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DESIGN AND IMPLEMENTATION OF A BALLOON CATHETER PRESSURE TESTING SYSTEM

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ABSTRACT

Medical device companies that aim to sell catheters with pressure sensing elements need a way to test their systems during the design phase. An example of one of these products is an Intra-aortic Balloon Pump (IABP) which provides mechanical pumping assistance to a patient experiencing cardiogenic shock.

To test these devices, companies will place the assembly in controlled pressure chamber to examine the response to pressure changes. However, commercially available systems are cost prohibitive.

To solve this problem, a custom, low-cost, pneumatic catheter test chamber was designed and built to provide a benchtop platform for experimentation.

In order to control the chamber pressure, the electromechanical system utilizes feedback control and solenoid valves controlled by an Arduino microcontroller. Since pneumatic systems exhibit nonlinear behavior, a novel control method was used to implement proportional-integral control and simulate the pressure profile experienced in the human body.

Keywords: Low-cost PI control, Catheter Testing

NOMENCLATURE

PI Control	Proportional-Integral Control
Electrical Analogue	Conversion of pneumatic system to a circuit for modeling purposes
System Identification	Determining system behavior from tests
IABP	Intra-Aortic Balloon Pump
RC Circuit	Resistor-Capacitor Circuit
SISO	Single Input Single Output
Arduino	Low-cost, off-the-shelf microcontroller

INTRODUCTION

Pressure sensing balloon catheters are currently used in a variety of procedures requiring *in vivo* pressure measurements. One of the most common devices utilizing this technology is an Intra-Aortic Balloon Pump (IABP). In this device, a pressure sensing balloon catheter is used for cardiac compensation in patients experiencing cardiogenic shock. When a patient's heart is unable to sufficiently pump, a catheter in the aorta inflates during diastole (relaxation phase) to increase coronary blood flow and deflates during systole to decrease cardiac afterload [1].

Companies that manufacture these catheters need a way to test their devices. This often involves placing the catheters in a pressure-controlled chamber to examine their response to pressure changes. Use of a benchtop experimentation platform can be extremely advantageous in assessing device design. Research shows that the preclinical stage of a new medical

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device can cost up to $20 million and take up to 3 years. Much of this cost is consumed during design iterations which use animal trials and benchtop tests to refine the device [2] . Furthermore, when applying for a 510(k) it is important to show a new device has "substantial equivalence" to an existing device. This is most often achieved through benchtop and animal testing [3].

Currently, low pressure controllers are available commercially from companies such as Mensor LP and Fluke Corporation. However, current products only achieve settling times of ~10s which makes it difficult to test rapidly changing pressures (Mensor CPC4000). Furthermore, low-end controllers are quoted at prices upwards of $6000, and high-end models, such as the Mensor CPC6050, are priced between $16,000-$20,000 [4-5].

For early-stage catheter design, it is important to test pressure sensing elements and system response before spending thousands on animal studies. However, buying a commercially available controller can cost up to two or three times more than one animal study. The lack of affordable options clearly show that there is a need for a controllable, low-cost, low-pressure, system for catheter testing.

To solve this need, a pneumatic chamber was built with a custom program used to alternate pressure in a similar manner to the human body. Since pneumatic systems exhibit nonlinear behavior, the control algorithm design was a significant engineering hurdle. A novel approach using an electrical analogue model was utilized in the design process. Furthermore, to keep the system low-cost, Arduinos were used as the digital controllers which produced additional engineering challenges. The design and results from this system are presented in this work.

1.1 DESIGN PROCESS

Before designing a controller, several important steps were taken to ensure proper design principles.

First, the physical system was built so the controller could be designed using system identification. In this process, data is taken from a basic system test and used in the modeling process to provide accurate model parameters.

Second, the nonlinear form of the system was converted to a linear, electrical circuit analogue model which is presented in *Section 1.3 Modeling*.

Third, a set of specifications was developed in order to provide parameters for controller design. These specifications were created with the average behavior of a human cardiovascular system in mind. Since the goal of the test system is to accurately mimic the body, these conditions formed the basis for the controller tuning. The specifications are presented below in Table 1.

Table 1: The parameters and target specifications represent the pressure profile of the average human heartbeat.

Parameter	Target Specification
Pressure Profile	Stable oscillations to mimic pressure changes in the body
Oscillation Amplitude	Average human blood pressure: 1.5 psi - 2.3 psi (80 mmHg – 120 mmHg)
Oscillation Frequency	Average human heart rate: 1 Hz (60 beats/minute)
Disturbance Rejection	Regain pressure profile within 1s after a disturbance

1.2 HARDWARE DESIGN

To keep costs minimal, the custom test system was assembled primarily using off-the-shelf parts. Once assembled, this provided the framework for the system modeling portion of the design process by allowing for the use of system identification. The final hardware cost was less than $500. The system flowchart is shown in Figure 1; the main components are listed below and shown in Figure 2. A closer look at the test chamber with a balloon catheter is shown in Figure 3.

1. **Air Storage Tank** – Air drawn directly from a lab air supply is stored in this tank before being transferred to the test chamber.
2. **Test Chamber** – The test portion consists of clear PVC with custom machined end caps and a custom 3D printed valve designed to fit balloon catheters.
3. **Dual Arduino Control Module** – In order to improve controllability, two Arduinos work in tandem to control the solenoid valves and monitor sensors.

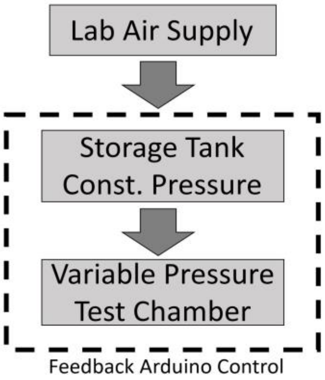

Figure 1. The catheter test system is supplied by a constant pressure compressed air system.

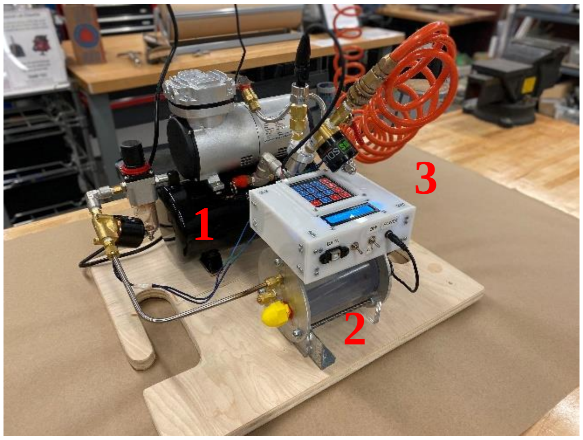

Figure 2: The physical system is shown with the three main components highlighted.

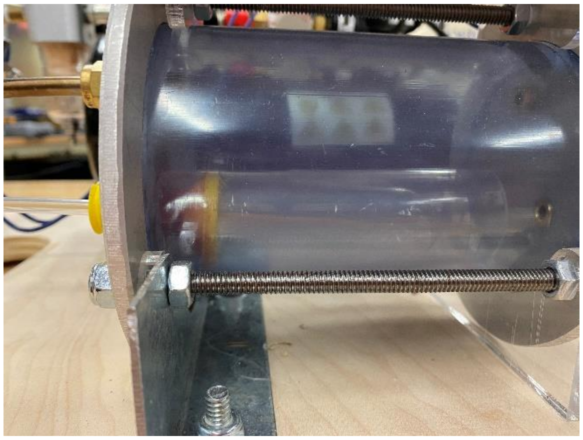

Figure 3. A balloon catheter is shown inflated inside the chamber. See *2.2 Results* and Figure 11.

To minimize cost, there were a few important design decisions made for key components. First, the use of direct-operated rather than proportional solenoid valves was an important cost saving decision. Proportional control allows for a valve to be open at various points throughout its stroke which gives a range of flow rates. Direct-operated valves are only fully opened or closed. However, proportional valves can be ten times as expensive as direct-operated valves. Therefore, the direct-operated valves were chosen for this design. Second, Arduino microcontrollers were chosen over other microcontroller options due to their low cost and ease of development. Third, since high-quality pressure sensors can easily cost hundreds of dollars, lower accuracy versions were chosen.

1.3 MODELING

It is well known that pressure systems operate in a nonlinear fashion. Since nonlinear control is both difficult and expensive to implement, a linear approximation is ideal for a low-cost design. Furthermore, when using an Arduino for process control, care should be taken to avoid exceeding the microcontroller capabilities since a computationally heavy algorithm can cause a system failure.

In order to achieve a linear approximation, the system was converted from a fluidic model to an electrical circuit model. In this analogy, the resistors represent the solenoid valves used to control flow while the capacitors represent the air storage tank and the test chamber. From this model, a linear state space realization of the circuit analogy was used as the framework for control of the pressure system (See Figure 4 below). This conversion from pneumatic to electrical is presented in *Modeling and Analysis of Dynamic Systems* by Close and Frederick [6].

Table 2. The pneumatic components and their electrical equivalents are presented below.

Pneumatic Component	Equivalent Electrical Component
Pressure	Voltage (Potential)
Storage Tank	Capacitor
Solenoid Valve	Resistor

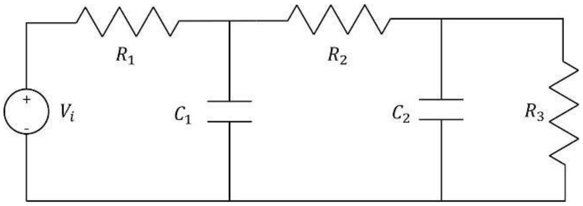

Figure 4: The electrical circuit analogy was used to realize a state space model of the pressure system.

1.4 ALGORITHM DESIGN

Since a single resistor-capacitor (RC) circuit is a simple single-input single-output (SISO) system, the dual RC system was split into two SISO loops. One drawback of using Arduino microcontrollers is that the hardware has limited capability for performing the calculations required for implementing feedback control. The SISO split ensured that the control algorithm is much less computationally expensive than other designs.

In order to find the RC values (time constants), system identification was performed to analyze behavior. A step input was applied to each loop, and pressure data was logged via the Arduinos. This collected data allowed for empirical determination of the system characteristics.

System identification also accounted for the storage tank dynamics, a key difference in the two SISO loops. Since the second RC loop is in series with the first RC loop, this behavior needed to be accurately modeled.

Using MATLAB, a proportional-integral (PI) controller was designed and implemented for each loop. The specifications developed (Table 1) were used to tune the controller gains and parameters. This controller was then converted to digital format and programmed into the control module.

$$\begin{bmatrix} \dot{V}_{C1} \\ \dot{V}_{C2} \end{bmatrix} = \begin{bmatrix} \frac{1}{C_1}\left(\frac{1}{R_2} - \frac{1}{R_1}\right) & \frac{1}{R_2 C_1} \\ -\frac{1}{R_2 C_2} & \frac{1}{C_2}\left(\frac{1}{R_3} - \frac{1}{R_2}\right) \end{bmatrix} \begin{bmatrix} V_{C1} \\ V_{C2} \end{bmatrix} + \begin{bmatrix} \frac{1}{R_1 C_1} \\ 0 \end{bmatrix} V_i(t) \quad (1)$$

$$V_{C2} = [0\ 1] \begin{bmatrix} V_{C1} \\ V_{C2} \end{bmatrix} \quad (2)$$

The state space model shows a realization where the voltage across the two capacitors are the state variables (Eq. 1). The output is represented as the voltage across the second capacitor (Eq. 2).

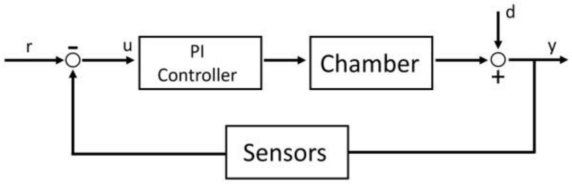

Figure 5: The block diagram above illustrates the presence of disturbances (d) in the system.

2.1 TEST METHODOLOGY

In order to evaluate the control algorithm design, we created a series of tests based on the design specifications. System stability over a range of oscillations was examined by inputting square waves of various frequencies and examining the system response. Square waves were chosen as the reference signal in order to avoid bogging down the Arduino with calculating a more complex input. By measuring the chamber pressure and comparing to the input, the system was evaluated for its ability to track a reference command. The system was also evaluated over several trials to determine repeatability. Additionally, the chamber safety valve was opened during one test to simulate a disturbance. Finally, a balloon catheter was inserted in the chamber and inflated during a test to examine how the system behaves in an actual test setting. This test was carried out using the setup shown in Figure 3.

2.2 RESULTS

The reference tracking results for various oscillations are shown in Figures 6-9. The results of the disturbance test, catheter test, and repeatability test are shown in Figures 10-12.

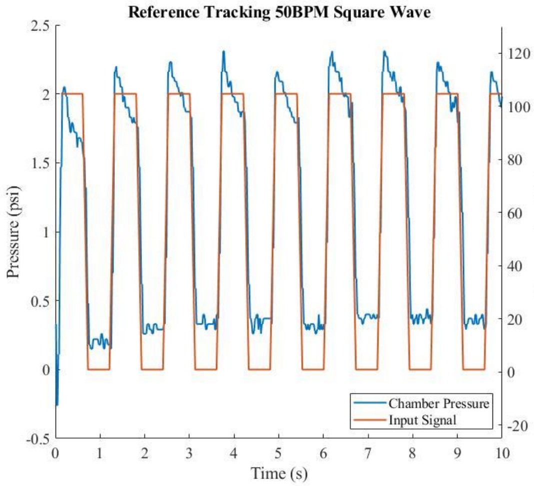

Figure 6. System tracking of a 50bpm square wave.

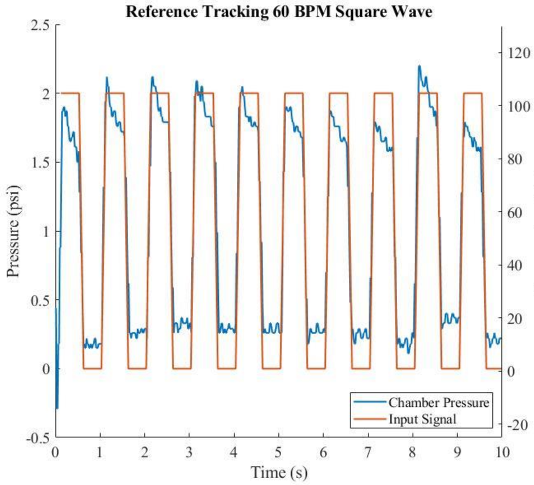

Figure 7. System tracking of a 60bpm square wave.

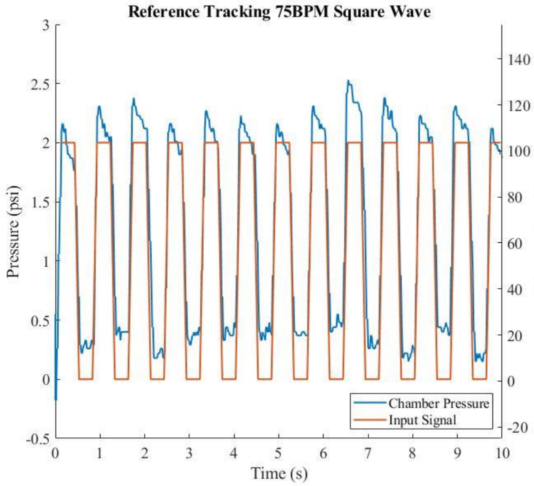

Figure 8. System tracking of a 75bpm square wave.

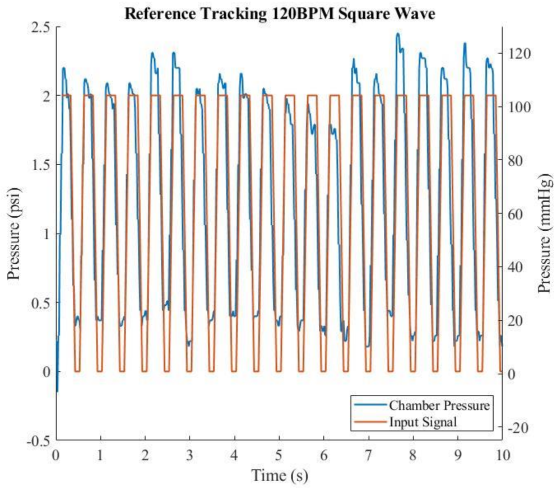

Figure 9. System tracking of a 120bpm square wave.

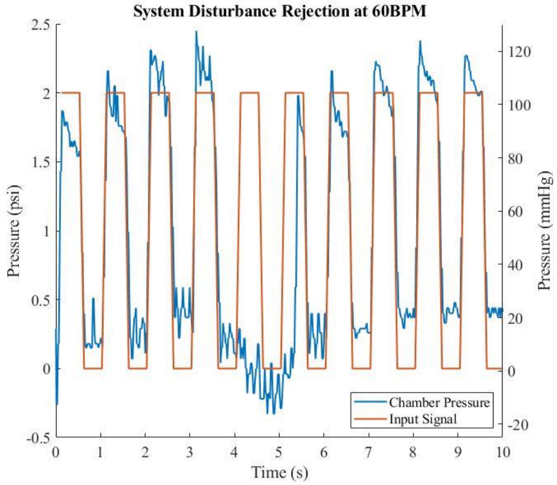

Figure 10. The system recovered from a disturbance applied at $t \approx 4s$.

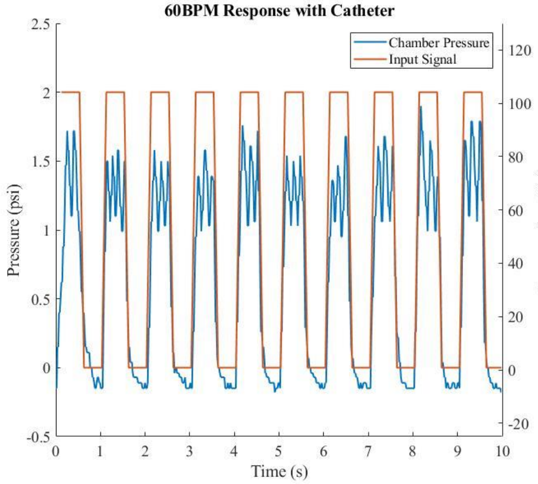

Figure 11. System test at 60bpm with an inserted, inflated balloon catheter (see Figure 3).

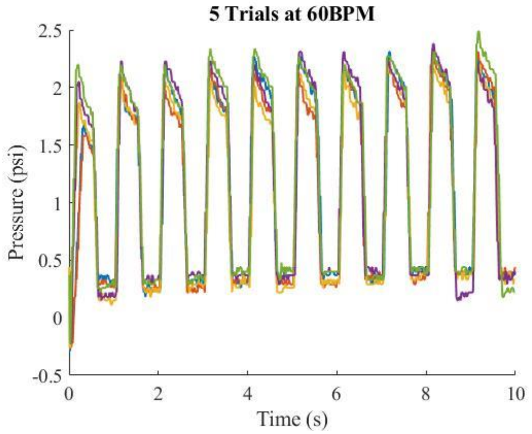

Figure 12. The results of 5 trials show the system has strong repeatability.

3.1 DISCUSSION

The system tests yielded performance which met the design specifications. As can be seen in the results, the system remained stable for oscillations ranging from 0.8-2Hz which accounts for a wide range of heartbeat rates. Furthermore, the system has the ability to reject significant disturbances and to operate with test balloon catheters.

Errors experienced in reference tracking are due to two factors: linear approximation of nonlinear behavior and lower quality components. It is well known that control of fluids is greatly complicated by nonlinearity, and many modern systems utilize complex control algorithms to account for this. However, low-cost hardware components necessitated a linear approximation, and when making approximations, the potential for error is naturally increased.

The use of low quality components also contributes significantly to error. With direct-operated solenoid valves, the system is limited by their ability to cycle between two states. More expensive valves would eliminate much of the error with their ability to modulate flow. Higher quality pressure sensors which have less sensor "bounce" would also reduce error. Finally, a more expensive microcontroller would be able to handle a more computationally intensive control algorithm as opposed to the relatively simple SISO PI controller that was implemented.

Since a primary goal of this system was to keep cost down, we determined that some system error was an acceptable tradeoff for a versatile test platform. The system cost makes it ideal for use in the design phase of a new catheter since the goal of benchtop testing is to perform large quantities of cheap tests. Furthermore, the system characteristics produced significant improvements over the commercial systems in terms of cycle time and settling time.

In conclusion, we believe the novel method of converting a nonlinear fluidic mathematical model to a linear electrical model allowed low-cost components to be used in an efficient way. Subsequently, we believe this system provides an effective alternative to the current market solutions.

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