



INFORMATION FOR LIMITED DISTRIBUTION

Technical Bulletin

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Issue date: March 2022

Product: INOmax DS_{IR}[®] Plus,
Investigational Blinded NO Delivery System,
Investigational NO Delivery System for Human Use Only and
Investigational NO Delivery System for Animal Use Only

Priority: Low

Affected parts: Gas Delivery Systems Compatibility

Classification: INFORMATION FOR LIMITED DISTRIBUTION

Subject: Ventilator/Gas Delivery Systems Compatibility List

WARNING:

- **In the United States, the approved patient population for the INOmax DS_{IR} and INOmax DS_{IR} Plus as specified in the drug labeling for INOMAX[®] (nitric oxide) for inhalation, is limited to term and near-term neonates with hypoxic respiratory failure. The INOmax DS_{IR} Plus is not intended to be used in other patient populations.**

The INOmax DS_{IR} Plus is compatible with most types of ventilators/gas delivery systems by connecting into the inspired limb of a patient’s breathing circuit. The system measures the gas flow in the breathing circuit and then injects a proportional amount of NO/N₂ gas to achieve the set NO concentration in ppm.

Conventional Ventilator Compatibility

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

Ventilator/Gas Delivery Systems Validation/Compatibility Testing

Mallinckrodt Pharmaceuticals performs validation testing which determines the compatibility of ventilators/gas delivery systems with INOMAX delivery systems as required¹. During this rigorous testing, INOMAX delivery systems are evaluated for the following parameters while connected to the ventilators/gas delivery systems:

- Devices and alarms function as intended by the manufacturer

¹ Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer, Section 10.2.2. dated January 24, 2000

- The nitric oxide set dose and measured dose remain within a pre-specified range of each other at all times while the ventilator/gas delivery system is run through a series of delivery mode tests that vary ventilation characteristics. The comparison of set vs measured dose is an important tool to ensure both delivery and monitoring systems are functioning properly.
- FiO₂ is maintained within acceptable limits
- NO₂ generation is minimal
- Any additional user instructions required for compatibility are identified

Mallinckrodt Pharmaceuticals develops formal reports outlining the outcome of the testing along with any safety concerns the customer needs to be aware of when using an INOMAX delivery system with a particular ventilator/gas delivery system.

In some cases, a ventilator/gas delivery system is not able to pass criteria for the entire test procedure based on device design or specifications. Technical Bulletins, which outline the reason(s) the ventilator/gas breathing system did not complete validation testing are available in most cases.

Below are the tables that list the ventilator/gas delivery systems that have successfully completed validation testing and are available in the United States (Table 1) and those that have not successfully completed validation testing (Table 2).

| Table 1: Ventilators/gas delivery systems validated for use with INOmax DSIR Plus, reviewed by FDA and available <u>in</u> the United States: | | | |
|--|----------------------------|---|--|
| Manufacturer * | Model | Ventilator Range Tested (neonatal) | Ventilator Range Tested (pediatric/adult) |
| A-plus Medical | Babi.Plus Bubble PAP Valve | N/A | N/A |
| Airon Corporation | pNeuton | N/A | ● |
| BD-CareFusion | AirLife nCPAP System | N/A | N/A |
| BD-CareFusion | Avea | ● | ● |
| BD-CareFusion | Bird VIP | ● | ● |
| BD-CareFusion | Infant Flow CPAP System | N/A | N/A |
| BD-CareFusion | Infant Flow SiPAP | N/A | N/A |
| BD-CareFusion | Pulmonetic LTV 1000 | N/A | ● |
| BD-CareFusion | Pulmonetic LTV 1200 | N/A | ● |
| BD-CareFusion | ReVel | ● | ● |
| BD-CareFusion | Sensormedics 3100A | ● | N/A |
| BD-CareFusion | Sensormedics 3100B | N/A | ● |

Table 1: Ventilators/gas delivery systems validated for use with INOmax DSIR Plus, reviewed by FDA and available in the United States:

| Manufacturer * | Model | Ventilator Range Tested (neonatal) | Ventilator Range Tested (pediatric/adult) |
|----------------------------|--|---|--|
| BD-CareFusion | Vela | ● | ● |
| Bear | 750ps (Cub) | ● | N/A |
| Bio-Med Devices | Crossvent 2 | ● | ● |
| Bio-Med Devices | Crossvent 4 | ● | ● |
| Bio-Med Devices | MVP-10 | ● | ● |
| Bio-Med Devices | TV-100 | ● | ● |
| Bunnell | Life Pulse 203/204 | ● | N/A |
| Covidien | PB 840 | ● | ● |
| Covidien | PB 980 | ● | ● |
| Dräger | Apollo | N/A | ● |
| Dräger | Babylog 8000 | ● | N/A |
| Dräger | Carina | ● | ● |
| Dräger | Evita | ● | ● |
| Dräger | Evita Babylog VN500 | ● | N/A |
| Dräger | Evita Infinity V500 | ● | ● |
| Dräger | Narcomed 2B | ● | ● |
| Dräger | Perseus A500 | ● | ● |
| eVent Medical | Inspiration LS | ● | ● |
| Fisher & Paykel Healthcare | Airvo 2 | ● | N/A |
| Fisher & Paykel Healthcare | Bubble CPAP System | N/A | N/A |
| Fisher & Paykel Healthcare | RT329 Breathing Circuit and BC Nasal Cannula | ● | N/A |
| Fisher & Paykel Healthcare | RT202 Breathing Circuit & Optiflow Adult Interface | ● | ● |
| Fisher & Paykel Healthcare | RT330 Breathing Circuit & Optiflow Jr | ● | N/A |
| GE Healthcare | Aespire 7100 | ● | ● |
| GE Healthcare | Aespire 7900 | ● | ● |
| GE Healthcare | Aestiva | ● | ● |
| GE Healthcare | Aisys | ● | ● |
| GE Healthcare | Avance | ● | ● |
| GE Healthcare | Carescape R860 | ● | ● |
| GE Healthcare | Centiva/5 | ● | ● |

Table 1: Ventilators/gas delivery systems validated for use with INOmax DSIR Plus, reviewed by FDA and available in the United States:

| Manufacturer * | Model | Ventilator Range Tested (neonatal) | Ventilator Range Tested (pediatric/adult) |
|---------------------------------------|----------------------|---|--|
| GE Healthcare | Engström Carestation | ● | ● |
| GE Healthcare | Excel SE 7800 | N/A | ● |
| GE Healthcare | Mod SE 7900 | ● | ● |
| Hamilton | Arabella | N/A | N/A |
| Hamilton | C1 | ● | ● |
| Hamilton | C2 | ● | ● |
| Hamilton | C3 | ● | ● |
| Hamilton | G5 | ● | ● |
| Hamilton | Galileo | ● | ● |
| Hamilton | T1 | ● | ● |
| Impact Instrumentation | EMV+ | ● | ● |
| Impact Instrumentation | Uni-Vent | ● | ● |
| IMT Medical | Bellavista | ● | ● |
| Infrasonics | Infant Star 100 | ● | N/A |
| Infrasonics | Infant Star 500 | ● | N/A |
| Infrasonics | Infant Star 950 | ● | N/A |
| Maquet | Flow-i | ● | ● |
| Maquet | Servo 300 | ● | ● |
| Maquet | Servo i | ● | ● |
| Maquet | Servo u/n | ● | ● |
| Medtronic | Newport E360 | ● | ● |
| Medtronic | Newport HT50 | N/A | ● |
| Medtronic | Newport Wave | ● | ● |
| Nasal Cannula (various manufacturers) | Nasal Cannula | N/A | N/A |
| Philips Healthcare | Respironics Esprit | ● | ● |
| Puritan Bennett | 7200 | N/A | ● |
| Sechrist | IV-100B | ● | N/A |
| Smiths Medical | BabyPAC 100 | ● | N/A |
| Smiths Medical | VentiPAC 200D | ● | ● |

Table 1: Ventilators/gas delivery systems validated for use with INOmax DSIR Plus, reviewed by FDA and available in the United States:

| Manufacturer * | Model | Ventilator Range Tested (neonatal) | Ventilator Range Tested (pediatric/adult) |
|-----------------------|---------------------------|---|--|
| Teleflex Medical | Comfort Flo Humid. System | N/A | N/A |
| Vapotherm | 2000i | N/A | N/A |
| Vapotherm | Precision Flow | N/A | N/A |

* Manufacturer at the time of validation testing.

Table 2: Ventilators/gas delivery systems that did not successfully complete validation testing:

| Manufacturer * | Model |
|---|--------------------|
| Philips Healthcare (formerly Respironics) | BiPAP Vision |
| Percussionaire | Bronchotron-i |
| Drager | Oxylog 3000 |
| Smiths Medical | paraPAC Medic 200D |
| Stephan | Sophie |
| Hill-Rom | MetaNeb |

* Manufacturer at the time of validation testing.

For technical assistance regarding the INOmax DSIR Plus delivery system, please contact product support at 1-877-566-9466.

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