# A Novel, Cassette-Based Nitric Oxide Delivery System Accurately Delivers Inhaled Nitric Oxide via the Anesthesia Machine at Low Fresh Gas Flows

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**Background:** Increased clinical use of inhaled nitric oxide (iNO) has encouraged industry to improve iNO delivery systems to make them safe, portable, and reliable.[1] The ideal system should accurately deliver set iNO dose regardless of ventilator type used. A major difference between ICU ventilators and anesthesia machines is that an ICU ventilator uses an open-breathing circuit with constant bias flow. In contrast, an anesthesia machine uses a semi-closed breathing circuit, removing $CO_2$ to enable low fresh gas flows (FGF), which conserves anesthetic agent and maintains heat and humidity.[2,3] Tank-based iNO systems (eg, INOmax $DS_{IR}$®, $NOxBOX_i$®) inject iNO based on measured inspiratory flow through the breathing circuit and do not account for rebreathing in semi-closed anesthesia circuits. This results in measured iNO levels significantly greater than set iNO dose and higher $NO_2$ levels, unless FGF rates are equal to or higher than minute ventilation (MV).[4] Thus, tank-based iNO systems negate the many benefits of low-flow anesthesia practice and introduce a potential error for the anesthesia provider who is unaware of delivery system limitations.[5] Providers will need to divert their attention from direct patient care to the anesthesia machine to adjust FGF to accommodate tank system limitations. Genosyl® DS (Vero Biotech) is a novel, cassette-based system that measures iNO concentration in the breathing circuit and uses the measured value in an advanced feedback control algorithm to accurately determine how much iNO should be injected when rebreathing in semi-closed anesthesia circuits.[6] The aim of this study was to test the use of the Genosyl® DS with the anesthesia machine under rebreathing conditions.

**Methods:** Genosyl® DS was tested with GE Aisys CS2 and Dräger Fabius GS Premium anesthesia machines with a test lung to determine if set iNO dose was affected by rebreathing conditions. Volume control, pressure control, and manual ventilation modes were tested with both neonatal and adult breathing circuits and a wide range of ventilatory parameters. The FGF ranged from 0.5–2.0 L/min to test rebreathing conditions.

**Results:** In the set NO dose range of 1–80 ppm, the Genosyl® DS maintained accurate iNO delivery within ±20% or ±2 ppm (whichever is greater) of set point for both neonatal and adult rebreathing conditions (Fig. 1). Measured $O_2$ levels remained acceptable at ≤1 ppm under all ventilation conditions when iNO was set to 40 ppm in 60% $O_2$.

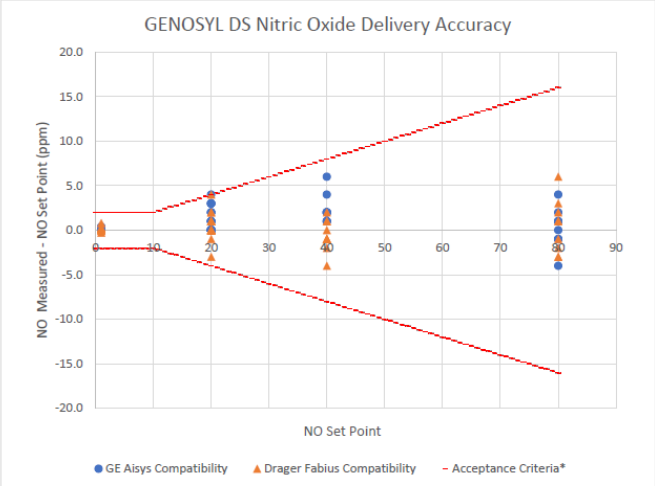


**Figure 1:** Accuracy of iNO delivery using GENOSYL DS in conjunction with GE and Drager anesthesia machines in mechanical and manual ventilation modes. *Acceptance criteria were according to Guidance for Industry for FDA Reviewers (CDRH. *Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer.* January 24, 2000.)

**Conclusion:** The Genosyl® DS is the first iNO delivery system capable of accurately delivering iNO with an anesthesia machine under rebreathing conditions in both neonatal and adult ventilation modes, enabling low FGF anesthesia with all its benefits.

## References

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