

WHY YOUR CHOICE OF INFUSION PUMP MATTERS TO PATIENT OUTCOMES

Understanding How Different Infusion Pump Technologies Impact Flow Accuracy, Resolution, and Continuity

Infusion Pump Overview

Infusion pumps are routinely used to deliver fluids, such as nutrients and medications, into a patient's body in controlled amounts.¹ Infusion pumps are used in a wide variety of settings including hospitals, clinics, infusion centers, and even in patients' homes. Infusion devices are designed for specific clinical applications, yet despite their widespread use, many of those who administer infusions may not fully understand how each system operates, and the differences of how each system actually delivers fluid.

Most devices used for delivery of liquids are designated as a "pump." Pumps can be further characterized by operation mechanism (mechanical, electronic), pumping mechanism design (peristaltic, elastomeric, syringe, diaphragm, rotary, piston, etc.), the medium being pumped (chemotherapy pump, pain pump, epidural pump, enteral pump, insulin pump, etc.), the application in which the pump is being used (ambulatory, stationary, etc.), special features (single-patient use, multi-therapy, "smart," etc.), by company name, or more.²

More advanced infusion pumps are equipped with safety features, such as alarms or other notifications that are intended to alert the user in the event of a potential problem. Some infusion pumps also include safety software to ensure that program settings remain within specified safety limits.

With so many types of infusion pumps available, careful consideration must be given when determining which device is appropriate for use in each scenario. Is the pump going to be used at a patient's bedside, or would an ambulatory pump, which is designed to be portable or wearable, be more appropriate? Is the fluid being infused considered to be high-risk, and does it require a higher degree of delivery accuracy? Are the additional safety features of integrated safety software applicable?

How infusion Pumps Operate

Understanding the basic mechanisms of how various pumping technologies operate can help ensure an optimal pump is chosen for use in specific applications. Summaries of how several of the most widely used infusion pump technologies operate is provided below.

Elastomeric Pumps



Elastomeric pumps use pressure to infuse medication. Fluid is loaded into the elastomeric pump, which is surrounded by the pressurized elastic reservoir. When the downstream tubing clamp is removed, the elastic constriction drives the fluid in the reservoir through the flow restrictor and into the patient. The flow restrictor, which is typically molded into the tubing or elastomeric reservoir, controls the accuracy of the rate of flow. The flow accuracy of these devices is typically $\pm 12 - 25\%$ or more. Elastomeric pumps are calibrated for accuracy under specific conditions by regulating temperature, altitude, the height of the device in relation to the patient's heart or insertion site, and viscosity (thickness) of the fluid being delivered. Any deviation in these conditions, including inadvertent pressure on the reservoir, can affect the delivery accuracy to an even greater degree than the calibrated accuracy described previously. These pumps are designed for use in applications where simplicity and portability are required, and flow accuracy is not important.

Syringe Pumps

Syringe pumps are electromechanical devices that use a motor mechanism to slowly compress the plunger of a loaded syringe, delivering its contents into a tubing connected with a patient. The motor of a syringe pump can either operate continuously (meaning that fluid is delivered constantly throughout the infusion) or pulsed (meaning that fluid is delivered in small boluses each time the motor rotates). The flow rate is controlled by frequency or speed at which the motor compresses the syringe. Syringe pumps, which are typically larger and heavier than other pumps, are often used in the hospital and are not intended for ambulatory use. Syringe pumps typically have a flow accuracy of ± 1 - 3%. These pumps are intended for use in applications where portability and pump size are not factors, and high flow accuracy is essential.

Peristaltic Pumps

Peristaltic pumps are electromechanical devices that use a series of small motor rotations to deliver fluid. Fluid is contained within flexible delivery tubing which is fitted inside the pump casing. As the motor in the pump turns, "fingers" or "rollers" squeeze and release the tubing, pushing a small amount of fluid towards the patient in a series of evenly spaced boluses, while prohibiting backflow.^{3,4,5}

Peristaltic pump motors are not constantly active during an infusion, but instead rotate in small, periodic rotations. The flow rate is controlled by changing the frequency of motor rotations. The flow accuracy of peristaltic pumps is typically between $\pm 2.5 - 6\%$. These pumps are often used in both hospital and ambulatory settings (depending on the size and weight of the pump). These pumps are ideal for use in applications where portability and safety are important, and high flow accuracy is required.

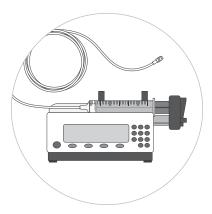
Understanding Resolution & Continuity of Flow

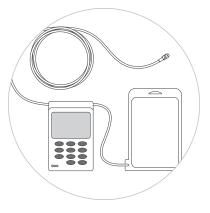
A solid understanding of infusion flow mechanics enables clinicians to optimally choose the appropriate device used to administer infusion therapies to their patients. Central to understanding infusion flow, and ultimately an infusion pump's therapeutic efficacy, is a pump's: 1) Accuracy, 2) Resolution of Flow, and 3) Continuity of Flow.

Accuracy

Accuracy is used to gauge how closely the average pump flow rate correlates with the programmed rate. Accuracy measurements are typically based on an average fluid delivery over a pre-determined amount of time. If a pump is programmed to deliver 50mL per hour, measuring the amount of actual fluid delivered after 60 minutes can show how accurate the pump is. If the pump delivered 55mL of fluid in 60 minutes, it is determined to have an accuracy of +10%.

actual mL delivered \div programmed mL = accuracy $55mL \div 50mL = 1.10, \text{ or } +10\%$



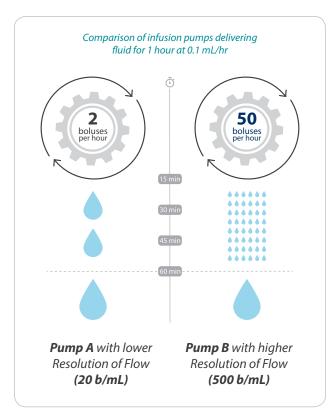


Resolution of Flow

In the printing industry, resolution is used to describe the amount of detail in a printed image. Print resolution is measured in dots per inch (DPI). The more dots of ink that are printed per inch, the higher the resolution of the image, therefore the higher the quality of image in terms of sharpness and detail.



Similarly, resolution can be used in infusion therapy to describe the amount of fluid pushed into the downstream tubing with each turn of the motor. Resolution of Flow can be quantified by determining the number of boluses required to deliver 1 milliliter of fluid - **boluses per milliliter delivered, or b/mL**. The more boluses that are delivered per milliliter of fluid delivery,



the higher the Resolution of Flow. Higher Resolution of Flow indicates that a pump is delivering fluid in smaller micro-boluses throughout the infusion.

For example, two infusion pumps are programmed to deliver medication at an infusion rate of 0.1 mL/hr. A pump with low Resolution of Flow may deliver 0.1 mL over 1 hour in only 2 boluses of fluid. This pump is determined to have a **Resolution** of Flow of 20 boluses per 1 mL delivered, or 20 b/mL. In comparison, a pump with high Resolution of Flow may deliver the same 0.1 mL over 1 hour in 50 smaller micro-boluses. This pump is determined to have a **Resolution of Flow of** 500 boluses per 1 mL delivered, or 500 b/mL.

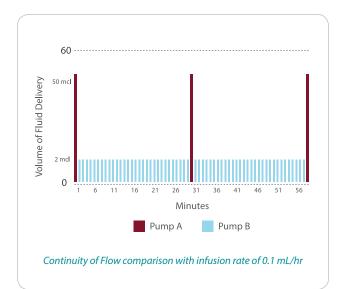
The same amount of medication was delivered with both pumps in 1 hour and with the same accuracy. However, the second pump had a Resolution of Flow that was 25 times higher than the 1st pump. This means that the second pump delivered the medication in smaller, more closely spaced microboluses throughout the infusion instead of in larger boluses with longer gaps between each bolus. Another way to view this example is to understand that while both pumps were set to the same flow rate, the first pump delivered a larger bolus of fluid every 30 minutes, while the second pump delivered a micro-bolus every 1.2 minutes. Infusion of smaller micro-boluses is often much more therapeutically effective than infusion of larger boluses administered less often, especially when infusing drugs at very low infusion rates (0.1 – 5mL/hr). This is even more important if these drugs have short half-lives. Evenly and closely spaced fluid delivery reduces the spiking and troughing of medication blood serum levels and provides a more constant therapeutic effect.

Many drugs have relatively short half-lives, and can be classified as critical or high-risk drugs. Most of these drugs infuse at very low infusion rates. Patients that are on these types of therapies are generally high-risk patients due to either their medical condition or the type of therapy that they are receiving. Some examples include inotropes, immunotherapy, chemotherapy, and pain management. In these cases, smaller, more closely spaced doses must be maintained for maximum clinical efficacy. At very low infusion rates, high Resolution of Flow becomes even more critical as it ensures that the time between infused boluses is minimized.^{6,7}

Continuity of Flow

Continuity of Flow describes a pump's ability to maintain accurate delivery of fluid boluses at precise time intervals throughout the entire infusion duration. In other words, Continuity of Flow represents how well a pump maintains its Resolution of Flow throughout the entire infusion therapy.

According to the Emergency Care Research Institute (ECRI), a no-flow period of 20-seconds or less maintains adequate drug levels and vessel patency. Pumps with higher Continuity of Flow ensure that this threshold is met by delivering boluses extremely close in time for more continuous fluid delivery. Such precise and steady medication transport to the patient ensures proper pain management,⁸ and increases the clinical efficacy of the drug.^{6,7}



The FDA's August 15, 2016 Syringe Pump Safety Communication emphasizes the importance of Continuity of Flow at low infusion

rates. Although syringe pumps have largely different indications than peristaltic pumps, programmable syringe pumps had routinely been used for low flow rate infusions. However, numerous reports of adverse events associated with programmable syringe pumps due to lack of flow continuity at low flow rates have been reported. The reports describe over- and under- infusion of high risk or life-sustaining medications, occlusion detection failures, inadvertent boluses caused by inconsistent fluid delivery, and other mechanical malfunctions that result in delays in therapy.⁹ These reports reinforce the importance of maintaining proper Continuity of Flow for optimal patient outcomes.

Ambulatory Infusion Pumps

An optimal infusion pump for critical drugs for at risk patients would combine the highest Resolution of Flow with consistent Continuity of Flow. The optimal pump would also incorporate many of the safety features designed into most electromechanical pumps, such as syringe and peristaltic devices. Resolution and Continuity of Flow are controlled by the fingers or rollers described previously in the Peristaltic Pump section. Adding more fingers or rollers increases Continuity of Flow, while placing these fingers closer together results in smaller volume of fluid in each bolus, which leads to higher Resolution of Flow.

A theoretical infusion pump could have a very large number of fingers or rollers that could be spaced very close together to deliver extremely high Resolution of Flow with consistent Continuity of Flow. However, although this pump may accurately deliver fluid, it would be much too large and heavy to use in an ambulatory setting. Designing an ambulatory pump meant for portability requires a delicate balance between fluid delivery performance and overall size.

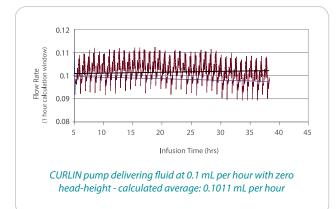
For an infusion pump to be used in ambulatory settings, it must be able to deliver fluid accurately, be of a size and weight appropriate for portability, offer sufficient battery life for a therapy's duration, and offer the programming and safety features necessary to ensure safe operation.

Various pumps on the market have been designed to deliver fluid as accurately as possible, while maintaining the other attributes required for ambulatory use. Each technology approaches these requirements from a different perspective, and each delivers unique strengths and weaknesses.

A Unique Curvilinear Design

Moog, a company with a deep history in precise motion control applications used across multiple industries, set out to create a design that would both maximize Resolution and





Continuity of Flow, yet could still be incorporated into an ambulatory sized device. The result was a unique curvilinear design of the pumping mechanism and fingers. The **CUR**vi**LIN**ear design (used in CURLIN brand ambulatory infusion pumps) essentially curves the pumping mechanism around the motor, allowing more fingers to be incorporated into a smaller space, resulting in a pump that delivers maximized Resolution and Continuity of Flow in a compact and durable footprint.⁹

Benchtop testing indicates that the CURLIN Ambulatory Infusion Pump is able to deliver an extremely high Resolution of Flow, even at low infusion rates. At an infusion rate of 0.1 mL/hr, the CURLIN pump delivers 50 microboluses per hour (500 b/mL) compared to the 2 boluses per hour with competitive infusion pumps (20 b/mL).⁷ Again, this translates to 1 micro-bolus every 1.2 minutes with the CURLIN pump, compared to 1 bolus per 30 minutes with competitive pumps. Fewer and smaller gaps between boluses while delivering the same amount of total fluid means the CURLIN pump delivers precise micro-boluses more accurately and more evenly throughout the infusion. The highly efficient delivery is ideal for short half-life drugs at low flow rates, any drug delivered at a low infusion rate, and for sensitive patient populations.

CURLIN infusion pumps are rooted in decades of proven curvilinear peristaltic pump technology, driven by clinical and market needs.³ These pumps have been carefully engineered to maintain maximum therapeutic efficacy while meeting today's toughest safety standards, making them an ideal infusion pump for today's home infusion market.

The Future of Ambulatory Infusion Care

The global home healthcare market is expected to grow to \$391 Billion USD in 2021.¹⁰ Much of this growth can be directly attributed to infusion pumps, which currently contribute to over one-half of all global home infusion market revenues.¹² This dramatic growth of home healthcare worldwide revenues is fueled by a convergence of pharmaceutical, institutional, legislative, payor provider, and patient drivers.

Specialty pharmacy products now dominate the pharmaceutical space^{10,12} and is the fastest growing segment.¹³ By 2020, one-half of all US drug spending will be on specialty products that serve only 2-4% of the patient population.¹³ Infused therapies alone comprise one-third of all specialty products.¹³

Providing a continuum of more proactive, timely, and infection-free care¹² has shifted these patients from hospitals to ambulatory settings with realized savings of up to 60% per infusion.¹⁴

Infusion therapy is also trending toward using biologics and micro-dosing. New intravenous drugs and biologic products are treating infections, cancer, and chronic diseases; and many of these medications can be administered more effectively in the patient's home. As a result, home infusion therapy pumps are getting smarter. These pumps are designed to increase accuracy, decrease usage errors, and promote efficiencies.¹⁵

With rising drug and biologics costs, every last drop truly counts - making efficient and accurate dosing even more important to payers, pharmacies, and patients.

But perhaps one of the most significant factors influencing the move towards ambulatory and home healthcare is the patients themselves. The U.S. Census Bureau reports that the number of Americans aged 65+ will double between now and 2050.¹⁶ Chronic disease risk,¹⁷ long-term care needs,¹⁰ and incidence of hospital-acquired disease is higher in this population.¹² High-risk patients requiring time intensive infusion-based therapies are proactively seeking more comfortable, convenient, and less costly ambulatory care alternatives.¹⁰

Clinicians today want more precise, accurate, and efficient infusion systems to meet the needs of the this quickly growing and more proactive high-risk population. The CURLIN Ambulatory Infusion Pump's unique curvilinear peristaltic design delivers the necessary Resolution and Continuity of Flow, ease-of-use, portability, and therapeutic efficiencies necessary for today's increasingly complex and changing home infusion market.

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For over 20 years, Moog Medical has been designing industry-leading curvilinear peristaltic infusion pumps. Our infusion expertise and collaboration with customers and patients continues to benefit healthcare delivery and enhance caregiver and patient outcomes.

Take an interactive tour of the CURLIN 6000 Pump at curlinpump.com. Or, call us at **800.970.2337** to schedule a demonstration or request additional information.



Speak live with a Moog Clinical Representative for pump questions and troubleshooting guidance 24 hours per day, 7 days per week.

Clinical & Customer Support 800.970.2337

Tel: 801.264.1001 Toll Free: 800.970.2337 Fax: 801.264.1051



4314 Zevex Park Lane Salt Lake City, UT 84123 USA

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curlinpump.com medcustomerservice@moog.com



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