ERCHONIA®
Healing Light, Perfected.

LunulaLaser™

Operation & Maintenance Manual

Read this entire booklet before using your Erchonia Lunula 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, cautions and safety information in this booklet before using your LunulaLaser™ 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: 1-864-531-0064
Email: info@erchonia.com

Or visit **erchonia.com**

ATTENTION: By purchase of the Erchonia device, you, the health care professional, acknowledges and bares full responsibly of the knowledge that laser, and the indications for use associated with the laser, are within your disciplines allowed scope of practice, as regulated by the state medical and professional boards.

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

CONTENTS

SECTION 1 GENERAL INFORMATION

The LunulaLaser™ Operator's Guide provides information operators need for the safe and effective use and care of the device. Procedures for daily checkout and device care are located in "Maintenance and Cleaning".
It is important that you read and understand all the information contained in this operator's guide before performing any treatments with the LunulaLaser™. If you have any questions, contact our Erchonia Customer Care representatives.

LUNULALASER™ TECHNOLOGY BACKGROUND

WHAT IS THE LUNULALASER™?

The LunulaLaser™ basis of action is Low Level Laser Technology (LLLT) which provides the temporary increase of clear nail in patients with onychomycosis, without the risks and harmful side effects of oral medication, or the pain and recovery time associated with other laser treatments. The LunulaLaser combines two different wavelength lasers: (1) 405 nm for direct fungicidal activity and (1) 635 nm to stimulate a natural immune response. The two lasers work together to increase clear nail in patients with onychomycosis. This is substantiated by a compilation of pre-procedure and six-month post-procedure photographs of one hundred (100) great toenails with varying degrees of onychomycosis disease involvement selected from amongst an existing pool of photographs taken during three prior Erchonia Corporation research studies wherein 4 sequential weekly 12-minute procedures with the LunulaLaser™ were administered. Sixty-nine percent (69%) of all study treated toenails evaluated in this study met the study individual toenail success criteria**,** exceeding the pre-established overall study success goal of 60% by 9%.
This outcome substantiates primary outcome analysis of prior clinical trial and validates the claim that the Erchonia LunulaLaser™ is an effective tool for increasing clear nail growth in toenails infected with onychomycosis, significantly increasing mm of clear nail over a 6-month period following completion of the 3-week procedure administration phase.

The LunulaLaser™ has been specifically designed for use by physicians and their staff, requiring very little set-up time and no operator intervention, creating a complete walk-away treatment thanks to preset dosage times and output energies. This innovative therapy provides effective relief for patients after just four treatments, by restoring growth of clear, healthy nails.

The LunulaLaser™ is designed to be used on the floor. It is easy to use, compact, all in one AC powered device that is easy to carry. The laser output heads are located in the enclosure, a fixed position that allows optimal coverage of the nail bed.

By design of the device, it is not possible for the patient to move the foot's position to any significant degree that would impact the intended exposure to the laser procedure, particularly considering that the laser beam is designed to cover the entire treated toe region. With the creative enclosure design, the laser light is confined to the treatment area, ensuring that no laser energy or light goes beyond the enclosure.

The user interface is a touch screen which communicates with the PLC to initiate, stop, pause or set the energy flow to the diodes. The diode 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.

PACKAGE CONTENTS

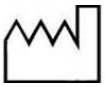
The LunulaLaser™ is shipped in one packing box.

- LunulaLaser™ device
- Power cord
- 1 patient glasses
- 2 Keys
- Operation and Maintenance (Manual) Card

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/EC and LVD 2014/35/EC
	Power ON/OFF
	Date of Manufacture
	Manufacturer
	Authorized representative in the European Community.
	Serial Number
	Consult instructions for use.
	**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.
Rx Only	Prescription only (In the US, Federal law restricts this device to sale by or on the order of a physician)

SAFETY INFORMATION

Read the following important safety information before using the LunulaLaser™.

WHEN NOT TO USE (CONTRAINDICATION)

	Safety of non-thermal lasers for use over a pregnant uterus has not been established.
	Physicians should exercise caution with patients that have skin that is infected, burned, cut or lack of skin sensitivity, as this could cause discomfort or irritation.

WARNINGS

	You must follow these Instructions for Use when using the LunulaLaser™. 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. To achieve the specified level of protection against spilled or splashed liquids, unplug the device from the power supply and thoroughly dry all exposed surfaces of this device and allow to dry thoroughly prior to operation.
	**DO NOT** disassemble, modify, or remodel the device or accessories. This may cause device damage, malfunction, electrical shock, fire, or personal injury.
	**Beware of electrocution.** 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.
	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.
	Laser treatment should not be applied over, or in proximity to (near), cancerous lesions (such as moles and other suspicious skin markings unless known not to be cancerous) as conclusive tests have not been conducted.
	To avoid risk of electric shock, do not defeat the safety purpose of the grounding-type plug. A grounding-type plug has two blades and a third grounding prong. The wide blade or third prong is provided for your safety. If the provided plug does not fit into your outlet, consult an electrician.

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 (6 inches) to other devices that emit frequency. If this device causes interference to other devices, which can be determined by turning the device off and on, you are encouraged to try to correct the interference by one of the following measures: ➢ Reorient or relocate the receiving device. ➢ Increase the separation between the equipment ➢ Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
	Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any laser device. Observe the cautionary 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.
	Avoid contact with flammable anesthetic with air or with oxygen or nitrous oxide.
	If you have difficulty operating the device after carefully reviewing this user's manual, contact Erchonia Corporation for assistance.
	This device should be operated in temperatures between 59° to 85°F (15° to 29°C), and transported in temperatures between -22° to 158°F (-30° to 70°C), with relative humidity less than 75%.
	Do not position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.
	Inspect electrical cord and associated connectors before each use. **ONLY** use the power cord supplied with the device. Using a different power cord could damage the device

NOTIFICATION OF ADVERSE EVENTS / VIGILANCE

As a health care provider, you may have responsibilities under the Medical Device Reporting for User Facilities (FDA 21 CFR part 803), or the local government Vigilance reporting requirements to report the occurrence of events that include device-related death and serious injury or illness. If such an event is brought to your attention, to ensure compliance; contact both the Agent identified on the label and the manufacturer, Erchonia Corporation. 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.

LUNULALASER™ INDICATIONS FOR USE

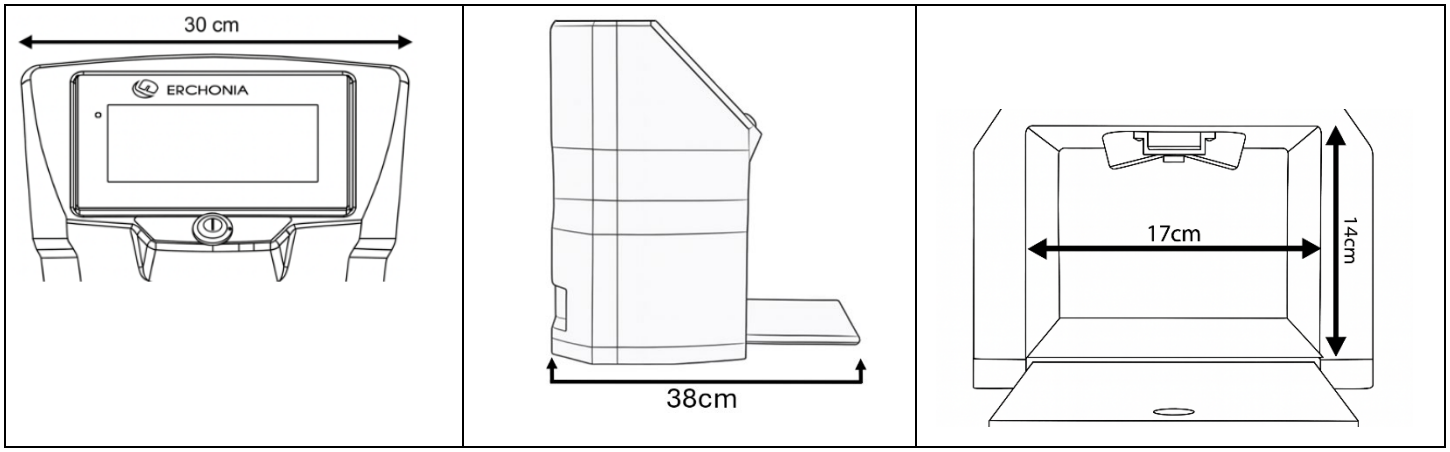
The LunulaLaser™ device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes trichophyton rubrum and t. mentagrophytes, and/or yeasts candida albicans, etc.)

SECTION 2 PRODUCT OVERVIEW

NOMENCLATURE AND LABELING

The Erchonia® LunulaLaser™ device contains two diodes, a 635nm and a 405nm diode, each with a tolerance of ±10 nanometer.
The Erchonia® LunulaLaser™ device 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 II.
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 unit ensuring the remainder of this manual is clearly communicated.

Weight: 19lbs / 8.62 kg
Height: 16in/40 cm Width: 12in/30 cm Depth: 10in/25.40cm (38 cm with platform extended)



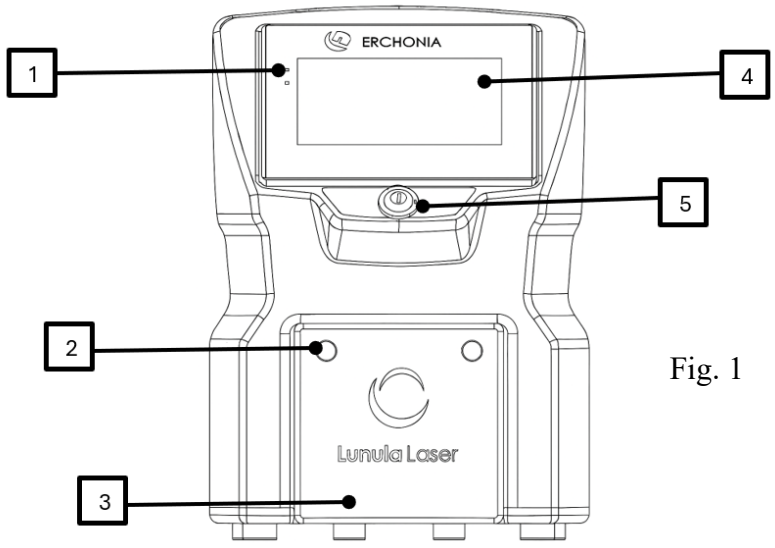


Fig. 1

1. Power Indicator Light
2. Pull Knobs / Stops
3. Door / Foot Platform
4. Touch Screen
5. Key Switch

POWER INDICATOR LIGHT [1]

When the LunulaLaser™ is ON, the power indicator light shows GREEN. When the device is OFF, the LED is NOT lit.

PULL KNOBS / STOPS [2]

On both sides of the door, there are protrusions that function as pull knobs when the door is closed. Pulling on these opens the door. Once the door is open, the protrusions function as stops, supporting the weight of the patient's foot.

DOOR / FOOT PLATFORM [3]

In the closed position (as shown on Fig 1), this element is a door. The door / foot platform is multifunctional, when open, the inside of the door becomes the back half of the treatment platform.

TOUCH SCREEN [4]

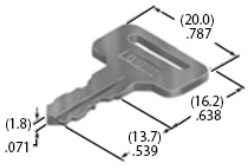
The touch screen functions as a display screen and an input panel, providing information to the user and a means to operate the device by touching the appropriate icon.

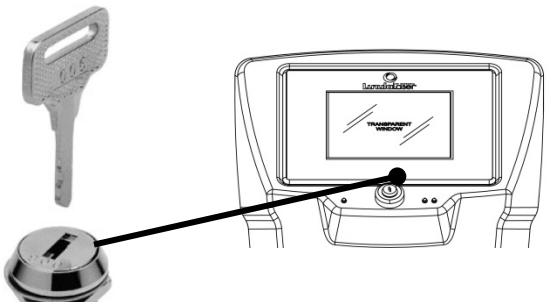
⚠	**CAUTION - DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the icons on the touch screen as damage may result. Avoid using abrasives (including paper towels) on the touch screen display window.

KEY SWITCH [5]

The Key Switch is the outwardly visible portion of an internal locking mechanism below the touch screen [4] that comes with an external key. Together they allow the end user to turn the device ON or OFF. ("O" = OFF and "|" = ON) In the OFF position the device is locked. From the locked position the external key can be removed. This is a code-regulated feature installed to ensure no unauthorized use of the laser device. The device will not operate if the key is in the OFF position. Turning the key to the OFF position while the device is in operation will immediately shut down the device. The key switch has a failsafe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The device uses a 2-amp fuse, which will only require replacement if there is an issue.

NOTE: Two keys are included with the LunulaLaser™. The key is brass with nickel plating, approximately 1.17 inch long. The device requires (1) key to operate; the key cannot be removed unless in the "O" OFF position. Place your spare key in a safe location in case the original is misplaced. Make sure you have inserted key into the key switch to use.





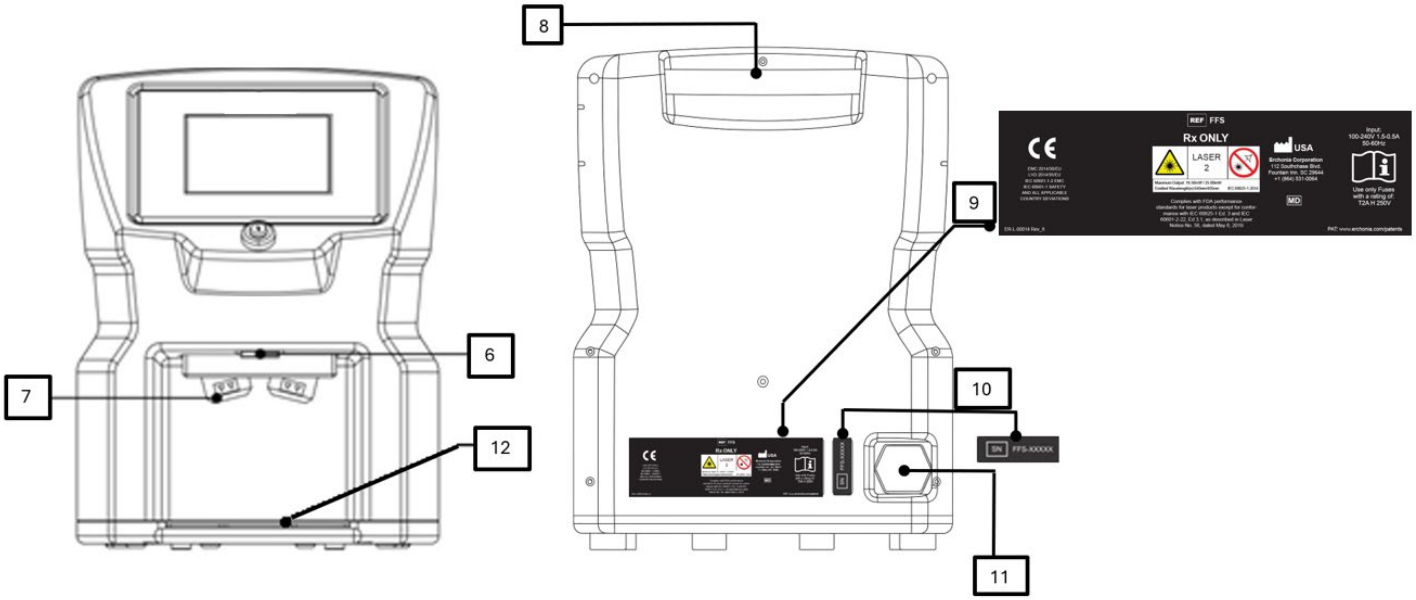


Fig. 2

6. Magnetic Latch
7. Laser Output Heads
8. Handle
9. Compliance Label
10. Serial Number
11. Power Inlet/Fuse Holder
12. Stainless Steel Plates

MAGNETIC LATCH [6]

The Door / Foot Platform are held in the closed position by this magnetic latch.

LASER OUTPUT HEADS [7]

Each one of the two output heads emits laser light, one a 405nm violet beam and the other 635nm red beam

HANDLE [8]

The handle enables the user to pick up, carry and / or move the device with ease.

COMPLIANCE LABEL [9]

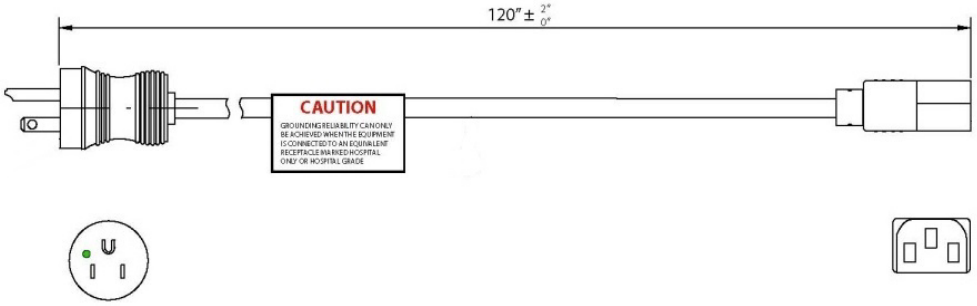
Contains all the governing agencies required information regarding the device, including but not limited to the US FDA device classification, EU classification, output information and power inlet symbols. Also includes the manufacturer name and address. (images are for reference only)

SERIAL NUMBER [10]

This is the unique identifier for the device. All information regarding this device is associated with the serial number.

POWER INLET MODULE/FUSE HOLDER [11]

The device contains a flexible detachable power cord. **NOTE:** Make sure the power cord is plugged into 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. Fuses to be rated a T2AH 250V with an input to cover 100 – 240V~ .5-1.5A, 50-60 Hz. Ref: Maintenance section for replacement instructions.



The power cord does not contain any operator-serviceable components. If the power cord needs replacement, contact an Erchonia Corporation representative.

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

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

⚠	**CAUTION - DO NOT** connect to an electrical outlet controlled by a wall switch or dimmer. For continued safety and performance, use only the power cord supplied by Erchonia®. Do not position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.

STAINLESS STEEL PLATES [12]

The device contains two stainless steel plates inside the treatment space. These plates are designed as a biocompatible material for the foot to lie upon during treatment. **NOTE:** Ensure the stainless-steel plates in treatment area are disinfected before use. For further instructions, see – MAINTENANCE AND CLEANING/ DISINFECTING STAINLESS STEEL PLATES INSTRUCTIONS section of manual.

PROTECTIVE EYEWEAR

The Erchonia® LUNULA™ 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. The safety glasses, sufficiently and effectively block the laser light spectrum at OD 2+ @ 635nm, OD 0.75 @ 405nm VLT60.

	**WARNING-** The patient should always be correctly fitted with the protective eyewear provided before turning on the laser and doing any treatment.

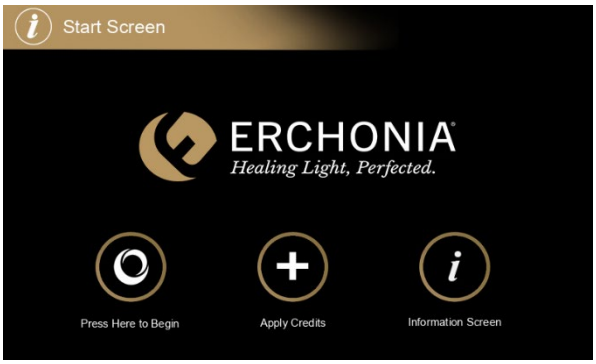
SECTION 3 LUNULALASER SETUP & OPERATION

Now that you understand the basic features of the LunulaLaser, it is important to understand how to use them when administering treatments.

CHANGING LANGUAGE

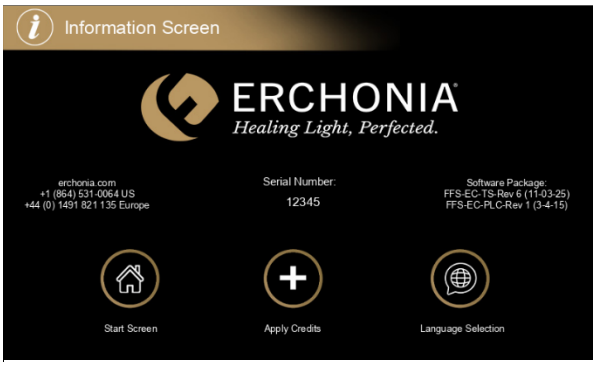
The LunulaLaser software FFS-EC has the ability to change the device language from English to French, German, Spanish, Italian, Portuguese, Russian and Polish. Changing the language will change all text on the touchscreen.

Start Screen



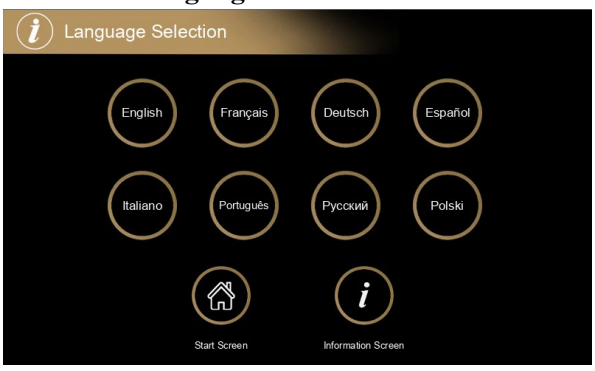
- Press the **"Information Screen"** button located on the **"Start Screen"**. This will display the **"Information Screen"**.

Device Information Screen



- Press the **"Language Selection"** button. This will display the **"Language Selection"** screen.

Language Selection Screen



- Press and select the desired language.
- Press the **"Start Screen"** button to return to the **"Start Screen"**.

All text displayed on each screen will now be changed to the applicable language that was selected.

STARTING, STOPPING, AND INTERRUPTING THE ERCHONIA LUNULALASER™ PROCEDURE

1. Position the LunulaLaser™ in front of the patient, on the floor.

2. Plug power cord into power inlet module [11], then plug into mains (wall socket).

3. Pull the Pull Knob /Stop [2] to open the treatment space.

4. Have patient place foot to be treated on the treatment platform. Heel on back, toes on front platform under laser output heads [7] (See Fig 3 for foot placement) **Note:** Ensure the stainless-steel plates in treatment area are disinfected before use. For further instructions, see – MAINTENANCE AND CLEANING/ DISINFECTING STAINLESS STEEL PLATES INSTRUCTIONS section of manual.

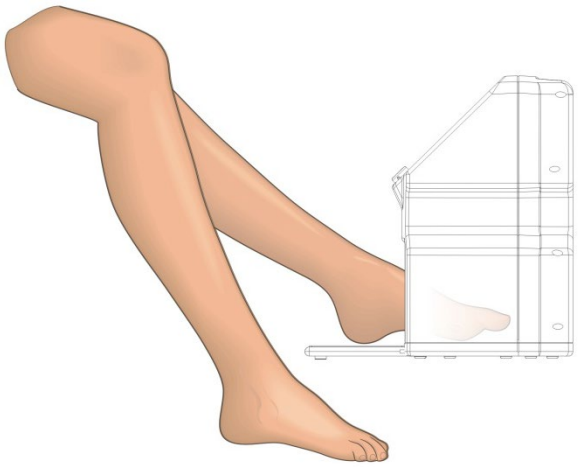


Fig 3

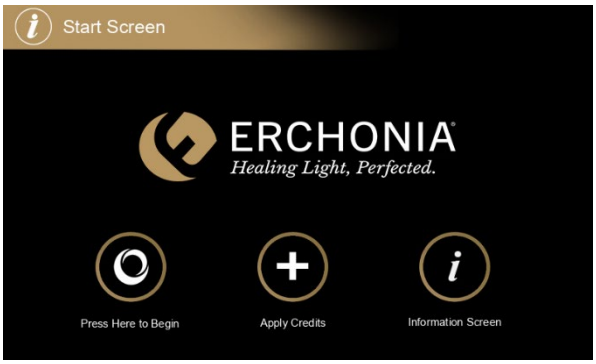
5. Turn the device ON by placing the key in the key lock and turn clockwise to the ON "|" position.

6. Ensure the power indicator light is lit [1].

NOTES:

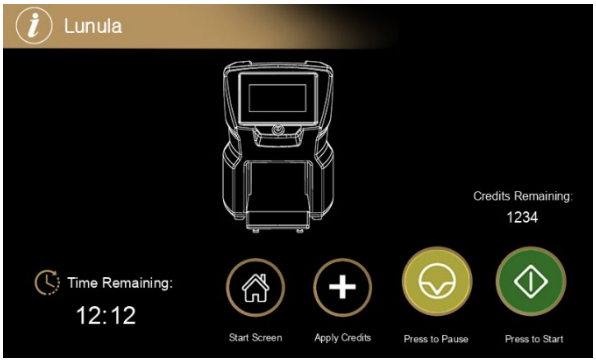
- The device requires a minimum of 30 -45 seconds to launch the programming contained with the internal computers. Once the device is ready for use, the touch screen will display the **"Start Screen"**.
- The protocol software is factory set and cannot be altered by the end user.
- Each icon touched successfully will result in a single audio "beep".
- If power is interrupted during the procedure, the device will automatically restart to the **"Start Screen**". The lasers will have to be reinitiated to begin the procedure.
- Press the **"Press Here to Begin"** button to access the **"Treatment Screen"**.
- Press the **"Apply Credits"** button to access the **"Apply Credits"** screen.
- Press the **"Information Screen"** button to access the **"Information Screen"**.

Start Screen



7. On the treatment screen, press the **"Press to Start"** icon to begin the non-invasive procedure. Once you start the procedure you will observe the following:
    a. The red and violet laser diodes both turn on and rotate clockwise.
    b. The **"Time Remaining"** timer begins counting down.
    c. The **"Press to Start"** button changes to the red **"Press to Stop"** button.
    d. The **"Credits Remaining"** counter is deducted by 1.

Treatment Screen



8. To pause the treatment, press the **"Press to Pause"** button. When the treatment is paused, you will observe the following:
    a. The red and violet laser diodes both turn off and stop rotating.
    b. The **"Time Remaining"** timer pauses.
    c. The **"Press to Pause"** button changes to the green **"Press to Resume"** button.

9. To resume the treatment, press the green **"Press to Resume"** button.

10. Once the **"Time Remaining"** timer reaches 0:00, both lasers will power off and the time will remain at 0:00.

11. Press the **"Start Screen"** button to return to the **"Start Screen"**, then turn the device off by turning the key counterclockwise to the **OFF "O"** position.

NOTES:

- You can access the **"Apply Credits"** screen by pressing the **"Apply Credits"** button.
- If the other foot requires treatment, place foot as shown in Fig 3 and repeat steps 6-9.
- To power off the device at any time, you can press the **"Press to Stop"** icon, then turn the key to the off position or unplug the device from the power outlet.

DEVICE INFORMATION SCREEN

Press the **"Information Screen"** button on the **"Start Screen"** to access the device information screen. This screen displays the following:

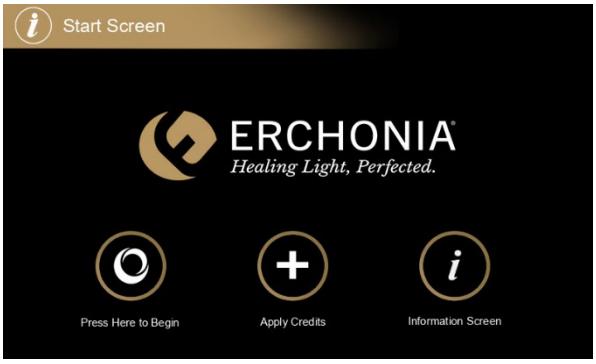
a. Manufacturer's contact information.
b. Software revision.
c. Device serial number.
d. **"Language Selection"** button, which when pressed will display the **"Language Selection"** screen.
e. **"Apply Credits"** button, which when pressed will display the **"Apply Credits"** screen.
f. **"Start Screen"** button, which when pressed will display the **"Start Screen"**.

For more information on your device contact:

Erchonia Customer Care
Phone: 1-864-531-0064
Email: info@erchonia.com

Or visit **erchonia.com**

Start Screen



Device Information Screen

CREDITS WARNING TEXT/APPLY CREDITS SCREEN

When the device is running low on credits, a warning text will appear on both the **"Treatment Screen"** and **"Start Screen"** to inform you that there are less than 10 credits remaining (image 1). When the device is out of credits (0 credits remaining), another warning text will appear on both the **"Treatment Screen"** and **"Start Screen"** to inform you that there are no credits remaining (image 2).

Treatment Screen

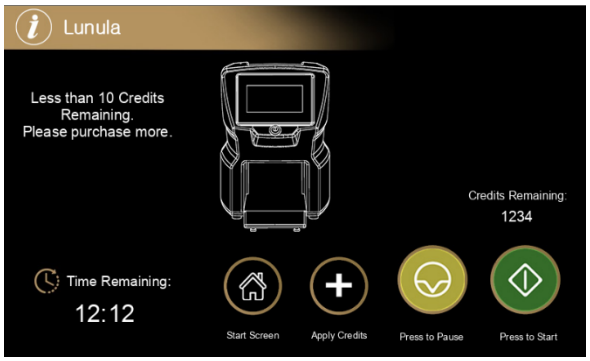


Image 1

Treatment Screen

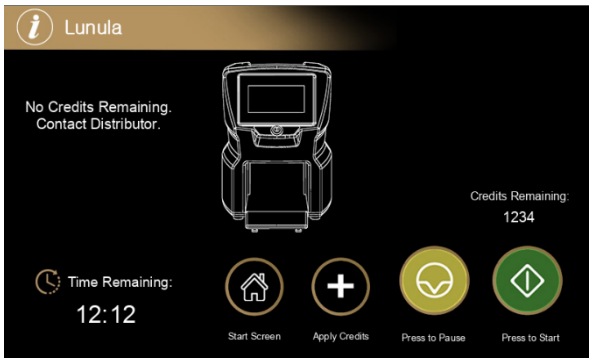


Image 2

To purchase more credits, you must go to the **"Apply Credits"** screen (image 3). You can get to this screen in three ways by touching the **"Apply Credits"** button on either the **"Treatment Screen"**, **"Start Screen",** or **"Information Screen"**.

Apply Credits Screen

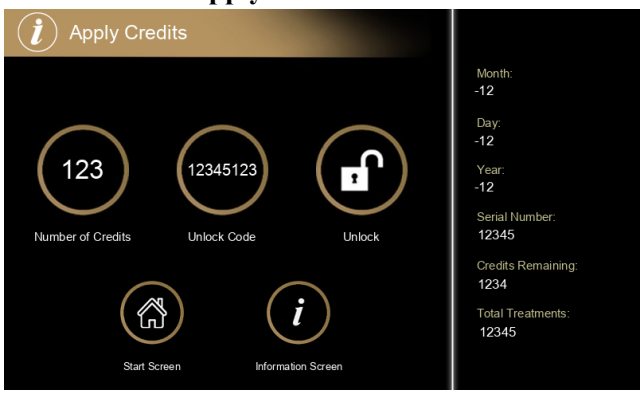


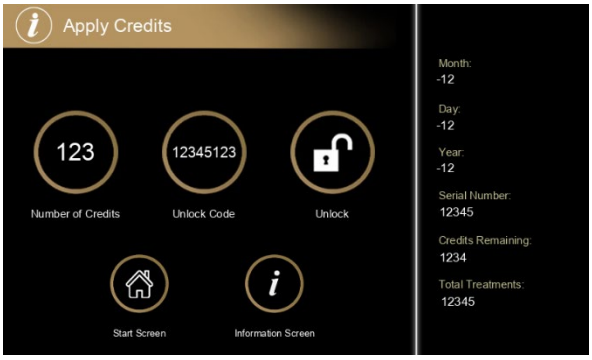
Image 3

PURCHASING CREDITS

On the **"Apply Credits"** screen (image 3), you can purchase credits from the distributor. Displayed on this screen is:

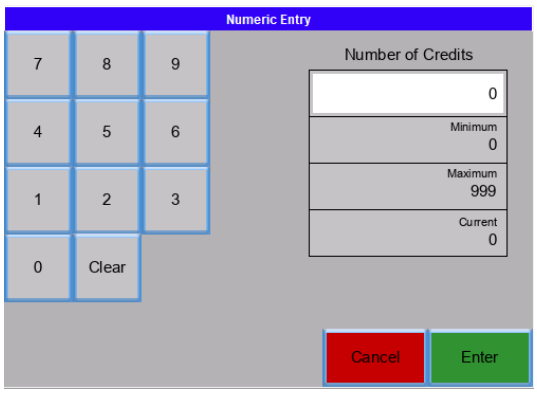
- The device computer date (Month, Day, and Year).
- The device serial number.
- The credits remaining currently on the device.
- The total treatments that have been used on the device.
- The number of credits to purchase.
- The unlock code to purchase.
- The **"Unlock"** button to apply purchased credits.
- The **"Start Screen"** button, which when pressed will return to the **"Start Screen"**.
- The **"Information Screen"** button, which when pressed will return to the **"Information Screen"**.

Apply Credits Screen



To purchase credits, first contact the distributor. You will need to provide your device serial number and the date displayed on the device. All of this information is available on the **"Apply Credits"** screen.

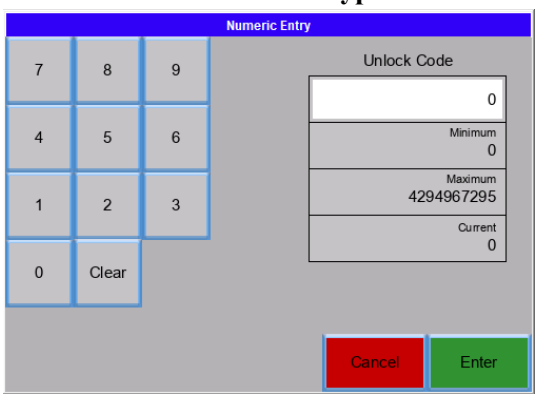
Number of Credits Keypad



1. Press the **"Number of Credits"** button on the **"Apply Credits"** screen to display the grey numeric keypad.
2. Enter the number of credits being purchased, then press the **"Enter"** button to accept and proceed back to the **"Apply Credits"** screen.

3. Next, press the **"Unlock Code"** button on the **"Apply Credits"** screen to display the grey numeric keypad.
4. Enter the unlock code given to you by the representative, then press the **"Enter"** button to accept and proceed back to the **"Apply Credits"** screen.
5. Next, press the **"Unlock"** button. If the correct number of credits and unlock code are entered to create a successful credit code entry, the **"Unlock"** text changes to **"Unlocked"** text and will display for 24hrs until credits can be added again.
   NOTE: If an incorrect credit code entry is applied, the **"Code Failure"** text will appear above the **"Unlock"** button. The **"Code Failure"** text is removed once a successful credit entry is applied.
6. Once credits have been added to the device, press the **"Start Screen"** button to return to the **"Start Screen"**.

Unlock Code Keypad



SECTION 4 PROFESSIONAL USE INSTRUCTIONS

APPLICATION/ADMINISTRATION

LunulaLaser™ is based on Low Level Laser Technology (LLLT) and provides temporary increase of clear nail growth in patients with onychomycosis without the risks and harmful side effects of oral medication, or the pain and recovery time associated with other laser treatments. The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia Corporation Researchers and IRB advisors (see clinical trial summary). Medical professionals in receipt of this device are to use the preset as their medical training and experience dictate.

Rx Only In the US, Federal law restricts this device to sale by or on the order of a physician

ERCHONIA LUNULALASER™ PROTOCOL

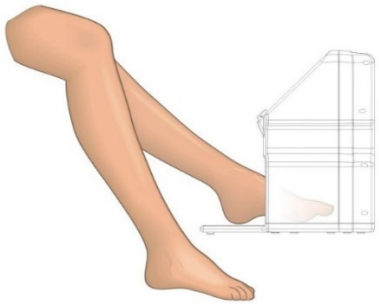
Now that you understand how to operate the LunulaLaser™, the following section describes the steps to follow each time you administer a treatment with the LunulaLaser™ to a patient. There are four treatment administrations with the Erchonia LunulaLaser™ device, each one week apart.

The treatment protocol for each of the four Erchonia LunulaLaser™ treatment administrations is as follows:

1. The patient is seated comfortably with the LunulaLaser™ placed on the floor in front. **Note:** Ensure the stainless-steel plates in treatment area are disinfected before use. For further instructions, see – MAINTENANCE AND CLEANING/ DISINFECTING STAINLESS STEEL PLATES INSTRUCTIONS section of manual.

2. Have patient put on protective eyewear.

3. The patient places the foot on the treatment platform inside the Erchonia LunulaLaser™ device – heel on the back, toes on the front platform under the laser output heads, as shown in the figure below.



4. The Erchonia LunulaLaser™ is activated such that the laser light is directed at the great toenail at a distance of approximately 4 inches above the toenail.

5. The dual frequencies of 405 nm and 635nm are activated simultaneously for 12 minutes of total treatment administration time.

By design of the device, it is not possible for the patient to move the foot's position to any significant degree that would impact the intended exposure to the laser procedure, particularly considering that the laser beam is designed to cover the entire treated toe region. The exception would be if the patient withdrew his or her foot entirely from the laser device mid-treatment administration, in which case, the foot would be re-inserted at once and the remaining minutes of exposure completed such that the total maximum exposure time in one session would not ever exceed the pre-determined 12-minutes.

6. The patient removes his or her foot from the LunulaLaser™.

7. The laser treatment administration is complete.

Post Treatment Patient Follow-up Recommendations:
12 weeks
36 weeks
48 weeks (based on severity of infection)

CLINICAL TRIAL SUMMARY

RESULTS SUMMARY AND CONCLUSION

BACKGROUND: The purpose of this study was to demonstrate through retrospective analysis the efficacy of the Erchonia LunulaLaser™, manufactured by Erchonia Corporation, for the increase of clear nail in patients with toenail onychomycosis, when applying the LunulaLaser™ to the toenail for 12 minutes one time per week for a total of 4 procedure administrations.

STUDY DESIGN: This study was a retrospective analysis of a compilation of pre-procedure and six-month post-procedure photographs of one hundred (100) great toenails with varying degrees of onychomycosis disease involvement selected from amongst an existing pool of photographs taken during three prior Erchonia Corporation research studies wherein 4 sequential weekly 12-minute procedures with the LunulaLaser™ were administered. The evaluating investigator was blinded to corresponding pre- and post-procedure photographs through application of a randomized numeric coding methodology.

STUDY MEASURES: The linear measurement of millimeter (mm) of clear nail from the proximal nail fold to the most proximal area of nail dystrophy was objectively measured from unmarked digital photographic images using the validated GNU Image Manipulation Program (GIMP 2.8) software system, a multi-platform image/photo manipulation software system, at baseline evaluation (prior to LunulaLaser™ procedure administration) and at 6 months following completion of the LunulaLaser™ procedure administration protocol.

STUDY PROCEDURE: Study great toenails had received 4 procedure administrations with the Erchonia LunulaLaser™ across a consecutive 3-week period: each procedure administration 7 days apart. Exposure time to the laser was 12 minutes, directed at and about 4 inches above the great toenail.

SUBJECTS AND SAMPLE: One hundred (100) treated great toenails of varying degrees of onychomycosis involvement at study entry were evaluated in this study. Subjects were 18 years or older with current bacterial/fungal infection classified by the investigator and confirmed through lab testing as positive for onychomycosis.

STUDY RESULTS

Primary Outcome Measure: Change in mm of Clear Nail from Baseline to Study Endpoint: The primary efficacy outcome measure in this study was the mm of clear nail growth at 6 months post procedure administration end relative to baseline (pre-procedure administration). Individual toenail success was defined as 3 mm or more of clear nail growth at 6 months post-procedure end relative to baseline. Overall study success was defined as an anticipated 60% of treated toenails meeting the individual toenail success criteria.

Sixty-nine percent (69%) of all study treated toenails evaluated in this study met the study individual toenail success criteria**,** exceeding the pre-established overall study success goal of 60% by 9%. The magnitude of the mean change in

mm of clear nail from baseline to 6 months post-procedure evaluation for all treated toenails was an increase of 6.07 mm, 3.07 mm in excess of the pre-established 3 mm increase success criteria. A t-test for paired samples found this mean change of +6.07 mm in clear nail to be statistically significant ($t=-10.74$; $df=99$; $p<0.0001$).

ADVERSE EVENTS: No adverse event was reported or observed for any subject throughout study duration in any of the three clinical trials from which this study's retrospective sample was drawn.

CONCLUSION: The Erchonia LunulaLaser™ is an effective tool for increasing clear nail in toenails infected with onychomycosis, significantly increasing mm of clear nail over a 6-month period following completion of the 3-week procedure administration phase.

SECTION 5 MAINTENANCE & WARRANTY INFORMATION

TECHNICAL INFORMATION

Technical documentation required by the customer, in case of necessary reparations, will be provided by Erchonia 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 filed and documented technical file.

SERVICE AND REPAIR

If a device requires service, contact the Erchonia Service and Repair Department at:
Telephone: 1-864-531-0064
Email: service@erchonia.com

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 and power cord 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
112 Southchase Blvd.
Fountain Inn, SC 29644 USA

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.

MAINTENANCE AND CLEANING

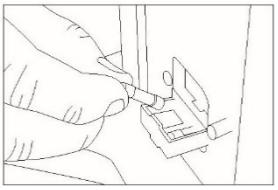
MAINTENANCE

The Erchonia® LunulaLaser™ device, 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 the power cord for signs of excessive wear (cuts in insulation or fraying). If during these inspections, you identify an area of concern, please contact the manufacture to purchase a replacement power cord.
2. If you notice a change in the performance of the device, while in the ON position, please contact the manufacture 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 manufacture.
4. Since the device contains a touchscreen interface, periodic cleaning of the touchscreen will be necessary. To clean the touchscreen, use a nearly dry cloth containing one of the mild cleaning agents listed below. Ensure there is **NOT** an excess of fluid.
5. The touchscreen back up battery is recommended to be replaced every five years. This must be done by the 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 input module with a small flathead screwdriver. Remove old fuses and insert new ones in place. Close fuse box. Fuses to be rated at T2AH 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.

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
Clean Laser glasses	Between each patient use
Disinfect stainless steel plates	Between each patient use

CLEAN 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.

⚠	**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. To achieve the specified level of protection against spilled or splashed liquids, unplug the device from the power supply and thoroughly dry all exposed surfaces of this device and allow to dry thoroughly prior to operation.

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 console, touchscreen, and the system electronics.

LASER OPTICS CLEANING

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**

DISINFECTING TREATMENT AREA (STAINLESS STEEL PLATE)

Disinfect the stainless-steel plates between patient use with a germicidal disposable wipe, such as Sani-Cloth® Plus or Sani-cloth® HB from Professional Disposables International Inc.[1.] This product has been validated as acceptable disinfecting agents through assessment of product specification, industry standards and medical best practices. Use one wipe per area, discarding wipe after use. **DO NOT REUSE.**

Allow ambient air drying until there is no more superficial moisture on the stainless-steel plates.

1. Sani-Cloth Plus and Sani-Cloth HB are registered trademarks of Professional Disposables International, Inc.

WARRANTY

LIMITED WARRANTY

The Erchonia® laser 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 to Erchonia from outside the US 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: 1-864-531-0064
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 and we will be happy to help.

PROBLEM	POSSIBLE CAUSE	HOW TO RESOLVE
POWER Device does not power on	AC power cord not plugged into device or line power.	Connect power cord.
	Blown fuse.	Replace using the correct fuses.
	Lockout key not positioned correctly.	("O" = OFF and "|" = ON)
	Blown fuse or tripped circuit breaker in building.	Contact a qualified service technician.

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 LunulaLaser™ [FFS] 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	± 6 kV contact ± 8 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% *U*T (30% dip in *U*T) 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% *U*T (30% dip in *U*T) 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	3 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	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 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 [FFS] 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.

TECHNICAL SPECIFICATIONS

Relevant Information

Erchonia Corporation
112 Southchase Blvd.
Fountain Inn, SC 29644

Trade name: LunulaLaser™
Model Number: FFS

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

EMC 2014/30/EC
UK Electromagnetic Compatibility Regulations 2016
LVD 2014/35/EC
UK Electrical Equipment (Safety) Regulations 2016
IEC 60601-1-2 EMC
IEC 60601-1 Safety
IEC 60825-1 – Laser Safety
CB Certified

Classifications

US
- Device Class: II
- Laser Class: II

EU
- Device Class: IIa
- Laser Class: 2

UL/CSA
- Electrical Class 1

International
- Device Class:II/IIa
- Laser Class: II/2

CE

Specifications

Device
- Weight: 19lbs / 8.62 kg
- Height:16in/40 cm Width:12in/30 cm Depth: 10in/25.40cm (38 cm with platform extended)
- Full Color TFT Touch Screen Control Center
- Chassis: Powder Coated Aircraft Aluminum Base Plate and Door
- Housing: Injection Molded Process with Non-Allergen Material/Plastic
- Applied Part: Type B

Laser
- 2 line generating diode modules
- Output: 635nm-17.25 ± 1.25mW / 405nm-23.00 ± 2.00mW
- Frequency: 635 nm & 405nm ± 10nm
- Modulation: Constant Wave (CW)

Power
- Source: 100-240VAC 50-60Hz
- Fuse Rating: T2AH 250V

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

Atmospheric Pressure (Altitude)
- Rated operating altitude ≤ 2000 m
- Normal barometric pressure 80.0 kPa

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
O&M-FFS-EC (N. America)	18-22-ADM	8	07/13/22
O&M-FFS-EC (N. America)	32-23-ADM	9	11/01/2023
O&M-FFS-EC (N. America)	27-25-ENG	10	01/26/2026

*Erchonia Credit Version (North America)

ERCHONIA®

Healing Light, Perfected.

Learn more about Erchonia lasers

erchonia.com | +1-864-531-0064