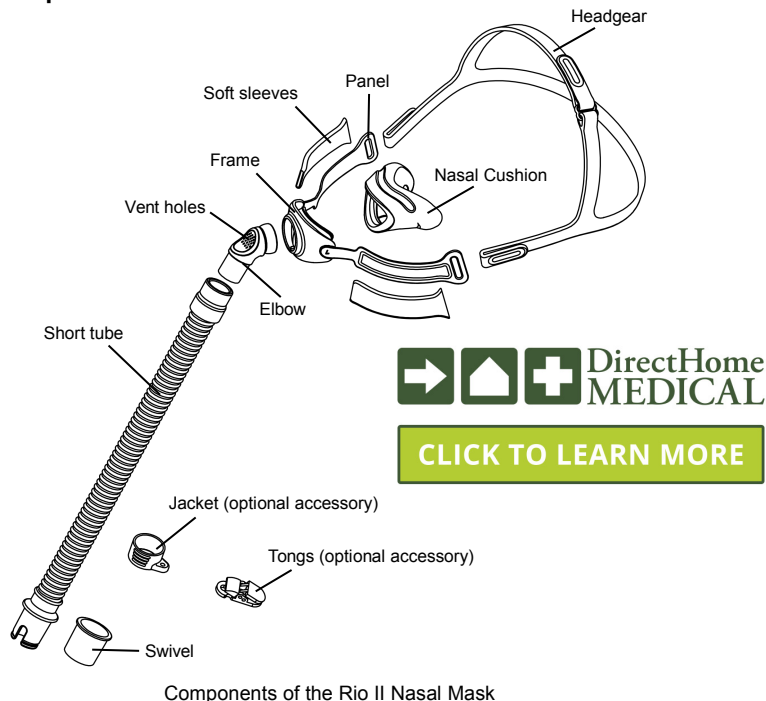


Rio II Nasal Mask

User Manual

Components of the Rio II Nasal Mask



Rio II Nasal Mask

Thank you for choosing the Rio II Nasal Mask. The mask 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 mask.

The mask is not made with natural rubber latex.

Intended use

The Rio II Nasal Mask channels airflow non-invasively to the patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Rio II Nasal Mask is:

- To be used by adult patients (> 66 lb / 30 kg) for whom positive airway pressure therapy has been prescribed.
- Intended for single-patient reuse in the home environment.

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

Before using the mask

⚠ WARNINGS

- Occlusion of the vent holes needs to be prevented to avoid having an adverse effect on the safety and quality of the therapy.
- This mask should only be used with CPAP or bi-level devices recommended by a physician or respiratory therapist.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air.
- **Explanation of Warning:** CPAP and bi-level devices are intended for use with special masks (or connectors) which have vent holes that allow continuous flow of air out of the mask. When the device is turned on and operating properly, the fresh air from the device flushes the exhaled air out through the attached mask vent holes. However, when the device is not operating, the fresh air supplied through the mask is insufficient, and exhaled air may be re-inhaled. Rebreathing of exhaled air for more than several minutes may, in some circumstances, lead to suffocation. This warning applies to most models of CPAP or bi-level devices.
- The mask is not suitable for patients requiring life support ventilation.
- Not for use with patients that have silicone allergies.
- This mask should not be used on patients who are uncooperative, unresponsive, or unable to remove the mask.
- Follow all precautions when using supplemental oxygen.

- Oxygen flow must be turned off when the CPAP or bi-level device is not in operation, so that unused oxygen does not accumulate in the device enclosure and create a fire hazard.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in a well-ventilated room.
- At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate.
- The technical specifications of the mask are provided for your clinician to check if it is compatible with the flow generator. If it is used beyond technical specifications or used with incompatible devices, the seal and comfort of the mask may not be effective, and optimum therapy may not be achieved. Leak or variation in the rate of leak, may affect the function of the CPAP or bi-level device.
- Stop using the Rio II Nasal Mask and consult your physician or sleep therapist, if you have ANY adverse reaction to the use of the mask.
- Refer to your CPAP or bi-level device manual for details on settings and operational information.
- Remove all packaging before using the mask.
- Images shown here are indicative only. If there is inconsistency between the image and actual product, the latter shall govern.
- This mask product complies with ISO 17510:2015 standard.

Fitting the mask

1. Thread the two side straps of the headgear through the gaps in the panels separately, then fold them back 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 straps evenly until the mask sits comfortably just under the nose. Reattach the fastening tabs.
4. Undo the fastening tab on the top strap and pull the strap until the mask is stable.
5. Move the mask away from your face then place it back to get a comfortable fit. Ensure the nasal cushion fits securely.
6. Finally connect the device air tubing to the end of the mask Short tube. Your mask is now fitted and ready to use.

Disassembling the mask

Note:

- *The Frame assembly cannot be disassembled.*

1. Undo and remove the side straps out of the gaps in the panels.
2. Remove the cushion from the Frame assembly.
3. Remove the Swivel from the Short tube.

Cleaning the mask

Notes:

- *The mask and headgear can only be cleaned by washing by hand.*
- *Do not remove the Short tube and the Elbow from the mask frame when cleaning.*
- *Wash the headgear before first-time use. The headgear may fade slightly, which is normal.*

⚠ CAUTIONS

- Do not use solutions containing bleach, chlorine, alcohol, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the mask. These solutions may cause damage and reduce the life of the product.
- Exposing any part of the mask 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.

Daily / After each use: Mask components except Headgear

- Disassemble the mask components according to the disassembly instructions.
- Clean the components thoroughly by gently rubbing in warm water (approx. 86°F/30°C) with a mild, unscented liquid dish detergent for up to 10 minutes.
- Use a soft bristle brush to clean the vent holes.
- Rinse all components well with drinking quality water and allow them to air dry out of direct sunlight.
- When all components are dry, reassemble the mask according to the reassembly instructions.

Weekly: Headgear

Hand wash the headgear in warm water (approx. 86°F/30°C) with a mild, unscented liquid dish detergent for up to 10 minutes. Rinse the headgear well with drinking quality water and allow it to air dry out of direct sunlight before reassembling.

Reassembling the mask

1



Attach the Swivel onto the Short tube and ensure that the Swivel is secure.

2



Attach the Cushion onto the Frame assembly and ensure that the Cushion is secure.

3



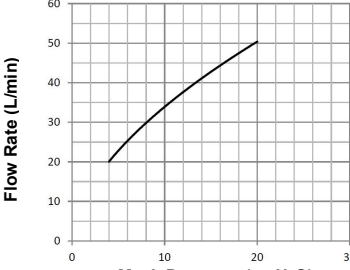
Thread the two side straps of the headgear through the gaps in the panels separately, then fold them back to secure.

Troubleshooting

Problem	Possible reason	Possible solution
Mask won't seal properly or is uncomfortable.	Mask may have been fitted incorrectly or is incorrectly adjusted.	Carefully follow instructions in "Fitting the Mask". Make sure the headgear is not over-tightened.
	Mask size is wrong.	Consult your clinician.
	Mask is not tightened correctly.	Tighten both upper and lower headgear straps.
	Cushion is misaligned or creased on face.	Ensure the cushion is properly aligned according to the instructions in "Reassembling the Mask". Make sure the cushion is not creased.
	Mask cushion may be dirty.	Clean the cushion according to instructions in "Cleaning the Mask".
Mask is too noisy.	Mask is assembled incorrectly.	Reassemble the mask.
	Vent holes are blocked or partially blocked.	Clean the vent holes according to instructions in "Cleaning the Mask".

Technical specifications

Pressure-flow curve



Mask 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 mask and short tube assembly up to the swivel. The dead space of the Rio II Nasal Mask for Large Cushion is 102 mL.
Therapy pressure	4 to 20 cmH ₂ O
Resistance	Drop in Pressure measured 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 mask is 26 dBA, with an uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 18 dBA, with an uncertainty of 3 dBA.
Environmental conditions	Operating temperature: +5°C–+40°C (41°F–104°F) Operating humidity: 10%–93% relative humidity non-condensing Storage and transport temperature: -20°C–+55°C (-4°F–131°F)

Storage and transport humidity:
10%–93% relative humidity non-condensing

Storage

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

Disposal

The Rio II Nasal Mask does not contain any hazardous substances and may be disposed of with your normal household refuse. If the patient has an infectious disease, the mask needs to be disposed of as medical waste.

Symbols

System and packaging



Caution



Model Number



Batch code



Manufacturer



Unique device identifier



Medical device



Catalogue number



Prescription use only



Made in China, date of manufacture



Use-by date



Temperature limit



Humidity limitation



Not made with natural rubber latex

Limited warranty

The expected service life of the Rio II Nasal Mask is one year from the date of first use.

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

Manufactured for:
REACT HEALTH
5475 Rings Road, Suite 550
Dublin, OH 43017
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