Phothera™

Operation Manual

Phothera 200

DT Controlled

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

Phothera

Serial Number: 669d5015-7b09-4913-a3cc-97f346fcfd52 accessed by Robert Doster (RDOSTER) on Fri, 09 May 2025 14:24:19 GMT.

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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

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

- **Timed:** You control the length of each treatment, based on instructions from your doctor.

Your physician may have prescribed your 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 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 that you write **"Concealed damage possible. Further inspection required"** on the delivery receipt.

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

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

4.0 Site Selection

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

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5.1 Swivel Stand

An optional Swivel stand is available that facilitates the treatment of both sides of your hands, or feet or other parts of your 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 you 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.

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- During extremely long treatments, some surfaces may become hot. Remove any body parts from those surfaces if it becomes uncomfortable. The unit should have a 50% duty cycle of 10 minutes on, 10 minutes off.

- 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 or, if hard wired, turning off quick disconnect.

- To avoid the risk of electric shock, this equipment must only be connected to a supply main with 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**

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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 section *12.0 Environmental Specifications*. If the device continues to malfunction cease operation and contact the Phothera Service Department.

- Prior to each use, always verify that the device is in correct working order and operating condition and plugs, sockets, lamps, and electrical cables and connections are not worn or damaged.

- 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 safety 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.

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- Do not treat if the lamps fail to ignite. Consult with doctor and/or contact customer service. (See *13.7 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 *13.7 Contact Information*)

- DT Controlled Phototherapy Devices are considered CISPR Group 1, Class A devices, to be used **for prescription use only**.

- 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

If your unit has been equipped with treatment exposure limiting software, there will be a red/pink label, in addition to the "safety key code" label, informing you that your unit has been equipped with this feature.

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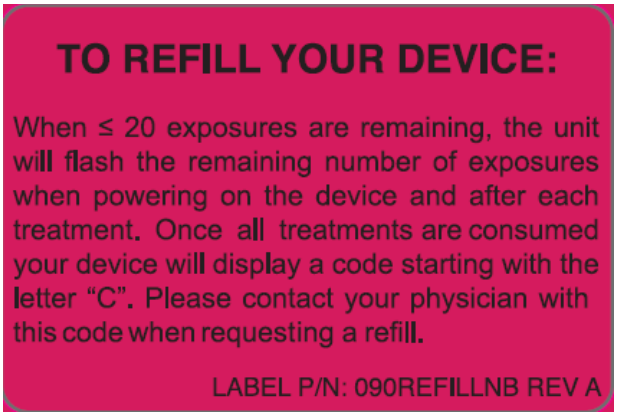

Figure 1 Refill Label

A warning label *(Figure 2 Symbols Label)* is affixed to your phototherapy device in a prominent and easily readable position. Please read the label carefully as it contains important safety information. See *Table 1 Symbols* for symbol identification and definition.

An identification label *(Figure 3 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.

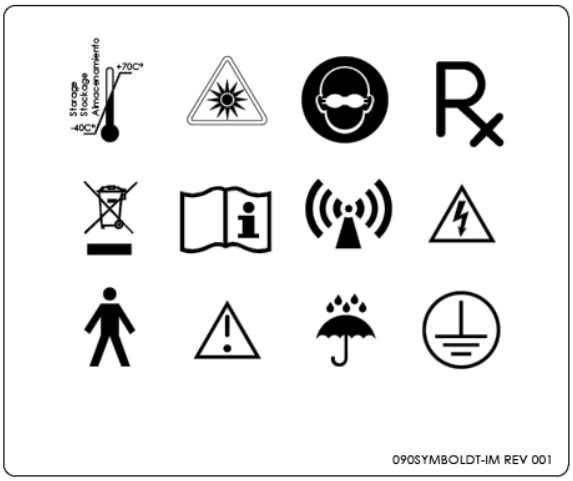

Figure 2 Symbols Label

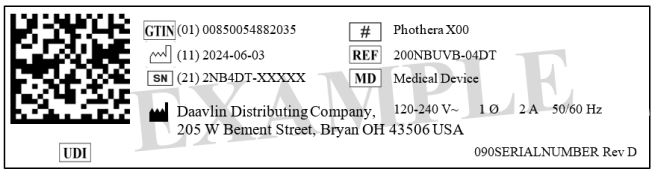

Figure 3 Identification Label

A removeable Keycode instruction label (*Figure 4 Keycode Label)* is located near the display to inform you that the device is locked for your safety and provides instructions for unlocking the controller.

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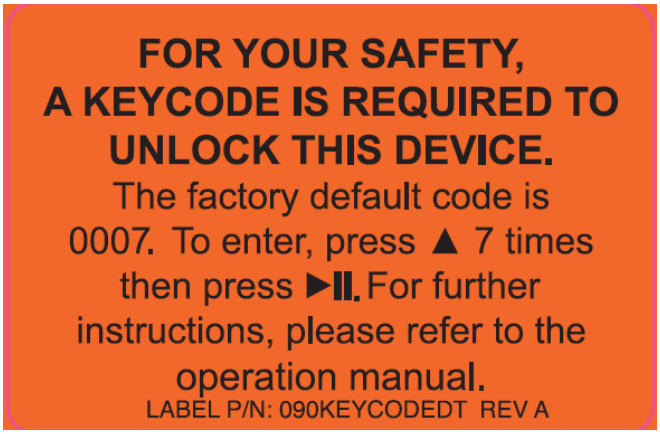

Figure 4 KeyCode Label

The following table lists all of 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

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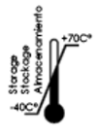
SYMBOL	DESCRIPTION
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	MEDICAL DEVICE
	AMBIENT STORAGE BETWEEN -40°C AND +70°C
	CAUTION: UV EMITTED FROM THIS DEVICE. EYE OR SKIN IRRITIATION MAY RESULT.
	WEAR GOGGLES DURING TREATMENT
	FOR USE UNDER DIRECTION OF A LICENSED PHYSICIAN ONLY. TREATMENTS SHOULD BE MONITORED BY TRAINED PERSONNEL.
	RECYCLE: ELECTRONIC EQUIPMENT
	TYPE B APPLIED PART
	MANUFACTURED BY
	SERIAL NUMBER

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SYMBOL	DESCRIPTION
	ALTERNATING CURRENT
	DATE OF MANUFACTURE

10.0 General Instructions

10.1 Pre-treatment Preparations

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

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

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

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10.2 Operating the DT Controller

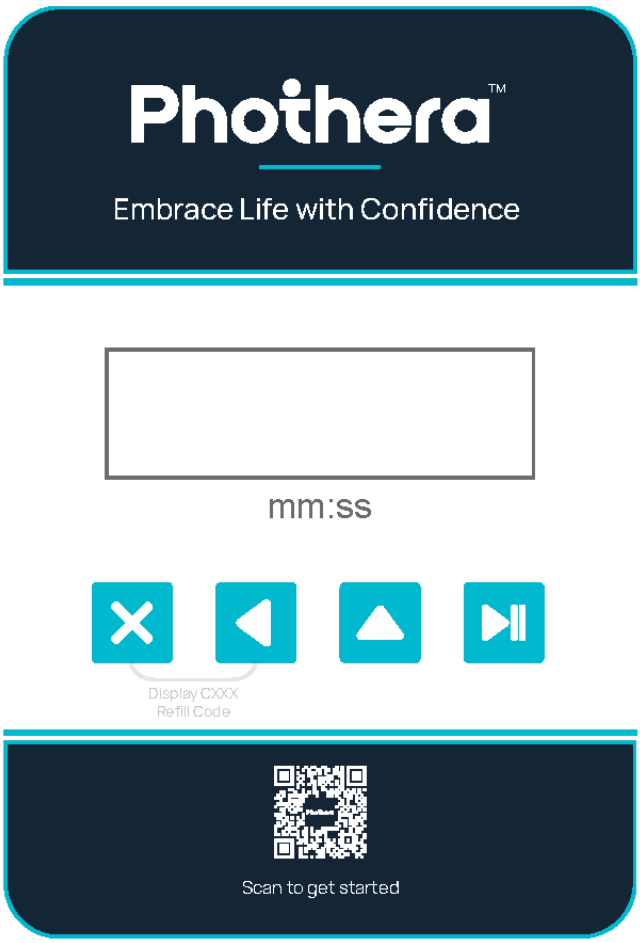

Figure 5 DT Controller Overlay

10.2.1 Unlocking the Device

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

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

10.2.2 Setting Up a Treatment Time

1. Enter in your key code. Unless you have changed it, the factory default key code is “0007.”
    a. If you have changed and forgotten your key code, contact Phothera Service to set up a new key code.

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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 10.3 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 your goggles are on and you are ready to begin treatment, press the PLAY/PAUSE button to begin treatment.
7. Pressing the PLAY/PAUSE button again will pause treatment.

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8. While paused, pressing the CANCEL button will end the treatment and prompt a new treatment.

10.2.3 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 your 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.

10.2.4 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.

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10.2.5 Refill the Controller

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

1. Enter your 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 service department will provide Treatment Refill Code to doctor or patient.

10.2.6 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. You must enter 01:00 minute 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.
   a. 0 exposures (locked), 75 exposures, 100 exposures, 250 exposures, or unlimited exposures (unlocked).

10.3 How to Position Yourself

Select a Treatment Distance: 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).

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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, you must determine the treatment time using the given time chart before administering a treatment. For example, if the 9 inch output is 5mW/cm2, and the 0" output is 20mW/cm2, a 300mJ treatment would take one minute to complete at 9", while it would only take 15 seconds to complete on the acrylic surface at 0 inches

Hands and Feet: Position the device on a flat surface with the lamps facing up. Place your hands or feet directly on top of the plastic lamp guard. For the best results you should position your hands, or feet, as close as possible to the center of the fixture. Reference the 0" calibration value from the calibration certificate and the appropriate time chart to calculate your desired treatment time.

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

Larger Area Treatment: Position the Phothera 200 so that the lamps are perpendicular to the surface on which the device is standing on. Position the part of your body that you wish to treat nine (9) inches away from the lamps. Reference the 9" calibration value from the calibration certificate and the appropriate time chart to calculate your desired treatment time.

10.4 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 6 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

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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 6 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
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

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Cleaner/Solution	Contact Time
70% Isopropyl Alcohol	3 min

Table 2 Tested Cleaners

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

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 manufacturers 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 Replacement

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

The Phothera 200 should be used in an electromagnetic environment as described below.

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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, radio-frequency, electromagnetic field immunity test following IEC 61000-4-3	80 MHz to 2.7GHz @ 10.0 V/m	80 MHz to 2.7GHz @ 10.0 V/m
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

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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

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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**
			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			

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13.0 Warranty

13.1 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

13.2 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.

13.3 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.

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13.4 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.

13.5 Disposal

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

13.6 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.

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13.7 Contact Information

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