



## Quick Start Guide for Porter Midas™ Flowmeter and eAVS

#### 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.

#### 2. Pre-Check

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 testing below. A start-up notification during Onboard Diagnostics may require servicing from the manufacturer, please refer to full instructions for use, FM-1496, Section 4.3.

For instructions on proper disposal of devices that are beyond their useful life, see Section 8 of this document.

Pre-Check Table	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

**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.



**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 pre-check test cannot be executed successfully, do not use this device and contact distributor.



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

#### Failsafe Failure Check:

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 <sub>2</sub> gas supply to the flowmeter by one of the following options:  • Close valve on O <sub>2</sub> gas cylinder Close shutoff valve in O <sub>2</sub> gas supply line	
5	<ul> <li>When the gas runs out, observe the following:</li> <li>O<sub>2</sub> Delivery Failure notification is displayed</li> <li>N<sub>2</sub>O flow shuts off</li> <li>Audible alert sounds</li> </ul>	
6	Turn on O <sub>2</sub> 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 Percentage (%) Delivery Test:**

1	Turn the Midas Flowmeter On and review the gas % and rate	
	setting for the maximum N <sub>2</sub> O or O <sub>2</sub> percentage	
2	Press and hold Start button for 1 second	
3	<ul> <li>a) If N<sub>2</sub>O 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.</li> <li>b) If O<sub>2</sub> 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.</li> </ul>	
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.	



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### **Indicated Flow Delivery Test:**

1	Turn the Midas Flowmeter On	
2	Press and hold Start button for 1 second	
3	Turn the percent mixture to 100% O <sub>2</sub>	
4	Press and drag the to 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.	

### N<sub>2</sub>O Failure Check:

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 N₂O gas supply to the flowmeter.	
5	When the gas runs out, observe the following:  • N <sub>2</sub> O Delivery Failure notification is displayed  • Audible alert sounds  100% O <sub>2</sub> 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.	

### Non-Rebreathing Valve Test:

	on Robiodining vario root.		
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 FM-1496 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.		

#### O<sub>2</sub> Flush Test:

1	Turn the Midas Flowmeter On	
2	Press and hold O <sub>2</sub> 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:

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 FM-1496 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

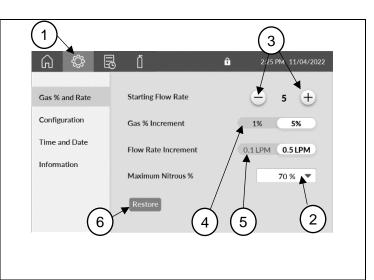
## **Emergency Air Intake Valve Test:**

1	Turn the flowmeter off by pressing the <b>On/Off Button</b> .	
2	Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of breathing circuit.  Refer to FM-1496 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 the breathing circuit. Air intake valve should open allowing you to breathe in room air.	
5	If you can not breahte in room air, contact your authorized distributor for service and troubleshooting.	

## 3. Settings Instructions

## 3.1. Gas % and Rate Settings Configuration

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

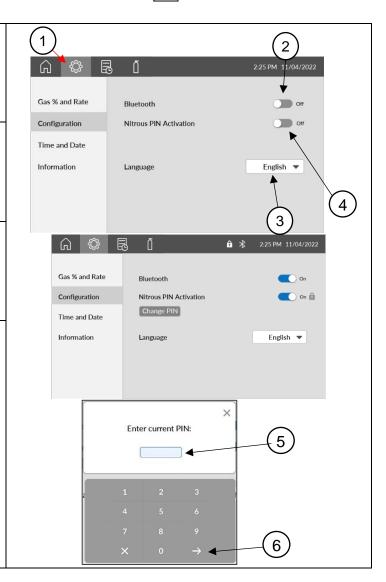






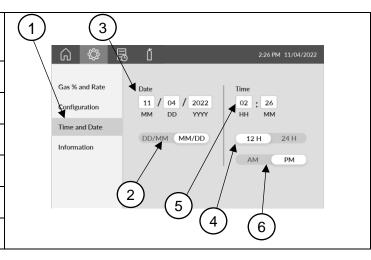
3.2. Configurations Settings Configuration

Press the **Settings** button (1). The Settings screen 1 appears, push Configurations to displaying the Configurations section. Turn on **Bluetooth** (2) if using the Porter Midas App to monitor and control the Flowmeter using an Apple 2 iPad. See Section 3.5 iPad Configuration and **Instructions** within **FM-1496** for setup and operation of the Midas Flowmeter using the Porter Midas App. Select the appropriate language for touchscreen 3 display (3). OPTIONAL: Turn on Nitrous Oxide PIN Activation (4). 4 If using PIN security to administer N2O, Select and enter a four-digit PIN (5) and press the arrow to save the PIN (6).



3.3. Date and Time Settings Configuration

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



# 4. Operating Instructions for Flowmeter

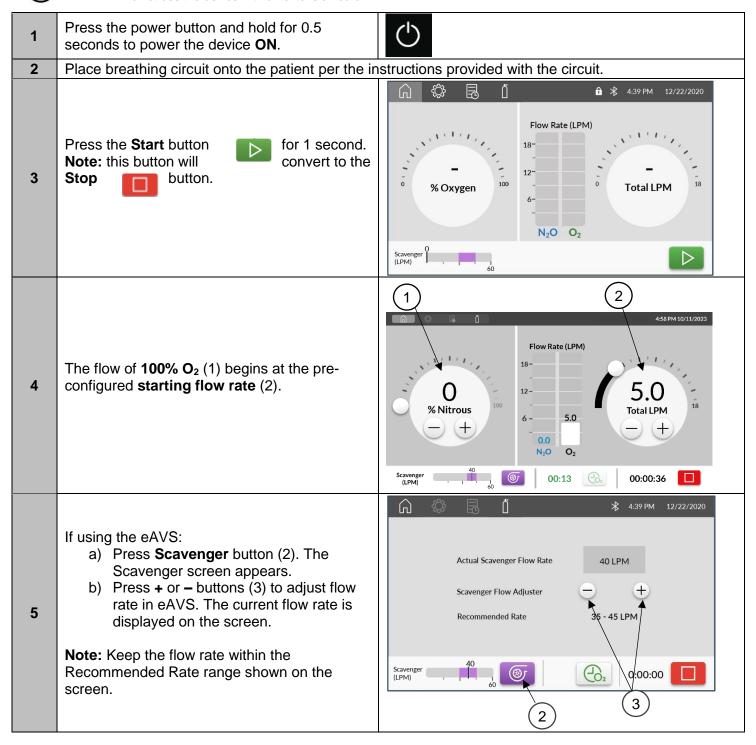






**WARNING:** To reduce the risk of electrical shock or electromagnetic interference:

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







	•	USA Office 215-725-4000
0	From the touchscreen, press + or – buttons (4) to set the appropriate mix percentage (% Oxygen or % Nitrous Oxide).	5 9 8 7:51 PM 11/04/2022
6	Alternatively, press and drag the <b>Adjuster</b> (5) to set the mix percentage. <b>Note:</b> If a PIN was set, enter the PIN to change the gas percentage (6).	50 % Nitrous 100 12- 5.0 Total LPM 18
7	Press + or – buttons (7) to set the appropriate flow rate in liters per minute.  Alternatively, press and drag the <b>Adjuster</b> (8) to set the flow rate.	Scaylenger (1)M)
8	The Flow Rate (LPM) N <sub>2</sub> O and O <sub>2</sub> flow bars (9) display the current flow rates.	1 2 3 4 5 6 7 8 9 × 0 →
9	During the patient procedure, monitor (and adjuftlow rate.	st as necessary) gas mixture, flow rate, and scavenger
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.	Flow Rate (LPM)  18-  12-  5.0
11	Press and hold <b>Stop</b> button (12) for 2 seconds to terminate the flow of gas when the procedure is complete.	% Nitrous  6 - 3.5 1.5 N <sub>2</sub> O O <sub>2</sub> Scavenger (LPM)  00:00:13 10 11 12
12	<b>Note:</b> If Stop button is pressed and held 2 second while flowing N <sub>2</sub> O and O <sub>2</sub> , 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





If needed, press and hold  $O_2$ Flush button (14) to deliver
100%  $O_2$  to the patient. Once
this button is released, the  $N_2O/O_2$  gas returns to the previously set
mixture.



- At the completion of the procedure, administer 100% O<sub>2</sub>. Remove the breathing circuit from the patient and dispose or clean per circuit's instructions for use.
- Always turn O<sub>2</sub> and N<sub>2</sub>O cylinders valves off (for cylinder gas supply configurations) to avoid unintentionally depleting source gases.

At the end of the day (after the last patient of the day), push the **Power button** (15) for 2 seconds to power down the display.



## 5. 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:



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- 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.
- Disconnect and dispose of any single use breathing circuit and/or single use nasal hood (if attached). For 1 cleaning instructions of re-useable breathing circuit and/or nasal hood refer to breathing circuit Instructions for 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 2 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. 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 3 cleaning agents into the breathing pathway of the device. Dampen a lint free cloth with tap water and wipe cleaning residue off Midas Touchscreen after the allotted 4 The bag port, breathing circuit port, and emergency air intake valve should not be exposed to the cleaners 5 or wiped to prevent moisture from entering the device. Avoid wiping and applying cleaner to the inside of the ports and the valve.





## 6. Safety Information



**WARNING:** This product contains lead and lead compounds, a chemical known to the State of California to cause cancer. For more information: <a href="www.P65Warnings.ca.gov">www.P65Warnings.ca.gov</a>



**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 full instructions for use for more information (FM-1496).



**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.



**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 nitrous oxide may suffer harmful effects. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average)



**WARNING:** The Midas Flowmeter and optional eAVS are used with the delivery of Oxygen (O<sub>2</sub>). 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.



**WARNING:** The healthcare professional should observe the patient to prevent over sedation in the event of an O<sub>2</sub> failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O<sub>2</sub>, 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<sub>2</sub> from an independent source.



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



**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.



**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas and 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

## 7. 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.

### 8. 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.



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

Refer to FM-1496 for complete instructions and safety information.

Rx Only

## 9. Representation

presentation		
	Legal Manufacturer	Parker Hannifin Corporation
		Precision Fluidics Division
USA		245 Township Line Road
		Hatfield, PA 19440 USA
		Office: (215) 723-4000
EC REP	European Communities	EMERGO Europe
	Authorized	Westervoortsedijk 60
	Representative	6827 AT Arnhem, The Netherlands
	-	Tel: +31 70 345 8570
<b>€</b> 2862	Conformité Européenne	Compliance with conformity assessment on quality
	(CE) Mark	management system and technical documentation per
		Regulations (EU) 2017/745 for Medical Device, Annex IX
		Chapters I & III