

Title: Verification and Calibration Method 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. The current techniques for calibrating the catheter are unknown and therefore unreliable in clinical trials.

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 300 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 will be translucent plastic to allow researchers to view the catheter during calibration. Also, the device will be made as aesthetically pleasing as possible as there is a good chance the calibration will be done in the room with the patient/research subject present.

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. This device was unsatisfactory because it could not maintain a steady pressure and was also unable to be used effectively with saline.

Testing System for Pressure Sensitive Cardiovascular Catheter

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Date: *Friday, Sept. 15th to Thursday, Sept. 21st*

Problem Statement:

In order to accurately measure internal blood pressures, a properly calibrated pressure sensitive cardiovascular catheter may be used. The current techniques for calibrating the catheter are unreliable, which causes concern about the validity of the test results. The goal of the project is to devise a testing system which more reliably calibrates and verifies the accuracy of the catheter in both atmospheric tests and tests which simulate internal bodily conditions.

Last Week's Team Goals:

- Research Millar catheters
- Begin tampering with test equipment
- Split up PDS and begin writing it

Individual Goals:

Danielle: Organize a team meeting at hospital, assemble PDS document
Tony: Get contact info of other resources, gather questions to send to Millar, work on PDS
Erik: Begin working on website, research, work on PDS
Anita: Assemble team binder, research, work on PDS

Summary of Accomplishments:

- Finished the first draft of the PDS document.
- Held a meeting at the hospital to read manuals and get familiar with equipment

This Week's Goals:

- Continue researching catheters and pressure sensors.
- Meet with client and other resources again to clarify remaining questions.
- Start brainstorming design ideas.

Project Difficulties: none

Activities:

Team: Split up PDS, met with advisor, held meeting at hospital	2.5 hours
Danielle: Assembled PDS, progress report, notebook, research.	5 hours

Tony: E-mailed client for contact info, PDS.	4 hours
Erik: Notebook, PDS, research Millar website	3.5 hours
Anita: Notebook, PDS, research	3.5 hours

Running Total

<i>Name</i>	<i>Hours</i>
Danielle Ebben	9.5
Anthony Wampole	6
Erik Yusko	6
Anita Zarebi	5.5
Team total	27

Project Timeline:

<i>Week starting:</i>	<i>Accomplishment/Goal</i>	<i>Completed</i>
Sept. 8 th , 2006	Assemble team, exchange contact info, establish roles	✓
	Meet with client	✓
	Begin researching topic	✓
Sept. 15 th , 2006	Continue research	✓
	start PDS draft	✓
Sept. 22 nd , 2006	Finish PDS	
	Meet with client and Divay Vj	
	Brainstorm	
Oct. 6 th , 2006	Choose three design alternatives	
	Complete rough draft of midsemester report for peer review	
Oct. 13 th , 2006	Work on midsemester presentation	
	Continue work on midsemester report	
Oct. 20 th , 2006	Give midsemester presentation	
	Hand in midsemester report and notebooks	
Oct. 27 th , 2006	Choose design	
	Gather materials and begin building prototype	
Nov. 3 rd , 2006	Work on prototype	
Nov. 10 th , 2006	Work on prototype	
Nov. 17 th , 2006	Work on prototype	
	Begin testing prototype	
Nov. 24 th , 2006	Finish building prototype	
	Prepare for final presentation	
	Begin final report	
Dec. 8 th , 2006	Give final presentation	
Dec. 13 th , 2006	Hand in final paper and notebooks	
	Meet with advisor	

Expenses: none