ERCHONIA® GVL

An Evaluation of the Effect of the Erchonia® GVL Green and Violet laser on Neck and Shoulder Pain

ERCHONIA CORPORATION

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STUDY INFORMATION

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PURPOSE OF STUDY
The purpose of this clinical study is to determine the effectiveness of the Erchonia® GVL (manfactured by Erchonia Corporation (the Company), when both the green and violet diodes are activated simultaneously, in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

INDICATION FOR USE
The indication (claim) being sought through support of the results of this clinical study is:

"The Erchonia® GVL is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin"

It is intended that the results of this clinical study be used to support a 510(k) submission to FDA for clearance to market the device for the intended indication.

EXPECTED RESULTS
Following completion of the study treatment administration protocol with the Erchonia® GVL green / violet dual-diode laser, it is anticipated that compared with when treatment administration occurs with the Erchonia® EVRL red / violet dual-diode laser, comparable (equivalent) or better (superior) results will be attained with respect to decrease in subjects' neck and shoulder pain on the 0-100 VAS scale at study endpoint relative to baseline.

DEVICE INFORMATION: ERCHONIA® GVL

REGULATORY BACKGROUND

Erchonia demonstrated the effectiveness of low-level lasers in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin in the following studies, each of which successfully supported FDA 510(k) clearances:

The Erchonia® PL2000, a red (635 nm) diode laser was evaluated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin in a double-blinded, sham-controlled, randomized clinical trial, the results of which successfully supported an FDA clearance under K012580 for the following indication:

“The TUCO Erchonia PL2000 is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.”

The TUCO Erchonia PL2000 was subsequently renamed the Erchonia EVRL and its indications updated under K152196 to include both the treatment of neck and shoulder pain as well as acne vulgaris, as follows:

“The Erchonia EVRL Laser is generally indicated:

a. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and
b. while using the blue diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris”

A non-inferiority study evaluating the Erchonia® EVRL laser employing dual red (635 nm) and violet (405 nm) diodes simultaneously yielded comparable (equivalent) results to the use of red diodes alone for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. The results of that clinical study successfully supported FDA clearance under K191257 for the following indication:

“The Erchonia EVRL Laser is generally indicated using the red and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin”

The present study is intended to evaluate efficacy of the Erchonia® GVL, a dual diode laser emitting green (520 nm) and violet (405 nm) diodes simultaneously for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. Therefore, evaluation of the Erchonia® GVL is experimental in this clinical study.

DEVICE DESCRIPTION & DETAILS

The Erchonia® GVL Laser used in this study is a hand held low level laser that uses two semi-conductor diodes; a 520 nanometer (visible green light) and a 405 nanometer (visible violet light), each emitting its wavelength with a tolerance of ±10 nanometer. The lasers are powered by an internal battery that is recharged using a separate inductive charging base powered by an external class II medical power supply. This configuration offers portability as well as consistency of power. The Erchonia® GVL is a variable hertz device. The variable hertz feature of the Erchonia® GVL is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The internal battery powers the two specially created and patented electronic diodes with an output of 7.5mW green ± 1 mW and <5 mW violet laser.

The device contains software that is embedded in a RAM chip on the PCB. This data includes the touch screen images (GUI) and the command prompts that activate the screen icons; work in conjunction with the component platform to ensure the device operates as intended. The exterior materials consist of 6061 T6 AL and Copolymer Acetal with powder coating finish.

The Erchonia® GVL has the following specifications:

Device
- Weight: Laser-.95lbs / .42kgs. Charger Base-.55lbs / .42kgs
- Full Color TFT Touch Screen Module
- Machined billet aluminum enclosure
- Dimensions: Laser-Length-6.9” (17.52cm) Width-3.10” (7.87cm) Depth-.76” (1.93cm), Charger Base- Length-5.7” (14.47cm) Width-3.5” (8.88cm) Depth-1.65” (4.19cm)

Laser
- 2 electronic diodes, with patented optics
- Output: 520nm 7.5mW ± 1mW (green)
- Output: 405 nm <5mW ± 1mW (violet)
- Wavelengths: 520 nm & 405nm +/- 10nm
- Duty Cycle: 50%

Power
- Battery: Lithium-ion Polymer 3.7V, 1500mAh, 5.6w

Inductive Charging Base
- 1.5A 12V

External Power Supply
- Model: ER-E-00182
- 100-240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A

Dosage calculations for the Erchonia® GVL
Total energy per diode:
- (diode output means) mW / 1000 (converting mW to W) * (time in seconds) ÷ 2 (50% duty cycle) = (total energy per diode per minute)
- 520 nm diode (green): 7.5 / 1000 * 60 ÷ 2 = .225J
- 405 nm diode (violet): 4.5 / 1000 * 60 ÷ 2 = .135J

- Total device diodes energy per minute: .36J
- The Erchonia® GVL used in this study is shown in Figure 1 below.

Figure 1

The following diagram identifies each component of the device and a complete description of the component follows.

Figure 2

#1 POWER BUTTON (ON/OFF)

The Power Button allows you to turn the device ON "|" or OFF "O". To turn the device ON, press and Hold this button, after approximately 3 seconds the green (#2 Power On Light) turns on. To turn off the device it is recommended to use the **"Powering Down"** method, explained in the **Operation Section** of the manual**.** In the unlikely event that your device stops responding to touches, by pressing and holding the power button for 15 seconds will force shut down the device. This is only recommended if the device cannot be turned off from the **"Powering Down"** method.

#2 LASERS ON LIGHT

The "Lasers On" light is an LED indicator that will light up when the Lasers are ON and turn off when the lasers are OFF.

#3 POWER ON LIGHT

The “Power On” light is an LED indicator that will display a constant green light when the device is powered on and turn off only when the device is OFF.

#4 TOUCH SCREEN

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

#5 PIVOTING LASER MOUNT

The Pivoting Laser Mount allows you to adjust the laser angle (up to 20º each direction) based on your preference.

#6 LASER DIODES

The Lasers consist of two electronic laser diodes, with patented optics. These laser diodes when activated by the internal power source generate laser energy thereby emitting on one side a green beam and the other side a violet beam. This is a specially designed and patented device created to ensure the laser beam is focused and directed for the most optimal use. The device can be programed with up to 4 defined Hz frequencies (two for each diode).

CHARGER BASE

Directions to set Device on Charger Base

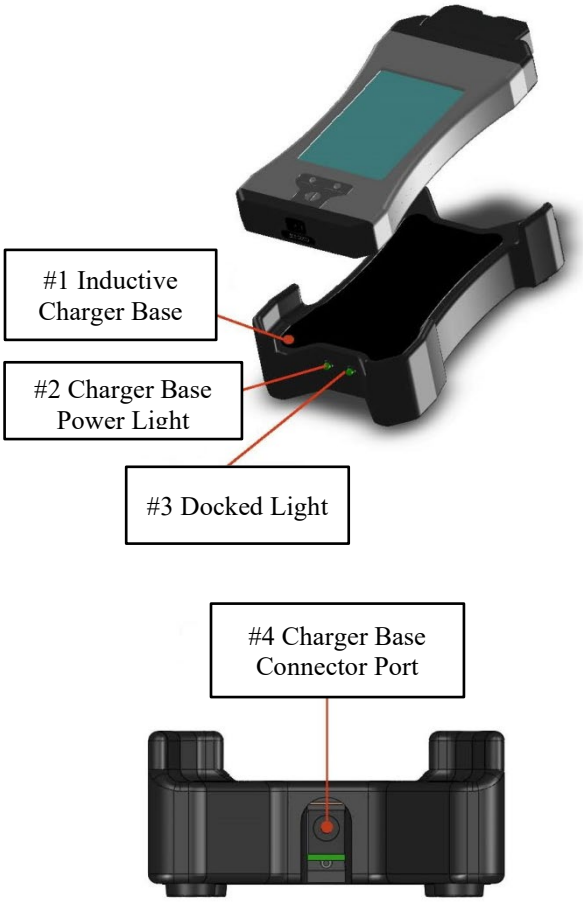


Figure 3

POWER SUPPLY

Figure 4

#1 INDUCTIVE CHARGER BASE

The Inductive Charger Base is a custom based system specifically designed to charge the laser device. It is an inductive charging system that charges the device wirelessly. The Charger Base must be plugged into the power supply and the power supply must be plugged into a wall socket for Charger Base to receive power. Once powered up, the Laser device is placed on Charger Base with the touch screen facing up and Laser diodes facing away from Charger Base LED lights.

#2 CHARGER BASE POWER LIGHT

The Charger Base "Power" Light is the power indicator LED that will light up when the energized Power Supply connector is plugged into the Inductive Charger Base.

#3 DOCKED LIGHT

The "Docked" light is an indicator LED that will light up to indicate the device is correctly docked in the inductive charger base. The LED will flash ON and OFF when correctly in place and turn off when removed from the inductive charger base.

#4 CHARGER BASE CONNECTOR PORT

The Charger Base Connector Port is the location to plug the Power Supply Connector in to supply power to the inductive charger base.

#5 POWER SUPPLY CONNECTOR

The Power Supply Connector plugs into the Inductive Charger Base Connector Port to provide power to charger base.

DEVICE SAFETY

RISK AND PREVENTION OF EYE INJURY

The Erchonia® GVL 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 subject. 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, eye protection is implemented for the subject receiving the laser procedure administrations.

A pair of safety glasses is provided for use during all procedure applications. These safety glasses are Noir laser shields. The safety glasses sufficiently and effectively block the laser light spectrum at OD 6+ @ 190-534nm, OD 1.5+ @ 620-650 nm, VLT 7%.

- Height: 47 mm
- Width: 130 mm
- Length: 130 mm

OTHER POTENTIAL RISKS

Other potential risks and their mitigation include:

(i) Electric shock: operator risk only: mitigated through electrical safety testing.
(ii) Electromagnetic interference: mitigated through EMC/EMI testing.
(iii) User error: mitigated through instructions for use documentation.

LABELING

The Erchonia® GVL to be used in this clinical study will be labeled, “CAUTION – Investigational device. Limited by United States law to investigational use.” Once the device has been cleared for market in the U.S., the device will be labeled as a prescription device, per 21 CFR § 801.109.

STUDY INDICATION, THEORY OF MECHANISM OF OPERATION, & SUPPORTING MATERIALS

STUDY INDICATION: CHRONIC NECK AND SHOULDER PAIN OF MUSCULOSKELETAL ORIGIN

Definition

Chronic pain of musculoskeletal origin arises from impairment of the muscles, ligaments and tendons, and bones. The neck refers to the cervical spine comprised of the top 7 vertebrae, the vertebral joints which connect them and the ligaments and muscles that provide neck stability, function, and movement. Impairment therein primarily results in pain and reduced range of motion in the neck and shoulders region.

Statistics

- Pain affects more Americans than diabetes, heart disease and cancer combined.
- In 2011, at least 100 million adult Americans reported chronic pain conditions, with women more likely to experience chronic pain than men.
- The total annual health care costs (medical costs and economic costs related to disability days and lost wages and productivity) related to treatment of chronic pain conditions in the United States ranges from $560 billion to $635 billion (averaging to about $2,000 per U.S. adult).
- Chronic pain is reported to have a significant impact on quality of life: 59% report an impact on overall enjoyment of life; 77% report feeling depressed; 70% report trouble concentrating; 74% reported reduced energy level; and 86% report sleep disruption.
- The National Institute of Health Statistics survey reports chronic neck pain as being the second most common pain complaint (second to low back pain), experienced by 15% of the U.S. adult population at any one time.
- Over half (53%) of the workforce reports some form of musculoskeletal pain at any one time, and about 13% lost productive work time averaging 5.5 hours per week while experiencing musculoskeletal pain.
  Source: American Academy of Pain Medicine

Anatomy of the Neck

The spine can be compartmentalized into 3 separate sections: the neck, the mid back and the low back. The neck refers to the cervical spine, which is comprised of the top 7 vertebrae, the vertebral joints which connect them, and the ligaments and muscles that provide neck stability, function, and movement. More than other areas of the spine, the neck has a greater range of motion, especially in rotation. The neck also balances the head, a significantly heavy object, through an infinite number and variety of positions for hours on end. Essentially, the neck has a complicated and important role to play and the specialization of its structures reflect these complex functions all of which means, in terms of potential muscle fatigue and the effect of degenerative changes or trauma, that the neck is vulnerable to injury and susceptible to pain.

Etiologies of Neck/Shoulder Pain

There are many causes of neck/shoulder pain, such as muscle sprain, strain and spasms, arthritis, disc problems, tendinitis, vascular problems, trauma and tumors. Causes of musculoskeletal neck/shoulder pain include muscle tissue damage due to wear and tear from daily activities; trauma (jerking movements, auto accidents, falls, fractures, sprains, dislocations, and direct blows to the muscle); postural strain; repetitive movements; overuse and prolonged immobilization.

In this clinical study, the most common cause of chronic neck/shoulder pain is being evaluated – **the musculoskeletal conditions of muscle sprain, strain and spasms.**

Muscle Strain, Sprain and Spasm of Musculoskeletal Origin

Muscle strain, sprain and muscle spasm of musculoskeletal origin refers to damage to a muscle or its attaching tendons due to undue pressure placed on muscles during the course of normal daily activities, including those that involve sudden heavy lifting, sports activities or other physical exertions, or while performing work tasks. Muscle damage can involve tearing of some or all of the muscle fibers and the tendons attached to the muscle. This tearing can also damage small blood vessels, causing local bleeding, or bruising, and pain caused by irritation of the nerve endings in the area.

Muscle sprain and strain occurs with a sudden stressful injury to the region causing stretching or tearing of the muscle/tendons/ligaments that results in pain and restricted range of motion. 'Sprain' refers to injury of the muscles, whereas 'strain' refers to injury of the ligaments.

The muscles and ligaments in the neck and shoulder regions are part of the body's upper extremity. The upper extremity is innervated by nerves originating in the cervical and thoracic spine. Sprain strain in the neck and/or shoulder regions refers to an injury that causes a sprain to a muscle or strain to a ligament that effects pain and restricts range of motion in those areas that is linked to degraded integrity of the accompanying cervical and thoracic nerve supply.

In a muscle strain, the tension or extreme stretching that occurs causes the muscles to cramp or tear during physical exertion. Efforts to move are then replaced by painful and limited movement. The pain of muscle strain or spasms arises from the sustained contraction of the muscle fibers, as well as from possible tearing of the fibers which may be felt as a hard knot in the strained muscle.

Chronic muscle spasms (also known as muscle cramp, -pulled" muscle, or tight muscle) are an indirect injury to a muscle, usually from muscle fatigue and overuse that results from involuntary contractions of a muscle or a group of muscles causing pain and interference with function.

Neck and shoulder spasms are involuntary contractions of the muscles in the neck and shoulders wherein the muscles get tight, hard, and painful. Neck spasms most commonly result from injury, overuse, poor posture, or stress

Common types of physical activity or exertion that may result in muscle strain/sprain/spasms and resultant pain in the neck and shoulder include running, climbing, extreme reaching with the arms, or turning/twisting of the head, neck, or back. Another common scenario is poor ergonomic designs and situations in work-related settings, such as holding the neck or back in an abnormal position while sitting at the desk or computer for prolonged periods and bad posture.

Symptoms

Primary symptoms of muscle strain/sprain/spasms of musculoskeletal origin include*:*

- pain and soreness in the neck/shoulders that worsens with movement
- neck/shoulder stiffness, tightness and weakness
- limited range of motion of the neck/shoulders

Additional potential symptoms include:

- headaches
- tender or trigger spots in the neck/shoulder
- a hard knot tender upon palpation
- fatigue
- sleep disturbances

Diagnosis

Comprehensive evaluation of neck and shoulder pain and its etiology determination comprises:

- Medical and patient history (including general lifestyle, work and typical and unusual physical activities) as well as detailed exploration of the events and activities surrounding onset of the pain
- Comprehensive physical examination, including evaluation of range of motion and neurologic evaluation of the spinal cord and limbs, including muscle strength, skin sensation, and examination of reflexes
- Diagnostic evaluation (possibly, if indicated) that may include routine lab tests, x-rays and imaging studies such as CT scan, MRI, and myelogram

Treatment Options

Standard conservative treatment options for muscle strain, sprain and spasm typically includes any one or more of the following applied sequentially or simultaneously:

- rest
- ice and heat application
- compression
- brace immobilization
- non-steroidal anti-inflammatory medicine (NSAIDs) such as ibuprofen or naproxen, analgesics such as acetaminophen or opioids, and muscle relaxants
- rehabilitation exercises such as strengthening or stretching exercises for the shoulder and upper and/or lower back muscles, rotation and side-bending exercises for the neck and chin exercises to improve posture
- Stress management

Other treatments may include:

- injections with anesthetic or anti-inflammatory medications in or around the painful sites
- physical or occupational therapy
- acupuncture or acupressure
- relaxation/biofeedback techniques
- osteopathic manipulation
- chiropractic care
- therapeutic massage

Current treatments for pain have yielded mixed results. Pain relief and anti-inflammatory medications remain the primary treatment option of choice; however, only about half of patients who take prescription and/or over-the-counter medication for chronic pain reported ineffective pain relief. Additionally, prescription painkiller use abuse and addiction rates are very high and a major contributor to unintentional drug deaths.

THEORY OF MECHANISM OF OPERATION OF THE APPLICATION OF LOW LEVEL LASER THERAPY TO REDUCING PAIN

"Low-energy photon irradiation by low level laser light lasers or LED arrays has been found to modulate various biological processes in cell culture and animal models. This mechanism of photobiomodulation by LLLT lasers or LED arrays at the cellular level has been ascribed to the activation of mitochondrial respiratory chain components, resulting in initiation of a signaling cascade that promotes cellular proliferation and cytoprotection."
Source: Proc Natl Acad Sci U S A. 2003 Mar18; 100(6): 3439-44. 2003 Mar 07.

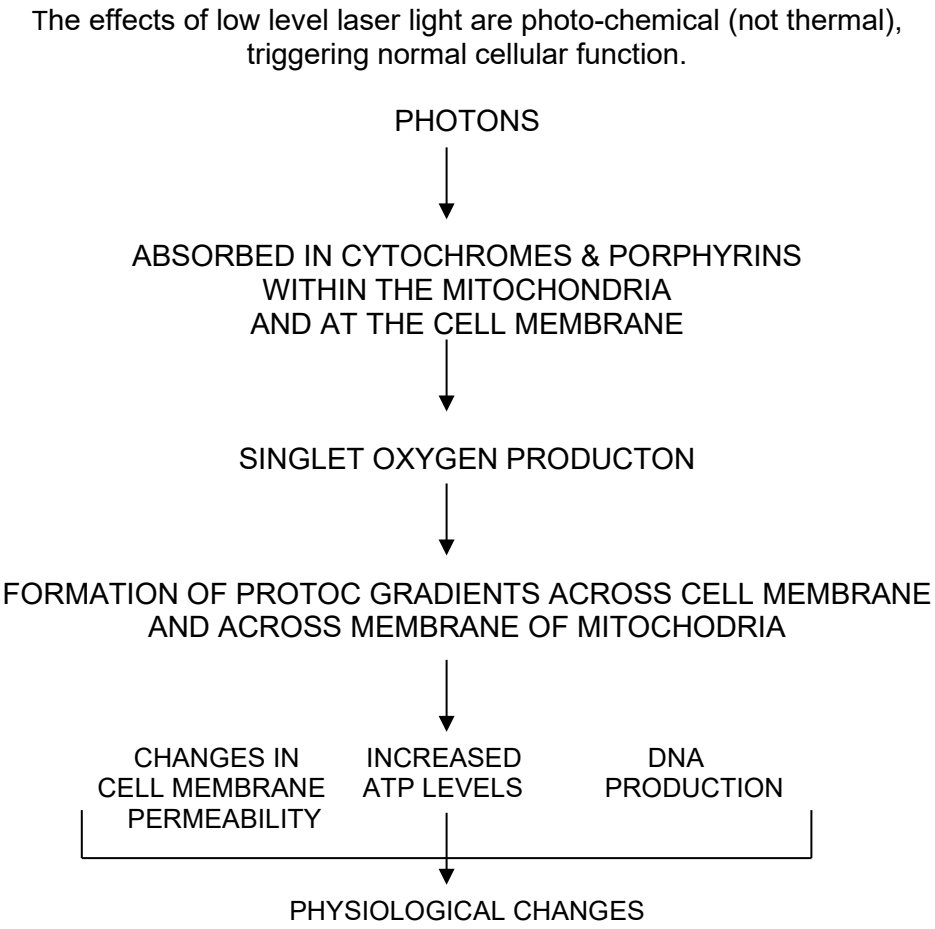
When applied to injuries and lesions, low level laser light has been shown to stimulate healing and to reduce pain by accelerating the speed, quality and strength of tissue repair and the reduction of inflammation. Laser therapy has been found to be particularly effective over other standard therapies in relieving pain and other symptoms associated with injuries as it impacts the complete system of targeted muscles, tendons, ligaments, connective tissue, bone, nerve, and dermal tissues.

Lasers can strengthen damaged cells. Using photochemical processes, laser light inserts bio-photons into damaged cells. The cells begin to produce energy (ATP), which improves their function, assists their division, strengthens the body's immune system, and causes the secretion of various hormones. The tissues are healed, and pain diminishes. If damaged cells have died, the bio-photons help the division of neighboring cells, generating new tissues, and thus bring about healing.

Therefore, LLLT:

- promotes healing by penetrating the skin, increasing ATP production and activating enzymes in the targeted cells
- cultivates a growth factor response within the cells and tissue as a result of increased ATP and protein synthesis
- improves cell proliferation
- provides pain relief as a result of increased endorphin release
- strengthens the immune system response via increasing levels of lymphocyte activity

The process by which low level laser light aids in the production of ATP, consequently providing cells with more energy which in turn optimizes the cells' condition to play their part in a natural healing process, is as follows:



THEORY OF MECHANISM OF OPERATION OF THE APPLICATION OF LOW LEVEL LASER THERAPY TO REDUCING CHRONIC NECK AND SHOULDER PAIN

Considering the general mechanism of operation of LLLT as explained above, it follows that LLLT provides relief from neck and shoulder pain arising from musculoskeletal conditions by:

• penetrating the skin of the neck and shoulder region through to the ligaments and tendons to increase the production of ATP and activate enzymes in the targeted cells of the tissue to promote healing of the tendons and ligaments

• cultivating a growth factor response within the cells and tissue as a result of the increased ATP production to promote new, healthier cell and tissue growth to strengthen and support ligaments and tendons, to restore strength and flexibility and to protect against further damage

• The anti-inflammatory properties of low level lasers reduce nerve irritation and inflammation that consequently provides pain relief.

SUPPORTING ERCHONIA CORPORATION CLINICAL DATA

Erchonia Corporation red diode only lasers and simultaneous red and violet diode lasers have received 510(k) market clearance for adjunctive use in the temporary reduction of minor chronic neck and shoulder pain of musculoskeletal origin, (K012580, K191257).

Each of these market clearances was based upon clinical data from the following:

1. Erchonia Corporation sponsored clinical study: TUCO Erchonia PL2000 Chronic Pain Clinical Study, Version 4.0, May 17, 2001.

2. Erchonia Corporation sponsored clinical study: An Evaluation of the Effect of the Erchonia® EVRL on Neck and Shoulder Pain, Version 1.0, March 21, 2008.

The published results from these studies are presented below.

STUDY JUSTIFICATION

The therapeutic healing and anti-inflammatory mechanisms of both red and violet laser light on reducing neck and shoulder pain of musculoskeletal origin has already been successfully demonstrated. It is believed that the differential properties of green laser light will interact with those of violet laser light to affect a comparable or greater therapeutic effect on the reduction of pain in individuals with neck and shoulder pain of musculoskeletal origin than application of either red diode energy alone or combination red and violet diode energy. It is the goal of this current study to evaluate this theory.

STUDY DESIGN

This clinical study is a single (active) group non-inferiority design to be conducted across three test sites to evaluate the efficacy of the Erchonia® GVL in the temporary reduction of neck and shoulder pain of musculoskeletal origin.

SUBJECT GROUP

There will be a single subject group in this study. All subjects will receive the active study procedure with the green and violet diodes of the Erchonia® GVL emitted simultaneously.

Comparative subject data for Erchonia® EVRL emitting the red and violet diodes simultaneously will be taken from the 2019 study whose results supported FDA market clearance for K191257.

BLINDING

As all subjects in this study will receive the active procedure administration with the Erchonia® GVL, neither subjects nor investigators will be blinded. The statistician analyzing the study results will however be blinded with respect to study success analysis. The data from this current GVL study and the retrospective data from the 2019 EVRL study will be deidentified and presented to the study statistician as 'Group A' and 'Group B'. The statistician will not be aware of which group – A or B – contains the current GVL study data and which contains the retrospective comparative EVRL study data.

RANDOMIZATION

As this study is a single treatment group study, randomization to procedure group is not applicable. Therefore, this is a non-randomized trial.

SUBJECTS

Subject Sample
Subjects will be males and females 18 years or older who present with chronic (30 consecutive days or longer) neck and/or shoulder pain diagnosed as being of musculoskeletal origin (osteoarthritis, chronic muscle spasm, cervical and thoracic spine sprain strain).

Sample Size
There will be 43 qualified subjects enrolled in this study.

Rationale for Sample Size
Sample size is determined to be identical to that intended to be enrolled in in the comparative reference EVRL study.

Recruitment
Subjects may be recruited from among:

(i) The Principal Investigator's/test site's pool of existing and new patients
(ii) Referrals from other suitable medical clinics and professionals
(iii) Subjects who respond to the following recruitment materials:

a) Flyer

WANTED

ADULTS WITH NECK AND SHOULDER PAIN ONGOING FOR THE LAST 30 DAYS FOR A CLINICAL STUDY OF THE EFFECTS OF LOW LEVEL LASER LIGHT ON REDUCING NECK AND SHOULDER PAIN

THIS STUDY INVOLVES A SINGLE LASER LIGHT PROCEDURE WITH THE ERCHONIA® GVL LASER AT THE TEST SITE

FOR MORE INFORMATION PLEASE CONTACT:

<PI name>
<test site name & location>
<phone # and/or e-mail>

b) Newspaper Ad

Neck and Shoulder Pain Research Study

This study is to see if the Erchonia® GVL, a non-invasive, investigational device that uses low-level laser light, can help to relieve neck and shoulder pain that has been ongoing for at least 30 days.

The study involves a single visit to the test site and recording some information at home for two more days.

Please contact <PI name> at <test site name & location> at <phone and/or e-mail> for details.

Compensation

A subject will not receive financial or any other form of compensation to participate in this clinical study. However, he or she will also not be charged for the cost of the study procedure with the Erchonia® GVL Laser or for the cost of any other directly-related evaluations or measurements that occur as a directly-associated part of his or her participation in the study.

STUDY PROCEDURE

STUDY TEST BATTERY

The following are the study measurement and assessment tools to be used and the variables to be recorded in this clinical study. At each evaluation point, the precise tools and variables that will be employed will be specified.

QUALIFICATION EVALUATION TOOL

PHYSICAL EXAMINATION

(i) Inspection: Manipulation of the neck, shoulders, and cervical spine to evaluate for knots (muscle spasms), tightness, swelling, osteophytes, etc.
(ii) Palpation Assessment: Physical assessment of the bony and soft tissues of the neck, shoulder, and cervical spine through touch with the pads of the fingers, to evaluate for muscle tightness and knotting, trigger points that cause pain and possibly also radiating pain.
(iii) Range of Motion (ROM) Assessment: ROM will be evaluated through active, passive, and manual resistance to evaluate for pain and pain worsening and weakness.

a) *Neck ROM*: Neck ROM will be evaluated across the six cardinal planes:
- Sagittal plane: flexion (max. 90º) and extension (max. 25º)
- Frontal plane: right lateral flexion and left lateral flexion (max. 45º)
- Transverse plane: right rotation and left rotation (max. 80º)

b) *Shoulder ROM*:
- Right and left abduction (max 150º)
- Right and left adduction (max. 30º)
- Right and left extension (max 50º)
- Right and left flexion (max. 50º)

BASELINE VARIABLES

NECK/SHOULDER PAIN VARIABLES

(i) Location of pain: right side/left side/back of neck; right/left shoulder
(ii) Duration of pain: months/years since onset of first episode of neck/shoulder pain

CONCOMITANT MEDICATION AND THERAPY USE

(i) Over the counter and prescription medications currently used to relieve neck/shoulder pain, including duration, dosage, and frequency of use
(ii) Non-drug treatments/therapies (conventional, alternative, and experimental) currently used to relieve neck/shoulder pain, including duration and frequency or use/application
(iii) Over the counter and prescription medications currently used, and therapies currently engaged in for any non-pain relief indication, including duration, dosage, and frequency of use

SUBJECT DEMOGRAPHICS: Age, gender, and ethnicity

OUTCOME ASSESSMENT TOOLS

VISUAL ANALOG SCALE (VAS) DEGREE OF PAIN RATING

Subjects will be asked to rate the overall degree of pain experienced in the neck / shoulder region on the following 0-100 mm (0 -10 cm) Visual Analog Pain Scale, by responding to the following question:

"Using the scale below, please mark with a cross (X) a SINGLE SPOT along the 0 to 100 line below that best shows how much **pain you feel in your neck / shoulder** right now. '0' means you feel no pain at all and '100' means you feel the worst pain imaginable. PLEASE MARK ONLY ONE SPOT. DO NOT THINK OF OR WRITE IN A NUMBER."

The Visual Analog Pain Scale (VAS) is one of the three most commonly used scales for assessing chronic pain. It is a simple scale that consists of a line anchored at one end by a label such as "NO PAIN" and at the other end "WORST POSSIBLE PAIN". The subject marks on the line the spot for the pain intensity, which is then measured.

Standard guidelines for effective use of the VAS that are followed in this clinical study are:

i. The line should be 10, 15 or 20cm long, as other lengths are less reliable.
ii. There should be a small vertical mark at each end, with numbers 0 and 100, and a verbal description.
iii. The verbal description must be in absolute terms (e.g., worst pain imaginable);
iv. The line itself should be clear of any markings and should be horizontal rather than vertical, for more reliable measurements.

Used in the above way, it has been shown that the VAS is a proper ratio scale. Like a thermometer, this means that its two ends are rooted, and a doubling of the score does accurately reflect a doubling of the pain. Consequently, sensitive t-tests and ANOVA methods can be used in the analysis, so that significant differences can be identified with relatively small sample sizes or small differences between groups.
Source: Measuring Pain by Adrian White, Acupuncture in Medicine, November 1998 – Vol 16 No. 2

LINEAR RANGE OF MOTION (ROM) MEASUREMENTS

Mobility in the neck/shoulder region will be measured using a universal inclinometer, as follows:

(i) *Shoulder ROM* will be measured from a seated passive abduction, the relaxed position of parallel to the side of the body through full extension above the head. Maximum movement is 180 degrees.
(ii) *Neck ROM* will be measured in a supine position, from forward position to face over shoulder. Maximum movement is 90 degrees.

SUBJECT SATISFACTION WITH STUDY OUTCOME

The subject is asked to rate how satisfied he or she is with any change in neck/shoulder pain following completion of the laser administration procedure with the Erchonia® GVL by using the 5-point Likert scale below to respond to the following question: “Overall, how satisfied or dissatisfied are you with any change in the pain in your neck and/or shoulder following the study procedures with the study laser device?”

- Very Satisfied
- Somewhat Satisfied
- Neither Satisfied nor Dissatisfied
- Not Very Satisfied
- Not at All Satisfied

STUDY PROCEDURE PROTOCOL

PRE-PROCEDURE ACTIVITIES

The pre-procedure activities will be conducted at the test site prior to administration of the study procedure with the Erchonia® GVL Laser.

STUDY QUALIFICATION

SIGNING OF INFORMED CONSENT FORM

The PI will commence by presenting and reviewing in detail the items in the informed consent form with the individual and answer any questions. To proceed, the individual must willingly sign the informed consent form.

ASSIGNMENT OF SUBJECT IDENTIFICATION NUMBER

The subject will be assigned a unique subject identification number based upon his or her order of entry into the study.

Additional information about the informed consent and subject ID number assignment is contained in a later section of the protocol titled, “SAFETY AND CONFIDENTIALITY ISSUES.”

STUDY QUALIFICATION EVALUATION: INCLUSION/EXCLUSION CRITERIA

INCLUSION CRITERIA

To be eligible for study participation, a subject must satisfy each of the following criteria.

1. Subject presents with one or more of:

   - chronic neck pain on the right side of the neck and/or the left side of the neck and/or the back of the neck; and/or
   - chronic shoulder pain on the right shoulder and/or the left shoulder.

2. Subject is diagnosed with of one or more of the following…

   - Osteoarthritis: Degenerative Joint Disorder (DJD)
   - Chronic Muscle Spasms
   - Cervical and Thoracic Spine Sprain Strain

   … determined according to the following four tools:

   - Patient History
   - Medication Use History
   - Records Review: where available, such as x-ray, MRI, and CAT scan reports
   - Physical Examination

Specific criteria to diagnose each condition are as follows:

A. Osteoarthritis: Degenerative Joint Disorder (DJD)
   - Patient History: Previous trauma or infection to the area.
   - Medication Use History: Anti-inflammatory medications; either over the counter (e.g., Advil, Motrin, Aspirin); prescription medications (e.g., Celebrex, Vioxx)
   - Previous Records Review: DJD indicated.
   - Physical Examination: Pain and pain with ROM evaluation; reduced ROM, particularly passive ROM motion; cracking/popping/creaking sound upon movement (ROM); possible joint swelling; possible bone spurs (osteophytes).

B. Chronic Muscle Spasms
   - Patient History: Previous trauma; "frozen" shoulder and/or neck; history of restricted range of motion; pain relief through heat application and/or physical manipulations such as massage and physical therapy.
   - Medication Use History: Over the counter/prescription muscle relaxers and palliatives.
   - Previous Records Review: Lack of DJD indicated.
   - Physical Examination: Limited ROM; muscle tightness/knotting; tenderness and pain upon palpation; possible radiation pain upon palpation of tender spots (trigger points).

C. Cervical and Thoracic Spine Sprain Strain
   - Patient History: Injury or pain initiated after motion or repetitive motion and exacerbated by motion; history of an old injury that can be exasperated acutely; pain and weakness on flexion; increased joint pain at the end range of motion.
   - Medication Use History: OTC and/or prescription muscle relaxants or anti-inflammatory medications.
   - Previous Records Review: Muscle or ligament injury indicated.
   - Physical Examination: Pain that worsens with movement (active and/or passive ROM); reduced ROM; muscle weakness; stiffness; tenderness upon palpation; possible swelling.

3. Pain is chronic: symptoms have persisted for longer than the past 30 days
4. Subject's self-reported Degree of Pain rating on the 0-100 VAS pain scale is 50 or greater
5. Subject is willing and able to refrain from consuming any over the counter and/or prescription medication(s) and/or herbal supplements intended for the relief of pain and/or inflammation, including muscle relaxants throughout the course of study participation,
6. Subject is willing and able to refrain from engaging in any non-study procedure therapies for the management of his or her neck/shoulder pain throughout the course of study participation, including conventional therapies such as physical therapy, occupational therapy and hot or cold packs, as well as alternative therapies such as chiropractic care and acupuncture
7. 18 years of age or older
8. Male or female
9. Primary language is English

EXCLUSION CRITERIA

A subject who satisfies any of the following criteria will be excluded from study participation:

1. Presenting primary pain is located outside or in addition to the region of the neck (right side/left side/back) or the shoulder (right and/or left side)
2. Etiology of neck/shoulder pain cannot be definitively diagnosed; or has bene diagnosed as being in whole or in part other than that of osteoarthritis, chronic muscle spasms or cervical and thoracic spine sprain strain; or other potentially contributing etiologies cannot be satisfactorily ruled out
3. Pain is acute: symptoms prevailed for fewer than each of the prior 30 days
4. Current active chronic pain disease: such as chronic fatigue syndrome and fibromyalgia
5. Use of analgesics or muscle relaxants within 7 days prior to study procedure administration
6. Use of systemic corticosteroid therapy (inhaled and topical corticosteroids permitted), narcotics or Botulinum toxin (Botox®) injection in the neck / shoulder region within 30 days prior to study procedure administration
7. Active cancer or treatment for cancer within the last 6 months
8. Unstable cardiac disease, such as recent cardiac arrhythmia, congestive heart failure or myocardial infarction
9. Prior surgery to the neck/shoulder region
10. Known herniated disc injury
11. Active infection, would or other external trauma to the areas to be treated with the laser
12. Medical, physical, or other contraindications for or sensitivity to light therapy
13. Serious known mental health illness such as dementia or schizophrenia; psychiatric hospitalization in the past two years
14. Pregnant or breast feeding
15. Participation in a research study within the past 30 days

PRE-PROCEDURE EVALUATIONS

The pre-procedure evaluation phase directly follows successful study qualification, on the same day.

BASELINE VARIABLES

- Neck / Shoulder Pain Variables
- Concomitant Medication and Therapy Use
- Subject Demographics

OUTCOME ASSESSMENTS

- Visual Analog Scale (VAS) Degree of Pain Rating
- Linear Range of Motion (ROM)

PROCEDURE ADMINISTRATION PHASE

PROCEDURE ADMINISTRATION PROTOCOL

- The procedure administration phase of the study directly follows successful completion of the pre-procedure evaluations phase, on the same day.
- The procedure administration phase comprises a single procedure administration with the Erchonia® GVL.
- The procedure administration lasts a total of 13 minutes.
- The procedure administration with the Erchonia® GVL is administered at the test site.
- The procedure administration protocol is identical to that in the retrospective control study, and is as follows:

1. The subject enters the procedure room and is seated comfortably.
2. The subject is correctly fitted with the protective eyewear.
3. The Erchonia® GVL is positioned and centered 6 inches above the subject's sagittal suture (top of the head).
4. One minute of pulsed laser is applied to the sagittal suture (top of the head).
5. Two minutes of pulsed laser is then applied to the left cervical, shoulder and torso area. The laser is applied starting in the cerebral region, at the top of the ear, lasering left cervical anterior and posterior muscles, working the laser down into the left shoulder and torso anterior and posterior muscles.
6. Step 5 is repeated to the subject's right cervical shoulder and torso area.
7. One minute of pulsed laser is then applied to right shoulder during passive external rotation of the shoulder. The anterior muscles of the right shoulder (pectoralis group) are lasered, with the subject's arm bent at the elbow.
8. One minute of pulsed laser is then applied to the right shoulder during passive adduction of the subject's right arm and shoulder. The posterior muscles of the right shoulder are lasered.
9. One minute of pulsed laser is then applied to the right cervical muscle and trapezius muscle during passive left lateral flexion of the cervical spine. Starting in the neutral position of the head, the laser light is applied to the right cervical muscles and right trapezius muscles.
10. One minute of pulsed laser is then applied to the right sternocleidomastoid and scalene muscles during passive range of motion. The laser light is applied to the right sternocleidomastoid and scalenus muscles.
11. Step 7 is then repeated to the left shoulder.
12. Step 8 is then repeated to the left shoulder.
13. Step 9 is then repeated to the left cervical spine.
14. Step 10 is then repeated to the left sternocleidomastoid and scalenus muscles.
15. The subject's protective eyewear is removed, and the single procedure administration session is over.

Justification for the Procedure Administration Protocol

The procedure administration protocol in this current study is identical to that which was evaluated in the comparative retrospective EVRL study to enable direct comparison of findings between the two studies and statistical analysis of different group outcomes.

PROCEDURE ADMINISTRATION PHASE EVALUATIONS: STUDY ENDPOINT

Within 3 minutes of completion of the procedure administration phase, study endpoint evaluation will occur.

OUTCOME ASSESSMENTS

- Visual Analog Scale (VAS) Degree of Pain Rating
- Linear Range of Motion (ROM)
- Subject Satisfaction with Study Outcome Rating
- Adverse Events Evaluation

POST-PROCEDURE ACTIVITIES

The post-procedure evaluation phase of this study will commence immediately following completion of the procedure administration phase evaluations and will last for 2 days (48 hours).

The post-procedure outcome assessments will be recorded by the subject in his or her own home on forms provided by the test site. The subject will be instructed on when and how to complete the forms and how to return them to the test site prior to leaving the test site on the procedure administration day.

24 HOURS AND 48 HOURS POST-PROCEDURE EVALUATIONS

The subject will be required to record the following at home on the forms provided by the test site at 24 hours and again at 48 hours after completion of the procedure administration phase at the test site.

OUTCOME ASSESSMENTS

- Visual Analog Scale (VAS) Degree of Pain Rating
- Linear Range of Motion (ROM)
- Subject Satisfaction with Study Outcome Rating
- Adverse Events Evaluation

ADVERSE EVENTS

At each evaluation point throughout the clinical study, and at any other time throughout the duration of the clinical trial that is necessary, any and all potential adverse events reported by a subject or observed by an investigator will be recorded on the case report form, and subsequently evaluated by a suitably qualified independent reviewer for determination of relationship to the study treatment and whether or not any corrective action needs to be taken. All potential adverse events recorded will be appropriately reported to the governing IRB, as applicable.

It is unlikely and not expected that any adverse events will result from implementation of this clinical study protocol. Prior clinical trials using low level laser light have not typically yielded any adverse events or reactions. However, potential adverse events that may feasibly occur from application of the Erchonia® GVL include, but are not necessarily limited to: skin irritation, discoloring, rash, indentations and infection.

PRIVACY AND CONFIDENTIALITY

Records for each subject in this clinical study will be maintained in separate files in a locked filing cabinet at the respective test site. The investigator at the test site will be responsible for ensuring that all records for a subject pertaining to his or her participation in the clinical study are stored in that subject's file at all times other than when information is being recorded on them.

Copies of all of the subject case report forms will be made and supplied to Regulatory Insight, Inc. and Erchonia Corporation. Regulatory Insight, Inc. and Erchonia Corporation will maintain these copies in a separate clinical study file that is kept in a locked filing cabinet at their respective premises. The original records will be maintained at the respective test sites.

Subjects' identities will be kept confidential by assigning each subject a subject ID upon acceptance into the study. The subject ID will comprise the investigator's two initials (first and last name initials) and a three-digit number that will be based upon the subject's order of entry into the clinical study. Each test site will be assigned a unique range of numbers. Test site #1 will be assigned numbers 001 to 100 (Subject ID RS001 to RS100). Test site #2 will be assigned numbers 101 to 200 (Subject ID AC101 to AC200). Test site #3 will be assigned numbers 201 to 300 (Subject ID KG101 to KG200). For example, the eighth subject to be enrolled at test site #2 with would have a subject ID of AC108. Neither the study Sponsor nor Regulatory Insight, Inc. will receive any additional identifying information about a subject and will therefore have no way of linking a Subject ID to a particular subject and his or her results.

STATISTICAL ANALYSIS PLAN

PRIMARY EFFICACY OUTCOME MEASURE: CHANGE IN SUBJECT SELF-REPORTED VAS PAIN RATING FROM BASELINE TO STUDY ENDPOINT

The primary efficacy outcome measure for this clinical study is the change in subject self-reported Visual Analog Scale (VAS) pain rating from baseline to study endpoint evaluation, with study endpoint defined as within 3 minutes of completion of the study single procedure administration with the Erchonia® GVL laser.

Individual Subject Success Criteria
individual subject success criteria is defined as a 30% or greater decrease in self-reported VAS pain rating at study endpoint relative to baseline.

Overall Study Success Criteria.
Overall study success criteria is defined as at least 75%±5% of subjects (70% to 80%) meeting the study individual success criteria.

Justification for Study Success Criteria
The clinical relevance and statistical justification of the individual subject and overall study success criteria is as follows:

- This study is established as a non-inferiority study, such that the research hypothesis is that green / violet dual-diode therapy with the Erchonia® GVL is either equivalent to or superior to red / violet dual-diode therapy with the Erchonia® EVRL in effecting a clinically meaningful temporary reduction in neck and shoulder pain of musculoskeletal origin when compared with the data attained from the red / violet dual-diode Erchonia® EVRL clinical trial conducted in 2019 (comparative reference study) whose results successfully supported 510(k) clearance of K191257, given that the application and evaluation of the Erchonia® GVL in the current study is intended to support clearance of the Erchonia® GVL for the identical indication as the Erchonia® EVRL.

Therefore:

- The individual subject success criteria in this clinical study as specified above is selected to be identical to that of the comparative reference study.
- The overall study success criteria in this clinical study is determined based on the actual proportion of individual subject successes attained during the comparative reference trial of 75%. The ±5% is the selected equivalence margin (δ), the maximally clinically acceptable difference for which the range of values (70% to 80%) for which the efficacies are “close enough” to be considered equivalent.
- Non-inferiority is established to be attained if the proportion of study subjects in this GVL study who meet the individual subject success criteria is no more than 5% less than the proportion of study subjects in the comparative reference EVRL study who met the same individual success criteria, i.e., no less than 70%.

This strategy is the identical strategy employed in the clinical study for the Erchonia® EVRL in red / violet dual-diode mode whose results supported FDA clearance of K191257 based on the same equivalency criteria to the comparative reference group of the active treatment arm of the Erchonia® EVRL in red-diode only mode that had previously received FDA clearance under K012580 and K152196, for the identical indication.

Hypotheses

- *Null Hypothesis*: Treatment application of the Erchonia® GVL in simultaneous green / violet dual-diode mode is inferior to treatment application of the Erchonia® EVRL in simultaneous red / violet dual-diode mode in reducing neck and shoulder pain of musculoskeletal origin.
- *Alternative Hypotheses*: Treatment application of the Erchonia® GVL in simultaneous green / violet dual-diode mode is NOT inferior to treatment application of the Erchonia® EVRL in simultaneous red / violet dual-diode mode only in reducing neck and shoulder pain of musculoskeletal origin.

Evaluation Time Point

Study endpoint evaluation is established as immediately (within 3 minutes) following the study single procedure administration. Study success analysis is established at study endpoint relative to baseline.

The study endpoint evaluation for this study was established to be identical to that in the reference comparative study.

Populations Examined

Primary analysis of efficacy will be according to intent to treat (ITT) analysis (including all enrolled subjects) supported by per protocol (PP) analysis (including only subjects who completed the study according to the full protocol). Non-inferiority will be established if both the ITT and PP analyses agree.

Handling of Missing Data

Missing data for the ITT population will be handled through Last Observation Carried Forward (LOCF): by carrying forward the last recorded observation to fill in the subsequent missing value

PRIMARY EFFICACY OUTCOME STATISTICAL EVALUATION

Primary efficacy outcome success will be determined as follows:

Proportion of Successes

- The percentage of individual subject successes in this clinical study will be calculated according to the pre-specified criteria of a decrease in VAS pain ratings of 30% or greater from baseline to endpoint evaluation.
- **Primary study success will be considered met, i.e., non-inferiority will be established, according to the pre-specified overall study success criteria, if this proportion is not less than 70%.**

Comparison of Proportions

A comparison of proportions test will be performed to evaluate if the two success proportions (GVL vs. EVRL) are equivalent to support the conclusion of the proportions of successes analysis. Significance levels will be considered at the $p<0.05$ level.

Change Scores

- T-test analysis of the difference in the mean change in VAS levels from baseline to endpoint between the dual-diode and red only diode treatment administration groups. Significance levels will be considered at the $p<0.05$ level.

- A t-test for two independent sample will be performed to evaluate the significance of the difference in the mean change in VAS pain scores from baseline to endpoint evaluation between the two study groups (GVL vs EVRL) to evaluate for equivalency to support the support the conclusion of the proportion of successes evaluation. Significance levels will be considered at the $p<0.05$ level.

SECONDARY EVALUATIONS

The following secondary evaluations will be performed on the GVL study data set. As no claims are intended to be made based on the secondary measures, the findings are presented through descriptive analysis and qualitative trending only, without evaluation for or claims of statistical significance.

- Change in mean VAS ratings across study duration: all study evaluation points (baseline, endpoint, 24 hours and 48 hours post-procedure).
- Change in linear ROM measurements across respective study evaluation points at study baseline and endpoint.
- Subject satisfaction with study outcome ratings across study duration.

INDIVIDUAL TEST SITES

Results will be presented by individual test site for comparison.

INDIVIDUAL SUBJECT RESULTS

Individual subject results for study outcome measures will also be presented.

SAFETY ANALYSES

Safety analyses will be based on all enrolled subjects and will be assessed by evaluating and comparing frequency and incidence of observed and/or reported adverse events between subjects in the GVL and the EVRL studies. A chi-square test with a continuity correction will be performed to compare the percentage of subjects who had adverse events between the two subject groups.

INFORMED CONSENT

- Informed consent will be an agreement between the individual investigator and each subject, having the capacity to understand and make an informed decision. Consent will be obtained prior to each potential subject's participation in this clinical study.
- Each subject participating in this clinical study will be made aware of the fact that his or her participation involves research and the intent of the research, the expected duration of his or her participation and a description of the procedures that will be followed.
- Each subject will be made aware of the reasonably expected benefits he or she might receive, as well as any risks or potential discomfort that are involved.
- Each subject will also be made aware of alternative treatments available to him or her.
- Each subject will be made aware that his or her records will remain confidential, but that the FDA and the IRB has the right to inspect his or her records.
- Each subject will be told that his or her participation in the clinical study is voluntary, without force or influence from the investigator or sponsor.
- Each subject will be given the name and method of contacting the appropriate person(s) to answer his or her questions about the research and in the event of a research-related injury.

The informed consent form that will be used to collect the data from each subject in this clinical study can be found in **Appendix B.**

CASE REPORT FORMS

The case report forms that will be used to collect the data from each subject in this clinical study can be found in **Appendix C.**

APPENDIX A

LETTER OF APPLICATION FOR NON-SIGNIFICANT RISK (NSR) DETERMINATION

ERCHONIA CORPORATION
LETTER OF APPLICATION FOR NONSIGNIFICANT RISK DETERMINATION FOR THE ERCHONIA® GVL LASER DEVICE FOR REDUCING NECK AND SHOULDER PAIN CLINICAL STUDY V1.0 07.31.20

NAME OF THE DEVICE: Erchonia® GVL

INVESTIGATIONAL INDICATION: The purpose of this clinical study is to determine the effectiveness of the Erchonia® GVL (manfactured by Erchonia Corporation (the Company), when both the green and violet diodes are activated simultaneously, in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

REGULATORY BACKGROUND

Erchonia demonstrated the effectiveness of low-level lasers in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin in the following studies, each of which successfully supported FDA 510(k) clearances:

The Erchonia® PL2000, a red (635 nm) diode laser was evaluated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin in a double-blinded, sham-controlled, randomized clinical trial, the results of which successfully supported an FDA clearance under K012580 for the following indication:

“The TUCO Erchonia PL2000 is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.”

The TUCO Erchonia PL2000 was subsequently renamed the Erchonia EVRL, and its indications updated under K152196 to include both the treatment of neck and shoulder pain as well as acne vulgaris, as follows:

“The Erchonia EVRL Laser is generally indicated:

a. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and
b. while using the blue diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris”

A non-inferiority study evaluating the Erchonia® EVRL laser employing dual red (635 nm) and violet (405 nm) diodes simultaneously yielded comparable (equivalent) results to the use of red diodes alone for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. The results of that clinical study successfully supported FDA clearance under K191257 for the following indication:

“The Erchonia EVRL Laser is generally indicated using the red and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin”

The present study evaluated efficacy of the Erchonia® GVL, a dual diode laser emitting green (520 nm) and violet (405 nm) diodes simultaneously for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

DEVICE DESCRIPTION & DETAILS

The Erchonia® GVL Laser used in this study is a hand held low level laser that uses two semi-conductor diodes; a 520 nanometer (visible green light) and a 405 nanometer (visible violet light), each emitting its wavelength with a tolerance of ±10 nanometer. The lasers are powered by an internal battery that is recharged using a separate inductive charging base powered by an external class II medical power supply. This configuration offers portability as well as consistency of power. The Erchonia® GVL is a variable hertz device. The variable hertz feature of the Erchonia® GVL is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The internal battery powers the two specially created and patented electronic diodes with an output of 7.5mW green ± 1 mW and <5 mW violet laser.

The device contains software that is embedded in a RAM chip on the PCB. This data includes the touch screen images (GUI) and the command prompts that activate the screen icons; work in conjunction with the component platform to ensure the device operates as intended. The exterior materials consist of 6061 T6 AL and Copolymer Acetal with powder coating finish.

The Erchonia® GVL has the following specifications:

Device
- Weight: Laser-.95lbs / .42kgs. Charger Base-.55lbs / .42kgs
- Full Color TFT Touch Screen Module
- Machined billet aluminum enclosure
- Dimensions: Laser-Length-6.9” (17.52cm) Width-3.10” (7.87cm) Depth-.76” (1.93cm), Charger Base- Length-5.7” (14.47cm) Width-3.5” (8.88cm) Depth-1.65” (4.19cm)

Laser
- 2 electronic diodes, with patented optics
- Output: 520 nm 7.5mW (green)
- Output: 405 nm <5 mW (violet)
- Wavelengths: 520 nm & 405nm +/- 10nm
- Duty Cycle: 50%

Power
- Battery: Lithium-ion Polymer 3.7V, 1500mAh, 5.6w

Inductive Charging Base
- 1.5A 12V

External Power Supply
- Model: ER-E-00182
- 100-240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A

Dosage calculations for the Erchonia® GVL
Total energy per diode:

- (diode output means) mW / 1000 (converting mW to W) * (time in seconds) ÷ 2 (50% duty cycle) = (total energy per diode per minute)
- 520 nm diode (green): 7.5 / 1000 * 60 ÷ 2 = .225J
- 405 nm diode (violet): 4.5 / 1000 * 60 ÷ 2 = .135J
- Total device diodes energy per minute: .36J
- The Erchonia® GVL used in this study is shown in Figure 1 below.

Figure 1

The following diagram identifies each component of the device and a complete description of the component follows.

Figure 2

#1 POWER BUTTON (ON/OFF)

The Power Button allows you to turn the device ON "|" or OFF "O". To turn the device ON, press and Hold this button, after approximately 3 seconds the green (#2 Power On Light) turns on. To turn off the device it is recommended to use the **"Powering Down"** method, explained in the **Operation Section** of the manual**.** In the unlikely event that your device stops responding to

touches, by pressing and holding the power button for 15 seconds will force shut down the device. This is only recommended if the device cannot be turned off from the **"Powering Down"** method.

#2 LASERS ON LIGHT

The "Lasers On" light is an LED indicator that will light up when the Lasers are ON and turn off when the lasers are OFF.

#3 POWER ON LIGHT

The "Power On" light is an LED indicator that will display a constant green light when the device is powered on and turn off only when the device is OFF.

#4 TOUCH SCREEN

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

#5 PIVOTING LASER MOUNT

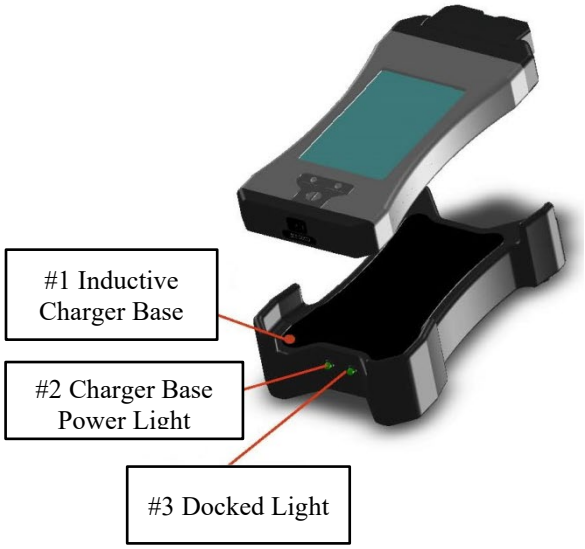
The Pivoting Laser Mount allows you to adjust the laser angle (up to 20º each direction) based on your preference.

#6 LASER DIODES

The Lasers consist of two electronic laser diodes, with patented optics. These laser diodes when activated by the internal power source generate laser energy thereby emitting on one side a red beam and the other side a violet beam. This is a specially designed and patented device created to ensure the laser beam is focused and directed for the most optimal use. The device can be programed with up to 4 defined Hz frequencies (two for each diode).

CHARGER BASE

Directions to set Device on Charger Base



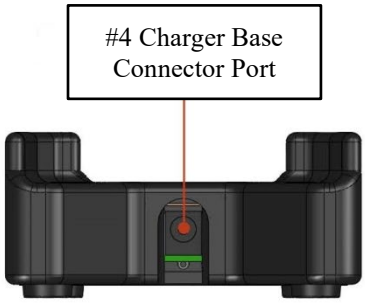


Figure 3

POWER SUPPLY

Figure 4

#1 INDUCTIVE CHARGER BASE

The Inductive Charger Base is a custom based system specifically designed to charge the laser device. It is an inductive charging system that charges the device wirelessly. The Charger Base must be plugged into the power supply and the power supply must be plugged into a wall socket for Charger Base to receive power. Once powered up, the Laser device is placed on Charger Base with the touch screen facing up and Laser diodes facing away from Charger Base LED lights.

#2 CHARGER BASE POWER LIGHT

The Charger Base “Power” Light is the power indicator LED that will light up when the energized Power Supply connector is plugged into the Inductive Charger Base.

#3 DOCKED LIGHT

The “Docked” light is an indicator LED that will light up to indicate the device is correctly docked in the inductive charger base. The LED will flash ON and OFF when correctly in place and turn off when removed from the inductive charger base.

#4 CHARGER BASE CONNECTOR PORT

The Charger Base Connector Port is the location to plug the Power Supply Connector in to supply power to the inductive charger base.

#5 POWER SUPPLY CONNECTOR

The Power Supply Connector plugs into the Inductive Charger Base Connector Port to provide power to charger base.

DEVICE SAFETY

RISK AND PREVENTION OF EYE INJURY

The Erchonia® GVL 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 subject. 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, eye protection is implemented for the subject receiving the laser procedure administrations.

A pair of safety glasses is provided for use during all procedure applications. These safety glasses are Noir laser shields. The safety glasses sufficiently and effectively block the laser light spectrum at OD 6+ @ 190-534nm, OD 1.5+ @ 620-650 nm, VLT 7%.

- Height: 47 mm
- Width: 130 mm
- Length: 130 mm

F

FOOD AND DRUG ADMINISTRATION (FDA) DETERMINATION OF NON-SIGNIFICANT RISK (NSR) STATUS

(i) Regulatory Clearances**:** The Food and Drug Administration (FDA) has determined the family of Erchonia® low level laser devices, including those employing 520 nm green diodes and 405 nm blue/violet diodes, to be non-significant risk (NSR) through numerous **510(k) clearances**, including several for pain relief indications, as follows.

1. **K132940:** *Erchonia® Allay™:* is indicated as an adjunct to reducing chronic heel pain arising from plantar fasciitis.

2. **K072206:** *Erchonia® EML Laser:* is indicated for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery.

3. **K050672:** *Erchonia® EVRL Laser*: The Erchonia EVRL Laser is generally indicated:
   a. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and
   b. while using the blue diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris.

4. **K041139:** *Erchonia® EML Laser*: is indicated as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process.

5. **K100509 & K130741:** *Erchonia® THL1 Laser & Erchonia® PL5000*: is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

6. **K130996:** *Erchonia® XLR8™*: The Erchonia XLR8™ is indicated for the following three indications:
   a. adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
   b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process
   c. temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery

7. **K142042:** *Erchonia® SHL Laser:* is indicated for use as a non-invasive dermatological aesthetic treatment for reduction of circumference of hips, waist and upper abdomen when applied to individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m².

8. **K130922:** *Erchonia® Verju Laser System with Massager*: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist and thighs. The Massager component is indicated for the temporary reduction in the appearance of cellulite.

9. **K123237 & K133718:** *Erchonia® Zerona™ 2.0 Laser & Zerona®-Z6*: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

10. **K121695 & K082609:** *Erchonia® ML Scanner (MLS) & Erchonia® Zerona:* is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

11. **K21690 & K120257:** *Erchonia® MLS, Zerona, Zerona-AD*: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

12. K101430: *MLS-AC Derma Scanner™:* is indicated while using the red diodes for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and while using the blue diode, to treat moderate inflammatory Acne Vulgaris.

13. K082609: *Erchonia® ML Scanner (MLS)*: is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist and thighs.

14. K191257: Erchonia EVRL is indicated while using the red and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin

(iii) Pre-IDE Reviews**:** FDA has previously reviewed numerous clinical study protocols employing various Erchonia® Corporation low level laser devices, including all of the clinical studies conducted in support of the above 510(k) clearances. For all of the FDA's pre-IDE reviews of Erchonia low level laser clinical study protocols, there was concurrence from FDA that the clinical study protocols and application of the Erchonia laser devices therein were considered non-significant risk (NSR).

INSTITUTIONAL REVIEW BOARD (IRB) DETERMINATION OF NON-SIGNIFICANT RISK (NSR) STATUS

Erchonia® Corporation low level laser devices have been determined to be non-significant risk (NSR) when applied in various clinical studies through several IRBs and application for pain reduction indications, as follows:

- Western Institutional Review Board (WIRB®) has previously determined Erchonia low level laser devices to be non-significant risk (NSR) when applied in the following clinical studies:

1. **WIRB PRO NUM: 20121548:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) laser on reducing pain associated with degenerative arthritis (osteoarthritis) of the midfoot clinical study protocol

2. **WIRB PRO NUM: 20120787:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on low back pain clinical study protocol

3. **WIRB PRO NUM: 20111793:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) laser on chronic heel pain clinical study protocol

4. **WIRB PRO NUM: 20110331:** Erchonia® MLS: An evaluation of the effectiveness of the Erchonia® ML Scanner (MLS) as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arms clinical study protocol

5. **WIRB PRO NUM: 20120911:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on body contouring of the waist, hips and thighs five-day treatment protocol clinical study protocol

6. **WIRB PRO NUM: 20110758**: Erchonia® MLS: A pilot evaluation of the effect of the Erchonia® ML Scanner (MLS) laser device on enhancing body weight loss, fat loss and circumference reduction of the waist, hips and thighs clinical study protocol

7. **WIRB PRO NUM: 20121330:** Erchonia LUNULA™**:** An Evaluation of the Effect of the Erchonia LUNULA™ on Treating Toenail Onychomycosis Clinical Study Protocol; Version 6.0 August 7, 2012

8. **WIRB PRO NUM: 20110461:** Erchonia FX-405™**:** An Evaluation of the Effect of the Erchonia FX-405™ on Treating Toenail Onychomycosis Clinical Study Protocol; Version 3.0 March 19, 2011

9. **WIRB PRO NUM: 20120489:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on lipid panel levels clinical study protocol.

10. **WIRB PRO NUM: 20180778:** Erchonia® EVRL: An Evaluation of the effect of the Erchonia® EVRL on Neck and Shoulder Pain

- Independent Review Consulting, Inc.'s/Ethical and Independent Review Services has previously determined Erchonia low level laser devices to be non-significant risk (NSR) when applied in the following clinical studies:

1. **IRC# 07150, NSR# DER-006:** Erchonia® MLS**:** A double blind, placebo-controlled randomied evaluation of the effect of the Erchonia® ML Scanner (MLS) on body contouring of the waist, hips and thighs clinical study protocol.

2. **IRC# 09120, NSR# DER-015:** Erchonia® MLS**:** A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on reducing the appearance of cellulite clinical study protocol.

3. **IRC# 08167, NSR# DER-009:** Erchonia® MLS**:** A double blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on capsular contracture clinical study protocol.

4. **IRC# 09059, NSR# DER-010:** Erchonia® MLS**:** A double blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) in combination with silicone sheets on cellulite pilot study protocol.

- Chesapeake Research Review, Inc. determined the Erchonia® ML Scanner (MLS) laser device to be a non-significant risk (NSR) device when applied in the following study:

(i) **Pro. # 00006393:** Erchonia® MLS**:** A pilot evaluation of the effect of the Erchonia® ML Scanner (MLS) as applied to the abdomen on reducing visceral abdominal fat in patients with HIV-associated lipodystrophy.

OTHER POTENTIAL RISKS

Other potential risks and their mitigation include:

(i) Electric shock: operator risk only: mitigated through electrical safety testing.
(ii) Electromagnetic interference: mitigated through EMC/EMI testing.
(iii) User error: mitigated through instructions for use documentation.

LABELING

The device used in this clinical study shall be labeled with the following statement:

"CAUTION – Investigational device. Limited by United States law to Investigational use."

- Do you contend that this device as used in this protocol is an NSR device?
  _✓_ Yes ___No

- Has another IRB decided this device is SR?
  ___ Yes _✓_ No

- Does this type of device appear as SR on the FDA Information Sheet?
  ___ Yes _✓_ No

APPENDIX B

INFORMED CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	An Evaluation of the Effect of the Erchonia® GVL on Neck and Shoulder Pain
PROTOCOL NO.:	None
SPONSOR:	Erchonia Corporation
INVESTIGATOR:	
SITE(S):	
STUDY-RELATED PHONE NUMBER(S):	

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study doctor or staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- This study involves experimental (investigational) device procedures that are being tested for a certain condition or illness. An investigational device is one that has not been approved by the U.S. Food & Drug Administration (FDA).

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What device and procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

In this study, the Sponsor, Erchonia Corporation, and investigators are studying the use of a device called the Erchonia® GVL that gives off low level laser light. This study is to see if using the Erchonia® GVL can help to reduce neck and shoulder pain. The Erchonia® EVRL is cleared for marketing by the U.S. Food and Drug Administration (FDA) to assist in temporarily reducing chronic neck and shoulder pain of musculoskeletal origin when using red and violet light together and red light alone. However; the use of both green and violet laser simultaneously in this study is investigational, as the Erchonia® GVL has not been cleared for market by the FDA.

PROCEDURES

- If you agree to take part in this study, you will be one of about 43 people taking part.
- If you agree to take part in this study, you will get the study treatment with the active GVL meaning it will be turned on.
- To take part in this study, you must agree to not take any medicines or try any other treatments to help with your neck and shoulder pain, until your part in the study is over.
- The study takes 48 hours (2 days) to complete.
- The study process is as follows:

Screening Visit (Visit 1)

If you are interested in taking part in this research study, we will conduct a screening visit at the test site. At this visit, we will review this informed consent document. Then we will:

- Get information about your neck and/or shoulder pain.
- Get information about your other medical history, including information about other current medical conditions you may have.
- Get information about medicines you are taking for your neck and/or shoulder pain.
- Do a simple physical examination of your neck, shoulder and spine.
- Review your previous medical records and diagnostic tests (like x-rays, MRIs, CT Scans, etc.) that relate to your neck and/or shoulder pain if any such information is available.
- Ask you to rate the level of your pain in your neck and/or shoulder on a scale from 0 to 100, where ‘0’ means ‘no pain’ and ‘100’ means ‘worst pain imaginable’.

The screening phase lasts about 20 minutes.

Pre-Treatment Phase (Visit 1)

The pre-treatment phase will start once you have successfully completed the screening visit, and we can confirm that you are still eligible for this study. At this visit, we will:

- Get some more information about your neck and/or shoulder pain.
- Get information about medications you are taking right now for any reason.
- Get information about your age, gender and ethnicity.
- Ask you to rate the level of your pain in your neck and/or shoulder on the 0-100 scale as you did during the screening visit.
- Do a simple test to see how you move back and forth and from side to side.

The pre-treatment phase visit lasts about 10 minutes.

Treatment Phase (Visit 1)

The treatment phase will start once you have successfully completed the pre-treatment phase, on the same day.

There is a single treatment administration with the Erchonia® GVL. The treatment session takes about 13 minutes. You will be seated comfortably in a chair and fitted with special glasses to block the laser light from your eyes. The light will shine across your neck, shoulder, head and back area, but it will not touch your skin. While the doctor is doing the study treatment, he or she will gently move your arms about.

You will be asked not to take any medication or do any other treatments to help with any neck and/or shoulder pain you may experience for the next 48 hours.

Immediately after the treatment with the Erchonia® GVL laser, we will:

- Ask you to rate the level of your pain in your neck and/or shoulder on a scale from 0 to 100, as you did during the screening and pre-treatment phases.
- Do the simple test to see how you move back and forth and from side to side as during the pre-treatment phase.
- Ask you to rate how satisfied you are with the outcome of the treatment administration with the Erchonia® GVL Laser on a five-point scale

Post-Treatment Phase (At Home)

At 24 hours and again at 48 hours after your treatment with the Erchonia® GVL, you will need to record the following information on the forms given to you at the test site. You will need to:

- Rate the level of your pain in your neck and/or shoulder on the 0-100 scale.
- Rate how satisfied you are with the outcome of the treatment administration with the Erchonia® GVL Laser on a five-point scale as you did immediately after the treatment administration with the GVL.

- ➢ You must not take any medications or do any treatments to help with any neck and/or shoulder pain you may be experiencing during the post-treatment phase.
- ➢ You must return the complete 24-hour and 48-hour forms to the test site as you have been instructed.
- ➢ Your part in the study is then over.

RISKS AND DISCOMFORTS

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 eye sight. As a precaution, when you are given the treatment with the Erchonia® GVL, you will be fitted with special darkened protective glasses to block out the light.

No adverse events have been noted during prior clinical trials using the Erchonia® Lasers. However, the complete risk profile or anticipated risks with the use of the Erchonia® GVL laser device is not known. There may be risks to using the device with this study procedure such as:

- skin irritation,
- itching,
- discoloring,
- rash,
- indentations,
- pain/discomfort, and
- infection.

It is possible that you will not get any improvement in the pain in your neck and/or shoulder or that it may even get worse.

Women who are pregnant or nursing a child may not take part in this study. If you are trying to get pregnant, you should not volunteer for this study.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
Your neck and/or shoulder pain may lessen while you are in this study; however, this cannot be promised. The results of this study may help people to lessen neck and/or shoulder pain in the future.

COSTS
It will not cost you anything to be part of the study. Erchonia Corporation, the sponsor of this research, will provide use of the Erchonia® GVL laser device to do the study treatment free of charge. The cost for all study-related procedures and measurements will also be covered by Erchonia Corporation. Nothing will be billed to you or to your insurance company.

PAYMENT FOR PARTICIPATION
You will not be paid for your part in this research study.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there is other care available to you, such as rest; medications to relieve pain and muscle spasms; local heat applications; massage; exercise; spinal manipulation; and surgical procedures; as well as alternative options such as acupuncture; biofeedback; traction, transcutaneous electrical nerve stimulation (TENS); and ultrasound. The study doctor will discuss these with you. You do not have to be in this study to be treated for your neck and/or shoulder pain.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Western Institutional Review Board® (WIRB®).

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

COMPENSATION FOR INJURY
If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate, or you may leave the study, at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.
Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;

- or for any other reason

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, Erchonia Corporation, will pay for this research study.

QUESTIONS
Contact <PI name> at <PI phone> (24 hours) for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study treatment, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____

Subject Name (printed)

CONSENT SIGNATURE:

_____

Signature of Subject (18 years and older) Date

_____

Signature of Person Conducting Informed Consent Discussion Date