



iVolve N2 Nasal Mask

User Manual

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iVolve N2 Nasal Mask

Thank you for choosing BMC's iVolve N2 Nasal Mask (BMC-NM2). The Nasal 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 guide provides you with the information you need for the correct use of your mask.

Intended Use

The iVolve N2 channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.

The iVolve N2 is:

- To be used by adult patients (>30 kg) for whom positive airway pressure 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.

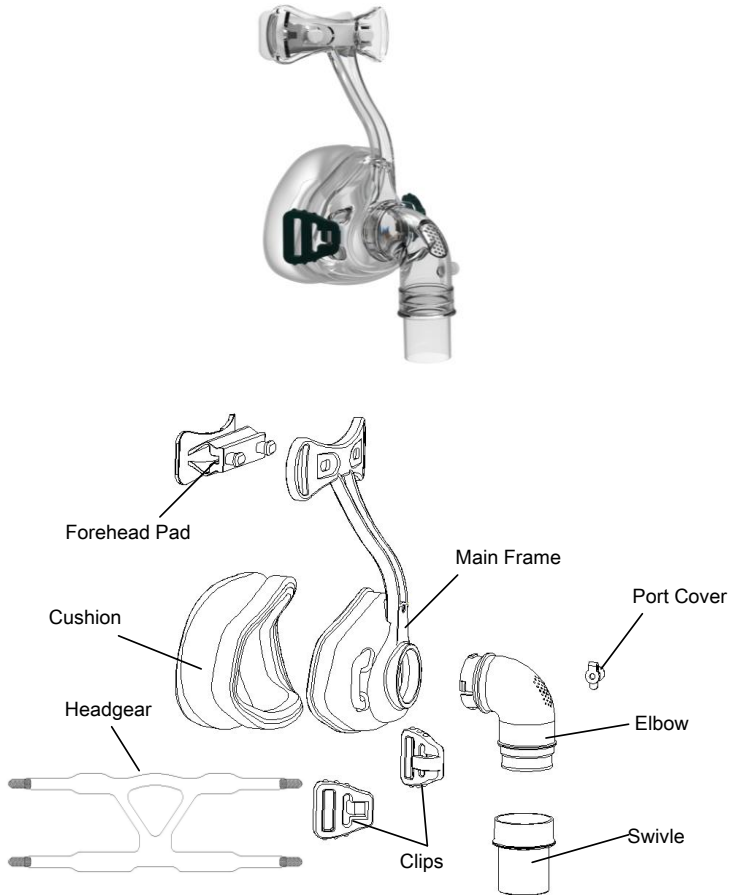
Before Using the Mask



WARNINGS

- The vent holes must be kept clear.
- 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 they are compatible with the flow generator. If used outside specification or if 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 flow generator function.
- Stop using the iVolve N2 if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- Refer to your flow generator manual for details on settings and operational information.

Parts of the Mask



Construction of the iVolve N2 Nasal Mask

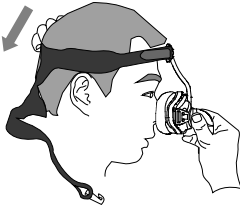
Fitting the Mask

1



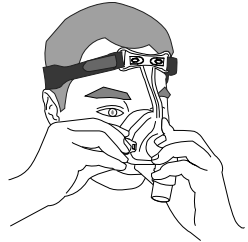
Attach the headgear straps by threading them through the gaps of forehead frame and clips.

2



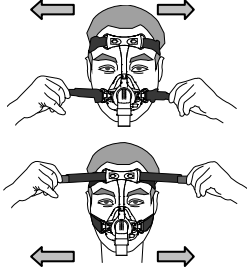
Hold the mask over your nose and pull the headgear over your head.

3



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

4



Adjust the headgear straps evenly until they are comfortable and firm, and reattach the mask.

5



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.

6



Connect the main air tubing to the swivel directly. Then connect the free end of the air tubing to your flow generator and turn the flow generator on.

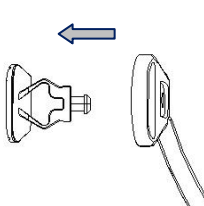
Disassembling the Mask

1



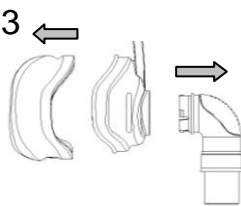
Detach the air tubing. Unclip the clips and unthread the upper headgear straps. It is not necessary to remove the clips from the headgear.

2



Remove the forehead pads from the forehead frame.

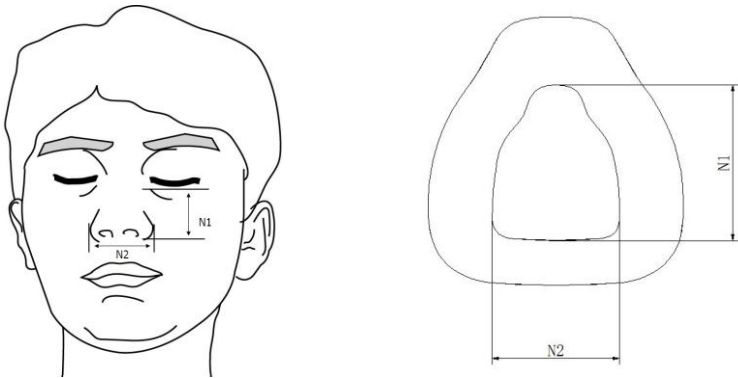
3



Remove the elbow and cushion assembly from the mask frame.

Getting the Right Cushion Size

- The following drawings are the different features of face. The length of the nose is “N1”, and the width of the nose is “N2”.
- There are masks in three different sizes provided for comfortable therapy. “S”, “M” and “L” represent Small, middle and large, respectively.
- The mask cushion is designed shaping with men’s nose, when the dimensions of patient’s nose are equal with the mask, the mask will fit the nose at the most fit place. Otherwise, he should choose another size.
- Choose the smallest size mask cushion that is wide enough to extend beyond the nostrils but does not obstruct breathing.



Dimensions of Face and the Mask

Cleaning the Mask in the Home

Notes:

- *The mask and headgear can only be cleaned by handwashing.*
- *The headgear may be washed without removing the clips.*



CAUTION

- 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.

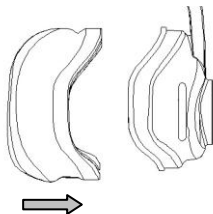
If the pick-off port cover requires cleaning use a soft bristle brush. Rinse all components well with drinking quality water and allow them to air dry out of direct sunlight. Do not soak the mask.

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.

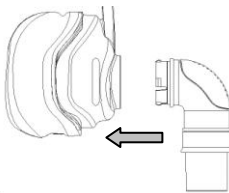
Reassembling the Mask

1



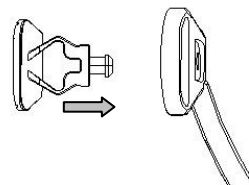
Insert the cushion onto the mask frame. Ensure that the bulge on the main frame embeds into the notch on the cushion.

2



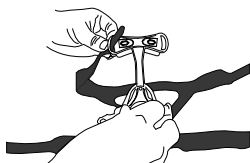
Attach the elbow assembly to the mask assembly. To do this, push the elbow into the seal ring until it clicks into place.

3



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

4



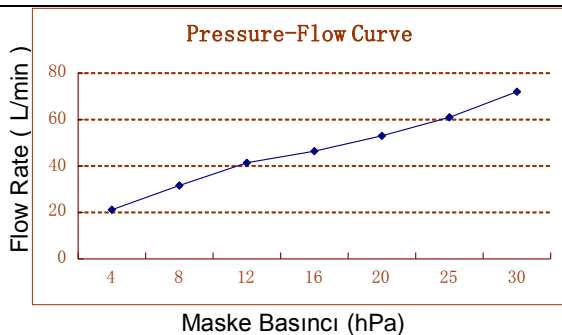
Attach the headgear straps by threading them through the gaps of forehead frame and clips.

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". Check headgear is not over-tightened. Revolve the main frame to find a suitable position.
	Mask is wrong size.	Talk to your clinician.
	Thin pad is misplaced on cushion frame.	Check insertion of thin pad and reinsert correctly according to the instructions in "Reassembling the Mask".
	Mask thin pad is misaligned or creased on face.	Ensure thin pad is properly aligned according to the instructions in "Reassembling the Mask". Make sure the thin pad has no creases in it: undo clips, check cushion and thin pad and reposition the mask over your nose.
	Mask cushion and thin pad may be dirty.	Clean cushion and thin pad according to instructions in "Cleaning the Mask in the Home".
Mask is too noisy	Mask is assembled incorrectly.	Reassemble mask.
	Vents are blocked or partially blocked.	Clean vents according to instructions in "Cleaning the Mask in the Home".

Technical Specifications

Pressure–Flow Curve



Dead Space Information

Dead space is the empty volume of the mask up to the swivel.
The dead space of the mask varies according to cushion sizes but is less than 135 mL.

Therapy Pressure

4 to 30 hPa.

Resistance

Drop in Pressure measured (average for 3 sizes)
at 50 L/min: 0.2 hPa
at 100 L/min: 0.5 hPa

Sound

DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 29 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1m is 24 dBA, with uncertainty 3 dBA.

Environmental Conditions

Operating temperature: +5°C to +40°C
Operating humidity: 0%–93 % relative humidity non-condensing
Storage and transport: - 20°C to + 55°C
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 N2 does not contain any hazardous substances and may be disposed of with your normal household refuse.

Symbols

System and Packaging



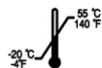
Caution, consult accompanying documents;



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 iVolve N2 Nasal 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 or:

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