Phothera™

Operation Manual

Phothera 200XL

DT Controlled

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

Phothera

Table of Contents

Dear Valued Customer,

Thank you for selecting a Phothera 200XL 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 200XL phototherapy unit is equipped with a Digital Timer (DT) Control System. The device was prescribed by a doctor to function in the mode listed below:

- **Timed:** The length of each treatment can be controlled, based on instructions from the doctor.

The physician may have prescribed the device with a system that limits the total number of exposures the device will deliver. Specific information about these systems is provided in this manual.

2.0 Indications for Use

The Phothera 200XL 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 200XL is shipped with a standard three-pronged plug power cable.

- The Phothera 200XL **should** be plugged into any grounded household electrical.
    - The Phothera 200XL **should not** be plugged into a residual current device (RCD) or an RCD protected circuit.
    - The Phothera 200XL **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 200XL 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 Stand Assembly

A stand will come with every Phothera 200XL phototherapy unit. The following instructions explain the assembly and setup of each stand.

5.1.1 Phothera 200XL 2-Lamp Model

1. Remove the device, stand and power cord from the packaging.
2. Set the device on a firm surface (table, counter, etc.) with the lamps facing upwards, ensuring it is stable.

Figure 1 Acrylic Stand Components

3. Separate the 3-piece acrylic stand and place them in front of you.
4. Place the tall, L-shaped sides into the rectangular base with two cutouts one at a time. See Figure 2 Assembled 2-Lamp Stand below:

Figure 2 Assembled 2-Lamp Stand

5.1.2 Phothera 200XL 4-Lamp Model

1. Remove the device, stand, and power cord from packaging.
2. Set the device on a firm surface (table, counter, etc.) with the lamps facing upwards, ensuring it is stable.

Figure 3 Stand Components

3. Separate the stand, knobs, and washers and place them in front of you.
4. Place one washer on each of the threaded portions of the two knobs.

Figure 4 Washers on Knobs

5. Lift up one side of the stand and place a knob with the washer through the top notch on the side so that the threaded portion is facing the inside of the L-shape. Repeat this step for the other side of the stand.
6. Both knobs should have threads facing toward the center of the stand and have one washer held on the outside as shown below in Figure 5 Knobs Held in the Stand.

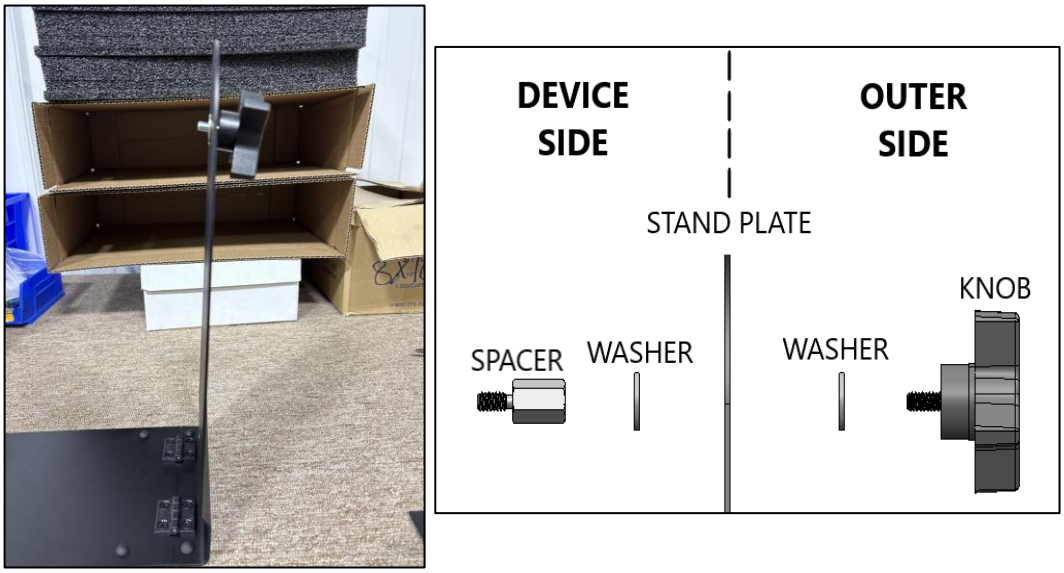

Figure 5 Knobs Held in the Stand

7. Place the remaining two washers, around the threaded portion of the knobs, against the inner face of the stand sides.
8. Move back over to where the main device is resting. Take the two male/female threaded adapters and hand tighten them into the sides of the main device as in Figure 6 Hand Tightened Spacers in Device.

Figure 6 Hand Tightened Spacers in Device

9. Lay the stand down and position the device in the center of the stand as shown in Figure 7 Device Centered in Stand below.

Figure 7 Device Centered in Stand

10. Align the knob to the threaded adapter and thread the knob into the threaded adapter to attach the stand to the device as shown in Figure 8 Threaded Knobs Aligned to Spacers below.

Figure 8 Threaded Knobs Aligned to Spacers

11. Repeat this process for the other knob and threaded insert.
12. Loosen both knobs just enough to move the device up so that it is set in the top notch. Do not remove the knobs from the threaded adapters.
13. When the device is in the top notch, tighten the knobs firmly to lock the rotation of the device as in Figure 9 Knobs Tightened into Spacers.

Figure 9 Knobs Tightened into Spacers

14. Stand the device and stand up and adjust the rotation to the desired position as shown in Figure 10 Fully Assembled Stand below.
15. Take the female end of the power cord and install it into the power cord port located on the right side of the device. Before plugging the device into a power outlet, ensure it is in the desired position with the knobs fully tightened.
16. When the device stand is fully assembled it should look like Figure 10 Fully Assembled Stand seen below.

Figure 10 Fully Assembled Stand

6.0 Lamp Inspection

Phothera 200XL 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

Narrowband UVB
PLL-36W/01

7.0 Precautions and Warnings

- To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. **Always use Phothera approved eyewear purchased through Phothera.**

- Do not remove protective eyewear, or any other protective equipment, during treatment.

- If psoralens (photosensitizing drugs) are being used as part of your treatment ("PUVA"), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with devices equipped with UVA lamps.

- Do not use over skin eruptions without express consent from the attending physician.

- If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.

- To protect unaffected skin during operation, the operator, patient, and anyone in view of the device must generously apply UV blocking skin protection to all exposed skin that the physician does not intend to treat.

- 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 14.7 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 14.7 Contact* Information*)*

- Caution – Use of controls or adjustments or performance of procedures other than those specified herein result in HAZARDOUS radiation exposure.

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

On top of the device's DT Controller is a safety key code label *(Figure 11 Keycode Label)* that explains how to unlock and begin using the device. This is a temporary label that will need to be removed prior to use. You may want to hold onto this label for future reference.

Figure 11 Keycode Label

If the unit is equipped with exposure limiting software, there will be a red/pink label *(Figure 12 Refill Label)*, in addition to the "safety key code" label, informing the user that the unit has been equipped with this feature.

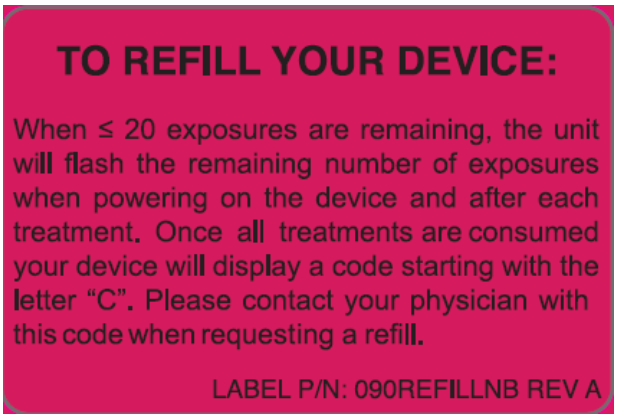

Figure 12 Refill Label

A warning label *(Figure 13 Warning Label)* is affixed to the Phothera phototherapy device in a prominent and easily readable position, above the controller. Please read the label carefully as it contains important safety information.

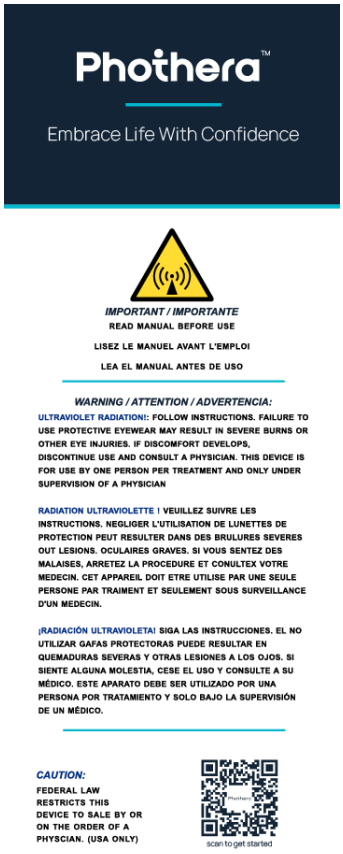

Figure 13 Warning Label

An identification label *(Figure 14 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 14 Identification Label

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

Table 1 Symbols

SYMBOL	DESCRIPTION
	WARNING, GENERAL, RISK OF PERSONAL INJURY
	WARNING, HOT SURFACE
	WARNING, ELECTRICITY
	WARNING, NON-IONIZING RADIATION
	WARNING, LAMPS CONTAIN MERCURY
	WARNING, PINCH POINT
	WARNING, ULTRAVIOLET RADIATION
	CAUTION, RISK OF DAMAGE TO MACHINERY, SOFTWARE OR PARTS
	NOTE
	OPERATING INSTRUCTIONS

SYMBOL	DESCRIPTION
	NO WASTE – UNIT CONTAINS ELECTRICAL AND ELECTRONIC EQUIPMENT THAT MUST BE DISPOSED OF AND/OR RECYCLED PROPERLY
	PROTECTIVE EARTH (GROUND)
	"ON" FOR EQUIPMENT
	"OFF" FOR EQUIPMENT

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.***

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 How to Position Yourself

Hands and Feet: Position the device on a flat surface or in the stand 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.

Topside of Hands and Feet:

2-Lamp Model: Remove the nylon screws at the bottom side of the device, circled in Figure 15 Screws to be Removed. Place these screws in a safe place where they will not be lost. Hand-tighten the supplied hex standoffs in the location that the screws were removed. Turn the device over, so

the lamps are facing downward, and slide the hands or feet under the device. The device should look the same as in Figure 16 Standoffs Attached to Device.

Figure 15 Screws to be Removed

Figure 16 Standoffs Attached to Device

4-Lamp Model: Move the device, on the stand, to the middle notch position and flip it upside down so the lamps are facing downward, as seen in Figure 17 below. To flip the device upside down, the device must first be moved to the top notch, then rotated. Hand-tighten the knobs of the stand

to ensure it is properly secured before starting treatment. Place the hands or feet onto the stand between the cutout marks on the stand itself.

Figure 17 Treatment Position for Tops of Hands and Bottom of Feet for 4-Lamp Model

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.

10.3 Operating the DT Controller

Figure 18 DT Controller Overlay

10.3.1 Unlocking the Device

To prevent unauthorized use, the device will “self-lock” when it has not been used for three (3) minutes. To unlock the unit:

1. Press any button to power on the device.
2. The unit will now display the word “C0dE”.
3. The factory default key code is “0007”. Press the UP-ARROW button until the unit displays “0007”.

4. Press the “PLAY/PAUSE” button to unlock the controller.

10.3.2 Setting Up a Treatment Time

1. Enter in the key code. Unless it has been changed, the factory default key code is “0007.”
    a. If the key code has been changed and forgotten, contact customer service to set up a new key code.
2. Once the key code has been entered, the display should read “00:00”.
3. The currently editable character will flash on and off to signal that it is the editable character.
4. Press the UP-ARROW button to increase the value of the flashing character by one (1).
5. Press the LEFT ARROW button to move the flashing character over by one position.
6. Once the desired time is present on the display, press the PLAY/PAUSE button to lock-in the treatment time.

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 10.2 How to Position Yourself for guidance.***

7. Press the PLAY/PAUSE button to begin the treatment.
8. Press the PLAY/PAUSE button to pause the treatment.
9. While treatment is paused or completed, press the CANCEL button to return to the treatment menu (“00:00” displayed with the right-most character flashing).
10. After a treatment is complete, the controller will enter Standby Mode. The controller will flash the most recently completed treatment while in standby mode.
    a. To repeat this treatment: press the PLAY/PAUSE button to re-enter Time Entry Mode. The rightmost character should now be flashing.
    b. Press the PLAY/PAUSE button again to set the treatment time.
    c. Press the PLAY/PAUSE button again to start the treatment.

EXAMPLE:

1. An example time of one minute and twenty-three seconds will be used (01:23).
2. The right most character should be flashing – press the UP-ARROW button three (3) times. The display should now read “00:03”.
3. Press the LEFT ARROW button one (1) time and the UP-ARROW button two (2) times. The display should now read “00:23”.
4. Press the LEFT ARROW button one (1) more time and the UP-ARROW button one (1) more time. The display should now read “01:23”.
5. Press the PLAY/PAUSE button one time to lock in the treatment time. The flashing character should stop flashing.

6. Now that the desired time is displayed (in this case 01:23), once the goggles are on and the user is ready to begin treatment, press the PLAY/PAUSE button to begin treatment.
7. Pressing the PLAY/PAUSE button again will pause treatment.
8. While paused, pressing the CANCEL button will end the treatment and prompt a new treatment.

10.3.3 Viewing Device Code for Treatment Refill

The Device Code is predetermined by the software. To view the next code on the Digital Timer controller:

1. Press the CANCEL and LEFT-ARROW at the same time, the CXXX code should display.

OR

1. Enter the Key Code to unlock the controller.
2. Simultaneously press CANCEL, LEFT-ARROW, and PLAY/PAUSE buttons.
3. While the screen displays "- - - 1", press the UP-ARROW button four (4) times. The screen should display "- - - 5".
4. Press the PLAY/PAUSE button to enter Menu 5.
5. The value displayed ("CXXX") is the next generated Device Code.
    a. Alternately, when there are ≤20 exposures remaining OR all exposures have been exhausted, the display will show this Device Code.
6. If all exposures have been exhausted and a wrong refill code is entered, the Digital Timer Controller will flash the entered code two (2) times then display the Device Code.

10.3.4 Treatment Refill Instructions

The exposure limiting software uses a "call and response" method. The 3-digit Device Code (CXXX) is randomly generated by the controller and is necessary to generate a 4-digit Treatment Code using a controlled algorithm.

10.3.5 Refill the Controller

To **REFILL** the number of treatments on the DT controller, follow the instructions below:

1. Enter the Key Code to unlock the controller.
2. Device Code 'CXXX' is displayed on screen

   Note: If Device Code is not displayed, there are exposures remaining and it will be displayed once all exposures have been used. Device Code can be viewed in Menu 5 prior to all exposures being used.
3. Contact prescribing physician and provide Device Code 'CXXX'
4. The physician will utilize the online Physician's Portal to obtain the Treatment Code, or the customer service department will provide Treatment Refill Code to doctor or patient.

10.3.6 Special Notes

1. The maximum time that can be entered is 59 minutes and 59 seconds (59:59).

   a. It is **not** possible to enter XX:60 seconds. 01:00 minute must be entered instead.

   b. The device will maintain a timer accuracy of ±5 % in a 10-minute period.

2. If power goes off during a treatment, the system will not remember how much of the treatment has elapsed. When power is restored, the controller will prompt for the Key Code and another treatment will have to be started.

   a. If exposure limiting software is activated and the controller loses power during a treatment, an exposure/full treatment will be assumed, and the remaining treatments will decrease by one (1) treatment.

3. If exposure limiting software is active, the display will flash the number of exposures remaining two (2) times after a treatment or at power up if the amount of remaining exposures is twenty (20) or less, signaling the user to obtain a new Treatment code soon.

4. There are 1000 Device Codes (C000-C999), each having five (5) four-digit Refill Codes (0000-9999) that set a predetermined amount of exposures to be allowed by the controller.

0 exposures (locked), 75 exposures, 100 exposures, 250 exposures, or unlimited exposures (unlocked).

10.4 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.

10.5 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 19 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.

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.

					↓				
	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 19 Example Time Chart

11.0 Care of the Unit

11.1 Recommended Maintenance Schedule

Item / Action	Frequency
Clean all patient contact surfaces	Between each treatment

Item / Action	Frequency
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.

11.2 Cleaning/Disinfection

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

11.2.2 Low-Level Disinfection

To reduce micro-organisms on the patient-contacting surfaces, disinfect these surfaces between uses of the device, including when the same patient has the device for use. For disinfection while the same patient uses the device, we have tested several cleaners that do not degrade the Acrylic and can be seen in *Table 2 Tested Cleaners.*

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

Table 2 Tested Cleaners

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

11.2.3 High-Level Disinfection

Follow a high-level disinfection protocol between the use of the device on different patients. Use a high-level disinfectant, such as Steris Corporation's Resert XL-HLD, and follow the 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.*

11.3 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.

11.3.1 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.

12.0 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.

13.0 Environmental Specifications

The Phothera 200XL 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 200XL device is suitable for healthcare environment operation in hospitals and clinics

Emissions Test	Conformity	EMC Environment Guide
Limits for harmonic current emissions following IEC 61000-3-2	Class A	The Phothera 200XL 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 200XL 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
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

Emissions Test	IEC 60601 Test Level	Actual Level
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			

14.0 Warranty

14.1 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

14.2 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.

14.3 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.

14.4 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.

14.5 Disposal

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

14.6 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.

14.7 Contact Information

Phone:	1-216-831-0600 *Press 2 for NatBio
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