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USER INSTRUCTIONS

FOR

ASSEMBLY INSTALLATION AND CLEANING

PORTER Scavenger System

- With the Silhouette Disposable Breathing Circuit

Silhouette
LOW PROFILE NASAL MASK

- Available with Automatic Vacuum Switch [AVS-5000]
- Available with Vacuum Control Block [5501-RK]

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 (Use with Silhouette)

Note: Refer to FM-809 for scavenger use with Porter brown Scavenger Rubber Goods System

The Silhouette low profile nasal mask design provides to the Medical Health Care market a mask and breathing circuit solution that will allow high visibility to the medical professional [especially dentist], and provide an adhesive based seal onto the patient's face, allowing its built-in scavenging system to effectively remove excess/exhaled nitrous oxide [N2O], with minimal loss to the environment. It allows the patient to receive the proper amount of Oxygen and Nitrous Oxide with normal respiratory effort.

The Nasal Mask is placed first (adhesive lamination cover removed first) on to the patient's nose. The Comfort Tubing is placed around the patient's ears. The Reusable Tubing is attached to the Fresh Gas and Vacuum Source connections. The Slide Bolo is placed to secure the Circuit at the patient's neck, completing a multi-point secure placement on the patient's face. A Fresh Gas Mixture of nitrous oxide and oxygen is delivered from the Flowmeter into the Circuit and into patient's nasal cavity via the Mask; exhalation is scavenged through to the Vacuum Source. Circuit is disposed after use.

The sight lines from the medical professional to the patient's mouth (work area) created by the low profile will be superior to existing devices.

The medical professional can easily manipulate the patient's mouth without interference to the fit of the Circuit, while the patient can turn the head side to side in comfort.

Applicable with or without the use of a Bag Tee (with 3-Liter Breathing Bag capped off).

Easy to Attach Sequence: Also refer to FM-1312 (supplied with each Circuit).

1. Use Silhouette Reusable SIL-CONN-KIT Connector Kit. Attach smaller diameter hose end to cannula barb or flowmeter adapter. Attach larger diameter hose end to Porter AVS or other vacuum source.
2. Place colored sizer masks over the nose to determine appropriate mask size for the patient. Sizers may be sterilized after each use.
3. The Silhouette disposable breathing circuit is packaged in a color-coded box and is first removed from the box for placement on the patient.
4. Prepare for placement of the mask on the patient's nose by removing the adhesive cover tab from the mask.
5. Pull the slide bolo down to create a loop large enough to place behind the patient's ears.
6. Place nasal cannula fully into the right nostril, flexing the mask as needed.
7. Rotate the mask down over the nose until contact is made.
8. Compress the mask adhesive at the bridge of the nose. Verify good seal is achieved around the entire mask.
9. Place the tubing over the top of the left and right ear.
10. Move the slide bolo up until the circuit is snug against the patient's neck.
11. Observe overall position of the patient, mask, and circuit for proper positioning with good mask seal and no evidence of tubing kinking. Use Clip Strap on Reusable Hose.
12. If End-tidal CO2 (EtCO2) monitoring is being used, disconnect the cap at the end of the disposable breathing circuit and attach the EtCO2 male Luer lock sample line.
13. You are now ready to turn on your Nitrous Oxide flowmeter.

After patient's treatment is completed, dispose of the Silhouette breathing circuit (36" disposable section only).

Part Numbers Silhouette (4 sizes of Mask)

Silhouette-PD, Silhouette-SM, Silhouette-MD, Silhouette-LG
Reorder Part Number: SIL-PEDO-12, SIL-SM-12, SIL-MED-12, SIL-LG-12 (Case of 12 Circuits)

Contents: One (1) Analgesia Disposable Breathing Circuit
Rx Only: Circuits for use by a physician or licensed healthcare Professional.

Disposable Circuit is for use with SIL-CONN-KIT with Reusable Paratubing (B-5581-000), Cap (62905510W [12]), Adapter (PA-1629-000; 22 mm x 5-7 taper), and Clip Strap (PA-1630-000)

FM-1312 Document
Individual Porter Silhouette Breathing Circuit

The Circuit provides a luer lock sample line connection to allow etCO2 capnography monitoring during the administration of nitrous oxide / oxygen conscious sedation to a patient.

Warning: If not monitoring capnography, the luer lock must be capped (included) to avoid N2O from leaking into the room.

Single Patient Use

Not made with natural rubber latex

Warning: A kinked delivery Comfort Hose will result in the Circuit being “popped” off the Flowmeter or Bag Tee attachment barb.

Porter Silhouette suggested instructions

1. Follow Flowmeter directions for use.
2. Deliver approximately 6 lpm total flow to every patient at first (typical procedure begins with 100% O2 and then moves to a chosen N2O mixture percentage).
3. Simply increase flow if more sedation is needed.
4. Or increase the N2O mixture percentage at a lower flow.
5. Always remind the patient to refrain from mouth breathing.
6. If delivered gas into the nostril is not comfortable, move to a lower flow rate and increase mixture percentage to maintain sedation level.
7. Note: Flowmeter Flush features may be used with discretion, observing patient comfort, as increased flush flow is delivered to one nostril.

Applicable with or without the use of a Bag Tee (with 3-Liter Breathing Bag capped off).

Use of Silhouette with a Bag Tee

The Silhouette Circuit may be used with or without a Bag Tee. When used with a Bag Tee (including those of most brands of flowmeters) the 3-Liter Breathing Bag should be capped off using the Cap (62905510W) found in kit SIL-CONN-KIT. The fresh gas Adapter (PA-1629-000) in the kit provides a 22mm adapter to 5-7 mm taper for the reusable paratubing hose (B-5581-000).

A Non-Rebreathing Valve (NRV) and Emergency Air Intake (EAI) is typically located on the Bag Tee to provide safety features. (See NRV and EAI tests below.)

Note: Patient inhalation through Silhouette Circuit (with Total Flow delivery of approximately 5 L/min or lower) will open the EAI valve for supplemental air intake. Primarily, the 4 holes featured in every Silhouette Mask provides air intake.

Porter Retrofit Kits

Porter Scavenger Retrofit Kits are available for most brands of flowmeters. You can update 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.

Emergency Air Intake (EAI) Test

With the flowmeter turned off and the breathing bag empty, or capped, 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.

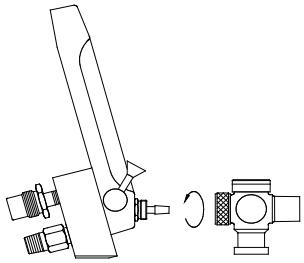
If your system fails this test, your system should be updated with a Porter Scavenger Retrofit Kit.

IMPORTANT: It is **recommended** to retrofit Porter Scavenger Rubber Goods to ADA Acceptable 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

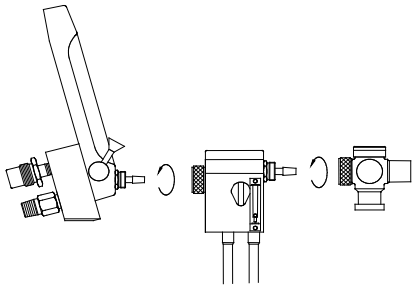
1. **Bag Tee to Flowmeter:**

   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. Fit the Silhouette Cap to the Breathing Bag (bottom) port and the Adapter to the 22mm port.



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. Alternatively, just attach the AVS and connect the Silhouette fresh gas tubing directly to the AVS output.



3. **Silhouette and Vacuum and Bag Tee:** *(Refer to item (#) in parts list on the next page and Figures 1 and 2 on pages 6 and 7 for assembly and hook-up options.)*

A. Existing Bag Tee assembly: Detach the 3 L bag from the bottom of the bag tee (#16).

B. Fit the Silhouette Cap to the Bag (bottom) port and the Adapter to the 22mm port.

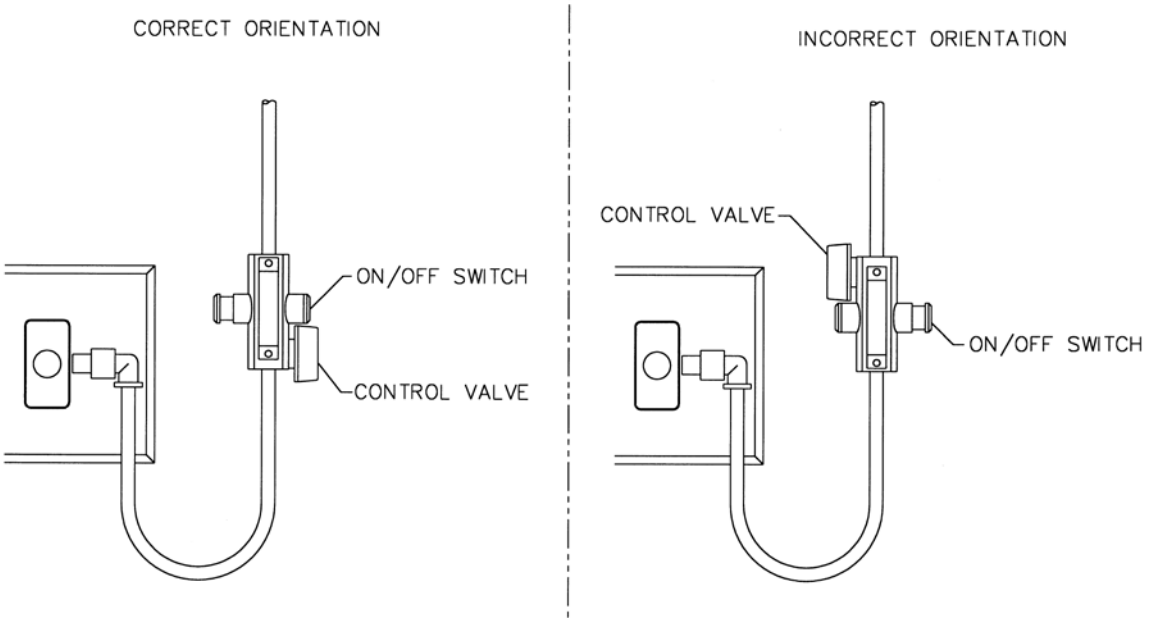
C. The Circuit design has Disposable and Reusable sections (connected to flowmeter and vacuum source). Use Silhouette Reusable SIL-CONN-KIT Connector Kit. Attach smaller ID hose end to flowmeter Adapter. Attach larger ID hose end to AVS or other vacuum source.

D. Attach Vacuum Hoses (#15): Refer to Figure 1 page 6.

1. *Automatic Vacuum Switch*: Attach one end of the Reusable vacuum hose (#15) to the Union of the Silhouette Disposable Circuit (diameter indexed) and the other end to the MASK port (labeled on body) of the AVS (#1). Attach a second vacuum hose (#15) to the VAC port (labeled on body) of the AVS (#1), then insert straight end of adapter (#20) into the other end of the vacuum hose and the tapered end of the adapter into the High Volume Evacuation (HVE) Line.

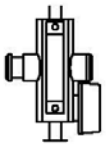
2. *Vacuum Control Block*: Attach one end of the Reusable vacuum hose (#8) to the Union of the Silhouette Disposable Circuit (diameter indexed) and the other end to the vacuum control block (#2).
The vacuum control block can then be inserted directly into the High Volume Evacuation (HVE) Line; or may 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



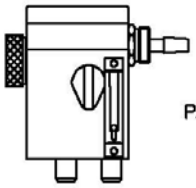
Note: An adapter (#17 or #18, refer to Figure 2 page 7) is provided if the installer wishes to "tee" into the vacuum line. The "tee" should be located after the solids collector.

FIGURE 2: OPTIONS FOR VACUUM HOOK–UP



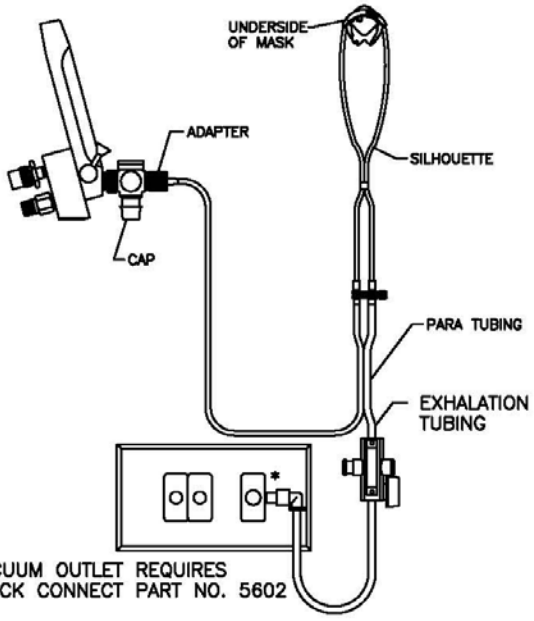
PART NO. 5501–RK

VACUUM CONTROL BLOCK



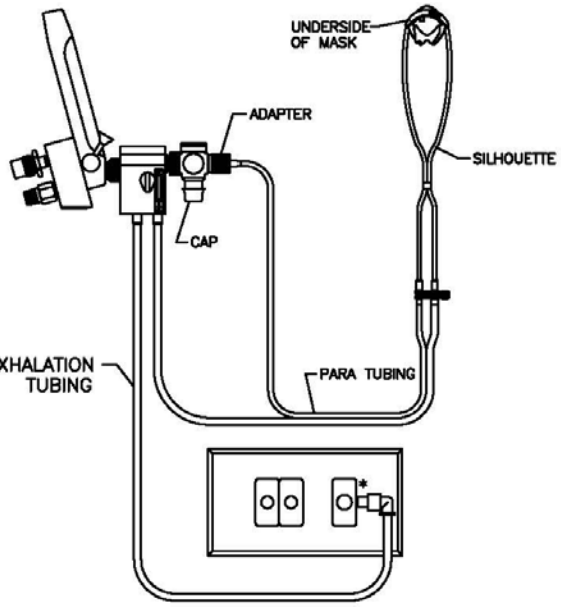
PART NO. AVS 5000

AUTOMATIC VACUUM SWITCH



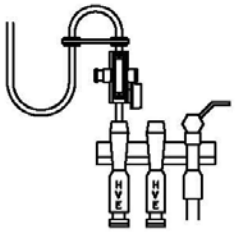
*–VACUUM OUTLET REQUIRES QUICK CONNECT PART NO. 5602

VACUUM OUTLET QUICK CONNECT

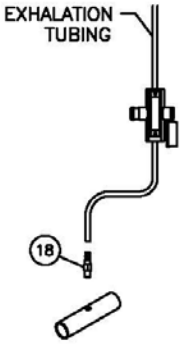


VACUUM OUTLET QUICK CONNECT

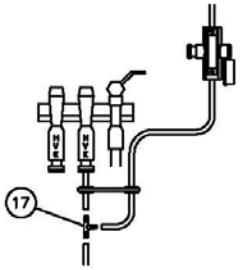
*–VACUUM OUTLET REQUIRES QUICK CONNECT PART NO. 5602



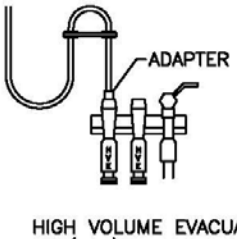
HIGH VOLUME EVACUATION (HVE) ATTACHMENT



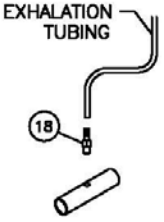
PVC VACUUM LINE HOOK–UP



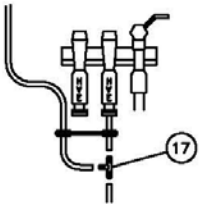
TEE CONNECTION IN THE VACUUM LINE



HIGH VOLUME EVACUATION (HVE) ATTACHMENT



PVC VACUUM LINE HOOK–UP



TEE CONNECTION IN THE VACUUM LINE

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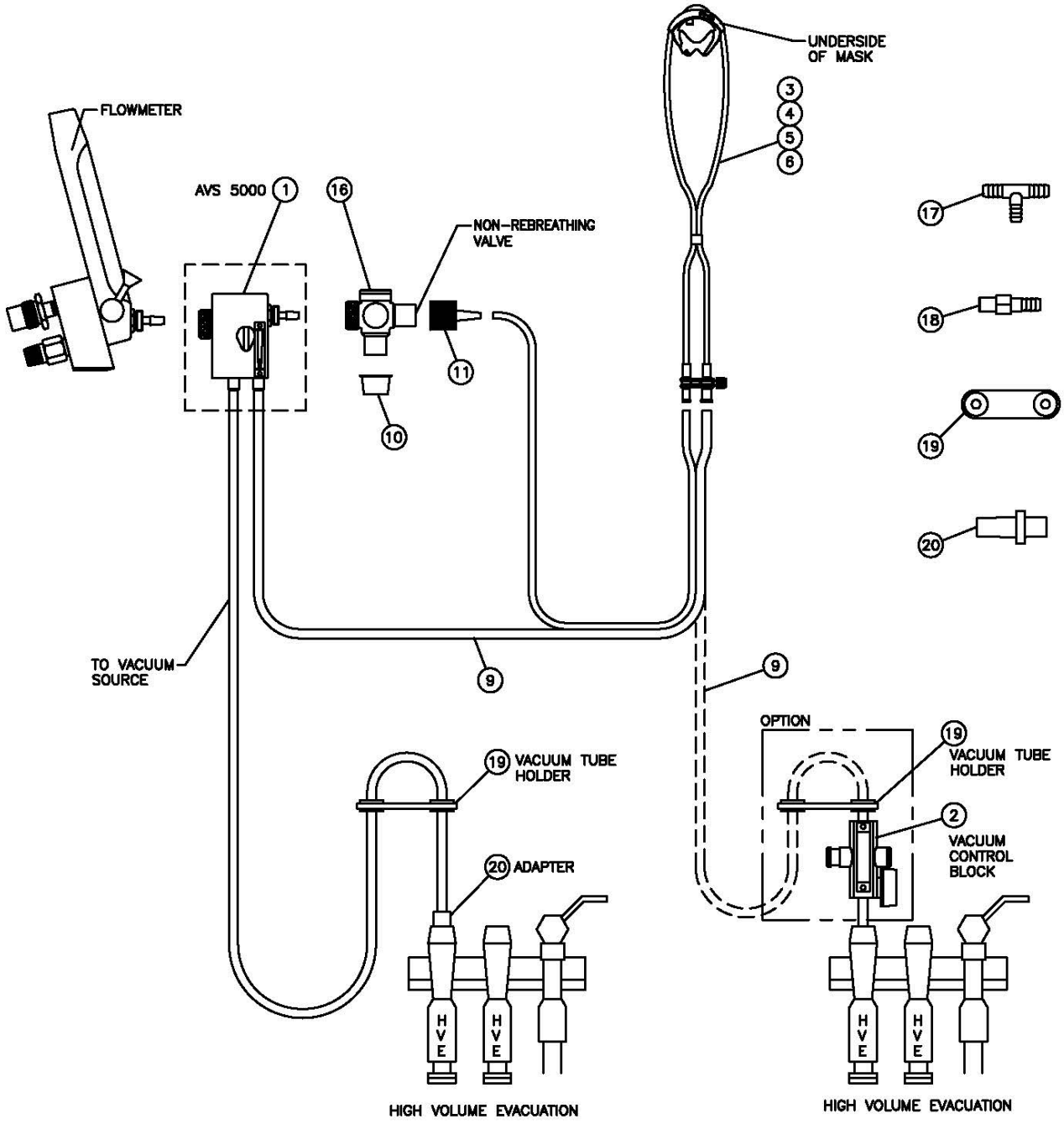
FIGURE 1

NITROUS OXIDE CONSCIOUS SEDATION DELIVERY SYSTEM



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	SIL-PEDO-12	Silhouette Circuit, Pediatric, 12 Pack
4	SIL-SM-12	Silhouette Circuit, Small, 12 Pack
5	SIL-MED-12	Silhouette Circuit, Medium, 12 Pack
6	SIL-LG-12	Silhouette Circuit, Large, 12 Pack
7	SIL-SAMP-KIT	Mask Sample Kit, 1 sample of PEDO, SM, MED
8	SIL-VAR-4X3	Mask Variety Pack, 3 circuits of each size
9	SIL-CONN-KIT	Connector Kit; Reusable Paratubing, Cap, Adapter, Strap
10	62905510W	Cap, White
11	PA-1629-000	Tubing Adapter, 22mm x 5-7 taper
12	B-5581-000	Reusable Paratubing, 6 ½ ft.
13	FM-1312	Silhouette Mask Instruction for User Insert
14	FM-1313	Silhouette User's Instructions
15	5059	Vacuum Hose (8 ft.)
16	P1407A (US)	Bag Tee (REF P1407E for European)
17	5063	1/2" 'T' Adapter for In-line Vacuum Block (See Figure 2)
17a	5068	5/8" 'T' Adapter for In-line Vacuum Block (See Figure 2)
18	5064	"Straight" Adapter for In-line Vacuum Block (See Figure 2)
19	5065	Vacuum Tube Holder
20	A-3679-000	Adapter, Black, ¾" Round (VAC/MASK)
21	PA-1630-000	Clip Strap
22	SIL-SIZER-4	Silhouette Sizers, 4 pack

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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 Vacuum Control using Silhouette Circuit:

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 without Silhouette Circuit attached.** Use 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 high within green bar is for highest vacuum flows.
3. Monitor the vacuum conditions during the procedure by observing the sight glass; Note: vacuum is indicated with Silhouette Circuit attached and ball "pegged high" in sight glass. Ball float at bottom indicates no vacuum flow. Repeat step 2 adjust vacuum flow as necessary. Adjust valve towards horizontal position to increase vacuum flow.
4. Note: Adjust vacuum flow with **Matrx** vacuum control block with **Silhouette Circuit attached.** Set to 5 minimum.
5. Note: Silhouette Circuit **attached for other brand** vacuum control blocks; set middle to high end settings.
6. Follow good work practices as recommended by NIOSH.
   - 6.1. Caution the patient not to talk unnecessarily or breathe through the mouth.
   - 6.2. The Silhouette Circuit Mask must be fitted properly to avoid leaks. (Pedo mask for children.)
   - 6.3. 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.
   - 6.4. All Silhouette Masks feature 4 holes in the front of the mask for supplementary air intake (also available, at lower delivery flow rates, through inhalation opening the EAI valve).
   - 6.5. Flow only the volume of gas required by the patient. Excessive gas flow could increase N_2O ppm exposures.
   - 6.6. 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 (Silhouette Circuit not attached):

1. **Set a high flow:** After assembly of AVS and prior to attachment of the Silhouette Circuit 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 high or 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 Silhouette Mask to patient, loop Comfort Hose around ears, place slide bolo to chin (multi-point security) so Mask is secure to the face. Vacuum needs to be drawn into 4 holes of mask during inhalation and exhalation.
6. Adhesive seal may be enhanced by removing facial oils at bridge of nose.
7. Use minimum N_2O levels to achieve desired analgesia effects.
8. 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.

Recommended Methods for Cleaning and Sterilizing

NOTE: The following items are <u>not</u> autoclaveable:
Fresh Gas Tubing, 3L Latex Bags and Vacuum Control Valves.

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.

***NOTE: The following items are <u>not</u> autoclaveable:**
Fresh Gas Tubing, 3L Latex Bags and Vacuum Control Valves.

Recommended Cleaning and Sterilizing			
Product	**Silhouette Disposable Circuit**	**Reusable Hoses***	**Latex-free 2L and 3L Bag***
Frequency	**<u>Dispose</u>** after every patient.	Once a week	Once a week
Cleaning	**Recommended:** Wash in warm water with a mild detergent. Proceed to sterilization step. Alternate Method: A thermal washer-disinfector may be used instead of warm soap and water. Proceed to sterilization step. (A washer-disinfector is <u>not</u> a substitute for sterilization, as it does not provide the same reduction in microbial contamination levels as sterilization.) Alternate Method: An ultrasonic cleaner may be used. Generally only required when dealing with blood or heavy bioburden. Proceed to sterilization step. **Required:** Rinse with water then follow the recommended <u>Sterilization</u>.		
Sterilize	Steam Autoclave: bag or wrap. 134°C to 137°C for 3 minutes minimum; or bag or wrap. 121°C to 123°C for 15 minutes minimum Chemical Vapor Sterilizer: Let cleaned items dry completely then sterilize on any cycle recommended by the sterilizer manufacturer. **Dry Heat Sterilization and Chemical Disinfectants should not be used!**		

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

3L Breathing Bag 4100 and Corrugated Tubing 4200: These 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.