



INFORMATION FOR LIMITED DISTRIBUTION

Technical Bulletin

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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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