

## SYSTEM SPECIFICATIONS

SPECIFICATION	DESCRIPTION
Electronic Medical Records Integration	Allows integration with an Electronic Medical Records (EMR) system, which enables auto-programming of infusion parameters and auto-documentation of infusion therapy information.
Pump and EMR Association Barcoding	<ul style="list-style-type: none"> <li>• 2-D Barcode on pump screen display</li> <li>• 1-D Barcode on pump screen display</li> <li>• Hospital Affixed Barcode</li> </ul>
Safety Features	<ul style="list-style-type: none"> <li>• Capability to integrate with hospital EMR for auto-programming and auto-documentation</li> <li>• Dose Error Reduction Software</li> <li>• Single Step Rate or Dose Change Limits</li> <li>• Time Change Alert</li> <li>• Keypad Lock</li> <li>• mL/hr Change Confirmation</li> <li>• Primary Check Flow Error Prevention</li> <li>• Secondary Check Flow Error Prevention</li> <li>• Allow/Disallow mL/hr programming for non-mL/hr dose modes</li> </ul>
Dose IQ Safety Software	<p>Web based software application that is used to configure a facility specific infusion pump drug library</p> <ul style="list-style-type: none"> <li>• Customizable drug alias for EMR integration</li> <li>• Safety limits for drugs and Care Area settings</li> <li>• Configurable single step rate change for all continuous and volume/time drugs</li> <li>• Integrated FDB Infusion Knowledge drug data entries based on clinical evidence</li> <li>• Drug library assigned with Digital Certificate for cybersecurity</li> <li>• Supports:               <ul style="list-style-type: none"> <li>○ 10,000 unique drugs and 32 care areas</li> <li>○ 1,000 modifiers, up to 5 per drug</li> <li>○ 800 clinical advisories</li> </ul> </li> <li>• Configuration of up to 5 concentrations per drug or modifier</li> </ul>

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Drug Library Transfer	<ul style="list-style-type: none"> <li>• Automatic drug library activation without end user intervention or power cycling of the pump</li> <li>• Transfer the drug library                             <ul style="list-style-type: none"> <li>• Using a wireless network connection any time the pump is on or off (when Sleep Mode is enabled in <b>Dose IQ</b> Safety Software)</li> <li>• Transfer the drug library from the PC to a pump using USB flash drive</li> </ul> </li> </ul>						
Real Time Location Services	When the system is in Sleep Mode (AC or Battery), the system reports its location to the network at the time interval ( $\pm 10\%$ ) set by the drug library file.						
Battery Sleep Mode	<p>The battery pack shall support Sleep Mode (Battery) of at least 14 consecutive days under the following conditions:</p> <ul style="list-style-type: none"> <li>• New, fully charged battery</li> <li>• Check-in interval of once per hour</li> </ul> <p>Available wireless network connectivity to Gateway</p>						
Weight	2.5 kg (5.5 lbs) – excludes power cord						
Overall Pump Size	<p>Excluding rubber feet:</p> <ul style="list-style-type: none"> <li>• Height: 10.4 cm (4.1 in)</li> <li>• Width: 25 cm (9.8 in)</li> <li>• Depth: 17 cm (6.7 in)</li> </ul>						
Alarms and Alerts Routing	The Secondary Alarm System (Alerts & Alarms Routing feature) sends Alarm Start and Stop messages from registered wireless connected infusion pumps to the Network Host (Gateway Server), which then translates those messages and routes them to a 3 <sup>rd</sup> party Alarms Management system for further distribution to Alarm Reporting devices.						
Volumetric Accuracy (Primary set codes)	<table border="1"> <thead> <tr> <th data-bbox="407 1591 727 1623">RATE</th> <th data-bbox="732 1591 1524 1623">ACCURACY</th> </tr> </thead> <tbody> <tr> <td data-bbox="407 1629 727 1667">0.1 – 0.9 mL/hr</td> <td data-bbox="732 1629 1524 1667"><math>\pm 10\%</math></td> </tr> <tr> <td data-bbox="407 1673 727 1711">1.0 – 1200 mL/hr</td> <td data-bbox="732 1673 1524 1711"><math>\pm 5\%</math></td> </tr> </tbody> </table> <p>Specified accuracy is maintained under standard conditions for up to 96 hours (maximum 12 liters).</p>	RATE	ACCURACY	0.1 – 0.9 mL/hr	$\pm 10\%$	1.0 – 1200 mL/hr	$\pm 5\%$
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1.0 – 1200 mL/hr	$\pm 5\%$						
Anti-Free-Flow System	Set-based, utilizing IV set slide clamp.						

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Infusion Delivery Modes	<ul style="list-style-type: none"> <li>• Continuous (Primary and Secondary)</li> <li>• Multi-Step</li> <li>• Amount/Time (Primary and Secondary)</li> <li>• Volume/Time (Primary and Secondary)</li> <li>• Basic mode</li> </ul>
Dose Modes: Continuous Infusions	mL/hr, mL/kg/min, mL/kg/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mg/kg/day, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, mcg/kg/day, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mUnits/kg/hr, mUnits/kg/min, mEq/hr, mEq/kg/hr, mmol/hr, mmol/kg/hr, MillionUnits/day
Dose Modes: Loading Dose and Bolus	mL, mL/kg, g, mg, mg/kg, mcg, mcg/kg, ng, ng/kg, Units, millionUnits, Units/kg, mUnits, mUnits/kg, mEq, mEq/kg, mmol, mmol/kg
Dose Modes: Amount/Time Infusions	mL/kg, g, g/kg, g/m <sup>2</sup> , mg, mg/kg, mg/m <sup>2</sup> , mcg, mcg/kg, mcg/m <sup>2</sup> , Units, Units/kg, Units/m <sup>2</sup> , mEq, mEq/kg, mmol, mmol/kg, MillionUnits, MillionUnits/kg, MillionUnits/m <sup>2</sup>
Flow Rate	0.01 – 99.99 mL/hr (precision 0.1 mL/hr) 100.0 – 1200.0 mL/hr (precision 1.0 mL/hr)
KVO	<p>Either <b>Dose IQ</b> configured KVO rate (default of 1 mL/hr if not configured) or the programmed rate between 0.1-50 mL/hr (whichever is less).</p> <p>For completion of secondary infusion, the pump will run at a fixed KVO rate of 1 mL/hr or the infusion rate if lower.</p>
Total Volume	0.1 to 9999 mL with 0.1 mL increments from 0.1 to 99.9 mL and 1.0 mL increments from 100 to 9999 mL
Patient Weight and BSA Limits	Weight Limits: 0.1 – 500 kg, BSA: 0.1 m <sup>2</sup> – 4m <sup>2</sup>
Tall Man Lettering	TALLman lettering functionality is provided to help distinguish between similar sound-alike drug names which may help reduce eye strain and assist the user in making the correct selection.

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Logging Memory	<ul style="list-style-type: none"> <li>While not in use, the pump’s memory will retain the last programmed setup screen for 24 hours.</li> </ul> <p>NOTE: Multi-step modes are retained until using the clear program soft key.</p> <ul style="list-style-type: none"> <li>The pump history log displays system errors and drug limit violation events in red type on the pump screen.</li> <li>In case the <b>Novum IQ</b> LVP pump is powered down, the pump history log will be maintained, and a time stamp will be added to the log recording the beginning and end of the down time.</li> <li>After a total loss of power, the contents of the log will not be lost.</li> <li>Minimum 4,400 Event Log Capacity</li> </ul> <p>NOTE: An event is any user-confirmed data entered into the pump. Once the maximum log file size is reached, the data for each new event replaces the data for the oldest event (the data for the oldest event is lost).</p>
AC Power Adaptor	<p>AC Power Adaptor, low profile, covers only one outlet, Medical Grade (IEC60601-1-2:2014):</p> <ul style="list-style-type: none"> <li>Input: 100-240 V~, 50-60 Hz, max current draw of 0.5A</li> <li>Output: 16 VDC/1.25A, short circuit protected</li> <li>Cord length: 3.0 m (approximately 9.8 ft)</li> </ul>
Battery Power and Capacity	<p><b>Novum IQ</b> Smart Battery Pack</p> <ul style="list-style-type: none"> <li>Lithium Ion, 10.8 VDC Nominal</li> <li>Battery operating time ≥8 hrs on a new fully charged battery (at 125 mL/hr at the default backlight setting and Wi-Fi on, without USB use)</li> <li>16 hr recharge time at 23°C ± 2°C (73.4° ± 3.6°F)</li> </ul>
Device Classification	<p>The <b>Novum IQ</b> LVP pump is classified according to Medical Electrical Equipment standards as:</p> <ul style="list-style-type: none"> <li>Class II Equipment</li> <li>Type CF Applied Part (Note: Applied part is IV Administration Set)</li> <li>Continuous Operation</li> <li>Disinfect according to manufacture cleaning instructions</li> </ul> <p>Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.</p> <p>IPX2 – Water protection (offers protection from dripping water when the device is rotated 15 degrees any direction from vertical for at least 10 minutes)</p>
Display	<p>Color LCD Front-Lit Super Fine TFT Screen with 800x400 pixel resolution</p>

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Alarm Volume and Tone	<ul style="list-style-type: none"> <li>• Variable, three levels: high, medium, low</li> <li>• Modern Tones as defined by IEC 60601-1 third edition</li> </ul>																
Maximum Allowable Pressure while in Downstream Occlusion	207 kPA (30 psi)																
Downstream Occlusion Detection	<p>Detection sensitivity is dependent on flow rate.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Setting</th> <th>Rate &lt;21 mL/hr</th> <th>Rate 21-00 mL/hr</th> <th>Rate &gt;200mL/hr</th> </tr> </thead> <tbody> <tr> <td>Low (L)</td> <td>2 psig</td> <td>4 psig</td> <td>6 psig</td> </tr> <tr> <td>Medium (M)</td> <td>5 psig</td> <td>8 psig</td> <td>11 psig</td> </tr> <tr> <td>High (H)</td> <td>9 psig</td> <td>12 psig</td> <td>15 psig</td> </tr> </tbody> </table> <p>The above table states nominal pressures.</p> <p>The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the maximum downstream occlusion alarm threshold is 0.6 mL. The maximum bolus volume generated as a result of operation of 25 mL/hr and reaching the maximum downstream occlusion alarm threshold is 1mL.</p>	Setting	Rate <21 mL/hr	Rate 21-00 mL/hr	Rate >200mL/hr	Low (L)	2 psig	4 psig	6 psig	Medium (M)	5 psig	8 psig	11 psig	High (H)	9 psig	12 psig	15 psig
Setting	Rate <21 mL/hr	Rate 21-00 mL/hr	Rate >200mL/hr														
Low (L)	2 psig	4 psig	6 psig														
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Bi-Directional Wireless Communication	<ul style="list-style-type: none"> <li>• EMR Integration</li> <li>• Drug Library Transfer</li> <li>• CQI Reporting</li> </ul> <p>Conforms to industry standards IHE profiles for device integration</p> <ul style="list-style-type: none"> <li>• PCD-01 (Auto-documentation volume increments)</li> <li>• PCD-10 (Auto-documentation events)</li> <li>• PCD-03 (Auto-programming)</li> <li>• PCD-04 (Alarm routing)</li> </ul>																
Operational Conditions	<p>Operating temperature: 15 °C to 40°C (59 to 104 °F), 10–80% relative humidity non-condensing.</p> <p>Atmospheric Pressure: 70 kPA to 102 kPA</p>																
Storage and Packing Conditions	<p>Storage temperature: -10 to +49 °C (14 to 120 °F), 10–80% relative humidity non-condensing.</p>																

SPECIFICATION	DESCRIPTION
Wireless Network Interface	<ul style="list-style-type: none"> <li>• Frequency: 2.4 Ghz, 5.0 Ghz</li> <li>• Standard: IEEE 802.11a/b/g/n/ac</li> </ul>
Software Updates	Wireless OTA Firmware, USB flash drive
Wireless Security	<ul style="list-style-type: none"> <li>• WEP (Wired Equivalent Privacy) <ul style="list-style-type: none"> <li>• Encryption: 64/128-bit (RC4)</li> </ul> </li> <li>• WPA/WPA2/802.11i <ul style="list-style-type: none"> <li>• Encryption: TKIP, CCMP(AES)</li> </ul> </li> <li>• WPA-PSK with passphrase</li> <li>• WPA2-PSK with passphrase</li> <li>• WPA-with • 802.1X Authentication</li> <li>• WPA2-with • 802.1X Authentication <ul style="list-style-type: none"> <li>• LEAP (WEP Only)</li> <li>• PEAP/MSCHAPv2</li> <li>• EAP-FAST</li> <li>• EAP-TLS</li> <li>• EAP-TTLS/PAP</li> <li>• EAP-TTLS/MSCHAPv2</li> <li>• TKIP</li> <li>• CBC-MAC Protocol-(AES-CCMP)</li> </ul> </li> </ul>
Air Detection:	<p>Detection sensitivity for the Air-In-Line Alarm is configurable through alarm settings to detect air bubbles greater than the following threshold limits: 50 µl, 100 µl, 200 µl, 400 µl.</p> <p>System also detects air accumulation 0.6mL to 1.5 mL over 15 minute period to provide a Max Air Detected Alarm.</p>

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Upstream Occlusion Detection	Time to detect upstream occlusion is dependent on occlusion distance and flow rate. Time to detection for an upstream occlusion 20 in. from the top of the pump is as follows:										
	<table border="1"> <thead> <tr> <th data-bbox="440 527 675 558">Flow Rate per hour</th> <th data-bbox="976 527 1146 558">Time to alarm</th> </tr> </thead> <tbody> <tr> <td data-bbox="440 579 529 611">0.1 mL</td> <td data-bbox="976 579 1154 611">&lt;270 minutes</td> </tr> <tr> <td data-bbox="440 632 659 663">1 mL to &lt;100 mL</td> <td data-bbox="976 632 1138 663">&lt;27 minutes</td> </tr> <tr> <td data-bbox="440 684 553 716">≥100 mL</td> <td data-bbox="976 684 1138 716">&lt;30 seconds</td> </tr> <tr> <td data-bbox="440 737 553 768">1200 mL</td> <td data-bbox="976 737 1138 768">&lt;30 seconds</td> </tr> </tbody> </table>	Flow Rate per hour	Time to alarm	0.1 mL	<270 minutes	1 mL to <100 mL	<27 minutes	≥100 mL	<30 seconds	1200 mL	<30 seconds
Flow Rate per hour	Time to alarm										
0.1 mL	<270 minutes										
1 mL to <100 mL	<27 minutes										
≥100 mL	<30 seconds										
1200 mL	<30 seconds										
	•										
External Interfaces	USB 2.0 Type-A receptacle, 250 mA										
Device Useful Life	10 years										

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GLBL/NIQ/20-0005 February 2020