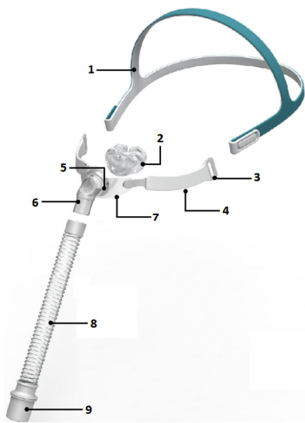


Rioll Nasal Pillows Interface

User Manual

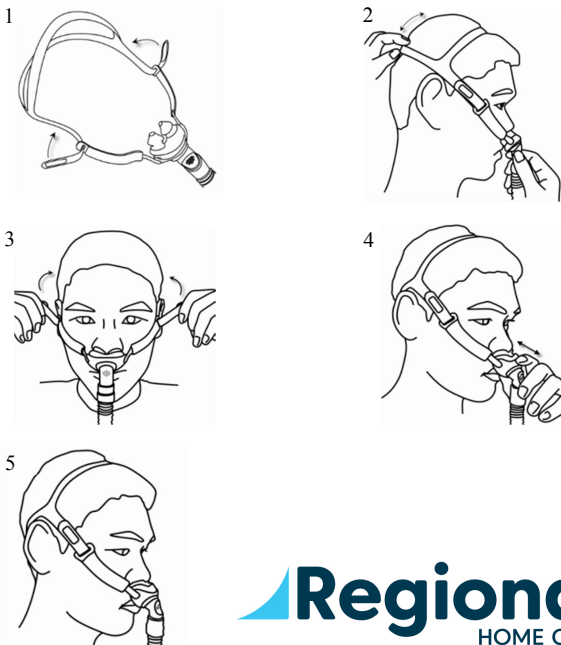


Rioll Components

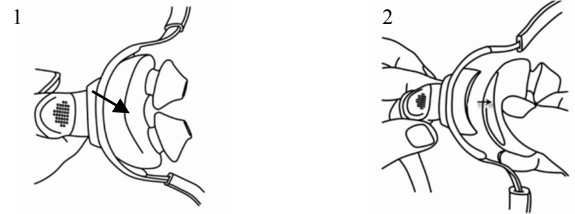


- | | | | |
|---|----------|---|--------------------------------------|
| 1 | Headgear | 2 | Nasal Pillows (available in S, M, L) |
| 3 | Panel | 4 | Soft sleeves |
| 5 | Clip | 6 | Elbow |
| 7 | Frame | 8 | Short tube |
| 9 | Swivel | | |

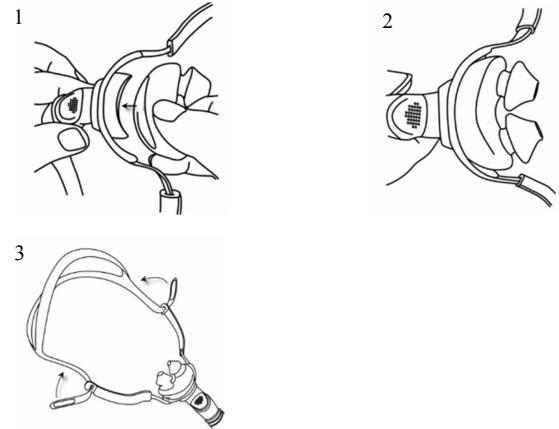
Fitting



Disassembly



Reassembly



Rioll Nasal Pillows Interface

Thank you for choosing the Rioll Nasal Pillows Interface. The Rioll 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 Rioll 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 Rioll 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.

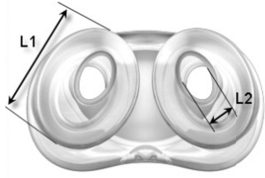
⚠ WARNING and CAUTION

- 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 for use with special interfaces with connectors which have vent holes (vent holes are located in the elbow) or separate exhalation devices that allow a continuous flow of air out of the interface. When the flow generator is on and operating properly, the fresh air from the flow generator will flush the exhaled air out through the attached exhalation port. However, when the flow generator is not operating (e.g. power failure), the fresh air supplied through the interface is insufficient, and exhaled air may be re-inhaled. In this situation, remove the Rioll immediately.
- The exhaust vent flow is lower at lower interface pressure (see section "Technical Specifications" section for details of the Pressure-Flow Curve). If the interface pressure during exhalation is too low, there may not be enough exhaust vent flow to completely flush the exhaled air delivery hose from the before the next inhalation begins.
- 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 in the flow generator enclosure. The accumulation of oxygen in the flow generator enclosure will create a fire hazard. This warning applies to most types of flow generators.
- Please refrain from smoking while oxygen is in use.
- The images shown here are indicative only. If there is inconsistency between the image and the 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 (inch) | L2 (inch) |
|------|-----------|-----------|
| S | 0.87 | 0.20 |
| M | 0.95 | 0.20 |
| L | 1.09 | 0.27 |

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 operation.

Three nasal pillows sizes (S, M, L) are available. Place the pillows over your nostrils to ensure that the Pillows size (e.g., M) correctly fits for you.

If you feel an air leak, readjust the angle of the nasal pillows to get a better seal. If you cannot 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 on 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 Rioll in the Home

Notes: Wash your hands before cleaning the interface.

Wash the headgear before first time use. The wrist belt may fade slightly that is normal. 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 water (approx. 86°F / 30°C) using mild, unscented liquid dish 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 them to air dry out of direct sunlight.
- When all components are dry, reassemble the interface according to the reassembly instructions.

Weekly

Hand wash the headgear and all components in warm water (approx. 86°F / 30°C), mild, unscented liquid dish detergent 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.reacthealth.com. An instructional video is available for viewing under the Rioll tab.

Storage

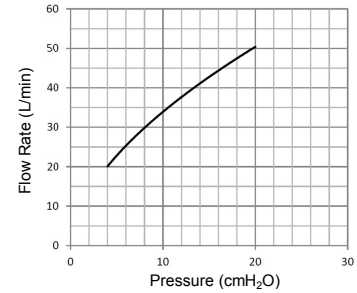
Ensure that the interface is thoroughly clean before storing it for any length of time. Store the interface in a dry place out of direct sunlight.

Note: The Rioll Nasal Pillows Interface is not made with natural rubber latex.

Disposal

The Rioll Nasal Pillows Interface does not contain any hazardous substances and may be disposed of with your normal household 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 cmH ₂ O. |
| Resistance | Drop in pressure measured (average for three nasal pillows sizes) at 50 L/min: 0.5 cmH ₂ O at 100 L/min: 1.6 cmH ₂ O |
| 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 an uncertainty of 3 dBA. The A-weighted sound pressure level of the interface at a distance of 1 m is 18 dBA, with an uncertainty of 3 dBA. |
| Environmental Conditions | Operating temperature: +5°C to +40°C (41°F to 104°F) Operating humidity: 10% to 93% relative humidity non-condensing. Storage and transport temperature: -20°C to +55°C (-4°F to 131°F) Storage and transport humidity: 10% to 93% relative humidity non-condensing. |

Symbols

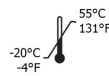
Interface and Packaging



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.



Batch code



Temperature limit



Humidity limitation



Prescription only (In the US, federal law restricts these devices to sale by or on the order of a physician)



Manufacturer



Date of Manufacture



Made in China



Use-by date



Unique device identifier



Not made with natural rubber latex

Limited Warranty

The expected service life of Rioll Nasal Pillows Interface is one year.

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

Manufactured for:

REACT HEALTH

5101 Fruitville Rd., Suite 200

Sarasota, FL 34232

T: (863) 226-6285

For additional information, please visit our Patient Resources Page at:

www.reacthealth.com

Manufacturer:

BMC Medical Co., Ltd.

Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road, Fengtai District, 100073

Beijing, PEOPLE'S REPUBLIC OF CHINA

URL: en.bmc-medical.com

E-mail: intl@bmc-medical.com

Tel: +86-10-51663880

Fax: +86-10-51663880 Ext. 810