

Removing the Headgear and Interface

You can quickly and easily remove the interface by sliding the headgear over your head or detaching one side of the headgear from the interface using the QuickClips.

Disposal of Parts

Dispose of any damaged or broken parts according to local regulations.

Replacing the Cushion

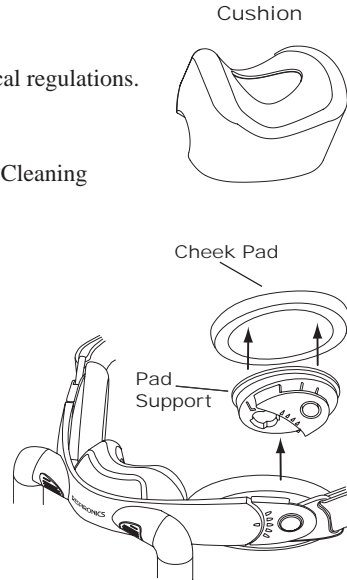
The nasal cushion comes in multiple sizes. Refer to the "Cleaning Instructions" section for detailed instructions on how to remove the current cushion and install the new one.

Removing and Replacing the Cheek Pads

NOTE: Remove the headgear for easier removal and reattachment of the cheek pads.

To remove the cheek pads, complete the following steps:

1. Grab the edge of the pad, and peel it away from the support to remove it.
2. To replace the pads, gently slip one of the pads over the edge of the pad support. Attach the other pad using the same method. NOTE: The pads are interchangeable.

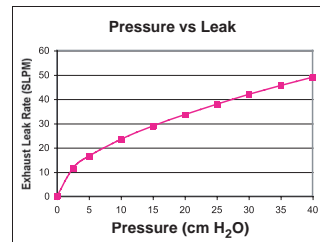


Pressure Drop

50 LPM Flow: 0.5
100 LPM Flow: 1.8

Enclosed Volume

Entire Assembly (typical): 110 ml
Nose Piece Only: 20.6 ml



1019214
JW 01/25/05

Reorder Numbers

| | |
|---------|---|
| 1019185 | ComfortCurve Interface, Headgear, and Tubing System (S, M, L) |
| 1022674 | ComfortCurve Cushion-Small |
| 1019143 | ComfortCurve Cushion-Medium |
| 1019144 | ComfortCurve Cushion-Large. |
| 1019206 | ComfortCurve Standard Headgear |
| 1022738 | ComfortCurve Tubing System (6 ft.) |
| 1019203 | ComfortCurve Silicone Cheek Pads - 2 Pk. |
| 1019207 | ComfortCurve Headgear Clips - 4 Pk. |
| 1019208 | ComfortCurve Pad Support - Left |
| 1019209 | ComfortCurve Pad Support - Right |
| 1019205 | ComfortCurve Cross Tube |
| 1022932 | ComfortCurve Bridge Color Variety - 5 Pk. |
| 1024767 | ComfortCurve Pouch |

ComfortCurve™

Nasal Interface, Headgear, and Tubing System

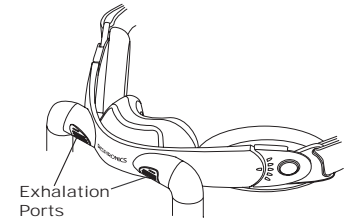
Single Patient Use
Reusable



Intended Use

The ComfortCurve is intended for use by adults to provide an interface for application of prescribed Respironics CPAP or bi-level therapy. **LATEX-FREE.**

NOTE: Exhalation ports are built into the ComfortCurve so that a separate exhalation device is not required. Before using the interface, the homecare provider should verify device pressure(s). The ComfortCurve is not suitable for providing life support ventilation.



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

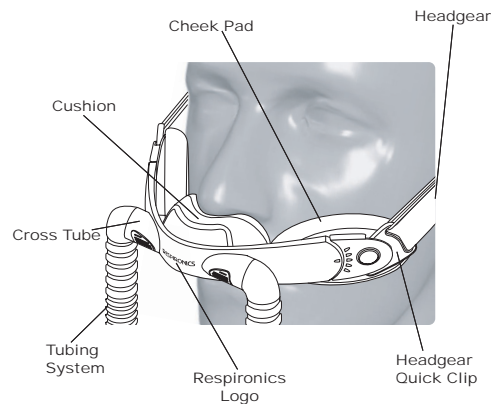
Warnings

- The ComfortCurve is designed for use with CPAP and bi-level systems recommended by your health care professional or respiratory therapist. Do not wear the interface 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 and bi-level systems have the potential to allow rebreathing of exhaled air. These systems are designed for use with interfaces (or connectors) that have vent holes or exhalation devices. When the system is turned on, fresh air from the system flushes the exhaled air out through the vent holes. If the system is not operating, the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- The complete assembly has an enclosed volume of approximately 110 ml. This volume may not be suitable for some patients. Explanation of warning: At low pressures (< 6 cm), the airflow through the exhalation port may not be enough to clear all of the exhaled gas (CO₂) from the mask. You may breathe in some of the air that you have exhaled.
- Some users may experience skin redness. If this happens, contact your health care professional.
- If oxygen is used with the CPAP or bi-level device, the oxygen flow must be turned off when the device is not operating. Explanation of the warning: When the CPAP or bi-level 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 enclosure may create a risk of fire. This warning applies to most types of CPAP and bi-level devices.
- 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 machines.

Putting on and Adjusting the ComfortCurve

Note: Clean your face and the interface thoroughly before each use. (See “Cleaning Instructions” later in this document.)

1. Attach the appropriate size cushion to the cross tube of the interface. Press the cushion firmly onto the cross tube until it snaps into place. Pull on the cushion gently to be sure it is completely attached.
2. If the headgear is attached, place the cheek pads against your cheeks and the cushion under your nose. To ensure proper orientation, make sure the Respronics logo is facing up. Pull the headgear over your head.
3. Adjust the headgear split strap so that the headgear cups the crown of your head. The lower strap should be positioned lower on the back of your head. The upper strap should be placed over the top of your head. Adjust the headgear side straps so the cheek pads and cushion rest snugly against your face. **Do not overtighten the headgear. Overtightening can irritate your face, increase leaks, or cause damage to the interface system.**
4. Adjust the angle of the cushion to the proper location under your nose by rotating the cheek pads. Rotate each cheek pad upwards or downwards until you reach a comfortable position. Be sure the cushion rests evenly under the nose.
5. Connect the tubing system (included with the ComfortCurve) to the CPAP or bi-level device. Turn on the airflow.
6. To ensure the best fit, after turning on the airflow, readjust the cheek pad positions as needed so that the cushion provides an adequate seal that minimizes leaks. Lie down in your normal sleeping position and breathe normally. Make any necessary final adjustments to ensure a comfortable and secure seal overnight.



Note: The ComfortCurve cushion is designed to be placed UNDER your nose. Do not place the tip of your nose inside of the cushion - this may cause unnecessary discomfort and irritation.

Cleaning Instructions

For Home Use: Begin by disconnecting the headgear from the interface. To disconnect the headgear, unhook the Quick Clips™ by pressing on the release button.

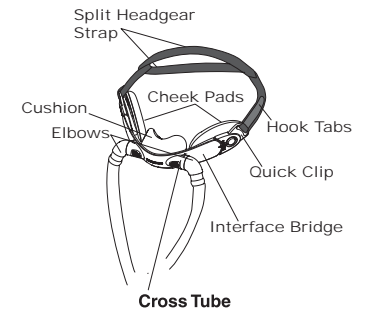
Interface and Nasal Cushion

Thoroughly clean the interface and nasal cushion each day, immediately after use.

Remove the cushion before cleaning as instructed below:

1. Remove the tubing system from the cross tube by unsnapping each elbow from the ends of the cross tube.
2. Unsnap the nasal cushion from the cross tube by pulling on the top of the cushion.

3. Remove the cross tube (optional). To do this, first press on the sides of the bridge so that it bends. Then slide the cross tube out through the holes in the interface bridge.

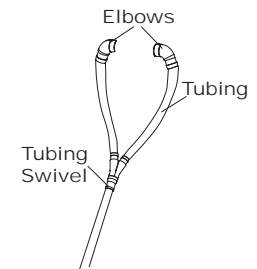


4. Hand wash the interface and cushion in warm water with a mild dishwashing detergent. **Do not** use bleach, alcohol, cleaning solutions containing alcohol, or any strong household cleaners. **Do not** use cleaners containing conditioners or moisturizers.
5. Rinse thoroughly. Air dry. Make sure all of the interface parts and the cushion are dry before use. Inspect the interface after cleaning. Carefully inspect the exhalation holes to make sure that they are free of debris. **Contact your home care provider to replace the interface if any parts are damaged or deteriorated.**
6. Reassemble the interface and nasal cushion by completing the following steps:
 - Press on the sides of the bridge so that it bends. Then slide the cross tube in through the holes of the interface bridge. Make sure to line up the triangular knob on the cross tube with the triangular recess on the bridge. Release the sides of the bridge, and pull them over the ridges on either side of the cross tube.
 - Snap the cushion onto the cross tube by first inserting the two clips at the bottom of the cushion into the two grooves at the bottom of the tube. Then snap the single clip at the top of the cushion into the top groove on the tube. **Make sure that the cushion snaps in firmly at both the top and bottom of the cross tube.**

Tubing System

While the tubing system is disconnected, clean it as instructed below.

1. Hand wash the tubing system in warm water with a mild dishwashing detergent. Run soapy water through the tubing to clean. **Do not** use bleach, alcohol, cleaning solutions containing alcohol, or any strong household cleaners. **Do not** use cleaners containing conditioners or moisturizers.
2. Rinse thoroughly. Shake gently to remove excess water. Air dry. Make sure the tubing system is completely dry before reattaching it to the interface.
3. Reattach the tubing system by snapping the elbows into place on the interface's cross tube.



Headgear with Clips

Clean the headgear at least once each week or more often if needed. Fasten the hook tabs onto the headgear straps so they don't catch other garments in the laundry.

1. Hand or machine wash the headgear with attached clips using a standard laundry detergent and warm water. Rinse thoroughly. Do not use bleach.
2. Line dry or machine dry at the medium heat setting.
3. Reattach the headgear and Quick Clips to the mask.

Note: You may need to slightly readjust the straps after repeated washings.