Parker Hannifin Corporation
Porter Instrument
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USER INSTRUCTIONS

FOR

ASSEMBLY
INSTALLATION
AND
CLEANING

PORTER Scavenger Rubber Goods System

- Available with Automatic Vacuum Switch (AVS)
- Available with Vacuum Control Block

NOTICE
READ MANUAL COMPLETELY
BEFORE OPERATING THIS DEVICE

The Quality System for Porter Instrument is Certified to ISO 13485. The scope of our registration is: "The design, manufacture, distribution and servicing of Dental Flowmeters, Gas Scavenging Systems, Gas Distribution Systems and Office Communication Systems for use in the Dental Profession."

User Instructions

The Porter System is designed to solve the problem of exposure to Nitrous Oxide. Comfortable and quiet, the unique design of the mask minimizes any "competition" between the vacuum source and the patient. It allows the patient to receive the proper amount of Oxygen and Nitrous Oxide with normal respiratory effort. The silicon tubing and mask have increased durability and are steam and chemical vapor autoclavable.

Porter features a mask-within-a-mask scavenging system. Metal and plastic parts have been eliminated from the mask so that x-rays can be taken during a procedure without removing the mask. The mask includes easy-to-remove inner liners that simplify cleaning and sterilization. The soft inner mask provides an excellent seal around the nose and a comfortable fit for the patient. Also available, are single-use personal mask liners for the Porter Scavenging System.

A Non-Rebreathing Valve (NRV) and Emergency Air Intake (EAI) located on the bag tee provide safety features and make the "breathing bag" the visual barometer for monitoring the patient's respiration rate. (See NRV and EAI tests below.)

Porter Retrofit Kits

Porter Scavenger Retrofit Kits are available for most brands of flowmeters. You can upate your present nitrous oxide system for improved safety, durability, and comfort. These kits provide the standard features of Non-Rebreathing Valves (NRV) and Emergency Air Intakes (EAI) - important safeguards your present system may not have. You can easily check your current system for these safeguards using the following tests:

Non-Rebreathing Valve (NRV) Test

Disassemble the fresh gas tubing from the mask and "Y" connector, and breathe back into the fresh gas corrugated tubing (Figure 1, Item 9) connected to the flowmeter. You should not be able to fill the reservoir bag with exhaled gas. If the bag fills, this breathing circuit has no NRV and would allow for carbon dioxide (CO_2) buildup in the breathing bag.

Emergency Air Intake (EAI) Test

With the flowmeter turned off and the breathing bag empty, inhale through the mask. A check valve assembly should open allowing "room air" into the breathing circuit. If no room air enters the breathing circuit, this circuit has no EAI - an essential component for the safe and effective administration of Nitrous Oxide and Oxygen.

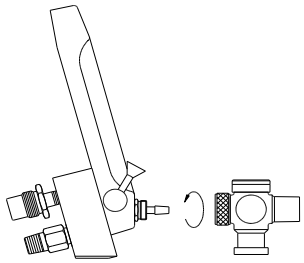
If your system fails either of these tests, your system should be updated with a Porter Scavenger Retrofit Kit.

IMPORTANT: It is **not recommended** to retrofit Porter Scavenger Rubber Goods to A-dec or Veriflo Flowmeters. It is **only recommended** to retrofit an AVS to the Porter Scavenger Systems and Porter Flowmeters, with the exception of the Porter Oral Surgeon unit (Model 3000-OS).

ASSEMBLY INSTRUCTIONS

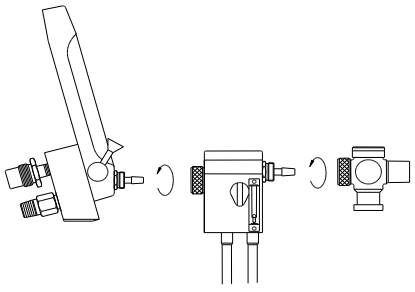
1. Bag Tee to Flowmeter:

Screw knurled seal nut down tight onto Flowmeter making sure the rubber washer is inside the seal nut. When tight, Bag Tee should not rotate.



2. AVS 5000 / Bag Tee to Flowmeter:

Screw AVS 5000 knurled seal nut down tight onto flowmeter making sure the rubber washer is inside seal nut. When tight, AVS should not rotate. Then, screw Bag Tee seal nut onto AVS. Bag Tee should not rotate.



3. **Rubber Goods to Bag Tee: (Refer** *to item (#) in parts list on the next page and Figures 1 and 2 on pages 4 and 5 for assembly and hook-up options.)*

A. Attach the nasal inhaler (#3 or #4) to the coaxial tubing assembly (#5) using the diameter indexed connectors (#11).

B. Attach one end of the fresh gas corrugated tubing (#9) to the coaxial tubing assembly (#5) at the fresh gas "Y" connector (#7) and the other end to the 22-mm right angle flowmeter adapter (#10). Press fit the 22-mm right angle flowmeter adapter (#10) onto the bag tee (#6).

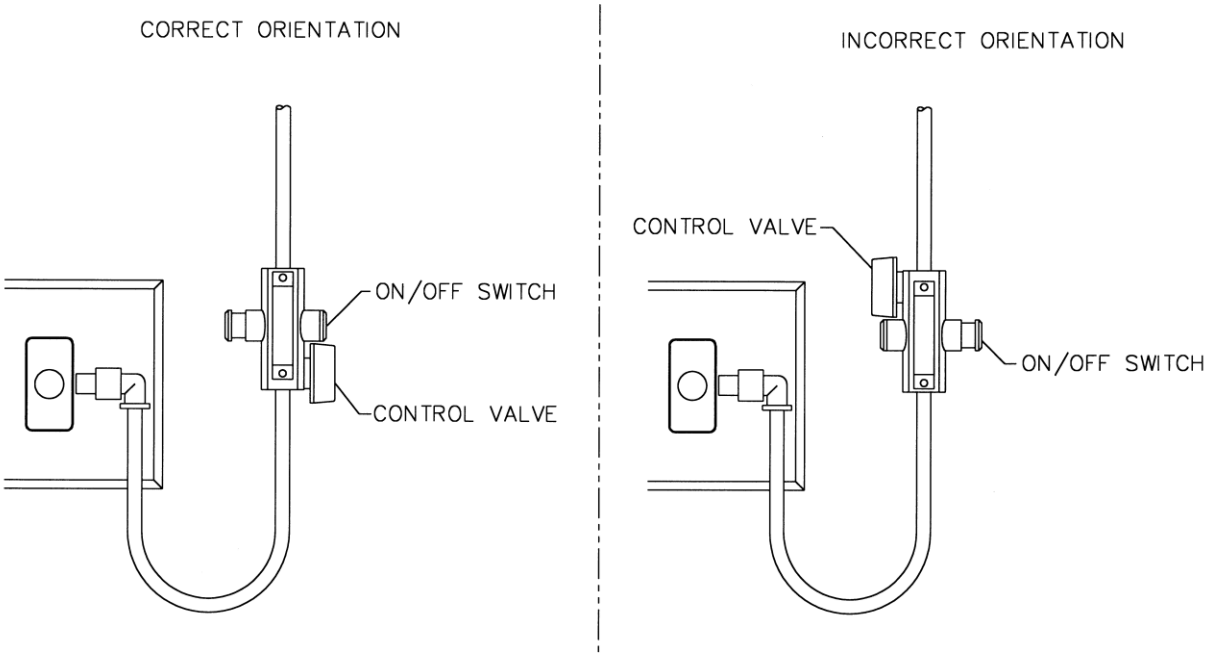
C. Attach the 3 L bag (#13) to the bottom of the bag tee (#6).

D. Attach Vacuum Hoses (#8): Refer to Figure 1 page 4.

1. *Automatic Vacuum Switch*: Attach one end of the vacuum hose (#8) to the vacuum hose "Y" connector (#12) and the other end to the MASK port (labeled on body) of the AVS (#1). Attach a second vacuum hose (#8) to the VAC port (labeled on body) of the AVS (#1), then insert straight end of adapter (#17) into the other end of the vacuum hose and the tapered end of the adapter into the High Volume Evacuation (HVE) Line.

2. *Vacuum Control Block*: Attach one end of the vacuum hose (#8) to the vacuum hose "Y" connector (#12) and the other end to the vacuum control block (#2).
The vacuum control block can then be inserted directly into the High Volume Evacuation (HVE) Line; or may be placed "in line" by cutting the vacuum hose and attaching the cut ends of the tubing to both ends of the vacuum control block. NOTE: To properly read vacuum levels, the vacuum control block must be held upright with the on / off switch above the control valve. See Figure "A" below.

Figure A



Note: An adapter (#14 or #15, refer to Figure 2 page 5) is provided if the installer wishes to "tee" into the vacuum line. The "tee" should be located after the solids collector.

ITEM	PART NUMBER. / REF	DESCRIPTION (Refer to Figure 1 for Assembly & Figure 2 for Options for Vacuum Hook-up.)
1	AVS 5000	Automatic Vacuum Switch (AVS)
2	5501-RK	Vacuum Control Block Kit (Optional)
3	5054A	Porter Adult Nasal Inhaler Complete with 3 liners.
3a	5054-1	Package of 3 Adult Inner Liners
4	5054B	Porter Pedo Nasal Inhaler Complete with 3 liners.
4a	5054-2	Package of 3 Pedo Inner Liners
5	5056	Coaxial Tubing Assembly (Set of 2)
6	P1407A (US)	Bag Tee (REF P1407E for European)
7	5058	Fresh Gas "Y" Connector
8	5059	Vacuum Hose (8 ft.)
9	5060-3	Fresh Gas Corrugated Tubing, Non-Latex (3 ft.)
9a	5060-6	Fresh Gas Corrugated Tubing, Non-Latex (6 ft.) (Optional)
9b	4200	Fresh Gas Corrugated Tubing, Latex (2 ½ ft.) (Optional)
10	1571-22	22mm Right Angle Flowmeter Adapter
10a	1570-24	24mm Right Angle Flowmeter Adapter (Optional)
11	5061	Mask to Tubing Plastic Connectors (Set of 2)
12	5062	Vacuum Hose "Y" Connector
13a	4100-3NL	3 Liter Bag, Non-Latex
13b	4100-2NL	2 Liter Bag, Non-Latex
14	5063	1/2" 'T' Adapter for In-line Vacuum Block (See Figure 2)
14a	5068	5/8" 'T' Adapter for In-line Vacuum Block (See Figure 2)
15	5064	"Straight" Adapter for In-line Vacuum Block (See Figure 2)
16	5065	Vacuum Tube Holder
17	A-3679-000	Adapter, Black, ¾" Round (VAC/MASK)

Quick Test to Check 3 Liter 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. Refer to Figure B.
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 3 liter bag starts to over-inflate or "balloon", then turn the meter off at the ON / OFF switch.
4. Observe the 3 liter bag for <u>five</u> minutes.
5. The bag should stay inflated. If so, the test has been successful and there are no excessive leaks.
6. If the bag does not stay inflated, the 3-liter bag or rubber goods have an excessive that leak. Replace any parts that leak and retest until results are successful.
7. Disconnect one of the duplex hoses from the plastic connector and re-install the nosepiece. **Figure B**

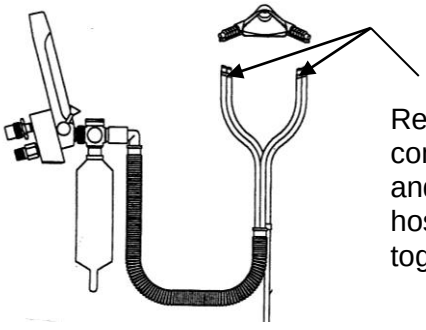


FIGURE 1

NITROUS OXIDE CONSCIOUS SEDATION DELIVERY SYSTEM

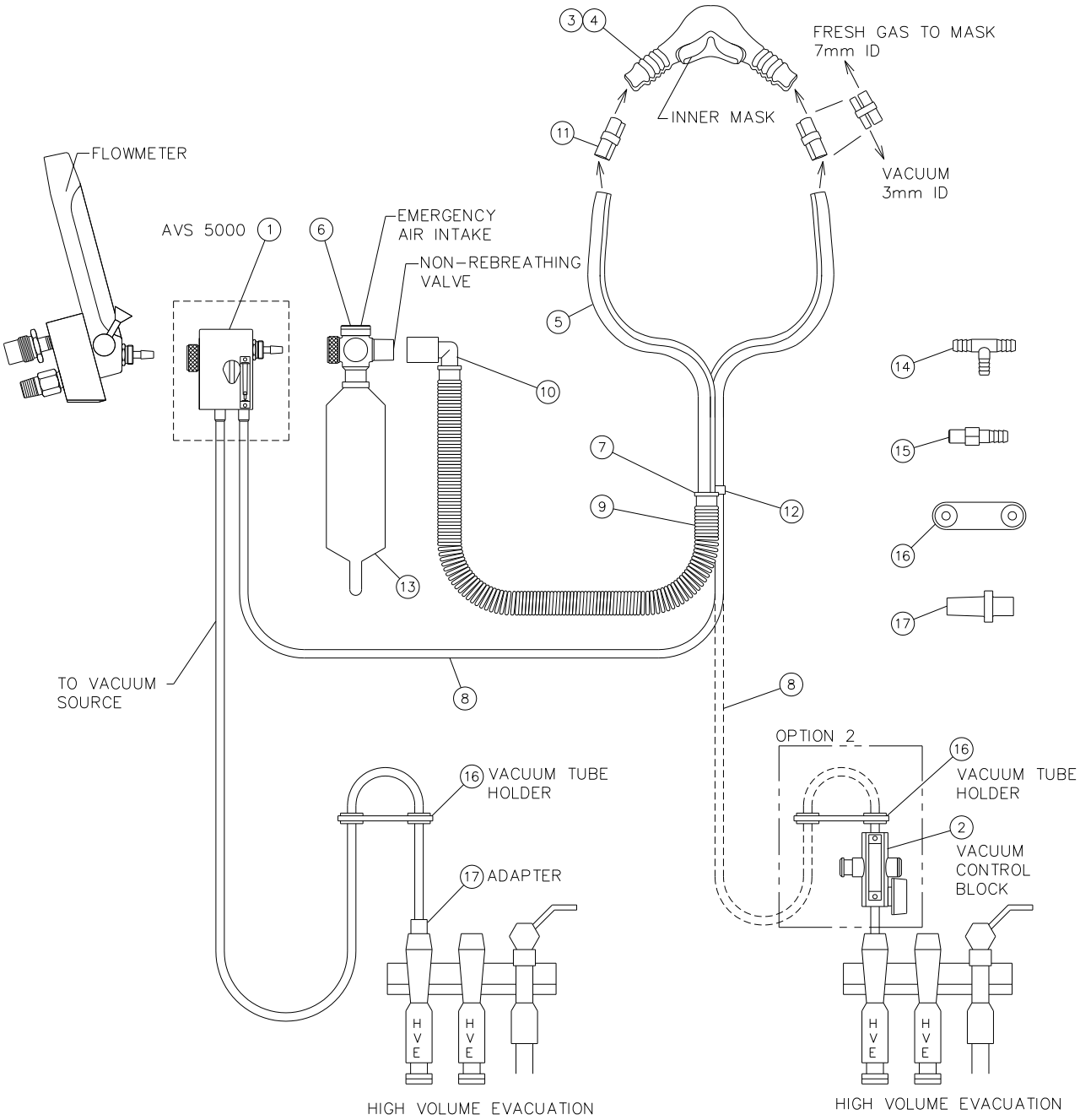
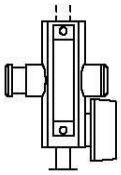
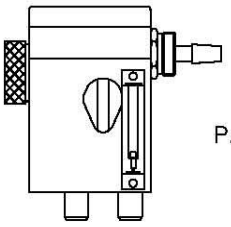


FIGURE 2: OPTIONS FOR VACUUM HOOK–UP



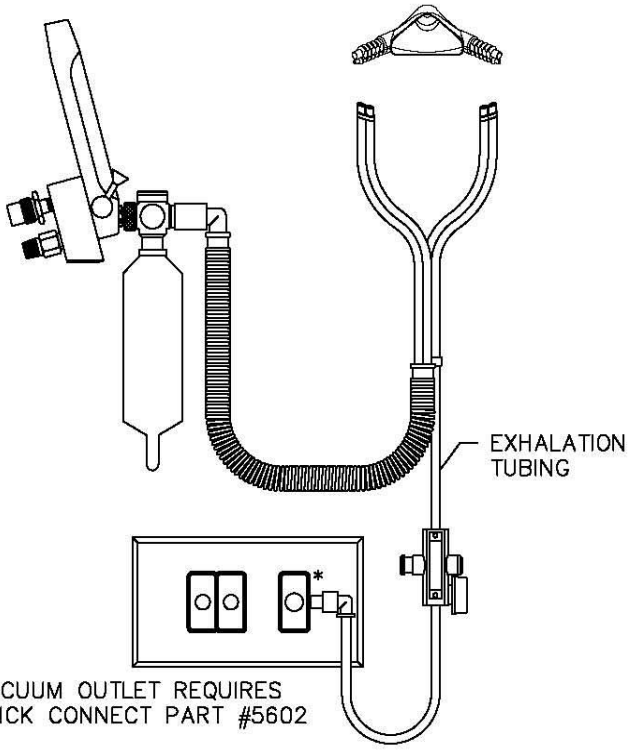
PART # 5501–RK

VACUUM CONTROL BLOCK

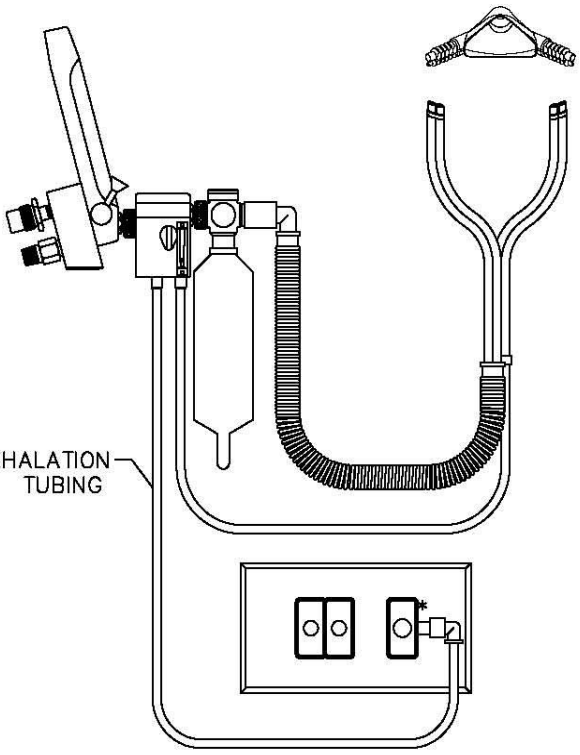


PART # AVS–5000

AUTOMATIC VACUUM SWITCH

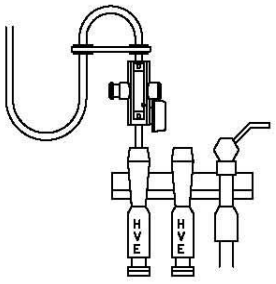


VACUUM OUTLET QUICK CONNECT

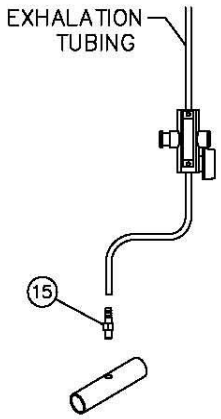


VACUUM OUTLET QUICK CONNECT

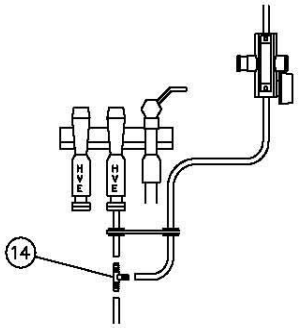
*–VACUUM OUTLET REQUIRES QUICK CONNECT PART #5602



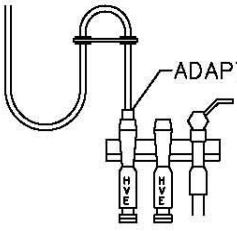
HIGH VOLUME EVACUATION (HVE) ATTACHMENT



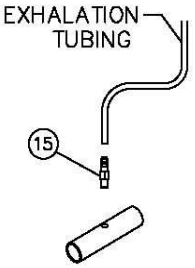
PVC VACUUM LINE HOOK–UP



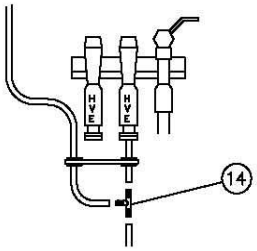
TEE CONNECTION IN THE VACUUM LINE



HIGH VOLUME EVACUATION (HVE) ATTACHMENT



PVC VACUUM LINE HOOK–UP



TEE CONNECTION IN THE VACUUM LINE

⚠ CAUTION

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

⚠ CAUTION

DO NOT PROCESS ANY LIQUIDS OR DEBRIS THROUGH THE AVS. This contamination can cause damage and affect the function of the unit. The AVS is designed to regulate the vacuum flow level for scavenging of Nitrous Oxide / Oxygen gas only.

Basic Operation:

For the AVS or Vacuum Control Block (Note: Use either an AVS or a Vacuum Control Block, not both):

1. AVS will **automatically** open upon the delivery of 1.5 to 3.5 L/min of gas flow. The Vacuum Control Block is manually operated and must be opened by pushing "on/off" toggle to "on" position.
2. Adjust vacuum flow by using vacuum control knob and acrylic sight glass on side of AVS or Vacuum Control block. Vacuum flow with ball float within the green bar area is effective; ball above green bar is for highest vacuum flows.
3. Monitor the vacuum conditions during the procedure by observing the sight glass; adjust vacuum flow at any time as necessary.
4. Follow good work practices as recommended by NIOSH.
   - 4.1. Caution the patient not to talk unnecessarily or breathe through the mouth.
   - 4.2. The mask must be fitted properly to avoid leaks. (Pedo mask for children.)
   - 4.3. 100% Oxygen only should be administered while the mask is being placed. Flowing Nitrous Oxide while fitting the mask will significantly increase N_2O ppm (parts per million) exposures.
   - 4.4. All Porter masks are sealed (no hole in the front of the mask). An open air valve or air dilution technique is not recommended.
   - 4.5. Flow only the volume of gas required by the patient. An over-full reservoir bag indicates excessive gas flow, which could increase N_2O ppm exposures.
   - 4.6. 100% Oxygen only should be administered for several minutes at the end of the procedure. This will flush the Nitrous Oxide from the patient. Failure to follow this procedure will result in higher N_2O ppm exposure in the operatory.

Field Performance Check of Adjustment of Vacuum Flow Using the AVS:

1. **Set a high flow:** After assembly of AVS and Scavenging System to the Flowmeter, set flowmeter to flow 8 L/min of 100% Oxygen to fully open AVS vacuum interlock.
2. **Set vacuum level (green bar or higher):** Turn vacuum control knob to set vacuum flow, as indicated by the vacuum indicator, in the desired area *.

   **Porter recommends that effective scavenging can be achieved with the ball float in the green bar area of the acrylic sight glass, however NIOSH publications conclude that higher vacuum flows of up to 45 L/min are most effective. To meet the NIOSH recommendation of 45 L/min, adjust the ball above the green bar area.*
3. **Close the flowmeter** flow to zero. The ball float will drop to the bottom of the sight glass.
4. **Check at low flow:** Open the flowmeter, again with 100% Oxygen, slowly to 3.5 L/min. Observe that the AVS vacuum flow indicator reaches the same level as in the setting of Step 2.

NOTE: If low flow check does not show high enough vacuum flow, repeat Steps 1 - 4, and adjust vacuum control knob to a higher vacuum flow setting. Effective scavenging is achieved if vacuum flow can be verified to be within the green bar area of the acrylic sight glass. However, if the check of Step 4 fails, it may be an indication that the AVS requires maintenance. Contact your Porter dealer.

Cleaning Methods:

For cleaning the AVS and accessories, we recommend the use of an approved disinfectant for the dental environment. Follow the disinfectant manufacturer's directions for use and their cautions. Recommended methods for cleaning and sterilizing rubber goods are listed in the chart.

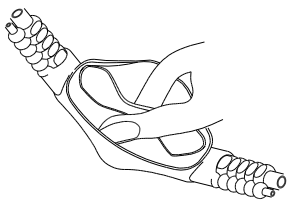
System Maintenance, Ventilation and Work Practices:

1. It is advisable, on a two (2) year cycle, to have the AVS and flowmeter factory checked and serviced.
2. Inspect and maintain the analgesia delivery system to prevent N_2O leaks in all hoses, connections, and fittings. Repair all leaks immediately.
3. Use scavenging. Exhaust ventilation of N_2O from the patient's mask should be maintained at an appropriate air flow rate as indicated by the calibrated flowmeter sight glass, and vented outdoors – not into the room ventilation system.
4. Supply and exhaust vents should be well separated to allow good mixing and prevent "short-circuiting."
5. Fit mask to patient so inner mask is secure to the face. **Outer mask should not be against face.** Vacuum needs to be drawn into outer mask during inhalation.
6. Use minimum N_2O levels to achieve desired analgesia effects.
7. Monitor work area for N_2O to insure controls are effective in achieving low levels of PPM exposure. Contact your Porter dealer for details on monitors and testing.

Methods for Cleaning and Sterilizing Porter Nasal Assembly

CAUTION: The Following Items Are Not Autoclaveable!
Fresh Gas Tubing 5060-3/5060-6 (older models with grey or black color only), Vacuum Control Valves, and Corrugated Tubing 4200 (black color).

<u>Nasal Hood and Liners</u>
Before cleaning, remove inner mask from hood. Pinch top and bottom of inner mask with thumb and forefinger then pull toward center. Follow recommended cleaning and sterilization as detailed below with hood and liner still separated. Then, replace inner mask into hood by pushing the tube connectors into large holes with thumb or forefinger.



WARNING: Chemical Disinfectants should not be used!
Disinfectants do not provide the same reduction in microbial contamination levels as sterilization. These techniques can leave a residue on the mask and liner that can irritate or even chemically burn the patient's skin or mucous membranes if the mask / liner is not rinsed thoroughly with clean water.

To ensure proper cleaning, follow the directions below.

Note: The nasal hood and coaxial hoses should be cleaned and sterilized after each use.

Note: The 2L or 3L breathing bag may be cleaned as needed, and is able to be cleaned using manual, automatic, and sterilization cleaning methods. The breathing bag can also be sterilized using a steam autoclave using the standard cycles recommended by the manufacturer of the autoclave.

1. Rinse the device under running utility (tap) water to remove gross soil. Ensure lumens are rinsed.

2. Follow the procedure below for manual cleaning.

   - Prepare a detergent bath using Neodisher Mediclean Forte (or equivalent alkaline and enzyme cleaner) solution at the manufacturer's recommendation of 5 mL per liter using utility (tap) water.

   - Immerse the articles for 10 minutes.

   - While immersed scrub the articles using a soft bristled nylon brush until visible soil is removed. Use an appropriately sized lumen brush to clean lumens. NOTE: Pay particular attention to crevices, lumens, connectors and other hard to clean areas.

   - Rinse components under running utility (tap) water. Ensure to thoroughly rinse all internal surfaces and lumens.

   - Dry the articles by air drying or using pressurized compressed air.

3. Follow the procedure below for automatic cleaning.

   - Transfer the test articles onto the 4–Level manifold rack accessory (or other appropriate rack system) contained inside the washer for processing. Angle the article in the washer basket to aid with drainage.

   - Document placement location inside the washer.

   - Select the appropriate cycle as listed below.

STAGE	RECIRCULATION TIME (MINUTES)	Temperature	detergent type and concentration (if applicable)
Pre-wash 1	2:00	Cold tap water	N/A
Wash 1	10:00	43°C (109°F) Tap water (Set Point)	Neodisher Mediclean Forte (or equivalent alkaline and enzyme cleaner) 2 mL/L
Rinse 1	1:00	43°C (109°F) Tap water (Set Point)	N/A
Pure Water Rinse	1:00	43°C (109°F) RO/DI water (Set Point)	N/A
Dry Time	7:00	90°C (194oF)	N/A

4. Autoclave all parts not included in the CAUTION.

5. Perform steam sterilization in accordance with the following sterilization set points.

   - Sterilizer type: Prevacuum

   - Full Cycle: Minimum of 4 minutes at 132°C (270°F), dry time 30 minutes.

   - Full Cycle: Minimum of 3 minutes at 134°C (273°F), dry time 40 minutes.

   - Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (sequential envelope folding)

WARNING:

Dental workers are exposed to Nitrous Oxide (N_2O) during administration of N_2O/ O_2 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 N_2O concentrations in dental operations. Your Porter Scavenger System is an important part of the system of controls.

CAUTION

Black Corrugated Tubing 4200: This products contain Natural Rubber Latex, which may cause allergic reactions.

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 Division 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 the local Parker Hannifin Corporation distributor. 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.

Parker Hannifin Corporation
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CE

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.

Authorized Representative:

EC REP

Contact Name: Parker Hannifin Manufacturing Sarl
Mailing Address: Via privata Archimede 1, 20094 Corsico, Italy

Phone: +0223077419