

ComfortGel™ Nasal Mask

Premium Headgear with EZPeel™ tabs

INSTRUCTIONS FOR USE

MULTI-PATIENT USE REUSABLE

LATEX FREE

INTENDED USE

The ComfortGel Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. The mask is for multi-patient reuse on adult patients in the home or hospital/institution environment. **An exhalation port is built into the interface so that a separate exhalation device is not required.**

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.

SYMBOLS



Follow instructions for use



Hand wash mask before use.



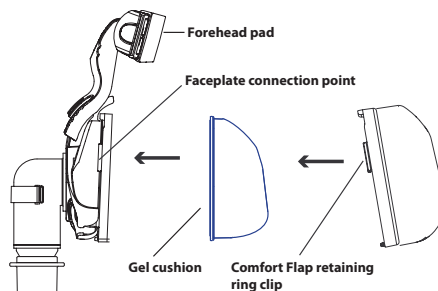
Warning! Hot

WARNINGS

- The ComfortGel Mask is designed for use with CPAP or bi-level systems recommended by your healthcare professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. **Do not try to block or 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.
- This warning applies to most CPAP devices. 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.
- 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 supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Some users may experience skin redness. If this occurs, consult your healthcare professional.

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 it 'clicks' into place.



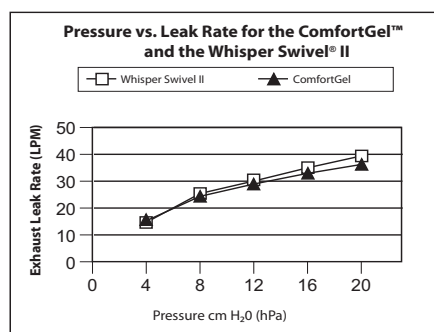
DISPOSAL

Dispose of device in accordance with local regulations.

REF

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 ₂ 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 for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 (US and Canada only) or 1-724-387-4000 to obtain a product catalog (#1027825).



Deadspace Volume

Petite Cushion: 83.6 cc
Small Cushion: 111.4 cc
Medium Cushion: 121.3 cc
Large Cushion: 142.6 cc

Pressure Drop cm H₂O (hPa)

	50 LPM	100 LPM
P-S-M-L	0.1	0.25

Storage

Temperature -20° C to 60° C
RH ≤ 95%, non-condensing

RESPIRONICS®

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www.respironics.com

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BEFORE USE

Hand wash mask following the instructions below.

CLEANING INSTRUCTIONS

Multi-Patient Use: Visit www.respironics.com or contact Respironics Customer Service at 1-800-345-6443 (US or Canada only) or 1-724-387-4000 to obtain Mask Disinfecting Instructions (REF# 1011138).

Home Use: Clean the mask, cushion, flap, and interface tubing daily. Clean the headgear at least once each week or more often if needed.

Cleaning the Mask

The mask, cushion, flap, and tubing should be cleaned daily or as needed.

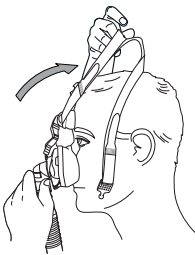
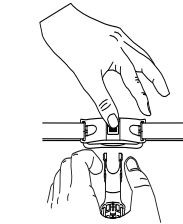
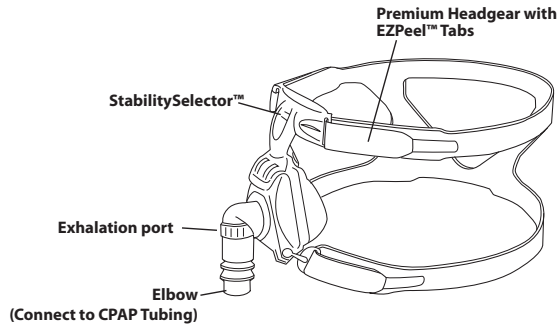
1. Hand wash in warm water with a mild dishwashing detergent. Do not use bleach, alcohol, or cleaning solutions containing alcohol. Do not use cleaners containing conditioners or moisturizers.
2. Rinse thoroughly. Pat with a paper towel and air dry completely before use.
3. Inspect all parts for damage or wear; replace if necessary.

Cleaning the Headgear

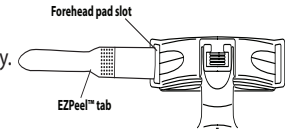
The headgear should be cleaned weekly or as needed, either by hand or machine wash in the gentle cycle. Attach the EZPeel tabs to the headgear straps so they do not catch on other items in the laundry. Line dry the headgear.

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 Quick Clips before putting on the headgear. Reconnect the Quick 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.



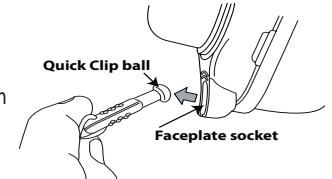
IMPORTANT! If you are not able to minimize the air leaks and obtain a comfortable fit, follow the directions for *Customizing the ComfortGel Cushion*.

5. **Remove the Mask and Headgear.** You can remove the mask in the following ways:

- Disconnect the neckstraps by removing the Quick Clip balls 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 Quick Clip balls from their sockets.



CUSTOMIZING THE COMFORTGEL CUSHION

Important! The headgear must be partially disconnected before you customize the gel cushion.

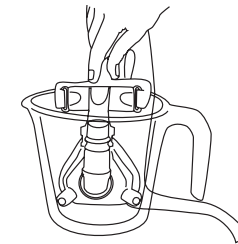
1. **Prepare the Mask and Water.** Disconnect the neckstraps by removing the swivel clips from their sockets. Fill a bowl with enough cold water to cover the entire mask cushion. SET ASIDE.

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.

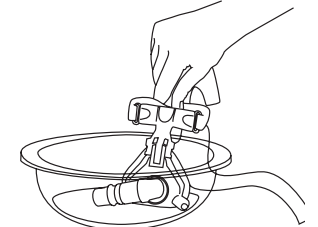
NOTE: DO NOT allow headgear to get wet!
CAUTION! DO NOT place Gel Cushion into Microwave!

CAUTION! DO NOT Microwave the Gel Cushion.

WARNING! Water and contents may be hot.



Soak mask in hot water for 4 minutes.



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

2. **Warm the Cushion.** Hold the mask by the headgear and place the mask cushion into 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.

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.