Phothera™

Operation Manual

Phothera HF

ClearLink™ Controlled

Modes of Operation:

Guided | Dosimetry | Timed

Your health is our purpose, and your care is our promise.

Phothera

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Dear Valued Customer,
Thank you for selecting a Phothera HF phototherapy unit. The use of light for the treatment of photoresponsive skin disorders has been our business since 1981. We are proud of our tradition of innovation in the field of phototherapy and are honored that you have chosen us for your phototherapy needs. Let's be clear. Our commitment to you starts…Now!

Sincerely,
The Phothera Staff

CAUTION: **Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the state in which he or she practices.**

1.0 Control Type

Your Phothera HF phototherapy unit is equipped with Phothera's ClearLink™ Control System. The device was prescribed by your doctor to function in one of the three modes listed below:

● **Guided:** The system controls the beginning dose and all subsequent does depending upon how your skin responds to the therapy. See pages 16 and 17 for operating instructions that are specific to this mode of operation.

● **Dosimetry:** You control the doses which are delivered in either Joules or MilliJoules. The system automatically adjusts the length of each treatment depending on the power of the lamps. The doses you take will be based on instructions from your doctor. See page 18 for operating instructions that are specific to this mode of operation.

● **Timed:** You control the length of each treatment, based on instructions from your doctor. See page 19 for operating instructions that are specific to this mode of operation.

***Exposure-Limiting Software*:** Your physician may have prescribed your device with a system that limits the total number of exposures the device will deliver before a refill code is required. Specific information about these systems is provided in this manual.

2.0 Indications for Use

The Phothera HF Phototherapy Devices are indicated for use to treat diagnosed skin disorders such, as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The physician will determine the light spectrum (ultraviolet to visible), the energy or duration of the treatment, as well as the treatment environment. The population may range from pediatric, when accompanied by a responsible adult to operate it, to geriatric.

3.0 Delivery and Inspection

Upon delivery, inspect both boxes and their contents. If it's not possible to inspect the unit before the driver leaves, we recommend that you write **"Concealed damage possible. Further inspection required"** on the delivery receipt. If damage is discovered after unpacking the unit, be sure to save **all** packing materials and call Phothera immediately to begin the claims process.

As part of the claims process, the delivering carrier may require that a damage inspection be conducted. The carrier may conduct the inspection at your home or they may elect to collect the package for inspection at their facilities.

Note: *In addition to notifying Phothera the delivering carrier **must also** be notified of any shipping damage within twenty-four (24) hours to protect your right to an insurance claim.*

4.0 Site Selection

A location for the device should be chosen within reach of a standard, grounded electrical outlet. Extension cords are not recommended. It is important that the unit be properly grounded. It should ***not*** be in a location where there is foot traffic or where water or moisture might collect. It should be protected from access by children. Exposure to ultraviolet light over extended periods of time may cause carpets, wall coverings and furnishings to fade.

4.1 Electrical Requirements

In the United States and Canada, the Phothera HF is shipped with a standard three-pronged plug power cable.

- The Phothera HF **should** be plugged into any grounded household electrical.

- The Phothera HF **should not** be plugged into a residual current device (RCD) or an RCD protected circuit
- The Phothera HF **should not** be plugged into a ground-fault circuit interrupter (GFCI) or a GFCI protected circuit.

Devices that will be used overseas will be equipped with a country appropriate electrical cord and plug.

All Phothera HF devices are equipped with an onboard fuse. The fuse holder is a part of the power cord receptacle that is located on the lower left-hand side of the device. If an onboard fuse fails, call Phothera's service department to determine an appropriate replacement.

5.0 Unpacking and Assembly

1. The Phothera HF will arrive in two separate boxes. The larger of the two contains the base along with all accessories and literature. The smaller box contains the hood.
2. Using two people, if possible, lift the base from its box and place it where you intend to use the device.

   Note: *Be sure to remove all of the accessories, such as the manual, power cord and eyewear before discarding the box.*
3. Remove the hood from the smaller box and place it on the base with the arched openings facing forward.

   Note: *There is a flange on the bottom of the hood that fits over the upper edge of the fixture. The hood is designed to fit tightly, so it may take some pressure to seat it properly.*
4. Connect the Phothera HF hood to the Base using 6x1/2" self tapping sheet metel screws on the backside of the device. Find the electrical cord extending from the back of the hood and plug it into the designated receptacle on the back of the base.
5. Install the Phothera HF power cord by inserting the male "D" shaped plug into the corresponding receptacle located on the back of the device near the "hood power cord only" label (see Figure 6). Plug the unit into a standard electrical outlet.
6. **Optional:** If using a Phothera HF table with your device, you can mount the device to the table by removing the rubber feet from the bottom of the device, drilling pilot holes through the table, and screwing 6-32 screws through the table into the device.

a. To mount the Phothera HF base to the table, use a 1/8” drill bit to drill a pilot hole (HOLE#1) in the bottom left corner of the table roughly 2.5 inches from the front and roughly 4.375 inches from the inside of the left wall.
b. From this original pilot hole, drill another pilot hole (HOLE#2) in line with the first, roughly 16 inches to the right. Drill another pilot hole (HOLE#3) directly in the center of these two holes, roughly 8 inches from each hole.
c. From the two most outer pilot holes, drill two more holes (HOLE#4 and HOLE#5) in line with the two corners roughly 17.5 inches above the two in the front corners.
d. A diagram of the pilot hole placement is shown below in Figure 1 Pilot Hole Guide.

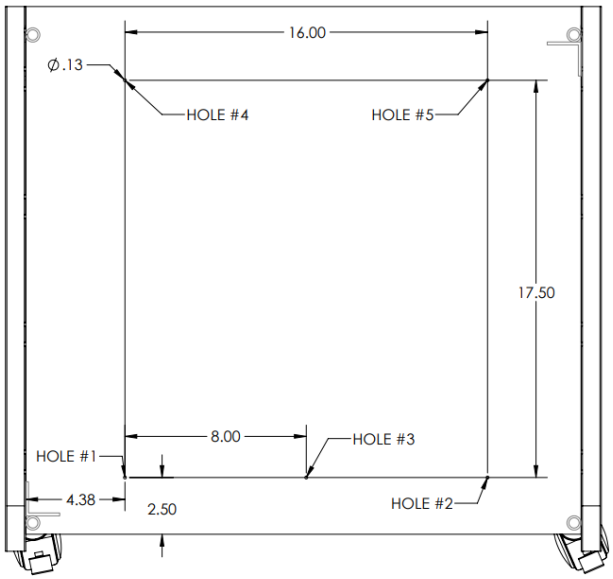

Figure 1 Pilot Hole Guide

6.0 Lamp Inspection

Phothera HF devices can be equipped with different types of lamps, each having a different effect on the skin. It is important to check that the proper lamps are installed. Consult the Lamp Specification Guide (see *Section 6.1 Lamp Specification Guide*.) If there is any question that your device is not equipped with the lamps that you have been prescribed, contact Phothera immediately. Lamps code numbers are generally located at the base of the lamp.

6.1 Lamp Specification Guide

UVA	Narrow Band UVB
PLL-36W/09	PLL-36W/01

7.0 Precautions and Warnings

- To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. Always use Phothera approved eyewear purchased through Phothera.
- Do not remove protective eyewear, or any other protective equipment, during treatment.
- If psoralens (photosensitizing drugs) are being used as part of your treatment ("PUVA"), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with devices equipped with UVA lamps.
- Do not use over skin eruptions without express consent from the attending physician.
- If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.
- To protect unaffected skin during operation, the operator, patient, and anyone in view of the device must generously apply UV blocking skin protection to all exposed skin that the physician does not intend to treat.
- Erythema can result in as little as 15 seconds of exposure, or approximately 200 millijoules of dose to UVB light. Prior to using your home phototherapy unit, contact your prescribing physician for specific treatment instructions and dosing information.
- Center patients between the lamps during treatment to avoid over exposure to isolated areas of the body.
- All people and pets should leave the area to avoid exposure to ultraviolet light.
- Ask your doctor about protecting areas of your body which have not been exposed to sunlight.
- Do not use this device for anything other than its intended purpose.
- This device is only to be used by authorized users.
- Do not operate this device with a damaged cord or plug.

- If appliance coupler or mains plug is used as the main point of disconnect, do not position the device so that it is difficult to operate the disconnection device. Ensure the device can be unplugged from the point of disconnect.
    - If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging the device or, if hard wired, turning off quick disconnect.
- To avoid the risk of electric shock this equipment must only be connected to a supply main with a protective earth.
- To prevent electric shock, remove power to the device prior to cleaning and servicing.
- To eliminate the risk of fire when replacing the fuse, replace ONLY with a fuse of the same type and rating.
- **NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED.** Unauthorized modification will void the warranty and may result in hazardous or improper device operation.
- **DANGER - ULTRAVIOLET RADIATION.** As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer. **ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE ERYTHEMA OR LONG-TERM INJURY TO THE EYES.** Medications or cosmetics may increase skin sensitivity to ultraviolet radiation. Inform physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.
- If the device malfunctions, cease operation immediately. If the device is placed close to other equipment, it is possible that the cause is interference by external noise sources and fields, in which case you should follow the remedies found under EMC Precautions. If the device continues to malfunction cease operation and contact the Phothera Service Department.
- Prior to each use, always verify that the device is in correct working order and operating condition and plugs, sockets, lamps, and electrical cables and connections are not worn or damaged.
- Only original components and accessories should be used with the device to avoid damage.
- This device should be a minimum of 12 inches (30 cm) away from RF generating equipment
- Before opening the device casing to perform maintenance or service, disconnect the device from the power source.

- The device must never be directly exposed to flowing or splashing liquids of any kind. If the device is inadvertently exposed to liquid, it must be tested for safe function before being placed in operation again.
- The device contains glass lamps. Avoid excessive force to the device to prevent lamp damage.
- The device control system display is susceptible to damage from excessive force. Avoid excessive force to the control system to prevent damage.
- All treatments must be administered under the direction of a licensed physician only.
- **WARNING:** Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Device is not to be used in MR environments that may include MRI, diathermy, electrocautery, or other high frequency equipment.
- Do not treat if the lamps fail to ignite. Consult with doctor and/or contact Phothera customer service. (See 18.7 Contact Information)
- If lamps turn on without treatment being started/resumed, or if lamps do not turn off when treatment is completed, unplug the device. Contact doctor and/or Phothera customer service. (See 18.7 Contact Information)
- ClearLink™ Controlled Phototherapy Devices are considered CISPR Group 1, Class A devices, to be used for prescription use only.

8.0 Operating Specifications

Ambient Temperature:	15°C to 30°C (59°F to 86°F)
Relative Humidity:	10% to 95%, Non-condensing
Liquid Ingress Rating:	IPX0 (This device does not have protection against ingress of water.)
Ocular Hazard Distance:	3 Meters (9.84 Feet)
Ambient Luminance:	250 – 500 lux

WARNING: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

9.0 Labels and Symbols

A removable label *(Figure 2 Unlocking Code)* located near the screen provides information on how to unlock the unit.

Figure 2 Unlocking Code

If the unit is equipped with exposure limiting software, there will be a label similar to the one shown below (Figure 3 Refill Label) informing you that your unit has been equipped with this feature and how to refill the device.

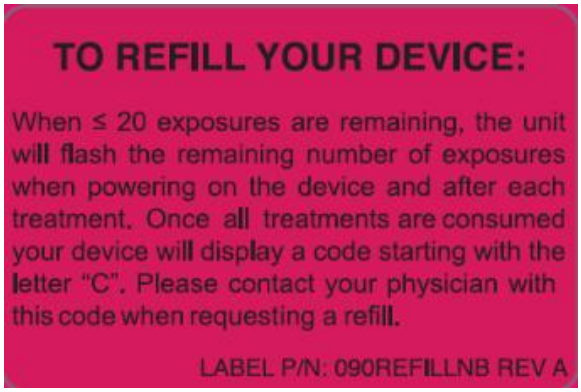

Figure 3 Refill Label

A warning label (*Figure 4 Warning Label)* is affixed to your phototherapy device in a prominent and easily readable position. Please read the label carefully as it contains important safety information.

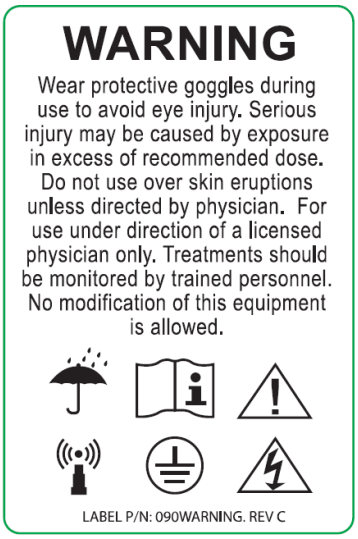

Figure 4 Warning Label

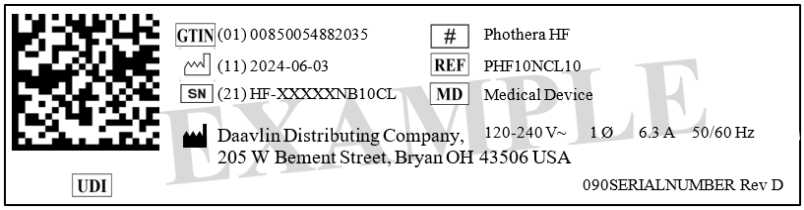

Figure 5 Identification Label

The identification label (*Figure 5 Identification Label*) is located on the back of the unit near the power cord receptacle.

Figure 6 Hood Power Cord Label

Figure 7 Hood Lamp Label

Figure 8 Terminal block Cover

The following table lists all of the symbols affixed to the device along with their meaning:

Table 1 Symbols

SYMBOL	DESCRIPTION
	DANGEROUS VOLTAGE
	NON-IONIZING RADIATION
	ON
	OFF
	PROTECTIVE EARTH (ground)
	OPERATING INSTRUCTIONS
	KEEP DRY
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	UVA LAMPS LABELS
	NBUVB LAMPS LABELS
	Type B applied part
	MEDICAL DEVICE

10.0 General Instructions (All Modes of Operation)

10.1 Pre-treatment Preparations

Before starting therapy, show your doctor these instructions. He or she is the final authority for your treatment, and, depending upon your particular circumstances, may change these directions. *Always follow your physician's instructions.*

The ClearLink Controller will track your treatment data. However, you may want a notebook, or treatment log, in which to record the date, dose and duration of each of your treatments along with any other notes regarding your treatment or treatment results. (For example, forgot lip balm, put sunscreen on tender area, etc.)

You will need to purchase lip balm and sunscreen with an SPF (Sun Protective Factor) of at least 30. Ask your doctor whether or not you should use an alcohol or cream-based sunscreen.

10.2 Hood Lamps

The hood lamps have an "**ON/OFF**" switch so that they can be turned off if desired. When the switch is in the **ON** position, the hood lamps will light when the base lamps turn on.

Note: *On combination UVA and UVB units, the hood will always be equipped with UVA lamps.*

With all combination units the UVA lamps will be the first four lamps in the unit. The UVB lamps will be the last four. Therefore, if you are using the UVA lamps, position your hands or feet at the front of the device. If using the UVB lamps, position your hands or feet in the back half of the unit. Combination units are NOT available with Guided Mode devices.

10.3 Unlocking the Device

To prevent unauthorized use, the device will self-lock when left idle for twenty (20) minutes.

1. Tap the blank screen. The Phothera logo will appear.
2. Tap the logo. The Lock Screen will appear (unless disabled)
3. Using the keypad, enter the number 7 (unlocking code)
    a. PIN will read as “0007”.
4. Press the Enter key → to unlock.

Figure 9 Logo Screen

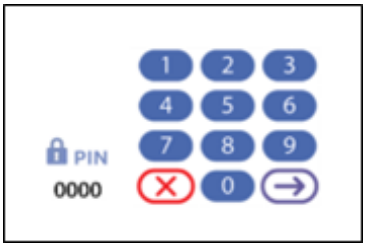

Figure 10 Lock Screen

10.4 Positioning Yourself

The hands, feet or elbows should be placed through the arched exposure ports in the front shield and laid directly on the acrylic guard that covers the lamps. Intensity is highest towards the horizontal center of the unit. Rings or other jewelry may cause scratching of the acrylic and should be removed

10.5 Common ClearLink™ Functions

The system beeps to signal the end of the treatment and will display the delivered dose along with the elapsed time.
If power goes off during a treatment, the system will track how much of the treatment has elapsed and will allow the treatment to resume when power is restored.

10.6 Post-Treatment

After a treatment, you may protect any areas that feel sunburned with sunscreen for the next several treatments or until they appear normal. (Make a note in your notebook.) You should see your physician at the intervals he or she requests when actively using the unit. Always take the notebook with you when you see your physician.

10.7 Treatment Limiting Software (Rx)

If your unit was prescribed with exposure-limiting software, a screen (Figure 11 Treatment Remaining Screen) will tell you how many exposures remain before you

need a refill prescription. See Section 14.3 Uploading Refill Prescriptions for refill instructions.

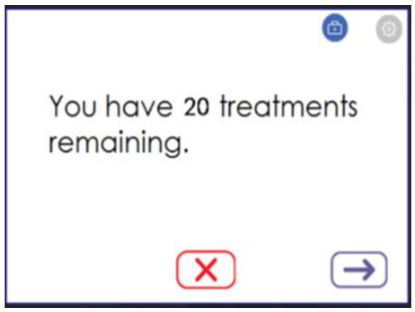

Figure 11 Treatment Remaining Screen

11.0 Guided Mode

11.1 Features of the ClearLink™ Guided Home-Control System

The ClearLink Guided Home-Control System automatically performs many safety checks on your behalf, as well as calculating dose increases based on your treatment schedule and your skin's response to treatment.

For example, each time you use the device, the ClearLink Controller will check the date of your last treatment. If you are on schedule, it will automatically proceed. However, if you have missed a treatment or treatments, the system will adjust accordingly to keep your dose at a safe level.

During the course of using the device, you may see screens with messages explaining these safety adjustments.

Figure 12 Treatment Scheduling

Integrating dosimetry is a feature of the device which uses a built-in sensor to monitor the amount of light energy being produced by the device. The system then automatically adjusts the length of your treatment to account for variations in light output caused by changes in room temperature or aging of the lamps.

Finally, before each treatment, the ClearLink Controller will ask about the current condition of your skin, such as whether or not there is any redness, mild or otherwise. It will use this information to calculate the next dose. It is normal to experience some "redness" within 8 – 12 hours of a treatment. It is typically gone before it is time for the next treatment.

11.2 Running a Treatment

Note: The first time you use the device, your dose will automatically appear, based on your doctor's prescription. After your first treatment, the screen will display the next scheduled treatment, but will ask if you experienced any pain or redness after your last treatment. Based on your response, the system will adjust the treatment according to your prescription.

1. After unlocking the device, the Treatment Screen will appear with the scheduled dose:
2. You will be asked, ***"Were you in pain or red after your last treatment?"***
3. You must choose one of the following responses:
    - No, or < 24 Hrs ("Not at all, or it was gone in less than 24 hours")
    - 24 – 48 Hrs ("I was in pain or red for 24-48 hours after the treatment")
    - > 48 Hrs ("I was in pain or red for more than 48 hours")
    - Still red / pain ("I am currently still red or have pain")

Note: *Selection of the "Still red / pain" option will lock the device until one treatment has been skipped. This prevents treating the skin until the erythema (redness) has resolved.*

4. Once you have highlighted your response, press the Enter → key.
5. The Treatment Confirmation screen will appear and will display the dose and an estimated time for the treatment. If changes need to be made, press the back ← arrow. Press ✕ to cancel.

Put on your goggles and position yourself per the instructions in section 10.4 Positioning Yourself.

6. Press the Enter → key to begin the treatment. After a 3 second countdown, the lamps will turn on and the screen will display your progress. The lamps will shut off when the treatment is over.
7. To pause an active treatment, press the Pause ⏸ button. To resume, press the Play ▷ button. To end or cancel an active treatment, first pause the treatment and then the Cancel ✕ button.

8. To repeat the dose, for treatment of additional areas of your body, touch the Repeat ↺ button. **Note:** Repeats will not be available after leaving the treatment screen.

12.0 Dosimetry Mode

12.1 Features of the ClearLink™ Dosimetry Home-Control System

The ClearLink Dosimetry Home-Control System uses a built-in sensor as part of a function called integrating dosimetry to monitor the amount of light energy being produced by the device. The system then automatically adjusts the length of each treatment to account for variations in light output caused by changes in room temperature and aging of the lamps.

12.2 Running a Treatment

After unlocking the device, the Treatment Screen will appear:

1. Press the Treat Patient button, then

2. Touch the ▲/▼ arrows to set the desired dose in MilliJoules (UVB) or Joules if you have a UVA device.

   Note: *UVB treatments are commonly dosed in MilliJoules. However, your doctor may have requested that UVB treatments be dosed in Joules. If so, your device will have been programmed accordingly.*

3. Press the Enter → arrow to enter the Treatment Confirmation screen.
4. Confirm the Dose and Estimated Treatment Time. If changes are needed to the dose, press the Return ← arrow and return to step 2.

Put on your goggles and position yourself per the instructions in section 10.4 Positioning Yourself.

5. If the Dose and Estimated Treatment Time are correct, press the Enter → key to begin the treatment. After a 3 second countdown, the lamps will turn on and the screen will display your progress. The lamps will shut off when the treatment is over.
6. To pause an active treatment, press the Pause ⏸ button. To resume, press the Play ▷ button. To end or cancel an active treatment, first pause the treatment and then the Cancel ✕ button.
7. To repeat the dose, for treatment of additional areas of your body, touch the Repeat ↺ button. **Note:** Repeats will not be available after leaving the treatment screen.

13.0 Timed Mode

13.1 Determining a Treatment Time

When using time as a dose, there are two treatment methods that can be used. The simplest is to start at a prescribed time and then increase treatment times by a specific time increment or by a percentage. Another method is to use the factory power output levels (shown on the *Calibration/Output Certificate*) to determine estimated "time equivalents" needed to deliver doses in milliJoules (UVB) or Joules (UVA or visible light).

To determine a "time equivalent", consult the laminated Time Chart that is provided and find the power output on the top row (horizontal axis). The numbers in the left most column (vertical axis) represent a range of potential treatment doses. Find the dose then trace that row to the right until it intersects with the column corresponding to the factory power output of the device. The time equivalent is shown where the two lines intersect. For example, if the factory power output is 4.0 mW/cm^2 and the dose to be delivered is 280 mJ, then the appropriate treatment time will be 01:10. A partial time chart illustrating this is shown below.

Note: For your convenience, and as an alternative to the UVB time chart, the latest version of our free web based calculator is available, google *Daavlin treatment time calculator* for additional information.

Partial UVB Time Chart

mW/cm2 mJoules	2.5	3.0	3.5	4.0 ↓	4.5	5.0	5.5	6.0	7.0
240	01:36	01:20	01:09	01:00	00:53	00:48	00:44	00:40	00:34
→ **280**	01.52	01:33	01:20	01:10*	01:02	00:56	00:51	00:47	00:40
320	02.08	01:47	01:31	01:20	01:11	01:04	00:58	00:53	00:46

The UVA Time Chart (not shown here) is configured the same as the UVB Time Chart. The doses are listed in Joules and the energy output levels and times are different than the UVB output levels. Each chart is clearly marked.

13.2 Running a Treatment

After unlocking the device, the Treatment Screen will appear:

1. Press the "Treat Patient" button.

2. Touch the ▲/▼ arrows to enter the desired treatment time. ***Note:*** *It is* ***not*** *possible to enter a time of 60 seconds. You must enter 1 minute instead.*

3. Press the Enter → arrow to enter the Treatment Confirmation screen.

4. Confirm the Time. If a change is needed, press the Return ← arrow and return to step 2.

Put on your goggles and position yourself per the instructions in section 10.4 Positioning Yourself.

5. If the Time is correct, press the Enter → key to begin the treatment. After a 3 second countdown, the lamps will turn on and the screen will display your progress. The lamps will shut off when the treatment is over.

6. To pause an active treatment, press the Pause ⏸ button. To resume, press the Play ▷ button. To end or cancel an active treatment, first pause the treatment and then the Cancel ✕ button.

7. To repeat the dose, for treatment of additional areas of your body, touch the Repeat button. **Note:** Repeats will not be available after leaving the treatment screen..

Calculating Increases: Phototherapy treatments usually start at a given time or dose and are increased with each treatment. Your doctor may ask you to increase each treatment by a set amount of time or may ask you to increase by a percentage, which is difficult when the treatment times are in minutes and seconds. Google *Daavlin treatment time calculator* and bookmark it on your phone. In that app, simply enter the time of your last treatment and the desired percentage increase and the calculator will give you the new treatment time instantaneously.

14.0 Care of the Unit

14.1 Recommended Maintenance Schedule

Item / Action	Frequency
Clean all patient contact surfaces	Between each treatment
Dusting of the unit and lamps	Once a month
Fully clean all internal reflectors, lamps and protective acrylic	Annually (behind the lamps)
Unit calibration	Every 100 hours or once a year (whichever occurs first) and when lamps are replaced. (Meters can be rented or purchased through Phothera)
Replace lamps	***UVB** – Approximately every 300 hours of use. ***UVA** – Approximately every 500 hours of use.

* Lamp life will vary significantly depending on average treatment time and other environmental conditions.

14.2 Cleaning/Disinfection

14.2.1 General Cleaning

For general use, use a clean non-abrasive cloth, not paper towels, and a mild cleaning solution such as Dawn Liquid Dishwashing Soap to gently wipe down the exterior of the device.

14.2.2 Low-Level Disinfection

To reduce micro-organisms on the patient-contacting surfaces, disinfect these surfaces between uses of the device, including when the same patient has the

device for use. For disinfection while the same patient uses the device, we have tested several cleaners that do not degrade the Acrylic and can be seen in Table 2 Tested Cleaners.

Cleaner/Solution	Contact Time
Monk brand Wipes	Follow the contact time instructions provided with the Monk brand Wipes
70% Isopropyl Alcohol	3 min

Table 2 Tested Cleaners

1. Thoroughly wipe down the surfaces and allow contact time listed in Table 2 Tested Cleaners.
2. Allow to air dry and inspect for visible contaminants.
3. If contaminants remain repeat until no visible containments remain repeat steps 1 and 2.

14.2.3 High-Level Disinfection

Follow a high-level disinfection protocol between the use of the device on different patients. Use a high-level disinfectant, such as Steris Corporation's Resert XL-HLD, and follow the manufactures guidelines. See also "FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices" available at: https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and.

14.3 Uploading Refill Prescriptions

When specified by your prescribing physician, Phothera home phototherapy devices are equipped with exposure-limiting software. For each sequence of exposures, the number of available treatments is reduced by one. A treatment sequence consists of the primary exposure plus up to three repeat exposures, if needed, for treating other areas of your body.

If the device is equipped with this feature, upon "waking up", the screen will display pre-set reminders of how many exposures are remaining. To ensure there are no interruptions in your therapy, we suggest that you contact your physician and give them the device code (CXXX) when 5 to 10 exposures remain. The physician will use this device code to generate a refill or "treatment" code for a "refill". Once you are out of exposures, the controller will prompt you to upload a new prescription, see Figure 13 (Device out of Treatments).

To enter this refill code, wake the controller from its sleep mode and enter the unlocking code. The controller will ask you to enter the refill code or you may press the Prescription button to begin.

Tap the screen and enter the code provided by your doctor by pressing the up arrows. Press the Enter key once you have verified that the code is entered correctly. The controller will display the number of exposures that have been uploaded, and you can then continue your normal routine.

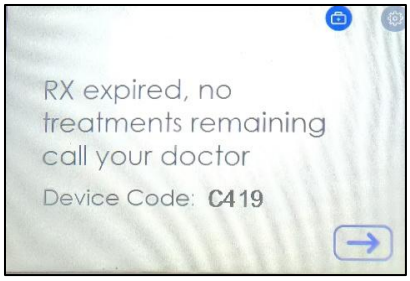

Figure 13 Device out of Treatments

14.4 Downloading Treatment History

Your doctor may require you to provide a treatment history file so that he or she can monitor your progress. To download history files, insert a USB drive into the USB port. The system will prompt you to press the "Export Data" button followed by the Enter key. When complete, remove the USB drive and take it to your doctor.

14.5 Calibration

Phothera recommends that the device be re-calibrated with an independent meter at least annually or at 100 hours of use or whenever lamps are replaced, whichever occurs sooner. This involves taking an output reading with a handheld meter (available for purchase or rent from Phothera) and checking it with the output reading from the Integrating dosimetry system. Please contact Phothera for calibration assistance.

14.6 Range and Accuracy (Applicable to Guided and Dosimetry Units Only.)

Dose Range:	**UVA**: 0.1 Joules - 999.9 Joules **UVB**: 1 Millijoule - 9999 Millijoules
Accuracy:	+ / - 5%
Calibration:	1 year or every 100 hours of use

14.7 Changing or Disabling the Unlocking Code

The unlocking code is a safety feature that prevents someone from accidentally turning on or tampering with the device. It works just like a key. To remove the unlocking code feature or to change it to a number that is easier to remember, contact Phothera's service department at 1-216-831-0600 for step-by-step instructions.

14.8 Lamp Removal and Replacement

Lamps may need to be replaced due to burnout or because their energy output has decreased to a point that your treatments may have become excessively long.

DO NOT REPLACE LAMPS INDIVIDUALLY. ALL LAMPS SHOULD BE REPLACED AT THE SAME TIME TO AVOID UNEVEN TREATMENTS OR ERYTHEMA. PLEASE CONTACT THE PHOTHERA SERVICE DEPARTMENT PRIOR TO REPLACING LAMPS TO OBTAIN IMPORTANT INFORMATION ON HOW THE OUTPUT OF THE UNIT WILL BE AFFECTED BY THE CHANGE.

Because of differences between brands, always replace lamps with the same brand as originally installed. Consult the Lamp Specification Guide on page 5 for replacement lamp guidance and contact the Phothera service department for a lamp replacement quote. They can be reached by dialing 1-216-831-0600 or via email at service@phothera.com.

14.8.1 How to Change Lamps

1. First, unplug the device then disconnect the hood cord from the base, and remove the hood. Set it aside.

2. Turning to the base, use a phillips head screwdriver to remove the screw, located at the back of the unit which holds the acrylic shield in place.

3. Slide the acrylic shield forward to remove it from the base.

4. Two clear, plastic clasps hold each lamp in position. To release the lamps from the clasp, place both thumbs on the top of the clasp and use your index fingers to pull the sides of the clasp outward until it releases, and the clasp can be removed.

5. There is a button on top of each lamp-holder that, when pushed, allows removal of the lamp from its lamp-holder. Press the button with one hand and use the other to carefully lift the lamp out of its lamp-holder.

6. To replace the lamps in their lamp-holders, press them straight down. A distinctive snapping sound will be heard which indicates that the lamps are properly seated.

7. To replace the hood lamps simply turn the hood upside down, remove the acrylic shield by removing the 4 screws holding it in place, exposing the hood lamps. Repeat steps 5-8.

8. Once reassembled, reset the lamp hours to zero.

14.8.2 Resetting Lamp Hours

When changing lamps, it is important to reset the lamp age to zero so the new lamp's operating hours can be tracked. Please contact the Phothera service department for instructions on resetting the device's lamp hours.

15.0 Clinical Benefit

UV phototherapy normally consists of two distinct phases: Clearing and Maintenance. The clearing phase increases exposure to the light to the levels required to clear the skin, but over a long enough period to minimize discomfort to the patient. The maintenance phase is employed to extend the benefits of the clearing phase treatment, while limiting total exposure. During the maintenance phase, treatments are normally continued at the last level reached during the clearing phase.

Typically, treatments are very brief and occur about three times a week. Results vary, but psoriasis symptoms commonly begin to improve in as little as 6 -8 treatments; vitiligo usually begins to re-pigment within about 8 weeks. Phototherapy is safe for most patients, including those who are pregnant, elderly or immuno-compromised.

16.0 Cybersecurity

The ClearLink controller is a stand-alone controller. There is no connection, wired or wireless, to any external network and/or the World Wide Web. The controller looks for encrypted .rx files only. All other files are ignored and cannot run. If an .rx file is not present, an encrypted .hst file is written to the USB drive. A J-Link adapter is required to transfer any executable files. The J-Link port is not accessible external to the device.

17.0 Environmental Specifications

The Phothera HF should be used in an electromagnetic environment as described below.

Table 3 Electromagnetic Emissions

Emissions Test	Conformity	EMC Environment Guide
RF Emission Following CISPR 11 (EN 55011)	Group 1	Test unit only radiates RF energy for internal use in powering lamps, and it seems unlikely that nearby medical devices would be affected.
RF Emission Following CISPR 11 (EN 55011)	Class B	The Phothera HF device is suitable for healthcare environment operation in hospitals and clinics
Limits for Harmonic Current Emissions Following IEC 61000-3-2	Class A	The Phothera HF device is suitable for healthcare environment operation in hospitals and clinics
Limits of Voltage Changes, Voltage Fluctuations, and Flicker Following IEC 61000-3-3	Compliant	The Phothera HF device is suitable for healthcare environment operation in hospitals and clinic

Table 4 Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Actual Level
Electrostatic discharge immunity test following IEC 61000-4-2	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)
Radiated, radio-frequency, electromagnetic field immunity test following IEC 61000-4-3	80 MHz to 2.7GHz @ 10.0 V/m	80 MHz to 2.7GHz @ 10.0 V/m

Emissions Test	IEC 60601 Test Level	Actual Level
Electrical fast transient/burst immunity test following IEC 61000-4-4	+/- 2kV	+/- 2kV
Surge immunity test following IEC 61000-4-5	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV
Conducted Immunity test following IEC 61000-4-6	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms
Power frequency magnetic field immunity test following IEC 61000-4-8	50 Hz, 30 A/m	50 Hz, 30 A/m
Voltage dips and interruptions immunity test following IEC 61000-4-11	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees, 100% Interruption at 5000 mS at 0 degrees	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees, 100% Interruption at 5000 mS at 0 degrees

Table 5 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHZ to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. [a] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
a. Field strength from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m			

18.0 Warranty

18.1 Limited Warranty Policy

This Limited Warranty is provided to the original purchaser (the "Purchaser") of the Phothera device (the "Equipment"). Phothera warrants Equipment to conform with the Equipment specifications and be free from defects in material and workmanship during the device Warranty Period. No warranty is made as to useful lamp life or as to reduction in ultraviolet output due to any cause. PHOTHERA MAKES NO OTHER WARRANTIES OF ANY KIND WHATSOEVER TO PURCHASER OR ANY THIRD PARTIES WITH RESPECT TO THE EQUIPMENT AND HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Product	**Warranty Period**
New Equipment	1 Year
Remanufactured Equipment	90 Days
Lamps	90 Days

18.2 Warranty Coverage

This Limited Warranty applies only to Equipment or components found to be defective due to materials and workmanship. This Limited Warranty does not apply when Equipment is purchased for the purposes of renting commercially to customers for home use. This Warranty does not apply to any Equipment which has been used, repaired or altered outside the factory in any way so as to affect the design, or operated in any way other than in accordance with our operating instructions. The Limited Warranty does not apply to Equipment failure or damage caused by shipping or customer abuse, misuse, or accident, incorrect customer installation, improper electrical service, lack of proper maintenance, and Acts of God. This Limited Warranty does not extend to repairs made necessary by use of parts or accessories not recommended by the manufacturer. Phothera shall not be responsible for any indirect, incidental, special, punitive, or consequential damages of Purchaser. Phothera does not provide end support for Microsoft Windows software installed on PCs that are part of a Phothera phototherapy system. PURCHASER'S SOLE REMEDY UNDER THIS LIMITED WARRANTY IS REPAIR OR REPELACMENT OF THE EQUIPMENT.

18.3 Customer Responsibility

In the event that warranty service is requested, the Purchaser must reasonably cooperate with Phothera to verify the warranty claim of the Purchaser, including conducting minor diagnostic work. Failure to participate in diagnostic work may result in being charged for on-site service calls. The Purchaser must allow Phothera, at Phothera's option, to inspect the Equipment or component parts on request.

18.4 Warranty Service

During the warranty period, Phothera will, at Phothera's option, repair or replace any Equipment or components that appear to have been defective in material or workmanship, with new or remanufactured materials. Phothera may require the return of merchandise claimed to be defective for its examination and shall be the sole judge as to whether material is in fact defective under the terms of this Limited Warranty. In such situations, Phothera will cover freight expenses in the continental USA to ship products covered under warranty both to and from Phothera's servicing center if the product fails during the first three months. If the product fails after three months during the warranty period, the customer is responsible for in-bound freight charges while Phothera pays freight charges back to the Purchaser. All Equipment ships ground unless the Purchaser covers costs for expedited shipping.

Phothera is not responsible for any delays occurring during transport of the Equipment.
During the term of the Limited Warranty, Phothera will, at Phothera's option, arrange for a qualified service technician to repair or replace any defective systems or components as covered in accordance with the terms and conditions of this Limited Warranty. It will be at Phothera's sole discretion whether subcontractors or Phothera employed technicians will perform the required warranty service work. However, this Limited Warranty will be declared null and void if non-qualified technicians perform any repair or maintenance on the Equipment unless prior written authorization has been obtained from Phothera. Even with Phothera's authorization, Phothera shall not be responsible or liable for any such work (in or out of warranty). Phothera reserves the right to bill for labor, expenses, and services for requested "warranty" service trips which result in work not covered by this Limited Warranty. This may include, but is not limited to, a tripped circuit breaker, an unplugged machine, or a blown fuse.

18.5 Disposal

Please visit www.Phothera.com and search our FAQ section for disposal instructions for the unit and/or all accessories.

18.6 Other Services

Extended warranties are available and may be purchased from Phothera's aftermarket sales department. In the event that this Limited Warranty conflicts with other warranties included in Phothera's Equipment manual, the terms and conditions of this Limited Warranty shall prevail.

18.7 Contact Information

Phone:	1-216-831-0600 *Press 1 for Daavlin
Fax:	1-419-636-1739
E-Mail:	service@phothera.com
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