

## Cleaning Instructions

**For multi-patient use reusable:** Contact Respironics Customer Service at 1-800-345-6443 or 1-724-387-4000 to obtain Mask Disinfecting instructions (Order #1011138).

**For Home Use:** Begin by removing or disconnecting the headstrap from the mask. Clean the headstrap at least once each week or more often if needed. Fasten the hook tabs on the straps so that they don't catch other garments in the laundry.

### Headstrap with QuickClip™ and Swivel Clip Mask Accessories

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

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

### Faceplate and Cushion

Thoroughly clean the mask each day, immediately after use, using the hand wash instructions. You can remove the cushions from the faceplate for easier and more thorough cleaning.

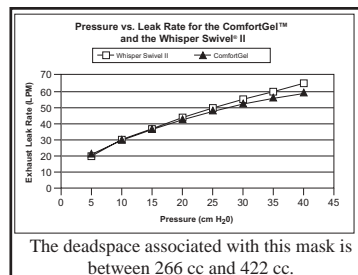
### Hand Wash Instructions

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.
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.

## Reorder Numbers

1009040	Petite Mask with Headgear	1010519	Small Mask
1009041	Small Mask with Headgear	1010640	Medium Mask
1009042	Medium Mask with Headgear	1010641	Large Mask
1009043	Large Mask with Headgear	1010646	Diffusion Elbow with Exhalation Kit
1009052	Silicone Flap, Petite	7041	Mask Swivel
1009053	Silicone Flap, Small	1002720	Split Washer Kit
1009054	Silicone Flap, Medium	1002800	Deluxe Headgear
1009109	Silicone Flap, Large	312710	O <sub>2</sub> Enrichment Attachment
1009721	Forehead Support Arm Subassembly	1009048	Petite Cushion
1009722	Silicone Forehead Pads, 4 pack	1009049	Small Cushion
1009723	Headgear Swivel Clips, 2 pack	1009050	Medium Cushion
1010518	Petite Mask	1009051	Large Cushion

The ComfortGel Custom Nasal Mask and Headstrap are covered by one or more of the following U.S. patents: 5647357, 5884624. Other U.S. and foreign patents pending.




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**NOTE:** Dispose of any damaged or broken parts according to local regulations.

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# ComfortGel™

## Custom Nasal Mask and Headstrap



**Intended Use:** The ComfortGel Custom Nasal Mask and Headstrap 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. **LATEX-FREE**

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

**Warning:** Do not wear this mask unless the CPAP or bi-level device is connected and the airflow is turned on.

**Warning:** This warning applies to most CPAP devices. At low CPAP pressures, the airflow through the exhalation port may not be enough to clear all of the exhaled gas (CO<sub>2</sub>) from the mask. You may breathe in some of the air that you have exhaled.

**Do not block or otherwise try to seal the vent holes on the exhalation port.**

**Warning:** Use caution when handling the heated water and the heated mask. Read all instructions before starting the procedure. Do not heat the mask by placing it into a microwave or conventional oven. The mask will be damaged.

**Warning:** Do not wear this mask over sores, or sunburned or irritated skin. If you experience skin irritation under the mask, stop using it and contact your health care professional.



## Adjusting the Mask and Headstrap to Fit Your Features

**Important!** Before adjusting the mask and headstrap, unhook the tabs on the headstrap and remove it from the mask. Rinse the mask cushion to remove any dust that may have gotten onto the mask during shipping. Allow the mask to dry.

Reconnect the headstrap. The headstrap has two sets of tabs for better adjustment. For larger head sizes, use the black tabs. For smaller head sizes, use the blue tabs. The extra tabs can be removed with scissors.



**1. Adjust the Forehead Support.** Hold the mask cushion gently over your nose. If the forehead support does not rest comfortably against your forehead, press the ridged sides at the bottom of the support arm, and slide the arm up and down the bar until the arm is in a position that is comfortable for you. Slide the headstrap over your head. You may want to disconnect one of the swivel clips before putting on the headstrap. Reconnect the swivel clip after you have the headstrap in position.

**2. Connect the CPAP or Bi-level System.** Connect the flexible tubing (included with your CPAP or bi-level 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. You may need to readjust the forehead support arm to reduce leaks.

**4. Adjust the Headstrap.** Unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably.

**Important!** If you are not able to minimize the air leaks and obtain a comfortable fit, follow the directions (see the next page) for customizing the ComfortGel cushion.

**5. Remove the Mask and Headstrap.** You can disconnect the headstrap from the mask in the following ways:

- Disconnect the forehead support by pressing on the center of the forehead spacer and then gently pressing the sides of the forehead support arm together.
- Disconnect the neck straps by removing the swivel clips from their sockets.
- Slide the headstrap over your head. The entire headstrap stretches.



## Customizing the Gel Cushion

**Important!** The headstrap 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 headstrap 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.*

### **4. Re-form the Cushion.**

Position the mask over your nose, and press the mask cushion gently against your face. Pull the headstrap over your head, and connect the swivel clips.

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 headstrap or connect the CPAP or bi-level device and use as directed.



### **Helpful Tips for Mask Comfort**

- Clean your face and the mask thoroughly before each use.
- Do not overtighten the headstrap. Overtightening can irritate your face and cause or increase leaks.
- Replace the mask if the cushion becomes hardened or if any parts become damaged.