Full Face Mask (F5A+)

User Manual

CE 0123

Full Face Mask (F5A+)

Thank you for choosing BMC's Full Face Mask (F5A+). 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. The Full Face Mask (F5A+) and accessories are not made with natural rubber latex or DEHP.

Intended Use

The Full Face Mask (F5A+) is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The Full Face Mask (F5A+) 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 this device to sale by or on the order of a physician.

Contraindications

This mask should be used with caution for patients with following conditions:

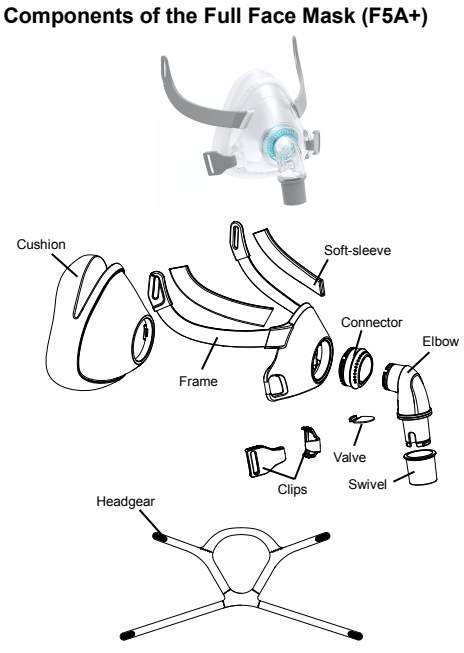
- Facial deformity.
- Injured facial skin which will contact with the mask during use.

Before Using the Mask

⚠ WARNINGS

- The vent holes must be kept undamaged and free of blockages.
- The mask is not suitable for patients who need ventilation to support life.
- This mask should only be used with CPAP or bi-level devices recommended by a physician or respiratory therapist.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air.
- ***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 turned 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 may 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.
- Not applicable for silicone-allergy user.
- This mask should not be used on patients who are uncooperative, unconscious, unresponsive, or unable to remove the mask.
- Using the mask may cause pain in the teeth, gums or jaw or aggravate existing dental conditions. If these conditions occur, consult your health care professional.
- When the patient is unable to remove the mask himself, the mask must be used under qualified supervision.
- 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.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well ventilated rooms.
- 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 Full Face Mask (F5A+) 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.
- Images shown here are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.
- Any serious incidents that occur in relation to this device should be reported to BMC and the competent authority in your country.
- Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents, or exceeding the number of processing cycles can have an adverse effect on the mask and consequently the safety or the quality of the therapy.

Components of the Full Face Mask (F5A+)

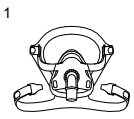


Note: The Frame assembly is composed of Frame, Connector, Elbow assembly and Swivel. The Elbow assembly is composed of Elbow and Valve.

Components of Full Face Mask (F5A+)

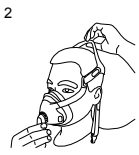
Fitting the Mask

1



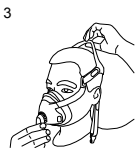
Pass the upper straps of the headgear through the installation hole of the mask as shown in the figure and secure it, repeat the process with the lower straps to join the headgear clip.

2



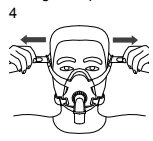
Place the mask on the face and extend the headgear to the back of the head. Please confirm that the label on the back of the headgear faces outward when the headgear is worn.

3



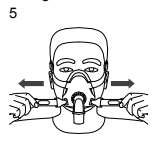
Bring the lower-half straps beneath the ear and insert the clips into the fixed hook on the lower-half part of the mask frame.

4



Extend the upper-half straps of the headgear as shown in the above figure until the mask is fixed properly.

5



Repeat the process for the lower-half headgear as shown in the above figure until the mask is fixed properly.

6



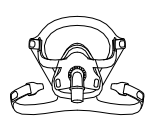
Simply adjust to a comfortable seal and don't over-tighten.

Disassembling the Mask

Notes:

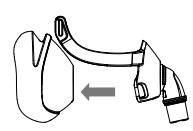
- *The elbow assembly and the connector cannot be disassembled from the frame assembly.*
- *The elbow assembly cannot be disintegrated.*
- *The valve cannot be disassembled. Or it may cause damage, and its installation would be difficult.*

1



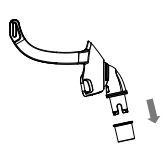
Undo and remove the upper-half headgear straps out of the hole on the Frame assembly.

2



Remove the cushion from the Frame assembly.

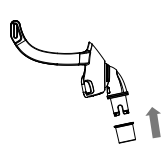
3



Remove the Swivel from the Elbow.

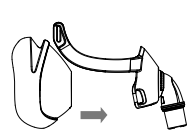
Reassembling the Mask

1



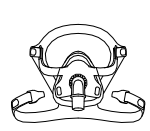
Install the Swivel onto the Frame assembly and confirm that the Swivel is reliable.

2



Install the Cushion onto the Frame assembly and confirm that the Cushion is reliable.

3



Install the upper-half headgear onto the upper-half installation hole of the Frame assembly.

Cleaning the Mask at Home

Notes:

- *The mask and headgear can only be cleaned by hand washing.*
- *The elbow assembly and the connector cannot be disassembled from the frame assembly for washing.*
- *The elbow and the valve cannot be disassembled from the elbow assembly 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.
- Visual criteria for product inspection: If there is any visible deterioration of a mask component (cracking, crazing, tears etc.), the component should be discarded and replaced.
- Replacement of parts must be carried out by professional service personnel.

Preparation before cleaning

1. Prepare tools: soft bristle brush, drinking quality water (10 litres per mask), mild liquid detergent (e.g., Alconox diluted to 1%).
2. Disassemble the mask components according to the disassembly instructions.

Daily / After each use

1. Soak the components in a solution of mild liquid detergent (e.g. Alconox diluted to 1%) with drinking quality water (25°C to 35°C) for 10 minutes.
2. While soaking, clean each component with a soft bristle brush for 1 minute. Pay special attention to all crevices and cavities.
3. Agitate the components vigorously twice in drinking quality water. 5 litres of water per mask at a time.
4. Allow the components to air dry and do not allow direct sunlight.
5. When all components are dry, reassemble the mask according to the reassembly instructions.

Note:

- *Cleaned once a day or after each use, the mask can be washed up to 365 times.*

Weekly

Handwash the headgear and its components in a solution of mild liquid detergent (e.g. Alconox diluted to 1%) with drinking quality water (25°C to 35°C) for 10 minutes. Rinse the headgear and its components well with drinking quality water and allow them to air dry out of direct sunlight.

Note:

- *Cleaned once a week, the headgear can be washed up to 52 times.*

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. If you do not have internet access, please contact your BMC representative.

Note:

- *The maximum number of disinfection cycles is 20.*

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.
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 at Home" section.

Intended Clinical Benefit

1. Improve patients' quality of sleep.
2. Improve patients' compliance with therapy.

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

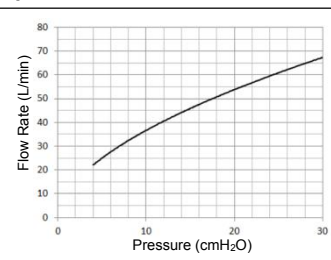
The mask does not contain any hazardous substances and may be disposed of with your normal household waste.
For patients with transmissible diseases, the product shall be discarded as medical waste, otherwise it may cause the spread of disease.

Service Life

The service life of the Full Face mask depends on the intensity of usage, maintenance, and environmental conditions to which the mask is used or stored. As this mask system and its components are modular in nature, it is recommended that the user maintain and inspect it on a regular basis, and replace the mask system or any components if deemed necessary or according to the "Visual criteria for product inspection" in the "Cleaning the Mask at Home" section of this manual. The mask should be replaced within 12 months from the date of first use.

Technical Specifications

Pressure–Flow Curve



Pressure (cmH_2O)	4	10	12	17	24	30
Flow Rate (L/min)	22	37	41	49	59	67

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 225 mL.
Therapy Pressure	4 to 30 cmH_2O
Resistance	Drop in Pressure measured at 50 L/min: 0.15 cmH_2O, at 100 L/min: 0.5 cmH_2O
Inspiratory and Expiratory Resistance	The inspiratory resistance of the mask (in combination with the valve) is 1.8 cmH_2O at 50 L/min. The expiratory resistance of the mask (in combination with the valve) is 2.0 cmH_2O at 50 L/min.
Anti Asphyxia Valve open-to-atmosphere pressure	< 4 cmH_2O
Anti Asphyxia Valve closed-to-atmosphere pressure	< 4 cmH_2O
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 25 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 17 dBA, with uncertainty 3 dBA.
Environmental Conditions	Operating temperature: +5°C to +40°C (41°F to 104°F) Operating humidity: 0% to 93% relative humidity non-condensing Storage and transport temperature: -20°C to +55°C (-4°F to 131°F) Storage and transport humidity: 0% to 93% relative humidity non-condensing
Date of Manufacture	See product label

Symbols

System and Packaging

	Caution		Use-by date
EC REP	Authorized Representative in the European Community	LATEX	Not made with natural rubber latex
LOT	Batch code		Importer
REF	Catalogue number	#	Model Number
55°C 131°F / -20°C -4°F	Temperature limit	CN	Made in China
93% / 0%	Humidity limitation	MD	Medical device
	Manufacturer	UDI	Unique device identifier

Limited Warranty

It is warranted that the Full Face Mask (F5A+), including Frame Assembly, Cushion, Headgear, Swivel 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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