

Nitronox Plus Quick Start Guide

1. Pre-Check

Note: To perform these tests, gas supply cylinders or gas supply shutoff valves are required in order to isolate the gas supply from the device. Attempting to perform these tests with central pipeline supplied gas without a local shut off mechanism is not recommended.



WARNING: Proper inspection and maintenance of this device is essential to prevent gas leaks. All hoses, fittings, and connections should be inspected regularly, and all leaks should be repaired immediately.



WARNING: If precheck test cannot be executed successfully, do not use this device and contact distributor.

Field Leak Test

1	To test the device for leaks in the field, ensure the N ₂ O Key Lock is in the ON position. For adjustable models, set the %N ₂ O knob to 50% (no setting required for 50/50 model)
2	Ensure gas supply lines are installed correctly. Open the supply valves to pressurize the system and confirm the O ₂ and N ₂ O inlet pressure gauges are within the green bands.
3	Turn off the supply valves and start a stopwatch.
4	After approximately 2 minutes, confirm that the pressure on the O ₂ and N ₂ O inlet pressure gauges has not dropped below 40 psi.
5	If either pressure has dropped below 40 psi, check the demand valve to ensure the quick-connect fitting is secure and the valve is firmly pushed into the delivery port. Inspect all hoses and connections for leaks; if any hoses are leaking, ensure the threads are tightened and the hose crimp is intact. Repair or replace any damaged or leaking hoses immediately. If leaks persist, contact your authorized distributor for service and troubleshooting.

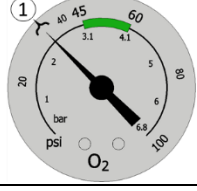

Failsafe Test

1	To test the failsafe mechanism, ensure the N ₂ O key lock is in the ON position. For adjustable models, set the %N ₂ O knob to 50% (no setting required for 50/50 model).
2	Ensure gas supply lines are installed. Open the supply valves to pressurize the system and confirm the O ₂ and N ₂ O inlet pressure gauges are within the green band and the mixture pressure gauge is within the green band.
3	Turn OFF the O ₂ supply valve.
4	While observing the O ₂ inlet pressure gauge, manually activate the demand valve by pushing on the back of the demand valve (where it says: "PRESS TO TEST") until the inlet pressure gauge reads 0 psi. The O ₂ low pressure alarm may activate briefly.
5	Continue manually activating the demand valve. Confirm that the mixture pressure gauge drops to 0 psi and that no gas flow comes out of the connection port while the O ₂ supply remains off.
6	If the mixture pressure does not deplete or the device is able to flow gas while the O ₂ supply is off, contact your authorized distributor for service and troubleshooting.

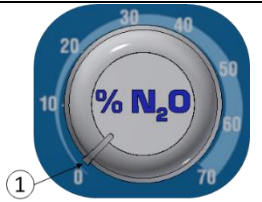
Emergency Air Intake Valve Test

1	To test the emergency air intake valve, turn the N ₂ O key lock to the OFF position. For adjustable models, set the %N ₂ O knob to 0% (no setting required for 50/50 model).
2	Ensure the gas supply lines are installed correctly. Open the supply valves to pressurize the system and confirm the O ₂ and N ₂ O inlet pressure gauges are within the green band.
3	Connect a new medical breathing circuit with mask or mouthpiece to the device.
4	Take a breath of 100% O ₂ from the device. Note the level of resistance against inhalation.
5	Turn the O ₂ gas supply valve OFF.
6	While monitoring the O ₂ inlet pressure gauge, continue breathing through the mask or mouthpiece. Observe the resistance against inhalation once the O ₂ supply gauge depletes to 0 psi.
7	If the resistance against inhalation only slightly increases as the gauge drops, the emergency air intake valve is functioning properly. If it becomes significantly difficult to inhale from the mask or mouthpiece, the emergency air intake valve may be malfunctioning; if so, contact your authorized distributor for service and troubleshooting.

Alarm Function Test

1	To test the device alarms, ensure the N ₂ O Key Lock is in the ON position. For adjustable models, set the %N ₂ O knob to 50% (no setting required for 50/50 model).	
2	Ensure the gas supply lines are installed correctly. Open the supply valves to pressurize the system and confirm the O ₂ and N ₂ O inlet pressure gauges are within the green band.	
3	Turn OFF the O ₂ gas supply valve. While observing the O ₂ inlet pressure gauge, manually activate the demand valve by pushing on the back of the demand valve (where it says: "PRESS TO TEST") until the alarm activates. Confirm the alarm whistles when the needle on the O ₂ inlet pressure gauge reads approximately 35 psi (1).	
4	Turn the O ₂ gas supply valve back ON and ensure the O ₂ and N ₂ O inlet pressure gauges are within the green band.	
5	Turn OFF the N ₂ O gas supply valve. While observing the N ₂ O inlet pressure gauge, manually activate the demand valve by pushing on the back of the demand valve (where it says: "PRESS TO TEST") until the alarm activates. Confirm the alarm whistles when the needle on the N ₂ O inlet pressure gauge reads approximately 35 psi (2).	
6	While the N ₂ O alarm is whistling, turn the N ₂ O Key Lock to the OFF position. Confirm the alarm stops once the key is turned OFF. Note: The N ₂ O low pressure alarm is driven by O ₂ . When the N ₂ O supply pressure drops below the alarm threshold, the device will alarm until either: 1) N ₂ O supply pressure is restored, 2) the N ₂ O Key Lock is turned to "OFF," or 3) the O ₂ supply pressure completely depletes.	
7	If either of the alarms do not activate once the pressure drops to approximately 35 psi, contact your authorized distributor for service and troubleshooting.	

2. Operating Instructions

1	Adjustable models: Set the desired concentration of nitrous oxide by adjusting the "%N ₂ O" dial (1) on the front of the device. It is recommended to start with a low percent of N ₂ O and titrate to the desired effect on the patient. Note: The 50/50 model is not adjustable and will deliver a preset 50% N ₂ O/O ₂ mixture.	
2	Instruct the patient to self-administer (or be assisted in administration) as necessary, by inhaling and exhaling using the mask or mouthpiece. If using a mask, ensure the patient holds the mask firmly against their face to form a complete seal. If using a mouthpiece, ensure the patient's lips are tight around the mouthpiece to form a complete seal.	
3	Always ensure the patient is exhaling back into the mask or mouthpiece to achieve effective scavenging.	
4	If, at any time, delivery of 100% O ₂ is desired, turn the "%N ₂ O" dial to 0%, then turn the N ₂ O Key Lock to the OFF position. This will close the internal nitrous oxide valve and supply the patient with 100% O ₂ .	
5	At the completion of the procedure, remove the face mask or mouthpiece from the patient. Dispose of any single-use items (such as the breathing circuit, face mask, or mouthpiece).	
6	Always turn the O ₂ and N ₂ O cylinder valves OFF (for cylinder gas supply configurations) or disconnect the supply lines from the appropriate outlet stations (for pipeline gas supply configurations) to avoid unintentionally depleting the source gases.	

3. Cleaning

The Nitronox Plus must be cleaned between each use in order to prevent the spread of infections. Cleaning of the device has been validated with Super Sani-Cloth™ Germicidal wipes.

WARNING: The following warning applies to the device and any device's components and accessories:



- Do not spray directly with disinfecting chemicals.
- Do not immerse in water, sanitizer, cleaning solution, or any other liquid.
- Do not sanitize or wipe the inside of the fittings, gas supply hoses, or connection ports.
- Always ensure the device and device's components and accessories are completely dry before use.

1	Disconnect and dispose of the single use breathing circuit and single use mask/mouthpiece (if attached).
2	Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the outer case, front panel, and back of the device until all visible dirt and soil is removed. Take extra care to wipe the outside of the connection port area, %N ₂ O knob, and key lock area as these are the most handled areas of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove.
3	Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the gas supply hoses and fittings until all visible dirt and soil is removed. Do not wipe the inside of the hoses or fittings as this may deposit cleaning agents into the breathing pathway of the device.
4	Perform the pre-use checks as specified in Section 1.

4. Safety Information



WARNING: This product can expose you to chemicals, including lead and formaldehyde, which are known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.



WARNING: Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.



WARNING: The Nitronox Plus Flowmeter is not intended to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the Nitronox Plus Flowmeter in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the Nitronox Plus Flowmeter should be considered "MR Unsafe" and should be kept outside of any MRI scanner rooms.



WARNING: Workers exposed to excessive N₂O may suffer harmful effects. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure. (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average).



WARNING: The Nitronox Plus Flowmeter are used with the delivery of Oxygen (O₂). Therefore, when these devices are used in conjunction with energy producing devices (such as lasers, radio frequency sources, or other heat sources), the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials.



WARNING: If the alarm whistle sounds, check the gas supply pressures to ensure there is an adequate supply of gas. If 100% O₂ delivery is desired without any N₂O supply pressure, turn the Key Lock to OFF to deactivate the N₂O alarm.



WARNING: Never use a mask strap to hold the mask to a patient's face. Self-administration is a safety feature of the Nitronox Plus; if for any reason the patient were to become over sedated, the patient will be unable to adequately hold the mask in a tight sealing position against the face. The lack of a tight seal results in the demand valve being unable to trigger, and therefore the supply of mixed gas will cease, allowing the patient to breathe room air through the mouth or nose. If the patient is unable to fully self-administer, a medical professional may aid in placing the mask in a sealing position against the patient's face. Patient observation must be maintained to prevent over sedation; immediately remove the mask upon any observation of over sedation.



WARNING: Always use clean, dry, medical grade gases and never oil or grease any part of the device.

- WARNING:** Do not change the connection fitting type or diameter of the supply hoses. The Diameter Indexed Safety System (DISS) is designed to prevent misconnection of N₂O and O₂ supply lines.
- WARNING:** To minimize the risk of fire or explosion:
 - Always ensure cylinder valves are clear of dust and dirt prior to connection. One method to clear dust and dirt is to briefly “crack” the cylinder valve open to blow out any debris in the line before installing the cylinder.
- Do not discharge the gas at any person or flammable material.
 - Always turn on Cylinder Valves slowly and fully.
- WARNING:** The user should observe the patient to prevent over sedation in the event of an O₂ failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O₂, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure O₂ from an independent source.
- WARNING:** Do not modify this equipment without authorization of the manufacturer.
- WARNING:** Do not use or replace any components or accessories, except those specified in these instructions for use and installation guide.

5. Representation

	Legal Manufacturer	Parker Hannifin Corporation Precision Fluidics Division 245 Township Line Road Hatfield, PA 19440 USA Office: (215) 723-4000
	European Communities Authorized Representative	EMERGO Europe Westervoortsedijk 60 6827 AT Arnhem, The Netherlands Tel: +31 70 345 8570
	Conformité Européenne (CE) Mark	Compliance with conformity assessment on quality management system and technical documentation per Regulations (EU) 2017/745 for Medical Device, Annex IX Chapters I & III
	Switzerland Authorized Representative	Medenvoy Gotthardstrasse 28 6302 Zug Switzerland +41 41 562 01 42



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Refer to FM-1406 for complete instructions and safety information.

