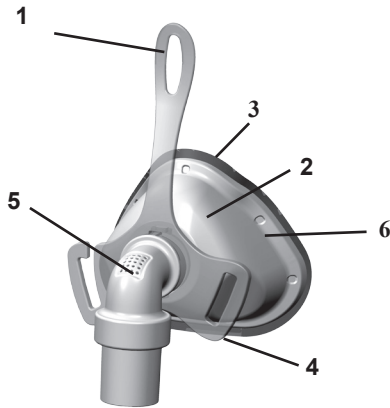
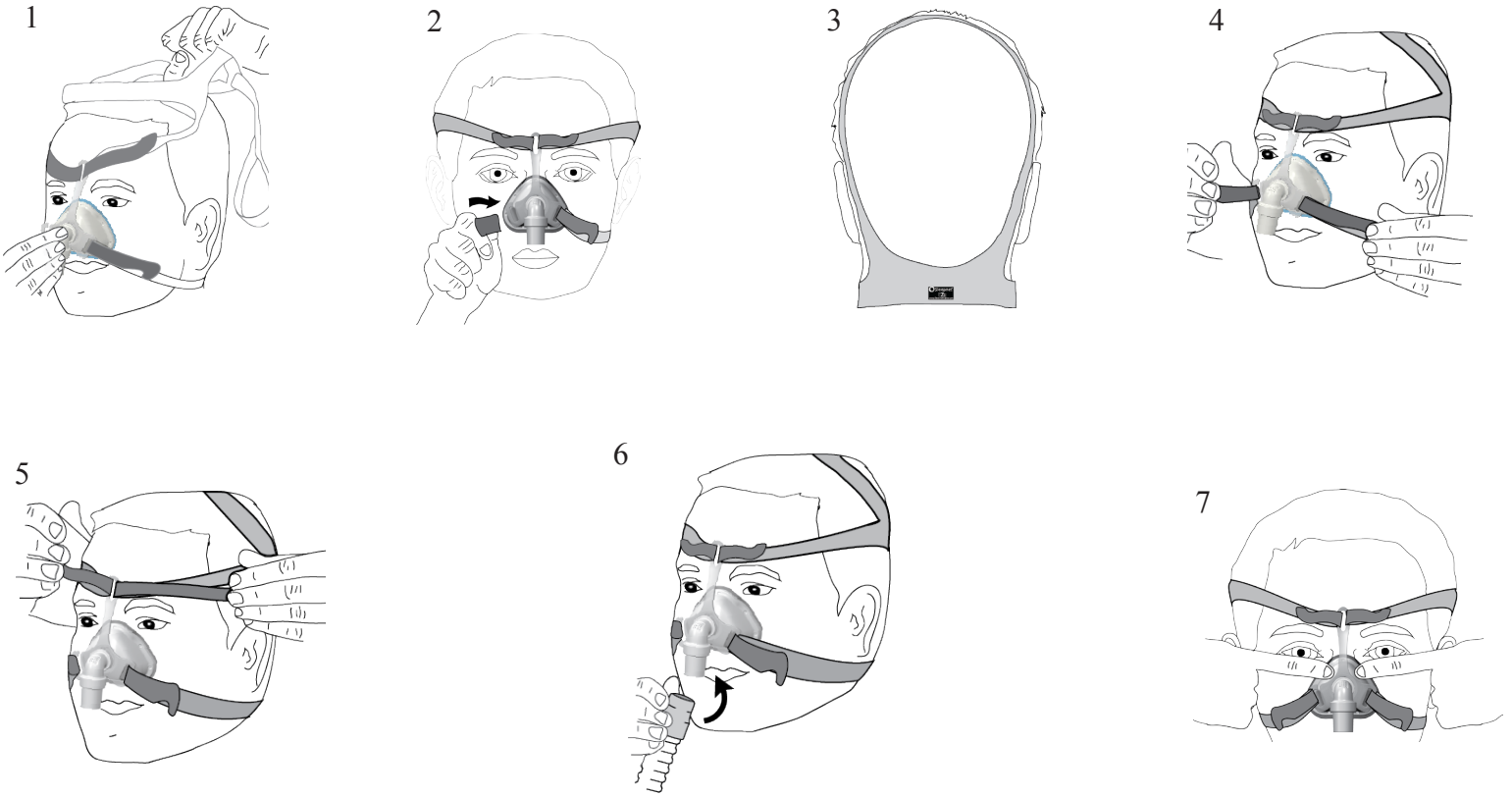


Aura™ Nasal Vented Mask

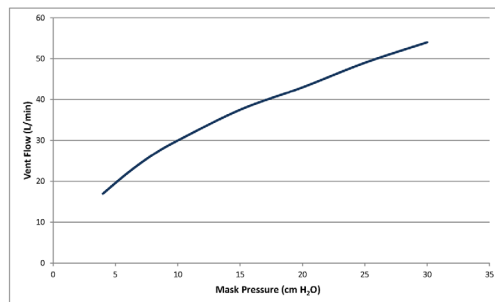


- Aura™ Mask**
1. Flexible Spacebar™
 2. Mask Shell
 3. Airgel™ Cushion
 4. Headgear Connector
 5. Vented Elbow Assembly
 6. Memory Wire™



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VENT HOLE PRESSURE/FLOW CHARACTERISTICS (Approx.)



Aura Nasal Vented Mask

Contents: Aura™ Nasal Vented Mask with headgear

Rx only

Made in the U.S.A of U.S. and imported parts



The Aura Nasal Vented Mask is intended to provide an interface for application of positive airway pressure therapy, such as Continuous Positive Airway Pressure (CPAP) or bi-level. The mask is intended for single patient, multi-use in the home, hospital, or institutional environment on adult patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

NOTES

- The mask system does not contain DEHP or phthalates. If the patient has ANY reaction to any part of the mask system, discontinue use.
- This product is not manufactured with natural rubber latex.
- An exhalation port is built into this mask so a separate exhalation port is not required.

CAUTIONS

- In the U.S., Federal Law restricts this device for sale by or on the order of a physician.
- Do not expose the mask to temperatures above 122°F (50°C).
- The mask may be cleaned and used repeatedly on the same person. Do not sterilize or disinfect.

WARNINGS

- This mask is not suitable for providing life support ventilation.
- At low pressures, the flow through the exhalation ports may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Do not use this mask with baseline pressure less than 4 cm H₂O.
- This mask should be used with the positive airway pressure device recommended by a physician or respiratory therapist.
- Do not block or try to seal the vent holes or non-rebreathing valve. The vent holes allow a continuous flow of air out of the mask.
- The mask should not be used unless the positive airway pressure device is turned on and operating properly. Explanation of the warning: When the positive airway pressure device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask's vent holes. When the positive airway pressure device is not operating, exhaled air may be rebreathed. Rebreathing of exhaled air can, in some circumstances, lead to suffocation. This warning applies to most models of CPAP machines and masks.
- If oxygen is used with this CPAP mask, the oxygen flow must be turned off when the CPAP machine is not operating. Explanation of the warning: When the CPAP device is not in operation, and the oxygen flow is left on, oxygen delivered into the device tubing may accumulate within the CPAP machine enclosure. Oxygen accumulated in the CPAP machine enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary, depending on pressure settings, patient breathing, and leak rate.
- No smoking or open flames such as candles may be used when oxygen is in use.
- Any unusual skin irritation, chest discomfort, shortness of breath, gastric distension, abdominal pain, belching or flatulence from ingested air, or severe headache experienced during or immediately after use should be reported to a healthcare professional.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult a physician or dentist.
- Consult a physician if you experience any of the following symptoms while using the mask: Drying of the eyes, eye pain, eye infections, or blurred vision. Consult an ophthalmologist if symptoms persist.
- Do not overtighten the headgear straps. Signs of overtightening include: excessive redness, sores, or bulging skin around the edges of the mask. Loosen headgear straps to alleviate symptoms.
- Significant unintentional leak may occur without properly fitting the mask.

GENERAL INFORMATION

This mask has a non-transferable three month limited warranty for manufacturer's defects from the date of purchase by the initial consumer. If a mask used under normal conditions should fail, Sleepnet will replace the mask or its components. For additional information about the Sleepnet Warranty, please visit <http://www.sleepnetmasks.com/products/our-promise.cfm>.

NOTE: Please dispose of the mask and accessories in accordance with local and regional guidelines.

CLEANING AND MAINTENANCE

Cleaning is recommended on a daily basis. Hand wash the mask and components in warm water using a mild detergent. Rinse the mask thoroughly after washing. Visually verify that the vent holes are clear and allow the mask to air dry. Washing your face prior to fitting the mask will remove excess facial oils and help extend the life of the mask.

HEADGEAR: Hand wash the headgear in warm water using mild detergent. Rinse after washing and allow to air dry.

NOTE: Inspect mask daily or prior to each use. Replace the mask if vent holes are blocked, if parts are damaged, or if gel cushion has tears or punctures.

NOTE: The gel cushion, although silky to the touch, will not tear, leak, or detach from the mask under normal use. The gel cushion is not indestructible. It will tear, cut, and rip if subjected to mishandling or abuse.

TECHNICAL INFORMATION

Resistance to air flow at 50 L/min: 0.22 cm H₂O

Resistance to air flow at 100 L/min: 0.95 cm H₂O

DEAD SPACE VOLUME (mL approx.): **Small** - 75 ml **Medium** - 82 ml **Large** - 102 ml

Operating Temperature: Do not expose the mask to temperatures above 122°F (50°C).

AURA MASK ASSEMBLY AND FITTING INSTRUCTIONS

1. Remove the mask and the headgear from the package.
 2. Place the headgear on a table, label side down with the narrowest part close to you.
 3. Set the mask with the gel side down onto the center of the headgear.
 4. Take each headgear strap and connect it to its respective location on the mask by looping the Velcro® strap through the headgear slots and attaching it back to itself.
 5. Once the headgear has been properly attached to the mask, follow the fitting tips below to fit the mask:
 6. Detach one Velcro® strap by sliding the Velcro® loop off the quick release hook, slip the headgear over the head and center the mask on the face (Figure 1).
 7. Find the detached Velcro® strap and slide the Velcro loop back on the quick release hook. (Figure 2)
 8. Be sure the headgear straps are parallel and the headgear is fully extended and flat across the back of the head. (Figure 3)
 9. Adjust the bottom headgear straps by using the tabs. After tightening, make sure the Active Headgear Connector™ can move freely. (Figure 4)
- NOTE:** Do NOT overtighten the headgear.
10. Adjust the upper headgear straps by using the tabs (Figure 5).
 11. Adjust the bottom headgear straps to make sure the bottom of the mask is sealed comfortably between the bridge of the nose and just above the upper lip.
- NOTE:** For optimal seal and comfort, the mask should be snug, but not tight. Adjust the tension by detaching the Velcro straps, tightening or loosening the straps, and reattaching the Velcro.
12. Connect the mask to the positive airway pressure device tubing and turn the device on to the prescribed pressure (Figure 6).
 13. Turn head from side to side while lying on the bed and identify areas of leak that may prevent sleep.
 14. If there are leaks, gently press along the Memory Wire™ to seal the leaks (Figure 7). Adjust the headgear straps as needed.
 15. If leaks persist despite customization of Memory Wire™ and adjustment of headgear straps, try moving the mask higher or lower around the nose to find the best fit.