

INOvent[®] delivery system

FOR NITRIC OXIDE THERAPY

INOvent application update #15

Please place with INOvent Operation and Maintenance Manual.

High Frequency Oscillatory (HFO) Ventilators Validated with Datex-Ohmeda INOvent delivery system

This Application Update is written to advise clinicians of the full list of HFO ventilators that have been validated for use with the INOvent delivery system.

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

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.

⚠ WARNING Patient disconnect and high pressure alarms are required for the ventilator.

⚠ WARNING Before using the INOvent delivery system on a patient with a ventilator that has not been validated, confirm compatibility in accordance with internal protocols or risk management guidelines.

⚠ CAUTION Note the airflow direction arrow on the injector module; the flow out of the ventilator must be through the injector module in the direction of the arrow on the module.

The injector module should only 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 on the patient side of the sample tee.

- When connecting breathing tubing, make sure it is long enough for any required equipment movement.
- Make sure that the system is not wheeled over tubing connected to a patient or to the equipment.

Important

Before using the INOvent delivery system, read and understand the Operation & Maintenance manual. Additionally read and understand the manuals for the ventilator, humidifier and any other accessory items used. Follow the manual instructions and obey Warnings and Cautions.

Know the proper setup and operation of the ventilator and the humidifier being used.

Keep all operation manuals readily available to answer questions.

The INOvent delivery system has been validated against the following high frequency ventilators used outside the United States:

F. Stephan GmbH *Stephanie**

Drager *Babylog 8000 +**

SensorMedics 3100A

SLE Life Support *SLE 2000 HFO and HFO+**

Note: The SLE 2000 HFO ventilators may require an additional patient sampling port in the inspiratory limb of the patient circuit. A suggested adaptor is Pennine Healthcare (UK) Neonatal T-piece part number N257-72.

Pennine website: www.penninehealthcare.co.uk

* New validations



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