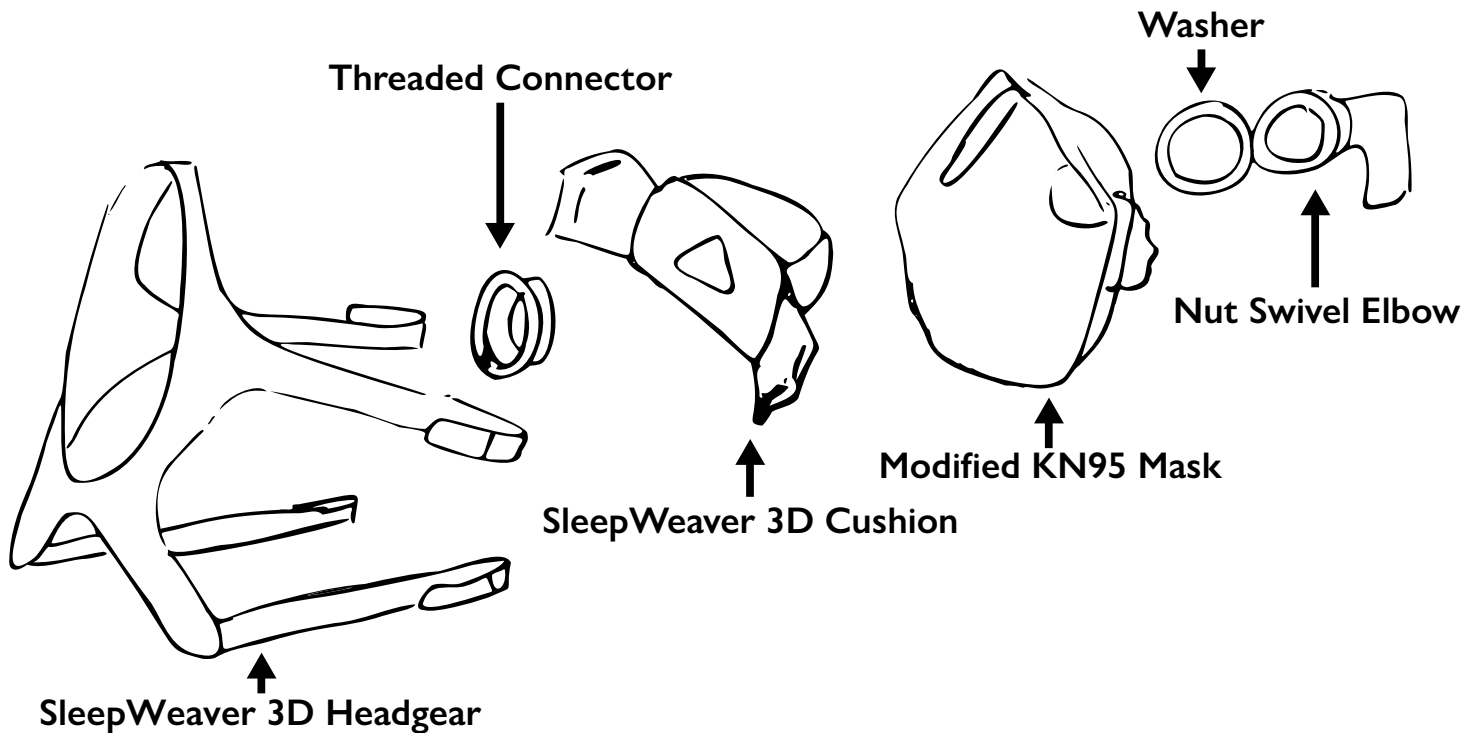


Combination Filter/CPAP Mask

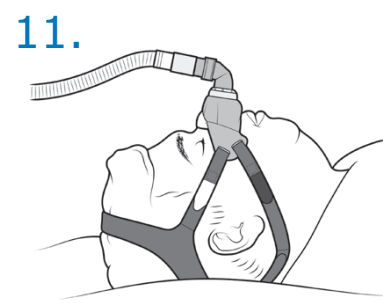
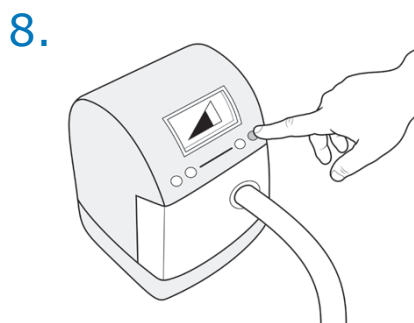
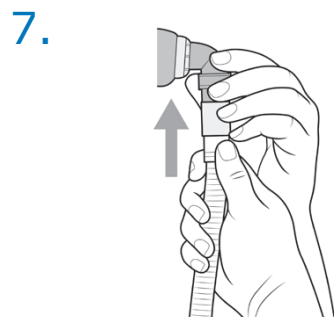
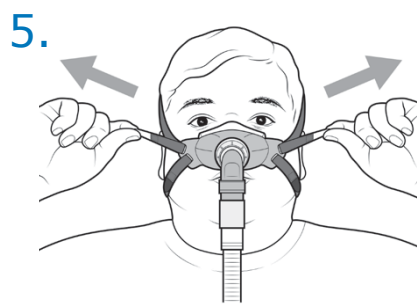
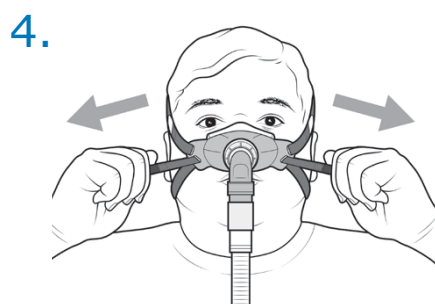
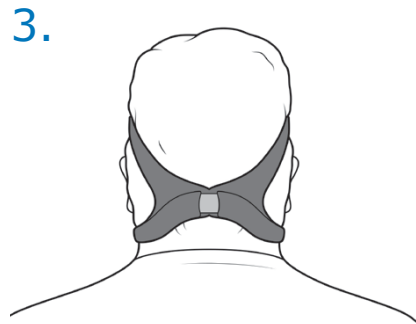
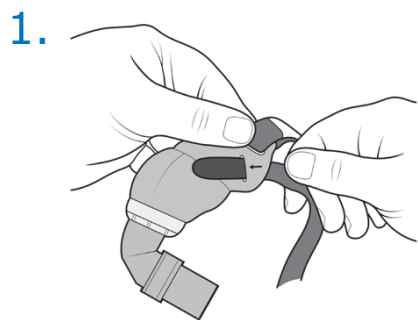


Our SleepWeaver 3D mask combined with the KN95 filter mask provides an additional level of isolation for CPAP/NIV patients with known or suspected respiratory infections.

- SleepWeaver Prevent does not prevent or treat COVID-19. The filter on SleepWeaver Prevent is intended to reduce (but cannot eliminate) exhaled aerosolized particles being spread to the environment. All people who come in contact with a patient who may have COVID-19 should use protective gear and personal hygiene to prevent the transmission of the disease;
- SleepWeaver Prevent has not been FDA cleared or approved;
- SleepWeaver Prevent has been authorized by FDA under an EUA;
- SleepWeaver Prevent is authorized only for the duration of the COVID-19 Emergency Declaration.

SleepWeaver Prevent - Quick Start Guide

*SleepWeaver Prevent comes with the CPAP mask installed.
The following instructions show the CPAP portion of the fitting.*



Intended Use

The SleepWeaver Prevent Nasal 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 single-patient reuse in the hospital / institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg). The filter mask present in SleepWeaver Prevent is intended to filter exhaled air to reduce the likelihood that the exhaled air may contaminate the room air around the person using the mask.

Fitting the CPAP Mask & Adjusting for Leaks

1. Remove Mask from packaging. If you have removed the Mask from the Headgear, re-attach the Headgear straps through the slits in the Mask wings. The black tabs will pass through the slits with a black arrow (picture 1).
2. Put Mask on by pulling the Headgear over your head so that the cup of the CPAP Mask is centered over the nose (picture 2).
3. The neck support of the Headgear should sit comfortably on the lower part of your neck (picture 3).
4. Adjust the bottom straps first so that the bottom of the CPAP Mask is comfortably resting on your upper lip just below your nostrils (picture 4).
5. Adjust the top straps to pull the Mask comfortably against your nose (picture 5).
6. Ensure Headgear is not overly tightened, you should be able to easily fit one finger under each strap of the Headgear (picture 6).
7. Connect the Tubing from the Machine to the Plastic Hose Connector on the front of the Mask (picture 7).
8. Turn on the Machine (picture 8).
9. If there are leaks, push the white interface material of the CPAP Mask down into the Mask and release the fabric. Allow the white material to blow out towards your nose to achieve a seal (picture 9).
10. You may also try to shift the Mask and/or white fabric around so that the fabric is able to form a seal against your skin. Slightly tightening or loosening the Headgear straps may also aid in obtaining a seal (picture 10).
11. Lie down in a normal sleeping position and readjust the Mask as necessary (picture 11).

Cleaning the CPAP Mask

- Hand wash the CPAP Mask and Headgear every day with a mild, nonabrasive soap in warm water. Air dry out of direct sunlight.
- The KN95 Mask Filter is not to be reused. Circadiance provides Replacement KN95 Filters for the SleepWeaver Prevent. See KN95 Filter Mask Replacement instructions.
- Replace the Filter Mask with a new KN95 Filter Mask daily. Recommend disposal in a biohazard container.

Replacing the KN95 Filter Mask

- Unscrew the Swivel.
- Remove the old KN95 Filter Mask.
- Dispose of the old KN95 Filter Mask. Recommend disposal in a biohazard container.
- Clean the CPAP mask. See Cleaning the CPAP Mask instructions.
- Replace the Filter Mask with a new Modified KN95 Filter Mask daily.
- Put the Threaded Connector through the hole in the Cushion from the inside of the Cushion.
- Put the Threaded Connector through the hole in the Modified KN95 Mask from the inside of the Mask. Be sure that the Modified KN95 Mask material is flat against the CPAP Mask Cushion and not in the threads of the Threaded Connector.
- Place the Washer over the modified KN95 Mask.
- Reattach the Swivel Nut Assembly to the Threaded Connector and screw it down until secure. Check the placement of the Modified KN95 Mask to ensure that there are no leaks or gaps between modified KN95 Mask and the Washer.
- Ensure that the top of the KN95 Mask (metal nose strip) is aligned with the top of the CPAP Mask. Note: The Headgear has white tabs on the top straps.
- Refit the CPAP Mask to the user / patient.

⚠ Warnings

- SleepWeaver Prevent does not prevent or treat COVID-19. The filter on SleepWeaver Prevent is intended to reduce (but cannot eliminate) aerosolized particles exhaled by the patient being spread to the environment. All people who come in contact with a patient who may have COVID-19 should use protective gear and personal hygiene to prevent the transmission of the disease;
- SleepWeaver Prevent has not been FDA cleared or approved;
- SleepWeaver Prevent has been authorized by FDA under an EUA;
- SleepWeaver Prevent is authorized only for the duration of the COVID-19 Emergency Declaration.
- Each patient should be monitored as appropriate; close monitoring of all patients will be critical since they may be paralyzed and sedated. Each patient should be assessed clinically, at a minimum of 15-30 minute intervals, including vital signs, oxygen saturation level, end tidal Co2, examinations of the chest for bilateral air movement, and, if indicated, assessments of arterial blood gas findings to assure clinical stability.

⚠ Further Warnings

- SleepWeaver Prevent is a vented mask and should not be used with a dual limb ventilation circuit.
- If there are any skin reactions to any part of this mask or headgear, discontinue use immediately.
- This system should be not be used unless the therapy device (CPAP or BiLevel Machine) is turned on and is operating properly.
- The vent holes should never be blocked.
- The SleepWeaver Prevent Mask is for single patient reuse only and is not approved for reprocessing (cleaning and disinfecting methods) in the clinical setting. SleepWeaver Prevent should not be used during a surgical procedure. 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 in the Quick Start Guide.
- 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.
- Please refrain from smoking while using this product.
- 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 Prevent and consequently the safety or quality of the therapy.

⚠ 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 Prevent mask 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 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.
- The portions of the mask that touch the skin are the CPAP Mask and Headgear, and the KN95 Mask and Ear Loops.
- In the USA, federal law restricts this device to sale by, or on the order of, a physician.
- Additionally: The following documents will be included in each mask package.
- Fact Sheet for Healthcare Providers: Emergency Use of Ventilators During the COVID-19 Pandemic
- Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

Contraindications

- None

Technical Specifications

1. Therapy Pressure range 4 to 20 cm H₂O
2. 22mm swivel connection
3. Resistance (pressure drop)
 - @ 50 lpm = 0.3 cm H₂O
 - @ 100 lpm = 0.5 cm H₂O
4. Fixed leak rate (flow may vary due to manufacturing variation):

Pressure (cm H ₂ O)	4	5	10	15	20
Flow (lpm)	18	21	32	41	50

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

6. Sound Levels

A-weighted Sound Power Level, 26dBA

A-weighted Sound Pressure Level @ 1m, 18dBA

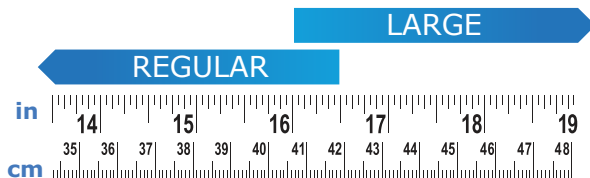
7. The Sleepweaver Prevent is expected to remain suitable for use under normal usage, cleaning conditions, and replacement of filters for a time period of at least 90 days.

8. This device is not made with natural rubber latex.

If your neck size (circumference) is 17" or less, then you can use the Mask with Regular Headgear. If your neck size (circumference) is 16" or more, then you can use the Mask with Large Headgear.

SleepWeaver Prevent
Neck Sizing Guide

Not actual size
Use cloth tape measure



Watch the SleepWeaver 3D Quick Fit Video Online for help with fitting the CPAP mask portion of the SleepWeaver Prevent:
www.circadiance.com/preventvideos

Reorder Information

101743	SleepWeaver Prevent Mask & Regular Headgear
101744	SleepWeaver Prevent Mask & Large Headgear
101745	SleepWeaver Prevent Replacement KN95 Filter Mask Pack of 10