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

Hemodynamic Analysis System

Final Report

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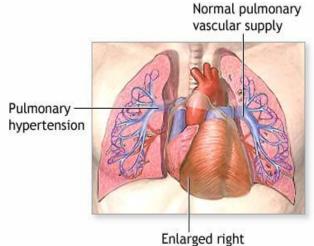
Abstract

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, the arterial pressure from right heart catheterization and blood flow from Doppler echocardiography must be synchronized in time. Therefore, the overall objective of this project is to design, construct, and test a system that will synchronize pressure and flow data. This semester, a system using a National Instruments myDAQ in conjunction with LabVIEW to synchronize, collect, process, and store Doppler ultrasound and imitated pressure signals was constructed. Development of analysis software in Matlab to calculate blood flow was also drafted. The accomplishments of this semester provided proof that the proposed methods are feasible and are worth pursuing and future semesters.

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 ventricle, fluid buildup in the liver and other tissues, and heart failure. Some of these physical changes such as enlarged right ventricle are depicted in Figure 1. Pulmonary hypertension can be triggered by pre-existing diseases and can cause further diseases such as Hypoxia [1].



Enlarged right ventricle 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:

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

In this equation, f_d is the observed frequency, f_o is the frequency initially emitted by the transducer, θ is the angle between the probe and the vessel, \mathcal{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].

Project Motivation

Pulmonary vascular impedance provides useful information about changes in right ventricular afterload (pulmonary vascular impedance) caused by oxygen depletion in pulmonary hypertension patients. However, the two differ

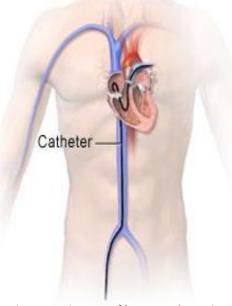


Figure 2: Diagram of how a catheter is inserted into the body [b].

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 long-term objective 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. 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 discourages 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 audio signals and right heart catheterization analog voltage signals to digital output. This means the new device must have at least two inputs, one compatible with the echocardiogram and one with the catheterization equipment. The 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). This comes out to 50 Hz data output rate. The maximum heart rate estimation is based on humans as the 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 cubic foot. Lastly, the entire system should cost less than \$1000.

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 cable. 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.

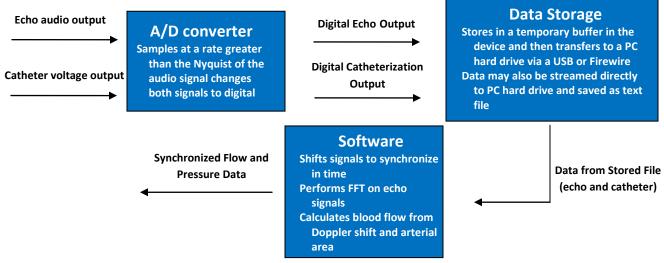


Figure 4: System diagram of proposed device.

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 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



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

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.

Design 3: PC Oscilloscope

The final design alternative uses an oscilloscope designed to operate in a PC environment as seen in Figure 6. 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 using the scope's associated software program and stored to a text file. The stored signal could then be exported to industry standard software such as LabVIEW or MatLab for further processing and analysis. This design offers high adaptability because the ADC is dynamically controlled by the connected PC. Moreover, the PC Oscilloscope design is the most simply of all the alternatives and will make



Figure 6: The Parallax PropScope is an example of a PC Oscilloscope with 2 inputs terminals [d].

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.

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 needs to be 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.

Proposed Final Design

At midsemster the team had proposed the final design to consist of a PC oscilloscope connected to a laptop and LabvVIEW or Matlab software code. The software component would perform signal processing such as filtering, calculation of blood pressure and flow, and storage of the final result to a text file. The PC oscilloscope itself would consist of two inputs, one for the echo audio signals and one for pressure voltage signals. It should acquire these signals simultaneously which would accomplish

synchronization. After researching different brands and types of PC oscilloscopes, the team proposed purchasing the Parallax PropScope shown in Figure 6 because it fit the specifications and was within the budget. The specifications of this model include two channels for signal capturing, a maximum 25 MHz sample rate, 10 bit resolution, and a 20 Vpp limit. The maximum input voltage and sample rate are more than sufficient for the purposes of this project and can be adjusted as needed. It also comes with a builtin expansion port that can add other features such as an external trigger that may be useful in simultaneous collection of two signals. Lastly, the PropScope costs \$249.99 plus shipping and handling [6].

Semester Objective

Before ordering the PC oscilloscope outlined above, the team needed to demonstrate proof of concept at the request of the client because the cost of the scope was significant. Thus, the objective for the semester became development of the software elements included in the proposed design using equipment already available to acquire signals. To prove that the selected design would work, the team set out to collect an audio signal from an echo machine and voltage signal from an arterial pressure sensor (right heart catheter), synchronize these signals, calculate blood flow, and save the results to a text file. Accomplishing these required specifications would demonstrate that the proposed design can be used as a hemodynamic analysis system and would justify purchase of the PC oscilloscope in a future semester to complete the design.

Justification of Approach

Since the semester objective was proving that the proposed methods were feasible, there was more flexibility in the instrumentation and approach used. Due to the invasive nature of right heart catheterization, collection of a true pulmonary arterial pressure was not possible. Thus, the team opted to collect pressure from the arteries of the arm because it would be feasible in a classroom setting. To avoid a delay between pressure and blood flow signals the team decided to also collect ultrasound data from the radial artery. Furthermore, collection of ultrasound data from the

The next step in the process was to demonstrate



pulmonary artery would have required an experienced technician and access to an echo machine for testing. To obtain the radial artery ultrasound, a Mini Dopplex 8 MHz probe (Figure 8) was used.

Figure 8: Mini Dopplex ultrasound transducer with an emission frequency of 8 MHz.

signal collection and synchronization in LabVIEW of pressure and ultrasound. Through the department, the team borrowed a National Instruments (NI) myDAQ (Figure 9), a device capable of acquiring audio and analog voltage signals together directly to LabVIEW. Once in LabVIEW, the synchronization of these signals would be accounted for. Additionally, the signals would be filtered to remove noise and stored to a text file. This text file could then be uploaded in Matab to calculate blood flow and view pressure from

the voltage signals. Blood flow is simply blood velocity multiplied by vessel area where blood velocity is determined by Equation 1.



Figure 9: Top and side views of NI myDAQ used for data acquisition.

Development and Testing

Signal Collection

Initially, the team focused on collection of audio data from the Doppler ultrasound because the Mini Dopplex was readily available. It was found that the NI myDAQ was capable of reading an audio signal emitted from the ultrasound device through the input audio port and outputting the data into LabVIEW. Next, the team tested that the NI myDAQ could receive a voltage signal such as a pressure signal through its analog input port at the same time as the audio port. The only available method of obtaining a pressure signal required construction of a system including a circuit,

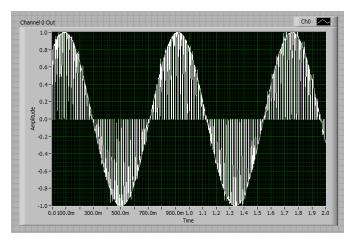


Figure 10: Extremely noisy sine wave collected through the NI myDAQ analog voltage input. The analog voltage inputs on the NI myDAQ were therefore not used in data collection.

blood pressure cuff, and pressure sensor. As construction of this system would be time consuming, the team tested the NI myDAQ with a sine wave produced by a waveform generator; a frequency of 1.2 Hz was used to mimic the frequency of a heart beat. This test demonstrated the excessive amount of noise generated by the NI myDAQ analog inputs (Figure 10). Also, it was found that the myDAQ was unable to collect signals through the analog and audio ports at the same time because the internal multiplexer could not handle the dual inputs.

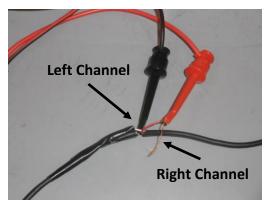


Figure 11: Close up of data collection audio cable showing cables carrying sine wave from waveform generator to the right audio

The second approach taken to collect ultrasound audio and a voltage signal synchronously involved acquisition of these signals through the one stereo audio port using a split cable. This was possible because the Mini Dopplex only used the left channel of the audio port. To accomplish this, a 3.5 mm dual audio cable was cut in half. The left channels were reattached for ultrasound signal collection and the right channel remained exposed to use for voltage signal collection (Figure 11). With this method, two signals were successfully collected simultaneously (Figure 12).

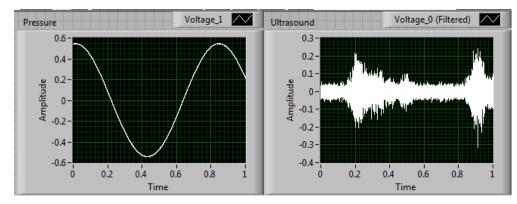


Figure 12: Plots of the collected sine wave (left) and ultrasound signal (right) showing the subjects pulse.

In LabVIEW, the signals from the NI myDAQ were collected using the DAQ Assistant function at a sampling rate of 50 kHz. The maximum audible frequency is 20 kHz thus the selected rate was sufficient as specified by the Nyquist frequency (twice the value of the greatest frequency in the signal). Furthermore, a fifth order high-pass Butterworth filter with a cutoff frequency of 200 Hz was applied to the ultrasound signal [7]. The cutoff frequency was chosen so as to remove low frequency noise generated by tissue movement. The sine wave and resulting ultrasound signal were plotted. The data was then stored to a text file containing three columns which included time, voltage sine wave, and ultrasound data. See Appendix B for the LabVIEW block diagram the team developed.

After successfully collecting and storing data, the team attempted to acquire an actual pressure signal using the blood pressure cuff system mentioned previously. The constructed circuit shown in Figure 13 included a pressure sensor attached to a blood pressure cuff and pressure gauge. It was proven that consistent quality signals were unattainable with this setup as the equipment used was unreliable. Being that the client will not use pressures obtained from the arm and that pressure is separate from the calculation of blood flow, the team

decided to use a sine wave as an imitation pressure signal. This enabled the team to focus on the more important and complex task of ultrasound signal analysis.

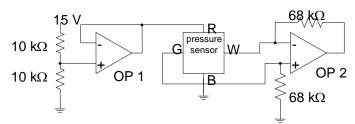


Figure 13: Circuit used to construct blood pressure cuff system.

Signal Analysis

The next phase of the project was calculation of blood flow from the ultrasound data. This could have been accomplished in either LabVIEW or Matlab, however, the client preferred Matlab. The first part of the flow calculation was determining blood velocity. This involved determining the frequencies of the ultrasound data and how they changed with time. In an attempt to accomplish this, the team developed the Matlab code in Appendix C. The code involved breaking down the stored ultrasound data points into smaller segments, running a Fast Fourier Transform (FFT) to convert the data in each segment from the time domain to the frequency domain, and selecting the maximum frequency that occurred within each segment. This maximum frequency was then used as the observed frequency in the calculation of velocity. The breakdown of the data into smaller segments enabled tracking of what time each frequency and thus each velocity occurred at. If the data had not been broken

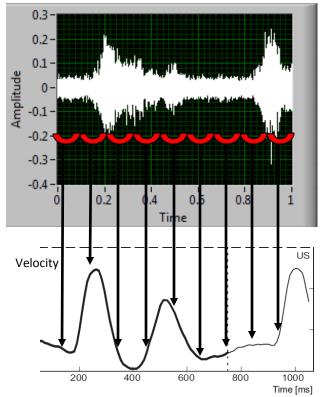


Figure 14: Diagram demonstrating the concept behind breaking the ultrasound data down into small segments for analysis. The red shapes represent each segment of data. From each segment, one velocity data point is recorded represented by the arrows. Note: the velocity plot is from another source [e]

into smaller pieces, the time each frequency occurred at would have been lost in the FFT and determination of velocity as a function of time would not have been possible. Figure 14 demonstrates this process.

In the calculation of blood velocity, the previously described method enabled the team to obtain the observed frequency (f_d) in Equation 1. The other terms in equation were

determined by the following information. The emitted frequency of the ultrasound probe (f_o) was 8 MHz as given by the Mini Dopplex. The velocity of sound in tissue was assumed to be 1540 m/s. Lastly, the probe angle with the radial artery (ϑ) was estimated during data collection to be 75°. Blood flow was then calculated by multiplying the velocity by an average radial artery area of 3.8 mm². This area was obtained by using an average radial diameter of 2.2 mm as found in previously conducted studies [8]. In a clinical setting, echo machines will display the probe angle and the artery diameter can also be determined via ultrasound imaging. Thus, for the purpose of proving the proposed methods, the team was not concerned with getting the exact probe angle and arterial diameter measurements.

Furthermore, the Matlab code developed averaged time and pressure over each segment. The final result yielded one velocity, pressure, and time data point per segment. Besides assigning a specific time to each observed frequency, this method reduced the total number of data points per second. This reduction in data points was desired as the data had been collected at 50 kHz which was an excessive amount for analysis. The final Matlab code still needs to be fine tuned because the plot of blood flow did not display a clear signal and the calculated velocities were far too high for the radial artery. However, there does appear to be a repeating peak consistent with the frequency of a heart beat (Figure 15). This was most likely due to low quality equipment used to acquire the ultrasound data. Perhaps testing with a clinical ultrasound would give more definitive results.

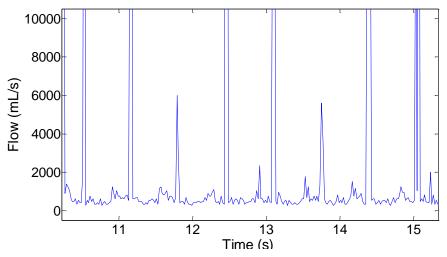


Figure 15: Blood flow plot resulting from developed Matlab code.

Summary of Accomplishments

In a more condensed manner, the final system chosen consisted of a Mini Dopplex probe, a waveform generator, a unifying cable, the NI myDAQ device, and a laptop on which both LabVIEW and Matlab were installed. The set-up of this system is shown in Figure 16. As specified by the client, two major criteria for the device were synchronization and data saving capabilities. By collecting ultrasound

and voltage data though the same cable, the synchronization of these signals was guaranteed. Filtration of the ultrasound audio signal was also essential so that the data was not tainted by noise. The LabVIEW code generated by the team accomplished this by separating the signals in order to filter only the audio. Next in the LabVIEW code, the voltage and filtered audio were written to a text file, which was easily saved onto the computer an external device, such as a flash drive. In Matlab, a script was written which uploads the text file and serves as a solid foundation for blood flow calculation. It is also important to note that since the text file was stored to an external device, the data could be moved to any computer with Matlab, as opposed to the current device

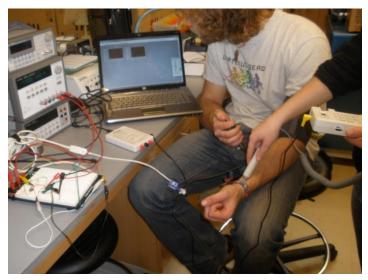


Figure 16: Image of the team conducting testing on the completed system including the Mini Dopplex (far right), NI myDAQ, laptop for data collection and analysis. This image also displays the blood pressure cuff including the circuit that the team attempted to use to collect pressure.

which can only be used with an outdated laptop. This allows any researcher to be able to analyze and reference the data at their leisure.

Future Work

Due to the fact that the team's semester objective was proof of concept, future work is necessary to improve, expand, and incorporate findings from this semester into a complete hemodynamic analysis system fitted to the client's specifications. For better qualitative data, a clinical Doppler ultrasound machine should be used in later work to collect accurate blood flow data as well as obtain a concrete value for the diameter of the artery being tested and the angle of the probe. Furthermore, a reliable pressure device should be used to collect precise data for arterial pressure. It is also important that the client will have access to any data collected by the team during testing to approve the data suitable for later analysis done by the client.

With use of higher quality Doppler ultrasound and pressure equipment, a more sophisticated data acquisition device should be used in place of the current NI myDAQ used this semester. The purchase of a PC oscilloscope proposed in the team's final design would be one option to pursue. Another option would be the purchase of a different NI DAQ model with better performance in data collection.

Other components to improve on in later work involve calculation of the blood flow velocity. By increasing the fraction of frequency data points analyzed at once in each segment of the ultrasound signal, the accuracy of the blood velocity calculation would increase when ran through the FFT in Matlab. Also, by overlapping the segments containing a certain fraction of frequency data points, a higher sampling rate could be obtained leading to more accurate blood velocity calculations. Overall, the Matlab code found in Appendix C should be optimized to achieve better results.

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 in the long term will still require human subjects approval. Each team member took the Institutional Review Board (IRB) training regarding human subjects testing in case the team needed to be present during testing of the device with actual subjects. In addition to human subject testing, the team was mindful not to copy the design of current competitive products. However, the team used the NI my DAQ and wrote the code used so there should be no problems with infringement on other intellectual property. Lastly, the team always cited sources from which information was obtained.

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Appendix A: PDS

Product Design Specifications – September 16, 2010

Project #42: Hemodynamic Analysis System

Team Members

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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.

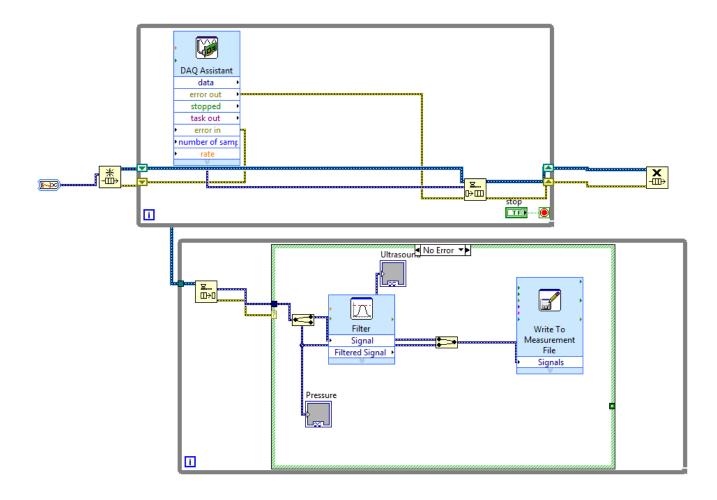
2. Production Characteristics

- 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.

Appendix B: LabVIEW block diagram



Appendix C: Matlab Code

```
ask = uigetfile('*.txt','Select the file to open');
data = load(ask); % load data
time = data(:,1); % time data
P = data(:,3); % pressure data
US = data(:,2); % ultrasound data
X = 1000 ; % number of data points in a segment
NFFT = 2^{\text{nextpow2}}(X);
dt = time(2) - time(1);
Fs = 1/dt;
ensdt = X*dt;
j=0 ;
c = 1540; % speed of sound in body tissue m/s^2
femit=8*10^6; % transducer emission frequency
angle=75; % angle of probe
for i = 1:round(length(time)/X)
    ensP(i) = mean(P(j+1:j+X));
    fftUS = fft(US(j+1:j+X),NFFT)/X;
    f = Fs/2*linspace(0, 1, NFFT/2+1);
    [big index big] = max(fftUS(1:length(f))) ;
    fbig = f(index_big) ;
    ensVel(i) = (fbig*c)/(femit*2*cosd(angle)) ; % m/s
    ensT(i) = mean(time(j+1:j+X));
    j = j + X;
end
diameter = 2.2; % mm
area = (pi()*(diameter/2)^2); % mm^2
mmVel = ensVel.*1000; % mm/s
flow = mmVel.*area; % mm^3/s
mlflow = flow.*.001; % mL/s
plot(ensT, flow)
xlabel('Time (s)')
ylabel('Flow (mL/s)')
```