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Matrx Breathing Circuit System

Instructions for Use and Installation Guide

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https://www.porterinstrument.com/

Representation

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	**Conformité Européenne (CE) Mark**	Compliance with conformity assessment on quality management system and technical documentation per Regulations (EU) 2017/745 for Medical Device, Annex IX Chapters i & III
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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.

Table of Contents

WARNING: This product can expose you to chemicals, including bisphenol A (BPA), which are known to the State of California to cause cancer and birth defects or other 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/breathing-circuits 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.

1. Device Information

1.1. Intended Use/Intended Purpose

The Matrx 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

The Matrx Breathing Circuit is available in three nasal hood sizes, with optional vacuum controller, different scents, and with various package quantity (described below). All instructions and information are the same for all models unless specified otherwise.

Device Model Table

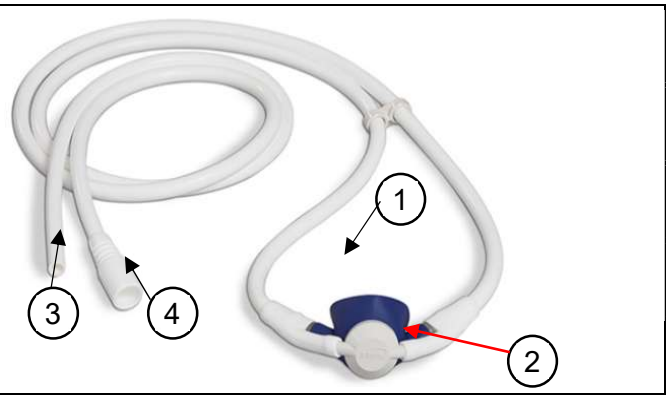
Model Number	Model Description	Model Number	Model Description
82501*	Large Scavenger with 3-Liter Breathing Bag and Scavenger Control	91515096*	Reusable Nasal Hood, Large
82502*	Medium Scavenger – with 3-Liter Breathing Bag and Scavenger Control	91515095*	Reusable Nasal Hood, Medium
82503*	Pediatric Scavenger with 3-Liter Breathing Bag and Scavenger Control	91515094*	Reusable Nasal Hood, Pediatric
82504*	Matrx Scavenger Large with 3-Liter Breathing Bag	91316482*	Disposable DynoMite Nasal Hood Bubble Gum Small -DynoMite 24 Pack Canister
82505*	Matrx Scavenger Medium with 3-Liter Breathing Bag	91316519*	Disposable DynoMite Nasal Hood Bubble Gum Medium - DynoMite 24 Pack Canister
82506*	Matrx Scavenger Pediatric with 3-Liter Breathing Bag	91316489*	Disposable DynoMite Nasal Hood Bubble Gum Large -DynoMite 24 Pack Canister
91515192*	Matrx Scavenger - Large Assemblies with Shut-Off Valve	91316483*	Disposable DynoMite Nasal Hood Strawberry Small - DynoMite 24 Pack Canister
91515193*	Matrx Scavenger - Medium Assemblies with Shut-Off Valve	91316520*	Disposable DynoMite Nasal Hood Strawberry Medium - DynoMite 24 Pack Canister
91515194*	Matrx Scavenger - Pediatric Assemblies with Shut-Off Valve	91316490*	Disposable DynoMite Nasal Hood Strawberry Large -DynoMite 24 Pack Canister
91515197*	Matrx Scavenger Without Hood	91316484*	Disposable DynoMite Nasal Hood Orange Small -DynoMite 24 Pack Canister
91515188*	Matrx Scavenger Large without Shut-off Valve	91316521*	Disposable DynoMite Nasal Hood Orange Medium -DynoMite 24 Pack Canister
91515189*	Matrx Scavenger Medium without Shut-off Valve	91316491*	Disposable DynoMite Nasal Hood Orange Large-DynoMite 24 Pack Canister
91515190*	Matrx Scavenger Pediatric without Shut-off Valve	91316485*	Disposable DynoMite Nasal Hood Vanilla Small -DynoMite 24 Pack Canister
91316522*	Disposable DynoMite Nasal Hood Vanilla Medium- DynoMite 24 Pack Canister	91316504*	Disposable DynoMite Nasal Hood Strawberry Medium -DynoMite 12 Pack
91316492*	Disposable DynoMite Nasal Hood Vanilla Large -DynoMite 24 Pack Canister	91316511*	Disposable DynoMite Nasal Hood Strawberry Large -DynoMite 12 Pack
91316486*	Disposable DynoMite Nasal Hood Plain Small -DynoMite 24 Pack Canister	91316498*	Disposable DynoMite Nasal Hood Orange Small -DynoMite 12 Pack
91316523*	Disposable DynoMite Nasal Hood Plain Medium -DynoMite 24 Pack with Canister	91316505*	Disposable DynoMite Nasal Hood Orange Medium -DynoMite 12 Pack
91316493*	Disposable DynoMite Nasal Hood Plain Large -DynoMite 24 Pack with Canister	91316512*	Disposable DynoMite Nasal Hood Orange Large -DynoMite 12 Pack
91316487*	Disposable DynoMite Nasal Hood Assorted Scents Small -DynoMite 24 Pack with Canister	91316499*	Disposable DynoMite Nasal Hood Vanilla Small -DynoMite 12 Pack
91316524*	Disposable DynoMite Nasal Hood Assorted Scents Medium - DynoMite 24 Pack with Canister	91316506*	Disposable DynoMite Nasal Hood Vanilla Medium - DynoMite 12 Pack
91316494*	Disposable DynoMite Nasal Hood Assorted Scents Large -DynoMite 24 Pack with Canister	91316513*	Disposable DynoMite Nasal Hood Vanilla Large -DynoMite 12 Pack

Model Number	Model Description	Model Number	Model Description
91316495*	Disposable DynoMite Nasal Hood Assorted Scents Various -DynoMite 24 Pack with Canister	91316500*	Disposable DynoMite Nasal Hood Plain Small - DynoMite 12 Pack
91316496*	Disposable DynoMite Nasal Hood Bubble Gum Small -DynoMite 12 Pack	91316507*	Disposable DynoMite Nasal Hood Plain Medium -DynoMite 12 Pack
91316503*	Disposable DynoMite Nasal Hood Bubble Gum Medium -DynoMite 12 Pack	91316514*	Disposable DynoMite Nasal Hood Plain Large - DynoMite 12 Pack
91316510*	Disposable DynoMite Nasal Hood Bubble Gum Large -DynoMite 12 Pack	91316501*	Disposable DynoMite Nasal Hood Assorted Scents Small -DynoMite 12 Pack
91316497*	Disposable DynoMite Nasal Hood Strawberry Small -DynoMite 12 Pack	91316508*	Disposable DynoMite Nasal Hood Assorted Scents Medium -DynoMite 12 Pack
91316515*	Disposable DynoMite Nasal Hood Assorted Scents Large -DynoMite 12 Pack	91316464*	Disposable DynoMite Nasal Hood Vanilla Small -DynoMite 24 Pack
91316516*	Disposable DynoMite Nasal Hood Assorted Scents Various - DynoMite 12 Pack	91316471*	Disposable DynoMite Nasal Hood Vanilla Medium -DynoMite 24 Pack
91316461*	Disposable DynoMite Nasal Hood Bubble Gum Small -DynoMite 24 Pack	91316465*	Disposable DynoMite Nasal Hood Plain Small - DynoMite 24 Pack
91316468*	Disposable DynoMite Nasal Hood Bubble Gum Medium -DynoMite 24 Pack	91316472*	Disposable DynoMite Nasal Hood Plain Medium -DynoMite 24 Pack
91316475*	Disposable DynoMite Nasal Hood Bubble Gum Large -DynoMite 24 Pack	91316479*	Disposable DynoMite Nasal Hood Plain Large - DynoMite 24 Pack
91316462*	Disposable DynoMite Nasal Hood Strawberry Small -DynoMite 24 Pack	91316466*	Disposable DynoMite Nasal Hood Assorted Scents Small -DynoMite 24 Pack
91316469*	Disposable DynoMite Nasal Hood Strawberry Medium -DynoMite 24 Pack	91316473*	Disposable DynoMite Nasal Hood Assorted Scents Medium -DynoMite 24 Pack
91316476*	Disposable DynoMite Nasal Hood Strawberry Large -DynoMite 24 Pack	91316480*	Disposable DynoMite Nasal Hood Assorted Scents Large -DynoMite 24 Pack
91316463*	Disposable DynoMite Nasal Hood Orange Small -DynoMite 24 Pack Bag	91316481*	Disposable DynoMite Nasal Hood Assorted Scents Various -DynoMite 24 Pack
91316470*	Disposable DynoMite Nasal Hood Orange Medium -DynoMite 24 Pack	91515142*	Universal Conversion Package: Matrx Disposable DynoMite Nasal Hood, Large, Breathing Circuit Adapter
91316477*	Disposable DynoMite Nasal Hood Orange Large -DynoMite 24 Pack	91515083*	Matrx Scavenger Control Valve for MDM Flowmeter
91525109*	Matrx Scavenger Control Valves -For Digital MDM	91316478*	Matrx Disposable DynoMite Nasal Hood Vanilla Large -DynoMite 24 Pack Bag

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

1.3. User Interface

#	Description
1	Matrx Nasal Hood
2	Scavenging Cone
3	Vacuum Tubing
4	Fresh Gas Tubing



1.4. General Description/Principles of Operation

The Matrx Breathing Circuit System is a device composed of an inhalation tubing line, exhalation tubing line, and nasal hood. The device features a one-way exhalation valve within a scavenging cone assembly. The nasal hood provides a seal around the nose and is available in three sizes (small, medium, and large) for proper fit onto a patient's nose. The nasal hood is available as a sterilizable re-usable component, or single-use disposable intended to be used for single patient use. The Matrx Breathing Circuit includes additional components used to support setup of the device in different device system configurations.

The Matrx 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 delivered to a patient continuously through the inhalation line of the breathing circuit and is deposited in the nasal hood component to direct the mixed gas to the upper airway of the patient. 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 ensures that the healthcare practitioner's exposure to nitrous oxide is limited to low levels of parts per million.

The Matrx Breathing Circuit is equipped with safety features described in Section 1.7.

1.5. Use of the Device

The Matrx Breathing Circuit is to be used by a medical professional trained in the use and administration of N_2O and O_2 gases. The device is designed for use in a gas delivery and scavenging system 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 Matrx 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 mask/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.

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.

1.6. 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 or death.

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.

1.8. Safety Features

Scavenging Cone System:

The Matrx Breathing Circuit includes a scavenging cone system, which has an outer scavenging cone component and a nasal hood that directs the mixed gas for inhalation and the waste gas from exhalation to the appropriate tubing lines. This also prevents competition between the patient and the connected vacuum source.

One-Way Valve:

The scavenger cone includes a one-way valve that prevents the patient from re-breathing exhaled waste analgesic gas.

Single-Use Disposable Design:

Certain models of the nasal hoods are designed to be single-use and are completely disposable to prevent cross-contamination between patients.

WARNING: The Matrx Breathing Circuit 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 Matrx Breathing Circuit in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the Matrx Breathing Circuit should be considered “MR Unsafe” and should be kept outside of any MRI scanner rooms.

WARNING: Workers exposed to N_2O 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 Matrx Breathing Circuit and Accessories are used with the delivery of Oxygen (O_2). Therefore, when these devices and accessories are 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.

1.9. Delivery Protocols

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

The Matrx Breathing Circuit is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur over the course of many hours may also be considered transient. The upper limit of use duration is at the discretion of the medical professional.

1.10. Safe Combination of devices

The Matrx Breathing Circuit is designed to be used within a nitrous oxide/oxygen conscious sedation delivery and scavenging system to deliver an accurate mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device system is also used to remove exhaled waste analgesic gas through a vacuum control system. The system is comprised of a series of devices and accessories, which includes a conscious sedation flowmeter, bag tee and breathing bag (if applicable), breathing circuit with nasal hood, vacuum controller, mounting stand, and gas supply hoses.

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

1.11. Specifications

Dimensions

See Section 5

Connections

Mixed Gas Inlet: Fresh Gas Tube connect to 22mm connection.

Vacuum: Fresh Gas and Vacuum Tube connect to 3/8 in connection.

Atmospheric Pressure

1 atm ± 0.2 atm (101 kPa ± 20 kPa)

Weight

See Section 5

Environmental

Temperature

Storage/Transport: 47°F - 82°F (8°C - 28°C)

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

Relative Humidity

Storage/Transport: ambient

Operational: ambient, non-condensing

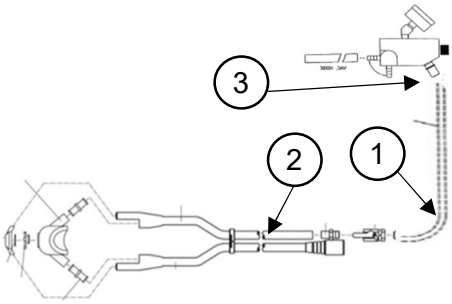
2. Installation Instructions

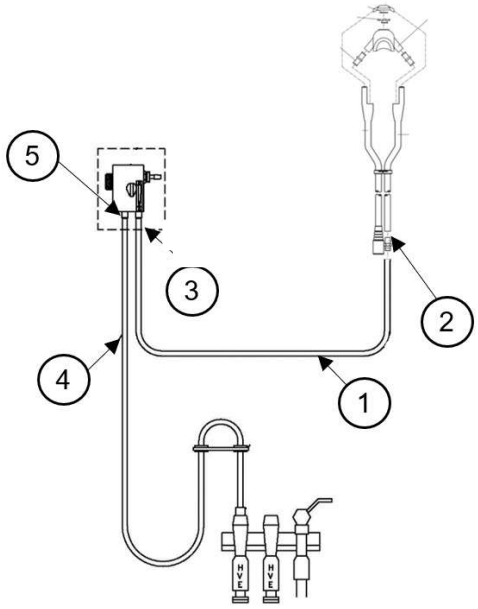
WARNING: For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99 and other international standards, the certified medical gas plumber and verifier should provide written documentation that all gas pipelines are connected properly, and that the system has been pressure tested prior to use. It is important that the user verify by their own test that all gas pipelines are connected properly prior to use.

2.1. Compatible Vacuum Controller Accessories

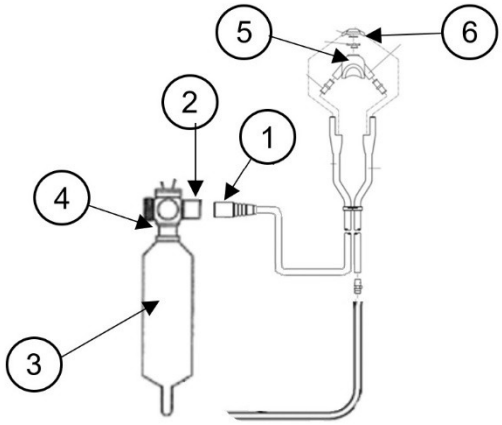
Matrx Scavenger Control Valve	AVS Automatic Vacuum Switch
	

2.2. Connecting the Vacuum Controller

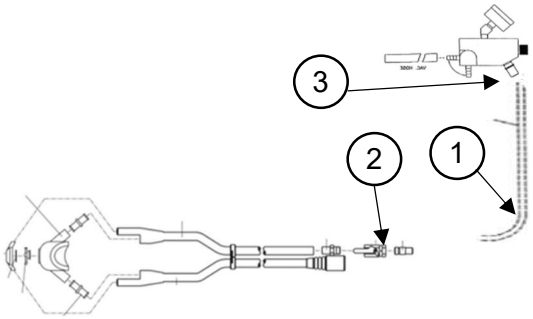
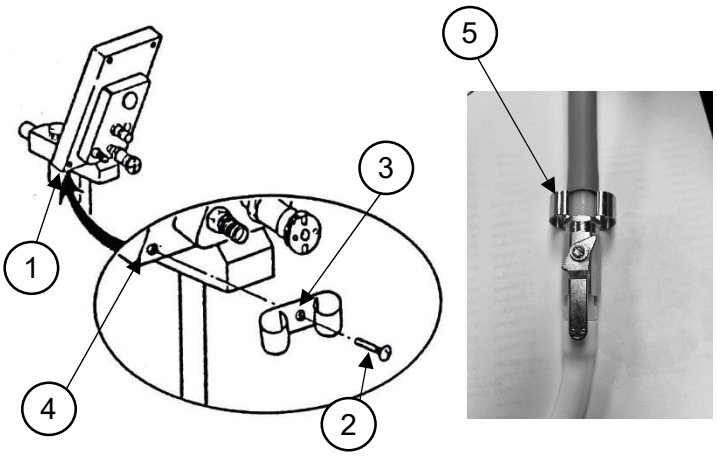
Matrx Scavenger Control Valve		
1	Attach the **Vacuum Hose** (1) to the smaller diameter of the vacuum tubing of the Matrx **Breathing Circuit** (2).	
2	Attach the other end of the Vacuum tubing to the white adapter on the front of the **Scavenger Control Valve** (3) **Note:** Opposite end of the Scavenger Control Valve must be connected to a vacuum source.	

Automatic Vacuum Switch		
1	Attach the **Vacuum Hose** (1) to the smaller diameter of the vacuum tubing of the **Matrx Breathing Circuit/shut off valve** (2)	
2	Attach the other end the **Vacuum Hose** (1) to the **MASK port** (labeled on body) of the **AVS** (3)	
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.	

2.3. Connecting the Conscious Sedation Flowmeter

Conscious Sedation Flowmeter Connection		
1	Attach the larger diameter of the fresh gas tubing of the **Matrx Breathing Circuit** (1) to breathing circuit port of the **Bag Tee** (2).	
2	Attach **Breathing Bag** (3) to the breathing bag port on the bottom of the **Bag Tee** (4). **Note: Nasal Hood** (5) and **Scavenging Cone** (6) are fully assembled when initially purchased. To attached nasal hood, refer to section 3.4.	

2.4. Connecting the Optional Shut-off Connection

Optional Matrx MDM/RA Flowmeter Shutoff Valve Connection		
1	Attach the **Vacuum Hose** (1) to the smaller diameter of the vacuum tubing with **shut off valve** (2).	
2	Attach the other end of the Vacuum tubing to the white adapter on the front of the **Scavenger Control Valve** (3) **Note:** Opposite end of Scavenger Control Valve must be connected to a vacuum source.	
3	From the rear of the flowmeter, remove the lower left hand cover **retaining screw** (1).	
4	Insert the **screw** (2) through the mounting hole in the **retaining clip** (3).	
5	Install the screw and secure the retaining clip to the **rear of the flowmeter** (4).	
6	Snap the **vacuum shutoff valve** (5) into the retaining clip.	

3. Instructions for Use

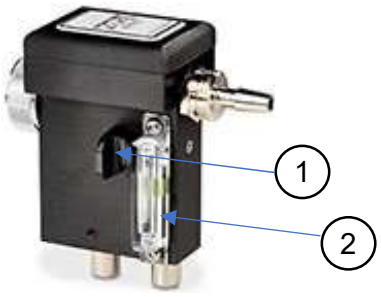
3.1. Setup and Prechecks

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 (described in **Section 2: Installation Instructions**).
2	Before using the Matrx Breathing Circuit, check the following: • Nasal hood and scavenging cone connections are secure. • Hose connections are secure. • The circuit is free of physical damage.
3	Ensure vacuum system is operating. **Note:** The American Dental Association recommends 45 LPM scavenging flow.

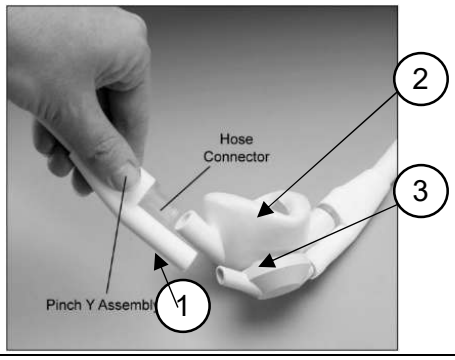
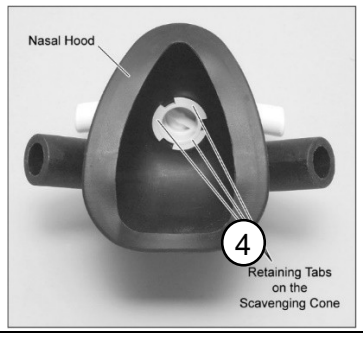
3.2. Operating Instructions for Vacuum Controller

	Matrx Scavenger Control Valve	AVS Automatic Vacuum Switch
1	The Scavenger Control Valve is manually operated and must be opened by turning the **flow control knob** (1).	The AVS will automatically open upon the delivery of 1.5 to 3.5 L/min of gas flow. Start **flow control knob** (1) in horizontal position.
2	Adjust vacuum flow by using **vacuum control knob** (1) and **pressure gauge** (2) on front of vacuum control block to monitor and control vacuum. 	Adjust vacuum flow by using the **vacuum control knob** (1) and **sight glass** (2) 
3	Turn the **vacuum control knob** until the pressure gauge is set to -5 inHg minimum. **Note:** The recommended vacuum flow is when the **pressure gauge** is within the green band. Low vacuum flow is indicated by the red 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:** The recommended vacuum flow is when the ball float is within the green band on the **sight glass**.
4	During use of conscious sedation use **the vacuum control knob** and **pressure gauge** to control and monitor vacuum.	During use of conscious sedation use the **vacuum control knob** and **sight glass** to control and monitor vacuum.

3.3. Operating Instructions for Matrx Breathing Circuit

1	Before the procedure starts, if desired, adjust the flowmeter to 100% O_2 ensuring the patients first breaths are 100% O_2.
2	Place nasal hood assembly onto the patient securely to the patient's face to avoid leaks.
3	Instruct the patient to inhale through the nasal hood. Patient should also be instructed to exhale through the nasal hood to achieve effective scavenging.
4	Monitor the vacuum conditions during the procedure and adjust vacuum flow as necessary to maintain effective scavenging (as described in **Section 3.2**). **Note:** The American Dental Association recommends 45 LPM scavenging flow. Any adjustment above this level improves scavenging efficiency.
5	If patient shows signs or communicates conditions of over-sedation, adjust the flowmeter to 100% O_2.
6	At The completion of the procedure, administer 100% Oxygen for several minutes to remove excess N_2O and prevent N_2O exposure in the environment. Remove the breathing circuit from the patient and dispose of any disposable parts. Refer to **Section 4** for cleaning instructions of reusable parts.

3.4. Operating Instructions for Installing Matrx Nasal Hood

1	Disconnect the long sections of the **Y assembly** (1) from the nasal hood.	
2	Pinch the Y assembly just behind the hose connector and remove the Y assembly from the nasal hood and scavenging cone.	
3	Hold the **nasal hood** (2) in one hand. With your other hand, gently pull the **scavenging cone assembly** (3) from the nasal hood.	
4	Turn the replacement nasal hood upside down. Place your thumbs inside the nasal hood.	
5	Gently stretch the hole in the nasal hood over the retaining tabs on the scavenging cone. When the cone is seated in the nasal hood properly, **three segments of the cone base** (4) are visible inside the nasal hood.	
6	Pinch the hose connector in the Y assembly, insert it into the nasal hood fully. Repeat on other side.	
7	Connect the long sections of the Y assembly to the two ports on the scavenging cone.	

4. Maintenance

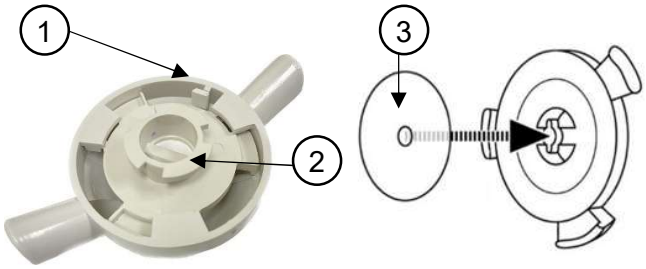
Certain models of Nasal Hood are single-use disposable components and do not require maintenance.

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

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Do not use or replace any components or accessories, except those specified in these instructions for use and installation guide.

4.1. Disassemble Scavenging Cone System

1	Pull the **Pinch Bar** (1) back.	
2	Turn **Exhalation Valve Cage** (2) clockwise and lift up to remove the exhalation valve cage from the scavenging cone.	
3	Remove the **Flapper valve** (3) from the Exhalation Valve Cage.	

4.2. Cleaning

The Matrx Breathing Circuit is a reusable device that includes a disposable or reusable nasal hood. Disposable nasal hoods should not be cleaned. Reusable components of the device must be cleaned between each use in order to prevent the spread of infections. Cleaning of the Matrx Breathing Circuit and reusable components has been validated with the following instructions.

WARNING: When using single-use breathing circuit 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.

WARNING: Do not use Isopropyl Alcohol; use of Isopropyl Alcohol to clean or disinfect may damage device.

Disposal (No Cleaning or Sterilization)

The following Disposable products are Single Use Only:

- Disposable Matrx Nasal Hood

Cleaning

Option 1: Manual Cleaning Method #1 (If Manual Cleaning Only)

The following reusable components may be cleaned using Manual cleaning method #1:

- Vacuum Nipple
- Vacuum Adapter
- Vacuum Shutoff Valve
- Scavenger Control Valve
- Autoclavable Nasal Hoods

Instruction: Using a Super Sani-Cloth™ or equivalent Germicidal wipe, thoroughly wipe down the device until all visible dirt and soil is removed. Avoid excess liquid. Take extra care to wipe the outside of the connection ports, but not internal surfaces of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove.

Dry product with clean, dry, lint free cloths.

Option 2: Manual Cleaning Method #2 (Manual Cleaning Only or Prep for Sterilization)

The following reusable components may be cleaned using Manual cleaning method #2:

- Reusable Nasal Hood
- Fresh Gas Tubing
- Vacuum Tubing

Instruction: 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. 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 scavenging cone system using a soft bristles nylon brush until visible soil is removed. If necessary, you can detach the cone from the cage by bending the pinch bar back and turning clockwise. 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.

Note: Pay particularly close attention to crevices, lumens, connectors, and other hard to clean areas.

Option 3: Automated Cleaning (Automated Cleaning Only or as Prep for Sterilization)

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

- Reusable Nasal Hood
- Fresh Gas Tubing
- Vacuum Tubing

Instructions: 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	02:00	Cold tap water	N/A
Wash 1	10:00	43°C Tap water (Set Point)	Neodisher Mediclean Forte 2 mL/L
Rinse 1	01:00	43°C Tap water (Set Point)	N/A
Pure Water Rinse	01:00	43°C RO/DI water (Set Point)	N/A
Dry Time	7:00	90°C	N/A

Visual Inspection of components following Manual or Automated Cleaning

Visually inspect the components 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.

Sterilization

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

The following reusable components may be sterilized:

- Fresh Gas Tubing
- Vacuum Tubing

The following reusable components should be sterilized:

- Reusable Nasal Hood

Note: Prior to sterilization, components must first go through Manual Cleaning Method #2 or Automated cleaning process as noted above.

Option A: Sterilizer type: Prevacuum

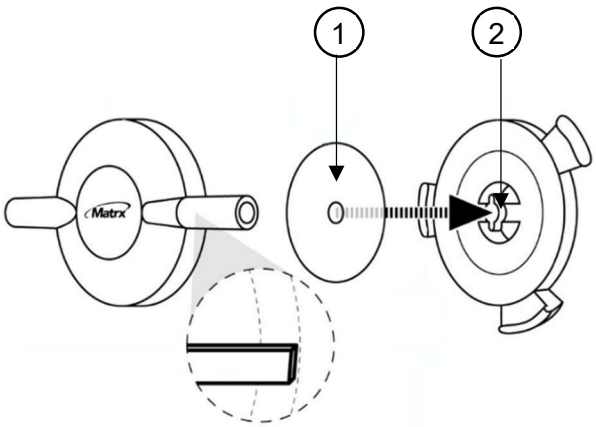
- Full Cycle: Minimum of 4 minutes at 132°C (270°F), dry time 30 minutes.
- Full Cycle: Minimum of 3 minutes at 134°C (273°F), dry time 40 minutes.
- Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (sequential envelope folding)

Option B: Sterilizer type: Gravity Displacement

- Full Cycle: Minimum of 15 minutes at 132°C (270°F), dry time 40 minutes or until fully dry.
- Configuration: Individually single pouched in a 13” x 18” pouch.

4.3. Reassemble Scavenging Cone System (after cleaning)

1	Attach **Flapper Valve** (1) to the **Exhalation Valve Cage** (2).
2	With flapper Valve facing the scavenging Cone, insert assembly into Cone.
3	Turn Exhalation Valve Cage counterclockwise until the tabs engage and the Pinch Bar snaps closed. When completely engaged, the Cone and the Exhalation Valve cannot disengage.



4.4. Disposal

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

5. Dimensions and Weights

*Device packages are not included in dimension and weight table.

Part Number	Dimensions (W x H x D)	Weight
91515192	64.44 in x 4.25 in x 2.8 in 163.68 cm x 10.8 cm x 7.11 cm	1.06 lbs (0.03 kg)
91515193	64.38 in x 3.75 in x 2.4 in 163.53 cm x 9.53 cm x 6.1 cm	1.055 lbs (0.48 kg)
91515194	64.38 in x 3.625 in x 2.09 in (163.53 cm x 9.21 cm x 5.31 cm	1.05 lbs (0.48 kg)
91515096	1.94 in x 4.25 in x 2.8 in 4.93 cm x 10.80 cm x 7.11cm	0.057 lbs (0.026 kg)
91515095	1.875 in x 9.53 in x 2.4 in 4.76 cm x 9.65 cm x 6.10 cm	0.052 lbs (0.024 kg)
91515094	1.875 in x 3.625 in x 2.09 in 4.76 cm x 9.208 cm x 5.31 cm	0.0485 lbs (0.022 kg)
91515083	6.2 in W x 3.8 in x 2 in 15.75 cm x 9.65 cm x 5.08 cm	0.8 lbs (0.36 kg)
91525109	6.8 in x 2.75 in H x 2.85 in D 71.27 cm x 6.99 cm x 7.24 cm	1.0 lbs (0.45 kg)
91316461, 91316462, 91316463, 91316464, 91316465, 91316466, 91316482, 91316483, 91316484, 91316485, 91316486, 91316487, 91316496, 91316497, 91316498, 91316499, 91316500, 91316501	1.62 in x 3.62 in x 2.13 in 4.11 cm x 9.19 cm x 5.41 cm	0.042 lbs (0.0191 kg)
91316468, 91316469, 91316470, 91316471, 91316472, 91316473, 91316503, 91316504, 91316505, 91316506, 91316507, 91316508, 91316519, 91316520, 91316521, 91316522, 91316523, 91316524	1.62 in x 3.62 in x 2.29 in 4.11 cm x 9.19 cm x 5.82 cm	0.045 lbs (0.0204 kg)
91316475, 91316476, 91316477, 91316478, 91316479, 91316480, 91316489, 91316490, 91316491, 91316492, 91316510, 91316511, 91316512, 91316513, 91316514, 91316515, 91316493, 91316494, 91316481	1.62 in x 3.62 in x 2.29 in 4.11 cm x 9.19 cm x 5.82 cm	0.061 lbs (0.0277 kg)
91515142	11 in x 6.7 in x 2.7 in 27.94 cm x 17.018 cm x 6.858 cm	

6. Symbols Glossary

The following symbols may use 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. [21 CFR 801.109 (b)(1)]
	**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]
	Use-by date	Indicates the date after which the medical device is not to be used [EN ISO 15223-1:2021, clause 5.1.4]
	**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
	**European Community Authorized Representative**	Indicates the authorized representative in the European Community (European Union) [EN ISO 15223-1:2021, clause 5.1.2]
	**Switzerland Authorized Representative**	Indicates the authorized representative in Switzerland. [MU600_00_016e / V3.0]
	**Conformité Européenne (CE) Mark**	Indicates that the product may be traded freely in any part of the European Economic Area, regardless of its country of origin. [2017/745 EU Annex V]

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.

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.

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RETURNS All returned merchandise will be handled through authorized Parker Hannifin Corporation distributors. 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.

To register your product: visit https://www.porterinstrument.com/dental-support and click on Warranty Registration Form button.