



iVolve Full Face Mask

User Manual

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iVolve Full Face Mask

Thank you for choosing BMC's iVolve Full Face Mask (BMC-FM). 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 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 Full Face Mask is:

- to be used by adult patients (> 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: Federal law restricts the sale of this device to sale by or on the order of a physician.

Before Using the Mask



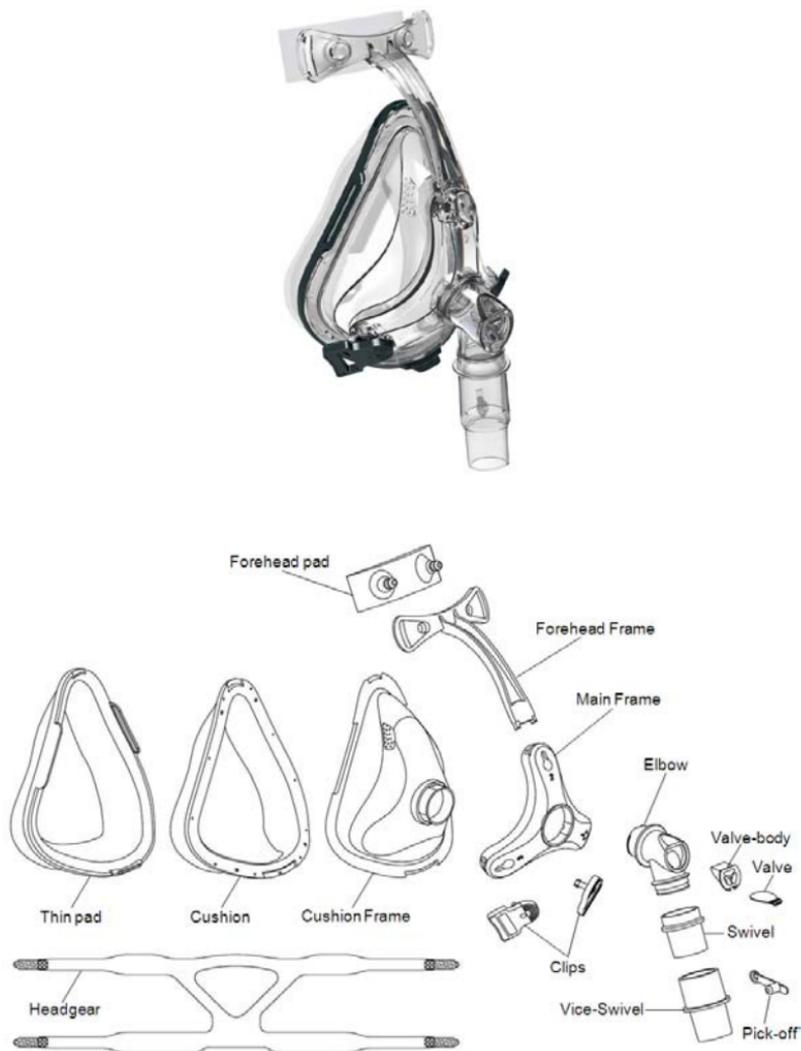
WARNINGS

- 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 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.

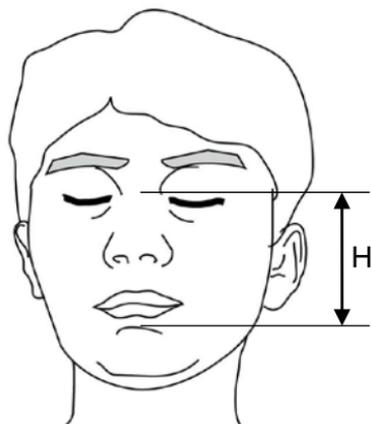
Parts of the iVolve Full Face Mask



Parts of the iVolve 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 for comfortable therapy.
- 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

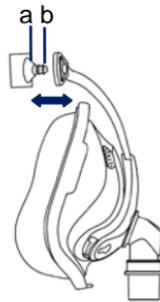
Fitting the Mask

1



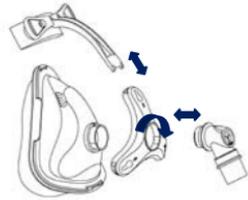
Hold the mask over your face to find whether the angle of the forehead frame is appropriate to you. Go to Step 4 if your answer is "Yes."

2



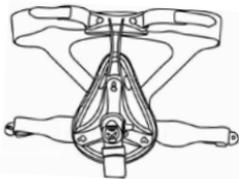
Adjust the forehead pad by pressing or pulling out the bulges on the forehead pad to an appropriate level. Go to Step 4 if it is OK.

3



Refer to "Adjusting the Forehead Pad" section to adjust the forehead pad. Repeat previous steps. Three levels marked as "1," "2," "3" are available.

4



Attach the headgear straps by threading them through the gaps of the forehead frame and clips.

5



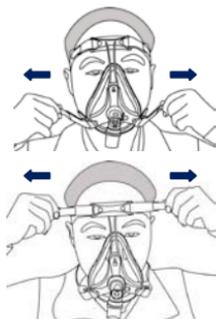
Hold the mask over your face and pull the headgear straps over your head.

6



Place the lower straps below your ears, and connect the clips to the main frame.

7



Adjust the headgear straps in the same way until they are comfortable and firm, and reattach the iVolve Full Face Mask.

8



Connect the main air tubing to the swivel directly or through the optional vice-swivel for the convenience of detachment. Then connect the free end of the air tubing to your flow generator and turn the flow generator on.

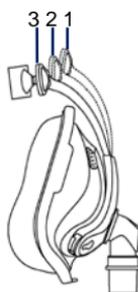
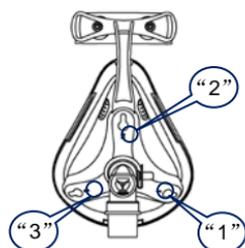
9



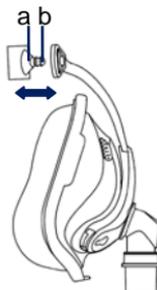
Adjust the main frame until the mask is evenly positioned on your face. It should be comfortable, with an effective seal. Adjust the headgear straps if necessary.

Adjusting the Forehead Pad

1



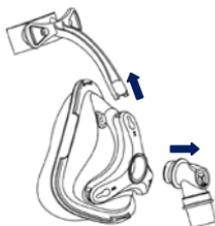
2



As the figure shows, the main frame has 3 positions for fitting different people's faces. Position "2" is the default position. You can do as described in Step 1 of "Fitting the Mask" section to find if the default position is appropriate to you.

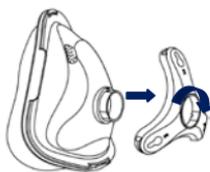
Adjust the forehead pad by pressing or pulling out the bulges on the forehead pad to an appropriate level. Go to Step 4 of "Fitting the Mask" section, if it is OK.

3



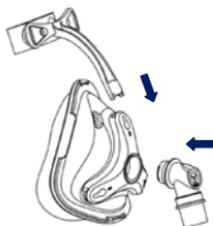
Pull out the elbow and forehead frame to make sure the main frame can be separated from cushion frame.

4



Separate the main frame and revolve the main frame to another position.

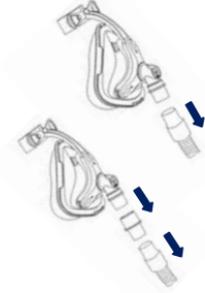
5



Insert the forehead frame to the set position, and insert the elbow to assemble the mask. Repeat steps 2 ~ 5 of this section until the mask fits best.

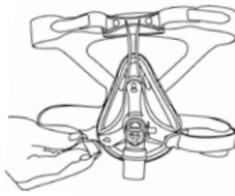
Disassembling the Mask

1



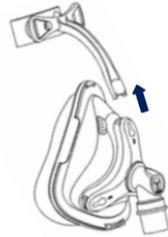
Detach the air tubing or the optional vice-swivel.

2



Unclip the clips and unthread the upper headgear straps. It is not necessary to remove the clips from the headgear.

3



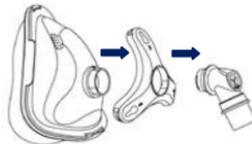
Pull the forehead frame out of the main frame.

4



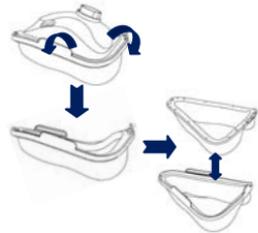
Remove the forehead pad from the forehead frame.

5



Remove the elbow assembly from the mask frame. The main frame will be apart.

6



Remove the thin pad and cushion from the cushion frame.

Cleaning the Mask at Home

Notes:

- *The mask and headgear can only be cleaned through hand washing.*
- *The headgear may be washed without removing the clips.*



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. Do not soak the mask.

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.

Disinfecting the Mask between Patients

The iVolve mask should be disinfected when used between patients. Detailed disinfection instructions are available in the Disinfection Instructions, and must be consulted before multi-patient use.

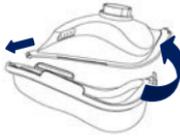
Reassembling the Mask

1



Align the cushion with the thin pad.

2



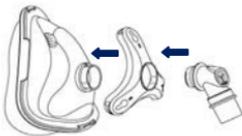
Cover the cushion with the thin pad. Make sure that the directions of thin pad and cushion are aligned.

3



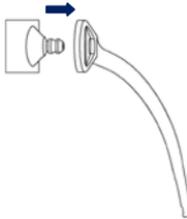
Gently push the main frame onto the cushion frame. Make sure the set position is comfortable and convenient for you and the mask is firmly sealed.

4



Attach the elbow assembly to the mask assembly. To do this, push the elbow into the seal ring until it clicks into place.

5



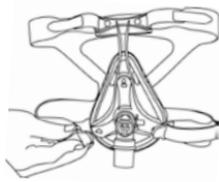
Insert the forehead pad into the forehead frame to the desirable position.

6



Insert the forehead frame into the selected position of the main frame.

7



Attach the headgear straps by threading them through the gaps of the forehead frame and clips.

8



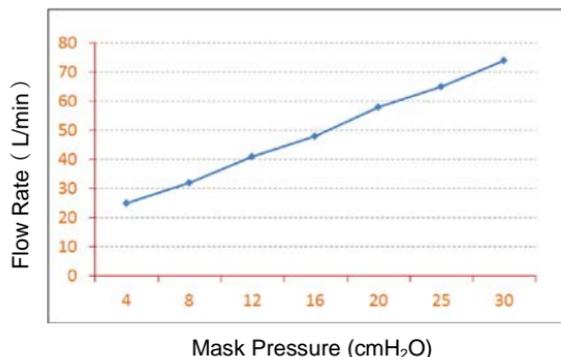
Connect the main air tubing to the swivel directly or through the optional vice-swivel for the convenience of detachment.

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" section. Make sure the headgear is not over-tightened. Adjust the main frame to find a suitable position.
	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. Undo clips, 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



Dead Space Information	<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>
Therapy Pressure	4 to 30 cmH ₂ O
Resistance	<p>Drop in Pressure measured (average for 3 sizes)</p> <p>at 50 L/min: 0.1 cmH₂O</p> <p>at 100 L/min: 0.5 cmH₂O</p>
Inspiratory and Expiratory Resistance	<p>The inspiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 1.2 cmH₂O per L/S.</p> <p>The expiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 1.4 cmH₂O per L/S.</p>
Sound	<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	<p>Operating temperature: +5°C to +40°C</p> <p>Operating humidity: 0% ~ 93% relative humidity non-condensing</p> <p>Storage and transport: -20°C to +55°C</p> <p>Storage and transport humidity: 0% ~ 93% relative humidity non-condensing</p>

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 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



Lot number



Does not contain latex



Temperature limitation



Humidity limitation

User Guide



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.

Limited Warranty

It is warranted that the iVolve Full Face Mask, including its components, frame, cushion, headgear, tubing 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.

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