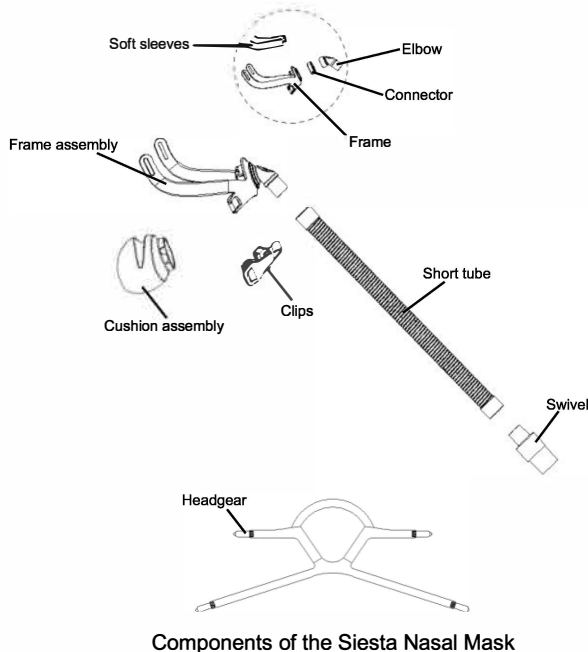


Siesta Nasal Mask

User Manual

Components of the Mask



Siesta Nasal Mask

Thank you for choosing 3B Medical's Siesta Nasal Mask. The Siesta Nasal Mask 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 Mask is not made with natural rubber latex.

Intended Use

The Siesta Nasal Mask channels airflow non-invasively to the patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Siesta Nasal Mask is:

- To be used by adult patients (> 66 lb / 30 kg) for whom positive airway pressure therapy has been prescribed.
- Intended for single-patient reuse.

CAUTION: In the US, Federal law restricts the sale of this device by or on the order of a physician.

Before Using the Mask

WARNINGS

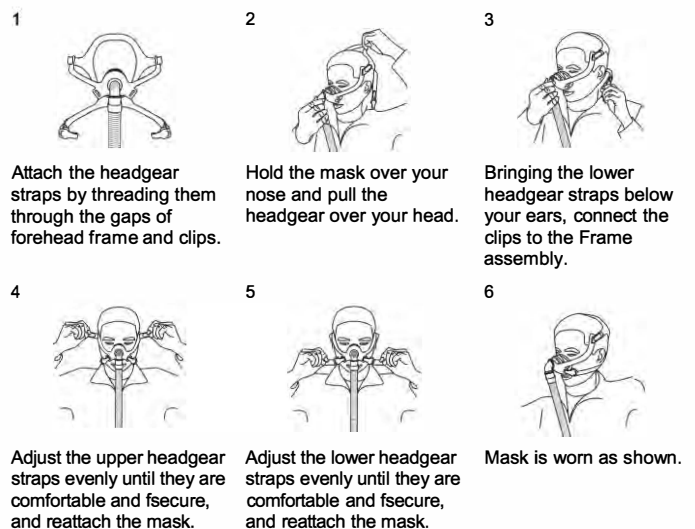
- The vent holes must be kept clear.
- This mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory therapist.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air.

Explanation: CPAP and bilevel devices are intended to be used with special masks (or connectors) which have vent holes to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through

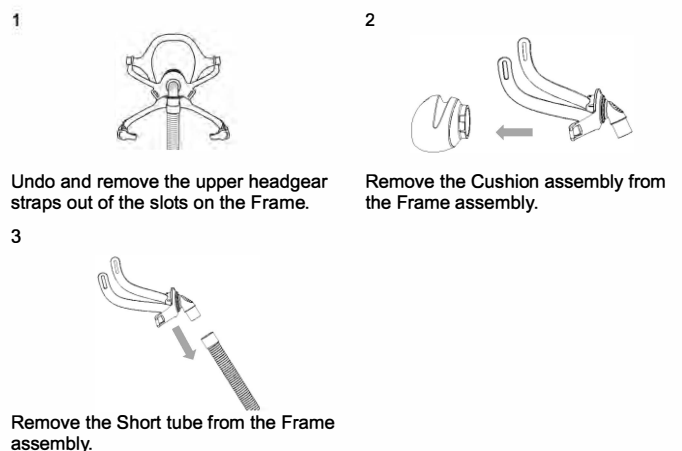
the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bilevel devices.

- This mask is made with silicone parts. Please do not use if patient has silicone allergy or sensitivity.
- 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 CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the device 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 Siesta Nasal Mask and consult your physician or sleep therapist, if you have ANY adverse reaction to the use of the mask.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- Remove all packaging before using the mask.

Fitting the Mask



Disassembling the Mask



Cleaning the Mask

Notes:

- The mask and headgear can only be cleaned through hand washing or placed in the Lumin device
- The headgear may be washed without removing the clips.
- When washing the mask, the Elbow and the Frame cannot be disassembled from the Frame assembly.

CAUTIONS

- Always follow cleaning instructions and 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, otherwise may damage the mask.
- 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

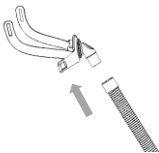
- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear), by gently rubbing in warm (approx. 30°C) water using mild liquid detergent (e.g., Alconox diluted at 1%) for up to 10 minutes.
- Use a soft bristle brush to clean the vent.
- Rinse all components well with drinking quality water and allow to air dry out of direct sunlight.
- When all components are dry, reassemble according to the reassembly instructions.

Weekly

Handwash the headgear and all components in warm (approx. 30°C) and mild liquid detergent (e.g., Alconox diluted at 1%) for up to 10 minutes. Rinse the components well with quality drinking water and allow them to air dry out of direct sunlight before assembling.

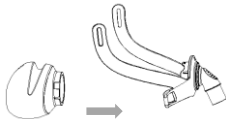
Reassembling the Mask

1



Install the Short tube onto the Frame assembly and confirm that the Swivel is securely attached.

2



Install the Cushion assembly onto the Frame assembly and confirm that the Cushion assembly is securely attached.

3



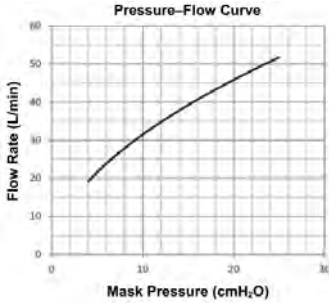
Install the upper-half of the headgear onto the upper slot of the Frame assembly.

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.
	Mask size is wrong.	Consult your clinician.
	Mask is not tightened correctly.	Tighten both upper and lower headgear straps.
	Cushion is misaligned or creased on face.	Ensure cushion is properly aligned according to the instructions in "Reassembling the Mask". Make sure cushion has no creases in it.
	Mask cushion may be dirty.	Clean cushion according to instructions in "Cleaning the Mask at Home".
Mask is too noisy.	Mask is assembled incorrectly.	Reassemble mask.
	Vents are blocked or partially blocked.	Clean the vents according to instructions in "Cleaning the Mask at Home" section.

Technical Specifications

Pressure-Flow Curve



Pressure (cmH ₂ O)	4	9	15	20	25
Flow Rate (L/min)	19	30	39	46	52

Dead Space Information	Dead space is the empty volume of the mask up to the elbow. The dead space of the mask varies according to cushion sizes but is less than 105 mL.
Therapy Pressure	4 to 25 cmH ₂ O
Resistance	Drop in Pressure measured (average for 3 sizes) at 50 L/min: 0.2 cmH ₂ O at 100 L/min: 0.8 cmH ₂ O
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 28 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 20 dBA, with uncertainty 3 dBA.
Environmental Conditions	Operating temperature: +5°C to +40°C (41°F to 104°F) Operating humidity: 10% ~ 93% relative humidity non-condensing Storage and transport: -20°C to +55°C (-4°F to 131°F) Storage and transport humidity: 10% ~ 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 Siesta Nasal 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. 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

Limited Warranty

It is warranted that Siesta Nasal Mask, including its Frame assembly, Cushion assembly, Swivel, Clips and Headgear 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.

The expected service life of Siesta Nasal Mask is one year. For any questions or comments concerning this product or the warranty, please contact:

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