

INFORMATION FOR LIMITED DISTRIBUTION



Technical Bulletin

Ref: **TB-19001-ENG**

Issue date: January 2020

Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus,
Investigational DS_{IR}[®] – Non-Blinded – Human,
Investigational DS_{IR}[®] – Non-Blinded – Animal,
Investigational DS_{IR}[®] - Blinded

Priority: Low

Affected parts: Nebulizer Disk Filter

Classification: Information for Limited Distribution

Subject: **Nebulizer Disk Filter – Sample line**

Country Affected: US

WARNING: Use only parts/accessories designated for use with the INOmax DS_{IR}, INOmax DS_{IR} Plus

This technical bulletin is written to advise clinicians that the 1.0 micron, glass fiber, disk filter (see Table #1 for part numbers), and the Patient Gas Sample Line with Nafion, will be available for use (see Figure #1 on Page 2 for instructions).

It has come to our attention that there are clinical situations that dictate the need to place the nebulizer upstream of the Sample Tee, exposing the device to higher levels of nebulized medications. In these situations, the clinician will now be able to choose which combination of Sample Line with Nafion and Filter they determine to provide the best results in order to extend monitoring capabilities.

Table #1

Disposable	Individual Part Number	Five-Pack Part Number
1.0 micron, glass fiber, disk filter	90829	50258
Patient Gas Sample Line with Nafion	90828	50257

1. Place the 1.0 micron disk filter on the INOmax DS_{IR} Plus sample line inlet (1).
2. Connect the Patient Gas Sample Line with Nafion to the filter (2).
3. Ensure all connections are secure to prevent leak and dilution of monitored values

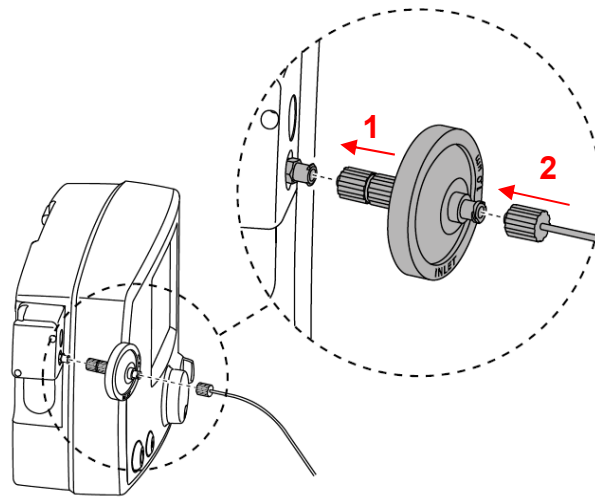


Figure #1 Connecting the Patient Gas Sample Line with Filter to the Sample Line Inlet

NOTE: Change the filter every 12 hours or more often if necessary (for example, if you see a “**Sample Line/Filter Block**” alarm.)

The other option for a clinician will continue to be the Patient Gas Sample Line with Filter (see Table #2 for part numbers, and Figure #2 on page 3 for instructions).

Table #2

Disposable	Individual Part Number	Five-Pack Part Number
Patient Gas Sample Line with Filter	50193	50194

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 #2 below) turning clockwise (2) using the patient gas sample line/filter junction (3) to tighten the Patient Gas Sample Line with Filter to the sample line inlet port Luer connector on the front of the device.
3. Connect the other end of the Sample Line to the sample tee in the breathing circuit.

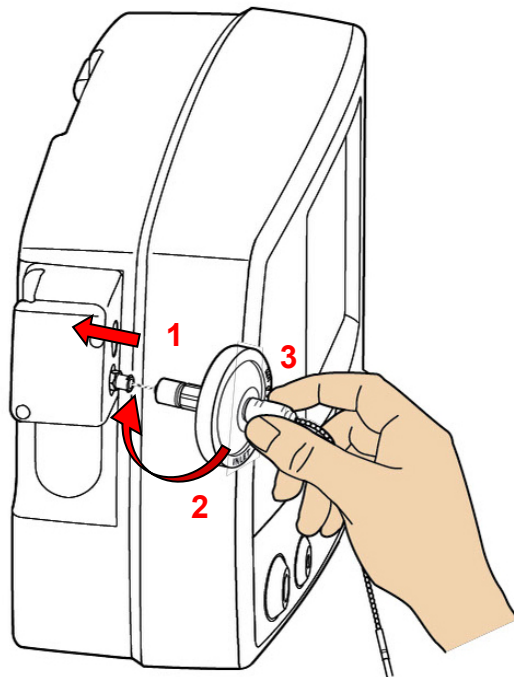


Figure #2 Connecting the Disk Filter to Sample Line Inlet

NOTE: Change the filter every 12 hours or more often if necessary (for example, if you see a “**Sample Line/Filter Block**” alarm.)

Troubleshooting while treating a patient:


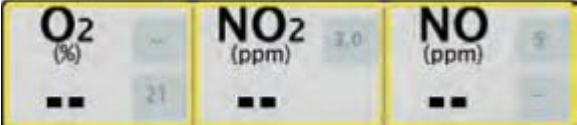
Alarm	Possible Cause	Recommended Action
<p>Sample Line/Filter Block</p> 	<p>The Patient Gas Sample Line with Filter may be blocked.</p>	<ol style="list-style-type: none"> 1. Replace the Patient Gas Sample Line with Filter. 2. Ensure the filter end is connected to the Sample Line Inlet and not to the breathing circuit.
<p>Monitoring Failure</p> 	<p>Monitor is failing to communicate correctly or is reporting a fault</p>	<ol style="list-style-type: none"> 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 4. Change water separator cartridge 5. Contact Technical Support

Table #3 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 #3). This helps to reduce contamination of the sample system.

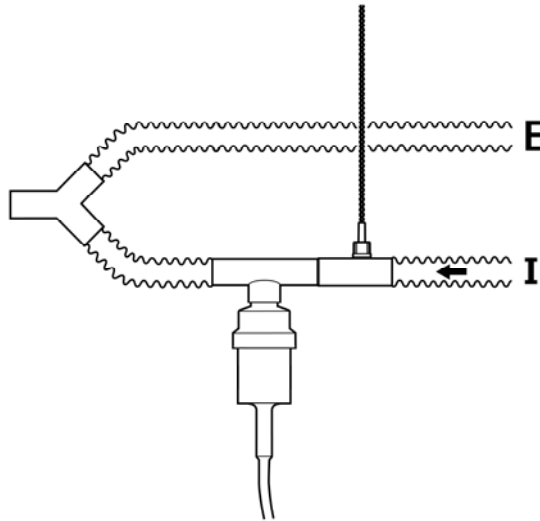


Figure #3 Connecting a Medication Nebulizer

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

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