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Porter Midas[™] Flowmeter and eAVS Instructions for Use and Installation Guide



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: <u>www.P65Warnings.ca.gov</u>

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

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

1. Device Information

1.1. Intended Use

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 (N₂O), and gas flow control. Dependent on model number the Flowmeter is factory configured to display N₂O or O₂ control. The factory configuration also determines the color of the percentage mixture control adjustment and the O₂ 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.

Model	Model Description (Remote)	Model	Model Description (Portable)
Number		Number	
6151	Midas Flowmeter Remote, 70% Max N ₂ O, White,	6051	Midas Flowmeter Portable, 70% Max N ₂ O,
0101	O ₂ -Control, Australia Fittings	0001	White, O ₂ -Control, Australia Fittings
6181	Midas Flowmeter Remote, 70% Max N ₂ O, White,	6081	Midas Flowmeter Portable, 70% Max N ₂ O,
	N ₂ O Control, Australia Fittings		White, N ₂ O Control, Australia Fittings
6142	Midas Flowmeter Remote, 60% Max N ₂ O, White,	6042	Midas Flowmeter Portable, 60% Max N ₂ O,
0142	O ₂ Control, Swedish Fittings	0042	White, O ₂ -Control, Swedish Fittings
6172	Midas Flowmeter Remote, 60% Max N ₂ O, White,	6072	Midas Flowmeter Portable, 60% Max N ₂ O,
0172	N ₂ O Control, Swedish Fittings	0072	White, N ₂ O Control, Swedish Fittings
	Midas Flowmeter Remote, 70% Max N ₂ O, Green,	6020	Midas Flowmeter Portable, 70% Max N ₂ O,
6120	N ₂ O Control	6020	Green, N₂O Control
	Midas Flowmeter Remote, 50% Max N ₂ O, White,		Midas Flowmeter Portable, 50% Max N ₂ O,
6130	O ₂ Control	6030	White, O ₂ Control
	Midas Flowmeter Remote, 60% Max N ₂ O, White,		Midas Flowmeter Portable, 60% Max N ₂ O,
6140	O ₂ Control	6040	White, O ₂ Control
	Midas Flowmeter Remote, 70% Max N ₂ O, White,		Midas Flowmeter Portable, 70% Max N ₂ O,
6150	O ₂ Control	6050	White, O ₂ Control
	Midas Flowmeter Remote, 50% Max N ₂ O, White,		Midas Flowmeter Portable, 50% Max N ₂ O,
6160	N ₂ O Control	6060	White, N ₂ O Control
	Midas Flowmeter Remote, 60% Max N ₂ O, White,		Midas Flowmeter Portable, 60% Max N ₂ O,
6170	N ₂ O Control	6070	White, N ₂ O Control
	Midas Flowmeter Remote, 70% Max N ₂ O, White,		Midas Flowmeter Portable, 70% Max N ₂ O,
6180	N ₂ O Control	6080	White, N ₂ O Control
All flowmeter models are available with eAVS included by adding "-EAVS" to the Model Number.			

Device Model Table

Accessories Model Table

Accessories	Part Number	Part Description	
Electronic Automatic Vacuum Switch	EAVS-5000	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	
Cabinat Maunta	2036-M	Midas, Under Counter Mounts	
Cabinet Mounts	2037-M	Midas, Left or Right Slide Brackets	
Handle Bracket	HANDLE-M	Midas, Wall Mount Bracket Handles	
Mobile Stands	2040	Mobile Stand, Compact	
2-Cylinder Mobile Carts	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
	2100-ISO-2	2-Cylinder Mobile Cart with Regulator O2, Regulator
		N2O, and Gas Supply Hoses
	2100-ISO-N	2-Cylinder Mobile Cart with Regulator, N2O, and Gas
		Supply Hose
	2045-3	E-Stand, Tall
E-Stands	2045-3CA	E-Stand, White Hose
	2045-3ISO	E-Stand, Tall with Gas Supply Hoses
Breathing Circuits	5155-X*	Porter Breathing Circuit
	915151XX*	Matrx Breathing Circuit
	SIL2-XXX-XXX*	Silhouette Breathing Circuit
Supply Hose	800X*	O2 DISS/DISS Hose
	850X*	N ₂ O DISS/DISS Hose
Breathing Bag	4100-3NL	3 Liter Breathing Bag
(If required)	4100-2NL	2 Liter Breathing Bag
	SIL-ADPT-PKG	Silhouette Adapter Package

*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.



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	Front View
1	Flowmeter Touchscreen	
2	eAVS	
3	Bag Tee	
4	Power Button	
5	O ₂ Flush Button	
6	Vacuum Source Connection	7 Bottom View 8
7	Breathing Circuit Vacuum Connection	
8	Breathing Circuit Fresh Gas Connection	
9	Breathing Bag Connection	
10	Emergency Air Intake Valve	
11	Mounting Hole Connection	
12	Fresh Gas Connection	

1.3.2. Touchscreen User Interface

#	Description	(2) (3) (4) (5)
1	Start Procedure Button	
2	Home Screen Button	458PM 10/11/2023
3	Settings Button	18- 18- 18-
4	Logs Button	⁰ % Nitrous ¹⁰⁰ ⁶ Total LPM ¹⁸
5	Liters Dispensed/Gas Remaining Button	N ₂ O O ₂
6	O ₂ or N ₂ O percentage mixture control (model dependent)	Scavenger (LPM)
7	Total Flow Setpoint (Liters Per Minute)	
8	Stop Button	G
9	O ₂ Recovery	Filev Rate (LPM)
10	Scavenger Control	50 % Nitrous 6- 5.0 Total LPM
11	Measured Scavenger Flow Rate	
12	Measured N ₂ O Flow Rate	Scavenger 40 60 00:00:32
13	Measured O ₂ Flow Rate	

1.3.3. Setting Screen User Interface

#	Description	1 (1) (1a)
1	Gas % and Rate a. Starting Flow Rate (LPM) b. Gas % Increment c. Flow Rate Increment d. Maximum N ₂ O %	Gas % and Rate Configuration Time and Date Information Maximum Nitrous % Restore Configuration Configura
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	2 2 2 2 2 2 2 2 2 2 2 2 2 2
3	Time and Date a. Date b. Day/Month vs Month/Day c. Time d. 12-hour vs 24 hour e. AM vs PM	3 3 3 3 3 3 3 3 3 3 3 3 3 3
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.	4 4a Gas % and Rate Flowmeter Name Configuration Serial Number Model Number 001 Model Number 00001 Hardware Revision 01 Information Controller Firmware Display Software 0.24 Scavenger Firmware 0.0 4d) 4d)

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.	ProceduresSystemNotificationsDateTimeDuration11/4/20222.18.17 PM0h 0m 16sDetais11/4/20222.17.05 PM0h 1m 3sDetais11/4/20222.17.05 PM0h 1m 3sDetais11/3/20220.05.51 PM4h 14m 28sDetais11/3/20229.33.41 PM0h 0m 17sDetais11/3/20229.33.45 PM0h 1m 9sDetais11/3/20223.32.46 PM0h 0m 42sDetais11/3/20223.29.32 PM0h 0m 57sDetais11/3/20223.29.32 PM0h 0m 57sDetais11/3/20222.3.15 PMStates0h 0m 57s11/3/20222.3.15 PMStates0h 0m 57s11/3/20232.3.15 PM
2	System Log Note: System Log contains 50 entries. You can swipe up on the touchscreen to view additional entries.	Date Time Events 11/3/2022 9.32.15 PM Language Change: Spanish 11/3/2022 9.32.15 PM Language Change: Spanish 11/3/2022 9.31.58 PM Gas flow settings have been restored to default. 11/3/2022 9.31.58 PM Gas flow settings have been restored to default. 11/3/2022 8.56.19 PM Gas flow settings have been restored to default. 11/3/2022 8.56.19 PM Gas flow settings have been restored to default. 11/3/2022 8.56.19 PM Gas Percentage Increment Change: 5% 11/3/2022 8.56.19 PM Flow Rate Increment Value Change: 0.5 LPM 11/3/2022 3.36.11 PM PIN Function Disabled
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.	3 3 Procedure System V12/2022 442 01 PM Display Communication Failure Ceased V12/2022 442 01 PM Display Communication Failure Ceased V12/2022 443 01 PM Display Communication Failure Ceased V12/2022 443 01 PM Display Communication Failure Ceased V12/2022 33 54 APM Oxygen Flush Flow Ceased V12/2022 33 54 APM Oxygen Flush Flow Ceased V12/2022 33 54 APM Oxygen Flush Flow Ceased V12/2022 33 54 APM Oxygen Flow Rate Oxygen Flush Flow Ceased Ceased V12/2022 33 54 APM Oxygen Flow Rate Oxygen Flow Rate Oxygen Flow Rate

1.3.5. Scavenger Screen User Interface

#	Description	
1	Measured Scavenger Flow (LPM)	Actual Scavenger Flow 40LPM
2	Adjust Flow Buttons	Adjust Flow - + Recommended Rate 35 - 45 LPM
3	Recommended Range (purple zone) / Recommended Rate	Scavenger (LPM) 00:00:25

1.3.6. Liters Dispensed / Gas Remaining Screen User Interface

#	Description	
1	Liters of Oxygen Dispensed	Liters of Oxygen Dispensed
2	Liters of Nitrous Dispensed	A Total Volume Dispensed: 0.0L Total Volume Dispensed: 0.0L Estimated Remaining: 100% Estimated Remaining: 100%
3	Estimated Remaining (when active)	Last Reset 11/04/2022 2:20 PM Reset C Reset C Reset C
4	Reset	Scavenger $\begin{pmatrix} 0 \\ (LPM) \end{pmatrix}$ $\begin{pmatrix} 0 \\ 60 \end{pmatrix}$ $\begin{pmatrix} 0 \\ 5 \end{pmatrix}$ $\begin{pmatrix} 4 \end{pmatrix}$
5	Settings Button	7 6 0 1 2:30 PM 11/04/2022
6	Display Estimated Remaining Button	Liters of C Estimate Remaining O2 On Sed
7	Cylinder Type	Total Volun Estimated F Last Reset: 14/04/00 Fill Volume Cylinder Type Fill Volume Cylinder Cylinder Type Fill Volume Cylinder Cylinder Cyl
8	Fill Volume Adjustment	
9	Exit Setting Button	Scavenger (LPM) 60 (10)
10	Save Setting Button	(9)

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 userprovided, 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 (CO₂) buildup.

Emergency Air Intake Valve:

In the event that the O₂ 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 N₂O 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 (O₂). 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-protectionsipad9ae59af9/16.0/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 PB1711-000 (0.3M) Portable P/N PB1711-001 (3M) Remote Mounted (std) P/N PB1711-001 (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

 $(10^{\circ}\text{C} - 40^{\circ}\text{C})$

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)

<u>Weight</u>

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

Vacuum Source Characteristic:

Pressure Range: 10-21 in Hg (33.8-7.1 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: 9.20 in W x 8.06 in H x 8.70 in D (23.37 cm W x 20.47 cm H x 22.10 cm D)

Weight (Portable or Remote Mount):

Control Module: 3.03 lbs (1.37 kg) Touchscreen: 1.92 lbs (0.87kg) Bag Tee: 1.20 lbs (0.54kg) Mixture Settings

N₂O: 0%-(50%/60%/70%) (factory set) O₂: (30%/40%/50%)-100% (factory set) Adjustment Step Options: 1% or 5%

O₂Flow Bar Color Settings

Green or White (factory set) <u>Delivery Flow Rate</u> 1 – 18 LPM total flow Adjustment Steps: 0.1 to 0.5 LPM (options) O₂ Flush: 20 LPM (minimum) <u>Delivery Accuracy*</u> N₂O setpoints: Setpoints > 5 LPM \pm 0.5 LPM Setpoints \leq 5 LPM \pm 0.3 LPM

O2 setpoints:

Setpoints > 5 LPM \pm 0.5 LPM Setpoints \leq 5 LPM \pm 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) Gas Supply: **Connection Fittings:** O₂ Inlet: DISS 1240 (male thread) N₂O Inlet: DISS 1040A (male thread) O₂Outlet: DISS 1240 demand valve (male thread) Mixed Gas Outlet: .875 inches OD fitting Gas Supply Pressure: O₂: 40 – 75 psi (275.8 – 517.1 kPa)

N₂O: 40 – 75 psi (275.8 – 517.1 kPa)

Applied Parts Type

Туре В

Remote Operation:

Device for Remote Application: Apple iPad Only

iPadOS Version Required: iPadOS Version 17 or later

Environmental

 $\frac{\text{Temperature}}{\text{Storage/Transport: -30°F} - 140°F} (-34°C - 60°C)$ Operational: 50°F - 104°F
(10°C - 40°C)

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

<u>Atmospheric Pressure</u> 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. Compatible Vacuum Controllers



2.2. Connecting the Vacuum Controller

	eAVS		
1	Attach the vacuum hose from the breathing circuit to the MASK port (1) of the eAVS.	-	
	Attach vacuum hose to the back of the eAVS (2) and then to a vacuum source.		
2	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.		

	Porter In-Line Vacuum Control			
Wł Us	When using a Porter In-Line Vacuum Control, refer to FM-809 (Porter breathing circuit Instructions for Use and Installation Guide) for instructions.			
1	Attach hose from the breathing circuit to the mask port (1) of the In-Line Vacuum Control Block.	1		
2	Attach vacuum hose to the vacuum port (2) of the In- Line Vacuum Control Block and other end to vacuum source.	2		

2.3. Connecting the Bag Tee – For Remote Models Only

	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		
2	Attach the Fresh Gas Hose from the breathing circuit to the Breathing Circuit Port (2) of the Bag Tee.	3		
3	Attach the Breathing Bag to the Breathing Bag Port (3) of the Bag Tee.			

2.4. 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)				

2.5. Mounting the Midas Flowmeter

	Wall Mount Install			
1	Attach Wall Mount Arm to the wall.			
2	Place split lock washers (1) over studs and install handles (2).			
3	Remove the screws (3) holding the Bag Tee and Optional eAVS from Flowmeter, discard screws			
4	Attach Bag Tee and optional eAVS to Flowmeter with the plate (4) in between using the included screws.			
5	Thread mounting pin (5) into mounting hole on bottom of the Bag Tee (6) until tight, then tighten locking nut (7) to secure pin.			





2.6. Under Counter Installation – Remote Models Only





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 ₂ O 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.		
	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 Flowmeter) and the gas supply hoses are con (as described in Section 2.7 Connecting Su	s described in Section 2. Inected to the correct fittings pply Lines).	5 Mounting the Midas on the Midas Flowmeter
2	Ensure the necessary pre-checks have been pre-check instructions are described in Section	performed, before using the on 4.1 Prechecks .	e Midas Flowmeter. The
3	Turn on the N ₂ O 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).		NITROUS OXIDE
4	When using a compatible portable mounti manufacturer. When using a wall supply, enside-75 psi (275.8-517.1 kPa).	ng accessory, supply pre- ure supply pressure is within	ssure is preset by the n specification,
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

2	Press the Settings button (1). The Settings screen appears, push Gas % and Rate to display the Gas % and Rate settings screen. Select the default maximum Nitrous % (2). Note: The absolute maximum allowable gas percentage is factory set.		3 [] û 2:75 PM 11/04/2022
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.	Gas % and Rate Configuration Time and Date	Starting Flow Rate - 5 + Gas % Increment 1% 5% Flow Rate Increment 0.1 LPM 0.5 LPM
4	Select the gas % increment (4). The smaller step size allows for a finer adjustment of the gas mixture.	Information	Maximum Nitrous % 70 % Restore
5	smaller step size allows for a finer adjustment of the flow rate.		6 (4) (5) (2)
6	Restore button (6) allows for all settings to go back to factory parameters.		

3.2.2. Configurations Settings Configuration



3.2.3. Date and Time Settings Configuration

1	Press the Settings button (1). The Settings screen appears, push Time and Date to displaying the Time and Date section.	1
2	Press Time and Date (1).	Gas % and Rate Configuration 11 / 04 / 2022 02 : 26
3	Select the date format (2).	Time and Date
4	Enter the current date (3).	DD/MM MM/DD 12 H 24 H
5	Select the time format (4).	
6	Enter the current time (5).	
7	Select AM/PM (6) (If applicable).	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

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.



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. 	Actual Scavenger Flow Rate 40 LPM Scavenger Flow Adjuster Recommended Rate 35 - 45 LPM Scavenger 40 (LPM) 60 00000
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).	5 9 8 7:51 PM 11/04/2022 Flow Rate (LPM) 18 50 % Nitrous - + + +
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.	Scawneer 40 60 00:00:32
8	The Flow Rate (LPM) N₂O and O₂ flow bars (9) display the current flow rates.	$\begin{array}{c} 4 \\ \hline \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\$
9	During the patient procedure, monitor (and scavenger flow rate.	adjust as necessary) gas mixture, flow rate, and

10	Press and hold O_2 Recovery button (10) for 1 second to terminate the flow of N ₂ O 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.	70 10 % Nitrous 10 6 3.5 1.5 1.5 Ns0 02
11	Press and hold Stop button (12) for 2 seconds to terminate the flow of gas when the procedure is complete.	Scavenger (LPM) 40 60 10 10 10 10 11 12
12	Note: If Stop button is pressed and held 2 seconds while flowing N ₂ O and O ₂ , the user must acknowledge pop-up box to stop mixed gas flow or continue the flow.	Stop All Gases? Do you want to stop the flow of N2O and O2? YES NO
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 ₂ O/ O ₂ gas returns to the previously set mixture.	MIDAS PORTER
14	At the completion of the procedure, administer patient and dispose or clean per circuit's instr	er 100% O_2 . Remove the breathing circuit from the ructions for use.
15	Always turn O ₂ and N ₂ O cylinders valves off (unintentionally depleting source gases.	for cylinder gas supply configurations) to avoid
16	At the end of the procedure or day (after the last patient), push the Power button (15) for 2 seconds to power down the display	MIDAS

3.4. PIN Configuration

	Setting PIN				
1	Push Setting Button (1).	Image: Constraint of the state of			
2	Select Configurations (2).	Configuration Nitrous PIN Activation On T Time and Date Information Language English 3			
3	Turn on Nitrous PIN Activation (3).	Enter current PIN:			
4	Enter a four-digit numeric PIN (4).				
5	Push the save button (5).	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			



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.			
6	From the iPad, open the app. Go to Setting / Bluetooth Setup and tap Add New Device.			
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 and a popup box some 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.





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	Frequency
Bluetooth Low Energy V5.2	2.45 GHz DSSS, 2 MHz channel spacing
Transmit Power	<u>Security</u>
-11 to +5 dBM	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	Before every use
wear that may have, or could lead to leaks.	
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 N₂O flow stops when O₂ is not flowing and notification for no O₂ 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 O₂ gas cyilnder 		
	 Close shutoff valve in O₂ gas supply line 		
5	When the gas runs out, observe the following:		
	 O₂ Delivery Failure notification is displayed 		
	 N₂O 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.		

N₂O Failure Check – Confirms notification for no N₂O 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 dependant)		
4	Turn off N ₂ O gas supply to the flowmeter.		
5	 When the gas runs out, observe the following: N₂O Delivery Failure notification is displayed Audible alert sounds 100% O₂ Flow at current total flow rate 		
6	Turn on N ₂ O 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 O₂ 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 notifcation 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 N₂O percentage or minimum O₂ percentage based on model/configuration.

1	Turn the Midas Flowmeter On and review the gas % and rate setting for the maximum N ₂ O or O ₂		
	percentage		
2	Press and hold Start button for 1 second		
3	 a) If N₂O 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 O₂ 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 notifcation 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.		

O₂ Flush Test – Confirms O₂ 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 insuffient.

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	Inhale through a test breathing circuit. With the breathing bag capped or empty the air intake valve should open allowing you to breath in room air	
4	Should open and wring you to breath in room an.	
4	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	 Verify N₂O supply is turned on. 	
	flow of N ₂ O	Verify adequate supply of N₂O.	
		Switch tanks if necessary.	
		4. If notification remains, contact distributo	or.
Oxygen Delivery Failure	Unable to provide the requested	 Verify O₂ supply is turned on. 	
	flow of O ₂ .	2. Verify adequate supply of O ₂ .	
		Switch tanks if necessary.	
		4. If notification remains, contact distributo	or.
Nitrous Valve Leak	Nitrous Oxide valve failed to fully	 Turn off O₂ and N₂O supply. 	
	close	Discontinue use of device.	
		Contact distributor.	
Oxygen Valve Leak	Oxygen valve failed to fully close	1. Turn off O ₂ and N ₂ O supply.	
		Discontinue use of device.	
		Contact distributor.	
Nitrous Sensor Fault	Unable to communicate with	 Turn off O₂ and N₂O supply. 	
	N ₂ O sensor	Discontinue use of device.	
		Contact distributor.	
Oxygen Sensor Fault	Unable to communicate with O ₂	 Turn off O₂ and N₂O supply. 	
	sensor	Discontinue use of device.	
		Contact distributor.	

Notification	Description	Recommended Action
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:
		 Turn off O₂ and N₂O supply. Discontinue use of device. Contact distributor.
Memory Error	Firmware or configuration memory is corrupted	 Turn off O₂ and N₂O supply. Discontinue use of device. Contact distributor.
Application Corrupted	Display software is corrupted or unable to run	 Turn off O₂ and N₂O supply. Discontinue use of device. Contact distributor.
Low O ₂ Flush Flow	O ₂ Flush flow rate is below 19.5 LPM.	 Check O₂ supply and replace gas cylinder as necessary. If notification remains, Contact distributor.
Scavenger Communication Failure	Flowmeter is unable to communicate with the scavenger.	 Verify communication cable is connected between Flowmeter and eAVS. 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.	 Contact distributor for service or replacement of eAVS.
Scavenger Failure	Scavenging is turned on but no flow / reduced flow is detected.	 Increase scavenger flow rate. Check vacuum source pressure. Replace mask fitting/filter assembly. (P/N: B-5816-000 Filter Assy, eAVS, Mask Port) If notification remains, contact distributor to replace eAVS.

Alert Description		Recommended Action	
Bluetooth Failure –Bluetooth Unable to communicate with E Disabled controller.		1. Check Bluetooth configuration and reconnect.	
Memory Error Detected – Configuration settings have been restored to default	User configuration settings were corrupted. Default values have been restored.	 Update configurations as necessary. 	
Memory Error Detected – Language has been restored to default	Language support files are corrupted. Reverted to English.	 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 Procedure log cleared. Detected – All procedure logs cleared		No user action required.	
Partial Procedure Logs Corruption – Some procedure logs lost	One or more Procedure log records cleared.	No user action required.	

Alert	Description	Recommended Action
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.	 Turn off O₂ and N₂O supply. Discontinue use of device. 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 O₂ Recovery, O₂ Flush, and Emergency O₂? (1) 	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. 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.
	App Store App and click on the account setting top right corner showing an app update is ava 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. 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	Group	Immunity	Result
		Class		Test Level	
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, Bower Borte		NI/A	NI/A	1.0 kV diff,	Deee
Surge immunity, Power Ports	IEC 61000-4-5	IN/A	IN/A	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	NI/A	NI/A	30 A/m 50	Dass
	IEC 01000-4-0	IN/A	N/A	Hz	r ass
Voltage Dips, Interrupts and Variations	IEC 61000-4-11	NI/A	NI/A	0.5s 30%	Pass
	120 01000-4-11	11/7	IN/A	dips, 5s 0V	1 855
Radiated Fields in Close Proximity Magnetic	IEC 61000-4-39	N/A	N/A	65 A/m	Pass
Fields, 10 kHz to 150 kHz	120 01000-4-09	11/7	11/7	007011	1 435
Radiated Fields in Close Proximity Magnetic	IEC 61000-4-39	N/A	N/A	7 5 A/m	Pass
Fields, 150 kHz to 25 MHz	12001000-4-00	11/7	11/7	7.07011	1 033

6. Symbols Glossary

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

Symbol	Title of Symbol	Description of Symbol
	Manufacturer Information	Indicates the medical device manufacturer and is accompanied by the name and address of the manufacturer. [EN ISO 15223-1:2021, clause 5.1.1]
USA	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]
REF	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]
SN	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]
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information. [EN ISO 15223-1:2021, clause 5.7.10]
Rx Only	Prescription device	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
MD	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]
i	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]
\triangle	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]
	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)]

X	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]	
Ť	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]	
X	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]	
Â	Electrical Shock / Electrocution	Indicates the components has risk of electric shock. [ISO 60601-1, Table D.2, No. 3]	
(\mathbf{S})	Disassembly Prohibition	Indicate a risk of injury, such as electric shock, if the equipment is disassembled.	
Ϋ́	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]	
	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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