

# AirLife®

## SuperNO<sub>2</sub>VA™ Et Mask – Medium, Large

**REF**

Catalogue number

**Rx ONLY**

U.S. Federal law restricts this device to sales by or on the order of a physician

**LOT**

Lot Number



Manufacturer

**QTY**

Quantity



Do not re-use  
Single Use



Not made with natural rubber latex



Use-by Date



Consult Instructions for Use



MR Safe



Caution



Storage Temperature



Humidity limitation



Medium



Not made with DEHP



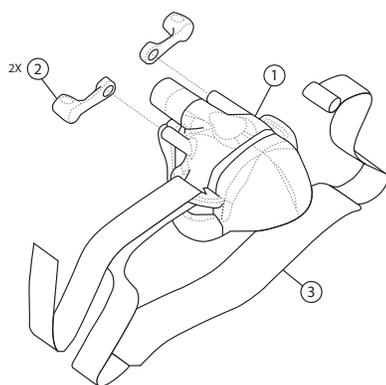
Large

### EN

### English

The SuperNO<sub>2</sub>VA Et Mask consists of:

1. Mask Chamber
2. Port caps
3. Strap



### Intended Use

The SuperNO<sub>2</sub>VA Et Mask is a nasal mask that creates a seal when positioned over a patient's nose to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care. It has a means for sampling expired gases from the patient's exhaled breath from the oral / nasal areas.

To be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of respiratory failure.

### Indications for Use

The SuperNO<sub>2</sub>VA Et Mask is intended for short-term (<24 hours) use on adult patients (>30 kg.). It is a single - patient use, disposable Mask.

### Instructions for Use

1. Review the sizing guidance chart to assist in choosing the best fitting SuperNO<sub>2</sub>VA Et Mask. The clinician should confirm proper fit to achieve required seal prior to selecting.



2. Remove SuperNO<sub>2</sub>VA Et Mask from packaging. Inspect the mask for damage. Discard and replace if necessary.
3. To monitor EtCO<sub>2</sub>, uncap gas sampling port on the SuperNOVA Et Mask. Attach the provided gas sampling line gently to the gas sampling port and the CO<sub>2</sub> monitoring device.
4. Lay patient down on the procedure surface with head on top of the head strap.
5. Place mask on patient's face and align the oral EtCO<sub>2</sub> hood to be just over the patient's mouth with the 15mm circuit port pointing cephalad.



6. To secure to the patient's face, wrap the head strap around patient's head, and slide the left head strap into the head strap cleat, and fold sideways over the cleat. With downward force, apply the desired pressure onto the patient's face and secure the head strap. The head strap may be placed above, below, or directly over the ear, depending on the user.



7. To connect to an anesthesia circuit, hyperinflation system or bag valve mask (BVM), make the connection to the standard 15mm fitting.



8. To use for continuous positive airway pressure (CPAP), or non-invasive ventilation (NIV), only connect with a circuit or device that has its own exhalation port.
9. To provide supplemental oxygen: First, disconnect the anesthesia circuit from the 15 mm circuit port. Second, remove the oxygen port cap and connect one side of oxygen tubing to the SuperNO<sub>2</sub>VA Et Mask's oxygen port and the other side to a transport oxygen tank or hospital wall supply oxygen.
10. Make sure all connections are secure.
11. For any seal leaks, adjust mask as needed.
12. To remove the SuperNO<sub>2</sub>VA Et Mask from the patient, simply detach the head strap from its connection and lift off the patient's face.

### Contraindications

The SuperNO<sub>2</sub>VA Et Mask is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.

### Warnings

1. Review the sizing guidance to assist in choosing the best fitting SuperNO<sub>2</sub>VA Et Mask. The clinician should confirm proper fit prior to use.
2. Excessive mask pressure can lead to facial/or optic nerve damage.
3. The SuperNO<sub>2</sub>VA Et Mask should only be used on adult patients >66lbs/30kg.
4. When used with anesthetic gases, ensure there is a proper connection to waste gas scavenging.
5. Do not allow the SuperNO<sub>2</sub>VA Et Mask's seal to come into direct contact with the patient's eyes; such action could lead to an eye injury. Use of mask may result in: drying of the eyes, eye pain, eye infections, or blurred vision.
6. Do not leave the head strap secured over the patient's ears for an extended period of time or use excessive pressure at any time; such action could lead to ear injury.
7. The mask may not be suitable for those predisposed to aspiration.
8. Discontinue using the mask if there is an allergic reaction to any part of the mask.
9. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary depending

**AU REP**

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on the pressure settings, patient breathing pattern, mask selection, and the leak rate. Monitor periodically the patient's oxygen levels while device is in use.

10. When the supplemental oxygen tubing is connected to the oxygen port and nasal ventilation is being performed, monitor peak airway pressures on the ventilator to avoid over-pressurization. Over-pressurization could cause lung injury (barotrauma).
11. The SuperNO<sub>2</sub>VA Et Mask is only for use by a trained clinician. Read all instructions prior to using the SuperNO<sub>2</sub>VA Et Mask.
12. Do not use the SuperNO<sub>2</sub>VA Et Mask near spark or open flame.
13. The SuperNO<sub>2</sub>VA Et Mask is MR safe when used with MRI compatible equipment.
14. The SuperNO<sub>2</sub>VA Et Mask is a single - patient device and is only to be used by one patient. Do not clean or sterilize. Sterilization or use of cleaning solutions may result in retention of harmful residues or leave the SuperNO<sub>2</sub>VA Et Mask nonfunctional.
15. Excess pressure may cause skin breakdown; evaluate the patient and periodically inspect for any signs of skin deterioration.
16. Do not use the SuperNO<sub>2</sub>VA Et Mask with an oral airway; such action may lead to oxygen desaturation.
17. Do not use the SuperNO<sub>2</sub>VA Et Mask when peak inspiratory pressures are anticipated to exceed 20cmH<sub>2</sub>O, as maintaining a proper seal to the face may be difficult and the use of high peak airway pressures may increase the risk for gastric insufflation.
18. The effect of mask dead space on patient ventilation should be evaluated on an individual basis.
19. Do not use after nasal surgery or if patient has nasal obstruction.
20. All connections must be secured prior to use.
21. To secure to the patient's face, wrap the head strap around patient's head, and slide the left head strap into the head strap cleat, and fold sideways over the cleat. With downward force, apply the desired pressure onto the patient's face and secure the head strap. The head strap may be placed above, below, or directly over the ear, depending on the user.
22. Remove SuperNO<sub>2</sub>VA Et Mask from the packaging, inspect the mask for damage, and discard and replace if necessary.
23. Conduct functional test prior to use.
24. To adjust gas flow to desired flow rate turn adjustable flow control valve to the fully closed position. Occlude patient connection knob on elbow by placing thumb over 15mm I.D. port opening and allow bag to inflate. Check for proper operation.

### Cautions

1. Federal (USA) law restricts this device to sale by or on the order of a physician.
2. To monitor EtCO<sub>2</sub>, uncap gas sampling port on the SuperNOVA Et Mask. Attach the provided gas sampling line gently to the gas sampling port and the CO<sub>2</sub> monitoring device.

### Storage Environment

Humidity: 0-85% RH  
Temperature: -20 to 50 ° C

### Performance Characteristics:

Max Pressure in Mask not to exceed 20cmH<sub>2</sub>O

### Clinical Benefits:

- Provides positive pressure to the airway to maintain upper airway patency
- Reduces the incidence and severity of hypoxemia
- Provides positive pressure ventilation

### Technical Specifications

Deadspace Volume:

Medium: 53ml

Large: 88ml

### Disposal Specifications

Dispose in container that is clearly labeled, leak-proof, and color-coded per local standards and state environmental regulations.

Incident Reporting: Notice to the user that any serious incident that has occurred in relation to the device should be reported to the manufacturer [productquality@myairlife.com](mailto:productquality@myairlife.com) and the competent authority of the Member State in which the user and/or patient is established.