

## ClearLink™ Home-Control Operation Manual

### *Modes of Operation*

- *Guided Mode*
- *Dosimetric Mode*
- *Timed Mode*



4series

|                          |  |           |
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*Dear Valued Customer,*

*Thank you for selecting a Daavlin 4 Series phototherapy unit. The use of light for the treatment of photoresponsive skin disorders has been our business since 1981. We are proud of our tradition of innovation in the field of phototherapy and are honored that you have chosen us for your phototherapy needs. Let's be clear. Our commitment to you starts...Now!*

*Sincerely,*

*The Daavlin Staff*

**CAUTION:** Federal law restricts this device to be sold 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 4 Series phototherapy unit is equipped with Daavlin's ClearLink™ Control System. The device was prescribed by your doctor to function in one of the three modes listed below:

- **Guided:** The system controls the beginning dose and all subsequent doses depending upon how your skin responds to the therapy. See pages 13 and 14 for operating instructions that are specific to this mode of operation.
- **Dosimetric:** You control the doses which are delivered in either Joules or Millijoules. The system automatically adjusts the length of each treatment depending on the power of the lamps. The doses you take will be based on instructions from your doctor. See page 15 for operating instructions that are specific to this mode of operation.
- **Timed:** You control the length of each treatment, based on instructions from your doctor. See page 16 for operating instructions that are specific to this mode of operation.

**FlexRx™** Your physician may have prescribed your device with FlexRx, a system that limits the total number of exposures the device will deliver. Specific information about these systems is provided in this manual.

## **2.0 Indications for Use**

The 4 series 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 damage is discovered, save all packing materials and call Daavlin immediately to begin the claims process. If it's not possible to inspect the unit before the driver leaves, we recommend that you write **“Concealed damage possible. Further inspection required”** on the delivery receipt.

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 decide 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.

### 4.0 Site Selection

A location for the device should be chosen within reach of a standard, grounded electrical outlet. Extension cords are not recommended. It is important that the unit be properly grounded. 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 4 Series 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 4 Series devices are equipped with an onboard fuse. The fuse holder is a part of the power cord receptacle that is located on the lower left side of the device. If an onboard fuse fails, call Daavlin's service department to determine an appropriate replacement.

### 5.0 Unpacking and Assembly

1. Open the box and grasp each side of the device. Pull it, along with the foam packers, up and out of the box. Remove the foam packers.

*Note: Be sure to remove all the accessories such as the manual, power cord, eyewear, and feet before discarding the box.*

2. Set the unit on a table so that the lamps are facing up and the end opposite the controller is hanging over the edge of the table.
3. On each side of the unit, you will find four thumb screws. Remove them. They will be used to attach the feet to the sides of the unit.
4. Take one of the feet and align the four pre-cut holes with the four holes on the side of the device that were created by removing the thumb screws.

*Note: The feet will only fit one way. Be sure that the widest part of the foot is level with the bottom of the unit and that the lip or rail faces away from the unit. For a picture of the proper foot alignment please see the cover of this manual.*

5. To secure the foot, thread the four thumb screws through the holes in the foot and into the side of the unit, tightening each of them lightly. Be sure to insert all the thumb screws before fully tightening them.

*Note: Tighten the thumb screws using your thumb and index finger. If necessary, the screws can be tightened with a flathead screwdriver.*

6. Repeat steps 4-5 to install the other foot.
7. Stand the unit up vertically and check all the screws to be sure they are tight.
8. Insert the “D” shaped male plug into the corresponding receptacle on the lower left side of the device. Plug the unit into any standard, electrical outlet.

## 6.0 Lamp Inspection

4 Series devices can be equipped with different types of lamps, each with its own effect on the skin. It is important to check that the proper lamps are installed. Consult the Lamp Specification Guide (see section Lamp Specification Guide.) If there is any question that the device is not equipped with the lamps that you have been prescribed, contact Daavlin immediately. Lamp code numbers are generally located at the base of the lamp.

### 6.1 Lamp Specification Guide

| UVA        | UVA-1      | Narrowband UVB | Broadband UVB | Blue (405) |
|------------|------------|----------------|---------------|------------|
| PLL-36W/09 | PLL-36W/10 | PLL-36W/01     | PLL-36W/-06   | PLL-36W/03 |

## 7.0 Precautions and 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.
- 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.
- 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.
- Erythema can result in as little as 15 seconds of exposure, or approximately 200 millijoules of dose 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 treatment area to avoid exposure to ultraviolet light.
- Ask your doctor about protecting areas of your body that 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.
- If appliance coupler or mains plug is used as the mains disconnect, do not position the ME equipment so that it is difficult to operate the disconnection 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.

- 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.
- If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging 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 and plugs, sockets, lamps, and electrical cables and connections are not worn or damaged.
- 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 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.

## 8.0 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 or with oxygen or nitrous oxide.

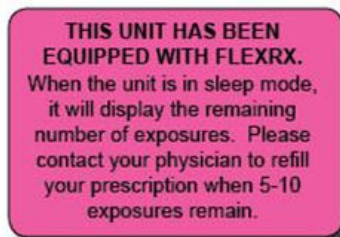
## 9.0 Labels and Symbols

A removable label (*Figure 1 Unlocking Code*) located near the keypad provides information on how to unlock the unit.



**Figure 1 Unlocking Code**

If the unit is equipped with FlexRx™ exposure limiting software, there will be a label similar to the one shown below (*Figure 2 FlexRx Label*) informing you that your unit has been equipped with this feature.



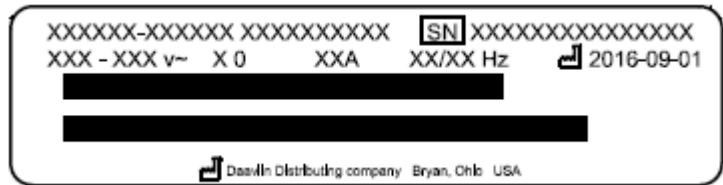
**Figure 2 FlexRx Label**



A warning label (*Figure 3 Warning Label*) is affixed to your Daavlin phototherapy device in a prominent and easily readable position. Please read the label carefully as it contains important safety information.











**Figure 3 Warning Label**



**Figure 4 Identification Label**

The following table lists all the symbols located on the device along with their meaning.

**Table 1 Symbols**

| SYMBOL  | DESCRIPTION                             |
|---|---|
|    | DANGEROUS VOLTAGE                       |
|    | NON-IONIZING RADIATION                  |
|    | EARTH (ground)                          |
|   | PROTECTIVE EARTH (ground)               |
|  | OPERATING INSTRUCTIONS                  |
|  | KEEP DRY                                |
|  | CAUTION, CONSULT ACCOMPANYING DOCUMENTS |
|  | FUSE IDENTIFICATION LABEL               |

## 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.*

The ClearLink Controller will track your treatment data. However, 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.Daavlin.com](http://www.Daavlin.com).*

You will need to purchase lip balm and sunscreen with an SPF (Sun Protective Factor) of at least 30. Ask your doctor whether or not you should use an alcohol or cream-based sunscreen.

### 10.2 Special instructions – 4 Series with 20 Lamps Only

*If you have a ten-lamp unit, treatments should only be taken from a distance of 9 inches!*

Your 4 Series **twenty lamp unit** has been designed to deliver accurate and effective treatments from two distinct treatment distances. If you have been prescribed a 20-lamp unit, treatments can be administered directly on the acrylic's surface (0 inches) or at a distance of nine inches from the acrylic (9 inches or 22 centimeters).

The intensity or power output of the device will be much greater when treating directly on the acrylic surface versus treating from nine inches away. For this reason, you must select the desired treatment distance before administering a treatment. See specific instructions under **Running a Treatment**.

By selecting the treatment distance, 0 in or 9 in, you are telling the system how it should calculate the length of the treatment based on the distance from the lamps.

### 10.3 How to Position Yourself


**Large Area Treatments:** The recommended distance from the lamps for treatment is 9 inches (22 centimeters). We also recommend that you mark that distance on the floor in some manner. Your torso should not be closer to the lamps than this line. Standing closer to the lamps will cause localized streaking or burning.

**Small Area Treatments at the Acrylic Surface (20 lamp 4 series only):** Place the area being treated directly on the acrylic lamp guard. For best results you should position the area being treated as close as possible to the center of the fixture.

**Note:** When treating, be careful to not place too much weight or pressure on the acrylic surface. Excess pressure can cause the acrylic surface to crack and break.

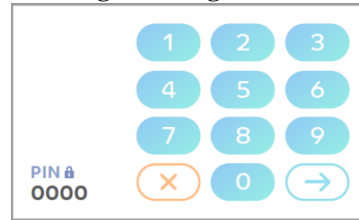
## 10.4 Unlocking the Device

To prevent unauthorized use, the device will self-lock when left idle for twenty (20) minutes.

1. Tap the blank screen. The Daavlin logo will appear.
2. Tap the logo. The Lock Screen will appear (unless disabled)
3. Using the keypad, enter the number 7 (unlocking code)
4. Press the Enter key  to unlock.



**Figure 5 Logo Screen**



**Figure 6 Lock Screen**

## 10.5 Common ClearLink™ Functions

The system beeps to signal the end of the treatment and displays the delivered dose with the elapsed time.

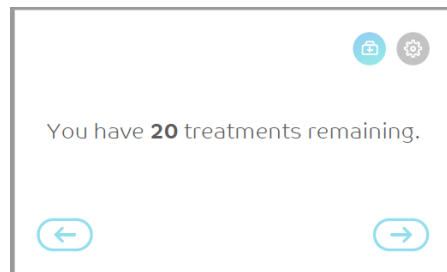
If power goes off during a treatment, the system will track how much of the treatment has elapsed and will allow the treatment to resume when power is restored.

## 10.6 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.

## 10.7 FlexRx™

If your unit was prescribed with FlexRx™, a screen (*Figure 7 FlexRx Screen*) will tell you how many exposures remain before you need a refill prescription. See *Section Uploading FlexRx™ Refill Prescriptions* for refill instructions.



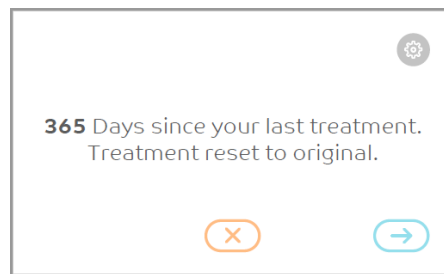
**Figure 7 FlexRx Screen**

## 11.0 Guided Mode

### 11.1 Features of the ClearLink™ Guided Home-Control System

The ClearLink Guided Home-Control System automatically performs many safety checks on your behalf, as well as calculating dose increases based on your treatment schedule and how your skin responds to treatment.

For example, each time you use the device, the ClearLink Controller will check the date of your last treatment. If you are on schedule, it will automatically proceed. However, if you have missed a treatment or treatments, the system will adjust accordingly to keep your dose at a safe level. A screen will appear advising you of the adjustment (*See Figure 8 below*).



**Figure 8**

Integrating dosimetry, another feature, uses a built-in sensor to monitor the amount of light energy being produced by the device. The system then automatically adjusts your treatment time to account for variations in light energy caused by changes in room temperature or the aging of the lamps.




Finally, before each treatment, the ClearLink Controller will ask about the current condition of your skin, such as whether or not there is any redness, mild or otherwise. It will use this information to calculate the next dose. Keep in mind, it is normal to experience some “redness” within 8 – 12 hours of a treatment but it is typically gone before it is time for the next treatment.

## 11.2 Running a Treatment






*Note: The first time you use the device, your dose will automatically appear, based on your doctor's prescription. After your first treatment, the screen will display the next scheduled treatment, but will ask if you experienced any pain or redness after your last treatment. Based on your response, the system will adjust the treatment according to your prescription.*

1. After unlocking the device, the Treatment Screen will appear with the scheduled dose.
2. You will be asked, ***“Were you in pain or red after your last treatment?”***
3. You must choose one of the following responses:
  - No, or < 24 Hrs (“Not at all, or it was gone in less than 24 hours”)
  - 24 – 48 Hrs (“I was in pain or red for 24-48 hours after the treatment”)
  - > 48 Hrs (“I was in pain or red for more than 48 hours”)
  - Still red / pain (“I am currently still red or have pain”)

*Note: Selection of the “Still red / pain” option will lock the device until one treatment has been skipped. This prevents treating the skin until the erythema (redness) has resolved.*

4. Once you have highlighted your response, press the Enter  key.
5. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button (**Only for 20 lamp units**)
6. The Treatment Confirmation screen will appear and will display the dose and an estimated time for the treatment. If changes need to be made, press the back  arrow. To cancel, press the Cancel  key.

***Put on your goggles and position yourself 9 inches from the front of the device or on the surface of the acrylic, as appropriate. See Section Error! Reference source not found. for guidance.***

7. Press the Enter  key to begin the treatment. A 3 second countdown will begin; the lamps will turn on and the screen will track your progress. The lamps will shut off when the treatment is over.
8. To repeat the same dose for exposure to another part of your body, touch the Repeat  button. ***Note: Repeats will not be available after leaving the treatment screen.***
9. To pause an active treatment, press the Pause  button. To resume, press the Play  button. To end or cancel an active treatment, first pause the treatment and then press the Cancel  button

## 12.0 Dosimetric Mode

### 12.1 Features of the ClearLink™ Dosimetric Home-Control System



The ClearLink Dosimetric Home-Control System uses a built-in sensor as part of a function called integrating dosimetry to monitor the amount of light energy being produced by the device. The system then automatically adjusts the length of each treatment to account for variations in light output caused by changes in room temperature and aging of the lamps.

### 12.2 Running a Treatment






After unlocking the device, the Treatment Screen will appear.

1. Press the Treat Patient button, then
2. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button (**Only for 20 lamp units**)
3. Touch the ▲/▼ arrows to set the desired dose in MilliJoules (UVB) or Joules if you have a UVA device.

**Note:** *UVB treatments are commonly dosed in MilliJoules. However, your doctor may have requested that the UVB treatments be dosed in Joules. If so, your device will have been programmed accordingly.*

4. Press the Enter  Arrow to enter the Treatment Confirmation screen.
5. Confirm the Dose and Estimated Treatment Time. If changes are needed to the dose, press the Return  Arrow and return to step 3.



***Put on your goggles and position yourself 9 inches from the front of the device or on the surface of the acrylic, as appropriate. See Section Error! Reference source not found. for guidance.***

6. Press the Enter  key to begin the treatment. A 3 second countdown will begin; the lamps will turn on and the screen will track your progress. The lamps will shut off when the treatment is over.
7. To repeat the same dose for exposure to another part of your body, touch the Repeat  button.  
**Note:** *Repeats will not be available after leaving the treatment screen.*
8. To pause an active treatment, press the Pause  button. To resume, press the Play  button. To end or cancel an active treatment, first pause the treatment and then press the Cancel  button.






## 13.0 Timed Mode

### 13.1 Running a Treatment

After unlocking the device, the Treatment Screen will appear with the scheduled dose.

1. Press the “Treat Patient” button.
2. Choose the treatment distance by pressing either the “9 in” button or the “0 in” button (**Only for 20 lamp units**)
3. Touch the ▲/▼ arrows to enter the desired treatment time. *Note: It is **not** possible to enter a time of 60 seconds. You must instead enter 1 minute.*
4. Press the Enter  Arrow to enter the Treatment Confirmation screen.
5. Confirm the Time. If a change is needed, press the Return  Arrow and return to step 3.

*Put on your goggles and position yourself 9 inches from the front of the device or on the surface of the acrylic, as appropriate. See Section Error! Reference source not found. for guidance.*

6. Press the Enter  key to begin the treatment. A 3 second countdown will begin; the lamps will turn on and the screen will track your progress. The lamps will shut off when the treatment is over.
7. To repeat the same dose for exposure to another part of your body, touch the Repeat  button. *Note: Repeats will not be available after leaving the treatment screen.*
8. To pause an active treatment, press the Pause  button. To resume, press the Play  button. To end or cancel an active treatment, first pause the treatment and then press the Cancel  button

**Calculating Increases:** Phototherapy treatments usually start at a given time or dose and are increased with each treatment. Your doctor may ask you to increase each treatment by a set amount of time or may ask you to increase by a percentage, which is difficult when the treatment times are in minutes and seconds. Google *Daavlin treatment time calculator* and bookmark it on your phone. In that app, simply enter the time of your last treatment and the desired percentage increase and the calculator will give you the new treatment time instantaneously.



## 14.0 Care of the Unit

### 14.1 Recommended Maintenance Schedule

| Item / Action   | Frequency   |
|---|---|
| Dusting of the unit and lamps                                     | Once a month  |
| Fully clean all internal reflectors, lamps and protective acrylic | Annually (behind the lamps)   |
| Unit calibration  | Every 100 hours of use or once a year (whichever occurs first) and when lamps are replaced. (Meters can be rented or purchased through Daavlin)                       |
| Replace lamps   | * <b>UVB</b> – Approximately every 300 hours of use.<br>* <b>UVA</b> – Approximately every 500 hours of use.<br>* <b>Blue</b> – Approximately every 500 hours of use. |


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

### 14.2 Uploading FlexRx™ Refill Prescriptions

When specified by your prescribing physician, Daavlin home phototherapy devices are equipped with FlexRx exposure limiting software. For each sequence of exposures, the number of available treatments is reduced by one. A treatment sequence consists of the primary exposure plus up to three repeat exposures, if needed, for treating other areas of your body.

If the device is equipped with FlexRx, upon “waking up”, the screen will display reminders of how many exposures are remaining. To ensure there are no interruptions in your therapy, we suggest that you contact your physician for a “refill” when 5 to 10 exposures remain. Once you are completely out of exposures, the controller will prompt you to upload a new FlexRx prescription.

To enter a FlexRx refill code, wake the controller from its sleep mode and enter the unlocking code. The controller will ask you to enter a FlexRx code or you may press the Prescription button to begin.


Tap the screen and enter the code provided by your doctor by pressing the up arrows. Press the Enter  key once you have verified that the code is entered correctly. The controller will then display the number of exposures that have been uploaded and you can then continue your normal routine.

### 14.3 Changing or Disabling the Unlocking Code

The unlocking code is a safety feature that prevents someone from accidentally turning on or tampering with the device. It works just like a key. To remove the unlocking code feature or to change it to a number that is easier to remember, contact Daavlin’s service department at 1-800-322-8546 for step-by-step instructions. Hours of operation are Monday through Thursday 7:30am - 8:00pm EST and Friday 8:30am - 5:00pm EST

### 14.4 Downloading Treatment History

Your doctor may require that you provide a treatment history file so he or she can monitor your progress. To download your history files, insert a USB drive into the USB port. Press the “Export Data” button then

press the Enter  key. When the download is complete, remove the USB drive and take it to your doctor.

## 14.5 Cleaning/Disinfection

### 14.5.1 General Cleaning

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

### 14.5.2 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, we have tested several cleaners that do not degrade the Acrylic and can be seen in Table 2 Daavlin 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   |

Table 2 Daavlin Tested Cleaners

1. Thoroughly wipe down the surfaces and allow contact time listed in Table 2 Daavlin Tested Cleaners.
2. Allow to air dry and inspect for visible contaminants.
3. If contaminants remain repeat until no visible containments remain repeat steps 0 and 2.

### 14.5.3 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 manufactures guidelines. See also “FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices” available at: <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and>.

We suggest using “Monk” Brand Wipes as they disinfect and will not harm any ultraviolet or light transmitting surfaces. These wipes are available for purchase from Daavlin. When dusting the unit and the lamps, we recommend using a feather duster or a similar non-abrasive cleaning device.

**Note:** Do not clean reflective surfaces with paper towels. They may scratch the surface.

At least once a year, we recommend that you remove the protective acrylic for a more thorough cleaning of the lamps and reflectors. Refer to Lamp Replacement instructions on how to remove the acrylic and lamps, as well as other important information on how to ensure that the lamps are safely and correctly replaced.

## 14.6 Calibration (Applicable to Guided and Dosimetric Units Only)

The power output of the device was measured before it left Daavlin’s manufacturing facility. A “Calibration Output Certificate” is included with the operating manual and contains the device’s factory measured power output. The certificate for ten (10) lamp units will state the power output of the device at a distance of nine (9) inches from the acrylic surface of the unit.

Because the 20 lamp 4 Series has been designed to deliver treatments from two specific distances, 0 inches and 9 inches, the output certificate for 20 lamp units will have two outputs noted in the “Current Value” box. The higher of the two values corresponds to the “0 inch” setting and the lower of the two corresponds to the “9 inch” setting.

## 14.7 Accuracy/Range (Applicable to Guided and Dosimetric Units Only)

The integrating dosimeter will maintain a 5% level of accuracy if the device is calibrated at least annually or whenever lamps are replaced or every one hundred (100) hours, whichever occurs sooner. The calibration process involves taking an output reading with a hand-held meter (available for purchase or rent from Daavlin) and checking it with the output reading from the integrating dosimetry system. Please contact Daavlin for calibration assistance.

|              |  |
|--------------|--|
| Dose Range:  | <b>UVA:</b> 0.1 Joules - 999.9 Joules<br><b>UVB:</b> 1 Millijoule - 9999 Millijoules |
| Accuracy:    | + / - 5%   |
| Calibration: | 1 year or every 100 hours of use or upon changing lamps                              |

## 14.8 Lamp Removal and Replacement

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 BURNS. PLEASE CONTACT THE DAAVLIN 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. Consult the Lamp Specification Guide **Error! Reference source not found.** on page 5 for replacement lamp guidance and contact the Daavlin service department for a lamp replacement quote. They can be reached by dialing 1-800-322-8546 or via email at [service@daavlin.com](mailto:service@daavlin.com).

### 14.8.1 Lamp Replacement

1. First, unplug the unit and then remove both feet by unscrewing the four thumb screws on each side. Once the feet have been removed lay the unit flat on a table with the lamps facing up.
2. Using a Phillips Head screwdriver, remove the four screws on each side of the unit. Once removed, lift off the top of the device as you would remove the top from a gift box.

3. On each lamp there are two clear plastic clasps that hold the lamps in position. To remove them, position both thumbs on the top of the clasp and use your index fingers to pull the sides of the clasp outward until it releases and can be removed.
4. On top of each lamp socket there will be a red button that, when pushed, will allow you to remove the base of the lamp from its corresponding lamp socket. With one hand, firmly press and hold the red button down while using your other hand to carefully lift the lamp up and out of the socket.
5. With one hand near the base of the lamp and the other at the opposite end, grasp the lamp and pull both ends upward at the same time until it clears both clasps and the lamp holder/socket.
6. To replace the lamps in their lamp-holders, press them straight down. A distinctive snapping sound will be heard which indicates that they are properly seated.
7. Once you have the new lamps in place, reassemble the 4 Series and reset the lamp hours to zero.

### 14.8.2 Resetting Lamp Hours

When changing lamps, it is important to reset the lamp age to zero so the operating hours of the new lamps can be tracked. Please contact the Daavlin service department for instructions on resetting the device's lamp hours.

## 15.0 Environmental Specifications

The 4 Series should be used in an electromagnetic environment as described below.

**Table 3 Electromagnetic Emissions**

| <b>Emissions Test</b>  | <b>Conformity</b> | <b>EMC Environment Guide</b>   |
|--|-------------------|--|
| 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 4 Series device is suitable for healthcare environment operation in hospitals and clinics  |
| Limits for harmonic current emissions Following IEC 61000-3-2                            | Class A           | The 4 Series 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 4 Series device is suitable for healthcare environment operation in hospitals and clinic   |

**Table 4 Electromagnetic Immunity**

| <b>Emissions Test</b>  | <b>IEC 60601 Test Level</b>  | <b>Actual Level</b>  |
|--|--|--|
| Electrostatic discharge immunity test following IEC 61000-4-2                          | +/- 8kV (conductive surfaces, coupling planes)<br>+/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)  | +/- 8kV (conductive surfaces, coupling planes)<br>+/- 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<br>6.765 MHz to 6.795 MHz @6.0 Vrms<br>13.553 MHz to 13.567 MHz @ 6.0 Vrms<br>26.057 MHz to 27.283 MHz @ 6.0 Vrms<br>40.66 MHz to 40.70 MHz @ 6.0 Vrms | 0.15 MHz to 80 MHz @ 3.0 Vrms<br>6.765 MHz to 6.795 MHz @6.0 Vrms<br>13.553 MHz to 13.567 MHz @ 6.0 Vrms<br>26.057 MHz to 27.283 MHz @ 6.0 Vrms<br>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,<br>100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees,<br><br>100% Interruption at 5000 mS at 0 degrees                 | 30% Reduction for 500 mS at 0 degrees,<br>100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees,<br><br>100% Interruption at 5000 mS at 0 degrees                 |

## 16.0 Warranty

### 16.1 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         |

### 16.2 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 REPLACEMENT OF THE EQUIPMENT.

### 16.3 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.

## **16.4 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.

## **16.5 Disposal**

Please visit [www.daavlin.com](http://www.daavlin.com) and search our FAQ section for disposal instructions for the unit and/or all accessories.

## **16.6 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.

## 16.7 Contact Information

USA & Canada: 1-800-322-8546  
Overseas: 1-419-636-6304  
Fax: 1-419-636-1739  
E-Mail: [service@daavlin.com](mailto:service@daavlin.com)  
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