Phothera™

Operation Manual

Phothera 100XL

DT Controlled

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

Phothera

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1.0 INDICATIONS FOR USE

The Phothera 100XL™ 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.

2.0 ACCURACY

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

The Phothera 100XL should be used in an electromagnetic environment as listed below.

Table 1 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 effected.
RF Emission Following CISPR 11 (EN 55011)	Class B	Phothera 100XL device is suitable for healthcare environment operation in hospitals and clinics

Emissions Test	Conformity	EMC Environment Guide
Mains Harmonics Following IEC 61000-3-2	Class A	Phothera 100XL device is suitable for healthcare environment operation in hospitals and clinics
Mains Voltage Dips and Flicker Following IEC 61000-3-3	Compliant	Phothera 100XL device is suitable for healthcare environment operation in hospitals and clinic

Table 2 Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Actual Level
ESD Following IEC 61000-4-2	+/-2kv, 4kv, 6kv, and 8kv (conductive surfaces) +/-2kv, 4kv, 8kv, and 15kv (non-conductive surfaces)	+/-2kv, 4kv, 6kv, and 8kv (conductive surfaces) +/-2kv, 4kv, 8kv, and 15kv (non-conductive surfaces)
Bursts following IEC 61000-4-4	+/- 2kv	+/- 2kv
Surges following IEC 61000-4-5	+/- 2kv	+/- 2kv
Voltage drops, etc. following IEC 61000-4-11	5% for 10ms, 40% for 100ms, 30% for 500ms, 0% for 5000ms	5% for 10ms, 40% for 100ms, 30% for 500ms, 0% for 5000ms
H-Field following IEC 61000-4-8	3 A/m	3A/m

Table 3 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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**
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			

3.0 WARNINGS

- CAUTION: Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the state in which they practice.
- 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.
- To prevent unnecessary exposure, exposed skin that is not being treated (face, neck, ears, forehead, etc.) should be covered with a sun block for both UVA and

UVB. The sunscreen should be rated at SPF 30 or higher. Not all sun blocks are the same. Follow sunscreen instructions for proper application and use.

- 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 all Phothera devices.
- DANGER - ULTRAVIOLET RADIATION. As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer. ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE ERYTHEMA OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase skin sensitivity to ultraviolet radiation. Inform your physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.
- This device should be a minimum of 12 inches (30 cm) away from RF generating equipment.
- Do not remove protective eyewear, or any other protective equipment, during treatment.
- Ask your doctor about protecting areas of your body that have not been exposed to sunlight.
- All people and pets should leave the treatment area to avoid exposure to ultraviolet light.
- 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.
- Erythema can result in as little as 15 seconds of exposure, or approximately 200 millijoules of dose to UVB light. If using the unit at home, contact your prescribing physician for specific treatment instructions and dosing information.
- The device contains glass lamps. Avoid excessive force to the device to prevent lamp damage.
- It is important to carefully determine the proper treatment time. Over-exposure will produce erythema and discomfort. Under-exposure will result in reduced therapeutic benefit while at the same time building resistance to future treatments.
- The Treatment Plans included in these operating instructions are intended as guidelines only.
- All treatments must be administered under the direction of a licensed physician only.
- Do not use this device for anything other than its intended purpose.
- This device is only to be used by authorized users.
- 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.
- Always inspect the device case, timer, power cord, and goggles prior to use to ensure they are in good working condition. Do not use the device if it appears to be damaged or altered in any way.

- Never block the outlet that is being used to power the device.
- If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging the device from the outlet.
- This device is available with different types of UV lamps. To avoid serious injury, verify that the UV lamp type of the device is the same as prescribed by the licensed physician. If the lamp type is not the same, do not use the device. Contact the manufacturer immediately if this is the case.
- To prevent electric shock, remove power to the device prior to cleaning and servicing.
- Do not operate the device with the treatment wand in the base or exposure surface blocked. This may cause overheating and damage the unit.
- Do not operate the device in extreme temperatures as extreme heat or cold can affect the operation of the lamp.
- 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.
- If the device malfunctions, cease operation immediately. If the device is placed close to other equipment, it is possible that the cause is interference by external noise sources and fields, in which case you should follow the remedies found under EMC Environment guide. If the device continues to

malfunction cease operation and contact the Service Department.

- 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 control system display is susceptible to damage from excessive force. Avoid excessive force to the control system to prevent damage.
- WARNING: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Caution – Use of controls or adjustments or performance of procedures other than those specified herein result in HAZARDOUS radiation exposure.

4.0 COMPATIBILITY

The Phothera 100XL™ system has been tested and found to comply with the EMC limits of the international standard EN 60601-1-2. These limits are designed to provide reasonable protection against interference in a typical medical installation. The System can radiate radio frequency energy if not installed in accordance with the instructions and may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If the

System does cause interference with other devices, which can be determined by turning the System off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient or relocate the receiving device
- Increase the separation between the equipment
- Connect the System into an outlet on a circuit different from that to which the other device(s) is connected

5.0 DELIVERY AND INSPECTION

Once the Phothera 100XL™ has been delivered, please inspect the box and its contents. If damage is discovered after unpacking the unit be sure to save **all** packing materials, and call Phothera immediately to begin the claims process.

As part of the claims process the delivering carrier may require that a damage inspection be conducted. The delivering carrier may request to conduct the inspection at the delivery site, provided that a mutually agreed upon date and time can be established, 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.

6.0 SELECT A SITE

A site should be chosen within reach of the specified electrical outlet and where the unit can be left in place without being in the way of traffic flow. Extension cords are not recommended. The site should not be in any area where

water or moisture might collect and 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.

7.0 UNPACKING AND ASSEMBLY

1. Open the top of the box. Once open, pull the Phothera 100XL™ and wand out of the box.
2. Plug the unit into any household electrical outlet that matches the voltage and frequency of the machine. The unit is now ready for use.

8.0 WHAT THE OPERATOR WILL NEED

- The lamp information found in this manual
- Physician's dosage and treatment instructions
- Power source appropriate to the device
- UV blocking goggles or UV blocking glasses with UV blocking side shields for anyone in view of the Phothera 100XL™ while in use
- Sunscreen with an SPF factor of 30 or above
- Accessory Comb
- Treatment record & writing instrument
- Phothera 100XL™ Operating Instructions

9.0 DUTY CYCLE/TEMPERATURE SPECIFICATIONS

The permissible environmental conditions of use, including conditions for transport and storage, are as follows:

- Ambient room temperature of -40 °C to +70 °C

- Non-condensing relative humidity range of 10% to 100%
- Atmospheric pressure range of 50 kPa to 106 kPa.

This device should be used in ambient temperatures of 25°C (77°F) or less, and with maximum treatment duration of 10 minutes. If the device is too cold, the patient could be under-dosed. If multiple sequential treatments are desired, the device should be allowed to cool down 10 minutes for every 10 minutes of operation. If the device is operated outside of its duty-cycle, it will likely shut off. This is likely behavior and if this happens, please let the unit cool for 30 minutes before using again.

10.0 ELECTRICAL SPECIFICATIONS

Voltage	**120 Volts AC (Alternating Current)**
Frequency	**60 Hertz**
Amps	**0.40 Amps**

11.0 REPLACEMENT LAMPS

11.1 UVB (Narrow Band)

Lamp Type PL-S 9W/01/2P
Part # 060PWNBUVBLAMP

12.0 LABELS AND SYMBOLS

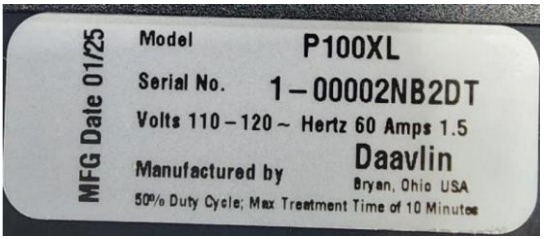
12.1 Warning Symbols

	WARNING, GENERAL, RISK OF PERSONAL INJURY
	WARNING, HOT SURFACE

	WARNING, ELECTRICITY
	WARNING, NON-IONIZING RADIATION
	WARNING, LAMPS CONTAIN MERCURY
	WARNING, PINCH POINT
	WARNING, ULTRAVIOLET RADIATION
	CAUTION, RISK OF DAMAGE TO MACHINERY, SOFTWARE OR PARTS
	NOTE
	OPERATING INSTRUCTIONS
	NO WASTE – UNIT CONTAINS ELECTRICAL AND ELECTRONIC EQUIPMENT THAT MUST BE DISPOSED OF AND/OR RECYCLED PROPERLY
	PROTECTIVE EARTH (GROUND)
	“ON” FOR EQUIPMENT
	“OFF” FOR EQUIMENT

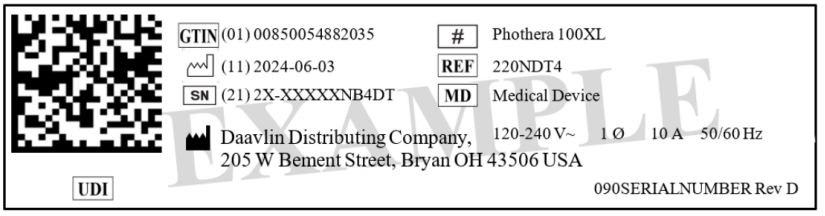
12.2 Small Serial Number Label

An identification label indicates the serial number and date of manufacture that is specific to your device. It is located on the backside of the main housing.



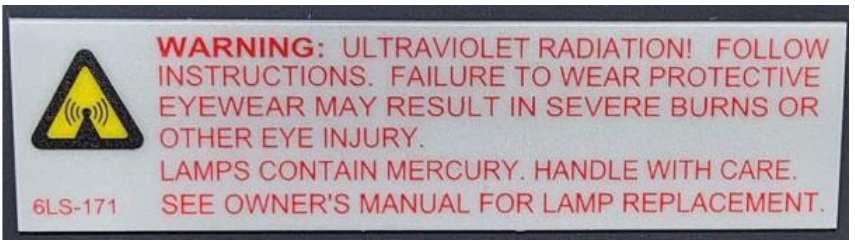
12.3 Large Serial Number Label

An identification label indicates the serial number and date of manufacture that is specific to your device. It is located on the shipping box.



12.4 Wand Warning Label

This is located on the wand side next to the cutout for the lamps.

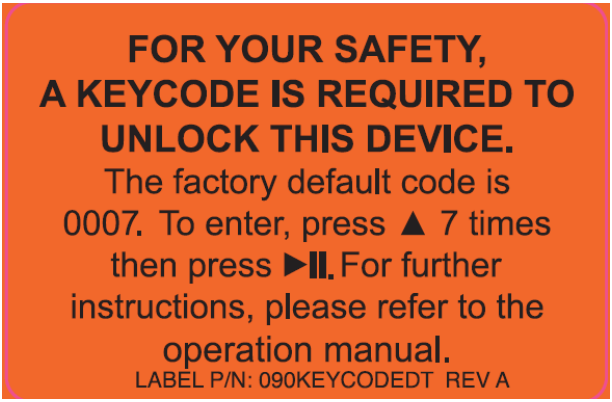


12.5 Control Box Warning Label

This warning label for the control box is placed on the underside of the control box in the cutout furthest from the power cord.

12.6 Keycode Label

Every Phothera 100XL™ comes affixed with a “keycode” label located on the top of the device. This label will provide you with important information about the passcode needed to unlock the unit.



12.7 Refill Label (Treatment-Limited Units Only)

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.

12.8 Medical Device Label

This label indicates that this is a medical device.

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13.0 GENERAL INSTRUCTIONS

13.1 UV Treatment Philosophy

UV treatment normally consists of two distinct phases: Clearing and *Maintenance*. The clearing phase builds up the UV exposure to the levels required to clear the skin over a long enough period to minimize discomfort to the patient. The maintenance phase is often employed to extend the benefits of the clearing phase treatment, while limiting the total exposure to UV. During the maintenance phase, treatments are normally continued at the last level reached during the clearing phase.

13.2 Patient Specific Treatment Instructions

A physician, based on the patient's skin type, MED, and lamp information located at the back of this manual, must determine individual patient treatments. *Phototherapy and Photochemotherapy of Skin Disease* by Warwick L. Morrison, M.D. and *Phototherapy Treatment Protocols* by Michael Zanolli, M.D. and Steven Feldman, M.D. are good sources of information for phototherapy treatment protocols.

14.0 TRAINING REQUIREMENTS

Phototherapy services require staff that have appropriate training, knowledge, and clinical skills in order to ensure effective outcomes and quality care for patients. Staff must be assessed as being competent to provide phototherapy treatments that maximize benefit and minimize adverse effects. Recommended training requirements include:

- Staff should be either a physician, nurse, or any other practitioner licensed by the law of the state or country in which he/she practices.
- Training and experience in Dermatology is important to provide holistic patient care. This knowledge includes:
    - Anatomy and the Physiology of the skin
    - Recognition and understanding of skin diseases
    - Skin assessment
    - Understanding of photo responsive diseases
- Theoretical knowledge of phototherapy and its use.
- Managers should ensure that staff members have, or are provided with, the appropriate level of training and education needed prior to administering phototherapy services.

14.1 General Home Treatment Guidelines

Always check with a physician before starting home treatments. Show the physician these instructions. The physician is the final authority for treatment. Depending upon individual circumstances, the physician may modify these directions. Always follow the physician's instructions.

For the first treatment, put on the protective eye goggles provided, set the timer for 15 seconds and treat an area of skin. If on the second day there is no redness or erythema, repeat the treatment adding 15 seconds to the exposure time. On subsequent days, repeat this procedure, adding 15 seconds per exposure until the skin starts to get pink. If the skin becomes red or uncomfortable after any treatment, do not resume the treatment until the redness has subsided. If redness and discomfort are severe, discuss this with the physician. Increases of less than 15 seconds may be necessary for some patients. Once initial pinkness has been achieved, follow the treatment regimen prescribed by the physician.

After each treatment, record the date of treatment, the length of each exposure, the time of day of the exposure and any other appropriate information, (e.g., forgot lip balm, put sunscreen on tender area of breast, etc.) Never take more than one treatment in a single day. Never treat sooner than 12 hours apart; that is, don't take a treatment late at night followed by an early morning treatment.

Important: *If after a treatment there are burned areas, have the patient protect those areas with sunscreen for as many treatments as it takes for the skin to become normal. (Make a note of this.)* ***See the physician regularly at the intervals he or she requests during periods of active use of the unit. Always make notes available to the physician.***

14.2 Recording Treatments

Using the sample treatment record provided at the back of this manual, keep a record of treatment data. This information should include the date and time of the treatment, the length of the treatment and any other pertinent information such as skin reaction to the treatment.

14.3 Installing the Comb

The Phothera 100XL™ is equipped with a comb to aid in the treatment of the scalp and to ensure that the light is held a consistent distance from the skin. To install the comb, follow these instructions.

1. Place the Phothera 100XL™ on a flat surface.
2. Hold the treatment wand firmly at the handle.
3. Slide the comb attachment over the wand so the tines (teeth) of the comb are on the same side as the exposure surface.
4. Comb is properly seated when a slight click is heard.

Note: *The exposure openings in the comb should align with the openings in the exposure surface of the wand and the contoured end of the comb should sit against the contoured end of the wand.*

14.4 Removing the Comb

The comb can be removed when the Phothera 100XL™ is stored. To remove the comb, follow these instructions.

1. Place the Phothera 100XL™ on a flat surface.

2. Hold the wand firmly at the end not covered by the comb.
3. With your other hand, grasp the comb and begin pulling the comb towards the top of the wand, away from the handle.
4. Once the removal process is started, pull the comb and wand in opposite directions until the comb is free of the wand.

15.0 TREATMENT INSTRUCTIONS

For best results, the Phothera 100XL™ should be warmed up for one minute immediately prior to treatment. To set a one-minute warm up time refer to the instructions for Time Entry Mode (Your Treatment Time) on page 27. The lamp will light automatically when the treatment is initiated, so be sure that **all individuals in the area, including the operator, are wearing proper eye and skin protection**.

***Important**: To avoid serious injury, always avoid having bystanders in the room when the lamp is on and verify the lamp type of the device to avoid serious injury. See the WARNINGS section of this manual.*

1. Install the comb if desired.
2. Plug the Phothera 100XL™ into the appropriate power source.
3. Apply sunscreen and eye protection, as necessary. See the WARNINGS section of this manual.

4. Hold the treatment wand over the desired treatment area.
5. Start the Phothera 100XL™ lamps by entering the time/dose prescribed by your physician, making use of the appropriate time chart.
6. Note the time on a separate timer or watch to verify the prescribed time of the treatment.

***Note**: The recommended treatment distance between the wand and the treatment surface is approximately 1.25 in / 3.18 cm. The comb can be used as a guide to maintain this treatment distance consistently.*

7. If treating the scalp, use the comb as necessary to move hair away from affected areas to allow for optimal treatment. Irradiate the affected area(s) evenly, while avoiding unaffected areas, as much as possible.

***Important:** Verify the time of treatment with the independent timer or watch. If the actual treatment time exceeds the set treatment time by more than 15%, stop the treatment by pressing the PLAY/PAUSE Button to pause the treatment, then pressing the CANCEL button to cancel the treatment and/or unplugging the unit from the power source. Contact Phothera if this situation persists.*

8. When the lamp turns off, record the treatment data, and properly clean and store the Phothera 100XL™. See the Cleaning/Disinfection & Storing the Phothera 100XL™ section of this manual.

Important: *To avoid serious injury and damage to the device, store the Phothera 100XL™ out of the reach of children in a dry area.*

15.1 Subsequent Treatments

If the treated area(s) of skin is red and sensitive 24 hours after treatment, consult your physician for instructions before proceeding with treatments.

16.0 HOW TO OPERATE THE DIGITAL TIMER

There are 6 modes of operation:

1. Security Code Activation
2. Time Entry
3. Countdown
4. Standby
5. Sleep
6. Prescription Refill Mode

16.1 Security Code Activation Mode:

Security Code Protection is an option with the Phothera 100XL™. If unauthorized use of the device is a possibility, we suggest that this system be activated. In the interests of simplicity, there is only one numerical code, so make sure that knowledge of the code number is limited. **The code is 0007.**

When the device is plugged in the security code will be activated. See Security Code Entry Mode instructions below.

16.2 Security Code Entry Mode:

1. In the Security Code Entry mode, the LCD will read C0dE with no colon.
2. Pressing the UP or LEFT button will take you to the code entry screen.
3. The device will read 00 00 with no colon and the digit furthest to the right will flash to indicate that it is the currently editable character.
4. Pressing the UP button will increase the flashing number from 0 to 1 to 2 and so forth. Pressing the LEFT button will move the currently editable character to the next number to the left. It will begin flashing. Press the UP button to set the desired number.
5. Press the LEFT button again to move to the third number and follow the same procedure as described above until all four digits are entered.

   NOTE: Pressing the LEFT button when in the leftmost position will cause the system to move to the rightmost position.

6. Pressing the CANCEL button at any time clears all values and allows the process to be started again.
7. Pressing the START/PAUSE button will enter the code. If the password is incorrect, the display will flash once, then the number furthest to the right will flash and the process will have to be restarted.
8. If the code is correct, the display will flash twice. On the second flash, the device will enter Time Entry Mode.

16.3 Time Entry Mode (Your Treatment Time)

1. Once the security code (if required) has been entered correctly; the display will show all zeros and the colon, and the number furthest to the right (the 1-second digit) will flash.
2. Pressing the UP button will increment (increase) the number that is flashing. The digit furthest to the right and the third digit from the right will roll over from 9 to 0, the second digit from the right and the fourth digit from the right will roll from 5 to 0. This limits the maximum treatment time to 59:59 (fifty-nine minutes and fifty-nine seconds).
3. Pressing the LEFT button will move to the next digit to the left.
4. Pressing the LEFT button, when in the leftmost position, will "round robin" the system to the digit furthest to the right.
5. Pressing CANCEL at any time will clear the display and allow you to restart the process.
6. Pressing START/PAUSE button, after the desired dose has been entered, will store the time in memory and all flashing will stop.

PUT ON GOGGLES BEFORE TURNING ON LAMP.

7. Pressing START/PAUSE button a second time will turn on the lamp and start the countdown.

16.4 Countdown Mode

1. When in Countdown mode, pressing the UP, LEFT, and/or CANCEL button will have no effect.
2. Pressing the START/PAUSE button will cause the lamp to shut off and the countdown to Pause. The lamp will go off and the display will flash.
3. If during Countdown mode the START/PAUSE button was pushed, to resume the treatment, press the START/PAUSE button. The lamp will come on, the display will stop flashing and the countdown will begin.
4. When the countdown continues to completion, the lamp will go off and the device will enter Standby mode.

16.5 Standby Mode

1. Upon completion of a treatment, the device will enter the Standby mode and the previous treatment time will be displayed (flashing). This can be a convenience as you may wish to use the device again to treat another area of your body and wish to use the same treatment time or wish to make just minor adjustments to the treatment time.
2. To use the previous treatment, press the START/PAUSE button twice to lock in the previous treatment time and then a third time to begin the treatment.
3. To make minor adjustments to the previous treatment time, press the START/PAUSE button to display the previous treatment time. Then use the LEFT and/or UP buttons to adjust the time as needed. Once the desired time is set, press the START/PAUSE button twice and the countdown will begin using the revised treatment time.

4. Or if you wish to start fresh, pressing the UP, LEFT, and/or CANCEL buttons will clear the display and enter the Time Entry mode (all zeros will be displayed). Follow the instructions under Time Entry mode above.

16.6 Sleep Mode

1. In all modes except Countdown mode and Pause mode, after three (3) minutes of inactivity (no buttons pressed), the device will enter Sleep mode and the LCD will turn off.
2. Pressing any button will cause the device to exit the Sleep mode. If Security Code Protection is activated, the unit will go into Security Code Entry mode. If Security Code Protection is inactive, the device will go into Time Entry mode. Any previous treatment times will not be recalled.

16.7 Prescription Refill Mode

1. The controller will automatically prompt the user to refill when it is out of exposures.
2. The controller will flash the number of exposures remaining after each exposure if exposures remaining are equal to 20 or less.
3. The LCD will display the word “CXXX” (See section 18.0 Additional Instructions – Treatment Refill).
4. Pressing the up button will advance the device and it will display 0000 with the rightmost digit flashing.
5. From here, the prescription refill code can be entered in the same way you would enter the security code.
6. If the code is correct, the device will flash the number of treatments added to the controller two times before it returns to Time Entry Mode and will be ready for use.

7. If the code is incorrect or invalid, the display will flash twice and display the password you entered. Check to make sure the code displayed is the same as the password you were given.

17.0 MAINTENANCE

17.1 Cleaning/Disinfection & Storing the Phothera 100XL™

17.1.1 Low Level Disinfection

Dust, dirt, and debris on the lamp will result in a loss of efficiency & effectiveness of the Phothera 100XL™. The goggles & comb may come into contact with broken skin during treatments, therefore an individual goggles & comb for each person treated is recommended. Follow these instructions after each use to keep the device clean.

1. Unplug the Phothera 100XL™ base from the power source.
2. Apply 70% isopropyl alcohol or 1-part bleach 3 parts water solution to a non-abrasive cloth and wipe the plastic and lamp surfaces free of any dust and debris.

***Note**: To avoid scratching the lamp, do not clean with paper towels. Do not apply liquid cleaner directly to any surface of the Phothera 100XL ™ base, wand, or lamp as it could cause damage to the electrical components.*

3. Clean the goggles & comb between treatments using a 70% isopropyl alcohol or a solution of 1 part bleach & 3 parts water solution. Soak the goggles and comb in the

solution for 5 minutes, then rinse thoroughly with water. Dry the goggles and comb before reusing.

4. Store the Phothera 100XL™ in a dry area out of the reach of children any time it is not in use.

17.1.2 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.

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 you remove the protective acrylic for a more thorough cleaning of the lamps and reflectors. Refer to 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.

17.2 Replacing the Lamp

As the Phothera 100XL™ is a time-only device, it, like all time-only phototherapy devices, will decrease in output over the life of a lamp. Typically, at the point of lamp failure the power will have decreased approximately 30% for initial value. As doses will have been increased to compensate for this, when the lamp is replaced, treatment times will need to be decreased proportionally. If the lamp is replaced without an accurate reading of the original lamp (such as would happen if the lamp has already failed), we advise a decrease in treatment time by 50% to avoid the risk of serious burns. Please contact customer service for additional information.

Note: *Timely lamp replacement will avoid this situation.*

Useful lamp life is approximately 200-250 hours for UVB lamps and 400-500 hours for UVA lamps; however, lamps will continue to emit visible light and low levels of UV light for hundreds of hours beyond the useful life. To ensure effective treatments, lamps should be replaced and properly disposed of once the hours of use have exceeded the lamps' useful life expectancy.

Your lamp may need to be replaced due to burnout or because the energy output has decreased to the point that you may no longer be receiving an effective treatment. When the time has come to replace your lamp, please follow the steps below.

1. Consult the REPLACEMENT LAMPS section, found on page 14, for replacement lamp specifications and contact the Phothera service department for a lamp replacement quote.

   Note: The Phothera service department can be reached toll free by dialing (216)-831-0600 or via email at service@phothera.com

2. Upon agreed return of the unit, our in-house service technician will replace the lamp and verify the new lamps' UV power output.
3. Once the lamp replacement and power output verification has been completed the Phothera service department will arrange for the Phothera 100XL™ to be shipped back to you.

***Important**: Consult a physician for instruction before commencing treatments after replacing the lamp. Because the replacement lamp may have a much higher output than the replaced lamp, treatment time must be reduced by at least 50% to avoid the risk of serious burns.*

Important: Lamps should not be reused or installed in any device not equipped with a timer. The lamp contains mercury, which can be hazardous if it comes into direct contact with the skin, is ingested, or disposed of improperly. If the lamp is broken, do not touch the lamp debris with the skin. Consult local regulations for proper fluorescent lamp disposal.

18.0 Additional Instructions – Treatment Refill

The device will automatically enter Prescription Entry mode after completion of your last exposure or when trying to start a treatment with no exposures remaining.

Each time the lamps are turned on initially for a treatment, the number of available exposures is reduced by one.

18.1 Refilling a Light Prescription – For Devices with Treatment Limiting Software

Your device will display a Device Code as “CXXX” when it is time to obtain a new refill code, where “XXX” are replaced with numerical values. To ensure no interruptions in your therapy, we suggest that you contact your physician for a “refill” when five to ten exposures remain. Give your physician the “CXXX” code. Your physician will call or send in a prescription to Phothera, and we will then contact you with a four-digit refill code. Once you have received your four-digit refill code, follow the instructions below to activate it.

18.1.1 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

2. Enter your Key Code to unlock the controller.
3. Simultaneously press CANCEL, LEFT-ARROW, and PLAY/PAUSE.
4. While the screen displays "- - - 1", press the UP-ARROW button four (4) times. The screen should display

   "- - - 5".

5. Press the PLAY/PAUSE button to enter Menu 5.
6. 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.

7. 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.

18.2 Entering Your New Refill Code

1. Press any key to awaken the unit. If Security Mode is enabled the word “C0dE” will be displayed. Enter the code normally and proceed to Time Entry Mode.
2. The controller should flash the number of exposures remaining at the end of the next treatment and at an initial power up.
    a. If there are exposures remaining, they must be completed before the refill code can be used.
    b. After the final exposure has been completed, the display will read “CXXX”.
3. Press the UP button when the display reads “CXXX”. The display will read “0000”. You can now enter your refill code.
4. Enter the four-digit refill code using the same procedure you would use to enter a dose or time and press Enter. If the code is correct, your device will enter Time Entry Mode and will be ready for use. If the code is incorrect, the display will flash and display what you entered.

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 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. PURCHASER'S SOLE REMEDY UNDER THIS LIMITED WARRANTY IS REPAIR OR REPELACMENT OF THE EQUIPMENT.

19.3 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.

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 the 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 the 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.

19.7 Contact Information

Phone:	1-216-831-0600 *Press 2 for NatBio
Fax:	1-419-636-1739
E-Mail:	service@phothera.com
Website:	www.Phothera.com

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