

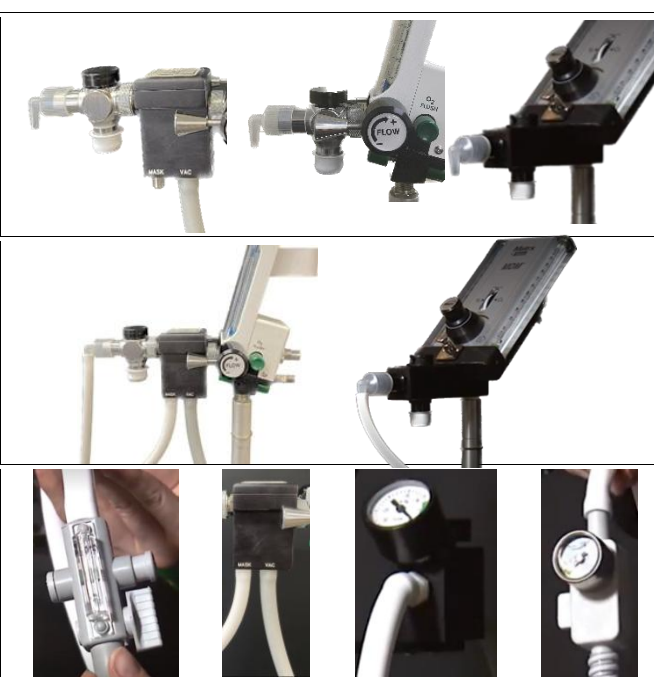
Quick Start Guide for Using the Porter Silhouette™ Retrofit Package (SIL2-RETRO-PKG)

Visit www.porterinstrument.com/silhouette for step-by-step video instructions and complete instructions for use.












1. Parts

| # | Description | |
|---|---|--|
| 1 | Silhouette Sizers (Pediatric, Small, Medium, Large) |  |
| 2 | Fresh Gas and Vacuum Hose (Paratubing) | |
| 3 | 22mm Cannula Adapter | |
| 4 | 22mm Bag Tee Cap | |
| 5 | Patient Clip | |
| 6 | Vacuum Block Adjuster | |

2. Instructions for Retrofit of Flowmeter and Vacuum Control

| # | Description | Image |
|---|--|---|
| 1 | Disconnect and remove the existing breathing circuit and breathing bag from the flowmeter bag tee. Disconnect the breathing circuit vacuum tubing from the vacuum control device. <u>Do not disconnect vacuum tubing from vacuum controller to HVE.</u> |  |
| 2 | Push the Cannula Adapter (3) on to the front of the bag tee fresh gas port with the cannula barb facing down. Attach the Bag Tee Cap (4) to the bottom of the bag tee (where the breathing bag previously was). | |
| 3 | <p>The Fresh Gas and Vacuum Hose (2) may be cut to a desired length depending on the distance to the flowmeter bag tee. The Fresh Gas and Vacuum tubing is a paratubing and the two hoses may be split apart by pulling.</p> <p>Attach the smaller diameter tubing to the Cannula Adapter.</p> <p>Attach the larger diameter tubing to the vacuum control device. The other end / side of the vacuum control device should have a separate hose connected to an HVE source.</p> | |
| 6 | <p>Optional - Only if using Porter In-Line (5501-RK) or Porter AVS (AVS-5000) Vacuum Control: Connect Vacuum Block Adjuster (VBA) (1) in line with the Silhouette vacuum hose and either In-Line or AVS controller. VBA must be on the breathing circuit / mask side of the vacuum controller. Cut approximately a 1" - 2" piece from the end of the white vacuum tubing (larger diameter). Connect VBA as shown and attach to vacuum controller. View videos and refer to FM-1500 for instructions for use.</p> | |

3. Instructions for Sizing and Silhouette Mask and Circuit

| | | |
|----|--|---|
| 1 | Before the procedure starts, begin flowing 100% O ₂ . | |
| 2 | Place the color-coded sizer masks over the patient's nose to determine appropriate mask size for the patient. Select appropriate size Silhouette circuit. |   |
| 3 | Pull the slide bolo down to create a loop large enough to place behind the patient's ears. | |
| 4 | Slightly flex the mask outwards and place nasal barb into the right nostril. Ensure nasal barb is inserted fully. |  |
| 5 | Rotate the nasal hood down over the nose until contact is made and release the mask so that it wraps down on the bridge of the nose. | |
| 6 | Gently pull tubing over the top of the left and right ears. Do not pull tubing behind the headrest. |  |
| 7 | Adjust the bolo by sliding it up under the patient's chin until the bolo is snug. Adjust tubing on the patient's cheeks as needed (may need to flex tubing down). The Silhouette tubing should come down across the patient's chest. |  |
| 8 | Join together the plastic connections on Silhouette Breathing Circuit to the Fresh Gas and Vacuum Hose. The hoses and plastic connectors are diameter indexed. |   |
| 9 | Use the Clip to secure the Fresh Gas and Vacuum Hose to side of chair or to patient clothing. |   |
| 10 | If End tidal CO ₂ (EtCO ₂) monitoring is being used, attach capnography barb (SIL2-CAPNO) (sold separate) to sample line luer lock, then insert capnography barb into capnography port of the Silhouette nasal hood. |   |
| 11 | Instruct the patient to inhale and exhale through the nasal hood. Avoid mouth breathing and talking. | |
| 12 | If patient shows signs or communicates conditions of over-sedation, adjust the flowmeter to 100% O ₂ . | |
| 13 | Monitor the vacuum conditions during the procedure and adjust vacuum flow as necessary to maintain effective scavenging. | |
| 14 | Upon completion of the procedure remove the breathing circuit from the patient and dispose of the Silhouette Circuit. Note: Do not dispose of the reusable accessories. Refer to in FM-1500 for cleaning and disinfection instructions for reusable accessories. | |

4. Cleaning & Sterilization

The Silhouette Breathing Circuit is a single-use disposable device and should not be cleaned. The components (Vacuum Block Adjustor and Fresh Gas and Vacuum Tube) are reusable and maybe cleaned between each patient use. As patient contacting components, the Silhouette Sizer Mask should be cleaned and sterilized between each patient use. **Refer to FM-1500 for complete cleaning instructions.**



WARNING: When using single-use breathing circuits or components, dispose of after the procedure to prevent patient cross-contamination. Do not attempt to clean, sterilize, sanitize, or reuse.



WARNING: To prevent potential patient harm, do not use dry heat or chemical sterilization methods.

4.1. Disposable Parts

Disposal (No Cleaning or Sterilization)

The following Disposable products are Single Use Only:

- Silhouette Breathing Circuit
- Capnography Barb

4.2. Manual Cleaning for Vacuum Components

Manual Cleaning Method

The following reusable components may be cleaned using Manual cleaning method:

- Vacuum Controllers and Vacuum Block Adjuster

4.3. Preparation for Sterilization of Tubing and Sizer Mask

Option 1: Manual Cleaning Method

The following reusable components may be cleaned using Manual cleaning method:

- Fresh Gas and Vacuum Tubing (dual hose)
- Sizer Masks (SIL-SIZER-4)

Option 2: Automated Cleaning

The following reusable components may be cleaned using the Automated cleaning method:

- Fresh Gas and Vacuum Tubing (dual hose)
- Sizer Masks (SIL-SIZER-4)

4.4. Sterilization of Tubing and Sizer Mask (After Sterilization Preparation)

For **Steam Sterilization** - Sterilize items that are in direct contact with the patient.

The following reusable components **may be** sterilized:

- Fresh Gas and Vacuum Tubing (dual hose)

The following reusable components **should be** sterilized:

- Sizer Masks (SIL-SIZER-4)

5. Safety Information



WARNING: This product can expose you to chemicals, including alpha methylstyrene, which is known to the State of California to cause cancer and reproductive harm, go to www.P65Warnings.ca.gov.



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



WARNING: Workers exposed to nitrous oxide may suffer harmful effects. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average)



WARNING: The Silhouette Breathing Circuit, Second Generation used with the delivery of Oxygen (O₂). Therefore, when this device is used in conjunction with energy producing devices (such as lasers, radio frequency sources, or other heat sources), the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials.



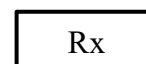
WARNING: The user should observe the patient to prevent over sedation in the event of an O₂ failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O₂, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure O₂ from an independent source.



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

Visit our website: <https://www.porterinstrument.com/silhouette> for additional information. To download Instructions for Use: visit <https://www.porterinstrument.com/dental-support> Choose "Breathing Circuits" from the dropdown within the "Product Download" section.

Refer to FM-1500 for complete instructions and safety information.



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