INFORMATION FOR LIMITED DISTRIBUTION

Mallinckrodt™ Pharmaceuticals

Technical Bulletin

Ref: **TB-25006-ENG**

Product: INOmax DS_I ® Plus, Investigational Blinded NO Delivery System, Investigational NO Delivery System for Human Use Only, Investigational NO Delivery System for Animal Use Only.

Issue date: 10-2025

Priority: Low

Classification: Information for Limited Distribution

Country Affected: US

Affected parts: Patient Gas Sample Line with Filter

Subject: **Patient Gas Sample Line with Filter**

WARNING: Use only parts/accessories designated for use with the INOmax DS_{IR} Plus family of devices listed above.

This technical bulletin is written to advise clinicians that the Patient Gas Sample Line with Filter Assembly is being replaced to improve reliability of the INOmax DS_{IR} Plus device. The appearance of the filter has changed. There is no change to patient workflows, filter life, or filter performance. (See Table 1 for product part information).

The current Patient Gas Sample Line with Filter Assembly can continue to be used as necessary.

Table 1

Disposable	Individual Part Number	Five-Pack Part Number
Patient Gas Sample Line with Filter, Capped Nafion, BCG, 10FT/3M	50444	50445

Please follow the current installation instructions:

1. Remove a new Patient Gas Sample Line with Filter from the package.
2. Connect the filter end of the sample line to the sample line inlet port (**1** - see Figure #1 below) turning clockwise using the patient gas sample line/filter junction to gently tighten the Patient Gas Sample Line with Filter to the sample line inlet port Luer connector on the front of the device (**2 -** see Figure #1 below).
3. Connect the other end of the Patient Gas Sample Line with Filter to the sampling port in the breathing circuit.

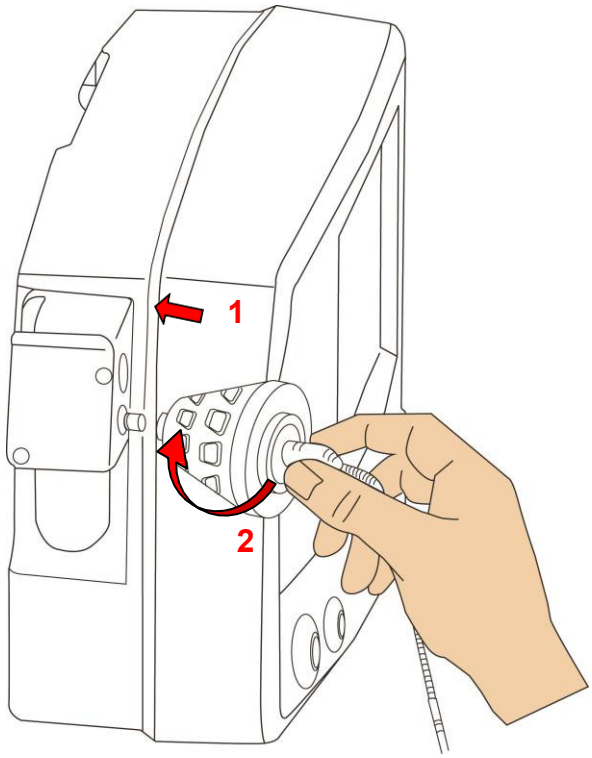


Figure 1 Connecting the Filter to Sample Line Inlet

NOTE: Change the filter every 12 hours or as required (for example, if a "**Sample Line/Filter Block"** alarm is displayed.)

Troubleshooting while treating a patient:

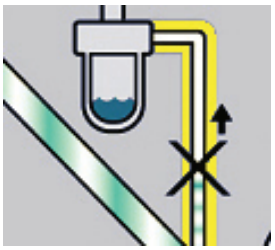
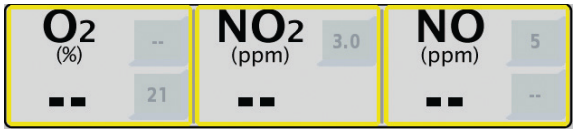
Alarm	Possible Cause	Recommended Action
Sample Line/Filter Block 	The Patient Gas Sample Line with Filter may be blocked.	1. Confirm sample line inlet and outlet ports are not obstructed. 2. Confirm patient gas sample line is not occluded. 3. Replace the Patient Gas Sample Line with Filter Assembly. 4. Ensure the filter end is connected to the Sample Line Inlet and not to the breathing circuit.
	The water separator cartridge may be blocked.	1. Replace water separator cartridge. 2. Contact Technical Support.
Monitoring Failure 	Monitor is failing to communicate correctly or is reporting a fault	1. Confirm the gas sample line is not occluded. 2. Confirm the water trap bottle and water separator cartridge are in place. 3. Change Patient Gas Sample Line with Filter 4. Change water separator cartridge 5. Contact Technical Support

Table 2 Sample Line/Filter Block and Monitoring Failure Alarm Troubleshooting

CAUTION: Pneumatic nebulizers will dilute the delivered INOMAX dose.

If a medication nebulizer is required to treat the patient, place the medication nebulizer downstream of the sample tee on the inspiratory limb (see Figure #2). This helps to reduce contamination of the sample system.

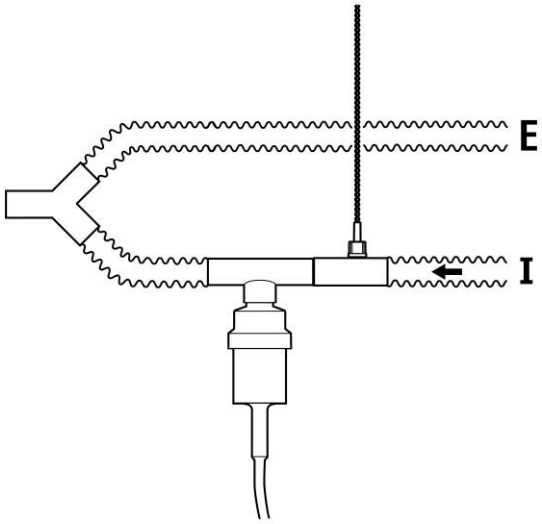


Figure 2 Connecting a Medication Nebulizer

For technical assistance, please contact technical support at 1-877-566-9466 (North America) or your specific country manager.

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