

F2 NV Full Face Mask (F2 NV1 / F2 NV2) User Manual

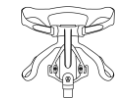
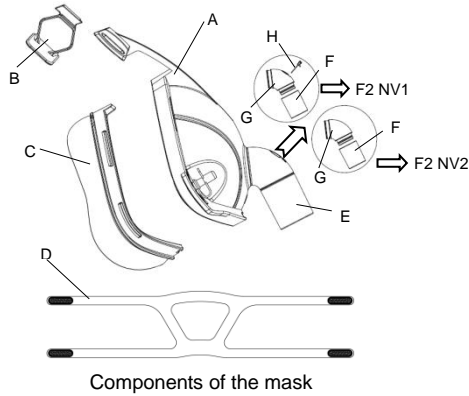


Fig.1



Fig.2



Fig.3



Fig.4



Fig.5



Fig.6

Fitting the Mask

F2 NV Full Face Mask

Thank you for choosing BMC's F2 NV Full Face Mask. F2 NV series have two models: F2 NV1 and F2 NV2, which are Non-Vented Masks. F2 NV series have a standard female 22 mm tapered that fit external connection to ventilator. F2 NV1 includes an anti-asphyxiation valve which is designed to insure patient to breathe when therapy device failure occurs. F2 NV2 is designed without anti-asphyxiation valve. This user manual provides you with complete the information you need for the proper use of F2 NV masks. The Mask is Not made with natural rubber latex.

Intended Use

The mask is intended to be used with active-exhaust-valve ventilator systems, to provide ventilatory assistance to patients with respiratory insufficiency and respiratory failure.

- The mask is to be used by adult patients (> 30 kg) requiring non-life-support ventilator assistance.
- The mask is intended for single-patient use, for a maximum of seven days, in the hospital or clinical environment.

Before Using the Mask

⚠ WARNINGS

- The mask should not be worn unless the ventilator system is turned on and operating properly.
- Not applicable for silicone-allergy user.
- This mask should not be used on patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask.
- 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.
- 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 F2 NV 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.
- Remove all packaging before using the mask.

Components of the Mask

- | | |
|-------------------|-------------------|
| A. Frame assembly | E. Elbow assembly |
| B. Forehead pad | F. Swivel |
| C. Cushion | G. Elbow |
| D. Headgear | H. Valve |

Fitting the Mask

Fitting the mask tips:

- Pass the upper straps of the headgear through the installation hole of the mask as shown in the figure and secure it, repeat the process with the lower straps. (Fig.1)
- Place the mask on the face and extend the headgear to the back of the head / Please confirm that the label on the back of the headgear faces outward when the headgear is worn. (Fig.2)
- Bring the lower-half straps beneath the ear and encircle the face and then insert it into the fixed hook on the lower-half part of the mask frame. (Fig.3)
- Extend the upper-half straps of the headgear as shown in the above figure until the mask is fixed properly. (Fig.4)
- Repeat the process for the lower-half headgear as shown in the above figure until the mask is fixed properly. (Fig.5)
- Open the device for the air supply. Attach the respiratory hose with the connector on the base of the mask. Adjust the position of the mask to confirm a tight seal. (Fig.6)

⚠ CAUTIONS

- The elbow assembly cannot be disassembled from the frame assembly.
- The elbow assembly cannot be disintegrated.
- The valve of F2 NV1 cannot be disassembled, or damage may be incurred and the re-installation will become more difficult.

Cleaning the Mask

This mask is disposable and should be discarded if heavily soiled. If lightly soiled, the mask may be cleaned by wiping with a 70% v/v isopropyl alcohol swab. Do not disassemble the mask.

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 according to cushion sizes but is less than 218 mL. |
| Therapy Pressure | 3 to 40 cmH ₂ O |
| Resistance | Drop in Pressure measured (average for 3 sizes) at 50 L/min: 0.15 cmH ₂ O |
| | at 100 L/min: 0.5 cmH ₂ O |
| Anti-asphyxiation valve closed to Atmosphere (F2 NV1) | 1.2 cmH ₂ O |
| Anti-asphyxiation valve open to Atmosphere (F2 NV1) | 1.0 cmH ₂ O |
| 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 |

Note:

- F2 NV2 does not have anti-asphyxiation valve.
- This product is not made with natural rubber latex, PVC or phthalates such as DEHP, DBP or BBP.

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

Dispose of in accordance with local regulations.

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



Catalog number



Temperature limitation



Humidity limitation



Manufacturer



Authorized Representative in the European Community



Single Use only

MANUFACTURER:

BMC MEDICAL CO., LTD.

Room 110 Tower A Fengyu Building, No. 115 Fucheng Road, Haidian, 100036
Beijing, PEOPLE'S REPUBLIC OF CHINA

Tel : +86-10-51663880

Fax : +86-10-51663880 Ext. 810

EU AUTHORISED REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

Tel : 0049-40-2513175

Fax : 0049-40-255726