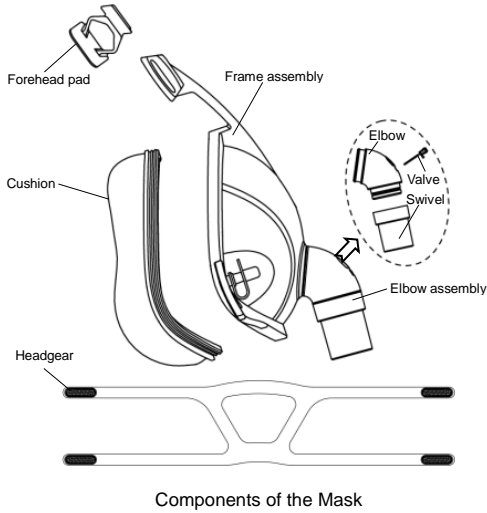


## F2 Single-Patient Vented Full Face Mask

### User Manual

#### Components of the Mask



#### F2 Single-Patient Vented Full Face Mask

Thank you for choosing F2 Single-Patient Vented 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 F2 Single-Patient Vented Full Face Mask is Not made with natural rubber latex.

#### Intended Use

The F2 Single-Patient Vented Full Face Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The F2 Single-Patient Vented 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.

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

#### Before Using the Mask

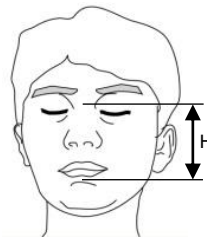
##### ⚠ WARNINGS

- The vent holes must be kept clear.
- Explanation of Warning: CPAP systems are intended for use with special masks with connectors which have vent holes that allow a 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 exhalation port. 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 exhaled port 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.
- 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 in the PAP Device enclosure and create a fire hazard.

- 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 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 actual product shall govern.

#### Getting the Right Cushion Size

- The following drawing describes the different features of face and the length of the face (H) you need to measure.
- The masks are available in three different sizes.
- Choose the appropriate size according to the table below.

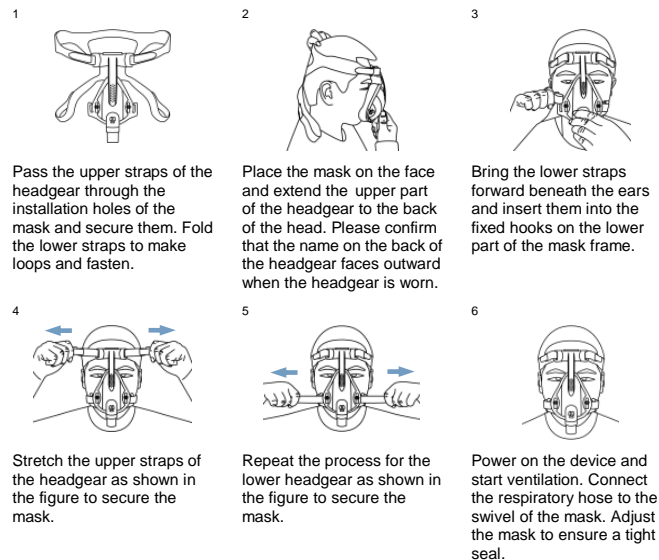


H (inch)	Size
3.15 ≤ H ≤ 3.54	S
3.54 < H ≤ 3.94	M
3.94 < H ≤ 4.53	L

#### Getting the Right Cushion Size

#### Fitting the Mask

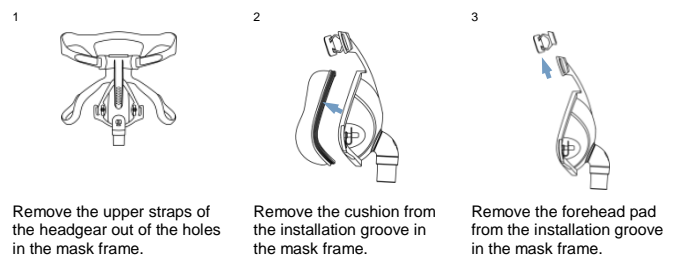
Use a standard conical connector if pressure readings and / or supplemental oxygen are required.



#### Disassembling the Mask

##### Notes:

- The elbow assembly cannot be disassembled from the frame assembly.
- The elbow assembly cannot be disassembled.
- The valve cannot be disassembled. Or it may cause damage, and its installation would be difficult.



## Cleaning the Mask

### Notes:

- The mask and headgear can only be cleaned by washing by hand.
- The elbow, the swivel and the valve cannot be disassembled for washing.

### CAUTIONS

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

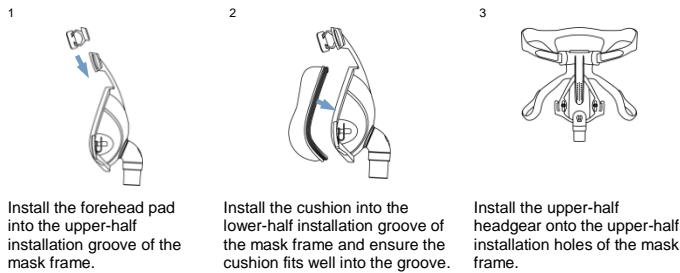
### Daily / After Each Use

- 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.
- 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.

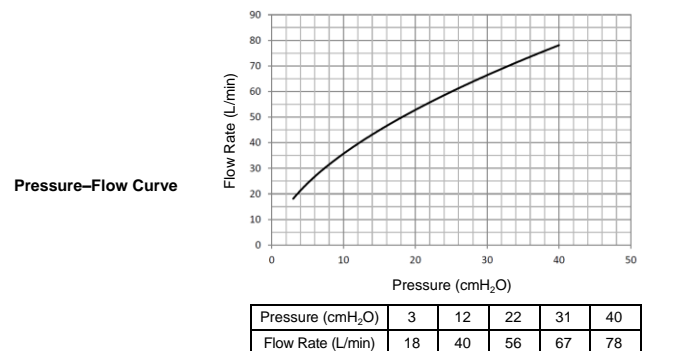
## Reassembling the Mask



## Technical Specifications

Problem	Possible Reason	Possible Solution
Mask won't seal properly or is uncomfortable.	Mask may have been fitted incorrectly.	Carefully follow instructions in "Fitting the Mask" section. Make sure the headgear is not over-tightened.
	Mask size is wrong.	Consult your clinician.
Mask leaks around the face.	The cushion is misplaced on the cushion frame.	Check insertion of the cushion and reinsert correctly according to the instructions in "Reassembling the Mask" section.
Mask is too noisy.	Mask size is wrong.	Consult your clinician.
	Vents are blocked or partially blocked.	Clean the vents according to the instructions in "Cleaning the Mask" section.

## Technical Specifications



<b>Dead Space Information</b>	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 218 mL.
<b>Therapy Pressure</b>	3 to 40 cmH <sub>2</sub> O
<b>Resistance</b>	Drop in Pressure measured (average for 3 sizes) at 50 L/min: 0.15 cmH <sub>2</sub> O at 100 L/min: 0.5 cmH <sub>2</sub> O

<b>Inspiratory and Expiratory Resistance</b>	The inspiratory resistance of the mask (in combination with the valve) is 1.8 cmH <sub>2</sub> O at 50 L/min. The expiratory resistance of the mask (in combination with the valve) is 2.0 cmH <sub>2</sub> O at 50 L/min.
<b>The Valve open-to-atmosphere pressure</b>	1.0 cmH <sub>2</sub> O
<b>The Valve closed-to-atmosphere pressure</b>	1.2 cmH <sub>2</sub> O
<b>Sound</b>	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 28 dBA, with an uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 20 dBA, with an uncertainty of 3 dBA.
<b>Environmental Conditions</b>	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.

## Symbols

### System 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

## Limited Warranty

The expected service life of F2 Single-Patient Vented Full Face Mask 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](http://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](http://en.bmc-medical.com)  
E-mail: [intl@bmc-medical.com](mailto:intl@bmc-medical.com)  
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Fax: +86-10-51663880 Ext. 810

### Contract Manufacturer:

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Tel: +86-22-82939881

### BMC (Dongguan) Medical Co., Ltd.

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