INOmax DS_{IR}®

(Delivery System)

Pocket Guide

Series 3 software

Automated Pre-Use Procedure
Integrated Pneumatic 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

Mallinckrodt™ Pharmaceuticals

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

Part No. 20751 Rev-01
2014-08

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}® Operation Manual. The Operation Manual is the source for specific, updated information regarding warnings, cautions, checklists, diagrams, and/or instructions contained in this guide.

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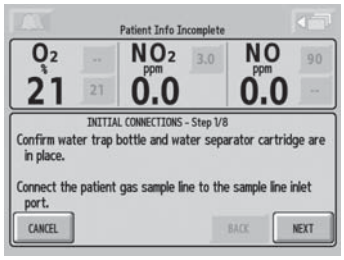
Contents

Automated Pre-Use Checkout

1. Turn INOmax DS_{IR} ON, verify speaker function.

   Note: A low range calibration automatically starts following the self test.

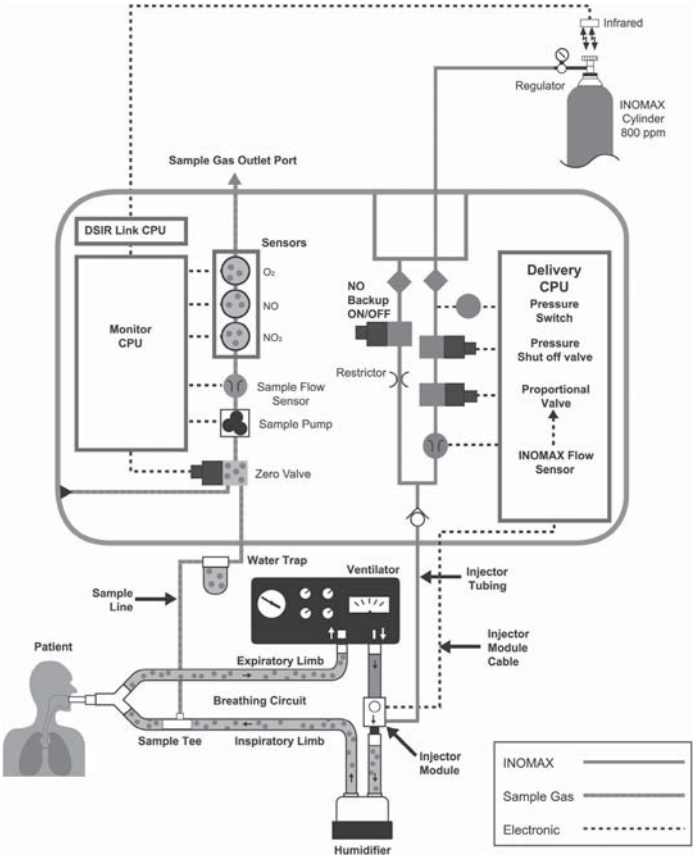
   A Pre-Use wizard will be displayed on the main screen, which will provide step-by-step instructions to complete the automated Pre-Use procedure.



- Pressing the NEXT button initiates the Pre-Use wizard.
- Pressing the CANCEL button exits the Pre-Use wizard. If you cancel the pre-use wizard, the manual pre-use checkout procedure can be found on the INOmax DS_{IR} Plus Pre-Use card, or in the INOmax DS_{IR} Operation Manual, section 9/Appendix.

  The Pre-Use wizard can also be initiated by entering the menu screen and selecting the Pre-Use Checkout button.

Pre-Use Checkout



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Integrated Pneumatic Backup INOMAX Delivery

Note: Use the integrated pneumatic backup function only for a short time, until a replacement delivery system can be obtained. The INOblender can also be used as a backup.

If the main delivery system fails, the INOmax DS_{IR} has an integrated pneumatic backup delivery function that allows the patient to remain connected to the ventilator. Backup NO delivery does not rely on the operation of the main system.

The INOmax DS_{IR} backup function:

· Uses a pneumatic on/off switch and a restrictor built into the delivery side of the system.

· Provides a fixed flow of INOMAX (250 mL/min) into the injector module. This fixed flow provides 20 ppm of NO when added to a continuous ventilator gas flow of 10 L/min.

WARNING:

When using the integrated pneumatic backup with breathing circuit gas flows of 5 L/min, the delivered NO dose will be approximately 40 ppm. Breathing circuit gas flows less than 5 L/min will deliver an NO dose greater than 40 ppm.

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 = estimated dose

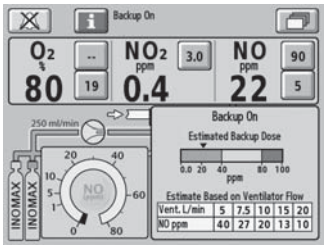
The main screen:

· Indicates that backup delivery is on and that the set dose is turned off.

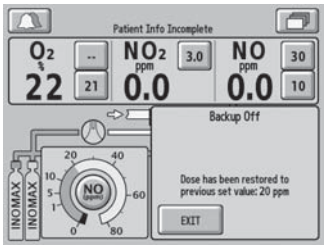
· Displays the estimated dose that the patient should be receiving, based on the ventilator flow.

· Displays the NO concentration table

Note: If the injector module is not functioning, the estimated backup dose graphic will be inactive.



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



Backup delivery mode OFF.

Transport Regulator/Cap Assembly

WARNING:

- **A new INOMAX cylinder and regulator must be purged before use to ensure the patient does not receive an excess level of NO_2.**
- **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 500 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

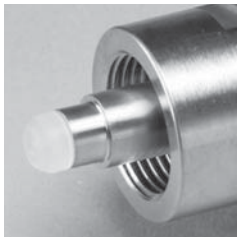


Figure 2

Step Two

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

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

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).

Figure 5

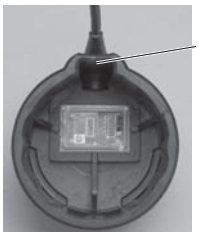


Figure 6

Step Five

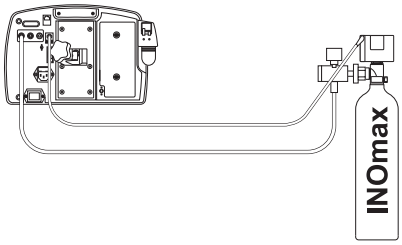
Grasp the Cap Assembly to open cylinder valve (see Figure 7 and 8).

Figure 7

Figure 8

Final Set-up Diagram

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



Additional Information

Communication will take place between the INOmax DS_{IR} and the INOmeter after the boot up phase of the INOmax 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)

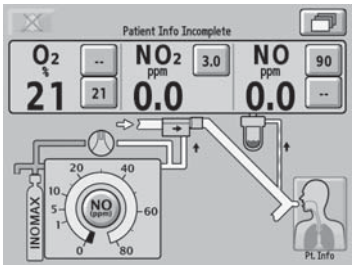


Figure 9

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Oxygen Dilution Chart

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

(Illustrative Only)

		Set FiO_2				
		.21	.40	.60	.80	1.00
INOMAX Dose	10	0.21	0.40	0.59	0.79	0.99
	20	⚠0.20	0.39	0.59	0.78	0.98
	40	⚠0.20	0.38	0.57	0.76	0.95
	80	⚠0.19	0.36	0.54	0.72	0.90
		Actual FiO_2				

⚠ Caution FiO_2 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**
INOMAX Dose (ppm)	5	39 Days	19.5 Days	9.8 Days	4.9 Days
	10	19.4 Days	9.7 Days	4.8 Days	2.4 Days
	20	9.6 Days	4.8 Days	2.4 Days	1.2 Days
	40	4.7 Days	2.3 Days	1.2 Days	14 Hours
	80	2.2 Days	1.1 Days	13.3 Hours	6.6 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 in the table above are based on a full cylinder, 138 bar (2000 psig), 1963 liter “88” cylinder, with a cylinder change at 14 bar (200 psig). The figures are calculated based on a total continuous breathing circuit gas flow and a cylinder conversion factor of 14.2 liters per bar/0.98 liters per psig.

- INOMAX flow = [Desired dose × total ventilator flow] ÷ [Cylinder concentration - desired dose]
- Cylinder volume = Cylinder conversion factor × cylinder pressure (bar/psig)
- Cylinder duration (hours) = (Cylinder volume ÷ INOMAX flow rate) ÷ 60

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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Duration Chart (D-size)

INOMAX Cylinder D-Size

INOMAX Dose (ppm)	FLOW				
	5 L/min	10 L/min	20 L/min	40 L/min	
5	7.0 Days	3.5 Days	1.8 Days	21 Hours	
10	3.5 Days	1.7 Days	21 Hours	10.5 Hours	
20	1.7 Days	20.7 Hours	10.3 Hours	5.2 Hours	
40	20 Hours	10 Hours	5 Hours	2.5 Hours	
80	9.5 Hours	4.8 Hours	2.4 Hours	1.2 Hours	

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 in the table above are based on a full cylinder, 138 bar (2000 psig), 353 liter “D” cylinder, with a cylinder change at 14 bar (200 psig). The figures are calculated based on a total continuous breathing circuit gas flow and a cylinder conversion factor of 2.6 liters per bar/0.18 liters per psig.

- INOMAX flow = [Desired dose × total ventilator flow] ÷ [Cylinder concentration - desired dose]
- Cylinder volume = Cylinder conversion factor × cylinder pressure (bar/psig)
- Cylinder duration (hours) = (Cylinder volume ÷ INOMAX flow rate) ÷ 60

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

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.

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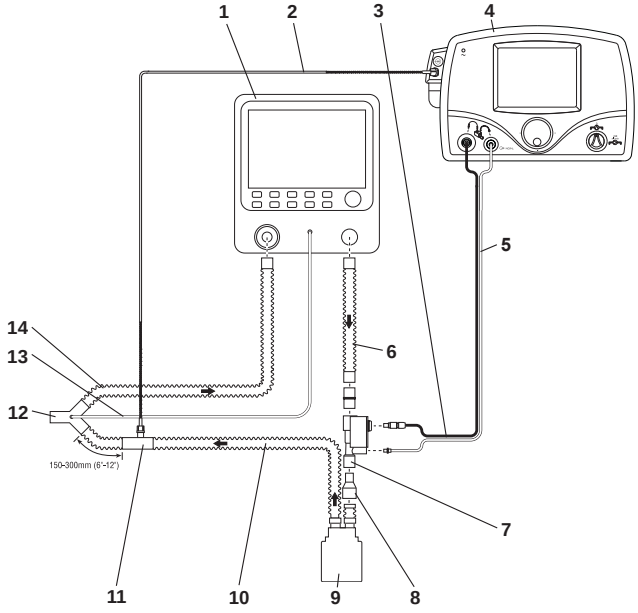
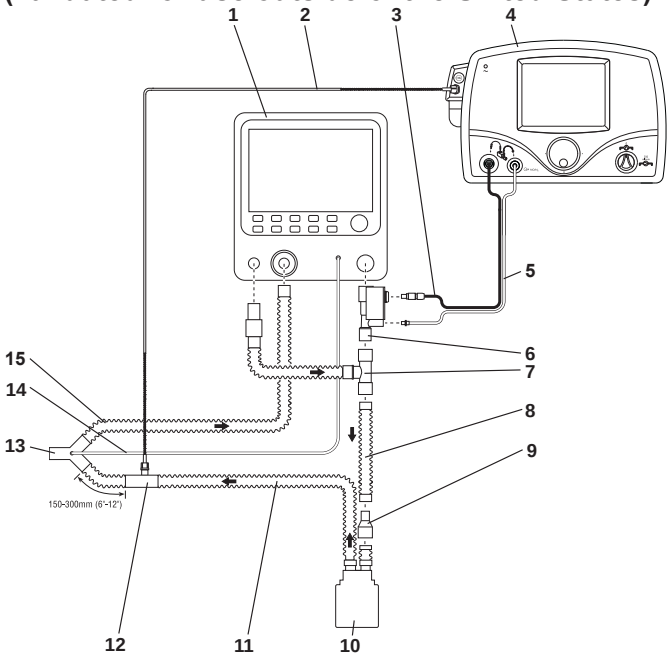
Acutronics Medical Systems AG Fabian +nCPAP Evolution (validated for use outside of the United States)



1. Fabian+ nCPAP Evolution
2. Patient Gas Sample Line with Nafion
3. Injector Module Electrical Cable
4. INOmax DS_{IR}
5. NO/N_2 Injector Tube
6. Connecting Tube (15 inches)
7. Injector Module
8. 22F X 15M Adapter
9. Humidifier
10. Inspiratory Breathing Circuit Hose
11. Gas Sample Tee
12. Patient Wye
13. Proximal Pressure Tube
14. Expiratory Breathing Circuit Hose

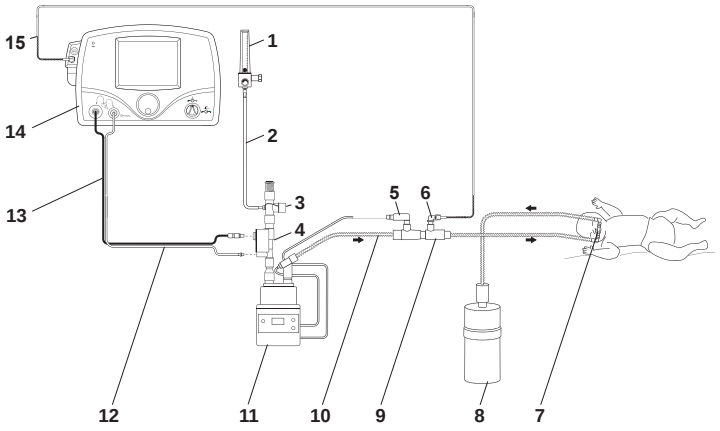
Acutronics Medical Systems AG Fabian HFO (validated for use outside of the United States)



1. Fabian HFO Ventilator
2. Patient Gas Sample Line with Nafion
3. Injector Module Electrical Cable
4. INOmax DS_{IR}
5. NO/N_2 Injector Tube
6. Injector Module
7. T-Connector Assembly, #7209.e
8. Connecting Tube (15 inches)
9. 22F X 15M Adapter
10. Humidifier
11. Inspiratory Breathing Circuit Hose
12. Gas Sample Tee
13. Patient Wye
14. Proximal Pressure Tube
15. Expiratory Breathing Circuit Hose

Circuit Connection Diagrams

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/N_2 Injector Tube
13. Injector Module Electrical Cable
14. INOmax DS_{IR}
15. Patient Gas Sample Line with Nafion

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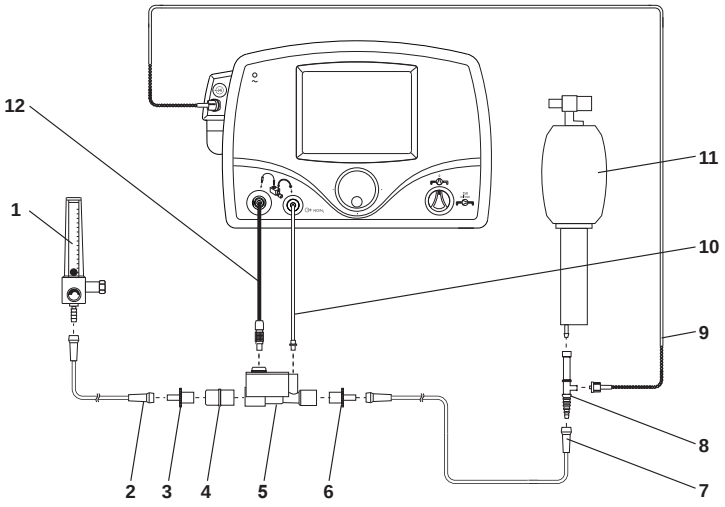
Bagging Systems While Using the Injector Module

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.**
- **Oxygen 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



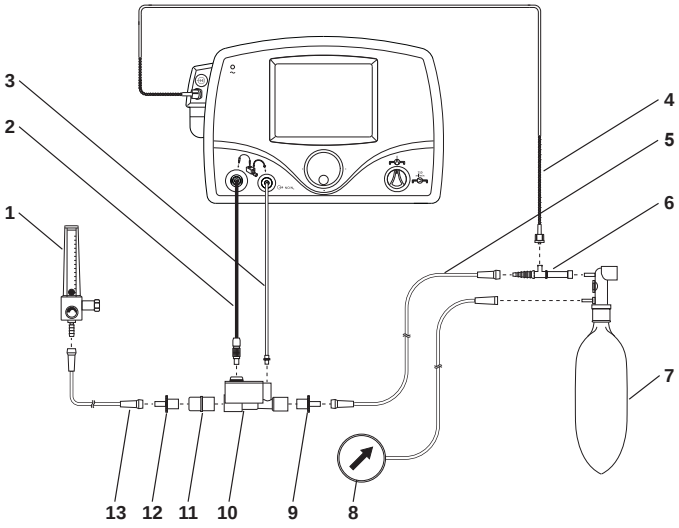
1. O_2 Flowmeter (wall outlet or cylinder)
2. O_2 Tubing
3. 15M X 4.5 mm Adapter
4. 22M/15F X 22M/15F Adapter
5. Injector Module
6. 15M X 4.5 mm Adapter
7. O_2 Tubing
8. O_2 Tubing Sample Tee
9. Patient Gas Sample Line with Nafion
10. NO/N_2 Injector Tube
11. Resuscitator Bag with O_2 Reservoir
12. Injector Module Electrical Cable

Circuit Connection Diagrams

WARNING:

- **The hyperinflation bag will, under some conditions, contain NO_2 in excess of 1 ppm. Use of large tidal volume breaths may expose the patients to the NO_2 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 NO_2 present in the hyperinflation bag.**
- **Adult and infant hyperinflation bags generate more NO_2 when used at lower minute ventilation. If use of the bag is interrupted (for example, to adjust a 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 NO_2, and the difficulty in monitoring the peak inhaled NO_2 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 NO_2 within the hyperinflation bag or self-inflating bag devices and the alarms for excessive NO_2 cannot warn of NO_2 produced within the manual bag system.**
- **To minimize the delivered concentration of NO_2, 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 NO_2 generation.**
  - **Use the smallest bag adequate to deliver the desired tidal volume.**
  - **Oxygen 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.**

Bagging Systems While Using the Injector Module



1. O_2 Flowmeter
2. Injector Module Electrical Cable
3. NO/N_2 Injector Tube
4. Patient Gas Sample Line with Nafion
5. O_2 Tubing
6. O_2 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. O_2 Tubing

Bunnell Life Pulse
High Frequency Ventilator Circuit

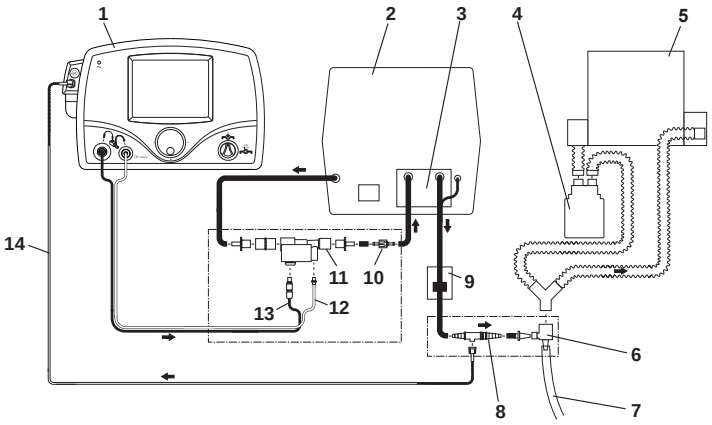
WARNING:

- **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 #50248 and tightly secure all connections.

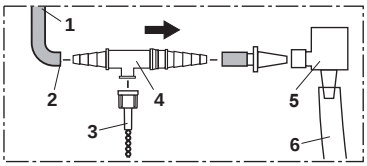
Bunnell Life Pulse
High Frequency Ventilator Circuit (cont.)



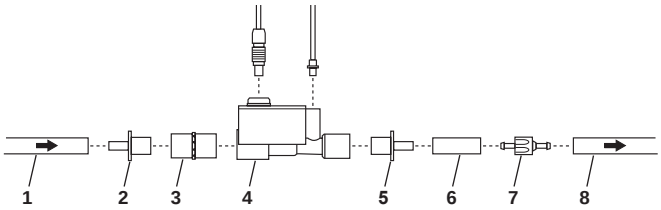
1. INOmax DS_{IR}
2. Bunnell Life Pulse
3. Humidifier
4. Humidifier
5. Conventional Ventilator
6. Life Port Adapter
7. Endotracheal Tube
8. Sample Tee
9. Patient Box
10. One-Way Valve
11. Injector Module
12. NO/N_2 Injector Tube
13. Injector Module Electrical Cable
14. Patient Gas Sample Line with Nafion

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

1. From Patient Box
2. Cut Green tube at midpoint (approximately six inches from the Life Port Adapter)
3. Patient Gas Sample Line with Nafion
4. Insert Sample Tee
5. Life Port Adapter
6. Endotracheal Tube

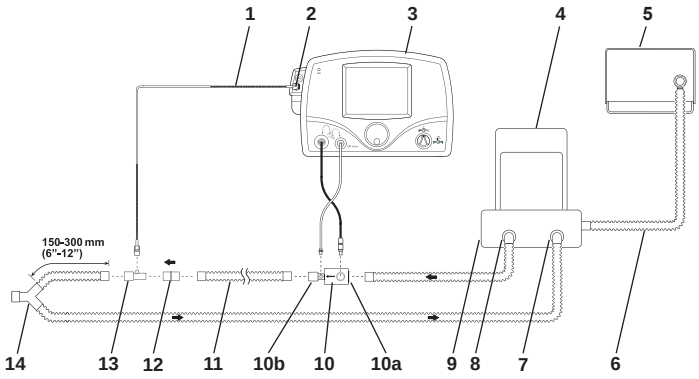


Connecting INOmax DS_{IR} Injector Module to the Bunnell Life Pulse Circuit



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

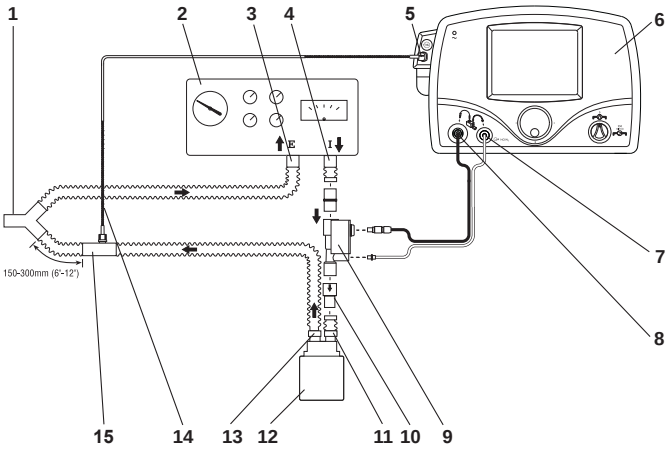
Circle Anesthesia System



1. Patient Gas Sample Line with Nafion
2. Patient Gas Sample Line Input Connection
3. INOmax DS_{IR}
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

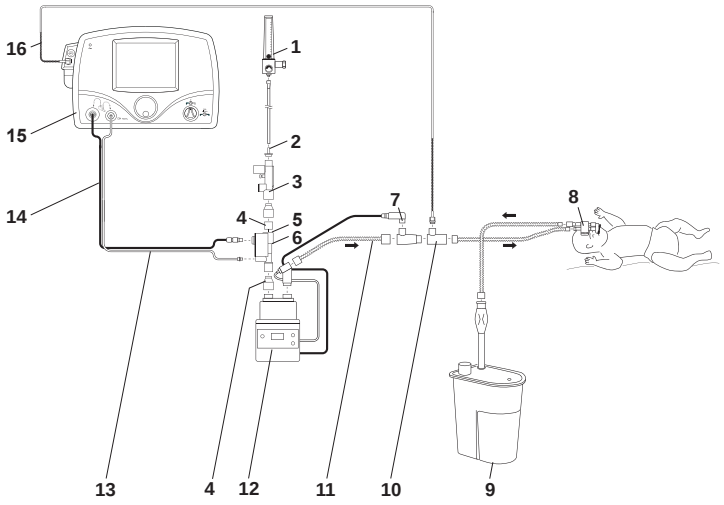
WARNING: Fresh gas flow should be equal to or greater than patient minute ventilation to avoid recirculation of gases.

Dräger Babylog VN500/Infinity Acute Care System and Heinen & Löwenstein Leoni-plus Ventilator (validated for use outside of the United States)



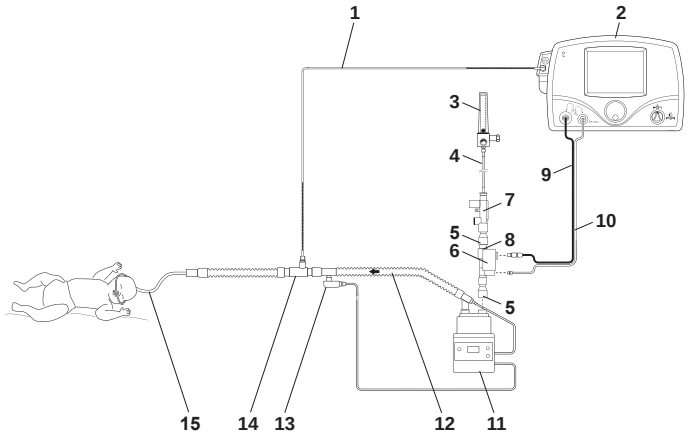
1. Patient wye
2. Dräger Babylog VN500 / Leoni-plus Ventilator
3. Ventilator Expiratory Port
4. Ventilator Inspiratory Port
5. Patient Gas Sample Line Input Connection
6. INOmax DS_{IR}
7. NO/N_2 Injector Tube Front Panel Connection
8. Injector Module Electrical Cable Front Panel Connection
9. Injector Module
10. One-Way Valve
11. Humidifier Inlet
12. Humidifier
13. Humidifier Outlet
14. Patient Gas Sample Line with Nafion
15. Gas Sample Tee

Fisher & Paykel Bubble CPAP



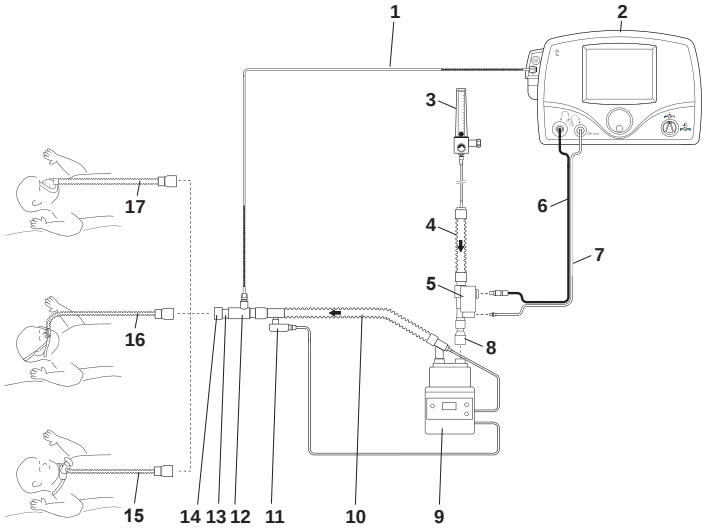
1. Oxygen Source
2. Oxygen Tubing
3. Bubble CPAP Pressure Manifold
4. 22F X 15M Adapter
5. 22M/15F X 22M/15F Adapter
6. Injector Module
7. Temperature Probe
8. Nasal Prong Infant Interface
9. Bubble CPAP Generator
10. F/P Inline Infant Nebulizer Kit (RT010) Adapter
11. Breathing Circuit
12. Humidifier
13. NO/N_2 Injector Tube
14. Injector Module Electrical Cable
15. INOmax DS_{IR}
16. Patient Gas Sample Line with Nafion

Fisher & Paykel Infant Circuit Nasal Cannula



1. Patient Gas Sample Line with Nafion
2. INOmax DS_{IR}
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/N_2 Injector Tube
11. Humidifier
12. Breathing Circuit
13. Temperature Probe
14. Gas Sample Tee
15. Nasal Cannula

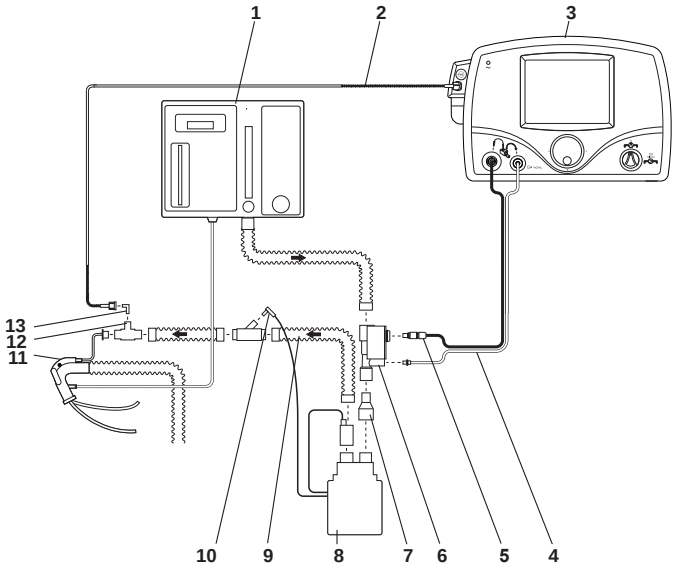
Fisher & Paykel Optiflow Breathing Circuit



1. Patient Gas Sample Line with Nafion
2. INOmax DS_{IR}
3. Oxygen Source
4. Breathing Circuit Hose
5. Injector Module
6. Injector Module Electrical Cable
7. NO/N_2 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

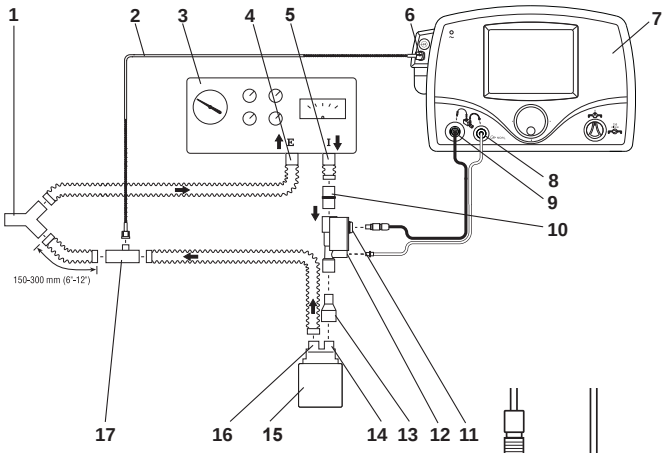
Circuit Connection Diagrams

Hamilton Arabella Nasal CPAP

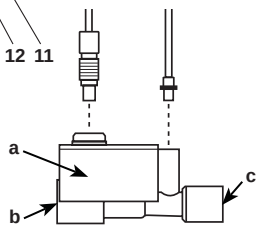


1. Arabella
2. Patient Gas Sample Line with Nafion
3. INOmax DS_{IR}
4. NO/N_2 Injector Tube
5. Injector Module Electrical Cable
6. Injector Module
7. 22F X 15M Adapter
8. Humidifier
9. Heated Delivery Circuit
10. Temperature Probe
11. Universal Generator
12. Arabella Sample Tee
13. 90 Degree Sample Port Adapter

ICU Ventilator Circuit

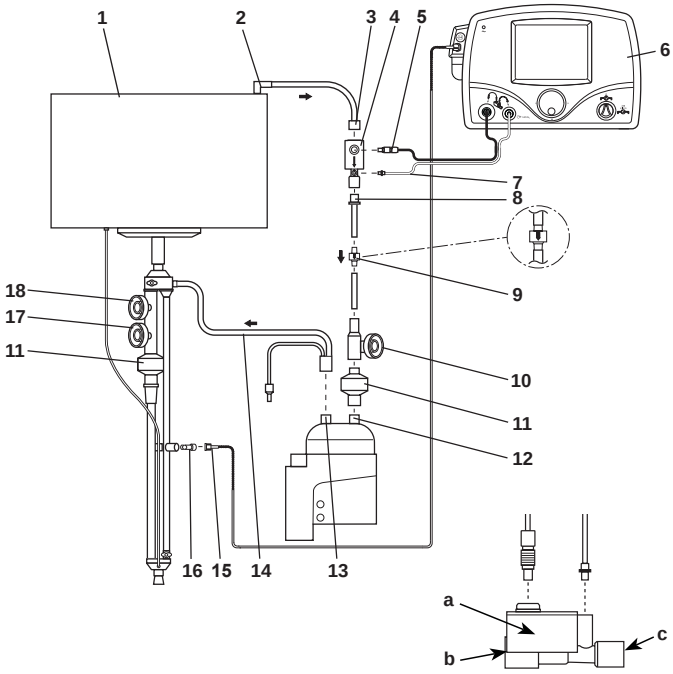


1. Patient Wye
2. Patient Gas Sample Line with Nafion
3. Ventilator
4. Ventilator Expiratory Port
5. Ventilator Inspiratory Port
6. Patient Gas Sample Line Input Connection
7. INOmax DS_{IR}
8. NO/N_2 Injector Tube Front Panel Connection
9. Injector Module Electrical Cable Front Panel Connection
10. 22M/15F X 22M/15F Adapter
11. Injector Module Electrical Cable Connection
12. Injector Module NO/N_2 Injector Tube Connection
13. 22F X 15M Adapter
14. Humidifier Inlet
15. Humidifier
16. Humidifier Outlet
17. Gas Sample Tee



a. Injector Module
b. 22F Inlet
c. 22M / 15F Outlet

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



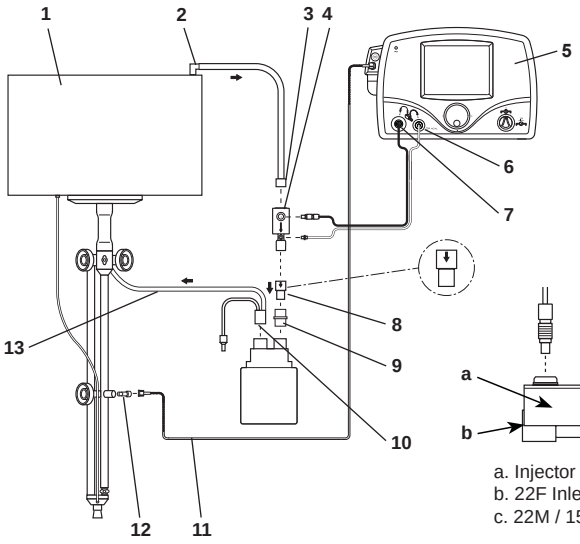
a. Injector Module
b. 22F Inlet
c. 22M / 15F Outlet

Circuit Connection Diagrams

1. Sensormedics 3100A/B Ventilator
2. Ventilator Outlet
3. 22M Adapter
4. Injector Module
5. Injector Module Electrical Cable Connection
6. INOmax DS_{IR}
7. NO/N_2 Injector Tube
8. 8 mm Tubing X 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



a. Injector Module
b. 22F Inlet
c. 22M / 15F Outlet

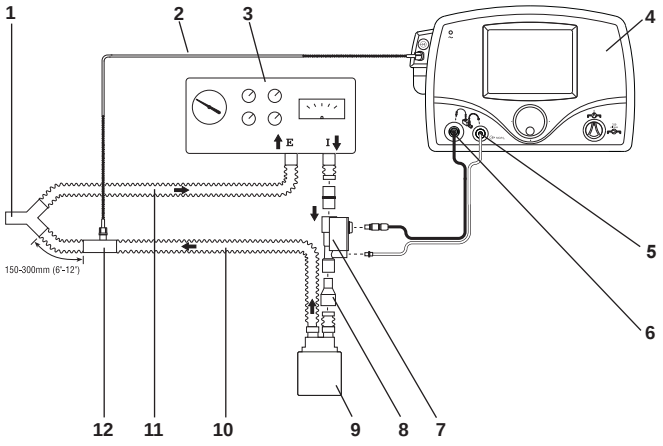
1. Sensormedics 3100A/B Ventilator
2. Ventilator Outlet
3. 22M Adapter
4. Injector Module
5. INOmax DS_{IR}
6. NO/N_2 Injector Tube Connection
7. Injector Module Electrical Cable Connection
8. One-Way Valve
9. Humidifier Inlet
10. Humidifier Outlet
11. Patient Gas Sample Line with Nafion
12. 90 Degree Sample Port Adapter
13. Bias Flow Tube

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

SLE Life Support SLE5000

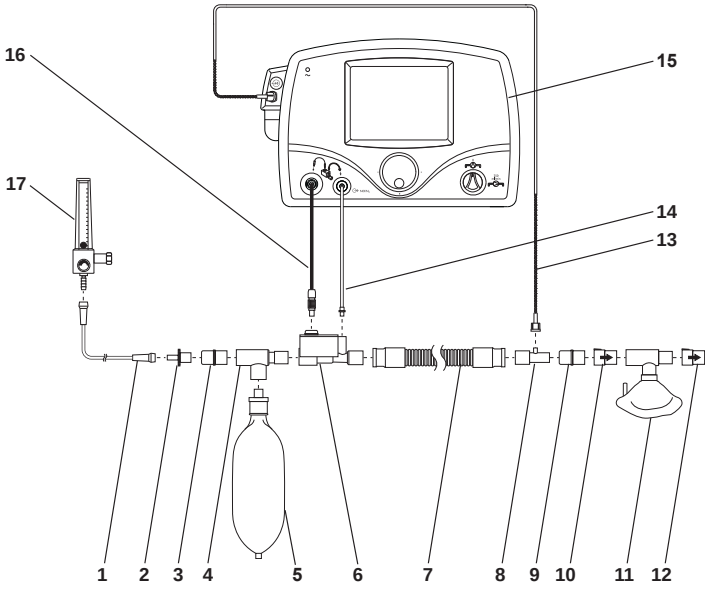
Note: • Validated for use outside of the United States.

• A one-way valve is not required for use during high frequency ventilation mode.



1. Patient Wye
2. Patient Gas Sample Line with Nafion
3. SLE5000
4. INOmax DS_{IR}
5. NO/N_2 Injector Tube
6. Injector Module Electrical Cable
7. Injector Module
8. 22F X 15M Adapter
9. Humidifier
10. Inspiratory Breathing Circuit Hose
11. Expiratory Breathing Circuit Hose
12. Gas Sample Tee

Spontaneous Breathing Patient on a Mask Circuit

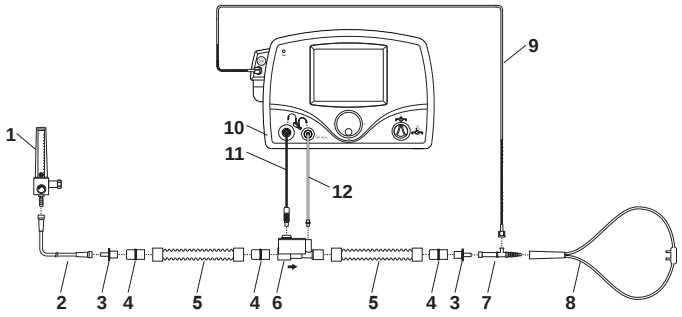


1. O_2 Tubing
2. 15M X 4.5 mm Adapter
3. 22M/15F X 22M/15F Adapter
4. Breathing Circuit Tee
5. Breathing Circuit Bag
6. Injector Module
7. Breathing Circuit Hose
8. Gas Sample Tee
9. 22M/15F X 22M/15F Adapter
10. One-Way Valve
11. Sealed Face Mask
12. One-Way Valve
13. Patient Gas Sample Line with Nafion
14. NO/N_2 Injector Tube
15. INOmax DS_{IR}
16. Injector Module Electrical Cable
17. O_2 Flowmeter (wall outlet or cylinder)

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.

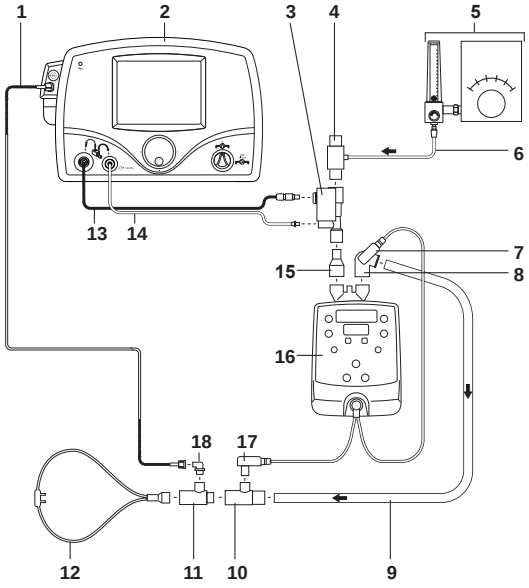
WARNING: Do not use the INOmax DS_{IR} backup mode with flow rates less than 5 L/min.



1. O_2 Flowmeter
2. O_2 Tubing
3. 15M x 4.5 mm Adapter
4. 22M/15F x 22M/15F Adapter
5. 300 mm of 22 mm Hose
6. Injector Module
7. O_2 Tubing Sample Tee
8. Patient Nasal Cannula
9. Patient Gas Sample Line with Nafion
10. INOmax DS_{IR}
11. Injector Module Electrical Cable
12. NO/N_2 Injector Tube

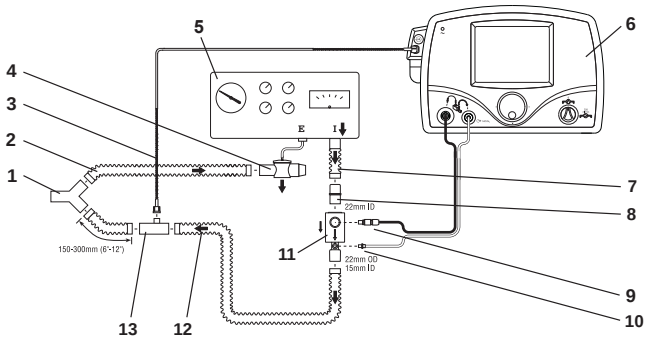
Circuit Connection Diagrams

Teleflex Medical Comfort Flo Humidification System



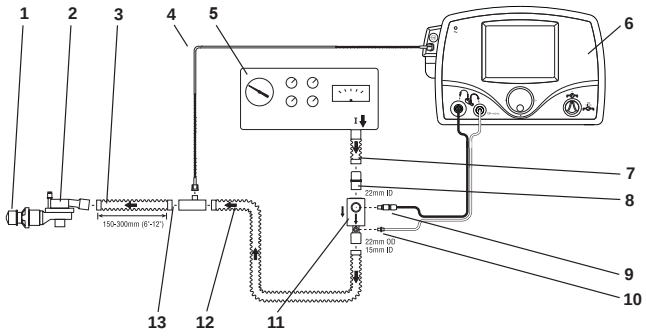
1. Patient Gas Sample Line with Nafion
2. INOmax DS_{IR}
3. Injector Module
4. System Pressure Relief Valve
5. Air/Oxygen Blender or Oxygen Blender
6. Oxygen Tubing
7. Temperature Probe (Short Cable)
8. Angled 22 mm Connector
9. Patient Circuit
10. Temperature Probe Connector
11. Second Temperature Probe Connector
12. Comfort Flo Cannula
13. Injector Module Electrical Cable
14. NO/N_2 Injector Tube
15. 22F X 15M Adapter
16. ConchaTherm Heated Humidifier
17. Temperature Probe (Long Cable)
18. 90 Degree Sample Port Adapter

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 DS_{IR}
7. Ventilator Inspiratory Port
8. 22M/15F X 22M/15F Adapter
9. Injector Module Electrical Cable
10. NO/N_2 Injector Tube
11. Injector Module
12. Inspiratory Breathing Circuit Hose
13. Gas Sample Tee

Single-Limb Transport Ventilator Diagram



1. PEEP/Exhalation Valve
2. Patient Wye
3. Circuit Hose
4. Patient Gas Sample Linewith Nafion
5. Ventilator
6. INOmax DS_{IR}
7. Ventilator Inspiratory Port
8. 22M/15F X 22M/15F Adapter
9. Injector Module Electrical Cable
10. NO/N_2 Injector Tube
11. Injector Module
12. Inspiratory Breathing Circuit Hose
13. Gas Sample Tee

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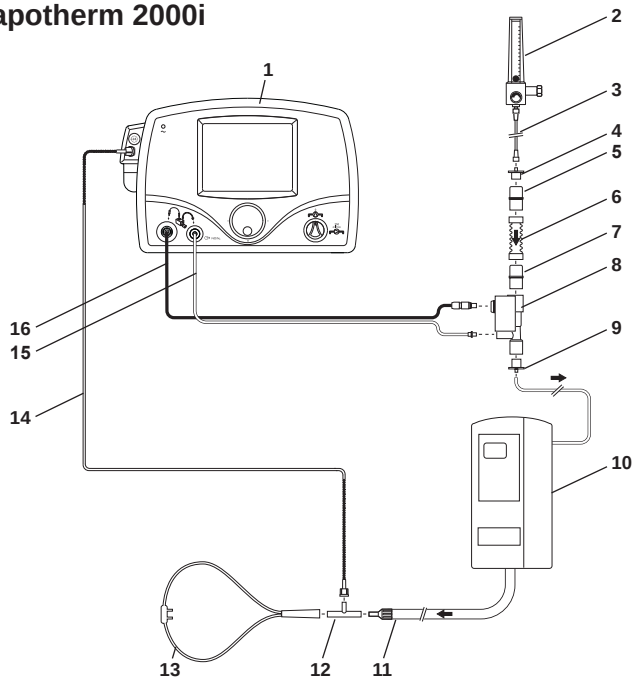
Circuit Connection Diagrams

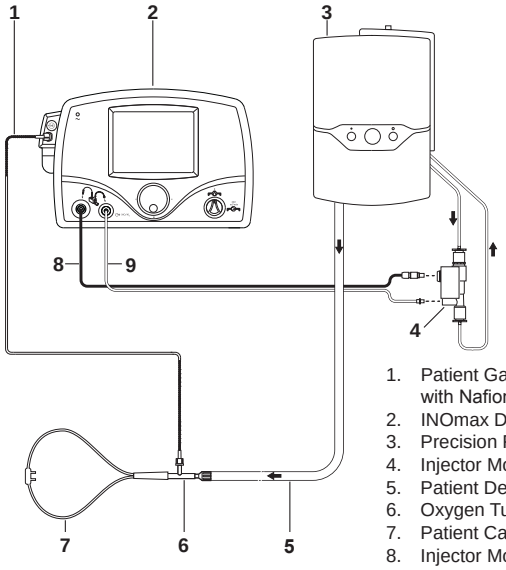
Vapotherm 2000i



1. INOmax DS_{IR}
2. O_2 Flowmeter
3. O_2 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. O_2 Tubing Sample Tee
13. Patient Cannula
14. Patient Gas Sample Line with Nafion
15. NO/N_2 Injector Tube
16. Injector Module Electrical Cable

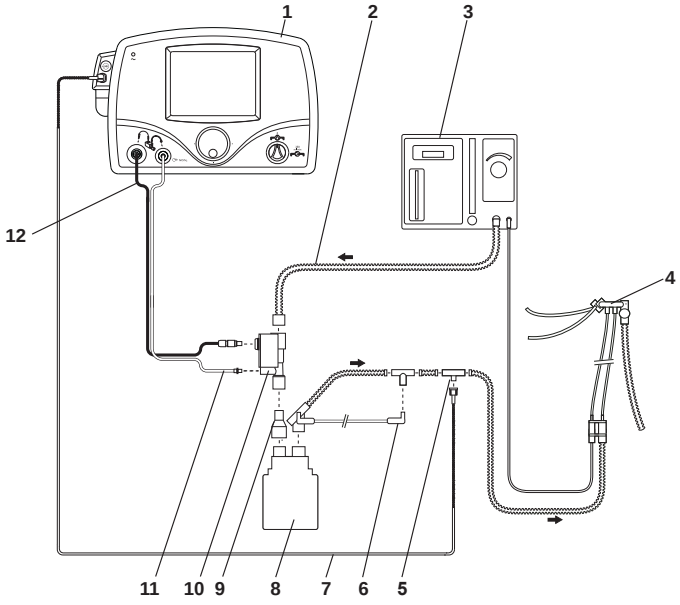
Connection to the Vapotherm Precision Flow

- The INOmax DS_{IR} adds NO/N_2 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.



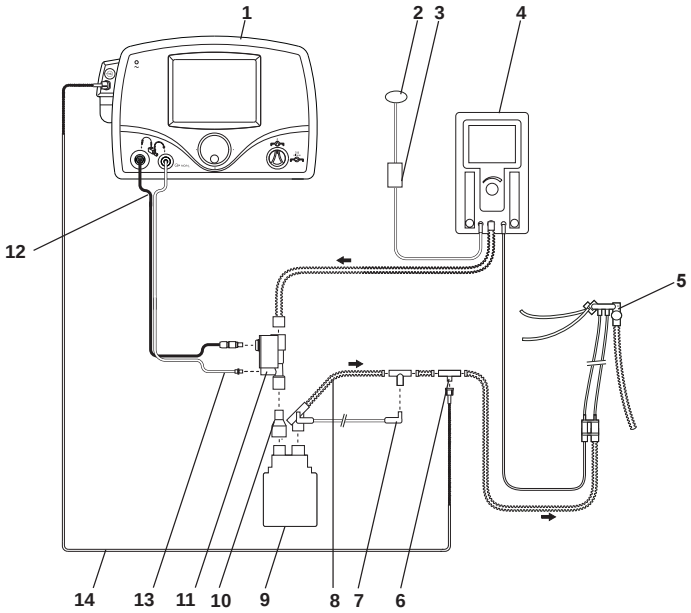
1. Patient Gas Sample Line with Nafion
2. INOmax DSIR
3. Precision Flow Unit
4. Injector Module
5. Patient Delivery Tube
6. Oxygen Tubing Sample Tee
7. Patient Cannula
8. Injector Module Electrical Cable
9. NO/N2 Injector Tube

Viasys Infant Flow CPAP System; Cardinal AirLife nCPAP System



1. INOmax DS_{IR}
2. Heated Delivery Circuit
3. Infant Flow System
4. Infant Flow Generator
5. Sample Tee
6. Temperature Probe
7. Patient Gas Sample Line with Nafion
8. Humidifier
9. 22F X 15M Adapter
10. Injector Module
11. NO/N_2 Injector Tube
12. Injector Module Electrical Cable

Viasys Infant Flow SiPAP



1. INOmax DS_{IR}
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/N_2 Injector Tube
14. Patient Gas Sample Line with Nafion

INOblender Circuit Connection Diagram

INOblender Warnings:

- **The purge procedure must be followed to help ensure NO_2 is purged from the pressure regulator, INOblender and hoses before the manual resuscitator bag is connected to the patient. The manual bag should be squeezed continuously during use to avoid NO_2 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.**

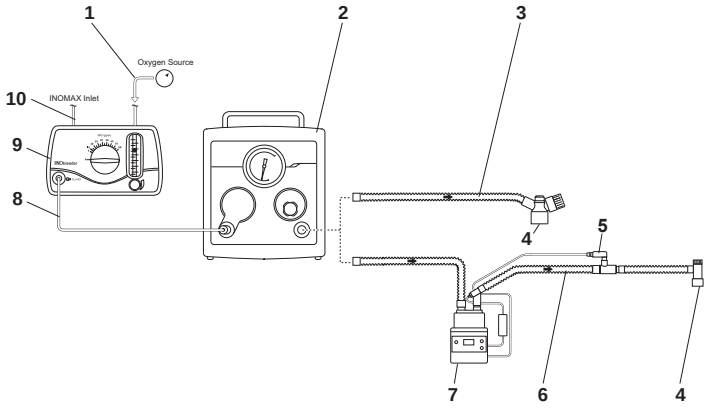
- **Persons using this device should be trained on and experienced in the use of this device to assure effective administration of INOMAX and to avoid injury to the patient or others resulting from inhalation of excess INOMAX, nitrogen dioxide or other reaction products.**

INOblender Cautions:

- Refer to the manufacturer's procedures for using the resuscitation bag. When finished, turn the INOMAX cylinder off and continue to flow O_2 until the NO pressure gauge reads zero, then turn the O_2 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:

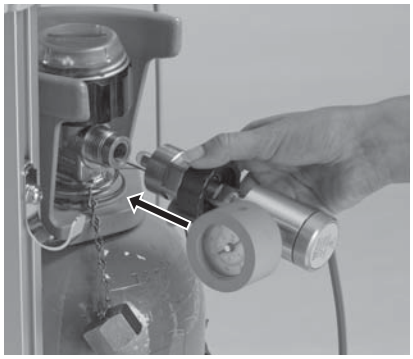
- **A new INOMAX cylinder and regulator must be purged before use to ensure the patient does not receive an excess level of NO_2.**
- **Loss of communication between the INOmax DS_{IR} and the INOMAX cylinder for more than one hour will result in interruption of INOMAX delivery.**

Caution:

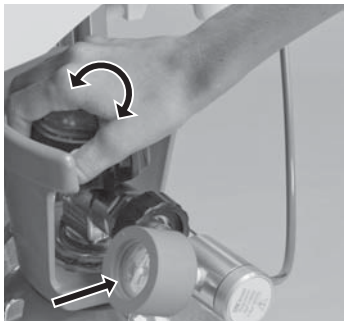
- Replace an INOMAX cylinder when its pressure is less than 200 psig.
- When using the Transport Regulator/Cap Assembly (PN 10022) ensure the cap is fully seated and in place on the INOmeter and the infrared cable is connected and latched to the infrared connector port on the back of the INOmax DS_{IR}.

Note: Ensure the white plastic tip is in place.

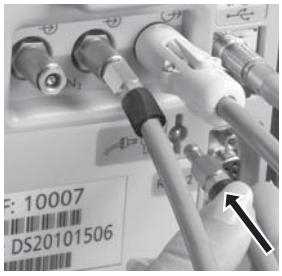
A. Attach a regulator to an INOMAX cylinder with greater than 500 psig.



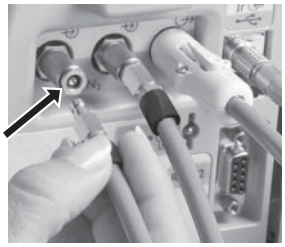
B. Perform high pressure leak test.



C. Purge the high pressure hose.



D. Connect the pressure hose.



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.

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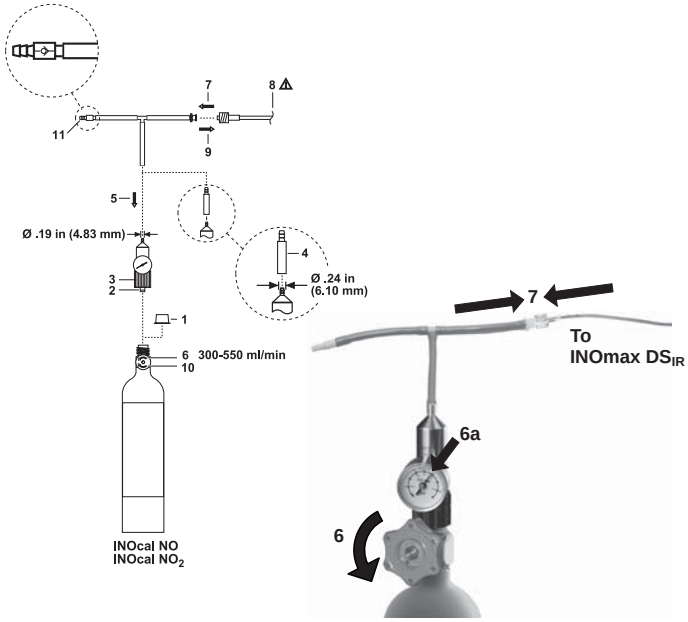
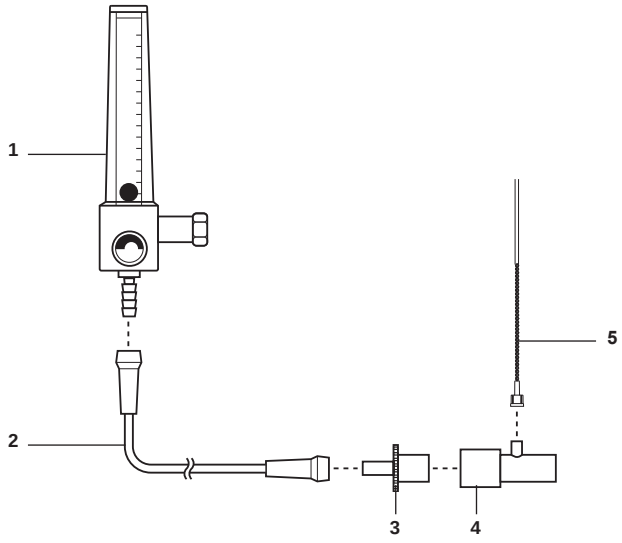
Connection Diagram for NO and NO_2 High Range Calibration



1. Cylinder Cap
2. Regulator Seal
3. Regulator
4. Tubing Adapter
5. Attach Tube Kit
6. Turn valve counter-clockwise to start gas flow

6a. If the pressure is in the red or black zone (0-25 psig) select another INOcal cylinder.
7. Attach tube kit to sample line
8. Calibrate sensor
9. Remove sample line from tube kit
10. Turn valve clockwise to stop gas flow
11. One-way Valve

Calibration Setup for O_2 High Range Calibration



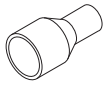
1. 100% O_2 Source
2. O_2 Tubing
3. 15M x 4.5mm I.D. Adapter
4. Gas Sample Tee
5. Patient Gas Sample Line with Nafion

INOmax DS_{IR} Patient Circuit Disposables

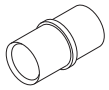
(Note: Graphics not actual size)

Adapter,
15M Fits 4.5mm ID Tubing

Adapter, 22F X 15M

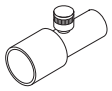


Adapter, 22M/15F X 22M/15F



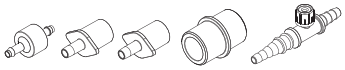
Adapter, Cuff, 22mm ID X 22mm ID

Adapter, Gas Sample Tee



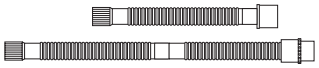
Adapter, 90 degree Sample Port

Bunnell Life Pulse Disposable
Adapters Convenience Pack

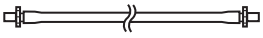


Disk Filter, 0.5 micron

Neonatal Tubing,
10mm (2 pieces)



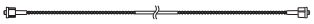
NO/N_2 Injector Tube



INOmax DS_{IR} Disposable Adapters

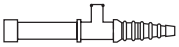
One-way Valve, 22F X 22M

Patient Gas Sample Line with Nafion

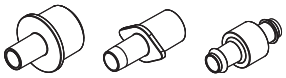


Pediatric Extension, 15 mm (6 inches)

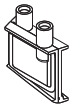
Sample Tee, O_2 Tubing



Sensormedics 3100A/B Filtered Circuit Disposable Adapters Convenience Pack



Water Separator Cartridge



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