DermaPal

with Digital Timer

Operating Instructions for CE Device

For all models:

UVA
Narrow Band UVB
Broad Band UVB

220-240 ~ Volts 50 H

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1.0 INDICATIONS FOR USE

The DermaPal™ is a hand-held ultraviolet light emitting fluorescent lamp. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

The Digital DermaPal Phototherapy Device is not a Class III or implantable device. The Summary of Safety and Clinical Performance is not required.

2.0 ACCURACY

The device will maintain an accuracy of +/- 5% in a 10-minute period.

The DermaPal should be used in an electromagnetic environment as listed below.

Table 1 Electromagnetic Emissions

Emissions Test	Conformity	EMC Environment Guide
RF Emission Following CISPR 11 (EN 55011)	Group 1	Test unit only radiates RF energy for internal use in powering lamps, and it seems unlikely that nearby medical devices would be effected.
RF Emission Following CISPR 11 (EN 55011)	Class B	DermaPal device is suitable for healthcare environment operation in hospitals and clinics
Mains Harmonics Following IEC 61000-3-2	Class A	DermaPal device is suitable for healthcare environment operation in hospitals and clinics

Emissions Test	Conformity	EMC Environment Guide
Mains Voltage Dips and Flicker Following IEC 61000-3-3	Compliant	DermaPal device is suitable for healthcare environment operation in hospitals and clinic

Table 2 Electromagnetic Immunity

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

Table 3 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 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]

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**
			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			

Table 4 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]

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3.0 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 Daavlin approved eyewear.
- To prevent unnecessary exposure, exposed skin that is not being treated (face, neck, ears, forehead, etc.) should be

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

- If psoralens (photosensitizing drugs) are being used as part of your treatment ("PUVA"), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with all Daavlin devices.
- DANGER - ULTRAVIOLET RADIATION. As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer. ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE ERYTHEMA OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase skin sensitivity to ultraviolet radiation. Inform your physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.
- This device should be a minimum of 12 inches (30 cm) away from RF generating equipment
- Do not remove protective eyewear, or any other protective equipment, during treatment.
- Ask your doctor about protecting areas of your body that have not been exposed to sunlight.
- All people and pets should leave the treatment area to avoid exposure to ultraviolet light.
- Do not use over skin eruptions without express consent from the attending physician.
- If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.
- Erythema can result in as little as 15 seconds of exposure, or approximately 200 millijoules of dose to UVB light. If using the unit at home, contact your prescribing physician for specific treatment instructions and dosing information.

- The device contains glass lamps. Avoid excessive force to the device to prevent lamp damage.
- It is important to carefully determine the proper treatment time. Over-exposure will produce erythema and discomfort. Under-exposure will result in reduced therapeutic benefit while at the same time building resistance to future treatments.
- The Treatment Plans included in these operating instructions are intended as guidelines only.
- All treatments must be administered under the direction of a licensed physician only.
- Do not use this device for anything other than its intended purpose.
- This device is only to be used by authorized users.
- During extremely long treatments, some surfaces may become hot. Remove any body parts from those surfaces if it becomes uncomfortable. The unit should have a 50% duty cycle of 10 minutes on, 10 minutes off.
- Always inspect the device case, timer, power cord, and goggles prior to use to ensure they are in good working condition. Do not use the device if it appears to be damaged or altered in any way.
- Never block the outlet that is being used to power the device.
- If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging device.
- This device is available with different types of UV lamps. To avoid serious injury, verify that the UV lamp type of the device is the same as prescribed by the licensed physician. If the lamp type is not the same, do not use the device. Contact Daavlin or your Daavlin distributor/sponsor immediately.
- To prevent electric shock, remove power to the device prior to cleaning and servicing.
- Do not operate the device with the treatment wand in the base or exposure surface blocked. This may cause overheating and damage the unit.
- Do not operate the device in extreme temperatures as extreme heat or cold can affect the operation of the lamp.

- To eliminate the risk of fire when replacing the fuse, replace ONLY with a fuse of the same type and rating.
- NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED. Unauthorized modification will void the warranty and may result in hazardous or improper device operation.
- If the device malfunctions, cease operation immediately. If the device is placed close to other equipment, it is possible that the cause is interference by external noise sources and fields, in which case you should follow the remedies found under EMC Precautions. If the device continues to malfunction cease operation and contact the Daavlin Service Department.
- Only original components and accessories should be used with the device to avoid damage.
- Before opening the device casing to perform maintenance or service, disconnect the device from the power source.
- The device must never be directly exposed to flowing or splashing liquids of any kind. If the device is inadvertently exposed to liquid, it must be tested for safe function before being placed in operation again.
- The device control system display is susceptible to damage from excessive force. Avoid excessive force to the control system to prevent damage.
- WARNING: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

4.0 COMPATIBILITY

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

interference with other devices, turn the System off and on. Try to correct the interference by one or more of the following measures:

- Re-orient or relocate the device being affected.
- Increase the separation between the two devices.
- Plug the DermaPal™ into an outlet on a circuit that is separate from the affected device(s).

5.0 DELIVERY AND INSPECTION

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

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

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

6.0 SELECT A SITE

A site should be chosen within reach of the specified electrical outlet and where the unit can be left in place without being in the way of traffic flow. Extension cords are not recommended. The site should not be in any area where water or moisture might collect and should be protected from access by children. Exposure to ultraviolet light over extended periods of time may cause carpets, wall coverings, and furnishings to fade.

7.0 UNPACKING AND ASSEMBLY

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

8.0 WHAT THE OPERATOR WILL NEED

- The lamp information found at the back of this manual.

- Physician's dosage and treatment instructions.
- Power source (electrical outlet) appropriate to the device.
- UV blocking goggles or UV blocking glasses with UV blocking side shields for anyone in view of the DermaPal™ while in use.
- Sunscreen with an SPF factor of 30 or above.
- Treatment record book & writing instrument.
- DermaPal™ Operating Instructions.

9.0 DUTY-CYCLE/TEMPERATURE SPECIFICATIONS

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

- Ambient room temperature of -40 °C to +70 °C
- Non-condensating relative humidity range of 10% to 100%
- Atmospheric pressure range of 50 kPa to 106 kPa.

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

10.0 ELECTRICAL SPECIFICATIONS

Voltage	220-240 ~ Volts, 50 Hz, .4 Amps

11.0 REPLACEMENT LAMPS

11.1 UVA

Manufacturer Philips
Lamp Type PL-S9W/10
Daavlin Part # 060DPUVALAMP

11.2 UVB (Broad Band)

Manufacturer Philips
Lamp Type PL-S9W/12
Daavlin Part # 060DPBBUVBLAMP

11.3 UVB (Narrow Band)

Manufacturer Philips
Lamp Type PL-S 9W/01/2P
Daavlin Part # 060DPNBUVBLAMP

12.0 LABELS AND SYMBOLS

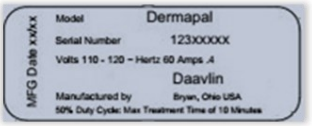
12.1 Symbols Identification Label

Place in the smaller recessed area on the back of the unit.

Symbol	Description
	Double Insulated
	Attention, consult accompanying documents
	Non-ionizing radiation

12.2 Small Serial Number Label

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



12.3 Large Serial Number Label

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

12.4 Warning/Lamp Label

This is located on the upper wand.

Different Label Based on Lamp Type

12.5 DermaPal Comb Label

Located on the back side of the comb.

12.6 Passcode Label

Every DermaPal™ comes affixed with a green “passcode” label located on the top of the device. This label provides important information about the passcode needed to unlock the unit.

12.7 UV Risk Group

According to IEC/EN 62471:2006, sources of optical radiation are classified into risk groups subject to their potential photobiological hazard. This device falls under Risk Group 2 (Moderate-Risk) and does not pose a severe hazard due to the natural aversion response to bright light or thermal discomfort. A Risk Group 2 warning label, which also includes the primary emission range and potential output range, is affixed to your device in a prominent and easily readable position.

12.8 CE Label

12.9 CE EU Rep Label

12.10 CE Packaging Label

12.11 Medica Device Label

This label indicates that this is a medical device.

13.0 DISPOSAL

Please contact Daavlin or Daavlin sponsor for disposal instructions for the unit and all accessories.

14.0 GENERAL INSTRUCTIONS

14.1 UV Treatment Philosophy

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

14.2 Patient Specific Treatment Instructions

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

15.0 TRAINING REQUIREMENTS

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

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

15.1 General Treatment Guidelines

For the first treatment, have the patient put on the protective eye goggles provided, set the timer for 15 seconds and treat an area of skin. If on the second day there is no redness or erythema, repeat the treatment adding 15 seconds to the exposure time. On subsequent days, repeat this procedure, adding 15 seconds per exposure until the skin starts to get pink. If the skin becomes red

or uncomfortable after any treatment, do not resume the treatment until the redness has subsided. Increases of less than 15 seconds may be necessary for some patients. Once initial pinkness has been achieved, follow the treatment regimen.

After each treatment, record the date of treatment, the length of each exposure, the time of day of the exposure and any other appropriate information, (e.g. patient forgot lip balm, or forgot to put sunscreen on tender area of breast, etc.)

Never deliver to a patient more than one treatment per day. Never treat any sooner than 12 hours after the last treatment. For example, don't take a treatment late at night followed by an early morning treatment.

Important: ***If after a treatment there are burned areas, have the patient protect those areas with sunscreen for as many treatments as it takes for the skin to become normal. (Make a note of this.)***

15.2 Recording Treatments

Keep a record of treatment data. This information should include the date and time of the treatment, the length of the treatment, and any other pertinent information such as skin reaction(s) to the treatment.

15.3 Installing the Comb

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

1. Place the DermaPal™ on a flat surface.
2. Remove the treatment wand from the base of the DermaPal™.
3. Slide the comb attachment over the wand so the tines of the comb are on the same side as the exposure surface.

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

15.4 Removing the Comb

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

1. Place the DermaPal™ on a flat surface.
2. Hold the wand firmly at the end not covered by the comb.
3. With your other hand, grasp the comb and begin pushing the wand out of the comb by inserting your index finger through the access hole at the end of the comb.
4. Once the removal process is started, pull the comb and wand in opposite directions until the comb is free of the wand.

16.0 TREATMENT INSTRUCTIONS

For best results, the DermaPal™ should be warmed up for one minute immediately prior to treatment. To set a one-minute warm up time, remove the wand from the base and refer to the instructions for Time Entry Mode on page 24. The lamp will light automatically when the treatment is initiated, so be sure that **all individuals in the area, including the operator, are wearing proper eye and skin protection.**

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

1. Install the comb if desired.
2. Plug the DermaPal™ into an appropriate power source.
3. Either apply or have the patient apply sunscreen and eye protection, as necessary. See Warning section of this manual.
4. Remove the treatment wand from the base.
5. Start the DermaPal™ by entering the prescribed dose.

6. Note the time on a separate timer or watch to verify the prescribed time of the treatment.

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

7. If treating the scalp, use the comb as necessary to move hair away from affected areas so that the UV can penetrate the hair and reach the scalp. Irradiate the affected area(s) evenly, while avoiding unaffected areas, as much as possible.

Important: Verify the time of treatment with an independent timer or watch. If the actual treatment time exceeds the set treatment time by more than 15%, stop the treatment by pressing the PAUSE Button. To pause the treatment, press the CANCEL button or unplug the unit from the power source. Contact Daavlin if this situation persists.

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

Important: To avoid serious injury and damage to the device, store the DermaPal™ out of the reach of unauthorized users.

16.1 Subsequent Treatments

If the treated area(s) of skin is/are red and sensitive twenty-four (24) hours after treatment, reevaluate the treatment regimen before proceeding with treatments.

17.0 HOW TO OPERATE THE DIGITAL TIMER

There are 5 modes of operation:

1. Security Code Activation
2. Time Entry
3. Countdown

4. Standby
5. Sleep

17.1 Security Code Activation Mode:

Security Code Protection is an option with the DermaPal™. If unauthorized use of the device is a possibility, we suggest that this system be activated. In the interests of simplicity, there is only one numerical code, so make sure that knowledge of the code number is limited. **The code is 0205.**

1. When the device is plugged in for the first time the security code will be activated. See Security Code Entry instructions below.
    a. If the Security Code Protection is on, after five (10) seconds the display will read OFF for three (3) seconds. No code number will then be necessary to initiate a treatment

2. With all of the Positions reading zero, press and hold the START/PAUSE button for five (5) seconds (all digits *must* read zero).
    a. If the Security Code Protection is off, after five (5) seconds the display will read ON for three (3) seconds. To activate it, put the device into Sleep mode *or* briefly unplug/re-plug it. After activation is complete it will be necessary to enter the code number before each use of the device.

17.2 Security Code Entry:

1. In the Security Code Entry, the LCD will read C0dE with no colon.
2. Pressing the UP or LEFT button will take you to the code entry screen.
3. The device will read 00 00 with no colon and the digit furthest to the right will flash.
4. Pressing the UP button will increase the flashing number from 0 to 1 to 2 and so forth. Pressing the LEFT button will

move to the next number to the left. It will begin flashing. Press the UP button to set the desired number.

5. Press the LEFT button again to move to the third number and follow the same procedure as described above until all four digits are entered.

NOTE: When in the position furthest to the left and the LEFT button is pressed, it will "round robin" to the number furthest to the right.

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

17.3 Time Entry Mode (Treatment Time):

1. Once the security code (if required) has been entered correctly; the display will show all zeros and the colon, and the number furthest to the right will flash.
2. Pressing the UP button will increase the number that is flashing. The digit furthest to the right and the third digit from the right will roll over from 9 to 0, the second digit from the right will roll from 5 to 0, and the fourth digit from the right will roll from 2 to 0. This limits the maximum treatment time to 29:59 (twenty-nine minutes and fifty-nine seconds).
3. Pressing the LEFT button will move to the next digit to the left.
4. Pressing the LEFT button, when in the leftmost position, will "round robin" the system to the digit furthest to the right.
5. Pressing CANCEL at any time will clear the display and allow the process to be restarted.

6. Pressing CANCEL a second time (or pressing CANCEL when in an initial step of Time Entry mode) will put the device into Sleep mode. The LCD will turn off and the screen will blank. Pushing any button will "awaken" the device from the sleep mode.
7. Pressing START/PAUSE button, after the desired dose has been entered, will store the time in memory and all flashing will stop.
8. Pressing the START/PAUSE button a second time will turn on the lamp and start the countdown.

17.4 Countdown Mode:

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

17.5 Standby Mode:

1. Upon completion of a treatment, the device will go into Standby mode and the previous treatment time will be displayed (flashing). This is convenient when you wish to treat another area of the patient with the same treatment time or wish to make minor adjustments to the treatment time.
2. To use the previous treatment, press the START/PAUSE button twice to lock in the previous treatment time and then a third time to begin the treatment.
3. To make minor adjustments to the previous treatment time, press the START/PAUSE button to display the previous treatment time. Then use the LEFT and/or UP buttons to adjust the time as needed. Once the desired time is set,

press the START/PAUSE button twice and the countdown will begin using the revised treatment time.

4. To start with an all new treatment time, press the UP, LEFT, and/or CANCEL buttons to clear the display and enter the Time Entry mode (all zeros will be displayed). Follow the instructions under Time Entry mode above.

17.6 Sleep Mode:

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

18.0 MAINTENANCE

18.1 Cleaning/Disinfection & Storing the DermaPal™

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

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

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

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

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

4. Store the DermaPal™ in a dry area safe from unauthorized users.

18.2 Replacing the Lamp

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

Note: *Timely lamp replacement by Daavlin or its authorized agent will avoid this situation.*

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

A lamp may need replacement due to burnout or because the output has decreased to the point that the patient may no longer be receiving an effective treatment. To replace the lamp, follow the steps below.

1. Consult the Lamp Guide, found on page 14, for replacement lamp specifications and contact Daavlin service or Daavlin sponsor for a lamp replacement quote.
   Note: Daavlin's service department can be reached at 1-800-322-8546 or 1.419.636.6304 (Menu Option Number 2) or via email at service@daavlin.com
2. Upon agreed return of the unit, our in-house service technician will replace the lamp and verify the new lamps UV power output.

3. Once the lamp replacement and power output verification have been completed, the unit will be returned.

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

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

19.0 WARRANTY

19.1 Limited Warranty Policy

This Limited Warranty is provided to the original purchaser (the "Purchaser") of the Daavlin device (the "Equipment"). Daavlin warrants Equipment to conform with the Equipment specifications and be free from defects in material and workmanship during the device Warranty Period. No warranty is made as to useful lamp life or as to reduction in ultraviolet output due to any cause. DAAVLIN MAKES NO OTHER WARRANTIES OF ANY KIND WHATSOEVER TO PURCHASER OR ANY THIRD PARTIES WITH RESPECT TO THE EQUIPMENT AND HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Product	**Warranty Period**
New Equipment	1 Year
Remanufactured Equipment	90 Days

Lamps	90 Days

19.2 Warranty Coverage

This Limited Warranty applies only to Equipment or components found to be defective due to materials and workmanship. This Limited Warranty does not apply when Equipment is purchased for the purposes of renting commercially to customers for home use. This Warranty does not apply to any Equipment which has been used, repaired or altered outside the factory in any way so as to affect the design, or operated in any way other than in accordance with our operating instructions. The Limited Warranty does not apply to Equipment failure or damage caused by shipping or customer abuse, misuse, or accident, incorrect customer installation, improper electrical service, lack of proper maintenance, and Acts of God. This Limited Warranty does not extend to repairs made necessary by use of parts or accessories not recommended by the manufacturer. Daavlin shall not be responsible for any indirect, incidental, special, punitive, or consequential damages of Purchaser. Daavlin does not provide end support for Microsoft Windows software installed on PCs that are part of a Daavlin phototherapy system. PURCHASER'S SOLE REMEDY UNDER THIS LIMITED WARRANTY IS REPAIR OR REPELACMENT OF THE EQUIPMENT.

19.3 Customer Responsibility

In the event that warranty service is requested, the Purchaser must reasonably cooperate with Daavlin to verify the warranty claim of the Purchaser, including conducting minor diagnostic work. Failure to participate in diagnostic work may result in being charged for on-site service calls. The Purchaser must allow Daavlin, at Daavlin's option, to inspect the Equipment or component parts on request.

19.4 Warranty Service

During the warranty period, Daavlin will, at Daavlin's option, repair or replace any Equipment or components that appear to have been defective in material or workmanship, with new or

remanufactured materials. Daavlin may require the return of merchandise claimed to be defective for its examination and shall be the sole judge as to whether material is in fact defective under the terms of this Limited Warranty. In such situations, Daavlin will cover freight expenses in the continental USA to ship products covered under warranty both to and from Daavlin'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 Daavlin pays freight charges back to the Purchaser. All Equipment ships ground unless the Purchaser covers costs for expedited shipping. Daavlin is not responsible for any delays occurring during transport of the Equipment.

During the term of the Limited Warranty, Daavlin will, at Daavlin's option, arrange for a qualified service technician to repair or replace any defective systems or components as covered in accordance with the terms and conditions of this Limited Warranty. It will be at Daavlin's sole discretion whether subcontractors or Daavlin employed technicians will perform the required warranty service work. However, this Limited Warranty will be declared null and void if non-qualified technicians perform any repair or maintenance on the Equipment unless prior written authorization has been obtained from Daavlin. Even with Daavlin's authorization, Daavlin shall not be responsible or liable for any such work (in or out of warranty). Daavlin reserves the right to bill for labor, expenses, and services for requested "warranty" service trips which result in work not covered by this Limited Warranty. This may include, but is not limited to, a tripped circuit breaker, an unplugged machine, or a blown fuse.

19.5 Disposal

Please contact Daavlin at 1-800-322-8546 for disposal instructions for the unit and/or cabinet and all accessories.

19.6 Other Services

Extended warranties are available and may be purchased from Daavlin's aftermarket sales department.

In the event that this Limited Warranty conflicts with other warranties included in Daavlin's Equipment manual, the terms and conditions of this Limited Warranty shall prevail.

19.7 Contact Information

USA & Canada:	1-800-322-8546
Overseas:	1-419-636-6304
Fax:	1-419-636-1739
E-Mail:	service@daavlin.com
Website:	www.daavlin.com

Daavlin Distributing Company
205 W. Bement Street
PO Box 626
Bryan, Ohio 43506 USA

20.0 DermaPal™ CALIBRATION RECORD

Patient Name:			Chart #
Treatment			
Date	Time (hh:mm)	Duration	Comments
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Lamp Information at the Time of Manufacture			
Lamp Type	Output (mw/cm^2)	Serial #	Tested by

Note: Lamp output taken at the tip of the comb (1.25 in / 3.18 cm).