5810 Van Allen Way, Carlsbad CA 92008
800.268.5354 | soundvet.com

USER MANUAL

SOUND® SMART RLT
Regenerative Laser with an IQ

Regenerative Laser Therapy

SMART RLT is a BWF-5 Series laser manufactured by B&W TEK for Sound Technologies, Inc.

Sound Technologies, Inc

5810 Van Allen Way, Carlsbad, CA 92008
Contact/Technical Support: 800-268-5354
http://www.Soundvet.com
Email: Techsupport@soundvet.com

B&W TEK

19 Shea Way, Newark, DE 19713
Tel: 302-368-7824
http://www.bwtek.com

5810 Van Allen Way, Carlsbad CA 92008
800.268.5354 | soundvet.com

WARNING!
This laser device is sold solely for **VETERINARY purposes only**! Under **NO** circumstances should this laser system be used as a medical device for use on Humans or companion animals!

CONTENTS

1 CONVENTIONS USED

Various precautions, warnings, recommendations and notes are presented throughout this document. Explanations of the categories are as follows:

CAUTION! A *PRECAUTION* describes measures that if properly followed beforehand, will prevent harm.

WARNING! A *WARNING* calls the reader's attention to specific danger in advance. If ignored or compromised, the situation could result in serious, irreversible personal injury or product damage.

RECOMMENDATION: A *RECOMMENDATION* offers guidance that may be worthy of acceptance or trial within a specific area of SMART RLT's application and may serve to optimize overall SMART RLT utilization.

NOTE: A *NOTE* describes the conditions or exceptions that may apply to the subject matter presented.

2 PRECAUTIONS

- Never allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.
- The protective eyewear supplied with this device has an optical density rating >5 in the 1064 nm region. **All** personnel present during device operation must wear this eyewear. Contact Sound Technologies, Inc. at 800-268-5354 Option 1 to purchase additional sets of protective eyewear for this device.
- Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser.
- Place "Laser Safety Warning" signs at location entrances where people will use the SMART RLT laser device.
- Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the hand piece or fiber optic.
- Never leave this device in the **READY** mode unattended. See the STANDBY to READY Mode in the Operations section of this manual.
- Log off the laser when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions.

- Turn the device off before relocating equipment in the same vicinity.
- Never press the hand-switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.
- During any laser procedure, do not allow any nonessential personnel into the treatment area.

3 WARNINGS!

- This laser device is sold solely for VETERINARY purposes only! More specifically for equine species! Under NO circumstances should this laser system be used as a medical device for Human use or companion and other animals!
- This laser device produces 1064 nanometer near infrared laser energy that is invisible and can be an extreme hazard to the eyes of any living being. Irreparable corneal and/or retinal damage may occur if a person exposes one or both eyes to direct or indirect (reflected) laser energy.
- IMPROPER USE OF SYSTEM CONTROLS or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.
- FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.
- NEVER direct the laser beam at anything other than the area to be treated.
- NEVER allow the eyes of any living being to look directly into the distal end of the optical fiber connected to an active laser device - WITH or WITHOUT wearing appropriate laser-emission protective eyewear.
- DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes and skin. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device.
- NEVER open or operate the system if damaged or not operating properly.
- THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Therefore, do not attempt to gain access to any internal device component. Doing so may cause serious and/or irreversible injury and void the warranty. For service, contact Sound Technologies, Inc. at 800-268-5354 Option 3.

- DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. To do this, the operator releases the hand -switch at completion of the treatment or cancels treatment by pressing “Laser Ready” button and waiting until the operator visually observes the laser device returning to Standby.

- AVOID THE USE of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

If the laser fails to operate properly, contact Sound Technologies, Inc. at 800-268-5354 Option 3.

4 RECOMMENDATION

Designate at least one person at each facility that utilizes this device as laser safety officer, responsible for providing training on all laser operating and safety procedures.

5 INTRODUCTION

The SMART RLT system is classified as a class 4 laser device.

5.1 Device Description

The SMART RLT system is designed for therapeutic treatment of the equine species, and more specifically tissue regeneration. The laser reaches deep into the body through intact skin to stimulate the body to achieve a highly beneficial result. The laser therapy increases circulation, reduces pain and inflammation, and promotes cellular metabolism in tissue. The regenerative aspect stems from photo-acoustic wave generation that modulates the extra-cellular matrix, releasing growth factors that revitalize injured tissue. Operating at a wavelength of 1064nm in the near infrared portion of the spectrum and delivered in short, energetic pulses, it has a vital combination of penetration and energy conversion.

The system is housed in a rugged case to protect the laser hardware and the laptop is mounted on the interior deck. There is a two meter fiber optic cable going to a hand piece with a button and a LED indicator. The deck to which the laptop is mounted also has the main emergency stop button and LED indicators reflecting power and laser emission.

The laser source of this device is a sold-state laser system. It produces invisible laser energy at the 1064 nanometer (nm) wavelength. The delivery system consists of a flexible optical fiber threaded through a lightweight hand piece. Activation occurs when the operator enables the laser and presses the hand-switch. There is a visible red aiming beam (650 nm) that is used to visualize the laser on the

treatment area. Release the finger -switch to deactivate the laser. Depending on laser system configuration, the finger-switch can function as on/off switch. A convenient and easy-to-use touch-screen design allows the operator to set and adjust laser output level with minimal effort. The laser can operate at controlled pulse mode. The device features selection of treatment areas that when selected bring up presets for treatment parameters which include: energy, Hertz (frequency), dose, and calculate the time necessary to perform the treatment.

5.2 Protective Eyewear

All Individuals present during the operation of this device must wear protective eyewear with an optical density of 5.0 or greater at 1064nm wavelength. Three (3) pairs are included with this device.

For additional pairs of protective eyewear, contact Sound Technologies, Inc. at 800-268-5354 Option 1.

5.3 Environmental Safety

The laser system must be stored, transported and operated in accordance with the environmental conditions provided in this manual.

The laser device is air-cooled and designed for use in a well-ventilated area that maintains relative humidity and temperature conditions conducive to conventional human productivity.

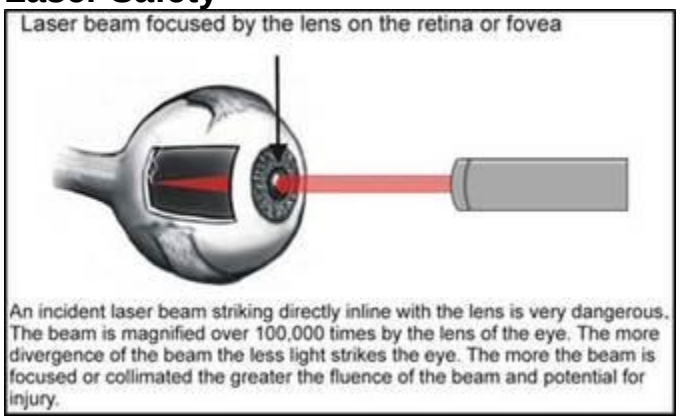
This laser device has specific requirements for environmental conditions for transportation, storage and operation.

Temperature Humidity and Air Pressure			
Condition	Temperature	Humidity	Air Pressure
Transportation and storage	-5-45°C (23-113°F)	10-95% non-condensing	700 hPA-1060-hPA (10-.5 lb/in2, 0.7-1.0 atm)
Operation	10-32°C (50-90°F)	30-75% non-condensing	700 hPA-1060-hPA (10-.5 lb/in2, 0.7-1.0 atm)

6 SAFETY

This section provides a collection of safety guidelines and safety-related statements relevant to the safe and effective operation of the SMART RLT system. Additional statement and protocols regarding safety appear elsewhere in this document. Use this laser device according to all printed guidelines, cautionary statements, and protocols.

Laser Safety



Laser therapy is extremely safe when basic protocols are followed by the laser operator and support staff. As with all therapeutic procedures, some element of risk is present through negligence or accident. These hazards are easily prevented or reduced with safety protocols for each application. Every clinic using a laser should have an individual trained in safe operation of laser therapy and regularly use a safety checklist. This individual (often the doctor), is the Laser Safety Officer (LSO).

Eye Protection
Class 4 Therapy Lasers can emit both visible and invisible radiation. Protective eyewear is necessary for both Class 3 and Class 4 lasers where irradiation of the eye is possible.

Required Users
• Administrator of the laser therapy treatment
• Patient (If treating near the head area of the horse, using a towel or blinkers to block any potential laser exposure is recommended.)
• Any other individuals in the room or treatment area

Safety Goggles
Not all Safety Goggles are the same. The protective eyewear that came with your laser is manufactured specifically for the wavelengths emitted by the laser. Do not use protective eyewear from other manufacturers as they may not provide the appropriate level of protection.

Technical Specifications for proper usage include:
• Wavelength Specific
• Blocks 1064nm

• Meets ANSI Safety Standards

Using Safety Goggle Correctly

Laser safety glasses are vital for eye protection in the presence of laser radiation. Since accidental laser radiation exposure can cause irreversible damage to the human eye, protective measures must not be taken lightly. Ensure that the eyewear has appropriate optical density for the wavelength of operation. Remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with the laser. Indirect or direct eye contact with the laser beam or with scattered laser light from any reflective surfaces will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. Do not allow any reflective object to fall into, or obstruct the path of the laser beam. Always wear protective eyewear. Any person present during the laser operation must wear protective eyewear.

Never look directly into the end of any laser hand piece.

Never direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated with or without the correct Safety Goggles.

Do not remove the Safety Goggles until the administrator of the laser has turned off the laser or notified the patient that it is safe to remove them.

Laser Safety Warning Signs

Lasers require the use of specific Warning Signs for the safe operations of each laser system. Warning signs must be in view outside and inside the room or treatment area where the laser treatment is being performed. Warning signs must meet ANSI recommendations.

Laser Safety Checklist
Checklist for the Laser Operator and Laser Safety Officer

- Appropriate warning signs posted
- Access to laser and treatment area is secure and controlled
- Visually inspect and clean all optical connectors for dirt, debris, etc.
- Inspect laser for proper function
- Visually inspect and clean all Safety Goggles
- Safety Goggles available for all persons in Nominal Ocular Hazard Zone
- Extra Safety Goggles placed outside treatment room if necessary
- Sources of potential laser beam reflection and scatter controlled
- Treatment protocol established for patient
- Laser injury management protocol in place for accidental injury
- Document laser treatment and post-treatment outcome

Contraindications

- Do not apply over an implanted device, i.e. a pacemaker. (pet microchip OK)
- Do not apply over the thyroid gland, ovaries or testicles.
- Do not treat over any cancer/malignancy.
- Do not treat over an actively hemorrhaging area.

Safety

- Familiarity with safety shutoff devices on laser
- Eye protection, specifically supplied goggles
- Patient- goggles and/or eye shields
- Attending therapists within the treatment room
- Others such as pet owners, etc. within the treatment room
- Post the “Laser Safety Warning” sign(s) in appropriate location(s)
- Consideration of therapy in a safe laser environment

6.1 Guidelines

Sound Technologies, Inc. user information is in compliance with EN / IEC 60825-1:2014 and IEC 60825-1:2007 (USA) Laser Notice #50.

6.2 Laser Safety Supervision

Designate at least one person at each facility that utilizes this device as Laser Safety Officer, responsible for providing training on all operating safety procedures.

6.3 Laser Safety

Precautions
Please refer to Section 2. PRECAUTIONS.

Warnings
Please refer to Section 3. WARNINGS.

6.4 Labels and Symbols

The following labels appear on the SMART RLT laser.
Manufacturer (Factory) Identification Label – Located on the top plate of the device above the lap top computer. The label indicates the manufacturer, model number, serial number (S/N i.e.: 160406-004) and date of manufacture (DOM = Month/Year i.e.: April 2016) of the SMART RLT.

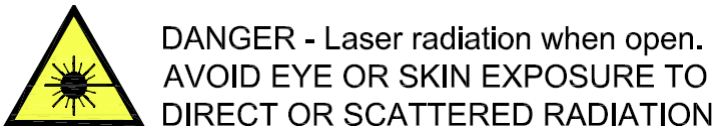
B & W TEK INC. 19 Shea Way, Newark, DE 19713, USA Tel: +1 (302) 368-7824 Web: www.bwtek.com	
Model No.	**SMART RLT**
Serial No.	**160801-011**
DOM	**August 2016**

Explanatory and classification label – Located on the top plate upper right hand side. These labels indicate the laser classification and laser safety warning.

Aperture label and Aperture Icon– Located on the hand piece. This label indicates the laser aperture. The laser emission can only be emitted from the laser aperture on the hand piece.

International Laser Hazard Symbol – This icon denotes a laser product located on the top deck in the upper right hand corner

Non-interlock protective housing label – Located on the top plate behind the laptop computer. The label indicates the laser safety warning when the panel is open.

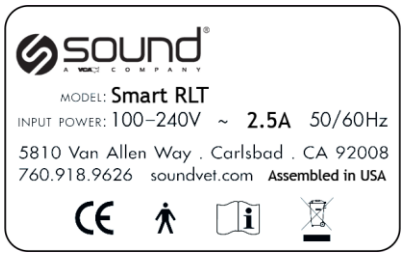


Warranty Seal Label – Located on the top plate in the upper right hand corner. Any attempt to open the top plate of this device will break this seal voiding the system warranty

Certification Label – Located above the laptop computer this label denotes Compliance with CDRH requirements.

THIS PRODUCT COMPLIES WITH FDA PERFORMANCE STANDARDS FOR LASER PRODUCTS EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 50 DATED JUNE 24 2007

Sound Label – Located on the outside of the system adjacent to the power entry module this label indicates electrical power requirements and additional regulatory information.



Type B Applied Part

Refer to User Manual

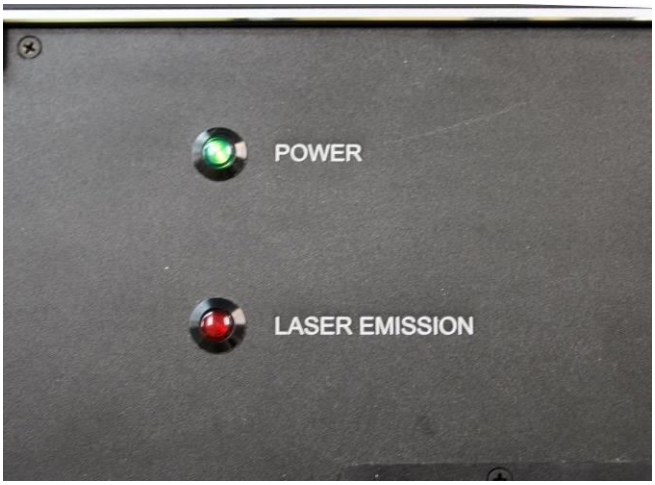
WEEE: Waste Electrical and Electronic Equipment

6.5 Safety Devices

The following component devices have specific safety-related features. All individuals who use this laser device should be familiar with the purpose and the operation of these components.

Emergency Power off Switch: This switch is located on the top plate of the SMART RLT. Pushing the switch down terminates all electrical power to the laser device's microprocessor and laser-emitting components. Resetting the switch restores power. To reset the Emergency Power Off Switch, the user must press, twist, and rotate in the direction indicated by the arrows, then release it as the switch pops out, returning it to its normal position. SMART RLT software must be stopped and restarted.

Power On/Off Visual Indicator: Located on the top plate of the laser device, the green LED indicator is illuminated continuously whenever the system is powered on, the laptop is running and the emergency power off switch is disabled.



Laser-Emission LED Indicator: The red LED on the top plate of the laser system will be illuminated flashing when the laser emission is ON.

Laser-Emission Audio Indicator: The laser will have an audio beeping sound when the laser is emitting. This audio comes from the laptop speakers so sound should never be muted or turned below an audible range on the laptop.

> WARNING!
> The operator should never mute or turn off the audio on the notebook computer. This audio is used as an additional indicator when the laser is in emission mode.

Remote Interlock: The purpose of the remote interlock connector is to permit the user to connect a remote barrier interlock, emergency stop switch, or similar device. The connector must be in place for the unit to function or a remote interlocking system is connected to the unit.

Laser-Emission Hand Piece LED Indicator: There is an LED on the hand piece that will flash when the laser is in emission mode.

On Screen Emission Indicator: The system software on the laptop will have a flashing red indicator that appears as follows on the screen during emission:

Watchdog Timer: The laser firmware will automatically halt laser emission if the laptop software does not message the firmware once every half second during laser operation. This is to prevent a loss of communication to the firmware preventing a hazardous situation.

6.6 Laser Eye Protection

The protective laser eyewear supplied with this device has an optical density rating > 5.0 for 1064nm laser emission. All personnel present during device operation must wear this eyewear. Contact Sound Technologies, Inc. at 800-268-5354 Option 1 to purchase additional sets of 1064-nm protective eyewear.

6.7 Electromagnetic Compatibility

This device complies with IEC/EN 60601-1-2:2007/AC:2010 Clause 4.1. General Requirements for electromagnetic compatibility of equipment and systems. Prevent the potential risk of electromagnetic interference between this equipment and other devices by following the recommendations here:

Emissions		
Test Type	Compliance Level	Comments
Conducted Emissions EN 55011:2009+A1:2010 CISPR11:2009+A1:2010	Class B Group 1 150 kHz to 30 MHz	The Smart RLT uses RF energy for its internal function. Nearby electronic equipment may be affected
Radiated Emissions EN 55011:2009+A1:2010 CISPR11:2009+A1:2010	Class B Group 1 30 MHz to 1 GHz	
Harmonics IEC/EN 61000-3-2:2014	Limit	None
Flicker IEC/EN 61000-3-3:2013	Limit	None

Immunity		
Test Type	Compliance Level	Comments
Electrostatic Discharge IEC/en 61000-4-2	+/- 2, 4, 6, kV contact discharge +/- 2, 4, 6, kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated Immunity IEC/EN 610000-4-3	80 MHz - 2.7 GHz 3V/m 80% @ 1 kHZ	Portable and mobile RF communications equipment should be used no closer to any part of the Smart RLT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = (3.5 / E1)√P 80 MHz to 800 MHz d = (7 / E1)√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Conducted Immunity: d = (3.5/V1)√P Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms 1 kHz AC Mains	
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	+/-2 kV AC Mains 5/50 5 KHZ	Mains power should that of a typical commercial or hospital environment
Surge Line to Line (AC Power) IEC/EN 61000-4-5	+/-1 kV Line to Line +/- 2 kV Line to Ground	Mains power quality should be that of a typical commercial or hospital environment
Magnetic Immunity IEC/EN-61000-4-8	3 A/m 50/60 Hz	Video display terminal and other electron-beam devices (e.g. X-ray image intensifiers) may use a justification for lower IMMUNITY COMPLIANCE LEVELS as allowed by 6.2.1.10.
Voltage Dips & Interruptions IEC/EN 61000-4-11	>95% DIP IN U_T.5 cycle 60% dip in U_T 5 cycles 30% dip in U_T 25 cycles >95% dip in U_T 5 Sec	If the user of the Smart RLT requires continued operation during mains interruption it is recommended that the Smart RLT be powered from an uninterruptable power supply or a battery

6.8 Electrical Safety

This device meets the general requirements for basic safety and essential performance per IEC/EN 60601-1:2012.

Electrical power sufficient to cause injury or death is present inside the Laser System components whenever they are connected to AC power. Take appropriate safety a precaution, use safety disconnects (such as fuses or breakers) wherever possible, and disconnect AC supply cables from components prior to removing covers for maintenance or service.

Do not block or restrict airflow into or out of the Laser System. Adequate air cooling is required to prevent overheating the components inside the enclosure.

Apply measures to prevent liquids, particularly toxic or hazardous fluids form coming into contact with the Laser system components and equipment. When cleaning the Laser System, do not spray or pour fluid directly onto the equipment surfaces. Gently dry dust the inner deck and laptop (both closed and open) with a tissue to remove visible dust and contamination

When electrical components must be replaced, use only components that are appropriately rated for the application. Replace fuse, switches or connectors only with components of the same type and rating as the original equipment. (Refer to Section 8.8.1 for replacement parts and components)

To avoid electrical shock, the Laser system must be powered form an AC supply circuit that includes an adequate earth ground.

WARNING!

The Laser system and its components are designed to be connected to a properly grounded AC supply sufficient to support system operations. Using power strips or other multiple-socket outlets that are not specifically approved for use with the Laser system may compromise safety grounding or present other power-related safety hazards.

6.9 Sources for Additional Information and Assistance on Laser Safety

CDRH-Radiological Health Program
Office of Communication, Education and Radiation Programs

Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue W066-4613
Silver Spring, MD 20993 USA
Tel: 1-800-638-2041
Fax: 1-301-847-8149
dsmica@fda.hhs.gov

Laser Institute of America
13501 Ingenuity Drive, Suite 128
Orlando, FL 32826 USA
Toll Free: 1-800-345-2737
Tel: 1-407-380-1553
Fax: 1-407-380-5588
www.lia.org

7 SYSTEM SET-UP

If national or local legal regulations require that specialized personnel perform the SMART RLT installation, these regulations must be complied with.

7.1 Receipt and Unpacking

Unpack your laser as follows:

1. Open the box.
2. Remove protective packaging cover.
3. Inspect the packaging contents.

7.2 Setup

WARNING!

DO NOT USE SYSTEM BEFORE FORMAL APPLICATIONS TRAINING BY Sound PERSONNEL.

Laser Setup

1. Setup Location
    a. Ensure that the surface will properly support the entire system.
    b. Place within 9 feet of an available 110 VAC/50-60Hz electrical outlet
    c. Ensure adequate airflow around the system
        - Be cautious not to block air vents on the side of the case.
        - There must be a minimum 4” clearance around the sides of the system.
2. Open the case and verify components are placed neatly inside.
    - Uncoil the fiber optic cable and inspect hand piece.
    - Make sure that the emergency stop button is disengaged and in the up position
3. Locate and uncoil the AC power cord.
4. Plug the power cord into the AC input on the left side of the laser system.
5. Plug the male end of the AC power cord into an available electrical outlet.

“Warning: To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth”

6. Refer to the Operation Section of the User Manual, located on the Laptop Desktop, to configure and operate the system.

8 OPERATION

When the laptop is powered on from the power switch, the software will launch automatically or you may double-click on the Smart RLT icon to start the software. A security screen will appear where you will be prompted to enter a four-digit security pin.

8.1 Main Menu Display

The patient search screen will display upon launch of the software. A view of this is shown below:

This screen allows for the searching and creation of patients. We have provided you with two ways to create a new patient using either the **Add Patient** as indicated by the plus icon .or the **Emergency Patient** control by clicking the icon. There is a help icon that will bring the user context sensitive help including documentation and videos detailing operation for the current screen.

The cog icon will bring up a menu with the options to close or update the application.

The AIS "cloud" button launches a full-page browser window that defaults to https://antechimagingservices.com/.

8.2 Search for Patient

You will be able to search for existing patients using the variety of search criteria provided in our search control including, **Patient, Owner, Operator, Treatment** and **Patient ID**.

You can further narrow the search by selecting a date range of **1 Day, 2 Days, 1 Week, 2 Weeks, 1 Month** or you can search through all of the studies.

To run a search, select your criteria, enter a value in the search field and tap the search icon . The results of the search will be displayed in horizontal tiles beneath the search control.

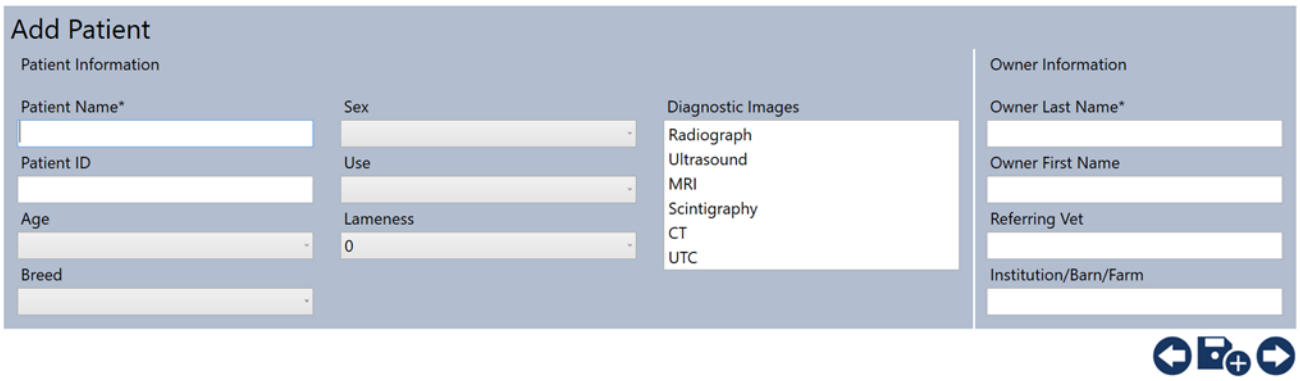
Each patient tile will show the **Patient Name, ID, Owner** and the **Number of Treatments** the patient has received.

Click on the patient tile to reveal additional patient information, an **Edit Patient Information** icon , a delete patient icon and an add treatment icon .

Existing treatments for this patient will be represented here as treatment tiles, which display information specific to the treatment, a begin/resume treatment icon and a display notes icon to view notes that were entered after the treatment.

8.3 Creating a Patient

For non-urgent situations, you will click the add patient icon . This will open the **Add Patient** form where you will enter both patient and owner information. Required fields will have an asterisk next to their labels as seen below:



The **Patient Information** fields are as follows:

1. Patient Name, where you will enter the name of the horse. This is a required field.
2. Patient ID
3. Age – Select the year the horse was born from the drop-down list.
4. Breed – Select a breed from the drop-down list.
5. Sex – Select the sex of the horse from the drop-down list.
6. Use – here you will note how the horse is used by selecting an option from the drop-down list.
7. Lameness – You can select a value to reflect the degree of lameness on a scale of 0-5, with 5 being the most lame.

If any diagnostic images have been used in the diagnosis of the horse, select their type from the diagnostic images list.

For the **Age, Breed, Sex, Use and Lameness** fields, you will use their drop down lists to select the appropriate value.

For **Age**, select the year the horse was born and for **Lameness**, select from a range of 0 to 5, with 5 being the lamest.

The **Owner Information** fields are as follows:

1. Owner Last Name – This is a required field.
2. Owner First Name
3. The Referring Vet
4. The Institution, barn or farm of the horse.

Once the required and selected optional fields are filled in, you have three options: 1) discard the information and return to the **Main Patient Screen** by tapping the left arrow, 2) save the information and 3) add another patient by tapping the **Save and Add** control or save the information and move to the treatment plan screen by tapping the right arrow.

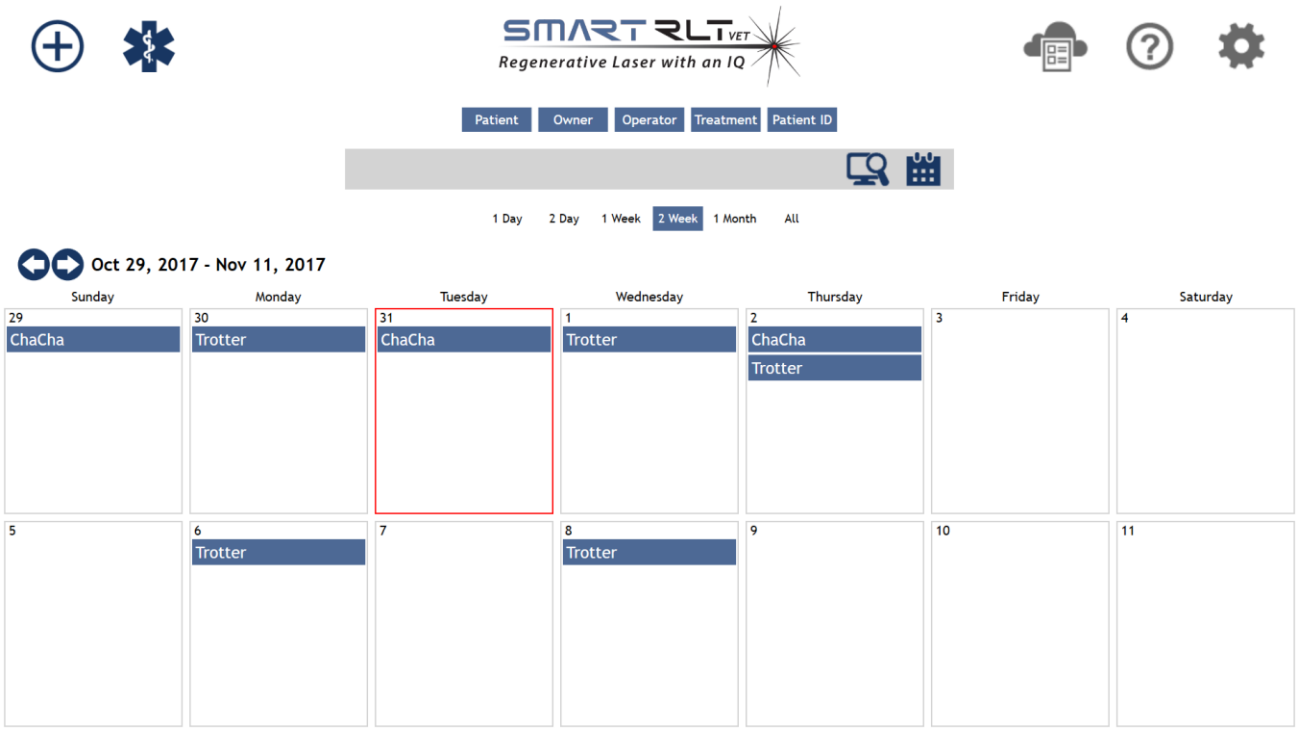
For emergency situations, you will click the **Add Emergency Patient** icon  . This will take you directly to the treatment plan screen.

8.4 Treatment Calendar

We have included a treatment calendar which allows you view all of your scheduled treatments at a glance, initiate any scheduled treatments, and see the details of past treatments without the need to search for a particular patient.

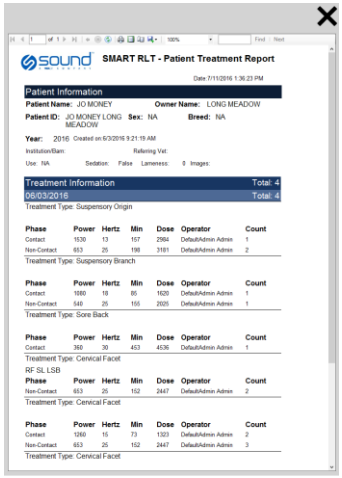
To open the treatment calendar simply click on the calendar icon  , which is located to the right of the search field and looks like a calendar. You will then see the current month displayed in calendar format, with the patient name for each scheduled treatment appearing on its scheduled day.

Past treatments are displayed by patient name be gray and planned treatments will be light blue. To begin a treatment, click on the patient's name and the select the resume treatment icon.



8.5 Patient Reporting

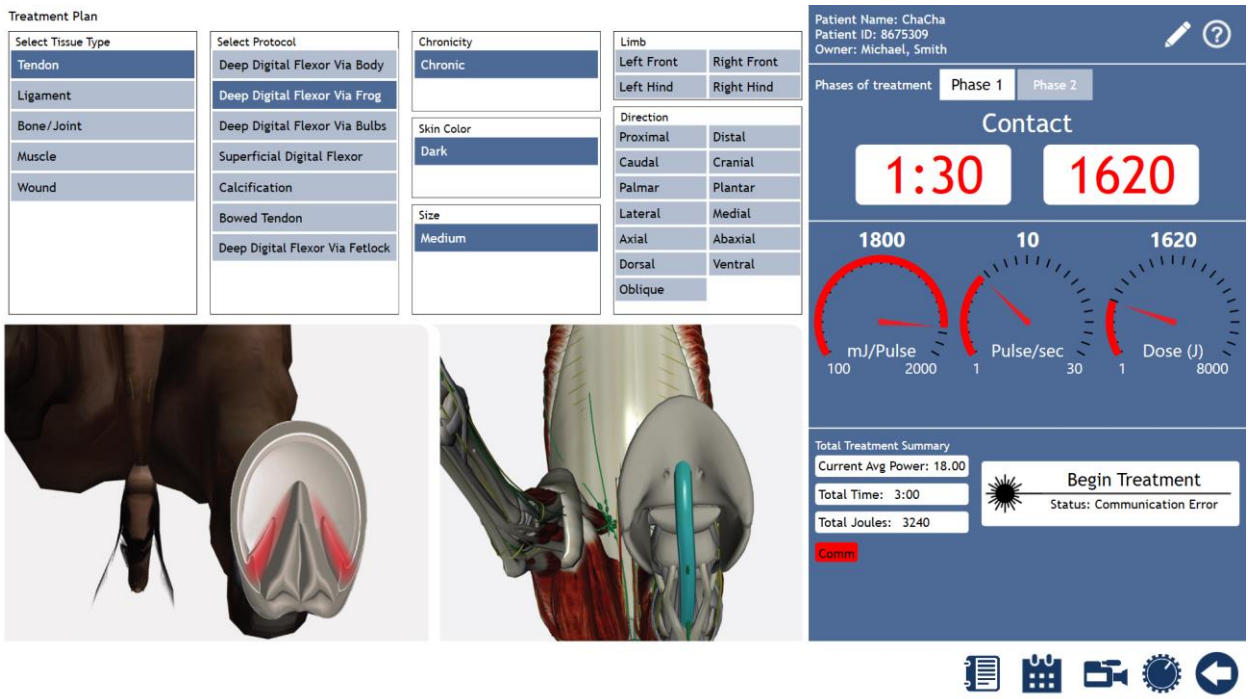
Patient reporting can be performed by clicking the report icon on the patient tile. The report will show patient data, all treatments performed on the patient as well as any scheduled appointments. The report may be printed or saved to word, pdf, or excel.



8.6 Treatment

8.6.1 Treatment Planning

This is the **Treatment Plan** screen:



This is the screen where the operator can schedule, configure and perform the patient's treatments. For newly created patients, you will select the **Tissue Type** to be treated, the **Locality** of the problem, its **Chronicity**, the patients **Skin Color** and patients **Size**.

New to version 1.2, we have added the optional fields of limb and direction for more accurate recall and tracking of the treatment area and how the treatment was performed. These selections do not alter the treatment protocol, but rather are included as reference notes for review or future use.

For existing patients, whom have already been treated and the resume treatment icon has been selected, these items will already be selected. The displayed images show the standard anatomical area to which the laser treatment will be applied.

There is basic patient information displayed on this screen and clicking the **Edit Patient** icon (white on screen) will allow you to edit the patient information. Clicking the question mark icon will display the help files for this screen. In the **Phases of Treatment** section, you will see if the treatment has 1 or 2 phases, whether it will be a contact or non-contact treatment, the time remaining, and the dosage for the phase.

Beneath this you will see three dials representing the following:

1. Millijoules per pulse
2. Pulses per second
3. Dose in Joules

The section beneath the dials contains a treatment summary listing the average power, the total time required and the total joules used for the entire treatment which will be the sum for all phases.

To the right is the main treatment button. This button will say “Begin Treatment” and have the current status of the laser system. Typically, this status will read “Standby” prior to operation. If the laptop is not communicating with the laser firmware you will see a status that reads “Communication Error”. Additionally, in the section below you will see a fault indicator that says “Comm” with a red background.

The software has several alarms for error conditions as follows

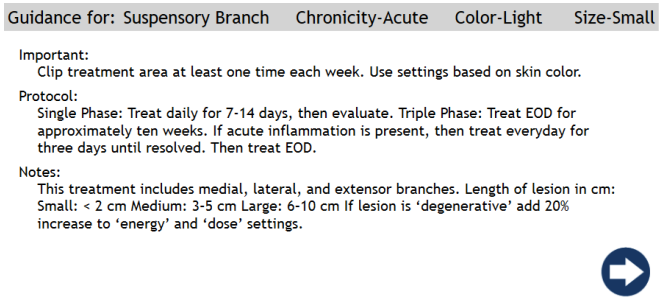
FD – Fiber disconnected
Interlock – Interlock is open
HR – High Reflectivity alarm
Temp - Laser is over temp
Comm - Communication between laser and software failure.
HS - Hand switch is pressed (Information).
LM – Laser Malfunction

8.6.2 Treatment Icons

At the bottom of the Treatment Plan screen are some icons. These icons appear as follows and are explained in the following subsections:

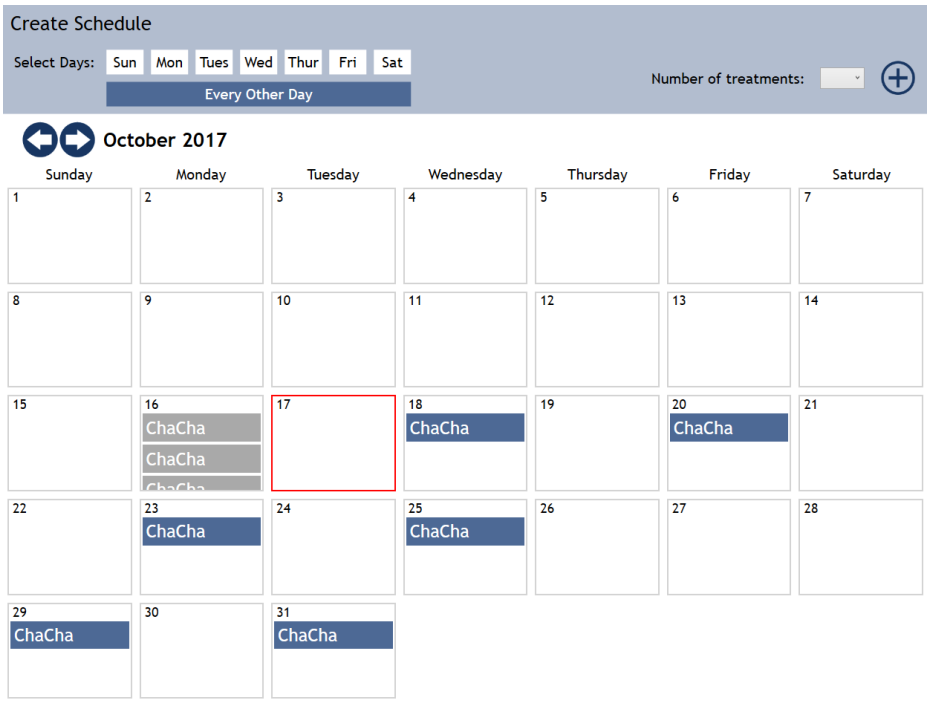
8.6.2.1 Treatment Guidance

The icon to the left that looks like a note book page is used to bring up the treatment guidance for the current selection. This has additional information and warnings about how to perform the selected treatment. It will appear as follows:



8.6.2.2 Patient Treatment Calendar

The calendar icon will bring up a calendar in scheduling mode. In this mode the operator will be able to create an appointment for treatment by clicking into a day in the calendar or can schedule periodic treatments by selecting the day(s) of the week and the total number of treatments at the top of the screen. You can select individual days to add, and for your convenience there is an Every-Other-Day (EOD) button. Workflow would be to select the start date (by pressing on the day in the calendar), then choosing the total number of treatments, then press "EOD", then the button to add them to the calendar.



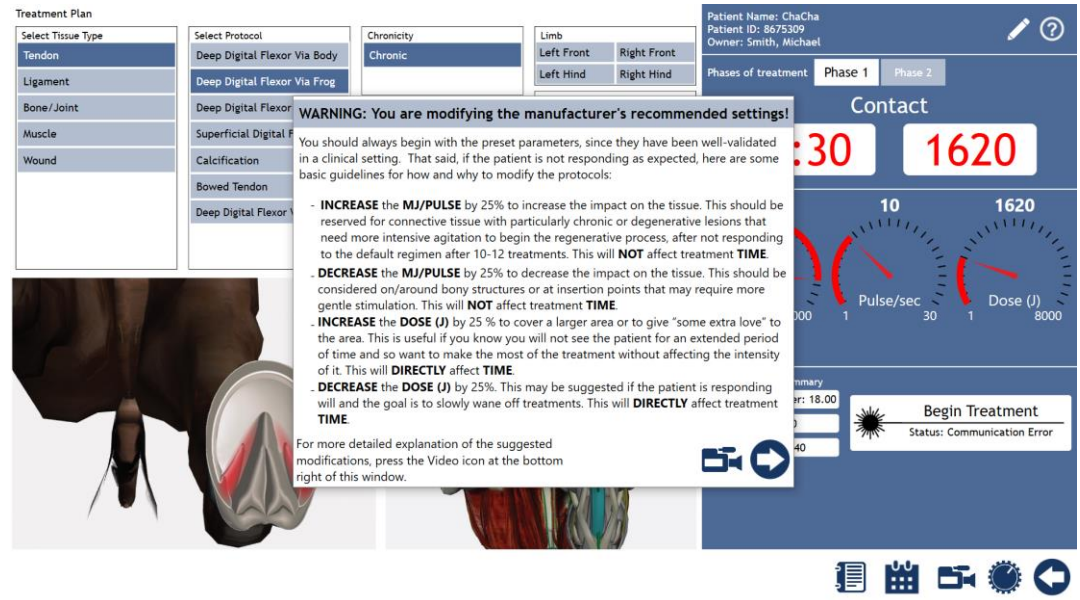
8.6.2.3 Treatment Video

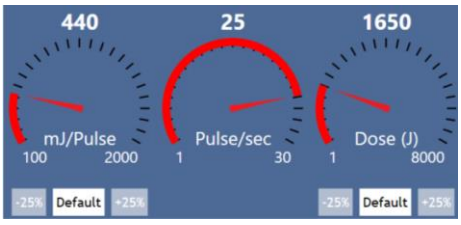
Clicking the video camera icon will bring up a video which will explain how to perform the selected treatment. This video will show the proper movement of the hand piece over the treatment area.

8.6.2.4 Treatment Manual Override

Clicking this button will allow you to override (manually adjust) the settings for mJ/Pulse and dose. Clicking this button will prompt the use with an alert window, with some text explanations of each option. There is also a video icon that launches a video explanation of the modifications in more detail. The workflow is:

1. User selects a protocol
2. User presses the Manual Settings Button
3. Alert window pops up with full text explanation of what to change when and how.
4. If user is satisfied, they press the button and the -25%/Default/+25% options appear
5. If user wants to learn more, they press the video button, which launches the video.
6. After the video (or whenever) the user presses the button to hide the video pane and the -25%/Default/+25% options appear





CAUTION! USE EXTREME CAUTION WHEN DEVIATING FROM MANUFACTURER RECOMMENDED SETTINGS.

CAUTION! USE OF CONTROLS OR ADJUSTMENTS OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN MAY RESULT IN HAZARDOUS RADIATION EXPOSURE.

8.6.3 Performing Treatment

Once all the parameters have selected the **Tissue Type** to be treated, the **Locality** of the problem, its **Chronicity**, the patients **Skin Color** and patients **Size,** you will be able to perform the treatment. The chronicity of the treatment will dictate the number of phases for the treatment. Acute treatments will have only 1 phase, while chronic treatments will have 2 phases.

Note– Do not press the hand-switch until you see "Status: Ready" on the Treatment control, as this safety measure will cause an error, this is to ensure a user is in positive control of the hand switch. Release the hand-switch at the end of each phase and do not press again until you see "Status Ready" on the treatment control again.

To get started, ensure that the **Begin Treatment** button shows Status: Standby. If there are any problems with the communication between the program and the laser, it will read Status: Communication Error. Once you see that it shows a standby status, click the Begin Treatment button. You will then see a message telling you to put your safety glasses on as shown below:

Click this button one more time and you will hear a countdown in a woman's voice and when the system is ready for treatment the main button will appear as follows:

CAUTION! - Be sure to keep the laser in motion during the procedure, as opposed to holding it in one place on the patient.

The treatment can now be performed by pressing the button on the hand switch. The main button will appear as follows:

The application will subtract time from the time remaining and will increase the dose delivered by the appropriate amounts automatically. When the time remaining reaches 0 the application will move to the next phase or stop the treatment automatically. Pressing the same button used to start the treatment will cancel the treatment at any point. A quick sequence of four audible beeps signals the end of the treatment.

WARNING!

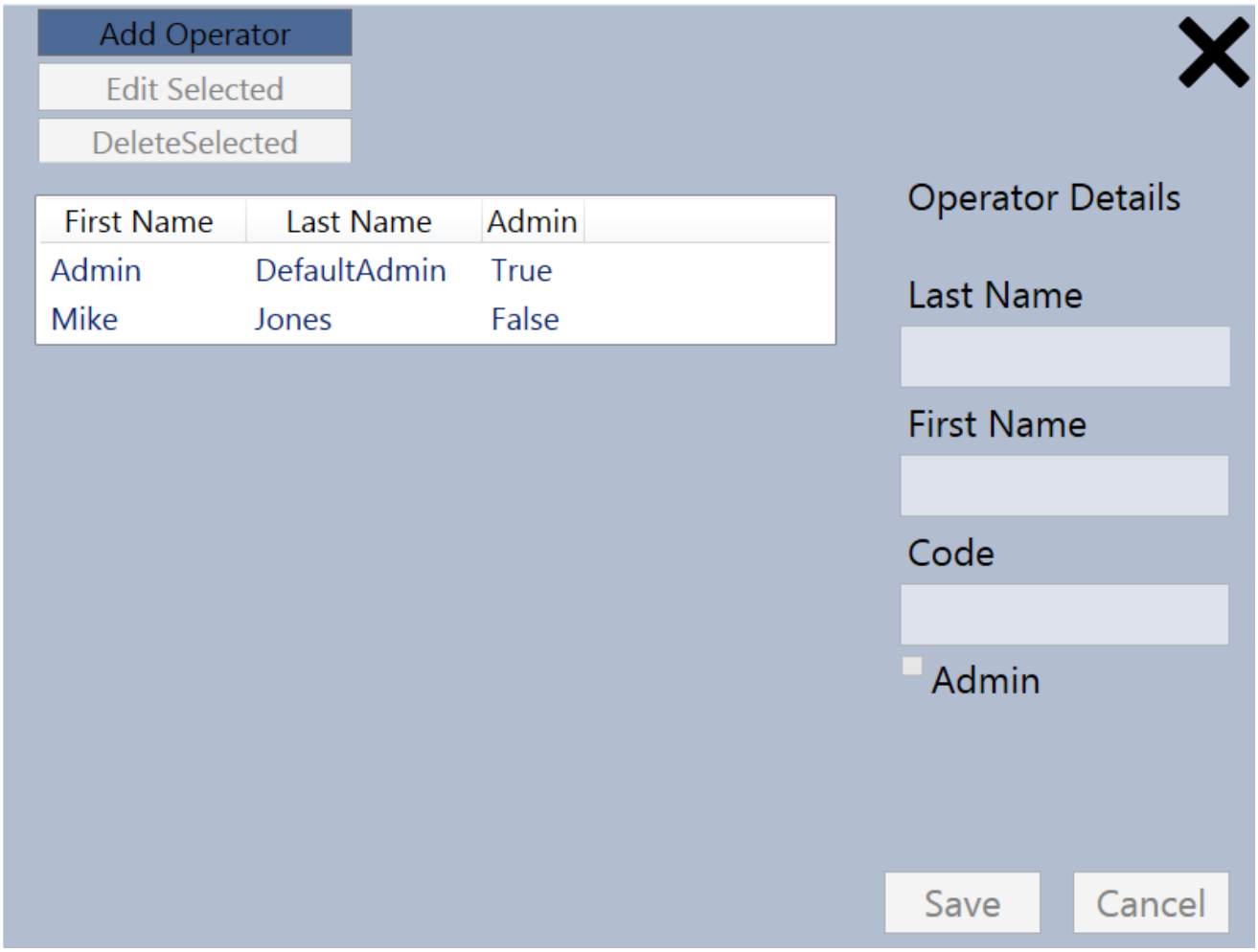
VISIBLE AND INVISIBLE LASER RADIATION AVOID EYE AND SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT.

CAUTION!

USE OF CONTROLS OR ADJUSTMENTS OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN MAY RESULT IN HAZARDOUS RADIATION EXPOSURE.

8.7 Operator Management

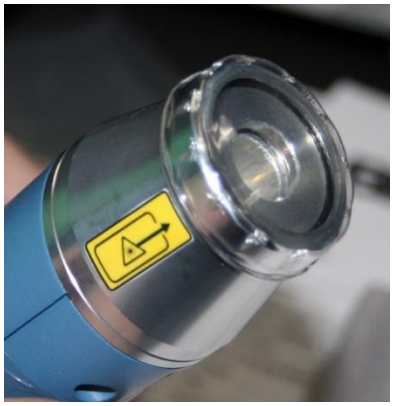
If the user is logged in as an administrator, then the operator management option selection will be available by clicking on the icon and selecting the operator icon. The administrator may add users, edit users, and delete users from this screen. The administrator will give the operator a four-digit key code to function the laser. The patient report will show who performed the treatment based on this information.



8.8 User Maintenance

Per Use

- Inspect output lens, before each use and before turning on the laser do a visual inspection off axis on the surface of the aperture lens. Verify that it is free of any visible residue or contaminant. If rainbow sheen is observed do not use as is, the lens must be completely clean before use. Never point the aperture directly at any subject you do not intend to treat. If the lens cannot be cleaned of all residuals contact service for replacement.
- Clean when needed, if contamination is visible use the provided micro cloth to gently remove any residue. With light pressure make circular motions starting in the center of the lens and working to the edge. Take care to store the cloth in the provided bag to reduce possibility of added contamination and don't use for other cleaning tasks.
- Clean gel residue, after completion of each procedure remove any remaining coupling gel using a water moistened tissue, take care to use minimum water the towel should not be "dripping wet" never store with residual gel.
- Disinfection of the aperture lens is possible by wiping with a sterile alcohol prep pad as sold by Medline and others, it is important that no residual moisture or fibers remain after the cleaning. Be sure to always inspect the lens after any cleaning before use.
- Using the Rough Surface Lens Cap Sound PN 70-129 will provide best protection against cross contamination between multiple treatments. Always inspect the cap prior to use. It must be free of scratches, particles or other residue. If not install a fresh new cap. It is installed by simple press fit over the hand piece aperture lens and easily removed by pulling it off. The Rough Surface Lens Cap also prevents damage to the hand piece aperture lens. Its use is highly recommended when treating any area that is hard and rough. It can be used for treatment of any area to provide protection to the aperture lens. It will prevent damage due to scratches but does require the same cleanliness as the lens itself to prevent thermal damage. Lens damage due to scratches and thermal cracks are not covered by your RLT warranty.



RLT Rough Surface Lens Cap

Weekly

- Check cooling flow, check for air flow by using "wrist test". With the system powered on face the machine and hold your exposed wrist in front of the air outlet on the left hand side. If no airflow is felt inspect the inlet filter located on the right. Using your hands gently brush any visible contamination away and check for airflow. If this does not correct air flow replace the filter. If airflow is still not felt call service.
- General Clean Up, gently dry dust the inner deck and laptop (both closed and open) with a tissue to remove visible dust and contamination

Monthly

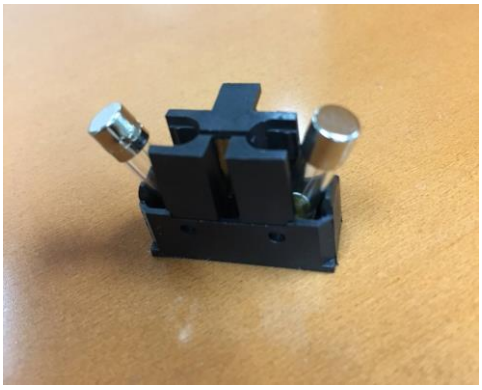
- Change the air filters, using factory supplied replacement filters, with the system off remove the filter frame and dispose of the old filter. Put the new filter in the frame and snap into position. ALWAYS DISCONNECT THE SYSTEM FROM THE MAIN ELECTRICAL OUTLET BEFORE SERVICING.
- Check posts for tightness; verify that the fiber and hand piece management pins are tight. Gently wiggle each pin, if it feels lose tighten with a Philips screw driver, careful not too tight a quarter turn past snug is sufficient.
- Visually inspect the case externals making sure the latches and handles are not lose from attachment or damaged. If so contact service.
- Check functionality of the Emergency Switch and Remote Interlock.

Annually

- Factory Recertification, these systems require factory test and inspection on an annual basis. Contact service to arrange for shipping back to the factory. This recertification is required to maintain all extended service plans.

On the instruction of Sound field service system fuse change is performed as follows:
The system fuses are located in a holder in the upper part of the plug power module. Never attempt to service the fuses when the plug is connected. To replace use two new BK/S500-3.15-R Glass fuse 3.15A 250VAC 5X20MM.

1. Remove the fuse holder by inserting a small screw driver or similar into the slot located in the center as shown. Don't use a sharp object like a knife that could damage the fuse holder.
2. Pull firmly directly away from the system to remove the holder. This does take a bit of force.
3. Remove both fuses by first tilting the fuse in the holder as shown before removing.
4. Change both fuses at the same time.
5. Reverse this procedure to reinstall be sure that the holder is flush with the receptacle.



8.8.1 User Spare Parts List

Description	PN
RLT Hand piece mounting pins	30-921
RLT Fab Filter Frame	30-922
RLT Fan Filter	30-923
RLT Aperture Lens Cloth	30-924
RLT Fiber Locating Pins	30-925
RLT Rough Surface Lens Cap	70-129
RLT Aperture Lens	30-926
RLT Case Handles w/pin	30-927
RLT Fiber Management L Bracket	30-928
RLT Remote Interlock Plug	50-426

9 SPECIFICATIONS

Wavelength	1064 nm
Avg Power	20W
Grouped Pulse Energy	1000 mJ in 50 ms
Grouped Pulse Frequency	20 Hz typical 1-30 Hz adjustable
Aiming Beam	650 nm
Spot Size	9 mm @ Contact, 13 mm @ 1" distance, 17 mm @ 2" distance
Optical Cable	800 micron 0.37 NA, 6Ft
Operating Temperature	10 - 30 °C
Storage Temperature	-10 - 50 °C
Cooling	Forced Air
Weight	~65 lbs
Voltage (Input)	110/220 VAC
Nominal Ocular Hazard Distance (NOHD)	>250m

