

Operations Manual

Phototherapy Devices with Narrowband UVB Lamps



999-200 Rev 019

Dear Valued Customer:

Thank you for purchasing a Nat Bio ultraviolet light phototherapy device. The attention to design and care in manufacturing will ensure many years of reliable service.

The instructions and guidelines presented in this manual are provided to aid in developing a treatment regimen for management of dermatological disorders. It is recommended that users and operators read and thoroughly familiarize themselves with its contents prior to treatment.

Nat Bio makes no medical claims, implied or otherwise stated, for the use of this device other than the fact it will emit ultraviolet light within the ranges and levels specified. This device is only to be used for treatment of dermatological disorders; it is never to be used for cosmetic tanning.

If there are any questions or concerns regarding this product or its function, please contact Nat Bio Sales or Customer Service for assistance.

Thank You,
Nat Bio

The model and serial numbers are found on a label on the exterior of the device. Please note these numbers below. Retain this manual, along with your proof of purchase, to serve as a record for warranty.

Purchased From: _____ Date: _____

Model No: _____ Serial No: _____

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INTRODUCTION



Read this manual prior to using your device.

SAVE THESE INSTRUCTIONS.

INTENDED USE

Phototherapy devices are for medical treatment of psoriasis, vitiligo, and other dermatological disorders.

INDICATIONS AND CONTRAINDICATIONS

Indications: This device may be used for therapeutic treatment of skin disorders. The primary disorders, as pictured below, include:



Psoriasis (plaque psoriasis shown)



Vitiligo

Contraindications: Unless otherwise directed by a physician, do not use this device if you:

- Have intensified light sensitivity, eye disease or damage, or hyperthyroidism,
- Have a history of invasive squamous cell carcinoma, or
- Have a life sustaining pacemaker.

SAFEGUARDS, CAUTIONS AND WARNINGS

Any use of the device except as prescribed by your physician may be hazardous. Such use may jeopardize the success of the therapy, cause health risk, and render the Nat Bio warranty null and void. The company shall not be liable for any damage caused by improper use of the device.

Safeguards, Cautions and Warnings

THIS DEVICE IS TO BE USED BY PRESCRIPTION ONLY

- Consult a physician before using any phototherapy device.
- Exposure times should be established and increased only as directed by a physician.
- Never expose more than once in 24 hours, unless otherwise directed by a physician.
- Phototherapy units have different UV outputs. Do not use prior treatment times as a basis for treating with new device.



SAFEGUARDS FOR PHOTOTHERAPY EQUIPMENT

- All persons who have access to this device should read and understand the instructions provided prior to use.
- Close monitoring of minors and others who require supervision is advised at all times. Do not leave the device unattended while it is operating.
- Remove the key when the device is not in use.
- To prevent electrical shock, do not use this device in or near any liquids, in conditions of extreme humidity, or out of doors.
- Follow power instructions for grounding (protective earth). It is recommended that the device be plugged into a dedicated surge protector.
- Unplug the device from the electrical outlet when the device is not in use, before cleaning, or before changing lamps.
- For proper air circulation, keep the area around the device free from dirt and debris, and provide sufficient clearance of at least 4" to 6" (10 to 15 cm) when operating.
- Exercise care when moving your device. Always use on a stable surface.
- Do not operate this device if it malfunctions, is dropped, has a damaged power cable, or if any damage is suspected.
- Use caution when adjusting doors or moving devices on uneven or inclined surfaces to avoid tipping.
- Do not put fingers or toes through the screen and touch the lamps when the device is on.
- This device is to be used by only one person at a time.
- This device is for the treatment of dermatological disorders only. It is never to be used for cosmetic tanning.



CAUTIONS AND WARNINGS FOR UV LIGHT EXPOSURE

- Avoid overexposure. As with natural sunlight, overexposure can cause eye damage, skin injury, and allergic reactions.
- Cover all areas of the body except those that your physician has specifically directed you to expose to UV light.
- Wear protective UV blocking eyewear (Nat Bio Part # 9PE-004) for the entire duration of the UV exposure. Failure to do so may result in long term injury to the eyes.
- There is a latency period of 3 to 24 hours from time of exposure until maximum reddening of skin occurs.
- Persons who do not pigment or who pigment poorly in natural sunlight, have a history of skin problems, or are especially sensitive to sunlight will experience similar results with phototherapy.
- Some medications, cosmetics, and foods may increase sensitivity to phototherapy.

Adverse reactions may include:

- Excessive erythema. This may be minimized or avoided if safety instructions and warnings are followed.
- Pruritus (itching). Consult with your physician.
- Pigmentation change.

Safeguards, Cautions and Warnings

DETERMINING YOUR SKIN TYPE

Consult your physician to determine your Skin Type. Treatment times are based on Skin Type or Minimal Erythmal Dose (MED). Each person has an overall Skin Type but different areas of skin such as those rarely exposed to UV light may react as a lower skin type. The scalp is always treated as Skin Type I regardless of Skin Type. If you have a history of sun burning, pre-existing erythema, or are otherwise sensitive to light, you may also react as a lower Skin Type. See Fitzpatrick Skin Types in the table below.

FITZPATRICK SKIN TYPE CLASSIFICATION		
Skin Type	Response to sun	Tone
Type I	Always burns, never tans.	Very fair skin. Blonde, red, or light brown hair. Blue, green, or gray eyes.
Type II	Usually burns, sometimes tans.	Fair skin. Blonde, red, or brown hair. Blue, green, gray, or brown eyes.
Type III	Sometimes burns, usually tans.	Black or brown hair. Brown eyes.
Type IV	Minimally burns, tans well.	Light brown skin.
Type V	Very rarely burns, tans profusely.	Moderately pigmented, brown skin.
Type VI	Almost never burns.	Deeply pigmented.

These guidelines serve only as a rough estimate of skin type. Do and Koo, 2004

EQUIPMENT CLASSIFICATION

This device falls under Safety Protection Class I. It has both insulation and fixed wiring to protect against electric shock.

This is an FDA Class II Medical Device.

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY, OR ON THE ORDER OF, A PHYSICIAN (USA ONLY).

POWER AND ELECTRICAL REQUIREMENTS

For safe operation, this device must be connected to a dedicated, grounded 15 A circuit or a grounded 20 A branch circuit. All electrical connections to the device must be in compliance with the National Electrical Code (NFPA 70).



WARNING! Improper use of a grounding (protective earth) plug can result in a risk of electric shock and will void the warranty. If your device is equipped with a three-prong plug, a three-to-two prong AC grounding adapter should **not** be used.

OPERATING CONDITIONS

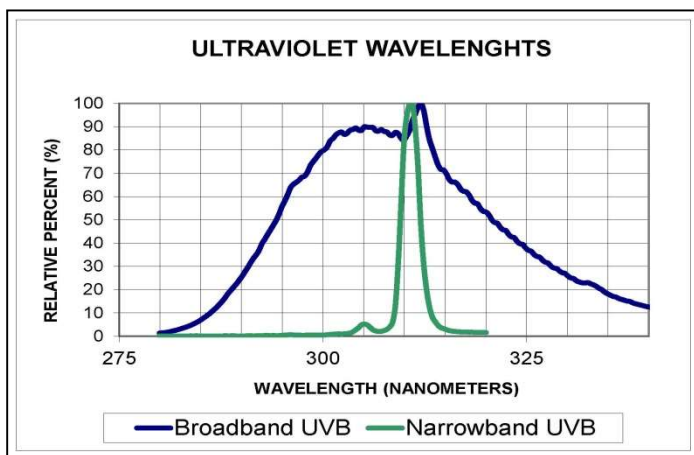
This product is designed for use in dry rooms with an ambient temperature between 60°F (16°C) and 100°F (38°C).

Be sure to protect the device from chemical vapors and never use it in potentially explosive atmospheres.

Use and store the device on a level surface. If possible, avoid bare, concrete floors as they are not insulated.

UV ENERGY

Narrowband UVB energy has been shown to be safe and effective. This spectrum ranges from 311 nm and 313 nm (shown by the green curve in the figure below). Intensity of UV energy depends on factors including the number of hours that lamps have been used and body positioning.



Narrowband UVB energy exposure range

CLEANING AND MAINTENANCE

This device will provide years of use with proper maintenance. It should be periodically checked for damage and cleaned. Lamps should be replaced at proper intervals for optimum treatment. Only use approved phototherapy lamps in this device.

Unplug the device from the electrical outlet before cleaning or replacing lamps.



CAUTION! Many commercial cleaning agents contain abrasives and chemicals which may scratch or leave residue on the lamps and reflective surfaces, reducing the effectiveness of treatment. Never wipe with a dry cloth.

To clean lamps and reflective surfaces, wipe using a soft cloth with 70% isopropyl alcohol. Lamps may be removed, cleaned, and set aside. To clean reflective surfaces, start at the top and wipe a section at a time, like cleaning a window.

To clean any dust or dirt from plastic, dampen a soft cloth with water mixed with mild detergent and wipe gently. Do not use alcohol on clear plastic windows and shields.

Do not clean the timer face unless absolutely necessary.

RETURN AUTHORIZATION PROCESS

If repairs or replacement parts are needed, please have the serial number and model number of your device available when calling Customer Service. The following procedures must be followed before sending any item back for repair or replacement:

1. Customer Service must be contacted, and a Return Authorization Number issued regardless of warranty status. Equipment returns which are not pre-approved or do not have a Return Authorization Number will not be accepted.
2. The customer has the responsibility for properly packaging devices and parts being returned to prevent transit damage or loss. Every effort should be made to return material in the same packaging as it was received. For further protection, it is recommended that customers insure return material with a value of \$100 or more.
3. Inside the package, include the following information:
 - a. Customer name, address, and phone number

- b. Name/description of return item(s) and serial number.
- c. Sales order number and date device/part was received.
- d. A brief description of the problem or reason for return
- e. Return authorization number that was provided.

4. The external package label should be addressed as follows:

National Biological Corporation
 23700 Mercantile Road
 Beachwood, Ohio 44122
 ATTN: Customer Service, REF: RA# _____

For any questions or general information about this or any other Nat Bio product, please contact Customer Service.

DEFINITIONS AND SYMBOLS

Medical terms and safety symbols that may be found in this manual or on your device are defined below.

Edema. An abnormal excess accumulation of serous fluid in connective tissue or in a serous cavity

Erythema. Abnormal redness of the skin due to capillary congestion (as in inflammation)

Latency period. The interval between stimulation and response

Melanoma. A benign or malignant skin tumor containing dark pigment.



















Minimal erythema dosage. The minimum amount of UV light that produces redness 24 hours after exposure.

Phototherapy. The application of light for therapeutic purposes

Pruritus. Localized or generalized itching due to irritation of sensory nerve endings.

Psoriasis. A chronic skin disease characterized by circumscribed red patches covered with white scales.

Vitiligo. A progressive skin disorder that is a form of leukoderma caused by the localized or generalized destruction of melanocytes and marked by sharply circumscribed white spots of skin.

WARNING SYMBOLS	
	WARNING, GENERAL, RISK OF PERSONAL INJURY
	WARNING, HOT SURFACE
	WARNING, ELECTRICITY
	WARNING, NON-IONIZING RADIATION
	WARNING, LAMPS CONTAIN MERCURY
	WARNING, PINCH POINT
	TIP WARNING
	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)
	CLASS II EQUIPMENT
	"ON" FOR EQUIPMENT
	"OFF" FOR EQUIPMENT
	"ON" FOR PART OF EQUIPMENT
	"OFF" FOR PART OF EQUIPMENT

GENERAL PHOTOTHERAPY GUIDELINES

This manual contains sample guidelines, dosage, and treatment times for psoriasis and vitiligo that your physician may direct you to follow. Guidelines are intended to support physician recommendations; where different, physician recommendations supersede these recommendations.

If phototherapy has been prescribed for any other dermatological disorder, consult your physician.

TREATMENT GUIDELINES FOR PSORIASIS¹

Your physician will determine the initial treatment time, changes in treatment times, and frequency. It is important to carefully adhere to your treatment schedule. A Psoriasis Protocol table that your physician may direct you to follow is provided in the section for your model.

Treatment is most effective at 85 to 90% of the Minimal Erythematous Dosage (MED). MED occurs if the skin reddens slightly. This reddening may take 3 to 24 hours following treatment to fully appear. Minor skin irritations may also occur.

Before starting treatment, remove any scales. Emollient creams, shampoo, and bath oils may be helpful in removing these scales and preventing excessive dryness. Wash off any sunscreen. If you are treating your scalp, treat while hair is slightly damp.

Cover all parts of your body except areas to be treated and put on UV protective goggles before you begin treatment. After treatment, apply sunscreen following manufacturer's directions.

If you do not respond to phototherapy or if your condition appears to worsen during treatment, consult your physician.

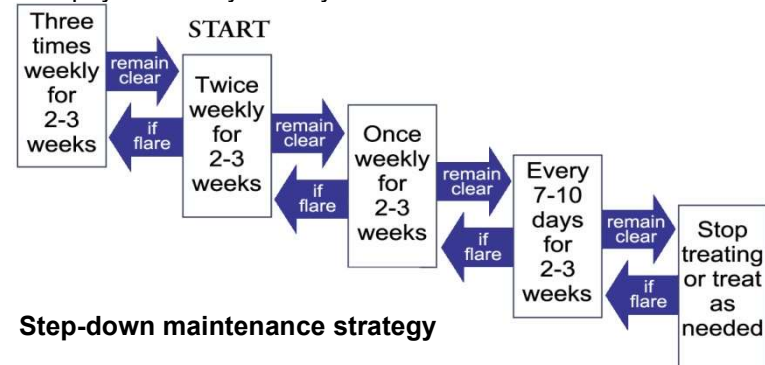
¹ Adapted from Shelk & Morgan, JDNA Dec 2000 using Leone Dermatology Center protocol

Maintenance phase for psoriasis²

The goal of maintenance is to remain symptom-free for as long as possible with the least amount of exposure. Maintenance therapy begins when psoriasis is at least 95% clear (completely flattened plaque including borders, though plaque may still be outlined by pigmentation).

There are two approaches to maintenance: stop treatments or continue treatments using a step-down approach such as shown in the chart below. Treatment frequency will depend on your response. During maintenance, threshold dose for erythema may gradually decrease. Maintenance treatment will be prescribed by your physician.

Your physician may direct you as follows:



Step-down maintenance strategy

- ERYTHEMA: If significant erythema appears, treatment time should be decreased by 25% until treatments no longer produce erythema.
- NEW PSORIASIS OUTBREAK: If new areas of psoriasis develop but skin remains 95% clear, treatment time may be increased by up to 10% at each treatment until the psoriasis is brought under control.
- FLARE-UP: If psoriasis develops on more than 5% of the originally involved areas, increase to a more frequent treatment schedule (see the Psoriasis Protocols for your model). The new schedule may be continued until your skin is 95% clear again. If the new schedule still does not control the psoriasis, consult your physician.

TREATMENT GUIDELINES FOR VITILIGO

Vitiligo patches are always treated as Skin Type I. With phototherapy treatment, brown freckles should eventually appear. These freckles should then spread. Active treatment continues until these patches fill in to touch pigmented skin.

² Do and Koo, 2004

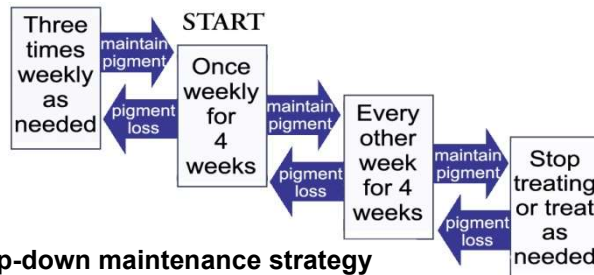
Your physician will determine the initial treatment time, changes in treatment times, and frequency. It is important to carefully adhere to your treatment schedule. A Vitiligo Treatment Protocol that your physician may direct you to follow is provided in the section for your model.

Treatment is most effective at 85 to 90% of the Minimal Erythema Dosage (MED). MED occurs if the skin reddens slightly. This reddening may take 3 to 24 hours following treatment to fully appear. Minor skin irritations may also occur.

Cover all parts of your body except areas to be treated and put on UV protective goggles before you begin treatment. After treatment, apply sunscreen and follow the manufacturer's directions.

Maintenance phase for vitiligo³

Vitiligo maintenance therapy typically begins when skin has re-pigmented at least 75%. If your physician prescribes slowing therapy rather than stopping therapy altogether, treatment time will remain the same as the most recent active treatment. Your physician may direct you as follows:



Continue maintenance therapy as long as pigmentation level is maintained. If a treatment is required and it has been more than 6 weeks since the last treatment, dosage should be the same as when beginning therapy since the threshold for erythema will have decreased.

³ Kumar et al, 2009

PANOSOL 3D® (8 AND 10 LAMP MODELS)

Panosol 3D®
With 8 or 10 lamps



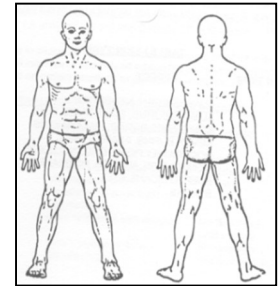
WARNING! Read safeguards, cautions, and warnings on pages 5 to 7 before use.

POSITIONING YOUR BODY

Stand 6 to 8 inches from the screen. Adjust the doors so that they are also 6 to 8 inches from your body. Note that product appearance and features may vary depending on your order and potential design changes over time. Device pictures found in this document, therefore, may not exactly resemble your unit. Be assured, however, that all instructions for use in this manual still apply.



Your stance should allow for maximum coverage of areas to be treated. For example, hold arms away from trunk when treating sides or inner arms and spread fingers apart when treating palms (see figure). Keep areas to be treated at a uniform distance from lamps as small changes in positioning can influence whether areas are under or overexposed.



Proper positioning



WARNING! Cover all parts of body except areas to be treated and wear UV protective goggles during treatment.

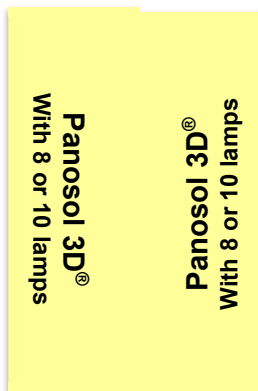
Treat the front or back of your body, allowing the lamps on the doors to reach spots on your sides and inside the elbow. If necessary, turn around to deliver another treatment for the other side of your body.

The doors provide approximately half the UV energy as the main panel, so your sides and the underside of your arms will get half of a treatment when you treat your front and the second half of a treatment when you treat your back.

TREATMENT PROTOCOLS


Review the [general phototherapy guidelines](#) on pages 13 to 15. The following tables provide specific treatment times and schedules for psoriasis and vitiligo based on these guidelines.

To assess if erythema has occurred (as referenced in the tables below), look for redness of the healthy skin surrounding treated lesions to appear from 3 to 24 hours after the last treatment.



VITILIGO PROTOCOLS, PANOSOL 3D[®] WITH 8 OR 10 LAMPS	
TREATMENT PROTOCOL	
<i>Non-pigmented skin is always treated as Skin Type I</i>	
Treatment distance	6" to 8" from screen
Initial exposure time	70% of MED. Start with 43 seconds if you do not know your MED.
Exposure increase schedule	Increase by 10% each session unless erythema occurs
If erythema occurs	Hold exposure time
If erythema persists	Decrease exposure time by 25%. When erythema resolves, increase exposure time by 5% per session.
Duration of treatment	Until re-pigmentation has occurred
Treatment frequency	3 times per week


Treatment protocol based on Hamzavi et al, 2004

 These protocols are only intended as guidelines. Consult your physician.

For the maintenance schedule, see page 15.

PSORIASIS PROTOCOLS, PANOSOL 3D[®] WITH 8 OR 10 LAMPS			
Treatment distance	6" to 8" from screen		
INITIAL EXPOSURE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Skin Type	Dosage (mJ/cm ²)	Time (min:sec)	
I	130	0:43	
II	220	1:13	
III	260	1:27	
IV	330	1:50	
V	350	1:57	
VI	400	2:13	
EXPOSURE INCREASE SCHEDULE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Erythema Response	Adjustments		
None	If you are:	Increase by:	
	Skin Type	Dosage	Time
	Type I	15 mJ/cm ²	5 seconds
	Type II	25 mJ/cm ²	8 seconds
	Type III	40 mJ/cm ²	13 seconds
	Type IV	45 mJ/cm ²	15 seconds
	Type V	60 mJ/cm ²	20 seconds
Type VI	65 mJ/cm ²	22 seconds	
Mild pinkening	Same dose		
Severe	No treatment. When erythema resolves, 50% of 1st dose, then increase by ≤10% unless otherwise directed by your physician		
ADJUSTMENTS FOR TREATMENT			
Days missed	Protocol		
8 to 11 days	Repeat previous dosage		
12 to 14 days	Decrease dosage by 2 treatments worth		
15 to 20 days	Decrease dosage by 25%		
21 to 27 days	Decrease dosage by 50%		
28 days or more	Start treatment over		

Treatment protocols adapted from Do and Koo, 2004


 These protocols are only intended as guidelines. Consult your physician.


For maintenance schedule, see page 14.

REPLACING LAMPS

Lamps should be replaced every 150-200 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. Your timer keeps track of your lamp usage.

To remove the screen, grasp near the center and pull straight up. Next, pull the bottom of screen away from base and then down and away from device.

 **WARNING!** It is recommended that all lamps be replaced at the same time. Replacing them separately will create uneven distribution of UV energy, which may result in severe erythema.

 **WARNING!** Lamps contain mercury. Use protective gloves and safety glasses when handling. Take old lamps to a waste recycling facility. Do not put in recycle bins.

If a lamp breaks, ventilate the room for 30 minutes. Place pieces in a sealable plastic bag. Use wet cloths. Do not vacuum.

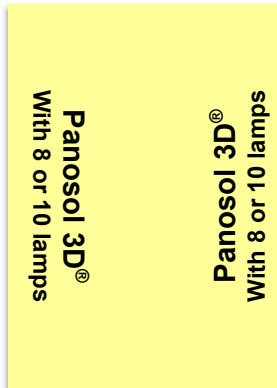
To remove a screen from a door, loosen the screw on the side of the door about halfway (five turns). Hold screen near the center opposite the screw and pull until the tab on the side comes out from under frame. Pull the pins out from bottom and top of frame.

To remove a lamp, press upward against the top spring-loaded socket until the lamp is out of the bottom socket. Pull the lamp down and away from the device. Set aside carefully where it will not fall or be damaged.

To install a lamp, hold it vertically with the label at the top. Insert the top of the lamp into the top spring-loaded socket. Push upward against the socket and lower the lamp into the bottom socket. Check that the lamp is properly seated.

To install the screen in the main panel, hold it with the black rubber bumpers at the bottom. Align and insert the top pins into the top socket plate. Insert the bottom pins into the bottom socket plate. Check that all pins are secure.

To install the screen in the door, put the top pins into the top socket plate. Next, put the bottom pins with the black rubber bumpers into the bottom socket plate. Slide the tab on the side of the screen under the frame and secure it into place. Tighten the screw.



SPECIFICATIONS

Specifications and replacement parts are in the following table.

SPECIFICATIONS, 8-LAMP PANOSOL 3D®	
Power supply and consumptions	120 VAC / 60 Hz / 8A
UV energy intensity	Up to 3.0 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions, closed	78" L x 29.5" W x 15" D (198 cm x 75 cm x 38 cm)
Dimensions, open as used	78" L x 48.5" W x 21" D (198 cm x 123 cm x 53 cm)
Dimension, panel depth	4" (10 cm)
Weight	109 lbs. (49.4 kg)
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	Part Number
Lamp	7TL-372
Goggles	9PE-004

SPECIFICATIONS, 10-LAMP PANOSOL 3D®	
Power supply and consumptions	120 VAC / 60 Hz / 8 A
UV energy intensity	Up to 3.0 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions, closed	78" L x 29.5" W x 15" D (198 cm x 75 cm x 38 cm)
Dimensions, open as used	78" L x 48.5" W x 21" D (198 cm x 123 cm x 53 cm)
Dimension, panel depth	4" (10 cm)
Weight	113 lbs. (51.3 kg)
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	Part Number
Lamp	7TL-372
Goggles	9PE-004

ASSEMBLY



Note. The entire assembly process can be completed with the device resting on the box.

Open box 1 of 2 containing the main panel.

Remove lamp box and set aside. This contains the main panel lamps.

Lift the side of the panel slightly and remove the accessories kit from underneath the panel.

Gently remove all foam packaging. Lift the bottom of the panel and slide it down so that the bottom of the panel rests on the edge of the box. See photo. Remove the plastic bag from the main panel.



Attach the doors and hinges

Open box 2 of 2. Remove the plastic bag from the right door labeled

“R”. Do not remove the foam spacers. Carefully lay the door over the right side of the main panel with the lamps facing down. Make sure that the “R” and the electrical connectors on the main panel and the door are at the top corner. The hinges are already attached to the doors. The screws required to mount the doors to the center section have been loosely installed in their respective holes in the center section. Carefully remove the screws from the center section and use them to mount the doors.



Panosol 3D®
With 8 or 10 lamps

Panosol 3D®
With 8 or 10 lamps

CAUTION! Carefully align screws to prevent damaged threads. Do not over-tighten.

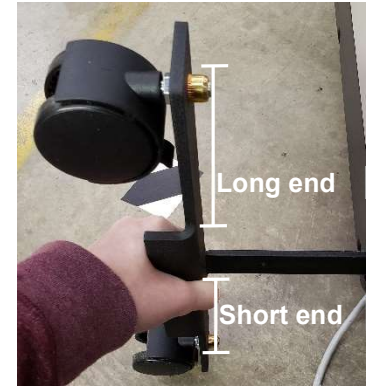
Align the hinge holes in the door and the main panel. Attach each hinge using 2 screws and a Phillips head screwdriver (see upper photo).

Repeat these steps to attach the left door labeled “L”.

Attach the support feet

Locate the right foot marked “R” in box 1 of 2.

With the long end pointing up (see top photo), simply align the holes in the support foot, insert the screws and tighten. Do not insert the foot through the bottom of the device. The foot should be attached to the outside surface of the device.

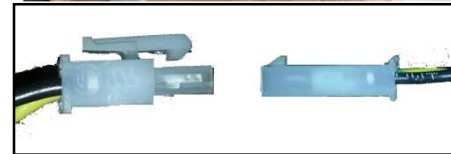


Repeat these steps to attach the left foot labeled “L”.



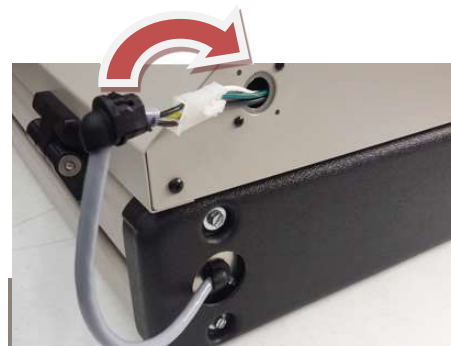
Attach cables

Plug white connectors together (shown in figure on right).



Slide connected wires into the hole. Insert black fitting until it snaps into place (see red arrow in picture on right).

Repeat with the cable on second door.



The seated fitting is shown in the picture on the right.



Stand device up and remove packaging.

Lock the casters on the feet.

Carefully stand the device upright. It is recommended that you have two people to do so. Do not let go of the device until it is standing firmly on its support feet.

Check that the device is balanced on a level floor and cannot easily tip or rock.

Make sure that each door can swing easily but not freely, remaining in whatever position in which it is placed. Correct the swing using the tension adjusting screw if necessary.

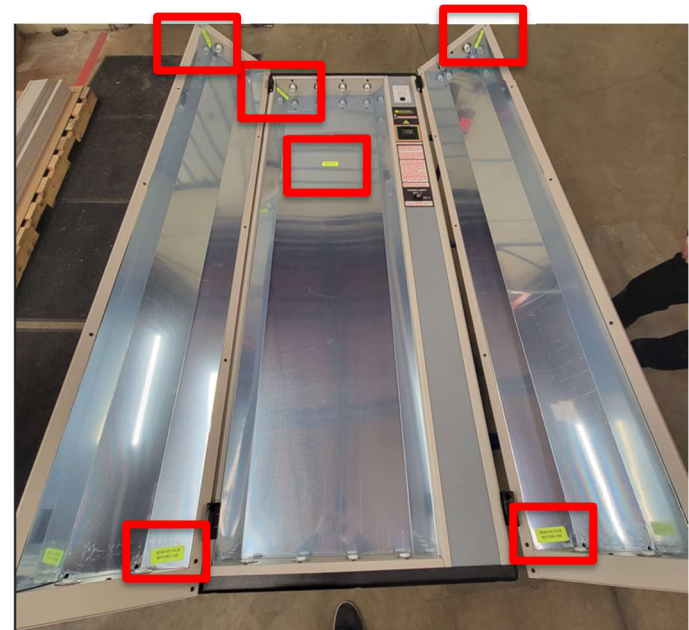


Adjust hinge tension

Remove the screen from the main panel (see page 19). The main and door sections are equipped with reflectors to improve your device's UV output. To protect the reflector surface from shipping damage, a protective film has been added. Prior to installing your device's lamps and using the device, this film must be removed by carefully peeling off the film from the reflectors. Look for the "Remove Film Before Use" labels applied to the section corners of your device (see image on the next page).

**Panosol 3D®
With 8 or 10 lamps**

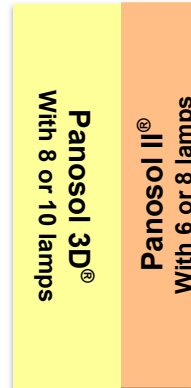
**Panosol 3D®
With 8 or 10 lamps**



Carefully peel away and discard the blue film from the reflector. This will pull up the "Remove Film Before Use" labels as well. You should see the bare reflector surface now.

Install lamps from the lamp box that was set aside, and then reinstall the screen on the center panel (see page 19).

To remove the film from each door, remove the foam spacer near the hinge and remove the screen from each door (see page 19). Remove the rubber shipping rings from the top of the lamps in each door. Remove the lamps from both doors (see page 19). Remove the bubble wrap from each lamp. Carefully peel away and discard the blue film from each door's reflector. This will pull up the "Remove Film Before Use" labels as well. You should see the bare reflector surface now. Replace the lamps and screen (see page 19).



PANOSOL II® (6 AND 8 LAMP MODELS)



WARNING! Read safeguards, cautions, and warnings on pages 5 to 7 before use.

POSITIONING YOUR BODY

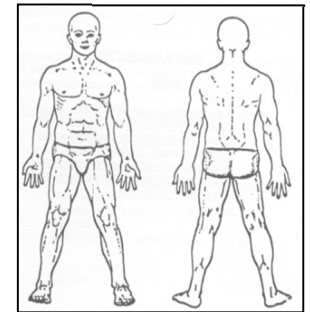
Proper body positioning for phototherapy is extremely important to ensure optimum effectiveness of the treatment. Stand with area to be treated approximately 6 to 8 inches from the screen surface. Note that product appearance and features may vary depending on your order and potential design changes over time. Device pictures found in this document, therefore, may not exactly resemble your unit. Be assured, however, that all instructions for use in this manual still apply.

Your stance should allow for maximum coverage of areas to be treated. For example, hold arms away from trunk when treating sides or inner arms and hands open with fingers spread apart when treating palms (see figure to the right). Keep areas to be treated at a uniform distance from lamps as small changes in positioning can influence whether areas are under or overexposed.



2' Panosol II® with 8 lamps

6' Panosol II® with 6 lamps



Proper positioning



WARNING! Cover all parts of body except areas to be treated and wear UV protective goggles during treatment.

TREATMENT PROTOCOLS

Review the [general phototherapy guidelines](#) on pages 13 to 15. The following tables provide specific treatment times and schedules for psoriasis and vitiligo based on these guidelines.

To assess if erythema has occurred (as referenced in the tables below), look for redness of the healthy skin surrounding treated lesions to appear from 3 to 24 hours after last treatment.



VITILIGO PROTOCOLS, PANOSOL II® WITH 6 OR 8 LAMPS	
TREATMENT PROTOCOL	
<i>Non-pigmented skin is always treated as Skin Type I</i>	
Treatment distance	6" to 8" from screen
Initial exposure time	70% of MED. Start with 43 seconds if you do not know your MED.
Exposure increase schedule	Increase by 10% each session unless erythema occurs
If erythema occurs	Hold exposure time
If erythema persists	Decrease exposure time by 25%. When erythema resolves, increase exposure time by 5% per session.
Duration of treatment	Until re-pigmentation has occurred
Treatment frequency	3 times per week

Treatment protocol based on Hamzavi et al, 2004

These protocols are only intended as guidelines. Consult your physician.

For the maintenance schedule, see page 15.

PSORIASIS PROTOCOLS, PANOSOL II® WITH 6 OR 8 LAMPS			
Treatment distance	6" to 8" from screen		
INITIAL EXPOSURE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Skin Type	Dosage (mJ/cm²)	Time (min:sec)	
I	130	0:43	
II	220	1:13	
III	260	1:27	
IV	330	1:50	
V	350	1:57	
VI	400	2:13	
EXPOSURE INCREASE SCHEDULE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Erythema Response	Adjustments		
None	If you are:	Increase by:	
	Skin Type	Dosage	Time
	Type I	15 mJ/cm ²	5 seconds
	Type II	25 mJ/cm ²	8 seconds
	Type III	40 mJ/cm ²	13 seconds
	Type IV	45 mJ/cm ²	15 seconds
	Type V	60 mJ/cm ²	20 seconds
Type VI	65 mJ/cm ²	22 seconds	
Mild pinkening	Same dose		
Severe	No treatment. When erythema resolves, 50% of 1st dose, then increase by ≤10% unless otherwise directed by your physician		
ADJUSTMENTS FOR TREATMENT			
Days missed	Protocol		
8 to 11 days	Repeat previous dosage		
12 to 14 days	Decrease dosage by 2 treatments worth		
15 to 20 days	Decrease dosage by 25%		
21 to 27 days	Decrease dosage by 50%		
28 days or more	Start treatment over		

Treatment protocols adapted from Do and Koo, 2004



These protocols are only intended as guidelines. Consult your physician.

For maintenance schedule, see page 14.

REPLACING LAMPS

Lamps should be replaced every 150-200 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. Your timer keeps track of your lamp usage.

To remove the screen, grasp near the center and pull straight up. Next, pull the bottom of screen away from base and then down and away from device.



WARNING! It is recommended that all lamps be replaced at the same time. Replacing them separately will create uneven distribution of UV energy, which may result in severe erythema.



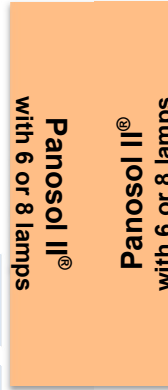
WARNING! Lamps contain mercury. Use protective gloves and safety glasses when handling. Take old lamps to a waste recycling facility. Do not put in recycle bins.

If a lamp breaks, ventilate the room for 30 minutes. Place pieces in a sealable plastic bag. Use wet cloths. Do not vacuum.

To remove a lamp, press upward against the top spring-loaded socket until the lamp is out of the bottom socket. Pull the lamp down and away from the device. Set aside carefully where it will not fall or be damaged.

To install a lamp, hold it vertically with the label at the top. Insert the top of the lamp into the top spring-loaded socket. Push upward against the socket and lower the lamp into the bottom socket. Check that the lamp is properly seated.

To install the screen, hold it with the black rubber bumpers at the bottom. Align and insert the top pins into the top socket plate. Insert the bottom pins into the bottom socket plate. Check that all pins are secure.



SPECIFICATIONS

Specifications and replacement parts are in the following tables.

SPECIFICATIONS, 6' PANOSOL II® WITH 6 LAMPS	
Power supply and consumptions	120 VAC / 60 Hz / 5 A
UV energy intensity	Up to 3.0 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions	78" L x 29.5" W x 15" D (198 cm x 75 cm x 38 cm)
Dimensions, panel depth	4" (10 cm)
Weight	78 lb (35.38 kg)
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	
Lamp	Part Number
Lamp	7TL-372
Goggles	9PE-004

SPECIFICATIONS, 2' PANOSOL II® WITH 8 LAMPS	
Power supply and consumptions	120 VAC / 60 Hz / 3 A
UV energy intensity	Up to 3.0 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions	29.5" L x 29.5" W x 11" D (75 cm x 75 cm x 28 cm)
Dimensions, panel depth	4" (10 cm)
Weight	41 lbs (18.6 kg)
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	
Lamp	Part Number
Lamp	7TL-012
Goggles	9PE-004

ASSEMBLY

6' device: Open the top of the box. Take box labeled "Lamp Box" and set aside.

2' device: Open the top of the box.



Lift the side of the panel slightly and remove the accessories kit.

Gently remove all foam packaging. Lift the bottom of the panel and slide it down so that it rests on the carton (top photo).

Remove the plastic bag from the panel but do not remove the bubble wrap.

The right foot is marked "R". With the long end marked "R" facing up (see second photo), slide the foot into the right channel.

6' device: Attach the foot using the 2 screws (see middle photo). Tighten using the hex tool provided.

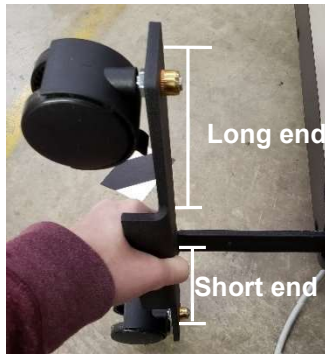
2' device: Align the holes in the clamping plate with the holes in the support foot (see bottom photo). Tighten the screws with the hex tool provided.

Repeat steps to attach the left foot. Lock the casters on the feet. Carefully stand the device upright.

Check that the device is balanced on a level floor and cannot easily tip or rock. If necessary, loosen the screws a turn or two, straighten the device, and retighten the screws.

6' device: Remove the screen (see page 29). Carefully peel off the reflective film (refer to pages 23-25). Remove lamps from lamp box and install lamps and screen (see page 29).

2' device: Remove the screen (see page 29). Remove the rubber shipping rings from the top of the lamps. Remove the lamps (see page 29). Remove the bubble wrap. Replace the lamps and screen (see page 29). Remove the label and protective film.



Panosol II®
with 6 or 8 lamps



PANOSOL II® (4 LAMP MODELS)

WARNING! Read safeguards, cautions, and warnings on pages 5 to 7 before use.

POSITIONING YOUR BODY

Proper body positioning for phototherapy is extremely important to ensure optimum effectiveness of the treatment. Stand with area to be treated approximately 6 to 8 inches from the screen surface.

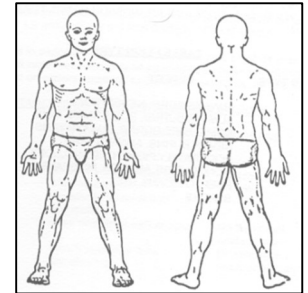


2' Panosol II® with 4 lamps



6' Panosol II® with 4 lamps

Your stance should allow for maximum coverage of areas to be treated. For example, hold arms away from trunk when treating sides or inner arms and hands open with fingers spread apart when treating palms (see figure). Keep areas to be treated at a uniform distance from lamps as small changes in positioning can influence whether areas are under or overexposed.



Proper positioning

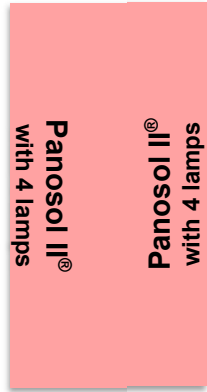


WARNING! Cover all parts of body except areas to be treated and wear UV protective goggles during treatment.

TREATMENT PROTOCOLS

Review the [general phototherapy guidelines](#) on pages 13 to 15. The following tables provide specific treatment times and schedules for psoriasis and vitiligo based on these guidelines.

To assess if erythema has occurred (as referenced in the tables below), look for redness of the healthy skin surrounding treated lesions to appear from 3 to 24 hours after last treatment.



VITILIGO PROTOCOLS, PANOSOL II® WITH 4 LAMPS	
TREATMENT PROTOCOL	
<i>Non-pigmented skin is always treated as Skin Type I</i>	
Treatment distance	6" to 8" from screen
Initial exposure time	70% of MED. Start with 52 seconds if you do not know your MED.
Exposure increase schedule	Increase by 10% each session unless erythema occurs
If erythema occurs	Hold exposure time
If erythema persists	Decrease exposure time by 25%. When erythema resolves, increase exposure time by 5% per session.
Duration of treatment	Until re-pigmentation has occurred
Treatment frequency	3 times per week

Treatment protocol based on Hamzavi et al, 2004

These protocols are only intended as guidelines. Consult your physician.

For maintenance schedule, see page 15.

PSORIASIS PROTOCOLS, PANOSOL II® WITH 4 LAMPS			
Treatment distance	6" to 8" from screen		
INITIAL EXPOSURE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Skin Type	Dosage (mJ/cm²)	Time (min:sec)	
I	130	0:52	
II	220	1:28	
III	260	1:44	
IV	330	2:12	
V	350	2:20	
VI	400	2:40	
EXPOSURE INCREASE SCHEDULE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Erythematous Response	Adjustments		
	If you are:	Increase by:	
None	Skin Type	Dosage	Time
	Type I	15 mJ/cm ²	6 seconds
	Type II	25 mJ/cm ²	10 seconds
	Type III	40 mJ/cm ²	16 seconds
	Type IV	45 mJ/cm ²	18 seconds
	Type V	60 mJ/cm ²	24 seconds
	Type VI	65 mJ/cm ²	26 seconds
Mild pinkening	Same dose		
Severe	No treatment. When erythema resolves, 50% of 1st dose, then increase by ≤10% unless otherwise directed by your physician		
ADJUSTMENTS FOR TREATMENT			
Days missed	Protocol		
8 to 11 days	Repeat previous dosage		
12 to 14 days	Decrease dosage by 2 treatments worth		
15 to 20 days	Decrease dosage by 25%		
21 to 27 days	Decrease dosage by 50%		
28 days or more	Start treatment over		

Treatment protocols adapted from Do and Koo, 2004


These protocols are only intended as guidelines. Consult your physician.


For maintenance schedule, see page 14.

REPLACING LAMPS

Lamps should be replaced every 150-200 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. Your timer keeps track of your lamp usage.

To remove the screen, grasp near the center and pull straight up. Next, pull the bottom of screen away from base and then down and away from device.

 **WARNING!** It is recommended that all lamps be replaced at the same time. Replacing them separately will create uneven distribution of UV energy, which may result in severe erythema.

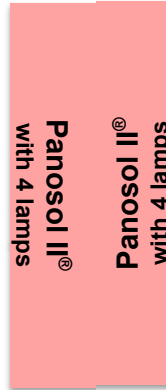
 **WARNING!** Lamps contain mercury. Use protective gloves and safety glasses when handling. Take old lamps to a waste recycling facility. Do not put in recycle bins.

If a lamp breaks, ventilate the room for 30 minutes. Place pieces in a sealable plastic bag. Use wet cloths. Do not vacuum.

To remove a lamp, press upward against the top spring-loaded socket until the bottom of the lamp is out of the socket. Pull the lamp down and away from the device. Set aside carefully where it will not fall or be damaged.

To install a lamp, hold it vertically with the label at the top. Insert the top of the lamp into the top spring-loaded socket. Push upward against the socket and lower the lamp into the bottom socket. Check that the lamp is properly seated.

To install the screen, hold it with the black rubber bumpers at the bottom. Align and insert the top pins into the top socket plate. Insert the bottom pins into the bottom socket plate. Check that all pins are secure.



SPECIFICATIONS

Specifications and replacement parts are in the following tables.

SPECIFICATIONS, 6' PANOSOL II® WITH 4 LAMPS	
Power supply and consumptions	120 VAC / 60 Hz / 3 A
UV energy intensity	Up to 2.5 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions	78" L x 29.5" W x 15" D (198 cm x 75 cm x 38 cm)
Dimensions, panel depth	4" (10 cm)
Weight	78 lb. (35.38 kg)
Warranty period	1 year excluding lamps
Dimensions, UV output window	20" x 70" (51 cm x 178 cm)
Replacement Lamp and Goggles	
Lamp	7TL-372
Goggles	9PE-004

SPECIFICATIONS, 2' PANOSOL II® WITH 4 LAMPS	
Power supply and consumptions	120 VAC / 60 Hz / 2 A
UV energy intensity	Up to 2.5 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions	29.5" L x 29.5" W x 11" D (75 cm x 75 cm x 28 cm)
Dimensions, panel depth	4" (10 cm)
Weight	41 lbs (18.6 kg)
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	
Lamp	7TL-012
Goggles	9PE-004

ASSEMBLY

6' device: Open the top of the box. Take box labeled "Lamp Box" and set aside.

2' device: Open the top of the box.



Lift the side of the panel slightly and remove the accessories kit.

Gently remove all foam packaging. Lift the bottom of the panel and slide it down so that it rests on the carton (top photo).

Remove the plastic bag from the panel but do not remove the bubble wrap.

The right foot is marked "R". With the long end marked "R" facing up (see second photo), slide the foot into the right channel.



Panosol II[®]
with 4 lamps

6' device: Attach the foot using the 2 screws (see third photo). Tighten using the hex tool provided.

2' device: Align the holes in the clamping plate with the holes in the support foot (see bottom photo). Tighten the screws with the hex tool provided.



Repeat steps to attach the left foot. Lock the casters on the feet. Carefully stand the device upright.

Check that the device is balanced on a level floor and cannot easily tip or rock. If necessary, loosen the screws a turn or two, straighten the device, and retighten the screws.



6' device: Remove the screen (see page 35). Remove the labels and protective film (refer to pages 23-25). Remove lamps from lamp box and install lamps and screen (see page 33).

2' device: Remove the screen (see page 35). Remove the rubber shipping rings from the top of the lamps. Remove the lamps (see page 35). Remove the bubble wrap. Replace the lamps and screen (see page 35). Remove the label and protective film.

HAND/FOOT II™



WARNING! Read safeguards, cautions, and warnings on pages 5 to 7 before use.

Two Hand/Foot II™ devices are shown at right along with the optional cart. The shelves of the optional cart are at optimum height to comfortably treat hands and feet.



POSITIONING YOUR BODY

Proper body positioning for phototherapy is extremely important to ensure optimum effectiveness of the treatment. Small changes in positioning can influence whether areas are under or overexposed. For instance, make sure that your hands are open with fingers spread.



WARNING! Cover all parts of body except areas to be treated and wear UV protective goggles during treatment.

Sit in a comfortable chair. Place hands and/or feet through the holes in shield and directly on the screen. Keep areas to be treated at a uniform distance from lamps.

Hand/Foot II™

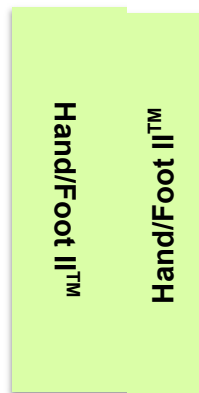
TREATMENT PROTOCOLS

Review the [general phototherapy guidelines](#) on pages 13 to 15. The following tables provide specific treatment times and schedules for psoriasis and vitiligo based on these guidelines.

To assess if erythema has occurred (as referenced in the tables below), look for redness of the healthy skin surrounding treated lesions to appear from 3 to 24 hours after last treatment.

VITILIGO PROTOCOLS, HAND/FOOT II™	
TREATMENT PROTOCOL	
<i>Non-pigmented skin is always treated as Skin Type I</i>	
Treatment distance	At surface of inner shield
Initial exposure time	70% of MED. Start with 29 seconds if you do not know your MED.
Exposure increase schedule	Increase by 10% each session unless erythema occurs
If erythema occurs	Hold exposure time
If erythema persists	Decrease exposure time by 25%. When erythema resolves, increase exposure time by 5% per session.
Duration of treatment	Until re-pigmentation has occurred
Treatment frequency	3 times per week

Treatment protocol based on Hamzavi et al, 2004



These protocols are only intended as guidelines. Consult your physician.

For the maintenance schedule, see page 15.

PSORIASIS PROTOCOLS, HAND/FOOT II™			
Treatment distance	At surface of inner shield		
INITIAL EXPOSURE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Skin Type	Dosage (mJ/cm ²)	Time (min:sec)	
I	130	0:29	
II	220	0:49	
III	260	0:58	
IV	330	1:13	
V	350	1:18	
VI	400	1:29	
EXPOSURE INCREASE SCHEDULE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Erythematous Response	Adjustments		
None	If you are:	Increase by:	
	Skin Type	Dosage	Time
	Type I	15 mJ/cm ²	3 seconds
	Type II	25 mJ/cm ²	6 seconds
	Type III	40 mJ/cm ²	9 seconds
	Type IV	45 mJ/cm ²	10 seconds
	Type V	60 mJ/cm ²	13 seconds
	Type VI	65 mJ/cm ²	14 seconds
Mild pinkening	Same dose		
Severe	No treatment. When erythema resolves, 50% of 1st dose, then increase by ≤10% unless otherwise directed by your physician		
ADJUSTMENTS FOR TREATMENT			
Days missed	Protocol		
8 to 11 days	Repeat previous dosage		
12 to 14 days	Decrease dosage by 2 treatments worth		
15 to 20 days	Decrease dosage by 25%		
21 to 27 days	Decrease dosage by 50%		
28 days or more	Start treatment over		

Treatment protocols adapted from Do and Koo, 2004



These protocols are only intended as guidelines. Consult your physician.

For maintenance schedule, see page 14.

REPLACING LAMPS

Lamps should be replaced every 150-200 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. Your timer keeps track of your lamp usage.

WARNING! It is recommended that all lamps be replaced at the same time. Replacing them separately will create uneven distribution of UV energy, which may result in severe erythema.

WARNING! Lamps contain mercury. Use protective gloves and safety glasses when handling. Take old lamps to a waste recycling facility. Do not put in recycle bins.

If a lamp breaks, ventilate the room for 30 minutes. Place pieces in a sealable plastic bag. Use wet cloths. Do not vacuum.

To remove a lamp, remove the hood of the cabinet. Hold the screen near the center and gently lift it off the device. Grab the lamp and twist counterclockwise in socket. Set aside carefully where it will not fall or be damaged.

To install a lamp, hold it vertically with the label at the top. Place the lamp in the socket and twist clockwise to lock it in place. Install the screen by placing it back in the device and replace the hood on the cabinet.

SPECIFICATIONS, HAND/FOOT II™	
Power supply and consumption	120 VAC / 60 Hz / 3 A
UV energy intensity	Up to 4.5 mW/cm ²
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Dimensions, Hand/Foot II™	24" L x 20" W x 12.75" D (61 cm x 51 cm x 32 cm)
Dimensions, optional cart	32" L x 29" W x 21.5" D (81 cm x 74 cm x 55 cm)
Weight, Hand/Foot II™	68 lbs. (30.8 kg)
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	Part Numbers
Lamp	7TL-012
Goggles	9PE-004

SPECIFICATIONS

Specifications and parts are in the following table.

DERMALUME 2X™

WARNING! Read safeguards, cautions, and warnings on pages 5 to 7 before use.

The DermaLume 2X™ is shown in the upper photo. The wand has three locking positions (see middle photo). Unfold the device to the position that will be most comfortable to hold for several minutes. Make sure that it locks into position. Be careful not to pinch fingers when folding or unfolding.



DermaLume 2X™

The comb is attached by sliding the four rib guides through the slots on the device until the comb snaps into position. With a gentle nudge, the comb can be unlocked and then slid off the device.



Locking positions

POSITIONING YOUR BODY

Proper body positioning for phototherapy is extremely important to ensure optimum effectiveness of the treatment. Find a position in which you can remain still during your treatment. Small changes in positioning can influence whether areas are under or overexposed.

WARNING! Cover all parts of body except areas to be treated and wear UV protective goggles during treatment.

Place the wand near, but not directly on, the area to be treated with the entire area at a uniform distance from lamps.

When the comb is placed directly on the skin (see lower photo), it can serve as a guide to keep your device at the optimum treatment distance. The end of the comb teeth are at the ideal distance for treatment.

WARNING! Take care not to rely solely on the comb to guide treatment for narrow or curved areas such as arms since the lamps may be too close to the skin toward the center of the comb.



Comb as distance guide



DermaLume 2X™

Hand/Foot II™



To avoid dropping or breakage, place the device on a stable surface between treatments in a series. Between uses, store the device in its case.

TREATMENT PROTOCOLS

Review the [general phototherapy guidelines](#) on pages 13 to 15. The following tables provide specific treatment times and schedules for psoriasis and vitiligo based on these guidelines.

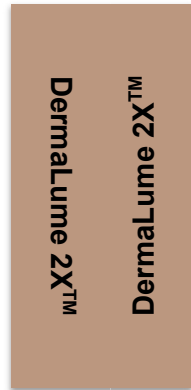
To assess if erythema has occurred (as referenced in the tables below), look for redness of the healthy skin surrounding treated lesions to appear from 3 to 24 hours after last treatment.

VITILIGO PROTOCOLS, DERMALUME 2X™	
TREATMENT PROTOCOL	
<i>Non-pigmented skin is always treated as Skin Type I</i>	
Treatment distance	At end of comb
Initial exposure time	70% of MED. Start with 26 seconds if you do not know your MED.
Exposure increase schedule	Increase by 10% each session unless erythema occurs
If erythema occurs	Hold exposure time
If erythema persists	Decrease exposure time by 25%. When erythema resolves, increase exposure time by 5% per session.
Duration of treatment	Until repigmentation has occurred
Treatment frequency	3 times per week

Treatment protocol based on Hamzavi et al, 2004

PSORIASIS PROTOCOLS, HAIR-COVERED SCALP	
<i>The scalp is always treated as Skin Type I</i>	
Combing hair continuously, treatment of entire scalp may take up to 4 to 5 minutes. Treatment time will vary depending on hair thickness, hair coverage, and size of area being treated.	
Use the comb to part hair to allow light to reach the scalp. Comb the hair from left to right and then front to back.	

i These protocols are only intended as guidelines. Consult your physician. For the maintenance schedule, see page 15.



PSORIASIS PROTOCOLS, DERMALUME 2X™			
Treatment distance	At end of comb		
INITIAL EXPOSURE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Skin Type	Dosage (mJ/cm ²)	Time (min:sec)	
I	130	0:26	
II	220	0:44	
III	260	0:52	
IV	330	1:06	
V	350	1:10	
VI	400	1:20	
EXPOSURE INCREASE SCHEDULE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Erythema Response	Adjustments		
	If you are:	Increase by:	
None	Skin Type	Dosage	Time
	Type I	15 mJ/cm ²	3 seconds
	Type II	25 mJ/cm ²	5 seconds
	Type III	40 mJ/cm ²	8 seconds
	Type IV	45 mJ/cm ²	9 seconds
	Type V	60 mJ/cm ²	12 seconds
	Type VI	65 mJ/cm ²	13 seconds
Mild pinkening	Same dose		
Severe	No treatment. When erythema resolves, 50% of 1st dose, then increase by ≤10% unless otherwise directed by your physician		
ADJUSTMENTS FOR TREATMENT			
Days missed	Protocol		
8 to 11 days	Repeat previous dosage		
12 to 14 days	Decrease dosage by 2 treatments worth		
15 to 20 days	Decrease dosage by 25%		
21 to 27 days	Decrease dosage by 50%		
28 days or more	Start treatment over		

Treatment protocols adapted from Do and Koo, 2004

i These protocols are only intended as guidelines. Consult your physician.

For maintenance schedule, see page 14.

REPLACING LAMPS

Lamps should be replaced every 100 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. Your timer keeps track of your lamp usage.



WARNING! It is recommended that all lamps be replaced at the same time. Replacing them separately will create uneven distribution of UV energy, which may result in severe erythema.



WARNING! Lamps contain mercury. Use protective gloves and safety glasses when handling. Take old lamps to a waste recycling facility. Do not put in recycle bins.

If a lamp breaks, ventilate the room for 30 minutes. Place pieces in a sealable plastic bag. Use wet cloths. Do not vacuum.

To replace the lamp, fold the handle in. Remove the four screws from the housing using a #1 Phillips screwdriver. Separate the two halves of the housing. While holding the socket with one hand, pull the lamp free from the socket with the other. Insert the new lamp in the socket until it clicks into place. Repeat for the other lamp. Replace the housing and secure with the 4 screws.



SPECIFICATIONS

Specifications and replacement parts are in the following table.

SPECIFICATIONS, DERMALUME 2X™	
Power supply and consumption	120 VAC / 60 Hz / 0.40 A
UV energy intensity	Up to 5.0 mW/cm ²
Number of pre-loaded treatments	250
Maximum timer setting	10 minutes
Dimensions, folded wand	9" L x 4.1" W x 3" D (23 cm x 10 cm x 8 cm)
Dimensions, open wand	15" L x 4.1" W x 3" D (38 cm x 10 cm x 8 cm)
Weight, all parts	4.5 lbs (2kg) total weight
Weight, wand excluding cable	1 lb (0.46kg) without cable
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	Part Numbers
Lamp	7TL-050
Goggles	9PE-004

DERMALIGHT®90



WARNING! Read safeguards, cautions, and warnings on pages 5 to 7 before use.

POSITIONING YOUR BODY

Proper body positioning for phototherapy is extremely important to ensure optimum effectiveness of the treatment. Find a position in which you can remain still during your treatment. Small changes in positioning can influence whether areas are under or overexposed.



Dermalight®90



WARNING! Cover all parts of body except areas to be treated and wear UV protective goggles during treatment.

Place the wand near, but not directly on, the area to be treated with entire area at a uniform distance from lamps. When the comb is placed directly on the skin, it can serve as a guide to keep your device at the optimum treatment distance.



WARNING! Take care not to rely solely on the comb to guide treatment for narrow, curved areas such as arms since the lamps may be too close to the skin toward the center of the comb.

To avoid dropping or breakage, place the device on a stable surface when not in use.

Dermalume 2X™

Dermalight®90

TREATMENT PROTOCOLS


Review the [general phototherapy guidelines](#) on pages 13 to 15. The following tables provide specific treatment times and schedules for psoriasis and vitiligo based on these guidelines.

To assess if erythema has occurred (as referenced in the tables below), look for redness of the healthy skin surrounding treated lesions to appear from 3 to 24 hours after last treatment.

VITILIGO PROTOCOLS, DERMALIGHT®90	
TREATMENT PROTOCOL	
<i>Non-pigmented skin is always treated as Skin Type I</i>	
Treatment distance	At end of comb
Initial exposure time	70% of MED. Start with 33 seconds if you do not know your MED.
Exposure increase schedule	Increase by 10% each session unless erythema occurs
If erythema occurs	Hold exposure time
If erythema persists	Decrease exposure time by 25%. When erythema resolves, increase exposure time by 5% per session.
Duration of treatment	Until re-pigmentation has occurred
Treatment frequency	3 times per week


Treatment protocol based on Hamzavi et al, 2004

PSORIASIS PROTOCOLS, HAIR-COVERED SCALP
<i>The scalp is always treated as Skin Type I</i>
Combing hair continuously, treatment of entire scalp may take up to 5 to 6 minutes. Treatment time will vary depending on hair thickness, hair coverage, and size of area being treated.
Use the comb to part hair to allow light to reach the scalp. Comb the hair from left to right and then front to back.

 These protocols are only intended as guidelines. Consult your physician. For the maintenance schedule, see page 15.

PSORIASIS PROTOCOLS, DERMALIGHT®90			
Treatment distance	At end of comb		
INITIAL EXPOSURE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Skin Type	Dosage (mJ/cm ²)	Time (min:sec)	
I	130	0:33	
II	220	0:55	
III	260	1:05	
IV	330	1:23	
V	350	1:28	
VI	400	1:40	
EXPOSURE INCREASE SCHEDULE			
<i>Clearing phase treatments are typically 3 times per week.</i>			
Erythematous Response	Adjustments		
None	If you are:	Increase by:	
	Skin Type	Dosage	Time
	Type I	15 mJ/cm ²	4 seconds
	Type II	25 mJ/cm ²	6 seconds
	Type III	40 mJ/cm ²	10 seconds
	Type IV	45 mJ/cm ²	11 seconds
	Type V	60 mJ/cm ²	15 seconds
Type VI	65 mJ/cm ²	16 seconds	
Mild pinkening	Same dose		
Severe	No treatment. When erythema resolves, 50% of 1st dose, then increase by ≤10% unless otherwise directed by your physician		
ADJUSTMENTS FOR TREATMENT			
Days missed	Protocol		
8 to 11 days	Repeat previous dosage		
12 to 14 days	Decrease dosage by 2 treatments worth		
15 to 20 days	Decrease dosage by 25%		
21 to 27 days	Decrease dosage by 50%		
28 days or more	Start treatment over		

Treatment protocols adapted from Do and Koo, 2004

 These protocols are only intended as guidelines. Consult your physician. For maintenance schedule, see page 14.

ATTACHING THE COMB

The comb is attached by sliding the four rib guides through the slots on the device until the two lugs on the comb snap into position. With a gentle nudge, the comb can be unlocked and then slid off the device.

REPLACING LAMPS

The lamp should be replaced every 100 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. The UV Checker can be used to test the lamp.

WARNING! Lamp contains mercury. Use protective gloves and safety glasses when handling. Take old lamp to a waste recycling facility. Do not put in a recycle bin.

If the lamp breaks, ventilate the room for 30 minutes. Place pieces in a sealable plastic bag. Use wet cloths. Do not vacuum.

Use a Phillips screwdriver to remove the three screws from the housing. Separate the two halves of the housing and place the half with the clear window on a soft, clean cloth where it cannot be scratched. Remove the small drop of clear sealant that secures the lamp base to the socket. Pull the lamp free of the socket. Insert the new lamp in the socket. The clear silicon sealer is used to prevent the lamp from dislodging during shipment and does not need to be replaced.

SPECIFICATIONS

Specifications and replacement parts are in the following table.

SPECIFICATIONS, DERMALIGHT®90	
Power supply and consumptions	120 VAC / 60 Hz / 0.17 A
UV energy intensity	Up to 4.0 mW/cm ²
Dimensions, carrying case	15.5" L x 11.75" W x 4.5" D (39.4 cm x 29.8 cm x 11.4 cm)
Dimensions, Wand	12.8" L x 3.2" W x 1.2" D (32.5 cm x 8 cm x 4.5 cm)
Weight, carrying case plus all parts	3.95 lbs (1.8 kg) total weight
Weight, wand	0.6 lb (0.27 kg) without cable
Warranty period	1 year excluding lamps
Replacement Lamp and Goggles	Part Number
Lamp	7TL-050
Goggles	9PE-004

Dermalight®90

TIMER OPERATION

Most Nat Bio phototherapy devices have an integrated Controlled Prescription Timer® (CPT™). The CPT™ controls the lights on the device and allows you to track the number of treatments you have remaining so that you can work with your physician to add treatments to your therapy regimen as appropriate. The timers are pictured below.



CPT™ Timer 1



CPT™ Timer 2

CPT™ TIMER 1

CPT™ Timer 1 is shown to the right.

Running a treatment

To begin operation, insert the key and turn clockwise to the ON position. The screen will momentarily display “nbc” followed by “0:00”.

Use the UP or DOWN buttons to select the precise time prescribed by your physician. By pressing once, time can be changed in one second increments.

To begin treatment, put on goggles and press the START/STOP button. The lamps will light, and the timer will count down. When the timer reaches 0:00, the lamps will turn off. You will hear three beeps. This completes one treatment.

Repeat these steps as prescribed for other areas of the body. After the series of treatments prescribed by your physician has been completed, turn the key counterclockwise to OFF, take off the goggles. Remove the key and store it in a safe place to prevent unauthorized use.



Interrupting a treatment

Generally, a treatment ends when the timer reaches zero. However, there are two methods to interrupt a treatment in progress.

1. Press the timer START/STOP button. The timer countdown will stop and the UV lamps will turn off. To resume therapy, depress the timer START/STOP button; the UV lamps will light, and the timer will resume the count down.
2. Turn the key-switch to the OFF position to interrupt power to the device, noting time remaining before you do so. When you are ready to resume, turn the key-switch back ON. The timer display will reset to 0:00. Reset the timer to resume remaining time and press START/STOP button.



WARNING! If treatment is interrupted, reset time at point when key-switch was turned off. Do not start treatment over or add more total time than prescribed.

Monitoring remaining treatments

Your device requires you to periodically contact your physician for a new Refill Code. One treatment is subtracted each time the START/STOP button is pressed for any reason. Your physician may prescribe a series of treatments to address multiple areas of your body.

To view the number of treatments remaining, press and hold the DOWN arrow button. The timer will beep once. Then it will display an “E” followed by three numbers (Ennn) indicating the number of treatments remaining. For example, if E122 is displayed, there are 122 treatments remaining. It is recommended that the number of treatments remaining be periodically checked.

When the number of treatments remaining is five or less, the yellow Indicator light labeled Call Doctor When Flashing will begin flashing. Your expiring 4-digit Refill Code (nnnn) will appear on the display in place of the usual timer (nn:nn). To use the remaining treatments, press START/STOP. If treatments remain, the timer will beep once, and the display will reset to “0:00”.

When you are out of treatments, the expired Refill Code will remain displayed. The timer will beep whenever START/STOP is pressed. The device will remain locked until a new Refill Code is entered.

Resetting the treatment refill code

You will need to provide your physician with your expiring Refill Code to obtain a new Refill Code.

Insert the key and turn clockwise to ON. The current or expired refill code will be displayed on the CPT™. Use the UP or DOWN arrows to scroll until the new refill code provided by your physician is displayed. Press the START/STOP button. If the new refill code has been entered correctly, the CPT™ will beep once, the “Call Doctor When Flashing” light will turn off, and the timer will display “0:00”.

If the timer beeps but the yellow Indicator light remains lit and the code displayed, the Refill Code is either incorrect or it was not entered properly. Repeat the steps above. If the timer does not reset after a few tries, contact your physician or Nat Bio Customer Service.

Checking effective lamp life

Your CPT™ keeps track of the number of hours that your lamps have been in operation. Begin with the key in the OFF position. Press and hold the START/STOP button. While the START/STOP button is depressed, turn the key to ON. The CPT™ will display “h” followed by three numbers (hnnn) where nnn is the lamp hours used. See your model’s lamp replacement section for recommended hours.

To reset the lamp hours meter, turn the key ON while holding the START/STOP button. When the CPT™ display shows hnnn reading, simultaneously press the UP and DOWN arrow buttons. The display will reset to h000.

Safety features

Watchdog Safety Circuit – Your device is equipped with a safety circuit to prevent overexposure in the event of potential device failure or malfunction. If an error is detected, the Watchdog will remove power to the UV lamps.

Key-lock switch - A key is required to turn on the device. Remove the key when the device is not in use and store it in a secure place to prevent unauthorized use.

CPT™ TIMER 2

CPT™ Timer 2 is shown to the right.

Running a treatment

To begin operation, insert the key and turn clockwise to ON.

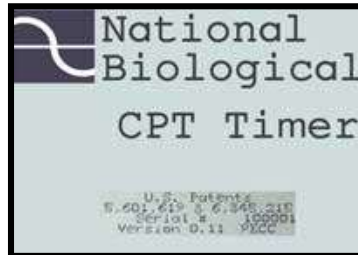
The screen will momentarily display the Intro screen (second figure) followed by the Set Time screen (third figure). The Set Time screen will display “00:00” the first time you turn on your device; after that, it will display the time most recently used.

Use **+** or **-** to select the precise time prescribed by your physician. By pressing once, time can be changed in one second increments. The longer a button is held, the faster the time will change.

To begin treatment, put on goggles and press Start/Stop **⏻**. The lamps will light, and the timer will start to count down to zero. The Treating screen will appear (bottom figure). This screen will display the time remaining in your treatment as the timer counts down to zero. The timer will beep every 15 seconds. When the timer reaches five seconds, it will beep each second until it has reached zero. When the timer reaches zero, it will sound a longer beep and the lamps will turn off. After the treatment has finished, the Set Time screen will reappear. This completes one treatment.



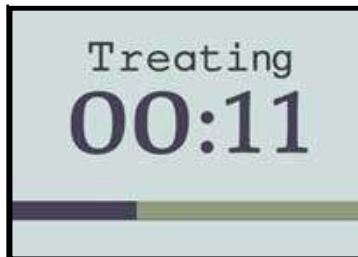
CPT™ Timer 2



Intro screen



Set Time screen



Treating screen

Set Time screen will reappear. This

Repeat these steps as prescribed for other areas of your body. After the series of treatments prescribed by your physician has been completed, take off the goggles. Remove the key and store it in a safe place to prevent unauthorized use.

Interrupting a treatment



WARNING: If treatment is interrupted, do not start treatment over or add more total time than prescribed.

Generally, a treatment ends when the timer cycle reaches zero. However, there are two ways to interrupt a treatment in progress.

1. Press PAUSE **||**. The countdown will halt, the lamps will shut off, and the Paused screen (photo below on left) will be displayed. You may either resume or cancel treatment. After 15 minutes, treatment will automatically be cancelled.

To resume the treatment, press PAUSE **||** again. The lamps will light, the Treating screen will reappear, and the timer will resume its countdown.

To cancel the treatment, press Start/Stop **⏻**. A Cancel Treatment screen (photo below on right) will be displayed. Verify that you want to cancel treatment by pressing **+**.

To resume the treatment from the cancel treatment screen, press Start/Stop **⏻**. You will see the Paused screen. Press **||**.

2. Turn the key-switch to the OFF position to interrupt the power to the device.



Paused screen



Cancel Treatment screen

Monitoring remaining treatments

Your device requires you to periodically contact your physician to renew your prescription. The number of treatments remaining is displayed at the bottom of the Set Time screen.

One treatment is subtracted each time the timer reaches zero, when a treatment is cancelled, or when power to the device is lost. Your physician may prescribe a series of treatments to address multiple areas of your body.

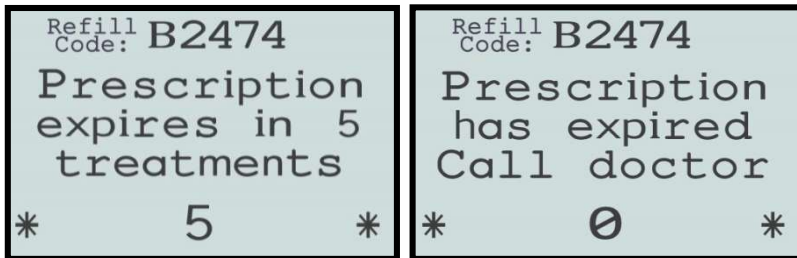
Once the number of treatments is 20 or less, a Prescription Expires screen (shown at bottom left) will alert you before each treatment. You are advised to contact your physician to review progress, evaluate the treatment regimen, and discuss your treatment plan.

If there are treatments remaining, you can press PAUSE || from the Prescription Expires screen to proceed to the Set Time screen. If not, the Prescription has Expired screen will indicate that you are out of treatments (see lower right figure). The device will remain locked until a new Refill Code is entered.

Resetting the treatment refill code

You will need to provide your physician with your expiring Refill Code located at the top of the screen to obtain a new Refill Code.

To enter a Refill Code, scroll using the + or - buttons until the new Refill Code is displayed. Press PAUSE ||. If the new Refill Code has been entered correctly, the Set Time screen will appear showing the last time setting and the new number of treatments available. The CPT™ is now enabled and therapy can continue.



i Note: Your Refill Code may differ from the sample Refill Code shown above.

Checking effective lamp life

Your CPT™ keeps track of the number of hours that your lamps have been in operation. To view the Lamp Usage screen (see photo at right), turn the key to ON. As soon as the Intro screen appears, press and hold both the + and - buttons at the same time. The Lamp Usage screen will display. Press EXIT to return to the Set Time screen.



Lamp Usage screen

To reset the Lamp Hours Usage meter, press reset.

Safety features

Watchdog Safety Circuit – Your device is equipped with a safety circuit to prevent overexposure in the event of potential device failure or malfunction. If any error condition is detected, the safety circuit will remove power to the lamps.

Key-lock switch - A key is required to turn on the device. Remove the key when the device is not in use and store it in a secure place to prevent unauthorized use.

TROUBLESHOOTING

TROUBLESHOOTING	
Problem	Action
The lamps fail to light.	Check that the device is plugged in and that the cord is intact and timer is illuminated.
The timer will not illuminate.	Check that <ul style="list-style-type: none"> • the key is in the ON position • the outlet is working
You cannot access the Set Time screen.	Check if a new Refill Code is needed. If so, contact your physician.
Your display shows the words “Call Doctor”, “Prescription expires”, or “Prescription has expired”.	Contact your physician to renew your prescription.
Your display shows the words “Call Doctor”, “Prescription expires”, or “Prescription has expired” even after entering your Refill Code.	Check that the new Refill Code was entered correctly. If you still see one of these screens, contact your physician to have your Refill code verified.
The timer displays an “F” error code and indicator light next to “Call Doctor when on Steady” is lit.	Attempt to clear the error by pressing the START/STOP button. If this does not clear the error, or if the error displays repeatedly, contact Customer Service.
A yellow Indicator next to “Call Doctor When Flashing” is flashing.	Contact your physician to issue a new Refill Code. See page 65.

Nat Bio Customer Service:
 Phone - 800-338-5045 or 216-831-0600
 Email - info@natbiocorp.com

NOTES

WARRANTY

This Warranty is provided to the original purchaser (the "Purchaser") of Nat Bio phototherapy devices (the "Equipment"). There is no Warranty associated with the Equipment except for the Purchaser. Nat Bio warrants the Equipment for defects in material and workmanship and is limited to claims made to Nat Bio within the device Warranty period, with respect to parts and labor, and from the date of shipment by Nat Bio and our distributors. The Warranty does not apply to equipment failure or damage caused by shipping or customer abuse, any use not in accordance with the instructions supplied with the Equipment including use of attachments or other items not sold or specified by Nat Bio, incorrect customer installation, improper electrical service, lack of proper maintenance, failure to follow the Equipment owner's manual, and Acts of God.

Warranty Period	
New Equipment	1 Year
Lamps	90 Days

The Purchaser must allow Nat Bio, at Nat Bio's option, to inspect the Equipment or component parts on request. The Purchaser must reasonably cooperate with Nat Bio to verify the Warranty claim of the Purchaser, including on-site or remote diagnostic work. Failure to cooperate in diagnostic work may result in being charged for on-site service calls.

During the Warranty period, Nat Bio will, at Nat Bio's option, repair or replace Equipment or components deemed to appear defective in material or workmanship, with new or remanufactured materials. Nat Bio 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 Warranty. In such situations, Nat Bio will cover reasonable freight expenses in the continental United States to ship products covered under Warranty both to and from Nat Bio'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 Nat Bio pays reasonable freight charges back to the customer. All Equipment ships ground unless the customer covers costs for expedited shipping. Nat Bio is not responsible for any delays occurring during transport of the Equipment.

In no case shall Nat Bio be liable for incidental, indirect, consequential, special, or punitive damages (including lost profits or lost wages) even if Nat Bio has been advised of the possibility of such damages. In addition, Nat Bio's total aggregate liability shall never be greater than the amount paid by the Purchaser for the device. The foregoing warranties are in lieu of all other warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In the event that this Warranty conflicts with other warranties included in Nat Bio's Equipment manual, the terms and conditions of this Warranty shall prevail.

Nat Bio shall not be responsible for any incidental, indirect, consequential, special, or punitive damages (including lost profits or lost wages) of Purchaser.

Some states do not allow limitations on how long an implied Warranty lasts, so the above limitations may not apply to you. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

