



iVolve F1A Full Face Mask

# User Manual

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## iVolve F1A Full Face Mask

Thank you for choosing BMC's iVolve F1A Full Face Mask (**BMC-FM1A**). The mask is comfortable, 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 mask.

### Intended Use

The iVolve F1A 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 iVolve F1A 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 re-use in the home environment and multi-patient re-use in the hospital / institutional environment.

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

## Before Using the Mask



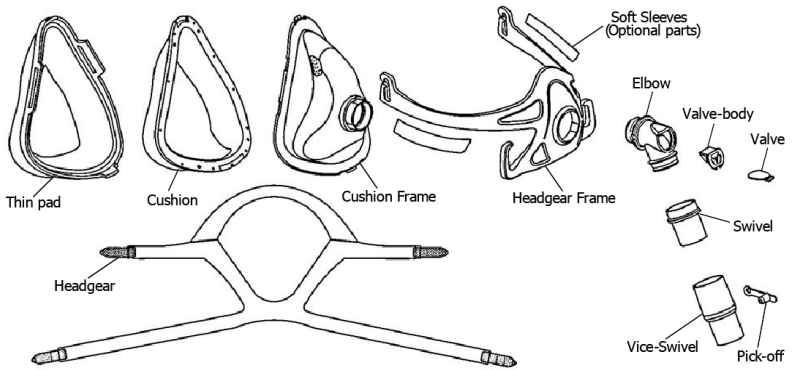
### WARNINGS

- The vent holes must be kept clear.
- **Explanation of Warning:** CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air will be rebreathed. Rebreathing of exhaled air for longer than several minutes can, 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 for 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 Non-Rebreathing Valve in place.
- This mask should not be used on patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the flow generator is not operating, so that unused oxygen does not accumulate within the flow generator enclosure and create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, 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, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect the function of the flow generator.

- Stop using the iVolve F1A 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 flow generator manual for details on settings and operational information.

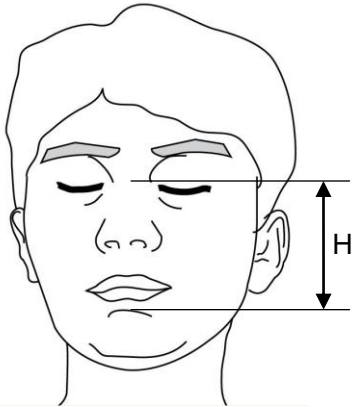
## Components of the iVolve F1A Full Face Mask



Components of the iVolve F1A Full Face Mask

## 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.

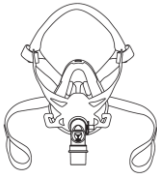


H (mm)	Size
$80 \leq H \leq 90$	S
$90 < H \leq 100$	M
$100 < H \leq 115$	L

## Getting the Right Cushion Size

## Fitting the Mask

1



Attach the upper headgear straps by threading them through the upper hooks of the headgear frame, and fold the lower headgear straps as shown in the picture.

2



Pull the upper straps over your head and hold the mask against your face.

3



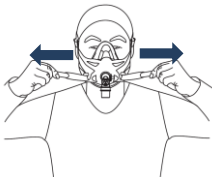
Bring the lower straps below your ears, and loop them into the lower hooks on the headgear frame.

4



Adjust the upper headgear straps evenly until they are comfortable.

5



Adjust the lower headgear straps evenly until they are comfortable.

6



Connect the air tubing to the swivel. Then turn on the device and adjust the mask to the right position without air leakage.



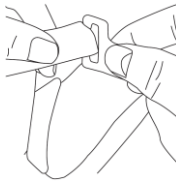
## Disassembling the Mask

1



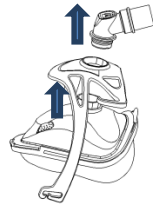
Detach the air tubing.

2



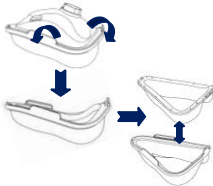
Detach the headgear straps by unthreading the upper and lower straps from the hooks of the headgear frame.

3



Remove the elbow assembly from the cushion frame, and then pulling away the headgear frame.

4



Remove the thin pad and cushion from the cushion frame, and detach the cushion from the thin pad.

## Cleaning the Mask at Home

### Notes:

- *The mask and headgear can only be cleaned through hand 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

To optimize the mask seal, facial oils should be removed from the cushion before use.

Handwash the mask by gently rubbing in warm (30°C) water using mild soap or diluted dishwashing detergent.

If the pick-off port cover requires cleaning, use a soft bristle brush.

Rinse all components well with drinking quality water and allow them to air dry out of direct sunlight.

### Weekly

Handwash the headgear and all components in warm (approx. 30°C) and soapy water. Use pure soap. Rinse the components well and allow them to air dry out of direct sunlight.

## Reprocessing the Mask between Patients

This mask should be reprocessed when used between patients. Cleaning and disinfection instructions are available from the BMC website, [www.bmc-medical.com](http://www.bmc-medical.com). If you do not have internet access, please contact your BMC representative.

## Reassembling the Mask

1



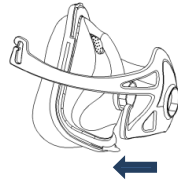
Fit the cushion into the thin pad to form a cushion assembly.

2



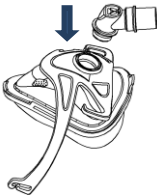
Lock the cushion assembly securely into the cushion frame.

3



Gently push the headgear frame onto the cushion frame.

4



Insert the elbow assembly to the cushion frame.

5



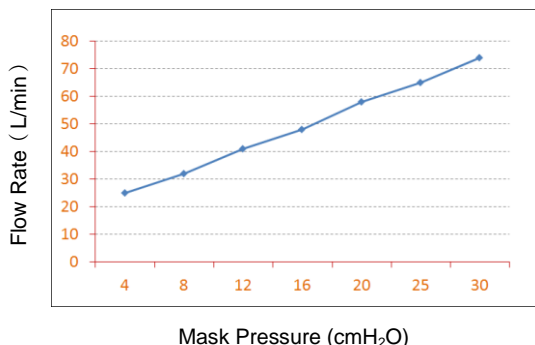
Attach the headgear straps to the frame as shown above.

## Troubleshooting

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.
	Thin pad is misplaced on the cushion frame.	Check insertion of the thin pad and reinsert correctly according to the instructions in "Reassembling the Mask" section.
	Mask's thin pad is misaligned or creased on the face.	Make sure the thin pad is properly aligned according to the instructions in "Reassembling the Mask" section. Make sure the thin pad has no creases. Check the cushion and thin pad, and reposition the mask over your face.
	Mask's cushion and thin pad may be dirty.	Clean the cushion and thin pad according to instructions in "Cleaning the Mask at Home" section.
Mask is too noisy.	Mask is assembled incorrectly.	Reassemble the mask.
	Vents are blocked or partially blocked.	Clean the vents according to the instructions in "Cleaning the Mask at Home" section.

## Technical Specifications

### Pressure–Flow Curve



<b>Dead Space Information</b>	<p>Dead space is the empty volume of the mask up to the swivel.</p> <p>The dead space of the mask varies according to cushion sizes but is less than 246 ml.</p>
<b>Therapy Pressure</b>	4 to 30 cmH <sub>2</sub> O
<b>Resistance</b>	<p>Drop in Pressure measured (average for 3 sizes)</p> <p>at 50 L/min: 0.1 cmH<sub>2</sub>O</p> <p>at 100 L/min: 0.5 cmH<sub>2</sub>O</p>
<b>Inspiratory and Expiratory Resistance</b>	<p>The inspiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 0.6 cmH<sub>2</sub>O per L/S.</p> <p>The expiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 1.7 cmH<sub>2</sub>O per L/S.</p>
<b>The Non-Rebreathing Valve open-to-atmosphere pressure</b>	0.9 cmH <sub>2</sub> O
<b>The Non-Rebreathing Valve closed-to-atmosphere pressure</b>	1.0 cmH <sub>2</sub> O
<b>Sound</b>	<p>DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 30 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 22 dBA, with uncertainty 3 dBA.</p>

**Environmental Conditions**

Operating temperature: +5°C to +40°C (41°F to 104°F)  
 Operating humidity: 0% ~ 93% relative humidity non-condensing  
 Storage and transport: -20°C to +55°C (-4°F to 131°F)  
 Storage and transport humidity: 0% ~ 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 iVolve F1A 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.



Lot number



Not made with natural rubber latex



Temperature limitation



Humidity limitation

## Limited Warranty

It is warranted that the iVolve F1A Full Face Mask, including its components, frame, cushion, headgear 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 the local authorized dealers.

The expected service life of iVolve F1A Full Face Mask is one year.

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