

NITRONOX® HD USER'S MANUAL / INSTRUCTIONS



Manufacturer:



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The Quality System for Porter Instrument is certified to ISO 13485.

Check our website: www.porterinstrument.com for additional information.

To register your product: www.porterinstrument.com/resources-dental choose Warranty tab.

To download a User's Manual: www.porterinstrument.com/resources-dental choose Manuals tab

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Examination

Examine shipping carton for signs of external damage.

Remove contents from carton and inspect for visible damage or missing parts.

If damage is discovered or suspected and/or parts are missing, notify Porter or authorized distributor immediately.

**IMPORTANT:
READ MANUAL COMPLETELY BEFORE OPERATING THIS DEVICE**

Basic delivery technique is described. Also, this manual contains instructions on periodically required checks to be performed by the user. These checks are necessary to insure the proper performance of this device and its safety features. Retain this manual for future reference.



WARNINGS AND PRECAUTIONS

These warnings and precautions are to help you to understand how to safely operate the Nitronox device. A **WARNING** alerts you to a possible hazard to people. A **CAUTION** alerts you to the possibility of equipment damage.

WARNING: New or modified installations - properly connected gas pipelines are absolutely essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. See next page for details.

WARNING: An oxygen enriched environment can accelerate the spread of ignited materials. Therefore, when 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: Nitronox Inhalation Analgesia systems are intended to be used by medical professionals trained in its use, and are responsible for administering nitrous oxide and oxygen for medical applications with consideration of contraindications for use as well as for other risks that could cause harm to the healthcare professional, staff, patient, or facility

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

WARNING: Inspect and maintain the analgesia delivery system to prevent N₂O leaks in all hoses, connections and fittings. Have all leaks repaired immediately.

WARNING: Use Scavenging: Medical workers are exposed to N₂O during administration of

N₂O/O₂ conscious sedation analgesia. Controls are effective in the patient treatment area to achieve low levels of ppm (parts per million) exposure. Controls include System Maintenance, Ventilation and Work Practices. Your accessory Scavenger System is an important part of the system of controls in medical settings.

WARNING: During any power outage, remember to turn OFF the tank valves (or external supplier). With centralized, electrically powered gas systems, if gas was flowing when the power went out and the Nitronox is left ON, gas will be capable of flowing when the power is restored.

WARNING: When using a single use full face mask (not supplied sterile), dispose of mask after use to prevent patient cross-contamination. When using multiple use mask, follow manufacturer's sterilization instructions.

WARNING: Always use clean, dry medical grade gases. Do not introduce moisture or other contaminants into the system and flowmeter device. **Never oil or grease any part of this system (minimize fire or explosion potential). Cylinder mount: Do not clean check valve entrance or sealing washer (replace as needed) with disinfectant.** User should ensure that the cylinder valve is clear of dust or dirt which may be carried to regulator and cause damage or accident. One clearing technique is to "crack" [secure] cylinder valve before installing cylinder to E-Block. Open valve slightly and then close. Do not discharge flow of gas at any person or flammable material.

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



WARNING:
NEW OR MODIFIED INSTALLATIONS
ALWAYS ASSURE THAT LINES ARE NOT CROSSED!

WARNING: New or modified central supply installations - **properly connected gas pipelines are absolutely essential to patient safety.** Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all gas pipelines are connected properly and that the system has been pressure tested prior to use. While this is a good business practice, it is important that the user verify by their own test, independent of the authorized distributor or contractor, that all gas pipelines are connected correctly prior to using the system. **The ultimate responsibility of assuring that lines are not crossed rests with the user.**

WARNING: Porter equipment utilizes the **cross+protection** system. The flexible hose and connectors that connect to the housing are diameter indexed; 3/8" O.D. for Nitrous Oxide and 1/2" O.D. for Oxygen. The **cross+protection** system is designed to prevent misconnection of Oxygen and Nitrous Oxide hoses. **DO NOT ATTEMPT TO CHANGE THE DIAMETERS OR CONNECTORS OF THE DEVICE!** Tampering with the **cross+protection** system constitutes acceptance of liability by the installer.

Do not allow crossed lines to defeat the safety features of the Nitronox and/or central gas supply manifold systems. **Crossed lines will create a dangerous and hazardous condition where, under a loss of oxygen supply, 100% nitrous oxide will be delivered through the oxygen delivery path and subsequently to the patient.**

User should observe the patient to prevent over sedation in the event of an oxygen failsafe malfunction or crossed lines. If a patient becomes over sedated when being delivered 100% oxygen [during an apparent loss of nitrous oxide supply], it is a definite indication of crossed lines or a failsafe malfunction. Remove the mask immediately and encourage mouth breathing. Deliver pure oxygen from an oxygen demand valve only if the oxygen source is independent from the suspected crossed lines area.

INPUT PRESSURE DIFFERENCES

WARNING: DO NOT use Nitronox if O₂ and N₂O input pressures are not within 15 psi (1 bar) of each other.

SIDE EFFECTS & CONTRAINDICATIONS

Note: This is not an exhaustive list. It is the responsibility of the medical establishment and the medical professional to have complete knowledge of side effects and contraindications.

Possible Side Effects of Nitrous Oxide – Oxygen Conscious Sedation: May experience nausea, vomiting, excessive sweating, euphoria, excitement, deep sedation, drowsiness, sleep, dizziness, lightheadedness, dysphoria, amnesia, and headaches.

Precautions and Contraindications for Nitrous Oxide Use

Precautions/Relative Contraindications

Discontinue the Nitrous Oxide delivery if observed: prolonged inspirations, irregular breathing, involuntary eye movements, swallowing or gagging, dilated pupils and rigid muscles.”

Side effects, e.g., nausea, vomiting, dizziness, dysphoria, etc., are not tolerable; Current vitamin B₁₂ deficiency; Bronchoconstrictive disease (asthma) – (at determination of medical professional)

The use with pediatric patients, especially age 1 to 4 years, requires caution and specific protocols developed by the medical professional; upper age limit at determination of medical professional. Weight limitations at the determination of medical professional.

Contraindications

Inability to hold own face mask, impaired oxygenation, or hemodynamic instability;

Acute drug or alcohol intoxication or impaired consciousness (head injury, endocrine or metabolic disease, patients taking antidepressant or psychotropic drugs), psychologic impairment, patient who has taken medication to induce sleep.

Decompression injuries, increased intracranial pressure, increased intraocular pressure, intraocular surgery, bowel obstruction, middle ear surgery, emphysema, pulmonary hypertension and others;

Current upper respiratory tract infection, chronic obstructive pulmonary disease (COPD), cystic fibrosis, shock, acute pulmonary edema (APE), pneumothorax, and major chest or maxillofacial trauma, bleomycin therapy, recent pneumoencephalography; Pregnancy (first trimester).

Development of Nitronox Delivery Protocols

It is the responsibility of the medical establishment and the medical professional to develop and establish specific delivery protocols.

The Nitronox® Inhalation Analgesia System is designed to deliver a fixed concentration of 50% nitrous oxide and 50% oxygen on the demand flow [self-administration] principle. The medical professional will turn on and observe the operating indicators of the device. In order to receive the analgesic, the patient will self-administer by holding the face mask firmly in place during the procedure. With the face mask sealed every time the patient takes a breath, the patient inhalation will open the demand valve and deliver the mixed gas through the face mask.

Common procedures conducted with Nitrous Oxide – Oxygen Sedation include:

General Pain Management, Labor and Delivery, Wound Debridement, Fracture Reduction, Catheter Insertion, Foreign Object Removal, Setting Broken Bones, Lacerations, Botulinium Injection, Barium Enema, Joint Injections, Gastrostomy, Sutures, IV Starts, CT Scans, Non-Invasive Lipolysis, Hair Removal, Tattoo Removal, and Skin Revitalization.

The Nitronox Inhalation Analgesia System is considered transient (less than 60 minutes) in terms of continuous use when providing Analgesia (pain management), Minimal Sedation or Moderate Sedation. However, a procedure or medical condition that occurs over the course of many hours, also is considered to be using transient delivery, in that, given self-administration techniques, the patient will be unlikely to hold the face mask to the face continuously for over 60 minutes. For example, a woman in labor may safely use Nitronox in a transient self-administration mode over the course of several hours as secondary labor and end labor stages are experienced. The upper limit of the number of hours of this described transient delivery is at the determination of the medical professional.

Patient Population (Adult and Pediatric): Used to deliver a gas mixture to a conscious spontaneously breathing patient who is awake, alert and cooperative and requires relief from moderate to severe pain and is under the supervision of a healthcare professional. Age/Weight limitations: see Relative Contraindications (at the determination of medical professional).

Note: Porter recommends the use of a disposable full face mask (DEHP-free and Latex-free) that is biocompatible for medical use. The disposable mask materials have been chosen by the medical device manufacturers of the masks intended for medical usage. Many establishment protocols also call for the use of a bacterial filter. Follow manufacturer's instructions.

Continuous flow vs. demand flow devices

Equipment to deliver nitrous oxide and oxygen sedation are often categorized as demand flow or continuous flow devices. The Nitronox is a demand flow device. Different specific delivery protocols will be established for the two categories of equipment. The differences center around self-administration for demand flow devices vs. direct administration by medical professionals for continuous flow devices. Also, continuous flow devices typically allow the administration of variable concentrations of nitrous oxide and variable flow rates of delivered mixture. However, some establishments have developed specific protocols for delivery with continuous flow devices, where the medical professional is able to adjust to deliver various percentage mixes, where, with supervision, the delivery could be described as "self-administration," in that the patient will hold the full face mask to the face.

SELF-ADMINISTRATION VS. ASSIST TO SELF-ADMINISTRATION

WARNING: Encourage patient to self-administer. Self-administration is a safety feature of the demand flow Nitronox in that, if for any reason the patient becomes over sedated, the patient will be unable to successfully hold the mask in a tight seal position on the face. The result will be that the mask falls away from the face and the demand flow will cease, allowing the patient to breathe room air in through the mouth or nose.

WARNING: If a patient is unable to fully self-administer, and the medical professional provides an assist to placement of the mask in a sealing position on the face, maintain patient observation to prevent over sedation under any conditions. Discontinue the assistance in mask placement immediately upon any observation of over sedation; remove the mask from the face entirely. Never use a mask strap to hold the mask to the face. Never force the mask on the face; the patient must always be spontaneously breathing.

At the determination of a medical professional, as an added precaution for procedures where an assist to self-administration is used, the medical establishment may elect to continuously sample the mixture delivery downstream from the demand valve by installation of an oxygen analyzer.

Self-administration for pediatric patients

Some establishments have developed specific protocols instructing the provider to administer (“assisted-mask application” of Nitronox) nitrous oxide to pediatric patients, typically ages 1 to 4. The concept that, for certain circumstances, the use of the Nitronox, or the use of other demand valve delivery systems, should have a protocol where the provider administers the nitrous oxide, as opposed to complete self-administration, is in potential conflict with protocols for labor analgesia, where there is an emphasis on self-administration. It is the responsibility of the medical establishment and the medical professional to develop and establish specific delivery protocols.

Self-administration for laboring women

Establishments that have developed specific protocols for laboring women often include a particular emphasis on self-administration and education for the laboring woman and for her support persons on the techniques of self-administration. In these specific protocols, the establishments have concluded that nitrous oxide can only safely be self-administered by the laboring woman; with support persons needing to be educated that they absolutely cannot assist in the delivery of nitrous oxide by holding the mask up to the laboring woman’s face, since an integral safety feature of nitrous oxide use is that when the woman has physiologically reached her limit of nitrous oxide intake, she will no longer be able to hold the mask up to her face for more, thus self-regulating the intake. The establishments have concluded that when someone else is allowed to hold the mask up to her face, the potential risk of losing consciousness increases dramatically. Thus, there is an initial and repetitive education for the laboring women and support persons.

DEMAND VALVE

Description: The demand valve of the Nitronox Inhalation Analgesia System is designed to be used with a full face mask (Porter recommends a standard, single use, disposable mask (not supplied sterile), DEHP-free, Latex-free, with materials chosen by the manufacturer for biocompatibility in a medical setting) for administration of nitrous oxide to a breathing patient. It contains no buttons or levers to force the gas into the patient and is for self-administration.

Do not strap mask on patient. Allow the patient to hold the mask over the nose and mouth to self-administer. Upon inhalation, the demand valve opens and the nitrous oxide / oxygen mixture will start to flow. Ceasing to inhale or if the patient stops breathing, the valve automatically closes to stop the flow of the nitrous oxide / oxygen mixture.



WARNING: Do not use near open flame or in an unventilated area. Can accelerate burning and be toxic.

Specifications:

Flow: The demand valve (through the Nitronox housing) is to be connected to gas supply capable of delivering a minimum of 100 LPM @ 40-90 psig (2.8–6.2 bar). The valve itself: 160 LPM set flow: As required in demand mode 0-160 LPM at 40 psig.

Inlet fitting: Quick connect.

Filter: 2 micron sintered stainless steel.

Outlet: 22 mm outside diameter x 15 mm inside diameter (fits standard medical masks).

Materials: Housing and plastic parts: "Noryl", polyester, polysulfone. Moving and adjusting parts: Stainless steel. Fasteners: Steel, brass and aluminum all plated for corrosion resistance. Rubber parts (except hose): Silicone

Installations

Instructions References

FM-1346 for 2 Cylinder Mobile Cart User's Manual / Instructions

FM-916 for 4 Cylinder Mobile "E" Tank Stand Installation and Instructions

FM-1330 for Medical Breathing Circuit Scavenger System User's Manual / Instructions



4 Cylinder E-Stand
With Nitronox



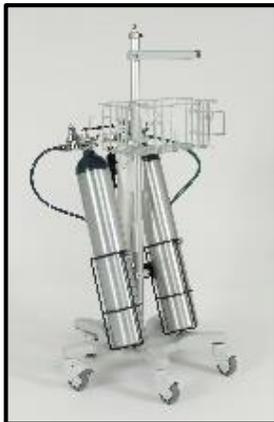
2 Cylinder Mobile Cart
With Nitronox



Wall Mount



4 Cylinder E-Stand



2 Cylinder Mobile Cart



Mounting on Mobile Stand



Preparation of Nitronox HD Demand Valve Bracket and Demand Valve

For further details, refer to Nitronox HD Scavenger System User's Manual FM-1330 and Porter Medical Breathing Circuit FM-1329

1. Attach Demand Valve Manifold Mount Assembly to the right side of the Nitronox HD using one screw on the top (Fig 1.1) and one screw on the bottom (Fig 1.2).

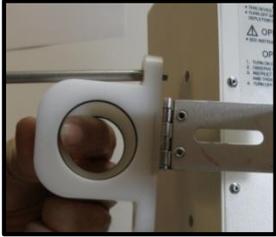


Fig. 1.1



Fig. 1.2

2. Push Demand Valve into Manifold (two sealing o-rings). (Fig. 2)



Fig. 2

3. Tighten thumb screw of Retaining Bracket to the side of the Manifold to secure the Demand Valve (Fig. 3)



Fig. 3



Fig. 4

4. Connect the Gas Delivery Hose to Demand Valve (Fig. 4). This is a quick connect attachment. Push the two ends together until click sound is heard. To remove – push the metal clip in – and pull apart.

5. Attach Mask Hanging Bracket to the Left side of the Nitronox HD (Fig. 5).



Fig. 5

6. Assembled Nitronox HD unit (Fig. 6).



Fig. 6

7. Attach the Nitronox Scavenger Interface to the Center Column (Figs. 7.1, 7.2).



Fig. 7.1



Fig. 7.2

8. For wall mount attachment see FM-1330.

Description of Unit

Nitronox[®] is an inhalation analgesia system designed to deliver a fixed concentration of 50% nitrous oxide and 50% oxygen on the demand flow principle. Nitronox operates either on pipeline gas supply using a Mobile Stand or Wall Mount, or medical “E” or “D” size cylinder supply by means of a small cylinder yoke block with regulators (4 Cylinder Mobile “E” Stand, 2 Cylinder Mobile Cart).

Nitronox[®] is available in various configurations offering three mounting styles.

1. Nitronox with 4 Cylinder or 2 Cylinder Mobile Cart (Fig. 8) and cylinder mount- (2) nitrous oxide and (2) oxygen – “E” or “D” size. Refer to FM-916 or FM-1346 for Installation and User Instructions.
2. Nitronox with Mobile Stand only (for use with pipeline gas supply only).
3. Nitronox with wall mount (for use with pipeline gas supply)

Use Nitronox in conjunction with Nitronox HD Scavenger System; Refer to User’s Manual / Instructions FM-1330.



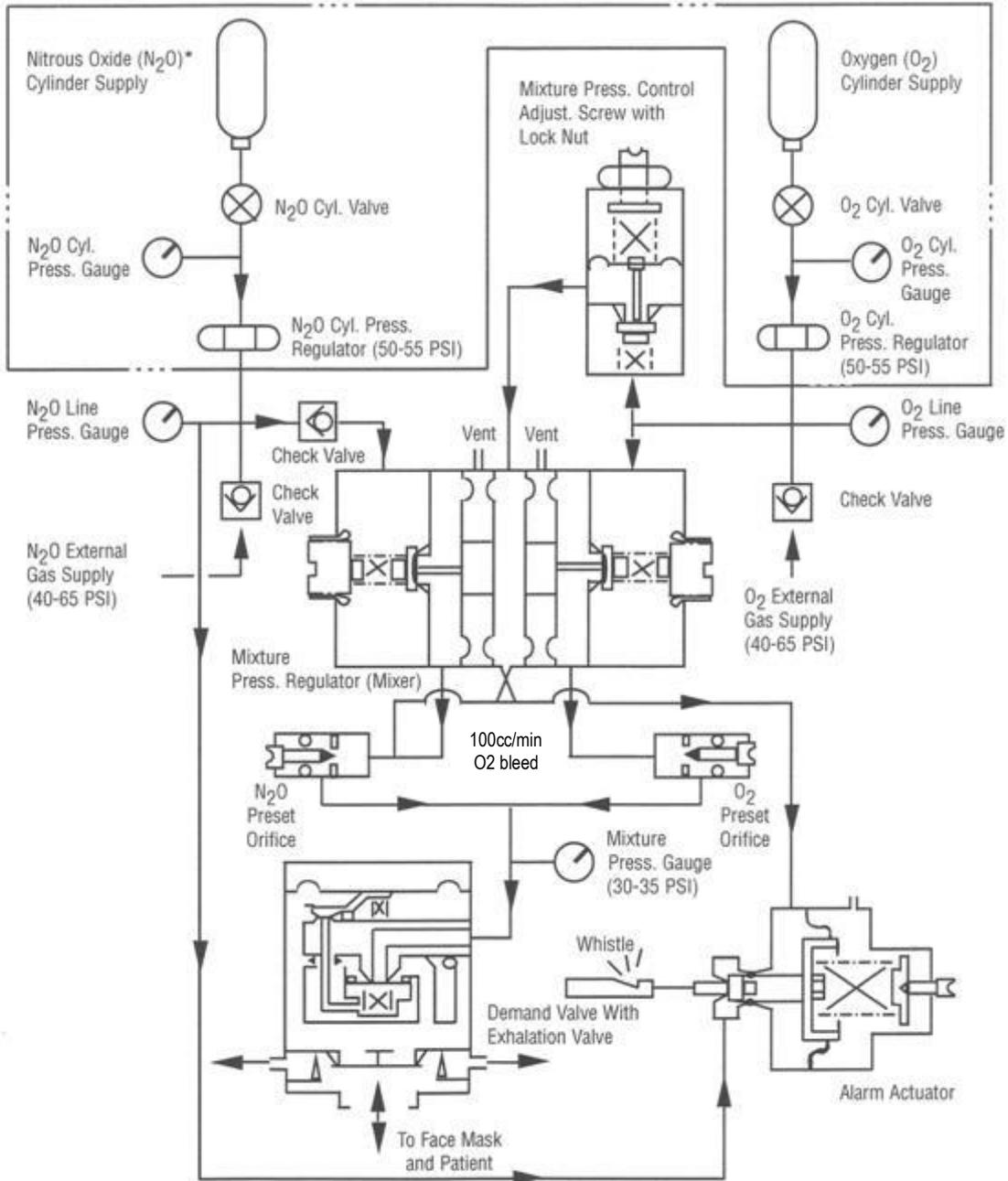
Fig. 9 – Nitronox Front Cover with Mixture Pressure and N₂O and O₂ Line Pressure Gauges



Fig. 8 - Nitronox with 2 Cylinder Mobile Cart

Nitronox® Inhalation Analgesia System

FUNCTIONAL SCHEMATIC



Specifications / Functional Features / Tests

Gas Supply Duration	Flow Capability	Mixture Concentration
"E" Size Cylinders At Normal Breathing Rates: N ₂ O Approximately 6 – 6.5 Hrs. O ₂ Approximately 2 – 2.5 Hrs.	114 LPM, Maximum	Mixture Concentration (Factory Adjusted) 50% N ₂ O and 50% O ₂ +/- 5 Percentage Points O ₂

Mixer Pressure Alarm: A whistle will sound when a gas mixture regulator seat malfunction affecting mixture concentration has occurred.



Warnings

- If **WHISTLE ALARM** sounds, discontinue patient use immediately and shut off gas supply.
- **DO NOT** use Nitronox (O₂ & N₂O on) if mixture pressure is out of green band, into red band, or if needle moves significantly below green band during each inspiration (26 psi or lower) (see "Maintenance"). Fig. 10

Fig. 10



Check the Whistle Alarm Actuation Point:

Factory set; then perform annual check.

1. Increase mixture pressure per Page 15, Step 2, "Maintenance", until gauge reading is in RED "Do Not Use" area, per gauge illustration (Fig. 14).
2. WHISTLE should sound in range of Fig. 14.
3. If WHISTLE sounds before or after this range, WHISTLE ALARM ACTUATOR must be adjusted (see "Maintenance").

Oxygen Fail Safe: If apparatus oxygen line pressure is depleted or disconnected, nitrous oxide flow and demand valve flow stops automatically. If apparatus nitrous oxide line pressure is depleted or disconnected, demand valve will continue to function

providing 100% oxygen at reduced flow capacity of about 55 LPM. With both gas pressures on, if patient takes repeated shallow breaths, oxygen concentration automatically increases (65% O₂ minimum at input pressures 45 psi to 60 psi).

Fail Safe Check-Out Test: Initially and Every 6 Months

NOTE: To vent pressures: Disconnect the Demand Valve from the Gas Delivery Hose by pushing the metal clip in – and pull apart. With Hose disconnected, vent the system pressure by depressing the Hose check valve by pushing against it with a clean Phillips head screwdriver. Verify both line pressure gauges are at 0 psi. Note: When testing is completed connect the Hose by pushing the Hose on to the Demand Valve until click sound is heard.

1. Turn on N₂O and O₂ pressure sources and verify line pressure gauges go to source pressure. Turn off N₂O source pressure, then turn off O₂ source pressure and immediately conduct vent pressures.
2. **Fail Safe Check-Out:** Turn on O₂ supply pressure and verify the O₂ line pressure gauge goes to source pressure (approx. 55 psi). Also verify the Mixture Pressure Gauge needle goes to the green band (approx. 33 psi).

Warning: DO NOT use Nitronox if mixture pressure reads low pressure (at or near 0 psi). Notify authorized distributor.

Warning: DO NOT use Nitronox if mixture pressure is out of the green band. Use Maintenance Mixture Pressure Control Adjustment Step 2 to bring reading into the green band. Notify authorized distributor if unable to successfully adjust.

3. If Nitronox passes step 2, turn on N₂O supply pressure and verify the N₂O line pressure gauge goes to source pressure (approx. 55 psi).
4. **Fail Safe Check-Out:** Now turn off or disconnect O₂ supply source pressure, depress the Hose check valve, vent flow and O₂ pressure will fall to 0 psi. The flow through the Hose will stop completely (with check valve depressed).

Warning: DO NOT use Nitronox if flow continues through the Hose even with O₂ pressure at 0 psi. Notify authorized distributor..

Operation / Maintenance

Cylinder Pressure Readings: Oxygen is a true compressed gas, while in the cylinder, thus the cylinder pressure gauge can be used to determine the amount of gas remaining in the cylinder. For example, 2000 psi indicates full, 1000 psi indicates half full, etc. Nitrous Oxide is a liquefied compressed gas that vaporizes in the cylinder, thus the cylinder pressure gauge cannot be used to determine the amount of gas remaining in the cylinder until all liquid in the cylinder vaporizes. While liquid remains in the cylinder, the cylinder pressure gauge indicates the vapor pressure which depends on and varies with the temperature of the liquid. For example, at 68°F (20°C), the vapor pressure is about 750 psi (50 bar); at 20°F (-7°C), it drops to about 400 psi (30 bar); while at 90°F (32°C), it increases to about 1000 psi (70 bar). After all the liquid vaporizes, the pressure will decrease normally as the gas is withdrawn, and the cylinder pressure gauge can then be used to determine the amount of gas remaining in the cylinder.

Caution

- **NEVER ATTEMPT TO LOOSEN cylinder valve packing nut. If valve stem is tight, return cylinder to supplier.**



Warning: Do not remove or alter gas indexing pins. Verify correct pin locations per illustrations.

Warning: Always turn on CYLINDER VALVES slowly and fully (“E” cylinder yoke models). (Minimize fire or explosion potential)

Good practices: Cylinders with Mobile Cart

1. Two cylinders of O₂ and two cylinders of N₂O are typically connected at all times. Exception: When using external gas supply of oxygen, the 4 Cylinder E- Stand may be populated with N₂O cylinders and O₂ cylinders are not placed on “E” Stand. [2 Cylinder Cart: Two cylinders of N₂O, or one cylinder of O₂ and one cylinder of N₂O are typically connected.]
2. Minimize leak risks: Confirm Yoke Washers are in place before replacing/mounting cylinders. Use Porter #A-3399-000 replacement washers (once/yr. or as needed). Have spare washers.
3. **Warning:** Keep the cylinder top clean while performing attachment so as to minimize possibility of any foreign substance entering the regulator cavities (minimize fire or explosion potential).

4. Minimize leak risks [E-Stand]: With cylinder in position, rotate swivel arm and move into secure locked position when Tee Handle is tightened. To prevent movement and potential damage to yoke pins, always fasten the Hook & Loop strap restraints around cylinders. [2 Cylinder]: Tighten Tee Handle securely, assuring washer is in flat sealing position and yoke pins are in place in cylinder post holes.
5. Assure Mobile Cart is populated with cylinders of O₂ and N₂O with adequate degree of fill before starting any procedure.
6. Label each cylinder with a tag or sticker indicating “In-Use” and “Full” (“Full” is reserve cylinder.)
7. Use Cylinder Valve Wrench to open the “In-Use” cylinders of O₂ and N₂O. Verify wrench is attached to Block / Cart.
8. Cylinder pressure gauges provide a visual indication of cylinder status (see details on Cylinder Pressure Readings)
9. **Caution: [E-Stand]** If all four cylinders (or both cylinders of one gas) are open, the two cylinders of O₂ and N₂O will deplete in tandem. The “Full” cylinder will empty with the “In-Use” cylinder and will not be available as a future spare.
10. E-Stand: When “In-Use” cylinder is fully depleted, open the spare “Full” cylinder (Close valve on empty cylinder). Do not remove and replace with partially full cylinder; only replace with new clean full cylinder.
11. When “In-Use” O₂ cylinder is depleted, the Oxygen Fail Safe will stop N₂O flow and demand valve flow automatically.
12. When “In-Use” N₂O cylinder is depleted, the Nitronox will deliver 100% O₂ through the Demand Valve.
13. After use, turn off cylinder valves. **Caution:** With O₂ cylinder turned on, the Nitronox will have an intentional small O₂ bleed (100 cc/min), which will tend to deplete the O₂ cylinder (after a prolonged period of time) if, after use, the O₂ cylinder valve is left on.

Models With “E” Cylinder Yoke (Simple Operation Procedure)

1. Open one each O₂ and N₂O Cylinder Valves (slowly and fully) with wrench provided.
2. Observe cylinder pressures. Replace cylinder when less than 300 psi (20 bar), at room temperature (21.1 °C, 70°F). During replacement, close all Cylinder Valves.
3. Observe line pressures (Figs. 11.1, 11.2). Ideal is 50-55 psi [3.4–3.8 bar] (green band) for static no-flow condition (40-65 psi allowed). Pressure will decrease slightly during each inspiration (see “Maintenance”). **WARNING: DO NOT use Nitronox if O₂ and N₂O input pressures are not within 15 psi (1 bar) of each other.**
4. Observe mixture pressure (Fig. 11.3). Normal is 30-35 psi [2.0–2.4 bar] (green band) for static no-flow condition. Pressure will decrease slightly during each inspiration (see “Maintenance”).
5. If all pressures are normal, Nitronox is ready to use. Instruct patient to hold Mask securely on face covering nose and mouth. Instruct to breathe normally, preferably through nose.

Encourage patient to self administer at all times [see Warnings page 6 for details].

Quick Failsafe Check: If patient over sedation is observed, oxygen failsafe function may be quickly checked. Remove the mask immediately and encourage mouth breathing. With N₂O supply pressure turned on, turn off or disconnect O₂ supply source pressure. Disconnect the Demand Valve from the Gas Delivery Hose by pushing the metal clip in – and pull apart. Depress the Hose check valve, which vents flow and O₂ pressure will fall to 0 psi. The flow through the Hose will stop completely (with check valve depressed).

Warning: DO NOT use Nitronox if flow continues through the Hose even with O₂ pressure at 0 psi. Notify authorized distributor.

Refer to page 12 for full Fail Safe Check-Out.

6. After use, turn off Cylinder Valves; store Demand Valve. Dispose of single use mask (not supplied sterile).

Models Using Pipeline or External Gas Supply (Mobile Stand or Wall Mt.)

1. Connect external gas supply hoses to DISS (Diameter Indexed Safety System) fittings. External pressure must be 40-65 psi (may be outside green) (2.8–4.5 bar), preferably 50-55 psi (3.4–3.8 bar). Observe external pressures on apparatus LINE PRESSURE GAUGES. **WARNING: DO NOT use Nitronox if O₂ and N₂O input pressures are not within 15 psi (1 bar) of each other.**
2. Observe mixture pressure as in step 4 above.
3. Follow step 5 procedure above.
4. After use, disconnect external gas supply.



Fig. 11.1



Fig. 11.2



Fig. 11.3

Functional Checks / Tests

Page 15	Line Pressures	Visual check	During operation
Page 14 / 15	Mixture Pressure	Visual check	During operation
Page 12 / 14	Oxygen Failsafe	Initial	Every 6 Months
Page 15	Leak Test System	Initial	Annually
Page 12 / 15	Whistle Alarm Actuation Point	Factory set	Annually

Maintenance

1. **Line Pressure Adjustment:** (Green Band for Model Using Mobile “E” Stand): Locate appropriate PRESSURE REGULATOR (blue lettering – nitrous oxide; green lettering – oxygen); remove 9/16” acorn nut; insert 5/32” hex socket key and adjust pressure to within green band.

2. **Mixture Pressure Control Adjustment:** (Green Band): Remove LOWER CHROME PLUG from case back. With wrench, loosen 7/16 inch hex nut (counterclockwise) approximately one quarter turn. Insert screwdriver through access hole, in bottom of case, into slot of adjusting screw. While holding nut with wrench, adjust counterclockwise to increase pressure – clockwise to decrease. After adjustment, tighten nut while holding screw in position with screwdriver (see illustration Fig. 12).

mixture pressure to middle of green band. Whistle sound must stop with pressure in green band and whistle must sound with pressure in range shown in Fig. 14 (about 40 psi [2.8 bar]). If this cannot be achieved, discontinue use of apparatus and notify authorized distributor immediately.

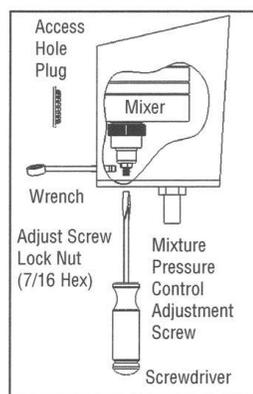


Fig. 12

3. **Leak Test System** – Initial & Annual Check of working pressure leaks. Verify hoses are attached from E-Stand to Nitronox Housing. Turn one O₂ and one N₂O cylinder on. Verify E-Stand pressure gauges read cylinder pressures. Verify Nitronox line pressure gauges read within green band. Note: fail safe is open and pressure reaches Demand Valve. Turn off N₂O cylinder valve. Verify that N₂O E-Stand gauge reads about 750 psi (50 bar). Note exact needle position. Verify that there is little or no movement [up to ½ increment] of the exact needle position in 15 minutes. Nitronox N₂O line pressure gauge needle will stay in green band with no movement. Turn off O₂ cylinder valve. It is normal that needle of O₂ E-Stand gauge will drop. Nitronox O₂ line pressure gauge needle will stay in green band with no movement (will eventually drop after E-Stand gauge pressure naturally depletes).



Fig. 13 Back of Case; Upper adjustment access

4. **Whistle Alarm Actuator Adjustment:** Remove UPPER CHROME PLUG from case back (Fig. 13). With mixture pressure temporarily adjusted (per Step 2, “Maintenance”) in middle of range shown (Fig. 14), insert 1/8” hex key (not provided) into adjustment screw at end of ALARM ACTUATOR. Adjust screw either clockwise or counterclockwise until whistle sounds clearly. DO NOT over adjust. Return

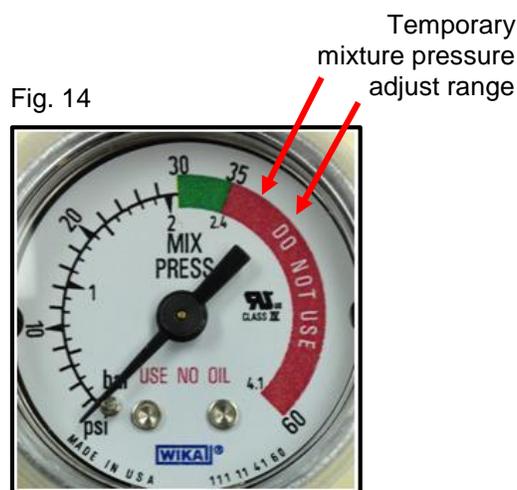


Fig. 14

Cleaning Methods & Maintenance

5. Maintenance



Field repair of the Nitronox is limited to maintenance adjustments and replacement parts obtained through a Porter authorized distributor and as outlined in this user manual. To assure a long useful product life, perform the periodic field performance tests and adjustments, including the Line Pressure Adjustment, the Mixture Pressure Control Adjustment, the Leak Testing of the System, and the Whistle Alarm Actuator Adjustment (as outlined in this user manual).

Porter advises (not required) an inspection by an authorized Porter representative every 2 years. Check local and state guidelines (if any) for certification regulations and requirements.

It is advised that the Nitronox device have a complete factory elastomer change out and calibration after 10 years of product operation in the field. The Nitronox device can be serviced and repaired for 20 years. Contact your Porter distributor or Porter for pricing information and more details.

Note: The Nitronox HD Scavenger System User's Manual / Instructions FM-1309, the maintenance is to replace the foam resistor every 6 months.

Note: See FM-916 E-Stand for illustrations and instructions for replacement of the Check Valve Assembly.

6. Cleaning Methods

We recommend the use of an approved disinfectant for the healthcare patient environment for cleaning the outside of the Nitronox device, demand valve, and accessories. Do not spray disinfectant directly onto housing. Spray disinfectant into disposable towel, or use disinfectant surface wipe (avoid excess disinfectant liquid), and wipe unit thoroughly removing excess disinfectant to eliminate buildup. Follow the disinfectant manufacturer's directions for use.

Introduction of moisture or other contaminants into this device may result in defective operation. Never oil or grease any part of this system (minimize fire or explosion potential). Cylinder mount: Do not clean check valve entrance or sealing washer (replace once/yr or earlier if needed) with disinfectant.

Demand Valve Cleaning



WARNING: Introduction of moisture or other contaminants into this device may result in defective operation. Never oil or grease any part of this system (minimize fire or explosion potential).

Standard Cleaning After Use

1. Remove (unscrew) the outlet adapter housing (mask connection outlet) and remove (lift) the exhalation valve assembly (with attached flapper valve) from the main demand valve subassembly.
2. Clean the adapter housing and exhalation valve assembly with mild soap solution, being careful not to get any liquid inside the demand valve subassembly. Rinse the parts thoroughly in clean water (not inside demand valve).

3. Carefully examine the assemblies of the demand valve. Discard and replace any cracked or damaged parts. Contact Porter or authorized distributor for replacement assemblies.
4. Disinfect the outside of demand valve main subassembly. Follow the disinfectant manufacturer's directions for use (see Page 16 Cleaning Methods for application technique).



WARNING: If the flapper is twisted or not properly positioned, the demand valve will not function properly. Make sure that the flapper valve lies flat against its seat.

5. If cleaning demand valve mounting bracket, do not apply disinfectant directly on to O-rings.
6. Reassemble the parts.

Replacement Parts: Outlet Adapter Housing, Exhalation Valve Assembly

Inspect the Demand Valve during the regular inspections of Nitronox (Pages 15/16 Maintenance).



WARNING: Do not disassemble or tamper with the main demand valve subassembly. In case of malfunction, return the demand valve to Porter or authorized distributor immediately.



Clean adapter housing, exhalation valve assembly, and outside surfaces of main demand valve

Troubleshooting

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
1. Leakage at YOKE CYLINDER VALVE connection.	Missing or defective yoke seal washer (models with "E" cylinder yoke); damaged pins.	Replace with Porter part No. A-3399-000.
2. Low or no reading on CYLINDER GAUGE with CYLINDER VALVES open.	Cylinder pressure too low or cylinders empty (models with "E" cylinder yoke).	Replace cylinder with full cylinder of appropriate gas.
3. O ₂ cylinder (or external supply) used too quickly	O ₂ cylinder valve (or external supply) left on after use and natural bleed depletes cylinder (or external supply). O ₂ E cylinder contains up to 2.5 hrs. breathing supply; N ₂ O E cylinder contains up to 6.5 hrs.	Use practice of turning off cylinder (or external supply) after use. Expect higher usage of O ₂ cylinders
4. Line pressure out of green band or broader functional pressures of 40 – 65 psi (2.8 – 4.5 bar).	Apparatus exposed to temperature below 32°F / 0°C. PRESSURE REGULATOR out of adjustment (models with "E" cylinder yoke). PRESSURE REGULATOR defective (models with "E" cylinder yoke).	Allow apparatus to return to room temperature before making adjustment. See "Maintenance" adjustment, Step 1. Discontinue use and notify authorized distributor.
5. Mixture pressures out of green band.	CONTROLLED PRESSURE REGULATOR section of mixture requires adjustment REGULATOR malfunction (models with "E" cylinder yoke).	See "Maintenance" adjustment, Step 2. Discontinue use and notify authorized distributor.
6. WHISTLE ALARM failure during functional test.	ALARM ACTUATOR out of adjustment. ACTUATOR DEFECTIVE	See "Maintenance" adjustment, Step 3. Discontinue use and notify authorized distributor.
7. WHISTLE ALARM sound Note: a momentary "chirp" sound is acceptable upon initial application of pressure if whistle then stops [reseats]	Leak at N ₂ O pressure control seat causing low O ₂ concentration. ACTUATOR DEFECTIVE.	Discontinue use and notify authorized distributor.

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RETURNS All returned merchandise will be handled through the local Parker Hannifin Corporation distributor. 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.

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“The design, manufacture, distribution and servicing of fluidic components and integrated systems for use in the Medical Equipment, Diagnostic, Biopharmaceutical, Agent Detection, Analytical Instrumentation and Industrial markets and Nitrous Oxide – Oxygen Sedation Flowmeters, Gas Scavenging Systems and Gas Distribution products for use by a physician, dentist or licensed healthcare professionals and the distribution of Steam Sterilizers.”