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Silhouette™ Disposable Breathing Circuit, Second Generation

Instructions for Use and Installation Guide

FM-1500 Rev. A
22JAN2024

www.PorterInstrument.com/Silhouette

READ INSTRUCTIONS FOR USE COMPLETELY BEFORE OPERATING THIS DEVICE

This document contains warnings, cautions, instructions for use, and maintenance information that the user must completely comprehend before using this device. Failure to properly operate and maintain this device may result in patient/user harm and/or damage to equipment.

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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. For more information, go to www.P65Warnings.ca.gov.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or dentist.

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.

For Patent information, please visit http://www.PorterInstrument.com/patents

1. Device Information

1.1. Intended Use

The Silhouette Breathing Circuit, second generation, (referred to as Silhouette Breathing Circuit) is intended to deliver a mixture of nitrous oxide and oxygen gases to a patient through an inhalation route and to scavenge waste analgesic gas through an exhalation route.

1.2. Models and Packages

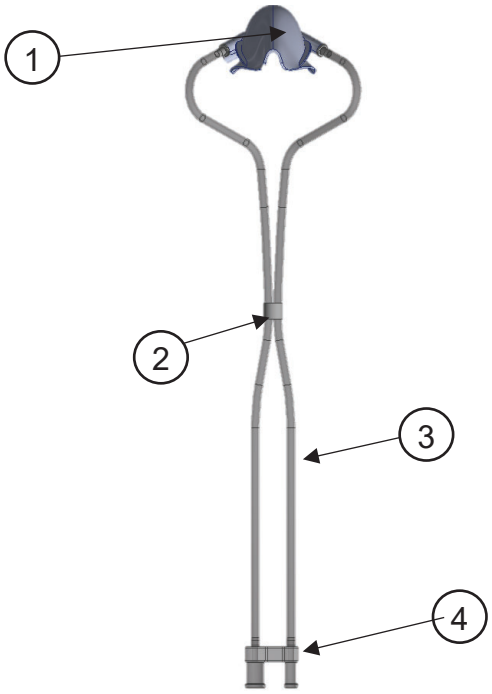
The Silhouette Breathing Circuit is available in four nasal hood sizes with various package quantities (described below). All instructions and information are the same for all models unless specified otherwise.

Part Numbers	Part Description
SIL-ADPT-PKG	Silhouette Breathing Circuit, Accessory Package
SIL-SIZER-4	Silhouette Sizers
SIL2-RETRO-PKG	Silhouette Retrofit Package
SIL2-LG-12	Silhouette Large 12 pk
SIL2-LG-144	Silhouette Large 144 pk
SIL2-LG-24	Silhouette Large 24 pk
SIL2-MED-12	Silhouette Medium 12 pk
SIL2-MED-144	Silhouette Medium 144 pk
SIL2-MED-24	Silhouette Medium 24 pk
SIL2-PEDO-12	Silhouette Pediatric 12 pk
SIL2-PEDO-144	Silhouette Pediatric 144 pk
SIL2-PEDO-24	Silhouette Pediatric 24 pk
SIL2-SM-12	Silhouette Small 12 pack
SIL2-SM-144	Silhouette Small 144 pk
SIL2-SM-24	Silhouette Small 24 pk
SIL2-VAR-4X3	Silhouette Variety 12 pk
SIL2-CAPNO	Capnography Barb, 25 pk
SIL-VAC	Silhouette Vacuum Block Adjuster

1.3. User Interface

1.3.1. Silhouette Breathing Circuit (disposable)

#	Description
1	Nasal Hood (Pediatric, Small, Medium, Large)
2	Slide Bolo
3	Inhalation (right) and Exhalation (left) Lines
4	H-Union
5	Capnography Barb



1.3.2. Silhouette Retro-Fit Package (SIL2-RETRO-PKG) (Reusable)

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

1.4. General Description/Principles of Operation

The Silhouette Breathing Circuit is a second-generation device composed of an inhalation tubing line, exhalation tubing line, and nasal hood. The device features a form-fitting design with a tight fit at the interface between the patient's face, cannula barb, and capnograph port. The device is available in four sizes (pediatric, small, medium, and large) for proper fit onto a patient's nose. The entire device is a single-use disposable intended to be used for single patient use. Additional components may be used to support setup of the device in different configurations.

The Silhouette Breathing Circuit is connected to a nitrous oxide (N_2O) and oxygen (O_2) gas mixing conscious sedation flowmeter and a vacuum source. The mixed gas is continuously delivered to a patient through the inhalation line of the breathing circuit and is directed to the patient’s right nostril. The patient is able to inhale the mixed gas using normal respiratory effort.

The exhalation line of the device is connected to a vacuum source, which removes the exhaled waste analgesic gas and any gas that was not inhaled by the patient from the nasal hood component. The vacuum source then removes the gas from the healthcare facility. Scavenging of waste analgesic gas minimizes the healthcare practitioner’s exposure to nitrous oxide.

1.5. Use of the Device

The Silhouette Breathing Circuit is to be used by a healthcare professional trained in the use and administration of N_2O and O_2 gases. The device is designed for use with a gas delivery and scavenging system intended for pain management and / or minimal conscious sedation, which is ideal for short, minimally invasive procedures to alleviate patient anxiety or minor pain and discomfort. It is the responsibility of the medical professional to consider the side effects, contraindications, and risks associated with administration of N_2O and use of conscious sedation.

The Silhouette Breathing Circuit is not used for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system. The user should observe the patient to prevent over sedation in the event of an O_2 failsafe malfunction or crossed lines. If a patient becomes overly sedated when being delivered 100% O_2, immediately remove the nasal hood, and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines; in this case, only deliver pure O_2 from an independent source.

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.

1.6. Patient Population

The patient population includes conscious, spontaneously breathing, awake, alert, and cooperative patients. Patients are selected by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. The medical professional must consider patients who are able to receive the gas mixture based on the risks associated with conscious sedation.

1.7. Warnings and Cautions

Warnings and cautions are listed where relevant to a certain section of this document.

A **WARNING** is an instruction, procedure, or explanation of hazards that may result in injury.

A **CAUTION** is an instruction, procedure, or explanation of hazards that may result in damage to a product, equipment, or the environment.

WARNINGS and **CAUTIONS** are presented throughout the document along with this symbol to alert the reader of their presence.

WARNING: The delivery system is not intended or expected to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the delivery system in the MR environment is unknown, but due to the possible presence of materials that may be ferromagnetic, the delivery system should be considered “MR Unsafe” and should be kept outside of any MRI scanner rooms.

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: An O_2 enriched environment can accelerate the spread of ignited materials. 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.

NOTE: If a serious incident (death or any intervention) has occurred while the device was in use, it should be reported to the manufacturer immediately and the Competent Authority of the member state in which the serious incident occurred.

1.8. Delivery Protocols

It is the responsibility of the medical establishment and the healthcare professional to develop specific delivery protocols for administration of N_2O using the Silhouette Breathing Circuit. Specific delivery protocols for adult and pediatric patients should be developed.

The Silhouette Breathing Circuit is used for procedures in which the maximum use is less than 24-hours, typically less than 60-minutes.

1.9. Safe Combination of devices

The Silhouette Breathing Circuit is designed to be used within a nitrous oxide and oxygen conscious sedation delivery and scavenging system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device system is also used to scavenge or remove exhaled waste analgesic gas through a vacuum system. The conscious sedation delivery and scavenging system is comprised of a series of devices and accessories, which may include a conscious sedation flowmeter, bag tee, the Silhouette Breathing Circuit, vacuum controller, mounting stand, and gas supply hoses.

To ensure safe combination of devices, user should follow the installation instructions in **Section 2** below and ensure all connections are secure and tight.

1.10.Specifications

Dimensions

See Section 5

Weight

See Section 5

Connections

Mixed Gas: Connect to 0.250 in. tube.

Vacuum: Connect to 0.400 in. tube.

Environmental

Temperature

Storage/Transport: 50°F - 80°F (10°C - 27°C)

Operational: 50°F - 100°F (10°C – 37.78°C)

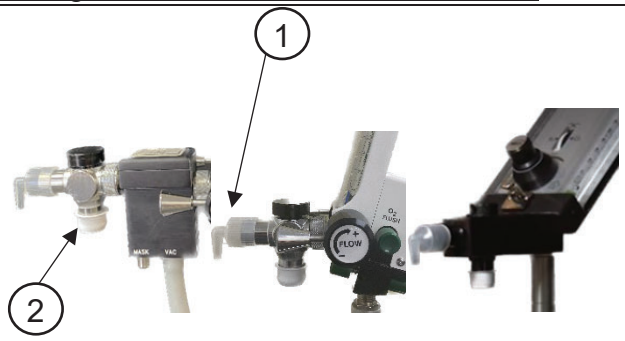
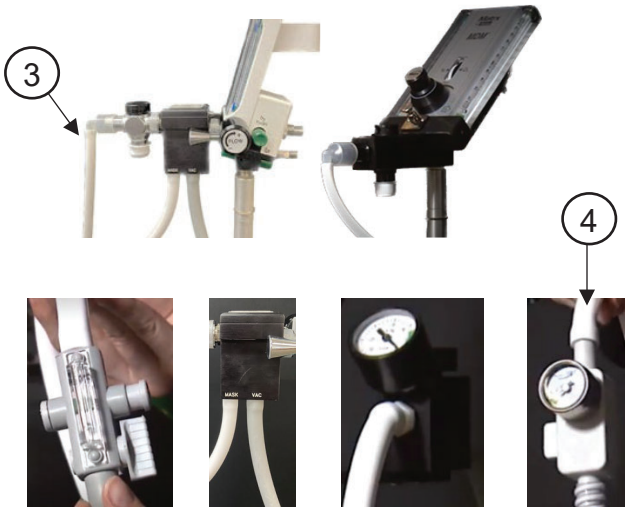
Relative Humidity

Storage/Transport: 40-60%

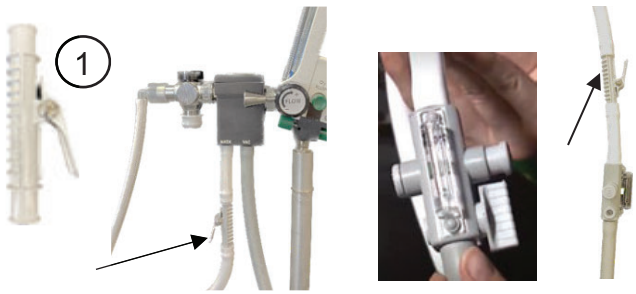
Operational: ambient, non-condensing

2. Installation Instructions

2.1. Retrofit Package Installation

Retrofit Package		
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. Do not disconnect vacuum tubing from vacuum controller to HVE.	
2	Push the **Cannula Adapter** (1) on to the front of the bag tee fresh gas port with the cannula barb facing down. Attach the **Bag Tee Cap** (2) to the bottom of the bag tee (where the breathing bag previously was).	
3	The Fresh Gas and Vacuum Hose 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. Attach the **smaller diameter tubing** (3) to the Cannula Adapter. Attach the **larger diameter tubing** (4) to the vacuum control device. The other end / side of the vacuum control device should have a separate hose connected to an HVE source.	

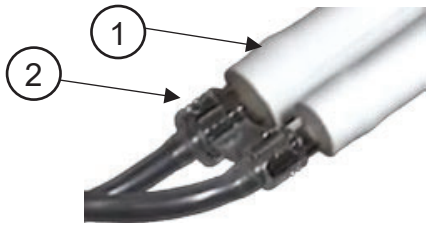
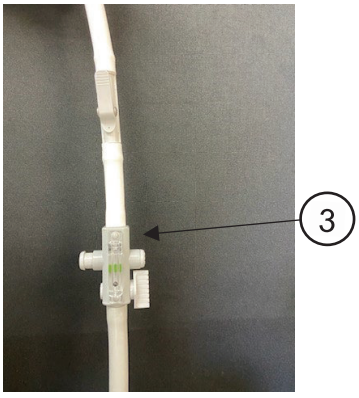
2.2. Vacuum Block Adjuster Installation

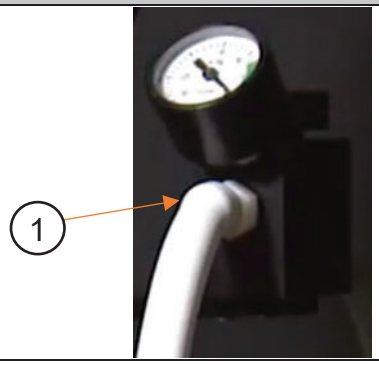
Vacuum Block Adjuster		
1	**Optional** - Only if using Porter In-Line (5501-RK) or Porter AVS (AVS-5000) Vacuum Control: Connect **Vacuum Block Adjuster** (VBA) (1) in line with the Silhouette vacuum hose and either In-Line or AVS controller. VBA must be on the breathing circuit / mask side of the vacuum 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.	AVS 5501-RK 

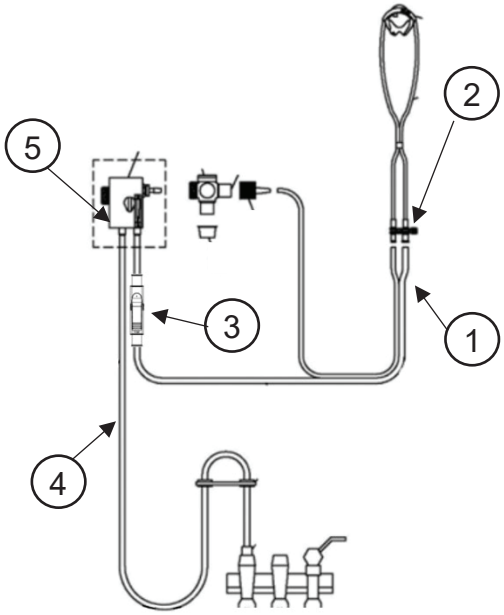
2.3. Compatible Vacuum Controllers

Porter In-Line Vacuum Control	Matrx Scavenger Control Valve	AVS Automatic Vacuum Switch
		

2.4. Scavenger Control Connection Options

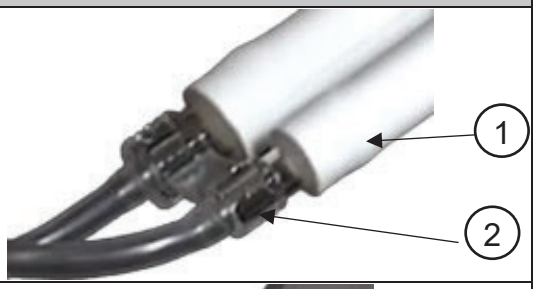
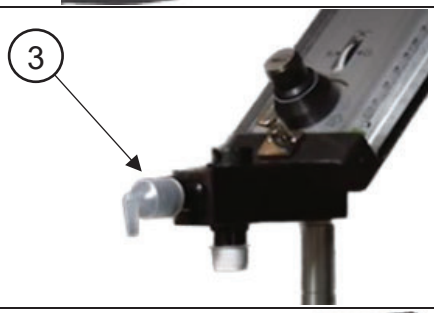
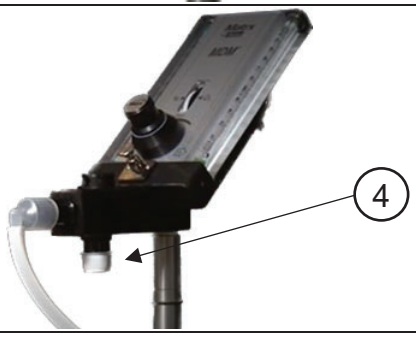
Porter In-Line Vacuum Control		
1	Attach one end of the larger diameter **Fresh Gas and Vacuum Hose** (1) to the larger diameter of the H-Union of the **Silhouette Breathing Circuit** (2).	
2	Attach the other end of the larger diameter **Fresh Gas and Vacuum Hose** to the **In-Line Vacuum Control** (3). **NOTE:** Opposite end of **In-line Vacuum Control** must be connected to a vacuum source.	

Matrx Scavenger Control Valve		
1	Attach one end of the larger diameter of the **Fresh Gas and Vacuum Hose** to the larger diameter of the H-Union of the **Silhouette Breathing Circuit**.	
2	Attach the other end of the larger diameter hose of the **Fresh Gas and Vacuum Reusable hose** to the White Adapter on the front of the **Scavenger Control Valve** (1).	

Automatic Vacuum Switch		
1	Attach one end of the larger diameter of the **Fresh Gas and Vacuum Hose** (1) to the larger diameter of the H-Union of the **Silhouette Breathing Circuit** (2).	
2	Following the steps in **Section 2.1 Vacuum Block Adjuster Installation**, connect the **vacuum block adjuster** (3) in line with the Silhouette Breathing Circuit and vacuum controller (AVS)	
3	Attach a second **vacuum hose** (4) to the **VAC port** (labeled on body) of the **AVS** (5)	
4	Attach the other end of the **vacuum hose** (4) to the vacuum source. **Note:** Additional parts may be needed in order to connect to a vacuum source.	

2.5. Connecting the Conscious Sedation Flowmeter

Note: Conscious Sedation Flowmeter shown is an MDM, however steps are the same with all flowmeters that have a 22mm fresh gas port.

Conscious Sedation Flowmeter Connection		
1	Attach one end of the smaller diameter **Fresh Gas and Vacuum Reusable Hose** (1) to the smaller diameter of the H-Union of the **Silhouette Breathing Circuit** (2).	
2	Attach the other end of the smaller diameter **Fresh Gas and Vacuum Hose** to the **Canula Adapter** (3) and attach the Canula Adapter to the Breathing Circuit Port of the flowmeter.	
3	When using a Flowmeter that has a Bag Tee, The Breathing Bag Port of the Bag Tee must be capped off using the **Bag Tee Cap** (4).	

3. Instructions for Use

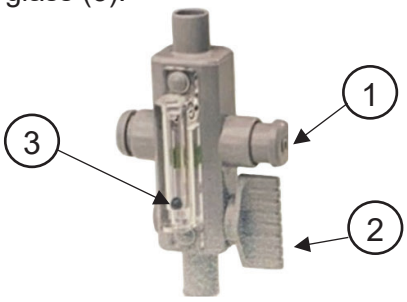
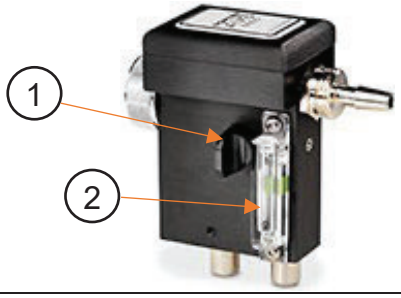
3.1. Setup and Prechecks

WARNING: The user should observe the patient to prevent over sedation in the event of an O_2 failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O_2, 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 O_2 from an independent source.

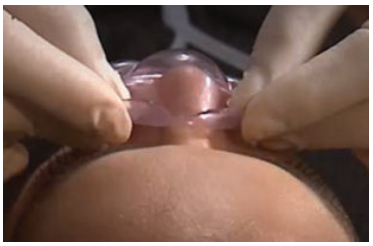
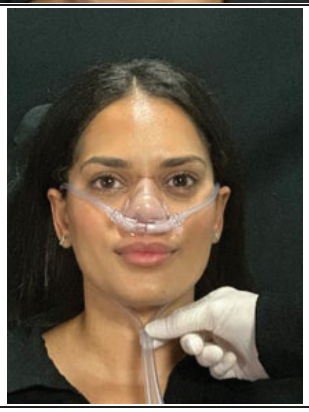
WARNING: Always use clean, dry, medical grade gases, and never oil or grease any part of the device.

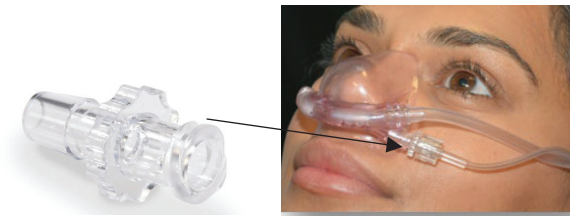
1	Ensure the device is properly connected (as described in **Section 2 Installation Instructions**).
2	Before using the Silhouette, check the following: • Hose connections and H-Union connections are secure. • Vacuum Block Adjuster (if used) is in the closed position. • The circuit is free of physical damage.
3	Ensure vacuum system is operating and adjust accordingly with a Vacuum Controller.

3.2. Operating Instructions for Vacuum Controller

	Porter In-Line Vacuum Control	AVS Automatic Vacuum Switch	Matrx Scavenger Control Valve
1	The In-Line Vacuum Control is manually operated and must be opened by pushing the **"on/off" toggle** (1) to "on" position.	The AVS will automatically open with a minimum of 1.5 L/min of gas flow. Start with the **flow control knob** (1) in horizontal position.	The Matrx Scavenger Control Valve is manually operated and must be opened by turning the **flow control knob** (1).
2	To adjust vacuum flow, Silhouette must be fully installed with the vacuum block adjuster.		
3	Vacuum Block Adjuster button must be held in the open position while adjusting the Porter In-Line Vacuum Control and the AVS.		
4	After adjustment of the vacuum pressure, release the button on the Vacuum Block Adjuster to fully close (failure to do so could result in ineffective scavenging). Upon closure the ball float will rise to and remain at the top.		
5	Ensure the device is held in a vertical position. Adjust the vacuum flow using **vacuum control knob** (2) and sight glass (3). 	Adjust vacuum flow by using the **vacuum control knob** (1) and **sight glass** (2) 	Adjust vacuum flow by using **vacuum control knob** (1) and **pressure gauge** (2). 
6	Set the **vacuum control knob** to the desired level of vacuum flow. The highest vacuum flow is vertical position. The lowest vacuum flow is horizontal position. **Note: For Silhouette, it is recommended to set the ball float at the bottom of the green band.**	Set the **vacuum control knob** to the desired level of vacuum flow. The highest vacuum flow is horizontal position. The lowest vacuum flow is vertical position. **Note: For Silhouette it is recommended to set the ball float at the bottom of the green band.**	Turn the **vacuum control knob** until the pressure gauge is set to -5 in.Hg minimum. **Note: For Silhouette it is recommended to set the needle at the bottom of the green zone.**
7	During use of conscious sedation use the **vacuum control knob** and **sight glass** to monitor and control vacuum.	During use of conscious sedation use the **vacuum control knob** and **sight glass** to monitor and control vacuum.	During use of conscious sedation use **the vacuum control knob** and **pressure gauge** to monitor and control vacuum.

3.3. Operating Instructions for Silhouette Breathing Circuit

1	Before the procedure starts, begin flowing 100% O2.	
2	Place the **colored sizer masks** over the patient's nose to determine appropriate mask size for the patient. Select appropriate size Silhouette circuit. **Note:** The Sizers are resuable, refer to **Section 4** for cleaning instructions.	
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 patients chin until the bolo is snug. Adjust tubing on the patient 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 Strap** 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 separately) 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 (as described in **Section 3.2**).	
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 reuasbale accessoires. Refer to **Section 4** for cleaning instructions for reusable parts.	

4. Maintenance

The Silhouette Breathing Circuit is a single-use disposable device and does not require maintenance.

WARNING: Proper inspection of this device is essential to prevent gas leaks. All hoses, fittings, and connections should be inspected.

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

4.1. Cleaning

Silhouette Breathing Circuit is a single-use disposable device and should not be cleaned. The accessories (Silhouette Sizers Mask and Fresh Gas and Vacuum Tube) are reusable and must be cleaned between each use. Cleaning of the Silhouette Breathing Circuit accessories has been validated with the following 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.

1	**<u>Disposal (no cleaning)</u>** Disposable components listed below are Single Use Only: ▪ Silhouette Breathing Circuit ▪ Capnography Barb
2	**<u>Manual Cleaning Only (Not Sterilizable)</u>** Reusable devices listed below require manual cleaning only. Cleaning of the device has been validated with Super Sani-Cloth™ Germicidal wipes or equivalent. ▪ Vacuum Controllers ▪ Vacuum Block Adjuster ▪ Vacuum Tubing Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the Vacuum Controller until all visible dirt and soil is removed. Take extra care to wipe the outside of the connection port area and vacuum control knob as these are the most handled areas of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove.
3	**<u>Manual, Automatic, and Sterilizable Cleaning</u>** Follow the validated cleaning and sterilization instructions described below for the reusable accessories listed below: ▪ Fresh Gas and Vacuum Tube o Manual, Automatic, and Sterilize Cleaning ▪ Sizer Masks (SIL-SIZER-4) o Manual, Automatic, and Sterilize Cleaning
4	Rinse the product under running water to remove soil and/or contaminants. Ensure lumens are rinsed. Use a syringe to flush all lumens and hard to reach places.
5	Prepare detergent bath using Valsure enzymatic solution (or equivalent) of 1/2 oz per gallon using water and immerse the product for two minutes.
6	While immersed scrub the articles using a soft bristled nylon brush until visible soil and/or contaminants are removed. Use an appropriately sized lumen brush to clean lumines. Flush all lumens to ensure contact with prepared detergent throughout. **Note:** Pay particularly close attention to crevices, lumens, connectors, and other hard to clean areas. Allow the product to soak for two minutes.

7	Hold the product upright to allow water to drain from the product. Rinse under running water for three minutes per component. Thoroughly rinse all lumens and internal surfaces.
8	**For Manual Cleaning**: Dry product with clean, dry, lint free cloths. **For Automated Cleaning**: Place the products onto the washer's rack system and run the washer.
9	Visually inspect the product under normal lighting to confirm removal of soil and/or contaminants. ▪ If visual inspection failure occurs, repeat the entire cleaning process, be sure to pay particular attention to the region that failed. ▪ If visual inspection failure occurs again, do not re-use, dispose of the product, and replace the product immediately.
10	Perform **Steam Sterilization** in accordance with the following sterilization set points: ▪ Sterilizer type: Prevacuum ▪ Preconditioning Pulses: 4 ▪ Full Cycle: 4 minutes at 270 °F (132 °C), dry time 30 minutes. ▪ Full Cycle: 3 minutes at 273 °F (134 °C), dry time 40 minutes. Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (sequential envelope folding)

4.2. Disposal

It is best practice to inquire with local authorities for proper disposal guidelines, if applicable.

5. Dimensions and Weights

Dimensions	Weight
Pediatric 2.46 in W x 1.78 in H x 1.075 in D 6.25 cm W x 4.52 cm H x 2.7305 cm D	**Pediatric** 0.0925 lbs. (0.042 kg)
Small 2.37 in W x 1.96 in H x 1.160 in D 6.02 cm W x 4.98 cm H x 2.946 cm D	**Small** 0.0935 lbs. (0.0424 kg)
Medium 2.58 in W x 2.24 in H x 1.596 in D 6.55 cm W x 5.69 cm H x 4.054 cm D	**Medium** 0.0975 lbs. (0.0442 kg)
Large 2.55 in W x 2.37 in H x 1.701 in D 6.47 cm W x 6.02 cm H x 4.321 cm D	**Large** 0.1005 lbs (0.0456 kg)
Vacuum Block Adjuster 0.600 in W x 1.206 in H x 3.180 in L 1.524 cm W x 1.206 cm H x 8.077 in L	**Vacuum Block Adjuster** 0.155 lbs. (0.007 kg)

6. Symbols Glossary

The following symbols may be used throughout this document, as well as on device labels and packaging.

Symbol	Title of Symbol	Description of Symbol
	**Manufacturer Information**	Indicates the medical device manufacturer and is accompanied by the name and address of the manufacturer. [EN ISO 15223-1:2021, clause 5.1.1]
	**Date of manufacture and Country of Manufacture**	Indicates the country where the device was manufactured. Also Indicates the date when the device was manufactured. This symbol is accompanied by four digits for the year the device was manufactured. (EN ISO 15223-1:2021, clause 5.1.3, 5.1.11]
	**Catalog Number**	Indicates the manufacturer's catalog number of the device and is used for identification of the device. [EN ISO 15223-1:2021, clause 5.1.6]
	**Serial Number**	Indicates the manufacturer's serial number of the device and is used for identification of the specific device. [EN ISO 15223-1:2021, clause 5.1.7]
	**Unique device identifier**	Indicates a carrier that contains unique device identifier information [EN ISO 15223-1:2021, clause 5.7.10]
	**Prescription device**	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
	**Medical Device**	Indicates the item is a medical device [EN ISO 15223-1:2021, clause 5.7.7]
	**Do not re-use**	Indicates a medical device that is intended for one single use only [EN ISO 15223-1:2021, clause 5.4.2]
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use [EN ISO 15223-1:2021, clause 5.4.3]

Symbol	Title of Symbol	Description of Symbol
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself. [EN ISO 15223-1:2021, clause 5.4.4]
	**Caution/Warning**	Indicates important cautionary or warning information to the user that is presented in the instructions for use that accompanies explanatory instructions to the user

7.Warranty

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 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, unopened.

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.