

The INOmax DS_{IR}[®] Plus was designed with safety in mind

The dual-channel design helps support neonates with hypoxic respiratory failure who require a pulmonary vasodilator



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[®]

Delivering during critical moments

The INOmax DS_{IR} Plus Delivery System has a **dual-channel architecture where INOmax® (nitric oxide) gas, for inhalation, delivery is independent of the monitoring system, helping to mitigate the following risks¹:**

- Delivery interruption not due to operator error²
- Incorrect dosing not due to operator error²

The delivery channel includes the delivery central processing unit (CPU), the flow controller, and the injector module to ensure accurate delivery of nitric oxide **independent** of the monitoring system.¹



- The delivery channel is able to deliver with the same level of accuracy regardless of the state of the monitoring system calibration (eg, out of calibration)¹
- The delivery channel is able to deliver INOmax even if monitoring is interrupted¹

The monitoring channel includes a separate monitor CPU, gas cells (nitric oxide, nitrogen dioxide, and oxygen), and a user interface, including the display and alarms, **independent** of the delivery system.¹

- The design allows for continued INOmax delivery during low and high calibrations and monitoring alarms (eg, sample line/filter block, monitoring interruption)¹

The INOmax DS_{IR} Plus is designed to ensure the following¹:

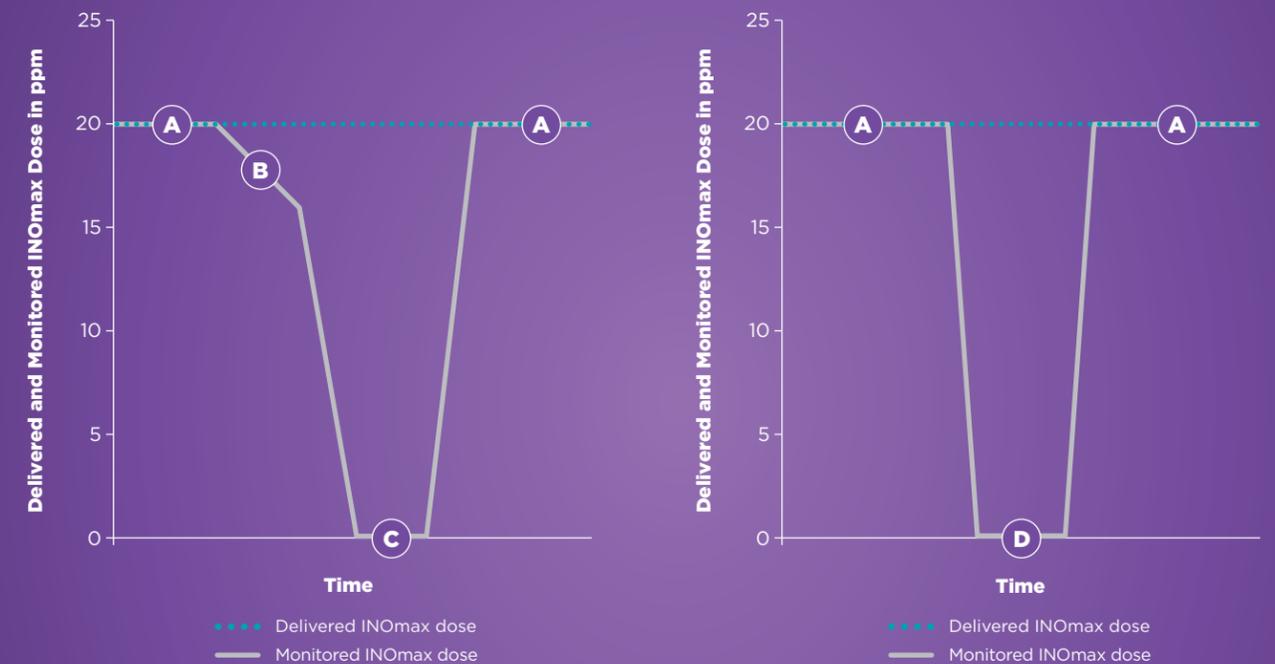
- ✓ Dual-channel delivery is independent of monitoring
- ✓ Delivery is not impacted by monitoring inaccuracy (eg, out of calibration, interrupted NO sensor)
- ✓ Delivers during low calibrations
- ✓ User can run high calibration during therapy
- ✓ Delivers during sample line/filter block alarms
- ✓ Delivers if monitoring is interrupted
- ✓ Delivers during monitoring-related user errors (eg, improper sample line connection, incorrect calibration)

With the INOmax DS_{IR} Plus, your team has additional support and protections in place to help provide uninterrupted INOmax delivery for your patients, because every moment counts.

INOmax DS_{IR} Plus Delivery Systems help your team address the importance of safety. Visit inomax.com/alarm to learn more.

The INOmax DS_{IR} Plus delivers the set dose regardless of monitoring events

Illustrations of Some Potential Monitoring-Related Events Taking Place During Therapy^{1,3}



Monitoring Events Legend

- A.** Monitoring system performing accurately
- B.** NO sensor drifting
- C.** Low calibration
- D.** Sample line filter block or monitoring interruption

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.

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Important Safety Information

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- 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.
- 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. Data on File – Ref-04544. Mallinckrodt Pharmaceuticals. 3. Data on File – Ref-05578. Mallinckrodt Pharmaceuticals.

