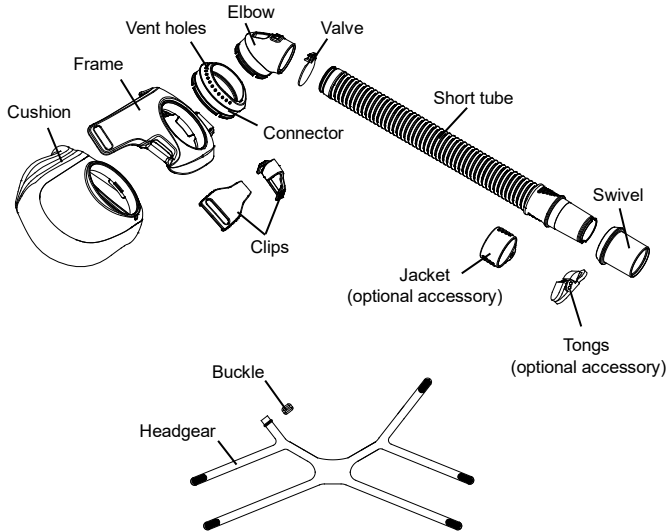


Rio II Full Face Mask

User Manual

Components of the Rio II Full Face Mask



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Rio II Full Face Mask

Thank you for choosing the Rio II Full Face 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 Full Face 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 Full Face 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.
- The mask is not suitable for patients requiring life support ventilation.
- 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 systems are intended for use with special masks with connectors which have vent holes that allow continuous flow of air out of the mask. When the CPAP machine is on and operating properly, the fresh air from the CPAP machine flushes the exhaled air out through the attached mask vent holes. However, when the CPAP machine is not operating, the fresh air supplied through the mask is insufficient, and exhaled air will 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 systems.
- At low CPAP pressures, the flow through the vent holes may be inadequate to clear all exhaled gas from the tube. Some rebreathing may occur.
- To minimize the risk of vomiting during sleep, the patient should avoid eating or drinking three hours before using the mask. This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Do not use the mask without the valve in place.
- Not for use with patients that have silicone allergies.
- This mask should not be used on patients who are uncooperative,

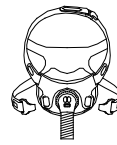
unresponsive, or unable to remove the mask.

- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the PAP Device is not in operation, so that unused oxygen does not accumulate within the PAP 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 PAP Device. 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 PAP device.
- Stop using the Rio II Full Face Mask and consult your physician or sleep therapist if you have ANY adverse reaction to the use of the mask.
- Refer to your PAP 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.

Fitting the mask

Use a standard conical connector if pressure readings and/or supplemental oxygen are required.

1



Pass the upper headgear straps through the installation holes on the mask frame as shown in the figure and fasten. Repeat the process for the lower straps to join the headgear clips.

2



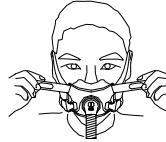
Hold the mask against your face and pull the headgear over your head. Please ensure that the label on the headgear is facing outwards.

3



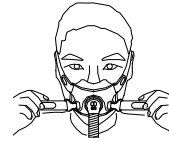
Pull the lower straps under the ears and attach the clips to the fixing hooks on the lower-half of the mask frame.

4



Pull the upper headgear straps as shown in the figure until the mask is positioned properly.

5



Repeat the process for the lower straps as shown in the figure until the mask is positioned properly.

6



Pull the top headgear straps as shown in the figure until the mask is positioned properly.

7



Adjust only enough for a comfortable seal and don't overtighten.

Disassembling the mask

Notes:

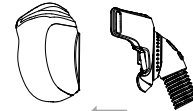
1. The elbow assembly and the connector cannot be disassembled from the frame assembly.
2. The elbow assembly cannot be disassembled.
3. The short tube cannot be disassembled from the elbow assembly.
4. The valve cannot be removed from the elbow assembly, or damage may be incurred and the re-installation will become more difficult.

1



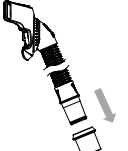
Undo and remove the upper headgear straps out of the installation holes on the mask frame.

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.
- The elbow assembly and the connector cannot be disassembled from the frame assembly for washing.
- The elbow and the valve cannot be disassembled from the elbow assembly for washing.
- 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

- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear) by gently rubbing in warm water (approx. 86°F/30°C) using 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

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

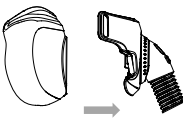
Reassembling the mask

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

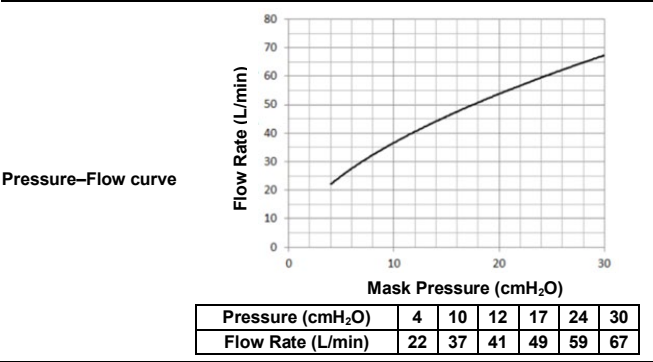


Attach the upper headgear straps to the installation holes on the mask frame.

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" section.

Technical specifications



Dead space information	Dead space is the empty volume of the mask up to the swivel. The dead space of the mask varies with cushion size but is less than 180 mL.
Therapy pressure	4 to 30 cmH ₂ O
Resistance with Anti-Asphyxia Valve closed to atmosphere	Drop in Pressure measured (nominal) at 50 L/min: 0.15 cmH ₂ O Drop in Pressure measured (nominal) at 100 L/min: 0.5 cmH ₂ O
Inspiratory and expiratory resistance with Anti-Asphyxia Valve open to atmosphere	Inspiration at 50 L/min: 1.8 cmH ₂ O Expiration at 50 L/min: 2.0 cmH ₂ O
Anti-Asphyxia Valve open-to-atmosphere pressure	≤ 4 cmH ₂ O
Anti-Asphyxia Valve closed-to-atmosphere pressure	≤ 4 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 25 dBA, with an uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 17 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 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



Use-by date



Temperature limit



Humidity limitation



Not made with natural rubber latex

Limited warranty

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

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
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