

## **INOmax™ (nitric oxide) gas, for inhalation and Coronavirus (COVID-19) Preparation**

### **Frequently Asked Questions (FAQs) for Customers (as of May 1, 2020)**

**1. Q: Is Mallinckrodt experiencing operational interruptions due to COVID-19?**

No. There is currently no impact to our logistics or supply chain as a result of COVID-19.

**2. Q: Does Mallinckrodt have a disaster preparedness/pandemic readiness program?**

Yes. Mallinckrodt has a documented preparedness plan that guides our response to natural disasters and other crises. We rely on close communication with our customers. We are monitoring the impact of COVID-19, and responding with appropriate inventory and supplies to meet patient and customer demand during this current situation.

**3. Q: How is Mallinckrodt supporting current demand for medical equipment in light of COVID-19?**

Mallinckrodt maintains a sufficient number of INOmax DS<sub>IR</sub>™ Plus devices for the delivery of inhaled nitric oxide (iNO) and has a team across the country working to maximize availability and striving to meet expected demand.

**4. Q: How much equipment will Mallinckrodt have available to support customers if COVID-19 becomes more widespread?**

As of May 1, 2020, Mallinckrodt has ample available equipment to meet patient and customer needs. If needed, we aim to scale the in-house manufacturing of both the drug and device to increase available inventory levels and support as needed. If you wish to discuss your inventory needs at any time, you can speak to your Mallinckrodt Customer Care Specialist at **(877) 566-9466**.

**5. Q: What if we require additional equipment on an ongoing or emergent basis?**

DS<sub>IR</sub>™ Plus and cylinder par level increase requests and all emergency orders can be placed 24/7/365 through a Mallinckrodt Customer Care Specialist at **(877) 566-9466**. Standard and emergent cylinder and disposable orders can also be placed 24/7/365 through our online ordering portal at [www.mallinckrodt.ca](http://www.mallinckrodt.ca). The needs of patients and customers remain our highest priority and we will continue to strive to fill orders as quickly as possible.

**6. Q: What precautions are you and your staff taking against the spread of COVID-19?**

- Across our operations, we remain focused on adhering to approved guidelines published by recognized bodies such as Health Canada and the World Health Organization (WHO).
- We have specific protocols in place to mitigate the spread of infectious viruses and pathogens.
- All members of our staff adhere to workplace standards and wear the appropriate personal protective equipment (PPE) when managing equipment.
- Mallinckrodt service center staff are trained on disinfection procedures for their work area.

**7. Q: As a customer, do I need to take additional steps to clean my INOmax DS<sub>IR</sub>™ Plus Delivery System?**

We ask that you use cleaning procedures listed in the operation manual and your institution's cleaning policy.

**8. Is your equipment clean, sanitized and patient-ready before delivery to our facility?**

Mallinckrodt is ISO 13485:2016 compliant across all Regional Service Centers. Our standard policies and procedures for prioritizing patient safety and minimizing infection risks include:

- Using recommended solutions to effectively clean and decontaminate devices and cylinders.
- Distinct work and storage areas for separation of returned and available equipment.
- Dedicated technicians trained on correct decontamination procedures for each device.
- Appropriate personal protective equipment is being used.
- Regional Service Centers are audited annually to ensure compliance.

**9. Q: What type of filters are included in the sampling system? How many microns are the filters?**

Please contact our Clinical Specialists if you require additional information at **(877) 566-9466**.

*If you have any additional questions about our preparedness and response plans related to COVID-19, please contact **Mallinckrodt Customer Care at (877) 566-9466**.*

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