

INFORMATION FOR LIMITED DISTRIBUTION



Technical Bulletin

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Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus and INOflo DS[®]

Priority: Low

Affected parts: Gas Delivery Systems Compatibility

Classification: Information for Limited Distribution

Subject: Ventilator/Gas Delivery Systems Compatibility List – **Outside the United States.**

This communication is to confirm that Mallinckrodt Pharmaceuticals have completed validation testing of the INOmax DS_{IR}, INOmax DS_{IR} Plus and INOflo DS with the Ventilator Gas Delivery Systems listed in Table 1 below. Testing was facilitated for all patient categories, Adult, Pediatric and Neonatal. No unexpected alarm conditions or anomalies occurred with any of the Ventilator Gas Delivery Systems or the DS_{IR} /INOflo NO Delivery Systems during testing. Test results demonstrate the INOmax DS_{IR}, INOmax DS_{IR} Plus and INOflo DS passed validation testing with all of the Ventilator Gas Delivery Systems tested.

WARNING:

- **Outside the United States, use of the INOmax DS_{IR}, INOmax DS_{IR} Plus and INOflo DS is limited to the use in accordance with INOMAX[®] or INOflo[®], nitric oxide for inhalation prescribing information as established with the national health authority.**

The INOmax DS_{IR}, INOmax DS_{IR} Plus and INOflo DS are 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 required. 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
- 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 outside 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 DS_{IR} listed products, available outside 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	•
Acutronics Medical Systems AG	Fabian +nCPAP Evolution	•	N/A
Acutronics Medical Systems AG	Fabian HFO	•	N/A
Acutronics Medical Systems AG	Fabian HFOi	•	N/A
Acutronics Medical Systems AG	Fabian Therapy	•	N/A
BD-CareFusion	AirLife nCPAP System	N/A	N/A
BD-CareFusion	Avea	•	•

Table 1: Ventilators/gas delivery systems validated for use with INOmax DS_{IR} listed products, available outside the United States:

Manufacturer *	Model	Ventilator Range Tested (neonatal)	Ventilator Range Tested (pediatric/adult)
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	•
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 Inc.	Life Pulse 203	•	N/A
Bunnell Inc.	Life Pulse 204	•	N/A
Covidien	PB 840	•	•
Covidien	PB 980	•	•
Dräger	Apollo	N/A	•
Dräger	Carina	•	•
Dräger	Evita	•	•
Dräger	Evita Babylog VN500	•	•
Dräger	Evita Infinity V500	•	•
Dräger	Narcomed 2B	•	•
Dräger	Perseus A500	•	•
Dräger	Fabius A500	•	•
Dräger	Primus	•	•
Dräger	Zeus	•	•
eVent Medical	Inspiration LS	•	N/A
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	•	•

Table 1: Ventilators/gas delivery systems validated for use with INOmax DS_{IR} listed products, available outside the United States:

Manufacturer *	Model	Ventilator Range Tested (neonatal)	Ventilator Range Tested (pediatric/adult)
Fisher & Paykel Healthcare	RT202 Breathing Circuit & Optiflow Adult Interface	•	N/A
Fisher & Paykel Healthcare	RT330 Breathing Circuit & Optiflow Jr	•	•
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	•	•
GE Healthcare	Engström Carestation	•	•
GE Healthcare	Excel SE 7800	N/A	•
GE Healthcare	Mod SE 7900	•	•
GE Healthcare	Aespire 7100	•	•
GE Healthcare	Aespire 7900	•	N/A
Hamilton	Arabella	N/A	•
Hamilton	C1	•	•
Hamilton	C2	•	•
Hamilton	C3	•	•
Hamilton	C6	•	•
Hamilton	G5	•	•
Hamilton	Galileo	•	•
Hamilton	T1	•	N/A
Impact Instrumentation	EMV+	•	•
Impact Instrumentation	Uni-Vent	•	•
IMT Medical	Bellavista	•	N/A
Infrasonics	Infant Star 100	•	N/A
Infrasonics	Infant Star 500	•	N/A
Infrasonics	Infant Star 950	•	•
Maquet	Flow-i	•	•
Maquet	Servo 300	•	•
Maquet	Servo i	•	•
Maquet	Servo n	•	N/A

Table 1: Ventilators/gas delivery systems validated for use with INOmax DS_{IR} listed products, available outside the United States:

Manufacturer *	Model	Ventilator Range Tested (neonatal)	Ventilator Range Tested (pediatric/adult)
Maquet	Servo u	N/A	•
Maquet	Servo n (HFO)	•	•
Medtronic	Newport E360	•	•
Medtronic	Newport HT50	N/A	•
Medtronic	Newport Wave	•	N/A
Metran	Humming HMX	•	N/A
Metran	Humming Vue	•	N/A
Nasal Cannula (various manufacturers)	Nasal Cannula	N/A	•
Philips	Trilogy 202	N/A	•
Philips	V680	N/A	•
Philips	Respironics Esprit	•	•
Puritan Bennett	7200	N/A	N/A
Sechrist	IV-100B	•	•
SLE Life Support	SLE 6000	•	N/A
SLE Life Support	SLE 5000	•	N/A
Smiths Medical	babyPAC 100	•	•
Smiths Medical	ventiPAC 200D	•	N/A
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 DS_{IR} / INOmax DS_{IR} Plus / INOflo DS delivery systems please contact technical support in North America at 1-877-566-9466 or your specific country manager.

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