

ULTRA MIRAGE™ NV MASK

RESMED

CLINICIAN'S GUIDE

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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.

CAUTION

In the USA, federal law restricts this device to sale by, or on the order of, a physician.

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.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

CAUTIONS

- 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_2 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 deadspace 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.

MASK CHARACTERISTICS

MASK DEADSPACE

ULTRA MIRAGE NV MASK 100 mL

Note: This value was obtained using a facial profile and measuring the volume from the surface of the face to the end of the elbow. The data is provided as an indication only. Actual volumes may vary depending on individual facial features.

MASK IMPEDANCE DATA

At a flow of 60 L/min the difference in pressure between the end of the elbow and inside the mask is less than 0.5 cm H₂O.

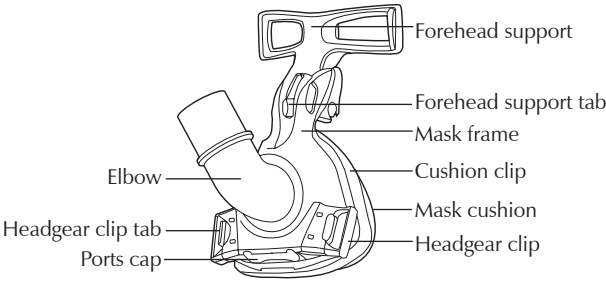
MASK LEAK

The leak from the mask, excluding leak between the face and the mask, is less than 6.0 L/min up to 20 cm H₂O.

ENVIRONMENTAL CONDITIONS

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

PARTS OF THE MASK

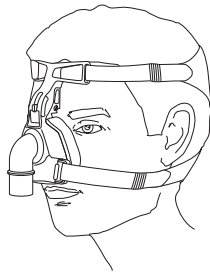


FITTING THE MASK

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.

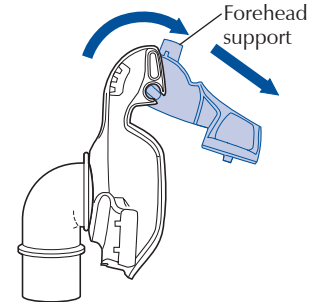
Adjust the forehead support by depressing its tab and moving it to one of the other slot positions.

- 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).

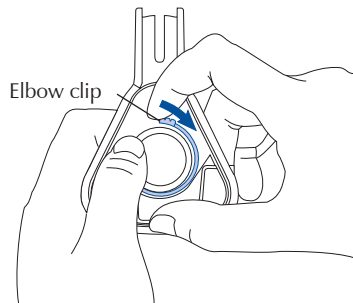
To remove the mask, depress the tabs of the headgear clips. This releases the headgear clips from the mask frame. Pull the mask and headgear away from your head.

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, moisturizing 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

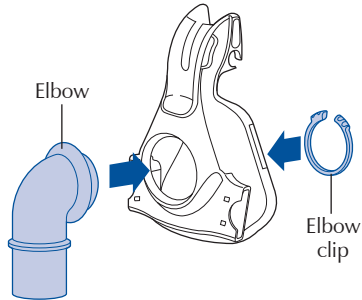
The mask should be reprocessed when used between patients.

Cleaning, disinfection and sterilization instructions are available from the ResMed website, www.resmed.com/masks/sterilization/americas.

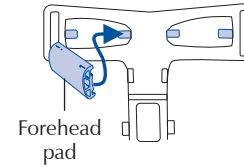
If you do not have Internet access, please contact your ResMed representative.

REASSEMBLING THE MASK

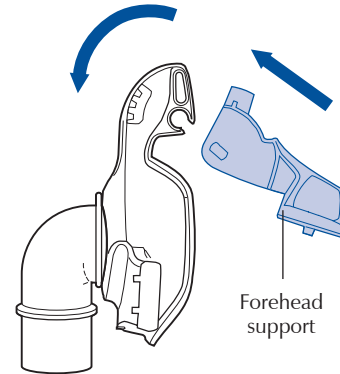
- 1 Insert the ports cap into the ports. Make sure the tabs of the ports cap face away from the mask.



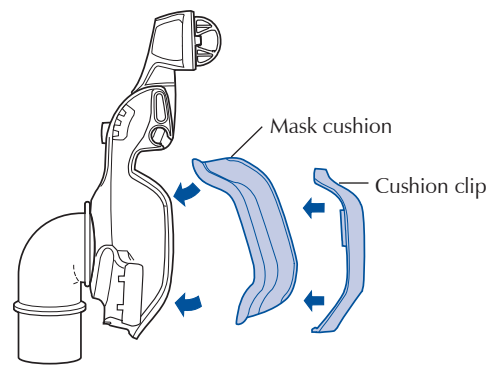
- 2 Insert the elbow into the mask frame and secure it with the elbow clip on the inside of the frame. The flat side of the elbow clip must face the mask frame. If you have fitted the elbow correctly, it should not move when you try to firmly pull it away from the frame.
- 3 Replace the forehead pads 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;
-  Batch Code;  Catalogue Number;
-  European Authorised Representative;
-  Temperature limitation;  Humidity limitation;
-  Does not contain natural rubber 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

Re•Med Pty 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 Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia

Distributed by:

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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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