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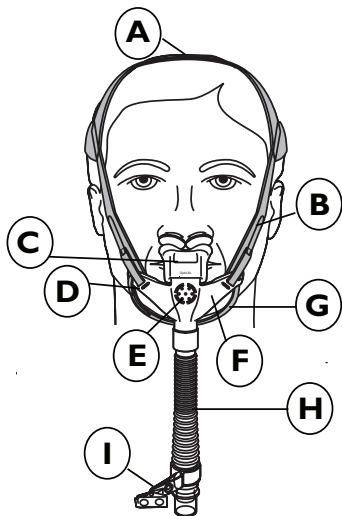
OptiLife  
Instructions for Use

**PHILIPS**  
RESPIRONICS

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# OptiLife Nasal Mask



◀ Figure 1

- A = Top Strap
- B = Side Strap
- C = Cushion
- D = Headgear Slots
- E = Exhalation Port (Do not block)
- F = Mask
- G = Support Band
- H = 6" Tube
- I = Tube Management Clip

**CAUTION**

*US federal law restricts this device to sale by or on the order of a physician.*

## Intended Use

The OptiLife 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 and 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.



**Important Note:** An exhalation port is built into the OptiLife Nasal Mask so a separate exhalation port is not required.

## Warnings:

- This mask is not suitable for providing life support ventilation.
- 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. This warning applies to most models of CPAP systems.
- If oxygen is used with the device, the



### Warning

A warning indicates the possibility of injury to the user or operator.



### Caution

A caution indicates the possibility of damage to the device.









### Note

A note places an emphasis on an operating characteristic.

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.

- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- 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.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- 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.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.

## Symbols

Symbol	Description
	General Caution or Warning
	Consult instructions for use
	Note
	Tip
	System One Resistance Control Setting
	Does not contain natural rubber latex

## Before Use

- Hand wash mask.
- Read and understand the instructions completely.
- Remove the Quick Fit Tips from the headgear.
- Clean your face before wearing the mask.

## 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.

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

**⚠ Caution:** Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.



For **multi-patient use** in the hospital/institutional environment, use the Mask Cleaning and Disinfection Instructions to reprocess the mask between patients. These instructions can be obtained by visiting [www.sleepapnea.com](http://www.sleepapnea.com) or contacting Respirationics Customer Service at 1-724-387-4000 or Respirationics Germany at +49 8152 93060.


### Dishwashing Instructions

In addition to hand washing, the mask may be cleaned in the dishwasher once a week.

 **Caution:** Use a mild liquid dish washing detergent only.

1. Remove the headgear. Do not wash the headgear in the dishwasher.
2. Separate the cushion and the faceplate and wash in the top shelf of the dishwasher.
3. Air dry. Make sure the mask is dry before use.
4. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

## System One Resistance Control

This mask uses the System One Resistance Control setting (e.g., X1). The following symbol may appear on your therapy device (e.g.,  ← X1). This represents the level of mask resistance compensation. Match the setting to the mask if appropriate.

Pillows		Cradle Cushion	
P	X3	S	X1
S	X4	M	X1
M	X2	LN	X1
L	X1	L	X1

### Important Notes:

- Verify the System One setting if the mask or mask cushion changes.
- The System One setting is not compatible with masks requiring a separate/additional exhalation device.

If your provider has locked the resistance compensation setting, you can view the setting but cannot change it, and the screen will display a lock symbol. If your provider has disabled the resistance compensation, you will not see this setting.

## Attaching the Cushion

Your mask may come with a Cradle Cushion in addition to the Pillows Cushion. Both cushions attach to the mask in the same way.

1. Look at the markings on the cushion to determine the correct placement of the cushion onto the attachment hub (Figure 2). The OptiLife name should be on the front (away from your face) and the arrows on the cushion and mask should be on the inside (closer to your face).
2. To attach a cushion, place one of the cushion attachment holes over the appropriate post, pull the cushion over the cushion attachment hub, and attach the other side in the same manner (Figure 3). The cushion will stretch without tearing.
3. To remove a cushion, simply peel it off of the cushion attachment hub. For best results, grab the bottom of one side of the cushion near the attachment post and pull the cushion over the hub.

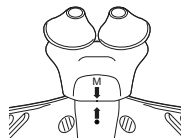


Figure 2

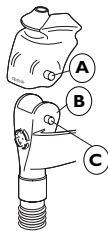


Figure 3

A = Hole

B = Cushion Attachment  
Hub

C = Post

## Sizing the Pillows Cushion

The OptiLife Pillows Cushions are available in multiple sizes to provide the most comfortable fit and to deliver the best therapy. To determine which size to use, select a cushion that fills your nostrils comfortably without any gaps between the cushion and the walls of your nostrils.

1. Rotate the pillows cushion so it is at an angle (approximately 45°) with the cushion attachment hub before inserting it into your nose (Figure 4).
2. Place the pillows cushion into your nostrils. Your chin should rest comfortably in the support band (Figure 5).

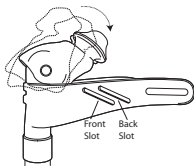


 Figure 4



 Figure 5

## Sizing the Cradle Cushion

The OptiLife Cradle Cushions are available in multiple sizes to provide the most comfortable fit and to deliver the best therapy. In most cases, the sizing of the Cradle Cushion matches the sizing of the

Pillows Cushion. To determine which size Cradle Cushion to use, first determine the correct pillows size to use. Then, use the table below as a starting point for the Cradle Cushion.

Pillows Cushion Size	Cradle Cushion Size
P	S
S	S or M
M	M
L	L or LN

1. Before putting on the mask, make sure the Cradle Cushion is in an upright position (Figure 6).
2. Place the cushion so that it rests underneath your nose. No part of your nose should be inserted into the cushion. Your chin should rest comfortably in the support band.



 Figure 6

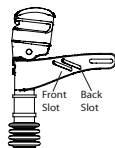


 Figure 7

### Comfort Tip

Position headgear in either slot to optimize fit and comfort. For the Pillows Cushion, start in the back slot and move to the front slot if necessary. For the Cradle Cushion, start in the front slot and move to the back slot if necessary.

## Fitting the Mask and Headgear

1. Pull the elastic headgear on over your head. The adjustable top strap should be placed comfortably over the top of your head so that the headgear side straps rest just above the ears. The back strap will sit at the base of your head.
2. Adjust the side straps so that the cushion fits snugly and comfortably in your nostrils (Pillows Cushion) or under your nose (Cradle Cushion). Do not overtighten the headgear side straps.

3. Adjust the support band so that it rests snugly against your chin. Do not overtighten the support band (Figure 8).
4. Adjust the angle of the cushion to achieve the best fit and comfort by rotating the cushion backward or forward on the cushion attachment hub.
5. Connect the interface to the tubing of your CPAP or bi-level device. Lie down and turn on the airflow.
6. Make final adjustments while lying down.

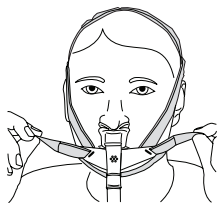


 Figure 8

### Headgear Fitting Tips

1. If the side headgear straps are sitting on or covering the ears, tighten the top strap to move the side straps up and off of the ears. Re-adjust the side straps and chin support band for comfort.
2. If the back headgear strap is sliding up on the head, loosen the top strap and move the back strap down toward the neck. Re-adjust the side straps and chin support band for comfort.
3. If you have long and silky hair, place your hair over the back headgear strap to help secure the headgear.

### Cushion Seal Fitting Tips

If you experience leaks,

1. Try a different size cushion.
2. Verify that the support band is not overtightened on your chin.
3. Move the headgear to a different slot on the interface.
4. Rotate the cushion forward or backward on the attachment hub.
5. Re-adjust the mask fitting while lying down.
6. Review Tube Management suggestions for additional tips.

## Removing the Headgear and Interface

You can quickly and easily remove the interface by grabbing the back headgear strap and sliding it forward over your head.



## Tube Management

Use the tube management clip to position the CPAP or bi-level tubing to accommodate your needs (Figure 9). The fabric ring can be placed anywhere along the tube and the clip can be attached to your clothing or pillow case for easier tube management.

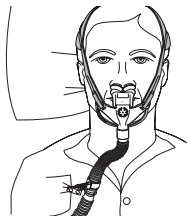


 Figure 9

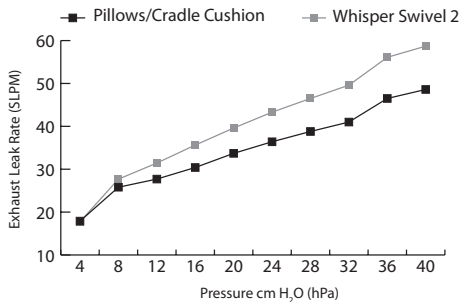
## Disposal

Dispose of in accordance with local regulations.

## 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.

### Intentional Leak



**Pressure Drop cm H<sub>2</sub>O (hPa)**

	50 slpm	100 slpm
All Sizes	< 2.9	< 9.5

**Deadspace**

Pillows Cushion ≤ 16.1 mL

Cradle Cushion ≤ 42.0 mL

**Storage Conditions**

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

15% to 95% relative humidity, 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.

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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.

