Parker Hannifin Corporation
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Matrx MDM®
Nitrous Oxide/Oxygen Sedation Flowmeter

Instructions for Use and Installation Guide

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www.porterinstrument.com

Representation

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	**Conformité Européenne (CE) Mark**	Compliance with conformity assessment on quality management system and technical documentation per Regulations (EU) 2017/745 for Medical Device, Annex IX Chapters i & III
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READ INSTRUCTIONS FOR USE COMPLETELY BEFORE OPERATING THIS DEVICE

This document contains warnings, cautions, instructions for use, and maintenance information that the user must completely comprehend before using this device. Failure to properly operate and maintain this device may result in patient/user harm and/or damage to equipment.

Table Of Contents

WARNING: This product can expose you to chemicals, including lead and formaldehyde, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

WARNING: This product contains the presence of SVHCs, phthalates/DEHPs, CMR, and EDC in excess of 0.1% weight-by-weight material composition. For more information, including precautionary measures for at risk patients, refer to **Section 5. Material Residual Risks**.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or dentist.

Visit our website: https://www.porterinstrument.com/upright-flowmeters for additional information.

To download Instructions for Use: visit https://www.porterinstrument.com/dental-support Choose “Flowmeter” from the dropdown within the “Product Download” section.

1. Device Information

1.1. Intended Use/Intended Purpose

The MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient.

1.2. Models

The MDM Flowmeter is available in nine models (described below). Flowmeters are available with different fitting configurations and minimum percentage oxygen (O_2). Throughout this document, the 94500011, USA fitting, 30% O_2 is pictured. All instructions and information are the same for all models unless specified otherwise.

Model Number	Model Description
94500011*	MDM Flowmeter, Std, USA fitting, 30% O_2
91500167*	MDM Flowmeter, Canada fitting, 30% O_2
91500333*	MDM Flowmeter, France, 50% Min O_2
91500401*	MDM Flowmeter, Swedish, 40% Min O_2
94500033	MDM Flowmeter, RA
94500150*	MDM Flowmeter, Std ISO
94500323*	MDM Flowmeter, Australia fitting, 30% O_2
94500457	MDM Flowmeter, RA-CAN
94500150SPAIN*	MDM Flowmeter, Spain

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

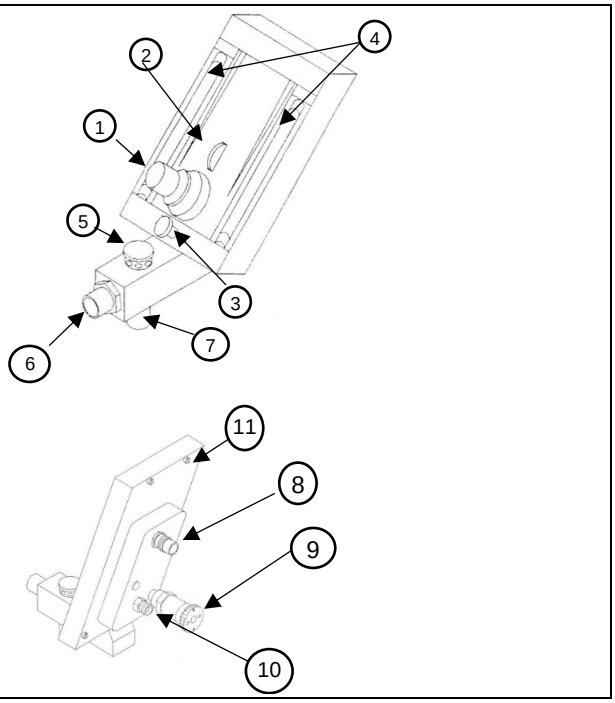
Accessories Model Table

Model Type	Model Number	Model Description
Wall Mount	2020	Wall Arm Mount
E-Stands	2045-2	E-Stand Assembly, Swivel Yoke
	2045-3	E-Stand, Tall
	2045-3CA	E-Stand, White Hose
	2045-3ISO*	E-Stand, Tall with Gas Supply Hoses
	2045-3RA	E-Stand, Extra Tall
	2045-SHORT	E-Stand, Short
	2045RAShort3	E-Stand, Short with Gas Supply Hoses
	2045-SHORT3	E-Stand, Compact
	2045-SHORT3-ISO*	E-Stand, International, Compact
Mobile Stands	2040*	Mobile Stand, Compact
	2042*	Tall Mobile Stand, Tall
	2044*	Mobile Stand, Extra Tall
2-Cylinder Mobile Carts	2100*	2-Cylinder Cart
	2100-2	2-Cylinder Cart with Dual Regulators and Hoses
	2100-N	2-Cylinder Cart with Nitrous Oxide Regulator
	2100-NC	2-Cylinder Cart, Nitrous Oxide Regulator and Hoses
	2100-ISO-2*	2-Cylinder Mobile Cart with Regulator O2, Regulator N2O, and Gas Supply Hoses
	2100-ISO-N*	2-Cylinder Mobile Cart with Regulator, N2O, and Gas Supply Hose

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

1.3. User Interface

#	Description
1	Flow Control Knob
2	Mixture Dial
3	O_2 Flush Button
4	N_2O and O_2 Flow Tubes
5	Emergency Air Intake Valve
6	Breathing Circuit Port
7	Breathing Bag Port
8	N_2O Gas Connection
9	Optional Ohio Female Quick Connect
10	O_2 Gas Connection
11	Head Screws



1.4. General Description/Principles of Operation

The MDM Flowmeter is a pneumatically driven gas mixing device that delivers a mixture of nitrous oxide (N_2O) and oxygen (O_2) to a conscious, spontaneously breathing patient. The device is powered by compressed N_2O and O_2 gas. Pressure is regulated within the device and gas is delivered to a patient at a low pressure. The device functions under the continuous flow principles of operation: when in use, the flowmeter will deliver gas on a continuous basis unless otherwise acted on by the healthcare professional.

The MDM Flowmeter controls the flowrate of N_2O and O_2 gases using a dial mixture percentage system. The device features an auto-compensation, pneumatic mixer technology that maintains flowrate and gas mixture percentage when the user changes these parameters using the flow control knob. Internal valves control gas mixture percentage and flowrate to supply mixed gas to the patient. The mixed gas flows into the connected breathing bag from which a patient draws from through the connected breathing circuit.

The MDM Flowmeter is equipped with safety features, which are described in Section 1.7.

1.5. Use of the Device

The MDM Flowmeter is to be used by a healthcare professional trained in the use and administration of N_2O and O_2 gases. The device is designed for use in a gas delivery and scavenging system for pain management and / or minimal conscious sedation, which is ideal for short, minimally invasive procedures to alleviate patient anxiety or minor pain and discomfort. It is the responsibility of the medical professional to consider the side effects, contraindications, and risks associated with administration of N_2O and use of conscious sedation.

The MDM Flowmeter is not used for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system. The user should observe the patient to

prevent over sedation in the event of an O_2 failsafe malfunction or crossed lines. If a patient becomes overly sedated when being delivered 100% O_2, immediately remove the nasal hood, and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines; in this case, only deliver pure O_2 from an independent source.

WARNING: Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

NOTE: If a serious incident (death or any intervention) has occurred while the device was in use, it should be reported to the manufacturer immediately and the Competent Authority of the member state in which the serious incident occurred.

1.6. Patient Population

The patient population includes conscious, spontaneously breathing, awake, alert, and cooperative patients.

Patients are selected by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. The medical professional must consider patients who are able to receive the gas mixture based on the risks associated with conscious sedation.

1.7. Warnings and Cautions

Warnings and cautions are listed where relevant to a certain section of this document.

A **WARNING** is an instruction, procedure, or explanation of hazards that may result in injury.

A **CAUTION** is an instruction, procedure, or explanation of hazards that may result in damage to a product, equipment, or the environment.

WARNINGS and **CAUTIONS** are presented throughout the document along with this symbol to alert the reader of their presence.

1.8. Safety Features

Failsafe:

The MDM Flowmeter utilizes an O_2 piloted regulator to ensure that the device only supplies N_2O when O_2 supply pressure is present. If the O_2 supply gas is depleted or disconnected, the device will discontinue mixed gas delivery until O_2 supply pressure is restored.

DISS Fittings:

The MDM Flowmeter is equipped with Diameter Indexed Safety System (DISS) fittings, which act in a key-like fashion to ensure that each correct hose can be connected to the correct appropriate fitting. This prevents an accidental crossing of the N_2O and O_2 gas lines.

Non-Rebreathing Check Valve:

The non-rebreathing valve contains a backflow check valve to prevent exhaled gases from entering the breathing bag preventing carbon dioxide (CO_2) buildup.

Emergency Air Intake Valve:

In the event that the O_2 gas supply is depleted or disconnected, and delivery of mixed gas is stopped, an Emergency Air Intake Valve will open that allows the patient to breathe room air through the breathing circuit.

WARNING: The MDM Flowmeter is not intended to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the MDM Flowmeter in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the MDM Flowmeter should be considered “MR Unsafe” and should be kept outside of any MRI scanner rooms.

WARNING: Workers exposed to N_2O may suffer harmful effects. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average).

WARNING: The MDM Flowmeter is used with the delivery of Oxygen (O_2). Therefore, when this device is used in conjunction with energy producing devices (such as lasers, radio frequency sources, or other heat sources), the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials.

1.9. Delivery Protocols

It is the responsibility of the medical establishment and the healthcare professional to develop specific delivery protocols for administration of N_2O using the MDM Flowmeter. Specific delivery protocols for adult and pediatric patients should be developed.

The MDM Flowmeter is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur intermittently over the course of many hours may also be considered transient. The upper limit of use duration is at the discretion of the medical professional.

1.10.Safe Combination of devices

The MDM Flowmeter is designed to be used within a nitrous oxide/oxygen conscious sedation delivery and scavenging system to deliver an accurate mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device system is also used to remove exhaled waste analgesic gas through a vacuum control system. The system is comprised of a series of devices and accessories, which includes a conscious sedation flowmeter, bag tee and breathing bag (if applicable), breathing circuit with nasal hood, vacuum controller, mounting stand, and gas supply hoses.

To ensure safe combination of device, user should follow the installation instructions in **Section 2** below and ensure all connections are secure and tight.

1.11. Specifications

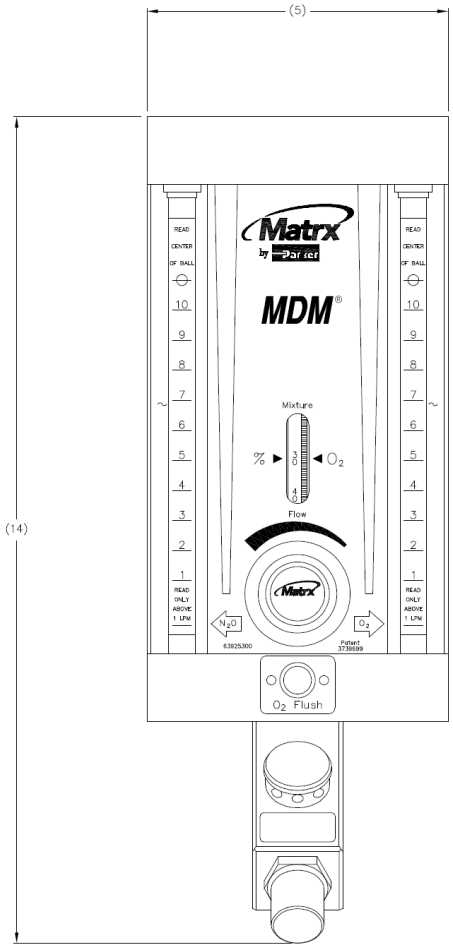
Dimensions
See below.
Mixture Setting
N_2O: 0% - (50%/60%/70%) (model based)
O_2: (30%/40%/50%) - 100% (model based)

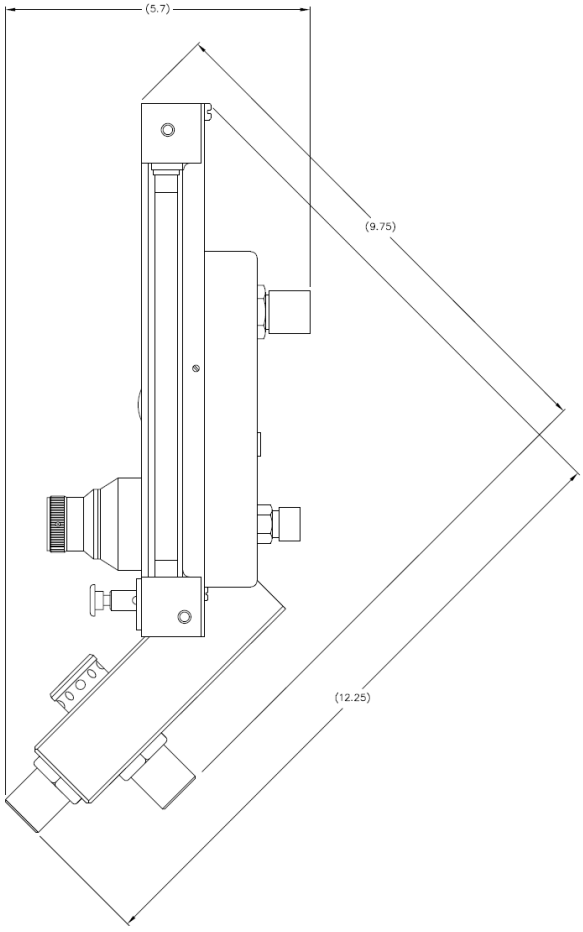
Mixture Dial Calibration
N_2O (50 - 55 psi, 10 LPM): ±0.5 LPM
O_2 (50 - 55 psi, 10 LPM): ±0.5 LPM
Total Flow (50 - 55 psi, 10 LPM): ±0.5 LPM
(as indicated on individual flow tubes)
N_2O/O_2 Flow Tube Accuracy
±0.5L (full scale)
Connection Fittings
O_2 Inlet: DISS 1240 (male thread)
(9/16 in - 18 thread)
N_2O Inlet: DISS 1040A (male thread)
(7/8 in - 14 thread)
Mixed Gas Port: 22mm outside diameter
15mm inside diameter
Reservoir bag: 22mm outside diameter

Weight
6.4 lbs. (2.9 kg)
Delivery Flowrate
O_2: 1 - 10 LPM
N_2O: 0 - 10 LPM
O_2 Flush: Up to 90 LPM
Gas Supply Pressure
O_2: 50 - 55psi (344.7 - 379.2 kPa)
N_2O: 50 - 55psi (344.7 - 379.2 kPa)

Atmospheric Pressure
1 atm ±0.2 atm (101 kPa ±20 kPa)
Environmental
<u>Temperature</u>
Storage/Transport: -10°F - 150°F (-23.3°C -65.6°C)
Operational: 50°F - 113°F (10°C - 45°C)

<u>Relative Humidity</u>
Storage/Transport: ambient
Operational: ambient, non-condensing

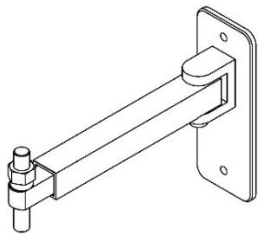
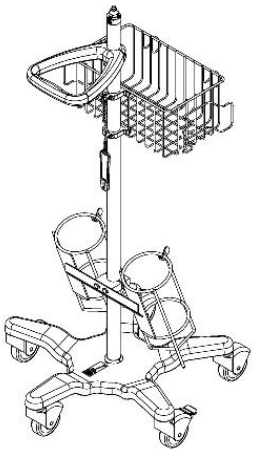
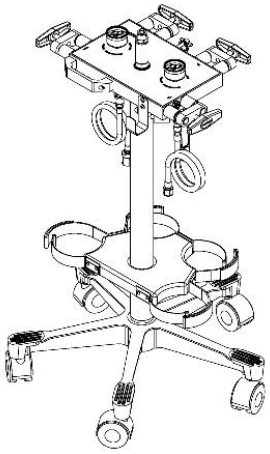
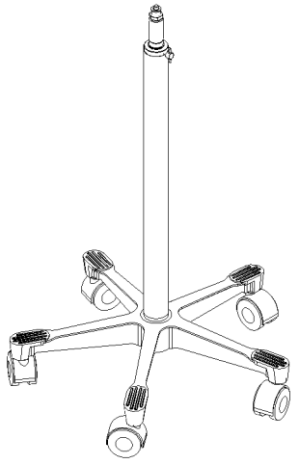




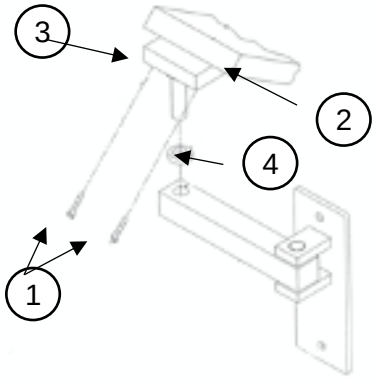
2. Installation Instructions

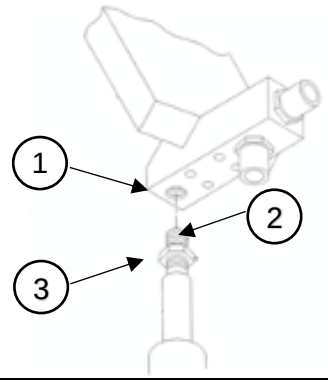
WARNING: For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all gas pipelines are connected properly and that all use points of the system have been tested prior to use. It is important that the user verify by their own test that all gas pipelines are connected properly prior to using the system.

2.1. Compatible Mounting Accessories

Wall Arm Mount	2-Cylinder Mobile Cart	E-Stand	Mobile Stand
			

2.2. Mounting the MDM Flowmeter

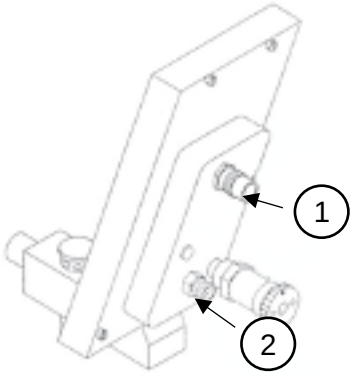
Wall Arm Mount		
1	Remove the two **10-32 x 1⁄4 in screws** (1) from the rear, **top of the head** (2).	
2	Assemble the **mounting bracket** (3) to the rear, top of the head by aligning the bracket with the bevel side to the head and align the 10 - 32 tapped holes in the head with the screw holes in the bracket.	
3	Screw the two 10 - 32 x 1 in screws (included) into the tapped holes through the clearance holes in the bracket until tight.	
4	Slide the mounting bracket pin with **washer** (4) into the wall arm.	

2-Cylinder Mobile Cart, E-Stand, and Mobile Stand		
1	Hold the MDM Flowmeter so that the **mounting hole** (1) is above the **mounting thread** (2) of the Mounting Stand.	
2	Thread stud into 5/8 - 18 **threaded hole** (3) on bottom of the outlet housing until nut is reached.	
3	**Note:** If you are attaching to a 2-Cylinder Mobile Cart, take the extra step to tighten the set screw in the collar of the 2-Cylinder Mobile Cart to keep the flowmeter from rotating freely.	

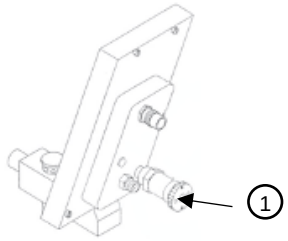
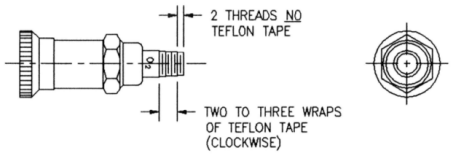
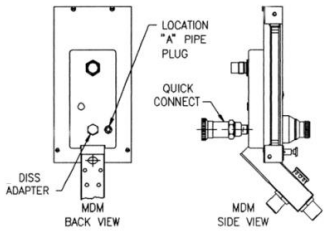
2.3. Connecting Gas Supply Lines

WARNING: Always use clean, dry, medical grade gases, and never oil or grease any part of the device.

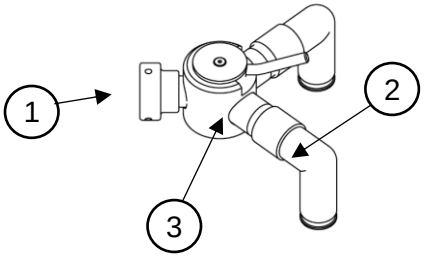
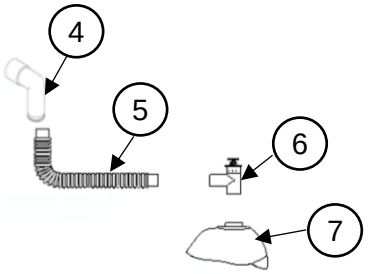
WARNING: Do not change the connection fitting type or diameter of the supply hoses. The Diameter Indexed Safety System (DISS) is designed to prevent misconnection of N_2O and O_2 supply lines.

Gas Supply Line Connections		
1	Connect the N_2O gas supply line to the **N_2O DISS inlet fitting** (1), then connect the O_2 gas supply line to the **O_2 DISS inlet fitting** (2).	
2	Verify gas-tight connections and that there are no leaks at the connections.	

Optional Ohio Female Quick Connect Installation

1	Remove pipe plug from **rear of the MDM Flowmeter** (1).	
2	Install oxygen quick connect with Teflon tape on thread into the vacated 1/4 in NPT cavity until tight.	
3	Verify gas-tight connection by opening oxygen flow to flowmeter. Apply soapy solution to the threaded joint. If bubbles appear, tighten quick connect and repeat test.	

Optional Matrx Directional "Y" Valve Connection

1	Verify that the sealing O-ring is in place. Place **directional "Y" valve adapter** (1) over the patient connector port of the MDM Flowmeter. Ensure adapter is fully seated on connector.	
2	Attach **right angle adaptor** (2) to each of the **gas outlet connections** (3).	
3	Attach to one of the **right-angle adaptors** (4) to the **corrugated tubing** (5), **non-rebreathing valve** (6), and **full-face mask** (7). This is the full-face mask line. Attach to the other right-angle adaptor the Matrx Breathing Circuit (not shown). This is the nasal hood line.	
4	The lever on the directional "Y" valve can be used to switch between the full-face mask line and nasal hood line.	

3.Instructions for Use

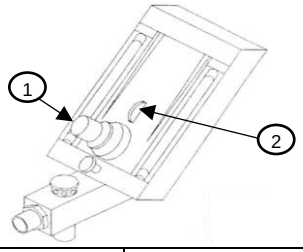
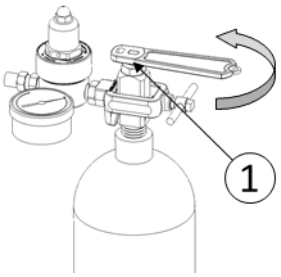
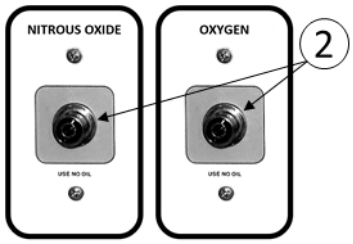
3.1. Setup and Prechecks

WARNING: To minimize the risk of fire or explosion:

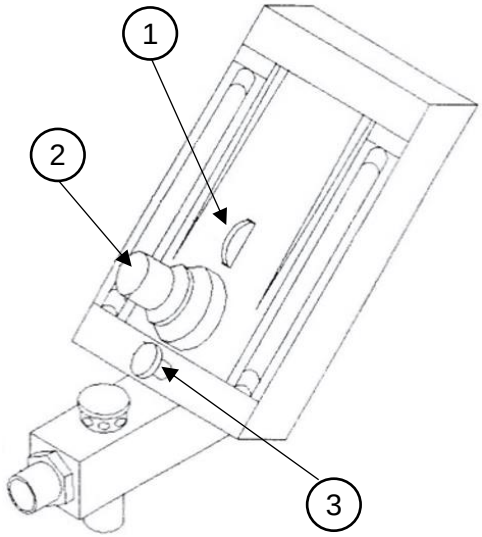
- Always ensure cylinder valves are clear of dust and dirt prior to connection. One method to clear dust and dirt is to briefly “crack” the cylinder valve open to blow out any debris in the line before installing the cylinder.
- Do not discharge the gas at any person or flammable material.
- Always turn on Cylinder Valves slowly and fully.

WARNING: The user should observe the patient to prevent over sedation in the event of an O_2 failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O_2, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure O_2 from an independent source.

CAUTION: It is best practice upon completion of the procedure to close the cylinders (if portable gas supply) or disconnect from wall outlets (if central gas supply). Failure to do so may result in gas depletion should there be a leak.

1	Ensure the device is securely mounted (as described in **Section 2.2 Mounting the MDM Flowmeter**) and the gas supply hoses are connected to the correct fittings on the MDM Flowmeter (as described in **Section 2.3 Connecting Gas Supply Lines**).	
2	Ensure the necessary prechecks have been performed, before using the MDM Flowmeter. The precheck instructions are described in **Section 4.1 Prechecks**.	
3	Rotate **Flow Control Knob** (1) fully counterclockwise, then Rotate **Mixture Dial** (2) to 100% position.	
4	Turn on the N_2O and the O_2 gas supplies. If using gas cylinders, slowly open the **cylinder valves** (1). If connecting to a wall supply, connect the supply lines to the appropriate **outlet connections** (2).	 
5	When using a compatible portable mounting accessory, supply pressure is preset by the manufacturer. When using a wall supply, ensure that the supply pressure is within specification, 50-55psi (344.7-503.3 kPa).	
6	Connect a compatible breathing circuit and breathing bag (as applicable).	

3.2. Operating Instructions

1	Adjust the **Mixture Dial** (1) to 100% O_2.	
2	Set the desired concentration of N_2O by adjusting the **Flow Control Knob** (2) on the front of the device. It is recommended to start with a low percent of N_2O and titrate to the desired effect on the patient.	
3	Before the procedure starts, if desired, press the **O_2 Flush Button** (3) to pre-fill the breathing bag (if connected) with 100% O_2 ensuring the patient's first breath is not from an empty breathing bag.	
4	Place breathing circuit nasal hood on patient and instruct the patient to inhale through the nasal hood. Patient should also be instructed to exhale through the nasal hood to achieve effective scavenging.	
5	When conditions call for the delivery of 100% O_2: **a)** Reduce the **Flow Control Knob** on the flowmeter to 0% N_2O. **b)** If using a directional Y valve, rotate the lever to full-face mask line. **c)** Control the desired flow of 100% O_2 through the **Flow Control Knob** on the flowmeter. **d)** Confirm delivery of 100% O_2 by monitoring locations of ball floats in the flowmeter tubes.	
6	If patient shows signs or communicates conditions of over-sedation, empty the breathing bag by squeezing it and then press and hold **O_2 Flush Button** to quickly fill the breathing bag with 100% O_2.	
7	At The completion of the procedure, remove the breathing circuit from the patient. Turn **Flow Control Knob** to zero. Dispose of any single use items (such as nasal hood or breathing circuit).	
8	Always turn O_2 and N_2O cylinder valves OFF (for cylinder gas supple configurations) or disconnect the supply lines from the appropriate outlet stations (for pipeline gas supply configurations) to avoid unintentionally depleting source gases.	

4. Maintenance

The MDM Flowmeter requires proper maintenance, pre-checks, and servicing according to the following table. It is recommended to return the device to the manufacturer for servicing every 2 years. Once the device reaches an age of 20 years, a failed pre-check will indicate that the device has reached the end of its useful life.

Check	Frequency
Inspect MDM Flowmeter, hoses, fittings, and connections for damage, wear, and leaks	Before every Use
Failsafe Test	Before every Use
100% O_2 Test	Once a month
Total Flow Test	Once a month
O_2 Flush Test	Once a month
Non-Rebreathing Valve Test	Once a month
Emergency Air Intake Valve Test	Once a month

WARNING: Proper inspection and maintenance of this device is essential to prevent gas leaks. All hoses, fittings, and connections should be inspected regularly, and all leaks should be repaired immediately.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Do not use or replace any components or accessories, except those specified in these instructions for use and installation guide.

4.1. Pre-Check

Note: To perform the following tests, gas supply cylinders or gas supply shut off valves are required in order to isolate the gas supply from the device. Attempting to perform these tests with central pipeline supplied gas without a local shutoff mechanism is not recommended.

WARNING: If precheck test cannot be executed successfully, do not use this device and contact distributor.

Failsafe Test

1	Open N_2O and O_2 gas supply
2	Set **Mixture Dial** to 50%.
3	Set **Flow Control Knob** to 5 LPM.
4	Shut off O_2 gas supply to MDM Flowmeter.
5	Confirm N_2O and O_2 flowmeter ball floats fall at the same rate.
6	If ball floats do not fall at the same rate, contact your authorized distributor for service and troubleshooting.

100% O_2 Test

1	Adjust **Mixture Dial** to 100% O_2 position, and rotate **Flow Control Knob** until 10 LPM is indicated on O_2 flowmeter tube.
2	Observe N_2O tube and ball float. The ball float may show some indication of motion, but the top of the ball float must remain below the 1 LPM mark on the tube.
3	If the N_2O ball float floats above 1 LPM, contact your authorized distributor for service and troubleshooting.

Total Flow Test

1	Adjust **Mixture Dial** to 50% O_2 position.
2	Adjust **Flow Control Knob** until O_2 and N_2O flowmeter tubes show approximately 5 LPM for each gas.
3	Without adjustment of the **Flow Control Knob**, adjust the **Mixture Dial** to lowest O_2 percent position, then to the 100% O_2 position.
4	While adjusting the **Mixture Dial** to various O_2 positions, total combined flowrate must be 10 LPM ±0.5 LPM.
5	If total combined flowrate is not 10 LPM ±0.5 LPM, contact your authorized distributor for service and troubleshooting.

O_2 Flush Test

1	Press and hold **O_2 Flush** B**utton**.
2	Observe that the breathing bag quickly inflates.
3	If the breathing bag does not inflate quickly, contact your authorized distributor for service and troubleshooting.

Non-Rebreathing Valve Test

1	Turn the **Flow Control Knob** off.
2	Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of Breathing Circuit.
3	Blow into the inhalation line of the breathing circuit, the breathing bag should not inflate.
4	If breathing bag inflates, contact your authorized distributor for service and troubleshooting.

Emergency Air Intake Valve Test

1	Turn the **Flow Control Knob** off.
2	Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of breathing circuit.
3	Remove the breathing bag from the bag tee and create a seal by placing hand over the bag port on the bag tee.
4	Inhale through the breathing circuit. Air intake valve should open allowing you to breath in room air.
5	If you can not breahting in room air, contact your authorized distributor for service and troubleshooting.

4.2. Cleaning

The MDM Flowmeter must be cleaned between each use in order to prevent the spread of infections. Cleaning of the device has been validated with Super Sani-Cloth™ Germicidal wipes.

WARNING: The following warning applies to the device and any device's components and accessories:

- Do not spray directly with disinfecting chemicals.
- Do not immerse in water, sanitizer, cleaning solution, or any other liquid.
- Do not sanitize or wipe the inside of the fittings, gas supply hoses, or connection ports.
- Always ensure the device and device's components and accessories are completely dry before use.

1	Disconnect and dispose of any single use breathing circuit and/or single use nasal hood (if attached). For cleaning instructions of re-useable breathing circuit and/or nasal hood refer to breathing circuit Instructions for Use.
2	Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the MDM Flowmeter until all visible dirt and soil is removed. Take extra care to wipe the outside of the connection port area, Mixture Dial, and Flow Control Knob as these are the most handled areas of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove.
3	Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the gas supply hoses and fittings until all visible dirt and soil is removed. Do not wipe the inside of the hoses or fittings as this may deposit cleaning agents into the breathing pathway of the device.
4	The **bag port**, **breathing circuit port**, and **emergency air intake valve** should not be exposed to the cleaners or wiped to prevent moisture from entering the device. Avoid wiping and applying cleaner to the inside of the ports and the valve.

4.3. Disposal

It is best practice to inquire with local authorities for proper disposal guidelines, if applicable.

5. Material Residual Risks

The device contains lead, cobalt, nickel, hexavalent chromium, chloroprene, and nickel hydroxide which were identified as CMR/EDC and believed to exceed the 0.1% weight-by-weight threshold requirements of REACH and Section 10.4 of the EU MDR 2017/745.

The residual risks posed by the presence of these substances in the device are low and do not impact the overall safe use of the device. No measures need to be taken by the end user to ensure patient safety regarding use of the device containing these substances.

The potential for exposure to these substances are limited to contact of gases with alloy components (such as aluminum and brass) containing these substances. Patient exposure requires that the substances produce volatile organic compounds, aldehydes, or particulate matter. Extensive biocompatibility testing has been conducted that has demonstrated the use of the materials of construction are unlikely to result in a toxicological effect. In addition, patient exposure is considered to be limited duration given the infrequent use and application intervals that are expected to be long relative to the elimination time of any leachable toxins from the body.

6. Symbols Glossary

The following symbols may be used throughout this document, as well as on device labels and packaging.

Symbol	Title of Symbol	Description of Symbol
	**Manufacturer Information**	Indicates the medical device manufacturer and is accompanied by the name and address of the manufacturer. [EN ISO 15223-1:2021, clause 5.1.1]
	**Date of manufacture and Country of Manufacture**	Indicates the country where the device was manufactured. Also Indicates the date when the device was manufactured. This symbol is accompanied by four digits for the year the device was manufactured. (EN ISO 15223-1:2021, clause 5.1.3, 5.1.11]
	**Catalog Number**	Indicates the manufacturer's catalog number of the device and is used for identification of the device. [EN ISO 15223-1:2021, clause 5.1.6]
	**Serial Number**	Indicates the manufacturer's serial number of the device and is used for identification of the specific device. [EN ISO 15223-1:2021, clause 5.1.7]
	**Unique device identifier**	Indicates a carrier that contains unique device identifier information [EN ISO 15223-1:2021, clause 5.7.10]
	**Prescription device**	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
	**Medical Device**	Indicates the item is a medical device [EN ISO 15223-1:2021, clause 5.7.7]
	**Use-by date**	Indicates the date after which the medical device is not to be used [EN ISO 15223-1:2021, clause 5.1.4]
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use [EN ISO 15223-1:2021, clause 5.4.3]

Symbol	Title of Symbol	Description of Symbol
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself. [EN ISO 15223-1:2021, clause 5.4.4]
	**Caution/Warning**	Indicates important cautionary or warning information to the user that is presented in the instructions for use that accompanies explanatory instructions to the user
	**European Community Authorized Representative**	Indicates the authorized representative in the European Community (European Union) [EN ISO 15223-1:2021, clause 5.1.2]
	**Switzerland Authorized Representative**	Indicates the authorized representative in Switzerland. [MU600_00_016e / V3.0]
	**Conformité Européenne (CE) Mark**	Indicates that the product may be traded freely in any part of the European Economic Area, regardless of its country of origin. [2017/745 EU Annex V]

7. Warranty

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 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 authorized Parker Hannifin Corporation distributors. 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.

To register your product: visit https://www.porterinstrument.com/dental-support and click on Warranty Registration Form button.