



Technical Bulletin

Ref: **TB-17004-ENG**

Issue date: October 2017

Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus

Priority: Low

INOmax DS_{IR}[®] Plus MRI, INOflo DS

Affected parts: Patient Gas Sample Line plus Filter

Classification: Information for Distribution

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

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

Caution: Pneumatic nebulizers placed downstream from the injector module will dilute the delivered INOMAX[®] dose.

As part of Mallinckrodt's commitment to continuously improve the clinician and patient experience, a new Patient Gas Sample Line assembly is being released to replace the current two piece sample line and filter configuration. This assembly may help reduce sample system clogging. The new Patient Gas Sample Line with Filter (see Table 1 below for variants) includes a Nafion sample line and an integrated, improved filter containing both coalescing and hydrophobic filter media. The previous filter (PN 90724, Disk Filter, 1.0 micron, glass fiber), that was provided for use during nebulization, included only a coalescing filter medium. The current patient sample line and filter can continue to be used, but because of the improvement to the new patient sample line and filter you may want to consider replacing your current inventory.

- Consider removing all older sample line and filters from your inventory
- Replace older sample line and filters with the new patient gas sample line with filter if in use on a patient as deemed appropriate by the clinician.
- Alarm troubleshooting instructions have changed (see below)

Table 1 New Patient Gas Sample Line with Filter Variants

Description	Length	Part Number Single	Part Number Five-Pack
Patient Gas Sample Line with Filter	10 feet	50193	50194
MR Patient Gas Sample Line with Filter	16 feet	50274	50275

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 **(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 INOmax DS_{IR}, INOmax DS_{IR} Plus, INOmax DS_{IR} Plus MRI or INOflo DS .
3. Connect the other end of the Sample Line to the sample tee in the breathing circuit.

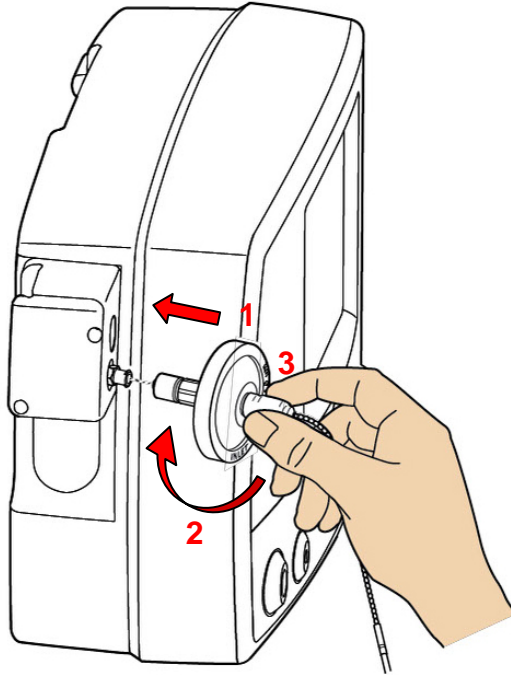


Figure 1 Connecting the Patient Gas Sample Line with Filter

Troubleshooting while treating a patient:

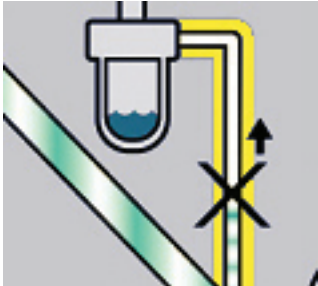
Alarm	Possible Cause	Recommended Action
<p>Sample Line/Filter Block</p> 	<p>The Patient Gas Sample Line with Filter may be blocked.</p> <hr/> <p>The water separator cartridge may be blocked.</p>	<p>1. Replace the Patient Gas Sample Line with Filter.</p> <p>2. Ensure the filter end is connected to the INOmax DSIR Plus and not to the breathing circuit.</p> <hr/> <p>1. Replace water separator cartridge.</p> <p>2. Contact Customer Support.</p>

Table 2 Sample Line/Filter Block Alarm Troubleshooting

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.

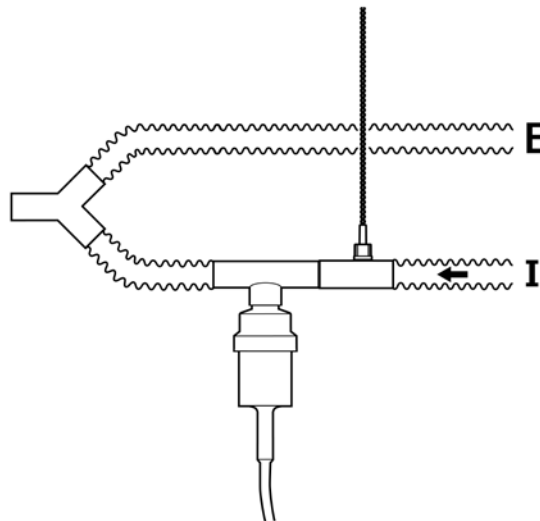


Figure 2 Connecting a Medication Nebulizer

Mallinckrodt Manufacturing LLC
 6603 Femrite Drive,
 Madison, WI 53718-6801 USA

Mallinckrodt, the "M" brand mark and the Mallinckrodt Pharmaceuticals logo are trademark of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owner. ©2017 Mallinckrodt