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ComfortGel INSTRUCTIONS FOR USE



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Instructions for Use

Package Contents

- ComfortGel nasal mask
 - Premium headgear w/ EZPeel tabs
 - Mask assembly
 - Gel cushion
 - Comfort flap
- Instructions for use
- Quick fit tips
- Comfort Guide DVD
- ♠ Note: Visit www.respironics.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 (USA or Canada only) or at 1-724-387-4000 to obtain a product catalog (REF 1027825).

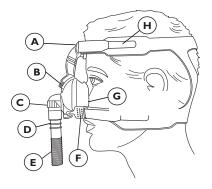




Figure 1

A = Forehead Pad
B = Forehead Support
Arm with Stability Selector
C = Exhalation Port - DO
NOT BLOCK
D = Mark Suited

D = Mask Swivel (Connects to Tubing) E = Tubing (Connects to CPAP Device) F = Quick Clip

G = Gel Cushion & Comfort Flap H = EZPeel Tab ▲ Caution: US federal law restricts this device to sale by or on the order of a physician.

Intended Use

The ComfortGel 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 Nasal Mask so a separate exhalation port is not required.
- **⊜ Important Note:** The ComfortGel mask is designed to fit comfortably on most adults. However, because of differences in facial features, some users need a customized fit. You can customize this mask by re-forming the gel to fit your face.

▲ 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

⚠ 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 emphasis on an operating characteristic.

- 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 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.

- Hand wash prior to first use. Inspect the mask for damage or wear (cracking ,crazing, tears, cushion damage resulting in gel exposure, 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.

Disposal

Dispose of in accordance with local regulations

Symbols

Symbol	Description	Symbol	Description
\triangle	Warning or Caution	X	Does not contain natural rubber latex
	Note		Does not contain DEHP (bis (2-ethylhexyl) phthalate)
⊗ .	Tip	X1	System One Resistance Control Setting
Ţį	Consult instructions for use	RONLY	Prescription required

Before Use

- Hand wash mask.
- Read and understand the instructions completely.
- Remove protective coverings.
- Wash face.
- Remove the quick fit tips.

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

Cleaning Instructions

For Multi-Patient Use:Visit www.respironics.com or contact Respironics Customer Service at 1-800-345-6443 (USA or Canada only) or at 1-724-387-4000 to obtain Mask Disinfection Instructions (REF 1011138).

For Home Use: The mask and tubing should be cleaned daily.

Cleaning the Mask

- **♦ Note:** It is not necessary to disconnect the headgear for daily use and cleaning.
- Hand wash mask in warm water with a mild dishwashing detergent.
- ▲ Caution: Do not use bleach, alcohol, or cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
- 2. Rinse thoroughly. Pat with a towel and air dry completely before use.
- 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.

Cleaning the Headgear

The headgear should be cleaned weekly by hand or machine wash in the gentle cycle. Lay the headgear flat or line dry. Do not place the headgear into the dryer.

COMFORTGEL

System One Resistance Control

This mask uses the System One Resistance Control setting K 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.

Removing and Attaching the Headgear

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

Method 1

<u>Undo the EZPeel tabs</u> (Figure 2) 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 to the forehead support arm, 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.

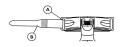




Figure 2

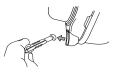
A = Forehead Pad Slot B= EZPeel Tab

Method 2

<u>Disconnect the Quick Clips and Forehead</u>
<u>Support Arm from the Forehead Support.</u>
Pull the Quick Clip ball up and away from the socket (Figure 3).

Do not pull the ball through the socket.

Press in on the center tab of the forehead support (Figure 4) and then squeeze the upper sides of the support arm together to disengage or re-engage the forehead support pad.





Disconnect Quick Clips



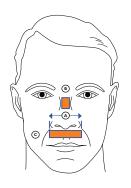


Press Center Tab — Squeeze ribbed sides of the support arm to engage and disengage.

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

Getting the Right Cushion Size

Identify the areas of the face (Figure 5) A)sides of the nostrils, B)bridge of the nose, and C)below the nose tip and above the lip. Use the sizing gauge integrated into the product bag to get the right size cushion. Choose the smallest size mask cushion that is wide enough to extend beyond the nostrils but does not obstruct breathing.







Areas of the Face

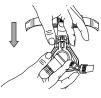
A = Sides of nostrils B = Bridge of nose zone C = Below the nose tip, above the lip

Achieving the Right Fit

 Open the headgear to a large setting and adjust the forehead arm (Figure 6) 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, we recommend disconnecting one of the Quick Clips.

- Put on the mask (Figure 7). Simply hold the mask cushion gently over nose and pull the headgear on over head. Then reconnect the Quick Clip when the headgear and mask is on.
- 3. Adjust the top (Figure 8) headgear strap first by using the EZPeel tabs on the headgear. The forehead pad should be touching the forehead lightly. Adjust the





Adjust the forehead arm to the highest position.





Put on the mask.

- bottom strap so that the mask is sitting gently on the face.
- 4. Connect the flexible tubing (Figure 9) (included with the CPAP or bi-level device) to the swivel on the mask elbow.
- 5. Turn on the airflow.





6. Lie down (Figure 10) and breathe normally through nose, keeping lips closed. Adjust the top strap. If the forehead support does not rest comfortably against the forehead, tighten the top headgear strap on the mask.

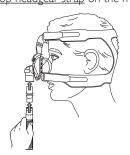




Figure 9

Connect the flexible tubing to the mask swivel. The mask swivel connects to the mask elbow.



Troubleshooting Leaks

Adjust the forehead support arm 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 under the nose or near the lip





Figure 11

Troubleshooting—Adjust the StabilitySelector to lessen leaks.

- 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.

Comfort Tip:

If not able to minimize the air leaks and obtain a comfortable fit, follow the directions for Customizing the ComfortGel Cushion.

Removing the Headgear and Mask

- 1. First remove one (or both) Quick Clips from the mask sockets (Figure 12).
- 2. Grasp the ball of the Quick Clip and gently pull it out of the socket away from the face.
- 3. After the Quick Clip is disengaged, slide the mask over head.

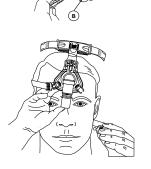




Figure 12

A = Quick Clip Ball B = Faceplate Slot

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

Customizing the ComfortGel Cushion

Tools Needed

- A clean pan to boil water
- A clean container for cold water
- Tongs or utensil to remove cushion from the hot water (optional)

Preparation

 Disconnect the bottom neckstraps by using the Quick Clips so the headgear does not get wet. Although the headgear is water resistant it may be uncomfortable to wear while customizing the gel cushion.

⚠ Caution: The headgear must be partially disconnected before customizing the gel cushion.

- 2. Fill a bowl with enough cold water to cover the entire mask cushion and set aside
- 3. Fill a pan with enough water to cover the entire mask cushion. Place the pan over medium heat and bring the water to a boil.

When the water reaches a boil, turn off the heat.

⚠ Caution: Do not place the gel cushion into the microwave.

- 4. Hold the forehead support pad (or use tongs) and submerge the mask cushion into the hot water for 4 minutes.
- Carefully remove the mask from the hot water and submerge into the cold water for 10 seconds to cool the cushion (Figure 13).
- 6. Remove the mask from the cold water and shake off excess water

▲ Warning: Carefully touch the mask cushion to be sure that it has cooled enough to prevent irritation or burning.





Cool the Cushion—
Submerge for 10 seconds.

- To form the gel cushion, position the mask over nose, and press the mask cushion gently against face. Pull the headgear over head, and connect the Quick Clips.
 - Do not apply excessive pressure to the cushion.
- 8. Wear the mask for 5 minutes to allow the gel cushion to set.
- Remove the mask and headgear or connect the therapy device and use as directed.

Removing and Attaching the Flap and Integrated Ring

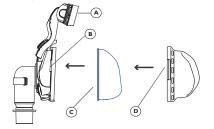
To Remove

- 1. Loosen the bottom and the sides of the retaining ring (Figure 14).
- 2. Remove the Comfort Flap with the integrated retaining ring.
- 3. Remove the cushion. Clean or replace the cushion as needed.

To Attach

Note the cutout on the top of the flap ring.

- 1. Place the cushion against the faceplate.
- 2. Place the gel cushion into the faceplate.
- Put the flap with ring around the cushion and press the connection points (Figure 15) firmly against the faceplate until the sides click into place.
- Gently tug on the cushion and the ring to make sure all of the parts are securely in place.







Loosen the bottom and sides of the retaining ring.



Figure 15

A = Forehead pad

B = Faceplate Connection
Point
C = Gel Cushion
D = Flap with Integrated
Retaining Ring

Operating and Storage Conditions

Operating:

15% to 95% relative humidity, non-condensing

Storage:

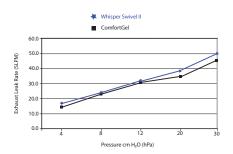
$$-4^{\circ}$$
 to 140° F (-20° to +60° C)

15% to 95% relative humidity, non-condensing

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:	0.1	0.25

Deadspace

Petite Cushion:	83.6 cc
Small Cushion:	111.4 cc
Medium Cushion:	121.3 cc
Large Cushion:	142.6 cc

COMFORTGEL

	Reorder Numbers
1009040	ComfortGel Mask with Premium Headgear, P (petite)
1009041	ComfortGel Mask with Premium Headgear, S (small)
1009042	ComfortGel Mask with Premium Headgear, M
(medium)	
1009043	ComfortGel Mask with Premium Headgear, L (large)
1010518	ComfortGel Mask, P
1010519	ComfortGel Mask, S
1010640	ComfortGel Mask, M
1010641	ComfortGel Mask, L
1033678	Premium Headgear w/ EZPeel tabs
1002800	Deluxe Headgear
1009048	Gel Cushion, P
1009049	Gel Cushion, S
1009050	Gel Cushion, M
1009051	Gel Cushion, L
1009052	Silicone Flap, P
1009053	Silicone Flap, S
1009054	Silicone Flap, M
1	

Reorder Numbers 1009109 Silicone Flap, L 1018401 Forehead Support and Pad 1009722 Silicone Forehead Pads, 4 pack 1010646 Diffusion Elbow with Exhalation Kit Mask Swivel 7041 1009723 Headgear Quick Clips, 2 pack 1002720 Split Washer Kit 312710 O, Enrichment Attachment

Visit www.respironics.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 (USA or Canada only) or at 1-724-387-4000 to obtain a product catalog (REF1027825).

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.

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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.

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