ERCHONIA® CORPORATION CFL

An Evaluation of the Effect of the Erchonia Corporation CFL Laser for non-invasive reduction of submental fat

NCT05954065

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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® CFL (manufactured by Erchonia Corporation (the Company), in providing noninvasive fat reduction in the submental area.

STUDY DURATION
The estimated total duration of the study is 16 weeks.

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

"The Erchonia CFL is indicated to affect the appearance of visible fat bulges in the submental area".

The indication for use of the Erchonia CFL is identical to Coolsculpting System (K151179) and SculpSure (K171992) which have obtained FDA market to "affect the appearance of visible fat bulges in the submental area". It is intended that the results of this clinical study be used to support a 510(k) submission for FDA market clearance.

EXPECTED RESULTS
Twelve weeks post-final treatment, it is anticipated that compared with pre-treatment, subjects will demonstrate a reduction in the appearance of submental fat. An Individual subject is defined as a "study responder" if at least 2 of the 3 Independent Blinded Evaluators correctly identify the subject's post-treatment photograph, with overall study success defined as a minimum responder rate of 80%.

The Week 16 12-week post-final treatment primary endpoint evaluation is identical to that employed in the clinical trials whose results supported the above-referenced FDA market cleared devices; Coolsculpting System (K151179) and SculpSure (K171992).

REGULATORY BACKGROUND AND JUSTIFICATION FOR THE CURRENT STUDY

BACKGROUND
Erchonia Corporation (manufacturer of the CFL Laser) has extensive regulatory background with the Food and Drug Administration (FDA) in non-invasive fat loss indications, under FDA product code OLI. Each of the below respective market clearances was supported by efficacy data from a full-scale controlled and powered clinical trial conducted by Erchonia Corporation.

- **K150446:** The Erchonia® Zerona 6 Headed Scanner (EZ6) device is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, thighs and upper abdomen when applied to individuals with a Body Mass Index (BMI) between 25 kg/m² and 40 kg/m².

- **K143007:** The Zerona® Z6 OTC device is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist and thighs.

- **K142042:** The 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.

- **K123237 & K133718:** The Erchonia® Zerona™ 2.0 Laser & Zerona®-Z6 device 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.

- **K121695 & K082609:** The Erchonia® ML Scanner (MLS) & Erchonia® Zerona device 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.

- **K121690 & K120257:** The Erchonia® MLS, Zerona, Zerona-AD Laser 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.

Each of these market clearances falls under **FDA Product Code OLI**, defined as follows:

Device	Fat Reducing Low Level Laser
Regulation Description	Low level laser system for aesthetic use
Definition	Non-invasive reduction in fat layer for body contouring
Physical State	laser system that emits laser energy in the red spectrum
Technical Method	use of low level laser energy to create pores in adipocyte cells to release lipoproteins
Target Method	adipocyte cells within the fat layer of the body, this could include waist, thighs, abdomen, hips, etc...
Device Class	2

GENERALIZED INDICATION FOR "REDUCTION OF BODY CIRCUMFERENCE"
Erchonia Corporation has demonstrated efficacy in the application of low-level lasers for non-invasive fat loss in the body areas of the thighs, hips, waist, upper abdomen, and upper arms. Based on Erchonia Corporation's collection of clinical data that demonstrated the generalizability of the therapeutic effects of the Erchonia LLLT across all body areas with no change in the anticipated efficacy outcome or safety profile, the FDA granted Erchonia Corporation low level laser devices a generalized indication for "Reduction of body circumference" under K192544, K220519, K162578.

While Erchonia corporation has obtained an FDA market clearance for generalized reduction of overall body circumference, it is intended that the results of the current proposed trial will support a specific indication "to affect the appearance of visible fat bulges in the submental area".

STUDY DEVICE

DEVICE DESCRIPTION

The Erchonia® CFL Laser is designed for clients seeking noninvasive fat loss of the submental (chin) area without invasive surgery. The CFL Laser allows the patient to continue their daily activities without interruptions from surgery, pain, wounds or garments. The CFL works by emulsifying adipose tissue which then releases into the interstitial space. The excess fat is then passed through the body during its normal course of detoxification. The CFL Laser was built on the clinical foundation of its predecessors, Zerona® and Zerona®-AD, and ZERONA® Z6 OTC, Verju, Emerald which were proven through clinical studies that supported clearances for said devices and respective indications for use to be safe and effective in the application of noninvasive fat loss.

The Erchonia® CFL Laser used in this study is a handheld low-level laser that uses two semi-conductor diodes; a 520 nanometer and a 405 nanometer, each emits 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 internal battery powers the two specially created and patented electronic diodes with an output of 7.5mW (± .50 mW) for both the green and 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 Erchonia® CFL has the following specifications:

Device

- Weight: Laser-.66lbs / .30kgs. Charger Base-.60lbs / .27kgs
- Full Color TFT Touch Screen Module
- Machined billet aluminum enclosure
- Dimensions: Laser-Length-6.8” (17.27cm) Width-3.10” (7.87cm) Depth-.75” (1.90cm),

Laser

- 2 electronic diodes, with patented optics
- Output: 520 nm 7.5mW ± .50mW (green)
- Output: 405 nm 7.5mW ± .50mW (violet)
- Wavelengths: 520 nm & 405nm ± 10nm

Power

- Battery: Lithium-ion Polymer 3.7V, ≤3000mAh, 6.7W

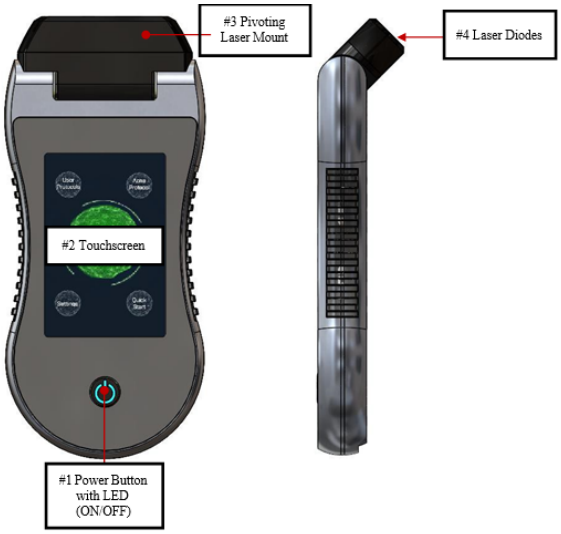
Inductive Charging Base

- 1.2A 15V

External Power Supply

- Model: ER-E-00375
- 100-240Vac, 47-63Hz, 0.5A; 15Vdc 1.2A
- 100-240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A

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



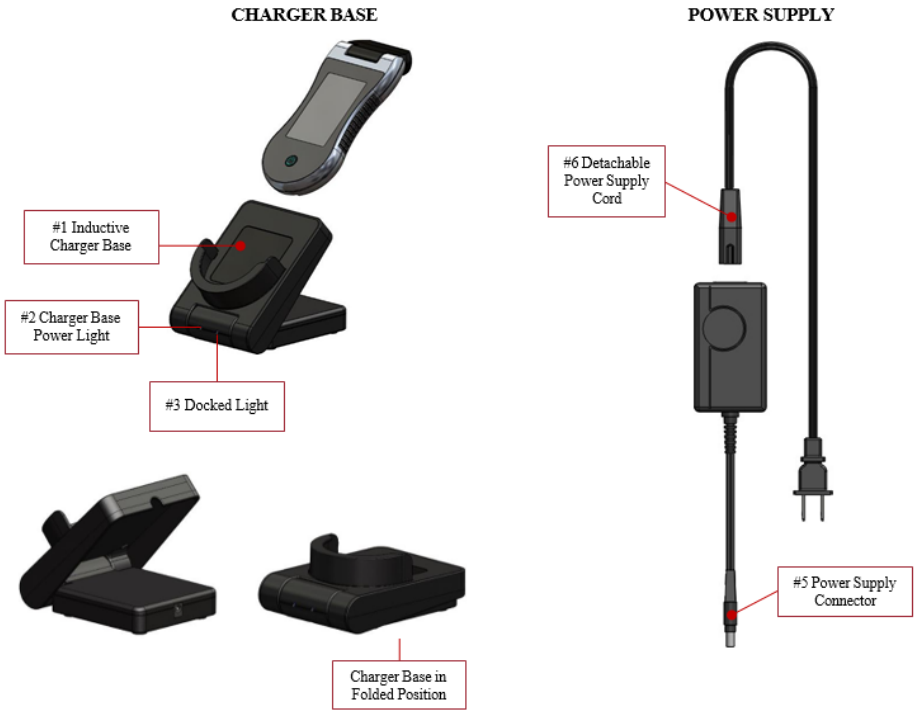
#1 POWER BUTTON WITH LED (ON/OFF)
The Power Button allows the user to turn the device ON "|" or OFF "O". To turn the device ON, the user presses and releasees this button so that the blue power LED turns on. To turn off the device, it is recommended to use the "Power Down" icon.

#2 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.

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

#3 PIVOTING LASER MOUNT
The Pivoting Laser Mount allows the user to adjust the laser angle 90 º in one direction and 45 º in the other direction, based on user preference.

#4 LASER DIODES
The device consists 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.



#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 connected to the power supply and the power supply must be plugged into a wall socket for the Charger Base to receive power. Once powered up, the laser device is placed on the Charger Base with the touch screen facing up and the Laser diodes facing away from the Charger Base LED lights. The Charger Base can also be placed in a folded position if preferred by pushing the Charger Base dock down towards the base.

NOTE: The lasers do NOT operate when the handheld device is in the charger base.

#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 [#5] 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. The Power Supply comes with a detachable power supply cord [#6] that must be plugged into the Power Supply and a wall socket in order to charge.

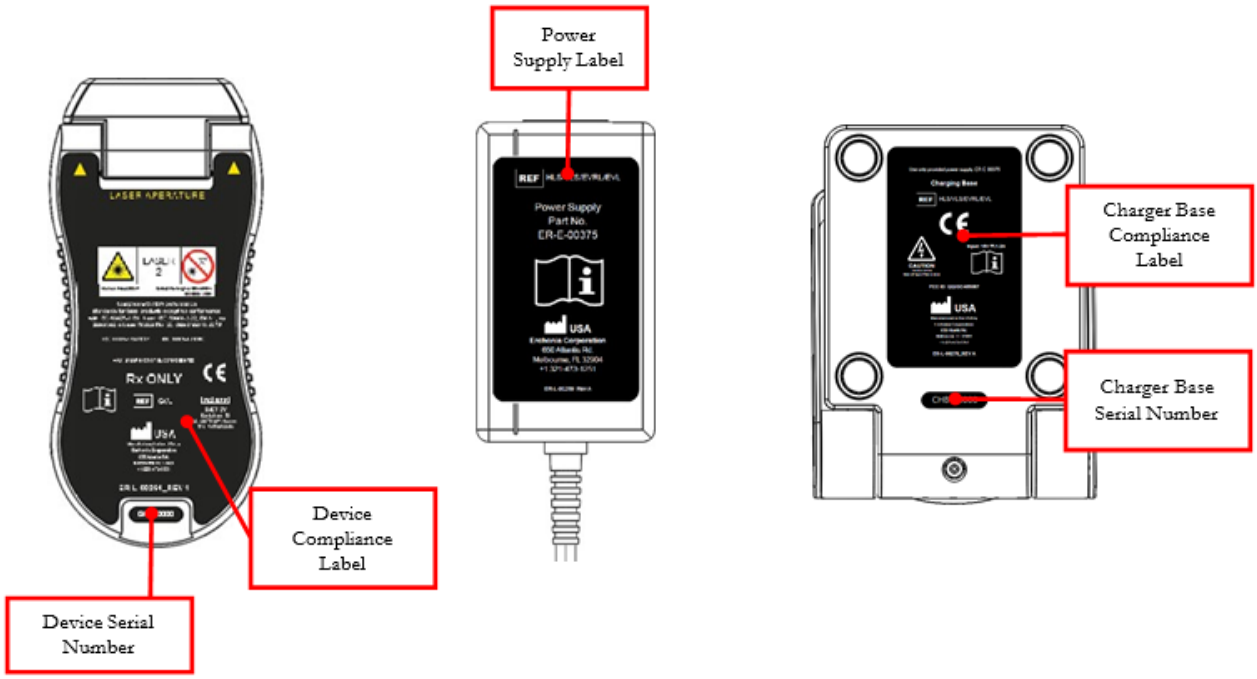
This device should be operated in temperatures between 59 to 85°F (15 to 29°C) <50% relative humidity and transported in temperatures between 14 to 140°F (-10 to 60°C) relative humidity <95%.

#6 DETACHABLE POWER SUPPLY CORD
The detachable power supply cord plugs directly into the power supply connector [#5] and into a wall socket in order for the power supply to operate.

LABELING
The Erchonia® CFL 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.

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

The compliance issues have been combined into one series of labels located on the back of the device and an output label alongside the probe. The following diagram shows the placement of the compliance information and an enlarged label on which it is printed.



SAFETY

PROTECTIVE WEAR
The Erchonia® CFL is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty glasses for use by the patient during treatment. The safety glasses sufficiently and effectively block the laser light spectrum at OD 7+ @ 180-532nm, OD 0.75 @ 405nm VLT60.

- Length: 144 mm
- Width: 145 mm
- Height: 50 mm

⚠	WARNING- The patient should always be correctly fitted with the safety glasses provided before turning on the laser and doing any treatment.

THEORY OF MECHANISM OF OPERATION OF THE APPLICATION OF ERCHONIA® LASERS FOR NON-INVASIVE FAT LOSS

The theory of mechanism of operation of the application of Erchonia® low level lasers for non-invasive fat loss has been well-established, proven and accepted.

Erchonia Corporation light laser devices have been cleared by the FDA under Product Code 'OLI'. Under 21 CFR 878,5400, FDA identifies this generic type of device as: "A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use."

This determination is supported by the results of a study performed by Dr. Neira using Erchonia diode lasers, wherein it was found using electron microscopy that a transitory pore in the adipocyte cell membrane formed following irradiation with the Erchonia laser diode. The formation of the transitory pore allowed for fat to pass from the intracellular space into the extra-cellular space. Dr. Neira's research was subsequently reaffirmed by Dr. Susan Lim using Standard and Cryo Scanning Electron Micrographs, in which she demonstrated the formation of the transitory pore as well as the movement of fat droplets across the membrane.

Therefore, the biochemical effect of Erchonia® low level laser light therapy devices stimulate the mitochondria of the adipocyte cells which in turn increases the production of ATP. The newly synthesized ATP triggers the up-regulation of cyclic adenosine monophosphate (cAMP). cAMP has been shown to stimulate cytoplasmic lipase, triggering the conversion of triglycerides into fatty acids and glycerol that can easily pass through the cell membrane. The transitory pore is

evidence that the laser is allowing for the movement of fatty acids, glycerol, and triglycerides to pass across the membrane and into extra- cellular space. Through vasodilation of nearby blood vessels and arteries, oxidization of the triglycerides and fatty acids occurs within the extra-cellular space.

SUPPORTING BIOLOGICAL DATA

The following abstract support the theory of adipose tissue liquefaction for the purpose of body contouring

Fat Liquefaction: Effect of Low-Level Laser Energy on Adipose Tissue.
Plastic & Reconstructive Surgery. 110(3):912-922, September 1, 2002.
Neira, Rodrigo M.D.; Arroyave, Jose B.S.C.E., T.E.M., S.E.M.; Ramirez, Hugo M.V.; Ortiz, Clara Lucia M.D.; Solarte, Efrain Dr. rer. nat.; Sequeda, Federico Ph.D.; Gutierrez, Maria Isabel M.D., M.Sc., Ph.D.

Low level laser energy has been increasingly used in the treatment of a broad range of conditions and has improved wound healing, reduced edema, and relieved pain of various etiologies. This study examined whether 635 nm low level lasers had an effect on adipose tissue in vivo and the procedural implementation of lipoplasty/liposuction techniques. The experiment investigated the effect of 635 nm, 10 mW diode laser radiation with exclusive energy dispersing optics. Total energy values of 1.2 J/cm2, 2.4 J/cm2, and 3.6 J/cm2 were applied on human adipose tissue taken from lipectomy samples of 12 healthy women. The tissue samples were irradiated for 0, 2, 4, and 6 minutes with and without tumescent solution and were studied using the protocols of transmission electron microscopy and scanning electron microscopy. Non-irradiated tissue samples were taken for reference. More than 180 images were recorded and professionally evaluated. All microscopic results showed that without laser exposure the normal adipose tissue appeared as a grape-shaped node. After 4 minutes of laser exposure, 80 percent of the fat was released from the adipose cells; at 6 minutes of laser exposure, 99 percent of the fat was released from the adipocyte. The released fat was collected in the interstitial space. Transmission electron microscopic images of the adipose tissue taken at x 60,000 showed a transitory pore and complete deflation of the adipocytes. The low level laser energy affected the adipose cell by causing a transitory pore in the cell membrane to open, which permitted the fat content to go from inside to outside the cell. The cells in the interstitial space and the capillaries remained intact. Low level laser-assisted lipoplasty has a significant impact on the procedural implementation of lipoplasty techniques.

SUPPORTING CLINICAL DATA: ERCHONIA CORPORATION CLINICAL TRIAL RESULTS

The following are summaries of the results of the clinical trials performed and submitted in support of the FDA clearances for the body contouring/fat reduction indications as reported above (K142042, K121695, K082609, K121690, K120257, K123237).

An Evaluation of the effectiveness of the Erchonia® Scanner device (GLS) as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the waist, hips and thighs; Version 2.0, March 24, 2011 (cleared and marketed as the Erchonia® Zerona™ 2.0 Laser)

PURPOSE OF STUDY
The purpose of this clinical study was to determine the effectiveness of the Erchonia® Scanner device (GLS) for non-invasive body contouring of the waist, hips and bilateral thighs by applying

green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, six times across two weeks, at the investigator's test site.

DEVICE DESCRIPTION
The Erchonia® Scanner device (GLS) used in this study employed 532 nm green laser diodes.

STUDY DESIGN
The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two independent test sites.

STUDY SUBJECT POPULATION
Sixty seven (67) subjects completed this study. Of the 67 participating subjects, 35 were randomized to the active procedure group and 32 were randomized to the placebo group.

Study subject age ranged from 20 to 63 years and averaged 38 years (n=49). Forty-six (46) subjects (84%) were female and 9 subjects were male (16%). Fifty-six (56) subjects (92%) were Caucasian, 3 subjects (5%) were Middle Eastern, and 2 subjects (3%) were African American.

PROCEDURE ADMINISTRATION
Subjects received six procedure administrations with the Erchonia® Scanner device (GLS) (active or sham) across a consecutive two-week period: three procedures per week, each procedure two to three days apart. For each procedure administration, exposure time to the Erchonia® GLS was 15 minutes across the frontal region and 15 minutes across the lateral region.

STUDY MEASURES
Circumference measurements (inches) of the waist, hips, right thigh and left thigh were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with procedure outcome was recorded at study endpoint.

STATISTICAL ANALYSIS
Primary Efficacy Outcome Analysis
The study primary outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from baseline (pre-procedure) to following completion of the two-week procedure administration phase (study endpoint: end of week 2).

INDIVIDUAL SUBJECT SUCCESS CRITERIA
It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch or greater reduction in total combined inches in circumference measurements across this primary evaluation period.

OVERALL STUDY SUCCESS CRITERIA
It was pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 35% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

68.57% of subjects who received the study procedures with the actual (active) Erchonia® GLS attained a decrease in combined circumference measurements of 3.0 inches or greater compared with 18.75% of subjects who received the study procedures with a 'fake' (placebo) laser device. A Fischer's Exact Test for two independent proportions found this difference of

49.82% between subject procedure groups to be statistically significant at p<0.0001.

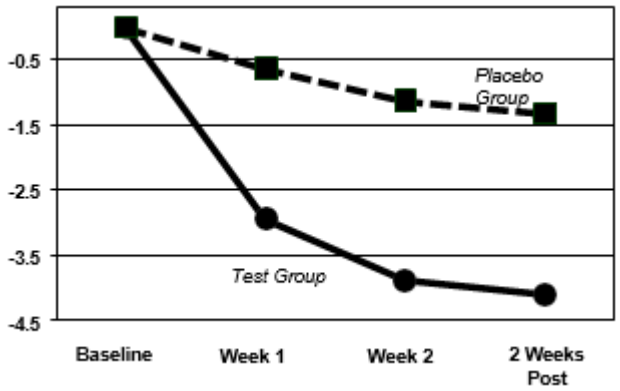
CHANGE SCORES
The mean change in combined circumference measurement for subjects who received the study procedures with the actual (active) Erchonia® GLS was a decrease of 3.895 inches, while the mean change in combined circumference measurements for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 1.135 inches. A t-test for two independent samples found the mean change in combined circumference measurements from baseline to study endpoint for test (active procedure) group subjects to be significantly greater than that for placebo (sham procedure) group subjects, at p<0.0001.

Table 13 and Chart 1 below show the mean change in combined circumference measurements (waist, hips, and right and left thigh circumference measurements combined) across the four study measurement time points for the intent-to-treat (ITT) study subject population.

Table 1: Mean total circumference measurements (ins.) across evaluation points evaluation point relative to baseline.

	Test Group	Placebo Group
Baseline	119.97	117.04
Midpoint (week 1)	117.03	116.41
Endpoint (week 2)	116.08	115.91
Follow-up (week 4)	115.86	115.72

Chart 1: Mean change in total circumference measurements (ins.) at each study.



For test group subjects, combined circumference measurements decreased progressively and significantly from baseline through post-procedure evaluation, indicating a progressive and cumulative treatment effect of the laser that prevailed for at least 2 weeks following the end of the laser procedure administration period. Total circumference measurements for placebo group subjects did not change significantly across the same evaluation period.

STUDY OUTCOME SATISFACTION RATINGS
At completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in the appearance of the waist-hips-bilateral thighs area attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. Sixty-five percent (65%) of test group subjects reported being 'Satisfied' ('Very Satisfied' or 'Somewhat Satisfied') with the outcome of the study procedures compared with 19% of placebo subjects.

ADVERSE EVENTS
No adverse event occurred for any subject throughout the duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

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; Version 1.1; January 4, 2011

PURPOSE OF STUDY
The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® ML Scanner (MLS) for non-invasive body contouring of the upper arms by applying the MLS to the upper arms six times across two weeks.

DEVICE DESCRIPTION
The Erchonia® MLS laser device used in this study employed 635nm red laser diodes.

STUDY DESIGN
The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two independent test sites.

STUDY SUBJECT POPULATION
Sixty two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Sixty (60) subjects (97%) were female and 2 subjects were male (3%). Thirty seven (37) subjects (60%) were Caucasian, 21 subjects (34%) were Hispanic, 2 subjects (3%) were African American, and 2 subjects (3%) were Caucasian and African American.

PROCEDURE ADMINISTRATION
Subjects received six total procedure administrations with the Erchonia® MLS (active or sham) to the right and left upper arms across a consecutive two-week period: three procedures per week, each procedure at two to three days apart, at the investigator's test site.

STUDY MEASURES
Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

STATISTICAL ANALYSIS
The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two- week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% of subjects who received the study procedures with a 'fake' (placebo) laser device. A Fischer's Exact Test for two independent proportions found this difference of 55% to be statistically significant at $p<0.000005$.

CHANGE SCORES

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 1 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 2 below.

Table 1: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 2: Paired samples t-tests for placebo group subjects

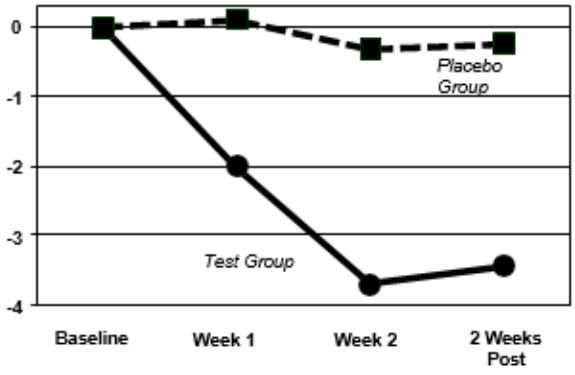
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 3 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 3: Mean total circumference

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm measurements (cms) across evaluation points circumference measurements (cms) at each study evaluation point relative to baseline.



STUDY OUTCOME SATISFACTION RATINGS
At completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in the appearance of the upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. Sixty-five per cent (65%) of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% of placebo subjects.

ADVERSE EVENTS
No adverse event occurred for any subject throughout the duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

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 clinical study protocol: *Version 5, September 18, 2007.*

PURPOSE OF STUDY
The purpose of this clinical study was to determine the effectiveness of the Erchonia® ML Scanner (MLS) manufactured by ERCHONIA CORPORATION (the Company) as a non-invasive alternate therapy to liposuction for the purpose of body contouring of the waist, hips and thighs.

DEVICE DESCRIPTION
The Erchonia® MLS laser device used in this study employed 635 nm red laser diodes.

STUDY DESIGN
This clinical study was a placebo-controlled, randomized, double-blind parallel group three-center design.

STUDY SUBJECT POPULATION
There were 67 enrolled subjects: 35 randomized to the active treatment group and 32 randomized to the placebo group. Sixty-four (64) subjects were female, and 3 subjects were male. Sixty-six (66) subjects were Caucasian, and one was Caucasian and African American.

PROCEDURE ADMINISTRATION
Each subject received six total procedure administrations with the Erchonia® MLS (active or sham) across a consecutive two-week period: three procedures per week, each procedure at least two days but no more than three days apart, at the investigator's test site.

STATISTICAL ANALYSIS
The primary efficacy outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from study baseline (pre-procedure) to study endpoint (following completion of the two-week procedure administration phase with the Erchonia® MLS laser device). The individual subject success criteria was defined as at least a 3.0-inch reduction in combined circumference measurements for the waist, hips and bilateral thighs from baseline to endpoint. Overall study success criteria was defined as at least a 35% difference between treatment groups, comparing the proportion of individual successes in each group.

PRIMARY OUTCOME MEASURE ANALYSES
Table 1 below shows the number and percentage of test and placebo group subjects who met the study **individual subject success criteria**

Table 1: Individual Success Criteria met by treatment group

	Test subjects	**Placebo subjects**
n	35	32
n meeting success criteria	22	2
% meeting success criteria	**62.86%**	**6.25%**

There is a **difference of 56.61% between procedure groups**, such that 56.61% more test group than placebo group subjects showed a total decrease in combined circumference measurements from pre-procedure to study end point of 3 inches or greater, exceeding the pre-established target of a 35% difference between treatment groups by almost 22%. A **Fischer's Exact Test for two independent proportions** was conducted to compare the proportion of successes between treatment groups. The results are as follows:

2 X 2 Table	**Success Met**	**Success Not Met**	
Test Group	22	13	35
Placebo Group	2	30	32
	24	43	67

- p(one-tailed) < 0.00001
- p(two-tailed) < 0.00001

The difference was found to be **statistically significant at p<0.00001**, meaning that the two treatment groups gave significantly different results, such that the greater treatment effect observed for subjects in the test group relative to subjects in the placebo group is statistically significant and can be attributed to the efficacy of the application of the Erchonia® MLS over a placebo device.

CHANGE SCORES
A **t-test for independent samples** was conducted to compare the two independent group means for the continuous variable of mean change in combined circumference (total number of inches) from study baseline to end point. The difference was found to be **statistically significant at p<0.0001:** μa-μb=-2.8378; t=-7.30; df=65; p(two-tailed)<0.0001, such that the mean decrease in number of total inches for test group subjects was significantly greater than for placebo group subjects. In confirmation, a **One-Way ANOVA for 2 Independent Samples** was conducted to compare the same two independent group means for means changed in combined inches lost. The results were significant at p<0.0001 (F=53.36).

Circumference measurements were recorded at baseline, end of procedure administration week 1, end of procedure administration week 2 (study end point) and 2 weeks post-procedure. Table 3 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points.

Table 3: Total circumference measurements across study duration by treatment group

	Test Group			Placebo Group		
	n	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline	35	120.31	7.96	32	122.99	10.54
Week 1	35	118.25	8.31	32	122.73	10.49
Week 2	35	116.79	8.11	32	122.31	10.82
2 weeks post	35	117.09	7.96	32	122.37	10.43

A double-blind, placebo-controlled, randomized evaluation of the effect of the Erchonia® Obesity Laser on the reduction of the circumference of the hips, waist and upper abdomen for individuals with Body Mass Index (BMI) of 30 to 40 kg/m²: Version 1.0, February 20, 2013

BACKGROUND
The purpose of this clinical study was to determine the effectiveness of the Erchonia® Obesity Laser in reducing circumference of the hips, waist and upper abdomen when applied to individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m², by applying the laser to the treatment area 12 times across 4 consecutive weeks.

STUDY DESIGN
The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two independent test sites.

SUBJECTS
Fifty-three (53) subjects completed the study, 28 of whom were randomized to the active procedure group and 25 who were randomized to the placebo group.

Subjects were 18 to 65 year old males and females with Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² who were indicated for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise.

Subject age averaged 47.09 years. Most subjects were Caucasian and there were more female than male subjects, as shown in Table 1 below.

Table 1: Baseline demographics

Gender	**Female**				**Male**			
n=53	*number*		*%*		*number*		*%*	
	45		85%		8		15%	
Ethnicity	**Caucasian**		**African American**		**Hispanic**		**Caucasian/Hispanic**	
n=53	*number*	*%*	*number*	*%*	*number*	*%*	*number*	*%*
	41	77%	9	17%	2	4%	1	2%

STUDY MEASURES
The study primary outcome measure of combined hips-waist-upper abdomen circumference was measured at baseline, mid-point (two weeks) of the procedure administration phase, at completion of the four-week procedure administration phase (study endpoint) and two weeks after completion of the procedure administration phase. Body Mass Index (BMI) was also measured at these same assessment points. Subject satisfaction with procedure outcome and subject and assessment investigator perceived subject group assignment were recorded at endpoint.

BASELINE MEASUREMENT
Table 2 below contains the mean (average) baseline circumference measurements (inches) and body mass index (BMI) by procedure group.

Table 2: Mean (Average) baseline measurements by procedure group

Circumference Measurements (inches)	**Test Group (n=28)**	**Placebo Group (n=25)**
Hips	44.53	43.11
Waist	39.60	40.43
Upper Abdomen	39.22	39.27
Total Body Circumference	***123.35***	***122.81***
Body Mass Index (BMI: kg/m²)	34.58	33.60

A series of t-tests for independent samples found there was no statistically significant difference in any of the above baseline measurements between subject procedure groups ($p>0.05$).

STUDY PROCEDURE
Subjects received twelve thirty-minute procedure administrations with the Erchonia® Obesity Laser across the frontal and dorsal aspects of the hips-waist-upper abdomen treatment region across a consecutive four-week period: three procedures per week, each procedure two or three days apart.

STUDY RESULTS
The study primary outcome measure was defined as the change in total combined inches in circumference measurements (hips, waist and upper abdomen) from baseline (pre-procedure) to following completion of the four-week procedure administration phase (study endpoint). It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch or greater reduction in total combined circumference across this primary evaluation period. It was also pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 40% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

71.43% of subjects who received the active study procedures with the Erchonia® Obesity Laser attained a decrease in combined circumference measurements of 3.0 inches or greater compared with 12% of subjects who received the 'fake' (placebo) laser procedures. A Fischer's Exact Test for two independent proportions found this difference of 59.43% between subject procedure groups to be statistically significant at $p<0.00005$.

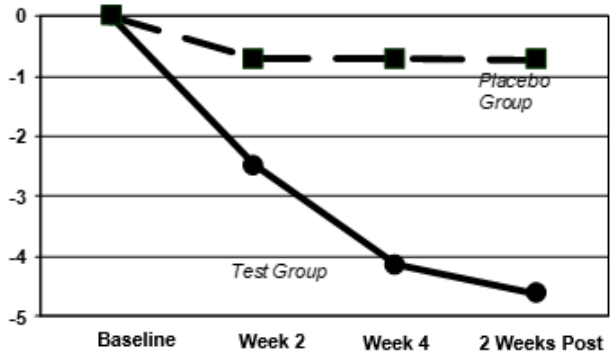
The mean change in combined circumference measurement for subjects who received the active study procedures with the Erchonia® Obesity Laser was a decrease of 4.14 inches, while the mean change in combined circumference measurements for subjects who received the 'fake' (placebo) laser procedures was a decrease of 0.71 inches. A t-test for two independent samples found the mean change in combined circumference measurements from baseline to study endpoint for test (active procedure) group subjects to be significantly greater than that for placebo (sham procedure) group subjects, at $p<0.0001$.

Table 3 and Chart 1 below show the mean change in combined circumference measurements across the four study evaluation points for test and placebo group subjects.

Table 3: Mean total circumference measurements (ins.) across evaluation points

	Test Group	Placebo Group
Baseline	123.35	122.81
Midpoint (week 2)	120.86	122.09
Endpoint (week 4)	119.21	122.10
2 Weeks Follow-up	118.73	122.08

Chart 1: Mean change in total circumference measurements (ins.) at each study evaluation point relative to baseline



For test subjects, total circumference measurements decreased progressively from baseline at each of the three subsequent evaluation points culminating in a mean decrease of 4.62 inches by 2 weeks post-procedure evaluation. For placebo subjects, the magnitude of the change was constant for all three subsequent evaluation points relative to baseline, indicating lack of any change in total circumference measurements beyond week 2 evaluation relative to baseline. Additionally, the magnitude of the changes relative to baseline for placebo group subjects were notably less that the respective changes for test group subjects relative to baseline. Considered together, these findings support progressive effectiveness of the Erchonia® Obesity Laser procedures over time compared with placebo.

At completion of study procedure administration, the subject was asked to rate how satisfied he or she was with any overall perceived change in the appearance of the hips-waist-upper abdomen area using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. 79% of test group subjects reported being ‘Satisfied’ (‘Very Satisfied’ or ‘Somewhat Satisfied’) with the study outcome compared with 16% of placebo subjects.

ADVERSE EVENTS

No adverse event occurred for any subject throughout duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

CONCLUSION

The Erchonia® Obesity Laser is an effective tool for reducing circumference measurements of the hips-waist-upper abdomen in individuals with Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² over a 4-week period.

STUDY DESIGN
This clinical study is a prospective open-label design with post-study independent blinded outcome analysis to evaluate the efficacy of the Erchonia® CFL Laser in providing noninvasive fat reduction in the submental area. As such, all enrolled subjects will receive active study treatments, and therefore, randomization to procedure group is not applicable.

STUDY BLINDING
As all subjects in this study will receive active procedure administrations with the Erchonia® CFL, neither subjects nor treating investigators will be blinded.

However, study outcome assessments, including primary study success determination, will be blinded through use of three (3) Independent Blinded Evaluators who will assess the study primary efficacy outcome through evaluation of coded, deidentified photographic images of subjects' submental regions' before (pre-treatment) treatment and 12 weeks after treatment (Week 16 Endpoint) that are provided in randomized order post-study endpoint. The digital photographs will be presented to each Independent Blinded Evaluator in blinded coded randomized fashion, with. randomization of photograph presentation order additionally occurring across test sites. Each Independent Blinded Evaluator will perform and record the study primary efficacy outcome assessment independently of each other, without input, consultation, comparison of determinations, or any other form of interaction or communication with each other during the assessment process. The Independent Blinded Evaluators will not have otherwise been involved with any aspect of study design or execution.

Randomization of order of subject post-hoc photo presentation will be attained using computer generation sequence methodology (www.randomization.com) ensuring that the randomization methodology and the generated allocation sequence is concealed from the Independent Blinded Evaluators. Each computer-generated randomization sequence is unique and will therefore not be able to be replicated.

INDEPENDENT BLINDED EVALUATORS
Independent Blinded Evaluators participating in this study will be licensed and qualified physicians such as MD's, DO's, Dermatologists, Plastic surgeons, Cosmetic surgeons, and Board-certified weight loss physicians who are trained and experienced in visualizing, treating, and observing for change in submental fat.

SUBJECTS

Subject Sample
Subjects will be males and females 18 to 65 years of age who present with visible fat bulges in the submental area and who subsequently satisfy all qualification criteria.

Sample Size
There will be 35 qualified subjects enrolled in this study.

Rationale for Sample Size
In consideration of the primary efficacy outcome assessment, a clinically important outcome is pre-established as at least 2 of the 3 Independent Blinded Evaluators correctly identifying a subject's Pre-Treatment and Post-Treatment (study Endpoint of Week 16 – 12 Weeks Post-Treatment End) photographic images of the submental region, with study success defined as a Responder Rate of 80% or greater.

Consequently, the planned sample size to provide sufficient power for a statistical comparison of the proportion of treatment responders (P) versus a reasonable cutoff (P0) is based on a power calculation utilizing the (one proportion) binomial exact test based on the following assumptions.

- H0: P ≤ P0 versus Ha: P > P0
- Type I error rate: α = 0.025
- Power = 90%
- Population proportion under the null hypothesis: P0 = 0.80
- Population proportion under the alternative hypothesis: P = 0.50
- Total N = 30 study participants

To account for a potential 15% subject attrition rate, a total of 35 subjects will be enrolled.

Recruitment
Subjects will be recruited from among:
(i) The test site's pool of existing and new clients
(ii) Subjects who respond to the recruitment materials found in **Appendix C.**

Compensation
A subject will not be offered money or any other form of compensation to participate in the study; however, he or she will also not be charged for the cost of the study procedures with the Erchonia® CFL or for the cost of any other directly-related evaluations or measurements that occur as part of his or her participation in the study.

STUDY PROCEDURE

STUDY TEST BATTERY
The following is a list of the study measurement tools to be used in this study. For each study phase, the precise tools from this list that will be employed will be specified.

BODY MASS INDEX (BMI): BMI is calculated as the ration of the subject's weight in kilograms (or pounds) to the square of the subject's height in meters (or feet).

PHOTOGRAPHS: Subjects will be photographed in a seated position. High-resolution digital images will be taken from the frontal view and from each lateral view (right and left side) at each evaluation visit. Photographs will be acquired using a standardized photography set-up (Apple iPad 12 [12-megapixel], ring light tripod) to ensure consistency, and will be taken in a standardized manner in the same room under the same lighting conditions, with effort made for the images to be taken by the same individual, with the same system settings fixed at the same location, with all subjects situated at the same distance from the lens for each photograph. At each post-baseline visit, the photographer will refer to the baseline photographs to ensure consistency in subject positioning and exposure. These same protocols will be employed across all study test sites.

Detailed instructions and the protocol for capturing the photographs are contained in **Appendix B: Photograph Methodology Instruction Sheet.**

SKINFOLD MEASUREMENT: The caliper measurement process involves pinching the tissue within the treatment area to obtain the measurement, thereby folding the tissue, and doubling the fat layer thickness. Measurements are taken with subjects standing in a neutral position, with the

head slightly lifted yet allowing the skin of the neck to remain loose such that a vertical fold is created above the hyoid bone.

The total measured value (mm) will be halved to reflect a single fat layer change and will not take into account the fold of tissue during the measurement process.

DEMOGRAPHICS: Age, gender, ethnicity, and Body Mass Index (BMI)

SUBJECT SATISFACTION WITH STUDY OUTCOME: The subject is asked to rate how satisfied he or she is with any change in the appearance of the fat pad under the chin following completion of the laser administration procedure with the Erchonia® CFL 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 appearance of the fat pad under your chin 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 PROCEDURES

PRE-TREATMENT ACTIVITIES

The pre-treatment activities will be conducted at the test site prior to administration of the initial study treatment with the Erchonia® CFL.

SIGNING OF INFORMED CONSENT FORM

The investigator 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 ID

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 participation in this study, a subject must satisfy each of the following.

- Male or female 18 to 65 years of age, inclusive.
- Submental and submandibular skin fold thickness > 1cm (measured by caliper).
- Subject agrees to maintain his/her weight (i.e., within 5%) by not making any major changes in diet or exercise routine during the course of the study.

- Subject agrees to abstain from partaking in any treatment to promote body contouring and/or weight loss during the course of study participation. Such treatments include, but are not limited to:
  - over-the-counter and/or prescription medications; dietary/herbal supplements and appetite suppressants.
  - weight loss programs/diet plans.
  - surgical procedures for sculpting of the chin fat pad/weight loss, e.g. submental lipectomy, lap bands
- Subject has signed a written informed consent form.

EXCLUSION CRITERIA

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

- Evidence of any cause of enlargement in the submental area other than localized subcutaneous fat, such as swollen lymph nodes or ptotic submandibular glands.
- Treatment with dermal fillers, radiofrequency or laser procedures, or chemical peels in the neck or chin area (below the mandible) within the past 6 months.
- Botulinum toxin or other aesthetic drug injections within the neck or chin area (below the mandible) within the past 6 months.
- History of a fat reduction procedure (e.g., liposuction, surgery, lipolytic agents, etc.) or implant in or adjacent to the area of intended treatment.
- Any dermatological conditions, such as scars in the location of the treatment area that may interfere with the treatment or evaluation.
- Active implanted device such as a pacemaker, defibrillator, or drug delivery system.
- Pregnant or intending to become pregnant in the next 6 months.
- Currently enrolled in a clinical study of an unapproved investigational drug or device.

PRE-TREATMENT EVALUATIONS

The following pre-treatment measures will be recorded prior to commencement of the treatment administration phase (prior to treatment administration #1).

BASELINE VARIABLES

- Subject Demographics
- Body Mass Index (BMI) Calculation
- Concomitant Medication and Therapy Use

PRE-TREATMENT OUTCOME ASSESSMENTS

- Photographs
- Skinfold measurements (mm).

The Pre-Treatment photographs and skinfold caliper measurement will serve as the Baseline data set for relative assessment of post-treatment change.

TREATMENT ADMINISTRATION PHASE

TREATMENT ADMINISTRATION PROTOCOL

- The treatment administration phase of the study may commence on the same day as the pre-treatment measurements are recorded.
- The treatment administration phase will extend over four consecutive weeks.
- Each subject will receive eight (8) treatment administrations with the Erchonia® CFL across the consecutive four-week treatment administration phase; two treatments per week; each one at least two days apart.
- Each treatment will take place at the investigator's test site.
- The treatment administration protocol for each session is as follows:

1. The subject enters the treatment administration room and lays comfortably on a treatment table.
2. The subject is correctly fitted with the safety glasses.
3. Utilizing the flexible laser stand, the investigator positions the Erchonia® CFL at a distance of about 3-4 inches from the surface of the skin, the device itself never touches the skin surface.
4. The device is aligned so that the emitted laser light beams that cross forming an "X" is centered on the fat pad under the chin.
5. The Erchonia® CFL treatment will run for fifteen (15) continuous minutes and will stop once the treatment time is at 0:00. Once the "Time Remaining" display reaches 0:00 the treatment is complete, the laser lights and the laser indicator light will turn off.
6. After the Erchonia® CFL is turned off, the subject removes the safety glasses and leaves the treatment administration room.

TREATMENT ADMINISTRATION RECORD

Following the completion of each treatment with the CFL laser, the investigator will record the following:

- Number of treatment administrations
- Date
- Investigator signature
- Adverse event (if applicable).

POST-TREATMENT ACTIVITIES

WEEK 4 EVALUATION: TREATMENT ENDPOINT: AT THE TIME OF TREATMENT PROTOCOL END

Following the final treatment at completion of the 4 weeks of study treatment administrations with the Erchonia® CFL, the following will be recorded on the provided Case Report Forms.

- Photographs
- Skinfold caliper measurements (mm)
- Body Mass Index (BMI) Calculation
- Subject Satisfaction with Study Outcome

WEEK 16 EVALUATION: STUDY EFFICACY ENDPOINT: 12 WEEK POST TREATMENT ADMINISTRATION END

Twelve (12) weeks following the completion of the 4-week treatment administration protocol, the following will be recorded on the provided Case Report Forms. These recordings will form the study endpoint data set from which change from baseline will be evaluated with respect to

assessing study outcome.

- Photographs
- Skinfold caliper measurements (mm)
- Body Mass Index (BMI) Calculation
- Subject Satisfaction with Study Outcome

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® CFL 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 Erchonia Corporation who will maintain these copies in a separate clinical study file that is kept in a locked filing cabinet at their premise. 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 first and last name initials followed by a three-digit number determined according to the subject's order of entry into the study. The first test site will be assigned a range of numbers from 001 to 100. The second test site will be assigned a range of numbers from 101 to 200. For example, the eighth subject to be enrolled at the first test site under PI John Black would have a subject ID of JB008. Neither the study Sponsor, Monitor, biostatistician, Independent Blinded Evaluators, nor any other pertinent party 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 study results.

STATISTICAL ANALYSIS PLAN

STUDY POPULATIONS

The following two study populations will be evaluated:

1. Intent-to-Treat (ITT) Population

Primary analysis of efficacy will be according to the intent to treat (mITT) analysis, including all consented and enrolled subjects.

2. Per Protocol Population.

Secondary analysis of efficacy to confirm the findings of the primary analysis will be conducted on the Per Protocol population, comprised of all subjects who completed the study per protocol inclusive of all assessment visits and activities and the full 4-week, 8-treatment administration protocol.

3. Handling of Missing Data

Missing data values will be imputed using regression analysis imputation methodology under the assumption of the data missing at random (MAR), provided that the assumption of the data being MAR can be supported as has been found through prior Erchonia studies and demonstrated through the following means, the first two of which are already established by the study design:

1. As there is no placebo group in this clinical study design, subjects are aware that they are receiving active study treatments, and therefore, subject lost to follow up cannot be attributed to potential study unblinding.
2. The primary outcome assessment is a binary response responder rate format determined by Independent Blinded Evaluators that is therefore independent of individual subject variables.
3. Comparison of demographics for the group of subjects with missing data to the entire subject ITT group will be performed to demonstrate comparability.
4. Comparison of the primary outcome assessment for the group of subjects with missing data to the entire subject ITT group will be performed to demonstrate comparability.

Given that the assumption of the data being MAR is supported, the missing data will be imputed using the regression imputation methodology with known variables approach wherein the regression equation is employed to calculate the marginal or conditional average for each individual subject's missing value based on the known Baseline value of the missing variable value being imputed for that subject if available or if not available, on the known Baseline value for other subject(s) with comparable demographic profiles.

DEMOGRAPHICS

The following subject demographics collected at the Pre-Treatment assessment visit will be analyzed descriptively as means, standard deviations, medians, and range (minimum, maximum) for continuous data and as number (N) and percentages(%) of the total sample for categorical data and presented in table format, as applicable for the ITT subject population.

- Gender
- Age

- Ethnicity
- Body Mass Index (BMI): weight (kg), Height (inches / meters).

BASELINE SKINFOLD MEASUREMENTS

Baseline skinfold measurements (mm) and submental skinfold thickness (mm) measurements will be presented descriptively in table format as means, standard deviations, medians, and range (minimum, maximum) for the ITT subject population.

BASELINE CONCOMITANT MEDICATION USE

Recorded baseline concomitant medication use will be presented in table format as number (N) and percentage (%) of totals and reported as individual medications and further groups by indication for use for the ITT subject population.

PRIMARY EFFICACY OUTCOME ANALYSIS

The primary goal of this study is to determine if the treatment effect of the Erchonia© CFL can affect the appearance of visible fat bulges in the submental area.

PRIMARY STUDY SUCCESS EVALUATION CRITERIA

The primary efficacy outcome for this clinical study is established as the proportion of accurately identified subject pre- and post-treatment photographs by at least two of the three Blinded Independent Evaluators.

In consideration of this primary efficacy outcome assessment, a clinically important outcome is defined as at least 2 of the 3 Independent Blinded Evaluators (i.e., 2 out of 3, or 3 out of 3) correctly identifying the order of a subject's Pre-Treatment (Baseline) and Week 16 (Endpoint) 12 Weeks Post-Final Treatment photograph for 80% or more of subjects.

This clinically important minimum upper limit criteria of 80% was selected to be identical to the respective primary efficacy endpoint assessment parameters from the clinical studies for the ZELTIQ CoolSculpting System (K151179), and SculpSure (K171992) whose outcomes successfully supported FDA clearances for the same indication as intended to be supported by the outcome of the current clinical study protocol.

HYPOTHESES

The null and alternative hypotheses for the Primary Efficacy Endpoint are the following:

Null Hypotheses: The overall responder rate will be less than 80%.

H_o: μA < 80%

Alternative Hypothesis: The overall responder rate will be 80% or greater.

H_o: μA ≥ 80%

PRIMARY EFFICACY OUTCOME ANALYSIS POPULATION

Determination of primary efficacy outcome success will be according to analysis of the outcome

for the subject ITT population as the primary analysis population. Primary efficacy outcome success will also be evaluated for the study Per Protocol population as a secondary analysis to provide support for and confirm the outcome of the primary analysis performed on the ITT subject population.

PRIMARY EFFICACY OUTCOME STATISTICAL EVALUATION
Primary study efficacy will be evaluated at Week 16, 12 Weeks Post-Final Treatment administration relative to Baseline (Pre-Treatment).

Primary efficacy outcome success will be evaluated via Responder Rate Analysis, wherein:

(i) An individual subject is defined as a Study Responder if at least 2 of the 3 Independent Blinded Evaluators correctly identify the subject's post-treatment photograph, and
(ii) Overall study success is defined as a minimum responder rate of 80%.

To determine primary efficacy outcome success, the following process will be followed:

1. The percentage of individual Study Responders will be calculated to determine the responder rate.
2. If the calculated responder rate is 80% or greater (≥ 80%), it will be concluded that primary efficacy success has been demonstrated.
3. If the calculated responder rate is less than 80% (< 80%), it will be concluded that primary efficacy success has not been demonstrated.

SECONDARY EVALUATIONS The secondary efficacy outcomes of submental skinfold and submental skinfold thickness, and subject satisfaction with treatment outcome will be assessed for each of the ITT and Per Protocol analysis populations, as applicable. As these secondary outcomes are provided as supportive evidence for the primary efficacy outcome only and the Sponsor **does not intend to seek clearance for any claims based on findings of these secondary efficacy outcomes**, the findings will be presented descriptively only as means, standard deviations, medians, and ranges for the continuous data and as number (N) and percentage (%) of the total for categorical data and will be presented in table and chart format, as applicable. Statistical analysis of change will not be performed.

- Submental skinfold and submental skinfold thickness measurements (mm) data will be recorded at each of the Pre-Treatment (Baseline), Week 4 (Treatment End), and Week 16 (12 Weeks Post-Treatment End) visits.
- Subject satisfaction with study outcome ratings will be recorded at each of the Week 4 (Treatment End) and Week 16 (12 Weeks Post-Treatment End) visits.

  'Positive' subject satisfaction with treatment outcome response is predefined as the sum of 'Very Satisfied' and 'Somewhat Satisfied' responses.

- Additionally, comparison of the mean, standard deviation, median, and range of Body Mass Index (BMI) recording at each of Pre-Treatment (Baseline), Week 4 (Treatment End), and Week 16 (12 Weeks Post-Treatment End) visits will be compared descriptively to confirm that changes in body BMI did not contribute to the study outcome.

SAFETY ANALYSES
Safety analyses will be based on all subjects who signed informed consent and were enrolled in the study.

Safety will be assessed by evaluating observed and/or reported adverse events.

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 study.
- Each subject participating in this 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 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 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 questions about the research and in the event of a research-related injury.

The Subject Informed Consent Form can be found in **Appendix D**.

CASE REPORT FORMS
The case report forms that will be used to collect the data from each subject in this study can be found in **Appendix E**.

END OF DOCUMENT