

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 and disinfecting methods.
- The patient should clean their face prior to wearing the mask.
- The patient/caregiver 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 20cm H₂O
2. 22mm swivel connection
3. Resistance (pressure drop)
 - @ 50 lpm = 0.4 cmH₂O
 - @ 100 lpm = 1.0 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	25	33	40

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



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

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Circadiance

SleepWeaver
Skin Friendly® Masks

Advance Pediatric

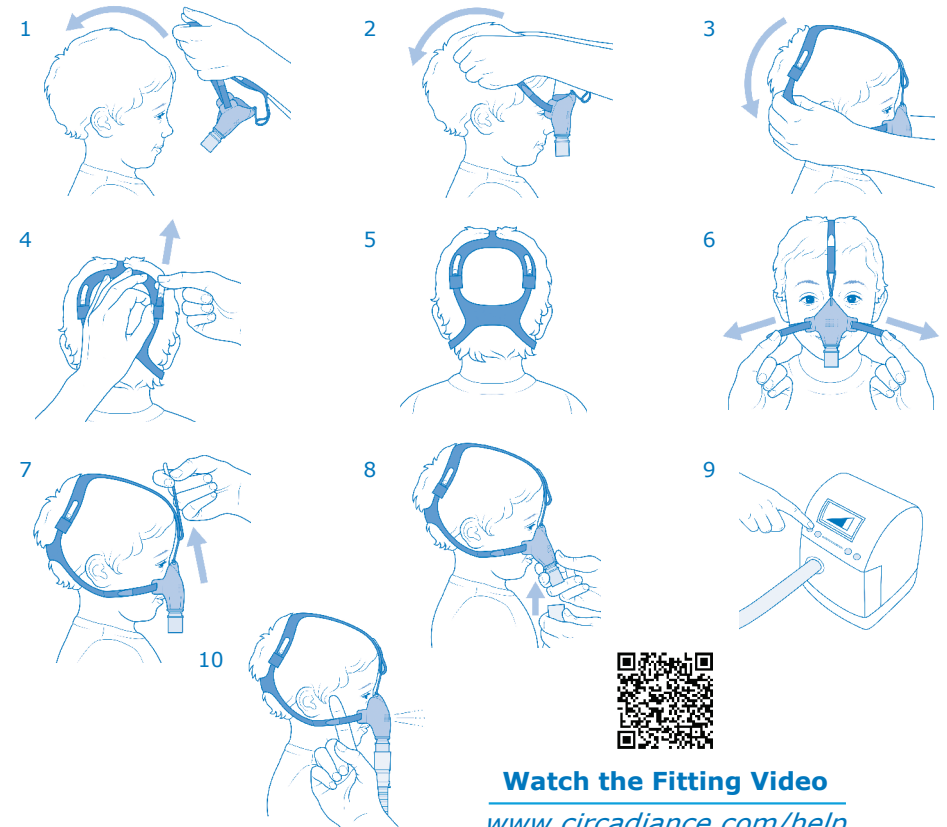
Instructions for Use

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 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.

Fitting the Mask



Watch the Fitting Video
www.circadiance.com/help



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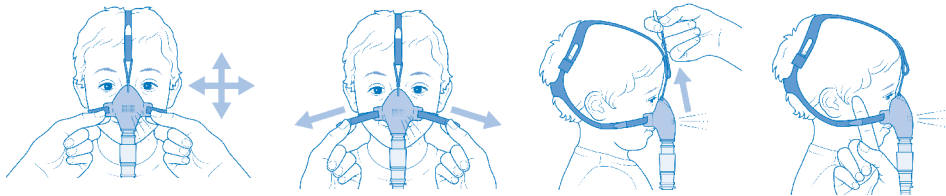
Fitting the Mask, Continued

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. 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 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.



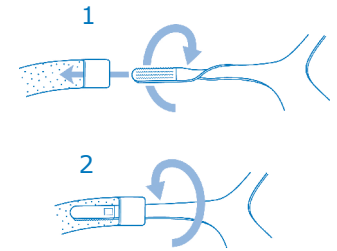
Cleaning the Mask

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. (instructions for reattaching the swivel are available online at www.circadiance.com/help)

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 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.



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.
- The SleepWeaver Advance Pediatric Mask is for single patient reuse only and is not approved for reprocessing (cleaning and disinfecting methods) in the clinical setting. For both the home and clinical setting, only the cleaning methods outlined in these instructions should be utilized.
- 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 Advance Pediatric mask and consequently the safety or quality of the therapy.
- 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.
- The 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.
- 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 the product is in use, especially if in the vicinity of supplemental oxygen therapy.
- 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.