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Ultra Mirage™ II Nasal Mask

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USER'S 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.

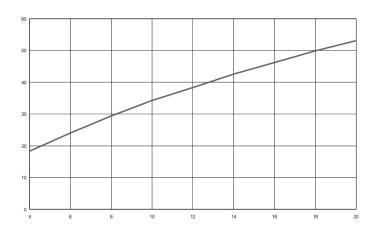
Note: As a result of manufacturing variations, the vent flow may vary from the values listed in the following table. / Remarque: en raison des variations de fabrication, le débit aux orifices de ventilation peut différer des valeurs indiquées dans le tableau suivant. / Nota: Como resultado de variaciones 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	Flow / Débit / Flujo / Fluxo
4	18
8	29
12	38
16	46
20	53



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

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



 $\mbox{\bf Mask Pressure} \ / \ \mbox{Pression dans le masque} \ / \ \mbox{Presión en la mascarilla} \ / \ \mbox{Pressão na máscara} \ \mbox{(cm H,O)}$

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Mask cushion / Bulle du masque / Almohadilla de la mascarilla / Almofada da máscara

Headgear clip / Clip du harnais / Broche del arnés para la cabeza / Clipe do arnês

Headgear clip slot / Fente pour le clip du harnais / Ranura del broche del arnés para la cabeza / Ranhura do clipe do arnês

Forehead support tab / Languette du support frontal / Lengüeta del apoyo para la frente / Lingueta do suporte da testa

Mask Frame / Entourage rigide / Armazón de la mascarilla / Armação da máscara

Elbow clip / Clip du coude / Traba del codo / Clipe do cotovelo

Swivel / Pièce pivotante / Pieza giratoria / Peça giratória

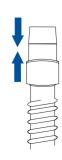
Vent cover on mask elbow / Cache des orifices de ventilation en place sur le coude du masque / Cubierta de la ventilación en el codo de la mascarilla / — Tampa do orifício de ventilação no cotovelo da máscara

"Click" sticker / Autocollant "Click" / Adhesivo "Clic" / Etiqueta adesiva "Click"

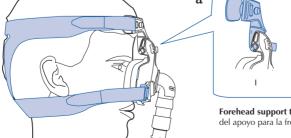
Mask elbow / Coude du masque / Codo de la mascarilla / Cotovelo da máscara

Fitting / Ajustement / Colocación / Ajuste

C-I



C-2



Ports cap / Bouchon d'entrées / Tapón de los

puertos / Tampa das portas





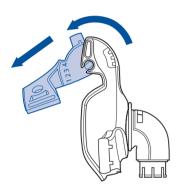


Forehead support tab – four positions / Languette du support frontal – quatre positions possibles / Lengüeta del apoyo para la frente – cuatro posiciones / Lingueta do suporte da testa – quatro posições

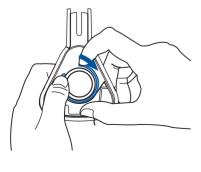
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Disassembling / Démontage / Desmontaje / Desmontar

D-I



D-2



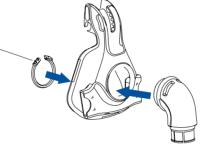


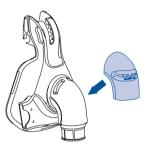
E-I

E-2

flat side of elbow clip faces mask frame /

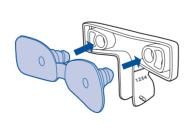
partie plate du clip du coude face à l'entourage rigide / el lado plano de la traba del codo mira hacia el armazón de la mascarilla / a face plana do clipe do cotovelo encontra-se virada para a armação da máscara

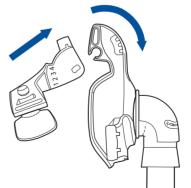


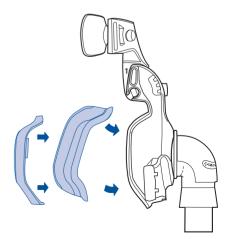


E-3

E-5







RESMED

Ultra Mirage™ II Nasal Mask

Thank you for choosing ResMed's ULTRA MIRAGE™ II NASAL MASK.

This mask is similar to the original ULTRA MIRAGE™ NASAL MASK and the two masks are equivalent in performance. The new upgraded mask includes an improved forehead support with flexible pads that conform to the shape of your forehead. This user's guide provides you with the information you need for the correct use of your mask.

INTENDED USE

The ULTRA MIRAGE II NASAL MASK is intended for multipatient use for adult patients 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.



Warnings and Cautions

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

Explanation of the Warning: CPAP and bilevel systems are intended to be used with special masks with connectors which may have vent holes or separate exhaust vents to allow continuous flow of air out of the mask. When the CPAP or bilevel device 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 CPAP or bilevel device 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 CPAP or bilevel systems.

- At low CPAP pressures, the flow through the exhaust vent may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur. Explanation of the Warning: The exhaust vent flow is lower at lower mask pressures (see Pressure–Flow Curve in section A on the illustrations sheet). To avoid rebreathing it is recommended that a mask pressure of 4 cm H₂O or more be used.
- turned off when the flow generator is not operating.

 Explanation of the Warning: When the CPAP or bilevel device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the flow generator enclosure. Oxygen

accumulated in the CPAP or bilevel

device enclosure will create a risk of fire.

This warning applies to most types of

 If oxygen is used with the CPAP or bilevel device, the oxygen flow must be

- CPAP or bilevel flow generators.
 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 rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and 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 "Cleaning the Mask in the Home".

I Push the air tubing all the way onto the swivel. The end of the air tubing and the ridge of the swivel must completely meet (Fig. C-I). Connect the other end of the air tubing to your flow generator.

2 Place the cushion over your nose, pull

- the headgear over your head and make the straps pass below your ears. Connect the other headgear clip to the mask frame. Use the Velcro® straps to adjust the fit of the headgear. Do not overtighten the
- straps (Fig. C-2).

 The pads of the forehead support
- should lightly touch your forehead when the mask is in place.

 Adjust the forehead support if required, by moving it to one of the other tab positions (Fig. C-2a). There are four tab positions (I 4). To change a tab position, first, loosen the headgear straps. Then, press the forehead support tab and move it upwards to the next position (eg, from position I move it to position 2). Once again, gently tighten the headgear straps.
- **4** Grasp the edges of the vent cover on both sides of the "Click" sticker at the same time. Firmly push the vent cover onto the mask elbow to make sure it is clicked securely in place.
- 5 Turn the flow generator on. Lie down and check that the mask is comfortable and there are no air leaks. If there are air leaks, you may need to readjust the Velcro straps (see Step 2) or forehead support (see Step 3).

Notes:

- If you are unable to resolve any leaks you may need to try another cushion size.
- Select "Ultra" as the mask option when using the ULTRA MIRAGE II with ResMed flow generators that have mask setting obtions.



(1) CAUTION

This mask is not compatible with those AutoSet T[™] flow generators that have an internal pressure sensor line. It is compatible with all other ResMed AutoSet[™] flow generators.

REMOVING THE MASK

To remove the mask, depress the tabs of the headgear clips. This releases the headgear clips from the mask frame. Pull the mask and headgear away from your head.

Notes:

- Do not pull the headgear off your head without releasing the headgear clips first.
- Check that you can remove the headgear clips or the headgear unaided.

DISASSEMBLING FOR CLEANING

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

- I Detach and separate the main air tubing, headgear, headgear clips, swivel, forehead pads, cushion clip, cushion, and ports cap.
- 2 Use your thumb on the side of the vent cover to remove it from the mask elbow.
- 3 Depress the forehead support tab and move it past the top tab position. This allows you to remove the forehead support from the mask frame (Fig. D-I).

4 From the inside of the mask frame, hold one side of the elbow clip in place and release the other side of the clip (Fig. D-2). Remove the clip and mask elbow from the mask frame.

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.

Dally/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.

WFFKLY

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



CAUTIONS

- Do not use solutions containing bleach, chlorine, alcohol, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the mask system or air tubing. 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 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.

REASSEMBLING THE MASK

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

- I Insert the ports cap into the ports. Make sure the tabs of the ports cap face away from the mask.
- 2 Insert the mask elbow into the mask frame and secure it with the elbow clip on the inside of the frame (Fig. E-I). The flat side of the elbow clip must face the mask frame. If you have fitted the mask elbow correctly, it should not move when you try to firmly pull it away from the frame.
- 3 Grasp the edges of the vent cover on both sides of the "Click" sticker at the same time. Firmly push the vent cover onto the mask elbow to make sure it is clicked securely in place (Fig. E-2).
- **4** Push the swivel onto the end of the mask elbow.
- 5 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 E-3). Push the pads firmly against the forehead support

- to ensure that the pads fit securely into the forehead support.
- 6 Reconnect the forehead support to the mask frame. Depress the tab and move the forehead support into one of the four tab positions (Fig. E-4).
- 7 Fit the grooved edge of the nasal 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. Push the cushion clip over the cushion onto the mask frame, ensuring it clicks into place in all locations (Fig. E-5).
- 8 Connect the headgear clips to the mask frame. Thread the headgear straps through the slots on the forehead support and the headgear clips. The ULTRA MIRAGE headgear label should face outwards and be near your neck when fitted. Fasten the Velcro straps.

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 135 mL.

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

REPLACEMENT PARTS

KLI LACLMLINI TAKIS		
Part No.	Item	
16563	Cushion clip	
16557	Cushion, Large	
16558	Cushion, Shallow	
16735	Cushion, Shallow-wide	
16556	Cushion, Standard	
16566	Elbow assembly	
16572	Elbow clip (1 pk.)	
16573	Elbow clip (10 pk.)	
60123	Forehead pads (1 pk.)	
60124	Forehead pads (10 pk.)	
16590	Forehead support with pads	
16594	Frame assembly	
16728	Frame System with Cushion, Large	
16727	Frame System with Cushion, Shallow	
16736	Frame System with Cushion, Shallow-wide	
16726	Frame System with Cushion, Standard	
16119	Headgear, Large	
16117	Headgear, Standard	
16118	Headgear, Small	
16569	Headgear clip (2 pk.)	
16734	Headgear clip (10 pk.)	
16560	Mask frame	
16570	Ports cap/s (2 pk.)	
16571	Ports cap/s (10 pk.)	
16565	Swivel	
16575	Vent cover	
103/3	vent cover	

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:

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Distributed by:

EC REP

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