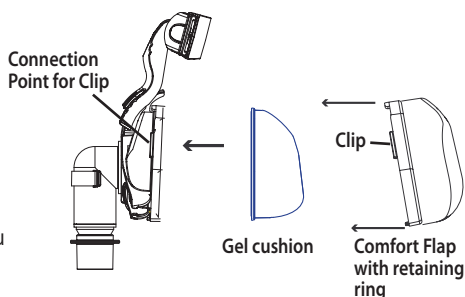


### CUSHION REMOVAL AND REATTACHMENT

Remove the Gel cushion by detaching the Comfort Flap® with its integrated retaining ring from the faceplate. Do this by unhooking the side and bottom clips of the ring from their connection points on the faceplate. Clean or discard the cushion if necessary. Place the cleaned or new Gel cushion into the faceplate. Place the Comfort Flap over the Gel cushion and push the retaining ring into the faceplate until you hear a clicking sound.



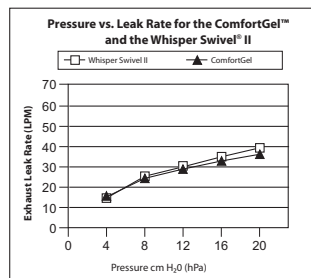
### DISPOSAL OF PARTS

Dispose of any damaged or broken parts in accordance with local regulations.

### REORDER NUMBERS

1033678	Premium Headgear w/ EZPeel™ tabs	1010518	ComfortGel Mask, P
1002800	Deluxe Headgear	1010519	ComfortGel Mask, S
1009040	ComfortGel Mask with Premium Headgear, P	1010640	ComfortGel Mask, M
1009041	ComfortGel Mask with Premium Headgear, S	1010641	ComfortGel Mask, L
1009042	ComfortGel Mask with Premium Headgear, M	1010646	Diffusion Elbow with Exhalation Kit
1009043	ComfortGel Mask with Premium Headgear, L	7041	Mask Swivel
1009052	Silicone Flap, P	1002720	Split Washer Kit
1009053	Silicone Flap, S	312710	O <sub>2</sub> Enrichment Attachment
1009054	Silicone Flap, M	1009048	Cushion, P
1009109	Silicone Flap, L	1009049	Cushion, S
1018401	Forehead Support and Pad	1009050	Cushion, M
1009722	Silicone Forehead Pads, 4 pack	1009051	Cushion, L
1009723	Headgear Swivel Clips, 2 pack		

Visit [www.respironics.com](http://www.respironics.com) for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 or 724-387-4000 to obtain a product catalog (#1027825). Visit [comfortseries.respironics.com](http://comfortseries.respironics.com) for information about the ComfortGel and other Comfort Series masks.



### Deadspace

P 83.6 cc  
S 111.4 cc  
M 121.3 cc  
L 142.6 cc

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

	50 LPM	100 LPM
All Cushion Sizes :		
P-S-M-L	0.1	0.25

Storage: Temperature -20° C to 60° C (-4° F to 140° F)  
Relative Humidity up to 95%, non-condensing

Covered by the following US patents: 6,851,425, 5647357, 5884624. Other patents pending.

1033258  
JW 04/20/06

# ComfortGel™

Custom Nasal Mask & Premium Headgear with EZPeel™ tabs

## INSTRUCTIONS FOR USE

**MULTI-PATIENT USE REUSABLE**

**LATEX FREE**

### INTENDED USE

The ComfortGel Custom Nasal Mask and Headgear are intended for use by adults as an interface with Respironics CPAP or bi-level devices. The mask contains an exhalation port and does not require the use of a separate exhalation device.

### IMPORTANT!

The ComfortGel mask is designed to fit comfortably on most adults. However, because of differences in facial features, some users need a customized fit. You can customize this mask by re-forming the gel to fit your face.

### CAUTION!

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

**SYMBOL** The symbol shown below is used on the device.



Attention, consult accompanying documents.

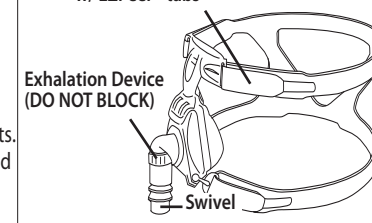
### WARNINGS

- This CPAP mask should be used only with CPAP systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP system is turned on and operating properly. The vent hole or holes associated with the mask should never be blocked.

**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.

- At low CPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

Premium Headgear w/ EZPeel™ tabs



### IMPORTANT!



Hand wash mask before use.

- 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 CPAP or bi-level systems.
- If oxygen is used with the CPAP or bi-level system, the oxygen flow must be turned off when the system is not in operation. **Explanation of the Warning:** When the CPAP or bi-level system is not in operation and the oxygen flow is left on, oxygen delivered in the ventilator tubing may accumulate within the CPAP or bi-level system enclosure. Oxygen accumulated in the CPAP or bi-level system will create a risk of fire. This warning applies to most CPAP or bi-level systems.
- Oxygen accelerates fires. Keep the CPAP or bi-level system and oxygen container away from heat, open flames, any oil substance, or other sources of ignition. Do not smoke in the area near the device or the oxygen container.
- Some users may experience skin redness. If this occurs, consult your healthcare professional.

**RESPIRONICS®**

1001 Murry Ridge Lane  
Murrysville, Pennsylvania  
15668-8550 USA

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**IMPORTANT!** Hand wash mask before use.

Before using the mask and headgear, unhook the EZPeel™ tabs on the Premium Headgear and remove it from the mask. Clean the mask following the instructions below.

## CLEANING INSTRUCTIONS

**For Multi-Patient Use Reusable.** Contact Respiration Customer Service at 1-800-345-6443 or 724-387-4000 to obtain Mask Disinfecting Instructions (order #1011138).

**For Home Use:** Begin by removing or disconnecting the headgear from the mask. Clean the headgear at least once each week or more often if needed. Fasten the EZPeel™ tabs on the straps so that they don't catch other garments in the laundry. Some Respiration masks allow the cushion to be disassembled from the faceplate. Please see *Cushion Removal and Reattachment* later in this document.

## Faceplate and Cushion

Thoroughly clean the mask each day, immediately after use, using the hand wash instructions.

## Hand Wash Instructions

- Step 1** Hand wash the mask in warm water with a mild dishwashing detergent. **Do not** use bleach, alcohol, cleaning solutions containing alcohol, or any strong household cleaners. **Do not** use cleaners containing conditioners or moisturizers.
- Step 2** Rinse thoroughly. Air dry. Make sure the mask is dry before use. Inspect the mask after cleaning. **Replace the mask if any parts are damaged or deteriorated.**

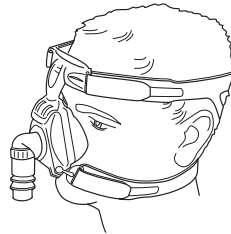
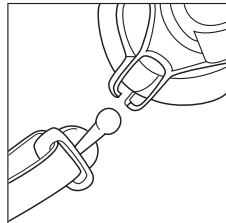
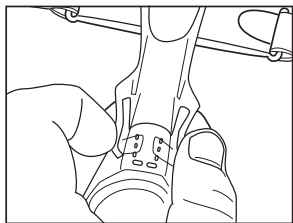
## Headgear with Swivel Clip Mask Accessories

- Step 1** Hand or machine wash the headgear and attached swivel clips with a standard laundry detergent and warm water. Rinse thoroughly. Do not use bleach.
- Step 2** Line dry or machine dry at the medium heat setting.

**NOTE** Slight readjustment of the straps may be needed after repeated washings.

## ADJUSTING THE COMFORTGEL MASK AND PREMIUM HEADGEAR TO FIT YOUR FEATURES

1. **Adjust the Forehead Support.** Position the StabilitySelector™ to its uppermost position. Hold the mask cushion gently over your nose. Slide the headgear over your head. You may want to disconnect one of the swivel clips before putting on the headgear. Reconnect the swivel clip after you have the headgear in position.



2. **Connect the CPAP or Bi-level System.** Connect the flexible tubing from your therapy device to the elbow on the mask. Turn on the airflow.
3. **Begin Therapy.** Lie down on your back and breathe normally through your nose, keeping your lips closed. Adjust the forehead support arm using the StabilitySelector™ to reduce leaks or reduce pressure points at the bridge or above the lip.

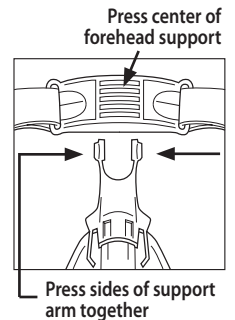
4. **Adjust the Premium Headgear with EZPeel tabs.** Unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably. Do not overtighten.

**IMPORTANT!** If you are not able to minimize the air leaks and obtain a comfortable fit, follow the directions for *Customizing the ComfortGel cushion*.

5. **Remove the Mask and Headgear.** You can remove the mask in the following ways:
- Disconnect the neckstraps by removing the swivel clips from their sockets.
  - Slide the headgear over your head. The entire headgear stretches.

To remove the headgear:

- Disconnect the forehead support by pressing on the center of the forehead support and then gently pressing the sides of the support arm together.
- Disconnect the swivel clips from their sockets.

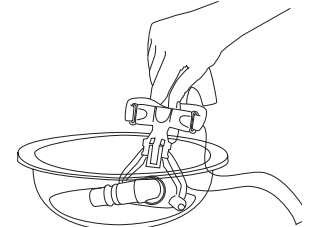
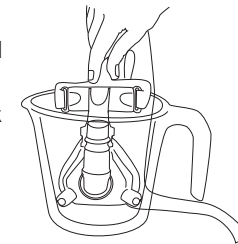


## CUSTOMIZING THE COMFORTGEL CUSHION

**IMPORTANT!** The headgear must be partially disconnected before you customize the gel cushion!

1. **Prepare the Mask and Water.** Disconnect the neckstraps by removing the swivel clips from their sockets. Fill a bowl with cold water (enough to cover the entire mask cushion). SET ASIDE. Fill a pan with enough water to cover the entire mask cushion. Place the pan over medium heat, and bring the water to a boil. REMOVE THE PAN FROM THE HEAT.
2. **Warm the Cushion.** Holding the mask by the headgear, place the mask cushion in the hot water. Let the mask soak for 4 minutes. Do not allow the headgear to get wet!
3. **Cool the Cushion.** Remove the mask from the hot water, and place it in the cold water. Let the mask cool for 10 seconds. Remove the mask from the cold water and shake any excess water from the mask. **IMPORTANT!** Touch the mask cushion to be sure that it has cooled enough to prevent irritation or burning.

**NOTE: DO NOT** allow headgear to get wet!  
**CAUTION! DO NOT** place Gel Cushion into Microwave!



**CAUTION! DO NOT** Microwave the Gel Cushion.

4. **Re-form the Cushion.** Position the mask over your nose, and press the mask cushion gently against your face. Pull the headgear over your head, and connect the swivel clips.

Soak mask in hot water for 4 minutes.

Fill bowl with cold water and cover the entire mask cushion.

Do not apply excessive pressure to the cushion. Wear the mask for 5 minutes, allowing the gel cushion to set. You can now remove the mask and headgear or connect the CPAP or bi-level device and use as directed.

## COMFORTGEL AND COMFORT FLAP

The Comfort Gel cushion and Comfort Flap can be replaced if needed. See the reorder list on the back page for part numbers. Follow the *Cushion Removal and Reattachment* instructions later in this document.