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Porter Midas™ Flowmeter and eAVS

Instructions for Use and Installation Guide



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www.PorterInstrument.com/Midas

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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WARNING: This product contains lead and lead compounds, a chemical known to the State of California to cause cancer. For more information: www.P65Warnings.ca.gov

WARNING: This product contains the presence of SVHCs, phthalates/DEHPs, CMR, and EDC in excess of 0.1% weight-by-weight material composition. For more information, including precautionary measures for at risk patients, refer to Section 5. Material Residual Risks.

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

Visit our website: www.PorterInstrument.com/Midas for additional information.
To download Instructions for Use: visit https://www.porterinstrument.com/dental-support Choose “Flowmeter” from the dropdown within the “Product Download” section.

1. Device Information

1.1. Intended Use/Intended Purpose

The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N_2O) and oxygen (O_2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas.

1.2. Models

The Midas Flowmeter is available in 22 flowmeter models (11 Portable and 11 Remote) (described below). Flowmeters are available with different fitting configurations, maximum percentage nitrous oxide (N_2O), and gas flow control. Dependent on model number the Flowmeter is factory configured to display N_2O or O_2 control. The factory configuration also determines the color of the percentage mixture control adjustment and the O_2 output flow bar on the display. Throughout this document, the 6020, USA fitting, 70% Max N_2O, Green, N_2O Controlled is pictured. All instructions and information are the same for all models unless specified otherwise. Accessories to the Midas Flowmeter are also described below.

Device Model Table

Model Number	Model Description (Remote)	Model Number	Model Description (Portable)
6151*	Midas Flowmeter Remote, 70% Max N_2O, White, O_2-Control, Australia Fittings	6051*	Midas Flowmeter Portable, 70% Max N_2O, White, O_2-Control, Australia Fittings
6181*	Midas Flowmeter Remote, 70% Max N_2O, White, N_2O Control, Australia Fittings	6081*	Midas Flowmeter Portable, 70% Max N_2O, White, N_2O Control, Australia Fittings
6142*	Midas Flowmeter Remote, 60% Max N_2O, White, O_2 Control, Swedish Fittings	6042*	Midas Flowmeter Portable, 60% Max N_2O, White, O_2-Control, Swedish Fittings
6172*	Midas Flowmeter Remote, 60% Max N_2O, White, N_2O Control, Swedish Fittings	6072*	Midas Flowmeter Portable, 60% Max N_2O, White, N_2O Control, Swedish Fittings
6120*	Midas Flowmeter Remote, 70% Max N_2O, Green, N_2O Control	6020*	Midas Flowmeter Portable, 70% Max N_2O, Green, N_2O Control
6130*	Midas Flowmeter Remote, 50% Max N_2O, White, O_2 Control	6030*	Midas Flowmeter Portable, 50% Max N_2O, White, O_2 Control
6140*	Midas Flowmeter Remote, 60% Max N_2O, White, O_2 Control	6040*	Midas Flowmeter Portable, 60% Max N_2O, White, O_2 Control
6150*	Midas Flowmeter Remote, 70% Max N_2O, White, O_2 Control	6050*	Midas Flowmeter Portable, 70% Max N_2O, White, O_2 Control
6160*	Midas Flowmeter Remote, 50% Max N_2O, White, N_2O Control	6060*	Midas Flowmeter Portable, 50% Max N_2O, White, N_2O Control
6170*	Midas Flowmeter Remote, 60% Max N_2O, White, N_2O Control	6070*	Midas Flowmeter Portable, 60% Max N_2O, White, N_2O Control
6180*	Midas Flowmeter Remote, 70% Max N_2O, White, N_2O Control	6080*	Midas Flowmeter Portable, 70% Max N_2O, White, N_2O Control
All flowmeter models are available with eAVS included by adding "-EAVS" to the Model Number. All flowmeter control modules are available by adding "MFCM-" to the Model Number.			

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

Accessories Model Table

Accessories	Part Number	Part Description
Electronic Automatic Vacuum Switch	EAVS-5000[2]	Electronic Automatic Vacuum Switch
Vacuum Control Block	5501-RK	Scavenger, In Line Vacuum Control Block
Wall Mount	2020	Telescope Wall Mount
Mounting Brackets	B-5555-00M	Midas Z-Mount Brackets
Cabinet Mounts	2036-M	Midas, Under Counter Mounts
	2037-M	Midas, Left or Right Slide Brackets
Handle Bracket	HANDLE-M	Midas, Wall Mount Bracket Handles
Mobile Stands	2040[2]	Mobile Stand, Compact
2-Cylinder Mobile Carts	[2] 2100	2-Cylinder Cart
	2100-2	2-Cylinder Cart with Dual Regulators and Hoses
	2100-N	2-Cylinder Cart with Nitrous Oxide Regulator

Accessories	Part Number	Part Description
	2100-NC	2-Cylinder Cart, Nitrous Oxide Regulator and Hoses
	[2] 2100-ISO-2	2-Cylinder Mobile Cart with Regulator O2, Regulator N2O, and Gas Supply Hoses
	[2] 2100-ISO-N	2-Cylinder Mobile Cart with Regulator, N2O, and Gas Supply Hose
E-Stands	2045-3	E-Stand, Tall
	2045-3CA	E-Stand, White Hose
	[2] 2045-3ISO	E-Stand, Tall with Gas Supply Hoses
Breathing Circuits	[1, 2] 5155-X	Porter Breathing Circuit
	[1, 2] 915151XX	Matrx Breathing Circuit
	[1, 2] SIL2-XXX-XXX	Silhouette Breathing Circuit
Supply Hose	[1, 2] 800X	O_2 DISS/DISS Hose
	[1, 2] 850X	N_2O DISS/DISS Hose
Breathing Bag (If required)	[2] 4100-3NL	3 Liter Breathing Bag
	[2] 4100-2NL	2 Liter Breathing Bag
	[2] SIL-ADPT-PKG	Silhouette Adapter Package
Bag Tee	[2] C-1777-000	Midas Bag Tee – Portable
	[2] C-1777-001	Midas Bag Tee – Remote

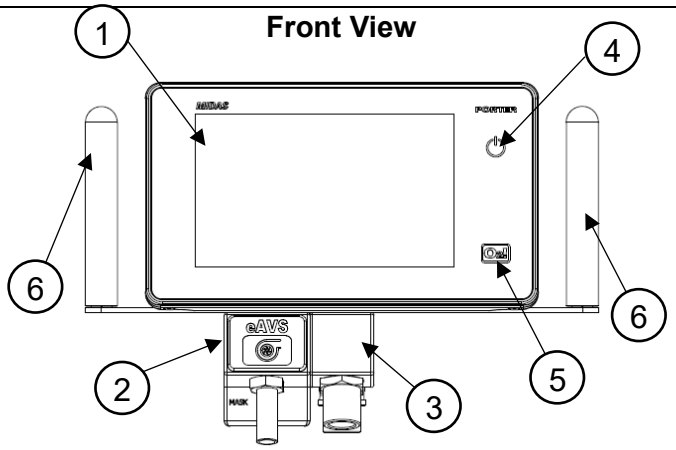
[1] The X is a place holder as there are multiple models associated with the part number. Please contact distributor for appropriate part number of the accessory.
[2] Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

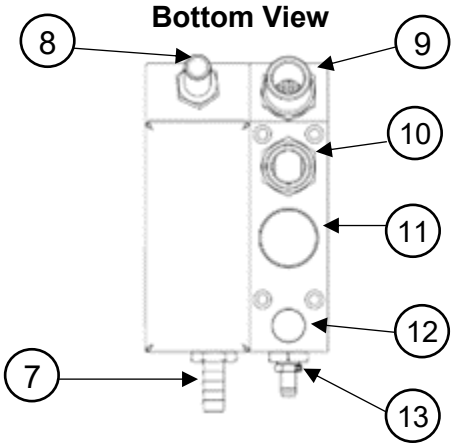
WARNING: The device has been validated with the above accessories. The use of alternatives could result in an unacceptable risk.

1.3. User Interface

1.3.1. Device User Interface

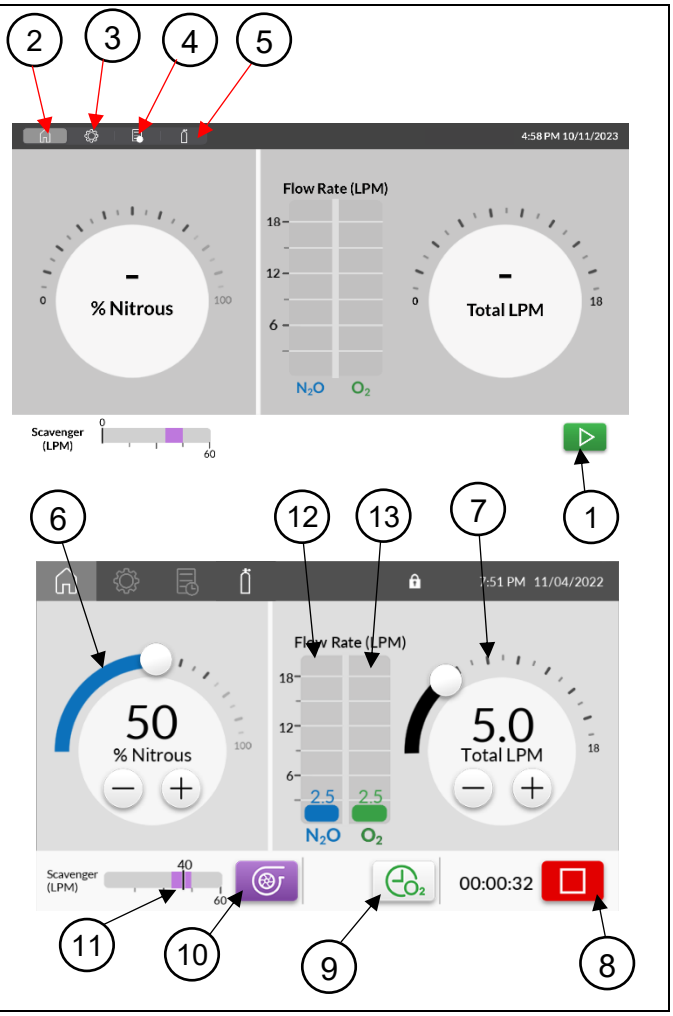
#	Description
1	Flowmeter Touchscreen
2	eAVS
3	Bag Tee
4	Power Button
5	O_2 Flush Button
6	Device Handle
7	Vacuum Source Connection
8	Breathing Circuit Vacuum Connection
9	Breathing Circuit Fresh Gas Connection
10	Breathing Bag Connection
11	Emergency Air Intake Valve
12	Mounting Hole Connection
13	Fresh Gas Connection



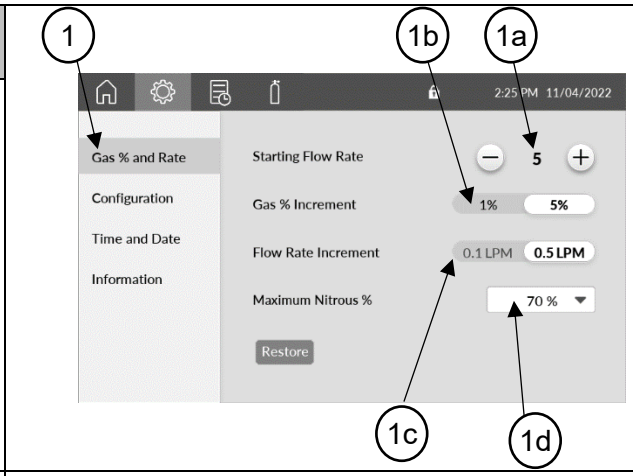
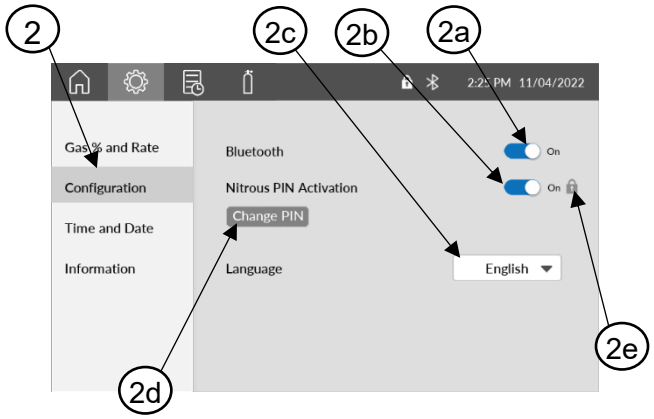
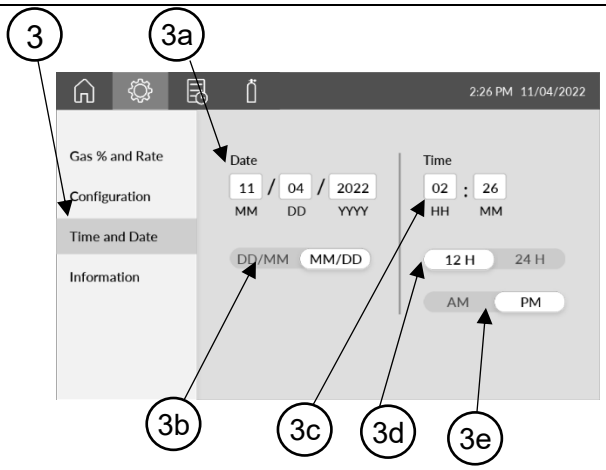
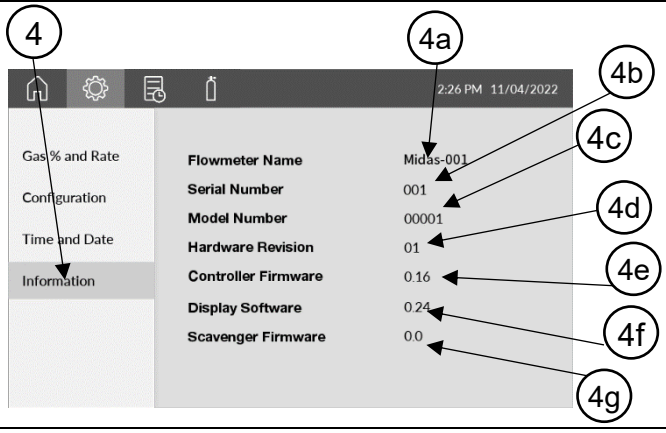


1.3.2. Touchscreen User Interface

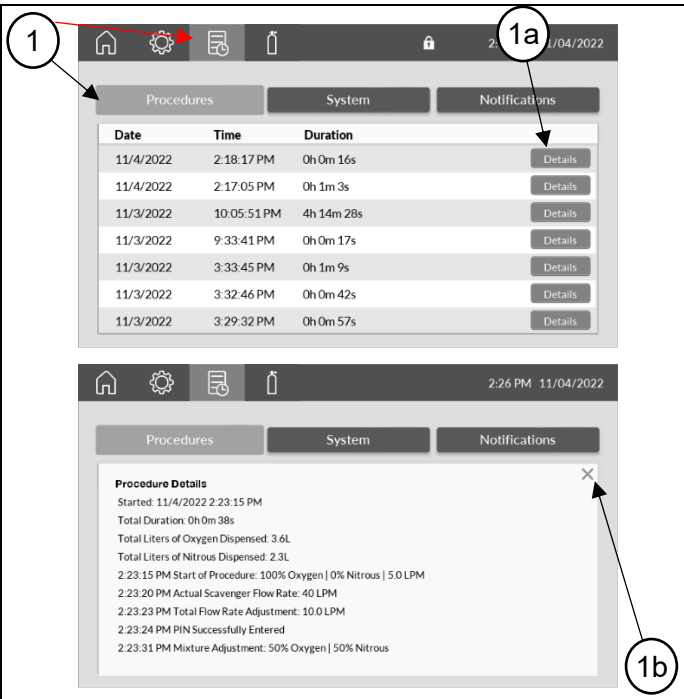
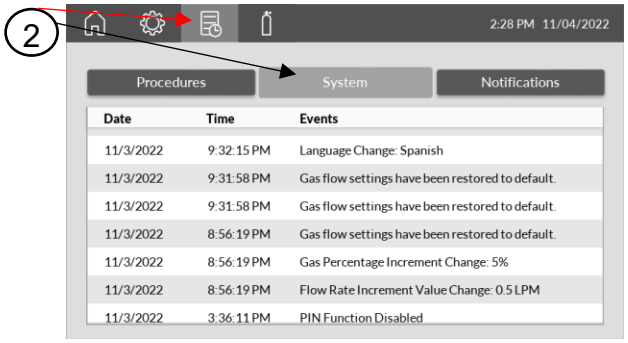
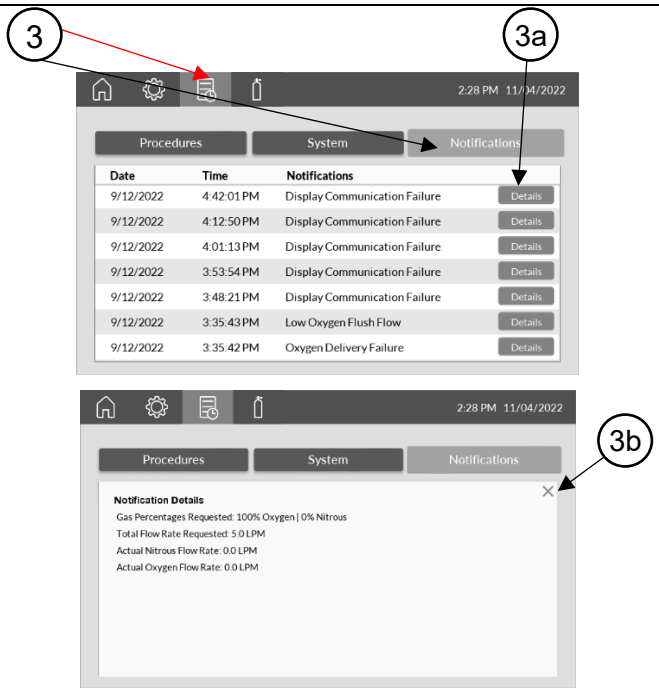
#	Description
1	Start Procedure Button
2	Home Screen Button
3	Settings Button
4	Logs Button
5	Liters Dispensed/Gas Remaining Button
6	O_2 or N_2O percentage mixture control (model dependent)
7	Total Flow Setpoint (Liters Per Minute)
8	Stop Button
9	O_2 Recovery
10	Scavenger Control
11	Measured Scavenger Flow Rate
12	Measured N_2O Flow Rate
13	Measured O_2 Flow Rate



1.3.3. Setting Screen User Interface

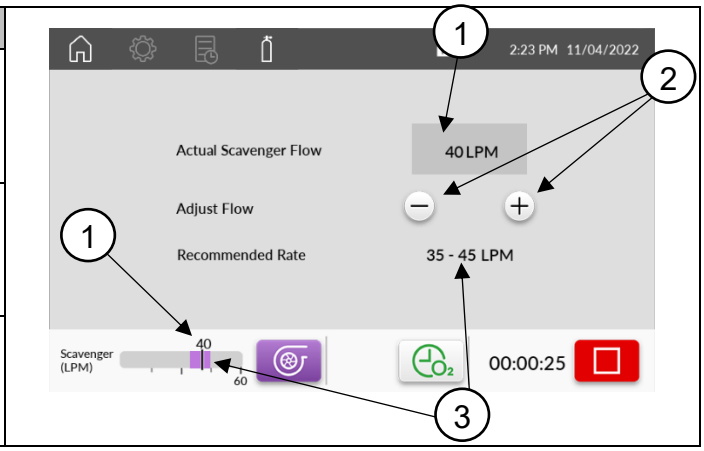
#	Description	
1	Gas % and Rate a. Starting Flow Rate (LPM) b. Gas % Increment c. Flow Rate Increment d. Maximum N_2O %	
2	Configuration a. Bluetooth b. Nitrous Pin Activation c. Language d. Change Pin **Note:** Change Pin Button is only present if pin is active e. Nitrous Pin Lock Indicator	
3	Time and Date a. Date b. Day/Month vs Month/Day c. Time d. 12-hour vs 24 hour e. AM vs PM	
4	Information a. Flowmeter Name b. Serial Number c. Model Number d. Hardware Revision e. Controller Firmware Version f. Display Software Version g. Scavenger Firmware Version **Note:** This Screen is displaying information only.	

1.3.4. Logs Screen User Interface

#	Description	
1	Procedures Log a. Open details b. Close details **Note:** Procedure Log contains 25 entries. You can swipe up on the touchscreen to view additional procedures.	
2	System Log **Note:** System Log contains 50 entries. You can swipe up on the touchscreen to view additional entries.	
3	Notifications Log a. Open details b. Close details **Note:** Notification Log contains 25 entries as you can swipe up on the touchscreen to view additional notifications.	

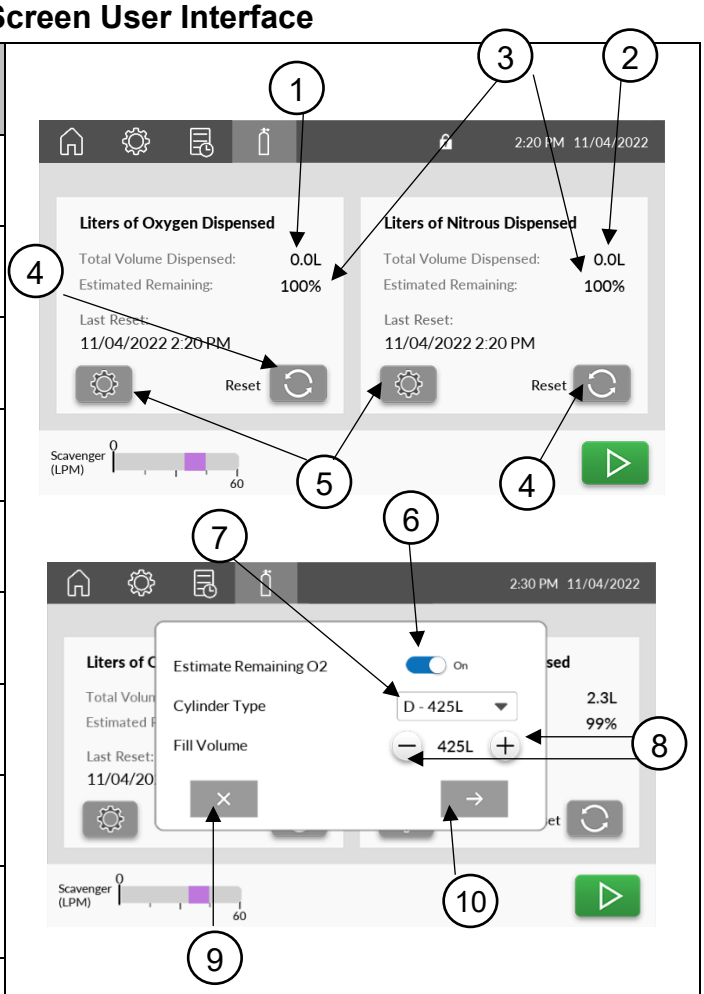
1.3.5. Scavenger Screen User Interface

#	Description
1	Measured Scavenger Flow (LPM)
2	Adjust Flow Buttons
3	Recommended Range (purple zone) / Recommended Rate



1.3.6. Liters Dispensed / Gas Remaining Screen User Interface

#	Description
1	Liters of Oxygen Dispensed
2	Liters of Nitrous Dispensed
3	Estimated Remaining (when active)
4	Reset
5	Settings Button
6	Display Estimated Remaining Button
7	Cylinder Type
8	Fill Volume Adjustment
9	Exit Setting Button
10	Save Setting Button



1.3.7. Porter Midas Remote Control Application (Porter Midas App)

The optional Porter Midas Remote Control Application controls the Midas Flowmeter, and runs on a user-provided, Bluetooth-enabled (BLE 5.2) Apple iPad. Refer to **Section 3.5. iPad Configuration and Instructions** for instructions on the use of the application.

1.4. General Description/Principles of Operation

1.4.1. Midas Flowmeter

The Midas Flowmeter is a gas mixing device that delivers a mixture of N_2O and O_2 gas to a conscious, spontaneously breathing patient. The device is supplied with regulated compressed N_2O and O_2 gas. The flow of each regulated gas is metered and controlled within the device and mixed gas is delivered to a patient. The device functions under the continuous flow principles of operation: when in use, the flowmeter will deliver gas on a continuous basis unless otherwise acted on by the healthcare professional.

The Midas Flowmeter controls the flowrate of N_2O and O_2 gases using firmware and electronic controls. The device features an auto-compensation, pneumatic mixer technology that maintains flowrate and gas mixture percentage when the user changes these parameters using the user interface. Internal valves control gas mixture percentage and flowrate to supply mixed gas to the patient through a connected breathing circuit.

Every Midas Flowmeter is provided with a Bag Tee. The eAVS electronic scavenging device is an optional device for use with the Midas Flowmeter. The Midas Flowmeter is equipped with various safety features, which are described in **Section 1.8**.

1.4.2. Electronic Automatic Vacuum Switch (eAVS)

The eAVS is an optional accessory to the Midas Flowmeter. It is used to control the vacuum flow rate for scavenging of patient exhaled nitrous oxide. The American Conference of Governmental Industrial Hygienists (ACGIH) recommends exposure limit for nitrous oxide to be 50 ppm as a time-weighted average during the period of administration.

The eAVS connects the exhalation line of the patient's breathing circuit to the vacuum source and controls the vacuum flowrate. The gas exits the eAVS through the vacuum tubing connected to the back of the eAVS and is removed from the healthcare facility via the vacuum source. The eAVS consists of a valve used to control vacuum flowrate, an air flow sensor used to measure the rate of scavenging flow, and a control board to communicate to the Midas Flowmeter.

The Midas Flowmeter and optional eAVS is equipped with various safety features, which are described in **Section 1.8**.

1.5. Use of the Device

The Midas Flowmeter and optional eAVS is to be used by a healthcare professional trained in the use and administration of N_2O and O_2 gases within a healthcare environment. 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 Midas Flowmeter and optional eAVS 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 O2 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.

CAUTION: Operate touchscreen with finger pressure only. Do not use hard or sharp objects. Otherwise, damage may result to the user interface.

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 within the relevant 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.

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. Safety Features

The performance of the Midas Flowmeter and optional eAVS is reflective of a basic safety requirement to provide a minimum of 20.9% oxygen while nitrous oxide is flowing. The Midas Flowmeter device is designed to be set at an absolute minimum Oxygen level of 30%, dependent on the model. The safety features below ensure the device provides basic safety.

Failsafe:

The Midas Flowmeter utilizes a combination of software and electronics to ensure that the device only supplies N_2O when O_2 flow is present. If the O_2 supply gas is depleted or disconnected, the device will discontinue mixed gas delivery until O_2 flow is restored. If power is lost to the flowmeter, the device will discontinue mixed gas delivery.

DISS Fittings:

The Midas Flowmeter is equipped with Diameter Indexed Safety System (DISS) fittings, which act in a key-like fashion to ensure that each hose can be connected to the correct appropriate fitting. This prevents an accidental crossing of the N_2O and O_2 gas hoses.

Non-Rebreathing Check Valve:

The non-rebreathing valve contains a backflow check valve to prevent exhaled gases from entering the breathing bag preventing carbon dioxide (CO_2) buildup.

Emergency Air Intake Valve:

In the event that the O_2 gas supply is depleted or disconnected, and delivery of mixed gas is stopped, an Emergency Air Intake Valve will open that allows the patient to breathe room air through the breathing circuit.

Automated Vacuum Activation

The eAVS (if used) is designed with an automated vacuum activation mechanism to ensure that vacuum flow will begin once gas begins to flow through the Midas Flowmeter.

Onboard Diagnostics:

The Midas Flowmeter uses onboard diagnostics to conduct self-checks at start-up and during operation. When an issue is detected, a notification will appear in the Notification Display and is accompanied by a continuous, audible alert. An audible notification may be silenced but the visual notification remains on screen until corrected.

- **Notifications** appear on screen and are accompanied by a continuous, audible alert. Notifications are fault condition reports, triggered by onboard diagnostics. All notifications should be addressed and will persist until the fault is resolved. Notifications are recorded in the Notifications Log, where the latest 50 entries are recorded. Valve leak tests, sensor tests, and memory integrity checks are first conducted when the flowmeter is first turned on.
- **Alerts** appear on screen as a pop-up window to convey information to the user. The user must acknowledge the alert to close the window. There is no other user action required. Alerts are recorded in the System or Notification Log, where the latest 50 entries are recorded.

Nitrous Oxide PIN Activation:

A locking mechanism allows the user to prevent unauthorized use of N_2O. Once the correct PIN is entered, the flow of N_2O is allowed. The PIN is a user selected, four-digit numeric pin that has no restriction on supply of 100% O_2 as needed. Once N_2O is flowing, it will remain flowing until turned off. Once off, the PIN is required to restart the flow of N_2O.

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

CAUTION: Use caution when using the Midas Flowmeter and eAVS around electromagnetic devices (ex: diathermy and electrocautery equipment) as interference from these devices may cause a malfunction of the Flowmeter or eAVS.

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 Midas Flowmeter and optional eAVS are used with the delivery of Oxygen (O_2). Therefore, when these devices 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. Recommended Security Controls

The Midas Flowmeter contains software components and utilizes Bluetooth (BLE 5.2) connection to enable use of the Porter Midas App. Best practices should be applied when using the device and optional remote features to ensure adequate security. Below are recommended actions to be taken to ensure security controls of the device are maintained during use.

- Ensure access to the Midas Flowmeter device is monitored at all times to prevent tampering with the device or its interfaces.
- Familiarize yourself with the Apple iPad Safety Check below prior to installing and using the (optional) Porter Midas App.

  (https://support.apple.com/guide/ipad/use-built-in-privacy-and-security-protections-ipad9ae59af9/16.0/ipados/16.0)
- Take actions to prevent unauthorized access to the iPad when using the Porter Midas App such as requiring Passcode and/or Face ID to unlock the iPad and enabling the Auto-lock feature.
- Monitor the performance of the Porter Midas App for unexpected changes. Report such abnormal behavior immediately to the distributor representative.
- Familiarize yourself with the Porter Midas App icon, and do not download any other app that appears similar to the Porter Midas App from the Apple app store.

- Ensure the latest version of the Porter Midas App is installed on the iPad. Correct operation of the app should be checked following an update of the Porter Midas App or the iPadOS to confirm compatibility and installation.
- Following initial download and installation, the Porter Midas App does not utilize (or require) Wi-Fi or Cellular internet connection to support any of its functionality.

The software bill-of-materials (SBOM) for the Midas Flowmeter includes supplier developed software (such as bootloader and drivers) with known cybersecurity information. There are no other Parker Hannifin designed and developed SBOM components. Individual component information and SBOM information can be made available upon request. Contact the distributor representative for more information.

1.10. 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 Midas Flowmeter. Specific delivery protocols for adult and pediatric patients should be developed. The Midas Flowmeter may be used for common dental and medical procedures (ex. extractions, implants, fillings, etc.) on where the maximum use is less than 24-hours, typically less than 60-minutes.

1.11. Safe Combination of devices

The Midas flowmeter, optional eAVS, and bag tee are 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 may include a conscious sedation flowmeter, bag tee and breathing bag, 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.

1.12. Specifications

1.12.1. eAVS Specifications

Dimensions
2.00 in W x 3.03 in H x 6.69 in D
(5.08 cm W x 7.70 cm H x 16.99 cm D)

Electrical
Connect via Parker Provided Cable:
P/N PB-1711-000 (0.3M) Portable
P/N PB-1711-001 (3M) Remote Mounted (std)
P/N PB-1711-002 (7.5M) Remote Mounted (opt)
Power Voltage: 12 volts

Environmental:

Temperature
Storage/Transport: -30°F – 140°F
(-34°C – 60°C)
Operational: 50°F – 104°F
(10°C – 40°C)

Relative Humidity
Storage/Transport (after use): 30-80% ambient and non-condensing
Operational: 30-80% ambient and non-condensing

Atmospheric Pressure
Operational: 10.44 – 15.23 PSI (72-105 kPA)

Weight
1.59 lbs (0.72kg)

Setting Accuracy*
Flow: Adjustable 0 – 60 LPM
<= 45 LPM ± 3LPM
>45 LPM ± 5LPM
*Flowrates standardized to 20°C and 1013mbar reference condition

Ingress Protection Rating
IPX0
(Not protected against the ingress of water or particulate material)

Vacuum Connection Fittings
Vacuum Source: 3/8-inch hose barb fitting
Breathing Circuit: ½ inch OD fitting

Recommended Vacuum Source Characteristic:
Pressure Range: 10-29.9 in Hg (33.8-101.3 kPa)
Flow Rate: 50 L/min. Minimum

1.12.2. Flow Meter Specifications

Dimensions:

Remote Mount Configuration:
Control Module:
6.80 in W x 3.86 in H x 7.35 in D
(17.27 cm W x 9.80 cm H x 18.67 cm D)

Touchscreen:
9.20 in W x 5.30 in H x 1.50 in D
(23.37 cm W x 13.46 cm H x 3.81 cm D)

Bag Tee:
1.50 in W x 2.81 in H x 6.40 in D
(3.81 cm W x 7.14 cm W x 16.26 cm D)

Portable Configuration:
12.00 in W x 8.18 in H x 8.70 in D
(30.48 cm W x 20.78 cm H x 22.10 cm D)

Weight (Portable or Remote Mount):

Control Module: 3.03 lbs (1.37 kg)
Touchscreen: 1.92 lbs (0.87 kg)
Bag Tee: 1.20 lbs (0.54 kg)
Handle: 0.82 lbs (0.372 kg)

Mixture Settings

N_2O: 0%-(50%/60%/70%) (factory set)
O_2: (30%/40%/50%)-100% (factory set)
Adjustment Step Options: 1% or 5%

O_2 Flow Bar Color Settings

Green or White (factory set)

Applied Parts Type

Type B

Delivery Flow Rate

1 – 18 LPM total flow
Adjustment Steps: 0.1 to 0.5 LPM (options)
O_2 Flush: 20 LPM (minimum)

Delivery Accuracy*

N_2O setpoints:
Setpoints > 5 LPM ± 0.5 LPM
Setpoints ≤ 5 LPM ± 0.3 LPM

O_2 setpoints:
Setpoints > 5 LPM ± 0.5 LPM
Setpoints ≤ 5 LPM ± 0.3 LPM
* flowrates standardized to 20°C and 1013mbar reference condition

Electrical:

Midas Power Supply
Meanwell P/N: GSH60A12-R7BVoltage:
100v – 240v
Frequency: 50Hz or 60Hz

External Power Supply Classification
Class I

Ingress Protection Rating: IPX0
(Not protected against the ingress of water or particulate material)

Remote Operation:

Device for Remote Application:
Apple iPad Only

iPadOS Version Required:
iPadOS Version 17 or later

Gas Supply:

Connection Fittings:
O_2 Inlet: DISS 1240 (male thread)
N_2O Inlet: DISS 1040A (male thread)
O_2 Outlet: DISS 1240 demand valve (male thread)
Mixed Gas Outlet: .875 inches OD fitting

Gas Supply Pressure:
O_2: 40 – 75 psi (275.8 – 517.1 kPa)
N_2O: 40 – 75 psi (275.8 – 517.1 kPa)

Note: The Midas Flowmeter can function properly from 40 to 75 psi. For USA offices using the Porter Manifold System with their gas supply, the manifold will alarm at 40psi (low pressure) and 70 psi (high pressure); therefore, users must take into account their gas supply system when setting the inlet gas pressure for O_2 and N_2O.

Environmental

Temperature
Storage/Transport: -30°F – 140°F
(-34°C – 60°C)
Operational: 50°F – 104°F
(10°C – 40°C)

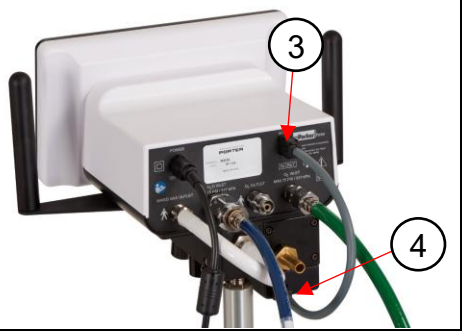
Relative Humidity
Storage/Transport (after use):
30-80% ambient and non-condensing
Operational: 30-80% ambient and non-condensing

Atmospheric Pressure
Operational: 10.44 – 15.23 PSI (72-105 kPA)

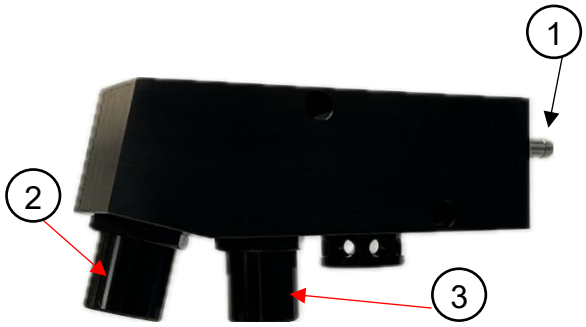
2. Installation Instructions

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.

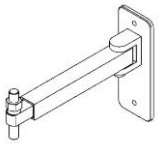
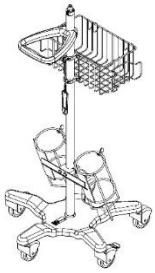
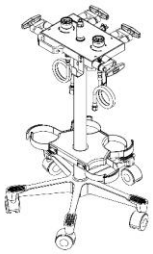
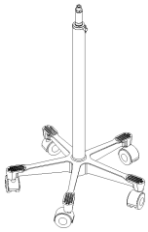
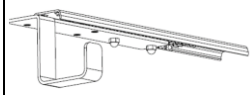
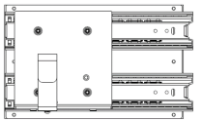
2.1. Connecting the eAVS Vacuum Controller (optional)

1	Attach the vacuum hose from the breathing circuit to the **MASK port** (1) of the eAVS.	
2	Attach vacuum hose to **the back of the eAVS** (2) and then to a vacuum source. **Note:** Orientation of elbow is adjustable. To change orientation, loosen hex, orient, then tighten hex. Be sure hex is tight to prevent leaks.	
3	Use the included cable to make the electrical connection between connector **SCAV** (3) on the Control Module and **COM** (4) the electrical connector on the eAVS.	

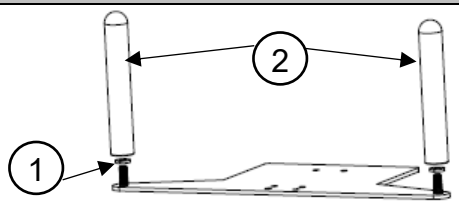
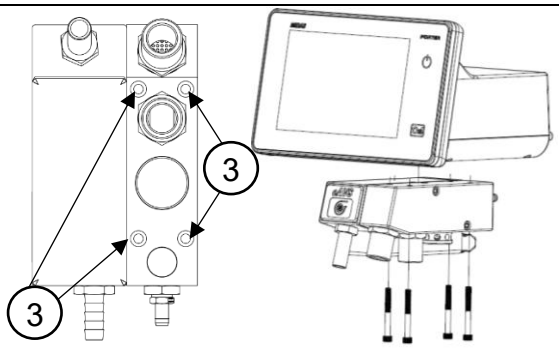
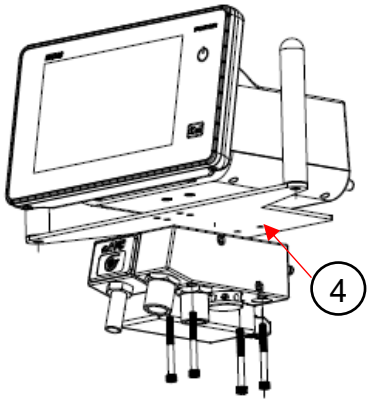
2.2. Connecting the Bag Tee – For Remote Models Only (P/N – C-1777-001)

Bag Tee		
1	Attach the Fresh Gas Hose from the Flowmeter to the **connection fitting** (1) on the rear of the Bag Tee. **Note:** Orientation of elbow is adjustable. To change orientation, loosen slotted screw, orient, then tighten slotted screw. Be sure slotted screw is tight to prevent leaks.	
2	Attach the Fresh Gas Hose from the breathing circuit to the **Breathing Circuit Port** (2) of the Bag Tee.	
3	Attach the Breathing Bag to the **Breathing Bag Port** (3) of the Bag Tee.	

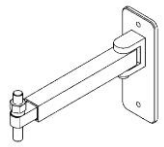
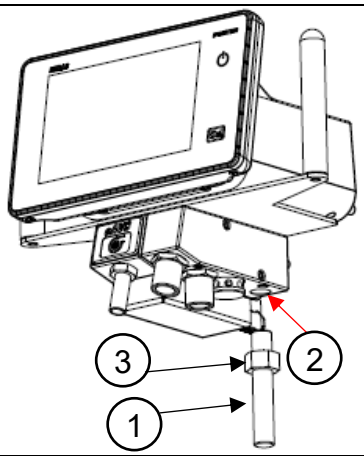
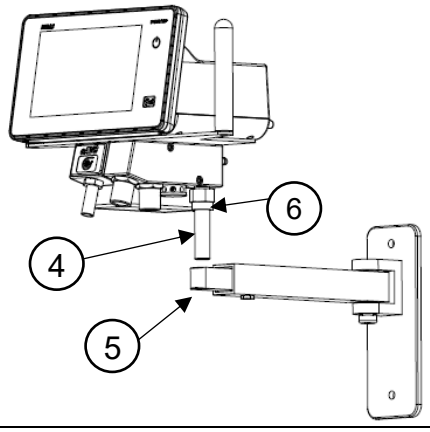
2.3. Compatible Mounting Accessories

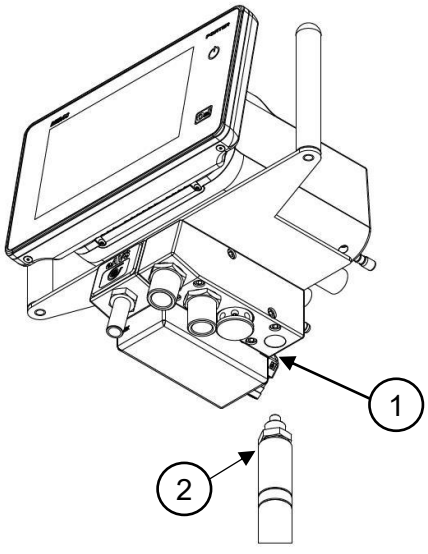
Wall Arm Mount	2-Cylinder Mobile Cart	E-Stand	Mobile Stand	Under Counter Mount	Left or Right Slide Bracket Mount
	 **Note:** Basket maximun weight = 10 lbs (4.5 kg)				

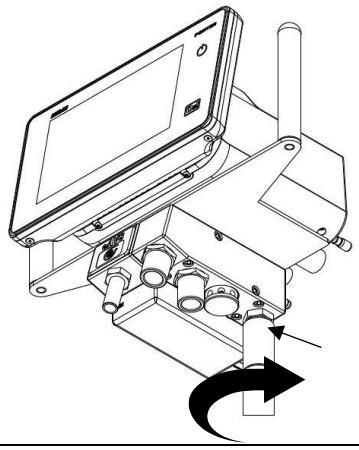
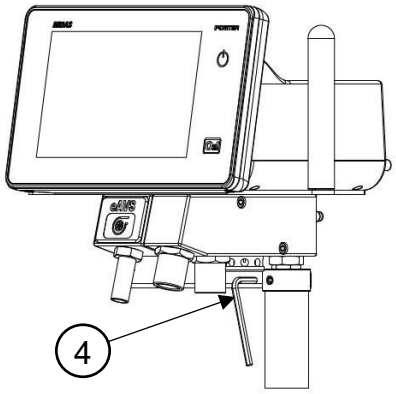
2.4. Attaching HANDLE-M to Midas Flowmeter

HANDLE-M		
1	Place **split lock washers** (1) over studs and install **handles** (2).	
2	Remove the **screws** (3) holding the Bag Tee and Optional eAVS from Flowmeter, discard screws.	
3	Attach Bag Tee and optional eAVS to Flowmeter with the **plate** (4) in between using the included screws.	

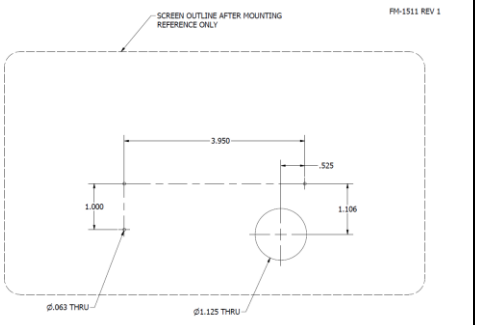
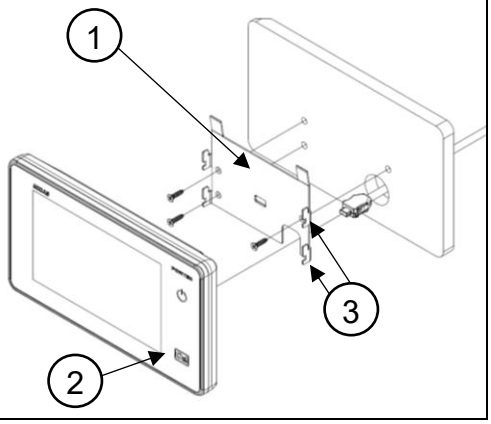
2.5. Mounting the Midas Flowmeter

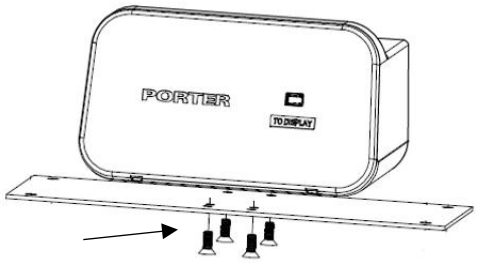
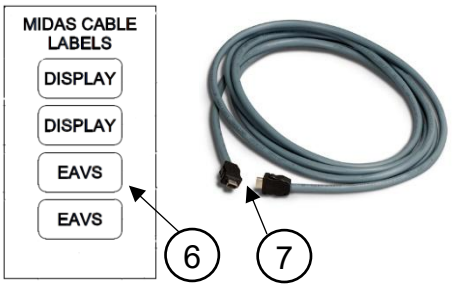
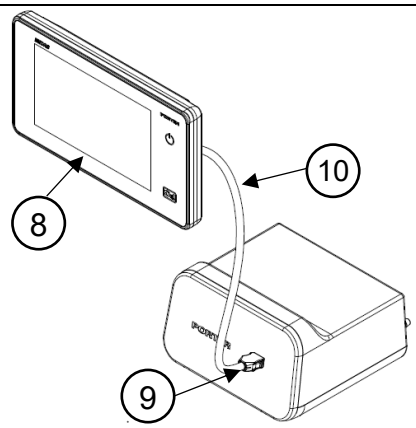
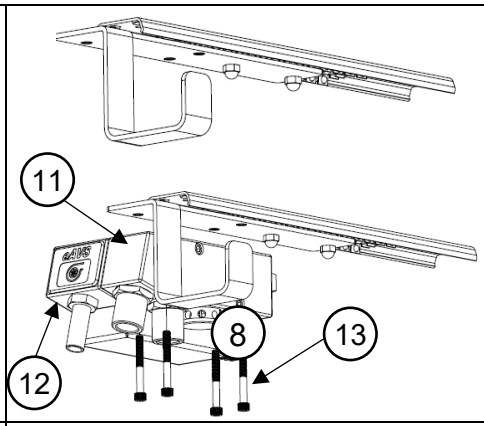
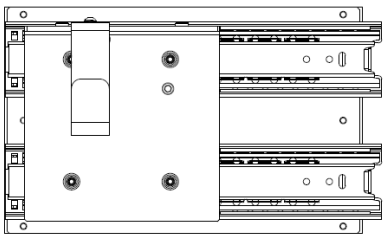
Wall Mount Install		
1	Attach Wall Mount Arm to the wall.	
2	Thread **mounting pin** (1) into mounting hole on bottom of the **Bag Tee** (2) until tight, then tighten **locking nut** (3) to secure pin.	
6	Lift the Midas Flowmeter and insert the **mounting pin** (4) into the mounting hole on the top of the **Wall Arm Mount** (5). **Note:** Included 2 x **bushing** (6) must be used stacked together.	

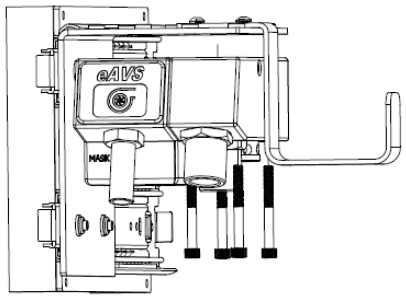
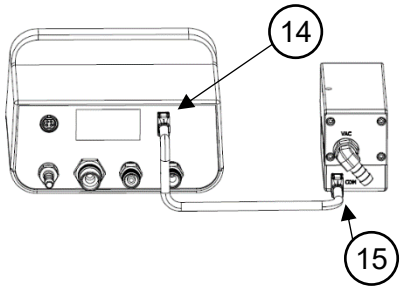
2 Cylinder Cart, E-Stand, and Mobile Stand Installs		
1	Lift Midas Flowmeter and carefully lower **mounting hole** (1) on the bottom of the Bag Tee onto **mounting thread** (2) on the top of the E-Stand/Mobile Stand.	

2 Cylinder Cart, E-Stand, and Mobile Stand Installs		
2	Spin **shaft** (3) until device is tightly threaded onto mounting post. Tighten locking nut on shaft to secure device.	
3	Note: If you are attaching to a 2-Cylinder Mobile Cart, take the extra step to tighten the set screw in the collar of the 2-Cylinder Mobile Cart to using a **5/32" Hex Key** (4) to keep the flowmeter from rotating freely.	

2.6. Under Counter Installation – Remote Models Only

Under Counter Mount Installation Instructions		
1	Using the template on **FM-1511**, mark the location and drill holes for screws and cable.	
2	Mount Sheet metal **mounting bracket** (1) to cabinet face.	
3	Run Interface Cable through the cabinet then out to the single connection on rear of **Midas Touchscreen** (2).	
4	Align **tabs** (3) of sheet metal mounting bracket with slots on rear of Midas Touchscreen.	
5	Push Touchscreen on tabs and slide touchscreen down. To ensure secure touchscreen snap touchscreen into place.	

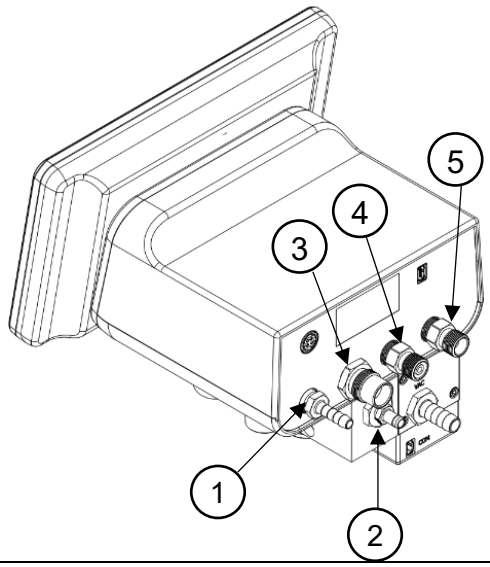
Under Counter Mount Installation Instructions		
6	Mount Control Module to Plate using provided **flat head screws** (5).	
7	Mount assembly inside cabinet. **Note:** Screws not provided, not shown.	
8	**For Remote models with eAVS** Before routing display and eAVS interface cables, use included **labels** (6) to keep them identified. Label both end **connectors** (7) of the cable with the same identifier, repeat on other cable with other identifier.	
9	Connect **Touchscreen** (8) to the **Control Module Unit** (9) using the provided **Interface Cable** (10).	
10	Mount **Bag Tee** and optional **eAVS** to one of the slide options below:	
10a	Mount the under-counter slide to cabinet. Then Mount the **Bag Tee** (11) and optional **eAVS** (12) to slide bracket using the included **screws** (13).	
10b	Mount the Left or Right Slide into the cabinet. Then mount the **Bag Tee** and optional **eAVS** onto the slide bracket using the included **screws**.	

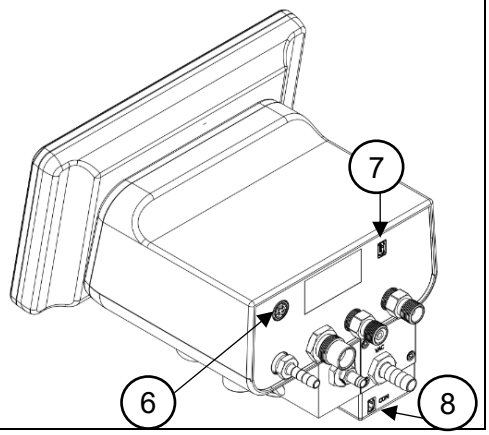
Under Counter Mount Installation Instructions		
		
11	Route and make the electrical connection between connector **SCAV** (14) on the Control Module and the **COM** (15) electrical connector on the eAVS.	

2.7. Connecting Supply Lines

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

WARNING: Do not change the connection fitting type or diameter of the supply hoses. The Diameter Indexed Safety System (DISS) is designed to prevent misconnection of N_2O and O_2 supply lines.

Gas Supply Line and Other Connections		
1	For Remote Models, Connect mixture hose to **Mixture fitting** (1).	
2	For Remote Models, Connect opposite end of the mixture hose to the **Bag Tee** (2).	
3	Connect N_2O gas supply hose to **N_2O DISS inlet fitting** (3). Hand-tighten and then tighten 1/8 turn with wrench. Do not overtighten.	
4	**Optional:** Connect Emergency O_2 hose to **O_2 DISS outlet fitting** (4). Hand tighten and then tighten 1/8 turn with wrench. Do not overtighten.	
	Note: Contact your authorized distributor for information pertaining to available emergency oxygen accessories.	
5	Connect O_2 gas supply hose to **O_2 DISS inlet fitting** (5). Hand-tighten and then tighten 1/8 turn with wrench. Do not overtighten.	
6	Connect power supply to the Flowmeter **Power port** (6) and plug in.	

Gas Supply Line and Other Connections		
	Note: Turn connector so flat side is facing down and insert until it clicks. (To remove, pull back on outer sleeve to release.) **Note:** To disconnect from the main power source, disconnect the flowmeter power supply power cord from the wall outlet.	
7	Connect one end of eAVS communication cable to the **Flowmeter SCAV port** (7).	
8	Connect other end of cable to **eAVS** COM port (8).	

3. Instructions for Use

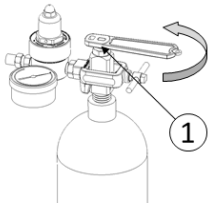
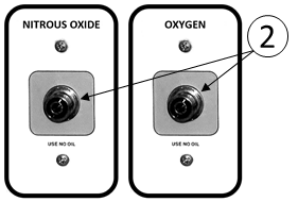
3.1. Setup

WARNING: To minimize the risk of fire or explosion:

- Always ensure cylinder valves are clear of dust and dirt prior to connection. One method to clear dust and dirt is to briefly "crack" the cylinder valve open to blow out any debris in the line before installing the cylinder.
- Do not discharge the gas at any person or flammable material.
- Always turn on Cylinder Valves slowly and fully.

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.

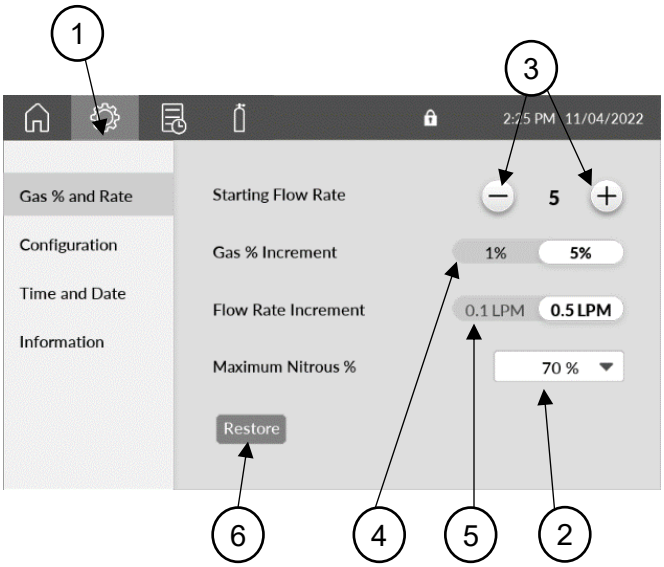
CAUTION: It is best practice upon completion of the procedure to close the cylinders (if portable gas supply) or disconnect from wall outlets (if central gas supply). Failure to do so may result in gas depletion should there be a leak.

1	Ensure the device is securely mounted (as described in **Section 2.6 Mounting the Midas Flowmeter**) and the gas supply hoses are connected to the correct fittings on the Midas Flowmeter (as described in **Section 2.7 Connecting Supply Lines**).		
2	Ensure the necessary pre-checks have been performed, before using the Midas Flowmeter. The pre-check instructions are described in **Section 4.1 Pre-check**.		
3	Turn on the N_2O and O_2 gas supplies. If using gas cylinders, slowly open the **cylinder valves** (1). If connecting to a wall supply, connect the supply lines to the appropriate **outlet connections** (2).		
4	When using a compatible portable mounting accessory, supply pressure is preset by the manufacturer. When using a wall supply, ensure supply pressure is within specification, 40-75 psi (275.8-517.1 kPa).		
5	Connect a compatible breathing circuit.		
6	Connect to vacuum source for scavenging.		

3.2. Flowmeter Configurations

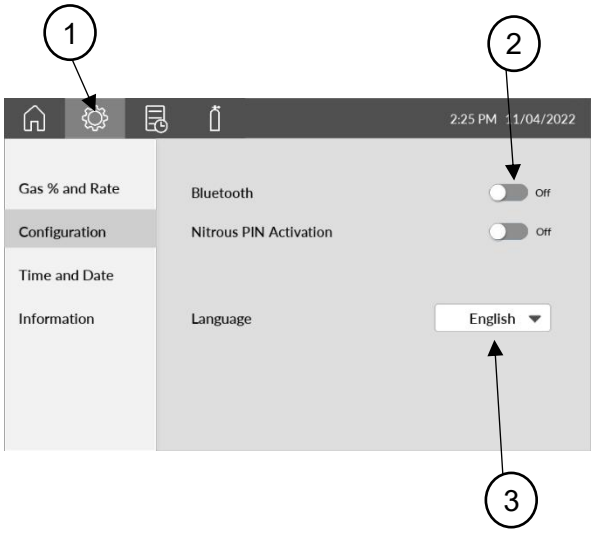
3.2.1. Gas % and Rate Settings Configuration

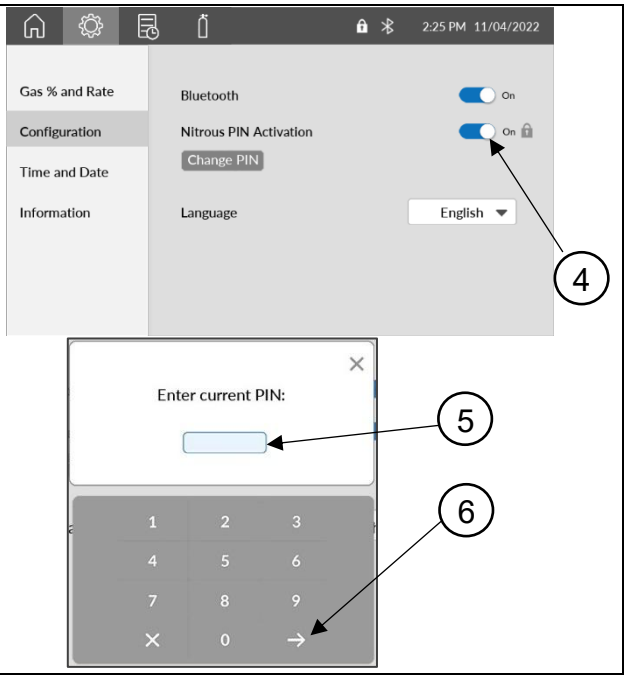
1	Press the **Settings button** (1). The Settings screen appears, push Gas % and Rate to display the Gas % and Rate settings screen.
2	Select the default maximum **Nitrous %** (2). **Note:** The absolute maximum allowable gas percentage is factory set.
3	Press the + and – buttons to adjust the starting **O_2 flow rate (liters per minute)** (3). This is the initial O_2 flow rate for when a procedure is started.
4	Select the **gas % increment** (4). The smaller step size allows for a finer adjustment of the gas mixture.
5	Select the **flow rate increment** (5). The smaller step size allows for a finer adjustment of the flow rate.
6	**Restore button** (6) allows for all settings to go back to factory parameters.



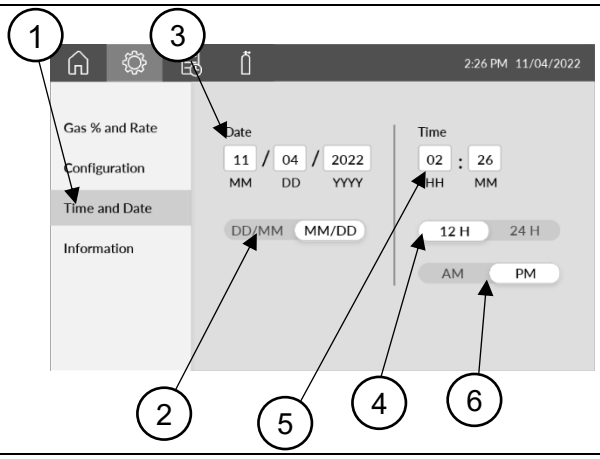
3.2.2. Configurations

1	Press the **Settings** button (1). The Settings screen appears, push Configurations to displaying the Configurations section.
2	Turn on **Bluetooth** (2) if using the Porter Midas App to monitor and control the Flowmeter using an Apple iPad. See **Section 3.5 iPad Configuration and Instructions** for setup and operation of the Midas Flowmeter using the Porter Midas App.
3	Select the appropriate language for **touchscreen display** (3).
4	OPTIONAL: Turn on **Nitrous Oxide PIN Activation** (4). If using PIN security to administer N_2O, Select and enter a **four-digit PIN** (5) and press the **arrow** to save the PIN (6).



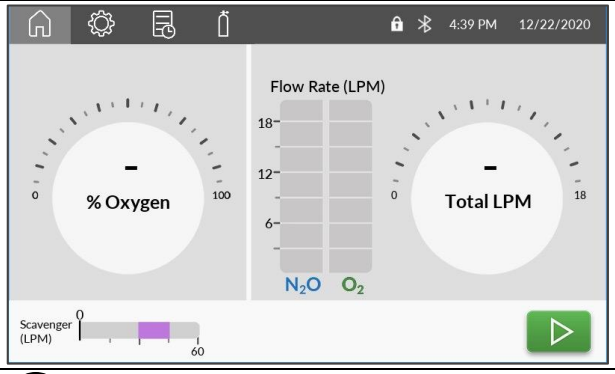
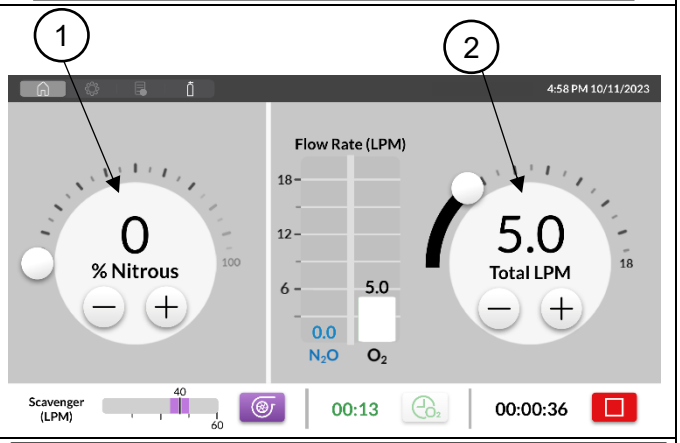
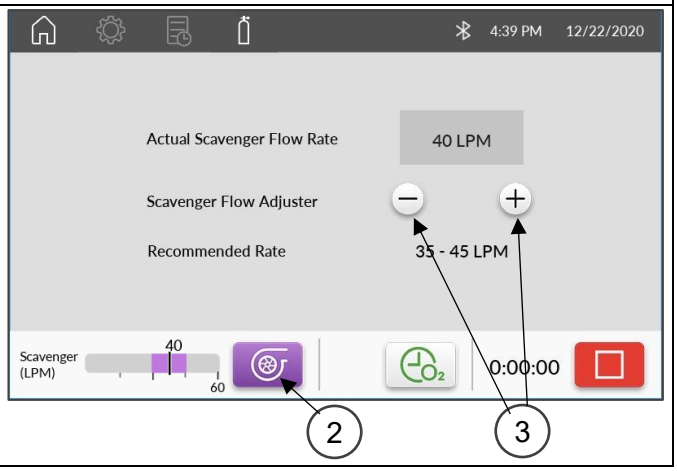
3.2.3. Date and Time Settings Configuration

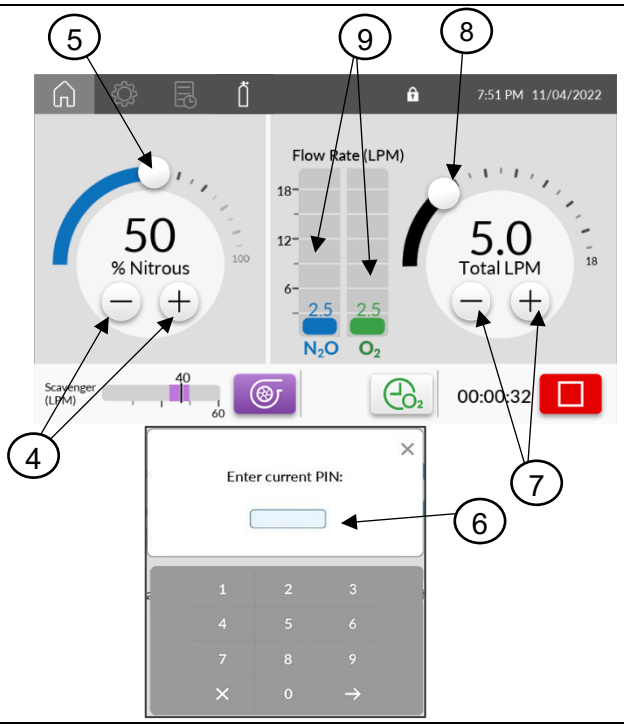
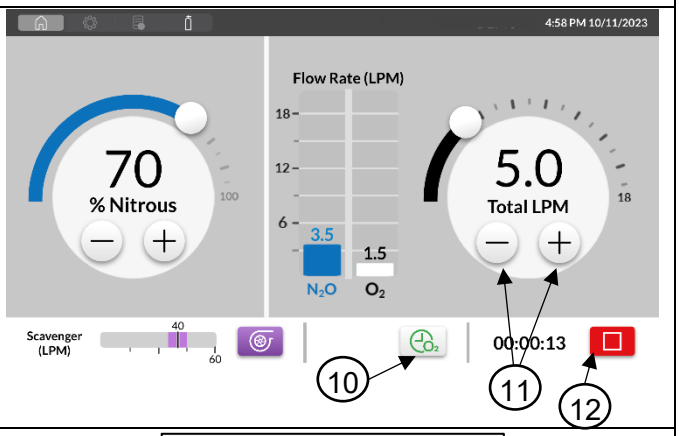
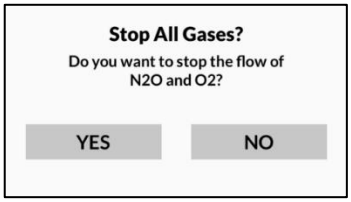
1	Press the **Settings** button. The Settings screen appears, push Time and Date to displaying the Time and Date section.	
2	Press **Time and Date** (1).	
3	Select the **date format** (2).	
4	Enter the **current date** (3).	
5	Select the **time format** (4).	
6	Enter the **current time** (5).	
7	Select **AM/PM** (6) (If applicable).	

3.3. Operating Instructions for Flowmeter

WARNING: To reduce the risk of electrical shock or electromagnetic interference:

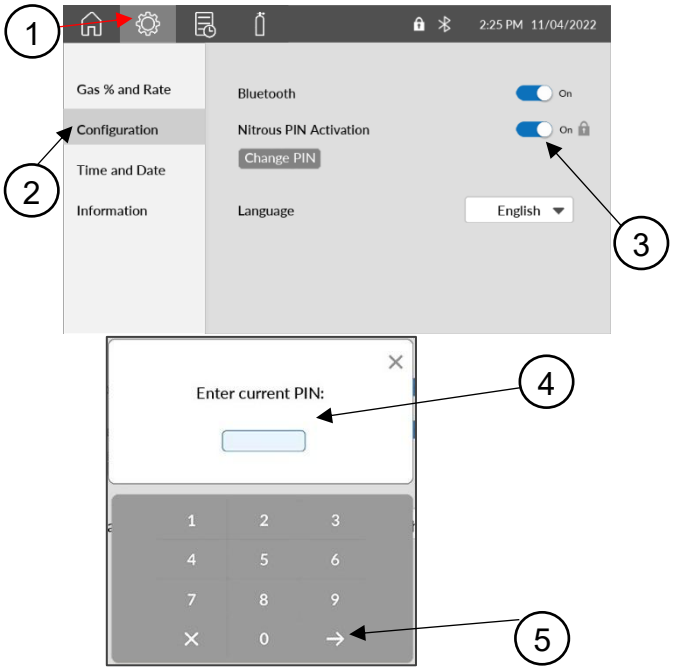
- The unit must be grounded.
- Do not use a damaged electrical cord.
- Do not use the device with an extension cord.

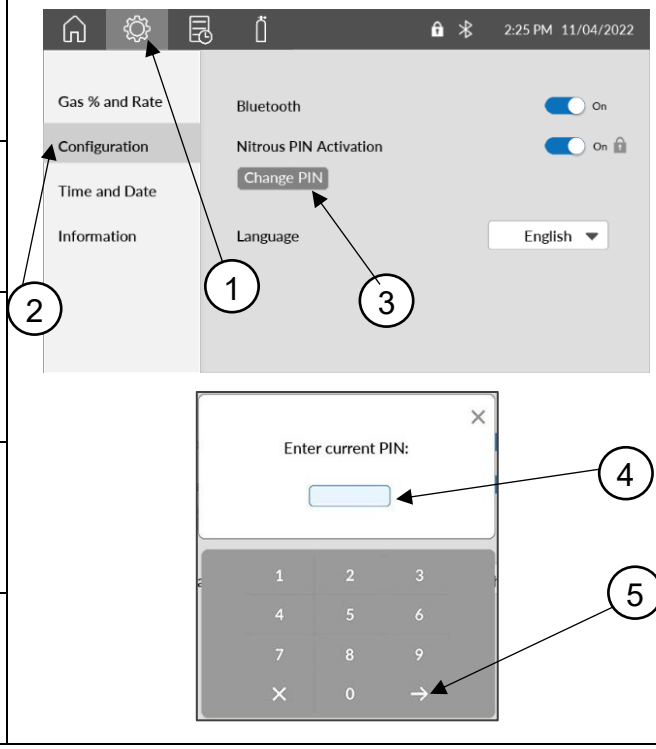
1	Press the power button and hold for 0.5 seconds to power the device **ON**.	
2	Place breathing circuit on the patient per the instructions provided with the circuit.	
3	Press the **Start** button for 1 second. **Note:** this button will convert to the **Stop** button.	
4	The flow of **100% O_2** (1) begins at the pre-configured **starting flow rate** (2).	
5	If using the eAVS: a) Press **Scavenger** button (2). The Scavenger screen appears. b) Press **+** or **–** buttons (3) to adjust flow rate in eAVS. The current flow rate is displayed on the screen. **Note:** Keep the flow rate within the Recommended Rate range shown on the screen.	

6	From the touchscreen, press **+** or **–** buttons (4) to set the appropriate mixture percentage (% Oxygen or % Nitrous Oxide). Alternatively, press and drag the **Adjuster** (5) to set the mixture percentage. **Note:** If a PIN was set, enter the PIN to change the gas percentage (6).	
7	Press **+** or **–** buttons (7) to set the appropriate flow rate in liters per minute. Alternatively, press and drag the **Adjuster** (8) to set the flow rate.	
8	The Flow Rate (LPM) **N_2O and O_2 flow bars** (9) display the current flow rates.	
9	During the patient procedure, monitor (and adjust as necessary) gas mixture, flow rate, and scavenger flow rate.	
10	Press and hold **O_2 Recovery** button (10) for 1 second to terminate the flow of N_2O and deliver 100% O_2 at the current flow rate. After 5 minutes, the timer will blink and beep, and will beep every 1 minute thereafter. **Adjust O_2 flow rate** (11) as necessary.	
11	Press and hold **Stop** button (12) for 1 seconds to terminate the flow of gas when the procedure is complete.	
12	**Note:** If Stop button is pressed and held 1 seconds while flowing N_2O and O_2, the user must acknowledge pop-up box to stop mixed gas flow or continue the flow.	
13	If needed, press and hold **O_2 Flush** button (14) to administer 100% O_2 to the patient. Once this button is released, the N_2O/ O_2 gas returns to the previously set mixture.	
14	At the completion of the procedure, administer 100% O_2. Remove the breathing circuit from the patient and dispose or clean per circuit's instructions for use.	

15	Always turn O_2 and N_2O cylinders valves off (for cylinder gas supply configurations) **to avoid unintentionally depleting source gases**.	
16	At the end of the procedure or day (after the last patient), push the **Power button** (15)  for 1 seconds to power down the display	

3.4. PIN Configuration

Setting PIN		
1	Push **Setting** Button (1).	
2	Select **Configurations** (2).	
3	Turn on **Nitrous PIN Activation** (3).	
4	Enter a four-digit numeric **PIN** (4).	
5	Push the **save** button (5).	

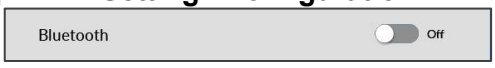
Changing PIN		
1	Push **Setting** Button (1).	
2	Select **Configurations** (2).	
3	Push **Change PIN** Button (3).	
4	Enter a four-digit numeric **PIN** (4).	
5	Push the **save** button (5).	

3.5. iPad Configuration and Instructions

Download, install, and configure the optional Porter Midas Remote Control (Porter Midas App) to control and monitor the Flowmeter. The app runs on a user-provided, Bluetooth-enabled Apple iPad only, iPadOS 17 or later. The app is available from the Apple App Store through the provided QR code located on the warranty card. If QR code is not provided, please call Porter Customer Service for assistance. The app must be installed prior to use. It is the user's responsibility to keep the app software up to date.

WARNING: The following warning applies when the Porter Midas Remote Control App on an iPad is in use during a patient procedure:

- Do not charge the iPad.
- Do not place iPad on patient.

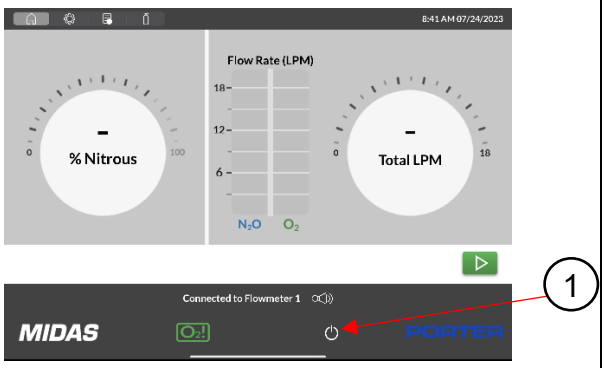
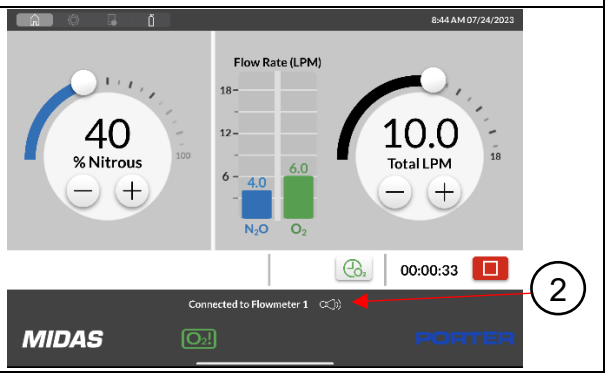
iPad Pairing Process	
1	Connect the iPad to Wi-Fi under **Settings** / **Wi-Fi**.
2	Scan QR Code provided on the warranty card.
3	Download the **Porter Midas Remote Control** app.
4	From the iPad, ensure the Bluetooth (BLE 5.2) radio is on by swiping down from the upper right corner. Confirm Bluetooth radio is on. Swipe in the opposite direction to close.
5	From the Midas Flowmeter display, open the **Setting / Configuration** screen. Tap the **Bluetooth** button to turn on the Bluetooth radio.  The Flowmeter will display a pairing dialog box with a six-digit pairing key.
6	From the iPad, open the app. Go to **Setting** / **Bluetooth Setup** and tap **Add New Device**.

iPad Pairing Process		
7	Tap the **ADD** button next to the Midas Flowmeter name that is displayed in the pairing dialog box on the Flowmeter.	
8	Enter the pairing key displayed on the Flowmeter.	
9	Tap the **Pair** button to pair the iPad and Flowmeter.	
10	To optionally set the name of the Flowmeter, tap the **Set Name** button, enter a unique name, and tap **OK** and **OK** again. The name must be at least 3 and up to 12 characters in length and cannot begin or end with a space.	
11	To confirm pairing, go to **Home** and tap the **horn** icon. A brief tone from the Flowmeter will confirm pairing with a popup box showing connection to iPad.	
12	The time/date on the flowmeter can be synchronized with the time/date on the iPad by going to **Setting** / **Time and Date** and tap **Sync with tablet**.	
13	To set time and date manual refer to **Section 3.2.3. Date and Time Settings Configuration**	

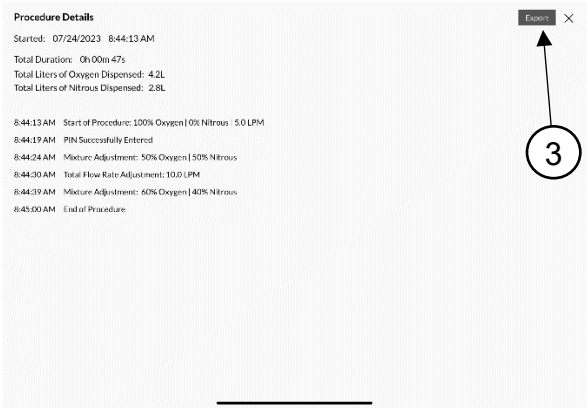
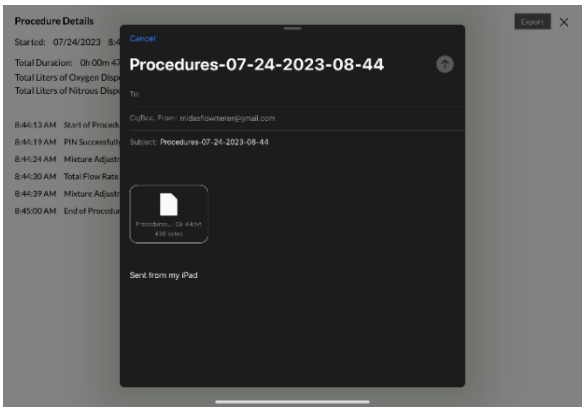
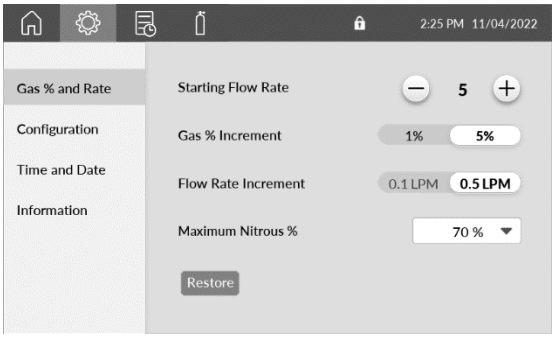
3.6. iPad Screen Controls

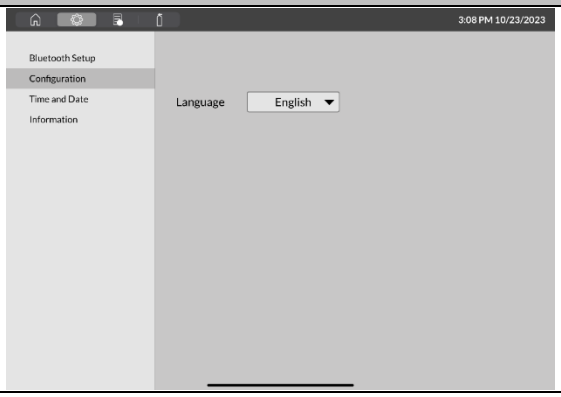
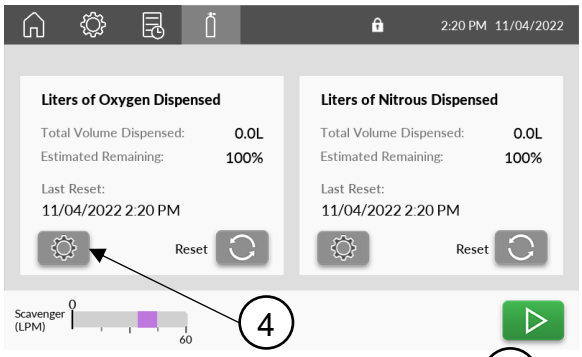
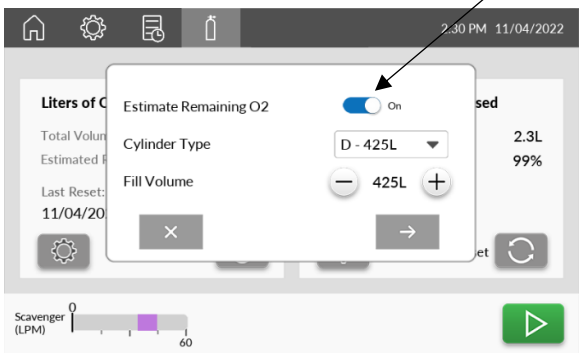
Porter Midas Remote Control Application (Porter Midas App) mirrors the Midas touchscreen flowmeter with the following functions: setting starting flow rate, setting gas percent increments, setting flowrate increments, setting maximum nitrous present. The Porter Midas App is connected via Bluetooth connection (BLE 5.2) and may have range restriction; a notification will appear if the Midas Flowmeter and Bluetooth connection is lost. The Porter Remote App is available from the App Store® and must be installed prior to use. It is the user's responsibility to keep the app software up to date, refer to **Section 4.4 Frequently Asked Questions** for how to update the remote app.

When setting the percentage and mixture rates for a procedure through the Porter Midas App, Parker recommends being present within the room to monitor the patient.

Differences from Flowmeter Screen and iPad Screen		
1	**Powering the Flowmeter:** The Porter Midas App has the ability to power the connected Midas Flowmeter on and off with a power button (1) at the bottom of the screen.	
2	**Powering the Flowmeter:** When a procedure is started, the power button disappears.	
3	**Connection Horn:** The Porter Midas App has a **horn button** (2) that can be used to generate an audible sound from connected flowmeter.	

Differences from Flowmeter Screen and iPad Screen

4	**Log Screen Export:** The Log Screen within the Porter Midas App has an **Export Button** (3) to allow logs to be sent to an email address. **NOTE**: Email must be set up on iPad through the mailing app to export logs.	 
5	**Gas % and Rate Settings** The Gas % and Rate Setting screen is only available on the Midas Flowmeter. The following settings can only be set on the flowmeter: • Starting Flow Rate • Gas % Increment • Flow Rate Increment • Maximum N2O %	**FLOWMETER SCREEN**  **PORTER MIDAS REMOTE APP SCREEN**

Differences from Flowmeter Screen and iPad Screen		
		
6	**Liters Dispensed / Gas Remaining Settings** (4) The Gas Remaining Setting Screen is only available on the Midas Flowmeter. (5) The option to turn gas remaining ON is only on the Midas Flowmeter. **Note**: Resetting the gas dispensed is available on the Midas Flowmeter and Porter Midas App.	**FLOWMETER SCREEN**  **FLOWMETER SCREEN** 5 

3.7. Bluetooth Connectivity and Compatibility

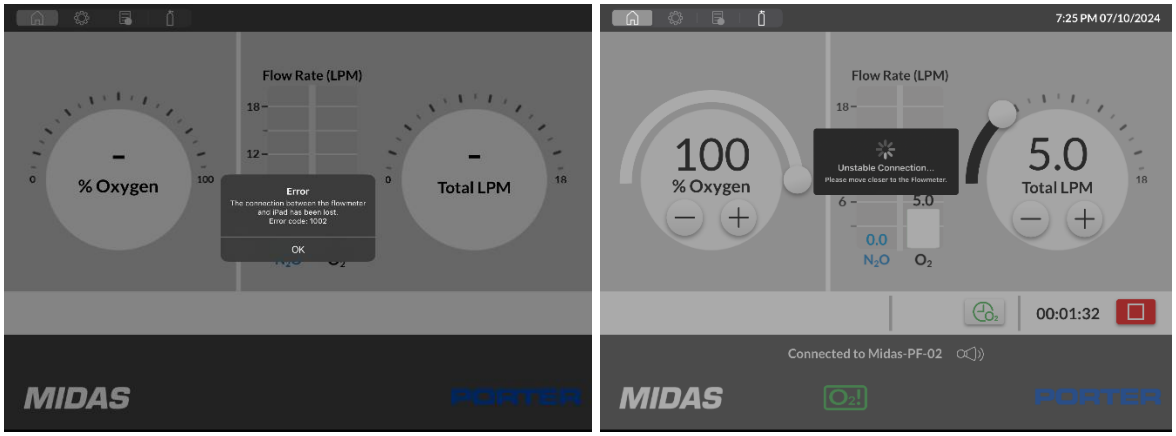
The Midas Flowmeter uses Bluetooth Low Energy (BLE) Version 5.2 to communicate with the Porter Midas Remote App on an Apple iPad. The Porter Midas Remote App can be used to provide a secondary display and set of controls but is not required to run the Midas Flowmeter.

The Midas Flowmeter should be configured and operated with the Porter Midas Remote App as described above in **Section 3.5, iPad Configuration and Instructions**. Specifications of the Bluetooth system are provided in the table below.

Version Bluetooth Low Energy V5.2	**Frequency** 2.45 GHz DSSS, 2 MHz channel spacing
Transmit Power -11 to +5 dBM	**Security** AES-128 encryption and decryption

When administering N_2O using the Midas Flowmeter and the Porter Midas Remote App, it is recommended to remain in the same room as the patient to avoid loss of Bluetooth Connectivity. It is recommended to keep the Midas Flowmeter and iPad within five (5) meters of each other. If Bluetooth connectivity is lost, the Porter Midas Remote App will notify the user, and will reconnect automatically when the iPad is moved back within range (images provided below). The Midas Flowmeter monitors a received signal strength indicator (RSSI) and notifies the user when the BLE signal goes out of range and the link is lost. The Midas Flowmeter will automatically restore the communication link when signal strength is of sufficient amplitude. It will notify the user that the BLE link is active, and the iPad will display the present state of the flowmeter, mirroring the main set of controls.

The Midas Flowmeter will maintain its operating state in the event of Bluetooth communication loss. If a procedure or oxygen recovery is underway, the flowmeter will continue to operate regardless of the state of the Bluetooth connection. As always, the flowmeter touchscreen display will show the status and offer a set of controls to run the flowmeter.



Bluetooth Communication Error

The Midas Flowmeter is designed such that anything that might disrupt Bluetooth communications, either accidental or malicious, will not affect basic safety, essential performance, or intended use of the medical device.

4. Maintenance

The Midas Flowmeter and optional eAVS have an expected lifetime of at least 10 years with proper maintenance. The Midas Flowmeter and optional eAVS require proper maintenance, pre-checks, and servicing. It is recommended to return the device to the manufacturer for servicing every 2 years. Following 10 years, the devices may need additional servicing and/or component replacement. A failed pre-check may require servicing from the manufacturer, please refer to Section 4.1. A start-up notification during Onboard Diagnostics may require servicing from the manufacturer, please refer to Section 4.3.

For instructions on proper disposal of devices that are beyond their useful life, see section 4.5 of this document.

Check	Frequency
Inspect Midas Flowmeter, hoses, fittings, and connections for damage and wear that may have, or could lead to leaks.	Before every use
Failsafe Failure Check	Daily
N2O Failure Check	Daily
Indicated Flow Delivery Test	Daily
Indicated Percentage (%) Delivery Test	Daily
O2 Flush Test	Daily
eAVS Check	Daily
Non-Rebreathing Valve Test	Once a month

Emergency Air Intake Valve	Once a month

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

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

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

4.1. Pre-Check

Note: To perform these tests, gas supply cylinders or gas supply shutoff valves are required in order to isolate the gas supply from the device. Attempting to perform these tests with central pipeline supplied gas without a local shut off mechanism is not recommended.

Failsafe Failure Check – Confirms N_2O flow stops when O_2 is not flowing and notification for no O_2 flow.

1	Turn the Midas Flowmeter On
2	Press and hold Start button for 1 second
3	Turn the percent mixture to 50%
4	Turn off O_2 gas supply to the flowmeter by one of the following options: • Close valve on O_2 gas cylinder • Close shutoff valve in O_2 gas supply line
5	When the gas runs out, observe the following: • O_2 Delivery Failure notification is displayed • N_2O flow shuts off • Audible alert sounds
6	Turn on O_2 gas supply. The flowmeter must return to normal operation. The alert may continue to chime for up to 5 seconds after restoration of gas pressure.
7	If the displays do not show the correct information or the alert does not sound, contact your authorized distributor for service and troubleshooting.

N_2O Failure Check – Confirms notification for no N_2O flow.

1	Turn the Midas Flowmeter On
2	Press and hold Start button for 1 second
3	Turn the percent mixture to 70% N_2O or 30% O_2 (model dependent)
4	Turn off N_2O gas supply to the flowmeter.
5	When the gas runs out, observe the following: • N_2O Delivery Failure notification is displayed • Audible alert sounds • 100% O_2 Flow at current total flow rate
6	Turn on N_2O gas supply. The flowmeter must return to normal operation. The alert may continue to chime for up to 5 seconds after restoration of gas pressure.
7	If the displays do not show the correct information or the alert does not sound, contact your authorized distributor for service and troubleshooting.

Indicated Flow Delivery Test – Confirms minimum 1 LPM O_2 flow.

1	Turn the Midas Flowmeter On
2	Press and hold Start button for 1 second
3	Turn the percent mixture to 100% O_2
4	Press and drag the total flow button to decrease the flow rate to 1.0 LPM, the total flow button should not allow you to drag below 1 LPM.
5	The Total Flow box should display a notification that the minimum total flow rate is 1.0 LPM
6	If the displays do not show the correct information, contact your authorized distributor for service and troubleshooting.

Indicated Percentage (%) Delivery Test – Confirms maximum N_2O percentage or minimum O_2 percentage based on model/configuration.

1	Turn the Midas Flowmeter On and review the gas % and rate setting for the maximum N_2O or O_2 minimum percentage
2	Press and hold Start button for 1 second
3	a) If N_2O control, Press and drag the percent mixture button to the upper limit allowed; the percent mixture button should not allow you to set the percentage above the upper limit. b) If O_2 control, Press and drag the percent mixture button to the lower limit allowed; the percent mixture button should not allow you to set the percentage below the lower limit.
4	The Percent Mixture box should display a notification of what the maximum/minimum percentage is allowed
5	If the displays do not show the correct information, contact your authorized distributor for service and troubleshooting.

O_2 Flush Test – Confirms O_2 flush functionality.

1	Turn the Midas Flowmeter On
2	Press and hold **O_2 Flush Button**.
3	Observe that the breathing bag quickly inflates.
4	If the breathing bag does not inflate quickly, contact your authorized distributor for service and troubleshooting.

eAVS Check – Confirms scavenger functionality.

1	Ensure the eAVS is connected to a vacuum source.
2	Ensure there is no vacuum hose connected from the mask port on the eAVS Refer to **Section 2.2 Connecting the Vacuum Controller** to identify mask port.
3	Turn the Midas Flowmeter On
4	Press and hold Start button for 1 second
5	Create a seal by placing your hand over the mask port on the eAVS, you should feel suction on your hand
6	If you feel no suction on your hand, contact your authorized distributor for service and troubleshooting

Non-Rebreathing Valve Test – Confirms patient exhalation can not enter the bag tee.

1	Turn the flowmeter off by pressing the **On/Off Button**.
2	Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of Breathing Circuit. Refer to **Section 1.3.1.Device User Interface** to identify bag tee and features.

3	Blow into the inhalation line of a test breathing circuit, the breathing bag should not inflate.
4	If breathing bag inflates, contact your authorized distributor for service and troubleshooting.

Emergency Air Intake Valve Test – Confirms room air can enter breathing pathway if gas supply is insufficient.

1	Turn the flowmeter off by pressing the **On/Off Button**.
2	Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of breathing circuit. Refer to **Section 1.3.1.Device User Interface** to identify bag tee and features.
3	Remove the breathing bag from the bag tee and create a seal by placing hand over the bag port on the bag tee.
4	Inhale through a test breathing circuit. With the breathing bag capped or empty the air intake valve should open allowing you to breathe in room air.
5	If you can not breathe in room air, contact your authorized distributor for service and troubleshooting.

4.2. Cleaning

The Midas Flowmeter and optional eAVS must be cleaned between each use in order to prevent the spread of infections. Cleaning the device has been validated with Super Sani-Cloth™ Germicidal wipes.

WARNING: The following warning applies to the device and any device's components and accessories:

- Do not spray directly with disinfecting chemicals.
- Do not immerse in water, sanitizer, cleaning solution, or any other liquid.
- Do not sanitize or wipe the inside of the fittings, gas supply hoses, or connection ports.
- Always ensure the device and device's components and accessories are completely dry before use.

1	Disconnect and dispose of any single use breathing circuit and/or single use nasal hood (if attached). For cleaning instructions of re-useable breathing circuit and/or nasal hood refer to breathing circuit Instructions for Use.
2	Using a Super Sani-Cloth™ Germicidal wipe, or equivalent, thoroughly wipe down the Midas Flowmeter until all visible dirt and soil is removed. Take extra care to wipe the entire display interface as this is the most handled area of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove. Note: If using bag tee and/or eAVS, ensure to follow the same procedure to cleaning these accessories.
3	Using a Super Sani-Cloth™ Germicidal wipe, or equivalent, thoroughly wipe down the gas supply hoses and fittings until all visible dirt and soil is removed. Do not wipe the inside of the hoses or fittings as this may deposit cleaning agents into the breathing pathway of the device.
4	Dampen a lint free cloth with tap water and wipe cleaning residue off Midas Touchscreen after the allotted contact time.
5	The **bag port**, **breathing circuit port**, and **emergency air intake valve** should not be exposed to the cleaners or wiped to prevent moisture from entering the device. Avoid wiping and applying cleaner to the inside of the ports and the valve.

4.3. Troubleshooting: Notifications and Alerts

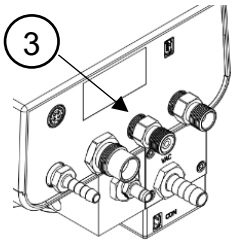
Notification	Description	Recommended Action
Nitrous Delivery Failure	Unable to provide the requested flow of N_2O	1. Verify N_2O supply is turned on. 2. Verify adequate supply of N_2O. 3. Switch tanks if necessary. 4. If notification remains, contact distributor.

Notification	Description	Recommended Action
Oxygen Delivery Failure	Unable to provide the requested flow of O_2.	1. Verify O_2 supply is turned on. 2. Verify adequate supply of O_2. 3. Switch tanks if necessary. 4. If notification remains, contact distributor.
Nitrous Valve Leak	Nitrous Oxide valve failed to fully close	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Oxygen Valve Leak	Oxygen valve failed to fully close	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Nitrous Sensor Fault	Unable to communicate with N_2O sensor	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Oxygen Sensor Fault	Unable to communicate with O_2 sensor	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Display Communication Failure	Unable to communicate with the Display	For remote configuration: 1. Verify cable is connected between Flowmeter and display. 2. If notification remains, discontinue use of device and contact distributor. If this is NOT a remote configuration: 1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Memory Error	Firmware or configuration memory is corrupted	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Application Corrupted	Display software is corrupted or unable to run	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Low O_2 Flush Flow	O_2 Flush flow rate is below 19.5 LPM.	1. Check O_2 supply and replace gas cylinder as necessary. 2. If notification remains, Contact distributor.
Scavenger Communication Failure	Flowmeter is unable to communicate with the scavenger.	1. Verify communication cable is connected between Flowmeter and eAVS. 2. If communication cable is connected and warning is still present, contact distributor.
Scavenger Sensor Fault	Scavenger is unable to read its sensor.	1. Contact distributor for service or replacement of eAVS.
Scavenger Leak	Flow through scavenger is detected when scavenging is stopped. Scavenger valve failed to fully close.	1. Contact distributor for service or replacement of eAVS.
Scavenger Failure	Scavenging is turned on but no flow / reduced flow is detected.	1. Increase scavenger flow rate. 2. Check vacuum source pressure. 3. Replace mask fitting/filter assembly. (P/N: B-5816-000 Filter Assy, eAVS, Mask Port) 4. If notification remains, contact distributor to replace eAVS.

Alert	Description	Recommended Action
Bluetooth Failure –Bluetooth Disabled	Unable to communicate with Bluetooth controller.	1. Check Bluetooth configuration and reconnect.

Alert	Description	Recommended Action
Memory Error Detected – Configuration settings have been restored to default	User configuration settings were corrupted. Default values have been restored.	1. Update configurations as necessary.
Memory Error Detected – Language has been restored to default	Language support files are corrupted. Reverted to English.	1. Reconfigure language as necessary.
Bluetooth Update Failed	Bluetooth Firmware update was unsuccessful.	Device functions as expected without Bluetooth capabilities.
Event Log Corruption Detected – Log cleared	Event log cleared.	No user action required.
Fault Log Corruption Detected – Log cleared	Notification log cleared.	No user action required.
Procedure Logs Corruption Detected – All procedure logs cleared	Procedure log cleared.	No user action required.
Partial Procedure Logs Corruption – Some procedure logs lost	One or more Procedure log records cleared.	No user action required.
Non-Critical Data Corruption Detected	Run-time data or statistics cleared.	No user action required.
Full File System Reformatting	File system within the flowmeter has been reformatted.	1. Turn off O_2 and N_2O supply. 2. Discontinue use of device. 3. Contact distributor.
Factory Setting Reset	Settings have reset to factory parameters. Starting Flow rate set to 5 LPM, Gas % Increment set to 5%, Flow rate increment set to 0.5 LPM, Maximum Nitrous % set to highest value of configuration	Device functions as expected. If problem persist, contact distributor.
Gas flow settings have been restored to default	Starting Flow rate set to 5 LPM, Gas % Increment set to 5%, Flow rate increment set to 0.5 LPM, Maximum Nitrous % set to highest value of configuration	No user action is required.

4.4. Frequently Asked Questions (FAQs)

Question	Answer
1. How do I turn the Flowmeter on and off?	Press the power button and hold for 0.5 seconds to power the device **ON**. Press the power button and hold for 2 seconds to power the device **OFF**. 
2. How do I turn off a Notification or Alert?	**Notification** will appear as an orange banner along with an audible beep. The beep may be muted. The orange bar will remain until the notification is corrected. **Alert** will appear within a message box with an **OK** button.
3. I have forgotten my PIN. How do I reset it?	Contact Porter Customer Service.
4. What is the difference between O_2 Recovery, O_2 Flush, and Emergency O_2?  1  2  3	**O_2 Recovery** (1) is used at the end of the procedure to allow the patient to recover after the procedure is completed. **O_2 Flush** (2) may be used during a procedure if the patient needs to breath 100% O_2 and not the gas mixture. **Emergency O_2** (3) is providing the patient with O2 gas from the tank supply.
5. What components are cleaned with what disinfected, and when?	Refer to Section 4.2. Cleaning.
6. Am I able to export the procedure details/log?	With the use of an iPad, procedures may be exported.

Question	Answer
	Refer to Section 3.6. Different from Flowmeter Screen and iPad Screen
7. Am I able to monitor the amount of gas used (defaulted off)	Yes, refer to Section 1.3.6. Gas Remaining Screen User Interface, to turn on.
8. How do I update the Porter Midas Remote App when a new version is released?	The App updated will be sent through the Apple App Store.  • If the iPad is set to “automatic updates” the app will updated automatically when needed. • If the iPad is not set to “automatic updates” the user will need to open the Apple App Store App and click on the account setting in the top right corner showing an app update is available. The press the Update Button for the Midas App.

4.5. Disposal



At end of life or as needed, the device and its electrical/electronic components should be recycled or disposed of according to local and national regulations and separate from municipal waste. Alternatively, the device and its electrical/electronic components may be returned to Parker / Porter for recycling.

5. Material Residual Risks

The device contains lead, cobalt, nickel, hexavalent chromium, chloroprene, and nickel hydroxide which were identified as CMR/EDC and believed to exceed the 0.1% weight-by-weight threshold requirements of REACH and Section 10.4 of the EU MDR 2017/745.

The residual risks posed by the presence of these substances in the device are low and do not impact the overall safe use of the device. No measures need to be taken by the end user to ensure patient safety regarding use of the device containing these substances.

The potential for exposure to these substances are limited to contact of gases with alloy components (such as aluminum and brass) containing these substances. Patient exposure requires that the substances produce volatile organic compounds, aldehydes, or particulate matter. Extensive biocompatibility testing has been conducted that has demonstrated the use of the materials of construction are unlikely to result in a toxicological effect. In addition, patient exposure is considered to be limited duration given the infrequent use and application intervals that are expected to be long relative to the elimination time of any leachable toxins from the body.

6. Electromagnetic Compatibility Information

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas, however, not including cell phones) should be used no closer than 2 meters to any part of the Midas Flowmeter and eAVS. Otherwise, the performance of the device may be degraded as a result.

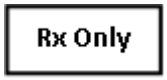
During worst case electromagnetic (EM) disturbances, the Midas Flowmeter may experience a corrupted or absent reading of an O_2 or N_2O flow sensor or a false trigger on a capacitive touch sensor, resulting in a shutdown. The Midas Flowmeter and eAVS prioritize basic safety and essential performance and will shut down the flowmeter if standard flowmeter operations are corrupted. A power cycle may be necessary to restore normal operation.

The below table provides compliance levels for emission and immunity testing for the Midas Flowmeter and eAVS. There were no deviations required to comply with the IEC 60601-1-2 standard.

Compliance Level for Midas Flowmeter and eAVS Emission and Immunity Testing to IEC 60601-1-2:2014 / AMD1 2020					
Test	**Standard**	**Emission Class**	**Group**	**Immunity Test Level**	**Result**
Conducted Emissions	CISPR 11	Class B	Group 1	N/A	Pass
Radiated Emission	CISPR 11	Class B	Group 1	N/A	Pass
Harmonic Current Emissions	IEC 61000-3-2	Class D	N/A	N/A	Pass
Voltage Fluctuation and Flicker	IEC 61000-3-3	Class B	N/A	N/A	Pass
Electrostatic Discharge	IEC 61000-4-2	N/A	N/A	+/- 15.0 kV	Pass
Radiated Immunity	IEC 61000-4-3	N/A	N/A	3-28 V/m	Pass
Electrical Fast Transient/Burst, Power Ports	IEC 61000-4-4	N/A	N/A	+/- 2.0 kV	Pass
Electrical Fast Transient/Burst, I/O Ports	IEC 61000-4-4	N/A	N/A	+/- 1.0 kV	Pass
Surge Immunity, Power Ports	IEC 61000-4-5	N/A	N/A	1.0 kV diff, 2.0 kV CM	Pass
Conducted Immunity, Power Ports	IEC 61000-4-6	N/A	N/A	3-6 Vrms	Pass
Conducted Immunity, I/O Ports	IEC 61000-4-6	N/A	N/A	3-6 Vrms	Pass
Magnetic Immunity	IEC 61000-4-8	N/A	N/A	30 A/m 50 Hz	Pass
Voltage Dips, Interrupts and Variations	IEC 61000-4-11	N/A	N/A	0.5s 30% dips, 5s 0V	Pass
Radiated Fields in Close Proximity Magnetic Fields, 10 kHz to 150 kHz	IEC 61000-4-39	N/A	N/A	65 A/m	Pass
Radiated Fields in Close Proximity Magnetic Fields, 150 kHz to 25 MHz	IEC 61000-4-39	N/A	N/A	7.5 A/m	Pass

7. 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]
	**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]

Symbol	Title of Symbol	Description of Symbol
	**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]
	**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. [EN ISO 15223-1:2021, clause 5.4.4]
	**Authorized Representative in the European Community**	Indicates the authorized representative in the European Community/ European Union [ISO 15223-1, Clause 5.1.2]
	**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]
	**Authorized Representative in Switzerland**	Indicates the authorized representative in the Switzerland [MU600_00_016, Section 3]
	**Protective Conductor Terminal**	Indicates that the product includes a terminal bonded to conductive parts for safety purposes and is intended to be connected to an external protective earthing system. [IEC60601-1: 2006 +A2:2021, clause 3.95, Symbol table D1 number 6 (Symbol also IEC60417-5019)]
	**Disposal of WEEE**	Indicates that the device may require separate municipal waste collection. [2012/19 EU, Article 14(4) Annex IX (Symbol also IEC60417-6414)]
	**Fragile, Handle with Care**	Indicates a medical device that can be broken or damaged if not handled carefully. [ISO 15223-1, Clause 5.3.1]
	**Follow Instructions for Use**	Indicates when the user should refer to the instructions for use manual/booklet for important information. [ISO 60601-1, Table D.2, No. 10]
	**Keep Dry**	Indicates a medical device that needs to be protected from moisture. [ISO 15223-1, Clause 5.3.4]
	**Non-ionizing electromagnetic radiation**	Indicates equipment or systems that include RF transmitters or apply RF electromagnetic energy for diagnosis or treatment. [ISO 60417]
	**Temperature Limits**	Indicates the upper and lower temperature limits to which the medical device can be safely exposed. [ISO 15223-1, Clause 5.3.7]
	**Electrical Shock / Electrocution**	Indicates the components has risk of electric shock. [ISO 60601-1, Table D.2, No. 3]
	**Disassembly Prohibition**	Indicate a risk of injury, such as electric shock, if the equipment is disassembled.
	**Type B Applied Part**	Indicate a medical device has a type B applied part (Connection for Breathing Circuit Connections). [IEC 60601-1, Table D.2, No. 19]

Symbol	Title of Symbol	Description of Symbol
⎓	**Direct Current**	Indicate a medical device has direct current (current flows in one direction). Power connection to the medical device input is for the direct current from the external power supply. [IEC 60601-1, Table D.2, No. 4]

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