

ERCHONIA EVRL REFERENCE MANUAL



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ERCHONIA® EVRL™ PROPER USE REFERENCE GUIDE

Prescription Home Use Device



Prescription Home Use / Non-invasive Laser

**Read this entire guide before using your EVRL™
device**

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 EVRL™ 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: 1-321-473-1251
Email: info@erchonia.com

Or visit erchonia.com

Written Correspondence
Erchonia Corporation
650 Atlantis Rd.
Melbourne, FL 32904 USA

ATTENTION: This device is sold for prescription home use. In order to use the device a prescription from a qualified and licensed health professional is required. If you are a qualified and licensed health professional using this device, you are solely responsible for your use of this device and for ensuring that this device is properly used in accordance with any professional or other regulations that may apply to your use of this device. The device should always be used in accordance with the instructions set forth in this manual.

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SECTION 1: GENERAL INFORMATION

HOW TO USE THIS REFERENCE GUIDE

This reference guide is designed to take you through the proper use of your ERCHONIA® EVRL™ device. It will cover the Device Basics, Treatment Protocol, Cautions and Warnings.

It is important that you read and understand all of the information contained in this reference guide before doing any treatments with the EVRL™ device. If you have any questions, contact our Erchonia Customer Care representatives

What is the EVRL Device™?

“The Erchonia® EVRL™ is indicated for adjunctive use in providing temporary relief of diabetic peripheral neuropathy foot pain in previously diagnosed individuals.”

Who is the EVRL™ Intended for?

- Individuals 18 years of age or older who have diabetic peripheral neuropathy foot pain.
- Individuals previously diagnosed with diabetic peripheral neuropathy by a qualified and licensed health professional

PACKAGE CONTENTS













The EVRL™ is shipped in a carrying case containing the following items:

- (1) EVRL™ Handheld device (no assembly required)
- (1) Laser Safety Goggles
- (1) Charger Base
- (1) Charger Base Power Supply Connector

When you receive the shipment, carefully inspect the container for damage. 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 at 1-888.242.0571. 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 reference guide or on the equipment:

| SYMBOL | DESCRIPTION |
|---|--|
|  | Temperature Limitation |
|  | Conformité Européenne - Complies with EMC 2004/108/EC and LVD 2006/95/EC. |
|  | Power ON/OFF |
|  | Date of Manufacture |
|  | Manufacturer |
|  | Authorized representative in the European Community. |
|  | Serial Number |
|  | Refer to Operating Instructions. |
|  | 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. |
|  | WEEE Symbol - Separate Collection Recommended |
|  | DO NOT STARE INTO LASER BEAM |

CONVENTIONS

This reference guide uses the following conventions:

Within the text, the names and labels for buttons appear in boldface type (for example, “Press the **Start** button or press the **Stop** button”).

| | |
|----------------|--|
| Warning | 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 | 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. |
| NOTE: | Throughout this reference guide, “ NOTE ” may be found. These Notes are helpful information to aid in the particular area or function being described. |



CAUTION

- 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.
- **DO NOT** place/operate this device in close proximity (15 cm) to other devices that emit frequency.
- **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.
- There are no user-serviceable parts inside the device. If a malfunction occurs, discontinue use immediately and contact Erchonia Corporation for repair service.
- **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, thoroughly dry all exposed surfaces of this device and allow to dry thoroughly prior to operation
- Avoid contact with flammable anesthetic or air with oxygen or nitrous oxide.
- If you have difficulty operating the device after carefully reviewing this reference guide, contact your Sales Representative for assistance.

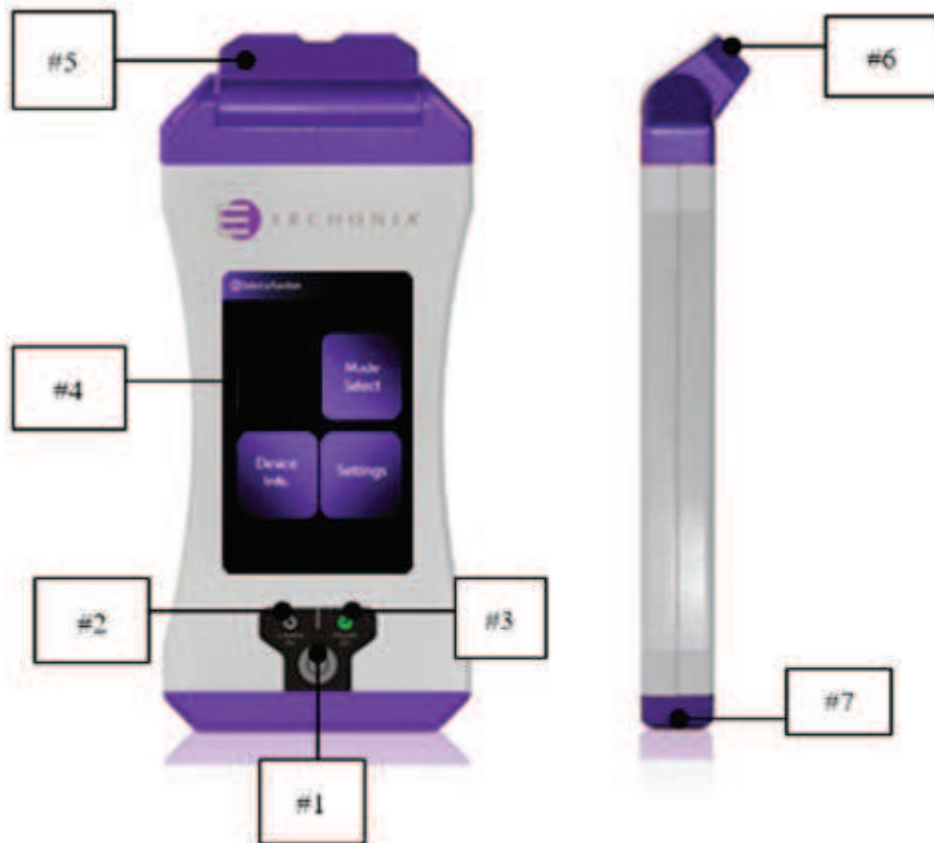


WARNING

- Read all instructions for operation before using the device.
- **DO NOT** use if you are pregnant or think you may be pregnant.
- **DO NOT** use if you are being treated for any cancerous growths on or around your feet
- **DO NOT** use if you have open wounds (sores, cuts, ulcers, etc.) around your feet.
- **DO NOT** place/operate this device in close proximity (near or around) mirrors or other reflective materials or surfaces as the laser light could be deflected off a mirror or reflective surface into someone's eyes, possibly causing eye damage.
- **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. Damage resulting from these conditions is not covered under the warranty.
- This device should be kept out of the reach of children.
- 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, receipt and the environment.
- Laser treatment should not be applied when in the bath or shower in fear of electrical shock.
- Laser protective eyewear should be worn to block light energy from the eyes during treatment.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- 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 treatment should be applied only to normal, intact, clean skin.
- Caution should be used over areas of skin that lack normal sensation.
- Avoid direct contact of the laser beam into human and animal eyes.

Section 2: EVRL™ DEVICE OVERVIEW

DIAGRAM OF MACHINE



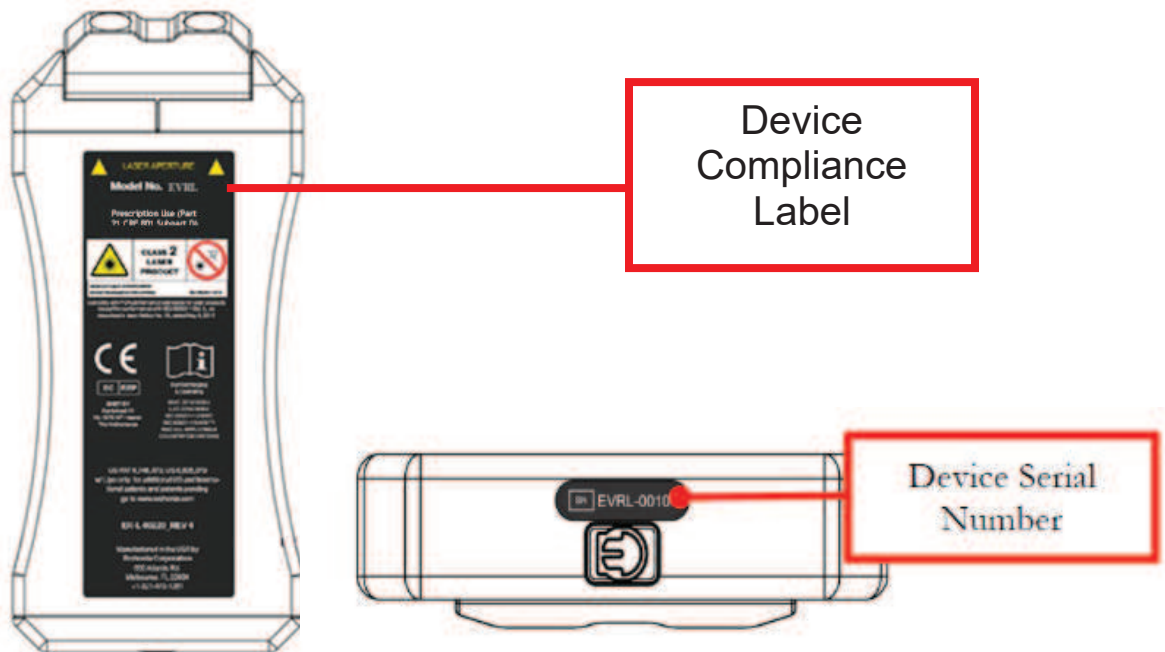
1. Power Button (ON/OFF)
2. Laser ON Light
3. Power ON Light
4. Touch Screen
5. Pivoting Laser Mount
6. Laser Diodes
7. Covered Micro USB (For Manufacturer Use Only)

Note: No Assembly is required, device is shipped ready for use.

LABELS

The device is manufactured in accordance to the Good Manufacturing Practices set forth by the FDA, ISO Standards (International) and CE (Conformité Européenne or European Conformity) 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 are affixed per 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 the compliance label, device serial number and their placement. 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.



RISK AND BENEFITS

The EVRL™ works by using a patented and clinically proven low-level laser technology. The EVRL™ laser lights promote local blood flow in the foot to activate repair mechanisms and produce anti-inflammatory properties to reduce nerve irritation and inflammation in the foot to provide pain relief.

RISKS

There have been other research studies using Erchonia low level lasers, in these studies, no side effects resulted from or reported by any participant from use of the device.

The only known or anticipated risk with the use of the laser device is that long-term exposure to laser light could cause damage to eyesight. As a precaution, when you are applying the treatments with the EVRL, ensure that you wear the special darkened protective goggles to block out the light.

Women who are pregnant or trying to get pregnant should not be treated.

It is possible that you will not get the relief of neuropathy foot pain that they desire.

BENEFITS

<The results of the placebo-controlled clinical trial will be listed here.>

PROTECTIVE EYEWEAR

- EVRL™ is classified by the FDA/IEC as a Class 2 laser device. This 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 keeping it there for a long period of time could damage the eyes.
- For added safety, we have included a pair of specialty glasses for use during treatment. The safety glasses, sufficiently and effectively block the laser light.
- You should always be correctly fitted with the safety glasses provided before turning on EVRL™ and doing any treatment.



WARNING

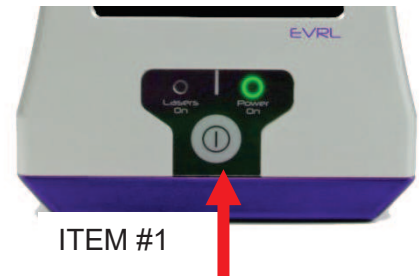
WARNING- Laser protective eyewear should be worn to block light energy from the eyes during treatment.



EVRL™ OPERATION

Powering ON the device

- To power on the EVRL™ device press and hold the Power Button (item #1) for 3 seconds until the “POWER ON” light illuminates green light.



- Once the device is powered ON, the loading screen will display for 30-45 seconds.



EVRL™ Touchscreen

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.



CAUTION

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.

STEP #1 “Passcode Screen”

Enter the passcode “1234” (factory set code), then press the “SIGN IN” icon.

Password Screen



STEP #2 “Function Screen”

- a) “Mode Select” icon
- b) “Settings” icon: *Not used in this clinical trial.*
- c) “Device Info” icon: *Not used in this clinical trial*

To proceed to the neuropathy foot pain treatment, press the “MODE SELECT” icon (ITEM #2)

Function Screen



ITEM #2

STEP #3 “Mode Select Screen”

- a) “User Protocol Mode” icon

To proceed to the neuropathy foot pain treatment, press the “User Protocol Mode” icon (ITEM #3).

Mode Select Screen

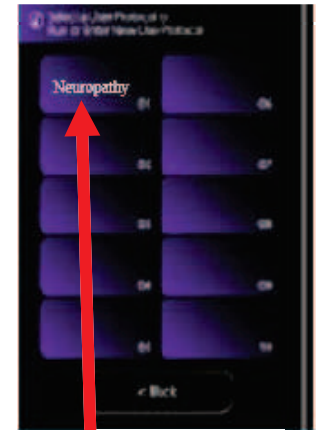


ITEM #3

STEP #4 “User Protocol Mode Screen”

To proceed to the neuropathy foot pain treatment, press the “Neuropathy” icon (Item #4)

User Protocol Mode



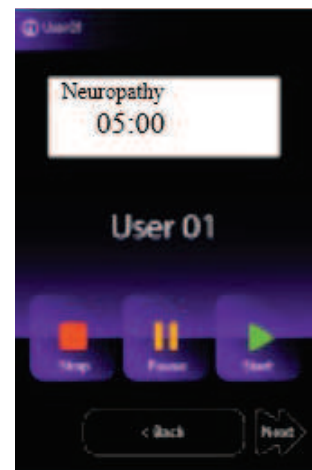
ITEM #4

STEP #5 “Neuropathy Treatment Screen”

The following functions are available on this screen:

- “START” icon will begin the EVRL™ treatment.
- “PAUSE” If for any reason you need to pause the treatment during a session, press the “PAUSE” icon. To resume with procedure, press the “PAUSE” icon again.
- “STOP” To Stop the treatment, press the “Stop” icon. This will completely reset the treatment time.

Neuropathy Treatment Screen



Note: The device is preprogrammed to treat for a total of 5:00 minutes. The treatment time display will automatically start counting down once the treatment is started, when the display reaches 0:00 the lasers will power off and the time will remain at 0:00

NOTE: READ THE ENTIRE “EVRL TREATMENT PROTOCOL” SECTION ON THE NEXT PAGE PRIOR TO STARTING TREATMENT.

EVRL™ TREATMENT PROTOCOL

Now that you understand how to use the EVRL™, the following section describes the steps to follow each time you administer a treatment with EVRL™.

You will need to administer 42 treatments with EVRL™ over 3 weeks. This means 2 treatments a day for 3 conservative weeks.

1. Turn the EVRL™ device on by pressing and holding the “Power Button” for 3 seconds.
2. Ensure the POWER ON indicator light is lit. Follow the EVRL Touchscreen steps 1-4 on the previous page to get to the Neuropathy Treatment, *by entering device password, choosing the “Mode Select” icon, followed by the “User Protocol Mode” Icon, and lastly the “Neuropathy” icon.*
3. **Put on the laser safety goggles.** Remove any shoes and socks.
4. Once the safety goggles are on, start the laser treatment by pressing the “START” icon on the treatment screen.
5. Ensure the laser indicator light is lite.
6. Once the treatment is started, aim the EVRL™ device over the top of your foot with the laser beams emitting long ways in the same direction of the foot.
7. Hold the EVRL™ at distance of approximately 3 to 6 inches from the skin surface throughout the entire 5-minute treatment. During the treatment hold the laser stationary (no sweeping motion necessity).

Note: The laser lights will cover the top of ankle and to the end of your toes.

(Shown in Fig 2 on next page)

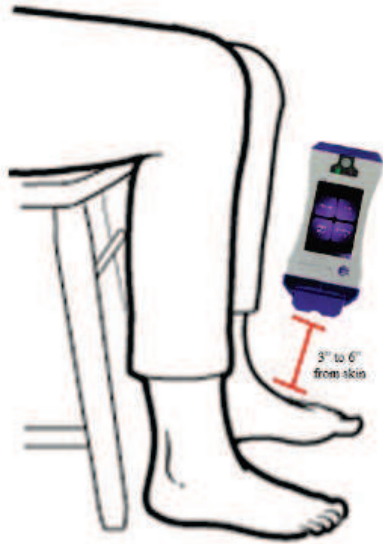


Fig 1. Treatment

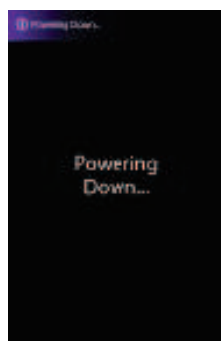


Fig 2. Treatment Close Up

8. The Erchonia® EVRL™ treatment will run for 5 continuous minutes and will stop once treatment time is at 0:00. Once the “Time Remaining” display reaches 0:00 the treatment is complete, the laser lights and the laser indicator light will turn off.
9. Step 4-7 is then repeated over the opposite foot. **Both the right and left foot will receive 5-minute treatment each.**
10. After you have treated both your right and left foot, the treatment is complete, and you may remove the safety glasses.

Powering OFF the device



To properly power down the device, press and release the Power Button (Ref in ITEM #1) while on any screen, this will prompt the “Power Down Device Screen”. Touch the “Power Down Device” icon. The Powering Down Screen will display until the device is properly shut down.



RECHARGING THE BATTERY

The Erchonia® EVRL™, fully charged will operate continuously for approx. 4 to 5 hours depending upon use. The device has a battery indicator on the touch screens which informs you of the status of the battery charge.



When the following battery meters are displayed   it is an indication that the battery needs to be recharged immediately.

To Recharge:

1. Plug the Power Supply Connector into the Charger Base Connector Port.
2. Connect the detachable Power Supply Cord into Power Supply, then insert the Power Supply cord into a 110-220V electric outlet. The charger base power light will come on and remain lit if power is correctly connected.
3. Place the laser device onto Charger Base with the touchscreen facing up and Lasers facing away from Charger Base LED lights. The docked light on the charger base will turn ON if docked correctly.
4. To ensure a full charge leave the laser device on the charger base for at least 2.5 hours continuously. When charging, the docked Light on the Charger Base will flash ON and OFF. You must view the battery indicator meter to determine the status of battery charge. When fully charged, the touch screen battery indicator meter will display full bars.
5. Docking the laser device in between uses is recommended. Charges in between use can be for shorter periods.

The battery is an internal, non-accessible unit, and as such can only be replaced by the manufacturer. There is no risk to the device and or the patient for the battery to remain within the device when not in use for extended periods.

The Erchonia® EVRL™ contains a unique battery system designed by specification to provide the end user with a constant and consistent power, capable of intense use for extended periods, while yet remaining lightweight for portability. The battery system encompasses the internal battery component, the inductive charger base, and the external power supply. The internal battery is sealed by the vendor and then encased within the device housing and can only be replaced by the manufacturer. The battery component is refreshed by the use of an external power supply used with the charger base. The power supply is an IEC 60601 3rd Ed. certified unit, compliant to CE/CB standards. If your power supply is lost or damaged, a replacement power supply can be purchased by contacting Erchonia Corporation.



WARNING - The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate. Contact the manufacturer for battery replacement. Use of another battery may present a risk of fire or explosion.”

Section 4: 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: 1-888-242-0571

Fax: 1-214-544-2228

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

- i. Before sending a device to the Erchonia Service and Repair Department for repair, obtain a service order (SO) number from the service representative.
- ii. 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:

For Customers in the U.S.A.

Erchonia Corporation

650 Atlantis Road

Melbourne, FL 32904

Attention: Service and Repair Department (SO Number)

MAINTENANCE & WARRANTY INFORMATION

MAINTENANCE

The Erchonia® EVRL™ laser, 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 Touch Screen for cracks in screen or any malfunction. If during these inspections, you identify an area of concern, 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, 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. Inspect the Charger Base and Power Supply for signs of damage (cuts in insulation or fraying). Replace if damaged.

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 |


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. |
|---|--|

ERCHONIA® EVRL™ PROPER USE REFERENCE GUIDE

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.

WARRANTY

LIMITED WARRANTY

The Erchonia® EVRL™ 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 overseas require special paperwork, available through the warranty department. If this paperwork is not obtained prior to shipping; your package will be delayed by customs.

- 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
 - Use of unapproved battery charger base or power supply
 - Alteration or disassembly
 - Loss of parts
 - Exposure to the elements
 - Ingress of liquid
 - Exposure to excessive electromagnetic frequency

Troubleshooting

Use the following information to help solve problems that may arise during use. If you still have questions, call Erchonia Customer Care at 1-321-473-1251, and we will be happy to help.

| Problem | Possible Cause | How to Resolve |
|---|---|---|
| Device does not power on | May not be charged | Recharge device for 2.5 hours by placing in inductive charger base |
| Charge base indicator lights does not come on when device is docked | Device may be placed in the charge base incorrectly or power supply is not plugged in correctly | Place device in charger base with the touch screen facing up and the laser heads in the opposite end of the charger base indicator lights |
| Device is not responding | Internal computer may need to be reset | Hold the ON/OFF button down until device powers off, then re-start |

Congratulations on completing the
Erchonia® EVRL™ Proper Use Reference
Guide.

You are now ready to use the Erchonia®
EVRL™

Other ManualsLib Projects



www.manualslib.com



www.manualslib.de



www.manualslib.es



www.manualslib.fr



www.manualslib.nl



www.manualslib.mx



www.manualslib.tech 30+ Languages