

AeroNOx

Portable Nitric Oxide Titration & Monitoring System

Operator's Manual

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AeroNOx

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SECTION I - IMPORTANT INFORMATION ABOUT NITRIC OXIDE DELIVERY

ATTENTION!

- AeroNOx Nitric Oxide Titration & Monitoring System delivers nitric oxide gas and measures nitric oxide and nitrogen dioxide gas concentrations in parts per million (ppm).
- “Caution: U. S. Federal and Canadian law restricts this device to sale by or on the order of a physician or other licensed medical practitioner. Outside Canada and the U. S., check with local laws for applicable restrictions.”
- “Persons using this device should be trained and experienced in the use of this device to assure effective administration of nitric oxide, and to avoid injury to the patient or to others resulting from inhalation of excess nitric oxide, nitrogen dioxide, or other reaction products.”
- “Persons using this device who may be particularly sensitive to nitric oxide or nitrogen dioxide, or who may be exposed to these gases for prolonged periods as a result of the use of this device, should be aware that the AeroNOx does not scavenge the exhaust gas, and that this gas is vented from the underside of the AeroNOx, or through the side vent in the event that the bottom port is occluded. Ambient concentrations of nitric oxide or nitrogen dioxide expected to result from the use of this device are less than 50 ppb.”

WARNING

The use of oxygen increases the danger of fire. Auxiliary equipment producing sparks should not be placed near the AeroNOx. Small quantities such as ether or alcohol left near the AeroNOx can cause fire.

Classification

According to the standard EN60601-1 of the International Electrotechnical Commission, *Medical electrical equipment, Part 1: General requirements for safety*, the AeroNOx is classified as follows:

- Class I / Internally Powered, according to the type of protection against electric shock.
- Ordinary, according to the degree of protection against harmful ingress of water.
- Continuous operation for the mode of operation.

SECTION II - UNPACKING AND SET-UP INSTRUCTIONS

Verify that the shipping carton (s) contain one of the following groups of equipment. Complete descriptions of these groupings can be found in this section.

1. **AeroNOx Transport, P/N 731-9148**
Nitric Oxide Titration & Monitoring System
2. **AeroNOx Bedside Option**
Nitric Oxide Titration & Monitoring System







The AeroNOx Transport P/N 731-9148
Nitric Oxide Titration & Monitoring System

Component	Part Number	Quantity
AeroNOx	731-9138	1
SS Hose with Quick Connect (3 ft.)	731-9371	1
AeroNOx Operating Manual	715-7000	1
AeroNOx Technical Manual	715-7001	1
12 V Universal Power Supply	293-0040	1
Medical Grade Power Cord	711-0179	1
SS NO Transport Delivery Regulators, CGA 626	731-9142	2
AeroNOx "NO WORRIES" Connector Sample Pak	731-9373	1
AeroNOx Calibration Circuit	415-0000	1
Single Calibration Screwdriver	416-0010	1

The AeroNOx must be used with calibration gas and accessories specified by the manufacturer.

Symbols

The following symbols appear in the AeroNOx documentation and labels. These internationally recognized symbols are defined by the International Electrotechnical Commission, IEC 417A and IEC 878 or by the Institute of Electrical and Electronics Engineers, 315(a).

	Direct current
	Positive to center pin, Negative to outer ring of connection
	Recycle or dispose of properly, contains sealed lead batteries
	Attention, consult accompanying documents

The AeroNOx Transport P/N 731-9148
Nitric Oxide Titration & Monitoring System

**Prepare the AeroNOx Transport Nitric Oxide
Titration & Monitoring System
for initial operation as follows:**

1. Unpack the AeroNOx and inspect for damage.
2. Install battery as per **SECTION III**, "Battery".
3. Unpack 12 V universal power supply (P/N 293-0040) and Medical Grade Power Cord (P/N 711-0179). Plug in AeroNOx and charge for ~ 24 hrs.
4. Calibrate AeroNOx. (See **SECTION V**.)
5. Attach CGA 626 regulators to the transport tanks as per "**Purge procedures to follow when changing tanks and/or regulators**" in this section.
6. Connect selected regulator outlet to the AeroNOx gas inlet using the stainless steel hose with quick connect adapters.
7. Turn on nitric oxide gas supply.
8. Attach the delivery line from the AeroNOx Bagger (See Diagram # 2) or the AeroNOx delivery line (P/N 415-0001) found in the AeroNOx "NO WORRIES" connector sample pak to the female luer connector marked "NITRIC OXIDE DELIVERY OUTLET" on the AeroNOx. Tee the other end of the delivery line into the patient breathing circuit at least 30 - 40 cm upstream of the sampling site (see Diagram # 1).
9. Attach the "NO WORRIES" sample line (P/N 415-0004) to the male luer connector marked "ANALYSIS SAMPLE INLET" on the AeroNOx.
10. Select the appropriate sample gas connector from your "NO WORRIES" connector sample pak and attach it to the free end of the sample line. *NB if attaching the sample line to the bagger, skip this step.
11. Connect the sample gas connector to the patient breathing circuit. The connector should be placed in the inspiratory limb, just prior to the patient wye connection (refer to Diagram # 1).

OR

- Connect the sample line to the sampling port on the bagger (see Diagram # 2).
12. "Flush" your system according to "Suggested flush procedure for the delivery portion of the AeroNOx system", or according to the instructions for the AeroNOx Bagger.
 13. You are now ready to deliver NO gas and sample mixed inspired gases.

CAUTION!

Never turn on the NO delivery gas without first turning on the ventilator or bagger flow. Failure to do this will result in undiluted delivery gas entering the sampling chamber and exposing the sensors to levels of NO and/or NO₂ which may damage the sensors.

CAUTION!

NO₂ gas may have collected in the AeroNOx delivery circuitry. Prior to delivering gas to the patient, "flush" your delivery system with fresh NO delivery gas. This should be repeated every time you begin NO gas administration. Analyze the gas for high NO₂ levels prior to patient connection.

Suggested “flush” procedure for the delivery portion of the AeroNOx system:

1. Set up the AeroNOx for delivery as outlined in “AeroNOx Transport Nitric Oxide Titration & Monitoring System for initial operation”.
2. Hook up the ventilator to a test lung (patient should be manually ventilated during this procedure and the ventilator parameters should be set to the patient’s pre-NO gas settings).
3. Inactivate the “Safety Shut Off” system by simultaneously depressing the NO and NO₂ alarm silence buttons for 5 seconds or until the display reads “SAFETY OFF”. For more information on the “Safety Shut Off” system, see “Safety Shut Off” in **SECTION III**.
4. Turn on the NO gas flow to 2 lpm by turning the knob on the precision metering valve in a counter-clockwise direction. This knob is located in the bottom right hand quadrant of the front panel of the AeroNOx below the LCD flow display. Allow the gas to flow into the ventilator circuit.
5. As soon as the NO₂ value has dropped to a stable level, allow the gas to run for an additional 3 seconds and then adjust the NO flow to the desired level (see **SECTION VII - Calculations for NO Delivery** to determine flow required for desired NO concentration).
6. Re-activate the “Safety Shut Off” system by simultaneously depressing the NO and NO₂ alarm silence buttons for at least 5 seconds or until the display reads “SAFETY ON”.
7. Once the desired NO concentration has been reached, ensure that NO₂ level is acceptable for patient administration. Below you will find a table which will give you the approximate NO₂ values you can expect for a given NO concentration and ventilator flow at an FiO₂ of 1.0.

Minute Volume / Ventilator Flow

[NO]	5	10	15	20
5 ppm	0.5	0.1	0.1	0.1
10 ppm	0.5	0.2	0.2	0.1
20 ppm	0.5	0.3	0.2	0.2
40 ppm	0.8	0.6	0.4	0.4
80 ppm	2.0	1.5	1.2	1.1

NO₂ in PPM

The table above is for reference only.

Factors such as the accuracy of the ventilator flow, percent error in delivery apparatus, and human error, may all affect the actual delivered patient dose. The calculated NO flow should be compared with the analyzed NO dose to confirm accurate NO dosing. Should the actual NO flow differ from the calculated NO flow by more than 10% beyond published specifications, the cause must be determined and corrected immediately. If the cause can not be immediately determined, ensure patient safety and contact International Biomedical at 1-512-873-0033 for further assistance.

8. Connect the patient to the ventilator and monitor according to study and/or institution protocol.

CAUTION!

The flush procedure must be performed each time NO therapy is started. This includes initial therapy starts, tank changes, and re-starting therapy after trials off NO.

Purge Procedures to follow when changing tanks and/or regulators.

Important!

Purge Procedure Required before Use

Please follow purge instructions below to ensure gas purity. Failure to follow these instructions may introduce potentially harmful contaminants into the patient's breathing gas or may affect the monitoring analyzer's accuracy by introduction of contaminants into the calibration gas.

Warning: Perform cylinder connection and purge procedures in well-ventilated areas to prevent inadvertent exposure to nitric oxide or nitrogen dioxide gas. Follow your facility's safety procedures for handling medical gas cylinders.

Purge Procedures for use with Medical Gas Regulators:

1. Connect cylinder to a matching CGA nitric oxide or nitrogen dioxide regulator only.
2. Open, then immediately close the cylinder valve.
3. Release (bleed) all of the gas from the regulator.
4. Repeat steps 2 and 3 four more times for a total of five purge cycles.
5. Leave the regulator installed until it is time to change to a new cylinder.
6. Repeat the purge procedure any time a regulator is reattached.

Any time a regulator is installed on a tank or cylinder of compressed gas, certain precautions must be followed. This is to prevent contamination of the gas in the tank and in the system by air that is trapped in the dead space of the regulator and fittings. To eliminate the possibility of the oxygen in this air reacting with the nitric oxide to form nitrogen dioxide in the system, the regulator and fittings must be purged before use. The valve on the tank must not be opened and left open until the regulator is purged. The stainless steel line must also be purged prior to connection to the AeroNOx.

CAUTION!

Should there be a sudden need to change therapy tanks, a second tank should always be purged and ready for immediate use. Perform the purge procedure immediately upon installation of a new regulator.

Although the dead space volume in the regulator and hose assembly is physically small, if it had been exposed to room air for a period of time it will contain sufficient oxygen to convert a significant amount of nitric oxide to nitrogen dioxide.

The following purge procedure must be followed any time a regulator is installed on a tank of gas. It should be done immediately after connecting a regulator to a tank to avoid contaminating a tank of gas with the air trapped in the dead space of the regulator in the event someone turns on and leaves on the valve on the tank.

1. Install and tighten the regulator onto the tank.
2. Insert the quick-connect on one end of the stainless steel hose into the quick-connect fitting on the regulator. Leave the other end of the stainless steel hose free.
3. Crack open and immediately close the tank valve.
4. Gently press the center tip of the quick-connect on the free end of the stainless steel hose against a clean hard surface and allow the pressure to bleed to zero. A small amount of high concentration delivery gas will be released at 50 psig. Keep the hose away from patients and clinicians in order to avoid exposure to the gas.
5. Repeat Step 3 and Step 4 above five times (five complete purge cycles).
6. Connect equipment and open the tank valve as needed.

Any time a regulator is installed onto a cylinder and before each patient use, the AeroNOx system should be purged. - NO EXCEPTIONS!!

AeroNOx Bagger: Instructions for use with the AeroNOx (See Diagram # 2.)

CAUTION!

- Oxygen and Nitric Oxide mix in the reservoir bag and stagnant flow will cause NO₂ to be formed. Turn off NO flow when not actively bagging patient. Flush the bagger with oxygen for a least 20 seconds to completely remove NO and NO₂ before and after patient use.
- Concentrations of nitrogen dioxide in the reservoir bag may exceed 1 ppm. Large tidal volumes may expose patients to the nitrogen dioxide in the reservoir bag.
- Flush the bagger with oxygen for at least 20 seconds to completely remove NO and NO₂ after any interruption in active patient bagging.
- The AeroNOx may not be able to detect rapid, short acting fluctuations in the concentration of the delivered gas, including nitrogen dioxide. For this reason, the AeroNOx Bagger is designed for short-term use only.
- If a patient requires nitric oxide concentrations other than 20 ppm, a separate system capable of providing the required concentration must be available. **DO NOT USE THE AERONOX BAGGER TO DELIVER CONCENTRATIONS IN EXCESS OF 20 PPM!** The generation of nitrogen dioxide increases rapidly above this concentration.
- Do not alter the length of the Bagger Gas Supply Tubing as this may cause generation of excessive levels of nitrogen dioxide.

- Do not substitute AeroNOx Bagger components! The AeroNOx Bagger has been designed and tested for patient safety with the components included in the current configuration.
 - The AeroNOx Bagger is designed for use only with the AeroNOx Delivery System. Do not attempt to use the AeroNOx with any other manual resuscitator. Do not attempt to use the AeroNOx Bagger with any other delivery system.
 - A backup system must always be available in the event that the primary system should fail. For instructions for use of a Back-Up System in the event of a failure of the AeroNOx system, please see **SECTION III**, Back-Up system.
 - The AeroNOx Bagger is intended to be connected directly to the patient's endotracheal tube. Do not insert any additional tubing between the AeroNOx Bagger and the endotracheal tube.
 - The AeroNOx Bagger is for single patient use only. Do not reprocess.
 - Persons using this device should be trained and experienced in the use of this device to assure effective administration of nitric oxide, and to avoid injury to the patient or to others resulting from inhalation of excess nitric oxide, nitrogen dioxide, or other reaction products.
 - Persons using this device who may be particularly sensitive to nitric oxide, or who may be exposed to these gases for prolonged periods as a result of the use of this device, should be aware that the gases exiting the AeroNOx Bagger are not scavenged.
1. Connect the large end of the bagger gas supply tubing to an oxygen source. Ensure that the small end of this tubing is connected to the NO / O₂ gas inlet port on the bagger.
 2. Connect AeroNOx Bagger gas delivery line to the AeroNOx delivery gas port.
 3. Connect male end of the sample line (P/N 415-0004) to the sampling port on the bagger gas supply tubing and the female end to the AeroNOx sampling port.
 4. Set O₂ flow on the O₂ flow meter to exactly 10 LPM. Let the oxygen run for at least 20 seconds to flush out any residual NO or NO₂ left in the AeroNOx Bagger.
 5. Turn on NO delivery gas source to 0.25 LPM. If you have correctly set your O₂ flow at exactly 10 LPM, the delivered NO concentration will be ~20 ppm and delivered NO₂ values should not exceed 0.2 ppm. **Do not exceed 20 ppm during manual ventilation!**
 6. Connect test lung and set overflow valve to desired positive end expiratory pressure (PEEP).

7. Continue to run the AeroNOx Bagger with the test lung until the analyzed NO and NO₂ values stabilize. This will prevent high doses of NO₂, which can form in the bagger and delivery line, from being delivered to your patient. **The NO₂ sensor in the AeroNOx Bagger may not react quickly enough to detect NO₂ boluses.** If you do not have time to use a test lung, in an emergency situation for example, **you must still flush the bagger with fresh gas for at least 20 seconds prior to patient connection!**
8. Analyze NO and NO₂ concentration prior to patient administration.
9. **Flush bagger with O₂ after each patient use to flush out residual NO and prevent NO₂ formation.**

AeroNOx Bagger Specifications:

O₂ Gas Flow	10 LPM
NO Gas Flow	0.25 LPM
Delivered [NO]	~ 20 ppm
NO₂ Generated	Maximum 0.2 ppm @ 20 ppm Delivered [NO]
Reservoir Volume	0.5 L
Bagger Dimensions	12" from Reservoir Bag to Patient Connection, ½" I. D.
Tidal Volume	Maximum 0.5 L (500 cc)
Breath Rate	Maximum 100 bpm at Pressures 18/5 (pip/peep) Maximum 50 bpm at Pressures 40/5 (Pressures Listed in cmH ₂ O)
I:E Ratio	Variable

Diagram # 1

- NO Titration with a Transport Ventilator

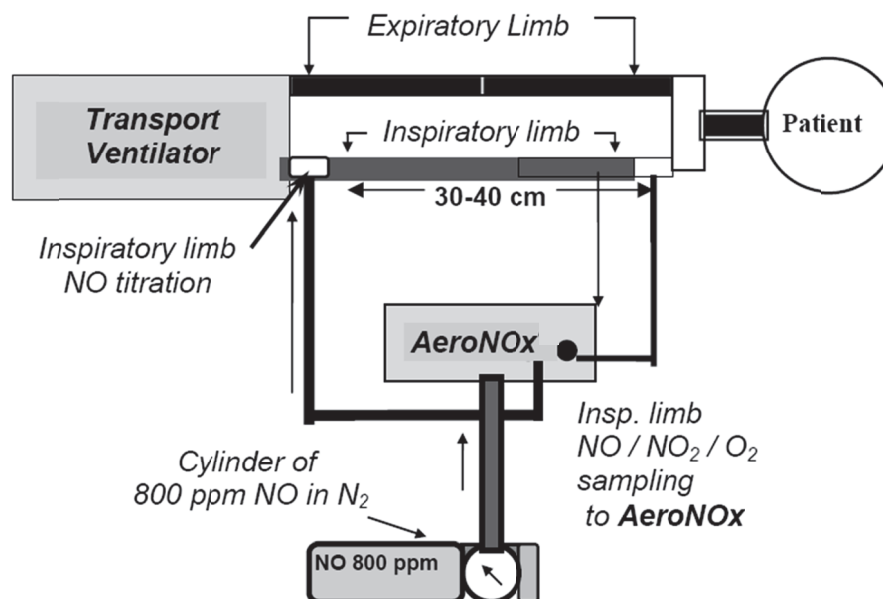
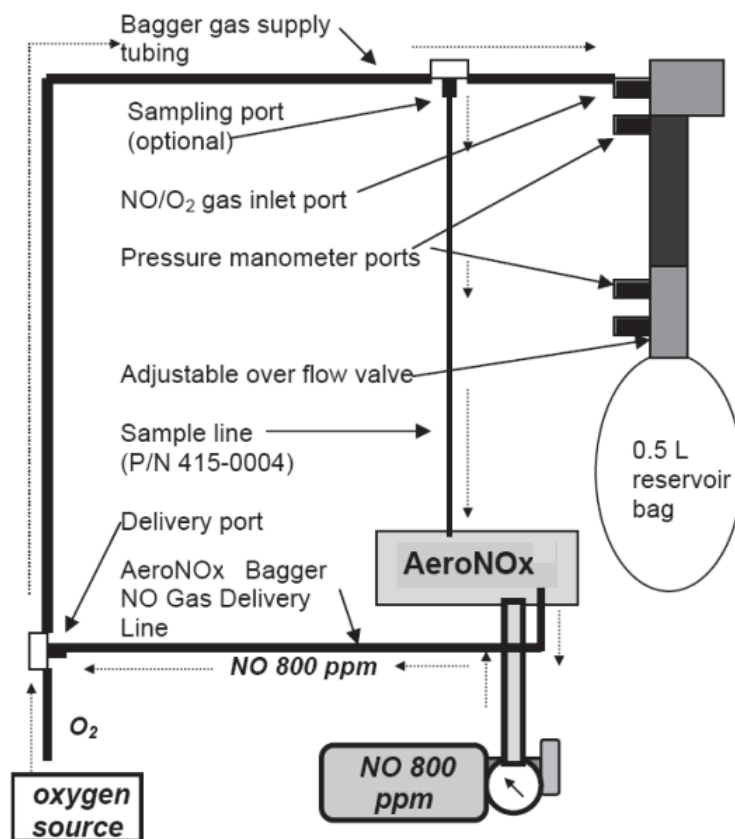


Diagram # 2 NO Titration with AeroNOx Bagger



The AeroNOx Bedside
Nitric Oxide Titration & Monitoring System

Component	Part Number	Quantity
AeroNOx	731-9138	1
AeroNOx Operating Manual	715-7000	1
AeroNOx Technical Manual	715-7001	1
AeroNOx Cart including Stand, Platform, Basket, & Power Bar		1
AeroNOx Mounting Block		1
12 V Universal Power Supply	293-0040	1
SS Hose with Quick Connect Fittings	731-9371	1
Medical Grade Power Cord	711-0179	1
CGA 626 NO Delivery Regulators	731-9142	2
AeroNOx "NO WORRIES" Connector Sample Pak	731-9373	1
AeroNOx Calibration Circuit	415-0000	1
Single Calibration Screwdriver	416-0010	1
Recommended Bedside Gases: (Not Included)		
Concentration: 800 ppm NO in balance N ₂ of pharmaceutical grade gas		2
Size: 38" (1 meter) height by 7" (18 cm) diameter		

The AeroNOx must be used with calibration gas and accessories specified by the manufacturer.

***Prepare the AeroNOx Bedside Nitric Oxide Titration & Monitoring System
for initial operation as follows:***

1. Unpack the AeroNOx and inspect for damage.
2. Install battery as per **SECTION III**, “Battery”.
3. Secure the therapeutic tanks to the AeroNOx cart.
4. Unpack 12 V universal power supply (P/N 293-0040) and Medical Grade Power Cord (P/N 711-0179). Plug in AeroNOx and charge for ~ 24 hrs.
5. Calibrate AeroNOx using the Calibration Kit (P/N 731-9145) NO and NO₂ Calibration Gas specified by the manufacturer and the instructions found in **SECTION V** of this manual.
6. Attach CGA 626 regulators (P/N 731-7142) to delivery gas cylinders as per **“Purge procedures to follow when changing tanks and/or regulators”** in this section.
7. Connect selected regulator outlet to the AeroNOx gas inlet using the stainless steel hose with quick connect adapters.
8. Turn on nitric oxide gas supply.
9. Attach the AeroNOx delivery line (P/N 415-0001) found in the AeroNOx “NO WORRIES” connector sample pak to the female luer connector marked “NITRIC OXIDE DELIVERY OUTLET” on the AeroNOx. Tee the other end of the delivery line into the patient breathing circuit at least 30 - 40 cm upstream of the sampling site. Attach the “NO WORRIES” sample line (P/N 415-0004) to the male luer connector marked “ANALYSIS SAMPLE INLET” on the AeroNOx.
10. Select the appropriate sample gas connector from your “NO WORRIES” connector sample pak and attach it to the free end of the sample line.
11. Connect the sample gas connector to the patient breathing circuit. The connector should be placed in the inspiratory limb, just prior to the patient wye connection (refer to Diagram # 3).
12. “Flush” your system according to “Suggested “flush” procedure for the delivery portion of the AeroNOx system”.
13. You are now ready to deliver NO gas and sample mixed inspired gases.

CAUTION!

Never turn on the NO delivery gas without first turning on the ventilator or bagger flow. Failure to do this will result in undiluted delivery gas entering the sampling chamber and exposing the sensors to levels of NO and/or NO₂ which may damage the sensors.

CAUTION!

NO₂ gas may have collected in the AeroNOx delivery circuitry. Prior to delivering gas to the patient, “flush” your delivery system with fresh NO delivery gas. This should be repeated every time you begin NO gas administration. Analyze the gas for high NO₂ levels prior to patient connection.

Suggested “flush” procedure for the delivery portion of the AeroNOx system:

1. Set up the AeroNOx for delivery as outlined in “AeroNOx Bedside Set-Up”.
2. Hook up the ventilator to a test lung (patient should be manually ventilated during this procedure and the ventilator parameters should be set to the patient’s pre-NO gas settings).
3. Inactivate the “Safety Shut Off” System by simultaneously depressing the NO and NO₂ alarm silence buttons for 5 seconds or until the display reads “SAFETY OFF”. For more information on the “Safety Shut Off” system, see “Safety Shut Off” in **SECTION III**.
4. Turn on the NO gas flow to 2 lpm by turning the knob on the precision metering valve in a counter-clockwise direction. This knob is located in the bottom right hand quadrant of the front panel of the AeroNOx below the LCD flow display. Allow the gas to flow into the ventilator circuit.
5. As soon as the NO₂ value has dropped to a stable level, allow the gas to run for an additional 3 seconds and then adjust the NO flow to the desired level (see **SECTION VII - Calculations for NO Delivery** to determine flow required for desired NO concentration).
6. Re-activate the “Safety Shut Off” system by simultaneously depressing the NO and NO₂ alarm silence buttons for at least 5 seconds or until the display reads “SAFETY ON”.
7. Once the desired NO concentration has been reached, ensure that NO₂ level is acceptable for patient administration. Following, you will find a table which will give you the approximate NO₂ values for a given NO concentration and ventilator flow at an FiO₂ of 1.0.

Minute Volume / Ventilator Flow

[NO]	5	10	15	20
5 ppm	0.5	0.1	0.1	0.1
10 ppm	0.5	0.2	0.2	0.1
20 ppm	0.5	0.3	0.2	0.2
40 ppm	0.8	0.6	0.4	0.4
80 ppm	2.0	1.5	1.2	1.1

NO₂ in PPM

The table above is for reference only.

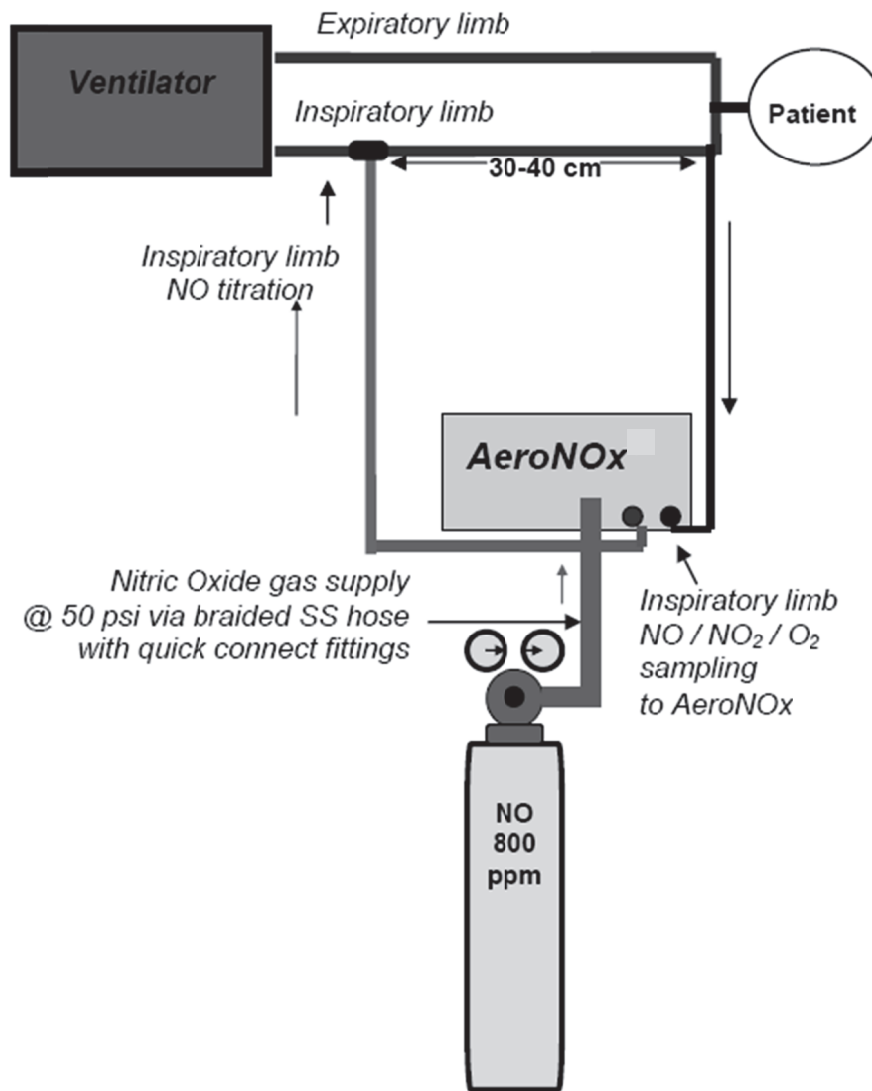
Factors such as the accuracy of the ventilator flow, percent error in delivery apparatus, human error, and accuracy of calibration of the AeroNOx may all affect the actual delivered patient dose. The calculated NO flow should be compared with the analyzed NO dose to confirm accurate NO dosing. Should the actual NO flow differ from the calculated NO flow by more than 10% beyond published specifications, the cause must be determined and corrected immediately. If the cause cannot be immediately determined, ensure patient safety and contact International Biomedical at 1-512-873-0033 for further assistance.

8. Connect the patient to the ventilator and monitor according to study and/or institution protocol.

CAUTION!

The flush procedure must be performed each time NO therapy is started. This includes initial therapy starts, tank changes, and re-starting therapy after trials off NO.

Diagram # 3 AeroNOx Bedside Set-Up



The Sensormedics 3100A or 3100B

To set up the AeroNOx for use with the 3100A & 3100B, tee in the AeroNOx Delivery Line (P/N 415-0001) immediately post humidifier. To connect the “NO WORRIES” sample line, you will require the 3100A / 3100B sample port adapter (P/N 415-0009). The port can be placed in one of three positions. All three positions are labeled as “temperature probe ports” in the 3100A / 3100B literature. The “set back” temperature port is pictured in Figure 1 and Figure 2. The proximal temperature port is pictured in Figure 3. The third port (not shown) is the second proximal temperature probe port located next to the “dump valve” on the inspired limb of the flexible circuit.

Sampling Ports for the Sensormedics 3100A / 3100B:

Figure 1 The “Set Back” Temperature Probe Port



Figure 2 The “Set Back” Temperature Probe Port



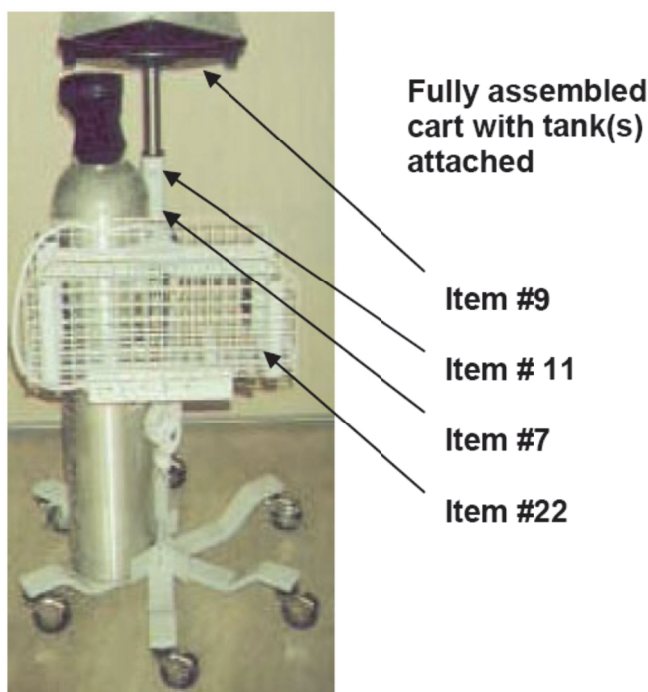
Figure 3 The Proximal Temperature Probe Port



AeroNOx
Portable Cylinder Cart and Platform

Initial Set-Up: See package insert for complete instructions.

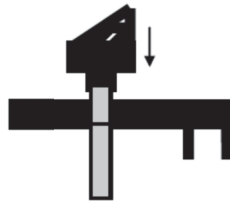
- **Tools Required:** Allen key (supplied)
- 1. Remove screws (Item 11) from base pole.
- 2. Lift support wheel (Item 9) so hole locations in base pole and support wheel pole (Item 7 & 9) are aligned.
- 3. Insert screw (Item 11) and tighten securely into base pole.
- 4. Attach basket assembly to tank bracket via the four button head 10-32 × 5/16 screws (Item 22) provided.



Description

- The AeroNOx Cart is a strong six-wheeled cart with two locking wheels. It can hold two 2040 L Aluminum cylinders which are ~ 38" (1 meter) in height and ~ 7" (18 cm) in diameter.
- Beneath the basket holder is a medical grade 120 V power bar with a 3 prong plug and four power outlets.
- The AeroNOx platform has a handle to allow movement of the cart, and a hook designed to mount to the bed's foot or headboard which allows the cart, cylinders, and AeroNOx system to be transported with the patient within the hospital. **(See Diagram # 5.)**
- The AeroNOx unit is attached to the cart platform by a metal block which fits into a ½" hole in the black platform. The AeroNOx unit is secured onto the mounting block by an aluminum sliding bracket, allowing secure bedside use and quick disconnect capabilities. **(See Diagram # 4.)**

Diagram # 4

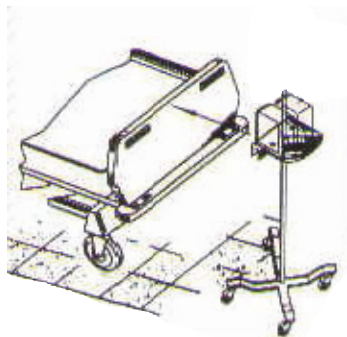


Mounting block fits into hole on the AeroNOx[®] platform.

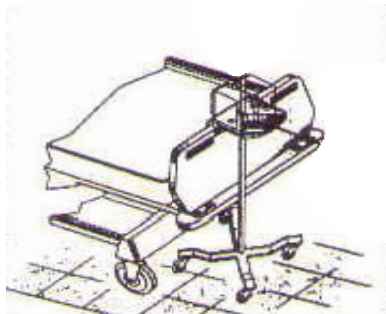
Room to Room Transport with the AeroNOx & Cart

The AeroNOx bedside system and tanks can be moved short distances with the patient by hooking the black platform onto the bed's foot or head board, and raising the bed slightly, so as to partially un-weight the wheels.

Diagram # 5



**AeroNOx & Cart
(tanks not shown for clarity)
ready to attach to the bed in
the lowered position.**



**AeroNOx and Cart partially
lifted by raising the bed
when the cart is attached to
the bed rail.**

CAUTION!

A fully loaded AeroNOx system with tanks weighs over 150 lbs (~ 68 kgs). Do not use the bed to lift the system completely off of the floor due to risk of serious injury to the patient, clinicians, or damage to the bed.

Stability & Safety:

The cart and monitor platform are designed to be stable when a NO cylinder is strapped to the cart. The unit occupies minimal floor area at the bedside, and can be placed behind or beside the mechanical ventilator.

CAUTION!

Support the cart when changing out tanks at the bedside.

SECTION III - DEVICE DESCRIPTION

General

The AeroNOx system includes an integrated nitric oxide gas delivery system and nitric oxide (NO), nitrogen dioxide (NO₂) and oxygen (O₂) analyzer. The AeroNOx is a stand-alone, lightweight, portable unit designed to continuously monitor NO, NO₂, and O₂ concentrations in a breathing circuit.

The AeroNOx system is specifically designed for the delivery and monitoring of gaseous nitric oxide (NO) in parts per million (ppm) concentrations.

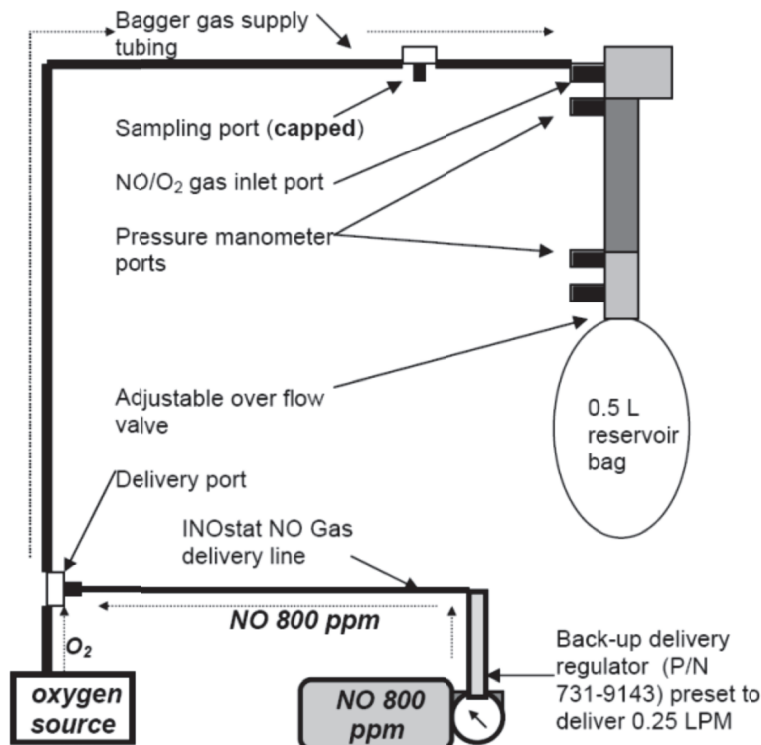
The construction materials are compatible with NO and will not contaminate the gas stream.

Recommended Use:

The AeroNOx Portable Nitric Oxide Titration & Monitoring System is designed for use with **continuous flow systems** as either a:

- Primary nitric oxide delivery system
- Transport system
- Backup delivery system in case of emergency
- The AeroNOx has been tested for use with the AeroNOx Bagger, the Bird VIP (in continuous flow modes only), the Sechrist 100IVB, the SensorMedics 3100A & 3100B, the Infant Star 100 Neonatal Ventilator, the MVP-10 Ventilator, the CV2i Ventilator, and the Percussionaire Bronchotron Ventilator.
- The AeroNOx is not MRI compatible.

**Diagram # 6 The INOstat Flow Inflating Bagger:
Use as a back-up system (independent of the AeroNOx system).**



Back-Up System:

An alternate means of delivering nitric oxide to your patient must be available should your primary system fail. For this reason International Biomedical has an available back-up system, the INOstat Kit (P/N 731-9147), for use in the event that your AeroNOx system should fail. This system consists of a flow inflating bagger, and a specially designed regulator with a preset NO delivery flow of 0.25 LPM.

Check INOstat Kit or other back up system for the AeroNOx for functionality on initial set up and periodically during use.

To ensure that the back up system to the AeroNOx is always ready for emergency use, the functionality of the system should be confirmed on initial set up and periodically during use.

To check the functionality for INOstat Kit baggers, follow the instructions provided in the package inserts. These instructions read:

Set Up:

1. Connect the large end of the bagger gas supply tubing to an oxygen source. Ensure that the small end of this tubing is connected to the NO/O₂ gas inlet port on the bagger.
2. Connect the back up delivery regulator (P/N 731-9143) to the INOstat NO gas delivery line.
3. Ensure that the sampling port on the bagger gas supply tubing is capped.
4. Place the system in a place that is readily accessible in the event of an emergency.

CAUTION! Confirm that the system is functional and delivering 20 ppm on initial set up by connecting the sampling system of the AeroNOx to the port that is normally kept capped on the bagger. Recheck functionality periodically.

CAUTION!

- Oxygen and Nitric Oxide mix in the reservoir bag and stagnant flow will cause NO₂ to be formed. Turn off NO flow when not actively bagging patient. Flush the bagger with oxygen for at least 20 seconds to completely remove NO and NO₂ before and after patient use.
- Concentrations of nitrogen dioxide in the reservoir bag may exceed 1 ppm. Large tidal volumes may expose patients to the nitrogen dioxide in the reservoir bag.
- Flush the bagger with oxygen for at least 20 seconds to completely remove NO and NO₂ after any interruption in active patient bagging.
- Rapid, short acting fluctuations in the concentration of the delivered gas, including nitrogen dioxide are possible. For this reason, the INOstat Bagger is designed for short-term use only.

- If a patient requires nitric oxide concentrations other than 20 ppm, a separate system capable of providing the required concentration must be available. **DO NOT USE THE INOSTAT BAGGER TO DELIVER CONCENTRATIONS IN EXCESS OF 20 PPM!** The generation of nitrogen dioxide increases rapidly above this concentration.
- Do not alter the length of the Bagger Gas Supply Tubing as this may cause generation of excessive levels of nitrogen dioxide.
- Do not substitute INOstat Bagger components! The INOstat Bagger has been designed and tested for patient safety with the components included in the current configuration.
- A backup system must always be available in the event that the primary system should fail.
- The INOstat Bagger is intended to be connected directly to the patient's endotracheal tube. Do not insert any additional tubing between the INOstat Bagger and the endotracheal tube.
- The INOstat Bagger is for single patient use only. Do not reprocess.
- The INOstat Kit is for use only in the event of primary nitric oxide delivery device (AeroNOx) failure and is not intended for use as a primary system.
- The Back-Up delivery regulator in the INOstat Kit has a preset flow and is for use only with the INOstat Bagger. Do not attempt to use this regulator as a delivery regulator for any other application.
- Persons using this device should be trained and experienced in the use of this device to assure effective administration of nitric oxide, and to avoid injury to the patient or to others resulting from inhalation of excess nitric oxide, nitrogen dioxide, or other reaction products.
- Persons using this device who may be particularly sensitive to nitric oxide, or who may be exposed to these gases for prolonged periods as a result of the use of this device, should be aware that the gases exiting the AeroNOx Bagger are not scavenged.

When used according to the instructions in this manual, the INOstat Kit will deliver a fixed concentration of 20 ppm NO (± 4 ppm). For this reason, the INOstat Kit should be used only during periods when the AeroNOx has failed or cannot be used for other unanticipated reasons, unless the patient is known to have no adverse effects at 20 ppm.

INostat Kit: Instructions for Use

Your back-up system should be set up and ready for use at all times during inhaled nitric oxide therapy. Clinicians should familiarize themselves with the use of the INostat Kit. The adjustable overflow valve in the flow inflating manual resuscitator (Bagger) will help to control the amount of PEEP delivered. It is adjusted by turning the valve to adjust the size of the opening to atmosphere.

Set-Up:

1. Connect the large end of the bagger gas supply tubing to an oxygen source. Ensure that the small end of this tubing is connected to the NO/O₂ gas inlet port on the bagger.
2. Connect the back-up delivery regulator (P/N 731-9143) to the INostat NO gas delivery line.
3. Ensure that the sampling port on the bagger gas supply tubing is capped.
4. Place the system in a place that is readily accessible in the event of an emergency.

Using the Bagger:

1. Start the oxygen flow at exactly 10 LPM.
2. Open up the valve on the back-up delivery gas cylinder. NO flow is preset at 0.25 LPM.
3. Allow 20 seconds for the combined gas supply to flow freely from the bagger. This will flush out any residual NO₂ that may have formed in the bagger or delivery system since the bagger was last used.
4. Begin manually ventilating your patient. If you have properly set the O₂ flow at exactly 10 LPM, the delivered NO dose will be ~ 20 ppm.
5. Once you are finished using the bagger, turn off the NO gas flow and run O₂ through the bagger (for at least 60 seconds) to flush out any residual NO or NO₂.

INostat Bagger Specifications:

O₂ Gas Flow	10 LPM
NO Gas Flow	0.25 LPM
Delivered [NO]	~ 20 ppm
NO₂ Generated	Maximum 0.2 ppm @ 20 ppm Delivered [NO]
Reservoir Volume	0.5 L
Bagger Dimensions	12" from Reservoir Bag to Patient Connection, ½" I. D.
Tidal Volume	Maximum 0.5 L (500 cc)
Breath Rate	Maximum 100 bpm at Pressures 18/5 (pip/peep) Maximum 50 bpm at Pressures 40/5 (Pressures Listed in cmH ₂ O)
I:E Ratio	Variable

Titration Delivery System

Nitric oxide gas is regulated to 50 psig by a CGA 626 nitric oxide regulator. It is then delivered via stainless steel high pressure hose to the AeroNOx unit. (See Diagram # 7.) A precision metering valve (controlled by the operator on the front panel) regulates the NO gas flow to the patient circuit.

CAUTION!

Powering the unit off will shut off the delivery gas flow. Gas flow is terminated when the unit is powered off, whether intentionally, or during a complete loss of power.

The NO gas flow is measured by a mass flow meter before it is delivered via the “NO WORRIES” delivery line (P/N 415-0001) into the breathing circuit. The mass flow meter’s range is from 0 - 2 LPM in 10 mL/min (0.01 LPM) increments.

CAUTION!

DO NOT exceed 2.00 LPM as displayed on the AeroNOx flow meter digital display. Displayed values in excess of 2.00 LPM are not accurate. If the flow on the AeroNOx flow meter is set at a value greater than 2.00 LPM, the delivered flow will be higher than the displayed flow value.

The suggested titration point is in the inspiratory circuit at least 30 - 40 cm upstream of the sampling site. The high concentration source gas (~800 ppm NO, balance N₂) is diluted in the breathing circuit’s air / oxygen mixture to the desired dosage.

This distance is required to ensure complete mixing of the nitric oxide with the carrier gas. Distances greater than 30 - 40 cm may increase the amount of NO₂ generated.

The initial nitric oxide flow rate required to get a desired [NO] can be **estimated** from the following dilution formula. For more information, see **SECTION VII**, Calculations and Troubleshooting.

$$\text{NO Flow (LPM)} = \frac{\text{Vent Flow (LPM)} \times [\text{NO}] \text{ Desired}}{\text{Source [NO] in Tank}}$$

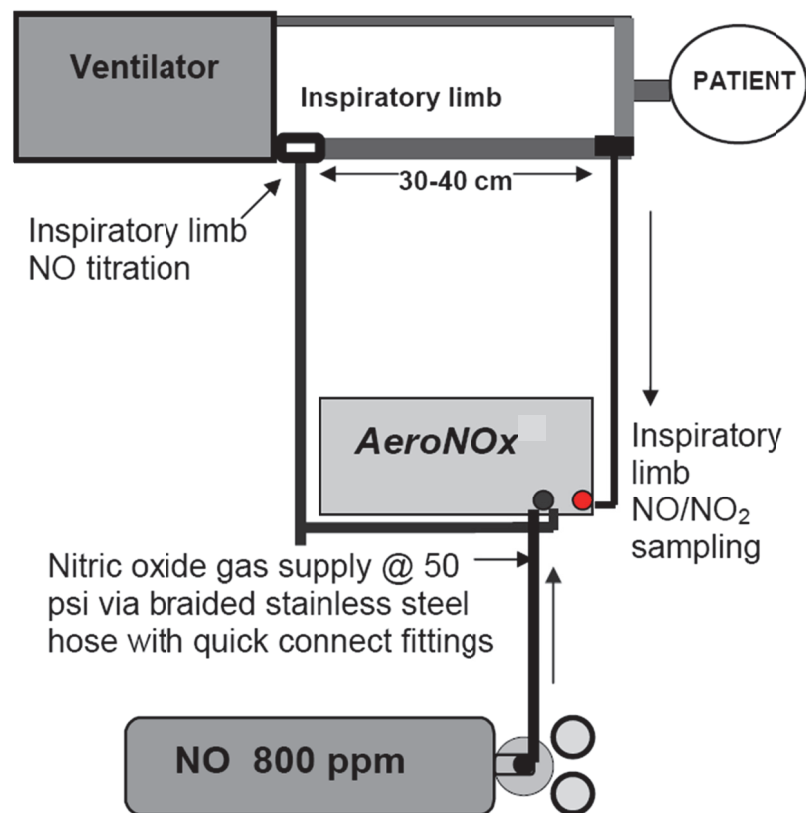
NO / NO₂ and O₂ Sampling

The AeroNOx system continuously draws a mixed gas sample @ ~ 150 mL/min from the breathing circuit at a point in the inspiratory circuit nearest the patient connection. **(See Diagram # 7.)** The sample is drawn through a **Nafion** gas drying element, which removes water vapor only, using a patented electrically charged membrane. The dry sample gas is then drawn through a 5 micron hydrophobic filter into the device and into the sensor housing where gas analysis of NO (ppm), NO₂ (ppm) and O₂ (%) takes place.

CAUTION!

Do not use the AeroNOx without the “NO WORRIES” sample line (P/N 415-0004) which includes both the Nafion tubing and the hydrophobic filter for removing condensing humidity from the sample gas. Failure to do so may impair the function of the AeroNOx as well as decrease the life of the internal components. WARRANTY MAY NOT BE HONORED FOR DAMAGE CAUSED IN THIS MANNER!

Diagram # 7 AeroNOx: Gas Supply, NO Delivery, and Gas Sampling



Sensors

The **AeroNOx** is supplied with one **nitric oxide** sensor and one **nitrogen dioxide** sensor in the delivery & analysis module. AeroNOx sensors are designed to provide trouble-free use for about twelve (12) months. Lifetime of the AeroNOx sensor will depend entirely on the concentration of NO or NO₂ being analyzed. The normal lifetime is about 1000 hours of continuous use when exposed to 100 ppm NO and 10 ppm NO₂ respectively.

The AeroNOx sensors must have a bias voltage going to them at all times. The battery must be charged in order to maintain this “bias voltage”. The AeroNOx maintains this voltage even when the power button is in the “off” position. This means that the battery is being drained even when the unit is powered off. For this reason, it is recommended that the AeroNOx be plugged in whenever possible to avoid the possibility of draining the battery to the point where it can no longer maintain the “bias voltage” necessary to keep the sensors in a ready state.

Unbiased sensors will need up to 48 hours to fully bias. This applies to the installation of new sensors as well as to sensors which have lost their bias due to a loss of battery power. Unbiased sensors will read a value greater than zero when exposed to room air. This value will continue to drop as the sensor biases. Once the value has dropped to zero, the AeroNOx must be re-calibrated prior to use.

CAUTION!

The NO₂ sensor may easily be damaged by inadvertent high levels of NO₂. Use nitrogen or air to flush the system after high levels of NO (> 100 ppm) or NO₂ (> 20 ppm) have been introduced to the sensor.

CAUTION!

Condensing humidity will impair the function of the AeroNOx sensors. Use only “NO WORRIES” sampling line (P/N 415-0004) which utilizes *Nafion* tubing to prevent condensing humidity from reaching the sensors.

In the unlikely event that the sensor(s) gets wet, turn the unit on and sample dry room air to allow the *AeroNOx delivery & analysis module* to dry out. Once dry, the AeroNOx sensors will function normally.

Analysis

Electrochemical sensors in the AeroNOx measure NO and NO₂ concentrations in parts per million (ppm). NO values are displayed to the nearest ppm while NO₂ values are displayed to the nearest tenth (0.1) parts per million. The electrochemical sensors operate by allowing NO and NO₂ molecules to diffuse across a membrane located on the top of the sensor. Once inside the cell, these molecules react in an electrolyte solution augmenting an electrical current between an anode and a cathode. The augmented current is proportional to the NO or the NO₂ concentration. The AeroNOx also samples oxygen % for added safety.

Alarms

The AeroNOx unit has adjustable alarm limits for NO & NO₂. Audible and visual alarms are activated at the value that is set by the user; with the exception of the NO₂ high alarm setting which can manually be adjusted to 99 ppm, but has a factory set default alarm of 11 ppm should the user set the alarm at 11 or higher. By carefully choosing alarm limits, any deviations in NO or NO₂ concentrations will be known as soon as possible.

CAUTION!

There are no alarms for the oxygen analysis portion of the AeroNOx. An auxiliary oxygen analyzer, such as the MiniOX 3000 by MSA, with audible and visual alarms must be used in conjunction with the AeroNOx.

Safety Shut Off

For patient safety, the AeroNOx has incorporated a “safety” shut-off system for the delivery of NO gas. The system is designed to avoid inadvertent high doses of NO being delivered to the patient by terminating the flow of NO gas to the delivery line. The system is activated when the NO dose analyzed is 5 ppm above that which has been set as the high NO alarm (or 100 ppm whichever is the lesser value) and 1 ppm above that set for the high NO₂ alarm (or 12 ppm whichever is the lesser value). The system is designed to restore the flow of gas to the delivery line once the analyzed NO and/or NO₂ values drop back to below the 5 ppm above and 1 ppm above alarm values. The default setting for this alarm is “activated”, that is, no action is required by the user to enable the safety system. To verify that the system is activated, simultaneously depress the NO and NO₂ alarm silence buttons. The display will read “SAFETY ON”. **Do not depress the alarm silence buttons for more than 4 seconds as this will disable the “safety” shut-off system!**

Should the “safety” shut-off system be triggered, (that is, an alarm condition has occurred) there will be an audible as well as a visual alarm, and the display will alternately read “NITRIC OFF” and the sensor data.

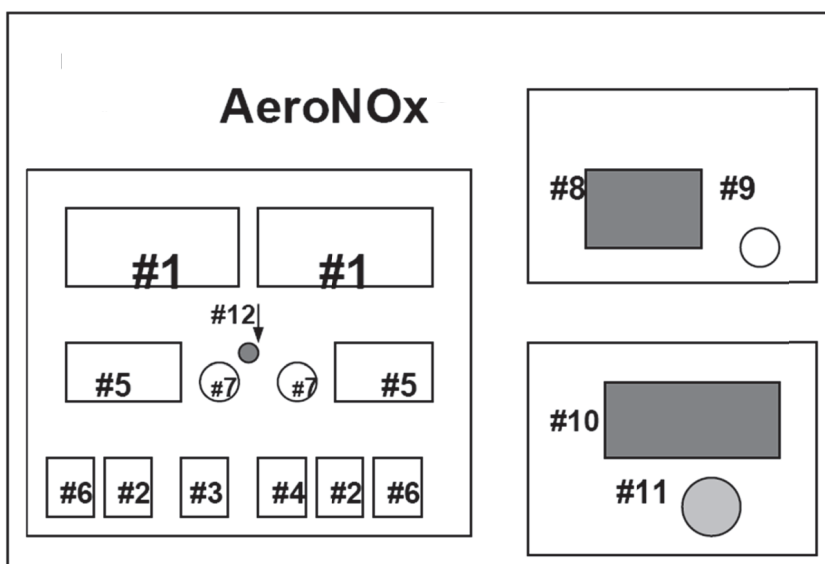
Your patient will not receive any NO gas from the AeroNOx system during this condition!

It is recommended that you manually ventilate your patient with a system such as the INOstat Kit, capable of delivering a safe and known concentration of NO to your patient, while you troubleshoot the system to determine why the “safety” shut-off system was triggered. For information on the INOstat Kit back-up delivery system, see **SECTION III, Back-Up System**.

To override the system, simultaneously depress the alarm silence buttons for 5 seconds. The display will read “SAFETY ON” until 5 seconds have elapsed at which time it will read “SAFETY OFF”. At this point, the “safety” shut-off system has been inactivated. During the time that this system remains inactivated, the display will alternately display the “SAFETY OFF” message and the sensor data. To restore the “safety” shut-off to the activated mode, you may either simultaneously depress the alarm silence buttons for 5 seconds, or you may power the machine off and then back on again.

Diagram # 8

AeroNOx Front Panel



AeroNOx Front Panel

CONTROL	FUNCTION
1. Display of NO & NO ₂ in ppm	Back-lit, digital liquid crystal display of NO and NO ₂ ppm, calibration status and battery condition. (See "Battery" SECTION III .) A "plug" character in the display indicates that the wall power is connected and that the unit is charging.
2. "Zero" NO & NO ₂	Automatically zeros the corresponding NO or NO ₂ sensor. Displays " DONE! " on the LCD when zeroed.
3. Power	Turns on / off power, except that which is necessary to maintain the sensor in a state of readiness.
4. LITE	Illuminates a back light for the LCD when depressed.
5. HIGH / LOW Adjustable Alarm Settings	Adjustable thumb-wheel alarm settings for high alarms (NO & NO ₂) and low alarms (NO).
6. Alarm Silence	Silences audible alarms for one minute .
7. Cal. NO & Cal. NO ₂ Calibration Pots	Turning these potentiometers adjusts the digital display to calibrate the analyzer against a known reference NO and NO ₂ gas source.
8. Oxygen %	Oxygen sensor with LED display
9. O ₂ Cal. Pot.	High point 100% calibration
10. NO Flow Meter	Mass flow meter with 3.5 digit LED display, range 0 - 2 LPM in 10 mL/min (0.01 LPM) increments
11. NO Flow Control	Precision metering valve
12. Check Sample Line	Illuminates when sample line becomes occluded

Diagram # 9



Gas connections:

1 2 3

1.	Quick Connect Gas Inlet	Female high pressure gas inlet, receives male connector on SS hose from delivery regulator
2.	Sample Gas Inlet	Male luer connector. Hydrophobic filter from sample line (P/N 415-0004) attaches here
3.	Delivery Gas Outlet	Female luer connector. Delivery line (P/N 415-0001) attaches here

CAUTION!

Luer fittings are common to both the AeroNOx and to most intravenous systems. Careful attention must be paid when connecting and disconnecting luer connections to avoid inadvertent administration of NO gas into a patient I. V. system.

Quick Connect Gas Fittings

The AeroNOx was designed with quick connect gas fittings for quick and easy connection from the AeroNOx to the delivery gas regulators. This can be utilized either when changing from an empty to a full cylinder, or when switching from a bedside to a transport cylinder and vice versa.

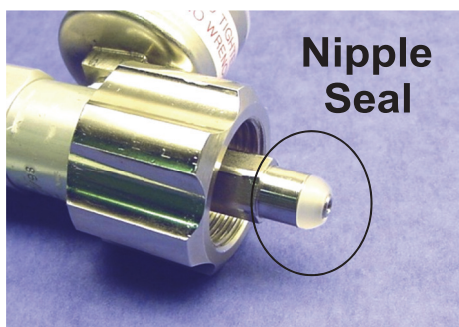
CAUTION!

Ensure the regulator is purged prior to connection to the patient circuit. See "Purge procedures to follow when changing tanks and/or regulators" in SECTION II.

To connect the fittings, insert the male quick connect on the SS hose into the female quick connect located on the AeroNOx unit and on the delivery regulators and push them together until an audible "click" is heard and the two connections stay together.

To disconnect, pull the sleeve on the female connector toward the male connector. The quick connects will release from each other with very little effort.

THE NIPPLE SEAL SHOWN IN THE PHOTO BELOW MAY LEAK IF NOT SECURELY FITTED TO THE NIPPLE.



TO ENSURE AN ADEQUATE SEAL BETWEEN THE TANK VALVE AND THE REGULATOR, HAND TIGHTEN THE NIPPLE SEAL UNTIL IT IS FULLY SEATED. DO NOT OVERTIGHTEN.

Luer Lock Connections

The sample gas inlet and the delivery gas outlet are equipped with luer connectors. These connectors are very common in the hospital environment because of the quick way that air tight connections can be made. These are the same connections found on I. V. tubing.

To attach the sample line (P/N 415-0004) to the sample gas inlet, simply fit the female luer on the hydrophobic filter on the sample line to the male luer located below and to the left of the handle on the AeroNOx and turn the hydrophobic filter in a clockwise direction until a firm connection is established. **To remove**, turn the hydrophobic filter in a counterclockwise direction, then gently pull the sample line free.

To attach the delivery line to the AeroNOx, fit the male end of the delivery line onto the female luer located below and to the right of the handle on the AeroNOx and turn in a clockwise direction until a firm connection is established. **To remove**, turn the male fitting in a counterclockwise direction.

CAUTION!

Do not use the AeroNOx without the “NO WORRIES” sample line (P/N 415-0004) which includes both the Nafion tubing and the hydrophobic filter for removing condensing humidity from the sample gas. Failure to do so may impair the function of the AeroNOx as well as decrease the life of the internal components. WARRANTY MAY NOT BE HONORED FOR DAMAGE CAUSED IN THIS MANNER!

Battery

The AeroNOx is supplied with a rechargeable 6 volt sealed lead acid battery. The unit is shipped with the battery disconnected to prevent the battery from fully discharging during shipping. To re-connect the battery, remove the battery compartment panel on the back of the AeroNOx. Connect the cable on the battery to the cable in the compartment. The expected life of the battery is approximately one (1) year. Battery life varies considerably depending on the amount of clinical use while the unit is unplugged.

The amount of charge that the battery holds is indicated by the letter “B” on the left hand side of the display. This character will appear as soon as the unit is disconnected from the power supply. As the charge that the battery holds increases, the letter “B” fills in until it resembles a solid “B”. There are six levels of charge indicated by how much of the “B” is filled in. When the power supply is connected to the AeroNOx, a character that resembles a power plug appears in place of the “B”. This character indicates that the unit is plugged in and is charging.

If “LOW BATTERY” Alarm Occurs:

- An audible alarm as well as a visual “LOW BATTERY” message will appear alternately with the sensor data when the battery no longer carries enough charge to reliably operate the electronics. This message will remain on the screen for approximately 4 minutes, depending on the condition of the battery. If the unit remains disconnected from the power supply, the screen will begin to alternately display the messages “CONNECT CHARGER”, “DATA INVALID”, and “NITRIC OFF” until the display fades out for lack of power. **GAS FLOW TO YOUR PATIENT WILL BE DISCONTINUED AT THIS TIME!** Gas flow to your patient is always terminated once the unit is powered off, intentionally or non-intentionally.

Should you completely lose battery function to the AeroNOx:

- Plug in the 12 V universal power supply and allow the internal charging circuit to recharge the battery.
- After the battery is recharged ~ 24 hours, recalibrate the sensors using the procedure in **SECTION V** of this manual.

Battery Maintenance & Storage:

- The battery discharges even when the monitor is turned off. For this reason, the AeroNOx should be kept plugged in whenever possible in order to prevent complete battery discharge.
- Should the AeroNOx need to be stored for periods greater than one week without being plugged in, the battery should be disconnected to prevent the battery from fully discharging.
- A fully discharged battery requires ~ 30 minutes to become functional and ~ 24 hrs to fully recharge.

Once the battery has discharged below a certain voltage, bias to the sensors is lost. An unbiased sensor can take up to 48 hours to become functional again. Unbiased sensors will read a value greater than zero when exposed to room air. This value will continue to drop as the sensor biases. Once the value has dropped to zero, the AeroNOx must be re-calibrated prior to use.

CAUTION!

Use only P/N 888-0115 as the battery source for the AeroNOx.

CAUTION!

Disconnect the battery when the unit is not in use for extended periods of time or if the system must remain unplugged for extended periods of time.

CAUTION!

Attempting to run the AeroNOx for longer than five hours on battery only could result in an interruption of Nitric Oxide Therapy.

Universal Power Supply

The universal power supply accepts a 100 - 240 V A/C ~ 50 - 60 Hz input, and supplies a +12 V D/C @ 3.3 A max. output.

For the AeroNOx, the universal power supply is both a voltage source for the internal charging circuit and an A/C power supply.

It will simultaneously power the analyzer and charge the internal battery. The internal charging circuit is self-regulating and will sense the condition of the battery, charging and not charging as required.

- It is recommended that the power supply be used whenever possible, to ensure the battery is kept fully charged.
- The analyzer is powered by the internal battery at all times. The plugging in or unplugging of the external power supply from either end will have no effect on the analyzer operation or battery life.

CAUTION!

Use only the universal power supply (P/N 293-0040) as a power supply to the AeroNOx.

SECTION IV - SPECIFICATIONS

NOTE: Standard conditions referred to throughout the specifications consist of the following:

Temperature (transport & storage)	- 20° C to + 40° C
Operating temperature	+ 5° C to + 40° C
Altitude	up to 3800 meters or 12,000 ft.
Relative Humidity	0 - 93% non-condensing

Functional Performance

Measurement range

- 0 to 100 ppm nitric oxide
- 0 to 12 ppm nitrogen dioxide
- 5 to 100 % oxygen

Meter Resolution

- 1.0 ppm nitric oxide
- 0.1 ppm nitrogen dioxide
- 0.1% oxygen

Sensor Accuracy

- ± 1 ppm nitric oxide
- ± 0.1 ppm nitrogen dioxide
- $\pm 2\%$ oxygen¹

Sensor Response Time

- 90% response to a change in [NO] in < 20 sec.
- 90% response to a change in [NO₂] in < 30 sec.
- 95% response to a change in O₂ (FiO₂) in < 30sec.

Sensor Stability

<2% signal loss per month

Device Accuracy²

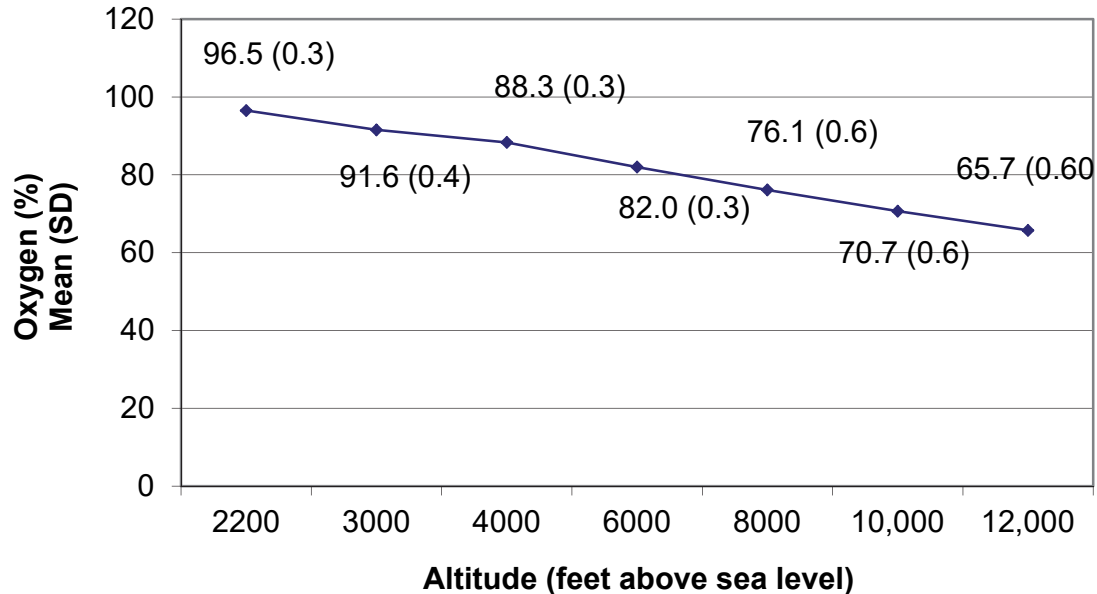
- ± 2 ppm nitric oxide
- ± 2 ppm nitrogen dioxide
- $\pm 3\%$ oxygen

¹ At the altitude at which it is calibrated, see next page for Effect of Altitude on the AeroNOx.

² Device accuracy is affected by the ventilator that is attached.

Effect of Altitude on the AeroNOx

Effect of Altitude on AeroNOx Oxygen Sensor
Test Conditions: PIP: 30 cmH₂O, PEEP: 5 cmH₂O, Ti: 0.3 seconds, RR: 60,
Flow: 10 LPM FiO₂: 1.0, NO: 20 ppm, ASCENDING
n=5



NO and NO₂ Sensors

The AeroNOx NO and NO₂ sensors are not pressure dependent and are thus unaffected by altitude changes during transport.

Oxygen Sensor

The oxygen sensor in the AeroNOx is affected by altitude (partial pressure) changes. The above graph shows a predictable linear slope for the first 4000 feet and then a nominal change between 4000 and 12,000 feet. As altitude increases, the oxygen percentage display will decrease to reflect the change in partial pressure at the corresponding change in altitude. The following formula can be used to calculate the predicted change in oxygen percentage at a specific altitude.

NOTE: Remember to first determine the effect of the NO delivery on the oxygen percentage as shown in **SECTION VII**, Calculations and Troubleshooting.

Step 1 - Calculate predicted change in oxygen percentage by multiplying the anticipated altitude reading by -4.71×10^{-3} . Use this factor between sea level and 4000 feet. If the flying altitude will be greater than 4000 feet above sea level, then use -2.56×10^{-3} factor. For example:

If the reading on the AeroNOx is 60% at an altitude of 2000 feet above sea level, then to calculate what the oxygen will be reading at a flying altitude of 8,000 feet above sea level you would calculate as follows:

$$\begin{aligned}\text{Calculated difference in Oxygen reading} &= (-2.56 \times 10^{-3}) \text{ New altitude} \\ &= (-2.56 \times 10^{-3}) 8,000 \\ &= -20.5\% \\ \text{New Oxygen reading} &= \text{Current reading} - \text{Calculated difference in Oxygen reading} \\ &= 60\% - 20.5\% \\ &= 39.5\%\end{aligned}$$

Flow Meter Display

The flow meter display will be affected nominally with a change in the altitude. However, the delivered and displayed NO will not change. The average change with flow meter displayed for 0.56 LPM at 2000 feet above sea level read 0.53 (SD=0.02) at 12,000 feet above sea level.

Alarms

- Manually adjusted thumb wheel switches with 1 ppm resolution
- NO: Low adjustable from 0 - 99, high adjustable from 0 - 99. Audible and visual alarm when actual value is at set alarm value
- NO₂: High audible and visual alarm when actual value is at set alarm value. Factory default setting for high NO₂ alarm is 11 ppm when thumb wheels are adjusted to 11 ppm or higher (thumb wheels adjustable to 99 ppm).
- Depressing the alarm silence button will deactivate the audible alarm, but not the visual alarm, for one minute. If the alarm condition corrects itself, the audible and visual alarm will deactivate. If the actual NO/NO₂ value reenters the alarm condition, the audible and visual alarms will be activated, even if one minute has not elapsed since the alarm silence button was pushed.

Sample Gas Flow

- 150 cc/min \pm 15%
- sampled gas is vented to the room through a vent located on the right-hand side of the AeroNOx

Sample Inlet Pressure

- Cyclic pressure up to 80 cmH₂O (Ti = 3.0 sec. and 6.6 cycles per minute)

Expected Life of Life-Limited Components under conditions of typical clinical usage:

- NO Sensormin. 2000 hours
- NO₂ Sensormin. 2000 hours
- Oxygen Cellmin. 2000 hours
- Sample Pump.....min. 2000 hours

Physical Specifications

Dimensions (H × W × D)	25.4 × 30.5 × 12.7 cm OR 10 × 12 × 5 inches
Weight (AeroNOx only)	~ 11 lb. (~ 4.8 kg.)
NO Flow Meter: Range Display Resolution Accuracy (Including Linearity)	0 - 2 LPM 10 cc ± 5% F. S.
Precision Metering Valve	~ 12 turns to fully open
Gas Supply	Recommend NO @ 800 ppm N ₂
Gas Fittings	CGA 626, Quick Connect & Luer
Power Supply	Internal 6 V sealed lead acid battery charged by Universal power supply
Battery Life	Fully charged will last at least 5 hours Battery life ~ 1 year

Safety

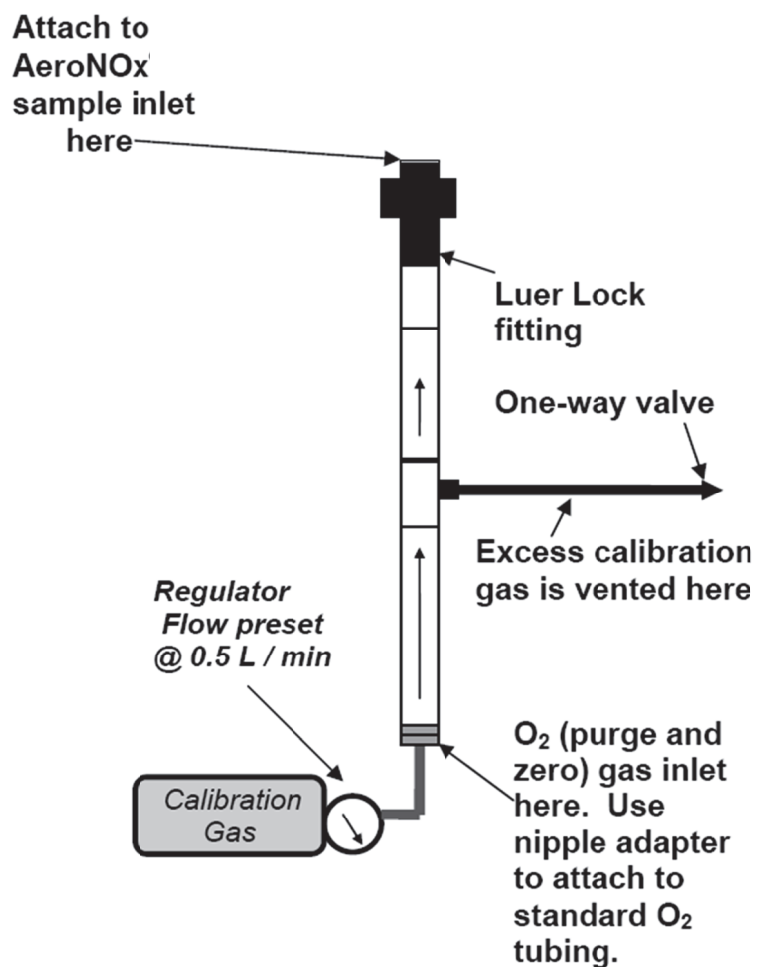
- **EMC:** Compliance with **EN60601-1-2**
- **Flammable anesthetics:** Not for use in the presence of flammable anesthetics
- **Regulatory Approvals:** CSA, ETL, CE
- Specifications are subject to change without notice.

SECTION V - CALIBRATION

Calibration of the AeroNOx NO / NO₂ / O₂ Analyzer

The AeroNOx must be used with calibration gas and accessories specified by the manufacturer.

Diagram # 10 AeroNOx Calibration Circuit (P/N 415-0000)



AeroNOx Calibration Procedure:

1. Turn Power on.
2. **Use only the calibration circuit supplied, P/N 415-0000.** Failure to use the supplied calibration circuit may result in damage to the AeroNOx or inaccurate calibration results.

OXYGEN SENSOR CALIBRATION

3. Connect the nipple end of the calibration circuit to oxygen tubing.
4. Run wall O₂ through the cal. circuit @ 0.5 LPM.
5. Connect the luer connector of the calibration circuit to the sample inlet of the AeroNOx.
6. Allow the O₂ reading to stabilize for 2 - 4 minutes. Calibrate oxygen sensor @ 100% by adjusting the calibration potentiometer using the calibration screwdriver (P/N 416-0010) provided. **** When using the oxygen analyzer to analyze oxygen concentrations below 30%, the oxygen analyzer should be re-calibrated to 21% oxygen to improve the accuracy in the lower range.**

ZERO BOTH NO & NO₂ SENSORS

The NO and NO₂ cells can be zeroed in oxygen or in room air. You may choose to leave the oxygen running during the zero procedure.

7. **NO Zero Procedure:** Zero the NO sensor by depressing and holding the NO zero button down. The words **ZERO NO** appear on the screen. The sensor is zeroed when the word **DONE!** appears.
8. **NO₂ Zero Procedure:** Zero the NO₂ sensor by depressing and holding the NO₂ zero button down. The words **ZERO NO₂** appear on the screen. The sensor is zeroed when the word **DONE!** appears.

CALIBRATE NO₂ SENSOR

9. Disconnect calibration circuit from the AeroNOx.
10. Disconnect the O₂ and attach NO₂ calibration gas to the calibration circuit.
11. Turn on the calibration gas flow by opening the valve located on the calibration gas cylinder. The calibration regulators (P/N 731-9141) are factory set to deliver 0.5 LPM. If you are not using these regulators, be sure to adjust the calibration gas flow to 0.5 LPM.
12. Connect calibration circuit to the AeroNOx as in Step 5.
13. Allow the NO₂ reading to stabilize for 2 - 4 minutes, or until the reading has not changed for at least 30 seconds. Adjust the NO₂ potentiometer on the front panel with the calibration screwdriver (clockwise to increase, counterclockwise to decrease) until the display matches the chemist's reported "ACTUAL" NO₂ reading on the gas cylinder label.

PURGE NO / NO₂ SENSORS

14. Disconnect the NO₂ calibration gas, and run oxygen through the calibration circuit @ 0.5 LPM (or allow room air to be drawn in to the analysis sample inlet) until both sensors read zero.

CALIBRATE NO SENSOR

15. Disconnect calibration circuit from the AeroNOx.
16. Disconnect the O₂ and attach NO calibration gas to the calibration circuit.
17. Turn on the calibration gas flow by opening the valve located on the calibration gas cylinder. The calibration regulators (**P/N 731-9141**) are factory set to deliver 0.5 LPM. If you are not using these regulators, be sure to adjust the calibration gas flow to 0.5 LPM.
18. Connect calibration circuit to the AeroNOx as in Step 5.
19. Allow the NO reading to stabilize for 2 - 4 minutes, or until the reading has not changed for at least 30 seconds. Adjust the NO potentiometer on the front panel with the calibration screwdriver (clockwise to increase, counterclockwise to decrease) until the display matches the chemist's reported "ACTUAL" NO reading on the gas cylinder label.
20. Disconnect the calibration circuit and allow room air to be sampled into the AeroNOx until the NO and NO₂ displays return to zero and the Oxygen sensor reads 21%. This is to flush out any calibration gas remaining in the AeroNOx sampling circuit after calibration. This step will help ensure the longevity of the AeroNOx sensors.

READY TO GO

The AeroNOx is calibrated and ready for use.

Important Reminders

1. The AeroNOx has been designed and tested for use with calibration gases specified by the manufacturer. International Biomedical cannot guarantee the accuracy of the AeroNOx when calibration gases other than specified gases are used.
2. Use only the calibration circuit provided to avoid damage to the AeroNOx or inaccurate calibration results.
3. Zero NO & NO₂ sensors daily & calibrate weekly when in use.
4. The AeroNOx holds its calibration even when the unit has been powered off. This allows for the unit to be calibrated and then stored until it is needed. There is no need to recalibrate the AeroNOx unless a period of one week or greater has elapsed since the last calibration.

Helpful Hint:

It is a good practice to calibrate the AeroNOx weekly even when not in use. This ensures that the AeroNOx is always ready for use.

SECTION VI - NITRIC OXIDE DELIVERY

The AeroNOx Nitric Oxide Titration & Monitoring System was designed to deliver a continuous flow of NO gas into the patient's bulk gas flow.

Inspiratory Limb NO Titration in Constant Flow Ventilators or Other Respiratory Gas Administration Systems

This technique is modeled after the system tested by Betit and colleagues published in ***Respiratory Care July 1995 Vol 40 No. 7 p 706-715***. With constant flow ventilators, stability of the [NO] is assured because both the NO gas and the gas flow from the ventilator are fixed (constant).

Precautions for Inspiratory Limb NO Titration

1. Carefully select "tight" NO & NO₂ alarms on the NO / NO₂ analyzer.
2. Where applicable, ensure that the minute ventilation supplied by the ventilator or by other respiratory gas administration systems is consistent. Carefully select "tight" minute volume alarms. This is critical.
3. Titrate the desired NO dose before you attach the system to the patient, using a test lung with both the ventilator & NO delivery system running for approximately 1 minute prior to patient connection.
4. Ensure that the dose measured by the AeroNOx is the actual desired nitric oxide concentration and that NO₂ values are acceptable. For acceptable limits, see the "NO₂ in ppm" table in **SECTION VII**.

Ventilators Safe for Use with the AeroNOx

In general, any ventilator which functions as a true continuous flow ventilator may be used with the AeroNOx. Some ventilators have modes labeled "continuous flow" but may not function as true continuous flow ventilators. Please consult the manufacturer of the ventilator you intend to use with the AeroNOx to determine if, and in what modes, your ventilator will operate as a continuous flow ventilator.

CAUTION!

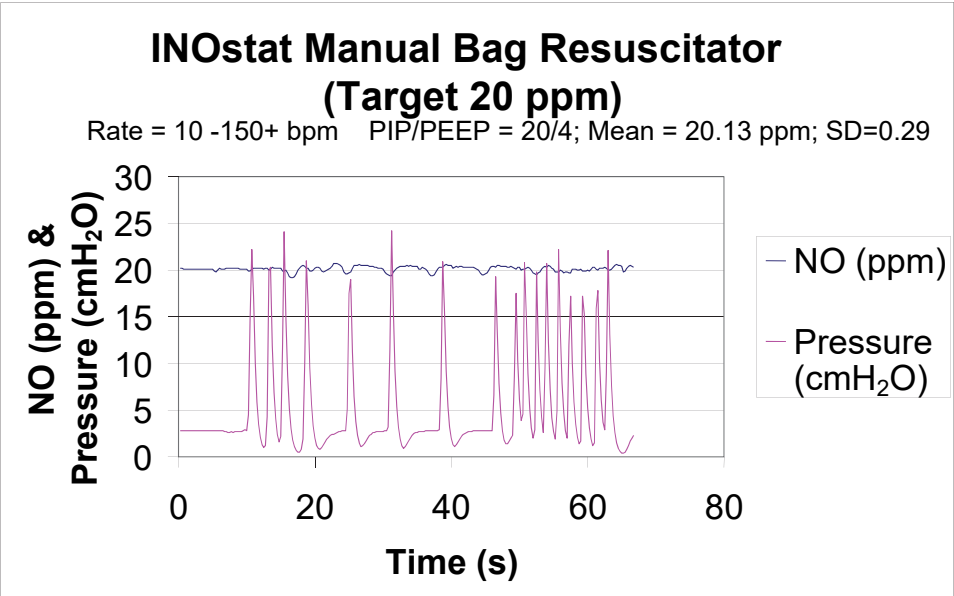
The AeroNOx is designed to be used with continuous flow ventilators only! Check with your ventilator manufacturer to determine the flow characteristics of the ventilator you wish to use.

The following ventilators have been tested for use with the AeroNOx:

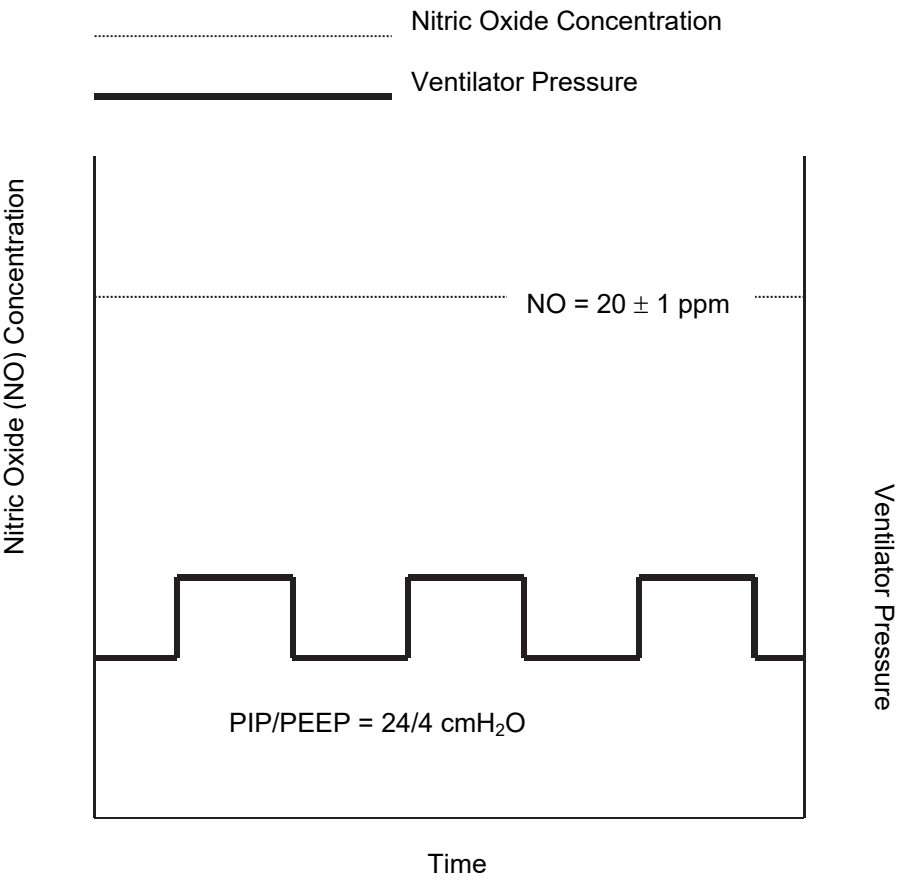
1. Sechrist 100IVB in all modes
2. Bird VIP in conjunction with the Infant Flow Sensor in the following time cycled modes:
 - a) Assist Control
 - b) SIMV
 - c) CPAP
3. Infant Star 100 Neonatal Ventilator
4. SensorMedics 3100A & 3100B
5. BioMed Devices MVP-10 Ventilator
6. BioMed Devices CV2i Ventilator
7. Percussionaire Bronchotron Ventilator

Nitric Oxide Concentration Profiles

The following graph represents the concentrations of nitric oxide representative of the delivered concentration to the patient throughout the respiratory cycle when using the INOstat Bagger.



The graph below represents the concentration of nitric oxide representative of the delivered concentration to the patient during mechanical ventilation with each ventilator tested for use with the AeroNOx.



SECTION VII - CALCULATIONS & TROUBLESHOOTING

1. CALCULATIONS FOR NITRIC OXIDE DELIVERY

- **Where to start?**
How to estimate initial NO flow
- **What is the diluted FiO₂?**
Estimating your FiO₂ after dilution with NO gas
- **How are we doing?**
Oxygen Index Calculation

2. CYLINDER DURATION NOMOGRAMS

- How long will this tank last?

3. AERONOX TROUBLESHOOTING GUIDE

- When all else fails, read the manual...

CALCULATIONS FOR NITRIC OXIDE DELIVERY

Where to start?

- It is imperative that you determine what NO flow to set, and what the NO flow reading should be during NO administration for the desired dose.
- To determine the initial Nitric Oxide (NO) flow rate, given your NO source gas concentration, [NO], ventilator minute ventilation & desired NO dose, use the formula below.
- To determine NO flow for use with the AeroNOx Bagger or other respiratory gas administration systems, substitute O₂ flow for ventilator flow in the equation below.

$$\text{Initial NO Flow (LPM)} = \frac{\text{Vent Flow (LPM)} \times \text{Desired [NO] ppm}}{\text{Source Tank [NO] ppm}}$$

Example:

- Minute volume, or ventilator flow = 10 LPM.
- Nitric oxide source tank = 800 ppm
- You want to deliver 25 ppm to your patient.

$$\text{Initial NO Flow (LPM)} = \frac{10 \text{ LPM} \times 25 \text{ ppm Desired [NO]}}{800 \text{ ppm Tank [NO]}} = \frac{250}{800} = 0.31 \text{ LPM}$$

- **Set 800 ppm NO source gas flow @ 0.31 LPM to get ~ 25 ppm NO diluted in 10 LPM fresh gas flow.**

The chart below was developed using the previous calculations. You may use it as a starting point for setting your NO flow rate. **Please note that these are reference points only. The actual dose delivered must be measured by the analysis portion of the AeroNOx.**

Minute Volume / Ventilator / Bagger Flow				
[NO]	5	10	15	20
5 ppm	0.03	0.06	0.09	0.13
10 ppm	0.06	0.13	0.19	0.25
20 ppm	0.13	0.25	0.38	0.50
40 ppm	0.25	0.50	0.75	1.00
80 ppm	0.50	1.00	1.50	2.00

NO Flow in LPM

The following table represents the average NO₂ value measured at an FiO₂ of 1.0 during testing with the ventilators listed in this manual. Use it as a reference for what NO₂ values you can expect when delivering the NO concentrations listed in the column on the left.

Minute Volume / Ventilator Flow				
[NO]	5	10	15	20
5 ppm	0.5	0.1	0.1	0.1
10 ppm	0.5	0.2	0.2	0.1
20 ppm	0.5	0.3	0.2	0.2
40 ppm	0.8	0.6	0.4	0.4
80 ppm	2.0	1.5	1.2	1.1

NO₂ in ppm

The tables above are for reference only. Factors such as the accuracy of the ventilator flow, percent error in delivery apparatus, and human error, may all affect the actual delivered patient dose. The calculated NO flow should be compared with the analyzed NO dose to confirm accurate NO dosing. Should the actual NO flow differ from the calculated NO flow by more than 10% beyond published specifications, the cause must be determined and corrected immediately. If the cause can not be immediately determined, ensure patient safety and contact International Biomedical at 1-512-873-0033 for further assistance.

CAUTION!
NO flow must be continually evaluated during Nitric Oxide administration to ensure accurate dosing!

What is the diluted FiO₂?

Estimating your FiO₂ after dilution with NO gas, given your NO flow setting, and total ventilator gas flow

$$\text{Estimated FiO}_2 = \frac{\text{Initial FiO}_2 - (\text{NO Flow} / \text{Total Flow O}_2 + \text{Total NO Flow}) \times 100}{1}$$

Example:

- Initial FiO₂ = 1.0 (100%)
- NO flow = 0.31 LPM (800 ppm gas, bal Nitrogen)
- Ventilator flow = 10 LPM
- Total flow = 10.31 LPM

$$\begin{aligned}\text{Estimated FiO}_2 &= 1 - (0.31 / 10.31 \text{ LPM}) = 0.97 \\ \text{Estimated \% O}_2 &= 1 - (0.31 / 10.31 \text{ LPM}) \times 100 = 97\%\end{aligned}$$

- *When delivering ~ 25 ppm NO (~ 0.31 LPM) in ~ 10 LPM of 100% oxygen, you can expect the % O₂ to be diluted by ~ 3%.*
- *In this case, the maximum FiO₂ you can expect is ~ 0.97.*

How are we doing?

Oxygen Index Calculation:

$$\text{Oxygen Index (OI)} = \text{Paw} \times \text{FiO}_2 \times 100 / \text{PaO}_2, (\text{mmHg})$$

Interpretation: Most centers interpret less than 15 as good.

- Mean airway pressure in cmH₂O = Paw
- Fraction of inspired oxygen = FiO₂
- Arterial oxygen tension in mmHg = PaO₂

Example: Pre Nitric Oxide Data

- FiO₂ = 1.0 (100%)
- PaO₂ = 65 mmHg
- Paw (Mean Airway Pressure) = 15 cmH₂O

$$\text{Oxygen Index (OI)} = 15 \times 1 \times 100 / 65 = 23$$

Post Nitric Oxide Data

- $\text{FiO}_2 = 0.55$ (55%)
- $\text{PaO}_2 = 75$ mmHg
- $\text{Paw} = 12$ mmHg

$$\text{Oxygen Index (OI)} = 12 \times 0.55 \times 100 / 75 = 8.8$$

In this example, OI improved markedly (23 to 8.8) after inhaled nitric oxide administration.

Calculation of Cylinder Duration

How long will this tank last?

- The volume of gas in your cylinder(s) is a function of the filling pressure and the capacity (size) of the cylinder. For compressed gases, this relationship is linear and can be expressed as a tank factor which is equal to cylinder volume / pressure expressed in LPM.

GAS SUPPLY

E. g. Large NO Cylinders

- Capacity (L): 2040
- Maximum Pressure (full): 2000 psig

$$\text{Tank Factor} = \frac{2040 \text{ L}}{2000 \text{ psig}} = 1.02 \text{ L/psig}$$

The amount of therapeutic gas remaining in a cylinder can be estimated in minutes or hours, provided that three things are known:

1. Tank Factor
2. Tank Pressure
3. Flow Rate

$$\text{Cylinder Duration (Minutes)} = \frac{\text{Cylinder Pressure (psig)} \times \text{Factor (L/psig)}}{\text{Flow Rate (LPM)}}$$

The two following nomograms can be used to estimate cylinder duration.



CYLINDER DURATION

Below you will find an example of how to determine cylinder duration based on the following:

- Rounded down to the nearest quarter hour
- Based on set flow rate and tank pressure
- Time listed is time to run the cylinder dry (cylinders should be changed out at 250 psig)

E. g. #1 - Cylinder Duration for a Cylinder with 2040 L @ 2000 psig

- Tank Factor = 2040 L Cylinder @ 2000 psig = 1.02 L/psig

Flow Rate (LPM)

Pressure	.125	.25	.5	.75	1.0	1.5
2000	272	136	68	45.25	34	22.5
1500	204	102	51	34	25.5	17
1000	136	69	34	22.5	17	11.25
500	68	34	17	11.25	8.5	5.5
250	34	17	8.5	5.5	4.25	2.75

Time in Hours***How much calibration gas do I need?***

Calibration gas regulators have a preset flow of 0.5 LPM. Since sensor stabilization usually takes ~ 2 - 4 minutes, one sensor calibration should take ~ 2 - 4 minutes and use ~ 2 L of calibration gas.

AERONOX TROUBLESHOOTING GUIDE

FRONT PANEL - OPERATIONAL MESSAGES

BUTTON PRESSED	PURPOSE	MESSAGE
Alarm Silence NO	Silences audible alarm for 1 minute	<u>ALARM SILENCE</u> Visual alarm persists until rectified
Alarm Silence NO ₂	Silences audible alarm for 1 minute	<u>ALARM SILENCE</u> Visual alarm persists until rectified
ZERO NO	Sets calibration baseline for selected sensor	<u>CAL NO</u> , after 5 seconds, <u>DONE!</u>
ZERO NO ₂	Sets calibration baseline for selected sensor	<u>CAL NO₂</u> , after 5 seconds, <u>DONE!</u>
ZERO NO & ZERO NO ₂ PRESSED TOGETHER	Displays the total time in hours that both sensors have been in service	<u>SENSOR TIME</u> , after 5 seconds, time in hours that both sensors have been in service
Visual LED	Alerts user that the sample line has become obstructed	<u>SAMPLE OBSTRUCTION</u>

ERROR / WARNING MESSAGES

MESSAGE	DESCRIPTION	ACTION
“LOW BATTERY” alternating with sensor data	Battery voltage < minimum operating voltage	Try to recharge the battery as outlined in SECTION III , Battery. If the battery still does not function, either the charger or battery must be inspected by a biomedical engineer.
“NO ZERO FAILURE”	Zero baseline calibration has been corrupted.	Power unit off and then back on. Calibrate as per SECTION V .
“NO₂ ZERO FAILURE”	Zero baseline calibration has been corrupted.	Power unit off and then back on. Calibrate as per SECTION V .
“ROM FAILURE”	Data stored in read only memory has been corrupted or damaged.	Return to International Biomedical for repair.
“CHECK SAMPLE LINE”	Sample line has become occluded, pump may have shut down.	Check sample line for occlusion. Remove occlusion. Power unit off for 3 - 5 seconds, then power back on. This will re-set pump flow.
“SAFETY OFF” alternately displayed with sensor data	“Safety” shut-off system has been disabled.	To re-enable the “safety” shut-off, a) simultaneously depress the NO and NO ₂ alarm silence buttons for 5 seconds until the display reads “SAFETY ON” or b) power the unit off, then back on again.
“NITRIC OFF” alternately displayed with sensor data	NO gas flow to your patient has been discontinued because NO analysis indicated NO delivery levels in excess of 5 ppm above the set “Hi” alarm limit or 100 ppm whichever is the less value or NO ₂ levels 1 ppm above the set “Hi” alarm limit or 12 ppm whichever is the less value.	Manually ventilate your patient with a bagger capable of delivering a safe and known concentration of NO gas to the patient. Determine the cause of the alarm. Do not resume NO administration with the AeroNOx until it is safe to do so.
“DATA INVALID” alternately displayed with “CONNECT CHARGER”	The battery voltage has dropped below a point where data can be accurately displayed.	Connect the AeroNOx to the power supply and plug into a wall outlet.

COMMON PROBLEMS ENCOUNTERED

SYMPTOM	CAUSE	ACTION
Sensors are slow to calibrate or will not calibrate	<ol style="list-style-type: none"> 1. Possible system leaks 2. Sensors may need replacing. Please refer to the section on Sensors for sensor life. 3. Calibration gas may have expired. 	<ol style="list-style-type: none"> 1. Ensure O₂ analyzer reads 100% oxygen during O₂ sampling and 0% during NO or NO₂ cal. gas sampling. If not, check for external leaks. Send to Biomedical engineering for internal system leak check. 2. Have Biomedical engineering change sensors. 3. Check "Analysis date" on cal. gas label.
NO / NO ₂ values drift during calibration, will not hold cal. values	<ol style="list-style-type: none"> 1. Sensors may need replacing. Please refer to the section on Sensors for sensor life. 2. Sensors may need additional time to be biased 	<ol style="list-style-type: none"> 1. Have Biomedical Engineering replace sensor(s). 2. Allow 24 - 48 hours for sensors to bias. Calibrate as per SECTION V.
NO / NO ₂ values drift during clinical use	<ol style="list-style-type: none"> 1. Sensors may need replacing. Please refer to the section on Sensors for sensor life. 2. Sensors may need additional time to be biased. 3. Incomplete gas mixing in your patient circuit may be occurring. 	<ol style="list-style-type: none"> 1. Have Biomedical Engineering replace sensor(s). 2. Allow 24 - 48 hours for sensors to bias. Calibrate as per SECTION V. 3. Refer to SECTION VI, Nitric Oxide Delivery Techniques.
Screen remains blank when unit is powered up. Pump will not run when unit is powered on.	<ol style="list-style-type: none"> 1. Internal battery has become discharged. 2. Internal battery requires replacement. 	<ol style="list-style-type: none"> 1. Plug "Universal Power Supply" into the AeroNOx and allow to charge for at least 30 min. 2. Have Biomedical Engineering replace the battery.
"AERONOX" is displayed even when the unit is powered off	<ol style="list-style-type: none"> 1. Battery is not fully charged. 2. Internal battery requires replacement. 	<ol style="list-style-type: none"> 1. Plug "Universal Power Supply" into the AeroNOx and allow it to charge for at least 30 min. 2. Have Biomedical Engineering replace the battery.
CAUTION! Disconnect the battery when the unit is not in use for extended periods of time or if the system must remain unplugged for extended periods of time.		

SYMPTOM	CAUSE	ACTION
NO screen displays "1600" and/or NO ₂ screen displays "21"	1. Bias voltage to the sensors has been lost.	1. Recharge or replace battery and allow 24 - 48 hours for the sensors to re-bias.
NO ₂ screen displays 21 and will not change	1. NO ₂ sensor has been exposed to NO ₂ values in excess of 21 ppm.	1. Allow room air or oxygen to be aspirated into the AeroNOx sampling block until NO ₂ value returns to zero. Calibrate the NO ₂ channel. Exposure to high levels of NO ₂ will decrease the sensor's life.
Either or both screens display a (-) hash mark	1. Sensors have drifted below zero.	1. Zero sensors as outlined in the calibration procedure (SECTION V).
NO / NO ₂ values drop suddenly after water has entered the AeroNOx sampling block	1. Water is preventing the sampling gas from reaching the sensor membrane.	1. Run room air or oxygen through the AeroNOx to dry out the sampling chamber. Calibrate the analyzer as in SECTION V prior to putting the AeroNOx back into clinical use. Use sample line P/N 415-0004 to prevent water from entering the AeroNOx.
NO sensor will not return to zero	1. Sensor has been exposed to high levels of NO (>100 ppm).	1. Run room air or oxygen through the analysis port until the value returns to zero. The length of time this will take will depend on how much NO the sensor was exposed to and for how long. Exposing the sensors to high levels of NO will decrease the sensor's life.

SECTION VIII - CLEANING & MAINTENANCE

CLEANING

1. Clean the AeroNOx system with mild detergent. Clean the AeroNOx analyzer and cable assembly surfaces by wiping them with a cloth moistened with a mild detergent or bactericidal agent. Avoid using alcohol on the liquid crystal display.

Caution!

- **DO NOT sterilize the AeroNOx analyzer by steam autoclave or gas sterilization techniques.**
- **DO NOT clean any parts with acetone or other strong solvents.**
- **DO NOT immerse or allow water or any other liquid to enter the AeroNOx analyzer or housing.**

REPAIRS AND REPLACEMENT

All routine maintenance, repairs, and replacement of standard parts should be conducted according to procedures outlined in the Technical manual. For all clinical or technical issues not addressed in the manual, please contact International Biomedical directly at:

Call 1-512-873-0033
FAX: 512-873-9090

CUSTOMER SERVICE

Should you need clinical or technical information, please feel free to contact International Biomedical. To help us to help you, please have the following information available:

- A complete description of the problem / observation
- Model #
- Serial #
- Your Institution address
- Your fax #

The above information is necessary to determine warranty status as well as to gather the information necessary for us to fill out a Return Merchandise Authorization (RMA) should you need to send anything back for repair. **Any equipment sent to International Biomedical without an RMA will not be accepted for delivery.** Do not ship any products to International Biomedical without first obtaining an RMA.

INSTRUCTIONS FOR DISPOSAL

To dispose of the AeroNOx:

1. Remove the battery and dispose of it in accordance with local regulations, or recycle it by calling the toll free number listed on the battery.
2. The remainder of the AeroNOx can be disposed of as per your hospital's policy for non-hazardous materials, or it may be returned to International Biomedical for disposal.

SECTION IX - WARRANTY

Subject to the **exceptions*** and upon the **conditions*** stated below, International Biomedical warrants that the products sold under this sales order shall be free from defects in workmanship and materials for **one year** after delivery of the products to the original Buyer by International Biomedical, and if any such products should prove to be defective within such one year period International Biomedical agrees, at its option, (i) to correct by repair or at International Biomedical's election, by replacement with equivalent product any such defective product, provided that investigation and factory inspection discloses that such defect developed under normal and proper use (ii) to refund the purchase price.

The exceptions* and conditions* mentioned above are as follows:

- a) Exchange, and/or factory repaired components are warranted for ninety (90) days from ship date, from factory.
- b) Upgraded parts are warranted for 6 (six) months from ship date from factory.
- c) Electrochemical sensors are warranted for 6 (six) months from ship date to the original buyer.
- d) Components or accessories manufactured by International Biomedical which by their nature are not intended to and will not function for one year are warranted only to give reasonable service: what constitutes reasonable shall be determined solely by International Biomedical. A complete list of such components and accessories is maintained at the factory.
- e) International Biomedical makes no warranty with respect to components or accessories not manufactured by it in the event of defect in any such component or accessory. International Biomedical will give reasonable assistance to the Buyer in obtaining from the respective manufacturer whatever adjustment is authorized by the manufacturer's own warranty.
- f) Any International Biomedical product claimed to be defective must, if required by International Biomedical, be returned to the factory, transportation charges prepaid, and will be returned to Buyer with transportation charges collect unless the product is found to be defective due to workmanship or materials, in which case International Biomedical will pay all transportation charges, subject to receipt of original shipping invoices. The customer will be responsible for duty, taxes, border charges, or claims resulting from but not limited to the improper processing of customs documents. Any damage incurred during transit from the Buyer to International Biomedical due to poor or insufficient packaging will be the responsibility of the Buyer.
- g) If the product is a disposable or the like, it is warranted only to conform to the quantity and content and for the period stated on the label at the time of delivery.
- h) International Biomedical may from time to time provide a special printed warranty with respect to a certain product, and where applicable, such warranty shall be deemed incorporated herein by reference.

- i) International Biomedical shall be released from all obligations under all warranties, either expressed or implied, if any product covered hereby is repaired or modified by persons other than its own authorized service personnel unless such repair by others is made with the written consent of International Biomedical.
-

IT IS EXPRESSLY AGREED THAT THE ABOVE WARRANTY SHALL BE IN LIEU OF ALL WARRANTIES OF FITNESS AND OF THE WARRANTY OF MERCHANTABILITY AND THAT INTERNATIONAL BIOMEDICAL SHALL HAVE NO LIABILITY FOR SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND OR FORM ANY CAUSE WHATSOEVER ARISING OUT OF THE MANUFACTURE, USE, INABILITY TO USE, SALE, HANDLING, REPAIR, MAINTENANCE, OR REPLACEMENT OF ANY OF THE PRODUCTS SOLD UNDER THIS SALES ORDER.

Representations and warranties made by any person, including dealers and representatives of International Biomedical, which are inconsistent or in conflict with the terms of this warranty, shall not be binding upon International Biomedical unless reduced to writing and approved by an expressly authorized officer of International Biomedical.

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SECTION X - COMPETENCY BASED PERFORMANCE CHECK-OFF TOOL

Introduction

In order to ensure patient safety, safe operation of clinical equipment is a necessity. Each employer is encouraged to have documented proof of employee competency in the operation of clinical equipment. For this purpose, International Biomedical has made available this competency based performance check-off.

This clinical check-off is based on criterion-referenced performance. Employee performance is measured against pre-established standards of behavior. These behaviors are called critical elements. Critical elements are single, discrete, observable behaviors that are mandatory for meeting the standards of acceptability. Since competency in equipment operations is required, all critical elements must be performed as specified in order to pass. 100% accuracy is recommended for completion of the clinical performance check-off.

Employees are strongly encouraged to review the Operating manual for the **AeroNOx Nitric Oxide Titration & Monitoring System** in order to familiarize themselves with the equipment functions, and to practice performing these functions independently as per the competency based check-off prior to the actual check-off by a clinician. During the actual check-off, the clinician is to merely observe the employee perform the required functions as per the check-off without offering assistance. As each function is performed, and if the criterion for performing the specified critical element is met, the clinician can tick off that item in the "criterion met" column. It may be necessary to provide teaching sessions or supervised practice sessions to staff prior to the clinical competency based check-off.

The following two competency based check-off tools are designed for:

- 1) *Routine (Weekly) AeroNOx Calibration*
- 2) *AeroNOx bedside or portable NO titration & analysis with a portable ventilator.*

AeroNOx

1) Routine (Weekly) AeroNOx Calibration

COMPETENCY BASED PERFORMANCE CHECK-OFF #1 of 2

Employee Name:
Date of Check-Off:
Supervised by:

1. Turn Power on. Use only the calibration circuit supplied (P/N 415-0000).	Check
2. Connect the barbed fitting to standard oxygen tubing.	
3. Run wall O ₂ through the cal. circuit @ 0.5 LPM.	
4. Connect the luer connector of the calibration circuit to the sample inlet of the AeroNOx.	
5. Allow the O ₂ reading to stabilize for 2 - 4 minutes. Calibrate oxygen sensor @ 100% by using the calibration screwdriver to adjust the calibration potentiometer.	
<u>ZERO BOTH NO & NO₂ SENSORS</u>	
6. Zero the NO sensor by depressing and holding the NO zero button down. ZERO NO appears on the screen. The sensor is zeroed when the word DONE! appears.	
7. Zero the NO ₂ sensor by depressing and holding the NO ₂ zero button down. ZERO NO₂ appears on the screen. The sensor is zeroed when the word DONE! Appears.	
<u>CALIBRATE NO₂ SENSOR</u>	
8. Disconnect calibration circuit from the AeroNOx.	
9. Disconnect the O ₂ and attach NO ₂ calibration gas to the calibration circuit.	
10. Connect the calibration circuit to the AeroNOx as in Step 4.	
11. Run the NO₂ cal. gas @ 0.5 LPM . Re-attach calibration circuit as in Step 5. Allow the NO ₂ reading to stabilize for 2 - 4 minutes. Adjust the NO ₂ potentiometer on the front panel with the calibration screwdriver until the reading matches the chemist's reported NO ₂ concentration on the NO ₂ calibration gas tank.	
<u>PURGE NO / NO₂ SENSORS</u>	Check
12. Disconnect the NO ₂ calibration gas, and run oxygen through the calibration circuit @ 0.5 LPM until both sensors read zero.	
<u>CALIBRATE NO SENSOR</u>	
13. Disconnect the calibration circuit from the AeroNOx.	
14. Disconnect the O ₂ and attach NO calibration gas, run the NO cal gas @ 0.5 LPM . Re-attach the calibration circuit as in Step 4. Allow the NO reading to stabilize for 2 - 4 minutes. Adjust the NO potentiometer on the front panel with the calibration screwdriver until the reading matches the chemist's reported NO concentration on the NO calibration gas tank.	
15. Disconnect the calibration circuit and allow room air to be sampled into the AeroNOx until the NO and NO ₂ displays return to zero and the Oxygen sensor reads 21%. This will flush out any calibration gas remaining in the AeroNOx sampling circuit after calibration. This step will help ensure the longevity of the AeroNOx sensors.	
<u>READY TO GO</u>	
The AeroNOx is calibrated and ready for use.	Done

NAME: _____, employee # _____ has successfully completed the AeroNOx Calibration competency.

Date: _____ Signature: _____

2) AeroNOx Portable & Bedside Set-Up

COMPETENCY BASED PERFORMANCE CHECK-OFF #2 of 2

Employee Name:
Date of Check-Off:
Supervised by:

CRITICAL ELEMENTS	Check
1. Completed Calibration check off	
2. AeroNOx SET-UP: TRANSPORT or BEDSIDE Attach regulators to 800 ppm NO tanks	
3. SOURCE GAS: Attach high pressure quick connect from regulator(s) to AeroNOx.	
4. DELIVERY: Attach delivery tubing (P/N 415-0001) from AeroNOx to pt. circuit at least 30 - 40 cm upstream from the sampling site.	
5. SAMPLING: Attach AeroNOx luer sample line from AeroNOx to inspiratory limb / bagger near patient connection.	
6. Double check [NO] of the cylinder & record = _____ ppm	
7. Double check NO tank pressure = _____ psig	
8. Calculate initial NO flow to achieve the desired [NO] (see SECTION V).	
9. Ventilator flow / gas flow = LPM	
10. Tank [NO] = _____ ppm	
11. Desired [NO] = _____ ppm	
12. Calculated Initial NO flow = _____ LPM	
13. Calculate maximal FiO ₂ (see SECTION VII). Maximum FiO₂ = _____	
14. Perform flush procedure.	
15. Set NO flow @ the initial flow rate you calculated (# 12).	
16. After readings stabilize, record the following from the AeroNOx. <ul style="list-style-type: none"> • Record [NO] _____ ppm • Record [NO₂] _____ ppm • Record % O₂ _____ ppm 	
17. Calculate the cylinder NO duration in hours & minutes (see SECTION VII). This _____ L tank of NO gas @ _____ psig will last _____ Hrs _____ Min @ _____ LPM.	

NAME: _____, employee # _____ has successfully completed the AeroNOx Portable & Bedside Set-Up competency.

Date: _____ **Signature:** _____