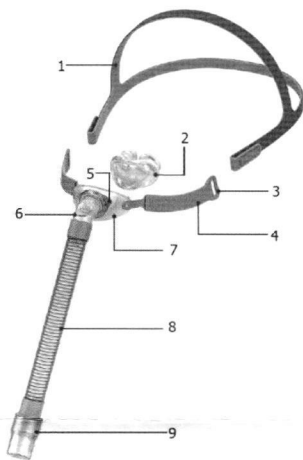


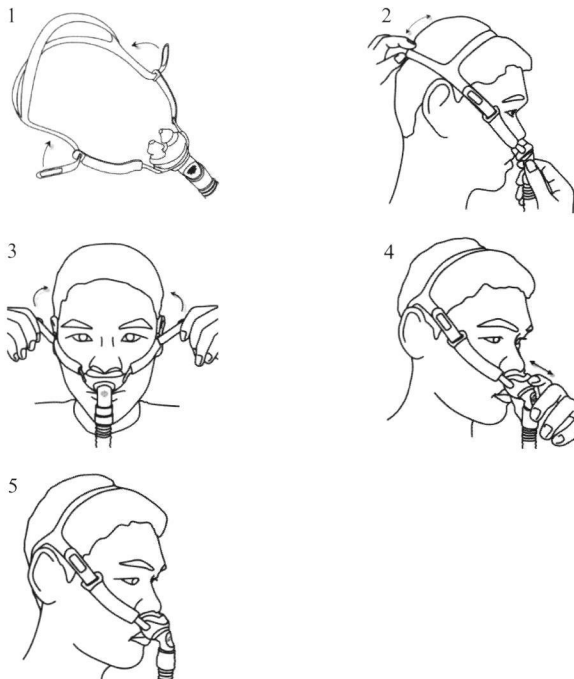


Rio™ II Components

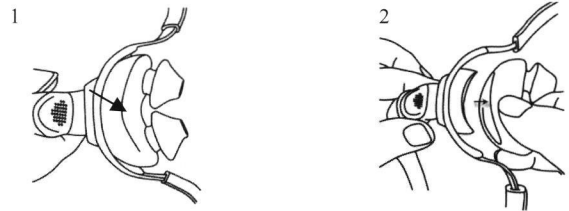


- | | | | |
|---|----------|---|--------------------------------------|
| 1 | Headgear | 2 | Nasal Pillows (available in S, M, L) |
| 3 | Panel | 4 | Soft sleeves |
| 5 | Clip | 6 | Elbow |
| 7 | Frame | 8 | Short tube |
| 9 | Swivel | | |

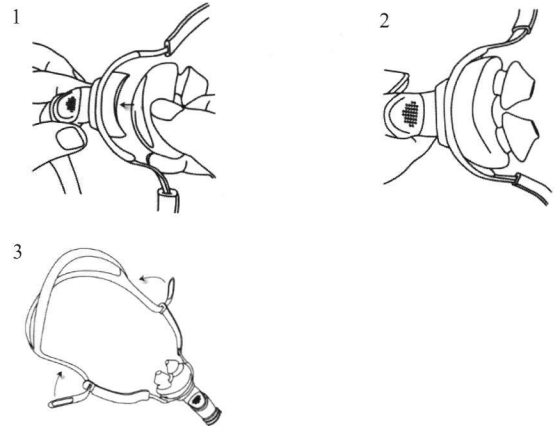
Fitting



Disassembly



Reassembly



Rio™ II Nasal Pillows Interface

Thank you for choosing the Rio™ II Nasal Pillows Interface. The Rio™ II Nasal Pillows Interface is light, flexible and quiet. It is designed to minimize contact with your face, thus ensuring that you feel comfortable during therapy. This user manual provides you with the information you need for the correct use of your system.

Intended Use

The Rio™ II is intended for adult patients (> 30 kg) prescribed continuous positive airway pressure or Bi-level therapy, and it is intended for single patient reuse in the home environment.

CAUTION: Federal law restricts the sale of this device to sale by or on the order of a physician.

Medical Information

Note: The Rio™ II does not contain latex, PVC, or DEHP materials. If you have ANY reaction to any part of the interface, discontinue use and consult your sleep therapist.

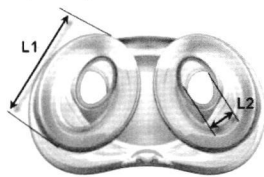
⚠ WARNING and CAUTION

- This interface should be used only with flow generators (CPAP or Bi-level) recommended by your physician or respiratory therapist. It should not be used unless the flow generator is turned on and operating properly. The vent holes should never be blocked.
- **Explanation of the Warning:** Flow generators are intended to be used with special interfaces with connectors which have vent holes (vent holes are located on the elbow) or separate exhalation devices to allow continuous flow of air out of the interface. When the flow generator is turned on and functioning properly, new air from the flow generator will flush the exhaled air out through the attached exhalation port. However, when the flow generator is not operating (ie, power failure), not enough fresh air will be provided through the interface, and exhaled air may be re-breathed. In this situation, remove the Rio™ II immediately.
- The exhaust vent flow is lower at lower interface pressure (see section "Technical Specifications" for Pressure-Flow Curve details). If the interface pressure during expiration is too low, there may not be enough exhaust vent flow to completely flush the air delivery hose of exhaled air before the start of the next inspiration.
- Discontinue using the interface if you frequently experience nasal irritation, and consult your physician.
- If oxygen is used with the flow generator, the oxygen flow must be turned off when the flow generator is not operating. **Explanation of the Warning:** When the flow generator is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the flow generator enclosure. Oxygen accumulated in the flow generator enclosure will create a risk of fire. This warning applies to most types of flow generators.
- Please refrain from smoking while oxygen is in use.
- Images shown here are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.

Note: At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, interface selection and the leak rate.

Nasal Pillows Size

You can choose the appropriate nasal pillows from “S”, “M” and “L” sizes, depending on individual dimensions.



Size	L1 (mm)	L2 (mm)
S	22.1	5.1
M	24.2	5.3
L	27.6	6.8

Fitting

1. Thread the two side straps of the headgear through the gaps in panels separately, then fold back over to secure.
2. Put the headgear over your head by holding the back strap and stretching it around the back of your head. The top strap should sit comfortably on top of your head.
3. Adjust each end of the side strap evenly until the interface sits comfortably just under the nose. Reattach the fastening tabs.
4. Move the interface away from your face then place it back to get a comfortable fit. Ensure the nasal pillows fit securely into your nostrils with both pillows positioned upright.
5. Finally connect the end of the interface tubing into your device air tubing. Your interface is now fitted and ready to use.

Notes: Refer to your flow generator manual for details on setting and operational information.

Three nasal pillows sizes (S, M, L) are available, hold the pillows on your nostrils ensuring that the Pillows size (ie, M) correctly fits for you.

If you feel air leak, readjust the angle of the nasal pillows to get a better seal. If you are unable to resolve any leaks, you may need an alternative nasal pillows size.

Removal

To remove the interface, pull the nasal pillows assembly away from your nose and lift the headgear off your head. You do not need to loosen the headgear straps.

Disassembly

1. Holding the short tube on the interface, squeeze and pull the nasal pillows away from the clip in the interface frame.
2. Remove the headgear from the interface.

Notes:

- The short tube assembly cannot be taken apart.
- Do not pull on the short tube or the flow generator tubing as they may get damaged.

Reassembly

1. Attach the nasal pillows to the clip in the interface frame. Make sure the Nasal pillows triangular opening and the frame platform opening is to point down.
2. The Nasal pillows is in the correct position. Make sure the frame and Nasal pillows will fit tightly together without any gaps.
3. Thread the two side straps of the headgear through the gaps in panels separately, then fold back over to secure.

Cleaning the Rio™ II in the Home

Notes:

- Wash your hands before cleaning the interface.
- Wash the headgear before first time use, as the dye may run. It is important to always hand wash the headgear.

Daily / After Each Use

- Disassemble the interface components according to the disassembly instructions.
- Thoroughly clean the separated interface components (excluding headgear), by gently rubbing in warm (approx. 30°C) water using mild liquid detergent for 10 min.
- Use a soft bristle brush to clean the vent.
- Rinse all components except the Left and Right Panel well with drinking quality water and allow to air dry out of direct sunlight.
- When all components are dry, reassemble according to the reassembly instructions.

Weekly

Hand wash the headgear and all components in warm, (approx. 30°C) water and mild liquid detergent (e.g., Alconox diluted at 1%) for up to 10 minutes. Rinse the components well and allow them to air dry out of direct sunlight.



CAUTIONS

- Always follow cleaning instructions and do not use solutions containing bleach, chlorine, alcohol, aromatics, moisturizers, antibacterial agents, or scented oils to clean any component of the interface or air tubing, they may damage the interface.
- Exposing any component of the interface or tubing to direct sunlight or heat may cause deterioration.
- If any visible deterioration of a component is apparent (cracking, crazing, tears etc), the component should be discarded and replaced.

Additional Information

Note:

For additional instruction, please visit our website at www.3Bproducts.com. An instructional video is available for viewing under the Rio™ II tab.

Storage

Ensure that the interface is thoroughly clean and before storing it for any length of time. Store the interface in a dry place out of direct sunlight.

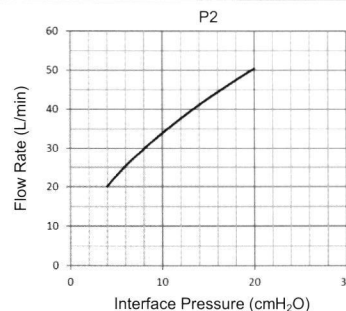
Note:

The Rio™ II Nasal Pillows Interface is not made with natural rubber latex.

Disposal

The Rio™ II Nasal Pillows Interface does not contain any hazardous substances and may be disposed of with your normal house hold refuse.

Technical Specifications



Pressure Flow Curve

Pressure (cmH ₂ O)	4	8	12	16	20
Flow Rate (L/min)	20	29	38	45	50

Dead Space Information

Dead space is the empty volume of the nasal pillows and short tube assembly up to the swivel. The dead space of the interface for Large Pillows is 92 ml.

Therapy Pressure 4 to 20 cmH₂O.

Resistance

Drop in pressure measured (average for three nasal pillows sizes) at 50 L/min: 0.5 cmH₂O
at 100 L/min: 1.6 cmH₂O

Sound

DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the interface is 26 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the interface at a distance of 1 m is 18 dBA, with uncertainty 3 dBA.

Environmental Conditions

Operating temperature: +5°C to +40°C (41°F to 104°F)
Operating humidity: 10% ~ 93% relative humidity non-condensing.
Storage and transport: -20°C to +55°C (-4°F to 131°F)
Storage and transport humidity: 10% ~ 93% relative humidity non-condensing.

Symbols

Interface and Packaging



Caution, consult accompanying documents. Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device.



Lot number



Catalog number



Temperature limitation



Humidity limitation



Manufacturer



Authorized Representative in the European Community

Limited Warranty

It is warranted that Rio™ II Nasal Pillows Interface, including its components, frame, nasal pillows, headgear, tubing and other accessories shall be free from defects in material and workmanship for a period of ninety (90) days from the date of purchase by the initial consumer.

To exercise the rights under this warranty, contact your local authorized dealers.

The expected service life of Rio™ II Nasal Pillows Interface is one year.

For any questions or comments concerning this product or the warranty, please contact:

Contract Manufacturer:

BMC (Tianjin) Medical Co., Ltd.

2 / F North Area and 3 / F, Building No.4, No.1 Xinxing Road, Wuqing District, (301700) Tianjin, P.R.China.

Tel: +86-22-82939881

3B Medical, Inc.

203 Avenue A NW, Suite 300

Winter Haven, FL 33881

Email: info@3Bproducts.com

www.3Bproducts.com