

Nitronox Plus[®]

Instructions for Use and Installation Guide



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

READ INSTRUCTIONS FOR USE COMPLETELY BEFORE OPERATING THIS DEVICE

This document contains warnings, cautions, and instructions for use, and maintenance information that the user must completely comprehend before using this device. Failure to properly operate and maintain this device may result in patient harm and/or damage to equipment.

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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.



CAUTION: Federal law restricts this device to sale by or on the order of a physician or dentist.

Visit our website: <http://www.porterinstrument.com/medical> for additional information.



To download Instructions for Use: visit www.porterinstrument.com/medical-support. Choose "Delivery Systems" from the dropdown within the "Product Download" section.

1. Device Information

1.1. Intended Use/Intended Purpose

The Nitronox Plus is intended to provide a mixture of N₂O/O₂, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates.

1.2. Models

The Nitronox Plus is available in three models (pictured below). Throughout this document, the 0-70% model is pictured; all instructions and information are the same for all three models unless specified otherwise.

**0-70% N₂O Model
(P/N NOX-PLUS-070)**



**0-50% N₂O Model
(P/N NOX-PLUS-050)**



**50% / 50% Model
(P/N NOX-PLUS-5050)**



Device Model Table

Model Type	Model Number	Model Description
Demand Systems	NOX-PLUS-070*	NITRONOX PLUS 0-70 MODEL
	NOX-PLUS-050*	NITRONOX PLUS 0-50 MODEL
	NOX-PLUS-5050*	NITRONOX PLUS 50/50 MODEL

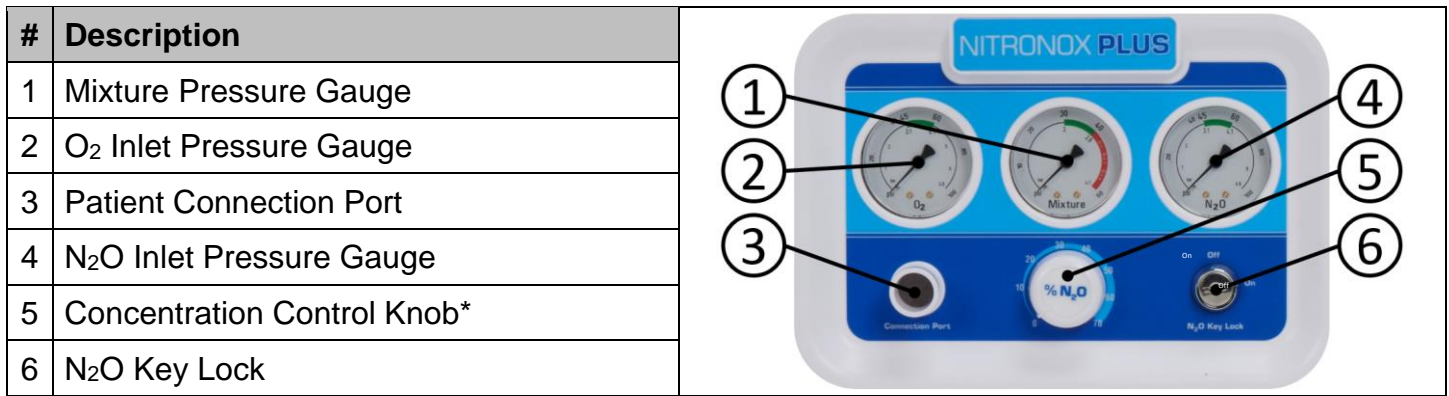
*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

Accessories Model Table

Model Type	Model Number	Model Description
Wall Mount	2020	Wall Arm Mount
E-Stands	2045-2	E-Stand Assembly, Swivel Yoke
	2045-3	E-Stand, Tall
	2045-3CA	E-Stand, White Hose
	2045-3ISO*	E-Stand, Tall with Gas Supply Hoses
	2045-3RA	E-Stand, Extra Tall
	2045-SHORT	E-Stand, Short
	2045-RAShort3	E-Stand, Short with Gas Supply Hoses
	2045-SHORT3	E-Stand, Compact
	2045-SHORT3-ISO*	E-Stand, International, Compact
Mobile Stands	2040*	Mobile Stand, Compact
	2042*	Tall Mobile Stand, Tall
	2044*	Mobile Stand, Extra Tall
2-Cylinder Mobile Carts	2100*	2-Cylinder Cart
	2100-2	2-Cylinder Cart with Dual Regulators and Hoses
	2100-N	2-Cylinder Cart with Nitrous Oxide Regulator
	2100-NC	2-Cylinder Cart, Nitrous Oxide Regulator and Hoses
	2100-ISO-2*	2-Cylinder Mobile Cart with Regulator O ₂ , Regulator N ₂ O, and Gas Supply Hoses
	2100-ISO-N*	2-Cylinder Mobile Cart with Regulator, N ₂ O, and Gas Supply Hose

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

1.3. User Interface



*Concentration Control Knob only present on adjustable models

1.4. General Description/Principles of Operation

The Nitronox Plus is a pneumatically driven gas mixing device that delivers a mixture of nitrous oxide (N₂O) and oxygen (O₂) to a conscious, spontaneously breathing patient. The device is powered by compressed N₂O and O₂ gas; pressure is regulated and equalized within the device, then delivered to a patient at a low pressure. The device functions under the demand flow principle of operation: upon patient inhalation, an internal demand valve triggers to supply mixed gas to the connected breathing circuit through the patient connection port. The Nitronox Plus is equipped with various safety features, which are described in Section 1.7.

1.5. Use of the Device

The Nitronox Plus system is to be used by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. The device is designed to provide a mixture of these gases to a patient for pain management and / or minimal conscious sedation, which is ideal for short, minimally invasive procedures to alleviate patient anxiety or minor pain and discomfort. It is the responsibility of the medical professional to consider the side effects, contraindications, and risks associated with administration of nitrous oxide and use of conscious sedation.

The Nitronox Plus is not used for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system. The user should observe the patient to prevent over sedation in the event of an oxygen failsafe malfunction or crossed lines. If a patient becomes overly sedated when being delivered 100% oxygen, 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 oxygen from an independent source.



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.

NOTE: If a serious incident (death or any intervention) has occurred while the device was in use, it should be reported to the manufacturer immediately and the Competent Authority of the member state in which the serious incident occurred.

1.6. Patient Population

The patient population includes conscious, spontaneously breathing, awake, alert, and cooperative patients.

Patients are selected by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. The medical professional must consider patients who are able to receive the gas mixture based on the risks associated with conscious sedation.

1.7. Warnings and Cautions

Warnings and cautions are listed where relevant to a certain section of this manual. A **WARNING** is an instruction, procedure, or explanation of hazards that may result in injury or death. A **CAUTION** is an instruction, procedure, or explanation of hazards that may result in damage to a product, equipment, or the environment.



WARNINGS and **CAUTIONS** are presented throughout the document along with this symbol to alert the reader of their presence.

1.8. Safety Features

Oxygen Piloted Regulator (Failsafe)

The Nitronox Plus utilizes an oxygen piloted regulator that only supplies nitrous oxide when oxygen supply pressure is present. If the oxygen supply gas is depleted or disconnected, the device will discontinue mixed gas delivery until oxygen supply pressure is restored.

DISS Fittings

The Nitronox Plus is equipped with Diameter Indexed Safety System (DISS) fittings; these fittings act in a key like fashion to ensure that only the correct hose can be connected to the appropriate fitting. This prevents an accidental crossing of the gas lines.

Low Inlet Pressure Alarms

When either oxygen or nitrous oxide gas supply pressure drops to approximately 35 psi (2.41 bar), a whistle alarm will sound to alert the user. In cases where only oxygen delivery is desired, the Key Lock feature can be turned OFF to prevent the nitrous oxide alarm from sounding.

Emergency Air Intake

In the event that the oxygen gas supply is depleted or disconnected, and delivery of mixed gas is stopped, an Emergency Air Intake Valve will open that allows the patient to breathe room air through the breathing circuit.

Key Lock

A locking mechanism allows the user to prevent unauthorized use of nitrous oxide. When turned to the OFF position, the lock closes an internal nitrous oxide valve. The key can then be removed and stored until nitrous oxide use is desired. While in the OFF position, the device is still capable of supplying 100% oxygen. When in the ON position, the device is capable of delivering nitrous oxide and the key cannot be removed until turned to the OFF position.

1.9. Delivery Protocols

It is the responsibility of the medical establishment and the medical professional to develop specific delivery protocols for administration of nitrous oxide using the Nitronox Plus. Specific delivery protocols for adult and pediatric patients should be developed; the Nitronox Plus is not intended to be used with infants or neonates.

The Nitronox Plus is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur intermittently over the course of many hours may also be considered transient. The upper limit of use duration is at the discretion of the medical professional.



WARNING: For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all gas pipelines are connected properly and that all use points of the system have been tested prior to use. It is important that the user verify by their own test that all gas pipelines are connected properly prior to using the system.



WARNING: The Nitronox Plus used with the delivery of Oxygen (O₂). Therefore, when this device is 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: The Nitronox Plus is not intended or expected 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 in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the Nitronox Plus should be considered “MR Unsafe” and should be kept outside of any MRI scanner rooms.

1.10. Safe Combination of devices

Nitronox Plus is designed to be used within a nitrous oxide/oxygen conscious sedation delivery and scavenging system to deliver an accurate mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device system is also used to remove exhaled waste analgesic gas through a vacuum control system. The system is comprised of a series of devices and accessories, which includes a demand system, breathing circuit with face mask or mouthpiece, vacuum controller with reservoir bag, mounting stand, and gas supply hoses.

To ensure safe combination of device, user should follow the installation instructions in **Section 2** below and ensure all connections are secure and tight.

1.11. Specifications

Dimensions

10.8 in L x 9.8 in W x 7.3 in H
(26.9 cm L x 25.1 cm W x 18.5 cm H)

Connection Fittings

Oxygen Inlet: DISS 1240 (Male)
Nitrous Oxide Inlet: DISS 1040A (Male)
Mixed Gas Connection Port: 22 mm taper

Gas Supply Pressure

O₂: 45 to 60 psi (310.3 to 413.6 kPa)
N₂O: 45 to 60 psi (310.3 to 413.6 kPa)

Delivery Accuracy

Normal and Heavy Breathing: ± 5% O₂
Light/Shallow Breathing: +20/-5% O₂

Alarm Activation

Whistle alarm signals low gas supply when pressure drops below approximately 35 psi (2.41 bar)

Gauges and Accuracy

Mixture Gauge 0-60 psi
Nitrous Oxide Gauge 0-100 psi
Oxygen Gauge 0-100 psi
Accuracy Range 3-2-3% of span*
*Accuracy for gauge reads in 3 sections

Weight

13 lbs. (5.9 kg)

Mixture Settings

Adjustable 0-70% N₂O (0-70% model)
Adjustable 0-50% N₂O (0-50% model)
Preset 50% N₂O/O₂ (50/50 model)

Delivery Flowrate

Up to 100 L/min total flow at 50% N₂O/O₂
Up to 80 L/min total flow at all other settings

Atmospheric Pressure

1 atm ± 0.2 atm (101 kPa ± 20 kPa)

Demand Valve

Cracking Pressure: < 2 cmH₂O
Use Life: 5 Years
Service Life: 10 Years

Environmental

Temperature

Storage and Transportation: -40°F to 140°F
(-40°C to 60°C)

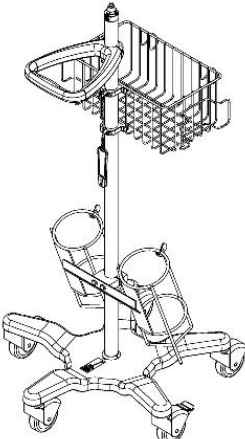
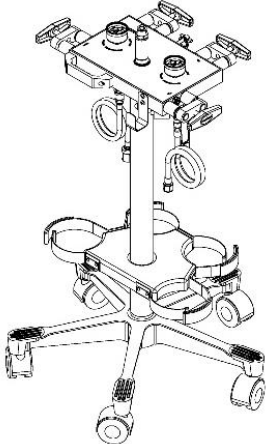
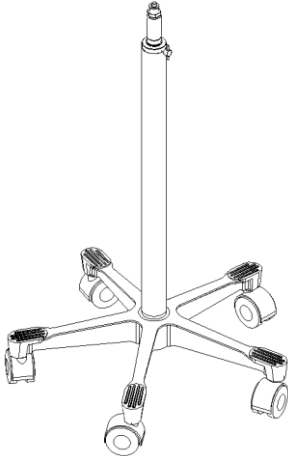
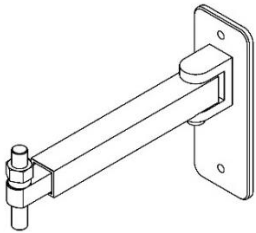
Operational: 41°F to 100°F
(5°C to 38°C)

Relative Humidity

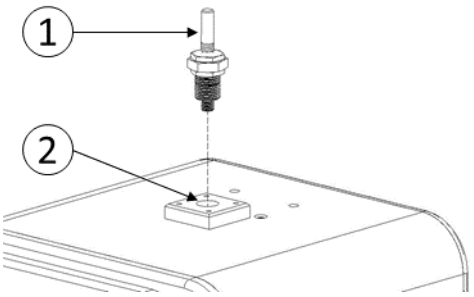
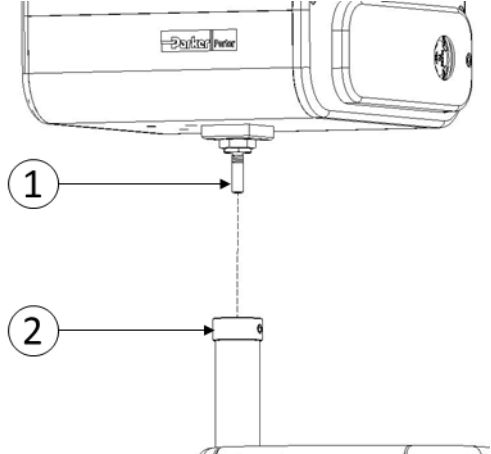
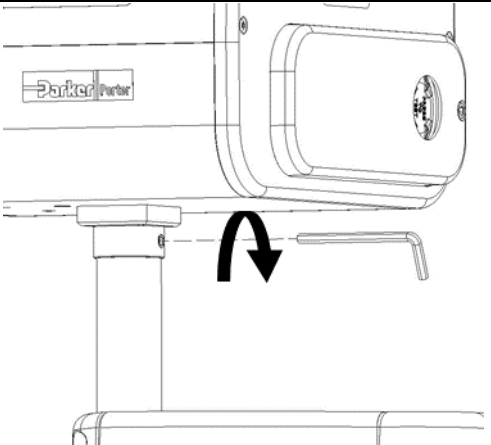
Storage and Transportation: 10 to 70%
Operational: 10 to 70%

2. Installation Instructions

2.1. Compatible Mounting Accessories

2 Cylinder Mobile Cart P/N 2100 See FM-1346	E-Stand P/N 2045-3 See FM-916	Mobile Stand P/N 2042	Wall Arm Mount P/N 2020
 <p>Note: Basket maximum weight = 10 lbs (4.5 kg)</p>			

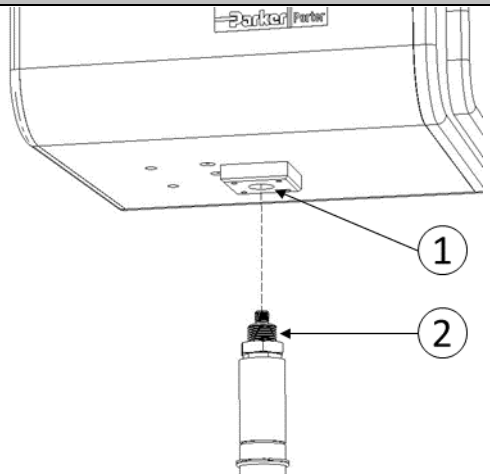
2.2. Mounting the Nitronox Plus

2 Cylinder Mobile Cart	
<p>1 Thread the mounting pin (1) into the mounting hole on the bottom of the Nitronox Plus (2) until it is tight, then tighten the locking nut to secure the pin.</p>	 <p>The diagram shows a close-up of the bottom of the Nitronox Plus cylinder. A mounting pin, labeled '1', is being inserted into a hole in the cylinder's base. The cylinder is labeled '2'. The pin is shown partially inserted, with a locking nut at the top.</p>
<p>2 Lift the Nitronox Plus and drop the mounting pin (1) into the mounting hole (2) on the top of the 2 Cylinder Mobile Cart.</p>	 <p>The diagram shows the Nitronox Plus cylinder being lifted. The mounting pin, labeled '1', is being inserted into a hole in the top of the 2 Cylinder Mobile Cart, which is labeled '2'. The cylinder is shown in a slightly elevated position, with the pin passing through the top of the cart.</p>
<p>3 Tighten the set screw on the 2 Cylinder Mobile Cart using a 5/32" Hex Key.</p>	 <p>The diagram shows the 2 Cylinder Mobile Cart with the Nitronox Plus cylinder attached. A set screw is being tightened on the cart using a 5/32" Hex Key. A curved arrow indicates the direction of rotation for the hex key.</p>

E-Stand/Mobile Stand

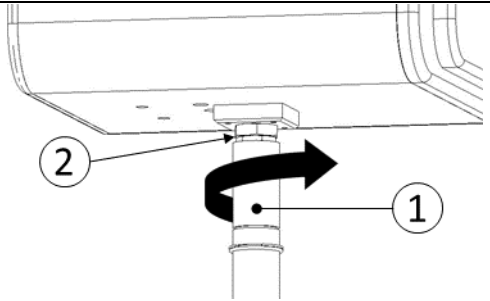
1

Hold the Nitronox Plus so that the mounting hole (1) is above the mounting thread of the E-Stand/Mobile Stand (2).



2

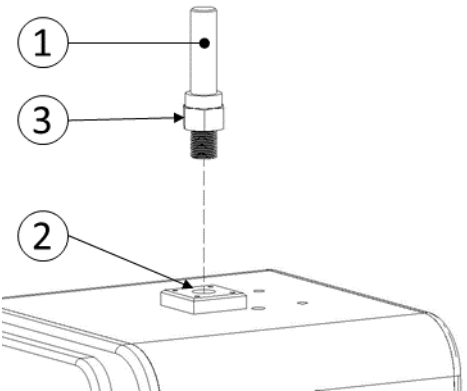
Lift and spin the shaft of the E-Stand/Mobile Stand (1) until the device is tightly threaded onto the mounting post. Tighten the locking nut on the mounting pin (2) to secure the device.



Wall Arm Mount

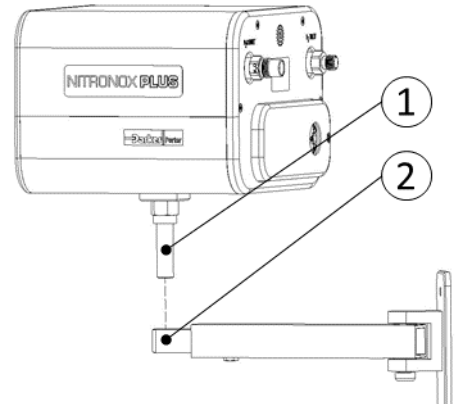
1

Thread the mounting pin (1) into the mounting hole on the bottom of the Nitronox Plus (2) until it is tight, then tighten the locking nut (3) to secure the pin.



2

Lift the Nitronox Plus and drop the mounting pin into the mounting hole on the top of the Wall Arm Mount.



2.3. Connecting Supply Lines



WARNING: Always use clean, dry, medical grade gases, and do not introduce moisture or other contaminants into the system. Never oil or grease any part of the system.

<p>1 Connect the N₂O gas supply line (1) to the N₂O DISS inlet fitting (2), then connect the O₂ gas supply line (3) to the O₂ DISS inlet fitting (4).</p>	
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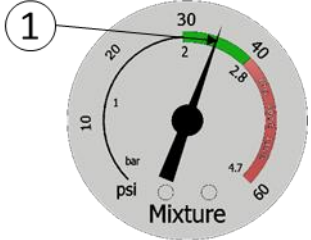
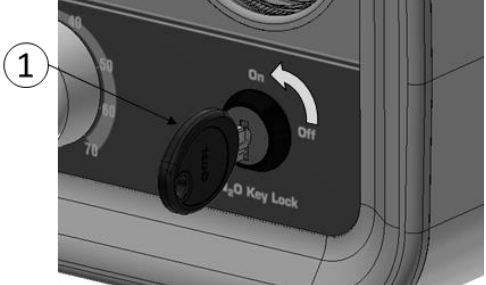
3. Instructions for Use

3.1. Setup and Pre-Use Checks



WARNING: 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.

<p>1 Ensure the device is securely mounted to an accessory (as described in Section 0) and the gas supply hoses are connected to the correct fittings on the Nitronox Plus (as described in Section 2.3).</p>		
<p>2 Turn on the gas supplies. If using gas cylinders, slowly open the cylinder valves (1). If connecting to a wall supply, connect the supply lines to the appropriate outlet connections (2).</p>		
<p>3 Ensure the O₂ supply pressure (1) and N₂O supply pressure (2) are within the green bands on the supply line pressure gauges (45-60 psi). If the inlet pressures are not within this band, delivered flowrates and mixture ratios may not be within specifications. Consult the mounting accessory or gas supply system instructions for use if adjustment is required.</p>		

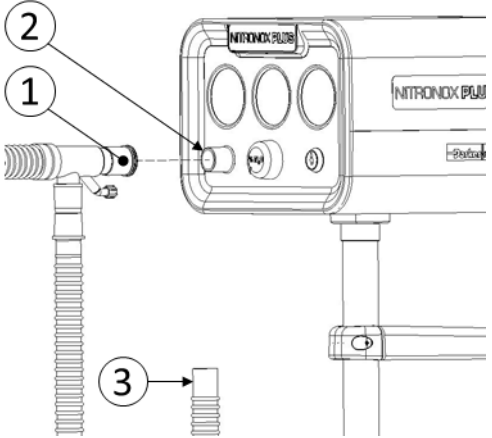
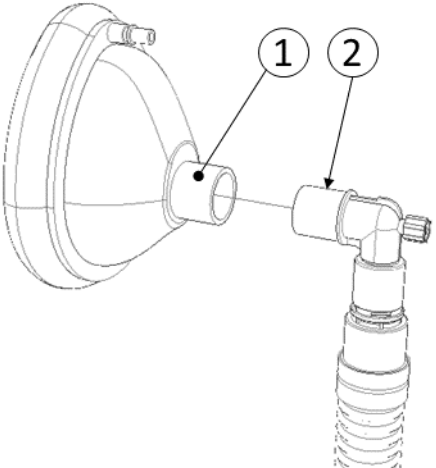
4	Confirm the mixture pressure is within the green band (1) on the mixture pressure gauge (30-40 psi).	
5	When the N ₂ O Key Lock is in the OFF position, only O ₂ can be administered. Turn the N ₂ O Key Lock to the ON position (1) to administer a mixture of N ₂ O and O ₂ .	



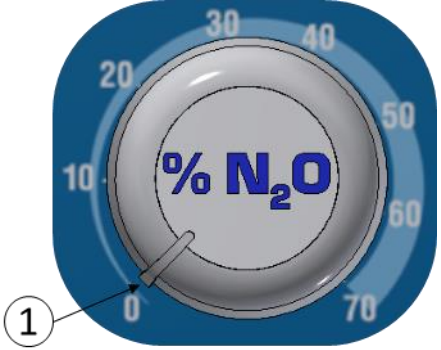
WARNING: Do not use the Nitronox Plus if the O₂ and N₂O supply pressures are out of the green band (45-60psi), or the mixture pressure is out of the green band (30-40 psi).

3.2. Breathing Circuit and Mask Installation

Note: The Nitronox Plus is compatible with the Medical Breathing Circuit (DMC-part series).

1	Connect the Tee fitting of the Medical Breathing Circuit (1) to the Connection Port (2) on the front of the Nitronox Plus. Connect the magenta scavenging hose (3) to the scavenging device; if not using a scavenger, the magenta hose may hang freely.	
2	Connect a breathing mask or mouthpiece (1) to the end of the Medical Breathing Circuit (2)	

3.3. Operating Instructions

1	<p>Adjustable models: Set the desired concentration of nitrous oxide by adjusting the “%N₂O” dial (1) on the front of the device. It is recommended to start with a low percent of N₂O and titrate to the desired effect on the patient.</p> <p>Note: The 50/50 model is not adjustable and will deliver a preset 50% N₂O/O₂ mixture.</p>	
2	<p>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.</p>	
3	<p>Always ensure the patient is exhaling back into the mask or mouthpiece to achieve effective scavenging.</p>	



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.

4	<p>If, at any time, delivery of 100% O₂ is desired, turn the “%N₂O” dial to 0%, then turn the N₂O Key Lock to the OFF position. This will close the internal nitrous oxide valve and supply the patient with 100% O₂.</p>	
5	<p>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).</p>	
6	<p>Always turn the O₂ and N₂O 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.</p>	



CAUTION: It is best practice upon completion of the procedure to close the cylinders (if portable gas supply) or disconnect from wall outlets (if central gas supply). Failure to do so may result in gas depletion should there be a leak.

4. Maintenance

The Nitronox Plus has an expected service lifetime of 10 years. The device requires proper maintenance, pre-checks, and servicing. Once the device reaches an age of 10 years, a failed pre-check will indicate that the device has reached the end of its useful life.

The Gas Supply Hose has an expected lifetime of 20 years and once it reaches this age, any damage will indicate that the device has reached the end of its useful life

Check	Section	Frequency
Inlet Pressure Check	3.1	Before every use
Mixture Pressure Check	3.1	Before every use
Field Leak Test	0	Every 6 months
Alarm Function Test	0	Every 6 months
Failsafe Test	0	Every 6 months
Emergency Air Intake Valve Test	0	Every 6 months
Cleaning the Device	4.2	As necessary
Servicing the Demand Valve	4.3	Every 5 years



WARNING: Proper inspection and maintenance of the Nitronox Plus system and accessories is essential to prevent nitrous oxide leaks. All hoses, fittings, and connections should be inspected regularly, and all leaks should be repaired immediately. 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), as nitrous oxide may cause harmful effect when over exposed.



WARNING: Do not attempt to change the inlet fittings or the diameters/fittings on the supply hoses. Diameter indexed fittings are designed to prevent misconnection of oxygen and nitrous oxide supply lines.



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.

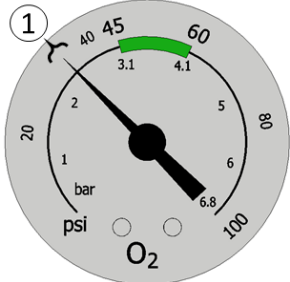
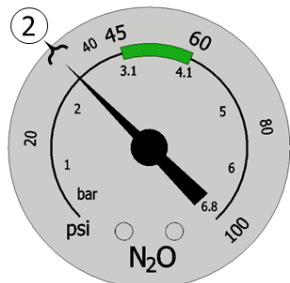
4.1. Periodic Checks

Note: To perform the following tests, gas supply cylinders or gas supply shut off 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 shutoff mechanism is not recommended.

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.

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.	

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.

4.2. Cleaning the Device

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.



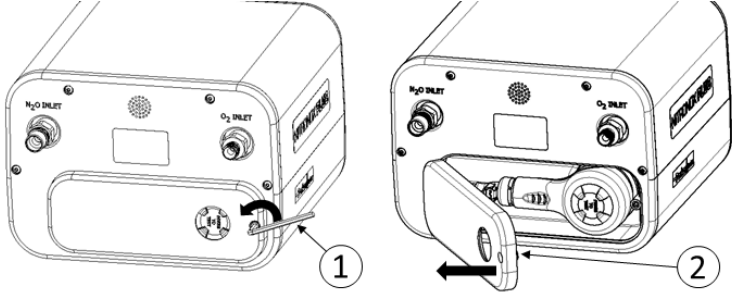
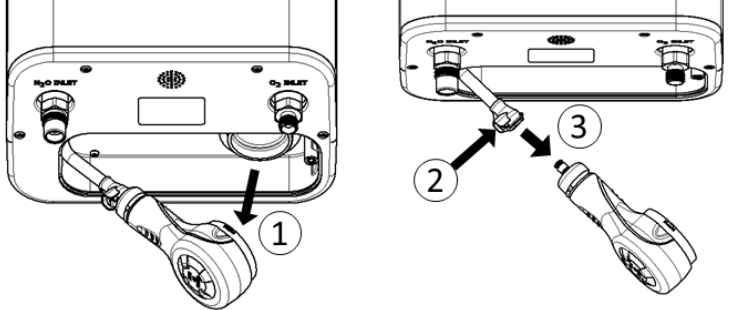
WARNING: Do not wipe the inside of the inlet fittings, gas supply hoses, or connection port as this may deposit cleaning agents into the breathing pathway of the device. Do not immerse the device or any of the device's components or accessories in water, cleaning solution, or any other liquid. Always ensure the device and the device's components and accessories are completely dry before use. The effectiveness of other cleaning agents has not been proven. Use of other cleaning agents may damage the labels or exterior housing of the device. The use of an unvalidated cleaning agent is not recommended.

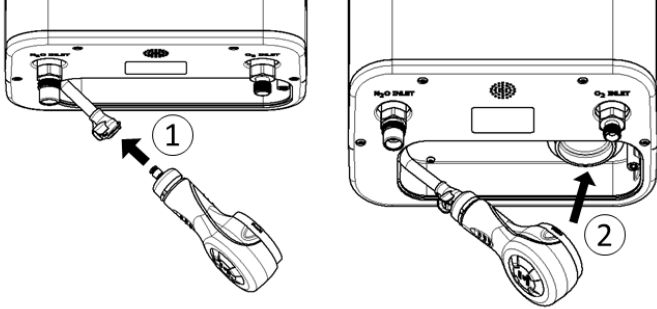
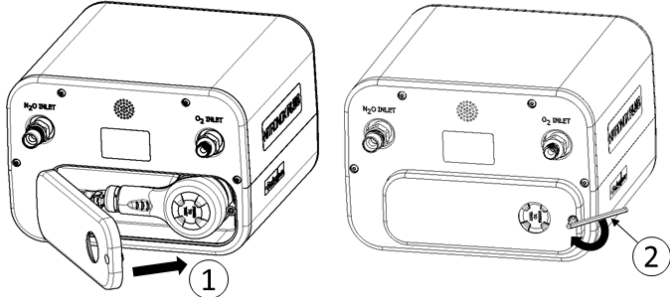
Cleaning Instructions

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 setup and pre-use checks as specified in Section 3.1.

4.3. Servicing the Demand Valve

The demand valve utilized in the Nitronox Plus requires periodic service (every 5 years). For information on servicing the demand valve, contact your authorized distributor.

Removing the Demand Valve	
1	<p>Loosen the rear panel screw using a 5/32" hex key (1) then remove the rear panel (2).</p> 
2	<p>Detach the Demand Valve from the delivery port (1), then remove the demand valve by pressing on the quick-connect tab (2) and pulling on the demand valve (3).</p> 










Re-installing the Demand Valve	
1	<p>Insert the demand valve into the quick-connect fitting (1) until it "clicks," then press the demand valve into the delivery port (2).</p> 
2	<p>Insert the rear panel (1), then tighten the rear panel screw using a 5/32" hex key (2)</p> 






4.4. Disposal

It is best practice to inquire with local authorities for proper disposal guidelines, if applicable.

5.Symbols Glossary

The following symbols are used throughout this document, as well as on device labels and packaging.

Symbol	Title of Symbol	Description of Symbol
	Manufacturer Information	Indicates the medical device manufacturer and is accompanied by the name and address of the manufacturer. [EN ISO 15223-1:2021, clause 5.1.1]
	Date of manufacture and Country of Manufacture	Indicates the country where the device was manufactured. Also Indicates the date when the device was manufactured. This symbol is accompanied by four digits for the year the device was manufactured. [EN ISO 15223-1:2021, clause 5.1.3, 5.1.11]
	Catalog Number	Indicates the manufacturer's catalog number of the device and is used for identification of the device. [EN ISO 15223-1:2021, clause 5.1.6]
	Serial Number	Indicates the manufacturer's serial number of the device and is used for identification of the specific device. [EN ISO 15223-1:2021, clause 5.1.7]
	Unique device identifier	Indicates a carrier that contains unique device identifier information. [EN ISO 15223-1:2021, clause 5.7.10]
	Prescription device	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
	Medical Device	Indicates the item is a medical device. [EN ISO 15223-1:2021, clause 5.7.7]
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use. [EN ISO 15223-1:2021, clause 5.4.3]
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself. [EN ISO 15223-1:2021, clause 5.4.4]

Symbol	Title of Symbol	Description of Symbol
	Caution/Warning	Indicates important cautionary or warning information to the user that is presented in the instructions for use that accompanies explanatory instructions to the user. [EN ISO 15223-1:2021, clause 5.4.4]
	MR Unsafe	Indicates that the product should not be used near any magnetic resonance equipment. [ASTM F2503-20 Table 1 and Table 2]
	European Community Authorized Representative	Indicates the authorized representative in the European Community (European Union) [EN ISO 15223-1:2021, clause 5.1.2]
	Switzerland Authorized Representative	Indicates the authorized representative in Switzerland. [MU600_00_016e / V3.0]
	Conformité Européenne (CE) Mark	Indicates that the product may be traded freely in any part of the European Economic Area, regardless of its country of origin. [2017/745 EU Annex V]

6. Warranty

CERTIFICATE OF WARRANTY

THIS WARRANTY IS GIVEN IN PLACE OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.

Under no circumstances shall Parker Hannifin Corporation be liable for incidental or consequential damages as those terms are defined in the uniform commercial code.

Parker Hannifin Corporation, Porter Instrument warrants that each product or part shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one (1) year from the date of delivery to customer unless otherwise specified in writing (three (3) years for Nitronox Plus device). All rubber and plastic parts and accessories are warranted under the same conditions for a period of ninety (90) days from date of purchase.

No statement or claim about the product by any employee, agent, representative, or dealer of Parker Hannifin Corporation shall constitute a warranty by Parker Hannifin Corporation or give to rise to any liability or obligation of Parker Hannifin Corporation.

Parker Hannifin Corporation shall not be liable for any damage, injury or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if, prior to such damage, injury or loss, the product was (1) damaged or misused; (2) repaired, altered or modified by persons other than Parker Hannifin Corporation; (3) not installed in strict compliance with applicable codes and ordinances; or (4) not installed by an authorized Parker Hannifin Corporation dealer. Parker Hannifin Corporation's obligation for breach of this warranty, or for negligence or otherwise, shall be strictly and exclusively limited to the repair or replacement of the product or part. This warranty shall be void on any product on which the serial number has been altered, defaced, or removed.

ORDERS All orders are to be made through authorized Parker Hannifin Corporation distributors. All billing will be done through said distributors. Direct orders will be handled through the authorized local dealer as determined by Parker Hannifin Corporation.

RETURNS All returned merchandise will be handled through authorized Parker Hannifin Corporation distributors. No returns will be accepted unless authorized in writing by Parker Hannifin Corporation and accompanied by the original shipping invoice. All returns are subject to restocking charge.

Policies subject to change without notice.

To register your product: visit www.porterinstrument.com/medical-support and click on Warranty Registration Form button.