


Instructions for Use

ComfortClassic Nasal Mask

Intended Use

The ComfortClassic 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 ComfortClassic Nasal Mask so a separate exhalation port is not required

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

Symbols



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 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.
- The gel mask is not customizable. Do not attempt to heat.
- 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,

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.

Before Each Use

- Remove the headgear from the mask and clean the mask using the instructions below.
- Wash your face
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.

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 or contacting Respironics 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.

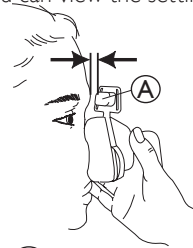
Important Notes:

- 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.

Sizing the Spacer and Headstrap

The gel forehead spacer provides support for your forehead while you are wearing the mask (Figure 1). The spacer has two different adjustable positions. To choose the position that is right for you, hold the mask gently against your face. If the spacer touches your forehead, it is in the correct position for you.



 **Figure 1**

If the spacer does not touch your forehead, take the gel spacer off *A = Spacer*

of the mask and turn it upside down. Insert the teeth of the spacer into the vertical slots at the top of the mask. This should help extract the spacer further away from the mask.

The headstrap has two sets of tabs for better adjustment (Figure 2). The black tabs are for larger sized heads. For a smaller head size, use the blue tabs. You can remove the extra tabs with scissors. Reconnect the headstrap to the mask.

Achieving the Right Fit

1. Hold the mask lightly against the patient's face, and slide the headstrap over his/her head (Figure 3). Use the tabs on the headstrap to adjust the strap length.

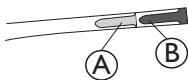


Figure 2

A = Blue Tabs
B = Black Tabs



Figure 3

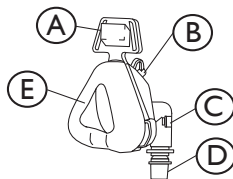


Figure 4

A = Foam Forehead Spacer
B = Removable Port Cap
C = Exhalation Port
(Do not block or seal)
D = Mask Swivel
E = Mask Cushion

2. Connect the flexible tubing (included with the CPAP or bi-level device) to the swivel elbow (Figure 4). Turn on the CPAP or bi-level device.
3. Lie down and breathe normally through your nose keeping your lips closed. Unhook and gradually tighten the straps until the mask has minimal leaks and fits comfortably.

Note: Do not overtighten the headstraps. Overtightening can irritate the patient's face, cause or worsen leaks, or cause damage to the mask.

Removing the Mask and Headstrap

Because the entire headstrap stretches, you should not need to unfasten the straps to remove the headstrap. Simply slide the mask and headstrap over your head. If necessary, unfasten either of the neck straps.

Disposal

Dispose of in accordance with local regulations.

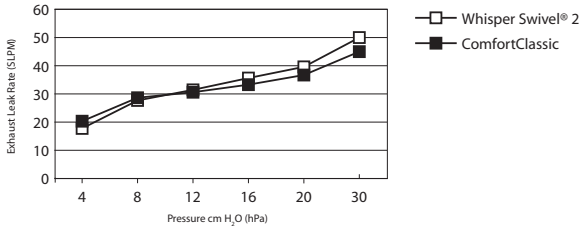
Order Information

Order #	Item	Order #	Item
1007963	ComfortClassic with Headgear, S	1002464	Gel Forehead Spacers Kit
1007964	ComfortClassic with Headgear, M	1008651	Foam Forehead Spacers, 5 pk
1007966	ComfortClassic Mask only, S	1002720	Split Washer Kit (5 ea.)
1007965	ComfortClassic Mask only, M	7041	Mask Swivel
1002800	Deluxe Headgear	1011138	Mask Disinfecting Instructions
1004395	Exhalation Elbow Kit		

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
S	0.1	0.2
M	0.1	0.3

Deadspace

S 96 cc

M 114 cc

Storage Conditions

Temperature: -4° F to +140° F (-20° C to +60° C)

Relative Humidity: 15% to 95%, non-condensing

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Murrysville, PA 15668 USA

