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 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.

NAT BIO
Phototherapy Solutions

999-391 Rev 003

INSTRUCTIONS FOR USE

Handisol Phototherapy Device:

With Narrowband UVB Lamps

NAT BIO
Phototherapy Solutions

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 service as a record for warranty.

Purchased From: _____ Date:_____

Model No: _____ Serial No: _____

NAT BIO
Phototherapy Solutions

23700 Mercantile Rd • Beachwood, OH 44122
(216) 831-0600 or (800) 338-5045 • Fax: (216) 765-0271
info@natbiocorp.com • www.NatBioCorp.com

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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

3. Contact prescribing physician and provide Device Code "CXXX".

The physician will utilize the Nat Bio Physician's Portal to obtain the Treatment Code.

SPECIAL NOTES

1. The maximum time that can be entered is 59 minutes and 59 seconds.
2. It is **not** possible to enter XX:60 seconds. You must enter 01:00 minute instead.
3. If power goes off during a treatment, the system will not remember how much of the treatment has elapsed. When power is restored, the controller will prompt for the Key Code and another treatment will have to be started.
    a. If the controller loses power during a treatment, an exposure/full treatment will be assumed, and the remaining treatments will decrease by one (1) treatment.
4. If the number of remaining treatments is twenty (20) or less, the display will flash the number of treatments remaining two (2) times after a treatment or at power up. This is signaling you to obtain a new treatment code soon.
5. There are 1000 Device Codes (C000-C999), each having five (5) four-digit Refill Codes (0000-9999) that set a predetermined number of exposures to be allowed by the controller.
    a. 0 exposures (locked), 75 exposures, 100 exposures, 250 exposures, or unlimited exposures (unlocked).

Troubleshooting

Nat Bio Customer Service:

Phone – 800-338-5045 or 216-831-0600

Email – info@natbiocorp.com

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5. Press the PLAY/PAUSE button one time to lock in the treatment time. The flashing character should stop flashing.
6. Now that the desired time is displayed (in this case 01:23), press the PLAY/PAUSE button to begin treatment.
7. Pressing the PLAY/PAUSE button again will pause treatment.
8. While paused, pressing the CANCEL button will end the treatment and prompt a new treatment.

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. Enter your Key Code to unlock the controller.
2. Simultaneously press CANCEL, LEFT-ARROW, and PLAY/PAUSE.
3. While the screen displays “---1”, press the UP-ARROW button four (4) times. The screen should display “---5”.
4. Press the PLAY/PAUSE button to enter Menu 5.
5. The value displayed (“CXXX”) is the next generated Device Code.
    a. Alternatively, when all treatments have been exhausted, the display will display this Device Code.

    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.

TREATMENT REFILLS

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

1. Enter your Key Code to unlock the controller.
2. Device Code “CXXX” is displayed on screen. Note: If the Device Code is not displayed, there are exposures remaining and it will be displayed once all exposures have been used.

3. The currently editable character will flash on and off to signal that it is the editable character.
4. Press the UP-ARROW button to increase the value of the flashing character by one (1).
5. Press the LEFT-ARROW button to move the flashing character over by one position.
6. Once the desired time is present on the display, press the PLAY/PAUSE button to lock-in the treatment time.
7. Press the PLAY/PAUSE button to begin the treatment.
8. Press the PLAY/PAUSE button to pause the treatment.
9. While treatment is paused or completed, press the CANCEL button to return to the treatment menu (“00:00” displayed with the right-most character flashing).
10. After a treatment is complete, the controller will enter Standby Mode. The controller will flash the most recently completed treatment while in standby mode. Record this treatment time in your treatment journal/log. You will want to save it for subsequent treatments.
    a. To repeat this treatment: press the PLAY/PAUSE button to re-enter Time Entry Mode. The rightmost character should now be flashing.
    b. Press the PLAY/PAUSE button again to set the treatment time.
    c. Press the PLAY/PAUSE button again to start the treatment.

EXAMPLE:

1. An example time of one minute and twenty-three seconds will be used (01:23).
2. The right most character should be flashing – press the UP-ARROW button three (3) times. The display should now read “00:03”.
3. Press the LEFT-ARROW button one (1) time and the UP-ARROW button two (2) times. The display should now read “00:23”.
4. Press the LEFT-ARROW button one (1) more time and the UP-ARROW button one (1) more time. The display should now read “01:23”.

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Introduction

Read this manual prior to using your device.

SAVE THESE INSTRUCTIONS.

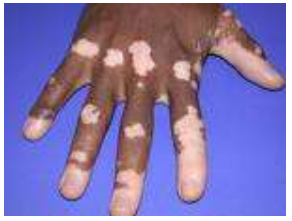
Intended Use

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.

Safeguards, Cautions and Warnings

WARNING! Changes or modifications to equipment not specified in this manual may result in serious injury or death. 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.

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 a new device.

SAFEGUARDS FOR PHOTOTHERAPY EQUIPMENT

- All persons who have access to this device should read and understand the instructions provided prior to use.
- Avoid device exposure to children or pets. Children prescribed the device must do so under adult and physician supervision. Do not leave the device unattended while it is operating.
- To prevent electrical shock, do not use this device in or near any liquids, in conditions of extreme humidity, or out of doors.
- 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 moving device on uneven or inclined surfaces to avoid tipping.
- This device is to be used by only one person at a time.
- This device is for treatment of dermatological disorders only. It is never to be used for cosmetic tanning.

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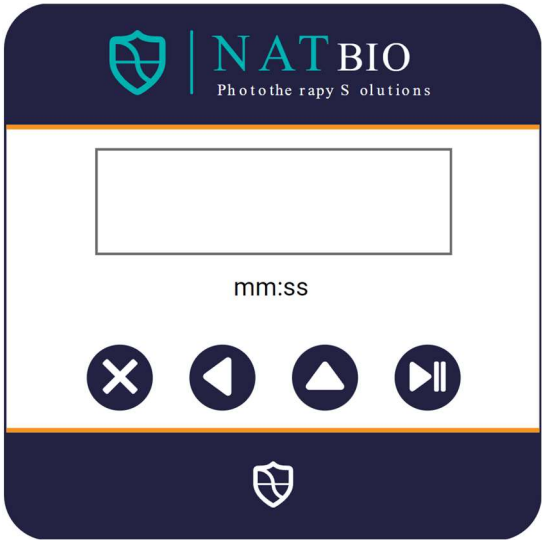
Operation of the DT Controller



DT Controller Overlay Label

Unlocking the Device

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

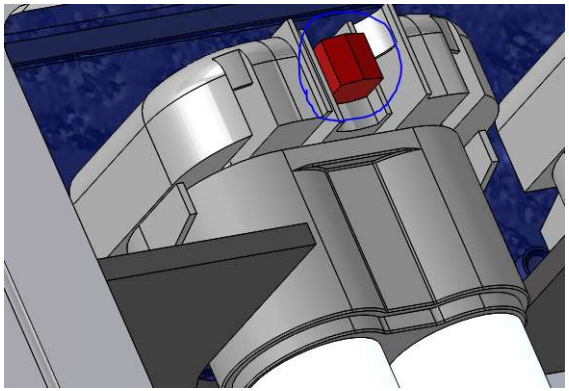
1. Press any button to power on the device.
2. Your unit will now display the word “C0dE”.
3. The factory default Key Code is “0007”. Press the UP-ARROW button until your unit displays “0007”.
4. Press the PLAY/PAUSE button to unlock the controller.

Setting Up a Treatment Time

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

1. Enter in your key code. Unless you have changed it, the factory default Key Code is “0007.”
2. Once the Key Code has been entered, the display should read “00:00” (minutes:seconds).

Push the red button on the lamp socket and lift the lamp out of the socket. The lamp is tywrapped to the support clip, which will carefully need to be cut.



To install lamps, place the lamp in the socket, aligning the pins. Ensure the lamp is tight against the socket and press down firmly until the lamp clicks into the support clip and the pins in the lamp click into the socket. You may opt to replace the support clip tywraps, but it is not necessary. Replace window utilizing previously removed screws.

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WARNING! Keep out of reach of children and pets. May result in device damage, serious injury, or death. The device is intended for indoor use. Pest infestation may cause the device to malfunction or result in serious injury and death.

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 of phototherapy.

Adverse reactions may include:

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

DETERMINING YOUR SKIN TYPE

Consult your physician to determine your Skin Type. Treatment times are based on Skin Type or Minimal Erythemal 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).

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

REPLACING LAMPS

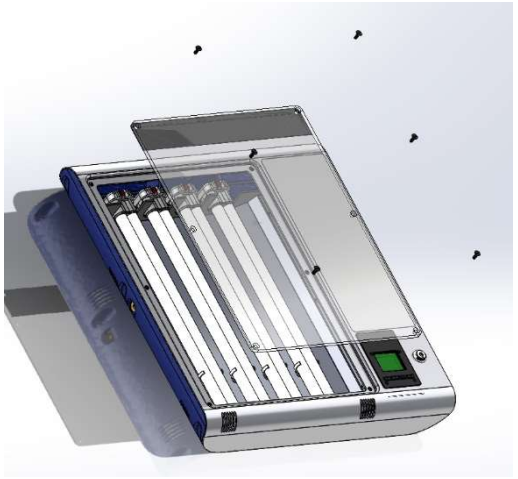
Lamps should be replaced every 150-200 operating hours. While lamps may still light and appear normal, UV energy intensity decreases with use, making treatment less effective. Your timer keeps track of your lamp usage.

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 replace lamps, remove the screws holding the window in place using a flathead screwdriver. Remove the window.



PSORIASIS PROTOCOLS, Premium Model (4-Lamp)			
Treatment distance		At surface of shield or 6-8” away	
TREATMENT PROTOCOL *Non-pigmented skin is always treated as Skin Type I*			
Skin Type	**Dosage (mJ/cm²)**	**Time (min:sec)**	
		Hands/Feet On Window	**Positioned 6-8” from device**
I	130	0:16	0:19
II	220	0:27	0:32
III	260	0:32	0:38
IV	330	0:41	0:48
V	350	0:43	0:51
VI	400	0:50	0:58
EXPOSURE INCREASE SCHEDULE *Clearing phase treatments are typically 3 times per week.*			
Erythemal Response	**Adjustments**		
None	**If you are:**	**Increase by:**	
	Skin Type	**Dosage**	**Time (min:sec)**
			Time (On Window) / **Time (6 to 8” from device)**
	I	15 mJ/cm²	0:01 / 0:02
	II	25 mJ/cm²	0:03 / 0:03
	III	40 mJ/cm²	0:05 / 0:05
	IV	45 mJ/cm²	0:05 / 0:06
	V	60 mJ/cm²	0:07 / 0:08
	VI	65 mJ/cm²	0:08 / 0:09
Mild Pinkening	Same dose		
Severe	No treatment. When erythema resolves, start at 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		

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

Treatment protocols adapted from Do and Koo, 2004

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POWER AND ELECTRICAL REQUIREMENTS

For safe operation, this device must be connected to a dedicated 15 A circuit or a 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. A three-to-two prong AC grounding adapter should **not** be used.

ELECTROMAGNETIC COMPATIBILITY AND INTERFERENCE (EMC/EMI)

Devices that could generate interference problems include:

- Mobile Phones
- Scanners
- Security Check Devices
- Radiofrequency Identification (RFID) Equipment
- Microwaves

Additionally, the system can radiate radio frequency energy if not installed in accordance with these 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 your 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
- Consult the manufacturer for help

OPERATING CONDITIONS

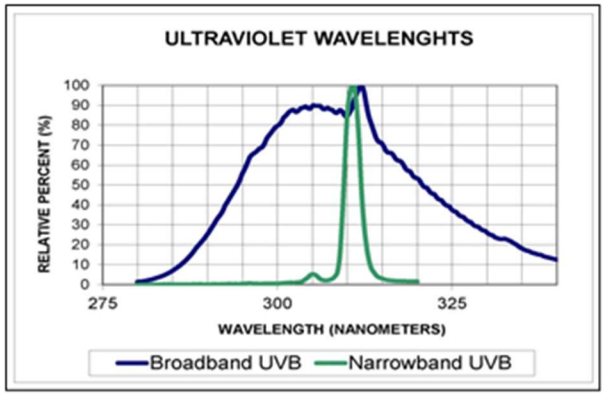
This product is designed for use in dry rooms with an ambient temperature between 40°F (4°C) and 90°F (32°C) and relative humidity of 20% - 90%.

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

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PSORIASIS PROTOCOLS, Basic Model (2-Lamp)			
Treatment distance	At surface of shield or 6-8” away		
TREATMENT PROTOCOL *Non-pigmented skin is always treated as Skin Type I*			
Skin Type	**Dosage (mJ/cm²)**	**Time (min:sec)**	
		Hands/Feet On Window	**Positioned 6-8” from device**
I	130	0:18	0:21
II	220	0:31	0:36
III	260	0:37	0:43
IV	330	0:47	0:55
V	350	0:50	0:58
VI	400	0:57	1:07

EXPOSURE INCREASE SCHEDULE *Clearing phase treatments are typically 3 times per week.*				
Erythemal Response	**Adjustments**			
None	**If you are:**	**Increase by:**		
	Skin Type	**Dosage**	**Time (min:sec)**	
			Hands/Feet On Window	**Positioned 6-8” from device**
	I	15 mJ/cm²	0:02	0:02
	II	25 mJ/cm²	0:03	0:04
	III	40 mJ/cm²	0:05	0:06
	IV	45 mJ/cm²	0:06	0:07
	V	60 mJ/cm²	0:08	0:10
	VI	65 mJ/cm²	0:09	0:10
Mild Pinkening	Same dose			
Severe	No treatment. When erythema resolves, start at 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

RECOMMENDED TREATMENT PROTOCOLS

Review the general phototherapy guidelines from earlier in this instruction. 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.

VITILGO PROTOCOLS	
TREATMENT PROTOCOL *Non-pigmented skin is always treated as Skin Type I*	
Treatment Distance	At surface of shield
Initial Exposure Time	70% of MED. Start with 22 seconds if you do not know your MED.
Exposure Increase Schedule	Increase by 10% each session unless burning occurs
If Light Burning Occurs	Hold exposure time
If Light Burning Persists	Decrease exposure time by 25%. When Light Burning 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 are only intended as guidelines. Consult your physician.

For maintenance (skin re-pigmented at least 75%) schedule, refer to the chart below:

Step-down maintenance strategy

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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, similar to 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. Avoid using a cloth that contains too much moisture as this may damage the device.

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.

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

DISPOSAL INSTRUCTIONS

Your Handisol device contains components that must be recycled and not thrown away. Before discarding your device, remove the UV lamps by following the instructions under the Replacing Lamps section of this manual. Then, take them to a fluorescent bulb recycling center. Electronic and metallic device components can then be taken to a metal recycling center. The plastic enclosure can be recycled via normal plastic recycling. Nat Bio is unable to service third party use of equipment or accept used equipment returns. Do not donate or sell your home phototherapy device to someone else. The serial number on the device is associated with your non-transferable prescription.

ALL OTHER TREATMENT AREAS

4-LAMP PREMIUM MODEL

To treat other areas of your body, place the device in the top notch of the stand. Adjust the angle to be parallel with the area of your body you are wishing to treat. Tighten the knobs of the stand before treating.

2-LAMP BASIC MODEL

Leave the device in the acrylic stand as shown.

2-Lamp Basic Model

Remove the nylon screws circled in the figure below. Refer to the Replacing Lamps procedure for details on removing screws. Keep the screws in a safe place. Hand-tighten the supplied hex standoffs in place of the removed screws. Turn the device over facedown. Slide your hands/feet under the device in between the hex standoffs for treatment.

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Definitions and Symbols

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

Term	Definition
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 treatment and response
Melanoma	A benign or malignant skin tumor containing dark pigment
Minimal Erythemal 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
	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 EQUIPMENT

weight onto the unit while treating the soles of your feet. If you have the 4-Lamp Premium model, you may elect to leave the device in the stand and set it faceup in the bottom notch. You can then position your soles or palms over the treatment window.

TOP OF HANDS OR TOP OF FEET

4-LAMP PREMIUM MODEL

To treat the tops of your hands or feet, move the device up to the middle notch of the stand and flip it upside down. To do this, move the device to the top notch and rotate the device so the lamps are facing downward. When treating your feet, adjust the angle of the device to be parallel with the angle of the top of your feet. When treating your hands, adjust the angle of the device to be parallel to the bottom of the stand. Tighten down the knobs of the stand before treating. Use the position indicators on the stand base to place your hands and feet for treatment.

Stand Setup Instructions (2-Lamp Model)

1. Remove device, stand, and power cord from packaging.
2. Set the device with the lamps facing upward on a firm surface (table, counter, etc.) and ensure it is stable.
3. Take the 3-piece acrylic stand out of the packaging.
4. Place the tall, L-shaped sides into the rectangular base with 2 cutouts one at a time. See image below:

WARNING! Strangulation Hazard: Use caution when choosing a wall outlet to plug in the power cord. Do not position your device in a way that makes it difficult to operate the disconnecting device (i.e., the power cord). Avoid placing the power cord in the way of high foot traffic. Keep out of reach of children.

Device Positioning for Specific Treatment Areas

Palms of Hands or Soles of Feet

To treat the soles of your feet or the palms of your hands, place the device on a sturdy table surface (palms) or the floor (feet) and follow the treatment position guidelines corresponding to your device model. Do not stand or apply too much of your body

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 Psoriasis[1]

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 that your physician may direct you to follow is provided on pages 27 and 28.

Treatment is most effective at 85% to 90% of the Minimal Erythemal Dosage (MED). MED occurs if the skin reddens slightly without burning the skin. 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.

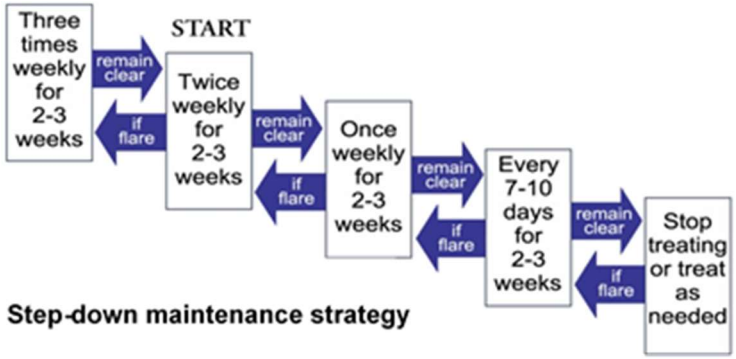
[1] *Adapted from Shelk & Morgan, JDNA Dec 2000 using Leone Dermatology Center protocol*

MAINTENANCE PHASE FOR PSORIASIS[2]

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 burning 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.

[2] *Do and Koo, 2004*

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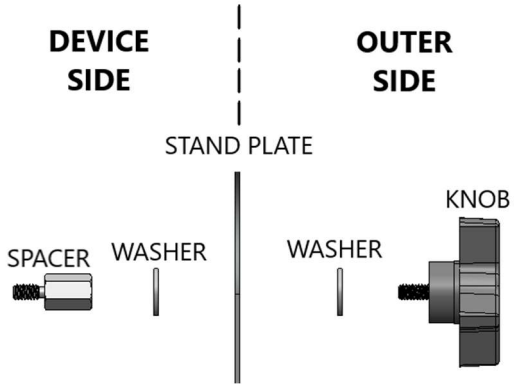

NOTE: The device is intended to be adjustable on the stand. The knobs must be tightened fully once the device is in position for treatment. Before readjusting the device position, the knobs must be loosened on the device. Do not use any tools to overtighten/torque the knobs. They should be hand tightened only.

To properly adjust the device position in the stand, loosen the knobs only while the device is held in a notch, loosening one knob at a time. When both knobs are loose, lift the device out of the notch using both hands. Move and rotate the device to the desired treatment position.

2. Set the device with the lamps facing upward on a firm surface (table, counter, etc.) and ensure it is stable.
3. Take the stand, two knobs and four washers away from the main device for now.
4. Take the two knobs and place one washer on each.
5. Lift up one side of the stand and place a knob-washer through the top notch on the side. Repeat this step for the other side of the stand.
6. Both knobs should have threads facing toward the center of the stand and have one washer held on the outside as shown below.
7. Place the remaining two washers against the inner face of the stand sides.
8. Move back over to where the main device is resting. Take the two male/female threaded adapters and hand tighten them into the sides of the main device.
9. Carefully grip the device placing one hand at the top and another at the bottom. Set the device standing upright, with the lamps facing towards you.
10. Steady the device on the ground in this position with one hand. Use the other hand to shift one knob down to the threaded adapter on the side. Thread the knob into the threaded adapter.
11. Repeat this process for the other knob and threaded insert.
12. Loosen both knobs just enough to move the device up so that it is set in the top notch. Do not remove the knobs from the threaded adapters.
13. When the device is in the top notch, tighten the knobs firmly to lock the rotation of the device.
14. Take the female end of the power cord and install it into the power cord port located on the right side of the device. Before plugging the device into a power outlet, ensure it is in the desired position with the knobs fully tightened.

WARNING! Strangulation Hazard: Use caution when choosing a wall outlet to plug in the power cord. Do not position your device in a way that makes it difficult to operate the disconnecting device (i.e., the power cord). Avoid placing the power cord in the way of high foot traffic. Keep out of reach of children.

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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.

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 this manual.

Treatment is most effective at 85% to 90% of the Minimal Erythemal 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 VITILIGO[3]

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:

Step-down maintenance strategy

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

[3] *Kumar et al, 2009*

when beginning therapy since the threshold for burning will have decreased.

Device Instructions

SPECIFICATIONS	
Power supply and consumption	120 VAC / 60 Hz / 1.2 A
UV energy intensity	Up to 8 mW/cm^2
Number of pre-loaded treatments	150
Maximum timer setting	10 minutes
Device Dimensions	19”W x 20”L x 3”D (48 cm x 51 cm x 8 cm)
Window Dimensions	17.2” x 13.2” (43 cm x 34 cm)
Weight	10 lbs
Replacement Lamp and Goggles	**Part Number**
Lamp	7PL-036
Goggles	9PE-004

WARNING! Read safeguards, cautions, and warnings at the beginning of this manual before use.

Positioning Your Body

Proper body positioning for phototherapy is extremely important to ensure optimum effectiveness of the treatment. Determine a position in which you can remain still for an entire treatment and position your body and device accordingly.

For both the Basic and Premium version of the device, only treat the soles of your feet or palms of your hands directly on the surface of the device. While treating the soles of your feet, ensure that you are in a seated position. Avoid standing or applying too much of your body weight on the unit. Do not overload. All other treatment areas should be done placed at 6”-8” (15-20 cm) centered with the window treatment area of the device. See the sections below for specific instructions for each model.

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

2-Lamp Model (Basic)

When using the 2-Lamp Basic version of the device, position your hands or feet individually centered over each lamp when treating the palms of your hands or the soles of your feet.

4-Lamp Model (Premium)

When using the 4-Lamp Standard version of the device, position your hands or feet centered on the window of the device with 0.5”-1.0” (1 – 2.5 cm) between appendages.

Utilizing The Stand

Follow the instructions below for safely using the stand and positioning your body. For all positions, ensure that the device is securely attached to the stand and is not at risk of tipping over. Always place the device and stand on a level, stable surface. Follow these instructions to install the stand to the device:

Stand Setup Instructions (4-Lamp Model)

1. Remove device, stand, and power cord from packaging.