



FOR IMMEDIATE RELEASE

BAXTER ANNOUNCES U.S. FDA CLEARANCE OF NOVUM IQ SYRINGE INFUSION PUMP WITH DOSE IQ SAFETY SOFTWARE

- *Furtheres Baxter's continued innovation in medication delivery and management*
- *Integrates Baxter's decades of leadership in infusion therapy with innovative digital health solutions to build on the company's proven technology for helping to protect infusions from medication errors*
- *Supports neonatal and pediatric clinicians and anesthesiologists to help provide safe, accurate infusions for vulnerable patients*

DEERFIELD, III., AUGUST 31, 2022 – Baxter International Inc. (NYSE:BAX), a leader in innovative technology for medication delivery, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of its new **Novum IQ** syringe infusion pump (SYR) with **Dose IQ** Safety Software, representing Baxter's latest developments for infusion therapy. The **Novum IQ** SYR has the capability to fully integrate with hospital electronic medical records (EMRs) through Baxter's **IQ Enterprise** Connectivity Suite.

Syringe infusion pumps are typically used to precisely deliver small amounts of fluid at low rates, often in pediatric, neonatal or anesthesia care settings. The **Novum IQ** SYR delivers a technologically integrated user experience with enhanced safety features, advanced connectivity, configurable anesthesia care settings and a robust portfolio of sets designed to help deliver optimum accuracy. Its user interface incorporates features including colored visual banners that clearly identify enteral delivery, a backlit keypad and guided syringe loading.

"We are thrilled to bring a new syringe infusion pump to the market that represents the next generation of Baxter's intelligent infusion ecosystem," said Heather Knight, president, Medication Delivery, Acute Therapies, Clinical Nutrition, Latin America and Canada. "Together, the **Novum IQ** syringe infusion pump, **Dose IQ** Safety Software and **IQ Enterprise** Connectivity Suite advance the interoperability and data insights needed to help prevent harm and personalize therapy for patients, including neonates and other fragile patients."

Protecting More Infusions with Advanced Technologies

Advancing the safety and efficiency of medication delivery and management is critical, as data continues to show the harmful burden of errors on patient safety.^{1,2} The **Novum IQ SYR** utilizes intuitive technologies built to help reduce infusion errors and was designed to meet rigorous FDA guidance for infusion devices, including cybersecurity.

The **Novum IQ SYR** features Baxter's **Dose IQ** Safety Software, a web-based, customizable drug library and dose error reduction system that supports clinicians and hospitals by:

- Helping ensure pumps are up to date with the latest drug and dose information through centralized access to drug library files
- Incorporating titration error prevention technology to provide additional safety measures for infusions
- Optimizing information technology infrastructure and accessibility
- Offering flexibility to scale as hospital systems and technologies evolve

In addition to fully integrating the **Novum IQ SYR** with hospital EMRs, Baxter's **IQ Enterprise Connectivity Suite**:

- Enables over-the-air operating system upgrades to all **Novum IQ SYRs** connected to a hospital's network
- Allows option to enable auto-programming and auto-documentation of infusion data through full bi-directional integration with EMRs
- Delivers near real-time infusion data and streamlined infusion reports
- Provides clear visualizations of infusion data across a hospital system, allowing efficient identification of safety and process issues at every level of care
- Offers option to implement tagless asset tracking that shows infusion pump location and status throughout the hospital, helping to save time and optimize resources

Baxter's **Novum IQ** platform, which currently includes the **Novum IQ SYR**, **Dose IQ** Safety Software and **IQ Enterprise** Connectivity Suite, was intentionally designed to be forward-looking, as Baxter plans to expand the platform through continued product development and additional

regulatory submissions. Another key part of the platform, the **Novum IQ** large volume pump (LVP), is currently available in Canada. Baxter's application for 510(k) clearance for the **Novum IQ** LVP in the U.S. remains pending. Subject to receipt of all necessary approvals, Baxter expects to introduce the **Novum IQ** platform in markets around the world to continue delivering a strong and streamlined experience for customers.

For more information on the **Novum IQ** SYR, please visit Baxter.com.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Novum IQ SYR Indications for Use

The **Novum IQ** syringe pump is intended to be used for the controlled administration of fluids. These include pharmaceutical drugs, parenteral nutrition, blood and blood products, and enteral nutrition. The **Novum IQ** syringe pump is intended to deliver an infusion through the following clinically accepted routes of administration: intravenous, arterial, enteral, and subcutaneous. The **Novum IQ** syringe pump is intended to be used in conjunction with legally marketed and compatible administration sets, syringes, and medications provided by the user. The **Novum IQ** syringe pump is suitable for patient care in hospitals and outpatient health care facilities. The **Novum IQ** syringe pump is intended for use on adults, pediatrics and neonates.

The **Novum IQ** syringe pump is intended to aid in the reduction of operator interaction through guided programming, including a way to automate the programming of infusion parameters and documentation of infusion therapies when integrated with an Electronic Medical Record (EMR) system. This automation is intended to aid in the reduction of programming errors. The **Novum IQ** syringe pump is intended to be used by trained healthcare professionals.

Dose IQ Safety Software Intended Use

Dose IQ Safety Software is intended to be used with the **Novum IQ** Syringe Pump to support the controlled administration of fluids. **Dose IQ** Safety Software is intended to allow users to create and



maintain drug libraries, including the configuration of pump settings for the **Novum IQ** Syringe Pump. **Dose IQ** Safety Software is intended to allow users to establish the facility-defined syringe list, which is a subset of Baxter's approved compatible syringes, for the **Novum IQ** Syringe Pump. **Dose IQ** Safety Software is intended to be used in hospitals and outpatient health care facilities.

Rx only. For safe and proper use of the products mentioned herein, please refer to the appropriate Operators Manual or Instructions for Use.

*This release includes forward-looking statements concerning the **Novum IQ** syringe pump, **Dose IQ** and **IQ Enterprise**, including potential benefits associated with their use and statements regarding future anticipated launches of the **Novum IQ** platform. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: demand for and market acceptance for new and existing products; product development risks; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of natural disasters, public health crises and epidemics/pandemics, regulatory actions or otherwise); satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filings on Form 10-K, Form 10-Q and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

Baxter, **Novum IQ**, **Dose IQ** and **IQ Enterprise** are registered trademarks of Baxter International Inc.

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¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5770837/pdf/bmjopen-2017-015912.pdf>

² <https://www.fda.gov/drugs/drug-information-consumers/working-reduce-medication-errors>