AirLife®

SuperNO$_2$VA™ Et System – Medium, Large

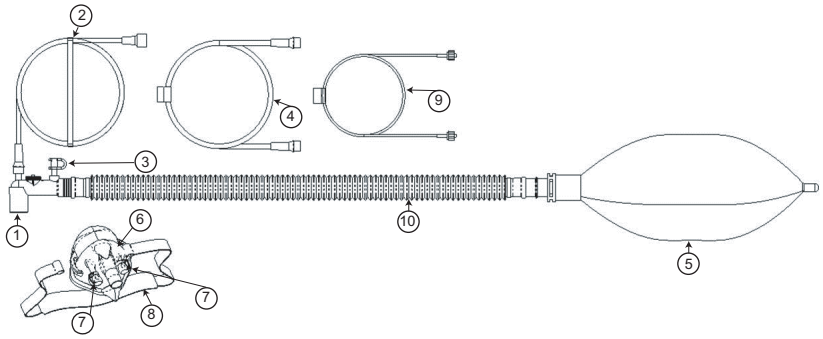
REF	Catalogue number	RX ONLY	U.S. Federal law restricts this device to sales by or on the order of a physician
LATEX	Not made with natural rubber latex		Manufacturer
	Caution	Single Use	Do not re-use
RHT DEHP	Not made with DEHP	MR	MR Safe
L	Large	M	Medium

en **English**

The SuperNO$_2$VA Et System consists of:

Flow-Inflating Bag:
1 Elbow circuit
2 Oxygen tubing
3 Manometer port cap
4 Manometer tubing
5 2L hyperinflation bag

SuperNO$_2$VA Et Mask:
6. Mask Chamber
7. Port Caps
8. Strap



Gas sampling line:
9 Gas sampling line

Corrugated tubing with bag adapter:
10 Corrugated tubing with bag adapter

Intended Use

The SuperNO$_2$VA Et System 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 through the compression of the hyper inflated reservoir bag, while allowing $EtCO_2$ sampling from the patient's exhaled breath from the oral/nasal areas.

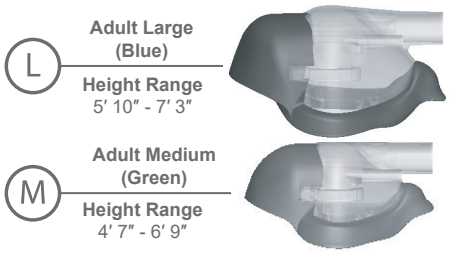
To be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of respiratory failure.

Indications for Use

The SuperNO$_2$VA Et System is intended for short-term (<24 hours) use on adult patients (>30 kg.). It is a single - patient use, disposable system.

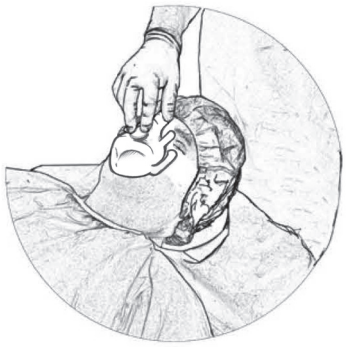
Instructions for Use

1. Review the sizing guidance chart to assist in choosing the best fitting SuperNO$_2$VA Et System. The clinician should confirm proper fit to achieve required seal prior to selecting.

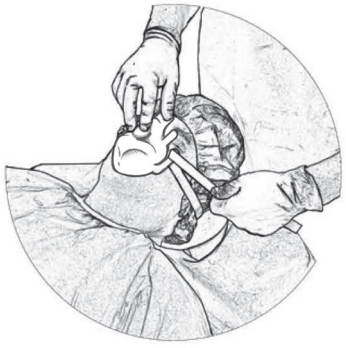


2. Remove SuperNO$_2$VA Et Mask and System frompackaging. Inspect the system for damage. Discardand replace if necessary.

3. Place mask on patient's face and align the oral $EtCO_2$ hood to be just over the patient's mouth with the 15mm circuit port pointing cephalad.



4. To secure to the patient's face, wrap the head straparound 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.



5. Attach the pre-assembled oxygen tubing to an oxygen flowmeter or an oxygen source and set to desired flow rate.
6. To monitor pressure, uncap manometer port and connect to appropriate manometer using tubing provided. Manometer port is located between adjustable flow control valve and the corrugated tubing.
7. Turn adjustable flow control valve to the fully closed position.
8. Occlude patient connection knob on elbow by placing thumb over 15mm I.D. port opening and allow bag to inflate. Check for proper operation.
9. With elbow still occluded, adjust flow meter and flow.
10. Connect hyperinflation system or bag valve mask (BVM) to standard 15mm fitting of the mask.
11. To monitor $EtCO_2$, uncap gas sampling port onthe SuperNOVA Et Mask. Attach the provided gas sampling line gently to the gas sampling port and the CO_2monitoring device.

AU REP

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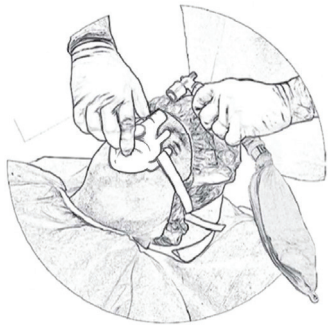
12. As bag inflates, initiate ventilation in accordance with recommended procedures. If bag overinflates, reduce gas flow and adjust flow control valve.



13. 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.
14. Make sure all connections are secure.
15. For any seal leaks, adjust mask as needed.
16. To only provide supplemental oxygen: First, disconnect the anesthesia circuit from the circuit port. Second, remove the oxygen port cap and connect one side of oxygen tubing to the SuperNO$_2$VA Et Mask oxygen port and the other side to a transport oxygen tank or hospital wall supply oxygen. Adjust gas flow to desired flow rate.
17. To remove the SuperNO$_2$VA Et Mask from the patient, simply detach the head strap from its connection and lift off the patient's face.

Contraindications

The SuperNO$_2$VA Et System 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$_2$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$_2$VA Et System should only be used on patients >66lbs/30kg.
4. When used with anesthetic gases insure there is a proper connection to waste gas scavenging.
5 Do not allow the SuperNO$_2$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. The SuperNO$_2$VA Et System is only for use by a trained clinician. Read all instructions prior to using the SuperNO$_2$VA Et System for the first time.
9. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary depending 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$_2$VA Et System shall be used in accordance with this IFU. Read all sections of this IFU prior to use. Improper use of this system may cause serious injury.
12. Do not use the SuperNO$_2$VA Et System near spark or open flame.
13. The SuperNO$_2$VA Et System is MRI safe when used with MRI compatible equipment.
14. The SuperNO$_2$VA Et System 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$_2$VA Et System 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$_2$VA Et Mask with an oral airway; such action may lead to oxygen desaturation.
17. Do not use the SuperNO$_2$VA Et Mask when peak inspiratory pressures are anticipated to exceed 20cmH$_2$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 Prior to system use on a patient, clinician should ensure that all connections and valves are operating correctly by setting the desired flow and pressure of the system before connecting to the SuperNO$_2$VA Et System. Failure to follow instructions could lead to patient injury.
21 This product should be used in conjunction with a manometer to determine the appropriate delivery pressure.
22 Only a pressure sensing device should be attached to the manometer port.
23. All connections must be secured prior to use.
24. 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.
25. Remove SuperNO$_2$VA Et System from the packaging, inspect the system for damage, and discard and replace if necessary.
26. Conduct functional test prior to use.
27. 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. The hyperinflation bag system is designed to be used by medical personnel familiar with manual ventilation and airway maintenance techniques.
2. Do not autoclave, gas, or chemically sterilize the system.
3. Re-use may degrade the performance of the product or contribute to cross contamination.
4. Federal (USA) law restricts this device to sale by or on the order of a physician.
5. To monitor EtCO$_2$, uncap gas sampling port on the SuperNOVA Et Mask. Attach the provided gas sampling line gently to the gas sampling port and the CO$_2$ monitoring device.

Storage Environment

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

Performance Characteristics:

Max Pressure in System not to exceed 20cmH$_2$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 : 58ml
Large 94ml

Disposal Specifications

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

Any serious incident that has occurred in relation to the device should be reported to the manufacturer at productquality@myairlife.com.