



# Addendum to the User Manual

Software Version V1.6.x



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# 1 Validated respiratory devices

## General information

Always refer to the respiratory device manufacturer's operating manual for instructions on use.




### Warning:

- Nasal cannula disconnection may not be detected. Always use additional patient monitoring (e.g. SpO<sub>2</sub>) during NO treatment.
- Do not use a Heat and Moisture Exchanger (HME) device containing cellulose together with iNO therapy.
- Only accessories, supplies, and auxiliary equipment recommended by iNOsystems should be used with the NO delivery and monitoring system. Use of any other accessories, spare parts or auxiliary equipment may cause degraded system performance and safety issues.
- Do not use with closed circle anesthesia systems. The recirculation of expired gases may cause NO<sub>2</sub> intoxication, NO overdosing or hypoxia. N<sub>2</sub>O and other volatile agents may also affect NO monitoring.


The NO delivery and monitoring system has been validated to function as intended according to its user's manual under worst-case conditions when used with the following respiratory devices:

Validated respiratory devices								
Manufacturer	Model	Neonatal	Pediatric	Adult	High Frequency	NCPAP	High Flow Nasal Cannula	Additional information
Bunnell	LifePulse 203	X	-	-	X	-	-	See <a href="#">Bunnell LifePulse 203 (on the next page)</a> .
Dräger	Evita 2 Dura	-	X	X	-	-	-	
Dräger	Evita 2	-	X	X	-	-	-	
Dräger	Evita 4	-	X	X	-	-	-	
Dräger	Evita 4 XL	X	X	X	-	-	-	
Dräger	Evita Infinity V500	X	X	X	-	-	-	
Dräger	Babylog 8000 plus	X	X	-	-	-	-	See <a href="#">Babylog (on the next page)</a> .
Dräger	Babylog VN500	X	X	-	X	-	-	
Fisher & Paykel	Bubble CPAP	X	-	-	-	X	-	
Fisher & Paykel	Optiflow High Flow Therapy	X	X	X	-	-	X	
Getinge	Servo-n	X	X	-	X	X	X	See <a href="#">Servo-n, Servo-u, Servo-i (on the next page)</a> .
Getinge	Servo-u	X	X	X	-	X	X	
Getinge	Servo-i	X	X	X	-	X	-	
Sensormedics	3100A	X	X	-	X	-	-	
SLE	SLE5000	X	X	-	X	-	-	See <a href="#">SLE5000 (on the next page)</a> .
Viasys	Infant Flow SIPAP	X	X	-	-	X	-	
Puritan Bennett	PB980	X	X	X	-	-	X	See <a href="#">PB980 (on the next page)</a> .
GE	Carescape R860	X	X	X	-	-	X	See <a href="#">R860 (on the next page)</a> .
Löwenstein Medical	LeoniPlus	X	X	-	X	X	X	See <a href="#">LeoniPlus (on the next page)</a> .


The following warning applies to ventilators with High Frequency Oscillation (HFO) Ventilation functionality:

 **Warning:** The backup system is ineffective for **HFOV** patients. Make sure that alternative backup solutions are available for these patients.


The following caution applies to ventilators with High Frequency Oscillation (HFO) Ventilation functionality:

 **Caution:** Always use **Auto Sense** mode when changing ventilator mode between High Frequency Oscillation (HFO) Ventilation and conventional ventilation.

The following caution applies to Dräger **Babylog 8000 plus**:

 **Caution:** At delivered NO concentrations above 20 ppm, **Babylog 8000 plus** can erroneously and intermittently present tidal volumes of "0 ml".


The following caution applies to **Getinge Servo-n, Servo-u** and **Servo-i**:

 **Caution:** At delivered NO concentrations above 40 ppm, when used with a **Servo-i, Servo-u** or **Servo-n** ventilator system, delivery of tidal volumes below 50 ml can exceed specified tolerances by a maximum of 10%.


The following warnings apply to **Bunnell LifePulse 203**:

 **Warning:**


- Ensure a stable Servo pressure with the **Bunnell LifePulse 203**. A loss or drop in Servo pressure during iNO treatment will cause delivery of a temporary high NO concentration bolus when the Servo pressure is restored.
- Exposing the flow sensor to back pressures exceeding 15 psi may cause leakage resulting in a decrease or stop of NO delivery.

 **Note:** The **SLE5000** ventilator activates the *Connected patient not treated* alarm in Standby, also when ventilation is Off.


The following note applies to **SLE5000** and **PB980**:

 **Note:** The **SLE5000** and **PB980** ventilators activates the *Connected patient not treated* alarm in Standby, also when ventilation is Off.


The following caution applies to **PB980**:


 **Caution:** Connection of the system will result in increased resistance and compliance changes in the patient circuit. Use the appropriate flow sensor and adapt the patient circuit to the patient category before performing a ventilator **Pre Operational Check**.

The following warning applies to Puritan **GE Carescape R860**:

 **Caution:** At NO set dose of 80 ppm and cylinder concentration of 450 ppm, the Carescape R860 may trigger the *Error of expiratory flow sensor* alarm due to the significant additional flow of NO/N<sub>2</sub>.

The following note applies to **Lowenstein LeoniPlus**:

 **Note:** The added NO gas (and especially the associated nitrogen (N<sub>2</sub>)) has a significant impact on the sensitivity of the inspiration trigger of **Lowenstein LeoniPlus**. Due to this effect, adjustments may be required to prevent auto-triggering of the respiratory device.

 **Caution:** In HFO ventilation mode, it is mandatory to use the **CONSTANT RATE** dosing mode on **SoKINOX** with a flow rate setting of 7.8 L/min (BTPS). This setting is equivalent to the 7 L/min (ATP) fixed bias flow of the **LeoniPlus** in HFOV mode.







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