

# Impedance Cardiography

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## **I. Problem Statement**

Current methods for measuring cardiac output are invasive. Impedance Cardiography is a non-invasive medical procedure utilized in order to properly analyze and depict the flow of blood through the body. With this technique, four electrodes are attached to the body -two on the neck and two on the chest, which take beat-by-beat measurements of blood volume and velocity changes in the aorta. However, our client hypothesizes that the current method withholds degrees of inaccuracy due to the mere fact that the electrodes are placed too far from the heart. The goal of this project is to design an accurate, reusable, spatially specific system that ensures more accurate and reliable cardiographic readings. Furthermore, this system must produce consistent results able to be accurately interpreted by industry professionals. More specifically, our primary goal is to ensure the device must not only collect an impedance signal, but it must also eliminate as much ECG interference in the signal as possible.

## **II. Background**

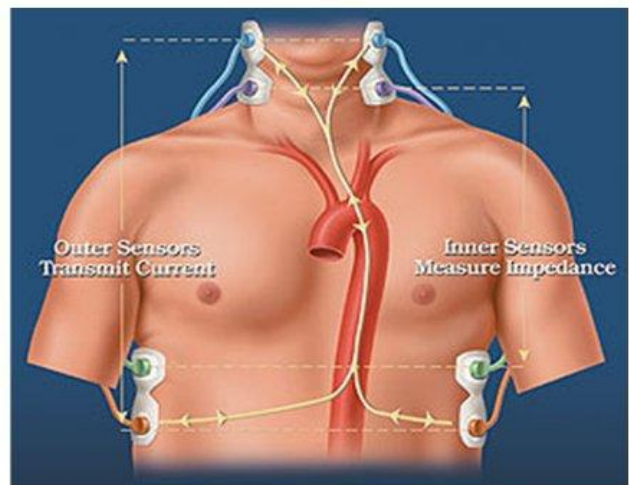
It is frequently necessary in the hospital setting to assess the state of a patient's circulation. Here the determination of simple measurements, such as heart rate and blood pressure, may be adequate for most patients, but if there is a cardiovascular condition such as sepsis or cardiomyopathy then a more detailed approach is needed. In order to non-invasively gather specific measurements on the volume of blood pumped by the heart (cardiac output) through the aorta, the technique of impedance cardiography can be used [3]. Impedance cardiography is used to measure the change in resistance of the aorta as blood passes through [2]. These changes in resistance can then be used in specific equations to calculate the pressure and flow blood out of the heart, this in turn can then be used to calculate cardiac output [1]. These measurements are useful both in establishing a patient's initial cardiovascular state and in measuring one's response to various therapeutic interventions such as transfusion, infusion of inotropic drugs, and infusion of vasoactive

drugs [4].

Existing methods of measuring cardiac output accurately are very invasive and because of this, these procedures are rarely used, despite the critical information that that could be used. If carefully carried out, the Fick method is accurate but requires a pulmonary artery catheter that is not practical in routine clinical practice. Several variants of this method have been devised, and the accuracy of invasive measures is unmatched thus far in impedance cardiography [4].

Transoesophageal echocardiography (TOE) provides diagnosis and monitoring of a variety of structural and functional abnormalities of the heart [3]. This process can be used to derive cardiac output from measurement of blood flow velocity by recording the Doppler shift of ultrasound waves reflected from the red blood cells [3]. The main disadvantage of this method is that a skilled operator is required to perform surgery. The probe is large and precision is required, as well as anesthesia on the patient, which drives up the cost of the operation. The equipment is very expensive, and the probe cannot be fixed to give continuous pressure and flow readings without an expert surgeon.

A non-invasive option that could potentially save money for the patient and increase ease of measuring cardiac output is impedance cardiography. First described by Nyoeer in 1940, the conventional impedance cardiogram is a record of variations of chest impedance (resistance to current flow), obtained by using an electric current passed from the neck to the upper abdomen as seen in Figure 1 [1]. This high frequency, non-stimulating current is not only noninvasive, but



**Figure 1: Current Impedance Cardiography electrode placement.**

painless to the patient as well. The frequency of the current (about 150 kHz) passing through the chest and heart is high enough to prevent sensation or muscle stimulation but low enough so that the pattern of current flow is similar to that of direct current [1]. Traditionally, chest impedance is recorded between the thoracic inlet at the base of the neck and the thoracic outlet at the level of the diaphragm [4]. The impedance signal is related to changes in the size and composition of blood-containing structures within the chest, and it is by this reasoning the impedance cardiogram promises to reveal meaningful information concerning cardiac output and the effectiveness of the heart as a pump on a beat-by-beat basis [4]. This would be extremely useful for monitoring critically ill patients and patients undergoing anesthesia, especially in cases where blood volume or cardiac output may change significantly.

Although indices derived from the chest impedance signal track cardiac stroke volume very well, the absolute values of stroke volume of blood per heartbeat are considered unreliable in most clinical settings [4]. This is especially the case in a situation involving congestive heart failure when the ventricular ejection fraction is greatly diminished, or in patients with either reduced or increased peripheral vascular resistance [4]. In addition, comparisons of impedance based stroke volume and cardiac output with results from the green dye dilution or the Fick methods show that the impedance cardiogram tends to overestimate stroke volume by 5 to 10 percent, with rather wide standard deviations, leading to the conclusion that the impedance cardiography method is not accurate [3]. Recent studies have emphasized that changes in the impedance of lungs, great vessels, cardiac atria, and cardiac ventricles during the cardiac cycle are complex and countervailing, leading to a small net signal of uncertain origin [4]. In sick patients with varying pathophysiology, such as reduced ventricular ejection fraction or reduced peripheral vascular, the factors that combine to give reasonable predictions in more healthy individuals may fail. Accordingly, interpretations of the data

from impedance cardiography have tended to be tentative and guarded, and acceptance of the technique is not widespread and has not been able to replace traditional invasive methods.

Despite these limitations, taking a new perspective on electrode arrangement that would force current through the cardiac ventricles [5]. By placing the electrodes directly over the heart instead of the neck and abdomen, it is proposed by Professor John Webster that we can attain a more accurate signal. Anatomic and physiologic modeling of this approach lead to several surprising results, and indicate that impedance based methods can provide accurate, painless, and noninvasive cardiac monitoring of cardiac output continuously during the entire cardiac cycle [5].

The goal of this project is to design an accurate, reusable, spatially specific system that ensures more accurate and reliable cardiographic readings. Furthermore, this system must produce consistent results able to be accurately interpreted by industry professionals. More specifically, our primary goal is to ensure the device must not only collect an impedance signal, it must also isolate the signal in its output using a variety of filters, including a phase sensitive demodulator. During the previous semester, the impedance cardiography group was able to develop a spatially specific electrode array for use in testing of the proposed new electrode positions by Professor Webster. While the group was able to attain some promising data of relative changes in resistance per heart beat in the aorta, the ECG signal was a huge interference on top of the changing resistance, along with noise associated with a the 60 Hz frequency have all electrical devices plugged into standard wall outlets. In order to fix this problem, this semester our new impedance cardiography group is designing two filters, a passive filter system and possibly a phase sensitive demodulator designed by Peter Klomberg and Tian Zhou. The final prototype will be used for research purposes in improving the cardiography technique and will eventually be used in a medical setting. We hope to use this new circuit and a new electrode array design to test human subjects this semester, barring our proposal for human testing to the IRB is accepted.

### **III. Client Specifications**

In June of 2010, we submitted a proposal to the IRB for human testing. Our main goal is to use a custom circuit and a specifically designed electrode array to test equal numbers of males and females to investigate the concept of impedance cardiography more thoroughly. Professor Webster would like us to design a spatially specific electrode array that can be adjustable in order to fit numerous varieties of electrode positions to determine optimal location. A new goal that we will be focusing on with respect to the electrode array is to format a new design so that we can fit females. Another crucial goal for this semester is to build a circuit that integrates a phase sensitive demodulator in order to better filter our signal so that we can read the pressure wave from the heart without the interference of the ECG signal or the noise associated with any electrical device. Ultimately, we will correlate the new demodulator circuit as well as the new electrode array to test human subjects once approval for our request to the IRB is accepted.

### **IV. Circuit**

In our previous semester, we built a standard ECG circuit that was presented in Professor Webster's bioinstrumentation 310 class. This circuit worked decently well for us initially, allowing us to see a distinct pressure wave on our 150 kHz carrying frequency. This simple circuit fell short because of the extensive interference from the lab around us and from the ECG signal of the heart. We attempted to filter out the interference with a simple set up of a diode to rectify the signal and subsequent high and low pass filters. The circuit actually became our main limiting factor to progress on the project because of the interference, so this is a focus this semester. With the extensive help of Peter Klomberg, Tian was able to draw a new circuit that incorporates three op amps and an analog switch that will act as our phase sensitive demodulator.

The purpose of using the demodulator is to separate and extract the pressure wave from the heart on the 150 kHz carrying signals. The specific chip we are using is the DG 413, which is

basically a phase sensitive rectifier with switches. The basic principle of this system is that when a sinusoidal wave function of a certain frequency is multiplied by another sinusoidal wave function of a different frequency not equal to the original frequency; then integrated over a longer time period, the result is zero. This means that the signal is eliminated so to speak from proceeding on in our circuit. When the two sinusoidal functions are the same, or in phase, the signal is maintained will proceed [7].

The first part of our new circuit is the chip LT 1920, this chip completely replaces the ECG amplifier that we built last semester all in one convenient chip. The ECG will amplify the signal that just traveled through the body at approximately ten times gain. This allows the demodulator to detect the signal, after the ECG chip the signal travels to the demodulator, which rectifies and gets rid of the 150 kHz signal, as well as other random noise present in every room with electrical devices. The last part of our new circuit is the Bandpass filters, this is an active system, therefore it filters signals from 0.5 Hz to 15 Hz and provides 50 times gain. This gives us the desired frequency range we are searching for our pressure wave and offers 500 times gain overall. Below, Figure 2, is the model of our circuit in the p spice program provided for us at this university, since this is a model the operational amplifiers and the demodulator chip are not exactly the same that we are using in our custom-built circuit.

In the second of the semester, we found it necessary to build another amplifier circuit to attempt to amplify the heart sounds and overlay them on our impedance waveforms. We were successful in building a simple circuit with a standard op amp, T 272a, to amplify sounds picked up by the microphone. Next semester while we take this project as an independent study, our goal will be to glue the microphone into a stethoscope. We will need to do this because this semester we tried to have the microphone just pick up the heart sounds by itself but it was unsuccessful.



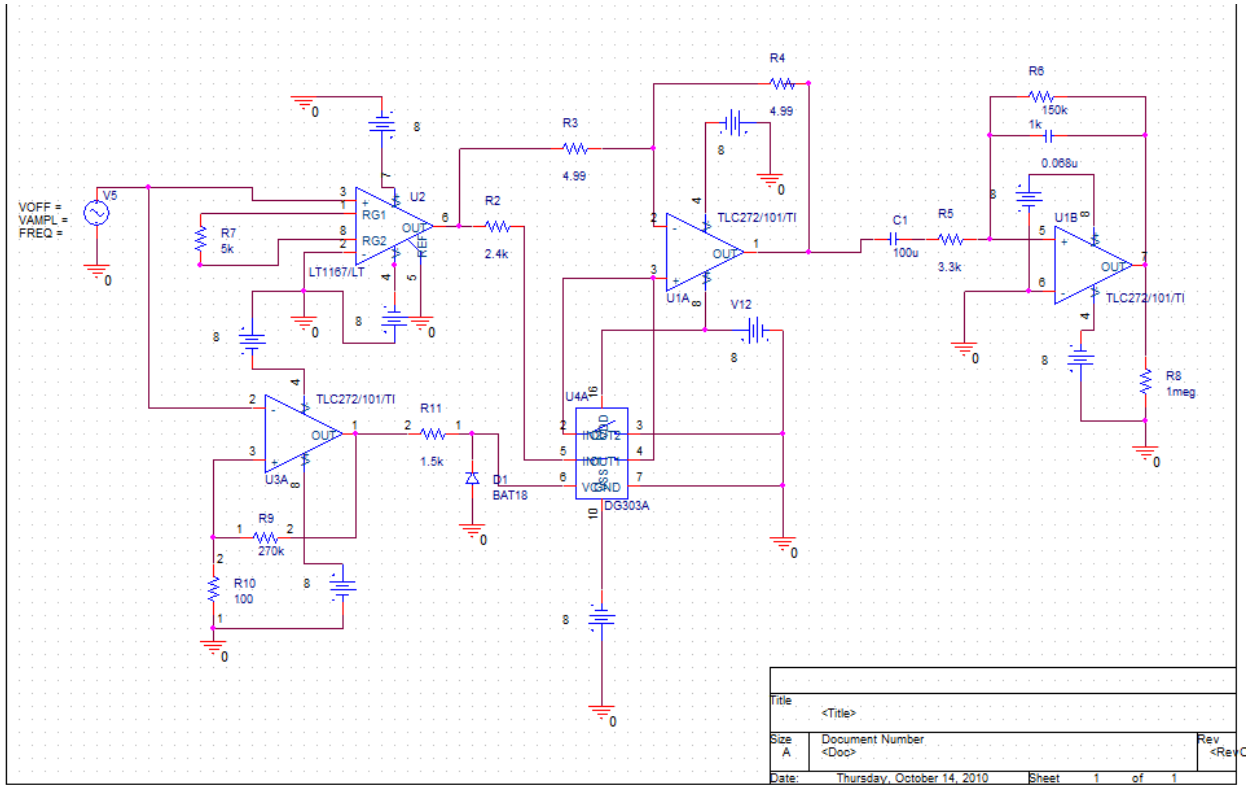


Figure 2: Schematic for our custom built circuit that we use to gather our data for impedance cardiography. The left portion of the graph is our initial EKG amplifier, which contains some filters to filter our data slightly, but the main goal is to amplify the signal. The middle portion of our schematic is the analog switch part of our circuit, the analog switch acts as our rectifier and helps to remove all signals that are not the same as the 150 kHz wave we are using. The last portion of the schematic represents our active filters that we use to filter out the 150 kHz signal, thus revealing our impedance waveform.

## V. Electrode Array

The final design has three parts: the two silicon mats that the electrodes connect to and the fabric that will be worn around the torso to hold the electrodes tight to the body. There are four electrode snaps, two per silicon mat. The two silicon mats are 2x4 inches with two 1.125 inch in

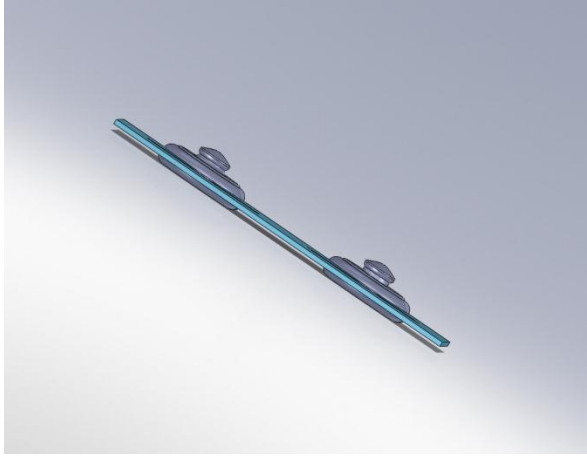
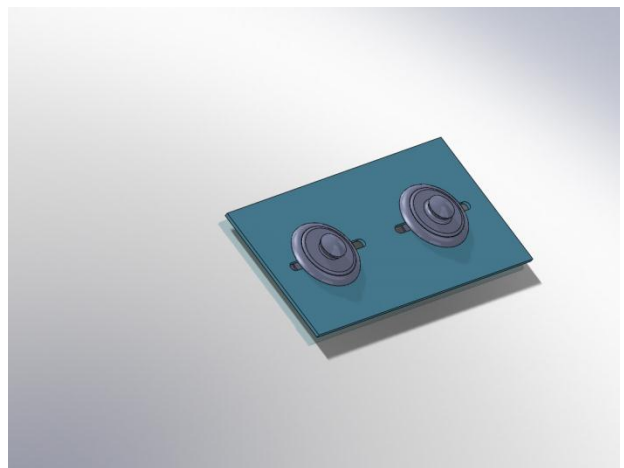
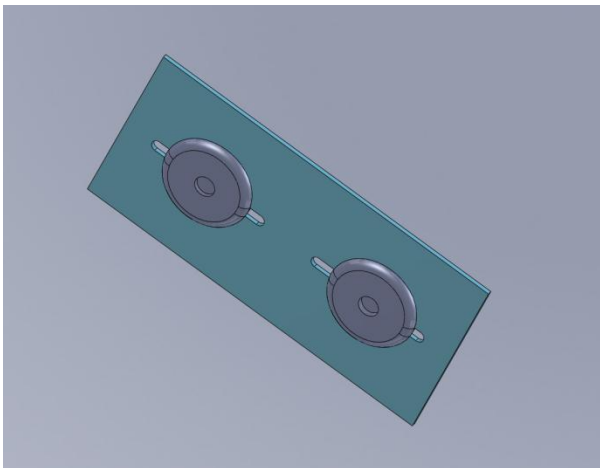


Figure 3 Side view of electrode array. From this view one can see our light blue silicon base, and the snaps that hold the electrode in place are located within the silicon. There are two 2.5 inch slits in each for the electrode snaps to slide in. The snaps are made of nickel and consist of three parts: the snap itself, the connector that slides in the tract and

connects the snap to the knob on top, and the knob on top, which the wires connect to. All of these parts were soldered together in order to have one piece that can snap on to electrodes and slide freely in the tract.

Our plan for the design was to create a prototype that could be used on multiple patients, multiple times. We achieved our goal by creating a design that would allow us to snap new electrodes into the nickel snaps for each new test subject.

Figure 4 and 5 below are the bottom and top view of the electrode array. The bottom view of the electrode array shows the holes where we snap in the electrodes. The top view displays the top part of the snaps that we attach the alligator clips to heading to the circuit input.



This would allow for quick testing with no issues involving the use of the same electrodes on different people. As shown in the pictures below, the electrode snaps can slide easily and have a large range of motion in the tracts. The knobs on top allow for easy connection of the alligator clips and the snaps fit tightly around the electrodes, providing us with a strong signal so we can obtain the data we are looking for.

## **VI. Materials**

### **6.1 Circuit**

The materials required for our designs consist primarily of standard circuit elements. We needed operational amplifiers, the T 272a, DG 413, and LT 1920, numerous resistors, diodes, capacitors, and a phase sensitive demodulator switch, which were each provided to us. We built this circuit with the intention to remove the EKG signal, the 150 kHz carrying wave, and cut down on 60 Hz interference. The phase sensitive demodulator should be able to sufficiently minimize each of these factors. We used some high quality resistors that have a lower error percentage than the resistors that we used last semester, every circuit element has better error percentages than our elements last semester. The first op amp we use is a LT 1920; this contains the entire ECG circuit we built last semester in one convenient chip. The phase sensitive demodulator we use is actually an analog switch model DG 413, this piece allows us to eliminate all signals that are not like the original 150 kHz carrying frequency. The last part of our circuit for impedance cardiography is an L 272a op amp, which we use for our two sets of single-phase active filters. This allows us to create more precise corner frequencies for our high and low pass filters.

### **6.2 Electrode Array**

Our newest electrode array is built with a silicon base to hold the electrodes. The base is 4 inches by 3 inches, and since silicon is very flexible, yet sturdy we have two separate pads for greater convenience. For the integral track design of our array, we cut two slits, approximately a centimeter

in width, about five centimeters apart. The crucial part of this apparatus is the snaps that will hold the electrodes while being able to move within the slits. The snaps are generic nickel snaps that were purchased from JoAnn Fabrics. We did not find one snap that worked in a sufficient fashion, so we had to solder together three different varieties of snaps. This will allow us to easily attach the banana clip to the snaps while the electrode is connected to the bottom. We used Monitrode electrodes, as they provide a good contact surface to the skin and have given us the best overall signal. Our testing electrode array is held to our body using a midwife belly band that was provided by Professor Webster; this apparatus holds the silicon pads close to the body, thus increasing electrode contact with the body.

## **VII. Testing and Methods**

### **7.1 Testing Protocol**

We are doing a test similar to the common EKG test. An electrocardiogram (EKG or ECG) is a test that checks the electrical activity of your heart. The amplifier takes inputs from electrodes that are attached to the body of the subject whose ECG is being taken. Because the signals are small, and the amplifier can be susceptible to various noise sources, it is important for the cables connecting the electrodes to the inputs of the circuit to be as short as possible and well shielded.

The testing procedure starts with hooking up our circuit. The circuit is powered by 8V and the demodulator is powered with 8+5V. The circuit is also synced with a 150 KHz signal that is sent through the body as a carrying wave. The inputs for the circuit are connected to the test subject via the inner electrodes in the array. The 150 KHz signal is connected to the outer two electrodes in the array. The final output is sent to the oscilloscope. With the QRS wave, our filters in the circuit can filter out the noise and any additional filtering can be done in Matlab.

### **7.2 Data Collection**

Once we have our impedance waveforms on the oscilloscope we can stop the oscilloscope and record the image and data points onto the computer connected to the oscilloscope. This allows us to make two matrices with our voltage and time data. The raw data is displayed conveniently with in an excel graph, but this graph often times is very noisy and needs to be further filtered using Matlab. For the figures presented later in this paper, I used a simple 5 Hz cutoff frequency butterworth filter on our data. This works well as it makes our waveforms more smooth and connected. This makes our graphs look nice but the raw data is ultimately what we would like because the filtered data

## **VII. Results**

### **8.1 Electrode Placement**

In figure 6 below, we have diagramed the electrode placements for the three methods we are involving in our experiments. The traditional approach was first developed over 60 years ago when the idea of impedance cardiography was first beginning. This method transmits an oscillating wave through the body between the neck and abdomen, this approach theoretically should be affected less by the impedance of the lungs because of the large distance between the electrodes. The principle that current will travel through the path of least resistance suggests that the current being transmitted into the body will travel along the major arteries, particularly the aorta.

The front and back electrode placement shown in figure 6 below is a possible new replacement for the traditional electrode placement; this approach is presented by Professor Babbs of Purdue University. Professor Babbs calculated that this precise placement of electrodes would give a 30 times greater signal than the traditional approach. The bases for his ideas come from him designing a circuit to represent the hemodynamics of the body, or blood flow.

The farthest right image on figure 6 represents our client Professor Webster's idea for the best way to improve impedance cardiogram signals. This method has the electrodes placed directly over the heart and aorta.

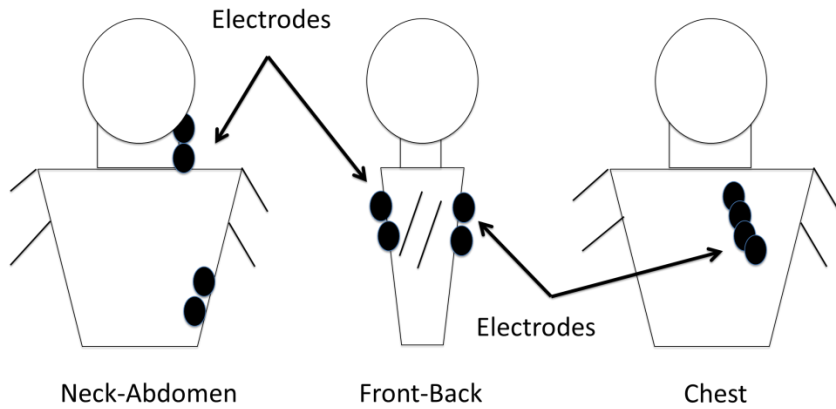


Figure 6: Schematic with the three electrode placements involved in our experiments

## 8.2 Traditional Approach

The traditional approach to impedance cardiography places the electrodes on the neck and abdomen. Our results gathered from these tests were typically very difficult to attain. Typically, we would gather a good EKG signal with this approach, but would not attain the desired impedance waveform that comes more easily using the front-back and chest approach. Figure 7 below shows our Matlab filtered data from the traditional impedance electrode placement on a 20-year-old male subject.

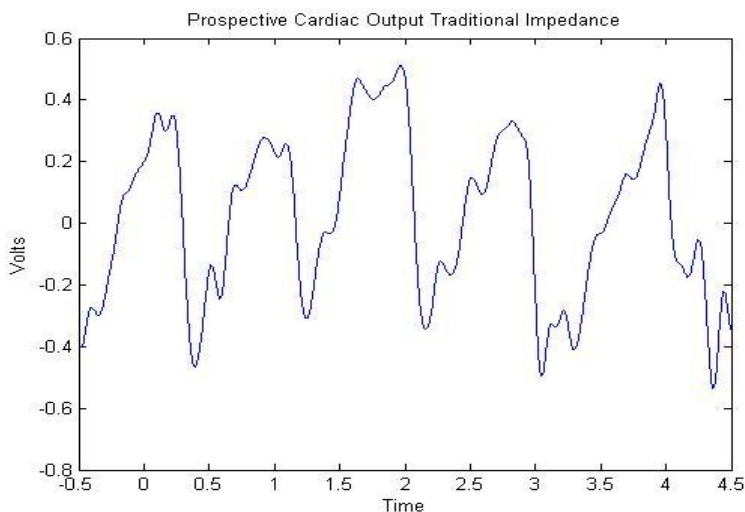


Figure 7: Traditional approach impedance waveform

### 8.3 Babbs Approach

The next electrode placement that we tested was the front and back electrode placement proposed by Professor Babbs. This approach generally was easier to find the impedance waveform than the traditional approach, but part of the potential with this method was because Professor Babbs calculated that the signal would be 30 times stronger than the traditional approach. As one compares figure 8 below to figure 7 above, one can easily see that the voltage signal from the known 150 kHz signal we sent through the body is not 30 times stronger for the Babbs approach. The signal is stronger but it is only by a factor of 2 to 3.

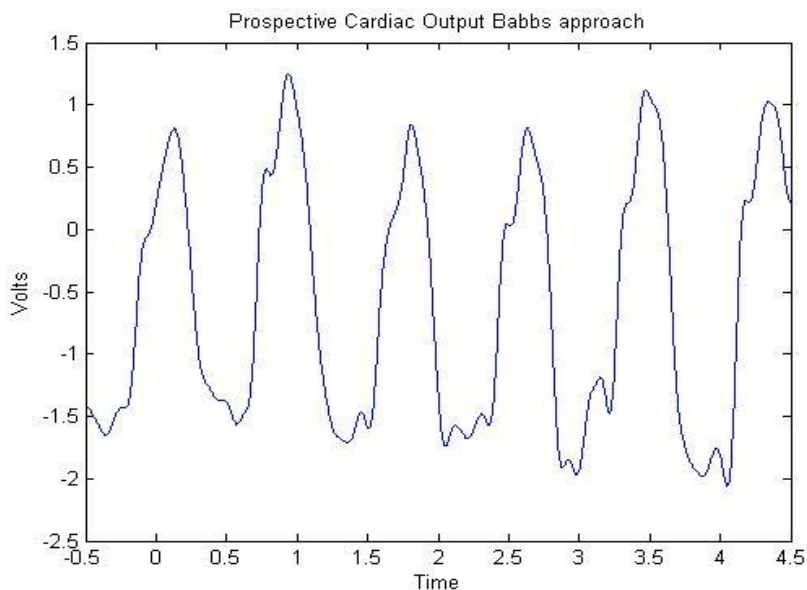


Figure 8: Matlab filtered data of the Babbs approach for 20 year old Male

### 8.4 Webster Approach

Our last technique that we tested this semester in lab was the four electrodes on the chest method as devised by our client Professor Webster. This method was the easiest for our group to routinely attain positive data. The four electrodes on the chest method also had the larger voltage signals as compared to both the Babbs and traditional approaches. The only real downside to the chest approach is the breathing of a patient under examination would limit the feasibility of the results. This is because the current we are allowing to travel through the body also is going through

the lung cavity, which has very well described impedance. Due to this, all of the test results attained using this method called for the patient to hold his breath. Below in figure 9 are the results from the chest approach.

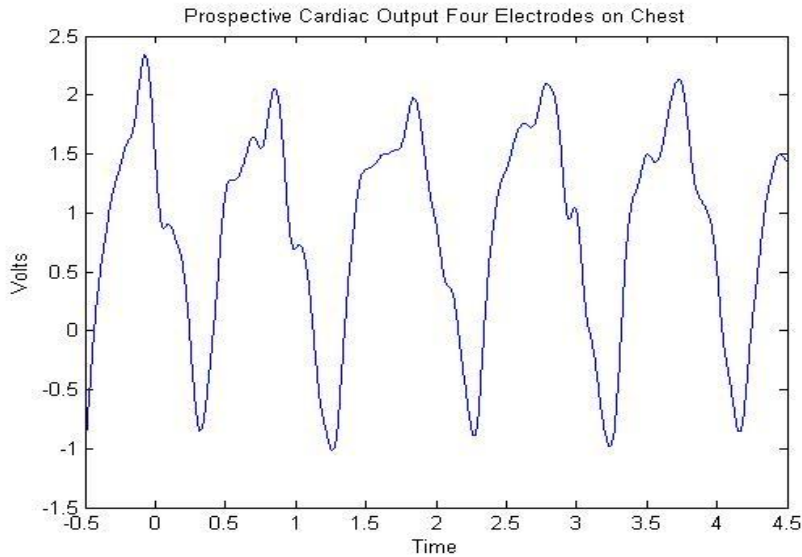


Figure 9: Matlab filtered data of chest approach from 20 year old male

Comparing this graph to the Babbs approach and traditional impedance approaches, one can easily see the stronger signal presented by the chest method placement of electrodes. Below in figure 10 is the filtered data attained from an older test subject.

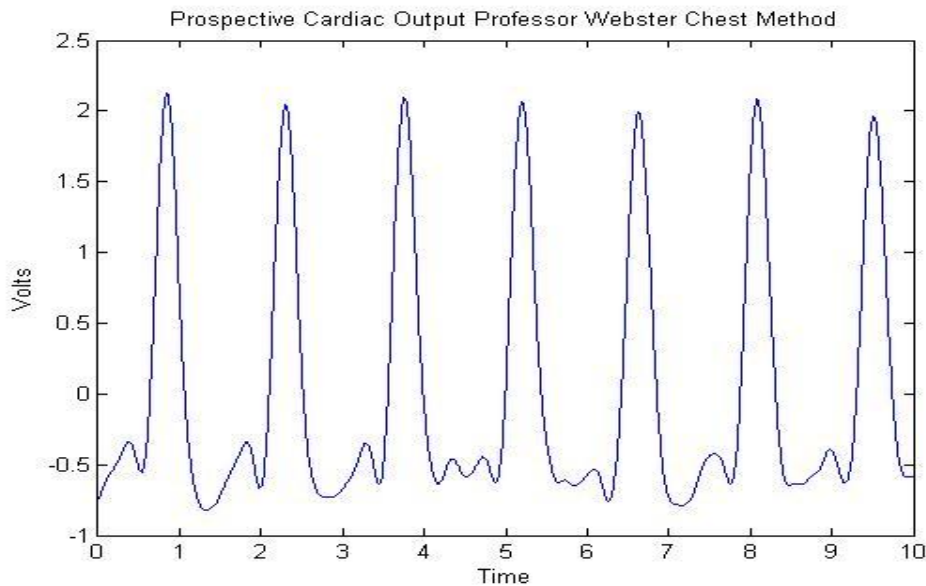


Figure 10: Chest approach from 70 year old male



The first difference between the two graphs of the chest method is the number of heartbeats per min. The 70 year old male has a much slower heartbeat, and subsequently has a sharper initial  $dZ/dt_{\max}$ . The two presented graphs are from two different people on two different days, yet the voltage signals for both are relatively similar which is to be expected since most people have a cardiac output around 5 L/min. Next, we will discuss how we can attain cardiac output from the impedance waveforms presented in the results.

## IX. Analysis

The cardiac output (CO) is calculated based on Heart Rate (HR) and Stroke Volume (SV). The Cardiac output is the product of these two parameters:

$$CO = HR * SV \quad \text{Eq.1}$$

According to the Z mark algorithm, the Stroke Volume (SV) is determined by the Volume of Electrically Participating Tissue (VEPT), Left Ventricular Ejection Time (LVET), and Velocity Index (VI).

$$SV = VEPT * LVET * VI \quad \text{Eq. 2}$$

The parameter VEPT is an independent constant reflecting the physical information of a subject (ie. Sex, height, weight and etc.). It is denoted as constant  $C_1$  in the equation described in Eq. 4. The LVET is the ejection time of the heart, and it is represented here as a constant fraction in a period of a heartbeat. The  $\Delta t$  represent the time of a cardiac cycle. In a normal healthy individual, the fraction of ejection time is approximately 20% time of a cardiac cycle. The constant  $C_2$  represents the ejection fraction.

$$LVET = C_2 * \Delta t \quad \text{Eq.3}$$

The Velocity Index is defined as  $dZ/dt_{\max} / TFI$ , where TFI is Thoracic Fluid Index, which is the baseline of thoracic impedance, denoted as  $Z_0$ . This constant  $I$  is unique for individual subject and it ranges between 21 to 37 ohm for female (1).  $dZ/dt_{\max}$  is the point of the greatest impedance

increase. This corresponds to the greatest increase of voltage as indicated in figure 11. The greatest increase of voltage could be calculated by taking the first derivatives of the curve. The maximum point in the derivative graph is the  $dZ/dt_{MAX}$ , denoted as  $V_{max}$  in the equation described below.

After substituting constants and rearranging the equations, we obtain:

$$SV = C1 * C2 * \Delta t * V_{max} / Z_0 \quad \text{Eq. 4}$$

The Heart Rate (HR) is defined as the number of heart beat in 60s. Therefore, the heart rate is calculated as:

$$HR = 60s / \Delta t \quad \text{Eq. 5}$$

After substituting SV and HR into the formula to calculate cardiac output. The time of a cardiac cycle,  $\Delta t$ , cancels out each other. And it leaves a linear relationship between cardiac output and  $V_{max}$ , which is the point on the graph with the greatest increase of impedance. The constant,  $K$ , is substituted to represent an accumulated constant:

$$K = C1 * C2 * 60s / Z_0 \quad \text{Eq.6}$$

$$CO = K * V_{max} \quad \text{Eq.7}$$

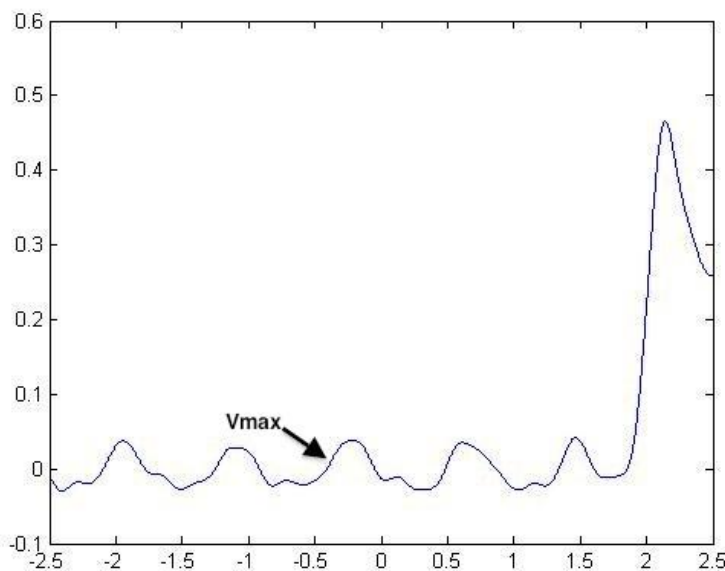


Figure 11 – A typical impedance graph with  $V_{max}$  labeled.

## **X. Social Considerations**

The first and foremost ethical consideration regarding this project is personal safety; the prototype and final product must be safe enough to both handle and use on human subjects. In this case, the primary concern is electrical safety. The 150 kHz, kilo Hertz, signal that we are using as our carrying signal is a sufficiently high frequency that the cells of the body are not affected by our produced signal. Safety is key with respect to any electrical current throughout the body because the body's ability to change concentrations of elements like sodium and potassium contribute to an electrical voltage that neurons rely on to send action potentials, and cells rely on to maintain proper levels of nutrients within the cell. Our 150 kHz wave has such a high frequency that as the current passes through these cells, the voltage does not change the ion concentration across the cell membrane, which is how our cells control voltage [7]. The product must be securely insulated and must be able to safely apply electricity to the body without creating the potential for serious harm. In other words, all aspects of the design, including the amplifier and electrode array, must be able to safely handle the electrical lode applied to it without failing or overloading.

## **XI. Future Work**

We plan to continue this project by collecting more measurements from a greater number of subjects. Ultimately, the results need to be compared to MRI or thermodilution measurements on patients.

## **XII. Appendices**

### **12.1 References**

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- [7] Webster, John G., *Medical Instrumentation*:

### **12.2 Matlab and Labview Code**

The voltage change reflects impedance changes in the aorta. In order to obtain the conversion constant of impedance and voltage for the system, a calibration of the system is required to obtain information of the impedance-voltage conversion ratio. The outline of calibration is described below:

1. Connect the circuit, measure a baseline pressure wave using the circuit.
2. Connect a  $10\Omega$  resistor in series with the chest. Obtain a pressure wave using the circuit.
3. Connect a  $1\text{mF}$  capacitor (or a  $1\text{H}$  inductor) in series with the chest. Obtain a pressure wave using the circuit

4. Use the maximum points of the graph as the reference to find out the voltage changes between the graph with resistor, capacitor or inductor, and the baseline.
5. The change produced by the resistor is the real part of the impedance, a.
6. The change produced by the capacitor or inductor is the imaginary part of the impedance, b.

\* Recall  $Z = a + jb$

The suggested experiment in the future; writing or lab manual; whatever... :

The LabVIEW data collection program:

The program block diagram is attached:

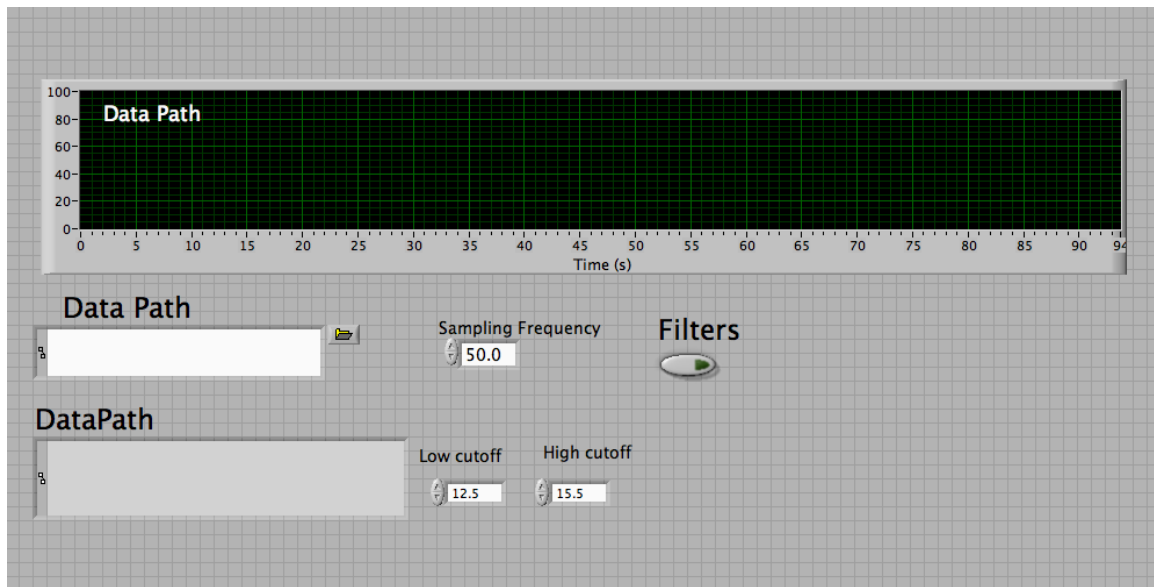


Figure x – The front panel of the CO input collection script in LabVIEW Version 9.2.

The function of the program are: 1) Display the data; 2) Collect and save the data. An digital collection board interface with LabVIEW is required.

The MATLAB script analyzing the cardiac output.....

1. Use the diff function in MATLAB to obtain the first derivative of the pressure wave graph.

2. Detect the peaks use the max function in MATLAB. A baseline should be drawn to the graph, in order to write a zero-across detection script.
3. Use if loops to write the thresholding script. (e.g. If x less than thresh, then...)
3. Multiple the constant, K, which is subject-dependent, with the maximum 1<sup>st</sup> derivatives to obtain the cardiac output of each cycle.
4. Use sum function to accumulate the parameters.
5. Notice that the data should be separated into 60 seconds epochs.

## 12.3 PDS

### Impedance Cardiography

David Schreier ( Team Leader Co-BWIG)

Jacob Meyer (Communicator Co-BWIG)

Ross Comer (BSAC)

Tian Zhou (Independent Study)

### Project Design Specifications

Function: Current methods for measuring cardiac output are invasive. Impedance Cardiography is a non-invasive medical procedure utilized in order to properly analyze and depict the flow of blood through the body. With this technique, four electrodes are attached to the body—two on the neck and two on the chest—which take beat by beat measurements of blood volume and velocity changes in the aorta. However, our client hypothesizes that the current method withholds degrees of inaccuracy due to the mere fact that the electrodes are placed too far from the heart. The goal of this project is to design an accurate, reusable, spatially specific system that ensures more accurate and reliable cardiographic readings. Furthermore, this system must produce consistent results able to be accurately interpreted by industry professionals. More specifically, our primary goal is to ensure the device must not only collect an impedance signal, it must also isolate the signal in its output using a variety of filters.

### Client Requirements

- Design Spatially specific electrode array, which can be adjustable in order fit numerous varieties of electrodes positions to determine the optimal location
- Design a way for our electrode array to fit females
- Method of determining ventricle location in patients
- Perform human testing once our approval from the IRB comes in
- System of holding electrode device to body, taking our current electrode matrix and improving upon it
- 150 kHz current system with ECG amplifier
- A filter to remove the ECG signal, for example a phase sensitive demodulator, or high pass filter, so we can use the 150 kHz signal

### Design Requirements:

#### 1. Physical and Operational Characteristics

- Performance Requirements: The team aims to design a system to acquire more accurate and reliable cardiographic data. The electrodes should be reusable and suitable for a wide range of subjects to be tested. The ECG signals returned should contain little interference and ready to be analyzed for further investigation.
- Safety: Must not put patient in danger of electric shock; must keep frequency above 100 kHz. Should have instructional manual and safety warnings for those operating device. This is an important ethical consideration in the production of this device.
- Accuracy and Reliability: In the long run, impedance cardiography machine should be as accurate or better as the current invasive catheter method currently used in hospitals to measure cardiac output. The device should Remove interference and acquire

continuous and clean data to be analyzed.

- **Life in Service:** Should be able to become a long-term fixture in hospital and lab settings, i.e. length of life in service should be measured in years.
- **Shelf Life:** Must withstand operating room conditions and should be built to last. Certain parts, particularly the electrodes, should be constructed to be reusable in order to increase the lifespan of the device.
- **Operating Environment:** Impedance device should be used in either a lab or medical setting.
- **Ergonomics:** The device must be comfortable and fit well on multiple body types
- **Size:** The electrode brace should be small enough to maneuver be placed easily on the body and lay within a close distance from the heart, but large enough to accommodate the 4 electrodes.
- **Weight:** The electrode matrix should be light enough to be able to be worn comfortably while the patient is standing.
- **Materials:** The electrode matrix must be made of nonconductive materials, so as not to distort the signal generated by the heart. The product must be made of a flexible, form-fitting material so that it can conform to the shape of different body types. There should also be a way to attach/detach the product from a body with ease without harming the patient.
- **Aesthetics, Appearance, and Finish:** These are not of primary concern, but the device should not scare the patient. Furthermore, the device should have no parts that could be harmful to the user/doctor (eg: no sharp edges).

## **2. Product Characteristics:**

- **Quantity:** One testing unit is necessary.
- **Target Product Cost:** This has not been determined.

## **3. Miscellaneous**

- **Standards:** If we are successful in our preliminary testing, human testing must be approved and implemented in order to determine accuracy and safety. Government approval must also be obtained for the device to be used in a hospital. We have submitted a proposal to the IRB for human testing.
- **Customer:** The device must be accurate, mobile (able to move from room to room), and should be comparable in cost (both initial and operational) to methods in place.
- **Patient Related Concerns:** Electrode brace should not be cold and hard and the patient should be able to stand comfortably. Non-invasive method will be easier for the patient compared to the invasive method.
- **Competition:** The main competition is the current invasive catheter method, which has proven accuracy and is already being used in most hospital settings.