

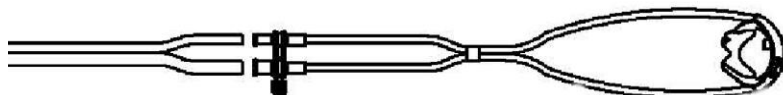
# **USER INSTRUCTIONS FOR PORTER**

## **Silhouette Disposable Breathing Circuit**



**Silhouette -PD, -SM, -MD, -LG**

**Disposable Section**



**Reusable Section**

**SIL-CONN-KIT**

**Smaller hose to Flowmeter**

**Larger hose to Vacuum Control Device**



**Usable with**

- **Porter Automatic Vacuum Switch (AVS-5000)**
- **Porter Vacuum Control Block [5501-RK]**
- **Matrx Vacuum Control Device (on flowmeter)**

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."

## Silhouette Introduction

Please review brief instructional setup and usage videos at [www.porterinstrument.com/silhouette](http://www.porterinstrument.com/silhouette)

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 [N<sub>2</sub>O], 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 Section is attached to the Fresh Gas and Vacuum Control Device 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 Control Device. Disposable Section is disposed after use.

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

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, without losing the seal.

Use Silhouette with or without a Bag Tee (see photos of Reusable vacuum and fresh gas attachments to Porter and Matrx flowmeters).

### Matrx



### Porter with AVS (and without Bag Tee)



Please review brief instructional setup, how to retrofit, and usage videos at [www.porterinstrument.com/silhouette](http://www.porterinstrument.com/silhouette)

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-5581-001).

Note: Primarily, the 4 holes featured in every Silhouette Mask provides air intake. Alternatively, patient inhalation through Silhouette Circuit (with Total Flow delivery of approximately 5 L/min or lower) will open the Emergency Air Intake EAI valve on a Bag Tee for supplemental air intake.

Do not block the 4 holes during a procedure.

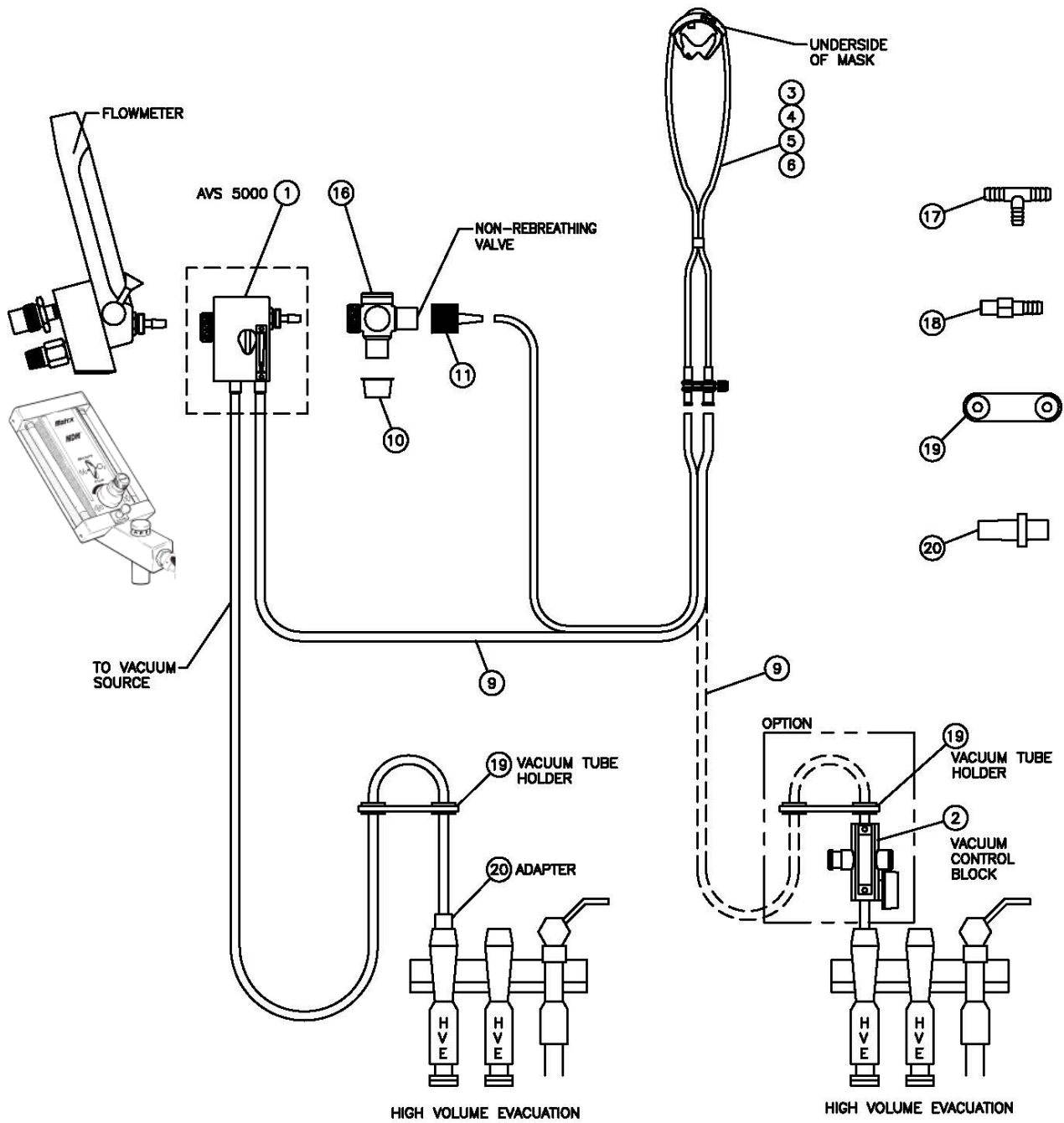
**Silhouette is simple to attach to a Flowmeter without a Bag Tee. Please review brief instructional setup and usage videos at [www.porterinstrument.com/silhouette](http://www.porterinstrument.com/silhouette)**

**For Silhouette and Vacuum and Bag Tee:**  
(Refer to item (#) in parts list Figure 1)

1. Existing Bag Tee assembly: Detach the 3 L bag from the bottom of the bag tee (#16).
2. Fit the Silhouette Cap to the Bag (bottom) port and the Adapter to the 22mm port.
3. 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.
4. Attach Vacuum Hoses (#15): Refer to Figure 1.
5. *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.
6. *Vacuum Control Block:* Attach one end of the Reusable vacuum hose (#9) 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.

FIGURE 1

NITROUS OXIDE CONSCIOUS SEDATION DELIVERY SYSTEM



ITEM	PART NUMBER. / REF	DESCRIPTION (Refer to Figure 1 for Assembly)
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-START-PK	Silhouette Starter Pack: 3 Mask Circuits, Reusable Paratubing, Cap, Adapter
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-5581-001	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

### 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)

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-5581-001), Cap (62905510W), Adapter (PA-1629-000; 22 mm x 5-7 taper), and Clip Strap (PA-1630-000)

FM-1312 Document for Individual Silhouette

The Circuit provides a luer lock sample line connection to allow etCO<sub>2</sub> 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 N<sub>2</sub>O from leaking into the room.



**Single Patient Use**



**Not made with natural rubber latex**



**Contents Not Sterile**

**Basic Operation of Vacuum Control using Silhouette Circuit: Setting Flow**

**For the Porter AVS or Vacuum Control Block**  
**(Note: Use one or the other, 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. **Adjusting vacuum flow using vacuum control knob position:** Highest scavenging flow: For AVS knob is horizontal; for 5501-RK knob is vertical. To lower flow, rotate knob up to 45° from full open position.
3. 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 (or even above) green bar is for highest vacuum flows.
4. **Adjusting vacuum flow with Silhouette Circuit attached:** Temporarily remove luer lock cap on union of Disposable Section and adjust using control knobs.
5. Start 5501-RK knob in vertical position (highest flow) and adjust flow down. Ball float position indicates higher and lower relative flows (exact position of ball dependent on strength of vacuum pump). Start AVS knob in horizontal position (highest flow).
6. **Best “clock face positions”** for the control knobs are listed in table on right. Set knobs at the designated clock face position ranges for best scavenging vacuum flow. Ball float may be above the green bar if vacuum pump vacuum is strong (high vacuum inches Mercury).
7. Remember to replace the luer cap again after adjustment.
8. 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 steps 2 through 7 to adjust vacuum flow as necessary.
9. Note: Adjust vacuum flow with **Matrx** vacuum control block with **Silhouette Circuit attached**. Set to 5 minimum.
10. Note: Silhouette Circuit **attached for other brand** vacuum control blocks; set middle to high end settings.

11. Follow good work practices as recommended by NIOSH.

11.1. Caution the patient not to talk unnecessarily or breathe through the mouth.

- 11.2. The Silhouette Circuit Mask must be fitted properly to avoid leaks. (Pedo mask for children.)
- 11.3. 100% Oxygen should be administered while the mask is being placed. Flowing Nitrous Oxide while fitting the mask will significantly increase N<sub>2</sub>O ppm (parts per million) exposures.
- 11.4. 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 of a Bag Tee).
- 11.5. Flow only the volume of gas required by the patient. Excessive gas flow could increase N<sub>2</sub>O ppm exposures.
- 11.6. 100% Oxygen 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<sub>2</sub>O ppm exposure in the operatory.

Set knobs at the designated clock face position ranges for best scavenging vacuum flow

	5501-RK	AVS
<b>Highest Flow</b>	<b>Knob Vertical</b>	<b>Knob Horizontal</b>
<b>Best Flow Range</b>	<b>11 o'clock to 1 o'clock</b>	<b>8 o'clock to 10 o'clock</b>

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

1. Please review brief instructional setup and usage videos at [www.porterinstrument.com/silhouette](http://www.porterinstrument.com/silhouette).
2. Use scavenging and set vacuum flow for Silhouette per instructions on Page 5 (read Warning on Nitrous Oxide exposure minimization on Page 8).
3. Use Disposable Silhouette with Reusable SIL-CONN-KIT Connector Kit. Attach smaller diameter hose end to attachment barb or flowmeter adapter. Attach larger diameter hose end to Porter AVS or other vacuum control device.
4. Place colored sizer masks over the nose to determine appropriate mask size for the patient. Sizers may be sterilized after each use.
5. The Silhouette disposable breathing circuit is packaged in a color-coded box and is first removed from the box for placement on the patient.
6. Prepare for placement of the mask on the patient's nose by removing the adhesive cover tab from the mask.
7. Pull the slide bolo down to create a loop large enough to place behind the patient's ears.
8. Place nasal barb fully into the right nostril, flexing the mask as needed.
9. Rotate the mask down over the nose until contact is made.
10. Compress the mask adhesive at the bridge of the nose. Verify good seal is achieved around the entire mask.
11. Place the tubing over the top of the left and right ear.
12. Move the slide bolo up until the circuit is snug against the patient's neck.
13. Connect disposable section union (diameter indexed) to gas and vacuum reusable hoses (SIL-CONN-KIT).
14. 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 to side of chair or to patient.
15. If End tidal CO<sub>2</sub> (EtCO<sub>2</sub>) monitoring is being used, disconnect the cap at the end of the disposable breathing section and attach the EtCO<sub>2</sub> male Luer lock sample line.



16. 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).



### Porter Silhouette suggested flow instructions

1. Use scavenging and set vacuum flow for Silhouette per instructions on Page 5 (read Warning on Nitrous Oxide exposure minimization on Page 8). Follow Flowmeter directions for use.
2. **How much total flow to start?** A general determination is the "4-5-6 Rule" where 6 is the liters per minute (lpm) for an average male, 5 is the lpm for the average female, and 4 is the lpm for a child [values represent Minute Breathing Volume] (typical procedure begins with 100% O<sub>2</sub> and then moves to a chosen N<sub>2</sub>O mixture percentage).
3. Increase flow or percentage as needed based on patient observation.
4. Always remind the patient to refrain from mouth breathing.



## Recommended Methods for Cleaning Silhouette Products


Silhouette Products are shipped Contents Not Sterile.

**Dispose (No Cleaning):** Silhouette Disposable Circuit [Disposable Section is Single Use Only]

**Cleaning Only (Not Autoclaveable):**

Connector Kit [SIL-CONN-KIT] components Cap and Adapter, and accessory Vacuum Control Valves [5501-RK]. Use approved disinfectant for the dental environment; warm water wash.

**Cleaning and Sterilizing:** See table below

Recommended Methods for Cleaning and Sterilizing Silhouette Products		
Product	Silhouette Sizers (SIL-SIZER-4)	Connector Kit [SIL-CONN-KIT] Reusable Hoses (B-5581-001)
Frequency	After every patient.	Once a week
Cleaning (First Step)	<b>Recommended:</b> Wash in warm water with a mild detergent. Proceed to sterilization step.	
Sterilize (Second Step)	<p>Do not use Silhouette original packaging to sterilize Sizers or Reusable Tubing. Use sterilizer manufacturer's recommendations for sterilization packaging, adequate for sterilization by steam. The user is responsible for any sterilization analysis of equipment used to sterilize Silhouette products.</p> <p>Steam Autoclave:      unwrapped, wrapped, or bag (pouch) 134°C to 137°C for 3 minutes minimum; or unwrapped, wrapped, or bag (pouch) 121°C to 123°C for 15 minutes minimum</p> <p><b>For unwrapped loading:</b> Load product into sterilizer (without using wrapping packaging or cassette) on to standard sterilizer rack or simple sterilizer tray. This method of loading is adequate for steam sterilization.</p> <p><b>For wrapped or bag (pouch) loading:</b> Load product into bag or wrap packaging according to sterilizer instructions. Assure that the packaging is adequate for steam sterilization.</p> <p> <b>Warning: Dry Heat Sterilization and Chemical Disinfectants should not be used!</b> Disinfectants do not provide the same reduction in microbial contamination levels as sterilization. These techniques can leave a residue on the Sizer that can irritate or even chemically burn the patient's skin or mucous membranes if the Sizer is not rinsed thoroughly with clean water.</p>	



### WARNING

Dental workers are exposed to Nitrous Oxide (N<sub>2</sub>O) during administration of N<sub>2</sub>O/ O<sub>2</sub> 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<sub>2</sub>O concentrations in dental operations. Your Porter Scavenger System is an important part of the system of controls.



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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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