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1067744
JAW 04/08/2010
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ComfortGel Full | INSTRUCTIONS FOR USE

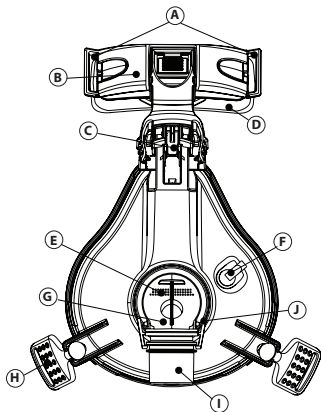


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Package Contents

- ComfortGel Full Face Mask
-includes gel cushion and Comfort Flap with Sure Seal Technology (SST)
- ComfortGel Full Headgear
- Instructions for Use
- QuickStart Fitting Tips



ComfortGel Full

 Note:

Not all packages contain listed items. Please contact your Home Care Provider or Respirationics for additional items.

Figure 1

A = Forehead Support Slots

B = Forehead Bracket

C = Stability Selector

D = Forehead Pad

E = Exhalation Port
(Do not block)

F = Pick Off Port

G = Entrainment Valve
(inside mask elbow)


H = Quick Clip

I = Swivel

J = Swivel Release

Intended Use

The ComfortGel 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 and multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) who are appropriate candidates for noninvasive ventilation.

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

 **Caution**

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

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.



Warning

A warning indicates the possibility of injury to the user or operator.



Caution

A caution indicates the possibility of damage to the device.



Note

A note places an emphasis on an operating characteristic.

Warnings (cont.)

- If oxygen is used with the device, the oxygen flow must be turned off when the device 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 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 and 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 mask 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.







Warnings (cont.)

- A minimum of 3cm H₂O (hPa) must be maintained when using this mask.
- This mask should not be used for patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask.
- This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.
- When including an additional exhalation device to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- The gel mask is not customizable. Do not attempt to heat.
- Hand wash prior to first use. Inspect the mask. If any visible deterioration of a system component is apparent (cracking, crazing, tears or cushion damage resulting in gel exposure, etc), the component should be discarded and replaced.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

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 patient is uncooperative, obtunded, unresponsive, or unable to remove the mask by themselves.

Symbols

Symbol	Description	Symbol	Description
	Warning or Caution		Does not contain natural rubber latex
	Note		System One Resistance Control Setting
	Tip		
	Consult instructions for use		

Before Use

- Hand wash the mask to remove any dust that accumulated during shipping or storage.
- Read and understand the instructions completely.
- Verify that the air entrainment valve functions correctly.
- Wash the patient's face.
- Remove the Quick Start fitting tips (if attached to the headgear).

Entrainment Valve

The entrainment valve consists of an air inlet and a flapper. With the airflow turned off, verify that the elbow with the flapper is lying flat (Figure 2) so that room air can flow in and out through the air inlet. Next, with the airflow on, the flapper should now cover the air inlet 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.

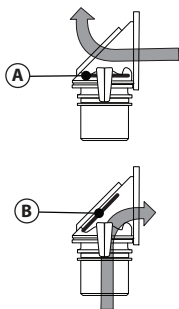


Figure 2

A = Flapper is lying flat

B = Flapper is covering the air inlet

Warning

Do not block or try to seal the entrainment valve or the exhalation vents.

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.
3. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
4. 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.

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 Respiroics 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  X1. 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.



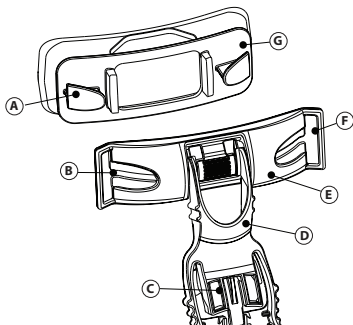
Important Notes:

- 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.

Replacing the Forehead Pad

The forehead pad will slide off and on the track of the forehead pad bracket (Figure 3). The forehead pad is strong and will stretch without tearing.



 **Figure 3**

- A = Forehead Pad Tab*
- B = Forehead Pad Slot*
- C = StabilitySelector*
- D = Forehead Support Arm*
- E = Forehead Bracket*
- F = Headgear Bracket Slot*
- G = Forehead Pad*

 **Note**

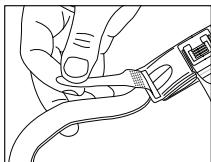
Do not detach the StabilitySelector from the faceplate rail.

Removing and Attaching the Headgear and Mask

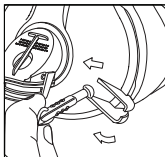
Method 1 (Brackets):

a. Removing - Undo the four headgear tabs on the headgear (Figure 4) and pull the straps out of the forehead bracket slots and on the Quick Clips.

b. Reattaching - Thread the top headgear straps into the slots in the forehead bracket and the Quick Clips. The headgear tabs fold back to catch the headgear straps.



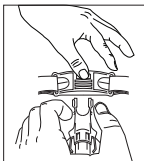
▲ Figure 4



▲ Figure 5

Method 2 (Ball Sockets):

a. Removing - Disconnect the Quick Clips and forehead support arm. Pull the Quick Clip ball up and away from the socket (Figure 5). Do not pull the ball through the socket. Next, disconnect the forehead bracket from the forehead support arm by pressing in on the center of the forehead bracket and then squeezing the upper sides of the support arm together to disengage the forehead bracket (Figure 6).



▲ Figure 6

b. Reattaching - Place the ball against the socket and gently press the ball into the socket. Press in on the center of the forehead bracket and then squeeze the upper sides of the support arm together. Slide the tabs into the forehead bracket until they latch into place.

Mask Use and Fit

1. Open the headgear to a large size setting and adjust the forehead arm to the highest position. To adjust, gently squeeze the arms of the StabilitySelector and slide the arm upwards.
2. Disconnect one, or both of the Quick Clips. Place the mask cushion against the face by first setting the base of the cushion under the lower lip then roll the cushion up the nose. Be sure the mouth remains slightly open. Pull the headgear on over your head. Connect the Quick Clips if detached.
3. Using both hands, adjust the top headgear strap first by using the headgear tabs on the headgear. The forehead pad should be touching your forehead lightly. Adjust the

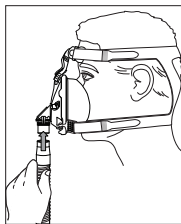
bottom strap so that the mask is sitting gently on your face.

4. Connect the tubing that is included with your CPAP or bi-level device to the swivel elbow on the mask (Figure 7).
5. Turn on the airflow.
6. Lie down and breathe normally. Be sure the mouth remains slightly open. If the forehead pad does not rest comfortably against your forehead, Tighten the top headgear strap. If there are any air leaks make any final adjustments. Some air leakage is normal. Do not overtighten the headgear.

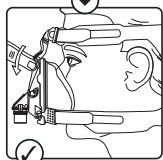
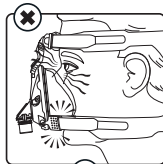
☰ Comfort Tips

Adjust the StabilitySelector on the forehead support arm to reduce leaks or reduce pressure points at the bridge of the nose 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 (Figure 8).

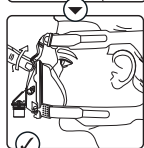
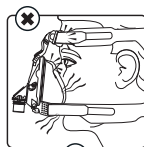


▶ Figure 7

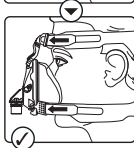
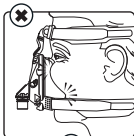


▶ Figure 8

- For leaks around or below the mouth gently squeeze the arms of the StabilitySelector and adjust to a higher position. Re-seat the mask by pulling it directly away from the face and gently setting it back into place (Figure 9).
- The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If your skin bulges around the mask, loosen the headgear straps. If you see red marks or the mask leaves impressions on your skin, loosen the headstraps (Figure 10).



▲ Figure 9



▲ Figure 10

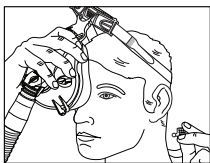
Taking Off the Headgear and Mask

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 face (Figure 11).

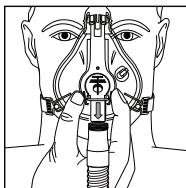
By using the Quick Clip to remove your mask, you'll be able to maintain your mask and headgear adjustments every day.

Tubing Quick Release

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



▶ Figure 11



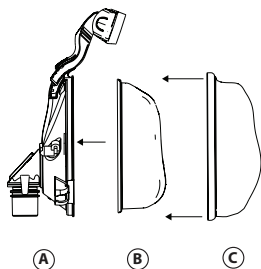
▶ Figure 12


Note to Home Care Providers: If a nasogastric tube or similar device is in place, use an optional nasogastric 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.

Assembling the Cushion and Flap

Remove the Gel cushion by detaching the comfort flap with its integrated retaining ring from the faceplate. Do this by pressing on the faceplate tabs at the bottom of the mask. Clean or discard the cushion as necessary.

First, place the Gel cushion onto the faceplate (Figure 13). Then, put the Comfort Flap over the Gel cushion and push the retaining ring onto the faceplate until the connection tabs click into place. Gently tug on the cushion to make sure all of the parts are securely in place.



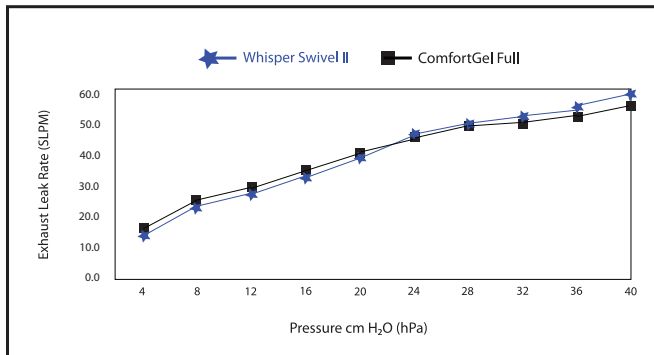
 **Figure 13**

- A = Mask Faceplate
- B = Gel Cushion
- C = ComfortFlap with Retaining Ring

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



ComfortGel Full

Pressure Drop cm H₂O (hPa)

	50 SLPM	100 SLPM
All mask sizes:	.4	1.0

Deadspace

Small 260 mL

Medium 280 mL

Large 300 mL

X-Large 320 mL

Disposal

Dispose of in accordance with local regulations.

Storage Conditions

-4° to 140° F (-20° to +60° C)

15% to 95% relative humidity, non-condensing

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.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME STATES DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

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.

Reorder Numbers

1040135	S ComfortGel Full Face Mask w/ Headgear
1040136	M ComfortGel Full Face Mask w/ Headgear
1040137	L ComfortGel Full Face Mask w/ Headgear
1062004	XL ComfortGel Full Face Mask w/ Headgear
1040568	S ComfortGel Full Face Mask w/o Headgear
1040569	M ComfortGel Full Face Mask w/o Headgear
1040570	L ComfortGel Full Face Mask w/o Headgear
1062003	XL ComfortGel Full Face Mask w/o Headgear
1044861	RP S ComfortGel Full Flap and Cushion
1044862	RP M ComfortGel Full Flap and Cushion
1044863	RP L ComfortGel Full Flap and Cushion
1062032	RP XL ComfortGel Full Flap and Cushion
1040798	RP S ComfortGel Full Face Mask Cushion
1040799	RP M ComfortGel Full Face Mask Cushion
1040800	RP L ComfortGel Full Face Mask Cushion
1062030	RP XL ComfortGel Full Face Mask Cushion

Reorder Numbers

1040795	RP S ComfortGel Full Face Mask Flap
1040796	RP M ComfortGel Full Face Mask Flap
1040797	RP L ComfortGel Full Face Mask Flap
1062031	RP XL ComfortGel Full Face Mask Flap
1040138	RP ComfortGel Full Headgear
1040139	RP Mushroom Swivel Clips, Blue
1040114	RP Silicone Pillow Forehead Pad
1049398	RP ComfortGel Full Entrainment Valve, Swivel, Blue

