



Technical Bulletin

Ref: **TB- 12004**

Issue date: **March 2015**

Product: INOMax DS_{IR}[®]

Priority: Low

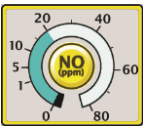

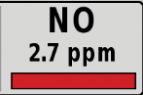
Affected parts: INOMax DS_{IR}

Classification: Information for Distribution

Subject: **Software Version 2.1.0 or 2.1.1**

INOMax DS_{IR} software versions 2.1.0 or 2.1.1 are follow-up releases to software version 2.0.4. Features are listed in the table below.

Changes to User Interface

	Alarm or Condition	2.1.0 or 2.1.1 Software Changes	User Impact
1	Under Delivery Alarm 	New Alarm: Under Delivery When the calculated INOMAX delivery is less than 50% of the set dose <u>for 12 consecutive seconds</u> , a low priority Under Delivery alarm activates This alarm is not active for set doses less than 5 ppm Drug delivery is NOT interrupted	New low priority alarm and graphic No interruption of therapy for under delivery condition
2	Delivery Failure Alarm 	<ul style="list-style-type: none"> <u>Delivery Failure Delay</u>: 12 second delay before high monitored value triggers delivery failure alarm <p>When the monitored NO is > 100 ppm, a High NO Alarm will be present. If the monitored NO remains above 100 ppm for 12 consecutive seconds, a Delivery Failure alarm occurs, immediately interrupting INOMAX delivery.</p> <ul style="list-style-type: none"> <u>Over Delivery Condition</u>: 12 second delay added to the over delivery condition <p>An over Delivery Condition is a calculated INOMAX dose greater than 200% of the set dose <u>for 12 consecutive seconds</u>. This results in a high priority Delivery Failure alarm interrupting INOMAX delivery</p>	The twelve second delay reduces the likelihood of a Delivery Failure alarm due to transient fluctuations in INOMAX monitored and delivered dose
3	Sensor Calibration 	High Calibration: Cross-checking during high O ₂ and NO calibrations Red calibration progress bar appears and high calibration fails when: <ul style="list-style-type: none"> At the end of O₂ high calibration NO₂ is greater than 5 ppm, or At the end of NO high calibration O₂ is greater than 10% 	Prevents high calibration if wrong calibration gas is used for O ₂ or NO

	Alarm or Condition	2.1.0 or 2.1.1 Software Changes	User Impact
4	Serial communications for use with hospital electronic health record (EHR) system	Data output active for INOmax DS _{IR} on rear RS 232 connector	Allows hospital data system connectivity Must be connected to Mallinckrodt specified third-party hardware and used only with the specified serial cable Contact an Mallinckrodt representative for more information

RS 232 Data Output

WARNING:

- **INOmax DS_{IR} should only be connected to RS 232 ports that have:**
 - **4 kV input to output isolation**
 - **4 kV input to mains isolation, and**
 - **an internal “reference voltage” “U” (as defined in section 20.3 of IEC 60601-1 ed. 2) of less than or equal to 50 VDC or 50 VRMS and dielectric isolation certified in accordance with IEC 60601-1. Interface cabling must not go outside of the room (e.g., into walls where potential isolation issues could exist).**
- **RS 232 cables must be shielded. The RS 232 cable shield shall have a minimum of 90% coverage. The shield shall only be connected at one end of the cable to minimize noise induced by ground currents.**

Notes:

- Connector retention jack posts can be found at the INOmax DS_{IR} RS 232 connector. The RS 232 interface cable/connector should be constructed to include cable retention fasteners to help ensure a robust connection.
- This serial communication protocol requires INOmax DS_{IR} software version 2.1.0 or 2.1.1 or higher to function. The software version of the device can be accessed by pressing the Menu Button on the Main Screen.

Data output includes:

Device information	Monitored values	Settings	Messages
<ul style="list-style-type: none"> • Device Model number • Device generated identifier • Software version • User generated patient identifier 	<ul style="list-style-type: none"> • O₂ • NO₂ • NO 	<ul style="list-style-type: none"> • INOMAX Dose Setting <p>Alarm set-points:</p> <ul style="list-style-type: none"> • High O₂ • Low O₂ • High NO₂ • High NO • Low NO 	<ul style="list-style-type: none"> • Device status • Alarm messages • INOMAX cylinder serial number and open/closed status

Note: A detailed document regarding output data format is available upon request. If you have further questions, please contact technical support at 1-877-566-9466 (North America) or your local representative.

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