Phothera®

Operation Manual

Phothera 600

ClearLink® Controlled

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

Phothera®

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Introduction:
Thank you for selecting the **Phothera® 600 Phototherapy Device.**

The Phothera 600 is manufactured by Daavlin Distributing Co., doing business as Phothera.

Phothera designs and manufactures FDA-cleared prescription phototherapy devices for the treatment of photo responsive skin conditions. This Operator Manual provides essential information for the setup, operation, maintenance, and care of your Phothera 600.

Read this manual carefully before operating the device. Retain this manual for future reference.

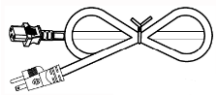
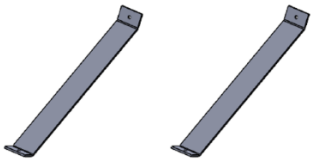
Regulatory Notice:
CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician. All treatments must be administered under the direction of a licensed physician.

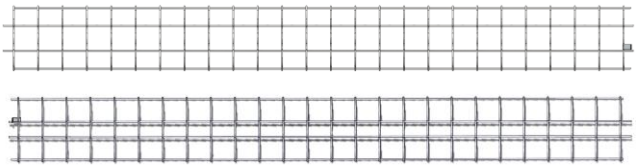
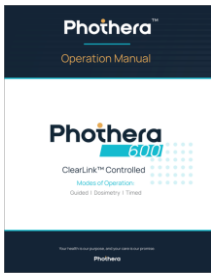
Proprietary Notice:
This document contains proprietary information belonging to Phothera. It is provided for the operation and maintenance of the Phothera 600 Phototherapy Device and may not be reproduced or distributed without written authorization.

1.0 Parts Enclosed

Ensure that the following parts, accessories, and documentation are accounted for:

Table 1 Accessories and Documentation

Protective Goggles (QTY: 1)  PN: 913GR or 913AM	**Power Cable (QTY: 1)**  PN: 072HGPWRCBL18AWGRA
Foot (QTY: 2)  PN: 550LS9	**Stabilizer Bracket (QTY: 2)**  PN: 567SB

Grid (QTY: 2 or 4)	Operation Manual (QTY: 1)
 PN: 100GD7SER2LA or 100GDFITCH3LA	 PN: MNL-00057

Note: *Depending on the number of lamps in the received device, the grid will differ.*

- *If the device received has 4 lamps and no doors, 2 of the 2-lamp grid (100GD7SER2LA) will be received in the device.*
- *If the device received has 6 lamps and no doors, 2 of the 3-lamp grid (100GDFITCH3LA) will be received in the device.*
- *If the device received has more than 6 lamps and doors, the 3-lamp grid (100GDFITCH3LA) will be received alongside the device.*

2.0 Delivery and Inspection

Upon delivery, inspect the shipping container and contents for damage. If damage is discovered:

- Retain all packaging materials
- Contact Phothera Customer Service (*see 24.7* Contact Information)

3.0 Device Placement

To help protect you, your home, and the device, is it recommended to place your device:

- Within reach of a grounded electrical outlet
- Protected from exposure to moisture
- Free of foot traffic and obstruction
- Prevents any unintended exposure to other people and pets

Prolonged ultraviolet exposure may cause fading or discoloration of nearby furnishings, wall coverings, or flooring.

The Phothera 600 is supplied with a standard three-pronged power cord - Connect only to a properly grounded household electrical outlet.

For optimal treatments, it is recommended your device be maintained in a temperature-controlled space that is between 59°F to 86°F and humidity to be between 10%-95%.

4.0 Unpacking and Assembly

WARNING: Fluorescent lamps may break if the device is not unpacked properly. Handle the device with care during unpacking and assembly.

For a step-by-step guide on how to unbox and set up your device, simply scan the QR code to the right on your mobile device or you can search for "Phothera 600 How To: Unbox and Set Up Your Device" on our YouTube page at https://www.youtube.com/@Phothera.

Note: *The Phothera 600 can weigh as much as 135 pounds (61 kilos). Always use two or more people when lifting the unit. Practice safe lifting techniques.*

Note: *Units with more than 4 lamps: The grid that will cover the lamps is not installed for shipping. When the box is unpacked, the grid will be on top and should be set aside so that it can be installed after the unit is standing.*

Note: *If device has already been unpackaged, skip to step 6.*

1. Place the shipping box/crate on the floor with the **bottom facing upward.** Ensure there is adequate space around the box for unpacking.
2. Cut the sealing tape using a knife or scissors and allow the bottom flaps to loosen.
3. Carefully flip the box upright so the flaps can be opened from the top.
4. Remove the top of the box/crate and set it aside. Using at least two people, lift the device, including the foam shock absorbers, from the box and lay it on its side. Do not remove the foam shock absorbers yet.
5. Remove all the packing material from the container. Ensure that the following parts and accessories are accounted for:
    a. **Protective Goggles** (1 pair)
    b. **Feet (2),** found in the top and bottom Foam shock absorbers or taped to inside of cardboard crate.
    c. **Stabilizer Bracket (2),** found in the middle shock absorber or taped to inside of cardboard crate.
    d. **Grid** (attached in units without doors)
    e. **Power Cord**
6. The screws to attach the feet are pre-inserted in the bottom of the unit at the factory – remove the top and bottom foam shock absorbers to locate the end of the device that has screws protruding (Units with doors: screws protrude from metal bracket); this is the bottom of the device. Using a #3 Phillips screwdriver, remove the screws, then position the first foot so that its "longer" side is toward the front (the lamp side of the device – see Figure 1 Feet Installation) and the side of the foot with the rubber pads is towards the floor. Mount the feet using the screws that were removed from the bottom of the device. Repeat the process for the second foot. Do not overtighten screws.

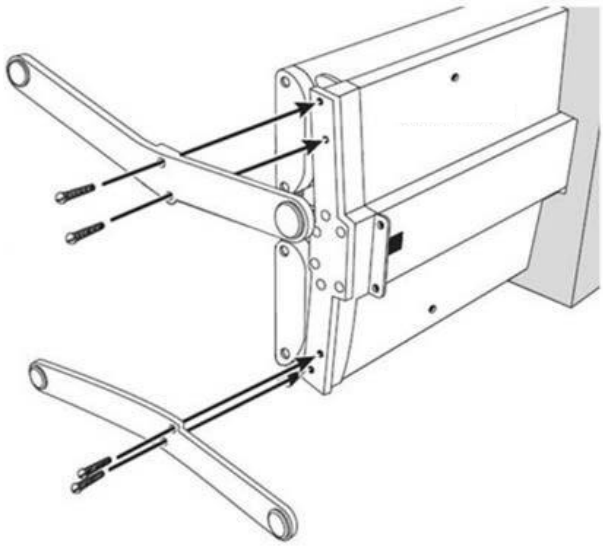


Figure 1 Feet Installation

7. Leaving the device on its side but with its feet attached, tilt it upright until both feet are on the floor.
8. Remove the foam shock absorbing pieces from the middle of the unit (Units with 4 lamps: ensure the stabilizers have been gathered from the foam).
9. Mount the two stabilizer brackets using the screws that are pre-inserted 14" (35cm) from the bottom of the unit and in each foot. Each stabilizer mounts to one foot and to the back side of the device. Locate the screw holes – they will be under a piece of masking tape on the foot and the back of the device. Using a #2 Philips screwdriver, remove the screws from the feet and the back of the device, position the holes in the brackets with the holes in the back of the unit and on the foot, and then reinsert the screws. Tighten completely.

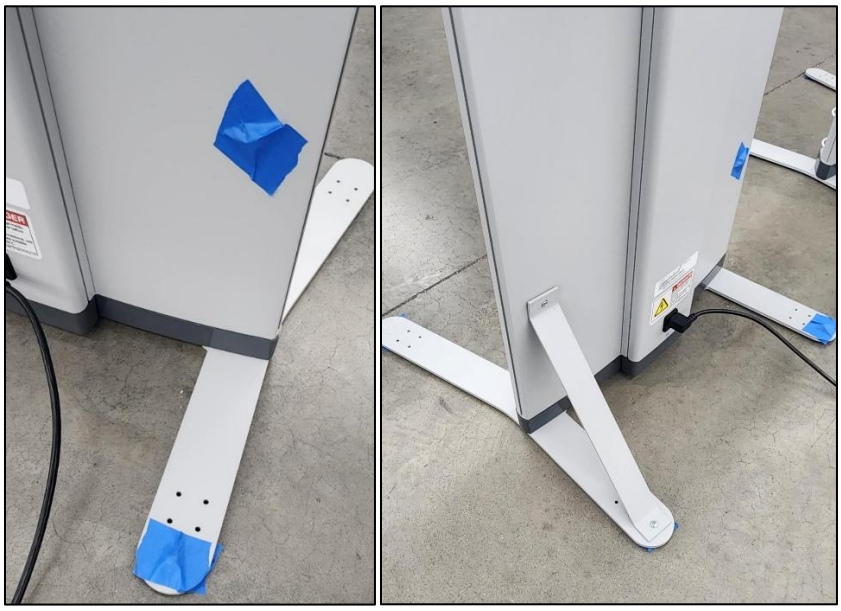


Figure 2 Left – Stabilizer screws covered by tape. Right – Stabilizer mounted.

10. Gently slide the unit into its permanent location.
11. Units with more than 4 lamps: Remove the screws at the bottom of the device in front of the lamps (Units without doors: 2 screws total, units with doors:4 screws total). Insert the perpendicular grid wires into the holes in the top lamp plate and push the grid all the way up. Swing the bottom of the grid in toward

the lamps and insert the grid wires into the two holes in the bottom lamp plate. Then, lower the grid until the bracket touches the bottom lamp plate. Using a 5/16" hex driver/socket, screw the bracket to the bottom lamp plate using one of the hex-headed, self-tapping screws provided.

12. Insert the male "D" shaped plug into the "D" shaped receptacle at the back of the device. Then, plug the unit into an appropriate, grounded electrical receptacle.

5.0 Precautions & Warning

1. General Warnings

- Do not use this device for anything other than its intended purpose. All treatments must be administered under the direction of a licensed physician only. This device is only to be used by authorized users. Do not use the device while distracted.
- Prior to each use, always verify that the device is in correct working order and operating condition. Plugs, sockets, lamps, electrical cables, and connections should not be worn or damaged. Do not operate this device with a damaged cord or plug.
- Only original components and accessories should be used with the device to avoid damage.
- 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's glass lamps and touch screen control system display are susceptible to damage from excessive force. Avoid excessive force to prevent damaged or broken glass.
- Do not treat if the lamps fail to ignite. Consult with doctor and/or contact customer service. *(See 24.7* 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 customer service. (See 24.7 Contact Information*).*
- **NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED**. Unauthorized modification will void the warranty and may result in hazardous or improper device operation.

2. Optical and Medical 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.
- All other people and pets should leave the area to avoid unwanted exposure to ultraviolet light.
- If psoralens (photosensitizing drugs) are being used as part of the treatment, the 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 UV lamps.
- Lip balm and/or sunscreen with **SPF ≥ 30** should be applied to non-treated areas as directed by your healthcare provider.
- Do not use over skin eruptions without express consent from your doctor.
- Unaffected body parts that are not to be treated must be shielded from UV light (clothing, towels, etc.).
    - If you are experiencing Erythema (reddening of the skin), do not start treatment until the noticeable effects subside, and always reduce the future treatment time.
    - 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 device, contact your prescribing physician for specific treatment instructions and dosing information**.**
- Center body between the lamps during treatment to avoid over exposure to isolated areas of the body.
- **Caution** – Use of controls or adjustments or performance of procedures other than those specified herein result in HAZARDOUS radiation exposure.

- **WARNING**: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- **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. Patient should inform physician before using this device if using medications or if patient has a history of skin problems or sensitivity to light.
- **C**arcinogen: Wu YH et al (2022) concluded that the findings of this systematic review and meta-analysis (n=228,607) suggest that UV phototherapy is a safe treatment for vitiligo with no significant risk of skin cancer.

3. Electrical and Radio Frequency (RF) Warnings

- If using a power strip as the main point of disconnect, do not position the device so that the switch on the power strip is difficult to access. Ensure the device can be unplugged from the point of disconnect. If necessary, operation of equipment may be terminated by unplugging device.
- 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.
- 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 the operator should follow the remedies found under EMC Precautions. If the device continues to malfunction cease operation and contact customer service. *(See 24.7* Contact Information*).*
    - This device should be a minimum of 12 inches (30 cm) away from RF generating equipment.
    - Device is not to be used in MR environments that may include MRI, diathermy, electrocautery, or other high frequency equipment.

6.0 Operating Specifications

For optimal treatments, it is recommended your device be maintained in the following

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

7.0 Quick Start Guide: Control Type

The Phothera 600 phototherapy unit is equipped with Phothera's ClearLink® Control System. The device was prescribed to function in only one of the following modes:

● **Guided Mode:** The system controls the beginning dose and all future doses depending upon how the users' skin responds to the therapy. Guided Mode is designed to provide the highest level of safety and consistency.

● **Dose Entry Mode:** The user enters the prescribed dose in millijoules (UVB). The system automatically calculates treatment time based on lamp output.

● **Time Entry Mode:** The user enters the prescribed dose in time (minute:second). The system follows this time for the dose.

7.1 Quick Start Guide: Device Unlocking and Activation

Touch the screen and the Phothera logo will appear. Tap the number 7 followed by the blue right arrow to unlock the device.

Upon powerup, the device may need to be activated. The following screen will appear ***(*Figure 3*).*** Enter the setup/refill code provided by the prescriber to activate the device.

For more detailed instructions see *section 8.3 Activating Device with Setup/Refill Codes*.

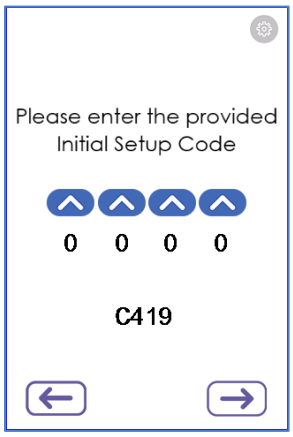


Figure 3 Initial Setup Code Screen

Upon activation, or if device was activated at the factory, one of the screen below ***(*Figure 4***Error! Reference source not found.)*** will be displayed – tap the button to confirm:

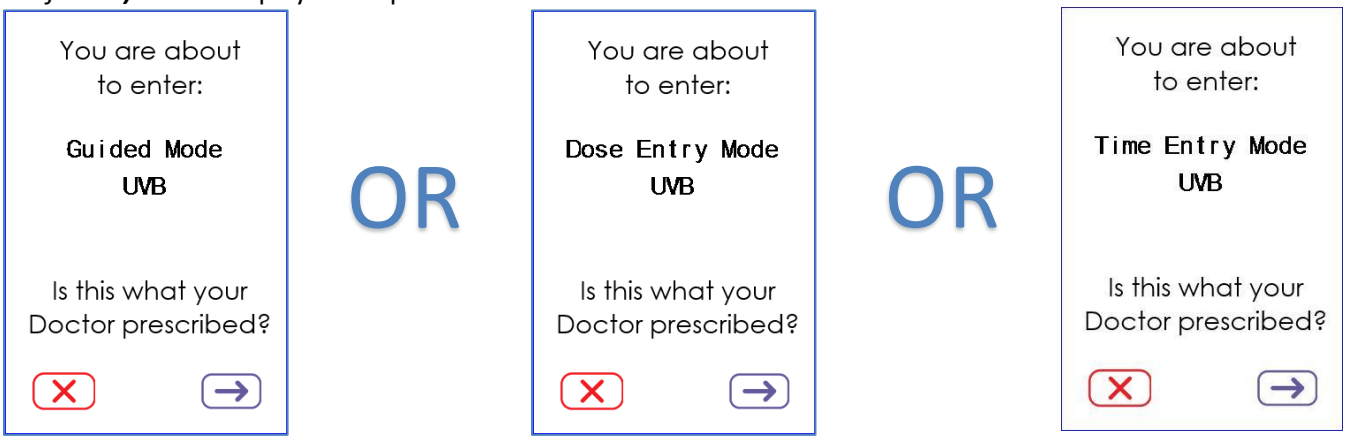


Figure 4 Operation Mode Confirmation Screens

NOTE: If your device needs activation, and a code was not provided, contact your prescriber.

7.1.1 Quick Start: Guided Mode

1. Unlock the device
2. Review the scheduled dose displayed.
3. Respond to the “red or in pain” skin-response prompt ().
4. Confirm dose.
5. Put on protective eyewear.
6. Press **Enter** to begin treatment.
7. Maintain 9-inch distance for body
8. Lamps activate after 5 second delay and turn off automatically at completion.

See *section 9.0 Guided Mode* for detailed instructions on Guided Mode operation.

7.1.2 Quick Start: Dose Entry Mode

1. Unlock the device.
2. Press **Treat Patient.**
3. Enter dose in millijoules.
4. Confirm dose.
5. Put on protective eyewear.
6. Press **Enter** to begin treatment.
7. Maintain 9-inch distance for body
8. Lamps activate after 5 second delay and turn off automatically at completion.

See *section 10.0 Dose Entry Mode* for detailed instructions on Dose Entry Mode operation.

7.1.3 Quick Start: Time Entry Mode

1. Unlock the device.
2. Press **Treat Patient**
3. Enter dose in time (minute:second)
4. Confirm dose
5. Put on protective eyewear
6. Press **Enter** to begin treatment
7. Maintain 9-inch distance for body
8. Lamps activate after 5 second delay and turn off automatically at completion.

See *section 11.0 Time Entry Mode* for detailed instructions on Time Entry Mode operation.

8.0 General Instructions (for all ClearLink® Control Types)

8.1 Pre-treatment Preparations

Before initiating therapy:

- Review all instructions with the prescribing physician.
- The prescribing physician is the final authority for treatment protocol and may modify instructions based on patient response.

- Always follow the physician's prescribed treatment plan.

The ClearLink® Controller automatically records treatment data. Patients or caregivers may optionally maintain a treatment log to record:

- Date of treatment
- Delivered dose or time
- Skin response
- Notes (e.g., missed sunscreen, sensitive areas)

8.2 Unlocking the Device using Security Code

To prevent unauthorized use, the device will self-lock when left idle for twenty (20) minutes. A security code must be entered before access to the device is permitted.

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 (Security Code).
    a. PIN will read as "0007".
4. Press the Enter key → to unlock.

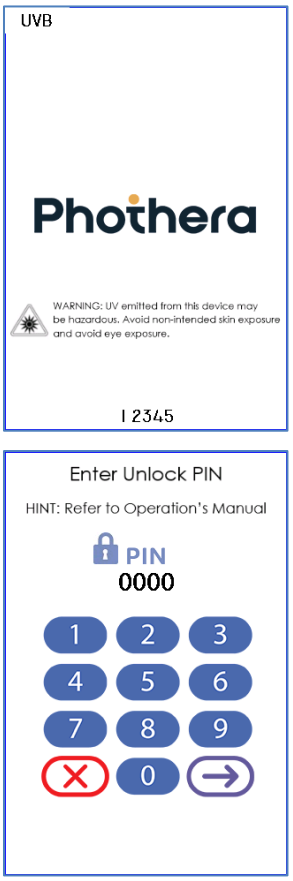


Figure 5 Lock Screen

5. If the device has been activated, it will unlock to the Operation Mode screen (Guided Mode or Dose Entry Mode – see **Figure 6**), otherwise, see *section 8.3 Activating Device with Setup/Refill Codes*.

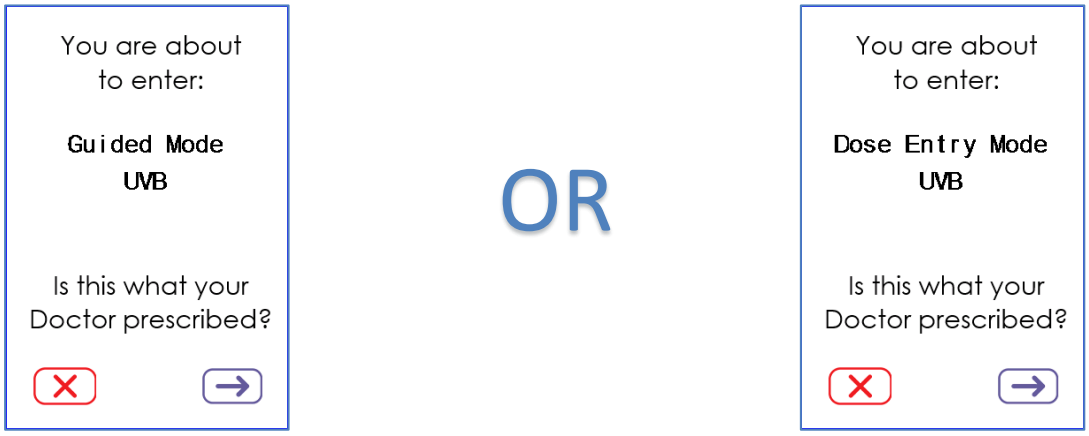


Figure 6 Operation Mode Confirmation Screens

8.3 Activating Device with Setup/Refill Codes

If this screen appears (), your provider will be giving you additional information about your treatments. With that information, a 4-digit code will be provided that will unlock your device. Review the documentation from your provider and enter the 4-digit code to activate your device. Use the arrows to enter the setup/refill code. Tap the key to enter the code to the controller.

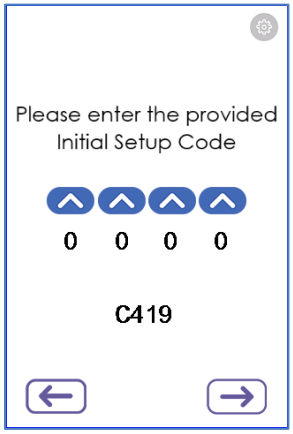


Figure 7 Initial Setup Screen for Locked Devices

**Note – the C419 code shown may vary. Ensure that this CXXX code is given to the prescribing physician when requesting new refill codes. The refill codes will not work if the prescribing physician is not given the correct code as displayed on the controller.*

8.4 How to Position Yourself

- The recommended treatment distance is **9 inches (22 cm)** from the lamps.
- Mark this distance on the floor *(see* Figure 9*)*.
- Standing closer than 9 inches may cause localized burning.
- Standing farther away reduces treatment effectiveness.
- Consistent body positioning is key to successful treatment.

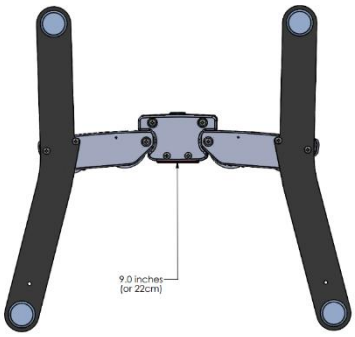


Figure 8 Marking a 9" point from the center of the device

8.5 Common ClearLink® Functions

The system beeps to signal the end of the treatment and displays the delivered dose with the elapsed time.

When the treatment is confirmed, the user will be taken to a treatment confirmation page which displays the entered dose for confirmation and warns the user to put on goggles. After confirming the treatment, there will be a 5 second delay to allow the user to position themselves. *(see **Figure 9**)*

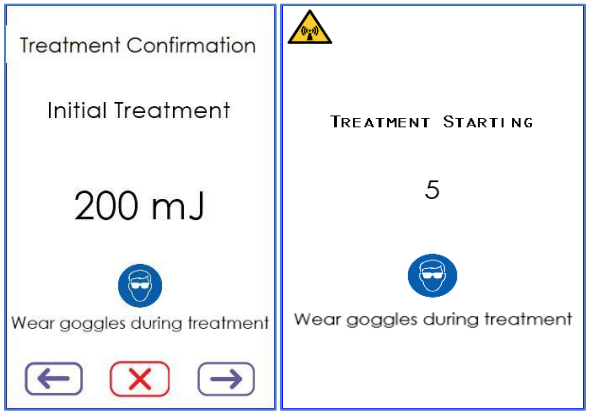


Figure 9 Treatment Confirmation and Start Delay

The system keeps track of how much of the treatment has elapsed. If the controller suddenly shuts down during a treatment (power outage of any kind) the treatment dose and elapsed time are remembered. When power is restored, the controller will start, however, the lamps will not automatically turn on. To resume the treatment where it left off, press the Play button.

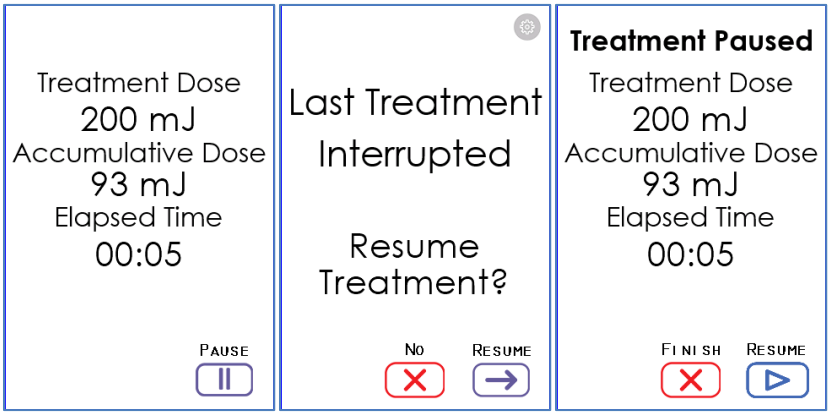


Figure 10 Treatment Interrupt Screens

To cancel a treatment, the active treatment must be paused using the Pause button. The Pause button will change to the Play button and a red X button (cancel) will appear *(see **Figure 11**)*. Press this cancel button to be prompted to cancel the treatment.

Figure 11 Cancel Treatment Screen

8.6 Post-Treatment

After a treatment, protect any areas that feel sunburned with sunscreen for the next several exposures or until they appear normal. (Make a note in the notebook.) A physician should be seen at the intervals he or she requests when actively using the device. Always take the notebook when seeing the prescribing physician.

The standard treatment schedule is three times per week with about 48 hours between treatments (i.e. Monday-Wednesday-Friday). Follow this schedule unless otherwise directed by your physician.

8.7 Treatment Limiting Software (Rx)

If the device was prescribed with exposure-limiting software, a screen ***(Figure 12)*** will say how many exposures remain before a refill prescription is needed. This information can also be found on the ClearLink® controller in Machine Info under Treatments Remaining. See 8.8 Uploading Refill Prescriptions for refill instructions.

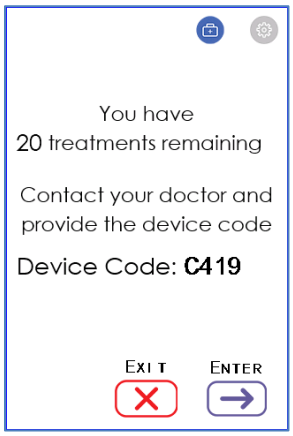


Figure 12 Treatment Remaining Screen

8.8 Uploading Refill Prescriptions

If the device is equipped with treatment limiting software, upon "waking up", the screen will display pre-set reminders of how many exposures are remaining. To ensure there are no interruptions in therapy, we suggest that the physician be contacted and given the device code (CXXX) when 20 exposures remain. The physician will use this device code to generate a refill or "treatment" code for a refill. Once out of exposures, the controller will prompt a new prescription be uploaded (*see **Figure 13***). If the refill code is entered before all treatments are used, some treatments may be lost. Refill code will set controller to a round number (100, 250, etc).

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

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

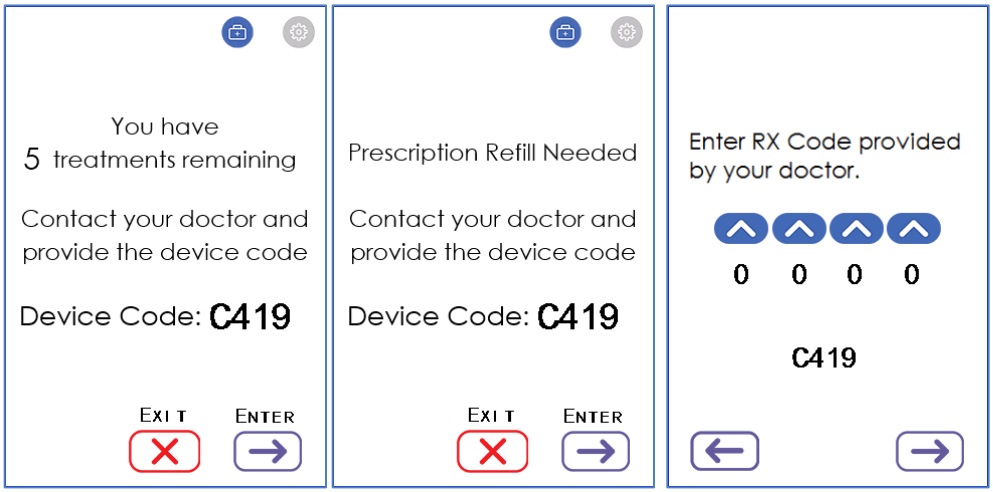


Figure 13 Treatment Refill Screens

8.9 Treatment Repeats

A treatment may also be considered a "treatment sequence", where the primary exposure (1st exposure) plus any additional exposures (repeats) will all be considered as the same treatment. 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 prescribed by the physician, for treating other areas of the body.
Note: Treatment repeats are to be performed under the instructions of the physician only.

Do NOT treat the same area twice in one session.

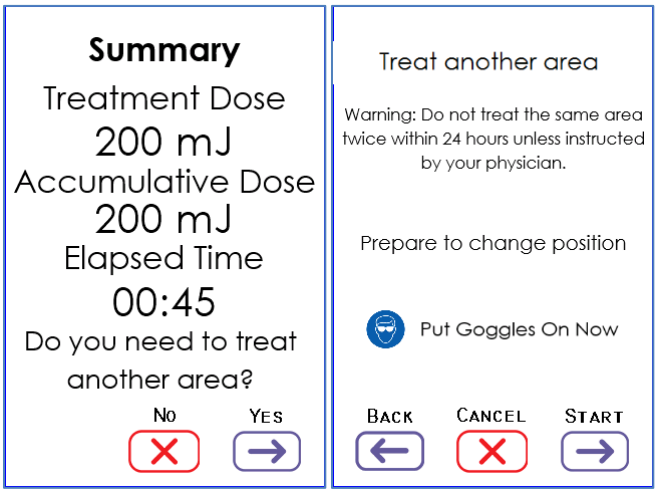


Figure 14 Repeat Treatment Screens

9.0 Guided Mode

If your device has either of these screens ***(Figure 15)*** displayed, your device has been set to deliver treatments in Guided Mode. Tap the blue right arrow to confirm.

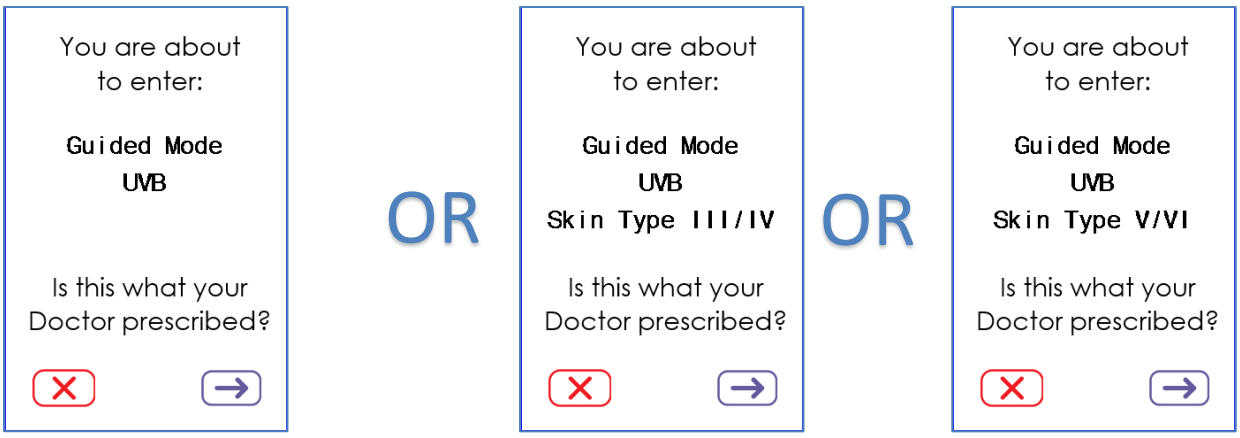


Figure 15 Guided Mode confirmation screens

9.1 Features of ClearLink® Guided Mode

The ClearLink® Guided Mode automatically performs many safety checks on behalf of the user, as well as calculating dose increases based on the treatment schedule and how the users' skin responds to treatment.

For example, each time the device is used, the Guided Mode software will check the date of the last treatment. If on schedule, it will automatically proceed. However, if one or multiple treatments have been missed, the system will adjust accordingly to keep the dose at a safe level. A screen will appear advising the user of the adjustment ***(Figure 16)***.

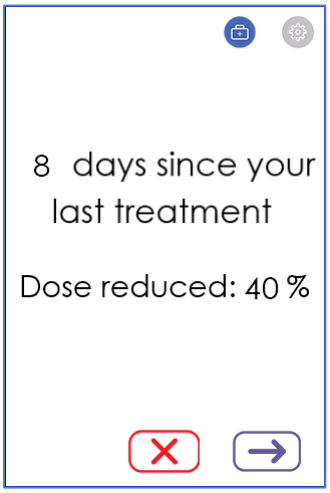


Figure 16 Treatment Reduction Screen

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

Finally, before each treatment, Guided Mode will ask about the current condition of the user's skin, such as whether or not there is any redness, mild or otherwise. It will use this information to calculate the next dose.

Keep in mind, it is normal to experience some “redness” within 8 – 12 hours of a treatment but it is typically gone before it is time for the next treatment.

If the physician suggests that the dose be lowered, it can be done using the  and  buttons, **but the controller will not allow a dose to be lowered beyond the starting dose or raised beyond the protocol requirements for percent increases**.

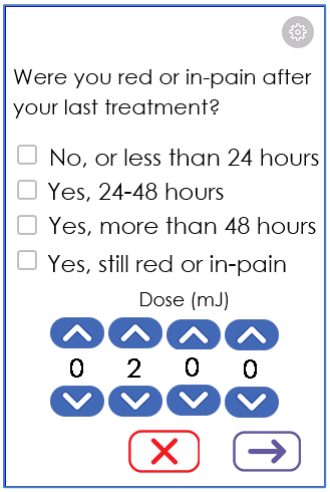


Figure 17 Guided Mode Prompts

9.2 Running a Treatment (Guided Mode)

1. Unlock the device.
2. Review the scheduled dose displayed.
3. Respond to the “red or in pain” skin-response prompt ***(Figure 17).***
4. Confirm dose.
5. Put on protective eyewear.
6. Press **Enter** to begin treatment.
7. Maintain 9-inch distance for body
8. Lamps activate after 5 second delay and turn off automatically at completion.

- **No or less than 24 hrs**
  → Increases dose by 15%
- **Yes, for 24 to 48 hrs**
  → Repeat previous dose
- **Yes, for more than 48 hrs**
  → Decreases dose by 15%
- **Still red / pain present**
  → Dose is decreased by 30% and device locks until one treatment is skipped

9.3 Treatment Lockouts

After a treatment sequence is complete or the red X is selected to end treatment, the device enforces a **16-hour lockout** to prevent premature advancement. There is no override of this status, so the patient must wait 16 hours until the next treatment session is permitted.

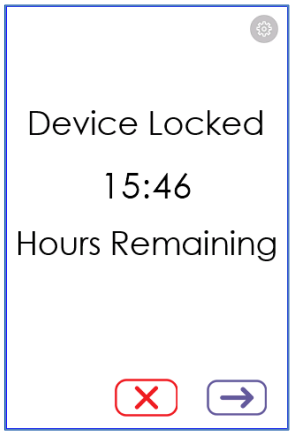


Figure 18 Treatment Lockout Screen

10.0 Dose Entry Mode

If your device has displayed this screen ***(Figure 19)***, your device has been set to deliver treatments in Dose Entry Mode using integrating dosimetry to deliver real time updates from the sensor to the controller. Tap the blue right arrow to confirm. If you don't believe your device should be in Dose Entry mode, contact customer service *(see 24.7* Contact Information*).*

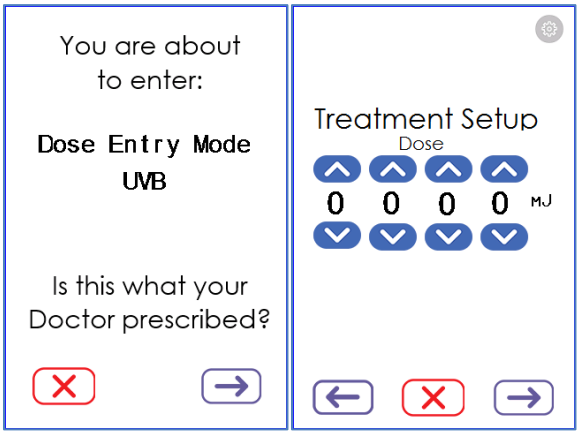


Figure 19 Dose Entry Mode Confirmation and Treatment Setup Screens

10.1 Features of ClearLink® Dose Entry Mode

- User enters prescribed dose
- Integrated sensor adjusts treatment time automatically
- Compensation for lamp aging and environmental conditions

10.2 Running a Treatment (Dose Entry Mode)

1. Unlock the device.
2. Press **Treat Patient**.
3. Enter dose in millijoules.
4. Confirm dose.
5. Put on protective eyewear.
6. Press **Enter** to begin treatment.
7. Lamps turn off automatically at completion.

Repeat, pause, and cancel functions operate as described in *Section 8.5* Common ClearLink® Functions.

11.0 Time Entry Mode

If your device has displayed this screen (Figure 20), your device has been set to deliver treatments in Time Entry Mode. Tap the blue right arrow to confirm. If you don't believe your device should be in Time Entry mode, contact customer service *(see 24.7* Contact Information*).*

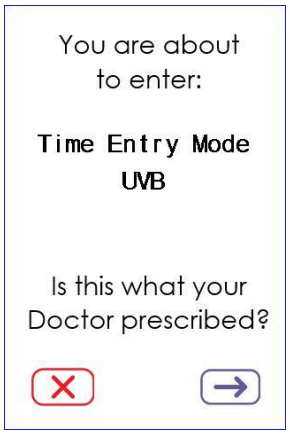


Figure 20 Time Entry Mode Confirmation and Treatment Setup Screens

11.1 Features of ClearLink® Time Entry Mode

- User sets the exposure time in the controller based on the factory-calibrated lamp output to achieve the required dose.

11.2 Running a Treatment (Time Entry Mode)

1. Unlock the device.
2. Press **Treat Patient**
3. Enter dose in time (minute:second)
4. Confirm dose
5. Put on protective eyewear
6. Press **Enter** to begin treatment
7. Lamps turn off automatically at completion

Repeat, pause, and cancel functions operate as described in *Section 8.5 Common ClearLink® Functions.*

12.0 Time-Based Output/Fixed Output Mode

ClearLink® devices support Guided Mode with Time-Based Dosing, which calculates treatment time using characterized device output. This mode also supports patient response-based dose adjustment to assist in guiding dose delivery. While this is enabled, a pushpin icon is displayed in the upper right corner of the Treatment Confirmation screen and remains visible while performing treatments.

13.0 Care of the Device

13.1 Recommended Maintenance Schedule

Table 2 Maintenance Schedule

Item / Action	Frequency
Dusting of the device and lamps	Once a month
Fully clean all internal reflectors, lamps	Annually (behind the lamps)
Replace lamps	***UVB – Approximately** every 300 hours of use.

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

13.2 Cleaning/Disinfection

13.2.1 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.

13.2.2 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 material and can be seen in Table 3 Tested Cleaners.

Table 3 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

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

13.2.3 High-Level Disinfection

Follow a high-level disinfection practice between the use of the device if you plan to have patients use the same device. Use a high-level disinfectant, such as Steris Corporation®'s Resert™ XL-HLD, and follow the manufacturer's 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

Note: *Do not clean reflective surfaces with paper towels as they may scratch the surface.*

13.3 Lamp Replacement and Removal

Do not replace lamps individually!

- All lamps must be replaced simultaneously.
- Use only the same brand and specification originally installed.
- Contact Phothera Customer Service to order replacement lamps.

Lamp replacement may be required due to burnout or reduced output causing excessive treatment times.

13.3.1 Lamp Replacement

1) When replacing the lamps, unplug the device, then, using either a 5/16" hex driver/socket or a #2 Phillips-head screwdriver, remove the screw from the bottom of the grid.
2) Lift the grid out of its holes in the bottom lamp plate, pull the bottom of the grid forward, then slide it out of the holes in the top of the device and set it aside.
3) Grasp the lamp to be removed with both hands and press down until it clears the top socket, then remove the lamp. Reverse the process to re-install the lamps and grid.
4) Once reassembled, reset the lamp hours to zero. See section *13.3.2 Resetting Lamp Hours*

13.3.2 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 customer service department at https://support.phothera.com/support/home for instructions on resetting the device's lamp hours.

14.0 Troubleshooting

Table 4 Troubleshooting Problem Resolution

Problem	Resolution
No power to screen	-Ensure power cord plugged into working outlet & device -Ensure On/Off button fully engaged -Check for blown fuse and contact Customer Service
Unlocking code not working	-Ensure code 0007 is being entered -If you see CXXX, you need a refill code. -Contact Phothera Support
Lamp(s) fail to ignite	-Ballast may be faulty -Lamp(s) may be faulty -Lamp(s) may not be seated properly in socket

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 contains embedded software designed to run on its own built-in software and does not connect to the internet.

- No user-installed software is permitted.
- Unauthorized access or modification is prohibited.
- Software updates are provided only by Phothera.

17.0 Output Spectrum

The treatment light on this device will be generated by a 100-Watt T12 low-pressure mercury vapor fluorescent lamp.

17.1 Narrowband Ultraviolet B (NB-UVB)

For NB-UVB devices, the light emitted is in the UVB band with a primary emission range of 310 – 315 nanometers. The output spectrum of the system is shown in **Figure 22.** Some of the light outside the 310 – 315 nm peak emission range is typical for these types of systems and does not affect safety or efficiency.

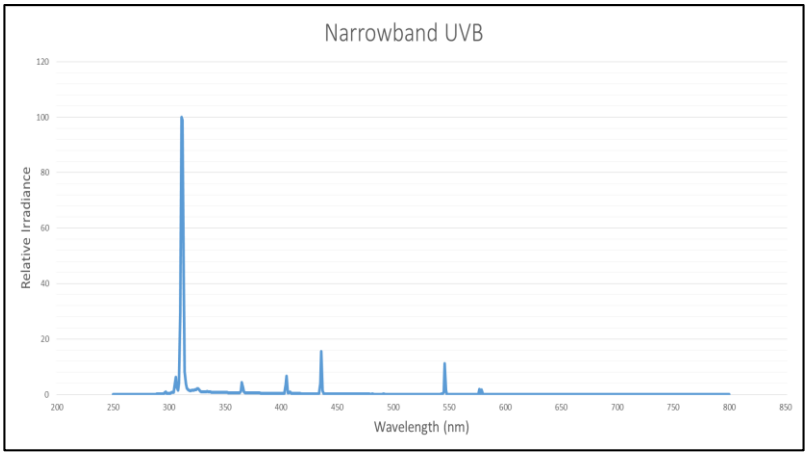


Figure 21 Narrowband UVB Spectrum

The power output of the prescribed device is dependent on the style and quantity of lamps contained within the device. The power output of the device is fixed and cannot be altered by the user.

Table 5 Power Output

Lamp Style:	100W T12 NBUVB				
	4 Lamp	**6 Lamp**	**8 Lamp**	**10 Lamp**	**12 Lamp**
Minimum Output:	9" Away: 2.0 mW/cm² (+/- 10%)	9" Away: 3.5 mW/cm² (+/- 10%)	9" Away: 3.0 mW/cm² (+/- 10%)	9" Away: 3.5 mW/cm² (+/- 10%)	9" Away: 4.0 mW/cm² (+/- 10%)
Maximum Output:	9" Away: 8.0 mW/cm² (+/- 10%)	9" Away: 12.0 mW/cm² (+/- 10%)	9" Away: 9.0 mW/cm² (+/- 10%)	9" Away: 12.0 mW/cm² (+/- 10%)	9" Away: 12.0 mW/cm² (+/- 10%)

The power output of the device was measured before it left Phothera's manufacturing facility. This value is fixed and cannot be altered by the user. The table below represents the possible output range of the device. (A "Calibration/Output Certificate" which contains the device's factory measured power output may be provided upon request).

17.2 Broadband Ultraviolet B (BB-UVB)

For BB-UVB devices, the light emitted is in the UVB band with a primary emission range of 285 – 350 nanometers. The output spectrum of the system is shown in **Figure 23.** Some of the light outside the 285 – 350 nm peak emission range is typical for these types of systems and does not affect safety or efficiency.

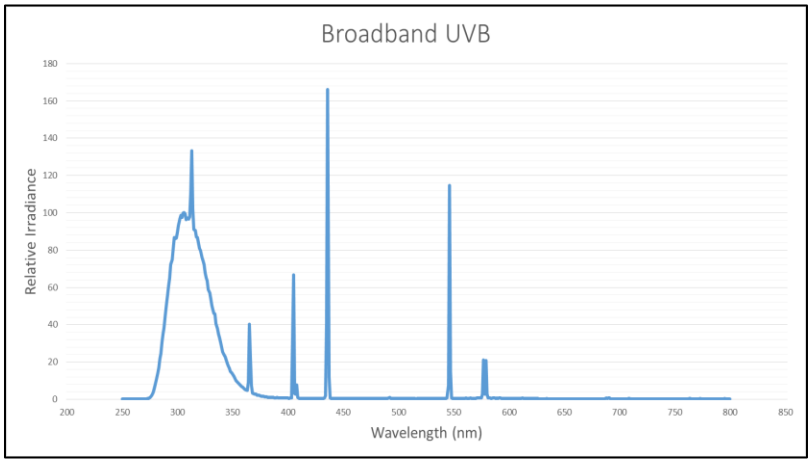


Figure 22 Broadband UVB Spectrum

The power output of the prescribed device is dependent on the style and quantity of lamps contained within the device. The power output of the device is fixed and cannot be altered by the user.

Table 6 Power Output

Lamp Style:	100W T12 BBUVB				
	4 Lamp	6 Lamp	8 Lamp	10 Lamp	12 Lamp
Minimum Output:	9" Away: 1.5 mW/cm² (+/- 10%)	9" Away: 2.5 mW/cm² (+/- 10%)	9" Away: 2.0 mW/cm² (+/- 10%)	9" Away: 2.5 mW/cm² (+/- 10%)	9" Away: 3.0 mW/cm² (+/- 10%)
Maximum Output:	9" Away: 3.0 mW/cm² (+/- 10%)	9" Away: 4.5 mW/cm² (+/- 10%)	9" Away: 3.5 mW/cm² (+/- 10%)	9" Away: 4.5 mW/cm² (+/- 10%)	9" Away: 4.5 mW/cm² (+/- 10%)

The power output of the device was measured before it left Phothera's manufacturing facility. This value is fixed and cannot be altered by the user. The table below represents the possible output range of the device. (A "Calibration/Output Certificate" which contains the device's factory measured power output may be provided upon request).

17.3 Ultraviolet A (UVA)

For UVA devices, the light emitted is in the UVA band with a primary emission range of 320 – 400 nanometers. The output spectrum of the system is shown in **Figure 24.** Some of the light outside the 320 – 400 nm peak emission range is typical for these types of systems and does not affect safety or efficiency.

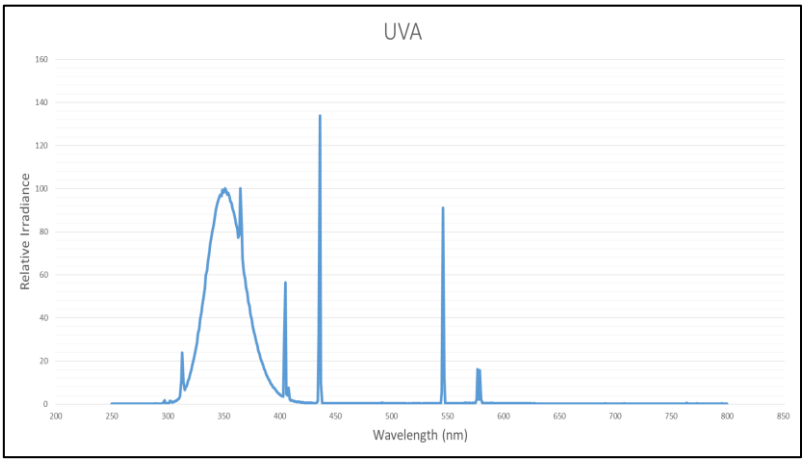


Figure 23 UVA Spectrum

The power output of the prescribed device is dependent on the style and quantity of lamps contained within the device. The power output of the device is fixed and cannot be altered by the user.

Table 7 Power Output

Lamp Style:	100W T12 UVA				
	4 Lamp	6 Lamp	8 Lamp	10 Lamp	12 Lamp
Minimum Output:	9" Away: 3.5 mW/cm² (+/- 10%)	9" Away: 7.0 mW/cm² (+/- 10%)	9" Away: 4.5 mW/cm² (+/- 10%)	9" Away: 7.0 mW/cm² (+/- 10%)	9" Away: 7.5 mW/cm² (+/- 10%)
Maximum Output:	9" Away: 7.0 mW/cm² (+/- 10%)	9" Away: 15.0 mW/cm² (+/- 10%)	9" Away: 8.0 mW/cm² (+/- 10%)	9" Away: 15.0 mW/cm² (+/- 10%)	9" Away: 15.0 mW/cm² (+/- 10%)

The power output of the device was measured before it left Phothera's manufacturing facility. This value is fixed and cannot be altered by the user. The table below represents the possible output range of the device.

- A “Calibration/Output Certificate” which contains the device’s factory measured power output may be provided upon request.

17.4 Accuracy/Range

Table 8 ClearLink Controller Accuracy and Dose Range

Dose Range:	UVB: 1 Millijoule - 9999 Millijoules
Dose Accuracy:	± 10%
Timer Accuracy:	±5% in a 10-minute treatment time

The integrating dosimeter will maintain a 10% level of accuracy if the device is calibrated at least annually in a clinical environment, whenever lamps are replaced, or every one hundred (100) hours, whichever occurs sooner. The calibration process involves taking an output reading with a hand-held meter (available for purchase or rent from Phothera) and checking it with the output reading from the integrating dosimetry system. Please contact customer service. *(See 24.7* Contact Information*)* for calibration assistance.

18.0 Environmental Specifications

The Phothera 600 should be used in an electromagnetic environment as described below.

Table 9 Electromagnetic Emissions

Emissions Test	Conformity	EMC Environment Guide
RF Emission Following CISPR 11 (EN 55011)	Group 1	Test device 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 device is suitable for healthcare environment operation in hospitals and clinics
Limits for Harmonic Current Emissions Following IEC 61000-3-2	Class A	The device is suitable for healthcare environment operation in hospitals and clinics
Limitation of Voltage Changes, Voltage Fluctuations, and Flicker Following IEC 61000-3-3	Compliant	The device is suitable for healthcare environment operation in hospitals and clinic

Table 10 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 @ 3.0 V/m
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, 60 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 20mS at 0 degrees. 100% Interruption at 5000 mS at 0 degrees

Table 11 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level
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

Electromagnetic environment - guidance

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.

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.

19.0 HIPAA Privacy Statement

HIPAA Privacy Policy:
THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.
The Health Insurance Portability & Accountability Act of 1996 ("HIPAA") is a federal program that requires that all medical records and other individually identifiable health information used or disclosed by us in any form, whether electronically, on paper or orally, are kept properly confidential. This Act gives you, the patient, significant new rights to understand and control how your health information is used. "HIPAA" provides penalties for covered entities that misuse personal health information.

Uses and Disclosures

Treatment: Your health information may be used by staff members or disclosed to other health care professionals for the purpose of evaluating your health, diagnosing medical conditions, and providing treatment.
Payment:. Your health information may be used to seek payment from your health plan, from other sources of coverage, or from credit card companies that you may use to pay for services. For example, your health plan may request and receive information regarding the medical condition being treated.
Health care operations: Your health information may be used, as necessary, to support the day-to-day activities and management of Daavlin. For example, information on the equipment you received may be used to support budgeting and financial reporting, and activities to evaluate and promote quality.
Law enforcement: Your health information may be disclosed to law enforcement agencies to support government audits and inspections, to facilitate law-enforcement investigations, and to comply with government-mandated reporting.
Other uses and disclosures require your authorization. Disclosure of your health information or its use for any purpose other than those listed above requires your specific written authorization. If you change your mind after authorizing a use or disclosure of your information, you may submit a written revocation of the authorization. However, your decision to revoke the authorization will not affect or undo any use or disclosure of information that occurred before you notified us of your decision to revoke your authorization.

Individual Rights

You have certain rights under the federal privacy standards. These include:

- The right to request restrictions on the use and disclosure of your protected health information
- The right to receive confidential communications concerning your medical condition and treatment
- The right to inspect and copy your protected health information
- The right to amend or submit corrections to your protected health information
- The right to receive an accounting of how and to whom your protected health information has been disclosed
- The right to receive a printed copy of this notice

Phothera is required by law to maintain the privacy of your protected health information and to provide you with this notice of privacy practices. We are also required to abide by the privacy policies and practices that are outlined in this notice. As permitted by law, we reserve the right to amend or modify our privacy policies and practices. These changes in our policies and practices may be required by changes in federal and state laws and regulations. Upon, request, we will provide you with the most recently revised notice.
You may generally inspect or copy the protected health information that we maintain. As permitted by federal regulation, we require that requests to inspect or copy protected health information be submitted in writing. If you would like to submit a comment or complaint about our privacy practices, you can do so by sending a letter outlining your concerns to: Phothera, 205 W. Bement St., Bryan, Ohio 43506. Phone 419-636-6304. If you believe that your privacy rights have been violated, you should call the matter to our attention by sending a letter describing the cause of your concern to the same address. You will not be penalized or otherwise retaliated against for filing a complaint. You may also use the above name and address to contact us for further information concerning our privacy practices.

Patient Responsibilities:

To ensure the finest care possible, you must understand your role in your health care. As a customer of Phothera, you are responsible for the following:

1. To provide complete and accurate information at all times, including but not limited to: Insurance Information and any/all Insurance changes; up to date name, address, and telephone numbers; up to date medical information including diagnosis, physician information, changes in status or need, etc.
2. To request additional assistance or information on any issue with your order that you don't fully understand.
3. To notify Phothera when encountering any problems with your medical device.
4. To notify Phothera of denial and/or restriction of the Phothera privacy policy.

Patient Bill of Rights:

As an individual receiving medical devices from Daavlin you have the following rights:

1. To select those who provide your medical devices.
2. To be provided with legitimate identification by any person or persons entering your residence to provide delivery services or maintenance of your medical device.
3. To be provided with adequate information from which you can give your informed authorization for the commencement of your order, the continuation of your order, the transfer of your order to another provider, or the termination of your order.
4. To be advised, before the order is shipped, of the extent to which payment for the medical device may be expected from Medicare/Medicaid, insurance, or your liability for payment, billing cycles and changes in payment.
5. To have your privacy respected at all times and to be treated with respect, consideration, and recognition of dignity and individuality. You may contact any of the following organizations with grievances: Ohio Medicare (800) 589-7337 or Ohio Medicaid (800) 324-8680 #2 or ACHC (919) 785-1214
6. To express concerns or grievances or recommend modifications to your home care service without fear of restraint, interference, coercion, discrimination, or reprisal.
7. To expect that information received by Phothera will be kept confidential and shall not be released without written authorization.
8. The right to review Phothera's Privacy Practices.
9. To receive the appropriate customer service in a professional manner without discrimination.

20.0 Medicare Standards:

Medicare DMEPOS Supplier Standards

This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).
1. A supplier must be in compliance with all applicable federal and state licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the contractor within 30 days.
3. A supplier must have an authorized individual whose signature is binding sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory or contract with other companies for the purchase of items necessary to fill orders. A supplier cannot contract with any entity that is currently excluded from the Medicare program, any state health care programs, or any other federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable state law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items this insurance must also cover product liability and completed operations.
11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 C.F.R. section 424.57(c)(11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair cost either directly or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. A supplier must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services for which the supplier

is accredited in order for the supplier to receive payment for those specific products and services (unless an exception applies).
23. A supplier must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. A supplier must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. A supplier must meet the surety bond requirements specified in 42 C.F.R. section 424.57(d) (unless an exception applies).
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. section 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act), physical and occupational therapists or DMEPOS suppliers working with custom made orthotics and prosthetics.

21.0 Symbols

The following table lists all of the symbols located on the device along with their meaning:

Table 12 Symbols

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	DANGEROUS VOLTAGE		SERIAL NUMBER
	NON-IONIZING RADIATION		ALTERNATING CURRENT
	PROTECTIVE EARTH (ground)		DATE OF MANUFACTURE
	OPERATING INSTRUCTIONS		"℞ only" Caution: Federal law restricts this device to sale by or on the order of a physician
	KEEP DRY		CAUTION: UV EMITTED FROM THIS DEVICE. EYE OR SKIN IRRITIATION MAY RESULT
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS		RECYCLE: ELECTRONIC EQUIPMENT
	MEDICAL DEVICE		WEAR GOGGLES DURING TREATMENT
	MANUFACTURED BY		

22.0 Indications for Use

The Phothera 600 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 population may range from pediatric to geriatric.

23.0 Essential Performance

The essential performance of the Phothera 600 is defined as follows:

- Lamps must activate when a treatment is initiated
- Lamps must deactivate when a treatment is completed

The device must operate according to the Essential Performance. If the device does not operate according to the Essential Performance, contact Phothera Customer Support.

24.0 Warranty

24.1 Limited Warranty Policy

Table 13 Warranty Periods

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

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.

24.2 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 REPLACEMENT OF THE EQUIPMENT.

24.3 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.

24.4 Warranty Service

No returns of equipment are allowed outside of warranty service under RMA authorization after 30 days. 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 device, or a blown fuse.

24.5 Disposal

Dispose of the device and lamps in accordance with local regulations for electronic equipment and mercury-containing lamps.

24.6 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.

24.7 Contact Information

24/7 Customer Support Website:	**Support.Phothera.com**
24/7 Customer Support Phone Number:	**1-844-676-2882**
Website:	**www.phothera.com**

205 W. Bement Street
PO Box 626
Bryan, Ohio 43506 USA

24.7.1 Additional Accessories

To purchase additional accessories, visit shop.phothera.com/support/home, or simply scan this QR code to be taken directly to the shop to purchase additional UV protective goggles, cleaning wipes, etc.