Technical Bulletin

Ref: **TB- 11006**

Issue date: **July 2011**

Product: INOmax® DS/DS$_{IR}$

Priority: Low

Affected parts: INOmax DS/DS$_{IR}$

Classification: Information for Distribution

Subject: **Ventilator Applications**

This technical bulletin is written to advise clinicians that the following are validated for use with INOMAX DS and INOMAX DS$_{IR}$ using the configurations shown below:

- **Dräger Babylog VN500/Infinity Acute Care System Workstation Neonatal Care Ventilator**
- **Dräger V500/Infinity Acute Care System Workstation Ventilator**
- **Impact Instrumentation EMV+**
- **Newport E360**
- **Teleflex Medical Comfort Flo Humidification System**
- **Vapotherm Precision Flow**

Warning:

- **The approved patient population for the INOmax DS/DS$_{IR}$, as specified in the drug labeling for INOMAX® (nitric oxide) for inhalation, is limited to neonates. The INOmax DS/DS$_{IR}$ is not intended to be used in other patient populations.**

- **The INOmax DS/DS$_{IR}$ subtracts gas from the breathing circuit via the gas sampling system at 230 mL per minute; this can effect the sensitivity of a flow triggered synchronized breath mode of some ventilators. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS/DS$_{IR}$ to the breathing circuit.**

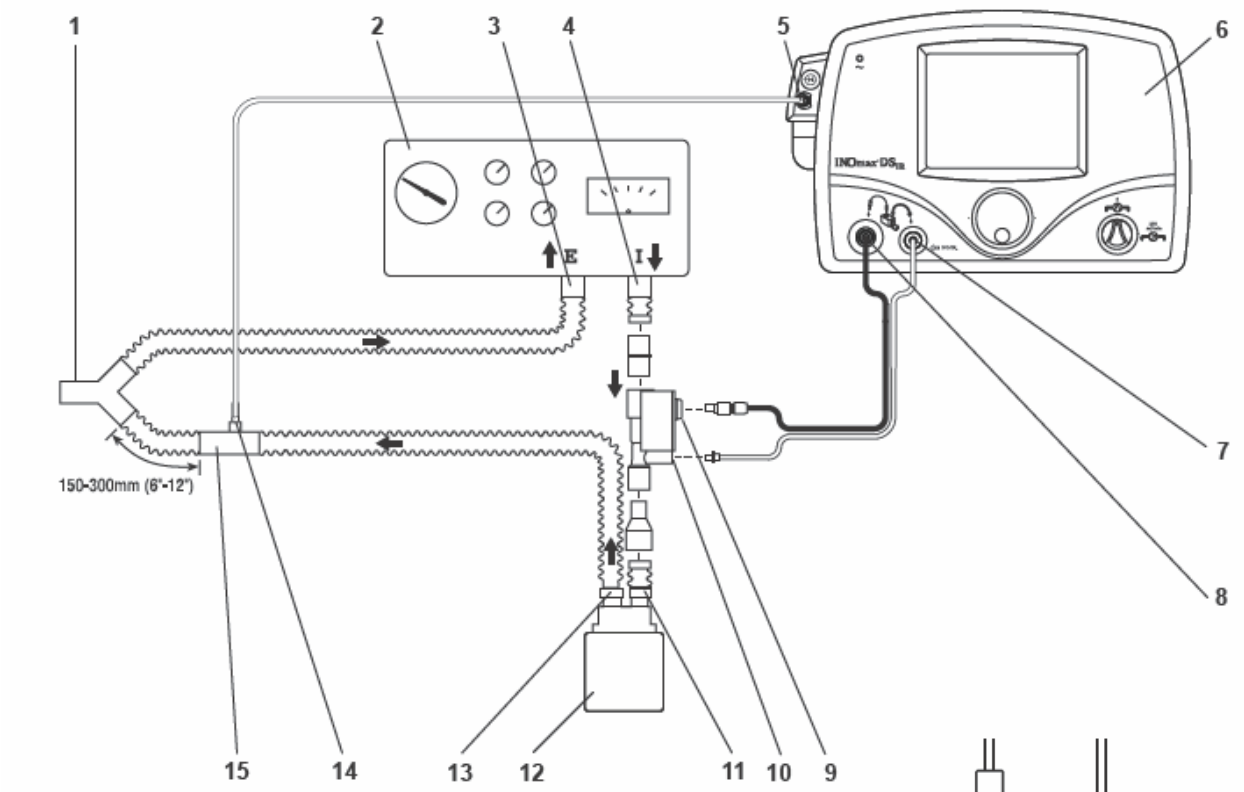
- **Patient disconnect and high pressure alarms are required for the ventilator.**

Caution:

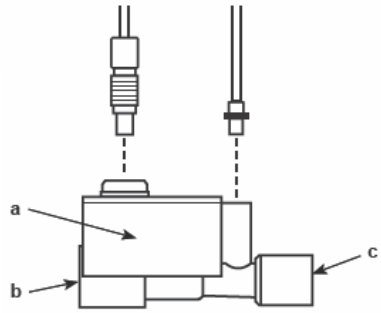
- Insert the Injector Module on the dry side of the breathing circuit prior to the humidifier (this will ensure correct flow measurement).

- Avoid medications interfering with the gas monitoring system; administer any aerosolized medications distal to the sampling tee.

Connection to a Dräger Babylog VN500, Dräger Infinity V500; Newport E360 Ventilator

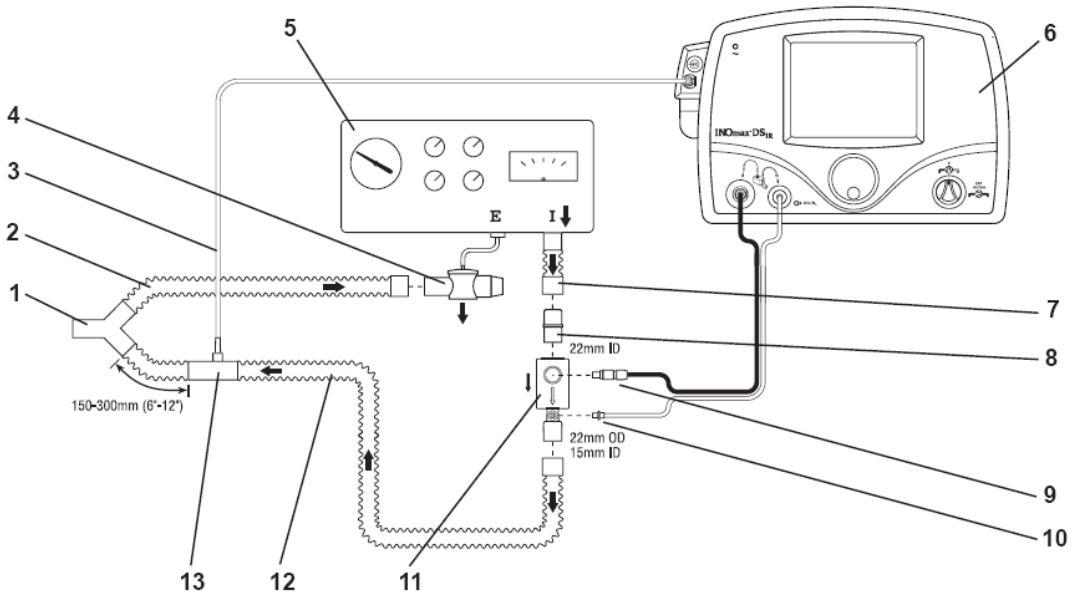


1. Patient Wye
2. Ventilator
3. Ventilator Expiratory port
4. Ventilator Inspiratory port
5. Patient Gas Sample Line Input Connection
6. INOmax DS/INOmax DS_{IR}
7. NO/N_2 Injector Tube Front Panel Connection
8. Injector Module Electrical Cable Front Panel Connection
9. Injector Module Electrical Cable Connection
10. Injector Module NO/N_2 Injector Tube Connection
11. Humidifier Inlet
12. Humidifier
13. Humidifier Outlet
14. Patient Gas Sample Line
15. Gas Sample Tee



a. Injector Module
b. 22F inlet
c. 22M / 15F outlet

Connection to an Impact Instrumentation EMV+ Ventilator

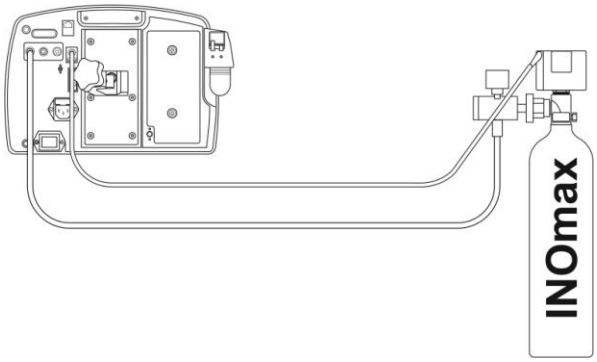


1. Patient Wye
2. Ventilator Expiratory Limb
3. Patient Gas Sample Line
4. Exhalation Valve
5. Ventilator
6. INOmax DS/INOmax DS_{IR}
7. Ventilator Inspiratory Port
8. 22mm Connector
9. Injector Module Electrical Connection
10. NO/N_2 Injector Tubing
11. Injector Module
12. Ventilator Inspiratory Limb
13. Gas Sample Tee

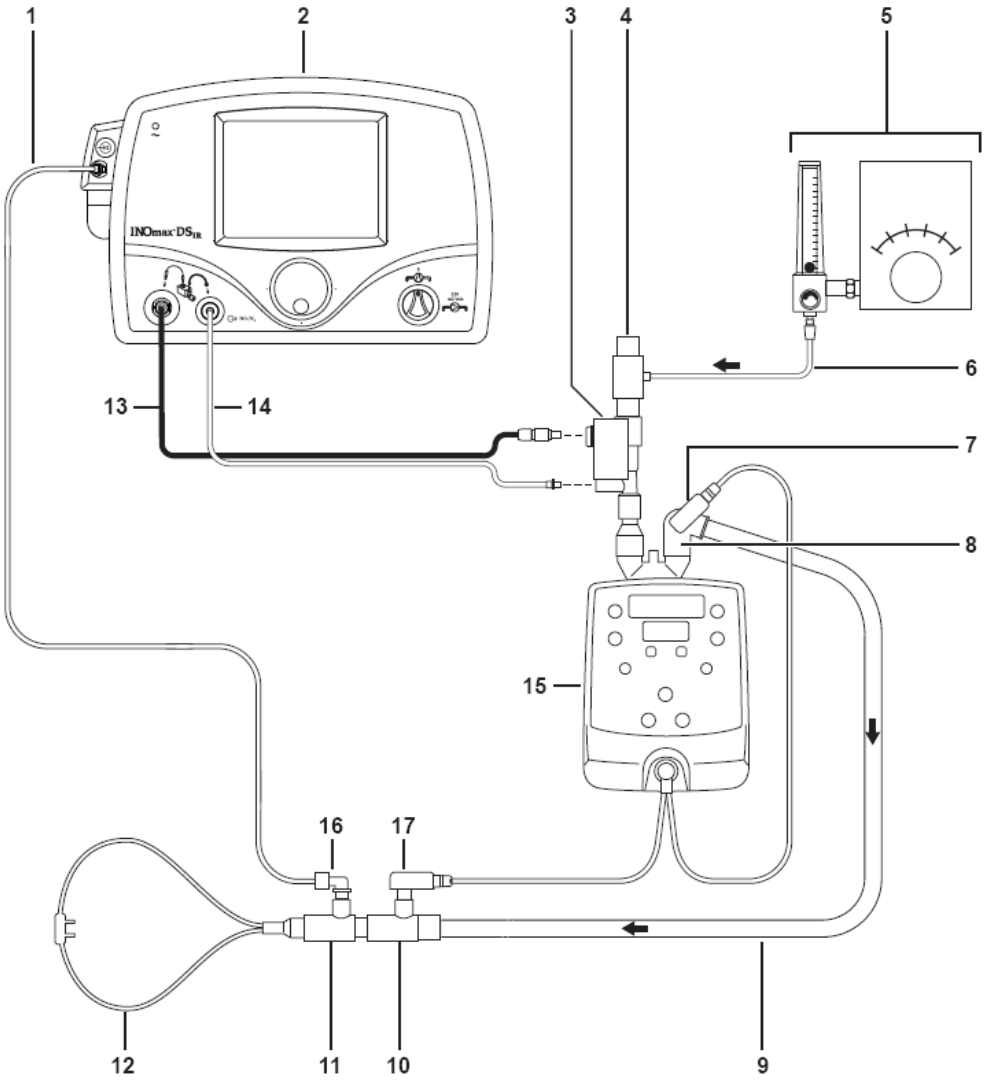
WARNING: If the INOmax DS/DS_{IR} is to be used in a transport vehicle, it should be affixed to the transport mounting post (part number 10009).

Transport Mounting Post

Caution: When using the Transport Regulator/Cap Assembly (PN 10022) ensure the cap is fully seated and in place on the INOmeter and the infrared cable is connected and latched to the infrared connector port on the back of the INOmax DS_{IR}.
It is recommended that a second Transport Regulator/Cap Assembly is available during all transports.



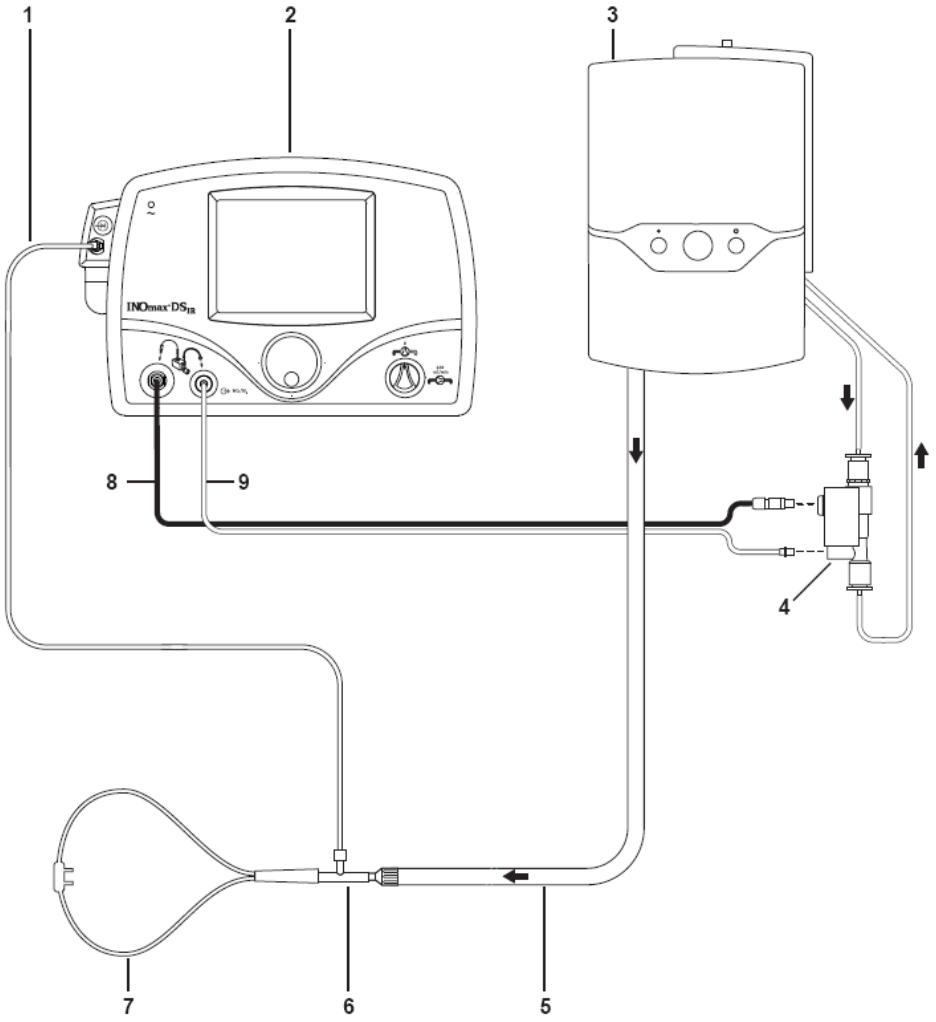
Connection to the Teleflex Medical Comfort Flo Humidification System



1. Patient Gas Sample Line
2. INOmax DS/INOmax DS$_{IR}$
3. Injector Module
4. System Pressure Relief Valve
5. Air/Oxygen Blender or Oxygen Flowmeter
6. Oxygen Tubing
7. Temperature Probe (Short Cable)
8. Angled 22 mm Connector
9. Patient Circuit
10. Temperature Probe Connector
11. Second Temperature Probe Connector
12. Comfort Flo Cannula
13. Injector Module Electrical Cable
14. NO/N_2 Injector Tube
15. ConchaTherm Heated Humidifier
16. 90 Degree Sample Port Adapter
17. Temperature Probe (Long Cable)

Connection to the Vapotherm Precision Flow

- The INOmax DS/INOmax DS_{IR} adds NO/N_2 gas flow to the breathing circuit flow in proportion to the NO setting (up to 10% at 80ppm) and subtracts gas from the breathing circuit via gas sampling at a nominal flow rate of 0.23 L/min.
- These effects impact the delivered gas flow rate when using the Vapotherm Precision Flow. It is recommended that after an NO setting change the user checks the delivered gas flow rate and adjusts the gas source flow rate as necessary.
- Follow all manufacturer instructions for connection to the Vapotherm Precision flow.



1. Patient Gas Sample Line
2. INOmax DS/INOmax DS_{IR}
3. Precision Flow Unit
4. Injector Module
5. Patient Delivery Tube
6. Oxygen Tubing Sample Tee
7. Patient Cannula
8. Injector Module Electrical Cable
9. NO/N_2 Injector Tube