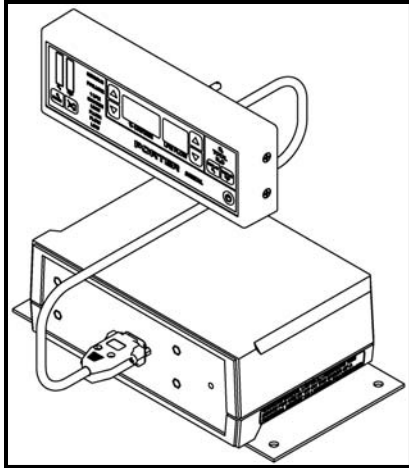




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PORTER DIGITAL MDM Operations and Installation Manual

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 Flowmeters, Gas Scavenging Systems, Gas Distribution Systems and Office Communication Systems for use by a physician, dentist or licensed healthcare Profession.”

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 PORTER Digital MDM 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).

Symbol	Description
	MEDICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS IN ACCORDANCE WITH UL 2601-1, AND CAN/CSA C22.2 NO. 601.1
	Alternating Current
	Protective Earth (ground)
	Attention, consult the accompanying documents

 **WARNINGS and PRECAUTIONS**

ELECTRICAL CONNECTIONS & GROUNDING INSTRUCTIONS

The unit must be grounded. If it should malfunction or breakdown, grounding provides a path of least resistance for electrical current to reduce the risk of electric shock.



A known Protective Earth (ground) connection must be made via one of the following methods:

- 1) The third wire on the power cord when plugged into an appropriate outlet that is properly installed and grounded in accordance with all local codes or ordinances.
- 2) The external ground lug on the rear of the device.

A Protective Earth (ground) connection is a connection attached to the facility grounding point outside the facility. A licensed electrical person should be consulted to confirm the Protective Earth (ground) connection.

Do not use an electrical cord with nicks, cuts, or other damage. Do not use the unit with an extension cord as it will be subject to electromagnetic interference (EMI).



REQUIREMENTS AND FEATURES

BAG TEE REQUIREMENTS

A bag tee containing an air inlet valve is required for use with this unit. The bag tee is provided separately for remote mounting. Porter Scavenging Nasal Inhalers provide the patient connection.

FACILITY PIPING

The user **MUST** perform tests independent of the dealer or contractor to verify that all pipelines are connected correctly. If you are unfamiliar with piping systems, consult NFPA-99 Health Care Facility piping guidelines. The user has the ultimate responsibility for properly connected pipelines essential to patient safety.

DIAMETER INDEXED SAFETY SYSTEM

Gas connections in the DIGITAL MDM mixer are mechanically indexed using the Diameter Indexed Safety System (DISS). This feature helps to prevent the crossing of pipelines. Under no circumstances should these connections be altered.

DISCONNECT POWER

There are no user-serviceable parts inside this unit. A shock hazard exists if power is not disconnected prior to any internal servicing or maintenance. Always disconnect the power source before inspection or repair.



SAFETY ALARM SYSTEM TEST

The user should test the alarm system for proper operation prior to each clinical use.

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. The devices permit the operator to adjust the percent of oxygen through a range of 100% to 30% (and thereby control the ratio of oxygen to nitrous oxide). The operator can also control the total volume of mixed gas up to 9.9 liters per minute.

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 oxide supply lines to the Diameter Indexed Safety System (DISS) fittings located on the back of the flowmeter base unit. It is important that the regulators for both gases be set to give pressures in the range of 50 PSIG to 55 PSIG. Confirm the absence of leaks at pressure connections on the base unit. Bubbles will appear at leaking locations when a soap / water solution is used.

User Responsibility

This product should not be repaired other than in accordance with written instructions provided by Porter. The user of this product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Porter. It is the user's responsibility to ensure that the correct gas, at the correct pressure, is supplied to the fittings at the rear of the base unit.

Machine Diagnostics

The DIGITAL MDM mixer performs self checks at start up and during operation. If any errors are detected, the unit displays EE on the %O₂ display and an error code on the FLOW display. If an error code appears, remove

the unit from patient service and call the Porter Technical Service Department at 1-888-723-4001. To aid in the diagnostics of the unit, make note of the final error code displayed.

Description of Unit: The DIGITAL MDM mixer consists of a Control Unit attached to a Base Unit via an Interface cable. Note - Control and Base Units are calibrated together and must remain together (match serial numbers on each unit). Only use Porter Interface cable (EMI protection). The Control Unit interface is shown in Figure 1. The device permits the operator to adjust the percent of oxygen through a range of 100% to 30% (and thereby control the ratio of oxygen to nitrous oxide). The operator can also control the total volume of mixed gas up to 9.9 liters per minute.

Mixture Control: The DIGITAL MDM mixer precisely mixes oxygen and nitrous oxide from local cylinders or pipeline gas systems, and delivers the electronically controlled mixture to the bag tee outlet.

Built-In Safety: A series of alarms (see Safety Alarm System page 6) alert the user to any problem condition within the DIGITAL MDM mixer unit or in the gas supply.

Displays and Indicators: In the following, the location numbers refer to Figure 1.

Flow Display: The LPM FLOW display (4) normally displays the total gas flow rate. It also displays the individual nitrous oxide or oxygen flow rates when either the N₂O or O₂ flow display controls (6) are pressed. The gas flow being displayed is indicated in the flow indicator (5) by O₂, TOTAL or N₂O.

% OXYGEN Display: The % OXYGEN display (3) indicates the oxygen concentration set point in the total flow.

Gas Flow Indicators: Gas flow is indicated by bar graph LEDs (1). A green bar graph represents O₂ while blue represents the N₂O flow. The number of lit bars gives a graphical indication of the flow level of a particular gas.

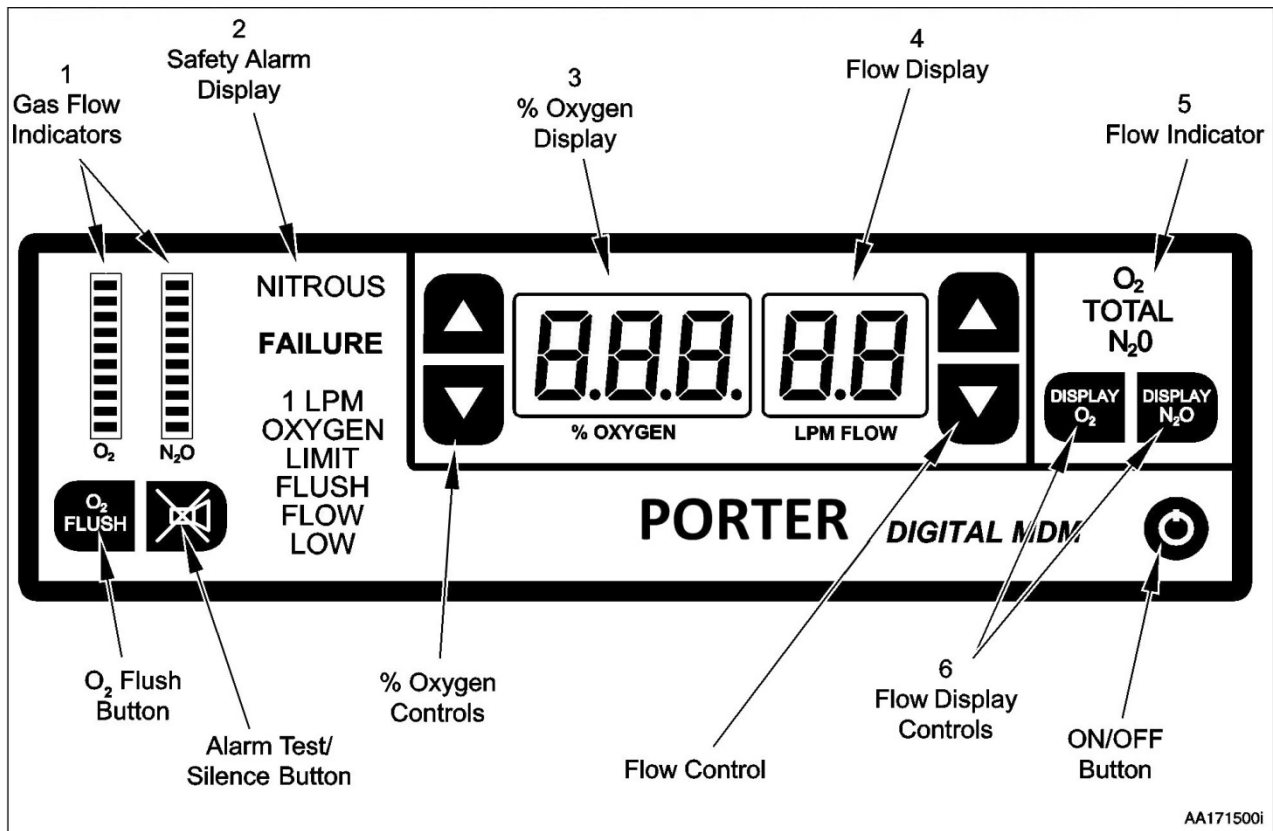


Figure 1. PORTER DIGITAL MDM Mixer Control Unit Front Panel (figure shows all LEDs illuminated)

SAFETY ALARM SYSTEM

There are four alarm conditions on the DIGITAL MDM mixer. They appear in the safety alarm display (see Figure 1, item 2) only when conditions warrant. Otherwise, they are not visible. The alarm conditions are:

OXYGEN FAILURE: This alarm indicates that the set oxygen (O_2) flow cannot be delivered. Check the oxygen supply. During an OXYGEN FAILURE alarm, the nitrous oxide delivery is automatically shut off. The LPM FLOW and % OXYGEN displays are off.

NITROUS FAILURE: This alarm indicates that the set nitrous oxide (N_2O) flow cannot be delivered. Check the nitrous oxide supply. During a NITROUS FAILURE alarm, the LPM FLOW display indicates oxygen flow and the % OXYGEN display is off.

Both the OXYGEN FAILURE and NITROUS FAILURE are self-canceling alarms. When the gas is restored, the unit returns to the flow rate and mixture ratio which were in effect before the alarm condition.

1 LPM OXYGEN LIMIT: This message is displayed when the oxygen flow rate reaches a value of 1 LPM (liter per minute); the unit will not allow the oxygen flow rate to go below this value. If the user attempts to lower the % OXYGEN while this message is displayed, the unit compensates by increasing the total flow rate.

FLUSH FLOW LOW: This message indicates that the oxygen flush flow rate is less than 10 LPM. Check the oxygen supply pressure.

KEY PAD CONTROLS

CAUTION: Operate key pad with finger pressure only. Do not use hard or sharp objects. Failure to do so may result in DAMAGE to front panel.

On/Off Key: The ON/OFF key controls the operation of the unit. Momentarily depressing the ON/OFF key changes power state from OFF to ON or ON to OFF.

Note: If the power to the unit is interrupted and then restored, either by disconnecting / reconnecting the power cord or by local power failure, the unit will display OFF. The operator must press the ON/OFF key to restart the unit. The unit will then display default values of 100% oxygen at 5 LPM.

CAUTION: After turning the device off, or when the unit is not in use, all oxygen and nitrous oxide supply cylinder valves must be closed.

Flow Control: The LPM FLOW key pad [\blacktriangle or \blacktriangledown] controls the total flow rate delivered by the unit. Pressing the appropriate key momentarily increases or decreases the total flow rate by 0.1 LPM. By pressing and holding a key, the total flow rate indication changes slowly for the first two steps, then changes at a faster rate for the remainder of the time the key is held. An audible signal indicates that a limit has been reached.

% O_2 Control: The % OXYGEN key pad [\blacktriangle or \blacktriangledown] controls the percentage of oxygen delivered by the unit. Press the appropriate key momentarily to increase

or decrease the oxygen percentage one step (1% or 5%). Pressing and holding the key changes the oxygen percentage slowly for the first two steps, then faster for

the remainder of the time the key is held. This varies the ratio of oxygen to nitrous oxide. An audible signal indicates that a limit has been reached.

Setting % OXYGEN Step Amount (1% or 5%): The DIGITAL MDM mixer is shipped from the factory programmed to change 1% for each press of the % OXYGEN key pad [\blacktriangle or \blacktriangledown]. The amount can be changed from 1% to 5% by using the DISPLAY N_2O and DISPLAY O_2 keys and the following procedure:

1. Press and hold the DISPLAY N_2O key.
2. While pressing the DISPLAY N_2O key, press the DISPLAY O_2 key until the audible alarm sounds.
3. Release both keys.

The audible signal indicates the change has occurred and is programmed in memory. The unit will remain in the new mode until this sequence is repeated. Unplugging or turning the unit off will not affect the programmed mode.

Flow Display Control: The key pad DISPLAY O₂ or DISPLAY N₂O select the gas flow rate displayed on the flow display. Press and hold the DISPLAY N₂O key to display the nitrous oxide component of the total flow. Press and hold the DISPLAY O₂ key to display the oxygen component of the total flow. If neither key is held, the LPM FLOW display indicates the total gas flow.

Oxygen Flush Key: Pushing the O₂ FLUSH key delivers 100% oxygen directly to the mixed gas outlet at the rear of the unit. This outlet is connected to the patient through the breathing tube connector (see Figure 2). While the key is pushed, 100% oxygen is delivered continuously at a minimum flow rate of 20 LPM. Releasing the key returns the unit to the flow rate and mixture ratio which were in effect prior to the flush.

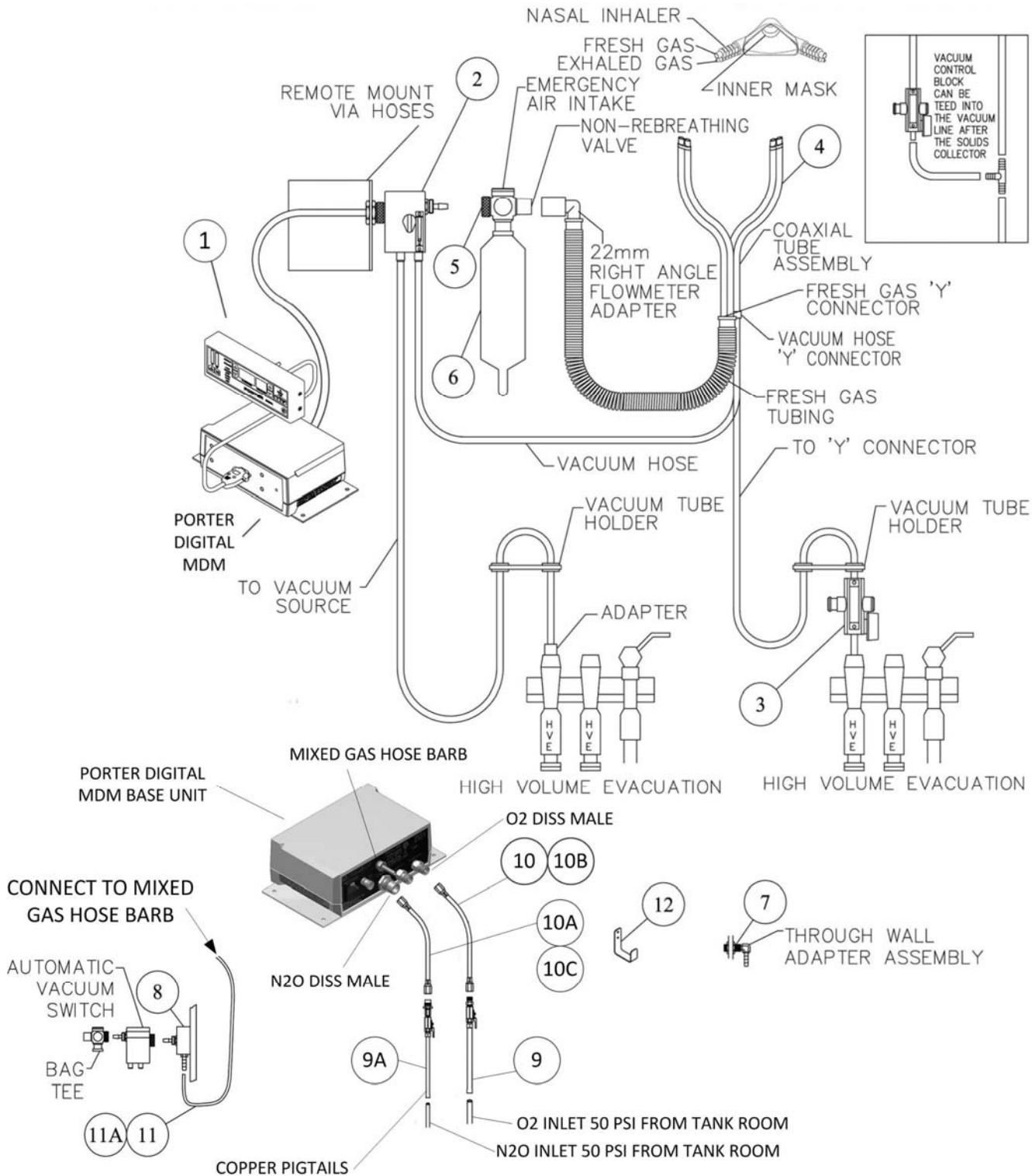
Alarm Test/Silence Key: The alarm test / silence key serves two functions. When pressed, all the display, indicators and the audible alarm turns ON. This key also silences the audible alarm when a NITROUS FAILURE condition exists. The audible alarm will be silent for about five minutes and then resume, unless the failure condition has been corrected.

Machine Diagnostics

The DIGITAL MDM mixer performs self checks at start up and during operation. If any errors are detected, the unit displays EE on the % OXYGEN display and an error code on the LPM FLOW display. If an error code appears, remove the unit from patient service and call the Porter Technical Service Department at 1-888-723-4001.

To aid in the diagnostics of the unit, make note of the final error code displayed.

PORTER DIGITAL MDM SYSTEM ILLUSTRATION



PORTER DIGITAL MDM SYSTEM COMPONENTS & ACCESSORIES

Item No.	Part Number	Description
1	40152601	PORTER DIGITAL MDM
2	AVS-5000	AVS optional
3	5501-RK	Vacuum Block Kit optional
4	5155-1	Adult Rubber Gds (w/ Vacuum Block)
4	5155-3	Adult Rubber Gds (no Vacuum Block)
5	P1407A	Bag Tee
6	4100	3L Bag
7	A-2633-000	Adapter for Bag Tee
8	A-1679	Remote Bag Tee Adapter
9	B-2460-001	O2 Check Valve
9A	B-2461-001	N2O Check Valve
10	8005	O2 Hose, Diss / Diss, 5 Ft
10A	8505	N2O Hose, Diss / Diss, 5 Ft
10B	80012	O2 Hose, Diss / Diss, 12 Ft
10C	85012	N2O Hose, Diss / Diss, 12 Ft
11	PA-450-1-002	O2 Hose, 12 Ft
11A	PA-450-1-001	O2 Hose, 20 Ft
12	A-2508-000	Kit, Rubber Gds Hook
-	B-5555-000	Kit, Recessed Face Mount
-	B-5555-001	Kit, Under Cabinet Mount
-	B-5555-002	Kit, "Z" Brackets, Under Cabinet Base Unit Mount (optional)
-	B-5485	Bracket, Face Mount
	Mounting Options for Bag Tee and AVS	
13	2036-4	3 1/2" Wide Slide (not shown)
14	2036-2	5" Wide Slide (not shown)
15	2037-1	7" Wide Under Cabinet Mt (not shown)

GENERAL INSTALLATION

Installation

1. Using the available brackets mount the Remote Interface Control Unit as desired (see Figure 2.) Shown for recessed into wall. (Kit B-5555-000)

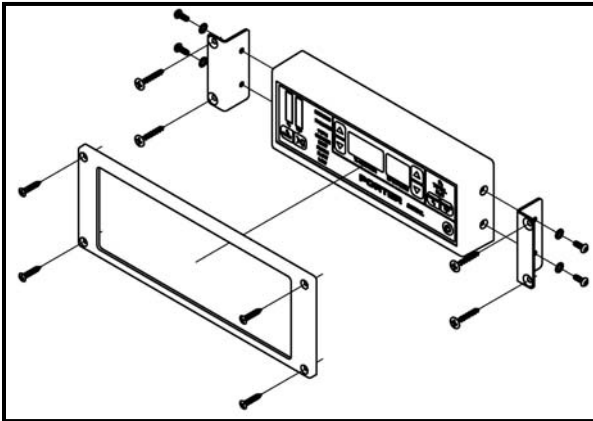


Figure 2. Control Unit recessed mount.

2. For mounting on to wall (see Figure 3), first remove side screws to separate back bracket from Control Unit. Mount back bracket to wall. Slide Control Unit on to back bracket and install and tighten side screws again. (Bracket B-5485)

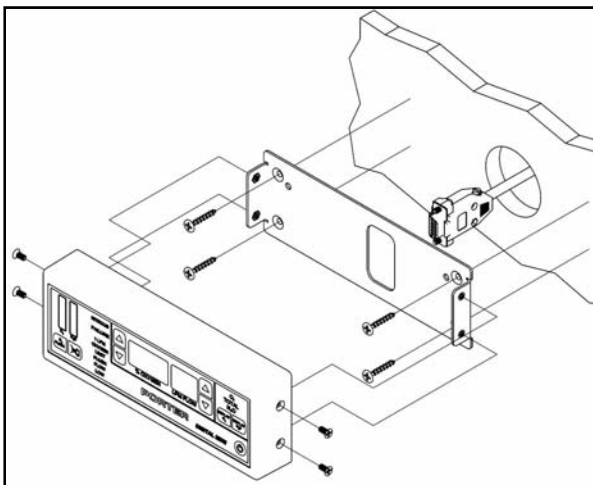


Figure 3. Control Unit mount directly to wall.

3. Use bracket shown in Figure 4 for under cabinet mounting. Turn same bracket upside-down (not shown) for table-top mount. (Kit B-5555-001)

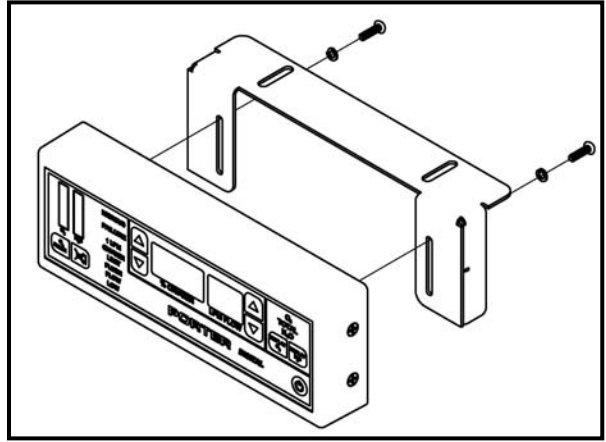


Figure 4. Control Unit under cabinet mount.

4. Typically mount the Base Unit in a horizontal orientation (Figure 5). Using same mounting plate, may also be mounted vertically up, down, or side. **Do not mount Base Unit upside-down.** Adding “Z” brackets allows for mounting Base Unit horizontally, but in an under cabinet orientation. (Kit B-5555-002, “Z” bracket)

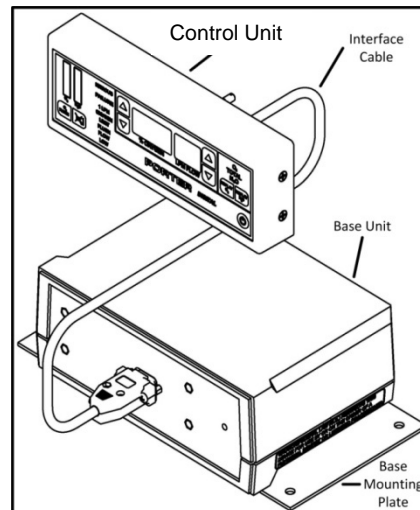


Figure 5. Porter Digital MDM connected with interface cable.

5. Attach one end of the Interface Cable to the Base Unit and the other end to the Control Unit. **Note - Be sure to use the Porter cable that came with the unit and that the cable connector is screwed in at each end.** (see Figure 5.)
6. Install the Remote Surface Bag Tee mount.

Installation of Rubber Goods

Refer to FM-809 for installation of Rubber Goods.

Installation of Power Cord

Insert the power cord into the input connector on the rear of the unit (see Figure 7).

WARNING

For safety a Protective Earth (ground) connection must be made through power cord 3rd wire or Ground Lug (see Figure 7).

WARNING

Not providing a valid Protective Earth (ground) connection can result in the risk of electric shock.

Connection of Oxygen – Nitrous Oxide

For safety reasons, gas connections are color-coded and mechanically indexed using the Diameter Indexed Safety System (DISS) to prevent accidental cross connection. DISS female hexagon fittings are standard for both hoses.

1. Connect the DISS female hexagon fitting of the nitrous oxide hose to the male DISS, N₂O INLET, fitting on the back of the mixer head (see Figure 6). Hand-tighten and then finish tightening with a 7/8" inch open end wrench (approximately 1/8 turn). *Do not over-tighten.*
2. Connect the DISS female hexagon fitting of the oxygen hose to the male DISS, O₂ INLET, fitting on the rear of the unit (see Figure 6). Hand-tighten and then finish tightening with a 11/16" inch open end wrench (approximately 1/8 turn). *Do not over-tighten.*

Hoses

Hoses are manufactured for connection to the gas source in various configurations:

- Quick Connect fittings are designed for rapid "no tool" connections with corresponding male / female fittings or outlet stations. Refer to the individual manufacturer's instructions for specific connection procedure.
- DISS to DISS hoses are designed primarily for portable systems. The gas source (male) DISS fittings are located on the regulators on the cylinder mount block provided with the portable units. Connect the DIGITAL MDM® mixer to the cylinder mount block using the appropriate nitrous oxide hose and the oxygen hose.

Demand Valve Resuscitator

An optional Demand Valve Resuscitator for emergency oxygen resuscitation is available from Porter (PN 1506-1) and connects directly to the O₂ outlet (Figure 6) on the rear of the unit.

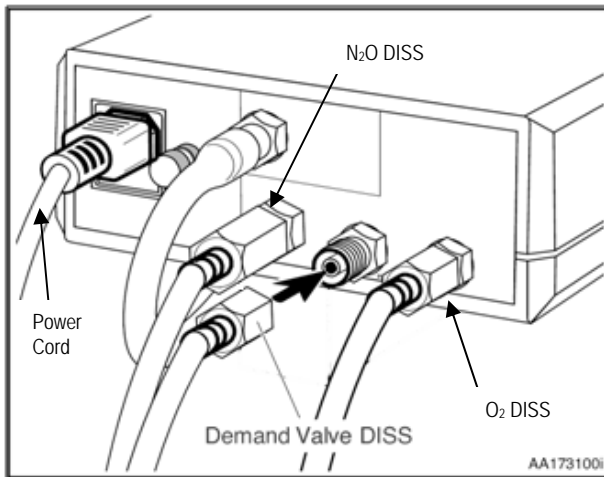


Figure 6. Connection to the back of unit.

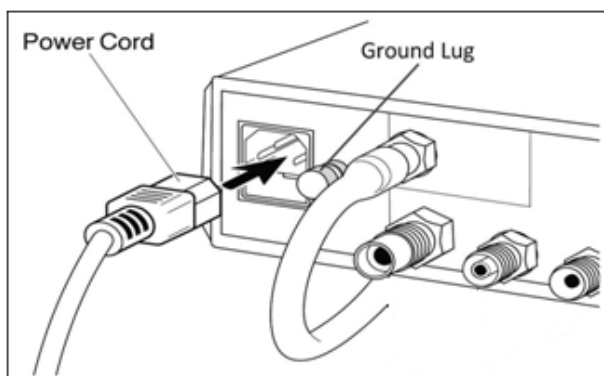
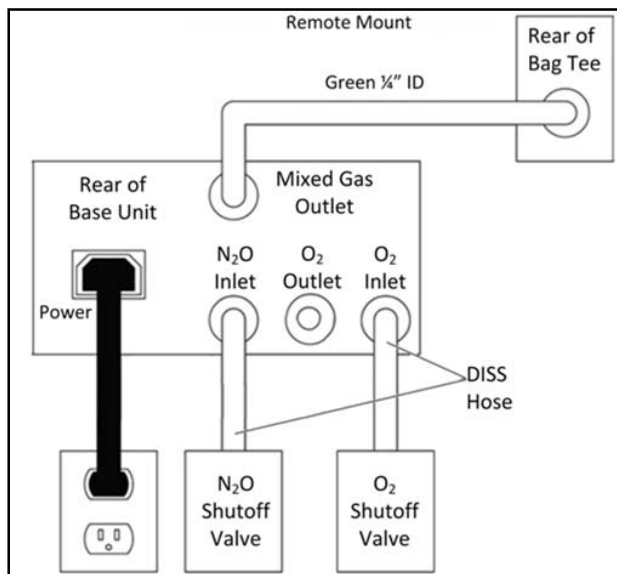


Figure 7 Installation of Power Cord.



**Figure 8. Connections Schematic
(some components may not be part of your installation).**

FLOWMETER ACCESSORIES

Three or Two Liter Reservoir Bag

Install the reservoir bag by sliding the opening over the outside of the bag tee downspout. The bag moves in and out with each inhalation and exhalation and becomes a visual barometer for monitoring the patient's respiration rate. Refer to FM-809 for User Instructions, Assembly, Installation and Cleaning.

Gas Scavenger Breathing Circuit

Gas scavenger system is used to remove exhaled gases during a dental analgesia conscious sedation procedure in a dental operator. The breathing circuit consists of a 22mm 90° elbow connector, fresh gas / coaxial tubing, a corrugated hose and hood assembly. Attach the nasal inhaler to the coaxial tubing assembly using the diameter-indexed connectors. Attach one end of the fresh gas corrugated tubing to the coaxial tubing assembly at the fresh gas "Y" connector and the other end to the 22mm right angle adapter. Press fit the 22mm right angle adapter onto the bag tee. Attach a 2L or 3L reservoir bag to the bottom / downspout of the bag tee. Attach the vacuum hoses to the vacuum control source (AVS or In-line Vacuum Control Block). Refer to FM-809 for User Instructions, Assembly, Installation and Cleaning.

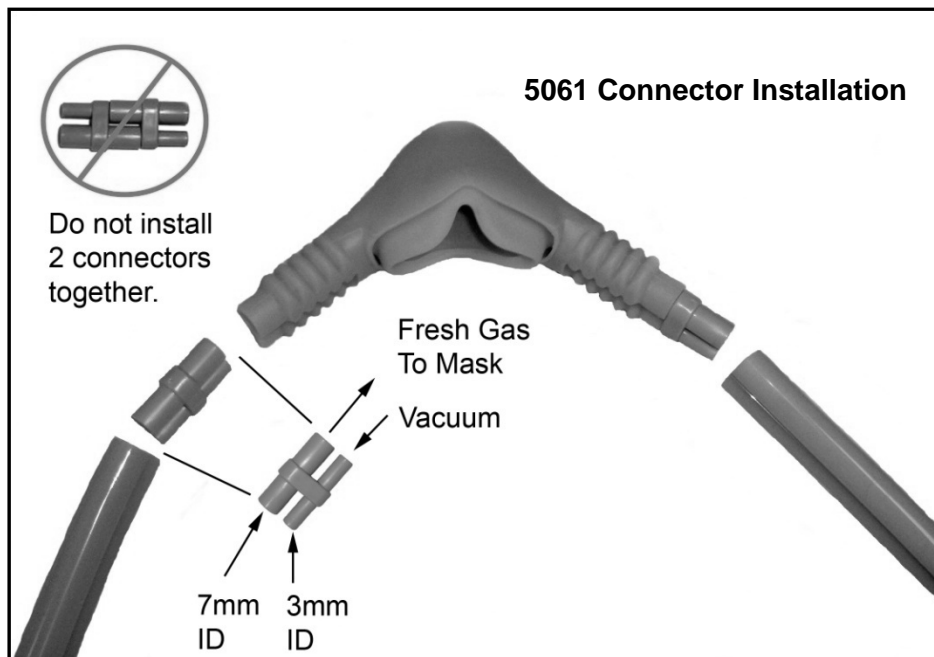


Figure 9. 5061 Connector Installation

Gas Scavenger Breathing Circuit (with AVS)

The AVS is used to control the vacuum flow in the gas scavenger breathing circuit and assure that the scavenging system is activated as soon as N_2O / O_2 is turned ON. Adjust the vacuum flow using the control knob. Vacuum flow is most effective when the ball float is set within the green bar area.

Installation of AVS to Flowmeter: Screw AVS 5000 knurled seal nut down tight onto flowmeter making sure the rubber washer is inside the seal nut. When tight, the AVS should not rotate. Then, screw the bag tee seal nut onto the AVS. Bag tee should not rotate.

Connecting AVS to Vacuum Hoses: Attach one end of the vacuum hose to the vacuum hose "Y" connector and the other end to the MASK port of the AVS. Attach a second vacuum hose to the VAC port of the AVS and the other end to the vacuum source. Refer to FM-809 for User Instructions, Assembly, Installation and Cleaning.

Porter recommends that effective scavenging can be achieved with the ball float in the green bar area of the acrylic sight glass, however NIOSH publications conclude that higher vacuum flows of up to 45 L/min are most effective. To meet the NIOSH recommendation of 45 L/min adjust the ball above the green bar area.

CAUTION: DO NOT PROCESS ANY LIQUIDS OR DEBRIS THROUGH THE AVS.

This contamination can cause damage and affect the function of the unit. The AVS is designed to regulate the vacuum flow level for scavenging of Nitrous Oxide / Oxygen gas only.

CAUTION: The vacuum system should be equipped with a back flow shutoff device to prevent carryover of fluids into equipment attached to the piping systems. It is recommended that a separate vacuum trap be used between the piping system and the vacuum station inlet or any equipment that is attached to the system.

In-line Vacuum Control Kit (Option)

The kit includes a vacuum control block with sight glass, vacuum tube holder, adapter “T” and straight fitting. The vacuum control block can be inserted directly into the High Volume Evacuation (HVE) line or may be placed “in-line” by cutting the vacuum hose and attaching the cut ends of the tubing to both ends of the vacuum control block. Adjust the vacuum flow using the control knob. Vacuum flow is most effective when the ball float is set within the green bar area. Refer to FM-809 for User Instructions, Assembly, Installation and Cleaning.

Bag Tee

The Bag Tee assembly features a Non-rebreathing Valve and an Emergency Air Intake located on the Bag Tee, which comply with American Dental Association guidelines. The non-rebreathing valve has a back flow check valve, which prevents exhaled gases from entering the breathing bag (no carbon dioxide buildup). The emergency air intake has a valve that allows room air to be inhaled into the breathing circuit by the patient. A breathing bag is attached to the metal portion of the Bag Tee and is a reservoir bag for the delivered analgesia gases, which when taken together with the two valves above, becomes the visual barometer for monitoring the patient’s respiration rate. The bag moves in and out with each inhalation and exhalation.

Bag Tee Installation to Flowmeter: Screw knurled seal down tight onto flowmeter making sure the rubber washer is inside the seal nut. When tight, the bag tee should not rotate.

Note: Fit mask to patient so inner mask is pulled down tight secure to the face. Outer mask should not be against the face. Vacuum needs to be drawn into outer mask during inhalation.

ACCESSORY MONTHLY CHECKS

Non-Rebreathing Valve - Check Monthly

Place the On / Standby switch in the STANDBY (Off) position. 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 (See Fig. 10 below) is not functioning properly and should be replaced.

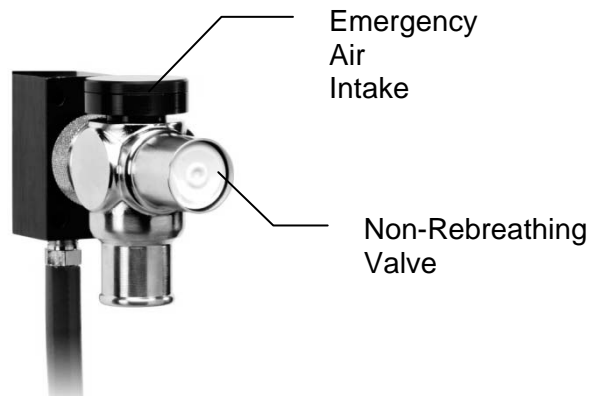


Figure 10

Emergency Air Valve - Check Monthly

Place the On / Standby switch in the STANDBY (Off) position. Disconnect the corrugated rubber tubing from the gas scavenging apparatus and draw air with your mouth through the corrugated tubing connected to the bag tee. With gas bag fully collapsed, you should be able to draw ambient air through the Emergency Air Valve (See Fig. 10 above). Air going through the valve sounds different than normal gas flow.

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 B₁₂ deficiency.

Bronchoconstrictive disease (asthma) – (at determination of medical professional).

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

Contraindications

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

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

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

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

Pregnancy (first trimester) – patient may wish to contact OBGYN / medical professional

PREPARATION FOR USE: TESTS, TECHNIQUES, MAINTENANCE

CAUTION: Before using the DIGITAL MDM mixer, check the operation of the unit by performing the following tests.

Performance Checks: These preliminary tests must be conducted to ensure that your analgesia mixer is performing correctly. If the unit fails any one of the following performance checks, the unit must be returned for service.

Machine Turn-On Test:

Press the ON/OFF key, as shown in Figure 1. After the device goes through an initialization routine, the % OXYGEN and LPM FLOW displays should indicate 100% and 5 LPM.

- the audible alarm sounds
- the LPM FLOW display indicates the oxygen flow being delivered
- the % OXYGEN display is OFF
- the N₂O gas flow indicator is OFF
- the O₂ gas flow indicator shows at least 3 bars

Alarm Indicator / Lamp Test:

Press the alarm test / silence key, as shown in Figure 1, and observe that all the alarm readouts illuminate. The % OXYGEN and LPM FLOW displays should show 8.8.8. and 8.8 respectively. The alarm readouts should illuminate with the numerical displays. 10 bars on each gas should illuminate. The audible alarm should also sound.

Turn on the nitrous oxide gas supply. The unit should return to normal operation. (The alarm may continue to chime for up to 20 seconds after restoration of gas pressure.)

Oxygen Failure Test:

Set the LPM FLOW display to 9.9 LPM. Set the % OXYGEN display to 50%. Turn off the oxygen gas supply to the unit. When the gas runs out, check for each of the following:

- the OXYGEN FAILURE alarm illuminates
- the audible alarm sounds
- the flow indicators are off
- the LPM FLOW and % OXYGEN displays are off
- the N₂O gas flow indicator shows no bars

Turn on the oxygen gas supply, and the unit should return to normal operation. (The alarm may continue to chime for up to 20 seconds after restoration of gas pressure.)

Nitrous Failure Test:

Set the LPM FLOW display to 9.9 LPM. Set the % OXYGEN display to 30%. Turn off the nitrous oxide gas supply to the unit. When the gas runs out, make sure each of the following occurs:

- the NITROUS FAILURE alarm illuminates

Indicated Flow Delivery Test:

Set the % OXYGEN display to 100%. Press the [▼] flow key and hold, as shown in Figure 1. The flow rate should decrease to 1.0 LPM. An audible alarm sounds at the lower limit while the key is held. Press the [▲] flow key and hold. The flow rate should increase to 9.9 LPM. An audible alarm will sound at the upper limit as long as the key is held.

Indicated Percentage (%) Delivery Test:

Set the LPM FLOW display to 9.9 LPM. Press and hold the [▼] % OXYGEN key. The % OXYGEN display should decrease to 30%. The audible alarm sounds at the lower limit while the key is held. Press and hold the [▲] % OXYGEN key, as shown in Figure 1. The % OXYGEN display should increase to 100%. An audible alarm sounds at the upper limit while the key is held.

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.

Maintenance

The DIGITAL MDM mixer is a precision analgesia mixing unit. As with any medical instrument, it requires periodic inspection and maintenance. The following routine maintenance procedures should be performed to ensure system integrity and trouble-free service.

-Inspect mixer, hoses, and connections daily for damage, wear, and leaks.

-Perform functional tests prior to each use. These tests are described in Performance Checks,

-While cleaning the outside of the unit, observe caution so that liquid does not get inside. Porter recommends using a damp (wrung toward dry) cloth moistened with a mild soap or a plastic-safe cleaner. Do not spray directly on the case. A hard surface disinfectant may be applied in the same manner. **CAUTION: DO NOT submerge the unit—use a damp cloth.**



WARNING: Before cleaning the unit, disconnect the DIGITAL MDM mixer's power cord from the electrical power supply.

Fuse Replacement in Domestic, 115-120V and International, 220-240V

1. To replace a blown fuse, turn the unit OFF, disconnect power to the unit by unplugging the power cord from the wall, and then remove the power cord from the input connector on the rear of the unit.
2. Open the fuse compartment, as shown in Figure 11.
3. Remove each blown fuse from its clip and replace it with a 5mm x 20mm cartridge fuse, rated 2.5 amp, 250 volt, slo-blo (time delay), part number 63882537. Two fuses are required for the unit to operate.

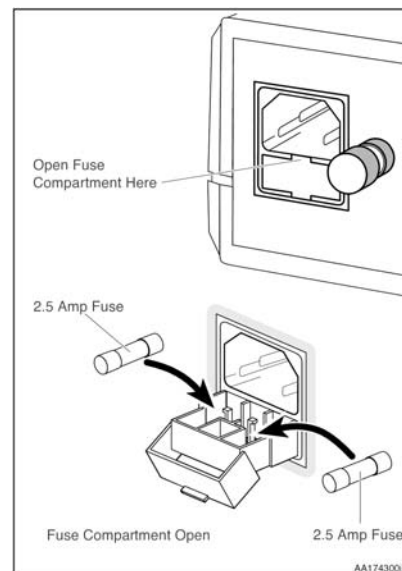


Figure 11 Fuse Replacement

SPECIFICATIONS

Base Unit Physical

Dimensions: 10" W x 5.5" H x 14" D with hoses and interface cable connected
Weight: 6 lbs.

Control Unit Physical

Dimensions: 3.5" H x 9.5" W x 1.5" D

Fittings

Mixed Gas Outlet: ¼" Hose Barb
Bag Tee Outlet: 22mm OD
Nitrous Oxide Inlet: Male DISS CGA 1040
Oxygen Inlet: Male DISS CGA 1240

Environmental

Storage Temperature: -10°F to 120°F
(-17°C to 48°C) (Allow to stabilize to room temperature before operating.)
Operating Temperature: 72°F nominal (22°C)
Humidity: Ambient, non-condensing

Gas Supply

Oxygen Inlet

Pressure Requirements: 50 to 55 psi
Flow Requirements: 30 LPM minimum flow

Nitrous Oxide Inlet

Pressure Requirements: 50 to 55 psi
Flow Requirements: 10 LPM minimum flow

Gas Delivery

Oxygen Flush: 10 to 30 LPM (20 LPM nominal @ 50 psi input)
Minimum Nitrous Oxide Concentration: 00%
Maximum Nitrous Oxide Concentration: 70%
Minimum Oxygen Concentration: 30%
Maximum Oxygen Concentration: 100%
Flow Range @ 100% Oxygen: 1.0 to 9.9 LPM
Flow Range @ Any % Mixture: up to 9.9 LPM†
(†Low end flow limited by 1.0 LPM oxygen limit)

Electrical (Domestic 115–120 V)

Input Voltage Supply: 115 VAC nominal
Input Line Frequency: 60Hz
Circuit Protection: two 2.5 amp time delay fuse (PN 63882537)

Electrical (International 220–240 V)

Input Line Frequency: 50–60Hz
Circuit Protection: two, 2.5 amp time delay fuses (PN 63882537)

Note: A minimum oxygen flow of 60 LPM is required when using the optional Demand Valve Resuscitator.

Performance and Accuracy (Controlled Variable 50 – 55 PSIG Sources)

Oxygen Flowrate from 1.0 to 9.9 ±0.5 LPM
Nitrous Oxide Flowrate from 1.0 to 7.0 LPM ±0.5 LPM
Nitrous Oxide Flowrate from 0.1 to 1.0 LPM +0.5 / -0.9 LPM
Percent O₂: ±5 % points @ N₂O > 1.0 LPM
Percent O₂: +20 / -10 % points @ N₂O < 1.0 LPM
Pure Oxygen Flush: 20 LPM Nominal at 50 PSIG Input

Check out our website www.porterinstrument.com for the following topics.

Flowmeter Mounting Options, Flowmeter Accessories, Product Warranty and Registration
And Downloading User Manuals