

# **Basic Setup & Return Instructions**

#### Important:



The enclosed DreamStation device is provided to you as a replacement for your existing 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** 

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.

# **Package Contents**

- Patient Support Resources Card
- Basic Setup & Return Instructions
- Cleaning and inspection instructions
- User / Humidifier Manual
- Packing Tape
- Pre-paid Return Postage Label (found in plastic sleeve affixed to carton exterior)

# Your Replacement DreamStation Machine

#### Components

- DreamStation
- Power Supply
- Power Cord



Carry bag



Humidifier

SD Card



15 mm Heated Tubing



Pollen (A) and Ultra-fine (B)



 This device comes with heated tubing. If you have a standard tube, keep, clean and inspect for reuse.

# Instructions: Basic Setup of DreamStation device



#### 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).



## Assemble the replacement therapy machine.

- Unpackage your replacement DreamStation 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.
- Attach tube.
- Attach mask.

# Instructions Continued: Basic Setup of DreamStation device



#### Starting Therapy.

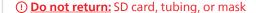
- Once the device is plugged in wait five minutes to allow the device settings to upload.
- Press the therapy button to initiate air flow and ensure proper operation.
   Your prescription pressure will be delivered.
- Please reference the User Manual for more detailed information about the device and operation.
- Your device is now ready to use.
- Update your device serial number information in DreamMapper.

### Instructions: Return Instructions for affected DreamStation device



# 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 to the right (top).
- 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 diagram to the right (bottom) as reference.
- Ensure the shipping box is securely taped and sealed to prevent it from breaking open during shipment.







#### 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 in this effort.

Please contact us at 833-262-1871 or www.philips.com/SRC-update if you have any questions.

Thank you for your cooperation and assistance in connection with Philips' efforts to remediate the recalled Respironics 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.