

RESMED

Ultra Mirage™ NON-VENTED FULL FACE MASK

Clinical Guide

English



Ultra Mirage™

NON-VENTED FULL FACE MASK

Illustrations Sheet / Illustrationsblatt / Fiche d'illustrations / Foglio delle Illustrazioni /
Hoja de Figuras / Folheto de Ilustrações / Illustratieblad

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

Hinweis: Vollständige Anweisungen finden Sie im Textabschnitt und in den Illustrationen auf diesem Blatt.

Remarque : pour les instructions complètes, veuillez lire le texte du guide avec cette fiche d'illustrations.

Nota: Per istruzioni complete, leggere la sezione con il testo insieme alle illustrazioni su questo foglio.

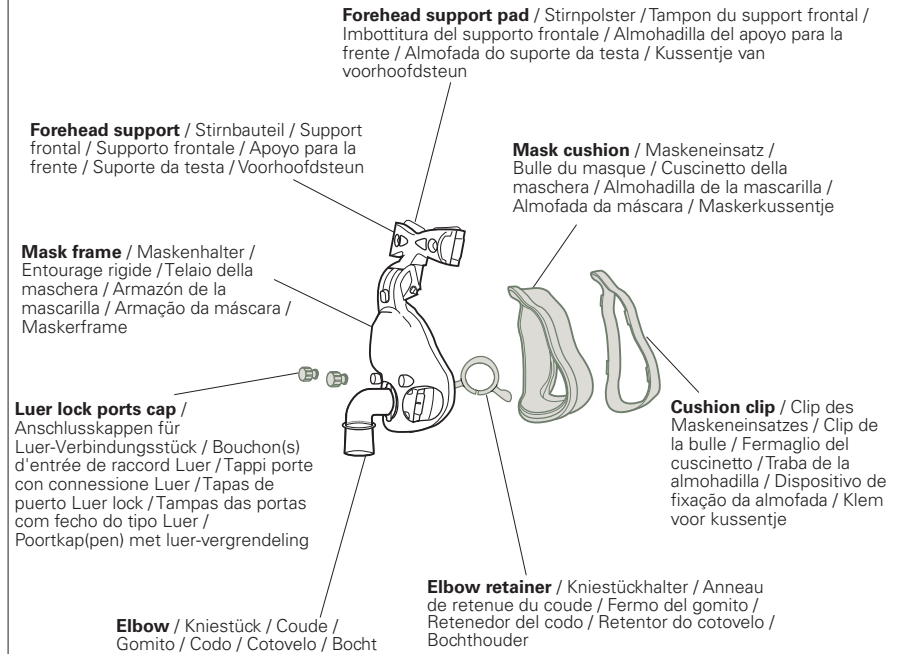
Nota: Para tener instrucciones completas, lea el texto en conjunto con las figuras de esta hoja.

Nota: Para obter as instruções completas, leia a secção de texto em conjugação com as ilustrações deste folheto.

Opm.: Raadpleeg voor een volledige beschrijving het tekstgedeelte en de bijbehorende illustraties op dit blad.

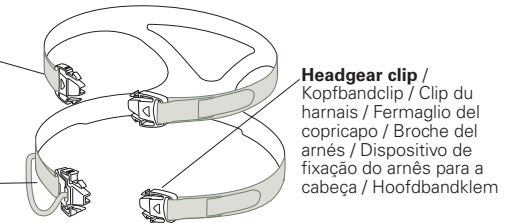
Component of: 608323/1

A Mask Parts / Teile der Maske / Composants du masque / Parti della maschera / Piezas de la mascarilla / Peças da máscara / Maskeronderdelen



Upper Velcro™ straps / Die oberen Velcro-Bänder / Bandes Velcro supérieures / Cinghie laterali superiori (Velcro) / Correas laterales superiores (Velcro) / Correias Velcro laterais superiores / Bovenste Velcro klittenbandbevestiging

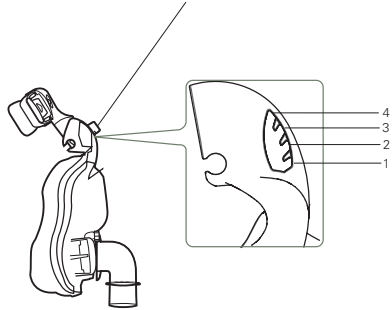
Lower Velcro straps / Die unteren Velcro-Bänder / Bandes Velcro inférieures / Cinghie laterali inferiori (Velcro) / Correas laterales inferiores (Velcro) / Correias Velcro laterais inferiores / Onderste Velcro klittenbandbevestiging



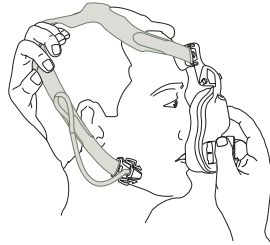
B Fitting the Mask / Anlegen der Maske / Mise en place du masque /
Come indossare la maschera / Colocación de la mascarilla / Colocação
da máscara / Het masker opzetten

Forehead support tab / Stirnbauteillasche /
languette du support frontal / Linguetta del
supporto frontale / Lengüeta del apoyo para la
frente / Dispositivo de fixação do suporte da
testa / Tab van de voorhoofdsteun

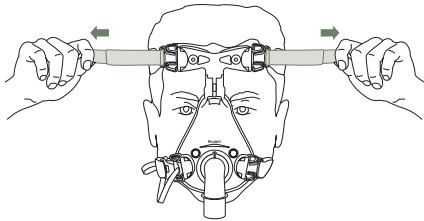
B-1



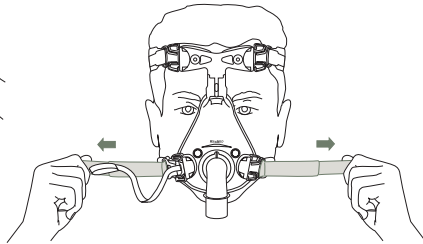
B-2



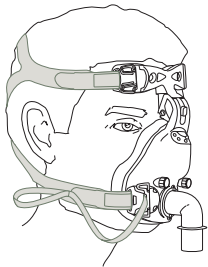
B-3



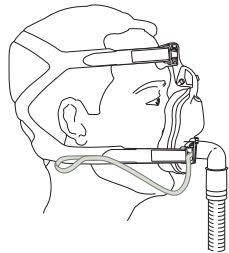
B-4



B-5



B-6

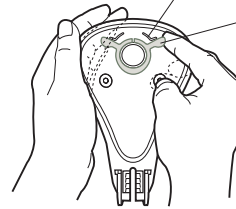


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C Disassembling for Cleaning / Demontage zu Reinigungszwecken /
Démontage pour le nettoyage / Smontaggio per la pulizia /
Desmontaje para la limpieza / Desmontagem para limpeza /
Demontage voor reiniging

C-1

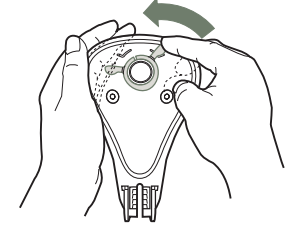
L-shaped ridge / L-förmige Leiste / Bord en L /
Costa sinistra a L / Borde en forma de L / Saliência
em forma de L / L-vormige rand



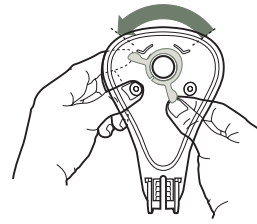
LIFT / HEBEN /
SOULEVER /
SOLLEVARE /
LEVANTE / LEVANTE /
OMHOOGDOEN

C-2

PUSH / DRÜCKEN / POUSSER /
SPINGERE / EMPUJE /
EMPURRE / DUWEN

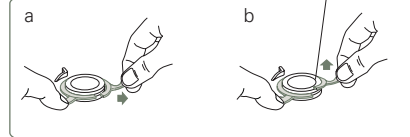
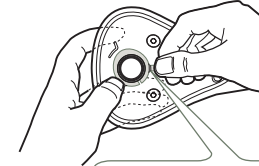


C-3

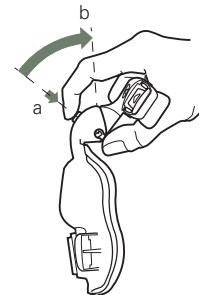


C-4

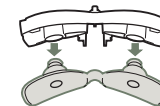
Elbow retainer / Kniestückhalter /
Anneau de retenue du coude /
Fermo del gomito / Retenedor del
codo / Retentor do cotovelo /
Bochthouder



C-5



C-6



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D Reassembling the Mask / Wiederzusammenbau der Maske / Remontage du masque / Riassetblaggio della maschera / Montaje de la mascarilla / Montagem da máscara / Het masker opnieuw monteren

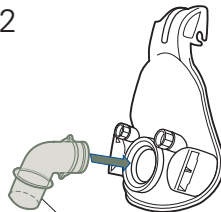
D-1



Luer lock ports cap /
Anschlusskappen für
Luer-Verbindungsstück / Bouchon(s)
d'entrée de raccord Luer / Tappi porte
con connessione Luer / Tapas de puerto
Luer lock / Tampas das portas com
fecho do tipo Luer / Poortkap(pen) met
luer-vergrendeling

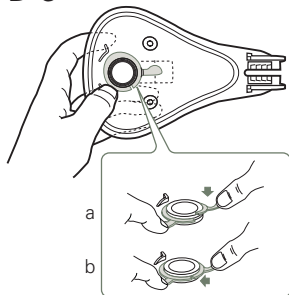
Mask port / Anschlussöffnung /
Port(s) du masque / Porta della
maschera / Puerto(s) de la mascarilla /
Orificio da máscara / Masterpoort(en)

D-2



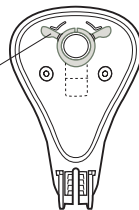
Elbow / Kniestück / Coude /
Gomito / Codo / Cotovelo /
Bocht

D-3

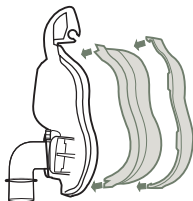


Elbow retainer / Kniestückhalter /
Anneau de retenue du coude /
Fermo del gomito / Retenedor del
codo / Retentor do cotovelo /
Bochthouder

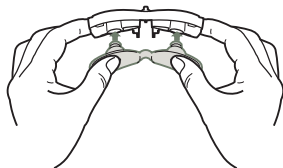
D-4



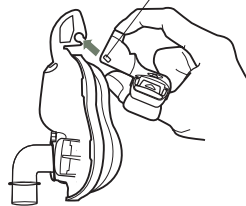
D-5



D-6



D-7



Pivot / Zapfen / Pivot /
Perno / Pivote / Pino /
Scharnier

Ultra Mirage™

NON-VENTED FULL FACE MASK

The Ultra Mirage NV (non-vented) Full Face Mask is a non-invasive device used for channelling air flow with or without supplemental oxygen.

Intended Use

The Ultra Mirage NV Full Face Mask is intended to be used with active-exhaust-valve ventilator systems, to provide ventilatory assistance to patients with respiratory insufficiency and respiratory failure.

The Ultra Mirage NV Full Face Mask is to be used on adult patients (>30 kg), requiring non-life-support ventilatory assistance.

The Ultra Mirage NV Full Face Mask is intended for single-patient re-use in the home or multipatient re-use in the hospital/institutional environment.



WARNINGS AND CAUTIONS

- The Ultra Mirage NV Full Face Mask, must not be used without qualified supervision for patients who are unable to remove the mask by themselves.
- This mask is not for use on patients with impaired laryngeal reflexes or other conditions predisposing to aspiration in the event of regurgitation or vomiting.
- The mask should not be worn unless the ventilator system is turned on and operating properly.
- At a fixed rate of supplemental oxygen flow (if used), the inhaled oxygen concentration will vary depending on the pressure settings, patient breathing pattern, mask size selection and the mask leak.
- If oxygen is used with the ventilator, the oxygen flow must be turned off when the ventilator is not operating.

Explanation: When the ventilator is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within

the ventilator enclosure. Oxygen accumulated in the ventilator enclosure will create a risk of fire. This warning applies to most types of ventilators.

- 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.

About the Mask

- The mask system does not contain latex, PVC or DEHP materials. If the patient has ANY reaction to any part of the mask system, discontinue use and investigate the possible causes.
- ResMed has tinted the Ultra Mirage NV Full Face Mask elbow blue to identify it as a non-vented mask for use with active exhaust non-invasive ventilator systems only.
- The mask has a standard female 22 mm tapered fitting (ISO5356-1) for external connection to the ventilator.
- Refer to the section “Technical Specifications” of this guide for information about mask leak, dead space and resistance.



CAUTION

The mask must be cleaned and disinfected/sterilised if it is used between patients. Refer to the section “Cleaning the Mask between Patients” for details.

Parts of the Mask

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

Fitting the Mask

Note: Refer to the relevant ventilator system operating instructions for detailed information about connecting the mask.

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

The Ultra Mirage NV Full Face Mask is supplied fully assembled.

- 1 Move the forehead support tab to Position 3. (Refer illustration **B-1** for location of Position 3.)
- 2 Disconnect one lower headgear clip. Place the mask on the face and pull the headgear over the patient's head (**B-2**). Ensure that the upper straps pass across the forehead and the lower straps below the ears.
- 3 Reattach the headgear clip to the mask frame.
- 4 Gently tighten the upper headgear straps (**B-3**).

5 Gently tighten the lower headgear straps (B-4).

The pads of the forehead support should sit comfortably on the forehead when the mask is in place. If the pads are at an angle and not completely seated on the forehead, change the position of the forehead support tab.

Note: Do not overtighten the headgear straps as this may cause discomfort, cushion creases and mask leak. The Ultra Mirage NV Full Face Mask has been designed to provide a comfortable seal without the need to overtighten the headgear.

6 The fitted mask should look like this (B-5).

7 Connect the main air tubing to the elbow (B-6). Then connect the free end of the air tubing to the ventilator and turn the ventilator on. If the patient experiences air leaks around the cushion, it may be necessary to gently tighten the headgear straps.

8 If the patient is unable to get a proper seal:

- reposition the mask by lifting it and placing the cushion comfortably on the face.
- adjust the position of the forehead support tab by testing all four positions and finding the one that best prevents leaks.
- gently tighten the headgear straps.

Notes:

- *If it is not possible to resolve any leaks, your patient may require another mask frame and/or another cushion size.*
- *As with all mask ventilation systems, significant leak may occur between the mask and the patient's face. The leak may vary depending on such factors as the patient's position and sleep stage. Variation in leak may significantly affect patient ventilation, potentially producing profound hypoventilation or hyperventilation. The magnitude of this effect depends on the ventilator's ability to compensate for leak.*
- *Leak or variation in the leak may cause mistriggering of the ventilator.*

Removing the Mask

Normal Release

To remove the Ultra Mirage NV Full Face Mask, squeeze one of the lower headgear clips and pull the mask and headgear up over the patient's head.

Emergency Release Cord

The Emergency Release Cord (Figure 1) allows the mask to come away from the face quickly in the event of an emergency.

Simply pull the Emergency Release Cord and the two part clip separates, allowing you to remove the mask from the face.

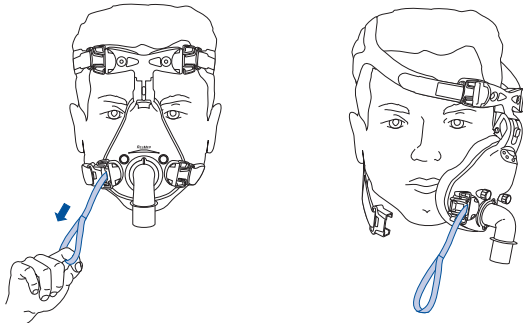


Figure 1: Emergency Release Cord.

Note: The Emergency Release Cord should only be used to remove the mask in the event of an emergency. Overuse of the Emergency Release Cord may result in the deterioration of the two part clip mechanism.

Disassembling for Cleaning

See section C 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 ports 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 (C-1) and push (C-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 C-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 (C-4a) and then up (C-4b) over the top of the elbow. Remove the elbow retainer and elbow from the mask frame.
- 8 To remove the forehead support from the mask, press the tab (C-5a) and move it upwards until it is possible to slide it off the mask frame (C-5b).
- 9 Pull firmly at the base of the forehead support pad plugs to release the pads from the forehead support (C-6).

Cleaning the Mask in the Home

Notes:

- Wash your hands before cleaning the mask.
- It is important to always handwash the headgear.
- The headgear may be washed without being disassembled from the headgear clips.

Daily/After each use

Handwash the mask components in warm (approximately 30°C) water for one minute using mild soap or detergent. Rinse the components well with drinking quality water and allow them to air dry out of direct sunlight.

Weekly

Handwash the headgear in warm (approximately 30°C) water using mild soap or detergent. Rinse well and allow to air dry out of direct sunlight.



CAUTION

- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturising 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.
- The headgear is sensitive to heat and must not be ironed.
- 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 sterilisation instructions are available from the ResMed website, www.resmed.com/masks/sterilization.

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

Reassembling the Mask

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

- 1 Twist the luer lock port caps onto the mask ports (**D-1**).
- 2 Hold the mask frame and the elbow firmly together (**D-2**).

- 3 To attach the elbow retainer, fit one side of the elbow retainer against the groove of the elbow. While holding one wing of the elbow retainer down (D-3a), press the other wing down until it clicks into place (D-3b).
- 4 Rotate the elbow retainer to its original position (D-4).
- 5 Check that you have fitted the elbow and elbow retainer correctly by firmly pulling the elbow away from the frame. If the elbow is fitted correctly, it should not separate from the frame.

If the elbow comes away from the frame, try refitting the elbow retainer as described in Steps 3 and 4. If the elbow still comes away from the frame when you pull on it, you may need to replace the elbow retainer.

- 6 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 and onto the mask frame, ensuring it clicks into place in all locations (D-5).
- 7 Attach the forehead pads to the forehead support by inserting the pad plugs into the two holes on the back of the forehead support (D-6). Push the pads firmly against the forehead support to ensure that the pads fit securely into the forehead support.
- 8 Connect the forehead support to the mask frame. Slide the pivots into the pivot slot on the mask frame (D-7). Depress the forehead support tab and move it into any of the tab positions.
- 9 Insert the headgear clips into the slots on the mask frame. The headgear label should face outward and be near the patient's neck when fitted.

Note: *The Emergency Release Cord must be attached to one of the bottom headgear straps in order to function correctly.*

Disposal

The Ultra Mirage NV Full Face Mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

Technical Specifications

When determining ventilator settings, and in particular the tidal volume for volume cycled ventilators, make appropriate allowances for mask dead space and leak.

Unintentional Mask Leak

The Unintentional Mask Leak comprises leak between the cushion-frame and elbow-frame interfaces.

Pressure (cm H ₂ O)	Maximum Leak (L/min)
4–20	6

Dead Space

Dead space is the empty volume of the mask up to the elbow.

The dead space of the mask varies according to cushion sizes but is less than 260 mL.

Standards

CE designation in accordance with EC directive 93/42/EEC, class IIa.
EN ISO 14971, ISO 5356-1, ISO 594-1, ISO 10993-1 and ISO 13485.

Operating Pressure

0 to 40 cm H₂O

Resistance

Drop in pressure measured

at 50 L/min: 0.5 cm H₂O

at 100 L/min: 1.5 cm H₂O

Dimensions

The dimensions of the mask (Medium) are:

H = 200 mm, W = 100 mm and D = 100 mm

Symbols

System and Packaging



Caution, consult accompanying documents



Batch Code



Catalogue Number



European Authorised Representative



Humidity limitation



Temperature limitation



Does not contain natural rubber latex



Manufacturer

Clinical 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 No. **Item**

System

60643	UM NVFFM System <i>Small, Standard</i> – Europe 1
60642	UM NVFFM System <i>Small, Shallow</i> – Europe 1
60645	UM NVFFM System <i>Medium, Standard</i> – Europe 1
60644	UM NVFFM System <i>Medium, Shallow</i> – Europe 1
60647	UM NVFFM System <i>Large, Standard</i> – Europe 1
60646	UM NVFFM System <i>Large, Shallow</i> – Europe 1

Replacement Parts

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.)
60678	Elbow (1 pk.)
60683	Elbow retainer (1 pk.)
60681	Luer lock ports caps (2 pk.)
60682	Luer lock ports caps (10 pk.)
60115	Headgear clip (2 pk.)
60116	Headgear clip (10 pk.)
60123	Forehead pad (1 pk.)

Part No.	Item
60124	Forehead pad (10 pk.)
60675	Mask Frame, <i>Small</i> (1 pk.)
60676	Mask Frame, <i>Medium</i> (1 pk.)
60677	Mask Frame, <i>Large</i> (1 pk.)
60673	Forehead Support (1 pk.)
60917	Headgear (1 pk.)
60618	Emergency Release Cord assembly (1 pk.)
60619	Emergency Release Cord assembly (10 pk.)

Europe 1 - English, German, French, Italian, Spanish, Portuguese, Dutch.

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.

Note: *Translations are based on the English version in this guide. However, there may be minor variations based on the disinfection/sterilisation procedures applicable in some countries. ResMed has reviewed these changes and all procedures included here have been validated.*



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

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Ultra Mirage NVFFM

CLINICAL

EUR 1 - ENG



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