Phothera™

Operation Manual

Phothera 200

ClearLink™ Controlled

Modes of Operation:

Guided | Dosimetry | Timed

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

Phothera

Table of Contents

Dear Valued Customer,

Thank you for selecting a Phothera 200 phototherapy unit. The use of light for the treatment of photoresponsive skin disorders is our business. 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 they practice.

1.0 Control Type

The Phothera 200 phototherapy unit is equipped with Phothera's ClearLink™ Control System. The device was prescribed by a doctor to function in one of the three modes listed below:

● **Guided:** The system controls the beginning dose and all subsequent doses depending upon how the user's skin responds to the therapy. See section 11.0 Guided Mode for operating instructions that are specific to this mode of operation.

● **Dosimetry:** The user controls 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 given will be based on instructions from a doctor. See section 12.0 Dosimetry Mode for operating instructions that are specific to this mode of operation.

● **Timed:** The user controls the length of each treatment, based on instructions from a doctor. See section 13.0 Timed Mode for operating instructions that are specific to this mode of operation.

Exposure-Limiting Software: A physician may have prescribed the 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 200 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.

3.0 Delivery and Inspection

Upon delivery, inspect the box and its contents. If damage is discovered, save **all** packing materials and call Phothera immediately to begin the claims process. If it's not possible to inspect the unit before the driver leaves, we recommend writing **"Concealed damage possible. Further inspection required"** on the delivery receipt.

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

Note: In addition to notifying the manufacturer, the delivering carrier **must also** be notified of any shipping damage within twenty-four (24) hours to protect the 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/solarize.

4.1 Electrical Requirements

In the United States and Canada, the Phothera 200 is shipped with a standard three-pronged plug power cable.

- The Phothera 200 **should** be plugged into any grounded household electrical.
    - The Phothera 200 **should not** be plugged into a residual current device (RCD) or an RCD protected circuit.
    - The Phothera 200 **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 200 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 the customer service department to determine an appropriate replacement.

5.0 Unpacking and Assembly

1. Open the top of the box and grasp both sides of the device. Pull it out of the box along with the air packers on each end – remove the air packers.

Note: Be sure to remove all of the accessories, such as the manual, power cord and eyewear before discarding the box.

2. Power Cable: Plug the "D" shape male fixture into the corresponding receptacle on the lower left-hand side of the device. Plug the unit into any grounded, household electrical outlet (see section 4.1 Electrical Requirements). The unit is now ready for use.

5.1 Swivel Stand

An optional Swivel stand is available that facilitates the treatment of both sides of the user's hands, or feet or other parts of the body. Installation instructions for this optional accessory are separate from this manual.

6.0 Lamp Inspection

Phothera 200 devices can be equipped with different types of lamps, each with its own effect on the skin. It is important to check that the proper lamps are installed. Consult the Lamp Specification Guide in section *6.1 Lamp Specification* Guide. If there is any question that the device is not equipped with the lamps that have been prescribed, contact Phothera immediately. Lamp code numbers are generally located at the base of the lamp.

6.1 Lamp Specification Guide

UVA	UVA-1	Narrowband UVB	Broadband UVB	Blue (405)
PLL-36W/09	PLL-36W/10	PLL-36W/01	PLL-36W/-06	PLL-36W/03

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.

- During extremely long treatments, some surfaces may become hot. Remove any body parts from those surfaces if it becomes uncomfortable.

- Erythema (sunburn) 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 treatment area to avoid exposure to ultraviolet light.

- Ask your doctor about protecting areas of the body that 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.

- 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 your physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.

- This device should be a minimum of 12 inches (30 cm) away from RF generating equipment

- 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 customer 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.

- The device should be placed a minimum of 1 inch (2.5 cm) away from surrounding walls, devices, and furniture to ensure proper cooling airflow.

- The room that the device is placed in should be vented to allow free air displacement to ensure the device and surroundings remain cool.

- Only original components and accessories should be used with the device to avoid damage.

- 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.

- 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 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 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 1 Unlocking Code)* located near the display provides instruction on how to unlock the unit.

Figure 1 Unlocking Code

If the unit is equipped with exposure limiting software, there will be a label similar to the one shown below *(Figure 2 Refill Label)* informing the user that the unit has been equipped with this feature and how to refill the device.

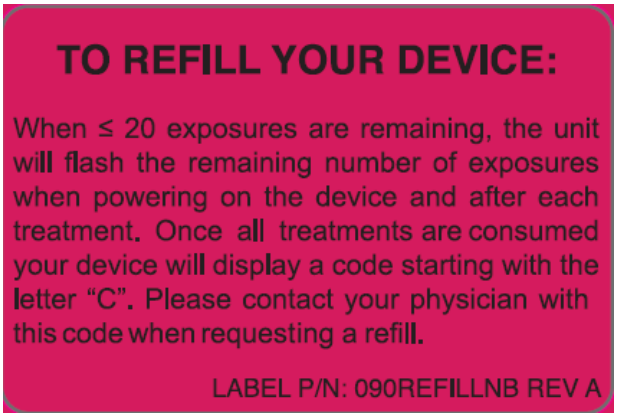


Figure 2 Refill Label

A warning label (*Figure 3 Warning Symbols Label*) is affixed to the Phothera phototherapy device in a prominent and easily readable position, centered on the back of the device. Please review the label carefully as it contains important safety information. See *Table 1 Symbols* for symbol identification and definitions.

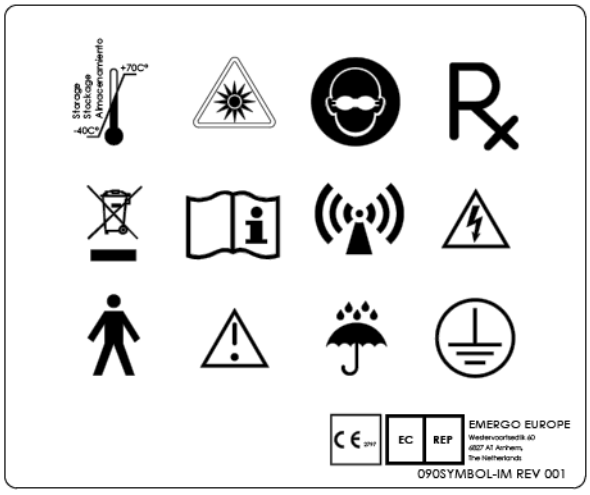


Figure 3 Warning Symbols Label

An identification label (*Figure 4 Identification Label)* will be affixed to the back side of the device, providing the serial number, manufacture date, model number, electrical information, and other information regarding the device.

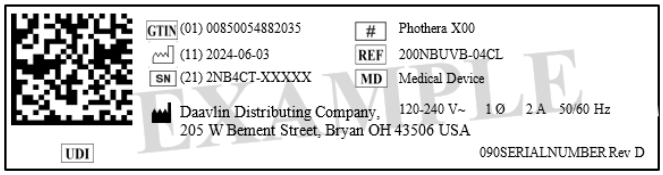
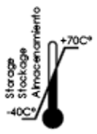


Figure 4 Identification Label

The following table lists all the symbols appearing on the device along with their meaning.

Table 1 Symbols

SYMBOL	DESCRIPTION
	DANGEROUS VOLTAGE
	NON-IONIZING RADIATION
	PROTECTIVE EARTH (ground)
	OPERATING INSTRUCTIONS
	KEEP DRY
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	MEDICAL DEVICE
	AMBIENT STORAGE BETWEEN -40°C AND +70°C
	CAUTION: UV EMITTED FROM THIS DEVICE. EYE OR SKIN IRRITIATION MAY RESULT.

SYMBOL	DESCRIPTION
	WEAR GOGGLES DURING TREATMENT
	FOR USE UNDER DIRECTION OF A LICENSED PHYSICIAN ONLY. TREATMENTS SHOULD BE MONITORED BY TRAINED PERSONNEL.
	RECYCLE: ELECTRONIC EQUIPMENT
	TYPE B APPLIED PART
	“CONFORMITE EUROPEENNE” - PRODUCT HAS BEEN ASSESSED AND MEETS THE SAFETY, HEALTH, AND ENVIRONMENTAL REQUIREMENTS OF THE EUROPEAN UNION (EU)
	MANUFACTURED BY
	SERIAL NUMBER
	ALTERNATING CURRENT
	DATE OF MANUFACTURE

10.0 General Instructions (All Modes of Operation)

10.1 Pre-treatment Preparations

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

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

Lip balm and sunscreen with an SPF (Sun Protective Factor) of at least 30 will need to be purchased. Ask the prescribing doctor whether or not an alcohol or cream-based sunscreen should be used.

10.2 Unlocking the Device

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

Figure 5 Logo Screen

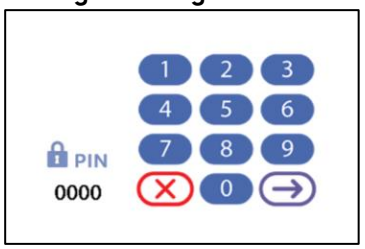


Figure 6 Lock Screen

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.

10.3 How to Position Yourself

Dual Point Calibration Selection: The Phothera 200 has been designed to deliver accurate and effective treatments from two distinct treatment distances. Treatments can be administered directly on the acrylic's surface (0 inches) or at a distance of nine inches from the acrylic (9 inches or 23 centimeters).

The intensity or power output of the device will be much greater when treating directly on the acrylic surface versus treating from nine inches away. For this reason, the user must select the desired treatment distance before administering a treatment. See specific instructions under **Running a Treatment.**

By selecting the treatment distance, 0 in or 9 in (see *Figure 7 Select Treatment Options*), you are telling the system how it should calculate the length of the treatment based on the distance from the lamps.

Figure 7 Select Treatment Options

Hands and Feet: (Choose 0 inches position when starting therapy). Position the device on a flat surface with the lamps facing up. Place the user's hands or feet directly on top of the plastic lamp guard. For best results the user should position their hands, or feet, as close as possible to the center of the fixture.

Note: When treating the hands and feet, be careful to not place too much weight or pressure on the acrylic surface. Excess pressure can cause the acrylic surface to crack and break.

Larger Area Treatment: (Choose the 9 inches position when starting therapy). Position the Phothera 200 so that the lamps are perpendicular to the surface on which the device is standing on. Position the part of the user's body that is to be treated nine (9) inches away from the lamps.

10.4 Common ClearLink™ Functions

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

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 time is remembered. When power is restored, the controller will start, however, the lamps will not automatically turn on. To resume, press the Play ▷ button.

10.5 Post-Treatment

After a treatment, protect any areas that feel sunburned with sunscreen for the next several treatments 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 unit. Always take the notebook when seeing the prescribing physician.

10.6 Treatment Limiting Software (Rx)

If the unit was prescribed with exposure-limiting software, a screen (*Figure 8 Treatment Remaining Screen)* will say how many exposures remain before a refill prescription is needed. See *Section 14.3 Uploading Refill* Prescriptions for refill instructions.

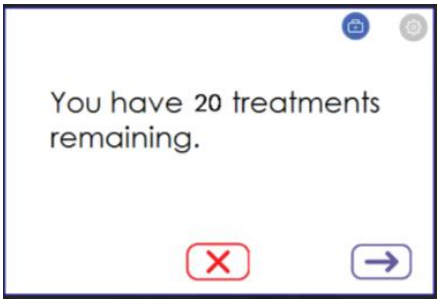


Figure 8 Treatment Remaining Screen

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 behalf of the user, as well as calculating dose increases based on the treatment schedule and how the user's skin responds to treatment.

For example, each time the device is used, the ClearLink Controller 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 (*See Figure 9 below*).

Figure 9 Treatment Scheduling

Integrating dosimetry, another feature, 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 aging of the lamps.

Finally, before each treatment, the ClearLink Controller 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.

11.2 Running a Treatment

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

1. After unlocking the device, the Treatment Screen will appear with the scheduled dose.
2. The user will be asked, ***"Were you in pain or red after your last treatment?"***
3. The user 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 the response has been highlighted, press the Enter → key.
5. Choose the treatment distance by pressing either the "9 in" button or the "0 in" button
6. 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. To cancel, press the Cancel ✕ key.

Put on your goggles ***and position yourself 9 inches from the front of the device or on the surface of the acrylic, as appropriate. See Section 10.3 How to Position Yourself for guidance.***

7. Press the Enter → key to begin the treatment. A 3 second countdown will begin. The lamps will turn on and the screen will track the user's progress. The lamps will shut off when the treatment is over.

8. To repeat the same dose for exposure to another part of the body, touch the Repeat button. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button. Confirm need to treat another part of the body, and position accordingly.

Note: *Repeats will not be available after leaving the treatment screen.*

9. 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 press the Cancel button.

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
2. Then, choose the treatment distance by pressing either the “9 in” button or the “0 in” button.
3. Touch the ▲/▼ arrows to set the desired dose in MilliJoules (UVB) or Joules (UVA).

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

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

Put on your goggles ***and position yourself 9 inches from the front of the device or on the surface of the acrylic, as appropriate. See Section 10.3 How to Position Yourself for guidance.***

6. Press the Enter key to begin the treatment. A 3 second countdown will begin. The lamps will turn on and the screen will track the user’s progress. The lamps will shut off when the treatment is over.

7. To repeat the same dose for exposure to another part of the body, touch the Repeat button. ***Note:*** *Repeats will not be available after leaving the treatment screen.*
8. 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 press the Cancel button.

13.0 Timed Mode

13.1 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. A time of 1 minute must be entered 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 9 inches from the front of the device or on the surface of the acrylic, as appropriate. See Section 10.3 How to Position Yourself for guidance.***

5. Press the Enter key to begin the treatment. A 3 second countdown will begin. The lamps will turn on and the screen will track the user's progress. The lamps will shut off when the treatment is over.
6. To repeat the same dose for exposure to another part of the body, touch the Repeat button. ***Note:*** *Repeats will not be available after leaving the treatment screen.*
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 press the Cancel button.

Calculating Increases: Phototherapy treatments usually start at a given time or dose and are increased with each treatment. The prescribing doctor may ask to increase each treatment by a set amount of time or may ask 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 a phone. In that app, simply enter the time of the last treatment and the desired percentage increase and the calculator will give the new treatment time instantaneously.

13.2 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, per the prescribing physician's protocol. Another method is to use the factory power output levels (shown on the Power Output Certificate) to determine estimated "time equivalents" needed to deliver doses in milliJoules (UVB) or Joules (UVA).
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 column on the left (vertival 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 in Figure 10 Example Time Chart).
Note: For your convenience, and as an alternative to the UVB time chart, the latest version of our free treatment time calculator is available for use. This can be accessed by visiting Calculators - Daavlin for a web-based calculator and additional information.

	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

Figure 10 Example Time Chart

14.0 Care of the Unit

14.1 Recommended Maintenance Schedule

Item / Action	Frequency
Clean all patient contact surfaces	Between each treatment
Unit calibration	Every 100 hours of use or once a year (whichever occurs first) and when lamps are replaced. (Meters can be rented or purchased through Phothera)
Replace lamps	***UVB** – Every 300 hours of use. ***UVA** – Every 500 hours of use. ***Blue** – Every 500 hours of use.

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

14.2 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 feature or to change it to a number that is easier to remember, contact the customer service department at 1-216-831-0600 for step-by-step instructions.

14.3 Uploading Refill Prescriptions

When specified by the 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 the 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 therapy, we suggest that the physician be contacted and given 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 out of exposures, the controller will prompt a new prescription be uploaded, see Figure 11 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 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.

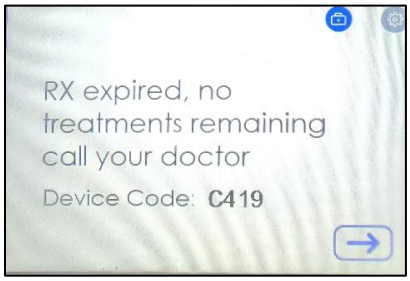


Figure 11 Device out of Treatments

14.4 Downloading Treatment History

The prescribing doctor may require that a treatment history file so he or she can monitor progress. To download the history files, insert a USB drive into the USB port. Press the "Export Data" button then the Enter key. When the download is complete, remove the USB drive and take it to the doctor.

14.5 Cleaning/Disinfection

14.5.1 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 or equivalent to gently wipe down the exterior of the device.

14.5.2 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 contaminants remain repeat steps 1 and 2.

14.5.3 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 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. They may scratch the surface.*

14.6 Calibration/Power Output

The power output of the device was measured before it left the manufacturing facility. A "Calibration/Output Certificate" is included with the operating manual and contains the device's factory measured power output.

14.6.1 Dosimeter Accuracy/Range (Applicable to Guided and Dosimetry units only.)

The integrating dosimetry system will maintain a 10% level of accuracy if the device is calibrated at least annually or whenever lamps are replaced or every one hundred (100) hours of use, whichever is 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 Phothera for calibration assistance.

Dose Range:	UVA: 0.1 Joules - 999.9 Joules UVB: 1 Millijoule - 9999 Millijoules
Accuracy:	± 10%
Calibration:	1 year or every 100 hours of use, or upon changing lamps

14.6.2 Timer Accuracy

The built in timer will maintain a ±5% level of accuracy in a 10 minute treatment time.

14.7 Lamp Removal and Replacement

Lamps may need to be replaced due to burnout or because their energy output has decreased to a point that treatments may have become excessively long. Please contact the service department to orchestrate lamp replacement, as the device may need to be returned to the manufacturer.

14.7.1 Resetting Lamp Hours

When changing lamps, it is important to reset the lamp age to zero so the new lamp's operational hours can be tracked. Please contact the 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 200 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 200 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 200 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 Phothera 200 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, radiofrequency, 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
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

Emissions Test	IEC 60601 Test Level	Actual Level
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			
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
Website:	www.phothera.com

The Daavlin Distributing Co.
205 W. Bement Street
PO Box 626
Bryan, Ohio 43506 USA