

## SYSTEM SPECIFICATIONS

SPECIFICATION	DESCRIPTION
Electronic Medical Records Integration	Allows integration with an Electronic Medical Records (EMR) system, which enables features such as 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 Unique Identifier Barcode on pump screen display</li> <li>• 1-D Unique Identifier Barcode on pump screen display</li> <li>• Unique Identifier number 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>• Clinical Advisory</li> <li>• Hard and Soft limits</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	<ul style="list-style-type: none"> <li>• Web based software application that is used to configure a facility specific drug library for <b>Novum IQ</b> Infusion Pump. 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>– 5,000 unique drugs</li> <li>– 32 care areas</li> <li>– 1,000 modifiers, up to 5 per drug</li> <li>– 800 clinical advisories</li> <li>– Configuration of up to 5 concentrations per drug or modifier</li> </ul> </li> </ul>

A drug that is linked across multiple care areas counts as 1 unique entry. As an example, 1 unique drug added to all 32 care areas as linked counts as 1 drug.

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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 the drug library file)</li> <li>– Transfer the drug library using USB flash drive</li> </ul> </li> </ul>	
Real Time Location Services	<p>When the system is in Sleep Mode (AC or Battery), the system reports its location to the network at the time interval (<math>\pm 10\%</math>) set in the drug library file.</p>	
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 <b>IQ Enterprise</b> Connectivity Suite.</p>	
Weight	<p>2.8 kg (6.17 lbs) – excludes power adapter.</p>	
Overall Pump Size	<p>With IV pole clamp:</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>	
Volumetric Accuracy	<p><b>RATE</b></p> <p>0.5 – 0.9 mL/hr</p> <p>1.0 – 1200 mL/hr</p>	<p><b>ACCURACY</b></p> <p><math>\pm 10\%</math></p> <p><math>\pm 5\%</math></p> <p>Specified accuracy is maintained with Baxter Primary Infusion Sets under standard conditions for up to 96 hours (maximum 12 liters).</p>
Anti-Free-Flow System	<p>Set-based, utilizing administration set slide clamp.</p>	
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>	

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<p><b>Dose Modes:</b>  <b>Continuous Infusions</b></p>	<p>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.</p>
<p><b>Dose Modes:</b>  <b>Loading Dose and Bolus</b></p>	<p>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.</p>
<p><b>Dose Modes:</b>  <b>Amount/Time Infusions</b></p>	<p>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>.</p>
<p><b>Flow Rate</b></p>	<ul style="list-style-type: none"> <li>• 0.5 – 99.99 mL/hr (precision 0.1 mL/hr)</li> <li>• 100.0 – 1200.0 mL/hr (precision 1.0 mL/hr)</li> </ul>
<p><b>KVO</b></p>	<p>Either <b>Dose IQ</b> configured KVO rate (default of 1 mL/hr if not configured) or the programmed rate between 0.5 – 50 mL/hr (whichever is less).                      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>
<p><b>Total Volume</b></p>	<ul style="list-style-type: none"> <li>• 0.1 mL increments from 0.1 to 99.9 mL</li> <li>• 1.0 mL increments from 100 to 9999 mL</li> </ul>
<p><b>Patient Weight and BSA Limits</b></p>	<p>Weight Limits: 0.1 – 500 kg                      BSA Limits: 0.1 m<sup>2</sup> – 4 m<sup>2</sup></p>
<p><b>Tall Man Lettering</b></p>	<p>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.</p>

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<p><b>Logging Memory</b></p>	<p>While not in use, the <b>Novum IQ LVP</b>'s memory will retain the last programmed setup screen for 24 hours.</p> <p>NOTE: Multi-step modes are retained until using the clear program soft key.</p> <ul style="list-style-type: none"> <li>• In case the <b>Novum IQ LVP</b> 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>
<p><b>AC Power Adaptor</b></p>	<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>
<p><b>Battery Power and Capacity</b></p>	<p><b>Novum IQ LVP Smart Battery Pack</b></p> <ul style="list-style-type: none"> <li>• Lithium Ion, 10.8 VDC Nominal</li> <li>• Capacity 8 hrs (new battery that's fully charged for a minimum of 30 minutes, at 125 mL/hr at the medium backlight setting and Wi-Fi on)</li> <li>• &lt;16 hr recharge time from depleted battery state at 23°C ± 2°C (73.4° ± 3.6°F) during pump operation at 125 mL/hr, default backlight setting and Wi-Fi on.</li> </ul>
<p><b>Device Classification</b></p>	<p>The <b>Novum IQ LVP</b> 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 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 <b>Novum IQ LVP</b> is rotated 15 degrees any direction from vertical for at least 10 minutes)</p>
<p><b>Display</b></p>	<p>Color LCD SFT with 800x480 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" data-bbox="440 743 1516 940"> <thead> <tr> <th>Setting</th> <th>Rate &lt;21 mL/hr</th> <th>Rate 21-100 mL/hr</th> <th>Rate &gt;200 mL/hr</th> </tr> </thead> <tbody> <tr> <td>Low (L)</td> <td>2 psi</td> <td>4 psi</td> <td>6 psi</td> </tr> <tr> <td>Medium (M)</td> <td>5 psi</td> <td>8 psi</td> <td>11 psi</td> </tr> <tr> <td>High (H)</td> <td>9 psi</td> <td>12 psi</td> <td>15 psi</td> </tr> </tbody> </table> <p>The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the minimum 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 1 mL.</p>	Setting	Rate <21 mL/hr	Rate 21-100 mL/hr	Rate >200 mL/hr	Low (L)	2 psi	4 psi	6 psi	Medium (M)	5 psi	8 psi	11 psi	High (H)	9 psi	12 psi	15 psi
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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> </ul>																
Operational Conditions	<p>Operating temperature: 15 to 40 °C (59 to 104 °F) 10 to 80% relative humidity non-condensing.</p> <p>Atmospheric Pressure: 70 kPa to 102 kPa.</p> <p><b>NOTE:</b> For optimal Smart Battery Pack performance, keep the Smart Battery Pack at an operating temperature of 15 to 25 °C.</p>																
Storage and Packing Conditions	<p>Storage temperature: -10 to +49 °C (14 to 120 °F), 10–80% relative humidity non-condensing with battery discharged between 15–25% and placed in Shipping Mode.</p> <p><b>NOTE:</b> For longer term storage (greater than 2 weeks) discharge battery to 15–25%, place in shipping mode and store between -10 and 30 °C.</p>																

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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>• Encryption: CCMP (AES) Wireless Security</li> <li>• WPA2-PSK</li> <li>• 802.1X authentication                             <ul style="list-style-type: none"> <li>- PEAP/MSCHAPv2</li> <li>- EAP-TLS</li> <li>- EAP-TTLS/PAP</li> <li>- EAP-TTLS/MSCHAPv2</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 (default), 200 µl, 400 µl.</p> <p>System also detects air accumulation 0.6 mL to 1.5 mL over 15-minute period to provide a Max Air Detected Alarm.</p>										
Upstream Occlusion Detection	<p>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:</p> <table border="1" data-bbox="440 1325 1024 1514"> <thead> <tr> <th>FLOW RATE PER HOUR</th> <th>TIME TO ALARM</th> </tr> </thead> <tbody> <tr> <td>0.5 mL</td> <td>&lt;270 minutes</td> </tr> <tr> <td>1 mL</td> <td>&lt;27 minutes</td> </tr> <tr> <td>100 mL</td> <td>&lt;30 seconds</td> </tr> <tr> <td>1200 mL</td> <td>&lt;30 seconds</td> </tr> </tbody> </table>	FLOW RATE PER HOUR	TIME TO ALARM	0.5 mL	<270 minutes	1 mL	<27 minutes	100 mL	<30 seconds	1200 mL	<30 seconds
FLOW RATE PER HOUR	TIME TO ALARM										
0.5 mL	<270 minutes										
1 mL	<27 minutes										
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External Interfaces	USB 2.0 Type-A receptacle, 250 mA.										
Device Useful Life	10 years.										