

AUTOMATED PERITONEAL DIALYSIS (APD) MACHINE MODELING

A PROJECT REPORT

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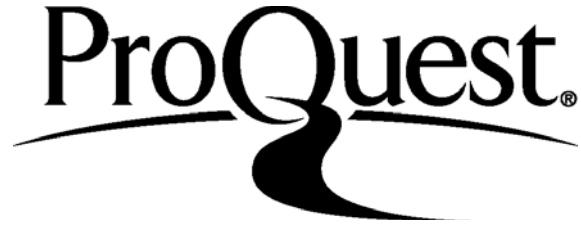
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ABSTRACT

AUTOMATED PERITONEAL DIALYSIS (APD) MACHINE MODELING

By

Marvin Rodriguez

December 2016

A peritoneal dialysis cyclor model was developed to be used by biomedical device manufacturers in order to aid them in the system development, system level requirement writing, and FDA device certification process. This generic model can be used as a plug and play model for companies to incorporate a specific dialysis pump that is commercially available and quickly integrate it into their system. The Simulink model was used to simulate the system behavior and analyze multi domain dynamic systems data. A mathematical representation of the physical system was derived using fluid dynamic equations. The mathematical equations were then translated into Simulink blocks for the computer environment to understand. A proportional integral derivative controller was designed and integrated into the system in order to compensate the flow rate for any difference between the flow set point and the actual flow. System monitors were developed to protect patients from hazardous conditions.

ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to my advisor Dr. Christopher Druzgalski for the continuous support of my MSEE study while at CSULB and for his motivation and immense knowledge. His guidance helped me throughout the research and writing portions of this thesis. I could not have imagined having a better advisor and mentor.

Last but not least, I would like to thank my family: my parents, my brother, and sister for instilling great educational values and for supporting me spiritually throughout.

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PREFACE

This thesis is submitted for the degree of Master of Electrical Engineering at California State University Long Beach. The research described herein was conducted under the supervision of Dr. Christopher Druzgalski in the Department of Electrical Engineering on August 2016. To the best of my knowledge this work is original, except where acknowledgements and references are made to previous work.

CHAPTER 1

INTRODUCTION

The human body is a complex system composed of millions of cells and chemical bonds that need to work precisely in synchrony in order to function correctly. The cornea, aqueous humor, iris, lens and optic nerve have to work perfectly with each other just to allow for the ability of sight. Another organ that is as equally important if not more important to the human body is the kidneys. The kidneys play a key role in the human body and they contain about one million nephrons that contain a very small filter that is also known as glomerulus. The kidney's functionality is to filter out the blood and remove waste products and balance the electrolyte levels in the body. According to J. Jones, the kidneys also help control the body's blood pressure and stimulate the production of red blood cells throughout the human body [1]. Renal failure treatment has increased exponentially over the last two decades in the United State causing several insurance companies and doctors to focus on preventative treatments and long term care of patients who are diagnosed with a chronic renal failure. Biomedical manufacturing companies can reduce manufacturing costs and develop safer products by developing a system model of their devices. Biomedical companies should invest in system modeling to help reduce costs due to design flaws and potential equipment recalls. This thesis summarizes the steps taken to develop a peritoneal dialysis cyler model using MATLAB's Simulink. System modeling will not only reduce costs, but it will allow companies the ability to redesign and even implement risky functionality for a fraction of the cost.

CHAPTER 2

RENAL FAILURE AND KIDNEY DISEASE

The kidneys are located in the lower back of the upper torso with each kidney on each side of the vertebrae. Both kidneys are connected to the bladder where they get their blood supply through the renal arteries directly from the aorta as shown in Figure 1.

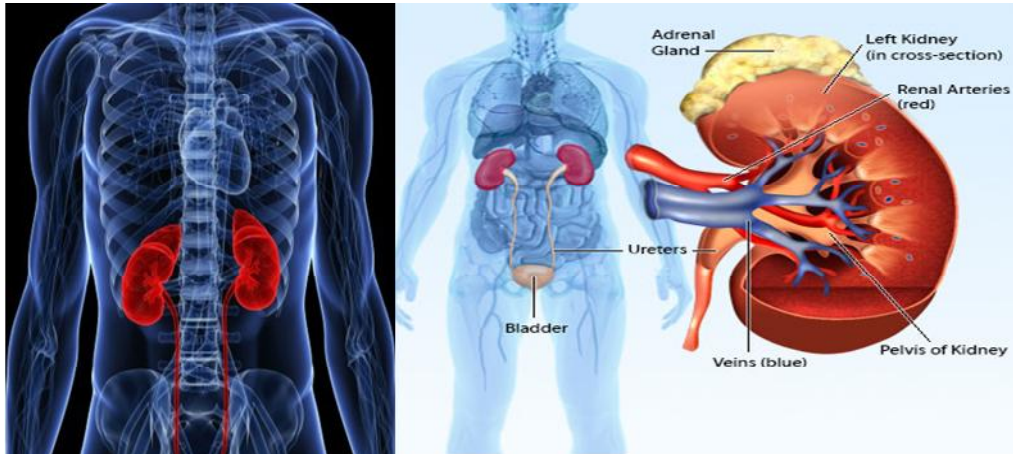


FIGURE 1. The kidneys filter waste products of body metabolism. The kidneys have the ability to monitor the amount of body fluid, the concentrations of electrolytes such as sodium and potassium and the acid-base balance of the body [2].

Kidney failure is a serious, life threatening, disease, most people who have chronic kidney disease (CKD) may not even be aware that their kidneys are starting to fail due to the subtle symptoms. Some of the early symptoms of kidney failure are a change in urination, swelling in parts of the body, fatigue, skin rash, itching, the sense of a metallic taste in the mouth, nausea and even vomiting. Small things such as waking up at night to urinate, producing bloody, foamy or bubbly urine as well as difficulty urinating could be symptoms of kidney disease.

A change in urination may occur due to the kidney's shutting down creating reduction in the body's waste filtration efficiency. This inefficacy leads to the kidney's producing less urine

that can lead to patients not being able to urinate on a daily basis. Fluids become trapped within the body and can cause abnormal swelling.

Abnormal swelling occurs when the failing kidneys are no longer able to remove the extra fluid from the body. This causes water build up and swelling to occur throughout the body. According to Benjamin Wedro, the face, arms and feet are places on the body where water build up is the most visible [3].

Irregular fatigue occurs when the kidneys are no longer able produce a hormone called erythropoietin that is used by the body to carry oxygen in the red blood cells. The human body requires a sufficient amount of oxygen in the blood in order for the muscles and brain to work correctly. This condition is referred to as anemia and can easily be treated with medicine.

According to doctor Christian Nordqvist, severe itching on the skin, nausea, and vomiting may occur due to the waste build up in the bloodstream that causes the body to become intoxicated. Dialysis and other waste removal processes help reduce the itching sensation [4].

In order to diagnose a kidney disorder a doctor can perform blood urea nitrogen (BUN) test. According to Doctor Jeanne Morrison, the BUN test measures the amount of nitrogen in the blood that comes from the waste product urea [5]. Urea is made in the liver and is produced when protein is broken down in the body. A BUN test is performed in order to determine how efficient the kidneys are working. If the kidneys are not able to remove urea from the blood normally, the BUN level increases. A blood creatinine test can also be performed to diagnose a possible kidney disease.

There are hundreds of conditions that may cause a form of kidney disease; determining what is causing the kidney disease and treating it can be the first step towards correcting the kidney abnormality. Several causes of kidney failure are treatable and once the conditions

causing the kidney failure are treated, the kidney functionality may return to normal. According to the *New England Journal of Medicine*, the main causes of chronic kidney disease can be prevented by simply controlling the body’s blood pressure and diabetes. Patients with diabetes are more likely to develop a chronic kidney disease as the diabetes creates the conditions required for the kidneys to fail [6]. The kidney functionality gradually decreases over time as it is apparent in the older population. Studies have shown that diabetes can accelerate the kidney failure process.

The statistics show that diabetes and dialysis is commonly found in older female patients who are Black or Hispanic. The “Age Adjusted Prevalence” of chronic kidney disease among the US adults between 1999 through 2010 is shown in Figure 2.

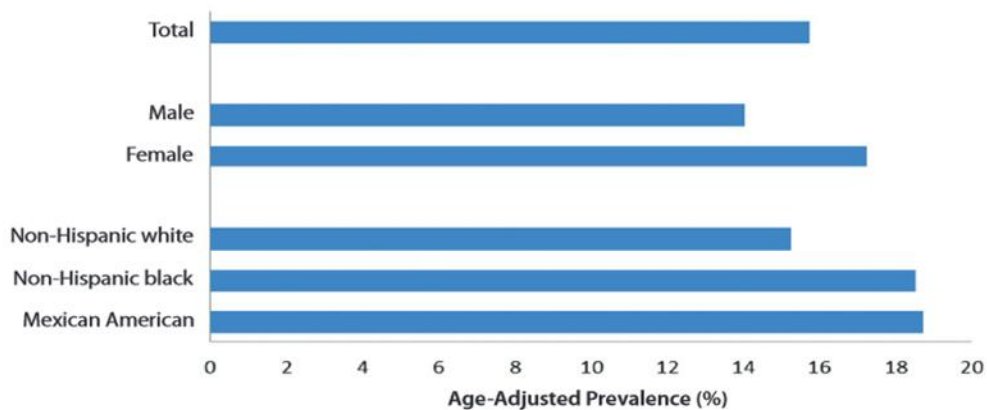


FIGURE 2. The figure shows the demographic distribution of patients who were diagnosed with a chronic kidney disease [7].

In addition to diabetes and race, certain chronic illnesses are commonly found in patients before starting dialysis. Approximately one out of three adults with diabetes and one out of five adults with high blood pressure were diagnosed with chronic kidney disease. The pie graph, shown in Figure 3, shows the statistics of patients who have recently been diagnosed with kidney failure.

New Cases of Kidney Failure by Primary Diagnosis-2011, United States Renal Data System

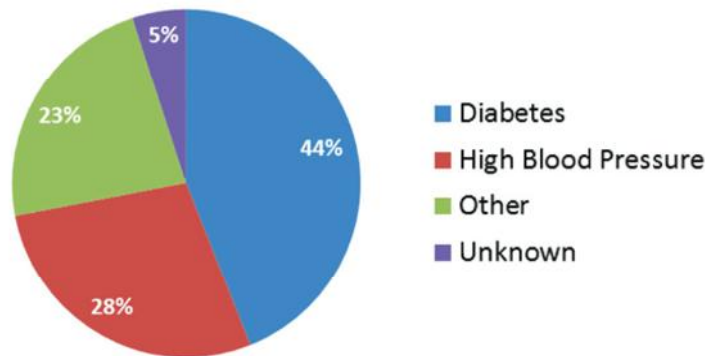


FIGURE 3. The pie chart shows the distribution of illnesses that leads to a chronic kidney disease [7].

According to the National Institute of Diabetes and Digestive and Kidney Diseases, statistics show that patients who suffer from high blood pressure and diabetes are more likely to suffer from a chronic kidney failure [8]. This information helps doctors diagnose and treat potential symptoms and conditions that may lead to a kidney disease at an early stage. Preventative treatments are ideal as once the kidneys fail, the human body may become intoxicated by its own waste causing the potassium levels to increase dramatically to the point where the heart will slow down and the patient will die. The only treatment options available once chronic kidney disease has been diagnosed and the kidney performance is no longer safe, is dialysis treatment or a kidney transplant.

CHAPTER 3

RENAL FAILURE OPTIONS

The kidney transplant process and the wait list for a new kidney can take several years to find a matching donor. Depending how advanced the kidney failure is the patient may need to start a form of dialysis during the time the patient waits for a possible kidney donor. According to Wikipedia's article on dialysis, the two main types of dialysis are hemodialysis and peritoneal dialysis [9].

According to the National Institute of Diabetes and Digestive and Kidney Diseases, hemodialysis is a type of dialysis that removes wastes and water from the body by circulating the blood outside the body through an external filter that contains a semipermeable membrane called a dialyzer [10]. In order for the hemodialysis process to work, the patient must go through an operation in order to install a type of catheter in the patient's arm as shown in Figure 4.

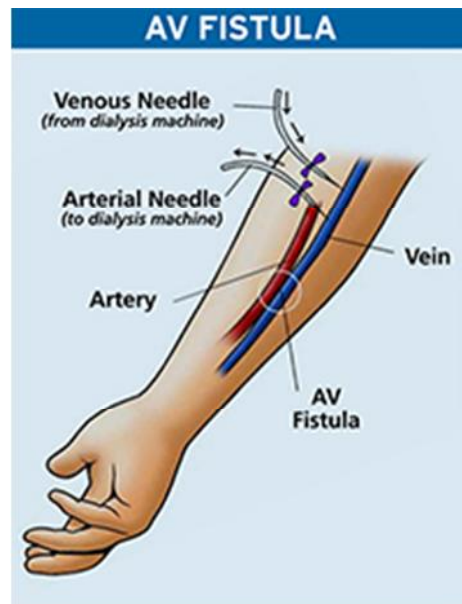


FIGURE 4. A surgeon creates an arteriovenous fistula by making a connection between an artery and a vein. This artificial connection allows the vein to become larger and for the walls of the vein to thicken, a process termed maturation. A mature fistula makes it easier for the vein to be punctured repeatedly for dialysis [11].

Peritoneal is a type of dialysis where wastes and water are removed from the blood inside the body using the peritoneum cavity as a natural semipermeable membrane. Peritoneal dialysis allows for bodily waste and excess water to be removed from the blood, across the peritoneal membrane. According to Doctor Sandhya Pruthi, there are three main stages to the peritoneal dialysis treatment, the fill, dwelling, and extraction. The initial fill requires the patient to insert a solution called “dialysate” into their body’s abdominal cavity by using either gravity or a dialysis cyclor. Figure 5 shows the peritoneal cavity and catheter used to insert dialysate into the body. According to Doctor Sandhya Pruthi, the dialysate solution has a composition similar to the fluid portion of blood [12]. The dwelling period is the amount of time that the patient leaves the dialysate solution in the abdomen. Lastly, the extraction stage is when the patient empties the solution from the abdomen into a waste bag.

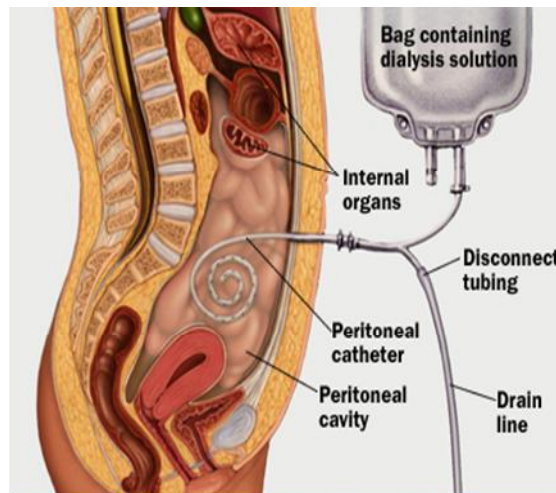


FIGURE 5. Peritoneal dialysis (PD). PD has evolved remarkably over the decades proving itself to be a competitive alternative to hemodialysis (HD). Now, PD is also recognized to offer some advantages over HD, including conserving dialysis access options and the convenience of performing dialysis overnight at home [12].

CHAPTER 4

DIALYSIS TREATMENT

According to J. Burkart, peritoneal dialysis has become a very popular treatment for patients who suffer from chronic kidney failures to the extent that it has created a huge demand for biomedical equipment to be developed in order to aid patient treatment and doctor diagnosis of dialysis patients [13]. Several companies have designed, developed and certified biomedical equipment used as cyclers during dialysis. These dialysis cyclers help automate the peritoneal dialysis process in order to achieve minimal impact to a patient's life style.

Fresenius Renal Technologies developed a cycler, "Liberty Cycler" often used by patients who perform peritoneal dialysis in the United States. Figure 6 shows functioning Liberty Cycler.



FIGURE 6. The Liberty Cycler. The cycler pumps dialysate (a cleansing solution used to draw waste products and extra fluids out of the blood) into the empty peritoneal cavity. There it absorbs waste through the body's natural membrane over a set amount of time [14].

Fresenius-The Healthcare Group designed, developed, and certified the Newton IQ Dialysis Machine. The Newton IQ Cycler offers Continuous Therapy and Intermittent Therapy. Continuous Therapy requires a minimum of 50% of the fill volume to remain in the abdomen at all times while the Intermittent Therapy allows for the option emptying the abdomen or

maintaining a small amount of the fill volume in the abdomen during cycles of the treatment.

Figure 7 shows a Newton IQ dialysis cyclers.



FIGURE 7. Newton IQ. The most advanced cycler for APD, provides customers with maximum functionality and flexibility[15].

DEKA Research and Development Corporation (DEKA) in partnership with Baxter has also designed, developed, certified and mass produced the Homechoice PD, a cycler that is one of the highest selling cyclers in the United States. Figure 8 shows the Homechoice PD cycler.

The cycler offers the patient the ability to choose from various types of profiles for the cycler to perform, a variable time of dwelling, and a programmable removable chip to help the care provider when changing the prescription.

Baxter's Homechoice PD



FIGURE 8. DEKA peritoneal dialysis. In an effort to alleviate the stress and burden of renal patients requiring frequent trips to a dialysis center, DEKA developed a home peritoneal dialysis system that allows patients to receive treatment in the comfort of their own homes [16].

CHAPTER 5

MODELING THE CONTINUOUS AMBULATORY PD

A system model of a peritoneal dialysis cyclers has been developed using MATLAB's Simulink environment. A peritoneal cyclers model was developed to show how system modeling can be used in the biomedical equipment development process in order to minimize design flaws as well as safety issues. The model can help verify system level performance and confirm system level functionality requirements. The data gathered from the system model can help determine if any system functionality can potentially lead to a hazardous condition. The model can also be used during the FDA's Center for Devices and Radiological Health certification process in order to prove through analysis that the model meets specific theoretical and analysis requirement specifications. The system model can also be used to create improvements in the model and determine if specific logic changes cause a system performance change before spending thousands of dollars in manufacturing of prototypes.

Function modeling was used when developing the dialysis cyclers in Simulink to take advantage of the functional block diagram and functional decomposition. This allows for the system model to be broken down into specific functions, represented as blocks that are then linked to each other to create a system level effect. This system is illustrated in Figure 9.

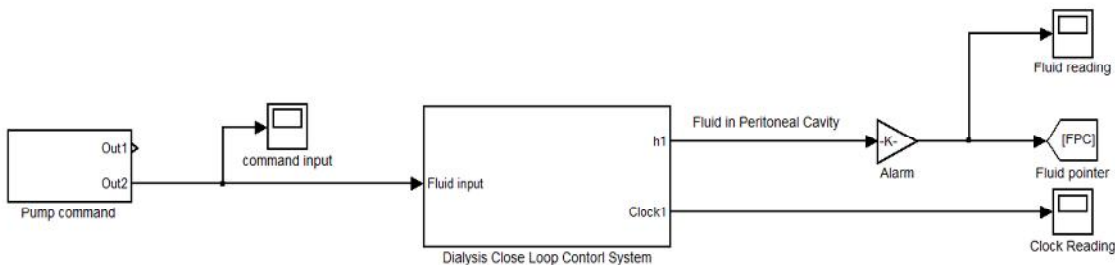


FIGURE 9. The peritoneal dialysis model at the top level shows several blocks used for function generations and test equipment used for analysis.

Developing a model can be complicated as it requires the designer to understand the physics behind the models application. Kinematics and fluid dynamics play a major role when developing a peritoneal dialysis cycler. In order to represent an accurate model in MATLAB's Simulink the physical kinematic equations must be properly derived and represented mathematically. In order to achieve this mathematical representation several things need to be taken as assumptions. The dialysate fluid density and the hose width will be assumed to be constant throughout the model. In addition, the dialysate fluid is assumed to not be a compressible fluid. The manual peritoneal dialysis process uses gravity, height, velocity, and pressure of the fluid to determine a flow rate that can be represented by Bernoulli's equation of fluid dynamics shown in Equation 1:

$$P_1 + \rho gh_1 + \frac{1}{2} \rho v_1^2 = P_2 + \rho gh_2 + \frac{1}{2} \rho v_2^2 \quad (1)$$

Where P_1 is the pressure, ρ is the fluid density, h_1 is the potential energy/height and v_1^2 is the velocity. " ρgh_1 " is also known as the potential energy of the fluid and " ρv_1^2 " is known as the kinetic energy. Bernoulli's equation of fluid dynamics can be viewed as Equation 2:

$$(Pressure) \quad (Potential) \quad (Speed) \quad (2)$$

From a fluids point of view the continuity equation states that the product of a specific cross sectional area and its velocity is equal to product of the cross sectional area and its velocity. The continuity equation that can also be derived from Newton's second law of motion is shown in Equation 3

$$A_1 V_1 = A_2 V_2 \quad (3)$$

Figure 10 demonstrates how the fluid flow across a tube with changing cross sectional area can be calculated using the continuity equation. Figure 10 shows the cross sectional area A_1

being much wider than A_2 , which means the fluid rate across this tube will need to accelerate causing V_2 to increase.

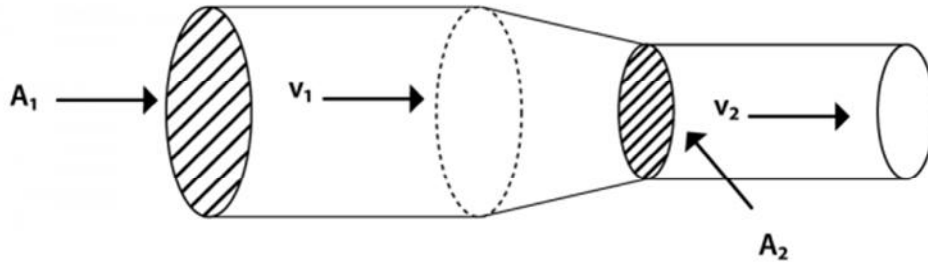


FIGURE 10. The Bernoulli equation. The equation states that if diameter of a pipe changes area at a constant height, the product of the area times the velocity at the initial point will be equal to the area times the velocity at a separate point [17].

Assuming A_1 is a cross sectional area of 10 and V_1 has a velocity of 5 and A_2 is a cross sectional area of 2 the fluid velocity, V_2 can be calculated using the continuity equation as shown in Equation 4:

$$A_1 V_1 = A_2 V_2 \quad (4)$$

$$10 \cdot 5 = 2 \cdot V_2$$

$$\frac{(10 \cdot 5)}{2} = V_2$$

$$\frac{(50)}{2} = V_2$$

$$25 = V_2$$

Bernoulli's equation uses the continuity equation principles and includes the gravitational potential energy as well as the fluid's density into consideration. Bernoulli's equation proves that the fluid conditions will be equal to the fluids ending conditions, as shown in Equation 5:

$$P_1 + \rho g h_1 + \frac{1}{2} \rho v_1^2 = P_2 + \rho g h_2 + \frac{1}{2} \rho v_2^2 \quad (5)$$

Bernoulli's equation is a derivation from Newton's 2nd law of motion, which states that “The acceleration of an object as produced by a net force is directly proportional to the magnitude of the net force, in the same direction as the net force and inversely proportional to the mass of the object” [17]. In other words if a volume of fluid is flowing at the same height from a region of high pressure to a region of low pressure it is because there is more pressure behind pushing it towards the region of lower pressure. Similarly “Bernoulli's principle states that an increase in the speed of a fluid velocity occurs with a decrease in pressure or a decrease in the fluid's potential energy” [17]. Bernoulli’s equation is directly derived from the physics principle of conservation of energy. Using Bernoulli’s equation the manual peritoneal process can be derived into a mathematical equation by simply following the dialysis steps.

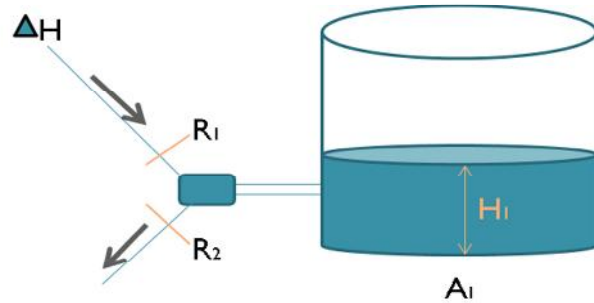
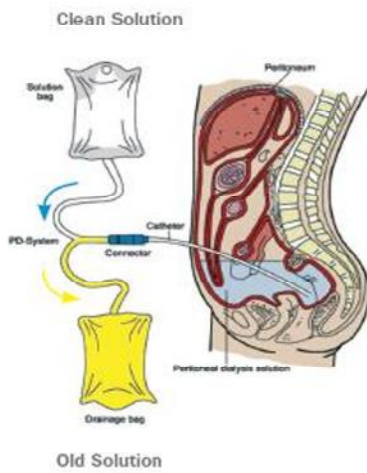
The initial fill requires the patient to insert a solution called “dialysate” into their abdominal cavity by placing the bag high, above their heads and allowing the fluid to flow down from a high pressure to a low pressure region. The patient will retain the fluid in their abdomen for however long their doctor has prescribed. The last step in peritoneal dialysis is the extraction that occurs when the patient empties the solution from the abdomen into a waste bag. The patient usually places the waste bag on the floor then stands up and opens the abdomen catheter in order to allow the flow of the dialysate and the body’s waste from the high pressure abdomen region and into the low pressure waste bag as depicted in Figure 11.



FIGURE 11. Manual peritoneal process [18].

Figure 12 shows how the peritoneal process can be modeled using a cylinder to represent a patient's abdomen. ΔH represents the dialysate bag containing the dialysis solution being raised higher than the patient's abdomen causing the solution to flow downward towards a lower pressure. During this initial step, the R_2 that leads to a waste bag will remain closed causing the flow across R_2 to be zero. Using the conservation of energy it can then be determined that all of the solution flowing across R_1 is entering the patient's abdomen causing H_1 in increase in height.

Continuous Ambulatory PD Mathematical Equations



The fluid in the peritoneal dialysis cavity is the summation of the water flow through ΔH across R_1 over time minus any leakage flow across R_2 .

ΔH - Is the input flow.

R_1 - Is the constant input orifices.

R_2 - Is the constant output orifices.

H_1 - Is the amount of fluid in the dialysis cavity.

$$A_1 \frac{dh_1(t)}{dt} = \frac{\Delta H - h_1(t)}{R_1} - \frac{h_1(t)}{R_2}$$

FIGURE 12. Fluid kinematic equation. The figure shows the peritoneal dialysis mock-up that depicts the solution flow from the dialysate bag into a patient's abdomen. The mathematical equation was derived from the physical kinematics [19].

The equation derived from the model can be manipulated to solve for the flow rate instead of the amount of fluid volume in a patient's abdomen. The derived equation states that the volume within the patient's abdomen is equal to the amount of flow across R_1 minus any leakage flow that may occur across R_2 as shown in Equation 6:

$$A_1 \frac{dh_1(t)}{dt} = \frac{H-h_1(t)}{R_1} - \frac{h_1(t)}{R_2} \quad (6)$$

Ideally, R2 should be initially closed causing the flow across R2 to be zero as shown in Equation 7:

$$A_1 \frac{dh_1(t)}{dt} = \frac{H-h_1(t)}{R_1} - 0 \quad (7)$$

Finally, the flow rate to the patient's abdomen can now be calculated using Equation 8 and assuming no leakage flow crosses across R2.

$$\frac{dh_1(t)}{dt} = \frac{\frac{H-h_1(t)}{R_1} - \frac{h_1(t)}{R_2}}{A_1} \quad (8)$$

$$\frac{dh_1(t)}{dt} = \frac{H-h_1(t)}{A_1 R_1} - 0$$

$$\frac{dh_1(t)}{dt} = \frac{H-h_1(t)}{A_1 R_1}$$

The equation can now be modeled using MATLAB's Simulink blocks. Figure 13 shows a Simulink model equivalent to the derived equation. Figure 14 illustrates the different types of pump outputs entering the system.

System model of derived equation:

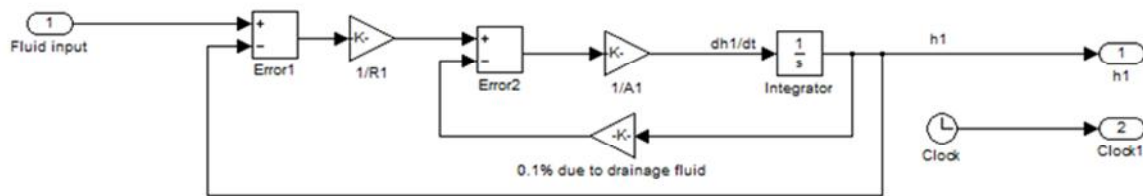


FIGURE 13. Leakage flow. The model has a 0.1% leakage flow across R₂ that is used to represent any type of leakage flow across the entire system.

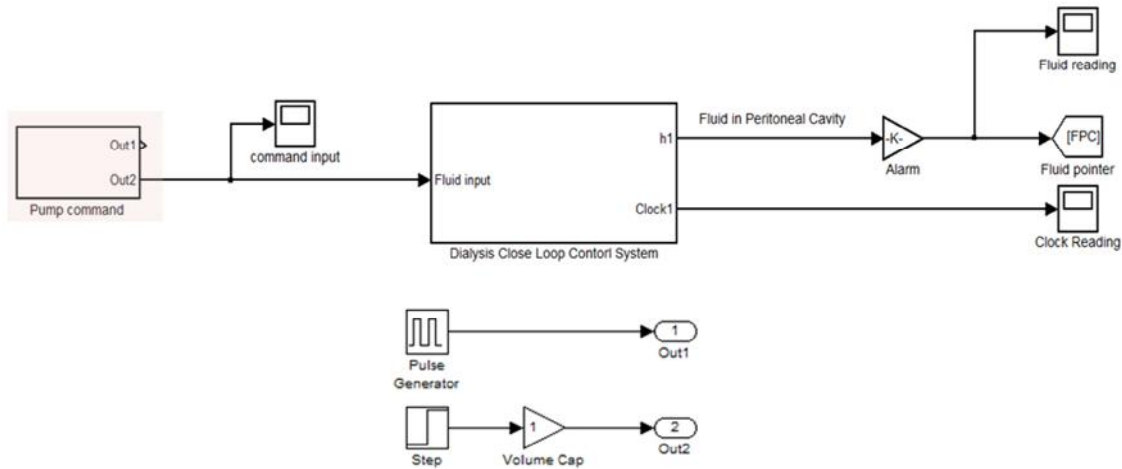


FIGURE 14. Simulink pump command block. The model uses the “Pump Command” block as a way to inject specific commands to the model. This block can be used as a way to drag and drop various biomedical pumps that are being considered in manufacturing to determine their impact and overall system response.

A step command was asserted to the input of the model to simulate the initial flow entering the model at time $T_{(s)}$. Using a step response allows for the initial response of the system to be captured using simulated oscilloscopes that capture data that can then be used to derive the systems transfer function. According to Eric Weisstein, the step response can also be represented as $(s) = \frac{1}{s}$ in the Laplace domain by using the Laplace transformation that allows developers to switch from the time domain to the frequency domain to simplify the math when working with differential equations [20].

The model’s transfer function will allow the developer to observe how the system is responding once a command is sent. The system response can then be controlled by developing a controller that ensures that the system behaves as expected by filtering out specific conditions that may create the system to become unstable. Control system knowledge is then used to determine the values that can cause the poles of the transfer function to be on the right hand plane. Notch filters can then be developed to prevent specific values from being asserted to the model. The oscilloscopes were placed at the output in order to monitor the step command, flow

and volume signals as well as the overall system response. The systems transfer function can be derived by looking at the ratio of the system output to the input of the system. Figure 15 shows the system model and test equipment configuration used to capture the Simulink data. The plots show the command signal being sent from the pump command block that uses a pulse generator to assert amplitude of 50 with a duty cycle of 75 percent. The volume signal continues to increase when the command signal is high and plateau when the command signal becomes 0 as expected.

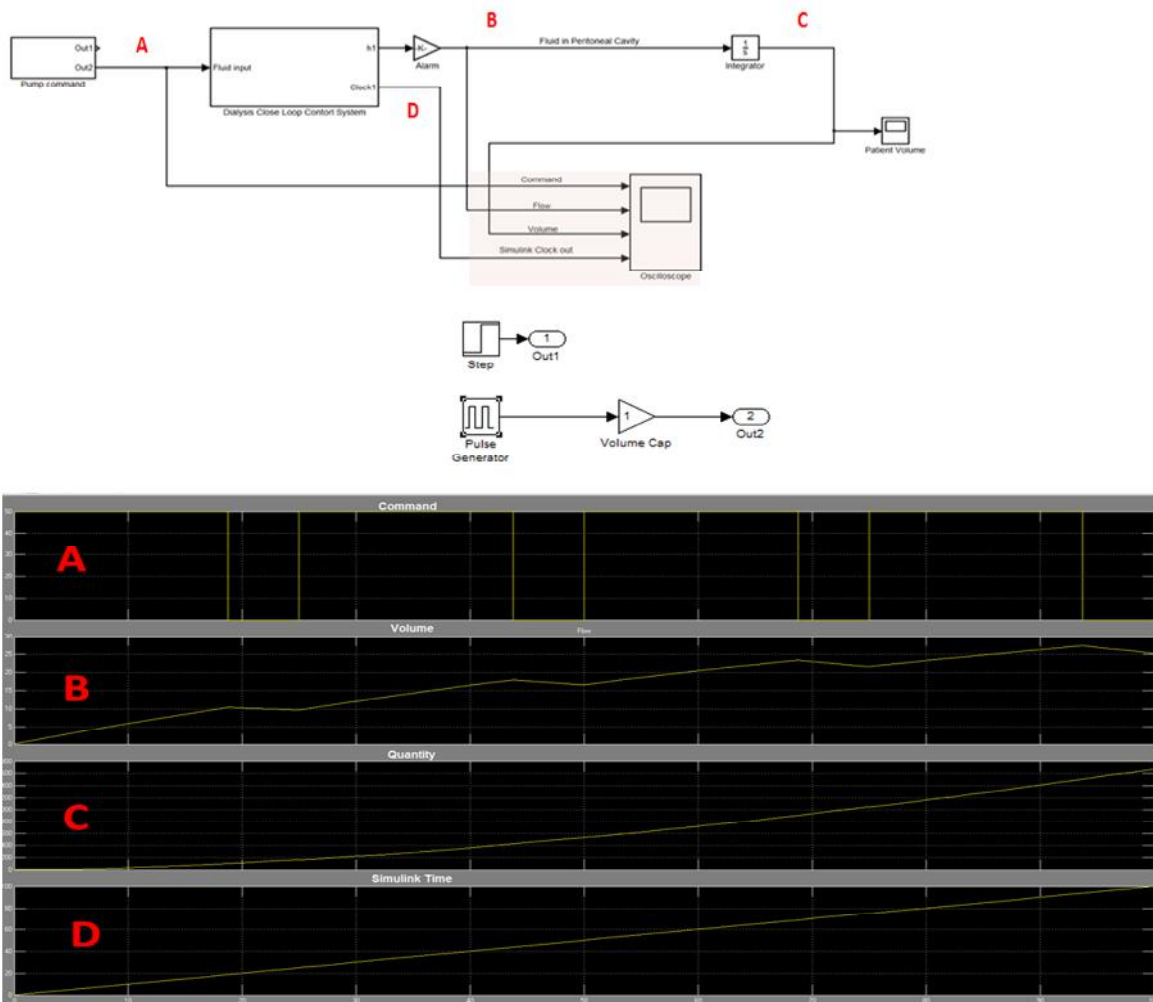


FIGURE 15. Pulse input response. The figure shows the system response when a pulse generator having amplitude of 50 and a period of 25 seconds with a duty cycle of 75% is asserted to the system.

The system response appears to be what is expected when compared to the physical process of conducting a manual peritoneal dialysis. The volume signal matches the expected behavior based on the pump command signal. Once the command drops to zero, the volume plateaus and remains constant. The quantity signal shows the volume signal after the integral and the final plot shows the digital electronic clock that is used when debugging the system. Even though the model is behaving as expected, a controller is required to maintain precision control and prevent hazardous conditions from occurring.

CHAPTER 6

PID CONTROLLER

A controller is required to ensure that system response is as expected and safety monitors can then be incorporated to prevent a hazardous situation. If a command is sent to the pump when the patient's abdomen volume is full that command will be ignored and no additional fluid will be forced into the patient's abdomen. Figure 16 shows the system model with a proportional–integral–derivative controller also known as a Proportional Interactive Derivative (PID) controller. The PID controller is a close loop control loop feedback that is commonly used in various types of industrial control systems. PID controllers continuously calculate the feedback error and adjust the gain to help compensate the command in order to achieve a pre-defined set point.

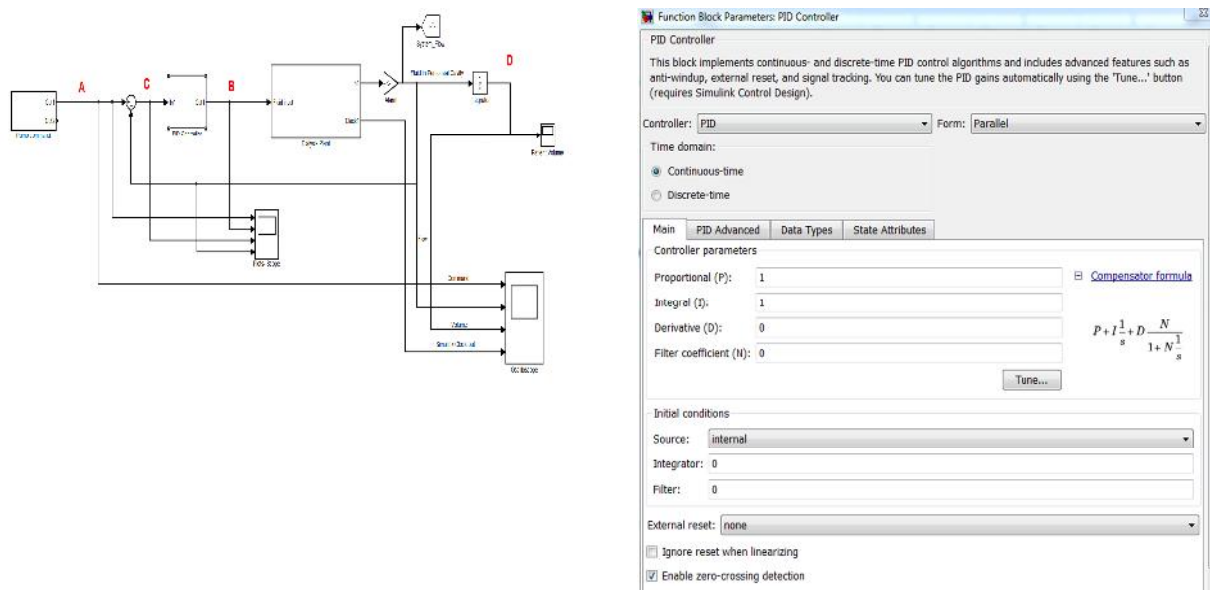


FIGURE 16. Simulink PID configuration. The figures show the peritoneal derived model with a proportional–integral–derivative controller as well as the controller's initial values for the Proportional, Gain and Derivative values used during simulation.

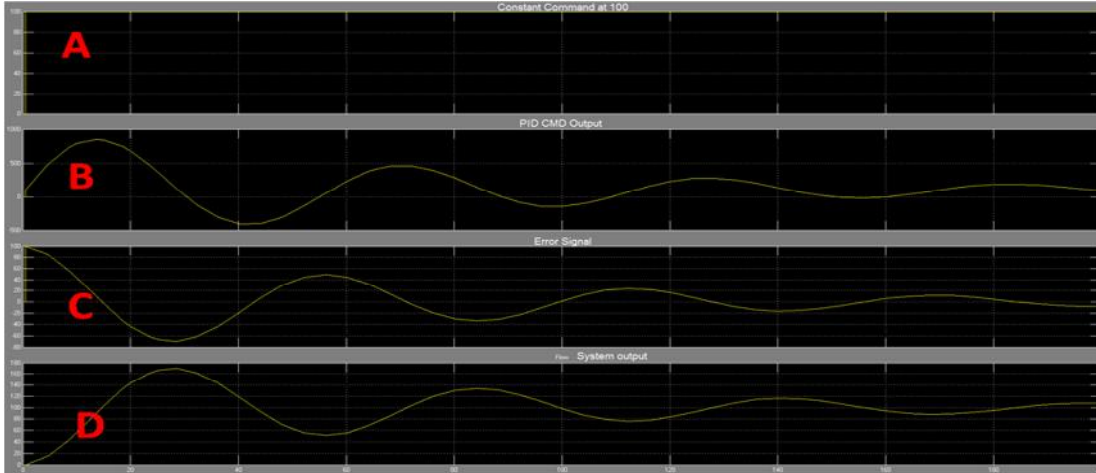


FIGURE 17. The plots show the initial system response when the PID controller is not properly tuned.

The plots shown in Figure 17 demonstrate how an improperly tuned PID controller can cause the model to be unstable. The plots depict that the error signal, C, never reaches steady state at 0 and that the system output continues to oscillate. In order to tune the PID controller, three variables will need to be adjusted so that each one compensates the other. According to Control Solutions, a PID controller is broken up into three different parts, the Proportional, the Integral and the Derivative part of the error signal [20]. Figure 18 shows the generic PID controller configuration. Once the computation is performed at each step, the resulting values of each step are added at the end to create the new command.

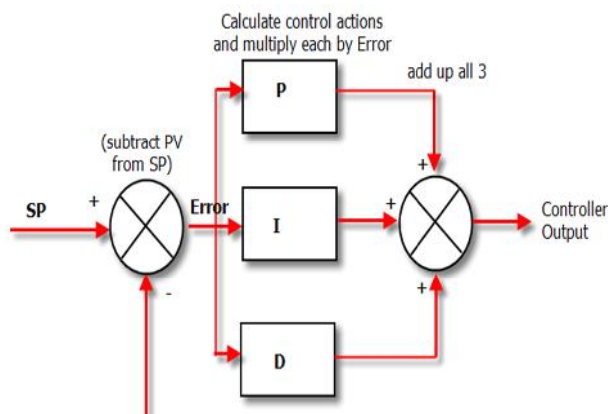


FIGURE 18. The figure shows the standard PID controller model [21].

Figure 19 shows the system response using a “tuned” PID controller as well as the calculated values used in the PID controller Simulink block. Figure 19 also shows that the overall system response quickly approaches a steady state response at 1, an ideal system response.

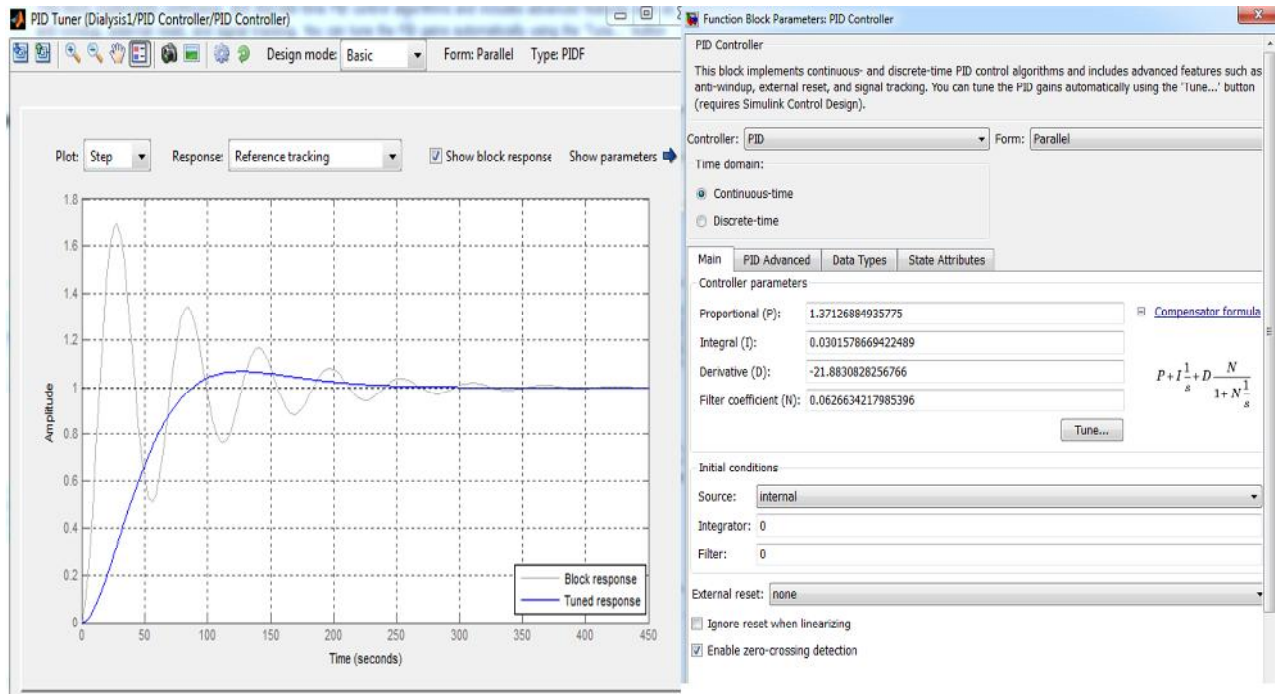


FIGURE 19. The PID system response. The PID controller has been tuned and the values that have been assigned to the Proportional, Integral and Derivative variables.

Once the PID controller has been tuned the simulation was rerun on the same model that was initially simulated. Figure 20 shows the system response being as close to the ideal conditions as possible. The error signal quickly starts to approach zero when the command remains as a constant 100. The PID output starts off with high amplitude in order to try to minimize the high error signal. The overall system output starts off at zero and as it starts to approach the set point value of 100 the error signal approaches zero.

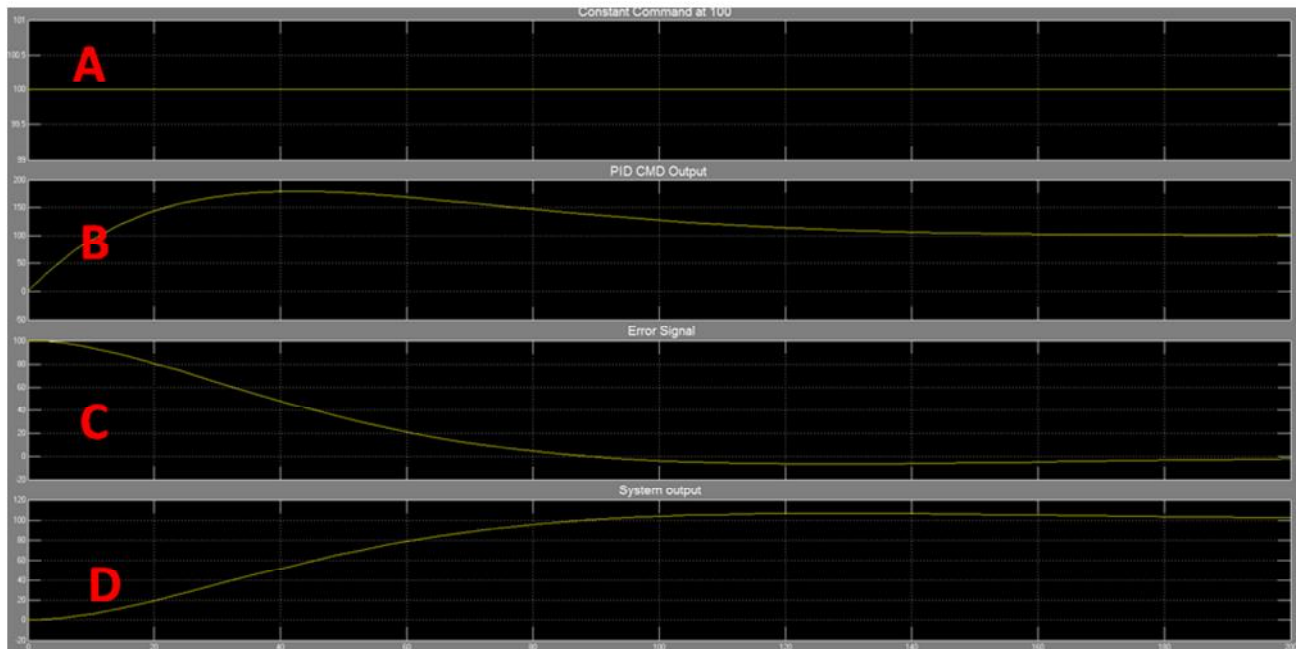
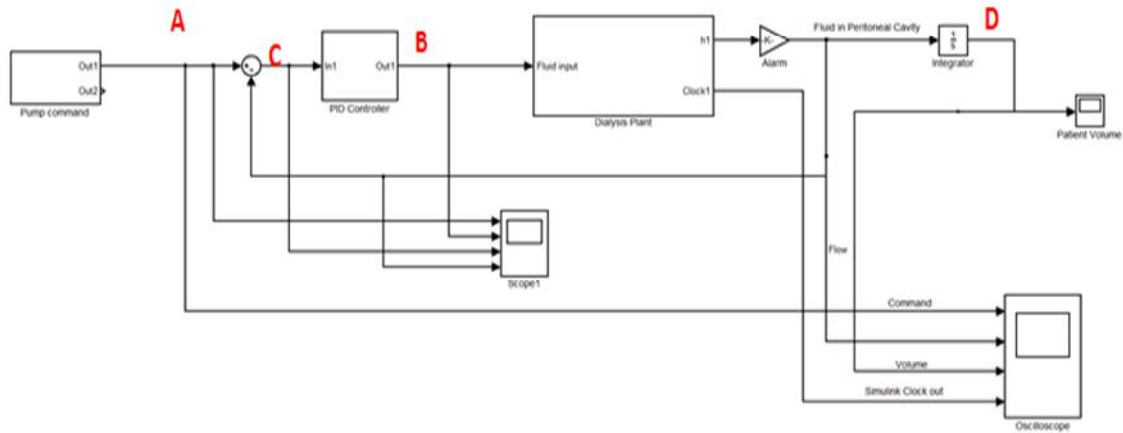


FIGURE 20. The overall system response with a properly tuned PID controller.

CHAPTER 7

SYSTEM MONITORS

Once the system has been developed and tuned to meet the expected behavior, several safety monitors can be incorporated to help minimize any potential hazardous conditions. The model was then updated to include an abdomen volume monitor that has been designed to detect the amount of fluid that has enter the patient and to “trip” a safety fault if the volume exceeds a preset value. A pressure sensor monitor was also incorporated to the model in order to prevent an excessive amount of pressure to build during treatment that can cause discomfort and possible illness to a patient. In addition to the patient’s health, this pressure monitor also helps in determining if any of the seals or pump heads starts to deteriorate. The flow rate monitor ensures that the delta pressure remains where expected and that a constant rate of flow is being delivered to the patient. In order to test the “fault” conditions and thresholds of these monitors a ramp input was asserted to them and the simulation was run for 100 frames. Figure 21 shows that each one of the monitors tripped when the ramp position reached the specific set point for each monitor. The logic used within the monitor block is broken down to individual blocks. Figure 22 shows the specific blocks that create the “Monitors” block.

Imbedded into each monitor block is a set of conditional statements that determine if specific system signals have exceeded a predefined set point and if so, the specific monitor will “trip” causing the monitor flag to toggle to a digital logic high. Figure 23 illustrates the conditional statements in a Simulink environment.

All of the monitors are not directly connected in the model in order to maintain clear visible traceability of what each block is connected to. The values are passed into the monitor blocks by the use of pointers. The overall system flow signal is also being sent to a “Goto”

Simulink block that allows the signal value to be stored into a variable and read from anywhere else in this model. Figure 24 illustrates how “Goto” blocks were used within the system structure.

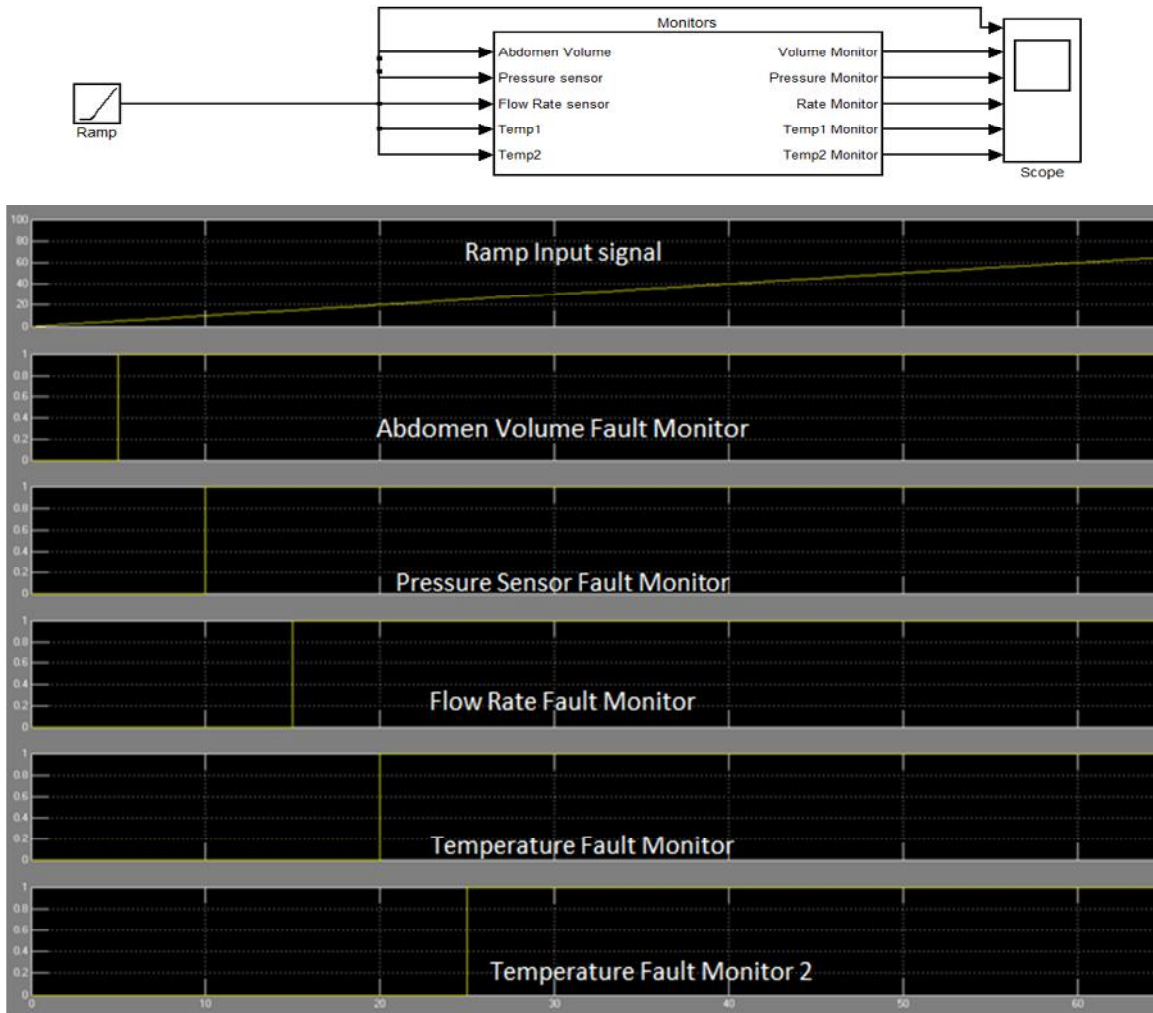


FIGURE 21. Safety monitors trip as expected when the ramp input command crosses their threshold.

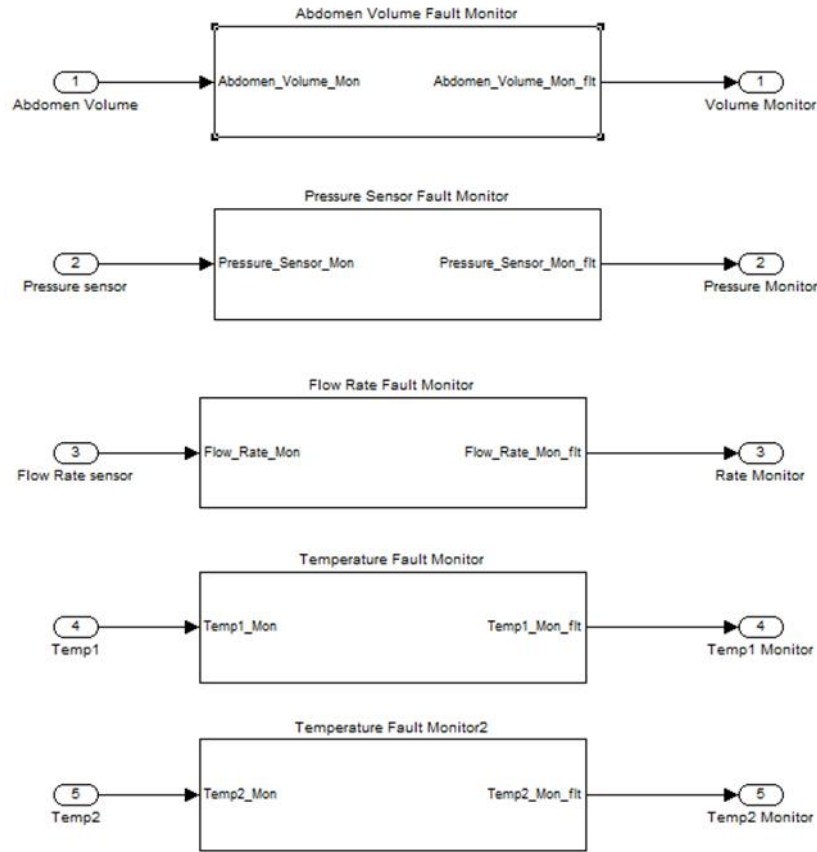


Figure 22. Simulink continuous monitoring. Continuous monitoring blocks were used to ensure parameters were within expected values through the simulation.

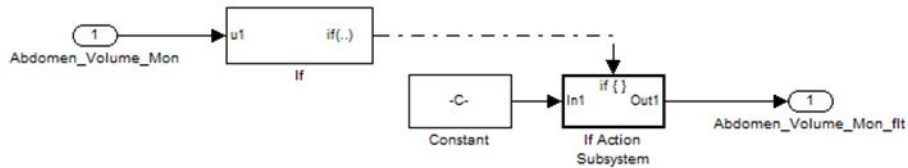


FIGURE 23. Simulink conditional statements. Conditional statement subsystems were used to determine if a specific variable had reached a predefined threshold.

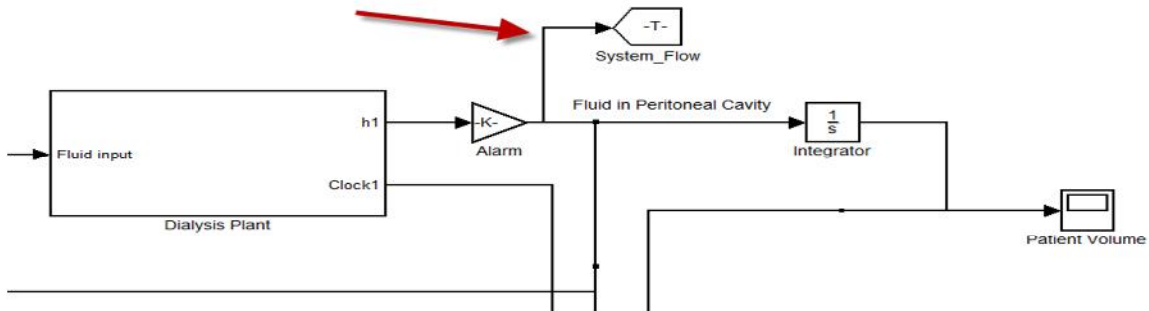


FIGURE 24. System pointers were used to reduce clutter in the system model.

Simulink's "Goto" block has been declared to be "System_Flow" and it has global visibility that allows the variable of "System_Flow" to be called from any imbedded block in the model. Figure 25 illustrates how each block is configured to use a global variable within the Simulink model. In this case, the variable "System_Flow" is being called from a "From" Simulink block that is being used in the "Abdomen Volume" monitor as shown in Figure 21. Figure 25 illustrates how the pointer is being used as a common input to the monitors block.

Figure 26 shows how several independent continuous monitors were merged into a single monitor block.

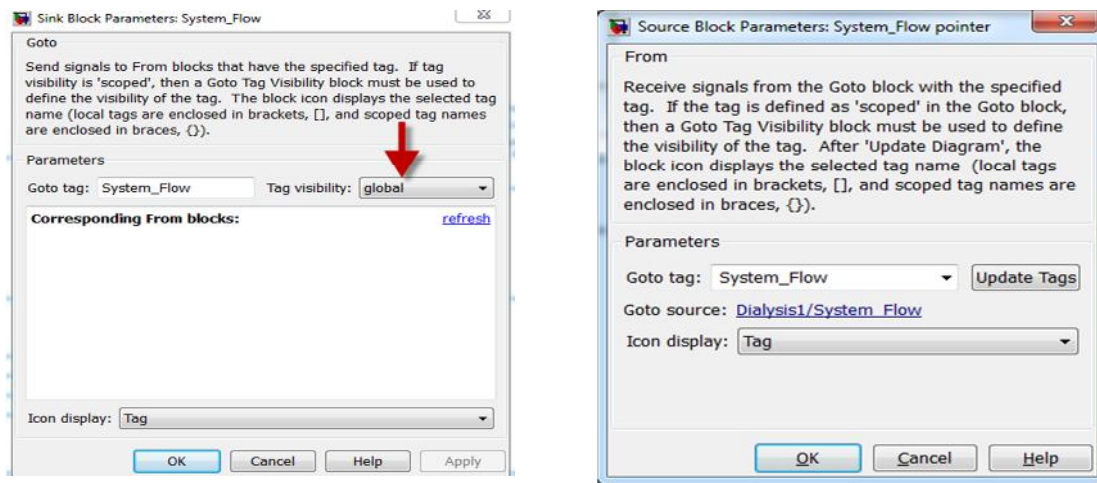


FIGURE 25. System pointers were assigned to MATLAB global variables.

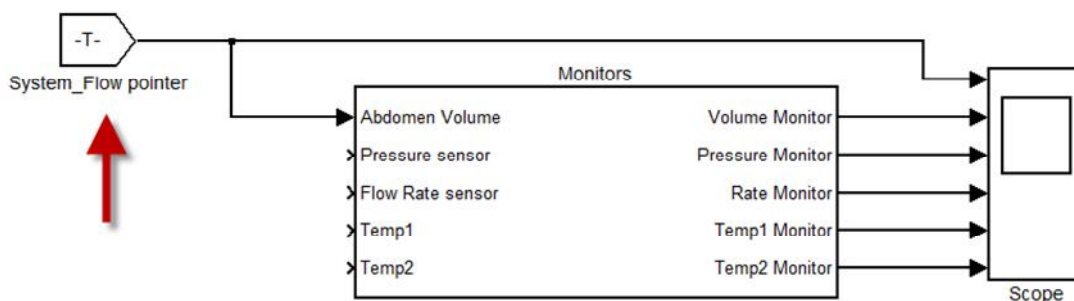


FIGURE 26. A Simulink monitors block. The monitors implemented in the model use a pointer type of coding to send signal value information from one place to another without having to connect the blocks.

CHAPTER 7

CONCLUSION

Chronic kidney disease is an ongoing epidemic in the United States that is continuing to grow as the older population is living longer and younger patients are being diagnosed with kidney failure at an earlier age. A clear cause of chronic kidney disease has not been determined but statistics show that certain illnesses, such as diabetes, may contribute to renal failure. Dialysis has become a high demand treatment and without a definite cure, medical companies have focused their businesses in long term care, such as peritoneal dialysis machines that help automate the PD process. Most biomedical equipment manufactures design their products to the best of their ability but every once in a while their equipment starts to malfunction and causes severe injuries to patients. Several class action law suits could have been avoided had the companies invested in their system modeling divisions. The peritoneal dialysis cyler model was developed in Simulink as MATLAB has a huge open source users group and databases that can easily be integrated into this model. Biomedical companies can use this model as a standard generic model that allows for the drag and drop feature of custom Simulink blocks. The drag and drop of custom Simulink blocks allows any company to quickly integrate their proprietary devices with their specifications to the model and simulate the system behavior.

This thesis shows how a peritoneal dialysis cyler model can be developed and simulated using the peritoneal kinematics. If this process is applied to all aspects of biomedical devices, it can help engineers design better system level requirements and manufacture safer equipment. Conditions that may typically damage the physical hardware can be simulated in a computer environment, such as Simulink, to determine how the system responds under special scenarios without having to destroy any equipment. Safety monitors and new technology can also be

incorporated into this model to determine whether any part of the system functionality is impacted before any production starts. This development will allow companies the ability to integrate multiple devices at a fraction of the cost and ultimately improve their products.

REFERENCES

REFERENCES

- [1] J. Jones. (1991, May 10). *Networks* 2nd ed, [Online]. Available:<http://www.atm.com>
- [2] National Institute of Diabetes and Digestive and Kidney Disease. (2004, May). The Kidneys and How They Work. [Online]. Available: <http://www.niddk.nih.gov/health-information/health-topics/Anatomy/kidneys-how-they-work/Pages/anatomy.aspx>
- [3] B. Wedro. (2015, Jan). Kidney Failure. [Online]. Available: http://www.medicinenet.com/kidney_failure/page2.htm
- [4] C. Nordqvist. (2015, Sep). Water Retention (Fluid Retention): Causes, Treatments. [Online]. Available:<http://www.medicalnewstoday.com/articles/187978.php>
- [5] J. Morrison. (2015, Dec 15). Creatinine Blood Test. [Online]. Available: <http://www.healthline.com/health/creatinine-blood>
- [6] C. Wanner, V. Krane, W. Marz, M. Olschewski, J.F.E. Mann, G. Ruf, and E. Ritz. (2005, Jul. 21). "Atorvastatin in Patients with Type 2 Diabetes Mellitus Undergoing Hemodialysis," *The New England Journal of Medicine*. [Online]. Available: <http://www.nejm.org/doi/full/10.1056/NEJMoa043545>
- [7] Centers of Disease Control and Prevention. (2013, Aug 05). National Chronic Kidney Disease Fact Sheet, 2014. [Online]. Available: http://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf
- [8] National Institute of Diabetes and Digestive and Kidney Diseases. (n.d). Kidney Disease Statistics for the United States. [Online]. Available: http://www.niddk.nih.gov/health-information/health-statistics/Documents/KU_Diseases_Stats_508.pdf
- [9] Wikimedia Foundation. (n.d). Dialysis. [Online]. Available: <https://en.wikipedia.org/wiki/Dialysis>
- [10] National Institute of Diabetes and Digestive and Kidney Diseases. (n.d). Treatment Methods for Kidney Failure: Hemodialysis. [Online]. Available: http://www.niddk.nih.gov/health-information/health-topics/kidney_disease/hemodialysis/Pages/facts.aspx
- [11] Vascular Surgery, University of Southern California Department of Surgery, Keck School of Medicine of USC. (2006, May 16). Types of Vascular Access. [Online]. Available: <http://www.surgery.usc.edu/vascular/vascularaccess.html>

- [12] S. Pruthi. (2016, May). Peritoneal Dialysis. [Online]. Available: <http://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/home/ovc-20202856>
- [13] J. Burkart. (2004, Dec.). The future of peritoneal dialysis in the United States: Optimizing its use. *Clinical J. Am. Soc. Nephrology*. [Online]. Available: <http://www.ncbi.nlm.nih.gov/pubmed/19995996>
- [14] Fresenius Medical Care. (n.d.). Liberty Cyclor. [Online]. Available: <http://www.freseniusmedicalcare.us/es/healthcare-professionals/renal-products/dialysis/home-therapies/>
- [15] Fresenius Medical Care North America. (2014, July). Newton IQ Cyclor Operation Manual. [Online]. Available: http://www.freseniusmedicalcare.us/fileadmin/data/us/pdf/HealthCareProfessionals/Renal_Products/Dialysis/PS_Documentation/01_Whats_New/470203_Rev_H.pdf
- [16] DEKA Research and Development Corp. (2014, Oct 10). Homechoice PD. [Online]. Available: <http://www.dekaresearch.com/homechoice.shtml>
- [17] ITACA Org. (2003, May). Fluid Mechanics For Gravity – Flow Water Systems and Pumps. [Online]. Available: <http://www.itacanet.org/fluid-mechanics-for-gravity-flow-water-systems-and-pumps/part-3-derivation-of-the-continuity-equation-3/>
- [18] Baxter. (2011, Dec 02). Peritoneal Dialysis. [Online]. Available: http://www.baxter.com.sg/patients_and_caregivers/therapies/renal/home_dialysis/peritoneal_dialysis.html
- [19] Emaze Amazing Presentations. (2015, April). Peritoneal Dialysis. [Online]. Available: <https://www.emaze.com/@ALRIWOOQ/Dialysis>
- [20] E. Weisstein. (2002, Mar.). Laplace Transform. [Online]. Available: <http://mathworld.wolfram.com/LaplaceTransform.html>
- [21] Control Solutions, Inc. (n.d.). Anatomy of a Feedback Control System. [Online]. Available: http://www.csimn.com/CSI_pages/PIDforDummies.html