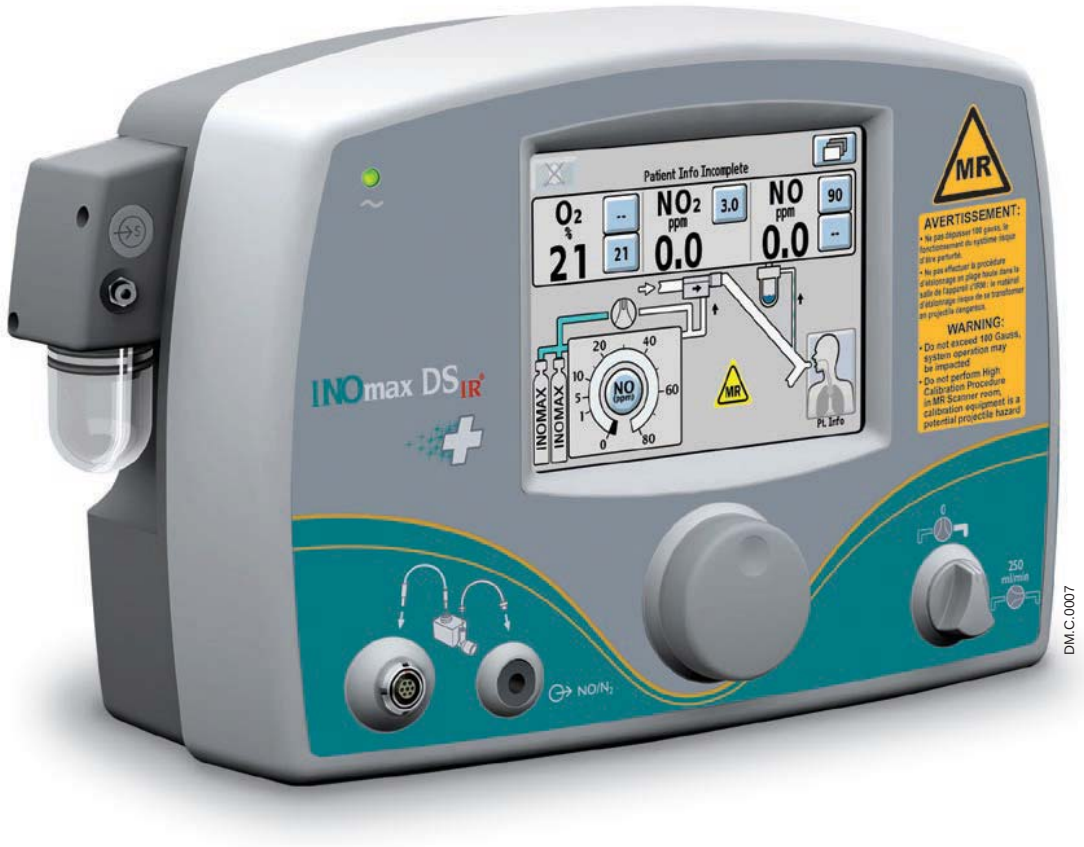
Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



Operation Manual

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

Software version 3 series

Part No. 20765 Rev-01
2015-08

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} Plus MRI, 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 10087	INOmax DS_{IR} Plus MRI, 800 ppm, French-Canadian
Ref 10077	INOblender, 800 ppm

Open Source Software

A CD-ROM is available upon request containing the full source code to the open source software used within this product.

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 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.**

Changing Cylinders

- **Only use manufacturer supplied drug cylinders, regulators and adapters (see Changing INOMAX Cylinders and Purging the Regulator Assembly, Section 3/ Patient Application).**
- **Cylinders should be stored between 59-86 degrees F (15-30 degrees C).**
- **Always secure a cylinder when not using it.**
- **Never lift a cylinder by its valve.**
- **Never drop a cylinder.**
- **Never use a hammer, pry or wedge to loosen a valve or protection cap. The valve and protection cap should be operated 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 attempt to repair a leaking 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 (52 degrees C).**
  - **where they can contact corrosive substances.**
  - **where they can be cut or abraded by an object.**
  - **next to a walkway, elevator or platform edge.**

WARNING:

Maintenance

- **Handle and dispose of sensors according to facility biohazard policies. Do not incinerate.**
- **If the MR injector module has been used in the wet/humidified part of the breathing circuit, it should be sterilized between each patient use.**
- **Do not use the RS 232 data output while in the MR scanner room.**
- **Use only RS 232 cables that are shielded (see Section 7/ Product Specifications for more detail).**
- **Keep the test magnet tool away from pacemakers, ICDs and other implanted medical devices.**

Manually Bagging a Patient with a MR Injector Module

- **Do not place the injector module in-line with a manual resuscitation bag.**

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 the INOmax DS_{IR} Plus MRI

- **All INOmax DS_{IR} Plus MRI devices must be purged before use to ensure the patient does not receive an excess level of NO_2.**
- **If the INOmax DS_{IR} Plus MRI is not going to be used on a patient within 10 minutes, depressurize the regulator supply line.**
- **If the INOmax DS_{IR} Plus MRI is not used and is pressurized for more than 10 minutes, repeat automated or manual purge procedure.**
- **If the INOmax DS_{IR} Plus MRI is depressurized and not used within 12 hours, repeat pre-use procedure.**

WARNING:

Troubleshooting or Calibrating

- **If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.**
- **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.**
- **Use caution when troubleshooting the INOmax DS_{IR} Plus MRI while in use for a patient. When possible, replace the unit in question and perform troubleshooting procedure once the unit is removed from the MR scanner room.**
- **Do not perform a high calibration procedure in the MR scanner room. Calibration equipment is a potential projectile hazard.**
- **Do not remove rear sensor cover in the MR scanner room due to potential projectile hazard.**
- **Do not change any sensor while delivering NO to a patient.**
- **Loss of communication between the INOmax DS_{IR} Plus MRI and the INOMAX cylinder for more than one hour will result in interruption of INOMAX delivery.**

Use in a MR Environment

- **A strong magnetic field such as that from an MRI system can affect the ability of the INOmeter to detect if the cylinder valve is open. This can cause a "Cylinder Valve Closed" alarm to occur when the cylinder valve is actually open. If this alarm occurs, reposition/rotate the INOmax DS_{IR} Plus MRI cart outside the 100 Gauss area to reduce the magnetic interference in the area of the INOmeter until the cylinder handle graphic on the display turns green. This will resolve the "Cylinder Valve Closed" alarm. Typically the required INOmax DS_{IR} Plus MRI cart location adjustment is less than 6 inches (15 cm) / 90 degrees. Note that Interruption of INOMAX therapy will occur one hour from point when the "Cylinder Valve Closed" alarm is activated if the alarm is not resolved.**
- **Only use a size "88" (1,963 liters) cylinder that is marked "MR Conditional. Keep cylinder at 100 gauss or less." with the INOmax DS_{IR} Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.**
- **The INOmax DS_{IR} Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.**
- **This device contains ferromagnetic components and hence will experience strong attraction close to the magnet. It should be operated at a fringe field of less than 100 gauss.**
- **Do not exceed 100 gauss; system operation may be impacted. Confirm cart auto-brake function. Optionally connect tether.**
- **Verify at least one gauss alarm is functioning properly prior to use.**
- **Do not use the INOmax DS_{IR} Plus MRI if neither gauss alarm is functional.**

WARNING:

Use in a MR Environment continued

- **The gauss alarm will sound if the INOmax DS_{IR} Plus MRI system is too close to the MR scanner. If alarm sounds, move system away from the MR scanner until the gauss alarm stops sounding.**
- **Always verify that the INOmax DS_{IR} Plus MRI auto-brake is engaged after positioning in the MR scanner room.**
- **Always verify that the INOmax DS_{IR} Plus MRI and INOblender are securely attached to the cart.**
- **Never attach an oxygen cylinder to the INOmax DS_{IR} Plus MRI cart.**
- **Arrange power cord, MR patient gas sample line, MR injector tubing and MR injector module cable to avoid entanglement, strangulation and/or a trip hazard.**
- **If the cart fails to move when the brake handle is pulled, or moves when the brake handle is not pulled, do not use the INOmax DS_{IR} Plus MRI and contact your local representative.**

Use Outside of Product Labeling

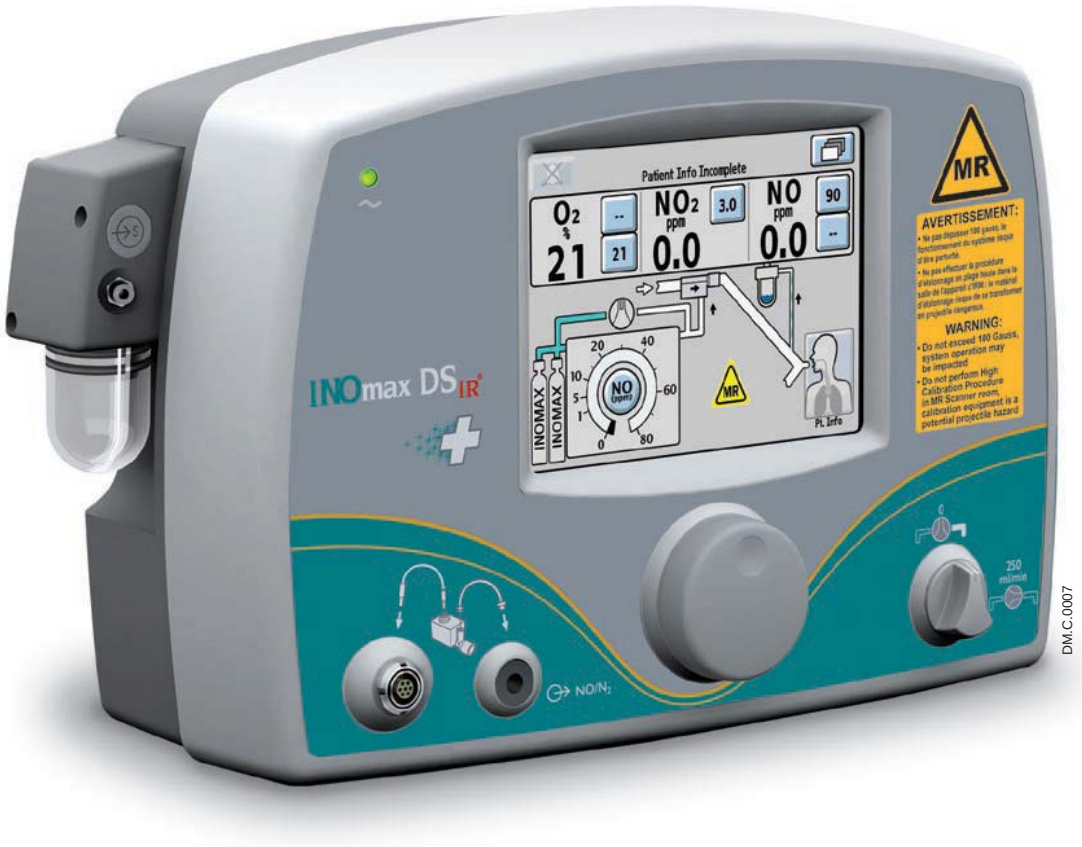
- **The INOmax DS_{IR} Plus MRI must only be used in accordance with the indications, usage, contraindications, warnings and precautions described in the INOMAX (nitric oxide) drug package inserts and labeling. Refer to this material prior to use.**
- **Outside of the United States, use of the INOmax DS_{IR} Plus MRI is limited to the use in accordance with INOMAX nitric oxide for inhalation prescribing information as established with the national health authority.**
- **Helium/oxygen mixtures should not be used with the INOmax DS_{IR} Plus MRI.**
- **The use of devices which radiate high-intensity electrical fields may affect the operation of the INOmax DS_{IR} Plus MRI. Constant surveillance of all monitoring and life support equipment is mandatory whenever interfering devices are in operation on or near a patient.**
- **The target patient population is controlled by the drug labeling for INOMAX and is currently neonates. The INOmax DS_{IR} Plus MRI is not intended to be used in other patient populations.**

Ventilators and Breathing Devices

- **The INOmax DS_{IR} Plus MRI 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} Plus MRI to the breathing circuit.**
- **Set the INOmax DS_{IR} Plus MRI 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 higher 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 minimize elevated NO_2 values.**
- **The patient gas sample tee must have the INOmax DS_{IR} Plus MRI sample line attached or be capped off to avoid loss of ventilator circuit pressure.**
- **Only use parts/accessories designated for use with this system.**

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI

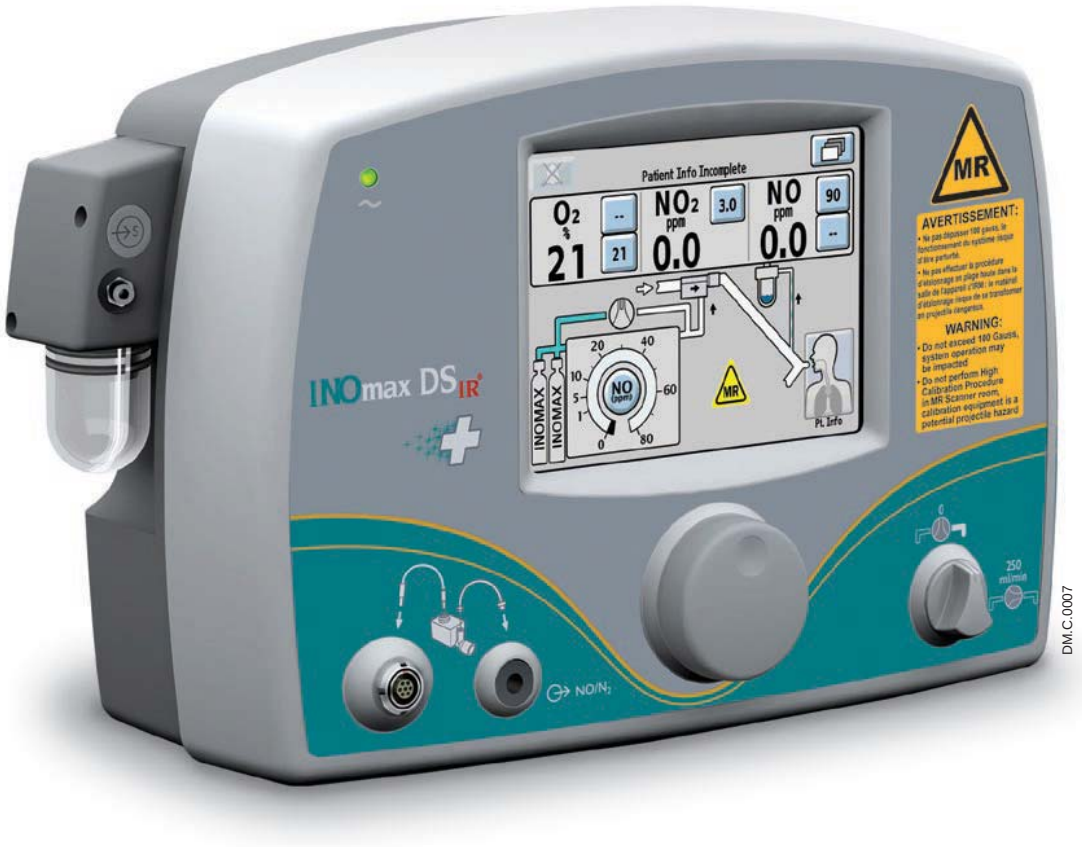


1/ General Information

Part No. 20765 Rev-01
2015-08

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



1/ General Information

Part No. 20765 Rev-01
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1/ General Information

Indications for Use

The INOmax DS_{IR} Plus MRI 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 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. The INOmax DS_{IR} Plus MRI is recommended for use only with MR conditional ventilators validated to be compatible, as identified in the device labeling.

The INOmax DS_{IR} Plus MRI provides continuous integrated monitoring of inspired O_2, NO_2, and NO, and a comprehensive alarm system.

The INOmax DS_{IR} Plus MRI incorporates a battery that provides up to 6 hours of uninterrupted NO delivery in the absence of an external power source.

The INOmax DS_{IR} Plus MRI includes a backup NO delivery capability that provides a fixed flow of 250 mL/min of NO which along with user supplied 10 L/min of oxygen provides 20 ppm in the gas flow to a patients breathing circuit. It may also use the INOblender for backup.

The INOmax DSI DS_{IR} R Plus MRI is classified as MR Conditional with the use of 1.5 Tesla and 3.0 Tesla static magnetic field scanners.

The target patient population is controlled by the drug labeling for INOMAX and is currently neonates. The primary targeted clinical setting is a clinical 1.5 Tesla and 3.0 Tesla diagnostic imaging environment.

Introduction to this Manual

Definitions and abbreviations

% v/v	% volume/volume.
Auto-brake	The mechanism which stops the INOmax DS_{IR} Plus MRI cart from rolling.
Auto-brake release	The yellow handle on the front of the INOmax DS_{IR} Plus MRI cart that, when engaged, allows the cart to roll.
Breathing circuit	Part of ventilator or breathing system that connects to the INOmax DS_{IR} Plus MRI.
Breathing system	Non-invasive breathing devices.
Control wheel	Rotary control used to change and confirm settings.
Cylinder	Aluminum cylinder containing INOMAX therapy gas.
INOblender®	Backup to the INOmax DS_{IR} Plus MRI. Allows manual ventilation of the patient, providing uninterrupted delivery of INOMAX.
INOMAX	NO (nitric oxide) for inhalation. Provided as a gas mixture of NO/N_2 in an aluminum cylinder at a concentration of 800 ppm. Drug is administered by the INOmax DS_{IR} Plus MRI.
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.
MRI	Magnetic Resonance Imaging.
MR Conditional	An item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
MR exclusion zone	Area in the MR scanner room where the magnetic field is greater than 100 gauss.
MR scanner	The MR device for diagnostic imaging.
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} Plus MRI pre-use checkout.
psig	Pounds per square inch gauge.
MR scanner bore	The MR scanner opening.
MR scanner room	The room where the MR scanner is located.
Set NO	The dose of INOMAX set by the user.
Tether attachment point	A metal loop on the INOmax DS_{IR} Plus MRI cart, where the user may fasten a tether to a secured point in the MR scanner room.

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

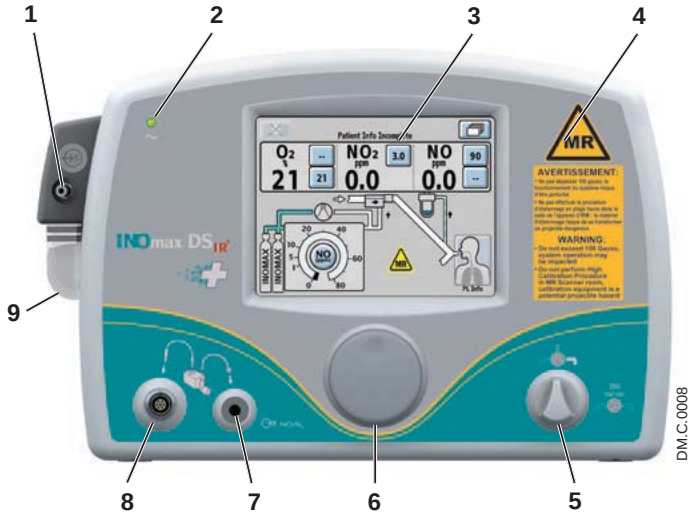

Figure 1-1 INOmax DS_{IR} Plus MRI Front View

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. MR Injector Module Tubing Outlet
8. MR Injector Module Cable Inlet
9. Water Bottle
10. Purge Port
11. INOMAX Gas Inlets
12. INOblender Gas Outlet
13. Ethernet Port
14. Infrared Connector
15. USB Port (disabled)
16. Water Separator Cartridge
17. Water Bottle
18. Sample Gas Outlet Port
19. Clamp Assembly
20. Electrical Cord Inlet
21. Equipotential Terminal
22. ON/Standby Switch
23. RS 232 Port

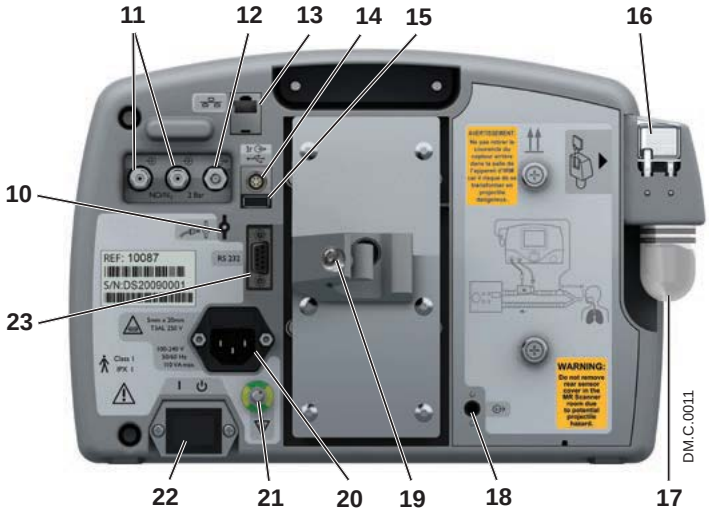

Figure 1-2 INOmax DS_{IR} Plus MRI Rear View

INOmax DS_{IR} Plus MRI Cart Operation

WARNING:

- **Always verify that the INOmax DS_{IR} Plus MRI auto-brake is engaged after positioning in the MR scanner room.**
- **Always verify that the INOmax DS_{IR} Plus MRI and INOblender are securely attached to the cart.**
- **Verify at least one gauss alarm is functioning properly prior to use. Do not use the INOmax DS_{IR} Plus MRI if neither gauss alarm is functional.**
- **The gauss alarm will sound if the INOmax DS_{IR} Plus MRI system is too close to the MR scanner. If alarm sounds, move system away from the MR scanner until the gauss alarm stops sounding.**
- **If the cart fails to move when the brake handle is pulled or moves when the brake handle is not pulled, do not use the INOmax DS_{IR} Plus MRI and contact your local representative.**

Note:

- The INOmax DS_{IR} Plus MRI cart provides an auto-brake to prevent inadvertent movement of the cart when in the scanner room.
- To move the INOmax DS_{IR} Plus MRI cart, pull up on the auto-brake handle, toward the cart handle.
- Two gauss alarms are attached to the cart and will sound if the cart is moved too close to the scanner bore.
- The tether attachment point allows for a facility supplied cable to be secured to the cart as a redundant means to limit the distance the cart can move.

Note: Pull the auto-brake handle up, toward the INOmax DS_{IR} Plus cart handle, to disengage the auto-brakes.

1. INOmax DS_{IR} Plus MRI
2. INOblender
3. Gauss Alarm (2) (see page 1-8)
4. Auto-brake Handle (see page 1-6)
5. Cylinder Mounting Strap
6. INOMAX Cylinder (2)
7. Auto-brake Caster (2)

Figure 1-3 INOmax DS_{IR} Plus MRI and Cart Front View

1. Auto-brake Handle
2. Gauss Alarm (2)
3. Auto-brake Caster (2)
4. INOmax DS_{IR} Plus MRI Mounting Bolt
5. INOblender MR Mounting Bolt
6. Tether Attachment Point

Figure 1-4 INOmax DS_{IR} Plus MRI and Cart Side View

Figure 1-5 INOmax DS_{IR} Plus MRI and Cart

WARNING: **Always verify that the INOmax DS_{IR} Plus MRI and INOblender are securely attached to the cart.**

1. INOmax DS_{IR} Plus MRI Mounting Assembly
2. INOMAX Regulator (2)
3. INOmeter
4. Gauss Alarm (2) (see page 1-8)
5. INOMAX Cylinder (2)
6. Tether Attachment Point

Figure 1-6 INOmax DS_{IR} Plus MRI and Cart Rear View

GaussAlert™ (gauss alarm)

WARNING: **Verify at least one gauss alarm is functioning properly prior to use. Do not use the INOmax DS_{IR} Plus MRI if neither gauss alarm is functional.**

GaussAlert Features:

The GaussAlert is designed to help keep the INOmax DS_{IR} Plus MRI outside of the MR exclusion zone. The GaussAlert is programmed to alarm when the preset magnetic field strength is exceeded. It produces a distinct audio alarm when the INOmax DS_{IR} Plus MRI is placed too close to the MR scanner bore.

- When the equipment to which GaussAlert is attached is exposed to a magnetic field strength greater than GaussAlert's set alarm threshold (100 gauss), a loud and piercing whoop tone will sound continuously as long as the unit remains in the exclusion zone.
- The alarm will cease when the INOmax DS_{IR} Plus MRI is moved away from the scanner bore to a location where the magnetic field strength is less than the alarm trip point (100 gauss).

Additional Information:

- The GaussAlert functionality should be checked monthly (see Section 6/Maintenance).
- Mallinckrodt will provide all maintenance for the GaussAlert.

Figure 1-7 GaussAlert Front View

1. Battery Indicator
2. Alarm Volume Adjustment
3. GaussAlert Side Bracket

Figure 1-8 GaussAlert Side View

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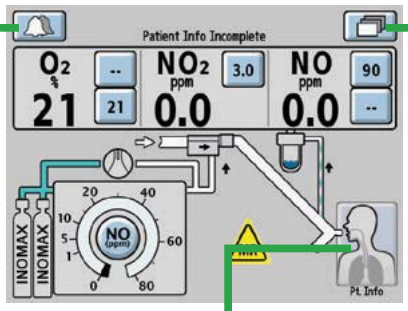
Navigating the Display Screens

Note: The specific level is identified by the highlighted card on the Menu Button.

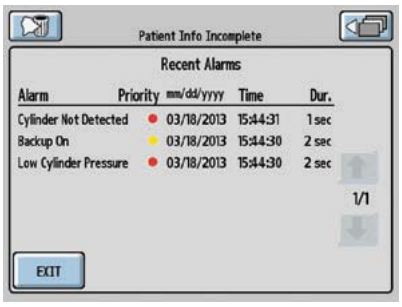

CS.S.0001

Main Screen (first level)



DM.S.0001

Recent Alarms Screen (second level)

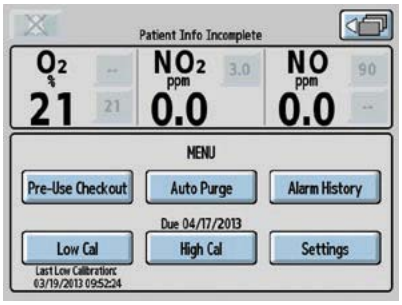


DM.S.0002

Patient Information Screen (second level)

DM.S.0003

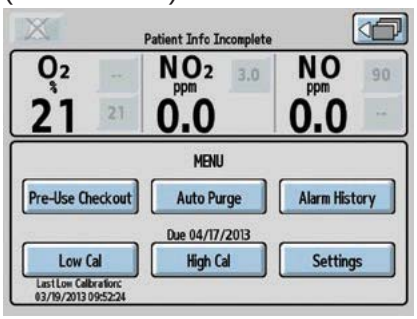
Menu Screen (second level)



DM.S.0004

Navigating the Menu Screen (see page 1-11)

Menu Screens
(second level)



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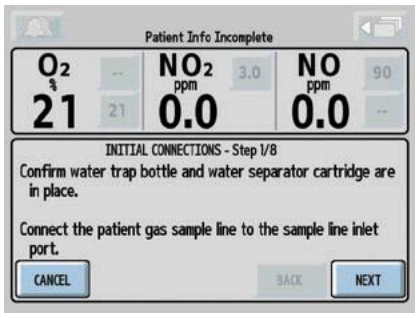
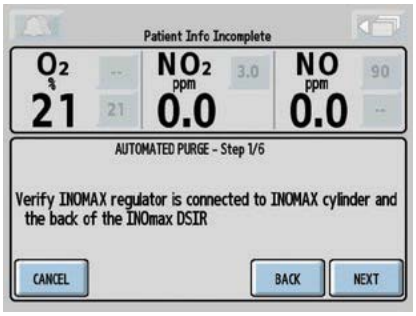


DM.S.0006

Pre-Use Checkout Wizard



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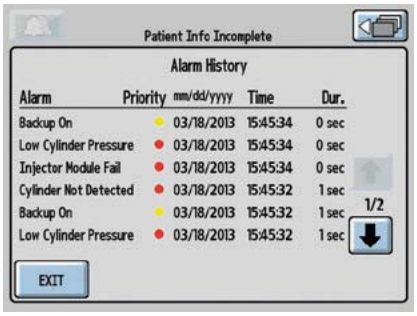
Automated Purge



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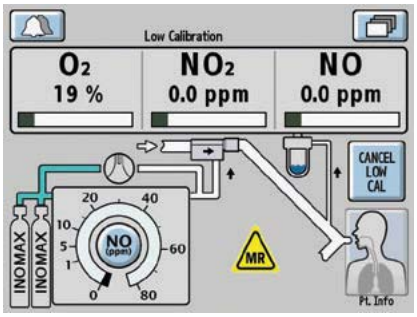
Alarm History



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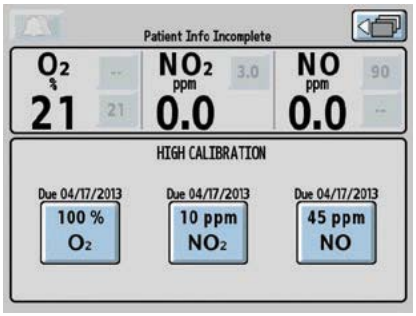
Low Calibration



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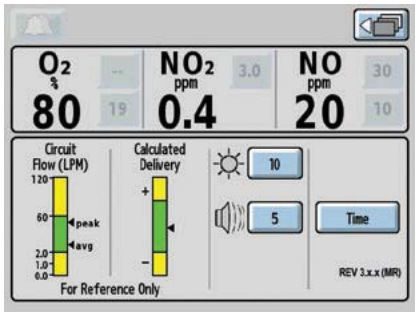
High Calibration



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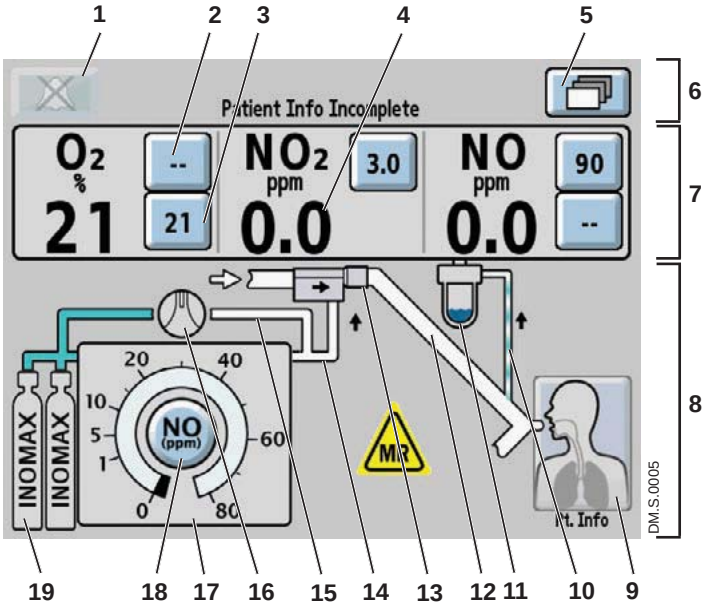
Settings

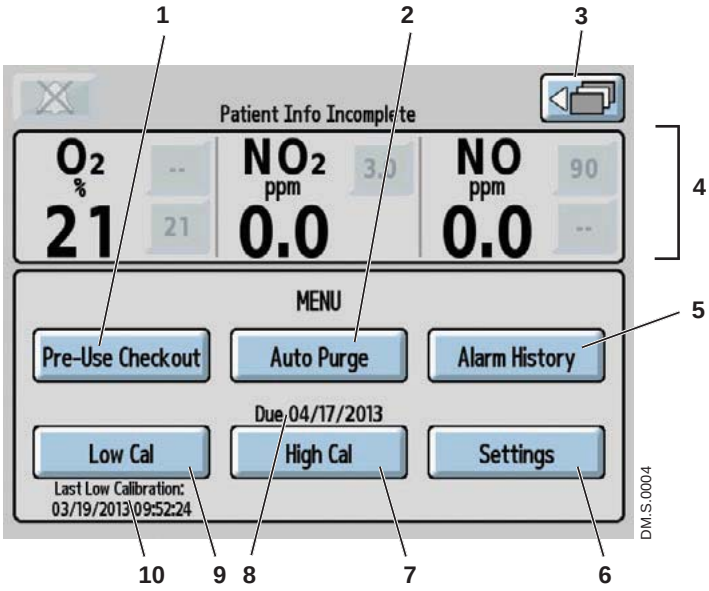


1. Alarm Silence Button
2. Upper Alarm Limit Button
3. Lower Alarm Limit Button
4. Monitored Value
5. Menu Button
6. Text Message Area
7. Monitor Area
8. Graphical Area
9. Patient Information Button
10. Sample Line Icon
11. Water Bottle Icon
12. Inspiratory Limb Icon
13. MR injector module Icon
14. Delivery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

Figure 1-9 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 1-10).



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

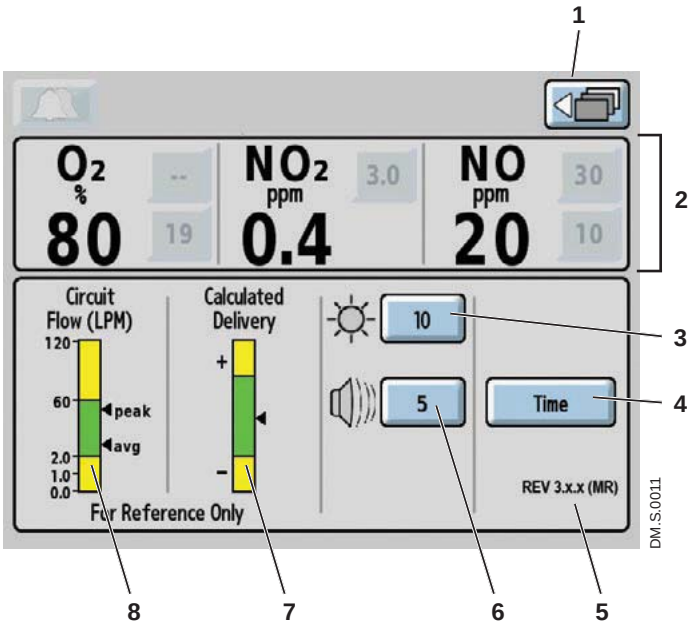
Figure 1-10 Menu Screen (second level)

Menu Screen (second level)

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

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 4/ Alarms).
- To initiate a low (room air) or high calibration, press either the Low Cal (#9) or High Cal (#7) buttons. (refer to Section 5/ 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 1-11).



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 1-11 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 MR injector module. The area in green represents the circuit flow range where the INOmax DS_{IR} Plus MRI system is rated to deliver NO from 1-80 ppm. (see maximum NO delivery graph page 1-29). Display graphic areas in yellow represents where some inaccuracy of NO delivery is to be expected.
- The calculated delivery graph displays the delivered dose as calculated by the delivery system. The system calculates the dose using the known variables of flow through the injector module, INOMAX cylinder concentration and set dose. The green zone represents that the delivered dose is within +/- 20% of the set dose, the yellow indicates a delivered dose greater (+) or less than (-) 20% of the set dose (see formula below).

Note: If the NO dose is not set, the Calculated Delivery graph will remain inactive.

Calculated Delivery Formula:
(NO flow / (NO flow + ventilator flow)) * cylinder concentration

Display and user controls

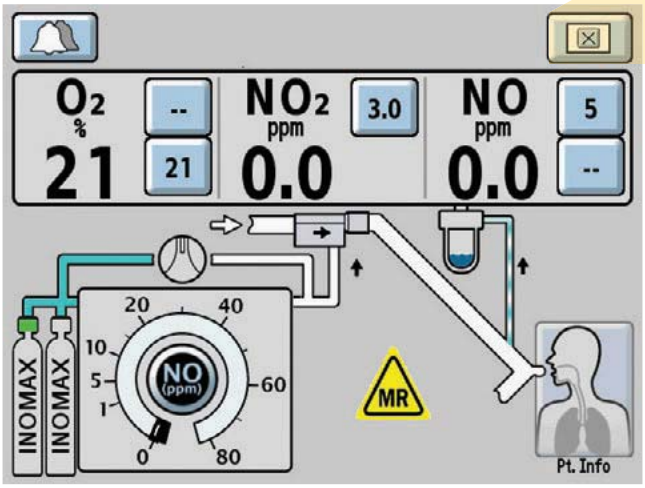
The INOmax DS_{IR} Plus MRI has a color touch screen display and a control wheel for adjusting and entering user settings. The buttons on the touch screen and the control wheel perform a variety of functions using a three-step procedure (see “Setting and making changes on the INOmax DS_{IR} Plus MRI”, page 1-16).

The touch screen buttons and control wheel are used to:

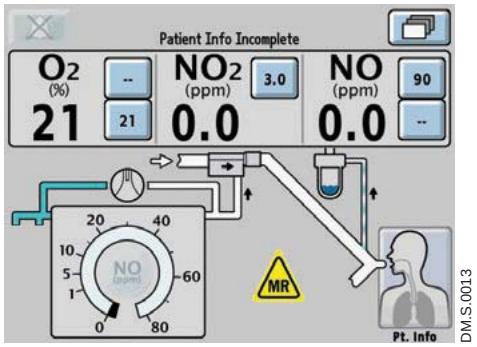
- Set the concentration of delivered NO
- Adjust alarm limits
- Silence alarms
- Calibrate the sensors
- Review alarm history
- Define setup options
- Enter patient information

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).

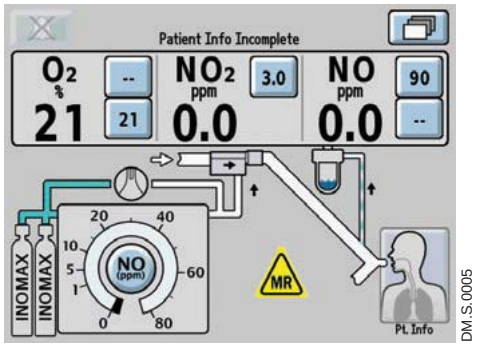


Main Screen

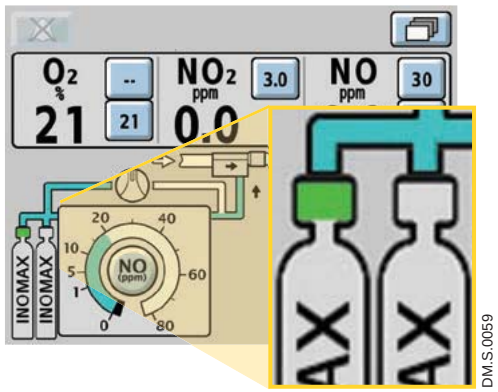
Cylinder icons are not visible and the NO delivery setpoint button will remain inactive until the INOmax DS_{IR} Plus MRI recognizes an INOMAX cylinder.

Caution:

High frequency and/or high intensity light emission, in the area of the INOmeter, may interfere with communication between the INOmax DS_{IR} Plus MRI and the INOmeter on the INOMAX cylinder (see Section 4/ Alarms and Troubleshooting).



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} Plus MRI.



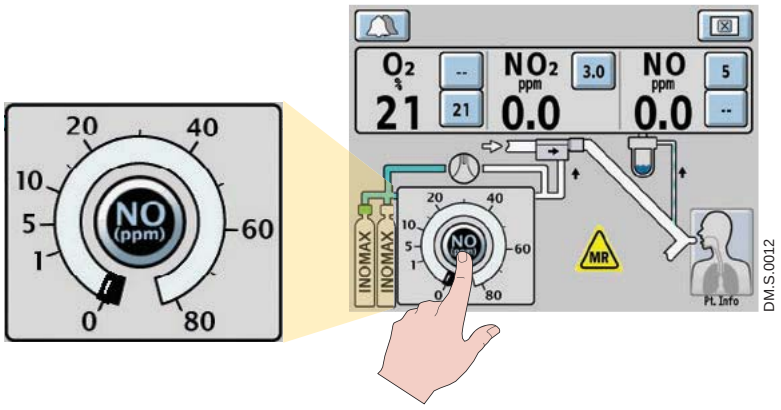
When an INOMAX cylinder valve is opened, the cylinder handle graphic will turn green representing an open INOMAX cylinder valve.

Setting and making changes on the INOmax DS_{IR} Plus MRI

Dose settings

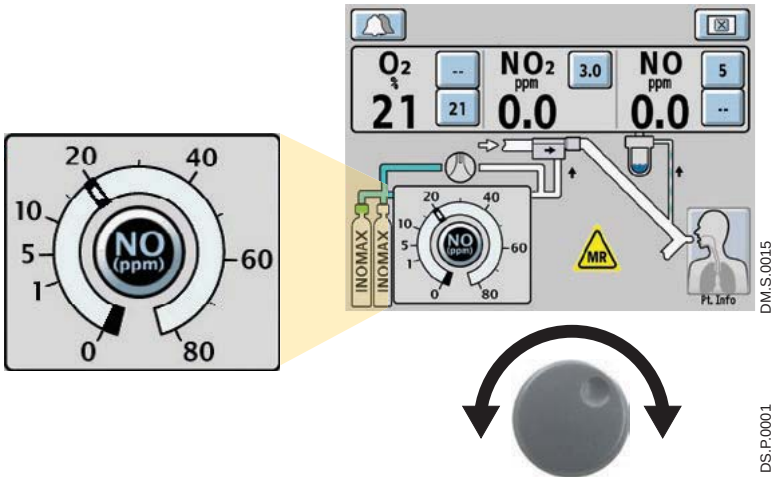
Displayed dose settings are 1, 5, 10, 20, 40, 60 and 80 ppm.

Adjusting Parameters (example: dose setting)

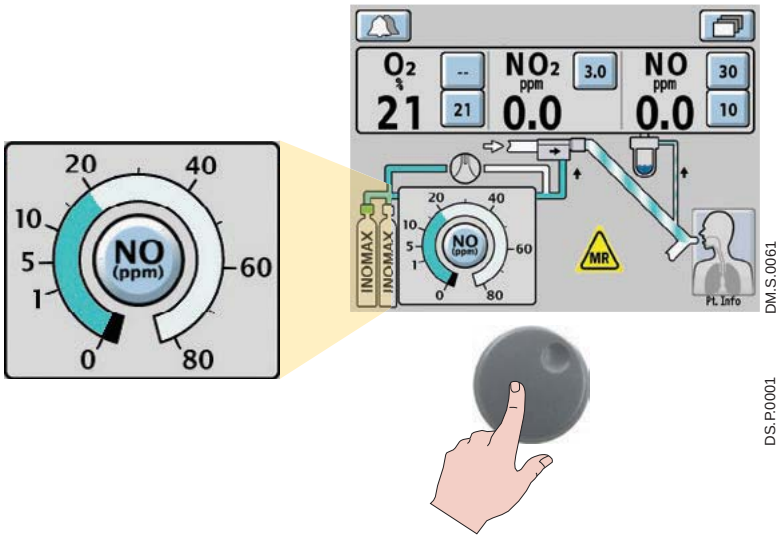


1. SELECT

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



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



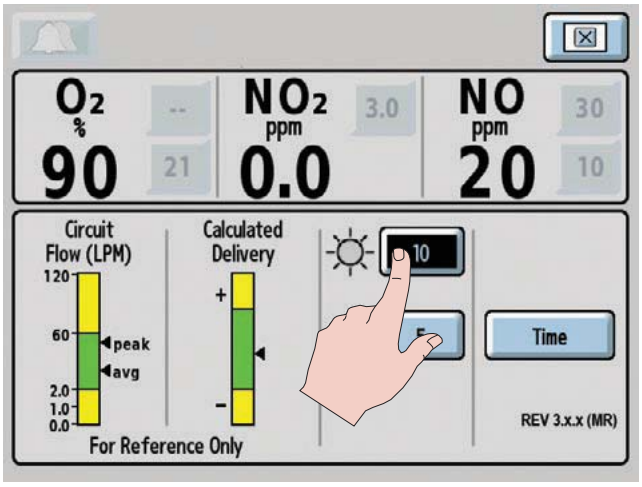
3. CONFIRM
the selection by pressing the control wheel or the button associated with the desired function again.

Caution: A two minute monitoring alarm delay will prevent the low NO monitoring alarm from occurring while the measured values stabilize.

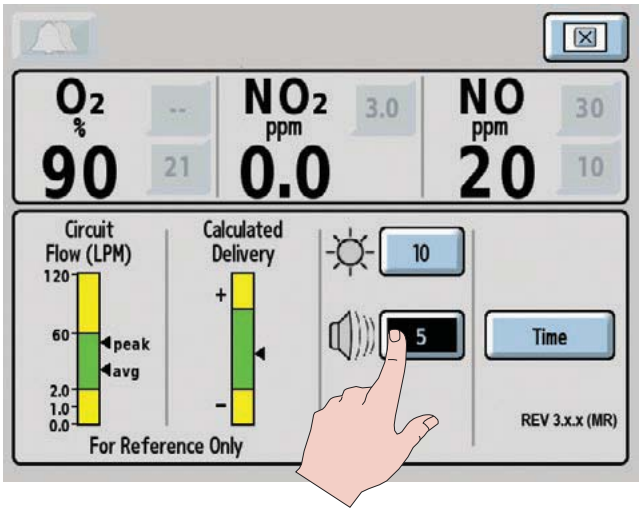
Note:

- After confirming a desired dose, the NO dose setting indicator will fill to the set dose, and the 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.

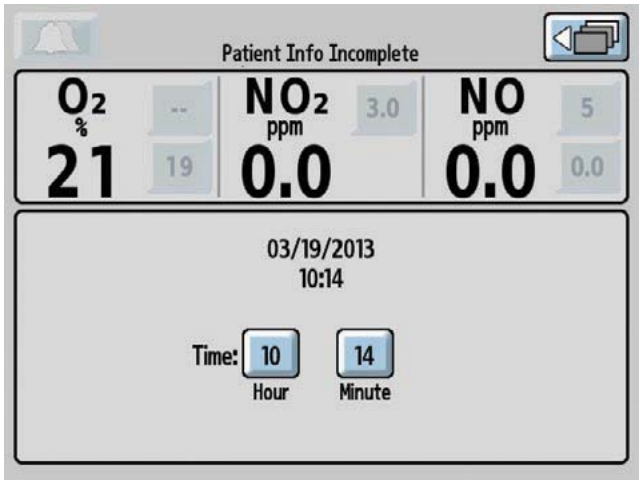
Settings Screen Adjustments



DM.S.0017



DM.S.0018



DM.S.0019

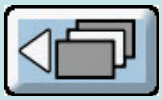
Access the settings screen (third menu level).

Display Brightness setting

1. Select the display brightness button on the touch screen.

CS.S.0003

2. Rotate the control wheel to indicate the display brightness level desired. Choices range from one (darkest) to 10 (brightest).
3. Confirm the selection by pressing the control wheel or the display brightness button again.
4. When finished with the menu screen, push the return to previous level button on the touch screen.

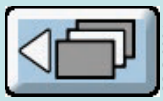

CS.S.0004

Alarm Volume setting

1. Select the alarm volume button on the touch screen.

CS.S.0005

2. Rotate the control wheel to indicate the volume level desired. Choices range from one (softest) to five (loudest).
3. Confirm the selection by pressing the control wheel or the alarm volume button again.
4. When finished with the menu screen push the return to previous level button on the touch screen.


CS.S.0004

Time Adjust setting

If the "Time" button is pressed the Time Adjust screen will appear.

CS.S.0006

1. Select the Hour or Minute button on the touch screen.
2. Rotate the control wheel to adjust the displayed hour or minute.
3. Confirm the selection by pressing the control wheel or the Hour or Minute buttons again.
4. When finished with the menu screen push the return to previous level button on the touch screen.


CS.S.0004

Note: Adjusting time on the INOmax DS_{IR} Plus MRI does not change the time recorded on the INOmeter. The INOmeter records events based on GMT time and remains separate from the INOmax DS_{IR} Plus MRI clock.

Infrared Communication between the INOMAX Cylinders and the INOmax DS$_{IR}$ Plus MRI

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

The INOmax DS$_{IR}$ Plus MRI has an interface using infrared (IR) technology which allows the INOmax DS$_{IR}$ Plus MRI to communicate with the INOmeter (which is mounted to each INOMAX cylinder). The INOmax DS$_{IR}$ Plus MRI checks the INOMAX cylinder for the correct expiration date and cylinder concentration. The INOmax DS$_{IR}$ Plus MRI also transmits a confirmed patient identifier to the INOmeter on any open INOMAX cylinder.

The INOmax DS$_{IR}$ Plus MRI cart (PN 10076) has a cover (see Figure 1-12, 1) with an infrared transceiver mounted directly above each INOMAX cylinder. When INOMAX cylinders are loaded, communication will take place between the INOmax DS$_{IR}$ Plus MRI and the INOmeter (see Figure 1-12, 2) after the boot up phase of the INOmax DS$_{IR}$ Plus MRI is complete. A cylinder icon will be displayed on the main screen when an INOMAX cylinder is recognized by the INOmax DS$_{IR}$ Plus MRI (see “Loading INOMAX Cylinders onto the INOmax DS$_{IR}$ Plus MRI Cart”, page 1-21).

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

Magnetic Interference

WARNING: **A strong magnetic field such as that from an MRI system can affect the ability of the INOmeter to detect if the cylinder valve is open. This can cause a “Cylinder Valve Closed” alarm to occur when the cylinder valve is actually open. If this alarm occurs, reposition/rotate the INOmax DS$_{IR}$ Plus MRI cart outside the 100 Gauss area to reduce the magnetic interference in the area of the INOmeter until the cylinder handle graphic on the display turns green. This will resolve the “Cylinder Valve Closed” alarm. Typically the required INOmax DS$_{IR}$ Plus MRI cart location adjustment is less than 6 inches (15 cm) / 90 degrees. Note that Interruption of INOMAX therapy will occur one hour from point when the “Cylinder Valve Closed” alarm is activated if the alarm is not resolved.**

Communication Interference

The INOmax DS$_{IR}$ Plus MRI transceiver is located under the cart cover and should be protected from outside interference. The INOmax DS$_{IR}$ Plus MRI cart was designed to protect the INOmeter from external light/IR energy sources. The INOmax DS$_{IR}$ Plus MRI transceiver transmits via a 30 degree transmission cone projecting towards the floor (see dotted lines in Figure 1-12). The specifications of the IR beam call for it to have a range of 20 cm (7.9 in). Based on these specifications it should not affect other devices in the vicinity of the INOmax DS$_{IR}$ Plus MRI.

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

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} Plus MRI and the INOmeter on the INOMAX cylinder.

If there is interference with the INOmax DS_{IR} Plus MRI/INOmeter communication, the cylinder icon on the user screen will not be displayed and a "Cylinder Valve Closed" or “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} Plus MRI cart, could affect INOmeter communications.

If external light interference occurs, we recommend taking the following action:

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

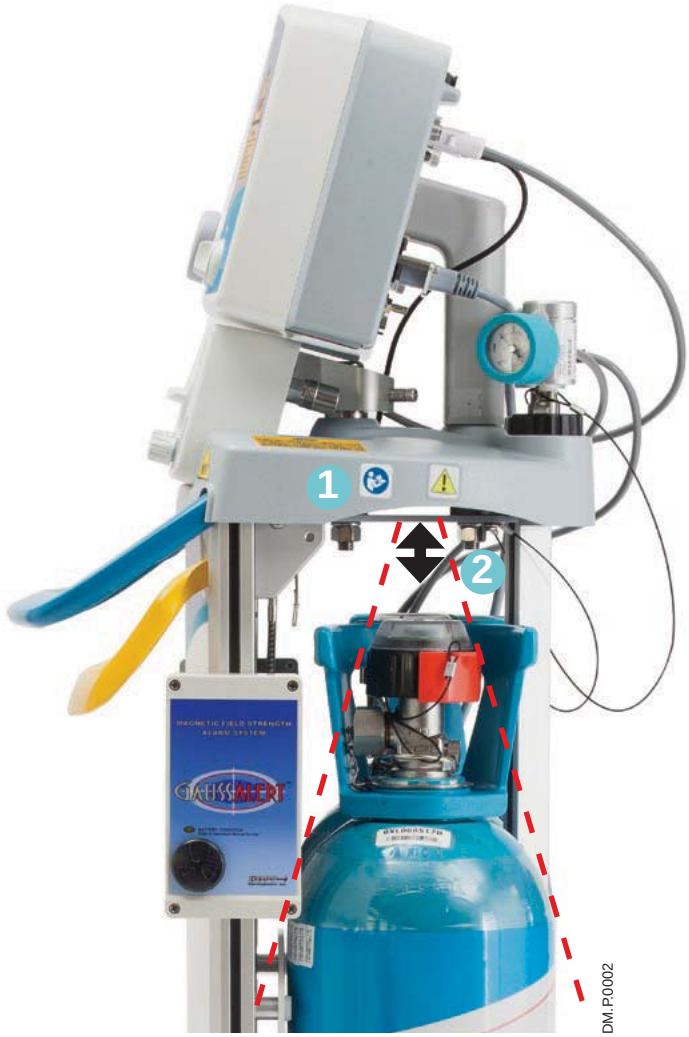
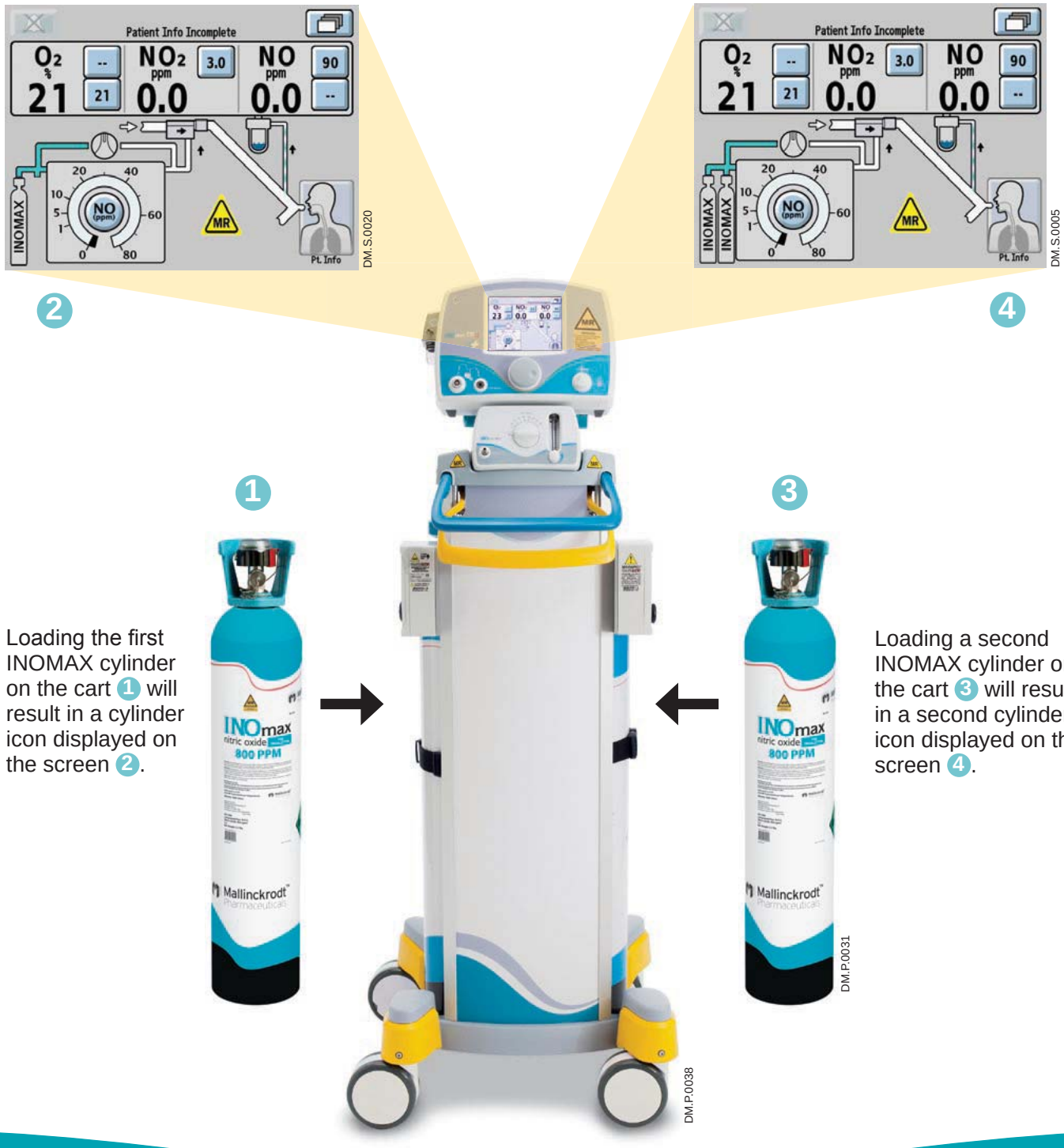


Figure 1-12

Loading INOMAX Cylinders Onto the INOmax DS_{IR} Plus MRI Cart

Note:

- The INOmax DS_{IR} Plus MRI checks INOMAX cylinders for the correct product identity, cylinder concentration and expiration date.
- The INOmax DS_{IR} Plus MRI recognizes the drug as expired on the first day of labeled expiration month on the INOMAX cylinder.



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

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

INOmeter Operation

- The INOmeter is a time-metric device which records the amount of time the INOMAX cylinder valve is opened.
- When used with INOmax DS_{IR} Plus MRI, two-way infrared (IR) communication occurs between the INOmax DS_{IR} Plus MRI and the INOmeter. The INOmeter communicates the INOMAX cylinder concentration and the expiration date to the INOmax DS_{IR} Plus MRI. Patient ID (when confirmed) and dose information are communicated from the INOmax DS_{IR} Plus MRI to the INOmeter.

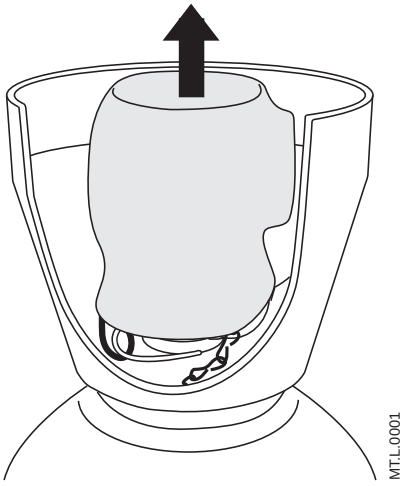


Figure 1-13

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 1-13).

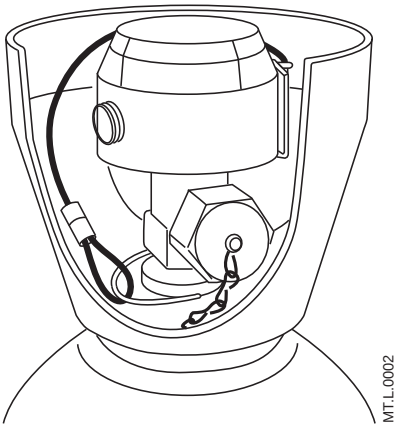


Figure 1-14

2. The lock is secured to the cylinder by a lanyard (see Figure 1-14).

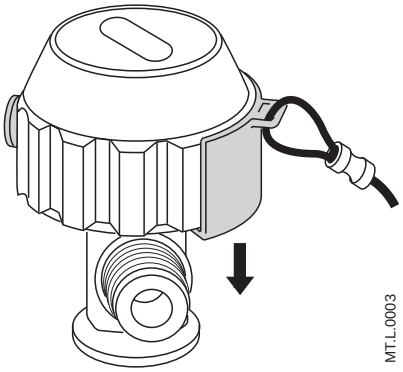


Figure 1-15

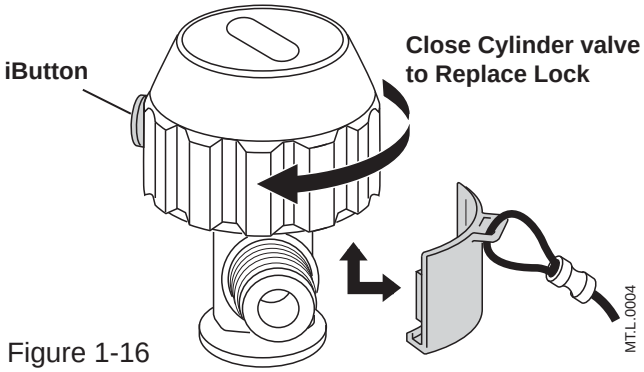


Figure 1-16

3. Press lock downward to remove from the INOmeter (see Figure 1-15).
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 1-16).

Note:

- The INOmeter is used to open and close the cylinder valve.
- Counter-clockwise rotation of the device serves to open the cylinder valve (see Figure 1-17).
- Clockwise rotation acts to close the cylinder valve (see Figure 1-18).

Figure 1-17 Cylinder Open

5. When the INOmeter is turned ON (cylinder open) the display will show a "+" (positive) sign (see Figure 1-17) 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.

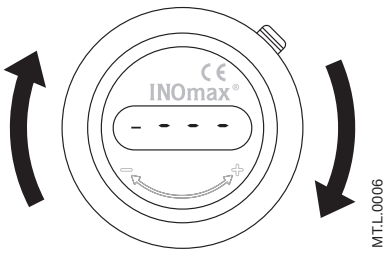


Figure 1-18 Cylinder Closed

6. When the INOmeter is turned OFF (cylinder closed) the display will show a "-" (negative) sign (see Figure 1-18) 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.

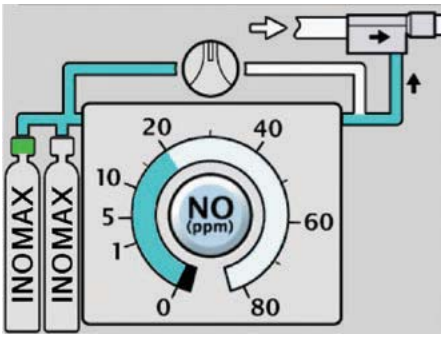


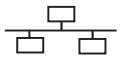
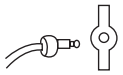
Figure 1-19

When the cylinder valve is open and delivery is normal, the main screen shows the handle as green (see Figure 1-19).

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 magnetic or light interference is suspected (see Section 4/ Alarms and Troubleshooting). If there is no magnetic or 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
134˚C	Autoclavable
avg	Average Flow Rate
	Calculated Dose Greater than 20% of the Set Dose
	Calculated Dose Less than 20% of the Set Dose
EC REP	CE European Representative
CE	CE Mark
	Do Not Push
EHR	Electronic Health Record
	Equipotential Stud
	Ethernet Port
	Fuse Rating
Ir 	Infrared Input/Output
	Keep Dry
LOT	Lot Number
Low Cal	Low Range Calibration
	Magnetic Resonance Conditional
	Main Power Connected
MAX	Maximum
	MR injector module
	NO Backup OFF
	NO Backup ON
	NO Gas Inlet
	NO Gas Outlet
	On
peak	Peak Flow Rate
	Pneumatic Inlet
	Pneumatic Outlet
Rx ONLY	Prescription use only
	Purge Location
	Refer to Instructions
	Running on Battery
	Sample Gas Inlet Port
	Sample Gas Outlet Port
	Separate Collection
SN	Serial Number
	Standby
REF	Stock Number
	Type B Electrical Equipment
	Use by yyyy-mm
	USB Port
	Water Separator Cartridge

Theory of Operation

The INOmax DS_{IR} Plus MRI provides a constant dose of INOMAX into the inspiratory limb of the ventilator circuit. The INOmax DS_{IR} Plus MRI uses a “dual-channel” design to provide delivery of INOMAX. The first channel has the delivery CPU, the flow controller and the MR 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 be interrupted should the monitored NO concentration become greater than 100 ppm for greater than 12 consecutive seconds. (See Figure 1-20 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} Plus MRI using one of the two NO/N_2 quick connect inlets on the back of the device.
3. The INOmax DS_{IR} Plus MRI checks the INOMAX cylinder for the correct expiration date and cylinder concentration.
4. The INOMAX enters the back of the INOmax DS_{IR} Plus MRI, passes through a filter, then a safety shutoff valve, which is open under normal operation.
5. A MR 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 MR injector module where it mixes with the breathing circuit gas flow to achieve the set dose. This allows the INOmax DS_{IR} Plus MRI to deliver a constant dose of INOMAX regardless of the ventilator flow pattern or breath rate (see Figure 1-21).
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 MR 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} Plus MRI 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 bottle, 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 - The INOmax DS_{IR} Plus MRI has an integrated pneumatic backup system that will supply a fixed flow of INOMAX at 250 mL per minute into the injector module. This system is completely pneumatic and does not rely on electronic control or power. The system will not allow a dose to be set on the INOmax DS_{IR} Plus MRI if the integrated pnuematic backup is in use.

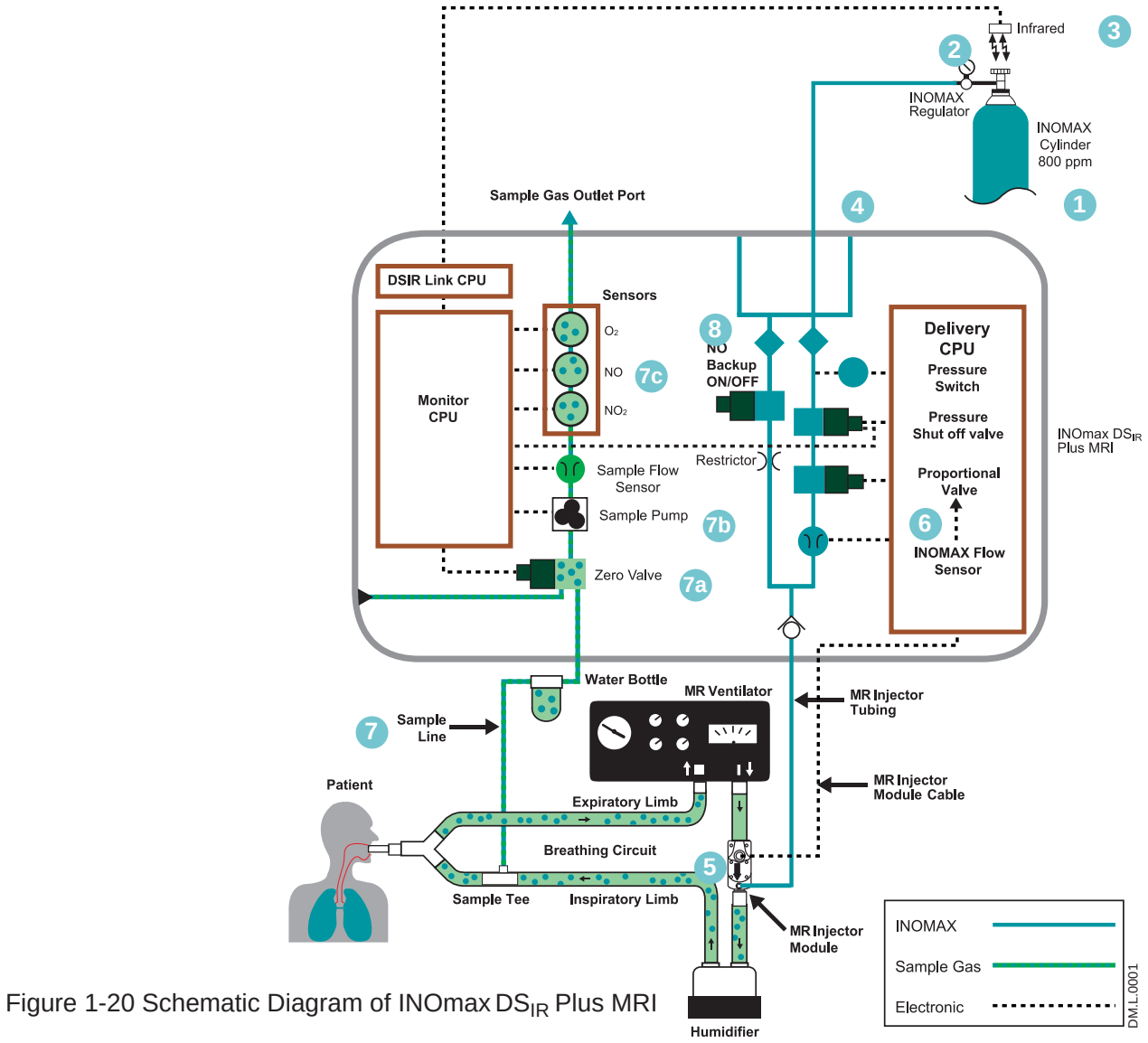


Figure 1-20 Schematic Diagram of INOmax DS_{IR} Plus MRI

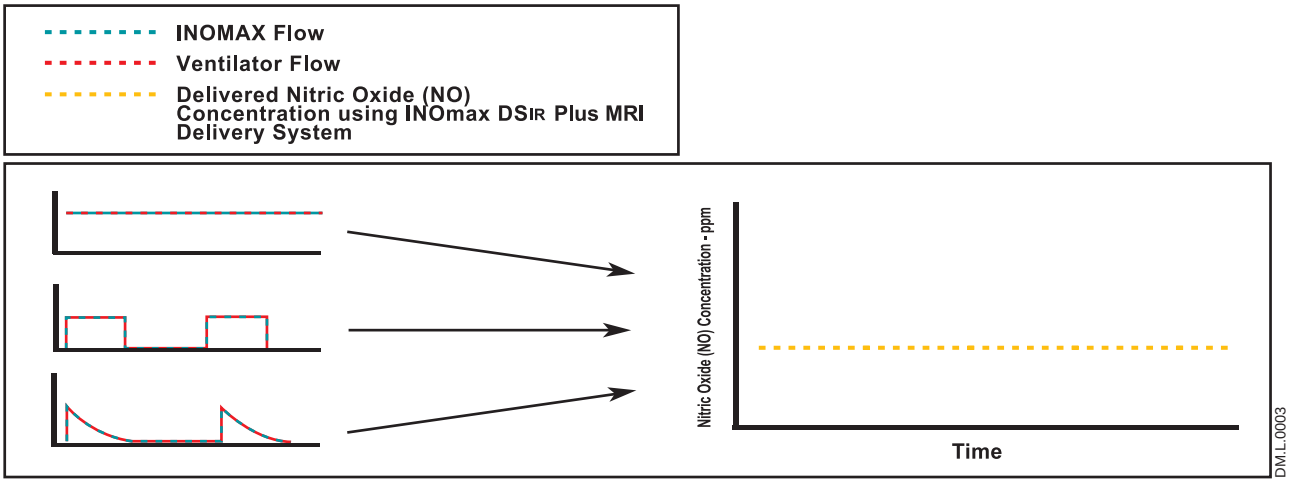


Figure 1-21 INOMAX injection method provides a constant NO concentration

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

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

1. The INOmax DS_{IR} Plus MRI 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} Plus MRI adds 2.5% more gas to that delivered by the ventilator and proportionally less for lower NO settings.
2. The INOmax DS_{IR} Plus MRI 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} Plus MRI 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} Plus MRI, 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} Plus MRI 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:

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

For a dose of 20 ppm (800 ppm cylinder) the additional volume would be
(20 X 10) ÷ (800 – 20) = 0.26 L/min

To calculate the net change in minute volume:
0.26 L/min INOMAX added - 0.23 L/min removed (sample system) = 0.03 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} Plus MRI 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} Plus MRI delivery system.

Circle Anesthesia Ventilator Systems

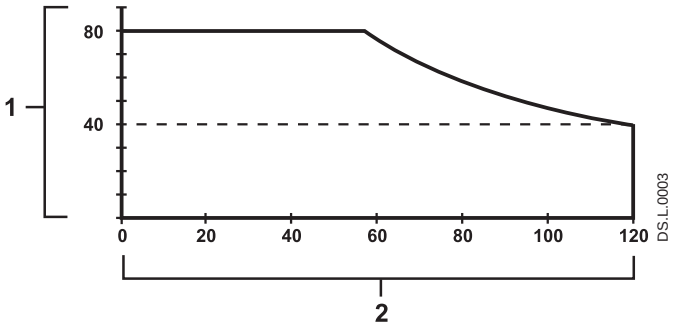
The use of the INOmax DS_{IR} Plus MRI with circle anesthesia ventilator systems (which use volume ventilation causes small changes in the delivered minute volume as noted previously (see Minute Volume, page 1-28).

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

Recirculation of gases may lead to a rapid increase in INOMAX dose levels creating a shutdown of the INOmax DS_{IR} Plus MRI. 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} Plus MRI is limited to a maximum NO flow of 6.35 L/min. Maximum deliverable dose is 80 ppm (800 ppm cylinders) when the breathing gas flow is 60 lpm or less. Breathing gas flows greater than 60 L/min. will reduce the delivered dose (resulting in a lower monitored NO value). See the graph below for estimated dosing based on breathing gas circuit flow rate.



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} Plus MRI 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 theoretical 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 MRI

2/ Automated Pre-Use Checkout

Part No. 20765 Rev-01
2015-08

Mallinckrodt™ Pharmaceuticals

Automated Pre-Use Checkout

INOmax DS$_{IR}$® Plus MRI

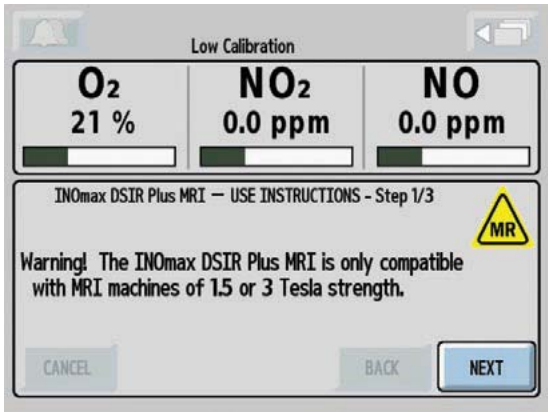
2/ Automated Pre-Use Checkout

Part No. 20765 Rev-01
2015-08

2/ Automated Pre-Use Checkout

Connect the INOmax DS$_{IR}$ Plus MRI power cord to a hospital-grade AC outlet. The power cord must always be connected to an electrical outlet to maintain a full battery charge.

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



DM.S.0021

1. Turn ON INOmax DS$_{IR}$ Plus MRI.

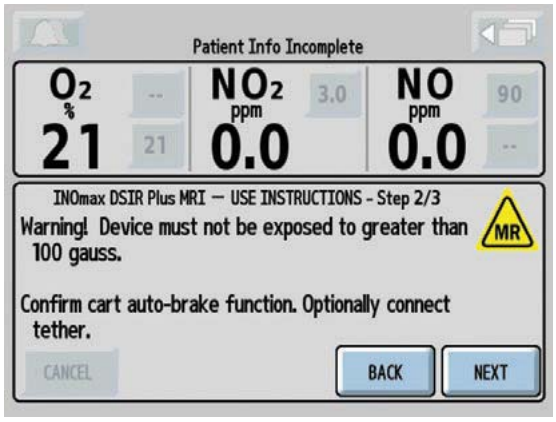
An INOmax DS$_{IR}$ Plus MRI splash screen will appear once the device is turned ON followed by the speaker sounding.

Note: Low calibration automatically starts following the INOmax DS$_{IR}$ Plus MRI self test.

2. Press the NEXT button to review the warnings (steps 1 to 3).

WARNING:

- **The INOmax DS$_{IR}$ Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.**
- **Do not exceed 100 Gauss; system operation may be impacted.**
- **Confirm cart auto-brake function. Optionally connect tether.**



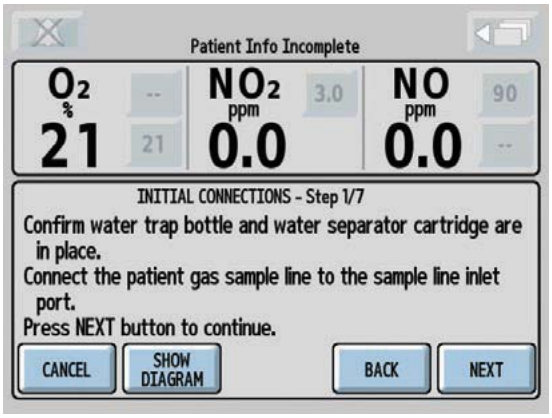
DM.S.0022

3. Test the auto-brake.

Note: Pull the yellow brake handle up, the INOmax DS$_{IR}$ Plus MRI cart should now move freely. Release the handle, the cart should not move when pushed. If the cart fails to move or moves when the brake handle is not pulled, contact your local representative.

WARNING:

- **If the cart fails to move when the brake handle is pulled, or moves when the brake handle is not pulled, do not use the INOmax DS$_{IR}$ Plus MRI and contact your local representative.**



4. 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 8/ Appendix.

Initial connections

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

1. Confirm the water 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} Plus MRI 1b.

Check cables and hoses for signs of wear and damage.

2. Insert the injector module cable into the INOmax DS_{IR} Plus MRI and the injector module, lining up the red dots on both ends 2a.
3. Connect the injector tubing to the INOmax DS_{IR} Plus MRI and the injector module 3.

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 MR injector module prior to initial setup.
- To remove this type of connector, the knurled sleeve 2b on the connector must be pulled outward before removing the connector from the MR injector module or the front panel.

DS.P.0007

4. Verify the power supply indicator is illuminated 4.

DM.P.0031

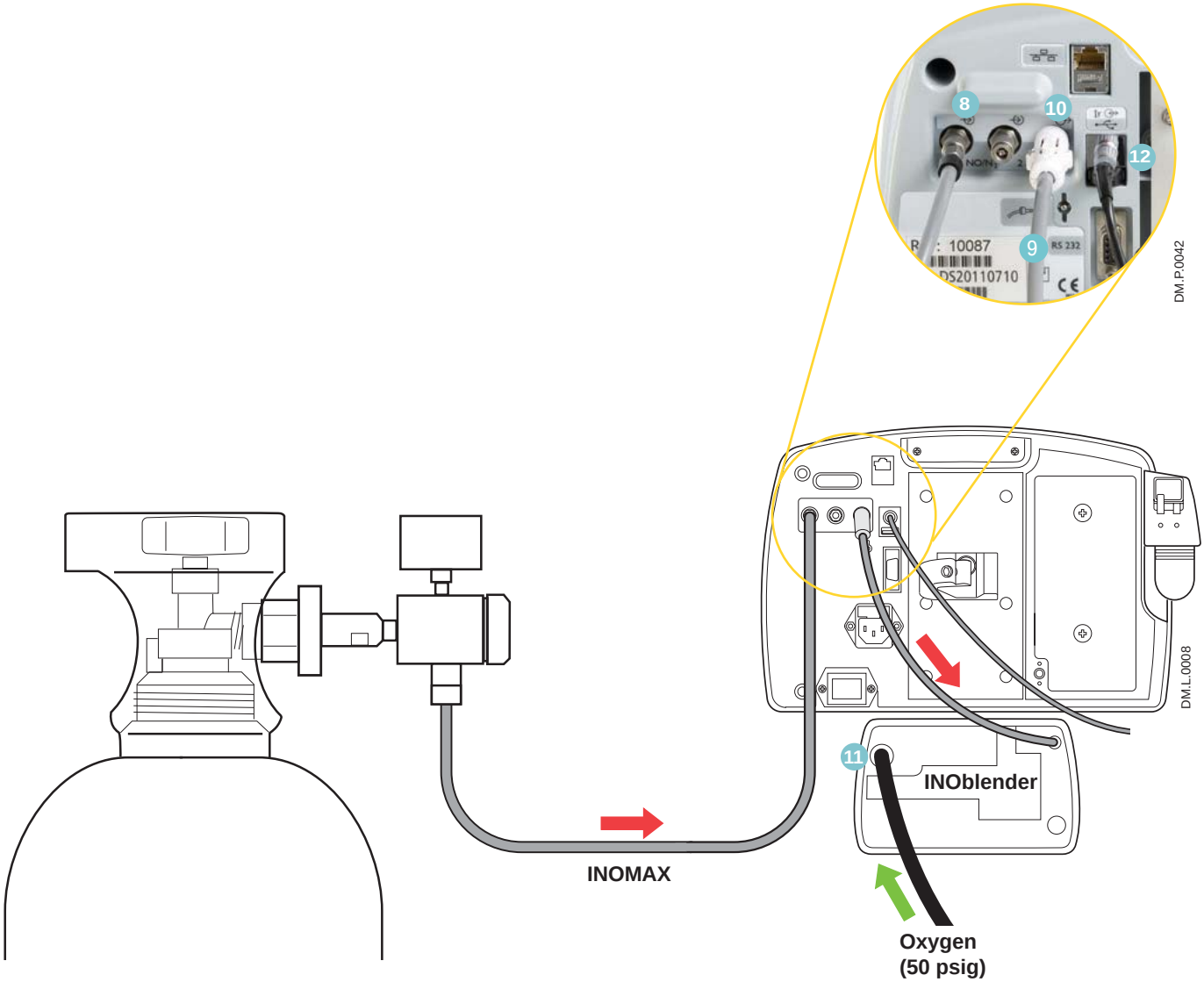
5. Load two INOMAX drug cylinders onto cart and check for correct product identity labels, cylinder concentration (800 ppm) and expiration date.

RG.P.0001

RG.P.0002

6. Ensure the white plastic tip is not damaged. Replace if necessary. (see Replacing the tip on the INOMAX regulator, Section 6/ Maintenance).
7. Connect an INOMAX regulator to one of the INOMAX cylinders, and hand tighten the fitting to the INOMAX cylinder.

8. Connect the INOMAX regulator hose to one of the INOMAX inlets (8).
9. Connect the INOblender inlet hose to the INOmax DS_{IR} Plus MRI INOblender outlet (9).
10. Slide the quick-connect cover into place (10).
11. Connect to a 50 psig oxygen supply hose to O_2 inlet fitting on back of INOblender (11).
12. Connect the Infrared cable from the INOmax DS_{IR} Plus MRI cart to the back of the INOmax DS_{IR} Plus MRI (12).

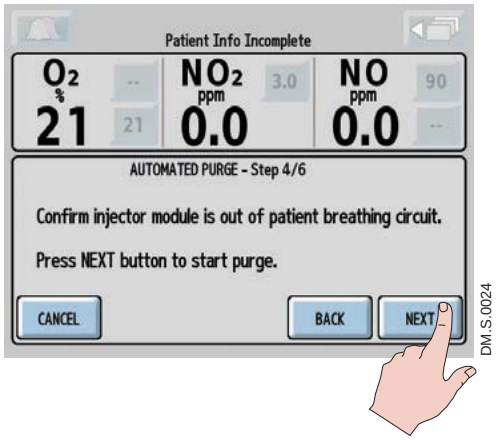


High Pressure Leak Test and Automated Purge

WARNING: **All INOmax DS_{IR} Plus MRI devices must be purged before use to ensure the patient does not receive an excess level of NO_2.**


RG.P.0003

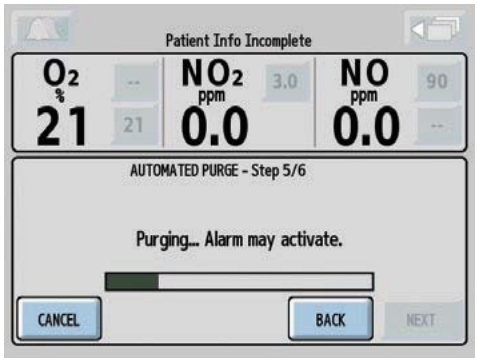
1. Verify one of the high pressure regulators is connected to an INOMAX cylinder.
2. Open and then close the cylinder valve. Verify cylinder has at least 500 psig.
3. Monitor pressure gauge for 30 seconds for any signs of pressure decrease. If no pressure decrease is observed, the high pressure leak test is successful. If there is an observed pressure decrease, see Section 6/ Maintenance; Cylinder Leak Check.



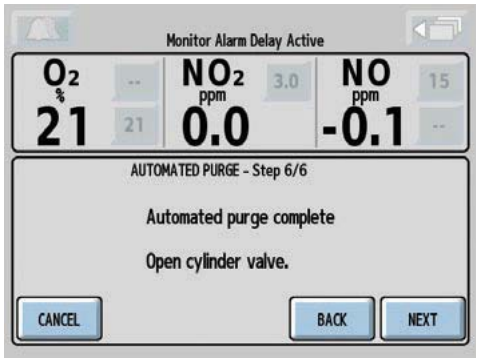
DM.S.0024

4. Confirm MR injector module is out of the pre-use circuit. Press NEXT button to start purge process.

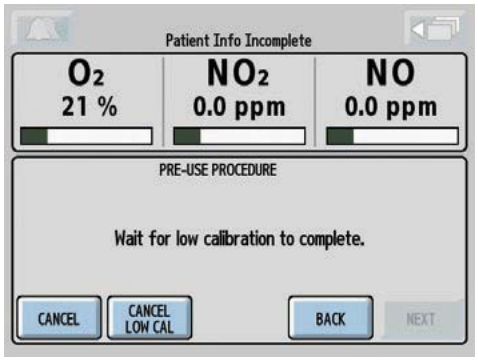
Note: Perform auto-purge with device plugged into AC power. Failure to do so may result in the procedure not completing.



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

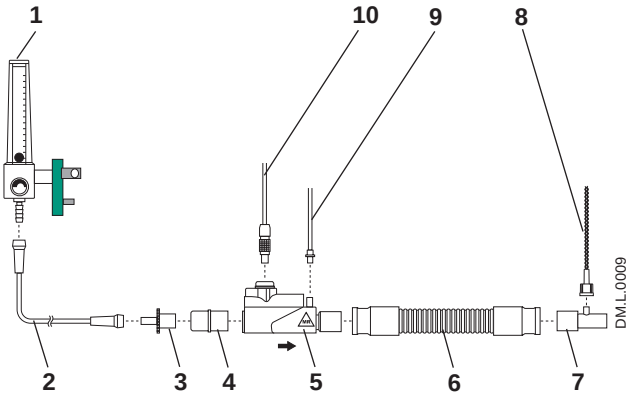


6. Open cylinder valve when purge is completed.



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. O_2 Tubing
3. 15M x 4.5 mm Adapter
4. 22M / 15F x 22M / 15F Adapter
5. MR Injector Module
6. 300 mm of 22 mm Hose
7. Gas Sample Tee
8. MR Patient Gas Sample Line with Nafion
9. MR NO/N_2 Injector Tube
10. MR Injector Module Electrical Cable

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 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

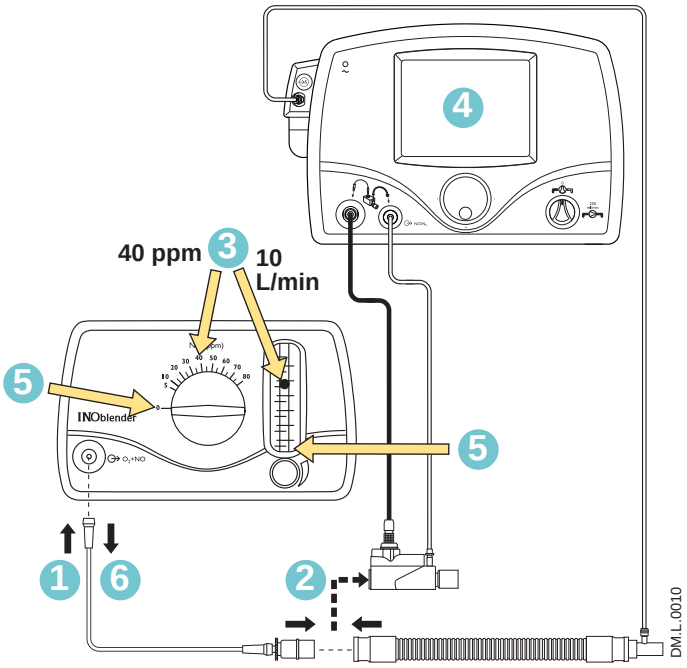
1. Using the pre-use set-up connectors, verify that the O_2 flowmeter is set to 10 L/min.
2. Press NEXT button to automatically set the INOMAX dose to 40 ppm.
3. Allow monitored values to stabilize (may take up to 3 minutes).

   Verify the NO, NO_2 and FiO_2 readings are within the ranges in the performance test table.
4. Performance test is complete.

   Press NEXT button to set the INOMAX dose to zero.

Note: If a monitored value is outside the range indicated, see Section 4/ Alarms and Troubleshooting Help.

INOblender Test



1. Remove oxygen tubing from O_2 flowmeter and connect to front of INOblender.
2. Remove the MR 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. Allow monitored values to stabilize (may take up to 3 minutes) and verify the NO value on the INOmax DS_{IR} Plus MRI using the table below:
5. Turn the dose and oxygen flow to zero.
6. 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} Plus MRI 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} Plus MRI is not used and is pressurized for more than 10 minutes, repeat automated or manual purge procedure.**
- **If the INOmax DS_{IR} Plus MRI is depressurized and not used within 12 hours, repeat pre-use procedure.**

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

Depressurizing the Regulator Supply Line


RG.P.0004

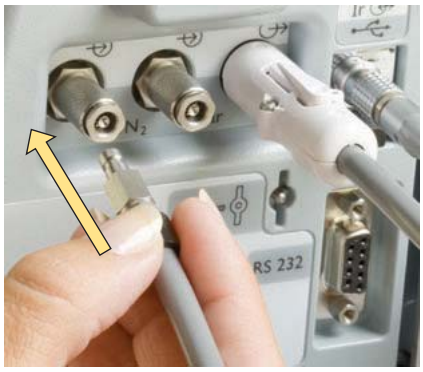
To depressurize the INOMAX regulator supply line:

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

DM.P.0043

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

   This depressurizes the regulator.



DM.P.0034

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 Section 6/Maintenance.

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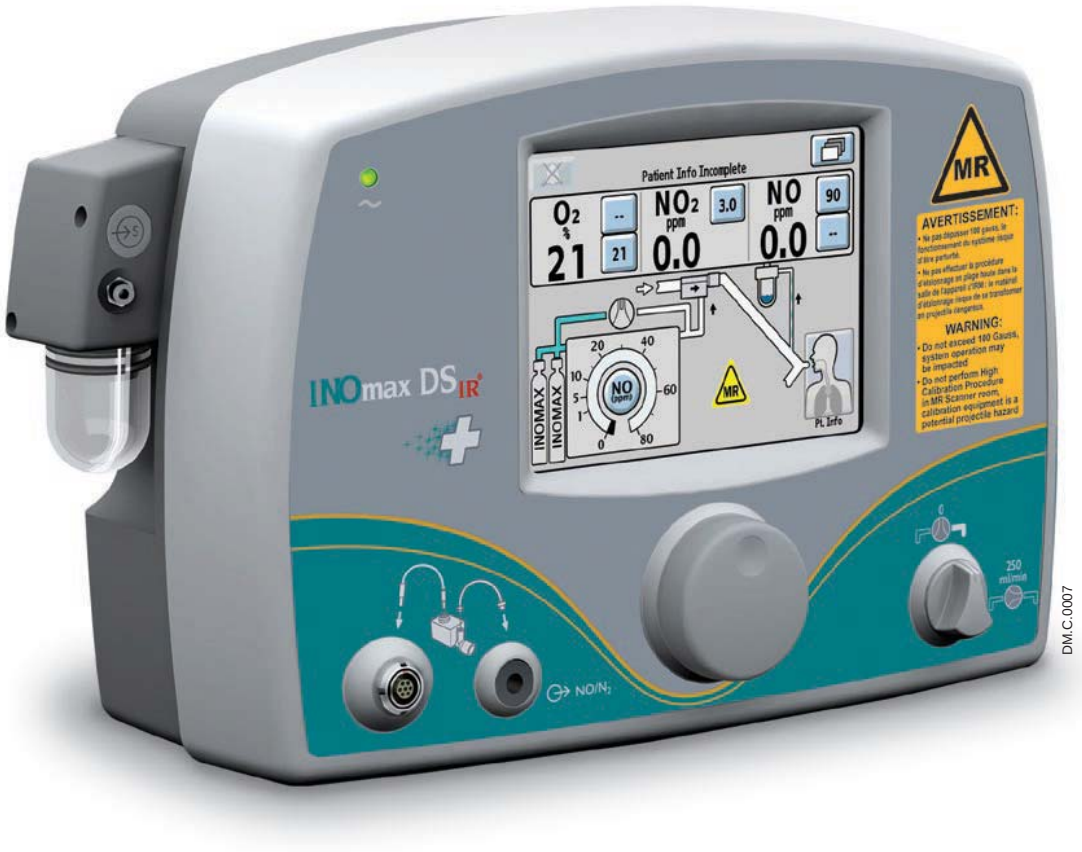


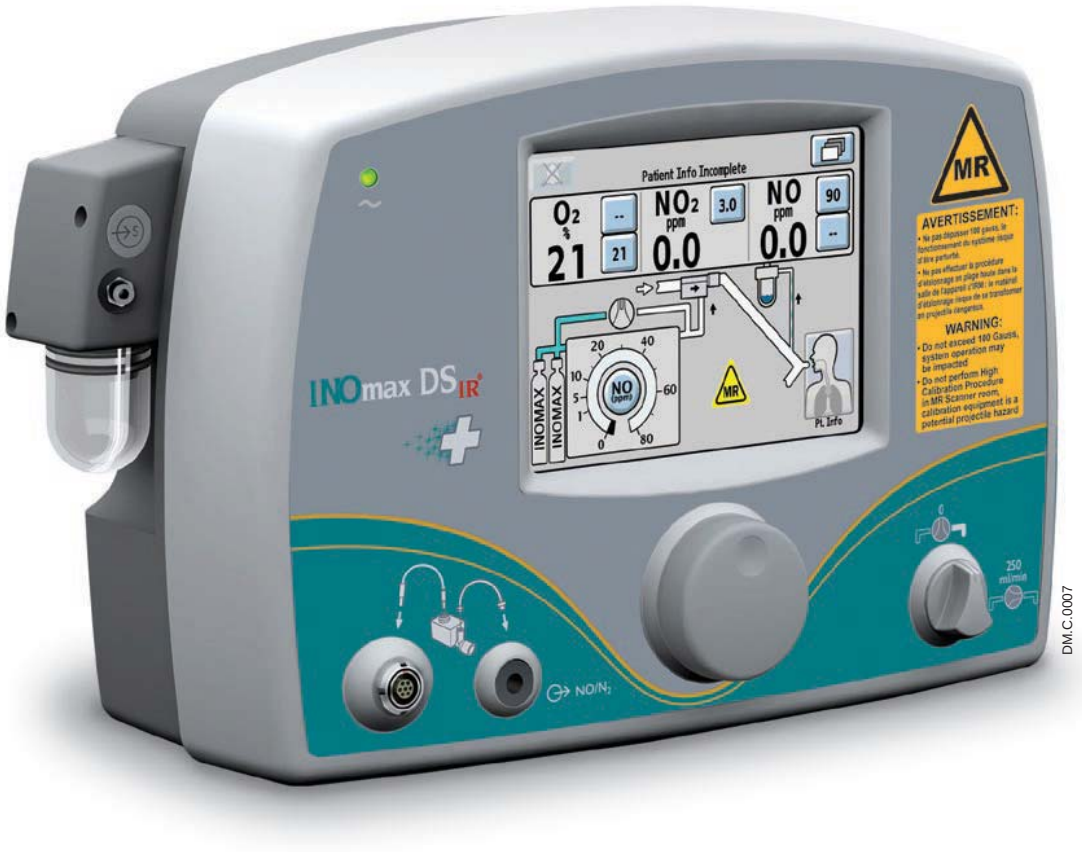
3/ Patient Application

Part No. 20765 Rev-01
2015-08

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI

Patient Application



3/ Patient Application

Part No. 20765 Rev-01
2015-08

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} Plus MRI into the patient's breathing circuit. (See the ventilator/breathing device manual for its setup and operation)

WARNING:

- **A strong magnetic field such as that from an MRI system can affect the ability of the INOmeter to detect if the cylinder valve is open. This can cause a "Cylinder Valve Closed" alarm to occur when the cylinder valve is actually open. If this alarm occurs, reposition/ rotate the INOmax DS_{IR} Plus MRI cart outside the 100 Gauss area to reduce the magnetic interference in the area of the INOmeter until the cylinder handle graphic on the display turns green. This will resolve the "Cylinder Valve Closed" alarm. Typically the required INOmax DS_{IR} Plus MRI cart location adjustment is less than 6 inches (15 cm) / 90 degrees. Note that Interruption of INOMAX therapy will occur one hour from point when the "Cylinder Valve Closed" alarm is activated if the alarm is not resolved**
- **Only use a size "88" (1,963 liters) cylinder that is marked "MR Conditional. Keep cylinder at 100 gauss or less." with the DS_{IR} Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.**
- **The INOmax DS_{IR} Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.**
- **This device contains ferromagnetic components and hence will experience strong attraction close to the magnet. It should be operated at a fringe field of less than 100 gauss.**
- **Do not exceed 100 Gauss; system operation may be impacted.**
- **Confirm cart auto-brake function. Optionally connect tether.**
- **Arrange power cord, MR patient gas sample line, MR injector tubing and MR injector module cable to avoid entanglement, strangulation and/or a trip hazard.**
- **Set the INOmax DS_{IR} Plus MRI alarm thresholds for the current patient conditions to monitor any inadvertent changes in treatment.**
- **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 the dose as described in the INOMAX Prescribing Information - The Effects of Nitrogen Dioxide. 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} Plus MRI 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.**
- **Helium/oxygen mixtures should not be used with the INOmax DS_{IR} Plus MRI.**
- **The use of devices which radiate high-intensity electrical fields may affect the operation of the INOmax DS_{IR} Plus MRI. Constant surveillance of all monitoring and life support equipment is mandatory whenever interfering devices are in operation on or near a patient.**
- **Only use parts/accessories designated for use with this system.**
- **The target patient population is controlled by the drug labeling for INOMAX and is currently neonates. The INOmax DS_{IR} Plus MRI is not intended to be used in other patient populations.**

Using the INOmax DS_{IR} Plus MRI in the MR Scanner Room

WARNING:

- **If the cart fails to move when the brake handle is pulled or moves when the brake handle is not pulled, do not use the INOmax DS_{IR} Plus MRI and contact your local representative.**
- **The gauss alarm will sound if the INOmax DS_{IR} Plus MRI system is too close to the MR scanner. If alarm sounds, move system away from the MR scanner until the gauss alarm stops sounding.**
- **Do not perform a high calibration procedure in MR scanner room, calibration equipment is a potential projectile hazard.**

Transferring to and from the MR scanner room

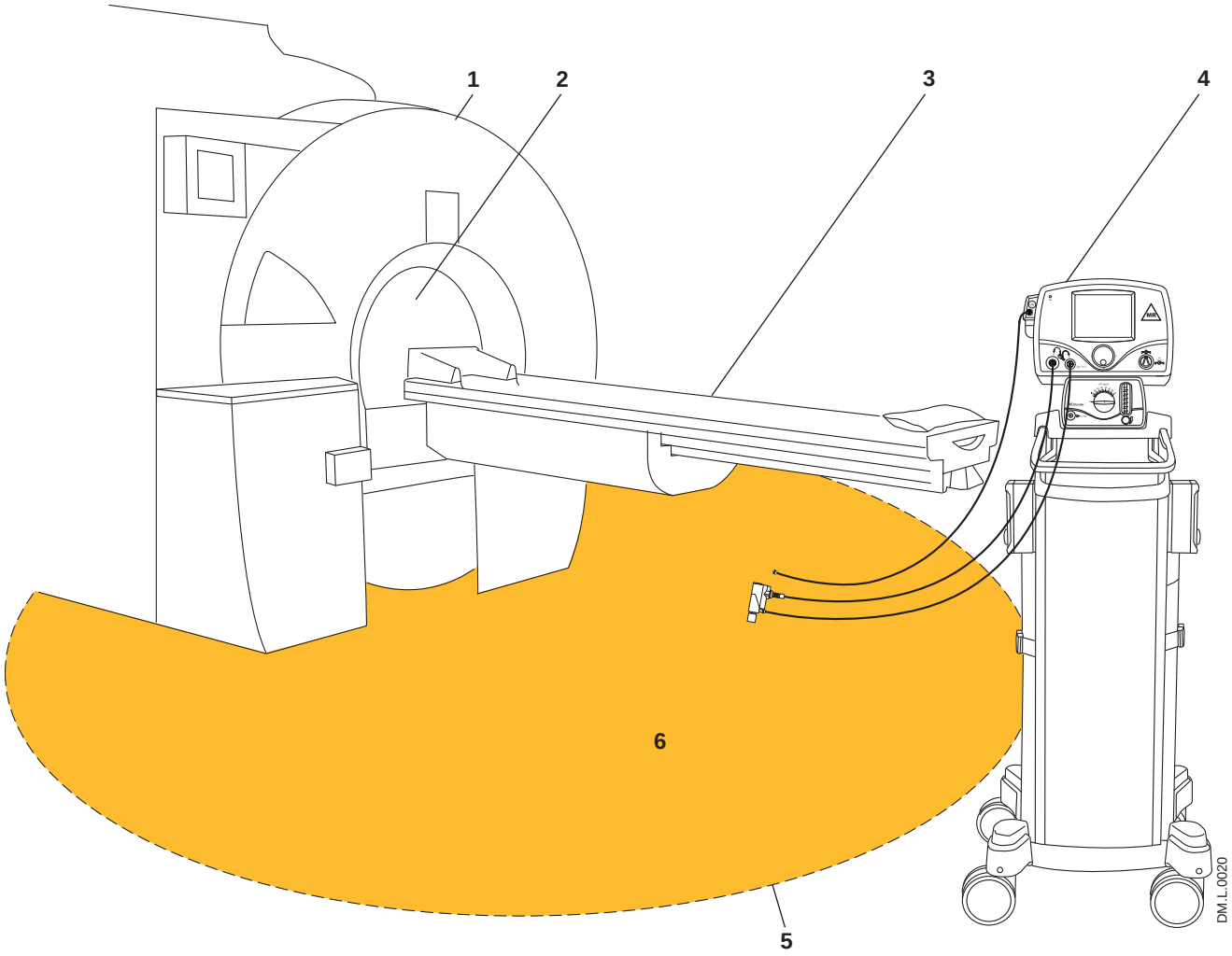
Prior to moving the patient into the MR scanner room, complete the following steps:

1. Complete a pre-use procedure on the INOmax DS_{IR} Plus MRI to verify the system is functioning properly.
2. Match the dose and alarm settings on the INOmax DS_{IR} Plus MRI with the INOmax DS_{IR} Plus that has transported the patient to the MR scanner room.
3. Remove the INOmax DS_{IR} Plus injector module from the patient ventilator circuit and immediately insert the INOmax DS_{IR} Plus MRI injector module. Repeat the same steps to change the patient gas sample line (for more detailed information, see page 3-4).
4. Move the patient, the MR ventilator and INOmax DS_{IR} Plus MRI into the MR scanner room.
5. Position the INOmax DS_{IR} Plus MRI outside of the MR exclusion zone (see Figure 3-1).

WARNING: **The gauss alarm will sound if the INOmax DS_{IR} Plus MRI system is too close to the MR scanner. If alarm sounds, move system away from the MR scanner until the gauss alarm stops sounding.**

6. The tether attachment point allows for a facility supplied cable to be secured to the cart as a redundant means to limit the distance the cart can move.
7. Keep the INOmax DS_{IR} Plus MRI outside of the MR exclusion zone.
8. Move the patient, the MR ventilator and INOmax DS_{IR} Plus MRI outside of the MR scanner room.
9. Remove the INOmax DS_{IR} Plus MRI injector module from the patient ventilator circuit and immediately insert the INOmax DS_{IR} Plus injector module. Repeat the same steps to change the patient gas sample line.
10. Verify ventilator and INOmax DS_{IR} Plus function following transition from the MR scanner room.

WARNING: **The gauss alarm will sound if the INOmax DS_{IR} Plus MRI system is too close to the MR scanner. If alarm sounds, move system away from the MR scanner until the gauss alarm stops sounding.**



1. MR Scanner
2. MR Scanner Bore
3. Patient Table
4. INOmax DS_{IR} Plus MRI
5. 100 Gauss Line
6. Exclusion Zone (illustration purposes only, actual shape will vary)

Figure 3-1 MR Scanner Room

Connection to the ventilator breathing circuit

WARNING: **The INOmax DS_{IR} Plus MRI 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} Plus MRI to the breathing circuit.**

Caution:

- For proper gas flow measurement, the MR injector module should not be connected directly to the ventilator's inspiratory outlet.
- Connect the MR injector module directly to the humidifier inlet.
- If it is not possible to connect the injector module to the inlet of the humidifier or if a humidifier is not used, a length of tubing (at least 6 inches) must be placed between the ventilator patient outlet and the injector module.

Note: Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Adapter diagrams can be found on page 6-13.

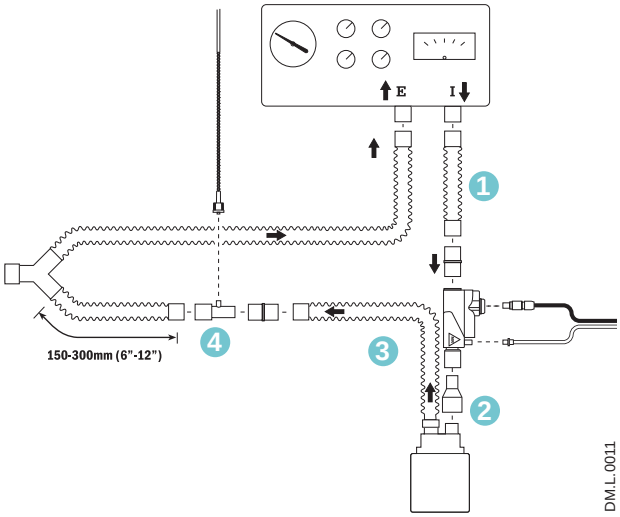
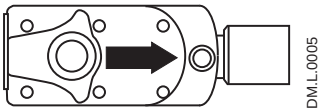


Figure 3-2

Injector Module Airflow Direction



Injector Module Top View

Figure 3-3

Connect the INOmax DS_{IR} Plus MRI 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 MR injector module (Fig. 3-2).
2. Connect the MR injector module to the humidifier inlet, note the airflow direction indicator on the injector module (see Figure 3-3).
3. The distance between the MR injector module and the sample tee must be greater than 24 inches to ensure proper gas mixing.
4. Insert the sample tee on the inspiratory side of the ventilator circuit, 6-12 inches (150-300 mm) from the patient wye. This minimizes the sampling of mixed inspired/ expired concentrations, and ensures correct patient NO/NO_2 measurement.

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

5. Select the dose button on the screen. On the INOmax DS_{IR} Plus MRI, rotate the control wheel to set the NO dose.
6. Confirm the change by pressing the Control wheel or dose button on the screen.
7. Set the user-adjustable alarm settings on the INOmax DS_{IR} Plus MRI and on the ventilator or breathing system.

Note: 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

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 should be turned off.
- 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%.
- Delivered INOMAX dose from the INOblender is affected by varying oxygen concentrations (see table below):

FiO_2	INOblender Accuracy Specification (at 50 psig)
1.0	+/- 20% of set value or 2 ppm whichever is greater
0.21 to 0.95	+/- 30% of set value or 3 ppm whichever is greater

Integrated Pnuematic 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.**

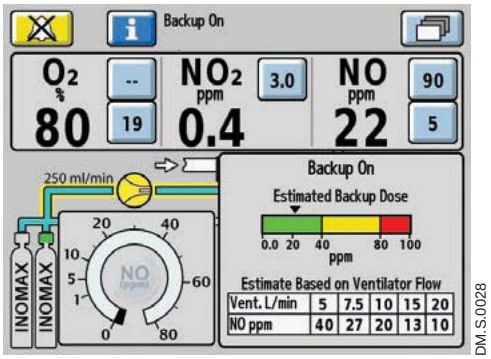


Figure 3-4

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 MR injector module.

The integrated pneumatic backup is not reliant on the operation of the main system (see Figure 3-6).

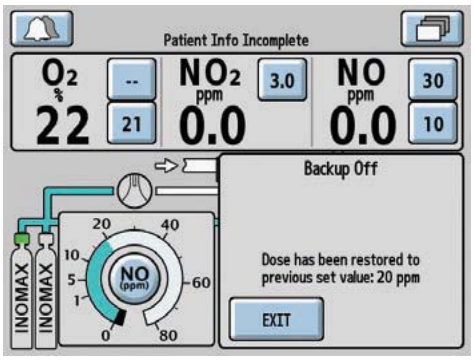
- The integrated pneumatic backup delivery is activated through the backup switch on the front panel. When activated, the set INOMAX dose will be automatically turned OFF. The high and low NO alarms are automatically set to 90 and 5 ppm respectively (see Figure 3-4).
- The estimated backup dose graphic (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 MR injector module (see Figure 3-4).
- The estimated NO dose table is also displayed on the main screen.

Note:

- If the MR 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 = estimated dose



- When the pneumatic backup switch is turned OFF, the dose setting will automatically be returned to the previous dose that was set as well as the alarm set points (see Figure 3-5).

Figure 3-5

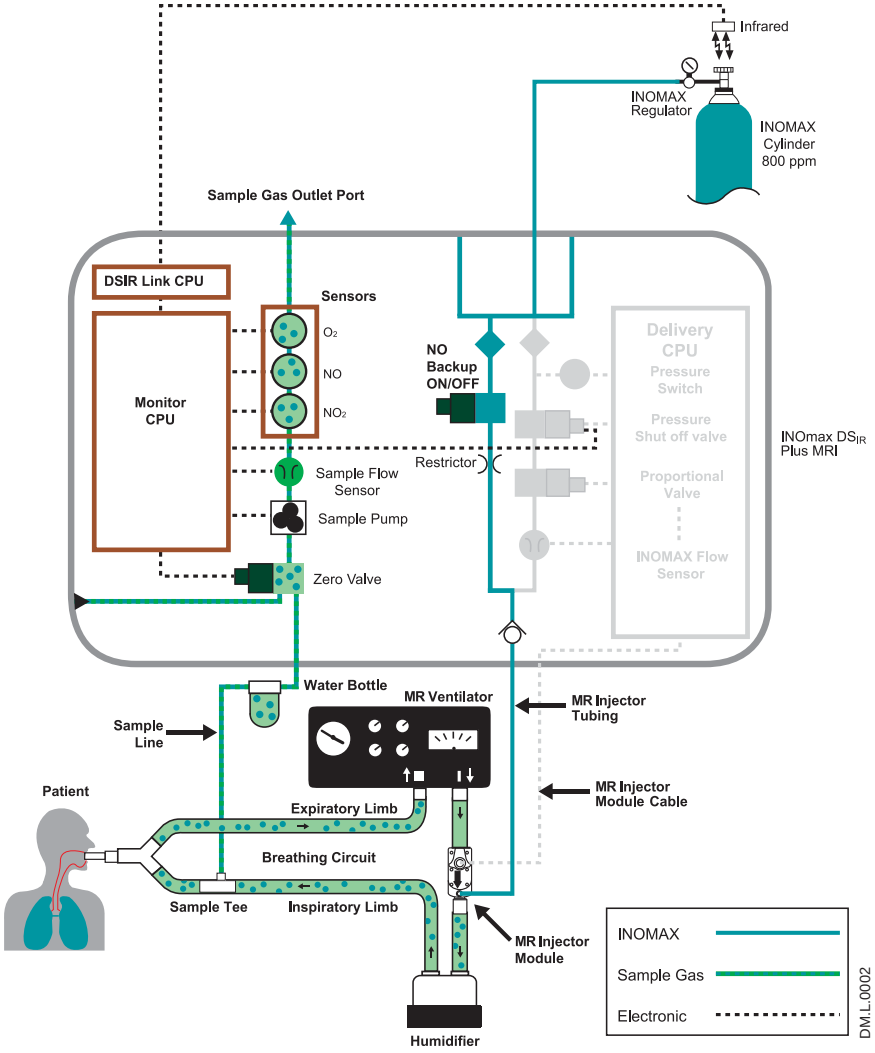


Figure 3-6

Cylinder Information

WARNING:

- **Only use a size “88” (1,963 liters) cylinder that is marked “MR Conditional. Keep cylinder at 100 gauss or less.” with the INOmax DS_{IR} Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.**
- **Only use manufacturer supplied drug cylinders, regulators and adapters.**
- **Cylinders should be stored between 59-86 degrees F (15-30 degrees C).**
- **Always secure a cylinder when not using it.**
- **Never lift a cylinder by its valve.**
- **Never drop a cylinder.**
- **Never use a hammer, pry or wedge to loosen a valve or protection cap. The valve and protection cap should be operated 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 attempt to repair a leaking 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 (52 degrees C).**
  - **where they can contact corrosive substances.**
  - **where they can be cut or abraded by an object.**
  - **next to a walkway, elevator or platform edge.**

DM.P0035

Size 88 Size D

Purging the INOmax DS_{IR} Plus MRI

- **All INOmax DS_{IR} Plus MRI devices must be purged before use to ensure the patient does not receive an excess level of NO_2.**
- **If the INOmax DS_{IR} Plus MRI is not going to be used on a patient within 10 minutes, depressurize the regulator supply line.**
- **If the INOmax DS_{IR} Plus MRI is not used and is pressurized for more than 10 minutes, repeat automated or manual purge procedure.**
- **If the INOmax DS_{IR} Plus MRI is depressurized and not used within 12 hours, repeat pre-use procedure.**

Note:

- 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.

RG.P.0005

1. Check the INOMAX gas cylinders for the correct product identity, cylinder concentration, and expiration date. Verify cylinder has at least 500 psig and tighten the fitting to the INOMAX cylinder.

   Attach a second INOmax DS_{IR} Plus MRI regulator (hand-tighten only) to the cylinder which is currently not in use.

Note:

- Do not attach the regulator hose to the INOmax DS_{IR} Plus MRI 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 6-9).

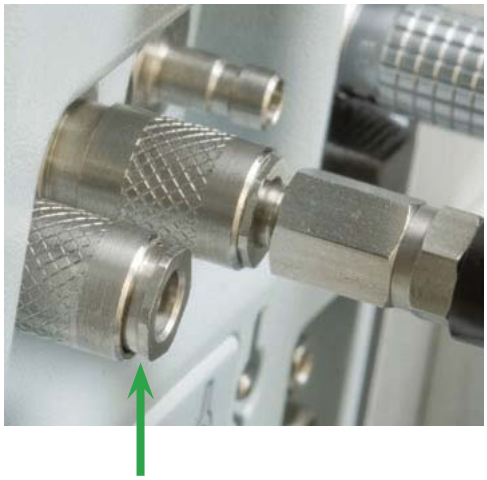
RG.P.0006

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 6/ Maintenance; Cylinder Leak Check).

DM.P.0044

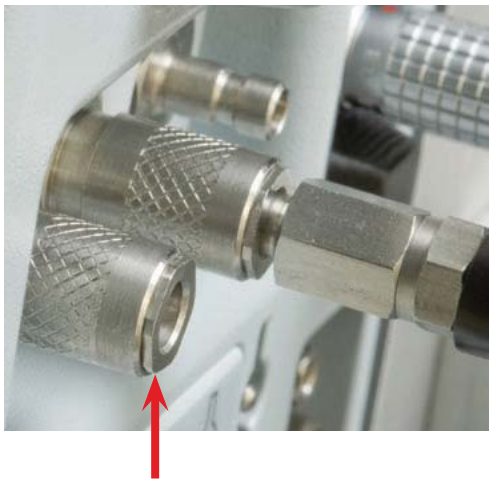
3. Insert the NO/N_2 quick-connect fitting into the purge port on the back of the INOmax DS_{IR} Plus MRI and firmly push until the regulator pressure gauge reads zero (this purges any NO_2 that has accumulated in the hose and regulator).

WARNING: **All INOmax DS_{IR} Plus MRI devices must be purged before use to ensure the patient does not receive excess of NO_2.**


DS.P.0002

4. Prior to connecting a regulator hose, ensure the inlet connectors, on the INOmax DS_{IR} Plus MRI unit, have the knurled sleeve set in the back position (toward the INOmax DS_{IR} Plus MRI unit, see Figure 3-7).

Figure 3-7 Correct Position


DS.P.0003

Incorrect Position

RG.P0003

5. Open the cylinder valve on the new cylinder (this may activate the “Two Cylinders Open” alarm until the empty cylinder valve is closed).
6. Close the cylinder valve on the empty cylinder and remove the supply line from the back of the INOmax DS_{IR} Plus MRI.
7. Depressurize by using the purge port on the back of the INOmax DS_{IR} Plus MRI prior to removing the regulator from the empty cylinder.
8. Replace the empty cylinder with a full cylinder on 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 0.21

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} Plus MRI 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

DM.P.0031

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

* All calculations in the table above are based on a full cylinder, 128 bar (1850 psig), 1,963 liter “88” cylinder, with a cylinder change at 14 bar (200 psig). The figures are calculated based on a total continuous breathing circuit gas flow and a cylinder conversion factor of 15.7 liters per bar/1.08 liters per psig.

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

Calculations are considered estimates and may vary under clinical circumstances.

For more information, call 1-877-KNOW-INO (1-877-566-9466)

Emptying the Water Bottle

The water bottle (see Figure 3-8) collects fluids separated from the patient gas sample.

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

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

Figure 3-8

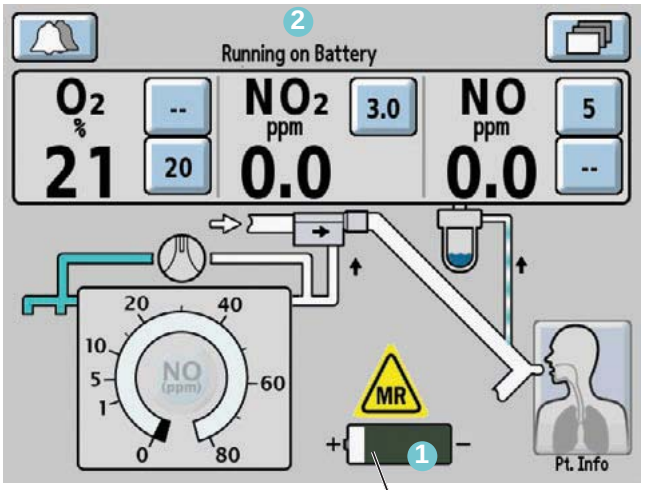
To empty the Water Bottle:

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 bottle housing protects the monitoring system from moisture and other contaminants and may need to be replaced occasionally while in use (refer to Section 6/ Maintenance).
2. To avoid medications interfering with the gas monitoring system, administer any aerosolized medications distal to the sampling tee in the breathing circuit.

Running on Battery

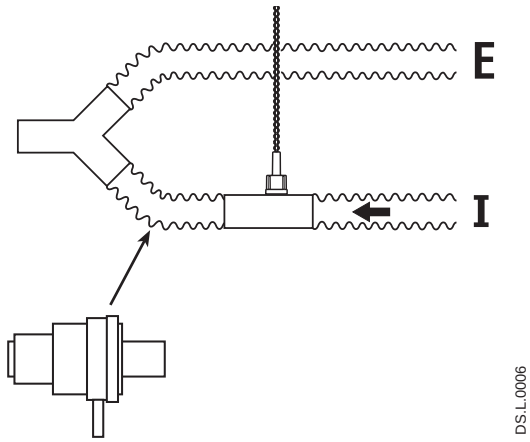


Battery icon

- When operating on the battery, a battery icon (1) is displayed on the screen along with the message “Running on Battery” (2) in the text message area.
- The low battery alarm will alert the user when there are approximately 30 minutes of battery life remaining.
- A fully charged battery will run the INOmax DS_{IR} Plus MRI 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 sample inspired gas during aerosol delivery:

- Place the medication nebulizer downstream of the sample tee on the inspiratory limb (see Figure 3-9).

This avoids over saturation of the water separator cartridge, or contamination of the sample system. In addition, it prevents the Sample Line/Filter Block alarm from occurring.

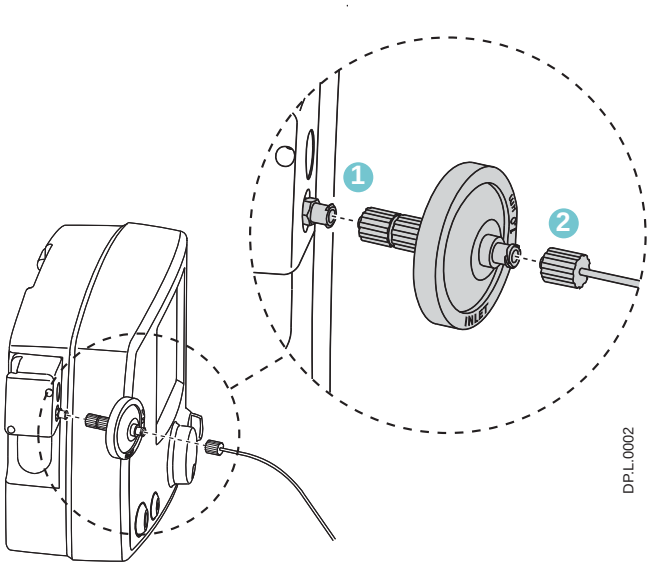


Figure 3-10

1. Place the 1.0 micron disk filter on the INOmax DS_{IR} Plus MRI sample line inlet (Fig. 3-10).
2. Connect the patient gas sample line to the filter. If monitored values change, check that all sample line and filter connections are secure.

This disk filter has been validated for this purpose.

After each treatment period, replace the disk filter:

Note:

- Change the filter every 12 hours or more often if necessary (due to Sample Line/Filter Block alarm). Replacing the disk filter reduces the replacement frequency of the water separator cartridge.
- Do not operate the INOmax DS_{IR} Plus MRI without the water separator cartridge. Always use the disk filter in conjunction with the INOmax DS_{IR} Plus MRI water separator cartridge.

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.

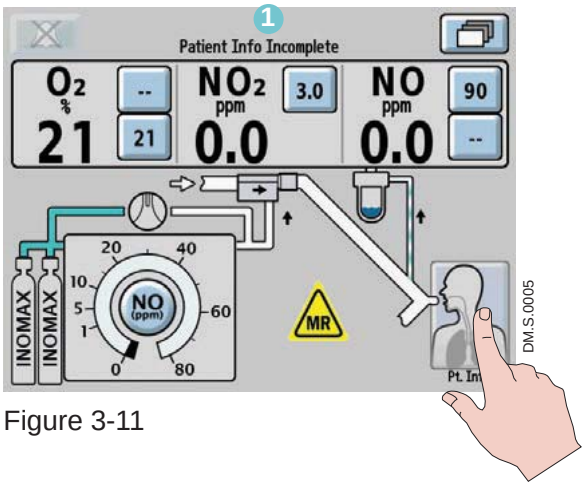


Figure 3-11

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).

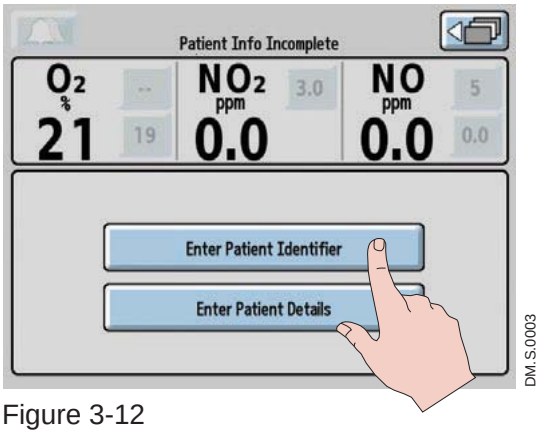


Figure 3-12

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.

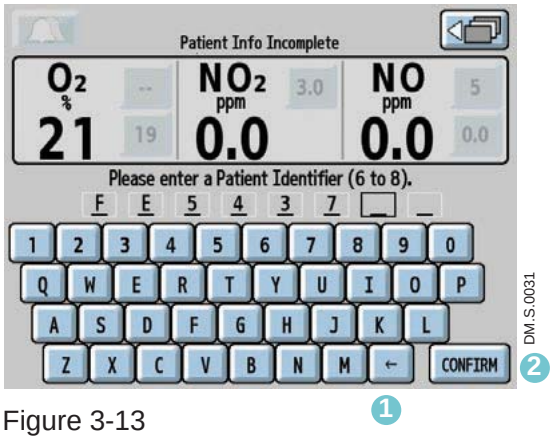


Figure 3-13

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).

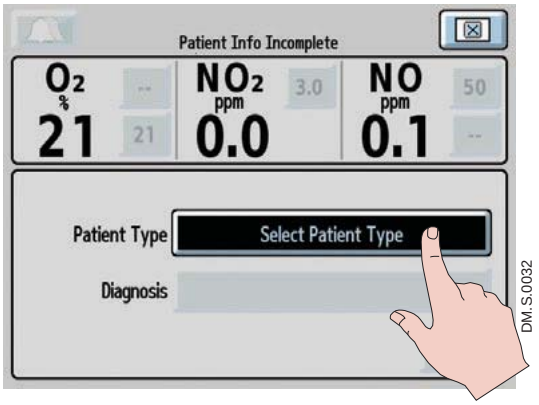


Figure 3-14

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).

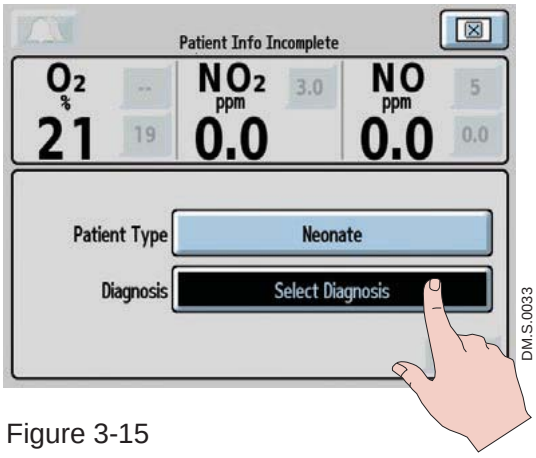


Figure 3-15

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

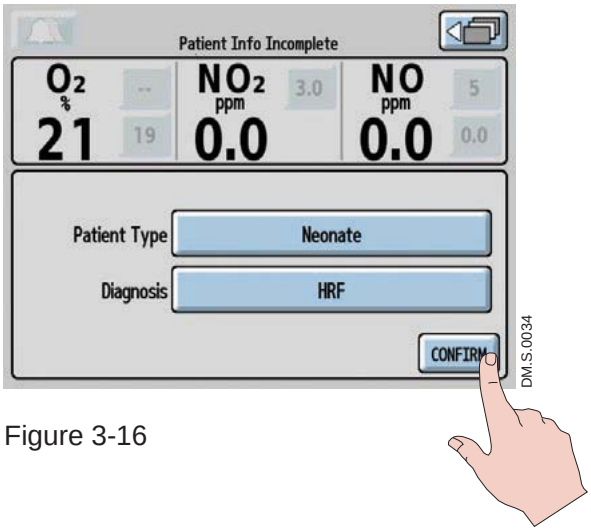


Figure 3-16

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

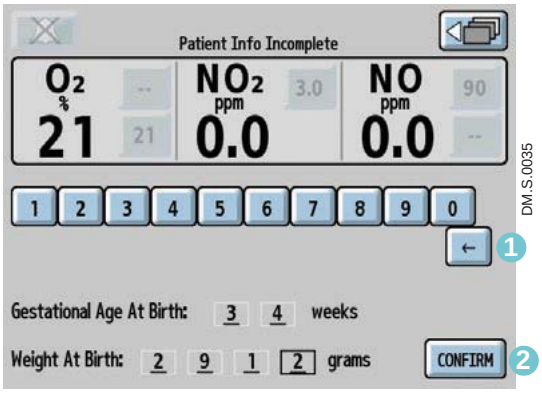


Figure 3-17

Prior to confirming the gestational age and birth weight (see Figure 3-17), 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.

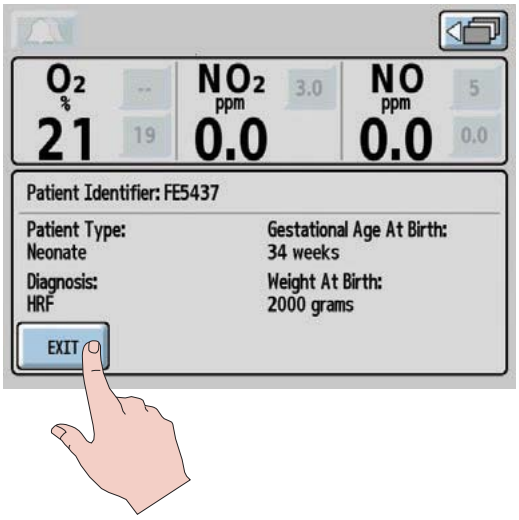
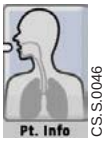


Figure 3-18

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} Plus MRI 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.**

Caution:

- The INOmax DS_{IR} Plus MRI is designed to function in the parameter ranges listed in Section 7/ Product Specifications. Use outside of these ranges is not recommended.
- Verify that the following parts are connected to the INOmax DS_{IR} Plus MRI system prior to completing the pre-use procedure (see Figure 2-1)
  - MR injector module (PN 90713)
  - MR injector module electrical cable (PN 90850)
  - MR NO/N_2 injector tube (PN 50260)
  - MR patient gas sample line (PN 50261)

Note:

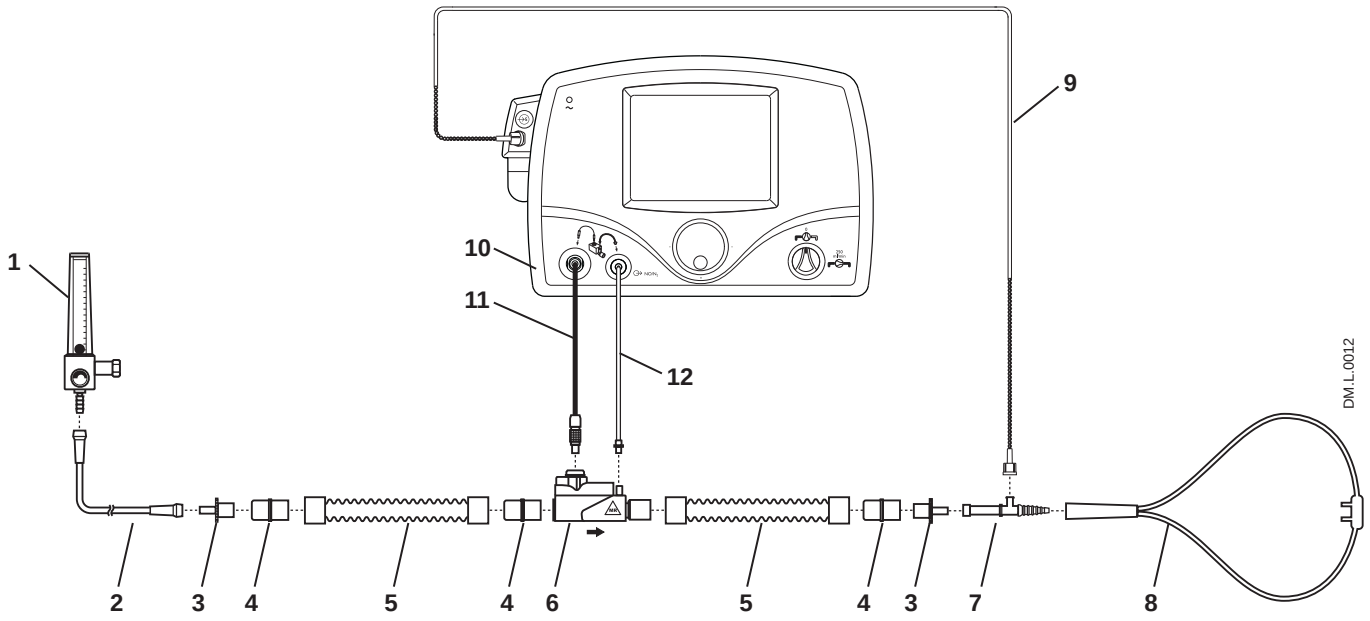
- Connections to various ventilators are unique to each manufacturer as well as their corresponding disposable circuits. Examples of adapter diagrams can be found on page 6-13.
- For a list of validated ventilators see Section 7/ Product Specifications.

Spontaneously Breathing Patient on a Nasal Cannula

The INOmax DS_{IR} Plus MRI can be used with a 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 MR 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 MR injector module.

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.**

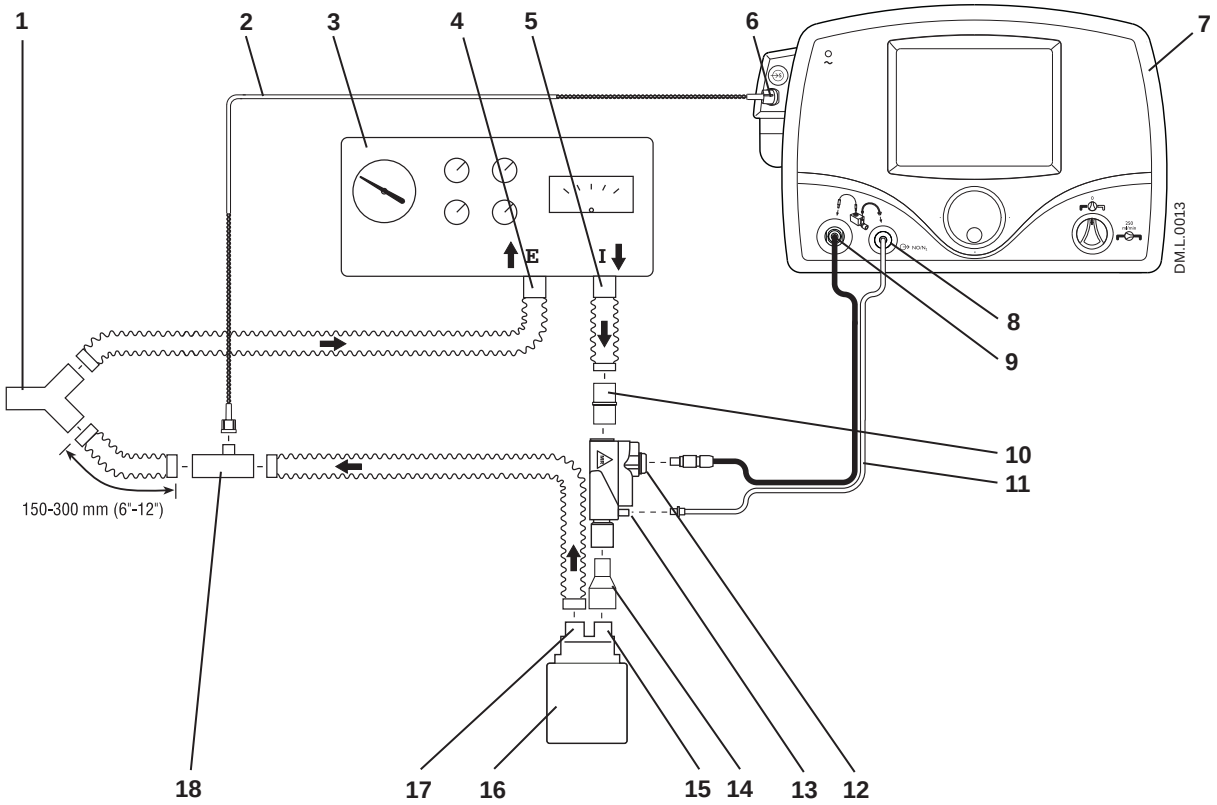


1. O_2 Flowmeter
2. O_2 Tubing
3. 15M x 4.5 mm Adapter
4. 22M/15F x 22M/15F Adapter
5. 300 mm of 22 mm Hose
6. MR injector module
7. O_2 Tubing Sample Tee
8. Patient Nasal Cannula
9. MR patient gas sample line with Nafion
10. INOmax DS_{IR} Plus MRI
11. MR injector module Electrical Cable
12. MR NO/N_2 injector tube

Figure 3-19 Example: Spontaneously Breathing Nasal Cannula Patient Circuit Diagram

MR Conditional Ventilator Circuit

WARNING: **The INOmax DS_{IR} Plus MRI 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} Plus MRI to the breathing circuit.**

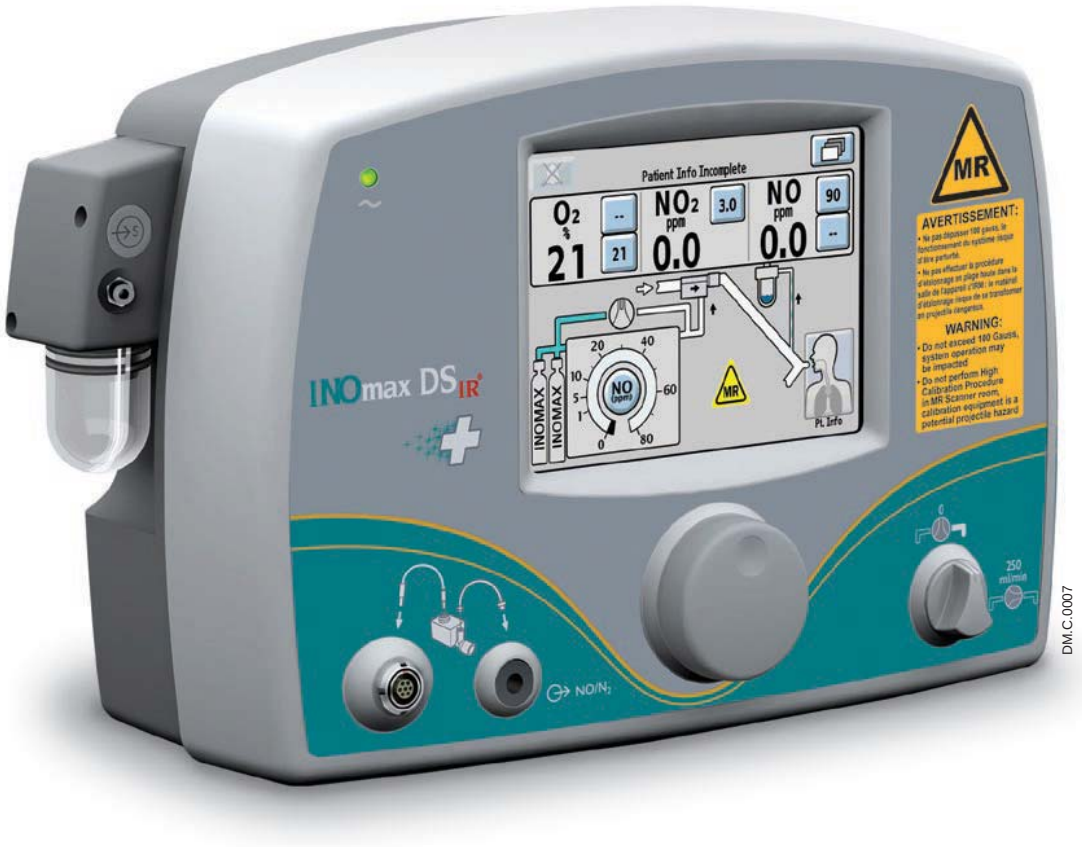


1. Patient Wye
2. MR patient gas sample line with Nafion
3. MR Conditional Ventilator
4. MR Conditional Ventilator Expiratory Port
5. MR Conditional Ventilator Inspiratory Port
6. MR patient gas sample line Input Connection
7. INOmax DS_{IR} Plus MRI
8. MR NO/N_2 injector tube Front Panel Connection
9. MR injector module Electrical Cable Front Panel Connection
10. 22M/15F X 22M/15F Adapter
11. MR NO/N_2 Injector Tube
12. MR injector module Electrical Cable Connection
13. MR Injector Module NO/N_2 Injector Tube Connection
14. 22F X 15M Adapter
15. Humidifier Inlet
16. Humidifier (optional)
17. Humidifier Outlet
18. Gas Sample Tee

Figure 3-20 Example: MR Conditional Ventilator Diagram

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



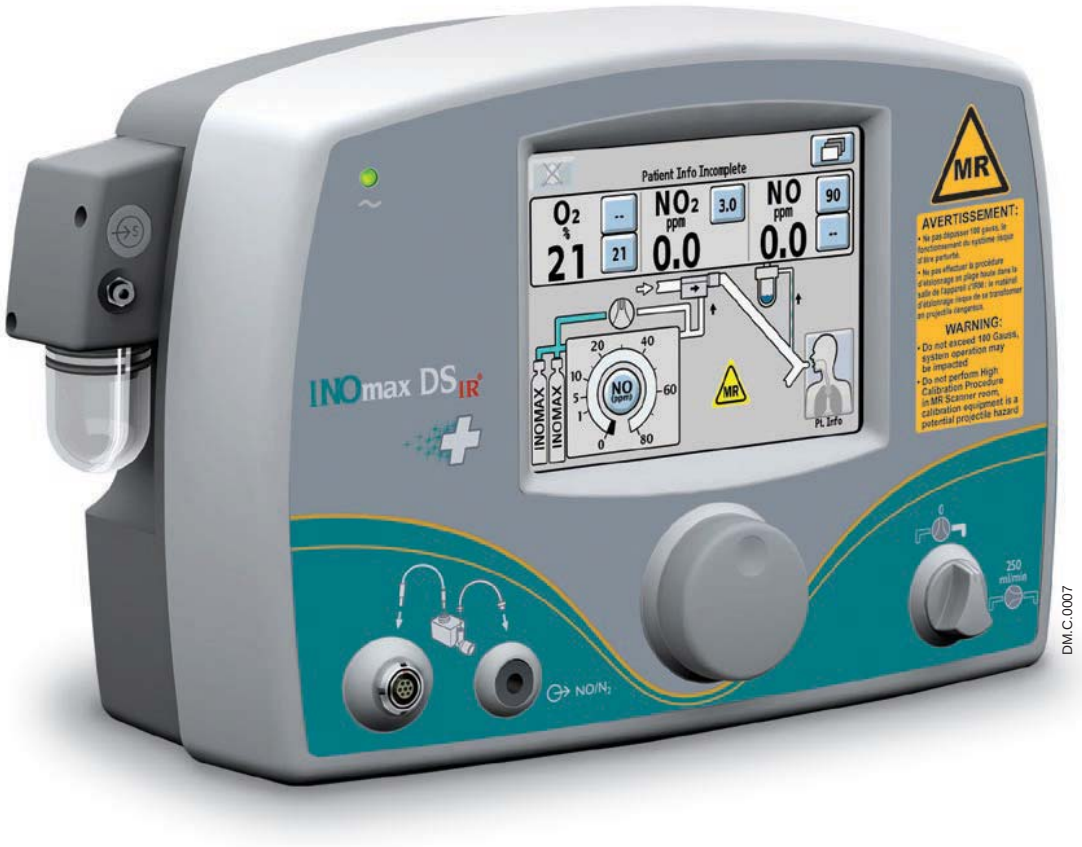
Alarms and Troubleshooting

4/ Alarms and Troubleshooting

Part No. 20765 Rev-01
2015-08

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



4/ Alarms and Troubleshooting

Part No. 20765 Rev-01
2015-08

4/ Alarms and Troubleshooting

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.**

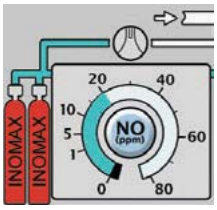
Continuous Audible Tone		
Alarm	**Possible Cause**	**Recommended Action**
Continuous Audible Tone from INOmax DS_{IR} Plus MRI	A component within the INOmax DS_{IR} Plus MRI has failed.	1. If the INOblender is available, manually ventilate the patient (see INOblender Operation Manual). 2. Replace the delivery system and remove from service. 3. Contact Technical Support.
Continuous Audible Tone from GaussAlert™	INOmax DS_{IR} Plus MRI is too close to the MR scanner.	Immediately move the INOmax DS_{IR} Plus MRI away from the MR scanner until the alarm discontinues.

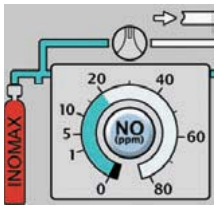
Alarm Help

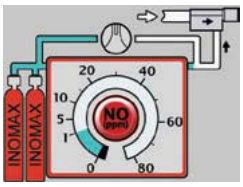
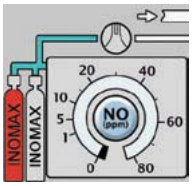
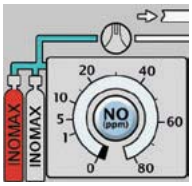
High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
1. High NO  CS.S.0009	The High NO alarm level may be inappropriately set.	Confirm High NO alarm limit is set appropriately.
	Circuit setup incorrect.	Check circuit for correct setup.
	NO sensor may require calibration.	Perform low calibration.
	MR injector module may not be functioning properly.	1. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON 2. Replace the MR injector module (INOMAX delivery will be interrupted). 3. Replace the MR injector module cable. (INOMAX delivery will be interrupted).
	NO sensor may require calibration.	Perform a high calibration outside of the MR scanner room. 1. Perform high NO calibration. 2. Contact Technical Support.

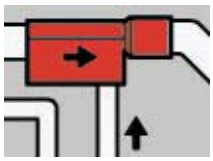
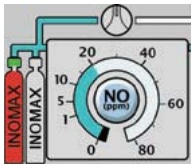
High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
2. Low NO  CS.S.0012	The Low NO alarm setting may be inappropriately set.	Confirm Low NO alarm limit is set appropriately.
	Circuit setup incorrect. The patient gas sample line or NO/N_2 injector tube may be disconnected.	1. Check circuit for correct setup. 2. Confirm water bottle, water separator cartridge, NO/N_2 injector tube and patient gas sample line are in place.
	Loss of NO delivery.	If loss of NO delivery is suspected, manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON
	NO sensor may require calibration.	Perform low calibration
	MR injector module may not be functioning properly.	1. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON 2. Replace the MR injector module (INOMAX delivery will be interrupted). 3. Replace the MR injector module cable (INOMAX delivery will be interrupted).
	NO sensor may require calibration.	Perform a high NO calibration outside of the MR scanner room.
	The NO sensor may not be properly seated.	1. Outside of the MR scanner room confirm the O-ring on the sensor is correctly seated and the sensor cover is fully closed. 2. Contact Technical Support.

High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
3. High NO_2  CS.S.0010	The High NO_2 alarm setting may be inappropriately set.	Confirm High NO_2 alarm limit is set appropriately.
	The patient circuit setup may be incorrect. -Patient circuit flow interrupted.	Check circuit for correct setup.
	Incomplete system purge	Repeat the purge procedure with the MR injector module out of the patient breathing circuit. Use INOblender if necessary.
	Monitored NO_2 value is too high.	Consider reducing the INOMAX dose according to INOMAX prescribing information.
	NO_2 sensor may require calibration.	1. Perform low calibration. 2. Perform a high NO_2 calibration outside of the MR scanner room. 3. Contact Technical Support.
4. High O_2  CS.S.0011	The High O_2 alarm setting may be inappropriately set.	Confirm High O_2 alarm limit is set appropriately.
	O_2 sensor may require calibration.	1. Perform low calibration. 2. Perform a high O_2 calibration outside of the MR scanner room. 3. Contact Technical Support.

High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
5. Low O_2  CS.S.0013 INOMAX can dilute set ventilator O_2 concentration by up to 10%.	The Low O_2 alarm setting may be inappropriately set.	Confirm Low O_2 alarm limit is set appropriately.
	The patient breathing circuit setup may be incorrect.	Check circuit for correct setup. Ensure patient gas sample line connections are secure.
	O_2 sensor may require calibration.	1. Perform low calibration. 2. Perform a high O_2 calibration outside of the MR scanner room. 3. Contact Technical Support.
6. Cylinder Not Detected  CS.S.0014 **WARNING:** Delivery Stopped will occur one hour from point when Cylinder Not Detected alarm is activated.	INOmax DS_{IR} Plus MRI infrared cart cable is not connected or has failed.	Confirm infrared cart cable is connected to infrared connector on back of INOmax DS_{IR} Plus MRI.
	Magnetic/IR interference.	1. Reposition/rotate INOmax DS_{IR} Plus MRI cart. 2. Remove any obstacle between INOmeter and cart. 3. Move the interfering light source. 4. Move the INOmax DS_{IR} Plus MRI cart to reduce the high intensity light in the area of the INOmeter. 5. Shield the INOmeter from the suspect light source.
	INOmeter may have failed.	1. Replace INOMAX cylinder. 2. Contact Technical Support.

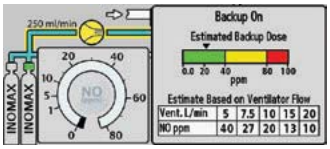
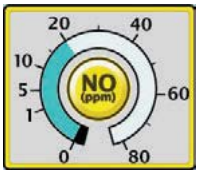
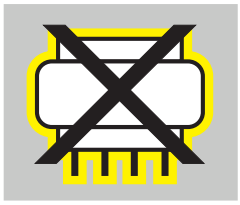
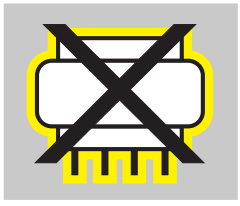
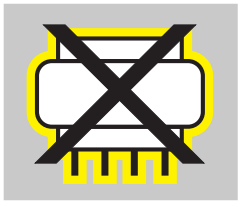
High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
7. Cylinder Valve Closed CS.S.0015  **WARNING:** Delivery Stopped will occur one hour from point when Cylinder Valve Closed alarm is activated.	INOMAX cylinder valve is closed.	Confirm INOMAX cylinder valve is fully open.
	When two cylinders are present on the cart, open cylinder may not be visible to the IR system due to magnetic interference or obstruction.	1. Reposition/rotate INOmax DS_{IR} Plus MRI cart. 2. Remove any obstacle between INOmeter and cart.
	INOmeter may have failed.	1. Replace INOMAX cylinder. 2. Contact Technical Support.
8. Delivery Failure CS.S.0016 	Over-delivery of INOMAX or an internal error has been detected. - (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	1. Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON 2. Turn INOmax DS_{IR} Plus MRI to standby, then restart. Once device is ready to restart therapy: 3. Turn integrated back up off (if used) and then set the INOMAX dose. 4. Confirm delivery and check alarms. 5. Contact Technical Support.

High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
9. Delivery Stopped  CS.S.0017	MONITORED NO > 100 ppm for at least 12 seconds.	Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON.
	Drug past expiry date.	Replace INOMAX cylinder.
	Drug concentration mismatch.	Replace INOMAX cylinder.
	INOmeter may have failed.	Replace INOMAX cylinder.
	INOMAX cylinder valve is closed.	Open INOMAX cylinder valve.
	INOMAX cylinder is not detected.	1. Replace INOMAX cylinder. 2. Contact Technical Support.
10. Drug Past Expiry Date  CS.S.0018 **WARNING:** Delivery Stopped will occur two minutes from point when Drug Past Expiry Date alarm is activated.	INOMAX cylinder is expired.	1. Close expired cylinder valve. 2. Remove expired INOMAX cylinder from INOmax DS_{IR} Plus MRI cart. 3. Connect an INOMAX cylinder with a valid expiration date. 4. Contact Technical Support.
11. Drug Concentration Mismatch  CS.S.0018 **WARNING:** Delivery Stopped will occur two minutes from point when Cylinder Concentration Mismatch alarm is activated.	INOMAX cylinder is the wrong concentration.	1. Close mismatched cylinder valve. 2. Remove wrong concentration INOMAX cylinder from INOmax DS_{IR} Plus MRI cart. 3. Connect an INOMAX cylinder with a valid concentration to INOmax DS_{IR} Plus MRI. 4. Contact Technical Support.

High Priority Alarms All of these actions can be performed while delivering INOMAX to the patient:		
Alarm	**Possible Cause**	**Recommended Action**
12. Injector Module Fail CS.S.0019 		Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON.
	The MR injector module electrical cable may be disconnected.	Disconnect and reconnect both ends of the injector module cable.
	The MR injector module may have failed.	Replace the MR injector module (INOMAX delivery will be interrupted).
	The MR injector module electrical cable may have failed.	1. Replace the MR injector module cable (INOMAX delivery will be interrupted). 2. Contact Technical Support.
13. Low Battery CS.S.0020 	Battery is running low.	Up to 30 minutes of battery life remains following low battery alarm activation. 1. Check AC power connection at wall and/ or back of INOmax DS_{IR} Plus MRI (green indicator light should be illuminated). 2. Contact Technical Support.
14. Low Cylinder Pressure CS.S.0021 	Cylinder valve is closed.	Confirm INOMAX cylinder valve is fully open.
	The regulator hose may not be connected.	Confirm correct INOMAX regulator hose is connected.
	The NO cylinder supply may be low.	Check the INOMAX regulator gauge pressure, replace the cylinder if necessary.
	INOmax DS_{IR} Plus MRI has developed an internal leak.	1. Bypass the INOmax DS_{IR} Plus MRI and connect the INOblender directly to the INOMAX regulator (see Appendix). 2. Contact Technical Support.
15. Service Required CS.S.0022  Manual Delivery Available Utilize the INOblender or Integrated pneumatic backup delivery.	The INOmax DS_{IR} Plus MRI has failed.	Manually ventilate patient with the INOblender or turn integrated pneumatic backup delivery ON. 1. Remove from service. 2. Contact Technical Support.

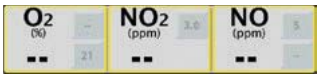
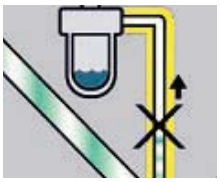
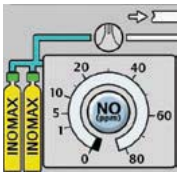
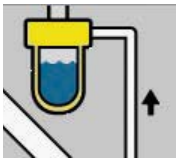
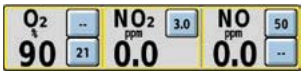
Low Priority Alarms

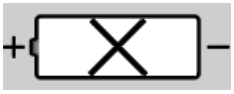
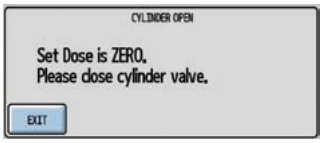
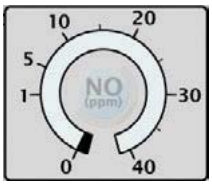
All of these actions can be performed while delivering INOMAX to the patient:

Alarm	Possible Cause	Recommended Action
16. Backup On  CS.S.0023	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 and monitor alarm settings have been restored. 3. Contact Technical Support.
17. Under Delivery  CS.S.0024	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.	1. Check calculated delivery graph on the settings screen. 2. Check circuit flow rate is 2-120 L/min. 3. Check if dose is >60 ppm with breathing circuit flow >60 L/min. 4. Contact Technical Support.
18. Failed NO Sensor  CS.S.0025	Delivery of INOMAX continues during this alarm.	
	NO calibration may have drifted out of specification.	1. Perform a low and high calibration outside of the MR scanner room. 2. Contact Technical Support.
19. Failed NO_2 Sensor  CS.S.0025	Delivery of INOMAX continues during this alarm.	
	NO_2 calibration may have drifted out of specification.	1. Perform a low and high calibration outside of the MR scanner room. 2. Contact Technical Support.
20. Failed O_2 Sensor  CS.S.0025	Delivery of INOMAX continues during this alarm.	
	O_2 calibration may have drifted out of specification.	1. Perform a low and high calibration outside of the MR scanner room. 2. Contact Technical Support.

Low Priority Alarms

All of these actions can be performed while delivering INOMAX to the patient:

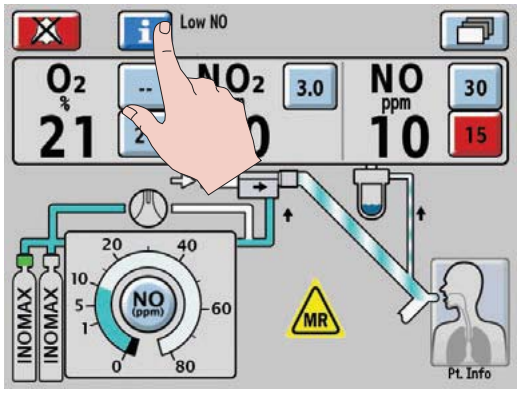
Alarm	Possible Cause	Recommended Action
21. Monitoring Failure CS.S.0026 	Delivery of INOMAX continues during this alarm.	
	Monitoring (sample) system has failed.	1. Remove from service. 2. Contact Technical Support.
22. Sample Line/Filter Block CS.S.0027 	The sample line may be blocked.	Confirm patient gas sample line is not occluded, replace if necessary.
	The water separator cartridge may be blocked.	Replace water separator cartridge.
	The 1.0 micron disk filter may be blocked.	1. Replace the 1.0 micron disk filter. 2. Contact Technical Support.
23. Two Cylinders Open CS.S.0028 	Two cylinder valves are open.	1. Close one INOMAX cylinder valve and depressurize regulator. 2. Contact Technical Support.
24. Water Bottle Full CS.S.0029 	The water bottle is full.	Empty water bottle.
	Water bottle is empty but the message remains in the alarm message box.	1. Remove water bottle and wipe off optical sensor. 2. Contact Technical Support.
25. Low Calibration Failed CS.S.0030 	Zeroing valve has failed.	1. Repeat manual low calibration. Wait for low calibration to complete (approximately three minutes). 2. Contact Technical Support.

Additional Indicators		
Indicator	**Possible Cause**	**Recommended Action**
26. Battery Failure CS.S.0031 	Device cannot communicate with battery.	Contact Technical Support.
27. Set Dose is Zero, Please Close Cylinder Valve CS.S.0032 	The set dose has been set to zero and the INOMAX cylinder valve is still open.	Close the INOMAX cylinder valve and depressurize regulator.
28. NO Delivery Button Inactive CS.S.0033 	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} Plus MRI cart cover. 3. Move the interfering light source. 4. Move the INOmax DS_{IR} Plus MRI cart to reduce the high intensity light in the area of the INOmeter. 5. Shield the INOmeter from the suspect light source. 6. Replace cylinder
	IR cable is not connected to the back of the INOmax DS_{IR} Plus MRI.	Verify the IR cable is connected to the back of the INOmax DS_{IR} Plus MRI.
	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.

Alarm Help

WARNING:

- **If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.**
- **Use caution when troubleshooting the INOmax DS_{IR} Plus MRI while in use for a patient.**
- **When possible, replace the unit in question and perform troubleshooting procedure once the unit is removed from the MR scanner room.**



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.
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 cannot be corrected:

Contact the Authorized Representative listed on the back cover of the operation manual.

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

Contact the Authorized Representative listed on the back cover of the operation manual.

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 cannot be silenced (see page 4-1, "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} Plus MRI 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 4-1) 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”.

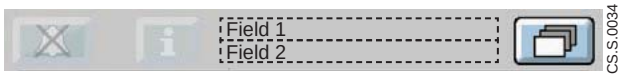


Figure 4-1 Text Message Area Showing Fields one and two.

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

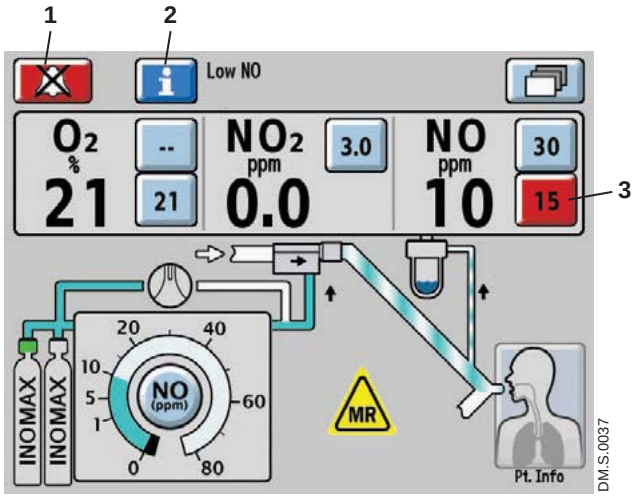
	Frequency	Description	Comment
High Priority	400 Hz	10-pulse group	Repeats after 10 sec. if not silenced.
Low Priority	400 Hz	1 pulse	Repeats after 40 sec. if not silenced.

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 4-2 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 affects 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 4-2).
- 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 4-2).

- 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

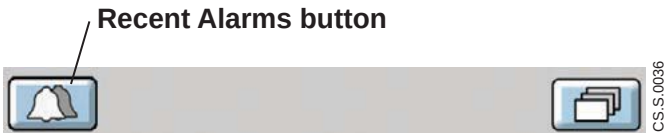


Figure 4-3 Recent Alarms Button on the Main Screen

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 4-4 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 1-18).
- 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.

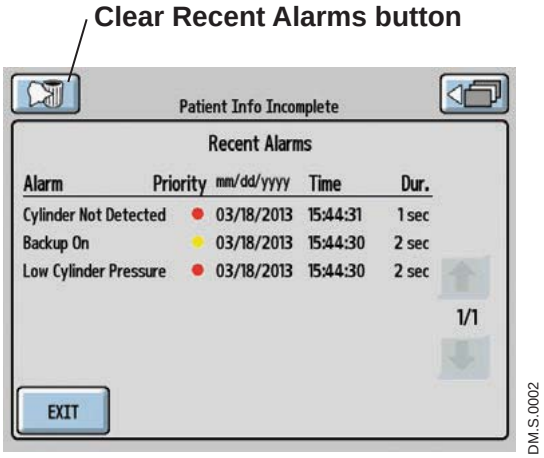
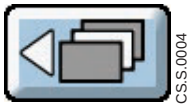


Figure 4-4 Recent Alarms Screen

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.



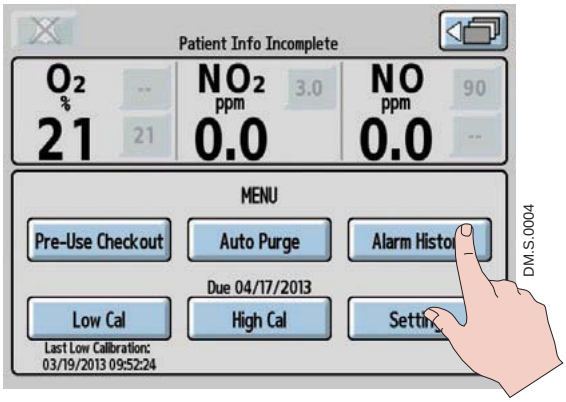


Figure 4-5 Menu Screen

A complete list of all alarms that have occured since the INOmax DS_{IR} Plus MRI has been turned ON can be viewed by pressing the Alarm History button on the menu screen (see figure 4-5).

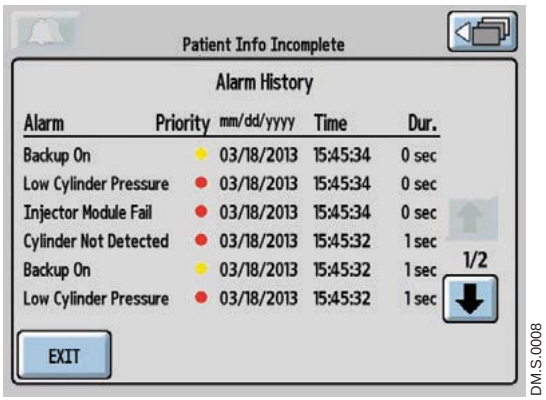


Figure 4-6 Alarm History Screen

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.

GaussAlert™ Alarm

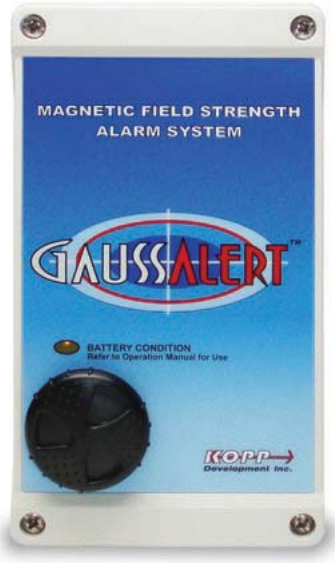


Figure 4-7 GaussAlert

The GaussAlert is designed to help keep MR Conditional equipment outside of the MR exclusion zone. GaussAlert is programmed to alarm when the preset magnetic field strength is exceeded. It produces a distinct audio alarm when MR Conditional equipment is placed too close to the MR magnet. For more information see Using the GaussAlert, page 1-8.

WARNING: **The gauss alarm will sound if the INOmax DS_{IR} Plus MRI system is too close to the MR scanner. If alarm sounds, move system away from the MR scanner until the gauss alarm stops sounding.**

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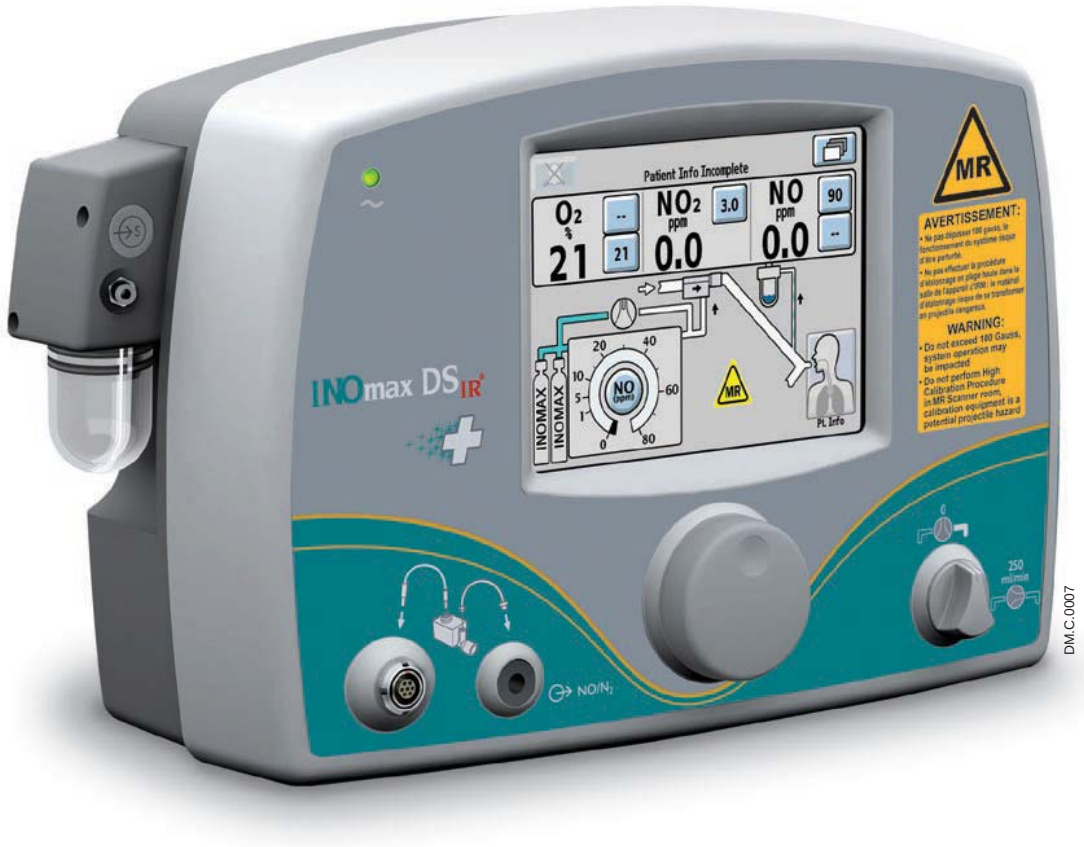
Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



Calibration

5/ Calibration

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI

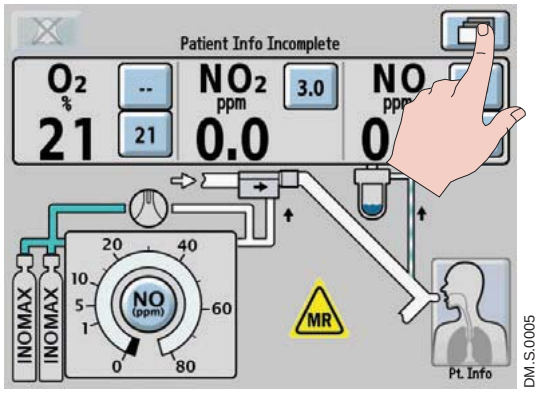
Calibration

5/ Calibration

5/ Calibration

WARNING: **Do not perform a high calibration procedure in the MR scanner room. Calibration equipment is a potential projectile hazard.**

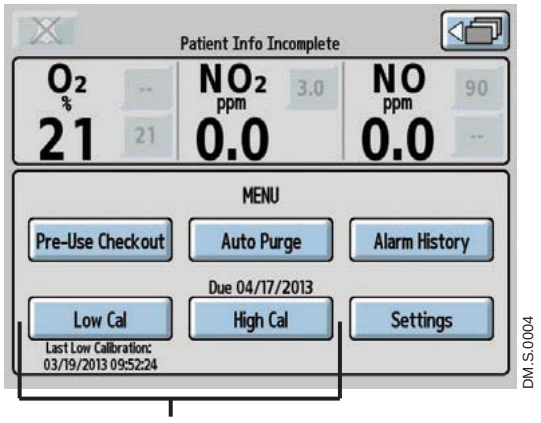
Note: During any calibration process, all other alarms remain active while monitoring alarms are disabled.



DM.S.0005

To access the calibration menu:

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



DM.S.0004

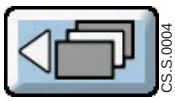
Calibration Area

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.


CS.S.0004

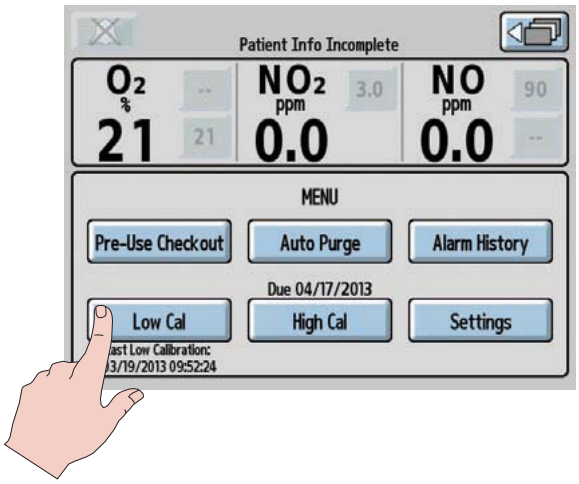
Instructions for completing a low and high calibration are on the following pages.

Low-Range Calibration

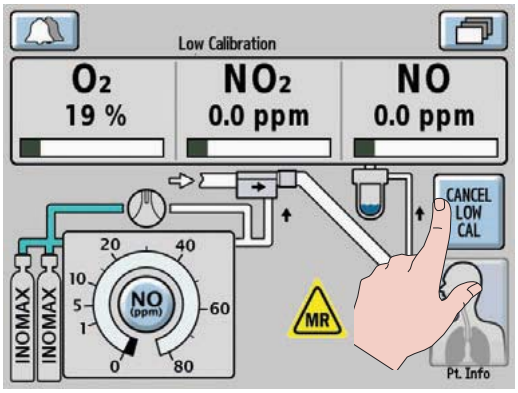
The low calibration of the monitor sensors uses room air to calibrate all three sensors at the same time. The system automatically draws in room air from an inlet port behind the water bottle, not the sample line. A low calibration is completed automatically when the INOmax DS_{IR} Plus MRI is turned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

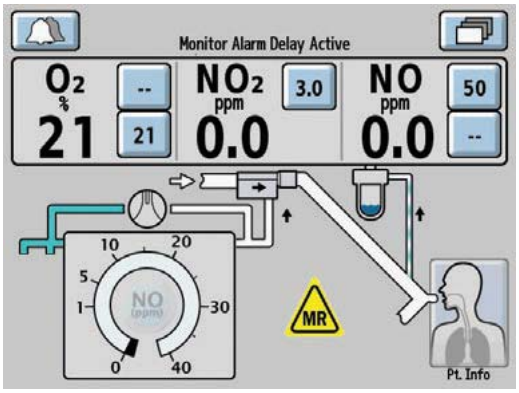


1. From the menu screen (second menu level), press the Low Cal button to initiate a low calibration.

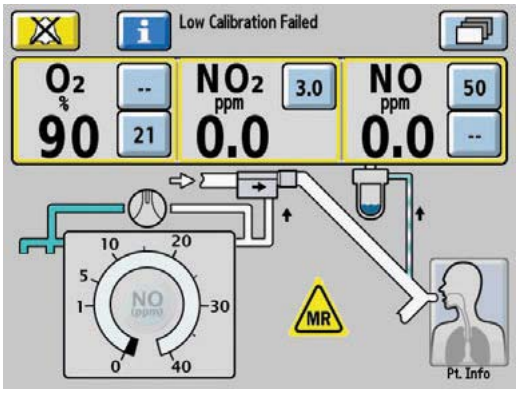


2. The calibration will take approximately three minutes, during which a progress bar for each sensor indicates the progress. A Low Calibration indicator will display in the alarm area of the screen during the low calibration.

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

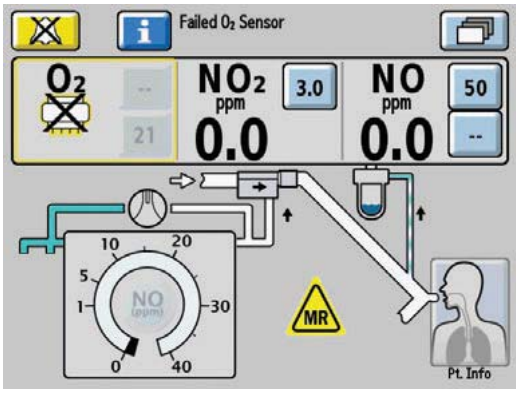


3. When the low calibration is successful, a single tone will be heard and the main screen will appear. A two minute Monitor Alarm Delay Active indicator will occur, preventing monitoring alarms from occurring while the measured value stabilizes. All system alarms are still active.



If the low calibration was unsuccessful, the INOmax DS_{IR} Plus MRI 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 4/ Alarms and Troubleshooting.)

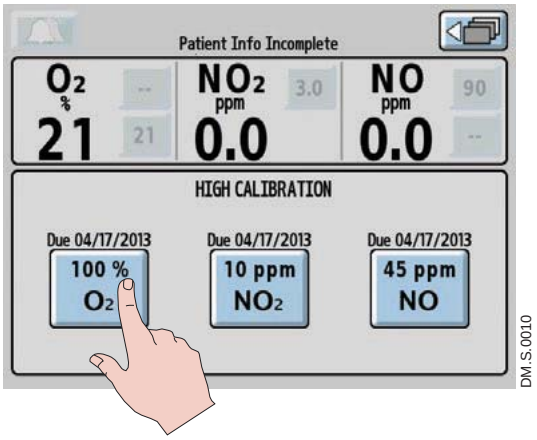
Oxygen Sensor High Calibration

WARNING: **Do not perform a high calibration procedure in the MR scanner room. Calibration equipment is a potential projectile hazard.**

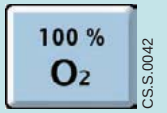
Caution: Never connect the sample line directly to a high pressure gas source (greater than 150 cmH_2O); this could damage the sampling system.

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

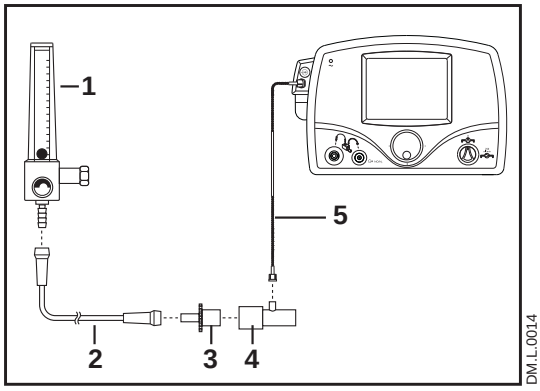
The oxygen high calibration requires a user supplied source of 100% oxygen.



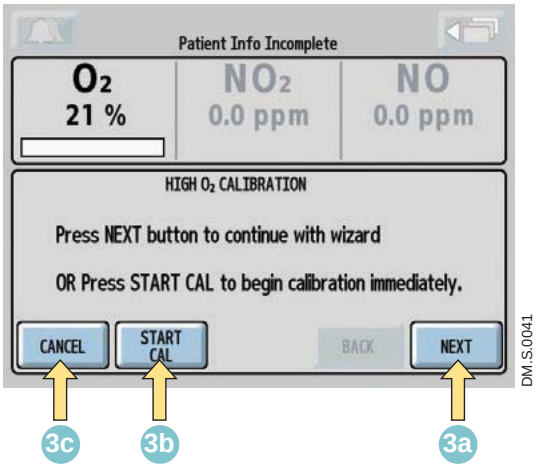
1. From the high calibration screen (third menu level), press the 100% O_2 button to initiate the O_2 high calibration wizard.



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



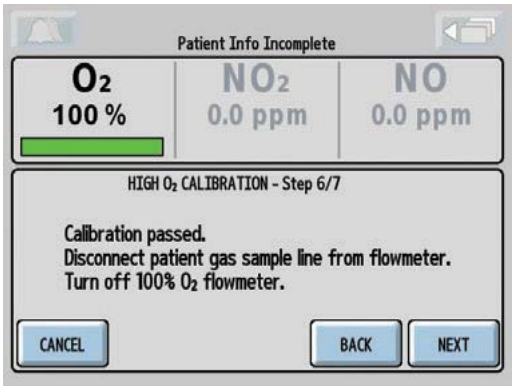
3a. To continue the high calibration wizard press the NEXT button.

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.

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.

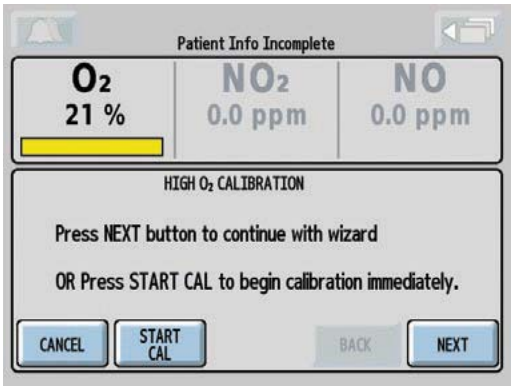
Note: If the CANCEL button is pressed during the high O_2 calibration process, the calibration will be cancelled and the user will be returned to the high calibration screen.



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.

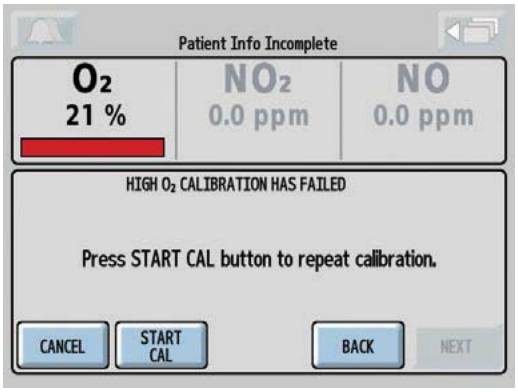
Disconnect the sample line from the calibration setup and turn OFF the O_2 flowmeter.



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 4/ Alarms and Troubleshooting 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.

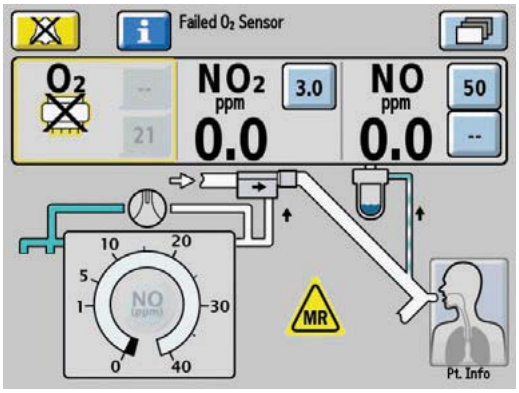
- Press the NEXT button to start the high calibration wizard.
- Press the START CAL button to start the calibration again.
- Press the CANCEL button to exit the O_2 high calibration screen.



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 4/ Alarms and Troubleshooting.)

NO Sensor High Calibration

WARNING: **Do not perform a high calibration procedure in the MR scanner room. Calibration equipment is a potential projectile hazard.**

Caution:

- When performing a high calibration, make sure to select the correct calibration gas (INOcal NO, 45 ppm, P/N BOM-COM-0150) 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 5-1

INOcal calibration gas kit sample tubing

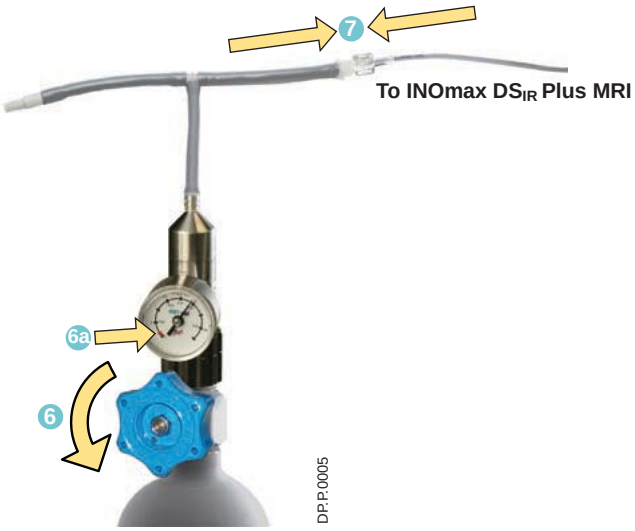
When using the calibration tubing kit (P/N 50239), which is supplied with the INOcal regulator kit (P/N 10090), ensure that the beige one-way valve supplied with the tubing is installed and oriented as indicated in Figure 5-1.

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.

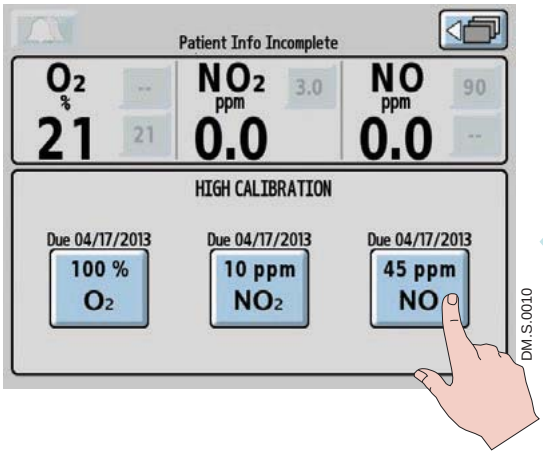
NOTE: Confirm water bottle, water separator cartridge and patient gas sample line are in place.



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

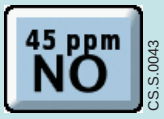
6a. If the pressure is in the red or black zone (0-25 psig) select another INOcal cylinder.

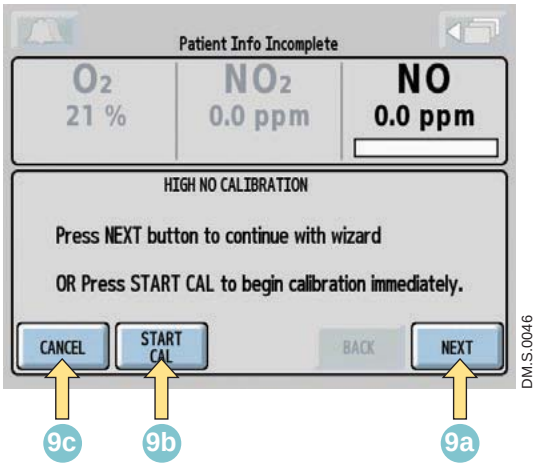
7. Attach tubing kit to patient gas sample line.



Note: 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.

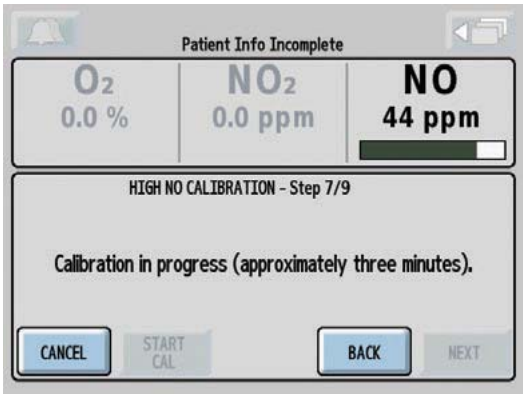




9a. To continue the high calibration wizard, press the NEXT button.

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

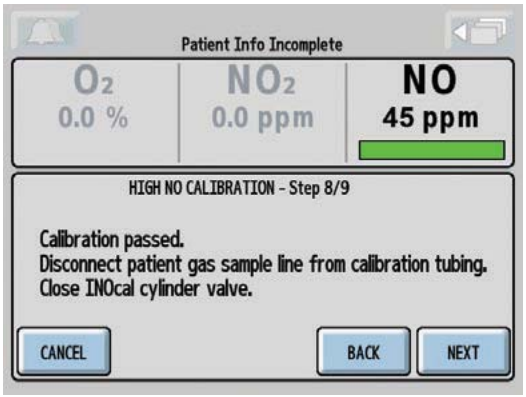
9c. To exit the NO high calibration, press the CANCEL button.



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.

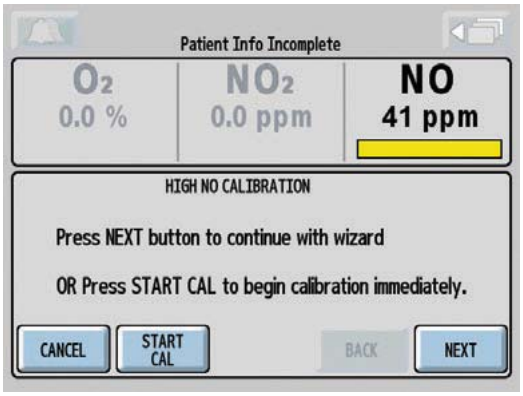
When the NO high calibration is successful, a single tone will be heard and the progress bar will turn green. Press the NEXT button to return to the high calibration screen.



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

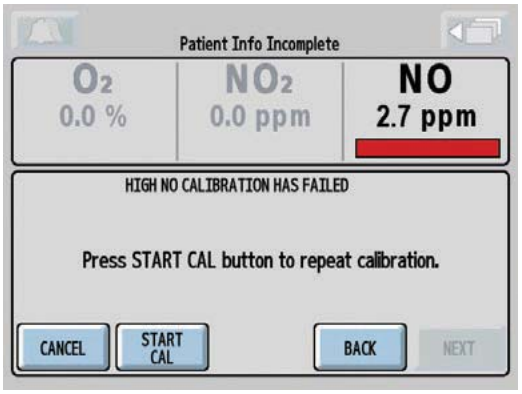
10. Disconnect the patient gas sample line from the calibration tubing and close the INOcal cylinder valve.

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 4/ Alarms and Troubleshooting 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.

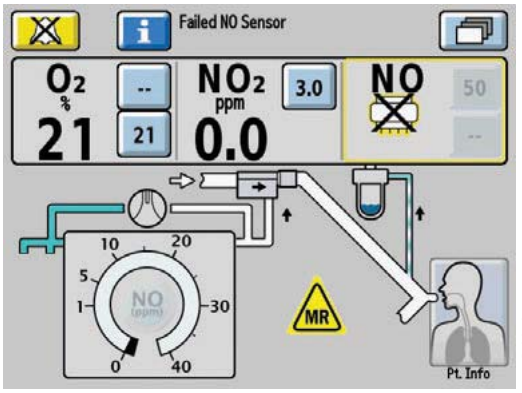
- Press the NEXT button to start the high calibration wizard.
- Press the START CAL button to start the calibration again.
- Press the CANCEL button to exit the NO high calibration screen.



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 4/ Alarms and Troubleshooting.)

NO_2 Sensor High Calibration

WARNING: **Do not perform a high calibration procedure in the MR scanner room. Calibration equipment is a potential projectile hazard.**

Caution:

- When performing a high calibration, make sure to select the correct calibration gas (INOcal NO_2, 10 ppm, P/N BOM-COM-0162) 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 5-2

INOcal calibration gas kit sample tubing

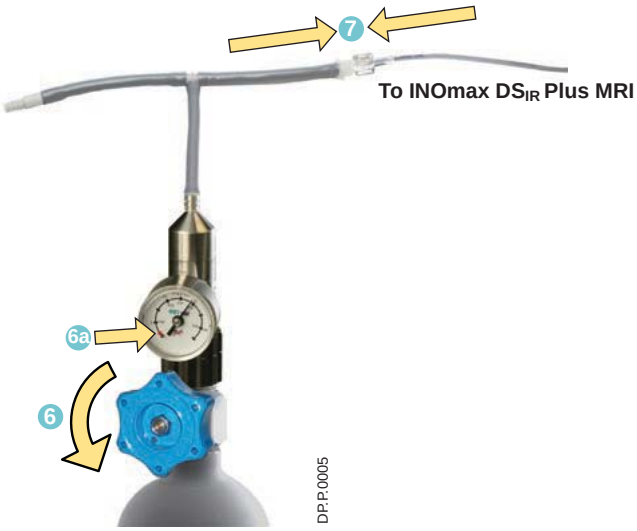
When using the calibration tubing kit (P/N 50239), which is supplied with the INOcal regulator kit (P/N 10090), ensure that the beige one-way valve supplied with the tubing is installed and oriented as indicated in Figure 5-2.

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.

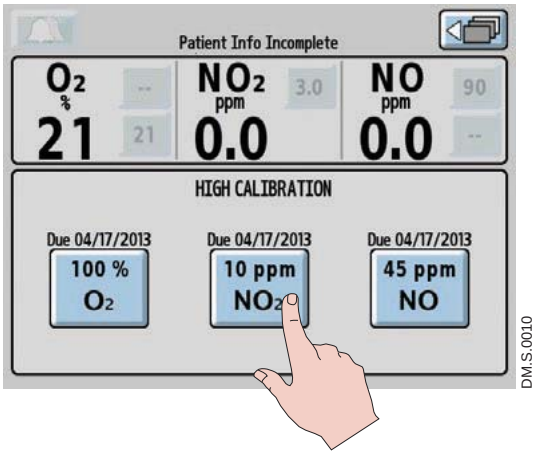
NOTE: Confirm water bottle, water separator cartridge and patient gas sample line are in place.



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

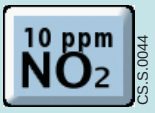
6a. If the pressure is in the red or black zone (0-25 psig) select another INOcal cylinder.

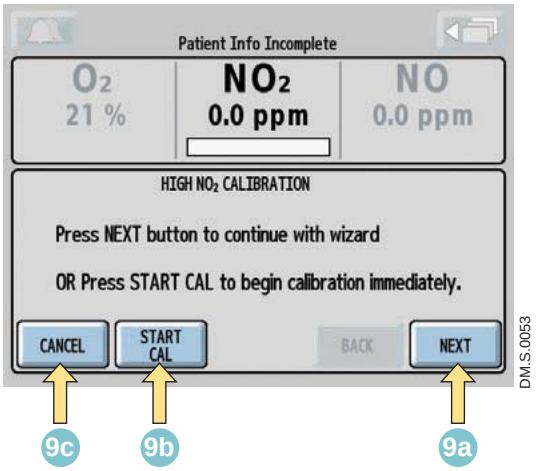
7. Attach tubing kit to patient gas sample line.



Note: 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.

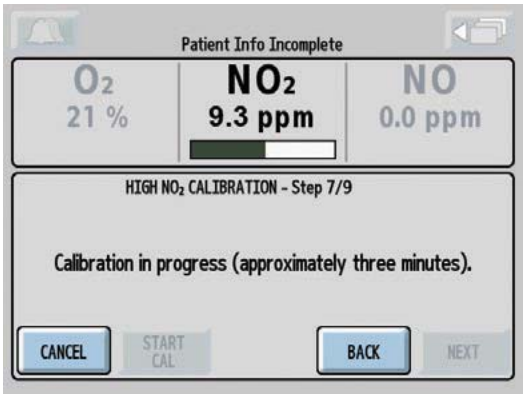




9a. To continue the high calibration wizard, press the NEXT button.

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

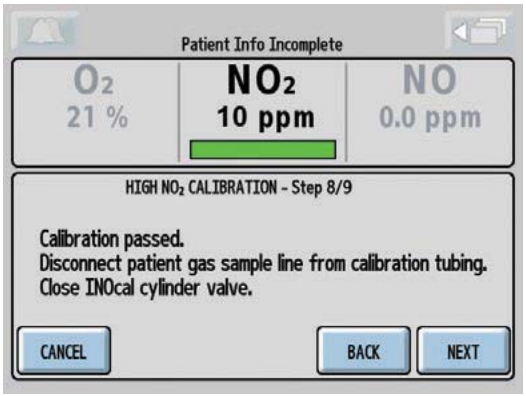
9c. To exit the NO_2 high calibration wizard, press the CANCEL button.



DM.S.0054

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.



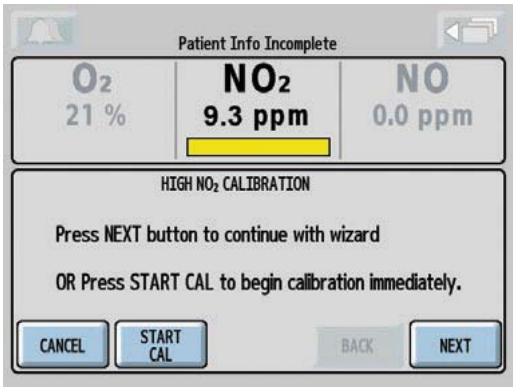
DM.S.0055

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.

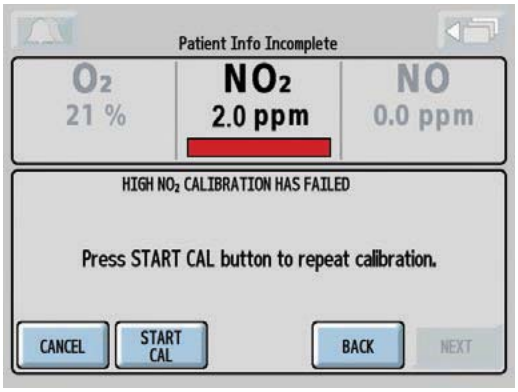
A Monitor Alarm Delay Active indicator will occur anytime the user exits the calibration screen, even if a calibration was not initiated. All other alarms are still active (see Section 4/ Alarms and Troubleshooting for additional information).



DM.S.0056

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.

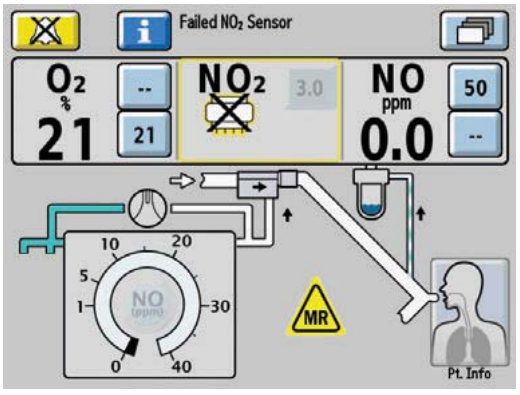


DM.S.0050

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.



DM.S.0057

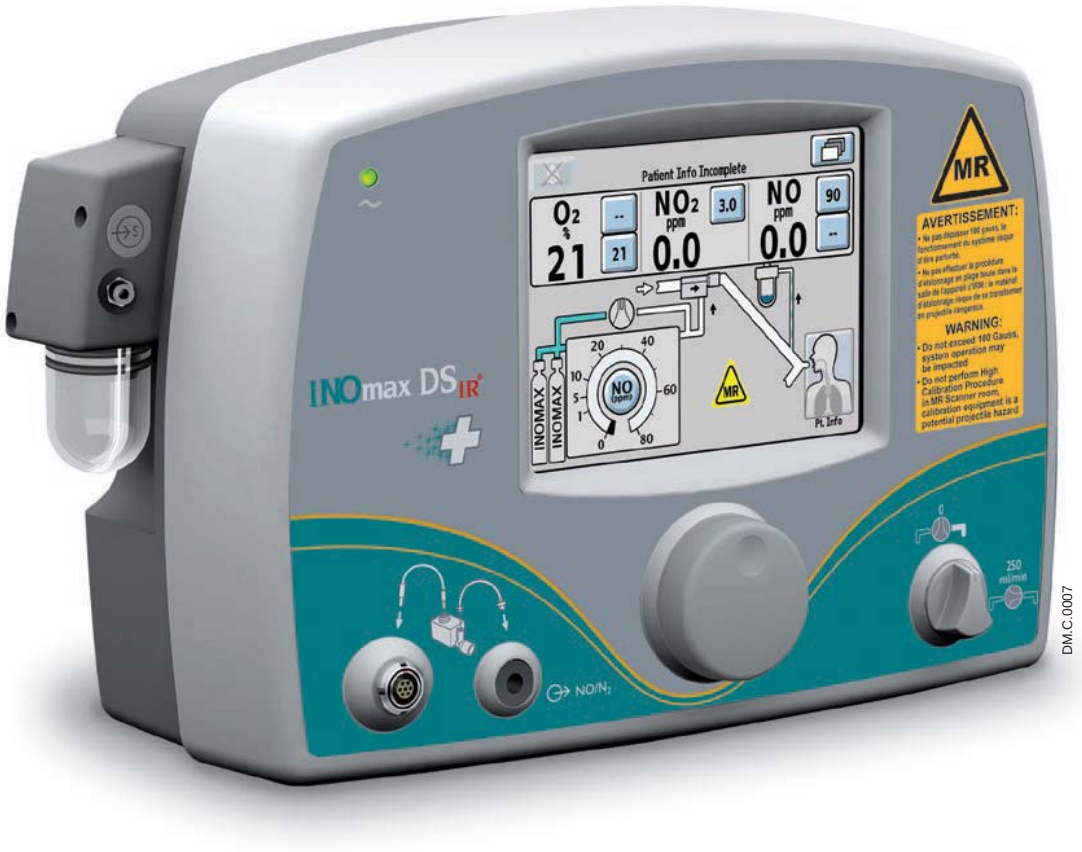
If the NO_2 sensor has failed the display indicates the failed sensor symbol in the monitoring area of that sensor.

Repeat calibration. (Press the alarm help button for on-screen alarm help or see Section 4/ Alarms and Troubleshooting.)

CS.S.0008

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



DM.C.0007

Maintenance

6/ Maintenance

Part No. 20765 Rev-01
2015-08

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI

Maintenance

6/ Maintenance

6/ Maintenance

User Maintenance Schedule

Frequency	Maintenance
During Patient Use	1. Check the INOMAX cylinder pressure. A cylinder with less than 200 psig should be replaced. 2. Empty the water bottle as needed.
Start of each patient	Must perform the Pre-Use Procedure.
Between each patient	1. Sterilize and/or disinfect the MR injector module. 2. Clean water 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. 3. Check the GaussAlert™ function.

Testing the GaussAlert Function

WARNING:

- **Keep the test magnet tool away from pacemakers, ICDs and other implanted medical devices.**
- **If either GaussAlert fails testing (does not alarm when the magnet tool is used), contact the Authorized Representative listed on the back cover of the operation manual to request a replacement INOmax DS_{IR} Plus MRI system.**
- **Do not use the INOmax DS_{IR} Plus MRI if neither gauss alarm is functional.**

Caution:

- Do not use or store the test magnet tool in the MR scanner room.
- Keep the test magnet tool away from the INOmax DS_{IR} Plus MRI user screen. Neodymium magnets can damage computer monitors, watches, pulse oximeters, and other mobile handheld devices.
- Keep the test magnet tool away from magnetic media such as credit cards, magnetic I.D. cards, cassette tapes, video tapes or other such devices.

1. Use the GaussAlert test magnet tool (PN 50192) to test alarm function.
2. Place the test magnet tool on the GaussAlert alarm in the area identified in Figure 6-1.
3. The alarm will activate and a short flash (less than two seconds) of the LED indicates proper function.
4. Move the test magnet tool away from the GaussAlert until the alarm stops sounding.
5. Repeat this procedure on the second GaussAlert.

Note: If the LED stays illuminated the entire time the gauss alarm is ON or does not illuminate at all, the battery needs to be replaced. Contact the Authorized Representative listed on the back cover of the operation manual to request a replacement INOmax DS_{IR} Plus MRI system.

Figure 6-1

Cleaning the INOmax DS_{IR} Plus MRI

Caution:

- Do not autoclave or gas sterilize the INOmax DS_{IR} Plus MRI.
- Do not clean with the power connected and the INOmax DS_{IR} Plus MRI turned ON.
- Be sure that the INOmax DS_{IR} Plus MRI is completely dry before using.
- Do not saturate the INOmax DS_{IR} Plus MRI 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} Plus MRI OFF before cleaning.
- Clean the outer surface of the INOmax DS_{IR} Plus MRI 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%

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

Cleaning Water Bottle

Caution: If alcohol is used to clean water 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 (bottle dries out).

Procedure

- Clean water bottle with a soft cloth dampened in a mild soap and water solution or with isopropyl alcohol (70%).
- Allow water 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} Plus MRI. Do not use these products to decontaminate the INOmax DS_{IR} Plus MRI or any ancillary products used with the INOmax DS_{IR} Plus MRI.

Cleaning the GaussAlert™

Use a soft cloth dampened with water to clean the enclosure. Use an aqueous solution of up to 75% isopropyl alcohol for more efficient cleaning. Disinfection may be accomplished with the use of denatured alcohol.

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.
- Be sure that the INOmeter 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.

MR Injector Module Sterilizing and/or Disinfecting

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

Caution: Remove the the injector module cable prior to sterilizing or disinfecting the injector module.

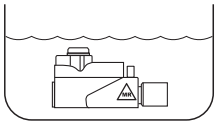
If the MR injector module has been used in the dry part of the breathing circuit, the MR injector module should be sterilized and/or disinfected in 70% ethyl alcohol after each patient use.

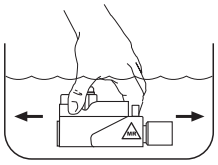
Autoclave Sterilizing the MR Injector Module

1. *Disconnect the electrical cable and the injector tube before autoclaving.*
2. Autoclave the MR injector module at 134° C for three minutes at 27 psig.
3. After sterilization, examine the parts.

Disinfecting the MR Injector Module

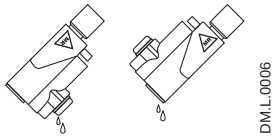
1. Fill a container with 70% ethyl alcohol.
2. Totally submerge the MR injector module in the 70% ethyl alcohol for at least 30 minutes. If debris is noticed on the hot wire sensor, gently agitate the module in the alcohol bath.
3. Remove the MR injector module from the liquid and drain the excess alcohol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





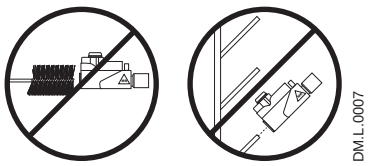
Note: If rinsing is required, use a separate bath filled with distilled water.

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



Note:

- Do not insert anything into the MR 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 Technical Support.



Note: Patient circuit adapters, patient gas sample line, MR 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:

- **Do not remove rear sensor cover in the MR scanner room due to potential projectile hazard.**
- **Handle and dispose of sensors according to facility biohazard policies. Do not incinerate.**

Figure 6-2

To replace any one of the three sensors:

Remove the rear sensor cover by turning the two screws counterclockwise until loose (see Figure 6-2).

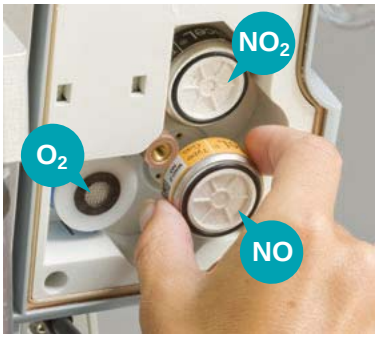


Figure 6-3

Grasp the sensor to be replaced on both sides and gently pull it from its socket (see Figure 6-3).

Note:

- The shorting wire must be removed from the NO_2 sensor before replacing (see Figure 6-7).
- Make sure all of the sensor O-rings are present and seated properly.

Figure 6-4

To install replacement NO or NO_2 sensor, align the pins with the socket and press it into place (see Figure 6-4).

To install O_2 sensor, remove the shorting button (see Figure 6-5) and insert the contact end (open end with three gold rings) into recess until it seats (no specific orientation is necessary).

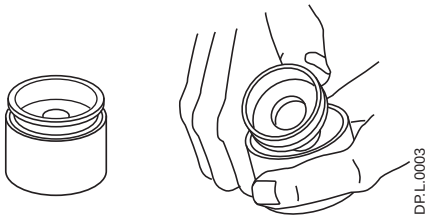


Figure 6-5

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

Figure 6-6

Replace the sensor cover and tighten the two screws clockwise (see Figure 6-6).

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 6-7
NO_2 Shorting Wire

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

Replacing the Water Separator Cartridge

Figure 6-8

The disposable water separator cartridge on the rear of the water bottle 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 6-8).
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 6-9

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} Plus MRI prior to removing from the cylinder valve.

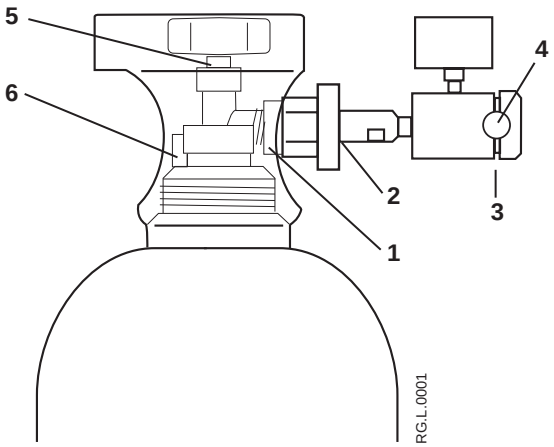
2. Remove the old CGA 626 tip by pulling on the tip 2a and turning it counterclockwise 2b (see Figure 6-9).
3. Ensure the threads are clean on the regulator tip (if required, use a lint free cloth).
4. Install the new tip:

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

Cylinder Leak Check

If a leak is suspected during the high pressure leak test (see Section 2/ Automated Pre-Use Checkout; High Pressure Leak Test), the following steps can be taken to check for leaks (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 6-10

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 6-10); if bubbles form, there is a leak.
3. If there are no bubbles, the leak may be inside the INOmax DS_{IR} Plus MRI and cannot be repaired.
   Replace the INOmax DS_{IR} Plus MRI 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:

- Replace 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.

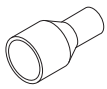
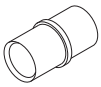
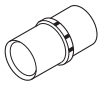
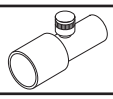
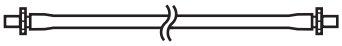
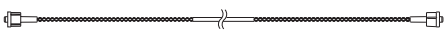
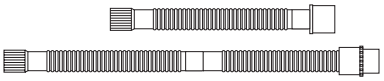
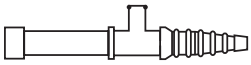
If an equipotential grounding system is installed, the ground system should be tested per chapter four of NFPA 99.

Figure 6-11

Parts and Accessories

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

Parts/Accessories	Part Number
Alarm, GaussAlert™, 100 Gauss	80629
Calibration Gas, INOcal NO, 45 ppm	BOM-COM-0150
Calibration Gas, INOcal NO_2, 10 ppm	BOM-COM-0162
Calibration Tubing Kit	50239
Cart, INOmax DS_{IR} Plus MRI, Canada	10088
Injector Module, MR Conditional	90713
Injector Module Cable, MR Conditional	90850
INOblender	10077
Magnet, GaussAlert Test Tool	50192
Manual, INOmax DS_{IR} Plus MRI Operation, English	20765
Manual, INOmax DS_{IR} Plus MRI Operation, French-Canadian	20870
Regulator, INOMAX CGA 626	10006
Regulator Kit, INOcal	10090
Sensor, O_2	80043
Sensor, NO	90844
Sensor, NO_2	90845
Tip, CGA 626 INOMAX Regulator	1605-3149-000
Water Bottle	90137

Disposables		Description
	AD.L.0001	Adapter 15M Fits 4.5 mm ID Tubing
	AD.L.0002	Adapter, 22F X 15M
	AD.L.0003	Adapter, 22M/15F X 22M/15F
	AD.L.0004	Adapter, Cuff, 22 mm ID X 22 mm ID
	AD.L.0005	Adapter, Gas Sample Tee
	AD.L.0006	Adapter, 90 degree Sample Port
	AD.L.0007	Disk Filter, 1.0 micron, glass fiber
	AD.L.0008	MR NO/N_2 Injector Tube
	AD.L.0009	MR Patient Gas Sample Line (Nafion)
	AD.L.0010	Neonatal Tubing, 10 mm (2 pieces)
	AD.L.0011	Pediatric Extension, 150 mm (six inches)
	AD.L.0012	Sample Tee, O_2 Tubing
	AD.L.0013	Water Separator Cartridge

(Note: Physical appearance may vary slightly)

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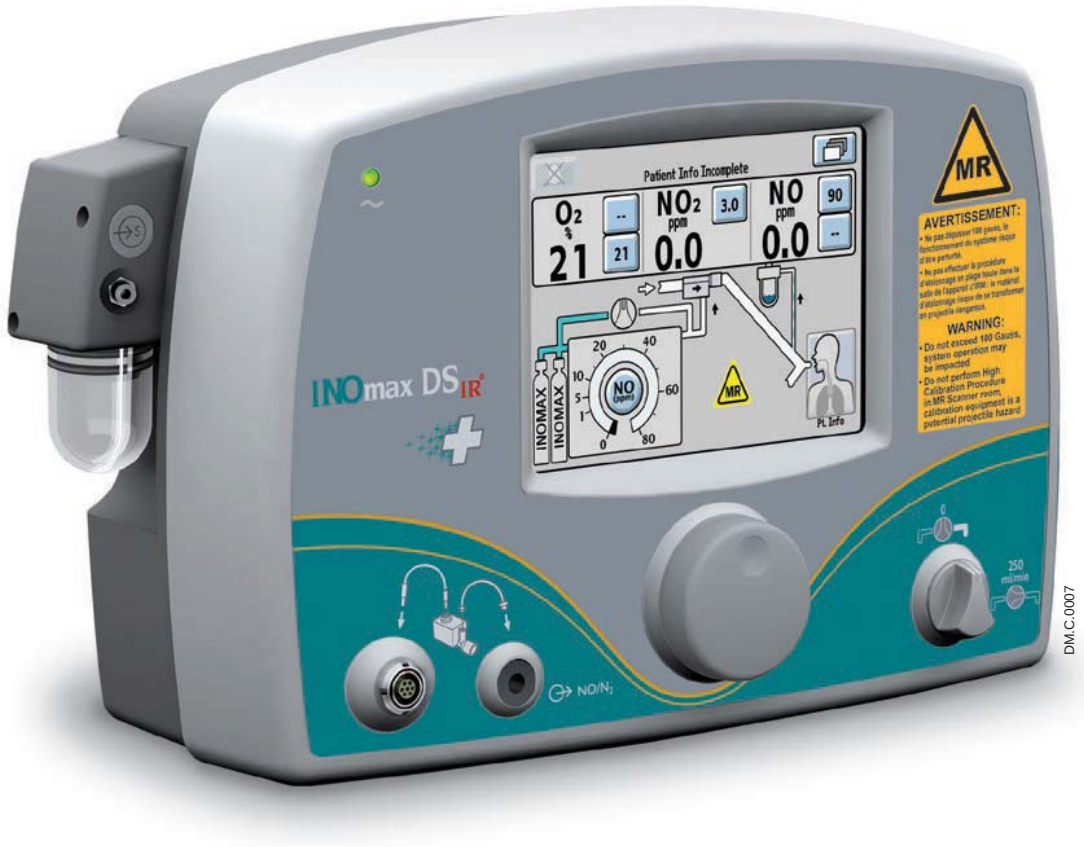
Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



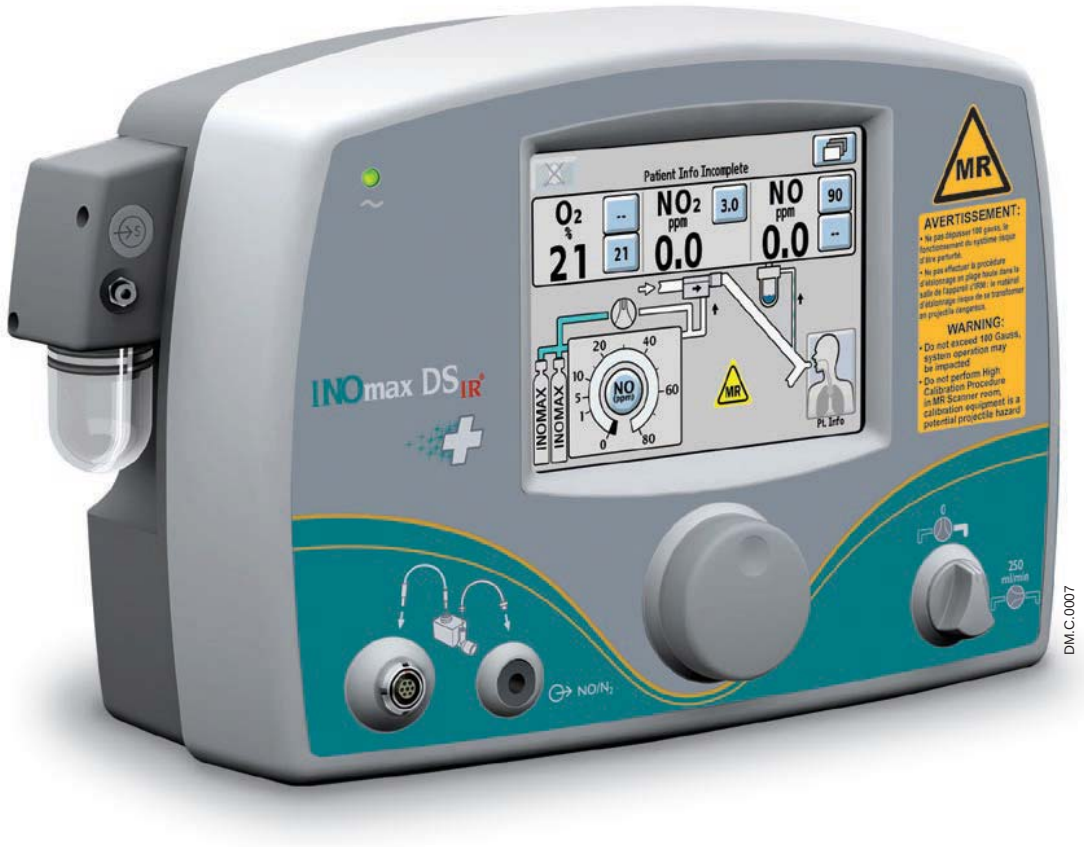
Product Specifications

7/ Product Specifications

Part No. 20765 Rev-01
2015-08

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



Product Specifications

7/ Product Specifications

Part No. 20765 Rev-01
2015-08

7/ Product Specifications

WARNING:

- **The target patient population is controlled by the drug labeling for INOMAX and is currently neonates. The INOmax DS_{IR} Plus MRI is not intended to be used in other patient populations.**
- **Outside of the United States, use of the INOmax DS_{IR} Plus MRI is limited to the use in accordance with INOMAX nitric oxide for inhalation prescribing information as established with the national health authority.**

The INOmax DS_{IR} Plus MRI is designed to function in the parameter ranges listed in this section. Use outside of these ranges is not recommended.

Ventilator Compatibility

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

The INOmax DS_{IR} Plus MRI is compatible with the ventilators listed below:

Ventilators/Breathing Systems validated for use in the United States		
Manufacturer	Model	MR Conditional
Bio-Med Devices	MVP-10	•
CareFusion (formerly Pulmonetic Systems)	LTV 1200 MRI	•
Nasal Cannula	Salter Labs, Infant, REF 1601, with 7 foot supply tube (or equivalent)	•
Maquet	Servo-i	•

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

MR 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 (including: INOmax DSIR Plus MRI, INOblender, cart, 2 regulators and 2 INOMAX cylinders)	
Nominal Weight:	80 kg (176 lb)
Nominal Width and Depth:	53 cm (21 inch) W x 56 cm (22 inch) D
Nominal Height:	149 cm (58 inch) H

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:	Disabled.
Ethernet Port:	For service only. Not for use when patient is connected.
RS 232:	Enables serial communications for use with hospital electronic health record (EHR) system.
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.

GaussAlert™ Specifications

Standard Factory Preset Alarm Thresholds:	100 Gauss (10mT)
Audio Alarm Typical Sound Pressure:	92dB (A) at 24 inches
Audio Alarm Frequency:	2900 Hz +/- 250Hz
Typical Battery life:	5 years
Sensor Type:	Mechanical with panoramic uniform sensitivity

MR Signal-to-Noise Ratio and Artifact Dimension Analysis

In testing with gradient and radiofrequency (RF) intensive scan sequences provided by scanner manufacturers according to IEC 60601-2-33, a less than 0.2 cm geometric difference was observed in a spherical, Bayol-oil phantom. Measured Signal to Noise Ratio (SNR) losses were under 20%.

Images were analyzed using the software OsiriX v.3.8.1 for quantitative analysis. Geometric dimensions of the phantom were measured to assess any geometric distortion, and these values were compared between the scans with and without the INOmax DS_{IR} Plus MRI system present. Images of the spherical phantom were quantitatively analyzed where geometric dimensions were measured to assess geometric distortion and the signal-to-noise ratio was calculated. These values were compared between scans that were conducted with and without the INOmax DS_{IR} Plus MRI system present in the MR scanner room.

The INOmax DS_{IR} Plus MRI compatibility test results are as follows:

Artifact Dimensional Analysis	1.5 T	The maximum dimensional change in images acquired during the operation of the INOmax system was 0.12 cm
	3 T	The maximum dimensional change in images acquired during the operation of the INOmax system was 0.11 cm
Image Quality Signal-to-Noise ratio analysis	1.5 T	The S/N change was -16% to +2% compared to images without the MR Conditional INOmax DS_{IR} Plus MRI system present.
	3 T	The S/N change was -18% to +1% compared to images without the MR Conditional INOmax DS_{IR} Plus MRI system present.

The operation of the INOmax DS_{IR} Plus MRI in the MR scanner room testing showed limited effects on the acquired image quality with respect to signal-to-noise ratio and geometric distortion when using sequences that are expected to be more susceptible to RF and gradient artifacts.

Note: The test results presented here were obtained with the INOmax DS_{IR} Plus MRI operating on battery power.

Electromagnetic Compatibility Information

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The INOmax DS_{IR} Plus MRI system (with GaussAlert™ alarms) is intended for use in the electromagnetic environment specified below. The user of the INOmax DS_{IR} Plus MRI system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF radiated emissions per CISPR 11 Ed. 5.1b:2010	Group 1 Class B	The INOmax DS_{IR} Plus MRI 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. The INOmax DS_{IR} Plus MRI 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.
RF conducted emissions per CISPR 11 Ed. 5.1b:2010	Class B	The INOmax DS_{IR} Plus MRI 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} Plus MRI system (with GaussAlert™ alarms) is intended for use in the electromagnetic environment specified below. The user of the INOmax DS_{IR} Plus MRI 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	± 0.5kV, ± 1.0kV and ± 2.0kV for power supply lines	± 0.5kV, ± 1.0kV and ± 2.0kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-to-line: ± 0.5 kV, ± 1 kV Line-to-earth: ± 0.5 kV, ± 1 kV, ± 2 kV	Line-to-line: ± 0.5 kV, ± 1 kV Line-to-earth: ± 0.5 kV, ± 1 kV, ± 2 kV	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	3 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} Plus MRI system (with GaussAlert™ alarms) is intended for use in the electromagnetic environment specified below. The user of the INOmax DS_{IR} Plus MRI system (with GaussAlert alarms) 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]	3 Vrms (V1)	Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the INOmax DS_{IR} Plus MRI system than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2*\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms (V2)	$d=1.2*\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 26MHz to 1 GHz	10 V/m 26 MHz to 1 GHz	$d=1.2*\sqrt{P}$ 80 MHz to 800 MHz $d=2.3*\sqrt{P}$ 800 MHz to 2.5 GHz
	3V/m 1GHz to 2.5GHz	3V/m 1GHz to 2.5GHz	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} Plus MRI system is used exceeds the applicable RF compliance level above, the INOmax DS_{IR} Plus MRI 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} Plus MRI 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} Plus MRI system (with GaussAlert™ alarms)

The INOmax DS_{IR} Plus MRI system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the INOmax DS_{IR} Plus MRI system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the INOmax DS_{IR} Plus MRI 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.

RS 232 Data Output

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

WARNING:

- **Do not use the RS 232 data output while in the MR scanner room.**
- **INOmax DS_{IR} Plus MRI 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.**
- **RS 232 cables must be shielded. The RS 232 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} Plus MRI connector. The RS 232 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} Plus MRI 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.

Definitions

Acronym/Definition	Description
CRC	Cyclic Redundancy Check
RS 232	RS 232 (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

RS 232 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

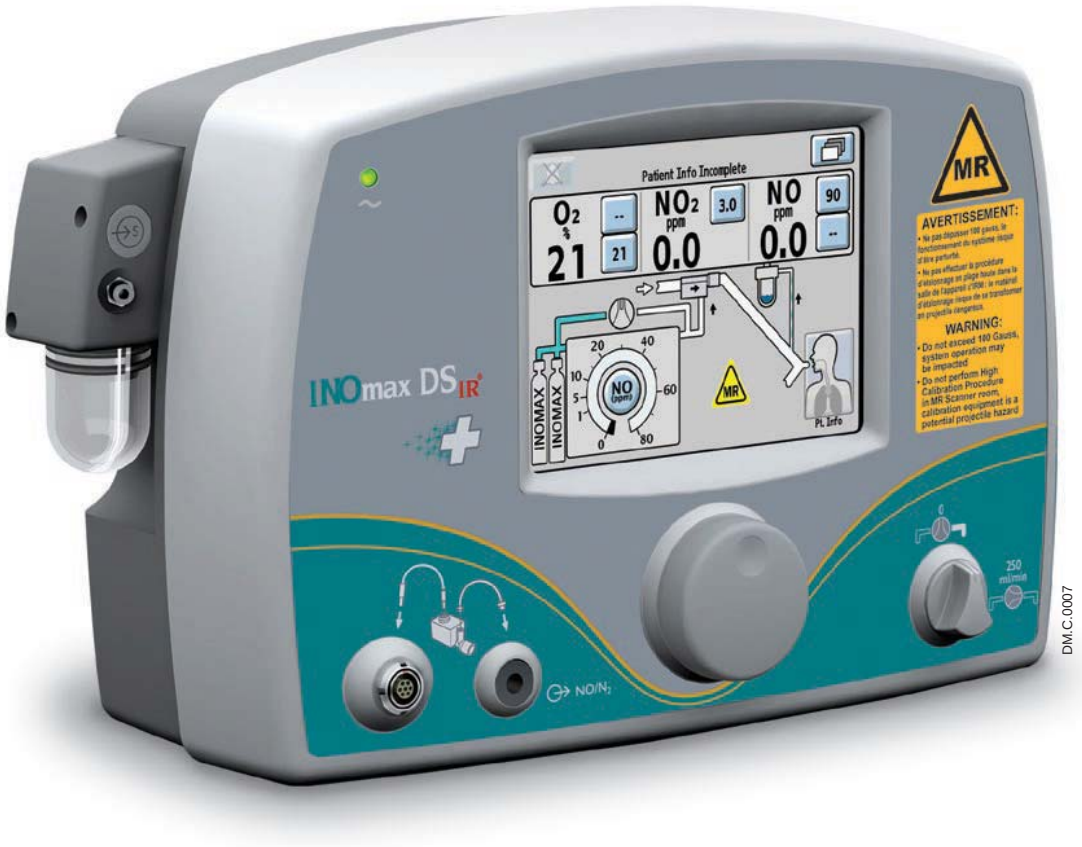
Data output includes:

- 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.

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI

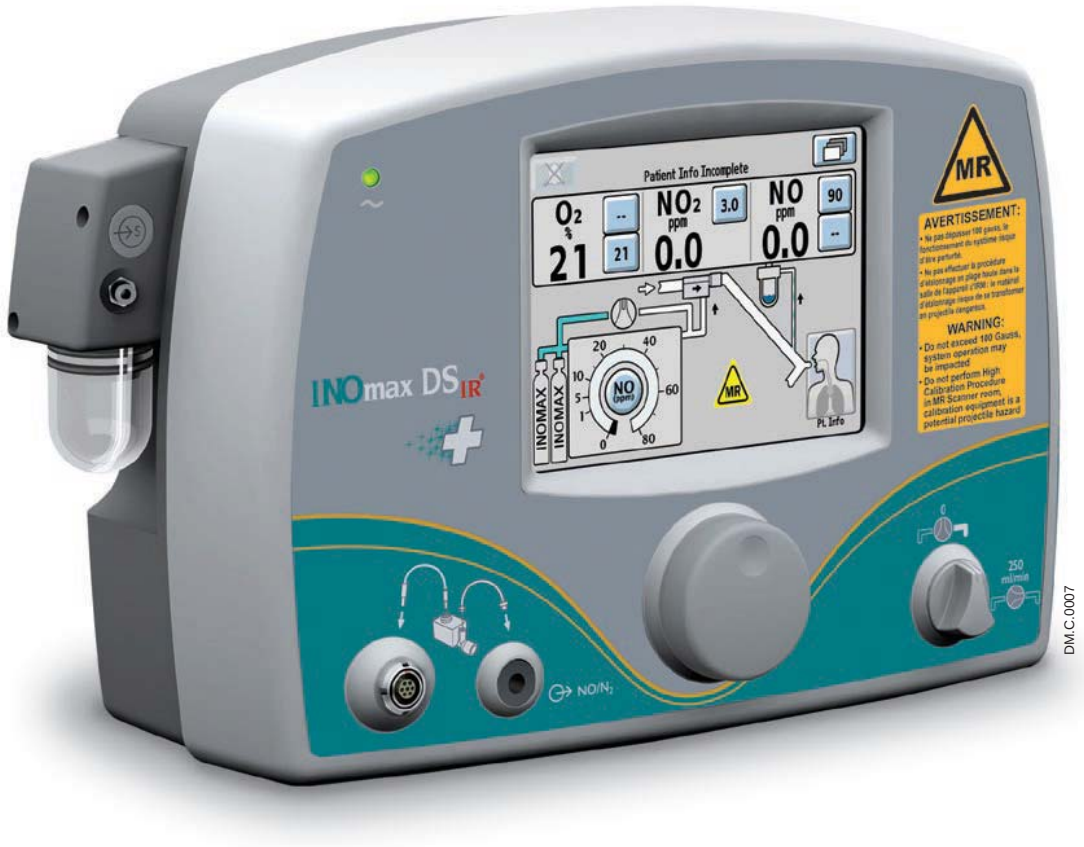


8/ Appendix

Appendix

Mallinckrodt™ Pharmaceuticals

INOmax DS$_{IR}$® Plus MRI



8/ Appendix

Part No. 20765 Rev-01
2015-08

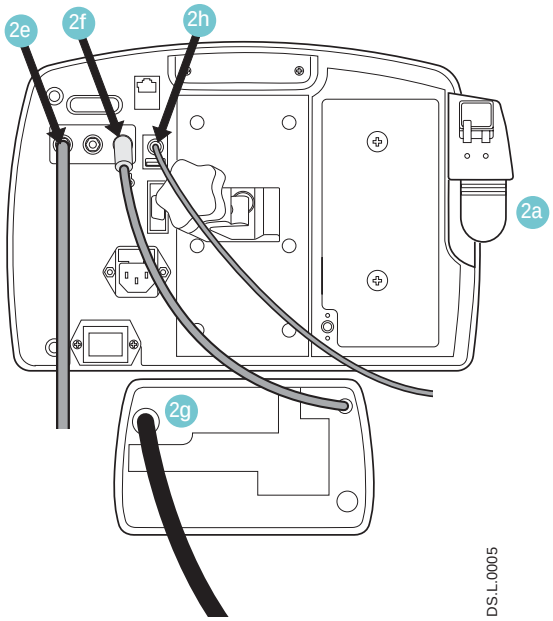
8/ Appendix

Manual Pre-Use Checkout

WARNING:

- **Only use a size “88” (1,963 liters) cylinder that is marked “MR Conditional. Keep cylinder at 100 gauss or less.” with the INOmax DS_{IR} Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.**
- **The INOmax DS_{IR} Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.**

The following instructions are provided for when the on-screen pre-use wizard is not used.



1. Turn device ON, low calibration will begin and complete (Continue with steps 2-4 while calibration completes).
2. **Initial Connections:**

   Confirm attachment of the following:

   a. Water separator cartridge, water bottle, and MR conditional patient gas sample line in place.

   b. MR conditional injector module cable and tubing are connected.

   c. Plug in power cord and verify AC power light is ON.

   d. Regulator to INOMAX cylinder.

   e. Regulator hose to INOmax DS_{IR} Plus MRI inlet.

   f. INOblender hose connected and white lock in place.

   g. Oxygen source (50 psig) to back of INOblender.

   h. IR cable in place.
3. Assemble pre-use set-up connectors (see Figure 8-1). Do Not turn on O_2 flowmeter yet.
4. **High Pressure Leak Test:**

   Open/close INOMAX cylinder valve.

   a. Verify, at least 34.5 bar (500 psig) cylinder pressure.

   b. Verify, no decrease in cylinder pressure for 30 seconds.

6b

DM.P.0011

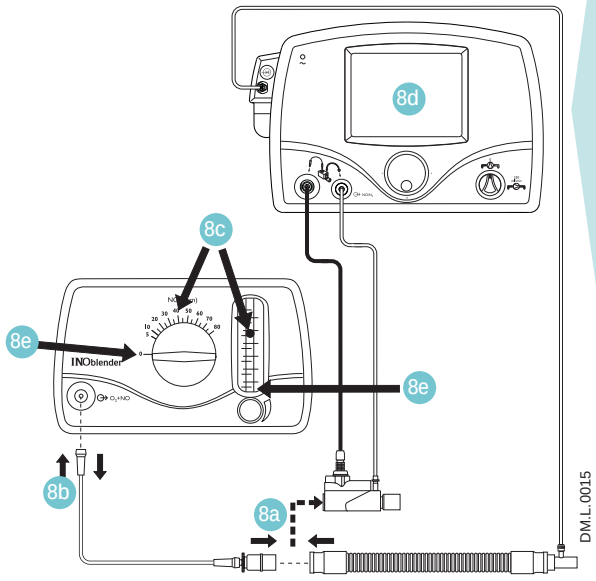
6e

DM.P.0012

5. **Manual Purge/Alarm Verification:**
   a. Press CANCEL to exit pre-use wizard (low calibration should be complete to continue).
   b. Verify INOMAX cylinder valve is closed.
   c. Set O_2 flowmeter to 10 L/min.
   d. Purge INOmax DS_{IR} Plus MRI.
      - Set the INOMAX dose to 40 ppm.
      - “Cylinder Valve Closed” alarm will occur.
      - Continue until cylinder gauge pressure drops 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.
   e. Turn INOMAX dose to zero.
   f. Open INOMAX cylinder valve.
6. **Integrated Pneumatic Backup Test:**
   a. Verify pre-use assembly flowmeter set to 10 L/min.
   b. Turn INOmax DS_{IR} Plus MRI backup switch ON.
   c. Allow monitored values to stabilize.
   d. Verify measured values:

NO (ppm)	14 - 26
NO_2 (ppm)	≤ 1.0

   e. Turn backup switch OFF.



7. **Performance Test:**
   a. Verify O_2 flowmeter is set to 10 L/min.
   b. Set INOMAX dose to 40 ppm.
   c. Verify monitored values:

Acceptable NO Value (ppm)	35 - 45
Acceptable NO_2 Value (ppm)	< 1.5
Acceptable FiO_2 (%)	95 ± 3

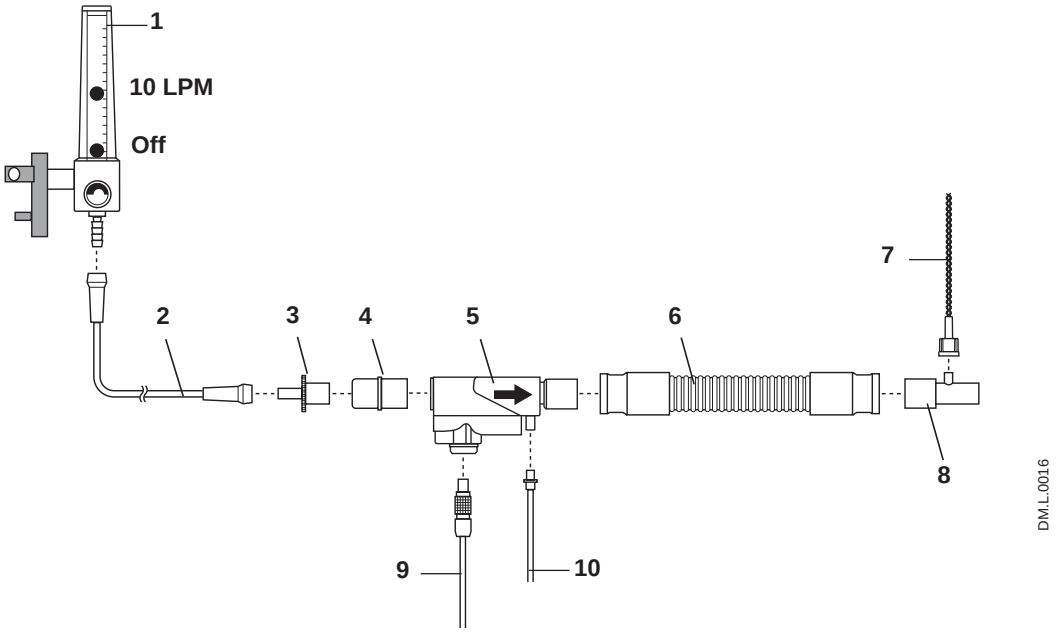
   d. Set INOMAX dose to 0 ppm.
      • "Set Dose is Zero, Please Close Cylinder Valve" reminder will appear- DO NOT close cylinder valve at this time, dismiss reminder.
   e. Turn oxygen flowmeter OFF.

8. **INOblender Test:**
   a. Remove injector module from pre-use assembly and reconnect tubing.
   b. Remove O_2 tubing from flowmeter and attach to INOblender outlet.
   c. Set INOblender flow to 10 L/min, INOMAX dose to 40 ppm.
   d. Verify monitored values on the INOmax DS_{IR} Plus MRI.

Acceptable NO Value (ppm)	32 - 48

   e. Set INOblender dose and flow to 0.

Pre-Use Assembly



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

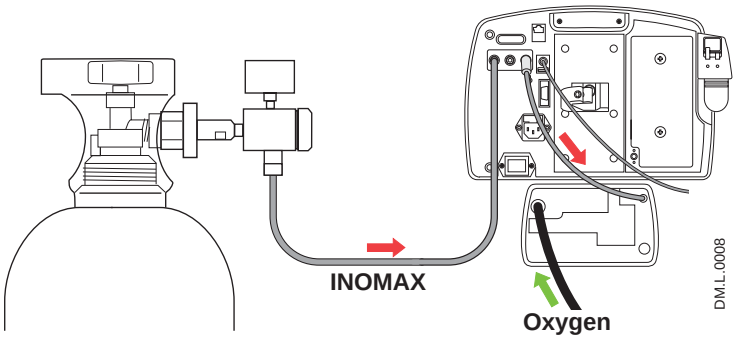
Figure 8-1

Additional Dose Setting Information

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.

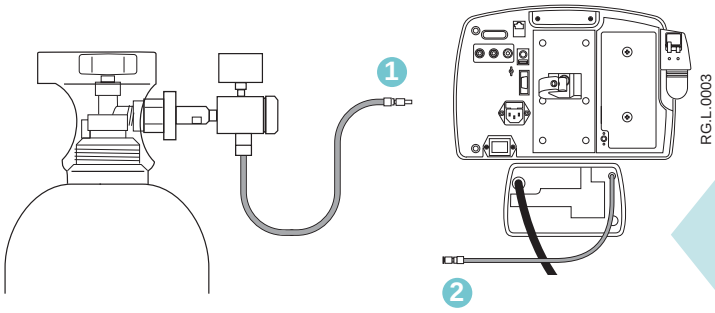
Dose Setting Range	Dose Change Per Click
1 to 40 ppm	1 ppm
40 to 80 ppm	2 ppm

Bypassing the INOmax DS_{IR} Plus MRI and Connecting the INOblender Directly to the INOMAX Regulator



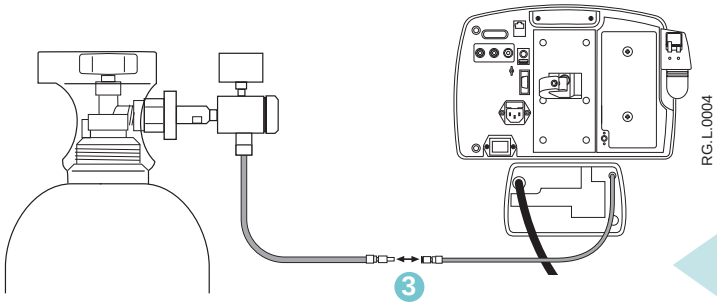
Typically the INOblender receives INOMAX from the INOmax DS_{IR} Plus MRI (INOMAX cylinder supplies both devices; see Figure 8-2).

Figure 8-2



As a stand-alone device INOMAX cylinder supplies just the INOblender. (see Figure 8-3).

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



3. Connect INOMAX regulator hose to INOblender inlet hose.

Figure 8-3

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