

Technical Bulletin

Ref: TB- 13006 Issue date: February 2022

Product: INOcal® Priority: Low

Affected parts: INOcal Tubing Assembly Classification: Information for Distribution

Subject: INOcal Tubing Assembly Change

This Technical Bulletin describes changes to the INOcal tubing assembly used during high calibration of the INOmax DS_{IR}.

A robust tubing material (super-thane) replaces the current silicone tubing

- An adapter (see #4 below) is needed to connect the tubing assembly to the older style INOcal regulators that have a larger bore outlet.
- A new compact tubing configuration changes the orientation of the check-valve and luer connector

Caution:

- This device is restricted to sale by or on the order of a medical practitioner.
- Only use INOcal regulator with INOcal calibration gas.
- Do not use regulator with cylinder pressures that exceed the maximum gauge pressure.

Instructions

(Step numbers refer to the drawing)

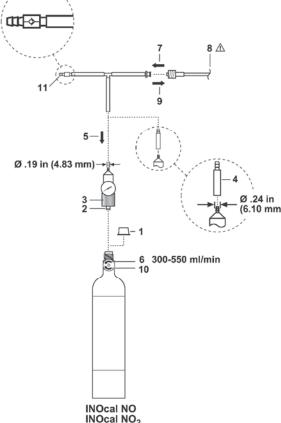
- 1. Remove cylinder cap and inspect for damaged threads and contaminants.
- 2. Check seal on regulator. Make sure it is correctly in place and undamaged.
- 3. Attach regulator to cylinder (Turn regulator nut counterclockwise to tighten).
- 4. NOTE: Tubing adapter will be required if regulator outlet diameter measures .24 in (6.10 mm).
- 5. Attach tube kit to regulator outlet.
- 6. Turn on/off valve counter-clockwise to flow gas.
- 7. Attach tube kit to monitor sample line.
- 8. Calibrate the monitor.
- 9. Remove sample line from tube kit.
- 10. Turn on/off valve clockwise to stop gas flow.

Note: Open to atmosphere and make sure one-way valve is not blocked (see #11 in diagram).

> Mallinckrodt Manufacturing LLC 6603 Femrite Drive,

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. ©2016 Mallinckrodt

Madison, WI 53718-6801 USA



MALLINCKRODT

Doc Title: TB-13006-ENG INOcal Tubing Assembly Change



Europe

European Authorized Representative MDSS GmbH Schiffgraben 41 30175 Hannover, Germany

2797