



DreamStation 2 Basic Setup & Return Instructions

Important:



The enclosed DreamStation 2 Auto CPAP Advanced device is provided to you as a replacement for your existing CPAP device. This document provides basic instructions for setting up your replacement device and for returning your affected device.

To ensure proper disposal of your current machine, please follow the instructions provided below.

Do not discard any of the packaging material. You will use it to return your recalled device.



Do not discard:

Please keep the following device components and accessories from your current device, you will need them to set-up your replacement device.

SD Card

Tubing

Mask

Package Contents

- Patient Support Resources Card
- Basic Setup & Return Instructions
- Single sheet Quick Start Guide – Basic Setup
- Patient Quick Start Guide – Device Navigation
- User Manual
- Cleaning & Inspection Instructions
- Packing Tape
- Pre-paid Return Postage Label (found in plastic sleeve affixed to carton exterior)

Device Components & Accessories

- DreamStation 2 Auto CPAP Advanced
- Carry bag
- Power Supply
- Power Cord
- Tubing
- Humidifier Water Tank
- Filters (one grey pollen filter in the device and one blue ultrafine filter in the accessory pack)

The enclosed device is being provided to you to replace your current device, which must be returned to Philips as soon as possible so that the old foam can be removed and replaced with silicone foam as part of the recall remediation plan. Failure to return your original device to Philips could result in your being billed for payment of that device, as you now have two devices, but have only paid for one device.

Instructions: Basic Setup of DreamStation 2 Auto CPAP Advanced device

- 1** **Disassemble your old machine.**

 - Disconnect the power supply, power cord, tubing, and mask.
 - If applicable, please ensure the humidifier does not contain any water.
 - Remove SD card (if applicable) and save.

- 2** **Assemble the replacement sleep apnea therapy machine.**

 - Unpackage your replacement DreamStation 2 device and clean the humidifier water tank per cleaning instructions in the user manual.
 - For device components and accessories you have kept, clean per the cleaning instructions in the user manual.
 - Connect the power supply and power cord to the bottom of the device and plug in the power cord to an outlet not controlled by a light switch.
 - Do not place the SD card from your existing device into your replacement device. Retain your existing device SD card in case your doctor needs it.
 - Reattach the humidifier water tank by sliding it onto the device.
 - Attach tube.
 - Attach mask.

- 3** **Allow for device settings to upload before starting therapy.**

 - Once the device is plugged in **wait five minutes** to allow the device settings to upload via the integrated cell modem. In some instances you may see an on-screen pop appear informing you of a prescription update/change.

NOTE: If applicable, verify that your new device serial number is now active in DreamMapper by checking your DreamMapper account/app.
 - Press the therapy button to initiate air flow and ensure proper operation. Your prescription pressure will be delivered.

NOTE: A solid ring indicates your prescribed therapy pressure is being delivered.
 - Please reference the Patient Quick Start Guide and User Manual for more detailed information about the device and operation.
 - Your device is now ready to use.

DreamStation Setting	DreamStation 2 Setting
Prescription Mode and Pressure	Matches DreamStation prescription setting
Tube Size	Matches DreamStation setting (if heated tube attached, device will automatically detect)
CFLEX or CFLEX+/AFLEX: Off, 1, 2, or 3	FLEX (CFLEX+/AFLEX): Off, 1, 2, or 3 (value matches DreamStation setting)
Mask Resistance	Matches DreamStation setting
Fixed or Smart Ramp	Ramp Plus
Ramp Time: 5-45min (5 min increments)	Ramp Plus Time: 15, 30, or 45 min (matches to closest previous setting)
Ramp Pressure	Ramp Plus pressure set to off (patient to select desired starting pressure)
Opti-Start	Enabled if enabled on DreamStation (will take 30 hours for device to identify optimal pressure. Ramp Plus pressure overrides Opti-Start pressure if activated)

Mapping of Device Settings
NOTE: If you had a Ramp pressure set on your device, you will need to reset on the DreamStation 2 device using the replacement Ramp Plus feature. This can be adjusted by tapping the Ramp Plus icon while therapy is running and tapping the +/- icons until the desired and comfortable start pressure is achieved. After Ramp Plus is set, the device will automatically deliver this pressure during the therapy session and future therapy sessions without additional activation.

Instructions: Return Instructions for affected device

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Package your old machine for return shipment.

- Using the packaging material that came with your replacement device, place your affected device in the shipping box provided.
- Tape the box after packaging is complete. The tape should be centered so equal amounts of tape extend down the sides of the shipping box as shown below (left).



- Peel the pre-paid label from its backing and attach it to the shipping box making sure you completely cover the original shipping label. Use the above diagram (right) as reference.
- Ensure the shipping box is securely taped and sealed to prevent it from breaking open during shipment.

⚠ **Do not return:** SD card, tubing, or mask

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Contact FedEx toll-free at (800) 463-3339 or go to FedEx.com.

- Find the closest drop off location or schedule a pickup.
- You may also give the package to any FedEx driver making regular pick ups or deliveries.
- Alternatively, you can take the package to an authorized FedEx shipping outlet.
- This return shipment is pre-paid, so there is no charge to you.

Thank you for your cooperation and assistance in connection with Philips' efforts to remediate the recalled Respiroics Sleep and Respiratory Care devices (each, an "Affected Device"). To expedite these efforts, Philips in many cases is (or will be) providing a replacement device (an "Advanced Exchange") in advance of the return of an Affected Device. By accepting the Advanced Exchange, you are agreeing to return your Affected Device to Philips so that, in many cases, Philips can expeditiously refurbish the returned Affected Device to help ensure another user receives a replacement device sooner. This is consistent with the FDA's direction for a prompt remediation.

Upon receipt of Advanced Exchange, please follow the instructions that you receive regarding the return of your Affected Device to Philips. Specifically, **it is important that you promptly return your Affected Device.** Your returned Affected Device will either be repaired to replace the foam insulation with an approved insulation, or will be destroyed.

Please note that to effectuate the Recall consistent with FDA laws and regulations, it is necessary that you return your Affected Device promptly. By participating in the Advanced Exchange or receiving a remediated device, you acknowledge and agree that the foam insulation will be removed and may be discarded, and that your Affected Device may be destroyed or refurbished. Thank you again for your assistance in this matter.