Intended Use

The Wisp Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Notes:

- An exhalation port is built into this mask so a separate exhalation port is not required.
- This mask does not contain natural rubber latex or DEHP.
- Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbol:

- Warning or Caution
- Note
- Tip
- Does Not Contain Natural Rubber Latex

Warnings:

- This mask is not suitable for providing life support ventilation.
- Hand wash prior to use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- Consult a physician if you encounter tooth, gum, or jaw soreness. Use of a mask may aggravate an existing dental condition.
- Consult an ophthalmologist if symptoms persist.
- The mask material should be away from your eyes.
- Do not block or seal off the exhalation ports.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, sores, or bulging skin around the edges of the mask. Loosen the headgear straps to alleviate discomfort.
- When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accelerated in the device enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure setting, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating.
- Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vents to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to all masks with CPAP and bi-level systems.
- If it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.
- Do not block or seal off the exhalation ports.
- This mask is not suitable for providing life support ventilation.

Specifications

- Warning: The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.
- Caution: This mask is not suitable for providing life support ventilation.

Pressure Flow Curve

Notes:

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Warning:

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Note:

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Tip:

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Does Not Contain Natural Rubber Latex

Table:

<table>
<thead>
<tr>
<th>Deadspace Volume</th>
<th>P</th>
<th>S/M</th>
<th>L</th>
<th>XL</th>
<th>50 SLPM</th>
<th>100 SLPM</th>
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</thead>
<tbody>
<tr>
<td>P</td>
<td>17 mL</td>
<td>49 mL</td>
<td>73 mL</td>
<td>85 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S/M</td>
<td>49 mL</td>
<td>73 mL</td>
<td>85 mL</td>
<td>100 mL</td>
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Notes:

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Warning:

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Note:

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Tip:

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Does Not Contain Natural Rubber Latex

Limited Warranty

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the “Product”) shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the “Warranty Period”). If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is non-transferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty. This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship. This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics.

Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

To exercise your rights under this limited warranty, contact your local authorized Respironics, Inc. dealer or Respironics, Inc. at 1001 Murray Ridge Lane, Murrysville, Pennsylvania 15668; 1-800-345-6443 (USA and Canada only) or 1-724-878-4000.
Before Use Read and Understand the Instructions Completely.

- Hand wash the entire mask.
- Wash your face. Do not use moisturizer/lotions on your hands or face.
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.

Cleaning Instructions
Hand wash the mask before first use and daily. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

- **Caution:**
  - Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
  - Any deviation from these instructions may impact the performance of the product.
  - Inspect the mask for damage or wear (cracking, crazing, tears, etc.). Discard and replace any components as necessary.
  - Rinse thoroughly. Air dry completely before use. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.

Institutional Disinfection
For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/respiratory or by contacting Philips Respironics Customer Service at 1-800-345-6443 (USA or Canada), or at 1-724-387-4000.

Achieving the Right Fit

- **Note:** Do not overtighten the headgear.

Before Putting on the Mask
1. Sizing: Select the cushion that fits the width of your nose without blocking your nostrils. The top of the cushion may sit between the bridge and tip of your nose.

Putting on the Mask
2. Headgear tab or clip: Disconnect one, or both. Peel the headgear tabs away from the headgear strap and pull through slot in the mask frame or if using the clip twist outward.
3. Headgear: Pull the headgear on over your head.
4. Cushion: Place the cushion over your nose.
5. Headgear tab or clip: Thread tab through slot in the mask frame or press the clip against the headgear slot to reattach.
6. Headgear: Peel the headgear tabs away from the headgear straps then press tabs against the headgear straps to reattach.
   - Connect the side strap to the headgear tab located at the base of the crown strap.
   - Connect the bottom strap tab near the back of the headgear.
7. Headgear: Adjust the side straps evenly.
8. Headgear: Adjust the bottom straps evenly.
   - The mask should rest comfortably against your face.

Using Tube Management (Optional)
You may position the tube over your head.

Using the Mask
9. Slide the mask tubing through the headgear crown loop before attaching the flexible tubing.

Using the Mask
10. Connect the flexible tubing (included with your CPAP or bi-level device) to the swivel.
11. Turn the therapy device on. Lie down. Breathe normally.
12. Assume different sleeping positions. Move around until comfortable. If there are any excessive air leaks, make final adjustments. Some air leaking is normal.

- **Comfort Tips:**
  - The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If your skin bulges around the mask or if you see red marks on your face, loosen the headgear.
  - Re-seat the mask by pulling it directly away from your face and gently setting it back into place.
  - Adjust the side headgear straps to reduce leaks around your eyes.