



Technical Bulletin

Ref: **CL-TB-0041**

Issue date: **March 2010**

Product: INOmax[®] DS

Priority: High

Affected parts: INOmax DS Monitoring/Delivery

Classification: Information

Subject: INOmax DS use with the Bunnell Life Pulse

WARNING: Place the Life Pulse in Standby prior to suctioning the patient to avoid NO delivery transiently exceeding the set dose by up to 30 ppm. Press ENTER to reestablish ventilation as soon as the catheter is removed from the airway. This will limit the extent of over delivery above the NO set dose.

Caution: If the set dose is below 5 ppm and the Servo pressure is 2.0 psi. or less, this will result in flow rates outside of the specification of the Injector Module and fluctuating NO values may result.

The specification for ventilator flow rates when using the INOmax DS is 2 to 120 L/min. The accuracy of INOMAX[®] delivery for flow rates below 2 L/min. is not specified.

Two conditions have been identified while treating infants with the INOmax DS and the Bunnell Life Pulse:

Condition #1 - When the Servo pressure dumps due to suctioning with in-line suction catheters (without placing the Life Pulse in Standby first), the ventilator flow quickly drops to zero.

However, the patient box pinch valve continues for 8-12 cycles before it stops running. The signal from this cycling makes the Injector Module think there is gas flow and this causes a small volume of INOMAX to be delivered into the circuit even though the ventilator is in a zero flow state. When ventilator flow is reestablished either automatically or when the user presses ENTER, a spike of NO (up to 30 ppm above the NO set dose) will be delivered to the patient.

Recommended action - This spike can be limited (up to 15 ppm above the NO set dose) by placing the Life Pulse in Standby prior to suctioning the patient and then pressing ENTER to reestablish ventilation as soon as the catheter is removed from the airway.

Condition #2 - With servo pressures below 2.0 psi (less than 1.0 L/min., which is below the Injector Module specification) and the set dose below 5 ppm, there have been reports of monitored NO values fluctuating and periodically dropping to zero. During testing, this was found to be caused by a combination of varying Servo pressures and energy from the patient box pinch valve creating a disturbance in the NO flow sensor signal readings. The magnitude of the

disturbance is strong enough that dosing below 5 ppm may not be accurate and/or repeatable.

Result – If the set dose is below 5 ppm and the Servo pressure is 2.0 psi. or less, this will result in flow rates outside of the specification of the Injector Module and fluctuating delivered values may result.

Note: Low NO alarm limits should always be set appropriately.

If you have further questions, please contact technical support at 1-877-566-9466.