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Mirage™ SoftGel

NASAL MASK

User Guide

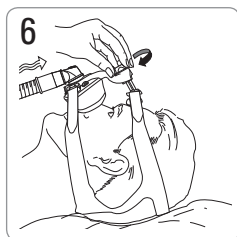
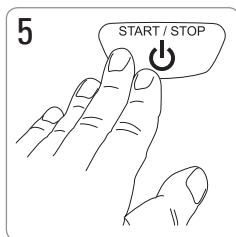
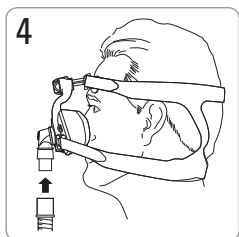
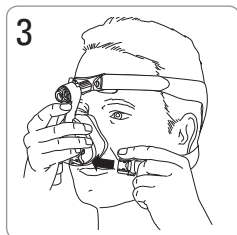
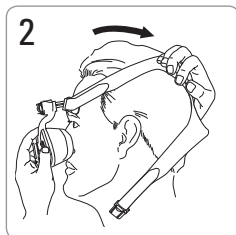
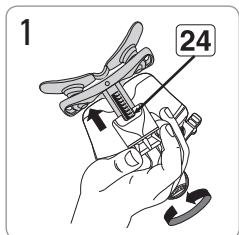
English



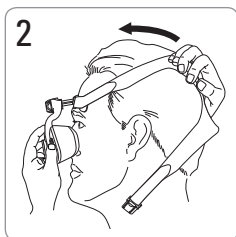
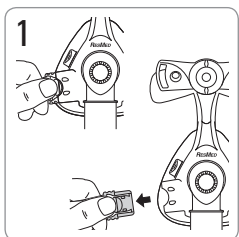
Mirage™ SoftGel

Rx Only /
Sur prescription uniquement /
Solamente bajo prescripción /
Somente com prescrição médica

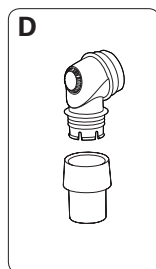
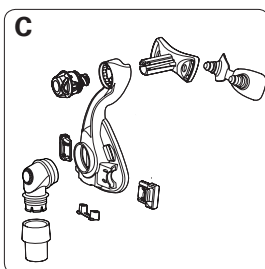
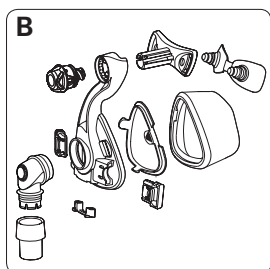
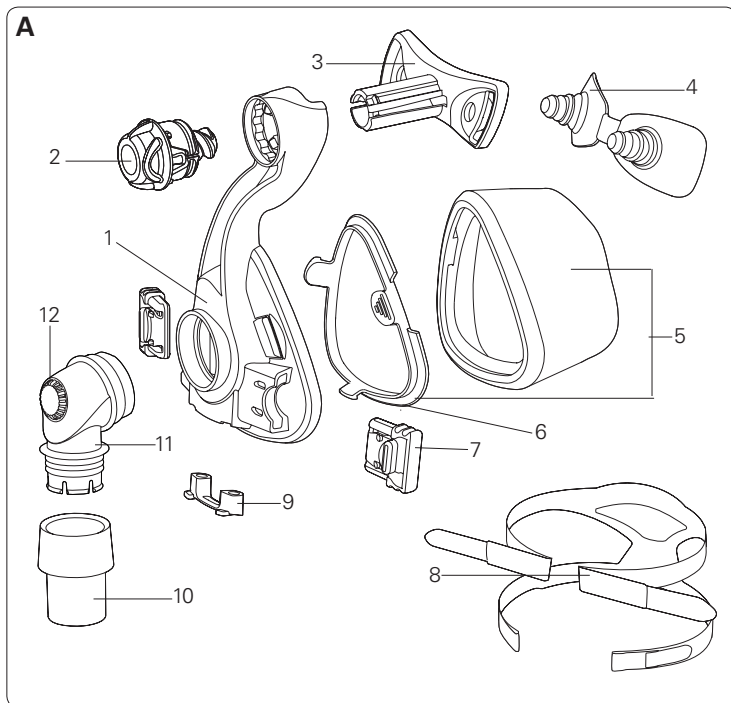
Fitting / Mise en place / Colocación / Colocação



Removal / Enlèvement du masque / Para quitarse la mascarilla / Remoção



Mirage SoftGel



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

Item / Article / Artículo / Item	Description / Description / Descripción / Descrição	Part number / Code produit / Número de parte / Código do produto:
1	Mask frame / Entourage rigide / Armazón de la mascarilla / Armação da máscara	60180 (St)
2	Dial / Molette de réglage / Disco / Botão giratório	61289
3	Forehead support / Support frontal / Apoyo para la frente / Suporte para a testa	16393
4	Forehead support pad / Tampon frontal / Almohadilla del apoyo para la frente / Almofada do suporte para a testa	60123 (1) 60124 (10)
5	Cushion & clip / Bulle et clip / Almohadilla y broche / Almofada e presilha	61632 (M) 61633 (L)
6	Cushion clip / Clip de la bulle / Broche de la almohadilla / Presilha da almofada	60176 (St)
7	Headgear clip / Clip d'attache du harnais / Broche del arnés / Presilha do arnés	16569 (2) 16734 (10)
8	Headgear / Harnais / Arnés / Arnês	16117 (M)
9	Ports cap / Bouchon d'entrées / Tapón de los puertos / Tampa das portas	16570 (2) 16571 (10)
10	Swivel / Pièce pivotante / Pieza giratoria / Peça giratória	16565
11	Elbow / Coude / Codo / Cotovelo	16387
12	Vent / Orifice de ventilation / Ventilación / Respiradouro	-

Item / Article / Artículo / Item	Description / Description / Descripción / Descrição	Part number / Code produit / Número de parte / Código do produto:
A	Complete system / Système complet / Sistema completo / Sistema completo	61601(M) 61602 (L)
B	Frame system / Entourage complet / Sistema de armazón / Sistema da armação	61627 (M) 61628 (L)
C	Frame assembly / Ensemble entourage / Conjunto del armazón / Conjunto da armação	60175 (St)
D	Elbow assembly / Ensemble coude / Conjunto del codo / Conjunto do cotovelo	16399
Also available / Également disponible / También está disponible / Também disponível		
	Headgear / Harnais / Arnés / Arnês	16118 (S) 16119 (L)

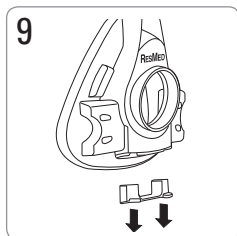
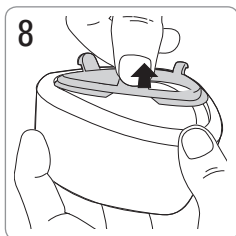
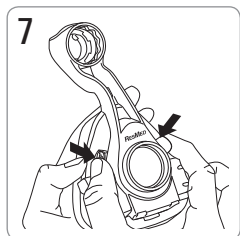
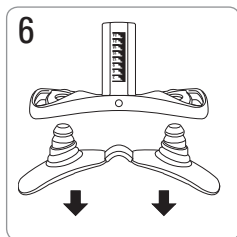
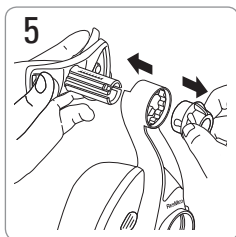
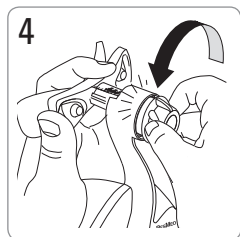
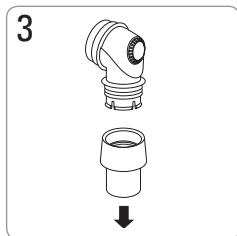
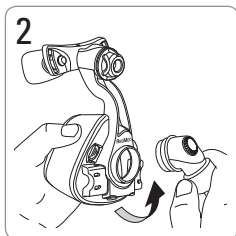
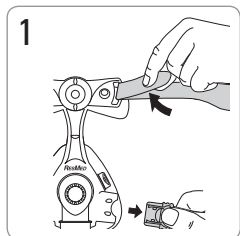
S Small / Petit / Pequeña / Pequeno(a)

M Medium / Moyen / Mediana / Médio(a)

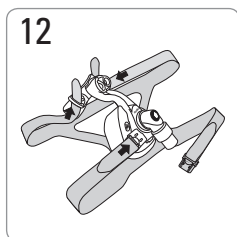
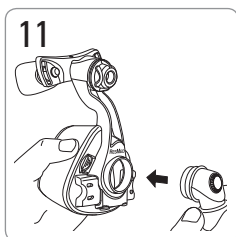
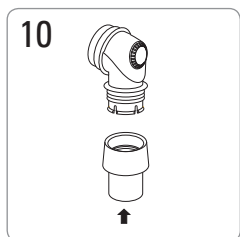
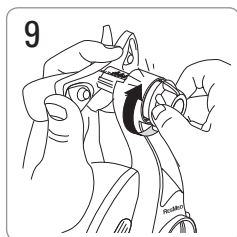
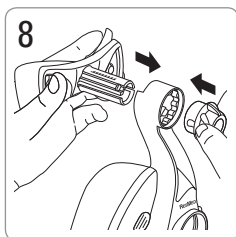
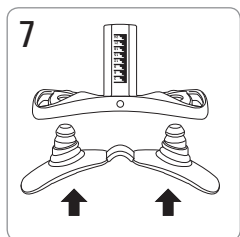
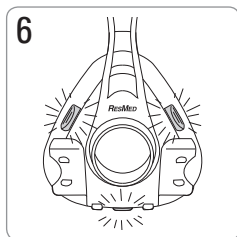
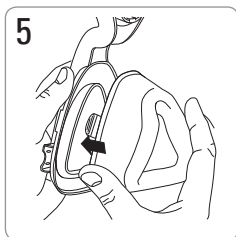
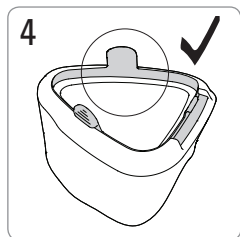
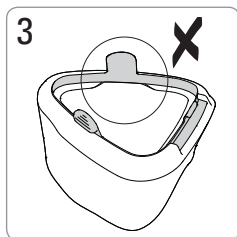
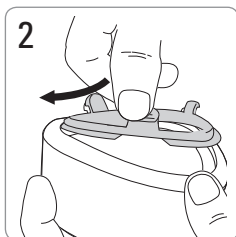
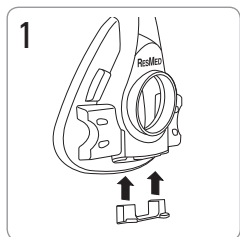
St Standard / Standard / Estándar / Standard

L Large / Grand / Grande / Grande

Disassembly / Démontage / Desmontaje / Desmontagem



Reassembly / Remontage / Montaje / Remontagem



Mirage™ SoftGel

NASAL MASK

Thank you for choosing the Mirage SoftGel.

Intended use

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

The Mirage SoftGel is:

- to be used by adult patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Using your mask

When using your mask with ResMed CPAP or bilevel devices that have mask setting options, refer to the Technical specifications section in this user guide for mask selection options.

For a full list of compatible devices for this mask, see the Mask/Device Compatibility List on www.resmed.com on the **Products** page under **Service & Support**. If you do not have internet access, please contact your ResMed representative.

Note: *If you experience nasal dryness or irritation, use of a humidifier is recommended.*



WARNING

- The vent holes must be kept clear.
- The mask should not be used unless the CPAP or bilevel device is turned on and operating properly.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the CPAP or bilevel device enclosure and create a risk of fire.
- At a fixed 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 that they are compatible with the CPAP or bilevel device. 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 CPAP or bilevel device function.
- Discontinue using this mask if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- Remove all packaging before using the mask.

Cleaning your mask in the home

Your mask and headgear should only be handwashed by gently rubbing in warm (approximately 86°F/30°C) water using mild soap. All components should be rinsed well with drinking quality water and allowed to air dry out of direct sunlight.

Daily/After each use:

- To optimize the mask seal, facial oils should be removed from the cushion after use.
- Handwash the separated mask components (excluding headgear).
- If the vent requires cleaning use a soft bristle brush.

Weekly:

- Handwash the headgear. It may be washed without being disassembled.

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.

CAUTION

- If any visible deterioration of a system component is apparent (cracking, crazing, tears or cushion damage resulting in gel exposure, etc), the component should be discarded and replaced.
- Avoid connecting flexible PVC products (eg, PVC tubing) directly to any part of the mask. Flexible PVC contains elements that can be detrimental to the materials of the mask, and may cause the components to crack or break.

Reprocessing the mask between patients

This 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.

Troubleshooting

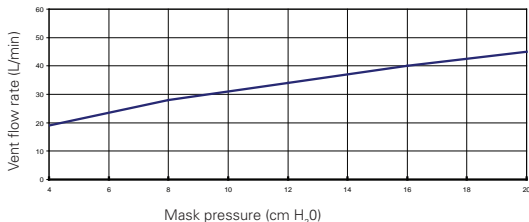
Problem/possible cause	Solution
Mask is uncomfortable	
Headgear straps are too tight.	Adjust straps evenly. The forehead support 'anchors' your mask and should sit firmly on your forehead.
Fit is too tight.	Wind out dial.
Mask is too noisy	
Cushion clip is not inserted correctly.	Remove cushion from frame and reinsert starting at the top. Check that the cushion clip is correctly inserted into the cushion and that the cushion is correctly clipped to the frame. If the problem persists, talk to your clinician.

Problem/possible cause	Solution
Ports cap or elbow incorrectly inserted.	Remove the ports cap or elbow from the mask, then reassemble according to the instructions.
Vent is blocked or partially blocked.	If the vent requires cleaning, use a soft bristle brush.
Mask leaks around the face	
Mask not positioned correctly.	Gently pull the cushion away from the face to reinflate. Reposition your mask according to the instructions.
Cushion clip is not inserted correctly.	Remove cushion from frame and reinsert starting at the top. Check that the cushion clip is correctly inserted into the cushion and that the cushion is correctly clipped to the frame. If the problem persists, talk to your clinician
Air leaking around the bridge of the nose.	Wind the dial in.
Air leaking around the top of the lip.	Wind the dial out and or tighten the bottom straps.
The mask does not fit properly	
Cushion could be the wrong size.	Talk to your clinician.
Mask is incorrectly assembled.	Disassemble the mask, then reassemble according to the instructions.
Cushion may be dirty.	Clean cushion according to the instructions.
Cannot insert forehead support into mask frame	
The dial has been inserted into the frame before the forehead support.	Push the end of the dial onto a hard surface until the dial comes out of the frame. Reassemble according to the instructions.

Technical specifications

Pressure–flow curve

The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.



Pressure (cm H ₂ O)	Flow (L/min)
4	19
8	28
12	34
16	40
20	45

Dead space information

Physical dead space is the empty volume of the mask to the end of the swivel. Using the large cushions it is 145 mL.

Therapy pressure

4 to 20 cm H₂O

Resistance

Drop in pressure measured (nominal)
at 50 L/min: 0.3 cm H₂O
at 100 L/min: 0.9 cm H₂O

Environmental conditions

Operating temperature: +41°F to 104°F (+5°C to +40°C)
Operating humidity: 15% to 95% relative humidity non-condensing
Storage and transport temperature: -4°F to 140°F (-20°C to +60°C)
Storage and transport humidity: up to 95% relative humidity non-condensing

Gross dimensions

Mask fully assembled - no headgear
Large: 6.10" (H) x 3.58" (W) x 4.65" (D)
(155 mm (H) x 91 mm (W) x 118 mm (D))

Mask setting options

Select 'STANDARD' otherwise select 'ACTIVA' as the mask option.

Notes:

- The mask system does not contain latex, PVC or DEHP materials.
- The manufacturer reserves the right to change these specifications without notice.












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

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

Symbols

 Caution, consult accompanying documents;  Lot number;  Part number;  Temperature limitation;  Humidity limitation;  Does not contain latex;  Manufacturer;  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.  Keep away from rain;  This way up;  Fragile, handle with care.

Limited warranty

ResMed Ltd (hereafter 'ResMed') warrants that your ResMed mask system (including mask frame, cushion, headgear and tubing) shall be free from defects in material and workmanship from the date of purchase for the period of 90 days or in the case of disposable masks the maximum use period.

This warranty is only available to the initial consumer. It is not transferable.

If the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components.

This limited warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs; and c) any damage or contamination due to cigarette, pipe, cigar or other smoke.

Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

Manufacturer:

ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia.

Distributed by:

ResMed Corp 9001 Spectrum Center Boulevard San Diego CA 92123 USA.

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

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

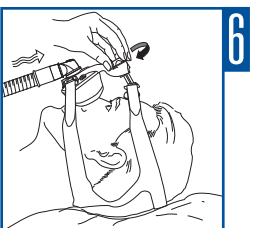
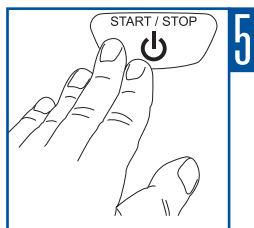
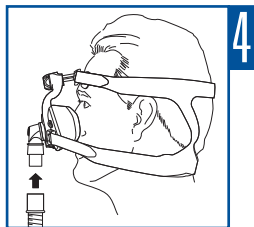
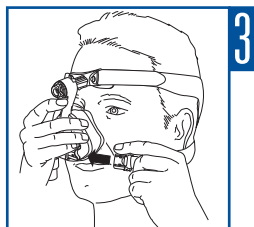
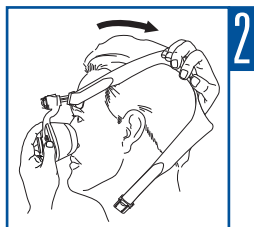
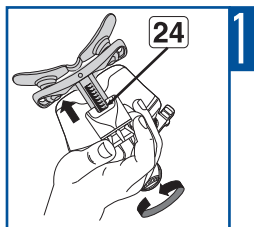
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Protected by patents: AU 741003, AU 766623, AU 775051, AU 777033, AU 785376, DE 20122844.0, EP 1187647, EP 1187649, EP 1187650, EP 1314445, EP 1582230, EP 1621225, EP 1640034, HK 1057714, JP 3686609, NZ 513052, NZ 526165, NZ 526166, NZ 526167, NZ 526168, NZ 542849, NZ 543939, US 6119693, US 6374826, US 6439230, US 6463931, US 6532961, US 6557556, US 6581594, US 6691708, US 6823865, US 6860269, US 6997188, US 7011090, US 7159587, US 7216647, US 7234466, US 7316230. Other patents pending.

Protected by design registrations: AU 156663, AU 156665, AU 321676, DE 40301991.5, FR 031425, FR 031430, JP 1192859, JP 1197930, NZ 411222, US D486227, US D487510, US D493521, US D493522, US D545960, US D567935. Others pending.

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