InnoVoyce Surgical Laser
User Manual

InnoVoyce
One Beacon St Floor 15
Boston, MA 02108
1 617 865 9401
Info@InnoVoyce.com
https://innovoyce.com/

Revision Number/Date

Caution: Federal Law restricts this device to sale by or on the order of a physician. Rx Ony.

1 CONTENTS

2 INTRODUCTION

InnoVoyce Surgical laser will be a solid-state laser device in which laser energy is generated by internal diodes. The laser output energy of the device is in the bluespectrum at wavelength comprised between 440-450nm.

2.1 USE OF THE OPERATOR MANUALS

	Warning! Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure. **DO NOT** operate the system before attempting to use or operate the system, practitioners operating the system should read this manual and become thoroughly familiar with all its safety requirements and operating procedures.

The system is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of how to properly operate the system. This manual has been prepared to aid medical and technical personnel to understand and operate the system. If any part of this manual is not clear, please contact your InnoVoyce representative for clarification.

The information provided in this manual is not intended to replace professional training on the clinical use of the system. Please contact your InnoVoyce representative for current information on available training.

This manual should always accompany the system and all operating personnel must know its location. Additional copies of this manual are available from InnoVoyce or your local InnoVoyce representative.

For further information about InnoVoyce, visit the company website at:
https://InnoVoyce.com/

2.2 User Profiler / Intended User

The system is intended to be used by professional practitioners (specialized physician/authorized technical personnel) in the medical field. The system is intended for use in professional healthcare facility environment (such as Physician offices, clinics, hospitals etc.) and intended for indoor environment use only.

2.3 Intended Use

The InnoVoyce Surgical Laser is intended for use in incision/excision, vaporization, ablation, and coagulation of soft tissue.

2.4 Physician Responsibility

Regulatory statutes in most countries restrict prescription of medical systems for sale by or on the order of a physician, or a properly licensed practitioner. The physician will be responsible for the use and operation of the system and for all operator qualifications. InnoVoyce makes no representations regarding state or local laws or regulations that might apply to the use and operation of any medical system. The physician is responsible for contacting his or her local licensing agencies to determine any credential required by law for clinical use and the operation of the system.

2.5 Maintenance

The system requires periodic routine maintenance service, which must be performed by InnoVoyce authorized technical personnel only. Failure to obtain service voids all warranties expressed and implied. Please contact InnoVoyce or your local representative for details.

2.6 Modification of the System or Accessories

	Warning! No modification of this equipment is allowed. Unauthorized modification of the hardware, software or specifications of the system and its accessories voids all warranties, expressed and implied. InnoVoyce takes no responsibility for the use or operation of such a modified system. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating correctly.

2.7 Abbreviations and Acronyms

3 Safety

This chapter describes general safety issues regarding the use of the system, with special emphasis on optical and electrical safety.

With proper operation and maintenance, trained and qualified medical practitioners can use the system safely. The supervising physician and all other personnel operating or maintaining the system must be familiar with the safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician and other personnel. Patient safety is mainly assured by a well-trained staff and a well laid out treatment room. Patient education is also important, including information about the nature of the treatment.

3.1 The Treatment Room

The treatment room must be clearly labeled with signs indicating that high intensity laser energy is in use. The treatment room sign that is supplied with the system is shown in figure below:

The treatment room should not include any light reflecting objects such as a mirror.

Access to the system treatment room should be allowed only to personnel essential to the procedure and who are well trained in the required safety procedures.

Assure that all the treatment room personnel are familiar with the system controls and know how to shut down the system instantly.

3.2 System Safety Measures

The system incorporates a number of safety measures to protect the patient and clinician. The following describes those measures.

- The system has an automatic shutoff if the fiber is removed while firing or the calport is removed during calibration
- In the startup state, the software performs a Power On Self-Test (POST) to verify all modules are working and system is ready to use.
- The software monitors the KEY-Switch and transits to the Power-Off state if the KEY-Switch is in the Off position.
- The software monitors the Emergency-STOP button and transits to the Fault state and turn off laser power if the E-STOP button is pressed.
- The software monitors the Remote Interlock Switch and transits to the Fault state and turn off laser power if the switch is open.
- There is an audible alarm to indicate error/fault detection.
- There is an audible alarm to indication laser emission.
- The software monitors the communication between SBC and RT Controller, the software will go to the Fault state and turn off laser power if the communication is broken.
- The hardware watchdog monitors the RT controller software - The RT controller will be reset if the software fails.
- The software monitors the IR sensor and transits to the Fault state and turn off laser power if the fiber tip flaring is detected.

Note: the software will turn off the laser power in the Fault state and Power-Off state.

3.3 Electrical Safety

1. Avoid contact with the ground or with parts that have appreciable capacitance to earth;
2. A semi-automatic circuit breaker protects the system by tripping when power overload occurs;
3. Software Protection

3.3.1 Light Safety

	Warning! Any energy emitting system can cause injury if used improperly. High voltages are present inside the system. Personnel who work with lasers must always be aware of the possible dangers and must take the proper safeguards as described in this manual. Use carefully. May cause serious burns.

- Precise optical engineering is used to transmit energy to the treatment site. Energy is emitted only through the output ports of the applicators.
- The system incorporates a safety remote interlock connector for connecting an external interlock on the entrance door to the treatment room. It disables the system and prevents operation when the entrance door is opened.
- An emergency shutoff knob expedites shutdown when necessary. When pressed, it immediately shuts down system operation.
- The system features visual and audible emission indicators when laser is firing.

3.3.2 Smoke Evacuation and Laser Plume Pollution Hazards

	Caution Laser plume, which may contain vaporized tissue particles, pathogens, and toxic gases emanating during laser procedures, is an occupational hazard and may also obscure the operative fields.

A commercial smoke evacuator designed for use with surgical medical lasers may be used; these are usually most effective when the plume is extensive. The vacuum tubing or probe used to evacuate the laser plume should not be used to suction blood or fluids unless it is specifically designed and set up to perform both functions simultaneously.

Special in-line vacuum systems designed for evacuation of the laser plume may be installed. Flow capabilities should be adequate to effectively remove the laser plume.

3.4 General Precautions and Cautions

The following precautions, cautions, and warning must be observed for the safe use of the system.

3.4.1 Precautions

- Physicians and clinicians should read this manual thoroughly before attempting to operate the system.

- Use of accessories and / or equipment other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3.4.2 Cautions

- Only InnoVoyce authorized personnel may service the system. This includes making internal adjustments to the power supply, cooling system, fiber, etc.
- Verify that the system is wired for the appropriate electrical voltage.
- Maintenance performed by the operator must only take place when the system is shut down and disconnected from the electrical power source. Performing maintenance procedures with the system powered-up can be hazardous to the operator and/or destructive to the system.
- Ensure proper connection of the fiber before each treatment.
- Always turn OFF the system when it is not in use.
- Never leave the system in READY mode unattended.
- Never allow untrained personnel to operate the system.
- Never press the applicator's trigger and / or footswitch unless the applicator is safely oriented at a specific and intended target.
- Never leave the system turned ON, open or unattended during system maintenance.

3.5 THE SYSTEM AND ALL ITS COMPONENTS MUST ALWAYS BE VISUALLY INSPECTED BEFORE TREATING THE PATIENT. IF ANY WEAR OR DAMAGE IS APPARENT, DO NOT USE.WARNINGS RELATED TO ENERGY EMISSION

3.5.1 Burn Hazards

The system radiation is invisible to the human eye and can cause third-degree burns, even when unfocused.

3.5.2 Direct and Reflected Eye Exposure Hazards

- It is essential that all people present in the treatment room during the treatment protect their eyes by wearing InnoVoyce recommended protective eyewear.
- The protective eyewear must be labeled according to the wavelength and optical density for which they offer protection.
- It is good practice to instruct the patient (if not anesthetized) to close their eyes during treatment even when wearing protective eye glasses.
- If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.

3.5.3 Laser Safety Eyewear

	Warning! Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and / or can be shattered by a high-power density beam, possibly causing severe eye damage.

- All personnel must use safety eyewear and should verify that the eyewear provides adequate protection.
- The safety eyewear and opaque eye protectors are supplied with the system and offer adequate protection. For additional safety eyewear ordering please contact your InnoVoyce representative.
- Eye protection must have a protection level for 440-465nm with OD 6+ or higher.
- Absorption of optical energy raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials in and around the treatment area.
- Have water available to extinguish small fires.
- The system is not suitable for use in the presence of flammable mixtures with air or oxygen.
- Do not operate in the presence of volatile solvents such as alcohol, gasoline or other solvents.
- Do not use any flammable substances such as alcohol or acetone in the preparation of the skin for treatment. If necessary, use soap and water to clean before treatment.
- If alcohol is used to clean any part of the system, allow it to dry thoroughly before operating the system. See Maintenance section below for proper cleaning instructions.
- Flammable substances must be kept at a safe distance from the system.
- During treatment also pay attention to the possible danger of ignition of endogenous gases.

Nominal Ocular Distances	• 4.74 meters for main beam • Main beam diffuse reflection 61.2cm • 6.12cm for aiming beam
NOHD for Main beam with OD 8 safety glasses	• 0.0474 cm

3.5.4 High Voltage Hazards

	Warning! The electrical cable should be removed from wall electrical outlet before any service or in case of any detected malfunction.

- The system utilizes high-voltage electricity. To avoid personnel injury, do not operate the system before ensuring that the exterior panels are undamaged and properly closed. Do not attempt to remove or disassemble the exterior panels.
- The system produces very high voltages in various components. Some components may retain a charge after the power supply has been turned OFF. No part of the exterior housing should be removed, except by InnoVoyce authorized personnel.
- Never leave the system turned ON, open or unattended during system maintenance.
- To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed. Do not attempt to remove or disassemble the exterior panels.

3.5.5 Grounding the System

The system is grounded through the grounding conductor in the power cable and internal grounding pin.

	Warning! To avoid the risk of electric shock, this equipment must only be connected to a grounded power outlet.

3.6 System Safety Features

The system is equipped with various safety features. All treatment room personnel should be familiar with the location and operation of these safety features. The detailed information provided in CHAPTER 3 – System Description:

Emergency Shut-off Knob	Circuit Breaker
Emissions Indicators	Remote Interlock
Footswitch	Key Lock

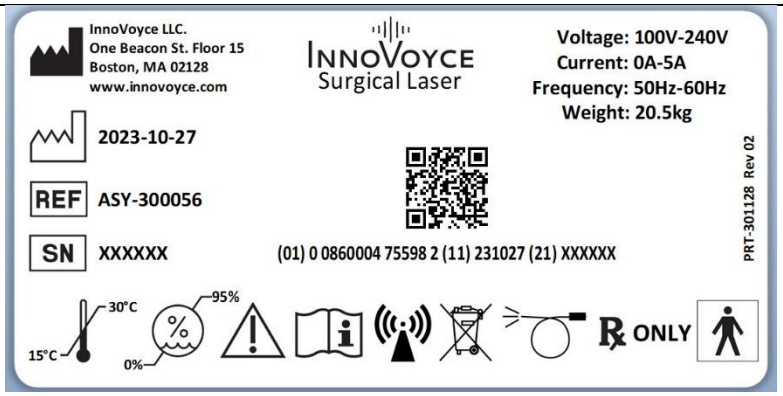
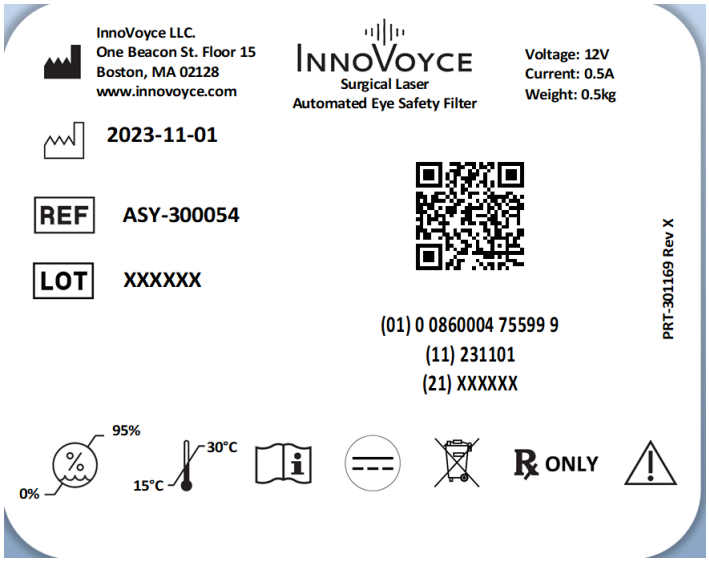
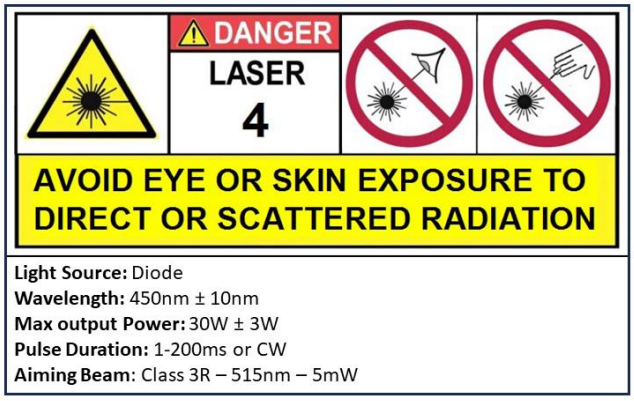
3.7 System and Equipment Classifications and Compliance

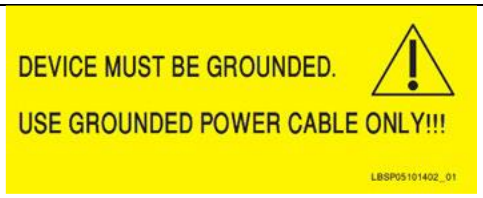
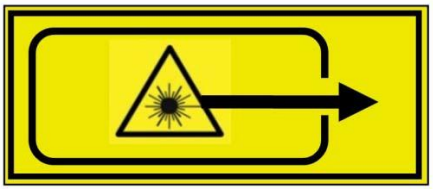
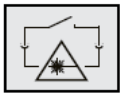
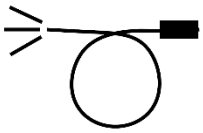
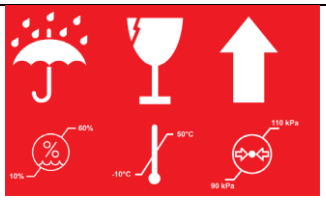
Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

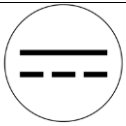
CDRH Laser Classification according to 21CFR 1040.10:	Class IV
Laser Classification according to EN 60825-1:	Class 4
Light Source Classification according to IEC60101-2-57:	Risk Group 3
Aiming Beam Class	Class 3R
Mode of Protection against Electric Shock:	Class I Equipment
Degree of Protection against Electric Shock:	Type BF Applied Part
Not suitable for use in presence of flammable anesthetic mixture with air or nitrous oxide.	

3.8 Labeling and Signs

The following labels are adhered to the system:

Identification/System Label	
Eye Safety Filter Label	
Laser Danger Class IV warning and information label.	

Grounded power cable warning label	
Electrical Requirement and Hazard label	
Laser aperture warning label (aperture at distal end of attachment)	
Laser radiation warning label	
Emergency Stop label located below the emergency shut-off knob	
Interlock port label	
Optical fibre applicator	
Footswitch port label	
Packaging label	
Prescription Only	

Sterile / ETO for fiber	
Waste Electrical and Electronic Equipment	
Manufacturer	
Manufactuer date	
Catalog number	
Serial number	
Applied Part Type BF	
Lot Number	
Manual Reference	
Radiofrequency warning	
Direct Current	

3.9 CONTRAINDICATIONS

- The laser system should only be used in conditions where its use is appropriate and of proven efficacy. Clinical applications should be performed by a qualified surgeon.
- The use of the laser is contraindicated for patients:
    - Whose general medical condition contraindicates surgical intervention.
    - Where appropriate anesthesia is contraindicated by patient history.
    - Where tissue (especially tumors) has calcified.
    - For hemostasis of vessels over approximately two millimeters in diameter.
    - Where laser therapy is not considered the treatment of choice.

4 SYSTEM DESCRIPTION

This chapter provides a detailed description of the system. The description covers the system's main components, controls, and system specifications.

4.1 GENERAL SYSTEM DESCRIPTION

The InnoVoyce Surgical Laser is a solid-state laser device in which laser energy is generated by internal diodes. The laser output energy of the device is in the surgical spectrum at a 440-450nm wavelength. The output settings of the laser can be adjusted by the user. The InnoVoyce Surgical Laser consists of a console with a graphical touch screen user interface, a footswitch, and single-use, disposable fibers. The system has four laser emission modes: Continuous Wave (CW), Pulsed Wave (PW), Quasi Pulsed Wave (QPW), and Quasi Continuous Wave (QCW).

InnoVoyce Fibers are sterile, single use, disposable laser delivery devices designed to deliver laser energy with the InnoVoyce Surgical Laser. Fibers are available in diameters of 300, 400, and 600 microns.

4.2 System Specifications

The system shall operate with fibers according to the General operating parameters as shown in the table below.

System Specifications

Light Source	Diode
Applied Part	Laser Fiber
Wavelength	450nm ± 10nm
Max Output Power	30W ± 3W
Divergence from Fiber	15° ± 3°
Aiming Beam Wavelength	515nm
Aiming Beam Max Output Power	5mW
Fiber Sizes	300µm, 400µm and 600µm
Nominal Ocular Distances	
Operating Temperature/Humidity requirements	15°C - 30°C (59°F - 86°F) / <95%
Operating Atmospheric Pressure	The device is not approved for operation at altitudes above 2000 m (SL) and for an air pressure between 1080 hPa and 750 hPa
Storage Temperature/Humidity Requirements	0°C - 40°C (32°F - 104°F) / <95%
Weight	20.5kg
Dimensions	13.4” x 14.7” x 14”
Power Requirements	100VAC to 240VAC +/- 10% 0 to 5A 50Hz to 60Hz
Size of fixed earthing conductor (lug)	6mm
Composition of coolant	1,2-propanediol, water, Methyl-1H-Benzotriazole, Sodium benzoate

Operating Parameters

Laser Emission Mode	Rep Rate (pps or Hz)	Macro Pulse Width	Micro Pulse Width	Fiber Output Setting Peak Power	Increment Steps
CW	NA	NA	NA	3W-30W	0.1W (3-10W) 1.0W (10-30W)
Pulsed Wave	1 to 10	1ms-200ms	NA	3W-30W	0.1W (3-10W) 1.0W (10-30W)
QPW	1 to 10	5ms-200ms	0.5ms-4.5ms	3W-30W	0.1W (3-10W) 1.0W (10-30W)
QCW	50 to 1000	NA	20-66% Duty Cycle	300um fiber: 3W - 15W 400um fiber: 3W - 15W 600um fiber: 3W - 30W	0.1W (3-10W) 1.0W (10-30W)

4.3 System Components and Controls

4.3.1 Control Panel

The system control Panel incorporates the following:

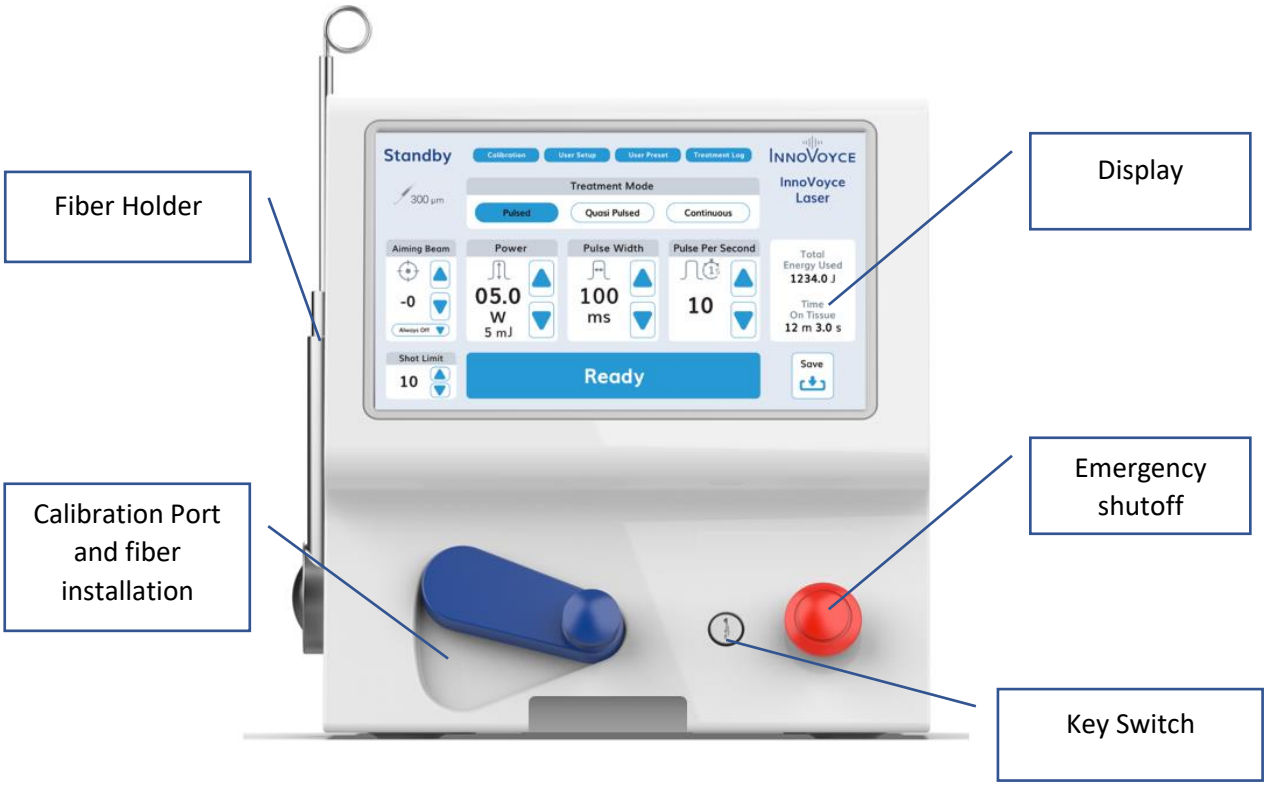


Figure 1 Front of Console

4.3.2 Display

The InnoVoyce system is controlled by a user friendly display where users can access system features and functions by touching the appropriate buttons on the screen. The screen is password protected.

4.3.3 Laser Fiber

The laser fiber is provided sterile and is single-use, except in the following special circumstances:

- The fiber has been assigned for use with the specified system
- The last fiber used by the system is the same fiber
- The previous treatment was not completed
- The system was power cycled as a result of a hard fault that has been resolved
- The fiber is reconnected to the system within a specified time after first use
- The fiber has emitted energy for less than a specified time limit
- The fiber has tried to reconnect no more than a specified number of times

Store the laser fiber in a clean environment. If the sterile pouch has been compromised in any way, dispose of the fiber and do not use for treatment.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s)from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and / or local government policy.

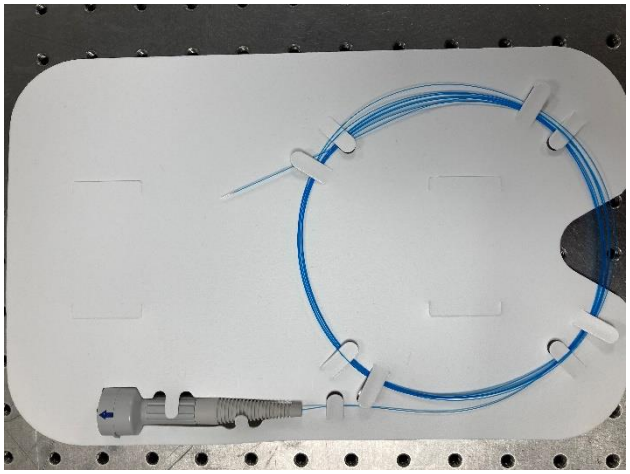
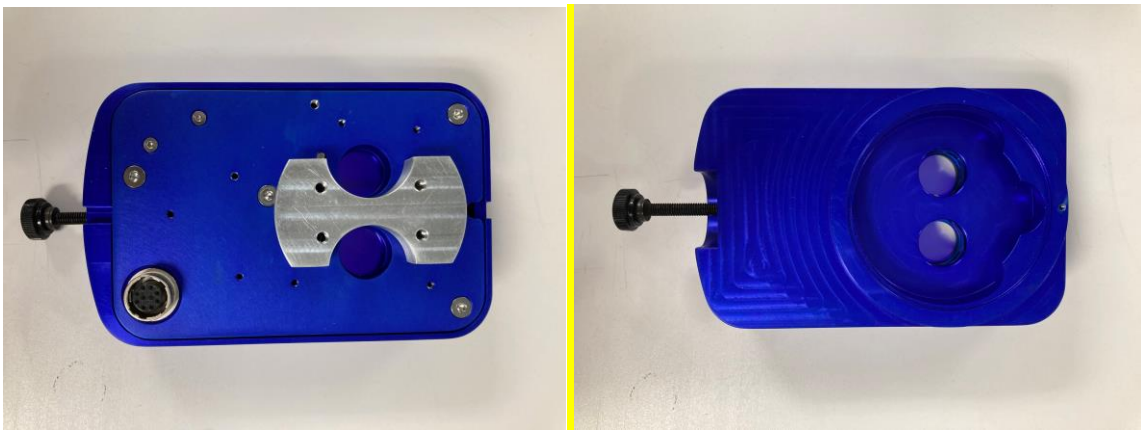


Figure 2: Laser Fiber in packaging

4.3.4 Microscope filter

The microscope filter enables the laser to be used in conjunction with operating room microscopes and provides eye protection to the surgeon. The device connects to the laser with an electrical cable on the rear of the console (see figure XX below). The system software allows the operator to select whether the microscope filter will be used during treatment.

Bottom Top



4.3.5 Cooling System

The InnoVoyce Surgical Laser systems includes internal coolant that will not degrade in performance over the expected shelf life of the device.

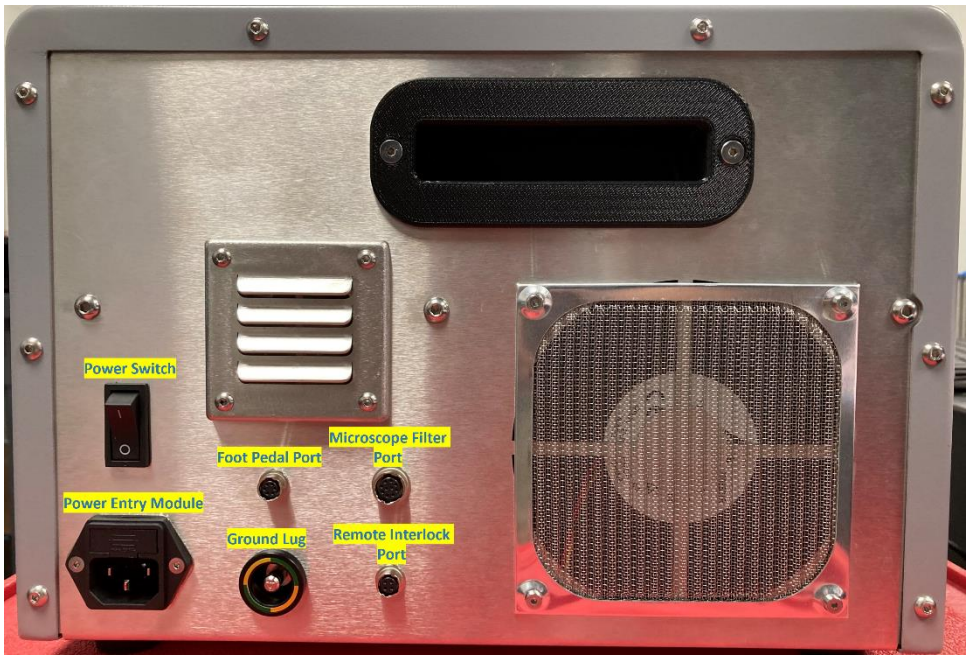
4.3.6 Emergency Shut-Off

The emergency shut-off is a red knob on the front of the system console. When pressed it immediately shuts off the system's power.

4.3.7 Emission Indicators

To indicate that the laser is being fired, the laser ready button on the display turns from green to red and there is an audible beep when the foot pedal is depressed.

4.3.8 Rear Panel



4.3.9 Main Power Switch

The main power switch is located on the rear of the console. See image XX above.

4.3.10 Footswitch

Laser emission is controlled by the user through the operation of a wired foot switch. The footswitch is connected to the device at a port on the rear of the console. See image xx above.

Footswitch Image

4.3.11 Remote Interlock

The system incorporates a safety remote interlock connector that connects an external interlock on the entrance door to the treatment room. The interlock disables the system and prevents operation when the treatment room door is opened. The remote interlock is connected to a port on the rear of the console. See image XX above.

5 INSTALLATION

NOTE: Any damage to the packaging or system found prior to opening the package should be reported to InnoVoyce.

The system is designed for installation in a surgical and clinical environment. A technician from InnoVoyce is required to perform the on-site installation.

5.1 EQUIPMENT LIST

- 1 x Laser Console
- 1 x Foot Switch
- 1 x Power Cord International, 12 feet Length
- 2 x Physician Laser Safety Goggles
- 6 x Supporting Laser Safety Goggles
- 1 x Instructions for Use, English
- 2 x Laser Safety Sign, English

- 1 x Remote Interlock connector, shorted
- 1 x Microscope Filter (Leica)
- 1 x Microscope Filter (Zeiss)

5.2 Facility Requirements

Before unpacking the system, ensure that the site meets the requirements described in the following sections.

5.2.1 Electrical requirements

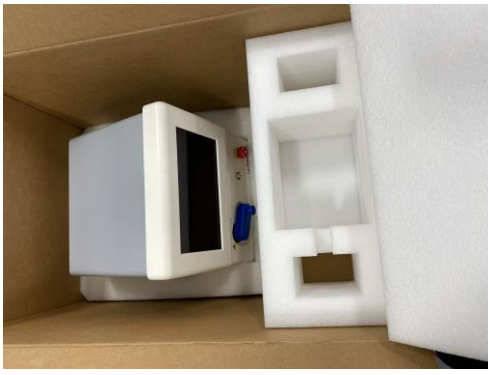
	Caution The system should be connected to a separate power line with a separate circuit breaker. InnoVoyce cannot guarantee the performance of the device unless it is connected to a dedicated circuit.

The system power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc. The system is grounded through the grounding conductor in the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation.

5.2.2 Environmental Requirements

Are there any specific environmental requirements? (Temp and humiditiy, space and positioning of the device, etc?)

5.3 Unpacking the System



5.4 MOVING THE SYSTEM

The Innovoyce Surgical Laser is a compact system that can be moved easily. The system console comes equipped with handles on the front and back that can be used to pick up the console. An optional cart can also be used to move the system.

To move the InnoVoyce Surgical Laser within the clinic:

1. Ensure the System is completely shutdown and the mains AC power switch is in the off position.
2. Disconnect the power cable.
3. If using the cart, ensure the caster wheels are unlocked.
4. Slowly push or pull the InnoVoyce Surgical Laser, using the handlebar on the cart to the desired location. Do not use the cart handlebar to lift the System off the floor.

5. If moving without the cart, ensure cable and accessories are properly stored or removed, and lift the system by the handles on the front and back of the console.

6 OPERATING INSTRUCTIONS

This chapter describes the operating instructions for the system. Specific treatment parameters and clinical guidance are provided separately.

6.1 CONNECTING THE SYSTEM

1. Confirm the system is in the off position.
2. Find the power cord for the system. Plug one end into the power connector on the rear panel of the system, and the other end into a grounded outlet.
3. Ensure cooling system vents are not blocked.
4. Ensure console is place in a location that does not block access to disconnecting the device (plug or appliance inlet).

6.2 ATTACHING THE MICROSCOPE FILTER

1. Attach the microscope filter cable to the port on the rear panel of the console (see image xx above).
2. When the system is turned on, the operated will be prompted to select whether the microscope filter is used during treatment.

6.3 REMOTE INTERLOCK AND FOOTSWITCH CONNECTION

1. Attach the Remote Interlock and footswitch cables to the appropriate port on the rear panel of the console (see image XX above).

6.4 OPERATING THE SYSTEM

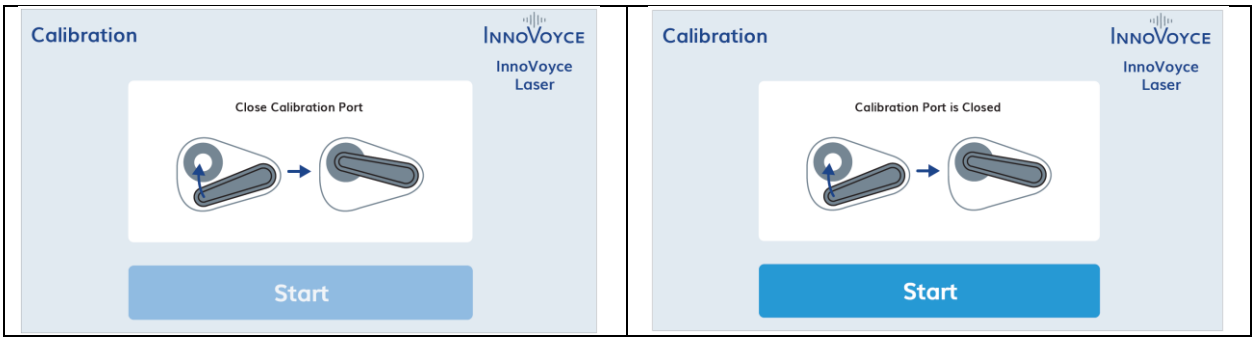
6.4.1 Turning ON the System

1. Turn the Keyswitch ON
2. Flip the AC power switch on the back of the device.
3. The control panel will display the following image when the system is turned on:

6.4.2 System Calibration

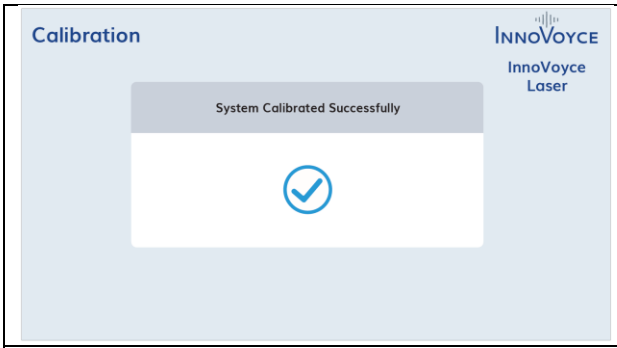
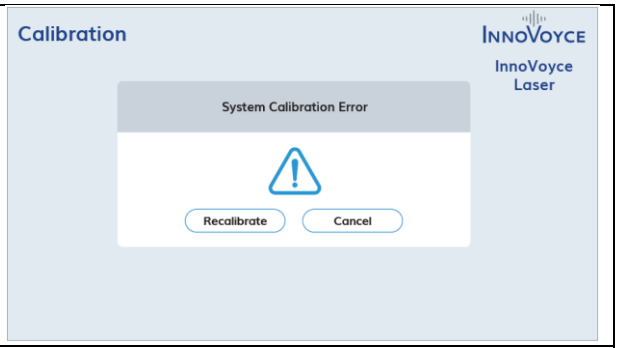
When the system start-up has completed, the system will conduct a calibration to ensure the device is transmitting the correct power. In order for the calibration to occur, the fiber must not be installed and the fiber port cover must be closed.

When calibration port is closed, the start button turns to a solid blue . Press “Start” to initialize the calibration process.



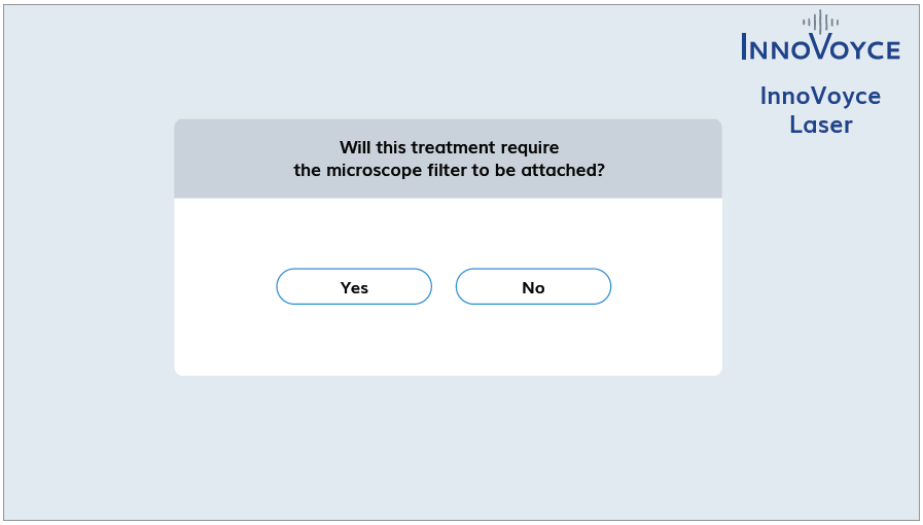
The calibration process is an automated routine that runs each time the device is powered on to test the laser output and calibrate the system for proper treatment levels. The calibration process can also be initiated anytime by the user when the system is in standby state.

If the calibration is a success, the system will display a message and allow the user to proceed to the treatment screen. However, if calibration is outside of acceptable range, then the system will prompt the user to recalibrate the system. The user may try up to five (5) time to recalibrate before the system will generate a fault and will become inoperable until a repair can be performed.

	
System message for successful calibration	System message for calibration error

6.4.3 Microscope Filter selection

Once calibration has succeeded, a popup window will appear to select if the microscope filter will be used by the system during treatment. If the microscope filter is to be used, the system will move the microscope filter into position during the laser emission state. The device will not fire until it senses that the microscope filter has been connected.

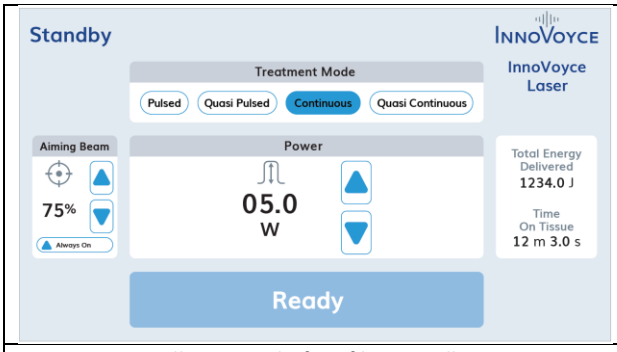
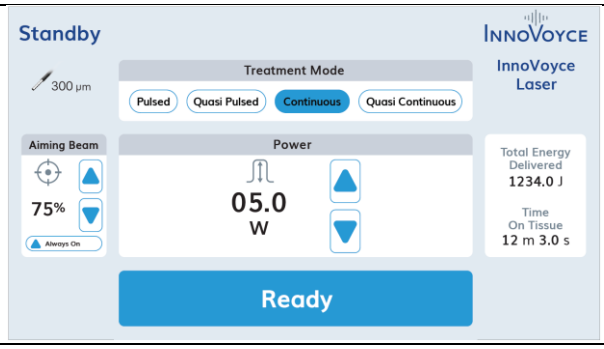


6.4.4 Installing the laser fiber

After the microscope filter has been moved into place (if selected), the system will display the standby screen (see image XX below) and the laser fiber can be installed into the calibration port. Open the calibration port and place the handle end of the fiber into the calibration port, and turn clockwise to secure it in place. The following images show the installation of the fiber.

	
Orientation of fiber for installation	Fiber installation

After installing the fiber, the system will conduct a fiber authentication to ensure a new fiber was installed.

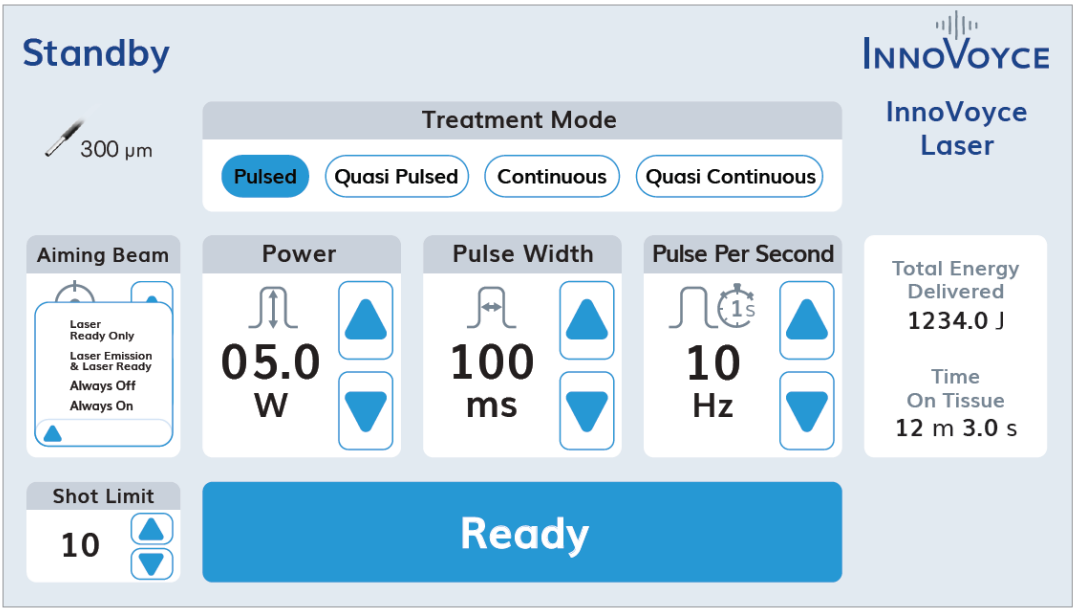
	
Standby screen before fiber installation	Standby screen with solid blue “Ready” button after fiber installation

After authentication, treatment parameters can be selected prior to firing the laser.

	*Caution when inserting, sharply bending, or improperly securing the fiber beam delivery and electrical harness. Failure to follow the instructions may lead to damage to the fiber beam delivery and may lead to harm to the patient or LASER OPERATOR due to fiber break and/or miss-alignment of the optics components.*

6.5 TREATMENT MODES AND PARAMETERS

The Standby state allows the user to select the desired laser operation mode as well as the various control parameters associated with each laser operational mode. The follow image is the display screen in Standby mode with adjustable parameters identified below.



6.5.1 Pulsed

The pulsed mode will cause the laser to emit discrete bursts of energy. In pulse mode, the user can adjust:

- Laser Power Output – Peak power the laser emits measured in Watts (W)
- Laser Pulse Duration – Amount of time the pulse is ON measured in milliseconds (ms)
- Pulse Per Second (p/s) – Number of pulses in a second. This ranges from 1 pulse up to a maximum of 10 pulses per second.
- Shot Limit Count – Maximum number of times the laser emits each time the footswitch is pressed. This can be set at either 1-10 or No Limit.
- Total Energy Delivered (J) – Summed total of all energy emitted during the treatment.

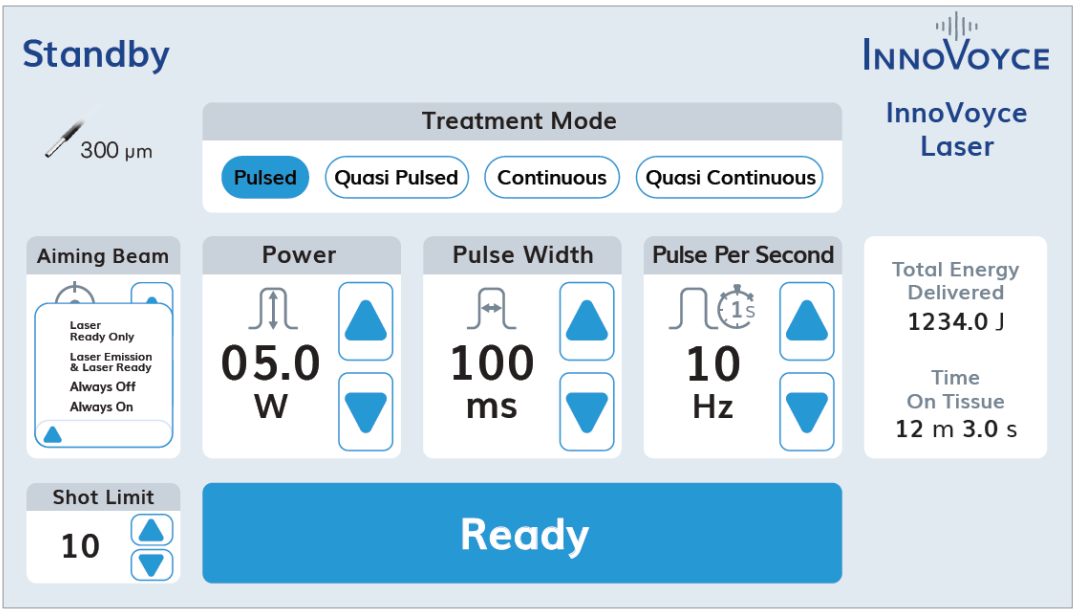


Figure 3 Treatment mode: Pulsed

6.5.2 Quasi-Pulsed

The quasi-pulse mode will cause the laser to emit energy in the form of macro pulses consisting of micro pulses. In quasi pulse mode, the user can adjust:

- Laser Power Output – Peak power the laser emits measured in Watts (W)
- Laser Macro Pulse Duration – Amount of time the pulse is ON measured in milliseconds (ms)
- Laser Micro Pulse Duration – Amount of time the pulse is ON measured in milliseconds (ms)
- Pulse Per Second (p/s) – Number of pulses (macro) in a second. This ranges from 1 pulse up to a maximum of 10 pulses per second.
- Shot Limit Count – Maximum number of times the laser emits each time the footswitch is pressed. This can be set at either 1-10 or No Limit.

- Total Energy Delivered (J) – Summed total of all energy emitted during the treatment.

Figure 4 Treatment Mode: Quasi-pulsed

6.5.3 Continuous

The continuous wave mode will cause the laser to emit laser power continuously without any modulation of power output. In continuous wave mode, the following can be adjusted:

- Power Output – Average power the laser emits measured in Watts (W)
- Treatment Timer – Amount of time the laser can emit laser power measured in minutes (min) and seconds (s)
- Total Energy Delivered (J) – Summed total of all energy emitted during the treatment.

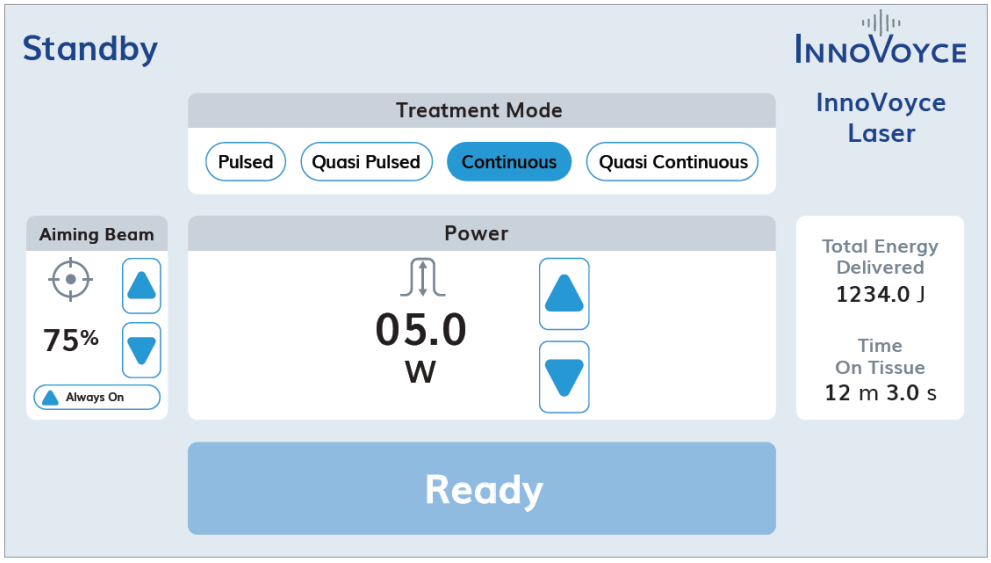
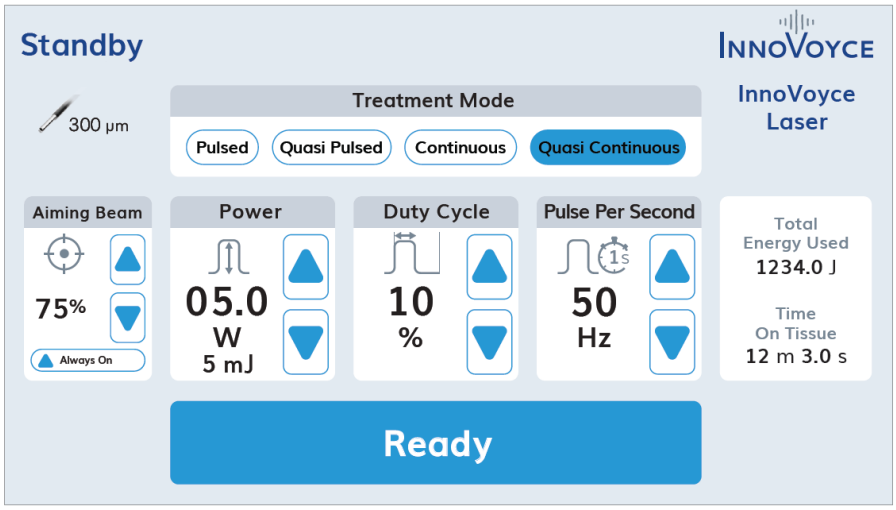


Figure 5 Treatment Mode: Continuous

6.5.4 Quasi Continuous

The quasi continuous wave mode will cause the laser to emit laser power continuously without any modulation of power output. In continuous wave mode, the following can be adjusted:

- Power Output – Average power the laser emits measured in Watts (W)
- Treatment Timer – Amount of time the laser can emit laser power measured in minutes (min) and seconds (s)
- Pulse Per Second (p/s) – Number of pulses in a second. This ranges from 1 pulse up to a maximum of 1 kHz.
- Duty Cyle – The ratio of time the laser is delivering energy.
- Total Energy Delivered (J) – Summed total of all energy emitted during the treatment.



Note!	The treatment does not have to be in a single pulse. Laser emission can be interrupted any time by lifting up on the foot switch. This will not interrupt the treatment time remaining timer.
Note!	If the continuous output power is 20W or higher, the system will impose a max emission time of 20sec per foot petal press.

6.5.5 Aiming Beam

In the *Standby* state, the operation of the aiming beam can be adjusted as follows:

- Always On – The aiming beam will be ON at all times
- Laser Emission and Laser Ready – The aiming beam will automatically turn ON when the system is in the *Laser Ready* and *Laser Emission* states. The aiming beam will be OFF at all other times.

- Laser Emission Only – The aiming beam will automatically turn ON only in the *Laser Emission* state. The aiming beam will be OFF at all other times.
- Always Off – The aiming beam will be OFF at all times

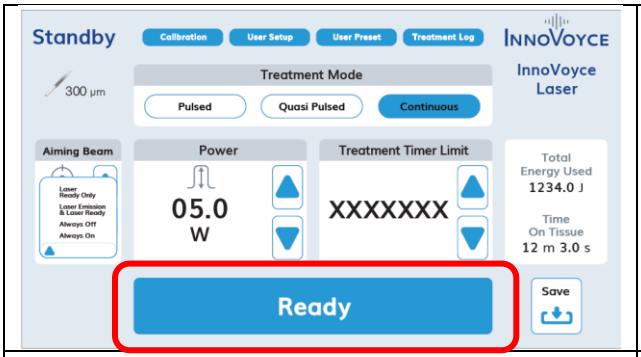
The aiming beam's intensity can be adjusted to be:

- 0% - The aiming beam intensity is set to 0% nominal output brightness
- 25% - The aiming beam intensity is set to 25% nominal output brightness
- 50% - The aiming beam intensity is set to 50% nominal output brightness
- 75% - The aiming beam intensity is set to 75% nominal output brightness
- 100% - The aiming beam intensity is set to 100% nominal output brightness

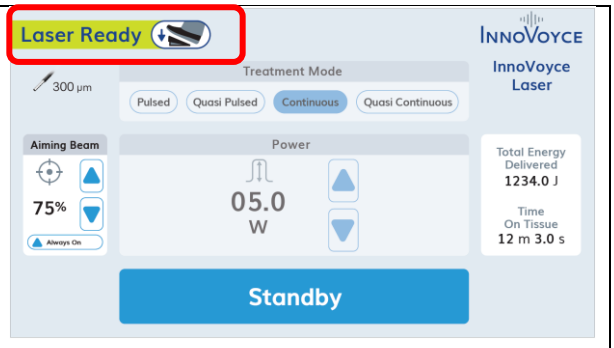
Note!	The aiming beam will be automatically set to 0% intensity if the aiming beam mode is set to be always off.

6.5.6 Firing the Laser

When the correct treatment parameters have been selected, pressing the "READY" button at the bottom of the screen will enable the laser to be fired. There is a 2 second delay with a beep when the device transitions from "Standby" to "Laser Ready." The top left corner of the screen will display "Laser Ready" and show that the footswitch can be depressed to fire the laser.



Press the "Ready" button to enable treatment



Indicator that laser is ready to fire

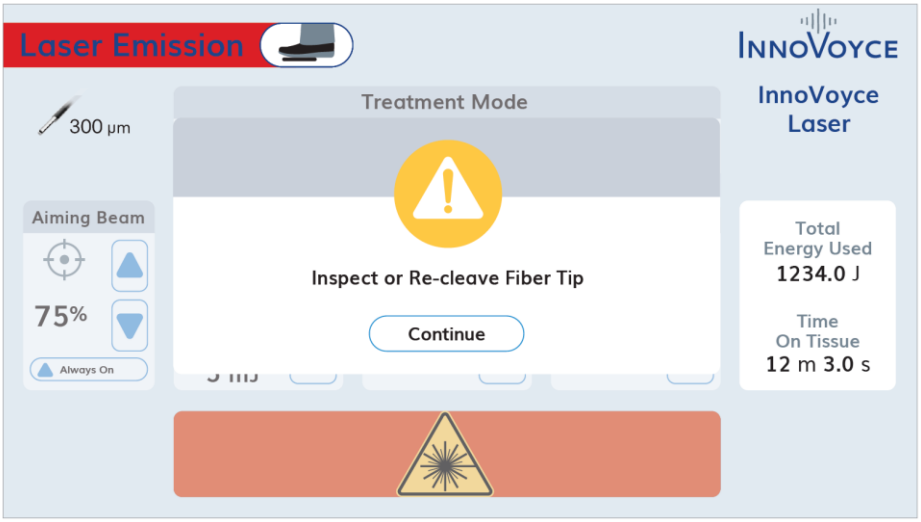
Note!	When the laser is in ready mode, only the aiming beam can be adjusted.

To fire the laser, depress the foot pedal. The system will make an audible sound while the laser is firing and the below image will be displayed.

	Warning! All personnel, including patient, should wear appropriate eye protection.

6.5.7 Fiber Tip Flare

The system is designed to detect when there is a fiber tip flare during use. When a flare occurs, the following error screen will display. Complete instructions for cleaving the fiber and fiber maintenance during surgery can be found in the Laser Fiber Instructions For Use. After cleaving the fiber, press “Continue” and the device will return to “Standby.”



6.5.8 Returning to Standby

When the footswitch is released, the system will return to “Laser Ready” screen.

Return to Standby by pressing the “Standby” button or anywhere on the screen *except* the aiming beam parameters. Those parameters can still be adjusted in the “Laser Ready” state.

If the system is idle for 3 minutes, it will automatically return to the “Standby” screen.

6.5.9 Shutting off the System

The system can be disconnected by unplugging the power cord from the wall socket.

6.6 Treatment Considerations

The InnoVoyce Surgical Laser is a surgical device that should be used only by physicians or surgeons who have been trained in laser surgery through courses, preceptorships, and under the guidance of other physicians or surgeons knowledgeable in laser use. No claim is made that the laser will cure any medical condition.

- BEFORE operating the laser system, surgeons and all staff operating the laser should carefully read this manual.
- Surgeons using the InnoVoyce Surgical Laser must understand the laser’s unique properties prior to using the device.
- Prior to turning the laser system on, operating room personnel and the patient should be wearing protective eyewear suitable for laser energy.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power and pulse duration should always be used.
- Tissue perforation can result if excessive laser energy is applied. This can occur through the use of excessive laser power or the application of power for excessive periods of time, particularly in diseased tissue.
- Aim and use the laser only on tissues that are in full view.
- Extra caution should be used when lasing tissue close to known arteries, nerves and veins.
- Begin laser treatment at the lowest power, with short duration exposures until fully familiar with the tissue effects of the applicable wavelength.
- Patients who experience discomfort during laser treatment may require analgesics.
- As with conventional non-laser surgical procedures, there is no guarantee that treatment with the InnoVoyce Surgical Laser will entirely eliminate the diseased entity. Repeated treatment or alternative therapies may subsequently be required.
- The laser may not be effective for coagulation in massive hemorrhage situations. The surgeon must be prepared to control hemorrhages with strident alternative non-laser techniques, such as ligature or cautery.
- Alterations in surgical approach or technique may be required to accommodate laser use.

- The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- A smoke evacuator and in-line filter should be used to capture the smoke plume that results from laser procedures. The plume should be regarded as a source of active biological material and a possible carcinogen.

7 MAINTENANCE AND CLEANING

7.1 MAINTENANCE AND CLEANING

This chapter contains maintenance and cleaning instructions for the system.

	Warning! Unauthorized servicing or modification of this system not described in this manual may expose the operator or patient to potential high voltage and laser radiation hazards. Improper use or adjustment of this system may invalidate the service warranty agreement. The system generates high voltages and laser radiation when powered up. Maintenance should be performed only when the system is shut down and the power cable disconnected from the mains power source. Performing maintenance procedures with the system turned on may be hazardous to the operator and/or destructive to the system.

Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed only by an InnoVoyce authorized technician.

7.2 CLEANING

7.2.1 Laser Fiber

The laser fiber is provided sterile and is intended for single-use. The laser fiber should be discarded after every patient or if damaged during use.

7.2.2 External Surfaces

External surfaces of reusable system components shall withstand wipe down without loss or degradation of performance or appearance with 70% Isopropyl Alcohol Solution.

The operator should periodically wipe the outside surfaces of the laser with a cloth dampened with 70% Isopropyl Alcohol. Stubborn marks can be removed with a cleaning cloth dampened with a weak

solution of water and mild detergent or a cleaning agent. Never use harsh or abrasive cleaners or pour water onto the device.

7.3 PERIODIC SERVICE

The system should be periodically inspected and maintained to keep it in peak operating condition. The routine service operations should be performed by an InnoVoyce authorized technician.

If periodic service is not performed according to schedule by an InnoVoyce-authorized service provider, any warranty agreement of the system and its associated applicators and/or accessories will be invalidated.

During periodic service, the system's protective panels must be opened. Therefore, this is performed only by InnoVoyce service personnel.

A recommended routine inspection and maintenance schedule:

Inspection/Service	Frequency	Inspected by:

7.4 SERVICE INFORMATION

In communications with InnoVoyce authorized representatives, always include the part number and serial number indicated on the system’s label.

Questions or problems should be referred to:

InnoVoyce Customer Service
(617) 865-9401

8 TROUBLE SHOOTING

8.1 System Faults

The following tables list the hard and soft system faults. Soft faults turn the laser power off, while hard faults require the software to power cycle the system in order to recover.

TABLE NUMBER: Soft Faults

Sr. No.	**Error Data Name**	**Error Details**
1	Fault 1	Software checksum mismatched
2	Fault 2	POST message failed
3	Fault 3	Microscope filter disconnected
4	Fault 4	Microscope filter is not in the field of view
5	Fault 5	Calibration process failed
6	Fault 6	Calibration process canceled
7	Fault 7	Fiber disconnected
8	Fault 8	Fiber used previously
9	Fault 9	System input voltage is out of acceptable range
10	Fault 10	Power rail voltage is out of acceptable range to power up laser module
11	Fault 11	Power rail voltage is out of acceptable range to power up SBC module
12	Fault 12	Real time laser-emission comparison mismatched
13	Fault 13	Calibration detector comparison mismatched
14	Fault 14	Communication interruption between SBC & RT Controller
15	Fault 15	Emergency stop button pressed
16	Fault 16 …. Fault 24	FUTURE USE

TABLE NUMBER: Hard Faults

Sr. No.	Error Data Name	Error Details

1	Fault 25	Calibration process failed for 5 times in a row
2	Fault 26	Laser diode temperature is less than or equal to 14 degrees Celsius
3	Fault 27	Laser diode temperature is greater than or equal to 44 degrees Celsius
4	Fault 28	Cooling liquid temperature is less than or equal to 14 degrees Celsius
5	Fault 29	Cooling liquid temperature is greater than or equal to 44 degrees Celsius
6	Fault 30	Microscope filter is not in the correct position
7	Fault 31	Communication broken between SBC & RT Controller
8	Fault 32	

9 ELECTROMAGNETIC COMPATIBILITY

FORTHCOMING

FCC Compliance
FCC ID: 2BDH3ASY300056
Changes or modifications not expressly approved by InnoVoyce could void the user's authority to operate the equipment.

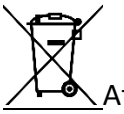
This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

> Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

10 ESSENTIAL PERFORMANCE

1. Power output	Display value should be +/- 20% emission in all modes (Continuous, Pulsed, QCW, QP) (See Matrix).
2. E Stop function	Emergency Stop button must stop laser power.

11 DISPOSAL OF DEVICE

 At the end of the useful life the system and its accessories should be returned to the manufacturer for appropriate processing and disposal.

APPENDIX A: PRE-TREATMENT PREPARATIONS

The following steps should be taken to ensure favorable treatment conditions.

- ☐ Determine if the patient can be treated and has no contraindications for treatment.
  - Whose general medical condition contraindicates surgical intervention.
  - Where appropriate anesthesia is contraindicated by patient history.
  - Where tissue (especially tumors) has calcified.
  - For hemostasis of vessels over approximately two millimeters in diameter.
  - Where laser therapy is not considered the treatment of choice.
- ☐ Determine why the patient is seeking treatment and what his/her expectations are.
- ☐ Complete or update the patient's medical and physical history.
- ☐ Inform the patient about the treatment protocol, typical treatment results and possible adverse effects and discomfort.
- ☐ Advise the patient about pre- and post-treatment care instructions.
- ☐ Instruct the patient about the safety issues of the treatment

Treatments may be performed according to the treatment mode used. Treatment should conform to all laser safety instructions and should be conducted according to the following guidelines:

- Dedicated eye protection must be worn during treatment by both the patient and staff.
- Care must be taken to avoid unintended exposure of the treatment beam to the patient's eyes or non-target tissue. Such exposure can cause possible damage.
- Once the laser operating parameters have been selected and the handpiece positioned at the proper treatment area, press the footswitch to activate the laser treatment.

APPENDIX B: POST TREATMENT LOG SHEET

Date:
Patient:_____

Laser Certified Surgeon(s):_____
Assistant: _____

Eye Protection: Patient:_____ Staff:_____

Windows Covered: YES/NO

Warning Signs: YES/NO

Fire Safety Measures: YES/NO

LASER Protocol Followed: YES/NO

Procedure done for:_____

Fiber Size: 300pm 400pm 600pm

Power Setting (Watts):_____ Mode: _____

Pulse Duration (msec):_____ Repetition Rate (pps):_____

Total energy output from laser (joules):_____

Total time on tissue:_____

***Total energy output from laser may not represent total energy delivered to the patient.

Comments: