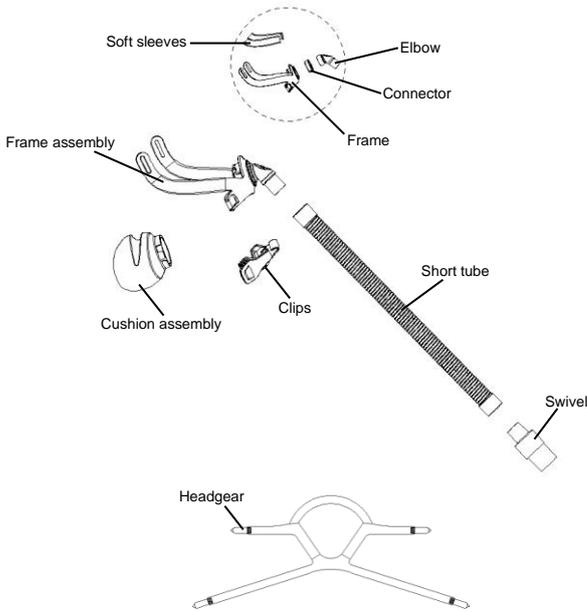


Siesta Nasal Mask

User Manual

Components of the Mask



Components of the Siesta Nasal Mask

Siesta Nasal Mask

Thank you for choosing REACT HEALTH'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 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.

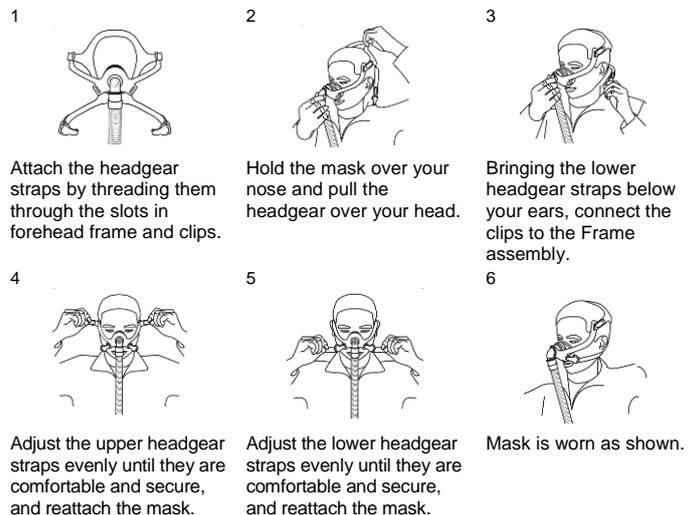
Explanation: CPAP and bi-level devices are intended to be used with special masks (or connectors) which have vent holes to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. 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 bi-level devices.

- This mask is made with silicone parts. Please do not use if the

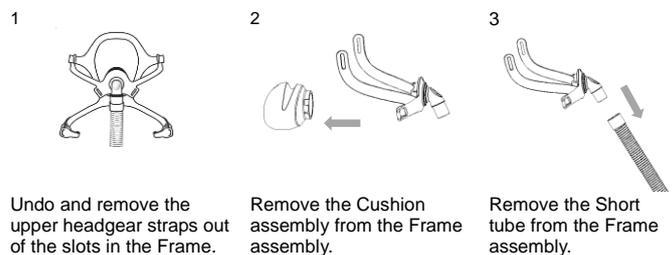
patient is allergic or sensitive to silicone.

- This mask should not be used on patients who are uncooperative, unresponsive, or unable to remove the mask.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bi-level device is not in operation, so that unused oxygen does not accumulate in the device enclosure and create a fire hazard.
- 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, 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, and optimum therapy may not be achieved. Leak or variation in the rate of leak, may affect the function of the CPAP or bi-level device.
- 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 bi-level device 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.

Fitting the Mask



Disassembling the Mask



Cleaning the Mask

Notes:

- The mask and headgear can only be cleaned by washing by hand.
- 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.

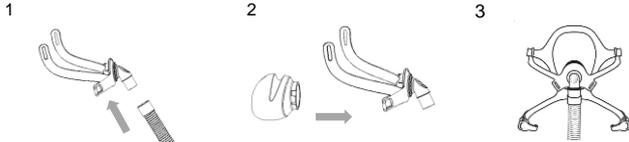
Daily / After Each Use

- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear) by gently rubbing in warm water (approx. 86°F / 30°C) using mild, unscented liquid dish detergent for up to 10 minutes.
- Use a soft bristle brush to clean the vent.
- Rinse all components well with drinking quality water and allow them to air dry out of direct sunlight.
- When all components are dry, reassemble the mask according to the reassembly instructions.

Weekly

Hand wash the headgear and all components in warm (approx. 86°F / 30°C), mild, unscented liquid dish detergent for up to 10 minutes. Rinse the components well with drinking quality water and allow them to air dry out of direct sunlight before reassembling.

Reassembling the Mask



1
Install the Short tube onto the Frame assembly and confirm that the Swivel is securely attached.

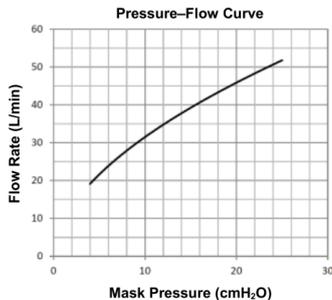
2
Install the Cushion assembly onto the Frame assembly and confirm that the Cushion assembly is securely attached.

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 is too noisy.	Mask cushion may be dirty.	Clean cushion according to instructions in "Cleaning the Mask".
	Mask is assembled incorrectly.	Reassemble mask.
Mask is too noisy.	Vents are blocked or partially blocked.	Clean the vents according to instructions in "Cleaning the Mask".

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 with cushion size 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 cmH₂O

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 an uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 20 dBA, with an uncertainty of 3 dBA.

Environmental Conditions

Operating temperature: +5°C ~ +40°C (41°F ~ 104°F)
 Operating humidity:
 10% ~ 93% relative humidity non-condensing
 Storage and transport temperature:
 -20°C ~ +55°C (-4°F ~ 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.



Batch code



Catalogue number



Temperature limit



Humidity limitation



Manufacturer



Authorized Representative in the European Community

Limited Warranty

The expected service life of Siesta Nasal Mask is one year.

For any questions or comments concerning this product, please contact:

Manufactured for:

REACT HEALTH

5101 Fruitville Rd., Suite 200

Sarasota, FL 34232

T: (863) 226-6285

For additional information, please visit our Patient Resources Page at: www.reacthealth.com

Manufacturer:

BMC Medical Co., Ltd.

Room 901, Building 1, No.28 Pingguoyuan Road, Shijingshan, Beijing 100041, CHINA

URL: en.bmc-medical.com

E-mail: intl@bmc-medical.com

Tel: +86-10-51663880

Fax: +86-10-51663880 Ext. 810

Contract Manufacturer:

BMC (Tianjin) Medical Co., Ltd.

2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, (301700) Tianjin, PEOPLE'S REPUBLIC OF CHINA

Tel: +86-22-82939881

BMC (Dongguan) Medical Co., Ltd.

3/F and 4/F, Building 3, No. 770 Xiecao Road, Xiegang Town, 523000 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA