

PHILIPS

RESPIRONICS

Instructions for Use

Wisp Nasal Mask

Intended Use

The Wisp Youth 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 7 years or older (>40 lbs/18kg) for whom CPAP or bi-level therapy has been prescribed.

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:

- Exhalation is built into this mask so a separate exhalation device is not required.
- This mask is not made with 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



Not Made with Natural Rubber Latex

X1 System One Resistance Control

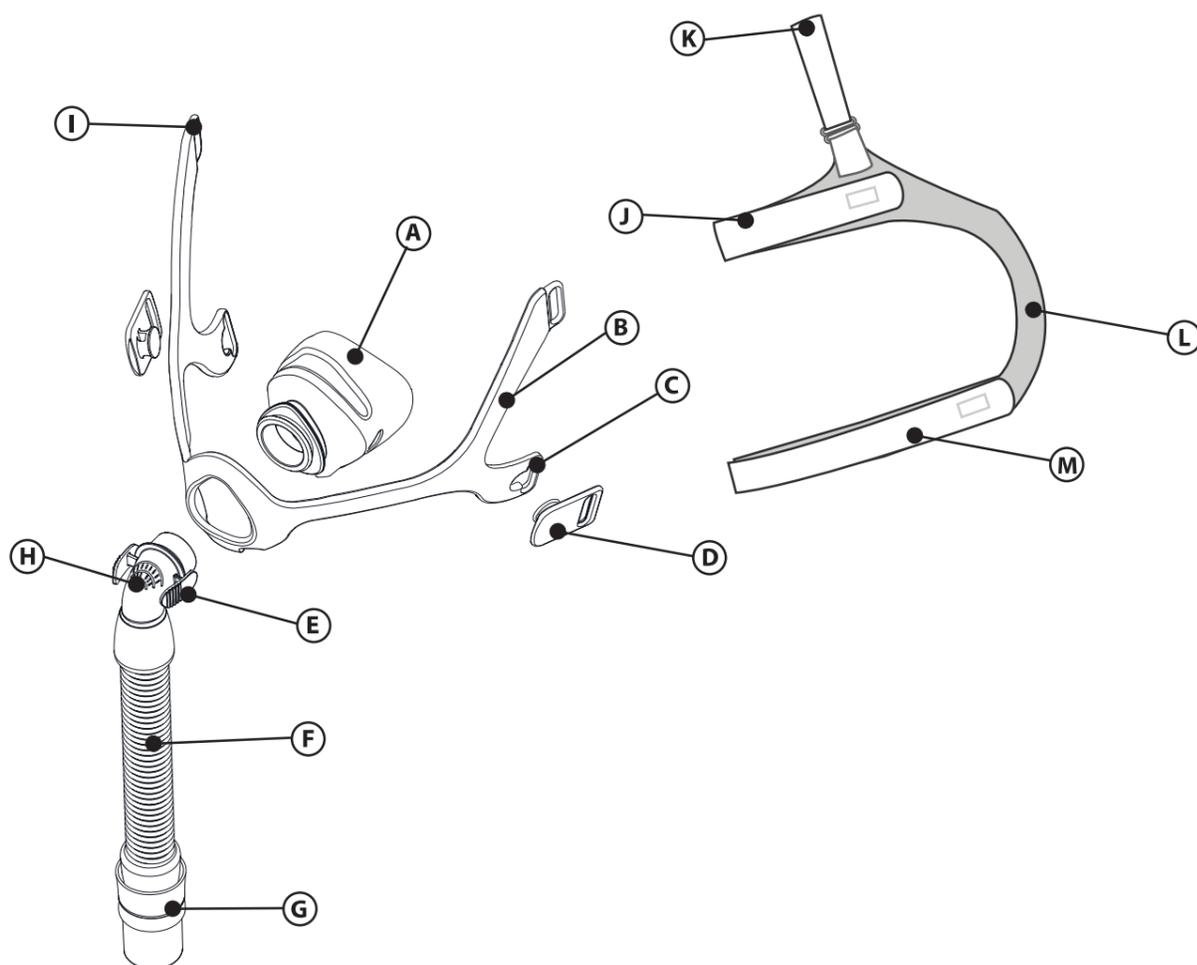
Warnings

- 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.

Features



- (A) Mask Cushion
- (B) Mask Frame (clear or fabric)
- (C) Frame Bottom Slot
- (D) Headgear Clip
- (E) Quick Release Tabs
- (F) Tubing Assembly
- (G) Swivel
- (H) Elbow with Built-in Exhalation (do not block)
- (I) Frame Top Slot
- (J) Headgear Top Strap
- (K) Headgear Crown Strap with Loop for Tube Management (optional)
- (L) Headgear Back Strap
- (M) Headgear Bottom Strap

Before Use Read and Understand the Instructions Completely.

- Hand wash the entire mask ①.
- Wash face. Do not use moisturizer/lotion on hands or face.
- Inspect the mask. Replace the cushion if hardened or torn. Replace any parts that are broken or worn.

Cleaning Instructions

Daily: Hand wash the non-fabric parts.

Weekly: Hand wash the fabric parts.

1. Wash in warm water with liquid dishwashing detergent.
2. Rinse thoroughly.
3. Air dry completely before use.

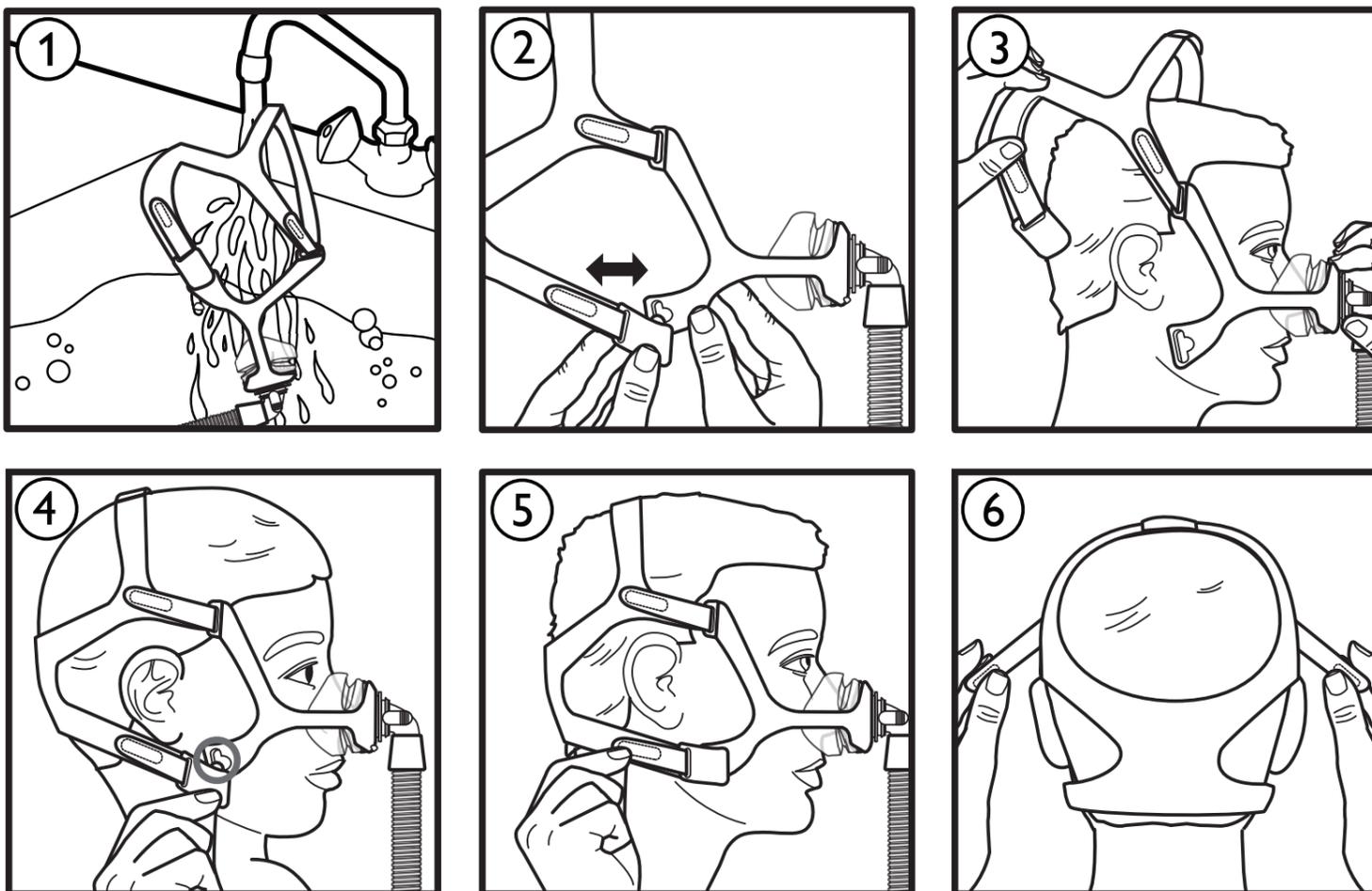
⚠ Cautions:

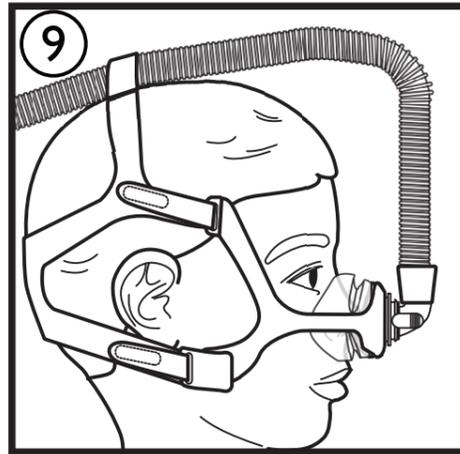
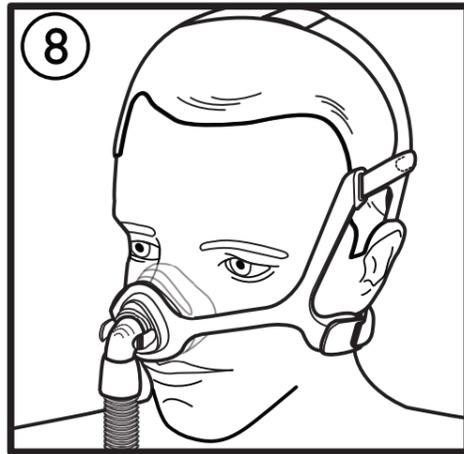
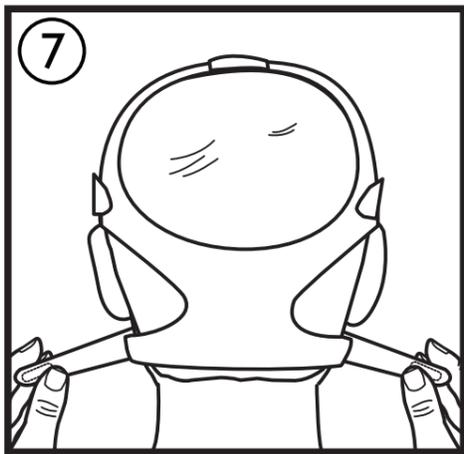
- Do not clean the mask with bleach, alcohol, solutions containing bleach or alcohol, or solutions containing conditioners or moisturizers.
- Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- Any deviation from these instructions will impact the performance of the product.

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 contacting Philips Respironics Customer Service at 1-800-345-6443 (USA or Canada) or at 1-724-387-4000.

Achieving the Right Fit





Before Putting on the Mask

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

Putting on the Mask

2. 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.
3. Headgear: Pull headgear on over head (3).
4. Cushion: Place cushion over nose.
5. Headgear tab or clip: Thread tab through slot in mask frame or press clip against the headgear slot to reattach (4).

Adjusting the Mask

6. Headgear: Peel the headgear tabs away from the headgear straps then press tabs against the headgear straps to reattach (5).
 - a Connect the side straps to the headgear tab located at the base of the crown strap.
 - b Connect the bottom strap tabs near the back of the headgear.
 7. Headgear: Adjust side straps evenly (6).
 8. Headgear: Adjust bottom straps evenly (7).
- The mask should rest comfortably against face (8).

Note: Do not overtighten the headgear.

Using Tube Management (Optional)

The flexible tubing may be placed over head.

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

Using the Mask

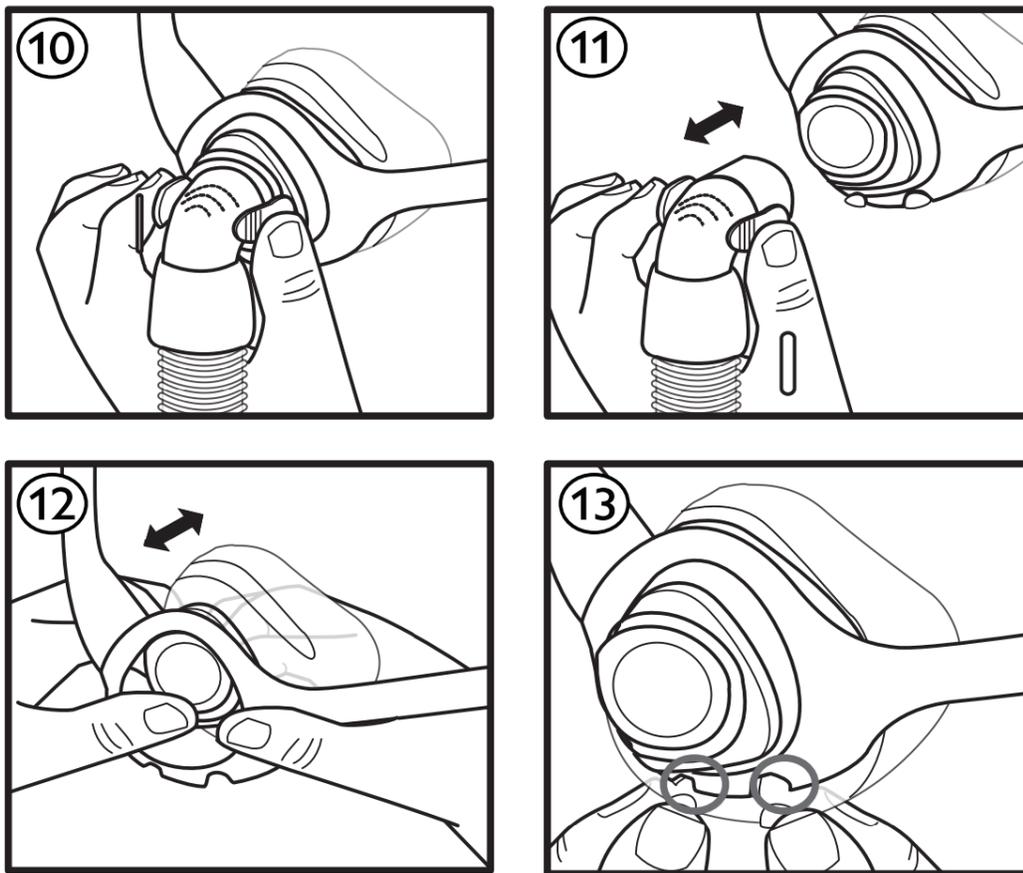
10. Connect the flexible tubing (included with the CPAP or bi-level device) to the swivel.
11. Turn the therapy device on. Lie down. Breathe normally.
12. Assume different sleeping positions. Move around until comfortable. If there are any excessive air leaks, make final adjustments. Some air leaking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

✳ Comfort Tips

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

Removing the Mask

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



Reversible Fabric Frame

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

Removing the Elbow and Tubing

1. Squeeze the Quick Release Tabs (10).
2. Pull the elbow away from the cushion (11).

Removing the Cushion

Push the cushion backwards through the frame (12).

Removing the Headgear

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

Attaching the Cushion

1. Push the cushion into the frame towards the front and press into place (12).
2. 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

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

Philips Respironics System One Resistance Control

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

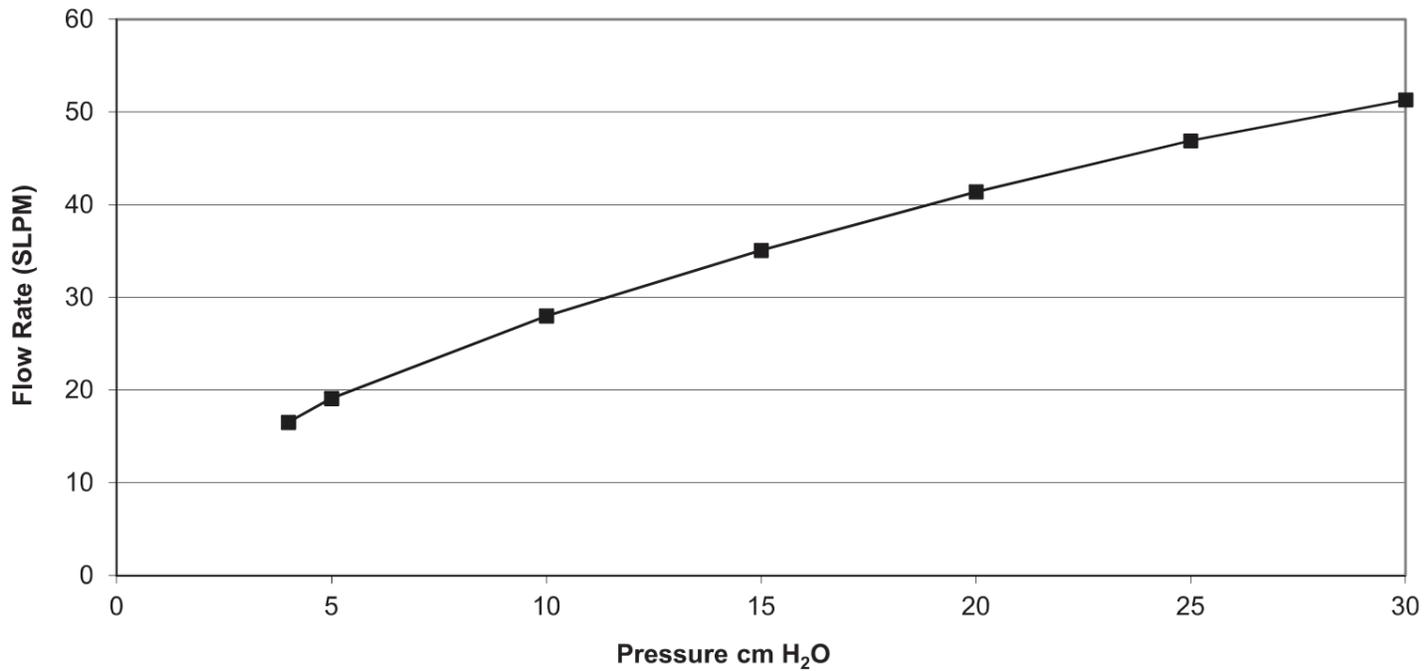
⊖ Notes:

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

Specifications

⚠ Warning: The technical specifications of the mask are provided for the healthcare professional to determine if it is compatible with the 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 (adult only)	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, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Mode d'emploi - Français-CA

Masque nasal Wisp

Usage préconisé

Le masque nasal Wisp Youth sert d'interface pour l'application d'un traitement par PPC ou à deux niveaux aux patients. Il est destiné à un usage unique à domicile ou à un usage multipatient dans un établissement hospitalier ou une institution spécialisée. Le masque est réservé aux patients âgés d'au moins 7 ans (> 18 kg/40 lb) auxquels un traitement par pression positive ou à deux niveaux a été prescrit.

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Remarques :

- Une valve d'expiration étant intégrée au masque, aucune valve d'expiration séparée n'est nécessaire.
- Ce masque n'est pas fabriqué avec du latex naturel ou du DEHP.

Symboles



Avertissement ou mise en garde



Remarque



Conseil



Fabriqué sans latex naturel

X1

Contrôle de résistance System One