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ComfortFusion  
INSTRUCTIONS FOR USE

**PHILIPS**  
RESPIRONICS

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## Package Contents

- ComfortFusion nasal mask
  - Headgear
  - Mask assembly
  - Cushion and Flap
- Instructions for use
- QuickStart fitting tips

DuoPacks and FitPacks may include extra cushion and flap with integrated retaining ring.



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

# ComfortFusion Nasal Mask

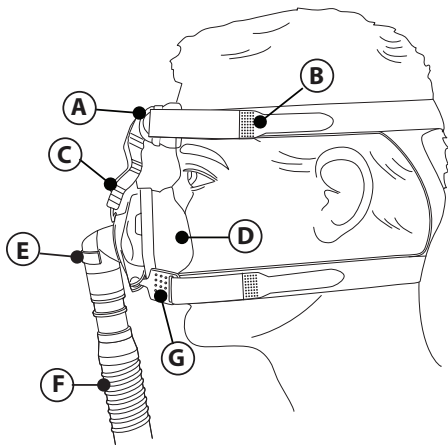


Figure 1

- A = Forehead pad
- B = Headgear tab
- C = Forehead support arm  
with StabilitySelector
- D = Cushion
- E = Exhalation port  
(Do not block)
- F = Tubing (connects to  
CPAP device)
- G = Quick Clip

INSTRUCTIONS FOR USE

**CAUTION**

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

## Intended Use

The ComfortFusion Nasal 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 (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.



**Important Note:** An exhalation port is built into the ComfortFusion Nasal Mask so that 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 the device, the oxygen flow must be turned off when the device is



### 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.

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 health care professional.
- 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.
- 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.
- 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.

## Symbols

Symbol	Description
	General Caution or Warning
	Consult instructions for use
×1	System One Resistance Control



## Before Use

- Hand wash the mask.
- Read and understand the instructions completely.
- Wash your face.
- Remove the Quick Start fitting tips (if attached to the headgear).

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.

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](http://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 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 the Headgear from the Mask

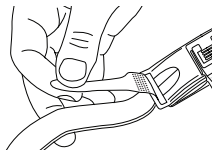
Please use one of the following methods to remove the headgear from the mask.

### Method 1

Undo the four headgear tabs (Figure 2) on the headgear and pull the straps out of the slots in the forehead support bracket and on the Quick Clips.

### Method 2

Disconnect the Quick Clips. Pull the Quick Clip ball up and away from the socket (Figure 3). Do not pull the ball through the socket. Leave the top headgear straps attached.



 **Figure 2**

*Undo Headgear Tabs*



 **Figure 3**

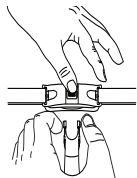
*Pull the ball up and away from the socket, not through the socket.*

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

## Attaching the Headgear to the Mask

1. To reattach the headgear to the forehead support arm, thread the top headgear straps into the slots in the forehead support bracket and fold the tabs to catch the headgear straps.
2. Attach the Quick Clips to the mask by placing the ball against the socket and gently pressing into place.

Then connect the forehead support arm by pressing in on the center of the forehead support pad and then squeezing the upper



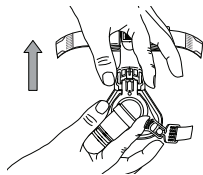
 **Figure 4**

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

sides of the support arm together and sliding the tabs into the forehead support pad until they latch into place.

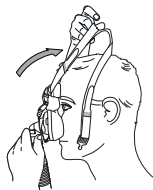
## Achieving the Right Fit

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.
2. Disconnect one, or both of the Quick Clips. Hold the mask cushion over your nose (Figure 6) and pull the headgear on over your head. Connect the Quick Clips if detached.



**Figure 5**

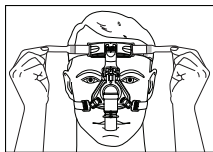
*Forehead Arm—gently squeeze the arms.*



**Figure 6**

*Put on the mask.*

3. Adjust the top headgear strap (Figure 7) using both hands and move the headgear tabs to a comfortable position. The forehead pad should be touching the forehead lightly. Adjust the bottom strap so that the mask is sitting gently on the face.
4. Connect the tubing (included with your CPAP or bi-level device) to the swivel elbow on the mask.
5. Turn on the airflow.
6. 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 7**

*Adjust the top strap.*

## Troubleshooting Leaks

You may need to adjust the forehead support arm to reduce leaks or pressure points at the bridge of the nose or above the lip. We offer these tips to adjust for leaks:

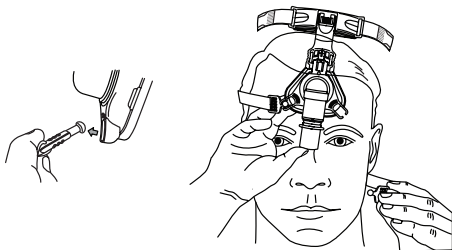
- For leaks around the bridge of the nose or into the eyes gently squeeze the arms of the StabilitySelector and adjust to a lower position.
- For leaks under the nose or near the lip gently squeeze the arms of the StabilitySelector and adjust to a higher position.
- Re-seat the mask by pulling it directly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



## Removing the Headgear & Mask

Disconnect one, or both Quick Clips from the mask sockets:

- Grasp the body of the Quick Clip and gently pull it out of the socket away from the face.
- After the Quick Clip is disengaged, slide the mask over your head.



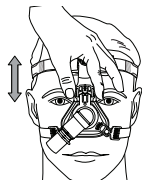
**Figure 8**

*To Remove—disconnect a Quick Clip (or both) and slide mask over head.*

## Headgear Tightness

The most common mistake is overtightening the headgear. The headgear should fit loose and the mask and headgear should feel comfortable when worn.

- 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 headgear straps.
- You should be able to easily run a finger under the headgear straps.



 **Figure 9**

*Troubleshooting—Adjust the StabilitySelector to lessen leaks.*

### **Comfort Tip!**

*Do not overtighten the headgear straps. Overtightening can cause or worsen leaks.*

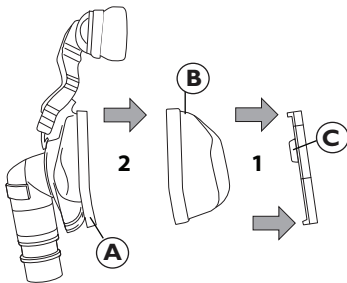
## Assembling the Retaining Ring and Cushion

### To Remove:

Unhook the retaining clips (Figure 10) on the bottom and the sides of the mask.

Step 1: Remove the retaining ring.

Step 2: Remove the cushion.



**Figure 10**

*Unhook the Retaining Clips—Remove the retaining ring first, then remove the cushion.*

*A = Faceplate*

*B = Cushion*

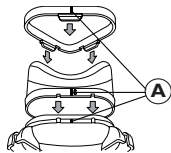
*C = Retaining Clip*

**To Attach:**

First, note the cutouts on the bottom of the cushion and the alignment marks (Figure 11) on the bottom of the cushion, faceplate and retaining ring.

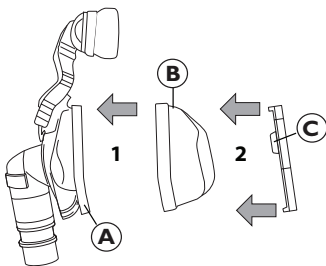
Step 1: Place the cushion against the faceplate.

Step 2: Put the retaining ring around the cushion. Press the ring (Figure 12) firmly against the faceplate until all three sides click into place. Gently tug on the cushion and the ring to make sure all of the parts are securely in place.



**Figure 11**

*A = Alignment Marks—  
The mask, faceplate, and  
retaining ring are marked  
for easy assembly.*



**Figure 12**

*Press the Ring—All three  
sides should click into  
place.*

*A = Faceplate*

*B = Cushion*

*C = Retaining Clip*

## Disposal

Dispose of in accordance with local regulations.

## 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.

### Deadspace Volume

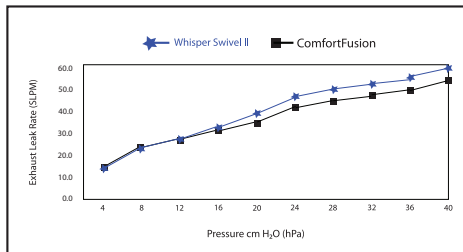
S 130ml

M 140ml

### Pressure Drop cm H<sub>2</sub>O (hPa)

	<u>50 SLPM</u>	<u>100 SLPM</u>
S	0.1	0.4
M	0.1	0.4

## Intentional Leak



## Storage Conditions

-4° to +140° F (-20° to +60° C)  
15% to 95% RH, 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 Respironics, Inc. dealer or Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Respironics, StabilitySelector, and Whisper Swivel are registered trademarks, and ComfortFusion, Quick Clip, DuoPack, FitPack and Fusion Headgear are trademarks, respectively, of Respironics, Inc. and its affiliates. Latex free.

## Reorder Numbers

1040768 ComfortFusion Mask w/ Headgear, FitPack, S/M  
1040769 ComfortFusion Mask w/ Headgear, S Cushion  
1040770 ComfortFusion Mask w/ Headgear, M Cushion  
1040842 ComfortFusion Mask w/ Headgear, DuoPack, S  
1040843 ComfortFusion Mask w/ Headgear, DuoPack, M  
1040836 ComfortFusion Mask, No Headgear, FitPack, S/M  
1042205 ComfortFusion Mask, No Headgear, S Cushion  
1042206 ComfortFusion Mask, No Headgear, M Cushion  
1040844 Fusion Headgear  
1040840 Cushion and Retaining Ring, S  
1040841 Cushion and Retaining Ring, M  
1040773 Premium Forehead Support w/ Pad, Blue  
1040774 Premium Forehead Pad, Blue, 4 pack  
1004395 Exhalation Elbow Kit  
1002720 Split Washer Kit, 5 pack  
7041 Mask Swivel  
312710 O<sub>2</sub> Enrichment Attachment  
1008814 Retaining Ring  
1009723 Headgear Quick Clips, 2 pack

Visit [www.sleepapnea.com](http://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 (REF 1027825).



