

ULTRA MIRAGE™ NV MASK

*RESMED*

CLINICIAN'S  
GUIDE

GEBRAUCHSANWEISUNG

MODE D'EMPLOI

GUIDA PER L'UTENTE

GUÍA DEL USUARIO

GUIA DO USUÁRIO

BRUKSANVISNING



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# ULTRA MIRAGE™ NV MASK

The *ULTRA MIRAGE™ NV MASK* system (non-vented) is only indicated for the treatment of adult patients using non-invasive ventilator systems that have an active exhaust.

## CONTRAINDICATIONS

- The *ULTRA MIRAGE NV MASK* must not be used without appropriately qualified supervision either when the patient is at risk of not responding to severe hypoxia or hypercapnia by arousal, or when the patient, having aroused, is unable to remove the mask.

## WARNINGS

- It is expected that if the ventilator fails, the mechanism of the ventilator will provide a low-deadspace path to room air, so that significant rebreathing does not occur. If the ventilator is such that this is not the case:
  - Prevention of rebreathing or total airway obstruction (depending on the ventilator) depends on the ability of the patient to open his or her mouth.
  - If the patient might fail to respond effectively

to failure of the ventilator by opening his or her mouth and breathing through the mouth, this mask should not be used.

- The mouth should never be taped or otherwise limited from opening to an extent which might compromise the patient's ability to open his or her mouth.
- 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 selection and the leak rate.
- The mask must not be used if the patient is known to be allergic to any of the following mask component materials: polycarbonate, silicone rubber, polyurethane, nylon and polyester.

## CAUTION

- The mask is not for use with ventilators which have a combination of:
  - a) little or no ability to compensate for mask leak and variation in mask leak (eg volume-cycled ventilators with no compensation for leak, or

pressure-cycled ventilators which are unable to deliver adequate extra flow in the presence of increased leak); and

b) no expired ventilation alarms.

If a ventilator with poor leak compensation is used, special reliance is placed on the expired ventilation alarm.

- 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.
- Increased face-to-mask leak will reduce effective deadspace by washing out expired gases. In a pressure-cycled ventilator which tolerates moderate leak, the effect may be a reduction in arterial PCO<sub>2</sub> with no change in ventilator settings.

## ADDITIONAL INFORMATION

- ResMed has tinted the *ULTRA MIRAGE NV MASK* frame and elbow blue to help you identify it as a non-vented mask for use with active-exhaust non-invasive ventilator systems only.
- The mask elbow has a standard female 22mm tapered fitting (ISO5356-1) for external connection to the ventilator.
- In determining the initial ventilator settings, and in particular the tidal volume for volume-cycled ventilators, make appropriate allowances for mask dead space and leak, both directly from the mask itself (primarily at the elbow-mask frame junction), and between the face and mask. Refer to the Mask Characteristics section for more information.
- Refer to the relevant ventilator system operating instructions for detailed information concerning connecting the mask.

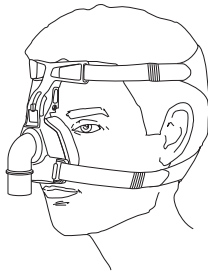


## FITTING THE MASK

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

- 1 Connect the ventilator 22mm male fitting to the mask elbow. Alternatively, do this after you have fitted the mask (Step 3).
- 2 Place the cushion over your nose, pull the headgear over your head and make the side lower Velcro® straps pass below your ears.

Use the Velcro straps to adjust the fit of the headgear. Do not pull the straps too tightly.



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

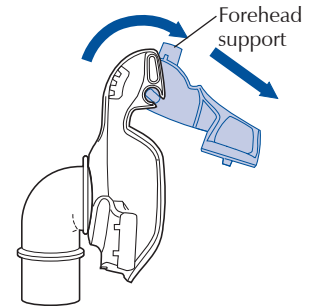
Adjust the forehead support by depressing its tab and moving it to one of the other slot positions.

- 4 Turn the ventilator 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).

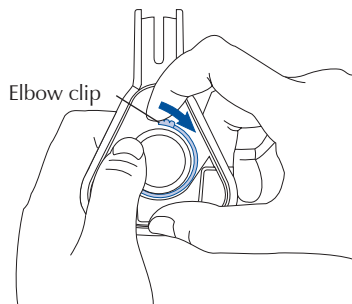
To remove the mask, depress the tabs of the headgear clips. This releases the headgear clips from the mask frame. Pull the mask and headgear away from your head.

## DISASSEMBLING THE MASK

- 1 Detach and separate the ventilator 22mm male fitting, headgear, headgear clips, forehead pads, cushion clip, cushion and ports cap.
- 2 Depress the forehead support tab and move it past the top slot position. This allows you to remove the forehead support from the mask frame.



- 3 From the inside of the mask frame, hold one side of the elbow clip in place and release the other side of the clip. Remove the clip and elbow from the mask frame.



### CAUTION

- Do not use bleach-, chlorine-, alcohol-, or aromatic-based solutions, moisturising or antibacterial soaps, or scented oils to clean the cushion, mask frame, forehead pads or headgear. These solutions may cause damage and reduce the life of the product.
- Do not expose any part of the mask system to direct sunlight as it may cause the product to deteriorate.

## CLEANING THE MASK IN THE HOME

*Note: Wash the headgear before first time use, as the dye may run. It is important to always hand wash the headgear.*

- 1 Hand wash the headgear in warm, soapy water. Use a mild detergent such as pure soap. Rinse well and allow it to air dry out of direct sunlight. Do this at least once per week.
- 2 Hand wash the mask components in warm, soapy water. Use a mild detergent such as pure soap. Rinse the components well and allow them to air dry out of direct sunlight. Do this after each use.

## REPROCESSING THE MASK BETWEEN PATIENTS

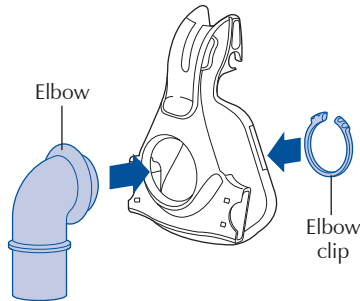
This mask should be reprocessed when used between patients. Cleaning, disinfection and sterilization instructions are available from the ResMed website, [www.resmed.com/masks/sterilization](http://www.resmed.com/masks/sterilization).

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

## REASSEMBLING THE MASK

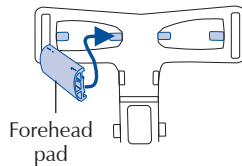
- 1 Insert the ports cap into the ports. Make sure the tabs of the ports cap face away from the mask.

- 2 Insert the elbow into the mask frame and secure it with the elbow clip on the inside of the frame. The flat side of the elbow clip

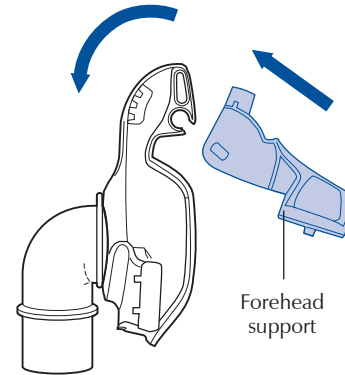


must face the mask frame. If you have fitted the elbow correctly, it should not move when you try to firmly pull it away from the frame.

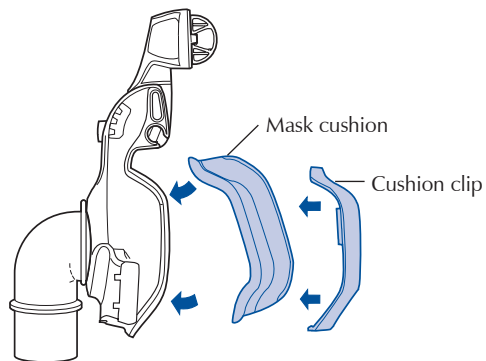
- 3 Replace the forehead pads by sliding the centre division of the pads onto the forehead pad holders.



- 4 Reconnect the forehead support to the mask frame. Depress the tab and move the forehead support into one of the four slot positions.



- 5 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.



- 6 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.

## ACCESSORIES AND REPLACEMENT PARTS

Description	Quantity per pack	Part Number
Cushion (Standard)	1	16556
Cushion (Large)	1	16557
Cushion (Shallow)	1	16558
Cushion Clip	1	16563
Elbow Assembly (includes Elbow Clip)	1	60916
Elbow Clip	1	16572
Elbow Clip	10	16573
Forehead Pad	2	16561
Forehead Pad	10	16574
Forehead Support	1	16562
Headgear	1	60917
Headgear Clips	2	16569
Headgear Clips	10	16734
Mask/Air Tubing Connector (Male 22mm taper/Male 22mm barbed)	1	60913
Mask/Air Tubing Connector (Male 22mm taper/Male 22mm barbed)	10	60914
Mask Frame	1	60915
Ports Cap	2	16570
Ports Cap	10	16571












## 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.

## CONSUMER WARRANTY (EUROPE)

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.

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See [www.resmed.com](http://www.resmed.com) for other ResMed locations worldwide.

Protected by patents: AU 710733, AU 741003, CA 2261790, AU 775051, EP 0956069, EP 1187647, EP 1187649, EP 1187650, EP 1479406, EP 1640034, JP 3686609, JP 4031422, NZ 542849, US 6112746, US 6357441, US 6374826, US 6412487, US 6463931, US 6581602, US 6634358, US 6796308, US 6860269, US 6997188, US 7021311, US 7069933, US 7234466. Other patents pending.

Protected by design registrations: AU 139764, DE 49911833, EU 600903, FR 997839, JP 1117921, NZ 408203, NZ 410169, NZ 410170, US D443355, US D576270, US D576271, US D586458, US D590059.

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