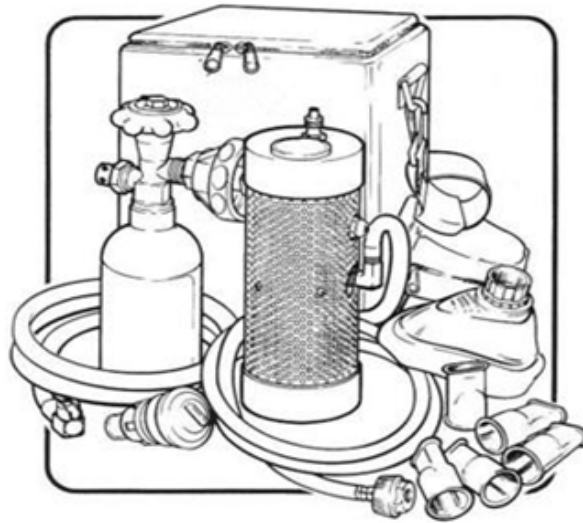


NITRONOX USER'S MANUAL

Nitronox[®] Field Unit Analgesia System



Safety Summary



Warnings and Precautions

Warning: The Nitronox® Inhalation Analgesia apparatus is a specialized medical device designed to be operated as indicated herein. Only personnel trained in its use should operate it. Carefully read this manual prior to operation and use.

Warning: The unit should be operated in an upright position. If the nitrous oxide cylinder is in a valve-down position while the valve is open, liquid may be expelled through the vent passages. This liquid, nitrous oxide, can cause burn by freezing on exposed skin.

SELF-ADMINISTRATION VS. ASSIST TO SELF-ADMINISTRATION

Warning: Patient must self-administer. Encourage patient to fully 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.

Warning: DO NOT USE if the mixture pressure is out of the green band. If the mixture pressure drops below the green band (30 PSI) during a breathing cycle, and the whistle alarm sounds, the nitrous oxide supply is depleted or shut off. When this happens, the unit will administer 100% oxygen. It is acceptable to administer oxygen in this manner.

Warning: If the whistle alarm sounds continuously, immediately discontinue use and shut off the gas supply. Contact Porter Instrument Division or Authorized Distributor for repair.

Caution: Always turn on cylinder valves slowly and fully.

Caution: Disconnect the oxygen supply and close the nitrous oxide valve when the unit is not in operation. Never store the unit with the nitrous oxide valve open.

User Responsibility

The Nitronox® Inhalation Analgesia apparatus is designed to perform to specifications when operated and maintained as instructed herein. Replace defective or worn parts immediately. Do not use a defective product. Do not repair this product other than in accordance with the written instructions provided by Porter. The user has the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alterations by anyone other than Porter.

Delivery Checkout

Examine the shipping carton for signs of external damage. Remove the contents from the carton and inspect for visible damage or missing parts. If any damage is discovered or suspected and/or parts are missing, notify Porter or authorized distributor immediately.

Note: Cylinders from Porter are shipped EMPTY.

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

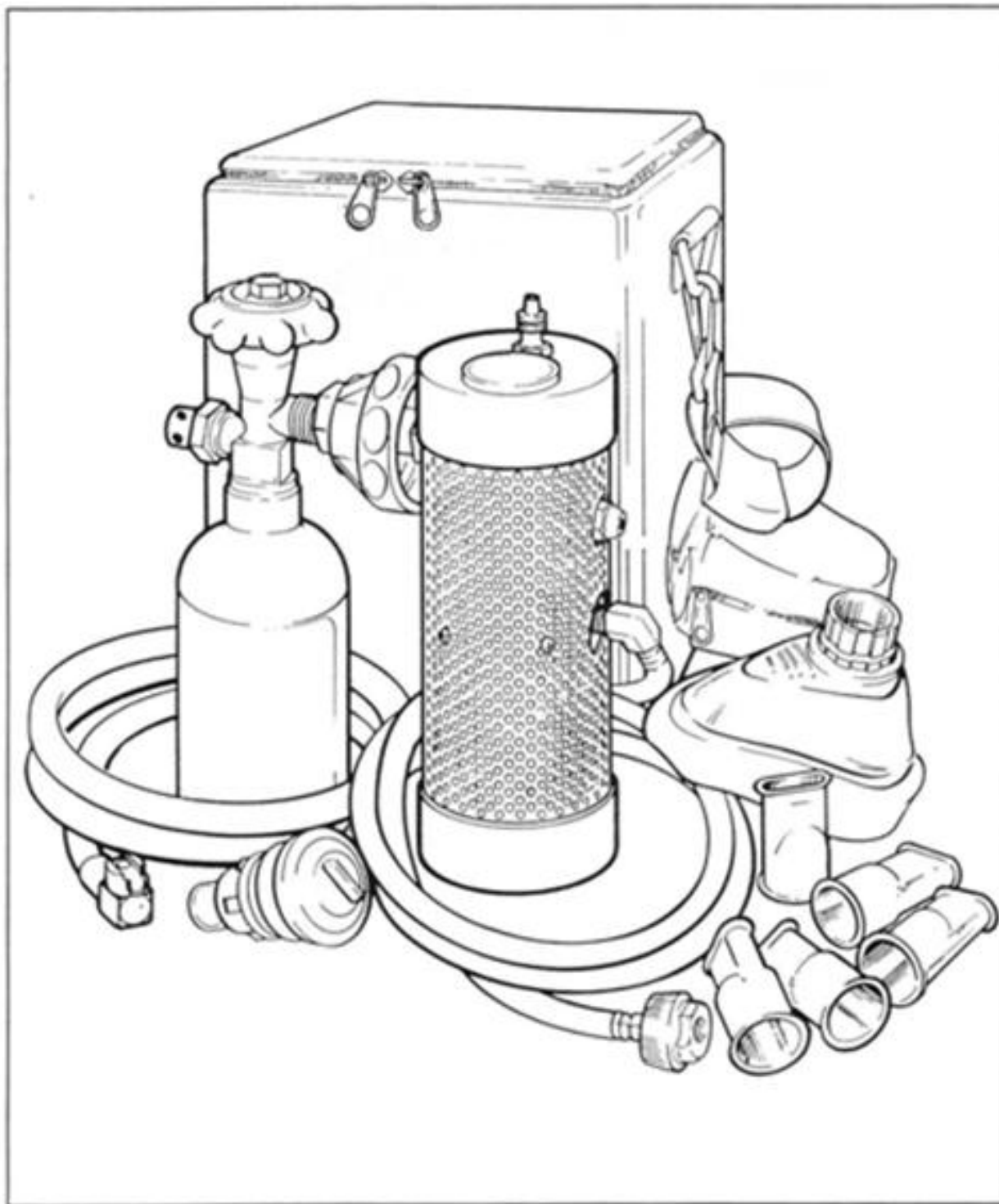
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Figure 1. Nitronox[®] Field Unit Analgesia System



Section 1 Description

The Nitronox[®] Field Unit, shown in Figure 1, is a portable inhalation analgesia system designed to deliver a 50% oxygen / 50% nitrous oxide analgesic gas mixture to a patient via patient-held demand [supply] valve and face mask or a disposable mouthpiece. It includes a single mission supply of nitrous oxide and utilizes an external supply of oxygen.

1.1 Capacities

The Nitronox system is capable of delivering peak flows of up to 100 liters per minute at normal breathing rates for approximately 30 minutes with one cylinder of nitrous oxide (14 ounces) and a continuous high pressure O₂ supply.

1.2 Mixture Setting

Mixture concentration is factory set at 50% nitrous oxide and 50% oxygen (+/- 5 percentage points oxygen).

1.3 Ambient Temperature Limits

Normal Operation

40°F (5°C) Minimum

100°F (38°C) Maximum

Operation Below 40°F

Start with a “warm” Nitronox Field Unit (stored at 60°F or higher). Move Unit into the cold ambient area and begin mission immediately. Nitrous Oxide delivery % becomes lower with colder temperatures (becomes oxygen enriched), and also lower over the mission time.

1.4 Safety Features

Several automatic safety features allow the medical professional to attend to patient injuries while the Nitronox is in use.

1.4.1 Oxygen Fail-Safe

If the oxygen line pressure drops or becomes disconnected, the nitrous oxide flow and the mixture supply demand valve flow stop automatically. If the nitrous oxide supply runs out or is shut off, the supply valve continues to provide 100% oxygen at a reduced peak flow of about 40 LPM.

1.4.2 Oxygen Enrichment

If the patient takes abnormal shallow breaths (100 to 200 mL tidal volume), oxygen concentration automatically increases. Also increases in colder ambient temperatures (see 1.3 Ambient Temperature Limits).

1.4.3 Mixer Pressure Alarm

If the nitrous oxide supply runs out or is shut off, the whistle alarm sounds during breathing cycles and the supply valve continues to provide 100% oxygen at a reduced peak flow of about 40 LPM. The whistle alarm also sounds when the mixture concentration changes due to a gas mixture regulator seat malfunction.

Section 2 Operation

The Nitronox[®] Field Unit system is a ready-to-use unit and needs only an external supply of oxygen. **Note: Cylinders from Porter are shipped EMPTY.**

2.1 Preparation for Use

Make sure that the nitrous oxide cylinder is replaced after each use. One full N₂O cylinder contains about a 30 minute supply, long enough for most single missions.

1. Remove the nitrous oxide cylinder and mixer assembly from the shipping cartons.
2. Remove the mixer assembly from the carrying case as shown in Figure 2. Remove small red caps.

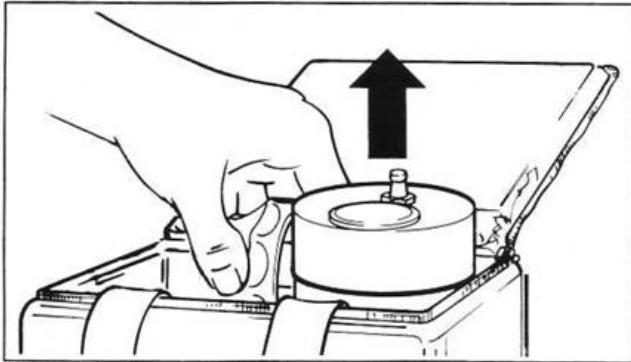


Figure 2. Removing Mixer from Case.

3. Remove the cap from the outlet of a fresh cylinder of nitrous oxide. Inspect the female connector on the mixer to assure that the O-ring is in place as shown in

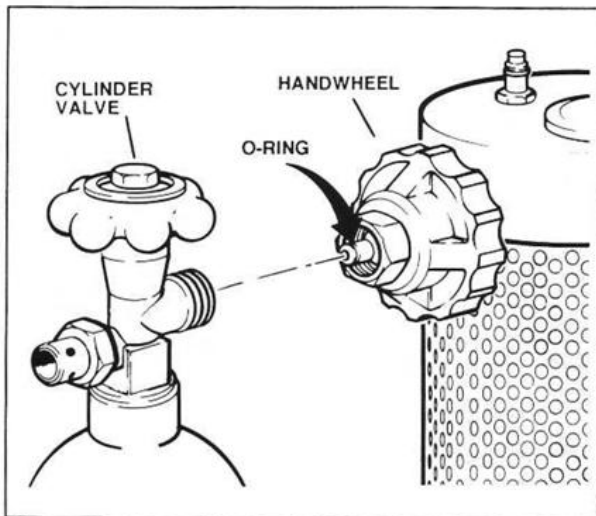


Figure 3. Nitrous Oxide Cylinder and Mixer.

Figure 3.

4. Attach the nitrous oxide cylinder to the mixer assembly by turning the hand-wheel clockwise until it is "hand-tight" as shown in Figure 4.

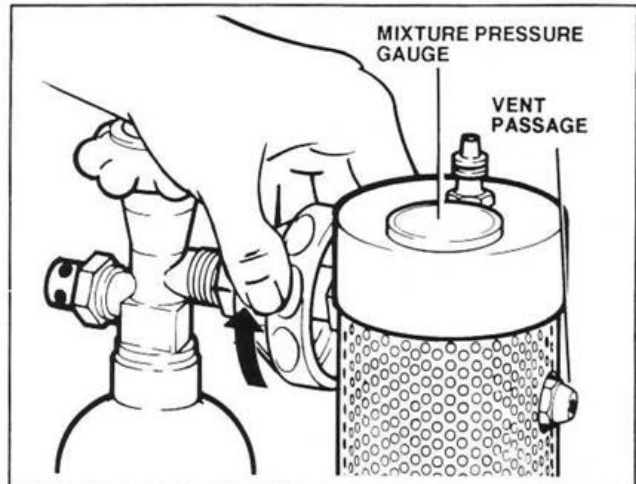


Figure 4. Attaching the Cylinder.

5. Check the connection by opening the cylinder valve slightly and listening for leakage. If a "hissing" noise is heard, close the valve and remove the cylinder. Recheck to ensure that the O-ring shown in Figure 3 is present and in good condition. Re-assemble and check the connection again to be sure that there is no leakage or "hissing" noise.
6. If the connection is not leaking, close the valve. **DO NOT store the unit with the cylinder valve open.**



Warning: If the cylinder is not in an upright position when the valve is open, liquid nitrous oxide can flow through the vent passages and cause burns by freezing exposed skin.

7. Install the cylinder / mixer assembly in its case as shown in Figure 5. Make sure that the mixture pressure gauge is visible. The apparatus is now ready for use.

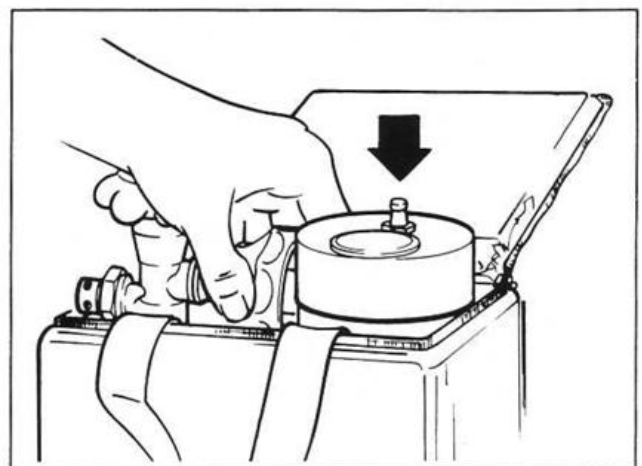


Figure 5. Reinstalling Assembly in the Case.

2.2 Functional Tests

Prior to first using the Nitronox[®] unit and **once a week** thereafter, perform the following tests:

1. Connect the nitrous oxide cylinder to the mixer, per procedure in 2.1.
2. Uncoil the oxygen supply hose from the case.
3. Remove the gas supply / delivery hose from the case and connect to the male portion of the quick disconnect fitting on top of the mixer.
4. Connect the oxygen hose to a 50 - 55 PSI oxygen supply. Turn on the oxygen supply and verify that mixture pressure shown on the mixer pressure gauge is 30 - 35 PSI (within the green band). (Adjust per Section 2.6.)
5. Turn on the nitrous oxide cylinder by turning the cylinder valve knob counterclockwise. Verify that there is no leakage at the connections or relief valve by listening or by applying a soap solution around the various fittings. If the whistle alarm sounds continuously, immediately discontinue use and shut off gas supply. Contact Porter for repair.
6. Cup/seal mouth on hand and hand on demand valve. Blow into the small test holes (Figure 6) on the back of the demand valve. Ensure that the valve energizes by hearing the high flow exit from the valve.

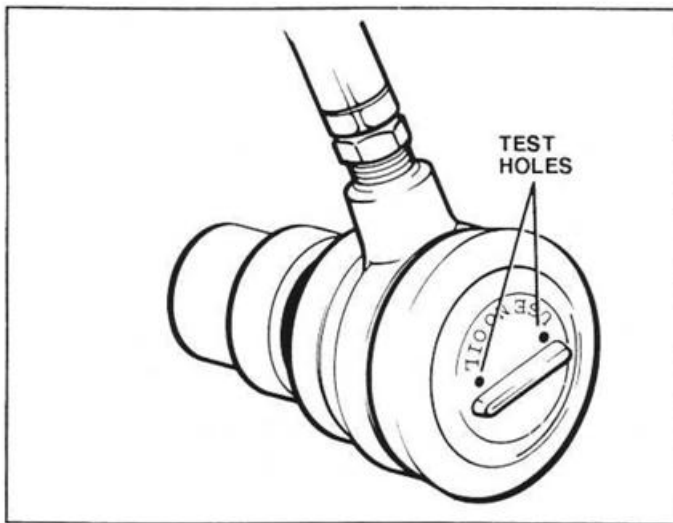


Figure 6. Supply Valve.

7. Close the nitrous oxide cylinder valve and (cup hand) blow into the small test holes (Figure 6) on the back of the supply valve. Ensure that the valve energizes by hearing the high flow exit from the valve. As the nitrous supply depletes the pressure in the hose, the whistle will sound with each test.
8. Shut off the oxygen supply and blow (cup hand) into the small test holes in the back of the valve (Figure 6) once more. Verify that the mixture pressure drops to zero and that flow through the valve stops.

9. Disconnect the gas supply/delivery hose at the outlet on top of the mixer. It is now ready for storage.



Warning

Always operate in an upright position (+/- 30° from vertical). The nitrous oxide cylinder outlet should always be elevated above the base, particularly for cold temperature operation.



Warning

Patient must self-administer at all times.



Warning

DO NOT USE when the mixture pressure is out of the green band. If the mixture pressure drops below the green band (30 PSI) during a breathing cycle, the whistle alarm sounds indicating that the nitrous oxide supply is depleted or shut off. Administration of 100% oxygen with this condition is acceptable.



Caution: Always turn on cylinder valves slowly and fully.

2.3 Operation

To operate Nitronox[®], refer to Figure 7 and:

1. Unzip the case top and uncoil the oxygen inlet hose (1) from the case. Connect the external, regulated oxygen supply (2) to the DISS oxygen fitting on the oxygen inlet hose. Set the oxygen supply pressure to 45 - 60 PSI, preferably within 50 - 55 PSI.
2. Remove the mixture gas supply hose w/ demand valve (3) from the case and connect it to the male portion of the quick disconnect fitting (4) on top of the mixer.
3. Turn on the oxygen supply (2) and open the nitrous oxide cylinder by turning the valve knob (5) counterclockwise.
4. Observe the mixture pressure gauge (6). Normal is 30 - 35 PSI (green band) for static, no flow, condition. The pressure will decrease slightly during each breathing cycle by the patient.

Note

If the mixture pressure drops below 30 PSI and whistle alarm sounds during breathing cycle, the nitrous oxide cylinder valve is closed or the cylinder is empty.

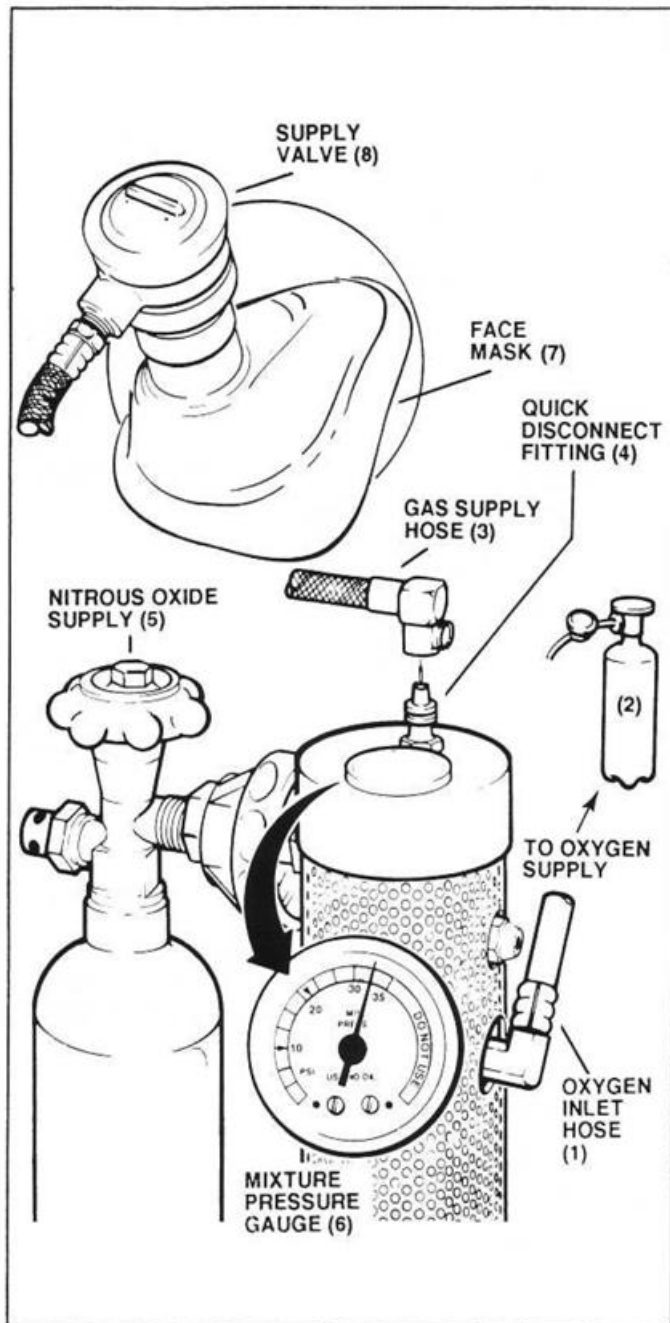


Figure 7. Set-Up Operation.



Figure 8. Patient Administered.

⚠ Caution

When the unit is not in use, ensure that the nitrous oxide cylinder is off and that the oxygen supply is disconnected or off.

⚠ Caution

The mixer bleeds off oxygen at a constant rate of 125 mL per minute when the oxygen supply is connected and turned on. This bleed, over time, can deplete the oxygen supply.

⚠ Caution

Make sure the nitrous oxide cylinder is replaced after each use. One cylinder contains approximately a 30-minute supply which is long enough for most single missions.

2.4 Nitrous Oxide Cylinder Replacement

1. Make sure the nitrous oxide cylinder valve is in a fully closed position by turning the valve knob (Figure 9) clockwise until it stops. Ensure that the oxygen supply to the unit is off and disconnected.

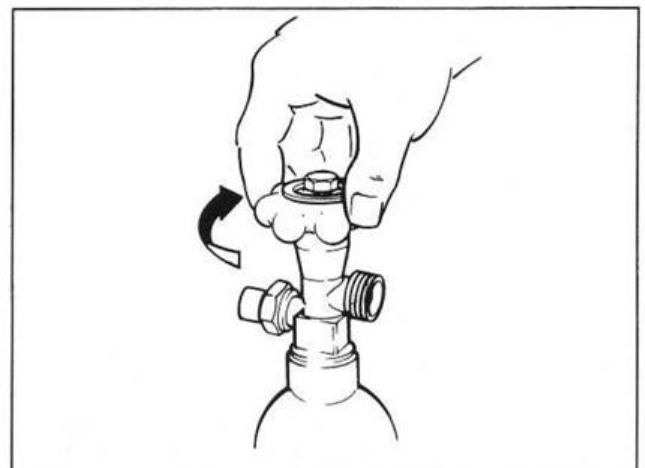


Figure 9. Valve Knob Fully Closed.

5. Attach a face mask (7), or a mouth piece to the supply valve (8). Instruct the patient to hold the face mask lightly on the face, covering the nose and mouth or seal lips over the mouth piece as shown in Figure 8. Instruct the patient to breathe normally.

⚠ Warning

Patient must self-administer at all times.

6. After use, turn off all cylinder valves and disconnect the oxygen supply. Clean the valve. Dispose of the mask or mouthpiece. Prepare the apparatus for the next use.

2. Remove the mixer assembly from the carrying case as shown in Figure 10.

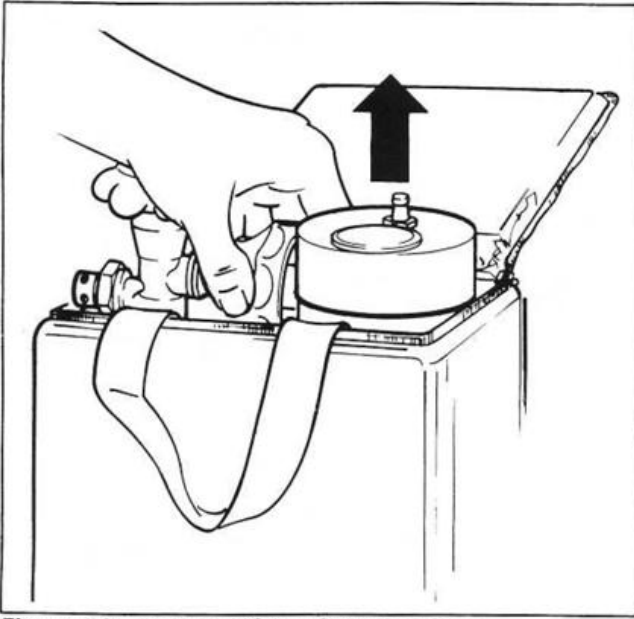


Figure 10. Removal from Carrying Case.

3. Hold the assembly in the upright position and slowly unscrew the large hand-wheel by turning it counterclockwise as shown in Figure 11.

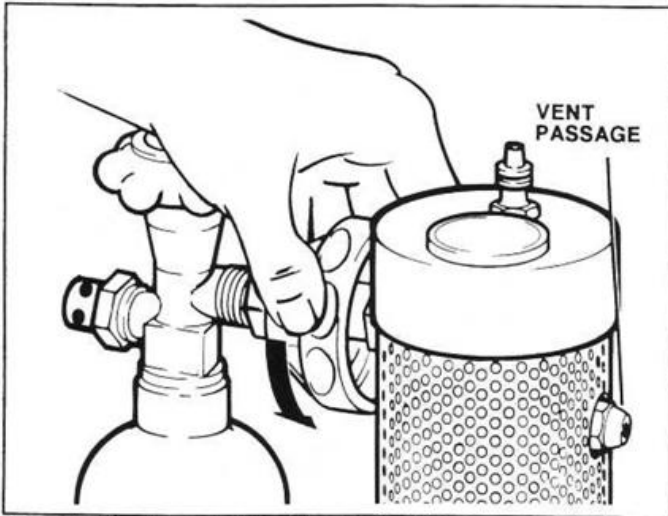


Figure 11. Separating the Cylinder.

Warning

If a hissing sound is heard, stop and recheck that the cylinder valve is closed and that the oxygen supply is off.

Warning

If the cylinder is not in an upright position when the valve is open, liquid nitrous oxide can flow through the vent passages and cause freeze burns by freezing exposed skin.

4. Continue by removing the cylinder and valve assembly. Tag the cylinder to show it is no longer full. Return the cylinder to a secure storage area.



Caution

Full cylinders have a cap on the outlet. Always assume that a cylinder without this cap is no longer full.

5. Remove the cap from the outlet of a fresh cylinder of nitrous oxide. Inspect the female connector on the mixer to assure that the O-ring (Figure 12) is in place. Attach the cylinder to the mixer assembly by turning the hand-wheel clockwise until "hand-tight."
6. Check the connection by opening the valve slightly and listening for leakage. If hissing is heard, close the valve and remove the cylinder as described in step 4. Recheck to ensure that the O-ring shown in Figure 12 is present and in good condition. Reassemble and check the connection once more to make sure there is no leak. If the connection is not leaking, close the valve. **Do not store the unit with the valve open.**

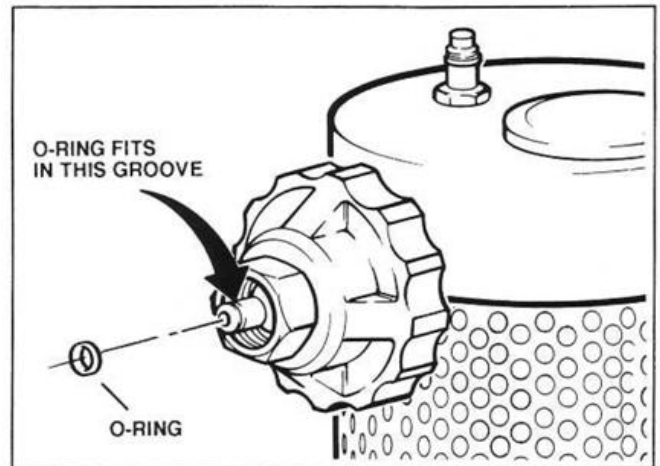


Figure 12. O-Ring Placement.

7. Reinstall the mixer / cylinder assembly in its case as shown in Figure 13. Make sure the mixture pressure gauge is visible. The apparatus is now ready to use.

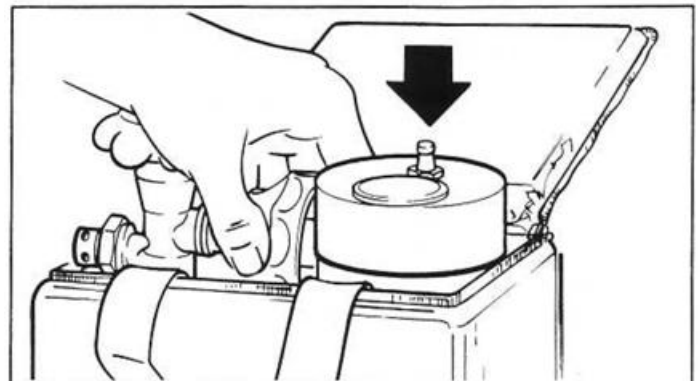


Figure 13. Reinstalling Assembly in Case.

2.5 System Security

Always store the Nitronox[®] unit in a secure area and use the double zipper feature to lock the case as shown in Figure 14. Alternatively, lock up demand supply valve assembly.

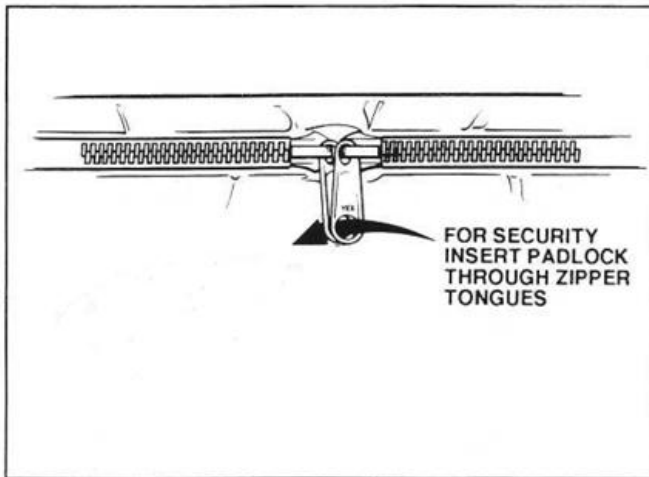


Figure 14. System Security.

2.6 Mixture Pressure Adjustment (Mixing assembly will be removed from carrying case and both gases will be connected and turned on for this adjustment.)

Warning

When adjusting the mixture pressure, ensure that the unit is upright. If the cylinder is not upright while the valve is open, liquid nitrous oxide can escape through the vent passages and will cause burns by freezing on exposed skin.

To adjust the mixture pressure, refer to Figure 15 and:

1. Follow **Section 2.4**, close cylinder valve (Fig.9), remove mixer assembly from case (Fig.10), separate cylinder (Fig.11).
2. (Fig.15) Carefully remove the two red end caps (not shown) on the mixer assembly.
3. Remove the screws (not shown) that hold the perforated metal cage (not shown) to the mixer.
4. Keeping tie and cap together, slide off the cable tie (1) and cap with whistle assembly (2) from the mixture pressure regulator (3) to expose the mixture pressure adjustment nut (4) and screw (5).
5. Attach cylinder **Section 2.1 Fig.4**. Turn on the unit **as described in Section 2.2**.
6. Use a wrench to loosen the 7/16 in. hex nut (4), approximately 1/4 turn (counterclockwise). With a screwdriver, turn the adjustment screw (5) in the center of the nut clockwise to decrease the pressure and counterclockwise to increase the pressure. Set the mixture pressure at the middle of the green band on the mixture pressure gauge.

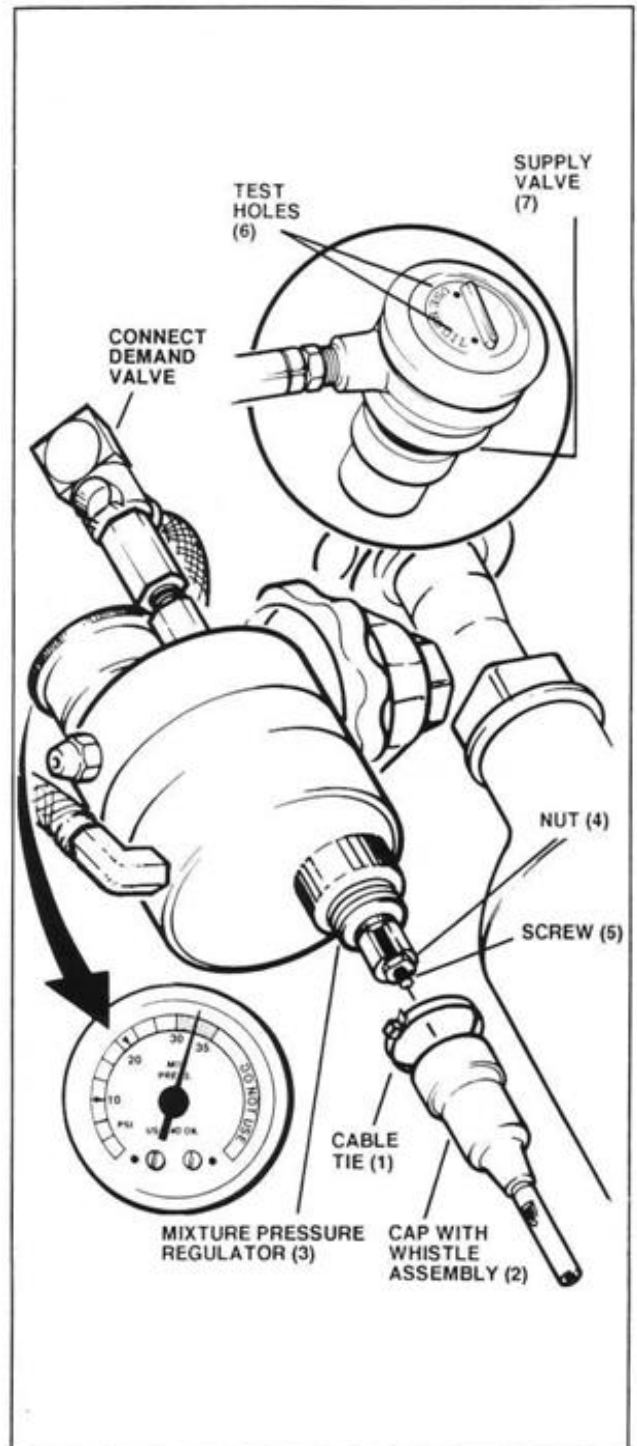


Figure 15. Mixture Pressure Adjustment.

7. Cup/seal mouth on hand and hand on demand valve. Blow into the small test holes (6) on the back of the supply valve (7) to cause flow through the valve. Make sure the mixture pressure remains in the green band.
8. Hold the adjustment screw (5) in position with the screwdriver and tighten the nut (4) with the wrench.
9. Turn off and disconnect the gas supplies.
10. Reinstall the cap with whistle assembly (2) and cable tie (1) over the regulator (3).
11. Secure the cage to the mixer with the screws. Reinstall the end caps. Follow **Section 2.1** Preparation for Use.

Section 3 Service

Field repair is limited to the maintenance and adjustments described in this manual. Refer all other repairs to Porter Instrument Division or Authorized Distributor.

3.1 Cleaning

Keep the Nitronox mixer clean by wiping it after each use with a damp cloth.



Caution

Do not submerge the mixer.



Caution

Do not autoclave any Nitronox components.

3.2 Inspection and Calibration

Porter recommends that you inspect your Nitronox unit regularly by performing the Section 2.2 functional tests. Every 2 years Porter also recommends that the unit calibration be factory certified.

3.3 Cylinder Filling Specifications

The following notes are for use by nitrous oxide vendors, in conjunction with their standard safety and nitrous oxide refilling procedures. The customer may photocopy these specifications and supply the refilling vendor.

Cylinder must be evacuated by vendor before refilling. Cylinders were originally cleaned for oxygen use per spec. RR-C-9016 paragraph 3.8.2. Inspect and reclean if necessary.

- Valve torque 75 foot pounds.
- The valve outlet is to be covered with a vendor supplied caplug.
- The paint on the neck of the cylinder is nitrous oxide blue spats paint #2162.
- The body of the cylinder is clear coated with DUPONT IMRON 500S to indicate exposure to elevated temperature. Do not refill if the cylinder is discolored.
- Fill with 14 oz. of nitrous oxide U.S.P.
- Certify for human consumption. Maintain certificate of analysis per lot and lot commodity code number.
- Re-label as necessary. Vendor is to supply product safety sheet, mark labels with lot number contents, expiration date and cylinder size.
- Customer returned empty cylinders to be accepted and refilled only if they are in good condition.

3.4 Troubleshooting

There are several indications when problems occur in the Nitronox. Use the table below as a guide when there appears to be a problem.

Indications	Possible Cause	Corrective Action
Leak around nitrous oxide cylinder	Missing or defective O-ring	Replace with Porter PN A-4358-003
Intermittent whistle. Mixture pressure in green band (or moves below 30 psi during breathing cycle)	Depletion of nitrous oxide	Replace nitrous oxide cylinder; fill cylinder before use
Continuous whistle. Mixture pressure in red band.	Seat leak in oxygen regulator. Or Seat leak in nitrous oxide regulator Or Seal leak / gas mixture regulator malfunction	Discontinue use. Return to Porter for service.
Mixture pressure out of green band.	Mixture pressure out of adjustment.	See mixture pressure adjustment in Section 2.6.
Mixture pressure in red band, but no gas supply hooked up.	Defective mixture pressure gauge.	Replace mixture pressure gauge Porter PN A-4358-004
No mixture pressure. Unit does not operate.	No oxygen supply.	Check oxygen supply.

Section 4 Replacement Parts

The following replacement parts may be obtained from Porter.

Item No.	Description	Part Number	Item No.	Description	Part Number
1	Mixture Pressure Gauge w / Instructions FM-1243	A-4358-004	11	Screw (Phillips Pan Head #6-32 x 3/8" Lg. for Mixer Support Tube) (Pkg/2) (Sect. 2.6)	A-4358-001
2	Standoff 1/8 NPT x 1-3/8" Lg.	Factory Replaced	12	Demand Supply Valve Hose Assembly (Fig. 7)	9112 0523
3	Coupling Insert (with Shut Off)	A-4358-006	13	Demand Supply Valve (Fig. 7)	9112 0028
4	Nipple 1/8 NPT x 1-1/2" Lg.	A-4358-006	14*	Users Manual	1022 3000
5	DISS Oxygen Inlet Hose Assembly w / Instructions FM-1244	A-4358-005	15*	Users Placard	6491 6100
6	Cable Tie (Pkg/3) (Fig. 15)	A-4358-000	16	Caplug Bottom (Sect. 2.6)	6290 5526
7	Whistle Assembly (less Orifice) (Fig. 15)	2013 2502	17	Caplug Top (Sect. 2.6)	2010 8700
8	Alarm Cap (Fig. 15)	1018 3000	18	Nitrous Oxide Cylinder (1 New; Empty) (Fig. 7)	C-1703-000
9	Mixer Support Tube (Sect. 2.6)	3011 3800	19	O-ring for Hand Tight Nut (Pkg/3) (Fig. 12)	A-4358-003
10	Soft Case w/Strap	6491 5800			

*Not Illustrated

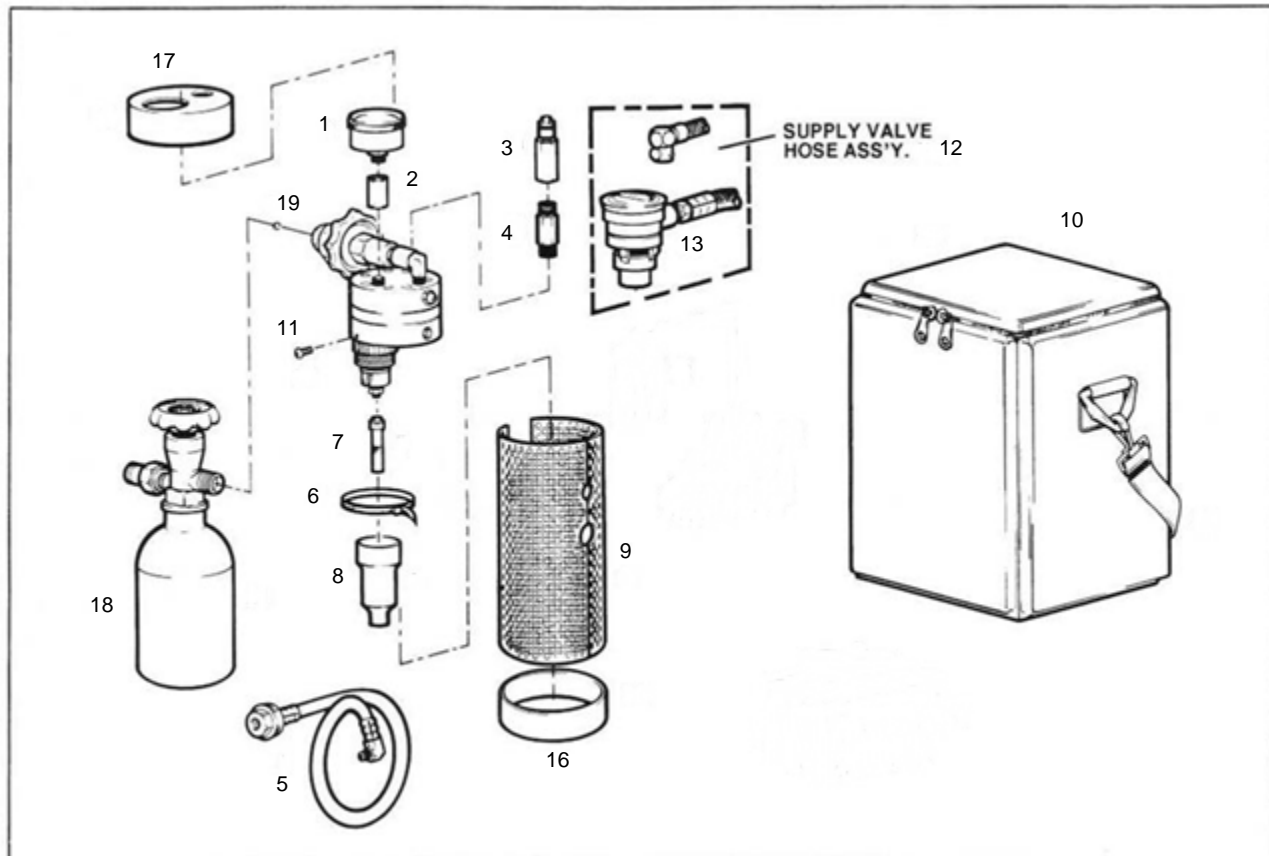


Figure 16. Exploded Parts Illustration.

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 Division 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. 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 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.

Policies subject to change without notice.

The Quality System for Porter Instrument 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.

REF 10223000 Rev. J 05/13