

Cautions

- Refer to your therapy device manual for details on settings and operational information.
- The technical specifications of the mask are provided for your clinician to check that they are compatible with the therapy device. If used outside specification, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, and leak or variation in the leak rate may affect device function.
- The mask should be cleaned every other day to prevent dirt and oil contamination from the skin building up on the mask.
- The mask should not be cleaned with unapproved cleaning or disinfecting methods.
- The user should clean their face prior to wearing the mask.
- The user should not alter the design of the mask.
- Do not place the mask in a clothes dryer.
- In the USA, federal law restricts this device to sale by, or on the order of, a physician.

Contraindications

- None

Technical Specifications

1. Therapy Pressure Range: 4 to 20cmH₂O
2. 22mm swivel connection
3. Resistance (pressure drop)
 - @ 50 lpm = 0.6 cmH₂O
 - @ 100 lpm = 0.9 cmH₂O
4. Fixed Leak rate (flow may vary due to manufacturing variation):

Pressure (cmH ₂ O)	4	5	10	15	20
Flow (lpm)	12.9	14.7	24.9	33.9	40.0

5. Environmental storage and operating conditions are not expected to effect the function of this device
6. Sound Level
 - A-weighted Sound Power Level, 26 dBA
 - A-weighted Sound Pressure Level @ 1m, 18 dBA
7. This device is expected to remain suitable for use under normal usage and cleaning conditions for a time period of at least 90 days.
8. The device is not made with natural rubber latex

Limited Warranty www.circadiance.com/help



SleepWeaver
Soft Cloth Masks

Advance

Instructions for Use

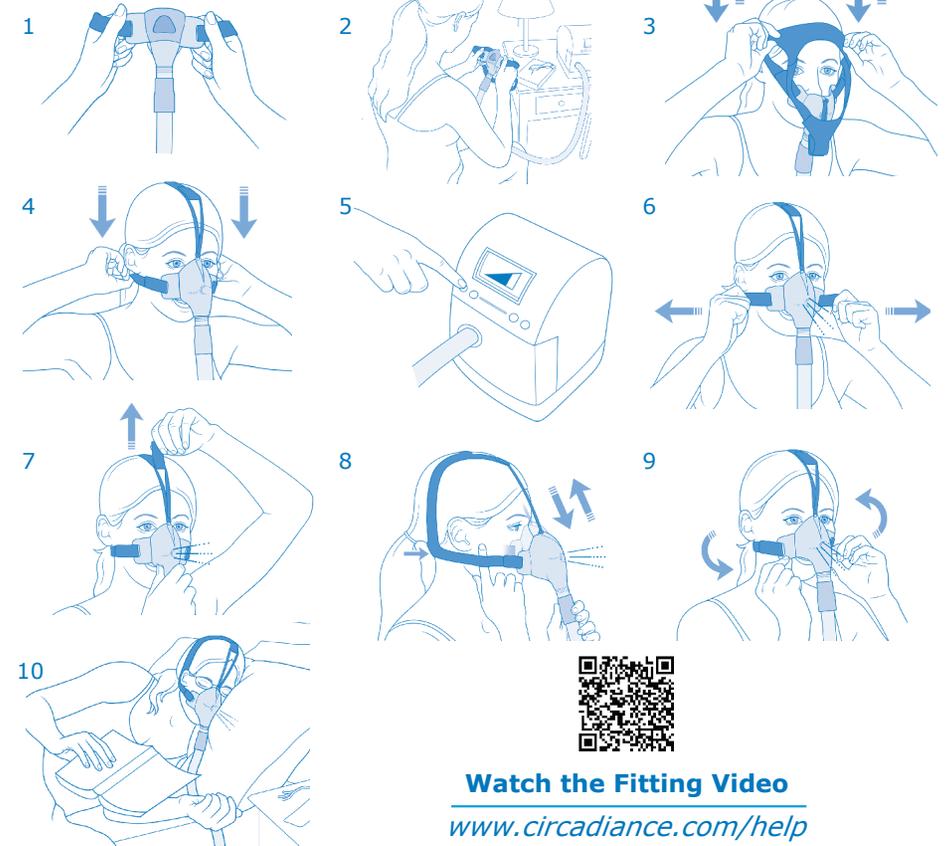
English

Intended Use

This SleepWeaver mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg).



Fitting the Mask



Watch the Fitting Video
www.circadiance.com/help



Mailing Address: PO Box 17480, Pittsburgh PA 15235
Physical Address: 1300 Rodi Road Turtle Creek PA 15145
Phone: 888-825-9640 or +1 724-858-2837
cservice@circadiance.com www.sleepweaver.com

Fitting the Mask, Continued

1. Remove mask from packaging. If you have removed the mask from the headgear, re-attach the headgear straps through the slits in the mask wings (picture 1). Connect the tubing from the machine to the plastic hose connector on the front of the mask.
2. Put mask on by pulling the headgear over your head so that the cup of the mask is centered over the nose and the head strap is centered on your forehead (pictures 2 & 3).
3. Pull the headgear over the back of your head until the neck strap rests below your ears (picture 4).
4. Turn on the machine (picture 5).
5. Adjust the neck straps first so that the bottom of the mask is comfortably resting on your upper lip just below your nostrils (picture 6).
6. Adjust the head strap to pull the mask comfortably against your nose (picture 7).
7. Ensure headgear is not overly tightened, you should be able to easily fit one finger under each strap of the headgear (picture 8).
8. Lie down in your normal sleeping position and if needed shift the mask around so that the fabric is able to form a seal against your skin. Additional adjustment tips are located in the following section and a detailed fitting video can be viewed at www.circadiance.com/help.

Adjusting for Leaks - If you experience leaks, try these steps:

1. With your CPAP or bilevel machine on and at your prescription pressure, pinch the portion of the mask directly over your nose, pull the mask slightly away from your face, towards your feet, and gently release.
2. If you experience leaks from the sides of the mask, adjust the Neck Straps by unhooking the tab from the strap and pulling the straps out to tighten the mask, then re-latching the tab to the strap.
3. If you experience leaks into your eyes, adjust the Head Strap.
4. At times it is possible to stop leaks and get a better fit by loosening the mask just a bit, then repeating Step 1.
5. Leaks can also occur if the headgear straps are too tight or too loose. With practice you should find the snug but comfortable fit that works for you.

Home Cleaning Instructions - Individual Use

1. Hand wash the mask every other day with a mild, nonabrasive soap in warm water. Air dry out of direct sunlight.
2. Hand wash the headgear weekly.
3. After a period of use, the medical tape that attaches the swivel to the mask will lose its adhesion and will need to be replaced.
4. The swivel is attached to the mask using latex free white medical tape. You may remove the swivel and clean it separately by soaking it in a solution of 1 part vinegar to 3 parts water ($\frac{1}{3}$ cup vinegar to 1 cup water).
5. Thoroughly rinse the swivel after soaking then let dry.
6. Re-attach the swivel with latex free medical tape.
(please refer to the Swivel sections)

Cleaning & Disinfecting between Patients

Please visit www.circadiance.com/help for instructions.

Removing the Mask

1. To remove the SleepWeaver, pull the mask away from your nose and lift the headgear off your head.
2. You will not need to loosen the headgear straps. With practice you will be able to pull it on and off after you have adjusted the fit for yourself.

Removing the Swivel - *It is not necessary to remove the swivel and replace the tape each time you wash the mask unless you have a chronic condition and your physician or RT has advised you to do so or if the mask is used in a Sleep Lab environment.*

1. Turn the mask inside out to expose the white medical tape attaching the swivel to the mask and remove the old tape.
2. Push the swivel through the nose hole and out of the mask for cleaning.
3. Clean the mask by following the home cleaning instructions.
4. Clean the swivel separately by soaking it in a solution of 1 part vinegar to 3 parts water. Rinse well after soaking then let dry.

Re-attaching the Swivel- Use latex free, waterproof, white medical tape

1. After both the swivel and mask are completely dry turn the mask inside out again.
2. Place the swivel inside the mask with the "male" (ridge) sticking out $\frac{1}{2}$ inch from the fabric.
3. Cut a piece of white latex free medical tape approximately 10 $\frac{1}{2}$ inches long
4. Hold the swivel in the mask with one hand while starting tape next to the ridge. Make sure your tape is $\frac{1}{2}$ way over the fabric and $\frac{1}{2}$ over the swivel.
5. Wrap the tape around the swivel and mask at least 3 times.
6. Cut off excess tape if necessary and finger smooth away any wrinkles with your finger.
7. Instructions are also available online at www.circadiance.com/help



⚠ Warnings

- The device is a vented mask and should not be used with a dual limb ventilation circuit.
- If there are any reactions to any part of this mask or headgear, discontinue use immediately.
- This system should not be used unless the therapy device is turned on and is operating properly.
- The vent holes should never be blocked.
- Ensure the mask is put on correctly. Ensure the mask and headgear are assembled and positioned as pictured on the front page of these instructions.
- If any visible deterioration of a system component is apparent (cracking, broken parts, tears, etc.), or if after cleaning any components remain unclean, the component should be discarded and replaced.
- Varying the frequency, method, or cleaning agent to clean this product other than what is detailed in these instructions may have an adverse effect on SleepWeaver Advance and consequently the safety or quality of the therapy.
- If the SleepWeaver Advance is being used with supplemental oxygen, the oxygen flow must be turned off if the machine is not operating because accumulated oxygen is a fire hazard.
- If the SleepWeaver Advance is being used with supplemental oxygen, the patient should refrain from smoking.