



# Technical Bulletin

Ref: **TB-08007**

Issue date: **November 2015**

Product: INOmax DS<sub>IR</sub><sup>®</sup>, INOmax DS<sub>IR</sub><sup>®</sup> Plus or INOflo DS<sup>®</sup>

Priority: Low

Affected parts: Breathing Systems Compatibility

Classification: Information for Distribution

Subject: **Ventilator/Breathing Systems Compatibility List**

**WARNING:**

- **In the United States, the approved patient population for the INOmax DS<sub>IR</sub> and INOmax DS<sub>IR</sub> Plus as specified in the drug labeling for INOMAX<sup>®</sup> (nitric oxide) for inhalation, is limited to term and near-term neonates with hypoxic respiratory failure. The INOmax DS<sub>IR</sub> and INOmax DS<sub>IR</sub> Plus are not intended to be used in other patient populations.**
- **Outside of the United States, use of the INOmax DS<sub>IR</sub>, INOmax DS<sub>IR</sub> Plus and INOflo DS is limited to the use in accordance with INOMAX or INOflo<sup>®</sup>, nitric oxide for inhalation prescribing information as established with the national health authority.**

The INOmax DS<sub>IR</sub>/ INOmax DS<sub>IR</sub> Plus/INOflo DS are compatible with most types of ventilators/breathing 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 NO/N<sub>2</sub> gas to produce the set NO concentration in ppm.

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

The INOmax DS<sub>IR</sub>/ INOmax DS<sub>IR</sub> Plus/INOflo DS have been validated against the following ventilators/breathing systems:

**Ventilators/Breathing Systems validated for use in the United States:**

Manufacturer	Model	Neonatal	Ped/ Adult	Transport	High Freq.	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
A-plus Medical	Baby-Plus Bubble CPAP						●	
Airon Corporation	pNeuton			●				
BD-CareFusion	AirLife nCPAP System						●	

Manufacturer	Model	Neonatal	Ped/ Adult	Transport	High Freq.	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
BD-CareFusion	Avea	●	●					
BD-CareFusion	Bird VIP	●	●					
BD-CareFusion	Infant Flow CPAP System						●	
BD-CareFusion	Infant Flow SiPAP						●	
BD-CareFusion	Pulmonetic LTV 1000		●					
BD-CareFusion	Pulmonetic LTV 1200		●					
BD-CareFusion	ReVel	●	●	●				
BD-CareFusion	Sensormedics 3100A				●			
BD-CareFusion	Sensormedics 3100B				●			
BD-CareFusion	Vela	●	●					
Bear	750ps (Cub)	●						
Bio-Med Devices	Crossvent 2			●				
Bio-Med Devices	Crossvent 4			●				
Bio-Med Devices	MVP-10			●				
Bunnell	Life Pulse				●			
Covidien	PB 840	●	●					
Dräger	Apollo					●		
Dräger	Babylog 8000	●						
Dräger	Evita	●	●					
Dräger	Evita Babylog VN500	●						
Dräger	Evita Infinity V500	●	●					
Dräger	Narcomed 2B					●		
eVent Medical	Inspiration LS	●	●					
Fisher & Paykel Healthcare	Bubble CPAP System						●	
Fisher & Paykel Healthcare	Infant Circuit Nasal Cannula							●
Fisher & Paykel Healthcare	Optiflow Breathing Circuit	●	●					●
GE Healthcare	Aespire 7100					●		
GE Healthcare	Aespire 7900					●		

Manufacturer	Model	Neonatal	Ped/ Adult	Transport	High Freq.	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
GE Healthcare	Aestiva					●		
GE Healthcare	Aisys					●		
GE Healthcare	Avance					●		
GE Healthcare	Centiva/5		●					
GE Healthcare	Engström Carestation	●	●					
GE Healthcare	Excel SE 7800					●		
GE Healthcare	Mod SE 7900					●		
Hamilton	Arabella						●	
Hamilton	C1	●	●					
Hamilton	C2	●	●					
Hamilton	G5	●	●					
Hamilton	Galileo	●	●					
Hamilton	T1			●				
Impact Instrumentation	EMV+			●				
Impact Instrumentation	Uni-Vent			●				
Infrasonics	Infant Star 100			●				
Infrasonics	Infant Star 500	●						
Infrasonics	Infant Star 950	●						
Maquet	Servo 300		●					
Maquet	Servo i	●	●					
Medtronic	Newport E360	●	●					
Medtronic	Newport HT50		●					
Medtronic	Newport Wave	●	●					
Nasal Cannula (various manufacturers)	Nasal Cannula							●
Phillips	Respironics Esprit	●	●					
Puritan Bennett	7200		●					
Sechrist	IV-100B	●						
Smiths Medical	babyPAC 100			●				
Smiths Medical	paraPAC Medic 200D			●				
Smiths Medical	ventiPAC 200D			●				
Teleflex Medical	Comfort Flo Humid. System							●

Manufacturer	Model	Neonatal	Ped/ Adult	Transport	High Freq.	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
Vapotherm	2000i							●
Vapotherm	Precision Flow							●

**Ventilators/Breathing Systems validated for use outside of the United States:**

Manufacturer	Model	Neonatal	Ped/ Adult	Transport	High Freq.	Anesthesia	Nasal Continuous Positive Airway Pressure (CPAP)	High Flow Nasal Cannula
Acutronics Medical Systems AG	Fabian +nCPAP Evolution	●						
Acutronics Medical Systems AG	Fabian HFO	●			●			
Dräger	Evita Babylog VN500	●			●			
Dräger	Zeus					●		
Heinen & Löwenstein	Leoni+	●			●			
Infrasonics	Infant Star 950	●			●			
Metran	Humming HMX	●			●			
Metran	Humming Vue	●			●		●	
SLE Life Support	SLE 5000	●			●			

For technical assistance regarding the INOmax DS<sub>IR</sub> please contact technical support at 1-877-566-9466 (North America) or your specific country manager.

Mallinckrodt Manufacturing LLC  
6603 Femrite Drive,  
Madison, WI 53718-6801 USA

Mallinckrodt, the "M" brand mark and the Mallinckrodt Pharmaceuticals logo are trademark of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owner. ©2016 Mallinckrodt.