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Porter Conscious Sedation Flowmeters and Bag Tee (Accessory)

Instructions and Safety Considerations



MXR MODELS / REF:

C3000
C3050
DTL-146W
DTL-164W

Bag Tee Accessory:
P1407E



This product complies with the Medical Device Directive (93 / 42 / EEC).
A “Declaration of Conformity” in accordance with the directive has been made and is on file.



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

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The Quality System for Porter Instrument is certified to ISO 13485. 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 Professional.”

Check our website: www.porterinstrument.com for additional information.
To register your product: www.porterinstrument.com/resources-dental choose Warranty tab.
To download a User’s Manual: www.porterinstrument.com/resources-dental choose Manuals tab.

IMPORTANT:
READ MANUAL COMPLETELY BEFORE OPERATING THIS DEVICE

Basic delivery technique is described. Also, this manual contains instructions on periodically required checks to be performed by the user. These checks are necessary to insure the proper performance of this device and its safety features. Retain this manual for future reference.



WARNINGS AND PRECAUTIONS

These warnings and precautions are to help you to understand how to safely operate the MXR Flowmeter. A **WARNING** alerts you to a possible hazard to people. A **CAUTION** alerts you to the possibility of equipment damage.

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

WARNING: Workers are exposed to N₂O during administration of N₂O/O₂ conscious sedation analgesia. NIOSH has recommended that exposures should be minimized. Contact NIOSH (1-800-35-NIOSH) to receive NIOSH Publications on *Control of Nitrous Oxide in Dental Operatories*. Exposure can be minimized by effective controls. National Institute for Occupational Safety and Health (NIOSH) publications state that controls, including System Maintenance, Ventilation and Work Practices can effectively reduce N₂O concentrations in patient procedures. Your flowmeter accessory Porter scavenger system is an important part of the system of controls.

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

To assure safe operation and conformation to local fire codes, all Porter Instrument flowmeter systems are designed to be used with sedation delivery systems mounted inside walls and they meet or exceed the guidelines established by the National Fire Protection Association for Nonflammable Medical Gas Systems, NFPA 99. Copies of NFPA 99 or portions thereof may be obtained by writing to:

National Fire Protection Association, Batterymarch Park, Quincy, MA 02269-9904; or call 1-800-344-3555

WARNING: New or modified installations - **properly connected gas pipelines are absolutely essential to patient safety.** The authorized distributor or contractor should provide written documentation that all gas pipelines are connected properly and that the system has been pressure tested prior to use. While this is a good business practice, it is important that the user verify by their own test, independent of the authorized distributor or contractor, that all gas pipelines are connected correctly prior to using the system. **The ultimate responsibility of assuring that lines are not crossed rests with the user.**

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

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

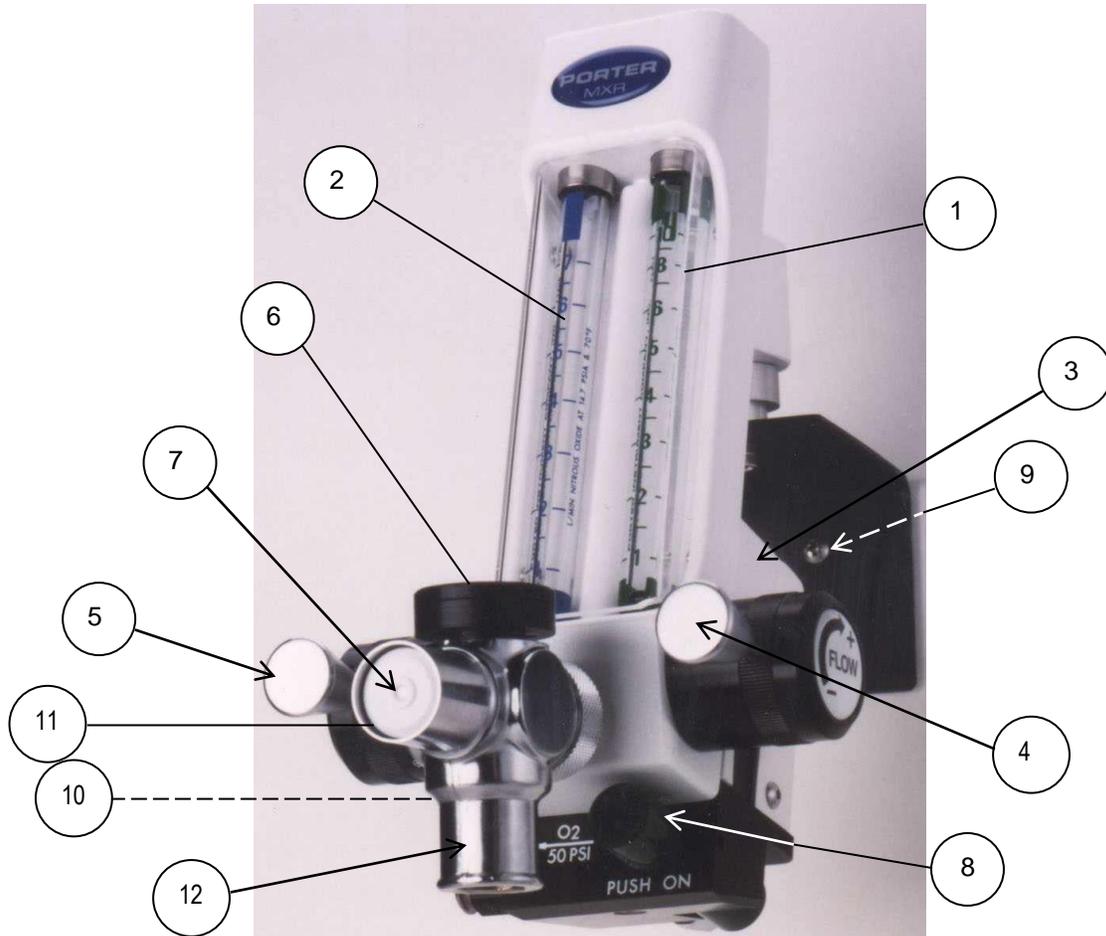
CAUTION: Always use clean, dry medical grade gases. Introduction of moisture or other contaminants into this device may result in defective operation.

CAUTION: Do not attempt to repair, alter or calibrate this device. Unauthorized repair, alteration or misuse of this device is likely to adversely affect the performance and will void the warranty.

CAUTION: Never oil or grease any part of this system (minimize fire or explosion potential).

FIGURE 1

FLOWMETER FEATURES



1. **Oxygen Flowmeter Tube** indicates the flow of O₂ in L/min \pm 5%.

2. **Nitrous Oxide Flowmeter Tube** indicates flow of N₂O in L/min \pm 5%.

3. **Nitrous Oxide Failsafe System.** Dual-seal oxygen-piloted valve system that automatically maintains the % N₂O concentration setting with any change in the O₂ flow or pressure. N₂O flow is proportionately reduced if O₂ is shut off or the pressure is reduced (check before each use).

4. **Flow Control Knob** controls the combined flow of O₂ and N₂O (or O₂ flow only when the Concentration Control Knob is set to 0%).

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

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

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

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

9. **Power Flush** provides extra delivery of O₂ to the breathing bag. (Check Monthly)

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

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

12. **3L and 2L Bag Connection**

INTENDED USE: **Flowmeter for Analgesia Delivery System**

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

USE SCAVENGING

Monitor for N₂O in the patient treatment area to insure that controls are effective in achieving low levels of PPM (parts per million) exposure. Contact your Porter dealer for details on monitors and testing.

GAS SUPPLY CONNECTION

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

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

MONTHLY LEAK CHECK (or if connections to flowmeter are disconnected and then reconnected, such as after a flowmeter service at the factory or if the DISS/DISS hose is replaced): Leak test the flowmeter system for working pressure leaks. After all hose connections are tightened, turn both control knobs to the off position and the on/off switch to the off position. Confirm that the DISS Shut-Off Valves are in the open position. Pressurize the sedation gas supply lines with 50 PSI. Observe any pressure decay after an overnight time period (5 PSI drop allowed).

Monitor O₂ gas pressures at the beginning of each procedure to assure sufficient gas remains in the tank to complete the procedure.

SAFETY FEATURE CHECKS

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

NITROUS OXIDE FAILSAFE SYSTEM

CHECK BEFORE EACH USE

1. Set the right-hand total Flow Control Knob to zero and set the left-hand Concentration Control Knob to zero. (See Figure 1-Items 4 and 5: Rotate control knobs to stop.)
2. Be sure O₂ and N₂O are connected to your MXR and line pressure for both gases is 50 PSIG (which is standard).
3. Turn the Concentration Control Knob to 50%. **There should be no flow of N₂O.** This is a check of the static position of the Nitrous Oxide Failsafe System valve.
NOTE: A momentary low flow of N₂O (about 1 L/min for about a second) may be seen if the Concentration Control Knob is turned to zero before turning the Flow Control Knob to zero. This is N₂O gas trapped between the Nitrous Oxide Failsafe System valve and the Concentration Control Knob valve and is a normal occurrence. **No other N₂O flow should be observed.**
4. With the Concentration Control Knob still set to 50%, turn the Flow Control Knob to achieve a flow of 3 to 4 L/min of O₂. You should observe an equal amount of N₂O flowing by gradually turning the Flow Control Knob. (Refer to Monthly Calibration Check on Page 4, to read ball float on flowmeter tubes.)
5. Interrupt the flow of O₂. This will check the dynamic status of the Nitrous Oxide Failsafe System valve. This can be done by either disconnecting the oxygen hose from the wall or shutting off the oxygen at the tank. **The Nitrous Oxide flow should drop as the Oxygen flow decreases, stopping completely before the Oxygen float drops to zero.**



WARNING

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

CONCENTRATION CONTROL KNOB VALVE – CHECK MONTHLY

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

POWER OXYGEN FLUSH CHECK MONTHLY

(O₂ SUPPLY PRESSURE AT 50 PSIG)

Disconnect the corrugated rubber tubing from the bag tee outlet (Figure 1, Item 11). With both control knob valves OFF, depress the power (O₂) flush button while blocking the flow from the front of the bag tee. For proper operation, the gas reservoir bag should fill within about 5 seconds. Also test for bag / rubber goods leak following steps 1 through 6.

Quick Test to Check Reservoir Bag / Rubber Goods for Leaks

1. With the flowmeter, bag tee and **Porter** rubber goods in place, remove the nosepiece and one of the two plastic connectors from the Porter rubber goods.
2. With the other plastic connector, join the two duplex hoses together making a closed system.
3. Taking care not to fill the bag too much (bag could burst), open the oxygen control valve until the reservoir bag starts to over-inflate or “balloon”, then close the valve.
4. Observe the reservoir bag for five minutes.
5. The bag should stay inflated. If so, the test has been successful and there are no excessive leaks. If the bag does not stay inflated, the reservoir bag or rubber goods have an excessive leak. Replace any parts that leak and retest until results are successful.
6. Disconnect one of the duplex hoses from the plastic connector and re-install the nosepiece.

BAG TEE

The Bag Tee assembly features a Non-rebreathing Valve and an Emergency Air Intake located on the Bag Tee (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 flowmeter.

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.

NON-REBREATHING VALVE CHECK MONTHLY

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

EMERGENCY AIR VALVE CHECK MONTHLY

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

MONTHLY CALIBRATION CHECK

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

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

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

DIRECTIONS FOR USE

NOTE: These directions detail a basic delivery technique. However, this is not a comprehensive description and not a substitute for a training course that emphasizes a practical, hands-on approach together with instruction on safe administration techniques.

1. Maintain patient observation during procedure.
2. Turn ON unit by pushing in the ON / OFF switch.
3. Open N₂O / O₂ tank valves.
4. Using Flow Control knob, set flow rate of O₂ to desired rate, keep bag about ¾'s full. Rotate flow control knob upwards (clockwise) to increase flow. (See Figure 1, Item 4)

Flow Control Knob



5. Set N₂O concentration to desired level by rotating Concentration Control Knob (See Figure 1-Item 5) upwards (counterclockwise) to increase concentration, as read by percentages inscribed on the control knob. Rotate slowly until desired level is achieved. Practice titration* with 10% nitrous upward movements every 60 seconds until endpoint achieved. Patients may typically experience relief of anxiety, tingling in extremities, and euphoria. Patients typically require less than 50% nitrous.

Concentration Control Knob



Setting
Shown at
60%

6. Flow Control knob may be re-adjusted to bring the total flow of gases back to desired level, when concentration is increased or decreased. Total flow is equal to the sum of right and left tube readings. Read center of ball float on flowmeter tube.

7. When the procedure is nearing completion, amounts of N₂O should be decreased. Terminate the flow of N₂O and deliver 100% O₂ to begin a minimum postoxygation period of 3 to 5 minutes. Assess the patient for appropriate recovery. Administer additional O₂ if necessary. Titration and post-procedure 100% O₂ will minimize nitrous exposure to the patient treatment area, potential patient side effects of lethargy, headache, or nausea, and any potential adverse effects of nitrous diffusion into air filled cavities.
8. When procedure is finally completed, turn off **both** control knob valves for gas shut off.
9. Place the ON / OFF switch (primary shut-off mechanism) in the OFF position. (Push from back of ON / OFF switch.) NOTE: If control valves are still open, gas flows should stop at this point.
10. Turn OFF the gas supply at the tank at the end of the day.

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.

IMPORTANT NOTE:

When the Concentration Control knob is open, the Flow Control knob is closed, and there is no N₂O flow indicated in the flow tube, the Nitrous Oxide Failsafe System will stop the flow of N₂O. However, this safety feature should not be used as the primary shut off mechanism. The control knobs are for primary shut-off.

NOTE: If your unit does not operate as described in Steps 1 through 10 under “Directions for Use”, please contact your authorized distributor Porter Instrument.

MAINTENANCE AND SERVICE

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

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

CLEANING METHODS

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

Control knobs can be autoclaved. Remove knobs from flowmeter. Clean using an appropriate disinfectant. Rinse with water then autoclave. Do not exceed 275°F for 15 minutes maximum.

TROUBLESHOOTING CHART FOR MXR FLOWMETERS

SYMPTOM	POSSIBLE CAUSE	REMEDY
No flow of O ₂ or N ₂ O when ON /OFF switch is ON and left knob is set at a concentration of N ₂ O or the right knob is rotated to give O ₂ or mixed gas flow.	1. O ₂ supply not turned ON. 2. Machine not connected to pipeline system. 3. Empty O ₂ cylinders.	1. Turn O ₂ regulator of Cylinder Valve ON. 2. Connect to wall outlet. 3. Replace with full cylinder.
Can get O ₂ flow but cannot get N ₂ O flow.	1. N ₂ O supply not turned ON. 2. N ₂ O cylinder empty.	1. Turn ON N ₂ O cylinder. 2. Replace with full cylinder.
With N ₂ O concentration set, both flows vary proportionally with no change in flow setting.	O ₂ regulator is varying pipeline pressure.	Check O ₂ regulator. Be sure O ₂ manifold pressure is 50 PSIG ±2 PSIG. If not, call Dealer for service.
Meter will flow N ₂ O without any O ₂ flow in the O ₂ tube.	Failsafe failure.	Take out of service and return to Porter.
Cannot get 9 ½ L/min O ₂ flow with concentration control knob OFF and flow control knob full ON.	Low O ₂ pressure setting.	Check O ₂ regulator. Be sure O ₂ manifold pressure is 50 PSIG ±2 PSIG. If not, call Dealer for service.
Ballooning of the gas bag.	90° Elbow connected onto bag tee is pushed on too far, blocking movement of the non-rebreathing valve.	Remove rubber goods and 90° elbow from bag tee. Reconnect elbow and rubber goods.
Gas is leaking from the ON/OFF switch.	Nick or cut in o’rings on the ON/OFF switch.	Call Dealer for service.
Patient not feeling effects of gases.	1. Outer mask is not fit properly to patient’s face. 2. Gas flows do not meet patient’s requirement. 3. Inner mask’s exhalation valve is missing. 4. Inner mask is missing (must have inner and outer mask together).	1. Fit so inner mask is secure to face but outer mask is just off face. 2. Re-adjust gas flows to obtain acceptable bag action. 3. Replace valve. 4. Replace inner mask.
Bag is going flat during procedure.	1. Gas flows do not meet patient’s requirement. 2. Outer mask is not fit properly to patient’s face.	1. Re-adjust gas flows to obtain acceptable bag action. 2. Fit so inner mask is secure to face but outer mask is just off face.

REF**VARIANTS / COMPARED TO THE BASIC MODEL**

	Basic Model MXR: 1-10 L/min O ₂ , Green Bands on flow tube, green buttons, 1-7 L/min N ₂ O, Blue Bands on flow tube. 70% Max Concentration N ₂ O
C3000	Similar to basic Model MXR design, except, different color-coding for Oxygen – white bands on flow tube and white buttons. Flowmeter body is painted white and has a failsafe block cover that is also painted white. The overall length of meter body and tube assemblies is reduced in length by approximately 1.23". 70% Max Concentration N ₂ O
C3050	Similar to basic Model MXR design, except, different color-coding for Oxygen – white bands on flow tube and white buttons. Flowmeter body is painted white and has a failsafe block cover that is also painted white. The overall length of meter body and tube assemblies is reduced in length by approximately 1.23". 50% Max Concentration N ₂ O
DTL-146W	Similar to basic Model MXR design, except, different color-coding for Oxygen – white bands on flow tube and white buttons. Flowmeter body is painted white and has a failsafe block cover that is also painted white. The overall length of meter body and tube assemblies is reduced in length by approximately 1.23". Also has special bag tee adapter. Note: The bag tee and breathing circuit accessories are supplied by the user.
DTL-164W	Similar to basic Model MXR design, except, different color-coding for Oxygen – white bands on flow tube and white buttons. Flowmeter body is painted white and has a failsafe block cover that is also painted white. The overall length of meter body and tube assemblies is reduced in length by approximately 1.23". Also has special Swedish connectors. 60% MXR
P1407E	Basic Model Bag Tee which includes a 22mm connector, serial number and warranty card with device.

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

Flowmeter Mounting Options

Flowmeter Accessories

Product Warranty and Registration

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