EMERALD

LASER

Operation & Maintenance Manual

Read this entire booklet before using your Erchonia® EMERALD Laser

READ THIS FIRST

To ensure proper use, and to achieve your best results, it is important that you read and understand the instructions, warnings, precautions and safety information in this booklet before using your Erchonia EMERALD Laser for the first time.

	This symbol appears next to information about possible safety risks.

Questions? Our Erchonia Customer Care representatives are available to help. Contact us at:

Erchonia Customer Care
Phone: 321-473-1251
Email: info@erchonia.com

Or visit **erchonia.com**

Erchonia Europe Customer Care
Phone: +44 (0)1491 821135
Email: info@erchoniaeurope.com

Or visit **erchonia.com**

ATTENTION: By purchasing this Erchonia device, you, the licensed health care professional, acknowledge that you are solely responsibly to ensure: (i) that your use of this device is within the scope of your professional practice; and (ii) that you use the device in accordance with all applicable laws, rules, and regulations, including without limitation, any regulations promulgated by any state medical or professional board applicable to your practice.

We recommend you periodically contact Erchonia Corporation to determine if additional product information updates are available.

Table of Contents

SECTION 1 GENERAL INFORMATION

This Erchonia® Emerald Operator's Guide is designed to take you through set-up and proper use of your Erchonia® Emerald (Model# SHL) device. It will cover Assembly, Proper Placement of Diodes, Treatment Protocol, Cautions and Warnings.

It is important that you read and understand all of the information contained in this operator's guide before performing any treatments with the Erchonia® Emerald device. Please thoroughly read the CAUTION and WARNING sections. If you have any questions, contact our Erchonia Customer Care representatives.

ERCHONIA® EMERALD TECHNOLOGY BACKGROUND

WHAT IS ERCHONIA® EMERALD?

The Erchonia® Emerald (Model# SHL) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) of up to 40 kg/m^2.

The Erchonia® Emerald is a new non-invasive body slimming procedure designed to slim the body without surgery, pain or needles. The Erchonia® Emerald allows patients to continue daily activity without interruption.

Clinical data on safety and effectiveness has only been generated for waist, hips, thighs, and upper abdomen from the clinical trials conducted on the predicate device(s) with which substantial equivalence has been claimed (the Erchonia® SHL Laser and the Erchonia® Zerona 2.0). Presently there does not exist clinical data on safety or effectiveness for other parts of the body.

Laser devices are typically constructed to emit a "spot" of light. The Erchonia® Emerald utilizes internal mechanics that collect the light emitted from the laser diode and process it through a proprietary patented lens, and then redirects the beam with a line refractor. This process produces a line 7 mm wide with a length of approx. 152 mm at 6 in (15.2 cm) away (rounded up to .0001 joules per cm^2 / second). With the treatment time being 30 minutes, the total fluence of all lasers is 288J and the total treatment area of all lasers is 5161.28cm^2.

The Erchonia® Emerald is a floor model, electromechanical device. The device is designed for the physician to easily maneuver and position the laser heads around the area with the greatest collection of fatty material. The laser head assembly is attached to the main arm that is manually raised and lowered. The user interface is a touch screen which communicates with the PCB to initiate, stop or pause the energy flow to the diodes. The diodes can only be on or off; there is no user interface that allows the end user to alter the diode output. The protocol software is factory set and cannot be altered by the end user.

HOW DOES ERCHONIA® EMERALD WORK?

The Erchonia® Emerald works by using a patented and clinically proven low-level laser technology. The Erchonia® Emerald emulsifies fat within the adipose tissue which is then released into the interstitial space. The excess fat is then passed through the body during its normal course of detoxification.

PACKAGE CONTENTS

Erchonia® EMERALD is shipped in one large packing box with:

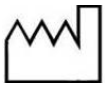
- Erchonia® EMERALD device
  - SHL device base
  - SHL laser head assembly

  Device Accessories (plastic bag)
  - Laser safety glasses (1) Patient & (1) Operator
  - Tape measure
  - Manual
  - Power cord
  - Large Screws (2)
  - 1/8 (Large) Allen Driver
  - Small Screws (4)
  - 1/16 (Small) Allen Driver
  - Wire Cover Plate
  - Arm Cover Overlay

When you receive the shipment, carefully inspect the container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the device has been checked for proper function. If the contents are incomplete or if there is mechanical damage, contact Erchonia Corporation. If the shipping container is damaged, also notify the carrier.

SYMBOLS USED ON THE EQUIPMENT

Any or all of the following symbols may be used in this manual or on this equipment:

SYMBOL	DESCRIPTION
	Temperature Limitation
	Type B patient connection - applied parts that are generally not conductive and can be immediately released from the patient.
	**Conformité Européenne** - Complies with EMC 2014/30/EU and LVD 2014/35/EU
	Power ON
	Power OFF
	Date of Manufacture
	Manufacturer
	Authorized representative in the European Community.
	Refer to Operating Instructions/ Follow Instructions for Use
	**Magnetic Resonance Unsafe** – device should not enter an MRI scanner room
	**Warning** alerts you about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
	**Caution** is used for the statement of a hazard alert that warns you of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
	Pinch point-keep hands clear
Rx Only	Prescription only (In the US, Federal law restricts this device to sale by or on the order of a physician)
	Do not Push-No pushing in this direction
	Do not stare into laser beam

SAFETY INFORMATION

Read the following important safety information before using the Erchonia Emerald laser.

WHEN NOT TO USE (CONTRAINDICATION)

	Laser treatment should not be applied over, or in proximity to (near), cancerous lesions as conclusive tests have not been conducted.
	Safety of non-thermal lasers for use over a pregnant uterus has not been established.
	DO NOT treat the face, neck or breast
	**DO NOT** use on patients who: ➢ Have a personal or family history of cancer ➢ Have a history of keloid or hypertrophic scar formation ➢ Have a history of herpes simplex ➢ Have active infections or a compromised immune system ➢ Are taking photo-sensitizing drugs, anti-coagulants, or aspirin

WARNINGS

	You must follow these Instructions for Use when using the Erchonia® Emerald Laser. Not following these instructions may result in serious injury.
	**DO NOT** permit any foreign materials or liquids to enter the device. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from entering the device. These may cause device damage, malfunction, electrical shock, fire, or personal injury.
	**DO NOT** disassemble, modify, or remodel the device or accessories. This may cause device damage, malfunction, electrical shock, fire, or personal injury.
	**DO NOT** submerge any part of the device in water. This could damage the device or cause an electric shock that may lead to serious injury or death. Damage resulting from this condition is not covered under the warranty.
	Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to re-orient or relocate the ME equipment or shield the location. The long-term effects of prolonged use of non-thermal laser exposure are unknown.
	Dispose of device in accordance with local and national regulations and codes. When spent and beyond repair or functional use, the device can be sent back to the manufacture for disposal. This ensures the proper separation and handling of all the internal parts and reduces any risk to the end user and the environment.
	DO NOT use this device in an oxygen enrich environment. Avoid contact with flammable anesthetic with air or with oxygen or nitrous oxide. This device is not intended and was not tested for use in this environment.

	**WARNING**-The equipment will overbalance at 10° under normal operation. It shall not be operated at a plane inclined angle of more than 5°.
	**DO NOT** use this device in an MRI environment

CAUTIONS

	In the US, Federal law restricts this device to sale by or on the order of a physician.
	This device should only be used under the supervision of a suitably qualified and licensed healthcare professional.
	**DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the touch screen as damage may result.
	**DO NOT** place/operate this device in close proximity (15 cm) to other devices that emit frequency.
	Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any laser device. Observe the precautionary and operational decals placed on the device.
	Failure to use and maintain the Erchonia laser and its accessories in accordance with the instructions outlined in this manual will void your warranty.
	There are no user-serviceable parts inside the device. If a malfunction occurs, discontinue use immediately and contact Erchonia Corporation for repair service.
	If you have difficulty operating the device after carefully reviewing this user's manual, contact Erchonia Corporation for assistance.
	Portable and mobile RF communications equipment can affect ME Equipment
	Caution should be used over areas of skin that lack normal sensation
	To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth. Make certain that the device is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
	Laser protective eyewear should be worn by the patient to block light energy from the eyes during treatment. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging.

	**DO NOT** position the equipment so that it is difficult to disconnect the power cord.

NOTIFICATION OF ADVERSE EVENTS

As a health care provider, you may have responsibilities under the Medical Device Reporting for User Facilities for reporting to Erchonia ® Corporation, and possibly to the FDA, the occurrence of certain events. These events, described in 21 CFR Part 803, include device-related death and serious injury or illness.
As part of our Quality Assurance Program, Erchonia® Corporation requests to be notified of device failures or malfunctions. This information is required to ensure that Erchonia ® Corporation provides only the highest quality products.

EMERALD LASER INDICATIONS FOR USE

The Erchonia® Emerald (Model#: SHL) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) of up to 40 kg/m^2.

EMERALD LASER SPECIFICATIONS

- Configuration: 10-Certified Class 2 Line Generated Laser Diode Modules
- Wavelength: 520-542nm
- Modulation: Constant Wave (CW)
- Display: Full Color TFT Touch Screen Control Center
- Adjustments:
    - Two Independent Adjustable Arms for Desired Laser Concentration
- Power Source: 100-240VAC, 50-60Hz, 1.5/0.5A
- Chassis:
    - Anodized Metal Frame
    - 4 Anti-Static Casters (4 Locking)
- Housing: High strength, flame retardant Urethane Plastic
- Weight: 118.5 lbs. / 53.75 kg

TECHNICAL INFORMATION

Technical documentation required by the customer, in case of necessary reparations, will be provided by Erchonia ® Corporation in the US and our EU agent, internationally. These documents will be supplied once the manufacturer makes the determination that the requested documents do not constitute a disclosure of proprietary or patent protected information and are a part of the documented technical file.

SERVICE AND REPAIR

If a device requires service, contact the Erchonia® Service and Repair Department at:

Telephone: 1-888-242-0571 (US only)
1-321-473-1251

When requesting service or repair, please provide the following information to the service representative:

- Device serial number (located on the back label)
- Description of the problem
- Name of the person to contact

RETURNING A DEVICE FOR SERVICE

- Before sending a device to the Erchonia® Service and Repair Department for repair, obtain a service order (SO) number from the service representative.
- Pack the device in the original containers (if available) or equivalent packaging. Be sure the assigned service order number appears on the package.

RETURN THE DEVICE TO:

Erchonia® Corporation
650 Atlantis Rd
Melbourne, FL. 32904
Attention: Service and Repair Department *(SO Number)*

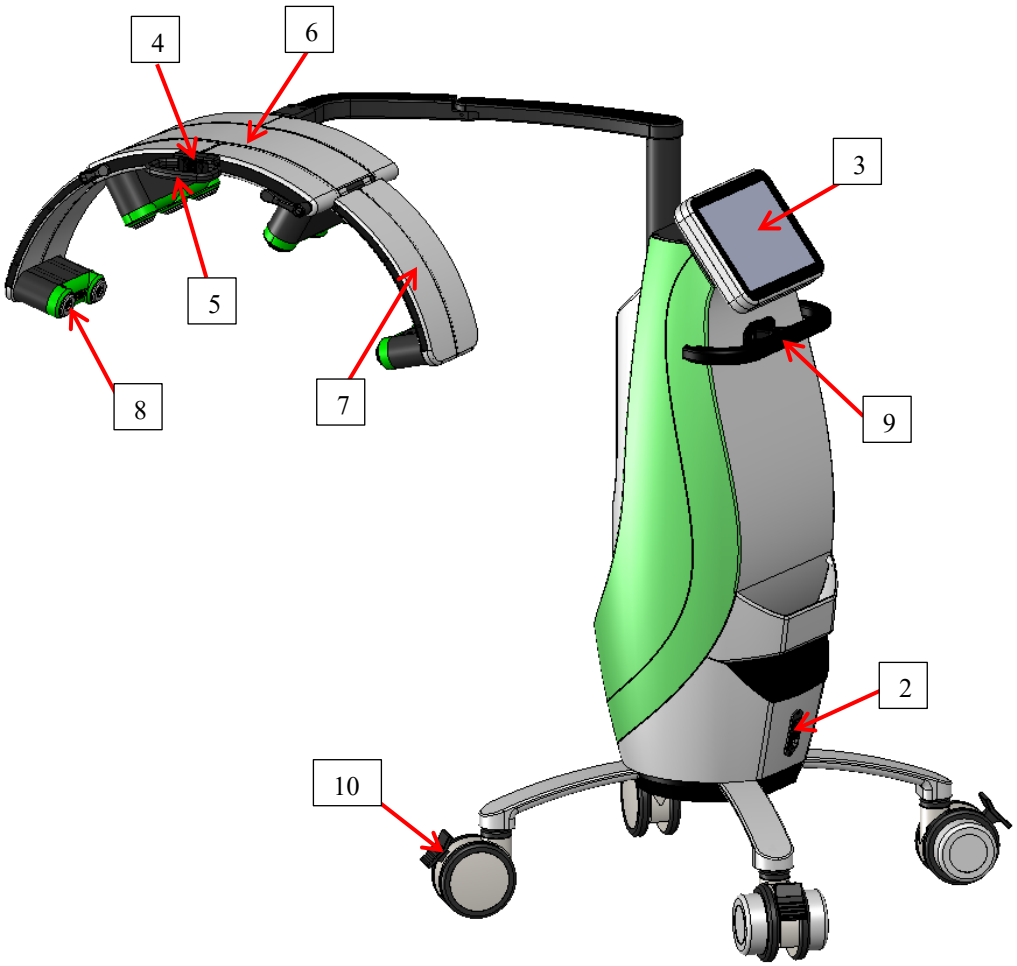
NOTE: For international customers, PRIOR to sending a unit in for repair you must obtain from the Erchonia® Service department an annually revised FDA Form 2877. The Radiation Control form (2877) will be sent to you partially complete, containing regulatory information. To complete, fill in the unique information associated with your device and the shipment thereof, such as serial number, port, etc. The completed form 2877 must accompany your shipment affixed to the outside of the package. Failure to include the form in the shipment may result in customs delays and fines. Any resulting fines are the responsibility of the customer.

SECTION 2 PRODUCT OVERVIEW

NOMENCLATURE

The Erchonia® Emerald is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA. Per ISO and FDA standards the device and laser are classified as Class 2.
Each of these governing agencies requires specific labeling. All required labels are affixed according to the relevant codes. Each label is pictured and described in this manual. Additionally, the placement of each label, on the Erchonia® device, is communicated.
This section is included to familiarize you with the components of the device ensuring the remainder of this manual is clearly communicated.

DEVICE
Weight: 118.5lbs / 53.75 kg
(Height x Depth x Width)
Size- Configuration 1 (standard treatment configuration): 52" x 56" x 36"/132.08cm x 142.24cm x 91.44cm
Size- Configuration 2 (max size configuration): 56" x 65" x 38"/142.24cm x 165.10cm x 96.52cm
Size- Configuration 3 (transportation configuration): 47.5" x 33" x 38"/120.65cm x 83.82cm x 96.52cm
Power cord [1] connects the device to mains power supply through power inlet [2].



1. Electrical Power Cord (not shown)
2. Power Inlet Module/Fuse Holder w/ Power Switch
3. Touch Screen
4. Arm Control Switch
5. Laser Head Assembly Handle
6. Laser Head Assembly
7. Outside Laser Arms
8. Laser Output Head
9. Device Handle
10. Wheel Locks

Fig. 1

[1] ELECTRICAL POWER CORD

The device contains a hospital grade flexible detachable power cord. Plug the power cord into the Power Inlet Module [2] prior to plugging the other end into a wall socket.

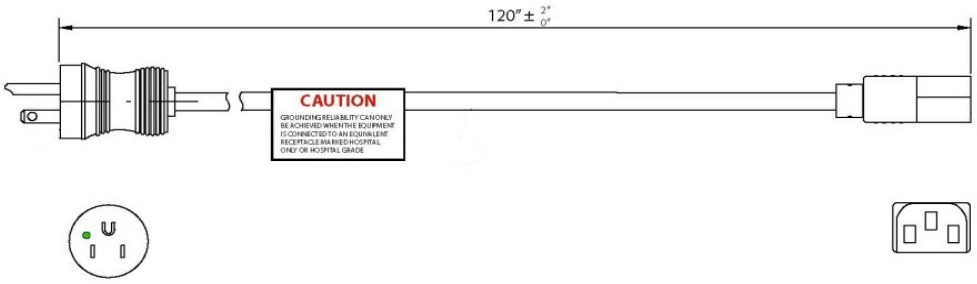


Fig. 2

⚠	**DO NOT** position the equipment so that it is difficult to disconnect the power cord.
⚠	**WARNING-SHOCK HAZARD** This device must only be connected to an electric supply main with protective earth. Make certain that the device is grounded by connecting only to a grounded 3 prong electrical socket conforming to the applicable national and local electrical codes. Use T2AH 250V Fuses only.

The device includes a transformer which converts AC supply power (110 V – 240 V) to match the power output (i.e. 110 V or 240 V). Only a 3 prong power cord is required (Hospital Grade Only). Once the power cord connector is affixed to the power inlet, plug into the wall socket. Input: 100 VAC / 240 VAC, 1.5 A/0.5 A, 50-60 Hz

[2] POWER INLET MODULE/FUSE HOLDER W/ POWER SWITCH

The device contains a medical type filtered power entry module with double fuse holder. This is the location on the device where the power cord [1] is connected. **NOTE:** Make sure the power cord is connected into the device at this location prior to plugging into a wall socket. The Power Inlet module also contains a fuse holder. Replacing the fuses is the only service that can be conducted by the end-user. To replace the fuses, refer to Maintenance section of this manual.

Contained within the power inlet module is the power switch. The power switch allows the end user to turn the device ON "|" or OFF "O". To turn the device ON the power cord must first be connected into the device and then into a wall socket. Once connected, the switch will need to be turned to the ON "|" position to power the device ON.
NOTE: The device takes approximately 15 seconds for the touchscreen to power ON.

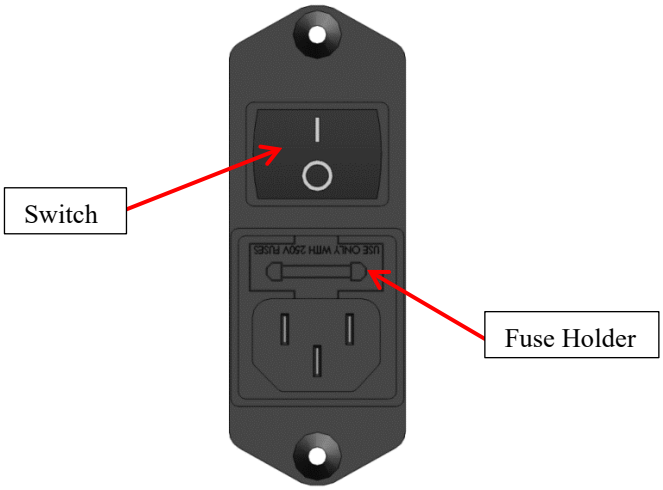


Fig. 3

⚠	**WARNING-SHOCK HAZARD** To avoid risk of electric shock, this device must only be connected to an electric supply mains with protective earth. Make certain that the device is grounded by connecting only to a grounded 3 prong electrical socket conforming to the applicable national and local electrical codes. Use T2AH 250V Fuses only.

The device includes a transformer which converts 110 V or 240 V AC supply power to match the power output (i.e. 110 V or 240 V). Only a 3-prong power cord is required (Hospital Grade Only). Once the power cord connector is affixed to the power inlet, plug into the wall socket. Input: 100 VAC / 240 VAC, 1.5 A/0.5 A, 50-60 Hz

[3] TOUCH SCREEN

The touch screen functions as a display screen and an input panel, providing information to the user and a means to operate the device by touching the appropriate icon.

⚠	**CAUTION - DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the icons on the touch screen as damage may result. Avoid using abrasives (including paper towels) on the touch screen display window.

[4] ARM CONTROL SWITCH

The arm control switch allows the end user to raise or lower the Laser Head Assembly [6] for proper height placement of lasers for treatment. To raise the head assembly, push the switch in the UP " ⇧ " position. To lower the head assembly, push the switch in the DOWN " ⇩ " position.

NOTE: Ensure that the laser diodes are powered OFF when lowering or raising the Laser Head Assembly. Pushing the Arm Control Switch in the opposite direction quickly while the laser diodes are powered ON may cause an electrical load on the system, causing the device to power off and reboot back to the start-up screen. Refer to "SECTION 4 ERCHONIA® EMERALD OPERATION – INSTRUCTIONS FOR USE" and "SECTION 5 PROFESSIONAL USE INSTRUCTIONS - ERCHONIA® EMERALD PROTOCOL" for proper set up of device prior to facilitating a treatment on the patient.

NOTE: If the mast has been disengaged from the lift system it may require manual assistance by pushing the main arm down to reengage onto the track, when done correctly the mast will raise and lower using the control switch.

NOTE: Once a protocol has ended the main arm will automatically raise up and away from the subject.

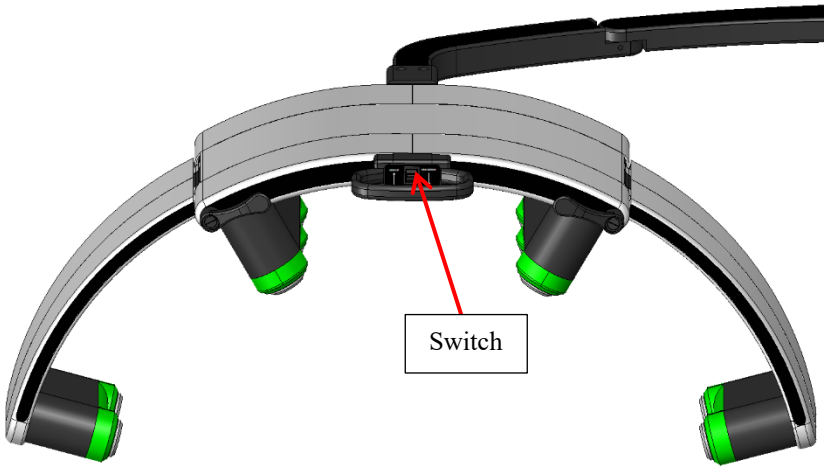


Fig. 4

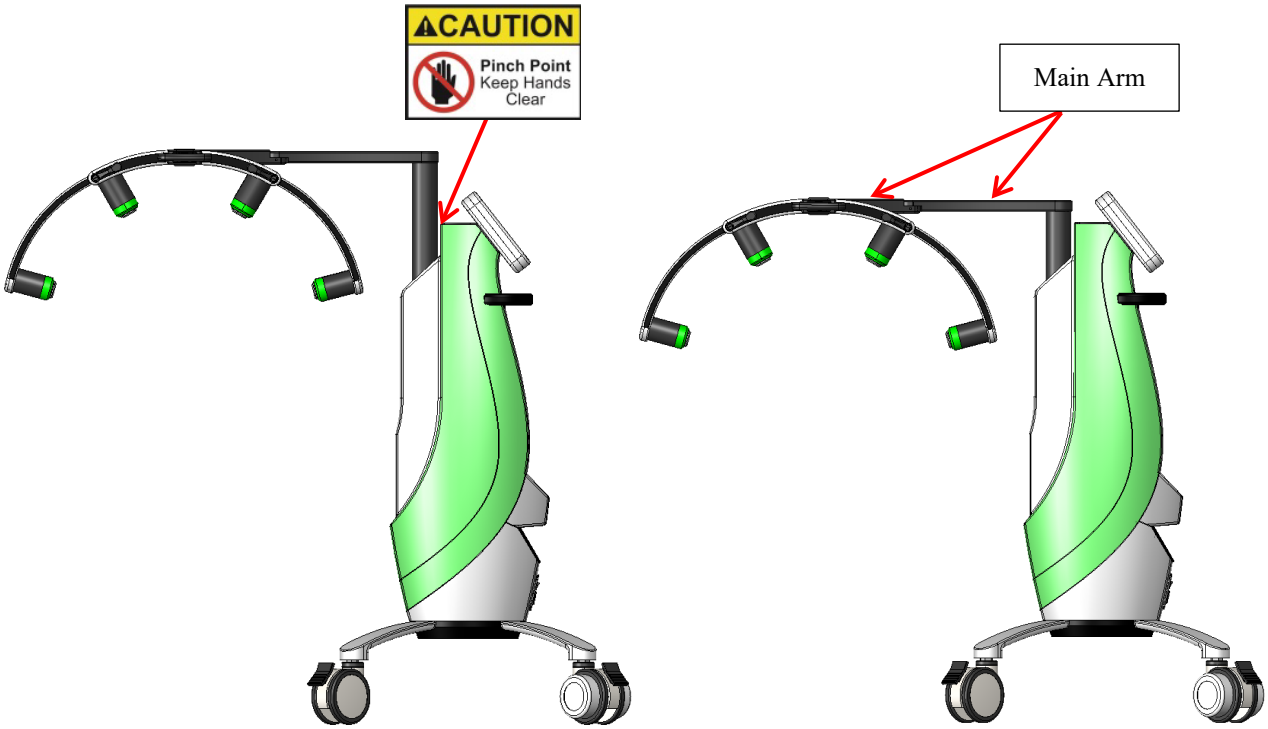


Fig. 5

CAUTION: PINCH HAZARD
Keep hands and fingers clear from areas indicated

[5] LASER HEAD ASSEMBLY HANDLE

The laser head assembly handle serves to position the Laser Head Assembly [6] for proper placement to the subject for treatment; the head assembly can be moved vertically (raise up or lower down) using the Arm Control Switch [4], and horizontally (move from side to side) by intentional force from the end user. To move vertically, see "*[4] ARM CONTROL SWITCH*". To move horizontally grab the laser head assembly handle and move the head assembly left or right to the required position. (See example figure below)

NOTE: When transporting device ensure that the main arm is in the fully lowered position using the arm control switch, then swing the main arm section "A" in towards the device base (laser head assembly towards device), then condense the outside laser arms [7] in towards the center of the head assembly.

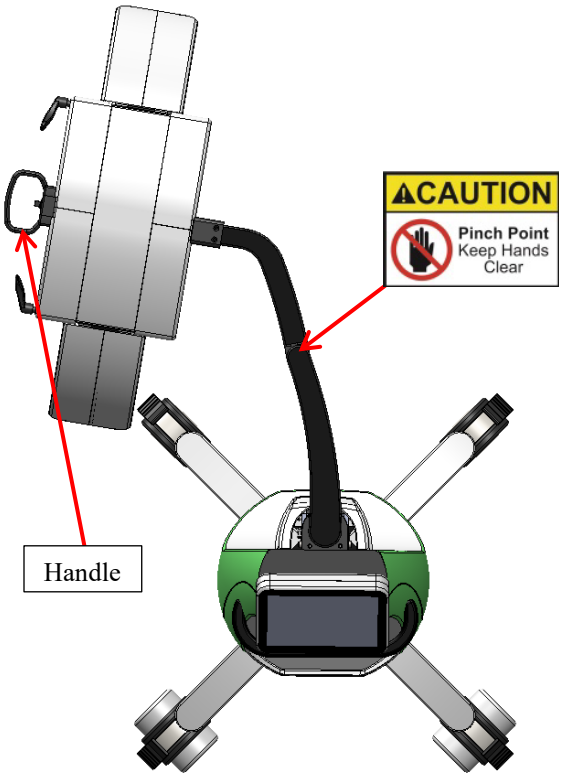


Fig. 6

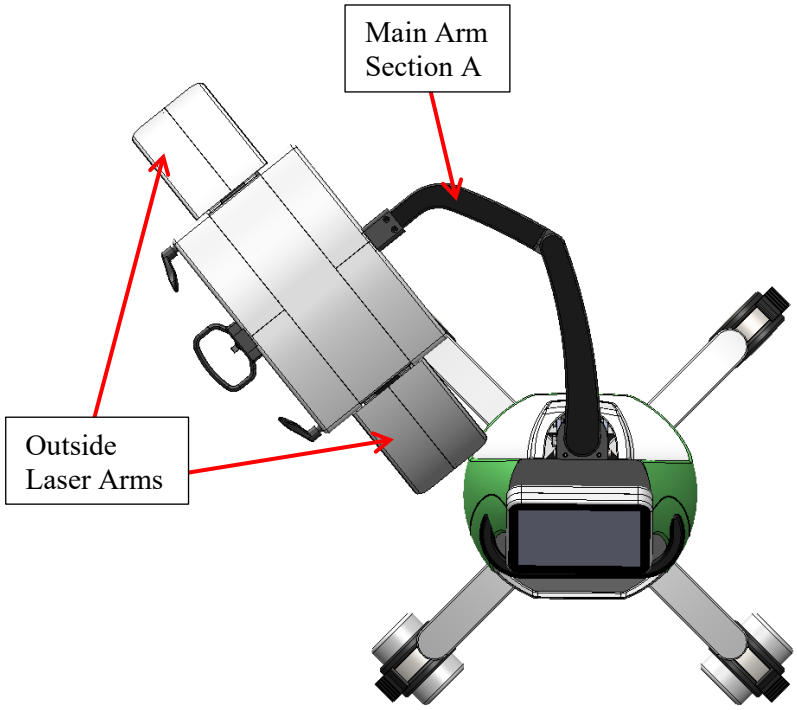


Fig. 7

CAUTION: PINCH HAZARD
Keep hands and fingers clear from areas indicated

[6] LASER HEAD ASSEMBLY

The laser head assembly located on the end of the main arm accommodates the Outside Laser Arms [7] and the ten Laser Output Heads [8]. This assembly can be raised or lowered by means of the Arm Control Switch [4] and manually moved side to side by means of the Laser Head Assembly Handle [5]. The outside laser arms can be moved in or out by manual adjustment and locked in place by the lever lock for proper treatment distance and positioning.

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[7] OUTSIDE LASER ARMS

There are two outside laser arms on the device, each arm houses two Laser Output Heads [8]. It is designed to adjust by intentional force from the end user. This allows the end user to angle these laser output heads in and out for proper positioning to patient for accurate treatment distance. To angle the outside laser arm in or out, hold the outside laser arm with one hand and loosen the lever lock by turning the lever lock counterclockwise with the other hand. Once the lever lock is loose, move the outside laser arm to the proper treatment distance and position, hold outside laser arm in place and then tighten the lever lock by turning the lever lock clockwise until the outside laser arm holds position.

NOTE: When transporting device ensure that the main arm is in the fully lowered position using the arm control switch, then swing the main arm section "A" in towards the device base (laser head assembly towards device), then condense the outside laser arms [7] in towards the center of the head assembly

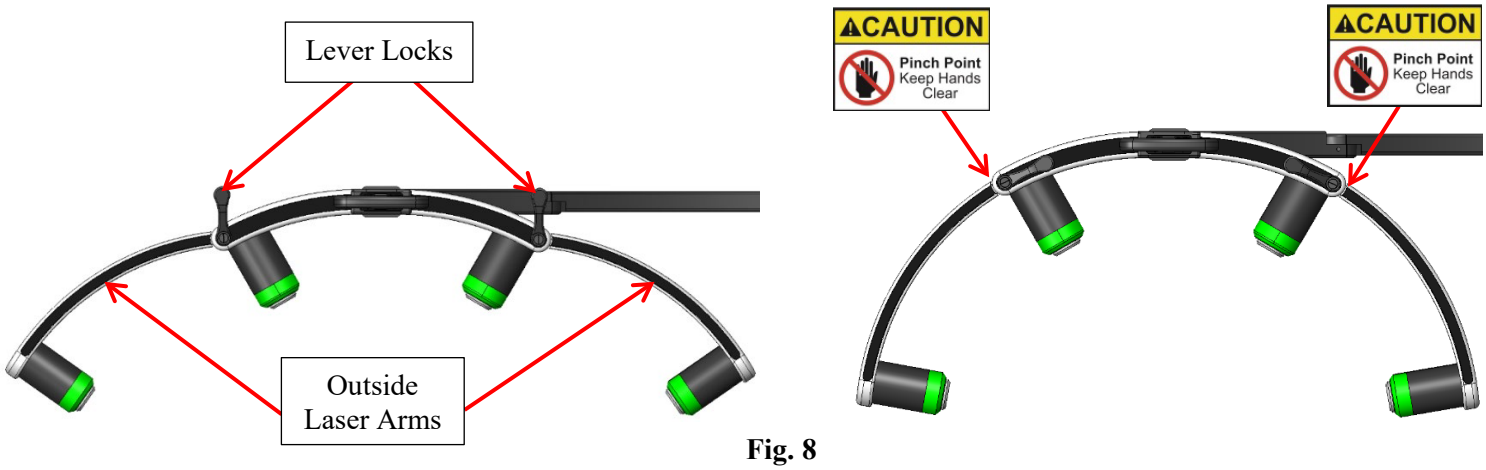


Fig. 8

CAUTION: PINCH HAZARD
Keep hands and fingers clear from areas indicated

[8] LASER OUTPUT HEAD

There are ten laser output heads on device. These heads are housed in plastic and accommodate the lens, laser diodes, motors, and their associated electronics. (for cleaning see maintenance section)

[9] DEVICE HANDLE

The device handle gives the user the ability to move the device for proper positioning to patient for accurate treatment location as well as move the device for storage or relocate to a different room. When the device is moved it is required to unlock the wheel locks [10]. **NOTE:** Hold the handle at all times during movement or relocation of the device.

[10] WHEEL LOCKS

The device includes four antistatic wheels that enable ease for maneuverability. Once the device is transported to the desired location the wheel locks should be engaged to eliminate excessive movement of the device.

Fig. 9

⚠	**WARNING-TIPPING HAZARD** When transporting the device (example: from one room to another) ensure that the main arm [5] position is fully down and the outside arms [7] are in towards center of laser head assembly, Hold device handle and take caution to ensure the device does not tip.

PROTECTIVE EYEWEAR

The Erchonia® Emerald is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

PATIENT GLASSES

The laser safety glasses are an ultra-light-weight comfortable frame with a double coated scratch-resistant polycarbonate laser filter. The fit-over-prescription style frame offers universal fit with wide field of view. Lens has superior optical clarity with virtually no distortion to reduce eye fatigue. It is ideal for use in most laser applications and comfortable for long periods of wear. These safety glasses sufficiently and effectively block the laser light spectrum at OD 7+.

Height: 63.8 mm
Width: 155.3 mm
Length: 140-160 mm

Fig. 10

OPERATOR GLASSES

The laser safety glasses are a light-weight comfortable black sport-warp frame with a double coated scratch-resistant polycarbonate laser filter. Lenses have superior optical clarity with virtually no distortion to reduce eye fatigue. It is ideal for use in most laser applications and comfortable for long periods of wear. These safety glasses effectively block 50-60% of the laser light spectrum at OD 2+.

Height: 40 mm
Width: 145 mm
Length: 165 mm

Fig. 11

SECTION 3 ASSEMBLY

The Erchonia® Emerald is shipped in two pieces and requires assembly for the device to be operational. This assembly may require two people.

PROVIDED PARTS FOR ASSEMBLY:

Device base (Qty: 1)

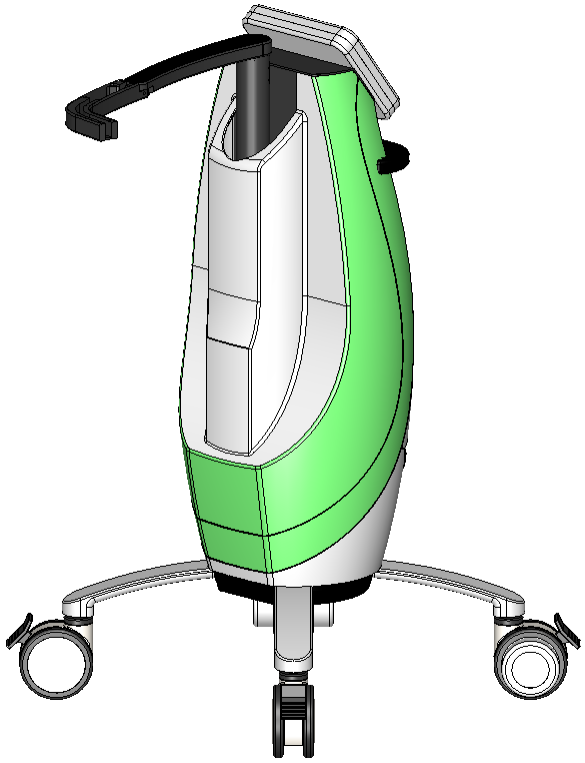


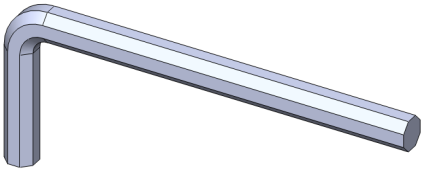
Fig. 12

Laser Head Assembly (Qty: 1)

Fig. 13

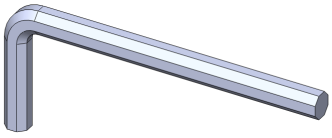
Large Screws (Qty: 2)

1/8 (Large) Allen Driver (Qty: 1)

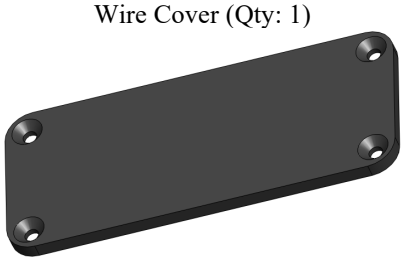


Small Screws (Qty: 4)

1/16 (Small) Allen Driver (Qty: 1)



Wire Cover (Qty: 1)



Arm Cover (Qty: 1)

Fig. 14

1. Lock all four wheels.
   -a). Insert the Laser Head Assembly onto the Main Arm on the Device base as shown in fig. 15, carefully feeding the cable from the Laser Head Assembly into the cable cutout in the Main Arm.
   -b). Once fully seated the screw holes on the Laser Head Assembly will align with the threaded holes on the Main Arm.

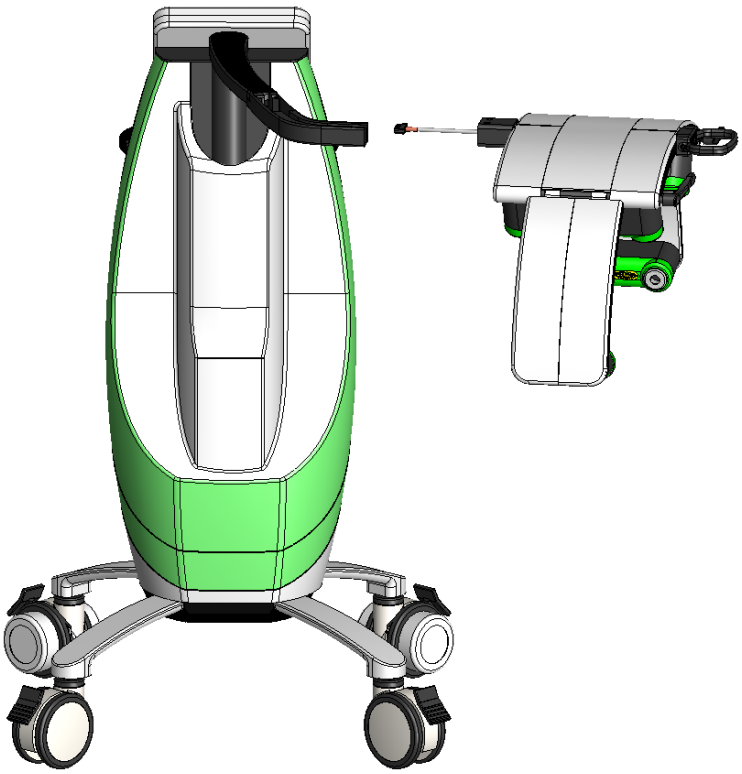


Fig. 15

2. Insert the provided Large Screws (2) into the screw holes on the Laser Head Assembly. Firmly tighten the screws into place using the provided 1/8 (Large) Allen Driver

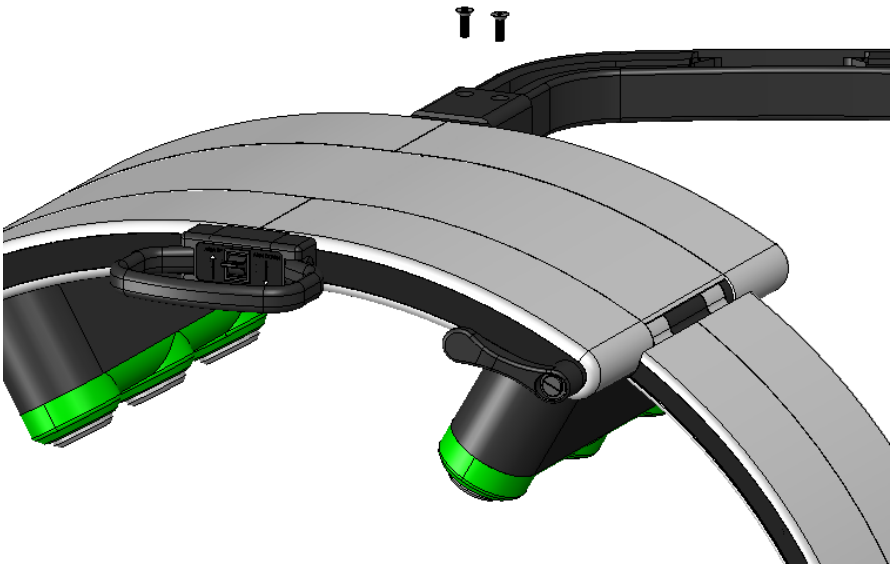


Fig. 16

3. Plug both connectors from the Laser Head Assembly into both connectors from the Main Arm until both locking tabs on the connectors are locked in place as shown in fig. 17
IMPORTANT: Both connectors must be fully seated to engage the lock, you will hear a snap and they will not pull apart.

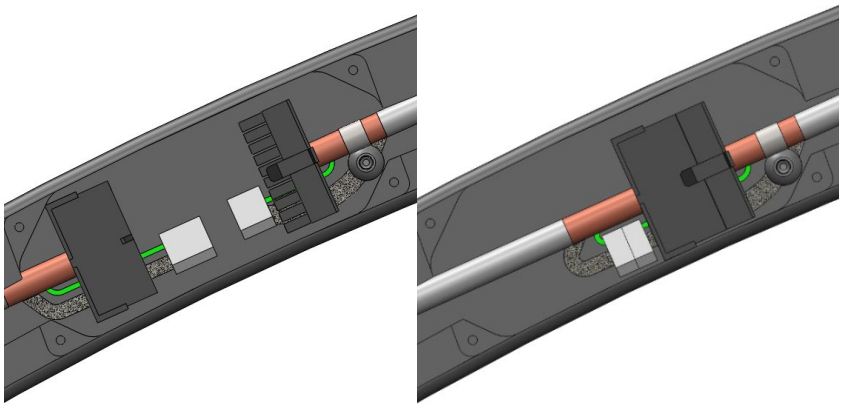


Fig. 17

4. Place the provided Wire Cover Plate (countersunk holes facing up) into the wire cover pocket on Main Arm.

5. Insert the provided (4) Small Screws into the screw holes on the Wire Cover. Firmly tighten the screws into place using the provided 1/16 (Small) Allen Driver

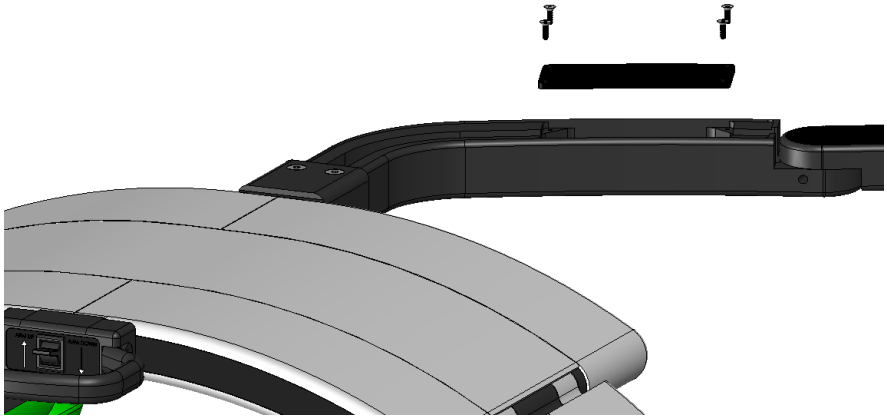


Fig. 18

6. Remove the adhesive liner from the provided Arm Cover Overlay and adhere the Arm Cover into the arm cover pocket on the Main Arm.

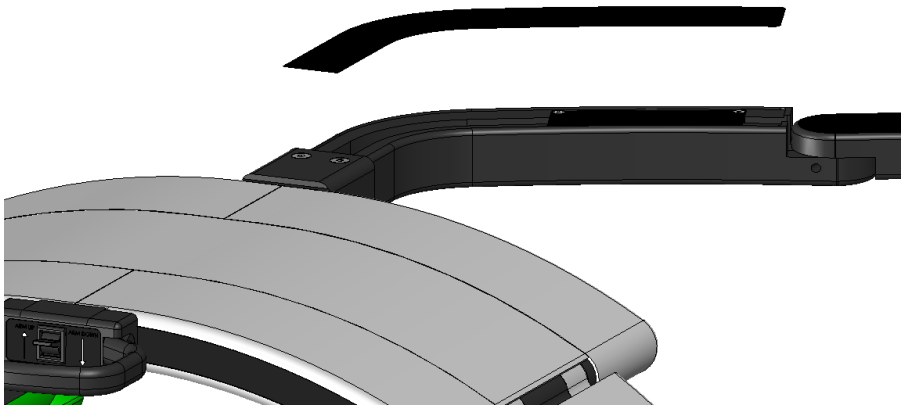


Fig. 19

SECTION 4 ERCHONIA® EMERALD OPERATION

Now that you understand the basic features of the Erchonia® EMERALD, it is important to understand how to use them when administering treatments. Below are the steps for setting the patient up for treatment.

WHEEL LOCKS

Fig. 20

1) Once you have moved device to the desired location, be sure to engage the wheel locks to avoid excessive movement of the device.

⚠	**WARNING-TIPPING HAZARD** When transporting the device (example: from one room to another) ensure that the main arm [5] position is fully down and the outside arms [7] are in towards center of laser head assembly, hold device handle and take caution to ensure the device does not tip.

2) Place subject in treatment position under the Laser Head Assembly. Raise or lower the Main Arm to the optimal height for treating patient using the Arm Control Switch [4].

NOTE: Ensure that the laser diodes are powered OFF when lowering or raising the Laser Head Assembly. Pushing the Arm Control Switch in the opposite direction quickly while the laser diodes are powered ON may cause an electrical load on the system, causing the device to power off and reboot back to the start-up screen. Refer to "SECTION 4 ERCHONIA® EMERALD OPERATION – INSTRUCTIONS FOR USE" and "SECTION 5 PROFESSIONAL USE INSTRUCTIONS - ERCHONIA® EMERALD PROTOCOL" for proper set up of device prior to facilitating a treatment on the patient.
NOTE: If the mast has been disengaged from the lift system it may require manual assistance by pushing the main arm down to reengage onto the track, when done correctly the mast will raise and lower using the control switch.
NOTE: Once a protocol has ended the main arm will automatically raise up and away from the subject.

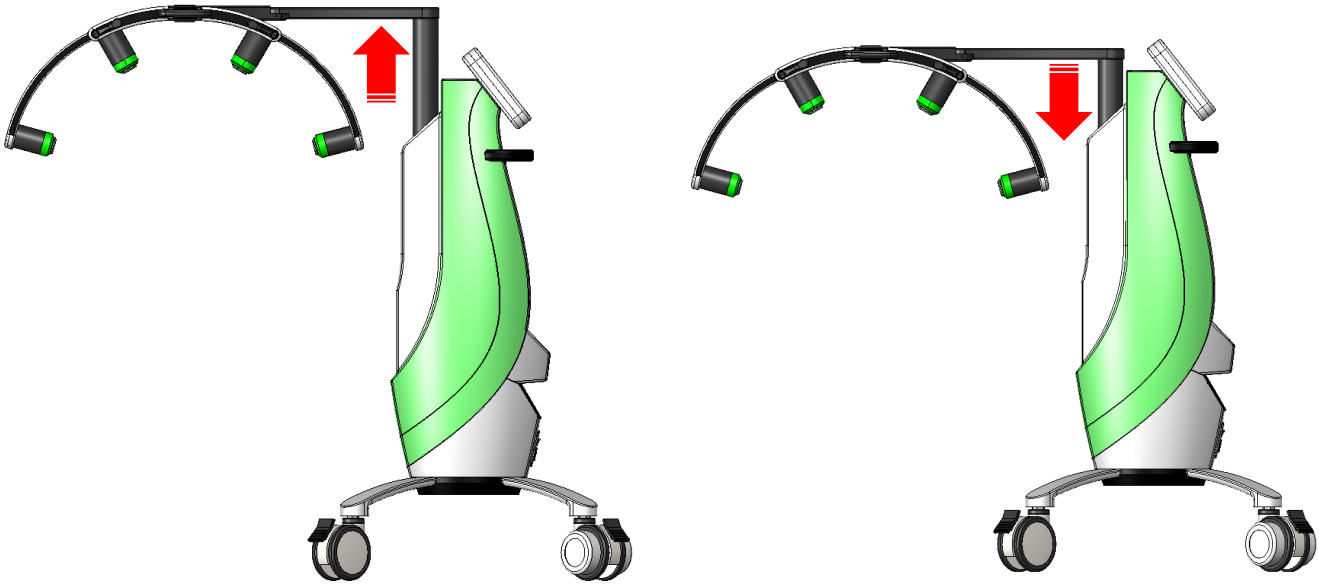


Fig. 21

3) Turn the Main Arm from side to side for the optimal treatment area for patient.

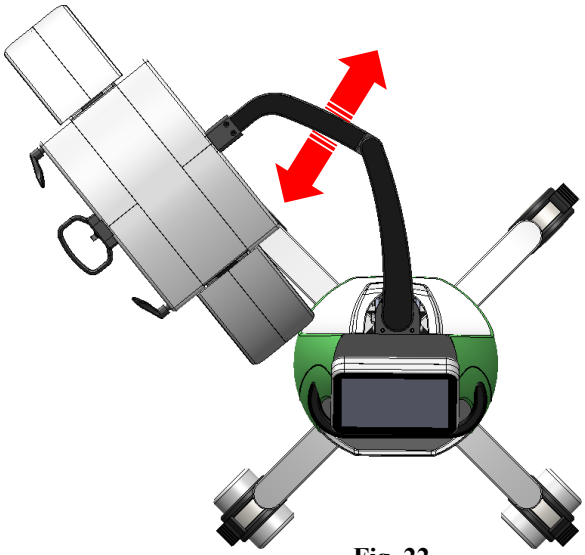


Fig. 22

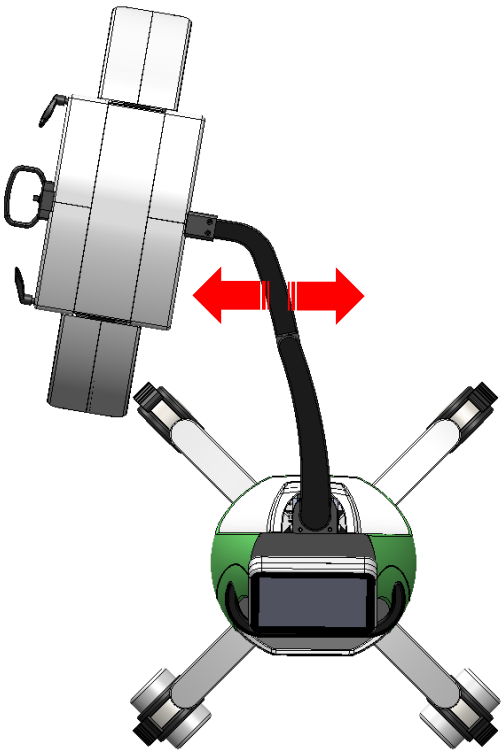


Fig. 23

4) Grab the Outside Laser Arms, unlock the lever locks and angle the Outside Laser Arms to the optimal angle for treating patient, then tighten lever locks to hold position.

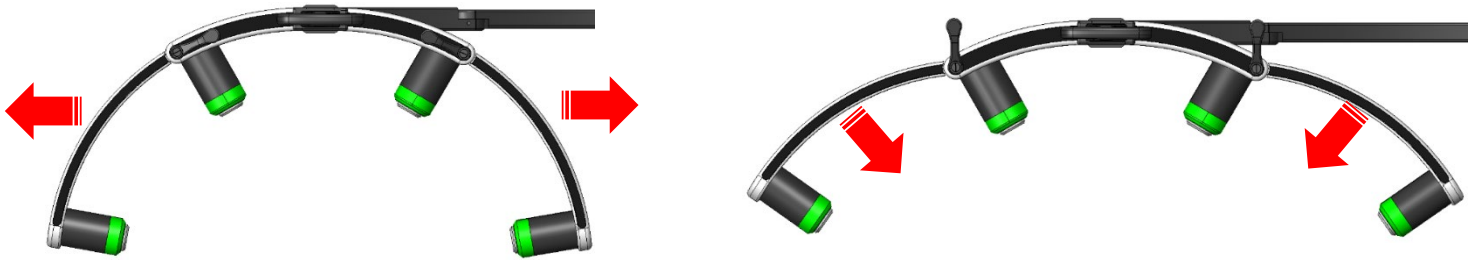


Fig. 24

EMERALD TOUCH SCREEN

The touch screen is both a display screen that provides information to the user and an input panel that allows the user to operate the device by touching the appropriate icon.

- Make sure the power cord is connected.
- Switch the device ON using the Power Switch located on the Power Entry Module to the ON "|" position.

NOTE: The device lasers may flash ON for a fraction of a second when device is powered ON.
NOTE: The device takes approximately 15 seconds for the touchscreen to power ON.

Fig. 25

Fig. 26

LOADING SCREEN

Image 1

- The touchscreen screen will display the "Loading Screen" for approximately 15 seconds then change to the "Data Entry Screen".

DATA ENTRY SCREEN

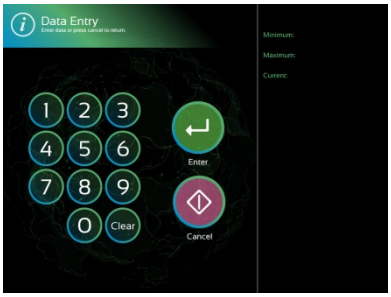


Image 2

- Enter the current 4-digit passcode **(1234 is the factory set default code)**; if passcode has been changed by the user, use the changed 4-digit passcode and then touch "Enter".
- Screen will change to the "Home Screen".

⚠	**CAUTION - DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the touch screen as damage may result. Avoid using abrasives (including paper towels) on the touch screen display window.

HOME SCREEN

Image 3

- Touch anywhere on screen.
- Screen will change to the “Menu Screen”.

NOTE: When “Home” icon is touched on any screen it will change to the “Home Screen”.

MENU SCREEN

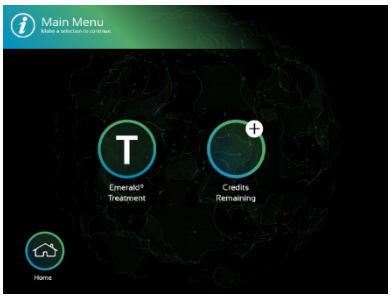


Image 4

The “Menu Screen” has 3 icons: “Emerald Treatment”, “Credits Remaining”, & “Home”. Touching any of these icons will change the screen to the applicable command.

- Touch the Emerald Treatment icon to go to the Emerald Treatment Screen

- **START:** Touch the **“Start”** icon to begin the non-invasive procedure. Once you start the procedure you will observe the following:
  - Ten visible green laser diodes turn on rotating clockwise;
  - The time remaining window starts counting down;
  - The **“Start”** icon changes to a **“Stop”** icon;
  - The **“Credits Remaining”** icon will deduct by one.

- **STOP:** To stop the procedure while the procedure is on, touch the **“Stop”** icon. When the procedure is stopped, you will observe the following:
  - All rotating green laser diodes turn off;
  - The time remaining counter resets to the applicable protocol time;
  - The **“Stop”** icon changes to a **“Start”** icon;
  - The main arm will automatically raise up and away from the subject.

- **PAUSE:** To pause, touch the **“Pause”** icon. When the procedure is paused, you will observe the following:
  - All rotating green laser diodes turn off;
  - The time remaining counter pauses;
  - The **“Pause”** icon changes to a **“Resume”** icon;

- **RESUME:** To resume the procedure, touch the **“Resume”** icon.

- Once the **“Time Remaining”** display reaches 0:00 the lasers will turn off,
  - you will hear 3 audio “beeps”
  - The main arm will automatically raise up and away from the subject.

NOTE: You can turn off individual lasers by simply touching the “ON/OFF Icons” located on Emerald Treatment Screen.

NOTE: If the mast has been disengaged from the lift system it may require manual assistance by pushing the main arm down to reengage onto the track, when done correctly the mast will raise and lower using the control switch.

EMERALD TREATMENT SCREEN

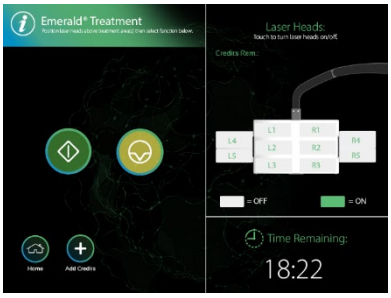


Image 5

INSTRUCTIONS FOR USE

STEP 1: Have your patient put on the safety glasses and lay on their back.
Position the center laser diodes and adjustable laser arms, no greater than 6 inches / 15 cm away from the patient's target treatment areas. The goal is to maximize the coverage of the laser beams to the target treatment areas of fat.
While the patient is lying on their back you should check for the areas of the greatest accumulation of fat, which will tend to be on the sides of the waist and hips.
Using the center laser diodes as your guide, position the center diodes over the area of greatest midline fat accumulation. The lateral (side) adjustable laser heads are position over the area of greatest waist and thigh fat accumulation on either side of the body.

STEP 2: Once positioned over patient, it is important to now locate the area of greatest fatty accumulation midline and laterally. Start by locating the greatest fatty accumulation along the patient's midline. This is accomplished by gently palpating the tissue until the largest collection is found. Once the midline fatty material is located, position the center diodes directly above the fatty accumulation. This step must also be carried out for both outside laser arms ensuring that each diode is carefully positioned over the greatest accumulation of fatty material.

STEP 3: Now that the diodes are physically positioned over the region of greatest fatty material, it is imperative to align the diode so that the line-generated beam is approaching the skin's surface at 90^{o} or perpendicular.
From this point, minor adjustments can be made to move the diodes closer to the skin.
Remember, to use the palm of your hand.

Make sure the power cord is connected.
Switch the device ON using the Power Switch located on the Power Entry Module to the ON "|" position.
NOTES:

- The device lasers may flash ON for a fraction of a second when device is powered ON.
- The device takes approximately 15 seconds for the touchscreen to power ON.
- Once the touchscreen powers ON the Loading Screen will display for approximately 15 seconds.
- The screen changes to the Passcode Screen. Enter the current passcode and touch Enter.
- The screen changes to the Home Screen. Touch anywhere on screen
- The screen changes to the Menu Screen

MENU SCREEN

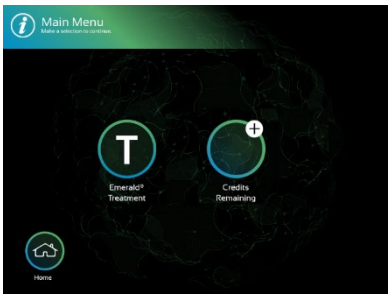


Image 6

- Touch the **"Emerald Treatment"** icon to go to the Emerald Treatment Screen.
  Note: *"Emerald Treatment" powers the 10 lasers for 30 minutes, with a halfway point at 15 minutes.*

- **START:** Touch **"Start"** icon to begin the non-invasive procedure. Once you start the procedure you will observe the following:
  - Ten visible green laser diodes turn on rotating clockwise;
  - The time remaining window starts counting down;
  - The **"Start"** icon changes to a **"Stop"** icon;
  - The **"Credits Remaining"** icon will deduct by one.

- **STOP:** To stop the procedure while the procedure is on, touch the **"Stop"** icon. When the procedure is stopped, you will observe the following:
  - All rotating green laser diodes turn off;
  - The time remaining counter resets to the applicable time;
  - The **"Stop"** icon changes to a **"Start"** icon;
  - The main arm will automatically raise up and away from the subject.

- **PAUSE:** To pause, touch the **"Pause"** icon. When the procedure is paused, you will observe the following:
  - All rotating green laser diodes turn off;
  - The time remaining counter pauses;
  - The **"Pause"** icon changes to a "**Resume"** icon;

- **RESUME:** To resume with the procedure, touch the **"Resume"** icon.

EMERALD TREATMENT SCREEN

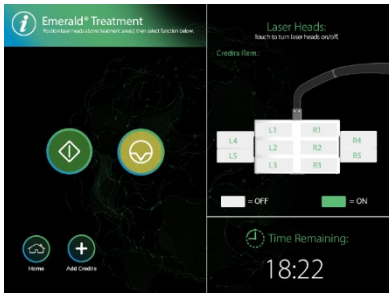


Image 7

- Once the **"Time Remaining"** display reaches half of the protocol time the lasers will power off,
  - you will hear three audio "beeps",
  - The Halfway Point Screen will display.

  This is to give the patient time to change from the front to the back-treatment position.
- Once the patient is ready in the back-treatment position (lying on their stomach) and you have properly positioned the diodes, touch anywhere on the screen to complete the remainder of the procedure.

HALFWAY POINT SCREEN

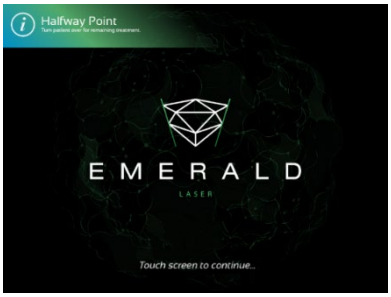


Image 8

- Once the **"Time Remaining"** display reaches 0:00 the lasers will power off,
  - you will hear 3 audio "beeps"
  - The main arm will automatically raise up and away from the subject.

NOTE: You can turn off individual lasers by simply touching the "ON/OFF Icons" located on Emerald Treatment Screen.

NOTE: If the mast has been disengaged from the lift system it may require manual assistance by pushing the main arm down to reengage onto the track, when done correctly the mast will raise and lower using the control switch

FRONT OF THE BODY

1. The patient lies comfortably flat on their back on the table. Position the patient so that their stomach (abdomen), their hips and frontal aspect of both thighs, are facing upward.

2. The six center diodes of the EMERALD Laser are positioned above the patient, centered along the body's midline (the line which vertically divides the body into two equal halves).

3. The EMERALD Laser is activated, and each laser diode emits to the patient a laser beam and creates a spiraling circle pattern which is totally random and independent from the others.

BACK OF THE BODY

1. The patient turns over to lie flat on their stomach. Position the patient so that their back, their hips and back aspect of both thighs, are facing upward.

2. The six center diodes of the EMERALD Laser are positioned above the patient, centered along the body's midline (the line which vertically divides the body into two equal halves).

3. The EMERALD Laser is activated and each laser diode emits to the patient a laser beam and creates a spiraling circle pattern which is totally random and independent from the others.

CREDIT & DEVICE INFORMATION SCREEN

To access the "Credit & Device Information Screen" touch the "Credits Remaining" icon on the "Menu Screen" or the "Emerald Treatment Screen" This multi-functional screen displays the following:

- Manufacturer's contact information
- General device information including software version and revision date, the *calendar date (*based on eastern standard time, USA), device serial number and total number of treatments the device has operated
- The entry icon for adding credits
- The entry icon for credit unlock code
- The unlock icon for applying unlock code
- The display of credits remaining
- Change Passcode – This feature is for the user to create a custom passcode to access the device
- Protocol Audio Beep – This feature is to turn OFF or ON the audio beep while a protocol is running a treatment

CREDIT & DEVICE INFORMATION SCREEN

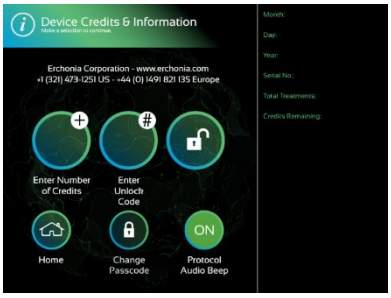


Image 9

CHANGE PASSCODE

- To change the passcode, touch the “Change Passcode” icon located on the “Credit & Device Information Screen”. Screen will change to the “Data Entry Screen”
- Enter the current 4-digit passcode **(1234 is the factory default set code)**; if passcode has been changed by the user, use the changed passcode and then touch “Enter”.
- Enter new passcode and touch enter (must be 4 digits)
- Re-enter new passcode and touch enter

The passcode is now changed. The new passcode entered is now the current passcode to access the device

IMPORTANT: Write down new passcode and keep in a safe place.

NOTE: If an incorrect passcode is entered the screen will display “Incorrect Passcode”. The device will power down after 5 failed passcode attempts. To power the device back on, turn the Power Switch off and then back on.
NOTE: If you forget your passcode you will need to contact Erchonia corporation’s Service and Repair Department. 1-888-242-0571 (US only)

DEVICE INFORMATION SCREEN

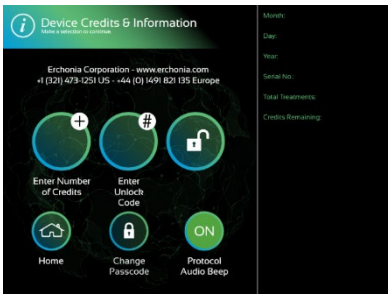


Image 9

DATA ENTRY SCREEN

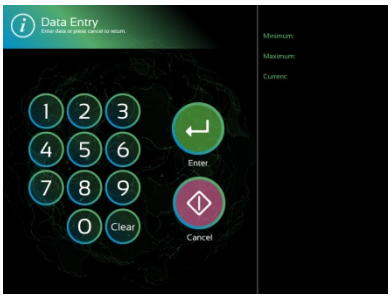


Image 10

PROTOCOL AUDIO BEEP

Located on the “Credit & Device Information Screen” is the “Protocol Audio Beep” icon. This feature is used to turn ON or OFF the audio beep heard while a protocol treatment is running. The icon will display ON if the audio beep feature is set on, or OFF if the audio beep feature is set off. To change the feature of the audio beep, (OFF or ON) simply touch the “PROTOCOL AUDIO BEEP” icon.

HOW DO CREDITS WORK?

Credits are required for the Emerald laser to operate the non-invasive procedures. The Emerald software for this device is developed to deduct one credit every time the **"START"** icon is touched. The Emerald Treatment Screen and the Credit & Device Information Screen allow you to view the amount of remaining credits on the device at any time. To ensure that your device is operational at all times, contact Erchonia's Sales Support before the Credits Remaining reaches 0. Once the credits remaining reaches 0, the device will no longer operate.

The following icons will display on screens when all credits have expired, and the device will no longer operate the non-invasive procedures.

MENU SCREEN

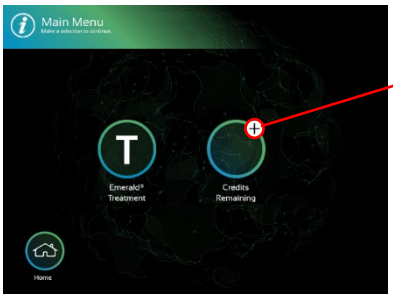


Image 13

The plus sign will blink continuously once there are zero credits remaining

EMERALD TREATMENT SCREEN

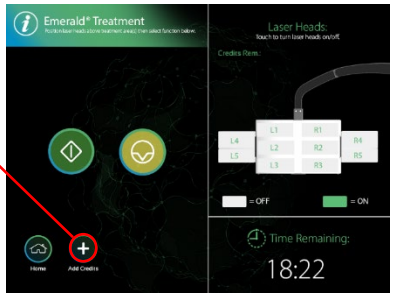


Image 14

TO ADD CREDITS

1. Contact Erchonia Sales Support. You will need to provide your device serial number and the date displayed on the device's **Credit & Device Information Screen**.
2. Touch the "Enter Number of Credits" icon. The screen will change to the **Data Entry Screen**.
3. Enter the number of credits purchased then touch the "ENTER" icon to accept. The screen will change back to the **Credit & Device Information Screen**.
4. Touch the "Enter Unlock Code" icon. The screen will change to the **Data Entry Screen**.
5. Enter the 8 digit unlock code given to you by the Erchonia representative then touch the "ENTER" icon. The screen will change back to the **Credit & Device Information Screen**.
6. Touch the "Unlock Credits" icon. Upon successful credit code entry, a "Credits Unlocked" text will be displayed beneath the "Unlock" icon, then "Unlock" icon will be grayed out and unable to be selected until after the 24-hour credit entry timer has expired

Note: If an improper code is entered, a "Invalid Code" icon will display beneath the "Unlock" icon

DEVICE INFORMATION SCREEN

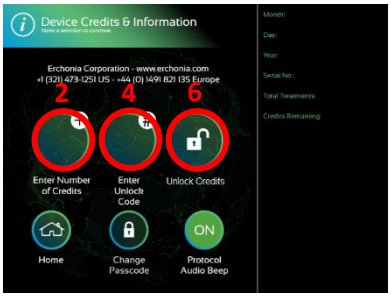


Image 9

NUMERIC KEYPAD SCREEN

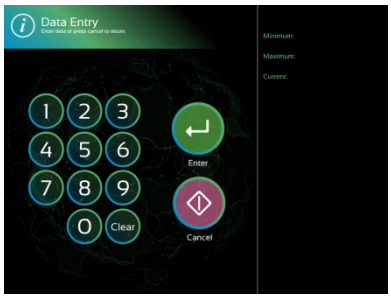


Image 10

LABELS USED ON DEVICE

The device is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA, ISO Standards (International) and CE (Certified European) standards and testing results per Article 9, the device is a Class I Shock Protection and a Class II Medical device. Each of these governing agencies requires specific labeling. All required labels affixed according to the relevant codes. Each label is pictured and described in this section. Additionally, the placement of each label, on the device, is communicated.

The following diagram shows images of the compliance label and serial number label and their placement. Integrated into the compliance label is the electrical input detail containing Volts, Amps and fuse specifications. The large black background label is this primary label and is compliant to FDA and ISO standards; the image captures the FDA code regulated classifications and International criteria. As a class 2 laser equipment the compliance label includes the class 2 laser caution label notifying not to stare into the laser beam.

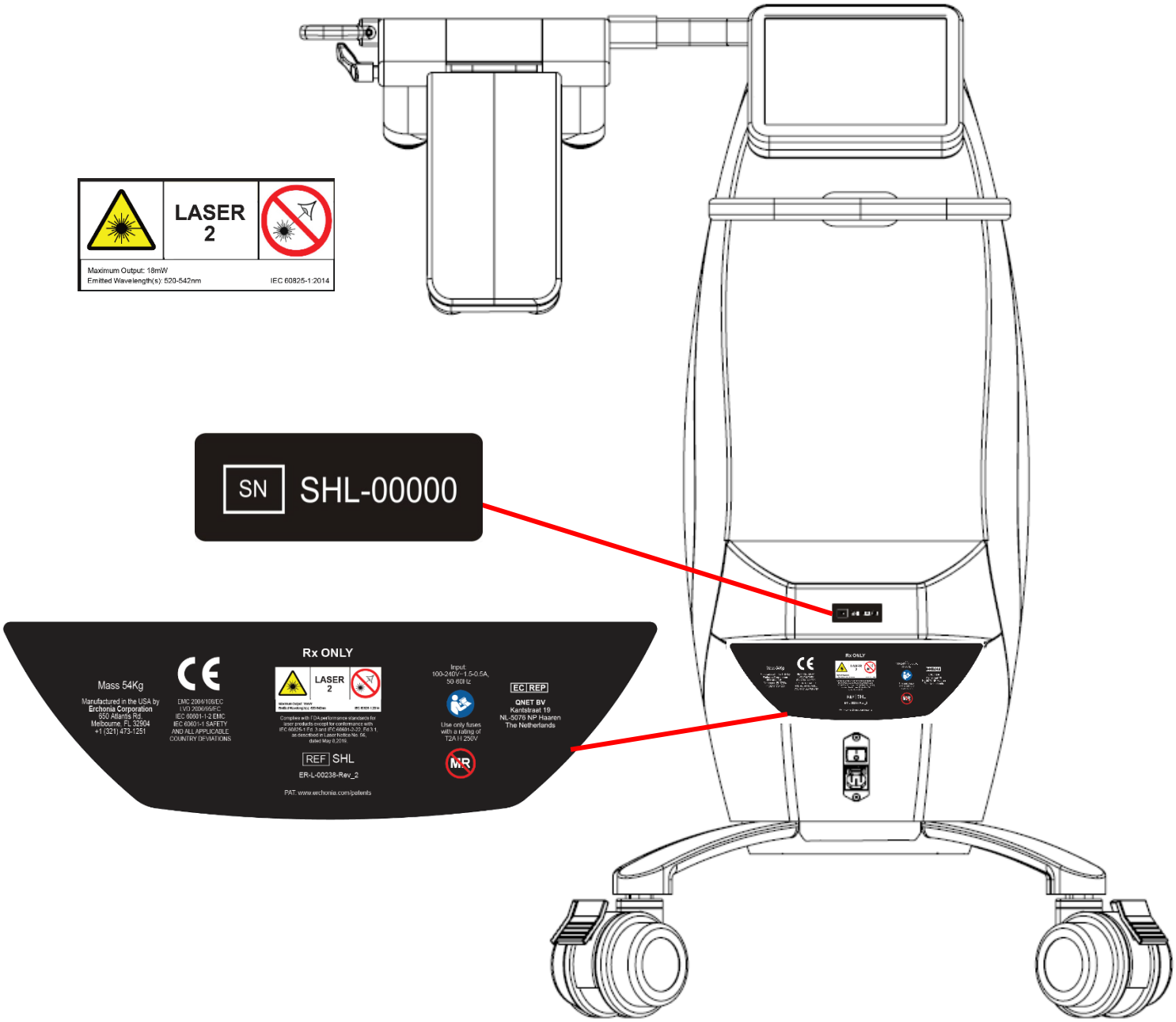


Fig. 27

The following diagram shows the location of the pinch point labels. The opposite side displays a duplicate pinch point label in the same location.

When transporting the device (example: from one room to another) ensure that the main arm [5] position is fully down and the outside arms [7] are condensed in towards center of laser head assembly, hold device handle and take caution to ensure the device does not tip.

Note: Reference “Main Arm”, “Arm Control Switch” and “Outside Laser Arms” in “Product Overview” section for further detail of pinch points and condensing the main arm.

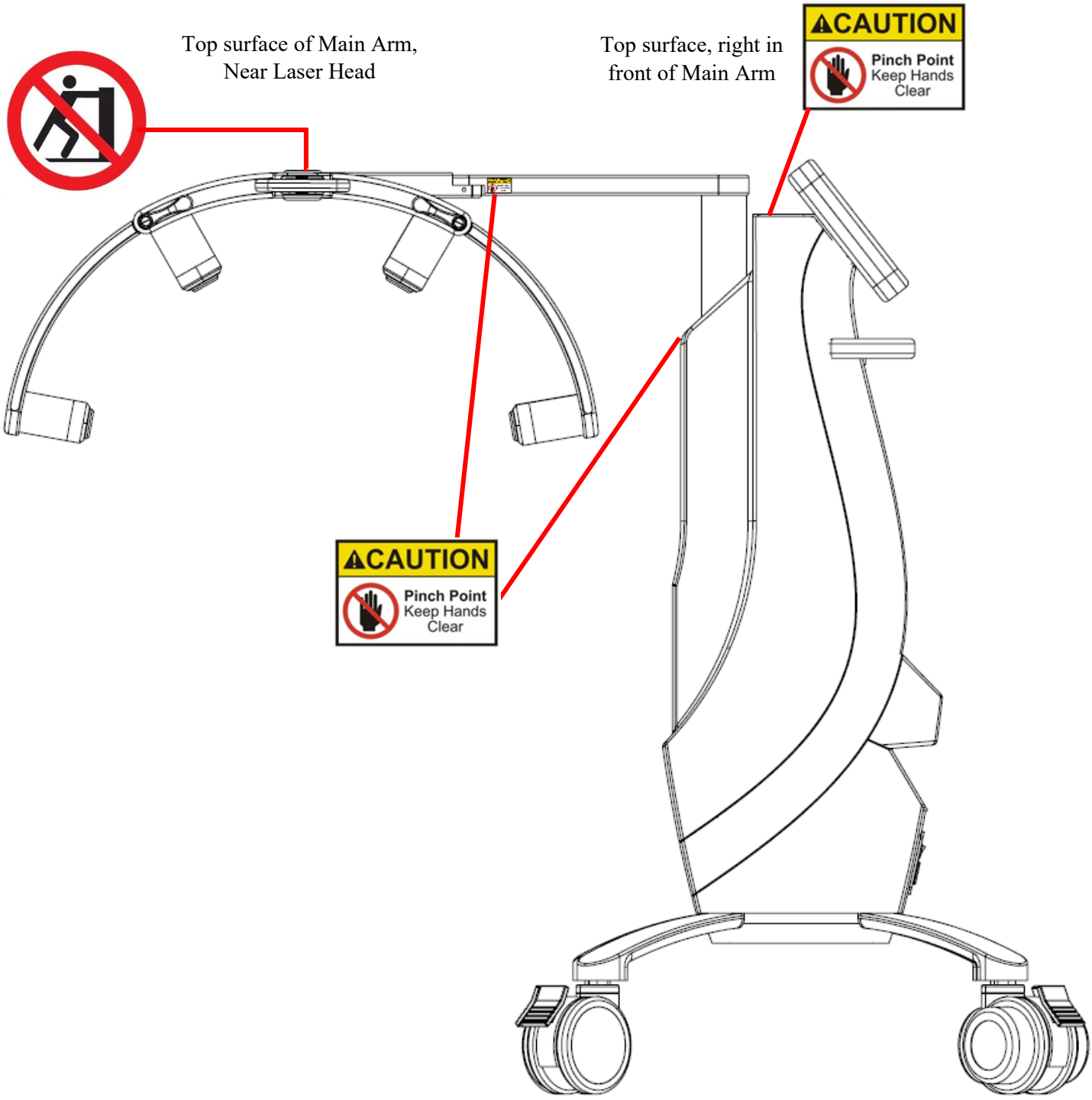


Fig. 28

The following diagram shows the image and location for each of the Laser Caution Labels that indicate the direction of the laser beam output. It shows an image of the Arm Control Switch Label indicating the direction for switch to move the arm up or down. In addition, shows location of the Pinch Point Label, the opposite side displays a duplicate pinch point label in the same location. A Laser Caution Label is provided on each laser output head for a total of 6.

Note: Reference "Main Arm", "Arm Control Switch" and "Outside Laser Arms" in "Product Overview" section for further detail of pinch points and moving the main arm up and down.

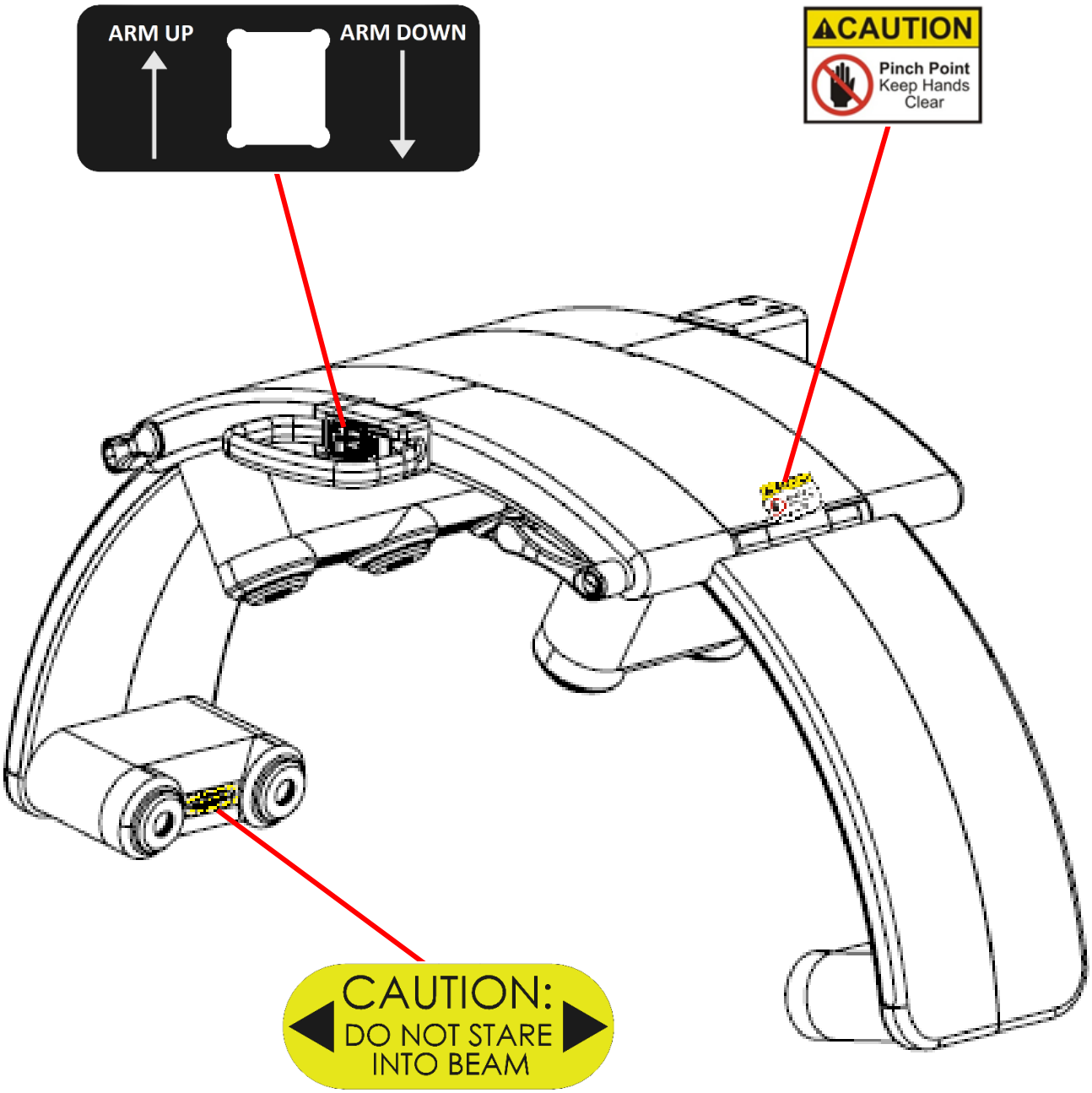


Fig. 29

SECTION 5 PROFESSIONAL USE INSTRUCTIONS

APPLICATION/ADMINISTRATION

This section defines instructions for the application of the laser energy and established protocols.

The Erchonia® Emerald is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) of up to 40 kg/m².
The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia® Corporation Researchers and IRB advisors. Medical and Healthcare professionals in receipt of this device are to use the preset as their medical training, and experience dictate, in accordance with the allowable limits of the laws of the state in which they practice; including but not limited to medical board, radiation control (if applicable) and the discipline license board.

Rx Only - IN THE US, FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

ERCHONIA® EMERALD PROTOCOL

Each patient receives twelve (12) total procedure administrations with the Erchonia® Emerald across a consecutive four-week period: three procedures per week evenly spaced. Exposure time to the Erchonia® Emerald per procedure administration is 15 minutes across the frontal treatment area (the targeted treatment areas) followed by 15 minutes across the corresponding dorsal treatment area.

The protocol is as follows:

1. Correctly fit the patient with the laser safety glasses.

2. The patient lies comfortably flat on their back on the table such that the front area of their body is facing upwards.

3. Position the center diodes of the Erchonia® Emerald at a distance of no more than 6 inches above the patient's targeted area following the procedure described in the previous section of this manual.

4. Activate the Erchonia® Emerald for 15 minutes over the patient's frontal region. Each laser diode emits to the patient a laser beam and creates a spiraling circle pattern that is totally random and independent from the others.

5. When session pauses (15 minutes), the patient then turns over to lie flat on their stomach.

6. Position the center diodes of the Erchonia® Emerald at a distance of no more than 6 inches above the patient's targeted area following the procedure described in the previous section of this manual.

7. Activate the Erchonia® Emerald for 15 minutes over the patient's back region. Each laser diode emits to the patient a laser beam and creates a spiraling circle pattern that is totally random and independent from the others.

8. Remove the patient's safety glasses and the procedure is complete.

ERCHONIA ® EMERALD PATIENT QUALIFICATION CHECKLIST

You should always use this Patient Qualification Checklist to make sure the patient is suitable for Erchonia® Emerald treatments before starting any treatments.

A. **PATIENT QUESTIONS:** Ask the patient all four questions below and check the answer as 'Yes' or 'No'

Question	**Yes**	**No**
Are you under 18 years of age?	☐	☐
(Female patients only): Are you pregnant or do you think you might be pregnant? ☐ Not applicable, patient is male	☐	☐
Do you have any open wounds (sores, cuts, ulcers, etc.)?	☐	☐
Do you have or are you being treated for any cancerous growths?	☐	☐

Check the correct box below and follow the action

☐	All of the 'No' boxes are checked => **continue with the patient qualification checklist**
☐	One or more 'Yes' boxes is checked => **the patient does not qualify for Erchonia ® Emerald treatments**

B. BODY MASS INDEX (BMI)

Calculate the patient's Body Mass Index (BMI) by following these steps:

1. Measure the patient's height in inches and write it in the table below
2. Measure the patient's weight in pounds and write it in the table below
3. Work out the patient's Body Mass Index (BMI) using the Body Mass Index Table on the next page by following these steps:
   a. Find the patient's height in inches that you measured in the furthest left-hand side column of the table.
   b. Move your finger from left to right across the row for that height until you find the patient's weight in pounds that you measured. This number may fall in between two other numbers. Move your finger to the closest number, which may be the number above or below the patient's weight number.
   c. Move your finger up the column for that weight until you reach the top row labeled 'BMI.' The number you land on is the patient's BMI.

For example, a patient whose height is 62 inches and weight is 160 pounds (closest to 158 pounds in that height row) has a BMI of 29.

4. Write the patient's BMI in the table below.

Patient's height (inches)	
Patient's weight (pounds)	
Patient's Body Mass Index (BMI)	

Check the correct box below and follow the action

☐	BMI is 40 or below => **the patient qualifies for Erchonia® Emerald treatment.**
☐	BMI is 41 or above=> **the patient <u>does not</u> qualify for Erchonia® Emerald treatment**

Body Mass Index Table

	Normal						Overweight					Obese										Extreme Obesity																
BMI	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**	**51**	**52**	**53**	**54**
Height (inches)	**Body Weight (pounds)**																																			
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Source: Adapted from *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.*

MEASUREMENT PROTOCOL

- We recommend taking patient measurements at the following times:

  1. Before the first treatment
  2. After the 12th treatment
  3. Two weeks after the 12th treatment

- To take proper measurements, the patient should stand with their feet shoulder width apart. Have them relax their muscles. **DO NOT** let them "suck it in," as this is a typical reflex of most patients.

- When taking measurements, make sure that the tape is pulled just tight enough so that it isn't sagging but at the same time it is not too snug.

- You may also want to take before and after photos of your patients. These are both great ways to show your patients' their progress!

SECTION 6 MAINTENANCE & WARRANTY INFORMATION

MAINTENANCE AND CLEANING

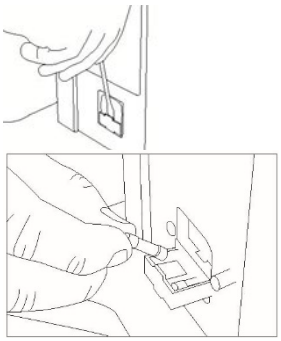
MAINTENANCE

The Erchonia® Emerald, if used according to the instructions contained within this manual will operate efficiently for years. To ensure proper care, it is advisable for the end user to perform:

1. Regular visual inspections to ensure there is no external damage other than normal wear and tear. Inspect all electrical cords for signs of excessive wear (cuts in insulation or fraying). If during these inspections, you identify an area of concern, please contact the manufacturer to determine if action is required.
2. If you notice a change in the performance of the device, while in the ON position, please contact the manufacturer to determine if action is required.
3. The internal components should not require any maintenance, however if an issue arises, which will show itself in the form of altered performance, the device must be sent to the manufacturer.
4. The PCB back up battery must be replaced every five years. This must be done by manufacturer.

FUSE REPLACEMENT

Replacing the fuses is the only service that can be conducted by the end-user.



To replace the fuses, unplug the AC power cord and open the fuse carrier door located in the power inlet module with a small flathead screwdriver. Remove old fuses and insert new ones in place. Close fuse box.
Fuses to be rated at T2AH 250 V with an input to cover 100 – 240 V~ 1.5-0.5 A, 50-60Hz.

ROUTINE USER MAINTENANCE

Clean the external surfaces of the device	Weekly, or as needed
Clean the touch screen display	Weekly, or as needed
Clean laser optics	Weekly, or as needed

CLEANING THE EXTERNAL SURFACES OF THE DEVICE

Use a cloth dampened with non-caustic cleaning solution, such as mild soap and water, isopropyl alcohol, or a "hospital-grade" disinfectant, to wipe the external surfaces of the device. Dry with a clean cloth, or allow to air dry.

CLEAN THE TOUCH SCREEN DISPLAY

Apply an alcohol-based cleaner to a soft cloth to clean the touch screen display.

	**DO NOT** spray or pour cleaning agents directly on the device or touch screen. You may damage the touchscreen and the system electronics.

LASER OPTICS CLEANING

If there is foreign material on the laser optics use lens paper or lens cloth **ONLY**. Abrasive material could cause laser light beam fragmentation, which may reduce the effectiveness of the treatment.

LASER GLASSES CLEANING

Use only mild soap, warm water and soft cloth to clean. **DO NOT USE CLEANING SOLVENTS**

WARRANTY

LIMITED WARRANTY

The Erchonia® Emerald device is warranted to be free from defect in material and workmanship for a period of TWO YEARS from the date of purchase.

For your device to be processed through the Service and Repair Department efficiently, contact the department prior to submitting your product. Repairs and Warranty work NOT coordinated through the Service and Repair Department prior to receipt can be delayed.

Items being sent in from oversees require special paperwork, available through the warranty department, if this paperwork is not obtained prior to shipping; your package will be delayed by customs.

TERMS AND CONDITIONS

- Shipping required facilitating warranty repair and or maintenance issues within the first 90-days, will be paid by manufacturer.
- Shipping required to facilitate warranty repair and or maintenance issues after 90-days, is the financial responsibility of the customer.
- Warranties of Erchonia® Corporation products are not transferable unless sold by a company-approved distributor, reseller and/or leasing company.
- The warranty DOES NOT cover instances involving or damages resulting from:
    - Accident, misuse or abuse
    - Lack of responsible care
    - Alteration or disassembly
    - Loss of parts
    - Exposure to the elements
    - Ingress of liquid
    - Exposure to excessive electromagnetic frequency

PRODUCT CHANGES

Erchonia Corporation reserves the right to make changes and improvements to its products without incurring any obligation to incorporate such improvements in products previously sold.

CONTACT US

Questions? If for any reason you are dissatisfied with this product, warranty concerns or questions regarding proper operation, please contact our Erchonia Customer Care representative for assistance. Contact us at:

Erchonia Customer Care
Phone: 1-888-242-0571
Email: info@erchonia.com

Or visit **erchonia.com**

TROUBLESHOOTING

Use the following information to help solve problems that may arise during use. If you still have questions, please call Erchonia® Customer Care at 1-888-242-0571, and we will be happy to help.

PROBLEM	POSSIBLE CAUSE	HOW TO RESOLVE
Device does not power on	AC power cord not plugged into device or power outlet.	Connect power cord.
	Power switch is in the OFF (O) position.	Turn the power switch to the ON (|) position.
	Blown fuse in device.	Replace using the correct fuses.
	Blown fuse or tripped circuit breaker in building.	Contact a qualified electric service technician.
Diode(s) does not power on	Electrical connector came apart.	Remove Arm Cover, Small Screws, Wire Cover and reconnect connectors (see: Section 3).
Motor(s) does not power on	Electrical connector came apart.	Remove Arm Cover, Small Screws, Wire Cover and reconnect connectors (see: Section 3).
Device powers off and reboots back to start-up screen	Laser diodes are powered ON while the Arm Control Switch quickly changes direction when lowering or raising the Laser Head Assembly. This may cause an electrical load on the device.	Adjust the height of the Laser Head Assembly to the patient with the diodes powered OFF prior to treatment.

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSIONS & IMMUNITY

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document. Portable and mobile RF communications equipment can affect the medical electrical equipment.
This declaration currently applies to the Erchonia ® Emerald, SHL device.

GUIDANCE AND MANUFACTURER'S DECLARATION-ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device 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	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

⚠WARNING

- This device should not be used adjacent to other equipment. If adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other that those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

GUIDANCE AND MANUFACTURER'S DECLARATION-ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EMERALD] is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes:

- UT is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE.

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SPECIFICATIONS

Relevant Information

Erchonia® Corporation
650 Atlantis Rd
Melbourne, FL 32904

Trade name: Erchonia ® EMERALD Laser
Model Number: SHL

Classifications

US

- Device Class: II
- Laser Class: 2

UL/CSA

- Electrical Class 1

Applicable Codes

FDA

21CFR 820 – Quality System Regulations
21CFR 1040.10 and 1040.11 by laser Notice 50

ISO

13485 – Medical Device Quality
14971 – Risk Management

IEC 60601-1-2 EMC
IEC 60601-1 Safety
IEC 60825-1 Laser Safety
CB Certified

Specifications

Device

- Weight: 118.5lbs / 53.75 kg
- Height: 56 in / 142.24 cm (Fully Extended)
- Full Color Touch Screen Control Center
- Two Independent Adjustable Arms for Desired Laser Concentration
- 4 Locking Anti-Static Casters
- Anodized Metal Frame
- Non-Allergenic Material
- Applied Part: Type B

Laser

- 10 Class 2 Line Generating Diode Modules
- Output: 16mW ± 2mW
- Wavelength: 520-542 nm
- Modulation: Constant Wave (CW)

Power

- Source: 100-240VAC, 50-60Hz, 1.5-0.5A
- Fuse Rating: T2AH 250V

Temperature

- Operating Temp: 59 to 85°F (15 to 29°C) Relative Humidly: <50%
- Transporting: -22 to 158°F (-30 to 70°C) Relative Humidly: <75%

Atmospheric Pressure (Altitude)

- Rated operating altitude ≤ 2000 m
- Pressure Range 80.0kPa- 105kPa

Legend:

FDA – US Food & Drug Administration, which includes the CDRH (Center for Device Radiological Health)
ISO – International Standards, Harmonized with US, Canadian, European and Asian standards

Doc No.	CR No.	Rev. Level	Rev. Date
OM-SHL2-C	CR# 01-22-ADM	05	01/14/2022
OM-SHL2-C	CR# 08-22-ADM	06	03/18/2022
OM-SHL2-C	CR# 15-22-ENG	07	06/10/2022

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LASER

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