

RESPIRONICS



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ComfortFull 2
INSTRUCTIONS FOR USE

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Package Contents

- ComfortFull 2 mask
 - Headgear
 - Mask assembly
- Instructions for use
- Quick Start fitting tips

 **Note:** *Not all packages contain listed items. Please contact your Home Care Provider or Respironics for additional items or replacement parts.*

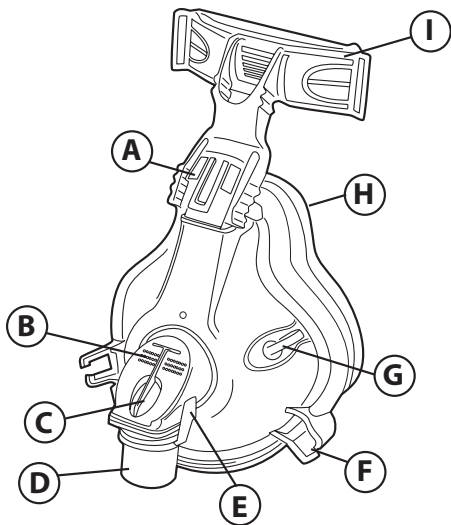



Figure 1

- A = StabilitySelector
- B = Exhalation Port
(Do not block)
- C = Entrainment Valve
- D = Elbow Swivel
- E = Tubing Quick Release
- F = Quick Clip Socket
- G = Port Cap
- H = Cushion
- I = Forehead Support

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

Intended Use

The ComfortFull 2 Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed.

 **Important Note:** An exhalation port is built into the ComfortFull 2 Full Face Mask so a separate exhalation port is not required.

Warnings

- This mask is not suitable for providing life support ventilation.
- This mask is designed for use with CPAP or 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.** **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. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- If oxygen is used with this device, 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



Warning:
Indicates the possibility of injury to the user or operator



Caution:
Indicates the possibility of damage to the device



Note:
A note places an emphasis on an operating characteristic.

may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.

- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- 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 or bi-level machines.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- The patient's physician should be contacted if the patient experiences the following symptoms while using the masks or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist.)
- At low CPAP or EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- A minimum of 3 cm H₂O (hPa) must be maintained when using this mask.
- This mask should not be used on patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.

- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- Use of a nasal or full face mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.
- Do not block or try to seal the entrainment valve.





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 by themselves.

Disposal

Dispose of in accordance with local regulations.

Symbols

Symbol	Description
	Consult instructions for use
	General caution or warning
	Note
	Tip
X1	System One Resistance Control

Before Use

- Hand wash the mask to remove particles that may have accumulated during shipping or storage.
- Read and understand the instructions completely.
- Verify that the entrainment valve functions correctly.
- Wash face.
- Remove the quick fit tips.

Comfort Tip

If you have sensitive skin, you can condition the mask before use. To condition, create a bath of warm, soapy water and soak the mask for 30-60 minutes. Use a mild detergent free of conditioners, moisturizers, or bleaching agents. Rinse thoroughly and air dry.

Cleaning Instructions

Hand wash the mask before first use and daily. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

1. Hand wash the mask and headgear in warm water with a mild liquid dish washing detergent.

⚠ Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.




Note:

It is not necessary to disconnect the headgear for daily use and cleaning.

For **multi-patient use** in the hospital/institutional environment, use the Mask Cleaning and Disinfection Instructions to reprocess the mask between patients. These instructions can be obtained by visiting www.sleepapnea.com or contacting Customer Service at 1-800-345-6443 (USA or Canada) or 1-724-387-4000.

System One Resistance Control

This mask uses the System One Resistance Control setting . This symbol may appear on your therapy device. This symbol represents the level of mask resistance compensation. Match the setting to the mask if appropriate.

Important Notes:

- Verify the System One setting if the mask or mask cushion changes.
- The System One setting is not compatible with masks requiring a separate/additional exhalation device.

If your provider has locked the resistance compensation setting, you can view the setting but cannot change it, and the screen will display a lock symbol. If your provider has disabled the resistance compensation, you will not see this setting.

Removing and Attaching the Headgear

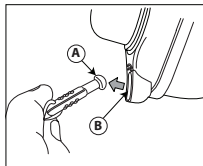
Please use one of the following methods to remove or attach the headgear:

- **Method One:** Undo the four EZPeel tabs (Figure 2) on the headgear and pull the straps out of the slots in the forehead support and on the Quick Clips.
- **Method Two:** Disconnect the Quick Clips and Forehead Support Arm: Pull the Quick Clip ball up and away from the socket (Figure 3). Do not pull the ball through the socket.



 **Figure 2**

Undo EZPeel Tabs.



 **Figure 3**

Pull the ball up and away from the socket.

A = Quick Clip Ball

B = Faceplate Socket

Next, disengage the forehead support pad (Figure 4) from the forehead support arm by pressing in on the center of the forehead support pad and then squeezing the upper sides of the support arm together to disengage the forehead support pad.

To attach, press the ball into the socket.

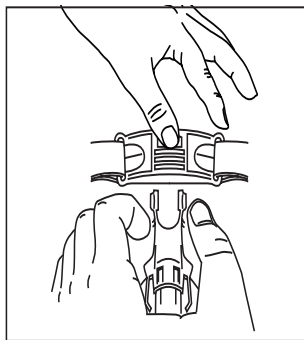


Figure 4
Disconnect the Forehead Support—Press center tab and squeeze ribbed sides of the support arm.

Achieving the Right Fit

1. Open the headgear to a large setting and adjust the forehead arm (Figure 5) to the highest position. To adjust, gently squeeze the arms of the StabilitySelector and slide the arm upwards.

To make it easier to place the mask and headgear on your face, we recommend disconnecting one of the Quick Clips.

2. Check the Entrainment Valve located inside the mask elbow.

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 (Figure 6A).

⚠ Warning: Do not block or try to seal the large opening or the exhalation ports on the valve.

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

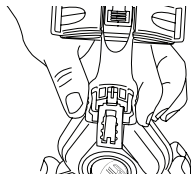


Figure 5

Adjust the forehead arm.

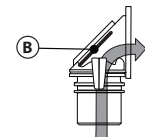
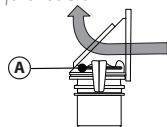


Figure 6

Check the entrainment valve.

Next, with the airflow on (Figure 6B), 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.

3. Put on the mask (Figure 7). Simply hold the mask cushion gently over your nose and mouth. Pull the headgear on over your head. Connect the Quick Clip if detached.

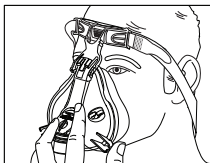
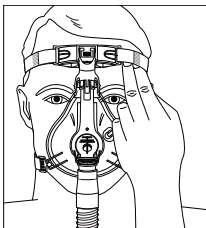


Figure 7
Put on the Mask.

4. First, adjust the top headgear straps evenly and at the same time using the EZPeel tabs on the headgear. The forehead pad should be touching your forehead lightly. Adjust the bottom strap so that the mask is sitting gently on your face. The headgear should stay loose. Do not overtighten. You should be able to run a finger under the headgear straps (Figure 8).



◀ **Figure 8**

Run a finger under the headgear to make sure it is loose to start.

5. Connect the tubing (Figure 9) that is included with your CPAP or bi-level device to the swivel elbow on the mask.
6. Turn on the airflow.
7. Lie down and breathe normally through your nose, keeping your lips closed.
If the forehead support does not rest comfortably against your forehead, tighten the top headgear strap.

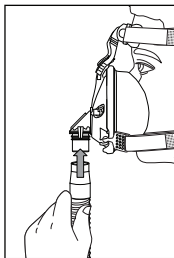


Figure 9
Connect the tubing to the swivel elbow.

Assume different sleeping positions (Figure 10) and move your head around. If there are any air leaks make any final adjustments. Some air leakage is normal. Do not overtighten the headgear. Overtightening the headgear may cause discomfort or irritation.

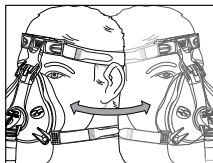


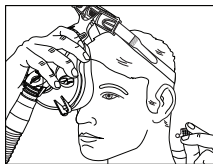
Figure 10
Lie down and assume different sleeping positions. Make any minor adjustments but DO NOT overtighten the headgear.

Comfort Tip

Keep the headgear loose! The improved headgear keeps its elasticity longer and better.

Removing the Mask and Headgear

To take off the mask and headgear first remove one or both Quick Clips from the mask sockets. Grasp the body of the Quick Clip and gently pull the ball out of the socket away from your face. After the Quick Clip is disengaged, slide the mask over your head (Figure 11).

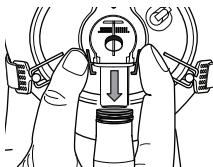


▶ **Figure 11**

Disengage the Quick Clips and slide mask off.

Tubing Quick Release

The mask elbow is equipped with a Tubing Quick Release (Figure 12). Simply squeeze the quick release tabs and the grey swivel will disengage from the mask and come loose with the tubing.



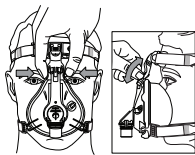
▶ **Figure 12**


Tubing Quick Release

Comfort Tips

You may need to adjust the StabilitySelector on the forehead support arm (Figure 13) to reduce leaks or reduce pressure points at the bridge or above the lip. Follow these tips to adjust for leaks:

- For leaks around the bridge of the nose or into the eyes gently squeeze the arms of the StabilitySelector and adjust to a lower position.
- For leaks around or below the mouth gently squeeze the arms of the StabilitySelector and adjust to a higher position.
- Reseat the mask by pulling it directly away from the face and gently setting it back into place.



 **Figure 13**
*Adjust the StabilitySelector
to lessen leaks.*

Replacing the Forehead Pad

If you need to replace the forehead pad (Figure 14) follow these instructions:

To remove: 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.

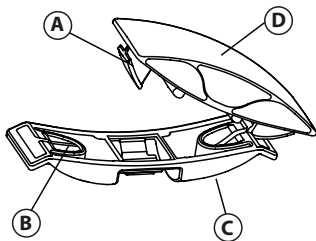


Figure 14

Replace the forehead pad


A = Connection Track

B = Connection Slot

C = Forehead Support


D = Forehead Pad

To attach: Slide one of the new pad's 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.

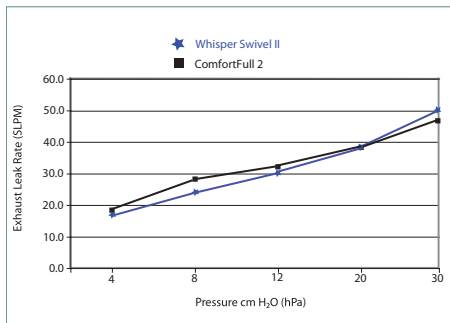
 **Note for Home Care Providers**

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.

Specifications

-  **Warning:** The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.

Intentional Leak

Pressure Drop cm H₂O (hPa)

	50 SLPM	100 SLPM
All mask sizes:	0.4	1.0

Deadspace

Small	280 cc
Medium	392 cc
Large	434 cc

ComfortFull 2

Storage Conditions:

-4° to 140° F (-20° to +60° C)

15% to 95% relative humidity, non-condensing

Reorder Numbers

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

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

LIMITED WARRANTY

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the "Product") shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the "Warranty Period").

If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is non-transferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty. This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship. This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics.

Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

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To exercise your rights under this limited warranty, contact your local authorized Respiration, Inc. dealer or Respiration, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.