ERCHONIA CORPORATION

LUNULALASER™ OTC

Human Factors Validation Testing for Over-the-Counter Use of the Erchonia® LunulaLaser™ OTC

Version 1.0

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1.1. SPONSOR

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2. STUDY PURPOSE AND GOALS

STUDY GOAL

It is intended that the results of this Human Factors Validation Testing be used to support an over-the-counter (OTC) use indication for the LunulaLaser™ OTC for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.). The indication for use is identical to the predicate device, the LunulaLaser™ cleared under K153164, with the only difference being the designation of Over-the-Counter (OTC) use. The LunulaLaser™ OTC delivers a nonthermal and non-invasive procedure designed to restore growth of clear, healthy nails in clients with onychomycosis without harmful side effects of oral medication, or the pain and recovery time associated with other laser treatments. Therefore, it is intended that the results of this Human Factors Validation Testing will demonstrate that the LunulaLaser™ OTC can be used by the intended users without serious errors or problems for the intended use and under the expected use conditions.

2.1. PURPOSE OF STUDY

The purpose of the LunulaLaser™ OTC Human Factors Validation Testing is to:

(i) evaluate the intended user's ability to correctly, safely and effectively set-up, activate and operate the LunulaLaser™ OTC to administer the treatment to the client;
(ii) evaluate the intended user's ability to understand and apply as applicable the information contained in the LunulaLaser™ OTC Use Device Installation and Proper Use Reference Guide, and device packaging and labeling materials; and
(iii) identify any and all use difficulties, problems and errors, including those pertaining to critical tasks and close calls demonstrated by intended users during device operation, and to subsequently mitigate each identified instance of use error through device and/or materials modification, and to subsequently evaluate the effectiveness of each modification, as applicable.

3. STUDY DEVICE: LUNULALASER™ OTC; ERCHONIA® CORPORATION

The LunulaLaser™ OTC (Figure 1) is intended to be indicated for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)

Figure 1: LunulaLaser™ OTC

The LunulaLaser™ OTC is a nonthermal and non-invasive procedure designed to restore growth of clear, healthy nails in clients with onychomycosis without harmful side effects of oral medication, or the pain and recovery time associated with other laser treatments.

The LunulaLaser™ OTC works by using a patented and clinically proven low-level laser technology. The Lunula laser combines two different wavelength lasers; one visible violet light (about 405 nanometer wavelength) for direct fungicidal activity and one visible red light (about 635 nanometer wavelength) to stimulate a natural immune response. The two lasers work together to increase clear nail in individuals with toenail onychomycosis.

The LunulaLaser™ OTC device and the intended use to be evaluated in this Human Factors Validation Study is identical to that which was cleared by FDA on June 3, 2016 for prescription use, as follows:

510(k) # K153164
Product Code: PDZ
Class II
Device Name: LunulaLaser
Indications for Use: The LunulaLaser™ device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)

Additional device details are contained in the **Installation and Proper Use Reference Guide** contained in **Appendix B**.

4. STUDY DESIGN

This study is an uncontrolled simulated-use human factors validation testing design to assess the intended user's ability to correctly, safely, and effectively set-up, activate and operate the LunulaLaser™ OTC, to administer a treatment to a client, and to understand the information contained in the Erchonia LunulaLaser™ OTC Installation and Proper Use Reference Guide and box labeling.

The study design is comprehensive in scope and conducted in a manner such that the results will be able to be generalized to the actual intended user and under intended conditions of actual use and be adequately sensitive to capture use errors arising from either the user interface design and/or the instructional and informative materials. Study data will be collected in a manner that will facilitate analysis of the root causes of use errors or problems during the testing.

4.1. STUDY DESIGN ELEMENTS

The key elements of the study design that support its ability to generalize study results to the intended user under intended use conditions are the following:

(i) Users (test participants) will represent the intended (actual) users of the LunulaLaser™ OTC; that is, users will be employees at nail salons, beauty salons and spas, fitness and wellness centers, and the like;
(ii) All critical tasks will be performed, observed and evaluated during the testing;
(iii) The device user interface and all associated instructional/informational materials will represent the final intended post-clearance (actual use) design; and
(iv) The simulated-use test conditions will be sufficiently realistic to represent the actual intended conditions of use. Under actual intended conditions of use, the user will receive the Erchonia LunulaLaser™ OTC device in its full packaging via delivery to the facility at which they are employed and will need to rely on the information/instructional information contained in the Installation and Proper Use Reference Guide and the device and packaging labeling to configure and operate the device for use.

(v) In this study, the user will simply be presented with the device in its intended packaging as if receiving it at their place of employment. No additional information, instruction or training will be provided by the Study Observer, or any other individual associated with the study. The user will be left to work out how to operate the Erchonia LunulaLaser™ OTC as independently and naturally as possible without interference or influence from the Study Observer. While the user will have received the instructional information in the packaging as in intended use, he or she will not be instructed to use any of the information. It will be up to the user as to if or how he or she chooses to use that information to set up operation of the device as would occur under actual conditions of intended use.

5. CRITICAL TASKS ANALYSIS

5.1. CRITICAL TASK: For the purpose of the critical tasks analysis for this study, a critical task is defined as a user task which, if performed incorrectly (use error) or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care (use-related hazard). Critical task analysis is part of the device risk analysis.

5.2. USER TASK: A user task is defined as an action or set of actions performed by a user to achieve a specific goal i.e., safe, and effective use of the device for the intended purpose.

5.3. USE ERROR: Use error is defined as a user action or lack of action that is different from that expected by the manufacturer and caused a result that was different from the result expected by the user; was not caused solely by device failure; and did or could result in harm.

5.4. HAZARDS

5.4.1. Non-Use Related Hazards: A non-use related hazard is a potential source of harm that is generally associated with instances of device or component failure that are not dependent on how the user interacts with the device.

Non-use related hazards traditionally considered in risk analysis include:

- Physical hazards (e.g., sharp corners or edges),
- Mechanical hazards (e.g., kinetic or potential energy from a moving object),
- Thermal hazards (e.g., high-temperature components),

- Electrical hazards (e.g., electrical current, electromagnetic interference (EMI)),
- Chemical hazards (e.g., toxic chemicals),
- Radiation hazards (e.g., ionizing and non-ionizing), and
- Biological hazards (e.g., allergens, bio-incompatible agents and infectious agents).

5.4.2. Use-Related Hazards: A use-related hazard is a potential source of harm derived from incorrect performance or lack of performance of a critical task by the device user interactions with the device. These hazards might result from aspects of the user interface design that cause the user to fail to adequately or correctly perceive, read, interpret, understand, or act on information from the device.

Use-related hazards are related to one or more of the following situations:

- Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user;
- Device use is inconsistent with the user's expectations or intuition about device operation;
- The use environment affects operation of the device and this effect is not recognized or understood by the user;
- The particular use environment impairs the user's physical, perceptual, or cognitive capabilities when using the device;
- Devices are used in ways that the manufacturer could have anticipated but did not consider; or
- Devices are used in ways that were anticipated but inappropriate (e.g., inappropriate user habits) and for which risk elimination or reduction could have been applied but was not.

Both non-use related and use-related hazards associated with the Erchonia LunulaLaser™ OTC have been included in the risk analysis and management process.

5.5 ANALYTICAL APPROACHES: Analytical approaches for identifying non-use related and use-related hazards (critical task analysis) include analysis of the expected needs of users of the new device, analysis of available information about the use of similar devices, and employment of one or more analytical methods.

5.5.1. Task Analysis Technique: Critical tasks analysis was conducted using the task analysis technique, defined as the process of studying how users of the device would likely perform each task and the potential use errors that may occur if any of the identified tasks are performed incorrectly or not performed at all. User interactions with the design interface will be examined with respect to perceptual inputs, cognitive processing and physical actions that comprise the successful execution of each individual task. Potential user errors that may arise from each of these task components will be analyzed to identify the potential consequences of the errors and the potential resulting harm from the errors. This comprehensive identification and categorization of user tasks led to the identification and development of the list of critical tasks that users should perform correctly for use of the Erchonia LunulaLaser™ OTC to be safe and effective.

For this identified list of critical tasks, each individual critical task was categorized based on the severity of the potential harm that could result from use error(s), as identified in the risk analysis, with the goal of identifying the task(s) that, if performed incorrectly or not performed at all, would or could cause serious harm.

5.5.2. Failure Modes Effects Analysis (FMEA): The risk analysis approach employed a team-based failure modes effects analysis (FMEA) to identify potential use errors and the potential harm that could result from each potential use error related to the user-device interaction as comprehensively as possible.

All risks associated with the warnings, cautions and contraindications in the labeling are included in the risk assessment.

The final list of critical tasks was used to structure the human factors validation test to ensure it focuses on the tasks that relate to device use safety and effectiveness. While every effort has been made to identify and consider all critical tasks, associated use errors and potential resultant harm to the user and/or patient from use error, it is possible that some potential use errors might not be recognized until the human factors validation testing is conducted. The test protocol therefore includes mechanisms to detect previously unanticipated use errors.

As part of the risk analysis process, **identification of known use-related problems,** if any, that have occurred with the use of similar devices with regards to use, the user interface or user

interactions, will be identified, considered, and evaluated as applicable to the Erchonia LunulaLaser™ OTC.

5.6. OUTCOME OF THE CRITICAL TASK ANALYSIS

Through the task analysis approach, the critical device analysis was conducted by systematically breaking down the device use process into discrete sequences of tasks. Each identified task was then analyzed to identify the user interface components involved, the potential use errors (with respect to each of potential perceptual, cognitive processing and physical errors, as applicable) that users could make and the potential results (consequences and harm) of each of those use errors, as well as the mitigation (method of control) in place to prevent or minimize the use error from occurring and/or to reduce the severity of potential harm in the event that the use error is still made.

Each potential use error was further categorized according to the probability or likelihood of the use error the associated hazard occurring, the severity of the potential associated hazard(s) were it to occur, and the risk level (Probability/Likelihood X Severity), according to the Tables 1, 2 and 3, respectively, below.

Table 1: PROBABILITY OF OCCURRENCE		
Category	**Rating**	**Description**
Frequent	5	Likely to occur about once every 100 uses.
Probable	4	A use error/hazard likely to occur about every 10,000 uses or about every 2 years of expected use.
Occasional	3	A hazard likely to cause harm every 100,000 uses or only on one of two systems over their 10 year expected lives.
Remote	2	A hazard likely to cause harm every 1,000,000 uses or only on one of twenty-one systems over their expected lives.
Improbable	1	A use error hazard likely to cause harm every 10 million uses or on no currently installed systems within their 10 year expected lives (assumes current installed base does not exceed 210 systems within 10-year period).

Table 2: SEVERITY		
Rating	**Rating**	**Description**
Catastrophic	5	Results in death
Critical	4	Results in permanent impairment or life-threatening injury

Serious	3	Results in injury or impairment requiring medical intervention
Minor	2	Results in injury or impairment not requiring medical intervention
Negligible	1	Inconvenience or temporary discomfort

Probability Rating	Severity Rating				
	1	2	3	4	5
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	15
2	2	4	6	8	10
1	1	2	3	4	5

The outcome of the critical tasks analysis is contained in **Appendix A**.

6. STUDY PARTICIPANT AND ENVIRONMENTAL DESIGN

6.1. SUBJECTS (USERS and CLIENTS)

6.1.1. USER SAMPLE

The study user sample will be representative of the population of intended users of the device who are employees at nail salons, beauty salons and spas, fitness and wellness centers, and the like.

In defining the device user and the potential impact of the device user characteristics on the user's ability to safely, and effectively, use the device, the following personal characteristics were considered and evaluated, with the outcome as follows:

Device User Characteristic	Outcome of Consideration
Physical size, strength, and stamina	Able to lift and carry 23lbs / 10.43 kg
Physical dexterity, flexibility, and coordination	Able to plug the power cord into the device and an electrical outlet; operate the key to turn the device on and off; open and close the magnetic door/foot platform using the knobs; operate the touchscreen; and correctly place the safety glasses on themselves and the client.

Sensory abilities such as vision, hearing, and tactile sensitivity	Able to read the information on the device screen display.
Cognitive abilities, including memory	Able to understand the instructions in the Installation and Proper Use Reference Guide for safe and effective use of the device; able to understand when to use the device and how to confirm client eligibility.
Medical condition for which the device is being used	n/a
Comorbidities	n/a
Literacy and language skills	English language; 5th Grade literacy skills.
General health status	n/a
Mental and emotional state	Sufficient stability.
Relevant level of education and health literacy	Able to read at 5th Grade level; aware of client eligibility criteria.
General knowledge of similar types of devices	Not necessary but beneficial.
Knowledge of and experience with the particular device	n/a
Ability to learn and adapt to a new device	Sufficient ability.
Willingness and motivation to learn to use a new device	Sufficient willingness and motivation.

In considering these specific characteristics of intended device users that may affect their interactions with the device, given the typical profile of the intended users of the LunulaLaser™ OTC, it was determined that there did not need to be specific evaluation of potential users within any of these specific device user categories.

Additionally, the development and design of the Erchonia LunulaLaser™ OTC and the Installation and Proper Use Reference Guide was modelled on the existing Installation and Proper Use Reference Guide for Erchonia Corporation's currently market cleared OTC device, the Erchonia Zerona Z6 OTC (K162578; K143007) indicated for: "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." The user sample in the Human Factors Validation Study whose results supported the market clearance for the Zerona Z6 OTC is comparable to that being evaluated in the current Human Factors Validation Study; that is, users in the prior study were employees of Fitness and Wellness centers and like facilities.

As in this current study, the only training device users received in the human factors evaluation of the Zerona Z6 OTC was that contained in the Installation and Proper Use Reference Guide and device packaging and labeling.

6.1.1.1. User Sample Eligibility Criteria

To qualify for study participation, the user must satisfy each of the following inclusion criteria and none of the exclusion criteria.

Inclusion Criteria

1. 18 years or older.
2. Male or female.
3. Currently employed at a nail salon, beauty salon and/or spa, fitness and wellness centers, or the like.
4. In possession of qualification(s), current licensure(s), certification(s), and/or accreditation(s), as applicable, to perform their designated tasks at their place of employment, e.g., cosmetology degree, nail technician, esthetician, massage therapist, etc.
5. Voluntarily signed consent form.

Exclusion Criteria

1. None.

6.1.1.2. User Sample Size

As per the United States Food and Drug Administration (U.S. FDA) document titled 'Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff'; February 3, 2016, Section 8.1.1 Test Participants (Users), the minimum number of 15 subjects is required to be enrolled in and complete this study. The minimum sample size of 15 subjects is applicable as the intended actual user population in this validation study is a homogenous group of adults who are applicably qualified/licensed/certified/

accredited employees at cosmetology-related facilities such as nail salons, beauty salons and/or spas, fitness and wellness centers, or the like.

6.1.1.3. User Sample Recruitment

The subject user sample will be recruited from nail salons, beauty salons and/or spas, fitness and wellness centers, or the like, in the geographical area within the vicinity of the test location.

A potential candidate who voluntarily signs the informed consent form and subsequently satisfies the enrollment criteria will be enrolled as a User in this Human Factors Validation Testing study.

6.1.1.4. User Compensation

The user will receive $100 as compensation for participation in this Human Factors Validation study.

6.1.2. CLIENT SAMPLE

The client sample will be employees of the study sponsor, Erchonia Corporation, who are not involved with the operation of the LunulaLaser OTC, acting as representative clients of the user sample. The acting treatment recipient will be instructed to not provide any insight or feedback during their participation, as if they were an actual client of the user.

6.1.2.1. Client Sample Recruitment

Representative clients will be recruited from amongst employees of the study sponsor, Erchonia Corporation, who are not involved with the operation of the LunulaLaser OTC.

6.1.2.2. Client Sample Compensation

Representative clients will not receive any compensation for participation in this Human Factors Validations study.

6.2. DEVICE USE ENVIRONMENTS

The Erchonia LunulaLaser™ OTC device use environments are the following non-clinical indoor environments:

1. Nail Salons
2. Beauty Salons and Spas
3. Fitness and Wellness Centers
4. Comparable facilities

The Erchonia LunulaLaser™ OTC Installation and Proper Use Reference Guide contains specific and comprehensive instructions on overall safe and effective use of the device across all intended device use environments, specifically as follows:

Safety Information: The *Safety Information* section contained on pages 4 through 6 of the Installation and Proper Use Reference Guide contains specific instructions for device environment restrictions and safety factors, as follows:

- PRECAUTION (page 5): **DO NOT** place/operate this device in close proximity (6 inches) to other devices that emit frequency.
- PRECAUTION (page 6): Avoid contact with flammable anesthetic with air or with oxygen or nitrous oxide.
- PRECAUTION (page 6): This device should be operated in temperatures between 59° to 85° F (15° to 29° C), … with relative humidity less than 75%
- PRECAUTION (page 6): **Do not** position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.

Relevant characteristics of the intended device use environments that were considered and accommodated during the medical device development and design process to mitigate potential conditions and factors that could affect safe and effective use of the Erchonia LunulaLaser™ OTC, are the following:

Device User Environment Characteristic	Mitigation of Consideration
Proximity to water, liquids and other foreign materials that may enter the device potentially resulting in damage to the device, user and/or treatment recipient.	•  **WARNING** in Installation and Proper Use Reference Guide that states: **DO NOT** permit any foreign materials or liquids to enter the device. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from

	entering the device. These may cause device damage, malfunction, electrical shock, fire, or personal injury. To achieve the specified level of protection against spilled or splashed liquids, unplug the device from the power supply and thoroughly dry all exposed surfaces of this device and allow to dry thoroughly prior to operation. •  **WARNING**: **Beware of electrocution**. Do not submerge any part of the device in water. This could damage the device or cause an electric shock that may lead to serious injury or death. Damage resulting from this condition is not covered under the warranty.
Proximity to other devices that emit frequency that may interfere with the accurate operation of LunulaLaser OTC.	 **PRECAUTION** in Installation and Proper Use Reference Guide that states: **DO NOT** place/operate this device in close proximity (6 inches) to other devices that emit frequency. If this device causes interference to other devices, which can be determined by turning the device off and on, you are encouraged to try to correct the interference by one of the following measures: ➢ Reorient or relocate the receiving device. ➢ Increase the separation between the equipment. ➢ Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

6.3. DEVICE USER INTERFACE

The device user interface is defined as all points of interaction between the user and the device, including all elements of the device with which the user interacts (i.e., those parts of the device that users see, hear, touch). This includes all sources of information transmitted by the device (including packaging, labeling), training and all physical controls and display elements (including alarms and the logic of operation of each device component and of the user interface system as a whole).

The Erchonia LunulaLaser™ OTC device user interface includes all points of interaction between the user and the device, including all elements and components of the device and its operation with which the user interacts.

The Erchonia LunulaLaser™ OTC device user interface **components and accessories** are the following:

1. LunulaLaser™ OTC Device
2. Power cord
3. 1 client safety glasses
4. 2 Keys
5. Sani-Cloth Germicidal Wipe (Sample pack)
6. Installation and Proper Use Reference Guide

The device user interface includes the following **controls, visual displays, and visual alarms and alerts**:

1. Touch Screen that displays the:
    - Power Indicator Light
    - Start Screen and related icons, Mode Screen and related icons, including Start, Stop, Pause, and Resume icons and Time Remaining icons.
    - Device Information Screen containing device and manufacturer information.
2. Pull Knobs/Stops
3. Door/Foot Platform
4. Key Switch
5. Diode Light Indicator

6. Magnetic Latch
7. Handle
8. Power Inlet/Fuse Holder

The device user interface includes the following **labeling**:

1. Installation and Proper Use Reference Guide
2. Box Labeling
3. Device Labelling

The device user interface is used by the device user under the following **conditions and sequence of operations**:

1. During initial setup of the device, including opening and unpacking the delivery box components.
2. During establishment of an appropriate device use environment.
3. During preparation and operation of the device, including plugging the electrical cord into the device and an electrical outlet, using the key to power the device on, opening the door/foot platform, using the touchscreen to initiate and manage treatment administration, ensuring correct fitting of the safety glasses to the client, ensuring correct placement of the subject's treatment foot in the device, and using the key to power the device off.
4. Understanding all warnings and precautions contained in the Installation and Proper Use Reference Guide.
5. Cleaning of the device and/or device components and accessories between uses.

The device user interface has been designed such that its use is logical and intuitive such that correct user actions are facilitated and actions that may result in harm (use errors) are prevented or discouraged. Through consideration and initial evaluation of the intended device user characteristics, the intended use of the device and thorough review of design specifications and operational, output, and functional displays of similar devices already on the market with demonstrated safety and efficacy of use by the same intended user population, the logic of information display and control actions have been engineered and designed to be consistent with users' expectations, abilities, likely behaviors and experiences with similar devices at any point during use.

Specifically, the following design elements were considered resulting in the associated logical and intuitive features of the device user interface:

Device User Interface Design Element Considered	Mitigation of Consideration
Device dimensions	The device design was targeted to be as small, compact, and lightweight as possible, with the following dimensions: • Weight: 23lbs / 10.43 kg • Height:16in/40 cm • Width:12in/30 cm • Depth: 10in/25.40cm (38 cm with platform extended)
The LCD screen (graphic user interface) that provides information to the user.	The LCD screen displays information pertaining to initiating, pausing, resuming, and stopping treatment; treatment time remaining; and device/ manufacturer information. To ensure that readability is always optimal, the LCD screen remains lit throughout the treatment administration process.
Components that the user attaches to the device, i.e., power cord and key.	Each of these components and the locations on the LunulaLaser™ OTC to which they are attached/inserted have been designed to be intuitive to determine and easy to locate, access and use. The design took into consideration the design of other similar devices currently on the OTC market. Additionally, the Installation and Proper Use Reference Guide has been clearly designed using both text and related labelled images to demonstrate each step of connection, removal, and operation, as applicable, of each individual component to the device, when and as necessary.
Hardware components to control device operation.	Following correct attachment of all components to the LunulaLaser™ OTC device, the user operates the device using the key and the icons on the touchscreen on the device interface. The key and the touchscreen placement were designed with consideration of intuitive use and ease of use restricted solely to the tasks the user must perform to safely, and effectively, activate and operate the device. The key is easily inserted into the keyhole and turns without effort to power the device on and off. The

	icons on the touchscreen are activated by gentle touch with the finger and encompass the Start, Stop, Pause, and Resume icons, and the Time Remaining icon. Each icon activation action is verified by the corresponding result being displayed on the touchscreen. This information is also clearly explained using text and images in the Installation and Proper Use Reference Guide.
Safety Glasses	The LUNULALASER™ OTC is classified by the FDA/IEC as a Class 2 laser device. This represents a current standard for use to ensure the safety of the client. 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, a pair of specialty safety glasses for use by the client during treatment is provided in the device packaging. The safety glasses, sufficiently and effectively block the laser light spectrum at OD 2+ @ 635nm, OD 0.75 @ 405nm VLT60. Additionally, the following warning is included in the Installation and Proper Use Reference Guide: ⚠ **WARNING**: The client should always be correctly fitted with the safety glasses provided before turning on the laser and doing any treatment. Furthermore, Step 6 of the LunulaLaser™ OTC Treatment Protocol on page 17 of the Installation and Proper Use Reference Guide reads as follows: “Have your client put on the safety glasses…”
Logic of the overall user-system interaction, including how, when, and in what form information (i.e., feedback) is provided to the user.	Set-up and use of the Erchonia LunulaLaser™ OTC device is designed to be inherently logical and sequential. Information, including visual confirmation via text and lights of user tasks performed are provided in real-time on the LCD and touch screen. These operations and interactions have also been designed with consideration of the design of comparable devices presently on the market.

Packaging and labeling, including the Installation and Proper Use Reference Guide.	Consideration in the design of the packaging and labeling materials was given to ensuring direct compatibility and correspondence between the sequential order of information presented in the Installation and Proper Use Reference Guide and the sequential order of device setup and operation to be performed by the user. All instructional materials contain related text and images for all operations, as applicable. Attention was made to ensuring all potential warnings, cautions and other potential hazards and risks that may potentially occur are included in the Reference Guides, as well as cleaning, troubleshooting, maintenance, and warranty information. As with the other elements of the design and development of the LunulaLaser OTC, consideration was given to the layout and content of Reference Guides/User Manuals for other comparable devices currently on the market.

6.4. STUDY OBSERVER

The Study Observer is an Erchonia Corporation employee who is suitably qualified, trained and experienced in conducting Human Factors Validation Testing and is specifically trained to all aspects of the set-up, start-up and use of the Erchonia LunulaLaser™ OTC; and to the information contained in the Installation and Proper Use Reference Guide, and device and package labeling.

The Study Observer's sequential role in this study is to:

(i) conduct the informed consent process with the user.
(ii) conduct the study qualification evaluation with the user.
(iii) observe the user's performance across each of the critical tasks associated with the process of using the LunulaLaser™ OTC from receipt of the packaged device through to operation and use of the device to administer a treatment, and to note his or her observations, including observations of use problems and errors and close calls, throughout the process on the respective Observation Forms.

The Study Observer is trained not to provide any guidance to the user through this process or to answer any questions, simply to observe and to record those observations, unless intervention becomes necessary for safety.

(iv) conduct a post-test debriefing interview to collect the user's perspectives to supplement the observer's observations, including attaining the user's subjective assessment of any use

difficulties experienced throughout the process of setting up and operating the device; gathering specific feedback on each critical task; and investigating all use difficulties, errors and close calls observed and noted by the Study Observer during the test phase.

(v) assess the user's understanding of the essential information contained in the Installation and Proper Use Reference Guide, and packaging and device labeling through administration of a knowledge task questionnaire.

7. STUDY PROCEDURE

7.1. STUDY MATERIALS

The following materials will be employed during this Human Factors Validation Testing.

(i) Erchonia LunulaLaser™ OTC Installation and Proper Use Reference Guide, contained in **Appendix A.**
(ii) Box Label for the Erchonia LunulaLaser™ OTC contained in **Appendix C**.
(iii) User Study Eligibility Evaluation Case Report Forms contained in **Appendix D.**
(iv) Device Use Study Observer Observation Record Form contained in **Appendix E**.

The Device Use Study Observer Observation Record Form will be used by the Study Observer to record his or her observations pertaining to the user's ability to correctly and safely set-up, start-up and operate the Erchonia LunulaLaser™ OTC.

(v) Post-Test Debriefing Interview Record Form contained in **Appendix F**.

The Post-Test Debriefing Interview Record Form includes specific assessment of the user's perspectives of the device operation, including attaining the user's subjective assessment of any use difficulties experienced throughout the process of setting up and operating the device; on each critical task; and regarding the specific use difficulties, errors and close calls observed and noted by the Study Observer during the test phase using open-ended and neutrally worded questions.

(vi) Knowledge Task User Questionnaire contained in **Appendix G**.

The Knowledge Task User Questionnaire includes specific verbal questioning and assessment of the user's understanding of the information contained in the Installation and

Proper Use Reference Guide, and device and packaging labeling using open-ended and neutrally worded questions. This includes assessment of the user's understanding of the indication for use; of how to assemble and operate the Erchonia LunulaLaser™ OTC; of all critical tasks and use scenarios; and of the specific warnings and cautions pertaining to use of the Erchonia LunulaLaser™ OTC.

(vii) Subject User Information and Consent Form contained in **Appendix H**.

7.2. STUDY PROCEDURE PROTOCOL

The following procedure protocol will be implemented sequentially and fully for each enrolled user and treatment recipient, as applicable.

7.2.1. SIGNING OF INFORMED CONSENT

The Study Observer will review the informed consent form with the potential candidate and answer any questions. A candidate who subsequently voluntarily signs the informed consent form will be enrolled as a user in the study and receive a unique de-identified subject ID. The Subject ID will comprise the Study Observer's first and last name initials followed by a 2-digit number from 01 onwards determined by the user's order of sequential enrollment. For example, the fifth user to be enrolled in this study will have a unique de-identified subject ID of TS05.

7.2.2. ELIGIBILITY EVALUATION

7.2.2.1. User

The Study Observer conducts the user eligibility evaluation to confirm that the user fully qualifies to take part in the study.

7.2.3. PROVISION OF STUDY DEVICE

The user is provided with the Erchonia LunulaLaser™ OTC in its intended packaging that also contains the Installation and Proper Use Reference Guide exactly as is intended to be supplied following FDA market clearance. The user is instructed to open the packaging and prepare the device for use exactly as they would if they were they to receive it at their place of employment.

N.B.: There will be no participant training in preparation or use of the device in this Human Factors Validation Testing study as it is not intended that users receive any training once the device has market clearance. It is intended that the user will receive delivery of the device in its packaging at

the place of employment. The user will need to set-up and operate the device based upon the information provided with the packaging, and therefore, this Human Factors Validation Testing study will also not implement user training to optimally simulate intended use of the Erchonia LunulaLaser™ OTC in real life. Additionally, users will be left to work out how to operate the Erchonia LunulaLaser™ OTC and to administer a treatment as independently and naturally as possible, without interference, influence, or instruction from the Study Observer, including whether or not the user chooses to read the instructional materials provided including the Installation and Proper Use Reference Guide.

7.2.4. USER USE OF DEVICE

The user is instructed to operate and use the device to administer treatment to the client following the exact process he or she would follow as if the device had just been received via delivery at his or her place of employment.

As this process is ongoing, the Study Observer will observe the user's performance from opening of the packaged device through to operation and use of the device, or otherwise to as far as the subject is able to complete the process, and will note his or her observations, including observations of use difficulties/problems, errors, and close calls on the Device Use Study Observer Observation Record Form (**Appendix E**).

The Study Observer will not provide any verbal, written or any other form of guidance or assistance to the user throughout this process, and although the Study Observer will record any questions asked by the user during this process, he or she will not answer any questions the user may ask or otherwise interfere in the process, unless intervention becomes necessary for safety reasons.

7.2.5. POST-TEST DEBRIEFING INTERVIEW

Once the user indicates that he or she has completed the device use and treatment application process, the Study Observer will conduct the Post-Test Debriefing Interview (**Appendix F**). The Study Observer will record verbatim the user's responses to each question but will otherwise not react to the user's responses. The Study Observer will not explain or reword any of the questions in the Knowledge Task Patient User Questionnaire and will not provide any guidance or feedback regarding the user's responses in any manner.

7.2.6. KNOWLEDGE TASKS EVALUATION

The knowledge tasks evaluation will take place once the Post-Test Debriefing Interview is complete. The knowledge tasks evaluation commences with the Study Observer requesting that the user read through the Installation and Proper Use Reference Guide and all other labeling information contained on the device and the packaging regardless of whether or not he or she did so during the use evaluation study component. The Study Observer will not point out any specific information in any of these materials to be read or noted, and although the Study Observer will record any questions asked by the user during the material review process, he or she will not answer any questions the user may ask or otherwise interfere with the process in any manner.

Once the user indicates that he or she has completed reading the supplied materials, the Study Observer will administer the Knowledge Task Patient User Questionnaire (**Appendix G**). The Study Observer will record verbatim the user's responses to each question but will otherwise not react to the user's responses. The Study Observer will not explain or reword any of the pre-established questions in the Knowledge Task Patient User Questionnaire and will not provide any guidance or feedback regarding the user's responses in any manner.

Following completion of the knowledge tasks evaluation, the user's participation in the study is complete.

8. REGULATORY AND ETHICAL CONSIDERATIONS

8.1. DATA MANAGEMENT

8.1.1. Data Administration

For each enrolled user, the Study Observer will be the only individual to record information on the study record forms and only the required data elements will be recorded. There will be no identifying information recorded that could potentially connect an individual user's data record to the individual. Unique de-identified codes will be used on each user's record forms.

The recorded data will only be used for the purposes of evaluating the objectives of this study. The sole parties who will have access to the record forms and the study data will be the Study Observer, the study Sponsor and the study analyst. Access to the record forms and data will not be given to outside parties at any time during the data collation and analysis process or in the future for any reason.

8.1.2. Compliance Statement

The Study Observer will perform the study in accordance with this protocol. Collection and recording of data will be accurate and will ensure the privacy, health, and welfare of users during and after the data collection process.

8.2. INFORMED CONSENT

8.2.1. Informed Consent

This Human Factors Validation Testing study will operate under appropriate Investigational Review Board (IRB) approval and will meet Health Insurance Portability and Accountability Act (HIPAA) Privacy Requirements. Prior to study enrollment, each user partaking in the study will be required to voluntarily sign the study informed consent form following review of the form with the Study Observer. The informed consent form for this study is contained in **Appendix H.**

8.2.2. Confidentiality

All data and record forms generated during this study will be kept confidential in accordance with HIPAA regulations on subject privacy. The Study Observer will not use the data and record forms for any purpose other than conducting the study. Coded de-identifiers will be used for all data entries.

8.3. RISK ASSESSMENT

8.3.1. Potential Risks of Participation

The only potential risk to subjects (users) in this study is breach of privacy and confidentiality. The application of a de-identified coding system to record subject data has been established to minimize this risk.

8.3.2. Potential Benefits of Participation

There is no direct benefit to the subject (user) from participation in this Human Factors Validation Testing study. There may be benefit to potential future users of the device and to individuals with diagnosed toenail onychomycosis who may be potential future recipients of treatment with the Erchonia LunulaLaser™ OTC in the user settings.

8.3.3. Risk-Benefit Assessment

The Risk-Benefit assessment reveals no negatives in conducting this Human Factors Validation Testing.

9. SAFETY MANAGEMENT

9.1. USER DIFFICULTIES AND ERRORS

All observed and reported user difficulties and errors will be recorded and evaluated as part of the study procedural protocol and consistent with the goal of this Human Factors Validation Testing.

9.2. ADVERSE EVENTS REPORTING

While it is not anticipated that any adverse events will occur during this Human Factors Validation Testing, any and all potential adverse events observed or reported will be recorded on the applicable record forms and subsequently evaluated and handled in accordance with the study site, IRB and FDA reporting and handling policies and requirements.

10. PUBLICATION

The outcome of this Human Factors Validation Testing will be written up for the purpose of inclusion in a 510(k) submission to the FDA seeking regulatory market clearance for OTC use of the Erchonia LunulaLaser™ OTC. In the event of inclusion of the outcome of this study in a potential future publication, there will be no identifiable information for any individual subject (user) and no individual case studies will be profiled.

11. ANALYSIS OF HUMAN FACTORS VALIDATION TESTING

11.1. PRIMARY ANALYSIS

A subject user in this study will be considered as either a study ‘pass’ or a study ‘fail,’ defined as follows:

- *Study Pass*: A subject user who satisfactorily completes both the device setup and treatment procedure will be determined a Study Pass.

- *Study Fail:* A subject user who does not satisfactorily complete either one or both of device setup and/or treatment procedure will be determined a Study Fail.

11.2. QUALITATIVE ANALYSIS

The results of the Human Factors Validation Testing will be analyzed qualitatively to determine if the design of the device and all associated instructional materials and labeling require modification to reduce any identified use-related risks to acceptable levels.

11.2.1. Root Cause Analysis

Observational and knowledge task data will be aggregated with the debriefing interview data and analyzed in detail to determine the root cause of any identified and/or reported use difficulties and/or errors, including close calls. The analysis will include evaluation of how the use errors or problems occurred within the context of device use, including the specific aspect of the user interface that caused problems for the user.

The root causes of all use errors and problems will be considered with respect to the associated risks to ascertain the potential for resulting harm and to consequently determine the need for and priority of implementing additional risk management measures.

11.2.2. Implementation of User Interface and Labeling Modifications

In consideration of each risk identified through the root cause analysis as having the potential for resulting harm, user interface modifications and labeling and any other necessary risk management measures will be determined and implemented with the goal of reducing the risk to acceptable levels. This includes consideration of any suggestions for modifications to address used problem and/or errors made by the users during the post-test debriefing interview.

11.2.3. Retesting

If indicated by the extent of user interface modifications and risk management strategies implemented, retesting may be performed to specifically address the aspects of the user interface that led to the use problems and errors and to evaluate the modified user interface elements to assess the risk management measures implemented in reducing risks to acceptable levels without introducing any new unacceptable risks.

11.2.4. Residual Risk Evaluation

All residual risks identified after user interface modification are finalized will be analyzed to determine if and where applicable, how, each can be reduced or eliminated.