

Porter MXR[®] Nitrous Oxide/Oxygen Sedation Flowmeter

Instructions for Use and Installation Guide



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.

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



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 Porter MXR 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 MXR Flowmeter is available in 5 models (described below). Flowmeters are available with different fitting configurations and maximum nitrous oxide (N₂O). Throughout this document, the 3000, USA fittings, 70% N₂O with bag tee is pictured. All instructions and information are the same for all models unless specified otherwise.

Model Number	Model Description
3000	MXR Flowmeter with bag tee
C3000*	MXR, White Markings for O ₂ , 70% Max N ₂ O
C3050*	MXR, White Markings for O ₂ , 50% Max N ₂ O
DTL-164W	MXR, Swedish Connectors, White Body
C3000A	MXR Flowmeter, Australian Fittings

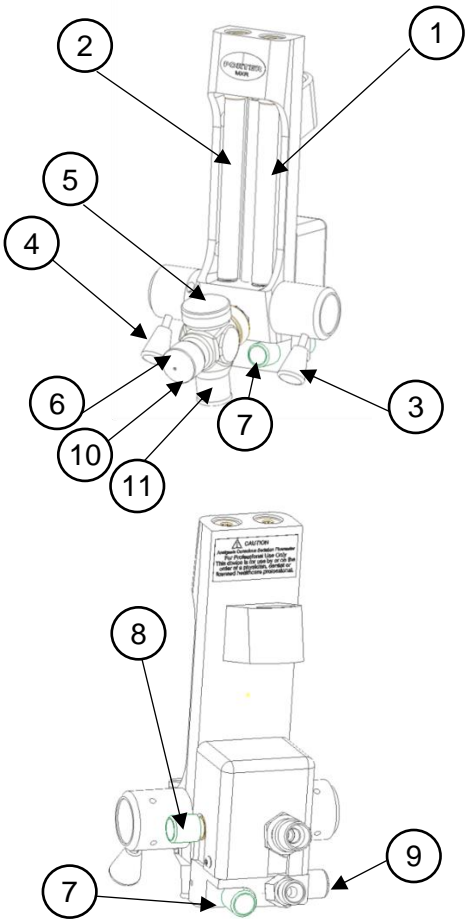
*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

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 O ₂ , Regulator N ₂ O, and Gas Supply Hoses
	2100-ISO-N*	2-Cylinder Mobile Cart with Regulator, N ₂ O, 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	O ₂ Flowmeter Tube	
2	N ₂ O Flowmeter Tube	
3	Flow Control Knob	
4	Concentration Control Knob	
5	Emergency Air Intake Valve	
6	Non-Rebreathing Valve	
7	Gas Flow On/Off Switch (Push On)	
8	O ₂ Flush Button	
9	O ₂ Quick Connect	
10	Breathing Circuit Port	
11	Breathing Bag Port	

1.4. General Description/Principles of Operation

The MXR Flowmeter is a pneumatically driven gas mixing device that delivers a mixture of nitrous oxide (N₂O) and oxygen (O₂) to a conscious, spontaneously breathing patient. The device is powered by compressed N₂O and O₂ 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 MXR Flowmeter controls the flowrate of N₂O and O₂ gases using control knobs. The device features an auto-compensation, pneumatic mixer technology that maintains flowrate and gas mixture percentage when the user changes these parameters using the control knobs. 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 MXR Flowmeter is equipped with safety features, which are described in Section 1.7.

1.5. Use of the Device

The MXR Flowmeter is to be used by a healthcare professional trained in the use and administration of N₂O and O₂ 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 N₂O and use of conscious sedation.

The MXR 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 O₂ failsafe malfunction or crossed lines. If a patient becomes overly sedated when being delivered 100% O₂, 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 O₂ 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. 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.

1.7. Safety Features

Failsafe:

The MXR Flowmeter utilizes an O₂ piloted regulator to ensure that the device only supplies N₂O when O₂ supply pressure is present. If the O₂ supply gas is depleted or disconnected, the device will discontinue mixed gas delivery until O₂ supply pressure is restored.

DISS Fittings:

The MXR 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 N₂O and O₂ 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 (CO₂) buildup.

Emergency Air Intake Valve:

In the event that the O₂ 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 MXR Flowmeter is not intended or expected to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the MXR Flowmeter in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the Porter MXR should be considered “MR Unsafe” and should be kept outside of any MRI scanner rooms.



WARNING: Workers exposed to excessive N₂O 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 MXR Flowmeter used with the delivery of Oxygen (O₂). Therefore, when these devices are 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.

1.8. Delivery Protocols

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

The MXR 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.

1.9. Safe Combination of devices

The MXR 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.

1.10. Specifications

Dimensions

Base: 7.0 in W x 8.75 in H x 5.0 in D
(17.78 cm W x 22.23 cm H x 12.70 cm D)

Mixture Settings

N₂O: 0% - 50% / 70%
O₂: 30% / 50% - 100%

Control Knob Calibration

N₂O (50 - 55 psi, 10 LPM): ± 0.5 LPM
O₂ (50 - 55 psi, 10 LPM): ± 0.5 LPM
Total Flow (50 - 55 psi, 10 LPM): ± 0.5 LPM
(as indicated on individual flow tubes)

N₂O/O₂: Flow Tube Accuracy

Full Scale: 0.5 L

Connection Fittings

O₂ Inlet: DISS 1240 (Male)
N₂O Inlet: DISS 1040A (Male)
Mixed Gas Outlet (meter): 0.25 in (6.35 mm)
Mixed Gas Outlet (bag tee): 0.87 in (22 mm)
Reservoir bag: 22mm outside diameter

Weight

5.6 lbs (2.54 kg)

Delivery Flow Rate

N₂O: 1 LPM – 7 LPM
O₂: 1 LPM – 10 LPM
O₂ Flush: 38.8 LPM

Gas Supply Pressure

O₂: 55 – 60 psi (344.7 – 379.2 kPa)
N₂O: 55 – 60 psi (344.7 – 379.2 kPa)

Atmospheric Pressure

1 atm \pm 0.2 atm (101 kPa \pm 20 kPa)

Environmental

Temperature

Storage/Transport: -10°F - 120°F
(-23°C - 49°C)
Operational: 50°F - 113°F (10°C - 45°C)

Relative Humidity

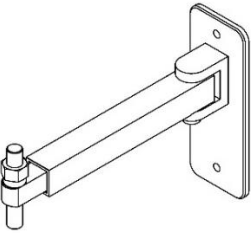
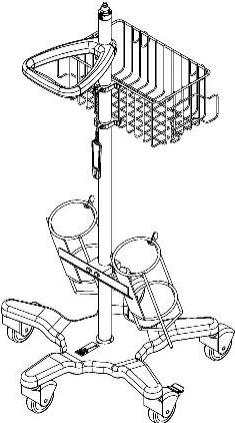
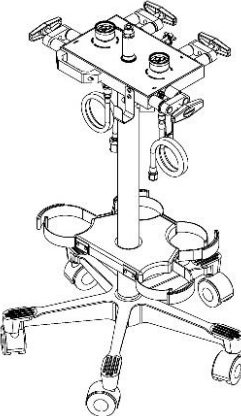
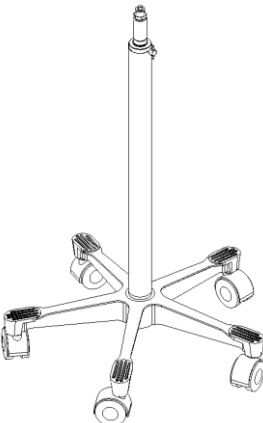
Storage/Transport: ambient
Operational: ambient, non-condensing

2. Installation Instructions



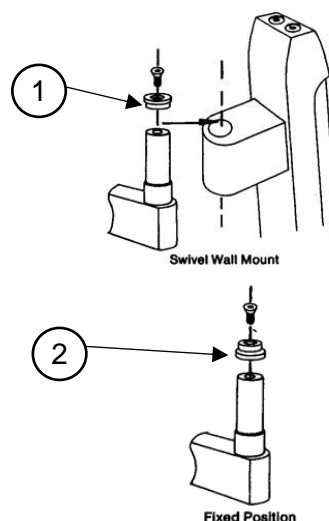
WARNING: For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all 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 Systems

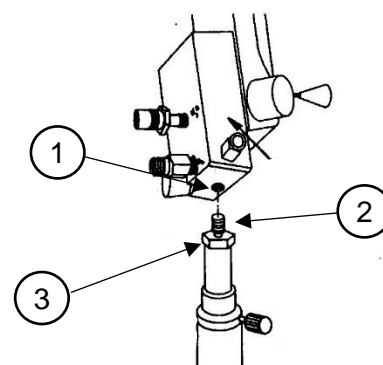
Wall Arm Mount	2-Cylinder Mobile Cart	E-Stand	Mobile Stand
	 <p>Note: Basket maximum weight = 10 lbs (4.5 kg)</p>		

2.2. Mounting the MXR Flowmeter

Wall Arm Mount	
1	Remove cap from the mounting post assembly.
2	Place angle mount (located on rear of Flowmeter) over post.
3	<p>Replace cap on top of mounting post.</p> <p>1) Position the small diameter of cap (1) down to allow for swivel mounting.</p> <p>2) Position the small diameter of cap (2) up to allow for fixed position of flowmeter.</p>
4	Tighten screw on the cap securely.



2-Cylinder Mobile Cart, E-Stand, and Mobile Stand	
1	Hold the MXR 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	<p>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.</p>



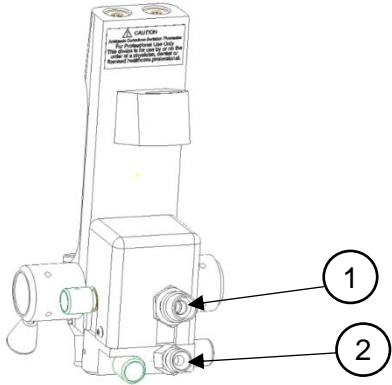
2.3. Connecting Supply Lines

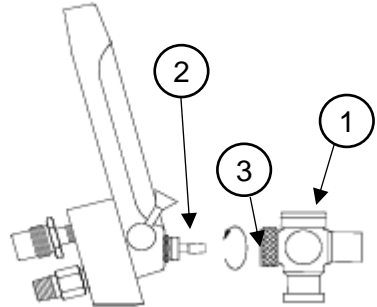


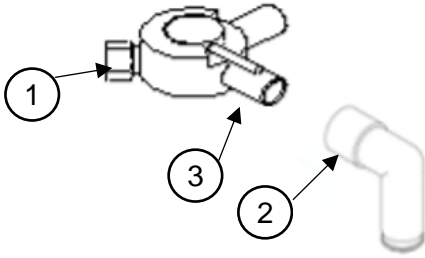
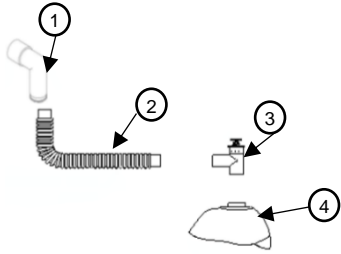
WARNING: Always use clean, dry, medical grade gases and never oil or grease any part of the device.



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 N₂O and O₂ supply lines.

Gas Supply Line Connection		
1	Connect the N ₂ O gas supply line to the N₂O DISS inlet fitting (1) , then connect the O ₂ gas supply line to the O₂ DISS inlet fitting (2) .	
2	Verify gas-tight connections and that there are no leaks at the connections.	

Bag Tee		
1	Connect the Bag Tee (1) to MXR Flowmeter gas outlet port (2)	
2	<p>Screw knurled seal nut (3) with rubber washer inside onto the MXR Flowmeter until tight.</p> <p>Note: Bag Tee cannot rotate when assembled correctly.</p>	

Optional 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 MXR Flowmeter. Ensure adapter is fully seated on connector.	
2	Attach right angle adaptor (2) to each of the gas outlet connections (3).	
3	<p>Attach to one of the right-angle adaptors (1) to the corrugated tubing (2), non-rebreathing valve (3), and full-face mask (4). This is the full-face mask line.</p> <p>Attach to the other right-angle adaptor the Porter Breathing Circuit (not shown). This is the nasal hood line.</p>	
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.



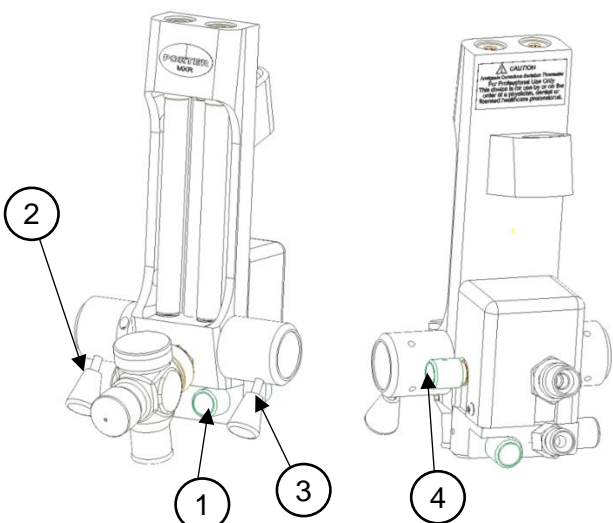
WARNING: The user should observe the patient to prevent over sedation in the event of an O₂ failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O₂, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure O₂ 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 MXR Flowmeter) and the gas supply hoses are connected to the correct fittings on the MXR Flowmeter (as described in Section 2.3 Connecting Gas Supply Lines).	
2	Ensure the necessary prechecks have been performed, before using the MXR Flowmeter. The precheck instructions are described in Section 4.1 Prechecks .	
3	Turn on On/Off Switch (1).	
4	Rotate Flow Control Knob (2) fully counterclockwise.	
5	Rotate Concentration Control Knob (3) to 0% N ₂ O position.	
4	Turn on the N ₂ O 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	Turn On/Off Switch (1)		
2	Adjust the Concentration Control Knob (2) to 0% N ₂ O.		
3	Adjust Flow Control Knob (3) to set the desired O ₂ flow rate.		
4	Before the procedure starts, if desired, press the O₂ Flush Button (4) 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.		
5	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.		
7	When conditions call for the delivery of 100% O ₂ : a) Decrease the Concentration Control Knob to 0% N ₂ O. 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.		
8	If patient shows signs or communicates conditions of over-sedation, empty the breathing bag by squeezing it and then press and hold O₂ Flush Button to quickly fill the breathing bag with 100% O ₂ .		
9	At The completion of the procedure, remove the breathing circuit from the patient. Turn Flow Control Knob and Concentration Control Knob to zero, then press the On/Off Switch to turn the device off. Dispose of any single use items (such as nasal hood or breathing circuit).		
10	Always turn O ₂ and N ₂ O cylinders valves off (for cylinder gas supply 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 MXR 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 MXR Flowmeter, hoses, fittings, and connections for damage, wear, and leaks.	Before every use
Failsafe Test	Before every use
Calibration Test	Once a month
Concentration Control Knob Test	Once a month
O ₂ Flush Test	Once a month
Non-Rebreathing Valve Test	Once a month
Emergency Air Intake Valve	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 these tests, gas supply cylinders or gas supply shutoff 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 shut off mechanism is not recommended.

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

Failsafe Test

1	Set Concentration Control Knob to 50% N ₂ O.
2	Set Flow Control Knob to 5 LPM.
3	Shut off O ₂ gas supply to MXR Flowmeter.
4	Confirm N ₂ O Flowmeter Tube and O ₂ Flowmeter Tube ball floats fall at the same rate.
5	If the flowmeter tubes ball floats do not fall at the same rate, contact your authorized distributor for service and troubleshooting.

Calibration Test:

1	Set Concentration Control Knob to 50%
2	Set Flow Control Knob to 3 - 4 L/min. Ball indicators will be about the same height.
3	Confirm ball indicators are within 0.5 L/min of each other
4	If the ball indicators are not within 0.5 L/min, contact your authorized distributor for service and troubleshooting.

Concentration Control Knob Test:

1	Set Concentration Control Knob to 50%.
2	Set Flow Control Knob to 2 – 3 L/min. Ball indicators will be at about the same height.
3	If ball indicators are not at about the same height, contact your authorized distributor for service and troubleshooting.
4	Set Concentration Control Knob to 0% N ₂ O. N ₂ O flow rate should drop to zero.
5	If N ₂ O flow rate does not drop to zero, contact your authorized distributor for service and troubleshooting.

O₂ Flush Test:

1	Disconnect Breathing Circuit from Bag Tee.
2	Set Concentration Control Knob to 0% N ₂ O.
3	Set Flow Control Knob to 0 L/min
4	Block mixed gas outlet from Bag Tee
5	Press and hold O₂ Flush Button .
6	Observe that the breathing bag quickly inflates.
7	If the breathing bag does not fill, contact your authorized distributor for service and troubleshooting.

Non-Rebreathing Valve Test

1	Turn off flowmeter by pressing the On/Off Switch .
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 flowmeter off by pressing the On/Off Switch .
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 breahing in room air, contact your authorized distributor for service and troubleshooting.

4.2. Cleaning

The MXR Flowmeter must be cleaned between each use in order to prevent the spread of infections. Cleaning 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.



CAUTION: The silver conical handles on the Concentration Control Knob and Flow Control Knob can be removed during cleaning. Never remove or adjust the black Control Knob components as doing so will affect the factory calibration of the device.










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 MXR Flowmeter until all visible dirt and soil is removed. Take extra care to wipe the outside of the connection port area, Concentration Control Knob, and Flow Control Knobs 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. Symbols Glossary

The following symbols may use 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 5.1.11)
	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 5.1.2)
	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 closeary 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. Note the number below the CE Mark does not appear for low risk devices. (EU 2017/745, Article 20, Annex V)

6. 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.