

Technical Specifications (cont.)

4. Anti-Asphyxia Valve (AAV) operation:

Open to atmosphere @ 1.6 cm H₂O

Close to atmosphere @ 2.1 cm H₂O

5. Fixed leak rate (flow may vary due to manufacturing variation):

Pressure (cm H ₂ O)	4	5	10	15	20	25	30
Flow (LPM)	16	18	30	41	50	58	67

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

⚠ Cautions & Warnings

- Does not contain natural rubber latex. If you have any reaction to any part of this mask or headgear discontinue use immediately.
- In the USA, federal law restricts this device to sale by, or on the order of, a physician.
- This system should be used only with the PAP system recommended by your physician or respiratory therapist.
- This mask should not be used unless the PAP machine is turned on and operating properly.
- The vent holes should never be blocked.
- Please refrain from smoking while using this product.
- The SleepWeaver Anew should not be cleaned with unapproved cleaning and disinfecting methods.
- The mask should be cleaned daily to prevent dirt and oil contamination from the skin building up on the mask.
- The patient should clean their face prior to wearing the mask.
- Ensure the mask is put on correctly. The oral portion of the mask contains the 90° Elbow AAV.
- The patient should not alter the design of the mask.
- Do not place the mask in a clothes dryer.
- Do not block or disable the AAV on the SleepWeaver Anew.
- The SleepWeaver Anew is not intended to be used on patients that are uncooperative, obtunded, unresponsive, or unable to remove the mask without clinical supervision.
- If the SleepWeaver Anew 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 Anew is being used with supplemental oxygen, the patient should refrain from smoking.
- To minimize the risk of vomiting during sleep, the patient should avoid eating or drinking for three hours before using the mask.
- The SleepWeaver Anew is for single patient re-use only and is not approved for clinical cleaning and disinfecting methods.
- At low pressures the flow through the ventilation holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

Contraindications

- The SleepWeaver Anew should not be used in conjunction with a volume ventilator that requires a non-vented mask.
- The SleepWeaver Anew is not intended to be used by those patients that are taking prescription drugs that may cause vomiting.
- The SleepWeaver Anew may not be suitable for persons with the following conditions: impaired cardiac sphincter, excessive reflux, impaired cough reflex, or hiatal hernia.

Limited Warranty

- www.circadiance.com/help



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SleepWeaver[®]

Soft Cloth Full Face PAP Mask

Anew[™]

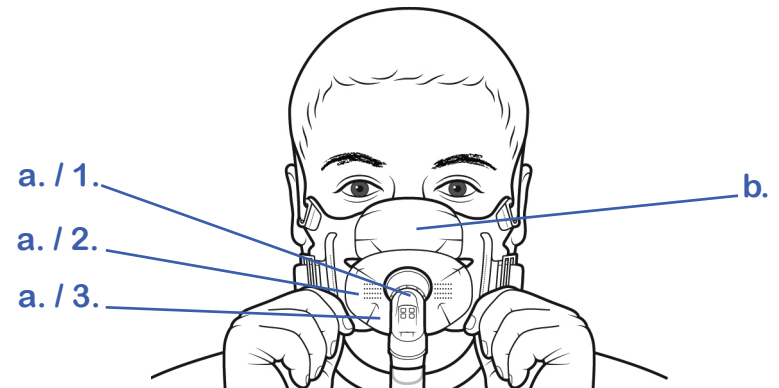


Intended Use

The SleepWeaver Anew Soft Cloth Full Face PAP Mask is intended to provide an interface for Positive Airway Pressure (PAP) therapy. This mask is intended for single-patient reuse in the home and in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg).

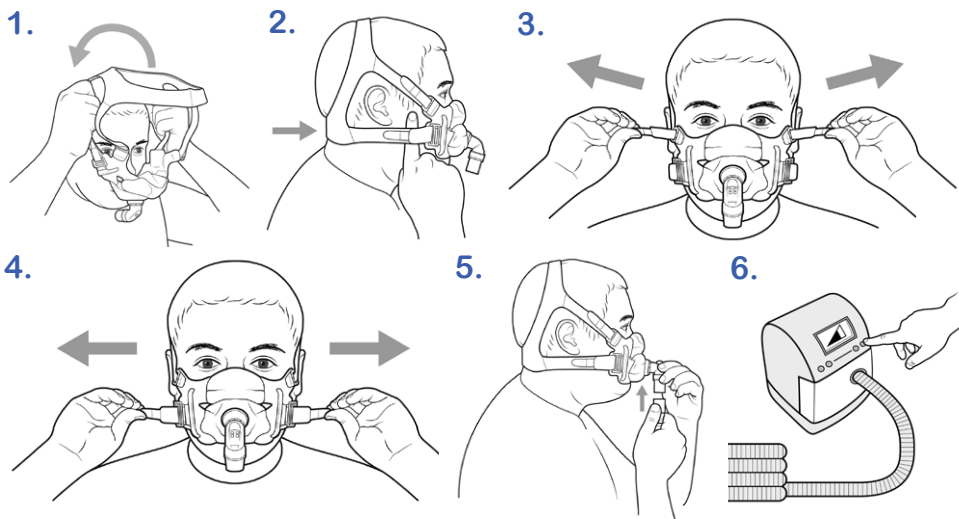
Mask Orientation

1. Remove your SleepWeaver Anew from the package.
2. Understand the proper orientation of the mask:
 - a. Oral interface covers your mouth
 1. Contains 90° Elbow Anti-Asphyxia Valve (AAV)
 2. Contains exhalation holes
 3. Contains mask size (Small, Regular, Large)
 - b. Nasal interface covers your nose



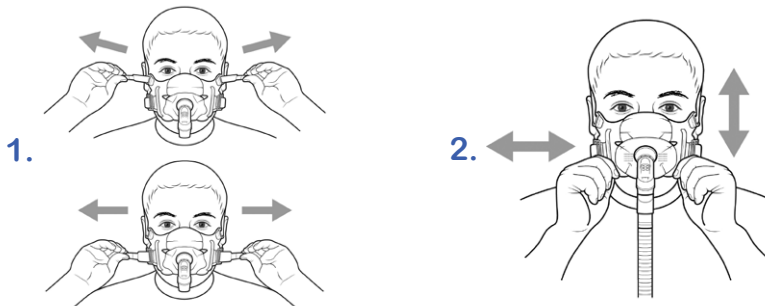
Fitting the Mask

1. Put the mask on by pulling the mask and headgear over your head.
 - a. NOTE- Make sure all straps are attached to the headgear with all strap lengths at their widest setting.
 - b. Snap the longer straps to the quick release clips.
2. The neck support of the headgear should sit comfortably on 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 top straps first so that the nasal interface of the mask is comfortably resting on your upper lip.
4. Adjust the bottom straps so that the oral interface of the mask is comfortably in place.
 - a. NOTE – It is helpful to slightly stick your lips out when tightening the bottom straps to ensure that the fabric is going around the lips and not over them.
5. Attach one end of the 6' PAP Tube to the PAP Machine and attach the other end to the 90° Elbow AAV on the Anew mask.
6. Turn the PAP machine on.



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

1. Adjust the straps as necessary to achieve a comfortable seal.
2. Wiggle the mask into place by shifting the mask left to right and up and down while gently pushing your nose into the nasal interface opening.



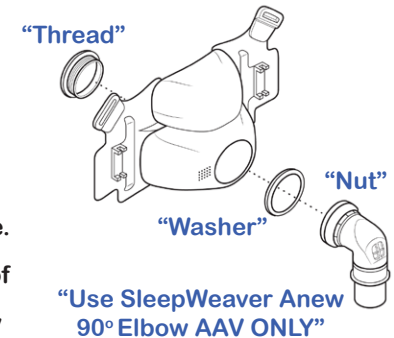
Attach Mask to Headgear

1. If the mask is not attached to the headgear, attach as follows:
 - a. The white label is located on the back of the headgear.
 - b. Attach the smaller top straps to the nasal portion of the mask.
 - c. Snap the longer straps to the quick release clips.
 - d. Ensure that all strap lengths are at their widest setting for initial fit.

Attaching the 90° Elbow with AAV

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.

 The 90° Elbow with AAV is a safety feature of the SleepWeaver Anew. Use only the AAV supplied with your mask. Do not substitute any other elbow or AAV.




Quick Release


1. The SleepWeaver Anew was designed with two quick release clips to remove the mask quickly.
2. Practice removing and attaching your mask by using the quick release clips.



Cleaning the Mask

1. Your SleepWeaver Anew 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. Hand wash the headgear weekly.
2. Rinse well with drinking quality water and allow to air dry out of direct sunlight.
3. You may keep the 90° Elbow AAV attached during cleaning or you may remove it and clean it separately. Refer to the "Attaching the 90° Elbow with AAV" if removed for cleaning.

 The anti-asphyxia valve is designed to open to atmosphere if the system loses pressure. The user must verify the AAV is able to move between the open and closed position before each use. The user must clean the anti-asphyxia valve daily to ensure all secretions are removed and that the holes to atmosphere are not covered or blocked. Do not block or disable the AAV.

 Inspect all parts for damage or wear after each cleaning and before each use.

Technical Specifications

1. Therapy pressure range
4 to 30 cm H₂O
2. Resistance (pressure drop) with AAV closed to atmosphere
@ 50 l/min = 0.3 cm H₂O
@ 100 l/min = 0.4 cm H₂O
3. Inspiratory and expiratory resistance with AAV open to atmosphere
Inspiration @ 50 l/min = 1.8 cm H₂O
Expiration @ 50 l/min = 1.7 cm H₂O