

# The INOmax DS<sub>IR</sub><sup>®</sup> Plus helps to mitigate the risks of interrupted nitric oxide delivery



The INOblender<sup>®</sup> system streamlines INOmax<sup>®</sup> (nitric oxide) gas, for inhalation, delivery during manual resuscitation



## Indication

INOmax<sup>®</sup> (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](http://inomax.com/PI).

**INOmax**  
Total Care<sup>®</sup>

# The INOmax DS<sub>IR</sub> Plus is equipped with 2 backup systems

Your institution and some of your most vulnerable neonatal patients depend on uninterrupted delivery of inhaled nitric oxide (iNO) to help mitigate the risk of rebound pulmonary hypertension.<sup>1</sup>

The INOmax DS<sub>IR</sub> Plus has been specially designed with a backup system called the INOblender to help minimize delivery interruptions when manual resuscitation is needed. Here's how it can benefit your team and help reduce some potential risks of user error that can lead to incorrect dosing and treatment interruption:



- In a crisis when there's little time to spare, the user-friendly design of the INOblender streamlines setup and activation
  - Set the iNO dose in **parts per million<sup>2</sup>**
    - Lookup tables or charts are not required to determine NO/O<sub>2</sub> flows<sup>2</sup>
  - Turn on the O<sub>2</sub> flow rate to the desired level<sup>2</sup>
    - The INOblender will deliver the set dose independent of the O<sub>2</sub> flow rate<sup>2</sup>
- The INOmax DS<sub>IR</sub> Plus has a second backup system for providing a fixed flow of INOmax (nitric oxide) gas, for inhalation, at 250 mL/min into the injector module. The dose is dependent on the ventilator flow rate. The onscreen guidance helps to assist the user with this process<sup>2</sup>

## INOblender<sup>2,3</sup>:

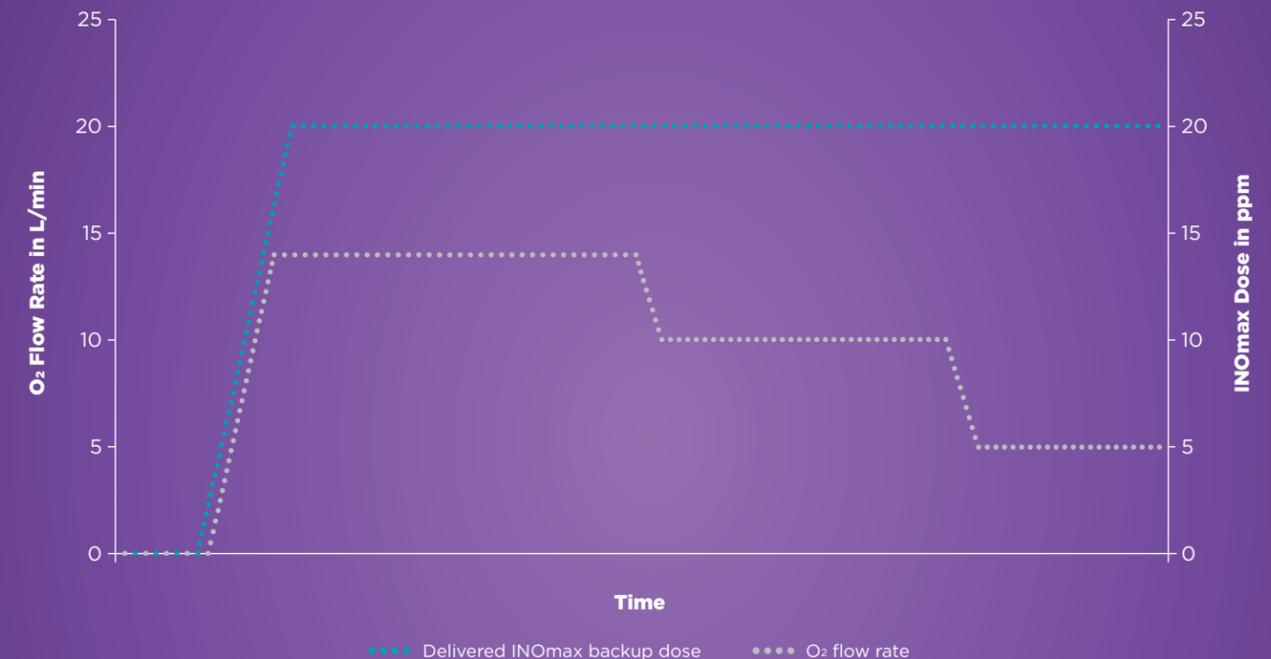
- ✓ Delivers a set dose in ppm independent of O<sub>2</sub> flow rate
- ✓ Dose-setting dial in ppm
- ✓ INOmax delivery stops automatically when O<sub>2</sub> flow rate is set to zero
- ✓ Option to leave backup dose set equal to primary delivery set point so only O<sub>2</sub> flow needs to be turned on to activate the blender
- ✓ Lookup tables are not required to set backup dose
- ✓ Can set any combination of O<sub>2</sub> flow rate and dose (5 to 14 L/min, dose 5 to 80 ppm)
- ✓ INOblender delivery can be active concurrently with primary delivery

In an emergency situation, when every minute counts, your NICU team can rely on the INOmax DS<sub>IR</sub> Plus to be ready to help them provide the care and treatment their patients need.

Visit [inomax.com/device-innovation](https://www.inomax.com/device-innovation)  
or contact your local team  
member for more information on the  
INOmax Delivery Systems.

The INOmax DS<sub>IR</sub> Plus delivers a constant backup dose independent of the O<sub>2</sub> flow rate via the INOblender

## Illustration of Backup Delivery (Timeline)<sup>4</sup>



The INOblender will deliver the set backup dose independent of the O<sub>2</sub> flow rate for the manual resuscitator<sup>2</sup>

## Select Important Safety Information

- Abrupt discontinuation of INOmax may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO<sub>2</sub> 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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- In patients with pre-existing left ventricular dysfunction, INOMax may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO<sub>2</sub>, inspired NO<sub>2</sub>, and methemoglobin during INOMax administration.
- INOMax must be administered using a calibrated FDA-cleared Nitric Oxide Delivery System.

## Applications

The INOMax DS<sub>IR</sub>® Plus Delivery Systems deliver INOMax. The INOMax DS<sub>IR</sub> 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 NO<sub>2</sub> 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/N<sub>2</sub>.

## Rx Only

Consult the Operation and Maintenance Manual, which may be found at [www.inomax.com/training-and-education/device-support-resources](http://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<sub>IR</sub> Plus Operation Manual at [inomax.com/dsirplusmanual](http://inomax.com/dsirplusmanual).**

**Please see accompanying Full Prescribing Information, also available at [inomax.com/PI](http://inomax.com/PI).**

**References:** **1.** INOMax. Package insert. Mallinckrodt Pharmaceuticals; 2021. **2.** INOMax DS<sub>IR</sub> Plus: Operation Manual. Mallinckrodt Pharmaceuticals Manufacturing, LLC; 2014:1-206. **3.** INOblender: Operation Manual. Mallinckrodt Pharmaceuticals Manufacturing, LLC; 2014:1-38. **4.** Data on File – Ref-05578. Mallinckrodt Pharmaceuticals.

