

Testing System for a Pressure Sensitive Cardiovascular Catheter

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I. Abstract

Blood pressures within the heart and surrounding vessels are often measured using catheters that are equipped with pressure transducers. The accuracy of blood pressure measurements from these catheters has been called into question as calibration data is not provided by the manufacturer. A product is needed to calibrate and verify the pressure transducer measurements while simulating in vivo conditions.

A product is being developed to encase the catheter in saline solution while achieving pressures up to 200mmHg. An air pump increases pressure in the chamber through manual or micro-controller control. Pressure in the chamber is monitored with an additional pressure transducer imbedded in the tank.

In a second-generation prototype a feedback loop will pressurize the chamber to a value specified by the user via a pressure sensor, micro-controller, and air pump.

II. Problem Statement

Internal blood pressures within the heart and surrounding vessels are typically measured with catheters that are equipped with pressure transducers. Properly calibrated catheters are required to ensure valid blood pressure measurements during diagnosis and clinical trials. Current calibration techniques are thought to be unreliable. A product is needed to calibrate and verify catheter pressure transducer measurements while simulating in vivo conditions.

III. Background

The traditional process of catheter use in cardiovascular surgery begins with a one hour evaluation of the patient's heart and body. After consent for surgery is granted, the catheter is guided into the heart via the femoral artery and aorta (Figure 1). A drug is then administered to lower the pressure within the heart's walls. Finally, pressure measurements are obtained with the catheter. Clinical trials are being conducted by our client to verify a new blood pressure monitoring technology. The pressure readings of the new technology are compared to those given by the catheter and EKG. The readings between these devices are expected to be nearly identical (within 2 mmHg). However,

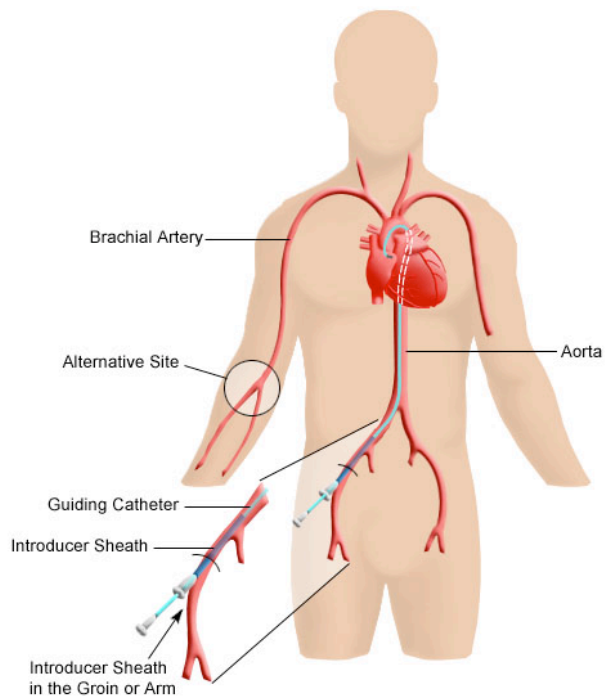


Figure 1: The catheter is inserted into the aorta and guided into the heart [1].

a significant amount of drift and inconsistency in the catheter's pressure readings has been observed, particularly at pressures near 200 mmHg [2].

First attempts to address this problem began with our client directly contacting Millar Instruments, the catheter manufacturer. After hearing the problem, Millar Instruments sent a new catheter to our client, stating that the problem would be fixed with a new catheter. During correspondence, our client often inquired as to what the validation and verification process for the catheter consisted of and Millar Instruments offered no response. Because of this, our client felt the need to develop her own method of verifying the catheter's accuracy and presented the problem to our team [2].

Our client had previously employed a student to address this problem, but the device and process they came up with was not satisfactory. A general schematic of this device is shown in Figure 2. Our client is dissatisfied with this design for

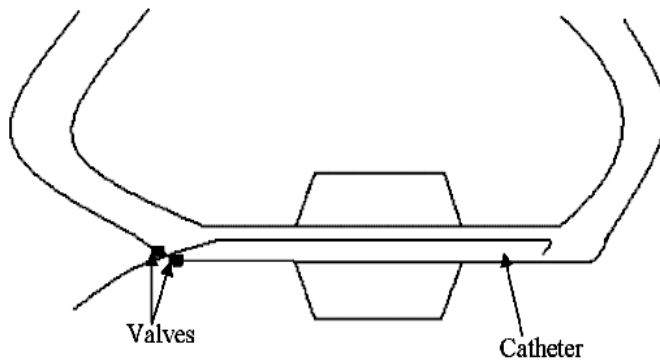


Figure 2: Previous attempt at a calibration design. In this device, the catheter is placed in a tube and secured in place

several reasons. The valves that were supposed to close behind the catheter and secure it in place within the tube were leaky. This makes the design messy and the pressure readings inconsistent and inaccurate. Even when the device was working as it should, constant pressure readings were still not observed, making the design ineffective in meeting the needs of our client.

IV. Design Constraints

Millar Instruments' current techniques for calibrating the catheter are unknown. Therefore, until a testing system is designed that validates the accuracy of the catheter's pressure readings, the catheter cannot be considered reliable for clinical use.

For the catheter's pressure readings to be considered accurate, several parameters for the testing system must be taken into account. The testing system should be able to validate the catheter's pressure sensor readings at both atmospheric and saline pressure values. Additionally, the calibration must be done in saline solution, where the pressure can be adjusted accordingly. A reference pressure sensor is thus needed to help validate and control these pressure values so that they are stable and accurate.

Because this design is meant to validate the catheter's readings, the testing system must be incredibly accurate itself - accurately measuring pressures within 2 mmHg. Our client has requested that the range of pressures covered extends from atmospheric to 200 mmHg and that the tests be conducted at increments of 50 mmHg. The catheter itself can read pressures of up to 300 mmHg. As such, all design components must be damage resistant at pressures up to 300 mmHg.

Operating characteristics comprise further concerns for this device. The testing system needs to be easily manipulated with one hand, so that the other hand is free to adjust the computer program or the catheter itself. Also, the device cannot be over 50 pounds, as it may need to be transported from one hospital room to another. Because the device may be used a few times a week until the client's research is complete, it must also be reliable for several years.

Safety is a paramount concern for this testing system, particularly because electrical components will be exposed to a conductive solution (saline). Additionally, the catheter will no longer be sterile after it is tested; therefore, it will require clear labeling and sterilization before being used in the operating room. To help with this concern, the testing system should be very easy to clean.

The final concern for our client is cost. The lab has little disposable income, so our client would prefer that the total cost of the design not exceed \$300.

V. Preliminary Design Alternatives

i. Design Alternative #1: Plunger Design

The first design alternative is a two chamber design. A saline filled chamber encloses a catheter and a pressure sensor. The catheter is held in place with interior structures such as tubes extending the length of the catheter with holes present at catheter pressure sensor locations. The second chamber is filled with air and has a variable volume. All chambers are entirely sealed with silicon rubber gaskets or caulk.

Figure 3 depicts a proposed geometry which embodies the concepts of the first design. Pressure is generated in chamber two by the movement of a piston, depicted as number 4 in Figure 3. Pressure is transferred to the saline filled chamber via a membrane, depicted as number 3 in Figure 3. The incompressibility of water results in near zero or negligible deflection in the membrane, allowing for equal pressure transfer between chambers.

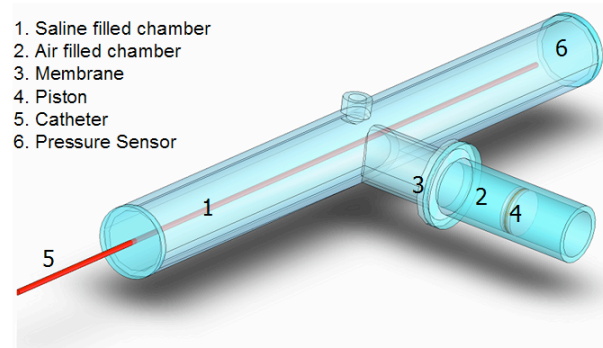


Figure 3: Plunger Design. A piston presses on the air filled chamber which will transfer pressure to the saline filled chamber.

The piston moves via a small linear actuator. A microcontroller determines the position of the linear actuator based on the desired pressure in the tank and the current pressure observed by the pressure sensor. Figure 4 depicts a similar control scheme that can be applied to design alternatives 1 and 2.

The feedback loop provides a constant method of monitoring and adapting pressure. This mechanism also allows the user to enter any pressure and determine the catheter's response. The membrane ensures no gas-liquid interface effects occur during calibration. However, the membrane and piston head add additional areas of potential leaking. In theory, a feedback loop could account for leaks if the response time of the system was fast relative to the leak.

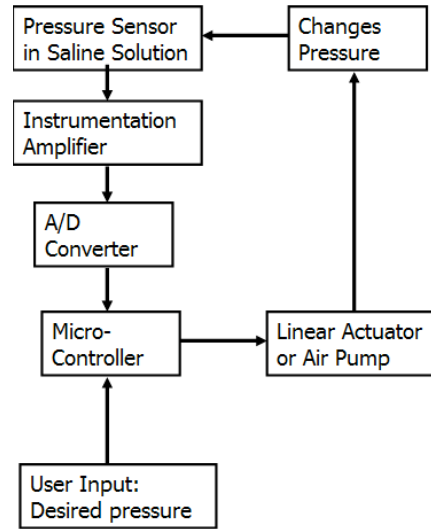


Figure 4: Feedback control scheme. A microcontroller integrates information from the pressure sensor and the user in order to create an appropriate pressure adjustment.

ii. Design Alternative #2: Balloon

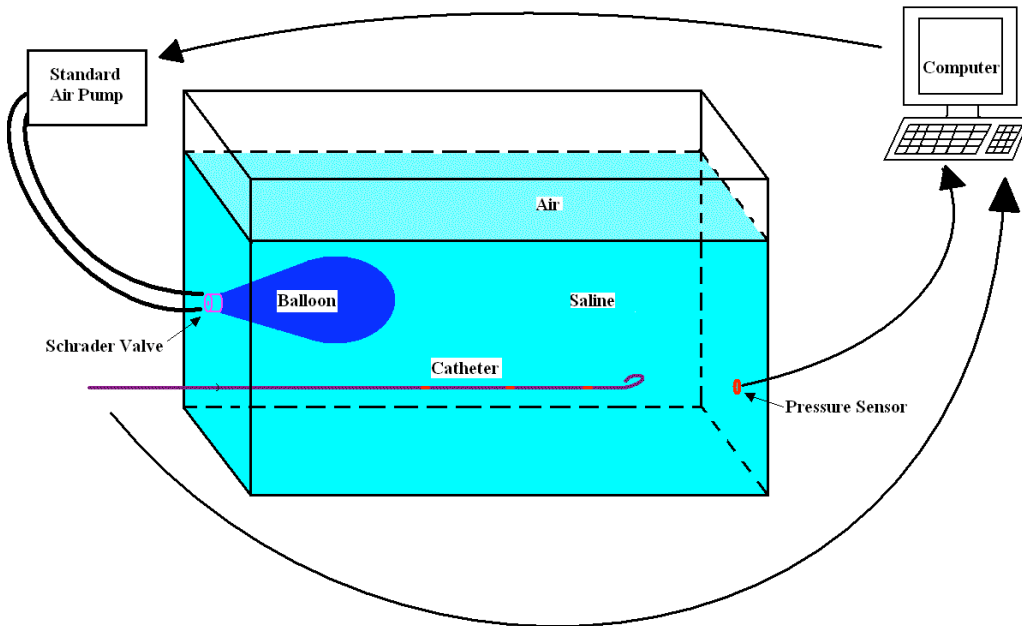


Figure 5: Balloon Design. The balloon is inflated by the air pump to create pressure in the container.

The second design alternative is depicted in Figure 5. It consists of an air-tight container that is partially filled with saline, a pressure sensor, a microprocessor, and an air pump. The catheter is suspended in the saline at the same level as the pressure sensor mounted on the inside wall of the container. An air pump is

connected to a balloon within the container. The user inputs a desired pressure into a computer. A microprocessor then compares the desired pressure to the pressure being measured by the pressure sensor on the wall of the container. If the pressure in the container is below the desired pressure, the microprocessor signals the air pump to begin inflating the balloon, which results in the pressurization of the air and saline. When the pressure within the container reaches the desired pressure, the air pump is signaled to turn off. Similarly, if the pressure in the container is above the desired pressure, the air pump will draw air out of the balloon and cause a drop in pressure within the container. To verify accuracy or diagnose a problem with the catheter sensors, the operator can compare the known pressure to the pressure readings given by the catheter.

iii. Design Alternative #3: Rotating Cylinder

A schematic overview of the Rotating Cylinder Design is shown in Figure 6. This design consists of a cylinder that has various size weights mounted on its surface. Using a computer, the operator can select a pressure at which they would like to calibrate the catheter. In response, the cylinder will rotate to that weight, and place the weight on the platform below.

After the user confirms the desired pressure selection, a release rod will retract into the cylinder, as shown in Figure 6A. Once the cylinder releases the weight, the full weight of the block is applied to the platform below. The platform mechanism consists of a falling platform with a plunger attached underneath. When the weight falls, the platform falls, causing the plunger to drop down onto the catheter, which lies in a tank of saline underneath the cylinder. On the bottom of the plunger is our own pressure sensor. Thus, when the weight falls both the catheter pressure sensors and our own pressure sensors take pressure readings.

After values have been compared for accuracy, the user can continue to the next pressure and its corresponding weight. When a new weight is selected, the release rod extends back out of the cylinder, picks up the weight, and draws it back flush to the surface of the cylinder. The cylinder then rotates to the next weight, and the process continues until the user chooses to stop the calibration.

This design would require a significant amount of fabrication and computer programming. The large cost of this design is another shortcoming. The biggest problem, however, is that the plunger applies a mechanical pressure rather than a fluid pressure. It is possible that the pressure sensors would react differently when contacted by the plunger than when contacted by pressurized saline alone.

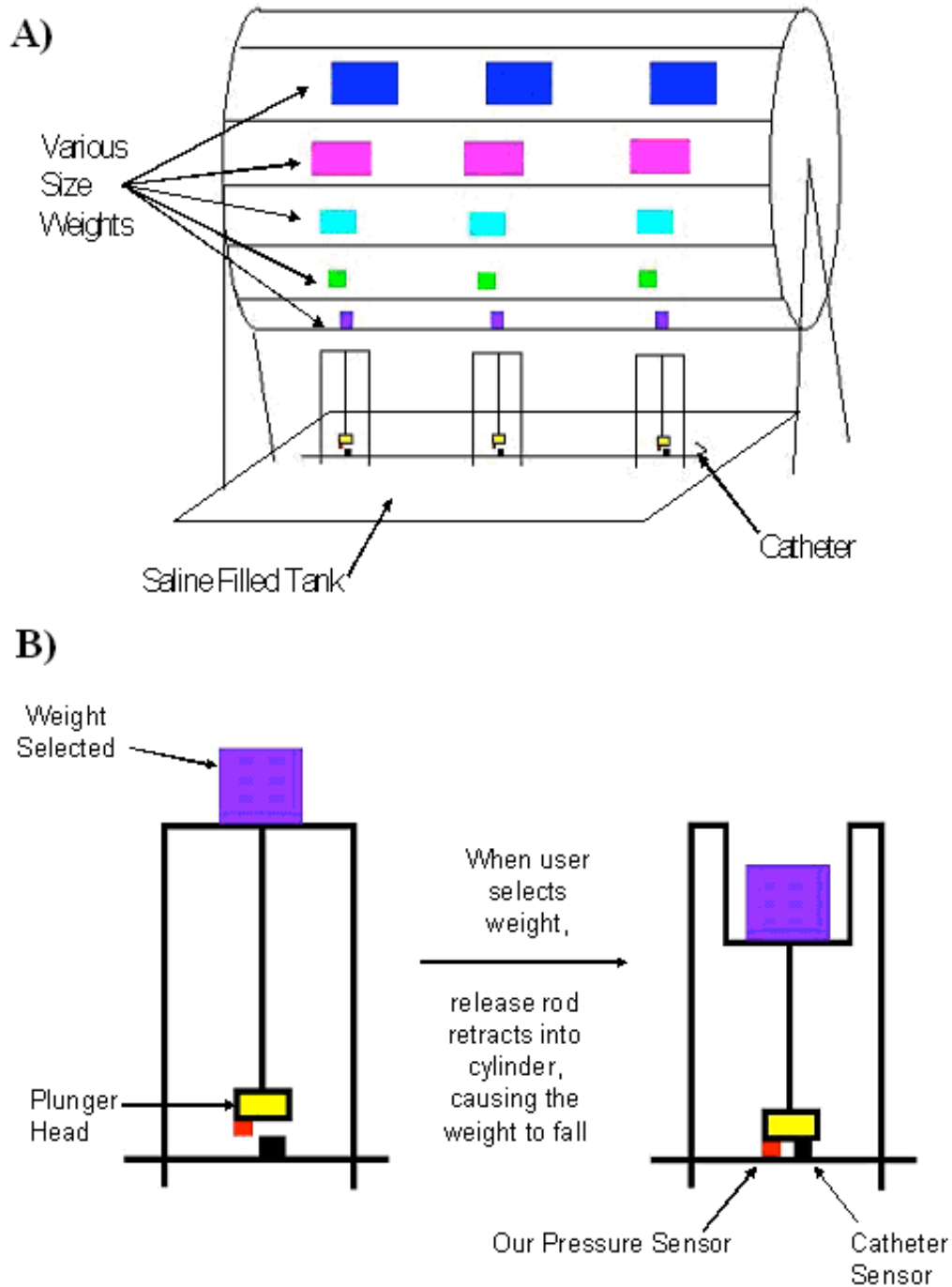


Figure 6: A) Rotating Cylinder design. The cylinder rotates and drops weights onto the platforms. **B) Close up of falling platform.** The weight falls on the platform, which transfers weight to a foam pad that compresses pressure sensor.

Along with the drawbacks, this design also displays several distinct advantages. The user has complete control over the entire calibration process, and the catheter's pressure sensor would be directly adjacent to our pressure sensor. This design is also very neat and easy to clean and saline can be removed and replaced with relative ease.

VI. Analysis of Design Options

All three of the proposed designs have positive and negative aspects associated with them. To determine the best design for the client a design matrix was constructed and is shown in Table 1. The matrix evaluates the designs based on effectiveness, cost, ease of production, user ease, size, complexity of programming required for automation, and maintenance. These categories are weighted according to their overall relevance to the client's requirements. Thus, effectiveness is the most vital while maintenance is least. Ease of use is important to the client and therefore is ranked second in the analysis, while cost is ranked third. Ease of production, size, and additional programming are of moderate importance. These qualities are not specifically stated in the client requirements, but they all have an effect on whether a working prototype is created within the allotted time. Using the design matrix, the team was able to decide on the balloon design.

Table 1: Design Matrix

	<i>Weight</i>	<i>Plunger</i>	<i>Balloon</i>	<i>Rotating Cylinder</i>
<i>Effectiveness</i>	0-6	6	6	4
<i>Cost</i>	0-4	2	2	3
<i>Ease of Production</i>	0-3	3	3	1
<i>Ease of Use</i>	0-5	4	5	5
<i>Size</i>	0-3	3	2	1
<i>Amount of Programming</i>	0-3	3	3	1
<i>Required Maintenance</i>	0-2	1	2	1
Totals		22	23	16

The main obstacles to the cylinder design were ease of production, size, and the amount of programming required to implement the design. Because it ranked so poorly in these areas, it was not considered a competitive choice for the final design. Although the plunger design and balloon design have scores that are very close, the balloon design was ultimately chosen because it scored best in the design matrix evaluation. In fact, the plunger design has equivocal marks in all categories except ease of use and required maintenance. Reduced marks in these categories are due to the membrane, cylindrical shape, and linear actuator associated with the design. If an air bubble is present in the plunger design the air inside the liquid chamber will compress and the membrane may reach a point where it cannot deform anymore. If the membrane cannot move any further and air is still present in the catheter chamber, the increased pressure against the

membrane will not result in an increase of the saline pressure. Therefore, the liquid chamber must be completely full, or else the compressed air (between the plunger and membrane) will not transfer all of the pressure. Also, cylindrically shaping the design means the user would not have an open area to correctly orient the catheter inside the chamber. The additional maintenance involved with the linear actuator is a relative estimate based on the involvement of moving parts in the design. Using the balloon design solves all these problems, and was the basis for our choice. Both the balloon and plunger design show equivalent ratings in effectiveness, cost, and programming. Taking all of the above particulars into account, we decided the construction of the balloon design would be better for the client.

VII. Final Design

Throughout the development process, the balloon design was altered significantly to produce the final design (developing prototype shown in Figure 7). While the general concept remains the same, the final design abandons the balloon and instead pressurizes the chamber by pumping air into the space above the saline. This design consists of three main components: the container, the air pump, and the pressure sensor.

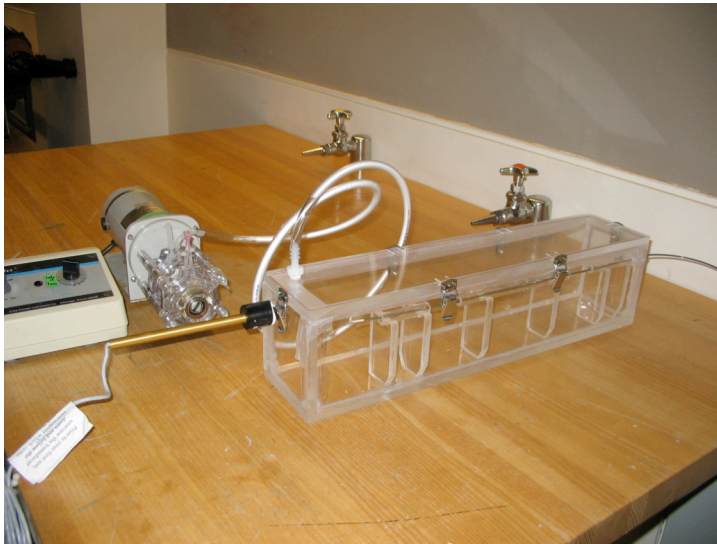


Figure 7: The prototype to date. This picture shows the container connected to the air pump.

The container is a 4" x 18.7" x 4.7" box with a removable top. It is made out of 0.35" thick acrylic, which was cut to dimension and chemically bound using ethylene dichloride. Holes for the catheter and pressure sensor insertion points were drilled on opposite ends of the box three inches from the bottom of the container and a half inch from the side. Another hole was drilled and threaded in the lid of the container for the hose adapter.

The catheter insertion point is mediated by a small plastic component. The catheter is threaded through the hole and then a knob is turned which cinches a rubber seal around the circumference of the catheter. After entry into the container, the catheter must be supported at the same level as the container's pressure sensor. To facilitate this, mounts were made out of three inch high blocks of acrylic and 2 ¼, 3, and 6 ½ inch segments of acrylic tubing (O.D. ½", I.D. ¼"). The tubes, shown in Figure 8, are spaced such that the pressure

sensors on the catheter will be openly exposed to the saline. When operating the device, the saline level just clear the top of the mounts.

Several measures were taken in an attempt to form an air tight seal. All fixed joints are sealed with silicon caulk and the threads of the hose adapter and pressure sensor are covered with Teflon tape for a tighter seal. Six metal draw latches are placed around the edges of the container (one on each end and two on each side) to tightly secure the lid. The junction between the lid and the container was initially sealed with a 1/8" rubber O-ring that was cut and caulked into a groove on the rim of the container. The O-ring failed to make a tight seal and was therefore removed. In another attempt to create an air-tight seal, a thin cork gasket material was cut into strips and applied to the lip of the container with epoxy. It is yet to be tested.



Figure 8: Close up of the container. This picture shows the tubular catheter mounts as well as the wall-mounted pressure sensor and cork gasket.

The pump currently being used is a Cole-Palmer LS Variable Speed Modular Drive Pump. It is intended for liquid applications and is on loan for the development stages of this design. The pump is equipped with a controller that allows the user to adjust the motor speed as desired. It is connected to the hose adapter in the lid of the container by a four-foot long, 1/4 inch inner diameter plastic tube.

The pressure sensor is a MLT1050 Precision Blood Pressure Transducer by PowerLab ADInstruments. It is a high quality sensor intended for wet applications. Within the sensor, the pressure inside the container is converted into a linearly proportional voltage output. The voltage can then be converted to pressure readings by the PowerLab software that accompanies the sensor.

VIII. Future Work

This design serves as an initial starting point for further development of the project but, several steps remain before the prototype is ready for client use. First, further tests must be conducted on the container to quantitatively verify its structural integrity and the presence of an air-tight seal. These tests will be

conducted with a manometer initially and then with the pressure sensor and computer program.

Another important improvement that must be made to the design is the acquisition of a new air pump. The pump currently in use is not intended for gas applications and is not able to provide a large enough air flow to generate 200mmHg in an acceptable amount of time (<10 seconds). Several pumps that are suitable substitutes and are within the budget have been found.

Once a new pump has been purchased, the feedback loop between the container-mounted pressure sensor and the pump may be developed. An 8-bit microprocessor will be programmed to turn the pump on or off until the pressure in the container matches the desired pressure entered by the user. In this way, the pressure inside the container will be automatically maintained throughout the calibration procedure.

The completed design should also have some sort of jacket surrounding the container. This jacket serves three purposes. First, it would maintain the container at a constant temperature, which is important since the pressure sensors are sensitive to temperature. Second, it would prevent light from interfering with the pressure readings because it would be made of opaque material. Third, it would provide additional structural support to the highly stressed walls of the container. Several design alternatives for this component will be considered.

Finally, after the design is completed and tested, a calibration protocol will be established and tested with functioning catheters.

IX. Ethical Considerations

The integrity of all testing data is the primary ethical concern for this project. The catheter will be used to monitor blood pressure readings, which currently are used in a study; however, the data that is collected from this study could eventually affect diagnosis and treatment of patients. Therefore, it is essential that our successes, failures, and data be accurately recorded and correctly represented. In addition, our device must be rigorously tested for accuracy in order to protect the patients. If the device falsely confirms catheter accuracy and the catheter is found to be erroneous during clinical use, the patient will have been unnecessarily exposed to the risks of invasive catheterization, as reliable data will not be recorded.

X. Conclusion

The first generation prototype that has been developed serves as a template for optimization of the design. The design is very user friendly in filling the unit with saline, securing the top to seal the container, and inserting and positioning the catheter. Several unforeseen complications arose through initial testing of this

first generation prototype including: strain within the top resulting in leaking, deformation of the draw latches, and potential fracture of the material if over-pressurized. As the project moves forward the positive aspects of the design will be retained, while faults in this first generation prototype will be addressed.

XI. References

[1] University of Virginia Health System. (2006, August). Cardiac Catheterization: What is a cardiac catheterization (also called cardiac cath)? Retrieved December 5, 2006:<http://www.healthsystem.virginia.edu>

[2] Vj, Divay. Personal Interview. 29 September, 2006.

Appendix A: Product Design Specification (PDS)

Title: Testing System for Pressure Sensitive Cardiovascular Catheters.

Client: Colette Wagner
Nancy Sweitzer, M.D., Ph.D.

Team Members: Danielle Ebben, team leader
Anthony Wampole, communications
Erik Yusko, BWIG
Anita Zarebi, BSAC

Function:

The device should serve as a testing tool which validates the accuracy of pressure readings from a pressure sensitive cardiovascular catheter. Currently, the techniques used by the manufacturer for calibrating the catheter are unknown and the accuracy of pressure readings is questionable.

Client requirements:

- Testing system to validate/calibrate catheter
- Test at atmospheric pressures
- Test at pressures other than atmospheric
- Test in a saline solution where pressure can be controlled
- Provide very stable and constant known pressures for validation

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* See client requirements

b. *Safety:* The validation and testing methods used with the catheter will likely not be a sterile environment. As such any catheters that have been tested should be clearly labeled as no longer sterile and in need of autoclaving and/or other sterilization procedures necessary. It would be desirable to have a system that could be easily cleaned and sterilized to prevent excessive contamination. In addition, precautions should be taken considering the fact that electrical components will be used in close proximity to relatively large volumes of saline.

c. *Accuracy and Reliability:* As the purpose of this project is to design a device that will test the accuracy and reliability of a catheter, the design must be incredibly accurate. The catheters themselves will register pressures from -50 mmHg to 300 mmHg with an error of +/- 3 mmHg. The calibration device must be able to

repeatedly produce a steady pressure of known magnitude with which the pressure reading from the catheter can be compared. This pressure should be able to be varied from atmospheric pressure to 200 mmHg.

d. *Life in Service*: The device must withstand several years of use. It will likely be used a few times a week for brief periods of time until the client's research study is completed.

e. *Shelf Life*: The device will be stored in a hospital setting. It will most likely be stored at room temperature in a dry environment.

f. *Operating Environment*: The operating environment will likely be at room temperature. The operation of the device will involve the use of saline as well as pressurized air. Therefore, all components must resist corrosion and be stable under 300 mmHg pressure. There will likely be electrical devices used in conjunction with the calibration device.

g. *Ergonomics*: The researcher should be able to operate the device with one hand so that the other hand may be available for manipulating the catheter or adjusting the computer program. Setting up the device should be relatively straightforward to avoid confusion and maintain efficiency. Operation of the product should not require more than 10 pounds of force.

h. *Size*: The prototype should be easily contained in a laboratory setting. Although there is no formal size restraint, the largest theoretical size of the device would be around 3 feet x 3 feet x 3 feet.

i. *Weight*: Weight is important because the device may have to be transported from one room to another. Thus, the weight should be under 50 lbs to allow for technicians to be able to place it on a cart for mobilization.

j. *Materials*: The materials used for the device will likely be composed of different plastics. Plastic plates or tubing will be used to contain this liquid to allow for optical vision and to prevent any degradation of the box due to its constant contact with liquid. There is a possibility for the use of metal supports in the device, but will be used sparingly. The device may also call for an electrical circuit containing typical circuit components.

k. *Aesthetics, Appearance, and Finish*: The device should be as aesthetically pleasing as possible. The finished product will be

opaque to shield the catheter from light which can interfere with the accuracy of pressure readings.

2. Production Characteristics

- a. *Quantity*: Based on the current quantity of test subjects that are being seen, one prototype calibration unit should be sufficient.

- b. *Target Product Cost*: The client has tentatively set a price ceiling at \$300, but has also stated that a working prototype would be worth more than that. Thus, it is feasible the device may be made under \$300, but almost certainly will fall in the range of \$100-\$500.

3. Miscellaneous

a. *Standards and Specifications*: This testing system cannot disrupt the surgical procedures surrounding its use. Rather, the system should be able to transition smoothly into and out of the surgical process as needed. As long as the catheters are sterilized after contacting the calibration device and before being used on test subjects, FDA approval should not be necessary.

b. *Customer*: Our client's major concern is accuracy of measurements. In addition, the client is also very adamant about the neatness of the design; extra messes cannot be tolerated in an operating room. Cost issues also concern our client; any budget related issues must be brought to the client first, and a log of where money was spent needs to be kept.

c. *Patient-related concerns*: Our device will need to be sterilized between uses along with the catheter calibrated. Mobile devices capable of storing information from a computer (such as key plug-in for a USB drive), are strictly prohibited in the area of the hospital we will be working in; this in an effort to safeguard patient confidentiality.

d. *Competition*: The company that manufactures the client's catheters has a method to calibrate their catheters but this method has not been shared with our client. Therefore, this method is not available for comparison with our design. In addition, our client had hired an intern to work on the project. The intern developed a tubular device which was intended to have a controlled pressure. The catheter was then placed inside the tube for calibration. The drawbacks of this device are that it can not maintain a steady pressure and it is unable to be used effectively with saline.