

SleepWeaver[®] 3D

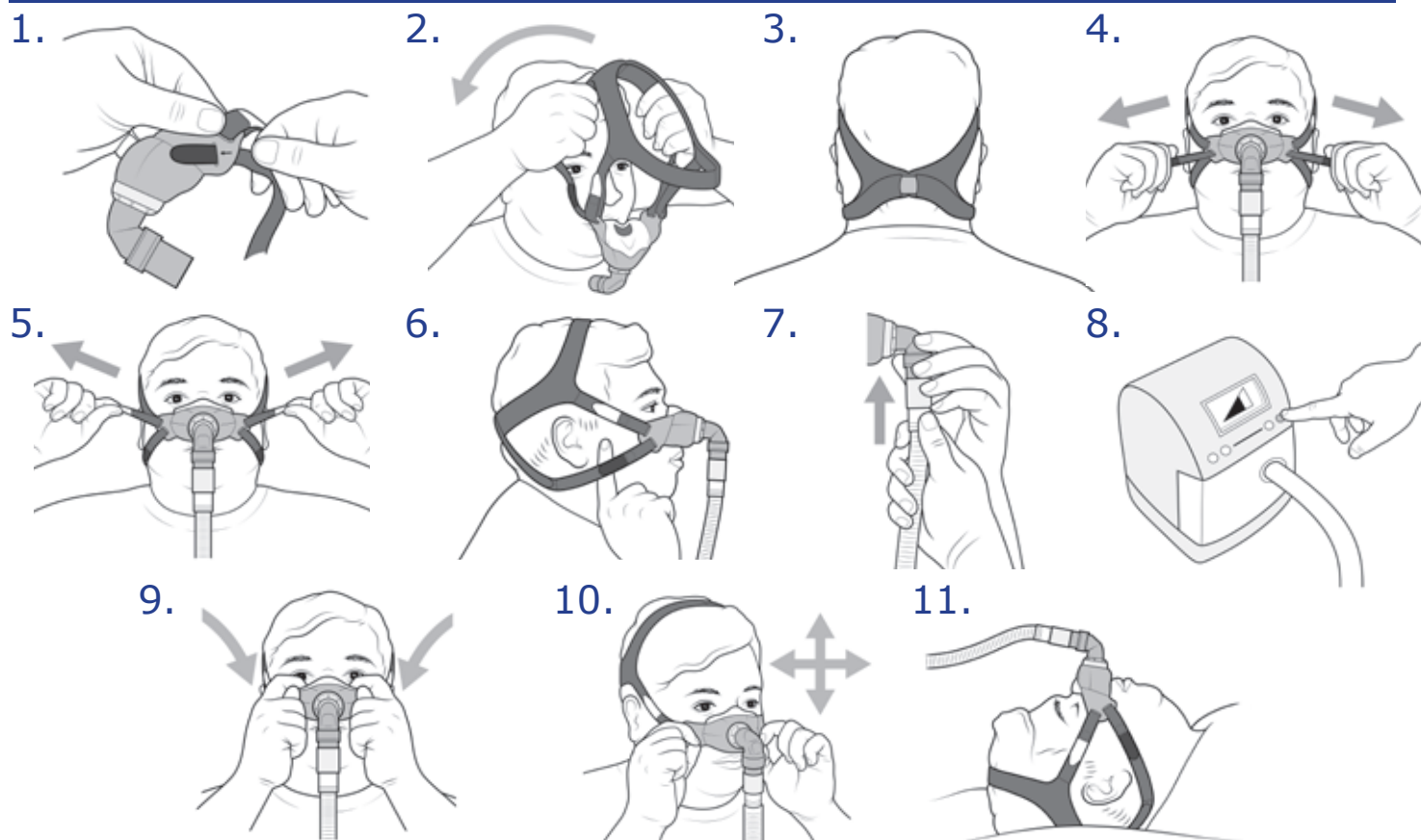
Soft Cloth Nasal PAP Mask

Instructions for Use

Intended Use

The SleepWeaver 3D 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 greater than 66 lbs (30 kg).

SleepWeaver 3D - Quick Start Guide



Fitting the Mask & Adjusting for Leaks:

- 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).
- Put mask on by pulling the headgear over your head so that the cup of the mask is centered over the nose (picture 2).
- The neck support of the headgear should sit comfortably on the lower part of your neck (picture 3).
- Adjust the bottom straps first so that the bottom of the mask is comfortably resting on your upper lip just below your nostrils (picture 4).
- Adjust the top straps to pull the mask comfortably against your nose (picture 5).
- Ensure headgear is not overly tightened, you should be able to easily fit one finger under each strap of the headgear (picture 6).
- Connect the tubing from the machine to the plastic hose connector on the front of the mask (picture 7).
- Turn on the machine (picture 8).
- If there are leaks, push the white interface material down into the mask and release the fabric. Allow the white material to blow out towards your nose to achieve a seal (picture 9).
- 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).
- Lie down in a normal sleeping position and readjust the mask as necessary (picture 11).

Cleaning the Mask

- Hand wash the mask every other day with a mild, nonabrasive soap in warm water. Air dry.
 - Hand wash the headgear weekly.
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⚠ Warnings

- The SleepWeaver 3D 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.
 - 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.
 - The SleepWeaver 3D Mask is for single patient use only and is not approved for clinical cleaning and disinfecting methods.
 - 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.
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⚠ 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 3D mask should not be cleaned with unapproved cleaning and disinfecting methods.
 - The mask should be cleaned every other day 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.
 - In the USA, federal law restricts this device to sale by, or on the order of, a physician.
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Contraindications

- None
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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)	17.7	20.5	31.7	41.3	50.2

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
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