

A Novel, Cassette-Based Nitric Oxide Delivery System Accurately Delivers Inhaled Nitric Oxide via the Anesthesia Machine Independent of Fresh Gas Flow Rate and Volatile Anesthetic Agent

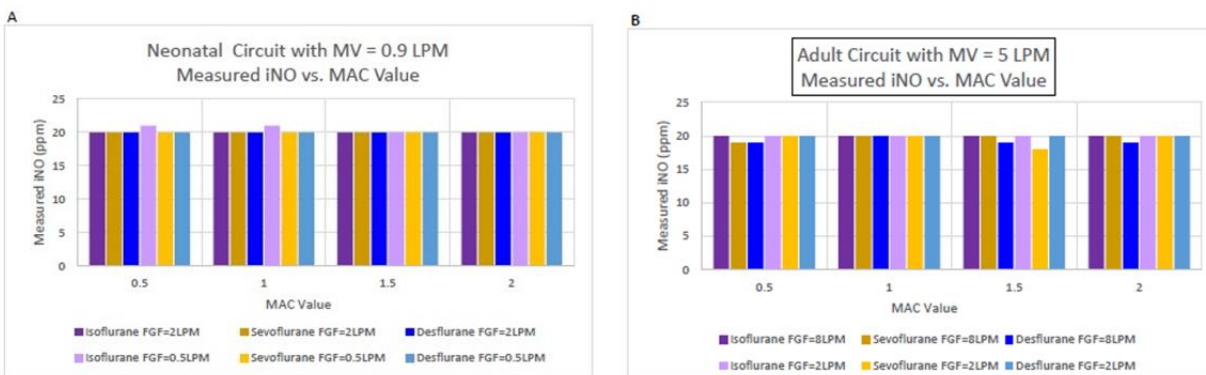
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Introduction: Increased clinical use of inhaled nitric oxide (iNO) has encouraged industry to improve delivery systems to make them safe, portable, and capable of delivering set iNO dose regardless of delivery mode, eg, ICU ventilator or anesthesia machine.¹ Tank-based iNO systems from Mallinckrodt Pharmaceuticals (INOMax DS_{IR}[®]) and Linde Gas & Equipment Inc (NOxBOX[®]) inject iNO based on inspiratory flow through the breathing circuit and do not account for rebreathing in semi-closed anesthesia circuits. Studies show that when using tank-based iNO systems with anesthesia machines, delivery of iNO is only accurate when fresh gas flow (FGF) is greater than minute ventilation (MV).² The INOMax labeling warns that when used with a circle anesthesia system, recirculation of gases should be avoided. The labeling also cautions that nitrous oxide (N₂O) and isoflurane will affect the set iNO dose vs the measured iNO value.³ The Genosyl[®] DS (Vero Biotech) is a novel, cassette-based system that measures iNO concentration in the inspiratory limb of the breathing circuit and uses an advanced feedback control algorithm to accurately determine how much iNO should be injected.⁴ The aim of this study was to test Genosyl[®] DS performance with anesthetic agents and FGF.

Methods: The Genosyl[®] DS was tested with a Flow-i anesthesia machine (Getinge) and a test lung to determine if set iNO dose was affected by FGF or type of volatile anesthetic agent at different MAC values.

Results: The Genosyl[®] DS maintained iNO delivery within $\pm 20\%$ of set iNO dose when isoflurane, sevoflurane, and desflurane concentrations were incrementally increased up to 2 minimum alveolar concentration (MAC) and when N₂O was used, regardless of FGF and MV (Fig. 1A & 1B). Measured NO₂ levels remained below 0.2 ppm for all test conditions, which is below the allowed threshold of 1 ppm.



Conclusions: The Genosyl[®] DS cassette-based system is the first iNO delivery system to accurately deliver set iNO dose with a semi-closed anesthesia circuit, independent of volatile anesthetic agent and FGF using the novel advanced feedback control algorithm. Anesthesia providers can simply set the iNO dose without adjusting FGF or anesthetic agent. This decreases provider distractions, maintains focus on the patient, and facilitates the transition of care between the ICU and OR for ventilated patients.

1. Gianni et al. *Respir Care* 2021
2. Sieffert et al. *J Clin Monit Comput* 1999
3. Mallinckrodt INOMax DS_{IR} Plus Operation Manual 2014
4. Lovich et al. *Nitric Oxide* 2014