

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 20 cmH₂O
2. 22mm Swivel Connection
3. Resistance (pressure drop)
 - @ 50 lpm = 0.4 cmH₂O
 - @ 100 lpm = 0.7 cmH₂O
4. Fixed leak rate (flow may vary due to manufacturing variation):

Pressure (cmH ₂ O)	4	5	10	15	20
Flow (lpm)	14	16	27	37	45

Environmental storage and operating conditions are not expected to effect the function of this device.

Sound Levels

- A-weighted Sound Power Level, L_{WA}
- A-weighted Sound Pressure Level, L_{pWA}

This device is expected to remain suitable for use under normal usage and cleaning conditions for a time period of at least 90 days.

The device is not made with natural rubber latex.

Limited Warranty www.circadiance.com/help



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For patents and trademarks applicable to Circadiance products, please visit www.Circadiance.com/IP

100673 REV 6



SleepWeaver
Soft Cloth Masks

Élan[®]

Instructions for Use

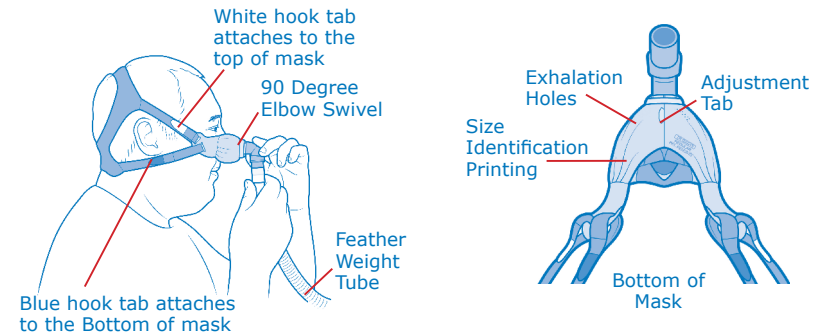
English



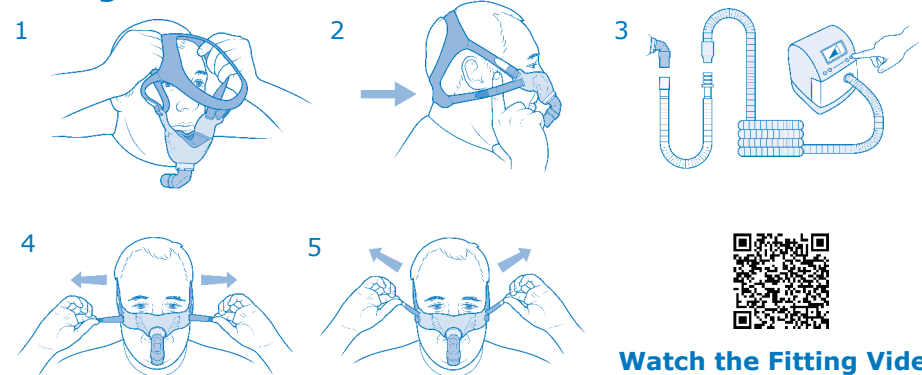
Intended Use

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).

Mask Orientation



Fitting the Mask



Watch the Fitting Video
www.circadiance.com/help



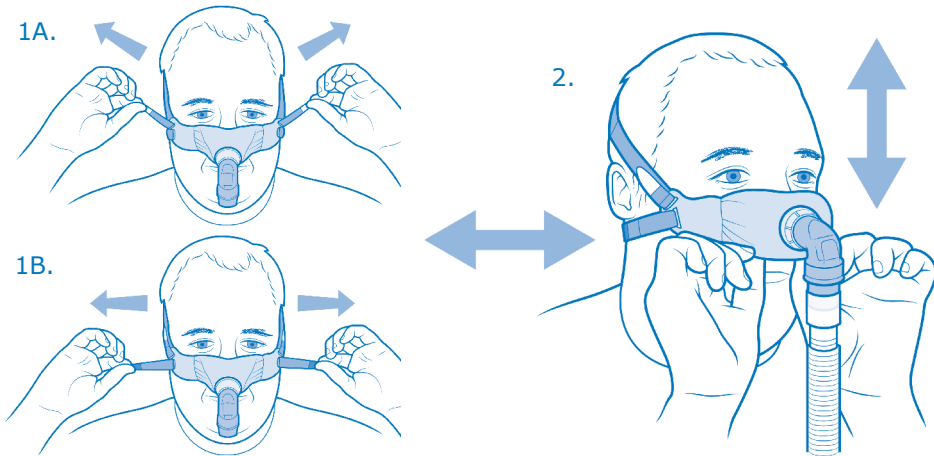
Mailing Address: PO Box 17480, Pittsburgh PA 15235
Physical Address: 1300 Rodi Road Turtle Creek PA 15145
Phone: 888-825-9640 or +1 724-858-2837
cservice@circadiance.com www.sleepweaver.com

Fitting the Mask Continued

1. Put the mask on by pulling the headgear over your head.
2. The neck support of the headgear should sit comfortably on the lower part of your neck. **IMPORTANT – DO NOT OVERTIGHTEN THE STRAPS. START WITH THE STRAPS LOOSE AND THEN TIGHTEN AS NECESSARY TO ACHIEVE AN AIR-TIGHT SEAL.**
3. Adjust the bottom (blue hook tab) straps to pull the mask comfortably against your nose. A small amount of the black fabric will show when the mask is in use.
4. Adjust the top (white hook tab) straps so that the bottom of the mask is comfortably resting on your upper lip just below your nostrils.
5. Attach the Feather Weight Tube® to the 90 degree elbow swivel then to the 6 foot tube that attaches to your CPAP or Bi-Level machine and turn on machine.
6. 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. Gently tighten the straps in very small increments to achieve a seal.
2. Wiggle the mask into place by shifting the mask left and right and up and down. The adjustment tab on the bottom of the mask can be used to assist during this process.



Cleaning the Mask in the home

- Your SleepWeaver Élan should be cleaned by hand washing with a mild nonabrasive soap in warm water every other day. Never use hot water. Repeat washing until visibly clean.
- Rinse well with drinking quality water and allow to air dry out of direct sunlight.
- You may keep the 90 degree elbow swivel attached during cleaning or you may remove it and clean it separately.
- Hand wash the headgear weekly.

Cleaning & Disinfecting Between Patients

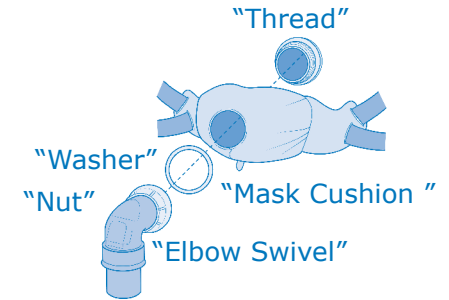
- Please visit www.circadiance.com/help for instructions.

Attach Mask to Headgear

1. Slide the "White" hook tabs through the top slits of the cushion.
2. Slide the "Blue" hook tabs through the bottom slits of the cushion.

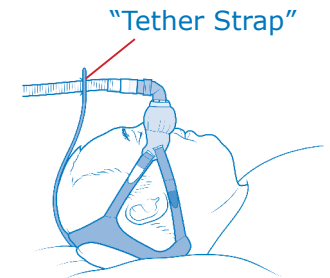
Attach 90 Degree Elbow Swivel to Mask Cushion

1. Slide the "Thread" piece through the opening from inside the mask.
2. Place the "Washer" piece over the "Thread" piece.
3. Ensure that the fabric does not ride up onto the thread piece.
4. Screw the "Nut" piece onto the "Thread" piece.



Attach Tether Strap to Headgear

1. Attach the "Tether Strap" to the Feather Weight Tube and to the top of the headgear to assist with tube management if the tube is directed over your head.
2. Ensure that the "Tether Strap" is not twisted when attached.



⚠ 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 shown 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 Élan and consequently the safety or quality of the therapy.
- If the mask is being used with supplemental oxygen, the patient should refrain from smoking
- If the mask 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.