. **A hazard can arise from untrained persons who use the device:**

Injury to the patient or operator

Damage to the unit

- The device may only be used by persons who can properly operate it due to their training or knowledge and practical experience.

Unauthorized persons or those who do not obtain a clinical qualification certificate shall not use the product for clinical treatment.

Note

The manufacturer assumes no liability for personal injury or damage arising from untrained persons.

Hazard from electrical power

Electrical shock

- Do not open any protective covers. Unauthorized opening of the device presents a risk of electric shock, as well as severe or irreversible injury or damage to persons or devices.
- Do not place any liquids on the device.
- In the event of an accidental ingress of a liquid, immediately stop the procedure, disconnect the power cable and contact Summus Medical Laser after sales maintenance for assistance.

Note

All optical components, especially the parts of the laser delivery system, must be handled with great care and protected from dust and dirt.

2.2.2 Laser Safety

The ***H1*** diode medical laser system is safe and reliable when used by trained personnel who take proper care in their operation.

CAUTION

The ***H1*** medical diode laser is a Class 4 laser system. Precautions should be taken to avoid accidental exposure to both directed and reflected laser beams. Severe eye or skin damage may be caused by diffused reflections as well as speckle of the laser beam.

CAUTION

The laser beam from most laser diodes is usually not visible to the human eye, which can seriously damage retinal tissue.

DO NOT look directly into the laser beam or into the working end of the optical fiber. Reflected laser beam may cause retinal damage. AVOID aiming the laser beam in the direction of reflective surfaces.

CAUTION

DO NOT wear any reflective jewelry or items during treatment. Avoid scattering or reflecting laser energy that may cause damage to eyes or skin.

CAUTION

All personnel in the procedural area, including the patient, must wear eye protection. Contact lenses are not viable protection.

Laser direct radiation or scattered radiation can cause irreversible damage to the cornea, and retina. All Individuals present during the operation of this device must wear protective eyewear.

Shield: 7+ (810, 915, 980nm) and 2+ (650nm)

Goggles: 5+ (810, 915, 980nm) and 2+ (650nm)

POST "LASER IN USE" IN THE PROCEDURAL AREA.

Limit access to the procedural area to personnel who are trained in the principles of laser safety. The laser system has an interlock that can be

activated to the procedural room door if necessary.

DO NOT operate the laser system with any protective panels removed or when the fiber delivery system is improperly connected.

DO NOT attempt to defeat the system or the enclosures, as they are designed for your protection. High voltage exists within the enclosure.

DO NOT attempt repairs of this system. Service and maintenance should only be performed by a qualified ***H1*** Service Technician.

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. Identify and correct the cause prior to resuming use. Reference Troubleshooting and Fault Diagnosis and Analysis sections. If necessary, please notify the designated dealer or the company for help.

Laser-related fire hazard

Surfaces can absorb laser energy. This can cause the surface temperature to rise and ignite the material.

- NEVER use the ***H1*** in explosive areas.
- If solvents and flammable liquids are used for cleaning and disinfecting prior to laser use, make sure that they evaporate before working with the laser.
- Materials such as cotton can be flammable during normal laser use when they are saturated with oxygen.
- Endogenous gases can explode.

Signs in the laser area

The area in which the maximum permissible radiation can be exceeded from the "laser procedure area" must be delimited and identified by a laser warning sign.

- Entrances shall be posted with the triangular laser warning sign.
- The Nominal Ocular Hazard Distance (NOHD) from the laser is 1.65m.
- An additional laser warning sign shall be provided by the manufacturer with each laser system. Signage shall be affixed to the entrance of the laser treatment room to warn entering persons of the laser in the room.

Hazard from direct and indirect laser radiation

Serious eye and skin damage

- NEVER look directly into the outlet of the hand piece or glass fiber bundle, even with protective glasses.
- Identify the laser area so that no unauthorized person will enter during treatment.

- Restrict access to the treatment room to the practitioner and trained associates.
- Cover windows and openings to the treatment room to prevent the laser from accidentally exiting.
- Only direct the active laser to the treatment site of the patient.
- No reflecting objects (instruments or holders) may be in the procedure area.
- Make sure that employees know how to turn off the laser in the

event of an emergency.

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

2.3 Laser System Safety Features

The ***H1*** system provides the following safety features for the operator and patient:

2.3.1 Laser Emission

The laser only emits when the READY button is activated and when the hand piece finger switch or foot switch is pressed. The device is in STANDBY mode after the power switch is set to ON position. The READY button needs to be activated to enable the hand piece or the foot switch. This is to remind the operator that the laser is going to emit. The user/ associate (s) and patient shall wear the protective shield/ goggles. The laser will emit when the hand piece finger or foot switch is pressed.

2.3.2 Visible and Audible Lasing Signals

Whenever the hand piece finger switch or foot switch is pressed, an audible signal (high pitch beeping) will sound. A visible LASER ON icon will also appear on the screen to indicate that the laser is emitting.

2.3.3 Password Protection

The device requires a password input of four digits in order to enter the main menu.

2.3.4 Emergency Shutdown Button

An Emergency Shutdown Button (red round button) located on the right side of the

device serves to immediately turn off the laser. It should only be used in emergencies, that is, when it is necessary to immediately stop the laser emission. Identify and correct the cause prior to resuming use. After the emergency, depress the stop button again to continue the procedure.

2.3.5 Remote Door 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.

The remote interlock head may be connected to an interlock interface (closed switch) on the entrance door of the therapy room by a qualified electrician who is responsible for the installation and maintenance of the electrical system to which the device is connected. When the therapy room door is opened, the equipment can no longer emit.

2.3.6 Shield/ Goggles

Post appropriate warnings in procedural areas where the lasers are to be used, so that appropriate shield/ goggles can be donned before entry into the area. The user, assistant, patient, and any other persons in the procedural area during laser procedures MUST wear the appropriate laser shield/ goggles for protection of emitting diode lasers. Class IV laser radiation is hazardous to the eye from the direct beam and diffuse reflections. Safety shields/ goggles not designed to this specification are not suitable for use with the H1 medical laser device.

WARNING: Non-specified protective shields/ goggles may cause damage to eyes.

WARNING: Inspect your glasses regularly for damage or breakage. Please contact the designated dealer or visit the company product web site to purchase replacement shields/ goggles.

CAUTION

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.

CAUTION

Laser direct radiation or scattered radiation can cause irreversible damage to the cornea, and retina. All Individuals present during the operation of this device must wear protective eyewear.

Shield: 7+ (810, 915, 980nm) and 2+ (650nm)

Goggles: 5+ (810, 915, 980nm) and 2+ (650nm)

CAUTION

DO NOT remove the protective shield/ goggles until the operator returns to the "Standby" mode.

Laser protective shields/ goggles can be purchased by visiting our product website or by contacting our company.

Shield

Goggles

2.4 Clinical Precautions for Laser Safety

CAUTION

Laser treatment may result in inadvertent exposure to adjacent tissues. Undue exposure can result in damage to the tissue, vessel perforation and bleeding. The practitioner should always set the laser system for minimal exposure to the patient. Optimal parameters for laser therapy may be achieved by starting with the power as low as possible and increase each parameter as necessary.

Only clinicians who are thoroughly trained in laser operation procedures, safety precautions and techniques should use ***H1*** units. A thorough understanding of the material presented in this manual is highly recommended before use.

Before treatment, clinicians need to determine the clinical symptoms of patients, and the analysis for appropriate treatment. Clinicians shall take full account of the risk of treatment and obtain the patient's permission.

Before and during treatment, clinicians should remind patients to pay attention in order to prevent distraction.

If the patient has special needs, such as people with disabilities, the clinician should assign at least one trained professional person to assist him/her during the procedure.

AVOID inadvertent laser emission. Turn the laser OFF with the power switch when not in use for an extended period of time.

DO NOT leave the laser in READY mode

DO NOT place the hand piece in an area where it may be accidentally pressed. When the laser is not in use, remove the hand piece from the immediate area.

DO NOT place the foot switch in an area where it may be accidentally pressed. When the laser is not in use, disconnect the foot switch.

3. PRODUCT DESCRIPTION

3.1 System Description

The ***H1*** is a therapy device designed with compactness, portability, reliability and user-friendliness. The ***H1*** utilizes a semiconductor diode with invisible infrared radiation as a laser source and visible red light as indicator light. The laser power is delivered to the treatment area via a flexible quartz fiber, which has a hand piece. The emission of the laser is activated by a hand piece finger switch or foot switch.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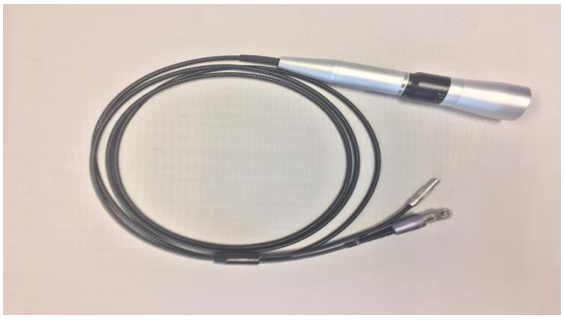

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Figure 1. Items

3.2 Components

#	ITEM	DESCRIPTION
1	Handle	For transporting the unit
2	Display	Display all the operation information
3	Indicator	Power (Green)/ alarm notation (Red)/ laser (Yellow)
4	Holder	Hand piece holder
5	Fiber spool	Stores fiber
6	Emergency stop button	Disables the device in the event of an

		emergency
7	Interface shield	Protect Hand piece port and Fiber port
8	Circuit breaker	Master ON/OFF switch
9	DC power connector	Connects power supply to the unit
10	Foot switch connector port	Connects wired foot switch (optional) to the unit
11	Remote interlock	A connector that connects an external controller to other parts of a laser product that are separated
12	USB port	Software update
13	Power line	AC power connection
14	Adapter	AC to DC
15	Hand piece	Laser output
16	Safety shield/ goggles	Laser protective glasses
17	Foot switch	The laser signal control
18	Lens	25 mm open lens

A large touch screen displays the working conditions and operation modes of the device. A menu allows the operator to select or change the system settings for the appropriate operation procedure. Additional safety features are built in (see Chapter 2).

3.3 Product Specifications

Feature	**H1**
Laser type	Gallium Aluminum Arsenide (GaAlAs) Diode

Operation mode	Continuous, Pulse and Intense Super Pulsed (ISP)
Wavelength (nm ± 10 nm)	650，810，915
Average Energy Output (Don’t turn on ISP in pulse mode）	7.5 W ± 0.8 W
Average Energy Output (Turn on ISP in pulse mode）	12 W ± 1.2 W
Wavelength (Indication) (±20 nm)	650
Max output power	15±1.5W
ISP Power	16±2W
Max indication power	＜2mW
Uncertainty for output power	≤±10%
Magnitudes of the cumulative measurement uncertainty	≤±20%
Expected increase in the measured quantities	≤±10%
NOHD	1.65m
Laser system	Class IV
Isolation class	Class II, type B
Fiber	Quartz
Emission frequency	1-20000Hz
Transmission system	600μm
Timer	0-3600s
Adapter input parameters	100-240VAC,47-63Hz
Main Unit input parameters	18VDC，5.55A

Battery capacity	3500mAh
Cooling Method	Closed loop, liquid filled, heat pipe thermal transfer system with fan/ air assist.
Weight	≤2KG NW
Dimensions	225 × 150 × 150 mm
Date of manufacture	See product nameplate
Numerical aperture （NA）	0.2
Divergence Angle	22°
Level of Protection	IPX0 (device) IPX8 (foot pedal switch)

Power Density Range **Minimum to Maximum Wattage power**			
Model	**Average Power** in CW and ISP (W)	**25mm tip** (W/cm^2)	**50mm tip **** (W/cm^2)
H1	0.5 5 10 15	0.1 1.02 2.04 3.06	0.03 0.25 0.51 0.76

** 50mm tip is an accessory sold separately to the H1 model

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

3.4 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 atmospheric pressure: 86~106kPa
- Avoid direct sunlight, rain is strictly prohibited
- Well ventilated
- Avoid storing in strong electromagnetic environment
- Avoid severe vibration
- Avoid storage in environments consisting of explosives, corrosive gases, excessive dust or high in salt.

The battery may be stored within an environmental range of -10ºC to 45ºC 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±5ºC 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.

The rechargeable battery might lose its loading capacity and no longer be rechargeable if a charge is not maintained.

3.5 Laser Beam Delivery

The laser beam from the ***H1*** is delivered by a flexible fiber or a fiber optic cable. The device accepts a fiber with single core of ∅600μm in diameter and with SMA905 connectors. The fiber cable should not be bent to a radius of less than 50mm or to an angle less than 120 to 180 degrees to prevent damage. A fiber holder is provided with the ***H1*** unit to help maintain the integrity of the fiber. The SMA905 connector of a fiber is inserted into laser output port located on the back side of the housing.

CAUTION

When connecting a new fiber to a *H1* unit:

- NEVER touch the end of fiber or put on a dirty surface. If contamination occurs, wipe the connector end with a soft tissue soaked with alcohol. Allow alcohol to evaporate/ volatize before attachment to the fiber port on the device body.

CAUTION

The optical fiber is made of glass such as fused silica. Although it has a protection buffer, it is still easy to break (sometimes internally) under localized physical stress.

- NEVER bend the fiber cable or apply stress. Keep the bending curvature radius larger than 50mm and at an angle of 120 to 180 degrees.
- NEVER pull the flexible part of the fiber cable when disconnecting from the device. Hold the metallic part of the connector.

4 SET UP AND INSTALLATION

4.1 Preparation Instructions

The acceptance and set up of Platinum Series medical laser device should be done with the assistance and guidance of our authorized technicians or agents.

Read carefully all instructions and be familiar with the safety requirements and intended use of the device before use. Mishandling and uninformed use may cause injury and or damage to the device.

Note

For the unit to be effectively air-cooled, a minimum distance of 20 cm shall be maintained to any objects in its surrounding.

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.

4.2 Unpacking

Immediately upon receipt of the ***H1*** system, the user should:

- Inspect the shipping carton in the presence of delivery courier as applicable. If there is any damage to the outer package, request the courier to sign a Notice of Damage receipt.
- Inspect and save all inner device and component cartons. Save the inner

device and component cartons during laser warranty period for possible service/upgrade returns.

- Inspect thoroughly the carrying case and components inside for damage and missing items.
- Unpack all components carefully and verify the presence of all components on the packing slip.
- Notify ***Summus Medical Laser, LLC*** immediately if there are any missing items.

4.3 Set Up Installation

Use of non-specified accessories may cause laser radiation hazards and device damage. If the foot switch, hand piece and other accessories are damaged or lost during use, or if you need to purchase items again, please contact your designated dealer or our company to purchase it.

- The H1 medical laser shall be protected from the intrusion of contaminates and liquids.
- The medical laser shall not be used in areas where the high presence of liquids is plausible.

In the event of an accidental ingress of a liquid, immediately stop the procedure, disconnect the power cable and contact Summus Medical Laser LLC after sales maintenance for assistance.

- Place the main unit of ***H1*** on a suitable table, cart, and shelf top, etc. with a minimum distance of 20 cm to the surroundings. Please choose a well-ventilated location for equipment installation. Attach all items in place in the following steps.

A. Insert the power cable on the power adapter to the socket which is on the left side of the main unit.

B. Connect one end of the power cord to the power adapter and the other end to the power supply.

C. Connect the interlock to the procedural room door if necessary.

Remote Interlock Installation

The remote interlock interface is located on the side of the device.

<table>
<tr><td>  </td><td>  </td></tr>
<tr><td>The location of interlock is marked on the picture. The default state of interlock is the connection state. When you need to use it, pull out the interlock</td><td>Insert the connecting wire provided by your qualified electrician during the installation of the interlock interface.</td></tr>
<tr><td colspan="2">  </td></tr>
<tr><td colspan="2">Connecting wire to the interlock interface; i.e. to the door of the operating room</td></tr>
</table>

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

Electricity - Electrical shock

- Turn off the unit first and unplug its main power supply before installing the remote door interlock to avoid electrical shock.

- The electrical system shall correspond to the voltage indicated on the rating plate or the power supply and in the technical specifications.

Note

The external contact must be grounded

D. Carefully take the fiber roller out of package and check for damage.

The fiber cable is approximately 3 meters long. **DO NOT** bend or apply physical pressure to the fiber with a radius less than 50mm or to an angle less than 120 to 180 degrees.

E. Connect the fiber cable with the hand piece.

F. Mounting the fiber roller.

G. Attach the other end of the fiber to the SMA socket on the main unit.

- Remove the protective cap of the SMA905 connector. Hold the metal plug in your hand and do not pull on the fiber.
- Unscrew the protective cap of the SMA socket on the unit.

Note

To protect the optical components in the device, the SMA905 socket in the unit must always be closed (with either a fiber cable or the protective cap).

Note

Only use fibers with clean fiber ends.

- Insert the SMA connector of the fiber completely into the SMA socket and screw the union nut tight. Do not twist the fiber!

Note

The fiber plug must be correctly screwed into the SMA socket to keep the light fiber from premature aging. Check this by moving the plug back and forth in an axial direction near the kink protection. Axial play means that the bare fiber is not correctly connected to the unit.

H. Turn on the unit by the switch on the upper left side of the unit and check the optical quality of the fiber output via the red aiming beam. Aim the hand piece perpendicular to the surface to shine the red beam.

The edge of the aiming beam spot should not be "frayed." A frayed edge indicates defects or soiling of one or both fiber ends.

I. Connect the hand piece to the unit.

J. Press the power switch to ON position at the left upper side of the unit. The LED will illuminate green for standby.

K. To turn off the unit, press the power switch to OFF position, or press the emergency button. In emergency circumstances press the emergency stop button. For a laser which has been operating for a long period of time, only turn off the unit after the fan has stopped. When the laser output is stopped, the fan will cease to work for a delayed period of time.

Emergency shutdown methods:

a) Press the emergency stop button.

b) Unplug the host plug or power adapter plug.

L. Set up of the H1 laser device shall be complete before putting the laser into use.

M. National Directives regarding electrical installations shall be observed.

Recommendation

As the AIMING BEAM passes down the same delivery system as the WORKING BEAM, it provides a good means of checking the integrity of the delivery system. If the AIMING BEAM is not present at the distal end of the delivery system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning delivery system.

4.4 Packing and Transporting

Note

NEVER pack or transport the unit with the main power on.

In the event that the ***H1*** unit needs to be relocated (this does not include moving within an office or a facility), place the system back into its device and component cartons adhering to the following steps:

A. Remove the fiber by slightly loosening compression nut. Disconnect the power cord and interlock if connected to the procedural room door.

B. Place the main body into its space in the device carton.

Note

DO NOT twist or bend the fiber with radius less than 50mm or to an angle less than 120 degrees.

C. Pack the hand piece, the power cable, and all other accessories in their pouches into appropriate spaces inside the carton.

4.5 Power Description

H1 has two power supply modes: external power supply adapter and internal lithium battery. H1 needs to be away from the wall at least 20 cm to ensure smooth ventilation and facilitate power switch operation. Press the power switch to the ON position to start the device.

External power supply: Directly insert the provided adapter plug into the DC jack on the left panel of the device. Plug the other end of the adapter into a grounded mains network to prevent electric shock;

To AVOID the risk of electric shock, this product shall only be connected to a supply mains with a protective earth.

Adapter parameters:

Input: 100~240VAC，47-63Hz

Output: 18VDC, 5.55A

Battery capacity: 3500mAH.

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

Note

When connecting to external power supply, use the provided external power adapter supply.

Note

Only use the certified battery specified by our company. Non-specified accessories may cause the equipment to malfunction or cause damage to the equipment

4.6 The Use of Hand Piece

After setting the desired treatment and while aiming the hand piece perpendicular to the treatment surface, select the "START TREATMENT" (Standby) button in the interface to enter into the "READY" state. In the "READY" state, align the handle head with the treatment site and press the finger/foot switch. The laser will be emitted for corresponding Medical Therapy.

WARNING

Laser radiation has irreversible damage on the eyes. During the course of treatment, the use of specific optical density protective shields or goggles are required. Do not look into the laser beam or the indicator light. AVOID eye exposure to direct or scattered radiation of laser.

WARNING

If the accessories (such as hand piece) are damaged, lost, or need to be replaced, please contact Summus Medical Laser. The use of non-designated accessories can result in injury or damage to the device from harmful laser radiation

5 DISINFECTION

The ***H1*** diode laser system is not supplied in sterilized condition. It should be disinfected before use. The following disinfecting procedures are recommended for the fixtures and attachments to the device:

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

Before using and between all uses of the device, check whether the end of the hand piece probe is clean. Otherwise, use alcohol and a soft cloth (or lens paper) to clean the probe end and hand piece.

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.

Allow the alcohol to completely evaporate/volatize before using the device. There is a risk the internal gas may be ignited.

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

Observe the instructions for use and all specifications provided by the manufacturers of the cleaning products and disinfectants.

6 OPERATION PROCEDURE

The H1 diode laser system is not supplied in sterilized condition. The main unit must be disinfected and applicable components disinfected or sterilized before use. Reference Disinfection and Maintenance sections of this manual.

Note

The H1 diode laser operates in three output modes: continuous, pulse and intense super pulse. The operator should choose a suitable protocol according to the patient's condition and treatment.

If the control device, regulator or is not used or operated according to the prescribed method, dangerous radiation will be produced, which can cause injury or damage to the device. Among them, the control devices and regulators include: LCD display, emergency stop switch, key switch, Interlock, etc.

6.1 Preparations

Make sure the following tasks are completed before you start the laser device:

- Operators, patients, and others present shall don laser safety shields/ goggles.
- The power line of the equipment is connected to a grounded outlet of the external power supply.
- The laser hand piece is firmly connected to the device.
- The Interlock is well connected.

6.2 System Boot

1）Turn on the power supply of the system, the power indicator lights up, the

system fan runs, and the LCD screen lights up.

2）System starts running.

3）Enter in the home page.

6.3 Operational Instructions for Customized Treatment Regimens

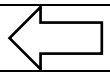
1. Turn on the device and enter the login page. The login interface is prompted after the equipment is powered on requesting the user's 4-digit security PIN identification for permissions.
2. Enter 1111 for super administrative privileges. Summus Medical Laser highly recommends changing the super administrative password to a unique 4-digit PIN applicable to your establishment.
3. Entering a wrong security PIN will elicit a temporary “PIN error” message and requires the user to re-enter the correct secure PIN.

Note

The login password is 4 digits.

CAUTION

The login password is owned by the authorized person. Unauthorized access is prohibited 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		WiFi connection
4		Favorites
5		Custom settings
6		Users
7		Customizations
8		Languages
9	2017/06/19 09:44	Date and time display found in customizations: Users can set the date and time in the settings interface.
10		Device Info
11	CW	Continuous Wave - the mode of emission delivery
12	ISP	Intense Super Pulse - the mode of emission delivery
13	650nm	650nm ±10 wavelength button
14	810nm	810nm ±10 wavelength button
15	915nm	915nm ±10 wavelength button
16	ISP On/ Off	Allows ISP setting for customized protocol treatments
17	↑25%	Time Boost and/or Power Boost to increase treatment time and or power for customized protocol treatments
18	↓25%	Time Bump and/or Power Bump to decrease treatment time and or power for customized protocol treatments
19	Go to Treatment	After protocol modifications you return to the treatment screen

20	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”

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.

Figure 4. Login page

4. Enter the home page interface to enter the secure PIN code (Figure 5) and select the treatment plan (Figure 6).

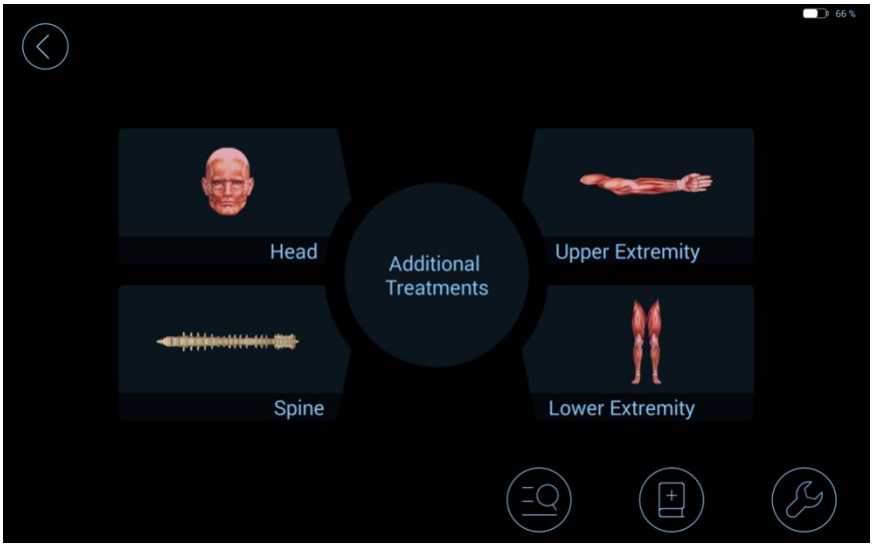


Figure 5. Home page

5. After selecting a body region, enter the body part interface (Figure 6).

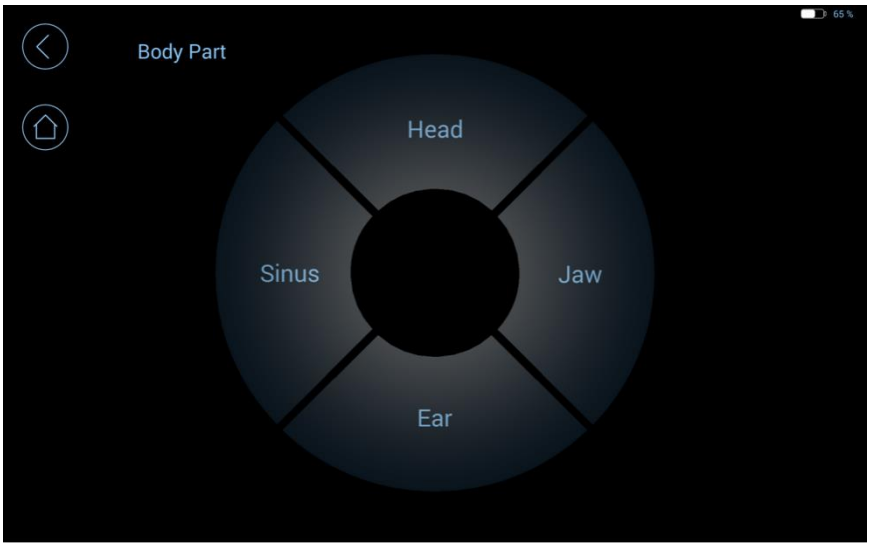


Figure 6. Body Part (Head example) selection interface

6. After choosing the body part, enter the customization pages.

7. After customizing a specific protocol, enter the treatment screen of that protocol (Figure 7).

Figure 7. Operation interface of protocol

8. Click on "START TREATMENT" and a red screen will appear alerting the user of the requirement for everyone in the treatment room to wear protective safety shields/ goggles (Figure 8).

Figure 8. Ready to emit interface

9. Press the hand piece finger switch and the button changes to "LASER ON", which is the interface when laser is emitting (Figure 9).

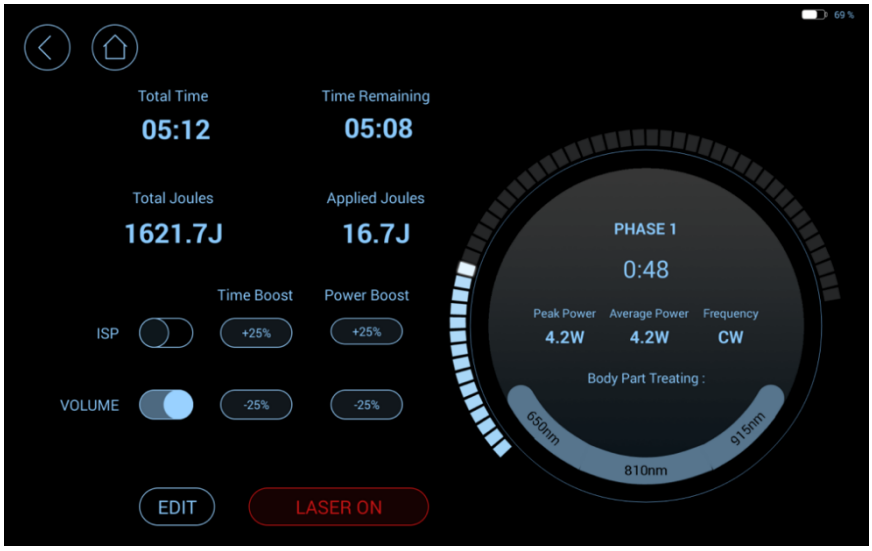


Figure 9. Laser emitting interface

10. Click "EDIT" to edit the protocol (Figure 10). After modifying the parameters, click "Go to Treatment" to reach the program operation interface.

Figure 10. Editing the official protocols Interface

11. Click  on the home interface to enter the user-defined customize interface, create a new treatment scheme, and click "Save As" to save the new protocol (Figure 11).

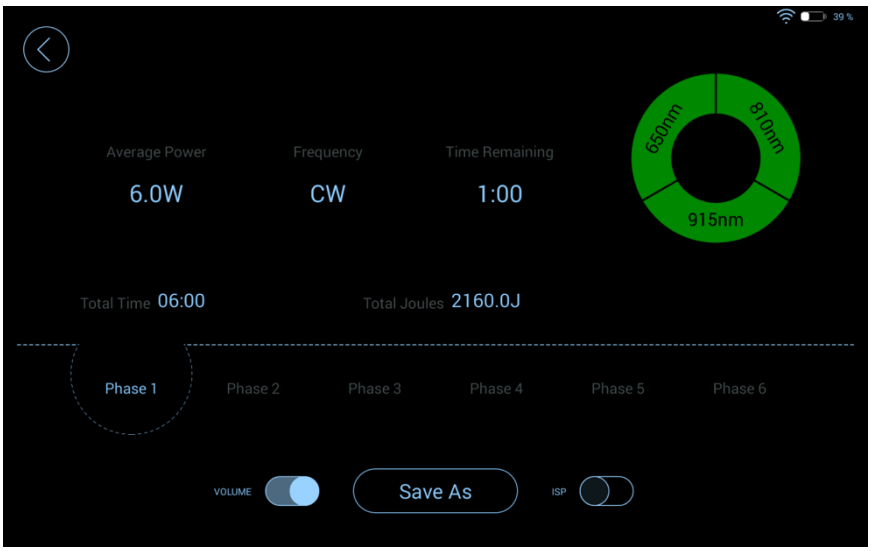
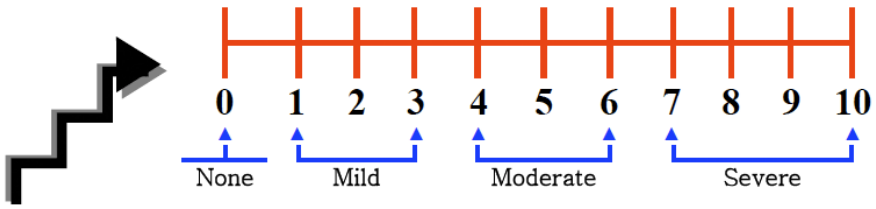


Figure 11. Customize Interface

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 form the power values and the time of emission
Wavelength	May be selected individually or in combined ISP modality
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.

Note In Intense Super Pulse (ISP) modality, the laser device automatically manages all the wavelengths combined and the operator cannot select the wavelengths.

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

H1 Max avg. output = 0.1 to 12 W ± 1 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.

A 25 mm diameter tip is 2.5 cm and has a 1.25 cm radius. Its area is 4.9 cm2.

A 50 mm diameter tip is 5.0 cm and has a 2.5 cm radius. Its area is 19.6 cm2. The 50mm tip is an accessory to the H1 model.

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	*
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	*

* 650, 810, 915nm

Power Density, Watts/cm2	**Treatment time, seconds**	**Total Dose delivered,**	**Treatment Area size, cm2**	**Dosage, J/cm2**	**Wavelength**

		J			
0.18	720	2520	400	6.3	*
0.20	840	3570	500	7.14	*
0.31	840	5040	500	10.08	*
0.20	720	2880	400	7.2	*
0.15	360	1080	200	5.4	*
0.13	480	1200	300	4	*
0.10	240	480	100	4.8	*
0.10	180	360	100	3.6	*
0.25	840	4200	500	8.4	*
0.23	840	3780	450	8.4	*
0.20	720	2880	400	7.2	*
0.18	600	2100	300	7	*
0.15	480	1440	200	7.2	*
0.13	300	750	100	7.5	*
0.05	90	90	25	3.6	*

* = 650, 810, 915nm

** For Fitzpatrick scale skin tones IV – VI, change any continuous wave (CW) phases to a pulsed frequency of 2 Hz

Note The 25mm or the 50mm treatment tip can be used with the H1 model on all listed body parts. The 50mm tip is an accessory sold separately to the H1 model.

The Guide To Hand Piece Lenses

Installation

The hand piece lenses are easily changed. Grasp the hand piece in one hand, the lens in the other and pull apart. Install a new lens by holding the hand piece and lens in each hand and pressing together. Carefully perform each step by pulling and pushing in a straight line.

Once a lens is removed, place the black protective cap on it immediately. Take great care to not allow any foreign matter to get inside the lens.

Care & Cleaning

If foreign matter does get in the lens, use compressed air to clean it.

The curved contact lens can be cleaned with any germicidal wipes used to clean

Lenses & Applications

25mm Zoom (Open) **Use in CONTACT or NON-CONTACT**

15 W Max Average Power

•Use for small and medium sized body parts.

•Keep in contact with the skin and hold perpendicular to the body part.

•Hold off the skin surface when treating over broken skin or if the patient cannot tolerate contact.

•The zoom can be used to reduce the spot size when indicated.

25mm (Curved) **Use in CONTACT ONLY**

15 W Max Average Power

•Use for small and medium sized body parts.

•Always keep in contact with the skin and hold perpendicular to the body part.

<table>
<tr><td>other surfaces in the clinic. Take care not to oversaturate and allow liquid to drip down to the hand piece.</td><td>•Do not hold off the skin surface.
•Use some pressure over trigger points.</td></tr>
<tr><td rowspan="2">Uses

• Use a 25mm lens for small and medium sized body parts. They can also be used on large body parts such as low back and hips, if the average power is at or below 15 W.

• Use a 50mm lens for large (core) body parts such as back and hips, or if the protocol needs to operate above 15 W of average power.</td><td>50mm (Open) Use in CONTACT or NON-CONTACT

•Use for large body parts such as back and hips.
•Keep in contact with the skin and hold perpendicular to the body part.
•Hold off the skin surface when treating over broken skin or if the patient cannot tolerate contact.</td></tr>
<tr><td>50mm (Curved) Use in CONTACT ONLY

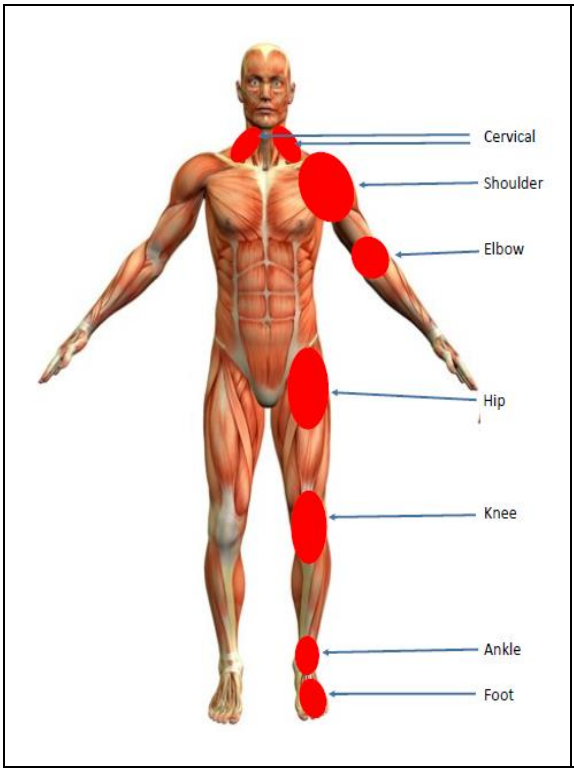
•Use for large body parts such as back and hips.

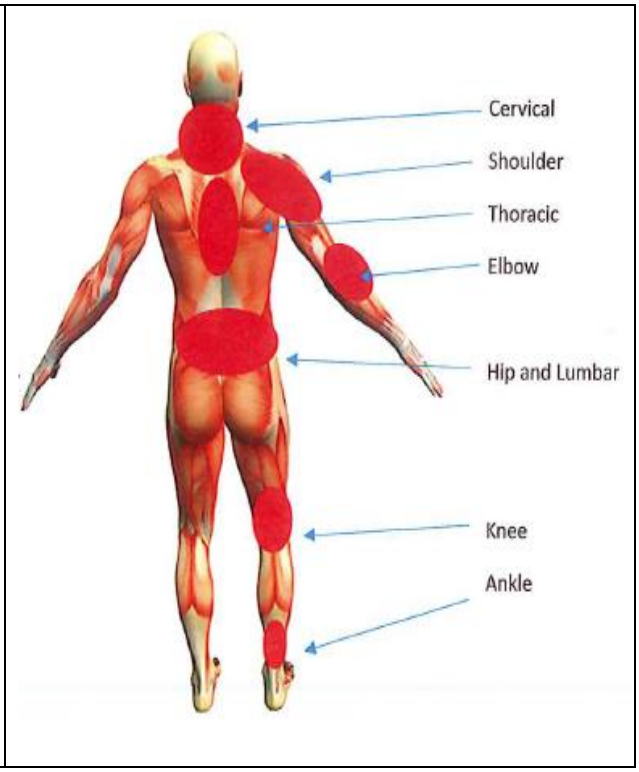
•Always keep in contact with the skin and hold perpendicular to the body part.

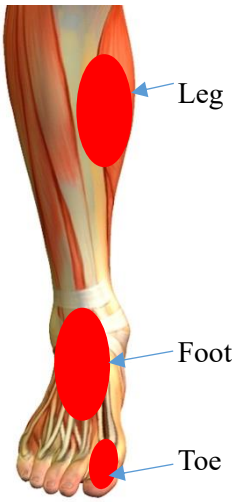
•Do not hold off the skin surface.</td></tr>
<tr><td colspan="2">Attachments may be included with your model and if not can be purchased as accessories.</td></tr>
</table>

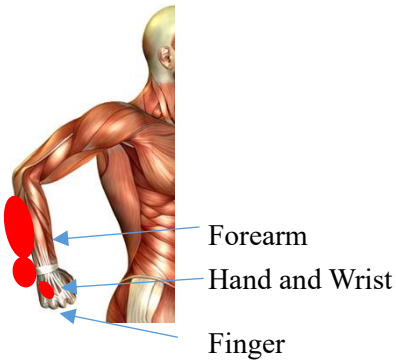
Treatment areas

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) 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%.

12. Enter  from the home interface, users can check the saved custom protocols (Figure 12).

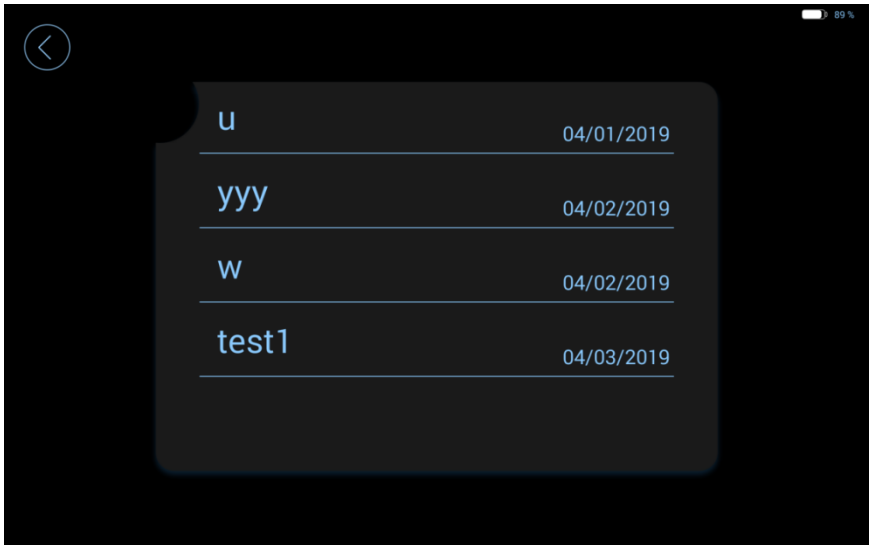


Figure 12. Saved custom protocols

13. Click  on the main interface, enter the custom settings interface "Customizations" to set the screen brightness, sound size and unit (Figure 13).

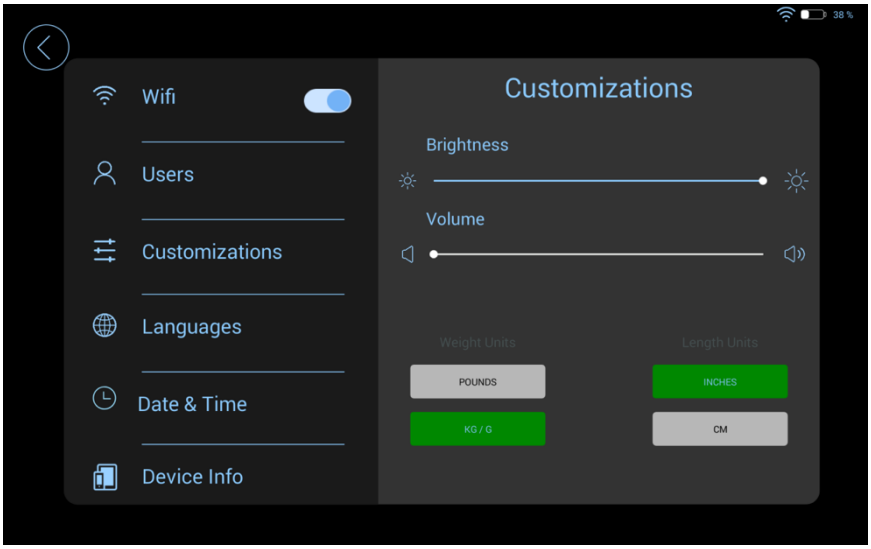


Figure 13. Custom Settings Page

14. Click “Wi-Fi” to enter the Wi-Fi list page (Figure 14). Click "Wi-Fi" and click "ON"

to connect to the wireless network. Wi-Fi, after opening, you can search the surrounding Wi-Fi search list, click to enter the password input box, the password will connect to Wi-Fi correctly. Long press to forget the Wi-Fi password, and enter the password input interface again.

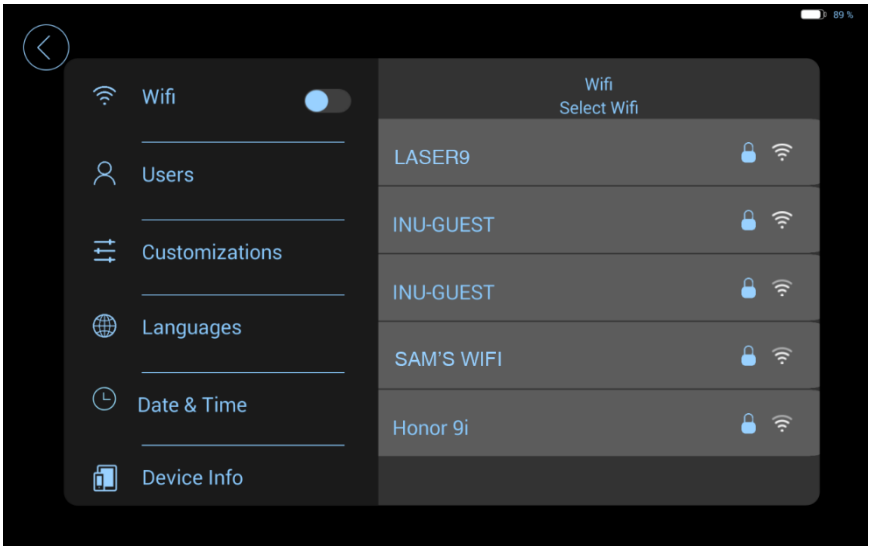


Figure 14. Wi-Fi List Page

15. Click user to enter the multi-user management interface, providing the function of creating new users and modifying users (Figure 15). The super admin can modify the creation and deletion. Other users can only view the user list but cannot create new users, cannot modify the username and password and cannot delete the user. The super admin can modify the super user information but cannot delete himself. The standard official scheme for each user is the same, but the self-modified official program and the respective collection of programs and the number of times the device is used are independent of each other.

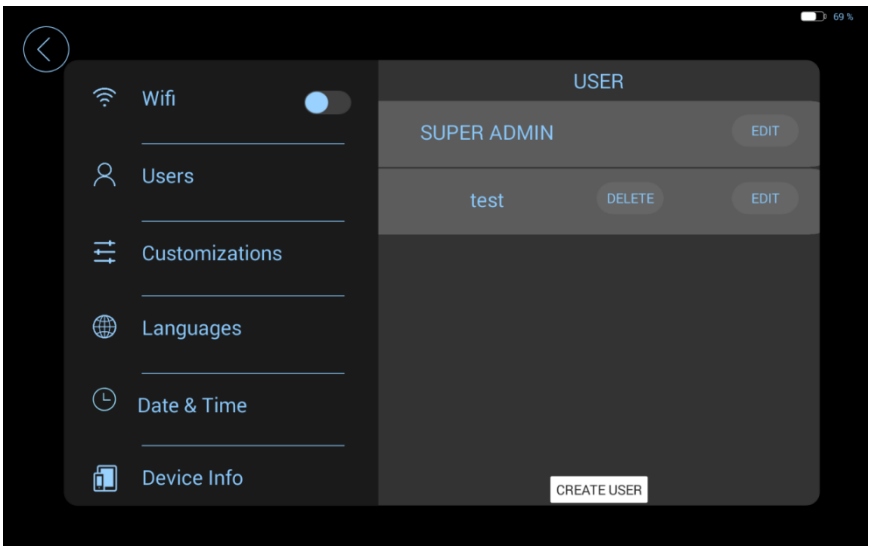


Figure 15. Multi-user Management Interface

16. Click Language: Language, set the software language (Figure 16).

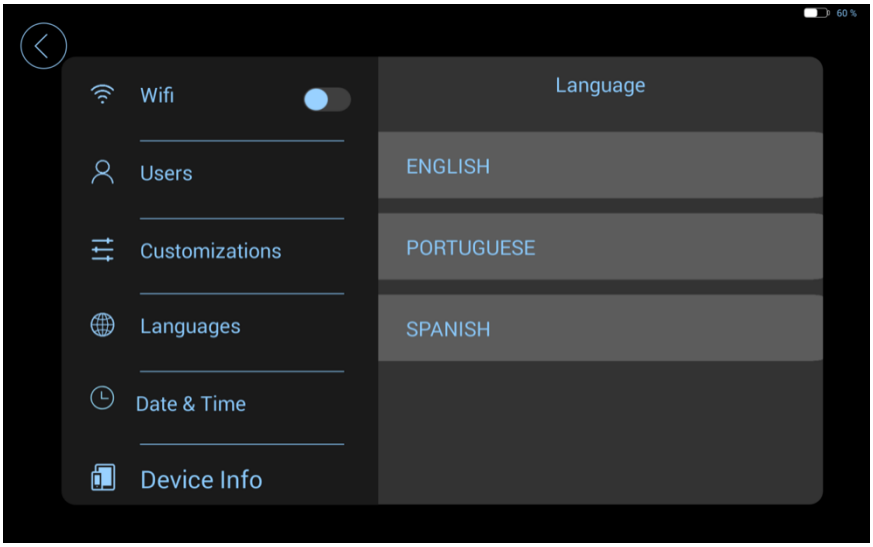


Figure 16. Setting the language interface

17. Click Date &Time: Time setting to set the date and time and time zone (Figure 17).

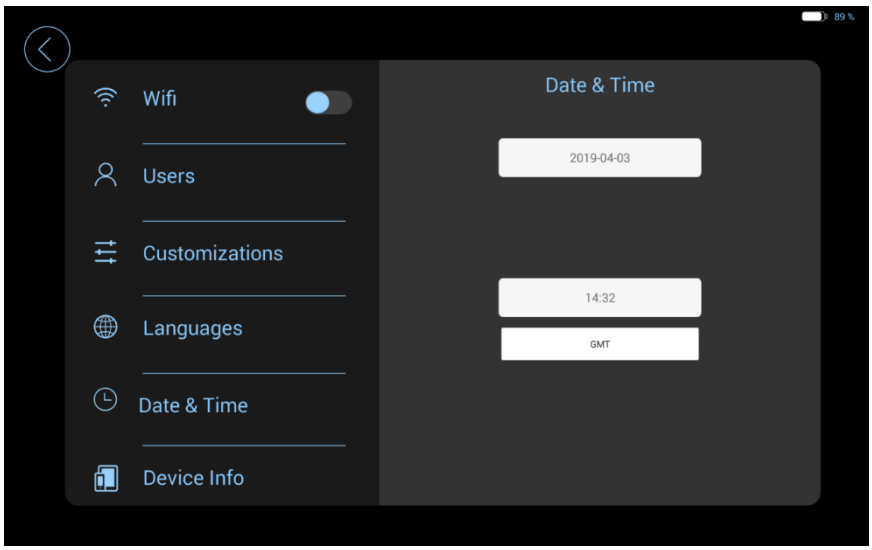


Figure 17. Time settings screen

18. Device Info: Device parameter information interface, you can view the device information (Figure 18)**.**

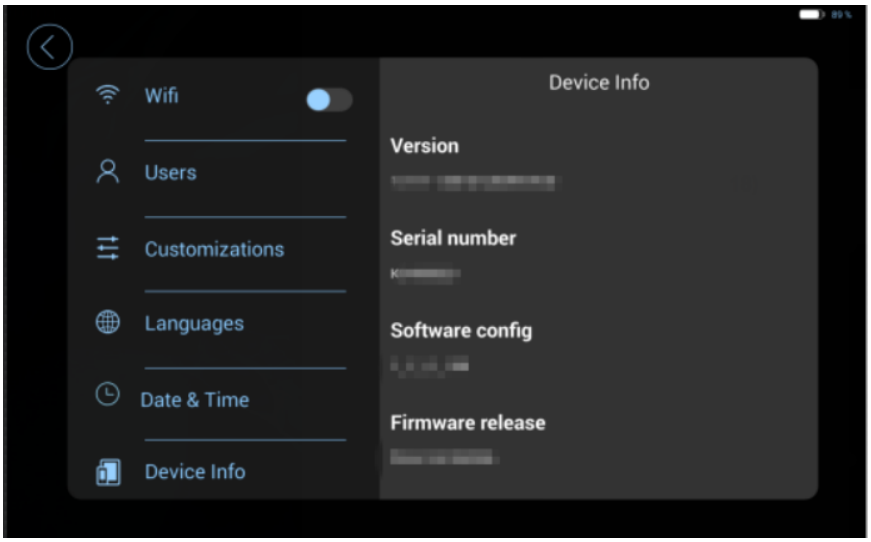


Figure 18. Device parameter information interface

7 TROUBLESHOOTING

7.1 Notation Type

The system provides eight notation prompts, namely:

1. High temperature notation
2. Low temperature notation
3. Remote interlock notation
4. Hand piece notation
5. Laser notation
6. Fiber notation
7. Battery power notation
8. Emergency notation

All of the above notations are technical notations. When a notation occurs, the user shall take appropriate steps to address the priority of the notation to prevent personnel and device damage.

7.2 Notation Mode

The Medical Diode Laser provides sound, graphical warning signs, notation indicator modes. An abnormal system will lead to notation and interrupt the laser outputting to ensure the safety of personnel and device. The notation delay is less than 1s.

7.2.1 Sound Notation

When the system detects an abnormal status, it will trigger an audible notation, notation contact, the audible notation stops.

7.2.2 Graphical Warning Signs

In the human-computer interaction interface, different types of notations correspond to different graphical warning signs. When the notation is acknowledged and released, the button returns to normal.

7.2.3 Indicating Light Notation

When the notation prompt appears, the red warning light of the notation indicator will be on. When the notation is acknowledged and released, the red light turns off.

7.3 Notation Function

The Medical Diode Laser monitors the operating status of the system in real time through sounds, indicators, and graphical warning signs to alert the user of unusual events and will interrupt the laser from outputting.

Notation Types	Triggering Conditions	Notation Release Method
High Temperature Notation	1. Laser temperature exceeds 45° C 2. Fiber coupler temperature exceeds 60 ℃ 3. Temperature sensor failure	1. Turn off the power, if the temperature notation 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.
Low temperature notation	Laser temperature is below 0℃;	1. Turn off the power; 2.Raise the ambient temperature;
Remote Interlock Notation	The remote interlock is not inserted correctly or is not plugged into the device.	1. Check the rear panel of the device and whether the remote interlock is correctly inserted into the device. 2. If the remote interlock is inserted into the device and the notation condition is still unresolved, please contact the company for after-sales maintenance.
Hand Piece Notation	1.The hand piece is not properly inserted or is not inserted into the device 2. Press the handle switch button when it's not into the "Ready" state	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, the notation status is still unresolved, please check the handle switch button is pressed or not. 3. Check the above operation, if there is still notation status, please contact the

Notation Types	Triggering Conditions	Notation Release Method
		company for after-sales maintenance.
Laser Notation	Safety interlock failure	Please contact the company for after-sales maintenance.
Fiber Notation	1. Fiber connector is not inserted into the laser window 2. Micro - switch of laser window fails	1. Insert the fiber connector into the laser window of the device. 2. If there is still a notation condition, please contact the company for after-sales maintenance.
Battery Power Notation	Battery is low	Use external power supply.
Emergency Notation	The emergency stop button was pressed.	Press the emergency stop button again.

7.4 Notation System Detection

The user can determine whether the notation system is normal by performing a self-test.

7.5 Fault Diagnosis and Analysis

WARNING

DO NOT use the device for treatment when the device is malfunctioning or in other abnormal conditions. Please comply 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	Emergency stop switch is not turned on.	Release of emergency stop switch.

does not start.		
The screen displays a notation.	1. Remote control interlock is not connected 2.The hand piece is not connected 3.Fiber is not connected 4.Laser failure 5.Battery is low	1. Check whether the remote interlock is connected properly. 2. Check the hand piece is connected properly. 3. Check whether the fiber is connected properly. 4. Use external power supply. 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 hand piece is with dust or other dirt 2. Laser attenuation	1. Clean the glass lens with a soft cloth, lens paper or paper towel 2. Calibrate the laser power according to 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 5. Battery is low	1. Use external power supply 2. Contact the company for after-sales maintenance

WARNING

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

8 MAINTENANCE

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 the damage on the human body and device that caused by the possible harmful laser radiation.

8.1 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 120 to 180 degrees

2. After removing the hand piece, immediately cover the dust cap to prevent dust pollution.

3. Do not let hard or sharp objects scratch the touch screen.

DO NOT use chemical reagents to clean the touch screen. Please wipe carefully with lens paper to avoid scratching or damaging 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 to avoid injury and damage to the device caused by the possible harmful laser radiation.

7. Summus Medical Laser, LLC recommends carrying out a routine inspection and maintenance and power calibration every 24-months under the guidance and operation of our authorized company personnel or designated dealers to avoid possible injury or damage to the device and harmful laser radiation.

8.2 Routine Inspection

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

1. Whether the safety device is normal: Safety interlock, optical switch, emergency stop switch
2. Whether the hand piece/ foot 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 (bent or 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.

8.3 Post Treatment Cleaning

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

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 immediately after treatment by the operator for all reusable components to assure all surfaces are completely free of any organic or inorganic material to prevent patient to patient transmission of potential bioburden.

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

WARNING

Cleaning following treatment, switch off the device and disconnect the power cable from the power supply.

8.4 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 lens.

8.5 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 evaporate/ volatize before use.

8.6 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 section of this manual.

WARNING: DO NOT clean and disinfect the unit using a washer and DO NOT submerge the unit in any liquid. Serious damage to the electrical medical laser will occur.

WARNING: Ensure the protective cap for the optical system is attached to the main unit prior to cleaning procedures.

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.

DO NOT use chemical reagents to rub the touch screen. Please wipe carefully with lens paper to avoid scratching or damaging the touch screen.

Observe the instructions for use provided by the manufacturers of the cleaning

products and disinfectants.

8.7 The Maintenance for Long-Term Storage

Please pack the device in accordance with the factory packaging for long-term storage

1. Turn the power switch to the "OFF" position and unplug the power adapter
2. Unplug the hand piece
3. Use the dust cap to protect both the hand piece, fiber and the device laser port
4. Place the main device, accessory bag, hand piece, power adapter, protective shields/ goggles, etc. in the packing box
5. After being packed, place the device in a well-ventilated, dry, cool environment

8.8 Power calibration

When the outputting power is found to be more than ± 10% of the setting power, please contact Summus Medical Laser or a designated dealer for power calibration. Calibrations shall be carried out under the direction of authorized personnel of Summus Medical Laser or a designated dealer to avoid possible injury or damage to the device from harmful laser radiation.

The suggested frequency for calibration is every 24 months. Contact a Summus Medical Laser Service Center to schedule the calibration. Calibration records shall be completed and maintained by Summus Medical Laser.

WARNING

Carry out the calibration of the device under the guidance of the authorized personnel of the company or the designated dealer. Eye protection is required during the calibration process to avoid possible harmful laser radiation to personnel and damage to the device.

9 ELECTROMAGNETIC COMPATIBILITY

H1 semiconductor laser treatment instrument is the basic performance of the laser output power accuracy.

The purchaser or user of the H1 semiconductor laser instrument should use the H1 semiconductor laser instrument in the electromagnetic environment specified in this section to ensure the operating functions of the device.

Note

The purchaser or user of the H1 semiconductor laser instrument should use the H1 semiconductor laser instrument in the electromagnetic environment specified in this section to ensure the operating functions of the device.

Note

Portable and mobile radio frequency communication equipment may

affect the normal use of H1 semiconductor laser treatment device. Please use the recommended electromagnetic environment during use of the H1 semiconductor laser treatment instrument.

CAUTION

The use of non-specified accessories and cables may result in an increase in the emission or immunity of the H1 semiconductor laser treatment instrument. Summus Medical Laser cannot guarantee that accessories, lines and transformers acquired outside of and not delivered from Summus Medical Laser, will correspond with EMC requirements of IEC 60601-1-2.

WARNING

H1 medical diode laser should not be close to or stacked with other equipment.

Accessory part/name	Length/dimensions
Non-heating apparatus connecting line	＜2.0m

Note

The diode laser medical system is exclusively intended for use by medical professionals. In residential areas, the diode laser medical system may cause radio interference in certain circumstances so that it may be necessary to undertake suitable measures such as realigning, rearranging or screening the diode laser medical system, or filtering the connection with the public power supply.

9.1 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	

9.2 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 /	Applicable Applicable	The network power supply should have a typical commercial or

Surge EN 61000-4-5	± 1kV line to line ± 2kV line to ground	Applicable Applicable	hospital environmental quality.
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)	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.			

9.3 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 Level	Match Level	Electromagnetic Environment Guidance

<table>
<tr>
<td></td>
<td></td>
<td>Not

Applicable</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

$d = \left(\frac{3.5}{E1}\right)\sqrt{P}$</td>
</tr>
<tr>
<td>conduction RF

EN 61000-4-6</td>
<td>3V(Valid values) 150KHz~80MHz</td>
<td>3V/m</td>
<td>80 MHz ~800MHz

$d = \left(\frac{7}{E1}\right)\sqrt{P}$</td>
</tr>
<tr>
<td>Radiation RF EN 61000-4-3</td>
<td>3V/m(Valid values)

80MHz ~2.5GHz</td>
<td>3V/m</td>
<td>800MHz ~2.5GHz

H1 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</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>
</table>

A fixed transmitter, 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 semiconductor laser treatment instrument.

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

9.4 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 H1 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.			

WARNING

Keep away from strong radiation sources and electromagnetic interference environment. External RFI and electromagnetic interference will affect the normal operation. Avoid use around or over cardiac pacemakers and other devices sensitive to electromagnetic environment.

10 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.

CAUTION

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 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.

CAUTION

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 615-595-7749 or an authorized Service Center.

11 SERVICE

11.1 Quality Commitment

Summus Medical Laser LLC guarantees the factory technical parameters of H1 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

11.2 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 specifications
3. Unauthorized removal of the shell, modified device. Disassembly is limited exclusively to Summus Medical Laser trained and authorized personnel.
4. Use of unapproved accessories that do not match the device. Components shall always be replaced with approved Summus Medical Laser parts upon failure.
5. Failure to follow the recommended maintenance schedule

Modifications to the laser devices design which affect the safety of the device, the owner/user, the patient, or any other persons are prohibited by law. For reasons of product safety, this product shall only be used with components and accessories approved by Summus Medical Laser. The user is responsible for any damage resulting from the use of non-approved components or accessories.

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 sole liability under contract or warranty or otherwise for the product.

12 FCC STATEMENT

This equipment has been tested and found to comply with the limits for a Class B 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. The device generates uses of and can radiate radio frequency energy. If not installed and used in accordance with the instructions for use, the device may cause interference to radio communications. These limits are designed to provide reasonable protection against potential radio frequency interference.

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

13 CONTACT INFORMATION

If you have any difficulties in the use of your 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 Street
	Franklin, TN 37064 U.S.A.
Tel:	615-595-7749
Fax:	615-261-3535
Email:	info@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.

The European Authorised Representative:

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 2017/745 concerning medical devices. Its compliance is based on the following standards: EN ISO 60601-1, EN ISO 60601-1-2, EN ISO EN ISO 60825-1, 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 62304 and IEC TR 60878.