Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

Operation Manual

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

Series 3 software

Part No. 20717 Rev-01
2014-07

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 two. A defective Product should not be used. Parts that are broken, missing, visibly worn, distorted or contaminated should be replaced immediately.

Should such repair or replacement become necessary, the manufacturer recommends that a telephone request for service advice be made to the local distributor. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by the manufacturer or local distributor. The Product must not be altered.

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 Mallinckrodt Representatives.

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.

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

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.

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

Part No. 20717 Rev-01
2014-07

Contents

WARNING: **Warnings tell the user 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 the user 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:

Integrated Pneumatic Backup

- **The integrated pneumatic 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.**
- **The integrated pneumatic backup delivers a variable concentration of NO to the patient depending on the ventilator flow being used.**
- **When using the integrated pneumatic backup with breathing circuit gas flows of 5 L/min, the delivered NO dose will be approximately 40 ppm. Breathing circuit gas flows less than 5 L/min will deliver an NO dose greater than 40 ppm.**
- **The integrated pneumatic backup (250 mL/min.) should not be used with the Bunnell Life Pulse as ventilator flow rates are normally below the recommended ventilator flows.**

Changing Cylinders

- **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 combustible come in contact with a cylinder or valve.**
- **Never remove or deface cylinder labeling or markings.**
- **Never modify equipment without first contacting the manufacturer.**
- **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 experience extreme 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.**

WARNING:

High Frequency Oscillatory and Jet Ventilator Circuits

- **Some high frequency ventilator circuits require a one-way valve to prevent high NO delivery.**
- **Place the Bunnell 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.**
- **Do not use dose settings above 40 ppm with the Acutronics Fabian HFO ventilator. Bidirectional flow through the Injector Module may cause over-delivery which can lead to measured NO values greater than 100 ppm**

Maintenance

- **For continued protection against hazard, replace the fuses only with the correct fuse type and rating.**
- **Handle and dispose of sensors according to facility biohazard policies. Do not incinerate.**
- **If the Injector Module has been used in the wet/humidified part of the breathing circuit, it should be sterilized between each patient use.**
- **INOmax DS_{IR} should only be connected to RS-232 ports that have:**
  - **4 kV input to output isolation**
  - **4 kV input to mains isolation, and**
  - **an internal “reference voltage” “U” (as defined in section 20.3 of IEC60601-1 ed. 2) of less than or equal to 50 VDC or 50 VRMS and dielectric isolation certified in accordance with IEC 60601-1. Interface cabling must not go outside of the room (e.g., into walls where potential isolation issues could exist). Adherence to the above provides compliance to clause 20.3 “Value of test Voltage” in edition 2 and clause(s) 8.5.4 “Working Voltage” and Clause 8.8.3 “Dielectric Strength" in edition 3.**
- **RS232 cable must be shielded. The RS232 cable shield shall have a minimum of 90% coverage. The shield shall only be connected at one end of the cable to minimize noise induced by ground currents.**

Manually Bagging a Patient with an Injector Module

- **The hyperinflation bag will, under some conditions, contain NO_2 in excess of one 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.**

WARNING:

Manually Bagging a Patient with an Injector Module continued

- **To minimize the delivered concentration of NO_2, the following steps should be taken for use with the manual resuscitator bags:**
  - **Concentrations greater than 20 ppm NO should not be used because of excessive NO_2 generation.**
  - **Use the smallest bag adequate to deliver the desired tidal volume.**
  - **Oxygen tubing lengths greater than 72 inches should not be used (between the injector module and the bag).**
  - **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.**

Manually Bagging a Patient with the INOblender

- **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.**

Purging Cylinders

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

WARNING:

Use Outside of Product Labeling

- **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 manufacturer 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. The use of helium/oxygen mixtures will lead to over-delivery of INOMAX which may lead to interruption of therapy.**
- **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.**
- **Do not connect items which are not specified as part of the system.**
- **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.**

Transport

- **If the INOmax DS_{IR} or INOblender is to be used in a transport vehicle, they should be affixed to the transport mounting post (part number 10009), which is part of the transport mounting bracket assembly (part number 50041).**
- **The transport mounting post and/or the transport mounting bracket assembly should be secured to the transport isolette/transport gurney in a manner which will secure the INOmax DS_{IR}/INOblender.**

Troubleshooting or Calibrating

- **If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.**
- **Use caution when troubleshooting the INOmax DS_{IR} delivery system 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 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 there is a risk that the system will shut down.**
- **INOMAX can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**
- **Loss of communication between the INOmax DS_{IR} and the INOMAX cylinder for more than one hour will result in interruption of INOMAX delivery.**

WARNING:

Ventilators and Breathing Devices

- **The INOmax DS_{IR} subtracts gas from the breathing circuit via the gas sampling system at 230 mL per minute which can cause the ventilator to auto-trigger. Adjusting the flow sensitivity may be necessary. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS_{IR} to the breathing circuit.**
- **Set the INOmax DS_{IR} alarm thresholds for the current patient conditions to monitor any inadvertent changes in treatment.**
- **Be certain all cables and hoses are positioned to help prevent damaging or occluding them.**
- **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.**
- **The humidifier chamber volume should not be more than 480 mL to prevent elevated NO_2 values.**
- **When handling any component of the patient circuit that comes in contact with patient's fluids wear personal protective equipment (PPE).**
- **Patient disconnect and high pressure alarms are required for the ventilator.**
- **Patient circuit pressure and gas loss will result if cap is not in place (secured).**
- **Use only "Latex-Free" breathing circuits and ventilators when using the INOmax DS_{IR}.**
- **If the INOmax DS_{IR} is to be used in a transport vehicle, it should be affixed to the transport mounting post.**
- **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.**
- **Only use parts/accessories designated for use with this system.**

(Intentionally left blank)

INOmax DS$_{IR}$® Plus

1 / General Information

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

1/ General Information

Part No. 20717 Rev-01
2014-07

1/ General Information

Indications for Use

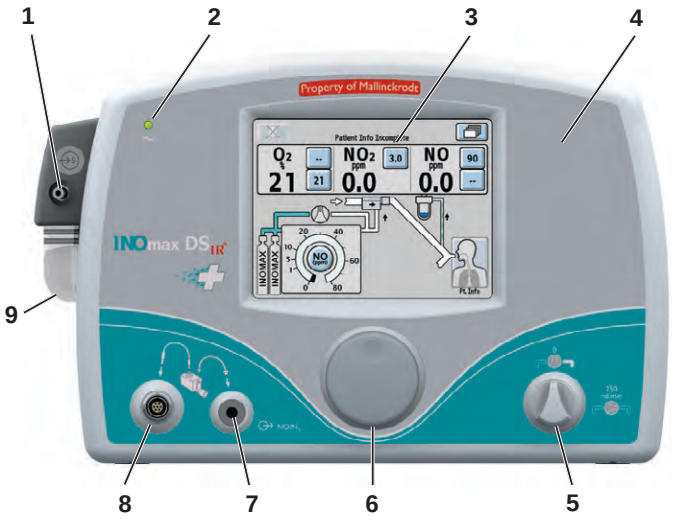
- The INOmax DS_{IR} (delivery system) delivers INOMAX (nitric oxide for inhalation) therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath. It uses 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 six 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 patient's breathing circuit. It may also use the INOblender for backup.
- The target population is controlled by the drug labeling for INOMAX which is currently neonates; refer to the drug label for specific information. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates.

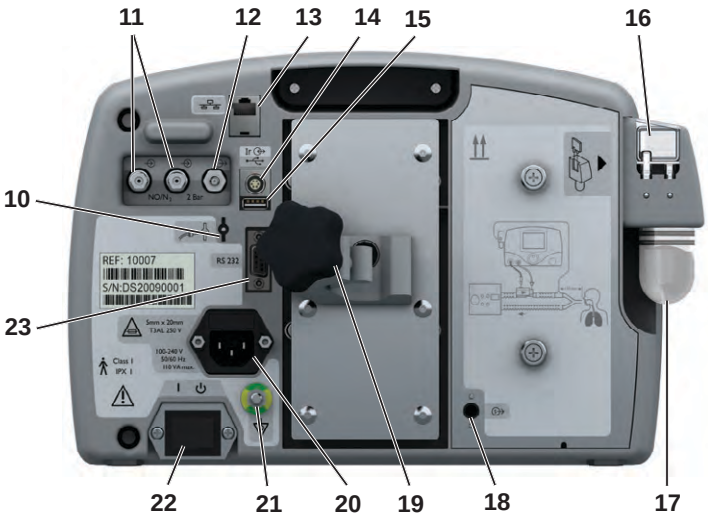
Introduction to this Manual

Definitions and abbreviations

Term	Definition
% v/v	% volume/volume
Breathing circuit	Part of ventilator or breathing system that connects to the INOmax DS_{IR}®.
Breathing system	Non-invasive breathing devices.
Control wheel	Rotary control used to change and confirm settings.
Cylinder	Aluminum cylinder containing INOMAX® therapy gas.
HFOV	High frequency oscillatory ventilation.
INOblender®	Back up to the INOmax DS_{IR}. Allows manual ventilation of the patient, providing uninterrupted delivery of INOMAX.
INOMAX	Nitric oxide for inhalation.
INOmeter®	Counter mounted on a cylinder that records the amount of time the INOMAX cylinder valve is open.
Infrared ($_{IR}$)	Infra-red technology by which the INOmax DS_{IR} communicates with the INOmeter mounted on each cylinder.
N_2	Nitrogen.
NO	Nitric oxide.
NO_2	Nitrogen dioxide.
O_2	Oxygen.
ppm	Parts per million.
Pre-use circuit	Connectors and tubing assembly required for INOmax DS_{IR} for pre-use checkout.
psig	Pounds per square inch gauge.
Set NO	Dose of INOMAX set by the user.

This manual shows the Set NO displays associated with the 0-80 ppm range.

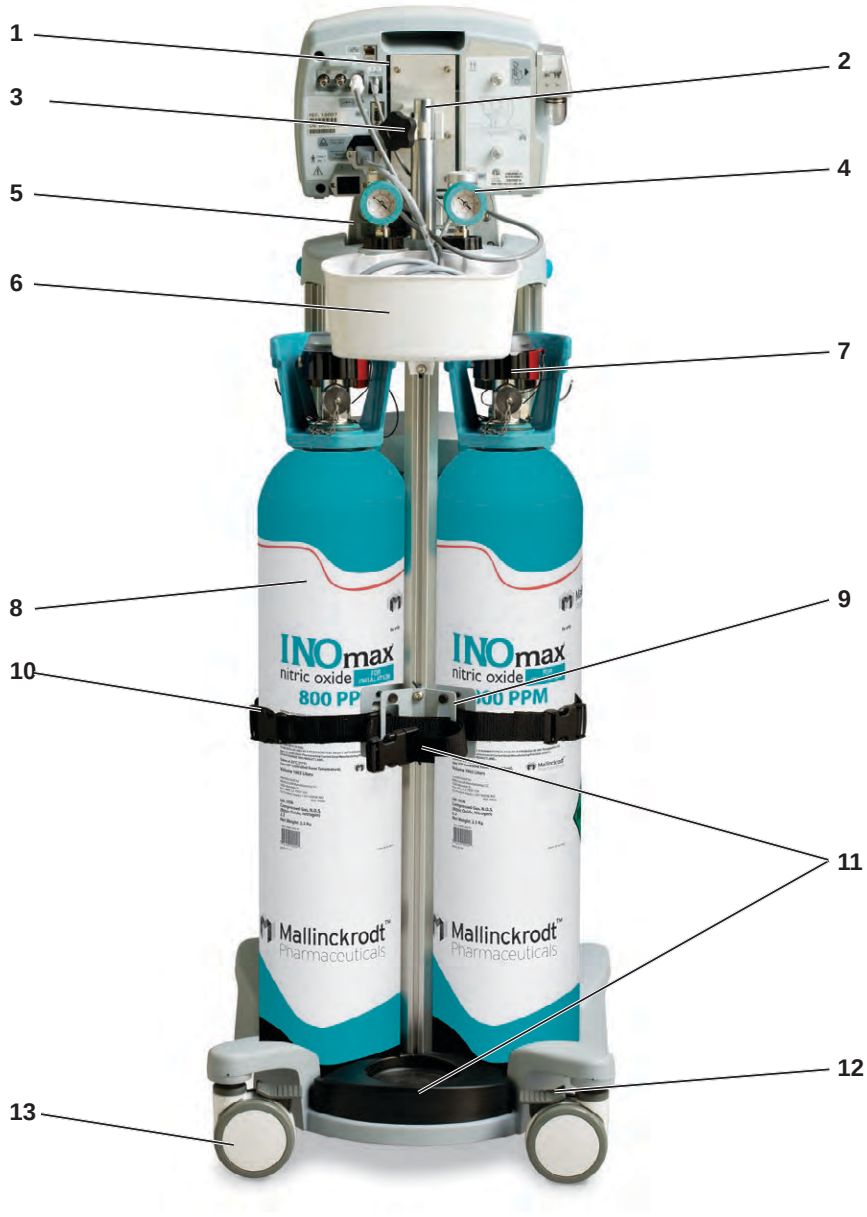




1. Sample Line Inlet
2. Main Power Indicator
3. Display Screen
4. Alarm Speaker (under front label)
5. Integrated Pneumatic Backup Switch
6. Control Wheel
7. Injector Module Tubing Outlet
8. Injector Module Cable Inlet
9. Water Trap Bottle
10. Purge Port
11. INOMAX Gas Inlets
12. Blender Gas Outlet
13. Ethernet Port
14. Infrared Connector
15. USB Port
16. Water Separator Cartridge
17. Water Trap Bottle
18. Sample Gas Outlet Port
19. Clamp Assembly
20. Electrical Cord Inlet
21. Equipotential Terminal
22. ON/Standby Switch
23. RS232 Port

Figure 1-1 INOmax DS_{IR} Front View

Figure 1-2 INOmax DS_{IR} Rear View



1. INOmax DS_{IR}
2. INOmax DS_{IR} Mounting Post
3. Clamp Assembly
4. INOMAX Regulator (2)
5. INOblender
6. Small Part Bin
7. INOmeter
8. INOMAX Cylinder
9. Cylinder Holding Bracket
10. Cylinder Mounting Strap
11. Oxygen Cylinder Bracket
12. Caster Lock Lever
13. Caster (4)

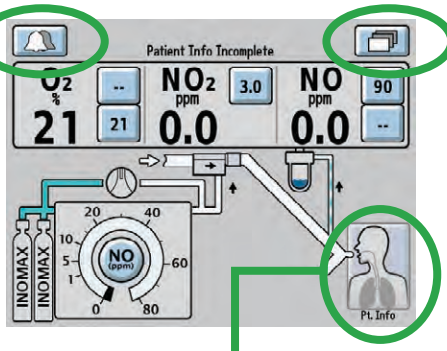
Figure 1-3 INOmax DS_{IR} and Cart

(Intentionally left blank)

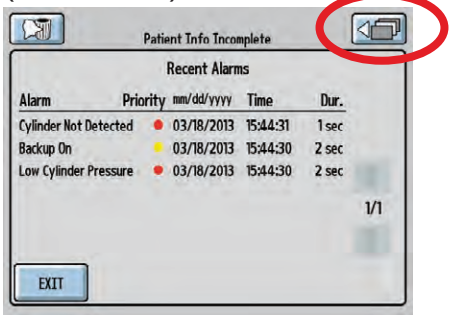
Navigating the Display Screens

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

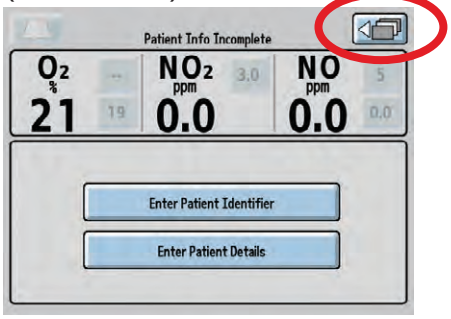
Main Screen (first level)



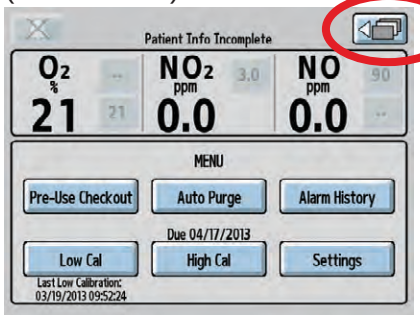
Recent Alarms Screen (second level)



Patient Information Screen (second level)

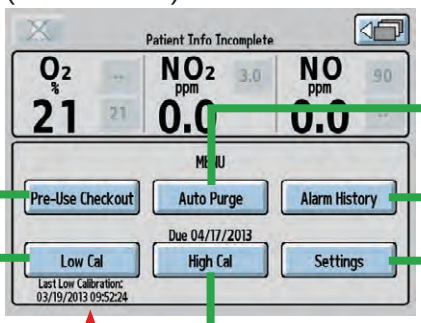


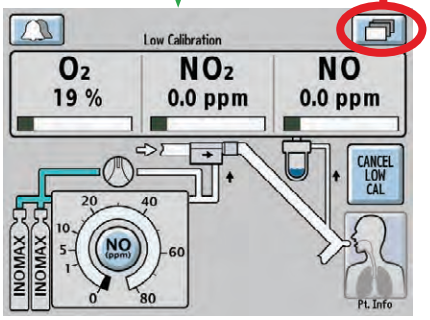
Menu Screen (second level)



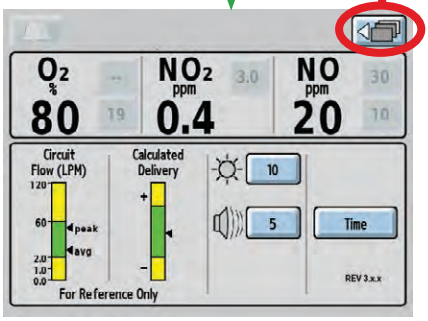
Navigating the Menu Screen (see page 1-8)

Menu Screen
(second level)

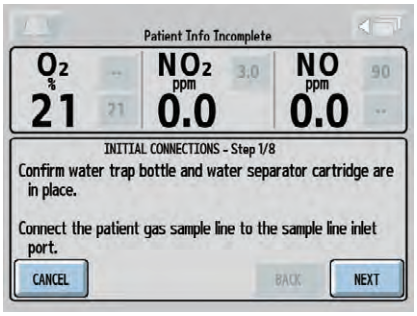




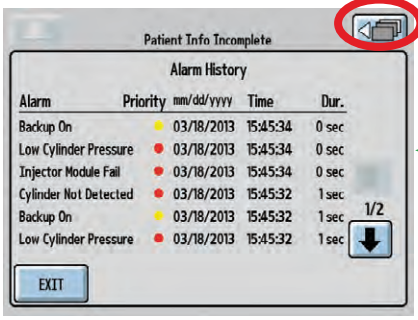
Low Calibration Screen



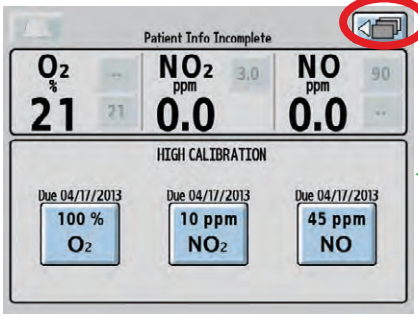
Settings Screen



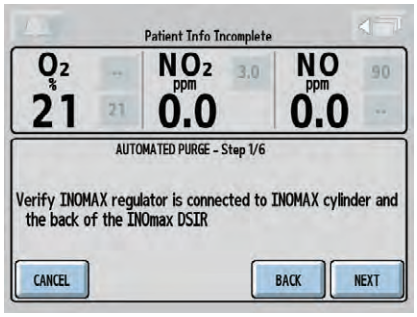
Pre-Use Wizard



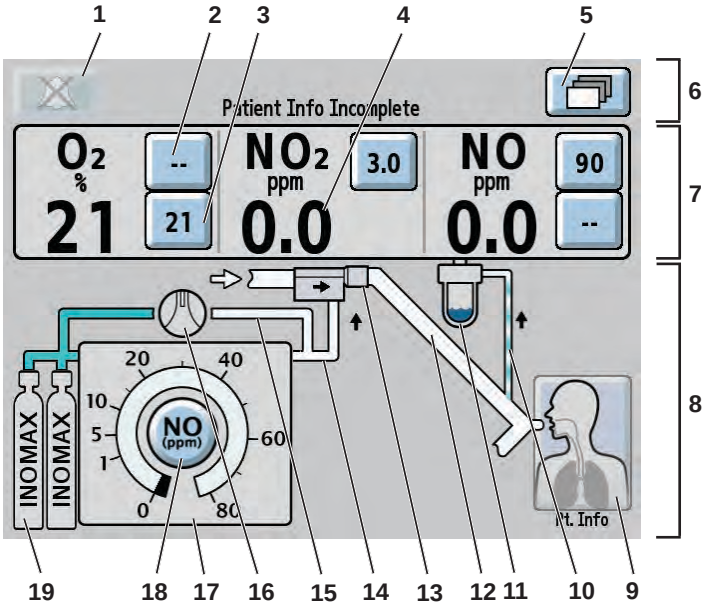
Alarm History Screen



High Calibration Screen



Automated Purge Screen

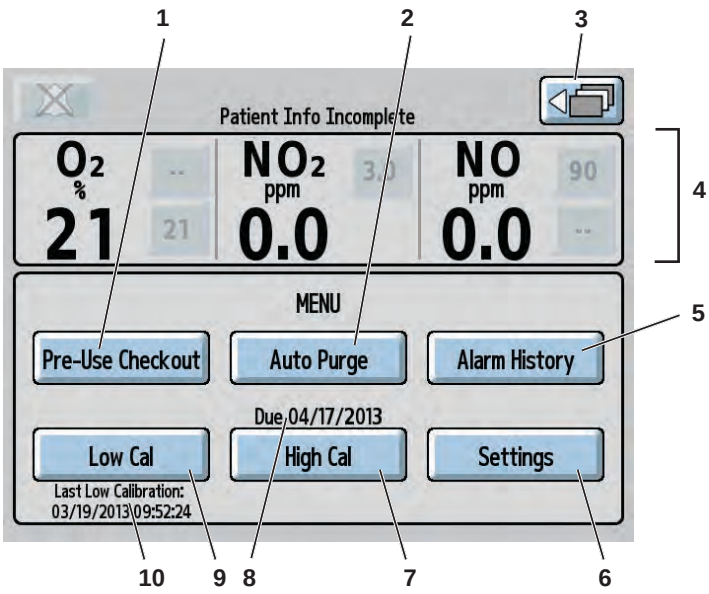


1. Alarm Silence Button
2. Upper Alarm Limit Button
3. Lower Alarm Limit Button
4. Monitored Value
5. Menu Button
6. Text Message Area
7. Monitor Area
8. Graphical Area
9. Patient Information Button
10. Sample Line Icon
11. Water Trap Bottle Icon
12. Inspiratory Limb Icon
13. Injector Module Icon
14. Delivery Line Icon
15. Integrated Pneumatic Backup Line Icon
16. Integrated Pneumatic 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. Pre-Use Checkout Button
2. Auto Purge Button
3. Return to Previous Level Button
4. Monitor Area
5. Alarm History Button
6. Settings Button
7. High Calibration Button
8. High Calibration Due Date
9. Low Calibration Button
10. Last Low Calibration Date

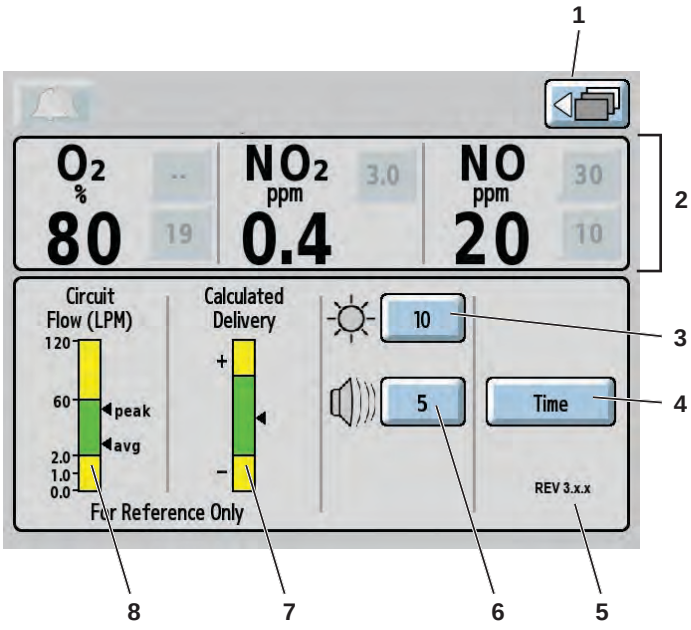
Figure 1-5 Menu Screen (second level)

Menu Screen (second level)

- On the menu screen the user can access the Pre-Use Checkout (#1) and the Auto Purge (#2) wizards.

Note: The Pre-Use Checkout and Auto Purge buttons are inactive (greyed out) if a dose is set.

- To review the complete alarm history, press the Alarm History button (#5), (refer to Section 5/ Alarms).
- To initiate a low (room air) or high calibration, press either the Low Cal (#9) or High Cal (#7) buttons. (refer to Section 6/ Calibration).
- Press the Settings button (#6) to view circuit flow and calculated delivery graphs, change display brightness, change alarm volume, change time zone and view software revision (see Figure 1-6).



1. Return to Previous Level Button
2. Monitor Area
3. Display Brightness Button
4. Time Adjust Button
5. Software Revision
6. Alarm Volume Button
7. Calculated Delivery Graph
8. Circuit Flow Rate Graph

Figure 1-6 Settings Screen

Settings Screen (third level)

- The circuit flow graph, combined with calculated delivery graph, is a user level tool to ascertain NO delivery system limitations in the context of mechanical ventilation.
- The circuit flow rate graph displays the real time peak and average flow rate in the breathing circuit over a 10 second time period, as measured by the injector module. The area in green represents the circuit flow range where the INOmax DS_{IR} system is rated to deliver NO from 1-80 ppm. (see maximum NO delivery graph page 1-25). Display graphic areas in yellow represents where some inaccuracy of NO delivery is to be expected.
- The calculated delivery graph displays the delivery subsystem calculated % error in NO delivery compared to the desired set dose over a 10 second time period. The green to yellow transition points are defined to be NO delivery error of +20% (over-delivery) to -20% (under-delivery) compared to the desired NO set dose. High set dose levels, high peak inspiratory flows and proportional NO flow control inaccuracies can contribute to the indicating arrow varying from the ideal midpoint.

Note:

- If the NO dose is not set, both graphs will remain inactive.
- See page 1-25 for further explanation of maximum deliverable NO concentration.

Display and user controls

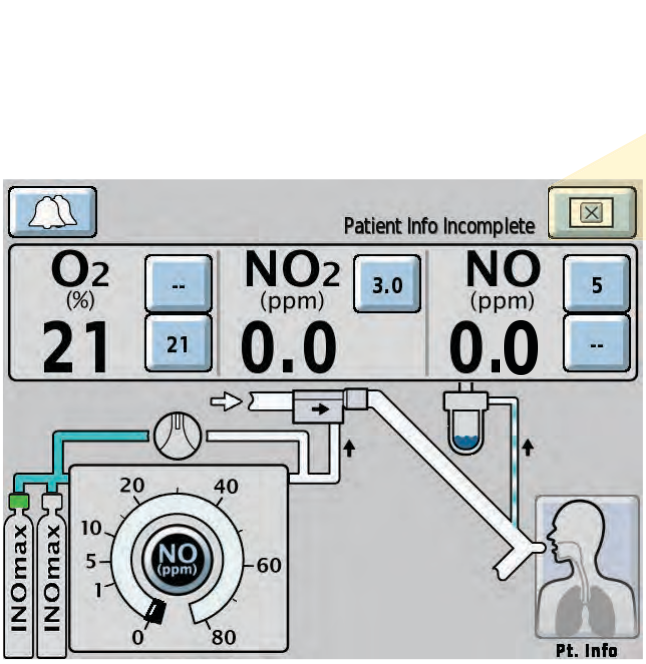
The INOmax DS_{IR} has a color touch screen display and a control wheel for adjusting and entering user settings. The buttons on the touch screen and the control wheel perform a variety of functions using a three-step procedure (see “Setting and making changes on the INOmax DS_{IR}” see page 1-12).

The touch screen buttons and control wheel are used to:

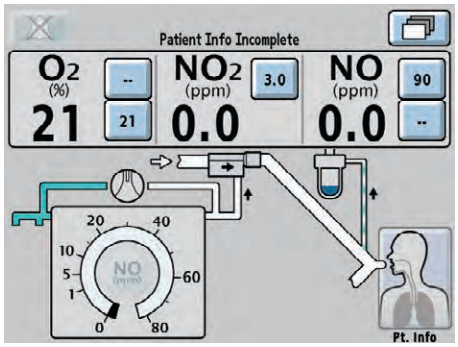
- Set the concentration of delivered NO
- Adjust alarm limits
- Silence alarms
- Calibrate the sensors
- Review alarm history
- Define setup options
- Enter patient information

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 greyed out, it is not active.
- Position delivery system so user screen is unobstructed and the speaker is not covered.



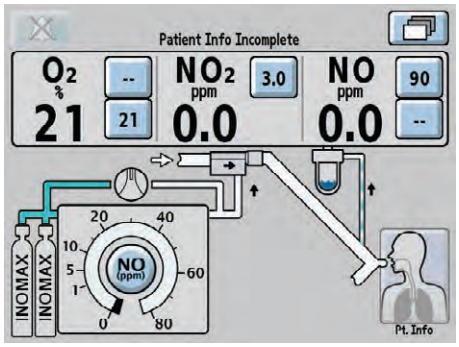
When a value is being changed, pressing the "Cancel Active Status" button during editing will stop the change and return the parameter to its original value (similar to the escape key on a computer).



Main Screen

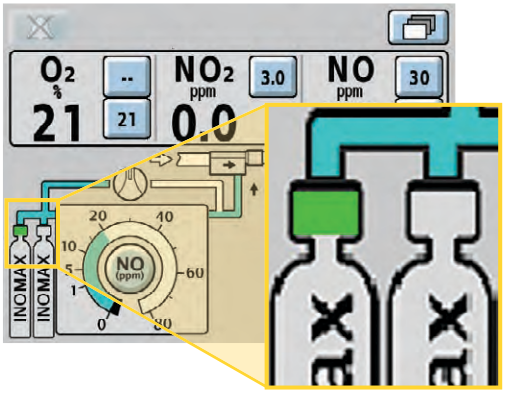
Cylinder icons are not visible and the NO delivery setpoint button will remain inactive until the INOmax DS_{IR} recognizes an INOMAX cylinder.

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 1-15).



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.

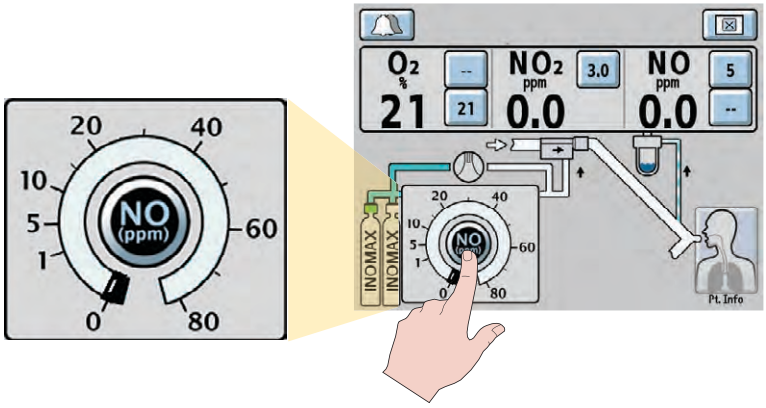
Setting and making changes on the INOmax DS_{IR}

Dose settings

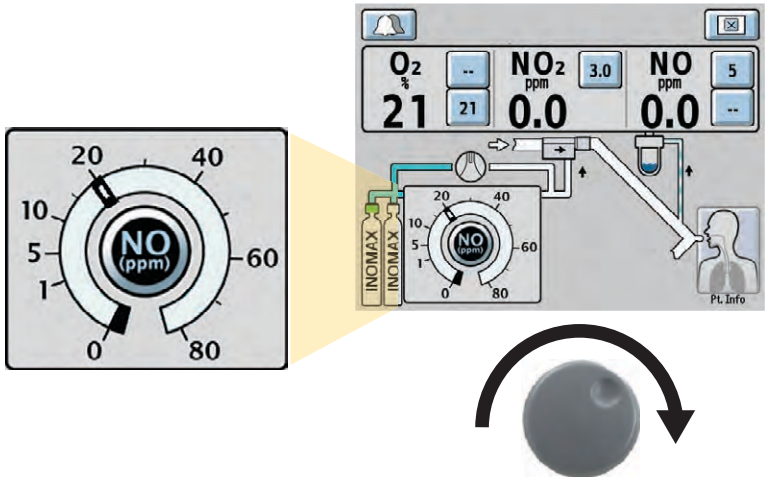
Displayed dose settings are 1, 5, 10, 20, 40, 60 and 80 ppm. Each click on the control knob corresponds to a known change in dose. The incremental dose per click corresponds to a value dependent upon the dose range in which the change is made, as illustrated in the table at right.

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

Dose Settings Adjustments

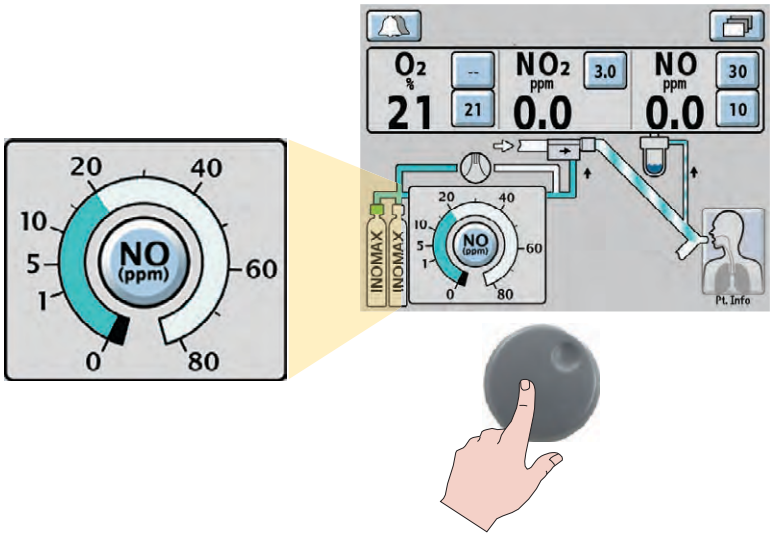


1. SELECT
(press) a button on the touch screen associated with the desired function. (An audible beep will sound when a button is selected, and the button will be displayed in inverse video.)



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

Part No. 20717 Rev-01
2014-07



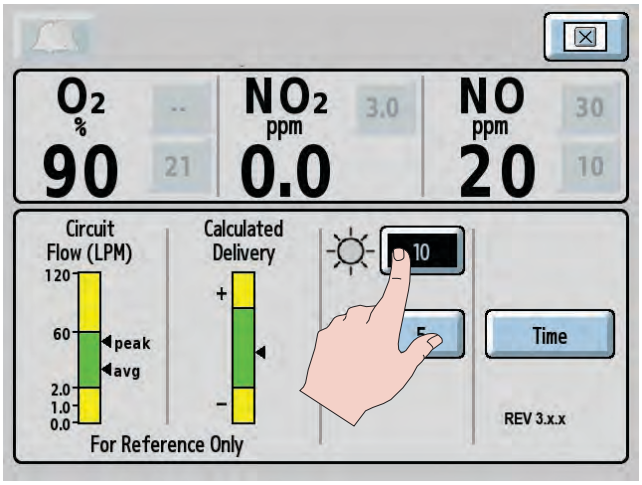
3. CONFIRM
the selection by pressing the control wheel or the button associated with the desired function again.

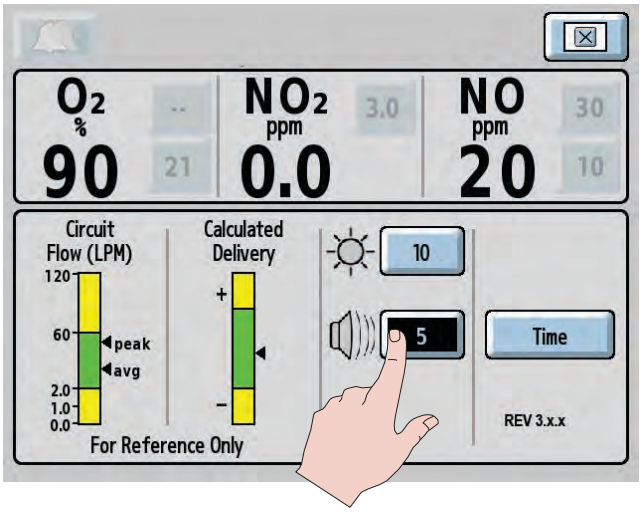
Note:

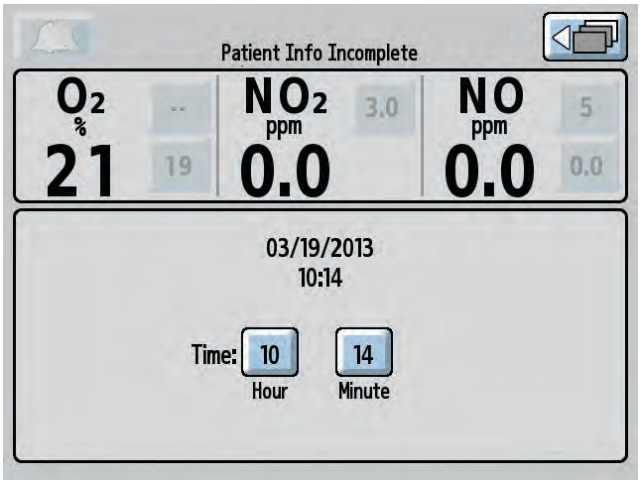
- After confirming a desired dose, the NO alarm setting (high and low) will automatically be set for the first setting only.
- Any other changes will require the high and low alarm settings to be adjusted.
- Also a two minute lockout period will prevent the low NO monitoring alarm from occurring while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

  The Monitor Alarm Delay Active indicator is not active following a dose change from zero.

Settings Screen Adjustments





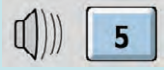


Access the settings screen (third menu level).

Display Brightness setting

1. Push the display brightness button on the touch screen. 
2. Turn the control wheel to indicate the display brightness level desired. Choices range from one (darkest) to 10 (brightest).
3. Push the control wheel to confirm the selection.
4. When finished with the menu screen, push the return to previous level button on the touch screen. 

Alarm Volume setting

1. Push the alarm volume button on the touch screen. 
2. Turn the control wheel to indicate the volume level desired. Choices range from one (softest) to five (loudest).
3. Push the control wheel to confirm the selection.
4. When finished with the menu screen push the return to previous level button on the touch screen. 

Time Adjust setting

1. If the "Time" button is pressed the Time Adjust screen will appear. 
2. Press the Hour or Minute button on the touch screen.
3. Turn the control wheel to adjust the displayed hour or minute.
4. Push the control wheel to confirm the selection.
5. When finished with the menu screen push the return to previous level button on the touch screen. 

Note: Changing the displayed time does not impact the time written to the INOmeter since the time written to the INOmeter is the GMT time, not the displayed time.

Infrared Communication between the INOMAX Cylinders and the INOmax DS_{IR}

WARNING: **Loss of communication between the INOmax DS_{IR} and the INOmeter for more than one hour will result in interruption of INOMAX delivery.**

The INOmax DS_{IR} has an interface using infrared (IR) technology which allows 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 (see Figure 1-7, 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 (see Figure 1-7, 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 1-17).

Caution: Nothing should be placed between the INOmeter and the cart to which it is attached.

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 1-7). The specifications of the IR beam call for it to have a range of 20 cm (7.9 in). Based on these specifications it sould 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 is mounted on the INOmax DS_{IR} cart.

Caution: A strong magnetic field could affect the ability of the INOmeter to detect if the cylinder valve is opened or closed. This may affect the ability of the INOmax DS_{IR} to detect the position (open or closed) of the cylinder valve.

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 there is a set INOMAX dose.

If IR communication interference occurs, we recommend taking 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 (PN 10022) may be utilized.

External Light Interference

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.

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 there is a set INOMAX dose.

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 taking the following actions:

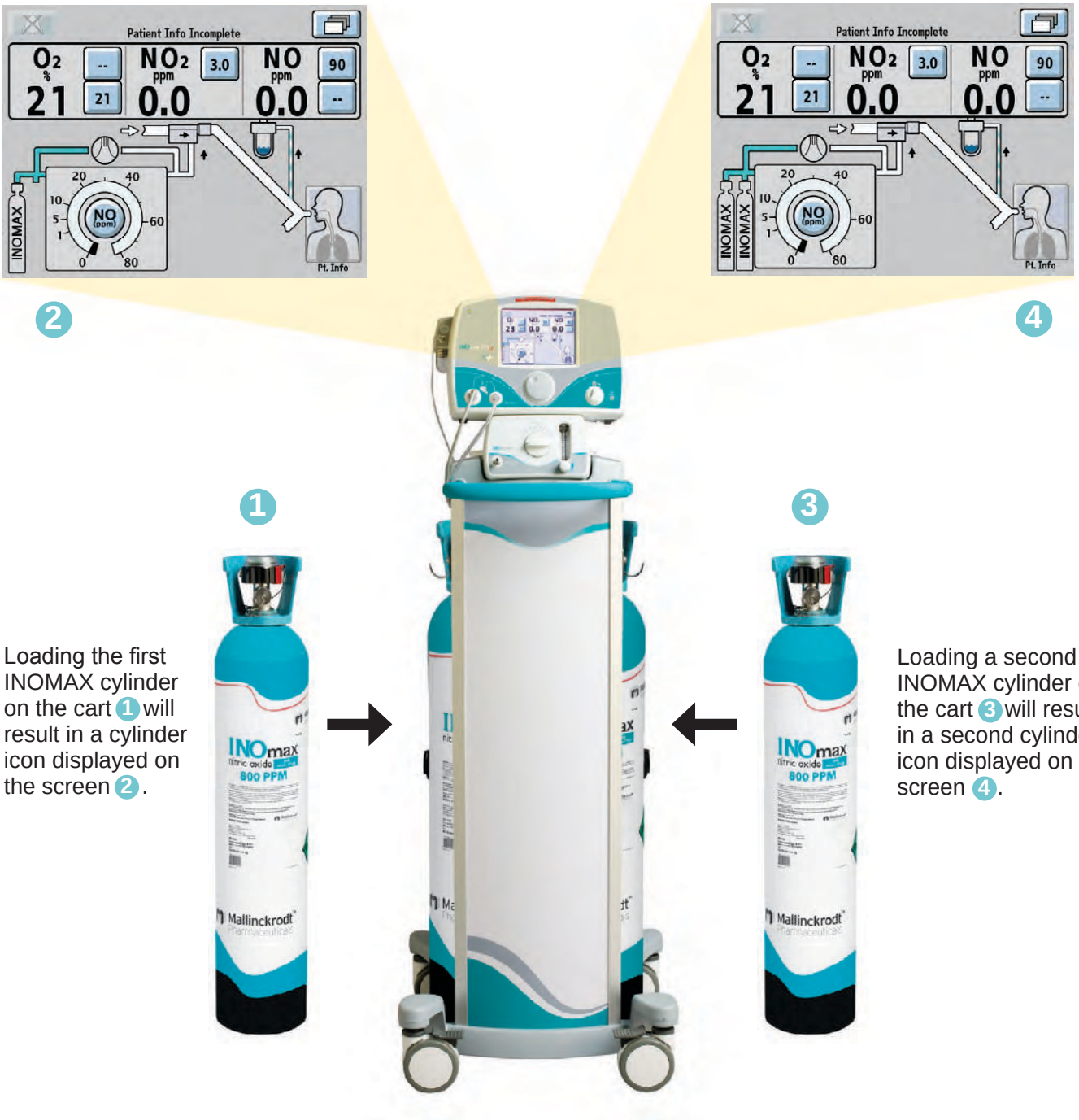
- Move the interfering light source
- Move the INOmax DS_{IR} cart to reduce the high intensity light in the area of the INOmeter
- Shield the INOmeter from the suspect light source

If the actions listed above do not remedy this issue, the transport regulator/cap assembly may be utilized.

Figure 1-7

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.



INOmeter Operation

- Removal of the INOmeter from the cylinder must be performed by authorized personnel. Do not dispose of the INOmeter.
- INOmeter battery replacement is only to be performed by authorized personnel.
- The INOmeter replaces the standard rubberized cylinder valve handle on the INOMAX cylinders and is used to open and close the cylinder valve. The INOmeter is a time-metric device which records the amount of time the INOMAX cylinder valve is opened.
- The INOmeter is designed for use with INOMAX cylinders and with the INOvent, INOmax DS and INOmax DS_{IR} delivery systems.
- When used with INOmax DS_{IR}, two-way infrared (IR) communication occurs between the INOmax DS_{IR} and the INOmeter. The INOmeter communicates the INOMAX cylinder concentration and the expiration date to the INOmax DS_{IR}. Patient ID (when confirmed) and dose information are communicated from the INOmax DS_{IR} to the INOmeter.

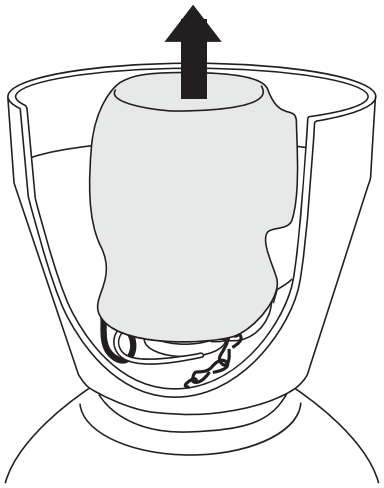


Figure 1-8

Note:

- Cylinders are shipped with the INOmeter covered in a tamper-proof seal.
- A valve lock is secured to the cylinder by a lanyard.
- The lock must be removed to open the cylinder valve for use.

1. Remove and properly dispose of tamper-proof seal or covering (see Figure 1-8).

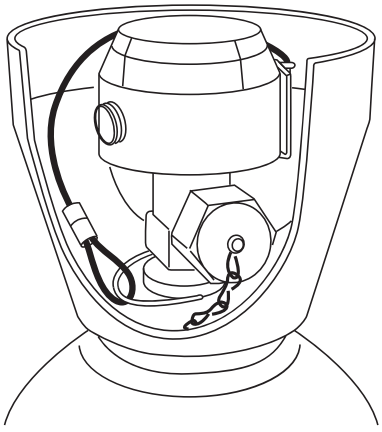


Figure 1-9

2. The lock is secured to the cylinder by a lanyard (see Figure 1-9).

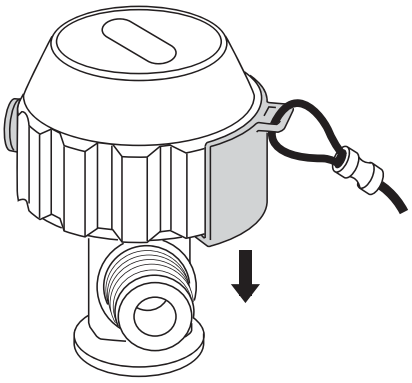


Figure 1-10

3. Press lock downward to remove from the INOmeter (see Figure 1-10).
4. The cylinder must be closed to reinsert the lock. Align directly across from the iButton and press upward into socket to attach lock (see Figure 1-11).

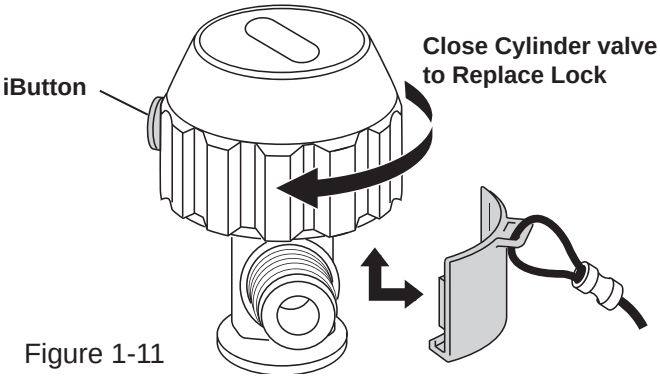


Figure 1-11

Note:
- The INOmeter is used to open and close the cylinder valve.
- Counter-clockwise rotation of the INOmeter serves to open the cylinder valve (see Figure 1-12).
- Clockwise rotation acts to close the cylinder valve (see Figure 1-13).

Figure 1-12 Cylinder Open

5. When the INOmeter is turned ON (cylinder open) the display will show a "+" (positive) sign (see Figure 1-12) and alternate between:
   a. The event time XX.X in hours since turned ON (eight seconds).
   b. The total cumulative time XXX in hours of all the ON events (four seconds).
   c. The display alternates between a and b for the indicated times in parenthesis above.

Note: If display is blank, replace cylinder.

Figure 1-13 Cylinder Closed

6. When the INOmeter is turned OFF (cylinder closed) the display will show a "-" (negative) sign (see Figure 1-13) and alternate between:
   a. Showing - - - on the display (eight seconds).
   b. The total cumulative time XXX in hours of all the ON events (four seconds).
   c. The display alternates between a and b for the indicated times in parenthesis above.

Note: If display is blank, replace cylinder.

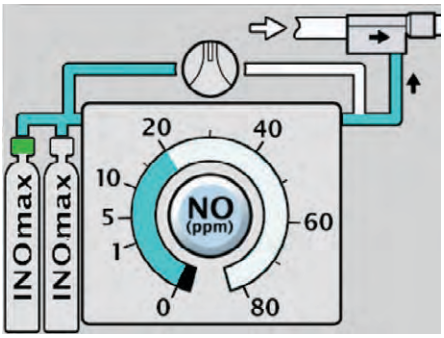


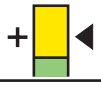
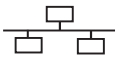
Figure 1-14

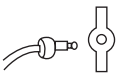
When the cylinder valve is open and delivery is normal, the main screen shows the handle as green (see Figure 1-14).

Note: When two INOMAX cylinders are loaded onto the cart and if both cylinder images do not appear on user screen, check to see if IR or light interference is suspected (see page 5-9 for troubleshooting). If there is no light interference, replace suspected right or left INOMAX cylinder.

Symbols used in this manual or on the system

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

	Alarm Silence
	Attention, consult accompanying documents!
134˚C	Autoclavable
◀avg	Average Flow Rate
EC REP	CE European Representative
CE	CE Mark
	Do Not Push
EHR	Electronic Health Record
	Equipotential Stud
	Estimated Dose Greater than 20% Calculated
	Estimated Dose Less than 20% Calculated
	Ethernet Port
	Fuse Rating
Ir 	Infrared Input/Output
	Injector Module
	Keep Dry
LOT	Lot Number
Low Cal	Low Range Calibration
	Main Power Connected
MAX	Maximum
	NO Backup OFF
	NO Backup ON

	NO Gas Inlet
	NO Gas Outlet
	Not Autoclavable
	On
◀peak	Peak Flow Rate
	Pneumatic Inlet
	Pneumatic Outlet
Rx ONLY	Prescription use only
	Purge Location
	Running on Battery
	Sample Gas Inlet Port
	Sample Gas Outlet Port
	Separate Collection
SN	Serial Number
	Standby
REF	Stock Number
	Type B Electrical Equipment
 YYYY-MM	Use by yyyy-mm
	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 1-15 for a schematic diagram).

1. INOMAX drug is stored as a gas mixture of NO/N_2 in an aluminum cylinder at a concentration of 800 ppm.
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 device.
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 1-16).
6. An internal flow sensor verifies the INOMAX flow from the proportioning valve, providing feedback to adjust the flow real time. This assures the calculated INOMAX flow necessary to achieve a given dose based on reported injector module flow. A one-way valve separates the flow sensor from potential reverse flow that may come from the ventilator circuit.
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.

    7a. The zero valve allows the gas sensors to be zeroed (during low calibration) without having to disconnect the sample line from the breathing circuit.

    7b. The pump and sample flow sensor ensure a sample gas flow rate is maintained to the monitoring sensors.

    7c. 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. Integrated Pneumatic Backup - 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 which is built into the delivery side of the system. This fixed flow of INOMAX will provide 20 ppm of NO when added to a continuous ventilator gas flow of 10 L/min. The backup is only for short term use until a replacement delivery system can be obtained. The "Backup On" alarm will warn the user whenever backup is on and the backup on window will be displayed. The INOblender can also be used as a backup.

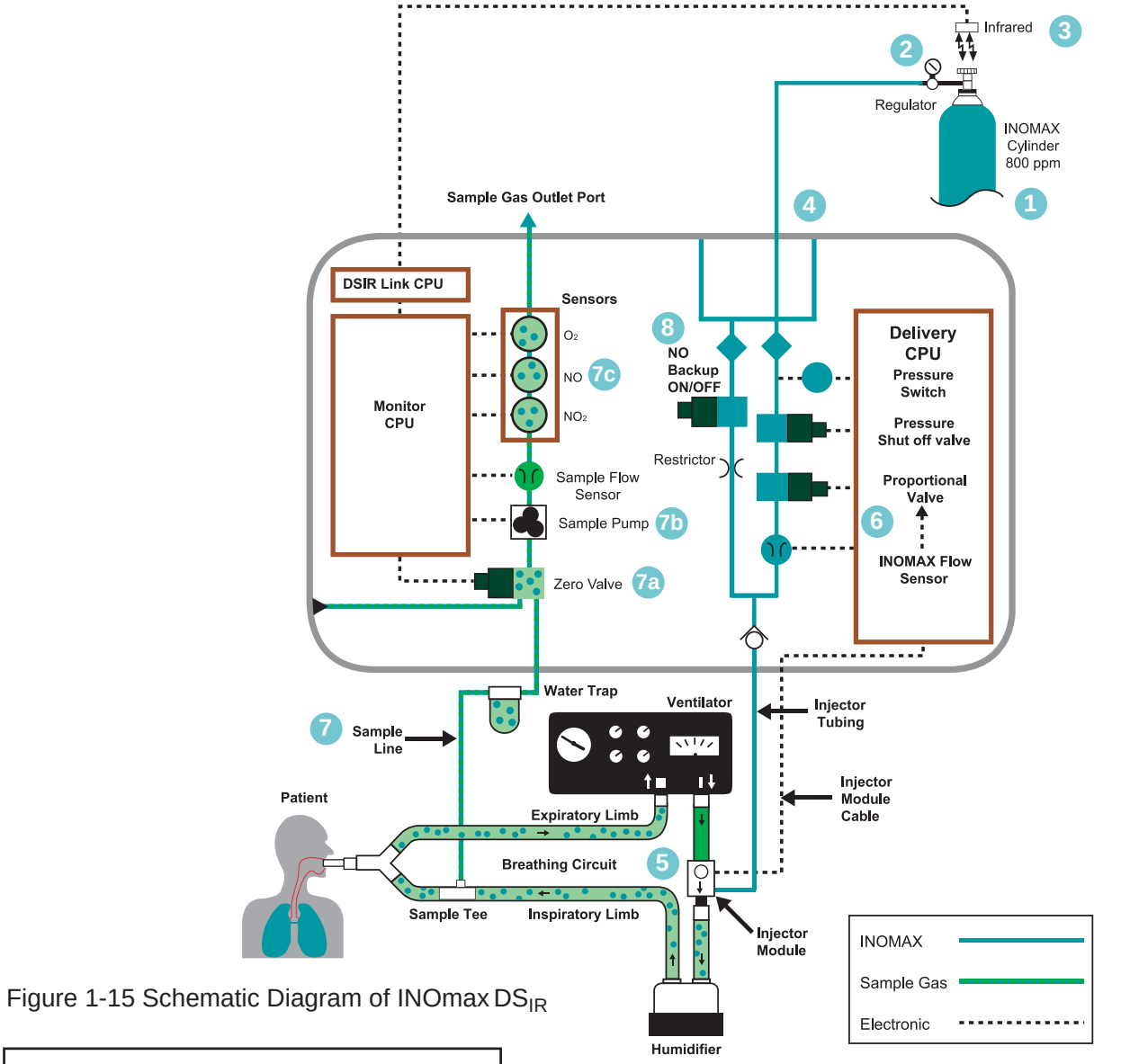


Figure 1-15 Schematic Diagram of INOmax DS_{IR}

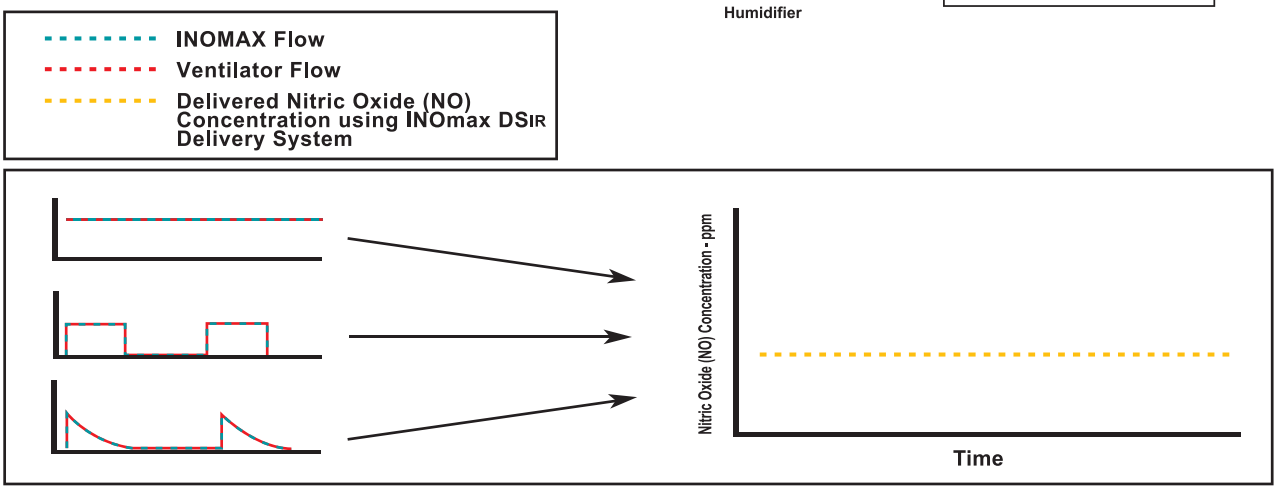


Figure 1-16 INOMAX injection method provides a constant NO concentration

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

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

1. 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 NO setting of 20 ppm with an 800 ppm NO cylinder, the INOmaxDS_{IR} adds 2.5% more gas to that delivered by the ventilator and proportionally less for lower NO settings.
2. 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 the INOMAX dose setting of 20 ppm, the added gas is 2.5%. Thus, the O_2 concentration is reduced by 2.5% of its original value. For example, if the original O_2 concentration was 60% v/v, then the O_2 value after injection, at the maximum setting, is 58.5% v/v.

Set Dose (ppm) 800 ppm Cylinder	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 INOmaxDS_{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:

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

For a dose of 20 ppm (800 ppm cylinder) 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 one L/min. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS_{IR} delivery system.

Circle Anesthesia Ventilator Systems

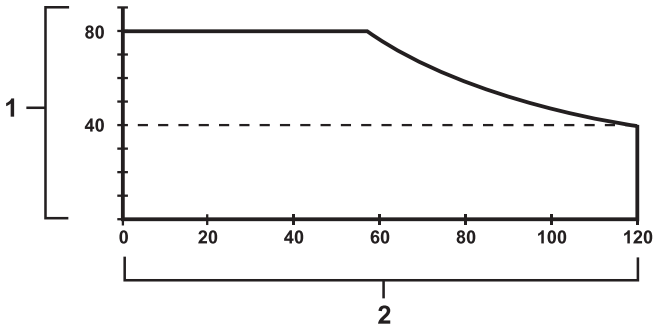
The use of the INOmax DS_{IR} with circle anesthesia ventilator systems (which use volume ventilation causes small changes in the delivered minute volume as noted previously (see Minute Volume, page 1-24).

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 INOmaxDS_{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 patient through the inspiratory limb of the breathing circuit.

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 which exceed 120 L/min may be achieved. 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 within 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).

For the test distilled water was used 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 six 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 nine 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	1000 ft^3
Room volume	28,300 L
Room ventilation (6 complete exchanges/hour)	2,830 L/min
NO flow into the room	80 ppm at 14 L/min
Average NO room concentration (80 x 14) ÷ 2,830 (80 x 14) ÷ 2,830 = 0.396 ppm (0.4 ppm)	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:

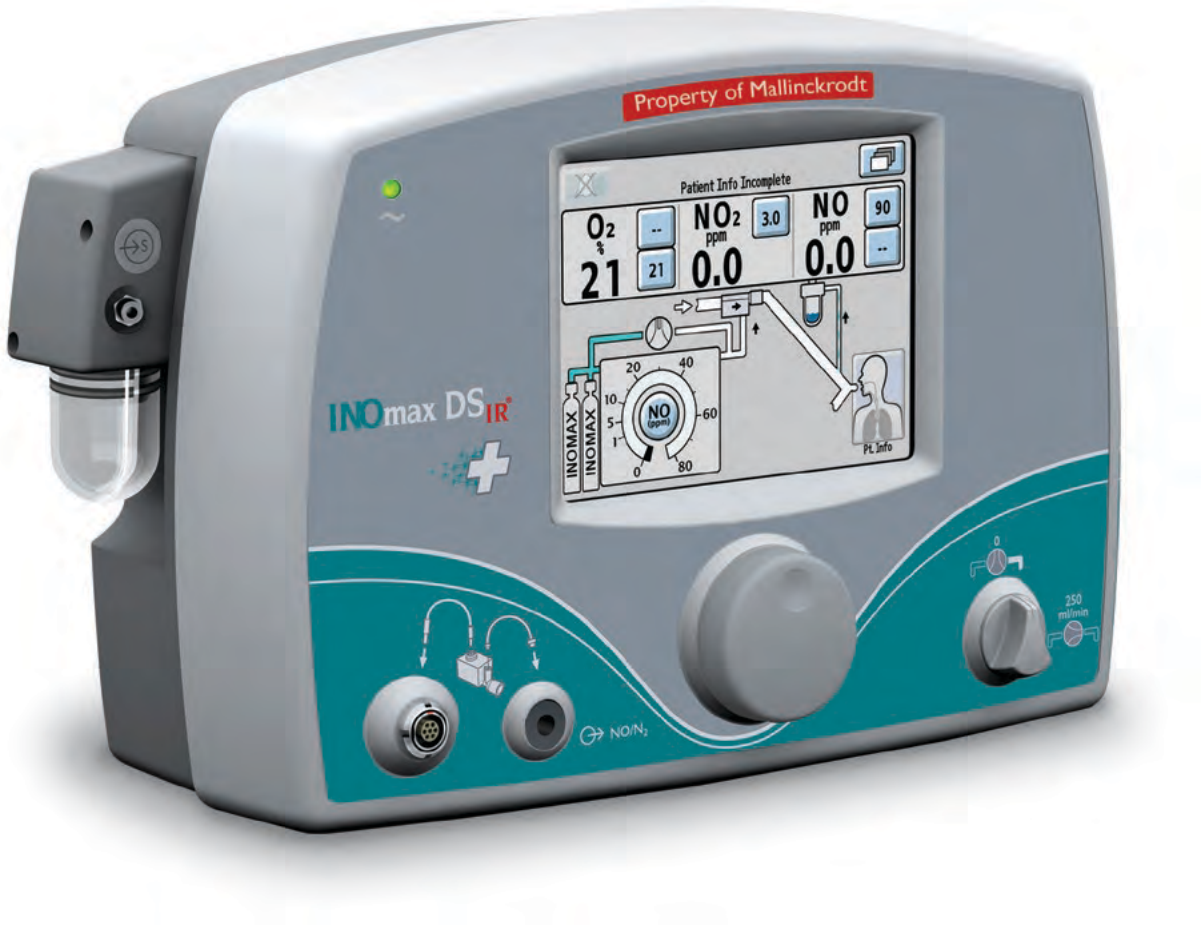
(Ref. 1) Centers for Disease Control, Atlanta, GA 30333 USA.

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.

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



2/ Automated Pre-Use Checkout

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

Automated Pre-Use Checkout

INOmax DS$_{IR}$® Plus

2/ Automated Pre-Use Checkout

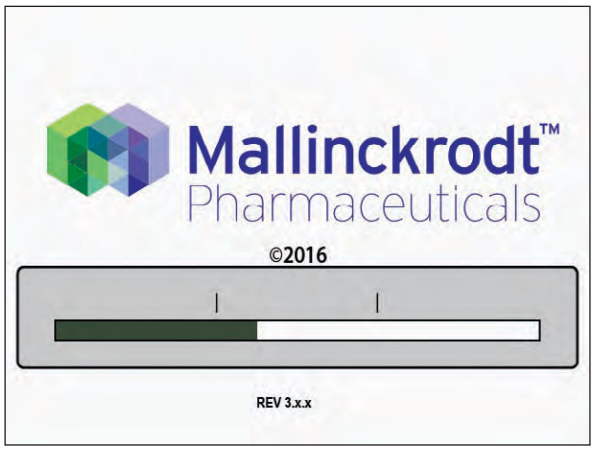
Part No. 20717 Rev-01
2014-07

2/ Automated Pre-Use Checkout

Note: Following unpacking and prior to the first use:

- 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.

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.



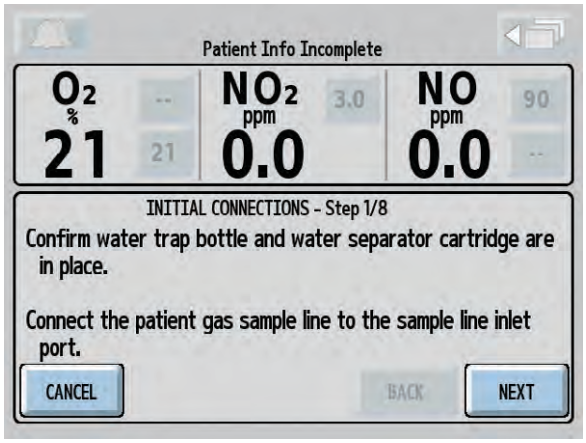
Self Test Screen

Turn ON INOmax DS_{IR}.

An INOmax DS_{IR} splash screen will appear once the device is turned ON followed by a Mallinckrodt test screen (confirm that the speaker sounds).

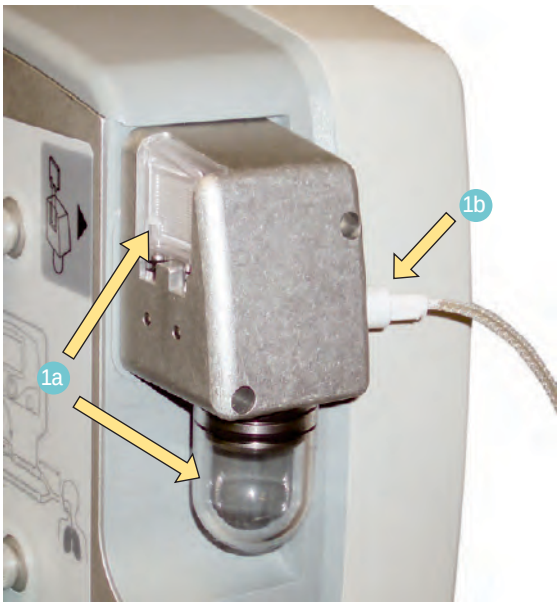
Note:

- Low calibration automatically starts following the INOmax DS_{IR} self test.
- A Pre-Use wizard will be displayed on the main screen, which will provide step-by-step instructions to complete the pre-use procedure.



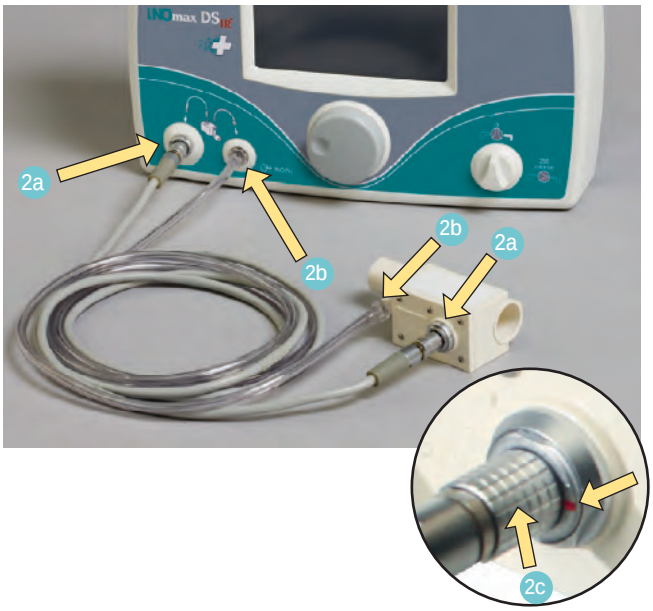
- Pressing the NEXT button initiates the Pre-Use wizard.
- Pressing the CANCEL button exits the Pre-Use wizard. If you cancel out of the pre-use wizard, the manual pre-use checkout procedure can be found in Section 9/Appendix.

Initial connections



1. Confirm the water trap bottle and water separator cartridge are in place 1a.

   Connect the patient gas sample line with Nafion to the sample line inlet port on the front of the INOmax DS_{IR} 1b .



Check cables and hoses for signs of wear and damage.

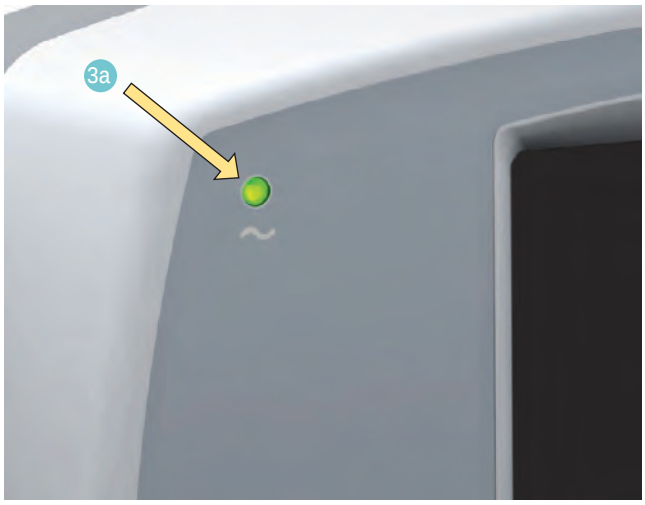
2. Connect one end of the injector module electrical cable to the injector module and the other end into the front of the INOmax DS_{IR} 2a.
   - Line up the red dot on both the connector and the injector module before inserting the connector (see inset detail).

   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} 2b.

WARNING: **Be certain all cables and hoses are positioned to help prevent damaging or occluding them.**

Note:

- It is recommended to disinfect or sterilize the injector module prior to initial setup.
- To remove this type of connector, the knurled sleeve 2c on the connector must be pulled outward before removing the connector from the injector module or the front panel.



3. 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.

   Verify the main power supply indicator light is illuminated (green) 3a. This indicates that the power cord is plugged into an electrical outlet.

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

4. Load two INOMAX drug cylinders onto cart and check for correct product identity labels, cylinder concentration (800 ppm) and expiration date.

Note: For the CGA-type INOMAX regulator connector, ensure the white plastic tip is not chipped or cracked. Remove and replace as necessary. (see Replacing the tip on the INOMAX regulator, Page 7-8).

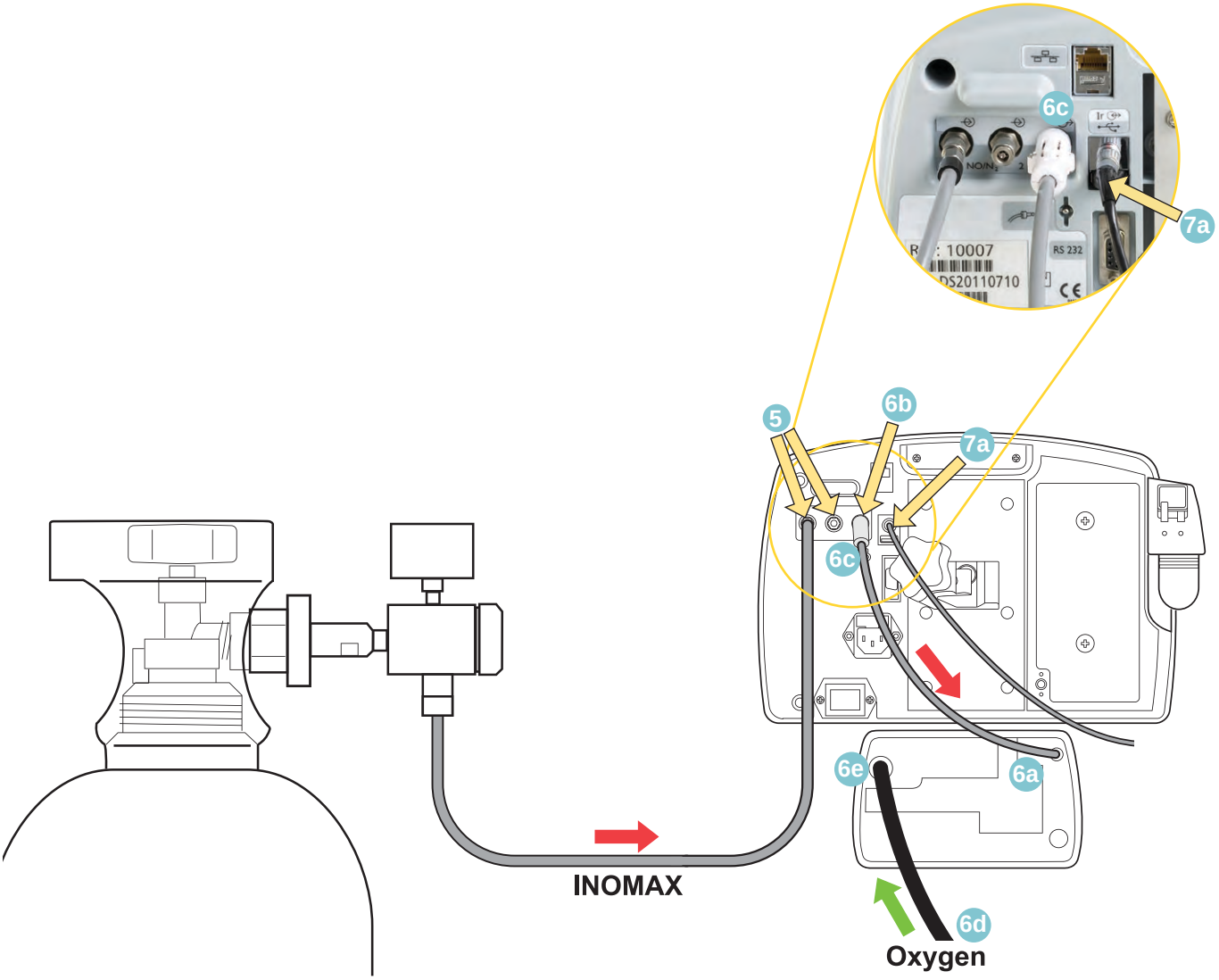
5. Connect an INOMAX regulator to one of the INOMAX cylinders, and hand tighten the fitting to the INOMAX cylinder.

   Connect the INOMAX regulator hose to one of the INOMAX inlets (see page 7-9 for additional instructions).

Caution: If using the transport regulator/cap assembly (PN 10022) see Figure 4-9, Section 4/ Transport.

6. If using the INOblender with the INOmax DS_{IR}, connect the INOblender inlet hose 6a to the INOmax DS_{IR} INOblender outlet 6b and slide the quick-connect cover into place 6c . Connect oxygen supply (wall source or cylinder oxygen, 6d) hose to O_2 inlet fitting on back of INOblender 6e . Note: 50 psig, nominal
7. Connect the Infrared cable from the INOmax DS_{IR} cart or transport regulator/cap assembly (PN 10022, CGA) to the back of the INOmax DS_{IR} 7a.

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



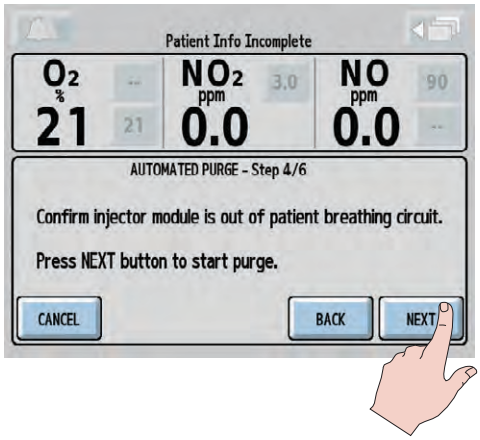
High Pressure Leak Test and Automated Purge

If you cancel the pre-use wizard or are unable to complete an automated purge, complete the high pressure leak test, manual purge and alarm verification starting on page 9-5.

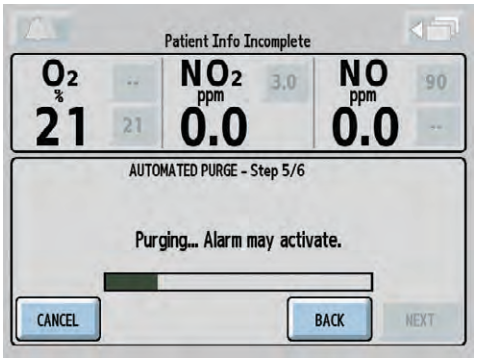
WARNING:

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

1. Verify one of the high pressure regulators is connected to an INOMAX cylinder.
2. Open and then close the cylinder valve. Verify cylinder has at least 500 psig (replace if 200 psig or less).
3. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no pressure decrease is observed, the high pressure leak test is successful. If there is an observed pressure decrease, see Section 7/ Maintenance; Cylinder Leak Check.

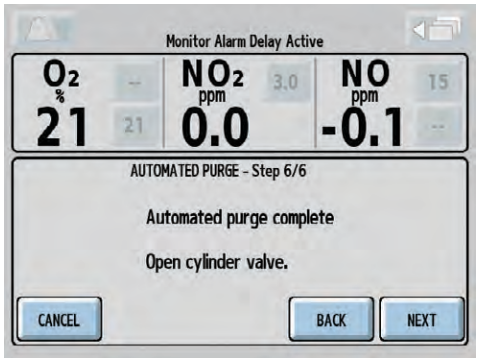


4. Confirm injector module is out of patient breathing circuit or pre-use circuit. Press NEXT button to start purge process.

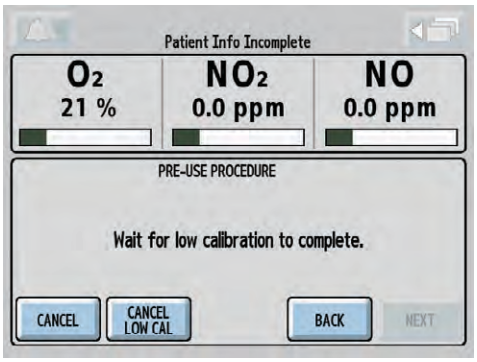


5. Low Cylinder Pressure alarm may activate following purge sequence.

Note: Perform auto-purge with device plugged in. Failure to do so may result in the procedure not completing. If this occurs, complete a manual purge (see page 9-6, Manual Purge).

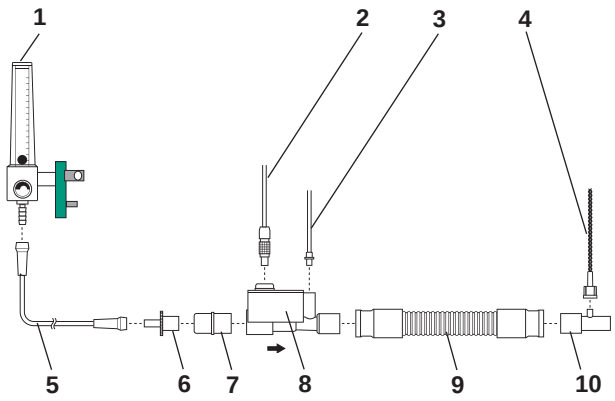


6. Open cylinder valve when purge is completed.



Note: If low calibration is still running after the automated purge completes, wait for low calibration to complete.

Integrated Pneumatic Backup INOMAX Delivery Test



1. Assemble pre-use set-up connectors and tubing (press SHOW DIAGRAM button if needed).

   Set the oxygen flowmeter to 10 L/min. (#1 in Figure 2-1).

1. O_2 Flowmeter (Connected to wall/tank)
2. Injector Module Electrical Cable
3. NO/N_2 Injector Tube
4. Patient Gas Sample Line with Nafion
5. O_2 Tubing
6. 15M x 4.5 mm Adapter
7. 22M / 15F x 22M / 15F Adapter
8. Injector Module
9. 300 mm of 22 mm Hose
10. Gas Sample Tee

Figure 2-1

2. Turn the integrated backup INOMAX delivery to ON (250 mL/min.).
   Verify "Backup ON" alarm occurs.
3. Allow monitored values to stabilize (may take up to 3 minutes).

   Verify the NO and NO_2 readings are within the following ranges:

NO = 14-26 ppm	NO_2 ≤ 1.0 ppm

4. Turn the backup INOMAX delivery to OFF.

Performance Test

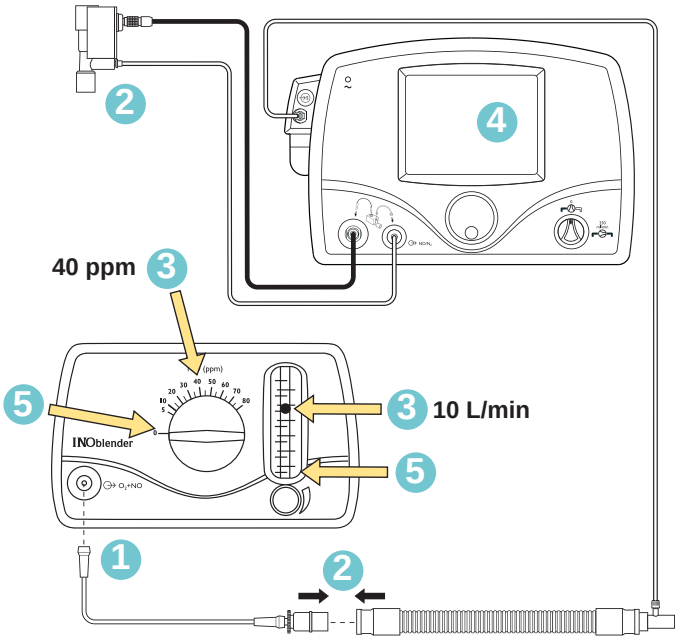
Set Dose	40 ppm
Acceptable O_2 Value	95% ± 3 %
Acceptable NO_2 Value	< 1.5 ppm
Acceptable NO Value	35-45 ppm

1. Using the pre-use set-up connectors, verify that the O_2 flowmeter is set to 10 L/min.
2. Press NEXT button to automatically set the INOMAX dose to 40 ppm.
3. Allow values to stabilize. Compare the INOmax DS_{IR} monitor values to the values in the table.
4. Performance test is complete.

   The INOMAX dose is automatically set to zero.

Note: If a monitored value is outside the range indicated, see section 5/ Alarm Help.

INOblender Test



1. Turn O_2 flowmeter OFF and remove pre-use oxygen tubing from O_2 flowmeter and connect to front of 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 INOblender flowmeter to 10 L/min.
4. Allow monitored NO value to stabilize and then verify acceptable NO value on the INOmax DS_{IR}.
5. Turn the dose and oxygen flow to zero. Remove the pre-use set-up from the INOblender.

Acceptable NO Value	4	32-48 ppm

Pre-use checkout complete.

WARNING:

- **If the INOmax DS_{IR} is not going to be used on a patient within 10 minutes, depressurize the regulator supply line (see next page "Depressurizing the Regulator Supply Line").**
- **If the INOmax DS_{IR} is not used and is pressurized for more than 10 minutes, repeat purge procedure (see page 2-5).**
- **If the INOmax DS_{IR} is depressurized and not used within 12 hours, repeat pre-use procedure (see page 2-1).**

The INOmax DS_{IR} is now ready to connect to the patient.
Proceed to Section 3/ Patient Application.

Depressurizing the Regulator Supply Line

Depressurizing the regulator supply line removes the buildup of NO_2 and allows the use of the INOmax DS_{IR}® at any time within the next 12 hours. If the regulator supply line is not depressurized, the INOmax DS_{IR} must be used within 10 minutes after completing pre-use checkout procedure.

To depressurize the INOMAX regulator supply line:

1. On the INOMAX cylinder, rotate the INOMAX cylinder handle clockwise to close the valve.

2. At the back of the INOmax DS_{IR}, remove the regulator hose from the INOMAX gas inlet and connect it to the purge port.

   This depressurizes the regulator.

3. When the regulator pressure gauge reads zero, remove the regulator hose from the purge port and connect it to the INOMAX gas inlet.

Note: If difficulties are encountered in connecting the regulator hose, refer to page 7-9.

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

3/ Patient Application

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

Patient Application

3/ Patient Application

Part No. 20717 Rev-01
2014-07

3/ Patient Application

Before Operation

Complete the initial connections and Pre-Use Checkout procedure as described in the previous sections before connecting the INOmax DS_{IR} into the patient's breathing circuit. (See the ventilator/breathing device manual for its setup and operation)

WARNING:

- **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.**
- **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.**
- **Abrupt discontinuation of INOMAX may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. To avoid abrupt discontinuation, utilize the INOblender or integrated pneumatic backup if necessary. If Rebound Pulmonary Hypertension occurs, reinstate INOMAX therapy immediately (See the INOMAX prescribing Information for further details.)**
- **If the high NO_2 alarm activates, the delivery system should be assessed for proper set up while maintaining INOMAX delivery. Adjust INOMAX and/or FiO_2 as appropriate. (See INOMAX Prescribing Information for further details on the effects of Nitrogen Dioxide, NO_2). If unable to determine the cause of the increased NO_2 levels, call technical support, do not discontinue therapy.**

Use Outside of Product Labeling

- **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 manufacturer 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. The use of helium/oxygen mixtures will lead to over-delivery of INOMAX which may lead to interruption of therapy.**
- **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.**
- **Do not connect items which are not specified as part of the system.**
- **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.**

Caution:

- Use distilled water in the humidifier to prevent the formation of bases or acids.
- 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 1-16).
- 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.

Connection to the ventilator breathing circuit

WARNING: **The INOmax DS_{IR} subtracts gas from the breathing circuit via the gas sampling system at 230 mL per minute which can cause the ventilator to auto-trigger. Adjusting the flow sensitivity may be necessary. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS_{IR} to the breathing circuit.**

Caution:

- For proper gas flow measurement, the injector module should not be connected directly to the ventilator's inspiratory outlet.
- Connect the injector module directly to the dry side of the humidifier chamber.
- If it is not possible to connect directly to the dry side of the humidifier, a filter or length of tubing may be placed between the inspiratory outlet and injector module which will condition the ventilator flow.

Note: Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Adapter diagrams can be found on page 7-13.

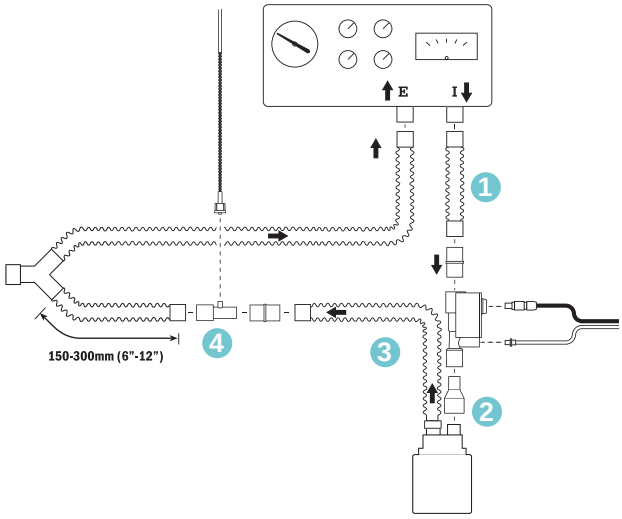
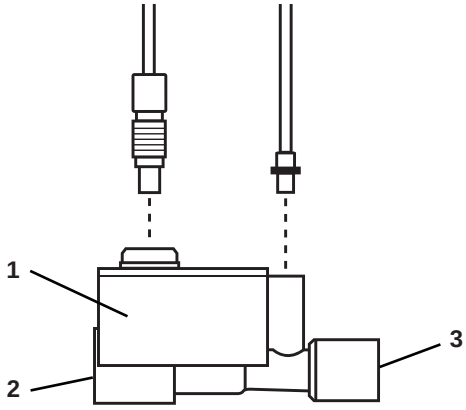


Figure 3-1

Connect the INOmax DS_{IR} into the breathing circuit as shown in the appropriate connection diagrams later in this section.

1. To ensure correct flow measurement, use breathing circuit tubing between the ventilator inspiratory port and the injector module (Fig. 3-1).
2. Connect the injector module prior the humidifier chamber on the dry side of the breathing circuit to ensure correct flow measurement.
3. The distance between the injector module and the sample tee must be greater than 24 inches. This ensures proper gas mixing, minimizes the sampling of mixed inspired/expired concentrations, and ensures correct patient NO/NO_2 measurement.
4. Insert the sample tee on the inspiratory side of the ventilator circuit, 6-12 inches (150-300 mm) from the patient wye.

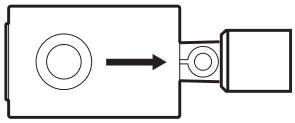
   Make sure that the sample tee port points upward. This helps to avoid fluid accumulation in the sample line.



A. Side View

1. Injector Module
2. 22F inlet
3. 22M / 15F outlet

Airflow Direction



B. Top View

Figure 3-2

5. On the injector module, note the airflow direction arrow (Fig. 3-2, B).

   Flow from the ventilator must pass through the injector module in the direction of the arrow.
6. Select the dose button on the screen. On the INOmax DS_{IR}, rotate the control wheel to set the NO dose.
7. Confirm the change by pressing the Control wheel or dose button on the screen.
8. Set the user-adjustable alarm settings on the INOmax DS_{IR} and on the ventilator or breathing system.

Note:

- After the INOmax DS_{IR} is connected to the ventilator or breathing system the trigger sensitivity on the ventilator may need adjustment due to the removal of gases by the sample system.
- The first time a dose is set from zero, the upper and lower NO alarm limits are set 50% above and 50% below the set dose.

INOblender Operation

Important: Read the INOblender Operation Manual PN 20732 before using the INOblender. Follow instructions and obey all Warnings and Cautions.

WARNING:

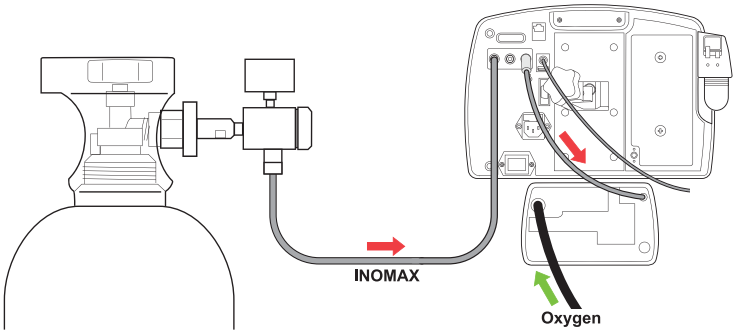
- **The purge procedure must be followed to help ensure NO_2 is purged from the system before the manual resuscitator bag is connected to the patient.**
- **The manual bag should be squeezed repeatedly during use to avoid NO_2 building up in the bag.**
- **If the bag is not squeezed repeatedly while 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.
- When the INOblender is used with an oxygen/air blender:
  - The specification for INOMAX delivery when using the INOblender with 100% oxygen is +/- 20% of setting or two 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 one ppm (whichever is greater) compared to using 100% oxygen alone, resulting in a cumulative error up to +/- 30% of setting or three ppm (whichever is greater).
- Refer to the manufacturer's procedures when using the manual resuscitator bag.
- When finished, turn the NO cylinder valve OFF and allow the oxygen to flow until the NO pressure gauge reads zero, then turn the oxygen flow OFF.

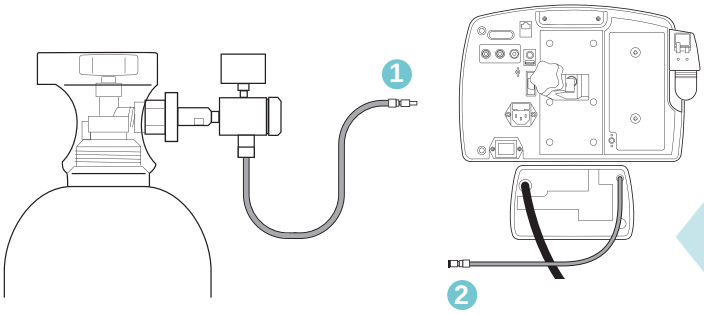
INOblender Used as a Stand-Alone Device

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



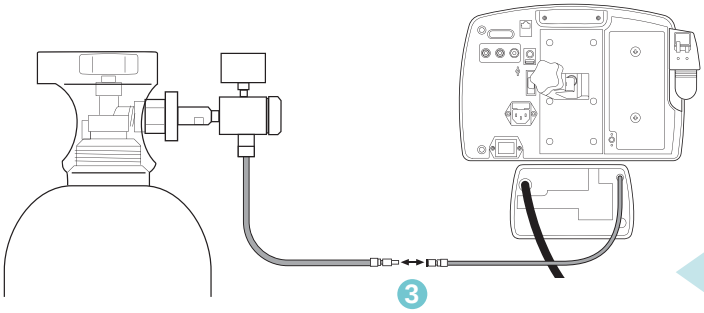
Typically the INOblender receives INOMAX from the INOmax DS_{IR} (INOMAX cylinder supplies both devices; see Figure 3-3).

Figure 3-3



As a stand-alone device INOMAX cylinder supplies just the INOblender. (see Figure 3-4).

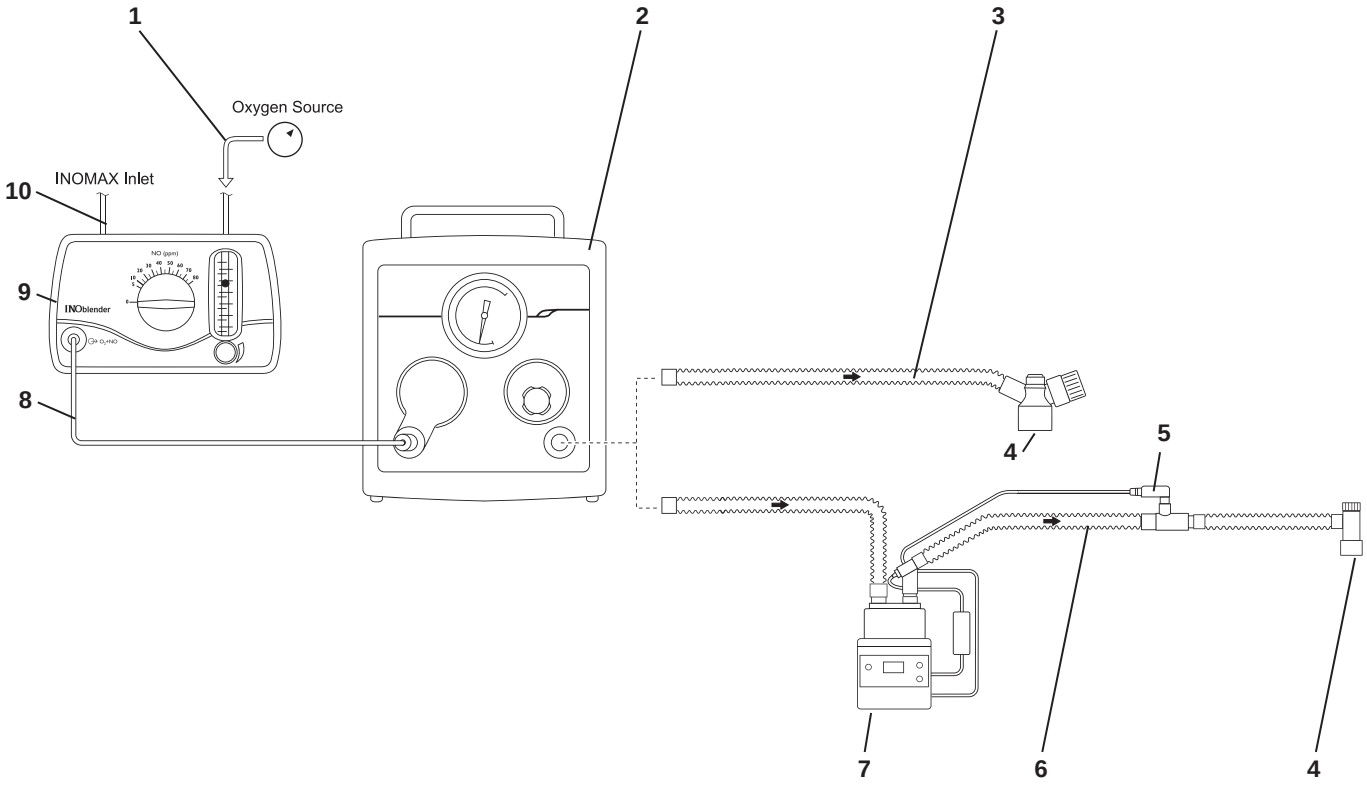
1. Disconnect INOMAX regulator hose from back of INOmax DS_{IR}.
2. Disconnect INOblender hose from back of INOmax DS_{IR}.



3. Connect INOMAX regulator hose to INOblender inlet hose.

Figure 3-4

INOblender use with the NeoPuff



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

Figure 3-5

Integrated Pneumatic Backup NO Delivery

WARNING:

- **When using the integrated pneumatic backup with breathing circuit gas flows of 5 L/min, the delivered NO dose will be approximately 40 ppm. Breathing circuit gas flows less than 5 L/min will deliver an NO dose greater than 40 ppm.**
- **The integrated pneumatic 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.**
- **The integrated pneumatic backup delivers a variable concentration of NO to the patient depending on the ventilator flow being used. See table below for details.**

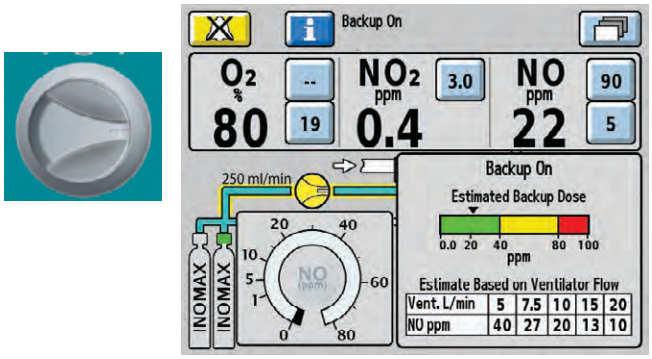


Figure 3-6

Integrated Pneumatic Backup NO Delivery Description

The integrated pneumatic backup delivery provides a fixed flow of 250 ml/min of INOMAX directly into the ventilator circuit through the injector module.

The integrated pneumatic backup is not reliant on the operation of the main system.

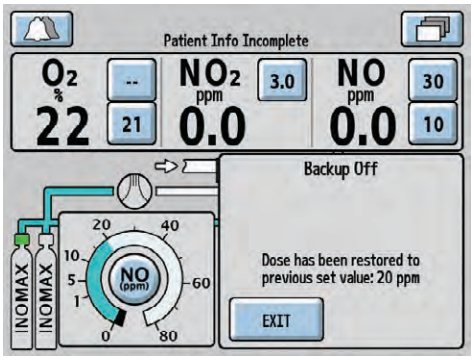
- The integrated pneumatic backup delivery is activated through the backup switch on the front panel. When activated, the set INOMAX dose will be automatically turned OFF. The high and low NO alarms are automatically set to 90 and 5 ppm respectively (see Figure 3-6).
- The estimated backup dose graphic (if displayed) represents the estimated dose the patient is receiving, by displaying a dose indicator. The estimated backup dose is calculated by using the circuit flow measured by the injector module (see Figure 3-6).
- The estimated NO dose table is also displayed on the main screen.

Note:

- If the injector module is not functioning, the estimated backup dose graphic will be inactive.
- The estimated backup dose graphic and the estimated backup dose based on ventilator flow table, will not be present during a Cylinder Concentration Mismatch alarm.

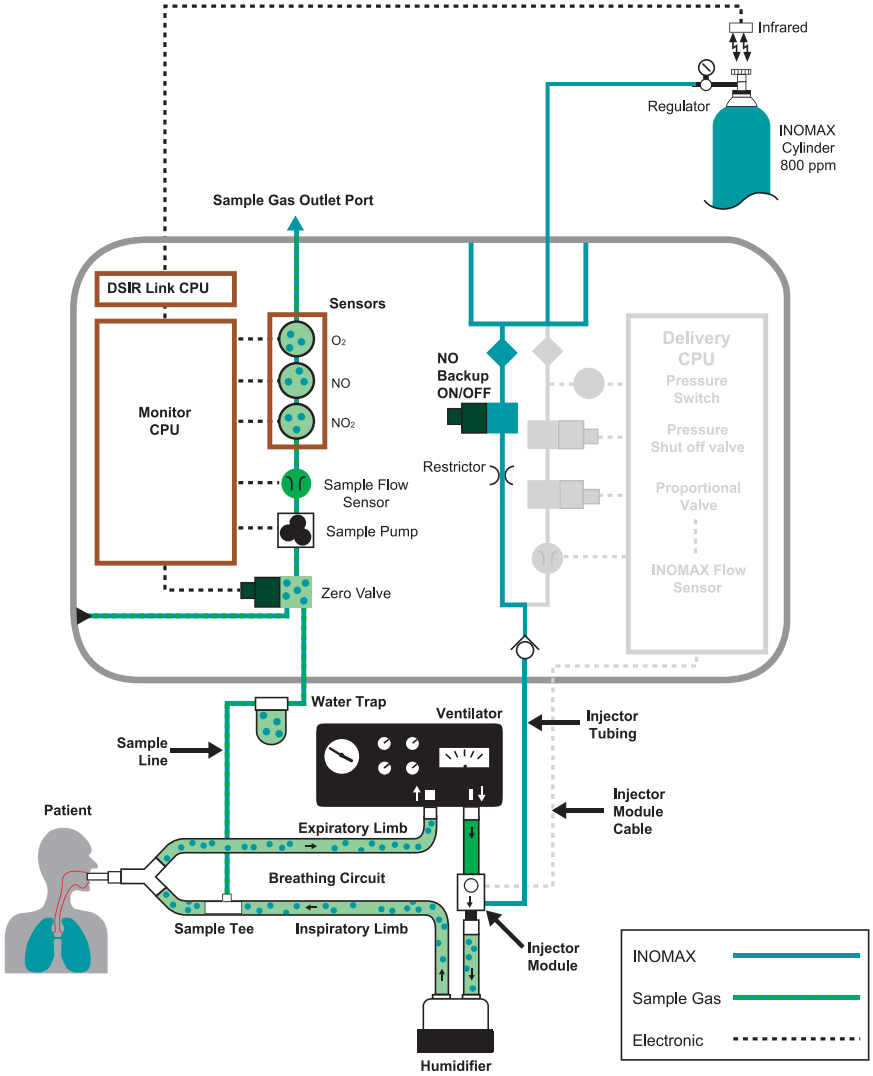
This table indicates nominal NO concentrations delivered for different ventilator gas flows.						
Ventilator Gas Flow	(L/min)	5	7.5	10	15	20
NO Concentration	(ppm)	40	27	20	13	10

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



- When the backup switch is turned OFF, the dose and alarm settings will return to the previous values (see Figure 3-7).

Figure 3-7



Cylinder Information

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 the manufacturer.**
- **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.**

Purging Cylinders

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

Note:

- 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.

Changing INOMAX Cylinders and Purging the Regulator Assembly

Caution: Replace an INOMAX cylinder when its pressure is less than 200 psig.

1. Check the INOMAX drug cylinders for the correct product identity, cylinder concentration, and expiration date. Verify cylinder has at least 500 psig (replace if 200 psig or less), and tighten the fitting to the INOMAX cylinder, attach a second INOmax DS_{IR} regulator (hand-tighten only) which is currently not in use.

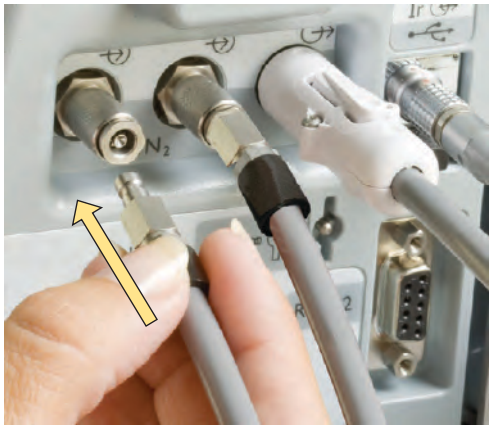
Note:

- 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 7-8).

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 7/ 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).

WARNING: **A new INOMAX cylinder and regulator must be purged before use to ensure the patient does not receive excess of NO_2.**



4. Connect the hose to the back (NO/N_2 inlet) of the INOmax DS_{IR}. When having difficulty connecting the INOMAX regulator hose, see page 7-9.

5. Open the cylinder valve on the new cylinder (this may activate the “Two Cylinders Open” alarm until the empty cylinder valve is closed).

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 Section 4/ Transport).

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 4-2). "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 by using the purge port on the back of the INOmax DS_{IR} and remove the regulator from the empty cylinder.

Caution: Depressurize the regulator and hose by using the purge port on the back of the INOmax DS_{IR} before removing the regulator from the INOMAX cylinder.

8. Load a new INOMAX cylinder onto the cart.

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)

INOMAX Dose (ppm)	FLOW			
	5 L/min	10 L/min	20 L/min	40 L/min
5	39 Days	19.5 Days	9.8 Days	4.9 Days
10	19.4 Days	9.7 Days	4.8 Days	2.4 Days
20	9.6 Days	4.8 Days	2.4 Days	1.2 Days
40	4.7 Days	2.3 Days	1.2 Days	14 Hours
80	2.2 Days	1.1 Days	13.3 Hours	6.6 Hours

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

* All calculations for the table above are based on a full cylinder of 138 bar (2000 psig), 1963 liters “88” cylinder, and also accounting for cylinder change at 14 bar (200 psig). The figures are calculated on total continuous flow cylinder conversion factor (14.2 liters per bar and 0.98 liters per psig).

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

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

Typically used in transport

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

* All calculations for the table above are based on a full cylinder of 138 bar (2000 psig), 353 liter “D” cylinder, and also accounting for cylinder change at 14 bar (200 psig). The figures are calculated on total continuous flow cylinder conversion factor (2.6 liters per bar and 0.18 liters per psig).

- INOMAX flow = [Desired dose × total ventilator flow] ÷ [Cylinder concentration - desired dose]
- Cylinder volume = Cylinder conversion factor × cylinder pressure (bar/psig)
- Cylinder duration = 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 (see Figure 3-8) 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 Trap Bottle Full" message will remind the user to empty and clean the fluid trap should it become full.

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

Figure 3-8

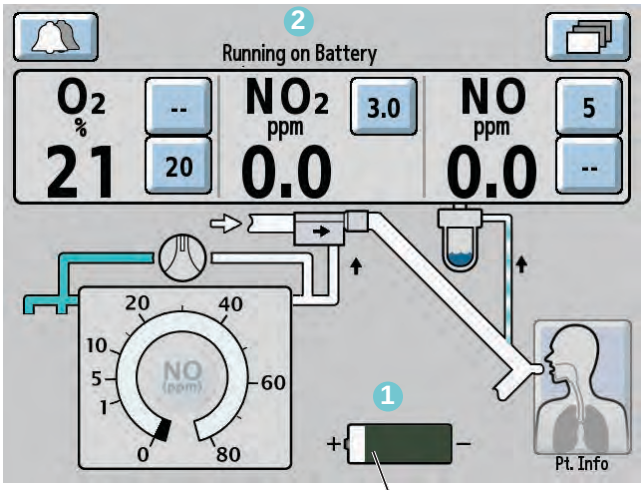
To empty the Water Trap Bottle:

1. Remove the bottle by pulling it straight down (see Figure 3-8).
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/Filter Block" 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 7/ Maintenance).
2. To avoid medications interfering with the gas monitoring system, administer any aerosolized medications distal to the sampling tee in the breathing circuit (refer to page 3-18).

Running on Battery



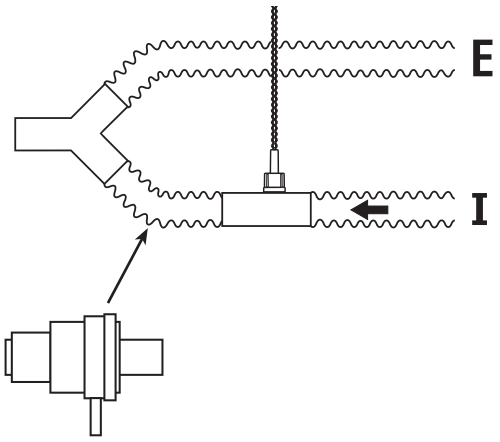
Battery icon

Note: When running on battery with a circuit flow greater than 20 L/min. and a set dose of 80 ppm, the delivered NO (measured NO value) may be less than the set dose.

- 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} for up to six 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 settings screen. See section 1/ General Information for instructions).

Inspired Gas Sampling During Aerosol Delivery

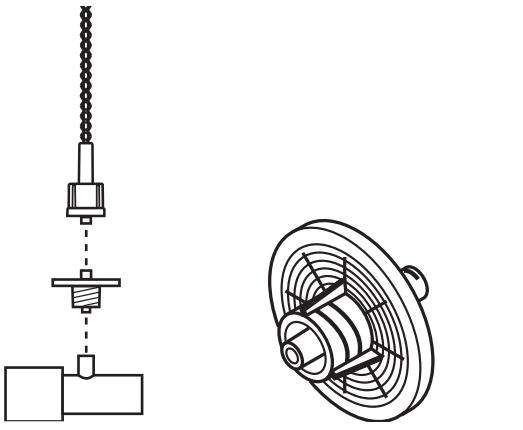
Caution: Pneumatic nebulizers will dilute the delivered INOMAX dose.



Location of nebulizer distal from the inspiratory gas sample tee

Figure 3-9

- 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 3-9).
- 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 3-10).



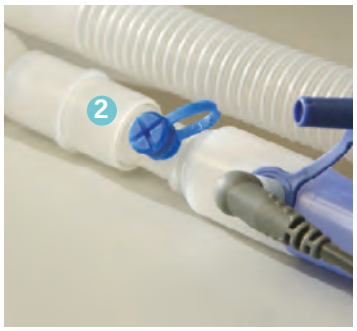
Disk Filter, 0.5 micron

Figure 3-10

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 must be replaced following each treatment period.
- During continuous medication delivery, frequent disk replacement may be necessary due to the disk becoming saturated with moisture/medication.
- Use of the filter will reduce the frequency of water separator cartridge replacement during medication delivery.

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.

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

3. Sample the room air with the sample line and read the NO and NO_2 readings.
4. After environmental monitoring, remove the Luer fitting cap on the sample tee and reconnect the sample line.

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.

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

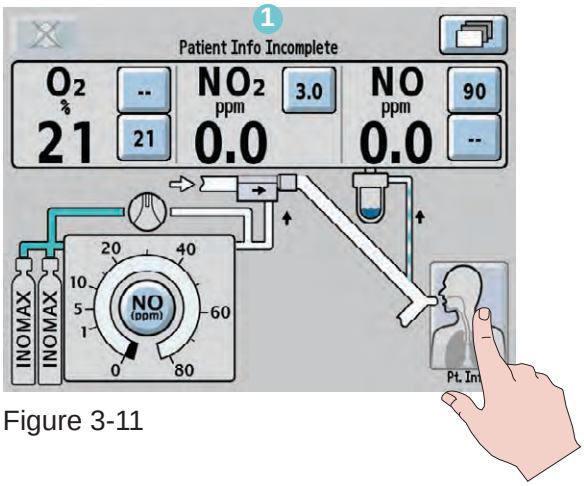


Figure 3-11

A patient identifier and patient details 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, unless an alarm condition is present. (see Figure 3-11).

After pressing the patient information button, the patient information screen will appear (see Figure 3-12).

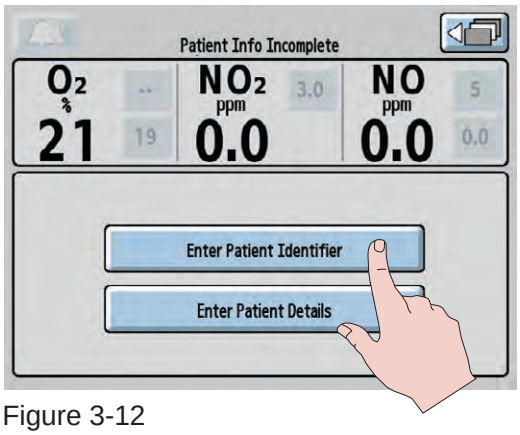


Figure 3-12

Press the "Enter Patient Identifier" button to access keyboard.

The patient identifier screen (see Figure 3-13) allows a unique alphanumeric patient identifier to be entered that contains six to eight characters (note: spaces will be accepted).

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

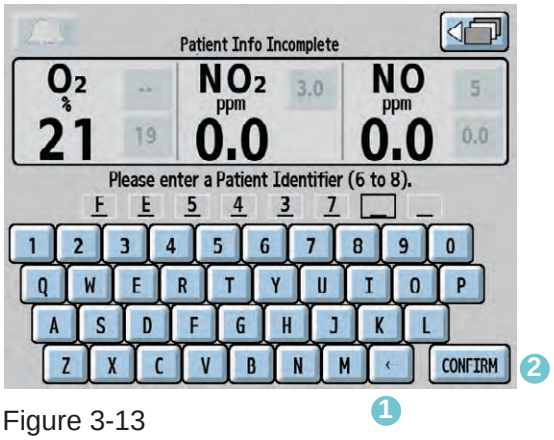


Figure 3-13

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 1 or pressing the digit that has been entered and typing over it.

The CONFIRM button 2 will illuminate when six 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).

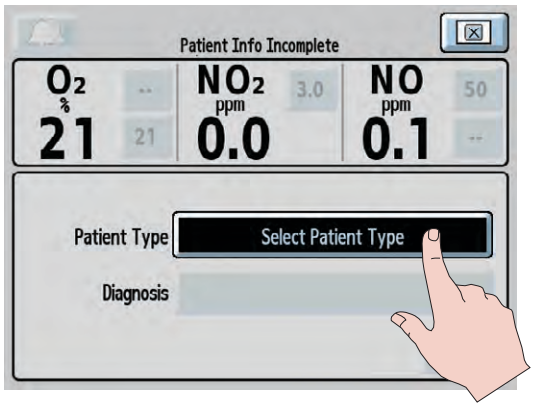


Figure 3-14

Press the Select Patient Type button and rotate the control wheel to select either neonate, pediatric or adult. Press the control wheel or button to confirm.

Once the patient type is confirmed the Select Diagnosis button will appear (see Figure 3-15).

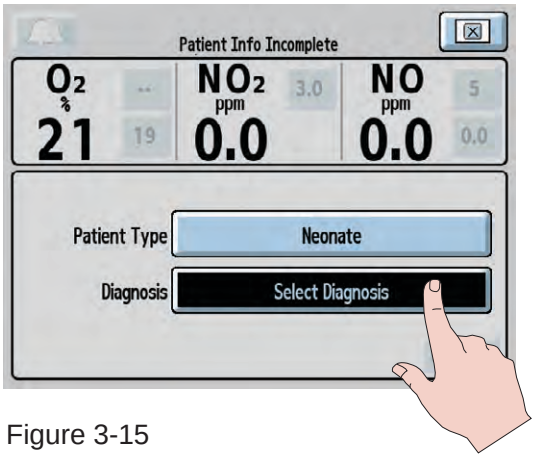


Figure 3-15

Press the Select Diagnosis button and rotate the control wheel to select the patient diagnosis. Press the control wheel or button to confirm.

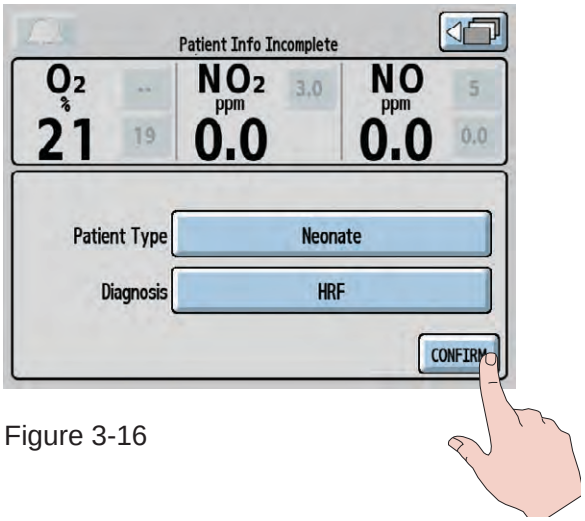


Figure 3-16

Press the CONFIRM button to enter the patient details selected (see Figure 3-16).

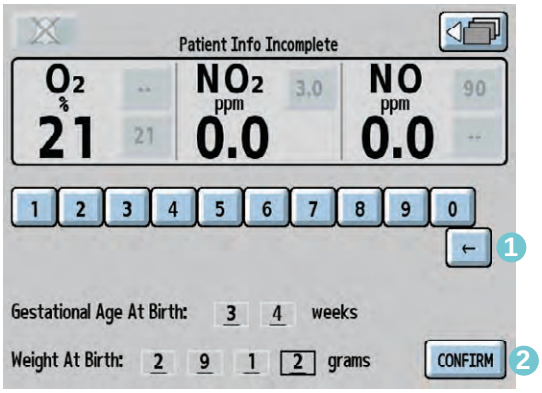


Figure 3-17

Prior to confirming the gestational age and birth weight, digits can be changed either by pressing the backspace button 1 or pressing the number that has been entered and selecting a new number.

The CONFIRM button 2 will illuminate when age and weight have been entered.

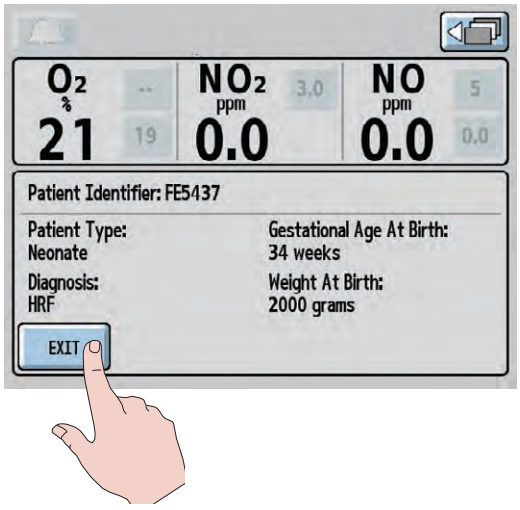


Figure 3-18

Note: Once the CONFIRM button has been pressed, the patient details are stored (see Figure 3-18) and the identifier remains unchangeable until therapy is ended by turning the device to Standby (OFF).

To access patient identifier information, press the patient information button on the main screen.

Press the EXIT button to return to the main screen.

Connection to Various Breathing Systems

WARNING:

- **The INOmax DS_{IR} should not be used with the BiPap Vision sytem or other single-lumen breathing systems with bidirectional flow, as over-dose of INOMAX (nitric oxide) and interruption of drug delivery to the patient may occur.**
- **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.**

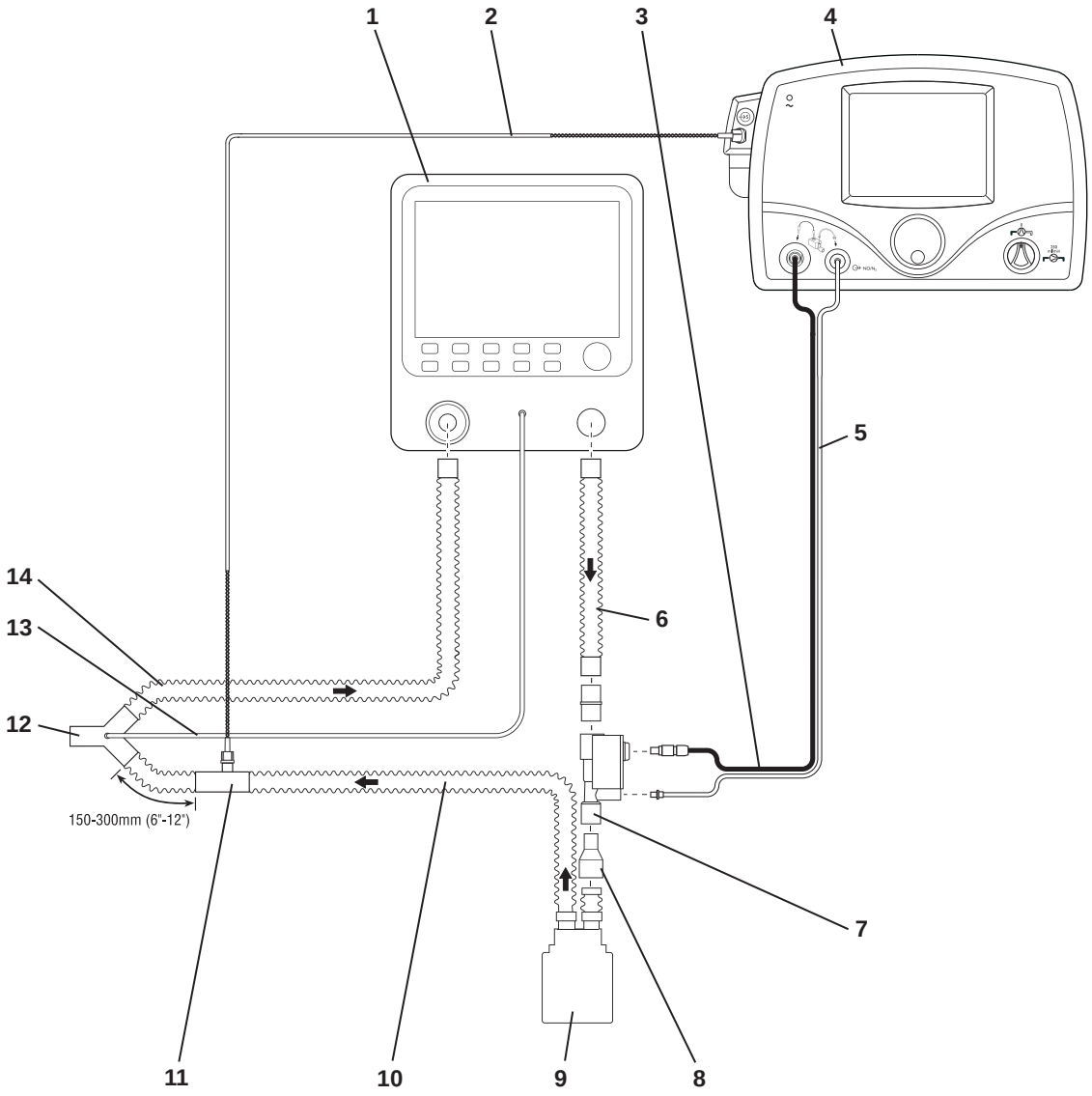
Caution: The INOmax DS_{IR} is designed to function in the parameter ranges listed in Section 8/ Product Specifications. Use outside of these ranges is not recommended.

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 7-13.
- For a list of validated ventilators see Section 8/Product Specifications.

Acutronics Medical Systems AG Fabian +nCPAP Evolution

Note: Validated for use outside of the United States.

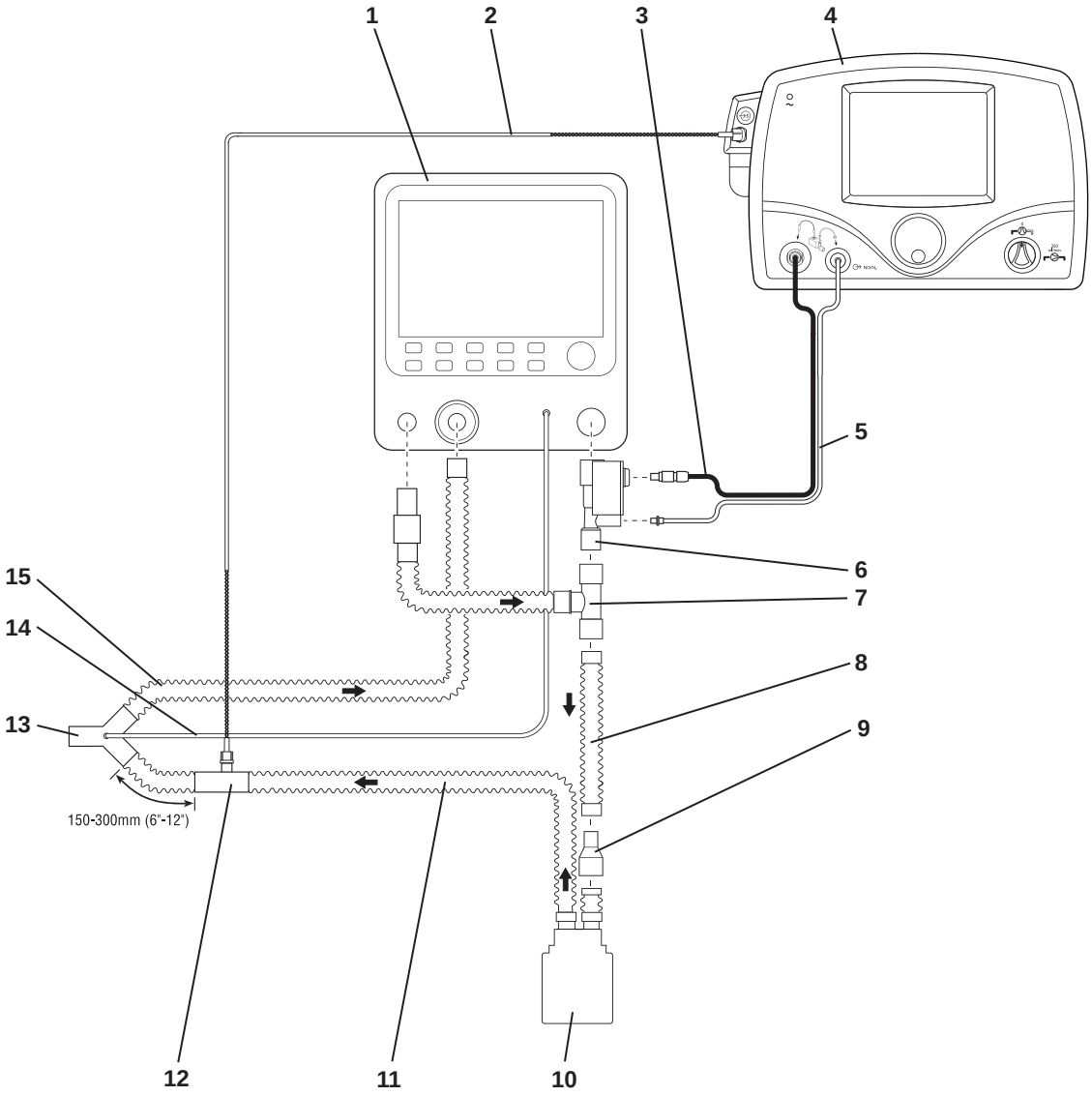


1. Fabian+ nCPAP Evolution
2. Patient Gas Sample Line with Nafion
3. Injector Module Electrical Cable
4. INOmax DS_{IR}
5. NO/N_2 Injector Tube
6. Connecting Tube (15 inches)
7. Injector Module
8. 22F X 15M Adapter
9. Humidifier
10. Inspiratory Breathing Circuit Hose
11. Gas Sample Tee
12. Patient Wye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

Figure 3-19 Example: Acutronics Medical Systems AG Fabian +nCPAP Circuit Diagram

Acutronics Medical Systems AG Fabian HFO

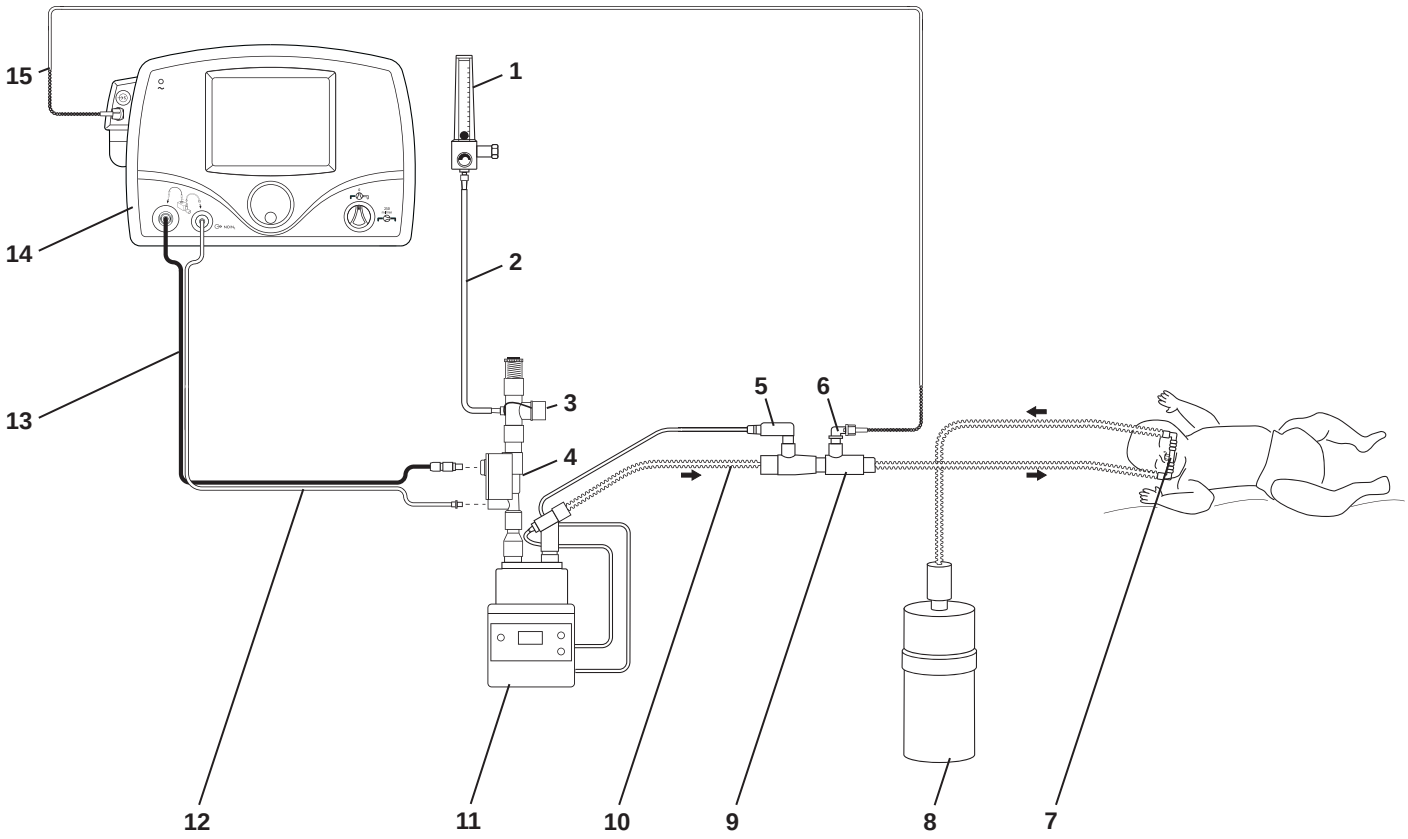
Note: Validated for use outside of the United States.



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

Figure 3-20 Example: Acutronics Medical Systems AG Fabian HFO Circuit Diagram

A-Plus Medical Babi-Plus Bubble CPAP Circuit



1. Oxygen Source
2. Oxygen Tubing
3. Pressure Relief Manifold
4. Injector Module
5. Temperature Probe
6. 90 Degree Sample Port Adapter
7. Nasal Prongs
8. Babi-Plus Bubble PAP Valve
9. Tee Adapter
10. Breathing Circuit
11. Humidifier
12. NO/N_2 Injector Tube
13. Injector Module Electrical Cable
14. INOmax DS_{IR}
15. Patient Gas Sample Line with Nafion

Figure 3-21 Example: A-Plus Medical Babi-Plus Bubble CPAP Circuit Diagram

Bagging Systems While Using the Injector Module

WARNING:

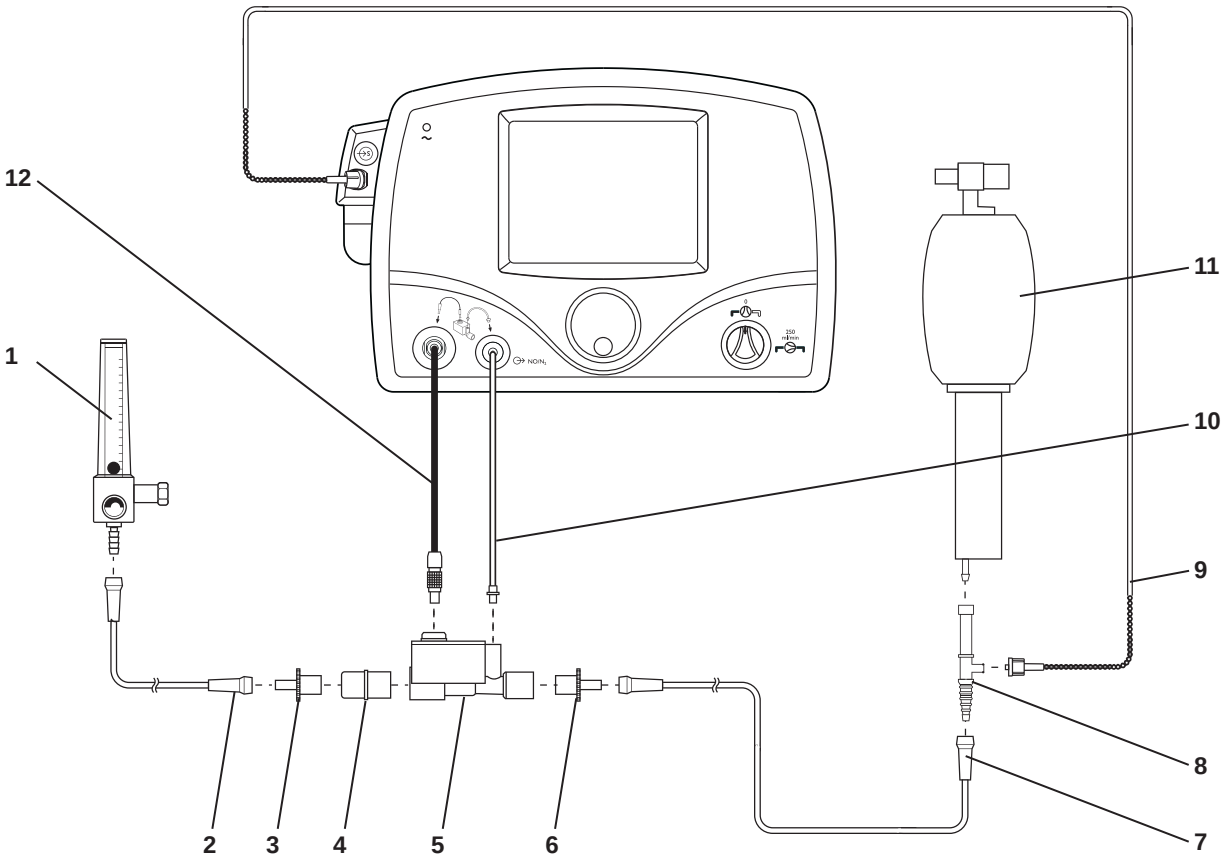
- **The hyperinflation bag will, under some conditions, contain NO_2 in excess of one ppm. Use of large tidal volume breaths may expose the patients to the NO_2 present in the bag for part of the breath. In general, if the inspiratory flow rate induced by the manual ventilation does not exceed the fresh 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:

- **Use the smallest bag adequate to deliver the desired tidal volume.**
- **Oxygen tubing lengths greater than 72 inches should not be used (between the injector module and the bag).**
- **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.**

Bagging Systems While Using the Injector Module

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



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

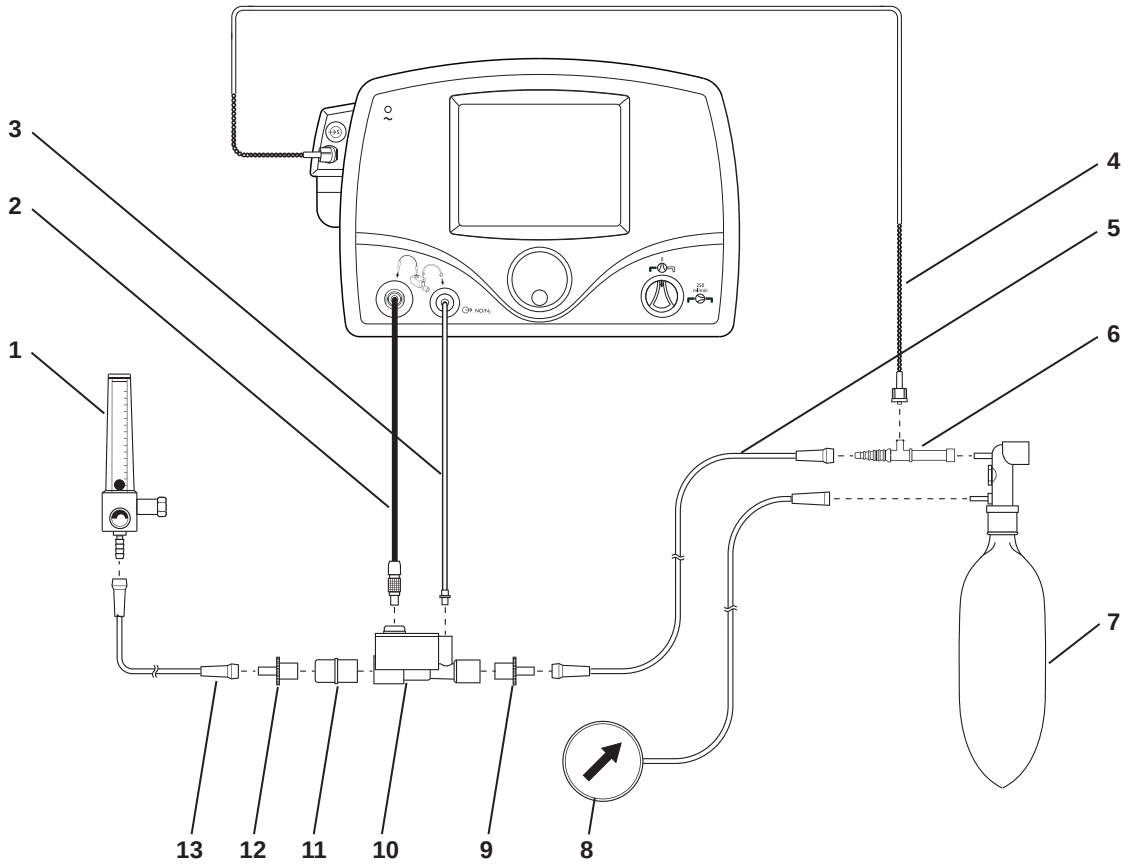
Figure 3-22 Example: Self-inflating Manual Bagging System Connection Diagram

Testing has 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

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.**
- **Oxygen tubing lengths greater than 72 inches should not be used (between the injector module and the bag).**
- **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
2. Injector Module Electrical Cable
3. NO/N_2 Injector Tube
4. Patient Gas Sample Line with Nafion
5. O_2 Tubing
6. O_2 Tubing Sample Tee
7. Hyper-Inflation Bag
8. Pressure Gauge
9. 15M X 4.5 mm Adapter
10. Injector Module
11. 22M/15F X 22M/15F Adapter
12. 15M X 4.5 mm Adapter
13. O_2 Tubing

Figure 3-23 Example: Hyperinflation Manual Bagging System Diagram

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

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

(Intentionally left blank)

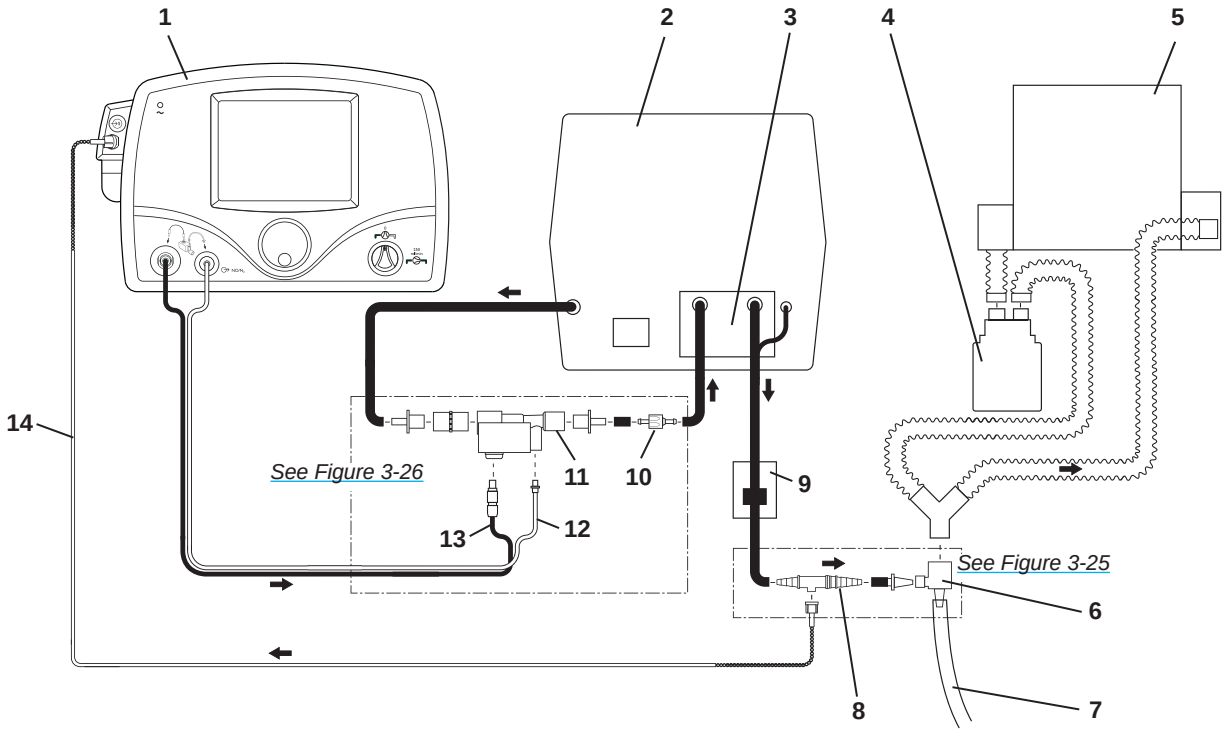
Bunnell Life Pulse High Frequency Ventilator Circuit

WARNING:

- **The integrated pneumatic backup (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 Bunnell Life Pulse in standby prior to suctioning the patient to avoid NO delivery transiently exceeding the set dose by up to 30 ppm. Press ENTER to reestablish ventilation as soon as the catheter is removed from the airway. This will limit the extent of over delivery above the NO set dose.**

Caution:

- If set dose is below five ppm and the Servo pressure is 2.0 psig. or less, this will result in flow rates outside of the specification of the injector module and fluctuating NO values may result.
- A one-way valve should be placed between the injector module and the humidifier chamber to prevent water from backing up into the injector module if the Life Pulse is either put into Standby or cycled OFF.
- There are higher pressures in the breathing circuit than normal; use only parts provided in disposable package #50248 and tightly secure all connections.



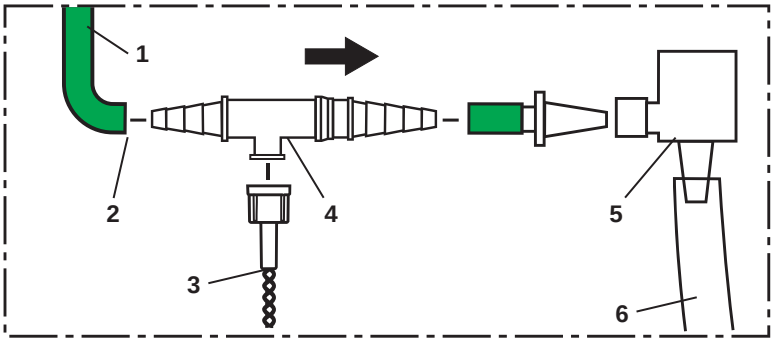
1. INOmax DS_{IR}
2. Bunnell Life Pulse
3. Humidifier
4. Humidifier
5. Conventional Ventilator
6. Life Port Adapter
7. Endotracheal Tube
8. Sample Tee
9. Patient Box
10. One-Way Valve
11. Injector Module
12. NO/N_2 Injector Tube
13. Injector Module Electrical Cable
14. Patient Gas Sample Line with Nafion

Figure 3-24 Example: Bunnell Life Pulse Ventilator Diagram

Connection Instructions:

1. Connect the sample Tee as shown in Figure 3-25.
2. Connect the injector module as shown in Figure 3-26. 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.

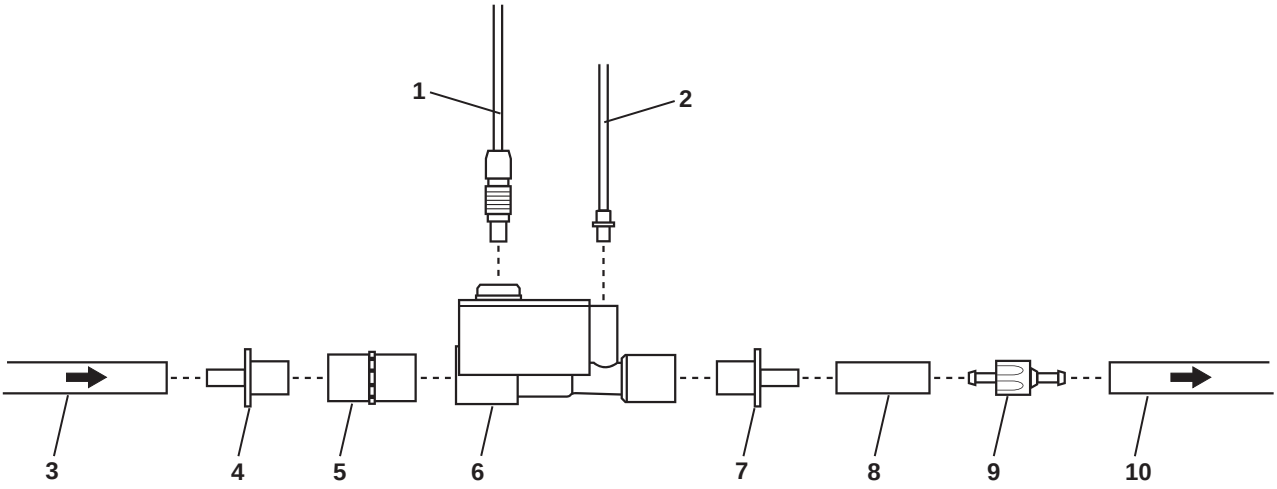
Connecting INOmax DS_{IR} Sample Tee to the Bunnell Life Pulse Circuit



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

Figure 3-25

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



1. Injector Module Electrical Cable
2. NO/N_2 Injector Tube
3. Gas Out Tube from Vent
4. 15M X 4.5 mm I.D. Adapter
5. 22M/15F X 22M/15F Adapter
6. Injector Module
7. 15M X 4.5 mm I.D. Adapter
8. Three cm Piece of Green Gas Out Tube
9. One-Way Valve
10. Green Gas Out Tube to Humidifier

Figure 3-26

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.**

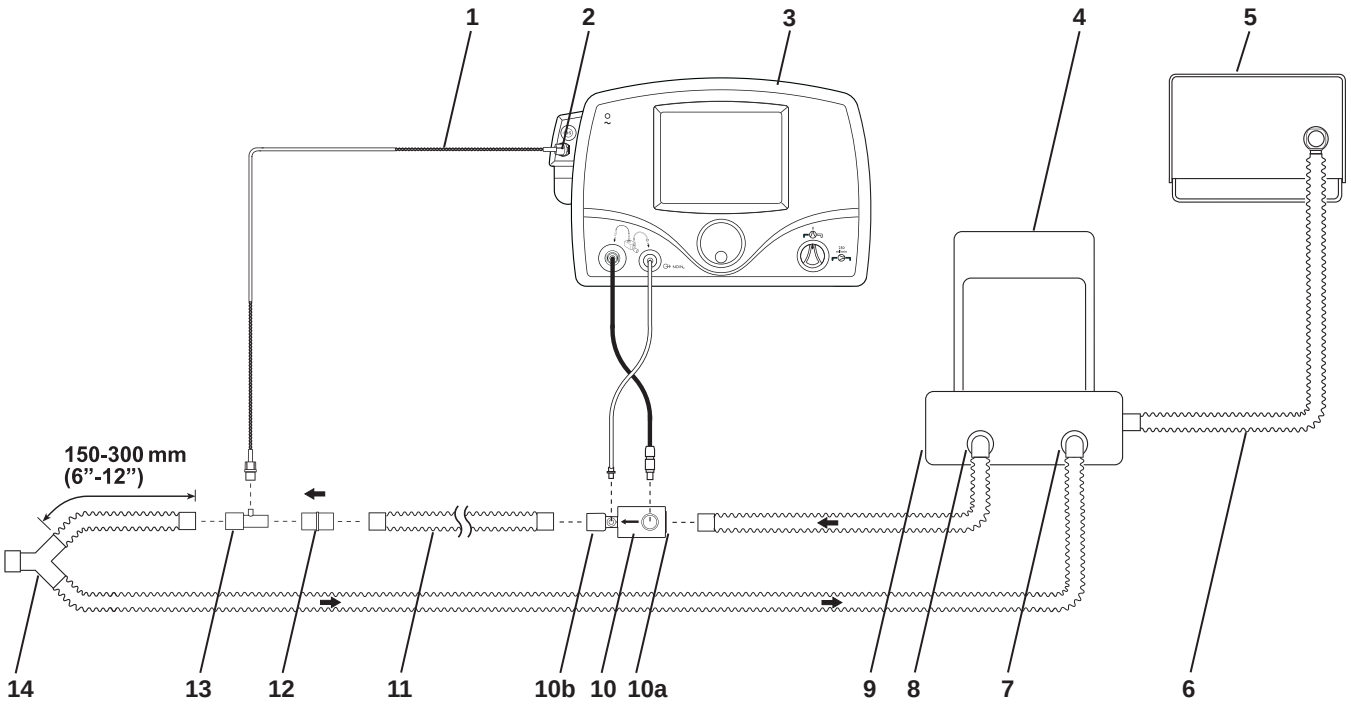
Caution:

- 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 two percent v/v Isoflurane will result in a high measured NO value of approximately three percent 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:

- 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 six and 12 inches (150-300 mm) long: greater than six 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.

Circle Anesthesia System



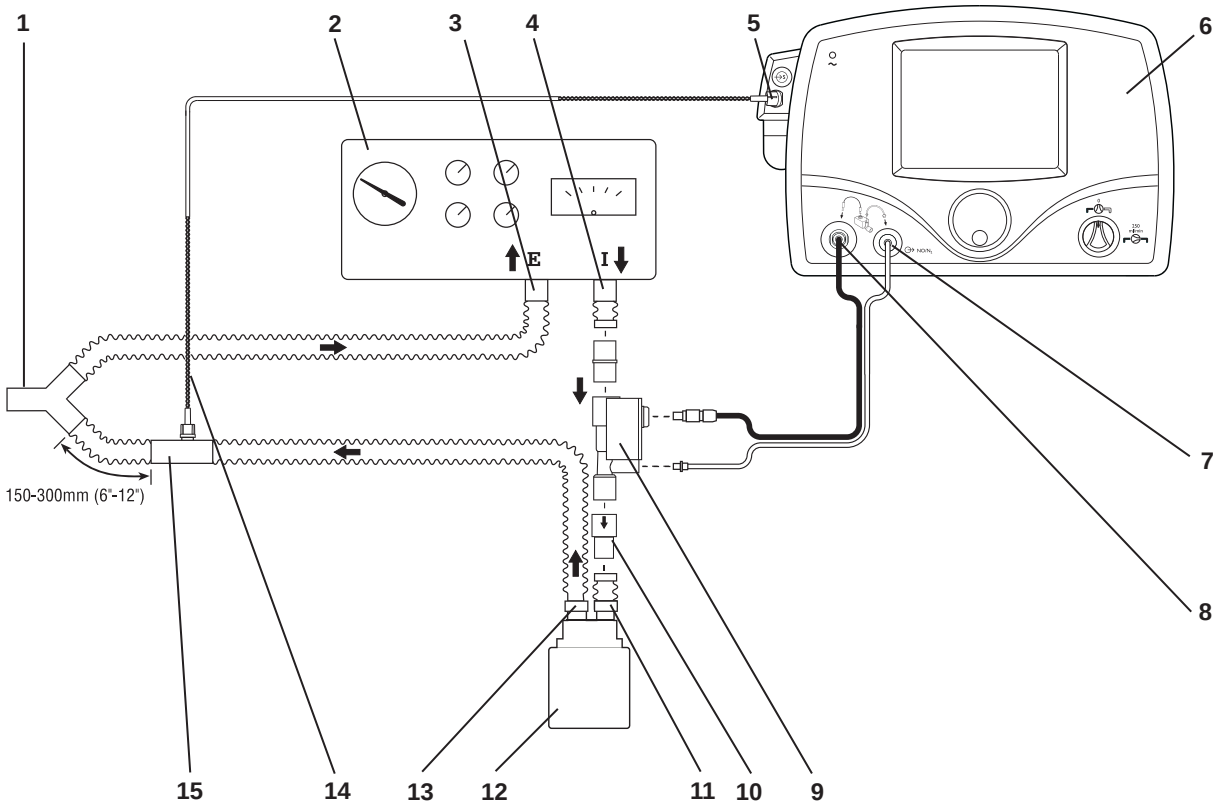
1. Patient Gas Sample Line with Nafion
2. Patient Gas Sample Line Input Connection
3. INOmax DS_{IR}
4. Bellows Assembly
5. Ventilator
6. Ventilator Drive Gas
7. Absorber Expiratory Port
8. Absorber Inspiratory Port
9. Absorber
10. Injector Module
    a. Injector Module Input End
    b. Injector Module Output End
11. Inspiratory Tubing
12. 22M/15F X 22M/15F Adapter
13. Gas Sample Tee
14. Patient Wye

Figure 3-27 Example: Anesthesia System with Ventilator Circuit Diagram

Dräger Babylog VN500/Infinity Acute Care System and Heinen & Löwenstein Leoni-plus Ventilator

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

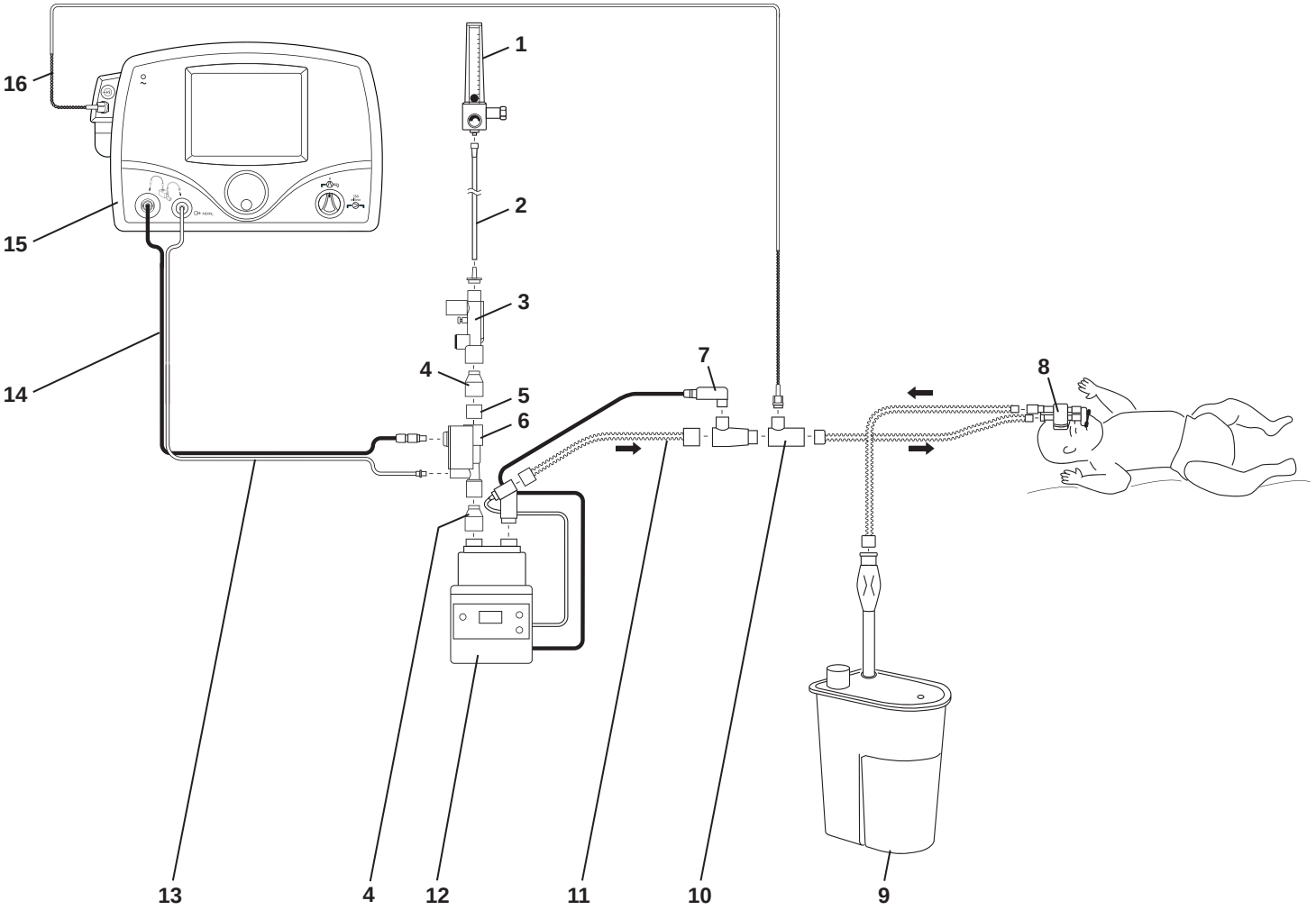
Note:
- Validated for use outside of the United States.
- Use a one-way valve (Part Number- 1605-3139-000) when ventilating during the HFOV mode.



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

Figure 3-28 Example: Dräger Babylog VN500 and Leoni-plus Circuit Diagram

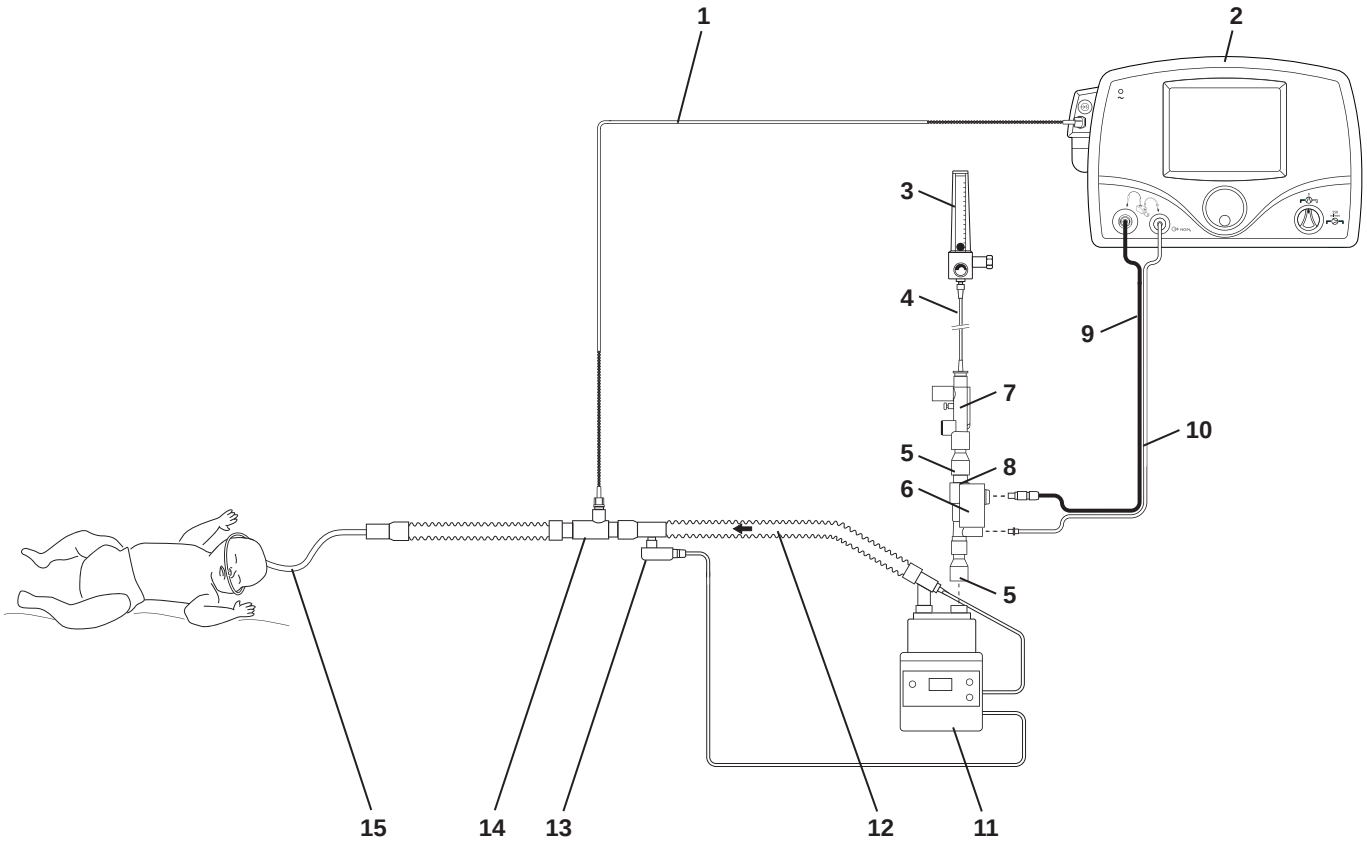
Fisher & Paykel Healthcare Bubble CPAP



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

Figure 3-29 Example: Fisher & Paykel Healthcare Bubble CPAP System Circuit Diagram

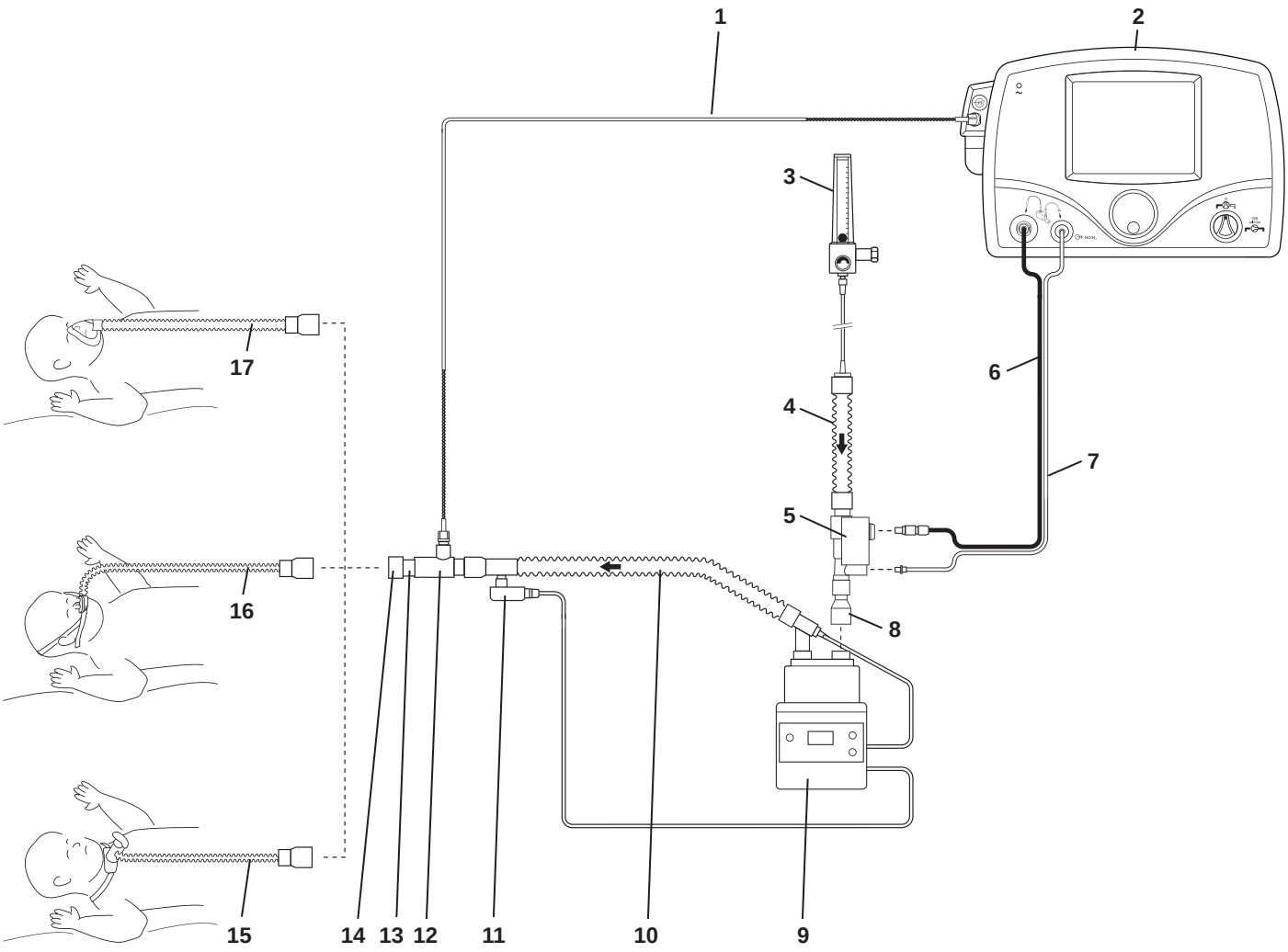
Fisher & Paykel Healthcare Infant Circuit Nasal Cannula



1. Patient Gas Sample Line with Nafion
2. INOmax DS_{IR}
3. Oxygen Source
4. Oxygen Tubing
5. 22F X 15M Adapter
6. Injector Module
7. Pressure Relief Manifold
8. 22M/15F X 22M/15F Adapter
9. Injector Module Electrical Cable
10. NO/N_2 Injector Tube
11. Humidifier
12. Breathing Circuit
13. Temperature Probe
14. Gas Sample Tee
15. Nasal Cannula

Figure 3-30 Example: Fisher & Paykel Healthcare Infant Circuit Nasal Cannula Diagram

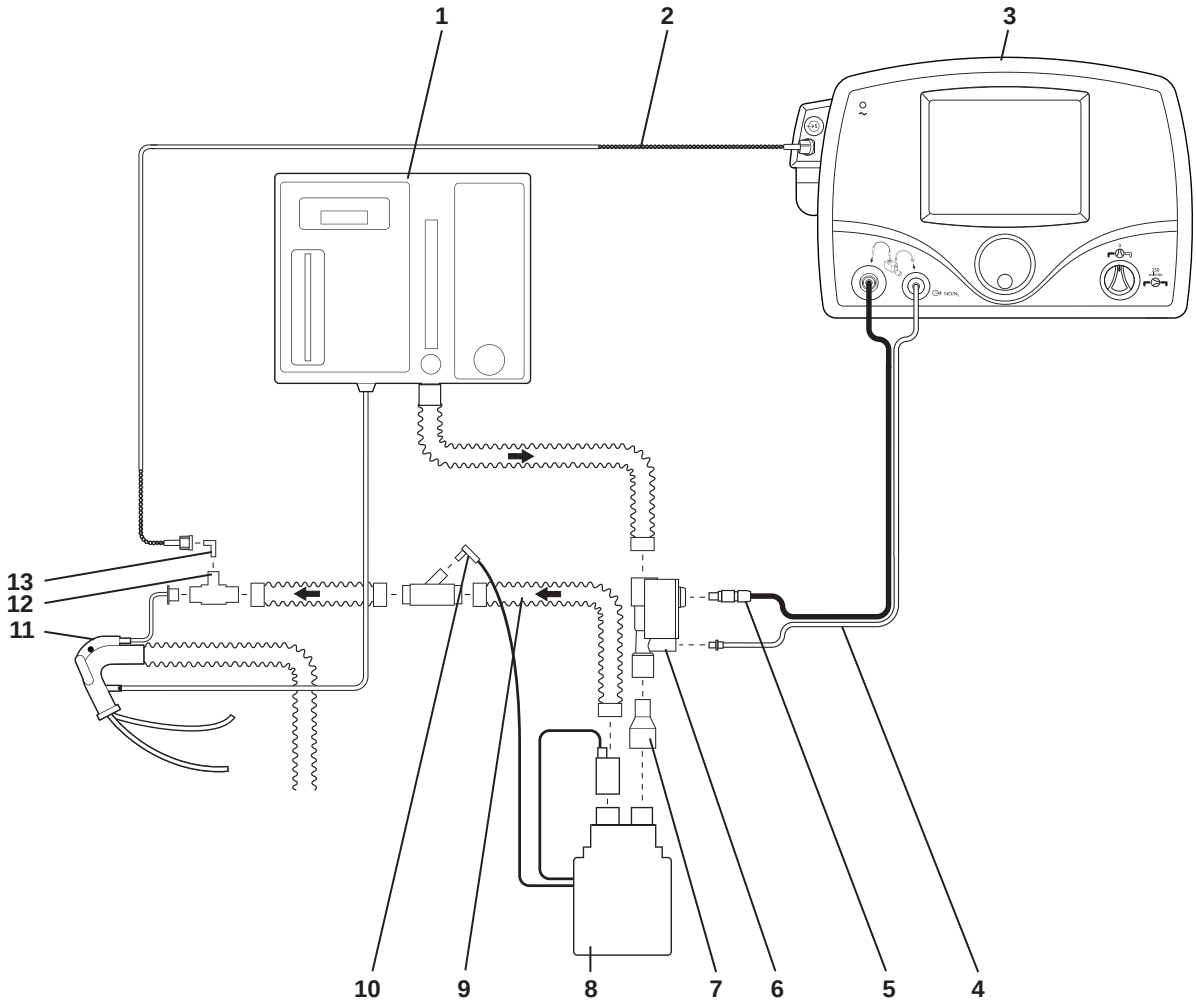
Fisher & Paykel Healthcare Optiflow Breathing Circuit



1. Patient Gas Sample Line with Nafion
2. INOmax DS_{IR}
3. Oxygen Source
4. Breathing Circuit Hose
5. Injector Module
6. Injector Module Electrical Cable
7. NO/N_2 Injector Tube
8. 22F X 15M Adapter
9. Humidifier
10. Breathing Circuit
11. Temperature Probe
12. Gas Sample Tee
13. 22M/15F X 22M/15F Adapter
14. 22 mm ID X 22 mm ID Cuff Adapter
15. Optiflow Tracheostomy
16. Optiflow Nasal Cannula
17. Optiflow Mask

Figure 3-31 Example: Fisher & Paykel Healthcare Optiflow Breathing Circuit Diagram

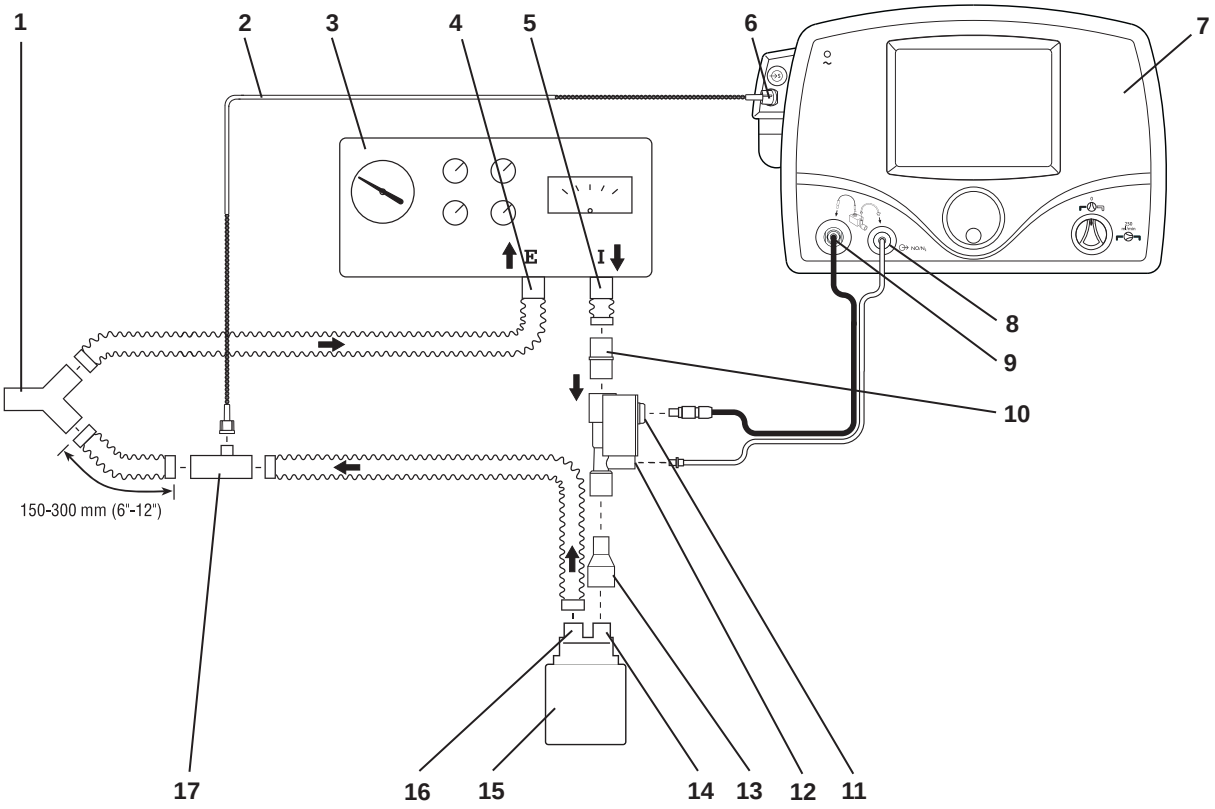
Hamilton Arabella Nasal CPAP



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

Figure 3-32 Example: Hamilton Arabella Nasal CPAP Circuit Diagram

ICU Ventilator Circuit



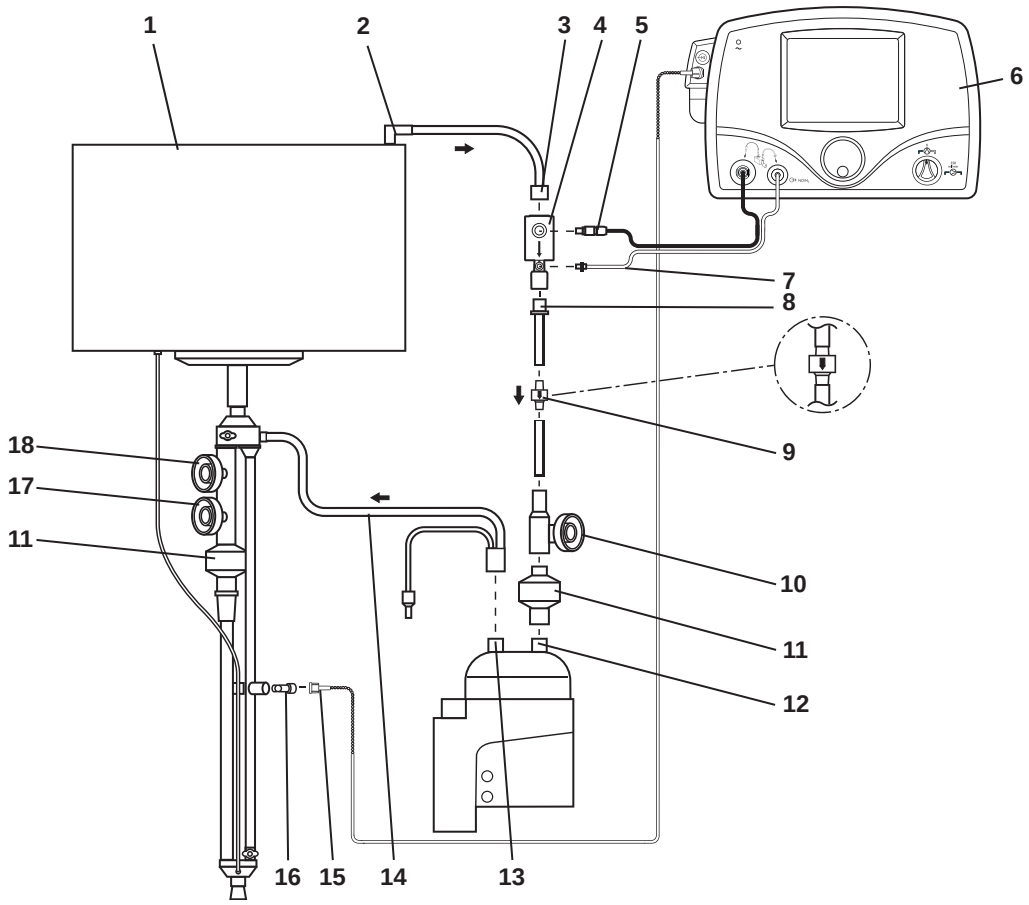
1. Patient Wye
2. Patient Gas Sample Line with Nafion
3. Ventilator
4. Ventilator Expiratory Port
5. Ventilator Inspiratory Port
6. Patient Gas Sample Line Input Connection
7. INOmax DS_{IR}
8. NO/N_2 Injector Tube Front Panel Connection
9. Injector Module Electrical Cable Front Panel Connection
10.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

Figure 3-33 Example: General Ventilator Diagram

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: Use only parts provided in disposable package #50250, and tightly secure all connections.

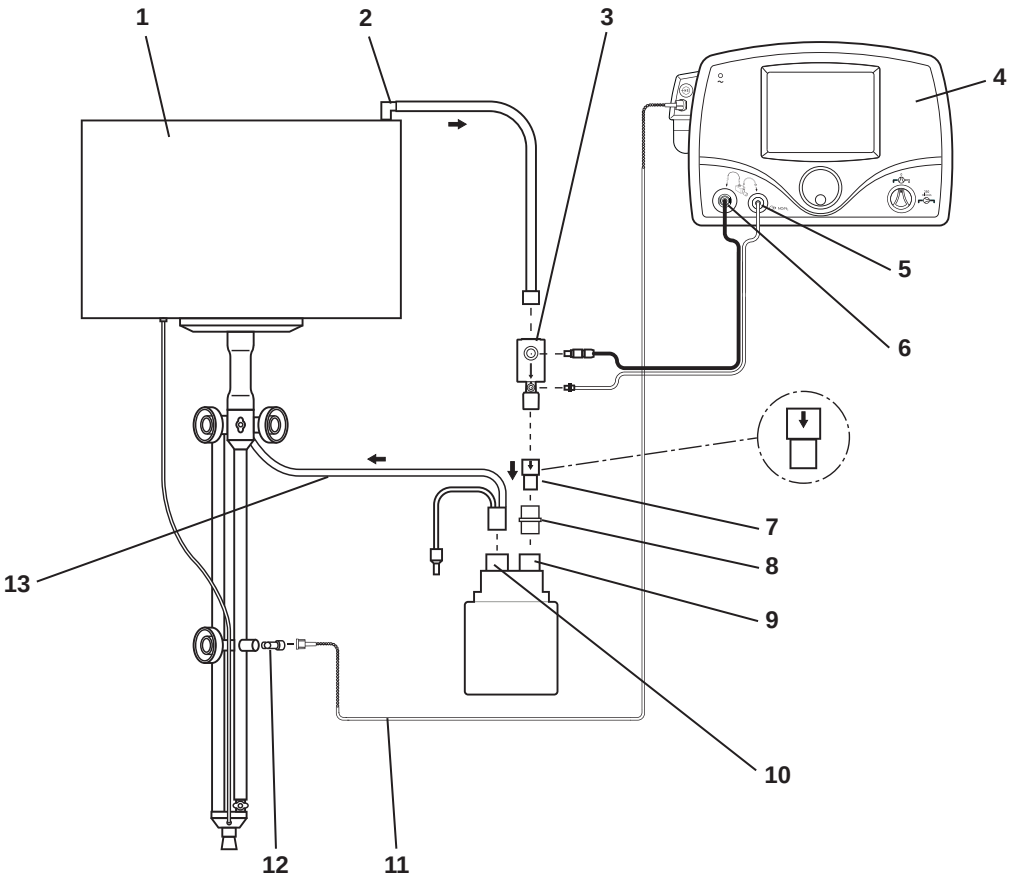


1. Sensormedics 3100A/B Ventilator
2. Ventilator Outlet
3. 22M Adapter
4. Injector Module
5. Injector Module Electrical Cable Connection
6. INOmax DS_{IR}
7. NO/N_2 Injector Tube
8. 8 mm Tubing X 15M Adapter
9. One-Way Valve
10. Paw Limit Valve Control
11. Filter
12. Humidifier Inlet
13. Humidifier Outlet
14. Bias Flow Tube
15. Patient Gas Sample Line with Nafion
16. 90 Degree Sample Port Adapter
17. Dump Valve Control
18. Paw Control Valve

Figure 3-34 Example: High Frequency Oscillatory Ventilator Diagram

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.**



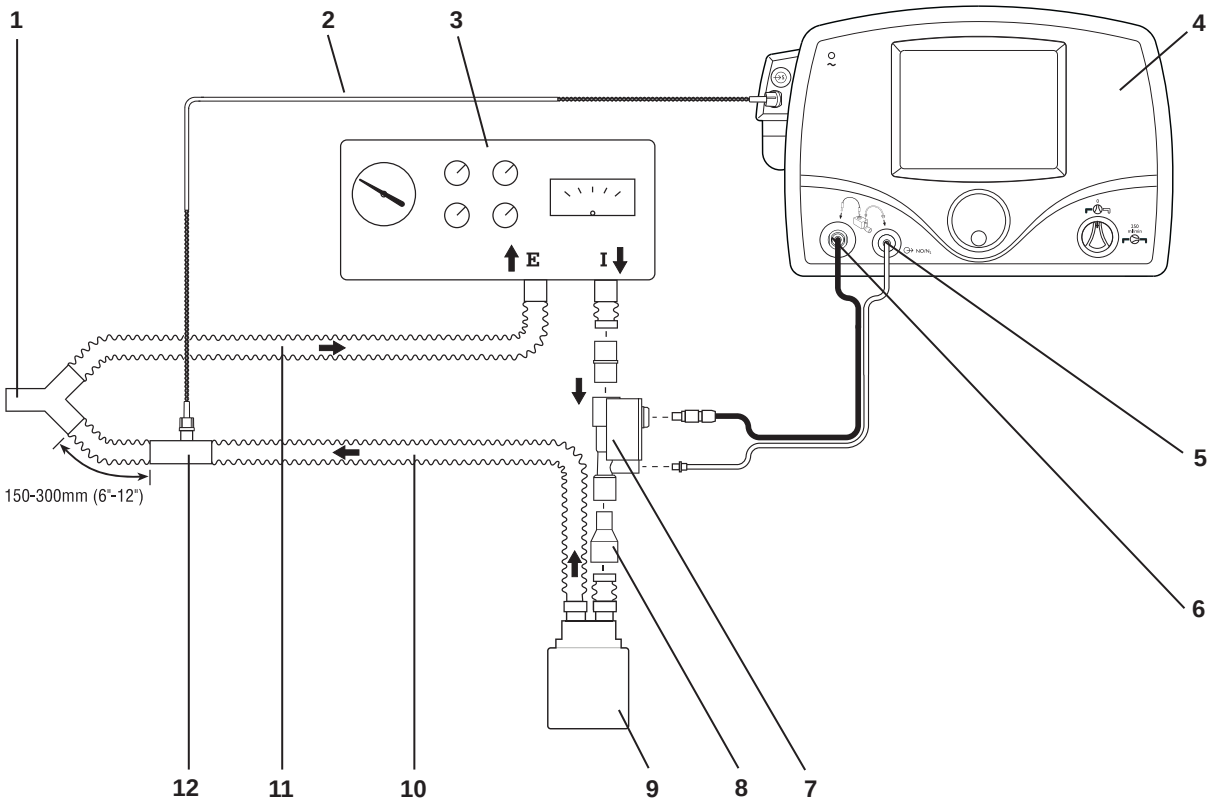
1. Sensormedics 3100A/B Ventilator
2. Ventilator Outlet
3. Injector Module
4. INOmax DS_{IR}
5. NO/N_2 Injector Tube Connection
6. Injector Module Electrical Cable Connection
7. One-Way Valve
8. 22 mm ID X 22 mm ID Cuff Adapter
9. Humidifier Inlet
10. Humidifier Outlet
11. Patient Gas Sample Line with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

Figure 3-35 Example: High Frequency Oscillatory Ventilator Diagram

SLE Life Support SLE5000

Note:

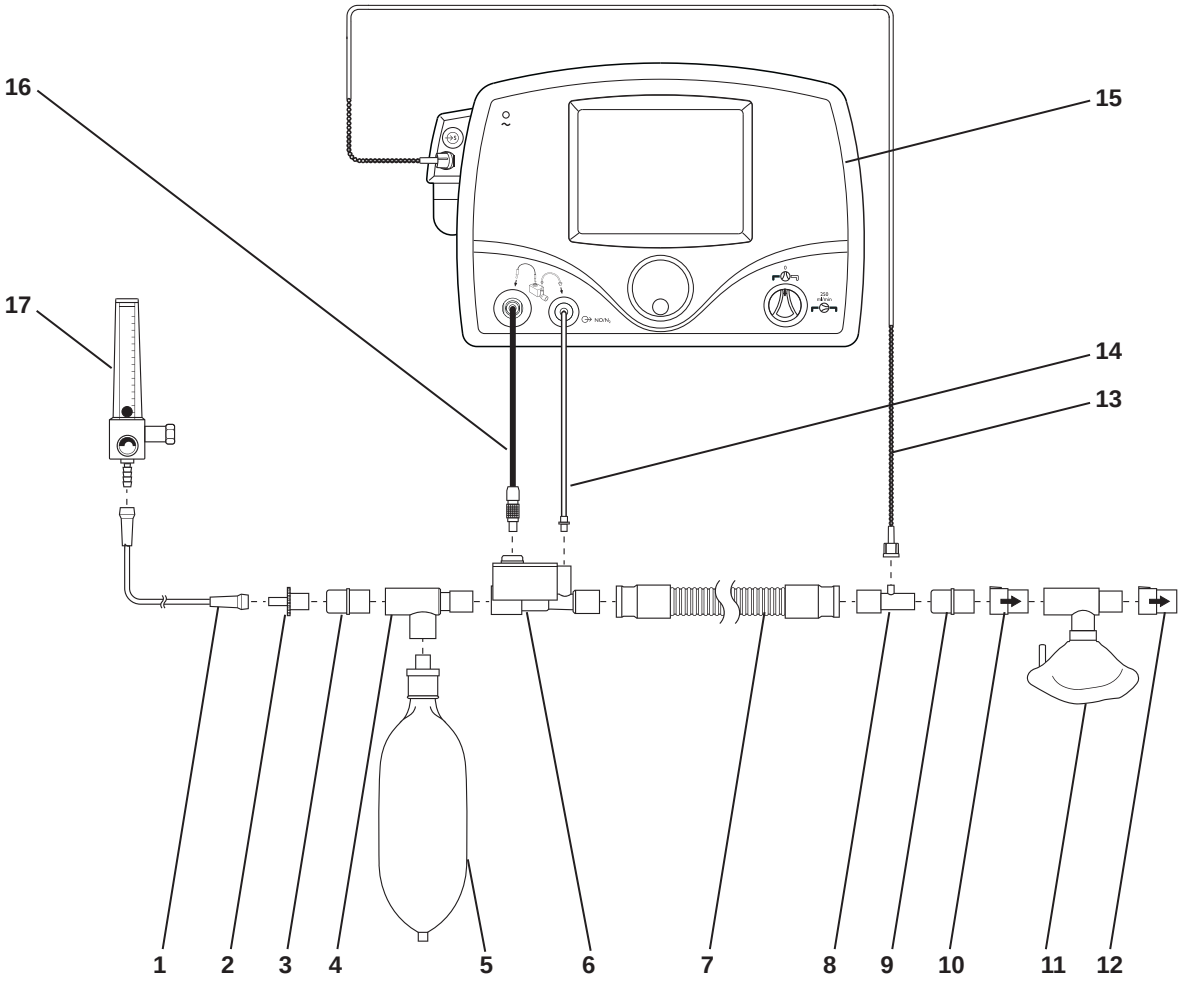
- Validated for use outside of the United States.
- A one-way valve is not required for use during high frequency ventilation mode.



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

Figure 3-36 Example: SLE Life Support SLE5000 Circuit Diagram

Spontaneous Breathing Patient on a Mask Circuit



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

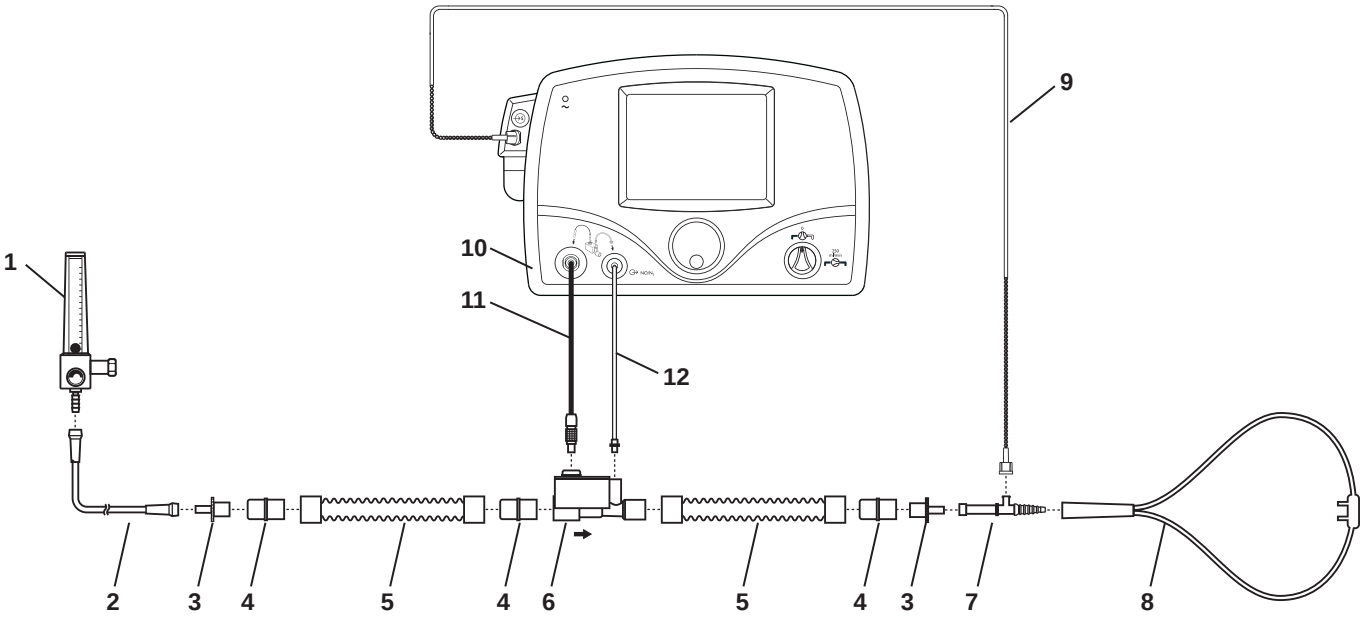
Figure 3-37 Example: Spontaneous Breathing Patient Circuit Diagram

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 two 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 22 mm hose between the oxygen tubing and the Injector Module.

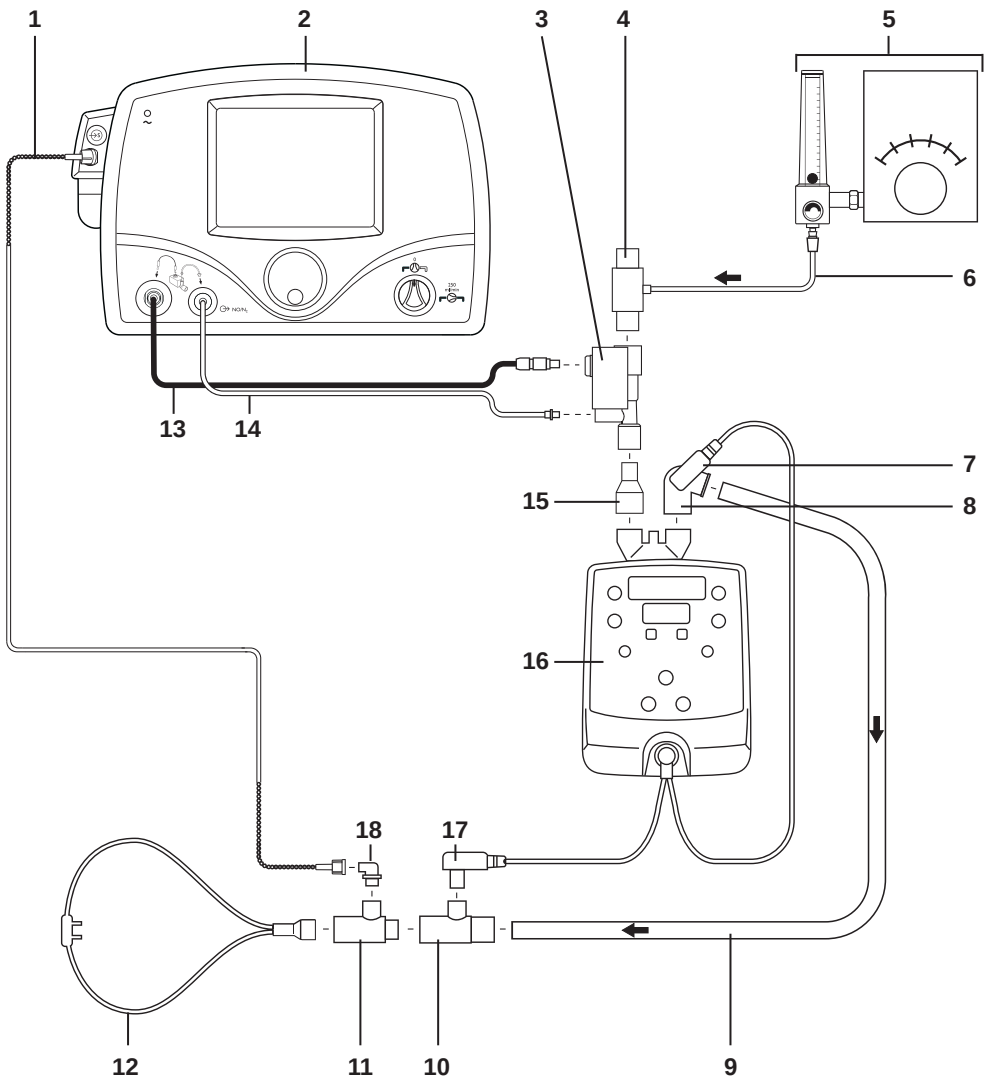
WARNING: **Do not use the integrated pneumatic backup with flow rates less than five L/min.**



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

Figure 3-38 Example: Spontaneous Breathing Nasal Cannula Patient Circuit Diagram

Teleflex Medical Comfort Flo Humidification System

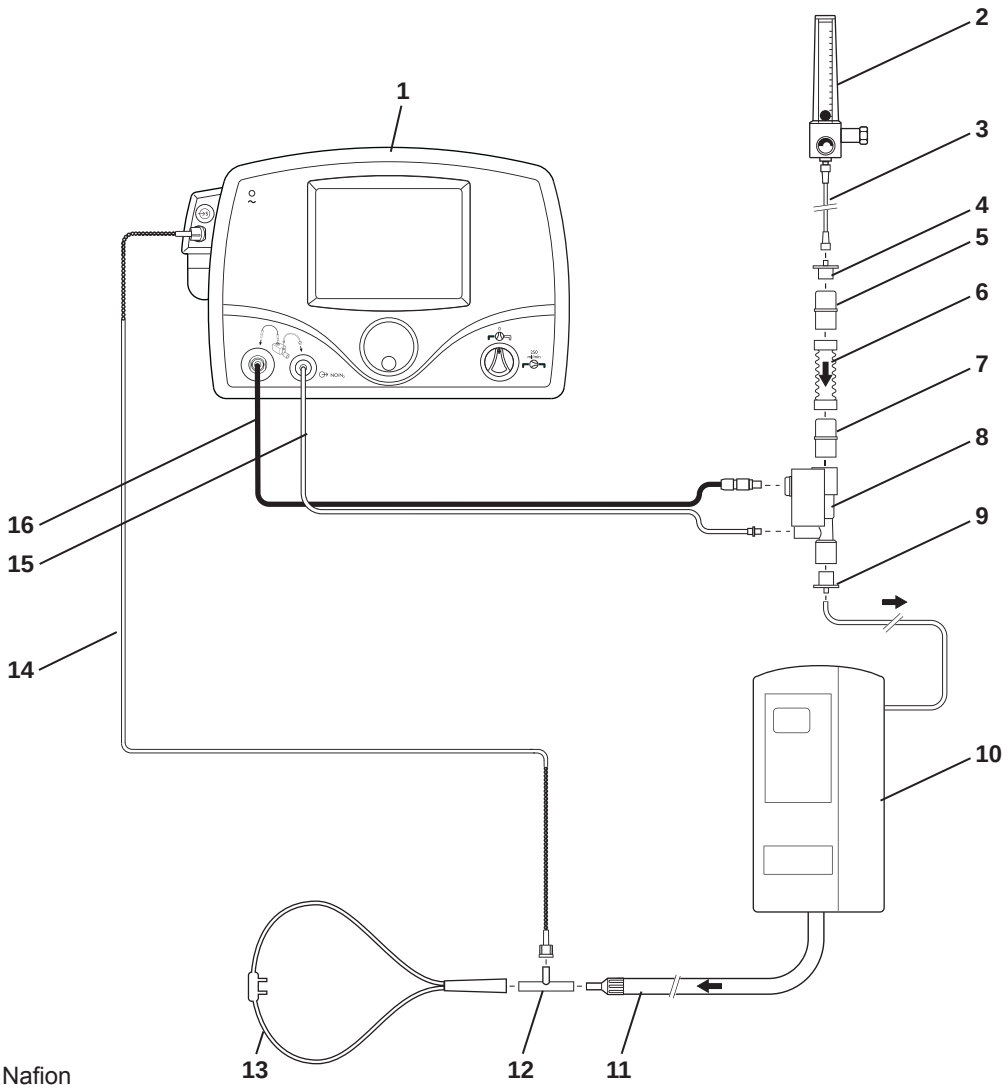


1. Patient Gas Sample Line with Nafion
2. INOmax DS_{IR}
3. Injector Module
4. System Pressure Relief Valve
5. Air/Oxygen Blender or Oxygen Blender
6. Oxygen Tubing
7. Temperature Probe (Short Cable)
8. Angled 22 mm Connector
9. Patient Circuit
10. Temperature Probe Connector
11. Second Temperature Probe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

Figure 3-39 Example: Teleflex Comfort Flo Patient Circuit Diagram

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 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 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.

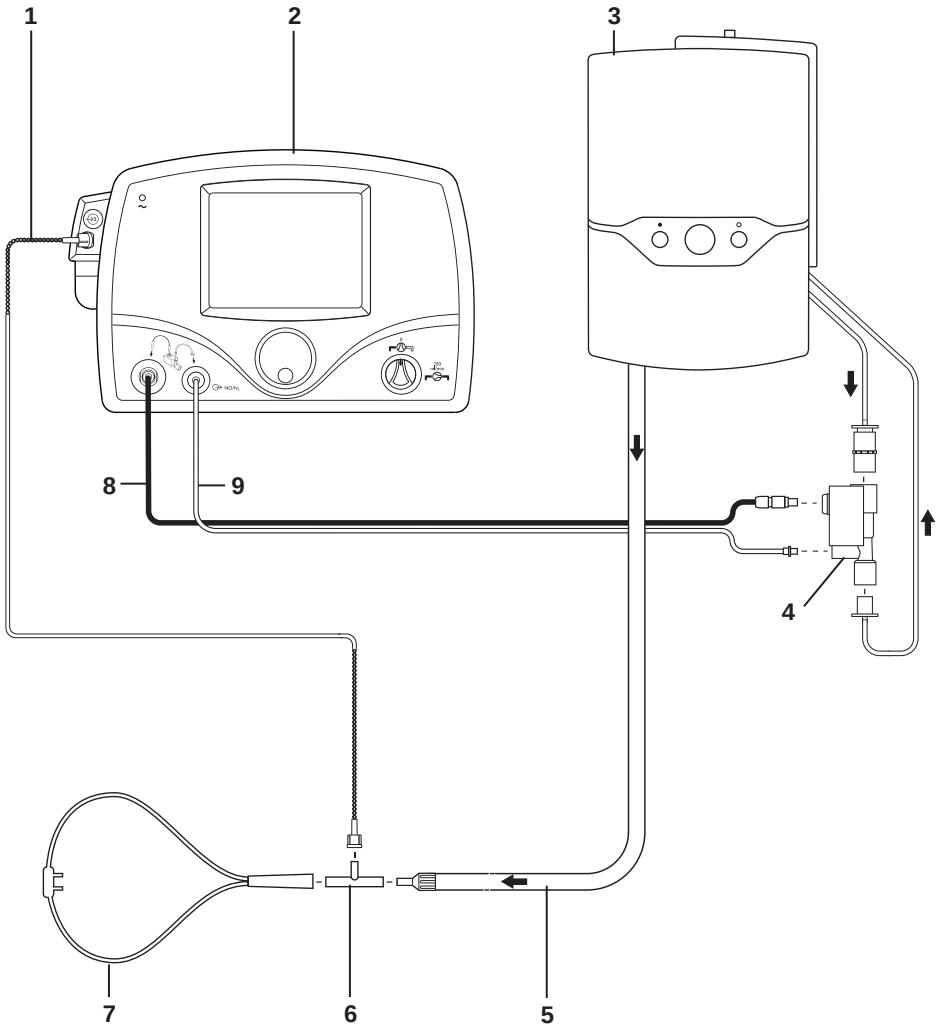


1. INOmax DS_{IR}
2. O_2 Flowmeter
3. O_2 Tubing
4. 15M x 4.5 mm Adapter
5. 22M/15F x 22M/15F Adapter
6. 300 mm of 22 mm Hose
7. 22M/15F x 22M/15F Adapter
8. Injector Module
9. 15M x 4.5 mm Adapter
10. Vapotherm 2000i
11. Patient Delivery Tube
12. O_2 Tubing Sample Tee
13. Patient Cannula
14. Patient Gas Sample Line with Nafion
15. NO/N_2 Injector Tube
16. Injector Module Electrical Cable

Figure 3-40 Example: Vapotherm 2000i Circuit Diagram

Vapotherm Precision Flow

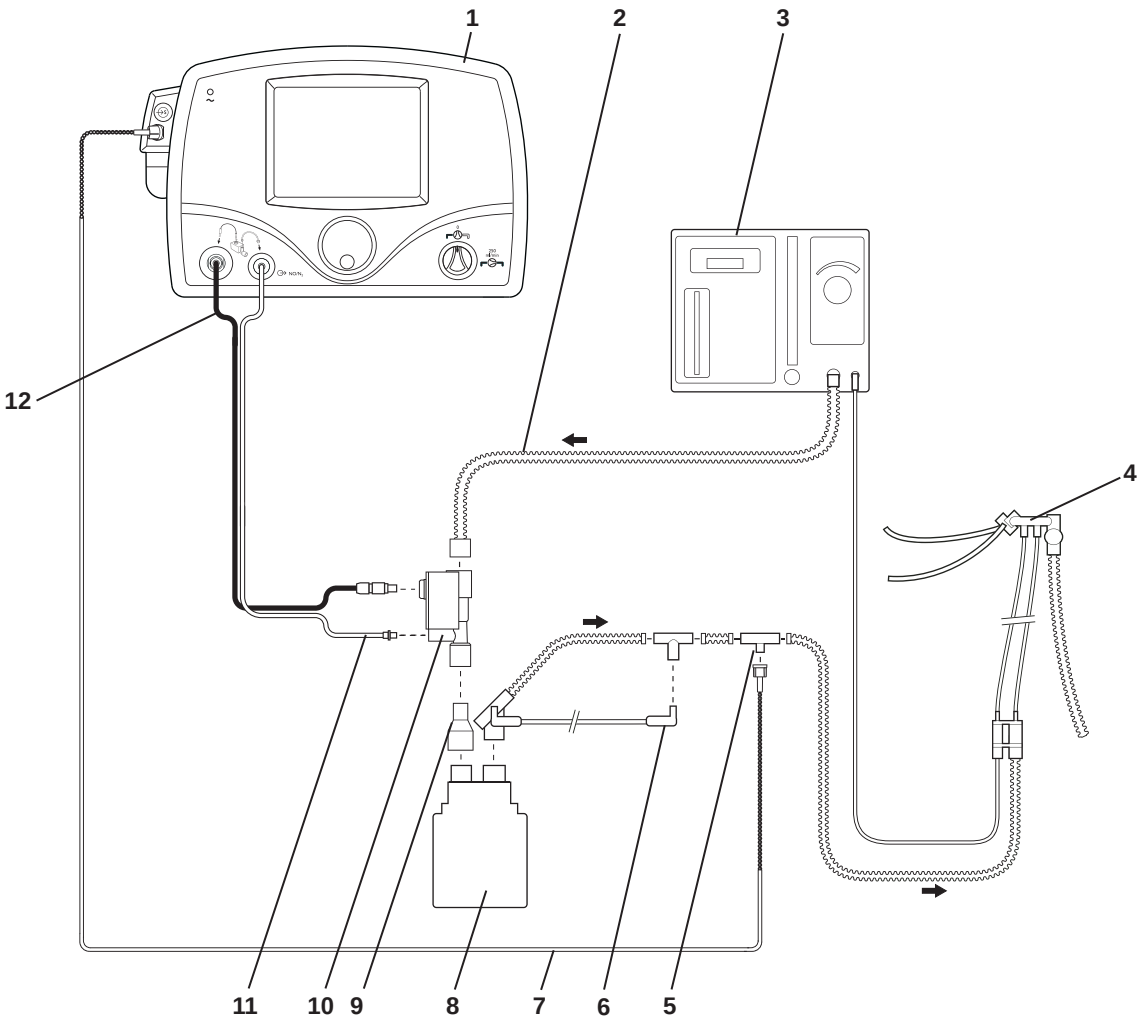
- The INOmax DS_{IR} adds NO/N_2 gas flow to the breathing circuit flow in proportion to the NO setting (up to 10% at 80 ppm) and subtracts gas from the breathing circuit via gas sampling at a nominal flow rate of 0.23 L/min.
- These effects impact the delivered gas flow rate when using the Vapotherm Precision Flow. It is recommended that after an NO setting change the user checks the delivered gas flow rate and adjusts the gas source flow rate as necessary.
- Follow all manufacturer instructions for connection to the Vapotherm Precision Flow.



1. Patient Gas Sample Line with Nafion
2. INOmax 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 3-41 Example: Vapotherm Precision Flow Circuit Diagram

Viasys Infant Flow CPAP System; Cardinal Airlife nCPAP System



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

Figure 3-42 Example: Viasys Infant Flow CPAP System Circuit Diagram

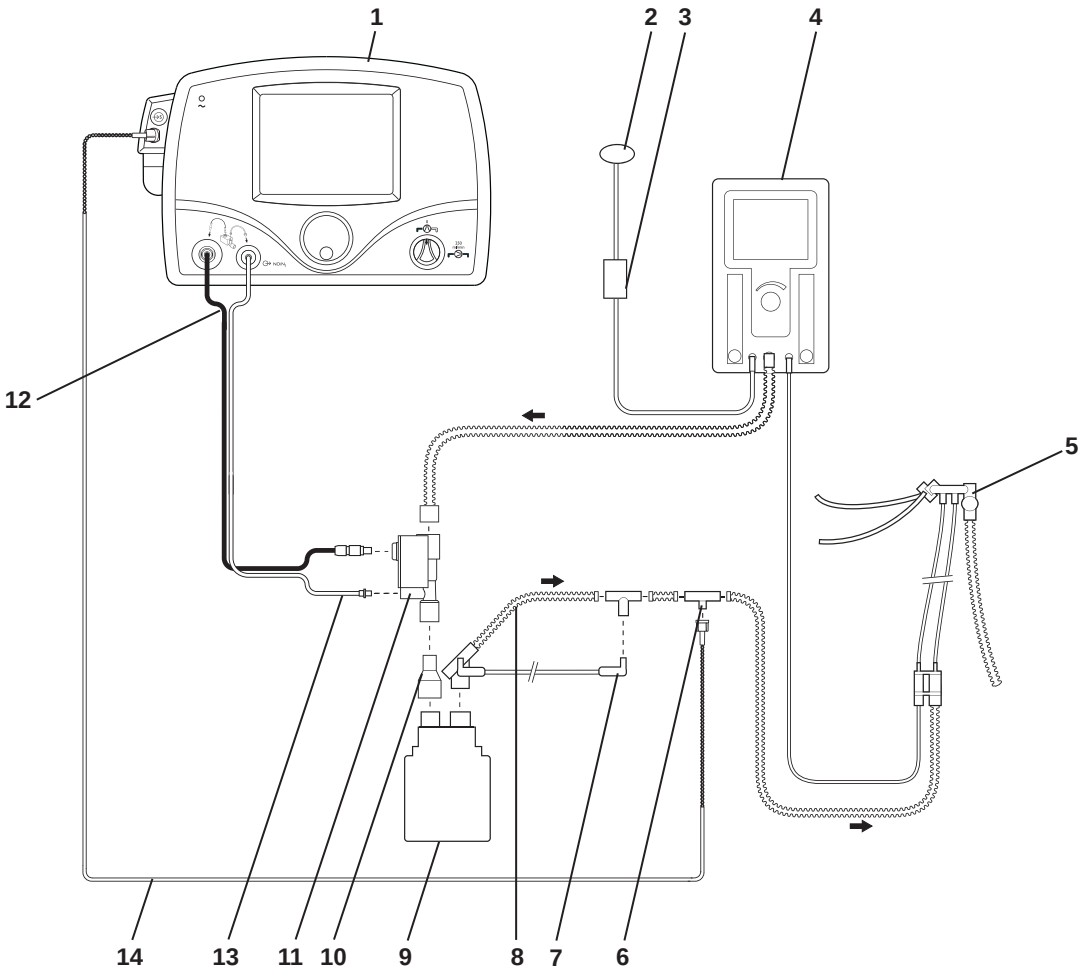
(Intentionally left blank)

Viasys Infant Flow SiPAP

- 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 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 two 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%

Viasys Infant Flow SiPAP



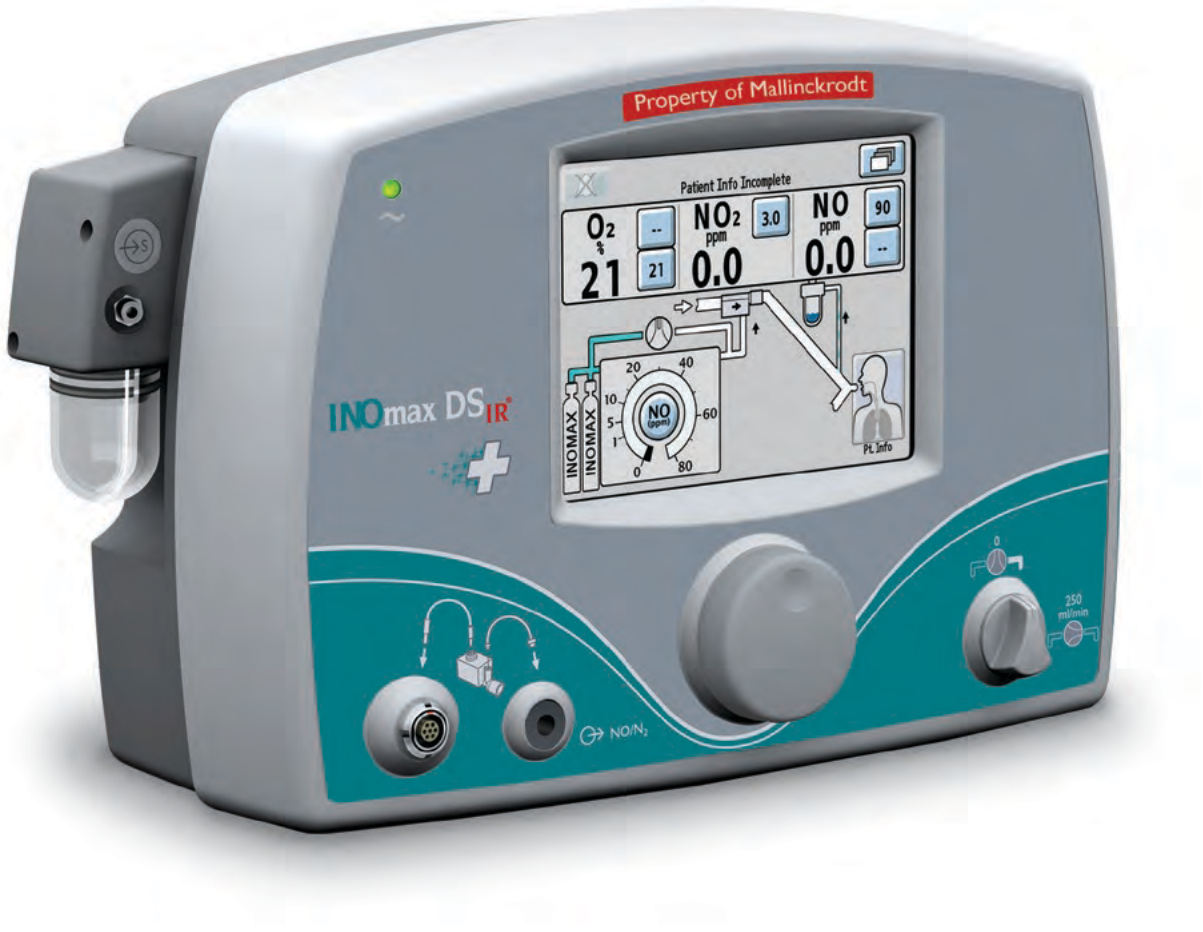
1. INOmax DS_{IR}
2. Abdominal Respiratory Sensor
3. Transducer Interface
4. Infant Flow SiPAP
5. Infant Flow Generator
6. Sample Tee
7. Temperature Probe
8. Heated Delivery Circuit
9. Humidifier
10. 22F X 15M Adapter
11. Injector Module
12. Injector Module Electrical Cable
13. NO/N_2 Injector Tube
14.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

Figure 3-43 Example: Viasys Infant Flow SiPAP Circuit Diagram

(Intentionally left blank)

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



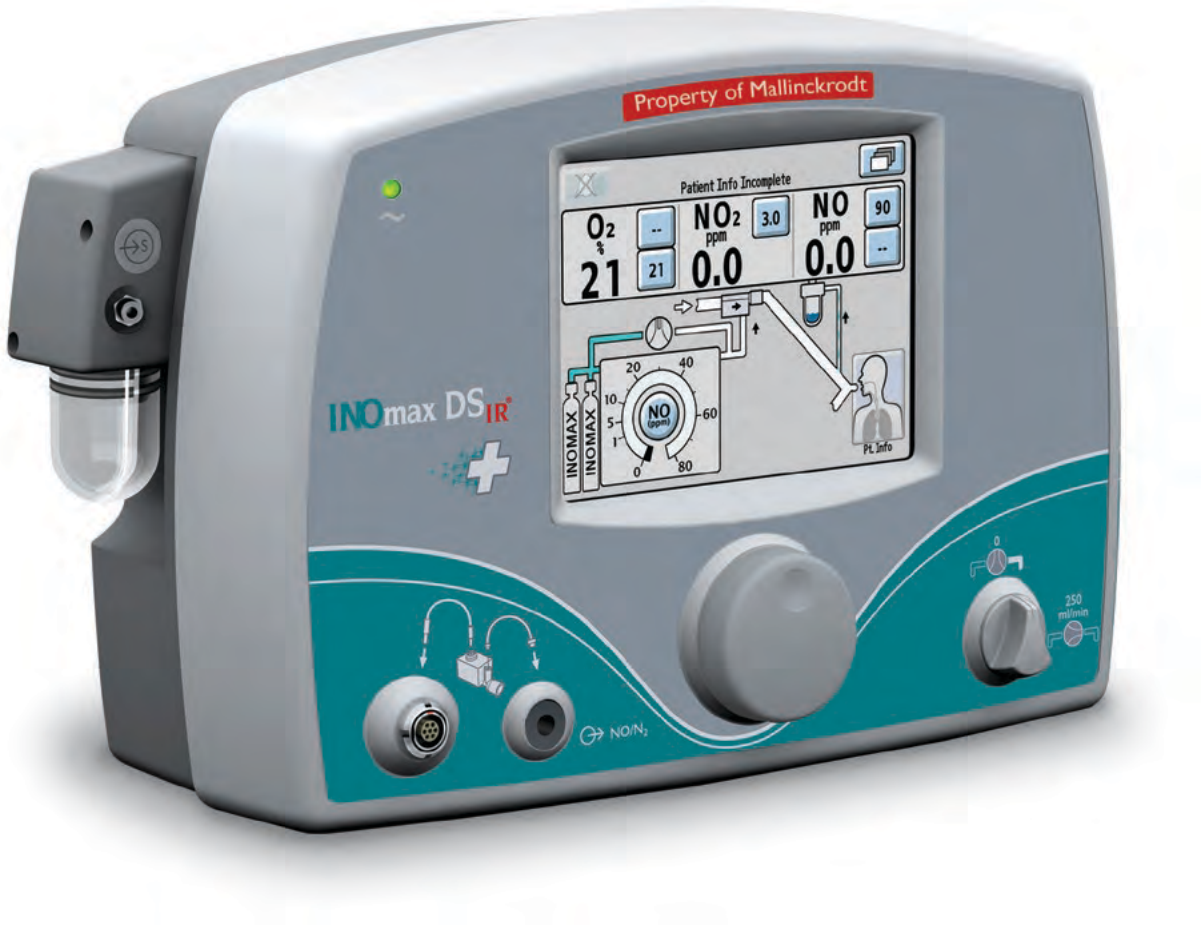
Transport

4/ Transport

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



4/ Transport

Part No. 20717 Rev-01
2014-07

4/ Transport

Caution:

- It is recommended that a second (backup) transport regulator cap assembly is available during all transports.
- It is recommended that a second (backup) cylinder of INOMAX is available during all transports.

Transport Options

A. When moving the INOmax DS_{IR} as a unit (cart and cylinders), (see Section A below).

B. When removing INOmax DS_{IR} and INOblender from the cart (see Section B below).

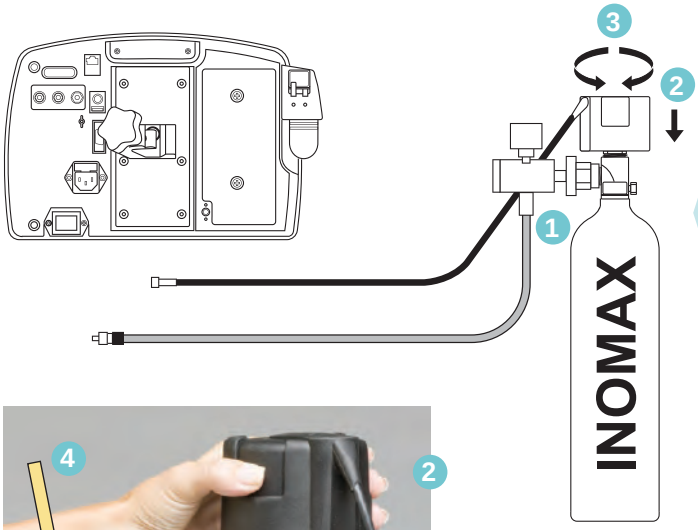
C. When using the INOblender as a stand-alone device (see Section C below).

D. When using a separate INOmax DS_{IR} and INOblender for transport (see Section D below).

A. Intrahospital transport (within the hospital) when moving the INOmax DS_{IR} as a unit (cart and cylinders)

1. Refer to cylinder duration chart as a guide to determine if there is enough drug to last through the transport, including unexpected delays. Bring additional cylinders as appropriate.
2. Connect the INOblender oxygen hose to a 50 psig portable oxygen source.
3 Manually ventilate the patient using the INOblender while configuring the INOmax DS_{IR} to the transport ventilator (see figure 4-11 or 4-12).
4. Upon return:
   a. Manually ventilate the patient while reattaching the INOmax DS_{IR} to the bedside ventilator.
   b. Confirm the operation of the INOmax DS_{IR}.
   c. Reconnect the INOblender oxygen hose to a 50 psig wall oxygen source.

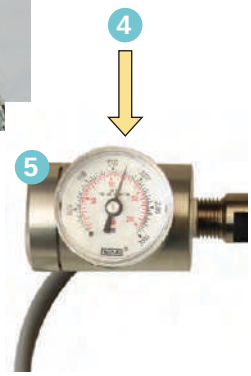
B. Intrahospital transport (within the hospital) when removing the INOmax DS_{IR} and INOblender from the cart.



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

1. Connect the high pressure transport regulator/cap assembly to the INOMAX transport cylinder, and tighten the fitting to the INOMAX cylinder.
2. Place the cap assembly over the INOmeter.
3. Open then close the INOMAX transport cylinder valve.

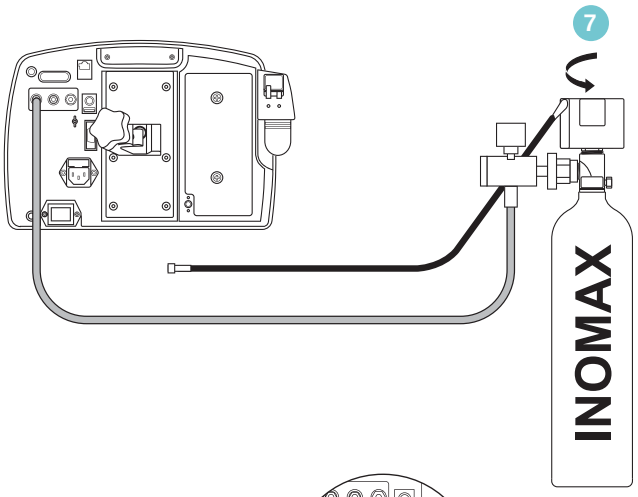
Note: Be sure to align the key way inside the Cap Assembly with the ibutton on the INOmeter.



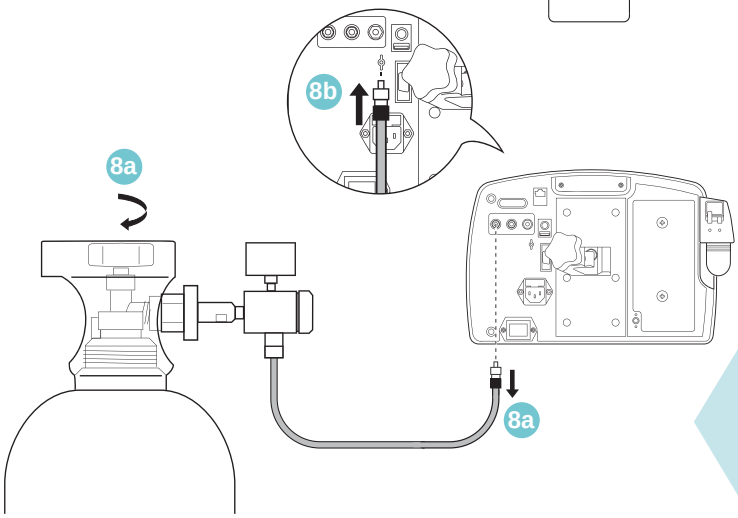
4. Check for adequate cylinder pressure. Verify cylinder has at least 500 psig (replace if 200 psig or less).
5. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no signs of pressure decrease is observed, the leak test is successful.

6a. Depressurize the transport cylinder regulator hose.

6b. Connect regulator hose to the available drug inlet.

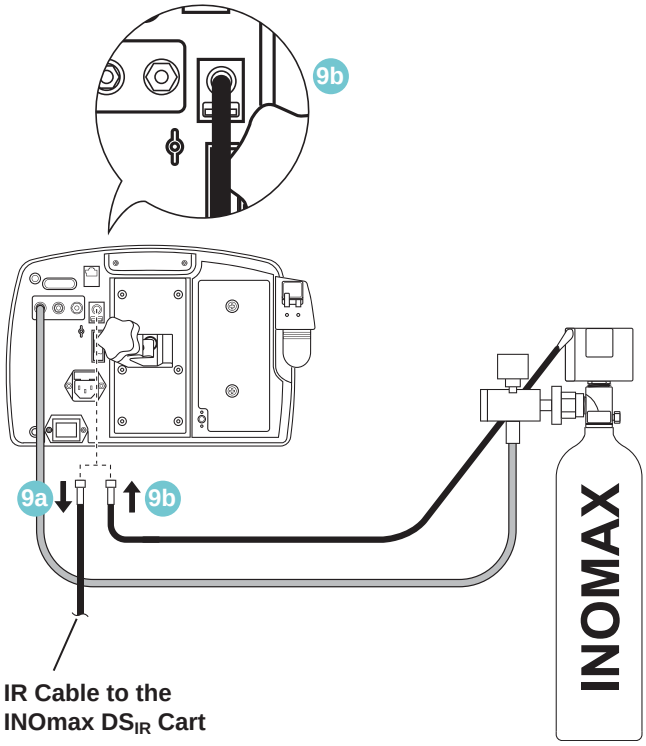


7. Open INOMAX transport cylinder valve.



8a. Immediately remove “88” INOMAX cylinder regulator hose, and close cylinder valve.

8b. Depressurize the "88" INOMAX cylinder regulator hose by pressing in the purge port.



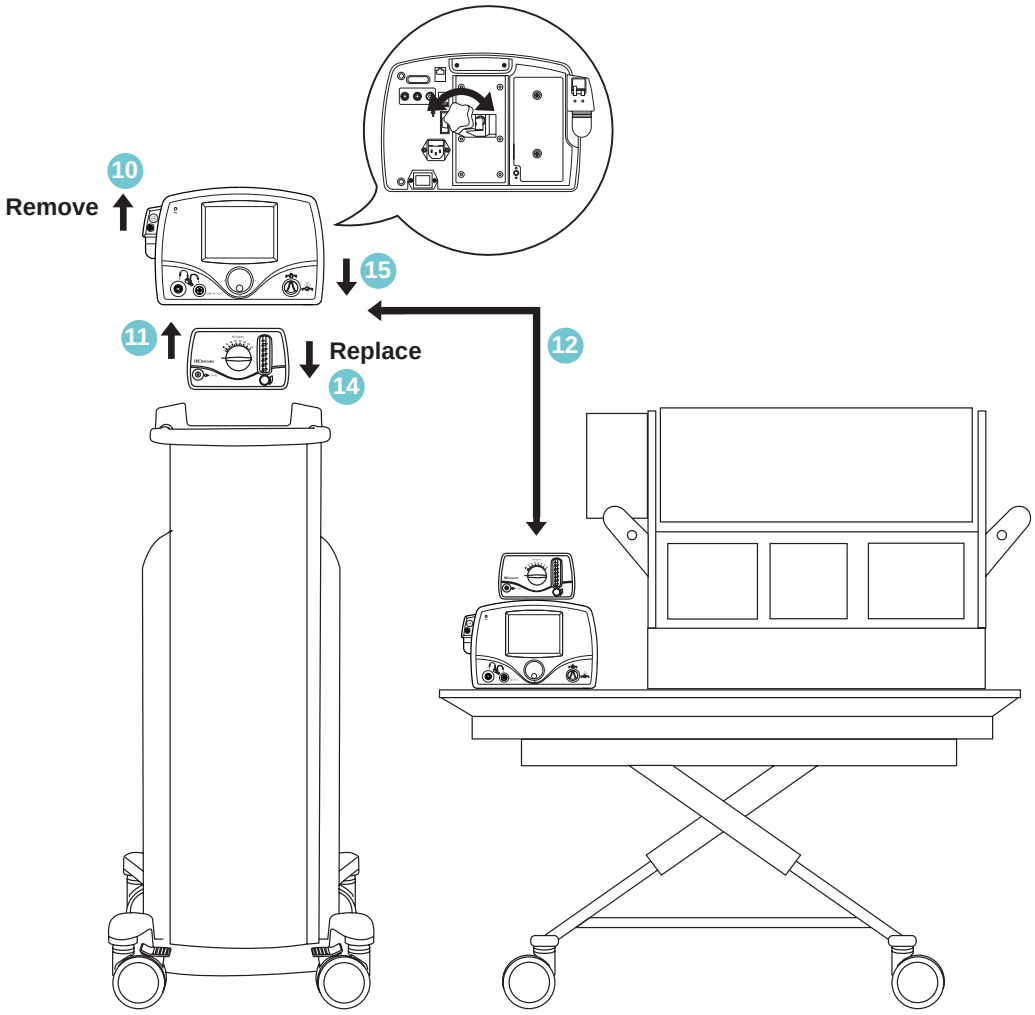
9a. Disconnect the cart infrared (IR) cable.

9b. Connect the IR cable from the transport regulator cap assembly to the back of the INOmax DS_{IR}.

10. Loosen clamp assembly knob on the back of the INOmax DS_{IR} and remove the INOmax DS_{IR} from the cart.
11. Loosen clamp assembly knob on the back of the INOblender and remove the INOblender from the cart.
12. Place both devices on the transport device and secure.
13. Connect the INOblender inlet hose to the INOmax DS_{IR} INOblender outlet and slide the quick-connect cover into place.

Upon return:

14. Return the INOblender to the cart and secure the clamp assembly.
15. Return the INOmax DS_{IR} to the cart and secure the clamp assembly.
16. Connect the INOblender inlet hose to the INOmax DS_{IR} INOblender outlet and slide the quick-connect cover into place.



Note: INOblender extension hose (PN 10014) will be required if the INOMAX DS_{IR} and the INOblender are positioned more than two feet apart.

Once the devices are secure on the cart:

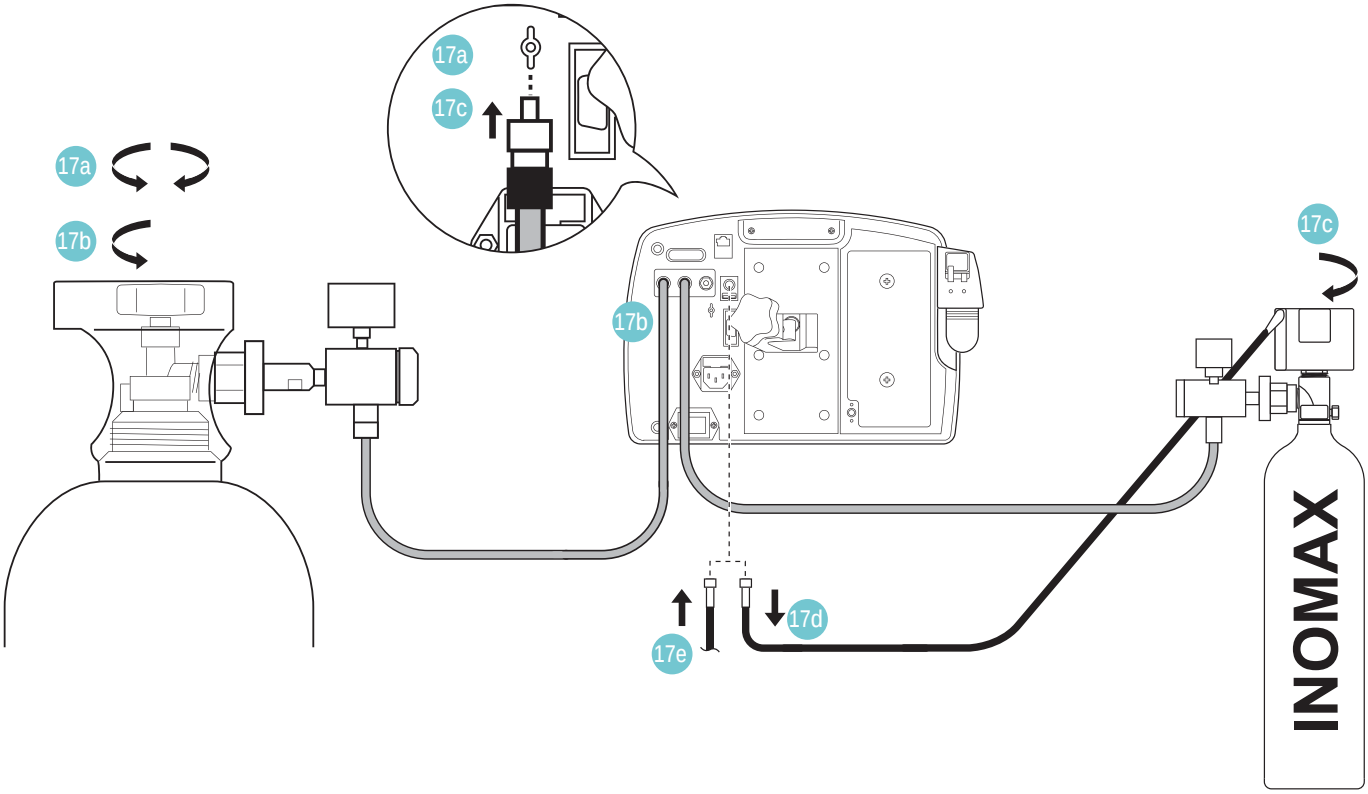
17a. Open/close “88” INOMAX cylinder, then depressurize the regulator hose by pressing the regulator hose into the purge port.

17b. Open the "88" INOMAX cylinder valve and insert the regulator hose into available INOMAX gas inlet.

17c. Close transport cylinder valve and remove the regulator hose from the INOMAX gas inlet and depressurize the regulator hose by pressing into the purge port.

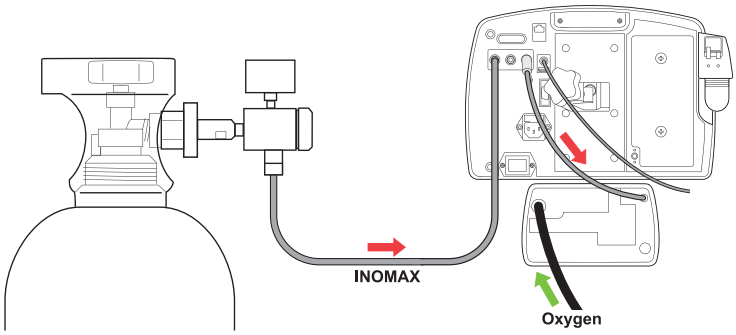
17d. Disconnect the transport cylinder IR cable from the back of the INOmax DS_{IR}.

17e. Attach IR cable from the cart to the back of the INOmax DS_{IR}.



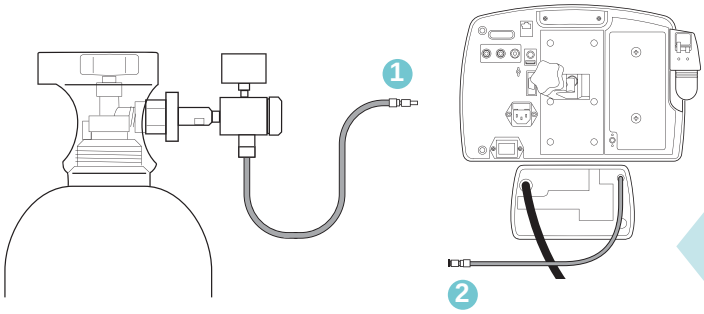
C. When using the INOblender as a stand-alone device.

Important: Read the INOblender Operation Manual PN 20732 before using the INOblender. Follow instructions and obey all Warnings and Cautions.



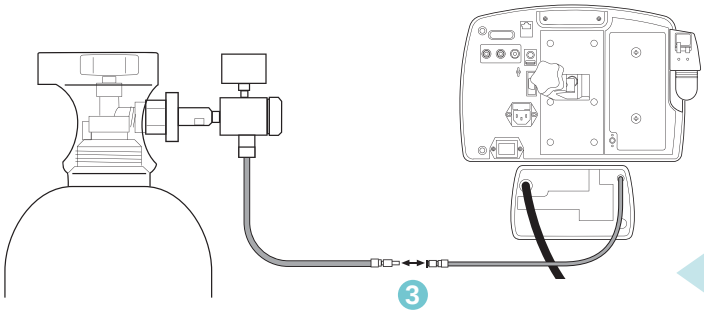
Typically the INOblender receives INOMAX from the INOmax DS_{IR} (INOMAX cylinder supplies both devices; see Figure 4-1).

Figure 4-1



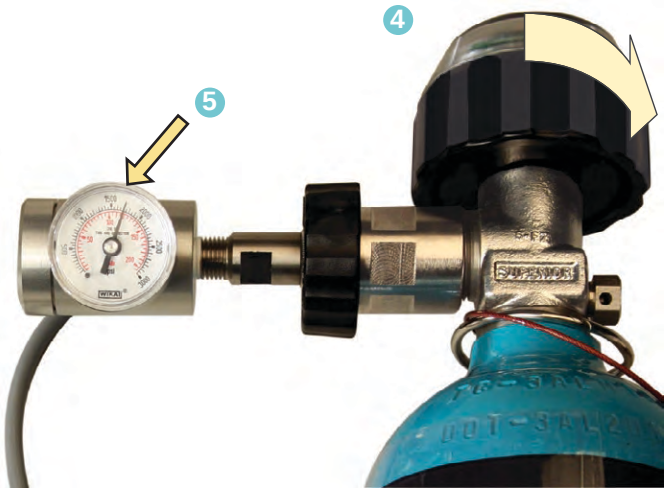
As a stand-alone device the INOMAX cylinder supplies INOMAX to the INOblender. (see Figure 4-2).

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 4-2



4. Verify INOMAX cylinder valve is open.
5. Verify cylinder has at least 500 psig (replace if 200 psig or less)."

Adjust Settings

6. Turn the INOblender setting dial to the desired concentration (5 to 80 ppm for an 800 ppm cylinder).
7. Turn the O_2 flowmeter to the desired flow rate (5 to 14 L/min).
8. Squeeze the manual resuscitator 3-4 times to purge the NO_2 from the system.

The INOblender is now ready for patient use.

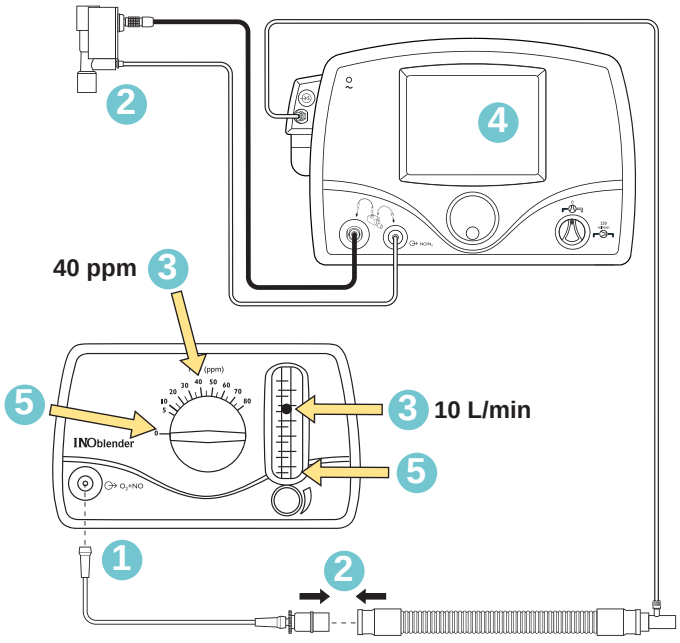
INOblender Test Using the INOmax DS_{IR} to Analyze Output

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.
- When the INOblender is used with an oxygen/air blender:
  - The specification for INOMAX delivery when using the INOblender with 100% oxygen is +/- 20% of setting or two 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 three ppm (whichever is greater).
- Refer to the manufacturer's procedures when using the manual resuscitator bag.
- When finished, turn the NO cylinder valve OFF and allow the oxygen to flow until the NO pressure gauge reads zero, then turn the oxygen flow OFF.



Acceptable NO Value	4	32-48 ppm

Note:

- Confirm INOblender inlet hose is connected to the INOMAX regulator hose and the Quick-Connect cover is in place.
- Confirm 50 psig oxygen supply hose is connected to O_2 inlet fitting on back of INOblender.

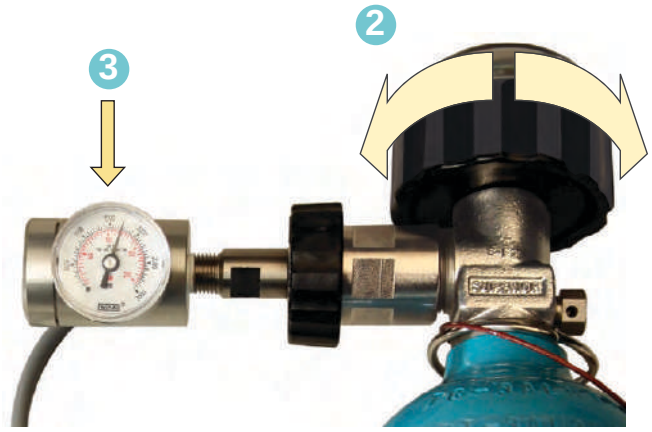
1. Use the Pre-Use set-up to connect to sample gas from the INOblender.

   Connect O_2 tubing to the front of the INOblender.

2. Confirm the injector module is removed from the Pre-Use set-up and connect the adapters.
3. On the INOblender, set the INOMAX dose to 40 ppm and O_2 flow to 10 L/min.
4. Verify NO value on the INOmax DS_{IR}.
5. Turn the dose and oxygen flow to zero.
6. Remove the Pre-Use set-up from the INOblender.

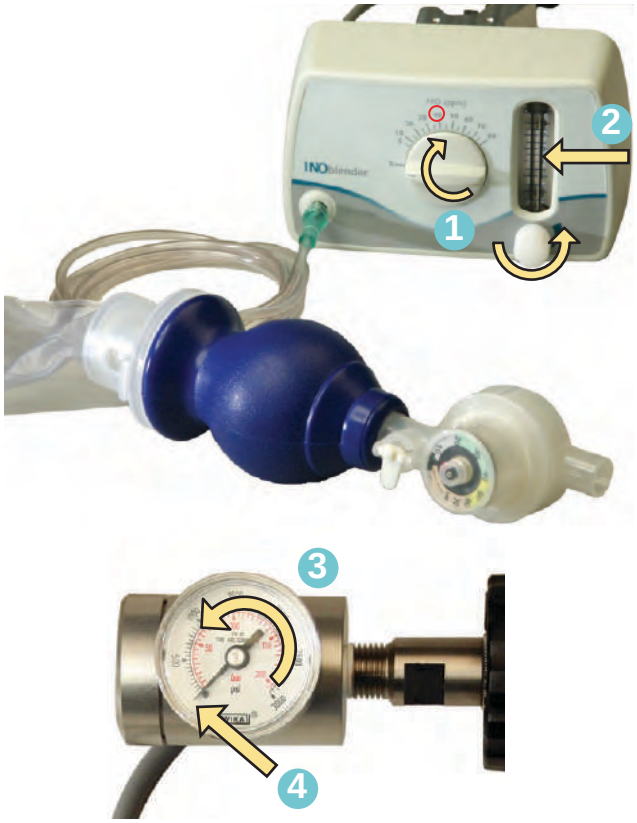
INOblender Stand-Alone Pre-use Checkout

Caution: To help ensure proper operation, complete the pre-use checkout prior to each use.



High-Pressure Leak Test

1. Make sure NO dose setting dial is turned to zero and flow meter is OFF.
2. Open and then close the INOMAX cylinder valve.
3. Check the INOMAX drug cylinders for the correct product identity, cylinder concentration, and expiration date. Verify cylinder has at least 500 psig (replace if 200 psig or less), and tighten the fitting to the INOMAX cylinder.
4. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no pressure decrease is observed, high-pressure leak test successful, proceed to Delivery Confirmation and Purge.
5. If observed pressure decrease continues, see Section 7/ Maintenance; Cylinder Leak Check.
6. If leak cannot be traced, replace the INOblender.



Delivery Confirmation and Purge

1. Set the INOblender to 40 ppm when using an 800 ppm cylinder.
2. Set the oxygen flow on the INOblender flow meter to 10 L/min to begin purge.
3. Ensure the pressure gauge decreases approximately 14 bar (200 psig) in 10 seconds (± two seconds).
4. Continue purging until pressure gauge reads zero.

Note: If the pressure does not decrease, then the INOblender is not delivering NO and the INOblender should be replaced.

D. InterHospital Transport (Between Hospitals) when using a separate INOmax DS_{IR} and INOblender for transport

WARNING:

- **If the INOmax DS_{IR} or INOblender is to be used in a transport vehicle, they should be affixed to the transport mounting post (part number 10009) which is part of the transport mounting bracket assembly (part number 50041).**
- **The transport mounting post and/or the transport mounting bracket assembly should be secured to the transport isolette/transport gurney in a manner which will secure the INOmax DS_{IR}/INOblender.**

Prior to Leaving the Hospital

1. Complete the pre-use checkout for the transport INOmax DS_{IR} unit.
   a. The pre-use checkout is mandatory to ensure proper function of the INOmax DS_{IR}, INOMAX regulator, transport regulator/cap assembly and INOblender.
   b. Change the injector module and/or perform a high calibration if monitored values are out of range during the pre-use checkout.
2. Bring appropriate backup equipment in case of a malfunction during the transport (see caution above).

Items recommended for interhospital transport:

- INOmax DS_{IR}
- Transport regulator/cap assembly (two)
- D-size transport INOMAX cylinder (two)
- INOblender
- Injector module (two)
- Injector module cables (two)
- Transport mounting bracket assembly (optional)
- Disposables
  - NO/N_2 injector tube (two)
  - Patient gas sample line with Nafion (two)
  - Water separator cartridge (two)
- Properly secure the INOmax DS_{IR}, INOblender and INOMAX cylinders per hospital/air carrier protocols.

Transport equipment weight should be calculated to assure transport system meets weight allowance.

Part Description	Weight	Dimensions
INOmax DS_{IR}	5.3 kg / 11.7 lb	350 mm (W) X 220 mm (H) X 160 mm (D)
INOblender	1.5 kg / 3.3 lb	200 mm (W) X 120 mm (H) X 110 mm (D)
INOMAX D-size Cylinder	3.6 kg / 8.0 lb	111 mm (W) X 517 mm (H)
Transport Regulator/Cap Assembly	0.90 kg / 2.0 lb	N/A
Transport Mounting Bracket Assembly	0.97 kg / 2.14 lb (post only 0.29 kg / 0.64 lb)	N/A
INOblender Extension Hose	0.06 kg / 0.13 lb	N/A

Note: All sizes and weights are approximate and may vary slightly.

Duration Chart

INOMAX Cylinder D-Size

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

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

Typically used in transport

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

* All calculations for the table above are based on a full cylinder of 138 bar (2000 psig), 353 liter “D” cylinder, and also accounting for cylinder change at 14 bar (200 psig). The figures are calculated on total continuous flow cylinder conversion factor (2.6 liters per bar and 0.18 liters per psig).

- INOMAX flow = [Desired dose X total ventilator flow] ÷ [Cylinder concentration - desired dose]
- Cylinder volume = Cylinder conversion factor X cylinder pressure (bar/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)

Transport Regulator/Cap Assembly Application

Note: Before leaving the bedside (intrahospital transport) or hospital (interhospital transport), check the INOMAX cylinder for the correct product identity labels, cylinder concentration and expiration date. Verify cylinder has at least 500 psig (replace if 200 psig or less), and tighten the fitting to the INOMAX cylinder.

1. Connect a high pressure regulator to an INOMAX cylinder and hand-tighten the fitting to the INOMAX cylinder (see Figure 4-3).

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 7-8).

2. Connect the INOMAX regulator hose to one of the INOMAX inlets on the back of the INOmax DS_{IR} (see Figure 4-3).

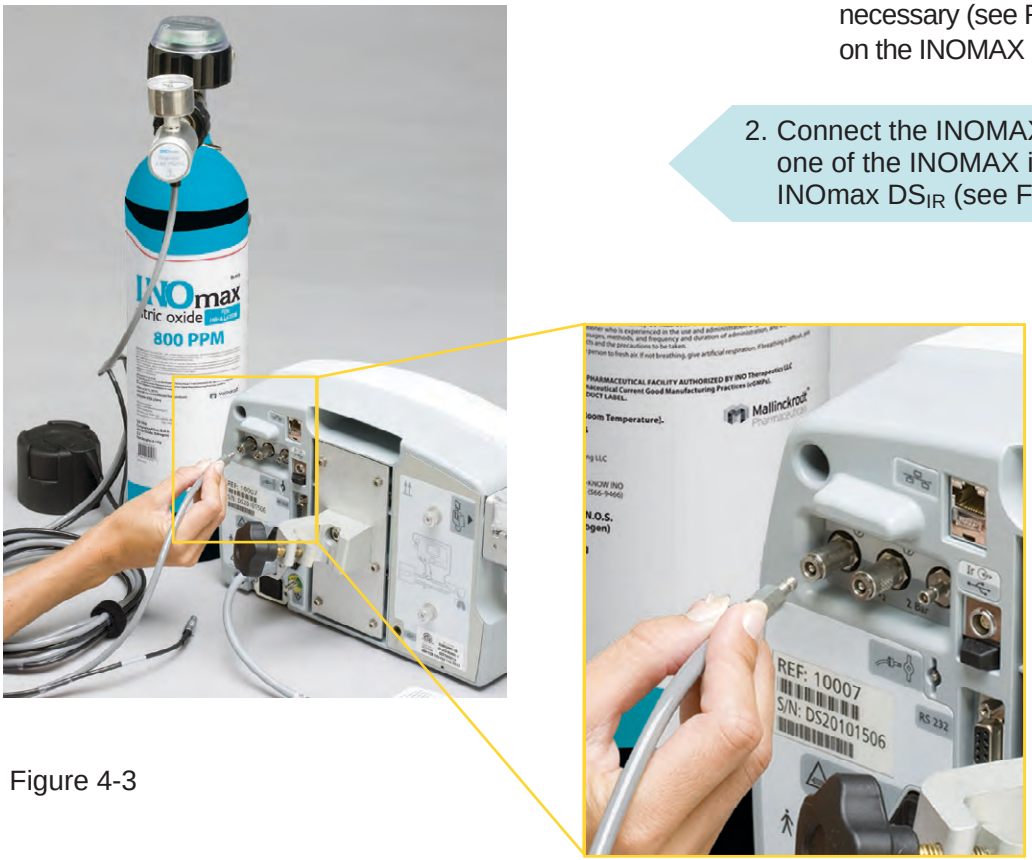


Figure 4-3

Figure 4-4

3. Connect the infrared cable from the transport regulator/cap assembly to the back of the INOmax DS_{IR} (see Figure 4-4).

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.

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}.

Figure 4-5

4. Place the cap assembly over the INOmeter (see Figure 4-5).

Note: Be sure to align the keyway inside the cap assembly with the iButton on the INOmeter (see Figure 4-5 and 4-6).

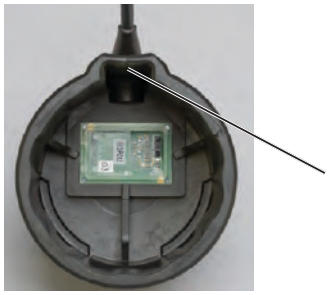


Figure 4-6

Figure 4-7

5. Grasp the cap assembly to open cylinder valve (see Figure 4-7 and 4-8).

Figure 4-8

Final Set-up Diagram

The following diagram (see Figure 4-9) and photo illustrates all of the components connected.

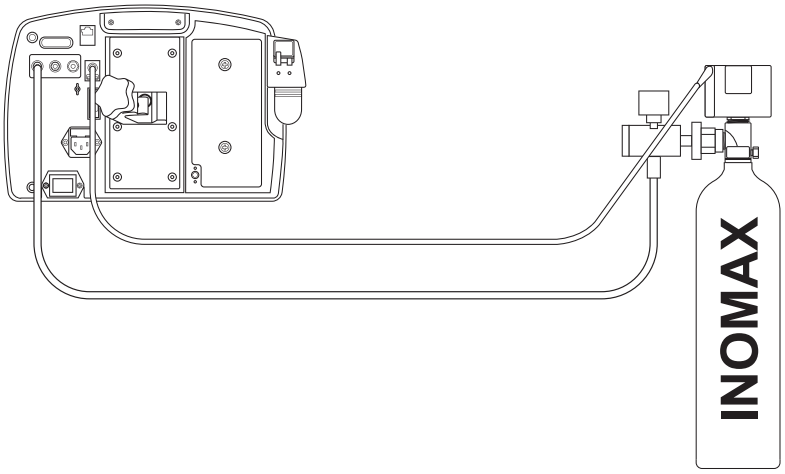


Figure 4-9

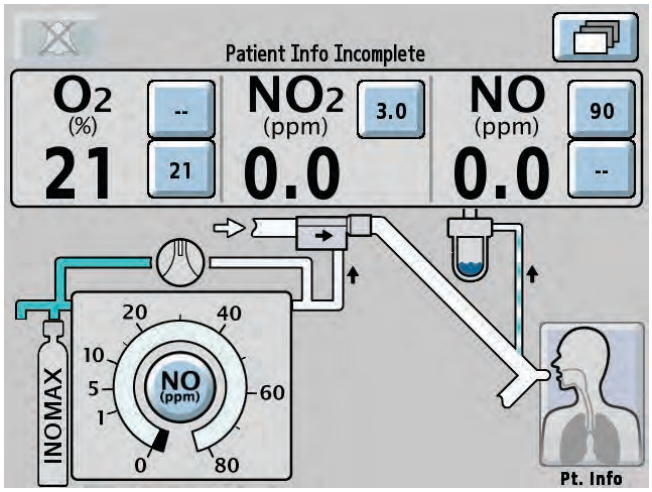


Figure 4-10

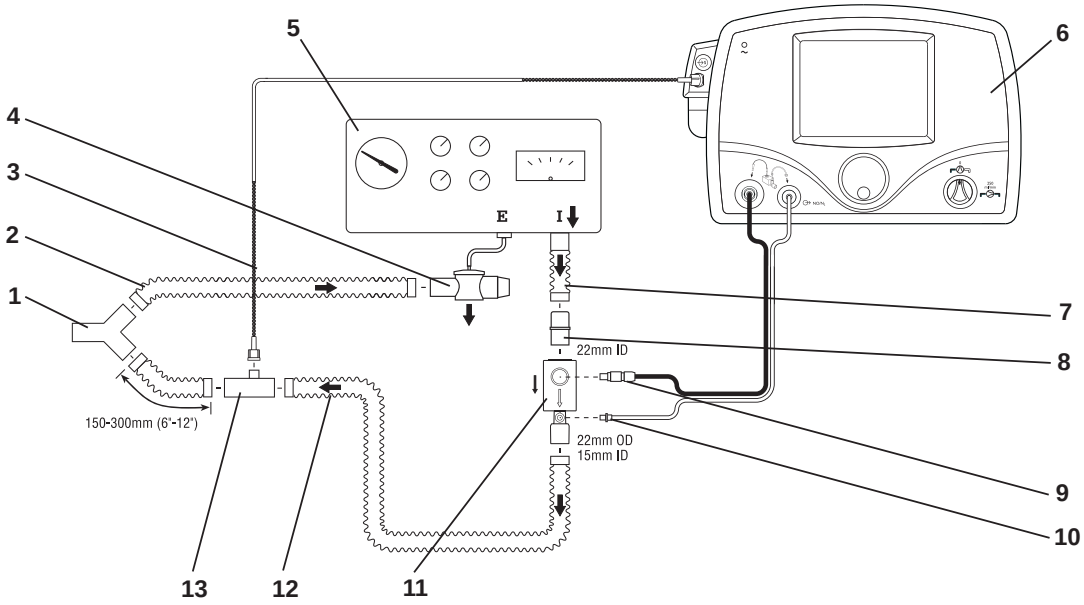
Communication will take place between the INOmax DS_{IR} and the INOmeter after the boot up phase of the INOmax DS_{IR} is complete.

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.**

Note:

- Cylinder icons are not visible and the NO delivery setpoint 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 4-10).

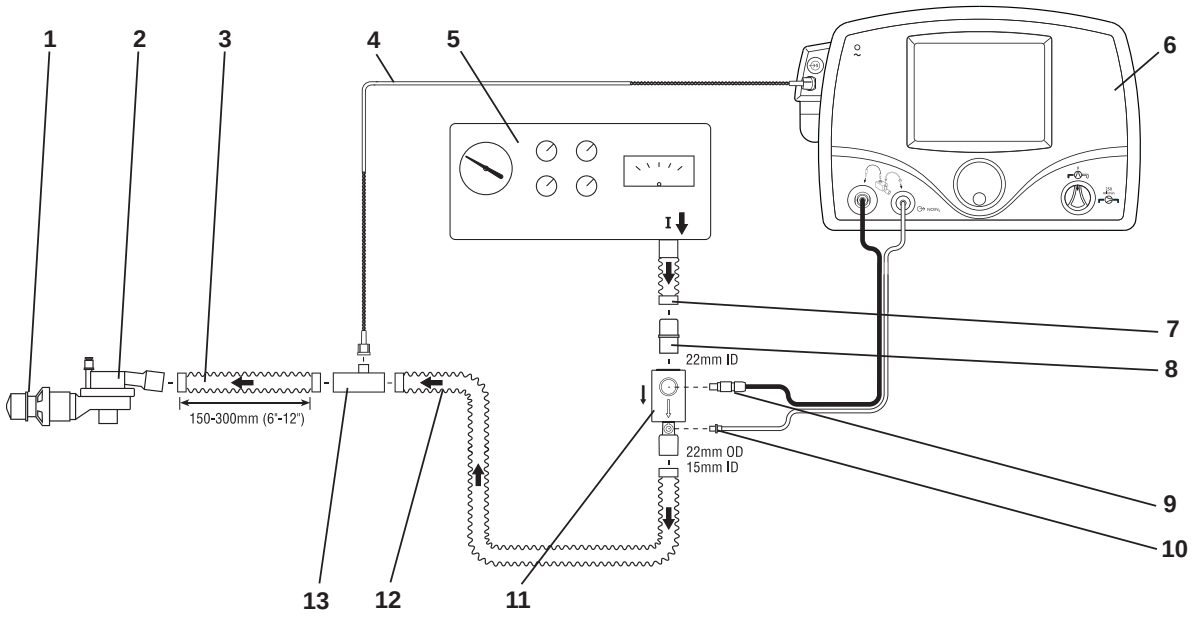
Connection to a Dual-Limb Transport Ventilator Circuit



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

Figure 4-11 Example: Transport Ventilator Diagram

Connection to a Single-Limb Transport Ventilator Circuit



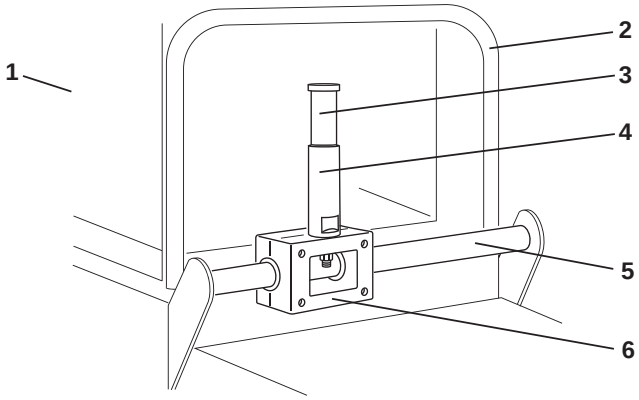
1. PEEP Valve
2. Patient Wye
3. Circuit Hose
4. Patient Gas Sample Line with Nafion
5. Ventilator
6. INOmax DS_{IR}
7. Ventilator Inspiratory Port
8. 22M/15F X 22M/15F Adapter
9. Injector Module Electrical Cable
10. NO/N_2 Injector Tube
11. Injector Module
12. Inspiratory Breathing Circuit Hose
13. Gas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

Figure 4-12 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 4-13.**

Figure 4-13 Universal Mounting Post

Note: The universal mounting post has a machined recess with an integrated cap to prevent twisting or accidental release of the device if the mounting clamp assembly becomes loose.



1. Transport Isolette
2. Isolette Bar
3. INOmax DS_{IR} or INOblender Mounting Area
4. Universal Mounting Post
5. Isolette Handle
6. Transport Mounting Bracket Assembly (PN 50041, includes universal mounting post)

Figure 4-14 Transport Mounting Bracket Assembly Attached to Transport Isolette

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 4-15).
- 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.

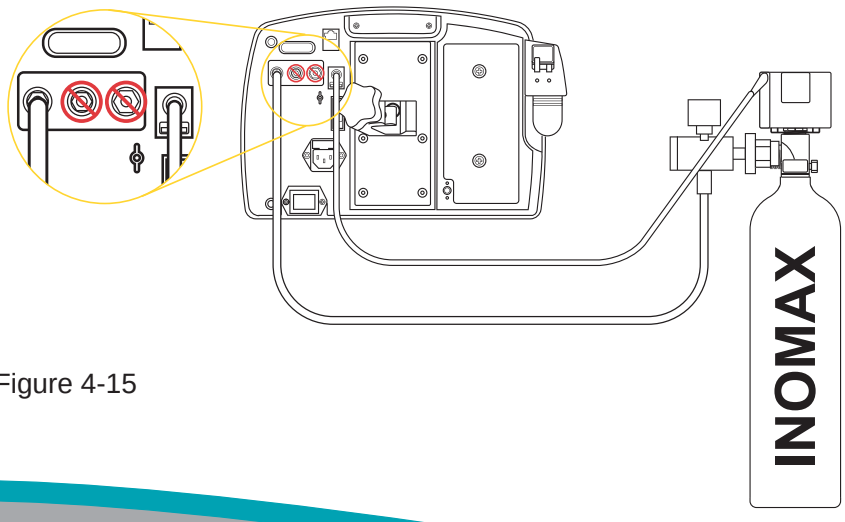
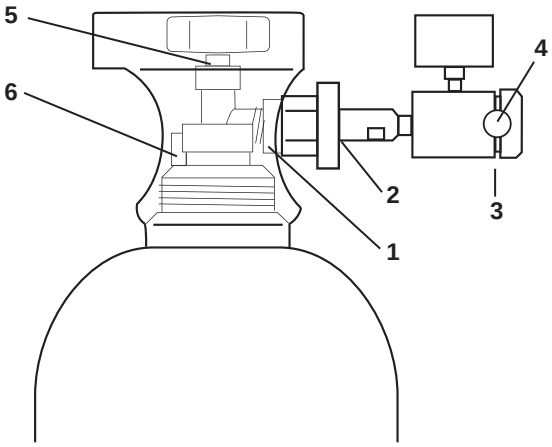


Figure 4-15

Cylinder Leak Check

If a leak is suspected during the high pressure leak test, the following steps can be taken to check for leaks (see Figure 4-16 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 4-16

1. Check the INOMAX drug cylinders for the correct product identity, cylinder concentration, and expiration date. Verify cylinder has at least 500 psig (replace if 200 psig or less), and tighten the fitting to the INOMAX cylinder.
2. Apply soapy water to points #1, #2, #3, #5 and #6 (see Figure 4-16); if bubbles form, there is a leak.
3. If there are no bubbles, the leak may be inside the INOmax DS_{IR} and cannot be repaired. Replace the INOmax DS_{IR} and contact Technical Support.

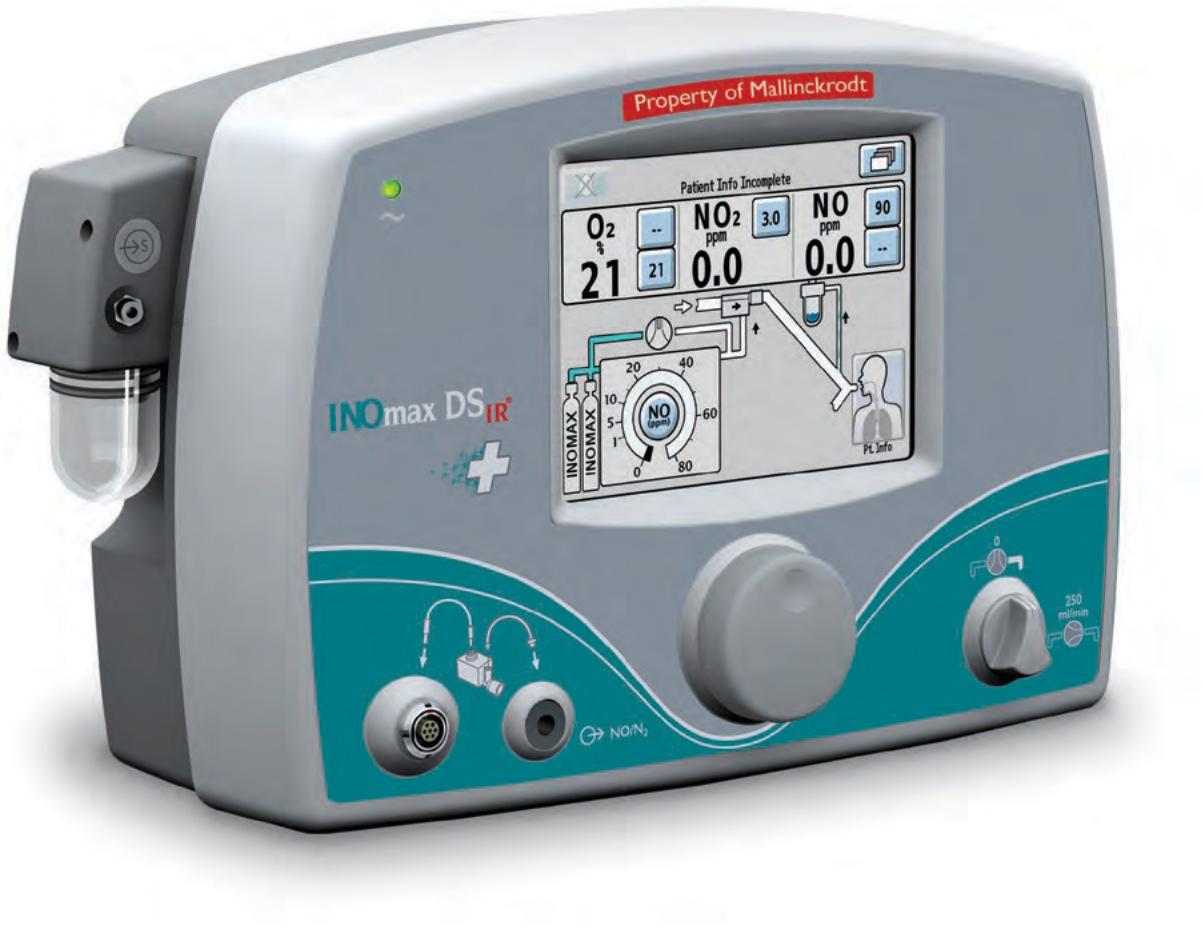
Recommended actions should a leak be detected:

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, relieve regulator pressure by purging, 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 page 7-8). 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 Technical Support.
3. A leak detected at the cylinder valve nut connection (see point #5) may not be repaired. Replace INOMAX cylinder and contact Technical Support.
4. A leak detected at the safety pressure release device (see point #6) may not be repaired. Replace INOMAX cylinder and contact Technical Support.

(Intentionally left blank)

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



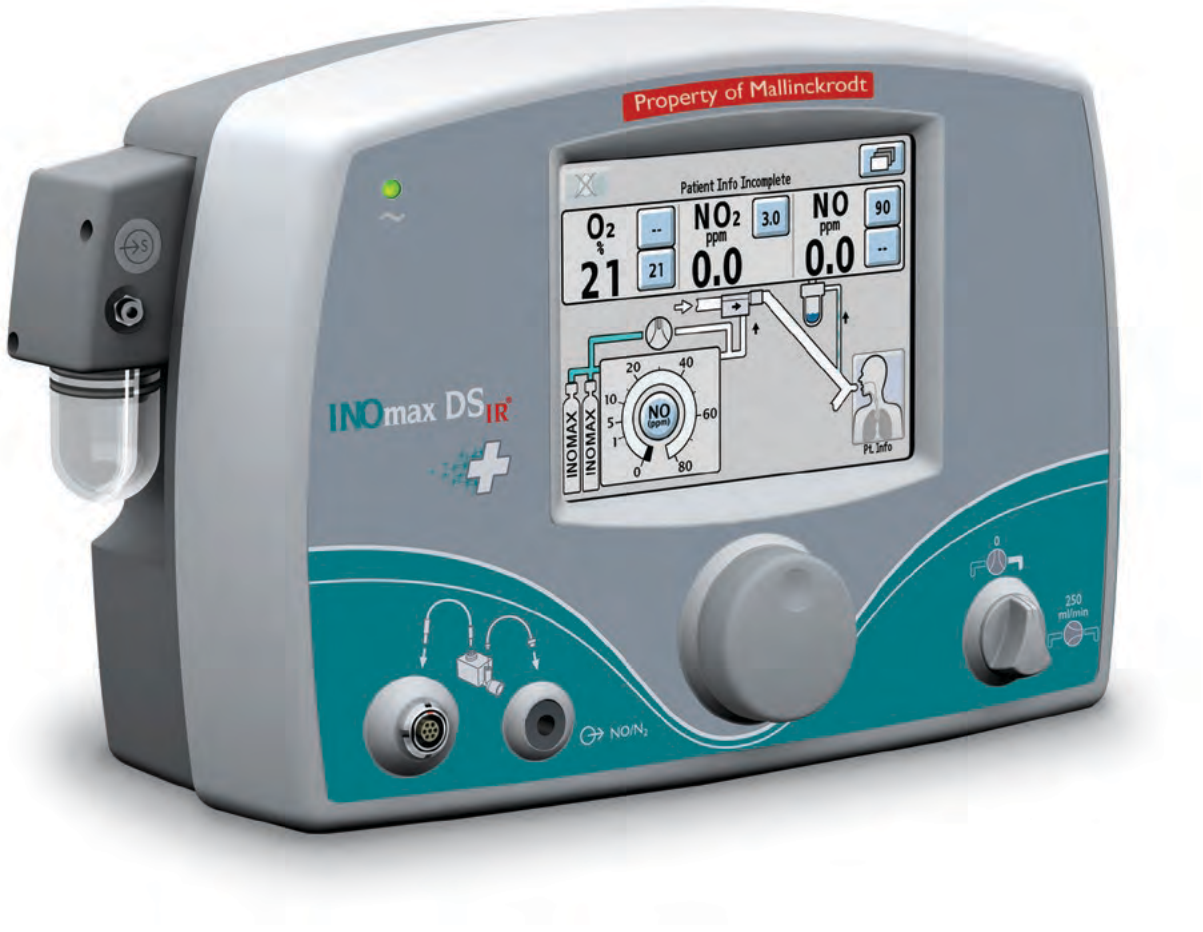
Alarms

5/ Alarms

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



Alarms

5/ Alarms

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 (see page 5-6, "Continuous Audible Tone").

Note: Status information will not be displayed during alarm conditions. Once the alarm clears the status information will be displayed.

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 one and two (see Figure 5-1) with the most recent message shown in field one.

Field 2 is used for status information such as “Running on Battery” and “Patient Info. Incomplete”.

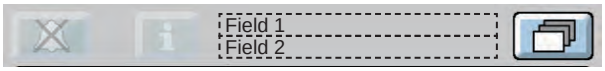


Figure 5-1 Text Message Area Showing Fields one and two.

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

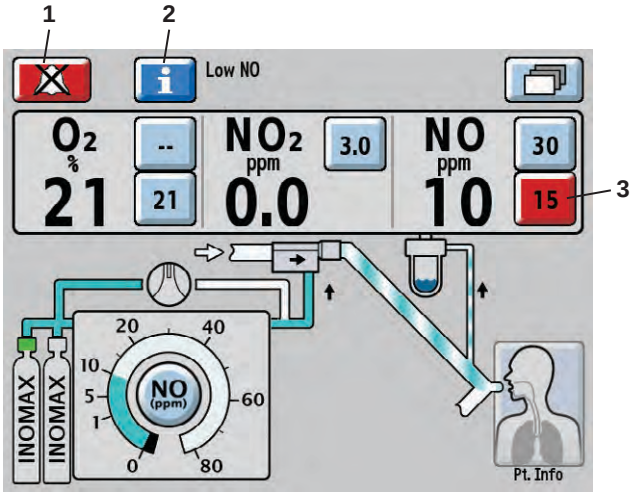
	Frequency	Description	Comment
High Priority	400 Hz	10-pulse group	Repeats after 10 sec. if not silenced.
Low Priority	400 Hz	1 pulse	Repeats after 40 sec. if not silenced.

Alarm silencing

Pushing the Alarm Silence button will silence high-priority alarms for 120 seconds (time will count down to zero). When a new alarm condition occurs, the audible alarm becomes active again.

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 Help Button
3. Violated Monitored Value Limit

Figure 5-2 Alarm Active Screen

To activate on-screen alarm help, press the Alarm Help Button next to the Alarm Silence button.

User adjustable monitor alarms

Caution: Do not set upper and lower alarm limits to extreme values, as this could reduce the effectiveness of the monitoring alarm system.

Monitor alarm delay active indicator

Monitor alarms for O_2, NO_2, and NO will be inactive anytime the Monitor Alarm Delay Active indicator is displayed. This delay only effects the monitor alarms, all other alarms remain active.

The Monitor Alarm Delay Active indicator will be displayed for two minutes:

- Upon exit from the calibration screen (whether or not a calibration was actually performed)
- Following an automatic low calibration
- Following completion of an auto purge

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 #3 in 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.

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

Alarm	Adjustment	Increments	Default	Priority
High NO (ppm)	1 to 100	NO *0.0-1.0 by 0.1 ppm *1-99 by 1 ppm	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	NO_2 by 0.1 ppm	3	High
High O_2 (% v/v)	21 to 100 Then OFF (--)	O_2 by 1%	-- (OFF)	High
Low O_2 (% v/v)	18 to 99		21 %	High

The first time a dose is set from zero, the upper and lower NO alarm limits are set 50% above and 50% below the set dose.

* 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 History

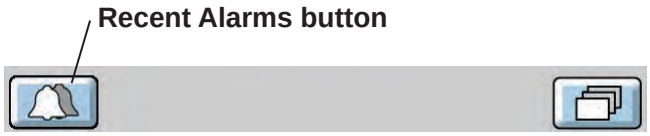


Figure 5-3 Recent Alarms Button on the Main Screen

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

The recent alarms can be seen by pressing the Recent Alarms button.

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

The alarms are displayed in chronological order, with most recent at the top (for example, Figure 5-4 the recent alarm conditions that have occurred).

Note:

- Alarm history dates and times are displayed per user-set off-set time (see Time Adjust setting, page 1-14).
- Alarm conditions lasting less than one second may not display in the alarm area of the user screen, but will post to the alarm log and alarm history.

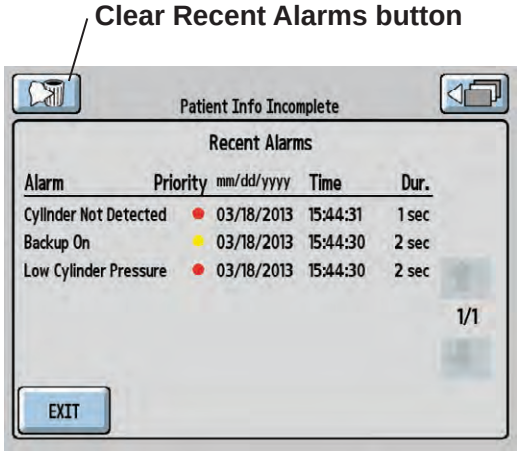


Figure 5-4 Recent Alarms Screen

Press the clear Recent Alarms button to clear the recent alarms and return to the main screen.

To return to the main screen without clearing the recent alarm history, press the EXIT or the Return to Previous Menu button. If no action is taken, the system will return to the main screen after 30 seconds.

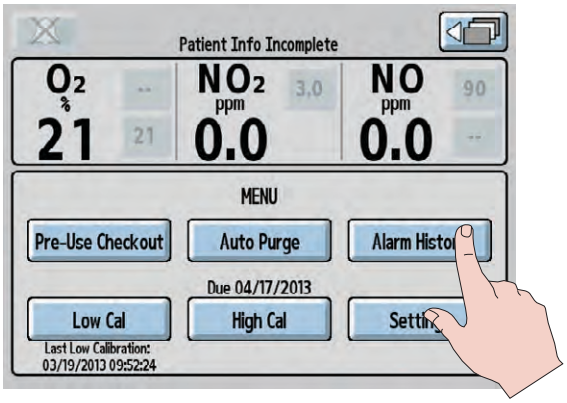


Figure 5-5 Menu Screen

A complete list of all alarms that have occured since the INOmax DS_{IR} has been turned ON can be viewed by pressing the ALARM HISTORY button on the menu screen (see figure 5-5).

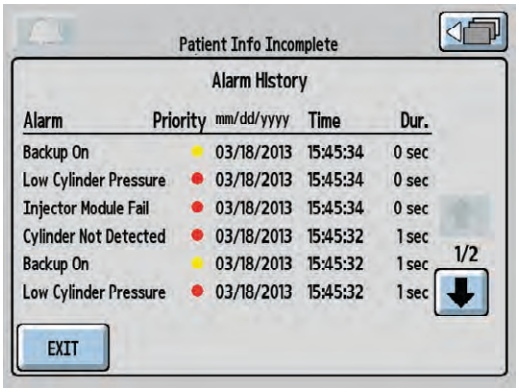


Figure 5-6 Alarm History Screen

Priority

A yellow dot signifies a low priority alarm, and a red dot signifies a high priority alarm.

Press the EXIT button or the Return to Previous Menu button to return to the menu screen.

The duration of an alarm is truncated to the second or minute "label" displayed in the format "xx label," where "xx" and "label" are as defined in the table below.

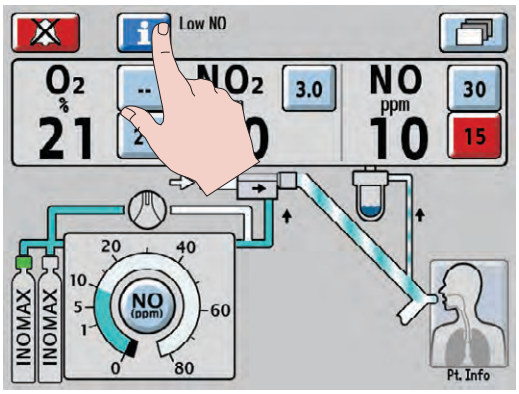
Alarm Duration Condition	Displayed Value	Label
xx < 1 second	<1	sec
1 second ≤ x < 1 minute	xx	sec
1 minute ≤ x < 61 minutes	xx	min
xx ≥ 61 minutes	> 60	min
in progress	Active	N/A

For example, an alarm that occurred for 38.9 seconds would display as "39 sec," while an alarm that occurred for 75 minutes would display as "> 60 min."

Alarm Help

WARNING:

- **If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.**
- **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.**



To activate on-screen alarm help, press the Alarm Help Button next to the Alarm Silence button.

If the system fails to operate properly:

1. Check the patient condition and take appropriate action.
2. Use the INOblender (see INOblender Operation Manual) or backup if necessary (see page 3-7).
3. Verify that the system is set up as detailed in 3/ Patient Application.
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 Customer Care (1-877-566-9466).

If the INOmax DS_{IR} must be returned for servicing:

1. Disconnect the following from the unit (refer to Figures 1-1 and 1-2).

   Remove and return with unit:

   - Injector module
   - Injector module cable

   Remove and discard:

   - Patient gas sample line
   - NO/N_2 injector tube

2. Pack the INOmax DS_{IR} and the accessories as requested by Customer Care. Use the original or service loaner packaging materials to protect the system during transit. If the proper packaging is not available, please contact Customer Care (1-877-566-9466).
3. Make sure the outside of the box is labeled: "FRAGILE MEDICAL EQUIPMENT, HANDLE WITH CARE."
4. Send the unit to the location specified by Customer Care.

WARNING:

- **Abrupt discontinuation of INOMAX may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. To avoid abrupt discontinuation, utilize the INOblender or integrated pneumatic backup if necessary. If Rebound Pulmonary Hypertension occurs, reinstate INOMAX therapy immediately. (See the INOMAX prescribing Information for further details).**
- **If the high NO_2 alarm activates, the delivery system should be assessed for proper setup while maintaining INOMAX delivery. Adjust INOMAX and/or FiO_2 as appropriate. (See INOMAX Prescribing Information for further details on the effects of Nitrogen Dioxide, NO_2). If unable to determine the cause of the increased NO_2 levels, call technical support and do not discontinue therapy.**

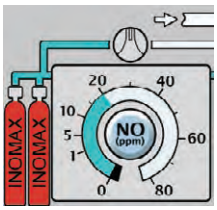
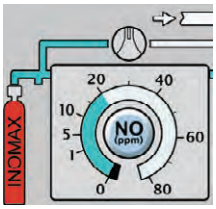
Continuous Audible Tone		
Alarm	**Possible Cause**	**Recommended Action**
Continuous Audible Tone	A component within the INOmax DS_{IR} has failed.	1. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). 2. Replace the delivery system and remove from service. 3. Contact Technical Support.

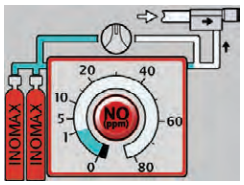
Alarm Help

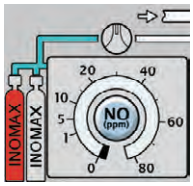
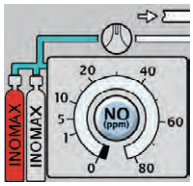
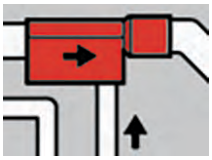
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
1. High NO alarm 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The High NO alarm level may be inappropriately set.	Confirm high NO alarm limit is set appropriately.
	b. Circuit setup incorrect.	Check circuit for correct setup.
	c. The NO calibration may have drifted.	1. Perform low calibration. 2. Perform high NO calibration.
	d. Injector module may not be functioning properly.	INOMAX delivery will be interrupted. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least five L/min ventilator gas flow in patient circuit). 1. Change injector module. 2. Change injector module cable. "Injector Module Failure" alarm will occur and NO delivery will be interrupted. This will resolve when injector module cable is reconnected.
		Contact Technical Support.

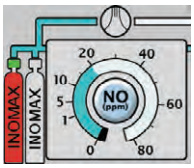
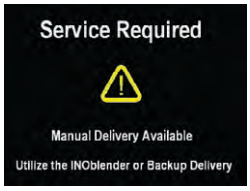
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
2. Low NO alarm 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The Low NO alarm setting may be inappropriately set.	Confirm low NO alarm limit is set appropriately.
	b. Circuit setup incorrect.	1. Check circuit for correct setup. 2. Confirm water trap bottle, water separator cartridge, NO/N_2 injector tube and patient gas sample line are in place.
	c. Loss of NO delivery.	If loss of NO delivery is suspected, manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least 5 L/min ventilator gas flow in patient circuit).
	d. The Patient Gas Sample line may be disconnected.	1. Check circuit for correct setup. 2. Confirm water trap bottle, water separator cartridge and patient gas sample line are in place.
	e. The NO calibration may have drifted.	1. Perform low calibration 2. Perform high calibration.
	f. The NO sensor may not be properly seated.	Confirm the O-rings on the sensor and sensor cover are correctly seated and the sensor cover is fully closed.
	g. Injector module may not be functioning properly.	INOMAX delivery will be interrupted. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least five L/min ventilator gas flow in patient circuit). 1. Change injector module. 2. Change injector module cable. “Injector Module Failure” alarm will occur and NO delivery will be interrupted. The injector module failure alarm will resolve when injector module cable is reconnected.
		Contact Technical Support.

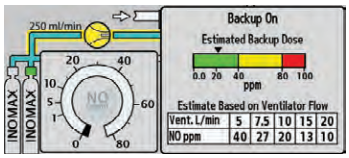
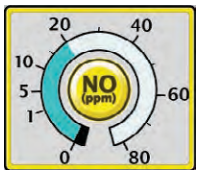
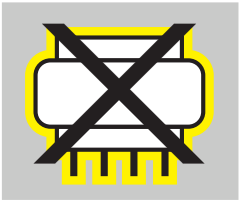
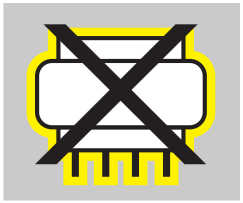
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
3. High NO_2 alarm 		All of these actions can be performed while delivering INOMAX to the patient:
	a. Incomplete System purge.	Verify device has been purged.
	b. The high NO_2 alarm setting may be inappropriately set.	Confirm high NO_2 alarm limit is set appropriately.
	c. Two cylinder valves are open.	If two cylinder valves are open, close one cylinder valve.
	d. The patient circuit setup may be incorrect. - Patient circuit flow interrupted.	1. Check circuit for correct setup. 2. Verify humidifier chamber is less than 480 mL.
	e. The NO_2 calibration may have drifted.	1. Perform low calibration. 2. Perform high NO_2 calibration.
	f. The INOmax DS_{IR} may have failed.	Contact Technical Support.
4. High O_2 alarm 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The high O_2 alarm setting may be inappropriately set.	Confirm high O_2 alarm limit is set appropriately.
	b. The patient breathing circuit setup may be incorrect.	Check circuit for correct setup.
	c. The O_2 calibration may have drifted.	1. Perform low calibration. 2. Perform high O_2 calibration.
		Contact Technical Support.
5. Low O_2 alarm 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The low O_2 alarm setting may be inappropriately set.	Confirm low O_2 alarm limit is set appropriately. INOMAX can dilute O_2 concentration set at the ventilator by up to 10%.
	b. The patient breathing circuit setup may be incorrect.	Check circuit for correct setup.
	c. The O_2 concentration setting at the ventilator was reduced.	Confirm low O_2 alarm limit is set appropriately. INOMAX can dilute O_2 concentration set at the ventilator by up to 10%.
	d. The O_2 calibration may have drifted.	1. Perform low calibration. 2. Perform high O_2 calibration.
	e. The O_2 sensor may not be properly seated.	Confirm sensors are correctly seated and sensor cover is fully closed.
		Contact Technical Support.

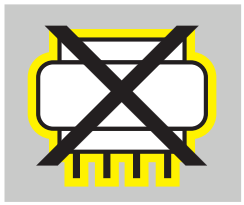
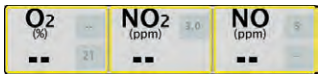
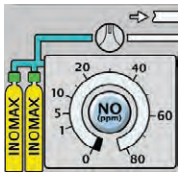
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
6. Cylinder Not Detected 	Communication between INOMAX cylinder and INOmax DS_{IR} has been lost. "Delivery Stopped" will occur 1 hour from point when communication is lost.	All of these actions can be performed while delivering INOMAX to the patient:
	a. INOmax DS_{IR} infrared cart cable is not connected or has failed.	Confirm infrared cart cable is connected to infrared connector on back of INOmax DS_{IR}.
	b. Interference with the Infrared communication link between the INOMAX cylinder and the INOmax DS_{IR}.	1. Remove obstruction between INOmeter and INOmax DS_{IR} cart transceiver. 2. Move interfering light source or reposition cart to reduce high intensity light in area of INOmeter.
	c. INOmeter may have failed.	Replace INOMAX cylinder on cart.
	d. Transport Cap not connected to the INOmeter	If utilizing a transport regulator/cap assembly: 1. Connect transport regulator/cap assembly cable to infrared connector on back of INOmax DS_{IR}. 2. Confirm transport cap assembly is over INOmeter. 3. Replace transport regulator/cap assembly. 4. Replace INOMAX cylinder.
		Contact Technical Support.
7. Cylinder Valve Closed 	"Delivery Stopped" will occur one hour from point when cylinder valve is closed.	All of these actions can be performed while delivering INOMAX to the patient:
	a. INOMAX cylinder valve is closed.	1. Open INOMAX cylinder valve. 2. If cylinder valve is open, confirm that it has been opened fully.
	b. When two cylinders are present on the cart, interference with the Infrared communication link between the open INOMAX cylinder and the INOmax DS_{IR} may result in a cylinder valve closed alarm.	Reposition INOmax DS_{IR} cart, remove any obstacle between INOmeter and cart.
	c. INOmeter may have failed.	Replace INOMAX cylinder.
		Contact Technical Support.

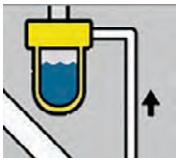
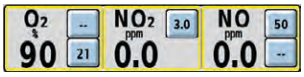
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
8. Delivery Failure 	a. Over-delivery of INOMAX. - (CALCULATED dose is >200% of set dose) AND (CALCULATED dose is > set dose + 10 PPM) for 12 consecutive seconds, or - CALCULATED dose > 100 for 12 seconds	INOMAX delivery has been interrupted. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least five L/min ventilator gas flow in patient circuit).
	b. The internal NO flow sensor temperature or measured flow rate is out of range. Other internal error detected (a temporary internal communication error that has been detected).	If Delivery Failure Alarm Occurs: 1. Use one of the back-up INOMAX delivery options 2. Turn INOmax DS_{IR} to standby, then restart. 3. Once device is ready to restart therapy: 4. Turn integrated back up off (if used) and then set the INOMAX dose. 5. Confirm delivery and check alarms.
		Contact Technical Support.
9. Delivery Stopped 	a. MONITORED NO > 100 ppm for at least 12 seconds (once MONITORED NO drops below 100 ppm for 12 seconds, alarm will resolve and INOMAX delivery will restart).	INOMAX delivery has been interrupted. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least five L/min ventilator gas flow in patient circuit).
	b. Drug past expiry date or drug concentration mismatch.	Replace INOMAX cylinder.
	c. INOmeter may have failed.	Replace INOMAX cylinder.
	d. INOMAX cylinder valve is closed.	Open INOMAX cylinder valve.
	e. INOMAX cylinder is not detected.	Replace INOMAX cylinder.
		Contact Technical Support.

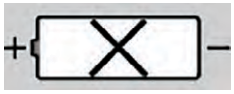
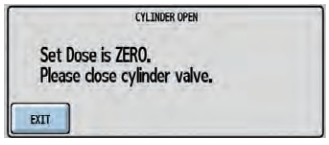
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
10. Drug Past Expiry Date 		If dose is set, “Delivery Stopped” will occur two minutes from point when cylinder valve is opened.
	a. INOMAX cylinder is expired. Note: The INOmax DS_{IR} recognizes the drug as expired on the first day of labeled expiration month on the INOMAX cylinder.	1. Close expired cylinder valve. 2. Remove expired INOMAX cylinder from INOmax DS_{IR} cart. 3. Connect an INOMAX cylinder with a valid expiration date.
		Contact Technical Support.
11. Drug Concentration Mismatch 		If dose is set, “Delivery Stopped” will occur two minutes from point when cylinder valve is opened.
	a. INOMAX cylinder is the wrong concentration.	1. Close mismatched cylinder valve. 2. Remove wrong concentration INOMAX cylinder from INOmax DS_{IR} cart. 3. Connect an INOMAX cylinder to INOmax DS_{IR} with a valid concentration.
		Contact Technical Support.
12. Injector Module Fail 		INOMAX delivery has been interrupted. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least five L/min ventilator gas flow in patient circuit).
	a. The Injector Module electrical cable may be disconnected.	Reconnect injector module cable.
	b. The Injector Module may have failed.	Change injector module. Pull back on knurled sleeve to release connector.
	c. The Injector Module electrical cable may have failed.	Change injector module cable.
		Contact Technical Support.

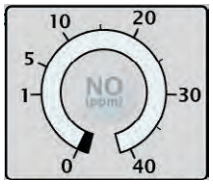
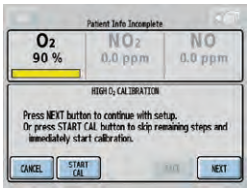
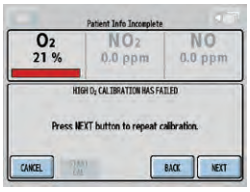
High Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
13. Low Battery Alarm.  		All of these actions can be performed while delivering INOMAX to the patient:
	a. Battery is running low.	Battery will deplete in approximately 30 minutes or less. Confirm main power supply indicator light is illuminated (green).
	b. Power cord disconnected from AC main power source.	Connect to AC main power source. Confirm main power supply indicator light is illuminated (green).
	c. Power cord disconnected from the back of the INOmax DS_{IR}.	Confirm power supply cord is fully inserted into power cord inlet and power cord clamp is secure.
		Contact Technical Support.
14. Low Cylinder Pressure  		All of these actions can be performed while delivering INOMAX to the patient:
	a. Cylinder valve is closed.	Confirm INOMAX cylinder valve is fully open.
	b. The NO cylinder supply may be low.	If INOMAX regulator gauge reads less than 14 bar (200 psig), change cylinder.
	c. The regulator hose may not be connected.	Confirm correct INOMAX regulator hose is connected.
	d. INOmax DS_{IR} has an internal leak.	Contact Technical Support.
15. Service Required  Manual Delivery Available Utilize the INOblender or Integrated pneumatic backup delivery.		The INOmax DS_{IR} has failed, INOMAX delivery has been interrupted. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON (verify at least five L/min ventilator gas flow in patient circuit).
	a. Internal flow sensor requires calibration.	The INOmax DS_{IR} requires an internal flow sensor calibration.
	b. The INOmax DS_{IR} has failed.	Remove from service.
		Contact Technical Support.

Low Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
16. Backup On 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The backup mode has been turned ON.	1. Correct the reason for initiating integrated pneumatic backup delivery. 2. Turn integrated pneumatic backup delivery OFF and confirm set NO dose has been restored.
		Contact Technical Support.
17. Under Delivery 		All of these actions can be performed while delivering INOMAX to the patient:
	a. INOMAX delivery is less than 50% of set dose. [CALCULATED dose is <50% of set dose) AND (CALCULATED dose is < set dose - 5 PPM)] for 12 consecutive seconds . The under-delivery alarm is inactive for dose settings less than 5 ppm.	Check for leaks in patient circuit or patient connection.
		Contact Technical Support.
18. Failed NO Sensor 		Delivery of INOMAX continues during this alarm.
	a. NO calibration may have drifted.	1. Perform low calibration. 2. Perform high NO calibration.
	b. There is a leak around the sensors.	Confirm the O-rings on the sensor and sensor cover are correctly seated and the sensor cover is fully closed.
	c. NO sensor absent or failed.	If NO sensor is newly installed, allow five hours for conditioning of sensor. 1. Perform low calibration. 2. Perform high NO calibration.
		Contact Technical Support.
19. Failed NO_2 Sensor 		Delivery of INOMAX continues during this alarm.
	a. NO_2 calibration may have drifted.	1. Perform low calibration. 2. Perform high NO_2 calibration.
	b. There is a leak around the sensors.	Confirm the O-rings on the sensor and sensor cover are correctly seated and the sensor cover is fully closed.
	c. NO_2 sensor absent or failed.	If NO_2 sensor is newly installed, confirm shorting wire has been removed and allow 40 minutes for conditioning of sensor. 1. Perform low calibration. 2. Perform high NO_2 calibration.
		Contact Technical Support.

Low Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
20. Failed O_2 Sensor 		Delivery of INOMAX continues during this alarm.
	a. O_2 calibration may have drifted.	1. Perform low calibration. 2. Perform high O_2 calibration.
	b. There is a leak around the sensors.	Confirm the O-rings on the sensor and sensor cover are correctly seated and the sensor cover is fully closed.
	c. O_2 sensor absent or failed.	If O_2 sensor is newly installed, allow 40 minutes for conditioning of sensor. 1. Perform low calibration. 2. Perform high O_2 calibration.
		Contact Technical Support.
21. Monitoring Failure 		Delivery of INOMAX continues during this alarm.
	a. Monitor is failing to communicate correctly or is reporting a fault.	1. Confirm patient gas sample line is not occluded. 2. Confirm water trap bottle and water separator cartridge are in place. 3. Change patient gas sample line. 4. Change water separator cartridge.
		Contact Technical Support.
22. Sample Line/Filter Block 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The sample line may be blocked.	1. Confirm sample line inlet and outlet ports are not obstructed. 2. Confirm patient gas sample line is not occluded. 3. Change patient gas sample line. 4. Replace disk filter (if in use).
	b. The water separator cartridge may be blocked.	Replace water separator cartridge.
		Contact Technical Support.
23. Two Cylinders Open 		All of these actions can be performed while delivering INOMAX to the patient:
	a. Two cylinder valves are open.	Close one INOMAX cylinder valve.
		Contact Technical Support.

Low Priority Alarms		
Alarm	**Possible Cause**	**Recommended Action**
24. Water Trap Bottle Full 		All of these actions can be performed while delivering INOMAX to the patient:
	a. The water trap bottle on the side of the INOmax DS_{IR} is full.	Empty water trap bottle.
	b. Water trap bottle is empty but the message remains in the alarm message box.	Remove water trap bottle and clean optical sensor level indicator with an alcohol swab.
		Contact Technical Support.
25. Low Calibration Failed 		All of these actions can be performed while delivering INOMAX to the patient:
	a. Zeroing valve has failed to switch.	Repeat low calibration. Wait for low calibration to complete (approximately three minutes).
	b. Sampling patient circuit gases during the low calibration.	Perform a manual low calibration.
		Contact Technical Support.

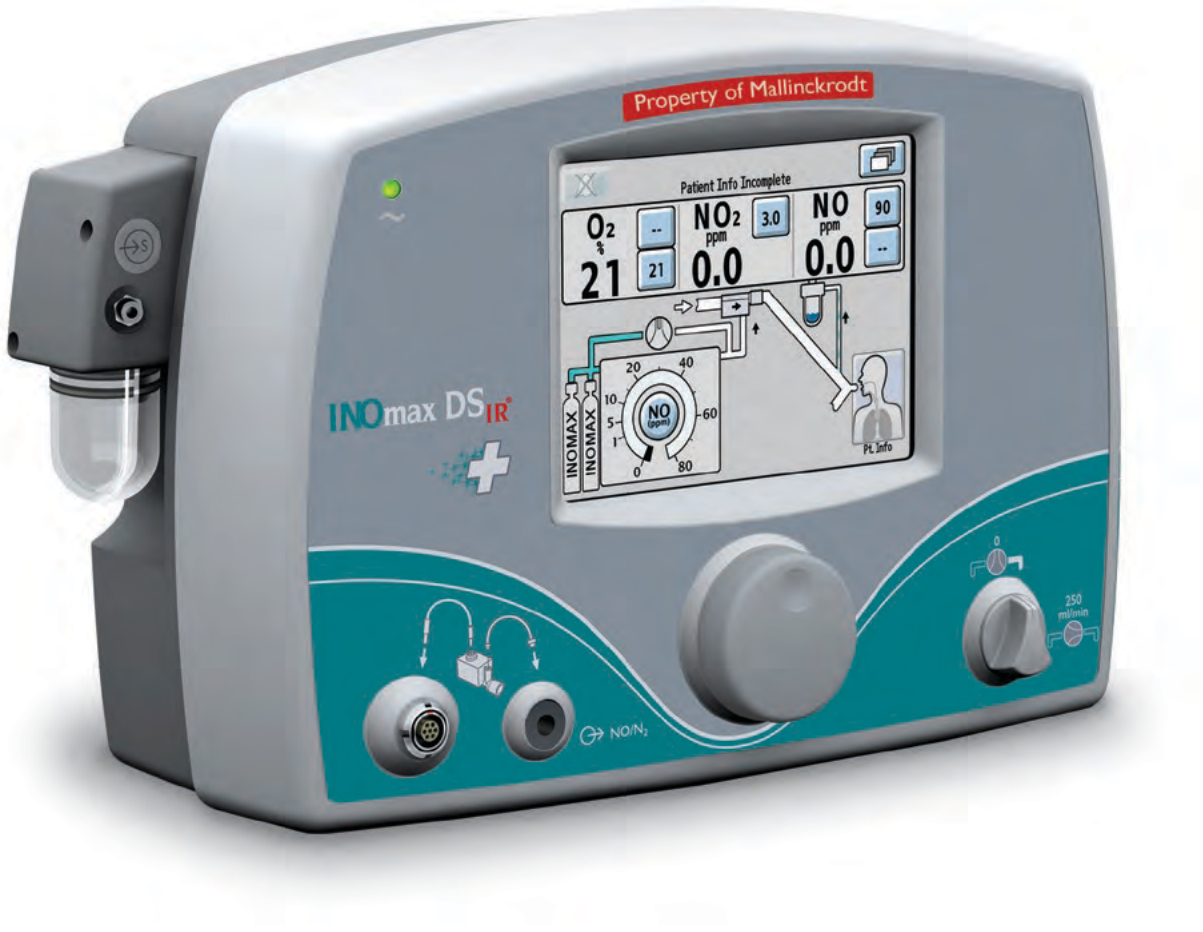
Indicators		
Indicator	**Possible Cause**	**Recommended Action**
26. Battery Failure 	a. Device cannot communicate with battery.	Contact Technical Support.
27. Low Calibration	a. Low calibration in progress. A Low Calibration indicator will display in the alarm area of the screen during the low calibration.	No user action required.
28. Monitor Alarm Delay Active	The Monitor Alarm Delay Active indicator will be displayed for two minutes:	
	a. Upon exit from the calibration screen (whether or not a calibration was actually performed)	No user action required.
	b. Following a calibration	No user action required.
	c. Following completion of an auto purge Monitor alarms for O_2, NO_2, and NO will be inactive anytime the Monitor Alarm Delay Active indicator is displayed. This delay only affects the monitor alarms, all other alarms remain active.	No user action required.
29. Patient Info Incomplete 	a. Patient identifier has not been entered.	Enter patient identifier.
30. Running on Battery 	a. Device is operating on the battery.	1. Connect to AC main power source when available (check main power indicator). 2. Make sure the power cord is fully inserted into the Power Cord Inlet and that the power cord clamp is secure.
31. Set Dose is Zero, Please Close Cylinder Valve 	a. The set dose has been set to zero and the INOMAX cylinder valve is still open.	Close the INOMAX cylinder valve and depressurize regulator.

Indicators		
Indicator	**Possible Cause**	**Recommended Action**
32. NO Delivery Button Inactive 	a. Device does not recognize an INOMAX cylinder, the dose knob will be greyed out and it will not allow the user to set an initial INOMAX dose.	1. Load INOMAX cylinder on to the cart. 2. Remove any obstruction between the INOmeter and the INOmax DS_{IR} cart cover. 3. Move the interfering light source. 4. Move the INOmax DS_{IR} cart to reduce the high intensity light in the area of the INOmeter. 5. Shield the INOmeter from the suspect light source.
	b. IR cable is not connected to the back of the INOmax DS_{IR}.	Verify the IR cable is connected to the back of the INOmax DS_{IR}.
	c. Integrated pneumatic backup switch is ON.	1. Correct the reason for initiating integrated pneumatic backup delivery. 2. Turn integrated pneumatic backup delivery OFF and confirm set NO dose has been restored.
33. High Calibration Cancelled 	a. If a high calibration is cancelled the progress bar will turn yellow.	Restart high calibration. or Exit calibration screen and return to main screen.
34. High Calibration Failed 	a. If a high calibration fails, the progress bar will turn red.	Repeat the high calibration.
		Contact Technical Support.

(Intentionally left blank)

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

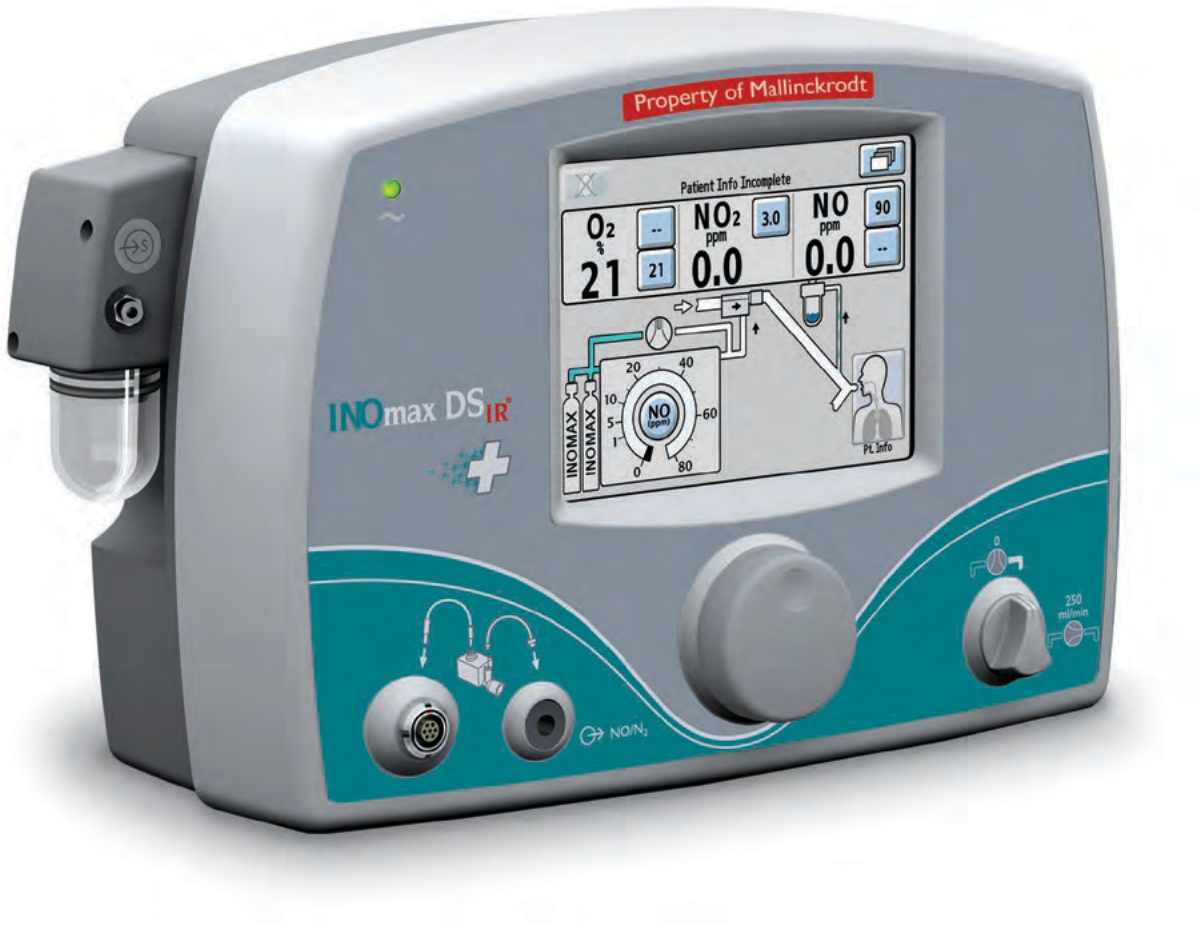


6/ Calibration

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



Calibration

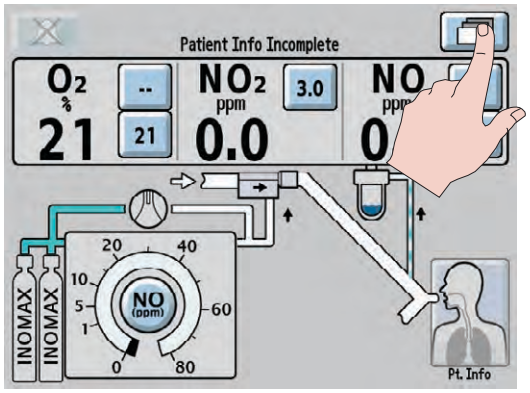
6/ Calibration

Part No. 20717 Rev-01
2014-07

6/ Calibration

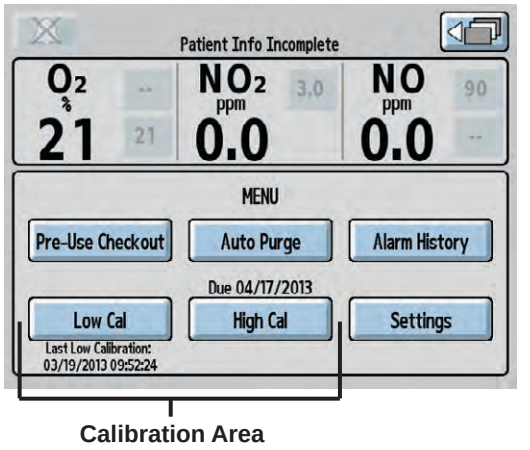
WARNING: **INOMAX can be administered during the sensor calibration process. However, inspired gases are not monitored and gas monitoring alarms are disabled.**

Note: During any calibration process, all other alarms remain active while monitoring alarms are disabled.



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 low calibration (Low Cal) and high calibration (High Cal) buttons.

- Select the Low Cal button to start a low calibration. The date and time the most recent low calibration occurred is displayed below the Low Cal button.
- Select the High Cal button to enter the high calibration screen. The earliest sensor high calibration due date is displayed above the High Cal button.

If the date is flashing, it signifies a 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.

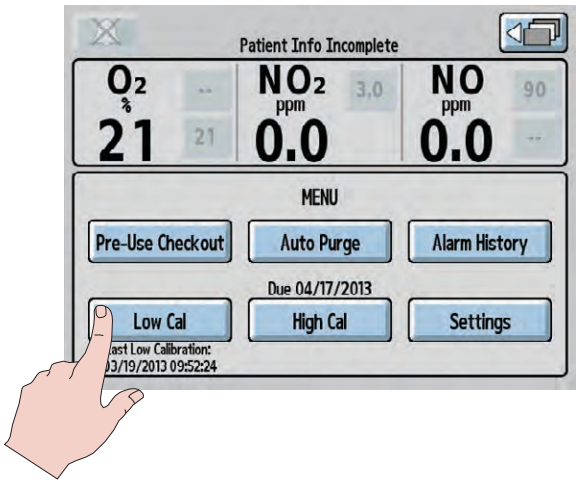
Instructions for completing a low and high calibration are on the following pages.

Low Calibration

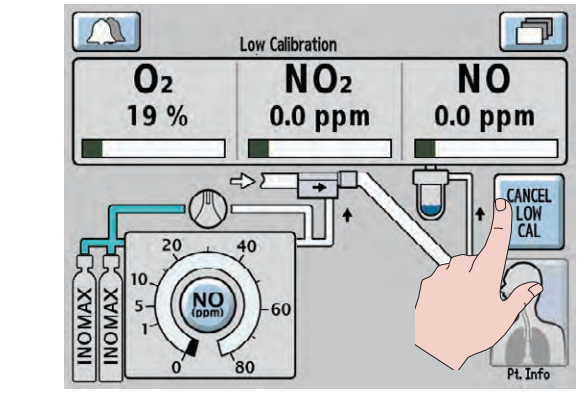
The low calibration of the monitor sensors uses room air to calibrate all three sensors at the same time. The system automatically draws in room air from an inlet port behind the water trap, not the sample line. A low calibration is completed automatically when the INOmax DS_{IR} is turned ON and during the following conditions:

- At 3, 6, and 12 hour intervals following each dose change.
- Every 12 hours as long as the dose is not changed.
- Every 24 hours when the INOmax DS_{IR} is turned ON and the dose is set to zero.
- If the low calibration is canceled after boot-up, the device will reattempt again every 15 minutes until successful.
- If an automatic low calibration fails, it will reattempt the calibration a second time. If it fails the second time, a Low Calibration failed alarm is raised. The next automatic calibration will occur at the next interval. For example, if the three hour calibration was just completed, the next calibration will occur in six hours.

Note: A fifteen minute period of time with no user screen interactions is required before an automatic low calibration will initiate.

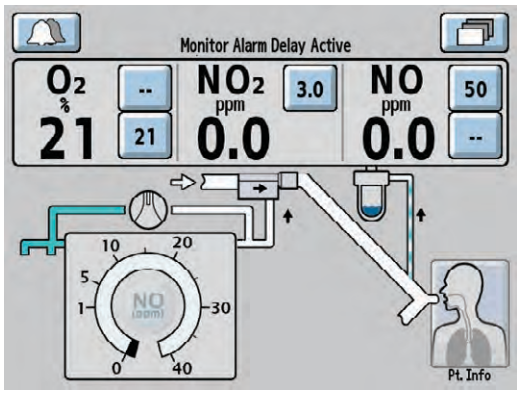


1. From the menu screen (second menu level), press the Low Cal button to initiate a low calibration.

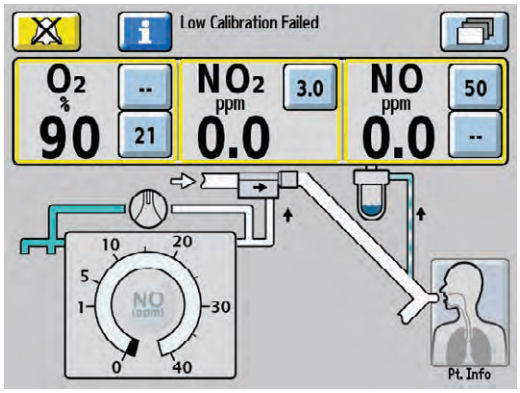


2. The calibration will take approximately three minutes, during which a progress bar for each sensor indicates the progress. A Low Calibration indicator will display in the alarm area of the screen during the low calibration.

   To cancel a low calibration, press the CANCEL LOW CAL button.

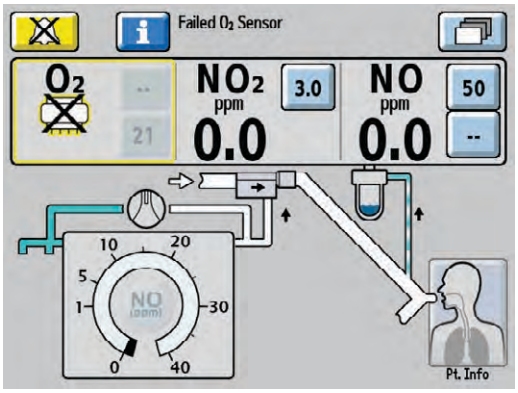


3. When the low calibration is successful, a single tone will be heard and the main screen will appear. A two minute Monitor Alarm Delay Active indicator will occur, preventing monitoring alarms from occurring while the measured value stabilizes. All system alarms are still active.



If the low calibration was unsuccessful, the INOmax DS_{IR} will automatically attempt another low calibration. If the second low calibration attempt fails, the alarm area will display a Low Calibration Failed alarm.

- Attempt a manual low calibration.



If a sensor has failed, the display will indicate the failed sensor symbol in the monitoring area of that sensor. (Press the Alarm Help button for on-screen alarm help or see Section 5/ Alarms.)

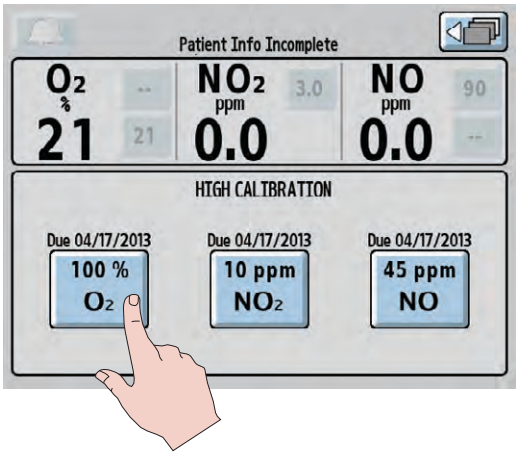
Oxygen Sensor High Calibration

Caution:

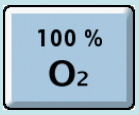
- When performing a high calibration, make sure to select the correct calibration gas and confirm the expiration date before using.
- Never connect the sample line directly to a high pressure gas source (greater than 150 cmH_2O); this could damage the sampling system.

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

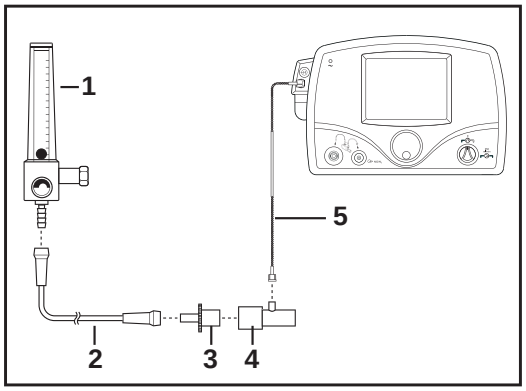
The oxygen high calibration requires a user supplied source of 100% oxygen.



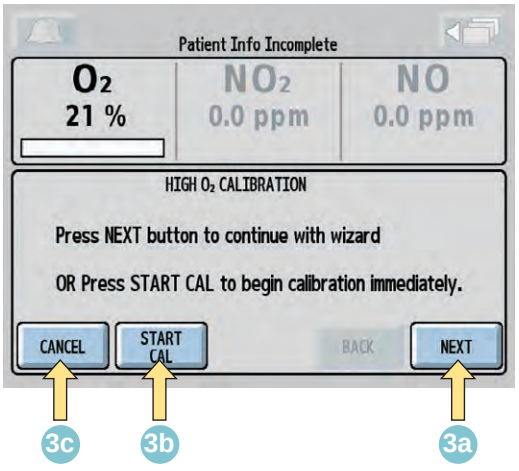
1. From the high calibration screen (third menu level), press the 100% O_2 button to initiate the O_2 high calibration wizard.



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 five L/min.
   (1) 100% O_2 Source
   (2) O_2 Tubing
   (3) 15M X 4.5 mm I.D Adapter
   (4) Gas Sample Tee
   (5) Patient Gas Sample Line with Nafion

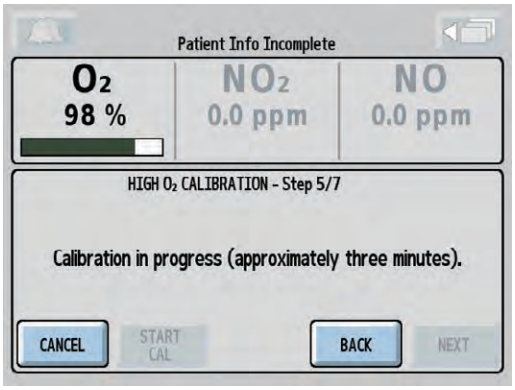


3a. To continue the high calibration wizard press the NEXT button.

3b. To start the high calibration without using the wizard, press the START CAL button

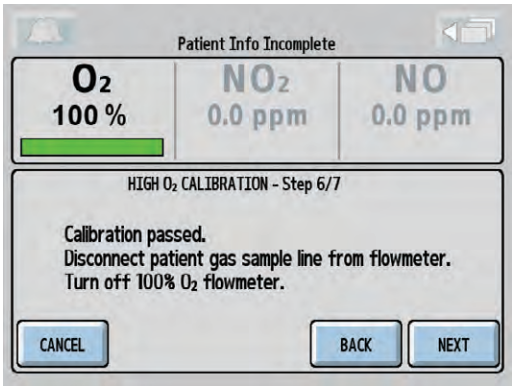
3c. To exit the O_2 high calibration wizard, press the CANCEL button.

Note: Cap off sample tee if patient gas sample line is removed from patient breathing circuit.



4. After reaching step 5 of the calibration wizard, the calibration will take approximately three minutes, during which a progress bar for the O_2 sensor indicates progress.

Note: If the CANCEL button is pressed during the high O_2 calibration process, the calibration will be cancelled and the user will be returned to the high calibration screen.



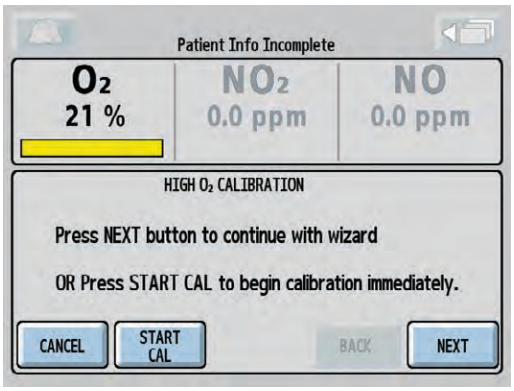
5. When the O_2 high calibration is successful, a single tone will be heard and the progress bar will turn green. Press the NEXT button to return to the high calibration screen.

Note: The monitor displays should indicate approximately 100% O_2, 0.0 ppm NO_2 and 0.0 ppm NO.

Disconnect the sample line from the calibration setup and turn OFF the O_2 flowmeter.

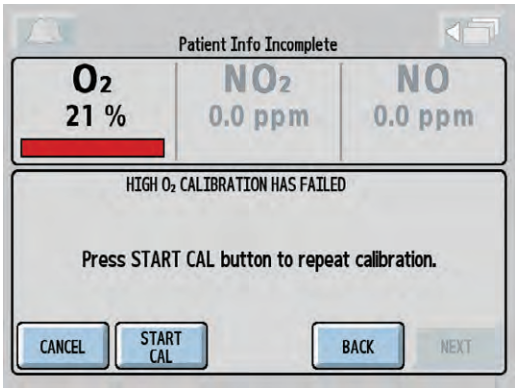
Note: Reconnect patient gas sample line if previously removed from patient breathing circuit.

A Monitor Alarm Delay Active indicator will occur anytime the user exits the calibration screen, even if a calibration was not initiated. All other alarms are still active (see section 5/ Alarms for additional information).



When using the high calibration wizard, if the BACK button is pressed during the O_2 high calibration process, the progress bar will turn yellow, signifying a cancelled calibration.

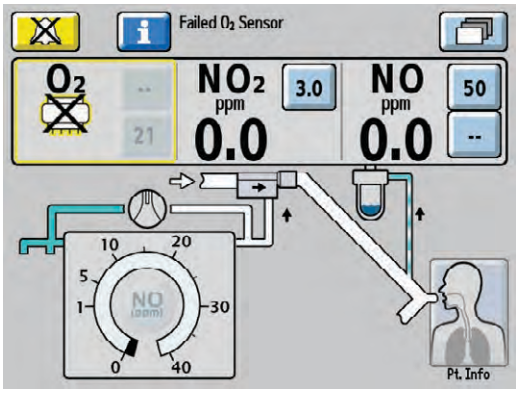
- Press the NEXT button to start the high calibration wizard.
- Press the START CAL button to start the calibration again.
- Press the CANCEL button to exit the O_2 high calibration screen.



If the calibration was unsuccessful, the O_2 progress bar will turn red.

- Attempt another calibration.

Note: To repeat the O_2 high calibration, press the START CAL button at the bottom of the screen.



If the O_2 sensor has failed, the display indicates the failed sensor symbol in the monitoring area of that sensor.

Repeat calibration, (press the Alarm Help button for on-screen alarm help or see Section 5/ Alarms.)

NO Sensor High Calibration

Caution:

- When performing a high 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: Complete a low calibration (see Low Calibration section) prior to completing the high calibration.

Figure 6-1

INOcal calibration gas kit sample tubing

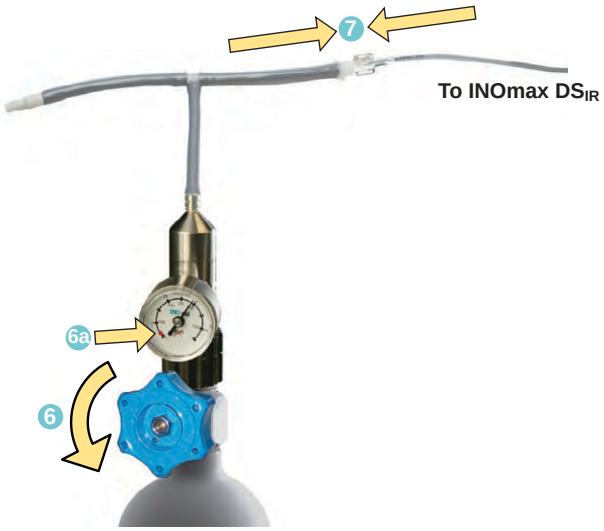
When using the calibration tubing kit (P/N 50239), which is supplied with the INOcal regulator kit (P/N 10090), ensure that the beige pressure relief valve supplied with the tubing is installed and oriented as indicated in Figure 6-1.

Caution: An incorrectly installed one-way valve can lead to over-pressurization of the sampling system. A leak in the calibration tubing kit (PN 50239) 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.

1. Remove cylinder cap and inspect for damaged threads and contaminants.
2. Check seal on regulator. Verify it is correctly in place and undamaged.
3. Attach regulator to cylinder (Turn regulator nut counter-clockwise to tighten).
4. NOTE: Tubing adapter will be required if regulator outlet diameter measures 0.24 in. (6.10 mm).
5. Attach tubing kit to regulator outlet.

NOTE: Confirm water trap bottle, water separator cartridge and patient gas sample line are in place.

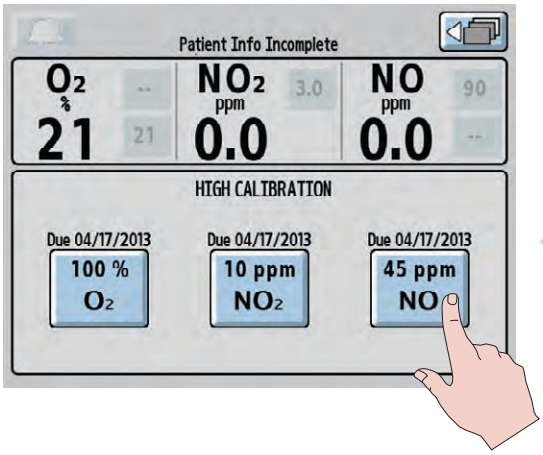


6. Open the INOcal cylinder valve (turn counter-clockwise) to flow gas.

6a. If the pressure is in the red or black zone (0-25 psig) select another INOcal cylinder.

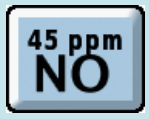
7. Attach tubing kit to patient gas sample line.

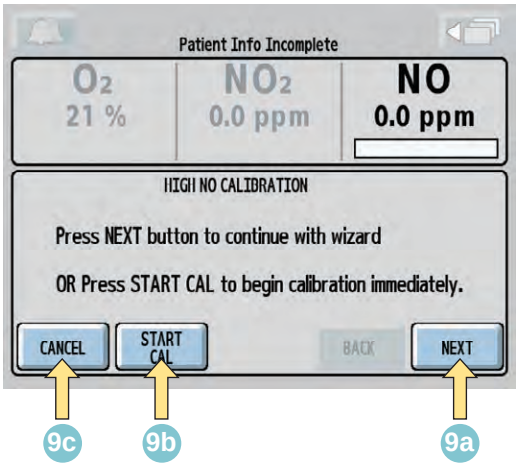
Note: Cap off sample tee if patient gas sample line is removed from patient breathing circuit.



Note: If the date is flashing on the high calibration screen, the calibration is past due.

8. From the high calibration screen (third menu level), press the 45 ppm NO button to initiate the NO high calibration.

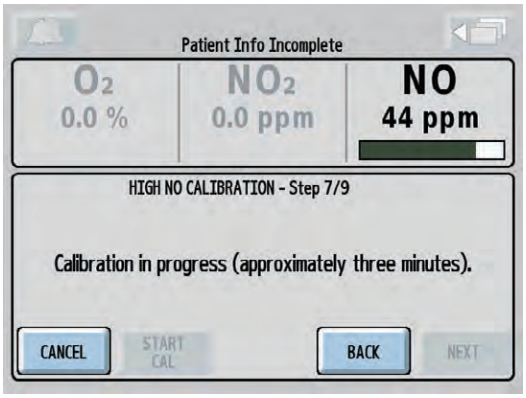




9a. To continue the high calibration wizard, press the NEXT button.

9b. To start the high calibration without using the wizard, press the START CAL button.

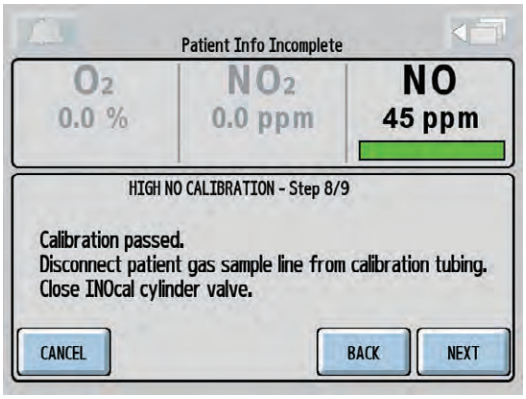
9c. To exit the NO high calibration, press the CANCEL button.



After reaching step 7 of the high calibration wizard, the calibration will take approximately three minutes, during which a progress bar for the sensor indicates progress.

Note: If the CANCEL button is pressed during the NO high calibration process, the calibration will be cancelled and the user will be returned to the high calibration screen.

When the NO high calibration is successful, a single tone will be heard and the progress bar will turn green. Press the NEXT button to return to the high calibration screen.

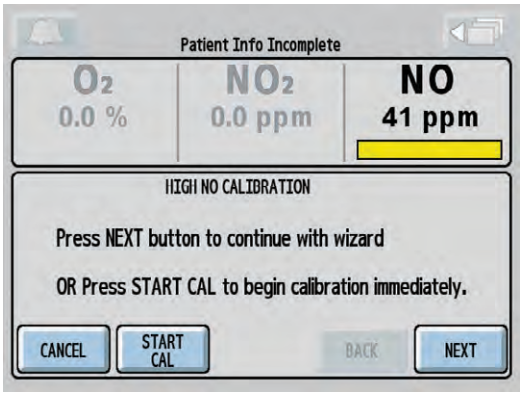


Note: The monitor displays should indicate approximately 0.0% O_2, 0.0 ppm NO_2 and 45 ppm NO.

10. Disconnect the patient gas sample line from the calibration tubing and close the INOcal cylinder valve.

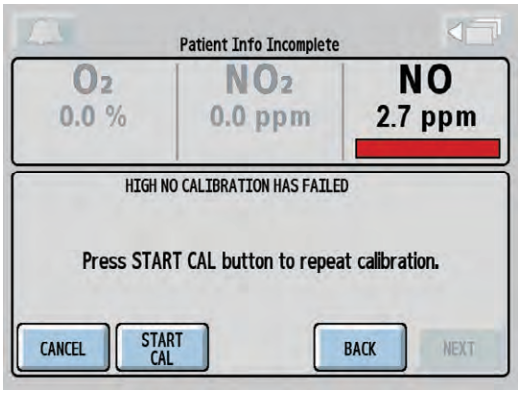
Note: Reconnect patient gas sample line if previously removed from patient breathing circuit.

A Monitor Alarm Delay Active indicator will occur anytime the user exits the calibration screen, even if a calibration was not initiated. All other alarms are still active (see section 5/ Alarms for additional information).



When using the high calibration wizard, if the BACK button is pressed during the NO high calibration process, the progress bar will turn yellow, signifying a cancelled calibration.

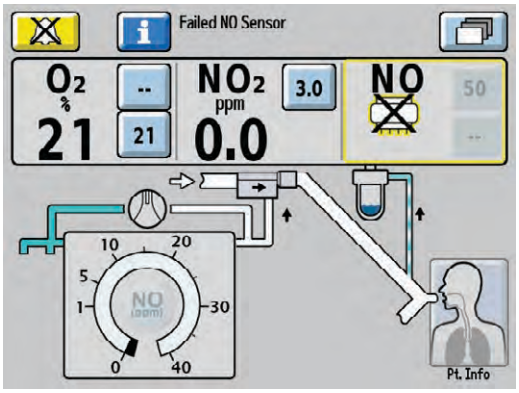
- Press the NEXT button to start the high calibration wizard.
- Press the START CAL button to start the calibration again.
- Press the CANCEL button to exit the NO high calibration screen.



If the calibration was unsuccessful, the NO progress bar will turn red.

- Attempt another calibration.

Note: To repeat the NO high calibration, press the START CAL button at the bottom 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. (Press the Alarm Help button for on-screen alarm help or see Section 5/ Alarms.)

NO_2 Sensor High Calibration

Caution:

- When performing a high 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: Complete a low calibration (see Low Calibration section) prior to completing the high calibration.

Figure 6-2

INOcal calibration gas kit sample tubing

When using the calibration tubing kit (P/N 50239), which is supplied with the INOcal regulator kit (P/N 10090), ensure that the beige pressure relief valve supplied with the tubing is installed and oriented as indicated in Figure 6-2.

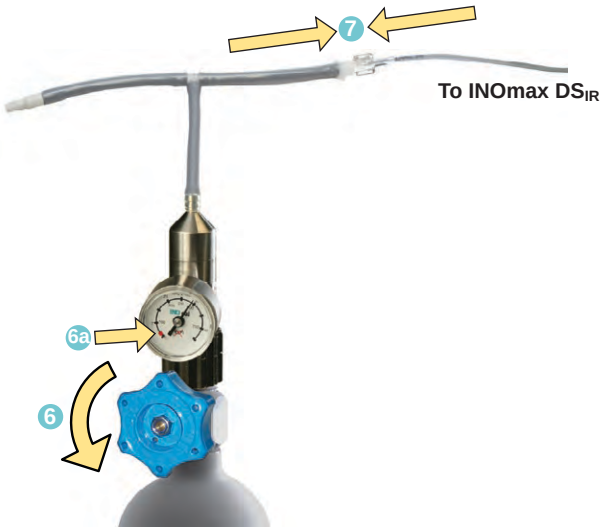
Caution:

An incorrectly installed one-way valve can lead to over-pressurization of the sampling system. A leak in the calibration tubing kit (P/N 50239) 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.

1. Remove cylinder cap and inspect for damaged threads and contaminants.
2. Check seal on regulator. Verify it is correctly in place and undamaged.
3. Attach regulator to cylinder (Turn regulator nut counter-clockwise to tighten).
4. NOTE: Tubing adapter will be required if regulator outlet diameter measures 0.24 in. (6.10 mm).
5. Attach tubing kit to regulator outlet.

NOTE: Confirm water trap bottle, water separator cartridge and patient gas sample line are in place.

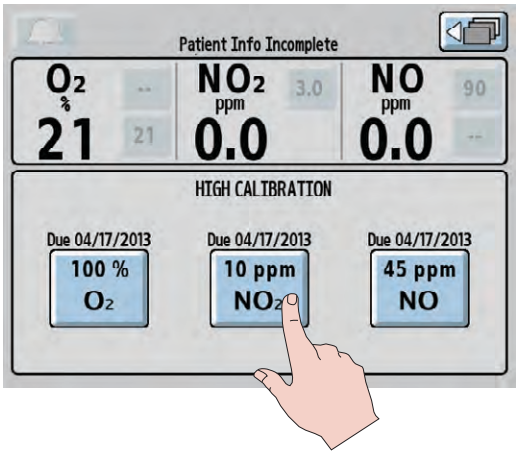


6. Open the INOcal cylinder valve (turn counter-clockwise) to flow gas.

6a. If the pressure is in the red or black zone (0-25 psig) select another INOcal cylinder.

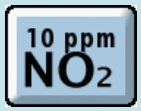
7. Attach tubing kit to patient gas sample line.

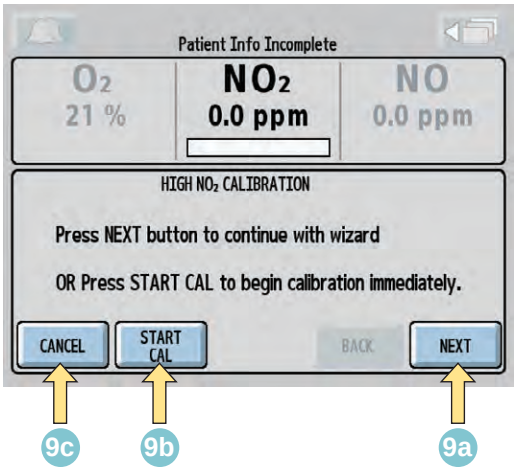
Note: Cap off sample tee if patient gas sample line is removed from patient breathing circuit.



Note: If the date is flashing on the high calibration screen, the calibration is past due.

8. From the high calibration screen (third menu level), press the 10 ppm NO_2 button to initiate the NO_2 high calibration.

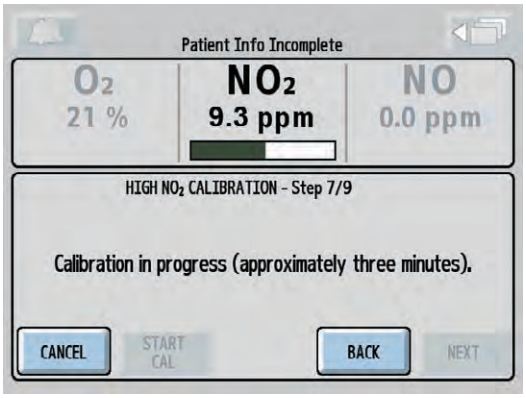




9a. To continue the high calibration wizard, press the NEXT button.

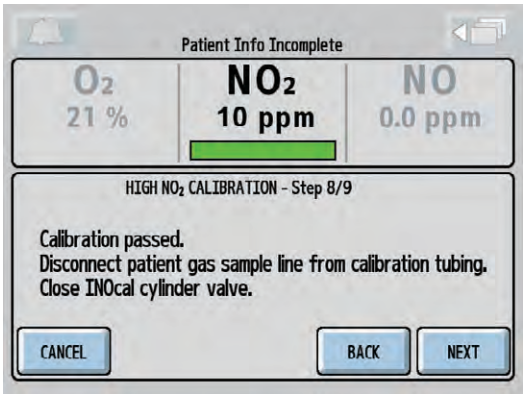
9b. To start the high calibration without using the wizard, press the START CAL button.

9c. To exit the NO_2 high calibration wizard, press the CANCEL button.



After reaching step 7 of the high calibration wizard, the calibration will take approximately three minutes, during which a progress bar for the sensor indicates progress.

Note: If the CANCEL button is pressed during the NO_2 high calibration process, the calibration will be cancelled and the user will be returned to the high calibration screen.



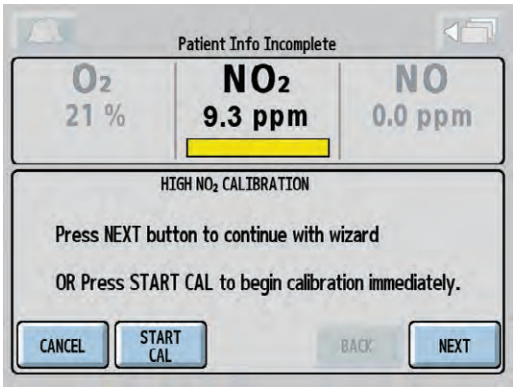
When the NO_2 high calibration is successful, a single tone will be heard and the progress bar will turn green. Press the NEXT button to return to the high calibration screen.

Note: The monitor displays should indicate approximately 21% O_2, 10 ppm NO_2 and 0.0 ppm NO.

10. Disconnect the patient gas sample line from the calibration tubing and close the INOcal cylinder valve.

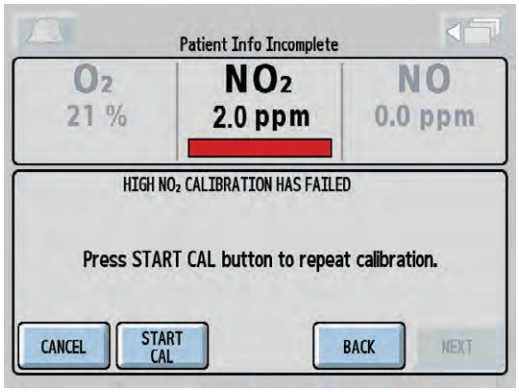
Note: Reconnect patient gas sample line if previously removed from patient breathing circuit.

A Monitor Alarm Delay Active indicator will occur anytime the user exits the calibration screen, even if a calibration was not initiated. All other alarms are still active (see section 5/ Alarms for additional information).



When using the high calibration wizard, if the BACK button is pressed during the NO_2 high calibration process, the progress bar will turn yellow, signifying a cancelled calibration.

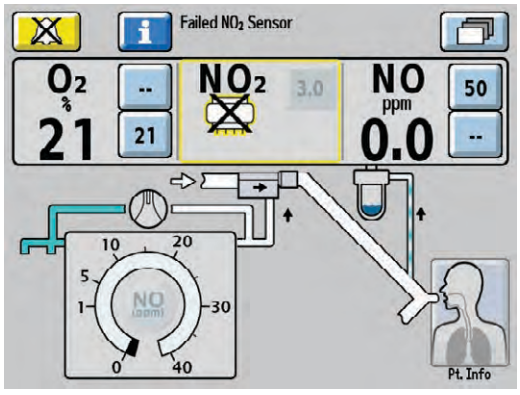
- Press the NEXT button to start the high calibration wizard.
- Press the START CAL button to start the calibration again.
- Press the CANCEL button to exit the NO_2 high calibration screen.



If the calibration was unsuccessful, the NO_2 progress bar will turn red.

- Attempt another calibration.

Note: To repeat the NO_2 high calibration, press the START CAL button at the bottom of the screen.

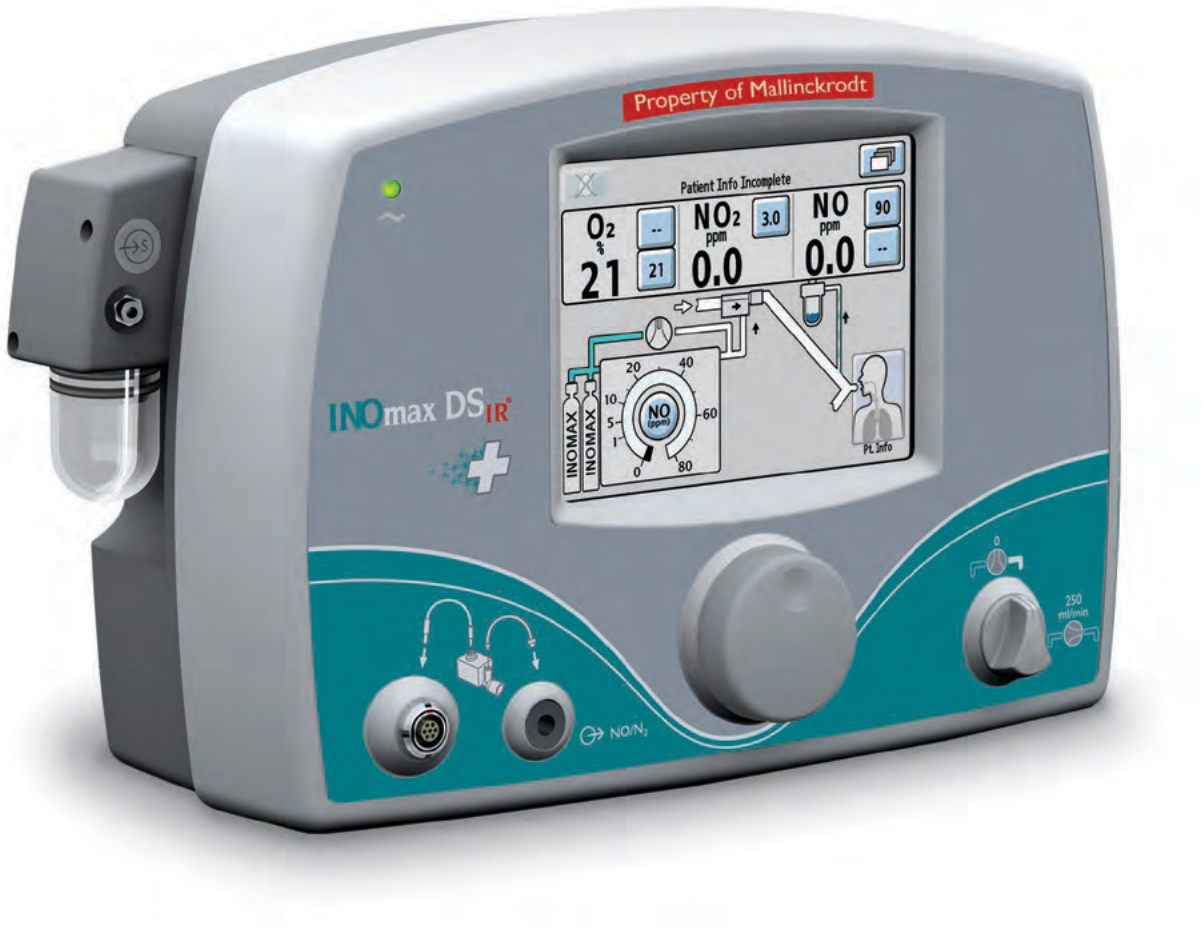


If the NO_2 sensor has failed the display indicates the failed sensor symbol in the monitoring area of that sensor.

Repeat calibration. (Press the alarm help button for on-screen alarm help or see Section 5/ Alarms.)

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



Maintenance

7/ Maintenance

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

Maintenance

7/ Maintenance

Part No. 20717 Rev-01
2014-07

7/ Maintenance

Caution:

- To help prevent fire, use only lubricants approved for O_2 equipment, such as KRYTOX®.
- Do not use lubricants which contain oil or grease, as 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. 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. Perform a low and a high calibration of NO, NO_2 and O_2. Note: A flashing date above the high sensor calibration button signifies a high calibration is past 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 and the INOmax DS_{IR} turned ON.
- Be sure that the INOmax DS_{IR} is completely dry before using.
- 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 to prevent pooling and direct contact with electrical connections which can cause damage over time.

External surfaces and the Display panel

- Disconnect the power cord from the wall outlet and turn the INOmax DS_{IR} OFF 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.

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%

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	Diisobutylphenooxyethoxyethyl 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 six ppm) and NO sensor to read low (approximately 0.5 to one 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 US 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}.

Cleaning the INOmeter

Caution:

- Apply cleaning agent to a cloth before application; do not spray directly on the INOmeter. It is important to prevent pooling and direct contact with electrical connections, which can cause damage over time.
- Do not autoclave or gas sterilize the INOmeter.
- Be sure that the INOmax DS_{IR} is completely dry before using.
- Do not saturate the INOmeter with excessive solution. Liquid may flow into the device 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).

External surfaces and the Display

- Clean the outer surface of the INOmeter with a soft cloth dampened in a mild soap and water solution, isopropyl alcohol (70%) or with one of the cleaning agents (see cleaning agent list above) while following the manufacturer's recommendations.

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.

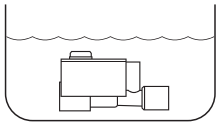
If the injector module has been used in the dry part of the breathing circuit, the injector module should be sterilized and/or disinfected in 70% ethyl alcohol after each patient use.

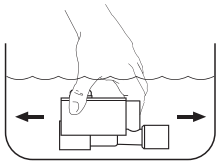
Autoclave Sterilizing the Injector Module

1. *Disconnect the electrical cable and the injector tube before autoclaving.*
2. Autoclave the injector module at 134° C for three minutes at 27 psig.
3. After sterilization, examine the parts.
4. Replace any broken, worn, distorted or discolored parts.

Disinfecting the Injector Module

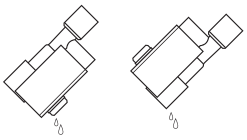
1. Fill a container with 70% ethyl alcohol.
2. Totally submerge the injector module in the 70% ethyl alcohol for at least 30 minutes. If debris is noticed on the hot wire sensor, gently agitate the module in the alcohol bath.
3. Remove the injector module from the liquid and drain the excess alcohol from the module's electrical connector, injector port and inside flowmeter.





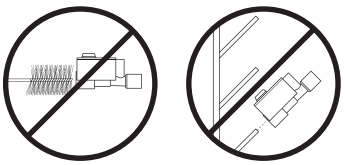
Note: If rinsing is required, use a separate bath filled with distilled water.

4. Allow liquid to evaporate completely before using the injector module.



Note:

- Do not insert anything into the injector module throat in an effort to remove contamination or to dry.
- If lint fibers remain wrapped around the hot wire sensor after drying, do not use the module. Remove it from service and contact Mallinckrodt Technical Support.



Note: Patient circuit adapters, patient gas 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 there is a risk that the system will shut down.**

Figure 7-1

To replace any one of the three sensors:

Remove the rear sensor cover by turning the two screws counterclockwise until loose (see Figure 7-1).

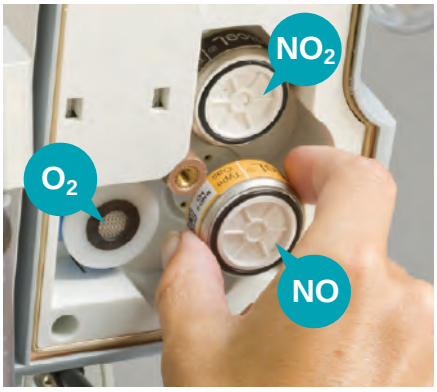


Figure 7-2

Grasp the sensor to be replaced on both sides and gently pull it from its socket (see Figure 7-2).

Note:

- The shorting wire must be removed from the NO_2 sensor before replacing (see Figure 7-5).
- Make sure all of the sensor O-rings are present and seated properly.

Figure 7-3

To install replacement NO or NO_2 sensor, align the pins with the socket and press it into place (see Figure 7-3).

To install O_2 sensor, remove the shorting button 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 7-4

Replace the sensor cover and tighten the two screws clockwise (see Figure 7-4).

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.	

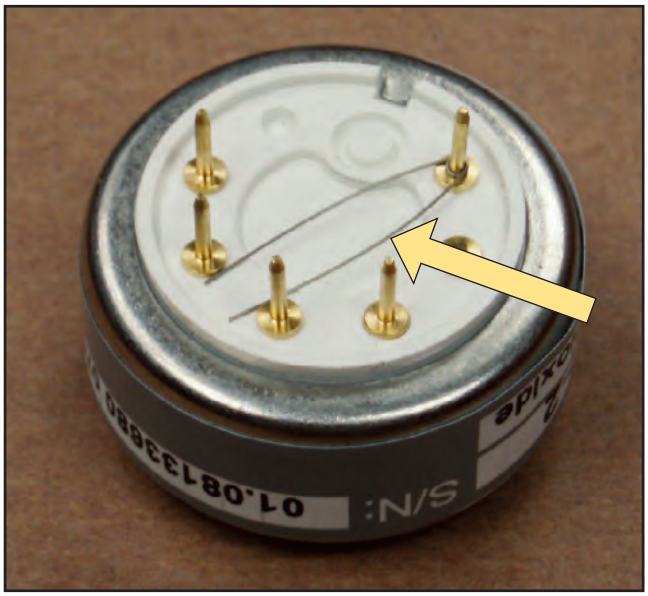


Figure 7-5
NO_2 Shorting Wire

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 7-6

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 7-6).
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

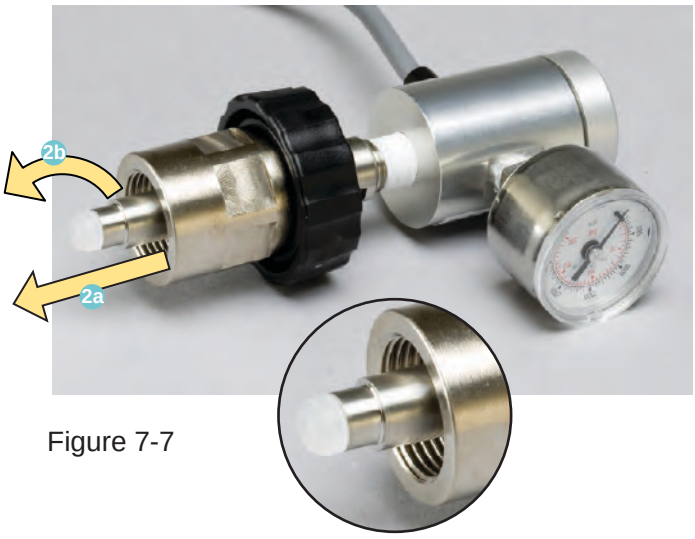


Figure 7-7

1. Disconnect the regulator from the INOMAX drug cylinder.

Note: Depressurize the INOMAX regulator by using the purge port on the back of the INOmax DS_{IR} prior to removing from the cylinder valve.

2. Remove the old CGA 626 tip by pulling on the tip 2a and turning it counterclockwise 2b (see Figure 7-7).
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.

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 7-8). 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 7-9).

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 7-8
INOMAX gas inlet with the knurled sleeve in the back position.

Ready for use

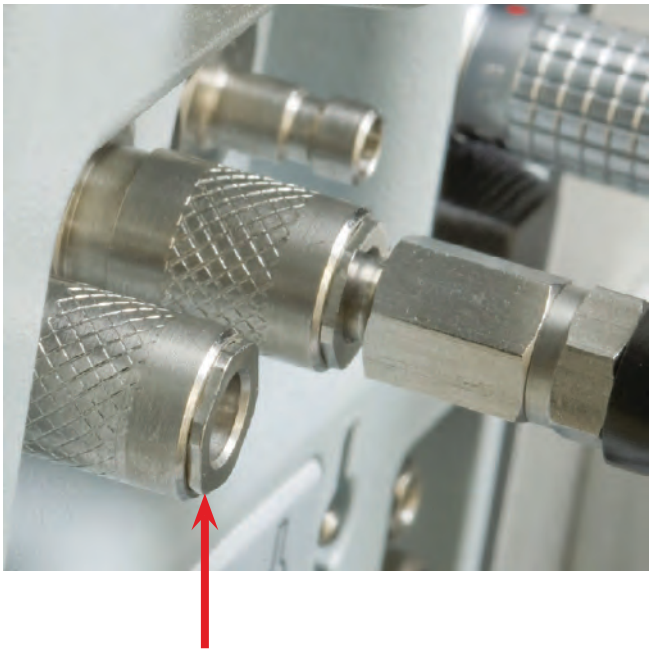


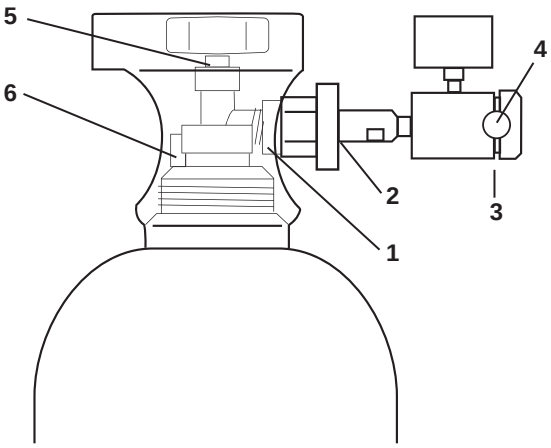
Figure 7-9
INOMAX gas inlet shown with the knurled sleeve in the forward position.

Reset prior to use

Cylinder Leak Check

If a leak is suspected during the high pressure leak test (see section 2/ Pre-Use Checkout; High Pressure Leak Test), the following steps can be taken to check for leaks (see Figure 7-10 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 7-10

1. Confirm that INOMAX regulator is connected to cylinder valve outlet (hand tighten only), cylinder valve is open and that the cylinder has more than 200 psig.
2. Apply soapy water to points #1, #2, #3, #5 and #6 (see Figure 7-10); if bubbles form, there is a leak.
3. If there are no bubbles, the leak may be inside the INOmax DS_{IR} and cannot be repaired. Replace the INOmax DS_{IR} and contact 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 Technical Support.
3. A leak detected at the cylinder valve nut connection (see point #5) may not be repaired. Replace INOMAX cylinder and contact Technical Support.
4. A leak detected at the safety pressure release device (see point #6) may not be repaired. Replace INOMAX cylinder and contact Technical Support.

Preventative Maintenance

Mallinckrodt performs the following maintenance task every year:

- Replace O_2 and NO sensors.

Mallinckrodt performs the following maintenance task every two years:

- Check battery.
- Check internal tubing.
- Replace sample system tubing and filters.
- Replace NO_2 sensor.

Equipotential grounding is the bonding of all conductive surfaces in the room together and to earth. This can be implemented in the patient care environment if it is crucial to keep all conductive surfaces at the same electrical potential or on the same ground plane.

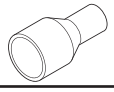
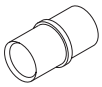
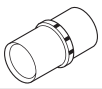
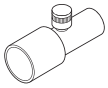
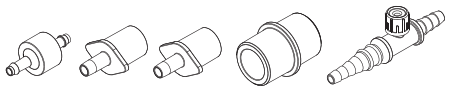
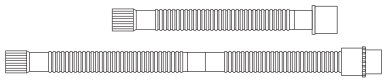
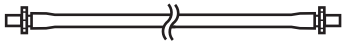
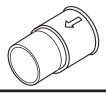
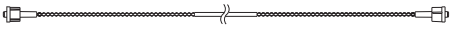
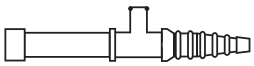
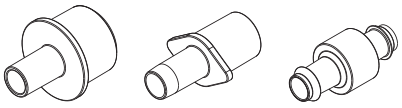
If an equipotential grounding system is installed, the ground system should be tested per chapter four of NFPA 99.

Figure 7-11

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	90439
Calibration Tubing Kit	50239
Clamp Assembly	10008
Injector Module	1605-3038-000
Injector Module Cable	90838
INOcal Calibration Gas, NO, 45 ppm	BOM-COM-0150
INOcal Calibration Gas, NO_2, 10 ppm	BOM-COM-0162
INOcal Regulator Kit	10090
INOmax DS_{IR} Cart	10018
INOMAX Regulator, CGA 626	10006
INOblender Extension Hose	10014
INOMAX Transport Regulator/Cap Assembly	10022
Mounting Post	10009
Operation and Maintenance Manual	20717
Sensor, O_2	80043
Sensor, NO	90844
Sensor, NO_2	90845
Tip, CGA 626 INOMAX Regulator	1605-3149-000
Transport Mounting Bracket Assembly	50041
Water Trap Bottle	90137

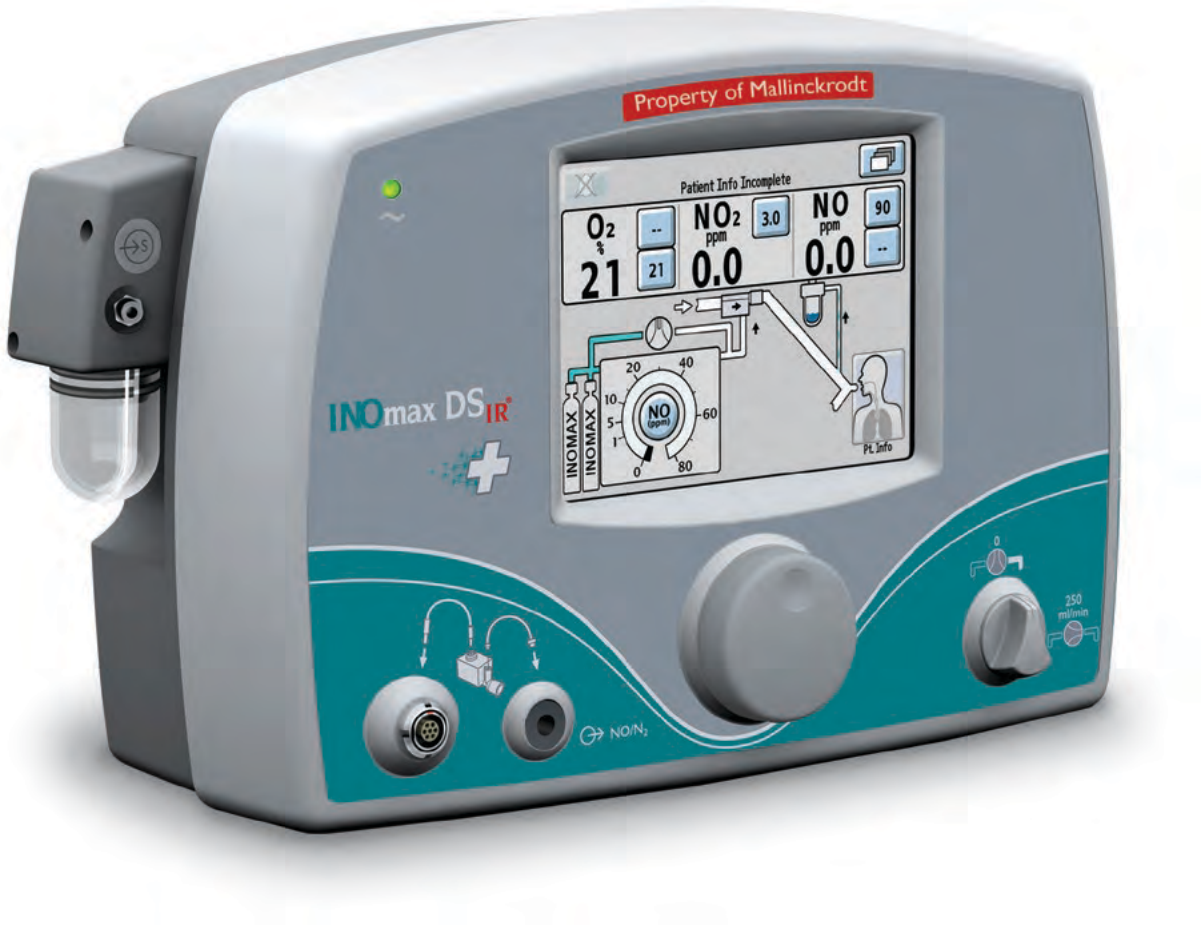
Disposables	Description
	Adapter 15M Fits 4.5 mm ID Tubing
	Adapter, 22F X 15M
	Adapter, 22M/15F X 22M/15F
	Adapter, Cuff, 22 mm ID X 22 mm ID
	Adapter, Gas Sample Tee
	Adapter, 90 degree Sample Port
	Bunnell Life Pulse Disposable Adapters Convenience Pack
	Disk Filter, 0.5 micron
	Neonatal Tubing, 10 mm (2 pieces)
	NO/N_2 Injector Tube
	One-way Valve, 22F X 22M
	Patient Gas Sample Line (Nafion)
	Pediatric Extension, 150 mm (six inches)
	Sample Tee, O_2 Tubing
	Sensormedics 3100A/B Filtered Circuit Disposable Adapters Convenience Pack
	Water Separator Cartridge

(Note: Physical appearance may vary slightly)

(Intentionally left blank)

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



8/ Product Specifications

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

8/ Product Specifications

Part No. 20717 Rev-01
2014-07

8/ Product Specifications

WARNING:

- **In the United States, the approved patient population for the INOmax DS_{IR}, as specified in the drug labeling for INOMAX® (nitric oxide) for inhalation, is limited to term and near-term neonates with hypoxic respiratory failure. The INOmax DS_{IR} is not intended to be used in other patient populations.**
- **Outside of the United States, use of the INOmax DS_{IR} is limited to the use in accordance with INOMAX or INOflo, nitric oxide for inhalation prescribing information as established with the national health authority.**
- **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

Ventilators/Breathing Systems validated for use in the United States								
Manufacturer	Model	Neonatal	Pediatric/ Adult	Transport	High Frequency	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
A-plus Medical	Baby-Plus Bubble CPAP						•	
Airon Corporation	pNeuton			•				
Bear	750ps (Cub)	•						
Bio-Med Devices	Crossvent 2			•				
Bio-Med Devices	Crossvent 4			•				
Bio-Med Devices	MVP-10			•				
Bird	VIP	•	•					

Ventilators/Breathing Systems validated for use in the United States								
Manufacturer	Model	Neonatal	Pediatric/ Adult	Transport	High Frequency	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
Bunnell	Life Pulse				●			
Cardinal Healthcare	AirLife nCPAP System						●	
Carefusion	ReVel	●	●	●				
Dräger	Apollo					●		
Dräger	Babylog 8000	●						
Dräger	Evita	●	●					
Dräger	Evita Babylog VN500	●						
Dräger	Infinity V500	●	●					
Dräger	Narcomed 2B					●		
eVent Medical	Inspiration LS	●	●					
Fisher & Paykel Healthcare	Bubble CPAP System						●	
Fisher & Paykel Healthcare	Infant Circuit Nasal Cannula Kit							●
Fisher & Paykel Healthcare	Optiflow Breathing Circuit							●
GE Healthcare	Aespire 7100					●		
GE Healthcare	Aespire 7900					●		
GE Healthcare	Aestiva					●		
GE Healthcare	Aisys					●		
GE Healthcare	Avance					●		
GE Healthcare	Centiva/5		●					
GE Healthcare	Engström Carestation	●	●					
GE Healthcare	Excel SE 7800					●		
GE Healthcare	Mod SE 7900					●		
Hamilton	Arabella						●	
Hamilton	C1	●	●					
Hamilton	C2	●	●					
Hamilton	G5	●	●					
Hamilton	Galileo	●	●					
Hamilton	T1			●				
Impact Instrumentation	EMV+			●				
Impact Instrumentation	Uni-Vent			●				
Infrasonics	Infant Star 100			●				
Infrasonics	Infant Star 500	●						

Ventilators/Breathing Systems validated for use in the United States								
Manufacturer	Model	Neonatal	Pediatric/ Adult	Transport	High Frequency	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
Infrasonics	Infant Star 950	●						
Maquet (formerly Siemens)	Servo 300		●					
Maquet (formerly Siemens)	Servo i	●	●					
Nasal Cannula	NA							●
Newport	E360	●	●					
Newport	HT50		●					
Newport	Wave	●	●					
Pulmonetic Systems	LTV 1000		●					
Pulmonetic Systems	LTV 1200		●					
Puritan Bennett	7200		●					
Puritan Bennett	840	●	●					
Respironics	Esprit	●	●					
Sechrist	IV-100B	●						
Sensormedics	3100 A (standard and filtered circuits)				●			
Sensormedics	3100B (standard and filtered circuits)				●			
Smiths Medical	babyPAC 100			●				
Smiths Medical	paraPAC Medic 200D			●				
Smiths Medical	ventiPAC 200D			●				
Teleflex Medical	Comfort Flo Humidification System							●
Vapotherm	2000i							●
Vapotherm	Precision Flow							●
Viasys	Infant Flow CPAP System						●	
Viasys	Infant Flow SiPAP						●	
Viasys	Avea	●	●					
Viasys	Vela	●	●					

Ventilators/Breathing Systems validated for use outside the United States								
Manufacturer	Model	Neonatal	Pediatric/ Adult	Transport	High Frequency	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
Acutronics Medical Systems AG	Fabian +nCPAP Evolution	●						
Acutronics Medical Systems AG	Fabian HFO	●			●			
Dräger	Evita Babylog VN500	●			●			
Dräger	Zeus					●		
Heinen & Löwenstein	Leoni+	●			●			
Infrasonics	Infant Star 950	●			●			
Metran	Humming HMX	●			●			
SLE Life Support	SLE 5000	●			●			

NO Delivery

Set NO Range:	0.1 - 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 (25 to 35 psig)
Maximum NO Supply Pressure:	2.4 Bar (35 psig)
NO Low Pressure Alarm:	1.6 Bar (23 psig) (nominal)
Max Circuit Pressure:	1.4 Bar (20 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

Integrated Pneumatic Backup Delivery

Integrated pneumatic 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 (200 to 2,248 psig)
Outlet Pressure: 1.7 to 2.4 Bar (25 to 35 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: CSA certified to meet the following for medical electrical equipment:
- UL 60601-1: 2003 edition 2
- ANSI/AAMI 60601-1: 2005 edition 3
- IEC 60601-1: 2005 edition 3

Battery Backup: A sealed lithium ion rechargeable battery provides power backup to operate the system for up to six 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, there are 30 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: Enables serial communications for use with hospital electronic health record (EHR) system (see specifications on page 8-7).

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.

RS232 Data Output

Enables serial communications for use with hospital electronic health record (EHR) system. Must be connected to the manufacturer-specified third-party hardware (to be determined).

WARNING:

- **INOmax DS_{IR} should only be connected to RS-232 ports that have:**
  - **Four kV input to output isolation**
  - **Four kV input to mains isolation and**
  - **an internal "reference voltage" "U" (as defined in section 20.3 of IEC60601-1 edition two) of less than or equal to 50 VDC or 50 VRMS and dielectric isolation certified in accordance with IEC 60601-1. Interface cabling must not go outside of the room (e.g., into walls where potential isolation issues could exist). Adherence to the above provide compliance to clause 20.3 "Value of test Voltage" in edition two and clause(s) 8.5.4 "Working Voltage" and Clause 8.8.3 "Dielectric Strength" in edition three.**
- **RS232 cables must be shielded. The RS232 cable shield shall have a minimum of 90% coverage. The shield shall only be connected at one end of the cable to minimize noise induced by ground currents.**

Note:

- Connector retention jack posts can be found at the INOmax DS_{IR} connector. The RS232 interface cable/connector should be constructed to include cable retention fasteners to help ensure a robust connection.
- This serial communication protocol requires INOmax DS_{IR} software revision 2.1 or higher to function. The software revision of the device can be accessed by pressing the Menu Button on the Main Screen and then the Settings Button (see Figure 1-6).

Definitions

Acronym/Definition	Description
CRC	Cyclic Redundancy Check
RS232	RS232 (Recommended Standard 232) is the traditional name for a series of standards for serial binary single ended data and control signals connecting between a DTE (Data Terminal Equipment) and a DCE (Data Circuit-terminating Equipment).
ASCII	American Standard Code for Information Interchange

RS232 Port:

- Nine pin female DSUB connector
- Pin two - received data, Pin three - transmitted data, Pin five - ground (isolated), Pin seven - RTS (unused), Pin eight - CTS (unused) and Pins one, four, six and nine - no connection
- 38,400 baud, one start bit, eight ASCII data bits, one stop bit, no parity, and no flow control
- Messages are output at a minimum rate of once per second, terminated with a checksum and carriage return

Data output includes:

- Device information
  - Model number, device generated identifier, software revision and user generated patient identifier
- Monitored values
  - Monitored O_2, NO_2 and NO
- Settings
  - Dose setpoint
  - Alarm setpoints
    - High O_2, low O_2, high NO_2, high NO and low NO
- Alarm messages
- Device status
- INOMAX cylinder serial number and open/closed status

Note: A detailed document regarding output data format is available upon request.

Electromagnetic Compatibility Information

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The INOmax DS_{IR} system is intended for use in the electromagnetic environment specified below. The user of the INOmax DS_{IR} system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The INOmax DS_{IR} system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The INOmax DS_{IR} system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The INOmax DS_{IR} system is intended for use in the electromagnetic environment specified below. The user of the INOmax DS_{IR} system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ±2 kV line(s) to earth	± 1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/ or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial and/ or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's declaration - Electromagnetic Immunity INOmax DS_{IR} system is intended for use in the electromagnetic environment specified below. The user of the INOmax DS_{IR} system should assure that they are used in such an environment			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	3 Vrms (V1) 10 Vrms (V2)	Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the INOmax DS_{IR} system than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2*\sqrt{P}$ $d=1.2*\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 26 MHz to 2.5 GHz (E1)	$d=1.2*\sqrt{P}$ 80 MHz to 800 MHz $d=2.3*\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. [b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that a portable communications device could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. [c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed R transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the INOmax DS_{IR} system is used exceeds the applicable RF compliance level above, the INOmax DS_{IR} system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the INOmax DS_{IR} system. [d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the INOmax DS_{IR} system

The INOmax DS_{IR} system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the INOmax DS_{IR} system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the INOmax DS_{IR} system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz Outside ISM bands $d=1.2*\sqrt{P}$	**150 kHz to 80 MHz In ISM bands** $d=1.2*\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2*\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3*\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

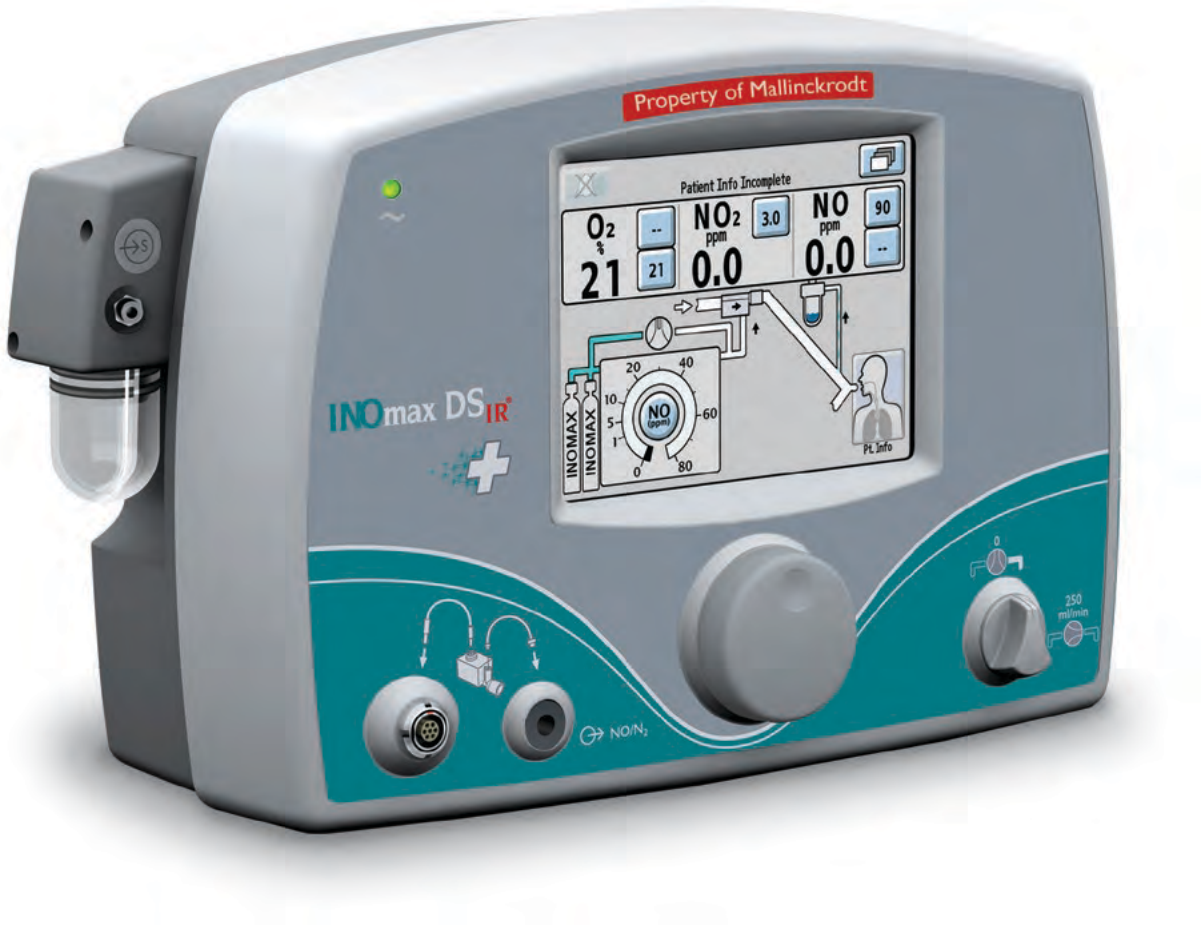
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus



9/ Appendix

Part No. 20717 Rev-01
2014-07

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus

9/ Appendix

Part No. 20717 Rev-01
2014-07

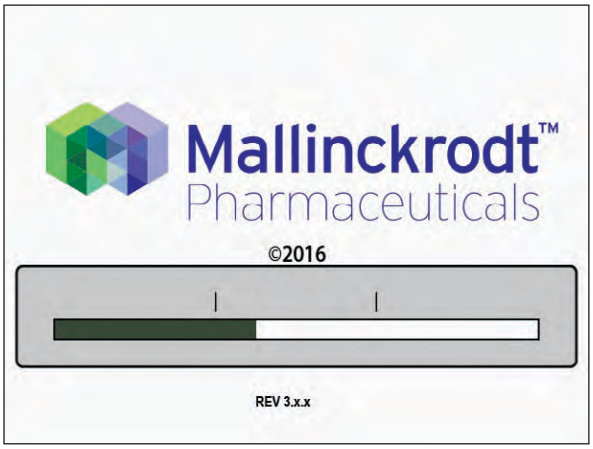
9/ Appendix

Manual Pre-Use Checkout

Note: Following unpacking and prior to the first use:

- 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.

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.

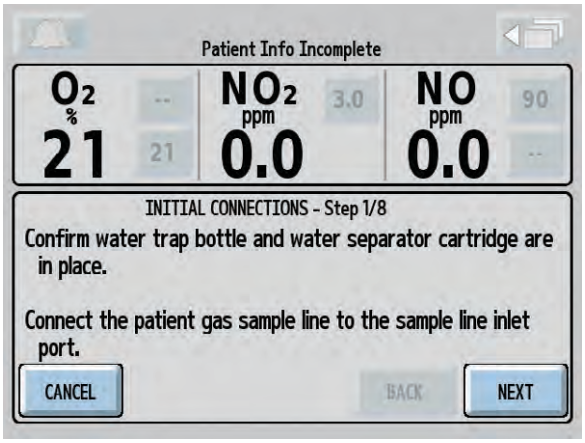


Self Test Screen

Turn ON INOmax DS_{IR}.

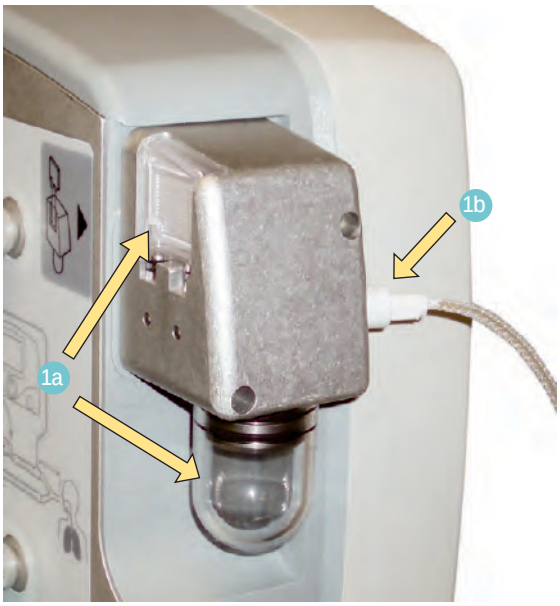
An INOmax DS_{IR} splash screen will appear once the device is turned ON followed by a Mallinckrodt test screen (confirm that the speaker sounds).

Note: Low calibration automatically starts following the INOmax DS_{IR} self test. Allow the low calibration to complete before completing the manual purge and alarm verification.



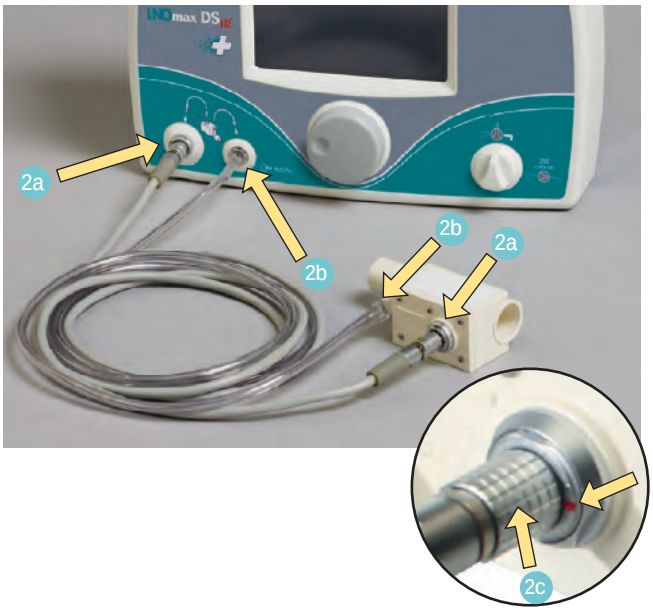
Pressing the CANCEL button exits the Pre-Use wizard.

Initial connections



1. Confirm the water trap bottle and water separator cartridge are in place 1a.

   Connect the patient gas sample line with Nafion to the sample line inlet port on the front of the INOmax DS_{IR} 1b .



Check cables and hoses for signs of wear and damage.

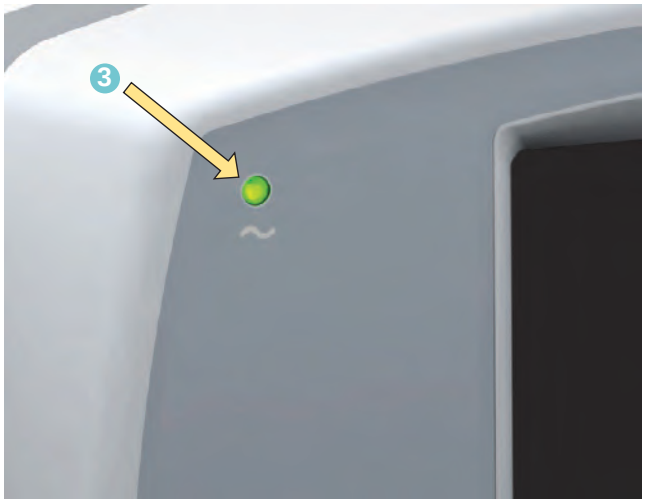
2. Connect one end of the injector module electrical cable to the injector module and the other end into the front of the INOmax DS_{IR} 2a.
   - Line up the red dot on both the connector and the injector module before inserting the connector (see inset detail).

   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} 2b.

WARNING: **Be certain all cables and hoses are positioned to help prevent damaging or occluding them.**

Note:

- It is recommended to disinfect or sterilize the injector module prior to initial setup.
- To remove this type of connector, the knurled sleeve 2c on the connector must be pulled outward before removing the connector from the injector module or the front panel.



3. 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.

   Verify the main power supply indicator light is illuminated (green). This indicates that the power cord is plugged into an electrical outlet.

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

4. Load two INOMAX drug cylinders onto cart and check for correct product identity labels, cylinder concentration (800 ppm) and expiration date.

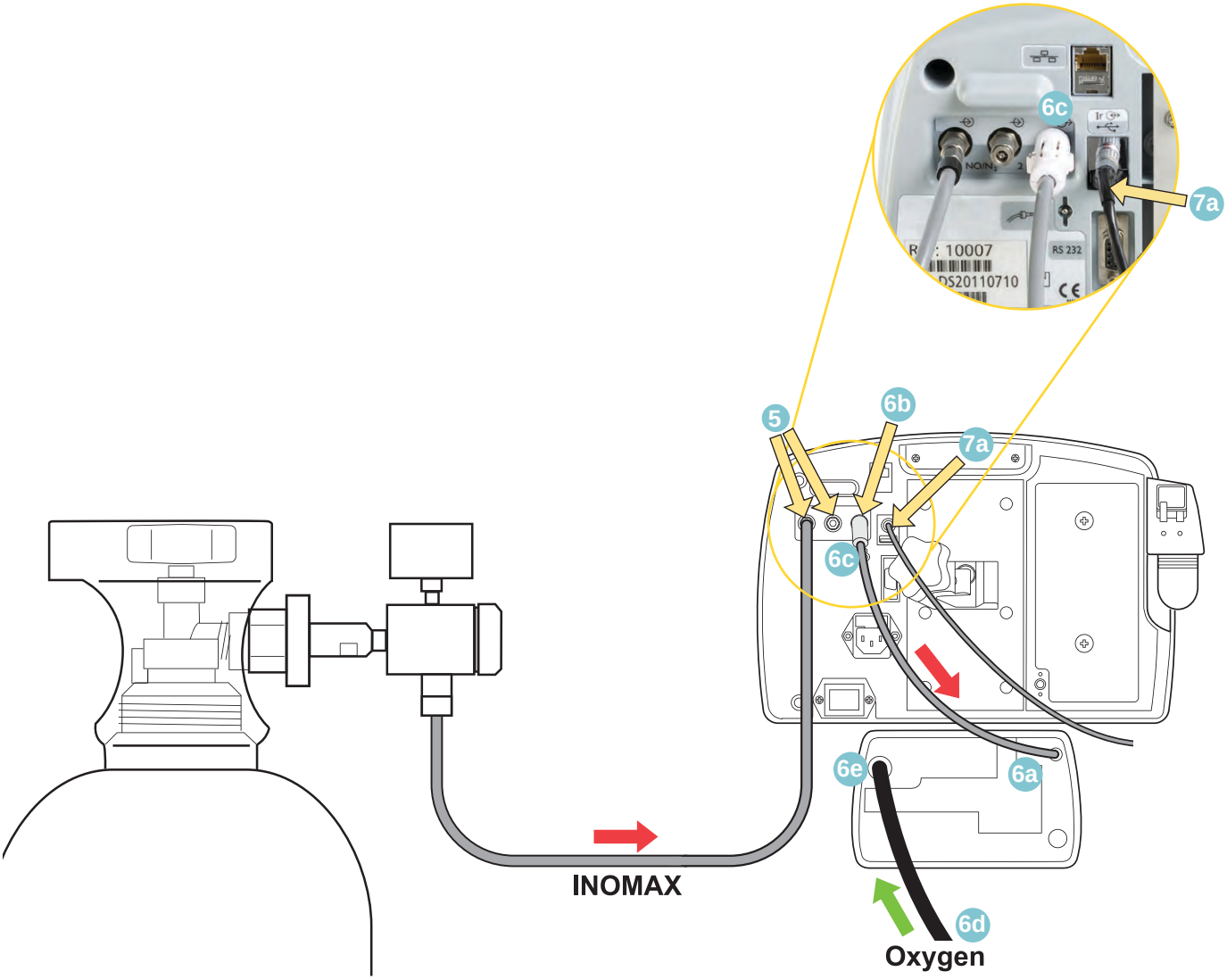
5. Connect an INOMAX regulator to one of the INOMAX cylinders, and hand tighten the fitting to the INOMAX cylinder. Connect the INOMAX regulator hose to one of the INOMAX inlets (see page 7-9 for additional instructions).

Caution: If using the transport regulator/cap assembly (PN 10022) see Figure 4-7, Section 4/ Transport.

Note: For the CGA-type INOMAX regulator connector, ensure the white plastic tip is not chipped or cracked. Remove and replace as necessary. (see Replacing the tip on the INOMAX regulator, Page 7-8).

6. If using the INOblender with the INOmax DS_{IR}, connect the INOblender inlet hose 6a to the INOmax DS_{IR} INOblender outlet 6b and slide the quick-connect cover into place 6c . Connect oxygen supply (wall source or cylinder oxygen, 6d) hose to O_2 inlet fitting on back of INOblender 6e . Note: 50 psig, nominal
7. Connect the Infrared cable from the INOmax DS_{IR} cart or transport regulator/cap assembly (PN 10022, CGA) to the back of the INOmax DS_{IR} 7a.

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



High Pressure Leak Test

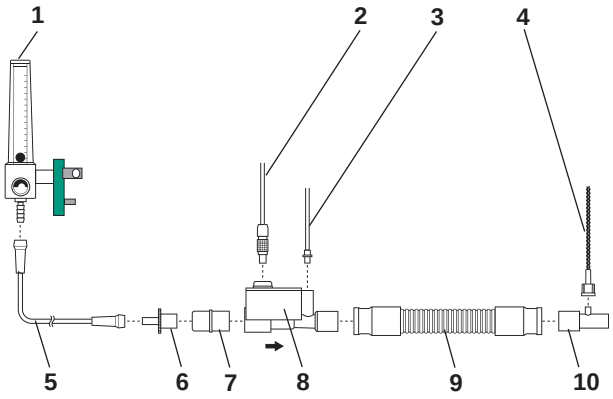
WARNING:

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

1. Open and then close the cylinder valve. Verify cylinder has at least 500 psig (replace if 200 psig or less).
2. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no pressure decrease is observed, high pressure leak test is successful. If there is an observed pressure decrease, see Section 7/ Maintenance; Cylinder Leak Check.

Manual Purge and Alarm Verification

Note: Allow the auto low calibration to complete before completing the manual purge and alarm verification.



1. O_2 Flowmeter (Connected to wall/tank)
2. Injector Module Electrical Cable
3. NO/N_2 Injector Tube
4. Patient Gas Sample Line with Nafion
5. O_2 Tubing
6. 15M x 4.5 mm Adapter
7. 22M / 15F x 22M / 15F Adapter
8. Injector Module
9. 300 mm of 22 mm Hose
10. Gas Sample Tee

Figure 9-1

Assemble connectors and tubing as shown in Figure 9-1 to perform the following three procedures:

1. Verify the INOMAX cylinder valve is closed.
2. Set the O_2 flowmeter to 10 L/min (#1 in Figure 9-1).
3. Purge INOmax DS_{IR}.
   - Set the INOMAX dose to 40 ppm.
   - "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 Cylinder 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.

Integrated Pneumatic Backup INOMAX Delivery Test

1. Verify that the O_2 flowmeter is set to 10 L/min.
2. Turn the integrated backup INOMAX delivery to ON (250 mL/min.).
   Verify "Backup ON" alarm occurs.
3. Allow monitored values to stabilize (may take up to 3 minutes) and make sure the NO and NO_2 readings are within the following ranges:

NO = 14-26 ppm	NO_2 ≤ 1.0 ppm

4. Turn the integrated backup INOMAX delivery to OFF.

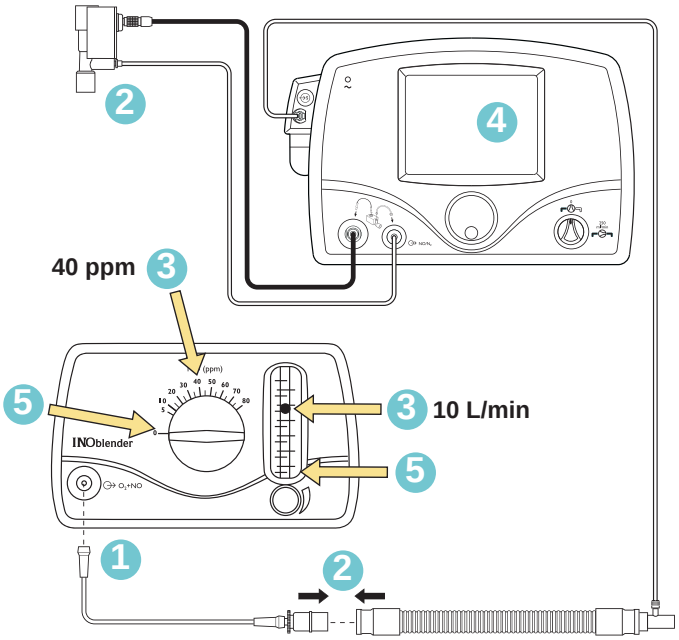
Performance Test

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

1. Verify that the O_2 flowmeter is set to 10 L/min.
2. Set the INOMAX dose to 40 ppm, allow values to stabilize.
3. Compare the INOmax DS_{IR} monitor values to the values in the table.
4. 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.

INOblender Test



Acceptable NO Value	32-48 ppm

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.

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.**

Pre-use checkout complete.

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

Proceed to Section 3/Patient Application.

(Intentionally left blank)

Mallinckrodt™
Pharmaceuticals

INOmax Total Care®

The TRUSTED 24/7 Service Package

Please see Full Prescribing Information at www.inomax.com

Mallinckrodt Manufacturing LLC
6603 Femrite Drive,
Madison, WI 53718-6801 USA
877-566-9466

Part No. 20717 Rev-01
2014-07