

VERO

BIOTECH

GENOSYL® Delivery System (GENOSYL® DS)



OPERATOR'S MANUAL

Technical Support: 877-337-4118

VERO BIOTECH, LLC
387 Technology Circle NW, Suite 125
Atlanta, GA 30313 USA

WARNINGS, CAUTIONS, AND NOTES

Please read all warnings and cautions in this Operator's Manual prior to using the GENOSYL DS.

Throughout this Operator's Manual, warning, cautions, and notes will be displayed in the following manner.

WARNING

The warning box will alert the user to possible injury, death, or serious adverse reactions associated with the use or misuse of the device.

CAUTION

The caution box will alert the user about proper use of the equipment and any conditions that could result in equipment damage or failure. The user should read and adhere to all warnings and cautions.

NOTE

The note box provides information, clarification or supplemental information to assist and educate the user on the use of the equipment.

A complete list of Warnings and Cautions for the GENOSYL DS are shown below. Where appropriate, some of these will also be shown throughout this manual.

WARNINGS

Please consult the package insert for a complete list of contraindications.

Alarms

- ALWAYS acknowledge and follow information provided from alarms. An alarm indicates an abnormal condition, and ignoring alarms can result in possible injury, death, or serious adverse reactions.
- ALWAYS use clinical judgement when setting upper or lower alarm limits. Failure to do so could result in possible injury or death.

Consoles

- ALWAYS have a second console in standby mode present and properly connected when the primary console is connected to the patient. If the primary console malfunctions and the second console is not available or properly connected, this may result in patient injury or death.
- DO NOT clean the GENOSYL DS with the power connected and the System turned ON, as this may lead to injury (e.g., shock). Unplug AC/DC power

WARNINGS

supply external to the System prior to cleaning.

- NEVER modify the equipment. Modifications of the equipment may result in malfunction, which may result in a fire, shock, injury, or death.
- NEVER turn the rear power switch OFF until the System has gone through a controlled shutdown. Turning the rear power switch OFF prematurely (e.g., while it is still in use) will immediately shut down the device. This may result in interruption in NO delivery to the patient, which may cause injury or death.

Cassette

- DO NOT reuse a Cassette. A Cassette is intended for a single use only. Re-use of a Cassette may affect its ability to provide the correct NO dosage to the patient, which may cause injury or death.
- DO NOT use a Cassette if the foil circle on the base of the Cassette has been punctured. A foil circle that is not intact indicates a used Cassette. Use of a used Cassette may affect the correct NO dosage to the patient, which may cause injury or death.
- DO NOT use the Cassette if the indicator is not blue. An indicator that is any color other than blue may affect the Cassette's ability to provide the correct NO dosage to the patient, which may cause injury or death.
- DO NOT use a Cassette that is beyond its expiration date. Using an expired Cassette may affect the Cassette's ability to provide the correct NO dosage to the patient, which may cause injury or death.
- MAKE SURE the System stabilizes to the prescribed concentration (ppm) of NO prior to leaving the Console unattended. Failure to do so could result in under delivery of the target NO, leading to injury or harm.
- ALWAYS replace a Cassette by transitioning to the Standby Console prior to Cassette depletion. A depleted Cassette interrupts patient dosing and can lead to under dosing and/or injury to the patient.
- ALWAYS follow Cassette inspection instructions prior to Cassette insertion. Not inspecting the Cassette prior to insertion may lead to using a faulty Cassette, resulting in injury.

Connections

- ALWAYS follow pre-use setup instructions for the routing and connections of tubing to avoid patient strangulation.
- MAKE SURE the System has all tubing connected as described in the instructions. Not connecting all tubing may result in inaccurate dosage and harm the patient.
- NEVER touch the electrical connectors of the System or its accessories, and the patient simultaneously. If the user touches another device with a ground-

WARNINGS

fault failure and simultaneously touches the GENOSYL DS, this can result in injury (e.g., shock) should a grounding failure be present.

Battery

- ONLY properly trained personnel should replace the battery. Incorrectly replacing the battery may result in a hazard such as excessive temperatures, fire, or explosion.
- MAKE SURE the GENOSYL DS is connected to AC wall power to charge the battery a minimum of once every 3 months to maintain a minimum battery charge. Failure to recharge the console battery for extended timeframes may result in full discharge of the battery. If a Battery Error message occurs during startup of the System, contact Technical Support at 877-337-4118 for assistance.

User

- ONLY intended users who are experienced in the use of this System should use this device. US federal law restricts device use to licensed medical professionals. If device is used by unintended users, device can be misused and lead to injury or death.

Alternative Means of Ventilation

- ALWAYS ensure that the manual flow displayed on the console matches the flow set into the resuscitation bag. Incorrect flow settings may result in an incorrect estimation of NO delivery. If the flow into the manual equipment is too low, there is risk of overdosing the patient with NO.
- ALWAYS squeeze the bag several times, after starting fresh gas flow, to empty residual gas in the bag prior to using the System to ventilate a patient. Failure to do so could result in higher NO₂ levels being delivered to the patient.
- ALWAYS use the smallest bag adequate to deliver the desired tidal volume. Failure to do so could result in higher NO₂ levels being delivered to the patient.

Patient Monitoring

- ALWAYS constantly monitor the patient. System malfunctions can occur if device and patient are not monitored and can result in injury or death. Careful monitoring is required by care personnel whenever the System is used on a patient. The use of an alarm and a monitoring system does not give an absolute assurance of warning for every malfunction that may occur. Certain alarms may require immediate response.

Use with Ventilators

- DO NOT use the GENOSYL DS with circle anesthesia ventilator systems. The GENOSYL DS has not been characterized or qualified for use with anesthesia breathing systems with recirculation of gases.
- ONLY use a manual resuscitation bag with the GENOSYL DS for a short time

WARNINGS

(e.g., less than one hour) when on battery only. Otherwise, the system will shut off and may result in injury or death.

- ALWAYS ensure the trigger sensitivity of the ventilator is checked after connecting the GENOSYL DS to the breathing circuit. The GENOSYL DS injects and samples gas from the patient respiratory circuit which may affect the triggering sensitivity of the ventilator.
- ALWAYS ensure the patient disconnect and high-pressure alarms are used with the ventilator. Otherwise the system is not working properly.

Set-up

- ONLY Vero Biotech authorized equipment technicians are to perform the initial System set-up prior to initial use. Failure to use an authorized equipment technician can result in a patient or user injury.
- ONLY store the GENOSYL DS as outlined in the storage instructions. Not storing the device in alignment with its storage instructions can cause the device to be unsafe and lead to injury or death.
- AVOID using the GENOSYL DS adjacent to or stacked with other equipment, as it may result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- DO NOT use accessories or cables other than those specified or provided by the manufacturer of this equipment, as this may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- DO NOT place portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30cm (12 inches) to any part of the GENOSYL DS, including cables specified. Otherwise, degradation of the performance of this equipment could occur, resulting in injury.
- Only connect to a power outlet with protective earth. Failure to connect to an outlet with protective earth may result in an electrical shock.

Troubleshooting

- ALWAYS ensure patient safety before troubleshooting (such as an activated alarm) or replacing a problematic item. Not monitoring the patient prior to attending to an alarm can result in injury or death.

Calibration

- ONLY use the calibration gas pressure regulators supplied by the manufacturer. Pressure regulators not supplied by the manufacturer may damage the sensors and may lead to patient injury.
- ALWAYS verify the correct NIST traceable calibration gas is being used and

WARNINGS

confirm the expiration date of the calibration gas prior to performing calibration. The use of incorrect or expired gas may result in inaccurate sensor readings and can lead to patient injury.

Cleaning and Maintenance

- NEVER submerge the GENOSYL DS in water. Submerging in water will damage the System and could cause electrical shorts which may result in injury or death.

Water Trap

- ALWAYS empty Water Trap when prompted by the System, and when the trap is more than half full. Allowing the Water Trap to completely fill will occlude the Sample Line which will interrupt patient gas NO, NO₂, and O₂ concentration monitoring. Failure to monitor the patient gas NO, NO₂, and O₂ concentrations may result in patient injury.
- ALWAYS conduct Water Trap test every time you empty and replace the Water Trap, as failure to do so may lead to an incorrect NO reading, which can result in injury or death.
- ALWAYS use a Water Trap supplied by the manufacturer. Using an incorrect Water Trap could result in non-functioning or inaccurate sensor readings.

Use Outside of Product Labeling

- ONLY use the GENOSYL DS, its parts, and accessories as instructed. Using non-specified components may result in product malfunction, injury or death.
- ALWAYS use the GENOSYL DS in accordance with the indications, usage, contraindications, warnings and precautions described in the GENOSYL prescribing information and labeling. Refer to latest approved prescribing information and labeling prior to use.
- ONLY trained personnel should operate the GENOSYL DS. Failure to do so can result in injury or death.
- ONLY mechanical ventilators validated with the GENOSYL DS should be used. Not using a validated ventilator system can result in injury or harm.

CAUTIONS**Supplied Instructions**

- ALWAYS refer to the instructions supplied with all equipment to be used in conjunction with the GENOSYL DS for their intended uses, contraindications, and potential complications. Misuse of the device or its components may damage the device.

CAUTIONS**Cassette**

- DO NOT remove Cassette from packaging until ready to use. Removing Cassette from packaging prior to its use may collect dust and debris and affect device performance.

Consoles

- ALWAYS operate the Console on a level surface to avoid potential interruption to nitric oxide (NO) delivery.
- ONLY use recommended cleaning agents or a damp cloth to clean the Console and limit use of liquids around Console. Excess water can permanently damage the device.
- ONLY use the GENOSYL DS with the power cord supplied by the manufacturer. Use of a generic power cord may cause output voltage instability leading to a touch screen failure.
- ALWAYS ensure the power cord is firmly seated into the power supply and the wall outlet. A loose connection can result in damage to the device or faulty operation.

Calibration

- ALWAYS perform a full-scale calibration of the GENOSYL DS when prompted by the System prior to use.
- ALWAYS confirm the correct flow direction of the installed one-way check valve in the sampling tee to avoid over pressurization of the sampling system and damage to the device.

Cleaning and Maintenance

- ALWAYS follow maintenance instructions in this manual for your safety and to prevent damage to the System.
- ALWAYS power down the GENOSYL DS Console and disconnect the power to the Console when not in use. Failure to do so may lead to permanent damage to the Console.
- DO NOT sterilize (e.g., autoclave, gas sterilize) any of the components of the System, as this may compromise performance.
- DO NOT use harsh cleaning agents. Doing so may impair the structural integrity and/or function of the device.
- DO NOT touch or rub the display screen with abrasive cleaning compounds, as they may scratch and damage the screens.
- ALWAYS ensure the System is completely dry after cleaning before powering it ON. Failure to do so could result in equipment damage.

CAUTIONS**Switching OFF the System**

- NEVER turn the rear power switch OFF until the System has gone through a controlled shutdown. Turning the rear power switch OFF prematurely (e.g., while it is still in use) will immediately shut down the device and may cause improper operation upon restart.

Cart

- DO NOT remove the bottom base of the cart. The bottom base has a weight permanently attached. Removing the weight can result in improper balance and instability of the cart.
- DO NOT stand or sit on the cart. Standing or sitting on the cart can damage the device.
- ALWAYS push or pull the cart using the handle only. NOT doing so may result in damage to the device.

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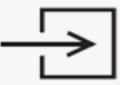





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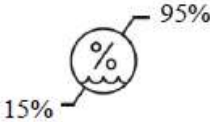

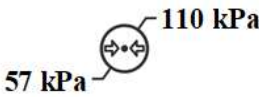



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Abbreviations, Terminology, and Definitions


ABBREVIATION / TERMINOLOGY	DEFINITION
DS	Delivery System
Backup	A situation whereby the Standby Console and its Cassette is activated in the event of a failure of the Primary Console.
Cassette	The Cassette contains the material used to make nitric oxide and when inserted into the Console is available for dosing the patient.
Cassette Activation Lever	A lever that will activate the Cassette when it is lowered to the bottom position.
Display	Electronic information panel located on the front of the Console.
GENOSYL	Nitric Oxide for inhalation
Keypad	A Graphical User Interface function built into the Console display and used to enter the Nitric Oxide dose to be administered to the patient.
L/min	Liters per minute
LPM	
Mixer	Ventilator circuit accessory used to mix the ventilator gas with the gas supplied by the GENOSYL DS for specific ventilator and tidal volume use cases, per Section 9.2 .
NICU	Neonatal Intensive Care Unit
NO	Nitric Oxide
NO Injection Port	Port on the front of the Console that introduces the concentrated NO into the ventilator stream.
Gas Sampling Port	Port on the front of the Console at the Water Trap that measures NO ₂ levels within the NO gas path prior to reaching the patient.
NO ₂	Nitrogen Dioxide
O ₂	Oxygen
ppm	Parts Per Million
Primary Console	The Console in Primary Mode and currently available for active NO administration.
Standby Console	The Console in Standby Mode and not actively delivering NO. When in Standby Mode, the Console is ready to transition to Primary Mode during normal operation, or ready to serve as the Back Up Console in the event of a failure of the Primary Console.
System	The System (GENOSYL DS) consists of a cart with two Consoles, Cassettes, and component parts used to set up the gas lines and GENOSYL DS Ventilator Circuit.
v	Electrical Volts

SYMBOLS



Symbol	Symbol Name	Description
	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging equipment.
	RF Interference	Devices marked with this symbol may interfere with the console.
	Water Trap Seal	Indicates the location where the Water Trap is to be attached.
	Unlock position	Direction to push to open the Water Trap.
	Insertion Point	Water Trap insertion guide for placement of the seal.
	NO Injection	Output port for GENOSYL to patient circuit
	Calibration Port	Input port for calibration gas
	Manual Ventilation	Output port for GENOSYL to manual ventilation system
	Operating Instructions	Refer to operating instructions for instructions for use, warnings, precautions, and other equipment information.
	AC	Indicates power input specification is alternating current (AC).
IPX1	Ingression	Code for the level of ingress protection tested. The enclosure was tested to be drip proof.





	Catalog or model number	Indicates the catalog number so that the medical device can be identified.
	Batch Code	Indicates the batch code so that the batch or lot can be identified.
	Serial Number	Indicates the serial number so that a specific medical device can be identified.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Attention	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Use by	Indicates the date after which the medical device is not to be used.



GENOSYL DS PARTS / COMPONENTS

PART	PART NAME	VERO BIOTECH PART NUMBER
	GENOSYL DS Console (2 required per System)	601588-01
	GENOSYL DS Console Cart	601260-01


The following parts are required to set up the GENOSYL DS and deliver nitric oxide to the patient ventilator circuit, using validated ventilators, ventilator circuits and manual ventilation equipment. All parts listed are single patient use.

PART	PART NAME	VERO BIOTECH PART NUMBER
	GENOSYL Cassette	601164-01
	GENOSYL DS Mixer	601445-01

PART	PART NAME	VERO BIOTECH PART NUMBER
	NO Gas Injection Adapter 22M/15F x 22F	601503-01
	Adapter 22F x 22F	601473-01
	Iso-Gard® Filter S	5003-0015
	GENOSYL DS Gas Lines: NO Injection Line (red) Sample Line (blue) Manual Ventilation Line (clear)	601690-01
	Neonatal Gas Sample Tee	601474-01

PART	PART NAME	VERO BIOTECH PART NUMBER
	Water Trap	600896-02
	High Flow Oscillatory Ventilator (HFOV) Gas Sampling Port	601744-01
	22M/15F x 15M Elbow Adapter	601746-01

The following parts are required to deliver nitric oxide using a manual ventilation system.

PART	PART NAME	VERO BIOTECH PART NUMBER
	GENOSYL DS Manual Ventilation Bag NO Adapter	601485-01

The following parts are required for routine maintenance.

PART	VERO BIOTECH PART NUMBER
Calibration Gas - 45 ppm NO	1003-0010
Calibration Gas - 10 ppm NO ₂	1003-0011
Calibration Regulator Kit	1005-0016
Calibration Gas Extension Tubing	601436-01
Calibration Gas Carrying Case	601564-01

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GENOSYL® DS



SECTION 1 GENERAL INFORMATION

1. GENERAL INFORMATION

1.1. User Responsibility

The GENOSYL DS (Console) will perform as described in this Operator's Manual, accompanying inserts, and/or labels when assembled, operated, maintained, and repaired in accordance with the instructions provided. The Console must be set up as described in [Section 3](#). If the Console does not perform as described in [Section 3](#) or during assembly, the parts are found to be broken, missing, contaminated, or visibly worn, they should be replaced immediately.

In the case of repair or replacement of the Console is required, a telephone service request should be made to **Technical Support at 877-337-4118**. The GENOSYL DS or any of its parts should not be serviced or repaired by anyone other than a Vero Biotech Technical Engineer or without written permission from Vero Biotech Technical Engineering Department.

Any malfunction resulting from faulty maintenance, improper repair, damage, alteration by anyone other than a Vero Biotech Technical Engineer, and/or improper use will be the sole responsibility of the User.

WARNING

The GENOSYL DS must only be used in accordance with the approved indications, usage, contraindications, precautions, and warning described in the GENOSYL DS labeling. Refer to the labeling prior to use.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician. Outside the U.S., check local laws for any restrictions that may apply.

NOTES

- Prior to using the GENOSYL DS, read through this Operator's Manual.
- Follow all instructions and obey the Warnings and Cautions.
- Keep this Operator's Manual available to readily answer questions.
- Read through all manufacturer Operator's Manuals for the ventilator, humidifier and any other accessory items used.

1.2. General Information and Indications for Use

GENOSYL DS generates and delivers NO for inhalation at the point of use. The concentration of NO, as set by the user, is monitored and adjusted to accurately dose the patient throughout an inspired breath. Only validated devices / components should be used with the GENOSYL DS.

The intended population for inhaled NO treatment is term and near-term neonates in neonatal intensive care units (NICUs). Refer to the GENOSYL (nitric oxide) for inhalation drug label for more detailed information.

The GENOSYL DS is intended for use by healthcare professionals (HCPs) who are licensed and actively practicing pediatric and/or neonatal respiratory therapists (RTs) in the United States. These users are required to set up, administer inhaled nitric oxide and provide respiratory care (including initiation and maintenance of mechanical ventilators) in the critically ill neonatal population. CAUTION: Federal law restricts this device to sale by or on the order of a physician.

The GENOSYL DS starts with liquid N_2O_4/NO_2 , which is then converted in a proprietary Cassette to NO. The GENOSYL DS delivers NO into the ventilator stream, where the NO joins a stream of air or O_2 and is diluted to the prescribed concentration. Where applicable, as indicated in the Operator's Manual, a Mixer then provides adequate mixing of the two gas streams.

The NO concentration (dose) to be delivered to the patient is selected by the user and is set and maintained independently by means of computer-controlled air pumps, Cassette heaters, and a feedback loop that measures the delivered NO concentration.

The GENOSYL DS takes a gas sample removed from the NO gas flow stream immediately prior to the patient and provides real-time output of the NO, NO_2 , and O_2 concentrations that are being delivered to the patient. The continuous integrated gas monitoring includes a comprehensive alarm system.

The NO concentration detected from the sample line is used in a feedback loop to adjust the NO concentration delivered into the ventilator circuit.

The GENOSYL DS includes a redundant Console for complete backup capability for delivery of NO for inhalation. Each Console has a back-up battery that provides at least 1 hour of NO delivery in the absence of an external power source.

1.3. Principles of Operation

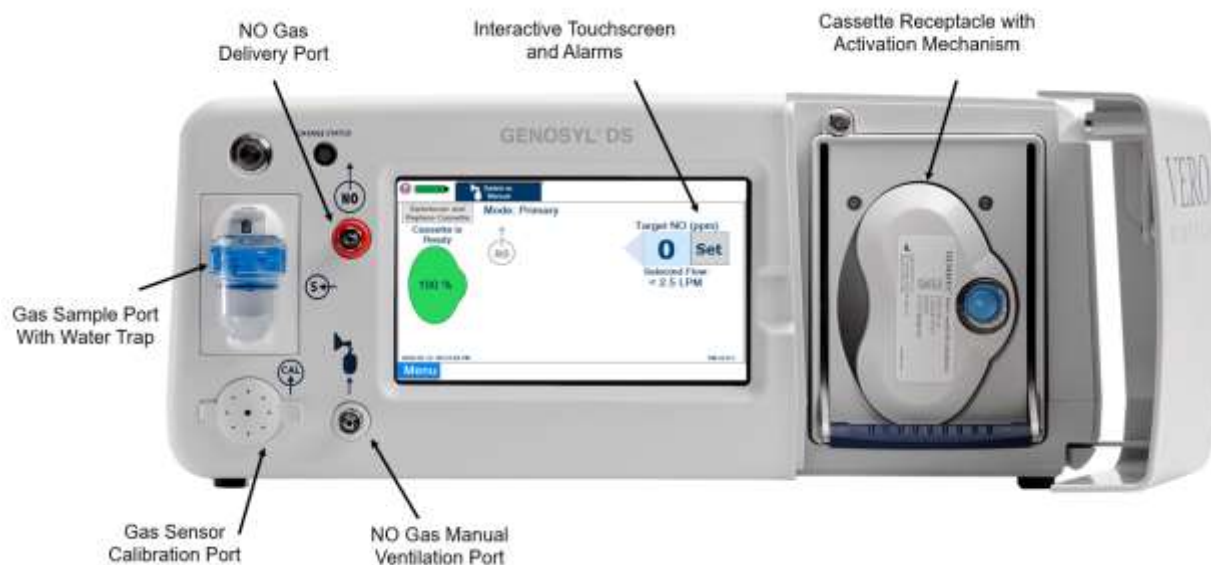
GENOSYL DS. The GENOSYL DS continuously introduces a precisely-controlled concentration of nitric oxide (NO) into the inspiratory limb of the ventilator circuit. GENOSYL DS utilizes the known properties of NO and other oxides of nitrogen, namely dinitrogen tetroxide (N₂O₄) and nitrogen dioxide (NO₂), to create a “tankless” drug/device combination System to produce, at the point of use, ultra-high purity NO for inhalation, providing a consistent, prescribed dose to the patient.

Console. The GENOSYL DS Console contains the electronics to control the production and to maintain the constant and precise delivery of NO.

The primary features of the Console front panel include (Figure 1):

- Interactive touch screen and alarms
- Cassette receptacle with activation mechanism
- NO gas delivery port
- Gas sensor calibration port
- Gas sampling port with Water Trap
- Manual ventilation port

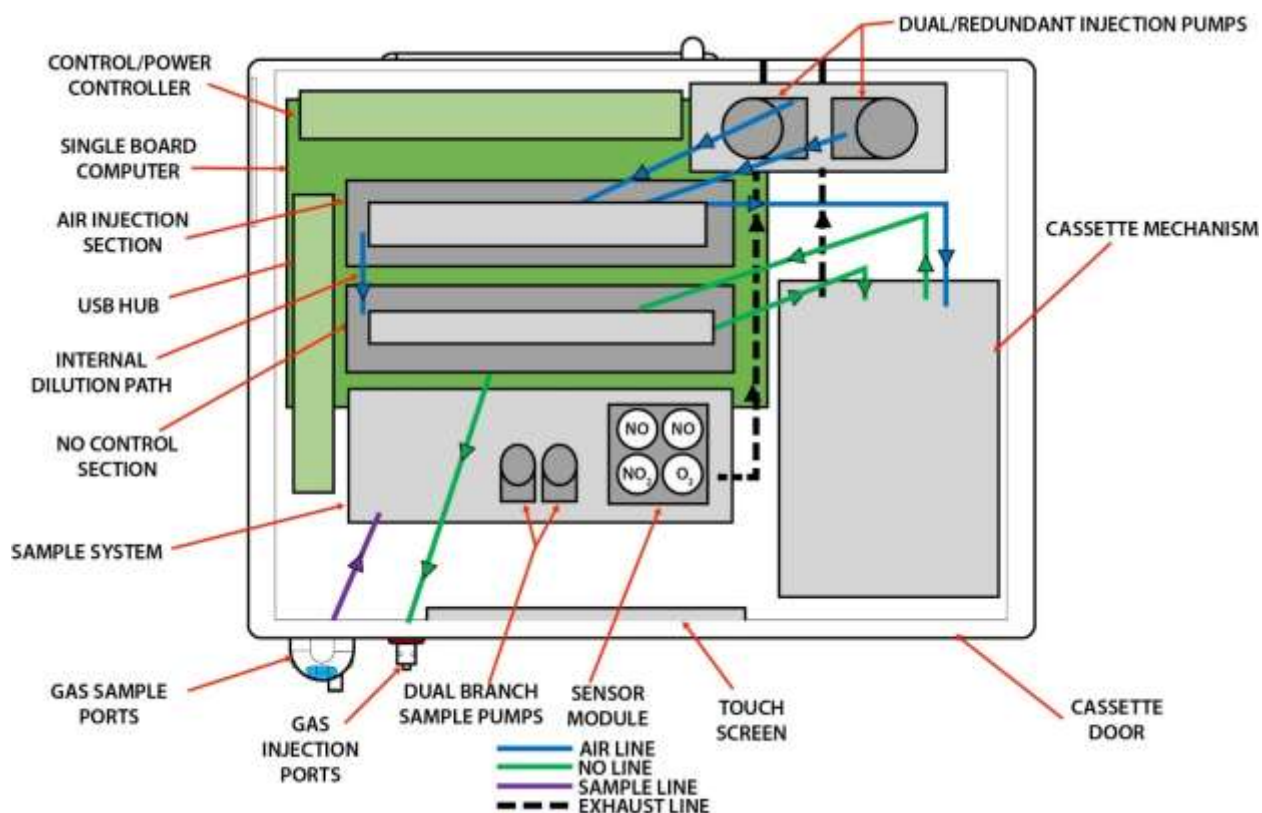
Figure 1: GENOSYL DS Console Front Panel View



The primary internal features of the Console are depicted in the GENOSYL DS Console Internal Diagram (Figure 2):

- Control / Power Controller
- Single Board Computer
- USB Hub
- Dual / Redundant Injection Pumps
- Air Injection Section
- Cassette Mechanism
- NO Control Section
- Injection Port
- Internal Dilution Path
- Gas Sensor and Cassette Exhaust Paths
- Sample System
 - Dual Branch Sample Pumps
 - Sensor Module (NO, O₂, NO₂)
 - Water Trap Sample Inlet
 - Calibration Port
- Touch Screen
- Cassette Door

Figure 2: GENOSYL DS Console Internal Diagram

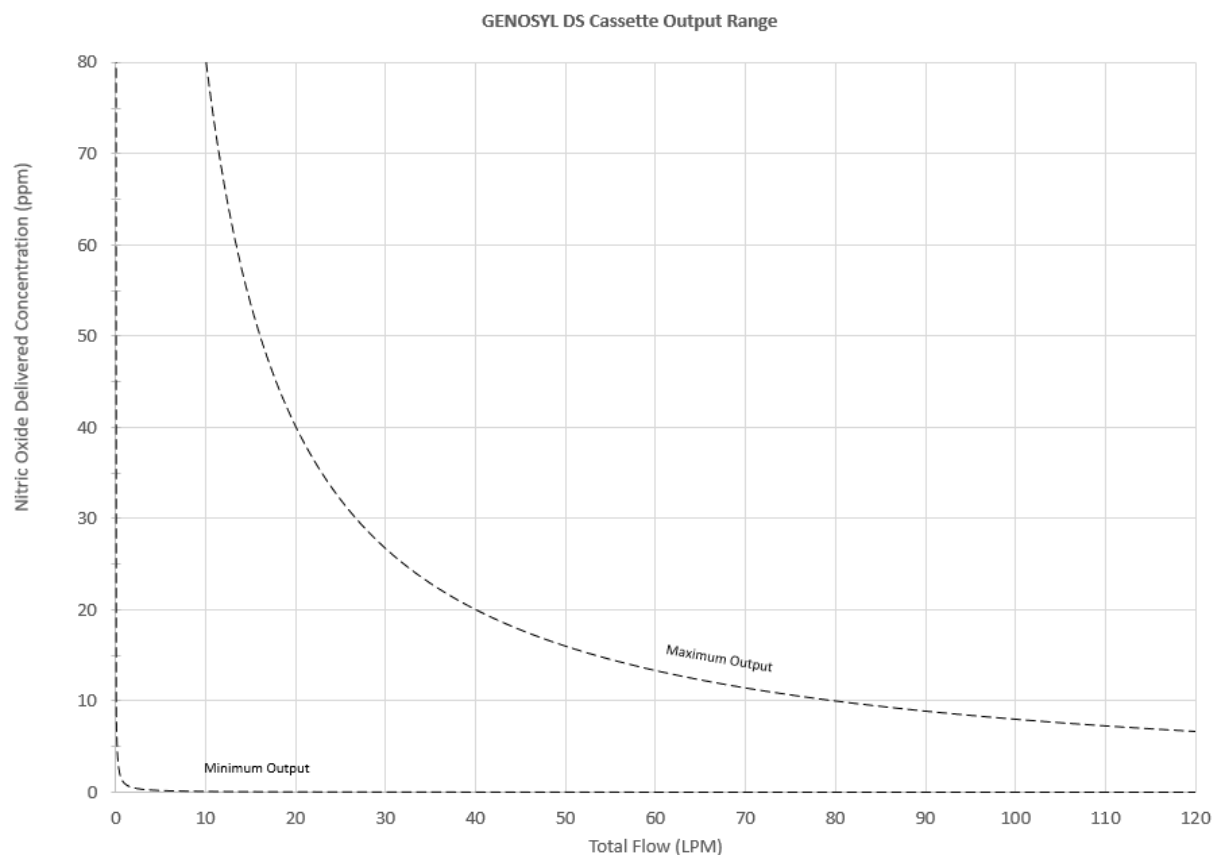


NO generation. The Console has a single Cassette containing liquid $\text{N}_2\text{O}_4/\text{NO}_2$ inside a stainless-steel vessel (the liquid module) and two antioxidant cartridges. Upon initiation of the Cassette, the liquid N_2O_4 is heated, producing NO_2 gas, which is mixed with 0.6 LPM ambient air supplied by the Console. The NO_2 /air is injected into the two antioxidant cartridges inside the Cassette, which converts NO_2 to NO .

The Cassette is designed to provide NO in concentrations up to 80 ppm. The maximum and minimum delivered dose for a range of constant inspiratory flow rates are presented in [Figure 3](#).

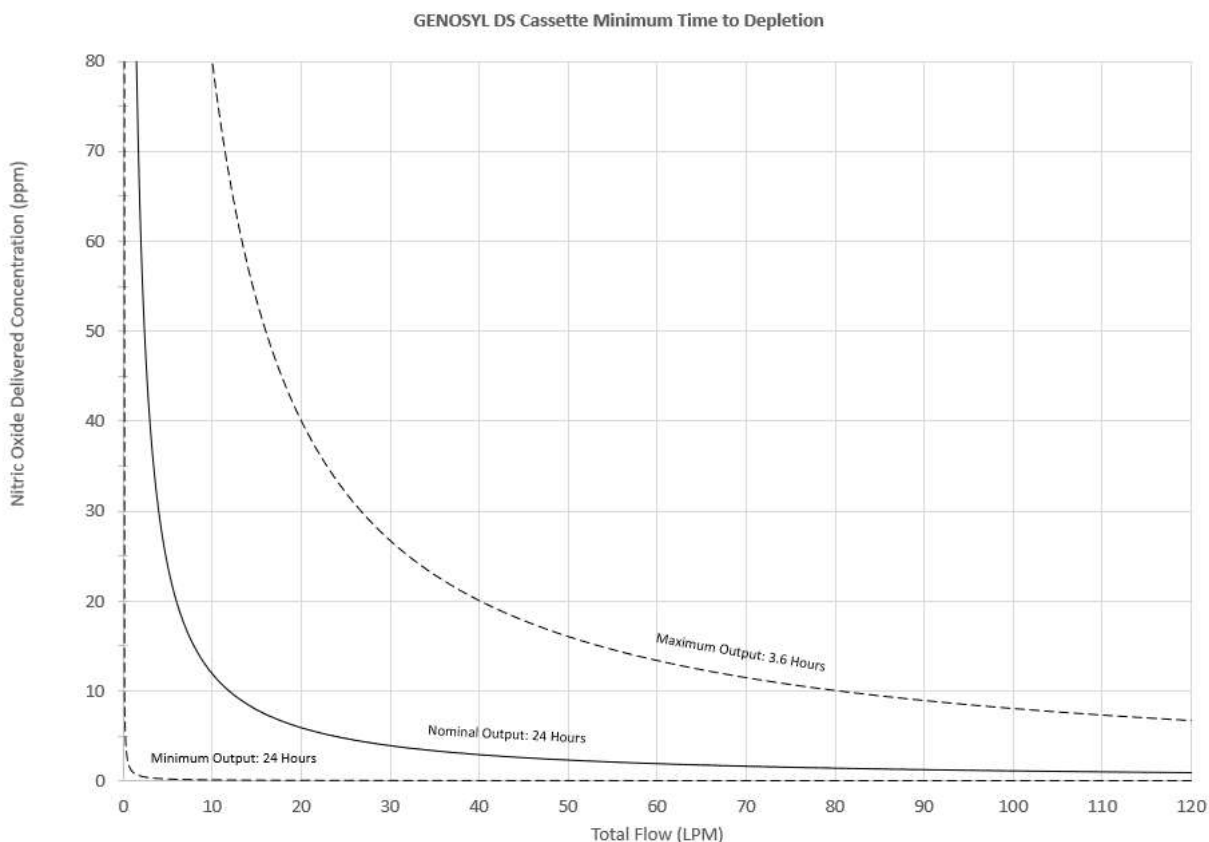
The maximum combination of dose (ppm) and flow (LPM) output of the System is 800 ppm x LPM (e.g., 20 ppm with 40 LPM, 40 ppm at 20 LPM, etc.). The System is capable of delivering NO at a minimum of 1 ppm x LPM (e.g., 1 ppm at 1 LPM).

Figure 3: Cassette Output Range



The total time to deplete the Cassette N_2O_4 contents depends on the rate of use. The minimum time to depletion based on use rate is shown in [Figure 4](#). The calculated minimum remaining contents at the current output rate is indicated by a gauge presented on the Console display during use.

Figure 4: Calculated Time to Cassette Depletion



NO Injection into the Ventilator Circuit. After NO is produced in the Cassette, the NO injector introduces the concentrated NO into the ventilator circuit where the NO is diluted to the prescribed concentration (dose) and mixed with the O₂ or air supplied to the patient.

Before the gas mixture reaches the patient, a sampling line removes a small gas sample and sends it back to the Console, where gas sensors continuously measure the supplied NO, NO₂ and O₂. The Console software then compares the measured NO concentration to the set NO concentration and continuously adjusts the delivery of NO to maintain the prescribed NO concentration (dose) delivered to the patient (closed loop control). The Console software commands the NO injection flow rate into the ventilator circuit with a maximum flow rate of 0.6 LPM. Changes in the ventilator settings by the user may cause brief transient changes in the measured NO value. The Console software will adjust the injected flow rate and the internal temperature of the Cassette to compensate for the changes in the total ventilator flow rate. For example, a higher minute ventilation will require a higher injection flow rate to produce the same NO concentration.

Mixer. An inline Mixer is used in the applicable ventilator circuit after the NO injection site and before the gas sampling site to mix NO from the Console with the gas supplied by the ventilator, for specific ventilator and tidal volume use cases per [Section 9.2](#).

Gas Monitoring. The gas mixture delivered to the patient by the GENOSYL DS is continuously monitored with two NO detectors, with one providing redundant back-up, as well as a detector for NO₂ and O₂. A sample of inspired gas is taken from the inspiratory limb, close to the patient, and is measured by the gas sensor within the Console. The gas monitoring sensors are electrochemical; they are specific to each gas and provide an electronic signal that is proportional to the concentration of gas present.

Alarms and Shutdown Safeguards. The GENOSYL DS alerts the user in the event of excursions of NO, NO₂, and Oxygen from their expected ranges. Nitric Oxide delivery shutdown conditions are as follows:

- a) NO > 100 ppm
- b) NO₂ reaches 3 ppm

The System will provide a visual and audible high priority alarm. The use of the Back-up Console is required in any of these conditions. Refer to [Section 7.1](#) for additional information on alarms and shutdown safeguards.

Back-up NO Delivery. The Console which is not actively used to administer NO is prepared as a Standby Console with a separate independent power supply, and a second Cassette loaded, but not activated. If the Primary Console fails to deliver NO, the Back-Up Console is activated to continue NO delivery.

Transition to a new Cassette. When a Cassette approaches depletion, the active/original Primary Console notifies the user to begin the transition to a new Cassette in the Standby Console.

During the transition, the target NO concentration is maintained by the two Systems. The original Primary Console decreases the proportion of NO delivered in a controlled manner while the new Primary (previous Standby) Console delivers the remaining NO required to maintain the target dose. When the transition is complete, the new Primary Console / Cassette delivers the entire dose and the depleted Cassette is removed from the previous (original) Primary Console and now becomes the Standby Console.

A new Cassette is inserted in the original Console, which is maintained in Standby mode for backup or transition as needed.

Disposal of the Cassette. Following use, any remaining Cassette contents are purged into an inerting chamber, where the contents are chemically neutralized, rendering the Cassette safe for disposal. When Cassette liquid contents are emptied into the inerting chamber, the inerting chamber color indicator (CI) on the top of the Cassette reddens and bleaches from its original blue color, providing an indication the Cassette is depleted.

1.4. Exposure of Healthcare Providers to NO and NO₂

Occupational exposure of healthcare providers to NO or NO₂ may occur during Inhaled NO therapy for patients. Below are examples of calculated and observed exposure to NO or NO₂, in the context of guideline workplace exposure limits.

Calculated and observational methods show that the exposure levels to NO or NO₂ from an NO delivery System are significantly less than the levels recommended by the National Institute for Occupational Safety and Health (NIOSH).

Workplace Limits: NIOSH has recommended workplace exposure limits as follows¹.

NO	time-weighted (8 hours) average concentration limit of 25 ppm
NO ₂	Recommended exposure limit of 1 ppm

Theoretical Calculation. The build-up of NO in a well-ventilated ICU room, with NO flowing directly into the room, can be evaluated using the following calculation:

Room size	1000 ft ³
Room volume	28,300 L
Room ventilation (6 complete exchanges/hour)	2,830 L/min
NO flow into the room	80 ppm at 14 L/min
Average NO room concentration	0.4 ppm of NO

Observations of NO Exposure. The theoretical calculation has been supplemented by actual measurements in three independent studies in actual therapeutic use settings.^{2,3,4} The studies found that detectable exposures to NO and NO₂ were brief, infrequent, and well below recommended exposure limits.

If the location for using NO has uncertain ventilation then the location should be evaluated for NO and NO₂ build-up prior to use.

¹ NIOSH Pocket Guide to Chemical Hazards, Dept of Health & Human Services, Centers for Disease Control and Prevention, National Inst for Occupational Safety & Health. Publication 2005-149, Sept 2007.

² Hess et al, Use of Inhaled Nitric Oxide in patients with Acute Respiratory Distress Syndrome. *Respiratory Care* 1996; 41(5):424-446.

³ Phillips M, Hall TA, Sekar K, Tomey JL. Assessment of Medical Personnel Exposure to Nitrogen Oxides During Inhaled Nitric Oxide Treatment of neonatal and Pediatric Patients. *Pediatrics*. 1999;104(5):1095-1110.

⁴ Qureshi MA, Shah NJ, Hemmen CW, Thill MC, Kruse JA. Exposure of Intensive Care Nurses to Nitric Oxide and Nitrogen Dioxide during Therapeutic use of Inhaled Nitric Oxide in Adults with Acute Respiratory Distress Syndrome. *Am. J. Crit Care*, 2003;12(2):147-153.

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GENOSYL® DS



SECTION 2

SYSTEM OVERVIEW

2. SYSTEM OVERVIEW

2.1. Frequently Used Functions

Detailed instructions are provided in this manual for the primary user interaction and frequently used functions of the GENOSYL DS, which include:

System Set-Up and Connections ([Section 3](#))

- GENOSYL DS Ventilator Circuit Assembly Pre-Check
- GENOSYL DS Mixer Assembly
- GENOSYL DS Injection Assembly
- GENOSYL DS Gas Lines Connections
- Manual Ventilation Connections
- Mechanical Ventilator Circuit Connections
- Connections to Various Breathing Systems

System Start-Up ([Section 4](#))

- Console Start-Up
- Cassette Insertion
- Water Trap / Sample Line Leak Test

Nitric Oxide Administration ([Section 5](#))

- Primary Console Selection
- Cassette Activation
- Nitric Oxide Dose Set-Up and Administration
- Transitioning to the Standby Console
- Manual Mode
 - Manual Ventilation Use (Bagging)
 - Console Use as a Backup
- Resuming Primary Dosing
- Weaning

Console Shutdown ([Section 6](#))

- Cassette Removal
- Console Shutdown
- Cassette Disposal

Alarms, Alerts, and Troubleshooting (Section 7)

- Alarms (High, Medium, and Low Priority)
- Informational messages
- Troubleshooting

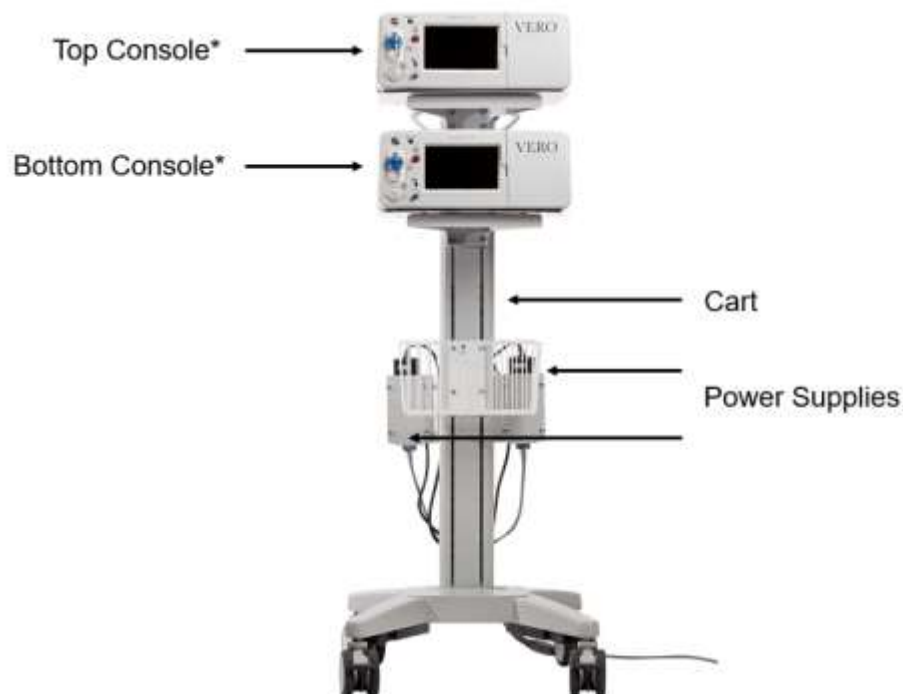
System Maintenance (Section 8)

- Calibration
- Maintenance Schedule
- Water Trap Maintenance
- Air Filter Maintenance
- Battery Replacement
- Cleaning
- Storage

2.2. GENOSYL DS Cart and Consoles

The following pages contain photos of the GENOSYL DS Consoles. The specific sections of the GENOSYL DS are numbered with the respective description listed to the right of the photo.

Figure 5: GENOSYL DS Assembled Cart



CAUTION

- ALWAYS operate the Console on a level surface to avoid potential interruption to nitric oxide (NO) delivery.
- DO NOT remove the bottom base of the cart. The bottom base has a weight permanently attached. Removing the weight can result in improper balance and instability of the cart.
- DO NOT stand or sit on the cart. Standing or sitting on the cart can damage device.
- ALWAYS push or pull the cart using the handle only. NOT doing so may result in damage to the device.

NOTE

Nomenclature for the top and bottom Consoles will change just prior to dosing. The top and bottom Consoles will later be referred to as the Primary Console and the Standby Console. Both Consoles will start-up in Standby Mode. One Console will be switched to Primary Mode and designated as the Primary Console. The other will remain in Standby Mode; ready to transition and become the Primary Console when needed or serve as the backup Console in the event of failure of the Primary Console. (See [Sections 4.1](#) and [5.1](#))

Figure 6: Front View GENOSYL DS Console

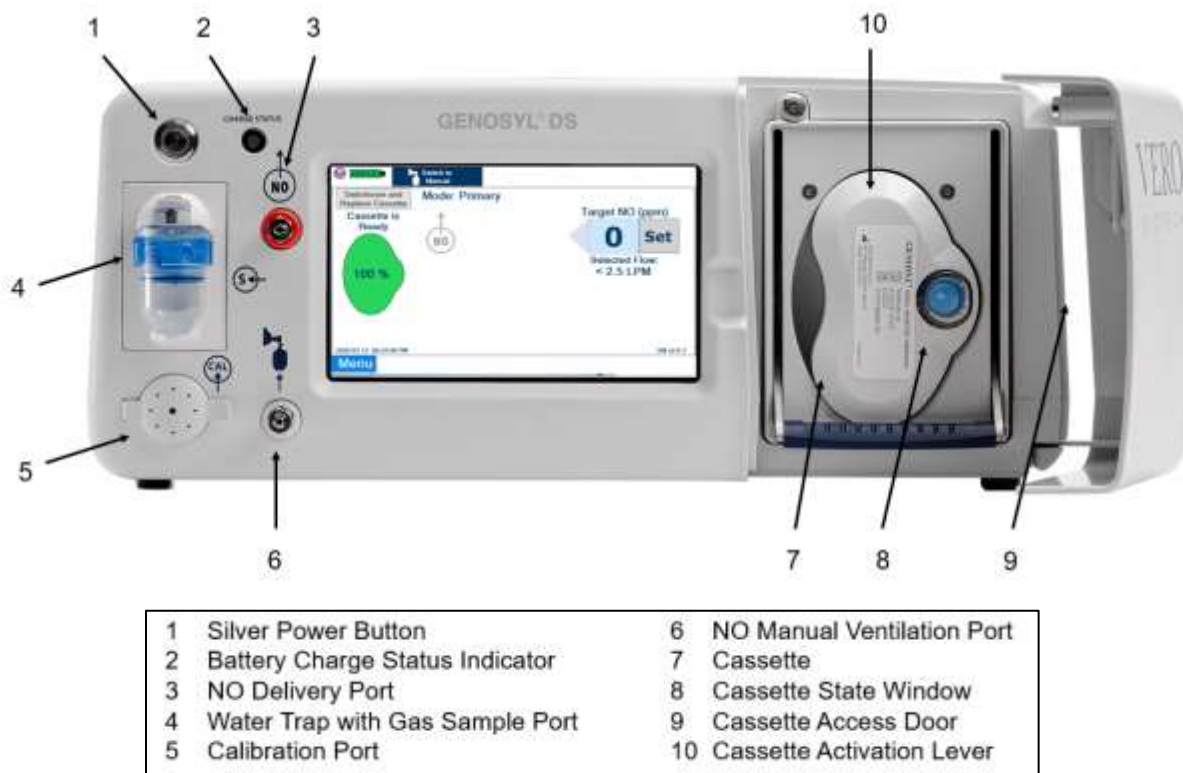


Figure 7: Back View GENOSYL DS Console

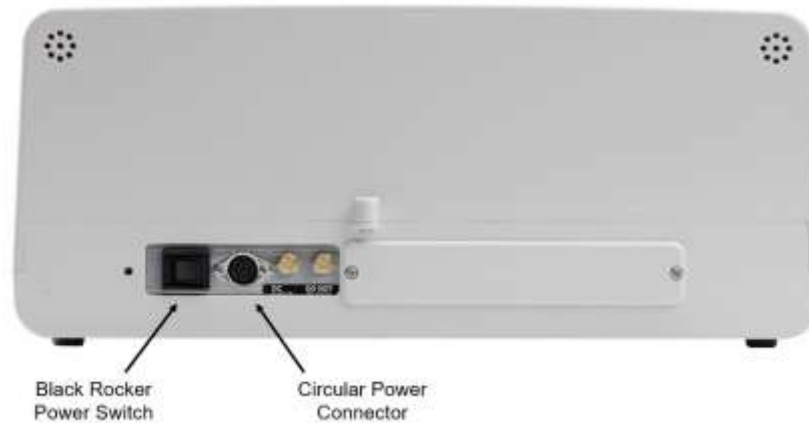


Figure 8: Right Side View GENOSYL DS Console



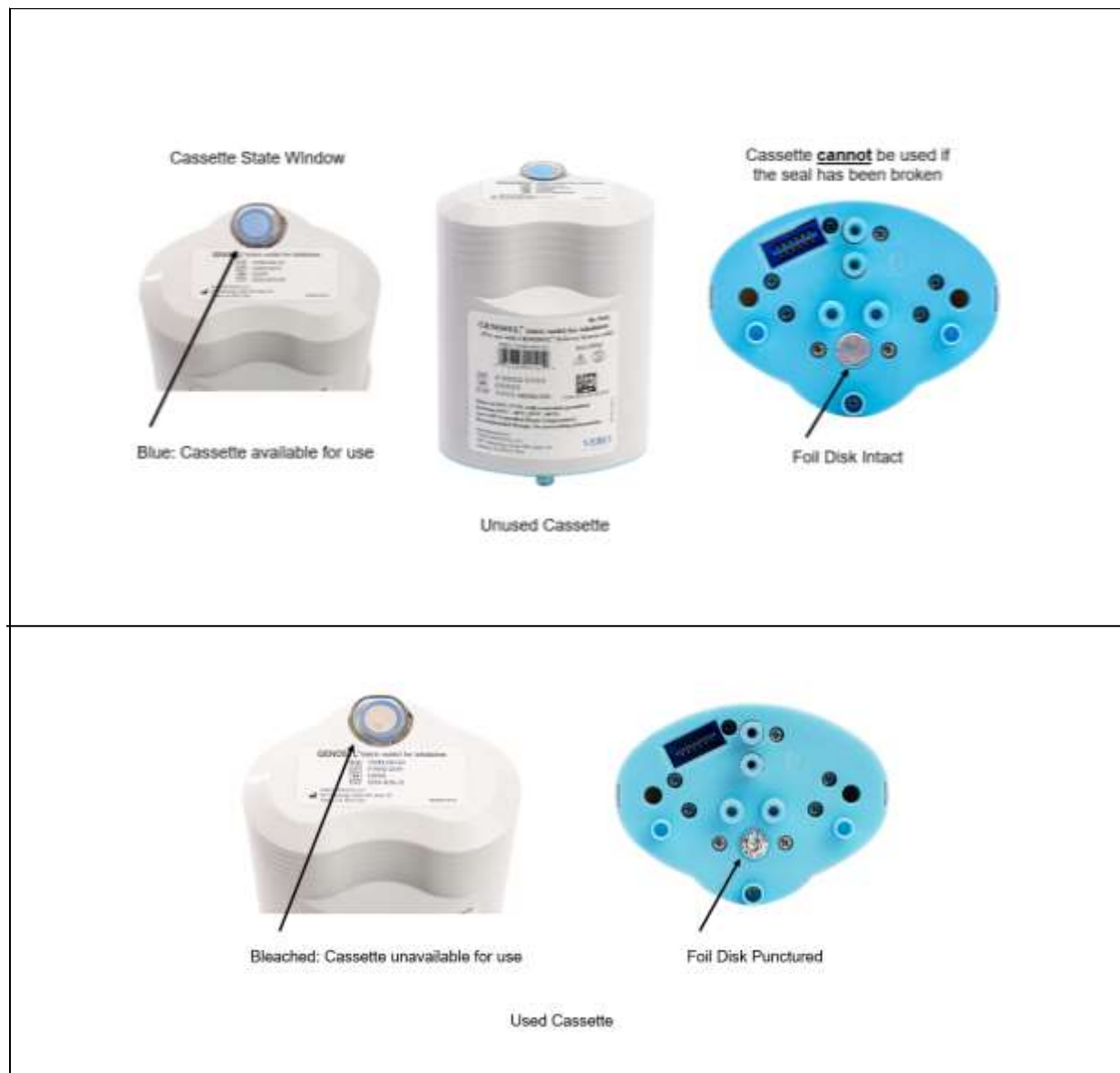
Figure 9: Left Side View GENOSYL DS Console



2.3. Cassette

The Cassette contains the material that will be converted to nitric oxide during the activation process. It is inserted into the GENOSYL DS Console and its shape helps ensure proper orientation during the insertion process. A Cassette State Window is located on the top of the Cassette to indicate if the Cassette is available for use (blue), or if it has been inerted and unavailable for use (bleached and reddened).

Figure 10: GENOSYL Cassette











CAUTION

DO NOT remove Cassette from packaging until ready to use. Removing Cassette from packaging prior to its use may collect dust and debris and affect device performance.

2.4. GENOSYL DS Ventilator Circuit Components

The following parts are required to set up the GENOSYL DS portion of the patient ventilator circuit, as specified in [Section 3.2](#).

PART	PART NAME	FUNCTION
	GENOSYL DS Mixer	Used to mix the NO gas with the gas supplied by the ventilator through a filter containing silica gel to provide intra-breath NO delivery for certain scenarios.
	Adapter 22F x 22F	Used as a coupler between the Mixer and the Gas Injection Adapter.
	NO Gas Injection Adapter 22M/15F x 22F	Used between the Adapter and the Mechanical Ventilator Inspiratory Outlet, and to connect to the NO Injection Line (red).
	Iso-Gard® Filter S	Used to filter air from the Injection Line.

PART	PART NAME	FUNCTION
	GENOSYL DS Gas Lines NO Injection Line (red) Sample Line (blue) NO Manual Ventilation Line (clear)	Used to deliver nitric oxide to the ventilator circuit and manual ventilation bag, and to sample gas within the ventilator circuit.
	Neonatal Gas Sample Tee	Used to connect the Sample Line to the ventilator circuit.
	GENOSYL DS Manual Ventilation Bag NO Adapter	Used to connect oxygen tubing to manual ventilation bagging system to deliver nitric oxide. Includes an NO Injection Port to connect to the NO Injection Line.
	Water Trap	Used to protect sampling system by collecting condensation and filtering contaminants from the sampled gas. The Water Trap may need to be emptied or changed while in use (refer to Section 8.3).

2.5. Gas Lines (detailed explanation)

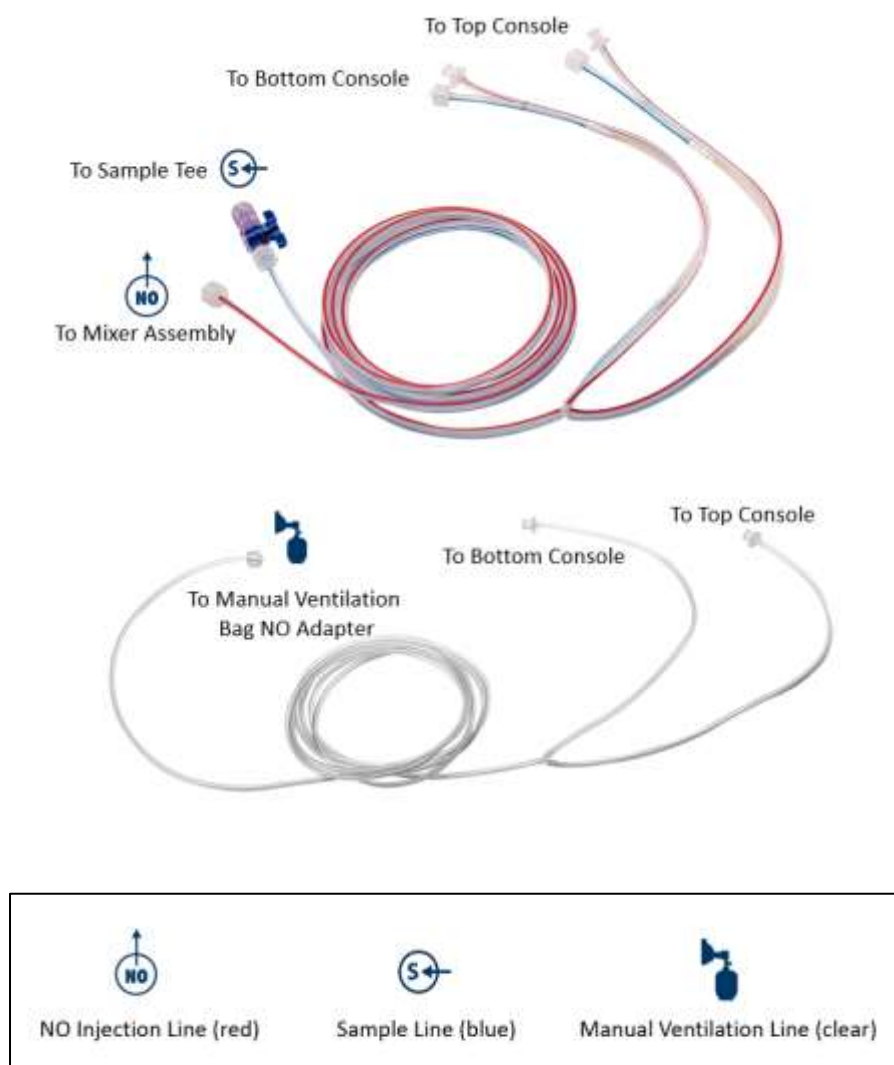
Used to deliver nitric oxide from the GENOSYL DS Consoles to the ventilator circuit and manual ventilation bag, and to sample gas within the ventilator circuit. The lines are color coded and labeled with icons corresponding to colors and icons on each Console.

The NO Injection Line (red) delivers nitric oxide from the Console to the mechanical ventilation circuit (described in [Section 3.7](#)).

The Sample Line (blue) also contains a stopcock to conduct the Water Trap / Sample Line Leak Test (described in [Section 4.2](#)).

The Manual Ventilation Line (clear) delivers nitric oxide from the Console to the Manual Ventilation Bag NO adapter (described in [Section 3.7](#)).

Figure 11: GENOSYL DS Gas Lines



2.6. Console Modes of Operation

During operation, a Console can be in one of three modes; **Primary**, **Standby**, or **Manual**. The user can switch the modes during normal operation to perform specific functions for certain conditions. The following table summarizes key characteristics of each mode.

MODE	FUNCTIONAL CHARACTERISTICS
Standby	<ul style="list-style-type: none">• After powering on, the Console will always start up in this mode.• Ready to enter Primary or Manual Mode.• Enters Primary Mode by pressing the Primary Mode button.• Enters Manual Mode by activating the Cassette.
Primary	<ul style="list-style-type: none">• The mode of operation for controlled dosing with feedback loop.
Manual	<ul style="list-style-type: none">• The mode of operation used for manual ventilation or as a backup due to the failure of a System Console.• Manually adjustable fixed dosing without the need of feedback for certain conditions.

2.7. Display Screen

The GENOSYL DS display screen is presented below (Figure 12) followed by a table with descriptive text corresponding to the numbers shown around the display screen.

Figure 12: GENOSYL DS Display Screen










1 Battery Charge Status Indicator	6 Target NO Dose (ppm)
2 Console Switchover Button	7 Menu Tabs
3 Mode Transition Button	8 Cassette Status Indicator
4 Console Mode	9 NO ₂ Measured Level (ppm)
5 Current NO Dose (ppm)	10 O ₂ Measured Level (ppm)










NOTE





Some confirmation display screens (e.g., “Yes”, “Accept”, etc.) will be semi-transparent after dosing has been initiated to allow the Operator to continue to see important information on the underlying screen (e.g. NO values, Alarms, Alerts, etc.).

2.8. Display Menu Tab Navigation

The table below consists of the available Menu tabs (Main, Alarms, Calibration, Events, and Settings) along with the functional description of each tab, and the buttons within each tab.

MENU TAB DISPLAY	TAB / BUTTON	DESCRIPTION
		Press this tab to access the sub-level tabs (Main, Alarms, Calibration, Events, and Settings).
		Press this button to set the targeted NO (ppm) dose when in Primary Mode.
		<p>Displayed when the Alarms Tab is selected, this screen is used to set the Upper and Lower Alarm Limits for NO (ppm), NO₂ (ppm), and O₂ (%).</p>
		<p>NOTE</p> <p>See Section 7 for additional information on alarms and alerts.</p> <p>Displayed after pressing the Alarms tab, press this button to switch to the default upper and lower limits for NO (ppm), NO₂ (ppm), and O₂ (%).</p>

MENU TAB DISPLAY	TAB / BUTTON	DESCRIPTION
		Displayed when the Alarms Tab is selected, this button is used to access a list of Alarms that have occurred since the last reset for the respective Console. The alarm history can be erased by pressing the Erase Alarms History Button.
		Press this tab to return to the main screen. Pressing the Main Tab will collapse the tab menu.
		Press this tab to access the calibration screen.
		NOTE See Section 8 for additional information on Calibration.
		Press this button to calibrate the low range of the NO and NO ₂ sensor.
		Press this button to calibrate the high range for the NO sensor.
		Press this button to calibrate the high range for the NO ₂ sensor.
		Press this button to initiate calibration for the selected gas.
		Press this button to stop the calibration in the middle of a calibration process. The






MENU TAB DISPLAY	TAB / BUTTON	DESCRIPTION
		previous calibration will remain to be used.
	Calibration History	Press this button to display the history of calibration.
	Events	Press this tab to access the events menu.
	Clear Events	Press this button to clear the events listed on the events screen.
	Settings	Press this tab to access the settings screen.
		Press this button to begin the process of shutting down the Console.
		Press this button to switch display to night mode.
	Change Date Time	Press this button to enter the screen to adjust the date and time.
	Change Machine Date Time	Press this button to adjust the date and time.
	Cancel	Press this button to cancel setting the date and time.
	Perform Leak Test	Press this button to perform a Water Trap / Sample Line leak test.
	Admin / Service Area	Used by service personnel only. Password controlled.

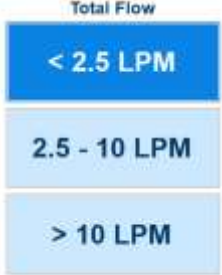
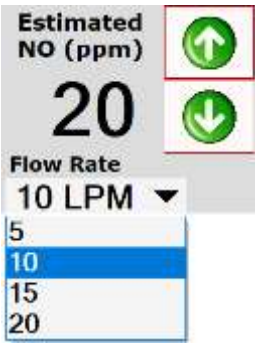

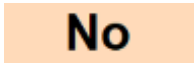



MENU TAB DISPLAY	TAB / BUTTON	DESCRIPTION
		NOTE Call Technical Support at 877-337-4118 for additional support.
		Night Mode: Press this tab to access the sub-level tabs (Main, Alarms, Calibration, Events, and Settings).
		Press this button to switch display from night mode to regular mode.


2.9. Display Screen Operational Buttons

The following buttons on the display screens allow the Operator to operate and adjust the GENOSYL DS prior to and during the delivery of nitric oxide.

Note: the following are shown in “regular mode” but are also available in “night” mode.

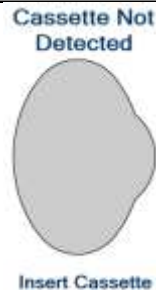
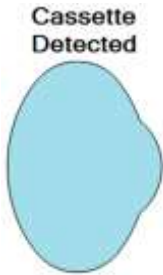
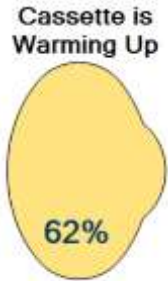
BUTTON	DESCRIPTION
	Press this button to cancel the Water Trap / Sample Line Leak Test. The Console will return to Standby Mode. When in Standby Mode, pulling the Activation Lever down will initiate Manual Mode on the Standby Console. Cancelling this test will disable dosing in Primary Mode.
	Press this button to switch a Console to Primary Mode from Standby Mode or Manual (Ventilation) Mode. When in Primary Mode, the dosage can be set to a user selected (prescribed) level.
	Press this button to switch a Console to Standby Mode from Primary Mode prior to dosing. When in Standby Mode, pulling the Activation Lever down will initiate Manual Mode on the Standby Console.
	Press this button to switch from Primary Mode to Manual Ventilation Mode. When in Manual Mode, the pre-set dosage and flow rates are estimated based upon typical dosages and ventilator flow rates for delivering NO to PPHN patients. These pre-set levels are user adjustable.
	Electronic keypad used to set and adjust the prescribed targeted nitric oxide dose to be delivered to the patient. Includes buttons to confirm (OK), cancel, or clear the entry.

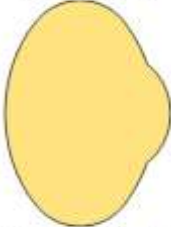

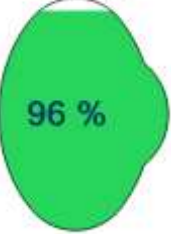
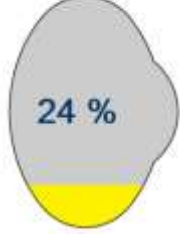
BUTTON	DESCRIPTION
	<p>The Total Flow range is selected by the user. Total Flow range is the sum of the ventilator (or ancillary equipment) Bias Flow and the minute ventilation of the patient.</p>
	<p>Displayed when in Manual Mode, press the green up or down arrows to adjust the dose to the patient, from the default dose.</p> <p>Pressing the down arrow will decrease the dose in increments of 1 ppm for 24 ppm and below. Pressing the up arrow will increase the dose in increments of 2 ppm above 24 ppm.</p> <p>Press the green LPM (liters per minute) button to activate a drop down menu and set a different dilution flow rate, from the default dilution flow rate.</p>
	<p>Press this button to confirm the action specified on the screen.</p>
	<p>Press this button to cancel the action specified on the screen.</p>
	<p>Press this button to acknowledge the information message displayed on the screen.</p>
	<p>Press this button to begin the process of switching the Standby Console to the Primary Console.</p> <div data-bbox="602 1549 1430 1717"> <p>NOTE</p> <p>Text color will be black prior to dosing. The process of switching can only occur after dosing has started and the text has turned blue.</p> </div>
	<p>Press this button to move to the next step.</p>

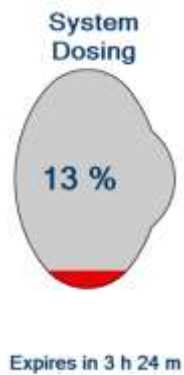
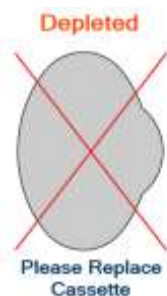
BUTTON	DESCRIPTION
	Press this button to cancel the current step.

2.10. Display Screen – Cassette Status

The following describes the Cassette status that will be shown on the display screen prior to, during, and post-delivery of nitric oxide.

CASSETTE DISPLAY	DESCRIPTION
	<p>This screen will be displayed when a Cassette is absent and not loaded into the Console.</p> <p>Prompt: The user is prompted to “Insert Cassette”</p>
	<p>This screen will be displayed when a Cassette has been detected.</p> <p>Following detection, if NO delivery is less than 1.0 ppm, the Water Trap / Sampling Line Leak Test will automatically be initiated and a corresponding screen will be displayed showing the test progress (see Section 4.2 Cassette Insertion & Water Trap / Sample Line Leak Test).</p>
	<p>This screen is displayed during the warm up phase and shows the progress towards achieving a fully preheated status.</p>


CASSETTE DISPLAY	DESCRIPTION
<p>Cassette is Preheated</p>  <p>Cassette Ready to Activate</p>	<p>This screen is displayed once the Cassette has achieved a fully preheated status.</p> <p>Although the Cassette should only be activated when ready to dose, the display indicates the “Cassette is Ready to Activate.”</p>
<p>Cassette is Ready</p>  <p>Press Set to start</p>	<p>This screen is displayed once the Cassette has been activated. The percentage displayed acts as a fuel gauge to inform the Operator the percent of nitric oxide remaining in the Cassette.</p> <p>Prompt: The user is prompted to “Press Set to Start.”</p>
<p>System Dosing</p>  <p>96 %</p>	<p>This screen is displayed during dosing and shows the percent of nitric oxide remaining in the Cassette.</p> <p>The display will remain green for percentages ranging from 100% to 30%.</p>
<p>System Dosing</p>  <p>24 %</p> <p>Expires in 6 h 31 m</p>	<p>This screen is displayed during dosing and shows the percent of nitric oxide remaining in the Cassette.</p> <p>The display will turn yellow for percentages ranging from 29% to 15%.</p> <p>Once the percent remaining is below 25%, the estimated time remaining is displayed. Estimated time remaining is based upon the remaining nitric oxide divided by the set flow rate. This will change should the flow rate be changed during this phase.</p>

CASSETTE DISPLAY	DESCRIPTION
 <p>System Dosing</p> <p>13 %</p> <p>Expires in 3 h 24 m</p>	<p>This screen is displayed during dosing and shows the percent of nitric oxide remaining in the Cassette.</p> <p>The display will turn red for percentages ranging from 14% to 0%.</p> <p>Once the display reaches a red status, the Console in Standby Mode should be switched to Primary Mode and its Cassette activated to avoid a disruption in the delivery of nitric oxide.</p>
 <p>Depleted</p> <p>Please Replace Cassette</p>	<p>This screen is displayed when the Cassette becomes depleted.</p> <p>Prompt: The user is prompted to “Please Replace Cassette.”</p>

2.11. Cassette position when placed in the Console

An important distinction exists between a Cassette that has been inserted into the Console or inserted and fully seated. Please note the following description for each position.

CASSETTE POSITION	PHOTO	DESCRIPTION
Cassette Inserted		<p>The Cassette has been inserted into the Console, but not fully seated.</p> <p>The Activation Lever has not dropped.</p>

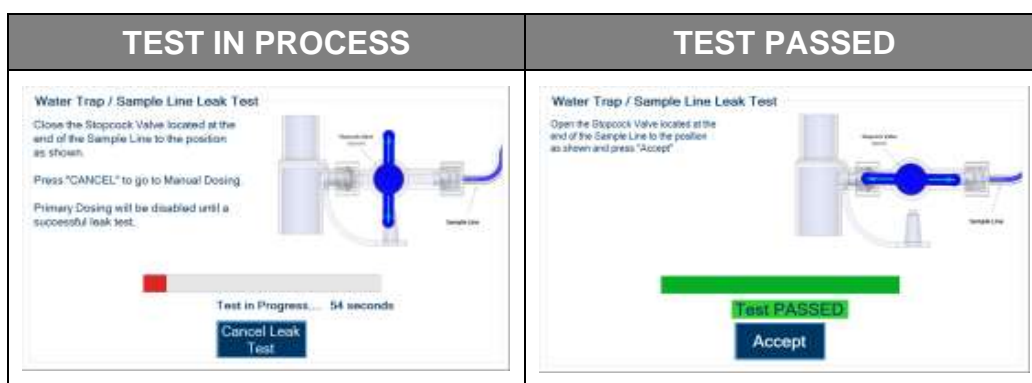
CASSETTE POSITION	PHOTO	DESCRIPTION
Cassette Fully Seated		<p>The Cassette has been inserted and fully seated into the Console and the Activation Lever has dropped.</p> <p>The Water Trap / Sample Line Leak Test will begin when the Cassette is fully seated, and the Activation Lever drops</p>

2.12. Water Trap / Sample Line Leak Test

A Water Trap / Sample Line Leak Test is initiated when a Cassette has been inserted into the Console and fully seated, and if the measured NO is less than 1.0 ppm. Its purpose is to test the integrity of the Water Trap seal, the proper seating of the Water Trap, and the Sample Line connection to each Console, prior to operation. This is important to ensure an accurate measurement of NO within the ventilator circuit.

After the test has been initiated, the screen will prompt the Operator to close the Stopcock Valve and the Operator will have **60 seconds within which to do this**. A numerical timer and a horizontal progress bar provide a visual representation of the time elapsed (red) and time remaining (gray). Once the Stopcock Valve has been closed and if the test has been successfully completed, the entire progress bar will turn green.

Figure 13: Water Trap / Sampling Line Leak Test



If the test has failed, the progress bar will remain red throughout the full 60 seconds. The Operator will be notified and prompted to troubleshoot the potential cause. Until the completion of a successful leak test, primary dosing (dosing in Primary Mode) will be disabled.

Prior to completion of the leak test and if a condition exists in which immediate NO delivery is required, the Operator may cancel the leak test. By pressing the “Cancel Leak Test” button, the Standby Mode screen will appear and allow dosing in Manual Mode (described in [Section 5.5](#)). To return to Primary Mode, a new successful test will be required.

The Leak test may also be initiated manually via the Settings Tab and pressing the “Perform Leak Test” button. This may be useful to test the integrity of the Water Trap and Sample Line independent of the need to initiate the delivery of nitric oxide (see Setting in [Section 2.8](#)).

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GENOSYL® DS



SECTION 3

SYSTEM SET-UP AND CONNECTIONS

3. SYSTEM SET-UP AND CONNECTIONS

3.1. GENOSYL DS Set-Up and Mechanical Ventilator Circuit Schematic

NOTE

- Naming conventions: The GENOSYL DS Ventilator Circuit consists of the GENOSYL Injection Assembly ([Section 3.4](#)), GENOSYL DS Mixer Assembly ([Section 3.5](#)) and the GENOSYL DS Gas Lines ([Section 3.6](#)).
- Connections and disposable circuits to ventilators may vary and are unique to individual manufacturers. Example circuit diagrams are provided for reference.

The schematic in [Figure 14](#) shows an example ventilator circuit set-up and connection to the GENOSYL DS, and a manual ventilation bagging system. For ventilator specific setup and details, reference [Section 3.2](#) and [Section 9, Table 5](#).

[Section 3.1](#) through [Section 3.6](#) in sequence, provides instructions that allow the Operator to set-up the GENOSYL DS Ventilator Circuit with minimal interruption of the existing mechanical ventilator circuit.

All required GENOSYL DS Parts / Components are listed in the front of this manual and should be removed from their packaging prior to set-up.

3.2. Connections to Various Breathing Systems

WARNING

- ONLY use the GENOSYL DS, its parts, and accessories as instructed. Using non-specified components may result in product malfunction, injury or death.
- ALWAYS follow pre-use setup instructions for the routing and connections of tubing to avoid patient strangulation.
- MAKE SURE the System has all tubing connected as described in the instructions. Not connecting all tubing may result in inaccurate dosage and harm to the patient.
- DO NOT use accessories or cables other than those specified or provided by the manufacturer of this equipment, as this may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTE

All circuit components, including GENOSYL DS circuit components, should be changed out and disposed of according to hospital protocol.

3.2.1 Standard Ventilators

Compatibility testing has demonstrated performance meeting requirements for the GENOSYL DS operating range of 0 to 80 ppm with the following standard ventilators at the operating ranges shown in [Table 1](#).

- Dräger VN500
- GE Healthcare R860
- Hamilton C1/T1
- Hamilton G5
- Maquet Servo-I
- Maquet Servo-U/N

NOTE

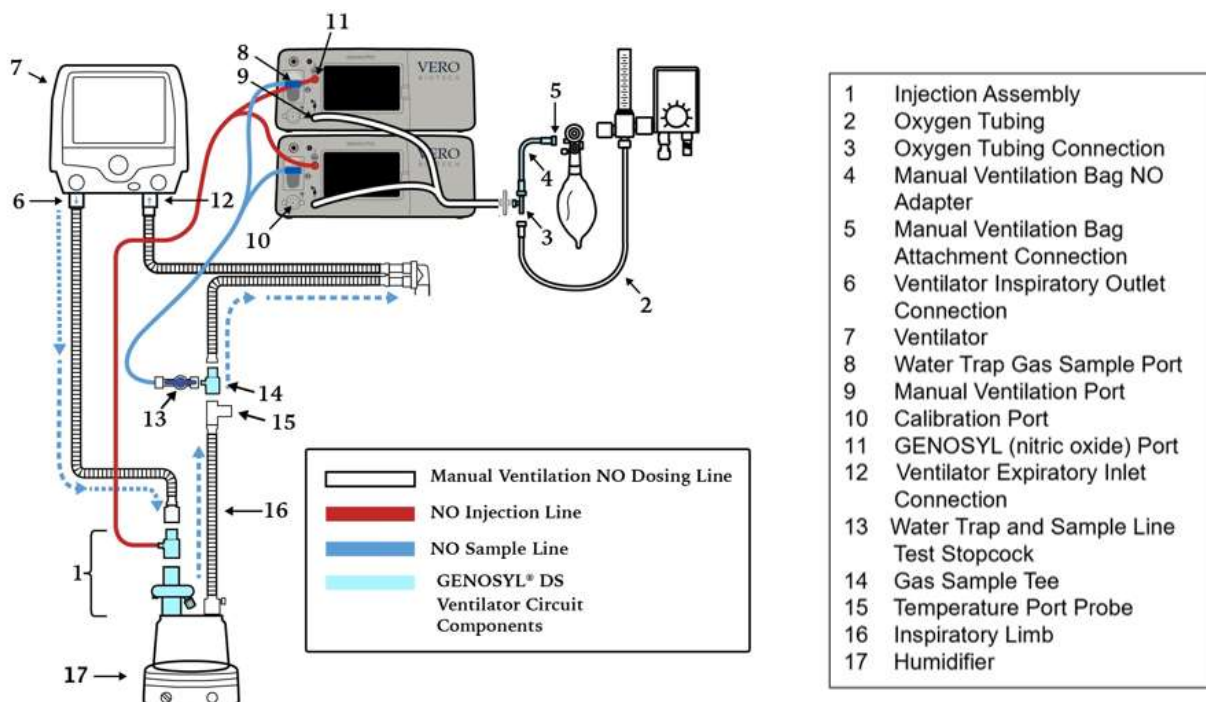
Use with Compliance Compensation OFF is recommended in the presence of a deliberate leak, per the Servo-I User Manual. With Compliance Compensation ON, the sample flow from the GENOSYL DS may cause a leak detection alarm to trigger for the lowest potential ventilator flows.

Table 1: Standard Ventilator Compatibility Test Ranges

Setting	Range	Unit
Inspiratory Flow Rate	2-120	LPM
Respiratory Rate	6-60	BPM
Peak Inspiratory Pressure	0-70	cmH ₂ O
PEEP	0-20	cmH ₂ O

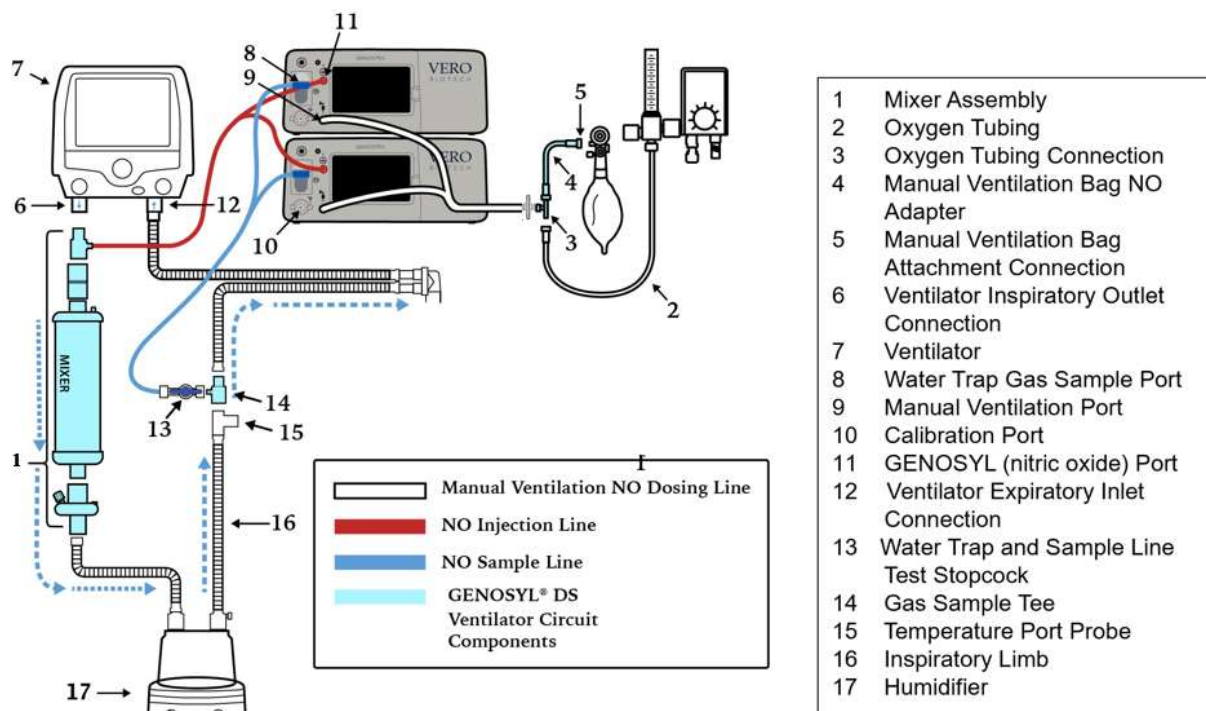
The ventilator circuit diagram for use without the Inline Mixer Accessory, required in certain scenarios, is shown in [Figure 14](#). See [Section 9.2](#), [Table 5](#) for applicable use scenarios.

Figure 14: Standard Ventilator Circuit Set-Up and Connections to the GENOSYL DS and a Manual Bagging System without the Inline Mixer



The ventilator circuit diagram for use with the Inline Mixer Accessory, required in certain scenarios, is shown in [Figure 15](#). See [Section 9.2](#), [Table 5](#) for applicable use scenarios.

Figure 15: Standard Ventilator Circuit Set-Up and Connection and a Manual Bagging System with the Inline Mixer



3.2.2 High Frequency Oscillatory Ventilators (HFOV)

Compatibility testing has demonstrated performance meeting requirements for the GENOSYL DS operating range of 0 to 80 ppm with the following high frequency oscillatory ventilators at operating ranges shown in [Table 2](#).

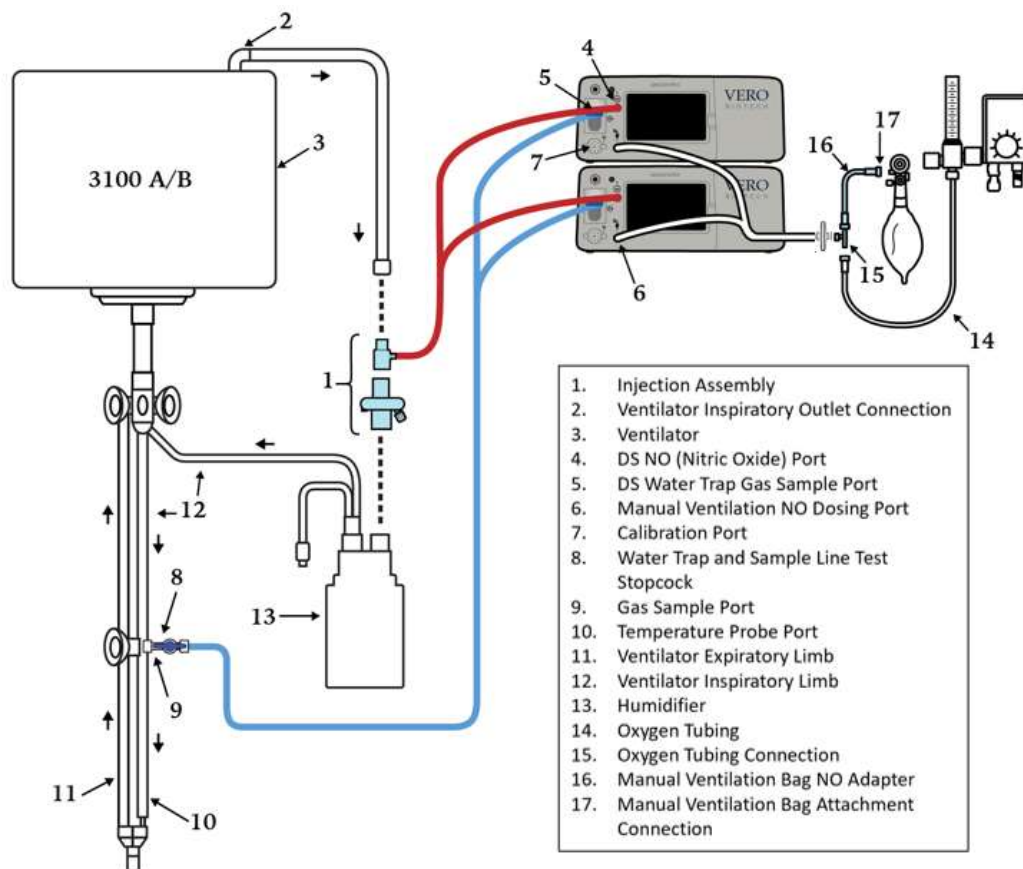
- Model 3100A High Frequency Oscillatory Ventilator
- Model 3100B High Frequency Oscillatory Ventilator

Table 2: High Frequency Oscillatory Ventilator Compatibility Table

Setting	Range	Unit
Bias Flow (Inspiratory Flow Equivalent)	10-40	LPM
Frequency	3-15	Hz
Mean Airway Pressure (PEEP Equivalent)	10-40	cmH ₂ O
Power	2.0-8.0	numeric

The ventilator circuit diagram for use with the 3100 A/B HFOV and the GENOSYL DS is shown in [Figure 16](#). See [Section 9.2](#), [Table 5](#) for applicable use scenarios.

Figure 16: 3100 A/B Ventilatory Circuit Diagram



3.2.3 Non-Invasive Gas Delivery Systems

Compatibility testing has demonstrated performance meeting requirements for the GENOSYL DS operating range of 0 to 80 ppm with the following non-invasive gas delivery systems at operating ranges shown in [Table 3](#).

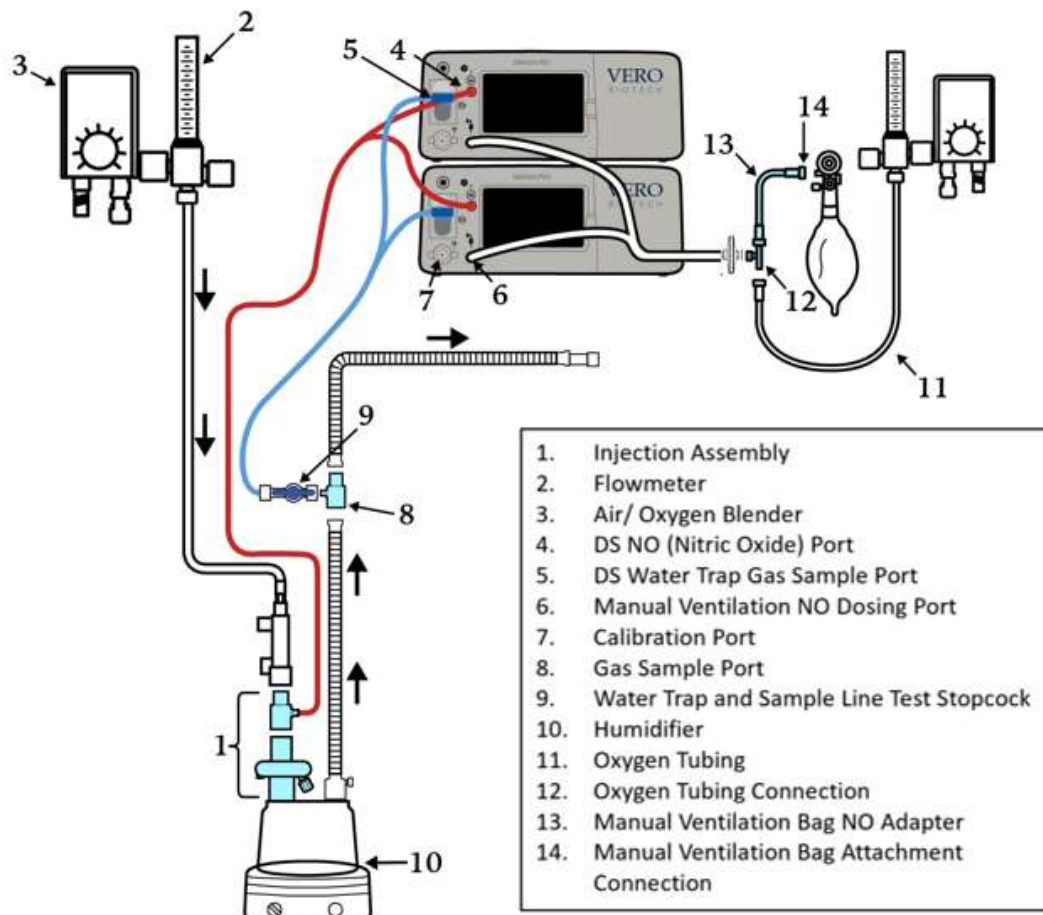
- High Flow Nasal Cannula (HFNC)
- Infant Bubble Continuous Positive Airway Pressure (CPAP)

Table 3: Non-Invasive Gas Delivery System Compatibility Test Ranges

Setting	Range	Unit
HFNC Continuous Flow Rate	2-60	LPM
Bubble CPAP Continuous Flow Rate	6-12	LPM
CPAP Pressure	3-10	cmH ₂ O

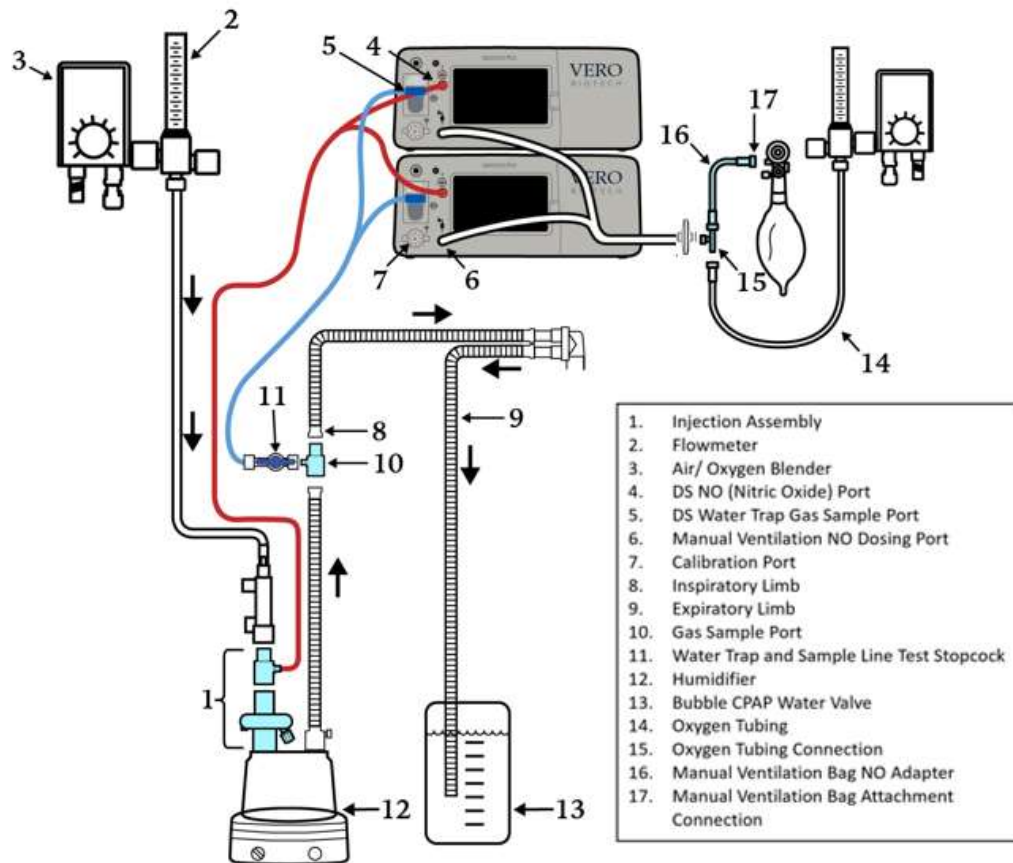
The high flow nasal cannula diagram for use with the GENOSYL DS is shown in [Figure 17](#). See [Section 9.5](#), [Table 5](#) for applicable use scenarios.

Figure 17: High Flow Nasal Cannula Diagram



The infant bubble CPAP diagram for use with the GENOSYL DS is shown in [Figure 18](#). See [Section 9](#), [Table 5](#) for applicable use scenarios.


Figure 18: Infant Bubble CPAP Diagram



3.3. GENOSYL DS Ventilator Circuit Assembly Pre-Check

Follow the steps listed below for the initial System pre-check prior to completing the ventilator circuit assembly.

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
<ul style="list-style-type: none"> • Cassettes – 2 ea. • Mixer (when required, per Section 9.2, Table 5) – 1 ea. • Adapter (22mm ID x 22mm ID) – 1ea. • Gas Injection Adapter – 1 ea. • Iso-Gard Filter – 1 ea. • Gas Lines – 1 ea. • Gas Sample Tee – 1 ea. • Manual Ventilation Bag NO Adapter – 1 ea. 	<ol style="list-style-type: none"> 1. <u>Remove</u> all items of the GENOSYL DS Parts / Components from packaging. 2. <u>Check</u> the expiration date for each Cassette and the Iso-Gard Filter, to ensure use is within the expiration date. 	<p>WARNING</p> <p>DO NOT use a Cassette that is beyond its expiration date. Using an expired Cassette may affect the Cassette's ability to provide the correct NO dosage to the patient, which may cause injury or death.</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>3. Visually inspect the Water Traps on both Consoles to ensure they are installed and empty.</p>	<p>WARNING</p> <p>ALWAYS empty Water Trap before each use, when prompted by the System, and when the trap is more than half full. Allowing the Water Trap to completely fill will occlude the Sample Line which will interrupt patient gas NO, NO₂, and O₂ concentration monitoring. Failure to monitor the patient gas NO, NO₂, and O₂ concentrations may result in patient injury.</p> <p>ALWAYS conduct Water Trap test every time you empty and replace the Water Trap, as failure to do so may lead to an incorrect NO reading, which can result in injury or death.</p> <p>NOTE</p> <p>To empty the Water Trap, see Section 8.3.1.</p>

3.4. GENOSYL DS Injection Assembly

Follow the instructions outlined below to assemble the GENOSYL DS Injection Assembly as shown in [Figure 19](#).

Figure 19: GENOSYL DS Injection Assembly

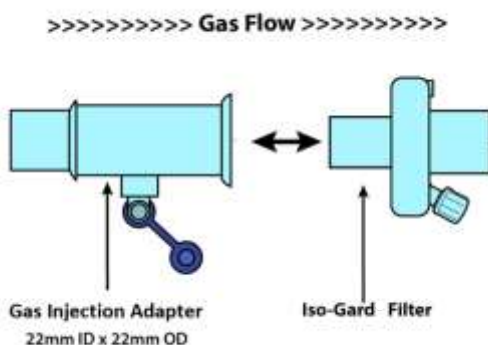


ILLUSTRATION	ACTION
<p>The diagram shows the 'Gas Injection Adapter' (22mm ID x 22mm OD) and the 'Iso-Gard Filter' connected by a double-headed arrow. Above them, the text '>>>>>>>> Gas Flow >>>>>>>>' indicates the direction of gas flow from left to right.</p>	<p>1. <u>Connect</u> the Iso-Gard Filter to the adapter with injection port.</p>

NOTE

The gas sampling adapter should be placed on the inspiratory limb 6 to 12 inches from the patient circuit Y-adapter.

3.5. GENOSYL DS Mixer Assembly

If required, follow the instructions outlined below to assemble the GENOSYL DS Mixer Assembly as shown in [Figure 20](#).

Figure 20: GENOSYL DS Mixer Assembly

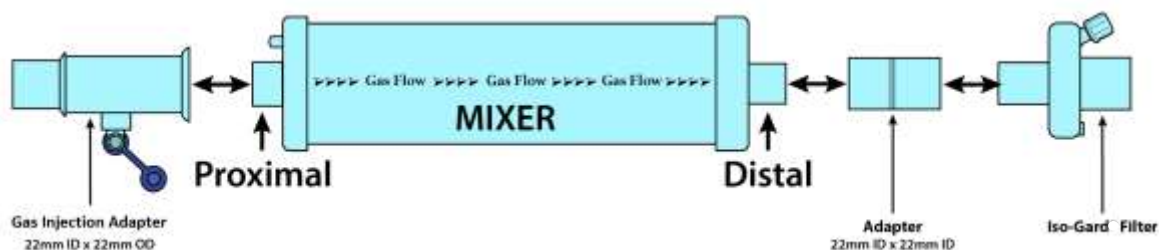


ILLUSTRATION	ACTION
	1. <u>Connect</u> the Iso-Gard Filter to the Adapter (22mm x 22 mm ID).
	2. <u>Connect</u> the Adapter (22mm x 22 mm ID) to the distal end of the Mixer.
	3. <u>Connect</u> the Gas Injection Adapter to the proximal end of the Mixer.

3.6. GENOSYL DS Gas Lines Connections

3.6.1. GENOSYL DS Console Connections

Follow the steps listed below to connect the Gas Lines to **both Consoles**.




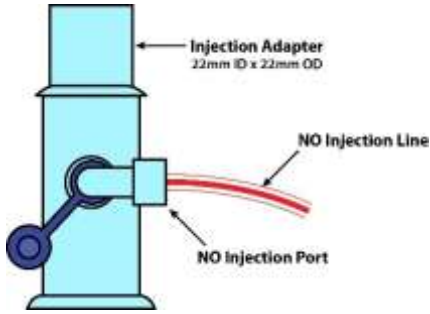
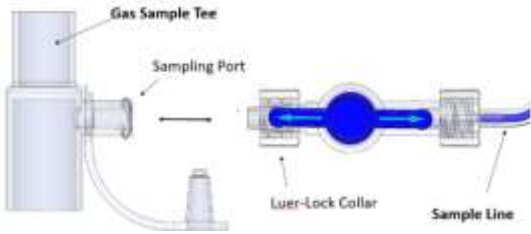
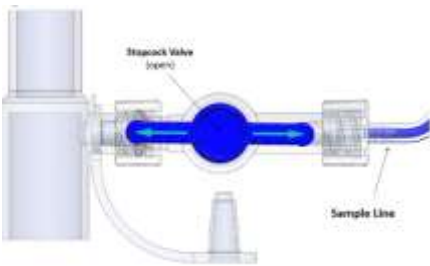
ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>1. <u>Push</u> and <u>twist</u> clockwise the short Y-end of the NO Injection Line (red) to the “NO” port (red) on the front panel of the top Console.</p>	

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>2. Push and twist the short Y-end of the Sample Line (blue) to the Gas Sample Port (blue) on the front of the Water Trap, attached to the top Console.</p>	<p>NOTE</p> <p>Ensure the Sample Lines are connected to the Water Traps on both Consoles.</p>
	<p>3. Push and twist clockwise the end of the Manual Ventilation Line (clear) to the Manual Ventilation Port (clear) on the front panel of the top Console</p> <p>4. Repeat steps 1, 2, and 3 on the bottom Console.</p>	

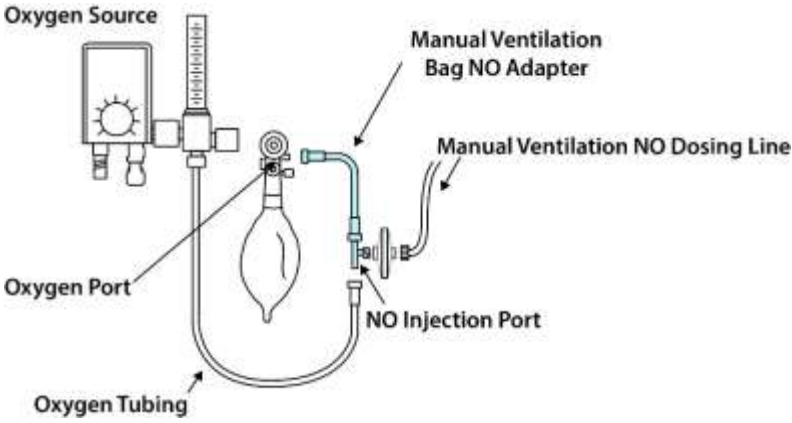
3.6.2. GENOSYL DS Ventilator Circuit Connections

Follow the steps listed below to connect the Gas Lines to the Injection Assembly and Sample Tee. If a Sample Tee already exists within the ventilator circuit, the Sample Line may be connected directly to the existing Sample Tee.

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>1. <u>Push</u> and <u>twist</u> clockwise the Luer-Lock Collar from the NO Injection Line onto the NO Injection Port of the Gas Injection Adapter on the Injection Assembly.</p>	<p>NOTE</p> <p>After connecting, the valve assembly may have rotated such that the orientation may appear different from what is shown here and on the display screen.</p>
	<p>2. <u>Push</u> and <u>twist</u> clockwise the Luer-Lock Collar of the Sample Line onto the Sampling Port of the Gas Sample Tee.</p>	<p>NOTE</p> <p>Skip this step if a Gas Sample Tee is already connected and in-line with the ventilator circuit.</p>
	<p>3. <u>Ensure</u> the blue Stopcock Valve is in the open position as shown.</p>	

3.7. Manual Ventilation (Bag) Connection

Follow the steps listed below to connect the Manual Ventilation Line to a manual bagging system.

ILLUSTRATION	ACTION
 <p>The diagram shows the following components and connections:</p> <ul style="list-style-type: none"> Oxygen Source: A device with a sun-like symbol and a flowmeter. Oxygen Tubing: A line connecting the Oxygen Source to the Oxygen Port. Oxygen Port: A port on the side of the Manual Ventilation Bag NO Adapter. Manual Ventilation Bag NO Adapter: A device with a bag and a port for the NO Injection Port. Manual Ventilation NO Dosing Line: A line connecting the Manual Ventilation Bag NO Adapter to the NO Injection Port. NO Injection Port: A port on the side of the Manual Ventilation Bag NO Adapter. 	<ol style="list-style-type: none"> 1. <u>Attach</u> the barbed end of the Manual Ventilation Bag NO Adapter into the oxygen tubing from the oxygen source. 2. <u>Attach</u> the other end of the NO Adapter to the oxygen port on the side of the Manual Ventilation Bag. 3. <u>Connect</u> the Manual Ventilation Line (clear) to the NO Injection Port of the Manual Ventilation Bag NO Adapter. 4. <u>Place</u> the Manual Ventilation Assembly in a clean accessible place if needed for future use.

3.8. Mechanical Ventilator Circuit Connections

Follow the steps outlined in this section to connect the GENOSYL DS Ventilator Circuit Assembly to the Mechanical Ventilator Circuit.

WARNING

- ALWAYS ensure the trigger sensitivity of the ventilator is checked after connecting the GENOSYL DS to the breathing circuit. The GENOSYL DS injects and samples gas from the patient respiratory circuit which may affect the triggering sensitivity of the ventilator.
- ALWAYS ensure the patient disconnect and high-pressure alarms are used with the ventilator. Otherwise the System is not working properly.

NOTE

All ventilator connections should be assembled and inspected prior to connecting to the mechanical ventilator circuit.

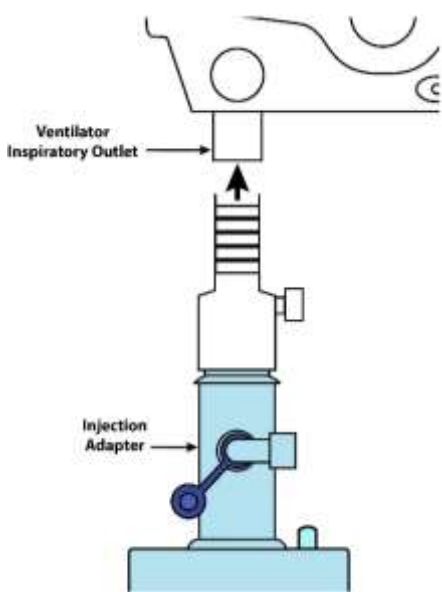
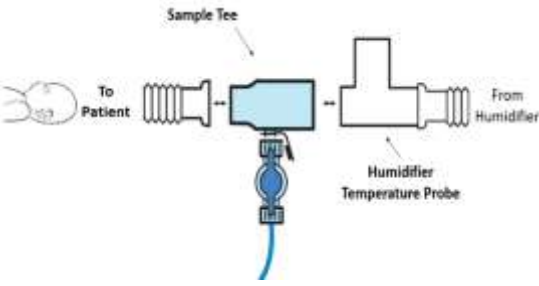
ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. <u>Disconnect</u> the Inspiratory Tubing from the Ventilator and attach it to the distal end of the Injection Assembly. 2. <u>Attach</u> the proximal end of the Injection Assembly to the Ventilator Inspiratory Outlet. 	

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>3. <u>Insert</u> the Sample Tee into the ventilator circuit at the proximal end of the temperature probe closest to the patient.</p>	<p>NOTE</p> <p>If a Gas Sample Tee is already connected and in-line with the ventilator circuit, connect the blue Sample Line directly to the existing Gas Sample Tee.</p>

GENOSYL® DS



SECTION 4 SYSTEM START-UP

4. SYSTEM START UP

4.1. Console Start-Up

Follow the instructions in this section to turn on both the Primary and Standby Consoles.


ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. Push the Circular Power Connectors into the back of the top and bottom Consoles. 2. Connect the main power cord to a grounded 120 V electrical outlet. 	<p>CAUTION</p> <p>ONLY use the GENOSYL DS with the power cord supplied by the manufacturer. Use of a generic power cord may cause output voltage instability leading to a touch screen failure.</p> <p>ALWAYS ensure the power cord is firmly seated into the power supply and the wall outlet. A loose connection can result in damage to the device or faulty operation.</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>3. Press the Black Rocker Power Switch, located on the back of each Console, to the right (ON position) to power on both Consoles.</p>	
	<p>4. Press the Silver Power Button, located at the top left corner on the front panel of each Console, to turn on the display screens on both Consoles. The display screen will illuminate, and the Consoles will beep, indicating the power is on.</p>	<div data-bbox="1143 800 1414 1192"> <p>CAUTION</p> <p>The System will conduct an internal self-test. If an alarm or failure message should occur, refer to Section 7 to resolve the issue.</p> </div> <div data-bbox="1143 1192 1414 1436"> <p>NOTE</p> <p>If the display screen does not turn on, see Troubleshooting, Section 7.6</p> </div>

4.2. Cassette Insertion & Water Trap / Sample Line Leak Test

The following steps should be taken on both the top and bottom Consoles. Initiating Console Start-Up and inserting a Cassette for the bottom Console at this stage will prepare it to serve as a backup for the top Console.

Upon the insertion of the Cassette, a test will be initiated on each Console to check and ensure the integrity of the Water Traps and Sample Line (see [Section 2.12](#)). This helps ensure the accuracy of NO being delivered to the ventilator circuit.

The Water Trap test is automatically initiated upon one or both of the following conditions: 1) Insertion and seating of the Cassette if the measured NO is less than 1.0 ppm and/or 2) Insertion and seating of the Water Trap.


ILLUSTRATION	ACTION	Warnings, Cautions and Notes
 <p>The screenshot shows a console screen with a status bar at the top indicating 'Switch to Primary' and 'Mode: Standby'. The main display area shows 'Cassette Not Detected' with a diagram of a cassette and the instruction 'Insert Cassette'. To the right, under 'Total Flow', there are three selectable options: '< 2.5 LPM' (highlighted in blue), '2.5 - 10 LPM', and '> 10 LPM'. At the bottom left is a 'Menu' button, and at the bottom right is a timestamp '2000-05-12 08:11:45 PM' and 'TW 42 0:3'.</p>	<p>The following steps should be taken to insert the Cassettes into the Consoles.</p>	<div data-bbox="1144 814 1421 1369" style="border: 2px solid red; padding: 5px;"> <p>WARNING</p> <p>ALWAYS follow Cassette inspection instructions prior to Cassette insertion. Not inspecting the Cassette prior to insertion may lead to using a faulty Cassette, resulting in injury.</p> </div> <div data-bbox="1144 1369 1421 1866" style="border: 2px solid green; padding: 5px;"> <p>NOTE</p> <p>Upon turning on the Consoles, the screen displays "Cassette Not Detected."</p> <p>Upon turning on the Consoles, <2.5 LPM will be pre-selected as "Total Flow"</p> </div>


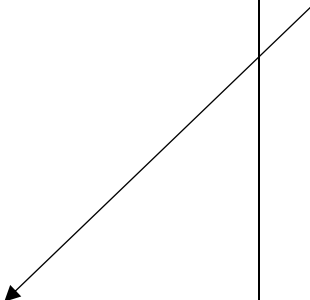
ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>1. Confirm the Cassette Status Indicator on each Cassette is blue.</p>	<p>WARNING</p> <p>DO NOT use the Cassette if the indicator is not blue. An indicator that is any color other than blue may affect the Cassette's ability to provide the correct NO dosage to the patient, which may cause injury or death.</p> <p>NOTE</p> <p>If the Cassette indicator is not blue, see Troubleshooting, Section 7.6</p>
	<p>2. Check the foil disc on the bottom of each Cassette base. The foil should be intact with no puncture marks or holes. If any puncture holes are present, the</p>	<p>WARNING</p> <p>DO NOT use a Cassette if the foil circle on the base of the Cassette has been punctured. A foil circle that is not intact indicates a used</p>



ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>Cassette will not activate, and a new Cassette must be used.</p>	<p>Cassette. Use of a used Cassette may affect the correct NO dosage to the patient, which may cause injury or death.</p>
	<p>3. Open the Cassette Access Doors and insert a Cassette into both Consoles.</p>	<p>NOTE</p> <p>Make sure Consoles are turned on before inserting the Cassette.</p> <p>The Water Trap / Sample Line Leak Test is automatically initiated when the Cassette has been inserted and fully seated and the measured NO is less than 1.0 ppm.</p> <p>After the first Cassette is fully seated, the Operator will have 60 seconds to close the blue Stopcock Valve to perform the test (Step 5 below).</p>



ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>4. On <u>BOTH</u> Consoles, <u>push</u> the middle of the Cassette until it clicks, and the handle partially drops, indicating the cassette has been fully seated.</p>	<p>CAUTION</p> <p>DO NOT push the handle completely down until ready to dose patient. See Section 5.</p> <p>NOTE</p> <p>The handle will partially drop once the Cassette has been fully seated.</p> <p>If the Cassette does not seat properly within the Console, see Troubleshooting, Section 7.6</p>
		<p>NOTE</p> <p>The Display Screen will temporarily indicate the Cassette has been detected, then automatically transition to the Water Trap / Sample Line Leak Test screen.</p>



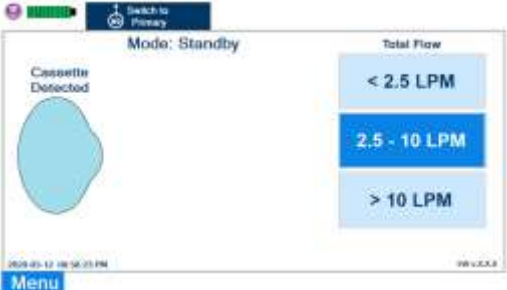
ILLUSTRATION	ACTION	Warnings, Cautions and Notes
<p>Water Trap / Sample Line Leak Test</p> <p>Close the Stopcock Valve located at the end of the Sample Line to the position as shown.</p> <p>Press "CANCEL" to go to Manual Dosing.</p> <p>Primary Dosing will be disabled until a successful leak test.</p> 	<p>5. <u>Follow</u> the onscreen instructions on both Consoles.</p>	<p>NOTE</p> <p>The screen will indicate the Water Trap / Sample Line Leak Test has started and the progress bar will be red until the stopcock valve has been closed, upon which it will then turn green if there is no leak detected.</p> <p>Pressing "Cancel Leak Test", will bring up the Standby Mode screen and allow for dosing in Manual Mode.</p> <p>See Section 5.5 for detail around dosing in Manual Mode.</p>
<p>Water Trap / Sample Line Leak Test</p> <p>Open the Stopcock Valve located at the end of the Sample Line to the position as shown and press "Accept"</p> 	<p>6. <u>Follow</u> the onscreen instructions on both Consoles.</p>	<p>CAUTION</p> <p>Open the blue Stopcock Valve <u>prior</u> to pressing "Accept".</p> <p>Failure to do so will result in a line occlusion error.</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	7. Select Total Flow range	NOTE The Total Flow range is selected by the user. Total Flow range is the sum of the ventilator (or ancillary equipment) Bias Flow and the minute ventilation of the patient.

NOTE

If the Water Trap / Sample Line Leak Test fails, follow the onscreen instructions below to resolve the issue. Also see Troubleshooting, [Section 7.6](#).

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>1. If this screen is displayed, <u>follow</u> the onscreen instructions on both Consoles.</p>	
	<p>2. <u>Press</u> Yes on both Consoles to begin a new Water Trap / Sample Line Leak Test.</p>	<p>NOTE</p> <p>Primary Dosing (e.g., Dosing in Primary Mode) is disabled until the completion of a successful Water Trap / Sample Line Leak test.</p>

GENOSYL® DS



SECTION 5

NITRIC OXIDE ADMINISTRATION

5. NITRIC OXIDE ADMINISTRATION

5.1. Primary Console Selection

When first powered on, the GENOSYL DS Console will default to Standby Mode status. By switching a Console to Primary Mode, the Operator is able to set the NO level and Total Flow range in order to administer nitric oxide. In this mode, the GENOSYL DS will monitor and automatically maintain the NO to that level over the range of ventilator settings.


ILLUSTRATION	ACTION	Warnings, Cautions and Notes
		<p>NOTE</p> <p>The screen will show the heating status as a percent of completion or will show the Cassette is preheated shown on the following screen.</p> <p>The Total Flow range will remain as selected upon Cassette insertion. See Section 4.2.</p>


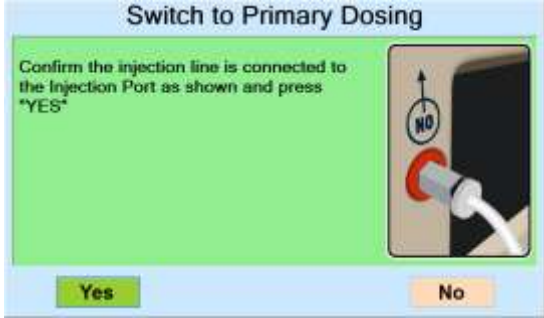

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. Confirm Total Flow range and Press the “Switch to Primary” button on the top Console only. Leave the bottom Cassette as is. 	<p>NOTE</p> <p>The default Total Flow Range of <2.5 LPM will be used unless a different Total Flow range has been selected. See Section 4.2.</p> <p>The top Console is now in Primary Mode and will be referred to as the “Primary” Console.</p> <p>The bottom console will remain in Standby Mode and will be referred to as the “Standby” Console.</p> <p>The nomenclature of the two Consoles will reverse when the Standby Console transitions to become the Primary Console, and vice versa (Section 5.4).</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>2. Accept the on-screen prompt after correct tubing connection is confirmed.</p>	
		<p>NOTE</p> <p>The display screen will look as shown after completing steps 1 and 2.</p> <p>The Selected Total Flow range will be displayed below the Target NO setpoint.</p>

5.2. Cassette Activation

The following steps are a continuation of [Section 4.2](#), in which the Cassette will now be activated for nitric oxide administration.

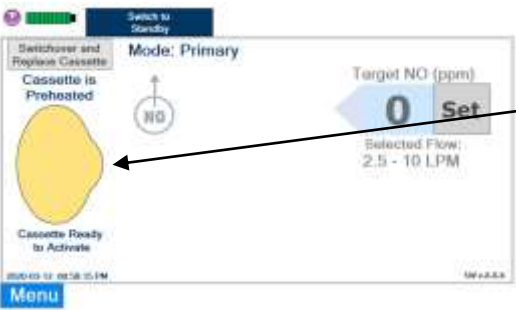

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
 <p>The screenshot shows the GENOSYL DS monitor interface. At the top, it says 'Switchover and Replace Cassette'. Below that, 'Cassette is Preheated' is displayed next to a yellow oval icon. Further down, 'Cassette Ready to Activate' is shown. On the right, 'Mode: Primary' is indicated. A 'Target NO (ppm)' is set to '0' with a 'Set' button. Below that, 'Selected Flow: 2.5 - 10 LPM' is shown. A 'Menu' button is at the bottom left. An arrow points from the 'Cassette Ready to Activate' text to the 'CAUTION' box in the adjacent column.</p>		<p>NOTE</p> <p>When the Cassette preheating is complete, the onscreen prompt will display "Cassette Ready to Activate."</p> <p>CAUTION</p> <p>If the Cassette is activated before fully preheated, it may take longer for the NO output to reach the target dose.</p>
 <p>A photograph showing a hand pulling a blue lever (the Cassette Activation Lever) down on the side of the GENOSYL DS console. The lever is currently in a partially raised position, and the hand is pulling it towards the bottom.</p>	<ol style="list-style-type: none"> 1. Ensure the top Console has been designated as the Primary Console before proceeding. 2. Pull the Cassette Activation Lever down, on the Primary Console only, to the bottom position to activate the Cassette. 	<p>NOTE</p> <p>Ensure the Cassette is fully seated before pulling down on the Activation Lever.</p> <ul style="list-style-type: none"> • A cassette is fully seated when upon insertion, the cassette is pushed in until it clicks, and the Activation Lever drops.



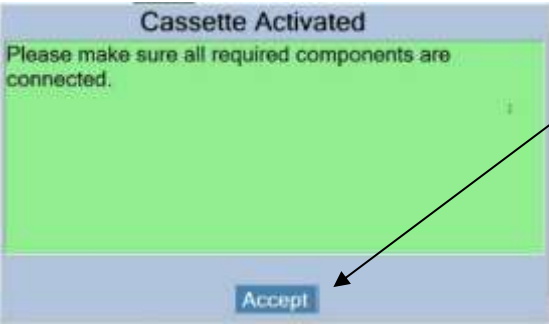

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
		<p>The cassette is a single use item. After activation, lifting the Activation Lever will cause the Cassette to inert the remaining NO within the Cassette and render it unusable for further use.</p>
	<p>3. Close the Cassette Access Door.</p>	
	<p>4. Press "Accept" to confirm the activation.</p>	<p>NOTE</p> <p>When the Cassette has been activated, the screen will display "Please make sure all required components are connected."</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
 <p>The screenshot shows the GENOSYL DS interface. At the top left, there's a status bar with a green bar and a 'Switch to Manual' button. Below it, a message says 'Switchover and Replace Cassette' and 'Cassette is Ready' with a green circle showing '100 %'. A 'Press Set to start' button is below the circle. In the center, 'Mode: Primary' is displayed. To the right, 'Target NO (ppm)' is shown with a large '0' and a 'Set' button. Below that, 'Selected Flow: 2.5 - 10 LPM' is displayed. At the bottom left, there's a 'Menu' button. At the bottom right, the date and time '2020-03-12 09:00:29 PM' and the version 'SW v. 3.3.3' are shown.</p>		<p>NOTE</p> <p>The display screen will look as shown after completing steps 1-4.</p> <p>“Selected Flow” is indicative of the Total Flow range selected by the user.</p>

5.3. Nitric Oxide Dose Set-Up and Administration

Once the Cassette on the Primary Console has been activated, complete the following steps to set the nitric oxide dose.

WARNING

- **MAKE SURE** the System stabilizes to the prescribed concentration (ppm) of NO prior to leaving the Console unattended. Failure to do so could result in under delivery of the target NO, leading to injury or harm.
- **ALWAYS** constantly monitor the patient. System malfunctions can occur if device and patient are not monitored and can result in injury or death. Careful monitoring is required by care personnel whenever the System is used on a patient. The use of an alarm and a monitoring system does not give an absolute assurance of warning for every malfunction that may occur. Certain alarms may require immediate response.


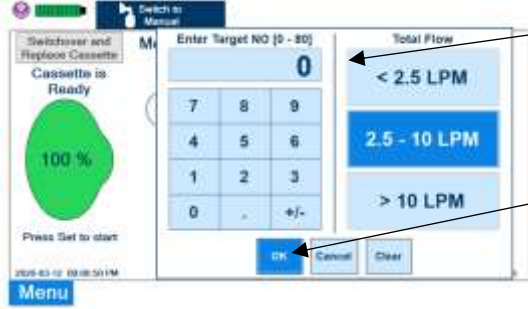


ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>1. Press the gray “Set” button on the display screen.</p>	
	<p>2. Enter the prescribed dose in ppm on the electronic keyboard and confirm Total Flow range is appropriately selected.</p> <p>3. Press OK to confirm the entry.</p>	<p>NOTE</p> <p>The time to reach target dose may vary up to 10 minutes.</p> <p>If unable to set the dose in primary mode, see Troubleshooting, Section 8.</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
<p>Nitric Oxide set point: 20 ppm</p> <p>Make sure all the required components are connected.</p> <p>Confirm the injection line is connected to the Injection Port as shown and press "YES" to start dosing or "NO" to cancel.</p> 	<p>4. Follow the onscreen instructions to begin NO administration.</p>	<p>NOTE</p> <p>If manual ventilation is required, proceed to Section 5.5. When ready to wean the patient, proceed to Section 5.7. If dosing is completed, proceed to Section 6.</p>
		<p>NOTE</p> <p>The display screen will look as shown after completing steps 1-4.</p> <p>NOTE</p> <p>The NO₂ sensor reading may appear as "--" for the first 30 seconds of dosing while the sampling system is preparing.</p>

5.4. Transitioning to the Standby Console

This section describes the steps to switch dosing from the Primary Console to the Standby Console (e.g., the Console in Standby Mode).

WARNING

ALWAYS replace a cassette by transitioning to the Standby Console prior to cassette depletion. A depleted cassette interrupts patient dosing and can lead to under dosing and/or injury to the patient.

NOTE


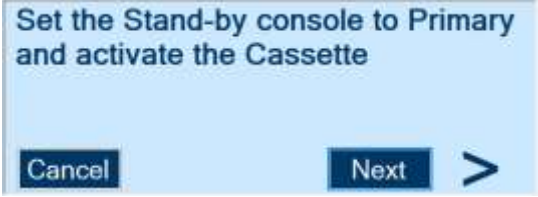
When the transition from the Primary Console to the Standby Console has completed the process, and the depleted cassette has been removed and replaced with a new cassette, the original Primary Console will become the new Standby Console (see [Section 2.2](#)).

Initiate the steps listed below to “Switchover” to the Standby Console due to depletion of the Cassette or failure of the Primary Console. The Primary Console will display the time remaining for Cassette depletion when fuel gauge shows less than 25% remaining. The Console will provide an Information Message within 2 hours of depletion and will provide an Alert within 1 hour of depletion.

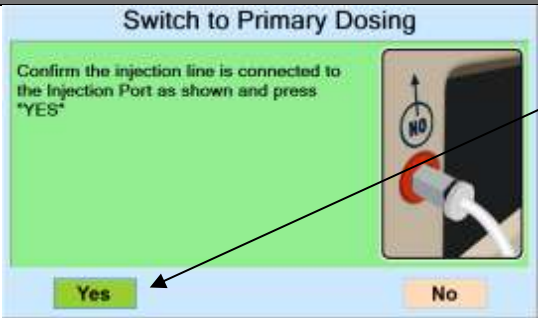
The System operates on a feedback loop mechanism to maintain the preset dosing level during normal operation and throughout the transition process. During this process, the original Primary Console begins to proportionally decrease NO output and ceases gas sampling, while the Standby Console proportionally increases NO output and begins gas sampling. After a period of time, the original Standby Console (now the Primary Console) will take over full NO administration, maintaining the preset dosing level.

The following section outlines the steps required to transition the delivery of nitric oxide from the Primary Console to the Standby Console. **By following the “Action” steps below and in sequence on both Consoles, the Operator will be guided throughout the transitioning process.**

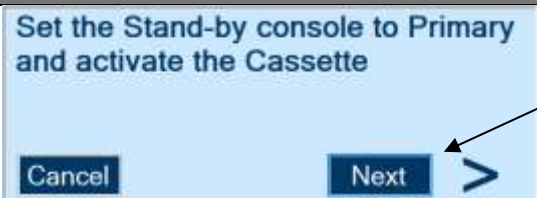
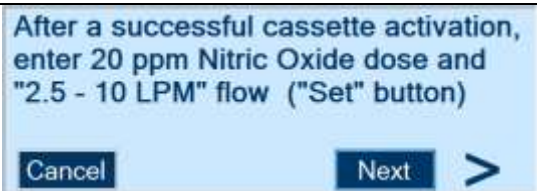
Primary Console Screen (Top Console)

DISPLAY	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. Press the button "Switchover and Replace Cassette" on the main screen of the Primary Console. 	
	<ol style="list-style-type: none"> 2. Set the Standby Console to Primary. 3. Activate the Cassette on the Standby Console. 	<p>NOTE</p> <p>Ensure step 2 and 3 are followed in sequence on the Standby Console.</p>



Standby Console Screen (Bottom Console)

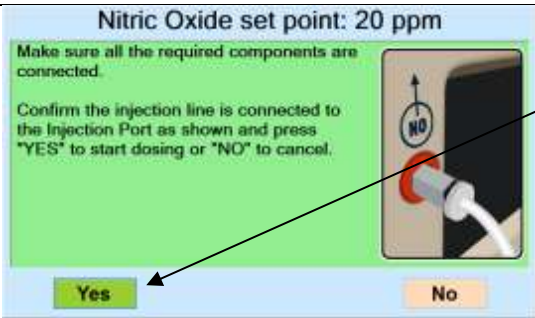
DISPLAY	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 4. Press "Yes". 	

Primary Console Screen (Top Console)

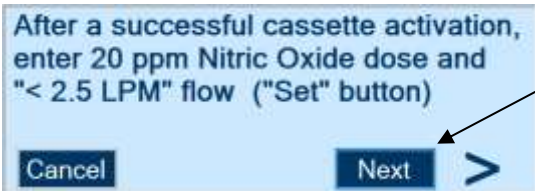

DISPLAY	ACTION	Warnings, Cautions and Notes
	5. Press "Next".	
		NOTE After pressing "next", the screen will look like this.

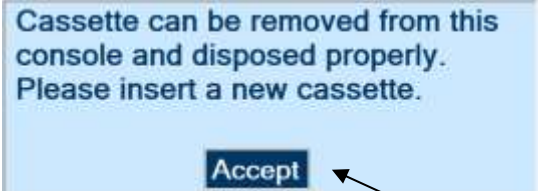
Standby Console Screen (Bottom Console)

DISPLAY	ACTION	Warnings, Cautions and Notes
	6. Press the gray "Set" button on the display screen.	
	7. Enter the dose set on the Primary Console, on the electronic keypad. 8. Confirm correct Total Flow range is selected. If a change is needed, adjust Total Flow range. 9. Press "OK" to confirm the entry.	NOTE The time to reach target dose may vary up to 10 minutes.

DISPLAY	ACTION	Warnings, Cautions and Notes
	10. <u>Press</u> "Yes".	

Primary Console Screen (Top Console)

DISPLAY	ACTION	Warnings, Cautions and Notes
	11. <u>Press</u> "Next".	
	12. <u>Wait</u> the specified amount of time as displayed on the screen during the transition process (approx. 30 mins.) before removing and replacing Cassette from the Primary Console.	CAUTION Do not remove the Cassette in the original Primary Console until after the transition has completed as a momentary drop-in concentration will occur and an Alarm will be activated.

DISPLAY	ACTION	Warnings, Cautions and Notes
	<p>13. <u>Remove</u> Cassette from the Primary Console. (See Section 0 for Cassette disposal instructions). Ensure a new Cassette is then inserted.</p> <p>14. <u>Press</u> "Accept".</p>	<p>NOTE</p> <p>After the transitioning process has been completed, the bottom Console is now the Primary Console and the top Console is the Standby Console. See Section 2.2 Note on nomenclature.</p>

5.5. Manual Mode

This section describes the conditions under which Manual Mode could be activated to quickly initiate or continue the delivery of nitric oxide.

Manual Mode may be activated for the following situations:

1. **When manual ventilation is required** (bagging) – Typically accessed in Primary Mode after dosing has been initiated by pressing the “Switch to Manual” button. (See Manual Ventilation Use - [Section 5.5.1](#)).
2. **When immediate back-up NO delivery is required** (e.g., due to a failure of the Primary Console or upon cancellation of the Water Trap / Sample Line Leak Test) – Available in Standby Mode by activating the Cassette. The delivery of NO is immediate to the ventilation circuit. (See Console Use as a Back-up [Section 5.5.2](#)).

NOTE

When entering Manual Mode, the set target dose in primary will carry over to Manual Mode if 5 ppm or greater. Less than 5 ppm set target dose in primary will default to 5 ppm dose in Manual Mode. However, dose and flow rate be adjusted for specific situations. The feedback loop is disabled while in Manual Mode. To reinitiate the feedback loop, switch back to Primary Mode as soon as the situation permits.

5.5.1. Manual Ventilation Use (Bagging)

This section will describe NO administration when manual ventilation is required.

WARNING

- ALWAYS ensure that the manual flow displayed on the Console matches the flow set into the resuscitation bag. Incorrect flow settings may result in an incorrect estimation of NO delivery. If the flow into the manual equipment is too low, there is risk of overdosing the patient with NO.
- ALWAYS squeeze the bag several times, after starting fresh gas flow, to empty residual gas in the bag prior to using the System to ventilate a patient. Failure to do so could result in higher NO₂ levels being delivered to the patient.
- ALWAYS use the smallest bag adequate to deliver the desired tidal volume. Failure to do so could result in higher NO₂ levels being delivered to the patient.
- ONLY use a manual resuscitation bag with the GENOSYL DS for a short time (e.g., less than one hour) when on battery only. Otherwise, the System may shut off and may result in injury or death.


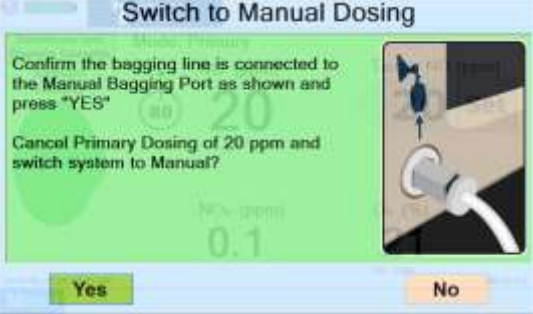




ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. Ensure the oxygen flow source is set at 10 LPM or adjust as needed. 2. Press the button “Switch to Manual” on the Primary Console. 	
	<ol style="list-style-type: none"> 3. Follow the onscreen instructions. 	<p>WARNING</p> <p>If the dilution flow rate displayed on the screen does not match the wall source, then the estimated NO may be inaccurate.</p>
		<p>NOTE</p> <p>Dosing has been initiated at the same dose setting (ppm) as in Primary Mode, at 10 LPM flow rate, however, these levels may be adjusted.</p> <p>If the primary dosing was set at “0” prior to pressing the “Switch to Manual” button, the estimated NO will also be</p>

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
		<p>at “0” and will need to be adjusted. If the primary dosing was set between 1 and 5 ppm prior to pressing the “Switch to Manual” button, the estimated NO dose will also be at “5 ppm” and may be adjusted.</p>
	<p>4. To resume primary dosing, see Section 5.6.</p>	<p>NOTE</p> <p>If an adjustment of the NO concentration is required, press the green up and down arrows.</p> <p>If an adjustment to the Dilution Flow Rate is required, press the LPM value and a drop down menu will expand. Press the prescribed value. The new value will be highlighted in blue and the drop down menu will collapse.</p>

5.5.2. Console Use as a Backup

This section describes the process of activating the Manual Mode on the Standby Console should there be a failure of the Primary Console or upon cancellation of the Water Trap / Sample Line Leak Test. Delivery of NO will begin immediately upon Cassette activation.

DISPLAY	ACTION	Warnings, Cautions and Notes
	<p>1. Confirm Total Flow range is appropriately selected.</p>	<p>NOTE</p> <p>The Standby Console screen will be as shown when in Standby Mode or after cancellation of the Water Trap / Sample Line Leak Test.</p> <p>The default Total Flow range displayed will be <2.5 LPM unless otherwise selected by the user. See Section 4.2</p>
	<p>2. Pull the Cassette Activation Lever down on the Standby Console to the bottom position to activate the Cassette.</p>	<p>NOTE</p> <p>The Standby Console is now in Primary Mode.</p> <p>The Cassette is a single use item. After activation, lifting the Activation Lever will cause the Cassette to inert the remaining NO within the Cassette and</p>

DISPLAY	ACTION	Warnings, Cautions and Notes
		<p>render it unusable for further use.</p> <p>Dosing has been initiated at the default setting of 20 ppm.</p>

5.6. Resuming Primary Dosing

This section describes the process for resuming primary dosing from Manual Mode.

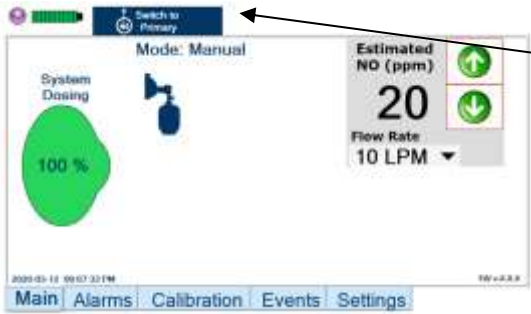

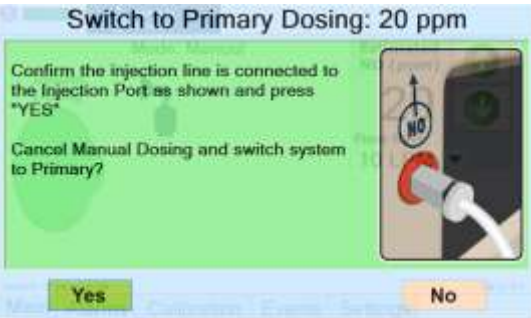



ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<p>1. Press the “Switch to Primary” button at the top of the Manual Mode screen. This now becomes the Primary Console.</p>	
	<p>2. Select Total Flow range or Confirm correct Total Flow range is displayed.</p> <p>3. Press “OK” to confirm the entry.</p>	<p>NOTE</p> <p>If the Ventilator has been changed during Bagging, the Total Flow range may be changed at this time.</p> <p>The NO dose used in Manual Mode will become the set target dose in Primary Mode.</p>
	<p>4. Follow the onscreen instructions.</p>	

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
 <p>The screenshot shows the GENOSYL DS user interface. At the top left, there's a 'Switch to Manual' button. Below it, a 'System Dosing' indicator shows '100 %'. The main display area shows 'Mode: Primary', 'NO (ppm)' at '20', 'Target NO (ppm)' at '20' with a 'Set' button, and 'Selected Flow: < 2.5 LPM'. Below this, 'NO2 (ppm)' is shown as '--' and 'O2 (%)' is shown as '21'. At the bottom, there's a status bar with 'Main Alarms Calibration Events Settings' and a timestamp '2023-03-12 09:10:10 PM'.</p>		<p>NOTE</p> <p>The display screen will look as shown after completing steps 1-4.</p>

5.7. Adjusting the Dose or Total Flow

To adjust the dose of nitric oxide administered per hospital protocol or physician order, follow the instructions listed below.

ILLUSTRATION	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. Press the gray “Set” button to access the electronic keypad on the display screen on the Primary Console. 	
	<ol style="list-style-type: none"> 2. Enter the prescribed ppm dose using the numeric keypad. 3. If Total Flow range requires a change, the Total Flow range may be adjusted at this time. 4. Press “OK” to confirm the dose and to start dosing administration. 5. Repeat steps 1-4 to increase or decrease the dose setting as needed. 	<div style="background-color: #008000; color: white; padding: 5px; text-align: center;">NOTE</div> <div style="border: 1px solid #008000; padding: 5px; margin-top: 5px;"> <p>If dosing is complete, proceed to Section 6.</p> </div>

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GENOSYL® DS



SECTION 6 CONSOLE SHUTDOWN

6. CONSOLE SHUTDOWN AND CASSETTE DISPOSAL**WARNING**

NEVER turn the rear power switch OFF until the System has gone through a controlled shutdown. Turning the rear power switch OFF prematurely (e.g., while it is still in use) will immediately shut down the device. This may result in interruption in NO delivery to the patient, which may cause injury or death.

CAUTION


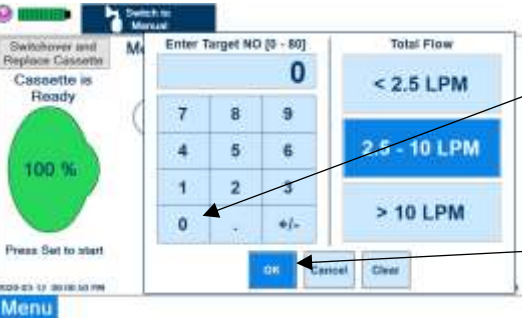

- NEVER turn the rear power switch OFF until the System has gone through a controlled shutdown. Turning the rear power switch OFF prematurely (e.g., while it is still in use) will immediately shut down the device and may cause improper operation upon restart.
- ALWAYS power down the GENOSYL DS Console and disconnect the power to the Console when not in use. Failure to do so may lead to permanent damage to the Console.



NOTE


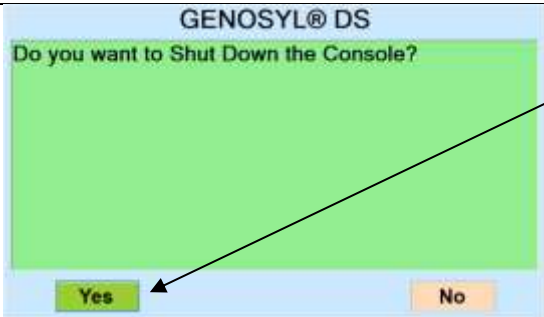

It is recommended that the Console be rebooted at least once every 30 days.

6.1. Console Shutdown

If the administration of NO must be stopped, then the dose level must be set to “0” and the Cassette must be removed prior to shutting down the Console. The following procedure describes how to remove the Cassette and the following section will describe how to shut down the Console.

DISPLAY	ACTION	Warnings, Cautions and Notes
	<p>1. Press the gray “Set” button to access the electronic keypad on the display screen.</p>	
	<p>2. Set the dose to “0” using the electronic keypad.</p> <p>3. Press “OK” to confirm the entry.</p>	
	<p>4. Open the Cassette Access Door.</p> <p>5. Lift the Cassette Activation Lever to the top position.</p>	<p>NOTE</p> <p>The Cassette is a single use item. After activation, lifting the Activation Lever will cause the Cassette to inert the remaining NO within the Cassette and render it unusable for further use.</p>

DISPLAY	ACTION	Warnings, Cautions and Notes
		
	<p>6. <u>Remove</u> the Cassette by pulling the Cassette straight out.</p> <p>7. <u>Dispose</u> the Cassette per hospital policy.</p>	<p>NOTE</p> <p>If the Back-up Console has not been activated, its Cassette can still be used.</p>
	<p>8. <u>Observe</u> "Cassette Not Detected" notification will be displayed on the screen upon Cassette removal.</p>	

DISPLAY	ACTION	Warnings, Cautions and Notes
	<p>9. If the Settings Tab is not displayed, press the “Menu” tab to access the sub-level tabs.</p> <p>10. Press the “Settings” tab on the display menu.</p> <p>11. Press the red “System Shut Down” icon.</p>	
	<p>12. Press “Yes” to confirm shutdown.</p> <p>13. Wait until the Console shuts down, the display screen appears blank, and the Console emits an audible beep.</p>	<p>NOTE</p> <p>If the System does not shut down, see Troubleshooting, Section 7.6</p>
	<p>14. Press the Black Rocker Power Switch to the “OFF” position.</p> <p>15. Repeat steps 1-14 for the other Console.</p>	<p>WARNING</p> <p>NEVER turn the rear power switch OFF until the System has gone through a controlled shutdown. Turning the rear power switch OFF prematurely (e.g., while it is still in use) will immediately shut down the device. This may result in interruption in</p>

DISPLAY	ACTION	Warnings, Cautions and Notes
		NO delivery to the patient, which may cause injury or death.
		CAUTION NEVER turn the rear power switch OFF until the System has gone through a controlled shutdown. Turning the rear power switch OFF prematurely (e.g., while it is still in use) will immediately shut down the device and may cause improper operation upon restart.

6.2. Cassette Disposal

Following use, any remaining Cassette liquid contents are purged into an inerting chamber that is built into the Cassette, where the contents are chemically neutralized, rendering the Cassette safe for disposal. When the Cassette liquid contents are emptied into the inerting chamber, the Cassette Status Indicator on the top of the Cassette reddens and bleaches from its original blue color, indicating the Cassette is depleted. The Cassette can now be disposed of per hospital policy.

WARNING

DO NOT reuse a Cassette. A Cassette is intended for a single use only. Re-use of a Cassette may affect its ability to provide the correct NO dosage to the patient, which may cause injury or death.

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GENOSYL® DS



SECTION 7

ALARMS, ALERTS, AND TROUBLESHOOTING

7. ALARMS, ALERTS, AND TROUBLESHOOTING

WARNING

ALWAYS ensure patient safety before troubleshooting (such as an activated alarm) or replacing a problematic item. Not monitoring the patient prior to attending to an alarm can result in injury or death.

7.1. Alarms, Alerts, and Troubleshooting

This section contains the System alarms and message in order of High (red), Medium (yellow), and Low Priority (cyan) followed by Informational Messages (green). The table shows the alarm/symptom, the possible cause(s) of the alarm and recommended action to resolve the alarm. If the alarm/issue cannot be resolved, contact Technical Support at **877-337-4118**.

A sample screen with an active alarm is shown below:



The alarm icon appears when there is at least one active alarm. Pressing the alarm icon will silence the alarm for 1 minute. The alarm banner contains a drop-down menu containing a list of all alarms should there be multiple activated. The alarm order, color, and audio signal will follow the highest priority alarm.

Alarm Characteristics:

Alarm Priority	Color	Flashing Frequency	Flashing Duty Cycle	Sound Level
High	Red	1.4 to 2.8 Hz	40-60%	79.8 dBA
Medium	Yellow	0.4 to 0.8 Hz	40-60%	76.1 dBA
Low	Cyan	Constant (on)	100%	63.3 dBA

Some alarms may be adjusted within the Settings Tab. See table below for adjustment characteristics. The System has a safety shutdown feature which will shut off the flow of NO when the sensors detect ≥ 100 ppm for NO and ≥ 3 ppm for NO₂. The System will always resort to the original default alarm settings upon reboot or complete power failure.

Alarm	Adjustment Range	Default Setting	Shut Down Condition
High NO (ppm)	0 – 100	+ 20% of set value	≥ 100 ppm
Low NO (ppm)	0 – 99	- 20% of set point	NA
High NO ₂ (ppm)	1-2	2	≥ 3 ppm
High O ₂ (% v/v)	22 – 100	100	NA
Low O ₂ (% v/v)	18 – 99	18	NA

An alarm history indicating the date, time, and type of alarm can be viewed by selecting the Alarms Tab and then selecting the alarms history button. The alarm history can be cleared by pressing the “Clear Alarm Button”. If the alarm history reaches capacity, the oldest alarms will begin rolling off and become non-visible to the user. Upon Console shut down or power loss, the alarm log is cleared.



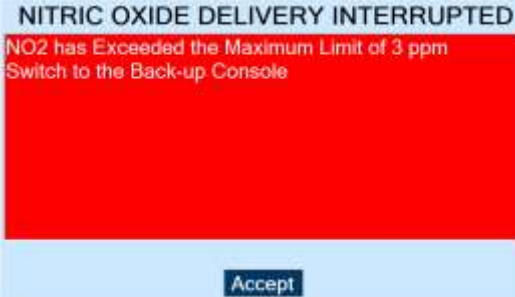

The audio alarm may be muted by pressing the alarm icon on the touchscreen display. The muted alarm lasts 2 minutes.


The operator of the equipment should be physically in front of the Console while interacting with the System. During NO delivery, the operator should remain within visual and auditory distance of the System.





The alarm system is automatically tested during the initial power-on self-test with an audible beep to confirm successful completion. Should there be an issue with communication to the alarms system electronics, a Hardware Failure error message will appear at the end of the self-test.


7.2. High Priority Alarms and Messages



High priority alarms and messages will have a red background. These alarms and messages require immediate operator response.






High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
High NO/NO shutdown Message Box:  Banner: 	Ventilator flow changed abruptly	<ul style="list-style-type: none"> Wait 5 minutes for the sensor measurement to adjust. Re-enter desired dosage. If the sensor measurement does not adjust, switch to Standby Console.
	Circuit set-up incorrectly	<ul style="list-style-type: none"> Resolve set-up issue. Re-enter desired dosage. If issue has not been resolved, switch to Standby Console.
	Sample line issue	<ul style="list-style-type: none"> Ensure sample line issue is resolved. Wait 5 minutes for the sensor measurement to adjust. Re-enter desired dosage. If the sensor measurement does not adjust, switch to Standby Console.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
High NO₂/NO shutdown Message Box:  Banner: 	Low ventilator flow	<ul style="list-style-type: none"> Increase ventilator flow. Wait 5 minutes to adjust. Set dose concentration to desired set point. If the sensor measurement does not adjust, switch to Standby.
	Excessive NO ₂ line formation	<ul style="list-style-type: none"> Lower FiO₂ and/or NO dose set point and/or increase ventilator flow.
	Ventilator flow changed abruptly	<ul style="list-style-type: none"> Wait 5 minutes for the sensor measurement to adjust. Set dose concentration to desired set point.




High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
		<ul style="list-style-type: none"> If the sensor measurement does not adjust, switch to Standby Console.
	Leak in ventilator flow	<ul style="list-style-type: none"> Resolve ventilator leak. Set dose concentration to desired set point. If the sensor measurement does not adjust, switch to Standby Console.
	NO ₂ sensor needs recalibration	<ul style="list-style-type: none"> Switch over to Standby Console. Recalibrate NO₂ sensor following procedure in Section 8.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
<p>High NO Alarm Message Box: None</p> <p>Banner:</p> 	Ventilator flow changed abruptly	<ul style="list-style-type: none"> Wait 5 minutes for the sensor measurement to adjust. If the sensor measurement does not adjust, switch to Standby Console.
	High NO alarm may be inappropriately set	<ul style="list-style-type: none"> Go to the Alarms screen and check the NO alarm setting. Set alarm to the desired setting.
	Circuit set-up incorrect	<ul style="list-style-type: none"> Check respiratory circuit for proper set-up and resolve any issues.
	NO sensor may require recalibration	<ul style="list-style-type: none"> Switch over to the Standby Console, if dosing. Follow calibration procedure in Section 8.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.

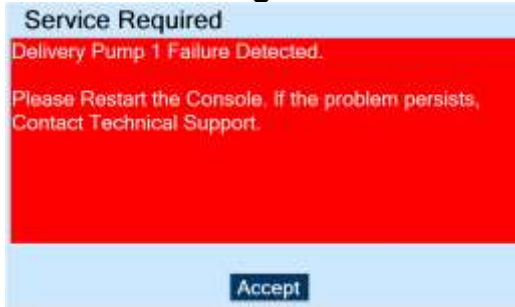


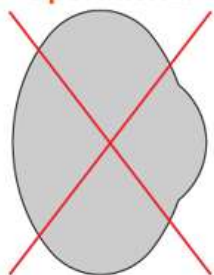
High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
High NO₂ Alarm Message Box: None Banner:  	Excessive NO ₂ line formation	<ul style="list-style-type: none"> Lower FiO₂ and/or NO dose set point and/or increase ventilator flow.
	Low Ventilator Flow	<ul style="list-style-type: none"> Increase Ventilator Flow. Wait 5 minutes to adjust.
	Ventilator flow changed abruptly	<ul style="list-style-type: none"> Wait 5 minutes for the sensor measurement to adjust. If the sensor measurement does not adjust, switch to Standby Console.
	NO ₂ sensor may need recalibration	<ul style="list-style-type: none"> Switch over to the Standby Console, if dosing. Follow calibration procedure in Section 8.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
Low NO alarm Message Box: None Banner:  	Injection line is not connected properly	<ul style="list-style-type: none"> Verify proper connection of the injection line and resolve any issues.
	Sampling line is not connected properly	<ul style="list-style-type: none"> Verify proper connection of the injection line and resolve any issues.
	Water Trap full	<ul style="list-style-type: none"> Empty Water Trap. If problem persists after emptying, replace Water Trap.
	Ventilator flow too high	<ul style="list-style-type: none"> Wait for up to 5 minutes for the sensor measurement to stabilize. Adjust ventilator settings.
	Alarm limit not adjusted properly	<ul style="list-style-type: none"> Go to alarms screen and check the NO alarm setting. Set the alarm to the desired setting.
	NO Cassette needs to be replaced	<ul style="list-style-type: none"> Transition to the Standby Console following the instruction in Section 5.4.

High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
	The dosing did not reach required concentration	<ul style="list-style-type: none"> Wait until dosing concentration reaches desired concentration. Activate Standby Console if the desired dosing is not achieved after 5 minutes after alarm begins. Call Technical Support.
	Cassette is almost empty	<ul style="list-style-type: none"> If Cassette is depleted, switchover to Standby Console.
	NO Sensor may need to be recalibrated	<ul style="list-style-type: none"> Switch over to the Standby Console, if dosing. Follow calibration procedure in Section 8.
	Gas sample tee placed too close to patient Y adapter	<ul style="list-style-type: none"> Ensure gas sample tee is placed 6 to 12 inches from the patient Y adapter.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
<p>Calibration Required Message Box: None</p> <p>Banner: </p>	Calibration for the sensor is required	<ul style="list-style-type: none"> If during dosing, transition to Standby Console (see Section 5.4). If not during dosing, then calibrate Console (see Section 8). If the calibration required alarm occurs after a successful calibration has been completed, call Technical Support.
Hardware Failure Message Box:	Internal hardware damage or	<ul style="list-style-type: none"> Switch to Standby Console. Replace Console.

High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
<p>Hardware Failure Switch to the Back-up Console. Hardware Communication Problem. Please Restart the Console. If the problem persists, Contact Technical Support.</p> <p>Continue</p> <p>Banner:</p> <p>Hardware Failure </p>	communication failure	<ul style="list-style-type: none"> • Call Technical Support.
<p>Hardware Failure – Power Board Message Box:</p> <p>Hardware Failure: Power Board not Found Switch to the Back-up Console. Hardware Communication Problem. Please Restart the Console. If the problem persists, Contact Technical Support.</p> <p>Continue</p> <p>Banner:</p> <p>Hardware Failure </p>	Internal hardware damage or communication failure	<ul style="list-style-type: none"> • Switch to Standby Console. • Replace Console. • Call Technical Support.
<p>Hardware Error During POST</p> <p>POST Hardware Communication Problem. Please Restart the Console. If the problem persists, Contact Technical Support.</p> <p>Hold the Silver Power Button down for 10 seconds to shut the system down.</p>	Problem occurring during boot-up sequence	<ul style="list-style-type: none"> • Re-boot by holding Silver Power Button down for 10 seconds. • If error message continues, replace Console and call technical support.
	Internal hardware damage or communication failure	<ul style="list-style-type: none"> • Use other console if NO delivery is needed immediately. • Replace Console. • Call Technical Support.
<p>Battery Error Message Box: None</p>	Internal battery error or battery fails to charge	<ul style="list-style-type: none"> • Plug in AC power. • If error persists and not dosing, re-start System.




High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
Banner:  	Battery becomes disconnected	<ul style="list-style-type: none"> If alarm does not clear, switch to Standby Console and service unit when possible.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
Line Occlusion Message Box: None Banner:  	Water Trap is full	<ul style="list-style-type: none"> Empty Water Tap. If occlusion persists after emptying, replace Water Trap.
	Stopcock valve on the Sample Line (blue) is in the closed position	<ul style="list-style-type: none"> Open the Stopcock valve.
	Line is kinked or occluded	<ul style="list-style-type: none"> Resolve kink or occlusion in line.
	Defective Water Trap	<ul style="list-style-type: none"> Replace Water Trap with a new Water Trap. Reconnect tubing. Continue dosing.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
Cassette Removed while dosing Message Box:  Banner: None	The lever was lifted while the System was dosing	<ul style="list-style-type: none"> Switchover to Standby Console and continue dosing. For the Primary Console <ul style="list-style-type: none"> Obtain new NO Cassette. Replace Cassette.
	Hardware damage which causes the System to not be able to detect the Cassette	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.
	Cause not determined	<ul style="list-style-type: none"> Switch over to Standby Console. Call Technical Support.


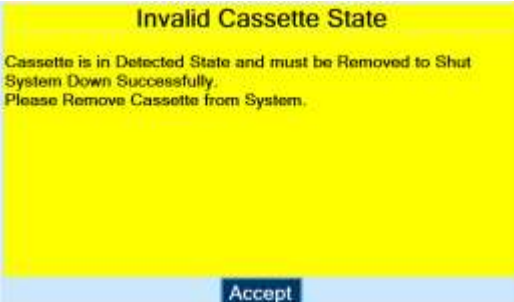

High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
Water Trap Not Detected Message Box: 	Water Trap not seated properly	<ul style="list-style-type: none"> • Re-seat Water Trap.
	Water Trap not present	<ul style="list-style-type: none"> • Insert new Water Trap.
	Cause not determined	<ul style="list-style-type: none"> • Switch over to Standby Console. • Call Technical Support.
Configuration Parameters Incorrect 	File integrity issue	<ul style="list-style-type: none"> • Switch to Standby Console. • Call Technical Support.
Battery Not Detected 	Battery is not connected properly or not operational	<ul style="list-style-type: none"> • Use back-up Console. • Call Technical Support.


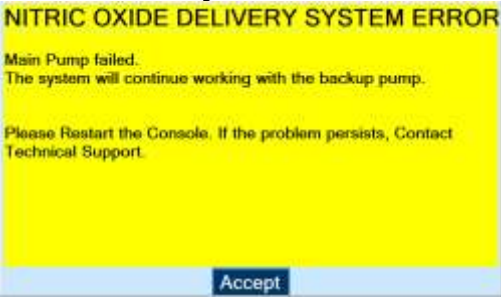
High Priority Alarms and Messages		
Alarm/Symptom	Possible Cause	Recommended Action
<p>Service Required Message Box:</p>  <p>Banner:</p> 	<p>Hardware failure occurred</p>	<ul style="list-style-type: none"> • Switch to Standby Console. • Replace Console. • Call Technical Support.
<p>Cassette Not Operational Message Box:</p>  <p>Symbol:</p> <p>Cassette Not Operational</p>  <p>Remove Cassette</p>	<p>Hardware failure within Cassette during dosing</p>	<ul style="list-style-type: none"> • Switch to Standby Console. • Replace Cassette in original primary unit. • If issue is not resolved, replace console. • Call Technical Support.

7.3. Medium Priority Alarms and Messages

Medium priority alarms and messages will have a yellow background. Medium priority alarms and messages require a prompt response from the operator.

Medium Priority Alarms and Messages		
Alarm/Message	Possible Cause	Recommended Action
Low Battery Alarm Message box: None Banner: 	Battery is about to run out of power	<ul style="list-style-type: none"> • Plug System into AC power. • If AC power is not available, switch to backup. • Then plug into AC power as soon as possible.
Cassette Failure Alarm CASSETTE NOT OPERATIONAL 	Hardware internal to the Cassette has failed	<ul style="list-style-type: none"> • Reinsert or replace Cassette if needed. • If issue persists with multiple Cassettes call Technical Support.
Service Due Date Expired POST 	Scheduled yearly Service date is past due	<ul style="list-style-type: none"> • Accept message. • Call Technical Support to service System at earliest convenience.

Medium Priority Alarms and Messages		
Alarm/Message	Possible Cause	Recommended Action
Cassette to Expire in 1 Hour 	Cassette will expire in 1 hour	<ul style="list-style-type: none"> Transition to Standby Console within 1 hour. Replace Cassette once transition is complete.
Invalid Cassette State 	Cassette has not been removed prior to an attempt to shutdown System	<ul style="list-style-type: none"> Remove Cassette. Press System Shutdown button again.
Low O2 Message box: none Banner: 	Ventilator setting is incorrect	<ul style="list-style-type: none"> Set ventilator to the correct setting.
	Alarm setting is incorrect	<ul style="list-style-type: none"> Set the alarm ranges to the correct setting.
	Ventilator flow is too low	<ul style="list-style-type: none"> Set ventilator setting to the correct setting.
	Cause not determined	<ul style="list-style-type: none"> Switch over to back-up Console. Call Technical Support.

Medium Priority Alarms and Messages		
Alarm/Message	Possible Cause	Recommended Action
<p>High O2 Message Box: none Banner:</p> 	Ventilator setting is incorrect	<ul style="list-style-type: none"> Set ventilator to the correct setting.
	Alarm setting is incorrect	<ul style="list-style-type: none"> Set the alarm ranges to the correct setting.
	Cause not determined	<ul style="list-style-type: none"> Switch over to back-up Console. Call Technical Support.
<p>Delivery Flow Error</p> 	Kink or blockage of the injection line	<ul style="list-style-type: none"> Resolve the kink or blockage. Ensure the air intake is not blocked. If problem persists, call Technical Support.
	Hardware issue caused a failure	<ul style="list-style-type: none"> Check for occlusion in injection line. Ensure the air intake is not blocked. If problem persists, call Technical Support.

7.4. Low Priority Alarms and Messages

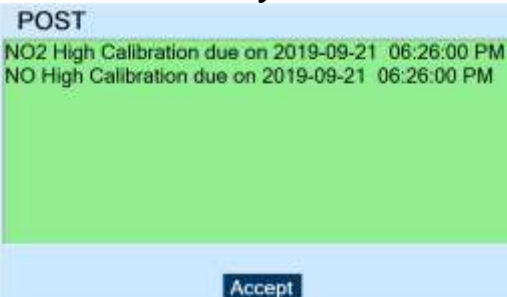
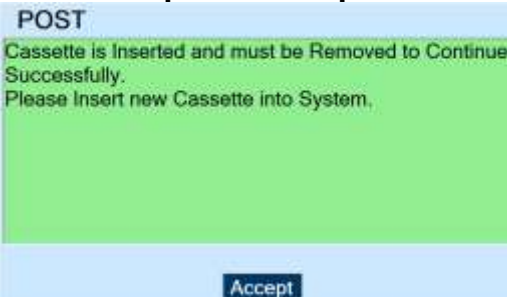
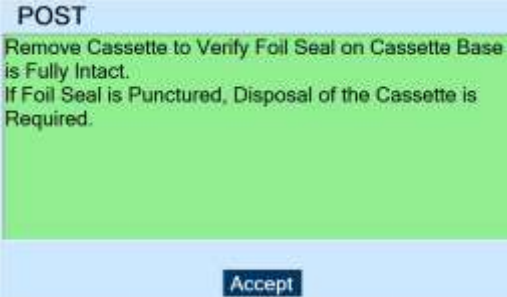
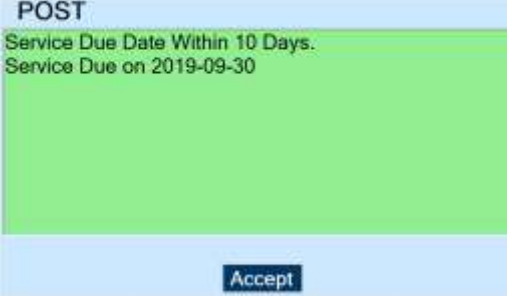
A low priority message will have a turquoise background. A low priority message will require that the operator is aware of the condition.

Low Priority Messages and Alarms		
Message/Alarm	Possible Cause	Recommended Action
System Running on Battery Only WARNING System Running on Battery. Please Connect the A/C Power Adapter. External Power Supply Disconnected Accept	AC power is not connected	<ul style="list-style-type: none"> • Check the AC power connection. • Check the power connector on the back of the unit. • Check AC power. • If connecting to AC power does not resolve issue, switch to back-up Console and call Technical Support.
Service Due Date Within 2 Days POST Service Due Date Within 1 Day. Service Due on 2019-09-21 Accept	Service date is scheduled within 2 days	<ul style="list-style-type: none"> • Accept message. • Contact Technical Support to have System serviced at earliest convenience.

7.5. Informational Messages

Informational messages will have a green background. These messages require that the user is notified of the condition.

Informational Messages		
Message/Alarm	Possible Cause	Recommended Action
<p>System has not Completed Calibration</p> <p>CALIBRATION FAILED</p> <p>Air Calibration Failed on 2019-09-20 06:18:53 PM Repeat Air calibration. If the problem persists, contact Technical Support.</p> <p>OK</p>	Calibration was not completed	<ul style="list-style-type: none"> Accept message. Perform gas calibration. See Calibration Section 8. If you continue to have problems, call Technical Support.
<p>CALIBRATION FAILED</p> <p>Nitric Oxide Calibration Failed on 2019-09-20 06:21:51 PM Please make sure you are using the correct calibration gas. If the problem persists, contact Technical Support.</p> <p>OK</p>	Wrong/empty calibration gas tank used	<ul style="list-style-type: none"> Accept message. Obtain correct/full calibration gas tank. Perform gas or air calibration. See Calibration Section 8. If you continue to have problems, call Technical Support.
<p>CALIBRATION FAILED</p> <p>NO2 Calibration Failed on 2019-09-20 06:24:50 PM Please make sure you are using the correct calibration gas. If the problem persists, contact Technical Support.</p> <p>OK</p>	Calibration tubing is incorrectly connected to the sample port	<ul style="list-style-type: none"> Accept message. Connect calibration tubing to Cal port. Perform gas or air calibration. See Calibration Section 8. If you continue to have problems, call Technical Support.
	Failed Gas Sensor	<ul style="list-style-type: none"> Accept message Verify that other issues noted above are not root cause. Call Technical Support.

Informational Messages		
Message/Alarm	Possible Cause	Recommended Action
Calibration Due in Less Than 3 Days 	Calibration is required in less than 3 days	<ul style="list-style-type: none"> Accept message. Perform gas calibration if desired. See Calibration Section 8.
Cassette Inserted And Activated Upon Boot-Up 	Cassette was inserted and activated prior to diagnostic	<ul style="list-style-type: none"> Accept message. Remove Cassette. Obtain new Cassette. Continue with set-up.
Cassette Inserted Upon Boot-Up 	Cassette was inserted prior to diagnostic test	<ul style="list-style-type: none"> Accept message. Remove Cassette. If foil is punctured, replace Cassette. Continue with set-up.
Service Due Date Within 14 Days 	Service date is scheduled within 14 days	<ul style="list-style-type: none"> Accept message. Contact Technical Support to have System serviced at convenience.

Informational Messages		
Message/Alarm	Possible Cause	Recommended Action
<p>Cassette Will Expire In 2 Hours</p> <p>CASSETTE TIME REMAINING</p> <p>2019-09-20 06:11:04 PM</p> <p>Cassette will Expire in Two Hours and Should be Replaced.</p> <p>Accept</p>	Cassette will expire within 2 hours	<ul style="list-style-type: none"> Transition to back-up unit within 2 hours. Replace Cassette after transition is complete.
<p>Calibration Due</p> <p>CALIBRATION DUE</p> <p>Expired: NO2 High Calibration</p> <p>Expired: NO High Calibration</p> <p>Expired: O2 High Calibration</p> <p>Skip the Calibration for 24 Hours?</p> <p>Yes No</p>	Calibration due date was passed	<ul style="list-style-type: none"> Perform calibration.

7.6. Troubleshooting

The table below provides resolutions to issues that may be encountered with the GENOSYL DS.

Issue/Symptom	Possible Cause	Recommend Action
Screen does not turn on	Battery discharged and not connected to AC power	<ul style="list-style-type: none"> • Ensure power is properly connected in the back of the unit and the wall outlet. Green light on power supply should be on. • Ensure battery is connected properly. • Wait for System to charge. • Power on System.
	Screen malfunction	<ul style="list-style-type: none"> • Call Technical Support.
	Issue not determined	<ul style="list-style-type: none"> • Call Technical Support.
Cassette does not seat properly within Console	Drop or other physical damage	<ul style="list-style-type: none"> • Discard damaged NO Cassette and replace with new Cassette. • If Cassette new Cassette does not seat properly, switch to back-up unit and call Technical Support.
Cassette indicator is not blue	Drop or other physical damage	<ul style="list-style-type: none"> • Discard damaged Cassette and replace with new Cassette.
	Cassette was previously activated	<ul style="list-style-type: none"> • Discard damaged Cassette and replace with new Cassette.
Pumps are louder than normal	Enclosure damage	<ul style="list-style-type: none"> • Call Technical Support.
	Pump malfunction	<ul style="list-style-type: none"> • Call Technical Support.
Cannot set dose in primary mode	Cassette has not been activated	<ul style="list-style-type: none"> • Pull activation lever down into activation state.
	Leak test was not performed	<ul style="list-style-type: none"> • Perform leak test if not already performed.

Issue/Symptom	Possible Cause	Recommend Action
	Calibration is required for at least one sensor	<ul style="list-style-type: none"> • Perform calibration if required.
System does not shutdown	Operating System issue or file corruption	<ul style="list-style-type: none"> • Hold the Silver power button on the front down for approximately 10 seconds. The System should shutdown. • If the above does not work, power the System off with the switch on the back. • Contact Technical Support if the issue remains.
Audible alarm tone does not sound after boot-up process	Speaker hardware failure	<ul style="list-style-type: none"> • Contact Technical Support.
Failed Water Trap / Sample Line Leak Test	Incorrectly connected the Sample Line to the CAL Port	<ul style="list-style-type: none"> • Disconnect from the CAL Port and attach to the Water Trap.
	Test timed out at 60 seconds	<ul style="list-style-type: none"> • Conduct test within 60 seconds.
	Sample line valve not closed properly	<ul style="list-style-type: none"> • Move the blue stopcock to the closed position.
	Loose gas lines connections	<ul style="list-style-type: none"> • Check all connections.
	Water Trap not sealed completely	<ul style="list-style-type: none"> • Check Water Trap seal.
	Water Trap seal leak	<ul style="list-style-type: none"> • Check Water Trap seal.

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GENOSYL® DS



SECTION 8 MAINTENANCE

8. MAINTENANCE

8.1. Calibration

This section describes the process for performing high and low calibration for NO, NO₂, and O₂. Before administering NO, calibration of the GENOSYL DS should be performed to ensure the accuracy of NO, NO₂, and O₂ measurements. Air calibrates the low range for the NO and NO₂ sensors. The high range of the NO and NO₂ sensors are calibrated by using calibration gas tanks. The software will notify the user when calibration is necessary.

The display within the calibration tab provides the status and the calibration due date of the different types of sensors. Air calibration provides the time of the last calibration since the System automatically performs this calibration every 4 hours. A green check under status indicates that sensor has successfully been executed within the calibration period. A red X under status indicates that the sensor has not successfully been executed within the calibration period.

During calibration, the display will provide measured readings from each sensor. Note, there are two redundant NO sensors which are used to verify and ensure accuracy of the dosage provided by the System. During calibration the display will provide a real-time status of the test with colored boxes to the right of the displayed sensor output. A yellow box indicates that the sensor is being calibrated. A green box indicates that calibration was successful for that sensor. A red box indicates that calibration for that sensor failed.



WARNING

- ONLY use the calibration gas pressure regulators supplied by the manufacturer. Pressure regulators not supplied by the manufacturer may damage the sensors and may lead to patient injury.
- ALWAYS verify the correct NIST traceable calibration gas is being used and confirm the expiration date of the calibration gas prior to performing calibration. The use of incorrect or expired gas may result in inaccurate sensor readings and can lead to patient injury.


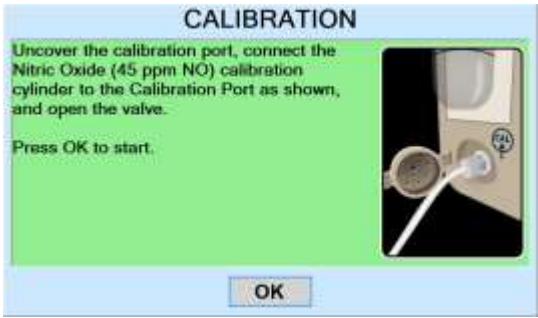
CAUTION

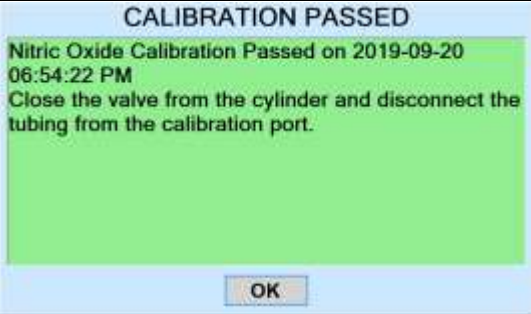
- ALWAYS perform a full-scale calibration of the GENOSYL DS when prompted by the System prior to use.
- ALWAYS confirm the correct flow direction of the installed one-way check valve in the sampling tee to avoid over pressurization of the sampling System and damage to the device.

8.1.1. Air Calibration


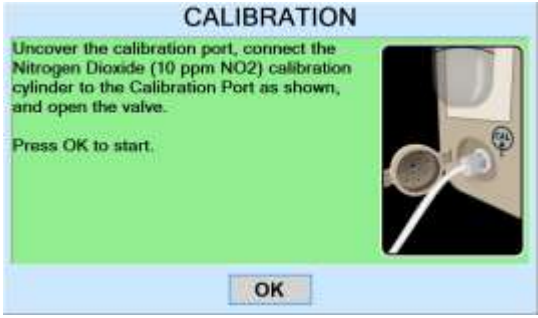
DISPLAY	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. Check to make sure nothing is connected to the CAL port during Air Calibration. 2. If the Calibration Tab is not displayed, press the “Menu” tab to access the sub-level tabs. 3. Press the “Calibration” tab on the display menu. 4. Press the Low Range “Air” button. 5. Press the blue “Start Calibration” button. 	<p>NOTE</p> <p>Air Calibration will take up to 2 minutes. A progress bar is displayed in the lower left-hand corner of the display screen during the calibration process.</p>
	<ol style="list-style-type: none"> 6. Press “OK” to continue once calibration is complete. 	<p>NOTE</p> <p>If calibration fails, check if there is anything connected to the CAL port.</p>

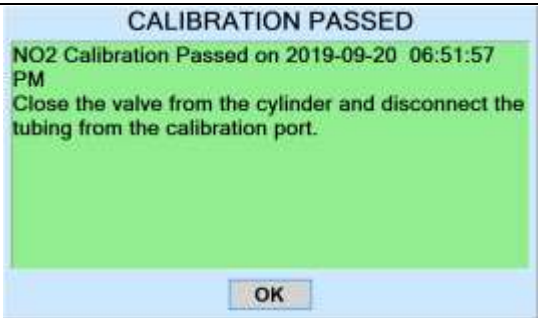
8.1.2. NO Calibration

DISPLAY	ACTION	Warnings, Cautions and Notes
	<ol style="list-style-type: none"> 1. If the Calibration Tab is not displayed, press the “Menu” tab to access the sub-level tabs. 2. Press the “Calibration” tab on the display menu. 3. Press the High Range “NO” button. 4. Press the blue “Start Calibration” button. 	
	<ol style="list-style-type: none"> 5. Follow the onscreen instructions. 	<p>WARNING</p> <p>DO NOT open the valve prior to connecting to the CAL port. Opening the valve first will expose the user to NO gas.</p> <p>DO NOT interrupt calibration until finished. If interrupted, the calibration will be cancelled.</p>

DISPLAY	ACTION	Warnings, Cautions and Notes
		NOTE NO calibration takes approximately 2 minutes. A progress bar is displayed in the lower left-hand corner of the display screen during the calibration process.
	<p>6. Follow the onscreen instructions</p> <p>7. Press "OK" to continue once calibration is complete.</p>	WARNING DO NOT disconnect tubing from the calibration port prior to closing the valve. Disconnecting the tubing first will expose the user to NO gas.

8.1.3. NO₂ Calibration

DISPLAY	ACTION	Warnings, Cautions and Notes
 <p>The screenshot shows the main display menu with a 'Start Calibration' button in the top right corner. Below the button, there are tabs for 'Low Range' and 'High Range'. Under 'Low Range', there are buttons for 'Air', 'NO', and 'NO₂'. Under 'High Range', there are buttons for 'NO₂' and 'O₂'. The 'NO₂' button is highlighted. Below the buttons, there are fields for 'NO', 'NO (Confirm)', 'NO₂', and 'O₂' with their respective values and units. To the right, there is a 'Calibration Due' section with a table showing dates and times for 'Air', 'NO', 'NO₂', and 'O₂'. At the bottom, there are tabs for 'Main', 'Alarms', 'Calibration', 'Events', and 'Settings'.</p>	<ol style="list-style-type: none"> 1. If the Calibration Tab is not displayed, press the “Menu” tab to access the sub-level tabs. 2. Press the “Calibration” tab on the display menu. 3. Press the High Range “NO₂” button. 4. Press the blue “Start Calibration” button. 	
 <p>The screenshot shows the 'CALIBRATION' screen with the following text: 'Uncover the calibration port, connect the Nitrogen Dioxide (10 ppm NO₂) calibration cylinder to the Calibration Port as shown, and open the valve. Press OK to start.' Below the text is a photo of the calibration port and a cylinder. At the bottom, there is an 'OK' button.</p>	<ol style="list-style-type: none"> 5. Follow the onscreen instructions. 	<p>WARNING</p> <p>DO NOT open the valve prior to connecting to the CAL port. Opening the valve first will expose the user to NO₂ gas.</p> <p>DO NOT interrupt calibration until finished. If interrupted, the calibration will be cancelled.</p> <p>NOTE</p> <p>NO₂ calibration takes approximately 2.5 minutes. A progress bar is displayed in the lower left-hand</p>

DISPLAY	ACTION	Warnings, Cautions and Notes
		corner of the display screen during the calibration process.
 <p>CALIBRATION PASSED NO2 Calibration Passed on 2019-09-20 06:51:57 PM Close the valve from the cylinder and disconnect the tubing from the calibration port.</p> <p>OK</p>	<p>6. Follow the onscreen instructions.</p> <p>7. Press "OK" once calibration is complete.</p>	<p>WARNING</p> <p>DO NOT disconnect tubing from the calibration port prior to closing the valve. Disconnecting the tubing first will expose the user to NO₂ gas.</p>

8.2. Maintenance Schedule

The Console components require the following maintenance:

COMPONENT	SCHEDULE
Water Trap	Per patient or as required (per Leak Test)
Console	Yearly

The Console requires yearly factory service. The System will display an Information Message to remind the operator when service is required. Call **Technical Support** at **877-337-4118** to schedule service or for disposal of the Console or cart.

8.3. Water Trap Maintenance



The following section will describe the emptying of the Water Trap. The Water Trap should be emptied when the liquid contents reach the horizontal black line marked on the Water Trap.

Prior to emptying the Water Trap, ensure the Gas Sample line is removed and reattached after emptying the Water Trap.

8.3.1. Emptying the Water Trap

WARNING

ALWAYS empty Water Trap before each use, when prompted by the System, and when the trap is more than half full. Allowing the Water Trap to completely fill will occlude the Sample Line which will interrupt patient gas NO, NO₂, and O₂ concentration monitoring. Failure to monitor the patient gas NO, NO₂, and O₂ concentrations may result in patient injury.



DISPLAY	ACTION
	<ol style="list-style-type: none"> 1. <u>Remove</u> Water Trap from Console by lifting latch and pulling the base of the Water Trap away from the Console. 2. <u>Remove</u> the lid by pulling the lid from the base. 3. <u>Empty</u> the liquid contents.
	<ol style="list-style-type: none"> 4. <u>Reattach</u> the lid by pushing it back onto base. 5. <u>Slide</u> the Water Trap back on the Console until it clicks into place.

8.3.2. Water Trap Replacement

If the Water Trap / Sample Line Leak Test does not meet requirements and the Sample Line integrity is confirmed or remains occluded, replace the Water Trap.

WARNING

- ALWAYS use a Water Trap supplied by the manufacturer. Using an incorrect water trap could result in non-functioning or inaccurate sensor readings.
- ALWAYS conduct Water Trap test every time you empty and replace the Water Trap, as failure to do so may lead to an incorrect NO reading, which can result in injury or death.

DISPLAY	ACTION
	<ol style="list-style-type: none">1. <u>Remove</u> old Water Trap from Console by lifting the latch and pulling the base of the Water Trap away from the Console.
	<ol style="list-style-type: none">2. <u>Slide</u> new Water Trap back on the Console until it clicks into place.3. <u>Discard</u> the old Water Trap.

8.4. Battery

The battery will be serviced during annual maintenance performed by the manufacturer. If the need arises to replace the battery sooner than scheduled contact **Technical Support at 877-337-4118** to schedule a maintenance appointment.

During storage, the GENOSYL DS may be stored with the power off, but the external power supply should be connected at least once every 3 months to ensure a minimum charge is maintained on the internal battery (see [Section 10.2.2](#) for additional information).

WARNING

ONLY properly trained personnel should replace the battery. Incorrectly replacing the battery may result in a hazard such as excessive temperatures, fire, or explosion.

8.5. Cleaning

8.5.1. Enclosure, Connections, and Surfaces Other Than the Display

Prior to performing any cleaning or maintenance operations ensure that the GENOSYL DS Console has been completely powered down as specified in [Section 6.1](#) and that the AC/DC power supply external to the GENOSYL DS Console has been unplugged. Apply any mild detergent to cloth prior to wiping down the System. Gently clean the outer surface of the unit with a soft damp cloth and mild detergent or isopropyl alcohol (70%).

CAUTION

- ALWAYS power down the GENOSYL DS Console and disconnect the power to the Console when not in use. Failure to do so may lead to permanent damage to the Console.
- DO NOT sterilize (e.g., autoclave, gas sterilize) any of the components of the System, as this may compromise performance.
- DO NOT use harsh cleaning agents on the GENOSYL DS. Doing so may impair the structural integrity and/or function of the device.
- ONLY use a damp cloth to clean the Console and limit use of liquids around Console. Excess water can permanently damage the device.
- ALWAYS ensure the System is completely dry after cleaning before powering it ON. Failure to do so could result in equipment damage.

WARNING

- NEVER submerge the GENOSYL DS in water. Submerging in water will damage the System and could cause electrical shorts which may result in injury or death.
- DO NOT clean the GENOSYL DS with the power connected and the System turned ON, as this may lead to injury (e.g., shock). Unplug AC/DC power supply external to the System prior to cleaning.

CLEANING AGENT	ACTIVE INGREDIENTS
Avert by Diversey	Sodium hypochlorite 1.312% Other ingredients 98.688%
Oxivir by Diversey	Hydrogen Peroxide 0.5% Other ingredients 99.5%
CaviWipesXL by Metrex	Disobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 0.28% Isopropanol 17.20% Inert ingredients 82.52%

CLEANING AGENT	ACTIVE INGREDIENTS
Sani-Cloth AF3 by PDI Healthcare	n -Alkyl dimethyl ethylbenzyl ammonium chlorides 0.14% n-Alkyl dimethyl benzyl ammonium chlorides 0.14% Other ingredients 99.72%
Super Sani-cloth by PDI Healthcare	n -Alkyl dimethyl ethylbenzyl ammonium chlorides 0.25% n-Alkyl dimethyl benzyl ammonium chlorides 0.25% Isopropyl Alcohol 55.00% Other ingredients 44.50%

8.5.2. Display Screen

Turn off Console and disconnect from AC power. Gently clean with a damp cloth.

CAUTION

- DO NOT touch or rub the display screen with abrasive cleaning compounds or organic solvents, as they may scratch and damage the screen.
- DO NOT spray or pour liquids directly on the controller or the display, as they may damage the screen.

8.6. Storage

8.6.1. Cart / Console Storage

The acceptable storage conditions for the Cart/Console are shown in the following table.

Cart / Console Storage	Temperature	-20°C to 60°C
	Humidity	15% to 95%, non-condensing
	Pressure	57kPa to 110kPa

During storage, the GENOSYL DS may be stored with the power off, but with the external power supply connected in which case the internal battery will be kept fully charged (see [Section 10.2.2](#) for additional information).

During storage, the GENOSYL DS may be stored with the power off, but the external power supply should be connected at least once every 3 months to ensure a minimum charge is maintained on the internal battery (see [Section 10.2.2](#) for additional information).

WARNING

- MAKE SURE the GENOSYL DS is connected to AC wall power to charge the battery a minimum of once every 3 months to maintain a minimum battery charge. Failure to recharge the Console battery for extended timeframes may result in full discharge of the battery. If a Battery Error message occurs during startup of the System, contact **Technical Support at 877-337-4118** for assistance.
- ONLY properly trained personnel should replace the battery. Incorrectly replacing the battery may result in a hazard such as excessive temperatures, fire, or explosion.
- ONLY store the GENOSYL DS as outlined in the storage instructions. Not storing the device in alignment with its storage instructions can cause the device to be unsafe and lead to injury or death.

8.6.2. Cassette / Accessory Storage

GENOSYL DS may not function correctly if the Cassette or any of the System Accessories have been exposed to high levels of heat or humidity. Cassettes are supplied in a foil sealed pouch and should remain unopened until use. Cassettes should be stored at 25°C (77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F). (See USP Controlled Room Temperature).

GENOSYL® DS



SECTION 9 MECHANICAL VENTILATION

9.0 MECHANICAL VENTILATION

WARNING

- ONLY mechanical ventilators validated with the GENOSYL DS should be used. Not using a validated ventilator system can result in injury or harm.
- DO NOT use the GENOSYL DS with circle anesthesia ventilator systems. The GENOSYL DS has not been characterized or qualified for use with anesthesia breathing systems with recirculation of gases.

9.1 Mechanical Ventilation

There are two main effects of connecting the GENOSYL DS to a ventilator breathing circuit:

1. The System injects up to 0.6 LPM of NO/air (21% Oxygen) into the output of the ventilator.
2. The System will remove up to 0.3 LPM of air from the ventilator circuit as a sample input to the built-in gas analyzers.

The results of adding and subtracting gas into the ventilator circuit are:

9.1.1 Oxygen Dilution

The ventilator typically is flowing gas to the patient with enhanced oxygen content from room air at 21% to pure oxygen at 100%. The DS is injecting the NO in air with a concentration of oxygen at nominally 21%. Thus, except for the case where the ventilator is supply gas to the patient at 21% oxygen, there is some dilution of the oxygen to the patient. This dilution is given by the following equation:

$$\text{Percent O}_2 \text{ to Patient} = \left[\frac{\% \text{O}_2 / 100 + (\text{Flow}_{\text{inj}} / \text{Flow}_{\text{vent}}) \times 0.21}{1 + (\text{Flow}_{\text{inj}} / \text{Flow}_{\text{vent}})} \right] \times 100$$

Where:

Flow_{inj} = Injection flow in same units as ventilator flow

$\text{Flow}_{\text{vent}}$ = Ventilator flow in same units as injection flow

$\% \text{O}_2$ = Percent oxygen out of ventilator

0.21 = Fraction of oxygen in injection flow (21%)

The table below shows the maximum effect on the actual concentration of oxygen supplied to the patient for set ventilator flow settings.

	Oxygen (%) Supplied from Ventilator				
	100	80	60	40	21
Ventilator Flow (LPM)	Oxygen (%) Delivered to Patient				
20	98	78	59	39	21
15	97	78	59	39	21
10	96	77	58	39	21
9	95	76	58	39	21
8	94	76	57	39	21
7	94	75	57	39	21
6	93	75	56	38	21
5	92	74	56	38	21
4	90	72	55	38	21
3	87	70	54	37	21

9.1.2 Minute Volume

When using volume ventilation with the GENOSYL DS, the tidal volume delivered to the patient shows small changes due to the addition and subtraction of gases by the Delivery System. Some minor ventilator adjustments to the minute volume may be required. The maximum total flow added to the ventilator circuit is 0.3 LPM with maximum injection flow of 0.6 LPM and the sampling flow of 0.3 LPM removed from the circuit. The maximum total flow subtracted from the ventilator circuit is 0.3 LPM in the case when the Consoles are not dosing, and the sample line is pulling 0.3 LPM.

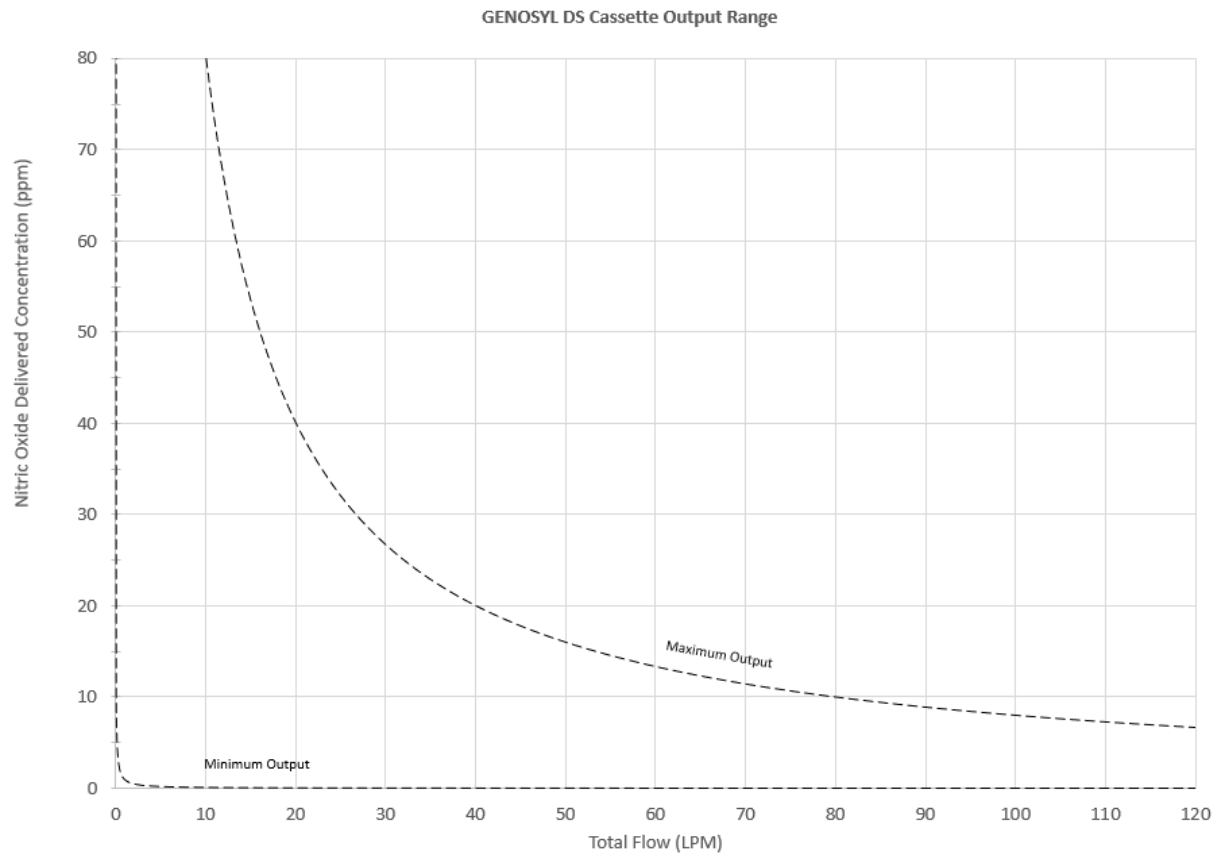
9.1.3 Trigger Sensitivity

The addition and subtraction of gases by the GENOSYL DS may affect the trigger sensitivity of the ventilator when using synchronized modes of ventilation. This may cause the ventilator to auto-trigger in ventilators which have flow trigger modes, especially where the trigger flow is less than the total flow added to the system.

9.1.4 Maximum NO Delivery

The maximum combination of dose (ppm) and flow (LPM) is 800 ppm x LPM (e.g., 20 ppm with 40 LPM, 40 ppm at 20 LPM, etc.). The System is capable of delivering NO at a minimum of 1 ppm x LPM (e.g. 1 ppm at 1 LPM). See the graph below for the minimum and maximum dose ranges for the System, based on ventilator circuit total minute volume.

Figure 21: Cassette Output Range



9.2 Ventilator Compatibility

The GENOSYL DS is compatible with the following equipment and accessories.

Table 4: Compatible Equipment and Accessories

MANUFACTURER	TYPE OF EQUIPMENT	MODEL
Fisher Paykel	Vent circuit kit	RT265
Fisher Paykel	Vent circuit kit	RT210
Fisher Paykel	Humidifier	850
Fisher Paykel	Humidifier	MR 290
Medline	Hyperinflated Resuscitator	Resus Hyperinf System 1/2L-LF
Laerdal	Self-inflated Resuscitator	Infant Silicone Resuscitators

Vero Biotech performs validation testing which determines the compatibility of ventilator/gas delivery systems with the GENOSYL DS. During this compatibility testing, the GENOSYL DS is evaluated for the following parameters while connected to each ventilator/gas delivery system:

- **NO Dose Accuracy:** Continuous and accurate delivery of a targeted dose of nitric oxide within $\pm 20\%$ of setpoint or within ± 2 ppm, whichever is greater.
- **Non-Invasive Gas Delivery and Alarms:** The non-invasive gas delivery device and alarms continue to function as intended by the manufacturer across the range of operating conditions.
- **NO₂ Performance:** NO₂ remains within acceptable limits less than 1.0 ppm with 60% FiO₂ and ≤ 40 ppm NO.
- **O₂ Dilution:** Post dilution O₂ level delivery is maintained within acceptable limits and conforms with the information presented in the GENOSYL DS Operator's Manual, [Section 9.1.1](#), "Oxygen Dilution".
- **NO Concentration Transients:** NO concentration transients are $\leq 150\%$ of mean concentration and as low as 0.0 ppm as long as the transient duration does not exceed 10% of the volumetric duration of the breath.

The testing performed demonstrated conformance with all specified requirements.

The following ventilators and non-invasive gas delivery systems have been validated for use with the GENOSYL DS. See [Section 3.2](#) for use configurations.

Table 5: Validated Ventilators and Non-Invasive Gas Delivery Systems

Manufacturer	Model	Ventilator Range Tested: Neonatal	Ventilator Range Tested: Pediatric/Adult	
		Ventilator Circuit <u>Without</u> Inline Mixer	Ventilator Circuit <u>Without</u> Inline Mixer	Ventilator Circuit <u>With</u> Inline Mixer
Dräger	VN500	•	•	N/A
GE Healthcare	R860	•	VT ≤ 350ml	VT > 350 – 650ml
Hamilton	C1/T1	•	VT ≤ 450ml	VT > 450 – 600ml
Hamilton	G5	•	VT ≤ 950ml	VT > 950 – 1400ml
Maquet	Servo-I	•	VT ≤ 650ml	VT > 650 – 1000ml
Maquet	Servo-U/N	•	VT ≤ 650ml	VT > 650 – 740ml
Manufacturer	Model	Ventilator Range Tested: Neonatal	Ventilator Range Tested: Pediatric/Adult	
Vyaire Medical Inc.	3100A	•	N/A	
Vyaire Medical Inc.	3100B	N/A	•	
Fisher & Paykel	RT330 Optiflow Junior Infant HFNC	•	N/A	
Fisher & Paykel	RT332 Optiflow Adult/Ped HFNC	N/A	•	
Fisher & Paykel	BC163 Bubble CPAP Infant Delivery System	•	N/A	

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GENOSYL® DS



SECTION 10

PRODUCT SPECIFICATIONS

10 PRODUCT SPECIFICATIONS

10.1 System Performance

NO DOSING	
Accuracy	+/- 20% or +/- 2 ppm (whichever is greater)
Range	1 to 80 ppm
Flow rate (max)	600 ml/min

GAS SENSOR			
	Range	Resolution	Accuracy
NO	0 - 10 ppm	0.1 ppm	≤20 ppm: +/- (20% of actual concentration + 0.5)
	10 – 100 ppm	1 ppm	>20 ppm: +/- (10% of actual concentration + 0.5)
NO ₂	0.0 - 12 ppm	0.1 ppm	+/- (20% of actual concentration + 0.5 ppm)
O ₂	18 - 100%	1%	+/- volume fraction of 2.5% +2.5% of gas level

10.1.1 System Classification

- Class I equipment
- Ordinary Equipment IPX1
- Continuous Use
- Essential Performance: The System shall continue to deliver a controlled dose, as configured by the user (e.g., 20 ppm @ 6 LPM within +/- 20%) with NO₂ < 2 ppm and O₂ = 21 +/- 3% in room air for the specified range of use conditions.

10.1.2 Testing

- ANSI ES 60601-1
- IEC 60601-1-2
- IEC 60601-1-8

10.2 Electrical

NOTE

Disconnect main power cord from the wall outlet to isolate equipment from main power. Do not position equipment to make it difficult to disconnect equipment from main power.

10.2.1 Power Supply

- Medical Grade Class I
- Input: 100-240 V, 50-60 Hz, 2 A
- Output: 18 V DC, 8.3 A
- 150 Watts Max

10.2.2 Battery

- Backup battery that provides at least 1 hour of uninterrupted nitric oxide delivery in the absence of an external power source.
- Typical battery life is 300 charge/discharge cycles.
- The battery will be serviced during annual maintenance performed by the manufacturer.
- If the need arises to replace or dispose of the battery sooner than scheduled contact Technical Support to schedule a maintenance appointment.

The battery has an embedded 5 segment LCD fuel gauge viewable through side panel window. The segments will display the following information:

- 5 segments filled – 81%-100% charged
- 4 segments filled – 61%-80% charged
- 3 segments filled – 41%-60% charged
- 2 segments filled – 21%-50% charged
- 1 segment filled – 1% - 20% charged
- No fuel gauge indication – below 1%
- Most significant segment flashing – charging
- Most significant segment not flashing – not charging

10.2.3 Display

- Touch screen – Resistive
- Brightness – 400 cd/m²
- Resolution – 800 x 480 pixels, color

10.3 Mechanical

CART	
Weight	29 kg (64 lbs)
Width x Length	55.9 cm (22.0 in) x 68.6 cm (27.0 in)
Height	139.7 cm (55.0 in)

CONSOLE	
Weight	7.3 kg (16 lbs)
Width x Length	40.6 cm x 30.5 cm (16 in x 12 in)
Height	16 cm (6.3 in)

CASSETTE	
Weight	0.5 kg
Width x Length	8.9 x 11.5 cm (3.5 x 4.5 in)
Height	14 cm (5.5 in)


10.4 Environmental

ENVIRONMENTAL RANGES		
Operating	Temperature	5° C to 40° C
	Humidity	15% to 95%, non-condensing
	Pressure	57kPa to 110kPa
Storage/Transport	Temperature	-20° C to 60° C
	Humidity	15% to 95%, non-condensing
	Pressure	57kPa to 110kPa
Water Ingress Protection	IPX1	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
The GENOSYL DS is intended for use in the electromagnetic environment specified below. The customer or the user of the GENOSYL DS should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1 Class B	<p>The GENOSYL DS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p> <p>The GENOSYL DS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</p>
RF conducted emissions per CISPR 11 Ed. 5.1b:2010	Class B	<p>The GENOSYL DS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</p>
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GENOSYL DS is intended for use in the electromagnetic environment specified below. The customer or the user of the GENOSYL DS should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T 95% dip in U_T For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T 95% dip in U_T For 5 sec	<5 % U_T 95% dip in U_T For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T 95% dip in U_T For 5 sec	Mains power should be that of a typical commercial or hospital environment. If the user of the GENOSYL DS requires continued operation during power mains interruptions, it is recommended that the GENOSYL DS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC main voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GENOSYL DS is intended for use in the electromagnetic environment specified below. The customer or the user of the GENOSYL DS should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside ISM bands ^a 6 V rms 150 kHz to 80 MHz in ISM bands ^a	3 V rms 150 kHz to 80 MHz (V1) 6 V rms 150 kHz to 80 MHz (V2)	Except as indicated on page 10-137, portable and mobile RF communications equipment, including cables, should be used no closer to any part of the GENOSYL DS than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GENOSYL DS is intended for use in the electromagnetic environment specified below. The customer or the user of the GENOSYL DS should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V /m 26MHz to 1 GHz	10 V /m 26 MHz to 1 GHz	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz
	3V /m 80GHz to 2.7GHz	3V /m 80GHz to 2.7GHz	$d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. ^d Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE			
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that a portable communications device could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

^c Field strengths from fixed transmitters, such as base stations for radio (cellular cordless) telephones and land mobile radios, amateur radio, AM and F M radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed R transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GENOSYL DS is used exceeds the applicable RF compliance level above, the GENOSYL DS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GENOSYL DS.

^d Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the GENOSYL DS

The GENOSYL DS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GENOSYL DS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GENOSYL DS as recommended below, according to the maximum output power of the communications equipment except as indicated on page 10-166.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter, m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Immunity Test	Standards Tested	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF AIM 7351731 - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers	<ul style="list-style-type: none">• ISO 14223 (Annex A)• ISO/IEC 14443-3 (Type A) (Annex B)• ISO/IEC 14443-4 (Type B) (Annex C)• ISO/IEC 15693 (ISO/IEC 18000-3 Mode 1) (Annex D)• ISO/IEC 18000-7 (Annex E)• ISO/IEC 18000-63 Type C (Annex F)• ISO/IEC 18000-3 (Mode 3)• ISO/IEC 18000-4 Mode 1 (Annex G)	Per the Annex in the standard	System tested as compatible with RFID tags/communication

Frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 in)

Band (MHz)	Service
380 - 390	TETRA 400
430 - 470	GMRS 460, FRS 460
704 - 787	LTE Band 13, 17
800 - 960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5
1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
5,100 – 5,800	WLAN 802.11 a/n

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