

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.

Symbols



Warning
or
Caution



Note



Tip



Does Not Contain
Natural Rubber Latex

X1

System One Resistance Control

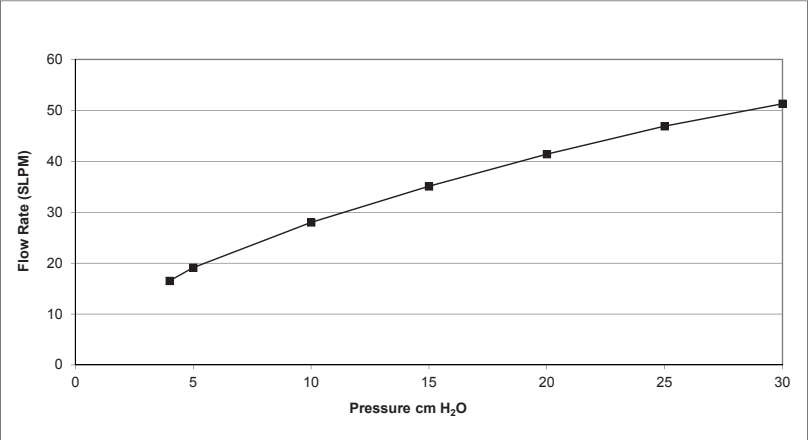
Warnings

- 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 or dentist if you encounter tooth, gum, or jaw soreness. Use of a mask may aggravate an existing dental condition.
- Consult a physician if you experience the following symptoms while using the mask or after removing it: Drying of the eyes, eye pain, eye infections, or blurred vision. 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 symptoms.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port. **Explanation of the Warning:** CPAP systems are intended to be used with special masks with connectors which have vent holes 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, enough 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 most models of CPAP systems.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. **Explanation of the Warning:** 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 accumulated 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 settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- At low CPAP or EPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.

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.

Pressure Flow Curve



Resistance

Drop in Pressure at

	50 SLPM	100 SLPM
All sizes	0.8 cm H ₂ O	3.2 cm H ₂ O

Deadspace Volume

P	37 mL
S/M	49 mL
L	73 mL
XL	85 mL

Sound Levels

A-weighted Sound Power Level 27 dBA

A-weighted Sound Pressure Level at 1 m 19 dBA

Disposal

Dispose of in accordance with local regulations.

Storage Conditions

Temperature: -4° to 140° F (-20° to +60° C)

Relative Humidity: 15% to 95% non-condensing

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.

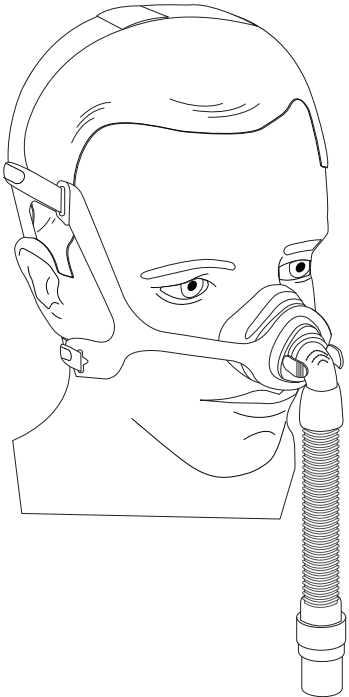
THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME STATES DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY 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 Murry Ridge Lane, Murrys ville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

PHILIPS
RESPIRONICS

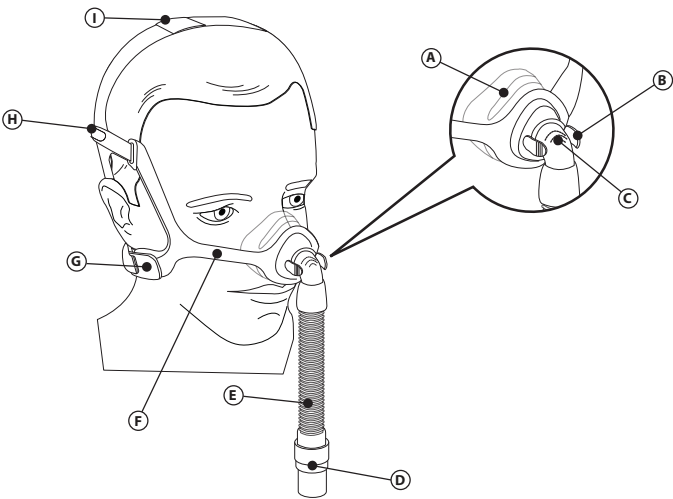
Instructions for Use

Wisp Nasal Mask



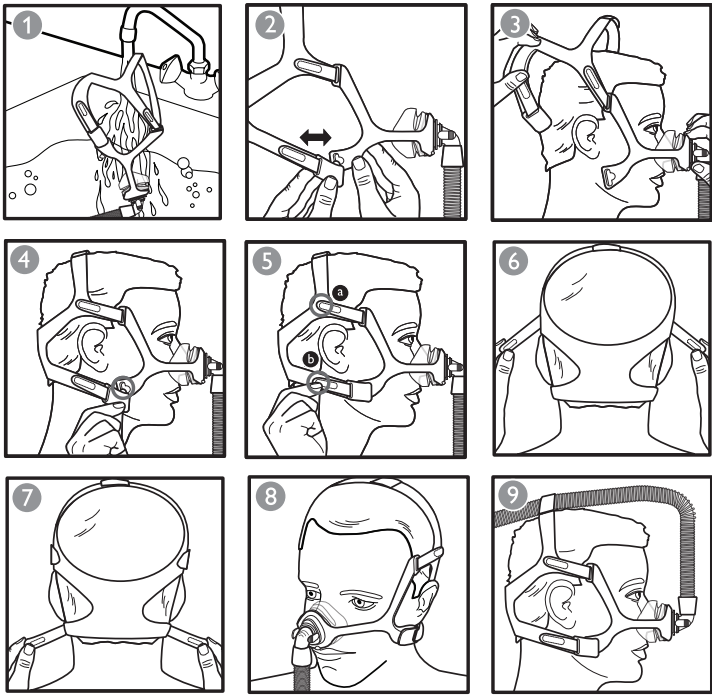
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA

Features

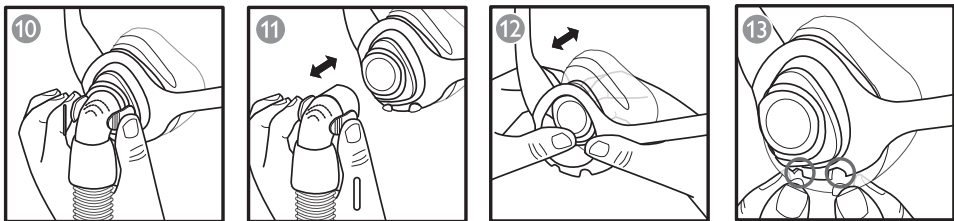


- A Mask Cushion
- B Quick Release Tabs
- C Elbow with Built-in Exhalation (do not block ports or vents)
- D Swivel
- E Tubing
- F Mask Frame (clear or reversible fabric)
- G Headgear Bottom Strap (shown with headgear clips)
- H Headgear Side Strap
- I Headgear Crown Loop for Tube Management

Cleaning / Fitting



Disassembly / Assembly



Before Use Read and Understand the Instructions Completely.

- Hand wash the entire mask 1.
- Wash your face. Do not use moisturizer/lotion 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.

- Hand wash the mask and headgear in warm water with a liquid dish washing detergent.

⚠Cautions:

- 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/respironics 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

- 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

- Headgear tab or clip: Disconnect one, or both 2. Peel the headgear tabs away from the headgear strap and pull through slot in the mask frame or if using the clip twist outward.
- Headgear: Pull the headgear on over your head 3.
- Cushion: Place the cushion over your nose.
- Headgear tab or clip: Thread tab through slot in the mask frame or press the clip against the headgear slot to reattach 4.

Adjusting the Mask

- Headgear: Peel the headgear tabs away from the headgear straps then press tabs against the headgear straps to reattach 5.
 - 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.
 - Headgear: Adjust the side straps evenly 6.
 - Headgear: Adjust the bottom straps evenly 7.
- The mask should rest comfortably against your face 8.

Using Tube Management (Optional)

You may position the tube over your head.

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

Using the Mask

- Connect the flexible tubing (included with your CPAP or bi-level device) to the swivel.
- Turn the therapy device on. Lie down. Breathe normally.
- 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.

Removing the Mask

Disconnect a bottom headgear clip. Slide the headgear forward over your head.

Disassembly

Removing the Elbow and Tubing

- Squeeze the Quick Release Tabs 10.
- Pull the elbow away from the cushion 11.

Removing the Cushion

Push the cushion backwards through the frame 12.

Removing the Headgear

- Detach the headgear bottom clips from the frame or undo the bottom tabs and pull.
- Undo the headgear top tabs and pull the straps through the frame.

Assembly

Reversible Fabric Frame

Choose the fabric that feels comfortable against your skin. That side will face inward toward the cushion and headgear. The clear frame is not reversible.

Attaching the Cushion

- Push the cushion into the frame towards the front and press into place 12.
- The bottom of the cushion will match the alignment cutouts of mask frame 13.

Attaching the Elbow and Tubing

Push the elbow into the cushion until the Quick Release Tabs click into place 11.

Attaching the Headgear

- Hold the crown strap upward.
- Make sure the wide strap marked with “Philips Respironics” is outward.
- Slide the headgear tabs into the longer frame arm slots.
- Connect the headgear clips to the frame or slide the tabs into the shorter frame arm slots if not using the headgear clips.

System One Resistance Control

Your mask when combined with a Philips Respironics System One device, provides optimal resistance compensation. This mask value is X1 and should be set by your provider.

⚠ Notes:

- Compare the mask to the device. See your device manual if the values do not match.
- System One is not compatible with masks that use a separate exhalation device.