CTS-DUO User Manual

Read the entire user manual before attempting to operate this device.

If you have any questions or problems with this device, please contact

Enovis Customer Care
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US and Canada: 1-877-627-3858 ext.1500

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℞ Only

Companion Animal Health d/b/a
Enovis Companion Animal Health

User Manual PN: RSR-000715-000 (B)
Applicable Software Version: 7.0.0+
Effective Date: 2024-06-01

Table of Contents

1 SAFETY

1.1 Terminology

Various Warnings, Cautions, Recommendations and Notes are presented throughout this manual. Explanations and the corresponding symbols are:

Warning: Specific or potential danger. If ignored or compromised, the situation could result in serious injury. Warning statements are preceded with a yellow symbol.

Caution: Possible problem with the device associated with its use or misuse. Problems include, but are not limited to, device failure, or damage to the device. Caution statements are preceded by a black-and-white symbol.

1.2 Laser Safety

Each facility and user of the laser device should follow all local laser safety requirements.

Recommendation: Offers guidance for the optimal application and usage of the device.

Note: Describes the conditions or exceptions that may apply to the subject matter presented.

Federal, state, and local regulations as well as national and international standards should be considered when developing laser safety programs.

Each person using the laser system must have completed basic laser safety orientation and proficiency training prior to operating the laser system.

Recommendation: Designate at least one person at each facility that uses this laser system as the Laser Safety Officer, responsible for providing training on all operating and safety procedures and for monitoring and overseeing control of all laser hazards.

Warning: 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.

1.3 Laser Treatment Controlled Area (LTCA)

Select a secure and well-ventilated location in which to install and operate the laser system. The location should be "light-tight" (not have windows or viewing ports) and should have a single lockable door access. The access door should be closed and locked from the inside throughout the entire treatment with the laser system.

If the door is equipped with an interlock switch, the door can be connected to the remote interlock on the laser system – See Section 1.5.3. When the treatment door is opened during a treatment, the laser will stop emission, produce an error message, and return to Standby mode.
If you choose to set up your laser system in a multi-use area, a blocking barrier, screen, or curtain, certified for blocking the laser beam, must be used to create a smaller area inside a larger room. The barrier should be set up to simulate a "light-tight" room with single entry access as described above.

Warning: Always post a laser safety sign on the outside of the treatment room door or single access point when the laser is in use.

1.4 Fire and Explosion Hazards

Warning: Do not operate this laser system in areas that have explosion hazards such as flammable materials, gases or substances. A fire or explosion could occur. The laser beam can ignite most nonmetallic materials. A fire extinguisher should be readily available.

1.5 Safety Features

The laser system has multiple safety features. All individuals who use this laser system should be trained and made aware of the following features:

1.5.1 Emergency Stop Button

This button **(Figure 1)** is located on the front of the laser system. Push the button to turn off all electrical power to the device's microprocessor and laser-emitting components in case of an emergency.

Figure 1

1.5.2 Password Entry

The laser system is equipped with a password entry as the key control that is required after powering on the device, to prevent unauthorized access to the system.

1.5.3 Remote Interlock Connector

The laser system is equipped with a remote interlock connector (Figure 2) located on the back of the device. The remote interlock connector stops laser emission when the terminals of the connector are open.

The mating connector (as shown in **Figure 2**) MUST be inserted (or remote interlock circuit closed / door closed) for the laser system to emit.

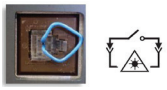


Figure 2

1.5.4 Laser Emission Indicators

When the laser system is emitting, an **EMISSION!** indicator **(Figure 3)** will appear on the touch screen and flash. See Section 5.3.6 for a full description of the transitions of this indicator based on the laser mode (i.e. Standby, Ready, or Emission).

Figure 3

The LED **(Figure 4)** next to the power button on the front bezel illuminates to indicate the state of the laser. When off, the laser is considered to be in a safe state - **Standby**. While transitioning from **Standby** to **Ready** mode, the LED blinks. When in **Ready** mode, it is constantly illuminated. While emitting, it blinks.

Figure 4

In addition, there is a red aiming beam that emits from the hand piece while in **Ready** and **Emission** modes which provides a visible indication of the treatment location.

Lastly, there is an **audible** warning during **Emission** that is a stead tone, or continuous beep, depending on the system settings. The audible warning sounds six times during the six second transition from **Standby** to **Ready** mode.

1.5.5 Unattended Protection

If the laser system is left in **Ready** mode for 100 seconds without any input, the system will automatically return to **Standby** mode.

1.5.6 Internal Laser Energy Monitor

To prevent over-exposure hazards due to excessive laser power, the laser system continuously monitors the output current of the diodes to ensure they are within the factory calibration settings. If it is detected that the electrical current levels exceed the upper limit that would result in 20% greater power output than selected, the laser will stop emission, display an error message, and return to **Standby** mode.

1.6 Laser Safety Eyewear

ANYONE in the Laser Treatment Controlled Area (LTCA) during laser treatment MUST wear the laser safety eyeware that is provided with the laser system. The eyewear has an optical density (OD) rating >5.0 for 808 nm AND 980 nm wavelengths, as identified on the lenses **(Figure 5)**. Animal patients may wear protective laser eyewear provided by the manufacturer, i.e. Doggles, **(Figure 6)** or may have their eyes covered with other completely opaque shielding. Additional protective eyewear can be purchased from the company webstore.

Figure 5

Figure 6

2 SYSTEM SET-UP

Caution: Possible problem with the device associated with its use or misuse. Problems include, but are not limited to, device failure, or damage to the device. Caution statements are preceded by a black-and-white symbol.

2.1 Location

Select a secure and well-ventilated location in which to install and operate the laser system (see Section 1.3 for description of Laser Treatment Controlled Area).

- The device should be within 1.8 meters (6 feet) of an available 100-240 V electrical outlet.
- Select a flat hard surface that can adequately support the laser system.
- Ensure adequate airflow around the laser system. The laser system is air-cooled and designed for use in a well-ventilated location. There must be a minimum 10 cm (4 in) clearance around the back of the device.
- An appropriate fire extinguisher should be readily available.

Warning: Do not operate the laser system in areas with explosion hazards such as flammable materials or gases.

Caution: If the Warranty Seal Label **(Figure 7)** is not found on the bottom of the device or is broken, **DO NOT** operate the device. Call LiteCure Customer Care.

Figure 7

2.2 Unpacking and Initial Set-up

Step 1. Carefully unpack the laser system and its accessories from the shipping carton.
Step 2. Inspect the laser system carefully for any damage, such as cracks, dents or bent parts.
Step 3. If items are missing or damaged, call Customer Care. Also, please notify the carrier if the damage appears to have occurred during shipping and retain packaging for evidence.
Step 4. Plug the female end of the power cord into the AC input at the back of the laser system **(Figure 8)**.
Step 5. Plug the male end of the AC power cord into a 100-240 grounded electrical outlet.

Figure 8

Caution: Do not force the external power supply cord into the DC input in the incorrect orientation (i.e. upside down). This may cause damage to the connecting pins and prevent the unit from charging properly.

2.3 Delivery System Connection

Caution:

- Do not remove the hand piece fiber cable from the emission port once it has been secured (unless the optical fiber cable needs to be replaced).
- Repeated insertion and removal of the hand piece fiber cable will increase the chance of emission port or fiber tip contamination. If the emission port or the fiber tip is contaminated, the optical fiber can be damaged during beam emission causing a loss in output and potential damage to the emission port.
- If the fiber must be removed, use the dust cap to help prevent dust and debris from contaminating the emission port. Do not leave the port unprotected.There must be a minimum 10 cm (4 in) clearance around the back of the device.
- Do not bend the optical fiber too sharply: the minimum permissible bending radius is 40 mm.

Note: The laser system will be delivered with the beam delivery assembly already connected. If a replacement is needed, follow the steps below to disconnect the old and attach the new beam delivery assembly.

Step 1. Unscrew metal fiber connector counter-clockwise until loose and gently pull fiber away from unit.
Step 2. After removing fiber, unplug finger switch cord by pulling plug away from unit **(Figure 9)**.
Step 3. Remove the new assembly from the protective foam packaging.
Step 4. Secure the finger switch connector by carefully pushing it into the finger switch port.
Step 5. Remove the protective dust cap from the end of the new optical fiber cable **(Figure 10)**.
Step 6. Insert the fiber tip straight into the emission port. Twist the metal connector clockwise onto the threaded emission port until tight **(Figure 11)**.

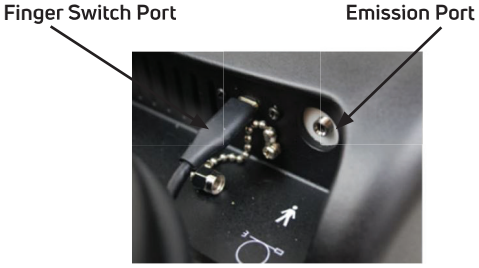


Figure 9 *Figure 10* *Figure 11*

2.4 Fiber Management

The top of the laser console has an easy-to-use Fiber Manager and Handpiece Clip that provide storage for the Empower IQ Delivery System while not in use.

When therapy is discontinued or between treatment cycles, the user may rest the hand piece in the Hand Piece Clip. For long term storage and during transport, the user may also wrap the fiber around the Fiber Manager Spool to avoid damage to the fiber.

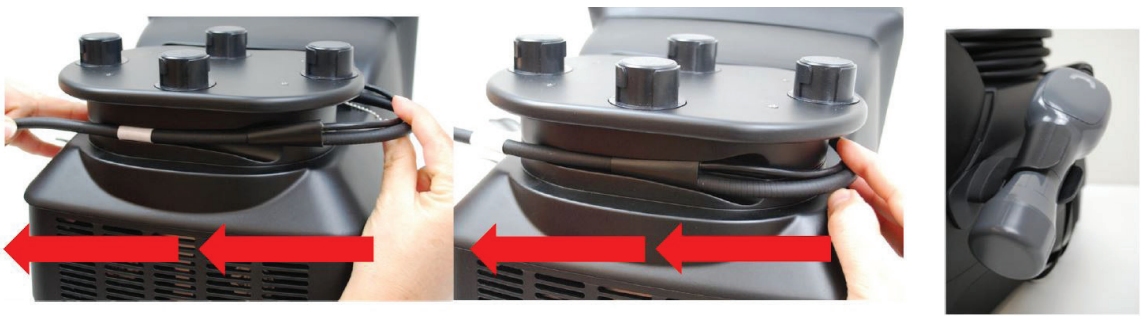


Figure 12

When wrapping the hand piece fiber around the fiber manager spool, the first fiber wrap should be fed into the Fiber Slot so the plastic Bifurcator, which couples the finger switch and fiber optic cables, snaps into the slot. Five more wraps (for a total of six) should be made tightly around the spool to provide enough length for the hand piece to feed into the Hand Piece Clip **(Figure 12)**.

2.5 CTS DUO+ Installation

Note: Component is only applicable to customers who purchased the CTS DUO+ or DUO+ Installation Kit.

Note: The CTS-DUO laser console must be on software version 7.0.0.0 or greater to utilize the DUO+ features.

2.5.1 The CTS DUO+ Installation Kit comes with the following components:

- CTS DUO+ ConnectBox
- USB 2.0 cable
- Fabric fastener tie for wire management
- Fabric fastener hook (rough side) and loop (soft side) for mounting

2.5.2 CTS DUO+ ConnectBox Mounting Locations

The connectivity module is recommended to be mounted to one of the following locations:

- Left side of the laser console **(Figure 13)**
- Bottom shelf of the laser console cart **(Figure 14)**

Figure 13

Figure 14

Warning: Mounting the connectivity module on the underside of the cart can cause interference with Wi-Fi connectivity and affect email sending. Recommended mounting locations should be used.

2.5.3 CTS DUO+ ConnectBox Mounting Instructions

To mount the connectivity module to the laser console, follow the steps below:

Step 1. Remove adhesive from one fabric fastener loop and attach to the right long edge of the connectivity module **(Figure 15)**.

Figure 15

Warning: Mounting the bottom of the connectivity module to the laser console could lead to computer overheating. The recommended long edge of the connectivity module should be used.

Step 2. Remove adhesive from one fabric fastener hook and attach to one of the recommended mounting locations from section 2.5.2 **(Figure 16)**.

Step 3. Plug the Micro-USB end of the USB cable into the Micro-USB port on the connectivity module. Plug the opposite end into the USB port on the back of the laser console **(Figure 17)**.

Figure 16

Figure 17

Step 4. Mount the connectivity module to the laser console by connecting the already placed fabric fastener pieces **(Figure 18)**. Coil the extra length of USB cable and neatly wrap using the provided fabric fastener ties **(Figure 19)**.

Figure 18

Figure 19

2.5.4 Enabling CTS DUO+ Mode

Step 1. Once the connectivity module is plugged in to the laser console USB port while the console is ON, the CTS-DUO will identify the presence of the connectivity module.

Note: This process can take multiple minutes to complete.

Step 2. Once the connectivity module is identified, the CTS-DUO will shift to CTS DUO+ mode. This will be evident by the updated logo on the home screen and the plus sign indication in the top right corner **(Figure 20)**.

Note: The + sign indication is yellow because the connectivity module is plugged in but not yet connected to Wi-Fi and email.

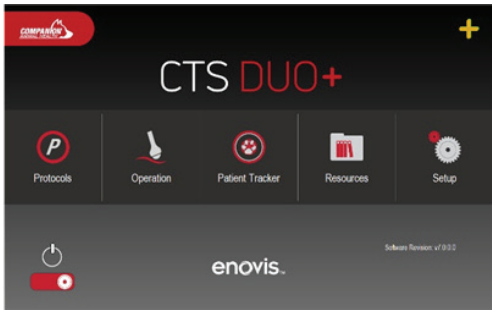


Figure 20

For setting up the email and Wi-Fi configuration of the CTS DUO+, refer to the CTS DUO+ Installation Guide: info.companionanimalhealth.com/cts-duo-7.0.0.1

3 DEVICE DESCRIPTION

The laser system includes a therapeutic laser and optical delivery system that is used for the treatment of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and for promoting relaxation of the muscle tissue and for temporary increase in local blood circulation. The optical delivery system consists of a hand piece with interchangeable treatment heads attached to a flexible optical fiber. A custom software application allows the operator to select from built-in treatment protocols, or to adjust and set the system's optical output power and treatment times with minimal effort. Once the operator has selected the desired treatment parameters, activation of laser emission requires that the operator follow a sequence of predetermined steps to activate laser emission. These steps are detailed in Section 5.

The CTS DUO+ enhances workflow in the practice by providing electronic access to patient laser console treatment records. Features provided by the CTS DUO+ are outlined in section 8.

3.1 Indications for Use

810 nm and/or 980 nm wavelength:

This laser system is indicated for emitting energy in the visible and near-infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis. It is also indicated for promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

The laser system is intended to be used by licensed veterinarians, or other practitioners, to provide animal patients photobiomodulation therapy to promote healing and reduce inflammation.

Caution: Federal law (USA) restricts this device to sale by or on the order of a veterinarian, or other practitioner licensed by the law of the State to use and/or prescribe use of the device.

Warning: 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.

3.2 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 not 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 assisting or holding the patient should always wear laser safety goggles.
- **Testicles:** Do not apply laser light to the testicles of the animal.
- **Injectable Medications:** Do not apply laser light directly over any area recently injected with any medication, vaccines, etc.
- **Photosensitive Medications:** Use caution in 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.
- **Cancer or Malignancy:** 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 patients with heart disease.
- **Cancer or Malignancy:** 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 patients with heart disease.

3.3 Maximum Permissible Exposure (MPE)

Maximum Permissible Exposure (MPE) is the highest power density (in W/cm2) from a light source that is considered safe. For the infrared radiation from this laser system, the MPE at the cornea for direct ocular exposure is determined by the wavelength, beam divergence, and exposure time. For exposure times between 10 and 3000 seconds, the MPE at the cornea for this laser system is 418.9 W/m2. For exposure times between 10 and 30,000 seconds, the skin MPE is 3027.1 W/m2.

3.4 Laser Console Diagrams

1. Power Button
2. Emission Indicator LED
3. Emergency Stop Button
4. Touchscreen Display
5. Front Vent & Speakers
6. Non-interlocked Protective Housing Label
7. UDI Label
8. Product Label
9. Remote Interlock
10. Warranty Seal
11. Rear Vents
12. Foot Switch Receptacle
13. VGA Port (For Mfg Use ONLY)
14. Additional Warnings Label
15. USB Port
16. Power Cord Receptacle
17. Hand piece Clip
18. Hand piece Handle
19. Strain Relief
20. Fiber Manager Spool

Figure 21

Figure 22

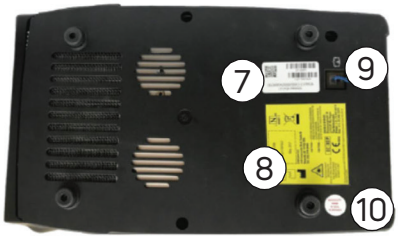


Figure 23

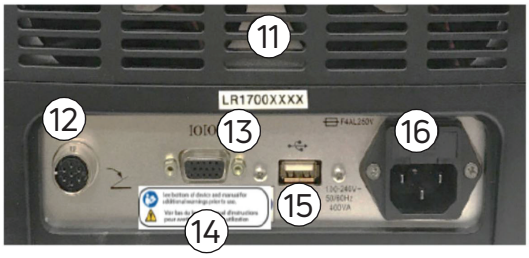


Figure 24

3.5 CTS DUO+ ConnectBox

1. Power Indicator LED
2. Micro-USB Port
3. Bottom Vents
4. Ethernet Port
5. Top Vents
6. Product Label
7. Left Side Vents
8. FCC/IC ID Label
9. Micro-USB-B End
10. USB-A 2.0 End
11. Fabric Fastener Tie

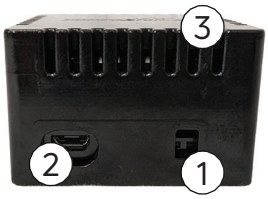


Figure 25

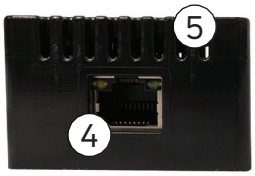


Figure 26

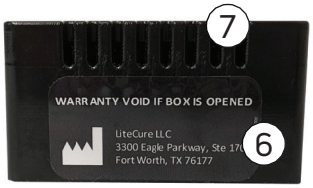


Figure 27

Figure 28

Figure 29

3.6 Empower IQ Delivery System

Warning:

- If any part of the Empower IQ Delivery System overheats or produces smoke, immediately power off the laser system, discontinue operation, and contact Customer Care for assistance.
- The use of accessories and/or optical fiber cables not specified for use with this laser system may result in unsafe emissions or damage to the laser system.

Caution: Do not bend the optical fiber too sharply: the minimum permissible bending radius is 40 mm.

The Empower IQ Delivery System is composed of a double-sheathed optic fiber and a hand piece with interchangeable treatment heads.
The laser emission is controlled with a finger switch on the hand piece **(Figure30)**.

Figure 30

Warning: DO NOT operate the laser system without a treatment head. This can cause serious injury.

The finger switch is an ON/OFF button for laser emission. When the operator is administering a treatment, the finger switch must be held down. Releasing the finger switch stops the laser emission and returns the laser to **Ready** mode. The laser system will remain in **Ready** mode until the operator holds the button down again to resume the treatment. If there is no input to the laser system by the finger switch for 100 seconds, then the laser system will automatically return to **Standby** mode.
There is a finger switch **OVERRIDE** setting that can be used by advanced users who do not want to hold the finger switch down throughout the entire treatment. More information on finger switch settings can be found in Setup.

Warning: Warning: The **Override** setting for the finger switch should be used by experienced operators only

When in **Ready**, the Emission Indicator Ring **(Figure 30)** will illuminate yellow. During emission, the Emission Indicator Ring will change colors during emission based on the dosing technique. During ideal dosing, the LED will remain green. When the hand piece is stopped or moved too slow during emission, the LED will turn red. When the hand piece is moved too fast during emission, the LED will turn yellow. When vibration feedback is turned on, the hand piece will vibrate when in the red or yellow condition **(Figure 31)**. During laser system shutdown, the Emission Indicator Ring will flash red.

Figure 31

Recommendation: If the Empower IQ is not performing as **described above, check the Empower IQ settings in Setup and reconnect the Empower IQ, if needed – see Section 5.2.2 for more details.**

Warning: The new Empower IQ features are not meant to replace user training or the need to observe and respond to patient feedback during treatment.

3.7 Quick Disconnect Treatment Heads

Prior to initiating any treatment, the shipping dust cap must be removed. To remove the dust cap or any treatment head attachment, hold the base of the hand piece with one hand and grasp the attachment with the other. Rotate the attachment counterclockwise approximately 1cm to unlock the attachment. Then, pull straight down to disengage and keep pulling to fully disconnect the attachment **(Figure 32)**.

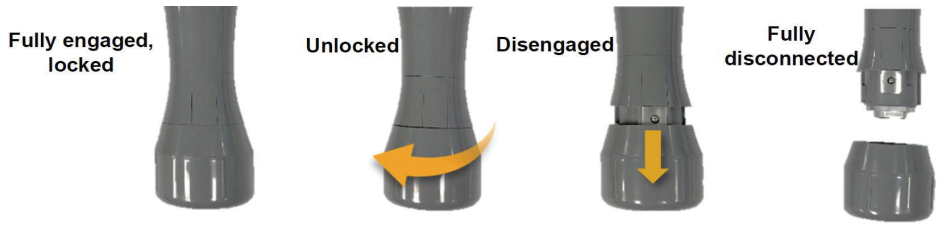


Figure 32

To attach a treatment head attachment, locate the metal insert on the inside of the attachment. Line up the slot within the metal insert with the bearing on the mating end of the hand piece **(Figure 33)**. The hand piece and attachments are keyed so they will only fit and attach in this orientation.

Figure 33

Once they are lined up, push the attachment onto the end of the hand piece so it is fully seated. Then while holding the hand piece, rotate the attachment clockwise until it clicks. This indicates the attachment is fully engaged, locked in, and ready for use. **(Figure 34)**

Figure 34

Warning: DO NOT operate the laser system with an improperly attached treatment head. This can cause serious injury.

To confirm successful connection, the corresponding treatment head icon on the Operation screen will be highlighted. The icon background color will be based on whether it is recommended or not based on the current Protocol or treatment settings.

3.8 Treatment Head Attachments

The following table lists the treatment heads included with the laser system and provides a description of when to use each.

Treatment Head	Name and Description
	**Small Non-Contact Treatment Head (Small Cone)** This treatment head is for general use and applications where fine control with no contact or soft tissue manipulation during treatment is desired. Indications for use of the small cone are very small wounds in tight spaces or near sensitive areas. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion. **The Small Cone is recommended for use only at power settings of 3W or below for optimal patient comfort and should NOT be held in place without movement during treatment, however it can be used at power settings up to 6W safely by expert users. The small cone lens should NOT be allowed to come in direct contact with the hair coat and should be held 1-2 inches from the skin and hair of the patient.**
	**Small Contact Deep Tissue Applicator (Small Ball)** This treatment head is for use in applications where contact and soft tissue manipulation during treatment are desired. Indications for use of the small ball are muscular or tissue injuries in tight spaces or near sensitive areas. The small ball is not recommended for use over open wounds, non-intact skin or areas that would be sensitive to contact. This head should be held perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion. **The Small Ball is recommended for use only at power settings of 3W or below for optimal patient comfort;** however, it can be used at power settings up to 6W by expert users.
	**Large Contact Deep Tissue Applicator (Large Ball)** This treatment head is for use in applications where contact and soft tissue manipulation during treatment are desired. Indications for use of the large ball are muscular or deep soft tissue injuries, arthritis, edema/swelling and other deep tissue conditions. The large ball is not recommended for use over open wounds, non-intact skin, or areas that would be sensitive to contact. This head should be held perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion. **The Large Ball can be used at power settings up to 18W.**
	**Large Non-Contact Treatment Head (Large Cone)** This treatment head is for use in applications where contact and soft tissue manipulation during treatment are desired. Indications for use of the large ball are muscular or deep soft tissue injuries, arthritis, edema/swelling and other deep tissue conditions. The large ball is not recommended for use over open wounds, non-intact skin, or areas that would be sensitive to contact. This head should be held perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion. **The Large Ball can be used at power settings up to 23.5W.**
	**XL Contact Deep Tissue Applicator (XL Ball)** This treatment head is for use in applications where contact and soft tissue manipulation during treatment are desired and treatment power exceeds 15W. Indications for use of the extra-large deep tissue applicator are muscular or deep soft tissue injuries, edema/swelling and other deep tissue conditions requiring more than 15W of power. The extra-large deep tissue applicator is not recommended for use over open wounds, non-intact skin, or areas that would be sensitive to contact. This head should be held perpendicular to the skin and not approaching at an angle. The area to be treated and a significant surrounding margin should be covered evenly in a "painting" or "serpentine" motion.

3.8.1 Treatment Head Parameters

Beam divergence and the Nominal Ocular Hazard Distance (NOHD) for each of the treatment heads are listed in the following table. NOHD is defined in ANSI Z136.3 as "the distance along the axis of the unobstructed beam from the laser to the human eye beyond which the irradiance or radiant exposure during normal operation is not expected to exceed the appropriate Maximum Permissible Exposure (MPE)." At distances greater than the NOHD, the beam intensity becomes lower than the MPE.

Treatment Head	Beam Divergence Full Angle		NOHD (m)	NOHD (ft' inches")
	Radians	Degrees		
Small Cone	0.8148	47	0.4	1' 4"
Small Ball	0.2258	13	1.1	3' 8"
Large Cone	0.8148	47	0.4	1' 4"
Large Ball	0.0566	3	5.4	17' 9"
XL Contact	0.1860	10.7	1.5	4'11"

4 DEVICE OPERATION

4.1 Safety Precautions

Note: Describes the conditions or exceptions that may apply to the subject matter presented.

Recommendation: DO NOT allow any nonessential personnel into the LTCA during any laser procedure.

Anyone in the Laser Treatment Controlled Area (LTCA) during laser operation (including the operator, all assistants, and the patient) must wear the protective eyewear supplied with this laser system.

Warning:

- The protective laser eyewear has an optical density rating > 5.0 for 810 nm and 980 nm laser emission (see specification sheet with eyewear). ONLY wear the protective eyewear supplied with this laser system.
- All personnel in the LTCA must wear laser safety eyewear.
- Replace any protective laser eyewear with eyewear from the manufacturer if there is any damage or photo-bleaching resulting from laser exposure.
- NEVER look directly into the distal end of the optical fiber connected to an active laser device WITH or WITHOUT the appropriate laser-emission protective eyewear.

Warning:

- NEVER aim the laser light directly into the eyes.
- NEVER direct the laser beam at anything other than the area to be treated. Direct or indirect eye contact with the output beam can cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.
- If you suspect injury, such as direct exposure to the eyes, seek medical attention immediately.
- FAILURE TO COMPLY with all safety instructions and warnings may expose everyone in the controlled laser treatment area to harmful levels of laser radiation and/or dangerous levels of electrical current.
- FAILURE TO COMPLY with the application techniques listed in the manual may lead to exposure to harmful levels of laser radiation.
- AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N_2O) and oxygen. The high temperatures produced during normal use of the laser system may ignite some materials, such as cotton or wool, when saturated with oxygen.
- DO NOT use treatment head until the alcohol solution used for cleaning completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.

Take the following steps to secure the treatment room, or the controlled area:

- Alert patients and personnel of laser safety precautions before they enter the Laser Treatment Controlled Area (LTCA). Post the included laser safety sign on the outside of the treatment room door when the laser is in use.
- Close the treatment room door during operation of the laser. The remote interlock connector can be connected to the treatment room door through an interlock circuit so that laser emission stops when the treatment room door is opened.

4.2 Treatment Information

The proper use of the CTS-DUO 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.

Recommendation: Proper diagnosis and treatment plans are to be completed by or under the direct supervision of a licensed professional.

4.3 Stored Protocols

Take the following steps to secure the treatment room, or the controlled area:

- Preset protocol will begin with CW (Continuous Wave) and may cycle through multiple frequencies.
- Depth of penetration is determined by spot size, tissue type being treated, wattage, and wavelength.
- An understanding of veterinary anatomy and laser tissue interaction is imperative for safe, optimal treatments.
- Once complete, the operator may reactivate the laser and repeat a protocol by pressing the finger switch.

4.4 Patient Preparation

Warning:

- Use carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation.
- DO NOT allow any reflective objects to fall into or obstruct the path of the laser while it is emitting. Direct or indirect eye contact with scattered laser light from any reflective surface can cause serious, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.
- DO NOT pretreat tissue (e.g., with a heating pad or wet compress) before laser treatment. Tissue to be treated must be dry and at normal temperature before laser treatment begins.

The following guidelines should be used when preparing patients for laser therapy treatments:

- The area to be treated must be exposed. (Do not treat through bandage material)
- The treatment area should be clean and free of surface dirt or oils. Any topical sprays, ointments, or lotions should be shampooed and rinsed off completely prior to treatment.
- If cleaning treatment head prior to administering laser therapy to patient, make sure to use only isopropyl alcohol of 70% alcohol or less. Ensure all alcohol is completely evaporated and treatment head completely dry prior to use on patient (see Section 7.1).

Warning: Ensure alcohol on the instrument has fully evaporated/dried before activating the laser.

- Examine treatment head surface (Ball surface, cone lens) to ensure it is free of cracks, burn marks, blemishes, or residue prior to use.
- Thermal effects vary with hair coat and pigmentation – darker pigments absorb more. If patient appears uncomfortable and/or haircoat feels excessively warm, increase distance and/ or move the handpiece more rapidly, and/or reduce power.

4.5 Treatment Considerations

Recommendation: For patients with excessively long or thick haircoats, user may part the hair while treating with your hands or clip/shave the fur.

- Treatments can be done in conjunction with stretching or gentle range-of-motion exercises.
- Monitor for superficial thermal discomfort.
- Keep beam perpendicular to skin surface at all times.
- Treat muscles connecting to a painful joint in addition to tendon attachments.

4.6 Contact Technique

- Treatments can be done on contact or at a slight distance from the skin.
- Monitor for superficial thermal discomfort.
- Continuously move probe in grid pattern **(Figure 35)**.
- Treat 1-2 inches, or 3-5 cm, of surrounding healthy tissue.

Figure 35

4.7 Laser Treatment Procedure

This section contains information about the protocols and settings on this device. The following treatment recommendations are provided for guidance only. The practitioner is the person who determines the settings and protocol to use when treating each individual patient.

4.8 Skin Color and Other Pigment Considerations

This laser system will deliver a dual wavelength of 810 nm and 980 nm light which has been found to provide therapeutic relief of pain. This laser system allows the operator to choose skin color for the patient. Since darker skin will absorb 810 nm light more than lighter skin, the software in the device will adjust the output so that it contains 100% 980 nm when the dark skin, or dark hair coat, setting is selected. Another circumstance when it may be appropriate to use this setting, include areas of mixed pigmentation, such as areas with a both dark and light-colored skin patches.

Recommendation: For patients with excessively long or thick haircoats, user may part the hair while treating with your hands or clip/shave the fur.

4.9 Dose

The laser energy dose delivered during a treatment is measured in joules. This number is recorded on the screen during a treatment and is calculated by multiplying the power (in watts) by treatment time (in seconds). Laser treatment should be applied to an area using a scanning application.

General guidelines are for the total dose to an area to be 4-20 J/cm^2 (actual dose will depend on area, condition, body type). The software in this laser system is programmed to deliver a dose appropriate for the treatment area and conditions input by the operator. It is recommended that treatment information (protocol and input setting or power, energy delivered, treatment time, treatment area) be recorded for each treatment.

- In general, doses are delivered to the area of pain, the surrounding tissues, and along the nerve pathway for the specific area experiencing the pain.
- Treat muscles connecting to a painful joint in addition to tendon attachments.

4.10 Treatment Technique

Warning:

- DO NOT allow any reflective objects to fall into or obstruct the path of the laser energy produced by this device. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, metal collars, and jewelry) prior to treatment with this device. Indirect or direct eye contact with scattered laser light from any reflective surface from the laser can cause serious, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.
- Use carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation.

Recommendation: It is recommended that the user briefly test the output on their skin prior to treating a patient to ensure the temperature is appropriate for the patient, especially with very small species.

- During treatment, it is important to observe feedback from the patient concerning their comfort level. The laser provides a soothing warmth. Be cautious in cases where the patient has limited sensation or is not able to respond to increases in temperature and consider treating at a lower power setting. If the patient expresses any discomfort; the power output should be reduced.
- Treatment should be delivered to exposed skin. Do not treat through fabric or bandages.
- The treatment area should be clean and free of surface dirt or oils.
- Treatments can be performed on or off contact. See the descriptions of the various treatment heads (Section 4.5.1) for recommended use.
- Isopropyl alcohol solution (70% alcohol) may be used to clean all instrument surfaces that contact the patient (See Section 7.1 for cleaning instructions).
- For optimal delivery of the dose, keep the treatment head perpendicular to the skin.
- Continuously move the treatment head at a rate of approximately 3-10 cm/sec (1-3 in/sec).
- To ensure an even distribution of the dose to the treatment area, continuously move the treatment head over the area first moving continuously back-and-forth horizontally, and then moving back-and-forth vertically in a grid pattern. Make sure to cover the entire area to be treated in a painting motion.
- Treatments can be applied in conjunction with stretching or gentle range of motion exercises.
- For application to joints, it is recommended that 25 to 50% of the dose be applied while gently moving the joint through its range of motion.

4.11 Error Messages

4.11.1 Operation Errors

The laser system will display error messages to caution the operator to fault conditions. If any of the following errors occur, the laser system will remain in Standby mode, or return to Standby mode, produce an audible warning and display the related message describing the fault condition. The following are examples of these fault conditions:

- Optical fiber is not properly inserted
- Remote interlock is not properly installed
- Finger/foot switch is depressed

To proceed, correct the error and press the exit button.

4.11.2 System Errors

The system continuously monitors the output current of the diodes to ensure they are within the factory calibration settings. If it is detected that the electrical current levels exceed the upper limit that would result in 20% greater power output than selected, the laser will produce an error message and audible alert, stop emission and return the laser to **Standby** mode.

Note: When the laser pulse rate is CW, the real laser output power is the same as the power setting on the display within operating tolerances.

Note: When the laser pulse rate is not CW (e.g. 10 Hz), the average output power is 50% of the power setting on the display, within operating tolerances.

The laser system will not enter or remain in **Emission** if the laser system is not within the operating temperature range. If temperatures exceed safety limits:

- There will be an audible warning.
- There will be an error message: Laser temperature is out of range.

Press the **exit** button to return to **Standby** mode.

Make sure that the ambient temperature of the laser system is within the operating temperature range of the device, which is 5°C to 40°C (41°F to 104°F).

Note: Errors related to connectivity are only applicable to CTS DUO+ devices.

4.11.3 Connectivity Errors

The laser console continuously monitors the status of the connectivity module to determine whether it is plugged in and connected to Wi-Fi. Additionally, the connectivity module uses the email configuration to send the reports to the desired recipient email addresses. If any of these features are affected, the following errors will occur.

4.11.3.1 Wi-Fi Connectivity Error

Connectivity module not connected to Wi-Fi. Report will still be exported and queued.

If the connectivity module is not connected to Wi-Fi, this error will be displayed.

This error is only meant as a warning that connectivity will need to be re-established for the email to be sent. The report will still be exported and the email queued until 7 days have passed or Wi-Fi connectivity is restored. To correct this error, re-connect your connectivity module to Wi-Fi by turning it back on within connectivity range of the configured Wi-Fi or by reconfiguring the Wi-Fi network for the device.

4.11.3.2 Connectivity Module Detection Error

Connectivity module not detected by CTS DUO+.

Please re-connect the connectivity module to export treatment report. If treatment report export not desired, select Cancel.

If the connectivity module is not connected to the laser console, this error will be displayed.

To continue with exporting the treatment report, the connectivity module must be re-connected to the laser console. Once re-connected, selecting the "Retry" button will tell the laser console to re-verify the status of the connectivity module to confirm it is properly connected. If the laser console detects the connectivity module, the export process will continue. If not, the error will re-appear.

If you do not wish to export a treatment report, click "Cancel" and you will exit the export workflow.

4.11.3.3 Email Failure Error

Email failed to send!

Email failed to send due to email configuration error. Report has been exported and queued.

Please verify information in email configuration web application per the IFU or contact customer care.

If the email configuration for the connectivity device has inaccurate information, this error will occur.

The report will successfully be exported and the email queued until 7 days have passed or the email configuration has been corrected. For clarification on the error:

Step 1. On the CTS DUO+ home screen, click on the + indication. Your unique email configuration website link will be displayed (e.g., https://10.0.0.211) **(Figure 36)**.

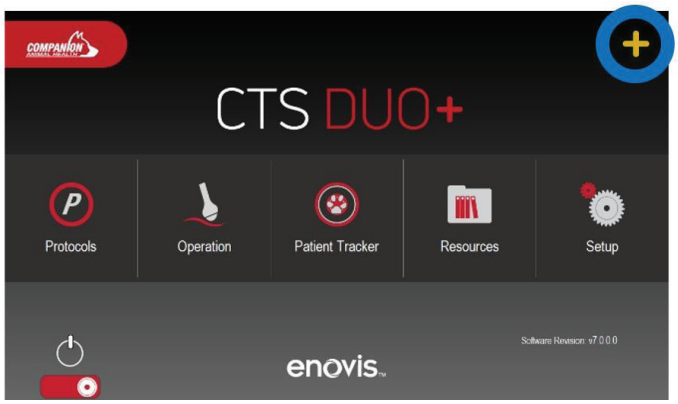


Figure 36

Step 2. In a web browser, enter the displayed hyperlink from the CTS DUO+ home screen to access the email configuration webpage. Login using your existing password **(Figure 37)**.

Note: If password has been forgotten or lost, go to section 9.3 to CTS DUO+ Email Configuration Password Reset.

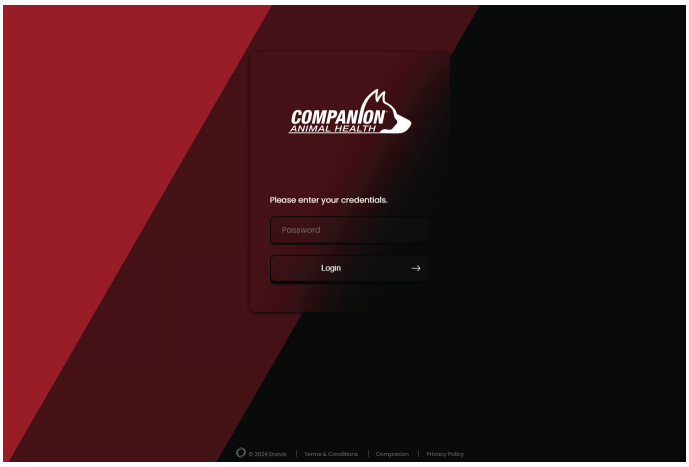


Figure 37

Step 3. In the email configuration webpage, confirm the screen indicates Ping Failed. Select the Configuration Page Icon (gear) in the upper left corner **(Figure 38)**.

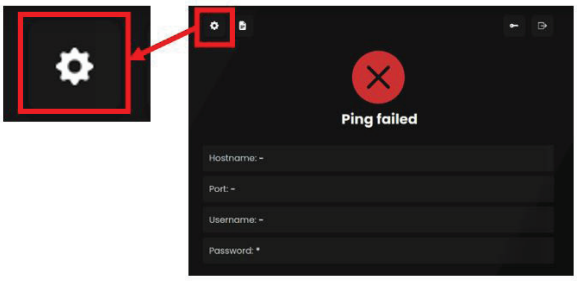


Figure 38

Step 4. Select the Send Test Email icon **(Figure 39)** on the lower right corner of the page.

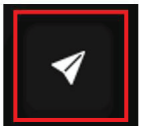


Figure 39

Step 5. Note the Email Configuration Error that is displayed and follow the steps for that specific error.

4.11.3.4 Email Configuration Errors

There are 3 types of email configuration errors that can occur:

- DNS Error
- Timeout Error
- Wrong Login/Pwd Error

DNS Error: Incorrect hostname entered in email configuration **(Figure 40)**.

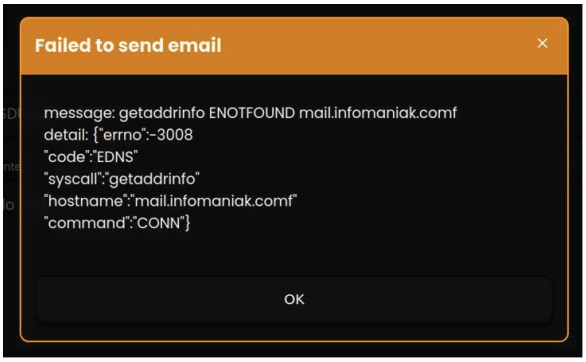


Figure 40

If you receive a DNS error, confirm the correct email address is listed under hostname with no spelling errors. If it is correct, send a test email by selecting the paper airplane icon in the lower right corner of the page. If the test email fails, please perform section 9.2 of this IFU on page 25 with a different email address or contact customer care for assistance.

Timeout Error: Incorrect port entered in email configuration **(Figure 41)**.

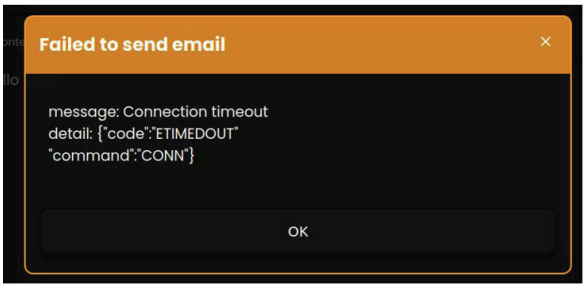


Figure 41

If you receive a DNS error, please perform section 9.2 of this IFU on page 25 to update the port or contact customer care for assistance.

Wrong Login/Pwd Error **(Figure 42)**: Incorrect username or password entered in email configuration.

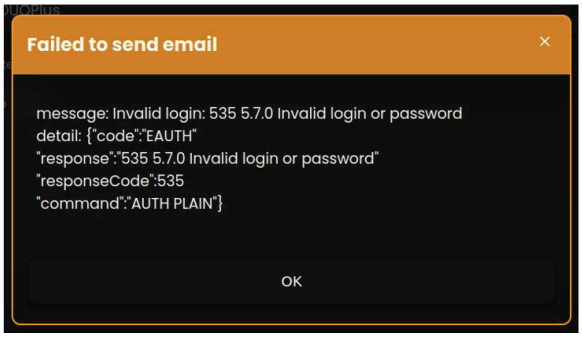


Figure 42

If you receive a DNS error, re-enter the password on the email configuration and try to resend a test email. If the test email fails, please perform section 9.2 of this IFU on page 25 to update the username or contact customer care for assistance.

5 POWER ON

After pressing the power button on the front of the console, there will be an audible beep and after initializing, the software displays the password screen **(Figure 43)**.

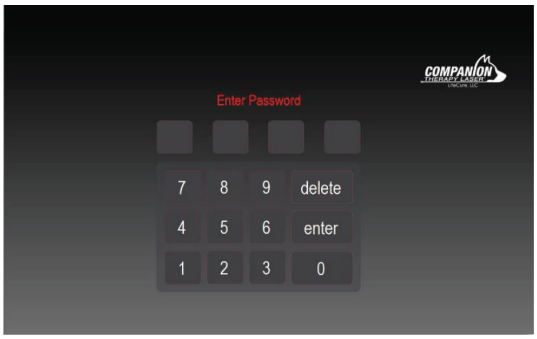


Figure 43

During initialization, the Emission Indicator Ring around the finger switch will flash blue three times (3x) to indicate successful connection to the Empower IQ Delivery System.

Note: When the laser pulse rate is CW, the real laser output power is the same as the power setting on the display within operating tolerances.

5.1 Main Menu

After entering the default password and pressing "**enter**," the user is taken to the Main Menu, which can be accessed in other screens by pressing the home icon in the upper left corner. User may also access the system using new Operator IDs created in Setup.

5.2 Setup

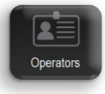
In **Setup**, the software allows the operator to change the aiming beam, unit volume, operation mode (finger/foot switch settings) and override settings. The user can also customize the language, measurement units, date/time/time zone to localize the device.

Note: CTS DUO+ added features are limited to the following languages: English, French and Spanish.

5.2.1 System Setup

Unit Volume – sets the sound that will occur during laser emission. The unit volume can be set to **low, medium, or high** with the option of a steady **Tone** or a **Beep.**

Operation Mode – sets how the operator controls the ON/OFF of laser emission. The operation mode can be set to **Foot Pedal** or **Finger Switch**.



Operators – allows user to create, edit or delete custom Operator IDs.

Note: Once assigned, a PIN cannot be changed and may only be permanently deleted. Deleting an Operator ID will delete all treatments associated with that PIN.

Note: Operator ID Numbers 9000-9999 are reserved for existing or future administrative features and may not be selected by Users as Operator ID Numbers.

Note: Once an Operator ID Number has been assigned, this new PIN (or the default "Guest" PIN "1234") may also be used to login to the laser at startup.

5.2.2 Handpiece Setup

Override - The Override can be used by advanced users who do not want to hold down the finger switch throughout the entire treatment. If the finger switch OVERRIDE setting is ON, pressing the finger switch for the first time will turn the laser emission on and laser emission will continue to emit until the finger switch is depressed a second time (or until the time remaining for laser emission counts down to zero).

Visual and Vibration Feedback – The Empower IQ has LED's that illuminate and the handle will vibrate to guide proper dosing technique. If Visual Feedback is turned Off, then the LED will remain white during emission. If Vibration Feedback is turned Off, then the hand piece will not vibrate when proper dosing technique is not followed. When both are turned On, the Empower IQ will behave as described in Section 3.5.

Aiming Beam – small pilot beam that provides the operator with a visual indication (red light) of the location of treatment beam. The aiming beam can be set to **Steady** or **Pulsed**.

Note: If a small treatment head is attached to an Empower IQ and the treatment power setting is above 6W, then the LED will illuminate Red regardless of the Visual Feedback setting. If Vibration Feedback is Off, though, the Empower IQ will not vibrate in this, or any, condition.

Set EIQ – If the Empower IQ is not illuminating or a new Empower IQ needs to be connected to the laser, then perform the following steps:

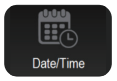
Step 1. Proceed to the Setup screen and press the "Handpiece" button on the right side of the screen. Then, press the "Set EIQ ID" button.
Step 2. On the following screen, enter the Empower IQ ID from the distal end of the hand piece and press Enter.

Note: If a treatment head is attached to the Empower IQ, it must be removed to reveal the ID. The ID will be alphanumeric and a maximum of 4 digits.

5.2.3 Localization Setup

Language – Allows user to select from English, Chinese, French, German, Japanese, Portuguese or Spanish.

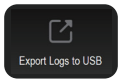
Measurement – Allows user to between Imperial or Metric systems of measurement.



Set Date/Time – Allows user to customize the date and time settings.

5.2.4 Diagnostics

Enhanced Logging – When toggled to the On position, allows for further logging verbosity for improved debugging information in the log files. Recommended setting for Enhanced Logging is Off. Spanish.



Export Logs to USB – Feature copies all log files to a USB drive. A USB drive must be inserted into the rear of the laser device before log files can be copied to the USB Drive. After clicking the "Export" button, a popup window will open confirming log files have been successfully transferred to the USB drive.surement.

Calibration Data – System will display "Calibrated For: PBMT Only" or "Calibrated For: PBMT and PTT" depending on if the CTS-DUO system is calibrated for Nanotherapy.tings.

5.3 Protocol Selection

After selecting **Protocols** on the **Main Menu** screen, the **Select Species** screen will prompt the user to select the species of the patient.

Next, the **Patient Characteristics** screen will prompt the user to enter patient characteristics that can affect the absorption or penetration of the light to the target tissue, including weight, body type, coat length, coat color, and skin color.

After the selection of patient characteristics, the user will be prompted to select the condition to treat.

Based on the condition selected, the user will be prompted to either:

1) Select the Area by Size,
2) Select Area(s) by Anatomy, or
3) The user will be taken directly to (Operation screen) Standby mode

Note: Only certain conditions will require selection of anatomic location – Arthritis, Pain/Trauma, and Edema/Swelling.

The software will determine the appropriate treatment power, treatment time and pulse frequency for the patient characteristics, selected area, and condition. Press **Next** or ➔ to proceed to **Standby** mode with the settings determined by the software. The selected parameters will appear on the right side of the screen.

5.4 Operation Screen (Protocols)

When using the preset protocols, the only parameter the user can modify is the **Power Setting**.

Each species/condition (protocol) selection also has recommended treatment heads programmed in that will be displayed underneath the power dial when the user reaches the operation screen. The colored rings around the treatment head icons indicate the appropriate treatment head(s) for the selected protocol and power setting. The following table summarizes the recommendation icons and their meanings:

Meaning	Large Ball	Large Cone	Small Ball	Small Cone
Recommended (Green)				
Exhibit caution (Yellow)	Large attachments will only appear Red or Green based on the protocol and power selection.			
Not Recommended (Red)				

During a multiple area treatment, after the treatment for one area commences, a pop-up screen will appear to prompt the user to move to the next area and resume treatment. If the area being treated, has the option of treating bilaterally, the user will be prompted once all of the one-sided treatments are complete.

- The protocols are based on a series of **Continuous Wave (CW)** or **Pulsed Rate** combinations. The "Time" section on the left side of the screen will display the time for the specific Pulsed Rate combination. The total time remaining will be displayed at the bottom of the screen.
- By selecting **Max TX**, which turns the **Max TX** button red **(Figure 44)**, all of the Pulsed Rate (if any) settings will be converted to Continuous Wave (CW). This will result in reduced treatment time.

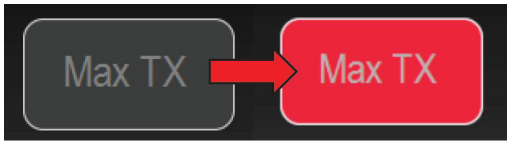


Figure 44

5.5 Operation Mode

Pressing **Operation** on the Main Menu will take the user to the Operation Screen and put the system in **Standby** Mode.

In **Standby** mode, the software allows the operator to change the treatment time, power, pulse frequency, and to reset the energy counter (**Figure 45**).

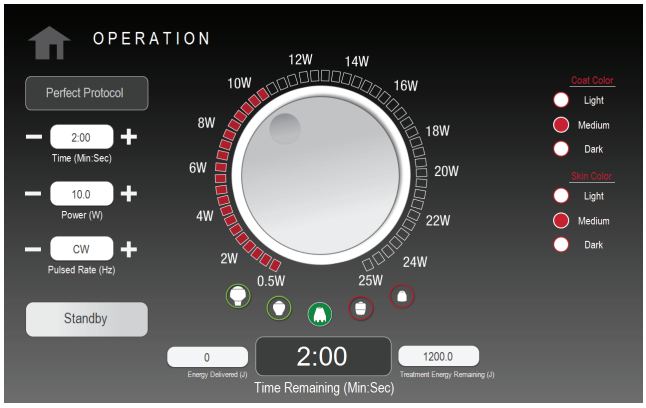


Figure 45

5.6 Operation Screen – Ready

In **Ready** mode, the laser will emit when the finger/foot switch is activated. The purpose of **Ready** mode is to wait for the user to press the finger/foot switch to start laser emission. The software has a 6 second delay (6 beeps) to warn the user of the transition from **Standby** to **Ready** mode.

Also, the Empower IQ Emission Indicator Ring will flash yellow during the transition from **Standby** to **Ready**. While in **Ready**, the light will remain yellow to indicate the laser state at the hand piece.

Warning: NEVER leave this device unattended in Ready mode.

To start laser emission, press the finger switch. To stop emission, remove finger from the finger switch or press finger switch again.

Note: If the unit is set up with finger switch override on, each time the finger switch is pressed, it will act as an on/off switch.

5.7 Operation Screen – Emission

During **Emission (Figure 46)**, the word "**EMISSION**!" blinks on the screen and the software does not allow the user to change any settings or exit the Operation screen. In addition, the laser system produces beeps or a steady audible tone, according to the audio settings chosen in **Setup**.

Figure 46

5.8 Operation Screen – Perfect Protocol™

In Operation mode, the Perfect Protocol button allows the operator to generate custom protocols **(Figure 47)**. The Perfect Protocol Calculator allows the operator to enter target treatment information (treatment area, treatment power, and target energy density) and the patient's coat color and skin color, and then calculates the appropriate treatment time and wavelength blend.

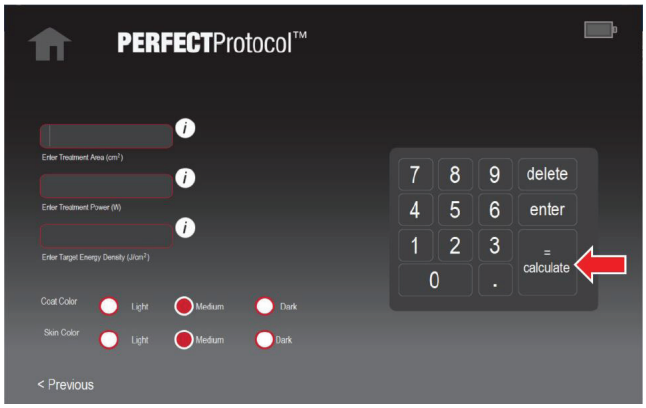


Figure 47

- The treatment area (in cm^2) should be entered in whole numbers.
- The treatment power can range from 1.0 W to 15 W in increments of 0.5 W.
- The energy density (in J/cm^2) should be entered in whole numbers.

After pressing **calculate** or **=**, the software proceeds to **Standby** mode with the selected settings.

6 RESOURCES

The laser system contains a library of resources that are available for educational purposes. Press **Resources** on the **Main Screen** to access the Resources menu.

- Press User Manual for instructions on how to view User Manual.
- Press **3D Anatomy** for high-resolution anatomical diagrams of the selected anatomy consisting of bone, muscle, and nerves for canine, equine, or feline species.
- Press **Video** for user training and patient education videos.

7 PATIENT TRACKER

Pressing **Patient Tracker** on the Main Menu will take the user to the **Patient Tracker Menu**. This menu gives the user access to the following options:

- Add a New Patient
- Search for Existing Patient
    - Edit or Export Patient Information
        - A folder named **Patient Tracker Reports** will be created on the USB drive and a PDF file containing the patient information and characteristics will be added.
    - View/Edit Patient Characteristics
    - Delete Patient
    - Start a New Treatment
    - View, Export, or Repeat Treatment
- Reports
- Delete, Backup or Restore Database
- Patient Tracker Settings
    - Save All Treatments, Track Operator IDs Settings

Note: The only way to save a treatment to Patient Tracker is by initializing the treatment by starting a new treatment through Add New Patient OR by starting a new treatment or repeating a previous treatment from Search for Existing Patient.

Note: For CTS DUO+, Backup and Restore Database functionality is disabled when the connectivity module is plugged-in to the laser console USB port.

8 CTS DUO+ WORKFLOW

Note: This workflow is only applicable to the CTS DUO+.

8.1 CTS-DUO to CTS DUO+ Mode

If the connectivity module is plugged in to the laser console USB port while the laser console is powered ON, the software application will identify its presence (can take multiple minutes). Once identified, the software will shift to CTS DUO+ mode. This will be evident by the updated logo on the home screen and the + sign indication in the upper right corner **(Figure 48)**.

Note: The + sign indication is yellow because the connectivity module is plugged in but not yet connected to Wi-Fi or email.

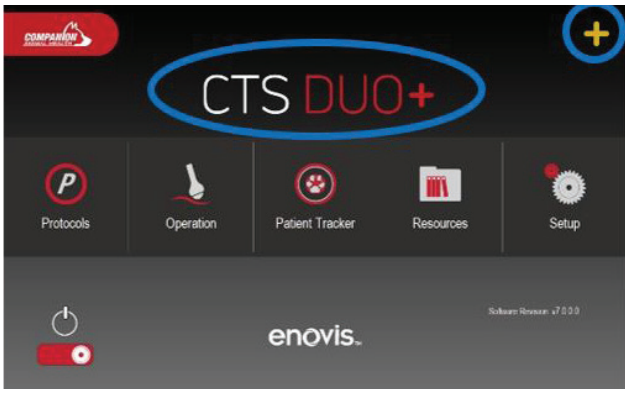


Figure 48

The CTS DUO+ provides the following functionality:

- With the Connectivity module plugged in and Wi-Fi and email is configured:
    - Upon completion of every laser therapy treatment, regardless of whether it has been initiated through Patient Tracker or not, treatment records will be automatically exported as a report and emailed to the configured clinic email address.
    - Patient Tracker Backup and Restore Database functionality is disabled.

- With the connectivity module plugged in and not connected to Wi-Fi:
    - Upon completion of every laser therapy treatment, regardless of whether it has been initiated through Patient Tracker or not, treatment records will be automatically exported as a report and queued to be emailed.
        - These reports will remain in the queue for up to 7 days.
        - If a report has been queued for 7 days without the Connectivity module reconnecting to Wi-Fi, the report will be deleted.
        - Once the connectivity module is reconnected to Wi-Fi, the queued reports will be automatically emailed to the configured clinic email address.
    - Patient Tracker Backup and Restore Database functionality is disabled.

- With the connectivity module not plugged in:
    - The CTS DUO+ will function the same as a CTS-DUO.
    - No reports will be generated from outside of Patient Tracker.
    - Patient Tracker reports are available for export with the use of a USB.
    - Patient Tracker Backup and Restore Database functionality is available with the use of a USB.

8.2 CTS DUO+ ConnectBox Status

The connection status of the connectivity module is denoted by a + sign indication in the upper right corner of the following screens **(Figure 49)**:

- Home
- Patient Record
- Patient Record: Treatment Details
- Reports by Operator
    - By Operator ID
    - By Condition(s)
    - By Patient Information
    - By Date Range

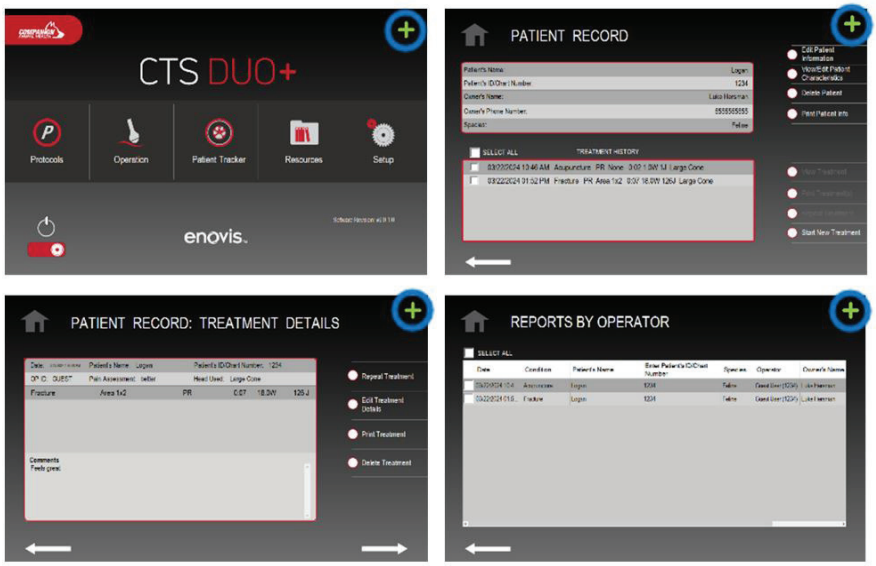


Figure 49

The different colors for the + sign indicate the status of the connectivity module:

Connectivity module plugged in and connected to Wi-Fi and email. Exported reports will be sent.

Connectivity module plugged in and not connected to Wi-Fi or email. Exported reports will queue.

Connectivity module is experiencing a software update and is unable to send emails during this time. DO NOT TURN OFF DEVICE DURING SOFTWARE UPDATE.

Connectivity module is not detected as plugged in. Laser software will operate as CTS-DUO.

9.1 CTS DUO+ Wi-Fi Configuration

Once the connectivity module is plugged in and powered on, the Wi-Fi connection is able to be configured.

To configure the Wi-Fi connection for the connectivity module, follow the steps below:

Step 1. Using a smartphone, computer, or tablet, select the wireless access point **Companion-Configuration-AP** under internet options.

Step 2. Connect to Companion-Configuration-AP using the following password: CTSDUOPlus. This will take you directly to the Wi-Fi configuration webpage **(Figure 50)**.

Step 3. On the webpage, select the Wi-Fi network you want to connect to and enter the Wi-Fi network password twice **(Figure 50)**.

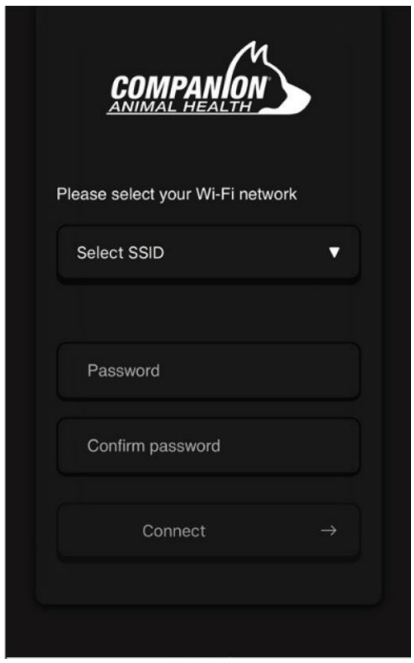


Figure 50

Step 4. When **"The device will try to connect"** is displayed, the device will try connecting. You can now close the browser **(Figure 51)**.

Figure 51

Step 5. On the ConnectBox, confirm that the green LED light is **ON** and the red LED light is **OFF**.

Note: If it has been 30 seconds since closing the browser and the connectivity module red LED is still **ON**, the configuration failed. Please restart this step.

9.2 CTS DUO+ Email Configuration

Step 1. On the CTS DUO+ home screen, click on the + indication. Your unique email configuration website link will be displayed (e.g., https://10.0.0.211) **(Figure 52)**.

Note: If password has been forgotten or lost, go to section 9.3 to CTS DUO+ Email Configuration Password Reset.

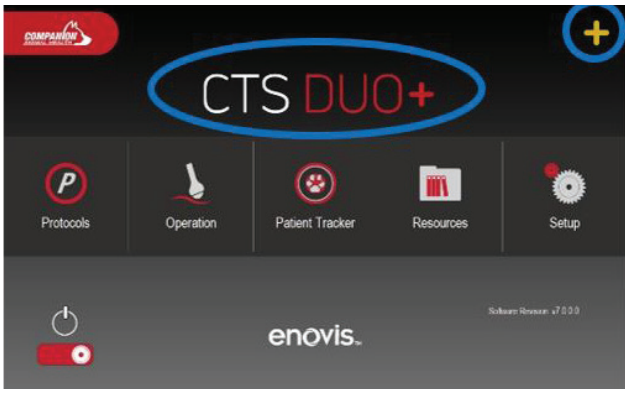


Figure 52

Step 2. In a web browser, enter the displayed hyperlink from the CTS DUO+ home screen to access the email configuration webpage. If you have previously configured your email, login using your existing password. If this is your first time logging in, use the default password: **CTSDUOPlus (Figure 53)**.

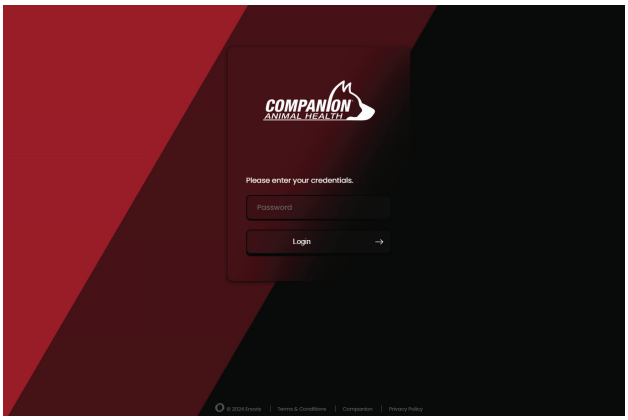


Figure 53

Step 3. If the email configuration password has expired or this is a first-time login, update the password meeting the following requirements **(Figure 54)**:

- 8 characters
- 1 uppercase
- 1 lowercase
- 1 special character
- Not same as previous password

Once your unique clinic password is set, DO NOT close the webpage.

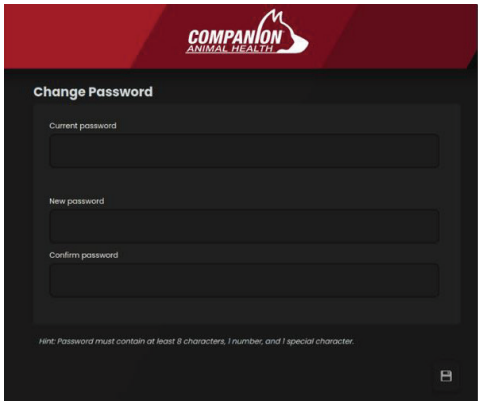


Figure 54

Step 4. In a separate tab from the configuration webpage, go to https://support.apple.com/mail

Note: This site can be accessed by any smart device (smartphone, computer, tablet) and any operating system.

Step 5. Under Mail Settings Lookup, enter the email address you would like to use as the sender email and select Verify. Information should display below showing Incoming Mail Server and Outgoing Mail Server information **(Figure 55)**.

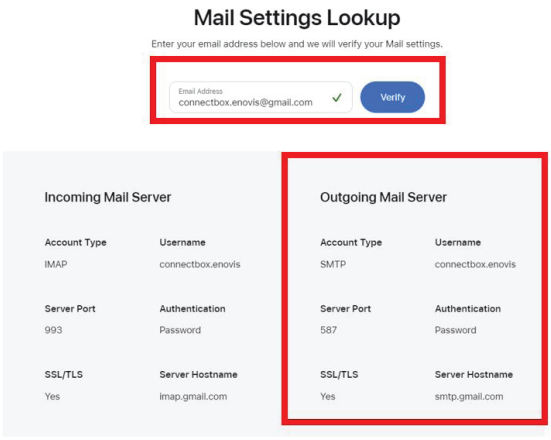


Figure 55

Note: The email address provided can be from either your clinic email server or an external provider (e.g., Outlook, Gmail).

Step 6. In the email configuration webpage, select the Configuration Page Icon (gear) in the upper left corner **(Figure 56)**.

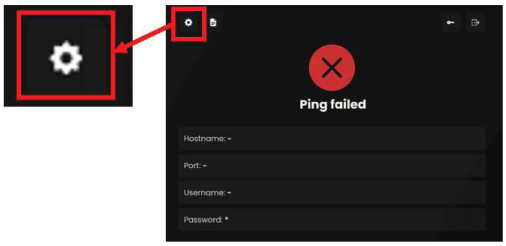


Figure 56

Step 7. On the **Configuration Page**, fill out the form fields using the Outgoing Mail Server information from the Mail Settings Lookup webpage **(Figure 57)**:

- **Server Hostname (required)**
- **Server Port (required)**
- **Username (required)**

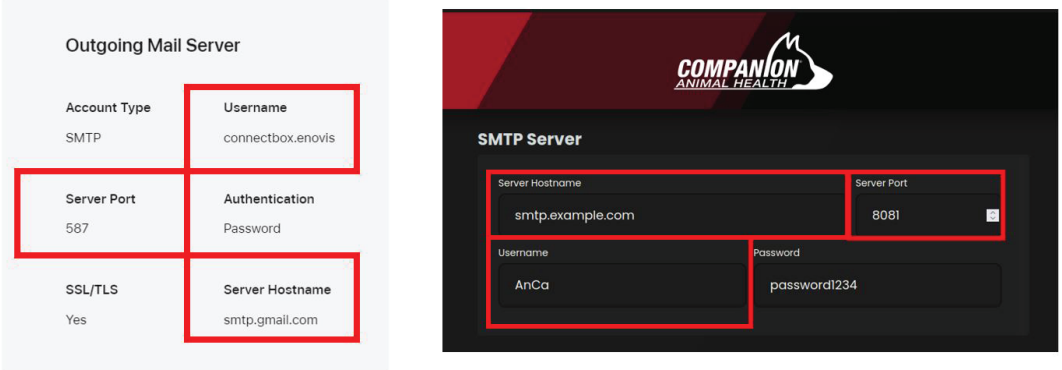


Figure 57

Step 8. Fill out the remaining fields as follows **(Figure 58)**:

- **Password (required):** Enter password for sender email account.
- **Recipient email address (required):** Enter all the email addresses you want treatment reports sent to.
- **Subject (required):** Enter the standard subject line you would like displayed for CTS DUO+ treatment report emails (e.g., Laser Treatment Report).
- **Content (optional):** Enter any standard email body content you would like added to the body of the emails.

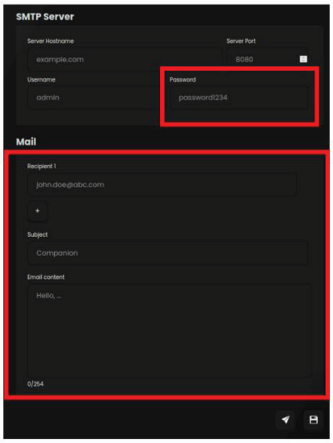


Figure 58

Note: The sender and receiver email addresses can be the same.

Note: A maximum of 4 email addresses may be entered for receiver separated with ','.

Step 9. Select Send Test Email **(Figure 59)**.

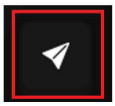


Figure 59

Step 10. Once a "Sent" confirmation is received on the webpage screen, check the inbox of the recipient email address and confirm receipt **(Figure 60)**.

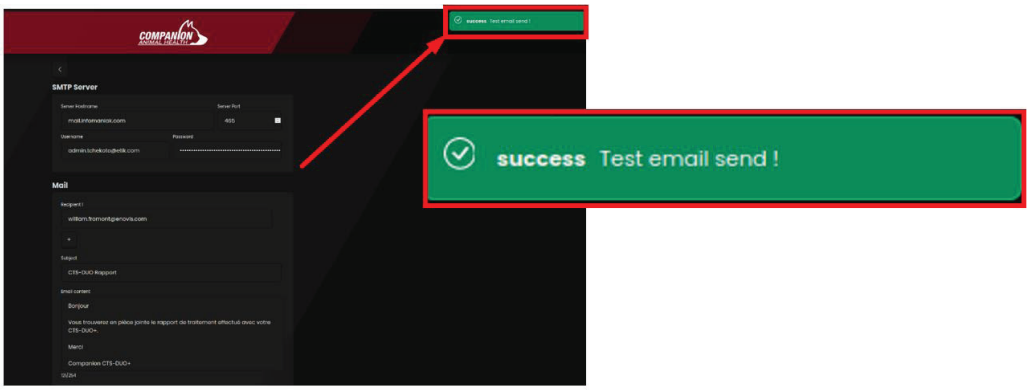


Figure 60

Step 11. Once a test email has been confirmed as sent and received, select "Save" to save the email configuration settings **(Figure 61)**.

Figure 61

Step 12. On the CTS DUO+ home screen, confirm that the + sign in the upper right corner has changed to green **(Figure 62)**.

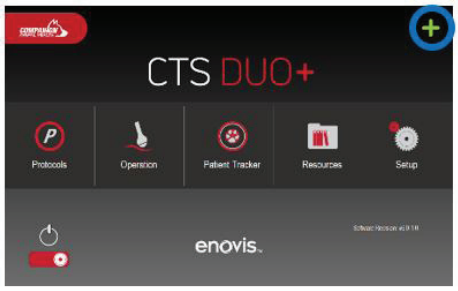


Figure 62

9.3 CTS DUO+ Email Configuration System Reset – Password Lost

If the email configuration password is forgotten, follow the steps below:

Step 1. On the CTS DUO+ home screen, click on the + indication. Your unique email configuration website link will be displayed (e.g., https://10.0.0.211) **(Figure 63)**.

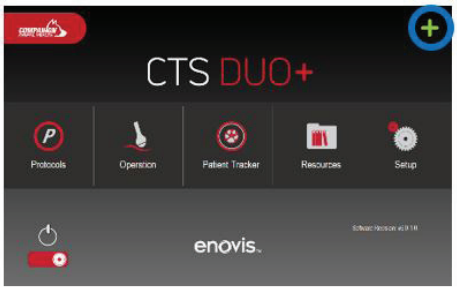


Figure 63

Step 2. In a web browser, enter the displayed hyperlink from the CTS DUO+ home screen to access the email configuration webpage and select **Terms and Conditions** on the lower portion of the screen **(Figure 64)**.

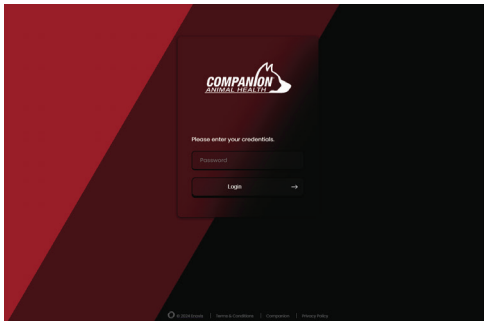


Figure 64

Step 3. On the Terms and Conditions page, select Reset to Factory in the lower right hand corner **(Figure 65)**.

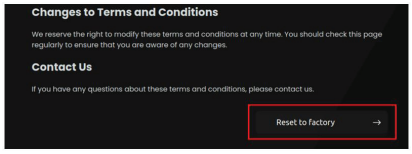


Figure 65

Note: Performing the next steps will reset the Email Configuration application ONLY. Any queued emails will be lost as will the previous application configuration. Once performed, email configuration will need to be reperformed using section 9.3 above.

Step 4. Fill in the form by typing in the required phrase as directed and select Reset to factory. The email configuration application is now reset **(Figure 66)**.

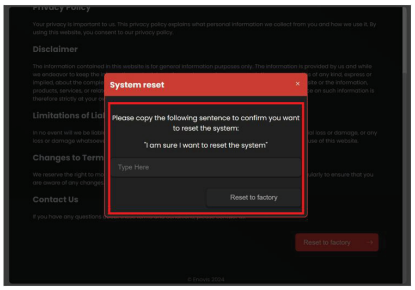


Figure 66

Step 5. When the next window box appears, select Yes to reset the system **(Figure 67)**.

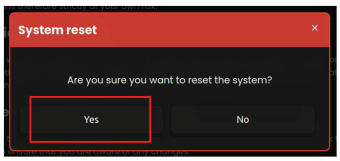


Figure 67

Step 6. Upon resetting the email application, reconfigure the email address for the connectivity module per section 9.3 on page 28.

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

10.1 Cleaning

Warning:
- Always turn off the laser system and unplug the power cord from the wall outlet before cleaning.
- Always use protective eyewear and gloves when cleaning and disinfecting any equipment.
- DO NOT use treatment head until alcohol solution used in cleaning procedure completely evaporates. Doing so may cause the laser to ignite alcohol solutions or vapors.

Caution: DO NOT clean the lens inside the hand piece. Doing so may damage the lens during laser emission.

Recommendation: Clean the contact treatment heads (large and small deep tissue applicators) between each treatment.

Note: The laser system uses solid-state laser technology. It is important to keep the unit and accessories free from dust.

10.1.1 Cleaning the Console

Step 1. Before cleaning the console, turn off the laser system and unplug the power cord from the wall outlet.

Step 2. The exterior surfaces of the unit and attachments can be cleaned by wiping with a soft, non-fibrous wipe (e.g., Kimwipes®) moistened with 70% isopropyl alcohol / 30% water solution.
- Ensure the solution is only 70% alcohol. Solutions of more than 70% alcohol can cause product damage.
- Avoid using soiled or gritty cloths.

Step 3. After cleaning, ensure that all cleansers have been removed and the parts are dry before use.

Figure 68

Warning: The vents of the connectivity module provide open access to the computer. Do not spray liquid or use damp cloths when cleaning the connectivity module to avoid liquid entering the casing and damaging the interior computer. USER-SERVICEABLE COMPONENTS inside this laser device.

10.1.2 Large Deep Tissue Applicator Cleaning

Step 1. Remove the elastic band from the large deep tissue applicator treatment head **(Figure 68)**.

Step 2. Unscrew the top portion of the large deep tissue applicator treatment head **(Figure 69)**.

Figure 69

Caution: Dropping the ball may damage the ball.

Recommendation: Be careful when unscrewing the top portion of the treatment head. It is recommended that this be done over a table to reduce the chance of dropping the ball directly on the floor.

Step 3. The ball can now be removed for cleaning. Use a soft, non-fibrous wipe (e.g., Kimwipes®) moistened with 70 % isopropyl alcohol / 30% water solution. Do not wipe with a dry cloth. Always dampen the cloth before wiping.

Step 4. Ensure that all cleansers have evaporated and the parts are dry before re-assembly and use.

Step 5. Reassemble treatment head by replacing the spacer ring, massage ball and screwing the top portion securely on the treatment head.

Figure 70

Note: Do not discard the spacer ring **(Figure 70)**. If the ring is upside-down or removed, the ball will rotate. It is recomended for the bacll not to move for veterinary applications.

Caution: Dropping the ball may damage the ball.

10.1.3 XL Deep Tissue Applicator Cleaning

Step 1. Remove the elastic band from the XL deep tissue applicator treatment head..

Step 2. Unscrew the top portion of the extra-large deep tissue applicator treatment head.

Recommendation: Be careful when unscrewing the top portion of the treatment head. It is recommended that this be done over a table or close to a soft surface to reduce the chance of dropping the ball directly on the floor.

Caution: Dropping the hemisphere may damage it.

Step 3. The hemisphere can now be removed for cleaning. Use a soft, non-fibrous wipe (e.g., Kimwipes®) moistened with 70 % isopropyl alcohol / 30% water solution. Do not wipe with a dry cloth. Always dampen the cloth before wiping.
Step 4. Ensure that all cleansers have evaporated and the parts are dry before re-assembly and use.
Step 5. Reassemble treatment head by replacing the hemisphere and screwing the top portion securely on the treatment head.

10.2 Before You Call—Troubleshooting

If you are having a problem with your laser system, please check the list below of common conditions that can occur that you may be able to resolve without having to contact Customer Care.

10.2.1 If the laser system will not turn on:

Make sure that the power cord is correctly attached and plugged into a functioning power outlet or that the battery is sufficiently charged.

Make sure that the remote interlock on the bottom of the laser system is properly inserted and wire loop is not damaged.

10.2.2 If there are scratches on the massage ball:

There may be minor scratches on the massage ball resulting from normal use. These will not affect the efficacy of the laser treatment. **Figure 71** shows a massage ball treatment head with a ball that has some minor scratches. If the scratches on the massage ball become significant, then the massage ball treatment head should be replaced (see **Figure 72**).

Figure 71

Figure 72

To minimize scratches, make sure that you use a soft, non-fibrous wipe (e.g., Kimwipes®) moistened with 70 % isopropyl alcohol solution when cleaning the massage ball between patients. Do not wipe with a dry cloth: always dampen the cloth before wiping.

10.3 Calibration Check Procedure

Regulatory agencies require that manufacturers of US FDA CDRH Class IIIb and IV laser products supply their customers with instructions for verifying the measurement system within the laser meets the requirements of 21 CFR1040.11. The instructions below provide steps for performing a calibration "check" that may be performed with certified, NIST traceable equipment.

This procedure is recommended to be performed once a year but is not required unless there is evidence of significant damage or diminished output.

If during the execution of this procedure, the stated requirements are not met, then factory maintenance and re-calibration may need to be performed on the device. Factory calibration must be performed by LiteCure®-certified Service Personnel.

Caution: Adjustment to any internal components by anyone other than certified LiteCure Service Personnel voids any existing manufacturer's warranty on the Laser System.

Warning: ALWAYS wear laser safety goggles when performing the laser calibration check procedure and follow all laser safety guidelines.

10.4 Laser Power Calibration Check Instructions:

Equipment Needed: Certified traceable power meter and detector with appropriate wavelength and power measurement capabilities

Step 1. Turn off the laser.
Step 2. Inspect and attach optical fiber. Make sure the optical fiber is clean and free of any dust, fluid or other contaminants.
Step 3. Turn on the laser system and enter Standby mode.
Step 4. Increase the power setting until it reaches the maximum wattage setting.
Step 5. Place the laser in Ready mode.
Step 6. Using the aiming beam, direct the distal end of the fiber into the active area of the power detector. Keep the fiber tip 2-3 cm away from the surface of the active area of the power detector.
Step 7. Activate the laser and record the value in watts from the power meter display. The laser power reading should be within ± 20% of the power setting.
   a. If the results are outside the 20% range, ensure that: all of the light from the fiber is entering the detector, the fiber is connected correctly, and the fiber is not damaged. Replace with a new fiber if necessary and repeat.
   b. If the results are still outside the 20% range, discontinue this procedure and contact Customer Care for assistance.

11.1 Laser Product Regulations

The Companion® laser system complies with 21 CFR Chapter 1, Subchapter J, as administered by the Center for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA).

11.2 Device Classification

According to the applicable standards, the laser system is classified as follows:

- Class I Type B device per EN/IEC 60601-1
- Class 4 laser product according to IEC 60825-1

In order to safely perform its intended use, the system requires the following Class I accessories:

- Empower™ Delivery System
- Laser Safety Eyewear

11.3 Declaration of Conformity (EU)

PRODUCT IDENTIFICATION		
Product name	Model/number	Description
Companion® CTS-DUO	LTS-2501-C-S8	Therapeutic laser system for animal use only

MANUFACTURER		
Name of company	Address	Representative
LiteCure, LLC	3300 Eagle Parkway Suite 170 Fort Worth, TX 76177 USA	Quality & Regulatory Manager

CE

LiteCure, LLC (the parent company of Companion®) declares under sole responsibility as the regulatory representative and legal manufacturer that the above-mentioned product is delivered in conformity with the following Council Directives as transposed in the national laws of the Member States through determination of compliance with the following standards:

CONFORMITY ASSESSMENT	
Legislation applied	Standards applied
Low Voltage Directive (2014/35/EU) Electromagnetic Compatibility Directive (2014/30/EU)	Safety: IEC 60601-1:2005+A1:2012 EMC: IEC 60601-1-2:2015 Usability: IEC 60601-1-6:2010+A1:2013 Laser: IEC 60601-2-22:2007+A1:2013 Laser: IEC 60825-1:2014

12 SPECIFICATIONS AND ENVIRONMENTAL CONDITIONS

12.1 Device Specifications

Model Name	Companion® CTS-DUO
Model Number	LTS-2501-C-S8

Device Classifications			
Electrical Equipment		Class I Type B device per EN/IEC 60601-1	
Laser Product		Class 4 laser product per IEC 60825-1	
User Interface			
Touch Screen Display		10" HD Display with Touch Screen	
Emission Indicator		Audible Signal (50 to 75 dB), LED (front display)	
Mechanical Specifications			
Dimensions		43 cm (L) x 26 cm (W) x 28 cm (H) | 17 in x 10 in x 11 in	
Weight		8.6 kg | 19.6 lb	
Environmental Specifications			
Operation temperature		10°C to 35°C	
Storage temperature		-20°C to 70°C	
Humidity		≤ 80% RH Non-Condensing	
Pressure		70-106 kPa	
Cooling		Thermal Electrically Cooled with Forced Air	
Optical Specifications			
PBMT	Treatment Wavelengths	980 nm ± 20 nm & 810 nm ± 20 nm	
	Skin/Coat Color Adjustments	Light (I, II) or Medium (III, IV)	Dark (V, VI)
	Maximum Output Power	25 W	25 W
	Wavelength Ratio	80% of 980 nm + 20% of 810 nm	100% 980 nm
PTT	Photothermal Therapy (PTT) Output & Wavelength	Up to 12 W of 810 nm only	
Aiming Beam Output		Red Diode Laser, <4.0 mW	
Aiming Beam Wavelength		650 nm ± 20 nm	
Operating Modes		CW or Pulsed	
Pulse Frequency		2, 10, 20, 100, 200, 500, 1000, 2500, 5000, 10000 Hz	
Pulse Duration		50% duty cycle at any given pulse frequency setting	
Laser Safety Goggles		OD5+ 808nm & 980nm	
Electrical Specifications			
Input Voltage		100-240 VAC; 50/60 Hz	
Input Current		≤ 400 VA	
Beam Delivery Assembly (BDA) Specifications			
BDA Model		Empower IQ Delivery System	
Handpiece Assembly (-S8)		Smart hand piece (SHP) with 800µm fiber core	
Empower IQ Attachments		Small Massage Ball-IQ, Large Massage Ball-IQ, Small Cone-IQ, Large Cone-IQ, Extra Large Hemisphere-IQ *(NOTE: "-IQ" indicates the attachment is the quick disconnect version with RFID tag)*	

12.2 Accessories

Warning: Do not use any accessories and/or cables not specified or sold by Companion as replacement parts. Use of unauthorized accessories and/or optical fibers not specified or sold for use with this system may result in unsafe treatment emissions or damage to the laser system.

Item	Description	Image
Beam Delivery Assembly	Double-sheathed 600 µm core fiber Empower-IQ hand piece & dust cap	
Beam Delivery Attachments	Small Non-Contact	
	Small Deep Tissue Applicator	
	Large Deep Tissue Applicator	
	Large Non-Contact	
	XL Deep Tissue Applicator	
Foot Switch	Medical grade foot switch with safety cover and 7 pin circular connection plug	
Safety Goggles	808 nm and 980 nm OD 5+ Over glasses	
Safety Goggles	808 nm and 980 nm OD 5+ Regular	
Power Cord	Medical Grade Power Cord, 2.9 m	
Doggles Kit	808 nm and 980 nm OD 5+ Doggle Sizes: XS, S, M, L	
CTS DUO+ Installation Kit	ConnectBox, USB 2.0 cable, Fabric fastener zip tie, Fabric fastener adhesive loop and hook	

12.3 Electromagnetic Compatibility (EMC) Tables

This laser system has been tested to comply with the requirements of EN 60601-1-2 for electromagnetic compatibility (EMC). The following pages list the tests performed and corresponding test levels. Also provided are guidance statements that give recommendations on equipment use. Guidance statements (those listed in the right-most column of the charts below) are not requirements for use of this product. The user, operator, installer, or assembler of this product is advised of the following:

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the information provided in this document.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use only the power cord provided with this product, or an alternate approved by LiteCure®.

Warning:

- The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of this product.
- Equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.to ignite alcohol solutions or vapors.

Caution: Adherence to the EMC guideline information provided in this manual and verification of all medical devices in simultaneous operation are required to ensure the electromagnetic compatibility and coexistence of all other medical devices prior to a laser therapy treatment.

12.4 Table: Guidance and Manufacturer's Declaration – Emissions

This laser system is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The **CTS-DUO** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Group 2	The **CTS-DUO** must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A or B	A
Harmonics IEC 61000-3-2	Class A, B, C, D or N/A	A
Flicker IEC 61000-3-3	Complies or N/A	Complies
RF Emissions CISPR 14-1	Complies	The **CTS-DUO** is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The **CTS-DUO** is not suitable for interconnection with other equipment.

12.5 Immunity Test Summary – For All Equipment and Systems

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD EN/IEC 61000-4-2	±6 kV Contact ±8 kV Air	As specified	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30 %.
EFT EN/IEC 61000-4-4	±2 kV Mains ±1 kV I/Os	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	±1 kV Differential ±2 kV Common	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout EN/IEC 61000-4-11	>95 % Dip for 0.5 Cycle 60 % Dip for 5 Cycles 30 % Dip for 25 Cycles >95 % Dip for 5 Seconds	As specified	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **CTS-DUO** requires continued operation during power mains interruptions, it is recommended that the 35700 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field EN/IEC 61000-4-8	3 A/m	As specified	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

12.6 Table: Guidance and Manufacturer's Declaration – Immunity – For Non-Life- Supporting Equipment

The CTS-DUO is intended for use in the electromagnetic environment specified below. The customer or user of the CTS-DUO should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000- 4-6 Radiated RF IEC 61000- 4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)Vrms (E1)V/m	Portable and mobile communications equipment should be separated from the **CTS-DUO** by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

12.7 Table: Recommended Separation Distances

The device is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Below is the table of recommended separation distances between portable and mobile RF communications equipment and the device and systems that are not life-supporting.

Max Output Power (watts)	Separation (m) 150 kHz to 80 MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800 MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800 MHz to 2.5 GHz D=(7/E1)(Sqrt P)
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.666	11.666	23.333

12.8 Disposal

If you plan to discontinue the use of this laser system and intend to dispose of it or any of its parts or accessories, you must observe the applicable regional legal provisions for its disposal. You may also contact your local distributor, authorized service center, or LiteCure® Customer Care for more information regarding the disposal of this laser system.

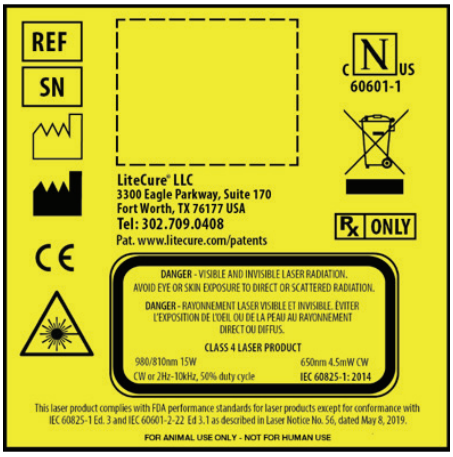
13 LABELING

13.1 Explanation of Symbols

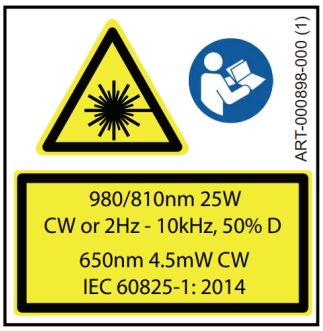
Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/386/EEC, 93/42/EEC and 98/79/EC.
	Authorized representative in the European Community	Indicates the Authorized representative in the European community.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Catalog number	Indicates the manufacturer's catalog, or model, number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Type B Applied Part	Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.
	Do not dispose in unsorted municipal waste (WEEE)	Equipment must not be disposed of as unsorted municipal waste.
	Laser Warning	Warning label for class 2 and higher laser radiation
	Remote interlock connector	Identifies remote interlock connection port
	Foot Switch	Identifies connection port for foot switch
	Optical fiber applicator	Identifies connection port for hand piece fiber
	Emergency Stop	Button used to terminate laser emission and shutdown the device in the event of an emergency.
	Fuse	To identify fuse boxes or their location. ***Note:*** *Not user replaceable.*
	Protective earth (ground)	To identify any terminal which is not intended for connection to an external conductor for protection against electrical shock in case of a fault, or the terminal of a protective earth (ground). ***Note:*** *This is located inside the device.*
	Follow Instructions	Indicates the need for the user to consult the instructions for use prior to operating the device.
	Power On/Off	Push/push power button

	USB Port	Connection for software updates, Instant Replay Backup / Restore, and ConnectBox
c N us 60601-1	Nemko-CCL Safety Mark with NRTL indicators	Indicates compliance with the Certification Body (Nemko-CCL) requirements regarding Electrical Safety (60601-1) in the US and Canada
Rx ONLY	Prescription devices	CAUTION – Federal law restricts this device to sale by or on the order of a licensed practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.
CE	CE Marking of Conformity	Certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.
FC	Federal Communications Commission Mark	This device complies with Part 15 of the FCC Rules. Operations 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.

13.2 Laser Product Label

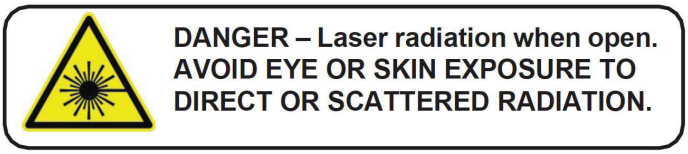


13.3 Therapy Laser 25W Label

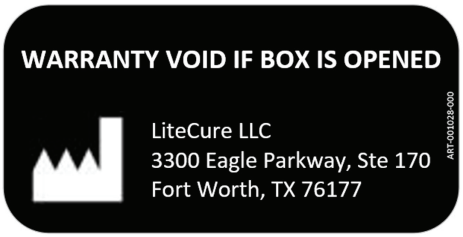


13.4 Warranty Seal

13.5 Non-Interlocked Protective Housing Label



13.6 CTS DUO+ ConnectBox Product Label



13.7 CTS DUO+ ConnectBox FCC/IC Label

14.1. Cancellation Fees

If Customer cancels or modifies the Order prior to Seller's shipment of the Order, a restocking fee of 25% of purchase price will be charged for returns to stock. Orders are non-cancellable once shipped by Seller. Unless agreed to in writing by a duly authorized representative of Seller, Seller objects to, and is not bound by, any term or condition in any Order or other document submitted by Customer that differs from or adds to the terms of the Agreement.

14.2. Warranty Coverage and Exclusions

14.2.1. Standard Warranty

Companion® laser products and components are warranted to be free from defects in materials and workmanship for a period of time specified within your sales order agreement. The warranty term will start from the date of the initial
shipment. Companion's liability under the standard warranty is limited to the following components:

- Laser internal and external components
- Laser diodes, laser hand piece, fiber and treatment heads
- Companion shall replace, or repair, any part during the original warranty period.

Products replaced under warranty will be warranted only for the balance of the warranty period for the plan under which such replacement was provided to the customer.

This warranty extends only to the original purchaser of the equipment from Companion Animal Health. The purchaser must notify Companion 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 with the transportation and insurance prepaid by purchaser. Repaired or replaced products will be returned to purchaser by Companion, 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 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'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.

Subject to the terms below, Seller provides the following limited warranty for the products. Seller warrants to the purchaser that any products purchased from Seller will be free from defects in materials and workmanship during the warranty period applicable to each such product. Warranty periods, which vary by product and/or product component, may be obtained by calling Seller's Customer Care Department at (302) 709-0408. The warranty period commences on the date of delivery to Customer. Seller's sole obligation for this limited warranty is to repair or replace a defective part or product at no charge to Customer, at Seller's discretion. This limited warranty does not apply if the defective product (a) is subject to abuse, neglect, misuse, or accident, (b) has not been used in accordance with Seller's written instructions for use (IFU), © was not purchased from Seller or an authorized dealer of Seller, or (d) was modified from its original configuration or repaired or altered by anyone other than Seller or a person authorized by Seller. Other warranty terms and limitations or service plans may apply to certain products.

SELLER HEREBY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTIES NOT SET FORTH IN THE FOREGOING LIMITED WARRANTY, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. SELLER WILL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OR LOST PROFITS, CAUSED BY ANY PRODUCT DEFECT WHETHER CLAIMS ARE BASED UPON TORT (INCLUDING NEGLIGENCE), WARRANTY, CONTRACT OR OTHERWISE, EVEN IF SELLER HAS BEEN ADVISED OF SUCH POTENTIAL LOSS OR DAMAGE. IN NO EVENT WILL THE AGGREGATE LIABILITY OF SELLER ARISING OUT OF OR RELATED TO THE AGREEMENT EXCEED THE TOTAL AMOUNT PAID BY CUSTOMER FOR THE ORDER. TO THE EXTENT THE FOREGOING DISCLAIMERS ARE NOT ALLOWED BY APPLICABLE LAW, ANY IMPLIED WARRANTIES WILL BE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY APPLICABLE TO THE PRODUCT. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES SO THE ABOVE LIMITATIONS MAY NOT APPLY TO CUSTOMER.

Customer must inspect the exterior of each shipping box upon delivery and notify Seller of any visible damage within 15 days. Any product damage
or discrepancies in quantity, sizing, or other omissions must be reported to Seller within 15 days of Customer opening the shipping box(es) or product installation by Seller, whichever is earlier. Failure to give such notice will constitute acceptance of the products.

Accessories purchased subsequent to the acquisition of a laser console, such as the ConnectBox, which are intended to work with the existing laser console will be warranted only for the balance of the warranty period for the plan under which the existing laser console is covered. Any extended warranty purchased for the laser console will also cover any accessories purchased for use with the laser console. Additional extended warranties may be purchased when the initial warranty subsides.

14.2.2 Extended Coverage

Companion may offer extended warranty or service plans for additional years beyond the duration of the Standard Warranty to provide coverage and support to certain products. Please contact Companion using the contact information provided on the back cover or your local representative for details.

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, or
(iii) Original identification markings, labels have been removed, defaced or altered, or
(iv) Any other claims not arising directly from defects in material or workmanship.

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

IN NO EVENT SHALL LITECURE 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.

14.2.3 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.
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.
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.

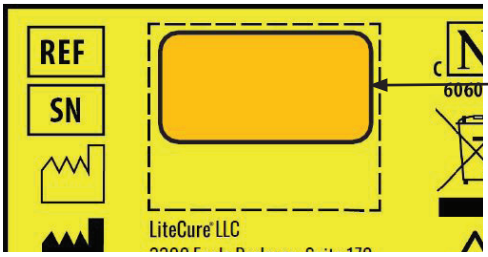
15 CONTACT INFORMATION

For immediate assistance, contact Customer Care directly. For medical/clinical inquiries only, please contact: medicalassistance@companiontherapy.com

If this laser system does not function as expected and/or if the laser system malfunctions, contact Customer Care.

Before you call, please have the following information so that Customer Care can provide you with the highest level of service:

1. Customer Account Number: _____
2. Model (REF) : _____
3. Serial Number (SN) : _____



Model (REF) and Serial Number (SN) of the device are found on the label located underneath the device.

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