White Paper

Tubing for Hemodialysis Pumps

Executive summary

Hemodialysis is the dominant form of treatment for patients with chronic kidney disease, particularly in countries that offer accessibility to dialysis clinics. This more common form of treatment, as compared to daily peritoneal dialysis, will continue to expand with the advent of home treatment hemodialysis options.

A unique attribute of hemodialysis is the use of a peristaltic pump for transporting blood from the patient to the dialyzer, and back to the patient. This pump transports fluids by repeatedly squeezing a segment of tubing, which places greater demand on this tubing section than any other within the hemodialysis system.

While tube size varies among device manufacturers, there is not a great deal of complexity in design, which is typically a single-lumen PVC construction. The exception is the pump segment tubing, which must have superior compression recovery and fatigue resistance characteristics The PVC compound, on the other hand, is quite complex. Changes in plasticizers, for example, can affect the hardness, extraction characteristics and clarity of hemodialysis tubing.

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Chronic kidney disease

Dialysis is a procedure used for patients with chronic kidney disease (CKD). According to the National Kidney Foundation, 10% of the population worldwide is affected by (CKD), with high blood pressure and diabetes being the main causes. More than 2 million people worldwide currently receive treatment (dialysis or a kidney transplant) for CKD to stay alive. Yet this number may only represent 10% of the people who actually need treatment to live.

There are two primary types of dialysis—hemodialysis and peritoneal. Hemodialysis is a procedure that typically occurs in a clinic that uses a machine for filtering waste and excess fluid from the patient's blood. One of the main benefits of this approach is that it does not require treatment every day. Typically, patients only require treatment three times each week.

Alternatively, peritoneal dialysis uses the lining of the patient's abdomen (peritoneum) as a filter to remove waste products from the blood. For this, the patient requires a procedure to insert a catheter into the abdomen that will remain for the required daily treatments. This type of dialysis is often preferred if the patient cannot easily access a dialysis center. Since it is done more continuously than hemodialysis, there is often greater dietary flexibility.

Because the procedure is less frequent, hemodialysis is the preferred treatment for almost 90% of all dialysis patients. Innovative home hemodialysis treatment options are emerging that will alleviate the difficulties associated with routine trips to dialysis centers.

Hemodialysis begins with the insertion of two needles in the patient's arm. Each needle is attached to a flexible tube connected to the dialysis machine. The dialysis machine uses a peristaltic pump to transport blood from the body to a filter and then return it. The filter, called a dialyzer, acts as an artificial kidney.

The tubing set used in the dialysis machine is typically specific to the machine model, and contains measuring points for monitoring pressure and air. There are numerous tube lines in the dialysis machine, including the blood flow lines, pressure transducer lines for monitoring occlusions in the needles, and anticoagulant administration lines to prevent blood clots. In most cases, these lines manage fluid flow without rigorous mechanical stress. However, the tube segment that passes through the peristaltic pump of the dialysis machine is exposed to constant flexural and compressive stress.

Hemodialysis tubing characteristics

The tubing sets that carry blood to the dialyzer and back to the body are known as **"blood lines."** Blood line sets are typically made from polyvinyl chloride (PVC) softened by plasticizers. Di-ethylhexyl phthalate (DEHP) is the most commonly used plasticizer to maintain certain features. However, the specific composition of the tubing differs among manufacturers.

PVC is used in part for its transparency and clarity. Being able to see the blood during dialysis is important to ensure that there isn't any tubing damage or blood clots. Other desirable blood line tubing characteristics include flexibility/drapability, blood compatibility, kink resistance, sterilizability and a smooth inner liner surface to minimize turbulence and potential damage to blood cells. Some of these requirements are critical. For example, kinks in blood line tubing could result in **hemolysis** (rupturing of red blood cells). This can result from shear stress arising from resistance or obstruction to blood flow through the tubing circuit, and is potentially fatal.

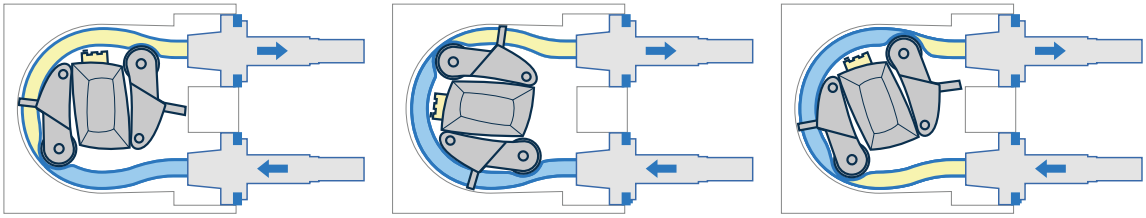
Blood cells can also be damaged or ruptured during the process of moving the blood through tubing. Therefore, to cut down on turbulence which can lead to hemolysis, and increase **lubricity** (the slipperiness and smoothness of the surface of the tubing), some manufacturers coat the inner surface of their tubing with a hydrophilic material. In addition, tubing surfaces can be coated with **anti-thrombogenic** (anti-clotting) materials, such as heparin, to prevent blood clot formations.

Since several investigations have reported the release of plasticizer material from bloodlines into the bloodstream, and concerns regarding exposure to phthalates have risen in recent years, many suppliers offer DEHP-free solutions for extracorporeal tubing.

Pump tubing segment

Because dialysis commonly uses a **peristaltic pump** (or **roller pump**), the section of tubing in the pump housing, sometimes called **pump segment** tubing, is subject to a variety of stresses that the remaining blood lines are not. With a peristaltic pump, a roller rotates and squeezes and flattens the flexible tubing along the pump housing, so the tubing is subject to constant compression and subsequent relaxation for the average four-hour duration of the hemodialysis treatment.

Therefore, this 6- to 8-inch (~15-20 centimeter) section of tubing must exhibit superior compression recovery or "hoop strength" and fatigue resistance. If this tubing loses its ability to recover from compression over time, pump throughput could be affected, meaning the patient will not receive the full benefit of their hemodialysis treatment session. Any cracks or leaks that develop could be more problematic, resulting in tube rupture, patient blood loss and/or air leakage into the circuit. In addition, tubing wear can lead to a process known as **spallation**, in which particles of the tubing may be shed into the circulatory system.



For these reasons, a different material is often used for the tubing section that passes through the pump housing than the rest of the blood line set. Since this tubing must demonstrate elasticity in order to allow the ongoing occlusion necessary to move blood, elastomers used can include silicone, polyvinyl chloride compounds and thermoplastic elastomer materials.

Tubing flexibility is critical for peristaltic pump usage. It is necessary to allow the motor to rotate and fluid to pass through the tubing. Tubing that is too hard can negatively impact motor longevity (and even cause failure), since it has to work harder. The target Shore A hardness value is between 50 and 65 for these applications.

In addition to the flexibility issue, tubing size is also critical to maintaining the proper operating condition of the pump. The gap between the housing and the roller is what determines the tubing thickness. Even variations that are in thousands of an inch can be enough to negatively impact pump life. **Figure 1.** It shows that a seal is prevented from being created due to a thin wall. This can cause pump failure. **Figure 2.** Conversely, tubing that is too thick can also contribute to increased pump wear. The ability to offer tight tube tolerances for inner diameter and wall thickness is therefore important, particularly in this section of tubing.

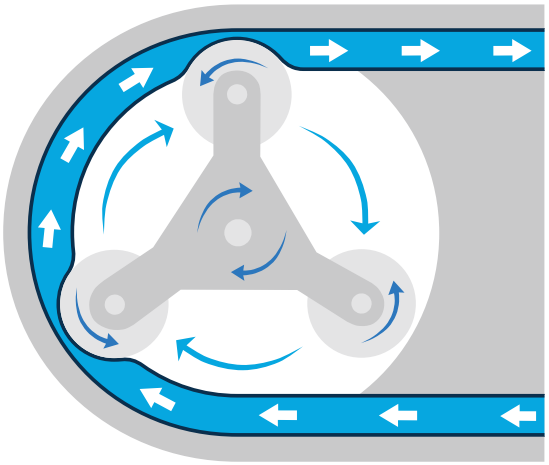


Figure 1

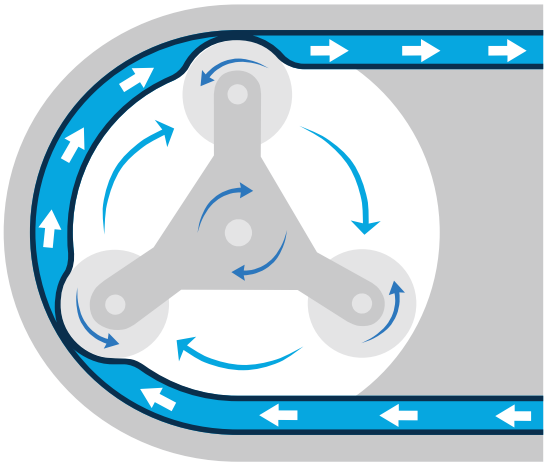


Figure 2

Tubing specifics for peristaltic pumps

Dialysis equipment manufacturers dedicate a significant amount of time and effort to create equipment that has its own unique features and benefits. As such, the tubing used for the peristaltic pump segment is not "one size fits all" with respect to dimensions or PVC compound formulation. Companies are looking for ways to balance performance and economics when they are producing their own unique dialysis machine.

The critical attributes/considerations for peristaltic pump tubing include Shore hardness, resin molecular weight and plasticizer type. Shore hardness and resin molecular weight impact mechanical performance and plasticizer type needs, which are important considerations for permanence/extractable requirements.

For peristaltic pump tubing, the typical PVC specification range is between 65 to 70 Shore A hardness. Typical sizes of tubing used for the pump segment - with varying length depending on the OEMs' requirements – are 0.250-inch ID x 0.375-inch OD and 0.345-inch ID x 0.425-inch OD.

The other important attribute is wall thickness consistency. For example, the ID and OD can be within specification for a pump, but if the wall thickness is uneven, that could also cause failure.

Commonly Used Materials by Tubing Component for Dialysis Procedures

Product Component	Typical Materials by Tubing Type				Typical Shore A
	PVC	TPE-S	TPU	Silicone	
Hemodialysis: Blood Line Tubing	✓	✓	N/A	N/A	65-78
Hemodialysis: Pump Head Tubing	✓	✓	N/A	✓	50-65
Peritoneal Dialysis: Peritoneal Catheter	N/A	N/A	✓	✓	60
Peritoneal Dialysis: Transfer Set	✓	✓	N/A	N/A	80

PVC compound considerations

Flexible PVC used for peristaltic pump tubing is comprised of major and minor components, collectively known as a compound. The major components include PVC resin and plasticizers. Minor components include stabilizers, lubricants and processing aides that help manage PVC's inherent low thermal stability and ensure that the PVC polymer does not rapidly degrade at the shear rates and temperatures required for melt processing.

Understanding product criteria specific to individual pump tubing applications is critical to selecting the most suitable PVC resin, plasticizer and minor component package. All three areas can have a significant impact on mechanical and spallation performance of the pump tubing segment and also whether the product is compliant with global regulations on the use of materials in medical devices.

For example, the type and level of plasticizers are very important. Plasticizers are used to impart flexibility and to control the durometer of the base PVC polymer. Depending on the Shore A hardness required of the compound, the plasticizer content can range from 15 to 50% of the overall formulation.

There are numerous different plasticizer chemistries used commercially. Phthalate esters have dominated the plasticizer market for almost 100 years. The three prominent phthalate plasticizers are DEHP, DINP and DIDP. DEHP has been most commonly used in medical device applications.

DEHP is economical and offers excellent performance (e.g., compatibility with PVC, plasticizer efficiency, low-temperature properties and low volatility). Also, the leaching of DEHP into blood has a stabilizing effect on red cell membranes, reducing hemolysis and prolonging shelf life.

However, DEHP has been battling detractors for decades and is probably one of the most studied substances in the medical device industry. As a result, there has been significant interest in

non-DEHP alternatives for medical-grade PVC compounds. These include ATBC, DEHT, DINCH, DOA, and TOTM. Yet, direct substitution of these plasticizers for DEHP can impact the performance of the peristaltic pump tubing segment. The following are just a few considerations for using alternative plasticizers in these applications:

1. The quantity of plasticizer required to make a specified Shore A can also highlight subtle differences in the compatibility of the various plasticizers with PVC polymer matrix. For a Shore A 75 PVC compound, the concentration of the plasticizer can vary from a low of 27% for DOA to a high of 32% for TOTM. In general, DEHT, DINCH & TOTM require higher levels of concentration than DEHP to match the same Shore A.

2. In addition to plasticizer chemistry and molecular weight, it is known that extraction rates for the plasticizer are also dependent on the nature of the extractant, the surface area in contact with the extractant, temperature, flow rate and contact period. Although the aqueous solubility of all the plasticizers are low, because they are not covalently bound in the PVC matrix, they can migrate into the contacting medium. Tekni-Plex Medical's studies of extraction rate in saline solutions of the various plasticizers at 50°C for Shore A 65 PVC compounds over a 24-hour period identified that slight differences in extraction rates exist. TOTM, the highest molecular weight plasticizer, resisted extraction the most. ATBC, a citrate plasticizer, showed higher levels of extraction in comparison to the other plasticizers tested.

3. One of the key attributes of PVC compounds is its excellent clarity. Tekni-Plex Medical's studies on the effects of plasticizer type on the percentage haze of Shore A 75 compounds highlight subtle differences in the compatibility of the various plasticizers with the PVC polymer matrix. The results demonstrate that all plasticizers show very low percentage haze and have excellent clarity. However, the results also show that there are differences in the percentage haze of the various plasticizers. DINCH and, to lesser extent TOTM and DOA, generally show higher percentage haze values.

For more information on how Tekni-Plex Medical can assist you with your dialysis tubing requirements, please contact us at: **Info.tekniplexmedical@tekni-plex.com.**