# ERCHONIA **OVEN PR** DRUG-FREE www.erchonia.com



The most researched non-invasive lasers in the world.

**Pg. 3 - XLR8** Perfect entry level hand-held.

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#### www.erchonia.com

#### Did you know

Erchonia is the World Leader in Low Level Laser technologies and every laser Erchonia manufactures has gone through the most rigorous clinical trial standards possible to prove the safety and effectiveness of our products.

#### **Leaders in Research**

For over two decades, Erchonia has been committed to the research of low level laser therapy (LLLT) through extensive clinical studies and has attained more than (18) FDA Market Clearances. Erchonia made history in 2002 when the FDA granted Erchonia market clearance for the first non-thermal laser in history. This created a new category for the FDA called NHN Laser, making Erchonia the gold standard for low level laser technology.





### ABOUT US

(888) 242-0571 www.erchonia.com Erchonia Corporation was founded in 1996 as a small family business, and even though we've grown into an international enterprise, we still operate under the founding principles that guided us to our present success. Our commitment to the legitimate advancement of low level laser therapy (3LT®) through scientific and clinical research has transformed Erchonia into a world leader in the field of LLLT technology. The integrity, diligence, quality and commitment of our company are evident in the rigorous process we follow in order to take a research hypothesis from concept to viable, agency-approved product and treatment method. To ensure a steadfast adherence to our unique all-encompassing approach, our company serves as manufacturer, marketer, developer, promoter, creator and user of all our products.

### Fundamentals of Photochemistry

The process of low-level laser therapy is based on a photochemical reaction in which discrete bundles of energy called photons are absorbed within the visible light spectrum of 380–700nm. The photon induced chemistry ultimately gives rise to the observable effect at the biological level. In order to achieve maximum photobiological effects, Erchonia adheres to the following delivery fundamentals:

- Laser light that is monochromatic and coherent having only one wavelength. Light from LEDs (Light Emitting Diodes) cannot achieve the same narrow band of wavelength, instead LEDs produce light that is disorganized or incoherent. Laser light is dramatically more effective in producing photochemical effects than LED. This is evident in over a dozen, double-blind, placebo controlled clinical trials using Erchonia lasers where test subjects established both statistical significance and clinically meaningful results over the placebo group which received LED treatment.
- Laser output under 500mw. Devices with a laser output above 500mw are not LLLT (Low-Level Laser Therapy). Instead, they are classified as High Intensity Laser (HIL) or Class 4 Lasers. These
  devices are FDA cleared under the ILY product code which started as a heating pad and has expanded to thermal lasers that are intended to "provide topical heating for the purpose of elevating
  tissue temperature for temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of
  muscle". The FDA has now made the ILY products 510(k) FDA exempt based on the device requirements of raising skin temperature to 40-45°C. LLLT is a non-thermal process and classified under
  FDA product code called NHN, powered light-based laser non-thermal instrument with non-heating effect for adjunctive use in pain therapy. Blinded and controlled trials are required for new
  510(k) indications.

#### "LLLT delivered at low doses tends to work better than the same wavelength delivered at high levels, which illustrates the basic concept of biphasic dose response or hormesis" (Calabrese 2001b)

• Lasers within the visible light spectrum of 380-700nm. The primary mechanism for the absorption of visible light photons is the elevation of electrons to higher energy levels through photochemistry. Another type of electromagnetic radiation is infrared (IR) which includes wavelengths higher than 780nm. The infrared light spectrum exhibits strong absorption from vibrations of the water molecule. The result of infrared absorption is heating of the tissue since it increases molecular vibrational activity. Simply, while visible light can produce photochemical effects, infrared only produces molecular rotations and vibrations.

### XLR8<sup>®</sup> LASER

The revolutionary XLR8 handheld laser device. This dual-diode laser features an easy to operate graphical user interface (GUI), with a sleek new cord-free design. With user definable channels and preset protocols, cold laser has become more flexible than ever before.

This is our most popular entry level laser — New to laser therapy? Then XLR8 is the laser for you!

#### Payments as low as \$155 per month.

\*Price may vary, does does not include tax & shipping.

#### **Specifications**

- Configuration: (2) 7.5 mW Line Generated Laser Diodes with Patented Optics
- Wavelength: 640nm
- Modulation: Constant Wave (CW) & Pulsed (Hz)
- 100 User Defined Memory Channels
- 7 Preset Protocol Channels
- Display: Full Color TFT Touchscreen Technology
- Power Source: 3.7 VDC Lithium-ion Polymer Battery
- Enclosure: Machined Billet Aluminum
- Weight: Less Than 1lb. (.30 kgs) (Device Only)
- Accessories: Power Cord, Wireless Charging Base, and Safety Glasses
- Compliant to: ISO 13485 Medical Device Quality, IEC 60601-1, 60601-1-2, IEC 60825-1, CB Certified, CE Mark, CMDCAS
- Laser Class 2 / Device Class II (USA); 2a (EU)

#### ORDER # XLR8

## EVRL LASER ★ MOST POPULAR

Introducing Erchonia's newest handheld laser, the EVRL. Since it's release, it has become our most popular handheld device by offering the versatility of a red and violet wavelength taking outcomes to a whole new level.

By combining these two specific wavelengths into one treatment modality, patients received better results during clinical studies than using just 635nm alone. Experience the freedom of this incredible new technology - Improving health and wellness has never been easier!

#### Payments as low as \$295 per month.

\*Price may vary, does does not include tax & shipping.

#### **Specifications**

• Configuration: (1) 7.5mW Line Generated Red Laser

Diode, (1) <5mW Line Generated Violet Laser Diode with Patented Optics

- Wavelength: 640nm & 405nm
- Modulation: Constant Wave (CW) & Pulsed (Hz) (Red Only)
- 100 User Defined Memory Channels
- Display: Full Color TFT Touchscreen Technology
- Power Source: 3.7 VDC Lithium-ion Polymer Battery
- Enclosure: Machined billet aluminum
- Weight: Less Than 1lb. (.30 kgs) (Device Only)
- Accessories: Power Cord, Wireless Charging Base, Safety Glasses
- Compliant to: ISO 13485 Medical Device Quality, IEC 60601-1,
- IEC 60601-1-2, IEC 60825-1, CB Certified, CE Mark, CMDCAS
- Laser Class 2 / Device Class II (USA); 2a (EU)



### BASE STATION

The Base Station is a desk top unit with three (3) handheld independent laser devices including (1) EVRL and (2) XLR8 lasers, a wireless charging station and the ability to program all of the lasers individually using their easy to use touchscreen GUI's. Physicians are able to use innovative laser therapy in 3 locations at once with this platform whether that be in separate offices or to rent out to patients.

+ Allows for the ability to rent lasers out to patients
+ Laser configuration can be customized to fit physician's needs

#### Payments as low as \$546 per month.

\*Price may vary, does does not include tax & shipping.

#### Specifications

- Configuration: 2-Handheld Devices with Dual 640nm/7.5mW Output Laser Diodes,
- 1-Handheld Device with One 640nm/7.5mW Laser Diode and One 405nm/<5mW Laser Diode
- Wavelength: 640nm/405nm
- Modulation: Constant Wave (CW) & Variable Hz
- Up to 100 Programmable Memory Channels
- Base Power Source: Input 100-240 VAC ~ 47-63 Hz/0.5A Max; Output +15 VDC/1.2A max
- Handheld Device Power Source: 3.7 VDC Rechargeable Lithium-ion Polymer Battery
- Enclosure: Machined Billet Aluminum
- Weight: Base Unit with Handheld Laser Devices 2.35 lbs. (1.07kgs.);

#### Handheld Lasers less than 1lbs. (.30 kgs.) Each

- Accessories Included: Power Supply & Laser Safety Glasses
- . Compliant to: ISO 13485 Medical Device Quality, IEC 60825-1, IEC 60601-1 Safety,

IEC 60601-1-2 EMC, CB Certified, CE Mark, CMDCAS

Laser Class: 2 Device Class II (USA); 2a (EU)

#### ORDER # BST



### THE MOST ADVANCED LASER SCANNERS IN THE WORLD



The FX 635 patented laser scanner provides physicians with a true self-opertaing procedure (press start and walk away).

The FX 635 offers the industy's most marketable procedure due to it's wide array of FDA Clearances including plantar fasciitis, chronic low back pain & overall musculoskeletal pain.

+ Touchless & Unattended Technology + Highest ROI

#### \*Ask About Pricing.



#### Specifications

- Configuration: (3) Class 2 17.25mW Line Generating Diodes
- Wavelength: 640nm
- Modulation: Variable
- Weight: 82lbs (37 kg)
- · Height: 70in (177.8 cm) (Average Adjustable)
- Two Independent Adjustable Arms For Desired Laser Concentration
- Display: Full Color Touch Screen Control
- Power Source: 100-240VAC, 50-60Hz, 1.5 A 0.5A
- Chassis: Powder Coated Aircraft Aluminum
- Housing & Covers: Non-Allergenic Material, Spray Finished
- Accessories: 2-Keys, Power Cord, Laser Safety Glasses,
- Compliant to: ISO 13485 Medical Device Quality, IEC 60825-1 Laser Safety, IEC 60601-1-2 EMC, IEC 60601-1 Safety, CE Mark, CB Certified
- FDA Laser Class 2 / FDA Device Class II / EU Device Class IIa, Laser Class II





The FX 405 Laser scanner offers all of the same benefits that the FX 635 does, with the advantage of adding violet laser for versatility in treaments.

+ Toucheless & Unattended Technology + Most Versatile Laser Scanner

\*Ask About Pricing.



#### **Specifications**

- Configuration: (3) Class 2, 17.25mW & (1) Class 2, 23mW Line Generating Diodes
- Wavelength: 640nm & 405nm
- Modulation: Variable
- Weight: 82lbs (37 kg)
- Height: 70in (177.8 cm) (Average Adjustable)
- Two Independent Adjustable Arms For Desired Laser Concentration
- Display: Full Color Touch Screen Control
- Power Source: 100-240VAC 50-60Hz, 1.5A 0.5A
- Chassis: Powder Coated Aircraft Aluminum
- Housing & Covers: Non-Allergenic Material, Spray Finished
- Accessories: 2-Keys, Power Cord, Laser Safety Glasses,
- Compliant to: ISO 13485 Medical Device Quality, IEC 60825-1 Laser Safety,
- IEC 60601-1-2 EMC, IEC 60601-1 Safety, CE Mark, CB Certified
- FDA Laser Class 2/FDA Device Class II/EU Device Class IIa, Laser Class II

#### ORDER # FX405

### **Erchonia Pain Market Clearances**

Erchonia complies with the highest clinical testing. All Erchonia level (1) clinical trials have gone through the FDA pre-IDE process, IRB approval, and are based on pilot research to ensure customers that the laser they are purchasing has been proven safe and effective by the FDA. 90% of all medical devices are substantially equivalent with no clinical research, of the 10% that are, only few submit blinded and controlled studies.

#### **United States Food and Drug Administration**

- 2002 Chronic Neck and Shoulder Pain
- 2004 Post-Surgical Pain after Liposuction
- 2008 Post-Surgical Pain after Breast Augmentation
- 2014 Chronic Plantar Fasciitis Pain
- 2018 Chronic Low Back Pain

FDA

- 2019 Chronic Neck and Shoulder Pain using Red and Violet Laser
- 2019 Overall Nociceptive Musculoskeletal Pain

Scan QR code to view all Erchonia FDA Clearances



Scan to visit site.

#### Level 1, Double Blind, Placebo Controlled, Multi-site Clinical Trials

#### FDA 510(k) Number: K130741

Indication for use: Relief of minor chronic neck and shoulder pain.

**Results:** Of the patients who received Erchonia laser treatment, 65.1% met individual success criteria in improvement of pain, while only 11.6% of the placebo subjects (LED's). The overall study success criteria, defined as at least 30% improvement following treatment.

#### FDA 510(k) Number: K041139

**Indication for use:** Adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process.

**Results:** Of the patients who received Erchonia laser treatment, 75% met their major success criteria compared with 32% of the placebo-group patients who received "LED" treatment.

#### FDA 510(k) Number: K072206

**Indication for use:** Reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery.

**Results:** Of the patients who received Erchonia laser treatment, 74% met their major success criteria compared with 37% of the placebo-group patients who received "LED" treatment.

#### FDA 510(k) Number: K190572

**Indication for use:** The Erchonia FX 635 Laser is indicated for providing relief of nociceptive musculoskeletal pain.

**Background:** Based on Erchonia's collective clinical performance of over 200 subjects on various musculoskeletal pain conditions, the subjects that met the overall study success was 66.5%, compared to just 17.2% for the sham (LED) group. The mean reduction in the VAS pain scale for the Erchonia laser groups was 50%.

#### FDA 510(k) Number: K132940

Indication for use: Reducing chronic heel pain arising from plantar fasciitis. Results: The patients who received Erchonia laser treatment demonstrated a mean improvement in heel pain on the VAS score of 29.6, compared to with the placebo subjects (LED treatment), mean improvement of just 5.4, a statistically significant difference between groups. In addition, patients which were administered Erchonia Laser completed 12 months of follow-up and demonstrated a continued improvement in heel pain VAS of 67.8 baseline down to 6.9, with no additional laser treatments applied.

#### FDA 510(k) Number: K180197

Indication for use: Relief of minor chronic low back pain of musculoskeletal origin. Results: 72.4% of subjects who received the active procedures with the Erchonia® FX 635 attained a 30% or greater decrease in low back pain VAS rating from baseline to endpoint compared with only 27.6% of subjects who received the LED "placebo" procedures, a statistically significant difference p<0.005. The secondary measure of change on the Oswestry Disability Index (ODI) found the 12.27% mean decrease from study baseline to endpoint for test group subjects to be about two and a half times greater than the relative 5.18% mean decrease for placebo group.

#### FDA 510(k) Number: K191257

Indication for use: The Erchonia EVRL, red and violet diode, for providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. Results: Among subjects treated with the red and violet lasers, mean VAS neck and shoulder pain scores decreased from 65.0 to 35.2 (p<0.0001). Most subjects in the study (75%) achieved ≥30% decrease in VAS scores. Subjects experienced a mean 29.07% improvement in neck and shoulder ROM.

# ROI

Retail Price	Average number of patients treated per day	Treatments Per Week (Based on 4 day week)	Charge Per Treatment (National Average)	Estimated Monthly Financing Cost	Revenue Per Month	Annual Revenue	1st Year Profit (Cost of device deducted)
<b>FX 635</b> \$39,900	5	20	\$100	\$780	\$8,000	\$96,000	\$56,100
<b>FX 405</b> \$44,900	5	20	\$100	\$878	\$8,000	\$96,000	\$51,100
<b>XLR8</b> \$9,900	5	20	\$30	\$194	\$2,400	\$28,800	\$18,900
<b>EVRL</b> \$15,900	5	20	\$40	\$311	\$3,200	\$38,400	\$22,500
<b>BST</b> *(3 Lasers) \$29,900	15	60	\$40	\$585	\$9,600	\$115,200	\$85,300

### Whatever you do, do it well.

Do it so well that when you do it they will want to come back and see you do it again and they will want to bring others and show them how well you do what you do. **- Walt Disney** 

# QUALITY **NOT** COMPROMISE





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