

Technical Bulletin

Ref: **TB- 08005**

Issue date: **September 2008**

Product: INOmax[®] DS and INOvent[®]

Priority: High

Affected parts: Injector Module / Delivery System / Monitoring

Classification: Warning

Subject: **Respironics BiPap[®] Vision[®] system or other single-lumen breathing systems creating bidirectional flow**

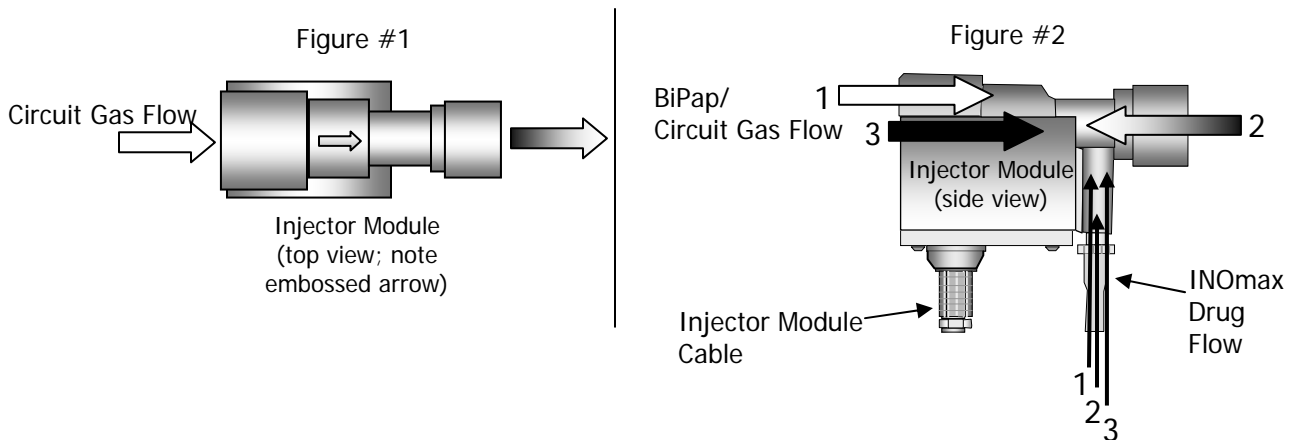
Warning: The INOmax DS/INOvent should not be used with the BiPap Vision system or other single-lumen breathing systems with bidirectional flow, as over-dose of INOmax[®] (nitric oxide) and interruption of drug delivery to the patient may occur.

Warning: The BiPap Vision system has been tested with the INOmax DS. The INOmax DS/INOvent has not received FDA clearance for use with the BiPap Vision system.

To ensure accurate delivery of INOmax the inspiratory flow should pass through the Injector Module in one direction only (see Figure #1).

The BiPap Vision system is known to have bidirectional flow through the single-lumen breathing circuit during ventilation of patients.

The Injector Module of the INOmax DS/INOvent **cannot** detect the direction of flow. The Injector Module however, will deliver INOmax each time flow passes through it. As a result, the INOmax DS/INOvent will inject INOmax during forward flow (1), reverse flow (2) and then again during forward flow (3) resulting in over-delivery of as much as three times the set dose (see Figure #2).



Depending on the settings of both devices (BiPap Vision and either the INOmax DS or INOvent) the following conditions may occur:

- Unpredictable changes in delivered dose.
- Dosage fluctuations may be unrecognized by the INOmax DS monitoring.
- Measured NO could exceed 100 ppm causing a delivery device failure and interruption of INOmax drug delivery to the patient.

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