

Phothera®

Operation Manual

Phothera

400

ClearLink™ Controlled

Modes of Operation:

Guided | Dosimetry | Timed

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

Phothera

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Hello!

Thank you for selecting the **Phothera® 400 Phototherapy Device**.

The Phothera 400 is manufactured by Daavlin Distributing Co., doing business as Phothera.

Phothera designs and manufactures FDA-cleared prescription phototherapy devices for the treatment of photo responsive skin conditions. This Operator Manual provides essential information for the installation, operation, maintenance, and care of the Phothera 400.

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

Regulatory Notice:

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

1.0 Control Type

The Phothera 400 phototherapy unit is equipped with Phothera's ClearLink® Controller. The device was prescribed by a doctor to function in one of the three modes listed below:

- **Guided:** The system controls the beginning dose and all subsequent doses depending upon how the users skin responds to the therapy. See section *11.0 Guided Mode* for operating instructions that are specific to this mode of operation.
- **Dosimetry:** The user controls the doses which are delivered in either Joules or Millijoules. The system automatically adjusts the length of each treatment depending on the power of the lamps. The doses given will be based on instructions from a doctor. See section *12.0 Dosimetry Mode* for operating instructions that are specific to this mode of operation.
- **Timed:** The user controls the length of each treatment, based on instructions from a doctor. See section *13.0 Timed Mode* for operating instructions that are specific to this mode of operation.

Exposure-Limiting Software: A physician may have prescribed the device with a system that limits the total number of exposures the device will deliver before a refill code is required. Specific information about these systems is provided in this manual.

2.0 Indications for Use

The ClearLink Controlled Phototherapy Equipment are medical ultraviolet devices, which are intended for use, by or under the direction of a physician, for therapeutic treatment for individuals who require ultraviolet radiation for diagnosed skin disorders. When equipped with blue lamps the ClearLink Controlled Phototherapy Equipment is intended for use for the treatment of mild to moderate acne vulgaris.

3.0 Delivery and Inspection

Upon delivery, inspect the box and its contents. If it's not possible for the receiver to inspect the unit before the driver leaves, we recommend writing "**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 delivery carrier may require that a damage inspection be conducted. They may conduct the inspection at the home, or they may elect to collect the package for inspection at their facilities.

Note: In addition to notifying the manufacturer, the delivery 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

We have listed a few recommendations for helping you select the best location for your device:

- Within reach of a standard, grounded electrical outlet and not using extension cords
- Located away from foot traffic to avoid tripping
- Avoid placing near water or where moisture can collect on the device
- Protected from access by children

Helpful note: 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 400 is shipped with a standard three-pronged plug power cable.

- The Phothera 400 **should** be plugged into any grounded household electrical.
 - The Phothera 400 **should not** be plugged into a residual current device (RCD) or an RCD protected circuit.
 - The Phothera 400 **should not** be plugged into a ground-fault circuit interrupter (GFCI) or a GFCI protected circuit.

All Phothera 400 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 box cut the packing board tape from the top - grasp each side of the device. Pull it, along with the foam packers, up and out of the box. Remove the foam packers.

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

2. Set the unit on a table so that the lamps are facing up and the end opposite the controller is hanging over the edge of the table.
3. On each side of the unit, there will be four thumb screws. Remove them. They will be used to attach the feet to the sides of the unit.
4. Take one of the feet and align the four precut holes with the four holes on the side of the device that were created by removing the thumb screws.

Note: The feet will only fit one way. Be sure that the widest part of the foot is level with the bottom of the unit and that the lip or rail faces away from the unit. For a picture of the proper foot alignment please see the cover of this manual.

- To secure the foot, thread the four thumb screws through the holes in the foot and into the side of the unit, tightening each of them lightly. Be sure to insert all the thumb screws before fully tightening them.

Note: Tighten the thumb screws using your thumb and index finger. If necessary, the screws can be tightened with a flathead screwdriver.

- Repeat steps 4-5 to install the other foot.
- Stand the unit up vertically and check all the screws to be sure they are tight.
- Insert the “D” shaped male plug into the corresponding receptacle on the lower left side of the device. Plug the unit into any standard, grounded electrical outlet.

6.0 Lamp Inspection

Phothera 400 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 (see 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 the manufacturer immediately. Lamp code numbers are generally located at the base of the lamp.

6.1 Lamp Specification Guide

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

7.0 Precautions and Warnings

- To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. Always use Phothera approved eyewear purchased through Phothera.
- Do not remove protective eyewear, or any other protective equipment, during treatment.
- If psoralens (photosensitizing drugs) are being used as part of your treatment (“PUVA”), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with devices equipped with UVA lamps.
- Do not use over skin eruptions without express consent from the attending physician.
- If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.
- To protect unaffected skin during operation, the operator, patient, and anyone in view of the device must generously apply UV blocking skin protection to all exposed skin that the physician does not intend to treat.
- During extremely long treatments, some surfaces may become hot. Remove any body parts from those surfaces if it becomes uncomfortable.

- Erythema 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 your 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 mains disconnect, do not position the device so that it is difficult to operate the disconnection device.
 - If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging device.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with a protective earth.
- To prevent electric shock, remove power to the device prior to cleaning and servicing.
- To eliminate the risk of fire when replacing the fuse, replace **ONLY** with a fuse of the same type and rating.
- **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 the 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.
- 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.

- **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 19.7 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 Phothera customer service. (See 19.7 Contact Information)
- ClearLink® 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

A removable label (*Figure 1 Unlocking Code*) located near the display provides information on how to unlock the unit.



Figure 1 Unlocking Code

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

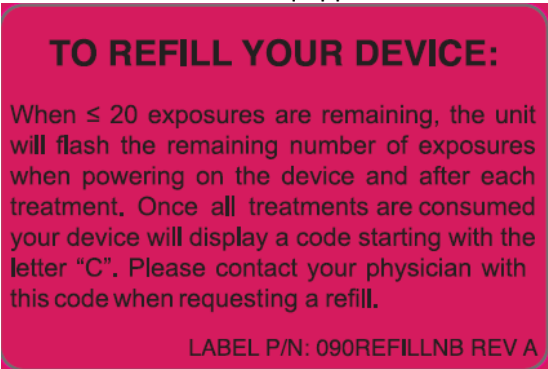


Figure 2 Refill Label

A warning label (*Figure 4 Warning Label*) is affixed to the phototherapy device in a prominent and easily readable position. Please read the label carefully as it contains important safety information.

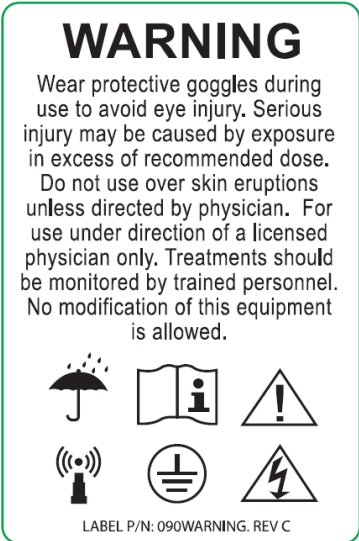


Figure 4 Warning Label

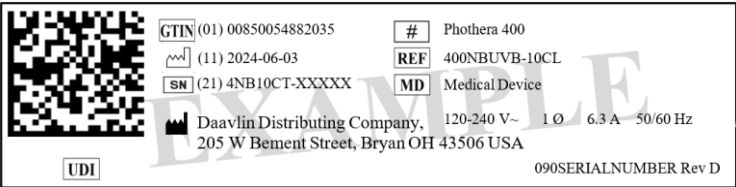


Figure 3 Identification Label

The serial number and manufacture date of the device are printed on an identification label (*Figure 3 Identification Label*) that is located at the back of the unit near the power cord.

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

Table 1 Symbols

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

10.0 General Instructions (All Modes of Operation)

10.1 Pre-treatment Preparations

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

The ClearLink Controller will track treatment data. However, a notebook, or treatment log may be wanted 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 Special instructions – Phothera 400 with 20 Lamps Only

If a ten-lamp unit has been prescribed, treatments should only be taken from a distance of 9 inches!

The Phothera 400 **twenty lamp unit** has been designed to deliver accurate and effective treatments from two distinct treatment distances. If a 20-lamp unit has been prescribed, 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 22 centimeters).

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

By selecting the treatment distance, 0 in or 9 in, you are telling the system how it should calculate the length of the treatment based on the distance from the lamps.

10.3 How to Position Yourself

Large Area Treatments: The recommended distance from the lamps for treatment is 9 inches (22 centimeters). We also recommend that the distance is marked on the floor in some manner. The user's torso should not be closer to the lamps than this line. Standing closer to the lamps will cause localized streaking or burning.

Small Area Treatments at the Acrylic Surface (20 lamp Phothera 400 only): Place the area being treated directly on the acrylic lamp guard. For the best results, the area being treated should be positioned as close as possible to the center of the fixture.

Note: When treating, 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.

10.4 Unlocking the Device

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

1. Tap the blank screen. The Phothera logo will appear.
2. Tap the logo. The Lock Screen will appear (unless disabled)
3. Using the keypad, enter the number 7 (unlocking code)
 - a. PIN will read as "0007".
4. Press the Enter key  to unlock.



Figure 5 Logo Screen

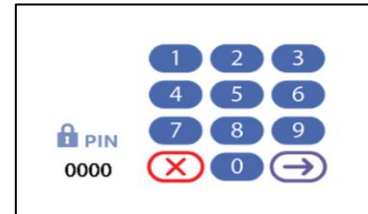


Figure 6 Lock Screen

10.5 Common ClearLink® Functions

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

10.6 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.

10.7 Treatment Limiting Software (Rx)

If the unit was prescribed with treatment limiting software, a screen (*Figure 7 Treatment Remaining Screen*) will say how many exposures remain before a refill prescription is needed. See Section 15.3 Uploading Refill Prescriptions)

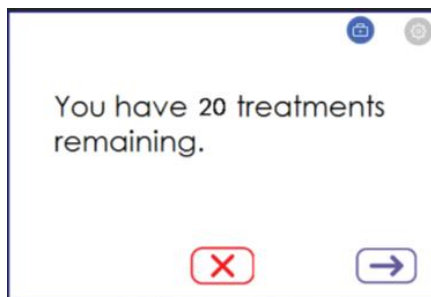


Figure 7 Treatment Remaining Screen

11.0 Guided Mode

11.1 Features of the ClearLink® Controller with Guided Mode technology

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

For example, each time the device is used, the ClearLink Controller will check the date of the last treatment. If on schedule, it will automatically proceed. However, if one or multiple treatments have been missed, the system will adjust accordingly to keep the dose at a safe level. A screen will appear advising the user of the adjustment (See Figure 8 below).

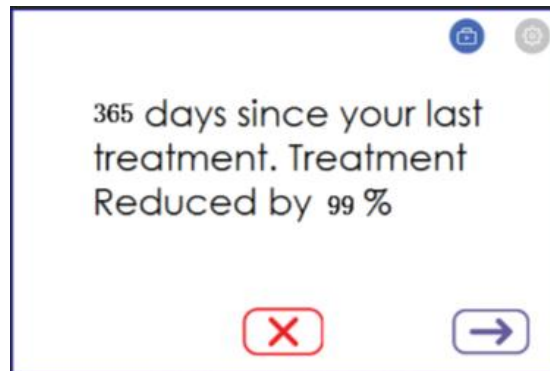


Figure 8 Treatment Adjustment message

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

Finally, before each treatment, the ClearLink Controller will ask about the current condition of the user's skin, such as whether or not there is any redness, mild or otherwise. It will use this information to calculate the next dose. Keep in mind, it is normal to experience some "redness" within 8 – 12 hours of a treatment but it is typically gone before it is time for the next treatment.

11.2 Running a Treatment

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

1. After unlocking the device, the Treatment Screen will appear with the scheduled dose.
2. The user will be asked, ***"Were you in pain or red after your last treatment?"***
3. The user must choose one of the following responses:
 - ☐ No, or < 24 Hrs ("Not at all, or it was gone in less than 24 hours")
 - ☐ 24 – 48 Hrs ("I was in pain or red for 24-48 hours after the treatment")
 - ☐ > 48 Hrs ("I was in pain or red for more than 48 hours")
 - ☐ Still red / pain ("I am currently still red or have pain")

Note: Selection of the “Still red / pain” option will lock the device until one treatment has been skipped. This prevents treating the skin until the erythema (redness) has resolved.

4. Once the response has been highlighted, press the Enter  key.
5. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button (**Only for 20 lamp units**)
6. The Treatment Confirmation screen will appear and will display the dose and an estimated time for the treatment. If changes need to be made, press the back  arrow. To cancel, press the Cancel  key.

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

7. Press the Enter  key to begin the treatment. A 3 second countdown will begin; the lamps will turn on and the screen will track the user’s progress. The lamps will shut off when the treatment is over.
8. To repeat the same dose for exposure to another part of the body, touch the Repeat  button. **Note:** Repeats will not be available after leaving the treatment screen.
9. To pause an active treatment, press the Pause  button. To resume, press the Play  button. To end or cancel an active treatment, first pause the treatment and then press the Cancel  button

12.0 Dosimetry Mode

12.1 Features of the ClearLink® Dosimetry Home-Control System

The ClearLink Dosimetry Home-Control System uses a built-in sensor as part of a function called integrating dosimetry to monitor the amount of light energy being produced by the device. The system then automatically adjusts the length of each treatment to account for variations in light output caused by changes in room temperature and aging of the lamps.

12.2 Running a Treatment

After unlocking the device, the Treatment Screen will appear.

1. Press the Treat Patient button, then
2. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button (**Only for 20 lamp units**)
3. Touch the ▲/▼ arrows to set the desired dose in Millijoules (UVB) or Joules if the device is a UVA device.

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

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

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

6. Press the Enter  key to begin the treatment. A 3 second countdown will begin; the lamps will turn on, and the screen will track the treatment progress. The lamps will shut off when the treatment is over.
7. To repeat the same dose for exposure to another part of the body, touch the Repeat  button. **Note:** Repeats will not be available after leaving the treatment screen.
8. To pause an active treatment, press the Pause  button. To resume, press the Play  button. To end or cancel an active treatment, first pause the treatment and then press the Cancel  button.

13.0 Timed Mode

13.1 Running a Treatment

After unlocking the device, the Treatment Screen will appear with the scheduled dose.

1. Press the “Treat Patient” button.
2. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button (**Only for 20 lamp units**)
3. Touch the ▲/▼ arrows to enter the desired treatment time. **Note:** It is **not** possible to enter a time of 60 seconds. A time of 1 minute must be entered.
4. Press the Enter  Arrow to enter the Treatment Confirmation screen.
5. Confirm the Time. If a change is needed, press the Return  Arrow and return to step 3.

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

6. Press the Enter  key to begin the treatment. A 3 second countdown will begin; the lamps will turn on, and the screen will track the treatment progress. The lamps will shut off when the treatment is over.
7. To repeat the same dose for exposure to another part of the body, touch the Repeat  button. **Note:** Repeats will not be available after leaving the treatment screen.
8. To pause an active treatment, press the Pause  button. To resume, press the Play  button. To end or cancel an active treatment, first pause the treatment and then press the Cancel  button

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. This can be accessed by visiting www.photherahcp.com/tools-resources/calculators/ for a web-based calculator and

additional information. In that app, simply enter the time of the last treatment and the desired percentage increase and the calculator will give the new treatment time instantaneously.

13.2 Determining a Treatment Time

When using time as a dose, there are two treatment methods that can be used. The simplest is to start at a prescribed time and then increase treatment times by a specific time increment or by a percentage, per the prescribing physician's protocol. Another method is to use the factory power output levels (shown on the Power Output Certificate) to determine estimated "time equivalents" needed to deliver doses in millijoules (UVB) or Joules (UVA).

To determine a "time equivalent", consult the laminated Time Chart that is provided and find the power output on the top row (horizontal axis). The numbers in the column on the left (vertical 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/cm² 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 9 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 www.photherahcp.com/tools-resources/calculators/ for a web-based calculator and additional information.

↓

mW/cm ² 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 9 Example Time Chart

14.0 Time-Based Output/Fixed Output Mode

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

15.0 Care of the Unit

15.1 Recommended Maintenance Schedule

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

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

15.2 Changing or Disabling the Unlocking Code

The unlocking code is a safety feature that prevents someone from accidentally turning on or tampering with the device. It works just like a key. To remove the feature or to change it to a number that is easier to remember, contact the customer service department at 1-216-831-0600 for step-by-step instructions.

15.3 Uploading Refill Prescriptions

When specified by the prescribing physician, Phothera home phototherapy devices are equipped with exposure-limiting software. For each sequence of exposures, the number of available treatments is reduced by one. A treatment sequence consists of the primary exposure plus up to three repeat exposures, if needed, for treating other areas of the body.

If the device is equipped with this feature, upon “waking up”, the screen will display pre-set reminders of how many exposures are remaining. To ensure there are no interruptions in therapy, we suggest that the physician be contacted and given the device code (CXXX) when 5 to 10 exposures remain. The physician will use this device code to generate a refill or “treatment” code for a “refill”. Once out of exposures, the controller will prompt a new prescription to be uploaded, see Figure 10 Device out of Treatments).

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

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

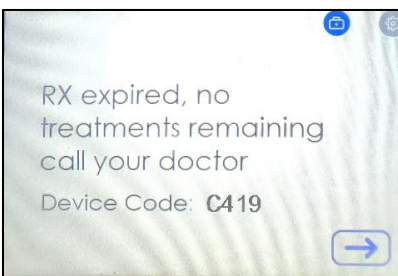


Figure 10 Device out of Treatments

15.4 Downloading Treatment History

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

15.5 Cleaning/Disinfection

15.5.1 General Cleaning

For general use, use a clean non-abrasive cloth, not paper towels, and a mild cleaning solution such as Dawn Liquid Dishwashing Soap to gently wipe down the exterior of the device.

15.5.2 Low-Level Disinfection

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

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

Table 2 Tested Cleaners

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

15.5.3 High-Level Disinfection

Follow a high-level disinfection protocol between the use of the device on different patients. Use a high-level disinfectant, such as Steris Corporation's Resert™ XL-HLD, and follow the manufacturer's guidelines. See also "FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices" available at: <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and>.

We suggest using "Monk" Brand Wipes as they disinfect and will not harm any ultraviolet or light transmitting surfaces. These wipes are available for purchase from Phothera. When dusting the unit and the lamps, we recommend using a feather duster or a similar non-abrasive cleaning device.

Note: Do not clean reflective surfaces with paper towels. They may scratch the surface.

At least once a year, we recommend that the protective acrylic be removed for a more thorough cleaning of the lamps and reflectors. Refer to the Lamp Replacement instructions on how to remove the acrylic and lamps, as well as other important information on how to ensure that the lamps are safely and correctly replaced.

15.6 Calibration/Power Output

The power output of the device was measured before it left the manufacturing facility. A "Calibration Output Certificate" is included with the operating manual and contains the device's factory measured power output. The certificate for ten (10) lamp units will state the power output of the device at a distance of nine (9) inches from the acrylic surface of the unit.

Because the 20 lamp Phothera 400 has been designed to deliver treatments from two specific distances, 0 inches and 9 inches, the output certificate for 20 lamp units will have two outputs noted in the "Current Value" box. The higher of the two values corresponds to the "0 inch" setting and the lower of the two corresponds to the "9 inch" setting.

15.6.1 Dosimeter Accuracy/Range (Applicable to Guided and Dosimetry Units Only)

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

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

15.6.2 Timer Accuracy

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

15.7 Lamp Removal and Replacement

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

15.7.1 Resetting Lamp Hours

When changing lamps, it is important to reset the lamp age to zero so the operating hours of the new lamps can be tracked. Please contact the customer service department for instructions on resetting the device's lamp hours.

16.0 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.

17.0 Cybersecurity

The ClearLink controller is a stand-alone controller. There is no connection, wired or wireless, to any external network and/or the World Wide Web. The controller looks for encrypted .rx files only. All other files are ignored and cannot run. If an .rx file is not present, an encrypted .hst file is written to the USB drive. A J-Link adapter is required to transfer any executable files. The J-Link port is not accessible externally to the device.

18.0 Environmental Specifications

The Phothera 400 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 A	The Phothera 400 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 400 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 400 device is suitable for healthcare environment operation in hospitals and clinic

Table 4 Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Actual Level
Electrostatic discharge immunity test following IEC 61000-4-2	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)
Radiated, radiofrequency, electromagnetic field immunity test following IEC 61000-4-3	80 MHz to 2.7GHz @ 10.0 V/m	80 MHz to 2.7GHz @ 10.0 V/m
Electrical fast transient/burst immunity test following IEC 61000-4-4	+/- 2kV	+/- 2kV
Surge immunity test following IEC 61000-4-5	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV

Emissions Test	IEC 60601 Test Level	Actual Level
Conducted Immunity test following IEC 61000-4-6	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @ 6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @ 6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms
Power frequency magnetic field immunity test following IEC 61000-4-8	50 Hz, 30 A/m	50 Hz, 30 A/m
Voltage dips and interruptions immunity test following IEC 61000-4-11	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270, 315 degrees, 100% Interruption at 5000 mS at 0 degrees	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270, 315 degrees, 100% Interruption at 5000 mS at 0 degrees

19.0 Warranty

19.1 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

19.2 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 purpose 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.

19.3 Customer Responsibility

In the event 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.

19.4 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.

19.5 Disposal

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

19.6 Other Services

Extended warranties are available and may be purchased from Phothera's aftermarket sales department. In the event this Limited Warranty conflicts with other warranties included in Phothera's Equipment manual, the terms and conditions of this Limited Warranty shall prevail.

19.7 Contact Information

24/7 Customer Support Website: Support.Phothera.com

24/7 Customer Support Phone Number: 1-844-676-2882

Website: www.phothera.com



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