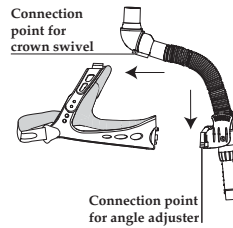


## Removing the Headgear

To remove the crown swivel from the crown strap, press inward on the sides of the crown swivel's connection point and slide it off of the tracks on the crown strap.

To remove the angle adjuster from the headgear, press inward on the sides of the angle adjuster's connection point and slide it off of the tracks on the crown strap.



## Removing the Nasal Cushions

To remove the nasal interface cushion from the mask, hold the mask with the nasal interface cushion facing you. Twist the nasal interface cushion to unhook the elbow connector from the vertical tube. Pull the nasal interface cushion off of the tube.

## Attaching the Headgear

The ComfortLite Headgear is not included in all packages, but may be purchased separately.

To attach the crown swivel to the crown strap, press inward on the sides of the crown swivel's connection point and slide it onto the tracks at the top of the crown strap. The two pieces should interlock with a clicking sound.

To attach the angle adjuster to the headgear, press inward on the sides of the angle adjuster's connection point and slide it onto the tracks at the front of the headband. The two pieces should interlock with a clicking sound.

## ComfortLite Reorder Numbers

Part Number	Description	Direct Seal Cushion Only		
		SIZE	SINGLE	5 PACK
1014205	ComfortLite Headgear**			
1014905	Mask Combo w/hgr, 4,5,S,M**	1	1021802	N/A
1014906	Mask Combo w/hgr, 5,6,M,L**	2	1021806	N/A
1014907	Mask w/hgr, Direct Seal Cushion, 4,5,6**	3	1021807	1020930
1014913	Mask w/hgr, Simple Cushion, S,M,L**	4	1021815	1020407
1025551	ComfortLite SubAssembly w/hgr**, no Cushion	5	1021816	1020408
1025550	ComfortLite SubAssembly, no Cushion	6	1021817	1020409
1014916	Mask Combo, 4,5,S,M*			
1014917	Mask Combo, 5,6,M,L*			
1014918	Mask, Direct Seal Cushion, 4,5,6*			
1014919	Mask, Simple Cushion, S,M,L*			
1018420	Direct Seal Pack, 1,2,3			
1020795	Rear Strap, Long			
		Simple Cushion Only		
		SIZE	SINGLE	5 PACK
	Petite		1021835	1020414
	Small		1021830	1020413
	Medium		1021823	1020412
	Large		1021821	1020411

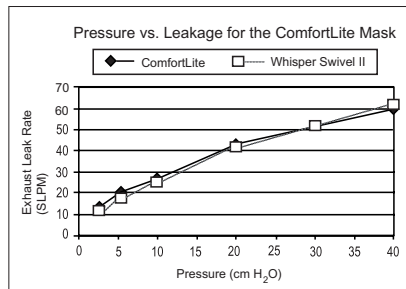
\*Includes cushions as listed and all other parts except the headgear. See diagram on front page.

\*\*Headgear includes headband, adjustable rear strap and crown strap.

## Deadspace Volume

Direct Seal Cushion: between 14cc and 38cc.

Simple Cushion: between 27cc and 65cc.



Patents pending.

1020963  
JW 05/04/05

# ComfortLite™

## Nasal Mask Instructions

Multi-Patient Use Reusable

Latex Free



**Intended Use:** The ComfortLite mask is intended for use by adults as an interface with CPAP or bi-level devices. An exhalation port is built into the mask so that 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

- Do not use this mask unless the CPAP or bi-level device is connected and the airflow is turned on. Explanation of Warning: At low pressures, the airflow through the exhalation port may not be enough to clear all of the exhaled gas (CO<sub>2</sub>) from the mask. The patient may rebreathe in some of the air previously exhaled.

- Do not block or otherwise try to seal the exhalation port(s). Explanation of Warning: Rebreathing of exhaled air for longer than several minutes, in some circumstances, may lead to suffocation.

- 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 CPAP or bi-level systems.

- If oxygen is used with the CPAP or bi-level system, the oxygen flow must be turned off when the system is not in operation.

Explanation of Warning: When the CPAP or bi-level system is not in operation and the oxygen flow is left on, oxygen delivered in the ventilator tubing may accumulate within the CPAP or bi-level system enclosure. Oxygen accumulated in the CPAP or bi-level system will create a risk of fire. This warning applies to most CPAP or bi-level systems.

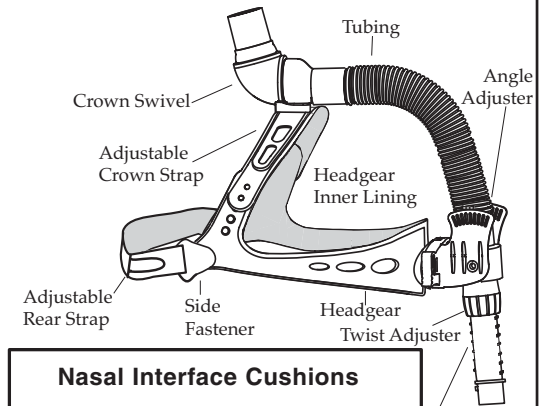
- Oxygen accelerates fires. Keep the CPAP or bi-level system and oxygen container away from heat, open flames, any oil substance, or other sources of ignition. Do not smoke in the area near the device or the oxygen container.
- Some users may experience skin redness. If this occurs, consult your healthcare professional.

**Important:** Device pressures should be verified when used by other vendor's auto-titrating devices. ComfortLite has been validated to work with all Respironics CPAP and Bi-level therapy devices.

## Package Contents

ComfortLite Nasal Mask  
Simple Cushions

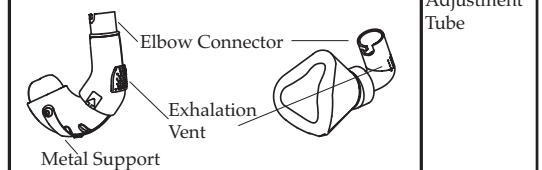
ComfortLite Headgear  
Direct Seal Cushions



## Nasal Interface Cushions

Direct Seal Cushion™ (sizes 1-6)\*

Simple Cushion™ (sizes P, S, M, L)\*\*



\* Standard adult sizes are 4, 5, and 6.

NOTE: The most common size is 5.

\*\* Standard adult sizes are S, M, and L.

NOTE: The most common size is M.

## Putting On and Adjusting the Headgear

**Note:** Clean your face and the ComfortLite mask, tubing, and nasal interface cushion thoroughly before use. (See “Cleaning Instructions” later in this document).

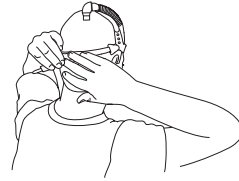
### Place the headgear over your head and adjust the straps:

a. Unfasten the Velcro® on the rear strap, and place the headgear over your head. Fasten the Velcro so that the fit is snug but comfortable.

**Important:** The front of the headgear should rest just above the eyebrows, and the sides should rest just above the ears. It may be necessary to unhook the crown strap in order to attain the proper positioning of the headgear above the eyebrows and ears.

b. Adjust the crown strap by detaching either the left or right (or both) plastic fastener(s) to two of the holes in the headgear so that the fit is snug and the rear strap sits naturally below your occipital lobe.

**Note:** The back edge of the crown strap should be in contact with the top of the head.



## Fitting the Cushion

The ComfortLite comes with an assortment of nasal interface cushions. Choose the one that provides the most comfortable fit, then follow the instructions below for fitting either the Direct Seal Cushion or the Simple Cushion.

### Direct Seal Cushion

To determine which size is appropriate, start with the largest cushion in the package. The bulbs of the Direct Seal Cushion should rest on the edge of the nostrils, blocking the ends. The bulbs should not be inserted into the nostrils. Therefore, you will want to choose a cushion with bulbs that are larger than your nostrils.

### Simple Cushion

To determine which size is appropriate, start with the smallest cushion in the package.

The cushion should not block or close the nostrils.

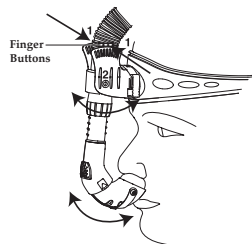
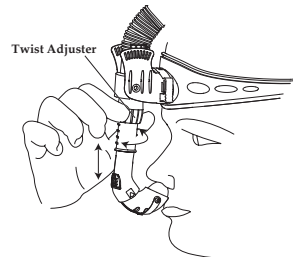
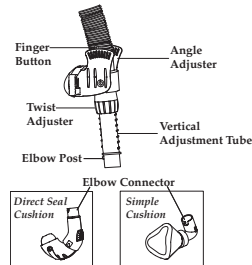
Once the appropriate cushion is selected, proceed with the following steps:

**Step 1** Use the twist adjuster to fully lengthen the vertical adjustment tube to allow for a personalized fit.

**Step 2** Change the position of the angle adjuster. Press the finger buttons at the top of the angle adjuster inward toward the tubing and pivot the buttons of the angle adjuster toward the headgear.

**Step 3** Attach the nasal interface cushion to the mask and hold the mask by the vertical adjustment tube. Turn the nasal interface cushion clockwise to hook the connector to the elbow post.

**Step 4** Connect the tubing of the CPAP or bi-level device to the swivel connector.



## Step 5 Adjust the Cushion

### Direct Seal Cushion

Use the twist adjuster to move the nasal interface cushion up or down so that it gently touches the outer rims of the nostrils. Repeat this step to achieve the most comfortable fit whenever necessary.

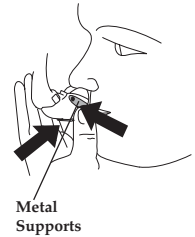
Use the angle adjuster to hold the nasal interface cushion against your face so that it rests above your upper lip.

### Simple Cushion

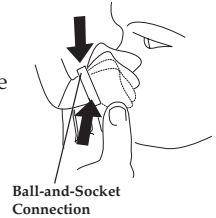
Tilt the Simple Cushion upward as far as it will go on the ball-and-socket connection.

Put on the headgear and mask. Turn the twist adjuster until the cushion touches the bottom of your nose. Pivot the angle adjuster until the fit is snug but not too tight.

Direct Seal Cushion



Simple Cushion



## Step 6 Check for air leaks. Turn on the CPAP or bi-level system.

Lie down and breathe normally through your nose with your lips closed.

## Cleaning Instructions

**For Multi-patient Use:** Contact Respironics Customer Service at 1-800-345-6443 to obtain Mask Disinfecting Instructions (Order #1011138).

**For Home Use:** Clean the mask and nasal interface cushion daily. Clean the headgear and tubing at least once each week or more often if needed.

## Daily Cleaning

**NOTE:** It is not necessary to disconnect the headgear for daily use and cleaning.

Hand wash the nasal interface cushion and mask in warm water with mild dishwashing detergent.

**Do not** use bleach, alcohol, or cleaning solutions containing alcohol.

**Do not** use cleaners containing conditioners or moisturizers.

Rinse thoroughly and air dry completely before use.

Inspect the mask and nasal interface cushion for damage or wear; replace if necessary.

## Weekly cleaning

Hand wash the headgear and tubing in warm water with mild dishwashing detergent.

**Do not** use bleach, alcohol, or cleaning solutions containing alcohol.

**Do not** use cleaners containing conditioners or moisturizers.

Rinse thoroughly. Pat with a towel to absorb excess moisture and air dry completely before use.

**NOTE:** For daily use, you do not have to unfasten the Velcro on the rear strap when putting on or removing the mask. When you are ready for bed, simply pull the mask and headgear on over your head as you would a cap. Make minor adjustments, as needed, to the height and angle of the nasal interface cushion or the metal support.

