

61850/2 o7 04 MIRAGE LIBERTY USER

**APAC ENG** 

### RESMED

### Mirage Liberty™

FULL FACE MASK

#### **User Guide**

English





Global leaders in sleep and respiratory medicine www.resmed.com

ResMed Ltd (Manufacturer) 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia ResMed Corp (US Designated Agent) 14040 Danielson Street Poway CA 92064-6857 USA ResMed (UK) Ltd (EU Authorized Representative) 65 Milton Park Abingdon Oxfordshire 0X14 4RX UK ResMed Offices Australia, Austria, Brazil, Finland, France, Germany, Hong Kong, Japan, Malaysia, Netherlands, New Zealand, Norway, Singapore, Spain, Sweden, Switzerland, UK, USA (see www.resmed.com for contact details).

Mirage Liberty Full Face Mask

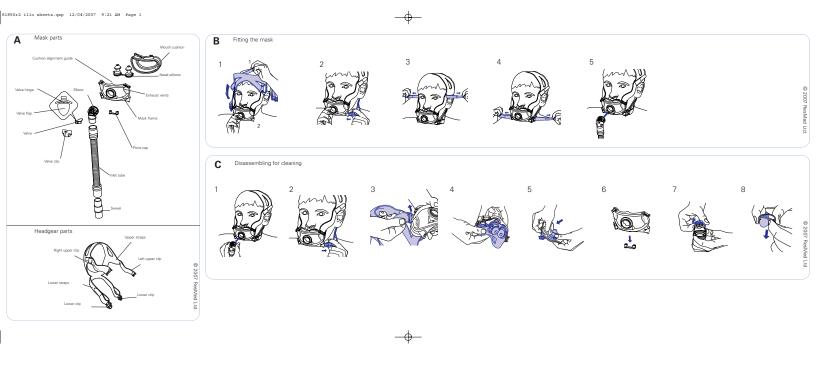
Protected by patents: EP 1314445, HK 1057714, US 6412487, US 6581594, US 6796308, US 6823865, US 7021311. Other patents pending.

Protected by design registrations: AU 312036, AU 312037, AU 312038, AU 312039, AU 312040, AU 312971, AU 312972, AU 312973, AU 312974, AU 312975, AU 312976, AU 312977, AU 312978, AU 312979, AU 312980, AU 312981, AU 312982, AU 312983, AU 312984, AU 313118, AU 313120, AU 313121, AU 313122, AU 313123, AU 313124, AU 313125. Others pending.

Mirage and Mirage Liberty are trademarks of ResMed Ltd and Mirage is registered in U.S. Patent and Trademark Office.

Velcro is a registered trademark of Velcro Industries B.V. STERRAD and CIDEX are trademarks of Johnson & Johnson. Alconox is a trademark of Alconox Ltd. Neodisher Medizyme is a trademark of Chemische Fabrik Dr Weigert.

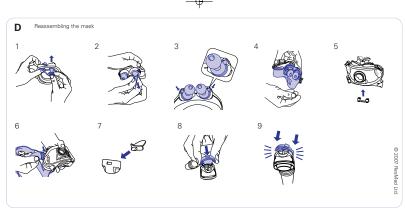
© 2007 ResMed Ltd.

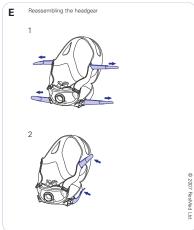


#### RESMED

### Mirage Liberty Full Face Mask

 $\label{Note:power} \textbf{Note} \hbox{: For complete instructions, please read the text section in conjunction with the illustrations on this sheet.}$ 





Component of: 61850/2

# RESMED

# Mirage Liberty™

**FULL FACE MASK** 

Thank you for choosing ResMed's Mirage Liberty. The Mirage Liberty is a full face mask that combines nasal pillows and a mouth cushion, creating a mask that is both unobtrusive and easy to use without compromising seal, stability and comfort.

The mask incorporates vent holes and a built-in valve so that you can continue to breathe fresh air if the airflow to your mask is impeded for any reason.

#### Intended Use

The Mirage Liberty channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Mirage Liberty is to be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed.

The Mirage Liberty is intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

### **Before Using the Mask**



#### **WARNING**

- The Mirage Liberty must be used under qualified supervision with patients who are unable to remove the mask by themselves. The mask may not be suitable for those predisposed to aspiration.
- The elbow and valve assembly have specific safety functions. They
  allow you to breathe fresh air if the airflow from your flow generator
  to your mask is impeded. The mask should not be worn if the valve is
  damaged as it will not be able to perform its safety function. The valve
  should be replaced if it is damaged, distorted or torn.
- The vent holes must be kept clear.
- Follow all precautions when using supplemental oxygen.

- Any supplemental 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 will vary, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate.
- The technical specifications of the mask and flow generator are provided for your clinician to check that they are compatible. If used outside specification or if 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 flow generator function.
- Discontinue using the Mirage Liberty if you have ANY adverse reaction to the mask system, and consult your physician or sleep therapist.
- Discontinue using the Mirage Liberty if you experience nasal irritation, and consult your physician or sleep therapist.
- Refer to your flow generator manual for details on settings and operational information.

### Using the Mask

Select 'Mir Full' or 'Full Face' as the mask option when using the Mirage Liberty with ResMed flow generators that have mask setting options.

### Fitting the mask

The diagrams in section A on the illustrations sheet show how the parts of the mask fit together.

The diagrams in section **B** show the suggested sequence for obtaining the best fit and comfort in using your mask. Please follow these instructions carefully.

- 1 Wash your face thoroughly before fitting the mask. It is recommended that you do not apply moisturiser where the mask contacts your face as it can affect the mask seal.
- 2 Place the headgear on your head, like you would a cap, and pull the mask forward onto your face (B-1). Make sure that the headgear fits evenly on the top of your head.
- 3 Fit the mask over your mouth. Insert the pillows so that they sit gently just inside the entrance to your nostrils.
- 4 Push the lower headgear clips into the slots on the mask frame until they click into place (B-2).

- 5 To tighten or loosen the headgear straps, peel the Velcro® tab off the headgear and reposition it. Gently and evenly adjust the upper headgear straps (B-3), then the lower straps (B-4). Alternate the adjustment of each set of straps until they are comfortable and firm and so that the upper headgear clips rest between your eye and your ear. The mask should gently 'float' on your face. Do not overtighten the headgear straps.
- 6 Connect one end of the main air tubing to your flow generator and the other end to the swivel.
- 7 Connect the elbow to the mask frame, holding the sides of the elbow then firmly pushing it onto the frame until it clicks into place (B-5). Rotate the elbow to check that it rotates freely and does not separate from the frame.
- 8 Turn your flow generator on.
- 9 If you feel air leaks, you may need to adjust your headgear. Return to step 5 or check through the suggestions in "Optimising mask seal and comfort" below.

### **Optimising mask seal and comfort**

To receive effective therapy it is important to have the best seal possible between your mask and your face. If you are experiencing leaks, please ensure that you have followed the fitting instructions carefully. Carry out a quick check after fitting your mask:

- Is the mouth cushion creased? Creases can allow air to leak out of the mask.
- Have you cleaned your mask recently? Oils on the cushion and pillows can affect the seal.
- Are the pillows correctly seated in your nostrils? Re-seat or adjust the pillows to obtain a proper seal.
- Are your headgear straps overtightened? Try not to alter the upper headgear straps once they have been tightened by your clinician.
- If you cannot establish a comfortable seal, do not overtighten the headgear. Consult your clinician.
- Try another nasal pillow size.

If you cannot resolve any problems, look at the Troubleshooting section, or talk to your clinician.

### Removing the Mask

To remove the Mirage Liberty:

- 1 Detach the elbow by squeezing the elbow on both sides (C-1).
- 2 Unclip both of the lower headgear clips (C-2) and remove the mask.

**Note:** You can detach the elbow from the mask frame and leave the mask on your face. You may prefer to do this when briefly stopping therapy, for example to go to the bathroom.

### Disassembling the Mask

See section C on the illustrations sheet.

- 1 Unclip the upper headgear clips from the frame (C-3).
- 2 Carefully pull the mouth cushion away from the frame (C-4).
- 3 Push the two nasal pillows down through the mouth cushion (C-5).
- 4 Remove the ports cap (C-6).
- 5 Detach the inlet tube assembly from the elbow.
  Note: The swivel does not need to be disconnected from the inlet tube.
- 6 Detach the valve clip from the elbow (C-7).
- 7 Peel the valve from the valve clip (C-8).

  Note: Do not pull on the valve flap, as this may cause it to tear.

### Cleaning the Mask in the Home

#### Notes:

- The mask and headgear can only be cleaned by handwashing.
- The headgear may be washed without removing the headgear clips.
- Do not soak any components of the mask.



#### **WARNING**

- Do not use aromatic-based solutions or scented oils (eg, eucalyptus or essential oils), bleach, alcohol or products that smell strongly (eg, citrus) to clean any of the mask components. Residual vapours from these solutions can be inhaled if not rinsed thoroughly. They may also damage the mask, causing cracks.
- Do not iron the headgear as the material is heat sensitive and will be damaged.

### Daily/After Each Use

To optimise the mask seal, facial oils should be removed from the cushion and pillows before use.

Handwash the mask by gently rubbing in warm (30°C) water using mild soap or diluted dishwashing detergent.

Clean the walls of the nasal pillows, including the space between the walls, of any debris using a small brush.

Do not twist the valve during cleaning as this may damage or tear the valve membrane or hinge. Take care when handling the valve.

If the vent requires cleaning, use a soft bristle brush.

Rinse all components well with drinking quality water and allow them to air dry out of direct sunlight.

### Weekly

Handwash the headgear by gently rubbing in warm (30°C) water using mild soap or diluted dishwashing detergent. Rinse the headgear well and allow it to air dry out of direct sunlight.

### **Cleaning the Mask between Patients**

The Mirage Liberty should be disinfected or sterilised when used between patients.

Detailed disinfection and sterilisation instructions are available from the ResMed website, www.resmed.com/masks/sterilization, and must be consulted before multipatient use.

### Reassembling the Mask

See section **D** on the illustrations sheet.

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged. Flexible PVC contains elements that can be detrimental to the materials of the mask. If flexible PVC tubing is used continuously, the attachment port should be inspected for cracking. Replace any parts that are damaged.

Refer to "Ordering Information" for re-order numbers.

- 1 Attach the nasal pillows to the mouth cushion:
  - a Push the nasal pillows through the holes in the mouth cushion (D-1).
  - **b** Pull the nasal pillows up until the grooves at their base fully engage around the mouth cushion holes (**D-2**).
  - c Check that the tabs on each pillow fit into the corresponding notches on the cushion (D-3). Check that the seal between the pillows and cushion is complete.
- 2 Attach the mouth cushion to the frame:
  - **a** Position the cushion alignment guide between the two nasal pillows and line up the triangle symbols on the bottom of the mask frame with those on the mouth cushion.
  - b Press the mouth cushion into the groove in the frame (D-4).
  - c Check that the mouth cushion is fully seated in the groove.
- 3 Insert the ports cap (D-5).
- 4 Clip the upper headgear clips onto the mask (D-6).

- 5 Assemble the elbow assembly:
  - a Push the tab of the valve up through the slot in the valve clip (D-7). Ensure that the valve locks into the slot.
  - b Feed the flap of the valve through the slot in the elbow (D-8).
  - **c** Press the valve clip onto the elbow until you hear both sides click into place (**D-9**).
- 6 Push the inlet tube assembly onto the elbow assembly.

### Reassembling the Headgear

If taken apart, the headgear has five parts: headgear straps, left and right upper headgear clips, and two lower clips.

- 1 Attach the upper headgear clips to the mask frame (D-6). The mask incorporates lock-out features to ensure that each upper clip attaches to the correct side of the mask frame.
- 2 Clip the lower headgear clips into the mask frame.
- 3 Lay out the headgear straps, label side down. The label is on the outer side of the headgear. The internal side is smooth, to be comfortable against your face.
- 4 Thread the top (short) straps through the upper headgear clips (E-1, E-2).
- 5 Thread the bottom (long) straps through the lower clips (E-1, E-2).
- 6 Check that the headgear is not twisted.

### **Storage**

Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a cool dry place out of direct sunlight.

### **Disposal**

The Mirage Liberty does not contain any hazardous substances and may be disposed of with your normal household refuse.

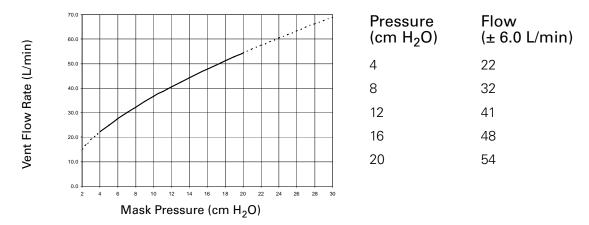
# **Troubleshooting**

Problem	Possible reason	Possible solution
Mask won't seal properly or is uncomfortable	Mouth cushion or pillows may be dirty.	Clean mask according to instructions in "Cleaning the Mask in the Home".
	Mask may have been fitted incorrectly.	Carefully follow instructions in "Fitting the mask".
	Mask is incorrectly adjusted.	Check headgear is not over- tightened.
	Mouth cushion is wrong size.	Talk to your clinician.
	Mouth cushion is skewed in mask frame.	Check insertion of cushion.
	Mouth cushion is misaligned or creased on face.	Ensure cushion is properly aligned and that there are no creases in it: undo headgear clip, check cushion and reposition the mask on your face.
	Mask pillows are the wrong size.	Try another size or talk to your clinician.
	Mask pillows are not correctly seated in your nostrils.	Re-seat pillows into nostrils.
	Mask pillows are skewed in cushion.	Check insertion of pillows.
	Mask is assembled incorrectly.	Reassemble mask.
Mask is too noisy	Vents are blocked or partially blocked.	Clean vents according to instructions in "Cleaning the Mask in the Home".
	Valve is misassembled.	Reassemble valve.
	Cushion is not properly inserted.	Check insertion of cushion.
	Mask is assembled incorrectly.	Reassemble mask.
	Valve is damaged, torn or distorted.	Replace valve.
	Pillows are not inserted correctly into cushion.	Check insertion of pillows.
	Mask is not sealing.	Check and adjust mask as necessary.

### **Technical Specifications**

**Note:** The mask system does not contain latex, PVC or DEHP materials.

#### **Pressure-Flow Curve**



**Note:** As a result of manufacturing variations, the vent flow may vary from that indicated in the graph.

#### **Dead Space Information**

Dead space is the empty volume of the mask up to the elbow.

The maximum dead space of the Mirage Liberty for all mask size combinations is 151 mL.

#### **Standards**

CE designation in accordance with EC directive 93/42/EEC, class IIa. ISO 14971, ISO 10993-1, ISO 17510-2, ISO 13485.

#### **Therapy Pressure**

4 to 20 cm H<sub>2</sub>O

#### Resistance

Drop in pressure measured (nominal)

at 50 L/min: 0.5 cm  $H_2O$  at 100 L/min: 1.6 cm  $H_2O$ 

#### Sound

The A-weighted sound power of the mask is 28 dBA.

#### **Environmental Conditions**

Operating temperature: +5°C to +40°C

Operating humidity: 10%-95% relative humidity non-condensing

Storage and transport temperature: -20°C to +60°C

Storage and transport humidity: 10%-95% relative humidity non-condensing

#### **Mask sizes**

(excludes inlet tube and headgear)

size	width (mm)	height (mm)	depth (mm)
small	110	92	95
large	110	100	100

### **Symbols**

### **System and Packaging**



Caution, consult accompanying documents



Lot number



Part number/Product code



No latex



95 Humidity limitation



Temperature limitation



Manufacturer

#### **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.

## **Ordering Information**

Ref.	Item		
System			
61310	Mirage Liberty Full Face Mask, Small – ANZ		
61311	Mirage Liberty Full Face Mask, Large – ANZ		
61312	Mirage Liberty Full Face Mask, Small – Asia-Pacific		
61313	Mirage Liberty Full Face Mask, Large – Asia-Pacific		
Replacement parts			
61330	Mouth cushion, Small (1 pk)		
61331	Mouth cushion, <i>Large</i> (1 pk)		
61333	Nasal pillows, Small (1 pk)		
61334	Nasal pillows, <i>Medium</i> (1 pk)		
61335	Nasal pillows, <i>Large</i> (1 pk)		
61337	Mask frame, <i>Small</i> (1 pk)		
61338	Mask frame, <i>Large</i> (1 pk)		
61340	Elbow assembly (elbow, valve and clip) (1 pk)		
61342	Valve and clip (1 pk)		
61343	Valve and clip (10 pk)		
60926	Inlet tube and swivel (1 pk)		
60927	Inlet tube and swivel (10 pk)		
61348	Headgear assembly, <i>Small</i> (1 pk)		
61349	Headgear assembly, <i>Standard</i> (1 pk)		
61352	Upper clips (2 pk)		
61353	Lower clips (2 pk)		
16570	Ports cap (2 pk)		
16571	Ports cap (10 pk)		
60014	Swivel (10 pk)		

### **Limited Warranty**

ResMed warrants that your ResMed mask system, including its components: mask frame, cushion, headgear, tubing and other accessories ("Product") 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.

For further details refer to the Warranty.