



Technical Bulletin

Ref: **TB- 09003**

Product: INOmax[®] DS / INOvent[®]

Affected parts: INOmax DS / INOvent

Subject: **Ventilator Applications**

Issue date: **August 2009**

Priority: Low

Classification: Information

This technical bulletin is written to advise clinicians that the Sensormedics 3100A/B with a filtered circuit and the Heinen & Löwenstein Leoni-plus ventilator (outside the U.S.A.) are validated for use.

Warning: The approved patient population for the INOmax DS / INOvent, as specified in the drug labeling for INOmax[®] (nitric oxide) for inhalation, is limited to neonates. The INOmax DS / INOvent is not intended to be used in other patient populations.

Warning: The INOmax DS / INOvent 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 INOvent to the breathing circuit.

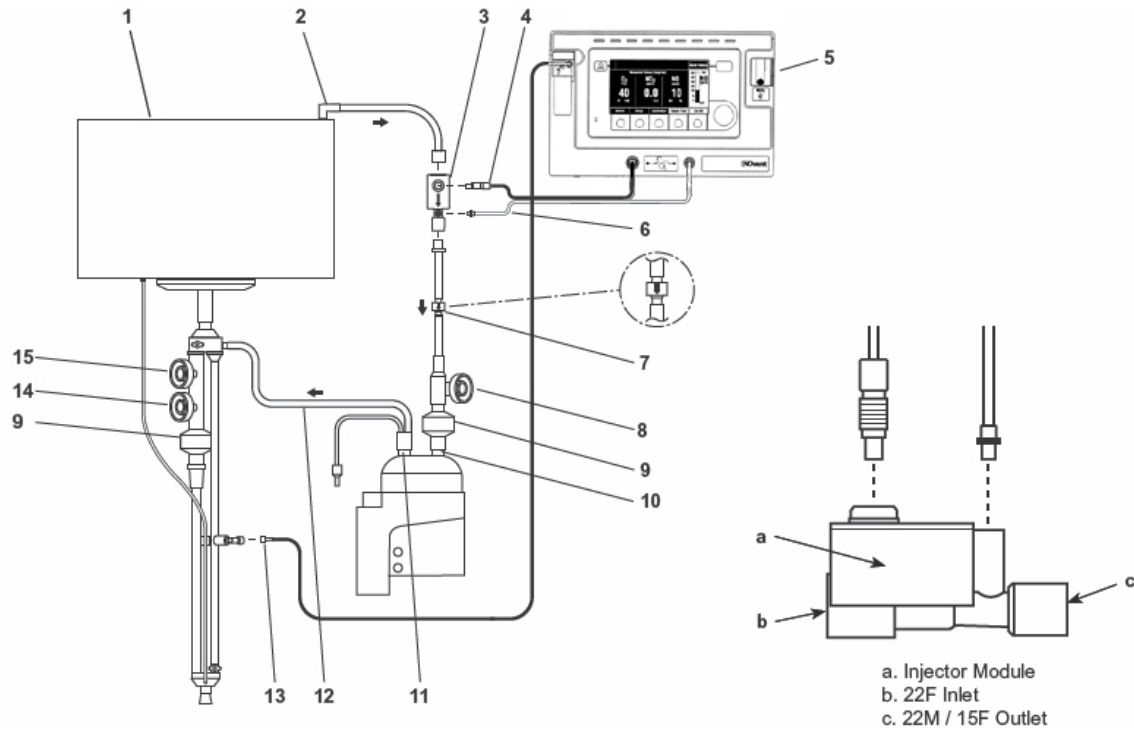
Warning: Omission of the one-way valve may result in high NO delivery when using High Frequency Oscillatory Ventilation (HFOV) with the Sensormedics 3100A/B and the Leoni+. Note the airflow direction arrow on the one-way valve. The flow out of the Injector Module must be through the one-way valve in the direction of the arrow on the valve.

The Injector Module should be used in the dry part of the breathing circuit to make sure flow measurement is correct.

To avoid medication interfering with the gas monitoring system, administer surfactants or other medications on the patient side of the sample tee.

Warning: Patient disconnect and high pressure alarms are required for the ventilator.

Connection to a Sensormedics 3100A/B Oscillatory Ventilator with a Filtered Circuit



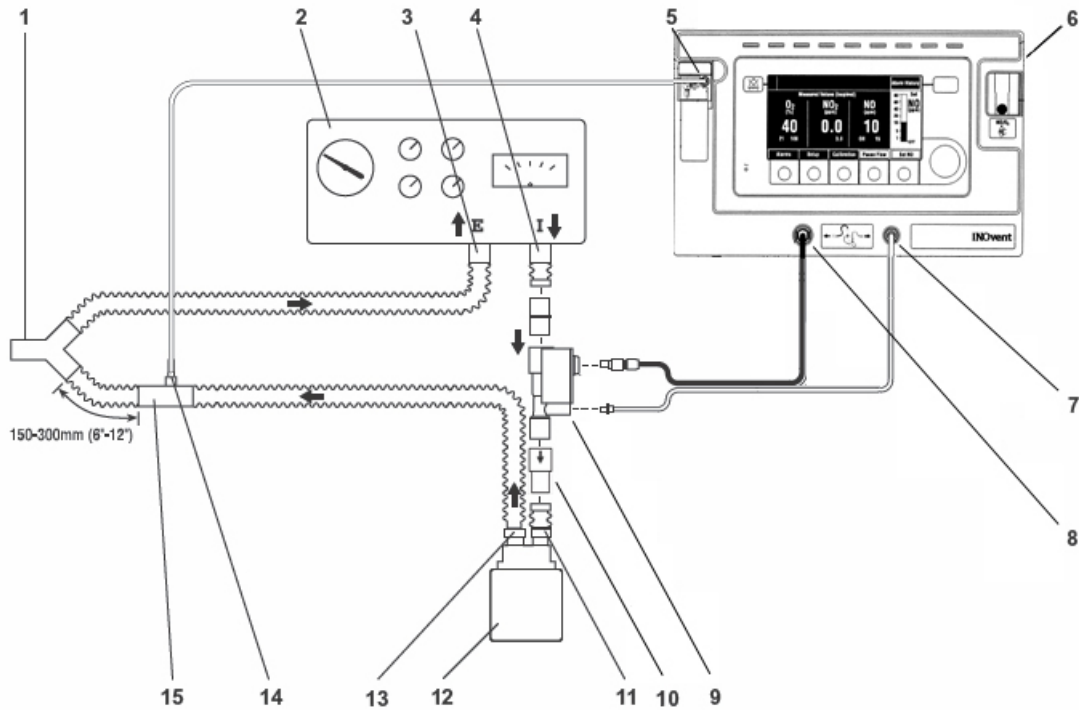
High Frequency Oscillatory Ventilator Diagram

1. Sensormedics 3100A/B Ventilator
2. Ventilator Outlet
3. Injector Module
4. Injector Module Electrical Cable Connection
5. INOmax® DS / INOvent®
6. NO/N₂ Injector Tube
7. One-Way Valve
8. Paw Limit Valve Control
9. Filter
10. Humidifier Inlet
11. Humidifier Outlet
12. Bias Flow Tube
13. Patient Gas Sample Line Connection
14. Dump Valve Control
15. Paw Control Valve

**Note: Use Sensormedics 3100A/B Filtered Circuit Disposable Adapters
Part Number-50071**

WARNING: Omission of the one-way valve may result in high NO delivery.

Connection to a Ventilator Circuit (Leoni-plus)



1. Patient wye
2. Leoni-plus Ventilator
3. Ventilator Expiratory Port
4. Ventilator Inspiratory Port
5. Patient Gas Sample Line Input Connection
6. INOmax® DS / INOvent®
7. NO/N2 Injector Tube Front Panel Connection
8. Injector Module Electrical Cable Front Panel Connection
9. Injector Module
10. One-Way Valve
11. Humidifier Inlet
12. Humidifier
13. Humidifier Outlet
14. Patient Gas Sample Line
15. Gas Sample Tee

Note: Use a one-way valve (Part Number- 1605-3139-000) when ventilating during the HFO mode.

WARNING: Omission of the one-way valve may result in high NO delivery.