

Cleaning Instructions (continued)

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.

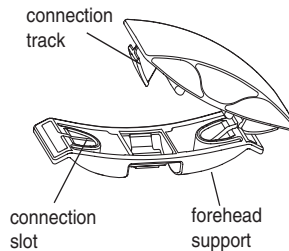
Step 2 Line dry or machine dry at the medium heat setting.

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

Replacing the Forehead Pad

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

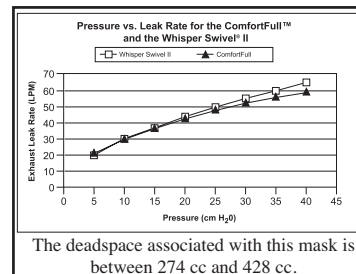
Step 1 Remove the pad. Slide the pad outward toward one edge of the forehead support, and lift it upward so the connection track on that side is released from the plastic connection slot. Next, pull the pad in the opposite direction to release the connection track on the other side from its connection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

Reorder Numbers

1004880	Small, with Headgear
1004872	Medium, with Headgear
1004950	Large, with Headgear
1010868	Small, mask only
1010869	Medium, mask only
1010870	Large, mask only
1014333	ComfortHeadgear
452040	NG Tube Sealing Pad (10/pack)
1018401	Forehead Support and Pad
1009722	Silicone Forehead Pads, 4 Pack
1009723	Ball-and-Socket Headgear Swivel Clips (2 pk.)
1004871	Entrainment Valve Swivel
1010872	Portcap (5/pack)



The deadspace associated with this mask is between 274 cc and 428 cc.

ComfortFull™

Full Face Mask and Headgear Instructions for Use

(Note: The headgear is not included in all packages and may be purchased separately.)

Intended Use The ComfortFull Reusable Full Face Mask and Headgear are intended for use by adults (>66 lbs. / 30 kg) as an interface with Respironics CPAP or bi-level devices. The mask covers the nose and mouth and is LATEX-FREE. An exhalation port is built into the ComfortFull 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.

Warnings

- Contact your health care professional if you experience unusual chest discomfort, shortness of breath, stomach distention, belching, or severe headache when you awaken or when you are using the ComfortFull mask.
- To minimize the risk of vomiting during sleep, avoid eating or drinking for three hours before using the mask. This mask is not recommended if you are taking a prescription drug that may cause vomiting.
- The ComfortFull mask is designed for use with CPAP and 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. CPAP and bi-level systems have the potential to allow rebreathing of exhaled air. CPAP systems are designed for use with masks (or connectors) that have vent holes or exhalation ports. When the CPAP system is turned on, fresh air from the system flushes the exhaled air out through the vent holes. If the CPAP 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.
- Some users may experience skin redness. If this happens, contact your health care professional.

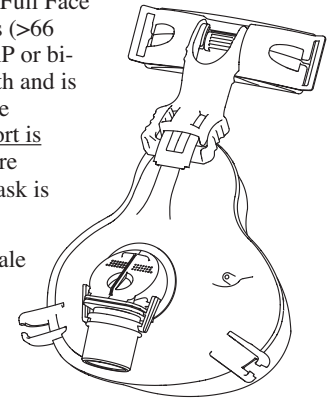
Notes

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.

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.



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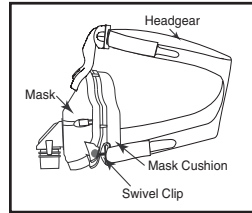
Covered by one or more of the following patents:
Des 464,728 and DES 475,453. Other patents pending.

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Headgear and Forehead Support Adjustment

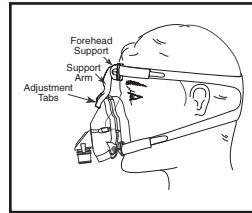
Important!

Before adjusting the mask and headgear, rinse the mask cushion to remove any dust that may have gotten onto the mask during shipping. To disconnect the headgear from the mask, unhook the top two tabs and remove the headgear from the forehead support. Remove the bottom two swivel clips from the mask by pulling the clips out and away from your face. Allow the mask to dry completely before use.



Adjustable Forehead Arm

The adjustable forehead arm has several different settings. To choose the setting that is right for you, hold the mask gently over your nose and mouth. If the forehead pad does not rest comfortably against your forehead, press the ridged adjustment tabs at the bottom of the support arm, and slide the arm up or down until it is in a position that is comfortable for you. The forehead adjustment is the key to eliminating leaks or pressure points around the eyes or below the mouth. An adjustment up or down 1 to 2 settings can easily fix these problems.



After adjusting the forehead support, reconnect the headgear.

Before each use

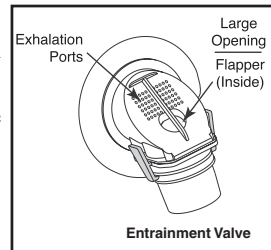
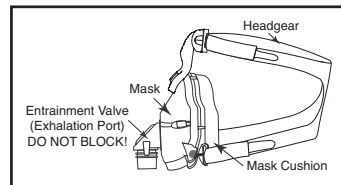
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.
- Wash your face.
- Check the entrainment valve.

Connect the flexible tubing (included with your CPAP or bi-level device) to the swivel on the mask and to the outlet port on the CPAP or bi-level device.

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.



Warning A minimum pressure of 3.0 cm H₂O 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.

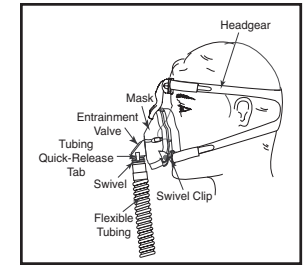
Ensure that the valve is not blocked with secretions and that the flapper is dry.

Disposal of Parts

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

Putting On and Adjusting the Headgear and Mask

Step 1 Hold the mask gently against your face, and slide the headgear over your head. You may want to disconnect one of the swivel clips before putting the headgear on. Reconnect the swivel clip after you have the headgear in position.



Step 2 Connect the flexible tubing (included with your CPAP or bi-level device) to the swivel on the mask. Turn on the airflow.

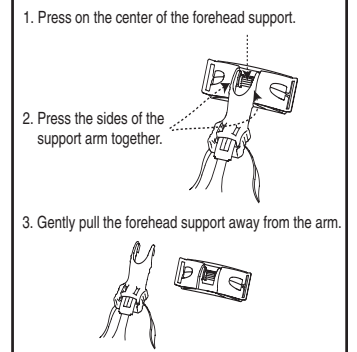
Step 3 Lie down on your back and breathe normally. Adjust the straps until the mask has minimal leaks and fits comfortably. **You may need to readjust the forehead arm to minimize leaks. Do not over-tighten the headgear! Overtightening can irritate your face, cause or worsen leaks, or damage the mask.**

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.



Cleaning Instructions

For multi-patient use reusable. Contact Respironics Customer Service at 1-724-387-4000 or 1-800-345-6443 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.**