



# Bravo™ Nasal Pillow System

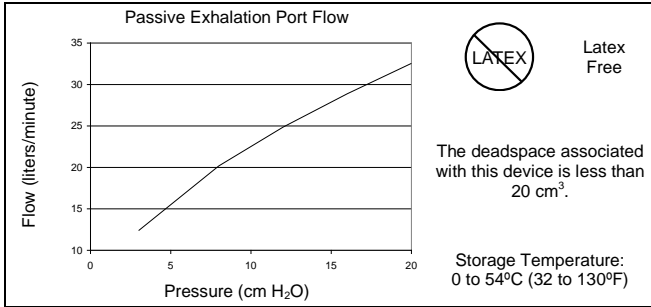
Instructions for Use – 07002 Rev D

EN: ENGLISH

### Intended Use

The Bravo Nasal Pillows System is intended for use by adults (> 30 kg) as a patient interface for Continuous Positive Airway Pressure (CPAP) or Bi-Level positive-pressure ventilation devices for the treatment of obstructive sleep apnea.

For homecare applications, the Bravo may be reused multiple times by a single patient. For institutional applications (i.e. sleep lab, other clinical settings), this interface may be reused multiple times by multiple patients.



### Warnings

- RX Only
- This device must be used only with a positive pressure ventilation device. This device should not be used unless the CPAP or Bi-level system is turned on and operating properly. The exhalation ports should never be blocked.
 

*Explanation of the Warning:* CPAP/Bi-level systems are intended to be used with special masks which have vent holes or exhalation ports to allow continuous flow of air out of the mask. When the CPAP/Bi-level machine is turned on and functioning properly, new air from the machine flushes the exhaled air out through the attached mask exhalation ports. However, when the CPAP/Bi-level machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP and Bi-level systems.
- This device may deactivate the pressure alarm on some ventilation systems. Confirm that your ventilation system pressure alarm works with the product before using the pressure alarm.
- If you notice redness or irritation of your skin, contact your physician. The device consists of silicone, polycarbonate, and polypropylene.
- Due to the risk of transmitting infection, disinfect between patients when reusing in the institutional setting.
- For homecare applications, this device is intended for single-patient use only and thus use by multiple patients is to be avoided due to the risk of transmitting infection. For homecare applications, do not attempt to sterilize or use disinfectants on this device or any of its components.

### Before Each Use

1. Clean the device as described in the cleaning instructions. For single patient use in the home, see Cleaning Instructions – Homecare Applications. For multiple patient reuse in institutional settings, see Cleaning and Disinfecting Instructions – Institutional Applications.
2. Insert the elbows of the Y-circuit into the circular fittings on the headgear. NOTE: The elbows should stop against the flange on the headgear as indicated by the arrow.
3. Before attaching the reservoir, notice that the reservoir is marked “R” and “L” and that the headgear is marked “R” and “L”. Insert the elbow on the “R” side of the headgear into the “R” side of the reservoir. Insert the elbow on the “L” side of the headgear into the “L” side of the reservoir. NOTE: The elbows should be inserted until the end of the reservoir completely overlaps the end of the circular fittings on the headgear.
4. Select the size of pillows that is appropriate for your nose. Insert the pillows into the reservoir. NOTE: The bar between the pillows should be closer to the vent side of the reservoir. NOTE: The bar between the pillows should be straight and not stretched or distorted in order to allow the pillows to be at the correct angles.
5. Attach the circuit tube from the CPAP or bi-level ventilation system to the Y-circuit

### Fitting the Device

1. Clean and thoroughly dry your face before putting on the interface.
2. Turn on your CPAP or bi-level system and make sure it is functioning properly.
3. Put the headgear on over the top of your head and insert the pillows into your nose. First adjust the back straps of the headgear. Second adjust the top straps. Continue to adjust all straps until the interface fits comfortably on your face with minimal air leakage. NOTE: The side straps and the back straps should be worn close to the ears. NOTE: The back straps should be on the lower part of the head closer to the neck, not near the top of the head.
4. Adjustments to the angle of the pillows can be made by rotating the reservoir on the headgear.
5. Breathe normally, and continue making minor adjustments until you have a comfortable fit with minimal leaks. If you are unable to achieve a comfortable fit or resolve leaks at the nose, you may need an alternative pillow size. NOTE: The bar between the pillows can be removed if needed to create more clearance between the bottom of the nose and the reservoir or to allow you to use two different size pillows.

6. The device can be worn with the tubing on your chest or over you head (using the Velcro rings) as you prefer.
7. To remove the interface, you usually do not need to release the straps. Just grasp the reservoir and pull it forward until it clears your nose, and then lift the interface off over your head.

### Cleaning Instructions – Homecare Applications

#### After Each Use:

1. Remove the pillows from the reservoir. Disassemble the reservoir and the headgear from the Y-circuit. NOTE: The headgear will be washed separately.
2. Wash the Y-circuit, pillows, and reservoir with mild soap and warm water. Do not use alcohol or petroleum products or strong cleaners.
3. Make sure that the exhalation ports on the reservoir are free of any obstructions.
4. Rinse thoroughly. Allow all components to completely air-dry, away from direct sunlight.
5. Carefully inspect each component for any wear or damage. If you see any cracks in the plastic or any tears or hardening of the silicone components, do not use the device. Discoloration is normal after several washings and should not be considered sign of wear. Contact your healthcare provider for a replacement.

#### At Least Every 7 Days:

1. Hand wash the headgear with mild soap and warm water. Do not use bleach.
2. Rinse thoroughly. Allow to completely air-dry, away from direct sunlight.
3. Carefully inspect the headgear for wear or damage. Do not use if you notice significant tears, fraying, or loss of elasticity. Contact your healthcare provider for a replacement.

### Cleaning and Disinfecting Instructions – Institutional Applications

#### After Each Use:

1. Remove the pillows from the reservoir. Disassemble the reservoir and the headgear from the Y-circuit.
2. Wash all components with mild soap and warm water. Do not use alcohol or petroleum products or strong cleaners.
3. Make sure that the exhalation ports on the reservoir are free of any obstructions.
4. Rinse thoroughly (3) three times with clear water.
5. If any residue remains on any components after cleaning, discard entire assembly and replace.
6. Prepare a solution of Cidex OPA (*ortho*-Phthaldehyde solution) per manufacturer’s instructions. Verify strength of Cidex OPA solution using Cidex OPA test strips.
7. Submerge all components (except headgear) into the prepared Cidex OPA solution for twelve (12) minutes.
8. Remove components. Shake excess solution from interior surfaces of components.
9. Rinse assembly three (3) times with clear water. Shake excess water from interior surfaces of components. Allow all components to completely air-dry, away from direct sunlight.
10. Carefully inspect each component for any wear or damage. If you see any cracks in the plastic or any tears or hardening of the silicone components, do not use the device. Discoloration is normal after several washings and should not be considered sign of wear. Contact your healthcare provider for a replacement.

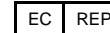
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### Reorder Information

Part Number	Description	Part Number	Description
BRV600	Bravo – Complete System	BRV621	Pillows, <i>Small</i>
BRV630	Headgear	BRV623	Pillows, <i>Medium</i>
		BRV625	Pillows, <i>Large</i>

