Parker Hannifin Corporation
245 Township Line Road
Hatfield, PA 19440 USA
Office 215-723-4000

# Matrx Digital MDM® Nitrous Oxide/Oxygen Sedation Flowmeter Quick Start Guide

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

**Machine Turn-On Test**

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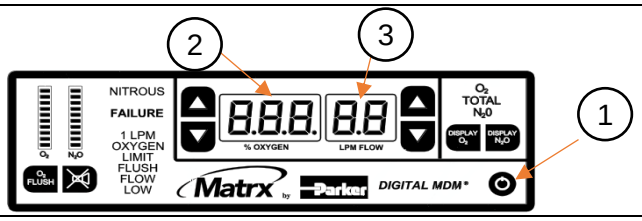
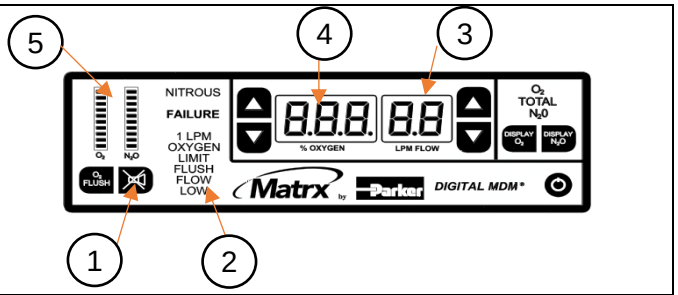
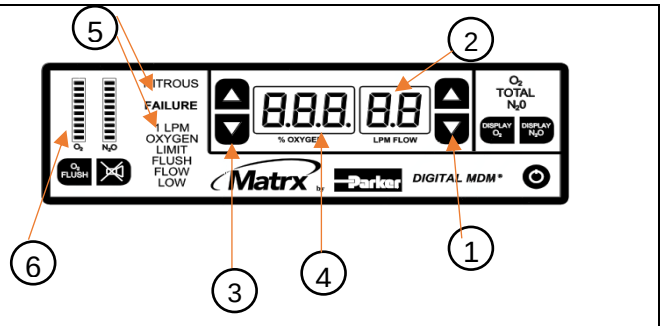
|---|---|---|
| **1** | Press the **ON/OFF** button (1) to turn the flowmeter on. After the flowmeter goes through an initialization routine, the **% $O_2$** (2) and **LPM Flow** (3) displays must display 100% and 5 LPM, respectively. |  |
| **2** | If the displays do not show the correct information, contact your authorized distributor for service and troubleshooting. | |

**Alarm Indicator / Lamp Test**

| | | |
|---|---|---|
| **1** | Press **Alarm Test/Silence** button (1), and observe that all **alarm readouts** (2) illuminate. The **% $O_2$** (3) and **LPM Flow** (4) displays must also read 8.8.8. and 8.8, respectively |  |
| **2** | The **alarm readouts** (2) must illuminate with numerical displays, 10 bars on the **Flow Indicators** (5) must illuminate for each gas, and the audible alert must sound. | |
| **3** | If the displays do not show the correct information or the alert does not sound, contact your authorized distributor for service and troubleshooting. | |

**$O_2$ Failure Test**

| | | |
|---|---|---|
| **1** | Press **Flow Control** ▲/▼ buttons (1) to set **LPM Flow display** (2) to 9.9 LPM. |  |
| **2** | Press % $O_2$ ▲/▼ button (3) to set **% $O_2$ display** (4) to 50%. | |
| **3** | Turn off $O_2$ gas supply to the flowmeter. | |
| **4** | When the gas runs out, observe the following:<br>• **$O_2$ Failure** alarm (5) illuminates<br>• Audible alert sounds<br>• **Flow Indicators** (6) are off<br>• **LPM Flow** (2) and **% $O_2$** (4) displays are off | |
| **5** | Turn on $O_2$ gas supply. The flowmeter must return to normal operation. The alarm may continue to chime for up to 20 seconds after restoration of gas pressure. | |
| **6** | If the displays do not show the correct information or the alert does not sound, contact your authorized distributor for service and troubleshooting. | |

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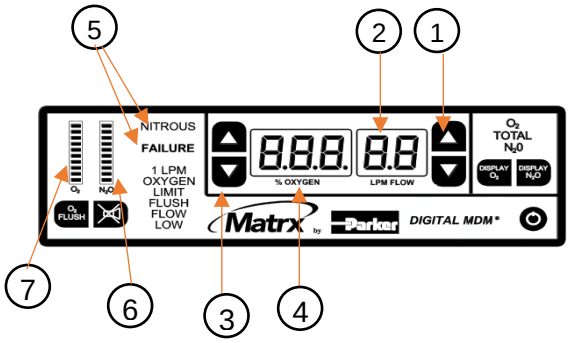
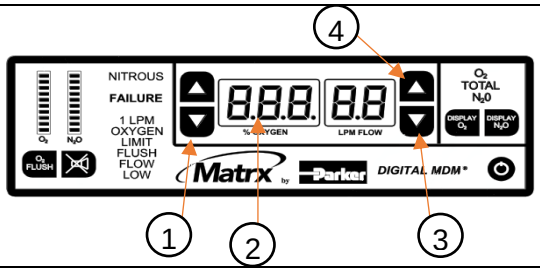
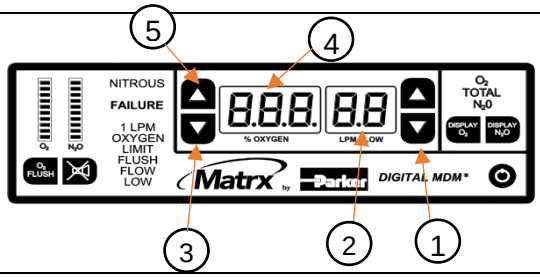
**$N_2O$ Failure Test**

| | | |
|---|---|---|
| 1 | Press **Flow Control ▲/▼** buttons (1) to set **LPM Flow display** (2) to 9.9 LPM. |  |
| 2 | Press % $O_2$ ▲/▼ button (3) to set **% $O_2$ display** (4) to 30%. | |
| 3 | Turn off $N_2O$ gas supply to the flowmeter. | |
| 4 | When the gas runs out, observe the following:<br>• **$N_2O$ Failure** alarm (5) illuminates<br>• Audible alert sounds<br>• **LPM Flow display** (2) indicates $O_2$ being delivered,<br>• the **% $O_2$** display (4) and **$N_2O$ gas flow indicator** (6) are off,<br>• **$O_2$ gas flow indicator** (7) shows at least 3 bars. | |
| 5 | Turn on $N_2O$ gas supply. The unit must return to normal operation. The alarm may continue to chime for up to 20 seconds after restoration of gas pressure. | |
| 6 | 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**

| | | |
|---|---|---|
| 1 | Press **% $O_2$** Control ▲/▼ buttons (1) to set the **% $O_2$** display (3) to 100%. |  |
| 2 | Press and hold the **Flow Control ▼** button (3) to decrease the flow rate to 1.0 LPM. An audible alert must sound at the lower limit while the button is held. | |
| 3 | Press and hold the **Flow Control ▲** button (4) to increase the flow rate to 9.9 LPM. An audible alert must sound at the upper limit while the button is held. | |
| 4 | If the alert does not sound or fails to continuously sound while the buttons are held, contact your authorized distributor for service and troubleshooting. | |

**Indicated Percentage (%) Delivery Test**

| | | |
|---|---|---|
| 1 | Press **Flow Control ▲/▼** buttons (1) to set the **LPM Flow display** (2) to 9.9 LPM. |  |
| 2 | Press and hold the **% $O_2$ Control ▼** button (2) to decrease the **% $O_2$ display** (3) to 30%. The audible alert must sound at the lower limit while the button is held. | |
| 3 | Press and hold the **% $O_2$ Control ▲** (3) button to increase the **% $O_2$ display** (4) to 100%. An audible alert must sound at the upper limit while the button is held. | |
| 4 | If the alert does not sound or fails to continuously sound while the buttons are held, contact your authorized distributor for service and troubleshooting. | |

**$O_2$ Flush Test:**

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| 1 | Press and hold **O2 Flush Button**. |
| 2 | Observe that the breathing bag quickly inflates. |
| 3 | If the breathing bag does not inflate quickly, contact your authorized distributor for service and troubleshooting. |

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**Non-Rebreathing Valve Test**

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|---|---|
| **1** | Turn off flowmeter by pressing the **On/Off Switch**. |
| **2** | Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of Breathing Circuit. |
| **3** | Blow into the inhalation line of the 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:**

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|---|---|
| **1** | Turn the flowmeter off by pressing the **On/Off Switch**. |
| **2** | Connect a breathing circuit to the bag tee. Disconnect the nasal hood from the rest of breathing circuit. |
| **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 breath in room air. |
| **5** | If you can not breahting in room air, contact your authorized distributor for service and troubleshooting. |

## 2. Operating Instructions

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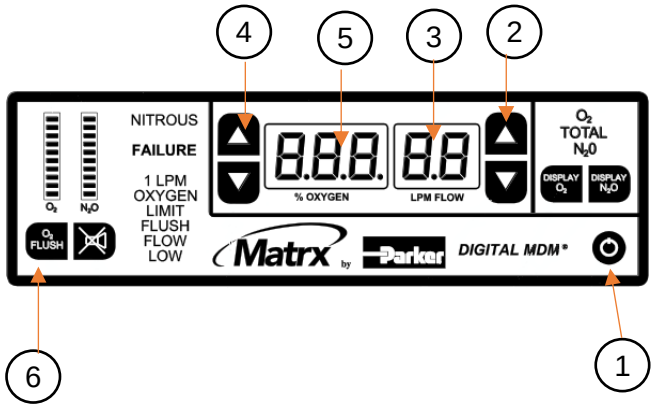
| **1** | Power device on using the **On/Off Button** (1) |
| **2** | Press **Flow Control ▲/▼** buttons (2) to set desired **flowrate** (3). |
| **3** | Press **% $O_2$ Control ▲/▼** buttons (4) to set desired **% $O_2$** (5). To lower observed patient level of conscious sedation, press **% $O_2$ Control ▲** button to increase % $O_2$. |
| **4** | Before the procedure starts, if desired, press the **$O_2$ Flush Button** (6) to pre-fill the breathing bag (if connected) with 100% $O_2$ ensuring the patient's first breath is not from an empty breathing bag. |
| **5** | Place breathing circuit nasal hood on patient and instruct the patient to inhale through the nasal hood. Patient should also be instructed to exhale through the nasal hood to achieve effective scavenging. |




| | |
|---|---|
| **6** | When conditions call for the delivery of 100% $O_2$:<br>**a)** increase the **%** $O_2$ on the flowmeter to 100%.<br>**b)** If using a directional Y valve, rotate the lever to full-face mask line.<br>**c)** Control the desired flow of 100% $O_2$ through the **Flow Control ▲/▼ buttons**.<br>**d)** Confirm delivery of 100% $O_2$ by monitoring patient condition. |
| **7** | If patient shows signs or communicates conditions of over-sedation, empty the breathing bag by squeezing it and then press and hold **$O_2$ Flush Button** to quickly fill the breathing bag with 100% $O_2$. |
| **8** | At the completion of the procedure, remove the breathing circuit from the patient. Press **Flow Control ▼** button to achieve zero flow, then press the **On/Off Button** (1) to power the device off. Dispose of any single use items (such as nasal hood or breathing circuit). |
| **9** | Always turn $O_2$ and $N_2O$ cylinders valves off (for cylinder gas supply configurations) or disconnect the supply lines from the appropriate outlet stations (for pipeline gas supply configurations) to avoid unintentionally depleting source gases. |

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## 3. Cleaning

The DMDM Flowmeter 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, thoroughly wipe down the Digital MDM Flowmeter until all visible dirt and soil is removed. Take extra care to wipe the touch control buttons as these are the most handled areas of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove. |
| **3** | Using a Super Sani-Cloth™ Germicidal wipe, 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** | 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. Safety Information

**WARNING:** This product can expose you to chemicals, including lead and formaldehyde, which are known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information, go to 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 full instructions for use document (Form 10545100-ENGLISH).

**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 keypad with finger pressure only. Do not use hard or sharp objects. Otherwise, damage may result to the user interface.

**WARNING:** The Digital MDM 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 Digital MDM Flowmeter in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the Digital MDM Flowmeter should be considered "MR Unsafe" and should be kept outside of any MRI scanner rooms.

**WARNING:** Workers exposed to excessive $N_2O$ 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 Digital MDM Flowmeter 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.

**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.

**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:** 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.

**WARNING:** Grounding Reliability can only be achieved when power supply is connected to an equivalent receptacle marked "Hospital ONLY" or "Hospital Grade"

**WARNING:** The user should observe the patient to prevent over sedation in the event of an $O_2$ failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% $O_2$, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure $O_2$ from an independent source.

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

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

## 5. Representation

| | | |
|---|---|---|
| | **Legal Manufacturer** | Parker Hannifin Corporation<br>Precision Fluidics Division<br>245 Township Line Road<br>Hatfield, PA 19440 USA<br>Office: (215) 723-4000 |
| EC REP | **European Communities Authorized Representative** | EMERGO Europe<br>Westervoortsedijk 60<br>6827 AT Arnhem, The Netherlands<br>Tel: +31 70 345 8570 |
| CE 2862 | **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 |
| CH REP | **Switzerland Authorized Representative** | Medenvoy<br>Gotthardstrasse 28<br>6302 Zug<br>Switzerland<br>+41 41 562 01 42 |

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

CE 2862

**Refer to 10545100-ENG for complete instructions and safety information.**

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Rx Only