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# Porter Breathing Circuit System

## Instructions for Use and Installation Guide

FM-809 Rev V
18JUN2025

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.

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**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 Porter Breathing Circuit is intended to deliver a mixture of nitrous oxide and oxygen gases to a patient through an inhalation route and scavenge waste analgesic gas through an exhalation route.

## 1.2. Models

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

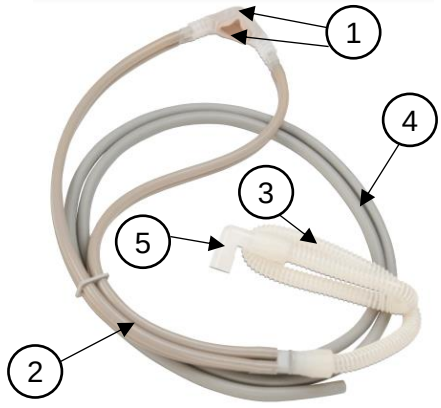
**Device Model Table**

| Model Name | Model Description |
|---|---|
| 5155-1* | Porter Adult Breathing Circuit with In-Line Vacuum Control |
| 5155-2* | Porter Pediatric Breathing Circuit with In-Line Vacuum Control |
| 5155-3* | Porter Adult Breathing Circuit, No Vacuum Control |
| 5155-3AV* | Porter Adult Breathing Circuit with AVS |
| 5155-4* | Porter Pediatric Breathing Circuit, No Vacuum Control |
| 5155-4AV* | Porter Pediatric Breathing Circuit with AVS |
| 5054-1* | Porter Adult Inner Mask Liners (3 Pack) |
| 5054-2* | Porter Pediatric Inner Mask Liners (3 Pack) |
| 5054A* | Porter Adult Double Mask Hood with 3 Inner Mask Liners |
| 5054B* | Porter Pediatric Double Mask Hood with 3 Inner Mask Liners |
| 5054C* | Porter Adult Double Mask with 1 Inner Mask Liner |
| 5054D* | Porter Pediatric Double Mask Hood Kit with 1 Inner Mask Liner |
| 5053AD12* | Porter Adult Disposable Inner Mask Liners (12 Pack) |
| 5053AD12C* | Porter Adult Disposable Inner Mask Liners, Citrus (12 Pack) |
| 5053AD144* | Porter Adult Disposable Inner Mask Liners (144 Pack) |
| 5053AD144C* | Porter Adult Disposable Inner Mask Liners, Citrus (144 Pack) |
| 5053PD12* | Porter Pediatric Disposable Inner Mask Liners (12 Pack) |
| 5053PD12C* | Porter Pediatric Disposable Inner Mask Liners, Citrus (12 Pack) |
| 5053PD144* | Porter Pediatric Disposable Inner Mask Liners (144 Pack) |
| 5053PD144C | Porter Pediatric Disposable Inner Mask Liners, Citrus (144 Pack) |

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

## 1.3. User Interface

| # | Description |
|---|---|
| **1** | Porter Nasal Hood and Liner |
| **2** | Coaxial Tubing |
| **3** | Fresh Gas Corrugated Hose |
| **4** | Vacuum Hose |
| **5** | Right Angle Adapter |



## 1.4. General Description/Principles of Operation

The Porter Breathing Circuit System is a device composed of an inhalation tubing line, exhalation tubing line, and nasal hood. The device features a mask-within-a-mask scavenging system and additional tubing for fresh gas delivery and waste gas scavenging. The nasal hood includes removable inner liners that provide a seal around the nose and are available in two sizes (adult and pediatric) for proper fit onto a patient's nose. The nasal hood and nasal hood liners are available as a sterilizable re-usable components, or single-use disposable intended to be used for single patient use. The Porter Breathing Circuit includes additional components used to support setup of the device in different device system configurations.

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

## 1.5. Use of the Device

The Porter 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 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 Porter 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.

**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.

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

**Mask-within-a-Mask System:**

The Porter Breathing Circuit includes a mask-within-a-mask scavenging system, which has an outer nasal hood component and an insertable inner nasal hood liner, 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.

**Flapper Valve:**

The nasal hood liners include a flapper valve that prevents the patient from re-breathing exhaled waste analgesic gas.

**Single-Use Disposable Design:**

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

**WARNING:** The Porter 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 Porter Breathing Circuit in the MR environment is unknown, but due to the presence of materials in the device's accessories that may be ferromagnetic, the Porter Breathing Circuit 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:** The Porter 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 healthcare professional to develop specific delivery protocols for administration of $N_2O$ using the Porter Breathing Circuit. Specific delivery protocols for adult and pediatric patients should be developed.

The Porter Breathing Circuit is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur intermittently 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

Porter 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.Specification

**Dimensions**

See Section 5 Dimensions and Weights

**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 Dimensions and Weights

**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

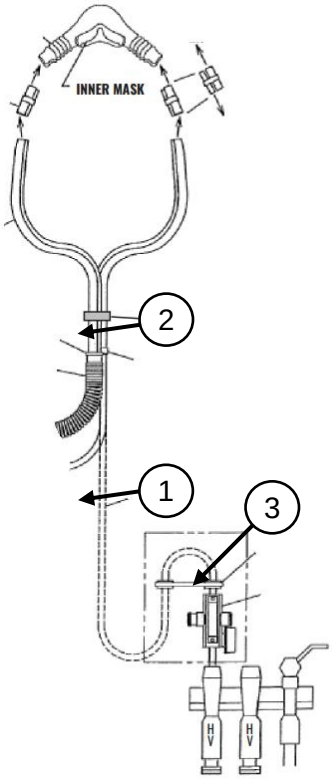
# 2.Installation Instructions

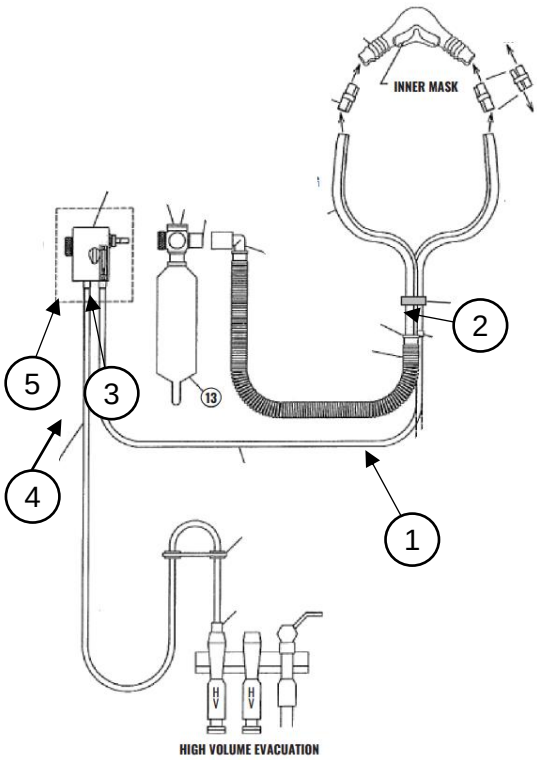
**WARNING:** For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that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

## 2.1. Compatible Vacuum Controller Accessories

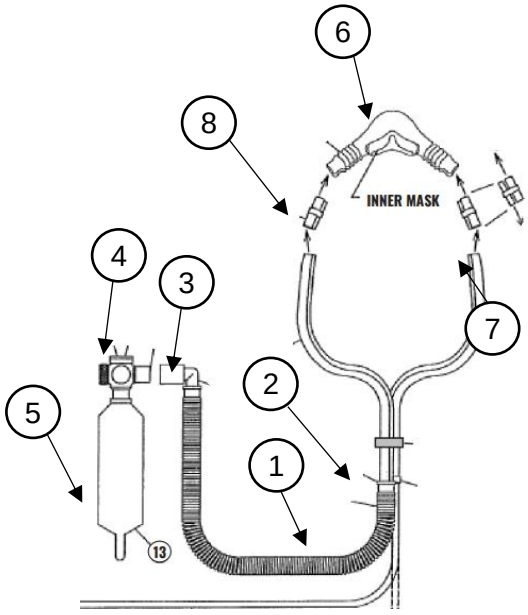
| Porter<br>In-Line Vacuum Control | AVS<br>Automatic Vacuum Switch |
|---|---|
|  |  |

## 2.2. Connecting the Vacuum Controller

| Porter In-Line Vacuum Control | | |
|---|---|---|
| **1** | Attach the **Vacuum Tubing** (1) to the smaller diameter of the **Porter Breathing Circuit (2)**. |  |
| **2** | Attach the other end of the **Vacuum Tubing** (2) to the **In-line Vacuum Control** (3).<br><br>**Note:** Opposite end of the **In-line Vacuum Control** must be connected to a vacuum source. | |

| Automatic Vacuum Switch | | |
|---|---|---|
| **1** | Attach the **Vacuum Hose** (1) to the smaller diameter of the **Porter Breathing Circuit** (2). |  |
| **2** | Attach the other end the **Vacuum Hose** (1) to the **MASK port** (labeled on body) of **AVS** (3) | |
| **3** | Attach a second **Vacuum Hose** (4) to the **VAC port** (labeled on body) of the **AVS** (5) | |
| **4** | Attach other end of the **Vacuum Hose** (4) to the vacuum source.<br><br>**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 one end of **Fresh Gas Corrugated Hose** (1) to the larger diameter of the **Porter Breathing Circuit** (2). |  |
| **2** | Place the smaller diameter of the **right-angle adapter** (3) on the other end of the **Fresh Gas Corrugated Hose** (1) | |
| **3** | Connect to the larger diameter end of the **right-angle adaptor** (3) to the breathing circuit port of the **Bag Tee** (4). | |
| **4** | Attach **Breathing Bag** (5) to the breathing bag port on the bottom of the **Bag Tee** (4). | |
| **5** | Connect **Nasal Hood** (6) and the **Coaxial Tubing** (7) by aligning the correct size diameters to the **connectors** (8). | |

# 3. Instructions for Use

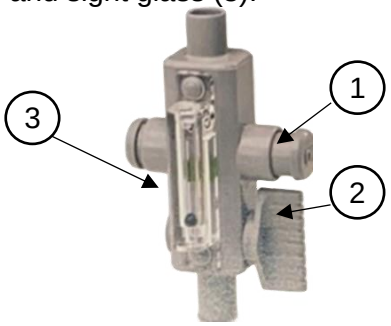
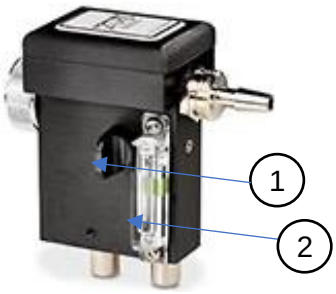
## 3.1. Setup and Prechecks

**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.

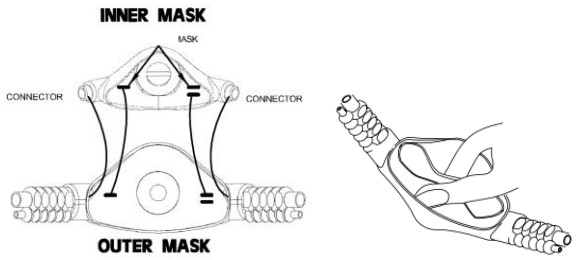
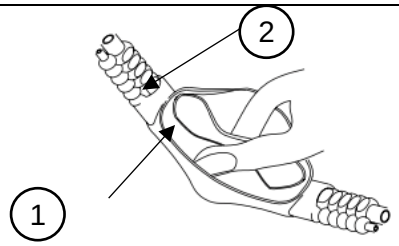
**WARNING:** Always use clean, dry, medical grade gases, and never oil or grease any part of the device.

| | |
|---|---|
| **1** | Ensure device is properly connected (described in Section 2 Installation Instructions). |
| **2** | Ensure the necessary prechecks have been performed, before using the Porter Breathing Circuit. The precheck instructions are described in **Section 4.1 Prechecks**. |
| **3** | Before using the Porter Breathing Circuit, check the following:<br>• Hose connections are secure.<br>• The circuit is free of physical damage |
| **4** | Ensure vacuum system is operating.<br>**Note:** The American Dental Association recommends 45 LPM scavenging flow. |

## 3.2. Operating Instructions for Vacuum Controller

| | **Porter**<br>**In-Line Vacuum Control** | **AVS**<br>**Automatic Vacuum Switch** |
|---|---|---|
| **2** | 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 upon the delivery of 1.5 to 3.5 L/min of gas flow. Start with the **flow control knob** (1) in horizontal position. |
| **3** | Ensure the device is held in a vertical position. Adjust the vacuum flow using **vacuum control knob** (2) and sight glass (3).<br>  | Adjust vacuum flow by using the **vacuum control knob** (1) and **sight glass** (2).<br>  |
| **4** | 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.<br><br>**Note:** The recommended vacuum flow is when the ball float is within the green band on the **sight glass**. | 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.<br><br>**Note:** The recommended vacuum flow is when the ball float is within the green band on the **sight glass**. |
| **5** | 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. |

## 3.3. Operating Instructions for Porter 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** | Locate the alignment marks within the nasal hood inner liner and the outer nasal hood. Align and insert the inner liner into the outer nasal hood.<br><br>**Note:** Ensure that the connection point of the inner liner is fully seated into the connection point in the outer nasal hood. |  |
| **3** | Place nasal hood assembly onto the patient so that the inner liner is secure to the patient's face to avoid leaks.<br>**Note:** Outer nasal hood should not be against the face. | |
| **4** | Instruct the patient to inhale through the nasal hood. Patient should also be instructed to exhale through the nasal hood to achieve effective scavenging. | |
| **5** | Monitor the vacuum conditions during the procedure and adjust vacuum flow as necessary to maintain effective scavenging (as described in **Section 3.2**). | |
| **6** | If patient shows signs or communicates conditions of over-sedation, adjust the flowmeter to 100% $O_2$. | |
| **7** | 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. | |
| **8** | To remove the inner line, hold the **outer nasal hood** (1) in one hand and pinch the top and bottom of the **inner liner** (2) with thumb and forefinger then pull outward. |  |

# 4. Maintenance

The Porter Breathing Circuit requires proper maintenance and pre-checks according to the following table.

| Check | Frequency |
|---|---|
| Leak Test | Once a week |

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

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

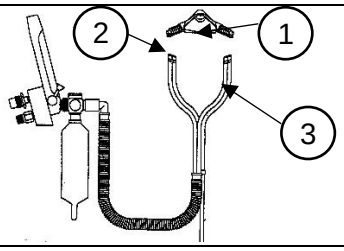
**WARNING:** Do not modify this equipment without authorization of the manufacturer.

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

## 4.1. Pre-Check

**WARNING:** If precheck test cannot be executed successfully, do not use this device and contact distributor.

**Leak Test**

| | | |
|---|---|---|
| **1** | With the flowmeter, bag tee and Porter Breathing Circuit System fully assembled, remove the **nasal hood assembly** (1) and one of the two **connectors** (2) from the **coaxial tubing** (3). |  |
| **2** | Join the two ends of the coaxial tube together using the remaining connector to make a closed system. | |
| **3** | Set the flowmeter to deliver 100% oxygen and fill the breathing bag. Do not overinflate the breathing bag. Once the breathing bag is filled, turn the flowmeter off. | |
| **4** | Observe the breathing bag for five minutes. The breathing bag should remain inflated. | |
| **5** | If the bag does not stay inflated, this indicates that the breathing bag or the Porter Breathing Circuit system is exhibiting an excessive leak. Replace any parts that leak and retest until results are successful. | |
| **6** | Disconnect one end of the coaxial tube from the plastic connector and using the connector that was previously removed, re-install the nasal hood assembly. (Refer to **Section 2.3** above) | |
| **7** | Inspect the breathing bag and Porter Breathing Circuit System for damage, replace any part that has been damaged.<br><br>**Note:** The main cause for a leak within the circuit is the flapper valve. To ensure proper funcitionally, inspected the flapper valve within the inner nasal hood for wear or tear. | |

## 4.2. Cleaning

The Porter Breathing Circuit is a reusable device that includes disposable or reusable nasal hoods inner liners. Disposable nasal hood inner liners 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 Porter Breathing Circuit and reusable outer nasal hood 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.

### 4.2.1. Disposable Parts

**Disposal (No Cleaning or Sterilization)**

The following Disposable products are Single Use Only:

- Disposable Nasal Hood Inner Liners

### 4.2.2. Manual Cleaning for Vacuum Components and Breathing Bag

**Manual Cleaning Method**

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

- Vacuum Controllers
- Breathing Bag

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.

### 4.2.3. Preparation for Sterilization of Tubing/Hoses and Nasal Hood

**Option 1: Manual Cleaning Method**

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

- Fresh Gas Corrugated Tubing
  **Note:** After 50 sterilization cleaning cycles it is recommended to inspect the tubing for wear and tear after each subsequent use.
- Coaxial Hoses

Instruction: Disassemble the test article into individual components. 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 components using a soft bristles nylon brush until visible soil is removed. Use an appropriately sized lumen brush to clean the tubing openings. (minimum 8 mm diameter brush for smaller diameter tubing and minimum 12 mm diameter brush for larger diameter tubing). 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 2: Automated Cleaning**

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

- Fresh Gas Corrugated Tubing
- Reusable Outer Nasal Hood and Inner Liner

Instructions: Instructions: Disassemble the test article into individual components. Rinse the device under running utility (tap) water to remove gross soil. Ensure lumens are rinsed. 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.

### 4.2.4. Sterilization of Tubing and Nasal Hoods (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 Corrugated Tubing

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

- Reusable Outer Nasal Hood and Inner Liner

**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. Disposal

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

# 5. Dimensions and Weight

| Dimensions | Weight |
|---|---|
| **5155-1**<br>70.65 in W x 2.05 in H x 6.23 in D<br>(179.5 cm W x 5.207 in H x 15.8 cm D | **5155-1**<br>1.29 lbs (0.6 kg) |
| **5155-2**<br>69.9 in W x 1.65 in H x 5.43 in D<br>(177.5 cm W x 4.2 cm H x 13.8 cm D) | **5155-2**<br>1.25 lbs (0.6 kg) |
| **5155-3**<br>70.65 in W x 2.05 in H x 6.23 in D<br>(179.5 cm W x 5.207 in H x 15.8 cm D) | **5155-3**<br>1.01 lbs (0.5 kg) |
| **5155-4**<br>69.9 in W x 1.65 in H x 5.43 in D<br>(177.5 cm W x 4.2 cm H x 13.8 cm D) | **5155-4**<br>1.05 lbs (0.5 kg) |
| **5054-1**<br>3.94 in W x 1.75 in H x 1.82 in D<br>(10.0 cm W x 4.4 cm H x 4.63 cm D) | **5054-1**<br>0.05 lbs (0.023 kg) |
| **5054-2**<br>3.41 in W x 1.54 in H x 1.44 in D<br>(8.66 cm W x 3.91 cm H x 3.66 cm D) | **5054-2**<br>0.05 lbs (0.023 kg) |
| **5054A**<br>6.23 in W x 2.05 in H x 3.65 in D<br>(15.8 cm W x 5.21 cm H x 9.27 cm D) | **5054A**<br>0.135 lbs (0.061 kg) |
| **5054B**<br>5.429 in W x 1.65 in H x 2.921 in D<br>(13.79 cm W x 4.19 cm H x 7.42 cm D) | **5054B**<br>0.0975 lbs(0.044 kg) |
| **5054C**<br>6.232 in W x 2.05 in H x 3.65 in D<br>(15.8 cm W x 5.21 cm H x 9.27 cm D) | **5054C:** 0.135 lbs(0.061 kg) |
| **5054D**<br>5.429 in W x 1.65 in H x 2.921 in D<br>(13.79 cm W x 4.19 cm H x 7.42 cm D) | **5054D**<br>0.0975 lbs(0.044 kg) |
| **5053AD12**<br>3.941 in W x 1.748 in H x 1.819 in D<br>(10.01 cm W x 4.44 cm H x 4.62 cm D) | **5053AD12**<br>0.05 lbs (0.023 kg) |
| **5053PD12**<br>3.406 in W x 1.543 in H x 1.44 in D<br>(8.65 cm W x 3.92 cm H x 3.66 cm D) | **5053PD12**<br>0.05 lbs (0.023 kg) |
| **5501-RK**<br>2 in W x 3.58 in H x 1.28 in D<br>(5.08 cm W x 9.09 cm H x 3.25 cm D) | **5501-RK**<br>0.05 lbs (0.023 kg) |

# 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.<br>[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.<br>(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.<br>[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.<br>[EN ISO 15223-1:2021, clause 5.1.7] |
|   | **Unique device identifier** | Indicates a carrier that contains unique device identifier information<br>[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<br>[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<br>[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<br>[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.<br>[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)<br>[EN ISO 15223-1:2021, clause 5.1.2] |
|  | **Switzerland Authorized Representative** | Indicates the authorized representative in Switzerland<br>[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. Note the number below the CE Mark does not appear for low-risk devices.<br>[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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To register your product: visit https://www.porterinstrument.com/dental-support and click on Warranty Registration Form button.