

RESMED

Mirage Quattro™

FULL FACE MASK

User Guide

English

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MIRAGE QUATTRO
USER
USA ENG



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Mirage Quattro Full Face Mask

Protected by patents: AU 777033, EP 1187649, EP 1314445, HK 1057714, US 6412487, US 6439230, US 6513526, US 6581594, US 6701927, US 6796308, US 6823865, US 6823869, US 6860269, US 7021311, US 7069933.
Other patents pending.

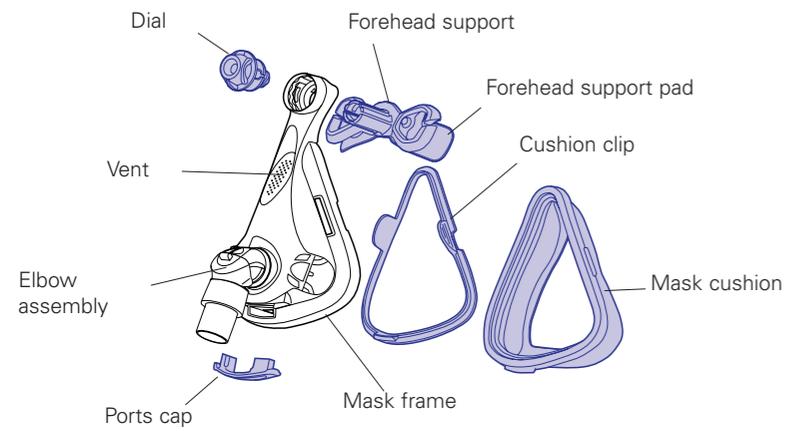
Protected by design registrations: AU 309495, AU 309789, AU 309800, AU 310242, AU 311114, AU 311132, AU 311133, AU 311134, AU 311135, AU 311136, AU 311137, AU 311186, AU 311187. Others pending.

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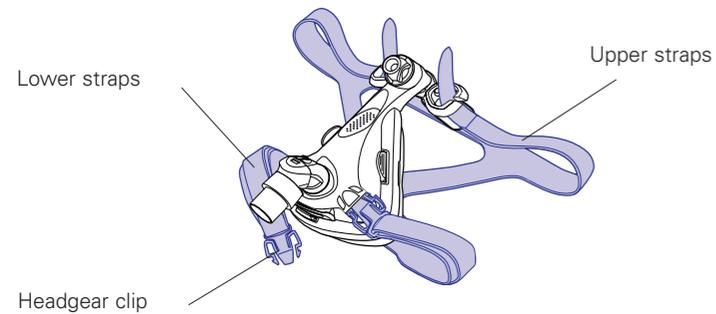
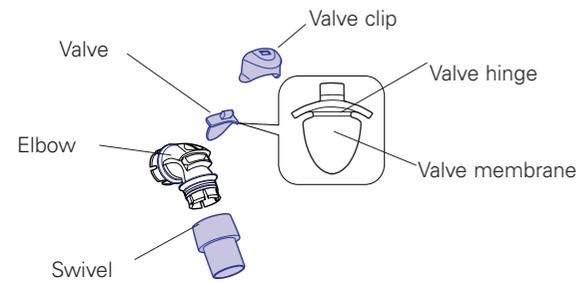
Velcro is a registered trademark of Velcro Industries B.V.

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A Mask parts

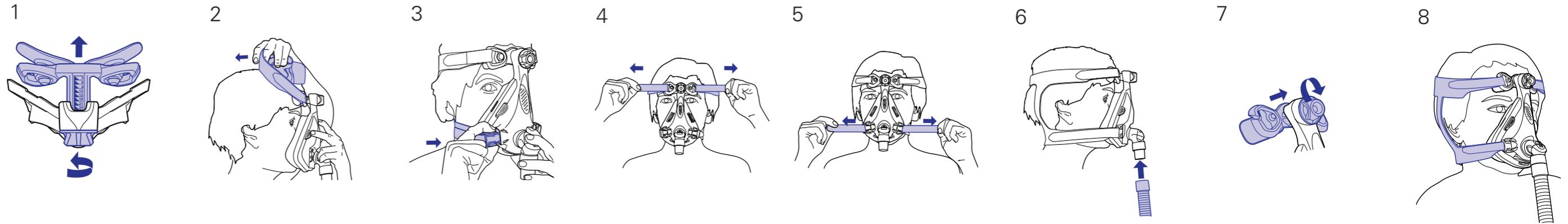


Elbow assembly



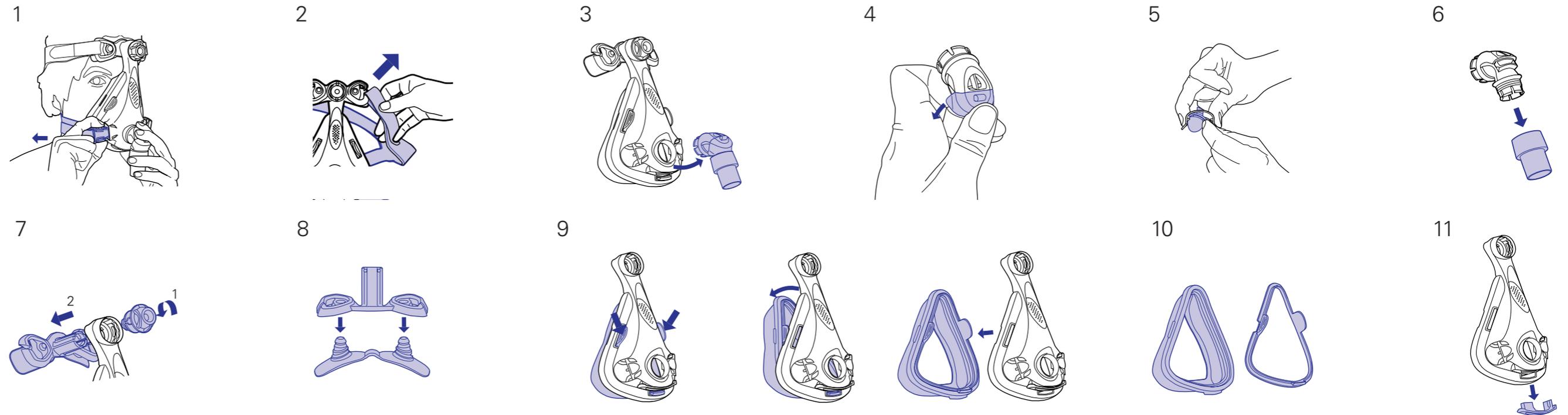
© 2006 ResMed Ltd.

B Fitting the mask



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C Disassembling for cleaning



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Mirage Quattro

Full Face Mask System

Illustrations Sheet

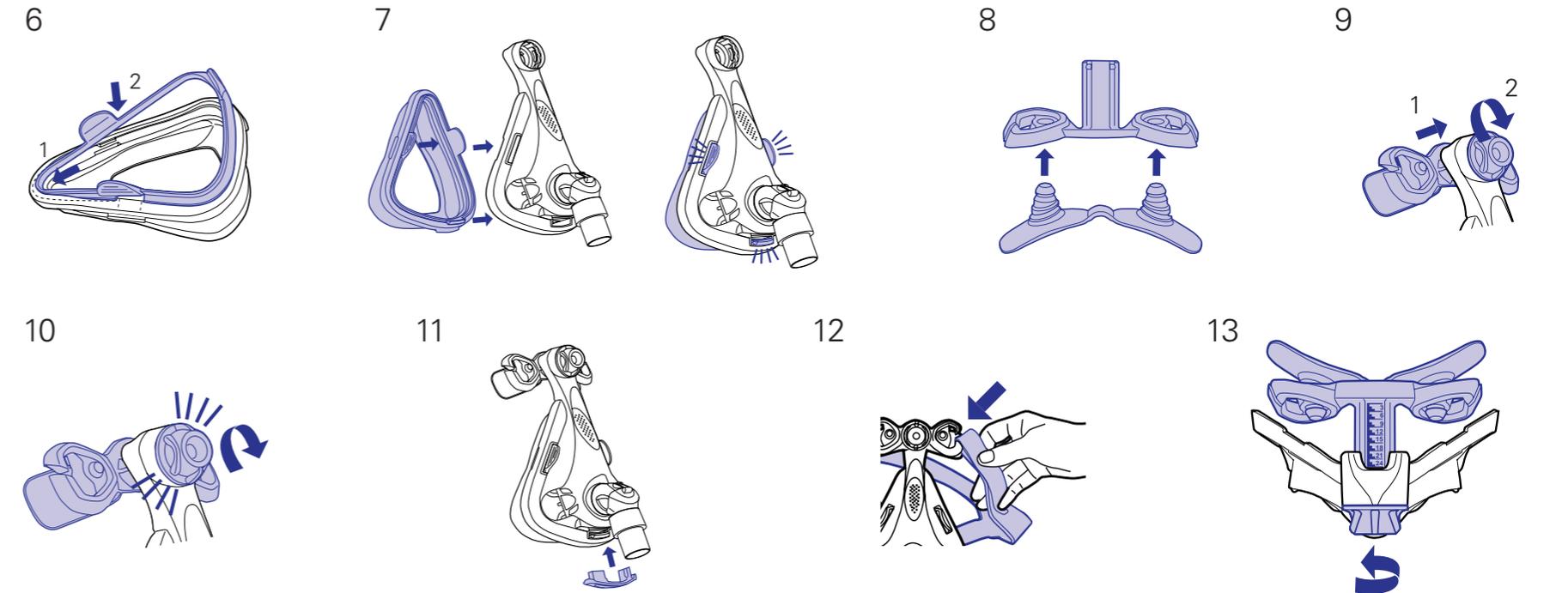
Note: For complete instructions, please read the text section in conjunction with the illustrations on this sheet.

D Reassembling the mask

Elbow Reassembly



Mask Reassembly



Mirage Quattro™

Full Face Mask

Thank you for choosing ResMed's Mirage Quattro Full Face Mask.

The Mirage Quattro is a full face mask system that covers your nose and mouth. This means that you can receive effective therapy even if you breathe through your mouth.

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 Quattro 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 Quattro is to be used by adult patients (>66 lb / 30 kg) for whom positive airway pressure has been prescribed.

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



CAUTION

In the USA, federal law restricts this device to sale by or on the order of a physician.

Before Using the Mask



WARNINGS

- The Mirage Quattro 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 are intended to be used with the Mirage Quattro and have specific safety functions. 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 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 Quattro if you have ANY adverse reaction to any part of the mask system, and consult your physician or sleep therapist.
- Refer to your flow generator manual for details on settings and operational information.



CAUTION

Avoid connecting flexible PVC products (eg, PVC tubing) directly to any part of this mask. Flexible PVC contains elements that can be detrimental to the materials of the mask, and may cause the components to crack or break.

Using the Mask

Select 'Mir Full' or 'Full Face' as the mask option when using the Mirage Quattro 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 sequence for obtaining the best fit and comfort in using your mask. Please follow these instructions carefully.

- 1 Twist the forehead support dial to Position 24, where the forehead support is fully extended (Fig. B-1).

- 2 Hold the mask steadily on your face (Fig. B-2) and pull the headgear over your head.
- 3 Bringing the lower straps below your ears, clip the headgear to the lower part of the mask frame (Fig. B-3).
- 4 Unfasten the Velcro[®], pull the upper headgear straps evenly until they are comfortable and firm, and reattach the Velcro (Fig. B-4).
- 5 Repeat step 4 with the lower headgear straps (Fig. B-5).
- 6 Test the functioning of the valve by sealing the swivel with your hand and ensuring that you can still breathe freely.
- 7 Connect the main air tubing to the swivel (Fig. B-6). Then connect the free end of the air tubing to your flow generator and turn the flow generator on.
- 8 Lie down in your sleeping position. Twist the forehead support dial (Fig. B-7) until you feel that the mask is evenly positioned on your face. It should be comfortable, with a satisfactory seal. Gently tighten the lower headgear straps if necessary.
- 9 The fitted mask is shown in Fig. B-8.

Optimizing 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 mask cushion creased? Creases can allow air to leak out of the mask.
- Have you cleaned your mask cushion recently? Oils on the cushion can affect the seal.
- Are your headgear straps overtightened? Try not to alter the upper headgear straps once they have been tightened by your clinician.
- You may need to slightly adjust the dial. Note the dial setting when comfortable.
- Does the mask seem too close to your eyes? You may need a smaller mask.

If you cannot resolve any problems, look at the Troubleshooting section, or talk to your clinician. You may require another mask size.

Removing the Mask

To remove the Mirage Quattro, disconnect one of the lower headgear clips and pull the mask and headgear up over your head.

Disassembling the Mask

See section C on the illustrations sheet.

- 1 Detach the air tubing.

- 2 Unclip the lower headgear clips (Fig. C-1) and unhook the upper headgear straps (Fig. C-2). It is not necessary to remove the headgear clips from the headgear.
- 3 Remove the elbow assembly from the mask frame (Fig. C-3). It's easier to pivot the bottom of the elbow away from the mask frame than to pull the elbow straight off.
- 4 Remove the valve clip from the elbow (Fig. C-4).
- 5 Peel the valve away from the valve clip (Fig. C-5). Do not pull on the membrane to remove the valve.
- 6 Detach the swivel from the elbow (Fig. C-6).
- 7 Note the position on the dial for the next time you use the mask.
- 8 Fully unscrew and remove the dial then pull the forehead support out of the mask frame (Fig. C-7).
- 9 Remove the forehead support pads from the forehead support (Fig. C-8).
- 10 Squeeze and push the upper side tabs on the cushion clip out of the mask frame. Pivot away from the mask, and gently pull out (Fig. C-9).
- 11 Separate the cushion from the cushion clip (Fig. C-10).
- 12 Remove the ports cap from the mask frame (Fig. C-11).

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.*



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 optimize the mask seal, facial oils should be removed from the cushion before use.

Handwash the mask by gently rubbing in warm (86°F / 30°C) water using mild soap or diluted dishwashing detergent.

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. Do not soak the mask.

Weekly

Handwash the headgear in warm (approx. 86°F/30°C) water using mild soap or diluted dishwashing detergent. Rinse well and allow it to air dry out of direct sunlight.

Cleaning the Mask between Patients

All mask components can be disinfected/sterilized using validated procedures. The following table presents a summary of the validated procedures for disinfection/sterilization of the system. Refer to the website www.resmed.com/masks/sterilization/americas for details.

Methods	Pre-disinfection/sterilization	Disinfection/Sterilization
Chemical	<i>Detergent</i>	<i>Solution</i> Ortho-phthalaldehyde 0.55% (eg, CIDEX™ OPA)
Thermal	<i>Detergent</i>	<i>Temperature-time (any one)</i> <ul style="list-style-type: none"> • 158°F (70°C) for 100 minutes • 167°F (75°C) for 30 minutes • 176°F (80°C) for 10 minutes • 194°F (90°C) for 1 minute
STERRAD™	<i>Detergent</i>	<i>System</i> STERRAD 100S and NX Sterilization Systems
<p>Notes:</p> <ul style="list-style-type: none"> • Testing by ResMed has shown that the components can withstand 20 cycles of disinfection/sterilization for the methods listed in the table. • When using detergents, disinfectants or sterilization agents, always follow the manufacturer's instructions. 		

To clean the headgear between patients use the method described in "Cleaning the Mask in the Home".

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.

Elbow Reassembly

- 1 Insert the valve into the valve clip (Fig. D-1).
- 2 Push the valve clip onto the elbow (Fig. D-2). Make sure both sides click into place (Fig. D-3).
- 3 Insert the swivel into the end of the elbow (Fig. D-4).

4 Insert the assembled elbow (Fig. D-5) into the mask frame.

Mask Reassembly

- 1 Fit the cushion clip into the grooved edge of the mask cushion. Fit the top section first, then work your way around, pushing the clip into the cushion (Fig. D-6). Ensure that the cushion is not twisted or distorted around the clip.
- 2 Align the cushion clip with the mask frame. Push the cushion clip into the mask frame, ensuring that all three clips click into place (Fig. D-7).
- 3 Push the forehead pads firmly into the forehead support (Fig. D-8).
- 4 Insert the forehead support into the mask frame and screw the dial clockwise onto the pole (Fig. D-9). Turn the dial until it clicks (Fig. D-10). Ensure the dial sits flush against the frame.
- 5 Insert the ports cap (Fig. D-11).
- 6 Reattach the top headgear by threading it through the loop (Fig. D-12).
- 7 Turn the dial until you reach the setting that gives you good comfort and seal (Fig. D-13).

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

Troubleshooting

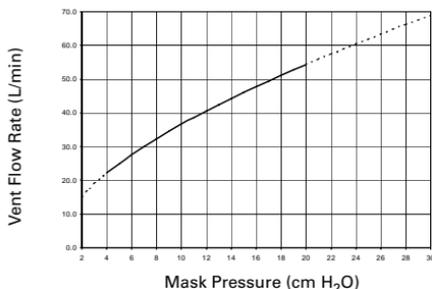
Problem	Possible reason	Possible solution
Mask won't seal properly or is uncomfortable	Mask cushion may be dirty.	Clean cushion according to instructions in "Cleaning the Mask in the Home".
	Mask may have been fitted incorrectly or is incorrectly adjusted.	Carefully follow instructions in "Fitting the Mask". Check headgear and dial are not over-tightened. Extend dial to apply more force to chin. Contract dial to increase force at nose bridge.
	Mask cushion is skewed in cushion clip.	Check insertion of cushion and reinsert correctly.
	Mask 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 is wrong size.	Talk to your clinician.

Problem	Possible reason	Possible solution
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 fully clipped in.	Check insertion of cushion.
	Mask is assembled incorrectly.	Reassemble mask.
	Valve is torn or distorted and is not sealing.	Replace valve.
Dial inserted into mask frame before forehead support	Misassembly.	Push dial base onto a hard surface until the dial comes out of the frame.

Technical Specifications

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

Pressure-Flow Curve



Pressure (cm H ₂ O)	Flow (± 6.0 L/min)
4	22
8	32
12	41
16	48
20	54

Note: As a result of manufacturing variations, the vent flow rate may vary.

Dead Space Information

Dead space: the empty volume of the mask up to the swivel.

The dead space of the mask varies according to cushion size. It is 242 mL for the large size.

Standards

CE designation in accordance with EC directive 93/42/EEC, class IIa.

ISO 14971, ISO 13485, ISO 10993-1 and ISO 17510-2.

Therapy Pressure

4 to 20 cm H₂O

Resistance

Drop in pressure measured (nominal)

at 50 L/min: 0.5 cm H₂O

at 100 L/min: 1.6 cm H₂O

Mask sizes

(Mask fully assembled with elbow assembly – no headgear)

size	height (mm)	width (mm)	depth (mm)
extra small	176	109	108
small	186	109	108
medium	196	109	108
large	206	109	108

Note: The manufacturer reserves the right to change these specifications without notice.

Symbols

System and Packaging



Caution, consult accompanying documents.



Lot number



Part number



No latex



95 Humidity limitation



Temperature 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.

Ordering Information

Part Number Item

Complete System

61200	Mirage Quattro Mask, <i>Extra Small</i>
61201	Mirage Quattro Mask, <i>Small</i>
61202	Mirage Quattro Mask, <i>Medium</i>
61203	Mirage Quattro Mask, <i>Large</i>

Replacement Parts

61260	Mask frame system (no headgear), <i>Extra Small</i> (1 pk)
61261	Mask frame system (no headgear), <i>Small</i> (1 pk)
61262	Mask frame system (no headgear), <i>Medium</i> (1 pk)
61263	Mask frame system (no headgear), <i>Large</i> (1 pk)
61264	Mask frame assembly (no headgear, no cushion), <i>Extra Small</i> (1 pk)
61265	Mask frame assembly (no headgear, no cushion), <i>Small</i> (1 pk)
61266	Mask frame assembly (no headgear, no cushion), <i>Medium</i> (1 pk)
61267	Mask frame assembly (no headgear, no cushion), <i>Large</i> (1 pk)
61270	Mask frame, <i>Extra Small</i> (1 pk)
61271	Mask frame, <i>Small</i> (1 pk)
61272	Mask frame, <i>Medium</i> (1 pk)
61273	Mask frame, <i>Large</i> (1 pk)
61274	Cushion clip, <i>Extra Small</i> (1 pk)
61275	Cushion clip, <i>Small</i> (1 pk)
61276	Cushion clip, <i>Medium</i> (1 pk)
61277	Cushion clip, <i>Large</i> (1 pk)
61282	Elbow (1 pk)
61286	Valve (AAV) + clip (1 pk)
61287	Valve (AAV) + clip (10 pk)
61288	Forehead support (1 pk)
61289	Dial (1 pk)
61290	Cushion + clip, <i>Extra Small</i> (1 pk)
61291	Cushion + clip, <i>Small</i> (1 pk)
61292	Cushion + clip, <i>Medium</i> (1 pk)
61293	Cushion + clip, <i>Large</i> (1 pk)
61294	Elbow assembly (elbow, valve, clip and swivel) (1 pk)
61295	Ports cap (2 pk)
61296	Ports cap (10 pk)
16565	Swivel (1 pk)
16118	Headgear, <i>Small</i> (1 pk)

Part Number	Item
16117	Headgear, <i>Standard</i> (1 pk)
16119	Headgear, <i>Large</i> (1 pk)
60115	Headgear clip (2 pk)
60116	Headgear clip, (10 pk)
60123	Forehead support pad (1 pk)
60124	Forehead support pad (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.