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NITRONOX
USER'S MANUAL / INSTRUCTIONS

10115900 Rev. P 05/2019

Manufacturer:

Parker Hannifin Corporation
Precision Fluidics Division
Porter Instrument
245 Township Line Road
Hatfield, PA 19440 USA
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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: 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 ½" 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.

WARNING: Nitronox® Inhalation Analgesia systems are intended to be used by medical personnel trained in its use and the use of nitrous oxide and oxygen for medical applications.

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: Use Scavenging

Monitor for N2O in the patient treatment area to insure that controls are effective in achieving low levels of ppm (parts per million) exposure. Contact Porter or Authorized Distributor for details on monitors and testing.

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

WARNING: Medical workers are exposed to N_2O during administration of N_2O/O_2 conscious sedation analgesia. NIOSH has recommended that exposures should be minimized. Contact NIOSH (1-800-35-NIOSH) to receive NIOSH Publications on *Control of Nitrous Oxide in Dental Operatories.* Exposure can be minimized by effective controls. National Institute for Occupational Safety and Health (NIOSH) publications state that controls, including System Maintenance, Ventilation and Work Practices can effectively reduce N_2O concentrations in patient procedures. Your accessory Porter Nitronox Scavenger System is an important part of the system of controls in medical settings.

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.

CAUTION: Always use clean, dry medical grade gases. Introduction of moisture or other contaminants into this device may result in defective operation.

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.

CAUTION: Never oil or grease any part of this system (minimize fire or explosion potential).

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.** The authorized distributor or contractor 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.**

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.

Maintain patient observation during procedures. Prevent over sedation. 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. If crossed lines are suspected, 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: Oxygen input pressure more than 15 psi (1 bar) higher than Nitrous Oxide input pressure will cause low oxygen percentage mixture delivery. DO NOT use Nitronox if O2 input exceeds N2O input by 15 psi or higher.

SIDE EFFECTS & CONTRAINDICATIONS

Note: This is not an exhaustive list. The list was prepared from published articles.

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 B_{12} 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) – patient may wish to contact OBGYN / medical professional.

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.

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 continuous 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. Follow manufacturer's instructions. 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 INSTRUCTIONS

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 a nitrous oxide 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: Standard male DISS.
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

Maintenance: Cleaning (specific to the demand valve)

WARNING: Since the described cleaning procedures for the **demand valve** call for disassembly of components, the procedures must be performed in a hydrocarbon residue free area because of the danger of spontaneous combustion when the residues are exposed to nitrous oxide.

Standard Cleaning and Disinfecting 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. Do not remove the hose assembly.

2. Clean all foreign matter from the adapter housing, exhalation valve assembly, and outside surfaces of main demand valve subassembly with mild soap solution, being careful not to get any liquid inside the demand valve subassembly. Rinse the parts thoroughly in clean water.

3. Carefully examine the three assemblies of the demand valve. Discard and replace any cracked or damaged parts. Contact Porter for replacement assemblies.

4. Disinfect the demand valve (and collection manifold).

Cold Disinfecting

1. Remove the outlet adapter and the exhalation valve assembly from the demand valve assembly as described above. Clean the outlet adapter and the exhalation valve assembly using a disinfecting solution approved by your facility. (Refer to Manufacturer's Recommendations). Do not allow any solution inside the demand valve subassembly.

2. Remove the outlet adapter and the exhalation valve assembly from the solution and rinse thoroughly with sterile water. Rinse repeatedly to be sure that all of the solution is removed from the parts.

3. Check the exhalation valve assembly to be sure the flapper valve is not twisted.

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.

4. Reassemble the parts

Maintenance:

Replacement Parts: Outlet Adapter Housing, Exhalation Valve Assembly, Sintered Stainless Steel Filter

Recommended Overhaul Period:

The demand valve should be overhauled annually. Contact Porter for details.

WARNING: Do not disassemble or tamper with the main demand valve subassembly. This will void the warranty. Improper disassembly or improper assembly procedures may alter the performance of the valve which could cause serious injury to the patient. In case of malfunction, return the demand valve to Porter immediately.

Installations

Nitronox Main Housing, Mobile E-Stand (Fig. 1.1), Mobile Stand, Wall Mount (Fig. 1.2), Demand Valve, Corrugated Hose, Scavenger Interface

Preparation of Mobile E-Stand Fig. 1.1
Also see FM-916 E-Stand User's Instructions

1. Slide Center Column with Cylinder Restraint and Cylinder Yoke Block into 5-Star Base (Fig. 2.1). Push down firmly until snug. Align Cylinder Restraint as shown. Base of cylinders will fit in between wheels (Fig. 2.2).

Fig. 2.1

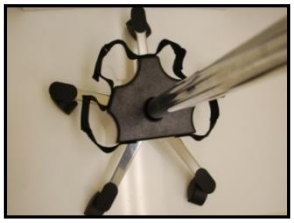


Fig. 2.2

2. Adjust the Recessed Mounting Post to highest height by loosening and tightening the small black handle (Fig. 3.1) on the Yoke Block – and raising the Mounting Post (Fig. 3.2).

Fig. 3.1

Fig. 3.2

3. The Nitronox Main Housing will mount on the Mounting Post of the E-Stand [or Mobile Stand] by sitting the bottom of the Housing (Fig. 4.1) on top of the Mounting Post (larger threads Fig. 4.2). Hold the Mounting Post in one hand and position the Housing with the other.

Fig. 4.1

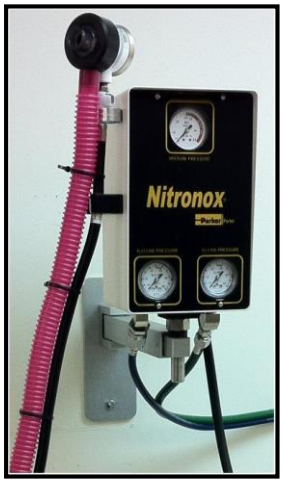
Fig. 4.2

4. Secure the Housing on the Mounting Post (Fig. 5.1) by twisting the Post (counterclockwise) with one hand and holding the Housing steady with the other hand. Twist until the Post is snug (Fig. 5.2).

Fig. 1.1

E-Stand with Nitronox

Fig. 1.2



Wall Mount

Fig. 5.1

Fig. 5.2

Preparation of Mobile E-Stand (continued)

5. Attach the Handle (Fig. 6.1) to the Mounting Post – just under the Retaining Ring / O-ring (Fig. 6.2). Firmly tighten both screws so that the Handle cannot be twisted. The back of the Handle should be positioned over the back two cylinders (Fig. 6.3).

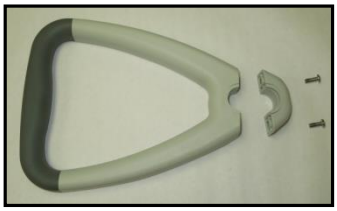


Fig. 6.1

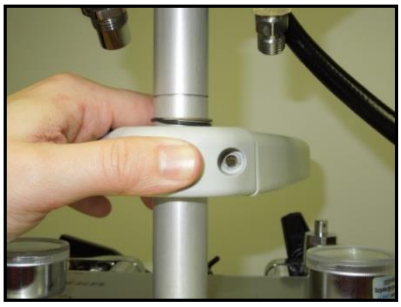


Fig. 6.2

Fig. 6.3

6. Carefully clip the [shipping accessory] plastic fasteners off of the green Oxygen Hose and blue Nitrous Oxide Hose – under the E-Stand Block (Fig. 7). Be careful – do not cut the Hoses.

Fig. 7

7. Connect the Diameter Indexed Safety System (DISS) color-coded green [white] Oxygen and blue Nitrous Oxide Hoses to the appropriate connections (Fig. 8.1) on the bottom of the Nitronox Main Housing. Slide the Hoses through the opening in the Handle (Fig. 8.2) before connecting. Firmly tighten the Hoses using a wrench.

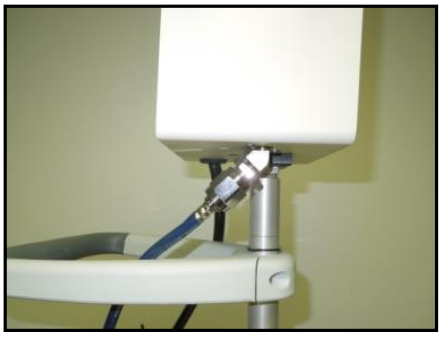


Fig. 8.1

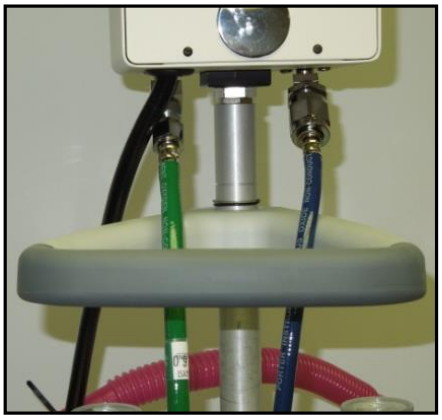


Fig. 8.2

Fig. 8.3 (shown with white hose)

Preparation of Nitronox Scavenger Parts

For further details, refer to Nitronox Scavenger System User's Manual 10152100

8. Connect the Demand Valve (Fig. 9.1) to the black Gas Delivery Hose (connected through underside of Nitronox Main Housing Fig. 9.2). This is a quick connect attachment. Push the two ends together until click sound is heard (Fig. 9.3). To remove – push the metal clip in – and pull apart.

Fig. 9.1

Fig. 9.2

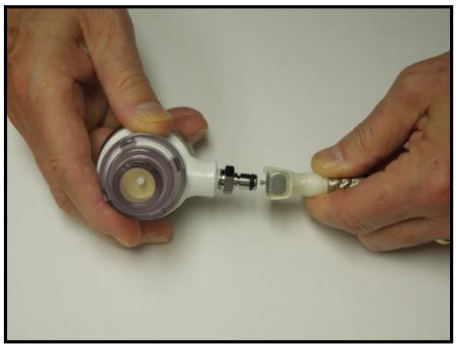


Fig. 9.3

9. The bracket and clip on the side of the Housing (Fig. 10.1) may be used to hold the Demand Valve assembly and Hoses when not in use (Fig. 10.2).

Fig. 10.1

Fig. 10.2

10. Follow instructions FM-1236 included with 19mm Magenta Hose: Part number 92120041 – 19mm Corrugated Scavenger Hose Assembly Instructions. (Figs. 11.1, 11.2, Fig. 12)

Fig. 11.1

Fig. 11.2

Fig. 12

Nitronox Scavenger on Housing

11. Attach the Nitronox Scavenger Interface to the Center Column (Figs. 13.1, 13.2).

Fig. 13.1

Fig. 13.2

Attachment of Cylinders

Caution: When operating the swivel yoke, take care not to catch or pinch fingers.

12. Loosen the Tee Handle (Fig. 14.1) until point is even with the inside of the Swivel Arm. Push Tee Handle inwards to flip to open position. Align Tee Handle vertically (Fig. 14.2).

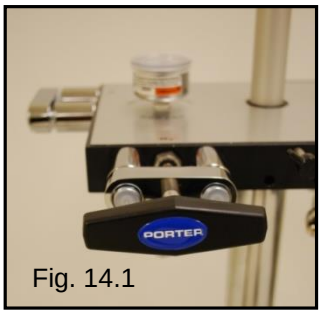


Fig. 14.1

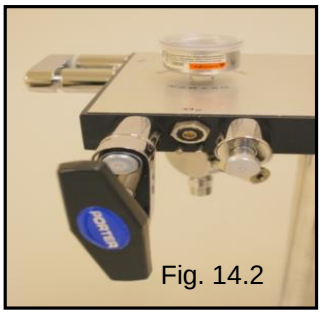


Fig. 14.2

13. Undo the Hook & Loop straps on the Cylinder Restraint (Fig. 15)


Fig. 15

14. Cylinder Preparation: Remove any plastic wrap from the top of cylinder, including the cylinder plastic washer. Verify that the rubber washer (Fig. 16.2) provided with the E-Stand is still in place. Use the E-Stand washer.

15. Mount the "E" cylinders of Oxygen and Nitrous Oxide (not included) to the E-Stand Block. Insert cylinders correctly on indexing pins and as marked on Block (N_2O Figs. 16.1, 16.2; O_2 Figs. 16.3, 16.4). Pins assure mounting in appropriate position.


Fig. 16.1


N_2O Pins **Rubber Washer**

Fig. 16.2


Fig. 16.3

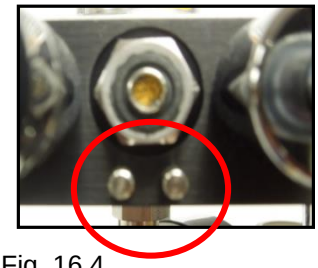


Fig. 16.4

O_2 Pins

Warning
Do not remove or alter gas indexing pins

16. Slide the cylinder into place by lining up the pins and pin holes on the cylinder. Push into place. Properly placed, the cylinder should hang on the pins (Fig. 17).

17. Cylinders should hang freely between wheel base. If the wheel base interferes, loosen and rotate cylinder restraint.

18. Rotate swivel clockwise to close (Fig. 18.1). Swivel will move into the locked position when Tee Handle is tightened. Secure the Hook & Loop straps to hold cylinder in place (Fig. 18.2).


Fig. 17

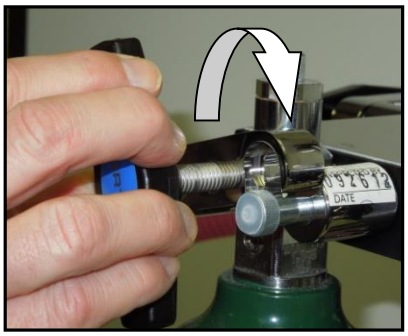


Fig. 18.1


Fig. 18.2


Fig. 19

19. The Cylinder Valve Wrench (hanging from black Knob) is used to open/close Cylinder Valves (Fig. 19). See FM-916 User's Instructions.

Description of Unit

The 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 (Mobile “E” Stand).

<u>The Nitronox® is available in various configurations offering three mounting styles.</u>

1. Nitronox with Mobile Stand only (for use with pipeline gas supply only).

2. Nitronox with Mobile “E” Stand (Fig. 20) and cylinder mount- (2) nitrous oxide and (2) oxygen – “E” or ”D” size. Refer to FM-916 for Installation and User Instructions.

3. Nitronox with wall mount (for use with pipeline gas supply)

Use Nitronox in conjunction with Nitronox Scavenger System; Refer to User’s Manual / Instructions 10152100.

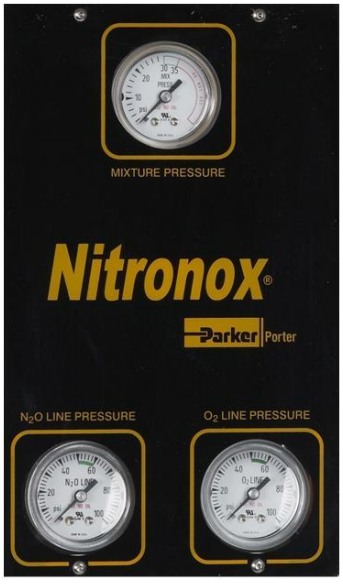


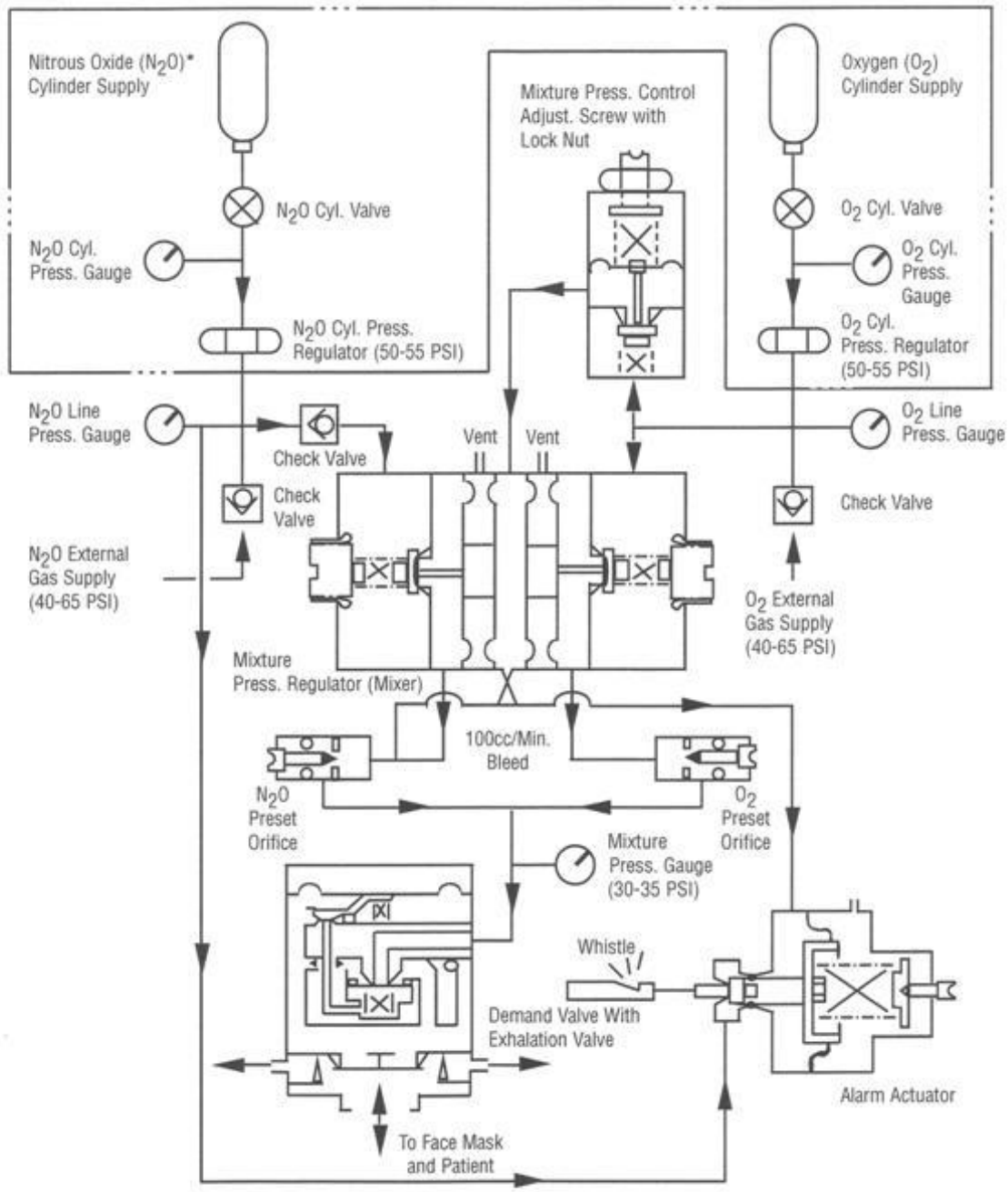
Fig. 21

Fig. 21 – Nitronox Front Cover with Mixture Pressure and N_2O and O_2 Line Pressure Gauges

Fig. 20

Fig. 20 - Nitronox with Mobile E- Stand

FUNCTIONAL SCHEMATIC



Specifications / Functional Features

Gas Supply Duration	Flow Capability	Mixture Concentration
"E" Size Cylinders At Normal Breathing Rates: N_2O Approximately 6 – 6.5 Hrs. O_2 Approximately 2 – 2.5 Hrs.	114 LPM, Maximum	Mixture Concentration (Factory Adjusted) 50% N_2O and 50% O_2 +/- 5 Percentage Points O_2

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. If patient takes abnormal shallow breaths (100 to 200 cc tidal volume), oxygen concentration automatically increases.

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

Warning: ***Nitronox® Inhalation Analgesia systems are intended to be used by medical personnel trained in its use and the use of nitrous oxide and oxygen for medical applications.***

Warnings

- **DO NOT use Nitronox if either line or mixture pressure is out of green band (see "Maintenance"). Figs. 22.1, 22.2**

Fig. 22.1

Fig. 22.2

- **Encourage patient to self administer at all times [see Warnings page 3 for details].**

Warnings

- **If WHISTLE ALARM sounds, discontinue patient use immediately and shut off gas supply.**
- **WARNING: DO NOT use Nitronox if O2 input exceeds N2O input by 15 psi (1 bar) or higher [see Warnings page 3]**

Functional Tests

Prior to first use and periodically thereafter (monthly is suggested), perform the following tests:

Whistle Alarm Actuation:

1. Increase mixture pressure per Page 7, Step 2, "Maintenance", until gauge reading is in RED "Do Not Use" area, per gauge illustration.
2. WHISTLE should sound in this range.
3. If WHISTLE sounds before or after this range, WHISTLE ALARM ACTUATOR must be adjusted (see "Maintenance").

Fail Safe Check-Out Test:

1. With unit in operation (one each O2&N2O gas supplies on), turn off or disconnect oxygen at supply source.
2. As oxygen pressure falls to zero (as read on oxygen line pressure gauge), demand valve flow must stop completely.

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 68ºF (20ºC), the vapor pressure is about 750 psi (50 bar); at 20ºF (-7ºC), it drops to about 400 psi (30 bar); while at 90ºF (32ºC), 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.

Cautions

- **Always turn on CYLINDER VALVES slowly and fully ("E" cylinder yoke models).**
- **Hex hole in cylinder valve wrench to be used only to tighten cylinder valve packing nut in event of a leak.**
- **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

Good practices: Cylinders with E- Stand

1. Two cylinders of O_2 and two cylinders of N_2O are typically connected at all times. Exception: When using external gas supply of oxygen, the E-Stand may be populated with N_2O cylinders and O_2 cylinders are not placed on "E" Stand.

2. Minimize leak risks: Confirm Yoke Washers are in place before replacing/mounting cylinders. Use Porter #A-3399-000 replacement washers (once/yr.). Have spare washers.

3. Minimize leak risks: 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.

4. Assure E- Stand is populated with at least one full cylinder of O_2 and N_2O before starting any procedure.

5. Label each cylinder with a tag or sticker indicating "In-Use" and "Full" ("Full" is reserve cylinder.)

6. Use Cylinder Valve Wrench to open the "In-Use" cylinders of O_2 and N_2O. Verify wrench is attached to Block.

7. Cylinder pressure gauges on Block provide a visual indication of cylinder status (see details on Cylinder Pressure Readings)

8. **Caution:** If all four cylinders (or both cylinders of one gas) are open, the two cylinders of O_2 and N_2O will deplete in tandem. The "Full" cylinder will empty with the "In-Use" cylinder and will not be available as a future spare.

9. When "In-Use" cylinder is depleted, open the spare "Full" cylinder (Close valve on empty cylinder).

10. When "In-Use" O_2 cylinder is depleted, the Oxygen Fail Safe will stop N_2O flow and demand valve flow automatically.

11. When "In-Use" N_2O cylinder is depleted, the Nitronox will deliver 100% O_2 through the Demand Valve.

12. After use, turn off cylinder valves. **Caution:** With O_2 cylinder turned on, the Nitronox will have an intentional small O_2 bleed, which will tend to deplete the O_2 cylinder if, after use, the O_2 cylinder valve is left on.

Models With "E" Cylinder Yoke (Simple Operation Procedure)

1. Open one each O_2 and N_2O Cylinder Valves with wrench provided.

2. Observe cylinder pressures. Replace cylinder when less than 300 psi (20 bar), at room temperature (21.1 ºC, 70ºF). During replacement, close all Cylinder Valves.

3. Observe line pressures (Figs. 23.1, 23.2). Normal is 50-55 psi [3.4–3.8 bar] (green band) for static no-flow condition. Pressure will decrease slightly during each inspiration (see "Maintenance").

4. Observe mixture pressure (Fig. 23.3). 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. Remove Demand Valve with Mask from storage bracket. Instruct patient to hold Mask lightly on face covering nose and mouth. Instruct to breathe normally, preferably through nose.

   Encourage patient to self administer at all times [see Warnings page 3 for details].

6. After use, turn off Cylinder Valves; store Demand Valve with Hose. 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 (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 input exceeds N2O input by 15 psi (1 bar) or higher.**

2. Observe mixture pressure as in step 4 above.

3. Follow step 5 procedure above.

4. After use, disconnect external gas supply.

Fig. 23.1

Fig. 23.2

Fig. 23.3

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. 24).

3. **Leak Test System –** Monthly Check of working pressure leaks. Verify hoses are attached from E-Stand to Nitronox Housing. Turn one O_2 and one N_2O 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 N_2O cylinder valve. Verify that N_2O 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 N_2O line pressure gauge needle will stay in green band with no movement. Turn off O_2 cylinder valve. It is normal that needle of O_2 E-Stand gauge will drop. Nitronox O_2 line pressure gauge needle will stay in green band with no movement (will eventually drop after E-Stand gauge pressure naturally depletes).

4. **Whistle Alarm Actuator Adjustment:** Remove UPPER CHROME PLUG from case back (Fig. 25). With mixture pressure temporarily adjusted (per Step 2, "Maintenance") in middle of range shown (Fig. 26), 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 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. 26 (about 40 psi [2.8 bar]). If this cannot be achieved, discontinue use of apparatus and notify authorized distributor immediately.

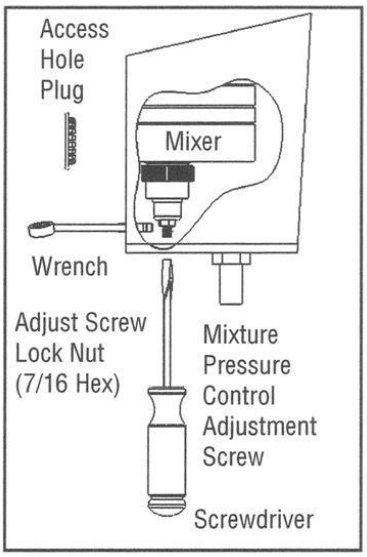


Fig. 24

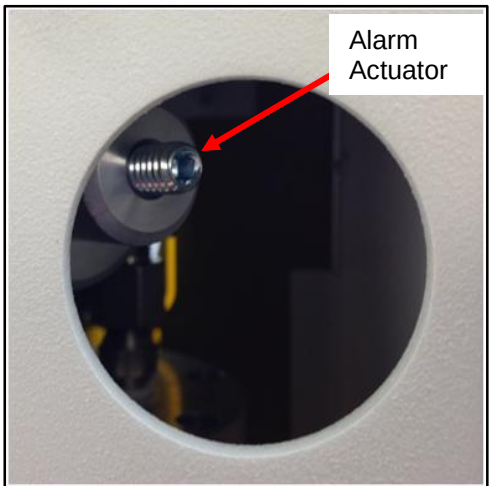


Fig. 25 Back of Case; Upper adjustment access

Temporary mixture pressure adjust range

Fig. 26

5. Cleaning Methods

We recommend the use of an approved disinfectant for the dental / medical environment for cleaning the **outside** of the Nitronox, demand valve, and accessories. Do not spray disinfectant directly onto housing. Spray disinfectant into disposable towel and wipe unit thoroughly removing excess disinfectant to eliminate buildup. Follow the 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).
See special demand valve cleaning instructions.

6. Replacing the E-Stand Check Valve

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

 Field repair of the Nitronox is limited to maintenance adjustments and **replacement parts obtained through Porter.** All other repairs should be performed by an authorized Porter service representative.

Although the materials contained in the Nitronox Inhalation Analgesia System do not have a specified shelf life, Porter advises a factory performance check and repair procedure every 2 years. It is Porter practice to recommend a complete factory elastomer change out after every 10 years of product operation in the field. Following this schedule of maintenance and repair will assure a useful product operation field life of 15 years or more.

Also, to assure a long useful product operation field 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.

Perform the specific cleaning procedures for the Demand Valve. It is advisable to overhaul the Demand Valve annually.

Note: In the Nitronox Scavenger System User's Manual / Instructions 10152100, the maintenance is to replace the foam resistor every 6 months.

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 (4 per Unit).
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 cylinder contains up to 2.5 hrs. breathing supply; N_2O 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.	Apparatus exposed to temperature below 32ºF / 0ºC. 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_2O pressure control seat causing low O_2 concentration. ACTUATOR DEFECTIVE.	Discontinue use and notify authorized distributor.

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The Quality System for Porter is certified to ISO 13485. The scope of our registration is: The design, manufacture, distribution and servicing of Nitrous Oxide - Oxygen Sedation Flow Meters, Gas Scavenging Systems, Steam Sterilizers, Gas Distribution and Office Communication Systems for use by a physician, dentist or licensed healthcare professional.