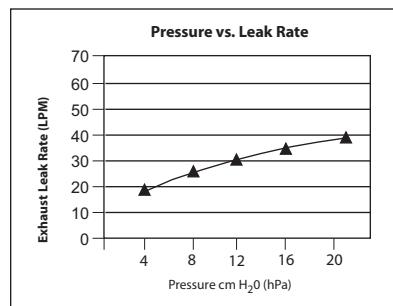


DISPOSAL OF PARTS

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

COMFORTFULL 2 REORDER NUMBERS			
1033678	Premium Headgear w/ EZPeel™ tabs	1010870	ComfortFull 2 Mask only, L
1014333	ComfortHeadgear	452040	NG Tube Sealing Pad (10/pack)
1004880	ComfortFull 2 with Premium Headgear, S	1018401	Forehead Support and Pad
1004872	ComfortFull 2 with Premium Headgear, M	1009722	Silicone Forehead Pads, 4 Pack
1004950	ComfortFull 2 with Premium Headgear, L	1009723	Headgear Swivel Clips (2 pk.)
1010868	ComfortFull 2 Mask only, S	1004871	Entrainment Valve Swivel
1010869	ComfortFull 2 Mask only, M	1010872	Portcap (5/pack)

Visit 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 www.comfortseries.respironics.com for information about the ComfortFull 2 and other Comfort Series masks.



Deadspace
 S 280 cc
 M 391.6 cc
 L 434.4 cc

Pressure Drop cm H₂O (hPa)
 50 LPM 100 LPM
 All Sizes: S-M-L 0.4 1.0

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

Covered by one or more of the following US patents:
 Des 464,728 and DES 475,453. Other patents pending.

RESPIRONICS®

1001 Murry Ridge Lane
 Murrysville, Pennsylvania
 15668-8550 USA

© 2006 Respironics, Inc. and its affiliates. All rights reserved.

1033269
 JW 04/20/06

ComfortFull™ 2

Full Face Mask and Premium Headgear with EZPeel™ tabs

Instructions for Use



MULTI-PATIENT USE REUSABLE

LATEX-FREE

INTENDED USE The ComfortFull 2 Reusable Full Face Mask and Premium Headgear are intended for use by adults as an interface with Respironics CPAP or bi-level devices. The mask covers the nose and mouth. An exhalation port is built into the ComfortFull 2 mask so that a separate exhalation port is not required. Before using this mask, the home care provider should verify device pressure(s). This mask is not suitable for providing life support ventilation.

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



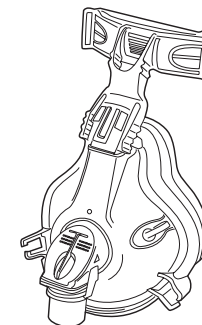
IMPORTANT! Hand wash mask before use.

WARNINGS

- This full face mask is designed for use with CPAP and bi-level systems. Do not place the mask on the patient unless the system is turned on and operating properly. Do not block or try to seal the exhalation port. **Explanation of the Warning:** CPAP and bi-level systems have the potential to allow rebreathing of exhaled air. These systems are designed for use with masks (or connectors) that have vent holes or exhalation ports. When the CPAP or bi-level system is turned on, fresh air from the system flushes the exhaled air out through the port holes. If the system is not operating, the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- If oxygen is used with this CPAP or bi-level machine, the oxygen flow must be turned off when the machine 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 machine enclosure. Oxygen accumulated in the machine enclosure will create a risk of fire. This warning applies to most types of CPAP and bi-level machines.
- 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.
- Contact a health care professional if patient experiences unusual chest discomfort, shortness of breath, stomach distention, belching, or severe headache when patient awakens or when using the ComfortFull 2 mask.
- To minimize the risk of vomiting during sleep, patient should avoid eating or drinking for three hours before using the mask. This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Oxygen accelerates fires. Keep the system and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. Do not smoke in the area near the CPAP or bi-level system or the oxygen container.
- Some users experience skin redness. If this happens, contact a health care professional.

CONTRAINDICATIONS

This mask may not be suitable for persons with the following conditions: impaired cardiac sphincter function, excessive reflux, impaired cough reflex, and hiatal hernia. It should not be used if the person is uncooperative, obtunded, unresponsive, or unable to remove the mask.



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 Respironics 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 hook tabs on the straps so that they don't catch other garments in the laundry.

MASK 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.

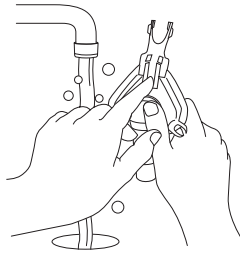
Step 2 Rinse thoroughly. Air dry. Make sure the mask is dry before use. Inspect the mask after cleaning. Replace the mask if any parts are damaged or deteriorated.

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.

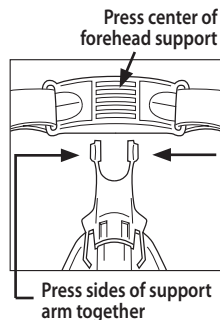


REMOVING THE HEADGEAR AND MASK

You can disconnect the headgear from the mask in the following ways:

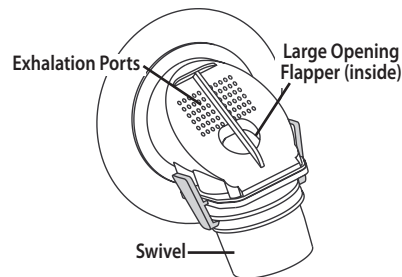
- Disconnect the forehead support by pressing on the center of the forehead support and then gently pressing the sides of the support arm together.
- Disconnect the neck straps by removing the swivel clips from their sockets on the mask.
- Slide the headgear over your head. The entire headgear stretches.

To quickly release the flexible tubing, press on both tubing quick-release tabs located on either side of the entrainment valve.



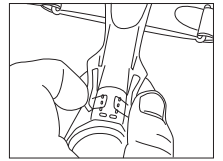
ADJUSTING THE COMFORTFULL 2 MASK AND PREMIUM HEADGEAR

1. Check the Entrainment Valve. With the airflow turned off, verify that the entrainment valve flapper is lying flat so that room air can flow through the large opening in the valve. Turn the airflow on; the flapper should now cover the large opening, and air from the CPAP or bi-level device should flow into the mask. If the flapper does not close or does not function properly, replace the mask.



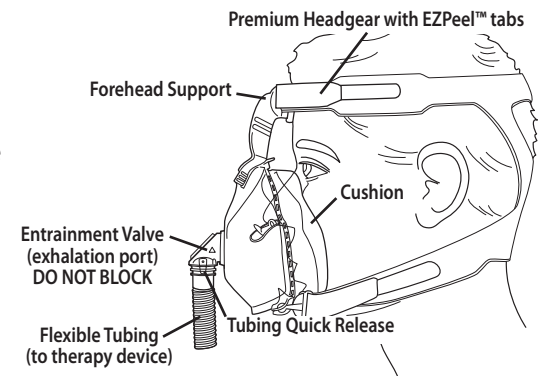
ADJUSTING THE COMFORTFULL 2 MASK AND PREMIUM HEADGEAR (CONT.)

2. Adjust the StabilitySelector™ of the Support Arm 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.
3. Connect the flexible tubing (included with your CPAP or bi-level device) to the swivel on the mask.
4. Turn on the airflow.
5. Lie down on your back and breathe normally. You may need to readjust the forehead arm to minimize leaks.
6. Loosen the EZPeel™ tabs to unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably. Do not overtighten the headgear! Overtightening can irritate your face, cause or worsen leaks, or damage the mask.



WARNING! A minimum pressure of 3.0 cm H₂O (hPa) at the mask (CPAP or EPAP) is required.

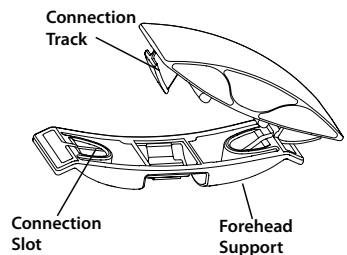
WARNING! Do not block or try to seal the large opening or the exhalation ports on the valve. Ensure that the valve is not blocked with secretions and that the flapper is dry.



REPLACING THE FOREHEAD PAD

If you need to replace the forehead pad, contact your home care provider to reorder. Follow the instructions below.

- Step 1** Remove the pad. Slide the pad outward toward one edge of the forehead support, and lift it upward so the connection track on that side is released from the plastic connection slot. Next, pull the pad in the opposite direction to release the connection track on the other side from its connection slot.



- Step 2** Install the new pad. Slide one of the connection tracks on the new pad into its connection slot on the support. Pull the pad in the opposite direction (toward the center) and slide the other connection track into its connection slot to lock the pad into place.

HOME CARE PROVIDERS

If a nasogastric (NG) tube or similar device is in place, use the optional NG tube sealing pad. Position the pad so that its flat surface is against the user's face and the C-shaped opening surrounds the tube.