

## Inhaled Nitric Oxide

**Purpose:** To deliver, and monitor delivery of Nitric Oxide gas to mechanically ventilated patients.

**Description:** The INOvent system for nitric oxide therapy is a device that delivers nitric oxide gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of NO, as set by the user, to the patient throughout the inspired breath. The INOvent system provides continuous on-line integrated monitoring of delivered O<sub>2</sub>, NO<sub>2</sub>, and NO with a comprehensive alarm system. Nitric Oxide therapy will only be initiated upon the order of the attending physician. The "INOtherapy Log Sheet", kept with the INOvent system, is to be filled out when the therapy is begun on each patient.

**Indications:**

1. Term or near term,  $\geq 34$  weeks, with pulmonary hypertension.
2. Compassionate use for PPHN
3. Patients with need for pulmonary vasodilation

**NOTE: An order for Nitric Oxide therapy requires the approval of the attending physician.**

**Equipment:**

1. INOvent Delivery System with nitric oxide gas at 800 ppm.
2. Purge and performance test kit includes:
  - a. O<sub>2</sub> flowmeter
  - b. O<sub>2</sub> tubing
  - c. 15 M x 4.5 mm adapter
  - d. 22 M/15 F x 22 M/15 F adapter
  - e. 300 mm of 22 mm hose
  - f. Sample tee
  - g. Inspiratory gas sample line
3. Manual NO delivery system purge and performance test kit includes:
  - a. Inspiratory gas sample line
  - b. Oxygen tubing
  - c. O<sub>2</sub> flowmeter with supply hose
  - d. 15 M x 4.5 mm adapter
  - e. Sample tee
4. Circuit kit includes:
  - a. Heated wire circuit
  - b. Humidification system
  - c. 22M/15F x 22M/15F adapter
  - d. 22F x 15M adapter
  - e. 15 mm O.D. to 3/8 in. tubing adapter
  - f. 22M/15F x 15M adapter with gas sample tee
  - g. 15 mm I.D. to 3/8 in. tubing adapter
  - h. Patient gas sample line

**Personnel:** Respiratory Therapists

**Procedure:** Pre-Use Procedures

1. Initial connections and leak test.
  - a. If necessary, connect the INOvent delivery system as described in Section 3/Setup of the operation and maintenance manual.
  - b. Check the cables and hoses for signs of wear and replace as needed.

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- c. Turn the INOvent on and confirm that the buzzer and speaker sound. Wait for the start-up routine to finish. (The Power-On display appears during self-tests followed by a normal display.)
  - d. Confirm that a monthly system checkout has been done in the last month. If it hasn't, do a monthly system checkout. See Section 10/Maintenance of the operation and maintenance manual.
  - e. Perform a system high pressure leak test.
    1. With the INOvent delivery system ON, turn each cylinder valve ON then OFF. Check for adequate cylinder pressures. Wait for 30 seconds and check for pressure decrease.
    2. If there is any decrease, make sure that the auxiliary oxygen flowmeter to the Manual NO System is not turned on and check for leaks around the hose connections using soapy water.
    3. Check for leaks at the NO cylinder valve outlet connection using soapy water.
    4. Replace NO gas cylinder when its pressure is less than 200 psig.
2. System purge and performance test.
- a. Connect the injector module to O<sub>2</sub> auxiliary flowmeter using O<sub>2</sub> tubing, a 4.5 mm to 15 mm adapter and a breathing circuit adapter to condition the flow before the injector module.
  - b. Connect a sample tee to the outlet of the injector module with 300 mm of 22 mm hose to ensure gas mixing prior to gas sampling. Attach a sampling line from the sample tee to the sample connector on the front panel.
  - c. Perform a low range calibration of the NO, NO<sub>2</sub>, and O<sub>2</sub> monitors.
  - d. Make sure both NO cylinders are turned off, after having been turned on.
  - e. Set the oxygen flow to 15 LPM and the Set NO concentration to its maximum setting.
  - f. Make sure both cylinder high pressure gauges go to zero to purge both high pressure circuits.
  - g. Check that the NO<sub>2</sub> value is higher than 0.2 ppm to verify that the NO<sub>2</sub> monitor is functional.
  - h. Make sure that the **Low NO/N<sub>2</sub> Pressure** and **Delivery Failure** alarms occur. (This may take a few minutes depending on the cylinder pressures at the start of the test.)
  - i. When the alarms have occurred, turn on the NO cylinder with which you intend to start therapy. Leave the other cylinder turned off.
  - j. Set the O<sub>2</sub> flow on the auxiliary flowmeter to 15 LPM and the Set NO to 40 ppm.
    1. Wait for 3 minutes or until the monitor readings are stable.
    2. Make sure that the O<sub>2</sub>, NO<sub>2</sub>, and NO readings are within the acceptable ranges given below. NOTE: These acceptable readings include the errors of the NO delivery system and the NO therapy gas.

O <sub>2</sub> %v/v ( $\pm 3$ %v/v)	95 %v/v
NO <sub>2</sub> ppm max.	1.5 ppm
NO ppm (min/max)	32/48
  - k. Perform the monitor high range calibrations if required.
3. Manual NO delivery system purge and performance test.
- a. Connect the Manual NO delivery system as described in Section 3/Setup of the operation and maintenance manual.

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- b. Disconnect the resuscitator bag. Connect the 22 mm/15 mm sample tee (with the sample line connected) to the oxygen tubing using a 15 M x 4.5 mm adapter.
  - c. Flow 15 LPM of O<sub>2</sub> from the auxiliary O<sub>2</sub> flowmeter into the manual delivery system and make sure the float moves to the middle of the NO flow indicator window.
  - d. Wait for the gas to flow through the oxygen tubing. Make sure that the NO reading is 20 ± 8 ppm and the NO<sub>2</sub> reading is less than 1.0 ppm. If the NO<sub>2</sub> reading is greater than 1.0, continue flowing gas until the limit is reached. NOTE: These acceptable readings include the errors of the NO delivery system and the NO therapy gas.
  - e. Reduce the O<sub>2</sub> flow to 1 LPM and make sure that the float drops to the bottom of the NO flow indicator.
  - f. Set the O<sub>2</sub> flow to zero and disconnect the sample tee and 15 M x 4.5 mm adapter from the oxygen tubing.
  - g. Reconnect the resuscitator bag to the oxygen tubing.
4. Changing NO Therapy cylinders and purging the regulator assembly.
- a. To purge the regulator assembly before using a new NO therapy gas cylinder:
    1. Determine which regulator assembly is not being used and requires purging. The cylinder valve should be closed on the regulator assembly that is not being used.
    2. On the regulator assembly that requires purging, disconnect the low pressure hose quick-connect fitting from the NO/N<sub>2</sub> input on the rear of the INOvent delivery system.
    3. Open the cylinder valve on the new NO therapy gas cylinder.
    4. Close the cylinder valve on the new NO therapy gas cylinder.
    5. Check for leaks at the cylinder valve outlet connection of the new therapy cylinder using soapy water.
    6. Insert the low pressure hose quick-connect fitting into the purge manifold.
    7. Firmly push and hold the quick-connect fitting in place while the pressure drops to zero on the regulator gauge.
    8. After the pressure drops to zero (approximately 15 seconds), reconnect the low pressure hose quick-connect fitting to the NO/N<sub>2</sub> input on the rear of the INOvent delivery system.
  - b. Open the cylinder valve on the new cylinder.
  - c. Close the cylinder valve on the empty cylinder and label appropriately.
  - d. Replace the empty NO therapy gas cylinder. Leave the cylinder valve on the replacement cylinder turned off until needed. The purge procedure will be performed on this cylinder immediately before its use.
5. NO, NO<sub>2</sub>, and O<sub>2</sub> Sensor low range calibration (Daily, Room Air)  
*Use the calibration menus to calibrate the low range (room air) of the three gas sensors (NO, NO<sub>2</sub> and O<sub>2</sub>) at the same time; the calibration may take up to five minutes. NO, NO<sub>2</sub> and O<sub>2</sub> room air levels are displayed during low range calibration and trend toward 0 ppm, 0 ppm and 21% respectively.*
- a. From a normal display with the INOvent delivery system operating, push the **Calibration** button to reach the first calibration menu. **NO, NO<sub>2</sub>, O<sub>2</sub>** option will be highlighted.
  - b. Push the control wheel to start the low calibration. **Sensor calibration in progress** and **This procedure can take up to 5 minutes** will be highlighted.

- c. When the calibration is successful, **Calibration of NO, NO<sub>2</sub> and O<sub>2</sub> low range succeeded** is displayed. Follow the instructions on the screen. You may turn the control wheel to “Exit to Normal Display” or continue on to “High Range Calibration (calibration gas.)”
  - d. If the calibration is unsuccessful for any of the sensors, an appropriate message is displayed:
    - Calibration of NO low range failed.**
    - \*Repeat Low Range calibration, or**
    - \*Replace the NO sensor, or**
    - \*See Operation & Maintenance Manual**
    - To continue, push the control wheel.**
  - e. To continue on to “High range calibration (calibration gas),” turn the control wheel to select “Go to Calibration of Sensors.” Push the control wheel to accept “Go to Calibration of Sensors” and continue with the following steps.
6. NO, NO<sub>2</sub> and O<sub>2</sub> Sensor high range calibration.  
*Use the calibration menus to calibrate the high range of the NO, NO<sub>2</sub> and O<sub>2</sub> sensors. Procedures for high range calibration of the three sensors are essentially the same as a low range, but a different calibration gas is used for each sensor. Calibration must be done individually: NO and NO<sub>2</sub> each with their respective cal gas and O<sub>2</sub> with a medical grade 100% O<sub>2</sub> from a wall or cylinder source.*
- a. Connect a sample line to the to the calibration gas cylinder pressure gauge for the sensor you are calibrating. When calibrating NO connect NO cal gas, when calibrating NO<sub>2</sub> connect NO<sub>2</sub> cal gas.
  - b. Connect a sample tee to a flowmeter with 100% source gas to calibrate high range O<sub>2</sub>.
  - c. On the calibration menu, turn the control wheel to highlight the NO, NO<sub>2</sub> or O<sub>2</sub> selection of “High Range (cal. Gas).”
  - d. Make sure that the calibration gas cylinder ON/OFF control is turned OFF. Attach the system sample line to the calibration gas source.
  - e. Turn the calibration gas source ON.
  - f. Push the control wheel to start the high range calibration of the selected sensor. Follow the instructions given on the display. They are:
    1. **Flow NO [NO<sub>2</sub> or 100% O<sub>2</sub>] calibration gas into the sample line.**
    2. **Wait for “Measured NO, NO<sub>2</sub> or 100% O<sub>2</sub>” to stabilize.**  
(Note: The “Measured” value is the monitored value of the calibration gas during sampling. This value updates continuously during the calibration process. After the “Measured” value has stabilized, push the control wheel.)
    3. **Set “Calibration XX” to cal. Gas value.**  
(Select “Calibration XX.” Then, turn the control wheel to set the value to that marked on the calibration gas cylinder label (or 100% for O<sub>2</sub>.) Then, push the control wheel to enter. “In progress” will be shown on the Calibration NO line of the display.
  - g. If the high range calibration fails, follow the instructions given on the display.
  - h. When the current sensor calibration is finished, select “**Go to the Calibration of Sensors**” and push the control wheel.
  - i. When the “**Calibration of Sensors**” display appears, select the next sensor for calibration.
  - j. If you are finished with all three sensor calibrations:
    1. Select “**Exit to Normal Display**” and push the control wheel.
    2. Turn the calibration gas cylinder ON/OFF control to OFF.
    3. Reconnect the sample line to the breathing circuit.

7. Operations
  - a. Assemble circuit kit and attach to ventilator.
  - b. Connect outlet port of the ventilator to the inlet port of the Injector module input end using the appropriate adapters.
  - c. Attach the output end of the Injector module to the humidifier inlet port.
  - d. Connect the gas sample line from the "Sample Inlet" port on the front of the fluid trap to the sample tee. Make sure that the sample port at the T-piece is pointing upward to help avoid fluid accumulation in the sample line.
  - e. The trigger sensitivity should be checked after connecting the INOvent delivery system to the patient circuit.
  
8. Setting the delivered NO concentration.
  - a. Turn the INOvent delivery system ON. The normal state display will have the **Set NO** bargraph at OFF after the start up tests are completed.
  - b. Push the **Set NO** button. The bargraph border now flashes; the bargraph becomes a movable double line indicating the current concentration setting.
  - c. Turn the control wheel clockwise to increase the NO concentration or counterclockwise to decrease the NO concentration.
  - d. Push either the **Set NO** button or the control wheel to confirm the newly-entered concentration. If you don't push either within five seconds, the reminder message appears to prompt you to do so. A highlight box around the display flashes. If you don't respond to the message within 15 seconds, the system defaults to its previous NO setting.
  - e. After the monitored values have stabilized, you can set or change the user-adjustable alarms.
  - f. The system is now ready for use. The new NO concentration is delivered when there is flow in the patient circuit.
  
9. Setting Alarms
  - a. With the monitor ON and after the monitored values have stabilized; push the Alarms button to show the Alarms menu. This menu lets you:
    1. Set a high limit for measured values of the three gases (NO, NO<sub>2</sub> and O<sub>2</sub>).
    2. Set a low limit for the measured values of NO and O<sub>2</sub>.
    3. Exit to the normal display.
  - b. Turn the control wheel to highlight the alarm setpoint you want to change.
  - c. Push the control wheel to select the highlighted alarm setpoint for change.
  - d. Turn the control wheel until the value you want is displayed in the selection box.
  - e. Push the control wheel to confirm your selection. The alarm limit is displayed below its respective measured gas value when the normal display is shown.
  - f. If you are finished with the Alarms menu, turn the control wheel to select **Exit to Normal Display**.
  - g. Alarm limits:
    1. NO should be set at +/- 1 ppm of the prescribed dosage.
    2. NO<sub>2</sub> should be set at 3 ppm.
    3. O<sub>2</sub> should be set at +/- 3% of the delivered FiO<sub>2</sub>.
  
10. Charting and Monitoring

- a. NO, NO<sub>2</sub> and O<sub>2</sub> will be charted Q4 hours and with each ventilator check on the ventilator flow sheet.
- b. Department charges will be noted on the Masters with a “new equipment set up” charge at the initiation of therapy and as an hourly charge while the therapy is in progress.
- c. When initiating NO therapy or changing the cylinder, **document the cylinder number and time the cylinder was started on the ventilator flow sheet.**

11. Manual NO Delivery System

*The Manual NO Delivery System permits continued NO delivery if the ventilator or the main INOvent system fails. The manual system is completely pneumatic and is not linked to the primary delivery system. The O<sub>2</sub> flowmeter provides the ON/OFF function and is used to set the O<sub>2</sub> flow at 15 LPM. A shut-off valve in the delivery system prevents NO flow if there is insufficient O<sub>2</sub> flow. When the manual NO delivery system is operating correctly, the float in the NO indicator window will be in position and will deliver a NO concentration of 20 ppm.*

- a. Manual NO Delivery System Connections:
  1. Connect O<sub>2</sub> tubing to the manual resuscitator bag (with O<sub>2</sub> reservoir) and to the NO/O<sub>2</sub> output connector on the back of the INOvent delivery system.
  2. Connect a pressure compensated O<sub>2</sub> flowmeter to an O<sub>2</sub> supply (wall or cylinder). The flowmeter must have a male DISS outlet.
  3. Connect the O<sub>2</sub> hose supplied with the INOvent delivery system to the flowmeter outlet and to the back of the INOvent delivery system at the O<sub>2</sub> inlet connector.
- b. Manual NO Delivery System Operation:
  1. To start the manual NO delivery system, set the O<sub>2</sub> flowmeter to 15 LPM.
  2. Check for movement of the float in the NO Flow Indicator on the right side of the INOvent delivery system. This float movement indicates NO flow. A shut-off valve prevents NO flow if there insufficient O<sub>2</sub>.
  3. Squeeze the resuscitator three to five times to purge the system before connecting the resuscitator bag to the patient.
  4. To stop the manual NO delivery, turn the O<sub>2</sub> flowmeter to OFF.

*Note: When not in use, the flowmeter should be kept in the OFF position to prevent the inadvertent loss of NO gas.*

After Use Procedure:

1. The Respiratory Therapist discontinuing the INOvent after use will be responsible for the after use procedure.
2. After discontinuing the INOvent, the ventilator is wiped down with aseptic solution. A label will be placed on the INOvent with the date and initials, denoting it as clean and ready to use.
3. Ventilator circuits, sample tees and tubing are single patient use items and are to be discarded after use.
4. The INOvent injector module and the water trap should be returned to the department. These pieces will then be sent to CMS for cleaning.
5. The INOvent should be returned to the NICU blood gas lab (5<sup>th</sup> Floor). Clean supplies are located in the nearby storage bins.
6. Make sure that purge and performance kit is complete and stocked on INOvent.

References: Operation and Maintenance manual, INOvent Delivery System by Datex-Ohmeda, 1999.

NOTE: Duplicate copies of this policy are posted in Proc11.12 (Special Care Procedures/Policies) and Proc17.32 (NICU Policies)

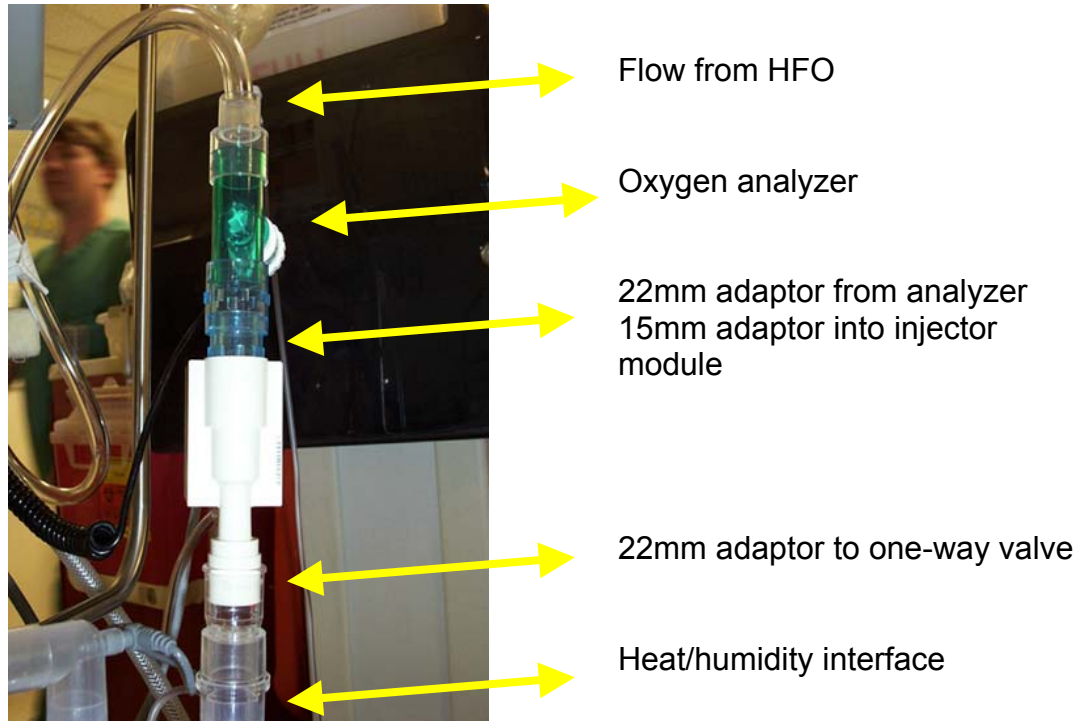
Written: September 1999

Reviewed: August 2000

Revised: July 2003

Revised: February 2006

## Module for HFO + INO



## HFOV circuit

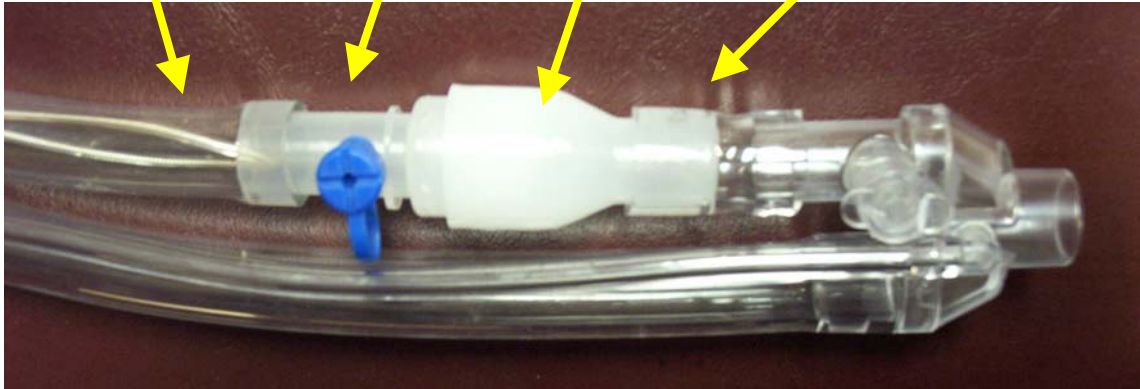
### Inspiratory Limb

Cut excess length to account for length of adaptor. Avoid heated wire.

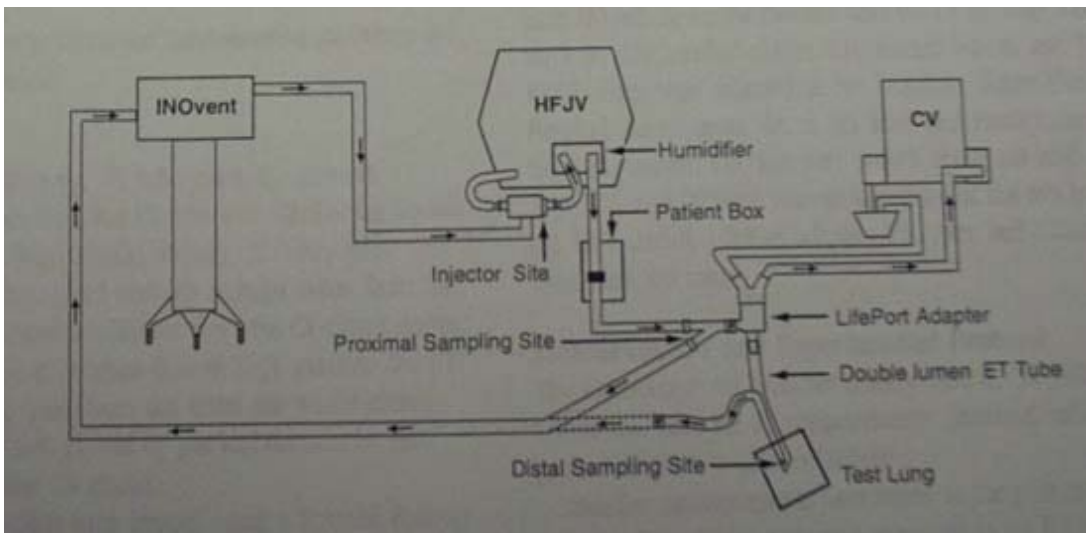
Sample line adaptor

22FX15M adaptor (INOvent cabinet-NICU)

Tubing cut from circuit



## INOvent with HFJV (see below for adaptors)



## Adaptors needed to place injector module in line with HFJV:

