
Operation Manual



DT Controller

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1.0 Indications for Use

The DT Controlled 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 population may range from pediatric to geriatric.





2.0 Electrical Specifications





The Digital Timer Controller is equipped with a 5VDC power supply rated for 100-277V (50/60Hz) input power. Ensure the input voltage is within these ranges before energizing the controller. Connect the Line wire of the AC mains to pin 4 of connector J3. Connect the Neutral wire of the AC mains to pin 3 of connector J3.

The Digital Timer Controller is equipped with a relay rated for 10A of current. When connecting loads, ensure they are less than 10 Amps to prevent damage to the board. The relay will pass the AC mains through its switch, so ensure that the load requires AC power. Connect the Line wire for the load to pin 2 of connector J3. Connect the Neutral wire of the load to pin 1 of connector J3.

NOTE: PIN 1 SIGNIFIED ON BOARD WITH SMALL WHITE DOT

3.0 Symbols

SYMBOL	DESCRIPTION
	DANGEROUS VOLTAGE
	NON-IONIZING RADIATION
	EARTH (ground)
	PROTECTIVE EARTH (ground)

SYMBOL	DESCRIPTION
	OPERATING INSTRUCTIONS
	KEEP DRY
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	MEDICAL DEVICE

4.0 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 the 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 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 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 and plugs, sockets, lamps, and electrical cables and connections are not worn or damaged.
- The device should be placed a minimum of 1 inch (2.5 cm) away from surrounding walls, devices, and furniture to ensure proper cooling airflow.
- The room that the device is placed in should be vented to allow free air displacement to ensure the device and surroundings remain cool.
- 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.
- Device is not to be used in MR environments that may include MRI, diathermy, electrocautery, or other high frequency equipment.
- Do not treat if the lamps fail to ignite. Consult with doctor and/or contact Daavlin customer service. (See page 12)
- If lamps turn on without treatment being started/resumed, or if lamps do not turn off when treatment is completed, unplug the device. Contact doctor and/or Daavlin customer service. (See page 12)
- DT Controlled Phototherapy Devices are considered CISPR Group 1, Class A devices, to be used **for prescription use only**.

5.0 Unlocking the Device

To prevent unauthorized use, the device will “self-lock” when it has not been used for three (3) minutes (unless in a Maintenance Menu). 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”.

- a. NOTE: “0007” is the default code for the device and can be changed in Maintenance Menu 3.
4. Press the “PLAY/PAUSE” button to unlock the controller.

NOTE: Regardless of the Key Code set in Maintenance Menu 3, the code “0205” will serve as a hard coded master unlock key.

6.0 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”.
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.
 - 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.

7.0 Opening and Navigating the Maintenance Menu

To view or change settings on the Digital Timer controller, the Maintenance Menu must be accessed.

1. Enter in your key code if prompted.
2. Simultaneously press the CANCEL + LEFT ARROW + PLAY/PAUSE buttons.
3. The screen should display “ - - - 1”, indicating that Menu 1 will be selected.
4. Press the UP-ARROW button to cycle through the available Menus, then press the PLAY/PAUSE button to enter the chosen Menu.
5. Press and hold the LEFT ARROW button then press the CANCEL button once in a selected menu to allow for reset/modifications if applicable (see 8.0 Maintenance Menu for applicable reset/modifications)
 - a. Pressing PLAY/PAUSE after modification will lock in changes to the menu.
6. Pressing the CANCEL button will return to the menu selection screen.

8.0 Maintenance Menus

The following list of menus is accessible once the Maintenance Menu has been accessed.

1. Menu 1 – Lamp Hours (Resettable)
2. Menu 2 – Software Version (Non-editable)
3. Menu 3 – Key Code (Editable)
4. Menu 4 – Max Treatment Time (Editable)
5. Menu 5 – Display next Flex Code (Non-editable)
6. Menu 6 – Display Treatments Remaining (Resettable)
 - a. NOTE: AFTER RESET, THE DEVICE WILL BE LOCKED AND WILL REQUIRE A TREATMENT CODE TO BE ENTERED TO RESUME USE.

9.0 Viewing or Resetting the Lamp Hours

The Digital Timer controller tracks how many hours the lamps have been turned on. To view or reset the Lamp Hours on the Digital Timer controller:

1. Enter your Key Code to unlock the controller.
2. Access the Maintenance Menu.
3. While the screen displays “ - - - 1”, press the PLAY/PAUSE button to enter Menu 1.
4. The number displayed is the total number of treatment hours the controller has accumulated.
 - a. To reset, press and hold the LEFT ARROW button then press the CANCEL button. The screen should display “ 0”.

5. Press the CANCEL button to return to the Maintenance Menu.

10.0 Changing/Disabling the Key Code

To change the Key Code on the Digital Timer controller:

1. Enter your Key Code to unlock the controller.
2. Access the Maintenance Menu.
3. While the screen displays “- - - 1”, press the UP-ARROW button two (2) times. The screen should display “- - - 3”.
4. Press the PLAY/PAUSE button to enter Menu 3.
5. The Key Code currently assigned to the controller will be displayed.
6. Press and hold the LEFT ARROW button then press the CANCEL button to modify the Key Code value. Successful execution will cause the display to flash on the currently selected character.
7. Use the UP ARROW and LEFT ARROW buttons to assign a new Key Code.
 - a. Set the code to “0000” to disable Key Code.
8. Pressing the PLAY/PAUSE button will save changes and return to the Maintenance Menu.

11.0 Changing/Disabling the Max Treatment Time

The Digital Timer can set a maximum time-limit on how long a treatment can last. The default is ten (10) minutes (displayed as “10:00”). To view or modify the Max Treatment time on the Digital Timer controller:

1. Enter your Key Code to unlock the controller.
2. Access the Maintenance Menu.
3. While the screen displays “- - - 1”, press the UP-ARROW button three (3) times. The screen should display “- - - 4”.
4. Press the PLAY/PAUSE button to enter Menu 4.
5. Press and hold the LEFT ARROW button then press the CANCEL button to modify the Max Treatment value. Successful execution will cause the display to flash on the currently selected character.
6. Use the UP ARROW and LEFT ARROW buttons to assign a new value.
 - a. Set the code to “0000” to disable Max Treatment option.
7. Pressing the PLAY/PAUSE button will save changes and return to the Maintenance Menu.

12.0 Viewing Device Code for Flex Rx

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. Access the Maintenance Menu.

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 (“Cxyz”) is the next generated Device Code.
 - a. Alternately, 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.

13.0 Enable/Disable/Refill FlexRX

The Flex Rx exposure limiting system uses a “call and response” method. The 3-digit Device Code (Cxyz) is randomly generated by the controller and is necessary to generate a 4-digit Treatment Code using an algorithm controlled by Daavlin.

13.1 Enable Flex Rx

To **ENABLE** Flex Rx on the DT controller, follow the instructions below:

1. Enter your Key Code to unlock the controller.
2. Access the Maintenance Menu – Menu 6.
3. The value displayed is the number of exposures remaining on the controller.
 - a. ‘0000’ = no exposures remaining, and a Treatment Code is required to resume treatments.
 - b. “9999” = unlimited treatments remaining (factory default setting).
 - c. Any other value indicates the number of exposures remaining and that FlexRX is active.
4. For the initial setup of Flex Rx, press the LEFT ARROW and then CANCEL buttons to reset ‘9999’ value to ‘0000’
5. Press PLAY/PAUSE to lock in the reset.
6. Press CANCEL to exit the Maintenance Menu.
7. Screen should display ‘C000’ (initial factory default code)

Note: If any other Device Code is displayed, desired Treatment Code will need to be obtained from Daavlin Service.

- a. Enter Treatment Code ‘0001’ for ZERO exposures – will generate new Device Code and lock device
- b. Enter Treatment Code ‘0002’ for 75 exposures
- c. Enter Treatment Code ‘0003’ for 100 exposures
- d. Enter Treatment Code ‘0004’ for 250 exposures
- e. Enter Treatment Code ‘0005’ for Unlimited exposures – FlexRX Off

8. Press the PLAY/PAUSE button to confirm the addition of treatments. The display will flash the amount of treatments added two times before returning to the Time Entry screen (00:00).

13.2 Disable FlexRx

To **DISABLE** FlexRX on the DT controller, follow the instructions below:

1. Enter your Key Code to unlock the controller.
2. If Device Code 'Cxyz' is displayed on screen, enter Treatment Code for Unlimited exposures to disable FlexRX
3. If Device Code is not displayed on screen
 - a. Access the Maintenance Menu – Menu 6.
 - b. The value displayed is the amount of treatments remaining on the controller
 - i. If '9999' is displayed on screen, FlexRX is already disabled.
 - c. If value other than '9999' is displayed on screen, press the LEFT ARROW and then CANCEL buttons to reset value to '0000'
 - d. Press PLAY/PAUSE to lock in the reset.
 - e. Press CANCEL to exit the Maintenance Menu.
 - f. Screen will display 'Cxyz' code
 - g. Enter corresponding Device Code for Unlimited exposures to disable FlexRX

13.3 Refill FlexRx

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

1. Enter your Key Code to unlock the controller.
2. Device Code 'Cxyz' is displayed on screen

Note: If Device Code is not displayed, there are exposures remaining and it will be displayed once all exposures have been used. Device Code can be viewed in Menu 5 prior to all exposures being used.
3. Contact prescribing physician and provide Device Code 'Cxyz'
4. Physician will contact Daavlin to authorize FlexRX refill
5. Daavlin Service will provide Treatment Refill Code to doctor or patient

14.0 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 Flex Rx is activated and 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 Flex Rx is active, the display will flash the number of treatments remaining two (2) times after a treatment or at power up if the amount of remaining exposures is twenty (20) or less, signaling the user to obtain a new Flex Rx Treatment code soon.
5. Per the Daavlin Flex Rx Algorithm, there are 1000 Device Codes (C000-C999), each having five (5) four-digit Flex Rx Treatment Codes (0000-9999) that set a predetermined amount of exposures to be allowed by the controller.
 - a. 0 exposures (locked), 75 exposures, 100 exposures, 250 exposures, or unlimited exposures (unlocked).

15.0 Contact Information

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