COMFORTLITE 2 REORDER NUMBERS

1030493 ComfortLite 2 w/ Headgear, Size S,M,L Pillows Cushions

1025111 ComfortLite 2 w/Headgear, Size S,M,L, Simple Cushion

1025127 ComfortLite2 w/Headgear, Size 4,5,6, Direct Seal Cushion

1025225 ComfortLite 2 w/Headgear, No Cushions

Combo Packs

1030494 ComfortLite2 Combo w/ Headgear, Size S,M, Pillows Cushion, Size S,M, Simple Cushion

1030495 ComfortLite 2 Combo w/ Headgear, Size M,L, Pillows Cushion, Size M,L, Simple Cushion

1025112 ComfortLite 2 Combo w/Headgear, Size 4,5, Direct Seal Cushion, Size S,M, Simple Cushion

1025113 ComfortLite 2 Combo w/Headgear, Size 5,6, Direct Seal Cushion, Size M,L, Simple Cushion

Replacement Parts

1025114 ComfortLite 2 Headgear - Strap only

1025117 ComfortLite 2 Headgear w/ Strap

1027999 Small Accessory Pouch

1032007 ComfortLite 2 Pillows Sizing Gauge (5 pk)

1031154 ComfortLite 2 Pillows Sizing Gauge (20 pk)

1018624 ComfortLite 2 Simple Cushion Sizing Gauge (20 pk)

1018665 ComfortLite 2 Direct Seal Cushion Sizing Gauge (20 pk)

CUSHIONS (1 Pk.)



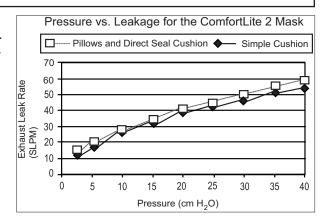
Presented With Compliments From www.DirectHomeMedical.com

<u>Pillows</u>	<u>Simple</u>	<u>Direct Seal</u>
1030502 - PETITE	1021835 - PETITE	1021802 - SIZE 1
1030503 - SMALL	1021830 - SMALL	1021806 - SIZE 2
1030504 - MEDIUM	1021823 - MEDIUM	1021807 - SIZE 3
1030505 - LARGE	1021821- LARGE	1021815 - SIZE 4
		1021816 - SIZE 5
		1021817 - SIZE 6

Visit www.respironics.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 to obtain a product catalog (#1027825).

Deadspace Volume

Pillows Cushion: between 19cc and 36cc. Simple Cushion: between 27cc and 65cc. Direct Seal Cushion: between 14cc and 38cc.



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1029515 Patents Pending IW 01/11/06

ComfortLite™2

NASAL MASK INSTRUCTIONS

MULTI-PATIENT USE REUSABLE LATEX FREE



INTENDED USE

The ComfortLite 2 mask is intended for use by adults as an interface with CPAP or bi-level devices. An exhalation vent is built into the mask so that a separate exhalation vent is not required.

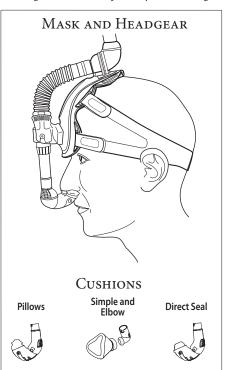
CAUTION! US federal law restricts this device to sale by or on the order of a physician.

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 (CO2) 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 bilevel 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 bilevel 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 2 has been validated to work with all Respironics CPAP and bi-level therapy devices.

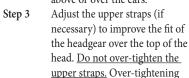


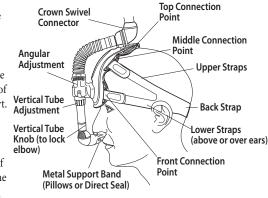
STEP-BY-STEP USAGE INSTRUCTIONS

NOTE: The headgear and mask only require a one-time sizing and fitting. 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.

Place the headgear against your forehead and pull the straps over your head. Step 1

Step 2 Tighten the lower straps to provide a firm vet comfortable level of stability. The front of the headgear should rest just above the eyebrows. The back strap of the headgear should be pulled down toward the back of the neck for maximum support The lower straps can be worn above or over the ears.





Vertical Tube

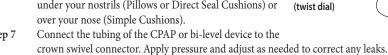
may cause the headgear to rise off of the head. NOTE: If you experience issues with stability or ear irritation, experiment with the top and middle connection points to find the best fit for you. Simply unfasten the hook and loop tab and thread the tab through the connection points.

Attach the appropriately-sized nasal cushion (see "Choosing a Cushion" in the next section). Step 4 Place the cushion's elbow connector onto the vertical tube and turn the elbow connector until it clicks onto the tab located on the vertical tube.

Move the cushion closer to your face by using the Step 5 angular adjustment. Simply squeeze the tabs located on the angular adjustment and pull them outward until the cushion rests gently against your face.

Move the cushion up or down using the vertical tube Step 6 adjustment. Twist the dial until the cushion rests gently under your nostrils (Pillows or Direct Seal Cushions) or over your nose (Simple Cushions).

Step 7

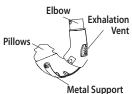


CHOOSING A CUSHION

The ComfortLite 2 may come with an assortment of nasal interface cushions, Follow the instructions below for fitting either the Pillows, or the Simple, or the Direct Seal Cushions.

Pillows Cushion

When choosing between pillows sizes, choose a larger size for a more robust seal with less insertion into the nostrils. Simply squeeze or adjust the metal support band to properly position the pillows to account for leaks.



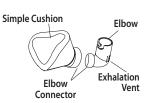
Angular

Adiustment

CHOOSING A CUSHION (CONT.)

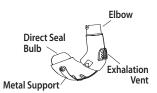
Simple Cushion

To determine which size is appropriate, start with the smallest cushion in the package. The cushion should not block or close the nostrils. The Simple Cushion and Elbow use a ball-and-socket connection. Slide the smaller opening of the Simple Cushion over the rounded end of the elbow. To angle the cushion to your features, just pivot the Simple Cushion as needed correct any leaks.



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 larger than your nostrils.



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.

<u>Do not</u> 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.

REMOVING THE MASK ASSEMBLY FROM THE HEADGEAR

First, completely unfasten the white retaining strap from the crown swivel and lift the mask assembly straight up. Squeeze the sides of the Mask Assembly (includes crown swivel, headgear clips located under the angular adjuster and slide them up and off the track. This will

completely remove the mask assembly from the headgear.

