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Ultra Mirage™ Full Face Mask User Guide

English

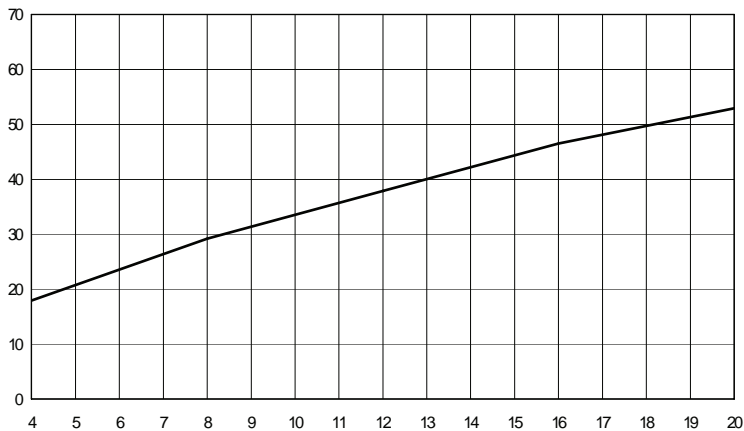


ILLUSTRATIONS SHEET / FICHE D'ILLUSTRATIONS / HOJA DE FIGURAS / FOLHETO DE ILUSTRAÇÕES

Note: For complete instructions, read the text section in conjunction with the illustrations on this sheet. / Remarque : pour les instructions complètes, veuillez vous référer au texte et aux illustrations de cette fiche. / Nota: Para instrucciones detalladas, sírvase leer el texto en conjunto con las ilustraciones de esta hoja. / Nota: Para obter informações completas, leia a secção de texto juntamente com as ilustrações que se encontram neste folheto.

A
Vent flow rate / Débit à l'orifice de ventilation /
Caudal de flujo por la ventilación / Taxa de fluxo de
ventilação (L/min)

Pressure-Flow Curve / Courbe Pression-Débit / Curva de Presión-Flujo / Curva de Pressão-Fluxo

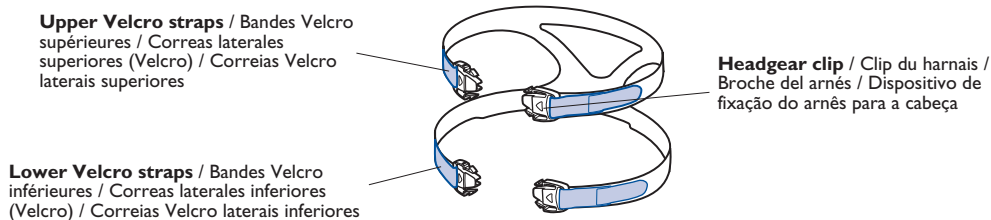
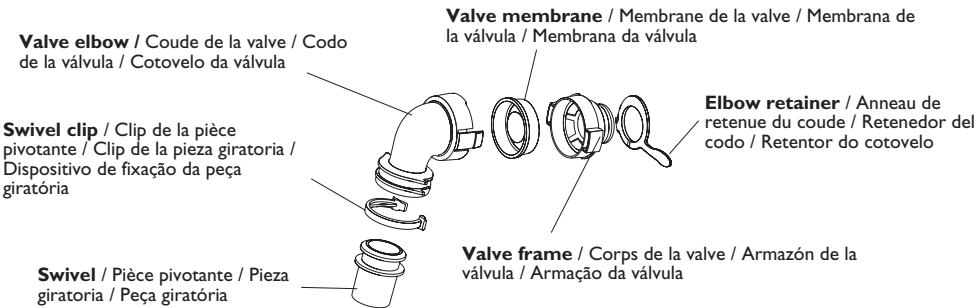
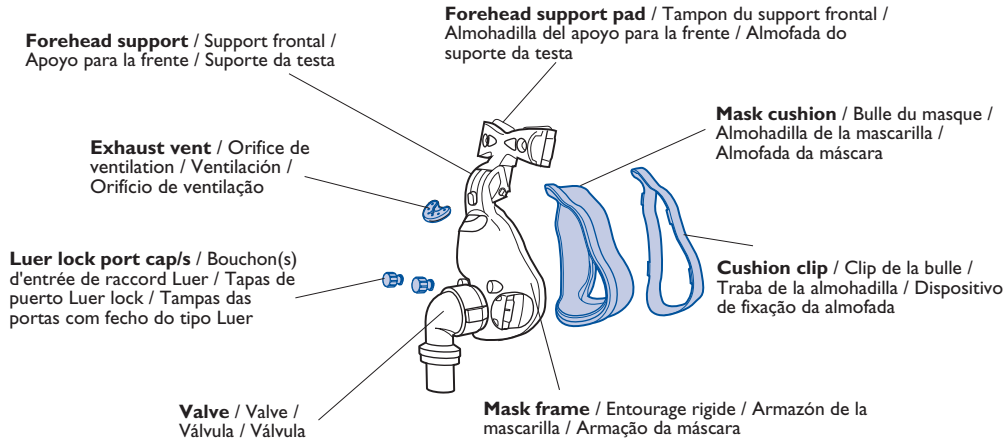


Mask Pressure / Pression dans le masque / Presión en la mascarilla / Pressão na máscara (cm H₂O)

Note: As a result of manufacturing variations, the vent flow may vary from the values listed in the following table. / Remarque : en raison des variations de fabrication, le débit aux orifices de ventilation peut différer des valeurs indiquées dans le tableau suivant. / Nota: Como resultado de variaciones en la fabricación, el flujo de ventilación podrá variar en relación con los valores listados en la siguiente tabla. / Nota: Como resultado de variações de fabrico, o fluxo de ventilação poderá variar em relação aos valores listados no quadro seguinte.

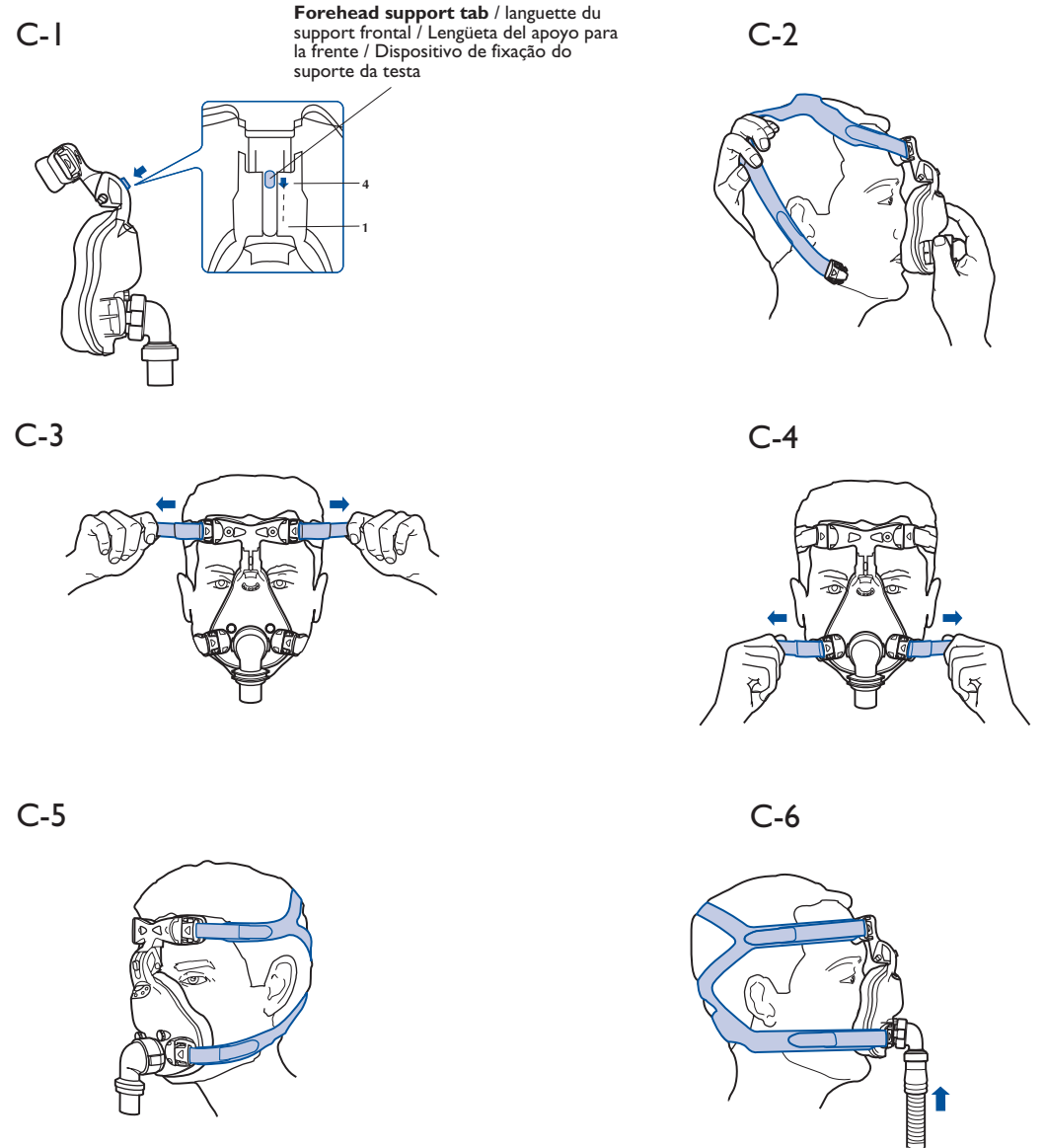
Pressure / Pression / Presión / Pressão (cm H ₂ O)	Flow / Débit / Flujo / Fluxo (L/min)
4	22
8	32
12	41
16	48
20	54

B Mask Parts / Composants du masque / Piezas de la mascarilla / Componentes da máscara



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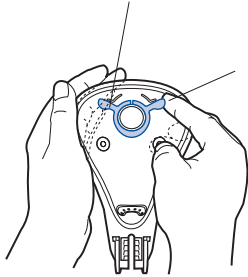
C Fitting the Mask / Mise en place du masque / Colocación de la mascarilla / Colocação da máscara



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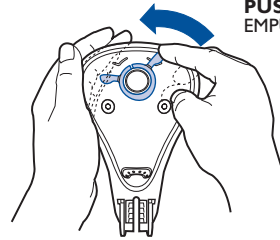
D Disassembling for Cleaning / Démontage pour le nettoyage / Desmontaje para la limpieza / Desmontagem para limpeza

D-1 **L-shaped ridge** / Bord en L / Borde en forma de L / Saliência em forma de L



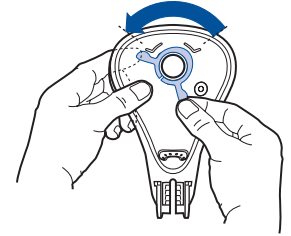
LIFT / SOULEVER / LEVANTE / LEVANTE

D-2

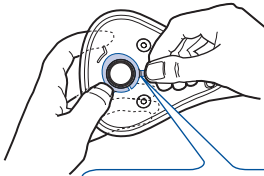


PUSH / POUSSER / EMPUJE / EMPURRE

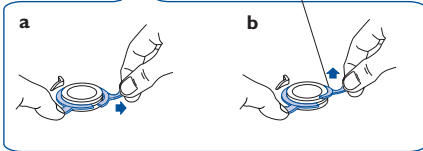
D-3



D-4

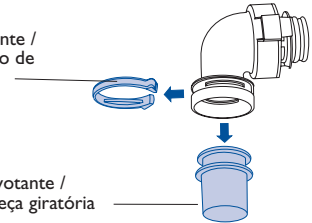


Elbow retainer / Anneau de retenue du coude / Retenedor del codo / Retentor do cotovelo



D-5

Swivel clip / Clip de la pièce pivotante / Clip de la pieza giratoria / Dispositivo de fixação da peça giratória

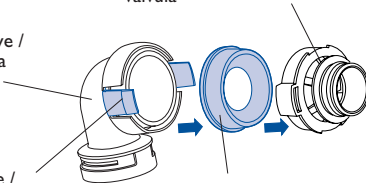


Swivel / Pièce pivotante / Pieza giratoria / Peça giratória

D-6

Valve elbow / Coude de la valve / Codo de la válvula / Cotovelo da válvula

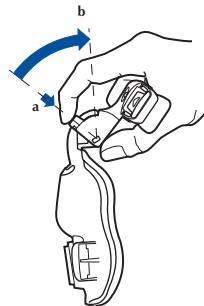
Valve frame / Corps de la valve / Armazón de la válvula / Armação da válvula



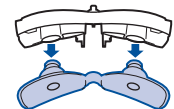
Tab / Patte d'attache / Lengüeta / Lingueta

Valve membrane / Membrane de la valve / Membrana de la válvula / Membrana da válvula

D-7

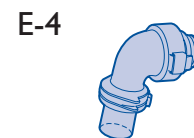
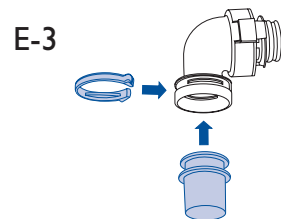
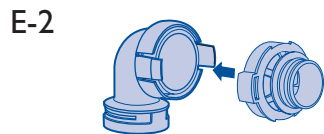
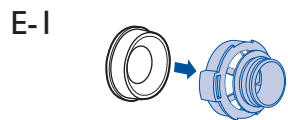


D-8

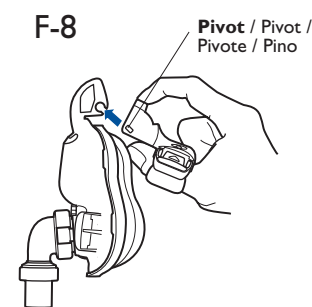
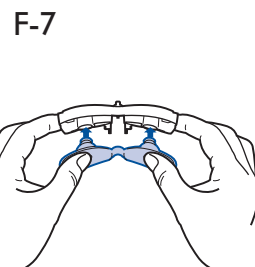
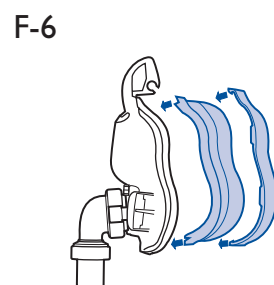
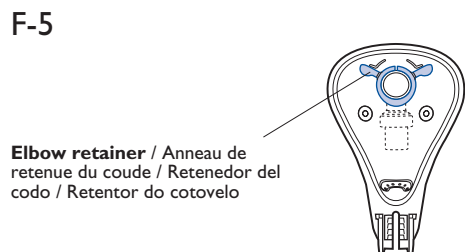
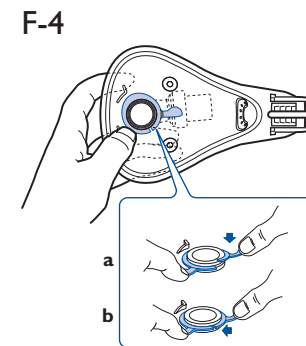
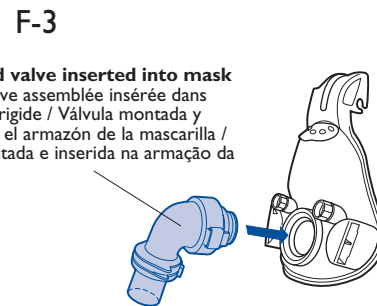
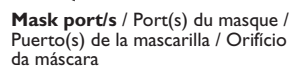
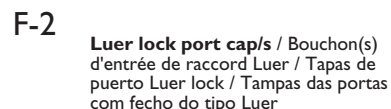
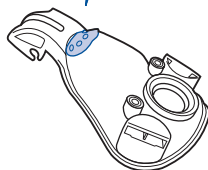
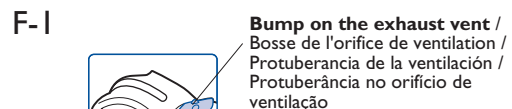


Reassembling the Mask / Remontage du masque / Montaje de la mascarilla / Montagem da máscara

E Valve Reassembly / Réassemblage de la valve / Montaje de la válvula / Montagem da válvula



F Mask Reassembly / Remontage du masque / Montaje de la mascarilla / Montagem da máscara



Ultra Mirage™ Full Face Mask

Thank you for choosing ResMed's
ULTRA MIRAGE™ FULL FACE MASK.

This is a full face mask which covers both the nose and the mouth. Thus, you can receive effective therapy even in the presence of mouth breathing and leak.

This user's guide provides you with the information you need for the correct use of your mask.

INTENDED USE

The **ULTRA MIRAGE FULL FACE MASK** is intended for multipatient use for adult patients (>30 kg) prescribed continuous positive airway pressure (CPAP) or bilevel therapy in hospital, clinic and/or home environments.

CAUTION

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

MEDICAL INFORMATION

Note: *The mask system does not contain latex materials. If you have ANY reaction to any part of the mask system, discontinue use and consult your sleep therapist.*

CONTRAINDICATION

The **ULTRA MIRAGE FULL FACE MASK**, must be used under qualified supervision for patients who are unable to remove the mask by themselves.

WARNINGS AND CAUTIONS

- This mask should be used only with flow generators (CPAP or bilevel) recommended by your physician or respiratory therapist. A mask should not be used unless the flow generator is turned on and operating properly. The exhaust vent should never be blocked.

Explanation of the Warning: Flow generators are intended to be used with special masks with connectors which have vent holes or separate exhaust vents to allow continuous flow of air out of the mask. When the flow generator is turned on and functioning properly, new air from the flow generator flushes the exhaled air out through the attached mask exhaust vent. However, when the flow generator is not operating, enough fresh air will not be provided through the mask, and exhaled air may 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 flow generators.

- The exhaust vent flow is lower at lower mask pressures (see Pressure/Flow Curve— section **A**). If the mask pressure during expiration is too low, there may not be enough exhaust vent flow to completely flush the air delivery hose of exhaled air before the start of the next inspiration.
- The mask should not be worn if the anti-asphyxia valve membrane is damaged or missing. If the valve membrane is damaged, distorted or torn, it should be replaced with a new valve membrane.
- The mask may not be suitable for those at increased risk of gastric regurgitation.
- The mask must be cleaned and disinfected/sterilized if it is used between patients. Refer to the section “Cleaning the Mask between Patients” for details.
- If oxygen is used with the flow generator, the oxygen flow must be turned off when the flow generator is not operating.

Explanation of the Warning: When the flow generator is not in operation and the oxygen flow is left on, oxygen delivered into the air delivery tubing may accumulate within the flow generator enclosure and create a risk of fire. This applies to most types of flow generators.

- Oxygen supports combustion. Oxygen should not be used while you are smoking or in the presence of an open flame.
- Always ensure airflow is being generated by the device before the oxygen supply is turned on.

- Always turn the oxygen supply off before stopping the airflow from the device.
- Please refrain from smoking while oxygen is in use.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

Note: *At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate.*

PARTS OF THE MASK

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

FITTING THE MASK

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

Note: *Before fitting the mask, refer to the section on “Cleaning the Mask in the Home”.*

The **ULTRA MIRAGE FULL FACE MASK** is supplied fully assembled.

- 1 Move the forehead support tab to Position 4 (**Fig. C-1**). Position 4 is the uppermost tab position.
- 2 Disconnect one lower headgear clip. Place the mask on the face and pull the headgear over your head (**Fig. C-2**). Ensure that the upper straps pass across your forehead and the lower straps below your ears.
- 3 Reattach the headgear clip to the mask frame.
- 4 Gently tighten the upper headgear straps (**Fig. C-3**).
- 5 Gently tighten the lower headgear straps (**Fig. C-4**).

The pads of the forehead support should lightly touch your forehead when the mask is in place. If the pads do not

touch your forehead, you may need to change the position of the forehead support tab as described in step 8.

- 6 The fitted mask should look like this (Fig. C-5).
- 7 Connect the main air tubing to the swivel (Fig. C-6). Then connect the free end of the air tubing to your flow generator and turn the flow generator on. If you feel air leaks around the cushion, you may need to gently tighten the headgear straps.

Note: Do not overtighten the headgear straps as this may cause discomfort, cushion creases, and mask leak.

- 8 If you are unable to get a proper seal through gently tightening the headgear, you will need to change the position of the forehead support tab. Loosen the headgear straps and move the forehead support tab to the next position (e.g., from Position 4 move it downwards to Position 3). Gently tighten the upper headgear straps and then the lower headgear straps.

Take time to test all four positions of the forehead support tab and to adjust the headgear straps so that you can achieve a secure and comfortable fit.

Notes:

- If you are unable to resolve any leaks you may require another mask frame and/or another cushion size.
- Select “Mir Full” as the mask option when using the ULTRA MIRAGE FULL FACE MASK with ResMed flow generators that have mask setting options.

REMOVING THE MASK

To remove the ULTRA MIRAGE FULL FACE MASK, disconnect one of the lower headgear clips and pull the mask and headgear up over your head.

Note: The headgear clips are easy to locate and disconnect. They allow you to quickly remove the mask from your face in the event of an emergency.

DISASSEMBLING FOR CLEANING

See section D on the illustrations sheet.

- 1 Detach the mask from the air tubing.
- 2 Disconnect the headgear clips to release them from the mask frame. It is not necessary to remove the headgear clips from the headgear.
- 3 Remove the exhaust vent and port caps from the mask frame.
- 4 Detach the cushion assembly from the mask frame by depressing the cushion clip at the base of the mask frame and gently pulling it off. This releases the cushion and cushion clip. Then, separate the cushion from the cushion clip.
- 5 To detach the elbow from the frame, lift (Fig. D-1) and push (Fig. D-2) the right wing of the elbow retainer over the right L-shaped ridge on the mask frame.
- 6 Rotate the elbow retainer to the position shown in Figure D-3. The elbow retainer is now in the correct position for removal.
- 7 To remove the elbow retainer, hold one wing of the elbow retainer down, and firmly pull the other wing out (Fig. D-4a) and then up (Fig. D-4b) over the top of the valve. Remove the elbow retainer and valve from the mask frame.

- 8 To remove the swivel, lift the swivel clip and slide it out (Fig. D-5).
- 9 Squeeze the tabs of the valve elbow to remove the valve frame from the valve elbow. Then, carefully remove the valve membrane from the valve frame (Fig. D-6).
- 10 To remove the forehead support from the mask, press the tab (Fig. D-7a) and move it upwards until you can slide it off the mask frame (Fig. D-7b).
- 11 Pull firmly at the base of the forehead support pad plugs to release the pads from the forehead support (Fig D-8).

CLEANING THE MASK IN THE HOME

Notes:

- Wash the headgear before first time use, as the dye may run. It is important to always handwash the headgear.
- The headgear may be washed without being disassembled.

DAILY/AFTER EACH USE

Handwash the mask components in lukewarm, soapy water. Use pure soap (an example of pure soap is Dove® soap, unscented; made by Unilever). Rinse the components well and allow them to air dry out of direct sunlight.

To clean the valve membrane, immerse it in soapy water and gently rub the membrane to remove any foreign matter. Rinse the membrane and allow it to air dry out of direct sunlight.

Inspect the valve membrane for wear and deterioration. If the valve membrane is damaged, distorted, or torn, replace it with a new valve membrane. Ensure that the membrane is clean and dry before re-inserting it into the valve.

WEEKLY

Handwash the headgear in warm, soapy water. Use pure soap. Rinse well and allow it to air dry out of direct sunlight.



CAUTION

- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps, or scented oils to clean any of the mask components. These solutions may cause damage and reduce the life of the product.
- Do not expose any part of the mask system or tubing to direct sunlight as it may cause the product to deteriorate.
- If any visible deterioration of a mask component is apparent (cracking, crazing, tears, etc), the mask component should be discarded and replaced.

REPROCESSING THE MASK BETWEEN PATIENTS

The mask should be reprocessed when used between patients. Cleaning, disinfection and sterilization instructions are available from the ResMed website, www.resmed.com/masks/sterilization/americas.

If you do not have Internet access, please contact your ResMed representative.



CAUTION

The valve membrane must be replaced with a new valve membrane when the mask is reused on another patient. This part cannot be disinfected or sterilized.

REASSEMBLING THE MASK

ATTENTION

It is important to follow the instructions detailed in this section. Any deviation from the specified order of assembly could affect the functioning of your mask.

Reassembling the entire mask involves two stages:

1. Valve Reassembly
2. Mask Reassembly

VALVE REASSEMBLY

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

Note: *This stage must be completed before Mask Reassembly.*

Make sure all parts of the mask system, especially the valve membrane, are clean and dry before reassembling. If the valve membrane is damaged, distorted or torn, replace it with a new valve membrane.

- 1 Insert the valve membrane into the valve frame and gently push it into place (**Fig. E-1**). Make sure it is seated evenly and flatly around the rim of the valve frame, as the membrane may produce a noise while you are breathing out, if it is fitted incorrectly.
- 2 Push the valve frame over the tabs of the valve elbow until they lock together (**Fig. E-2**). Make sure the valve frame and valve elbow are securely connected to each other.
- 3 Insert the swivel into the end of the valve elbow and secure it with the swivel clip (**Fig. E-3**).
- 4 Set the assembled valve (**Fig. E-4**) aside for use in the following stage.

MASK REASSEMBLY

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

- 1 Check that the holes in the exhaust vent are not obstructed. If they are obstructed, replace the exhaust vent. Push the exhaust vent onto the mask frame so the small round bump on the exhaust vent is on the outside of the mask frame (**Fig. F-1**).

CAUTION

The exhaust vent must be correctly inserted into the mask frame to prevent leakage. Poor sealing may reduce pressure and affect therapy.

- 2 Twist the luer lock port caps onto the mask ports (**Fig. F-2**).
- 3 Insert the assembled valve into the mask frame (**Fig. F-3**).

Note: *The valve must be assembled (as depicted in Figure E-4), before it is inserted into the mask frame.*

- 4 Hold the mask frame and the inserted valve firmly together.
- 5 To attach the elbow retainer, fit one side of the elbow retainer against the groove of the valve. While holding one wing of the elbow retainer down (**Fig. F-4a**), press the other wing down until the elbow retainer clicks into place (**Fig. F-4b**).
- 6 Rotate the elbow retainer to its original position (**Fig. F-5**).
- 7 Check that you have fitted the valve and elbow retainer correctly by firmly pulling the valve away from the frame. If the valve is fitted correctly, it should not separate from the frame.

If the valve comes away from the frame, try refitting the elbow retainer as described in Steps 4 and 5. If the valve

still comes away from the frame when you pull on it, you may need to replace the elbow retainer with a new one.

- 8** Fit the grooved edge of the mask cushion to the mask frame. Fit the top section first, then work your way around the mask, pushing the cushion onto the frame, ensuring a good seal has been achieved.

Then push the cushion clip over the cushion onto the mask frame, ensuring it clicks into place in all locations (**Fig. F-6**).

- 9** Attach the forehead pads to the forehead support by inserting the pad plugs into the two holes on the back of the forehead support (**Fig F-7**). Push the pads firmly against the forehead support to ensure that the pads fit securely into the forehead support.

- 10** Connect the forehead support to the mask frame. Slide the pivots into the pivot slot on the mask frame (**Fig. F-8**). Depress the forehead support tab and move it into any of the tab positions.

- 11** Insert the headgear clips into the slots on the mask frame. The headgear label should face outwards and be near your neck when fitted.

TECHNICAL SPECIFICATIONS

PRESSURE–FLOW CURVE

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

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 258 mL.

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

REPLACEMENT PARTS

Part No.	Item
16613	Anti-asphyxia valve (1 pk.)
16604	Cushion, <i>Small, Standard</i> (1 pk.)
16671	Cushion, <i>Small, Shallow</i> (1 pk.)
16605	Cushion, <i>Medium, Standard</i> (1 pk.)
16672	Cushion, <i>Medium, Shallow</i> (1 pk.)
16606	Cushion, <i>Large, Standard</i> (1 pk.)
16673	Cushion, <i>Large, Shallow</i> (1 pk.)
16674	Cushion clip, <i>Small</i> (1 pk.)
16675	Cushion clip, <i>Medium</i> (1 pk.)
16676	Cushion clip, <i>Large</i> (1 pk.)
60683	Elbow retainer (1 pk.)
16509	Exhaust vent (1 pk.)
16510	Exhaust vent (10 pk.)
60681	Luer lock port caps (2 pk.)
60682	Luer lock port caps (10 pk.)
16689	Swivel (1 pk.)
60680	Swivel clip (1 pk.)
16637	Swivel clip (5 pk.) and Elbow clip (5 pk.)
16624	Valve elbow (1 pk.)
16617	Valve membrane (1 pk.)
16618	Valve membrane (10 pk.)
60115	Headgear clip (2 pk.)
60116	Headgear clip (10 pk.)
60123	Forehead pad (1 pk.)
60124	Forehead pad (10 pk.)
60670	Mask Frame, <i>Small</i> (1 pk.)
60671	Mask Frame, <i>Medium</i> (1 pk.)
60672	Mask Frame, <i>Large</i> (1 pk.)
60673	Forehead Support (1 pk.)
60674	Headgear (1 pk.)
60620	Frame System with cushion, (excluding headgear) <i>Small, Standard</i>

Part No.	Item
60621	Frame System with cushion, (excluding headgear) <i>Small, Shallow</i>
60622	Frame System with cushion, (excluding headgear) <i>Medium, Standard</i>
60623	Frame System with cushion, (excluding headgear) <i>Medium, Shallow</i>
60624	Frame System with cushion, (excluding headgear) <i>Large, Standard</i>
60625	Frame System with cushion, (excluding headgear) <i>Large, Shallow</i>

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.



Manufacturer:

ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia

Distributed by:

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ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK

See www.resmed.com for other ResMed locations worldwide.



For patent information, see www.resmed.com/ip.

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

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ULTRA MIRAGE FULL FACE MASK

User

AMER - ENG