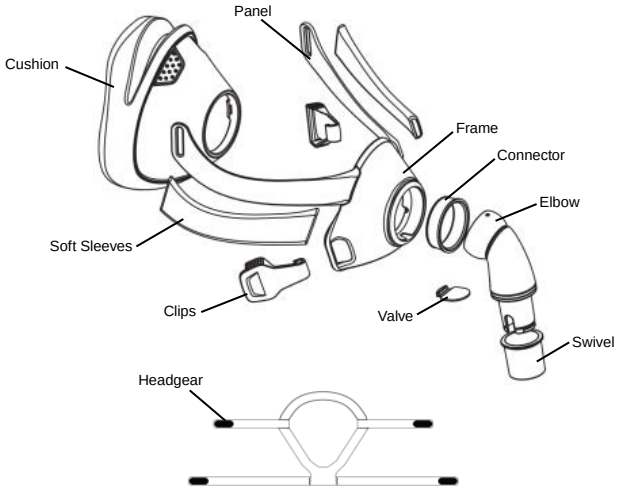
Siesta Full Face Mask

User Manual

Components of the Siesta Full Face Mask



Components of the Siesta Full Face Mask

Siesta Full Face Mask

Thank you for choosing 3B Medical's Siesta Full Face Mask. The 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 contains no natural rubber latex.

Intended Use

The Siesta Full Face 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 Full Face 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 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.

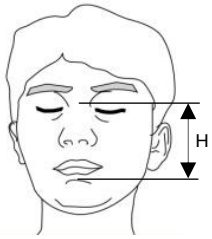
Before Using the Mask

⚠ WARNINGS

- The vent holes must be kept clear.
- This mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory therapist.
- **Explanation of Warning:** CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air will be rebreathed. Rebreathing of exhaled air for longer than several minutes can, 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 for 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 Non-Rebreathing Valve in place.
- 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.
- 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 Siesta 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.

Getting the Right Cushion Size

- The following drawing describes the different features of the face and the length of the face (H) you need to measure.
- The masks are available in three different sizes.
- Choose the appropriate size according to the table below.



H (mm)	Size
80 ≤ H ≤ 90	S
90 < H ≤ 100	M
100 < H ≤ 115	L

Getting the Right Cushion Size

Fitting the Mask

Use a standard conical connector if pressure readings and / or supplemental oxygen are required.

1

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

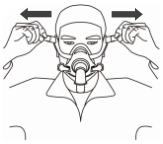
2

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 part of the mask frame.

4



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

5

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

6

Connect the air tubing to the swivel. Then turn on the device and adjust the mask to the correct position.

Disassembling the Mask

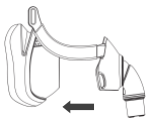
Notes:

1. *The elbow assembly cannot be dissembled from the frame assembly.*
2. *The valve cannot be dissembled, or damage may be incurred and the re-installation will become more difficult.*

1

Undo and remove the upper-half headgear straps out of the slot on the mask frame.

2



Remove the cushion from the mask frame.

3

Remove the Swivel from the Elbow.

Cleaning the Mask at Home

Notes:

- *The mask and headgear can only be cleaned through hand washing or placed in the Lumin device.*
- *The elbow and the valve cannot be dissembled 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.
- If any visible deterioration of a component is apparent (cracking, crazing, tears etc), the component should be discarded and replaced.

Daily / After Each Use

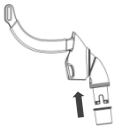
- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear), by gently rubbing in warm (approx. 30°C) water using mild liquid detergent (e.g., Alconox diluted at 1%) for up to 10 minutes.
- Use a soft bristle brush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

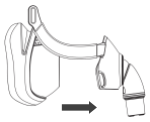
Reassembling the Mask

1



Install the forehead pad onto the upper-half installation groove of the mask frame.

2



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

3

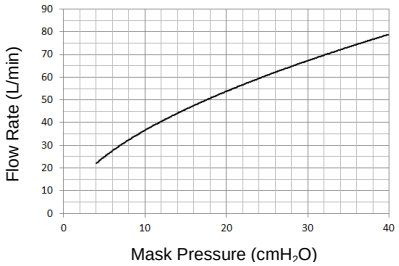
Install the upper-half headgear onto the upper-half installation hole of the mask frame.

Technical Specifications

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.

Technical Specifications

Pressure–Flow Curve



Pressure（cmH_2O）	3	12	22	31	40
Flow Rate（L/min）	19	41	57	69	79

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	3 to 40 cmH_2O
Resistance	Drop in Pressure measured (average for 3 sizes) 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 Non-Rebreathing Valve) is 1.8 cmH_2O at 50 L/min. The expiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 2.0 cmH_2O at 50 L/min.
The Non-Rebreathing Valve open-to-atmosphere pressure	≤ 2.8 cmH_2O
The Non-Rebreathing Valve closed-to-atmosphere pressure	≤ 2.8 cmH_2O
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 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	Lot number
REF	Catalog number
55 °C 131 °F -20 °C -4 °F	Temperature limitation
93 10	Humidity limitation
	Manufacturer
EC REP	Authorized Representative in the European Community

Limited Warranty

It is warranted that the Siesta Full Face Mask, including Frame assembly, Cushion, Forehead pad, 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 Full Face Mask is one year.