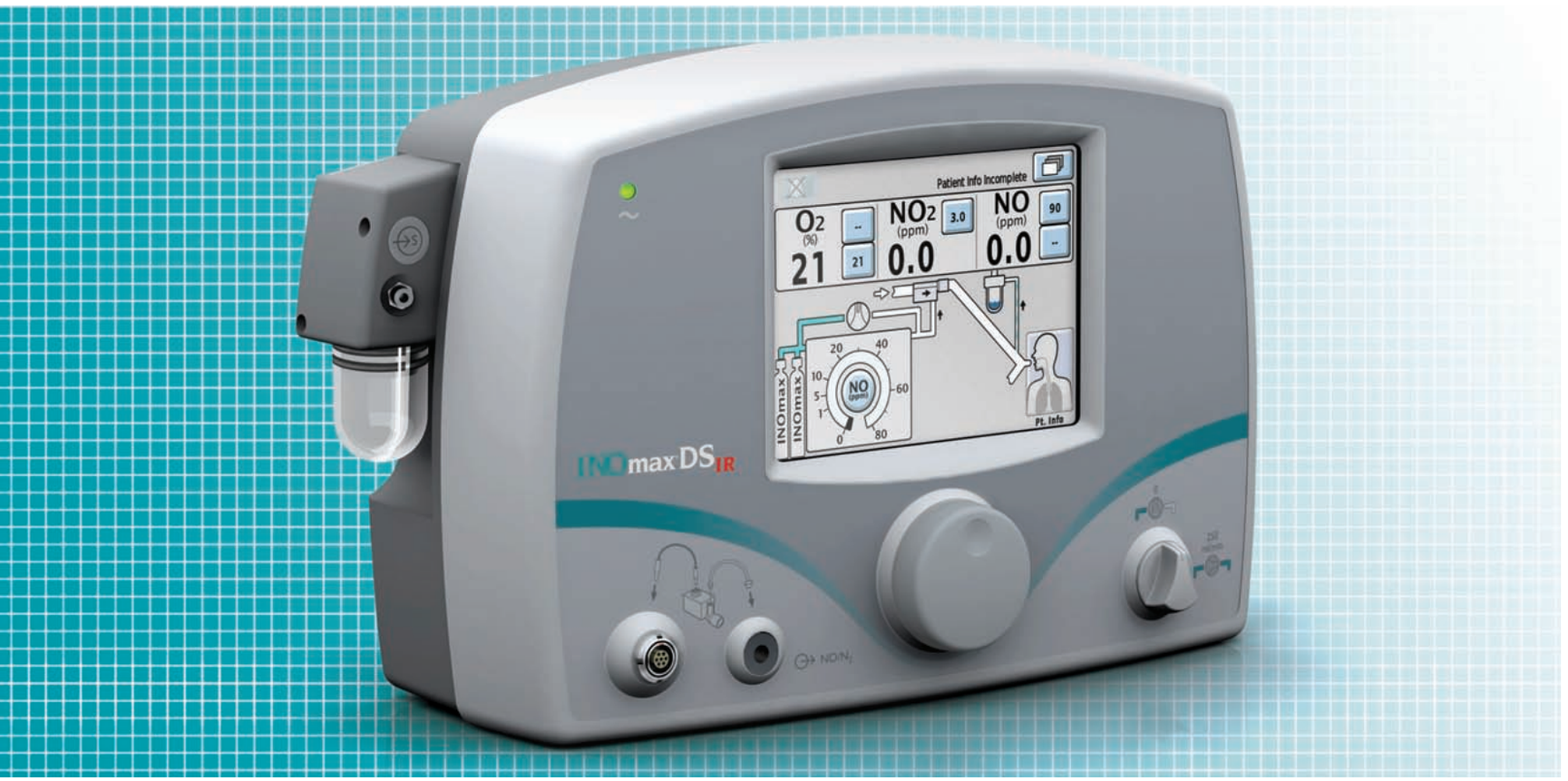
IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



Operation Manual

(800 ppm INOMAX® (nitric oxide) for inhalation)

Part No. 20010 Rev-05
2012-03

User Responsibility

This Product will perform in conformity with the description contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked prior to use following the Pre-Use Checkout procedure described in section 3, and periodically as required. A defective Product should not be used. Parts that are broken, missing, visably worn, distorted or contaminated should be replaced immediately.

Should such repair or replacement become necessary, INO Therapeutics LLC d/b/a Ikaria® recommends that a telephone request for service advice be made to the nearest Field Technical Service Support Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Ikaria. The Product must not be altered without the prior written approval of Ikaria Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Ikaria.

Caution: U. S. Federal and Canadian law restrict this device to sale by or on the order of a licensed medical practitioner. Outside the U. S. A. and Canada, check local laws for any restrictions that may apply.

Inhaled Nitric Oxide mixtures must be handled and stored in compliance with federal, state and local regulations.

Ikaria products have unit serial numbers with coded logic which indicates the year of manufacture and a sequential unit number for identification.

20051234	The first four numeric digits indicate the year of product manufacture, and the next 4 digits are the sequential unit number produced.
10007	INOmax DS_{IR}® part number

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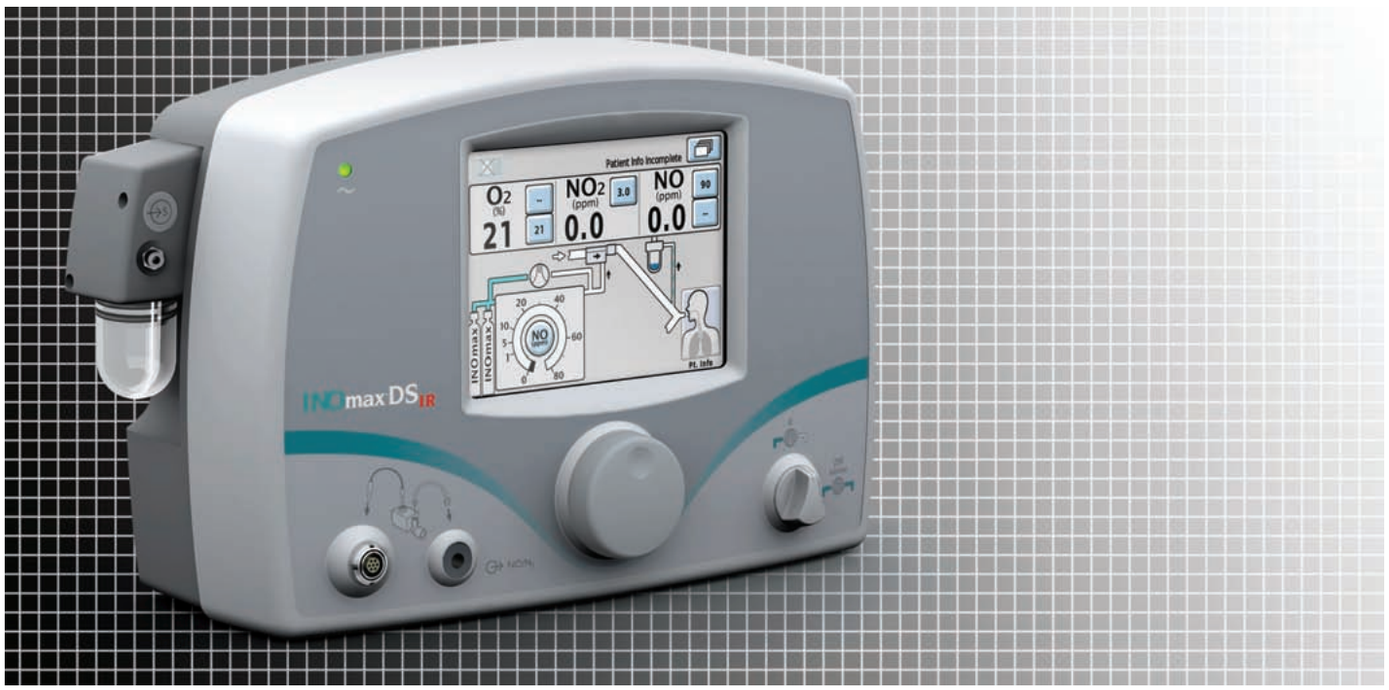
Contents

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



1/ General Information

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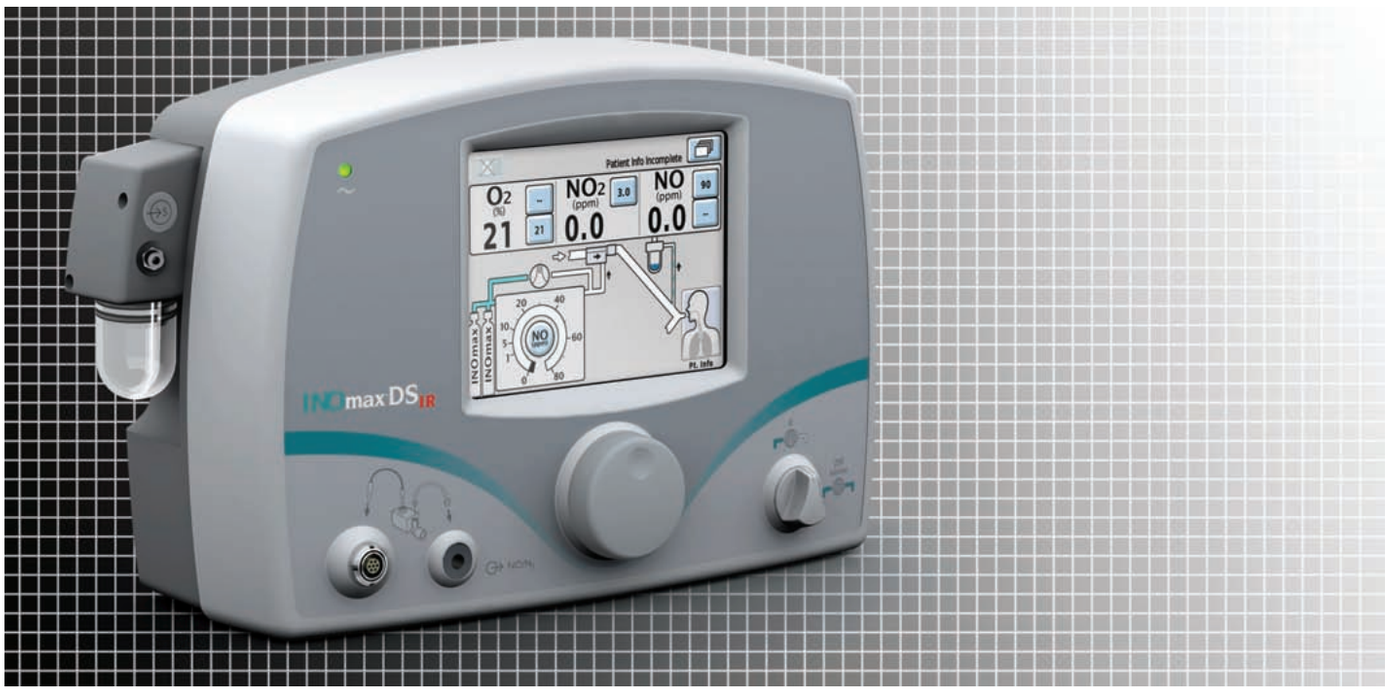

1/ General Information

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1/ General Information

- The INOmax DS_{IR}® (delivery system) delivers INOMAX® (nitric oxide for inhalation) therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module, which enables tracking of the ventilator waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with most ventilators.
- The INOmax DS_{IR} provides continuous integrated monitoring of inspired O_2, NO_2 , and NO and a comprehensive alarm system.
- The INOmax DS_{IR} incorporates a battery that provides up to 6 hours of uninterrupted INOMAX delivery in the absence of an external power source.
- The INOmax DS_{IR} includes a backup NO delivery capability that provides a fixed flow of 250 mL/min of NO which along with user supplied 10 L/min of oxygen provides 20 ppm in the gas flow to a patients breathing circuit. It may also use the INOblender for backup.
- The target population is controlled by the drug labeling for INOMAX and is currently neonates. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates.

Important:

Before using the INOmax DS_{IR}, read through this manual.

Read through the manuals for the ventilator, humidifier and any other accessory items used. Follow the manual instructions and obey the Warnings and Cautions.

Keep this manual readily available to answer questions.

Read the User Responsibility statement on the inside front cover of this manual; it describes what the user must do to maintain proper use and functioning of this product.

WARNING:

Warnings tell you about dangerous conditions that can cause injury to the operator or the patient if you do not obey all of the instructions in this manual.

Caution:

Cautions tell you about how to properly use the equipment and conditions that could cause damage to the equipment.

Read and obey all warnings and cautions.

Note:

Notes provide clarification or supplemental information.

Blue arrow denotes required user action.

WARNING:

- **If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.**
- **Use only pharmaceutical grade NO/N_2.**
- **The INOmax DS_{IR} must only be used in accordance with the indications, usage, contraindications, warnings and precautions described in the INOMAX (nitric oxide) drug package inserts and labeling. Refer to this material prior to use.**
- **The use of devices which radiate high intensity electrical fields may affect the operation of the INOmax DS_{IR}. Constant surveillance of all monitoring and life support equipment is mandatory whenever interfering devices are in operation on or near a patient.**
- **INO Therapeutics does not recommend that the INOmax DS_{IR} be utilized with helium/oxygen mixtures in any situation. The INOmax DS_{IR} is intended to deliver INOMAX therapy gas only in conjunction with the delivery of air and oxygen.**
- **Do not connect items, which are not specified as part of the system.**

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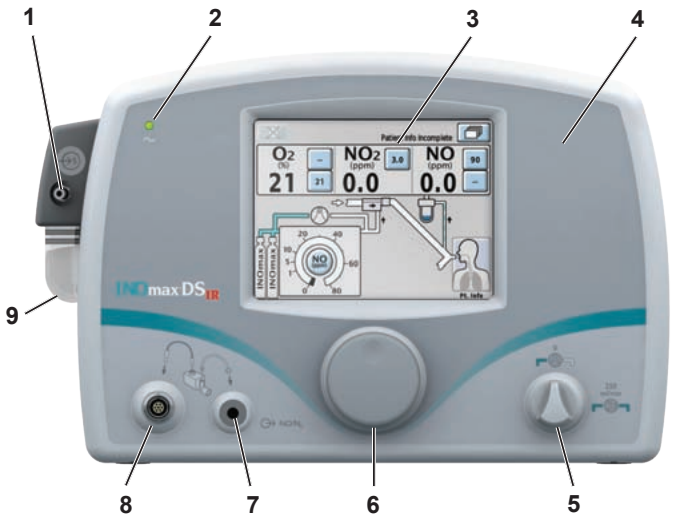
Introduction to this Manual

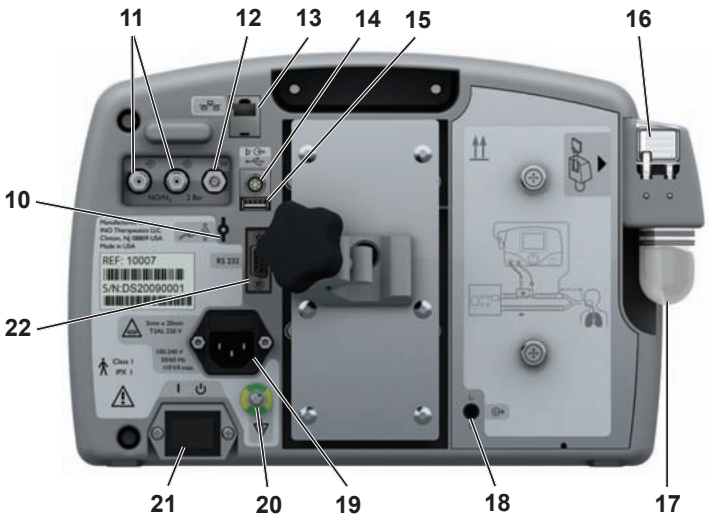
Definitions and abbreviations

% v/v	% volume/volume
Control wheel	Rotary control used to change and confirm settings
Display	The electronic information panel on the front of the delivery system
HFOV	High frequency oscillating ventilator
Menu	A list of available choices for an operation
N_2	Nitrogen
NO	INOMAX® (nitric oxide) for inhalation
NO_2	Nitrogen dioxide
NO/N_2	Nitric oxide (NO) and nitrogen (N_2) gas mixture
O_2	Oxygen
ppm	Parts Per Million
Resolved alarm	An alarm condition that has been corrected
Set NO	The dose of INOMAX set by the user
Touch screen	A display screen sensitive to touch used to select a function



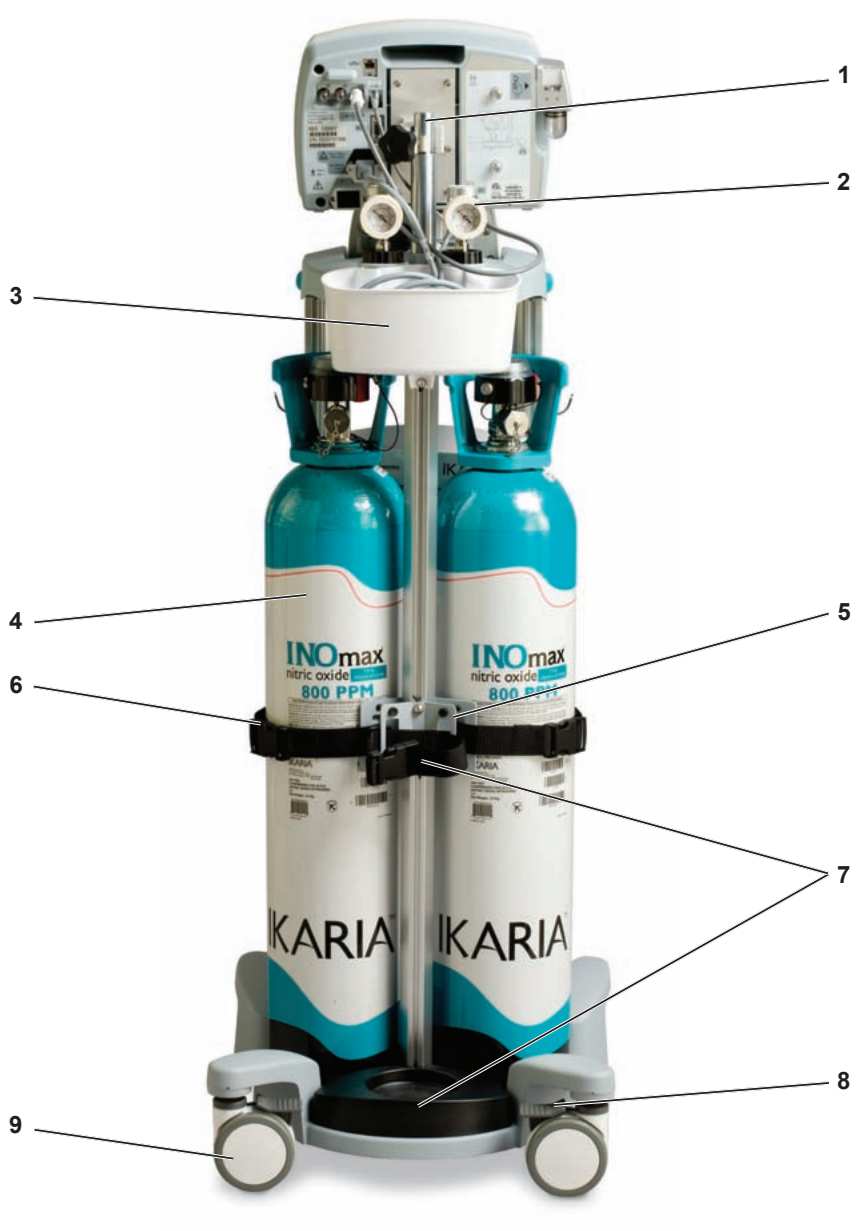
1. Sample Line Inlet
2. Main Power Indicator
3. Display Screen
4. Alarm Speaker (under front label)
5. Backup Switch
6. Control Wheel
7. Injector Module Tubing Outlet

Figure 1-1 INOmax DS_{IR}® Front View



8. Injector Module Cable Inlet
9. Water Trap Bottle
10. Purge Port
11. INOMAX Gas Inlets
12. Blender Gas Outlet
13. Ethernet Port
14. Infrared Connector
15. USB Port
16. Water Separator Cartridge
17. Water Trap Bottle
18. Sample Gas Outlet Port
19. Power Cord Inlet
20. Ground
21. ON/Standby Switch
22. RS232 Port

Figure 1-2 INOmax DS_{IR} Rear View

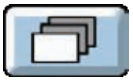


1. INOmax DS_{IR}® Mounting Post
2. INOMAX® Regulator (2)
3. Small Part Bin
4. INOMAX Cylinder
5. Cylinder Holding Bracket
6. Cylinder Mounting Strap
7. Oxygen Cylinder Bracket
8. Caster Lock Lever
9. Caster (4)

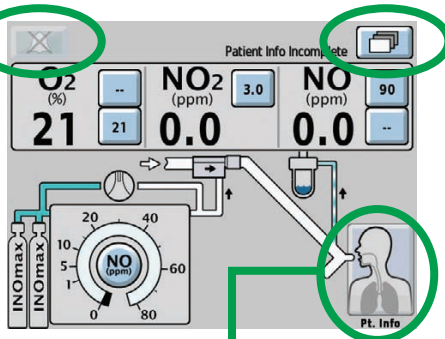
Figure 1-3 INOmax DS_{IR} and Cart

Navigating the Display Screens

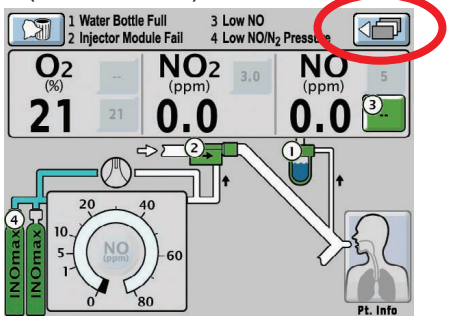
There are five screens that can be displayed on the INOmax DS_{IR}®.

Note:	The specific level is identified by the highlighted card on the Menu Button. The red arrows indicate going back to a previous screen. 

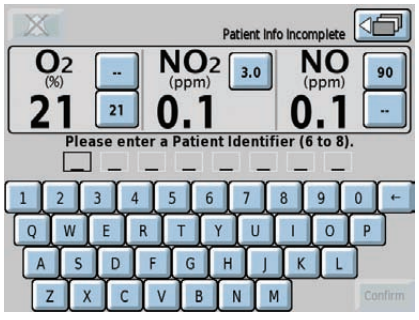
Main Screen (first level)



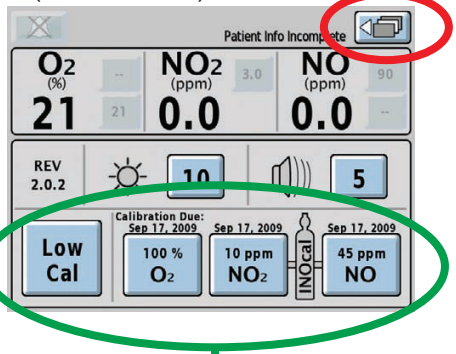
Alarm History Screen
(second level)



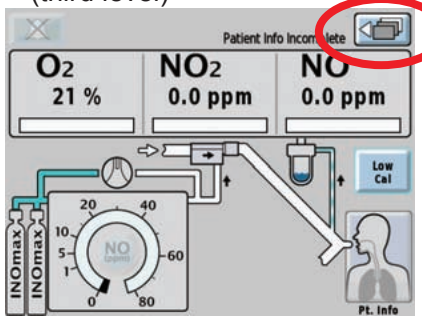
Patient Information Screen

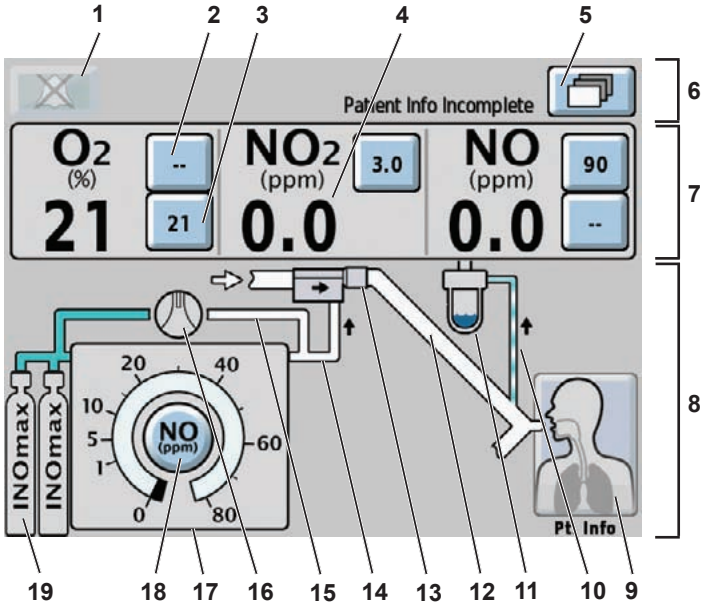


Menu Screen
(second level)



Calibration Screen
(third level)



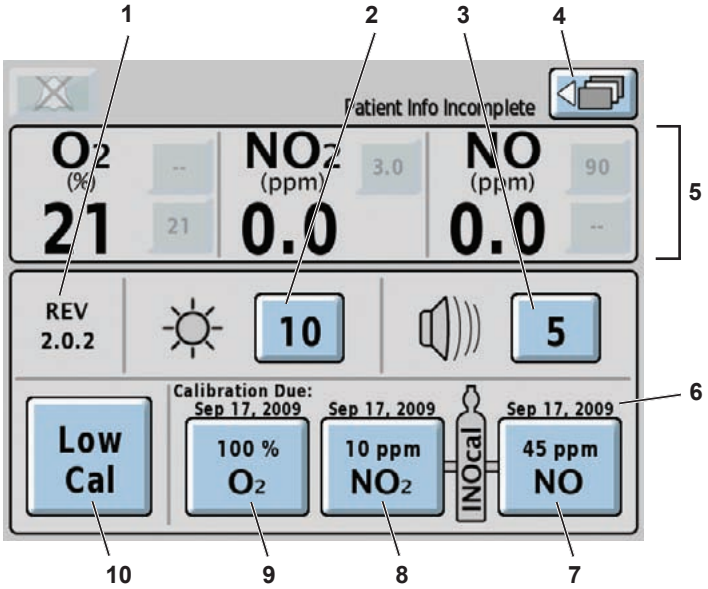


1. Alarm Silence Button
2. Upper Alarm Limit Button
3. Lower Alarm Limit Button
4. Monitored Value
5. Menu Button
6. Text Message Area
7. Monitor Area
8. Graphical Area
9. Patient Information Button
10. Sample Line Icon
11. Water Trap Icon
12. Inspiratory Limb Icon
13. Injector Module Icon
14. Delivery Line Icon
15. Backup Line Icon
16. Backup Switch Icon
17. Delivery Setpoint Display
18. NO Delivery Setpoint Button
19. Cylinder Icon

Figure 1-4 Main Display Screen

Main Display Screen

- On the Main Screen the user can view alarm messages, monitored values and graphical information.
- By pressing the “Menu Button” on the touch screen (top right hand corner), the user can access the Menu Screen (see Figure 1-5).



1. Software Revision Field
2. Display Brightness Button
3. Alarm Volume Button
4. Return to Previous Level Button
5. Monitor Area
6. Calibration Due Dates
7. NO Calibration Button
8. NO_2 Calibration Button
9. Oxygen Calibration Button
10. Room Air Calibration Button

Figure 1-5 Menu Screen (second level)

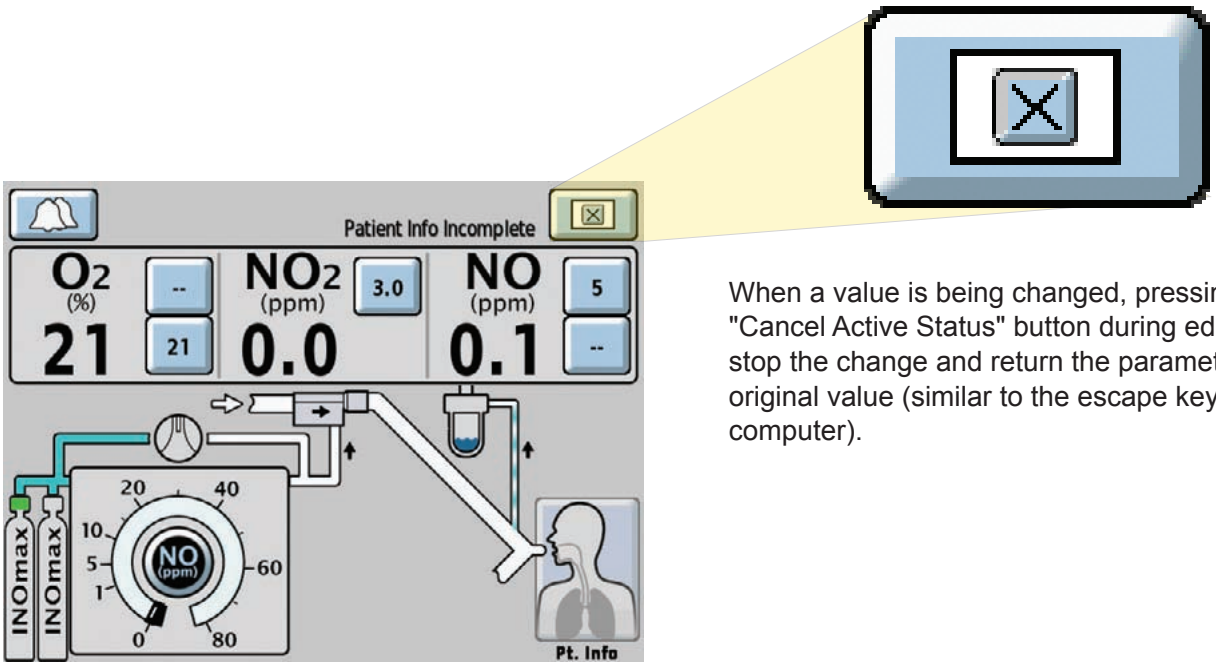
Menu Screen (second level)

- On the Menu Screen the user can change the alarm volume and the display brightness and view the software version.
- To review the Alarm History Screen (second level), refer to Section 5/ Alarms.
- It also lets the user select different calibration options (third level) which will be covered in Section 7/ Calibration.

Display and user controls

The INOmax DS_{IR}® has a color touch screen display and a control wheel for adjusting and entering user settings. The buttons on the touch screen and the control wheel perform a variety of functions using a three-step procedure (see “Setting and making changes on the INOmax DS_{IR}”).

Note:	• If a button has been selected and no activity has been sensed within 20 seconds, the display will return to its previous condition. If a button is de-emphasized (grayed out), it is not accessible. • Position delivery system so user screen is unobstructed and the speaker is not covered.



When a value is being changed, pressing the "Cancel Active Status" button during editing will stop the change and return the parameter to its original value (similar to the escape key on a computer).

Dose settings

Displayed dose settings are 1, 5, 10, 20, 40, 60 and 80 ppm. Each click on the control knob corresponds to a known change in dose. The incremental dose per click corresponds to a value dependent upon the dose range in which the change is made, as illustrated in the table at right.

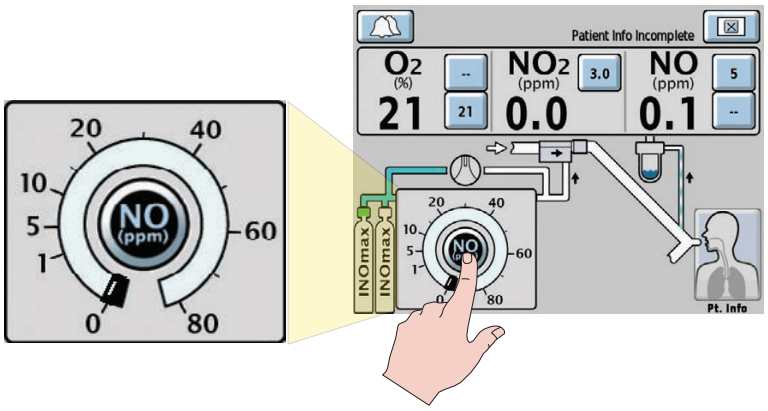
Dose Setting Range	Dose Change Per Click
< 1 ppm	0.1 ppm
1 to 40 ppm	1 ppm
40 to 80 ppm	2 ppm

Setting and making changes on the INOmax DS$_{IR}$®

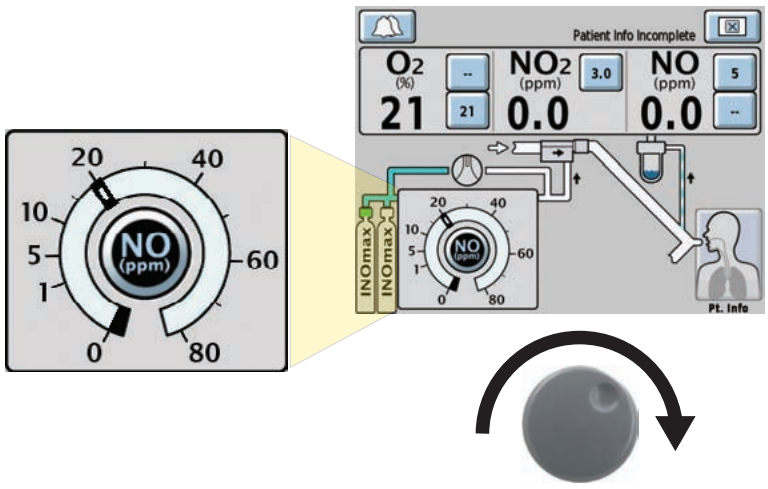
The touch screen buttons and control wheel are used to:

- Set the concentration of delivered NO
- Adjust alarm limits
- Silence alarms
- Calibrate the sensors
- Review alarm history
- Define setup options
- Enter patient identifier

1. SELECT
   (press) a button on the touch screen associated with the desired function.
   (an audible beep will sound when a button is selected, and the button will be displayed in inverse video)

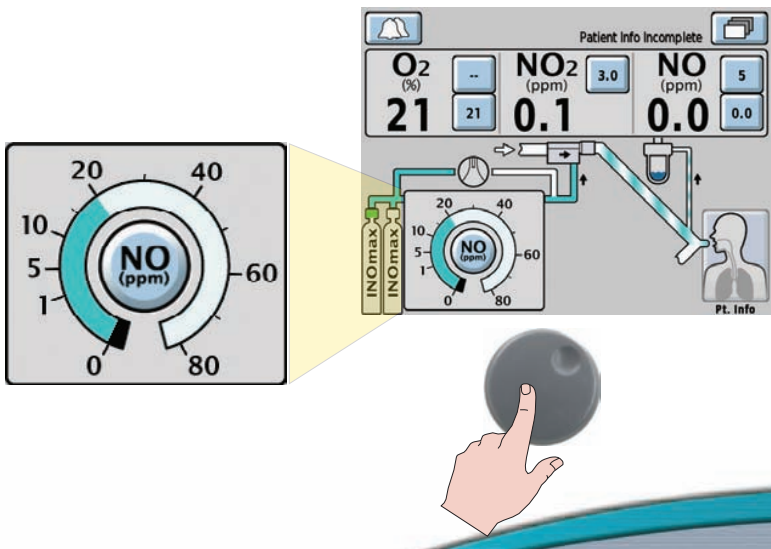


2. ROTATE
   the control wheel clockwise or counterclockwise to adjust the value.



3. CONFIRM
   the selection by pressing the control wheel or the button associated with the desired function again.

Note:	After confirming a desired dose, the NO alarm setting (high and low) will automatically be set for the <u>first</u> setting only. Any other changes will require the high and low alarm settings to be adjusted. Also, a two minute lockout period will prevent monitoring alarms from occurring while measured values stabilize.



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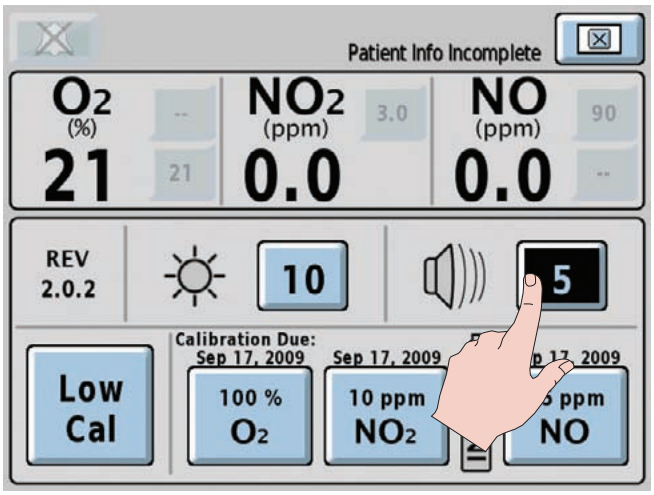
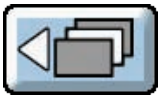
Settings

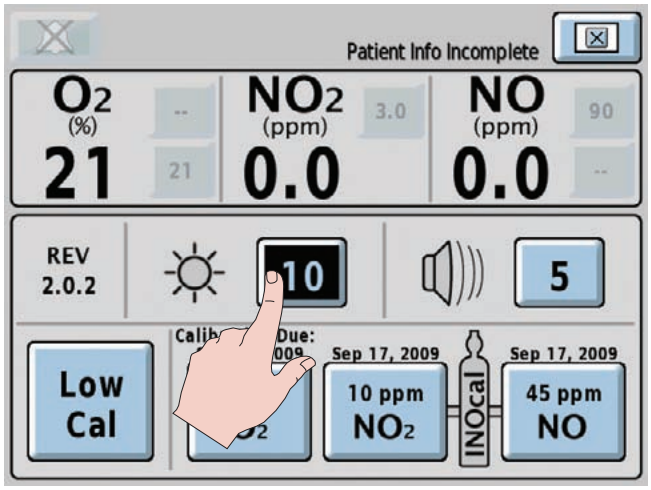


Access the menu screen (second menu level).

Alarm Volume setting

1. Push the alarm volume button on the touch screen.
2. Turn the control wheel to indicate the volume level you want. Choices range from 1 (softest) to 5 (loudest).
3. Push the control wheel to confirm your selection.
4. If you are finished with the Menu Screen push the return to previous level button on the touch screen.





Display Brightness setting

1. Push the display brightness button on the touch screen.
2. Turn the control wheel to indicate the display brightness level you want. Choices range from 1 (darkest) to 10 (brightest).
3. Push the control wheel to confirm your selection.
4. If you are finished with the Menu Screen, push the return to previous level button on the touch screen.

Infrared Communication between the INOMAX® Cylinders and the 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} checks the INOMAX cylinder for the correct expiration date and cylinder concentration. The INOmax DS_{IR} also transmits a confirmed patient identifier to the INOmeter on any open INOMAX cylinder.

The INOmax DS_{IR} cart (PN 10018) has a cover (1) 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 (2) (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} (see “Loading INOMAX Cylinders onto the INOmax DS_{IR} Cart”, page 11).

IR Communication Interference

The INOmax DS_{IR} transceiver is located under the cart cover and should be protected from outside IR sources. The INOmax DS_{IR} cart was designed to protect the INOmeter from external light/IR energy sources. The INOmax DS_{IR} transceiver transmits via a 30 degree transmission cone projecting towards the floor (see dotted lines in Figure 1-6). The specifications of the IR beam call for it to have a range of 20 cm (7.9 in), so based on these specifications it would not affect other devices in the vicinity of the INOmax DS_{IR}.

The INOmeter uses a lower energy source which results in a lower IR beam range than the INOmax DS_{IR} cart. The INOmeter does not transmit IR signals unless it mounted on the INOmax DS_{IR} cart.

If there is interference with the INOmax DS_{IR}/INOmeter communication, the cylinder icon on the user screen will not be displayed and a “Cylinder Not Detected” alarm will activate.

If IR communication interference occurs, we recommend you take the following actions:

- Move the external IR source
- Move the INOmax DS_{IR} cart to reduce the external IR source in the area of the INOmeter
- Shield the INOmeter from the suspect IR source

If the actions listed above do not remedy this issue, the Transport Regulator/Cap Assembly could be utilized.

External Light Interference

High frequency and/or high intensity light emission, in the area of the INOmeter, may interfere with communication between the INOmax DS_{IR}® and the INOmeter on the INOMAX cylinder. If there is interference with the INOmax DS_{IR}/INOmeter communication, the cylinder icon on the user screen will not be displayed and a “Cylinder Not Detected” alarm will activate.

Test results have demonstrated susceptibility to unintended infrared energy from artificial light sources. Most notably, various compact fluorescent lighting fixtures that focus or reflect light, increasing the light intensity in the vicinity of the INOmax DS_{IR} cart, could affect INOmeter communications.

If external light interference occurs, we recommend you take the following actions:

- Move the interfering light source
- Move the INOmax DS_{IR} cart to reduce the high intensity light in the area of the INOmeter
- Shield the INOmeter from the suspect light source

If the actions listed above do not remedy this issue, the Transport Regulator/Cap Assembly could be utilized.

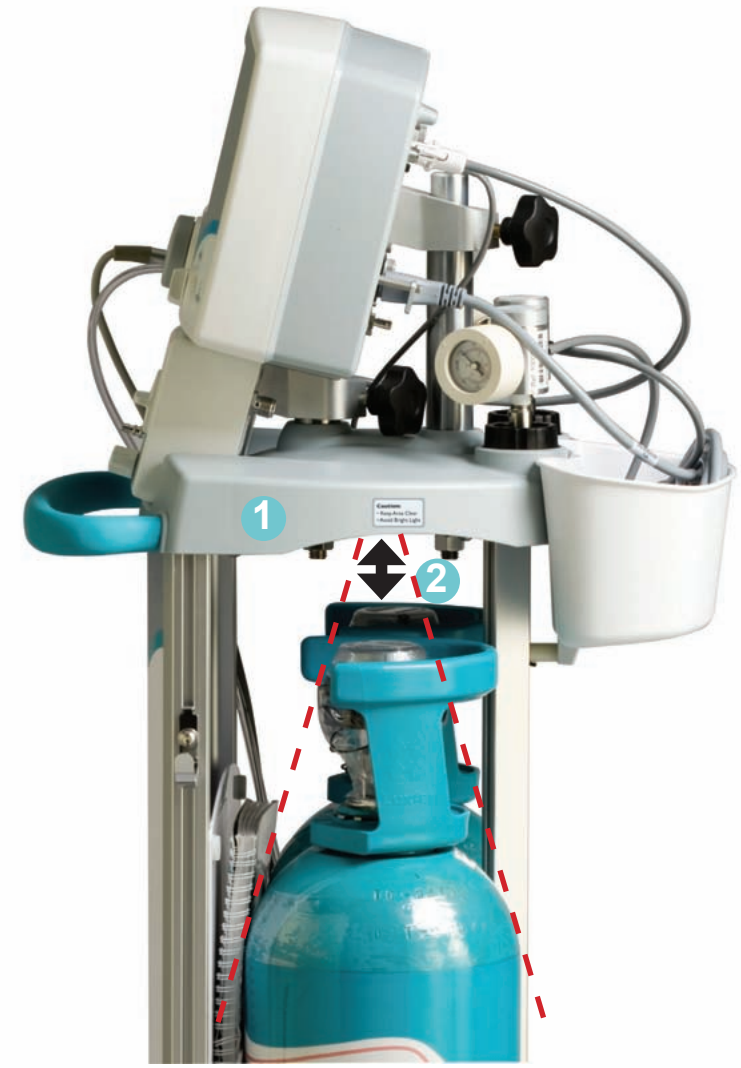
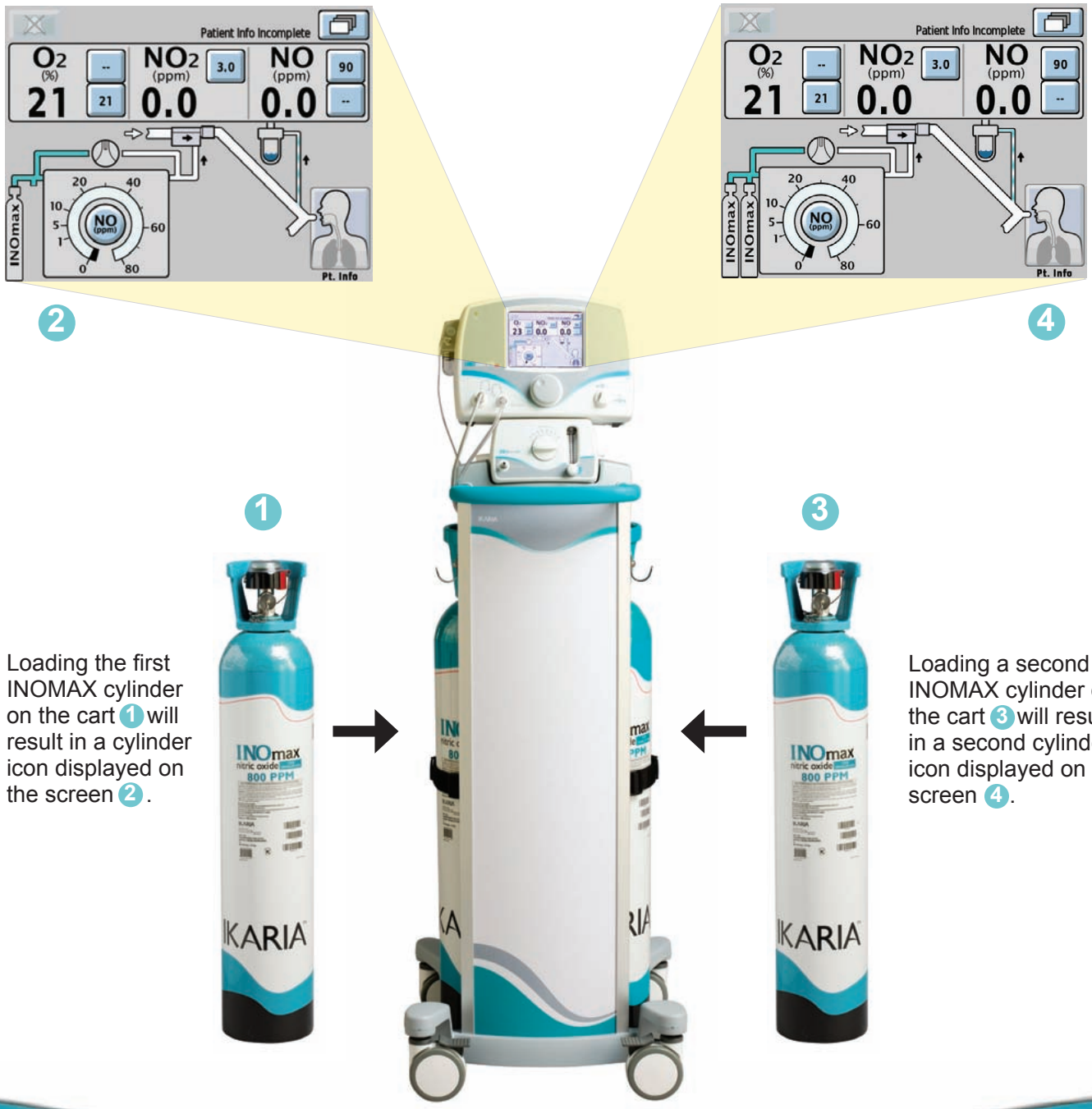


Figure 1-6

Loading INOMAX® Cylinders onto the INOmax DS$_{IR}$® Cart

Note:	Check the INOMAX gas cylinders for the correct product identity labels, cylinder concentration and expiration date.

Ensure at least one INOMAX gas cylinder (with more than 200 psig) is available.
Refer to Section 3 / Pre-Use Checkout prior to use.



Loading the first INOMAX cylinder on the cart 1 will result in a cylinder icon displayed on the screen 2.

Loading a second INOMAX cylinder onto the cart 3 will result in a second cylinder icon displayed on the screen 4.

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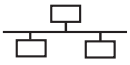
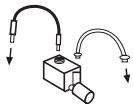
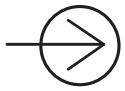
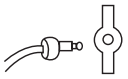
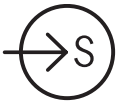
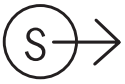
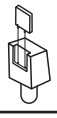
Symbols used in this manual or on the system

Symbols replace words on the equipment and/or in this manual. These symbols include:

	Attention, consult accompanying documents!
	Alarm Silence
	Equipotential Stud
	Ethernet Port
	Fuse Rating
	Infrared Input/Output
	Injector Module
Low Cal	Low Range Calibration
	Main Power Connected
	NO Backup OFF
	NO Backup ON

	NO Gas Inlet
	NO Gas Outlet
	On
	Purge Location
	Sample Gas Inlet Port
	Sample Gas Outlet Port
SN	Serial Number
	Standby
REF	Stock Number
	Type B Electrical Equipment
	USB Port
	Water Separator Cartridge

Theory of Operation

The INOmax DS_{IR}® provides a constant dose of INOMAX® into the inspiratory limb of the ventilator circuit. The INOmax DS_{IR} uses a “dual-channel” design to ensure the safe delivery of INOMAX. The first channel has the delivery CPU, the flow controller and the injector module to ensure the accurate delivery of NO. The second channel is the monitoring system, which includes a separate monitor CPU, the gas sensors (NO, NO_2, and O_2 sensors) and the user interface, including the display and alarms. The dual-channel approach to delivery and monitoring permits INOMAX delivery independent of monitoring. This allows the monitoring system to shutdown INOMAX delivery, if it detects a fault in the delivery system. For example, INOMAX delivery will shut down should the monitored NO concentration become greater than 100 ppm. (See Figure 1-7 for a schematic diagram).

1. INOMAX drug is stored as a gas mixture of NO/N_2 in an aluminum cylinder at a nominal pressure of 2000 psig.

2. The cylinder is attached to a high pressure regulator, which incorporates a pressure gauge that indicates cylinder pressure when the cylinder valve is open. The cylinder regulator is attached via tubing to the INOmax DS_{IR} using one of the two NO/N_2 quick connect inlets on the back of the machine.

3. The INOmax DS_{IR} checks the INOMAX cylinder for the correct expiration date and cylinder concentration.

4. The INOMAX enters the back of the INOmax DS_{IR}, passes through a filter, then a safety shutoff valve, which is open under normal operation.

5. An injector module is placed in the ventilator gas flow between the ventilator inspiratory outlet and the humidifier. Based on the ventilator flow, the INOMAX cylinder concentration and set INOMAX dose, the proportional solenoid valve delivers 800 ppm INOMAX into the ventilator circuit via the injector module where it mixes with the breathing circuit gas flow to achieve the set dose. This allows the INOmax DS_{IR} to deliver a constant dose of INOMAX regardless of the ventilator flow pattern or breath rate (see Figure 1-8).

6. A flow sensor inside the INOmax DS_{IR} also monitors the NO flow out of the machine. A check valve is included prior to the INOmax DS_{IR} drug outlet to prevent pressure effects from the ventilator breathing circuit interfering with the NO flow sensor reading.

7. Gas Monitoring - The INOmax DS_{IR} gas monitoring system provides monitored values for inspired NO, NO_2, and O_2. The sample gas is withdrawn from the breathing circuit and goes through a water trap, a zero valve, a sample pump and finally a sample flow sensor to the gas monitoring sensors.

   - The zero valve allows the gas sensors to be zeroed (during low calibration) without having to disconnect the sample line from the breathing circuit.
   - The pump and sample flow sensor ensure a sample gas flow rate is maintained to the monitoring sensors.
   - The gas monitoring sensors are electrochemical; they are specific to each gas and provide an electronic signal which is proportional to the concentration of the gas present.

8. Backup Delivery - If the delivery system does go into shutdown, the INOmax DS_{IR} has an integrated backup function which provides a fixed flow of INOMAX (250 mL/min) into the injector module using a pneumatic on/off switch and a restrictor built into the delivery side of the system. This fixed flow of INOMAX will provide 20 ppm of NO when the continuous ventilator gas flow is 10 L/min. The backup is only for short term use until a replacement delivery system can be obtained. An alarm will warn the user if the backup system is turned on while the main delivery system is in use for INOMAX delivery. The INOblender® can also be used as a backup.

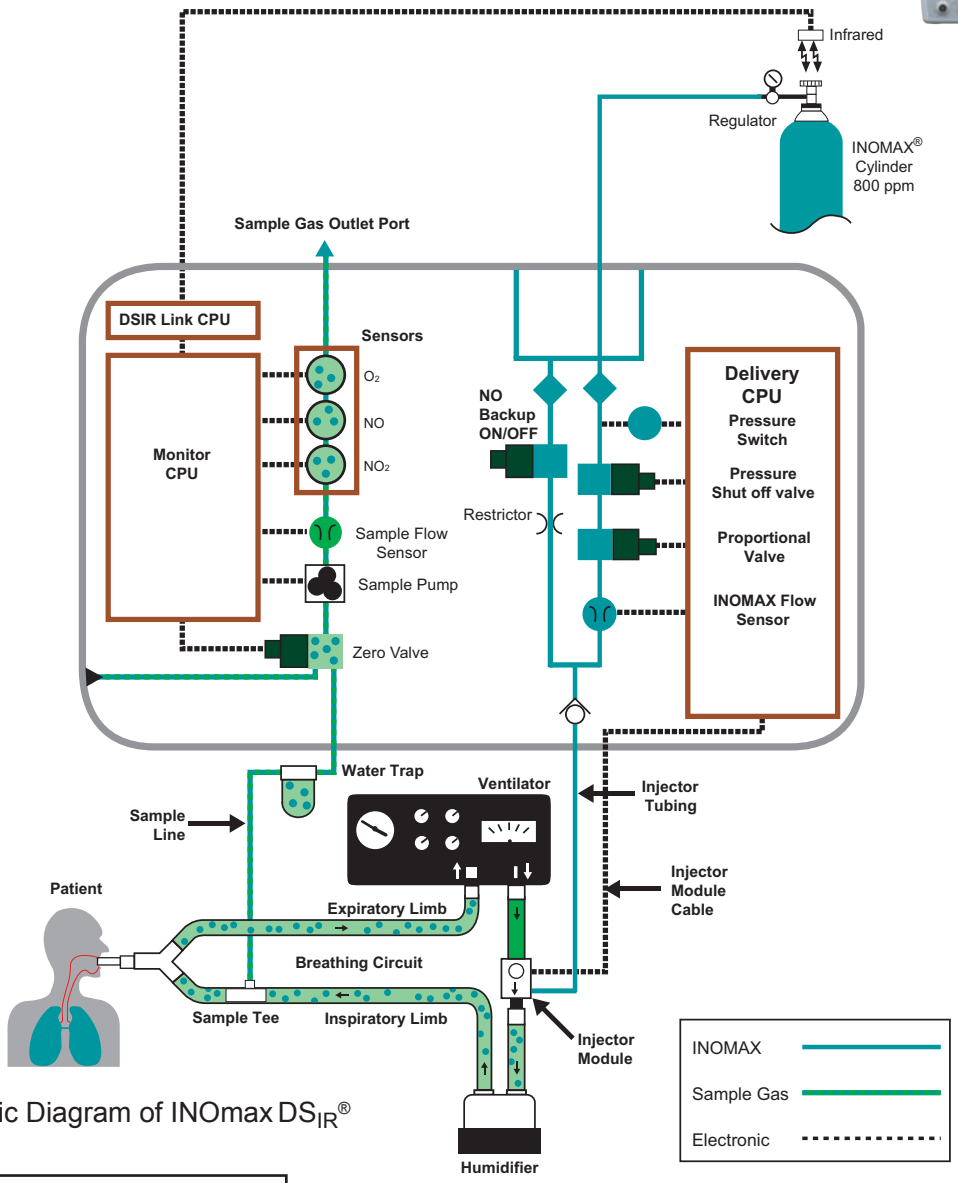


Figure 1-7 Schematic Diagram of INOmax DS_{IR}®

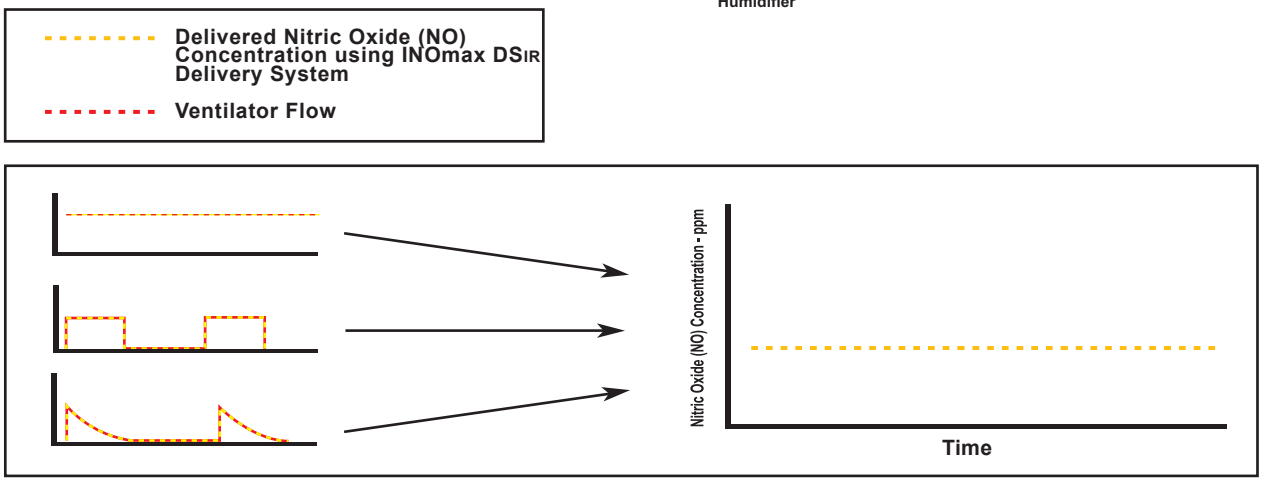


Figure 1-8 INOMAX injection method provides a constant NO concentration

Effect of the INOmax DS_{IR}® in a ventilator circuit

There are two main effects of connecting and using the INOmax DS_{IR} in a ventilator breathing circuit.

- First, the INOmax DS_{IR} adds NO/N_2 gas to the breathing circuit in proportion to the NO setting and the ventilator flowrate. For example, at an 80 ppm NO setting (the maximum NO setting with an 800 ppm NO cylinder concentration) the INOmax DS_{IR} adds 10% more gas to that delivered by the ventilator, 5% more for a 40 ppm setting, etc.
- Second, the INOmax DS_{IR} subtracts gas from the breathing circuit via the gas sampling system at a nominal flow rate of 0.23 L/min.

These two effects of adding and subtracting gas from the ventilator breathing circuit have the following effects:

Oxygen Dilution

The INOmax DS_{IR} adds gas to the breathing circuit in proportion to the NO setting as described above. The NO/N_2 mixture added to the ventilator gas dilutes the oxygen in proportion to the set INOMAX® dose. At an INOMAX dose setting of 80 ppm with a cylinder concentration of 800 ppm NO, the added gas is 10%. Thus, the O_2 concentration is reduced by 10% of its original value. For example, if the original O_2 concentration is 50% v/v, then the value after injection, at the 80 ppm setting, should be 45% v/v.

INOMAX Dose (ppm)	Oxygen Dilution % v/v
80	10
40	5
20	2.5

Minute Volume

When using volume ventilation with the INOmax DS_{IR}, the measured tidal volume delivered to the patient shows small changes depending on the NO setting being used due to the addition and subtraction of gases by the delivery system. Some minor ventilator adjustments to the minute volume may be required. The net result of the INOmax DS_{IR} on the delivered minute ventilation can be calculated as follows:

If the patient's minute ventilation is 10 L/min
(500 cc X 20 breaths/min)

The additional minute volume due to the INOMAX can be calculated as follows:

$$\frac{\text{INOMAX dose} \times \text{Minute Volume}}{\text{Cylinder Concentration} - \text{INOMAX Dose}} = \text{Additional INOMAX volume added per minute}$$

For a dose of 20 ppm the additional volume would be
(20 X 10 / 800 – 20) = 0.25 L/min

To calculate the net change in minute volume:
0.25 L/min INOMAX added - 0.23 L/min removed (sample system) = 0.02 L/min (net change)

This formula may be used when calculating the changes to continuous flow on continuous flow ventilators as well (using the continuous flow in place of minute ventilation).

Trigger Sensitivity

The addition and subtraction of gases by the INOmax DS_{IR} may affect the trigger sensitivity of the ventilator when using synchronized modes of ventilation. This may cause the ventilator to auto-trigger in ventilators which have flow trigger modes, especially where the trigger flow is set to less than 1 L/min. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS_{IR} delivery system.

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Circle Anesthesia Ventilator Systems

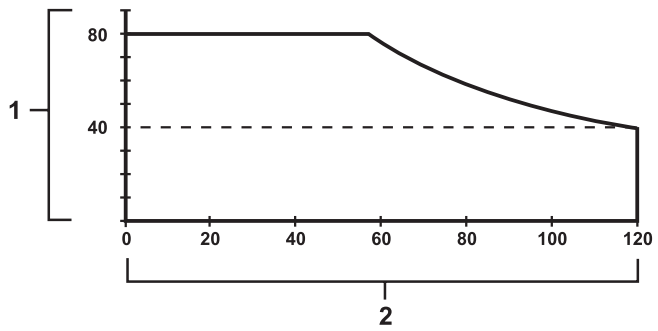
The effect of the INOmax DS_{IR}® on circle anesthesia ventilator systems (which use volume ventilation) is to cause small changes in the delivered minute volume as noted previously (see **Minute Volume).**

Recirculation of INOMAX® in circle breathing systems should be avoided. The gas in the ventilator bellows may also contain undesirable levels of NO_2 which may not be removed by the CO_2 absorbent.

Recirculation of gases may lead to a rapid increase in INOMAX dose levels creating a shutdown of the INOmax DS_{IR}. This can be avoided by using a fresh gas flow rate equal to or above that of the patient's minute volume. This will ensure that there is sufficient fresh gas in the absorber such that no accumulated gas from the ventilator bellows reaches the inspiratory limb of the breathing circuit and hence the patient.

Maximum NO Delivery

The INOmax DS_{IR} is limited to a maximum NO flow of 6.35 L/min. This means the maximum deliverable NO concentration will vary based on the ventilator flow rate. The maximum deliverable NO concentration will vary from approximately 80 ppm at a constant flow of 60 L/min to approximately 40 ppm at constant flow 120 L/min.



1. Maximum deliverable NO concentration (ppm)
2. Constant inspiratory flowrate (L/min)

When intermittent inspiratory flow rates are used, peak ventilator flows may be achieved which will exceed 120 L/min. Peak inspiratory flow rates are transient and extremely short in duration. As a result, the portion of the breath which is not matched by the INOmax DS_{IR} is extremely small and the effect on the delivered concentration of NO with respect to the entire range of the breath is small.

Does acid form in the humidifier or breathing circuit when delivering INOMAX?

A long term test was performed at Datex-Ohmeda to determine if acid would build up in a breathing circuit over time when delivering inhaled Nitric Oxide.

The test equipment was a *Sechrist* IV-100B neonatal ventilator and a *Fisher Paykel* MR500 humidifier. The ventilator settings were Rate 40 breaths per minute, Flow 6 L/min and Oxygen 100% v/v and the humidifier was set to 36 degree's C.

The pH level was measured at the humidifier (the water in the humidifier chamber), at the patient Y (the condensate in the breathing circuit) and at the exhalation valve back at the ventilator (the condensate in the breathing circuit).

Distilled water was used for the test which had an initial pH of 5.75 and the pH was measured with Hydrion Paper (4.5 to 7.5).

A control test without NO being delivered was run initially to see if the pH would change over time due to the slightly acidic nature of distilled water. The control test was run for 6 days with no change in the pH at any of the test points.

The test was then repeated with 80 ppm of NO being delivered continuously for 9 days with the pH being tested daily at each of the test points. There was no change of pH at any of the test points for any of the daily tests.

Environmental Effects

The National Institute for Occupational Safety and Health (NIOSH) have recommended exposure limits as follows (Ref. 1).

NO	time-weighted (8 hours) average concentration limit of 25 ppm
NO_2	ceiling limit of 1 ppm.

The environmental build up of NO in a well ventilated ICU room can be evaluated using the following calculation.

Room size	10 ft square (approx. 3 meters)
Room volume of air	27,000 L
Room ventilation at 6 room changes / hour	2,700 L/min
NO flow into the room	14 L/min at 80 ppm
Average room concentration of NO (80 x 14 / 2,700)	0.4 ppm of NO

This theoretic calculation can be supplemented by measurements as performed by Hess et al (Ref. 2). The NO and NO_2 concentrations were measured using a chemiluminescence analyzer when 100 ppm of NO at 8 L/min was delivered into a room with no scavenging being used. The maximum NO and NO_2 concentrations measured over a one hour period were 0.12 ppm of NO and 0.03 ppm of NO_2.

Both these methods show that the exposure levels are significantly less than the levels recommended by NIOSH.

If the location for using NO has uncertain ventilation then the location should be evaluated for NO and NO_2 build up prior to use.

References:

(Ref. 1) Centers for Disease Control, Atlanta, GA 30333 USA.

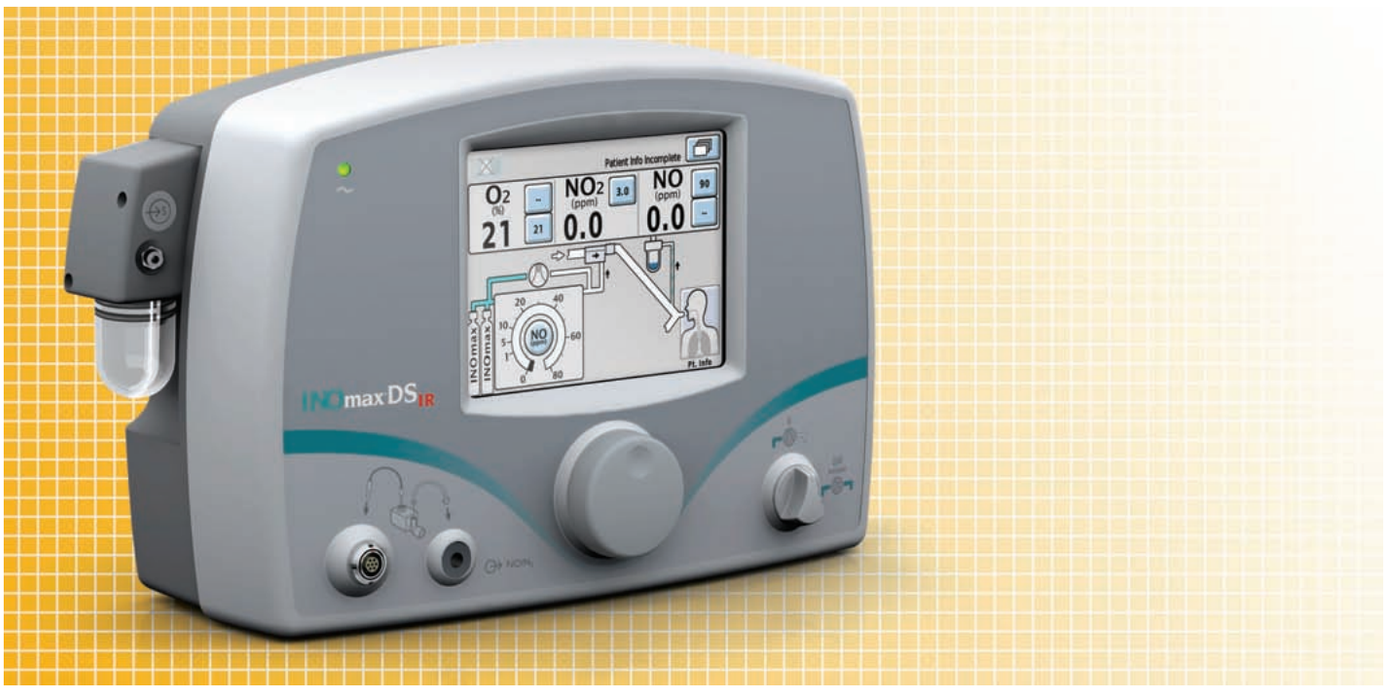
NIOSH Recommendations for Occupational Safety and Health Standards 1988. August 26, 1988 / vol. 37 / No. 9.

(Ref. 2) Hess et al, Use of Inhaled Nitric Oxide in patients with Acute Respiratory Distress Syndrome.
Respiratory Care, 1996, vol. 41, No. 5, pg. 424-446.

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



2/ Setup

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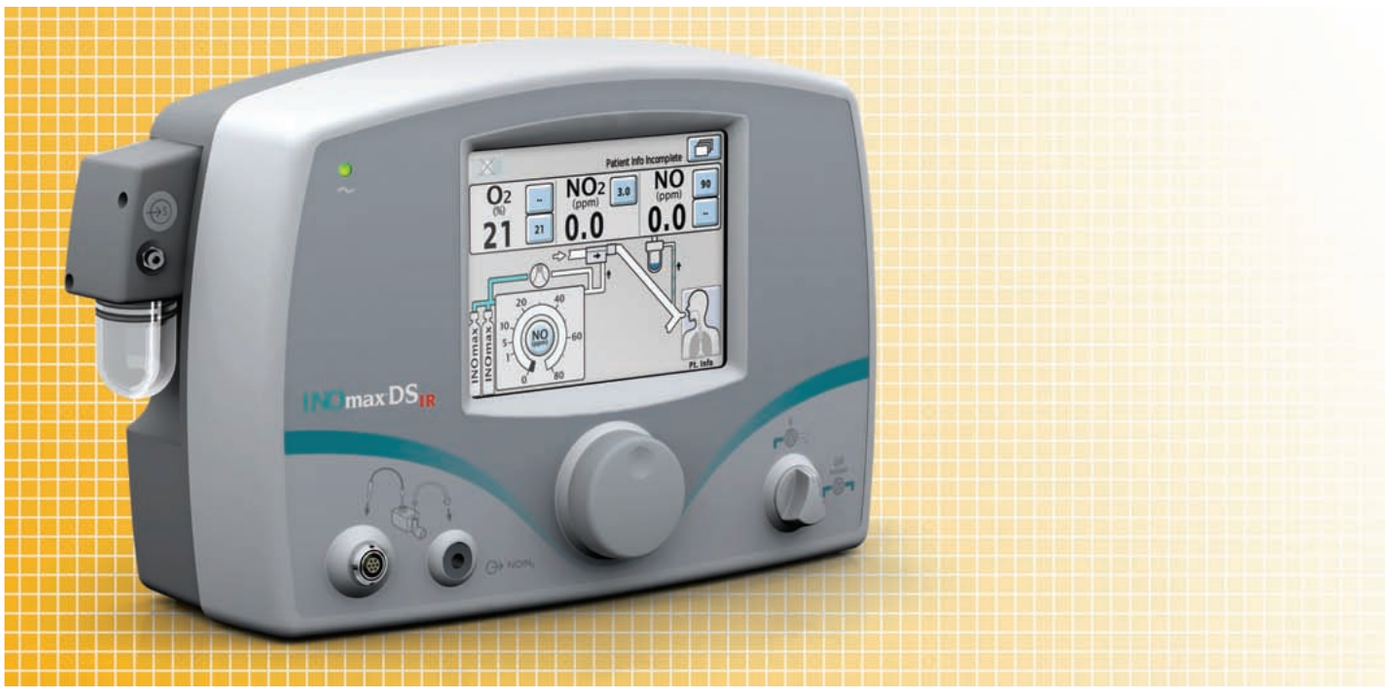
INOmax DS$_{IR}$®

(Delivery System)



2/ Setup

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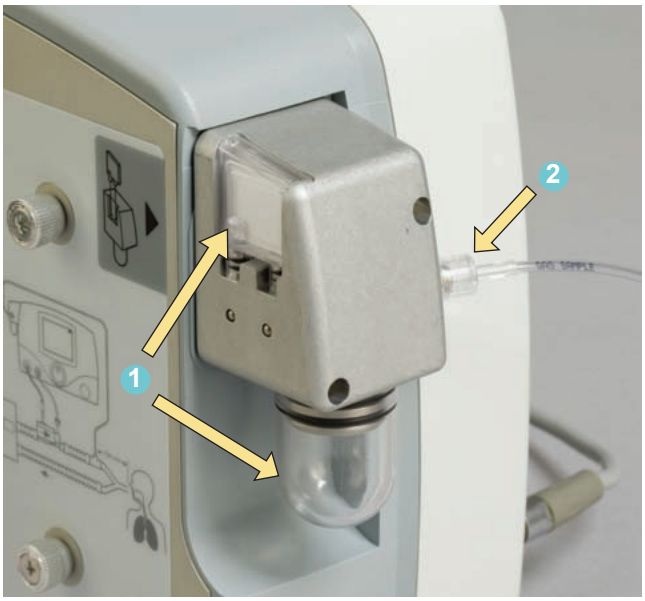
2/ Setup

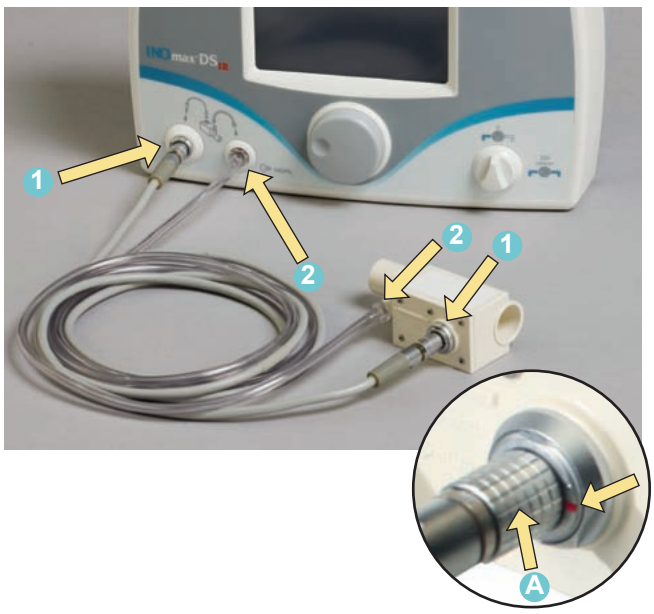
Note:	It is recommended to disinfect or sterilize the Injector Module prior to initial setup.

INOmax DS_{IR}® connections

- Remove any protective caps from the connectors and ports on the INOmax DS_{IR}.
- Ensure the INOmax DS_{IR} is on a flat surface or is fixed securely to a cart or transport sled.

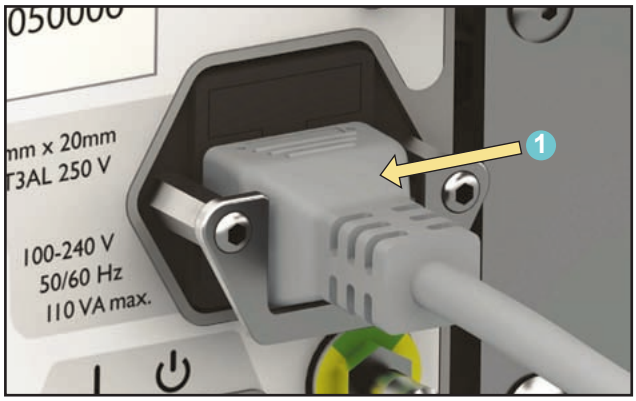


1. Ensure the water trap bottle and water separator cartridge are connected.
2. Connect the sample line to the sample line inlet port on the front of the INOmax DS_{IR}.



1. Connect one end of the Injector Module Electrical Cable to the Injector Module and the other end into the front of the INOmax DS_{IR}.
   - Line up the red dot on both the connector and the Injector Module before inserting the connector (see inset detail).
2. Connect one end of the INOMAX® Injector Tube to the Injector Module and the other end into the front panel of the INOmax DS_{IR}.

Note:	To remove this type of connector, the knurled sleeve (A) on the connector must be pulled outward before removing the connector from the Injector Module or the front panel.



1. Connect the power cord to the INOmax DS_{IR}® and tighten the power cord clamp.
2. The front panel green Main Power light indicates that the power cord is plugged into an electrical outlet.

   (Connect the INOmax DS_{IR} power cord to an emergency-power-backed hospital-grade outlet. The power cord must always be connected to an electrical outlet to maintain a full battery charge).

Caution:	Keep the power cord off of the ground and away from moving parts.

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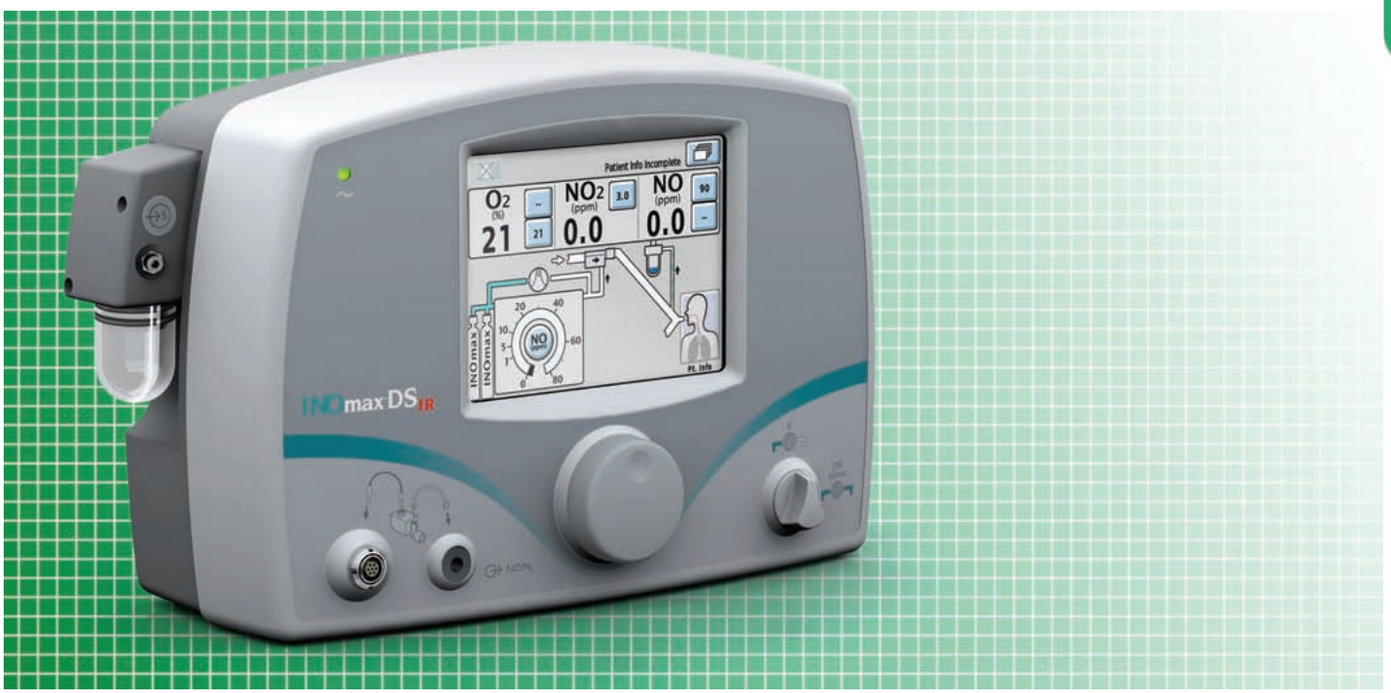
INOmax DS$_{IR}$®

(Delivery System)



3/ Pre-Use Checkout

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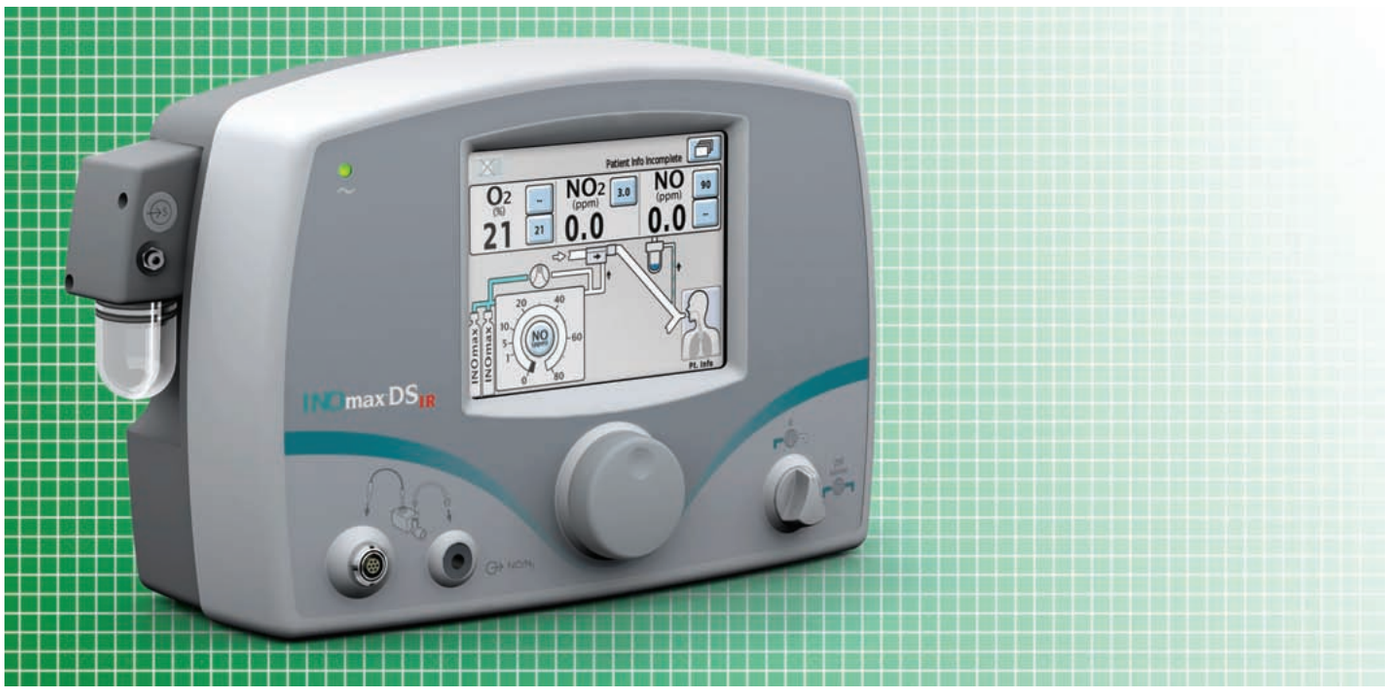
IKARIA®

INOmax DS$_{IR}$®

(Delivery System)

Pre-Use Checkout



3/ Pre-Use Checkout

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3/ Pre-Use Checkout

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 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:	High frequency and/or high intensity light emission, in the area of the INOmeter®, may interfere with communication between the INOmax DS_{IR} and the INOmeter on the INOMAX cylinder (see page 9).

The Pre-Use procedures consist of the following tests which must be done before delivering INOMAX to a patient:

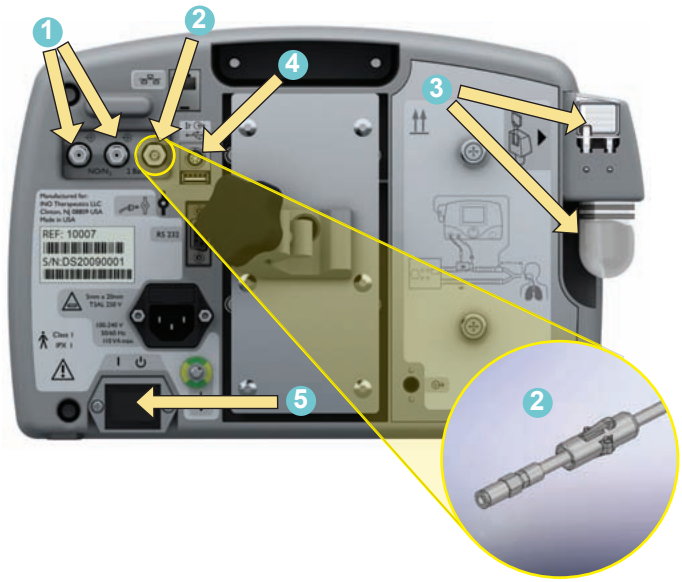
Check the INOMAX gas cylinders for the correct product identity labels, cylinder concentration and expiration date.

Ensure at least one INOMAX gas cylinder (with more than 200 psig) is available.

Connect one of the high pressure regulators to an INOMAX cylinder and tighten the fitting to the INOMAX cylinder.

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 4-11, Section 4/Patient Application).

Note:	Ensure the white plastic tip is in place on the regulator connector and not chipped or cracked. Remove and replace as necessary (see page 103).



Initial Connections

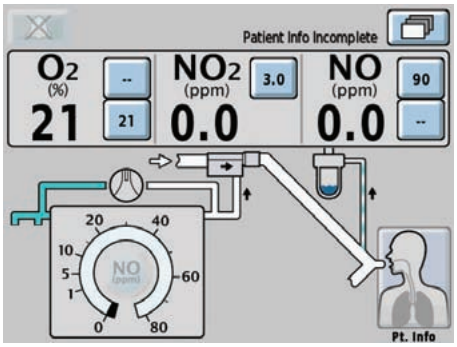
Connect the INOmax DS_{IR}® as described in Section 2/ Setup and check the cables and hoses for signs of wear or damage.

1. Connect the INOMAX® regulator hose to one of the INOMAX inlets (see page 28).
2. If using the INOblender® with the INOmax DS_{IR}, connect the INOblender inlet hose to the INOmax DS_{IR} blender outlet and slide the Quick-Connect cover into place. Connect oxygen supply (wall source or cylinder oxygen) hose to O_2 inlet fitting on back of INOblender.
   Note: 50 psig (nominal)
3. Ensure water trap bottle and water separator cartridge are in place.
4. Connect the Infrared cable from the INOmax DS_{IR} cart or Transport Regulator/ Cap Assembly (PN 10022) to the back of the INOmax DS_{IR} (see Figure 4-6, Section 4/Patient Application).
5. Turn the INOmax DS_{IR} ON.

Note:	Do not attempt to connect the transport regulator cap assembly electrical plug to the INOblender outlet port. This will damage the connector plug electrical pins.

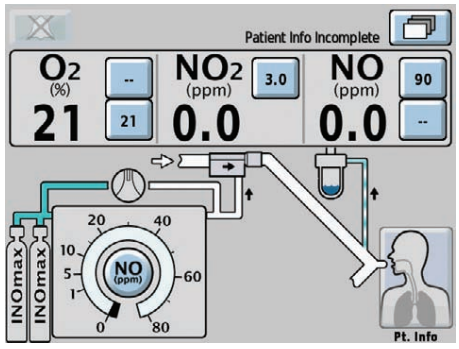
Self Test Screen

An INOmax DS_{IR} splash screen will appear once the device is turned ON followed by an Ikaria test screen (confirm that the speaker sounds). This will be followed by the main screen.



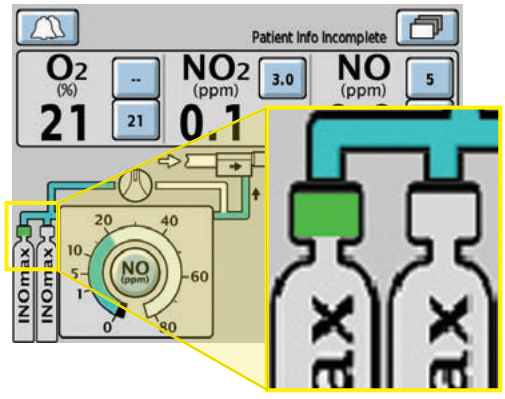
Main Screen

Cylinder icons are not visible and the dose control button will remain inactive until the INOmax DS$_{IR}$® recognizes an INOMAX® cylinder.



The cylinder icons will appear on the main screen in relation to their position on the cart when the user is facing the INOmax DS$_{IR}$.

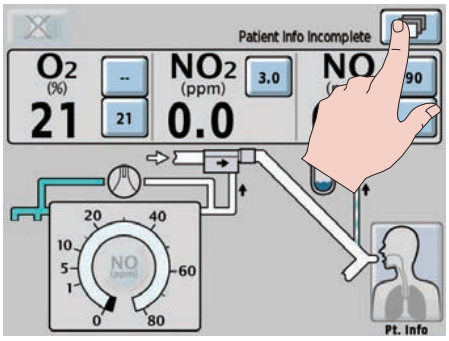
Note:	When using the Transport Regulator/Cap Assembly (PN 10022) only one cylinder will be displayed.



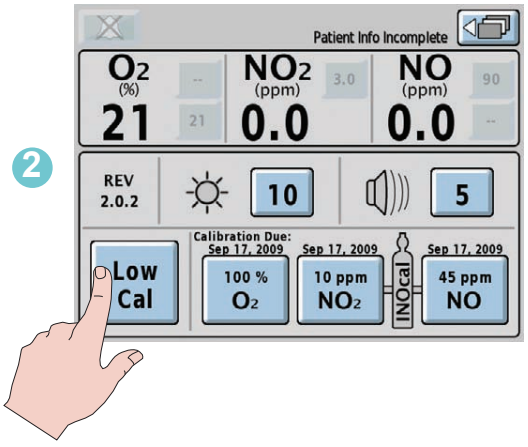
When an INOMAX cylinder valve is opened, the cylinder handle graphic will turn green representing an open INOMAX cylinder valve.

High Pressure Leak Test

1. Make sure INOblender® and backup NO delivery are OFF.
2. Open and then close the cylinder valve.
3. Check for adequate cylinder pressure.
4. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no pressure decrease is observed, high pressure leak test is successful; proceed to Low Range Calibration.
5. If there is an observed pressure decrease, see Section 8/ Maintenance; Cylinder Leak Check.



1



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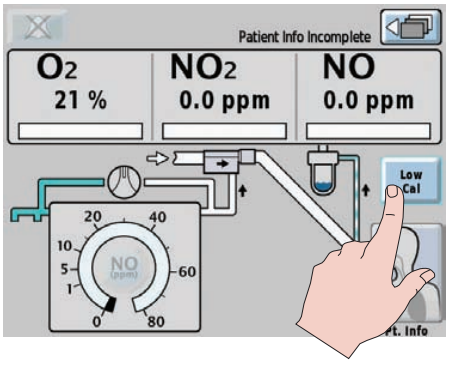

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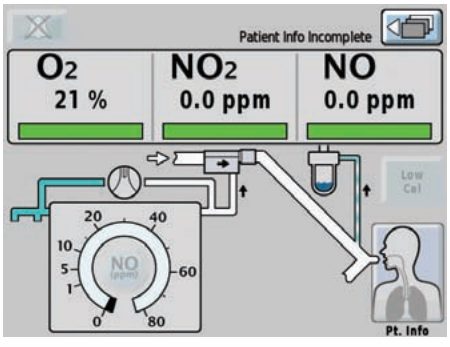


4

Low Range Calibration

Perform low range calibration prior to initiation on a patient (see Section 7/ Calibration for procedure).

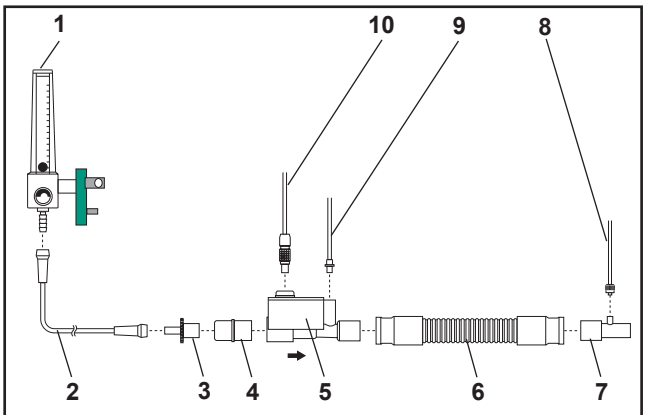
1. Access the menu screen (second menu layer).

2. Press the “Low Cal” button.

3. Initiate the low range calibration.

4. When the low range calibration is successful, the graph bars will turn green and a single tone will be heard. Press the menu button twice to return to the Main Screen.

Note:	The low calibration does not require calibration gases.



1. O_2 Flowmeter (Connected to wall/tank)
2. O_2 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
9. NO/N_2 Injector Tube
10. Injector Module Electrical Cable

Figure 3-1

Purge and Alarm Verification

Assemble connectors and tubing as shown in Figure 3-1 to perform the following three procedures:

1. Ensure the INOMAX® cylinder valve is closed.
2. Set the O_2 flowmeter to 10 L/min (#1 in Figure 3-1).
3. Purge INOmax DS_{IR}®.
   - Set the INOMAX dose to 40 ppm. (see page 7)
   - "Cylinder Valve Closed" alarm will occur.
   - Cylinder gauge pressure should drop to 0 psig.
   - Measured NO_2 will increase and then decrease as NO_2 is purged from the system.
   - "Low NO/N_2 Pressure" alarm will occur.
4. Open the INOMAX cylinder valve.
5. Turn the INOMAX dose to zero. The "Set Dose is Zero, Close Cylinder Valve" indicator will appear. This indicator will display anytime the set dose is returned to zero; however, during this pre-use procedure, leave the cylinder open and touch the screen to reset the indicator.

Backup INOMAX Delivery Test

Ensure the oxygen flowmeter is set to 10 L/min.

(#1 in Figure 3-1).

1. Turn the backup INOMAX delivery to ON (250 mL/min.).
   Note: "Backup ON" alarm will occur.
2. Allow 2-3 minutes for the monitored values to stabilize and make sure the NO and NO_2 readings are within the following ranges:

NO = 14-26 ppm	$NO_2 \leq 1.0$ ppm

3. Turn the backup INOMAX delivery to OFF.

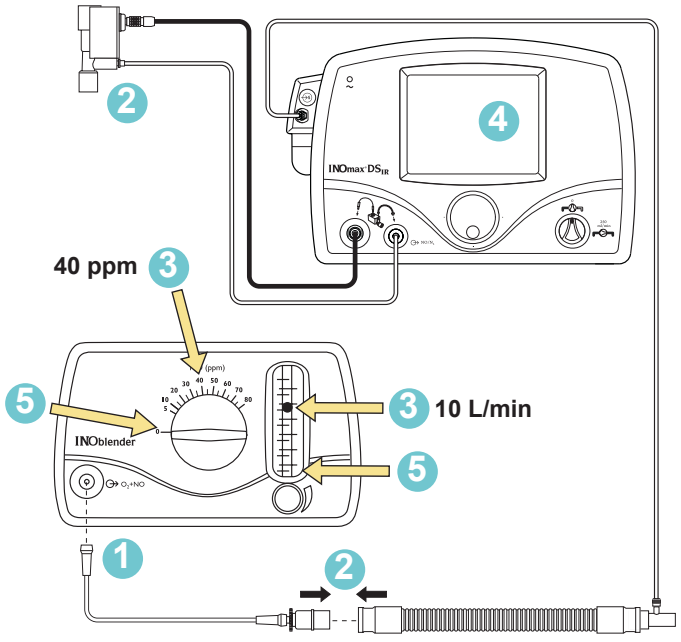
Performance Test

Ensure that the O_2 flowmeter is set to 10 L/min. (Use the same assembly as in the purge procedure, see Figure 3-1 on page 25).

Set INOMAX® Dose	40 ppm
Acceptable NO Value	35-45 ppm
Acceptable NO_2 Value	< 1.5 ppm
FiO_2	95% ± 3 %

1. Set the INOMAX dose to 40 ppm, allow values to stabilize.
2. Compare the INOmax DS_{IR}® monitor values to the values in the table.
3. Turn INOMAX dose to zero.

Note:	Allow 2-3 minutes for monitored values to stabilize. If a monitored value is outside the range indicated, do a high range calibration for that sensor.



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. • Ensure oxygen supply hose is connected to O_2 inlet fitting on back of INOblender.

1. Remove the Pre-Use set-up oxygen tubing from the oxygen flowmeter and connect it to the front of the INOblender.
2. Remove the Injector Module from the Pre-Use set-up and reconnect the adapters.
3. On the INOblender, set the INOMAX dose to 40 ppm and O_2 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.

Acceptable NO Value	32-48 ppm

WARNING:	• **If the INOmax DS_{IR} is not going to be used on a patient within 10 minutes, depressurize the regulator supply line.** • **If the INOmax DS_{IR} is not used and is pressurized for more than 10 minutes, repeat purge procedure.**

The INOmax DS_{IR} is now ready to connect to the patient. Proceed to Patient Application (section 4).

Purging the Regulator Supply Line

1. If not immediately connecting to a patient, turn the INOMAX® cylinder to OFF.

2. Purge the pressure from the regulator using the purge port on the back of the INOmax DS_{IR}®.

3. Reconnect regulator line to INOmax DS_{IR} inlet.

Note:	If you are having difficulty connecting the INOMAX regulator hose, see page 28 at the end of this section.

WARNING:	**If the INOmax DS_{IR} is depressurized and not used within 12 hours, repeat pre-use procedure.**

Using the INOMAX® Gas Inlet Connector

Proper use of the INOMAX inlet connectors is essential for safe and effective delivery of INOMAX. Follow the steps below to ensure the regulator hose is attached correctly.

1. Visually inspect the two inlet connectors and the outlet connector for signs of wear or damage.

2. Prior to connecting a regulator hose, ensure the inlet connectors, on the INOmax DS_{IR}® unit, have the knurled sleeve set in the back position (toward the INOmax DS_{IR} unit, see Figure 3-2). Should the sleeve be in the forward position the inlet valve will be open and the INOMAX regulator hose will not securely connect to the inlet (see Figure 3-3).

3. Insert the connector from the regulator hose into the gas inlet. Ensure the knurled sleeve moves and clicks into the forward position, locking the connector in place.

4. To disconnect the INOmax DS_{IR} regulator hose, push the knurled sleeve toward the back of the INOmax DS_{IR} unit until the hose disengages.

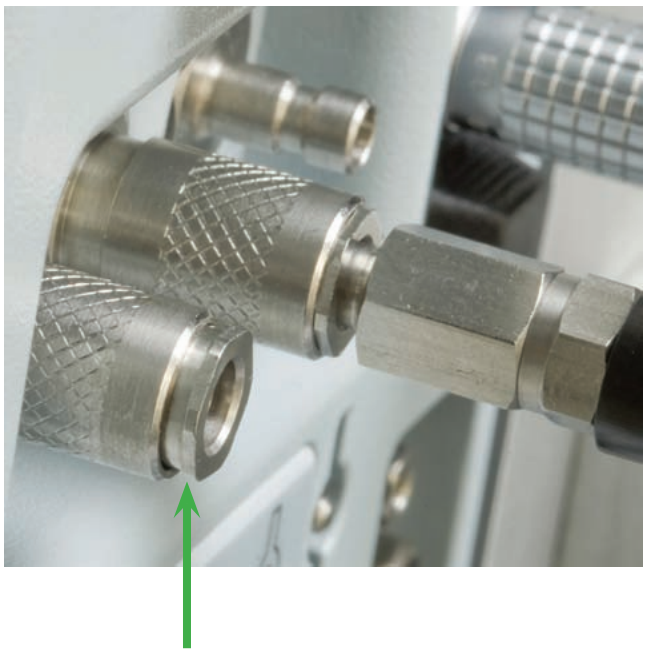


Figure 3-2
INOMAX gas inlet with the knurled sleeve in the back position.

Ready for use

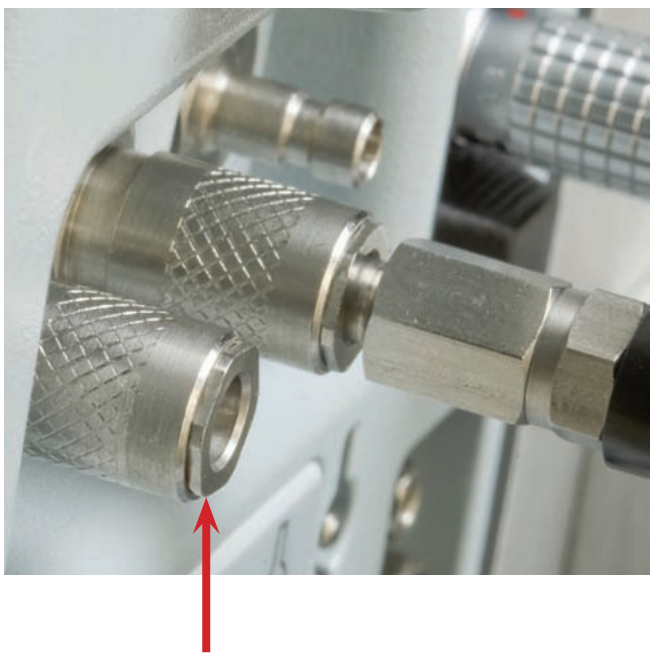


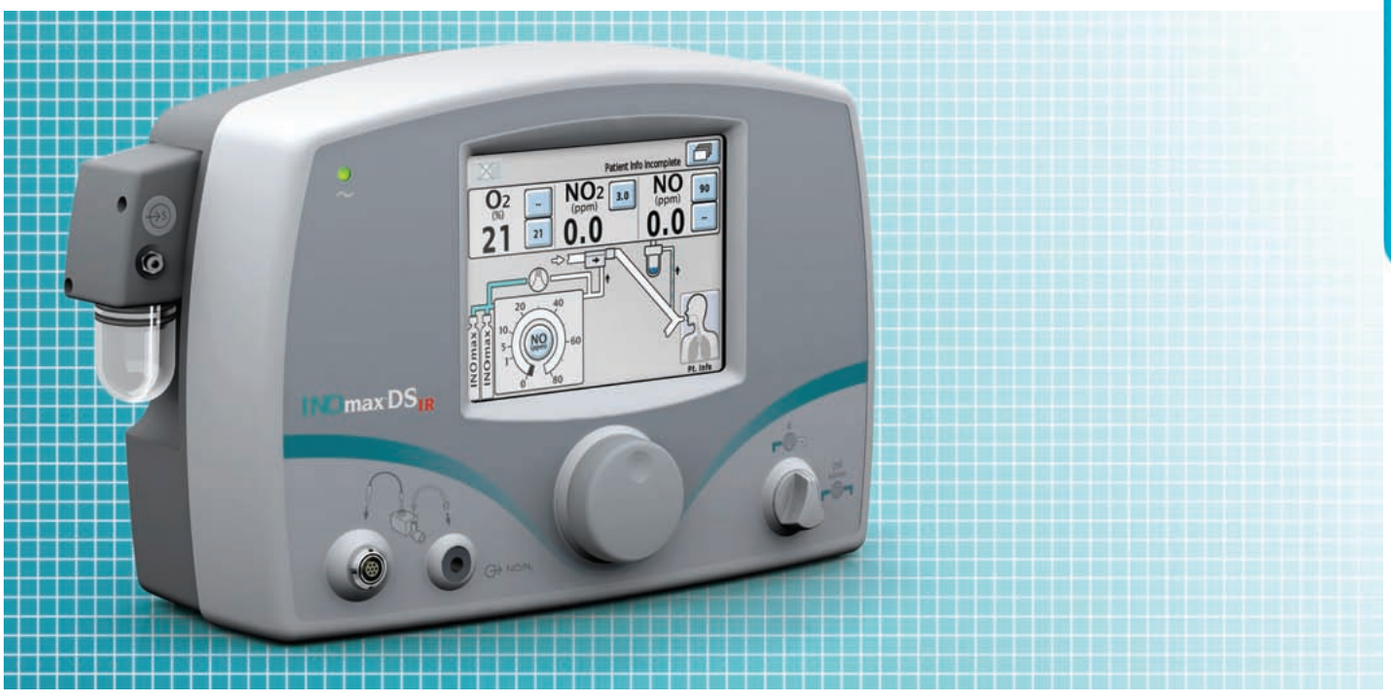
Figure 3-3
INOMAX gas inlet shown with the knurled sleeve in the forward position.

Reset prior to use

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



4/ Patient Application

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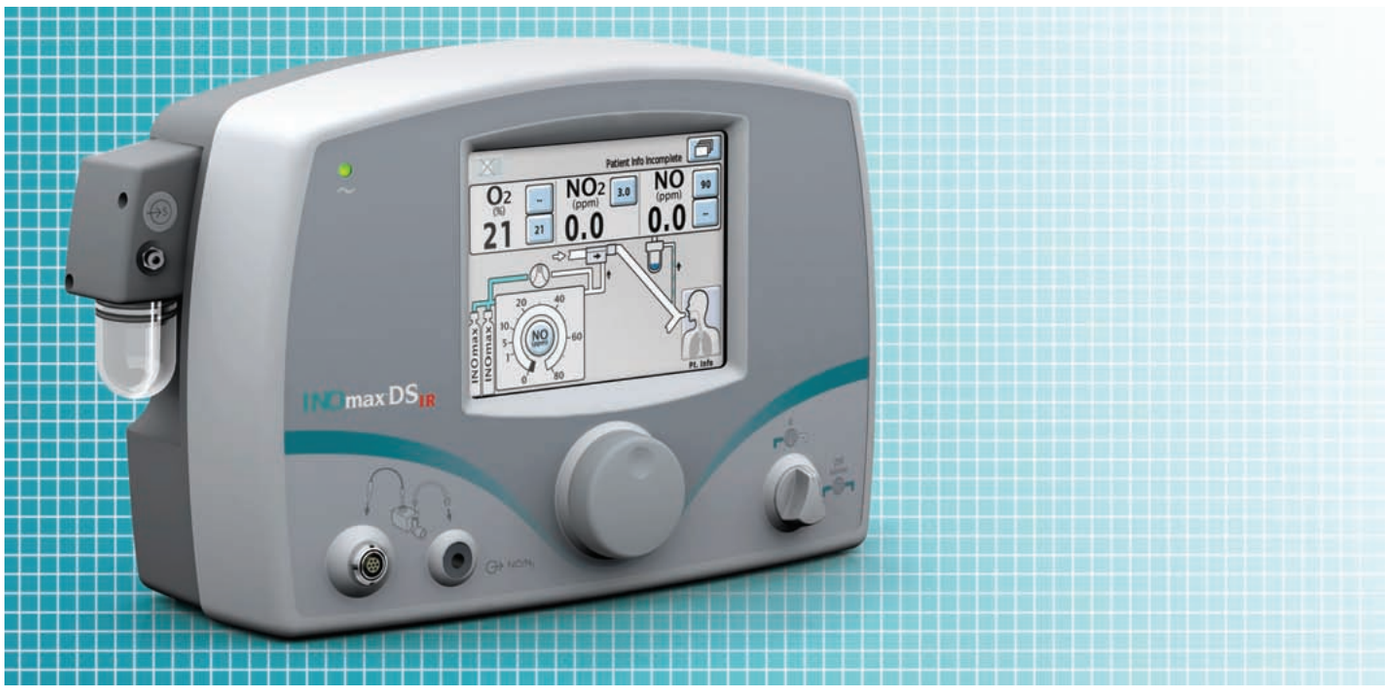
IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



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4/ Patient Application

WARNING:

- **The use of devices, which radiate high-intensity electrical fields, may affect the operation of the INOmax DS_{IR}®. Constant surveillance of all monitoring and life support equipment is mandatory whenever interfering devices are in operation on or near a patient.**
- **Set the INOmax DS_{IR} alarm thresholds for the current patient conditions to monitor any inadvertent changes in treatment. For alarm information, see Section 5/ Alarms.**
- **If the INOmax DS_{IR} is not going to be used on a patient within 10 minutes, depressurize the regulator supply line.**
- **If the INOmax DS_{IR} is not used and is pressurized for more than 10 minutes, repeat purge procedure.**
- **If the INOmax DS_{IR} is depressurized and not used within 12 hours, repeat pre-use procedure.**
- **Be certain all cables and hoses are positioned to help prevent damaging or occluding them.**
- **The 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.**
- **The use of pediatric and neonatal ventilator settings with adult size breathing circuits can result in high levels of NO_2. Always use the size of breathing circuit that is appropriate for the patient.**

- **Use only "Latex-Free" breathing circuits and ventilators when using the INOmax DS_{IR}.**
- **The humidifier chamber volume should not be more than 480 mL to prevent elevated NO_2 values.**
- **Patient disconnect and high pressure alarms are required for the ventilator.**

Caution:

- Use distilled water in the humidifier to prevent the formation of bases or acids.
- Note the airflow direction arrow on the Injector Module. Flow out of the ventilator must pass through the Injector Module in the direction of the arrow on the module.
- Insert the Injector Module on the dry side of the breathing circuit prior to the humidifier. (This will ensure correct flow measurement).
- To condition ventilator flow and ensure flow measurements are accurate, connect the Injector Module to the humidifier chamber; then connect to the ventilator inspiratory port using breathing circuit tubing. This can also be done by placing a breathing circuit filter between the Injector Module and the ventilator.
- High frequency and/or high intensity light emission, in the area of the INOmeter®, may interfere with communication between the INOmax DS_{IR} and the INOmeter on the INOMAX® cylinder (see page 9).

Before Operation

Complete the Setup and Pre-use procedures as described in the previous sections before connecting the INOmax DS_{IR}® into the patient's ventilator breathing circuit. (See the ventilator manual for its setup and operation)

Caution:	The gas sensors in the INOmax DS_{IR} monitoring system require humidity in the sample gas to function correctly over the long term. Using the INOmax DS_{IR} without water in the humidifier will shorten the life of the gas sensors.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Adapter diagrams can be found on page 72.

Connection to the ventilator breathing circuit

(Connect the INOmax DS_{IR} into the breathing circuit as shown in the appropriate connection diagrams later in this section, page 48)

1. Insert the Injector Module on the dry side of the breathing circuit prior to the humidifier (this will ensure correct flow measurement; see Figure 4-0 and 4-1 for connection sizes).
2. The distance between the Injector Module and the sample tee must be greater than 24" to ensure proper gas mixing.
3. Make sure the port in the sample tee is pointing upward (this helps to avoid fluid accumulation in the sample line).
4. The distance between the sample tee and the patient wye should be between 150 to 300 mm (6-12 inches) long. Important: This will minimize the sampling of mixed inspired / expired concentrations and to ensure correct patient INOMAX®/NO_2 measurement.
5. Set the INOMAX dose to be delivered to the patient (select, rotate, confirm).
6. Set the appropriate alarm settings on the INOmax DS_{IR} and breathing device.

After connecting the INOmax DS_{IR} to the breathing circuit, the trigger sensitivity may need to be adjusted, due to the removal of gases by the sample system.

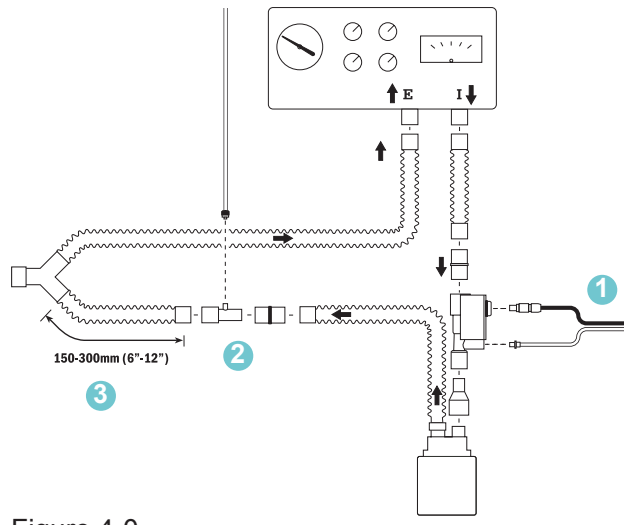
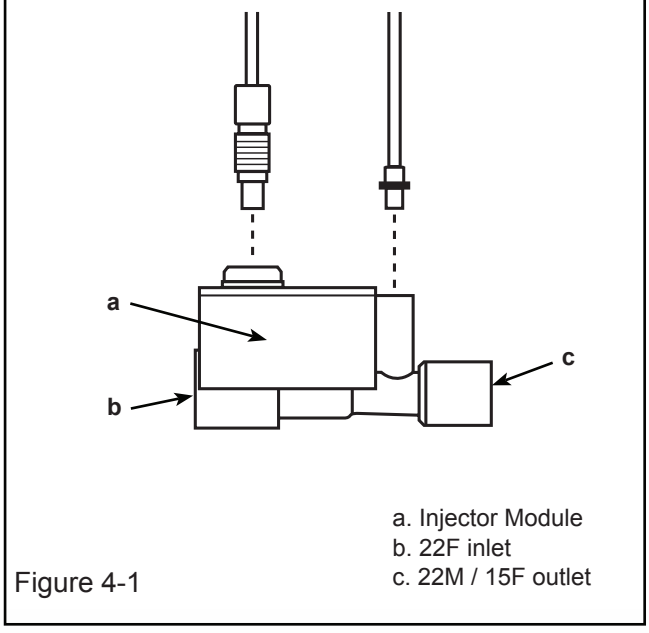


Figure 4-0



a. Injector Module
b. 22F inlet
c. 22M / 15F outlet

Figure 4-1

INOblender® Operation

Important: Read the INOblender Operation Manual PN 20004 before using the INOblender. Follow instructions and obey all Warnings and Cautions.

WARNING:	• **The purge procedure must be followed to help ensure NO_2 is purged from the system before the manual resuscitator bag is connected to the patient.** • **The manual bag should be squeezed repeatedly during use to avoid NO_2 building up in the bag.** • **If the bag is not squeezed repeatedly while delivering INOMAX®, the bag should be removed from the patient and the bag purge procedure performed before continuing.** • **The INOblender should be upright when setting the oxygen flowrate for accurate setting.** • **Do not use pneumatically powered nebulizers with the INOblender. This will result in significant over delivery of INOMAX in excess of 80 parts per million (ppm).** - **The INOblender outlet pressure has been validated for use up to 400 millibar (5.8 psig) pressure. The amount of back-pressure generated by pneumatic nebulizers is significantly greater (20-30 psig) and will result in over delivery of INOMAX in excess of 80 ppm. The user adjusted dose setting on the INOblender will not correlate with, or have an effect on the actual delivered dose.** - **In addition, the INOblender flowmeter is not back-pressure compensated and will display a lower flow rate than actual when pressure is applied to the outlet.**

Caution:	• When not in use, the oxygen flowmeter and the INOMAX cylinder valve should be turned off. • INOblender used with an oxygen/air blender. - The specification for INOMAX delivery when using the INOblender with 100% oxygen is +/- 20% of setting or 2 ppm (whichever is greater). The use of 100% oxygen at 50 psig is the labeled specification for the INOblender. - A user may determine that some clinical conditions may necessitate the use of an oxygen/air blender with the INOblender to achieve FiO_2 levels less than 100%. - Using oxygen/air mixtures (21% to 95% v/v) will reduce the delivered NO concentration by up to 10% of setting or 1 ppm (whichever is greater) compared to using 100% oxygen alone, resulting in a cumulative error up to +/- 30% of setting or 3 ppm (whichever is greater).

Backup NO Delivery

WARNING:

- **When the backup NO delivery mode is used, a flow of at least 5 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 device 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.**

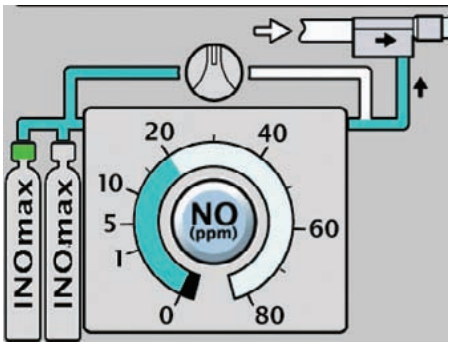


Figure 4-2

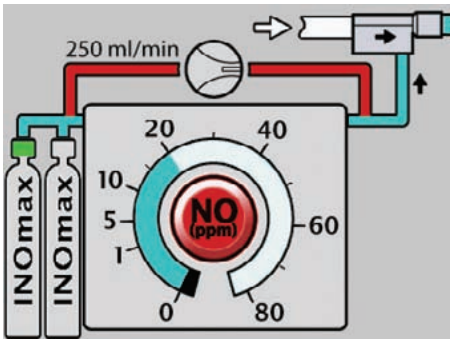


Figure 4-3

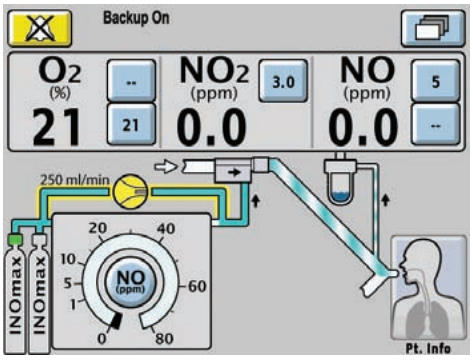


Figure 4-4

Backup NO Delivery Description

The advantage of this backup delivery mode is that the patient does not have to be removed from the ventilator and manually ventilated to continue with INOMAX therapy if the main electronic delivery system fails.

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.

- When the backup switch is OFF the main screen displays the backup system as off (see Figure 4-2).
- If both the Set NO delivery and backup delivery are active simultaneously, then a high priority alarm will sound and the graphic is displayed on the main screen (see Figure 4-3).
- The backup delivery is activated through the backup switch on the front panel. The INOMAX dose should then be turned off.
- If the display is active, the main screen indicates that backup delivery is on and the set dose is turned off (see Figure 4-4).

This table indicates nominal NO 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

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Transport Regulator/Cap Assembly Application

WARNING:	**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 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:	Check the INOMAX cylinder for the correct product identity labels, cylinder concentration and expiration date. Ensure the INOMAX gas cylinder has a pressure of more than 200 psig.

1. Connect a high pressure regulator to an INOMAX cylinder and tighten the fitting to the INOMAX cylinder (see Figure 4-5).

Note:	Ensure the white plastic tip is in place on the regulator connector and not chipped or cracked. Remove and replace as necessary (see Replacing the CGA 626 tip on the INOMAX regulator, page 103).

2. Connect the INOMAX regulator hose to one of the INOMAX inlets on the back of the INOmax DS$_{IR}$ (see Figure 4-5).

Figure 4-5

Figure 4-6

3. Connect the infrared cable from the Transport Regulator/Cap Assembly to the back of the INOmax DS_{IR}® (see Figure 4-6).

Note:	Notice that the connector clicks to indicate that it is latched in place. Do not attempt to connect the transport regulator cap assembly electrical plug to the INOblender® outlet port. This will damage the connector plug electrical pins.

Figure 4-7

4. Place the Cap Assembly over the INOmeter (see Figure 4-7).

Note:	Be sure to align the keyway inside the Cap Assembly with the iButton on the INOmeter® (see Figure 4-7 and 4-8).

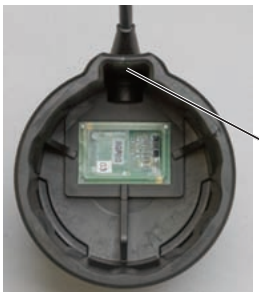


Figure 4-8

Figure 4-9

5. Grasp the Cap Assembly to open cylinder valve (see Figure 4-9 and 4-10).

Figure 4-10

Final Set-up Diagram

The following diagram (see Figure 4-11) illustrates all of the components connected.

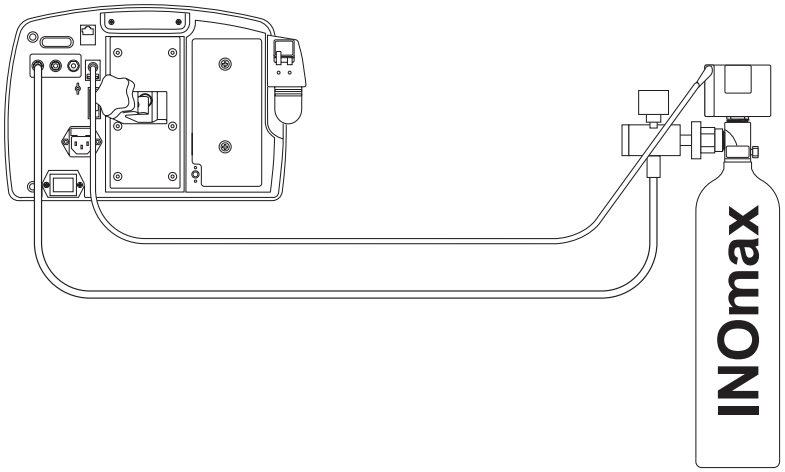


Figure 4-11

Additional Information

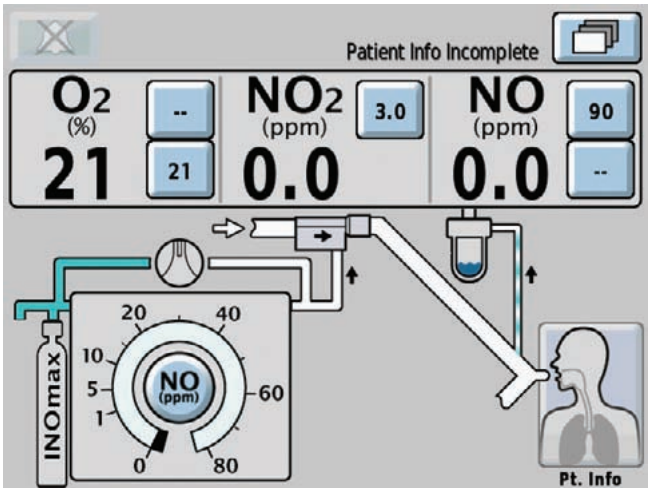


Figure 4-12

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. • When using the Transport Regulator/ Cap Assembly only one cylinder will be displayed (see Figure 4-12).

Cylinder Information

Always:

- Check the product label for correct product, expiration date and cylinder concentration.
- Use a properly designed cart to move a cylinder and properly secure the cylinder when moving it.
- Apply a proper pressure regulating device to the cylinder before using it.
- Periodically check the cylinder pressure.
- Apply the valve outlet cap and valve protective cap to a cylinder when it is not connected.

WARNING:

- **Always secure a cylinder when not using it.**
- **Never lift a cylinder by its valve or valve protection cap or by using a chain, sling or magnet.**
- **Never drop a cylinder.**
- **Never use a hammer, pry or wedge to loosen a valve or protection cap. The valve and protection cap should operate by hand.**
- **Never let oil, grease or other combustibles come in contact with a cylinder or valve.**
- **Never remove or deface cylinder labeling or markings.**
- **Never modify equipment without first contacting Ikaria.**
- **Never use an adaptor to connect a cylinder to the system.**
- **Never use equipment not designed to use INOMAX® mixtures.**
- **Never attempt to repair a leak on a cylinder valve or its safety relief device.**
- **Never operate equipment that is leaking.**
- **Never ship a leaking cylinder.**
- **Never store cylinders:**
  - **Where damage can result from the elements, such as standing water or temperatures over 125 degrees F.**
  - **Where they can contact artificially low temperatures.**
  - **Where they can contact corrosive substances.**
  - **Where they can be cut or abraded by an object.**
  - **Next to a walkway, elevator or platform edge.**
  - **Unless they are properly secured.**

Changing INOMAX® cylinders and purging the regulator 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 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} (see Figure 4-6).

1. Using an INOMAX cylinder with greater than 200 psig, attach a second INOmax DS_{IR} regulator which is currently not in use.

Note:	• Do not attach the regulator hose to the INOmax DS_{IR} at this time. • Ensure the white plastic tip is in place on the regulator connector and not chipped or cracked. Remove and replace as necessary (see page 103).

2. Open and then close the valve on the new INOMAX cylinder. Check for adequate cylinder pressure. Monitor pressure gauge for 30 seconds for any signs of leakage. If there is a decrease, check for leaks around the hose connections and cylinder valve connector using soapy water. (see Section 8/ Maintenance; Cylinder Leak Check).

3. Insert the NO/N_2 quick-connect fitting into the purge port on the back of the INOmax DS_{IR}® and firmly push until the regulator pressure gauge reads zero (this purges any NO_2 that has accumulated in the hose and regulator).

4. Connect the hose to the back (NO/N_2 inlet) of the INOmax DS_{IR}. If you are having difficulty connecting the INOMAX regulator hose, see page 28.

5. Open the cylinder valve on the new cylinder (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 (see page 33). "Cylinder Not Detected" alarm may occur.

6. Close the cylinder valve on the empty cylinder and remove the supply line from the back of the INOmax DS_{IR}.

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

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 (ppm)	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 the recommended therapeutic dose.

Calculations are considered estimates and may vary under clinical circumstances.

All numbers have been rounded to the nearest hundredth.

Duration Chart

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 ppm	43.3 Days	21.7 Days	10.8 Days	5.4 Days	
	10 ppm	21.5 Days	10.7 Days	5.4 Days	2.7 Days	
	20 ppm	10.6 Days	5.3 Days	2.6 Days	31 Hours	
	40 ppm	5.2 Days	2.6 Days	31 Hours	15 Hours	
	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 the recommended therapeutic dose.

* All calculations are based on a full cylinder (2000 psig, 1963 liters “88”) changed at 200 psig. Based 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 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)

Duration Chart

INOMAX® Cylinder D-Size

For an D-Size 800 ppm Cylinder Concentration* (typically used in transport) (Illustrative Only)

		FLOW				
		5 L/min	10 L/min	20 L/min	40 L/min	
INOMAX Dose (ppm)	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	
	80 ppm	10 Hours	5 Hours	2 Hours	1 Hour	

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

* All calculations are based on a full cylinder (2000 psig, 353 liters “88”) changed at 200 psig. Based on total continuous flow. (cylinder conversion factor = 0.17).

INOMAX flow = [Desired dose X total ventilator flow] / Cylinder concentration – desired dose
Cylinder volume = Cylinder conversion factor X cylinder 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)

Emptying the Water Trap Bottle

WARNING:	When handling any component of the patient circuit that comes in contact with patient's fluids wear protective safety equipment.

The water trap bottle on the left side of the system (see Figure 4-13) collects fluids separated from the patient gas sample.

- Empty and clean the water trap bottle before each patient use and empty whenever the trap is more than half full.
- Empty the water trap bottle routinely. Allowing it to fill and overflow may cause system errors.
- A "Water Bottle Full" message will remind you to empty and clean the fluid trap should it become full.

Note:	Monitoring will be temporarily interrupted when the "Water Bottle Full" message is indicated.

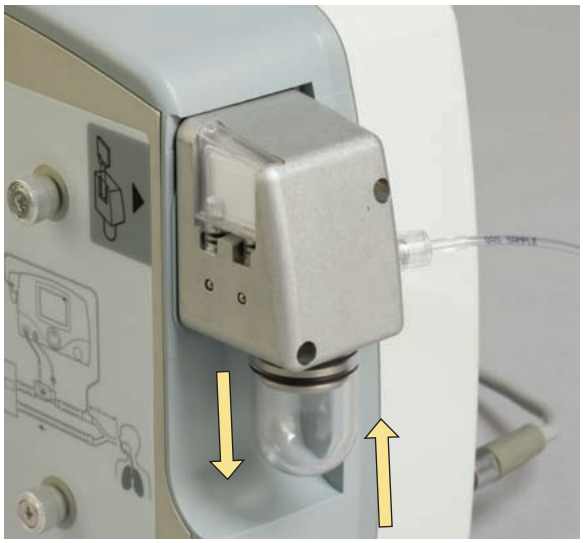


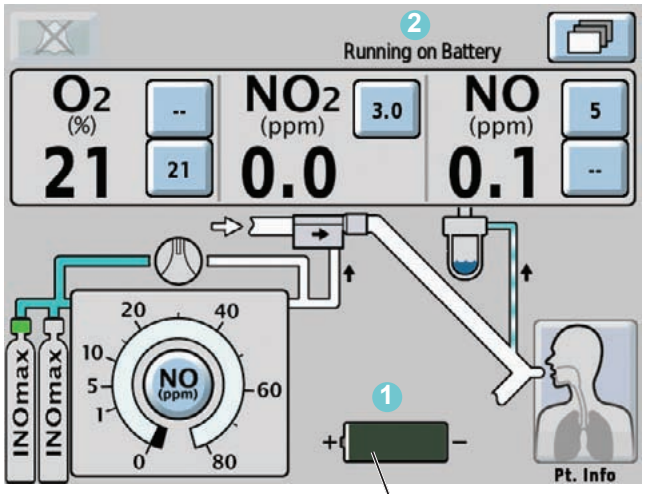
Figure 4-13

To empty the Water Trap Bottle:

1. Remove the bottle by pulling it straight down (see Figure 4-13).
2. Discard the contents according to an approved fluid waste disposal policy.
3. Clean the bottle.
4. Replace the bottle by pushing it up into position.
5. Check for leaks by running the system and occluding the sample line until the sample line occlusion alarm message appears.

Note:	During delivery of INOMAX® to a patient 1. The disposable Water Separator Cartridge on the rear of the water trap housing protects the monitoring system from moisture and other contaminants and may need to be replaced occasionally while in use. (Refer to Section 8/ Maintenance). 2. To avoid medications interfering with the gas monitoring system, administer any aerosolized medications distal to the sampling tee (refer to page 44).

Running on Battery



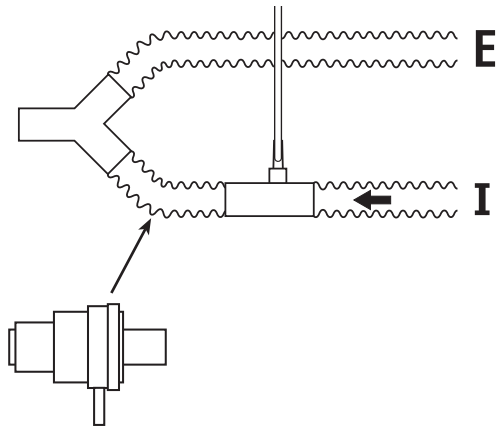
Battery icon

- When operating on the battery, a battery icon (1) is displayed on the screen along with the message “Running on Battery” (2) in the text message area.
- The low battery alarm will alert the user when there are approximately 30 minutes remaining.
- A fully charged battery will run the INOmax DS_{IR}® normally 6 hours in optimal conditions.
- Battery life can be extended by keeping the display brightness and the audio alarm volume to the minimum. (Display brightness and alarm volume can be changed by accessing the setup menu).

Inspired gas sampling during aerosol delivery

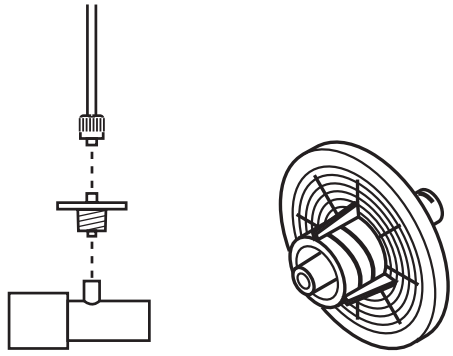
- To avoid a “sample line/filter block” alarm condition, place the medication nebulizer downstream of the sample tee on the inspiratory limb to avoid over saturation of the water separator cartridge or contamination of the sample system. (see Figure 4-14).
- To minimize replacement of filters during aerosol delivery, a small 0.5 micron hydrophobic disk filter with luer connections must be placed between the sample line and sample tee (see Figure 4-15).

Note:	The disk filter is to be used in conjunction with the INOmax DS_{IR}® water separator cartridge. The INOmax DS_{IR} must never be operated without the water separator cartridge. • This disk filter has been validated for this purpose. • This disk filter should be replaced at each treatment period. • During continuous medication delivery, frequent disk replacement may be necessary due to the disk becoming saturated with moisture/medication. • However, it will reduce the frequency of water separator cartridge replacement during medication delivery.



Location of nebulizer distal from the inspiratory gas sample tee

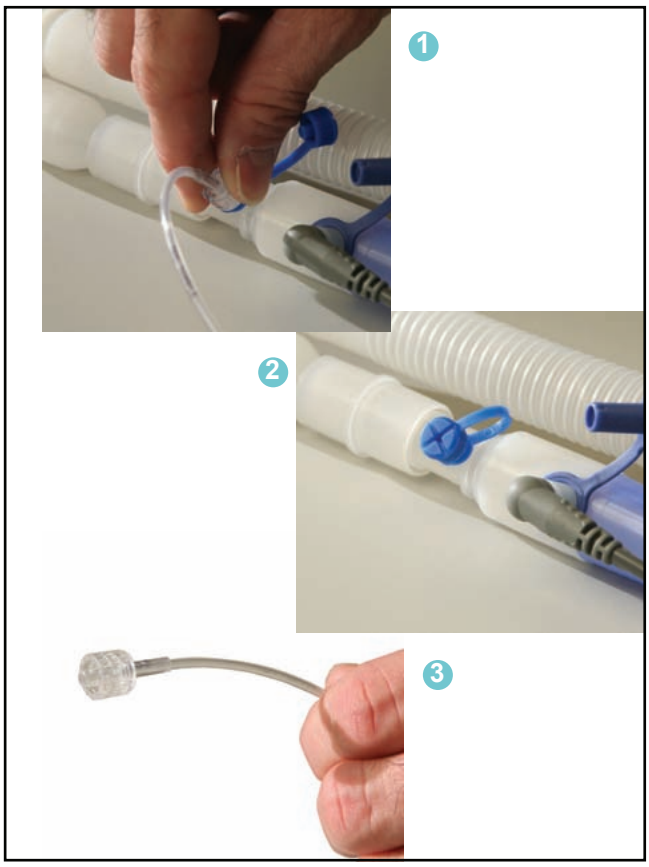
Figure 4-14



Disk Filter, 0.5 micron

Figure 4-15

Monitoring the Environment



The INOmax DS_{IR}® monitoring system can measure the environmental levels of NO and NO_2.

1. Disconnect the sample line connector from the sample tee.
2. Cap the Luer fitting on the sample tee.
3. Sample the room air with the sample line and read the NO and NO_2 readings.

   After environmental monitoring, remove the Luer fitting cap on the sample tee and reconnect the sample line.

WARNING:	**Patient circuit pressure and gas loss will result if cap is not placed (secured).**

Note:	Monitoring alarms may occur during the performance of this test.

Entering Patient Information

The following are instructions of how to use the patient identifier screen.

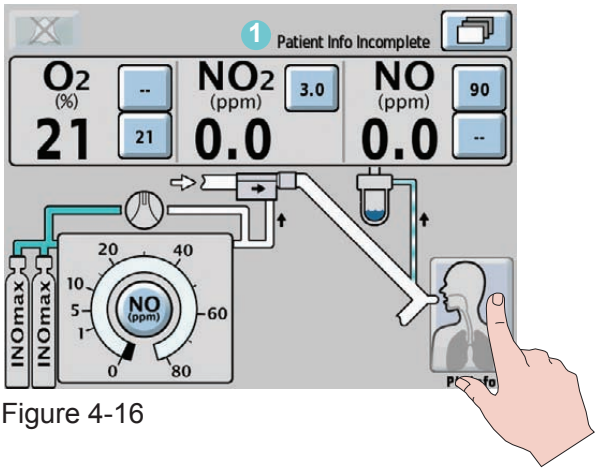


Figure 4-16

A patient identifier can be entered at any time during the treatment of a patient by pressing the patient information button in the right-lower corner of the main screen.

Note:	If patient identifier has not been entered a “Patient Info. Incomplete” indicator (1) will stay illuminated in the text message area of the screen (see Figure 4-16).

After pressing the patient information button, the following screen will appear (see Figure 4-17).

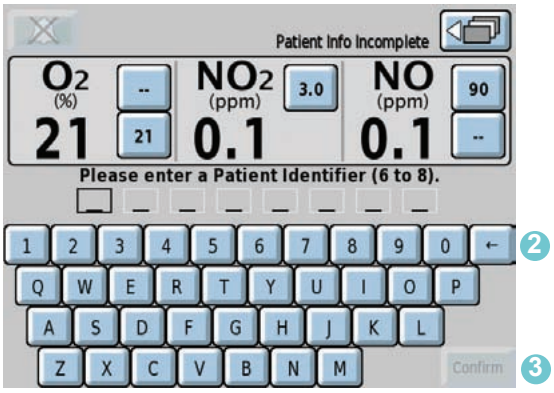


Figure 4-17

Note:	Any identifier entered will be linked with each INOMAX cylinder used during treatment.

The Patient Identifier screen (see Figure 4-17) allows a unique alphanumeric patient identifier to be entered that contains 6 to 8 digits (note: spaces will be accepted).

Note:	For HIPAA compliance, do not use identifiers traceable to a specific patient. Consult and comply with your internal hospital HIPAA guidelines when entering a patient identifier.

- Pressing the keys on the keyboard allows the user to enter a sequential alphanumeric identifier.
- Prior to confirming the identifier, digits can be changed either by pressing the backspace button (2) or pressing the digit that has been entered and typing over it.
- The “Confirm” button (3) will illuminate when 6 characters have been entered.

Note:	Once the “Confirm” button has been pressed, the identifier remains unchangeable until therapy is ended by turning the device to Standby (OFF).

Note:	A patient identifier may be entered at any time by pressing the Patient Information button. 

At any time should you need to return to the main screen, press the return to previous menu button. 

Connection to Various Breathing Systems

WARNING:

- **The INOmax DS_{IR}® subtracts gas from the breathing circuit via the gas sampling system at 230 mL per minute; this can effect 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.**
- **The humidifier chamber volume should not be more than 480 mL to prevent elevated NO_2 values.**
- **Patient disconnect and high pressure alarms are required for the ventilator.**
- **The INOmax DS_{IR} should not be used with the BiPap Vision sytem or other single-lumen breathing sytems with bidirectional flow, as over-dose of INOMAX® (nitric oxide) and interruption of drug delivery to the patient may occur.**

Caution:

- Note the airflow direction arrow on the Injector Module. Flow out of the ventilator must pass through the Injector Module in the direction of the arrow on the module.
- Insert the Injector Module on the dry side of the breathing circuit prior to the humidifier (this will ensure correct flow measurement).
- To condition ventilator flow and ensure flow measurements are accurate, connect the Injector Module to the humidifier chamber inlet; then, connect to the ventilator inspiratory port using breathing circuit tubing. This can also be done by placing a breathing circuit filter between the Injector Module and the ventilator.
- Avoid medications interfering with the gas monitoring system; administer any aerosolized medications downstream of the sampling tee.

* The INOmax DS_{IR} is designed to function in the parameter ranges listed in Section 9/ Product Specifications. Use outside of these ranges is not recommended.

Note:

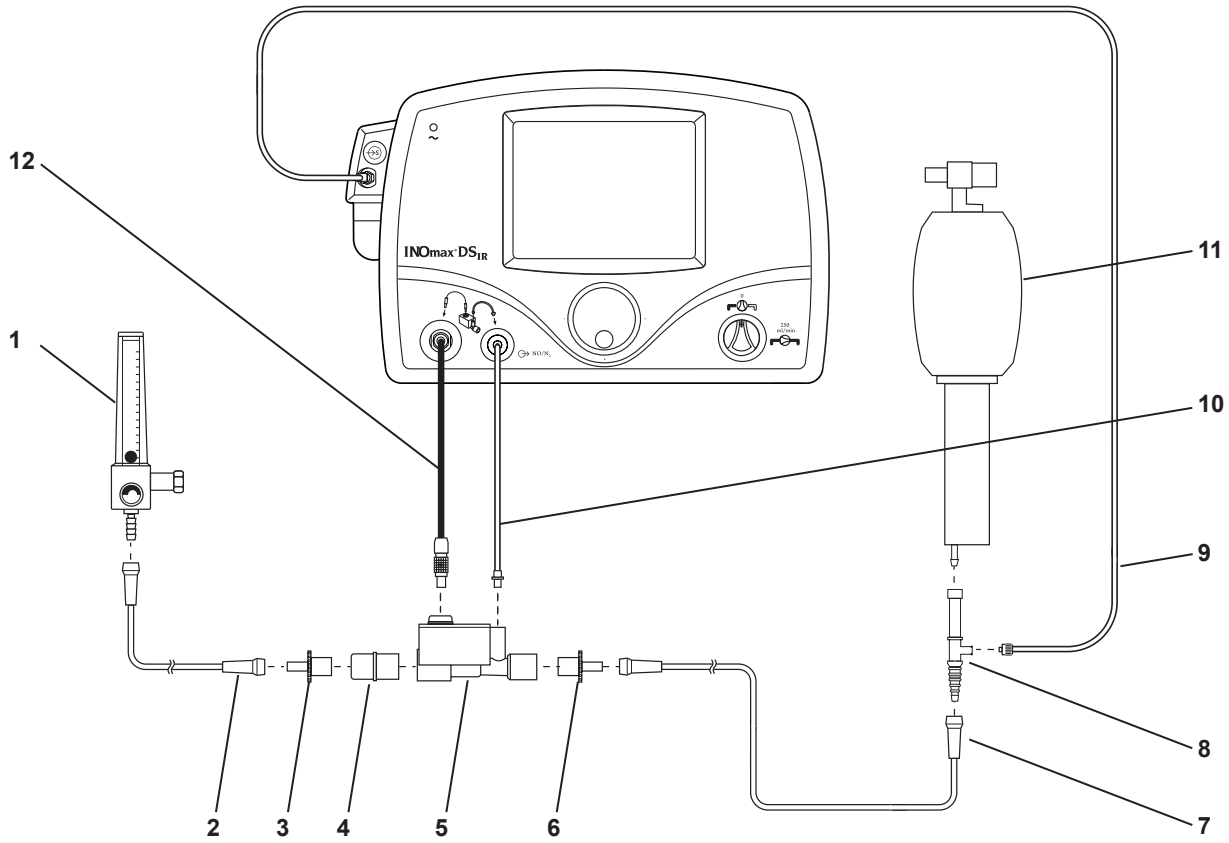
- Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72.

Connection to Bagging Systems While Using the Injector Module

WARNING:

To minimize the delivered concentration of NO_2, 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. O_2 Flowmeter (wall outlet or cylinder)
2. O_2 Tubing
3. 15M X 4.5mm Adapter
4. 22M/15F X 22M/15F Adapter
5. Injector Module
6. 15M X 4.5mm Adapter
7. O_2 Tubing
8. O_2 Tubing Sample Tee
9. Patient Gas Sample Line
10. NO/N_2 Injector Tube
11. Resuscitator Bag with O_2 Reservoir
12. Injector Module Electrical Cable

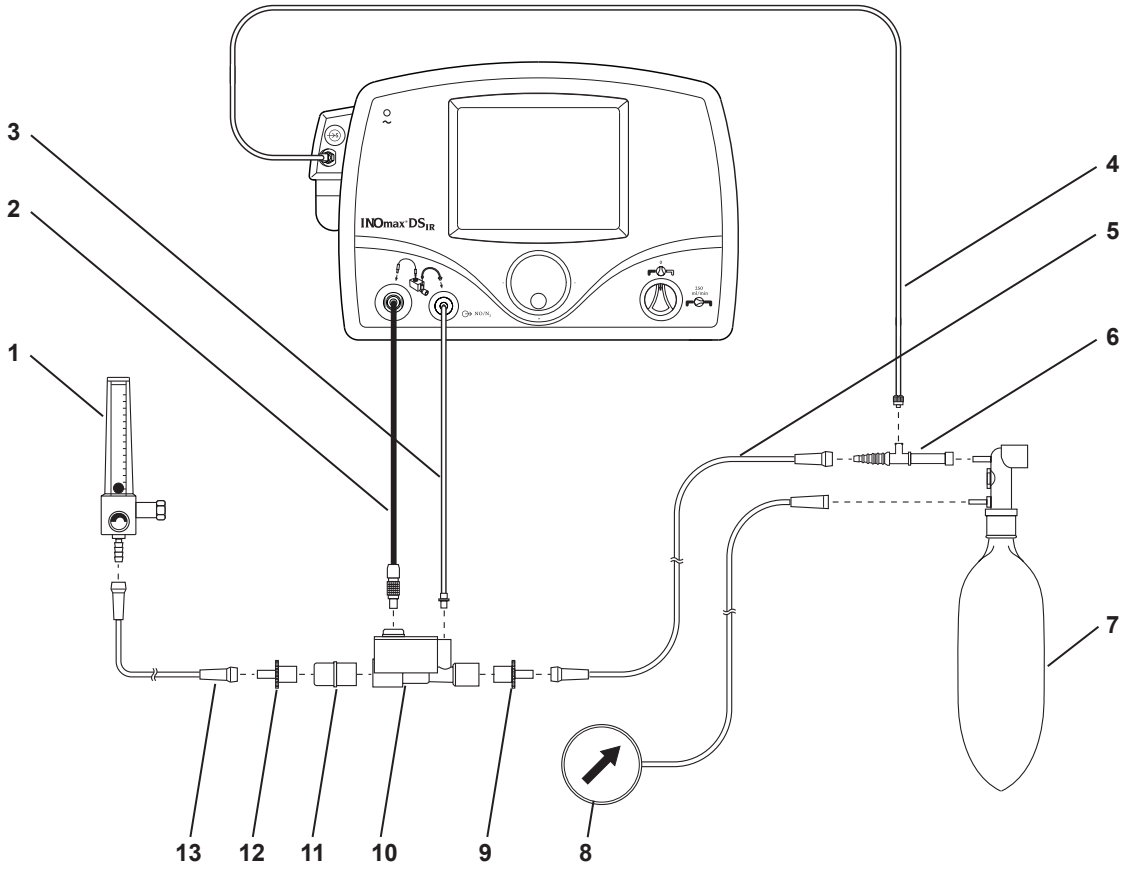
Figure 4-18 Example: Self-inflating Manual Bagging System Connection Diagram

Connection to Bagging Systems While Using the Injector Module

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 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 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 DS_{IR}® 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.**
  - **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.**

Caution: New O_2 tubing must be used each time for optimal fit on the 4.5 mm adapter.



1. O_2 Flowmeter
2. Injector Module Electrical Cable
3. NO/N_2 Injector Tube
4. Patient Gas Sample Line
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

Figure 4-19 Example: Hyperinflation Manual Bagging System Diagram

Testing has only been conducted using the following hyperinflation and self-inflating bag systems.

- Hudson RCI Hyperinflation 1L Adult # 5404
- Hudson RCI Hyperinflation 0.5L Neonatal # 5403
- Nellcor-Puritan Bennett Self-inflating 1.76 L Adult # 655005
- Nellcor-Puritan Bennett Self-inflating 0.52 L Infant # 616416

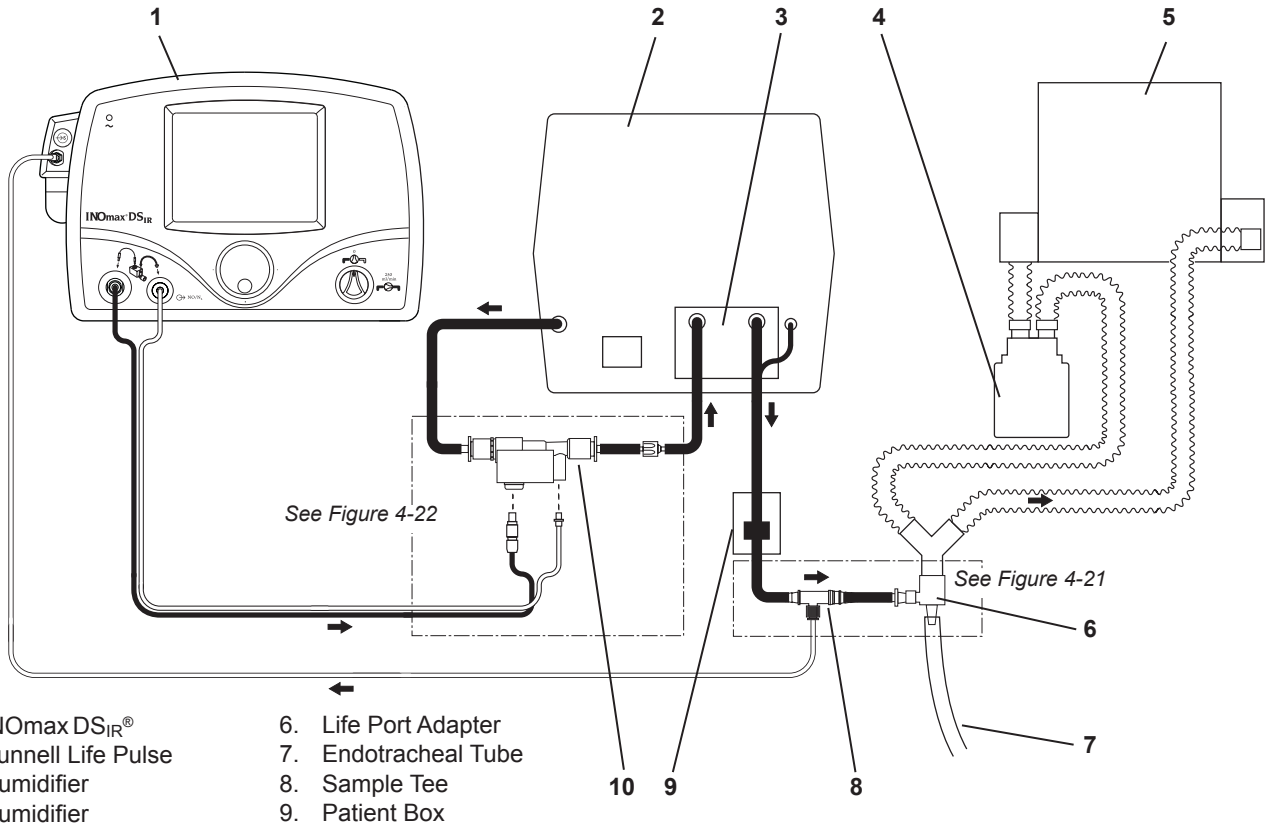
Connection to a Bunnell Life Pulse High Frequency Ventilator Circuit

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:

- Refer to page 48 for a list of general precautions.
- If 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.



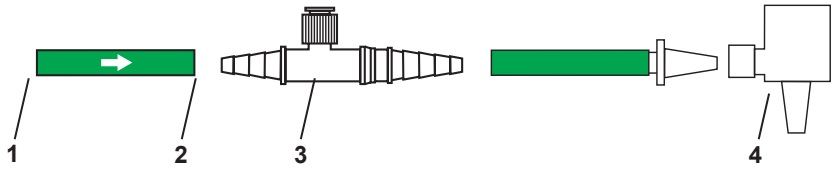
1. INOmax DS_{IR}®
2. Bunnell Life Pulse
3. Humidifier
4. Humidifier
5. Conventional Ventilator
6. Life Port Adapter
7. Endotracheal Tube
8. Sample Tee
9. Patient Box
10. Injector Module

Figure 4-20 Example: Bunnell Life Pulse Ventilator Diagram

Connection Instructions:

1. Connect the sample Tee as shown in Figure 4-20 and 4-21.
2. Connect the injector module as shown in Figure 4-20 and 4-22. The one-way valve prevents water from backing up into the injector module if the Life Pulse is either put into Standby or cycled OFF.

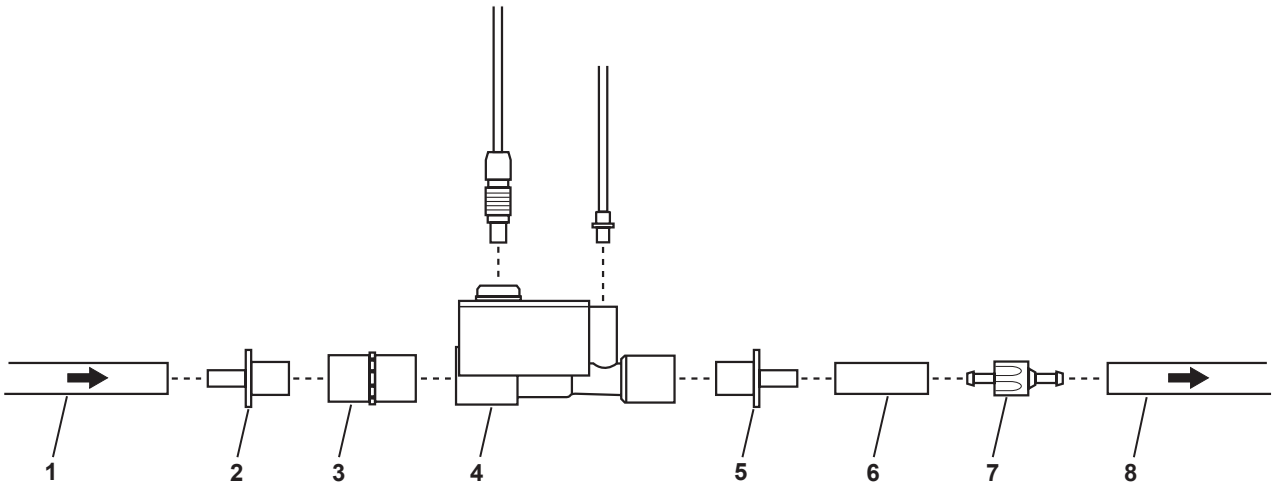
Connecting INOmax DS$_{IR}$® Sample Tee to the Bunnell Life Pulse Circuit



1. From Patient Box
2. Cut Green tube at midpoint
   (approximately 6 in. from the Life Port Adapter)
3. Insert Sample Tee
4. Life Port Adapter

Figure 4-21

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

Figure 4-22

Connection to a Circle Anesthesia System

WARNING:

- **Avoid recirculation of gases. Undesired recirculation of gases will occur if fresh gas flows are less than the patient minute volume and may result in:**
  - **Higher NO_2 levels due to the limited ability of the carbon dioxide absorbent to remove NO_2.**
  - **Higher NO concentrations than those set due to NO recirculated through the absorber.**
  - **Reduction in O_2 concentration because nitrogen is the balance gas for nitric oxide and will be present in the re-circulated gases.**

Caution:

- Refer to page 48 for a list of general precautions.
- Note the airflow direction arrow on the Injector Module: the flow out of the absorber must pass through the Injector Module in the direction of the arrow on the module.
- Nitrous Oxide (N_2O) will also affect the Set NO versus the measured NO value. For a 50% N_2O, 50% O_2 composition, the measured NO value will be approximately 7% less than the same Set NO value at 100% O_2. For example, at a Set NO value of 20 ppm, measured NO will be approximately 18 ppm.
- Similarly, the effect of 2% v/v Isoflurane will result in a high measured NO value of approximately 3% indicated for the same Set NO value at 100% O_2.
- Sudden changes in anesthetic agent concentration may cause brief transient changes in the measured NO and NO_2 values.

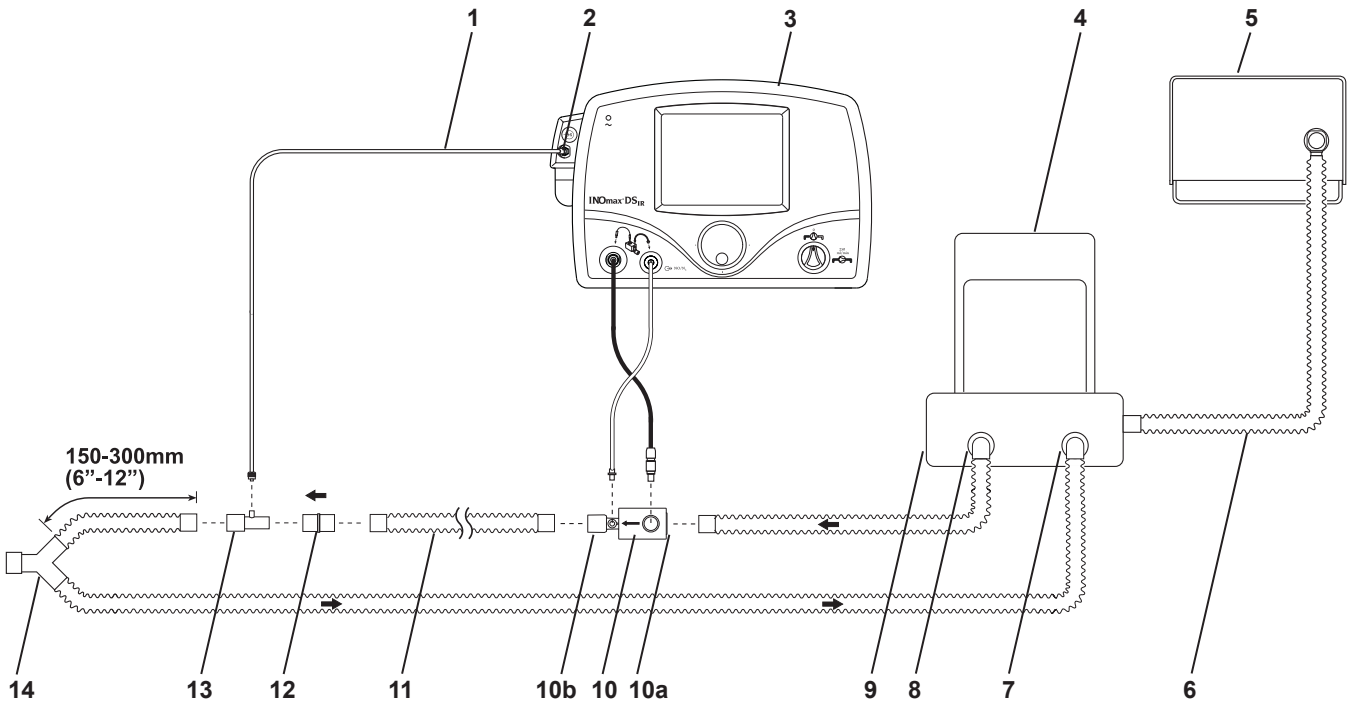
Note:

- Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).
- With a circle anesthesia breathing circuit, the INOmax $DS_{IR®}$ will perform as specified in the technical specifications with fresh gas flow rates equal to or more than the patient minute volume.

  The breathing circuit between the sample tee and the patient Y should be between 6 and 12 inches (150-300mm) long: greater than 6 inches to minimize the sampling of mixed inspired/expired concentrations and less than 12 inches to help ensure correct patient NO_2 measurement.

  For OR ventilation systems with the inspiratory flow measurements at the inspiratory port of the absorber, place the Injector Module upstream of the inspiratory flow sensor.

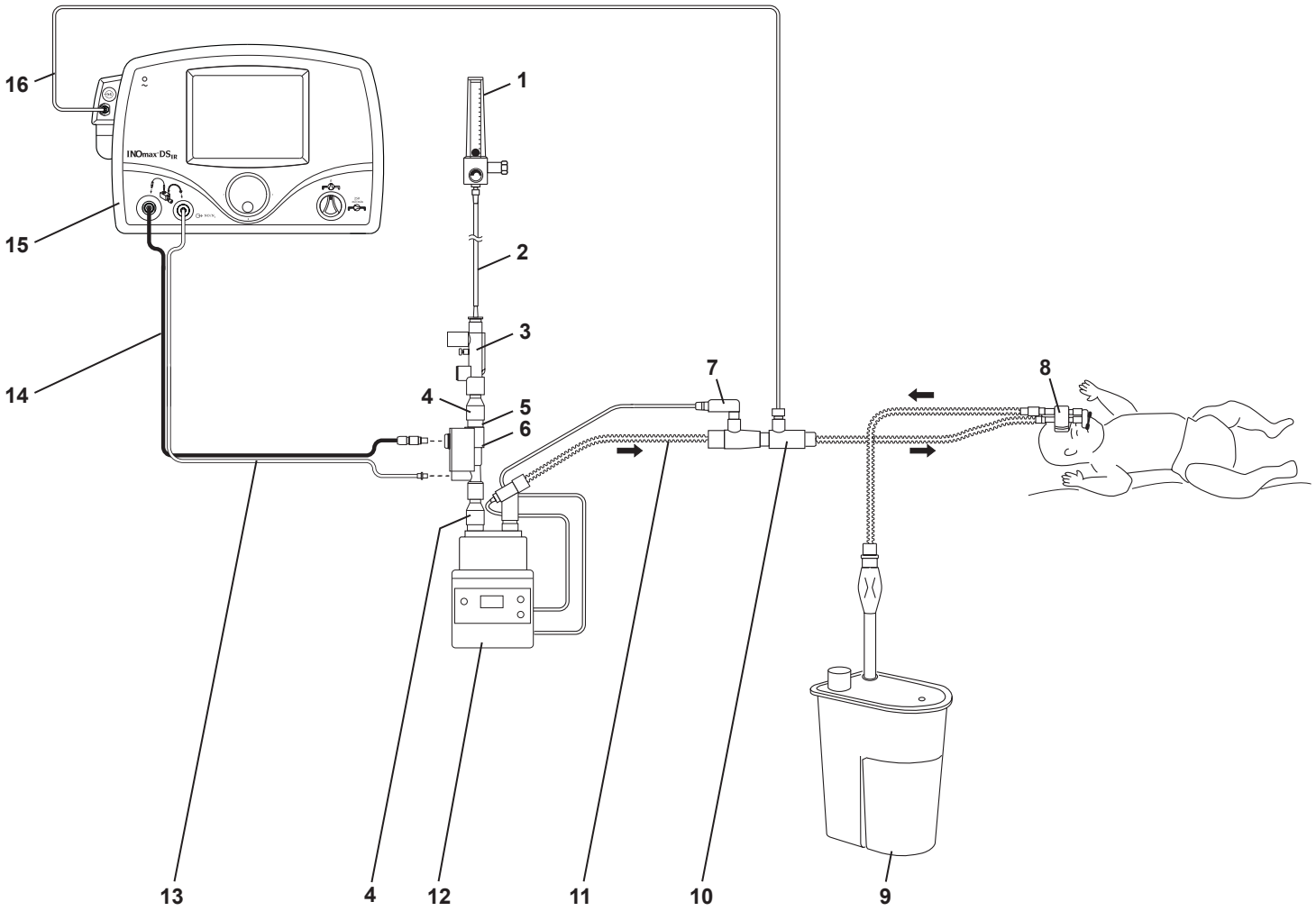
Connection to a Circle Anesthesia System



1. Patient Gas Sample Line
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

Figure 4-23 Example: Anesthesia System with Ventilator Circuit Diagram

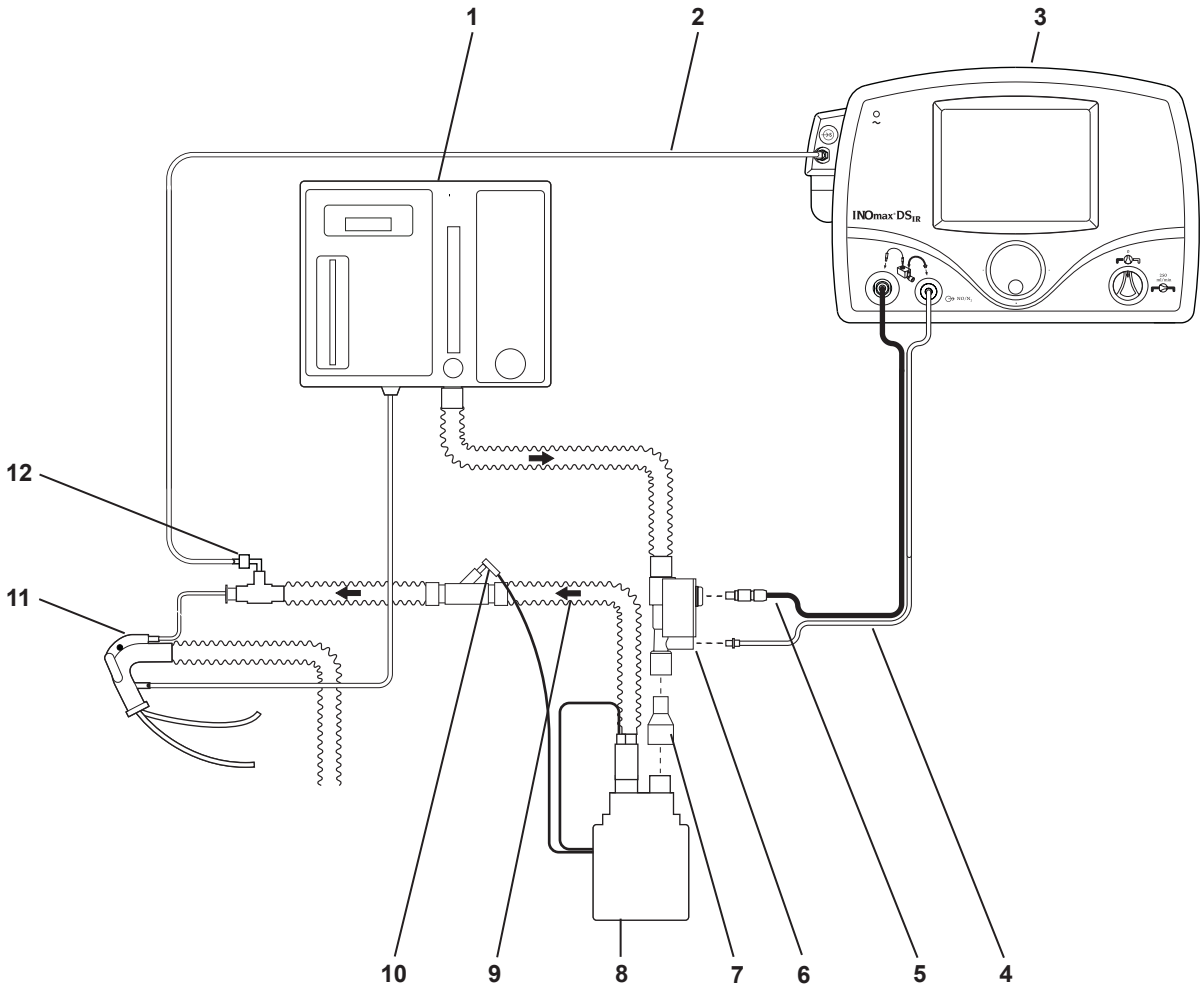
Connection to the Fisher/Paykel Bubble CPAP



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/N_2 Injector Tube
14. Injector Module Electrical Cable
15. INOmax DS_{IR}®
16. Patient Gas Sample Line

Figure 4-24 Example: Fisher/Paykel Bubble CPAP System Circuit Diagram

Connection to the Hamilton Arabella Nasal CPAP



1. Arabella
2. Patient Gas Sample Line
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. 90 Degree Sample Port Adapter

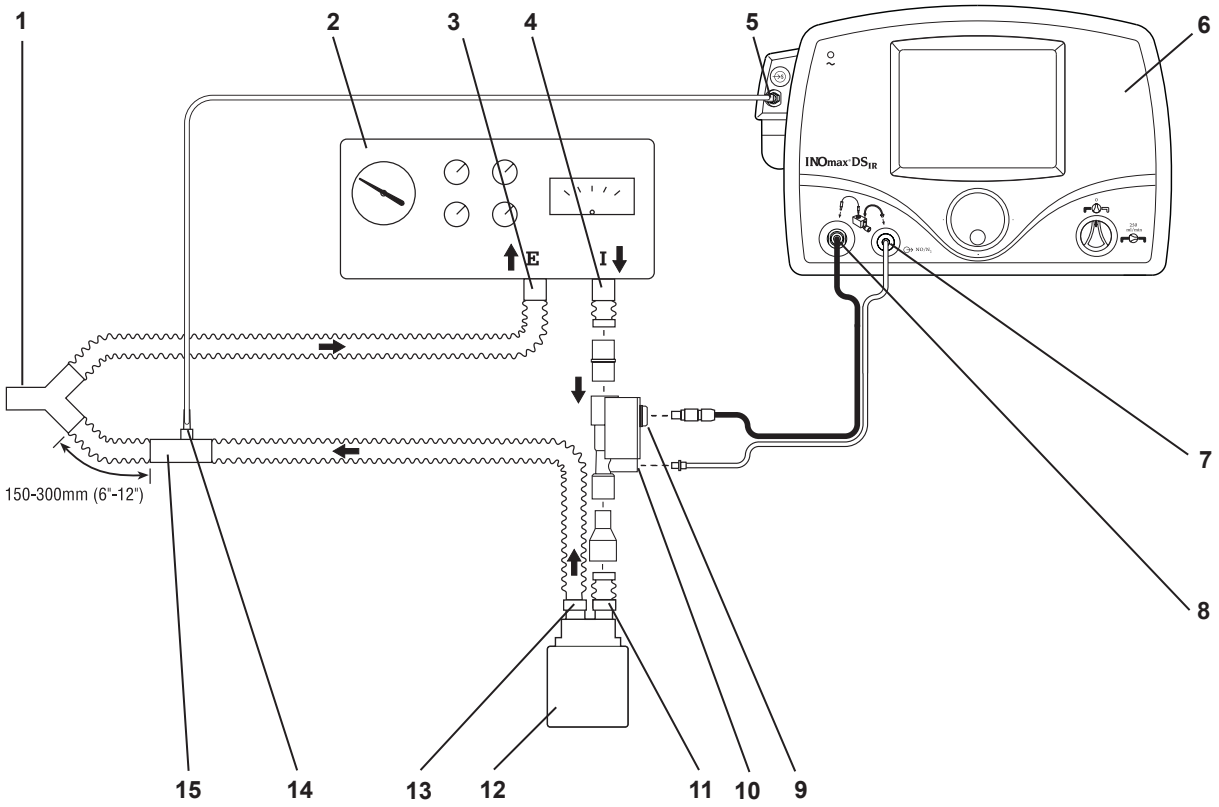
Figure 4-25 Example: Hamilton Arabella Nasal CPAP Circuit Diagram

Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

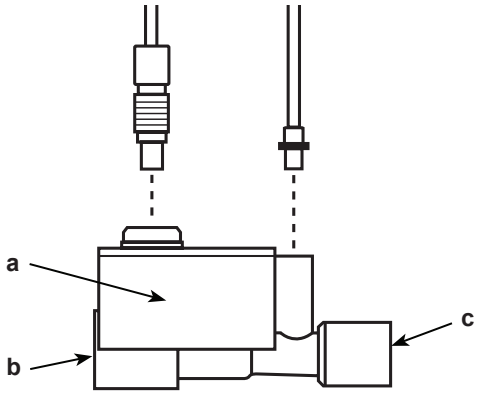
Connection to an ICU Ventilator Circuit

Caution:	Refer to page 48 for a list of general precautions.



1. Patient Wye
2. 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 Electrical Cable Connection
10. Injector Module NO/N_2 Injector Tube Connection
11. Humidifier Inlet
12. Humidifier
13. Humidifier Outlet
14. Patient Gas Sample Line
15. Gas Sample Tee

Figure 4-26 Example: General Ventilator Diagram



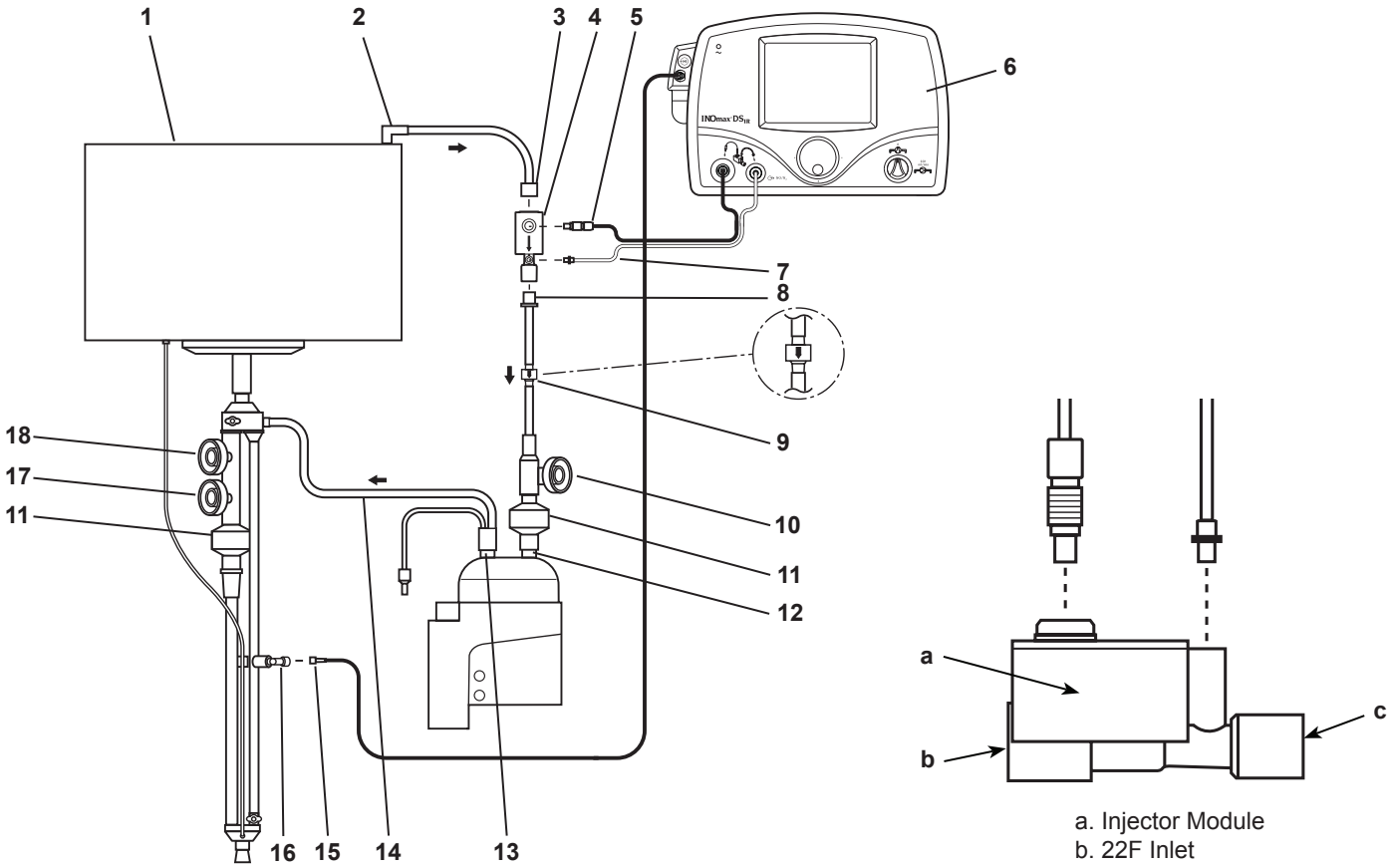
a. Injector Module
b. 22F Inlet
c. 22M / 15F Outlet

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

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

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

Caution:	• Refer to page 48 for a list of general precautions. • Use only parts provided in disposable package #50071, and tightly secure all connections.



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. Injector Module Electrical Cable Connection
6. INOmax DS_{IR}®
7. NO/N_2 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 Connection
16. 90 Degree Sample Port Adapter
17. Dump Valve Control
18. Paw Control Valve

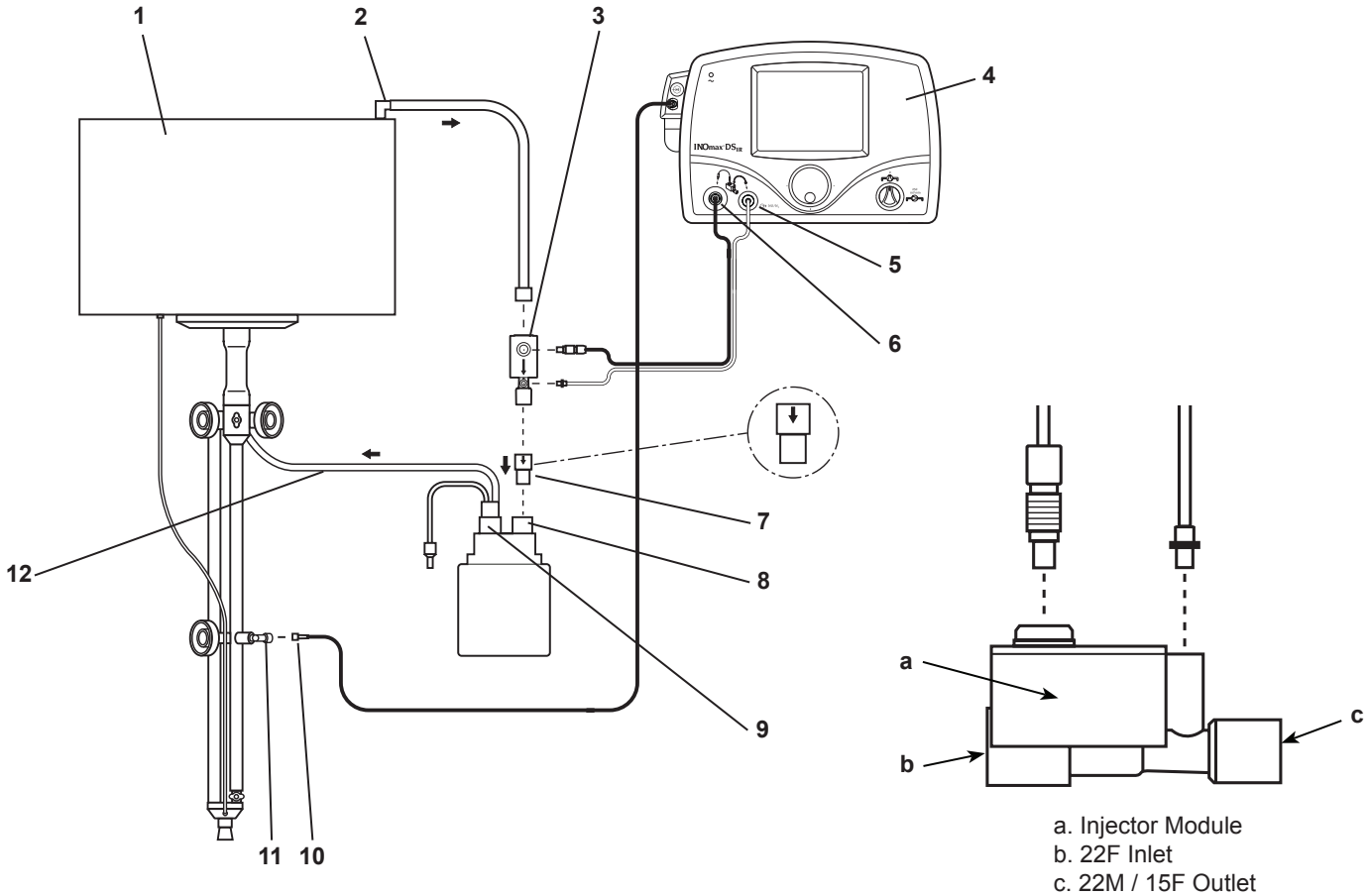
Figure 4-27 Example: High Frequency Oscillatory Ventilator Diagram

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

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

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

Caution: Refer to page 48 for a list of general precautions.



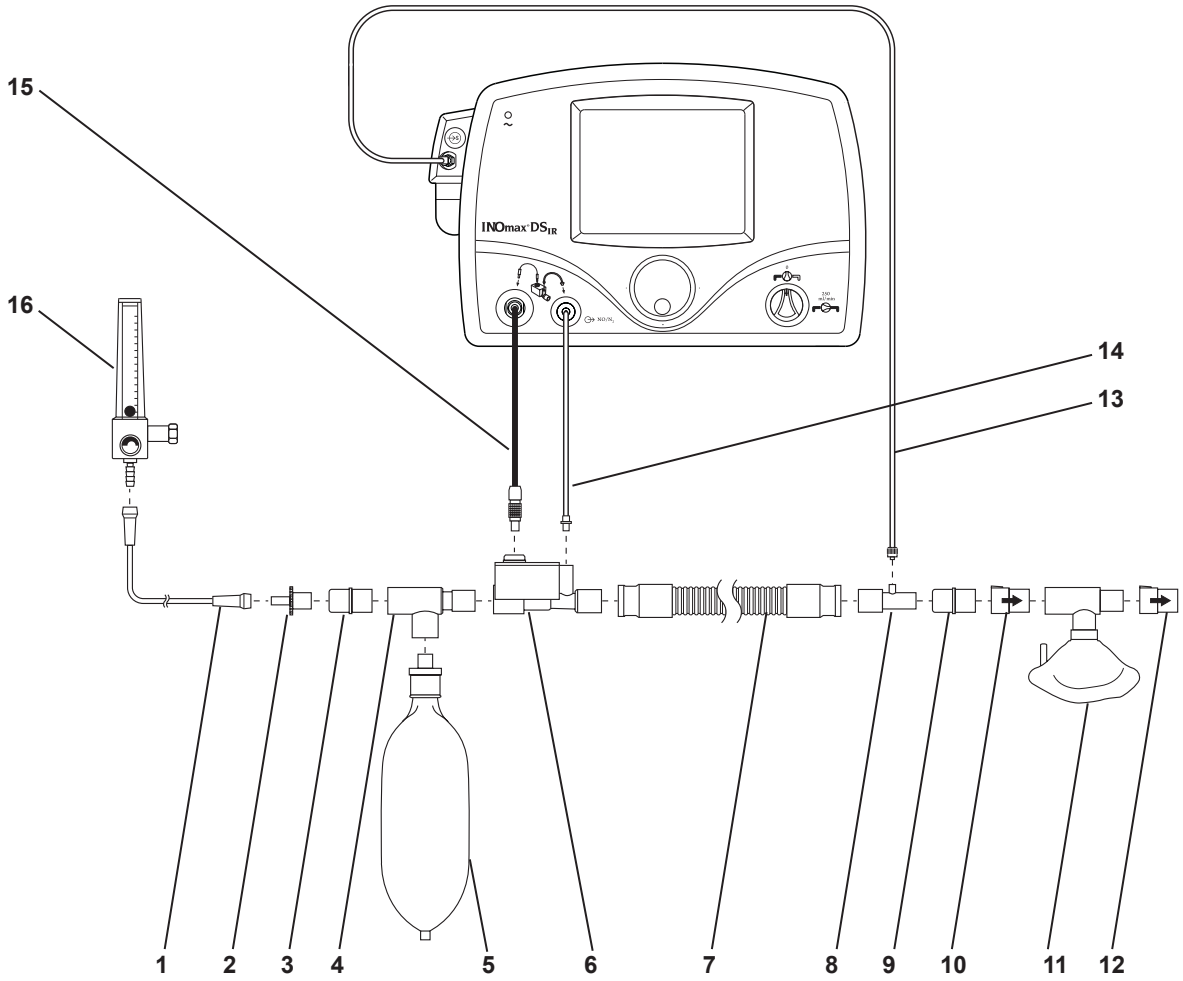
a. Injector Module
b. 22F Inlet
c. 22M / 15F Outlet

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

Figure 4-28 Example: High Frequency Oscillatory Ventilator Diagram

Note: Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

Connection to Spontaneous Breathing Patient on a Mask Circuit



1. O_2 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
14. NO/N_2 Injector Tube
15. Injector Module Electrical Cable
16. O_2 Flowmeter (wall outlet or cylinder)

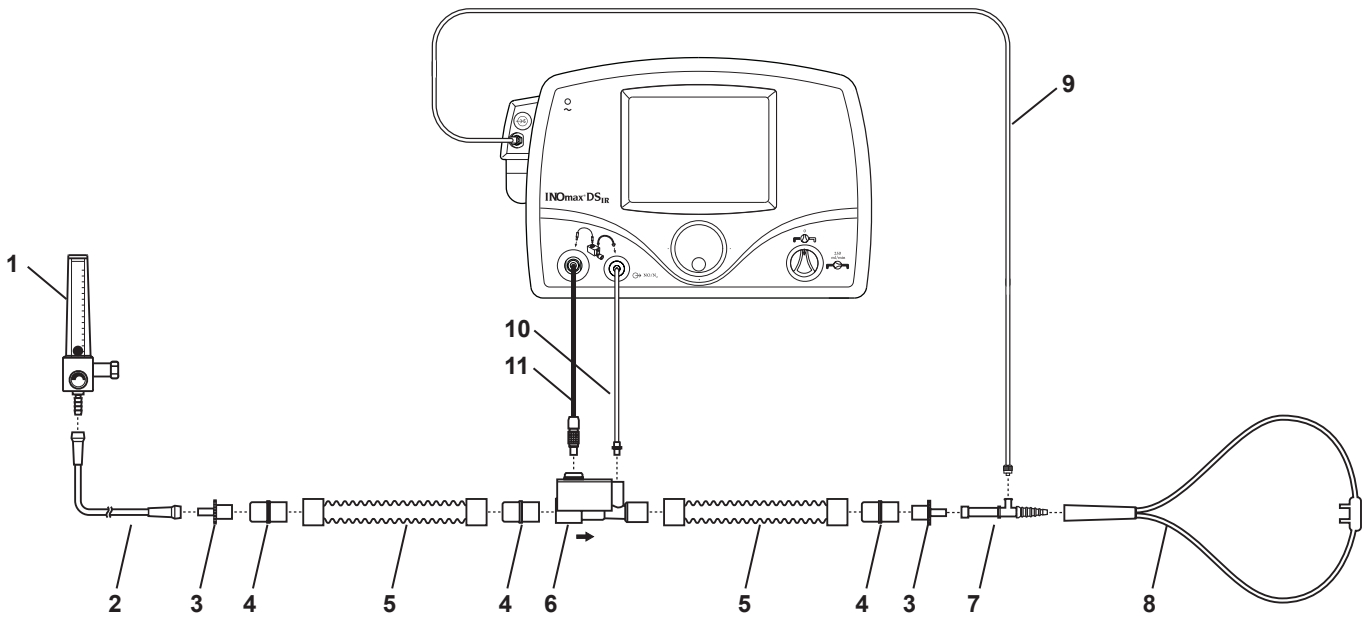
Figure 4-29 Example: Spontaneous Breathing Patient Circuit Diagram

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.

Conditioning of the oxygen flow prior to delivery through the injector module will help ensure the most accurate flow measurement. Conditioning can be achieved by adding 300 mm of 22mm hose between the oxygen tubing and the Injector Module.

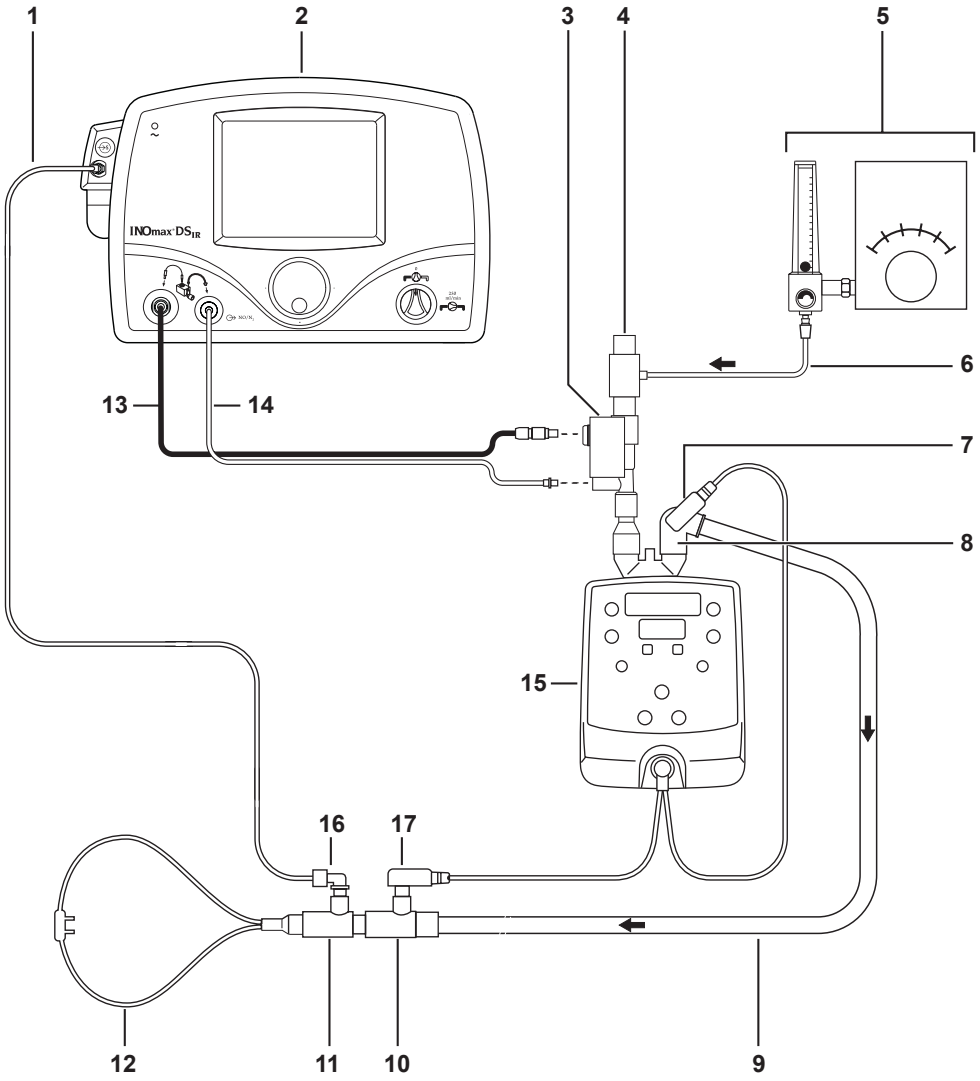
WARNING:	**Do not use the INOmax DS_{IR} backup mode with flow rates less than 5 L/min.**



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

Figure 4-30 Example: Spontaneous Breathing Nasal Cannula Patient Circuit Diagram

Connection to the Teleflex Medical Comfort Flo Humidification System



1. Patient Gas Sample Line
2. INOmax DS/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. ConchaTherm Heated Humidifier
16. 90 Degree Sample Port Adapter
17. Temperature Probe (Long Cable)

Figure 4-31 Example: Teleflex Comfort Flo Patient Circuit Diagram

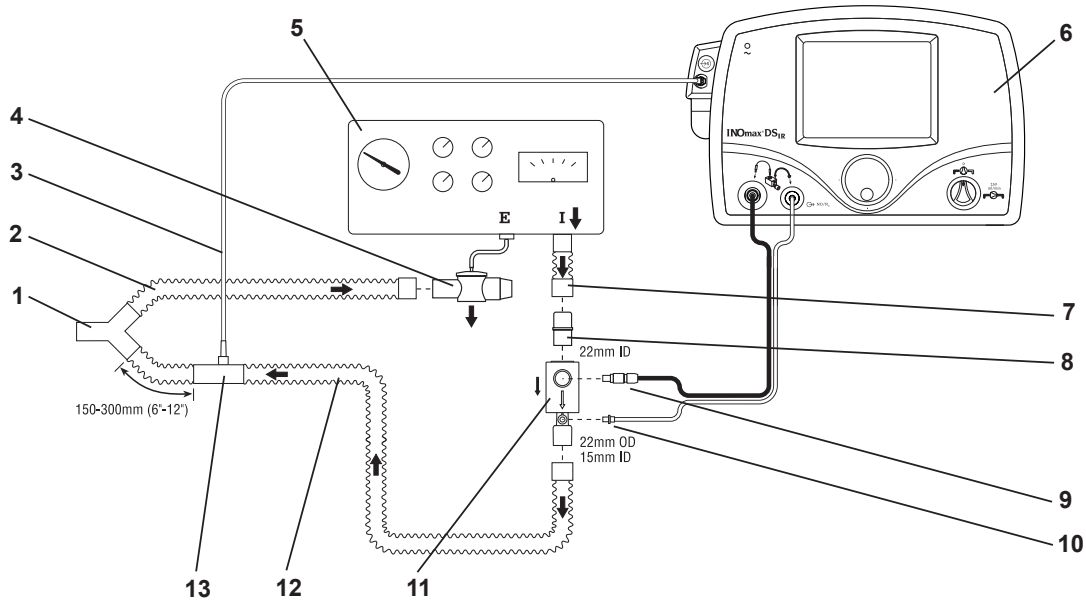
Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

Connection to a Transport Ventilator Circuit

Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).



1. Patient Wye
2. Expiratory Breathing Circuit Hose
3. Patient Gas Sample Line
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

Figure 4-32 Example: Transport Ventilator Diagram

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 4-33.**

Figure 4-33 Universal Mounting Post

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 page 34). • It is recommended that a second Transport Regulator/Cap Assembly is available during all transports.

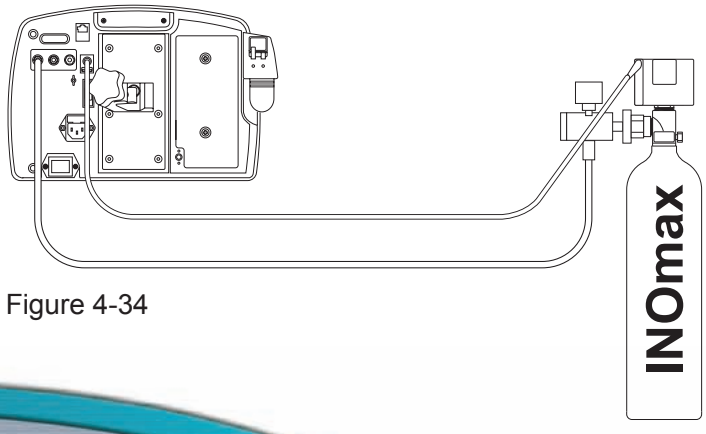


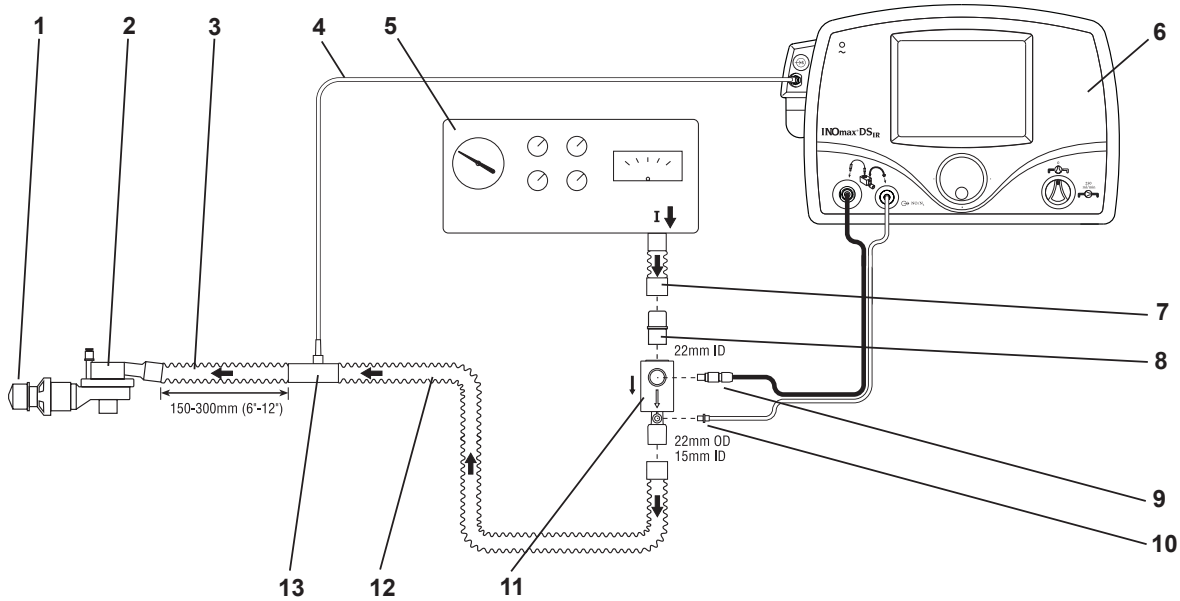
Figure 4-34

Note:	Do not attempt to connect the transport regulator cap assembly electrical plug to the INOblender® outlet port. This will damage the connector plug electrical pins.

Connection to a Transport Ventilator Circuit

Caution: Refer to page 48 for a list of general precautions.

Note: Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).



1. PEEP Valve
2. Patient Wye
3. Circuit Hose
4. Patient Gas Sample Line
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

Figure 4-35 Example: Single-Limb Transport Ventilator Diagram

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 4-33.**

Figure 4-33 Universal Mounting Post

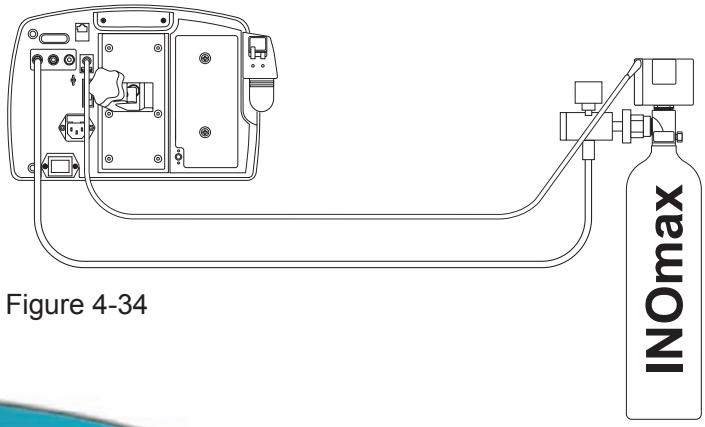


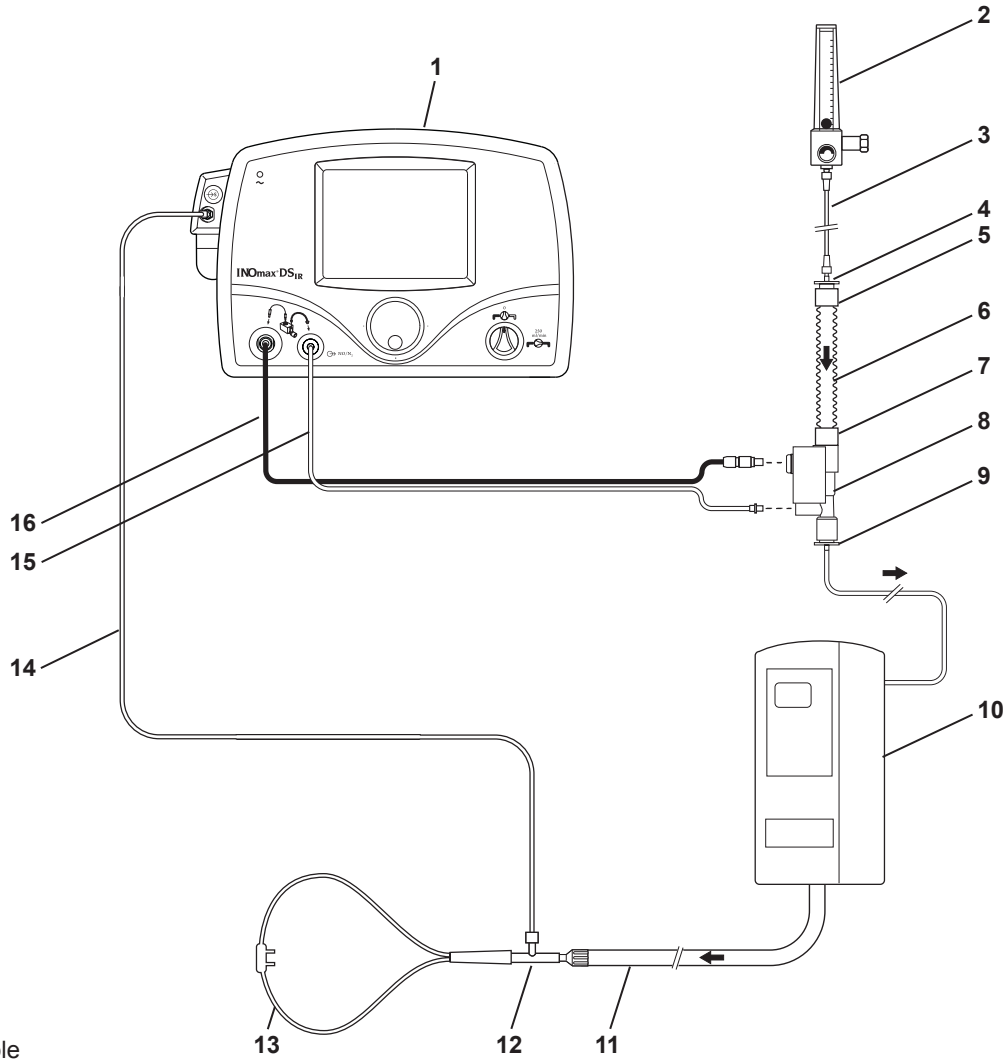
Figure 4-34

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 page 34).
- It is recommended that a second Transport Regulator/Cap Assembly is available during all transports.

Note: Do not attempt to connect the transport regulator cap assembly electrical plug to the INOblender® outlet port. This will damage the connector plug electrical pins.

Connection to the Vapotherm 2000i

- 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 80ppm) 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 2000i. 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.



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
15. NO/N_2 Injector Tube
16. Injector Module Electrical Cable

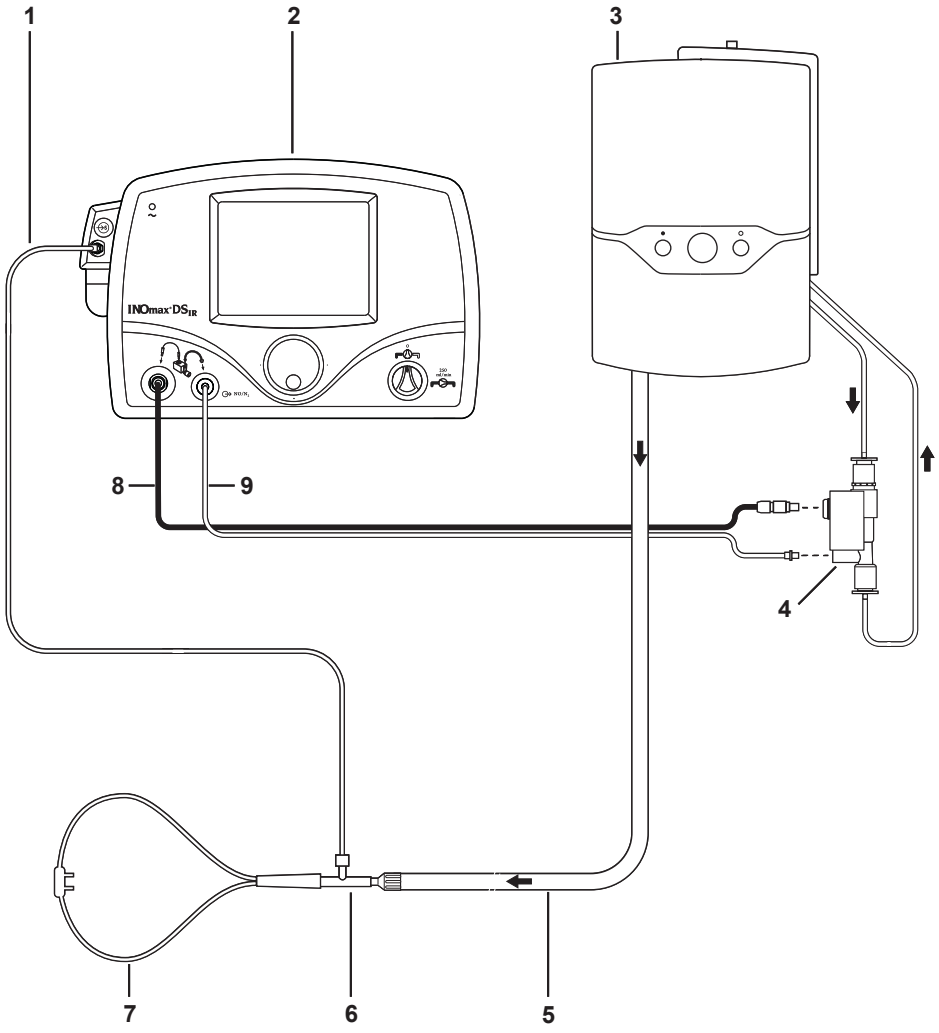
Figure 4-36 Example: Vapotherm 2000i Circuit Diagram

Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

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.



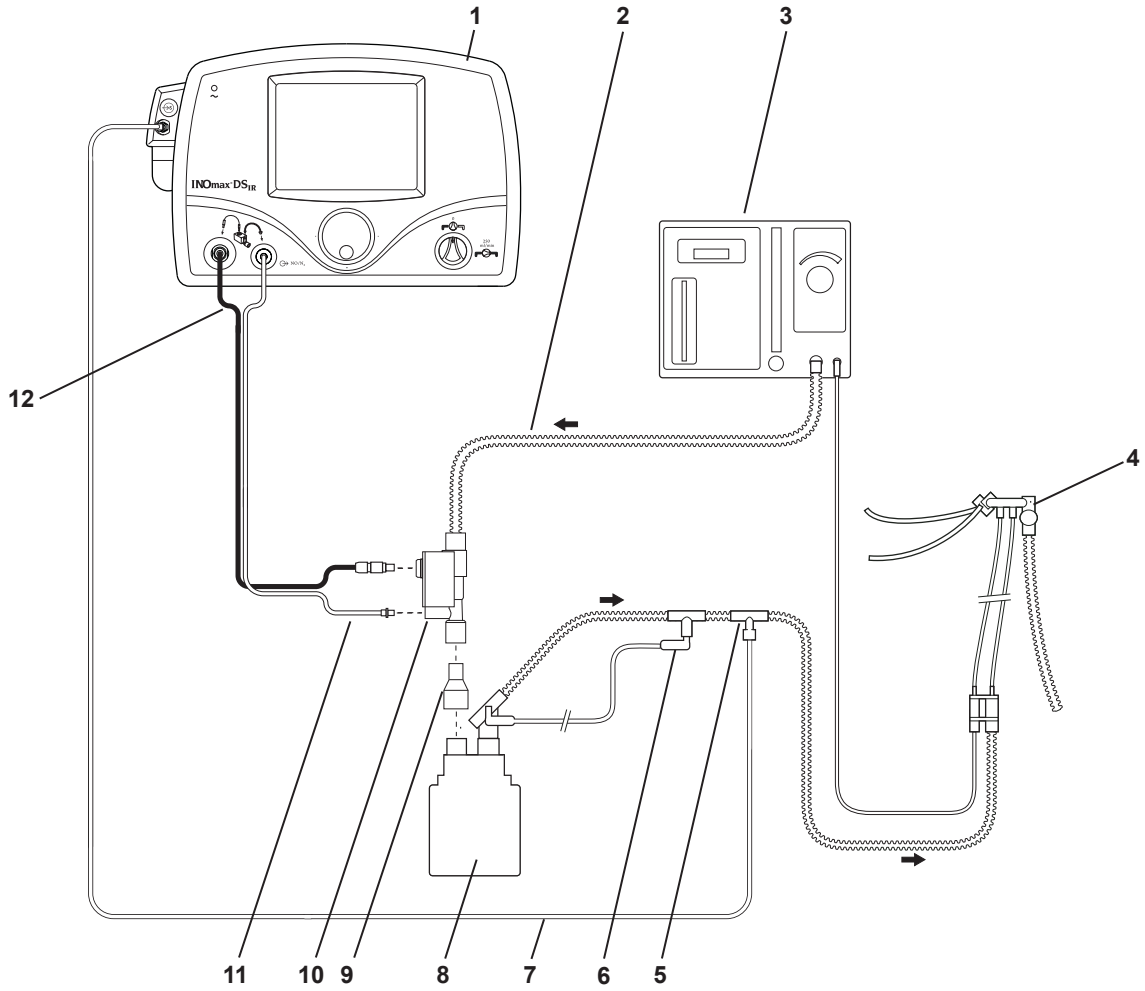
1. Patient Gas Sample Line
2. INOmax DS_{IR}
3. Precision Flow Unit
4. Injector Module
5. Patient Delivery Tube
6. Oxygen Tubing Sample Tee
7. Patient Cannula
8. Injector Module Electrical Cable
9. NO/N_2 Injector Tube

Figure 4-37 Example: Vapotherm Precision Flow Circuit Diagram

Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

Connection to the 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
8. Humidifier
9. 22F X 15M Adapter
10. Injector Module
11. NO/N_2 Injector Tube
12. Injector Module Electrical Cable

Figure 4-38 Example: Viasys Infant Flow CPAP System Circuit Diagram

Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

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Connection to the Viasys Infant Flow SiPAP

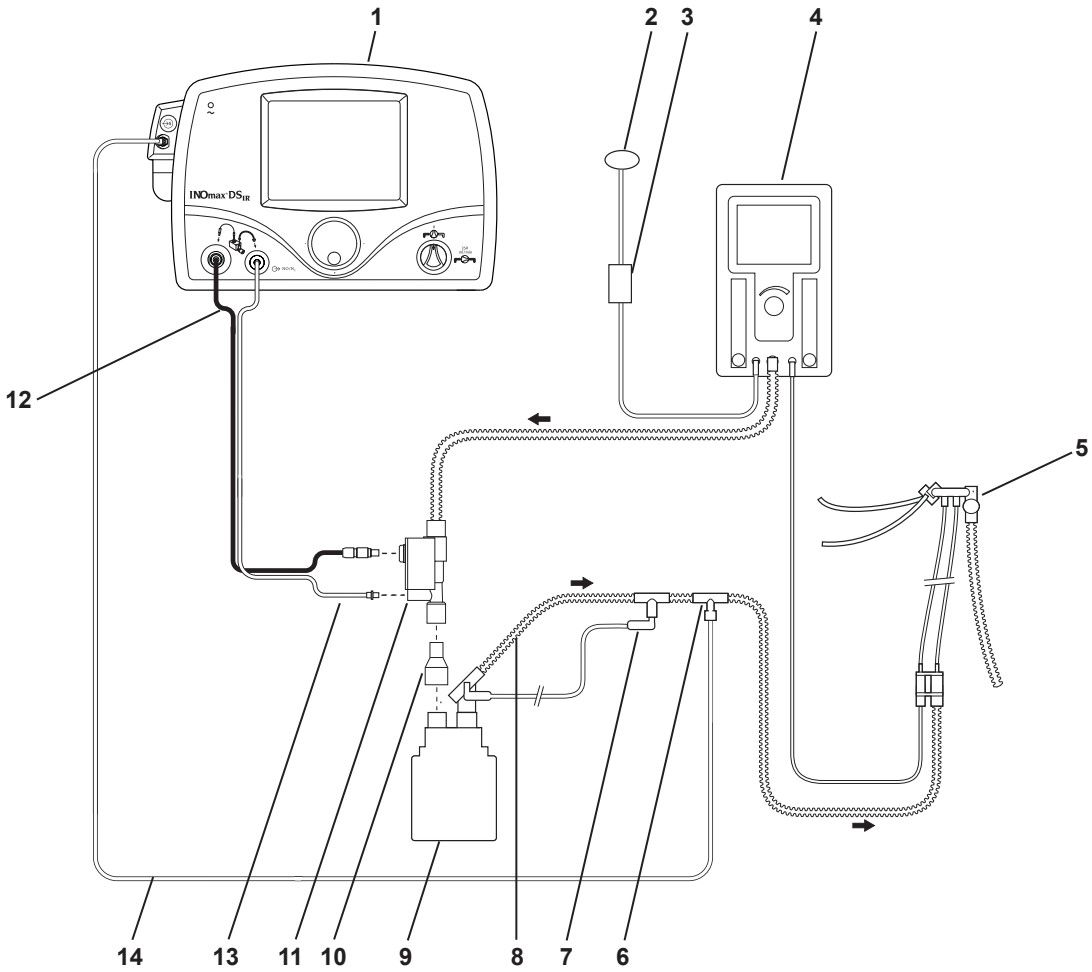
Caution:	Refer to page 48 for a list of general precautions.

Note:	Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 72. For technical assistance, please contact Ikaria® (1-877-566-9466).

- 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 80ppm) and subtracts gas from the breathing circuit via gas sampling at a nominal flow rate of 0.23 L/min.
- These effects change the flow going to the nasal adapter and can therefore impact the CPAP level established by specific flow settings (See table below). The maximum flow error is approximately 11% at 2 L/min which is within the accuracy of the flow meter specification (+/-15%).
- It is recommended that after an NO setting change the user checks the CPAP level on the Infant Flow SiPAP front panel display and adjusts as necessary.

	Flow (L/min)	Flow (L/min)	Flow (L/min)	Flow (L/min)	Flow (L/min)
SiPAP Flow Setting	2	4	6	8	10
After INOmax DS_{IR} Set @ 0 ppm	1.77	3.77	5.77	7.77	9.77
% error	-11.5%	-5.8%	-3.8%	-2.9%	-2.3%
After INOmax DS_{IR} Set @ 80 ppm	1.97	4.17	6.37	8.57	10.77
% error	-1.5%	4.3%	6.2%	7.1%	7.7%

Connection to the Viasys Infant Flow SiPAP



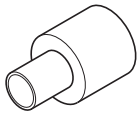
1. INOmax DS_{IR}®
2. Abdominal Respiratory Sensor
3. Transducer Interface
4. Infant Flow SiPAP
5. Infant Flow Generator
6. Sample Tee
7. Temperature Probe
8. Heated Delivery Circuit
9. Humidifier
10. 22F X 15M Adapter
11. Injector Module
12. Injector Module Electrical Cable
13. NO/N_2 Injector Tube
14. Patient Gas Sample Line

Figure 4-39 Example: Viasys Infant Flow SiPAP Circuit Diagram

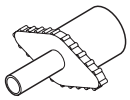
INOmax DS_{IR}® Patient Circuit Disposables

(Note: graphics not actual size)

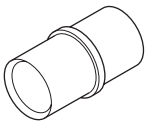
Adapter, 15mm ID X 10mm OD



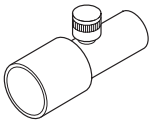
Adapter, 15M Fits 4.5mm ID Tubing



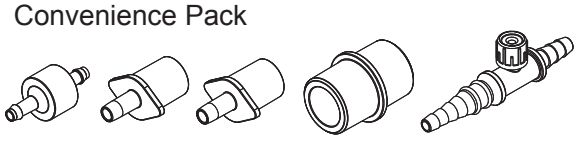
Adapter, 22M/15F X 22M/15F



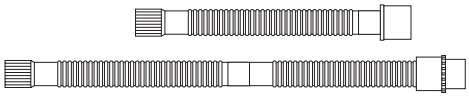
Adapter, Gas Sample Tee



Bunnell Life Pulse Disposable Adapters Convenience Pack



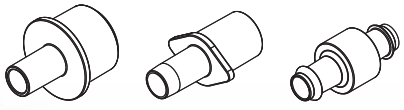
Neonatal Tubing, 10mm (2 pieces)



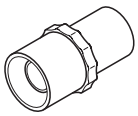
One-way Valve, 22F X 22M

Pediatric Extension, 15 mm (6 inches)

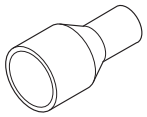
Sensormedics 3100A/B Filtered Circuit Disposable Adapters Convenience Pack



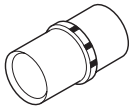
Adapter, 15mm OD X 15mm ID X 10mm OD



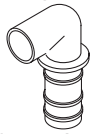
Adapter, 22F X 15M



Adapter, Cuff, 22mm ID X 22mm ID



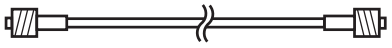
Adapter, 90 degree Sample Port



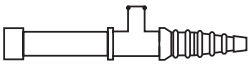
Disk Filter, 0.5 micron

NO/N_2 Injector Tube

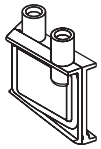
Patient Gas Sample Line



Sample Tee, O_2 Tubing



Water Separator Cartridge



IKARIA®

INOmax DS$_{IR}$®

(Delivery System)

5/ Alarms

Part No. 20010 Rev-05
2012-03

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)

5/ Alarms

Part No. 20010 Rev-05
2012-03

5/ Alarms

Caution:

- Any alarm setpoint adjustments made will not be maintained when system power is cycled.
- Default values will be used following a complete power loss (no AC main power and depleted battery).

General alarm information

A listing of alarm messages is provided at the end of this section.

All alarms have audible tones and visual messages.

In the event of a total power failure or a main alarm speaker failure, a secondary audible alarm circuit activates, providing a continuous buzzing tone that can not be silenced.

When exiting the Calibration Screen a two minute lockout period activates to prevent monitoring alarms from occurring while measured values stabilize.

High and low priority alarms

The INOmax DS_{IR}® has both high and low alarm priorities.

High priority alarms are accompanied with a red flashing Alarm Silence button.

Low priority alarm conditions will display a continuous yellow Alarm Silence button.

High and low priority alarm messages are displayed in fields 1 through 3 (see Figure 5-1) with the most recent message shown in field 1.

Field 4 is used for status information such as “Running on Battery” and “Patient Info. Incomplete”.

Figure 5-1
Text Message Area Showing fields 1 through 4

The following table provides the audible alarm tone information for high and low priority alarms.

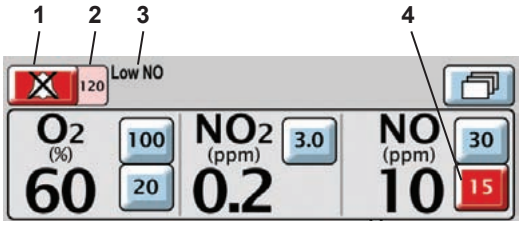
	Frequency	Description	Comment
High Priority	400 Hz	10-pulse group	Repeats after 10 sec. if not silenced.
Low Priority	400 Hz	1 pulse	Repeats after 40 sec. if not silenced.

Alarm silencing

Pushing the Alarm Silence button will silence high priority alarms for 120 seconds. When a new alarm condition occurs, the audible alarm becomes active again (see Figure 5-2).

A low priority alarm event is permanently silenced when the Alarm Silence button is pressed. When a new low alarm condition occurs, the audible alarm becomes active again.

Alarm messages remain displayed during the alarm silence period as long as the alarm condition is active.



1. Alarm Silence Button
2. Alarm Silence Counter
3. Alarm Text
4. Violated Monitored Value Limit

Figure 5-2
Alarm Silence Activated and Showing Counter

User adjustable monitor alarms

Caution:

Do not set upper and lower alarm limits to extreme values as this could render alarm system useless.

The O_2, NO_2, and NO monitors have user adjustable alarm settings that are displayed to the side of the monitored value.

The top button is the high level alarm setting and the lower button is the low level alarm setting (see Figure 5-2).

A low alarm limit cannot be set above the high limit setting.

When an alarm occurs for a monitored value, the violated alarm setting button flashes Red (see Figure 5-2).

To adjust an alarm level to a new value, press the selected alarm level button on the touch screen, rotate the control wheel to adjust to the new level and then confirm by pushing the control wheel or the selected alarm level button again.
If the new alarm level is not confirmed within 20 seconds the alarm level defaults back to its previous value.

Part No. 20010 Rev-05
2012-03

The adjustment range for these alarm settings are shown in the table below.

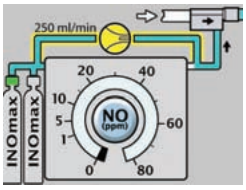
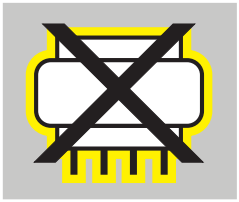
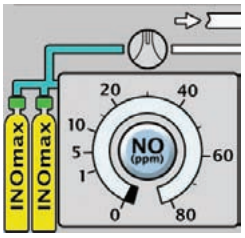
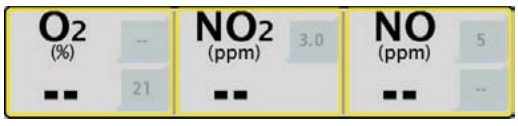
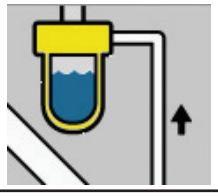
Alarm	Adjustment	Default	Priority
High NO (ppm)	1 to 100	Initially 90, then 50% above the initial set dose*	High
Low NO (ppm)	0 to 99	OFF (--) then 50% below the initial set dose ±	High
High NO_2 (ppm)	0 to 5	3	High
High O_2 (% v/v)	21 to 100 Then OFF (--)	-- (OFF)	High
Low O_2 (% v/v)	18 to 99	21 %	High

* Dose settings < 3 ppm will result in a high alarm setting of 5 ppm; otherwise rounded up to the nearest ppm and limited to 90 ppm maximum.

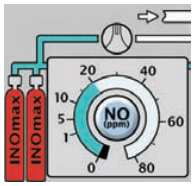
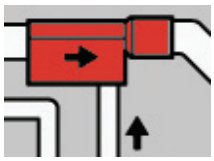
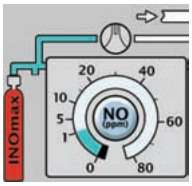
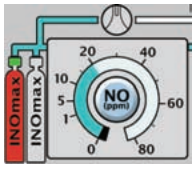
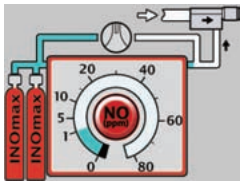
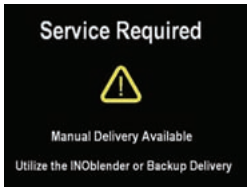
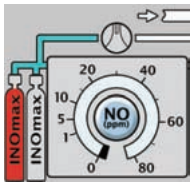
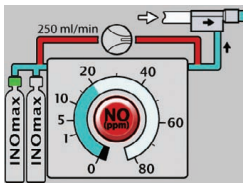
± Rounded down to the nearest ppm.

Alarm Table

The following alarm table provides a list of the other system alarms along with a graphic representation (see Section 6/ Troubleshooting, for a description of each alarm).

Low Priority Alarms			
Backup On		**Sample Line/Filter Block**	
Failed NO Sensor **or** **Failed NO_2 Sensor** **or** **Failed O_2 Sensor**		**Two Cylinders Open**	
Monitoring Failure		**Water Trap Bottle Full**	

Alarm Table continued

High Priority Alarms			
Cylinder Not Detected		**Injector Module Failure**	
Cylinder Valve Closed		**Low Battery**	
Delivery Failure **Power the INOmax DS$_{IR}$® to STANDBY and then back ON to reset.**		**Low NO/N_2 Pressure**	
Delivery Stopped		**Service Required**	
Drug Concentration Mismatch **or** **Drug Past Expiry Date**		**Set NO and Backup On**	

Alarm History

When an alarm condition has been resolved, the alarm message is no longer displayed on the main screen.

The last four resolved alarms can be seen by pressing the alarm history button.

The alarm history button is present and displayed as a “double-bell” when there are no active alarms and any previously resolved alarms have not been cleared.

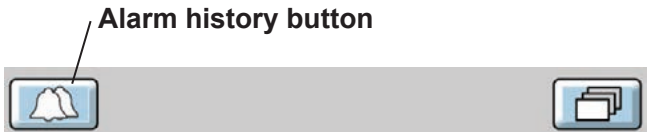


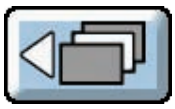
Figure 5-3
Alarm History Button On The Main Screen

The alarms are displayed in chronological order, with number one being the alarm that occurred most recently (for example, Figure 5-4 shows four alarm conditions that have occurred).

The NO set and alarm level buttons on the main screen are not active (grayed out) in the alarm history page.

Press the clear alarm history button to clear the alarm history and return to the main screen.

To return to the main screen without clearing the alarm history, press the return to previous menu button. If no action is taken the system will return to the main screen after 30 seconds.



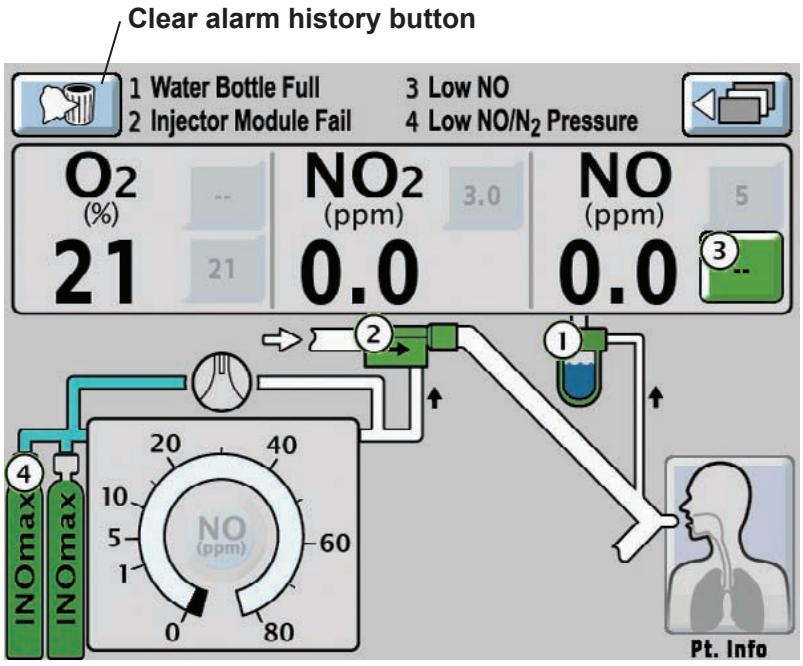
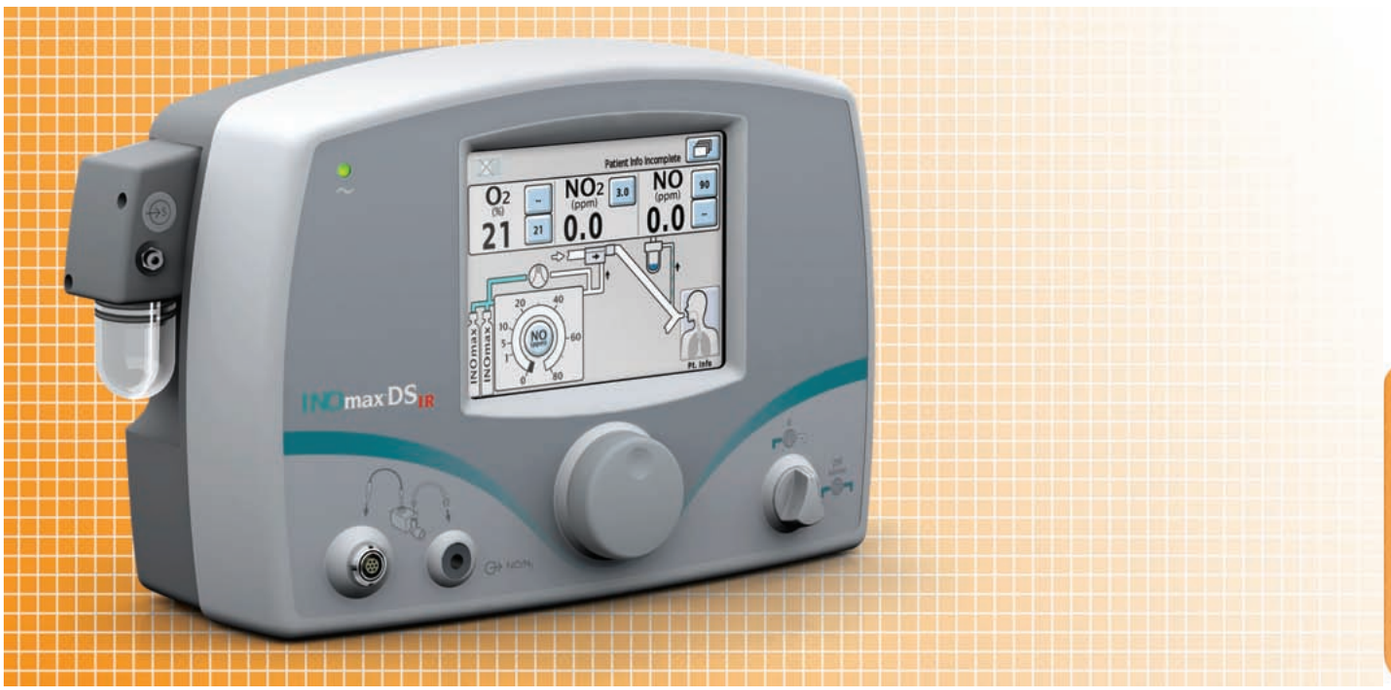


Figure 5-4
Alarm History Screen

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



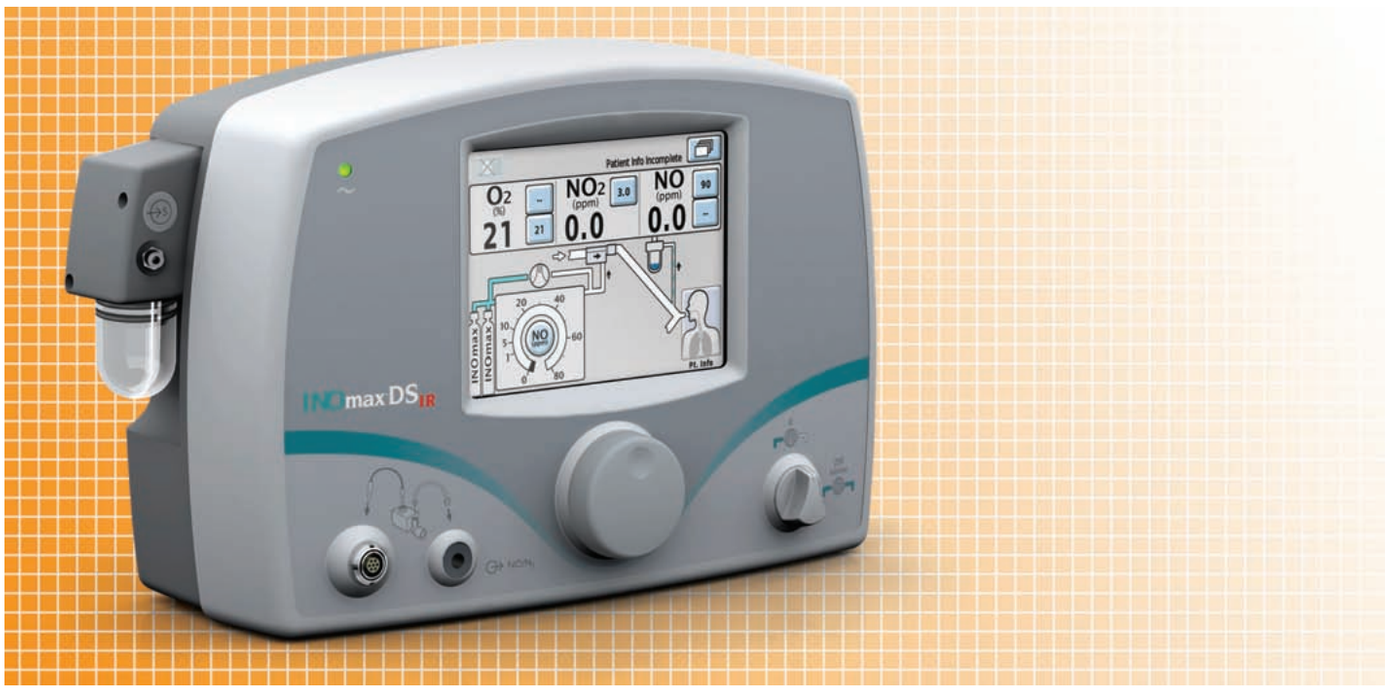
6/ Troubleshooting

Part No. 20010 Rev-05
2012-03

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



Troubleshooting

6/ Troubleshooting

Part No. 20010 Rev-05
2012-03

6/ Troubleshooting

WARNING: **Use caution when troubleshooting the INOmax DS$_{IR}$® while in use for a patient. When possible, replace the unit in question, and perform troubleshooting procedure once the unit is removed from the patient.**

If the system fails to operate properly:

1. Check the patient condition and take appropriate action.
2. Verify that the system is set up as detailed in Section 2/ Setup.
3. Use the INOblender® (see INOblender Operation Manual) or backup mode if necessary (see page 32).
4. Find a symptom or alarm condition in the troubleshooting table which best describes the problem and follow the recommended actions to resolve the problem.

If the problem can't be corrected:

Contact Ikaria® Customer Care (1-877-566-9466).

If the INOmax DS$_{IR}$ must be returned for servicing:

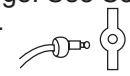
1. Use the original or service loaner packaging materials to protect the system during transit. If the proper packaging is not available, please contact Ikaria Customer Care (1-877-566-9466).
2. Disconnect the following from the unit (refer to Figures 1-1 and 1-2.)

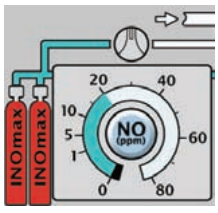
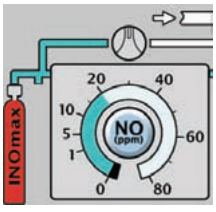
   Remove and return with unit
   1. Injector module
   2. Injector module cable
   3. Power cord

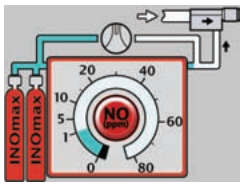
   Remove and discard
   1. Sample line
   2. Injector tubing
3. Pack the INOmax DS$_{IR}$ and the accessories as requested by Ikaria Customer Care.
4. Make sure the outside of the box is labeled: "FRAGILE MEDICAL EQUIPMENT, HANDLE WITH CARE."
5. Send the unit to the location specified by Ikaria Customer Care.

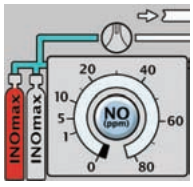
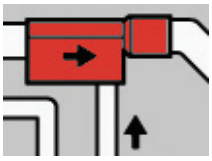
Troubleshooting Guide

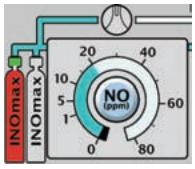
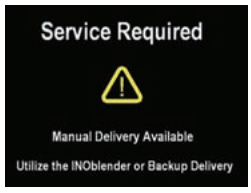
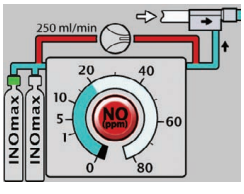
High Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
1. High NO alarm 	A. Note: A newly installed NO sensor will give high readings until fully conditioned (about 5 hours) and calibrated.	a. After installation of the NO sensor perform a low and high calibration. b. Wait 5 hours and repeat both the low and high calibration.
	B. The High NO alarm level may be inappropriately set.	a. Make sure the High NO alarm is set greater than the Set NO value.
	C. The NO calibration may have drifted.	a. Perform a low and high range calibration of the NO sensor. b. Check calibration sample tee for leaks.
	D. Circuit setup incorrect.	a. Check circuit setup for correct use of adapters and/or check valves.

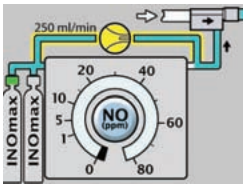
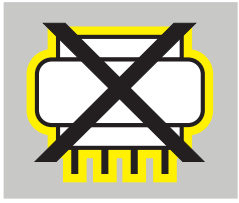
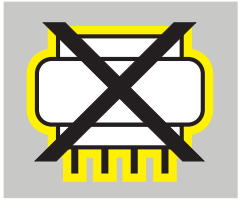
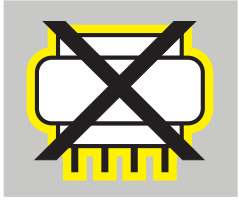
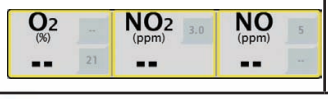
High Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
2. Low NO alarm 	A. The Patient Gas Sample line may be disconnected.	a. Reconnect the Patient Gas Sample line.
	B. The Low NO alarm setting may be inappropriately set.	a. Make sure the Low NO alarm is set less than the Set NO value.
	C. The NO calibration may have drifted.	a. Perform a low and high range calibration of the NO sensor.
	D. The NO sensor may not be properly seated.	a. Make sure the sensors are correctly seated with the O-rings and the sensor cover is fully closed.
	E. Loss of NO delivery.	a. If the INOblender® is available, manually ventilate the patient (see INOblender Operation Manual). or b. Turn the backup mode ON (see page 32).
3. High NO_2 alarm 	A. Incomplete System purge.	a. Perform a system purge. See Section 3/ Pre-Use Checkout. 
	B. Ventilator flow stopped.	a. Allow the ventilator gas to flush NO and NO_2 from the breathing circuit before connecting to the patient.
	C. Two cylinder valves are open.	a. Close one of the cylinder valves.
	D. The NO_2 alarm limit may be set too low.	a. Make sure the NO_2 alarm limit is appropriate for the Set NO level.
	E. The NO_2 calibration may have drifted.	a. Perform a low and high range calibration of the NO_2 sensor. b. Check calibration sample tee for leaks.
	F. Out of date or the wrong calibration gas was used.	a. Verify the calibration gas expiration date. b. If needed replace the calibration gas and perform a low and high range calibration of the NO_2 sensor.
	G. The patient circuit setup may be incorrect.	a. Make sure the patient circuit hoses and lengths are correct (see Section 4/ Patient Application). b. Verify the humidifier chamber is less than 480 mL.
	H. Sample line occlusion. In this case, this alarm may occur with a Sample Line Block alarm.	a. Confirm whether the High NO_2 alarm occurs concurrently with a sample line block alarm. b. If so, this alarm will clear within 10 seconds after the sample line alarm is remedied.
	I. The INOmax DS_{IR}® may have failed.	a. Contact Ikaria® - Technical Support. b. Replace the delivery system if in use. c. Do not use the delivery system until serviced.

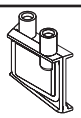
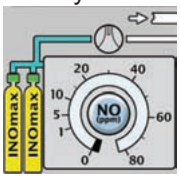
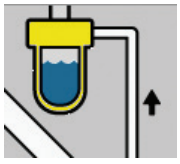
High Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
4. High O_2 alarm 	A. The O_2 alarm setting may be inappropriate.	a. Make sure the High O_2 alarm is set appropriately for the O_2 setting being used on the ventilator.
	B. The O_2 calibration may have drifted.	a. Perform a low and high range calibration of the O_2 sensor. b. Change the O_2 sensor if the monitor fails to calibrate. c. Contact Ikaria® - Technical Support. d. Replace the delivery system if in use. e. Do not use the delivery system until serviced.
5. Low O_2 alarm 	A. The O_2 concentration setting at the ventilator was reduced.	a. Make sure the O_2 alarm setting is correct for the setting at the ventilator.
	B. The O_2 alarm setting may be inappropriate.	a. The INOmax DS_{IR}® can dilute the O_2 concentration set at the ventilator by up to 10%. b. Verify that the alarm is set appropriately for the O_2 setting being used on the ventilator.
	C. The O_2 sensor may not be properly seated.	a. Make sure the sensors are correctly seated and the sensor cover is fully closed.
	D. The O_2 calibration may have drifted.	a. Perform a low and high range calibration of the O_2 sensor. b. Contact Ikaria - Technical Support.
6. Cylinder Not Detected  or Cylinder Valve Closed 	A. Interference with the Infrared communication link between the INOMAX® cylinder and the INOmax DS_{IR} (Delivery Stopped will occur one hour from the point when communication is lost).	a. Remove obstruction between the INOMAX cylinder and the INOmax DS_{IR}. b. Move the interfering light or the cart to reduce the high intensity light in the area of the INOmeter®.
	B. INOMAX cylinder valve is closed (Delivery Stopped will occur one hour from the point when the cylinder valve is closed).	a. Open INOMAX cylinder valve.
	C. Transport Cap not connected to the INOmeter (Delivery Stopped will occur one hour from the point when communication is lost).	a. Attach the Transport Cap to the INOmeter on the INOMAX cylinder. b. Connect the Transport Regulator/Cap Assembly cable to the infrared connector on the back of the INOmax DS_{IR}.
	D. INOMAX cylinder not present on the INOmax DS_{IR} (Delivery Stopped will occur one hour from the point when communication is lost).	a. Load an INOMAX cylinder onto the INOmax DS_{IR} cart.
	E. INOmeter may have failed.	a. Replace the INOMAX cylinder on the INOmax DS_{IR} cart.
	F. INOmax DS_{IR} infrared cart cable is not connected or has failed.	a. Connect infrared cart cable to the infrared connector on the back of the INOmax DS_{IR}. b. Replace the INOmax DS_{IR} System.

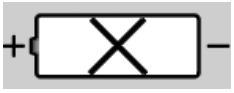
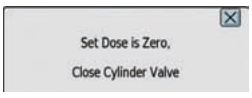
High Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
7. Delivery Failure  	A. Monitored NO levels ≥ 100 ppm or B. The INOmax DS_{IR}® has failed.	a. If the INOblender® is available, manually ventilate the patient (see INOblender Operation Manual). or b. Turn the backup mode ON (see page 32). c. Power the INOmax DS_{IR} to STANDBY and then back ON to reset the delivery system. If this does not work contact Ikaria® - Technical Support. d. Replace the delivery system if in use. e. Do not use the delivery system until serviced.
8. Delivery Stopped  	A. Infrared communication link between the INOMAX® cylinder and the INOmax DS_{IR} has been lost for one hour.	a. Remove obstruction between the INOMAX cylinder and the INOmax DS_{IR}. b. Move the interfering light or the cart to reduce the high intensity light in the area of the INOmeter®. c. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). or d. Turn the backup mode ON (see page 32).
	B. INOMAX cylinder is expired and cylinder valve has been open for two minutes.	a. Remove expired INOMAX cylinder from the INOmax DS_{IR} cart. b. Connect an INOMAX cylinder to the INOmax DS_{IR} with a valid expiration date.
	C. INOMAX cylinder is the wrong concentration and cylinder valve has been open for two minutes.	a. Remove the INOMAX cylinder with the wrong concentration from the INOmax DS_{IR} cart. b. Connect an INOMAX cylinder to the INOmax DS_{IR} with a valid concentration.
	D. INOmeter may have failed.	a. Replace the INOMAX cylinder on the INOmax DS_{IR} cart.
	E. INOMAX cylinder valve is closed.	a. Open INOMAX cylinder valve. b. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). or c. Turn the backup mode ON (see page 32).
	F. INOMAX cylinder not present on the INOmax DS_{IR}.	a. Load an INOMAX cylinder onto the INOmax DS_{IR} cart. b. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). or c. Turn the backup mode ON (see page 32).

High Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
9. Drug Past Expiry Date Or Drug Concentration Mismatch 	A. INOMAX♀ cylinder is expired (Delivery Stopped will occur two minutes from the point when the cylinder valve is opened).	a. Close the cylinder valve. b. Remove expired INOMAX cylinder from the INOmax DS_{IR}® cart. c. Replace the expired INOMAX cylinder on the INOmax DS_{IR} cart.
	B. INOMAX cylinder is the wrong concentration (Delivery Stopped will occur two minutes from the point when the cylinder valve is opened).	a. Close the cylinder valve. b. Remove the INOMAX cylinder with the wrong concentration from the INOmax DS_{IR} cart. c. Replace the INOMAX cylinder with the wrong concentration on the INOmax DS_{IR} cart.
10. Injector Module Fail 	A. The Injector Module electrical cable may be disconnected.	a. Reconnect the Injector Module electrical cable. b. Turn OFF the INOmax DS_{IR} set dose to silence the alarm. c. If the INOblender is available, manually ventilate the patient (see INOblender♀ Operation Manual). or d. Turn the backup mode ON (see page 32).
	B. The Injector Module may have failed.	a. Turn OFF the INOmax DS_{IR} set dose to silence the alarm. b. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). or c. Turn the backup mode ON (see page 32). d. Replace the Injector Module. e. Set the delivered dose and turn OFF the INOblender or the backup mode.
	C. The Injector Module electrical cable may have failed.	a. Turn OFF the INOmax DS_{IR} set dose to silence the alarm. b. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). or c. Turn the backup mode ON (see page 32). d. Replace the Injector Module electrical cable. e. Reset the delivered dose and turn OFF the INOblender or the backup mode.

High Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
11. Low Battery Alarm. 	A. Battery is running low (approximately 30 minutes or less until battery depletion).	a. Check main power indicator. b. Connect to AC main power source. c. Make sure the power cord is fully inserted into the Power Cord Inlet and that the power cord clamp is secure. d. Check and replace fuse if necessary. e. Contact Ikaria® - Technical Support.
12. Low NO/N_2 Pressure. 	A. The NO cylinder supply may be low.	a. Make sure the NO cylinder is turned ON. b. If the high pressure cylinder gauge reads less than 200 psig, change the cylinder. c. If the INOblender® is available, manually ventilate the patient (see INOblender Operation Manual). or d. Turn the backup mode ON (see page 32).
	B. The supply line may not be connected.	a. If the cylinder gauge reads greater than 200 psig: b. Verify the low pressure hoses are connected correctly to the back of the INOmax DS_{IR}®. c. If the INOblender® is available, manually ventilate the patient (see INOblender Operation Manual). or d. Turn the backup mode ON (see page 32).
	C. INOmax DS_{IR} has an internal leak.	a. Use INOblender as a stand-alone device and manually ventilate the patient (see page 105)
13. Service Required  Manual Delivery Available Utilize the INOblender or Backup Delivery.	A. The INOmax DS_{IR} has failed.	a. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). or b. Turn the backup mode ON (see page 32). c. Turn the INOmax DS_{IR} to STANDBY and then back ON to rest the delivery system. Please contact Ikaria - Technical Support and replace the delivery system as soon as possible.
14. Set NO and Backup On 	A. The backup mode has been turned ON and the set dose is still set.	a.Turn the INOmax DS_{IR} set dose to zero. b. Correct the reason for initiating the backup mode. c. Turn ON the INOmax DS_{IR} set dose. d. Turn the backup mode OFF. e. If this does not work contact Ikaria - Technical Support.

Low Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
15. Backup On 	A. The backup mode has been turned ON and the set dose is zero.	a. Correct the reason for initiating the backup mode. b. Turn ON the INOmax DS_{IR}® set dose. c. Turn the backup mode OFF.
16. Failed NO Sensor 	A. The wrong calibration gas may have been used.	a. Make sure the correct calibration gas is used and ensure sample tubing connections are secure and do not leak.
	B. There is a leak around the sensors.	a. Make sure the sensors are correctly seated with the O-rings and the sensor cover is fully closed.
	C. NO sensor absent or failed.	a. Replace sensor. b. Complete a low calibration first, and then repeat the high calibration. c. Replace the delivery system if in use. d. Contact Ikaria® - Technical Support.
17. Failed NO_2 Sensor 	A. The wrong calibration gas may have been used.	a. Make sure the correct calibration gas is used and ensure sample tubing connections are secure and do not leak.
	B. There is a leak around the sensors.	a. Make sure the sensors are correctly seated with the O-rings and the sensor cover is fully closed.
	C. NO_2 sensor absent or failed.	a. Replace sensor. b. Complete a low calibration first, and then repeat the high calibration. c. Replace the delivery system if in use. d. Contact Ikaria® - Technical Support.
18. Failed O_2 Sensor 	A. The wrong calibration gas may have been used.	a. Make sure the correct calibration gas is used and ensure sample tubing connections are secure and do not leak.
	B. There is a leak around the sensors.	a. Make sure the sensors are correctly seated and the sensor cover is fully closed.
	C. O_2 sensor absent or failed.	a. Replace sensor. b. Complete a low calibration first, and then repeat the high calibration. c. Replace the delivery system if in use. d. Contact Ikaria - Technical Support.
19. Monitoring Failure 	A. Monitor is failing to communicate correctly or is reporting a fault.	a. Does not stop delivery of INOMAX® to the patient. b. Contact Ikaria® - Technical Support.

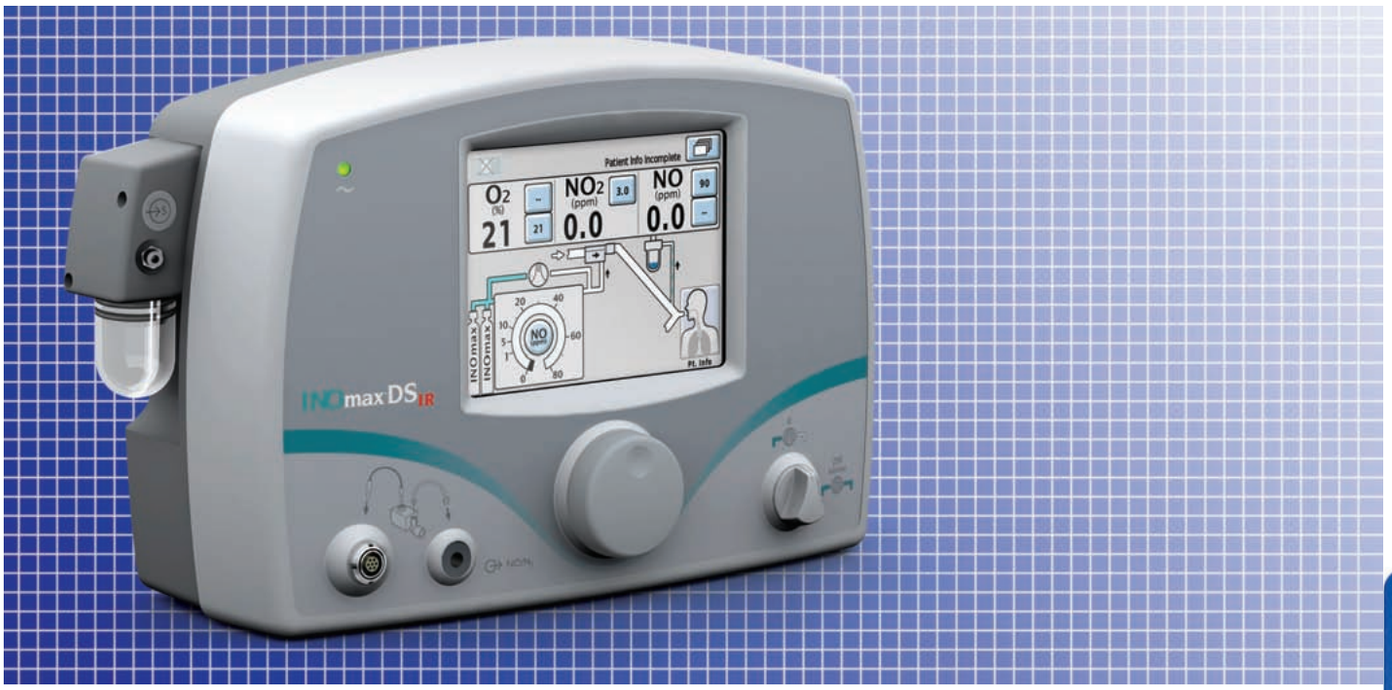
Low Priority Alarms		
Symptom/Alarm	**Possible Cause**	**Recommended Action**
20. Sample Line/Filter Block 	A. The sample line may be blocked.	a. Make sure the sample inlet line and outlet ports are not obstructed. b. Change the sample line.
	B. The water separator cartridge may be blocked.	a. Replace the water separator cartridge. 
21. Two Cylinders Open 	A. Two cylinder valves are open.	a. Close one of the cylinder valves.
22. Water Trap Bottle Full 	A. The water trap bottle on the side of the INOmax DS_{IR}® is full.	a. Empty the water trap bottle.
	B. Water trap bottle is empty but the message remains in the alarm message box.	a. Remove the water trap bottle and clean the optical sensor level indicator with an alcohol swab.
	C. The INOmax DS_{IR} may have failed.	a. Contact Ikaria - Technical Support. b. Replace the delivery system if in use.

Indicators		
Symptom/Indicator	**Possible Cause**	**Recommended Action**
23. Battery Failure 	A. Communication failure with battery.	a. Connect to AC main power source. b. Check main power indicator.  c. Make sure the power cord is fully inserted into the Power Cord Inlet and that the power cord clamp is secure.
24. Patient Info Incomplete 	A. Patient identifier has not been entered.	a. Enter patient identifier.
25. Running on Battery 	A. Device is operating on the battery.	a. Connect to AC main power source when available. b. Check main power indicator.  c. Make sure the power cord is fully inserted into the Power Cord Inlet and that the power cord clamp is secure.
26. Set Dose is Zero, Close Cylinder Valve 	A. The set dose has been set to zero and the INOMAX cylinder valve is still open.	a. Close the INOMAX cylinder valve if treatment has been stopped.

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



Calibration

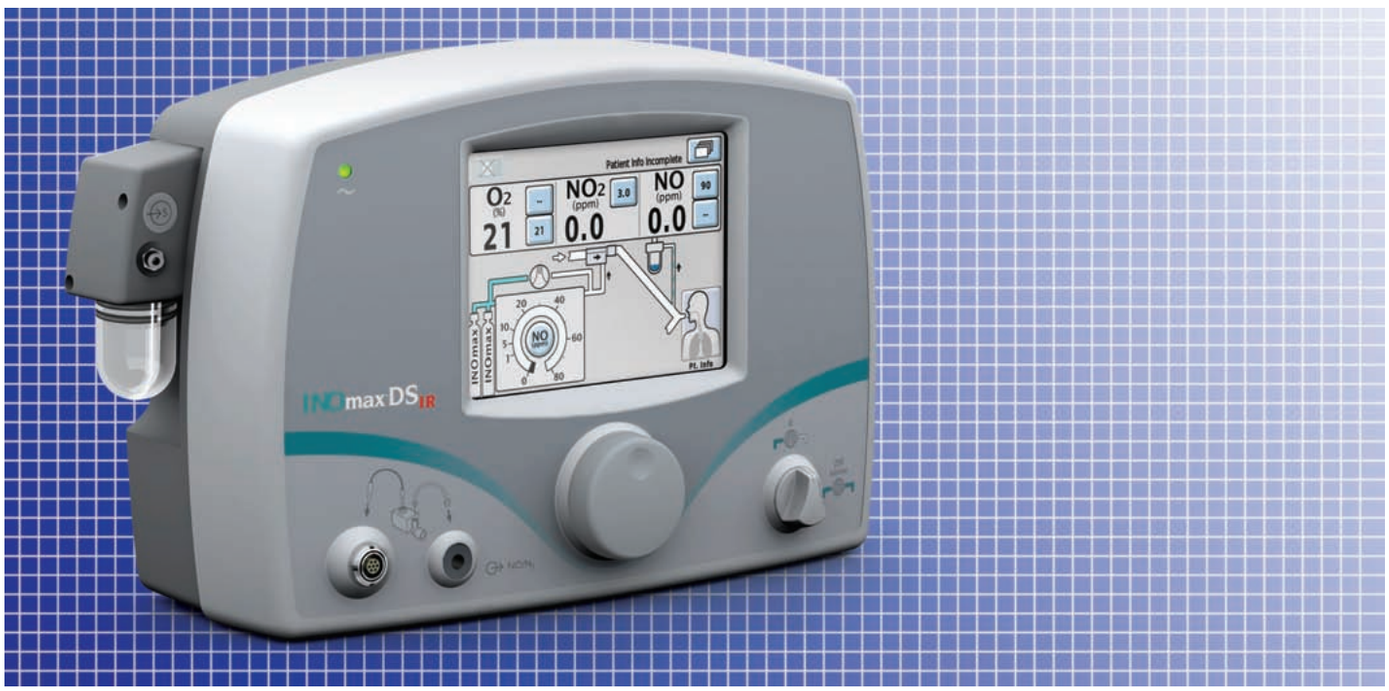
7/ Calibration

Part No. 20010 Rev-05
2012-03

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



Calibration

7/ Calibration

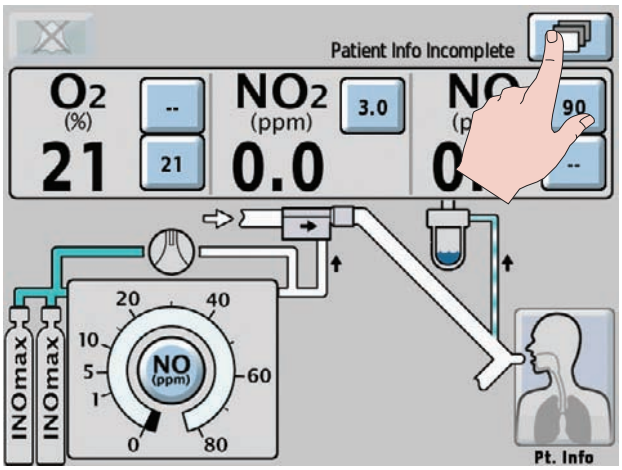
Part No. 20010 Rev-05
2012-03

7/ Calibration

WARNING:	**INOMAX® can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**

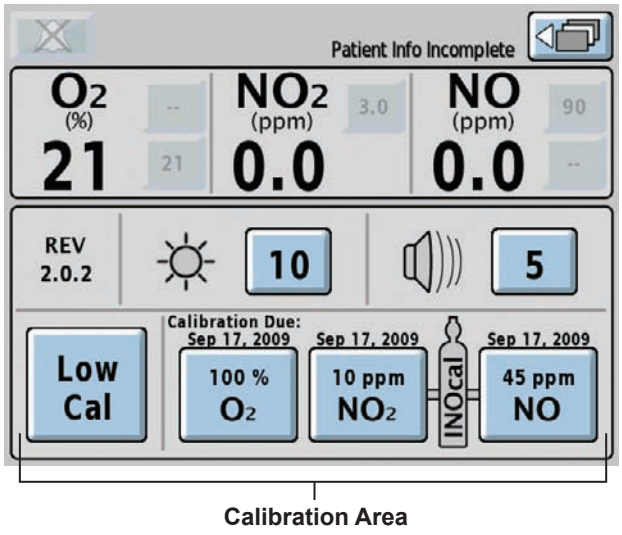
Caution:	When performing a high range calibration make sure to select the correct calibration gas and confirm the expiration date before using. Never connect the sample line directly to a high pressure gas source (greater than 150 cmH_2O); this could damage the sampling system.

Note:	The calibration process can be stopped at anytime by pushing the "Cancel Active Status" button on the touch screen. 



To access the calibration menu:

Press the menu button on the main screen to enter the menu screen (second menu level).

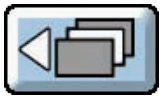


Calibration Area

The lower part of the screen displays the four calibration buttons.

The sensor high calibration due date is displayed above the respective calibration button.

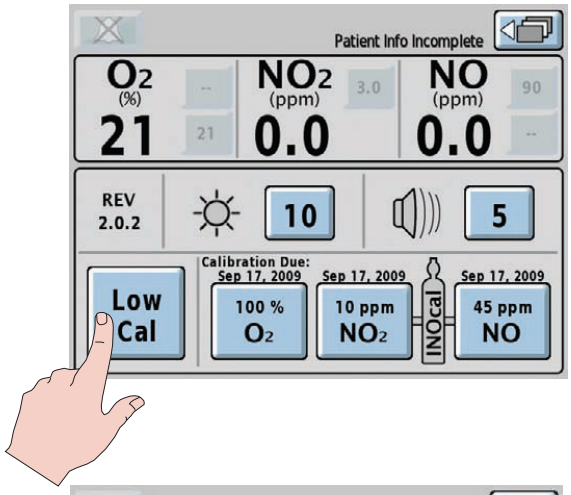
If the date is flashing it signifies the calibration is past due.

Note:	To return to the main screen, press the return to the previous level button in the top right of the screen. 

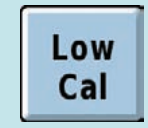
Low Range Calibration

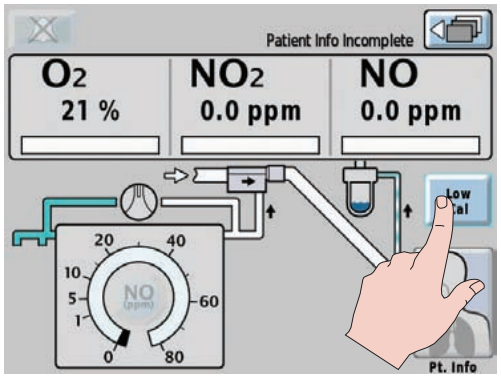
WARNING: **INOMAX® can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**

The low range calibration of the monitor sensors uses room air to calibrate all three sensors at the same time. The system automatically draws in room air from an inlet port behind the water trap, not the sample line.

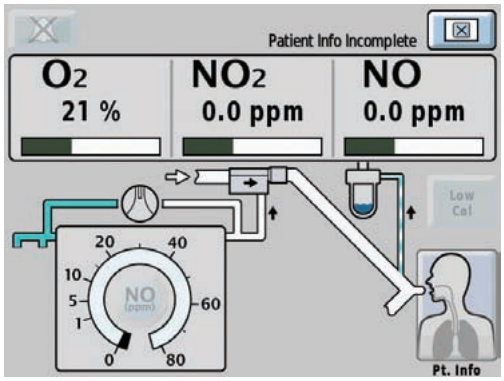


1. From the menu display (second menu level), press the Low Cal button to bring up the low range calibration screen (third menu level).

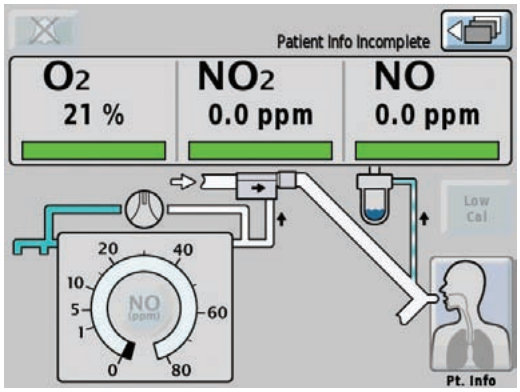




2. Start the low range calibration by pressing the flashing Low Cal button on the right hand of the screen.

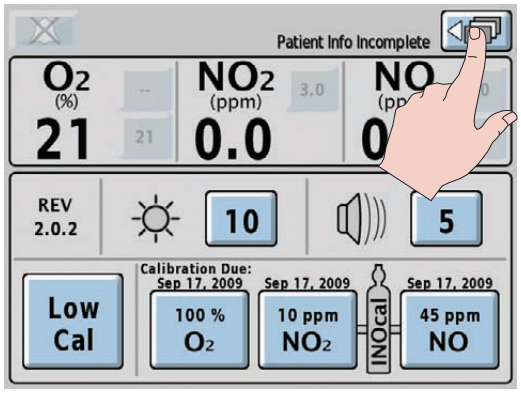


3. The calibration will take approximately three minutes during which a bar graph for each sensor indicates the progress.

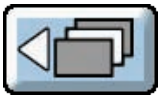


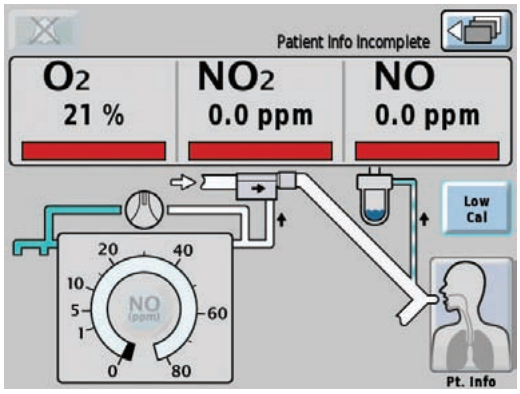
4. When the low range calibration is successful the display indicates the progress bar graphs fully green and a single tone will be heard.

   (The monitor displays should indicate approximately 21% O_2, 0.0 ppm NO_2 and 0.0 ppm NO)



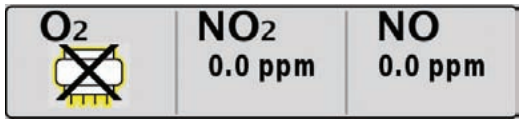
Note:

- To return to the menu screen, press the return to previous level button.  This will also activate a two minute lockout period to prevent monitoring alarms from occurring while measured values stabilize.
- To return to the main screen, press the return to the previous level button again.



If the calibration was unsuccessful, the display will indicate the progress bars fully red. You should attempt another calibration.

Note: To repeat the room air calibration, press the flashing Low Cal button on the right hand of the screen. 



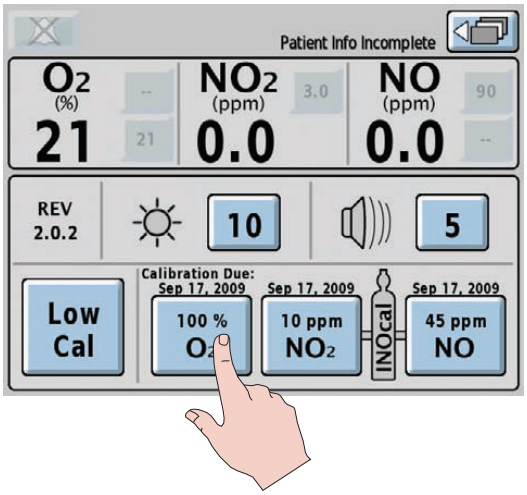
If a sensor has failed, the display will indicate the failed sensor symbol in the monitoring area of that sensor (see Section 6/ Troubleshooting).

Oxygen Sensor High Range Calibration

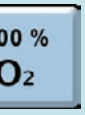
WARNING:	**INOMAX®can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**

Note:	Complete a low calibration (see Low Range Calibration section) prior to completing the high calibration.

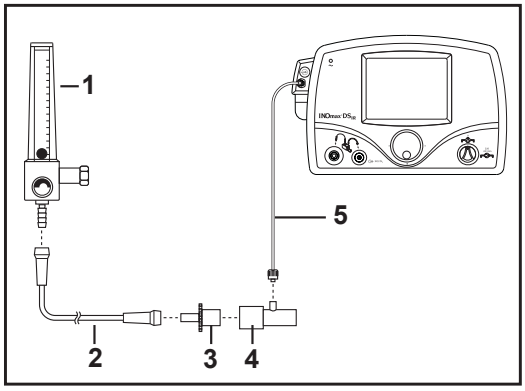
The oxygen high range calibration requires a user supplied source of 100% oxygen.



1. From the menu screen (second menu level) press the 100% O_2 button to bring up the O_2 high range calibration screen (third menu level), and to return to the menu screen, press the return to previous level button.

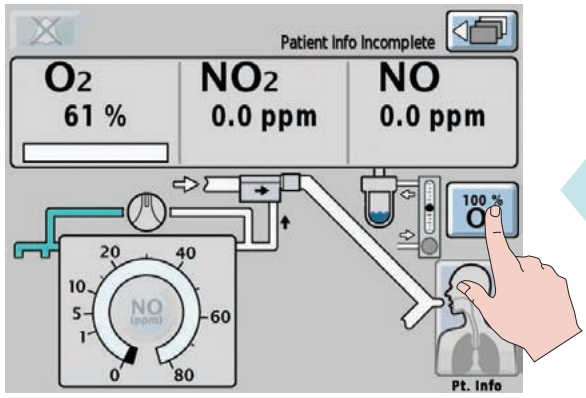


Note:	If the date is flashing it signifies the calibration is past due.

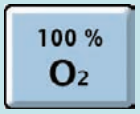


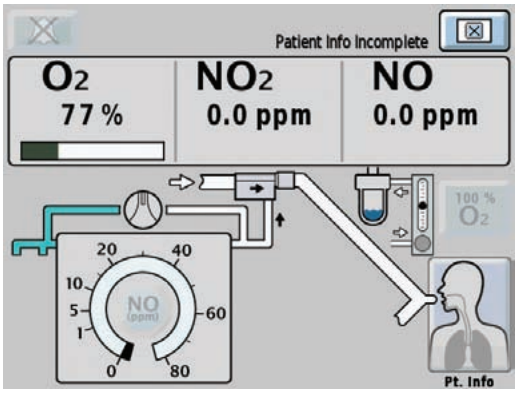
2. Assemble connectors into a calibration setup and set oxygen flow to 5 L/min.

   (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

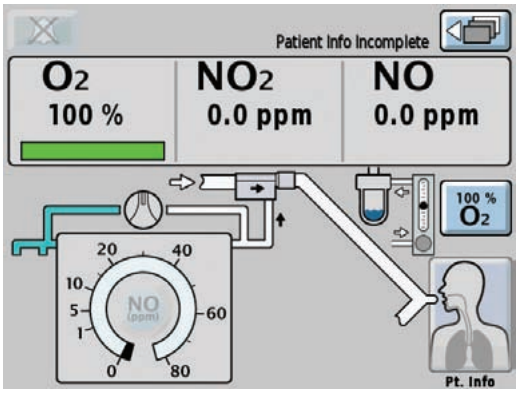


3. To start the O_2 high range calibration, press the flashing 100% O_2 button on the right hand side of the screen.



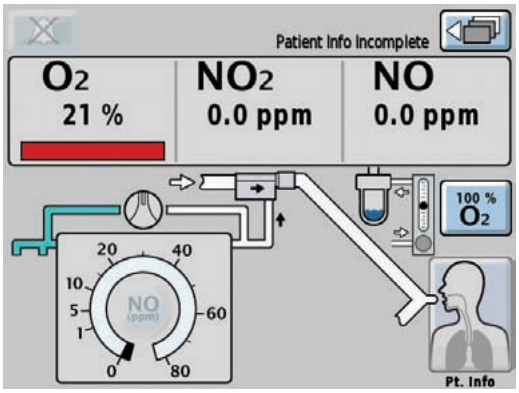


4. The calibration will take approximately three minutes, during which a bar graph for the O_2 sensor indicates the progress.



5. When the calibration is successful, the display indicates the progress bar graph fully green and a single tone will be heard. Disconnect sample line and turn OFF the O_2.

   (The monitor displays should indicate approximately 100% O_2, 0.0 ppm NO_2 and 0.0 ppm NO)

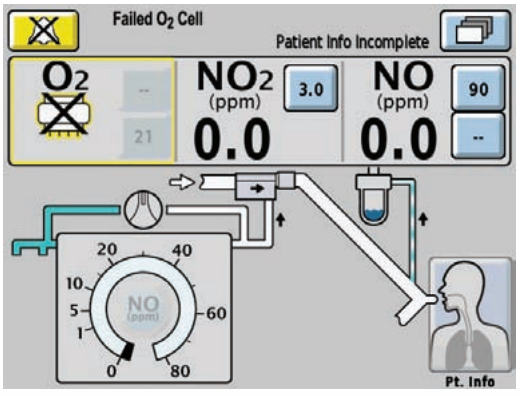


Note:

- To return to the menu screen, press the return to previous level button. This will also activate a two minute lockout period to prevent monitoring alarms from occurring while measured values stabilize.

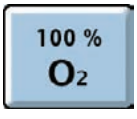
- To return to the main screen, press the return to the previous level button again.

If the calibration was unsuccessful, the display will indicate the O_2 progress bar fully red. You should attempt another calibration.



If the O_2 sensor has failed, the display indicates the failed sensor symbol in the monitoring area of that sensor. Repeat calibration, (see Section 6/ Troubleshooting).

To repeat the O_2 high range calibration press the flashing 100% O_2 button on the right hand of the screen.



NO Sensor High Range Calibration

WARNING: **INOMAX® can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**

Caution: An incorrectly installed one-way valve can lead to over-pressurization of the sampling system. A leak in the calibration tubing kit (PN 6002-0000-106) attached to the calibration cylinder regulator can result in displayed NO values greater than the set dose value after passing a low and high calibration successfully. This can be caused by aging of the calibration tubing. The calibration tubing kit should be replaced under the following circumstances:

- The tubing is discolored or stiff.
- There is a crack or break in the tubing.

Note: Complete a low calibration (see Low Range Calibration section) prior to completing the high calibration.

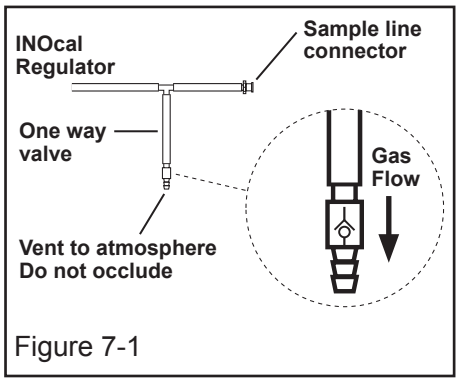
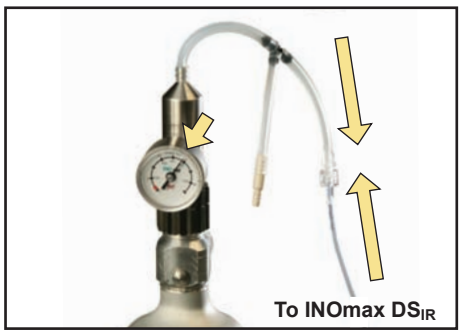
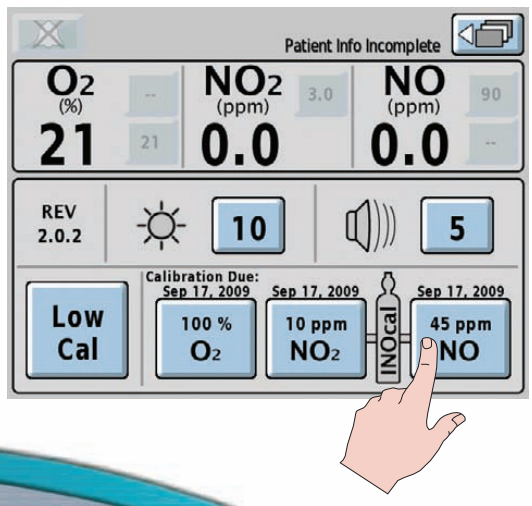


Figure 7-1





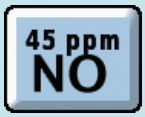
INOcal® calibration gas kit sample tubing

When using the calibration tubing kit (P/N 6002-0000-106), which is supplied with the INOcal regulator kit (P/N 000-013), ensure that the one way check valve supplied with the tubing is installed and oriented as indicated in Figure 7-1.

1. Connect the calibration regulator (left hand thread) and approved calibration sample tubing tee to the cylinder.
2. Confirm INOcal cylinder expiration date.

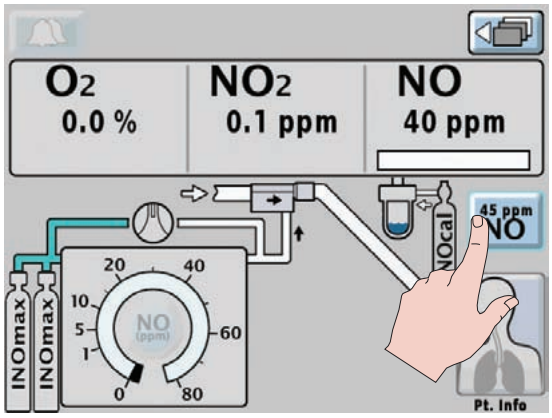
This procedure is for calibrating the NO sensor. The NO high range calibration requires an INOcal cylinder of 45 ppm NO (teal label).

3. From the menu screen (second menu level), press the 45 ppm NO button to bring up the NO calibration screen (third menu level).

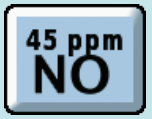


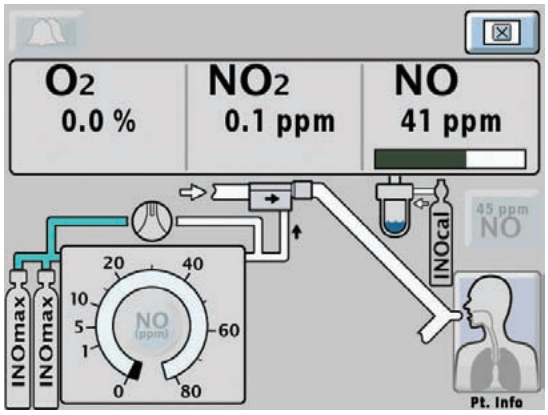
Note: If the date is flashing it signifies the calibration is past due.

4. Turn the INOcal cylinder on and check there is adequate pressure (replace if in the RED zone).
5. Attach the INOcal sample tee to the sample line of the INOmax DSIR® (beige adaptor is a pressure relief; see Figure 7-1).



6. To start the 45 ppm NO high range calibration, press the flashing NO button on the right hand side of the screen.

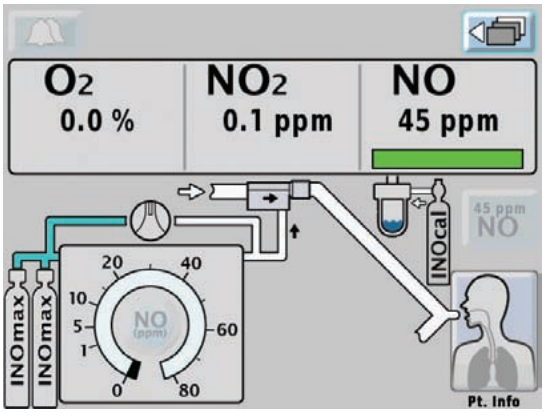




The calibration will take approximately three minutes during which a bar graph for the sensor indicates the progress.

When the calibration is successful, the display indicates the progress bar fully green and a single tone will be heard. Turn the calibration cylinder OFF and disconnect the sample line.

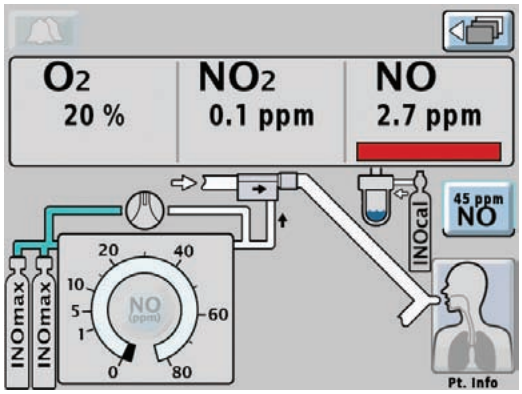
(The monitor displays should indicate approximately 0.0% O_2, 0.0 ppm NO_2 and 45 ppm NO)



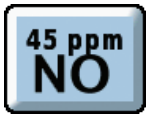
Note:

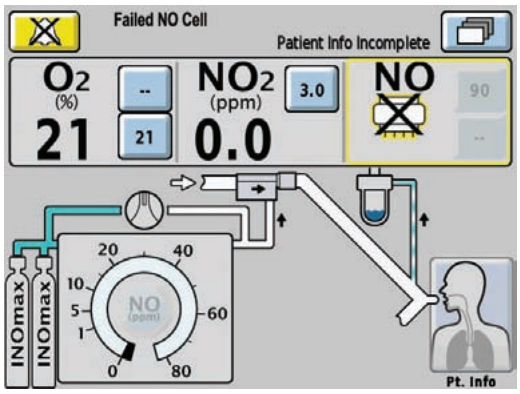
- To return to the menu screen, press the return to previous level button. This will also activate a two minute lockout period to prevent monitoring alarms from occurring while measured values stabilize.

- To return to the main screen, press the return to the previous level button again.

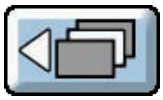


If the calibration was unsuccessful, the display will show the NO progress bar of the sensor fully red. You should attempt another calibration.

Note:	To repeat the NO high range calibration press the flashing 45 ppm NO button on the right hand side of the screen. 



If the NO sensor has failed the display indicates the failed sensor symbol in the monitoring area of that sensor. Repeat calibration, (see Section 6/ Troubleshooting).

Note:	To return to the menu screen press the return to previous level button. 

NO_2 Sensor High Range Calibration

WARNING: **INOMAX® can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**

Caution: An incorrectly installed one-way valve can lead to over-pressurization of the sampling system. A leak in the calibration tubing kit (PN 6002-0000-106) attached to the calibration cylinder regulator can result in displayed NO_2 values greater than the set dose value after passing a low and high calibration successfully. This can be caused by aging of the calibration tubing. The calibration tubing kit should be replaced under the following circumstances:

- The tubing is discolored or stiff.
- There is a crack or break in the tubing.

Note: Complete a low calibration (see Low Range Calibration section) prior to completing the high calibration.

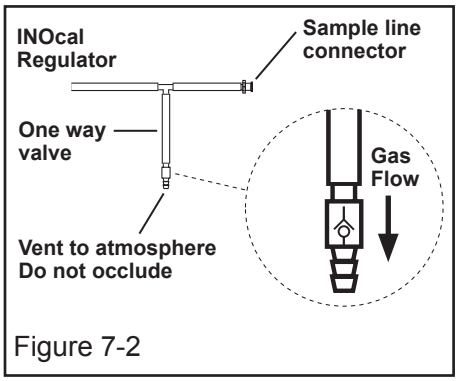
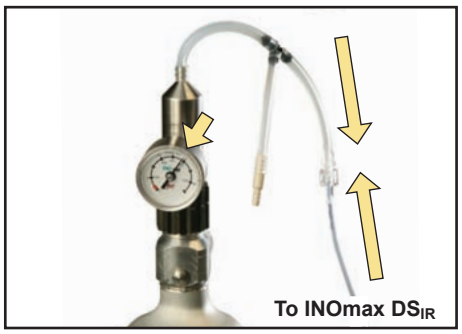
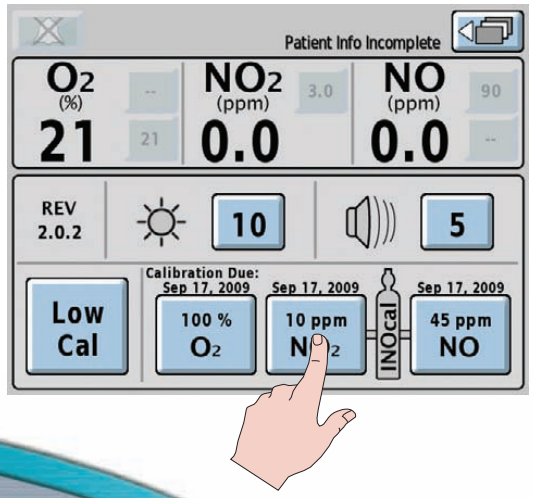


Figure 7-2





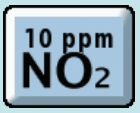
INOcal® calibration gas kit sample tubing

When using the calibration tubing kit (P/N 6002-0000-106), which is supplied with the INOcal regulator kit (P/N 000-013), ensure that the one-way check valve supplied with the tubing is installed and oriented as indicated in Figure 7-2.

1. Connect the calibration regulator (left hand thread) and approved calibration sample tubing tee to the cylinder.
2. Confirm INOcal cylinder expiration date.

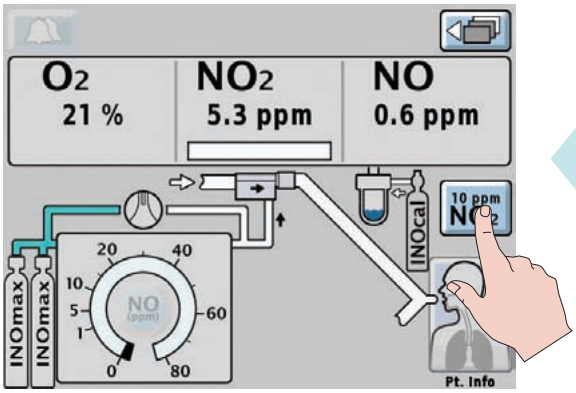
This procedure is for calibrating the NO_2 sensor. The NO_2 high range calibration requires an INOcal cylinder of 10 ppm NO_2 (pink label).

3. From the menu screen (second menu level), press the10 ppm NO_2 button to bring up the NO_2 calibration screen (third menu level).

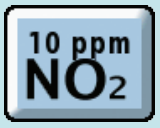


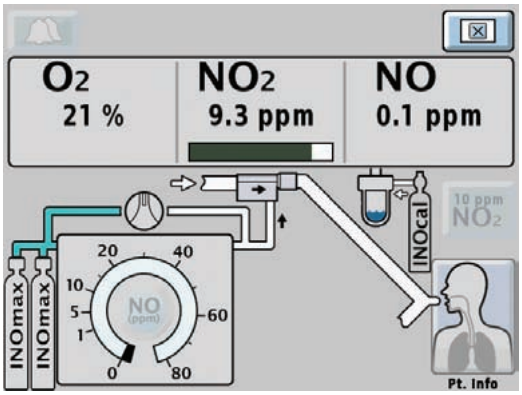
Note: If the date is flashing it signifies the calibration is past due.

4. Turn the INOcal cylinder on and check there is adequate pressure (replace if in the RED zone).
5. Attach the INOcal sample tee to the sample line of the INOmax DS_{IR}® (beige adaptor is a pressure relief; see Figure 7-2).



6. To start the NO_2 high range calibration, press the flashing 10 ppm NO_2 button on the right hand side of the screen.

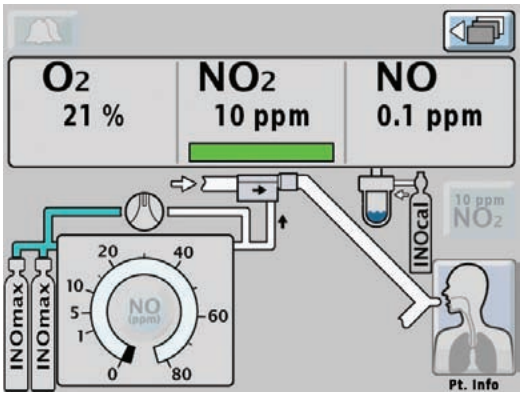




The calibration will take approximately 3 minutes, during which a bar graph for the NO_2 sensor indicates the progress.

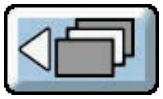
When the calibration is successful, the display indicates the progress bar fully green and a single tone will be heard. Turn the calibration cylinder OFF and disconnect the sample line.

(The monitor displays should indicate approximately 21% O_2, 10 ppm NO_2 and 0.0 ppm NO)

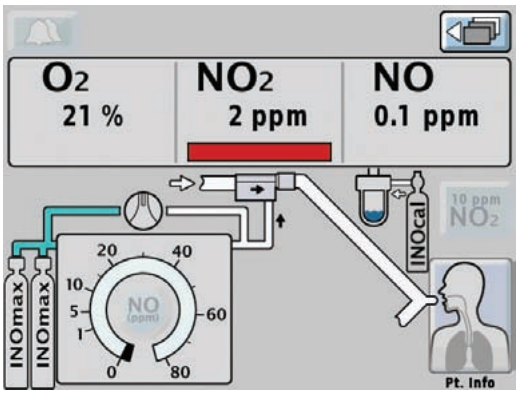


Note:

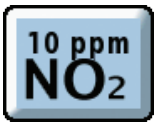
- To return to the menu screen, press the return to previous level button. This will also activate a two minute lockout period to prevent monitoring alarms from occurring while measured values stabilize.

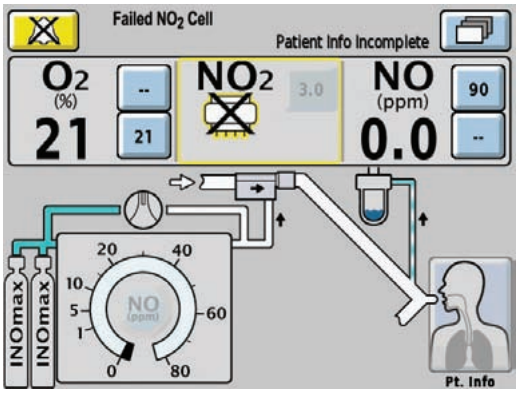


- To return to the main screen, press the return to the previous level button again.

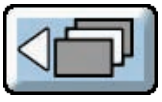


If the calibration was unsuccessful, the display will show the progress bar of the sensor fully red. You should attempt another calibration.

Note:	To repeat the NO_2 high range calibration press the flashing 10 ppm NO_2 button on the right hand side of the screen. 



If the NO_2 sensor has failed, the display indicates the failed sensor symbol in the monitoring area. Repeat calibration, (see Section 6/ Troubleshooting).

To return to the menu screen press the return to previous level button. 

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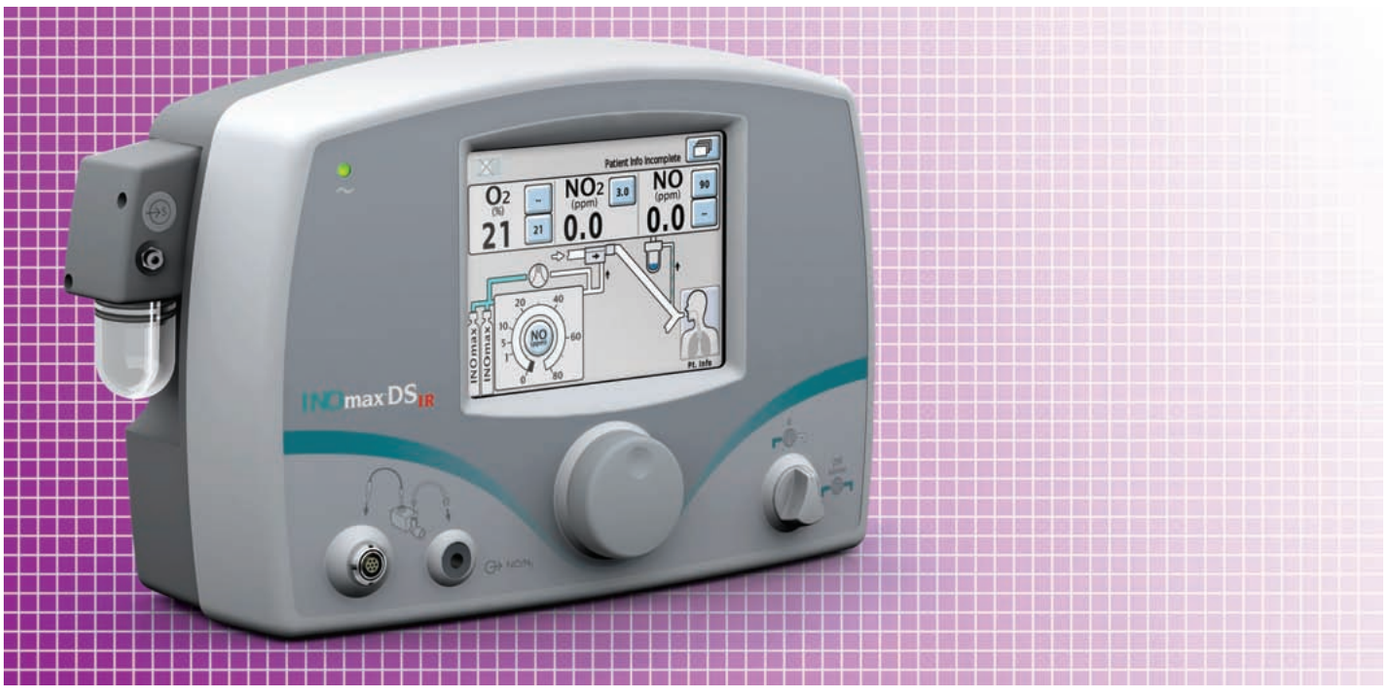
IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



8/ Maintenance

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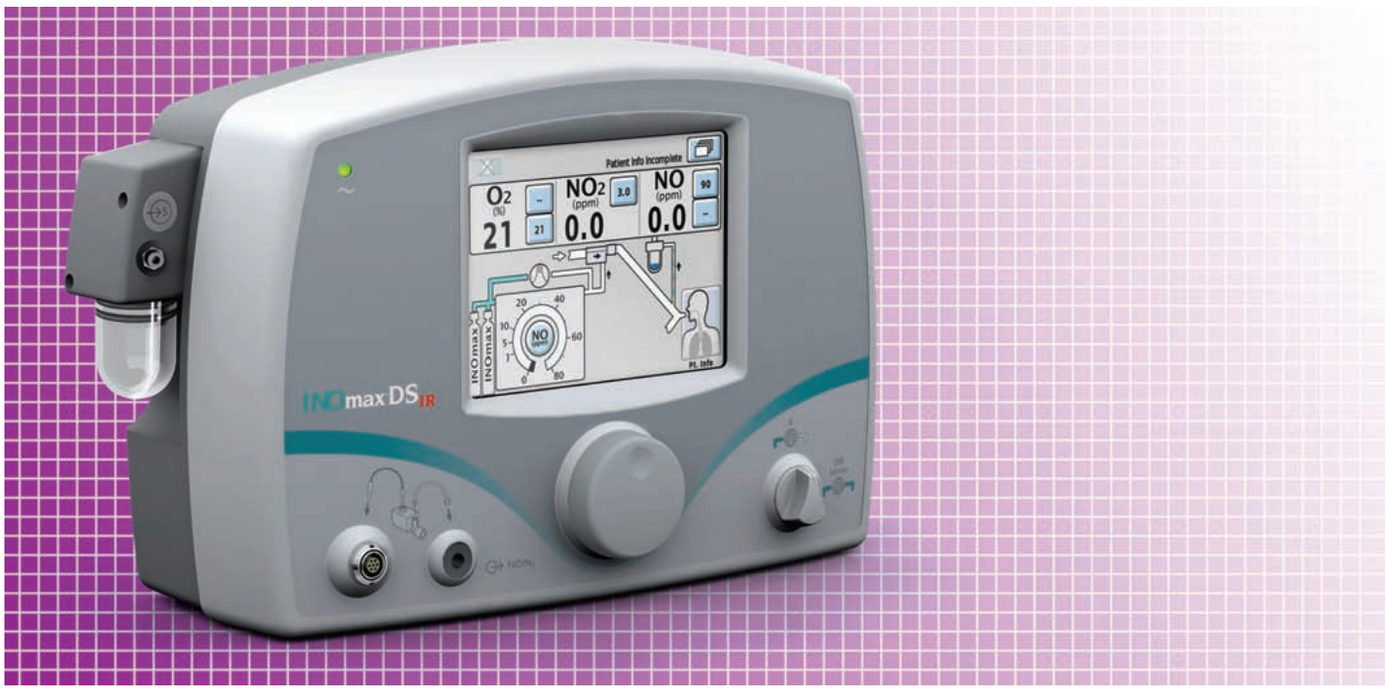
IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



Maintenance

8/ Maintenance

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8/ Maintenance

Caution:	To help prevent fire, use only lubricants approved for O_2 equipment, such as KRYTOX®. Don't use lubricants which contain oil or grease: they burn or explode in high O_2 concentrations. Do not sterilize or disinfect with the power connected.

Note:	The INOmax DS_{IR}® does not contain any user repairable parts.

User Maintenance Schedule

Frequency	Maintenance
Daily	1. Check the INOMAX® cylinder pressure: a cylinder with less than 200 psig should be replaced. 2. Perform the low range calibration. 3. Empty the water trap bottle as needed.
Start of each patient	Must perform the Pre-Use Procedure.
Between each patient	1. Sterilize and/or disinfect the Injector Module. 2. Clean water trap bottle. 3. Replace the single patient use items. 4. Make sure that the delivery system power cord is always plugged into an emergency-power-backed electrical outlet. 5. Make sure the connectors, hoses, and cables are in good condition.
Monthly	1. Do the high range calibration of NO, NO_2, and O_2. Note: A flashing date above the high sensor calibration button signifies a high calibration is due. 2. Check INOMAX regulators for leaks.

Cleaning the INOmax DS_{IR}®

Caution:	• Do not autoclave or gas sterilize the INOmax DS_{IR}. • Do not clean with the power connected. • Be sure that the unit is completely dry before using it. • Do not saturate the INOmax DS_{IR} with excessive solution. Liquid may flow into the system and damage internal components. • Do not use organic, petroleum based solvents, glass cleaners, acetone, or other harsh cleaning agents. • Do not use abrasive cleaning agents (such as steel wool, silver polish or cleaner). • Do not touch or rub the display panel with abrasive cleaning compounds or anything which can scratch the panel. • Do not use organic solvents to clean the display panel.

Cleaning Procedure

Caution:	Apply cleaning agent to a cloth before application; do not spray directly on the delivery system. It is important to prevent pooling and direct contact with electrical connections which can cause damage over time.

External surfaces and the Display panel

- Disconnect the power before cleaning.
- Clean the outer surface of the INOmax DS_{IR} with a soft cloth dampened in a mild soap and water solution, isopropyl alcohol (70%) or with one of the following cleaning agents while following the manufacturer's recommendations.
- Do not autoclave the delivery system.

Cleaning Agent	Active Ingredients
Precise Hospital Foam Cleaner Disinfectant by Caltech Industries	o-Phenylphenol < 0.37% Other ingredients 99.63%
Pure Green 24 by Pure Green, LLC	SDC – silver ions 0.003% Citric acid 4.84% Other ingredients 95.157%

Cleaning Agent	Active Ingredients
PDI Super Sani Cloth by PDI	n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.25% n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.25% Isopropyl alcohol 55% Inert ingredients 44.50%
Sani Cloth HB by PDI	n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.07% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.07% Inert ingredients 99.86%
Asepti-HB by Ecolab Inc.	n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 0.07% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.07% Inert ingredients 99.86%
Cavicide and CaviWipes by Metrex	Dilsobutylphenooxyethoxyethyl dimethyl benzyl ammonium chloride 0.28% Isopropyl alcohol 17.2% Inert ingredients 82.52%

Cleaning Water Trap Bottle

Caution:	If alcohol is used to clean water trap bottle, make sure alcohol is completely evaporated before placing back onto sample block. • Alcohol vapors will cause NO_2 sensor to read high (as much as 6 ppm) and NO sensor to read low (approximately 0.5 to 1 ppm). • This is a transient response, and will stop once alcohol vapors dissipate (trap dries out).

Procedure

- Clean water trap bottle with a soft cloth dampened in a mild soap and water solution or with isopropyl alcohol (70%).
- Allow water trap bottle to air dry.

Bioquell Hydrogen Peroxide Sterilant

Bioquell Hydrogen Peroxide Sterilant and hydrogen peroxide vapor generators are regulated by the USA Environmental Protection Agency (EPA) as pesticide chemicals in accordance with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Use of these products in cleaning/disinfection processes have not been validated with the INOmax DS_{IR}. Do not use these products to decontaminate the INOmax DS_{IR} or any ancillary products used with the INOmax DS_{IR}.

Injector Module Sterilizing and/or Disinfecting

WARNING:	**If the Injector Module was used in the wet/humidified part of the breathing circuit, it should be sterilized between each patient use.**

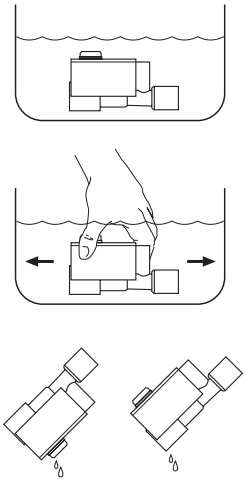
Caution:	Do not sterilize or disinfect with the power connected.

If the Injector Module has been used in the dry part of the breathing circuit, the Injector Module should be sterilized and/or disinfected in 70% ethyl alcohol after each patient use.

Autoclave Sterilizing the Injector Module

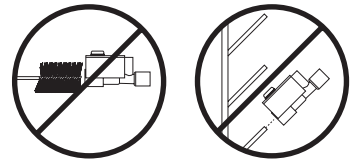
1. *Disconnect the electrical cable and the injector tube before autoclaving.*
2. Autoclave settings: 134° C for three minutes at 27 psig.
3. After sterilization, examine the parts. Any which are broken, worn, distorted or discolored should be replaced immediately.

Disinfecting the Injector Module



1. Fill a container with ethyl alcohol (70% by volume).
2. Totally submerge the Injector Module in the alcohol for at least 30 minutes.
3. To remove contamination if lint or fibers were noticed wrapped around the hot wire sensor in the module, gently agitate the module to splash the alcohol through the module openings.
4. If rinsing is required, use distilled water only.
5. When removing the module from the liquid, dump the excess alcohol from the modules' electrical connector, injector port and inside flowmeter.
6. Allow any liquid to evaporate completely before using the module.
   - Using low air pressure to dry the module or remove lint fiber is acceptable.

Caution:	• If lint fibers remain wrapped around the hot wire sensor in the module after drying, do not use the module: remove it from service. • Do not physically remove the fibers from the extremely delicate sensor. Do not insert anything into the module throat to remove contamination or to dry.



Note:	Patient circuit adapters, sample line, Injector Module tubing and water separator cartridge are single-patient use items. Do not sterilize them. Dispose of all single-patient use items in accordance with Universal Precautions for contamination.

Replacing the O_2, NO and NO_2 Sensors

WARNING:

- **Handle and dispose of sensors according to facility biohazard policies. Do not incinerate.**
- **If changing an NO sensor while delivering NO to a patient, install the NO sensor only when the NO high range calibration screen is displayed otherwise the system will shut down.**

Figure 8-1

To replace any one of the three sensors:

Remove the rear sensor cover by turning the two screws counterclockwise until loose (see Figure 8-1).

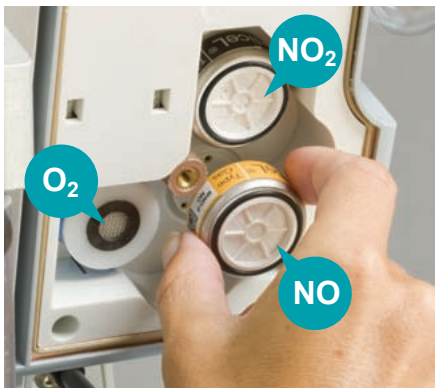


Figure 8-2

Grasp the sensor to be replaced on both sides and gently pull it from its socket (see Figure 8-2).

Note:

- The shorting wire must be removed from the NO_2 sensor before replacing (see Figure 8-5).
- Make sure all of the sensor O-rings are present and seated properly.

Figure 8-3

To install the replacement sensor, align the pins (NO and NO_2) with the socket and press it into place (see Figure 8-3).

To install O_2 sensor, remove the shorting screen and insert the contact end (open end with three gold rings) into recess until it seats (no specific orientation is necessary).

Replacing the O_2, NO and NO_2 Sensors (cont'd)

Figure 8-4

Replace the sensor cover and tighten the two screws clockwise (see Figure 8-4).

Note:	
Newly Installed Sensor	Time to Condition Prior to Calibration
O_2 and NO_2	40 minutes
NO	5 hours
Insufficient conditioning will result in inaccurate gas readings.	

Figure 8-5
Shorting Wire

Perform a low and high calibration for the sensor before returning the system to use.

Replacing the Water Separator Cartridge

WARNING: **When handling any component of the patient circuit that comes in contact with patient's fluids wear protective safety equipment.**

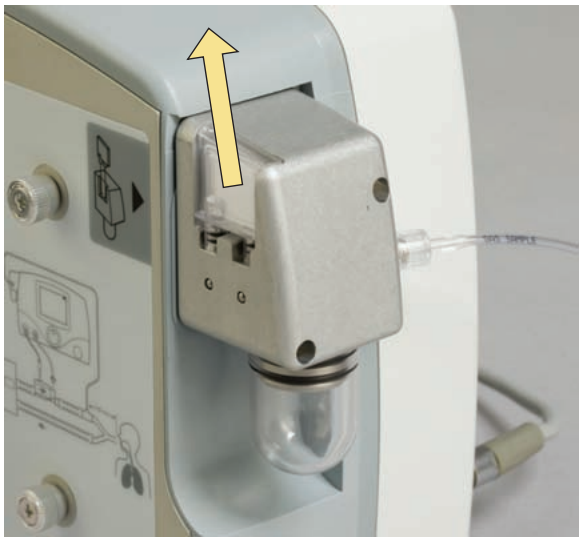


Figure 8-6

The disposable water separator cartridge on the rear of the water trap housing protects the monitoring system from moisture and other contaminants.

To replace the Water Separator Cartridge:

1. Grasp the cartridge on the back and top edge and gently pull it up, and out of the dovetail slot in the sampling block (see Figure 8-6).
2. Discard the used cartridge in a receptacle designated for medical wastes.
3. To replace the cartridge, line it up with the dovetail slot and push it into place until it seats properly.
4. Check for leaks by running the system, occluding the sample line until the sample line occlusion alarm message appears.

Replacing the CGA 626 tip on the INOMAX® regulator

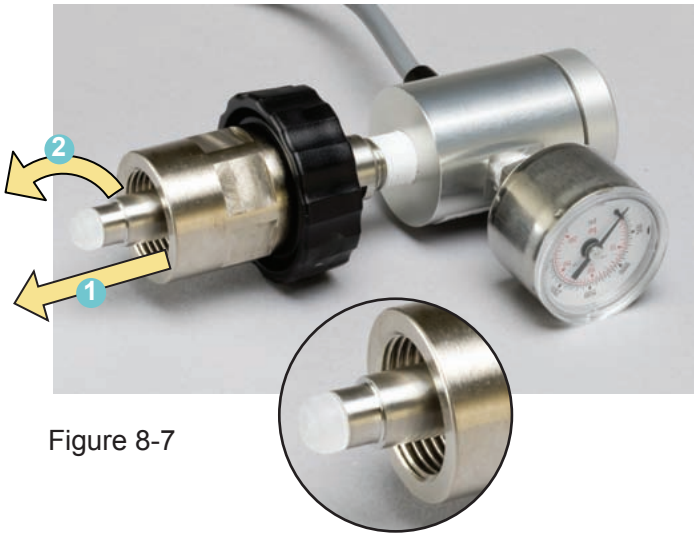


Figure 8-7

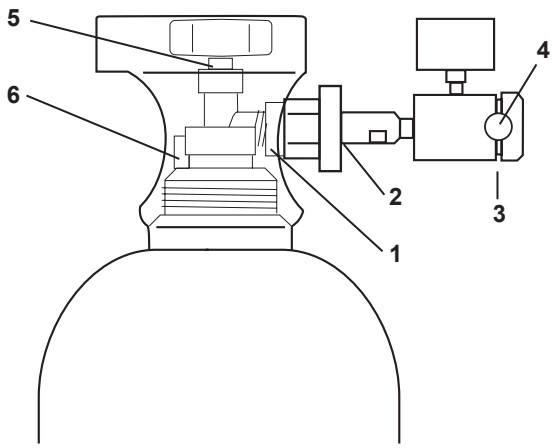
1. Disconnect the regulator from the INOMAX gas cylinder.
2. Remove the old CGA 626 tip by pulling on the tip and turning it counterclockwise (see Figure 8-7).
3. Ensure the threads are clean on the regulator tip (if required, use a lint free cloth).
4. Install the new tip:

   Flex the four prongs by squeezing two prongs at a time using only your fingers. This will help start the new tip into the threads. Turn the tip clockwise when threading the tip. When the tip is fully inserted, it should turn freely.

Cylinder Leak Check

If a leak is suspected during the high pressure leak test (see section 3/Pre-Use Checkout; High Pressure Leak Test), the following steps can be taken to check for leaks (see Figure 8-8 for possible cylinder gas leak locations) in the INOMAX Regulator or INOMAX cylinder.

Note:	Refer to hospital policies and procedures for dealing with leaking gas cylinders. Additional information regarding environmental effects can be found in the section 1/General Information.



1. Cylinder Valve Regulator Connection
2. INOMAX Regulator Hand Wheel Connection
3. Regulator End Cap Connection
4. Tamper Evident Tape
5. Valve Nut
6. Safety Pressure Release Device

Figure 8-8

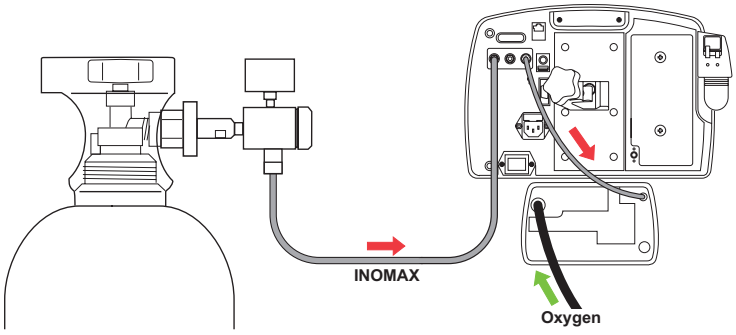
1. Ensure that INOMAX regulator is connected to cylinder valve outlet and cylinder valve is open.
2. Apply soapy water to points 1, 2, 3, 5 and 6 (see Figure 8-8); if bubbles form, there is a leak.
3. If there are no bubbles, leak may be inside INOmax DS_{IR} and cannot be repaired. Replace INOmax DS_{IR} and contact Ikaria® – Technical Support.

Recommended actions should a leak be detected:

1. A leak detected at points 1 and 2 may be corrected by tightening the INOMAX regulator hand wheel.
   a. If cylinder valve is open, close cylinder valve and tighten INOMAX regulator hand wheel.
   b. Open cylinder valve and reapply soapy water to points 1 and 2.
   c. If bubbles form, there is a leak.
   d. Remove INOMAX regulator and check white plastic tip on INOMAX regulator for chips or cracks. Replace if necessary (see Replacing the CGA 626 tip on the INOMAX regulator). Repeat step b (note: If leak remains, replace INOMAX regulator).
2. If a leak is detected between the regulator body and regulator end cap (see point 3) replace INOMAX regulator and contact Ikaria – Technical Support.
3. A leak detected at cylinder valve nut connection (see point 5) may not be repaired. Replace INOMAX cylinder and contact Ikaria – Technical Support.
4. A leak detected at safety pressure release device (see point 6) may not be repaired. Replace INOMAX cylinder and contact Ikaria – Technical Support.

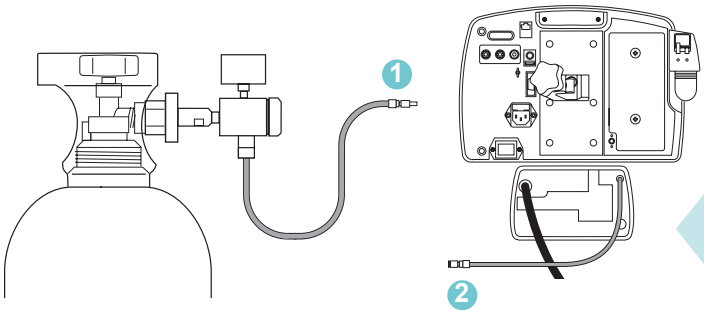
INOblender® Used as a Stand-Alone Device

This section explains how to use the INOblender as a stand-alone device.



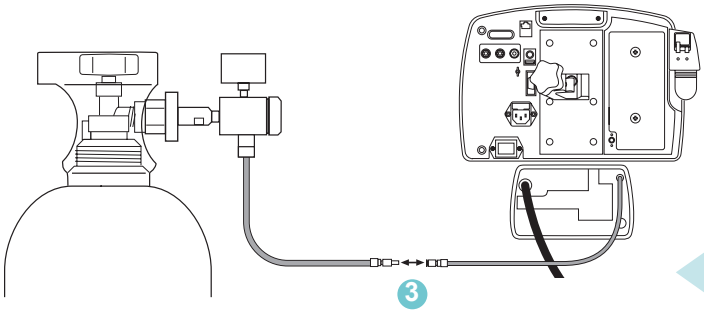
Typically the INOblender receives INOMAX® from the INOmax DS$_{IR}$® (INOMAX cylinder supplies both devices; see Figure 8-9).

Figure 8-9



As a stand-alone device INOMAX cylinder supplies just the INOblender. (see Figure 8-10).

1. Disconnect INOMAX regulator hose from back of INOmax DS$_{IR}$.
2. Disconnect INOblender hose from back of INOmax DS$_{IR}$.



3. Connect INOMAX regulator hose to INOblender inlet hose.

Figure 8-10

Preventative Maintenance

Two year planned maintenance

- Check battery.
- Check internal tubing.
- Replace sample system tubing and filters.
- Full system check.

Fuse Replacement

WARNING:	**For continued protection against hazard, replace the fuses only with the correct fuse type and rating.**

1. Turn the INOmax DS_{IR}® to STANDBY and remove the power cord from the power source.
2. Pull on the lower portion of the power input fuse cover latch and pull the cover out.
3. Remove the old fuse(s) and replace with the correct rated fuse(s) (see Figure 8-11).
4. Make sure the fuses are straight in the module cover; insert it back into the power input module and ensure that it is fully seated.
5. Replace the power cord and retainer and test the delivery system for proper operation.

Figure 8-11

Parts and Accessories

WARNING: **Only use parts/accessories designated for use with this system.**

Parts/Accessories	Part Number
Calibration Gas Regulator, for NO or NO_2 Calibration Gas	6020-0000-010
Calibration Tubing Kit	6002-0000-106
Clamp Assembly	10008
Injector Module	1605-3038-000
Injector Module Cable	1605-3057-000
INOcal® Calibration Gas, NO, 45 ppm	111-119
INOcal Calibration Gas, NO_2, 10 ppm	111-120
INOcal Regulator Kit	000-013
INOmax DS_{IR}® Cart	10018
INOMAX® Regulator, CGA 626	10006
INOMAX Transport Regulator/Cap Assembly	10022
INOMAX Regulator Extension Hose	10014
Mounting Post	10009
Operation and Maintenance Manual	20010
Sensor, O_2	80043
Sensor, NO	6050-0004-318
Sensor, NO_2	6050-0004-319
Tip, CGA 626 INOMAX Regulator	1605-3149-000
Transport Mounting Bracket Assembly	50041
Water Trap Bottle	90137

Disposables	Part Number
Bunnell Life Pulse Disposable Adapters Convenience Pack	50046
NO/N_2 Injector Tube	1605-3044-000
Patient Gas Sample Line	73319-HEL
Sample Tee, O_2 Tubing	1605-3171-000
Sensormedics 3100A/BFiltered Circuit Disposable Adapters Convenience Pack	50071
Water Separator Cartridge	50017

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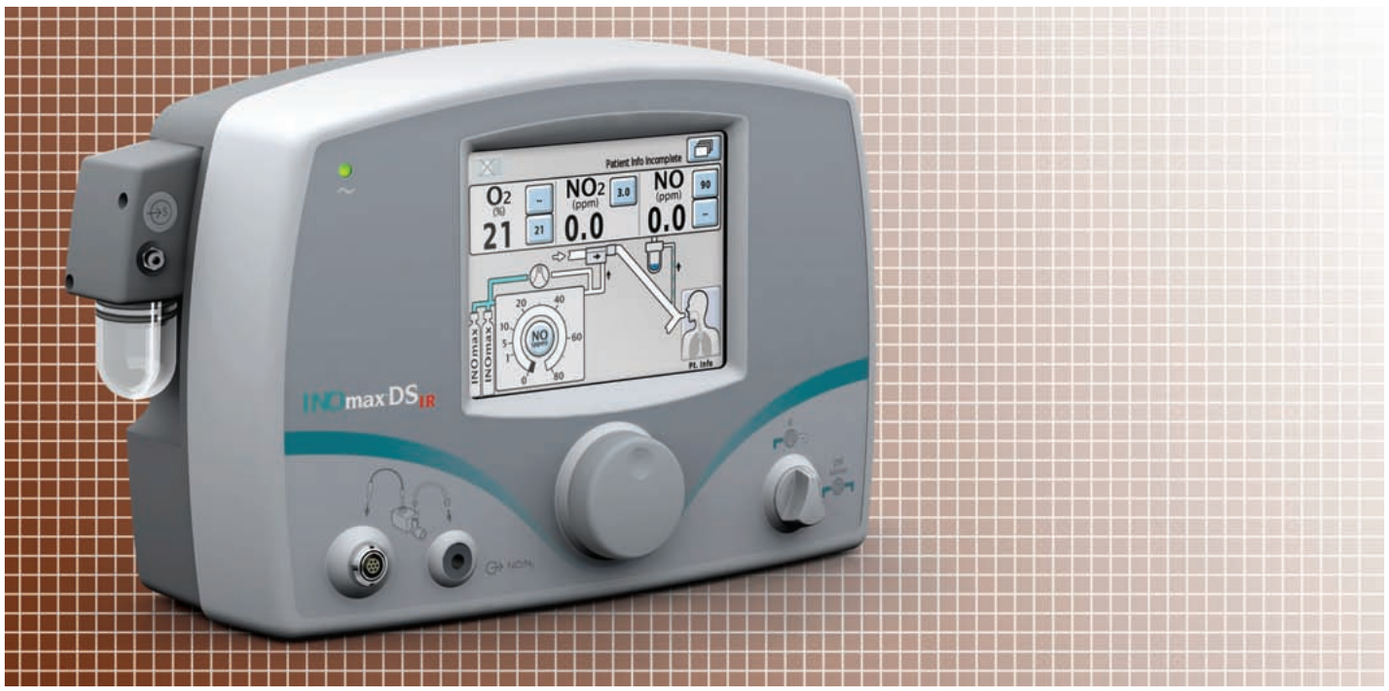
IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



9/ Product Specifications

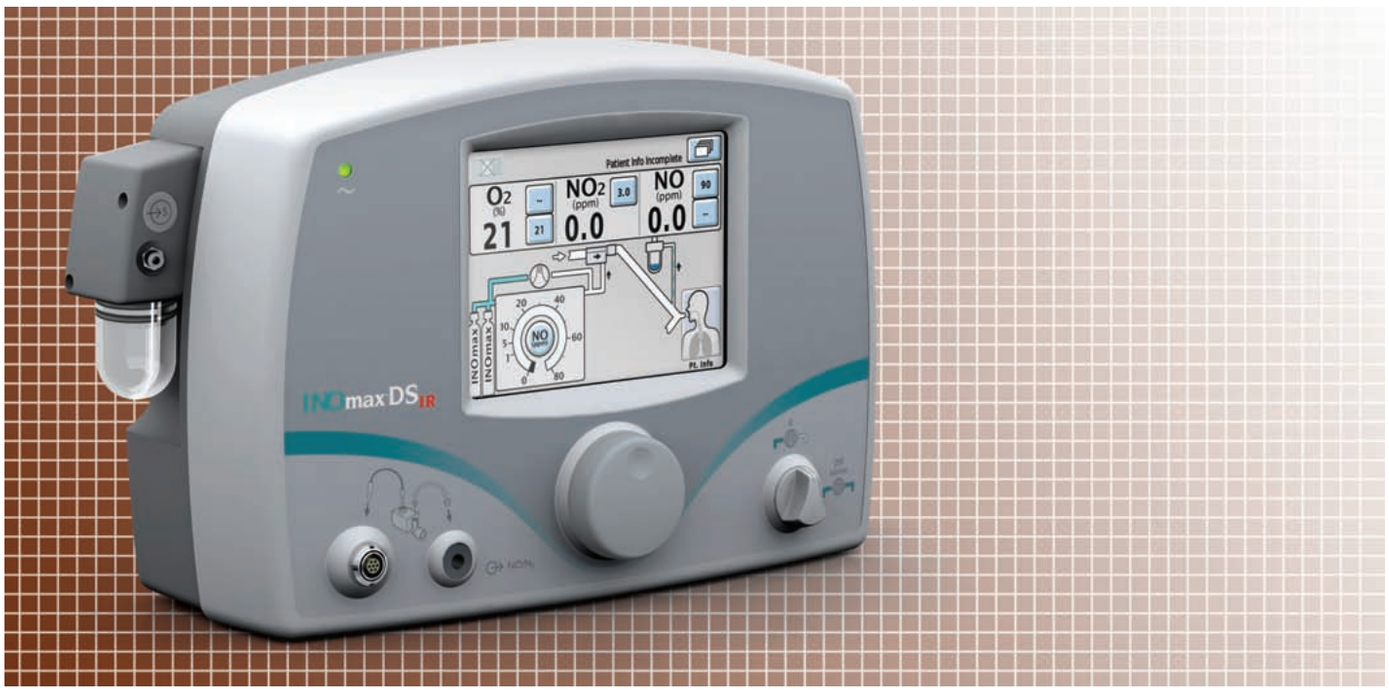
Product Specifications

Part No. 20010 Rev-05
2012-03

IKARIA®

INOmax DS$_{IR}$®

(Delivery System)



9/ Product Specifications

Product Specifications

Part No. 20010 Rev-05
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9/ Product Specifications

WARNING:

- **The approved patient population for the INOmax DS_{IR}®, as specified in the drug labeling for INOMAX® (nitric oxide) for inhalation, is limited to neonates. The INOmax DS_{IR} is not intended to be used in other patient populations.**
- **Patient disconnect and high pressure alarms are required for the ventilator.**

The INOmax DS_{IR} is compatible with most types of ventilators by connecting into the inspired limb of a patient's breathing circuit. The system measures the gas flow in the breathing circuit and then injects NO/N_2 gas to produce the set NO concentration in ppm.

Ventilator Compatibility

	Measure	Specification
Inspiratory Flow Rate:	L/min	2 - 120
Respiratory Rate:	bpm	6 - 60
Airway Peak Pressure:	cmH_2O	0 - 70
PEEP:	cmH_2O	0 - 20

The INOmax DS_{IR} has been validated with the following ventilators.

Ventilators Transport	Airon Corporation	pNeuton
	Bio-Med Devices	Crossvent 2
	Bio-Med Devices	Crossvent 4
	Bio-Med Devices	MVP-10
	Impact Instrumentarium	EMV+
	Impact Instrumentation	Uni-Vent
	Infrasonics	InfantStar 100
	Smiths Medical	babyPAC 100
	Smiths Medical	ventiPAC 200D
	Smiths Medical	paraPAC Medic 200D
Neonatal	Bear	750ps (Cub)
	Bird	VIP
	Dräger	Babylog 8000
	Dräger	Evita
	Dräger	Evita Babylog VN500
	Dräger	Infinity V500
	eVent Medical	Inspiration LS
	GE Healthcare	Engstrom Carestation
	Hamilton	C2
	Hamilton	G5
	Hamilton	Galileo
	Infrasonics	Infant Star 500
	Infrasonics	Infant Star 950 (not HFV mode)
	Maquet (formerly Siemens)	Servo i
	Newport	E360
	Newport	Wave
	Puritan Bennett	840
	Respironics	Esprit
	Sechrist	IV-100B
	Viasys	Avea
	Viasys	Vela

Adult/Pediatric	Bird	VIP
	Dräger	Evita
	Dräger	Infinity V500
	eVent Medical	Inspiration LS
	GE Healthcare	Centiva/5
	GE Healthcare	Engstrom Carestation
	Hamilton	C2
	Hamilton	G5
	Hamilton	Galileo
	Maquet (formerly Siemens)	Servo 300
	Maquet (formerly Siemens)	Servo i
	Newport	E360
	Newport	HT50
	Newport	Wave
	Pulmonetic Systems	LTV 1000
	Pulmonetic Systems	LTV 1200
	Puritan Bennett	7200
	Puritan Bennett	840
	Respironics	Esprit
	Viasys	Avea
	Viasys	Vela
High Frequency	Bunnell	Life Pulse
	Sensormedics	3100A (standard and filtered circuits)
	Sensormedics	3100B (standard and filtered circuits)
Anesthesia	Dräger	Narkomed 2B
	GE Healthcare	Aespire 7100
	GE Healthcare	Aespire 7900
	GE Healthcare	Aestiva
	GE Healthcare	Aisys
	GE Healthcare	Avance
	GE Healthcare	Excel SE 7800
	GE Healthcare	Mod SE 7900
Nasal Continuous Positive Airway Pressure (CPAP)	Cardinal Healthcare	Airlife nCPAP System
	Fisher/Paykel	Bubble CPAP System
	Hamilton	Arabella
	Viasys	Infant Flow CPAP System
	Viasys	Infant Flow SiPAP
High Flow Nasal Cannula	Teleflex Medical	Comfort Flo Humidification System
	Vapotherm	2000i
	Vapotherm	Precision Flow

NO Delivery

Set NO Range:	0 - 80 ppm (800 ppm cylinder)
Set NO Resolution:	0.1 ppm from 0 to 1 ppm 1 ppm from 1 to 40 ppm 2 ppm from 40 to 80 ppm
Accuracy @ 20°C:	± 20% or 2 ppm, whichever is the greater
NO Inlet Pressure:	1.7 to 2.4 Bar (24.7 to 34.8 psig)
Maximum NO Supply Pressure:	2.4 Bar (34.8 psig)
NO Low Pressure Alarm:	1.6 Bar (23 psig)
Max Circuit Pressure:	1.4 Bar (20.3 psig)
Breathing Circuit Gas Composition:	Air / O_2 mixtures

Injector Module

Conical Connectors:	Inlet, 22 mm female. Outlet, 22 mm male and 15 mm female.
Autoclavability:	Autoclavable at 134°C for 3 minutes at 27 psig.
Maximum Pressure Drop:	1.5 cmH_2O at 60 L/min

Gas Monitoring

Gas	Range	Resolution	Accuracy
Nitric Oxide:	0 - 10 ppm	0.1	± (20% of reading + 0.5 ppm)
	10 - 100 ppm	1	± (10% of reading + 0.5 ppm)
Nitrogen Dioxide:	0 - 10 ppm	0.1	± (20% of reading or 0.5 ppm whichever is greater)
Oxygen:	18 - 100 % v/v	1	± 3% v/v

Max Breathing Circuit Pressure:	150 cmH_20
Calibration:	Daily zero; span when needed
Rise Time:	30 seconds (10 - 90 %)
Sample Flow:	230 mL/min

Backup Delivery

Backup Delivery = 250 mL/min Fixed Flow of NO/N_2

Physical

Delivery system	
Max. Weight:	5.3 kg
Max. Width and Depth:	350 mm W x 160 mm D
Max. Height:	220 mm

Environmental

	Operating:	Transport/Storage:
Temperature:	5 to 40°C	-20 to + 60°C
Humidity:	15 to 95% RH non-condensing	15 to 95% RH non-condensing
Ambient Pressure:	57 to 110 kPa	57 to 110 kPa
Water Ingress Protection:	IPX1	

INOMAX® Regulator

Inlet Pressure:	14 to 155 Bar (203 to 2,248 psig)
Outlet Pressure:	1.7 to 2.4 Bar (24.7 to 34.8 psig)
Cylinder Valve Connector:	CGA 626

Electrical

Important:	Disconnect main power cord to isolate equipment from main power.

Input Voltage:	100-240 V AC @ 50 / 60 Hz
Input Power:	110 VA max
Input Fuse:	3 A
Classification:	Class I, Type B
Standards:	ETL certified to meet IEC 60601-1: 1988 + A1:1991 + A2:1995 and 60601-1-2 (2nd Edition, Am 1) for medical electrical equipment.
Battery Backup:	A sealed lithium ion rechargeable battery provides power backup to operate the system for up to 6 hours when fully charged.
	Connect the system to an electrical outlet for at least ten hours to charge the battery.
	When the low battery alarm occurs, you have10 minutes until battery depletion.
	Dispose of used batteries according to local regulations.
USB Port:	Not used. Not for use when patient is connected.
Ethernet Port:	For service only. Not for use when patient is connected.
RS232:	Not used. Not for use when patient is connected.
Infrared Port:	Infrared communication with the INOMAX® cylinder.

Alarm Log

The alarm history is deleted when device is turned off. However, the service log which is accessible by service personnel is maintained (including alarm log) when power is cycled and/ or when total power loss occurs.

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