



Nitronox Plus®

Instructions for Use



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 <u>www.porterinstrument.com/medical-support</u>. Choose "Delivery Systems" from the dropdown within the "Resources" section.

1. Device Information

1.1. Intended Use

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). Two of the three models are able to deliver a ratio of mixed gas that can be adjusted by the healthcare professional via a concentration control knob, while the third model delivers a fixed, factory set 50% / 50% ratio of N_2O/O_2 mixed gas. 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)







1.3. User Interface

#	Description	NITRONOX PLUS		
1	Mixture Pressure Gauge	\bigcirc		
2	O ₂ Inlet Pressure Gauge			
3	Patient Connection Port	Maxture N ₂ O		
4	N ₂ O Inlet Pressure Gauge	(3)		
5	Concentration Control Knob*	Commerciant Parts 11 N ₂ O Kry Lock		
6	N ₂ O Key Lock			

^{*}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 though 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.

1.6. 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.

1.7. 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.

1.8. 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 designed to deliver a mixture of nitrous oxide and oxygen gases based on the demand flow principle. In order to receive the analgesia, the patient must self-administer (or be assisted in administration) by holding the face mask firmly in place during the procedure. When the patient takes a breath, the inhalation triggers the demand valve to deliver the mixed gas through the face mask. If a patient is unable to adequately hold the mask in place, assistance may be provided by a medical professional so long as the patient is constantly monitored for over sedation.

The Nitronox Plus is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur over the course of many hours, such as an extended labor and delivery, may also be considered transient; the patient may safely use the Nitronox Plus intermittently throughout the entire duration of the procedure. 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: An oxygen enriched environment can accelerate the spread of ignited materials. Therefore, when the Nitronox Plus is used in conjunction with energy producing devices (such as lasers, RF 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.

1.9. 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)

Weight

13 lbs. (5.9 kg)

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)

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)

Humidity

Storage and Transportation: 10 to 70%

Operational: 10 to 70%

Atmospheric Pressure

1 atm \pm 0.2 atm (101 kPa \pm 20 kPa)

Mixture Settings

Adjustable 0-70% N_2O (0-70% model) Adjustable 0-50% N_2O (0-50% model) Preset 50% N_2O/O_2 (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

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)

Demand Valve

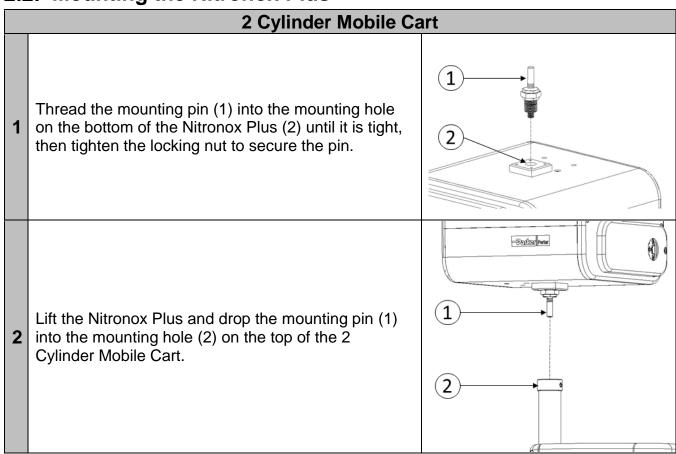
Cracking Pressure: < 2 cmH₂O

2. Installation Instructions

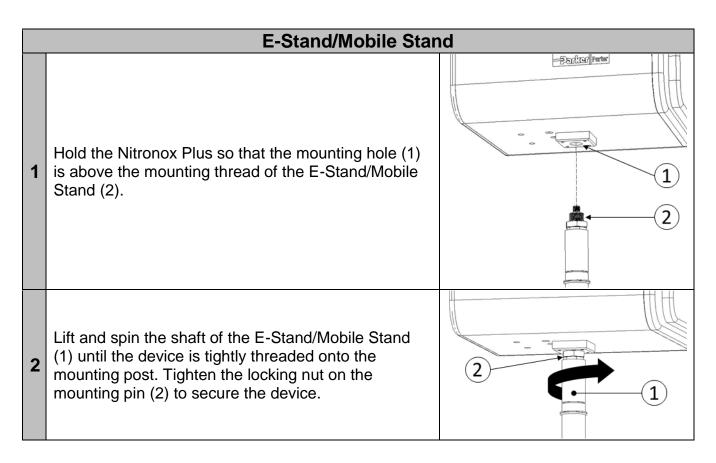
2.1. Compatible Mounting Accessories

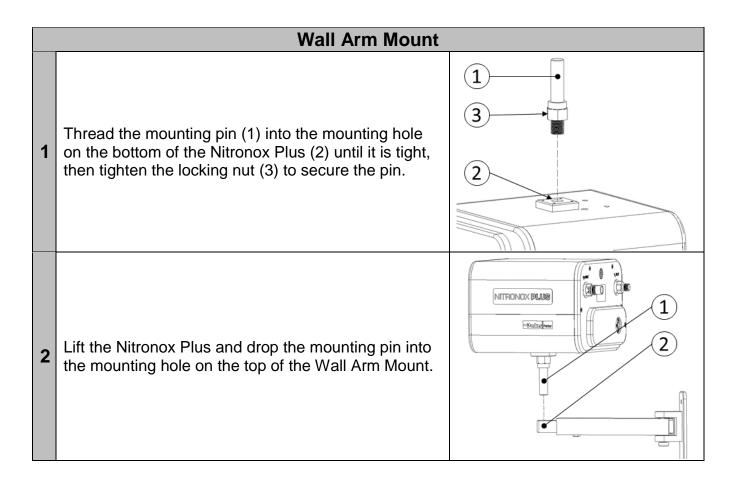
2 Cylinder Mobile Cart	E-Stand	Mobile Stand	Wall Arm Mount
P/N 2100	P/N 2045-3	P/N 2042	P/N 2020
See FM-1346	See FM-916		2020

2.2. Mounting the Nitronox Plus



Tighten the set screw on the 2 Cylinder Mobile Cart using a 5/32" Hex Key.





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.

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).

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.

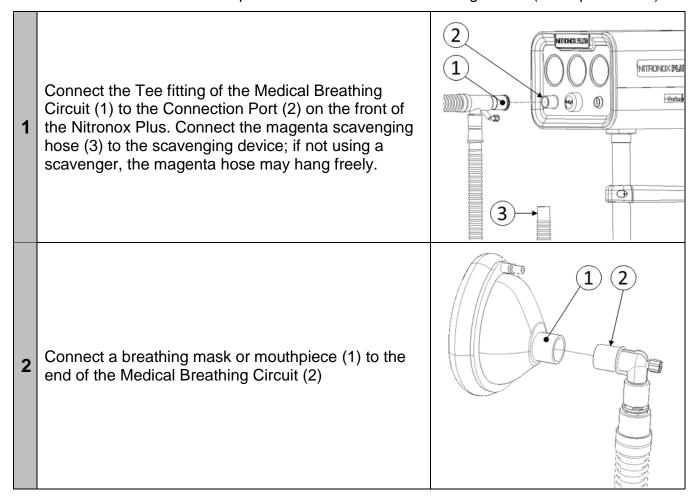
Ensure the device is securely mounted to an accessory (as described in Section 0) and the gas supply hoses are connected to the correct fittings on the Nitronox Plus (as described in Section 2.3). 2 Turn on the gas supplies. If using gas cylinders, slowly open the cylinder valves (1). If connecting to a wall supply, connect the supply lines to 1 appropriate outlet connections (2). Ensure the O₂ supply pressure (1) and N₂O supply 1 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. Confirm the mixture pressure is within the green band (1) on the mixture pressure gauge (30-40 psi). Mixture When the N₂O Key Lock is in the OFF position, only O₂ can be administered. Turn the N₂O Kev Lock to the ON position (1) to administer a mixture of N₂O and O₂.



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).



3.3. Operating Instructions

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.

Note: The 50/50 model is not adjustable and will deliver a preset 50% N2O/O2 mixture.

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.

Always ensure the patient is exhaling back into the mask or mouthpiece to achieve effective scavenging.



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.

- 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.
- 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).
- 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.



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 lifetime of at least 10 years with proper maintenance. The device requires periodic checks and service according to the following table:

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.



CAUTION: Do not attempt to repair, calibrate, or alter this device. Unauthorized repair, calibration, alteration, or misuse of the device is likely to adversely affect performance and will void the warranty.

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

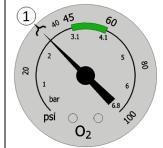
1	To test the device for leaks in the field, ensure the N ₂ O Key Lock is in the ON position. For adjustable models, set the %N ₂ O knob to 50% (no setting required for 50/50 model)	
2	Ensure gas supply lines are installed correctly. Open the supply valves to pressurize the system and confirm the O_2 and N_2O 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

- To test the device alarms, ensure the N₂O Key Lock is in the ON position. For adjustable models, set the %N₂O knob to 50% (no setting required for 50/50 model).
- Ensure the gas supply lines are installed correctly. Open the supply valves to pressurize the system and confirm the O_2 and N_2O inlet pressure gauges are within the green band.

Turn OFF the O₂ gas supply valve. While observing the O₂ 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 O₂ inlet pressure gauge reads approximately 35 psi (1).



Turn the O₂ gas supply valve back ON and ensure the O₂ and N₂O inlet pressure gauges are within the green band.

Turn OFF the N₂O gas supply valve. While observing the N₂O 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 N₂O inlet pressure gauge reads approximately 35 psi (2).



While the N₂O alarm is whistling, turn the N₂O Key Lock to the OFF position. Confirm the alarm stops once the key is turned OFF.

- **Note:** The N₂O low pressure alarm is driven by O₂. When the N₂O supply pressure drops below the alarm threshold, the device will alarm until either: 1) N₂O supply pressure is restored, 2) the N₂O Key Lock is turned to "OFF," or 3) the O₂ supply pressure completely depletes.
- 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

- To test the failsafe mechanism, ensure the N₂O key lock is in the ON position. For adjustable models, set the %N₂O knob to 50% (no setting required for 50/50 model).
- Ensure gas supply lines are installed. Open the supply valves to pressurize the system and confirm the O₂ and N₂O inlet pressure gauges are within the green band and the mixture pressure gauge is within the green band.
- **3** Turn OFF the O₂ supply valve.
- While observing the O₂ 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 O₂ 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 O₂ supply remains off.
- If the mixture pressure does not deplete or the device is able to flow gas while the O₂ supply is off, contact your authorized distributor for service and troubleshooting.

Emergency Air Intake Valve Test

- To test the emergency air intake valve, turn the N₂O key lock to the OFF position. For adjustable models, set the %N₂O 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 O₂ and N₂O 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% O₂ from the device. Note the level of resistance against inhalation.
- **5** Turn the O₂ gas supply valve OFF.
- While monitoring the O₂ inlet pressure gauge, continue breathing through the mask or mouthpiece. Observe the resistance against inhalation once the O₂ supply gauge depletes to 0 psi.
- 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

Disconnect and dispose of the single use breathing circuit and single use mask/mouthpiece (if attached).

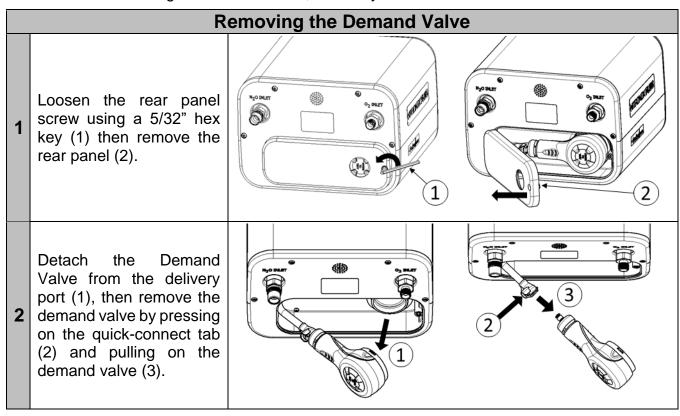
Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the outer case, front panel, and back of the device until all visible dirt and soil is removed. Take extra care to wipe the outside of the connection port area, %N₂O knob, and key lock area as these are the most handled areas of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove.

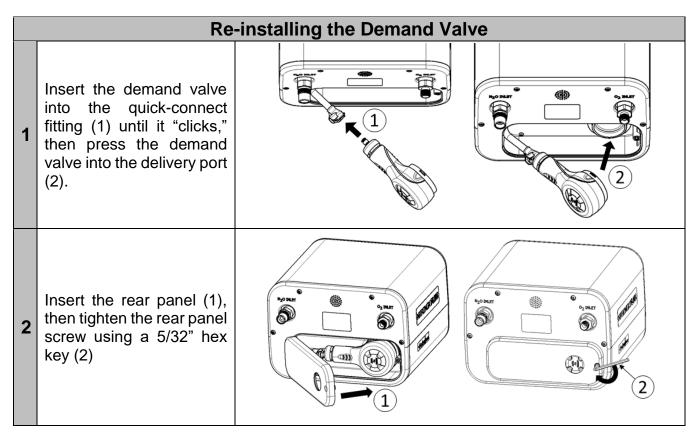
Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the gas supply hoses and fittings until all visible dirt and soil is removed. Do not wipe the inside of the hoses or fittings as this may deposit cleaning agents into the breathing pathway of the device.

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.





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.
~~ <u> </u>	Date of manufacture	Indicates the date when the device was manufactured. This symbol is accompanied by four digits for the year the device was manufactured.
USA	Country of manufacture	Indicates the country where the device was manufactured.
REF	Catalog Number	Indicates the manufacturer's catalog number of the device and is used for identification of the device.
SN	Serial Number	Indicates the manufacturer's serial number of the device and is used for identification of the specific device.
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information
Rx Only	Prescription device	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
MD	Medical Device	Indicates the item is a medical device
[]i	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
\triangle	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.
\triangle	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

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 <u>www.porterinstrument.com/medical-support</u> and click on Warranty Registration Form button.