

GENOSYL® Delivery System

PRODUCT SPECIFICATIONS

Vero Biotech's GENOSYL Delivery System (DS) delivers GENOSYL (nitric oxide, NO) gas, for inhalation. The GENOSYL DS uses an injection and monitoring channel design to ensure safe delivery of NO. Nitric oxide gas is supplied into the injection channel from a single use cassette which is loaded into the GENOSYL DS. The GENOSYL DS controls the NO gas production and injection flow for the injection channel to ensure safe and accurate delivery of NO. A monitoring channel is used to draw sample gas from the patient circuit and measure the patient gas concentration using gas sensors (NO, NO₂, and O₂). The GENOSYL DS uses the data from the monitoring channel gas cells to regulate NO gas delivery in the injection channel in the primary dosing mode. The GENOSYL DS provides a manual dosing mode, which delivers NO on a separate injection channel dedicated to manual ventilation at a fixed concentration and rate. The GENOSYL DS is configured with two fully redundant delivery console systems. In the unlikely event of a fault condition during dosing, the second console is activated to ensure sustained NO dose delivery.

GENOSYL® DS Cassette



GENOSYL® DS Console



Weight	1.0 lb (0.5 kg)
Dimensions	5.5" H x 4.5" W x 3.5" D (14 cm x 11.5 cm x 8.9 cm)
Dose Setting	Disposable nitric oxide source
Storage	Temperature: 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F)
Battery Duration	N/A
System Operation	N/A










Weight	16.0 lbs (7.25 kg)
Dimensions	7.5" H x 16.0" W x 12.0" D (19 cm x 40.6 cm x 30.6 cm)
Dose Setting	1 – 80 ppm
Storage	Temperature: -20°C to 60°C (-4°F to 140°F) Humidity: 15% to 95%, non-condensing Pressure: 57kPa - 110kPa
Battery Duration	Single battery at least 1.0 hour of active dosing
System Operation	Power: AC Power Supply 110V Operation: Simple LCD Display Control Function Use: Portable System, designed for intra-hospital use

Please see inserted full prescribing information.

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GENOSYL® DS Accessories

<p>GENOSYL DS Console Cart Height: 55" (139.7 cm)</p> 		GENOSYL DS Gas Lines	<p>GENOSYL® DS Operating Manual / Quick Reference Guide</p> 
		GENOSYL DS Mixer	
		NO Gas Injection Adapter (22M/15F x 22F)	
		Adapter 22F x 22F	
		Neonatal Gas Sample Tee	
		Iso-Gard® Filter S	
		Water Trap	

Request a free information kit or speak to a Vero Representative to learn more about our product: 1-877-337-4118

INDICATION & IMPORTANT SAFETY INFORMATION:

GENOSYL is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

- GENOSYL is **contraindicated** in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of GENOSYL (nitric oxide) gas, for inhalation may lead to worsening oxygenation and increasing pulmonary artery pressure.
- Methemoglobin, NO₂, and PaO₂ should be monitored during nitric oxide administration.

- In patients with pre-existing left ventricular dysfunction, GENOSYL may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- The most common adverse reaction is hypotension.
- Nitric oxide donor compounds may have an additive effect with GENOSYL on the risk of developing methemoglobinemia.
- GENOSYL must be administered using a calibrated GENOSYL Delivery System. Only validated ventilator systems or nasal cannulas should be used in conjunction with GENOSYL.
- See package insert for additional **Important Safety Information**.

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Please see inserted full prescribing information.
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