

# Daavlin 7 Series: Participant Information Packet

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This is an information packet for participants in the REVEAL Trial who have chosen to have at-home nbUVB phototherapy for the next 20 to 24 weeks. It explains the delivery, usage and return of the Daavlin 7 series home phototherapy unit provided for your use during the study. In addition, you may visit <https://www.revealstudy.org> to watch a video of the following information. If you have any questions regarding the Daavlin home phototherapy unit that are not answered by this information packet, the video, or the Daavlin 7 series Home-Control Operation Manual, please feel free to contact Daavlin by email at [info@daavlin.com](mailto:info@daavlin.com) or by calling 800-322-8546 x 212 or x 314, Monday through Friday, 8:30 am – 4:30 pm, Eastern.

## Section 1: Delivery and Set-Up

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The phototherapy unit being used for the REVEAL Trial is a 6-foot-tall panel unit with 8 lamps. A staff member from Daavlin will contact you before shipping the unit to confirm your address and preferred phone number. The trucking company will call ahead to set up a “window” of time to deliver the unit. Someone will need to be home during this time to accept the delivery. Once a delivery time has been determined, a Daavlin Service Technician will be scheduled to come to your home to assist with unpacking the unit, setting it up, and demonstrating its use.

When the phototherapy unit is delivered by the trucking company, please inspect the box for any signs of shipping damage. Make sure you note any damage on the delivery receipt that the driver will have you sign, and then call Daavlin to report the damage immediately. Delivery will be to a front door, garage, or other ground-floor entry way that is protected from the weather and theft. The unit may remain in its box in this location until the Daavlin service technician arrives to set it up for you.

Before the technician arrives, please decide where you would like to place the unit. You should choose a location that has at least 3 square feet of space near a standard 3 prong grounded electrical outlet. Avoid areas with excessive moisture, such as right beside a shower. Most people prefer a location such as a bedroom where they can close the door during their treatment. Please clear the area of furniture and belongings before the technician arrives to set up the unit.

**Please Note:** Your Daavlin 7 Series Phototherapy Unit will be delivered with the following additional materials: UVB Goggles, Stylus, Daavlin 7 Series Home-Control Operation Manual, Phototherapy Unit Instruction Card, and a USB Stick.

## Section 2: Storing the Shipping Box

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The shipping box will be needed to return the phototherapy unit to Daavlin once you are finished using it. The service technician will fold the box and lid for storage. You can store the flattened box in a garage, basement, shed, under a bed or other location until it is time to return the unit.




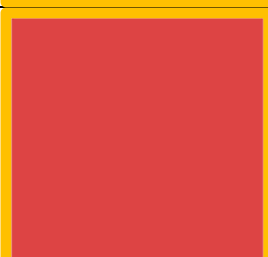
## Section 3: Using the 7 Series with the ClearLink Controller

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When you are ready to use the 7 Series phototherapy unit, touch the screen to awaken the unit and open the Logo screen. Touch the Logo screen again, and the Lock screen will appear. Enter in the REVEAL Study key code **0007** using the onscreen keypad.

Once the key code is entered, the Treatment Set Up screen will appear. The first time you use the unit, your first treatment dose, according to your study doctor’s prescription, will appear.





For all following treatments, this screen will display the information for your next scheduled dose. You will first be prompted to complete a self-examination of your vitiligo spots and respond to questions about your skin redness and comfort level following your last treatment. The table below shows the *phototherapy unit instruction card* that will be included with your unit. Use the descriptions in the ‘self-examination of vitiligo spots’ column and corresponding color descriptions to guide the selection in the Unit Display. Based on your response, the ClearLink Controller will adjust your treatment according to your prescription.


Unit Display: “Were you in pain or red after last TX?”	Self-examination of vitiligo spots	Dose Adjustment	Color of vitiligo spots
No or <24 hours	I do not have any pink or red color on my spots of vitiligo today	Level 1: Unit will increase dose by 10-15%	
24 to 48 hours	My spots of vitiligo are pink today	Level 2: Unit will hold dose at same level as last treatment	
More than 48 hours	My spots of vitiligo are red today but there is no discomfort at all	Level 3: Stop treatment until skin is pink. Then restart treatment-unit will decrease dose by 10-15%	
Still red/pain	My vitiligo spots are red today AND there is discomfort and/or blistering of my skin	Level 4: Stop treatment, call your study doctor.  Unit will be locked so that no treatment can be given today	

**Please Note:** The term “discomfort” refers to the type of soreness your skin may have as a reaction to being exposed to too much sun, similar to a sun burn.

Once you have highlighted your response, tap the Enter  key. The Treatment Confirmation screen will appear and will display the dose and an estimated time for your treatment. If changes need to be made, press the back  arrow. To cancel press  X.

**Put on your goggles and position yourself 9 inches from the front of the device.**

Tap the Enter  key to begin the treatment. A 3 second countdown will begin, and then the lamps will turn on. To pause in the middle of the treatment, tap the Pause  button. Tap the Play  button to resume. During your treatment, the screen will display your progress and the lamps will shut off when the treatment is over. You have now treated one half of your body. If you have been instructed to treat your entire body, you will need to repeat the same dose on the other half. Tap the Repeat  button and then turn around to expose the other half of your body to the lamps.

Once the lamps turn off, if you have completed all necessary exposures and are finished treating, the screen will display the elapsed time and the accumulative dose. This information will be saved by the ClearLink controller, and you may press the X  button to exit and turn off the unit until it is time for your next treatment.

**Please Note:** Message screens may appear to guide you in certain situations. For example, if you attempt to treat too soon after your last treatment, a message screen will appear letting you know that it is too soon. Please refer to the *Daavlin 7 Series Home-Control Operation Manual* for more detailed information about the ClearLink controller.

## Section 4: Returning the Unit

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When your participation in the REVEAL study is complete, Daavlin will contact you to set up a time for a service technician to return to pack the unit in the shipping box and prepare it for return to Daavlin. Once it has been packed and placed in a location for pickup, a Daavlin representative will notify the shipping company to return to pick up the unit.

**If you have any questions at any time regarding your phototherapy unit, please contact Daavlin at [info@daavlin.com](mailto:info@daavlin.com) or call 800-322-8546 x 212 or x 314.**