Watson-Marlow Pumps Group

A Spirax-Sarco Engineering Company

Design Considerations When Sourcing Pumps for Medical Applications

machine design

medical design

Contents

Medical device manufacturers look for pumps that perform as specified, are simple to integrate into their equipment and are cost-effective. Their customers demand pumps that deliver consistent flow performance, are easy to set-up and maintain with reliable and easy change-over.

Medical manufacturers specify Positive Displacement (PD) pumps for controlled fluid movement, as they deliver a fixed volume per revolution or stroke, making them ideal for critical medical applications. Peristaltic pumps (sometimes referred to as "tubing pumps") fall into the PD pump category.

Peristaltic pumps are inherently hygienic by design and there are no valves or seals. The fluid is sealed within a tube so there is no contamination while delivering a wide range of flows and pressures with low shear. Above all, ease of tube changing makes peristaltic pumps suited for working with disposable tube sets in applications such as irrigation, flushing, ablation and dilution.

Watson-Marlow Pumps Group (WMPG) is the world-leading peristaltic pump manufacturer, continually investing in the development of new pumps, drives, controls and tubing. Combining new technologies into innovative pump solutions extends the use of peristaltic pumps to medical devices, meeting the needs of device manufacturers consistently and cost-effectively.

An in-depth understanding of WMPG peristaltic pump design features and corresponding benefits are provided in this eBook.

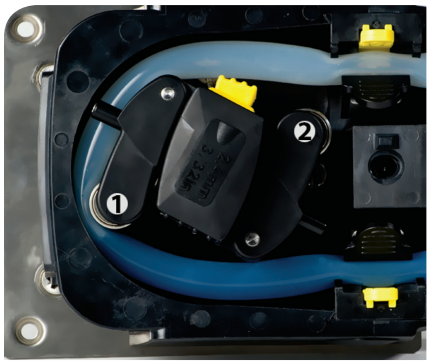


Figure 1A: Roller #1
Compresses the tube and fluid is drawn in behind the roller.

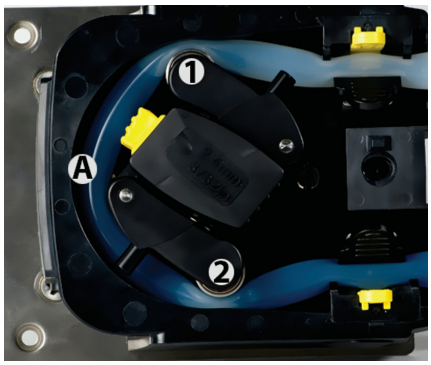


Figure 1B: Roller #2
Pinches off the tube behind the fluid column A drawn in behind roller #1.

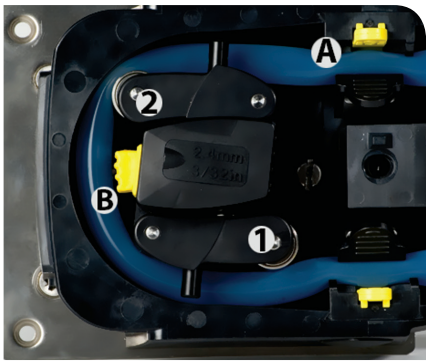


Figure 1C: Roller #2
Expels fluid column A, and draws in fluid that will get pinched off by Roller #1 and become fluid column B. B gets expelled by roller #1 and the cycle repeats.

How Peristaltic Pumps Work

A peristaltic pump derives its name from "peristalsis," which is the bodily process of moving fluids through a tubular organ by progressively squeezing and expanding it through the use of muscles on the outside. The most common example of peristalsis is the esophagus that enables us to swallow liquids even when upside-down, as the constricting peristaltic action overcomes the force of gravity on the liquid. The peristaltic pumping action extends natural "peristalsis," into a controllable and accurate fluid delivery system.

To mimic this natural process in a peristaltic pump, an elastomeric tube is squeezed against a semicircular track by two or more rollers mounted to a rotating rotor. The tube gets compressed by first roller contact and recovers to its full cross-sectional area after the roller passes. This creates a vacuum that draws fluid into the cavity created behind the advancing roller. As the rotor rotates, the rollers continue to push as well as draw in new fluid under, creating a continuous flow rate. **[Fig 1]**

The mechanical ability of the tube to recover its cross-sectional area after its compression (or occlusion) against varying suction and discharge pressure conditions is the determining factor of a peristaltic pump's performance and reliability.

Compressing a tube by squeezing it between a roller and track may seem straightforward, but it's the primary design consideration of a peristaltic pump, taking into account heat dissipation, tube wall thickness and hardness, tube surface abrasion and creep, track diameter and the diameter and number of rollers required to hold prime.

When designing a pump, it is crucial to consider all of the aforementioned design variables that often conflict and will result in a poorly performing pump. Peristaltic pumps designed by WMPG are developed through years of experience and testing, using high-end engineered plastics, low-friction bearings, spring-loaded rotors and tracks, and special tubing formulations in a range of configurations to guarantee consistent flow for the longest period possible.

WMPG peristaltic pumps for medical devices have the following attributes

- Flow rates range from 1 microliter per minute to 2 liters per minute
- Pressure capability to 100 psi for the smaller flows
- Multiple tube sizes can be used in the same pump to change the capacity of the pump
- No pump or fluid contamination
- Ease of operation/maintenance
- No valves, seals or glands
- Accurate and repeatable flow rates
- Reversible flow direction
- Self-priming and dry running

Flow rate. The flow rate of a peristaltic pump is proportional to the square of the diameter of the tube I.D. (inner diameter). With the ability to accommodate a range of tube diameters, a single WMPG pump can cover multiple flow ranges, whereas other technologies require many different models to accommodate varying flows.

Pressure and suction. A peristaltic pump can overcome up to 0.9 bar suction pressure and displace up to 100 psi back pressure, maintaining flow linearity.

No pump or fluid contamination. With a peristaltic pump, the only wetted part is the elastomeric tube. In a sanitary medical application, the pump will not contaminate a sterile fluid in the tube, and the pump will not require cleaning. In most medical applications, the tube is part of a disposable tube-set that is connected to other components such as a catheter.

Ease of operation. In applications where a disposable tube set is required, the tube must be replaced once per procedure, which could occur several times each day. It is critical that tube changeover is done correctly to avoid compromising pump performance and adversely affecting patient care. Ease of operation comes from simple tube loading. WMPG first introduced "flip-top" pumpheads to meet this need with the 313, later followed by the 114 and 400RXMD, each breaking ground for wider use of peristaltic pumps across the medical device market.

No valves or seals. A peristaltic pump requires no valves in its operation because at least one roller is always compressing the tube against the track, preventing backflow or siphoning when the pump stops.

Accurate, repeatable flow rates. Because peristaltic pumps are positive displacement pumps moving a fixed volume for each revolution, flow rates are linearly proportional to speed over the pump's recommended speed range. When calibrated to account for system losses, the pump can achieve a metering or dosing accuracy of +/-0.5%.

Reversible flow direction. Peristaltic pumps are reversible and can be used to flush out and empty lines.

Self-priming and dry-running. Peristaltic pumps need no priming and can run dry without damage. This feature allows the pump to pump air and gas mixtures.

Pulsation control. With most positive displacement pumps that deliver a fixed volume per pump stroke or revolution, pulsation or pressure drop can be observed. This is easily overcome with peristaltic pumps by offsetting pump rotors or tracks in conjunction with twin tubing manifolds to deliver a continuous fluid stream.

Pump Design

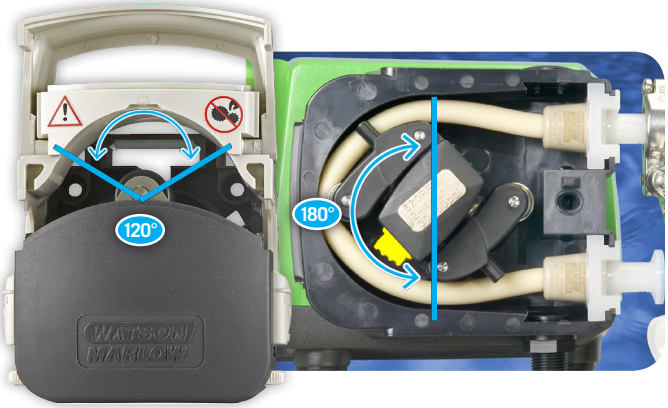


Figure 2: Typical track angles for peristaltic pumps.

The basic hardware of a peristaltic pump is the track and rotor that holds the rollers. The track describes the arc of a circle, and is specified by pitch circle diameter and track angle. The track angle is the portion of the circle where the rollers engage the tubing. Typical track angles are 180 degrees or 120 degrees. To function, the tubing pump must have at least one roller sealing the tube at all times. To achieve this, the minimum number of rollers that a pump must have is equal to 360/track angle. This means that a 180 degree track must have at least two rollers, and a 120 degree track must have at least three. **[Fig 2]**

Pumps with a 180 degree track angle offer a higher flow per revolution and fewer tube compressions, leading to longer tube life. The 120 degree pumps are more compact, and offer a lower magnitude pressure pulse on the outlet stream.

Another key design parameter is the amount of occlusion, or the amount of compression, that is applied to the tube by the rollers. The gap is specified in relation to the wall thickness of the tube and represents an over-compression less than two times the wall thickness. If the compression is too low, the seal and pressure performance will be compromised and there will be no safety margin to account for variations in the wall thickness. If the compression is too tight, tube life will decrease and the flow will drop off more quickly.

High-quality designs use a spring in the rotor arms or track. A spring provides a method to make up for tolerances of the tubing and pump components. Spring-loaded designs also offer longer tube life and more stable flow rates over time.

Custom Products

The 313 pumphead can be customized for coloring to match a company's logo or branding.

Custom Products

Although many standard products usually exist in a manufacturer's portfolio, most generally require some level of re-engineering or customization to extend the capability of a pump, or simply to value engineer a standard solution to meet a budget. These changes can range from a simple adjustment in roller diameter to accommodate special tubing, or more involved work such as custom drive software, or even complete new pump designs.

The key to successful customization is experience in solving design issues that arise when integrating a pump into a larger complex medical device. WMPG offers the unique service of dedicated engineering teams for OEM customer projects, working with customer R&D engineers to validate pump performance and support integration into existing electronics and controls to achieve necessary design approvals. This is especially relevant to motors and drives to ensure accurate control of the pump flow rate through varying fluid system conditions.

Quality and Regulatory Issues

Products that are proven and accepted in the medical device industry will shorten the development time for customers looking to use that same pump in a new device. This will save considerable costs upfront and get the product to market faster where it can start generating revenue. It is also important that a supplier have a robust quality system registered to standards such as ISO 9001 and ISO 9002. The quality system must have sufficient design controls in place to provide notifications to customers of any changes to the product.

Peristaltic Pumps Designed for Medical Device Applications

To best illustrate how design knowledge is applied to deliver marketable pump solutions, a number of new products developed by Watson-Marlow Pumps Group and applications are now discussed.

Small, Smart, Secure 114 OEM Pumps
Watson-Marlow 400RXMD OEM Pump.

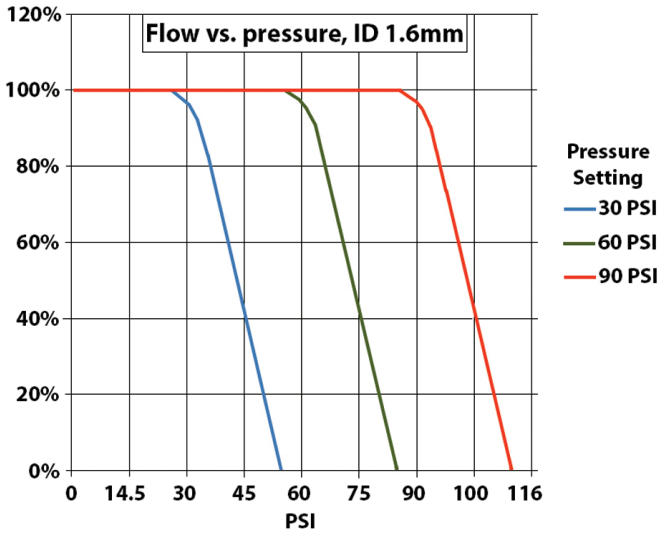
400RXMD Pumps

The latest product launch from WMPG is the new 400RXMD pump range, specifically designed for the surgical ablation market. With a range of pressure settings up to 87 psi, improved flow accuracy and innovative safety features, the 400RXMD illustrates how extensive research and development with market-leading medical companies ensures a pump meets the demands of surgical ablation applications to improve treatment of cardiac arrhythmia and cancer, as well as many other surgical procedures.

The newly launched 400RXMD pump range retains the dependable performance and design features of its predecessor, yet contains many new improvements, including a range of precise pressure settings that allows tailoring to specific application requirements. An innovative spring mechanism provides up to 50 percent improved flow accuracy, while a new profiled tube holder ensures the tube locates in the right position every time the safety lid is closed, providing rapid, trouble-free tube loading. This minimizes the risk of human error, safeguarding the process.

This simple, robust, market-leading pump solution is perfect for equipment that requires cooling as part of a radio frequency (RF) ablation system. As such the pump is part of a larger system that includes an RF generator and a catheter. The 400RXMD device pumps cooling fluid to provide precise temperature control, producing a more effective treatment and preventing scarring and unwanted tissue damage.

Figure 3: 400RXMD



The 400RXMD is available in many different variants that provide a highly precise pumping action, ideal for the medical device industry. The 400RXMD pump offers flow rates up to 500 ml/min and pressures up to 90 psi depending on tube size [Fig 3]. With stepper and brushless motors options available, the 400RXMD pump can be adapted to a wide range of pressure and flow rates according to application requirements.

114 OEM pumps

The 114 range of pumpheads is a continuation of the very successful 313 series, filling the medical device market niche for flow rates up to 350ml/min in a very compact and appealing panel-mount pumphead design.

The 114 retains the iconic design styling of the 313 and is available in a range of colors, adding appeal to any medical device. The flip top design allows for easy, fast and foolproof tube changes. Its spring-loaded track provides superior tube life and adjustable pressure performance.

Small, smart, secure 114 OEM Pumps

Complete product range for low flow OEM applications.

The pumps come with a range of motor options and can be supplied with both a revolution counter and safety interlock feature. Its high quality, low-audible noise gear motor package provides exceptional service life and control flexibility as a robust, well-balanced 'plug-and-play' solution. These unique features of the 114 pumphead range have universal appeal across a range of OEM Medical Device market sectors including dental, surgical and dialysis equipment.

TIP Pumps can be supplied in colors that match a company's logo or branding, which makes the pumps look like an integrated part of the machine.

DriveSure™
The fully integrated panel mount pump drive solution for OEMs by Watson-Marlow is designed to drive a variety of pumpheads. Shown: DriveSure 313 pumphead configuration (right) and DriveSure 400RXMD pumphead configuration (below).

Drive Consideration

When selecting a panel-mount peristaltic pump, correct gear motor and drive specification is a key contributor to reliable pump performance. Manufacturers need to match the torque requirement of a particular pumphead and tube with the torque deliverable of the gear motor through the desired speed control range. As such this selection should be a key contender for unit cost allocation.

However, proper evaluation of gear motor and drive options available is often ignored in the face of a low-cost solution that could, on the face of it, provide an overall device cost saving. This ironically can be one of the most expensive decisions an OEM can make. It remains commonplace in the market for OEMs to specify inexpensive gear motors and drives that function well in a controlled environment but often fail against the rigors of day to day device use.

Noting the difficulty customers often experience when matching gear motors to varying torque requirements of peristaltic pumpheads, WMPG recently launched DriveSure™, a plug-and-play integrated brushless DC gear motor and controller range that is designed to drive the 102R, 114, 313, 400RXMD, 501RL and 520R pumpheads.

The panel-mount DC brushless motor with integrated speed controller eliminates time, design uncertainty, and the risk associated with the separate specification of pump motor, gearbox and drive and comes with a comprehensive two year warranty. DriveSure features 8-408 rpm (51:1) speed control and directly accepts market-standard analogue control signals such as 0-10V and 4-20mA and is available in 24V and 48V supply options.

Application Examples

Peristaltic pumps lend themselves to a wide range of applications. A few specific examples of medical design solutions from Watson-Marlow are given below, along with the main benefit for choosing that particular pump design.

Sterile pumping: KaVo Surgical Systems, a manufacturer of surgical dental equipment, uses Watson-Marlow 313 series pumpheads in their dental implant equipment, the highly sophisticated and flexible INTRAsurg® 1000 and INTRAsurg® 1000 Air. Both products are used by dental surgeons during surgical implant procedures where the pumps deliver sterile NaCl cooling solution to the patient's mouth during the procedure. Because the liquid does not come into contact with anything but the autoclaved pump tube, risk of contamination is eliminated. With hygiene being vital in dentistry, KaVo chose Watson-Marlow pumps because they provide completely sterile pumping, are compact, easy to operate, and deliver an accurate and reliable flow.

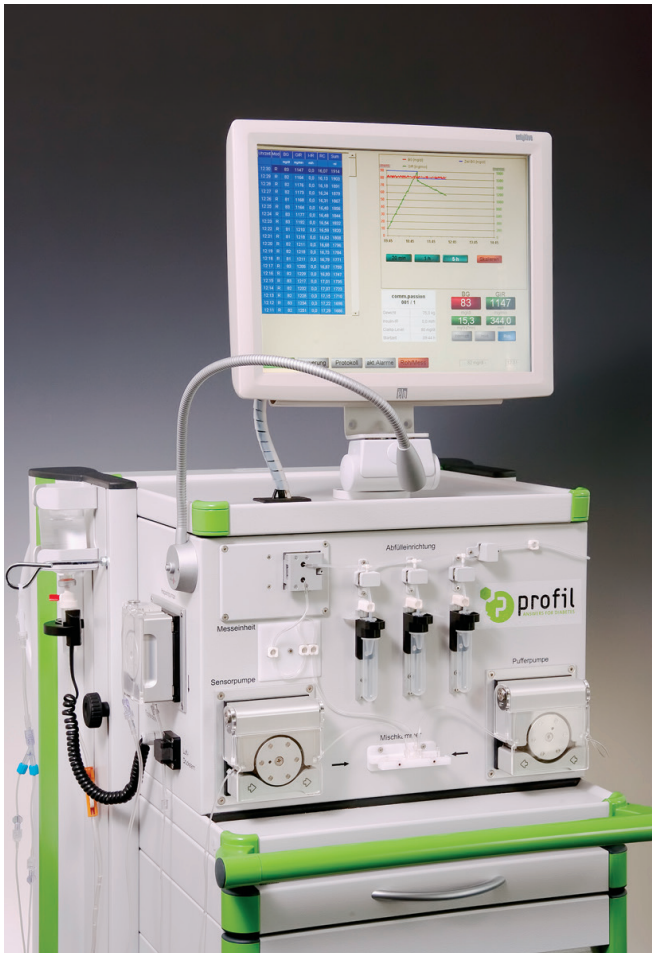
Watson-Marlow 313 Series pumps gives surgical dental equipment OEMs the confidence and reliability of sterile pumping.

Top: Rapid, trouble-free tube loading reduces the risk of human error.

Above: 400RXMD: purpose-designed for incorporation into medical applications such as cardiac ablation procedures.

High pressure and high reliability: Watson-Marlow's 400RXMD peristaltic pumps are ideal for catheter cooling systems used for cardiac ablation procedures. Delivering consistent flow rates at high pressure, these pumps allow cooling fluid to be circulated through a catheter, providing cooling at the tip with exceptional precision and reliability. The 400RXMD also allows for the use of a disposable fluid path that can handle the high pressure generated by open or closed catheters. The ingenious design of the 400RXMD enables easy, quick and reliable change of the disposable tubing; as the cover is closed, the tube holders engage and ensure that the tube is seated properly in the pump. As part of safety regulations, these pumps feature an interlock design that prevents the pumps from running while the cover is open.

TIP Pumpheads are available with a range of motors for a fully integrated design.



Watson-Marlow OEM pumps can be configured to meet specific customer requirements.

Custom Tailored: Profil, a world-leading contract research institute, is using Watson-Marlow OEM pump technology in their medical device ClampArt®, a glucose clamp device designed to automatically measure and control blood sugar levels in diabetic patients. Pump selection was a critical factor in the development of ClampArt®. Profil experimented with several different pumps, none of which provided the required precision at very low flow rates before they selected Watson-Marlow's 400ST/RX pumps, which are designed for flow rates of just 0.2 l/min to 2 l/min.

TIP Valves, filters and bends in the tubing all affect pump pressure and must be considered in the design.

Conclusion

Peristaltic pumps have long been synonymous with medical device design due to their hygienic, gentle fluid handling and ease of use for medical professionals. The advent of disposable fluid paths that guarantee no contamination has strengthened that synergy as tubing in peristaltic pumps is a suitable low-cost consumable.

As medical devices are developed to improve patient care, the demands on peristaltic pumps increase whether that is in terms of performance within a particular space envelope, flow controllability, highly specialized high pressure handling, or simply designing to a very tight budget.

WMPG understands these challenges and is unique in its ability to offer manufacturers a range of customizable products, comprehensive design development, test validation and installation/commissioning support. ■

Peristaltic Pump Tubing

Even though the tube set is disposable, choosing the right tubing is critical as it affects fluid system characteristics and the ensuing pump design process to guarantee flow rate delivery against system pressure while also being compatible to the fluid itself.

There are many factors to consider:

Design the pump for the tubing and the tubing for the pump. WMPG is the only peristaltic pump manufacturer that extrudes both Thermoplastic Elastomers (TPE) and Silicones in state of the art extrusion plants that adhere to cGMP regulations. In terms of pump design and performance, WMPG controls the complete set of design and manufacturing tolerances of both tubing and pumphead to guarantee a reliable and predictable pump solution for our customers. No other peristaltic pump manufacturers have this capability, instead directing their OEM customers to suppliers that can't guarantee peristaltic pump performance with their tubing. This sets WMPG aside to lead the peristaltic pump market, proven by its extension of peristaltic technology into the wider life science market.

Tube life: In the medical device industry, the norm is for customers to use a disposable tube set to connect the pump to other parts of the device. Therefore, tube life is rarely more than a few hours, the time generally needed to complete a procedure. In these cases, a formulation of PVC is typically satisfactory. If the tube is to be replaced less often, longer-life tubes such as Bioprene are used because they can achieve life in the thousands of hours in a typical application.

Chemical compatibility: For applications that require pumping of saline solution or washing solution, chemical compatibility is usually not a concern. For other applications where harsher chemicals are necessary, Bioprene TPE offers enhanced chemical compatibility. Applications that pump sensitive fluids must use a material that is compatible with the fluid, such as Pumpsil, which has a very smooth inner wall to avoid particles adhering to the inside of the tube.

Pressure: The tubing material must be able to withstand the system pressure without leakage or failure. Rather than making a compromise between smaller tubing that performs better against pressure but delivers lower flow, WMPG offers a range of tubing formulations that can accommodate pressure up to 100 psi.

Temperature: Most applications pump fluids at ambient temperature or slightly colder. Most tubing can handle fluids from 32 °F up to 176 °F. If the application needs to pump warmer or cooler fluids, the tubing material must be selected to withstand those requirements.

Size: The tubing must be correctly sized in order to fit within the pumphead and operate effectively. Smaller inner diameters in the tubing will increase pressure and must be sized according to pumphead design tolerances, not single pumphead samples that may vary through their life in production.

Transparency: If the fluid needs to be viewed during pumping, the tubing material should be transparent such as PVC, or at least translucent, as with silicone.

Sterilization: In some applications, the tubing material must withstand gamma sterilization, autoclaving or other sterilization methods.

Cost: Especially in cases where the tubing set is disposed, the cost of the tubing can play an important factor. For applications where the tubing is used continuously, the cost must be weighed against tube life and the cost to replace the material.

Frequently Asked Questions

Q. Do you have a pump that meets my application requirements?
A. Watson-Marlow Pumps Group has hundreds of standard pump designs and can easily create a custom design to meet a new requirement. Knowing the flow rate, pressure, duty cycle and what you need the pump to do are the first steps to obtaining the right solution.

Q. Do you certify the device with the FDA?
A. The pump as a component of the medical device can be specified according to medical requirements and performance validated accordingly by WMPG, but final equipment or device approval to relevant medical standards can only be completed by the OEM as the seller of that equipment to end users.

Q. Do you only supply the pump?
A. Watson-Marlow Pumps Group is a total solution provider. That may be just a panel-mount pumphead, or a fully integrated gear motor controller and pumphead solution. Regardless of what the OEM needs may be, the WMPG objective is to meet those needs as a reliable, conscientious supplier that fully understands the medical device market.

Q. What is the process for working with Watson-Marlow Pumps Group?
A. First the OEM customer and WMPG field sales engineers discuss design requirements for the application. A collaborative discovery process leads to a custom solution developed by specialized OEM project engineers at one of our design development facilities. After our own pump performance validation, samples are provided to the customer for further evaluation until design sign off and production planning.

Q. What mistakes are typically made with pump designs?
A. The typical mistakes made with pump designs are:

- Misinterpretation of fluid system characteristics
- Poor matching of pump and tubing
- Incorrect drive and controls specification
- Insufficient solution testing and validation
- Lack of consideration of pump service life in applied use

All of the above factors must be carefully evaluated during the design phase of the peristaltic pump in order to ensure consistent performance of the finished medical device.

WMPG will ensure that none of the above is a problem for our OEM customers, which is why many medical device users seek out devices that have a WMPG pump installed.

Q. What differentiates you from your competitors?
A. Watson-Marlow Pumps Group is a global organization with more than 50 years expertise in designing and manufacturing custom OEM pump and tubing solutions for the medical device industry. Our team of OEM design engineers align themselves as a partner through every step of the design process from off-the-shelf products to customized solutions. In our state-of-the-art ISO9001 manufacturing facilities, we manufacture our own pumps and tubing to ensure delivery of the highest quality products to our customers all over the world.