UNIVERSITY OF WISCONSIN – MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 200/300 – DESIGN

Hemodynamic Analysis System

Mid-Semester Report

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Abstract

Researchers are currently looking for improved methods to diagnose pulmonary hypertension. One such method involves the calculation of pulmonary vascular impedance (PVZ) which can be used to locate defects in arteries as well as quantify arterial stiffness that can result from pulmonary hypertension. To determine PVZ arterial pressure from right heart catheterization and blood flow from Doppler echocardiography must be synchronized in time. Therefore, the objective of this project is to design, construct, and test a system that will synchronize pressure and flow data. Thus far, the team has compiled the specifications for such a device, developed three design alternatives, and chosen a final design to pursue. The final design involves two PC oscilloscopes working in unison with LabVIEW software. The next steps in this project involve ordering components, building the device, and testing the entire system.

Background

Pulmonary Hypertension

Pulmonary hypertension is defined to be pressure exceeding 25 mmHg in the pulmonary arteries when measured with right heart catheterization. This high pressure becomes too much for the heart to keep up with and prevents sufficient quantities of blood from circulating to the lungs to pick up oxygen. In turn, the oxygen deprivation leads to symptoms including: tiredness, shortness of breath, enlargement of the right heart, fluid buildup in the liver and other tissues, and heart failure. Some of these physical changes are depicted in Figure 1. Pulmonary hypertension can be triggered by pre-existing diseases and can cause further diseases such as Hypoxia [1].

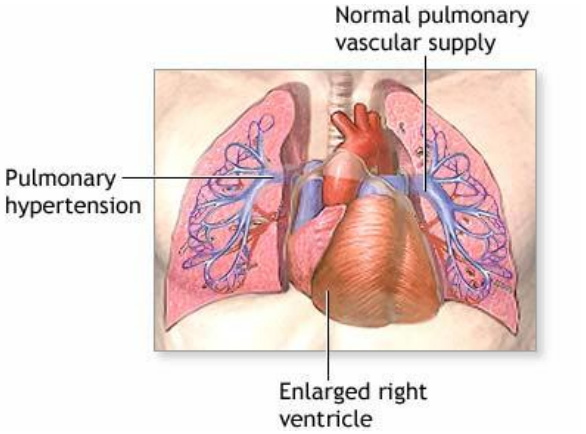

Figure 1: Diagram of the physiological changes that occur in a patient with pulmonary hypertension. [a]

A chest x-ray, electrocardiogram, Doppler echocardiography, or right heart catheterization may be used to diagnose pulmonary hypertension. Chest x-rays may show enlargement of the right heart that is indicative of pulmonary hypertension. An electrocardiogram shows abnormalities that are suggestive of right heart failure which is also associated with pulmonary hypertension. However, in both of these tests, the data obtained is not very conclusive or useful in analyzing the condition of the patient. Therefore, Doppler echocardiography and right heart catheterization are the preferred tests to diagnose pulmonary hypertension, and the use of the two tests together can yield important details of the severity of the disease [2].

Doppler Echocardiography

Doppler echocardiography is the use of standard ultrasound to image the heart and obtain data on velocity and flow of blood. The test is simple and noninvasive and therefore preferred in diagnosis of pulmonary hypertension. In this method, a transducer emits an acoustic signal at a known frequency, which is then reflected off the targeted blood vessel and finally returned to the transducer [3]. The

frequency of this returned signal undergoes a Doppler shift due to the motion of blood through the vessel. The two known frequencies are related by the following equation:

$$f_d = \frac{2f_o v \cos\vartheta}{c} \qquad \text{(Equation 1)}$$

In this equation, f_d is the Doppler shifted frequency, f_o is the frequency initially emitted by the transducer, θ is the angle between the probe and the vessel, v is the blood velocity, and c is the velocity of sound in blood, assumed to be 1540 m/s. Since both frequencies are known, the velocity can be calculated by substituting all the values into Equation 1 [4]. The accuracy of Doppler echocardiography is influenced by several factors such as obesity and hyper-inflated lungs that may alter the position of the heart in relation to the probe. For this and other reasons, right heart catheterization is typically used in conjunction with Doppler echocardiography in diagnosing and monitoring pulmonary hypertension.

Right Heart Catheterization

In right heart catheterization, a catheter is inserted into either the femoral, subclavian, or jugular vein, threaded into the heart, through the tricuspid and pulmonary valves, and finally into the pulmonary artery as shown in Figure 2. This test measures the actual magnitude of pressure in millimeters of mercury in the right heart and pulmonary artery. While right heart catheterization is invasive and more complicated than Doppler echocardiography, it eliminates the possibility of error due to other conditions of the patient [3].

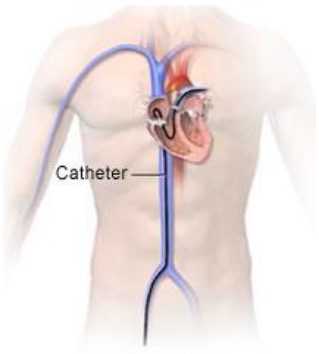

Figure 2: Diagram of how a catheter is inserted into the body [b].

Project Motivation

Pulmonary vascular impedance provides useful information about changes in right ventricular afterload caused by oxygen depletion in pulmonary hypertension patients. Afterload is sometimes defined to be pulmonary vascular resistance. However, the two differ because resistance does not include pulsatile flow abnormalities, or changes in blood-flow velocity due to cardiac action. Impedance is affected by pulsatile, instantaneous, and time-averaged hemodynamics and is therefore a more complete indicator of ventricular afterload than resistance. Synchronized time and frequency domain analyses from Doppler echocardiography and right heart catheterization are used to calculate impedance which can then be used to determine right ventricular afterload. Arterial stiffness as well as locations of defects within the vessel are two examples of important details obtained by the calculation of impedance and afterload. Arterial stiffness is significant because it has been shown to be a powerful predictor of mortality in patients with pulmonary hypertension. This information would be useful for earlier and more efficient diagnosis and treatment of pulmonary hypertension [5]. Therefore, the purpose of this project is to construct a data collection and analysis system that can synchronize arterial flow and pressure data in time, export the information to a file, and store it for later interpretation.

Current Device

Professor Chesler, the client in this project, along with other researchers special ordered the Noninvasive Hemodynamic Workstation made by Cardiac Engineering Inc. shown in Figure 3. It can be used measure blood flow, arterial pressure, and electrocardiogram (ECG) of either mice or humans. The benefits of this device include the ability to convert analog echocardiogram and right-heart catheterization to digital signals and data storage capabilities on a PC hard drive for later recall.

However, the disadvantages of this device outweigh these benefits. The most important disadvantage is that this current device cannot synchronize raw blood flow and pressure data. This makes calculation of pulmonary vascular impedance difficult. Additionally, the software program accompanying this device analyzes the results further than is desired for the researchers. It would be better to have a text file of the raw data that the operator could analyze as they please. The ECG is also an extra feature that is not necessary for current research and only complicates use of the device. Furthermore, the device must be used in conjunction with an outdated, heavy laptop which inhibits portability and adaptability of the device. Lastly, the cost of a single Noninvasive Hemodynamic Workstation is $30,000. As Professor Chesler's lab is not the only lab on campus that desires such a device, $30,000 is not a feasible option especially since it does not meet the desired functions. Thus, a new device that can implement the basic processes of the Noninvasive Hemodynamic System, add signal synchronization, and simplify the output is needed.

Figure 3: Depicted here are several views of the current device. Shown on the left is the current device connected to its PC with a data acquisition card. At the top-right is the front view and the back view is shown in the bottom-right.

Design Specifications

To improve on the current device, several requirements must be met. First, like the current device, the new design must convert echocardiogram and right heart catheterization analog signals to digital output. The echocardiogram the device will be used with has two outbound signals and the catheterization has one output. This means the new device must have at least three inputs, two

compatible with the echocardiogram and one with the catheterization equipment. Our prototype must output a data sample 20 times per cardiac cycle assuming that the maximum heart rate the device will be exposed to is 150 beats per minute (such as during exercise). The maximum heart rate estimation is based on humans as system to be developed does not need to be adaptable for use with mice or other animals.

Furthermore, the data collected must be synchronized and stored, which the current device is incapable of doing. Synchronization will align the Doppler shift information from the echocardiogram and pressure information from the catheter in time. This data must also be stored either in the device or on PC working in conjunction with the device. The data being stored should be raw and does not need significant analysis. A text file containing the arterial pressure, blood velocity, artery diameter, and time is sufficient. However, some software code will be necessary to convert the echocardiogram Doppler shift data into blood velocity. From the blood velocity and arterial diameter the researcher will be able to calculate flow on their own. Thus, the software and data storage interface should be user-friendly.

Other specifications involve life in service, aesthetic, and cost expectations. As mentioned previously, researchers will use this system to test patients at rest and during exercise. This will require the device to constantly collect data for at least 30 minutes at a time. The lifetime of the device should be five years with expected use being twice weekly. This means the device hardware must be durable and reliable. Furthermore, the device will be used in a clinical setting so its appearance should be aesthetically pleasing and professional. For safety of the operator, the system should have no sharp corners or exposed wires. Also, the prototype must be portable and thus weigh less than ten pounds and occupy less volume than a 12 inch cube. Lastly, the entire system should cost less than $1000 and if time permits a second system should be constructed.

System Diagram

Before developing design alternatives, a system diagram of the processes the device must accomplish was created. The result is seen below in Figure 4. First, the analog signals from the echocardiogram and right heart catheter must be converted to digital output. This can be done with an analog to digital converter that will also sample the signals at a rate sufficient to capture audio without signal aliasing. Once the signals are in a discrete digital form, the data must be stored. Storage can either be done by a buffer in the device where it can be spooled to a PC later or the data can be directly transferred to the hard drive of a PC. Data transfer from device to PC can be done by a USB or Firewire cord. With the data stored in the hard drive, a software program on the PC can be used to synchronize the signals in time. Additionally, the software system can be used to convert the digital echocardiogram output to a frequency signal so blood velocity can be calculated from the Doppler shift via Equation 1. The output from the software is then synchronized blood velocity and pressure data that can be interpreted and stored for later recall. Arterial blood flow can be calculated by the operator by using blood velocity and the arterial diameter.

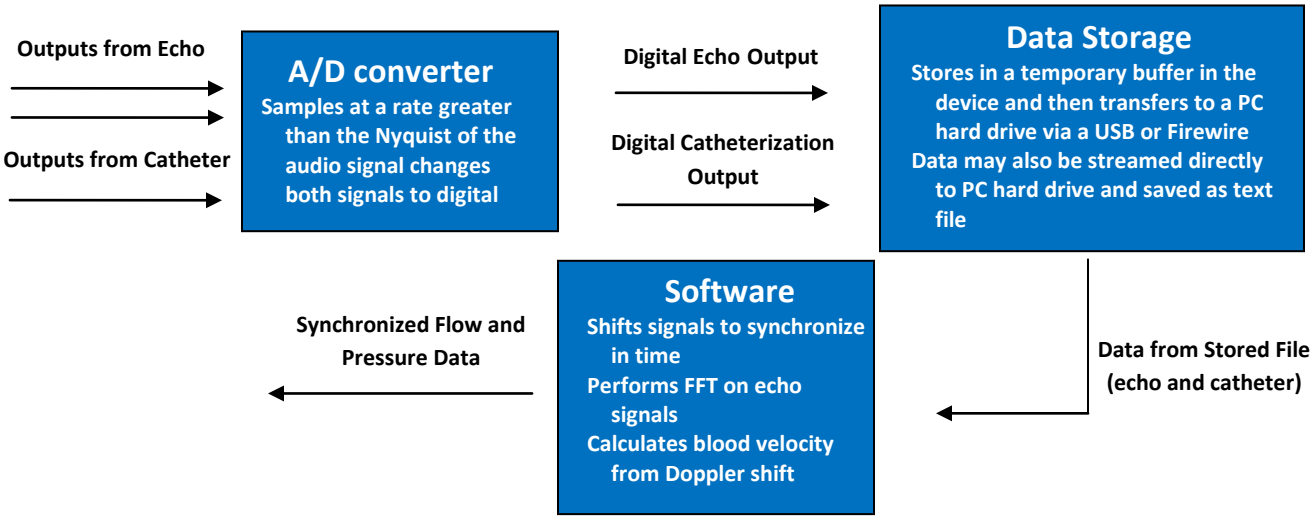

Figure 4: System diagram of proposed device.

Design Alternatives

Design 1: Dedicated Hardware Device

This device would be an all in one box designed only to meet the client's needs. The "box" would accept the two audio and pressure inputs, convert the signals from analog to digital, process the digital signals to a synchronized flow and pressure reading, and save processed data on an onboard hard drive buffer. The user would then connect to the hard drive with USB or Firewire and receive the processed file. This design is most similar to our client's current device. While this design provides the most straightforward approach there are many disadvantages. One disadvantage is its inability to adapt to different echocardiograms or pressure transducers. Furthermore, construction of this design would require more than a semester to complete and significant assistance getting the many hardware components to communicate with one another.

Design 2: Microcontroller

In this design, an Arduino microcontroller (Figure 5) is used as a central hub for the hardware components to communicate with another and run code for signal processing including synchronization and blood flow calculations. However, an analog to digital converter would need to be incorporated before the signals pass through the microcontroller. Processed data could then be stored either onboard the device or could be directly outputted to a PC hard drive. This design has disadvantages similar to the Dedicated Hardware Device in that in includes many hardware components and would be challenging to construct. Additionally, signal processing within the microcontroller would not be ideal because it would use the JAVA programming language which is too slow for the data acquisition needed.

Figure 5: Example of an Arduino microcontroller [c].

Design 3: PC Oscilloscope

The final design uses an oscilloscope designed to operate in a PC environment. The signals would go into the scope's ADC and through a USB to the PC. Once the signal is in the PC environment, it can be viewed an analyzed with a software oscilloscope program as shown in Figure 6. The program also exports signal data which can be processed using industry standard software such as LabVIEW or MatLab. This design offers high adaptability because the ADC is dynamically controlled by the connected PC. Moreover, the PC Oscilloscope design is the most simplistic of all the alternatives and will make construction more feasible. The major disadvantage of this system is cost because two scopes would need to be used simultaneously since typical oscilloscopes only have two inputs.

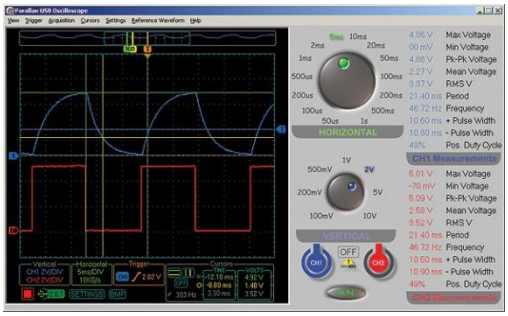

Figure 6: Graphical user interface associated with Parallax PC [d].

Design Matrix

Creation of a design matrix was done to help narrow down the three design alternatives to only one final design selection. The three alternative designs once again being the microcontroller, a dedicated hardware device, and the PC oscilloscope. Eight criteria considered in the design matrix include: cost, ease of production, ability to synchronize, aesthetics, sampling frequency, a user-friendly interface, size and adaptability. Cost, aesthetics and size were each given the lowest weight of a five out of one hundred mainly because they were not the most important requirements for the hemodynamic analysis device, but were still aspects to consider. For cost, the team was given a rough budget of $1000.00, but this value could fluctuate if the final device design was reliable, strong and worth investing money into. The appearance of the device should be professional and pleasing to the eye. Overall, though, the exterior of the device is less essential than the interior function. Portability and storage are the main issues regarding the size of the device which would not be difficult to accomplish. These criteria and their weights are show in Figure 7.

Criteria	Weight	Microcontroller	Hardware Device	PC Oscilloscope
Cost	5	5	4	1
Ease of Production	15	9	5	13
Ability to Synchronize	20	15	15	20
Aesthetics	5	5	5	5
Sampling Frequency	20	20	20	20
User Friendly Interface	20	12	12	18
Size	5	5	5	5
Adaptability	10	5	2	10
Total	**100**	**76**	**68**	**92**

Figure 7: Design matrix developed to assess the quality of the design options.

Ability to synchronize, sampling frequency and a user-friendly interface were each given the highest weight of a twenty out of a hundred because these three criteria were specific requests from the client and are key elements for developing a new hemodynamic analysis apparatus. The ability for the device to synchronize both audio signals from the echo machine and the pressure signal from the right heart catheter is the main concern when building the system for accurate data analysis. Also for precise data acquisition from different subjects, the device's sampling frequency sufficiently high for collection of an audio signal. All of the design alternatives met this requirement. Finally, a necessity of the device is a user-friendly interface so any operator has the ability to use it with little difficulty; it should be easily connected to the right heart catheter and echo machine as well as a computer. Further, it should store data with no complications and the programming should work efficiently.

Additionally, two key criteria established the difference seen between the design options. These criteria include ease of production, weighted a fifteen out of one hundred, and adaptability, weighted a ten out of one hundred. For the amount of time given this semester to complete our device, the PC oscilloscope will be the most simplistic to build and finish. As for adaptability, the PC oscilloscope will work best with different computers, right heart catheters, and echo machines. The design matrix narrowed the three design options to one: the PC oscilloscope.

Final Design

The device will consist of two PC oscilloscopes working together to form four inputs. Two inputs will be for the audio signals, one for the pressure signal, and one can be connected to a potentiometer to calibrate the input gain. If this fourth input is connected a potentiometer, it will allow users to change the signal collection depending on the size and rate of signals coming from different right heart catheter and echo machines. After researching different brands and types of PC oscilloscopes, the team decided to purchase the Parallax USB model (Figure 8)because it fit the specifications and was within the

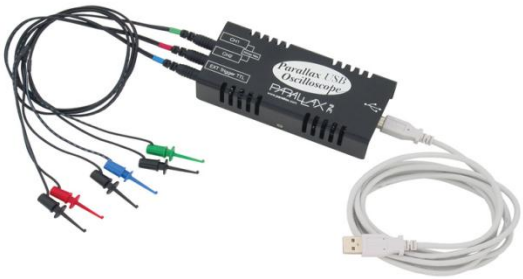

Figure 8: Parallax PC oscilloscope that will be incorporated into the final design [d].

budget. Individually, one Parallax USB PC oscilloscope costs $139.95. The design specifications of this model include two channels for signal capturing, a 500 KHz sample rate, a 200 KHz bandwidth and an 8 bit vertical resolution [6]. The 500 KHz sample rate is a large value, but is necessary when dealing with audio signal capturing. Also, the 200 KHz bandwidth will improve the speed of sending and receiving signals. After ordering the PC oscilloscopes, the device will be constructed and tested.

Proposed Testing

Testing the hemodynamic analysis device will begin with the synchronization of the PC oscilloscopes. This will be accomplished by passing an identical square wave through each scope and comparing their alignment. The interval between both square waves will be at most milliseconds apart; if this is the case, the signals will be shifted so they are synchronized. In order to test the function of the device, both the right heart catheter and the echo machine must be present as both need to be connected to our device at the same time. These two machines are located in clinics and labs making it difficult for the team to have complete access to both at any given time. Due to this issue, the team will need to plan accordingly and schedule times for use. Another aspect of the testing process is to have a human subject present to capture data from. After everything is connected, the software and programming will be tested to make sure the blood flow velocity is being calculated correctly, the signals are synchronized and the collected data is being stored.

Ethical Considerations

While this device does not interact with patients directly and thus does not need to meet FDA medical device requirements; testing of the product will still require human subjects. Each team member will take the Institutional Review Board (IRB) training regarding human subjects testing in case the team is present during testing of the device with actual subjects. In addition to human subject testing, the team must be mindful not to copy the design of current competitive products. However, as the final design utilizes a PC oscilloscope infringement on the current design should not be an issue. Lastly, the team always cited sources from which information was obtained.

Future Work/Time Management

With half of the design semester already completed, it is important to stay on track and complete future work in a time orderly fashion. Starting the week following the mid-semester presentation, the PC oscilloscopes have to be ordered as well as any other necessary parts for the device. Once all parts arrive, the fabrication process will begin and will continue through the end of November. In this time, the hemodynamic analysis apparatus will have to be built which includes synchronizing the PC oscilloscopes and programming the software. A code to calculate the blood flow velocity will be created in LabVIEW. The diameter of the artery being tested for pressure and blood flow

will be included somewhere in the program as well. In early November, the testing of the device should begin which will involve scheduling times to use both the right heart catheter and echo machine. During the fabrication process, the team will need to become acquainted with the program LabVIEW since each member has little experience using it; this is essential in designing the device and should be completed sooner than later.

By the end of November, the device should be coming close to completion. There are many aspects of the design process which need to be completed by then. As of right now the team has only chosen the final design for the hemodynamic analysis system. Building and programming the device is the next phase.

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Figure References

[a] http://www.pphlaw.com

[b]http://www.musculoskeletalnetwork.com/hypertension/content/article/1145425/1404927?pageNumber=8

[c] http://arduino.cc/en/uploads/Main/ArduinoUnoFront.jpg

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Appendix A: PDS

Product Design Specifications – September 16, 2010

Project #42: Hemodynamic Analysis System

Team Members

Sarah Czaplewski – Team Leader
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Sara Schmitz – BWIG
William Zuleger – BSAC

Problem Statement

Currently, Echocardiography and right-heart catheterization are used separately to screen for pulmonary hypertension (high blood pressure in the arteries of the lungs); however, better diagnostic techniques are needed. In order to accomplish this, it would be advantageous to measure flow and pressure from the echocardiogram and catheterization simultaneously. Therefore, the purpose of this project is to construct a data collection and analysis system that can synchronize and export time, flow, and pressure to a data file for interpretation.

Client Requirements

- Conversion of analog inputs from echocardiography and right heart catheterization to digital output
- Synchronization of output including time, blood velocity, pulmonary pressure, and arterial diameter
- Collection of several data points per cardiac cycle
- Capability to store data and recall it later
- Optimization for use on humans (i.e. does not need to be adaptable to for use on animals) during rest and exercise

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:* The device should be able to withstand operation at least twice per week for 60 minutes at a time.

    b. *Safety:* For safety of the operator, the device should have no sharp corners and all circuitry should be enclosed. Also, the unit should not emit excessive heat.

    c. *Accuracy and Reliability:* Collection of time, velocity, and pressure data should occur 20 times per cardiac cycle at a maximum heart rate of 150 beats per minute.

    d. *Life in Service:* The device should maintain function for at least 5 years.

e. *Operating Environment:* The final prototype of the device will be used in a clinical setting. As such, it should be able to sustain movement associated with transport without loss of function.

f. *Ergonomics:* The device should be portable. Thus, it should be easy to hold and lift. Additionally, data output files should be easily accessible with an intuitive user interface.

g. *Size:* The maximum size of the device is 12 in x 12 in x 12 in.

h. *Weight:* The weight of the device should not exceed 10 pounds.

i. *Aesthetics:* The appearance of the unit should be professional, as it will be in clinical setting.

2. Production Characteristics

a. *Quantity:* Two functional prototypes should be constructed.

b. *Product Cost:* Total cost for materials and construction should not exceed $1000 per device.

3. Miscellaneous

a. *Customer:* The primary user of the device will be our client, Naomi Chesler. William Schrage, in the UW-Madison physiology department, would also benefit from the creation of our device and use it in his testing. Additionally, researchers at Northwestern University are interested in utilizing a successful prototype of our device.

b. *Competition:* A Doppler audio converter has recently been developed that calculates fluid flow velocity using ultrasound audio signals. Our device must perform this function and synchronize the flow to pulmonary pressure. There are no current devices that can perform this synchronization step.