

COMPANION THERAPY LASER USER MANUAL CTS-15

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1. INTRODUCTION

The COMPANION Therapy Laser, Model Number CTS-15, is classified as a Class IV laser device. There are a variety of, therapeutic applications. The maximum output power is 15W.

This laser device is sold solely for VETERINARY, INDUSTRIAL, OR SCIENTIFIC purposes only! Under NO circumstances should this laser system be employed as a medical device for human use.

1.1 Device Description

The laser source of this device is a solid-state system. It produces near infrared laser energy at 980nm and 810nm wavelengths. The delivery system consists of a flexible optical fiber threaded through a lightweight hand piece. Activation occurs when the operator enables the laser by pressing the foot/finger switch. Releasing the foot/finger switch will deactivate the laser. Depending on laser system configuration, the foot/finger switch can function as on/off switch. A convenient and easy-to-use touch-screen display panel allows the operator to adjust or set laser output level with minimal effort. The laser can operate in continuous wave mode or controlled pulse mode.

1.2. Usage Prerequisites

Every facility or institution utilizing this device is encouraged to adopt an ongoing **Training and Safety Program**. Such programs are outlined in the latest revision of the ANSI Standard Z136.3 for the Safe Use of the Lasers in Health Care facilities, as well as in standard training sections of Curriculum Guidelines.

RECOMMENDATION

Individuals planning to use the COMPANION Therapy Laser are actively encouraged to attend laser orientation and education sessions to achieve progressive levels of operational proficiency.

1.3. 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 980nm and 810nm wavelengths.

Protective glasses are included with the original purchase of this device.

For additional pairs of protective eyewear, contact the LiteCure,LLC at 302-709-0408.

CAUTION!

DO NOT remove protective eyewear until the operator returns the laser device to **Standby** mode. To do this, the operator must release the foot/finger switch, touch the **Ready** screen button on the display panel, and visually observes the laser device returning to **Standby**.

1.4. Air Cooled Design

The laser device is air-cooled and designed for use in indoor and outdoor environments.

CAUTION!

Place Laser Warning Sign at location entrance where people will use the COMPANION Therapy Laser device.



2. SAFETY

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

2.1. Guidelines

Operator's information is in compliance with section 1040.10 of Title 21 of the code of Federal Regulations, Chapter1, Subchapter J of Health and Human Services, Food and drug Administration, and center for the devices and Radiological Health.

2.2. Laser Safety Supervision

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

2.3. Warnings

Please read and adhere to the following warnings:

Note: If laser fails to operate properly, contact the LiteCure,LLC immediately at 302-709-0408.

- This laser device is sold solely for VETERINARY, INDUSTRIAL, OR SCIENTIFIC purposes only! Under NO circumstances should this laser system be employed as a medical device for human use!
- This laser device produces 980nm and 810n 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 being treated.
- NEVER allow the eyes of any living being to look directly into the distal end of a hand piece that is 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,
 collars, tags, leashes and jewelry) prior to treatment with this device.
- 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.
- DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. To do
 this, the operator release the foot/finger switch, touches the Ready screen button on the display panel,
 and visually observes the laser device returning to Standby.
- AVOID THE USE of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) 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. Solvents, adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.



2.4. Precautions

Please read and adhere to the following precautions:

- Never allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.
- This laser device produces 980 and 810 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 many occur if a person exposes one or both eyes to direct of indirect (reflected) laser energy.
- The protective eyewear supplied with this device has an optical density rating >5 at 980nm and 810nm and meets ANSI Z136.1 and Z136.3. **All** personnel present during device operation must wear protective eyewear. If needed, Contact the LiteCure,LLC at 302-709-0408 to purchase additional sets of protective eyewear.
- DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. To do
 this, the operator releases the foot/finger switch, touches the Ready screen button on the display panel,
 and visually observes the laser device returning to Standby.
- Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser.
- Place "Laser in Use" signs at location entrances where people will use the laser device.
- Always put the laser in Standby mode or switch the device off prior to connecting or disconnecting the hand piece.
- Never leave this device in the READY mode unattended.
- Remove the key from the device's key switch when not in use to prevent unauthorized and/or unqualified use of the device. This will also prevent inadvertent laser emissions.
- Turn the device off before moving, lifting or relocating the laser device.
- Never press the foot/finger switch button without first verifying the safe orientation and proper
 positioning of the hand piece and ensuring compliance with all safety precautions.
- During any laser procedure, do not allow any nonessential personnel into the treatment area.
- If the laser fails to operate properly, contact the LiteCure, LLC immediately at 302-709-0408.



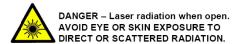
2.5. Laser Safety Labels and Symbols

The following labels appear on the laser device.

Manufacturer's General Identification Label (See Figure) The label displays the manufacturer, model number, serial number and date of manufacture. This label also contains various regulatory compliance declarations.



General Safety Declaration Label (See Figure) Located on the bottom of the device and warns of the radiation exposure hazard potential to eyes and skin.



Laser Warning label – Hazard symbol (See Figure) Located at the center of the rear panel.



NOTE

The laser WILL NOT operate unless the fiber is inserted into the emission

Laser Emission (Aperture) Located close to the emission port on the top of the device, the laser emission label indicates that the laser energy emission occurs at the distal end of a properly connected hand piece.



Warranty Seal Label (See Figure) Located on the bottom of the laser device in such a way that any attempt to open the panels of this device will break this seal.





2.6. Safety Device Features

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

Emergency Power Off Switch





POWER OFF - ENGAGED

POWER ON - DISENGAGED

This switch is located on the top panel of the COMPANION LASER. 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.

Key Activated Power Switch



This switch is located on the rear panel of the COMPANION LASER. A key is required to activate the laser system. The operator inserts the supplied key into the key-switch and turns it 90 degree clockwise. When the key switch is in this position, it cannot be removed.

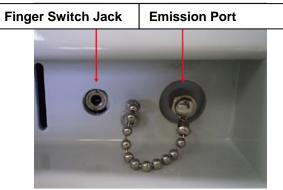
O I

off on

After powering OFF the device using the key switch (a 90-degree, counter-clockwise turn), the operator should remove the key and store it properly to prevent unauthorized or unexpected laser system operation.

Laser Emission Port

This port is located on the back of the device. Laser can not emit without the fiber attached. A metal emission port cap which is permanently attached to the unit can be secured on the emission port when fiber is not connected.





Remote Interlock



This device is equipped with a remote interlock located at the bottom of the device. If the interlock is not inserted into the connector, all electrical power to the controls and laser components is terminated. The remote interlock MUST be inserted before the device can power on.

System Power On/Off Visual Indicator



Located on the front top of the laser device, the LCD panel is illuminated continuously whenever the user activates the key switch and the emergency power off switch is disabled.

A green LED located above the LCD panel will illuminate when system power is on.

Laser-Emission Indicator

The laser emission indicator during the emission mode.

Internal Laser Energy Monitor

There is an internal system that monitors the intensity of laser energy generated whenever laser emission occurs. If the laser emission is not within the system tolerance, laser emission will be aborted. If the laser device is unable to maintain the preset laser power output set by the user then the laser emission will be terminated.

The laser system will automatically shut off when the emission output is out of the range of +/-20% of set value. The touch screen will display an error message.

To reset the device the user is required to press the EXIT button when this error/warning message is displayed.

Operation Errors

- 1) The device shall not leave STANDBY mode and enter READY mode and error message shall show if any of the following conditions occur.
 - Optical fiber is not properly inserted
 - Safety interlock is not properly installed
 - Foot/Finger Switch is depressed



- Also, the device shall not keep in READY mode or EMISSION mode and error message shall show if any of the following conditions occur.
 - Optical fiber is not properly inserted
 - · Safety interlock is not properly installed

2.7. Laser Eye Protection

The protective laser eyewear supplied with this device has an optical density rating > 5.0 for 980 and 810nm laser emission. **All** personnel present during device operation must wear this eyewear. Contact LiteCure,LLC at 302-709-0408 to purchase additional sets of protective eyewear.

2.8. Sources for Additional Information and Assistance on Laser Safety

Center for Devices and Radiological Health

Office of Compliance 2098 Gaither Rd. Rockville, MD 20850 Tel: 301-594-4654

Fax: 301-594-4654

http://www.fda.gov/cdrh/index.html

Laser Institute of America

12424 Research Parkway, Suite 125 Orlando, FL 32826

Tel: 407 380 1553 Fax: 407 380 5588

http://www.laserinstitute.org/

3. SYSTEM SET-UP

3.1. Unpacking

Using the COMPANION LASER packing list, unpack the COMPANION System and its accessories from the shipping carton. Check for missing parts and inspect the unit carefully for damage such as cracks, dents or bent parts. If items are missing or any physical damage is apparent, please call LiteCure, LLC at 302-709-0408 for assistance. Notify the carrier if the damage appears to be the result of a shipping mishap.

3.2. Usage Prerequisites

RECOMMENDATION

Individuals planning to use the laser system should attend laser orientation and education sessions to achieve operational proficiency.

Every facility or institution utilizing this device is encouraged to adopt an ongoing training and safety program.



3.3. Setup

WARNING!

DO NOT attempt to gain access to any internal device components. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Doing so may cause serious and/or irreversible injury.

CAUTION

ALWAYS post Warning Signs for Class IV laser products.

ALWAYS post Warning Signs in the area of the laser beam to alert those present.

ALWAYS place "Laser in Use" signs at location entrances where people will use the COMPANION laser device.

ALWAYS Turn the device OFF before relocating, lifting or moving this equipment.

- 3.3.1. Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser device.
- 3.3.2. Ensure that the surface on which the device is placed will properly support the entire device.
- 3.3.3. Place within 6 feet of an available 100-240Vac electrical outlet.
- 3.3.4. Ensure adequate airflow around the device. The laser device is air-cooled and designed for use in a well-ventilated environment.
 - 3.3.4.1. Select a flat hard surface (not a surface that will inhibit airflow through the bottom of the device).
 - 3.3.4.2. There must be a minimum 4" clearance around the rear of the device.
- 3.3.5. Locate and uncoil the AC power cord.
- 3.3.6. Plug the power cord into the AC input on the rear of the laser device. Plugging the device in should only be done last, after all hardware has been attached.



3.3.7. Plug the male end of the AC power cord into a **grounded** electrical outlet.



3.3.8. Connect the finger switch connector into finger switch jack on COMPANION top panel or connect the foot switch connector into foot switch port on COMPANION rear panel.



- 3.3.9. Remove the dust cap from the emission port DO NOT touch the fiber tip to any surface. If the fiber tip or the emission port is contaminated then the device might be damaged during laser beam output emission. Install the fiber optic into the emission port connector. Securely tightened the screw nut to the emission port. The fiber shall not be bent at a bend radius smaller than 5cm during the operation. Improper inserting, steeply bending and improper securing the fiber optic may lead to the damage to the fiber optic or delivery system and /or harm to the users.
- 3.3.10. IMPORTANT! Please DO NOT remove the fiber from the emission port once it has been secured for the first time unless the device is being packaged or transported to another location. Repeated insertion and removal of the fiber before and after every procedure will increase the chance of emission port and fiber tip contamination. If you must disconnect the fiber from the device then immediately attach the fiber tip cap.

Sections 3.3.11 and 3.3.12 contain general instructions for hand piece use. Specific instructions for the hand piece furnished with the unit including recommended power settings and cleaning procedures can be found in the separately provided Hand Piece manual.

3.3.11. Use Hand Piece







WARNING!





DO NOT use Hand Piece without Hand Piece Head or inadequately secured Hand Piece Head on the Hand Piece Handle.

Doing so may cause serious and/or irreversible injury.

3.3.12. Exchange Hand Piece Head.

The Hand Piece Head is changeable.

WARNING!

ALWAYS <u>Power Off in the device accordance with the User Manual</u> before changing Hand Piece Head.

Remove Hand Piece Head from Hand Piece Handle, and DO NOT touch the distal of the Hand Piece Handle.

Securely tighten the new Hand Piece Head to Hand Piece Handle.



WARNING!





DO NOT use Hand Piece without Hand Piece Head or inadequately secured Hand Piece Head on the Hand Piece Handle.

Doing so may cause serious and/or irreversible injury.

WARNING!

Wear Laser Safety Eyewear provided with the laser before operating the laser device.

CAUTION

Please do not remove the hand piece fiber from the emission port once it has been secured unless the device is being packaged or transported to another location. Constant insertion and removal of the hand piece fiber before and after every procedure will increase the chance of emission port and fiber tip contamination. If the emission port or the fiber tip is contaminated then the device might be damaged during laser beam output emission.

The dust cap is installed by the manufacturer as a means to prevent dust and debris from contaminating the emission port during shipping and before device installation and is not intended as the primary means to protect the emission port connector during normal use.

We recommend the following procedure:

- 1. Before using the device for the first time, install and secure the hand piece fiber in accordance with the User Manual.
- 2. Use the device as required.
- 3. When done using the device, power off in accordance with the User Manual and leave the hand piece connected.

Bending Limits of the Hand Piece Cable:

The radiation transferred within the hand piece cable goes through a very small diameter glass rod (an optical fiber). It can be damaged if bent too sharply. The maximum permissible bending radius of optical fiber is 5 cm.

Laser Hand Piece Troubleshooting:

If the any part of the hand piece assembly is overheating or producing smoke, then immediately power off device and discontinue operation. And then call LiteCure, LLC at 302-709-0408 immediately for assistance.



4. OPERATION

WARNING!

DO NOT use the System Controls or perform procedures other than those specified in this manual. Failure to comply 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.

AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N2O) and oxygen or endogenous gases. 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.

CAUTION

Federal law (USA) restricts this device to sale by, or on the order of a licensed practitioner.

NEVER allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.

DO NOT leave the key in device's key switch when not in use. Prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions.

DO NOT allow any nonessential personnel into the treatment area during any laser procedure.

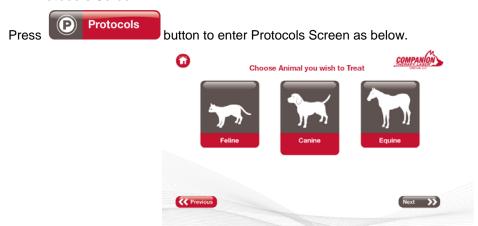
4.1. Power On

The initiation of the power-on sequence shall be accompanied by audible alerts, and then the HOME Screen (as below) will be displayed.





4.2. Protocols Screen



4.2.1. Choose Animal

Choose the animal you wish to treat on the screen. The animal you choose is red highlighted as below, e.g., if Feline is chosen.





4.2.2. Choose Skin Color and Coat Color

Choose the Skin Color and Coat Color of the animal you wish to treat. After choosing the Skin Color and Coat Color of the animal, the button is red highlighted as below, e.g., if Feline, Light and Medium are chosen.



For Canine, in addition to the Skin Color and Coat Color the weight of the canine needs to be chosen. After choosing the Skin Color, Coat Color and weight of the canine, the button is red highlighted as below, e.g., if Canine, Light, Medium and 0-20 lbs are chosen.



Click Next button to enter Conditions Screen.



4.2.3. 3D Anatomy

To help you understand the body structure of the animal, the following two control buttons can help you to demonstrate.



4.2.4. Choose Conditions



Click the checkbox of you desired condition. After choosing the condition, the checkbox of the chosen condition is red highlighted as below, e.g., if Arthritis is chosen.



4.2.5. Choose Treatment Area(s)

Click the treatment area(s) you desired on the body. After that, the chosen area(s) is red highlighted as below, e.g., if Shoulder and Carpus are chosen.



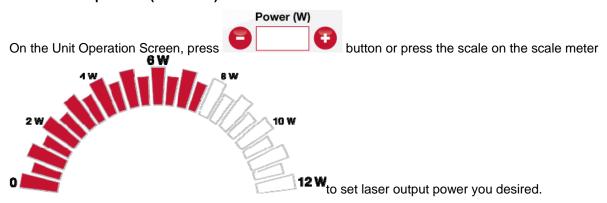


Click Next button to enter Unit Operation Screen and the current is Standby mode as below.



The settings you already chose are listed on the left side of the screen.

4.2.6. Unit Operation (Protocols)



When button is pressed the unit sounds 6 beeps (6 seconds delay) and the STANDBY button correspondingly flashes to indicate that the laser is entering the Ready mode. When the beeping stops and the button is solid red, the laser is ready for emission.



Also, when the beeping stops, the aiming beam is activated (if Aiming Beam setting is not Off in Setup Screen) and allows the operator to aim the red light onto the treatment site in preparation for the treatment.



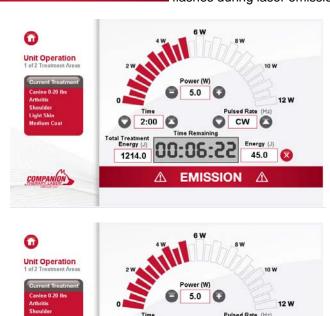
The device does not leave Standby mode to enter Ready mode, and error message will show on the screen if any of the following conditions occur.

- Optical fiber is not properly inserted
- Safety interlock is not properly installed
- Footswitch is depressed

The aiming beam can be shut off by pressing either the Ready mode.



In Ready mode, when press the foot/finger switch, the device enters Emission mode. The laser emission indicator flashes during laser emission.



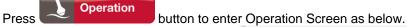
2:00

EMISSION

1004.0



4.3. Operation Screen





Press drop-down button at Custom Settings as below. The new protocol can be created and named by operator.



Click "Create NewSet" in the drop-down options, then enter Create New Set screen as below.





After setting the Power (W), Pulse Rate (Hz) and Time (min.), i.e., 0.5W, CW and 0:02 min.

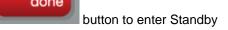


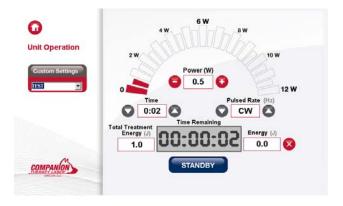
Click

button to save the settings and enter the Mini Keyboard screen as below.



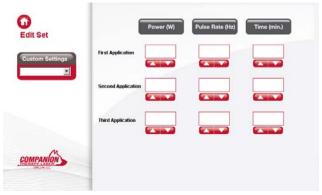
Type in the desired name of the protocol, i.e., TEST, and click screen as below.



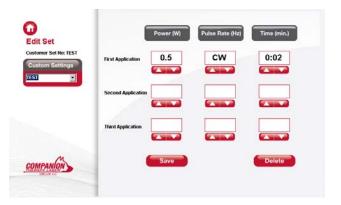




To edit the existing protocol, press the drop-down button at Custom Settings as below. Click "Edit Set" in the drop-down options, then enter Edit Set screen as below.



Click the existing desired protocol, i.e., TEST, in the drop-down options, then enter existing protocol edit screen as below. The existing protocol can be edited and renamed.



Click

button to save the settings and enter the Mini Keyboard screen as below.



Type in the new name of the protocol. Then click

done button to enter Standby screen.



In Standby screen, press relevant control button, the operator can change the laser output power (W), treatment time, pulsed rate (Hz).

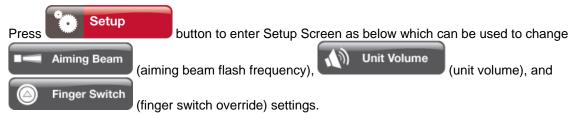
4.4.3D Anatomy

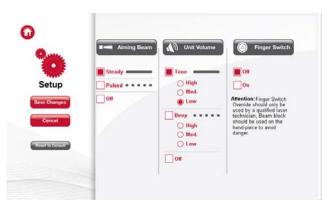
Press button to enter 3D Anatomy Screen which shows the 3D movie of the animal body structure.

4.5. Library

Press button to enter Library Screen which shows the user instructions and literatures of this product.

4.6. Setup





Press Save Changes button to save the changed settings. Press button to exit the Setup Screen.



5. Maintenance

5.1. Maintenance and Calibration

This laser device is designed for maintenance free operation with normal use.

No maintenance and calibration operations are required by the end user.

The maintenance and calibration can only be made by the manufacturer.

The manufacturer recommends one calibration for each calendar year of use.

For detailed maintenance and calibration information contacts the manufacturer.



COMPANION Therapy Laser CTS-15

Specifications

| Model | COMPANION |
|---------------------------------|--|
| Treatment Laser Wavelength | 980, 810 nm |
| Laser Power | 15W |
| Spot Sizes | Adjustable |
| Operating modes | Continuous Wave (CW) 2Hz, 10Hz, 20Hz, 100Hz, 200Hz, 500Hz, 1000Hz, 2500Hz, 5000Hz, and 10000Hz |
| Aiming Laser Wavelength | 650nm |
| Aiming Laser Power | 3.5+/-1.0mW |
| Aiming Laser Frequency | Off/Steady/Pulsed |
| Audio Warning Signal | OFF/CW/Beep |
| Unit Volume | High/Med./Low |
| Foot/Finger Switch Operation | ON/OFF |
| Weight | <30 lbs |
| Dimensions | 265mmx257mmx397mm (10.4"x10"x15.6") |
| Power requirement | 100 to 240VAC/50-60Hz |
| Operation temperature | 10°C to 35 °C |
| Storage temperature | -20 °C to 70 °C |



Treatment Information

The proper use of the Companion Therapy Laser requires appropriate laser safety practices and knowledge of laser/tissue interaction. In addition, an understanding of laser wavelength, frequency, target tissue, and anatomy are essential.

It is recommended that proper diagnosis and treatment plans are to be completed by or under the direct supervision of a licensed professional.

Veterinary Treatment Stored Protocols in the Laser

- Each protocol will begin with CW (Continuous Wave) and cycle through multiple frequencies for optimal treatment effect.
- Depth of penetration is determined by spot size, wattage, and wavelength.
- An understanding of veterinary anatomy and laser tissue interaction is imperative for safe, optimal treatments
- Small Animal preset wattage is set for patients ranging from 40 60 lbs.
- Larger patients may need the protocol repeated (medial/lateral) or an increase in power to 10W for treatment of lager areas. Once complete, the operator may reactivate the laser and repeat a protocol by pressing the finger switch.
- To maximize this feature, consider bi-lateral treatment of the target area before moving to different target area (i.e. R & L Hip before Back).

Preparation of Patient for Laser Therapy Treatment

- The area to be treated must be exposed.
- The treatment area should be clean and free of surface dirt or oils.
- Use rubbing alcohol to clean all instrument surfaces in contact with the patient.

CAUTION! Assure alcohol on the instrument has fully evaporated before activating the laser.

- Thermal effects vary with hair coat and pigmentation darker pigments absorb more. If there is a
 withdrawal response, increase distance and/or move the handpiece more rapidly, and/or reduce
 power.
- Spraying water on a dark hair coat is recommended. You can also part the hair with your hands or clip.

Laser Therapy Treatment Considerations

- Treatments can be done in conjunction with stretching or Range Of Motion.
- Monitor for superficial thermal discomfort.
- Keep beam perpendicular to muscle fibers.
- Keep beam parallel to joint surfaces.
- Treat muscles connecting to a painful joint in addition to tendon attachments.
- Higher energy densities are required for deeper penetration.

Laser Therapy Treatment Techniques

- Treat area from proximal to distal.
- Treat biomechanical connected muscles and joints in the kinematics chain.
- Post-Operative or acute injuries use shorter times and/or lower power.



Contact Technique

- Treatments can be done on contact or at a slight distance from the skin ~1/2 inch.
- Monitor for superficial thermal discomfort.
- Change in tissue consistency can be felt during steady pressure.
- Move probe in grid pattern ~ 3 seconds per point perpendicular to joint capsule.
- Treat 1-2 inches of surrounding healthy tissue.
- Most patients will show at least a mild positive response in 1-2 treatments.
- 4 20 joules at the surface per point.

Treatment Plans

The effects of laser therapy are cumulative. A suggested treatment would include initial treatment and ongoing maintenance treatments as needed. Patients may show signs of improvement within the first 2 treatments, but long term benefits result from a complete treatment protocol.

<u>Treatment Schedule for Chronic Conditions (6 total treatments)</u>

Week 1 - Monday, Wednesday, & Friday

Week 2 - Tuesday & Friday

Week 3 – Single treatment 1 week after last treatment

Week 5 or 6 – Office Visit Re-Check (Treatment if needed)

Maintenance treatment when needed

Treatment Schedule for Acute Injuries (6 total treatments)

Two treatments per week for 3 weeks or with injury re-check or bandage change

Treatment Contraindications

Contraindications for Laser Therapy are based upon prudence as opposed to experimental or clinical data. The following contraindications are presented as a precaution for safe and effective treatment.

Laser Therapy should <u>not</u> be administered in the following situations:

Hemorrhaging

Do not apply laser light to any actively hemorrhaging lesion.

• Eyes: Direct Irradiation of the Eyes

Lasers are potentially harmful to the retina of the eye. Never shine laser light into the eye at any time, even while wearing safety goggles. The technician administering laser therapy and all individuals including those holding the animal should wear safety goggles at all times.

Testicles

Do not apply laser light to the testicles of the animal.

• Corticosteroids

Do not apply laser light to any area recently injected with corticosteroids.

Photosensitive Medications

Do not apply laser light to any animal currently receiving photosensitive medications.

Epiphysitis

When applying laser light to epiphysitis, use a low dose initially and use only those treatments necessary to reduce swelling.



Carcinomas: Melanomas and Sarcoids

Do not use laser over any known primary or secondary lesions. Laser application to horses with Melanomas and Sarcoids should only occur under the supervision of a veterinarian.

Pregnancy

Laser therapy is contraindicated for use over the pregnant uterus. Do not apply laser light to the pregnant animal

• Treatment Over Sympathetic Ganglia, the Vagus Nerves & Cardiac Region In Animals With Heart Disease

Laser therapy may significantly alter neural function, and is therefore contraindicated over these regions in horses with heart disease.

Eye Protection

Protective eyewear is necessary for both Class III and Class IV lasers. The Companion Therapy Laser emits visible and Infrared (which is invisible) radiation and it is imperative that the supplied eye protect is worn,

Safety Warnings

It is safe to operate the laser only when the users follow all suggested safety measures:

Post clearly visible warnings in the area where the laser beam passes to alert those present.

Keep all unauthorized personnel out of the area where the laser is operated.

Maintain the laser in Standby mode or OFF when not in use.

Never look directly into the laser beam path or scattered laser light from any reflective surfaces. Never look directly into the laser source.

As a precaution against accidental exposures to the laser beam or its reflection, operators should wear laser safety goggles provide by LiteCure. Additional goggles can be purchased from LiteCure. (302-709-0408)

For further information regarding laser safety issues, contact the following independent organizations:

Center for Device and Radiological Health

Office of Compliance 2098 Gaither Rd. Rockville, MD 20850 Tel: 301 594 4654 Laser Institute of America 2424 Research Parkway, #125 Orlando, FL 32826 Tel: 407 380 1553

Fax: 407 380 5588



Laser Cleaning Guide: Equipment Care

Assembly and Disassembly

It is recommended that the laser remain assembled and ready for use. If this is not appropriate, make sure the laser aperture is never left open.

The fiber or protective plug should always be in place to ensure no dust, dirt, hair, or dander enters the optical fiber socket.

General Cleaning



Warning

Always turn off the system and unplug the power cord from the wall outlet before cleaning.



Warning

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

Laser

The outer casing can be wiped with dry soft cloth.

• Fiber Handling and Care

The maximum permissible bending radius of optical fiber is 5 cm. Short term (during use): Radius = 5 cm



COMPANION Therapy Laser

Returns

A Return Material Authorization number (RMA) is required for any returned goods. Original purchase order number, date of shipment and serial number must be provided before the RMA number can be issued. All returns should be shipped with the original packaging materials with the assigned RMA number(s) clearly marked.

A cost estimate will be provided by COMPANION Therapy Laser for out of warranty items. Specially designed products damaged by the customer may not be returned.

Return Instructions

Should you ever have to return a COMPANION Therapy Laser product you must:

- 1. First obtain an RMA number, prior to returning goods. Please contact the Company first to obtain a RMA number
- 2. Submit a written request or form via Mail or Fax. After submitting the form,a Returns Department representative will contact you within 24 hours. You may be asked for additional information regarding your return.
- 3. Attach all forms and any test results data you have to the items you are returning.
- 4. Package the items according to the Packaging Instructions
- 5. Write the RMA Number on the outside of the box or include it on the shipping label. IMPORTANT-Without an RMA number on the outside of the box it my be returned to you without processing
- 6. Label and ship to:

LiteCure, LLC 250 Corporate Blvd., Suite B Newark, DE 19702

Phone: 302-709-0408 Fax: 302-709-0409

Packaging Instructions

- 1. Pack the items you are returning in the original packaging material If the original packaging material is not available, please follow these guidelines: Insert or wrap and protect all ESD sensitive components separately in either static dissipative or static shielded packaging or materials.
- 2. Wrap each item separately. Fragile components need adequate cushioning from each other and the sides of the box.
- 3. Use enough cushioning material inside the box, and around each item, to ensure that the contents cannot move when you shake the box.

Note: Fiber Cables - Do not bend the fiber less than the minimum allowable fiber bend radius.

4. Use adequate protection when covering sensitive fiber tips or optical components.



5. Use a double box method for shipping all fragile electronic/optical components and equipment.

Important: The warranty may be considered void if the items received by the company are not packaged in a manner that complies with the Packaging Instructions.

Cancellation Fees

Should it become necessary to cancel or modify orders prior to shipment, a restocking fee of 15 to 50% of the total order amount will be charged by COMPANION Therapy Laser for returns to stock.



Warranty Terms and Conditions

Standard Warranty Plan

COMPANION Therapy Laser products and components are warranted to be free from defects in materials and workmanship for a period of 36 months from the date of initial shipment. COMPANION Therapy Laser's liability under this 36 month warranty is limited to:

Laser Internal and External Components - 36 months

Laser Diodes, Laser Hand piece Cable and Laser Hand piece Probe – 36 months

COMPANION Therapy Laser shall replace any part during the original warranty period.

Extended Warranty Plan

COMPANION Therapy Laser will provide an extended warranty for additional years beyond the Standard Warranty Plan. Please contact LiteCure, LLC for details.

Notice:

The Standard and the Extended Warranty Plans will not apply to those products which have been:

- (i) Repaired or altered other than in accordance with the terms of this Agreement, or
- (ii) Abused, misused, improper handling in use, or storage, or used in an unauthorized or improper manner or without following written procedures supplied by COMPANION Therapy Laser, or
- (iii) Original identification markings, labels have been removed, defaced or altered, or
- (iv) Any other claims not arising directly from material defects in material or workmanship.

Special contracts or contracts for non-standard products may have modified terms of warranty and, in such cases; the terms as stated in the individual contract must be signed by the duly authorized officer of COMPANION Therapy Laser and will supersede the standard terms.

COMPANION Therapy Laser will make final determination as to cause or existence of defect and, at its option, repair or replace the products which prove to be defective during the warranty period. Products replaced under warranty will be warranted only for the balance of the warranty period from the original supplied equipment.

This warranty extends only to the original purchaser of the equipment from COMPANION Therapy Laser. The purchaser must notify COMPANION Therapy Laser within 15 days of first noticing the defect and promptly return the defective product upon receipt of RMA number(s) before expiration of the warranty period.

Products believed by purchaser to be defective shall be returned to COMPANION Therapy Laser with the transportation and insurance prepaid by purchaser. Repaired or replaced products will be returned to purchaser by COMPANION Therapy Laser, FOB city destination within the Continental United States. Transportation beyond these limits will be charged to purchaser. The warranty set out in above paragraph is the exclusive warranty made by COMPANION Therapy Laser and is in lieu of all other warranties (except for specific product performance warranties), whether written, oral, or implied, including any warranty of merchantability or fitness for a particular purpose, and shall be customer's sole remedy and COMPANION Therapy Laser's sole liability on contract or warranty of otherwise for the products.

This warranty shall not be modified or amended without the written approval of an officer of COMPANION Therapy Laser.

IN NO EVENT SHALL COMPANION THERAPY LASER BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE FAILURE TO PERFORM UNDER THIS AGREEMENT OR THE FURNISHING, PERFORMANCE OR USE OF ANY GOODS OR SERVICES SOLD PURSUANT HERETO, WHETHER DUE TO BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE OR OTHERWISE.