INOmax DS_{IR}®

(Delivery System)

Pocket Guide



Pre-Use Procedure Backup INOMAX® Delivery Transport Regulator/Cap Assembly Oxygen Dilution Chart INOMAX Cylinder Duration Chart Circuit Connection Diagrams Changing INOMAX Cylinders High Calibration Connection Diagrams INOmax DS_{IR} Disposable Adapters



For 24 Hour Assistance Call 1-877-566-9466

Part No. 20131 Rev-02 2012-09 IMPORTANT: This guide is provided as a convenience and for general information only. Do not use this product without clearly and thoroughly understanding the most recent revision of the INOmax DS_{IR}^{\otimes} Operation Manual. The Operation Manual is the source for specific, updated information regarding warnings, cautions, checklists, diagrams, and/or instructions contained in this guide.

Overview

INOmax DSIR

The INOmax DS_{IR} has an interface using infrared (IR) technology which will allow the INOmax DS_{IR} to communicate with the INOmeter[®] (which is mounted to each INOMAX[®] cylinder).

The INOmax DS_{IR} cart (PN 10018) has a cover with an infrared transceiver mounted directly above each INOMAX cylinder. When INOMAX cylinders are loaded, communication will take place between the INOmax DS_{IR} and the INOmeter after the boot up phase of the INOmax DS_{IR} is complete. A cylinder icon will be displayed on the main screen when an INOMAX cylinder is recognized by the INOmax DS_{IR} .

INOmax DS_{IR} Transport Regulator/Cap Assembly

This assembly is used during medical transport to provide pressurized INOMAX to the INOmax DS_{IR} as well as communicate INOMAX use information via Infrared transceivers between the INOmax DS_{IR} (PN 10007) and the INOmeter.

The transport cap assembly provides Infrared technology molded in the cap. This allows the INOmax DS_{IR} to communicate via Infrared with the INOmeter, which is mounted to each INOMAX cylinder.

Definitions

INOmeter - The factory installed INOmeter is designed for use with INOMAX cylinders only. This time-metric device records the amount of time the cylinder valve is opened.

iButton - Raised silver data port on the side of the INOmeter.

Symbols

Ir ↔ Infrared Input/Output

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Pre-Use Checkout Outline

- A. Initial Connections
- B. High Pressure Leak Test
- C. Low Range Calibration
- D. Purge and Alarm Verification
- E. Backup INOMAX Delivery Test
- F. INOmax DS_{IR} Performance Test
- G. INOblender Test

Pre-Use Checkout

A. Initial Connections

1. Check white plastic tip.



2. Connect high pressure regulator.



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- 3. Connect the INOMAX regulator hose to one of the INOMAX inlets
- Connect the INOblender inlet hose to the INOmax DS_{IR} blender outlet
- 5. Connect the infrared cable to the back of the INOmax DS_{IR}
- 6. Connect the oxygen hose to the INOblender oxygen inlet
- 7. Ensure the water separator cartridge/water trap bottle/ sample line and injector module are all in place
- Turn INOmax DS_{IR} ON, verify speaker function.







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B. Perform High Pressure Leak Test

(Open/Close INOMAX cylinder valve)

Wait 30 seconds and ensure no pressure drop.

Note: Make sure INOmax DS_{IR} backup and INOblender are OFF.

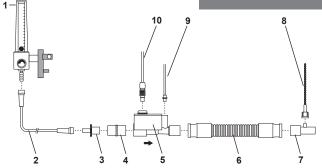


C. Perform Low Range Calibration (second menu level)



Note: Once the calibration is completed (bars turn green and single tone sounds) press the menu button twice to return to the main screen.

Pre-Use Checkout



- 1. O₂ Flowmeter (Connected to wall/tank)
- 2. O₂ Tubing
- 3. 15M x 4.5mm Adapter
- 4. 22M / 15F x 22M / 15F Adapter
- 5. Injector Module

- 6. 300mm of 22mm Hose
- 7. Gas Sample Tee
- 8. Patient Gas Sample Line with Nafion
- 9. NO/N₂ Injector Tube
- 10. Injector Module Electrical Cable

(Assemble connectors and tubing as shown)

D. Perform Purge and Alarm Verification

- 1. Ensure cylinder valve is closed.
- 2. Set O₂ flowmeter to 10 L/min.
- 3. Purge INOmax DS_{IR}.
 - a. Set INOMAX dose to 40 ppm
 - b. "Cylinder Valve Closed" alarm will occur
 - c. Cylinder gauge pressure should drop to 0 psig
 - d. Purge is complete when "Low NO/N2 Pressure" alarm activates
- 4. Open cylinder valve.
- 5. Turn INOMAX dose to zero (note: The "Set Dose is Zero, Close Cylinder Valve" indicator will appear).

Pre-Use Checkout

E. Perform Backup INOMAX Delivery Test

- 1. Turn backup delivery ON.
- 2. Verify "Backup ON" alarm activates.



3. Verify values.

NO = 14-26 ppm NO₂ = <1.0 ppm

4. Turn backup delivery OFF.



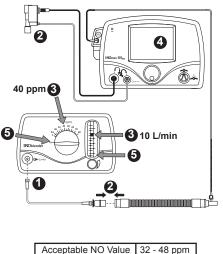
F. Complete INOmax DS_{IR} Performance Test

Set Dose	40 ppm	
Acceptable NO Value	35-45 ppm	
Acceptable NO ₂ Value	<1.5 ppm	
FiO ₂	95% ±3%	

- 1. Ensure oxygen flow of 10 L/min.
- 2. Set INOMAX dose to 40 ppm and allow values to stabilize.
- 3. Verify values (see table).
- 4. Turn the INOMAX dose to zero.

G. Perform INOblender Test

- Note: Ensure INOblender inlet hose is connected to the back of the INOmax DS_{IR} and the quick-connect cover is in place.
- Remove the Pre-Use setup oxygen tubing from the oxygen flowmeter and connect it to the front of the INOblender.
- Remove the Injector Module from the Pre-Use set-up and reconnect adapters.
- 3. On the INOblender, set INOMAX dose to 40 ppm and O₂ flow to 10 L/min.
- 4. Verify values on the INOmax DS_{IR}.
- 5. Turn the dose and flow to zero and remove the Pre-Use set-up from the INOblender.



The INOmax DS_{IR} is now ready to connect to the patient.

- · Set the INOMAX dose to be delivered to the patient.
- Set the appropriate alarm settings on the INOmax $\mathsf{DS}_{\mathsf{IR}}$ and breathing device.

WARNING: If not starting therapy within 10 minutes, depressurize the INOMAX regulator.

End of Pre-Use Checkout

WARNING:

When the backup NO delivery mode is used, a flow of at least 5.0 L/min should be present in the ventilator circuit to avoid INOMAX concentrations greater than 40 ppm.

The backup is intended for short term use when the electronic delivery system fails until a replacement NO delivery can be brought to the bedside.

If the backup is on, along with the main delivery system an INOMAX value greater than set will be delivered (a high priority alarm will be present).

The backup mode delivers a variable concentration of NO to the patient depending on the ventilator flow being used. See table below for details.

The table below indicates the nominal concentrations delivered for different ventilator gas flows.

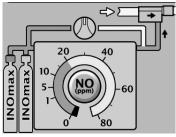
Ventilator/Gas Flow (L/min)	5	7.5	10	15	20
NO Concentration (ppm)	40	27	20	13	10

INOMAX cylinder conc. X 0.25 L/min / ventilator flow = delivered dose

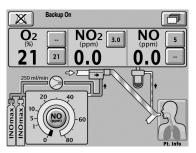
The backup delivery provides a fixed flow of 250 mL/min of INOMAX directly into the ventilator circuit through the Injector Module.

Backup NO delivery is completely pneumatic and is not reliant on the operation of the main system.





Backup delivery mode OFF.





Backup delivery mode ON (with a Low Priority alarm).

Transport Regulator/Cap Assembly

WARNING:

- A new INOMAX cylinder and regulator must be purged before use to ensure the patient does not receive greater than 1.0 ppm of NO₂.
- Loss of communication between the INOmax DS_{IR} and the INOMAX cylinder for more than one hour will result in interruption of INOMAX delivery.
- Caution: When using the Transport Regulator/Cap Assembly (PN 10022) ensure the cap is in place on the cylinder and the infrared cable is connected to the infrared connector port on the back of the INOmax DS_{IR}.
- Note: Check the INOMAX cylinder for the correct product identity labels, cylinder concentration and expiration date. Ensure the INOMAX gas cylinder has more than 200 psig.

Step One

Note: Ensure the white plastic tip is in place on the regulator connector and not chipped or cracked (see Figure 2).

Connect a high pressure regulator to an INOMAX cylinder and tighten the fitting to the INOMAX cylinder (see Figure 1).





Figure 1



Transport Regulator/ Cap Assembly

Step Two

Connect the INOMAX regulator hose to one of the INOMAX inlets on the back of the INOmax DS_{IR} (see Figure 3).



Step Three

Connect the Infrared cable from the Transport Regulator/Cap Assembly to the back of the INOmax DS_{IR} (see Figure 4).



Figure 4

Transport Regulator/ Cap Assembly

Step Four

Place the Cap Assembly over the INOmeter (see Figure 5).

Note: Be sure to align the keyway inside the Cap Assembly with the iButton on the INOmeter (see Figure 5 and 6).



, iButton



The electrical cord exits the cap directly above the iButton keyway

Figure 5

Step Five

Grasp the Cap Assembly to open cylinder valve (see Figure 7 and 8).



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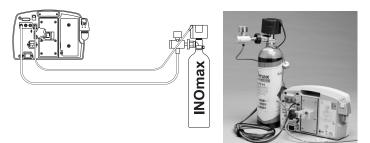
Figure 7 Part No. 20131 Rev-02





Final Set-up Diagram

The following diagram and photo illustrates all of the components connected.



Additional Information

Communication will take place between the INOmax $\rm DS_{IR}$ and the INOmeter after the boot up phase of the INOmax $\rm DS_{IR}$ is complete.

- Note: Cylinder icons are not visible and the dose control button will remain inactive until the INOmax DS_{IR} recognizes an INOMAX cylinder.
- Note: When using the Transport Regulator/Cap Assembly only one cylinder will be displayed (see Figure 9).

Proceed with the INOmax DS_{IR} Pre-Use Checkout

(see page 6)

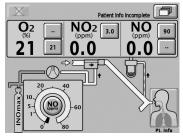


Figure 9

For delivery with 800 ppm cylinder of INOMAX (nitric oxide) for inhalation.

(Illustrative Only)

	Set FiO ₂					
		.21	.40	.60	.80	1.00
9 0	10	0.21	0.40	0.59	0.79	0.99
Dos	20	▲0.20	0.39	0.59	0.78	0.98
INOMAX Dose	40	▲0.20	0.38	0.57	0.76	0.95
MO	80	▲0.19	0.36	0.54	0.72	0.90
Z		Actual FiO ₂				

▲ Caution FiO₂ less than 21%

Please Note:

The calculations on this chart have been determined based on an 800 ppm cylinder of INOMAX (nitric oxide) for inhalation.

This chart is representative of a range of doses available on the INOmax DS_{IR} and doses higher than 20 ppm are not intended as the recommended therapeutic dose.

Calculations are considered estimates and may vary under clinical conditions.

All numbers have been rounded to the nearest hundredth.

INOMAX Cylinder 88-Size

For an **88-Size** 800 ppm Cylinder Concentration* (Illustrative Only)

	FLOW						
		5 L/min	10 L/min	20 L/min	40 L/min		
	5 ppm	43.3 Days	21.7 Days	10.8 Days	5.4 Days	197	
ose	10 ppm	21.5 Days	10.7 Days	5.4 Days	2.7 Days		
AX D	20 ppm	10.6 Days	5.3 Days	2.6 Days	31 Hours	INOmax Boo PPM	
INOMAX Dose	40 ppm	5.2 Days	2.6 Days	31 Hours	15 Hours	KARIA	
	80 ppm	2.4 Days	29 Hours	14 Hours	7 Hours		

This chart is representative of a range of doses available on the INOmax DS_{IR} and doses higher than 20 ppm are not intended as the recommended therapeutic dose.

* All calculations for the table above are based on a full cylinder of 2000 psig, 1963 liters "88" cylinder, and also accounting for cylinder change at 200 psig. The figures are calculated on total continuous flow cylinder conversion factor 0.98.

- INOMAX flow = [Desired dose X total ventilator flow] / [Cylinder concentration desired dose]
- Cylinder volume = Cylinder conversion factor X cylinder pressure psig
- Cylinder duration = Cylinder volume / INOMAX flow rate

Calculations are considered estimates and may vary under clinical circumstances. For more information, call 1-877-KNOW-INO (1-877-566-9466).

INOMAX Cylinder D-Size

For a **D-Size** 800 ppm Cylinder Concentration* (Illustrative Only)

FLOW						
		5 L/min	10 L/min	20 L/min	40 L/min	
INOMAX Dose	5 ppm	7.8 Days	3.9 Days	46 Hours	23 Hours	
	10 ppm	3.9 Days	46 Hours	23 Hours	11 Hours	
	20 ppm	45 Hours	22 Hours	11 Hours	5 Hours	
	40 ppm	22 Hours	11 Hours	5 Hours	2 Hours	all all
	80 ppm	10 Hours	5 Hours	2 Hours	1 Hour	

Typically used in transport

This chart is representative of a range of doses available on the INOmax DS_{IR} and doses higher than 20 ppm are not intended as the recommended therapeutic dose.

* All calculations for the table above are based on a full cylinder of 2000 psig, 353 liter "D" cylinder, and also accounting for cylinder change at 200 psig. The figures are calculated on total continuous flow cylinder conversion factor 0.18.

- INOMAX flow = [Desired dose X total ventilator flow] / [Cylinder concentration - desired dose]
- Cylinder volume = Cylinder conversion factor X cylinder pressure psig
- Cylinder duration = Cylinder volume / INOMAX flow rate

Calculations are considered estimates and may vary under clinical circumstances. For more information, call 1-877-KNOW-INO (1-877-566-9466).

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Proper use of these products depends on careful reading and understanding of labeling and instructions. Please refer to the INOmax DS_{IR} and INOblender operation manuals for guidance. Also refer to the specific breathing device operation manual or instructions for use.

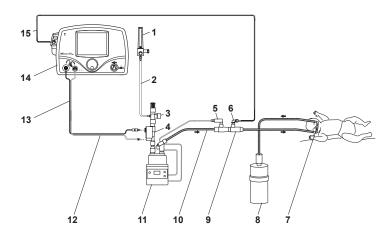
INOmax DS_{IR} Warnings:

- INOmax DS_{IR} subtracts gas from the breathing circuit via the gas sampling system at 230 mL per minute; this can affect the sensitivity of a flow triggered synchronized breath mode of some ventilators. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS_{IR} to the breathing circuit.
- Patient disconnect and high-pressure alarms are required for the ventilator.

INOmax DS_{IR} Cautions:

- Insert the Injector Module on the dry side of the breathing circuit prior to the humidifier (this will ensure correct flow measurement).
- Avoid medications interfering with the gas monitoring system; administer any aerosolized medications distal to the sampling tee.

Connection to the A-Plus Medical Babi-Plus Bubble CPAP

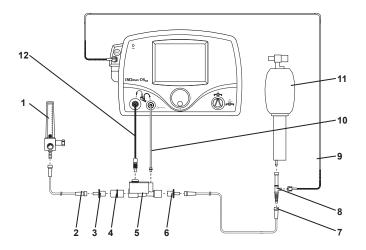


- 1. Oxygen Source
- 2. Oxygen Tubing
- 3. Pressure Relief Manifold
- 4. Injector Module
- 5. Temperature Probe
- 6. 90 Degree Sample Port Adapter
- 7. Nasal Prongs
- 8. Babi Plus Bubble PAP Valve

- 9. Tee Adapter
- 10. Breathing Circuit
- 11. Humidifier
- 12. NO/N₂ Injector Tube
- 13. Injector Module Electrical Cable
- 14. INOmax DSIR
- 15. Patient Gas Sample Line with Nafion

Connection to Bagging Systems While Using the Injector Module

- WARNING: To minimize the delivered concentration of NO2, the following steps should be taken for use with the manual resuscitator bags:
 - Use the smallest bag adequate to deliver the desired tidal volume.
 - Inspiratory tubing lengths greater than 72 inches should not be used.
 - Use the highest fresh gas flow rated (up to 15 L/min) that is practical.
 - Use the lowest practical inspired oxygen concentration.
 - After starting fresh gas flow, squeeze the bag several times to empty residual gas in the bag prior to using the system to ventilate a patient.



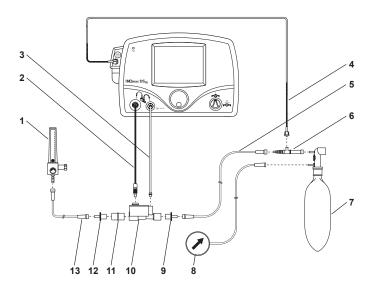
- 1. O₂ Flowmeter (wall outlet or cylinder)
- 2. O₂ Tubing
- 3. 15M X 4.5mm Adapter
- 4. 22M/15F X 22M/15F Adapter
- 5. Injector Module
- 6. 15M X 4.5mm Adapter
- 7. O₂ Tubing
- 8. O2 Tubing Sample Tee
- 9. Patient Gas Sample Line with Nafion
- 10. NO/N₂ Injector Tube
- 11. Resuscitator Bag with O2 Reservoir
- 12. Injector Module Electrical Cable

WARNING:

- The hyperinflation bag will, under some conditions, contain NO₂ in excess of 1 ppm. Use of large tidal volume breaths may expose the patients to the NO₂ present in the bag, for part of the breath. In general, if the inspiratory flow rate induced by the manual ventilation does not exceed the fresh gas flow rate, the patient should not be exposed to the concentrations of NO₂ present in the hyperinflation bag.
- Adult and infant hyperinflation bags generate more NO₂ when used at lower minute ventilation. If use of the bag is interrupted (for example to adjust the tracheal tube), before resuming ventilation of the patient, the user should squeeze the bag several times to empty residual gas from the bag.
- Because of the potential for inhalation of excessive concentrations of NO₂, and the difficulty in monitoring the peak inhaled NO₂ concentrations, ventilation with a hyperinflation bag or self inflating bag is intended only for short term use.
- The monitoring system within the INOmax DSIR will not detect generation of NO₂ within the hyperinflation bag or self-inflating bag devices and the alarms for excessive NO₂ cannot warn of NO₂ produced within the manual bag system.
- To minimize the delivered concentration of NO₂, the following steps should be taken for use with the manual resuscitator bags:
 - Concentrations greater than 20 ppm NO should not be used because of excessive NO₂ generation.
 - Use the smallest bag adequate to deliver the desired tidal volume.
 - Inspiratory tubing lengths greater than 72 inches should not be used.
 - Use the highest fresh gas flow rate (up to 15 L/min) that is practical.
 - Use the lowest practical inspired oxygen concentration.
 - After starting fresh gas flow, squeeze the bag several times to empty residual gas in the bag prior to using the system to ventilate a patient.

Circuit Connection Diagrams

Connection to Bagging Systems While Using the Injector Module



- 1. O₂ Flowmeter
- 2. Injector Module Electrical Cable
- 3. NO/N₂ Injector Tube
- 4. Patient Gas Sample Line with Nafion
- 5. O₂ Tubing
- 6. O2 Tubing Sample Tee
- 7. Hyper-Inflation Bag

- 8. Pressure Gauge
- 9. 15M X 4.5mm Adapter
- 10. Injector Module
- 11. 22M/15F X 22M/15F Adapter
- 12. 15M X 4.5mm Adapter
- 13. O₂ Tubing

Connection to a Bunnell Life Pulse High Frequency Ventilator Circuit

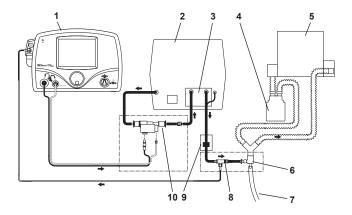
WARNING:

- The INOmax DS_{IR} backup mode (250 mL/min.) should not be used with the Bunnell Life Pulse as ventilator flow rates are normally below the recommended ventilator flows.
- Place the Life Pulse in Standby prior to suctioning the patient to avoid NO delivery transiently exceeding the set dose by up to 30 ppm. Press ENTER to reestablish ventilation as soon as the catheter is removed from the airway. This will limit the extent of over delivery above the NO set dose.

Caution:

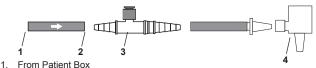
- If the set dose is below 5 ppm and the Servo pressure is 2.0 psig. or less, this will result in flow rates outside of the specification of the Injector Module and fluctuating NO values may result.
- A one-way valve should be placed between the injector module and the humidifier chamber to prevent water from backing up into the injector module if the Life Pulse is either put into Standby or cycled OFF.
- There are higher pressures in the breathing circuit than normal; use only parts provided in disposable package #50046 and tightly secure all connections.

Connection to a Bunnell Life Pulse High Frequency Ventilator Circuit (cont.)



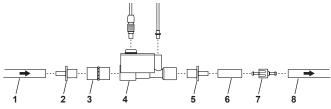
- 1. INOmax DSIR
- 2. Bunnell Life Pulse
- 3. Humidifier
- 4. Humidifier
- 5. Conventional Ventilator
- 6. Life Port Adapter
- 7. Endotracheal Tube
- 8. Sample Tee
- 9. Patient Box
- 10. Injector Module

Connecting INOmax DS_{IR} Sample Tee to the Bunnell Life Pulse Circuit



- Cut Green tube at midpoint (approximately 6 in. from the Life Port Adapter)
- 3. Insert Sample Tee
- 4. Life Port Adapter

Connecting INOmax DS_{IR} Injector Module to the Bunnell Life Pulse Circuit



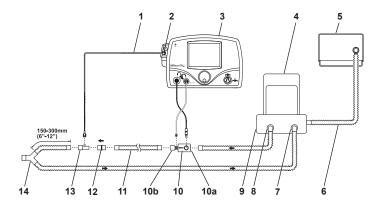
- 1. Gas Out Tube from Vent
- 2. 15M X 4.5mm I.D. Adapter
- 3. 22M/15F X 22M/15F Adapter
- 4. Injector Module

- 5. 15M X 4.5mm I.D. Adapter
- 6. 3cm Piece of Green Gas Out Tube
- 7. One-Way Valve
- 8. Green Gas Out Tube to Humidifier

WARNING:

- The INOmax DS_{IR} backup mode (250 mL/min.) should not be used with the Bunnell Life Pulse as ventilator flow rates are normally below the recommended ventilator flows.
- Place the Life Pulse in Standby prior to suctioning the patient to avoid NO delivery transiently exceeding the set dose by up to 30 ppm. Press ENTER to reestablish ventilation as soon as the catheter is removed from the airway. This will limit the extent of over delivery above the NO set dose.

Connection to a Circle Anesthesia System

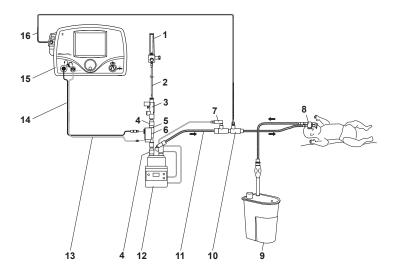


- 1. Patient Gas Sample Line with Nafion
- 2. Patient Gas Sample Line Input Connection
- 3. INOmax DSIR
- 4. Bellows Assembly
- 5. Ventilator
- 6. Ventilator Drive Gas
- 7. Absorber Expiratory Port

- 8. Absorber Inspiratory Port
- 9. Absorber
- 10. Injector Module
 - a. Injector Module Input End
 - b. Injector Module Output End
- 11. Inspiratory Tubing
- 12. 22M/15F X 22M/15F Adapter
- 13. Gas Sample Tee
- 14. Patient Wye

WARNING: Fresh gas flow should be equal to or greater than patient minute ventilation to avoid recirculation of gases.

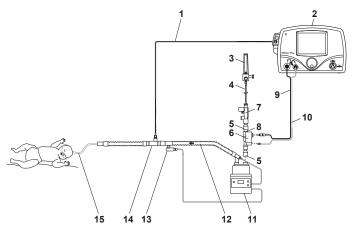
Connection to the Fisher & Paykel Bubble CPAP



- 1. Oxygen Source
- 2. Oxygen Tubing
- 3. Bubble CPAP Pressure Manifold
- 4. 22F X 15M Adapter
- 5. 22M/15F X 22M/15F Adapter
- 6. Injector Module
- 7. Temperature Probe
- 8. Nasal Prong Infant Interface
- 9. Bubble CPAP Generator

- 10. F/P Inline Infant Nebulizer Kit (RT010) Adapter
- 11. Breathing Circuit
- 12. Humidifier
- 13. NO/N₂ Injector Tube
- 14. Injector Module Electrical Cable
- 15. INOmax DSIR
- 16. Patient Gas Sample Line with Nafion

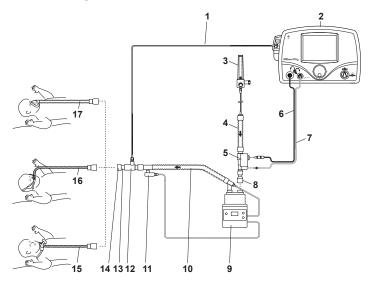
Connection to the Fisher & Paykel Infant Circuit Nasal Cannula



- 1. Patient Gas Sample Line with Nafion
- 2. INOmax DSIR
- 3. Oxygen Source
- 4. Oxygen Tubing
- 5. 22F X 15M Adapter
- 6. Injector Module
- 7. Pressure Relief Manifold
- 8. 22M/15F X 22M/15F Adapter

- 9. Injector Module Electrical Cable
- 10. NO/N₂ Injector Tube
- 11. Humidifier
- 12. Breathing Circuit
- 13. Temperature Probe
- 14. Gas Sample Tee
- 15. Nasal Cannula

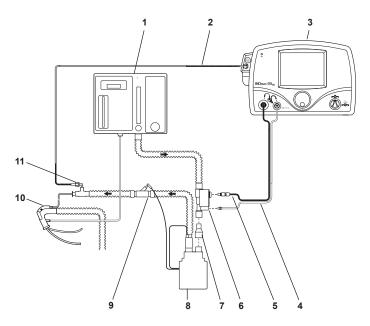
Connection to the Fisher & Paykel Optiflow Breathing Circuit



- 1. Patient Gas Sample Line with Nafion
- 2. INOmax DSIR
- 3. Oxygen Source
- 4. Breathing Circuit Hose
- 5. Injector Module
- 6. Injector Module Electrical Cable
- 7. NO/N₂ Injector Tube
- 8. 22F X 15M Adapter
- 9. Humidifier

- 10. Breathing Circuit
- 11. Temperature Probe
- 12. Gas Sample Tee
- 13. 22M/15F X 22M/15F Adapter
- 14. 22 mm ID X 22 mm ID Cuff Adapter
- 15. Optiflow Tracheostomy
- 16. Optiflow Nasal Cannula
- 17. Optiflow Mask

Connection to the Hamilton Arabella Nasal CPAP

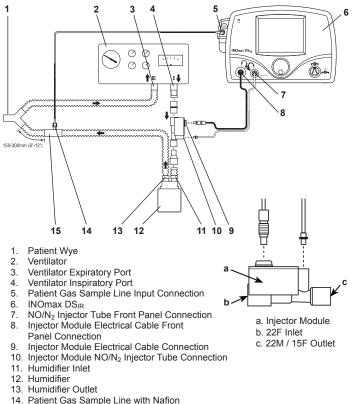


- 1. Arabella
- 2. Patient Gas Sample Line with Nafion
- 3. INOmax DSIR
- 4. NO/N₂ Injector Tube
- 5. Injector Module Electrical Cable
- 6. Injector Module

- 7. 22F X 15M Adapter
- 8. Humidifier
- 9. Heated Delivery Circuit
- 10. Universal Generator
- 11. 90 Degree Sample Port Adapter

Circuit Connection Diagrams

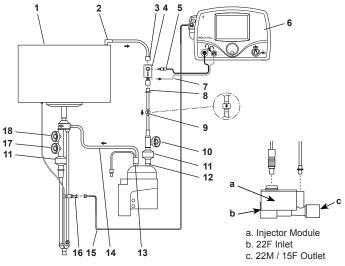
ICU Ventilator Circuit



15. Gas Sample Tee

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Sensormedics 3100A/B High Frequency Oscillatory Ventilator with a Filtered Circuit

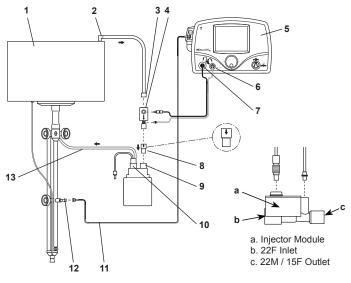


- 1. Sensormedics 3100A/B Ventilator
- 2. Ventilator Outlet
- 3. 22M Adapter
- 4. Injector Module
- 5. Injector Module Electrical Cable Connection
- 6. INOmax DSIR
- 7. NO/N₂ Injector Tube
- 8. 15M Adapter
- 9. One-Way Valve

- 10. Paw Limit Valve Control
- 11. Filter
- 12. Humidifier Inlet
- 13. Humidifier Outlet
- 14. Bias Flow Tube
- 15. Patient Gas Sample Line with Nafion
- 16. 90 Degree Sample Port Adapter
- 17. Dump Valve Control
- 18. Paw Control Valve

WARNING: Omission of the one-way valve may result in high NO delivery.

Sensormedics 3100A/B High Frequency Oscillatory Ventilator with a Rigid or Flexible Circuit



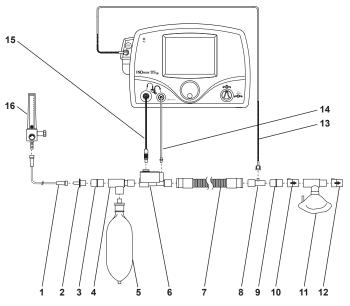
- 1. Sensormedics 3100A/B Ventilator
- 2. Ventilator Outlet
- 3. 22M Adapter
- 4. Injector Module
- 5. INOmax DSIR
- 6. NO/N₂ Injector Tube Connection
- 7. Injector Module Electrical Cable Connection
- 8. One-Way Valve

WARNING: Omission of the one-way valve may result in high NO delivery.

- 9. Humidifier Inlet
- 10. Humidifier Outlet
- 11. Patient Gas Sample Line with Nafion
- 12. 90 Degree Sample Port Adapter
- 13. Bias Flow Tube

Circuit Connection Diagrams

Connection to Spontaneous Breathing Patient on a Mask Circuit



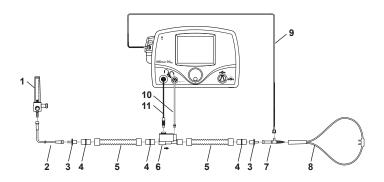
- 1. O₂ Tubing
- 2. 15M X 4.5mm Adapter
- 3. 22M/15F X 22M/15F Adapter
- 4. Breathing Circuit Tee
- 5. Breathing Circuit Bag
- 6. Injector Module
- 7. Breathing Circuit Hose
- 8. Gas Sample Tee

- 9. 22M/15F X 22M/15F Adapter
- 10. One-Way Valve
- 11. Sealed Face Mask
- 12. One-Way Valve
- 13. Patient Gas Sample Line with Nafion
- 14. NO/N₂ Injector Tube
- 15. Injector Module Electrical Cable
- 16. O₂ Flowmeter (wall outlet or cylinder)

Connection to Spontaneous Breathing Patient on a Nasal Cannula

The INOmax DS_{IR} can be used with nasal cannula to deliver INOMAX concentrations from 5-80 ppm and an oxygen flow rate as low as 2 L/min.

WARNING: Do not use the INOmax DS_{IR} backup mode with flow rates less than 5 L/min.

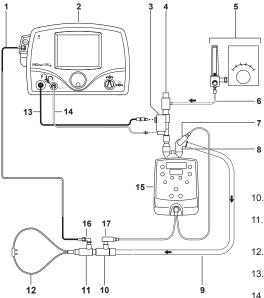


- 1. O₂ Flowmeter
- 2. O₂ Tubing
- 3. 15M x 4.5mm Adapter
- 4. 22M/15F x 22M/15F Adapter
- 5. 300mm of 22mm Hose
- 6. Injector Module

- 7. O₂ Tubing Sample Tee
- 8. Patient Nasal Cannula
- 9. Patient Gas Sample Line with Nafion
- 10. NO/N₂ Injector Tube
- 11. Injector Module Electrical Cable

Circuit Connection Diagrams

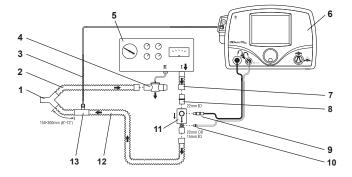
Connection to the Teleflex Medical Comfort Flo Humidification System



- 1. Patient Gas Sample Line with Nafion
- 2. INOmax DS_{IR}
- 3. Injector Module
- 4. System Pressure Relief Valve
- 5. Air/Oxygen Blender or Oxygen Blender
- 6. Oxygen Tubing
- 7. Temperature Probe (Short Cable)
- 8. Angled 22 mm Connector
- 9. Patient Circuit

- 10. Temperature Probe Connector
- 11. Second Temperature Probe Connector
- 12. Comfort Flo Cannula
- 13. Injector Module Electrical Cable
- 14. NO/N₂ Injector Tube
- 15. ConchaTherm Heated Humidifier
- 90 Degree Sample Port Adapter
- 17. Temperature Probe (Long Cable)

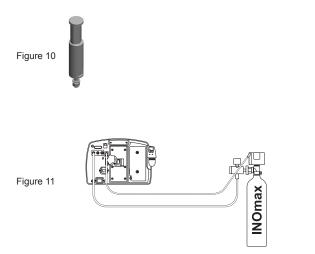
Transport Ventilator Diagram



- 1. Patient Wye
- 2. Expiratory Breathing Circuit Hose
- 3. Patient Gas Sample Line with Nafion
- 4. Ventilator Expiratory Valve
- 5. Ventilator
- 6. INOmax DSIR

- 7. Ventilator Inspiratory Port
- 8. 22M/15F X 22M/15F Adapter
- 9. Injector Module Electrical Cable
- 10. NO/N₂ Injector Tube
- 11. Injector Module
- 12. Inspiratory Breathing Circuit Hose
- 13. Gas Sample Tee

WARNING: If the INOmax DS_{IR} is to be used in a transport vehicle, it should be affixed to the transport mounting post part number 10009 (see Figure 10).

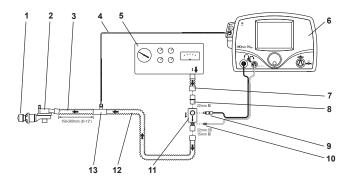


Caution:

When using the Transport Regulator/Cap Assembly (PN 10022) ensure the cap is fully seated and in place on the INOmeter and the infrared cable is connected and latched to the infrared connector port on the back of the INOmax DS_{IR} (see Figure 11).

It is recommended that a second transport regulator cap assembly is available during all transports.

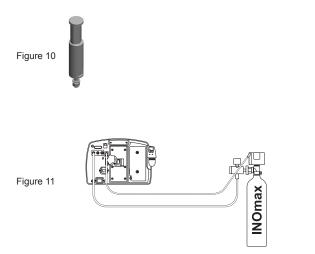
Single-Limb Transport Ventilator Diagram



- 1. PEEP/Exhalation Valve
- 2. Patient Wye
- 3. Circuit Hose
- 4. Patient Gas Sample Line with Nafion
- 5. Ventilator
- 6. INOmax DSIR

- 7. Ventilator Inspiratory Port
- 8. 22M/15F X 22M/15F Adapter
- 9. Injector Module Electrical Cable
- 10. NO/N₂ Injector Tube
- 11. Injector Module
- 12. Inspiratory Breathing Circuit Hose
- 13. Gas Sample Tee

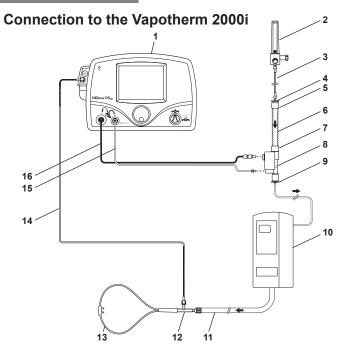
WARNING: If the INOmax DS_{IR} is to be used in a transport vehicle, it should be affixed to the transport mounting post part number 10009 (see Figure 10).



Caution:

When using the Transport Regulator/Cap Assembly (PN 10022) ensure the cap is fully seated and in place on the INOmeter and the infrared cable is connected and latched to the infrared connector port on the back of the INOmax DS_{IR} (see Figure 11).

It is recommended that a second transport regulator cap assembly is available during all transports.

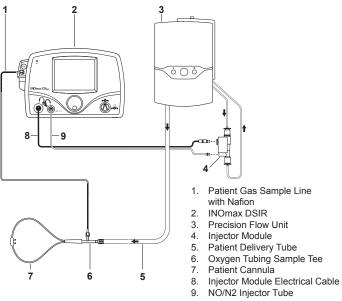


- 1. INOmax DSIR
- 2. O₂ Flowmeter
- 3. O₂ Tubing
- 4. 15M x 4.5mm Adapter
- 5. 22M/15F x 22M/15F Adapter
- 6. 300mm of 22mm Hose
- 7. 22M/15F x 22M/15F Adapter
- 8. Injector Module

- 9. 15M x 4.5mm Adapter
- 10. Vapotherm 2000i
- 11. Patient Delivery Tube
- 12. O2 Tubing Sample Tee
- 13. Patient Cannula
- 14. Patient Gas Sample Line with Nafion
- 15. NO/N₂ Injector Tube
- 16. Injector Module Electrical Cable

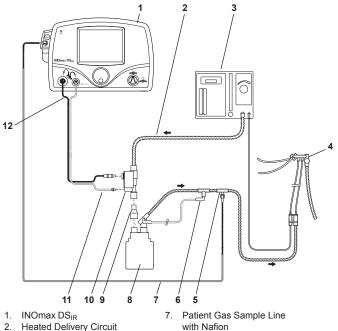
Connection to the Vapotherm Precision Flow

- The INOmax DS_{IR} adds NO/N₂ gas flow to the breathing circuit flow in proportion to the NO setting (up to 10% at 80 ppm) and subtracts gas from the breathing circuit via gas sampling at a nominal flow rate of 0.23 L/min.
- These effects impact the delivered gas flow rate when using the Vapotherm Precision Flow. It is recommended that after an NO setting change the user checks the delivered gas flow rate and adjusts the gas source flow rate as necessary.
- Follow all manufacturer instructions for connection to the Vapotherm Precision Flow.



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Connection to the Viasys Infant Flow CPAP System; Cardinal AirLife nCPAP System

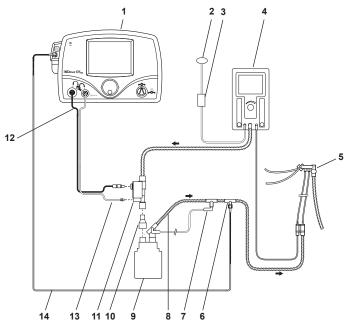


- 3. Infant Flow System; Cardinal AirLife nCPAP System
- 4. Infant Flow Generator
- 5 Sample Tee
- **Temperature Probe** 6.

- 8. Humidifier
- 9. 22F X 15M Adapter
- 10. Injector Module
- 11. NO/N₂ Injector Tube
- 12. Injector Module Electrical Cable

Circuit Connection Diagrams

Connection to the Viasys Infant Flow SiPAP



- 1. INOmax DSIR
- 2. Abdominal Respiratory Sensor
- 3. Transducer Interface
- 4. Infant Flow SiPAP
- 5. Infant Flow Generator
- 6. Sample Tee
- 7. Temperature Probe

- 8. Heated Delivery Circuit
- 9. Humidifier
- 10. 22F X 15M Adapter
- 11. Injector Module
- 12. Injector Module Electrical Cable
- 13. NO/N₂ Injector Tube
- 14. Patient Gas Sample Line with Nafion

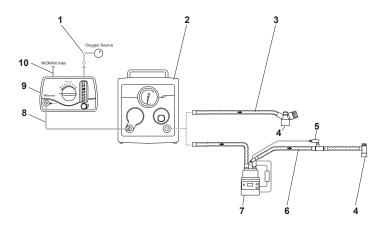
INOblender Warnings:

- The purge procedure must be followed to help ensure NO₂ is purged from the pressure regulator, INOblender and hoses before the manual resuscitator bag or nasal cannula is connected to the patient. The manual bag should be squeezed continuously during use to avoid NO₂ building up in the bag. If the bag is not squeezed continuously while delivering INOMAX, the bag should be removed from the patient and the purge procedure performed before continuing.
- Persons using this device should be trained on and experienced in the use of this device to assure effective administration of INOMAX and to avoid injury to the patient or others resulting from inhalation of excess INOMAX, nitrogen dioxide or other reaction products.

INOblender Cautions:

- Refer to the manufacturer's procedures for using the resuscitation bag. When finished, turn the INOMAX cylinder off and continue to flow O₂ until the NO pressure gauge reads zero, then turn the O₂ flow off and the NO dial to zero ppm.
- Note: Connections to various ventilators as well as their corresponding disposable circuits, are unique to each manufacturer. Please refer to the specific breathing device operation manual or instructions for use for guidance.

INOblender Connection to the Fisher & Paykel Neopuff Resuscitator



- 1. Oxygen Source
- 2. Neopuff
- 3. T-Piece Circuit (with Duckbill Port)
- 4. Patient Connection
- 5. Temperature Probe
- 6. Humidified Resuscitation System Circuit
- 7. Humidifier
- 8. Oxygen Tubing
- 9. INOblender
- 10. INOMAX Inlet

Changing INOMAX Cylinders

WARNING:

- A new INOMAX cylinder and regulator must be purged before use to ensure the patient does not receive greater than 1.0 ppm of NO₂.
- Loss of communication between the INOmax DS_{IR} and the INOMAX cylinder for more than one hour will result in interruption of INOMAX delivery.

Caution:

- Replace an INOMAX cylinder when its pressure is less than 200 psig.
- When using the Transport Regulator/Cap Assembly (PN 10022) ensure the cap is fully seated and in place on the INOmeter and the infrared cable is connected and latched to the infrared connector port on the back of the INOmax DS_{IR.}
- Note: Ensure the white plastic tip is in place.
- A. Attach a regulator to an INOMAX cylinder with greater than 200 psig.



Changing INOMAX Cylinders

B. Perform high pressure leak test.



C. Purge the high pressure hose.



D. Connect the pressure hose.



Changing INOMAX Cylinders

Changing INOMAX Cylinders (cont.)

- E. Open the cylinder valve (this may activate the "Two Cylinders Open" alarm until the empty cylinder valve is closed).
- Note: If using the INOmax DS_{IR} Transport Regulator/Cap Assembly, transfer the cap from the exhausted INOMAX cylinder to the new INOMAX cylinder at this time; the "Cylinder Not Detected" alarm may occur.
- F. Close the cylinder valve on the empty cylinder and remove the hose from the back of the INOmax DS_{IR} .

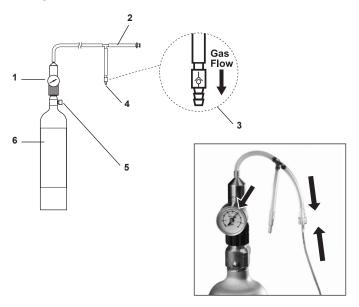


G. Depressurize and remove the regulator from the empty cylinder.

Changing INOMAX Cylinders

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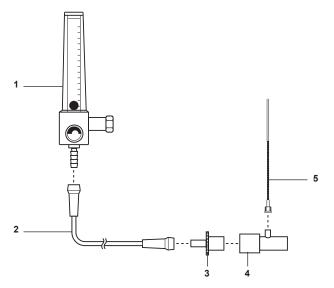
Connection Diagram for NO and NO₂ High Range Calibration



- 1. Calibration Gas Cylinder Pressure Gauge
- 2. Sample Line Connection
- 3. One-way Valve
- 4. Vent to Atmosphere or Scavenge Do Not Occlude
- 5. Cylinder ON/OFF Control
- 6. NO or NO₂ Calibration Gas Cylinder

High Calibration Connection Diagrams

Connection Diagram for O₂ High Range Calibration



- 1. 100% O2 Source
- 2. O₂ Tubing
- 3. 15M x 4.5mm I.D. Adapter
- 4. Gas Sample Tee
- 5. Patient Gas Sample Line with Nafion

INOmax DSIR Patient Circuit Disposables

(Note: Graphics not actual size)

Adapter,

15M Fits 4.5mm ID Tubing



Adapter, 22F X 15M



Adapter, 22M/15F X 22M/15F



Adapter, Cuff, 22mm ID X 22mm ID



Adapter, Gas Sample Tee



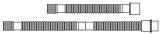
Adapter, 90 degree Sample Port



Bunnell Life Pulse Disposable Adapters Convenience Pack



Neonatal Tubing, 10mm (2 pieces)



Disk Filter, 0.5 micron



NO/N₂ Injector Tube



INOmax DS_{IR} Disposable Adapters

One-way Valve, 22F X 22M



Pediatric Extension, 15 mm (6 inches)



Sensormedics 3100A/B Filtered Circuit Disposable Adapters Convenience Pack

Patient Gas Sample Line with Nafion



Sample Tee, O₂ Tubing



Water Separator Cartridge



INO Therapeutics d/b/a Ikaria, Inc. Perryville III Corporate Park 53 Frontage Road, Third Floor Hampton, NJ 08827-9001, USA 1-877-566-9466

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