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Manufactured for:
Respironics Inc.
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1067013
JAW 01/12/10



ComfortGel Blue

INSTRUCTIONS FOR USE

PHILIPS
RESPIRONICS

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Package Contents

- COMFORTGEL BLUE
 - faceplate
 - comfort flap
 - gel cushion
- Premium headgear
- Instructions for use
- Quick fit tips



Note

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

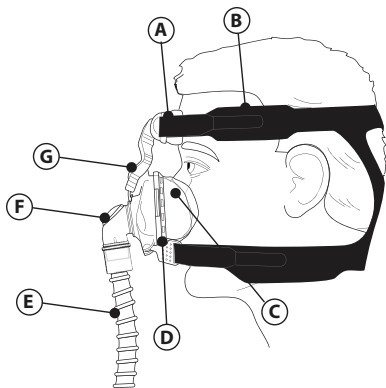


Figure 1

A = Forehead Pad
B = Headgear Tab
C = Gel Cushion with Comfort Flap
D = Quick Clip and Faceplate Socket
E = Tubing
F = Elbow with Exhalation
(Do not block or remove)
G = Stability Selector

COMFORTGEL BLUE

Intended Use

The ComfortGel Blue 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 ComfortGel Blue mask so a separate exhalation port is not required.



Warnings, Cautions and Notes



Caution

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

Warnings, Cautions and Notes (cont.)

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, Cautions and Notes (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.
- 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.
- 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.
- The gel mask is not customizable. Do not attempt to heat.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears or cushion damage resulting in gel exposure, etc). Discard and replace any component 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.

Symbols

Symbol	Description
	Consult instructions for use
	Caution or Warning
	Tip
	Note
	System One Resistance Control Setting

Symbols

Symbol	Description
	Does not contain natural rubber latex
	Does not contain DEHP (bis (2-ethylhexyl)phthalate)

Before Use

- Read and understand the instructions.
- Hand wash mask.
- Inspect all parts for damage; replace any parts that are visibly deteriorated (cracking, crazing, tears, etc).
- Clean your/the patient's face.
- Verify that the mask and headgear are the correct size.

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.

COMFORTGEL BLUE

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  $\leftarrow \times 1$. 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.

Taking Off the Headgear

Undo the EZPeel tabs on the headgear and pull them through the slots in the forehead support and through the slots on the Quick Clips.

To reattach the headgear, thread the top headgear straps through the slots in the forehead support and through the slots on the Quick Clips. Fold the EZPeel tabs to latch onto the headgear straps.

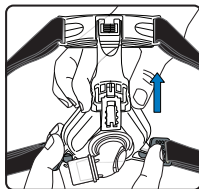



Figure 2

Achieving the Right Fit

1. Position the stability selector to its uppermost position (Figure 2). Hold the mask cushion over your nose.
 Note: You may want to disconnect a quick clip before putting on the headgear.
2. Slide the headgear over your head (Figure 3). Reconnect the quick clip after you have the headgear in position.
3. Adjust the headgear evenly using the top (Figure 4) and bottom (Figure 5) headgear

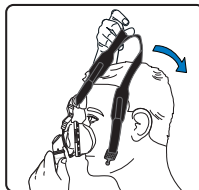


Figure 3

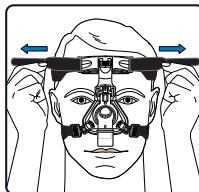
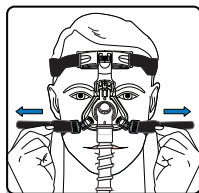


Figure 4

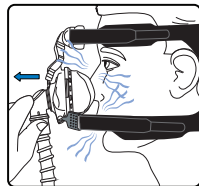
straps. The mask should rest comfortably against your face.

DO NOT OVERTIGHTEN THE HEADGEAR!

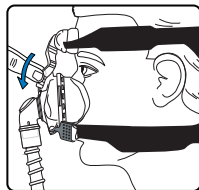
4. Connect the flexible tubing from your therapy device to the mask elbow. Turn on the airflow.
5. Minimal leaks are acceptable. Small adjustments are all that are needed to eliminate excessive leaks. We suggest the following adjustments:
 - Re-seat the mask by pulling the mask directly away from your face and set it back into place gently (*Figure 6*).
 - For leaks around the eyes, use the stability selector and adjust downward one click at a time (*Figure 7*).
 - For leaks around the mouth, a slight adjustment to the lower headgear straps will minimize the leak, do not overtighten.
6. Make any final adjustments lying down.



 **Figure 5**



 **Figure 6**



 **Figure 7**

Comfort Tips

- *Re-seat the mask by pulling it directly away from your face and gently setting it back into place.*
- *Use the stability selector to adjust for leaks or pressure. Some leakage is normal.*
- *The headgear should fit comfortably and the mask should not dig into your skin. If your skin bulges around the mask or if you see red marks on your face due to tightness, loosen the headgear.*

Note

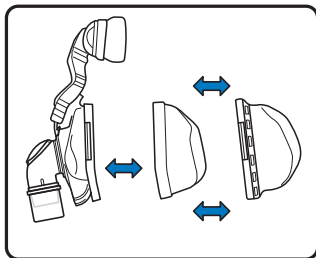
Do not attempt to separate the StabilitySelector from the faceplate rail.



COMFORTGEL BLUE

Cushion Removal and Attachment

1. Remove the gel cushion by detaching the comfort flap with its integrated retaining ring from the faceplate. Do this by unhooking the side and bottom clips of the ring from their connection points on the faceplate and separating the pieces.
2. Clean or discard the gel cushion as necessary.
3. To attach, place the clean or new gel cushion into the faceplate. Then place the comfort flap over the gel cushion and push the retaining ring into the faceplate until it clicks into place.

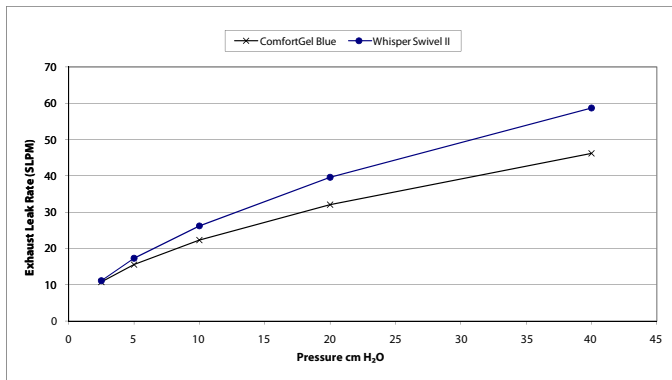


Specifications

⚠ 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 BLUE

Pressure Drop cm H₂O

	50 SLPM	100 SLPM
P-S-M-L	0.2	0.7

Deadspace Volume

Petite:	76 mL
Small:	97 mL
Medium:	99 mL
Large:	118 mL

Disposal

Dispose of in accordance with the local regulations.

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.

Reorder Numbers

1070037 L COMFORTGEL BLUE NASAL MASK W/HGR
1070038 M COMFORTGEL BLUE NASAL MASK W/HGR
1070039 S COMFORTGEL BLUE NASAL MASK W/HGR
1070040 P COMFORTGEL BLUE NASAL MASK W/HGR
1070041 L COMFORTGEL BLUE NASAL MASK W/O HGR
1070042 M COMFORTGEL BLUE NASAL MASK W/O HGR
1070043 S COMFORTGEL BLUE NASAL MASK W/O HGR
1070044 P COMFORTGEL BLUE NASAL MASK W/O HGR
1070049 L COMFORTGEL BLUE NASAL MASK DUOPCK W/HGR
1070050 M COMFORTGEL BLUE NASAL MASK DUOPCK W/HGR
1070051 S COMFORTGEL BLUE NASAL MASK DUOPCK W/HGR
1070052 P COMFORTGEL BLUE NASAL MASK DUOPCK W/HGR
1070053 M/S COMFORTGEL BLUE NASAL MASK FTPK W/HGR

COMFORTGEL BLUE

Reorder Numbers

1070105	RP L COMFORTGEL BLUE FLAP AND GEL CUSHION
1070106	RP M COMFORTGEL BLUE FLAP AND GEL CUSHION
1070107	RP S COMFORTGEL BLUE FLAP AND GEL CUSHION
1070108	RP P COMFORTGEL BLUE FLAP AND GEL CUSHION
1070114	RP SILICONE FOREHEAD PAD 1PK
1009723	COMFORTGEL HDGR SWIVEL CLIPS,2PK
1012040	RP COMFORTGEL SIZING GAUGE
1033678	RP PREMIUM HEADGEAR
1059236	RS PREMIUM HEADGEAR

Visit us on-line at www.respironics.com for a complete list of products and reorder numbers, or contact customer service at 1-800-345-6443 (USA or Canada) or 1-724-387-4000.

