

Fealite Nasal Pillows System

# User Manual

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# Fealite Nasal Pillows System

Thank you for choosing BMC's Fealite Nasal Pillows System. The nasal pillows system is light, 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 system.

## Intended Use

The Fealite is intended for single patient reuse by adult patients (> 30 kg) prescribed continuous positive airway pressure or Bi-level therapy for use in home, hospitals or clinics.

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

## Medical Information

**Note:** *The Fealite does not contain latex, PVC, or DEHP materials. If you have ANY reaction to any part of the system, discontinue use and consult your sleep therapist.*



### **WARNING and CAUTION**

- This system should be used only with flow generators (CPAP or Bi-level) recommended by your physician or respiratory therapist. It should not be used unless the flow generator is turned on and operating properly. The vent holes should never be blocked.
- **Explanation of the Warning:** Flow generators are intended to

be used with special interfaces with connectors which have vent holes (vent holes are located on the elbow) or separate exhalation devices to allow continuous flow of air out of the interface. When the flow generator is turned on and functioning properly, new air from the flow generator will flush the exhaled air out through the attached exhalation port. However, when the flow generator is not operating (eg, power failure), not enough fresh air will be provided through the system, and exhaled air may be re-breathed. In this situation, remove the Fealite immediately.

- The exhaust vent flow is lower at lower system pressure (see section “Technical Specifications” for Pressure-Flow Curve details). If the system pressure during expiration is too low, there may not be enough exhaust vent flow to completely flush the air delivery hose of exhaled air before the start of the next inspiration.
- Discontinue using the Fealite if you frequently experience nasal irritation, and consult your physician.
- If oxygen is used with the flow generator, the oxygen flow must be turned off when the flow generator is not operating. Explanation of the Warning: When the flow generator is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the flow generator enclosure. Oxygen accumulated in the flow generator enclosure will create a risk of fire. This warning applies to most types of flow generators.
- Please refrain from smoking while oxygen is in use.

**Note:** *At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, interface selection and the leak rate.*

## Parts of the Fealite



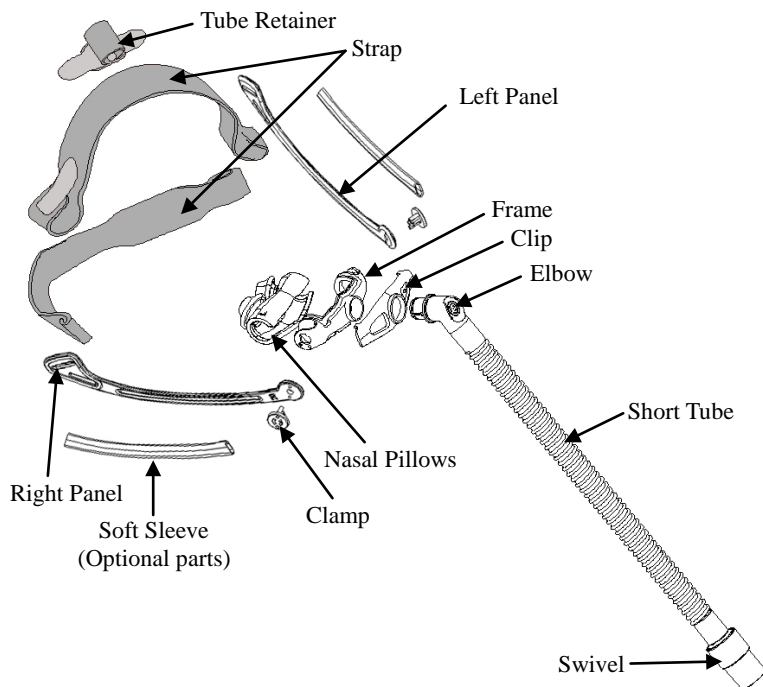
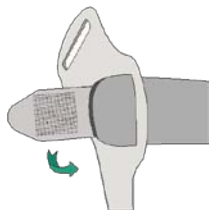


Figure 1 Construction of the Fealite

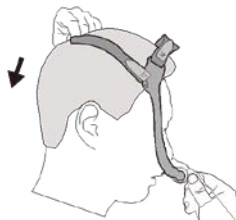
# Fitting the Fealite

1



Thread the two straps through the gaps in panels separately, then fold back over to secure.

2



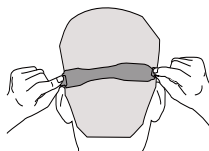
Put the headgear on your head and Insert the nasal pillows into your nostrils. Make sure the top strap passes over the top of your head.

3



Gently tighten the top strap (overtightening may cause excess pressure on your nose).

4



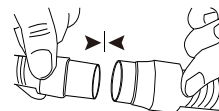
Adjust each end of the back strap (overtightening may cause excess pressure on upper lips).

5



Alternate the adjustment of headgear straps until they rest comfortably and rotate nasal pillows assembly to adjust nasal pillows angle to ensure them sit comfortably inside your nostrils.

6



Connect one end of the main air tubing to your flow generator and the other end to the swivel. Turn your flow generator on.

## 7



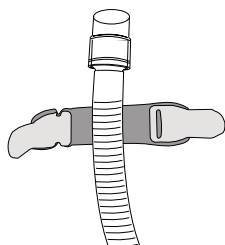
Take time to adjust the headgear straps, angle of the pillow assembly and position of the short tube assembly to achieve a secure and comfortable fit.

**Note:** Refer to your flow generator manual for details on setting and operational information.

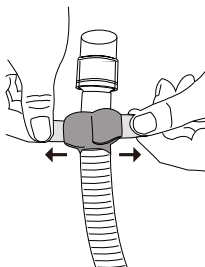
*If you feel air leak, readjust the angle of the nasal pillows to get a better seal. If you are unable to resolve any leaks, you may need an alternative nasal pillows size.*



## Using Tube Retainer (Optional)



Wrap tube retainer over the short tube. Make sure smooth surface sits outside.



Thread one end of the tube retainer into the gap of the other end.



Attach both ends of the tube retainer onto the top strap.

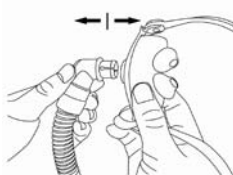
## Removing the Fealite

To remove the Fealite, pull the nasal pillows assembly away from your nose and lift the headgear off your head. You do not need to loosen the headgear straps.

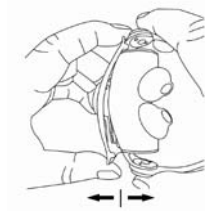
## Disassembling for Cleaning



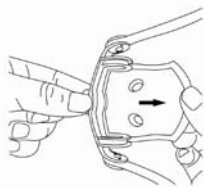
Disconnect the flow generator tubing. Hold the swivel and pull it away from the flow generator tubing.



Detach the short tube assembly. To do this, hold the elbow and pull it away from the frame.



Remove clip from frame.



Disassemble the nasal pillows assembly. To do this, detach the clip and peel the nasal pillows off the frame.

**Note:** The short tube assembly cannot be taken apart.



### CAUTION

- Do not pull on the short tube or the flow generator tubing as they may get damaged.

To disassemble the Fealite for daily cleaning, follow steps 1-3.

To disassemble the Fealite for weekly cleaning, follow steps 1-5.

## Cleaning the Fealite in the Home

### Notes:

- *Wash your hands before cleaning the mask.*
- *Wash the headgear before first time use, as the dye may run. It is important to always handwash the headgear.*

### Daily

Handwash the nasal pillows assembly, short tube assembly and cap in warm (approx. 30°C), soapy water for one minute. Use pure soap. Rinse the components well with drinking quality water and allow to air dry out of direct sunlight and heat.

**Note:** *Ensure that the vent holes are not blocked. Use a soft bristle brush to clean the vent.*

### 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.

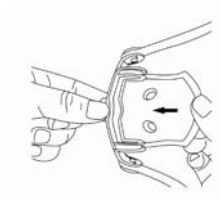


### CAUTION

- 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.

# Reassembling the Fealite

1



Wrap the nasal pillows around the frame in the correct position. Make sure the nasal pillows are pointing upwards.

2



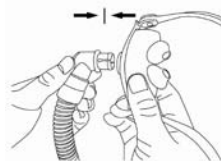
Insert the nasal pillows edges into the groove of the frame. Make sure assemble it in the right side, or it cannot be attached tightly to the frame.

3



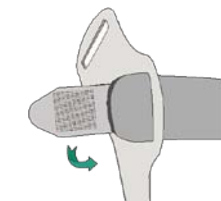
Hold the clip and align the circle in its middle with the one on the frame. Gently push the clip onto the frame to secure the nasal pillows in place.

4



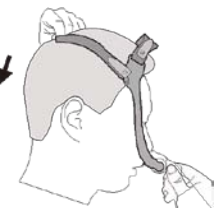
Attach the short tube assembly to the nasal pillows assembly. To do this, push the elbow into the seal ring until it clicks into place.

5



Thread both ends of two straps through the gaps in the panels. Make sure rough surface of straps sits outside.

6



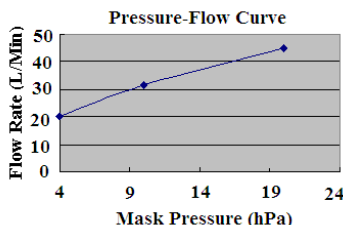
Slip the headgear on your head and adjust the position.

## Disposal

The Fealite Nasal Pillows System does not contain any hazardous substances and may be disposed of with your normal household refuse.

## Technical Specifications

### Pressure Flow Curve



### Dead Space Information

Dead space is the empty volume of the nasal pillows and short tube assembly up to the swivel. The dead space of the Fealite for all nasal pillows sizes is 96 mL.

### Therapy Pressure

4 to 20 hPa.

### Resistance

Drop in pressure measured (average for three nasal pillows sizes) at 50 L/min: 1.0 hPa at 100 L/min: 3.1 hPa.

### Sound

DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 26 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1m is 18 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.

# 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 Fealite Nasal Pillows System, including its components, frame, nasal pillows, 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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