

Think of the INOmax DS_{IR}[®] Plus as another member of your NICU team



A specially designed single electronic injector module (IM) and proportional INOmax[®] (nitric oxide) gas, for inhalation, delivery control system help deliver constant concentration dosing through breath cycles and across ventilator modes



Indication

INOmax[®] (nitric oxide) gas, for inhalation, is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

Select Important Safety Information

- INOmax is **contraindicated** in the treatment of neonates dependent on right-to-left shunting of blood.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, also available at inomax.com/PI.

INOmax
Total Care[®]

The INOmax DS_{IR}® Plus is designed to help mitigate the risk of rebound pulmonary hypertension

Because every neonate's ventilation needs are different, the INOmax DS_{IR} Plus is equipped with an **IM and proportional delivery system and is validated with numerous ventilators**, delivering a constant concentration of INOmax (nitric oxide) gas, for inhalation. Regardless of the ventilator flow pattern or breath rate, the IM and proportional delivery system are designed to **help reduce some of the risks of incorrect dosing and user error, which could lead to delivery interruption.**¹⁻³

- The IM measures the ventilator flow and modifies the continuous INOmax proportional flow output between 0 and 6.35 L/min¹
- An internal flow sensor verifies the INOmax flow from the proportional valve, providing feedback to adjust the flow in real time¹
- The feedback loop executes at **1000 times per second** throughout the entire breath phase to maintain a constant dose in parts per million, reducing the risk of incorrect dosing^{3,4}
- Each IM is custom calibrated at the factory, enabling a single IM to be used with all validated ventilators¹
- The delivery system automatically detects and compensates for changes in ventilation settings or spontaneous breathing without the need for manual adjustments (eg, entry of ventilator flow rate), which potentially can be a source of user error¹
- The single IM eliminates the risk of potentially choosing the wrong IM and having to open the breathing circuit to replace the IM, resulting in delivery interruption¹
- INOmax is delivered through the IM, adjacent to the integrated flow sensor, mitigating the risk of incorrect dosing in the event of a leak in the breathing circuit^{1,3}



INOmax DS_{IR} Plus:

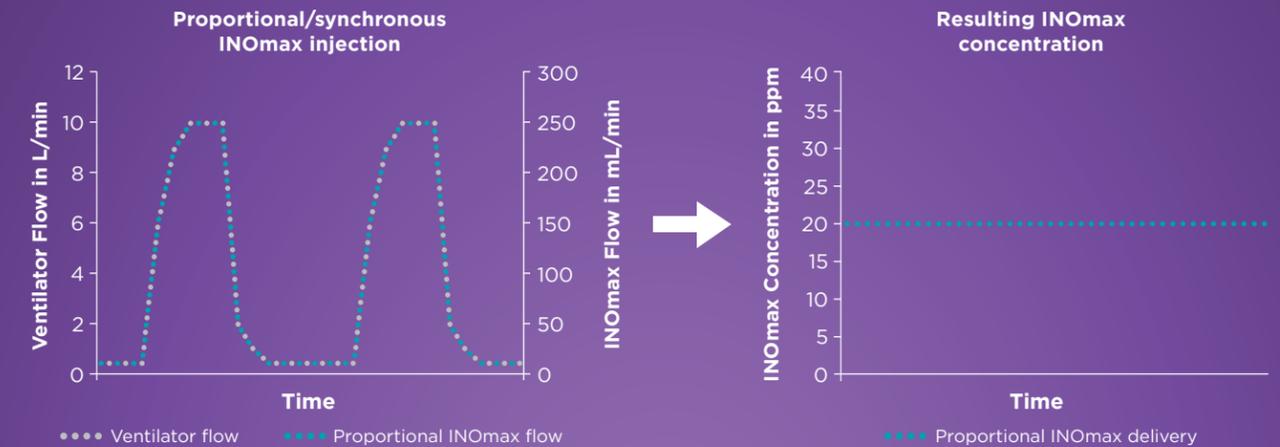
- ✓ Proportional delivery dose stays constant regardless of ventilator flow rate
- ✓ Single reusable injector module measures breathing circuit flow in real time
- ✓ Validated with numerous ventilation devices
- ✓ No need to enter ventilator flow rate

Visit [inomax.com/inomax-devices](https://www.inomax.com/inomax-devices) to see the full lineup of delivery systems and learn more about this important team member.

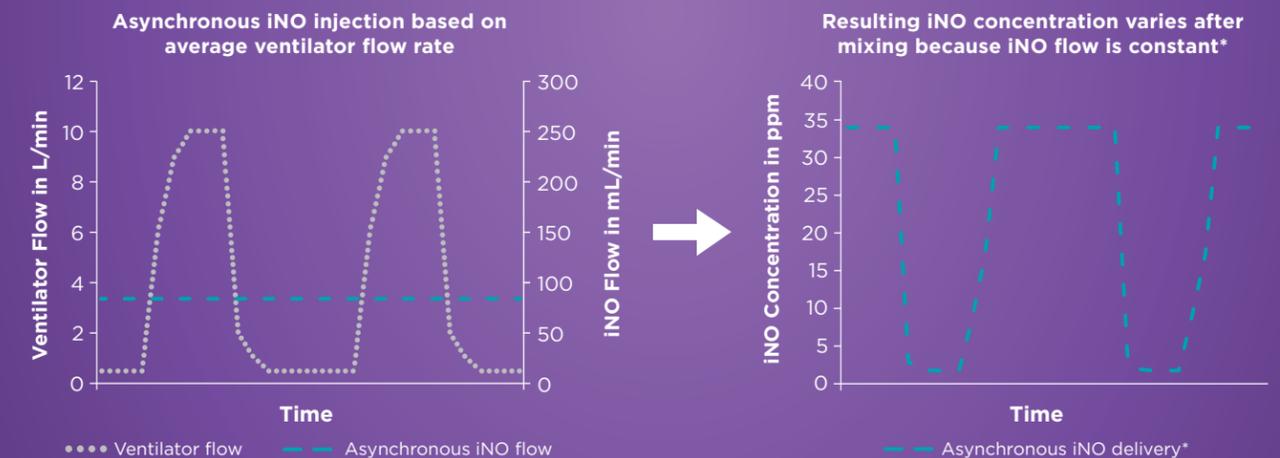
In an emergency situation, your NICU team doesn't have a minute to spare. The INOmax DS_{IR} Plus is always there and always ready to help them provide constant delivery of INOmax.

Exemplary illustration showing proportional/synchronous delivery and asynchronous iNO delivery, at 20 ppm dose

Proportional/synchronous INOmax injection results in a constant iNO concentration⁵



Asynchronous iNO flow injection method may result in a variable iNO concentration^{5*}



*Represents concentration at point of injection into the breathing circuit. Downstream mixing may occur prior to the patient and vary based on ventilator type/parameters, breathing circuit type, and volumes where gasses may mix, including humidifier chambers. In addition, monitoring systems with electrochemical sensors display a time-weighted average measured iNO concentration.

Select Important Safety Information

- Abrupt discontinuation of INOmax may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO₂ levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOmax on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, also available at [inomax.com/PI](https://www.inomax.com/PI).

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- Abrupt discontinuation of INOMax may lead to increasing pulmonary artery pressure and worsening oxygenation.
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- In patients with pre-existing left ventricular dysfunction, INOMax may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO₂, inspired NO₂, and methemoglobin during INOMax administration.
- INOMax must be administered using a calibrated FDA-cleared Nitric Oxide Delivery System.

Applications

The INOMax DS_{IR}® Plus Delivery Systems deliver INOMax. The INOMax DS_{IR} Plus Delivery Systems must only be used in accordance with the indications, usage, contraindications, and warnings and precautions described in the INOMax package inserts and labeling. The approved patient population is limited to neonates. Refer to the INOMax Full Prescribing Information prior to use.

Device Warnings

- Abrupt discontinuation of INOMax can lead to worsening oxygenation and increasing pulmonary artery pressure (rebound pulmonary hypertension syndrome). To avoid abrupt discontinuation, use the INOblender® or backup mode immediately to reinstate INOMax therapy and refer to the INOMax package insert.
- If the high NO₂ alarm activates, the delivery system should be assessed for proper setup while maintaining INOMax delivery.
- Do not connect items that are not specified as part of the system.
- If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.
- Use only INOMax, pharmaceutical grade NO/N₂.

Rx Only

Consult the Operation and Maintenance Manual, which may be found at www.inomax.com/training-and-education/device-support-resources, for complete information. For technical assistance, call (877) 566-9466.

For additional information, technical assistance, or a complete list of warnings regarding use of validated ventilators, please refer to the INOMax DS_{IR} Plus Operation Manual at inomax.com/dsirplusmanual.

Please see accompanying Full Prescribing Information, also available at inomax.com/PI.

- References:** **1.** INOMax DS_{IR} Plus: Operation Manual. Mallinckrodt Pharmaceuticals Manufacturing, LLC; 2014:1-206. **2.** INOMax. Package insert. Mallinckrodt Pharmaceuticals; 2021. **3.** Data on File – Ref-04544. Mallinckrodt Pharmaceuticals. **4.** Data on File – Ref-04451. Mallinckrodt Pharmaceuticals. **5.** Data on File – Ref-05578. Mallinckrodt Pharmaceuticals.

