Panosol 6 and Panosol 6-3D
Operations Manual

Devices are built to specific customer requirements.
The device you receive may be configured differently than what is shown on the cover.

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Dear Valued Customer:

Thank you for purchasing a National Biological Corporation 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.

National Biological 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 National Biological Corporation Sales or Customer Service for assistance.

Thank You,

National Biological Corporation

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the state in which he or she practices.

1.0 Control Type

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

2.0 Indications for Use

The Panosol 6 and Panosol 6-3D Phototherapy Devices are indicated for use to treat diagnosed skin disorders such as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The physician will determine the light spectrum (ultraviolet to visible), the energy or duration of the treatment, as well as the treatment environment. The population may range from pediatric, when accompanied by a responsible adult to operate it, to geriatric.

3.0 Delivery and Inspection

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

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As part of the claims process, the delivering carrier may require that a damage inspection be conducted. They may conduct the inspection at your home, or they may elect to collect the package for inspection at their facilities.

Note: In addition to notifying National Biological, the delivering carrier **must also** be notified of any shipping damage within twenty-four (24) hours to protect your right to an insurance claim.

4.0 Site Selection

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

4.1 Electrical Requirements

In the United States and Canada, the device is shipped with a standard three-pronged plug and can be plugged into any grounded household electrical outlet installed on a standard, non-Residual Current Device (RCD) or ground fault circuit interrupter (GFCI) breaker. Devices to be used overseas will be equipped with a country appropriate electrical cord and plug.

All devices are equipped with an onboard fuse. The fuse holder is a part of the power cord receptacle that is located on the back of the device. If an onboard fuse fails, call National Biological's Customer Service department to determine an appropriate replacement.

5.0 Unpacking and Assembly

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

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

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

2. Remove all packing materials from the container. Ensure that the following parts and accessories are accounted for:
   a. **Protective** Goggles (1 pair)
   b. Feet (2) - found in the top and bottom foam shock absorbers or taped to the inside of cardboard crate: see Figure 1: Feet.
   c. Stabilizer Bracket (2) - found in the middle shock absorber or taped to inside of the cardboard crate: see Figure 2: Stabilizer Brackets.

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d. Grid (attached in units without doors)
e. Power Cord

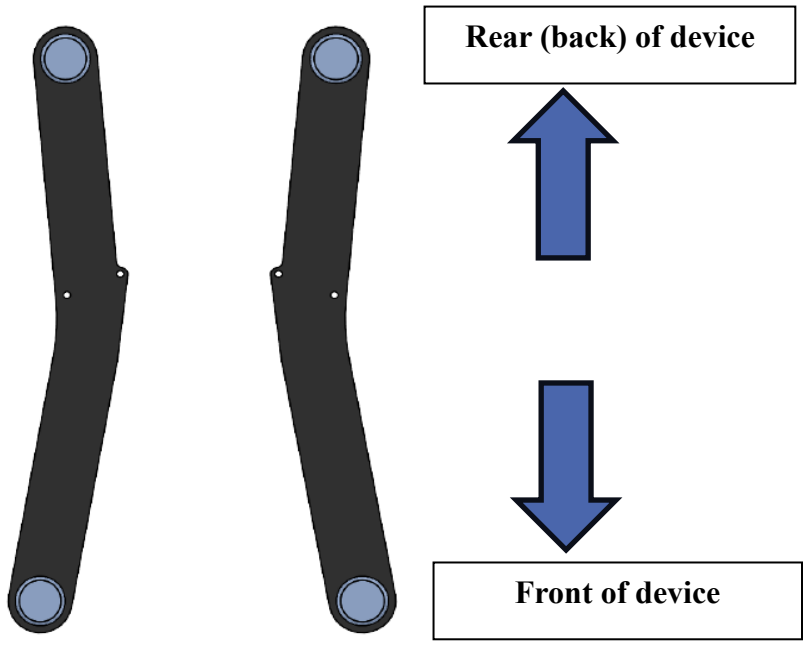

Figure 1: Feet

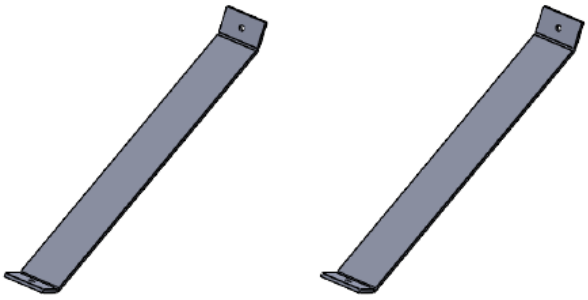

Figure 2: Stabilizer Brackets

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

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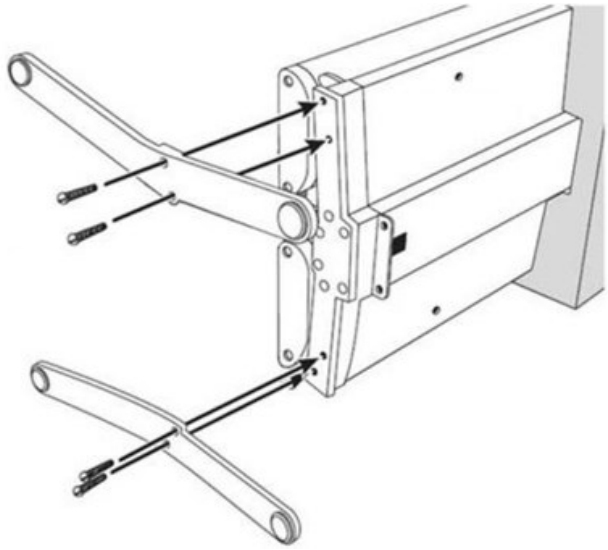

Figure 3 Feet Installation

4. Leaving the device on its side but with its feet attached, tilt it upright until both feet are on the floor.
5. Remove the foam shock absorbing pieces from the middle of the unit (Units with 4 lamps: ensure you have gathered the stabilizers from the foam).
6. Mount the two stabilizer brackets using the screws that are pre-inserted 14" (35cm) from the bottom of the unit and in each foot. Each stabilizer mounts to one foot and to the back side of the device. Using a #2 Philips screwdriver, remove the screws from the feet and the back of the device, position the holes in the brackets with the holes in the back of the unit and on the foot, and then reinsert the screws. Tighten completely.
7. Gently slide the unit into its permanent location.
8. Units with more than 4 lamps: Remove the screws at the bottom of the device in front of the lamps (Units without doors: 2 screws total, units with doors:4 screws total). Insert the perpendicular grid wires into the holes in the top lamp plate and push the grid all the way up. Swing the bottom of the grid in toward the lamps and insert the grid wires into the two holes in the bottom lamp plate. Then, lower the grid until the bracket touches the bottom lamp plate. Using a 5/16" hex driver/socket, screw the bracket to the bottom lamp plate using one of the hex-headed, self-tapping screws provided.
9. Insert the male "D" shaped plug into the "D" shaped receptacle at the back of the device. Then, plug the unit into an appropriate, grounded electrical receptacle.

6.0 Lamp Inspection

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

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7.0 Precautions & Warnings

- To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. **Always use National Biological approved eyewear.**
- Do not remove protective eyewear, or any other protective equipment, during treatment.
- If psoralens (photosensitizing drugs) are being used as part of your treatment ("PUVA"), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with devices equipped with UVA lamps.
- Do not use over skin eruptions without express consent from the attending physician.
- If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.
- To protect unaffected skin during operation, the operator, patient, and anyone in view of the device must generously apply UV blocking skin protection to all exposed skin that the physician does not intend to treat.
- Erythema can result in as little as 15 seconds of exposure to UVB light. Prior to using your home phototherapy unit, contact your prescribing physician for specific treatment instructions and dosing information**.**
- Center patients between the lamps during treatment to avoid over exposure to isolated areas of the body.
- All people and pets should leave the area to avoid exposure to ultraviolet light.
- Ask your doctor about protecting areas of your body which have not been exposed to sunlight.
- Do not use this device for anything other than its intended purpose.
- This device is only to be used by authorized users.
- Do not operate this device with a damaged cord or plug.
- Do not position the device in such a way that it is difficult to disconnect power (i.e. unplug the device).
- To avoid the risk of electric shock this equipment must only be connected to a supply main with a protective earth.
- To prevent electric shock, remove power to the device prior to cleaning and servicing.
- To eliminate the risk of fire when replacing the fuse, replace **ONLY** with a fuse of the same type and rating.
- **NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED**. Unauthorized modification will void the warranty and may result in hazardous or improper device operation.
- **DANGER - ULTRAVIOLET RADIATION**. As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer. **ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE ERYTHEMA OR LONG-TERM INJURY TO THE EYES**. Medications or cosmetics may increase skin sensitivity to ultraviolet radiation. Inform your physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.

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- If the device malfunctions, cease operation immediately. If the device is placed close to other equipment, it is possible that the cause is interference by external noise sources and fields, in which case you should follow the remedies found under Environmental Specifications. If the device continues to malfunction cease operation and contact National Biological Customer Service.
- If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging the device or, if hard wired, turning off quick disconnect.
- Prior to each use, always verify that the device is in correct working order and operating condition. Ensure that plugs, sockets, lamps, and electrical cables/connections are not worn or damaged.
- Only original components and accessories should be used with the device to avoid damage.
- This device should be a minimum of 12 inches (30 cm) away from radio frequency (RF) generating equipment.
- Before opening the device casing to perform maintenance or service, disconnect the device from the power source.
- The device must never be directly exposed to flowing or splashing liquids of any kind. If the device is inadvertently exposed to liquid, it must be tested for safe function before being placed in operation again.
- The device contains glass lamps. Avoid excessive force to the device to prevent lamp damage.
- The device control system display is susceptible to damage from excessive force. Avoid excessive force to the control system to prevent damage.
- All treatments must be administered under the direction of a licensed physician only.
- **WARNING**: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

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8.0 Operating Specifications

Table 1 Operating Specifications

Ambient Temperature:	15°C to 30°C (59°F to 86°F)
Relative Humidity:	10% to 95%, Non-condensing
Liquid Ingress Rating:	IPX0 (This device does not have protection against ingress of water.)
Ocular Hazard Distance:	3 Meters (9.84 Feet)
Ambient Luminance:	250 – 500 lux

WARNING: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

9.0 Labels and Symbols

An overlay label will be found with both instances of the serial number label on the device. This label prompts the user to read the Operating Manual for indications for use, dosage, warnings, and directions for use. This label also includes National Biological's manufacturing address.

Figure 4 : Overlay Label

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

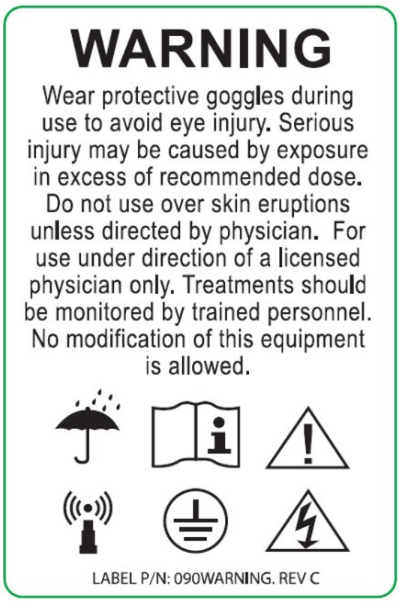

Figure 5 : Warning Label

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

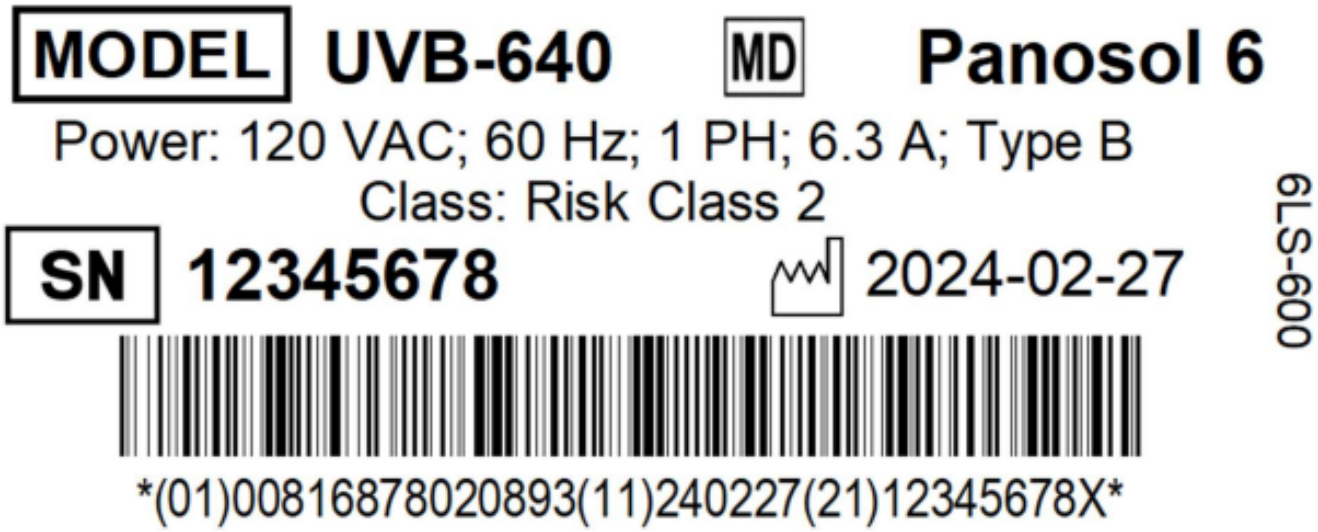

Figure 6 : Serial Label

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

Figure 7 Hazardous Voltage Label

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

Figure 8 Refill Label

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On top of your device's DT Controller is a label that explains how to unlock and begin using the device. This is a temporary label that will need to be removed prior to use. You may want to hold on to this label for future reference. See **Figure 9** below:

Figure 9 Keycode Label

Figure 10 : Medical Device Label

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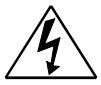
Table 2 Symbols lists all the symbols located on the device along with their meaning:

Table 2 Symbols

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

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10.0 General Instructions (All Modes of Operation)

10.1 Pre-treatment Preparations

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

You may want a notebook, or treatment log, in which to record the date, dose and duration of each of your treatments along with any other notes regarding your treatment or treatment results. (For example, forgot lip balm, put sunscreen on tender area, etc.)

Note: *A free printable treatment log is available for download at www.natbiocorp.com.*

You will need to purchase lip balm and sunscreen with an SPF (Sun Protective Factor) of at least 30. Ask your doctor if you should use alcohol or cream-based sunscreen. To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. Always use National Biological approved eyewear. Do not remove protective eyewear, or any other protective equipment, during treatment. Always stand 6"-8" away from the center panel of the device.

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 Table 3 Fitzpatrick Skin Type

Table 3 Fitzpatrick Skin Type

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.

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This manual contains sample guidelines and treatment times for Narrowband UVB (NB-UVB) treatment of 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, or if your device is equipped with lamps that are not NB-UVB (i.e. UVA), consult your physician.

Treatment Guidelines for Psoriasis

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 below. The protocol is comprised of two sections: Clearing and Maintenance.

Clearing Phase for Psoriasis

The goal of the clearing phase is to put psoriasis plaques into remission (at least 95% clear). Gradually, treatment times may increase until mild pinkening/skin redness (MED) has been achieved. Treatments should occur 3 times per week and at evenly spaced intervals. This means there should be roughly 48 hours between treatments (i.e. Monday, Wednesday, Friday schedule). Always stand 6”-8” away from the center panel of the device. Initial treatment times are based on your skin type and are listed in
Table 4 Initial Exposure Treatment Times:

Table 4 Initial Exposure Treatment Times

PSORIASIS PROTOCOLS	
Treatment distance	6” to 8” from screen
INITIAL EXPOSURE	
Skin Type	**Time (min:sec)**
I	0:43
II	1:13
III	1:27
IV	1:50
V	1:57
VI	2:13

Allow 24 hours to pass after your treatment. Record your erythemal response (how red/pink your skin is) in a journal or treatment log (recommended). Your subsequent treatment times will be based on your response to each treatment, which are defined within the three categories in **Table 5 Exposure Increase Schedule**:

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Table 5 Exposure Increase Schedule

PSORIASIS PROTOCOLS		
EXPOSURE INCREASE SCHEDULE		
Erythemal Response	**Adjustments**	
None	**If you are:**	**Increase by:**
	Skin Type	**Time**
	Type I	5 seconds
	Type II	8 seconds
	Type III	13 seconds
	Type IV	15 seconds
	Type V	20 seconds
	Type VI	22 seconds
Mild pinkening	Same, Do Not Increase Treatment Time	
Severe	Stop Treatment Until Erythema Resolves	

If your erythemal response is severe, wait until the erythema has resolved. Then, you can resume treatments starting at half of your original initial treatment time. Continue to record and adjust your treatment times until your psoriasis is at least 95% clear (completely flattened plaque, including borders, though plaque may still be outlined by pigmentation).

If, for any reason, there are significant time lapses (greater than 1 week) between treatments within the Clearing Phase, the adjustments listed in **Table 6 Adjustments for Treatment** should be taken:

Table 6 Adjustments for Treatment

PSORIASIS PROTOCOLS	
ADJUSTMENTS FOR TREATMENT	
Days missed	**Protocol**
8 to 11 days	Repeat previous treatment time
12 to 14 days	Decrease time by 2 treatments worth
15 days or more	Start Treatment Over

Treatment is most effective at 85% to 90% of the Minimal Erythemal Dosage (MED), or a slight reddening of 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.

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Maintenance Phase for Psoriasis

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 (see Figure 11). Treatment frequency will depend on your response. During maintenance, the threshold dose for erythema may gradually decrease. Maintenance treatment will be prescribed by your physician, but they may direct you as shown in **Figure 11**.

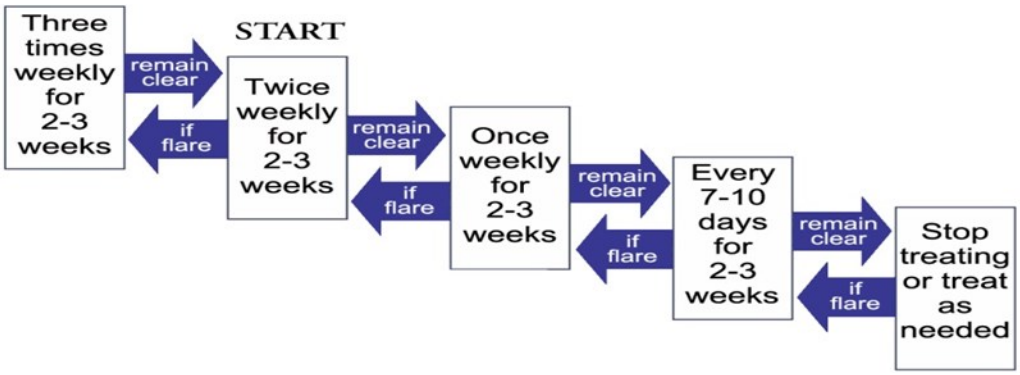

Figure 11 Step-Down Maintenance Strategy for Psoriasis

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. If directed by your physician, follow the suggested Vitiligo Protocol below:

Begin treatments at 43 seconds, standing 6”-8” away from the center panel of the device. Allow 24 hours to pass after your treatment. Record your erythemal response (how red/pink your skin is) in a journal or treatment log (recommended). If there is no erythemal response, increase your subsequent treatment time by 5 seconds. If there is mild erythema (skin is mildly pink), do not increase your treatment time. If severe erythema persists, decrease your treatment time by 25% and only increase your treatment time when erythema is resolved.

Treatment is most effective at 85% to 90% of the Minimal Erythemal Dosage (MED). MED is reached 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.

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Maintenance Phase for Vitiligo

Vitiligo maintenance therapy typically begins when skin has reached 75% re-pigmentation. 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 shown in **Figure 12**.

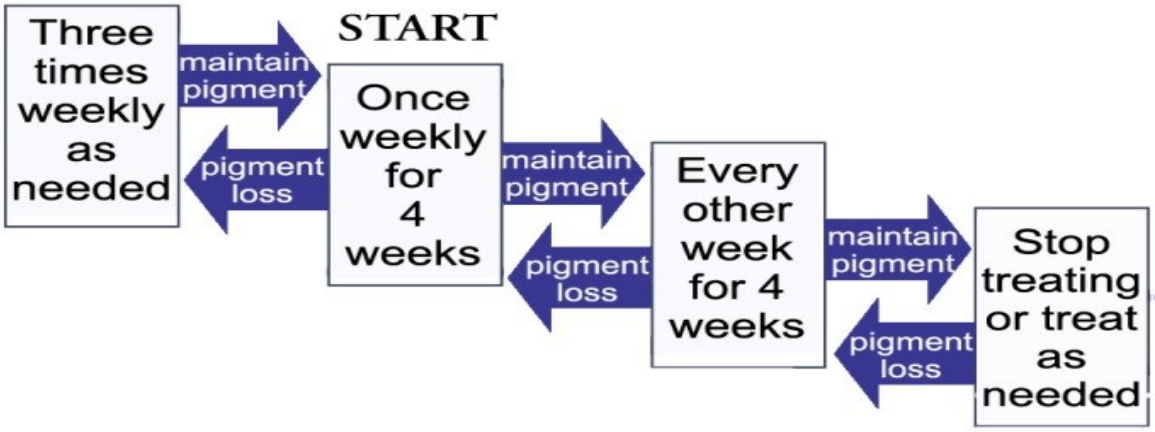

Figure 12 Step-Down Maintenance Strategy for Vitiligo

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, the treatment time should be the same as when beginning therapy, since the threshold for erythema will have decreased.

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10.2 Operation of the DT Controller

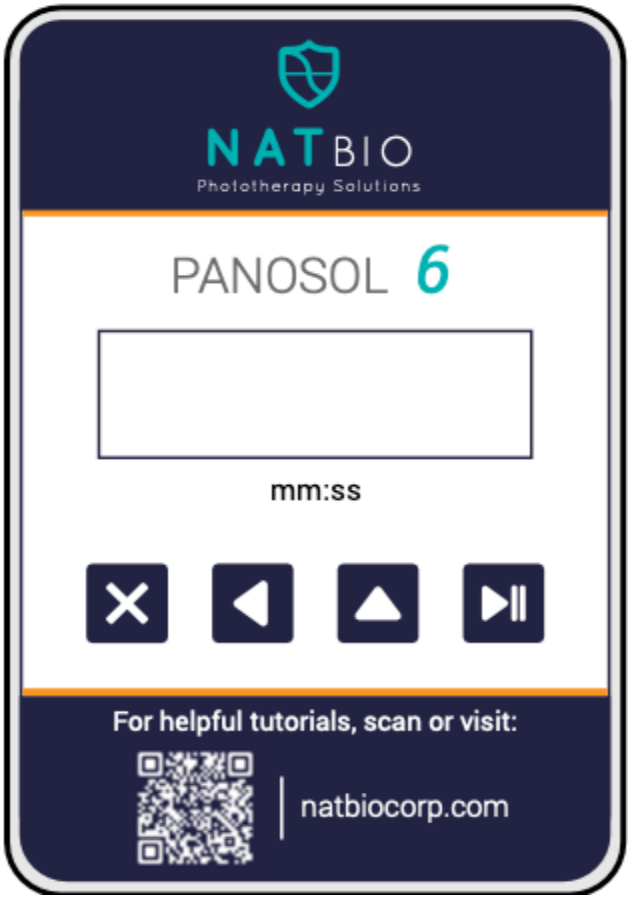

Figure 13 DT Controller Overlay Label

10.2.1 Unlocking the Device

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

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

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10.2.2 Setting Up a Treatment Time

1. Enter in your key code. Unless you have changed it, the factory default Key Code is "0007."
2. Once the Key Code has been entered, the display should read "00:00" (minutes:seconds).
3. The currently editable character will flash on and off to signal that it is the editable character.
4. Press the UP-ARROW button to increase the value of the flashing character by one (1).
5. Press the LEFT-ARROW button to move the flashing character over by one position.
6. Once the desired time is present on the display, press the PLAY/PAUSE button to lock-in the treatment time.
7. Press the PLAY/PAUSE button to begin the treatment.
8. Press the PLAY/PAUSE button to pause the treatment.
9. While treatment is paused or completed, press the CANCEL button to return to the treatment menu ("00:00" displayed with the right-most character flashing).
10. After a treatment is complete, the controller will enter Standby Mode. The controller will flash the most recently completed treatment while in standby mode. Record this treatment time in your treatment journal/log. You will want to save it for subsequent treatments.
    a. To repeat this treatment: press the PLAY/PAUSE button to re-enter Time Entry Mode. The rightmost character should now be flashing.
    b. Press the PLAY/PAUSE button again to set the treatment time.
    c. Press the PLAY/PAUSE button again to start the treatment.

EXAMPLE:

1. An example time of one minute and twenty-three seconds will be used (01:23).
2. The right most character should be flashing – press the UP-ARROW button three (3) times. The display should now read "00:03".
3. Press the LEFT-ARROW button one (1) time and the UP-ARROW button two (2) times. The display should now read "00:23".
4. Press the LEFT-ARROW button one (1) more time and the UP-ARROW button one (1) more time. The display should now read "01:23".
5. Press the PLAY/PAUSE button one time to lock in the treatment time. The flashing character should stop flashing.
6. Now that the desired time is displayed (in this case 01:23), press the PLAY/PAUSE button to begin treatment.
7. Pressing the PLAY/PAUSE button again will pause treatment.
8. While paused, pressing the CANCEL button will end the treatment and prompt a new treatment.

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10.2.3 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.
6. If all treatments have been exhausted and a wrong refill code is entered, the Digital Timer Controller will flash the entered code two (2) times then display the Device Code.

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

The physician will utilize the National Biological Physician's Portal to obtain the Treatment Code.

10.2.5 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 1:00 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).

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10.3 Post-Treatment

After a treatment, you may protect any areas that feel sunburned with sunscreen for the next several treatments or until they appear normal. (Make a note in your notebook.) You should see your physician at the intervals he or she requests when actively using the unit. Always take the notebook with you when you see your physician.

11.0 Care of the Unit

11.1 Recommended Maintenance Schedule

Table 7 Recommended Maintenance Schedule

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

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

11.2 Cleaning/Disinfection

11.2.1 General Cleaning

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

11.2.2 Low-Level Disinfection

To reduce micro-organisms on the patient-contacting surfaces, disinfect these surfaces between uses of the device, including when the same patient has the device for use. For disinfection while the same patient uses the device, several cleaners have been tested that do not degrade the integrity of the components and can be seen in **Table 8 Tested Cleaners**

Table 8 Tested Cleaners

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

1. Thoroughly wipe down the surfaces and allow contact time listed in Table 8.
2. Allow to air dry and inspect for visible contaminants.
3. If contaminants remain repeat until no visible contaminants remain.

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11.2.3 High-Level Disinfection

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

11.3 Lamp Replacement and Removal

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

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

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

11.3.1 How to Change Lamps

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

11.3.2 Resetting Lamp Hours

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

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12.0 Environmental Specifications

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

Table 9 Electromagnetic Emissions

Emissions Test	Conformity	EMC Environment Guide
RF Emission Following CISPR 11 (EN 55011)	Group 1	Test unit only radiates RF energy for internal use in powering lamps, and it seems unlikely that nearby medical devices would be affected.
RF Emission Following CISPR 11 (EN 55011)	Class B	The device is suitable for healthcare environment operation in hospitals and clinics
Limits for Harmonic Current Emissions Following IEC 61000-3-2	Class A	The device is suitable for healthcare environment operation in hospitals and clinics
Limitation of Voltage Changes, Voltage Fluctuations, and Flicker Following IEC 61000-3-3	Compliant	The device is suitable for healthcare environment operation in hospitals and clinic

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Table 10 Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Actual Level
Electrostatic discharge immunity test following IEC 61000-4-2	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)
Radiated, radio-frequency, electromagnetic field immunity test following IEC 61000-4-3	80 MHz to 2.7GHz @ 10.0 V/m	80 MHz to 2.7GHz @ 10.0 V/m
Electrical fast transient/burst immunity test following IEC 61000-4-4	+/- 2kV	+/- 2kV
Surge immunity test following IEC 61000-4-5	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV
Conducted Immunity test following IEC 61000-4-6	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms
Power frequency magnetic field immunity test following IEC 61000-4-8	50 Hz, 30 A/m	50 Hz, 30 A/m
Voltage dips and interruptions immunity test following IEC 61000-4-11	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees, 100% Interruption at 5000 mS at 0 degrees	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees, 100% Interruption at 5000 mS at 0 degrees

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Table 11 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHZ to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. [a] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strength from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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13.0 Notes

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14.0 Warranty

- This Warranty is provided to the original purchaser (the "Purchaser") of National Biological phototherapy devices (the "Equipment"). There is no Warranty associated with the Equipment except for the Purchaser. National Biological warrants the Equipment for defects in material and workmanship and is limited to claims made to National Biological within the device Warranty period shown in **Table 12 Warranty Period**, with respect to parts and labor, and from the date of shipment by National Biological 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 National Biological, incorrect customer installation, improper electrical service, lack of proper maintenance, failure to follow the Equipment owner's manual, and Acts of God.

Table 12 Warranty Period

Warranty Period	
New Equipment	1 Year
Lamps	90 Days

- The Purchaser must allow National Biological, at National Biological's option, to inspect the Equipment or component parts on request. The Purchaser must reasonably cooperate with National Biological 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, National Biological will, at National Biological's option, repair or replace Equipment or components deemed to appear defective in material or workmanship, with new or remanufactured materials. National Biological 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, National Biological will cover reasonable freight expenses in the continental United States to ship products covered under Warranty both to and from National Biological'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 National Biological pays reasonable freight charges back to the customer. All Equipment ships ground unless the customer covers costs for expedited shipping. National Biological is not responsible for any delays occurring during transport of the Equipment.

- In no case shall National Biological be liable for incidental, indirect, consequential, special, or punitive damages (including lost profits or lost wages) even if National Biological has been advised of the possibility of such damages. In addition, National Biological'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 National Biological's Equipment manual, the terms and conditions of this Warranty shall prevail.

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- National Biological 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.

14.1 Disposal

Your device contains components that must be recycled and not thrown away. Before discarding your device, remove the UV lamps and take them to a fluorescent bulb recycling center. Electronic and metallic device components can then be taken to a metal recycling center. National Biological Corporation 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.

14.2 Contact Information

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