



Warnings

- The SleepWeaver Advance Pediatric is a vented mask and should not be used with a dual limb ventilation circuit.
- CPAP therapy may cause nasal dryness or irritation which may be reduced with the use of a CPAP humidifier.
- If there are any reactions to any part of this mask or headgear, discontinue use immediately for the patient.
NOTE: Does not contain natural rubber latex.
- When disassembling the mask, always keep all accessories and components out of the reach of small children as small parts might present a choking hazard. Seek immediate medical attention if choking occurs or if any small parts have been swallowed.
- This system should be not be used unless the therapy device is turned on and is operating properly.
- The vent holes should never be blocked.
- If the SleepWeaver Advance Pediatric 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.
- Oxygen must not be used in the presence of an open flame, as oxygen supports combustion. Only use oxygen in well ventilated rooms. In addition, please refrain from smoking while using this product, especially if supplemental oxygen is in use.
- At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate.
- At low pressures, the flow through the ventilation holes may be inadequate to clear all exhaled gas from the tubing. As is the case with all masks, some rebreathing may occur.
- This mask is designed to obtain a leak free seal with moderate strap tension. High strap tension may lead to facial deformities with long-term use. Clinician review of patient growth patterns and the use of different styles of masks is recommended.
- The mask must be used under qualified supervision for patients who are unable to remove the mask themselves.
- The mask may not be suitable for those predisposed to aspiration.
- If the mask has been prescribed for children with serious congenital conditions or cognitive impairments, then using a device with appropriate alarms is recommended. The correct operation of the complete patient circuit, including alarms must be tested before commencing therapy.
- Using a mask may cause gum, jaw, or tooth soreness or aggravate an existing dental condition. If symptoms occur, consult the patient's physician or dentist.
- Ensure that the nasal cushion does not block the nostrils at any time during fitting or use.
- Do not leave long lengths of air tubing around the top of the patient's bed. It could twist around the patient's head or neck while sleeping.



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 SleepWeaver Advance Pediatric should not be cleaned with unapproved cleaning and disinfecting methods.
- In the USA, federal law restricts this device to sale by, or on the order of a physician.
- The SleepWeaver Advance Pediatric mask is made of moisture vapor breathable material which wicks moisture away from the patient's face by allowing moisture to evaporate into the outside environment. If the mask is noticed to be wet or damp, the humidity level within the mask may be higher than the mask material is able to pass moisture to the outside environment. Consider reducing the humidity level on the CPAP humidifier to resolve this problem.
- The mask should be cleaned every other day 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.
- The patient or caregiver should not alter the design of the mask.
- Do not place the mask in a clothes dryer.
- The SleepWeaver Advance Pediatric is for single patient use only and is not approved for clinical cleaning and disinfecting methods.
- 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.

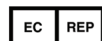
Limited Warranty

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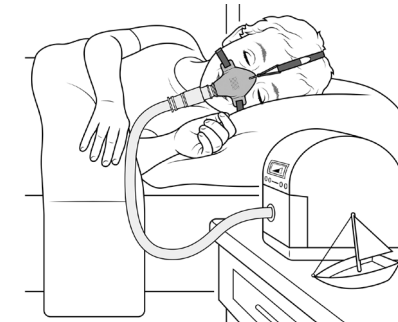
SleepWeaver

Soft Cloth Nasal CPAP Masks

Advance Pediatric

Instructions For Use

Rx Only



Introduction to Your Mask

Your SleepWeaver Advance Pediatric Mask is attached to headgear, as shown above. The headgear has five adjustment points – one on each side of the mask, one on each side of the headgear, and one on the center Head Strap. A 22mm swivel connector attaches to the hose from your CPAP or bi-level machine. **The device is for single patient use and prescription use only.**

Intended Use

The SleepWeaver Advance Pediatric Nasal Mask is intended to provide an interface for noninvasive Positive Airway Pressure (PAP) ventilation therapy. This mask is intended for single-patient use in the home and single-patient use in the hospital / institutional environment. This mask is to be used on patients between 2 and 7 years of age.

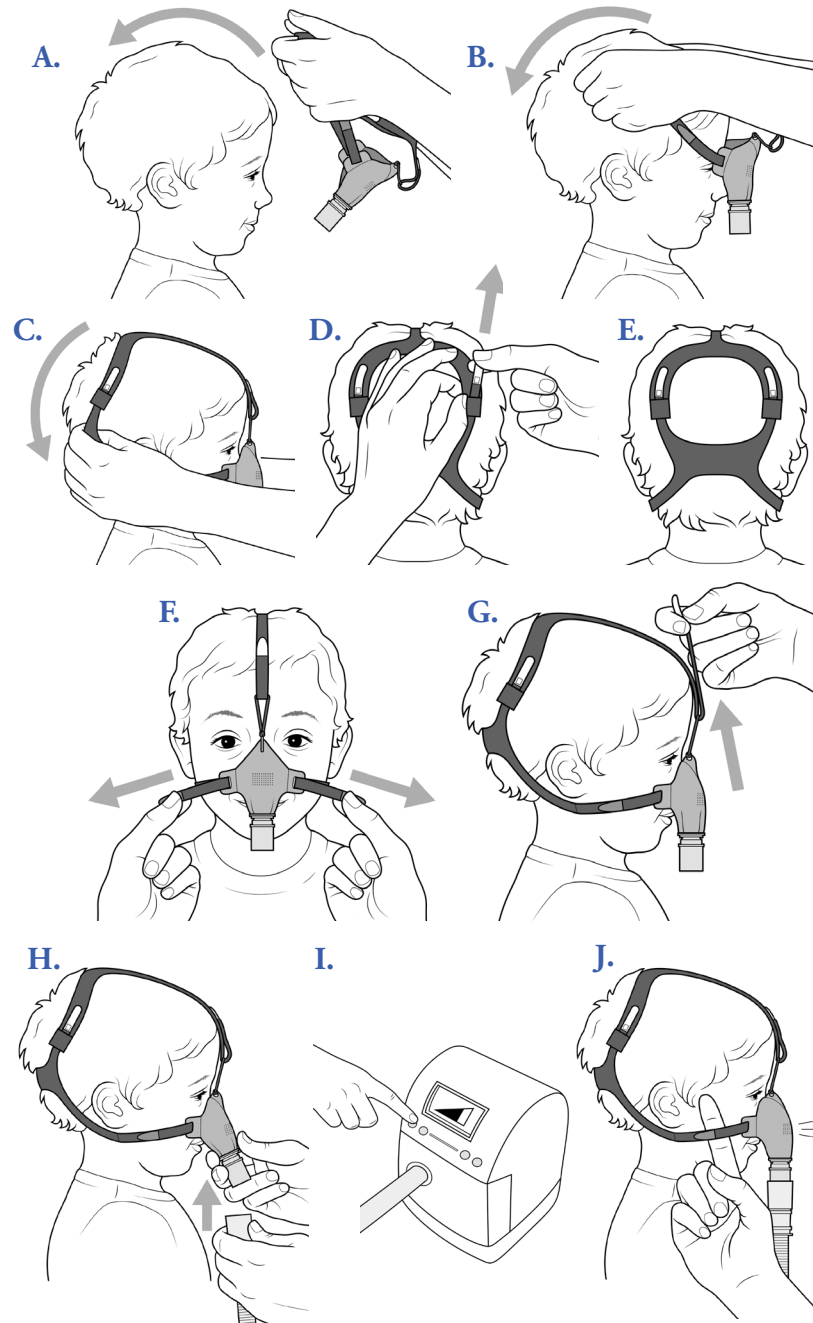
Contraindications

None

Fitting the Mask

1. Remove the SleepWeaver Advance Pediatric Mask from the packaging.
2. Hold the headgear with both hands and position the mask over the patient's nose, then pull the headgear over the patient's head. Make sure that the cup of the mask is centered over the nose and align the top front adjustment tab to the center of the head.
3. Adjust the rear headgear straps evenly so that the top loop of the headgear rests on the back of the patient's head.
4. Adjust both side straps evenly until the straps are snug just below the ears. Also adjust the center head strap so that it is snug on the patient's head. NOTE: Ensure that the mask does not block the nose or mouth at any time.
5. Connect the tubing from the CPAP or bi-level machine to the Swivel Connector on the front of the mask.
6. Turn on the CPAP or bi-level machine to the patient's prescribed pressure.
7. If there are leaks, please refer to the "Adjusting for Leaks" section.
8. The patient should then lie down in a normal sleeping position. If any leaks occur, readjust the mask.

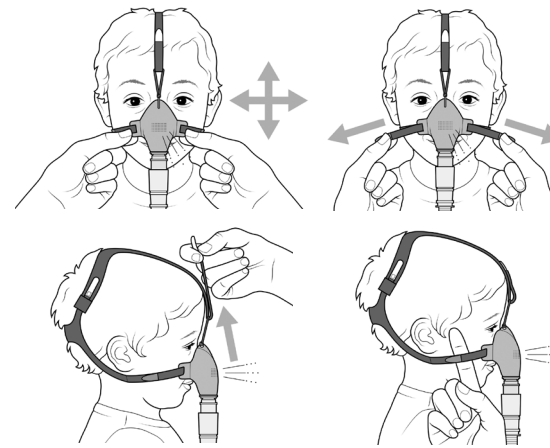
Fitting the Mask Quick Start



If there are leaks, please refer to the "Adjusting for Leaks" section.

Adjusting for Leaks

- If there are leaks, try these steps:
1. With the CPAP or bi-level machine on and at the patient's prescribed pressure, pinch the portion of the mask directly over the nose, pull the mask slightly away from the face, towards the chin, and gently release.
 2. If there are leaks from the sides of the mask, adjust the side straps by unhooking the blue tab from the strap and pulling the straps out to tighten the mask, then re-attach the tab to the strap.
 3. If the patient experiences leaks into one or both eyes, adjust the center 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 occur if the headgear straps are too tight or too loose. With practice, you should find the snug but comfortable fit that works for the patient.



SleepWeaver Advance Pediatric Mask & Headgear



Cleaning the Mask

1. The SleepWeaver Advance Pediatric 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.

Exhalation Valve

There is no jet of air with exhalation. Venting is through a series of small pinholes. The flow through the exhalation valve plus leaks from the swivel and other sources combine to give the fixed leak rate detailed in the Technical Specifications section.

Technical Specifications

1. Therapy pressure range
4 to 20 cm H₂O
2. 22mm swivel connection
3. Resistance (pressure drop)
@ 50 l/min = 0.4 cm H₂O
@ 100 l/min = 1.0 cm H₂O
4. Fixed leak rate (flow may vary due to manufacturing variation):

| Pressure(cmH20) | 4 | 5 | 10 | 15 | 20 |
|-----------------|----|----|----|----|----|
| Flow (lpm) | 14 | 16 | 25 | 33 | 40 |

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

Sound Levels

A-weighted Sound Power Level 26 dBA
A-weighted Sound Pressure Level at 1 m 18 dBA



See warnings and cautions compatibility information.

Headgear Reassembly

NOTE: You do not need to disassemble the headgear to wash it.

1. Lay the headgear on a flat surface with the white tabs facing downward and the black tab facing upward.
2. Feed one back white adjustment tab through the loop and attach the Velcro tab to the strap. This is most easily accomplished by twisting the white-tab strap so that the Velcro faces upwards and doesn't stick to the headgear as it is threaded through the loop. (see figure 1)
3. Untwist the strap so that it lays flat and will stick to the headgear strap. (see figure 2) Repeat steps 1 through 3 for remaining white tab.
4. Feed the top front adjustment tab through the elastic band on the mask and attach it to the strap.
5. Feed the two blue adjustment tabs through the mask wings and attach.

