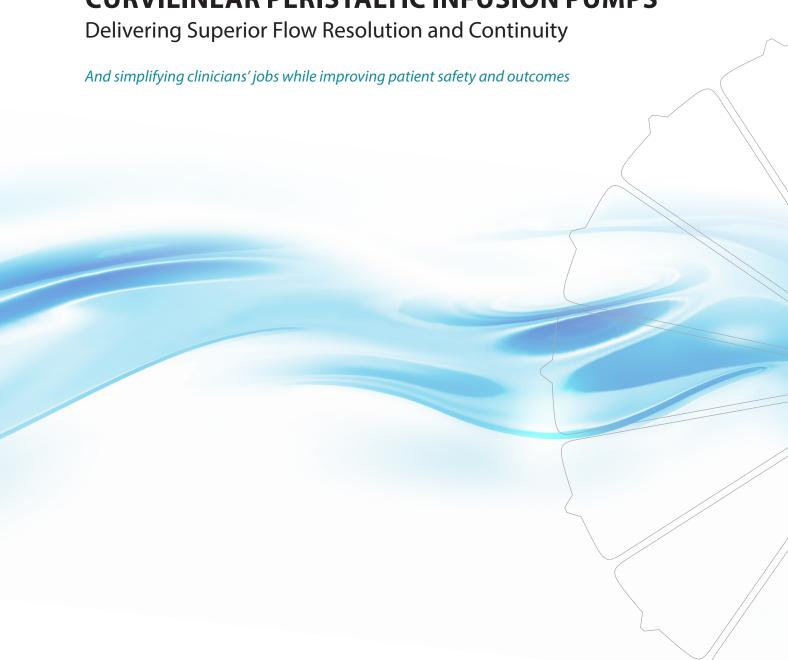


CURVILINEAR PERISTALTIC INFUSION PUMPS



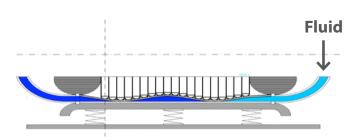
Curvilinear Peristaltic Infusion Pumps

The Peristaltic Infusion Pump, and in particular the more curved curvilinear design, is not only a preeminent infusion pump in today's medical field but is gaining traction as the infusion pump that can meet tomorrow's needs in delivering the most precise, accurate dosing.

Curvilinear peristaltic pumps are positive displacement pumps used for fluid transport in a variety of industries. They can deliver large volume fluids at both medium- to high-flow rates and slower rates where precision and accuracy are paramount. Today curvilinear peristaltic pumps are indicated for a variety of infusions such as continuous, patient controlled analgesia (PCA), total parenteral nutrition (TPN), intermittent and variable therapies, some of which may include intravenous, epidural, or subcutaneous delivery methods.

How Peristaltic Pumps Work

Peristaltic pump mechanisms are either linear or curvilinear. Both operate in similar fashion, using a sequence of pump strokes or "boluses". With each motor rotation, tubing is squeezed and released, thereby pushing fluid towards the patient in a series of evenly spaced micro-boluses while prohibiting backflow.^{2-3,5} Pumps utilize "fingers" to exert and release pressure on tubing to direct fluid flow towards the patient. Fluid volume and speed is dictated by factors including roller/finger size and number, pump settings that determine how close in time the "boluses" occur,³ the chosen infusion therapy and patient need.



"Fingers" of a peristalic pump move up and down, pushing fluid through the fluid path.

Physics of Flow Contribute to Clinical Outcomes

Just as a peristaltic pump's sound design contributes to clinical outcomes, so does careful patient assessment and clinician knowledge of pump and flow mechanics.⁶ Understanding venous and arterial pressure, vasculature

quality, medication, and patient age and condition is important to safe, effective delivery.⁶

Also key to patient outcome is understanding the physics of flow, which helps maintain adequate pressure and viscosity, keeps fluid pathways open, aids in selecting appropriate tubing/catheters, and prevents technical problems and complications such as infiltration.⁶

Central to the physics of flow, and ultimately an infusion pump's therapeutic efficacy, are:

- Resolution of Flow
- Continuity of Flow

Curvilinear Peristaltic Pumps Provide Enhanced Resolution of Flow

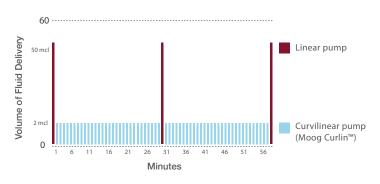
Curvilinear peristaltic pumps provide both accurate flow⁷ (Resolution of Flow) and steady, precise fluid delivery for even, extended duration (Continuity of Flow).⁴

Resolution of Flow occurs when the pump delivers large volumes of fluid in small, precisely timed increments. Fluid, in increments as low as 0.1-10 mL/hr, is delivered to the patient via small boluses at each motor rotation. With Curvilinear peristaltic pumps, small amounts of fluid can be delivered evenly over extended time periods. This allows for the administration of highly accurate low-rate infusions.

Resolution of Flow - Comparison of Linear and Curvilinear Pumps

For curvilinear infusion pumps, volume is delivered in smaller, more accurate increments than with linear pumps.





Expanding Applications for Curvilinear Pumps

Initially used primarily for inotropic therapies such as those delivering Dopamine and DOBUTamine to critically

ill patients³, curvilinear pump usage has been widely and successfully adapted, especially for:

High-risk populations:

- Neonatal
- Pediatrics
- Geriatrics

Chronic conditions:

- Cancers
- Cardiovascular & respiratory diseases
- Diabetes

Patients with these indications & conditions:4

- Fluid restrictions
- Severe shock
- Low rate infusions

Certain pharmaceuticals:

- Short half-life drugs
- Biologics
- Pain Management

Short half-life drugs are often selected for high-risk patients who also require low infusion rates. Accurate, evenly spaced doses must be maintained for clinical efficacy.

Today's pharmaceutical market and the future of infusion therapy are also trending toward using biologics and microdosing. 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. Products are designed to increase accuracy, decrease usage errors and promote efficiencies.⁸

According to the FDA, biologics may more effectively treat diseases, including those without current treatment methods.⁹ However, they also contribute to pharmaceutical price inflation. In 2008, biologics were used by 0.2% of the population, but totaled 8% of insured patient cost.¹⁰ Microdosing helps decrease R&D costs and can personalize medicine to more effectively treat disease.¹¹

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

Curvilinear Peristaltic Pumps Provide Effective Continuity of Flow

Continuity of Flow, defined as steady and precise fluid delivery, is equally important to a pump's therapeutic efficacy in critical patient populations.

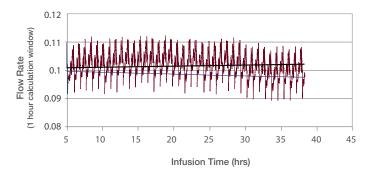
According to the Emergency Care Research Institute (ECRI), a respected organization for medical device review and testing, a no-flow period of 20-seconds or less maintains adequate drug levels and vessel patency. The curvilinear peristaltic pumps' fingers exceed these standards delivering boluses extremely close in time for more continuous fluid delivery. Such precise and steady medication transport to the patient minimizes catheter clotting⁷ and ensures proper pain management.⁴

The importance of Continuity of Flow is underscored with short half-life drugs. Smaller micro-boluses given more often are much more therapeutically effective than larger micro-boluses administered less often for drugs with short half-lives. This approach reduces the spiking and troughing of medication blood serum levels and provides a more constant therapeutic effect.

Continuity of Flow - Comparison of Linear and Curvilinear Pumps

For curvilinear pumps, volume is delivered in highly accurate, precisely timed increments even at low flow rates.

Curlin Pump delivering at .1 mL per hour with zero headlight Calculated Average: 0.1011 mL per hour



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 curvilinear peristaltic pumps, programmable syringe pumps had routinely been used for low flow rate infusions. Numerous reports of adverse events including delayed therapy, over- and underinfusion due to the lack of precise, steady fluid delivery had occurred¹² reinforcing the importance of Resolution of and Continuity of Flow to patient outcomes.

Other Benefits of Curvilinear Peristaltic Pumps:

Inherent to the curvilinear pump design is manifold, or pump housing, and tubing separation. Separation keeps fluid contained and both the fluid itself and the pump heads and their mechanisms contaminant free.¹⁻² This makes them ideal for sensitive and aggressive medical fluids,¹⁻² keeps pumps clean and sterile,² and minimizes, if not eliminates, the pump's exposure to abrasive material which prolongs pump life.²

Curvilinear peristaltic pumps offer priming flexibility, as they are capable of both self- and gravity-priming.² They also do not contain valves, seals or glands, which minimizes costs and chance of malfunction.²

The design of the curviliner peristaltic pump is also smaller, making it popular for use in ambulatory settings. The curved, streamlined design and widespread indications for use in numerous patient populations greatly interests specialty pharmacies. As a result, curvilinear peristaltic pumps are becoming popular with specialty pharmacies looking to trim operating costs via reduced inventory and offer one pump suitable for a wide patient audience.

Moog — Providing Safer, More Efficient Curvilinear Peristaltic Technology

Increased usage naturally increases medical error. Medication administration errors are the number one mistake occurring in hospitals today¹³ with IV therapy totaling 60% of all life-threatening errors.¹⁴ In 2012, the ECRI called infusion pumps one of the most dangerous technologies in medicine.¹⁵

Today's nurses, doctors and pharmacists proactively seek infusion therapies with safety protocols that make their jobs easier and peristaltic technology that improves patient outcomes.

Curvilinear peristaltic infusion pumps from Moog Medical Devices Group answer specialty pharmacy and, in particular, home infusion market demand. They bring the right combination of safety, clinical accuracy and precision, and ease of use.

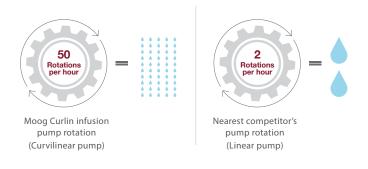


Moog Curlin Curvilinear Peristaltic Pump

Moog's patented CURviLINear (Curlin) Peristaltic Infusion Pump offers a unique, curved ambulatory design that's compact, durable and clinically reliable.⁴

At a low infusion rate of 0.1 mL/hr, the Curlin pump motor rotates 50 times per hour compared to the 2 rotations per hour with a linear pump. Fewer gaps between motor pulses to deliver the same amount of total fluid means the Curlin Pump delivers smaller, more precise doses more accurately and evenly per hour.

One hour at 0.1 mL/hr



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.

Additional benefits include: color-coded design features; upstream and downstream occlusion sensors; air bubble detectors; four lock levels; two-key turnoff function; and software checks and balance protocols that reduce medication and programming errors, ultimately minimizing both patient and caregiver risk.

Moog's multi-therapy infusion pump also meets most clinical needs via its continuous, intermittent, variable, TPN and PCA infusion options. Its simple, intuitive interface includes menu-driven protocols, HELP screens, and Information on Demand (IOD) status updates for increased ease of use and reinforced safety. The associated administration sets permit gravity-priming if desired, and include features that prevent over-infusion and minimize air bubbles and bacteria.

Moog's Curlin infusion pumps are rooted in decades of proven curvilinear peristaltic pump technology, driven by clinical and market needs.² They have been carefully engineered to maintain maximum therapeutic efficacy while meeting today's toughest safety standards, making them the perfect infusion pump for today's home infusion market.

Home Healthcare Market Revenues & Growth on the Rise

Today's global home healthcare market, an expected 355.3 billion USD valuation by 2020,¹⁶ can thank home infusion therapy–and specifically infusion pumps–for its surging revenues and demand.

Global home infusion therapy revenues total 13.2 billion USD, nearly 4% of the overall home healthcare market,¹⁷ with predicted 9% compound annual growth rate (CAGR) from 2016-2023.¹⁷ Infusion pumps currently contribute to over half of all global home infusion market revenues.¹⁷

Drivers Behind the Shift From Traditional to Home Healthcare

The home healthcare explosion and worldwide revenues are being fueled by a convergence of pharmaceutical, institutional, legislative, and patient drivers.

Pharmaceutical & Institutional Drivers

Specialty pharmacy products now dominate the pharmaceutical space and, despite their rising costs, ¹⁶⁻¹⁷ are the fastest growing segment. ¹⁸ By 2020, half of all US drug spending will be on specialty products that serve only 2-4% of the patient population. ¹⁸ Infused therapies alone comprise one-third of all specialty products. ¹⁸

Providing a continuum of more proactive¹⁹, timely and infection-free care¹⁷ has shifted these patients from hospitals to ambulatory settings with realized savings of up to 60% per infusion.²⁰

Legislative & Patient Drivers

Despite its challenges, navigating the specialty pharmacy world is often the preferred alternative to the ambiguous benefit and reimbursement payer environment.^{8, 21}

But perhaps one of the most significant factors influencing the move toward ambulatory and home healthcare are the patients themselves.

- The U.S. Census Bureau reports Americans aged 65+ will double between now and 2050.²²
- Chronic disease risk,²³ long-term care¹⁶ needs, and incidence of hospital-acquired disease is higher in this population.¹⁷
- High-risk patients requiring time intensive infusionbased therapies are proactively seeking more comfortable, convenient and less costly ambulatory care alternatives.⁸

Today's clinicians want more precise, accurate and efficient infusion devices to meet the needs of tomorrow's burgeoning, increasingly high-risk and more proactive patient population. The curvilinear peristaltic pump's thoughtful, curved ambulatory design delivers the flow resolution, continuity and therapeutic efficiencies necessary for today's discerning and increasingly complex home infusion market.

REFERENCES

- Dhumal, S. and Kadam, (April 2012) S.S. Design & Development of Rotary Peristaltic Pump. *International Journal of Science and Advanced Technology (ISSN 2221-8386)*, 2:157-63.
- Klespitz, J. and Kovacs, L. (January 23-25, 2014) Peristaltic pumps

 a review on working and control possibilities. IEEE International
 Symposium on Applied Machine Intelligence and Informatics, Herl'any,
 Slovakia, 191-194.
- Poxon, I. (July 1, 2004) Infusion pumps How to pick the best pump for the delivery of fluids. Nursing Times, Retrieved September 15, 2016, from https://www.nursingtimes.net/clinical-archive/medicine-management/infusion-pumps-how-to-pick-the-best-pump-for-the-delivery-of-fluids/200125.article
- Moog, Inc. (2011) 6000 CMS[™] and 6000 CMS[™] IOD[™] Ambulatory Infusion Systems Curlin Infusion Manual.
- World Health Organization (WHO), (2012) Infusion pumps, ambulatory. Retrieved September 15, 2016, from http://www.who.int/medical_devices/hospt_equip_15.pdf
- Mackin, D. Infusion Pump Therapy: A Guide for Clinicians and Educators. Retrieved September 20, 2016, from https://www.hospira.com/en/images/P11 3241 Infusion Pump Therapy Pocket Guide FINAL tcm81-90336.pdf
- Moog, Inc. (2012) Moog Medical Devices Group Internal Training 2012 Curlin Electronic Ambulatory Pumps.
- McClinton, Denis. (n.d.) The Right Dose. HomeCare Magazine, Retrieved September 15, 2016, from http://homecaremag.com/print/mag/home-infusion-therapy--200910
- Food and Drug Administration. What Are "Biologics" Questions and Answers. Retrieved October 1, 2016, from www.fda.gov/AboutFDA/ CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ ucm133077.htm
- LaFleur, J., et. Al. (May 2008) Trends in Pharmaceutical Expenditures: The Impact on Drug Benefit Design. American Health Drug Benefits, 1:4, 29-34, Retrieved October 1, 2016, from www.ncbi.hlm.nih.gov/pmc/ articles/PMC4106630
- Sennaar, K. (February 24, 2016) Microdosing and Drug Discovery.
 Retrieved October 1, 2016, from <u>www.almost/thedoctorschannel.com/microdosing-drug-discovery/</u>
- Food and Drug Administration (FDA). (August 15, 2016) Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences: FDA Safety Communication. Retrieved September 20, 2016, from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm518049.htm
- Ohashi, K., et. al. (2013) Evaluation of Intravenous Medication Errors with Smart Infusion Pumps in an Academic Medical Center. AMAI Annual Symposium Proceedings, 1089-1098.

- 14. Dennison, Donohoe. (November 2006) High-alert drugs: Strategies for safe I.V. infusions. *American Nurse Today*, 1:2, 1-9, Retrieved September 20, 2016, from https://www.americannursetoday.co/high-alert-drugs-strategies-for-safe-i-v-infusions/
- ECRI Institute via Healthcare IT News Release. (2012) ECRI Releases "The Top 10 Health Technology Hazards for 2013". Retrieved September 27, 2016, from www.healthcareitnews.com/press-release/ecri-releasestop-10-health-technology-hazards-2013
- Grand View Research, Inc. (Posted July 24, 2016) Home Healthcare Market to Witness Enhanced Demand in Infusion Therapy Services and Telemetry Till 2020: Grand View Research, Inc. Retrieved September 15, 2016, from http://www.grandviewresearch.com/press-release/global-home-healthcare-market
- 17. Global Market Insights (May 2016) Home Infusion Therapy Market Size By Product [Infusion Pump, Intravenous Sets, IV Cannulas, Needleless Connectors], By Application [Anti-infective, Hydration Therapy, Chemotherapy, Enteral Nutrition, Parenteral Nutrition, Specialty Pharmaceuticals] Industry Analysis Report, Regional Outlook (U.S., Canada, Germany, UK, China, Japan, Brazil, Mexico, South Africa), Application Potential, Competitive Market Share & Forecast, 2016-2023. Retrieved September 15, 2016, from http://www.gminsights.com/ industry-analysis/home-infusion-therapy-market
- Cassano, A., et. al. (2015) ASHP Specialty Pharmacy RESOURCE GUIDE. Retrieved September 15, 2016, from http://www.ashp.org/Specialty-Pharm-Guide-2015
- Marketsandmarkets.com (February 2010) Home Healthcare Market (Equipment, Service & Telehealth/Telemedicine) Current Trends, Opportunities & Global Forecasts to 2016. Retrieved September 15, 2016, from http://www.prnewswire.com/news-releases/home-healthcare-market-equipment-service-telehealthtelemedicine-current-trends-opportunities-global-forecasts-to-2016-161096445.html
- 20. Dalovisio, J., et. al. (April 4, 2000) Financial Impact of a Home Intravenous Antibiotic Program on a Medicare Managed Care Program. *Clinical Infectious Diseases*, 30:639-42.
- 21. URAC. 2011 Specialty Pharmacy White Paper The Patient Outgrowth of Specialty Pharmacy, 1-12.
- 22. U.S. Census Bureau, Economics and Statistics Administration, U.S. Department of Commerce (May 1995) *Sixty-Five Plus in the United States*. Retrieved September 28, 2016, from http://www.census.gov/population/socdemo/statbriefs/agebrief/html
- 23. HarrisWilliams &Co. (June 24, 2014) Home Infusion Industry Overview.

 Retrieved September 28, 2016, from www.harriswilliams.com/system/files/industry_update/2014.6.24_home_infusion_industry_overview.pdf



For more information or a complimentary demonstration of any of Moog's Infusion Therapy Devices, please contact (800) 970-2337.