Phothera™

Operation Manual

Phothera 600

DT Controlled

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

Phothera

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Dear Valued Customer,

Thank you for selecting a Phothera 600 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 he or she practices.

1.0 Control Type

Your phototherapy unit is equipped with the Digital Timer (DT) Controller. Please refer to Section 10.2 Operation of the DT Controller for instructions and details.

2.0 Indications for Use

The Phothera 600 Phototherapy Devices are indicated for use to treat diagnosed skin disorders such as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The population may range from pediatric to geriatric.

3.0 Delivery and Inspection

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

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 elect 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 your right to an insurance claim.

4.0 Site Selection

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

4.1 Electrical Requirements

In the United States and Canada, the Phothera 600 is shipped with a standard three-pronged plug power cable.

- The Phothera 600 **should** be plugged into any grounded household electrical.
    - The Phothera 600 **should not** be plugged into a residual current device (RCD) or an RCD protected circuit.
    - The Phothera 600 **should not** be plugged into a ground-fault circuit interrupter (GFCI) or a GFCI protected circuit.

All Phothera 600 devices are equipped with an onboard fuse. The fuse holder is a part of the power cord receptacle that is located on the lower rear side of the device. If an onboard fuse fails, call Phothera's service department to determine an appropriate replacement.

5.0 Unpacking and Assembly

Be careful, fluorescent lamps can break if the unit is not unpacked properly!

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

1. Remove the top of the box/crate and set it aside. Using at least two people, lift the device, including the foam shock absorbers, from the box and lay it on its side. Do not remove the foam shock absorbers yet.
   Note: *The device can weigh as much as 135 pounds (61 kilos). Always use two or more people when lifting the unit. Practice safe lifting techniques.*

2. Remove all packing materials from the container. Ensure that the following parts and accessories are accounted for:
    a. **Protective** Goggles (1 pair)
    b. Feet (2) - found in the top and bottom foam shock absorbers or taped to the inside of cardboard crate: see *Figure 1: Feet.*
    c. Stabilizer Bracket (2) - found in the middle shock absorber or taped to inside of the cardboard crate: see *Figure 2: Stabilizer Brackets.*
    d. Grid (attached in units without doors)
    e. Power Cord

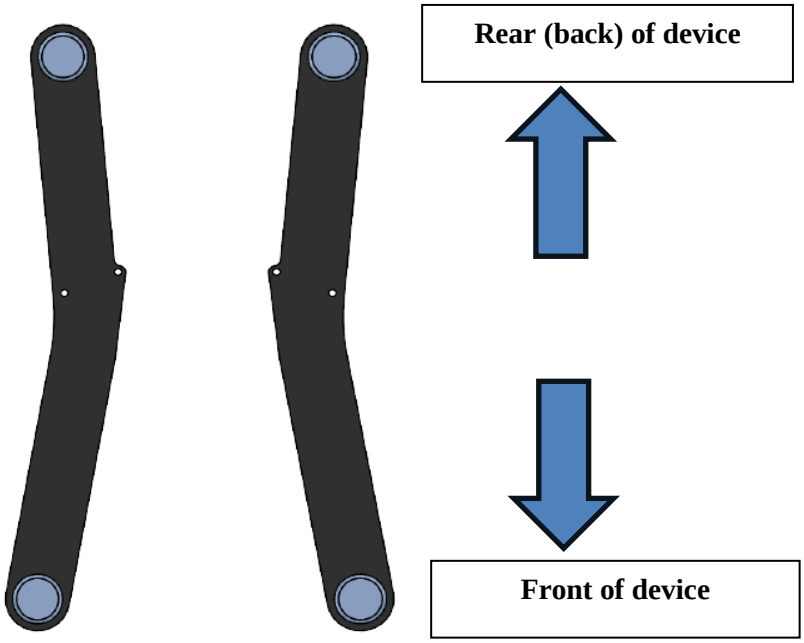

Figure 1: Feet

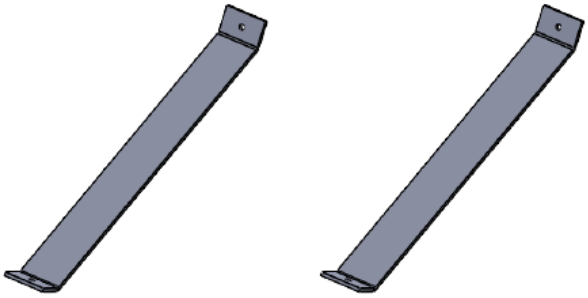

Figure 2: Stabilizer Brackets

3. The screws to attach the feet are pre-inserted in the bottom of the unit at the factory – remove the top and bottom foam shock absorbers to locate the end of the device that has screws protruding (Units with doors: screws protrude from metal bracket); this is the bottom of the device. Using a #3 Phillips screwdriver, remove the screws, then position the first foot so that its "longer" side is toward the front (the lamp side of the device – see ***Figure 3***) and the side of the foot with the rubber pads is towards the floor. Mount the feet using the screws that you removed from the bottom of the device. Repeat the process for the second foot. Do not overtighten screws.

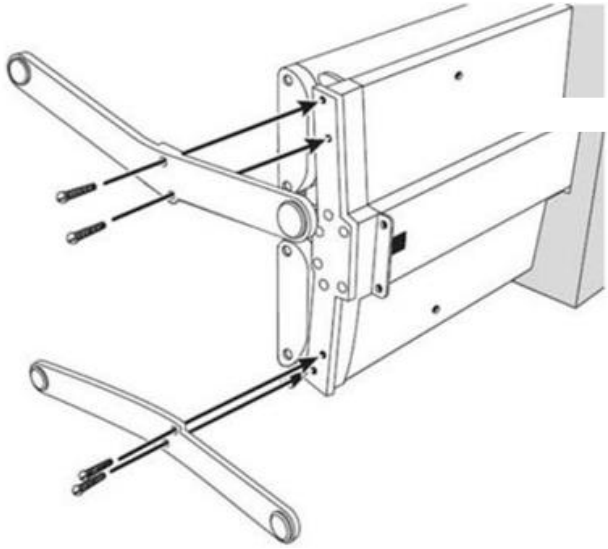

Figure 3 Feet Installation

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

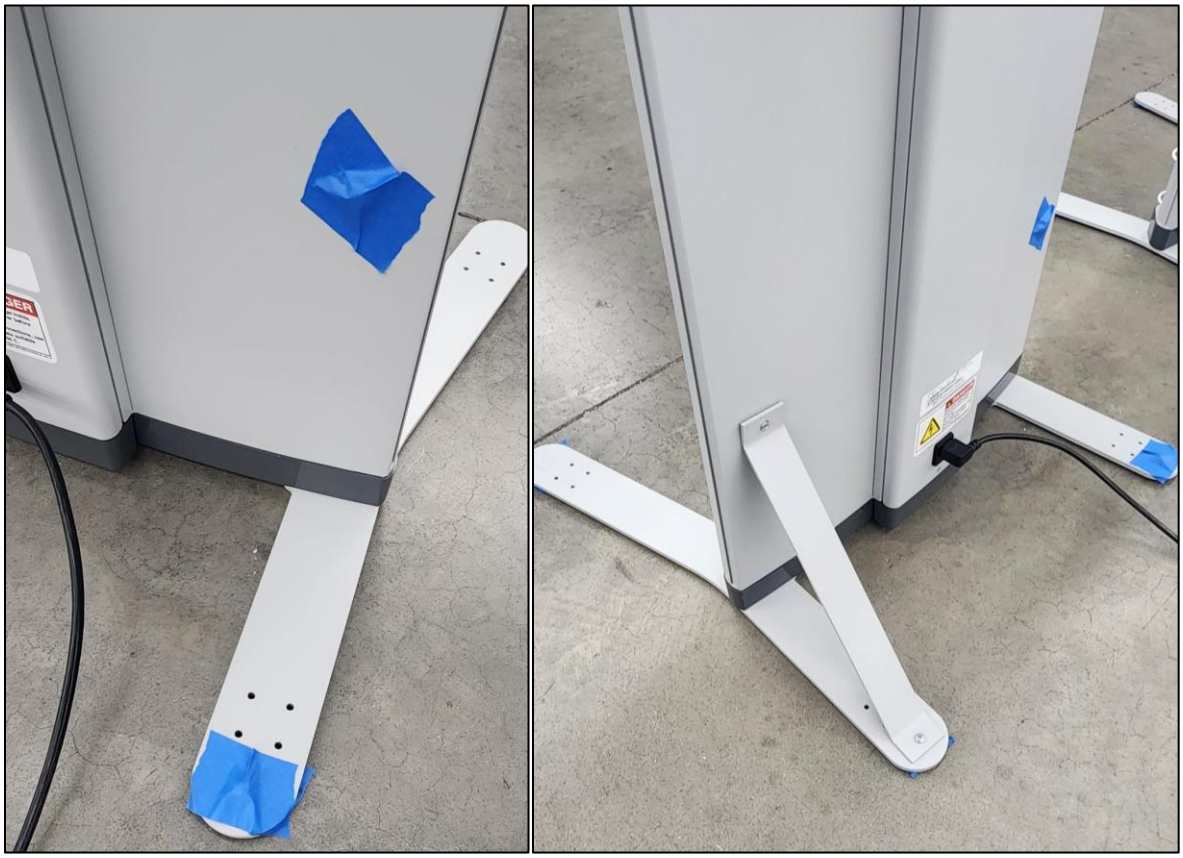

Figure 4 Left – Stabilizer screws covered by tape. Right – Stabilizer mounted.

7. Gently slide the unit into its permanent location.
8. Units with more than 4 lamps: Remove the screws at the bottom of the device in front of the lamps (Units without doors: 2 screws total, units with doors:4 screws total). Insert the perpendicular grid wires into the holes in the top lamp plate and push the grid all the way up. Swing the bottom of the grid in toward the lamps and insert the grid wires into the two holes in the bottom lamp plate. Then, lower the grid until the bracket touches the bottom lamp plate. Using a 5/16" hex driver/socket, screw the bracket to the bottom lamp plate using one of the hex-headed, self-tapping screws provided.
9. Insert the male "D" shaped plug into the "D" shaped receptacle at the back of the device. Then, plug the unit into an appropriate, grounded electrical receptacle.

6.0 Lamp Inspection

The device can be prescribed with several different types of lamps ranging within the ultraviolet spectrum, each having a different effect on the skin. It is important to check that the proper lamps are installed in the device. If there is any question that the unit is not equipped with the lamps you have been prescribed, contact the manufacturer immediately. The lamp's code numbers are generally located at the base of the lamp.

7.0 Precautions & Warnings

- To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. **Always use Phothera approved eyewear purchased through Phothera.**
- Do not remove protective eyewear, or any other protective equipment, during treatment.
- If psoralens (photosensitizing drugs) are being used as part of your treatment ("PUVA"), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with devices equipped with UVA lamps.
- Do not use over skin eruptions without express consent from the attending physician.
- If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.
- To protect unaffected skin during operation, the operator, patient, and anyone in view of the device must generously apply UV blocking skin protection to all exposed skin that the physician does not intend to treat.
- Erythema can result in as little as 15 seconds of exposure to UVB light. Prior to using your home phototherapy unit, contact your prescribing physician for specific treatment instructions and dosing information.
- Center patients between the lamps during treatment to avoid over exposure to isolated areas of the body.
- All people and pets should leave the area to avoid exposure to ultraviolet light.
- Ask your doctor about protecting areas of your body which have not been exposed to sunlight.
- Do not use this device for anything other than its intended purpose.
- This device is only to be used by authorized users.
- Do not operate this device with a damaged cord or plug.
- Do not position the device in such a way that it is difficult to disconnect power (i.e. unplug 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.
- 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 Environmental Specifications. If the device continues to malfunction cease operation and contact Customer Service.
- 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.
- Prior to each use, always verify that the device is in correct working order and operating condition. Ensure that plugs, sockets, lamps, and electrical cables/connections are not worn or damaged.
- Only original components and accessories should be used with the device to avoid damage.
- This device should be a minimum of 12 inches (30 cm) away from radio frequency (RF) generating equipment.
- Before opening the device casing to perform maintenance or service, disconnect the device from the power source.
- The device must never be directly exposed to flowing or splashing liquids of any kind. If the device is inadvertently exposed to liquid, it must be tested for safe function before being placed in operation again.
- The device contains glass lamps. Avoid excessive force to the device to prevent lamp damage.
- The device control system display is susceptible to damage from excessive force. Avoid excessive force to the control system to prevent damage.
- All treatments must be administered under the direction of a licensed physician only.
- **WARNING**: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Device is not to be used in MR environments that may include MRI, diathermy, electrocautery, or other high frequency equipment.

- Do not treat if the lamps fail to ignite. Consult with doctor and/or contact 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

Table 1 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, oxygen, or nitrous oxide.

9.0 Labels and Symbols

A warning label *(Figure 5 : Warning Label)* is affixed to the device in a prominent and easily readable position. Please read the label carefully as it contains important safety information.

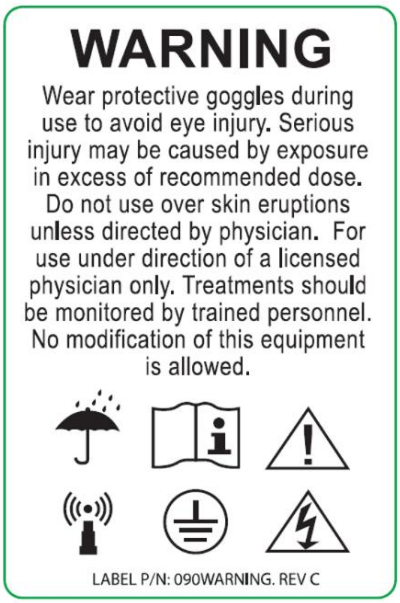

Figure 5 : Warning Label

The serial number and manufacture date of the device are printed on an identification label ***(Figure 6)*** that is located at the back of the unit near the power cord.

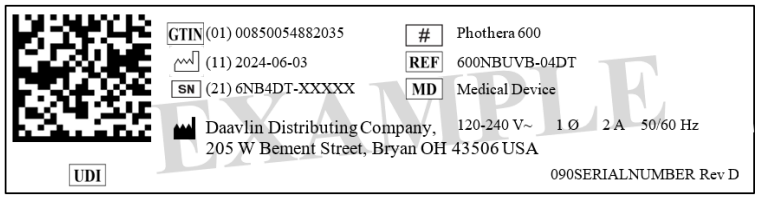

Figure 6 : Serial Label

Also, on the back of the unit near the power cord is a hazard label indicating high voltage. Please read the label carefully as it contains important safety information regarding high voltage and servicing.

Figure 7 Hazardous Voltage Label

Near the DT Controller on your device is a label that explains how to obtain treatment refills. See ***Figure 8*** below:

Figure 8 Refill Label

On top of your device's DT Controller is a 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 on to this label for future reference. See ***Figure 9*** below:

Figure 9 Keycode Label

Table 2 Symbols lists all the symbols located on the device along with their meaning:

Table 2 Symbols

SYMBOL	DESCRIPTION
	DANGEROUS VOLTAGE
	NON-IONIZING RADIATION
	PROTECTIVE EARTH (ground)
	OPERATING INSTRUCTIONS
	KEEP DRY
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	MEDICAL DEVICE
	MANUFACTURED BY
	SERIAL NUMBER

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 if you should use alcohol or cream-based sunscreen. 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 manufacturer's approved eyewear. Do not remove protective eyewear, or any other protective equipment, during treatment. Always stand 9" away from the center panel of the device.

10.2 Operation of the DT Controller

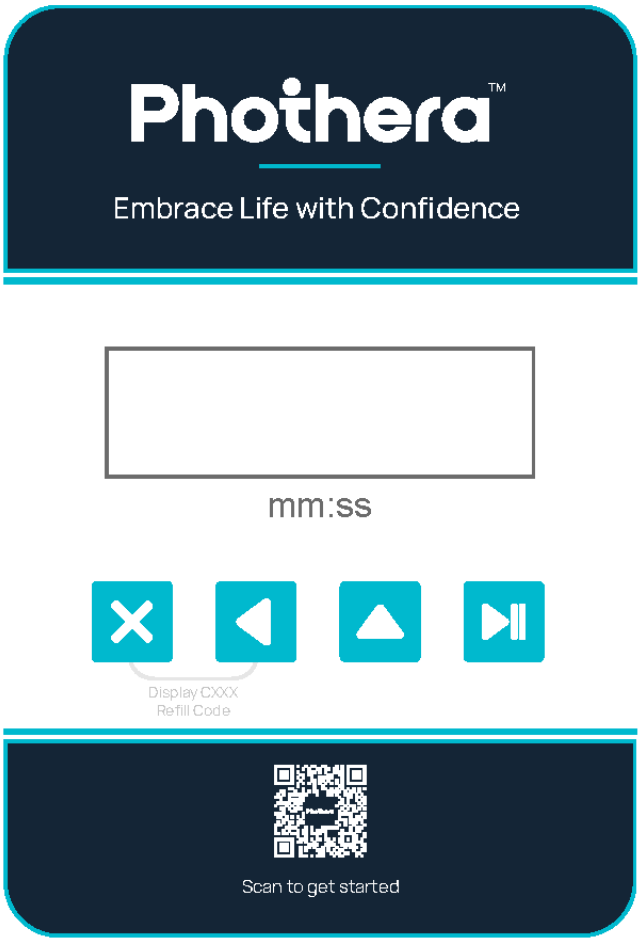

Figure 10 DT Controller Overlay Label

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 Viewing Device Code for Treatment Refills

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.
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. Alternatively, when all treatments have been exhausted, the display will display this Device Code.
6. If all treatments 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.

10.2.3 Setting Up a Treatment Time

1. Enter in your key code. Unless you have changed it, the factory default Key Code is "0007."
2. Once the Key Code has been entered, the display should read "00:00" (minutes:seconds).
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.
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. Record this treatment time in your treatment journal/log. You will want to save it for subsequent treatments.
    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), 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.

10.2.4 Treatment Refills

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.

To **REFILL** your 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 the Device Code is not displayed, there are exposures remaining and it will be displayed once all exposures have been 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.

10.2.5 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 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 11 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 11 Example Time Chart

11.0 Care of the Unit

11.1 Recommended Maintenance Schedule

Table 3 Recommended Maintenance Schedule

Item / Action	Frequency
Dusting of the unit and lamps	Once a month
Fully clean all internal reflectors, lamps	Annually (behind the lamps)
Replace lamps	***UVB – Approximately** every 300 hours of use. ***UVA – Approximately** every 500 hours of use.

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

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 liquid dishwashing soap 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, several cleaners have been tested that do not degrade the integrity of the components and can be seen in **Table 4 Tested Cleaners**

Table 4 Tested Cleaners

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

1. Thoroughly wipe down the surfaces and allow contact time listed in Table 4.

2. Allow to air dry and inspect for visible contaminants.
3. If contaminants remain repeat until no visible contaminants remain.

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

11.3 Lamp Replacement and Removal

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

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

Because of differences between brands, always replace lamps with the same brand as originally installed. Contact the Service department for a lamp replacement quote.

11.3.1 How to Change Lamps

1. When replacing the lamps unplug the machine, then, using either a 5/16" hex driver/socket or a #2 Philips-head screwdriver, remove the screw from the bottom of each grid.
2. Lift each grid out of its holes in the bottom lamp plate, pull the bottom of the grid forward, then slide it out of the holes in the top of the unit and set it aside.
3. Grasp the lamp to be removed with both hands and press down until it clears the top socket, then remove the lamp. Reverse the process to re-install the lamps and grid.
4. Reset the lamp hours to zero.

11.3.2 Resetting Lamp Hours

When changing lamps, it is important to reset the lamp age to zero so the new lamp's operating hours can be tracked. Please refer to Customer Service for instructions on resetting lamp hours.

12.0 Environmental Specifications

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

Table 5 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 device is suitable for healthcare environment operation in hospitals and clinics
Limits for Harmonic Current Emissions Following IEC 61000-3-2	Class A	The device is suitable for healthcare environment operation in hospitals and clinics
Limitation of Voltage Changes, Voltage Fluctuations, and Flicker Following IEC 61000-3-3	Compliant	The device is suitable for healthcare environment operation in hospitals and clinic

Table 6 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
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 7 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.

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 REPLACEMENT 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.

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 our 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.

13.7 Contact Information

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