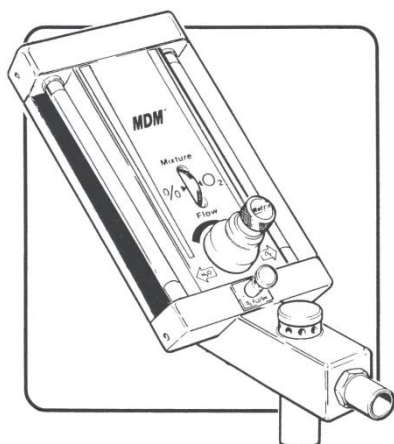




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MDM Monitored Dial Mixer Nitrous Oxide – Oxygen Sedation Flow Meter Installation Manual



CE
0413



European Communities should contact the Authorized Representative listed below regarding any Medical Device Directive (MDD) inquiries.

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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

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 MXR Flowmeter. A WARNING alerts you to a possible hazard to people. A CAUTION alerts you to the possibility of equipment damage.

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: Workers are exposed to N₂O during administration of N₂O/O₂ 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 N₂O concentrations in patient procedures. Your flowmeter accessory Porter scavenger system is an important part of the system of controls.

WARNING: Porter Instrument equipment utilizes the **cross+protection** system. The flexible hose and connectors that connect to the flowmeter are diameter indexed; 3/8" O.D. for Nitrous Oxide and 1/2" for Oxygen. The **cross+protection** system is designed to prevent misconnection of Oxygen and Nitrous Oxide piping. **DO NOT ATTEMPT TO CHANGE THE DIAMETERS OR CONNECTORS OF THE FLOWMETER!** Tampering with the **cross+protection** system constitutes acceptance of liability by the installer. For your own protection, as well as that of the Doctor and the patients, use 3/8" O.D. tubing for all Nitrous Oxide lines and 1/2" O.D. tubing for all Oxygen lines.

To assure safe operation and conformation to local fire codes, all Porter Instrument flowmeter systems are designed to be used with sedation delivery

systems mounted inside walls and they 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; or call 1-800-344-3555

WARNING: New or modified 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.**

WARNING: During any power outage, remember to turn OFF the flowmeter and manually turn OFF the tank valves. With centralized, electrically powered gas systems, if gas was flowing when the power went out and the flowmeter is left ON, gas will be flowing when the power is restored.

CAUTION: This device is for use by or on the order of a physician, dentist or licensed healthcare professional.

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).

DESCRIPTION AND MECHANICAL ASSEMBLY

This manual covers the operation of the MDM Nitrous Oxide/Oxygen mixer. The MDM is a mechanical mixer for regulating the flow of Nitrous Oxide and Oxygen from a gas supply to a conscious patient for the purpose of conscious sedation analgesia. Each MDM model includes the **MDM Flowmeter Head** with one of the following:

Conventional Rubber Goods: 4" Breathing Tube, Large Nasal Inhaler and 3 Liter Breathing Bag

Assembly Procedure:

1. Position breathing bag as shown and slide opening in breathing bag over outside diameter of bag mount. (Figure 1)
2. Slide one end of breathing tube over outside diameter of breathing tube connector.
3. Slide connector "Y" fitting of large nasal inhaler into free end of breathing tube.

Or

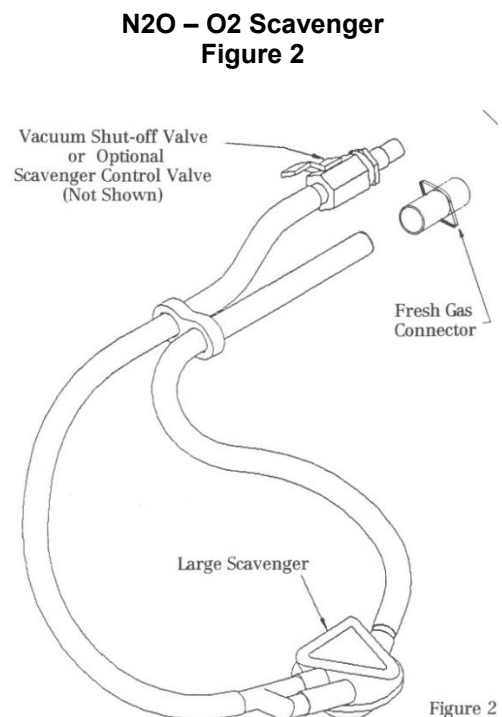
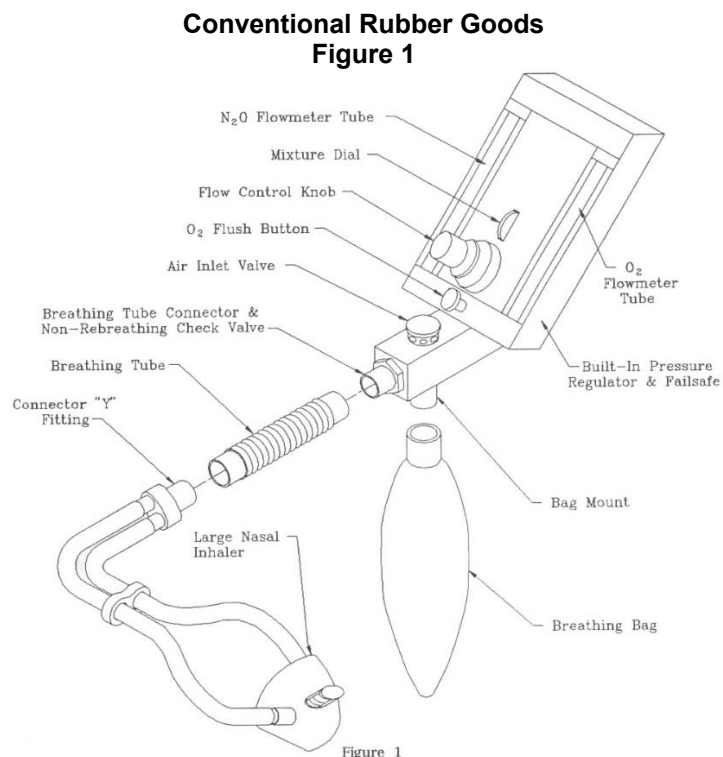
N₂O - O₂ Scavenger: Large Scavenger and 3 Liter Breathing Bag (Figure 2)

Assembly Procedure:

1. Position breathing bag as shown and slide opening in breathing bag over outside diameter of bag mount. (Figure 1)
2. Slide the 22mm hose cuff of the scavenger over the breathing tube connector. (Figure 2)
3. Refer to scavenging nasal inhaler instructions for methods of connecting vacuum shut-off valve

MDM AS SUPPLIED WITH CONVENTIONAL RUBBER GOODS

The following assembly procedure is common for all MDM models supplied with conventional rubber goods (see Figure 1):



INTENDED USE:

Flowmeter for Analgesia Delivery System

This device is intended for patient use by an attending physician, dentist or licensed professional properly trained in its use. Porter Instrument 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.

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 your Porter dealer for details on monitors and testing.

GAS SUPPLY CONNECTION

After installation of the flowmeter, connect the nitrous oxide and oxygen supply lines to the Diameter Indexed Safety System (DISS) fittings located on the back of the flowmeter unit. It is important that the regulators for both gases be set to give pressures in the range of 53 PSIG \pm 2 PSIG.

Confirm the absence of leaks at pressure connections on the unit. Bubbles will appear at leaking locations when a soap / water solution is used. This procedure is recommended each time a cylinder is changed.

Refer to FM-916 Mobile "E" Tank Stand Installation and Instructions for connecting gas supply to the flowmeter and tank installation to mobile stand.

MDM SPECIFICATIONS: (Figure 3)

Physical Size: 5" wide x 9 $\frac{3}{4}$ " high x 12 $\frac{1}{4}$ " deep

Weight: 7 lb.

Fresh Gas Outlet Size: 15mm ID x 22 mm OD

Nitrous Oxide Inlet: Male DISS

Oxygen Inlet: Male DISS

Maximum Oxygen Flow Rate: 10 LPM

Maximum Nitrous Oxide Flow Rate: 10 LPM

Minimum Nitrous Oxide Concentration: 0%

Maximum Nitrous Oxide Concentration: 70%

Optional Maximum N₂O Concentration: 50%

Oxygen and Nitrous Oxide Flow Tube: Accuracy (Full Scale) $\frac{1}{2}$ L

Inlet Oxygen Pressure Maximum: 50 - 55 PSIG

Inlet Nitrous Oxide Pressure Maximum: 50 - 55 PSIG

Mixture Dial Calibrations: With supply pressure at 50 to 55 PSIG and total flow of 10 LPM, oxygen and nitrous oxide flow rates within $\frac{1}{2}$ LPM of mixture dial calibration. (As indicated on individual flow tubes.)

Total Flow Range 2 to 16 LPM at 50 to 55 PSIG supply pressure and dial mixture set at 50% (As indicated on individual flow tubes.)

Total Flow Variation with supply pressure at 50 to 55 PSIG and total flow of 10 LPM, total flow variation within $\frac{1}{2}$ LPM of total flow throughout mixture dial range. (As indicated on individual flow tubes.)

NOTE: All specifications subject to manufacturing tolerance.

MDM SPECIFICATION DIAGRAMS:

STANDARD MDM FLOWMETER HEADS

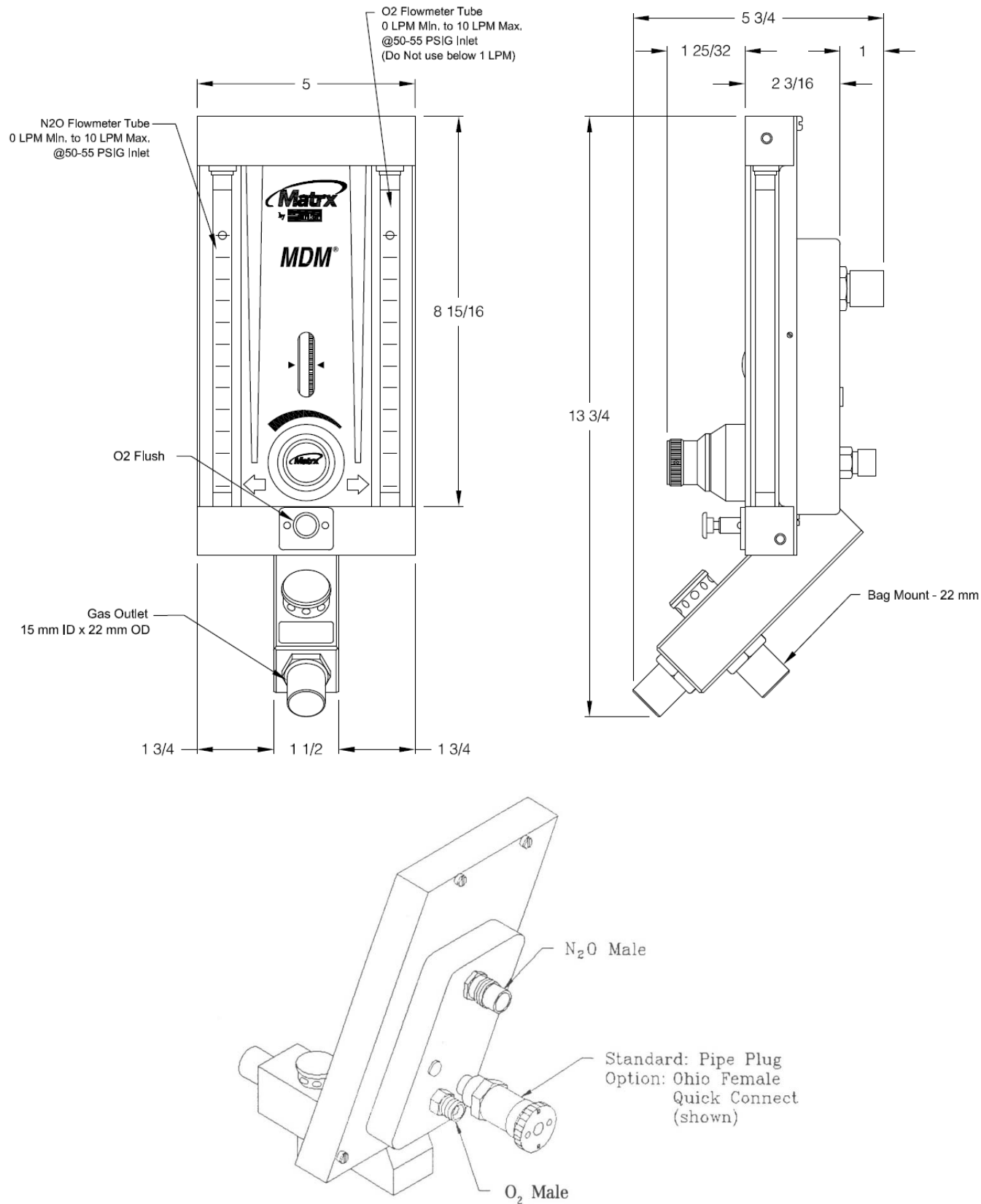


Figure 3

PRE-OPERATION

1. Rotate flow control valve fully counter-clockwise (See Figure 4). Rotate mixture dial to 100% position.
2. Connect hoses to the medical gas source (to flowmeter) and to the gas supply cylinder. (Refer to FM-916 for Mobile "E"-Tank Stand Installation and Instructions).
3. Activate gas source. **NOTE** For initial start up of analgesia head, always have a medical gas source shut-off. For multiple outlet station manifold systems utilizing quick-connect fittings, the analgesia unit can be moved from station to station without shutting off the medical gas source once pre-operation and functional tests are completed.
4. Turn on manifold medical gas system as per manufacturer's instructions. Adjust line pressures as instructed. Pressure must be 50 - 55 PSIG.
5. For portable systems utilizing "E" cylinder tanks, refer to FM-916 Mobile "E" Tank Stand Installation and Instructions.

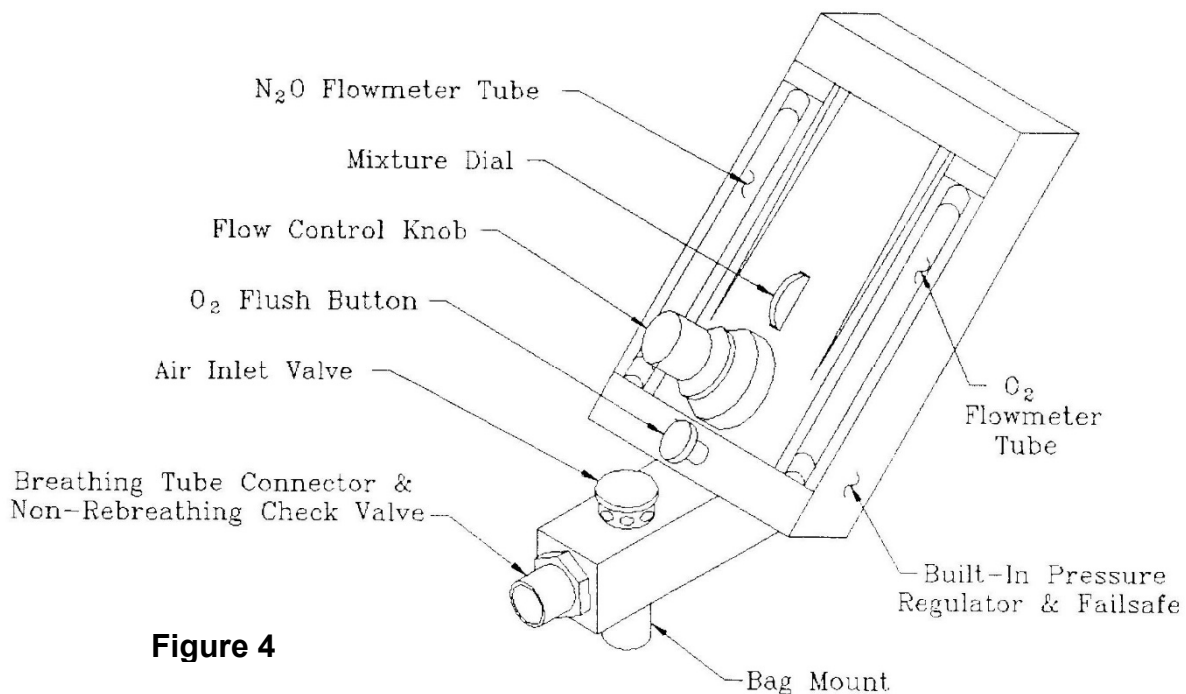


Figure 4

The Controls and Indicators

Mixture Dial - controls setting of oxygen concentration of gas mixture. Adjustment of this control does not affect total flow rate.

Flow Control Knob- controls total flow rate of gas mixture. Adjustment of this control does not affect mixture concentration.

Oxygen Flush Button - when manually pressed, provides rapid inflation of the breathing bag with oxygen when required.

Nitrous Oxide and Oxygen Flowmeters - the amount of gas flowing is indicated by reading the position of the center (maximum diameter) of the ball in the glass tube.

FUNCTIONAL TESTS

NOTE: The failure of any one of the following tests will require the analgesia unit to be returned for service. These tests must be conducted periodically to insure that your analgesia unit is performing optimally (see Figure 4).

1. Machine Turn-On Test – Check Monthly

With gas source activated and mixture dial set at 100%, turn the unit on by rotating the flow control knob counter-clockwise. The ball located in the oxygen flowmeter tube should start to move up the tube within one (360°) rotation of the flow control valve.

2. 100% Oxygen Test – Check Monthly

Adjust mixture dial to 100% oxygen position and rotate flow control valve until 10 LPM is indicated on oxygen flowmeter tube. Observe nitrous oxide tube and ball. The ball may show some indication of motion but the top of the ball must remain below the 1 LPM mark on the tube.

3. Total Flow Test – Check Monthly

Adjust mixture dial to 50% oxygen position. Adjust flow control until Oxygen and Nitrous Oxide flowmeter tubes show approximately 5 LPM each gas.

Without further adjustment of flow control knob and a total of 10 LPM, move mixture dial through full travel. Total flow must be within ½ LPM of 10 LPM through full travel. (As indicated on the individual flow tubes.)

4. Failsafe Test – Check Before Each Use

Turn off and disconnect from wall outlet oxygen gas supply to MDM and observe that nitrous oxide flowmeter float falls at same rate as oxygen flowmeter float.

5. Oxygen Flush Test – Check Monthly

Depress and release oxygen flush button to assure that breathing bag can be inflated.

6. Non-Rebreathing Valve Test – Check Monthly

Blow into the breathing tube connector. Exhaled air must not pass through breathing connector.

7. Air Inlet Valve Test – Check Monthly

Temporarily plug breathing bag mount and inhale through breathing tube connector. Room air must enter through air inlet valve. (Remove temporary plug).

Then temporarily plug the breathing tube connector and blow into breathing bag port. Exhaled air must not escape through air inlet valve. (Remove temporary plug.)

BASIC DELIVERY TECHNIQUE:

Practice titration. Titration is a method of administering a substance by adding definitive amounts of a drug until an endpoint is reached. For nitrous oxide / oxygen (N₂O) / O₂) sedation, N₂O is given in incremental doses until a patient has reached a comfortable relaxed state of sedation. The ability to titrate N₂O is a significant advantage because it limits the amount of drug to that which is required by the patient. If titration is done properly, the patient does not receive any more of the drug than is necessary. The amount of N₂O required by a patient on any given day or time varies.

For information on titration, a most valuable resource for the practitioner is the Handbook of Nitrous Oxide and Oxygen Sedation, written by Clark and Brunswick and published by Mosby (www.mosby.com). This text is a concise and contemporary guide for nitrous oxide / oxygen administration.

OPERATION

1. Set the mixture control to 100% Oxygen.
2. Set the Oxygen flow rate to equal total gas flow to be administered to the patient.
3. Apply nasal hood to patient.
4. Gradually decrease percentage of Oxygen until determined ratio is reached.
5. To remove patient from conscious sedation, set mixture valve to 100% Oxygen.
6. If Oxygen is required, press Oxygen flush button.
7. When procedure is completed, shut off machine.
8. If using a portable cylinder mount system, turn off the tanks. If using a central gas system, disconnect the gas system then disconnect the gas supply hose from the outlet station.

MAINTENANCE AND SERVICE

It is advisable, on a two (2) year cycle, to have the MXR Flowmeter factory checked and serviced.

Perform "Functional Tests" Monthly as described on page 4.

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

All service and repair must be accomplished at Matrix by Parker. Have your authorized distributor return the unit to our factory and arrange for a loaner unit for yourself.

CLEANING METHODS

We recommend the use of an approved disinfectant for the healthcare environment for cleaning the outside of the flowmeter. Do not spray disinfectant directly onto meter. Spray disinfectant into disposable towel and wipe unit thoroughly removing excess disinfectant to eliminate buildup.