PORTER INSTRUMENT COMPANY, INC.

MXR FLOWMETER

Instructions and Safety Considerations MXR Models of Porter Conscious Sedation Flowmeters and Bag Tee (Accessory)

Wall Mount Models: 2000 and 2000-OS, 3000 Cabinet Mount Models: 2050, 2055 and 2060 Bag Tee Models: P1407A, P2407A and P1407B

NOTICE READ MANUAL COMPLETELY BEFORE OPERATING THIS DEVICE

This manual contains instructions on periodic 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.









IMPORTANT NOTES TO THE USER

INTENDED USE: Analgesia Delivery System

This device is intended for patient use by an attending physician or dentist properly trained in its use. Porter Instrument Company, Inc. recommends the user be thoroughly familiar with the use of Nitrous Oxide - Oxygen Conscious Sedation for patient analgesia and be properly trained in its administration prior to using this product. For training requirements on the administration of Nitrous Oxide - Oxygen Conscious Sedation, contact the appropriate regulatory authority in your country, state, or province. Training is recommended to provide a practical, hands-on capability and an understanding of the behavioral aspects of Nitrous Oxide Sedation and will complement the safety features of this device.

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.

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

It is advisable, on a two (2) year cycle, to have the MXR Flowmeter factory checked and serviced. The Nitrous Oxide Failsafe System is made of moving parts. Between servicing intervals, it is advisable to safeguard against potential malfunctions by performing the failsafe check before each and every use of the unit. Safe operating techniques, learned during your $N_2O - O_2$ Conscious Sedation training, should always be used.

Inspect and maintain the analgesia delivery system to prevent N_2O leaks in all hoses, connections and fittings. Repair all leaks immediately.

Use scavenging. Monitor for N_2O in the operatory to insure that controls are effective in achieving low levels of ppm (<u>parts per million</u>) exposure. Contact your Porter dealer for details on monitors and testing.



New or modified installations - properly connected gas pipelines are absolutely essential to patient safety. The dealer 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 dealer 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.

SAFETY FEATURE CHECKS

IMPORTANT: These are safety features, which you should routinely check to assure proper function. If any of these safety features are not functioning properly, contact your Dental Dealer or Porter Instrument Company and arrange for the necessary repairs. Porter Instrument Company recommends the repairs be made

before reusing the device.



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.

NITROUS OXIDE FAILSAFE SYSTEM CHECK BEFORE EACH USE

- 1. Set the right-hand total Flow Control Knob to zero and set the left-hand Concentration Control Knob to zero. (See Figure 1-Items 4 and 5: Rotate control knobs to stop.)
- 2. Be sure O_2 and N_2O are connected to your MXR and line pressure for both gases is 50 PSIG (which is standard).
- 3. Turn the Concentration Control Knob to 50%. There should be no flow of N_2O . This is a check of the static position of the Nitrous Oxide Failsafe System valve.

NOTE: A momentary low flow of N_2O (about 1 L/min for about a second) may be seen if the Concentration Control Knob is turned to zero before turning the Flow Control Knob to zero. This is N_2O gas trapped between the Nitrous Oxide Failsafe System valve and the Concentration Control Knob valve and is a normal occurrence. No other N_2O flow should be observed.

- 4. With the Concentration Control Knob still set to 50%, turn the Flow Control Knob to achieve a flow of 3 to 4 L/min of O₂. You should observe an equal amount of N₂O flowing by gradually turning the Flow Control Knob. (Refer to Monthly Calibration Check on Page 8, to read ball float on flowmeter tubes.)
- 5. Interrupt the flow of O₂. This will check the dynamic status of the Nitrous Oxide Failsafe System valve. This can be done by either disconnecting the oxygen hose from the wall or shutting off the oxygen at the tank. The Nitrous Oxide flow should drop as the Oxygen flow decreases, stopping completely before the Oxygen float drops to zero.



If the Nitrous Oxide Failsafe System fails to perform as indicated, do not use this product prior to repair. Improper function of this safety feature may permit Nitrous Oxide to flow independently of the flow control knob, potentially allowing Nitrous Oxide to flow to the patient without Oxygen.

CONCENTRATION CONTROL KNOB VALVE CHECK MONTHLY

Set the Concentration Control Knob to 50%, and Flow Control Knob to 2 to 3 L/min. The ball indicators will be at about the same height (If not, refer to **Monthly Calibration Check** section on Page 7 for the procedure on checking the accuracy of the meter.). Turn the Concentration Control Knob to zero. The N₂O flow should drop to zero. You essentially perform the check at the end of every procedure when you oxygenate the patient with 100% O₂.

POWER OXYGEN FLUSH CHECK MONTHLY (O₂ SUPPLY PRESSURE AT 50 PSIG)

Disconnect the corrugated rubber tubing from the bag tee outlet (Figure 1, Item 11). With both control knob valves OFF, depress the power (O_2) flush button while blocking the flow from the front of the bag tee. For proper operation, the gas reservoir bag

should fill within about 5 seconds.



NON-REBREATHING VALVE

CHECK MONTHLY

With unit turned OFF, disconnect the corrugated rubber tubing from the Rubber Goods and breathe into the corrugated tubing connected to the bag tee. You should not be able to fill the bag with exhalation gas. If the bag fills, the system's Non-Rebreathing Valve is not functioning properly and should be replaced.



EMERGENCY AIR VALVE CHECK MONTHLY

With unit turned OFF, disconnect the corrugated rubber tubing from the Rubber Goods and draw air with your mouth through the corrugated tubing connected to the bag tee. You should be able to draw ambient air through the Emergency Air Valve (the gas bag may have to fully collapse first). Air going through the valve sounds

different than normal gas flow.

FEATURES:



1. Oxygen Flowmeter Tube indicates the flow of O_2 in L/min $\pm 5\%$.

2. Nitrous Oxide Flowmeter Tube indicates flow of N_2O in L/min $\pm 5\%$.

3. Nitrous Oxide Failsafe System. Dualseal oxygen-piloted valve system that automatically maintains the % N_2O concentration setting with any change in the O_2 flow or pressure N_2O flow is proportionately reduced if O_2 is shut off or the pressure is reduced (check before each use).

4. Flow Control Knob controls the combined flow of O_2 and N_2O (or O_2 flow only when the Concentration Control Knob is set to 0%).

5. Concentration Control Knob controls the % concentration of N₂O but does not change the O₂ flow rate. (70% Maximum N₂O delivery.) (Check Monthly)

6. **Emergency Air Valve** automatically provides the patient with ambient air if gas flow is interrupted. (Check Monthly)

7. **Non-Rebreathing Valve** guards against CO₂ build-up and rebreathing of used gases. (Check Monthly)

8. **Positive On - Off Switch** Reduces the possibility of accidentally leaving the machine ON.

9. **Power Flush** provides extra delivery of O_2 to the breathing bag. (Check Monthly)

10. **O₂ Quick Connect** (left side of machine), facilitates connection of positive pressure/ demand valve for emergency Oxygen.

11. **Bag Tee Outlet** connects to fresh gas tubing.

12. 3 L Bag Connection

DIRECTIONS FOR USE

NOTE: These directions provide a basic mechanical working's description. A training course that emphasizes a practical, hands-on approach together with instruction on safe administration techniques is recommended.

- 1. Turn ON unit by pushing in the ON / OFF switch.
- 2. Open N_2O / O_2 tank valves.
- Using Flow Control knob, set flow rate of O₂ to desired rate, keep bag about ¾'s full. Rotate flow control knob upwards (clockwise) to increase flow. (See Figure 1, Item 4)



 Set N₂O concentration to desired level by rotating Concentration Control knob upwards (counterclockwise) to increase concentration, as read by percentages inscribed on the control knob. Rotate slowly until desired level is achieved. (See Figure 1-Item 5)



- 5. Flow Control knob may be re-adjusted to bring the total flow of gases back to desired level, when concentration is increased or decreased. Total flow is equal to the sum of right and left tube readings. (See Figure 2, to read ball float on flowmeter tube.)
- 6. When the procedure is nearing completion and patient is placed on O_2 only, use Power Flush to evacuate N_2O from bag. Push button in and hold to activate. Release button to stop the power flush.
- 7. When procedure is finally completed, turn off **both** control knob valves for gas shut off.

IMPORTANT NOTE: When the Concentration Control knob is open, the Flow Control knob is closed, and there is no N_2O flow indicated in the flow tube, the Nitrous Oxide Failsafe System is designed to stop the flow of N_2O . This safety feature should not be used as the primary shut off mechanism.

- 8. Place the ON / OFF switch (primary shut-off mechanism) in the OFF position. (Push from <u>back</u> of ON / OFF switch.) NOTE: If control valves are still open, gas flows should stop at this point.
- 9. Turn OFF the gas supply at the tank at the end of the day.

NOTE: If your unit does not operate as described above, please contact your Dental Dealer or Porter Instrument Company.

MONTHLY CALIBRATION CHECK

The MXR Flowmeter is designed to maintain its accuracy and performance without routine user maintenance being required. The flowmeter tubes and ball floats are very resistant to accuracy changes over time such that the direct readings of the L/min on the scales maintain their accuracy. However, the user can check the relative accuracies of the % concentration and total flow valve system by performing a simple check.

1. A calibration check of the % concentration can be done by setting the % concentration knob to 50% and the flow control knob to 3 to 4 L/min. Check to see if the tube readings are within 0.5 L/min of each other. Servicing is indicated if the readings are out of this tolerance.



NOTE: Adequate and safe conscious sedation can be achieved even if the % concentration is outside of the listed tolerance, since tube scale accuracies are maintained. However, a change in the % concentration calibration is an indication of overall flowmeter condition. Porter servicing is available, including recalibration, pressure testing, internal component checking and replacement, and final factory testing by contacting your Authorized Porter Dental Dealer. It is advisable, on a two (2) year cycle, to have the MXR Flowmeter factory checked and serviced.

SYMPTOM	POSSIBLE CAUSE	REMEDY
No flow of O ₂ or N ₂ O when ON /OFF switch is ON and left knob is set at a concentration of N ₂ O or O ₂ the right knob is rotated to give flow.	 O₂ supply not turned ON. Machine not connected to pipeline system. Empty O₂ cylinders. 	 Turn O₂ regulator in tank room ON. Connect to wall outlet. Replace with full cylinder.
Can get O ₂ flow but cannot get N ₂ O flow.	 N₂O supply not turned ON. N₂O cylinder empty. 	 Turn ON N₂O cylinder. Replace with full cylinder. .
With N2O concentration set, both flows vary proportionally with no change in flow setting.	O2 regulator is varying pipeline pressure.	Check O_2 regulator. Be sure O_2 manifold pressure is 50 PSIG ±2 PSIG. If not, call Dealer for service.
Meter will flow N_2O without any O_2 flow in the O_2 tube.	Failsafe failure.	Take out of service and return to Porter.
Cannot get 9 ½ L/min O ₂ flow with concentration control knob OFF and flow control knob full ON.	Low O2 pressure setting.	Check O_2 regulator. Be sure O_2 manifold pressure is 50 PSIG ±2 PSIG. If not, call Dealer for service.
Ballooning of the gas bag.	90° Elbow connected onto bag tee is pushed on too far, blocking movement of the non- rebreathing valve.	Remove rubber goods and 90° elbow from bag tee. Reconnect elbow and rubber goods.
Gas is leaking from the ON/OFF switch.	Nick or cut in o'rings on the ON/OFF switch.	Call Dealer for service.

TROUBLESHOOTING CHART FOR MXR FLOWMETERS

CLEANING METHODS: For cleaning the outside of the flowmeter and accessories, we recommend the use of an approved disinfectant for the dental environment. Follow the disinfectant manufacturer's directions for use and their cautions.

FLOWMETER MOUNTING: The Dental Flowmeter may be mounted to a telescoping wall mount using the existing hanger on the back of the flowmeter, or to a mobile stand using the threaded hole at the bottom of the failsafe block. There are various options for mounting the flowmeter within cabinets. Contact your local dental dealer for mounting options.

MXR FLOWMETER FEATURES AND SPECIFICATIONS

Flowmeter: Indicates flow in L/min and percent N₂O of total flow with accuracy of \pm 5%. Includes Diameter Index Safety System (DISS) for N₂O and O₂ connectors.

Flowmeter Tubes: Direct reading flow tubes for Oxygen and Nitrous Oxide for accurate, visual flow readings.

Dual Seal Fail-Safe: Automatically reduces N₂O if O₂ is shut off or pressure is reduced

Gas Control Block: One-piece, solid aluminum construction. Eliminates internal gas leaks.

Gas Flow Adjustment Knobs: Control knob-type knobs for quick, accurate, one-hand adjustment of gas flows.

Emergency Air Valve: Automatically provides patient with ambient Air if gas flow is interrupted for any reason.

Non-rebreathing Check Valve: Prevents rebreathing of used gases and guards against CO_2 build-up.

Positive ON / OFF Switch: Eliminates possibility of accidentally leaving the machine on. Color-coded for Oxygen.

Oxygen Power Flush Button: Provides extra delivery of O₂. Button is accessible to override all other gas flows and deliver 100% O₂. Color-coded for Oxygen.

Flow Control knob: Total flow adjustment knob which controls flow of both N_2O and O_2 at any desired concentration. Total flow can be adjusted without affecting concentration. Includes posistop needle valves for adjustment of all flows—prevents damage to valves and seats.

Oxygen Quick Connect: Facilitates connection of resuscitation equipment to the central system.

SAFETY:

ADA Guidelines: In addition to the fail-safe and other safety features found on most sedation machines, effective August 1976, the following specifications were added to those required for acceptance by the ADA Council on Dental Materials and Devices: 1. Emergency Air Valve; 2. Non-rebreathing Check Valve; and 3. Resuscitator Quick Connect.

In addition, the ADA Council requires that: 1. The gas storage and delivery system meet the recommendations of the National Fire Protection Association (NFPA).; 2. The system be installed by a competent supplier of gases and equipment.

NFPA Codes: To assure safe operation and conformation to local fire codes, Porter Instrument Company, Inc. Nitrous Oxide Sedation Systems meet or exceed the guidelines established by the National Fire Protection Association for Nonflammable Medical Gas Systems, NFPA 99. Copies of NFPA 99 or portions thereof may be obtained by writing to *National Fire Protection Association*, *Batterymarch Park, Quincy, MA 02269-9904 USA* or call: 1-800-344-3555

PARTIAL LISTING OF REFERENCE MATERIAL

<u>Dentists' Desk Reference: Materials, Instruments & Equipment</u> - American Dental Association

<u>Relative Analgesia in Dental: Inhalation Analgesia and Sedation with Nitrous Oxide</u> -Harry Langa, D.D.S.

Conscious - Sedation in Dental Practice - C. Richard Bennett

Sedation - A Guide to Patient Management - Stanley F. Malamed

<u>The Practical Use Nitrous Oxide - Oxygen Conscious Sedation</u> - Robert E. Hamric, D.M.D

WARRANTY

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 Porter Instrument Company, Inc. be liable for incidental or consequential damages as those terms are defined in the uniform commercial code.

Porter Instrument Company, Inc. 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 Porter Instrument Company, Inc. shall constitute a warranty by Porter Instrument Company, Inc. or give to rise to any liability or obligation of Porter Instrument Company, Inc.

Porter Instrument Company, Inc. 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 Porter Instrument Company, Inc.; (3) not installed in strict compliance with applicable codes and ordinances; or (4) not installed by an authorized Porter Instrument Company, Inc. Porter Instrument Company, Inc.'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 Porter Instrument Company, Inc. distributors. All billing will be done through said distributors. Direct orders will be handled through the authorized local dealer as determined by Porter Instrument Company, Inc.

RETURNS All returned merchandise will be handled through the local Porter Instrument Company, Inc. distributor. No returns will be accepted unless authorized in writing by Porter Instrument Company, Inc. and accompanied by the original shipping invoice. All returns are subject to restocking charge.

Policies subject to change without notice.



Porter Sedation Systems are accepted as devices for use in providing Nitrous Oxide / Oxygen inhalation sedation in dentistry. Council on Scientific Affairs – American Dental Association.



The Quality System for Porter Instrument Company, Inc. is Certified to ISO 9001. The scope of our registration is: "The design, manufacture, distribution and servicing of Dental Flowmeters, Gas Scavenging Systems, Dental Steam Sterilizers, Gas Distribution Systems and Office Communication Systems for use in the Dental Profession."