

RESMED

Mirage™ SoftGel

NASAL MASK

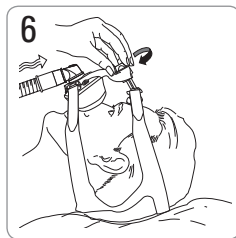
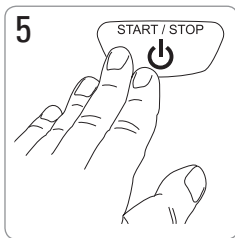
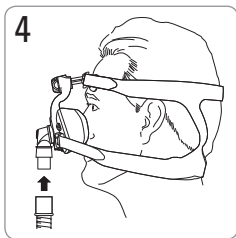
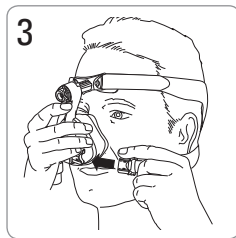
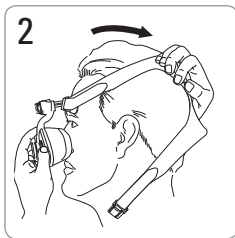
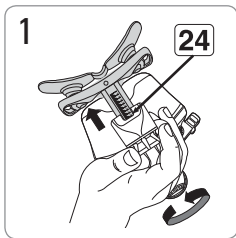
User Guide

English

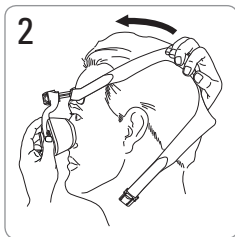
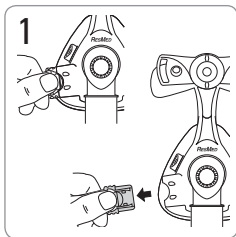


Mirage™ SoftGel

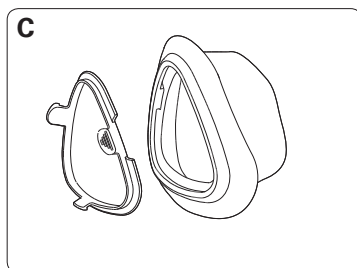
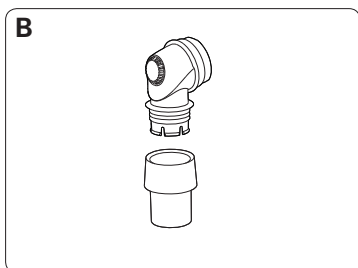
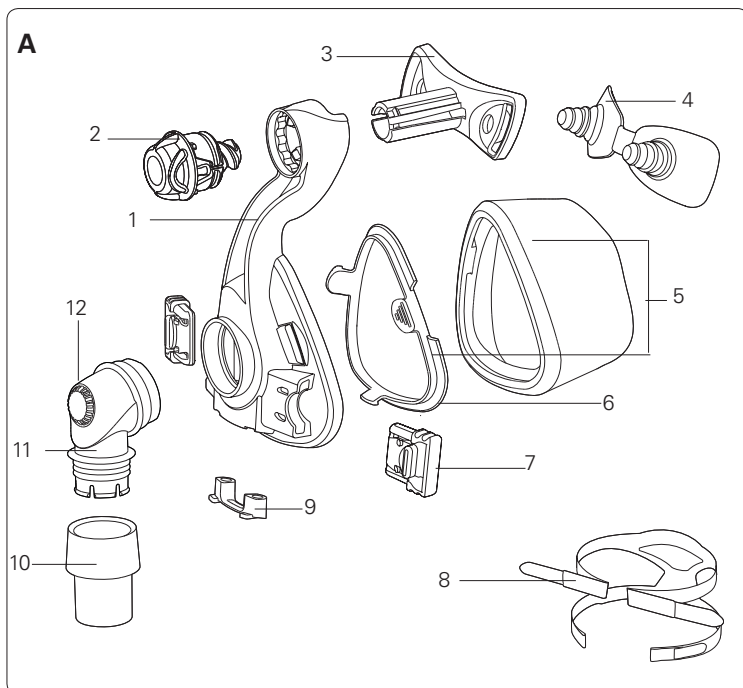
Fitting / Anlegen / Mise en place / Applicazione



Removal / Abnehmen der Maske / Retrait / Rimozione della maschera



Mirage SoftGel



Mask components / Maskenkomponenten / Composants du masque / Componenti della maschera

Item / Artikel / Article / Articolo / Artikel	Description / Beschreibung / Description / Descrizione / Beschrijving	Part number / Artikelnummer / Code produit / Numero parte / Onderdeelnummer
1	Mask frame / Maskenrahmen / Entourage rigide / Telaio della maschera / Maskerframe	60180 (St) 60193 (S)
2	Dial / Drehregler / Molette de réglage / Selettore di regolazione / Draaiknop	61289
3	Forehead support / Stirnstütze / Support frontal / Supporto frontale / Voorhoofdsteun	16393
4	Forehead support pad / Stirnpolster / Tampon frontal / Imbottitura del supporto frontale / Kussentje van voorhoofdsteun	60123 (1) 60124 (10)
5	SoftGel Cushion & clip / Maskenkissen und Clip / Bulle et clip / Cuscinetto e fermaglio / Kussentje en klem	61631 (S) 61632 (M) 61633 (L) 61634 (LV)
6	Cushion clip / Maskenkissen-Clip / Clip de la bulle / Fermaglio del cuscinetto / Klem voor kussentje	60176 (St) 60197 (S)
7	Headgear clip / Kopfband-Clip / Clip d'attache du harnais / Fermaglio del copricapo / Hoofdbandklem	16569 (2) 16734 (10)
8	Headgear / Kopfband / Harnais / Copricapo / Hoofdband	16118 (S) 16117 (M) 16119 (L)
9	Ports cap / Anschlusskappe / Bouchon d'entrées / Coperchio delle prese / Poortkap	16570 (2) 16571 (10)
10	Swivel / Drehadapter / Pièce pivotante / Giunto rotante / Draaibare kop	16565
11	Elbow / Kniestück / Coude / Gomito / Bocht	16387
12	Vent / Luftauslassöffnung / Orifice de ventilation / Foro per l'esalazione / Ventilatieopening	-

A	Complete system / Komplettes System / Masque complet / Maschera con tutti i componenti / Volledig systeem	61605 (S) 61606 (M) 61607 (L) 61608 (LW)
B	Elbow assembly / Kniestück mit Drehadapter / Coude / Complesso del gomito / Complete bocht	16399
Also available / Außerdem erhältlich / Également disponible / Altri prodotti		
C	Acriva LT Cushion & clip / Maskenkissen und Clip / Bulle et clip / Cuscinetto e fermaglio / Kussentje en klem	60198 (S) 60177 (M) 60178 (L) 60179 (LW)

S Small / Small / Petit / Small / Small

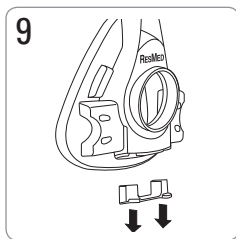
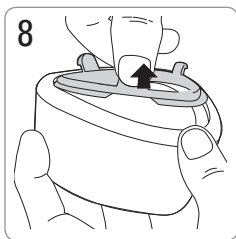
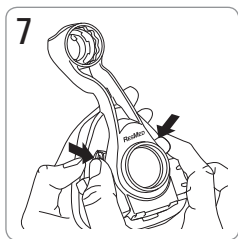
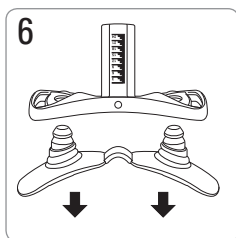
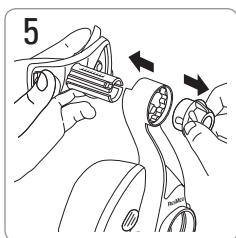
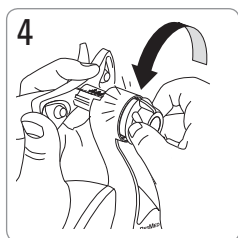
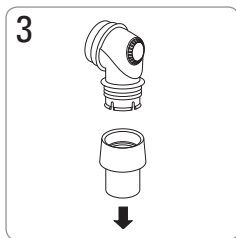
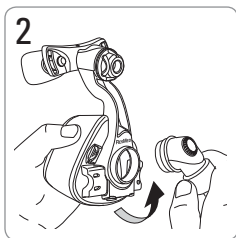
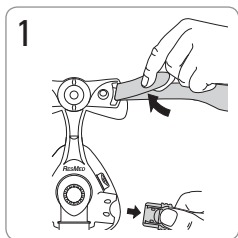
M Medium / Medium / Médium / Medium / Medium

L Large / Large / Grand / Large / Large

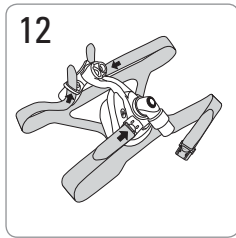
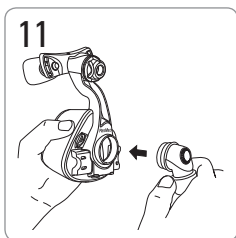
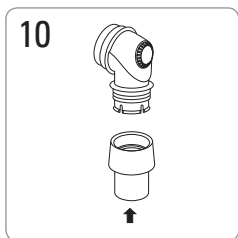
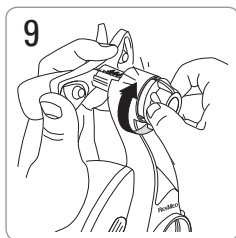
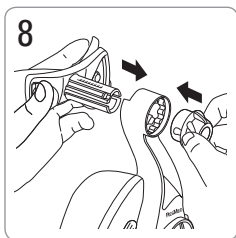
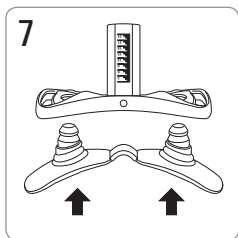
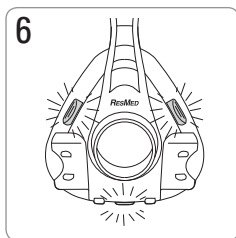
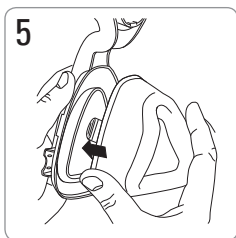
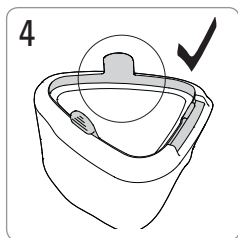
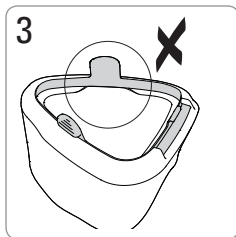
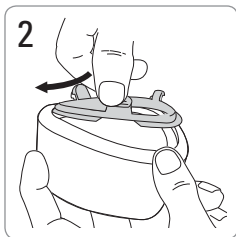
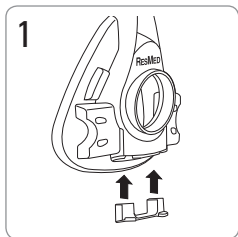
LW Large Wide / Large Wide / Large Wide / Grande larga / Large Wide

St Standard / Standard / Standard / Standard / Standaard

Disassembly / Auseinanderbau / Démontage / Smontaggio



Reassembly / Zusammenbau / Remontage / Riassemblaggio



Mirage™ SoftGel

NASAL MASK

Thank you for choosing the Mirage SoftGel.

The Mirage SoftGel is the first of ResMed's masks offering a choice of two high performance cushions (Mirage SoftGel and Mirage Activa LT) on the one durable frame. For further information, refer to the Activa LT User Information section in this User Guide.

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 (> 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 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 optimise 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.

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

Troubleshooting

Problem/possible cause	Solution
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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.
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.
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.

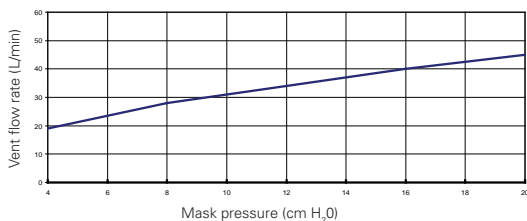
Cannot insert forehead support into mask frame

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.
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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

Sound

DECLARED DUAL NUMBERED NOISE EMISSION VALUES IN ACCORDANCE WITH ISO 4871

The A weighted sound power level of the mask is 29 dBA, with uncertainty 3 dBA.

The A-weighted sound pressure level of the mask at a distance of 1m is 22 dBA, with uncertainty 3 dBA.

Environmental conditions

Operating temperature: +5°C to +40°C
Operating humidity: 15% to 95% relative humidity non-condensing
Storage and transport: -20°C to +60°C
Storage and transport humidity: up to 95% relative humidity non-condensing

Gross dimensions

Mask fully assembled – no headgear
Large: 155 mm (H) x 91 mm (W) x 118 mm (D)

Mask setting options

Select 'ACTIVA' (if available), otherwise select 'STANDARD' 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;  Batch code;  Catalogue Number;  European Authorised Representative;  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.

Consumer warranty

ResMed acknowledges all consumer rights granted under the EU Directive 1999/44/EG and the respective national laws within the EU for products sold within the European Union.

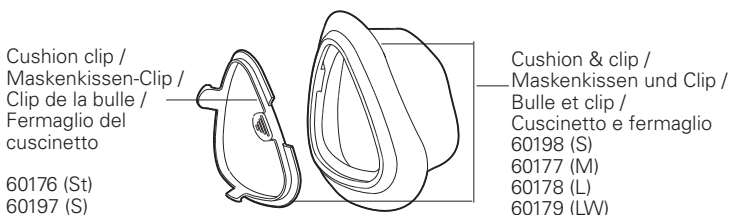
RESMED

Mirage Activa™ LT

NASAL MASK / NASENMASKE / MASQUE NASAL /
MASCHERA NASALE

User information

English • Deutsch • Français • Italiano



English

Please read this information in conjunction with your Mirage™ SoftGel User Guide when changing your Mirage SoftGel cushion to the Mirage Activa LT cushion.

Intended use

The Mirage Activa LT 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 Activa LT is:

- to be used by adult patients (> 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.

Troubleshooting

Problem/possible cause	Solution
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Mask is uncomfortable

Cushion incorrectly inflated.	With the air turned off, adjust the straps so that you can insert two fingers between your cheek and the lower headgear strap.
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Technical specifications

Dead space information	The dead space of the mask varies according to cushion size. It is 185 mL for the Medium size.
Resistance	Drop in pressure measured (nominal) at 50 L/min: 0.1 cm H ₂ O at 100 L/min: 0.7 cm H ₂ O
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 30 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 22 dBA, with uncertainty 3 dBA.
Gross dimensions	Mask fully assembled – no headgear. S 141 mm (H) x 91 mm (W) x 107 mm (D) M, L, LW: 154 mm (H) x 95 mm (W) x 117 mm (D)
Mask setting options	Select 'Activa' (if available) or 'Standard' as the mask option when using the Mirage Activa LT with ResMed devices that have mask setting options.

Deutsch

Lesen Sie diese Informationen bitte als Ergänzung zu Ihrer Mirage™ SoftGel Gebrauchsanweisung, wenn Sie vom Mirage SoftGel Maskenkissen zum Mirage Activa LT Maskenkissen wechseln.

Verwendungszweck

Die Mirage Activa LT führt dem Patienten auf nicht-invasive Weise einen Luftfluss von einem PAP-Atemtherapiegerät wie z. B. einem CPAP- oder Bilevel-Gerät zu.

Die Mirage Activa LT ist:

- für erwachsene Patienten (>30 kg) vorgesehen, denen positiver Atemwegsdruck verschrieben wurde
- für den wiederholten Gebrauch durch einen einzelnen Patienten zu Hause sowie durch mehrere Patienten in der Klinik oder Schlafklinik geeignet.

Fehlersuche

Problem/Mögliche Ursache	Lösung
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Maske ist unbequem

Maskenkissen ist nicht richtig aufgeblasen.	Stellen Sie die Bänder bei abgeschaltetem Luftfluss so ein, dass Sie zwei Finger zwischen Ihre Wange und das untere Kopfband schieben können.
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Technische Daten

Informationen zum Totraum

Der Totraum der Maske ist je nach Maskenkissengröße unterschiedlich. Bei Maskenkissengröße Medium beträgt er 185 ml.

Widerstand

Gemessene Drucksenkung (Sollwert)
bei 50 l/min: 0,1 cm H₂O
bei 100 l/min: 0,7 cm H₂O

Geräuschpegel

ANGEGEBENER ZWEIZAHL-GERÄUSCHEMISSIONSWERT nach ISO 4871. Der A-gewichtete Schalldruckpegel der Maske liegt bei 30 dBA (mit einem Unsicherheitsfaktor von 3 dBA). Der A-gewichtete Schalldruckpegel der Maske bei 1 m Entfernung liegt bei 22 dBA (mit einem Unsicherheitsfaktor von 3 dBA).

Abmessungen

Die Maske wird vollständig zusammengebaut und ohne Kopfband geliefert.

S	141 mm (H) x 91 mm (B) x 107 mm (T)
M, L, LW:	154 mm (H) x 95 mm x (B) x 117 mm (T)

Maskeneinstelloptionen

Wählen Sie (falls vorhanden) „Activa“ und ansonsten „Standard“ als Maskenoption aus, wenn Sie die Mirage Activa LT zusammen mit ResMed-Geräten benutzen, die über Maskeneinstelloptionen verfügen.

Français

Veuillez lire ces informations en conjonction avec le guide utilisateur Mirage™ SoftGel lors du remplacement de la bulle Mirage SoftGel par la bulle Mirage Activa LT.

Usage prévu

Le Mirage Activa LT achemine au patient de façon non-invasive le débit d'air produit par un appareil à pression positive tel un appareil de PPC ou de VNDP. Le Mirage Activa LT est prévu :

- pour une utilisation par des patients adultes (> 30 kg) à qui une pression positive a été prescrite ;
- pour un usage multiple par un seul patient à domicile ou pour un usage multiple par plusieurs patients en milieu médical.

Stratégie de dépannage

Problème/cause possible Solution

Le masque n'est pas confortable

La bulle n'est pas correctement gonflée.

Lorsque le débit d'air est fermé, ajustez les sangles de manière à pouvoir insérer deux doigts entre votre joue et la sangle inférieure du harnais.

Caractéristiques

Informations concernant l'espace mort

L'espace mort du masque varie en fonction de la taille de la bulle. Pour la taille Medium, il est de 185 ml.

Résistance

Chute de pression mesurée (nominale)
à 50 l/min : 0,1 cm H₂O
à 100 l/min : 0,7 cm H₂O

Niveau acoustique

VALEURS D'ÉMISSION SONORE À DEUX CHIFFRES DÉCLARÉES conformes à la norme ISO 4871. Le niveau acoustique pondéré A du masque est de 30dBA avec une incertitude de 3 dBA. Le niveau de pression acoustique pondéré A du masque à une distance d'1 m est de 22 dBA, avec une incertitude de 3 dBA.

Dimensions brutes

Masque entièrement assemblé – sans harnais.
S 141 mm (H) x 91 mm (W) x 107 mm (D)
M, L, LW : 154 mm (H) x 95 mm (W) x 117 mm (D)

Fonction de sélection du masque

Sélectionnez « Activa » (si disponible), sinon sélectionnez « Standard » comme réglage lors de l'utilisation de Mirage Activa LT avec les appareils ResMed ayant des options de réglage du masque.

Italiano

Leggere questo libretto informativo insieme alla Guida per l'utente di Mirage™ SoftGel nel passaggio dal cuscinetto Mirage SoftGel al cuscinetto Mirage Activa LT.

Indicazioni per l'uso

La maschera Mirage Activa LT eroga in modo non invasivo al paziente il flusso d'aria proveniente da un dispositivo a pressione positiva alle vie respiratorie, ad esempio un sistema CPAP (a pressione positiva continua alle vie respiratorie) o bilevel.

La Mirage Activa LT:

- va utilizzata da pazienti adulti (>30 kg) cui sia stata prescritta una terapia a base di pressione positiva alle vie respiratorie;
- è di tipo monopaziente nell'uso a domicilio e multipaziente in contesto ospedaliero.

Risoluzione dei problemi

Problema/Possibile causa Soluzione

La maschera è scomoda

Il cuscinetto è stato gonfiato in modo non corretto.

Ad aria spenta, regolare le cinghie in modo da poter inserire due dita tra la guancia e la cinghia inferiore del copricapo.

Specifiche tecniche

Informazioni sullo spazio morto

Lo spazio morto della maschera varia secondo la misura del cuscinetto. Per la misura Medium esso è pari a 185 mL.

Resistenza

Caduta di pressione misurata (nominale)
a 50 L/min: 0,1 cm H₂O
a 100 L/min: 0,7 cm H₂O

Potenza acustica

NUMERO BINARIO EMISSIONI ACUSTICHE
DICHARATE come da norma ISO 4871. La potenza acustica della maschera secondo la ponderazione A è di 30 dBA, con un margine di errore di 3 dBA. Il livello di pressione acustica della maschera secondo la ponderazione A alla distanza di 1 m è di 22 dBA, con un margine di errore di 3 dBA.

Dimensioni lorde

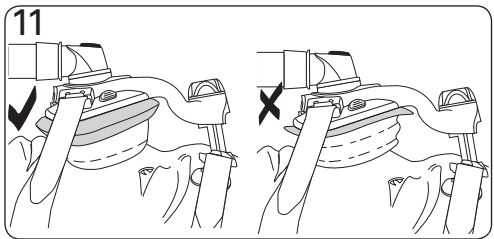
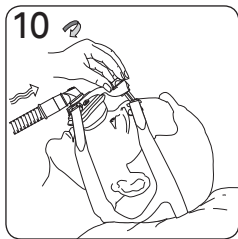
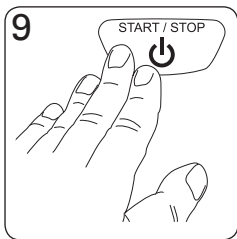
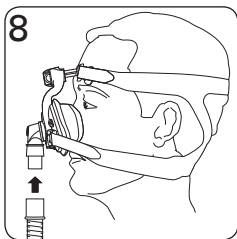
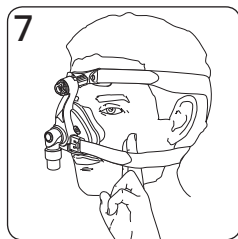
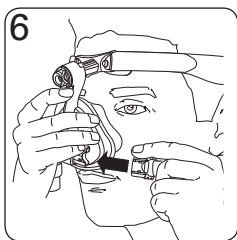
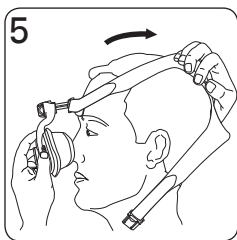
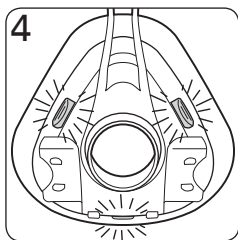
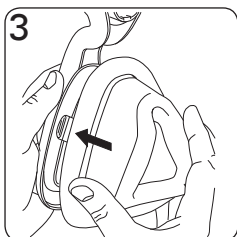
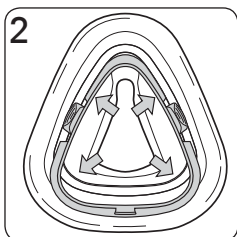
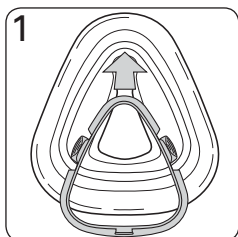
S
M, L, LW:

Maschera completamente assemblata – senza copricapo.
141 mm (H) x 91 mm (W) x 107 mm (D)
154 mm (H) x 95 mm (W) x 117 mm (D)

Opzioni di impostazione della maschera

Selezionare l'opzione di maschera 'Attiva' (se disponibile) o 'Standard' quando si utilizza la Mirage Activa LT con apparecchi ResMed dotati di opzioni d'impostazione della maschera.

**Fitting and assembly / Anpassung und Zusammenbau /
Ajustement et montage / Applicazione e assemblaggio**





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

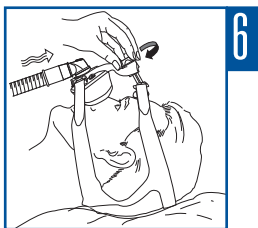
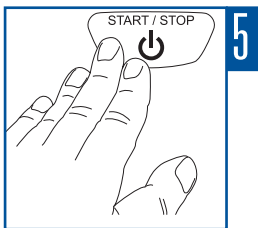
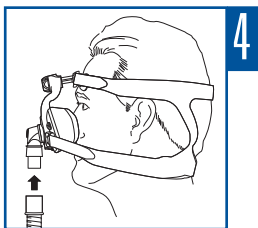
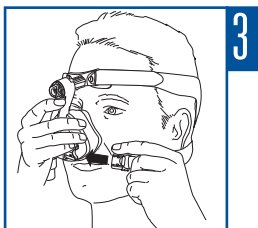
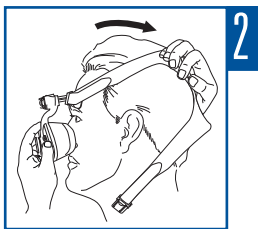
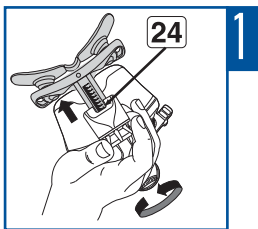
See www.resmed.com for other ResMed locations worldwide.

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

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