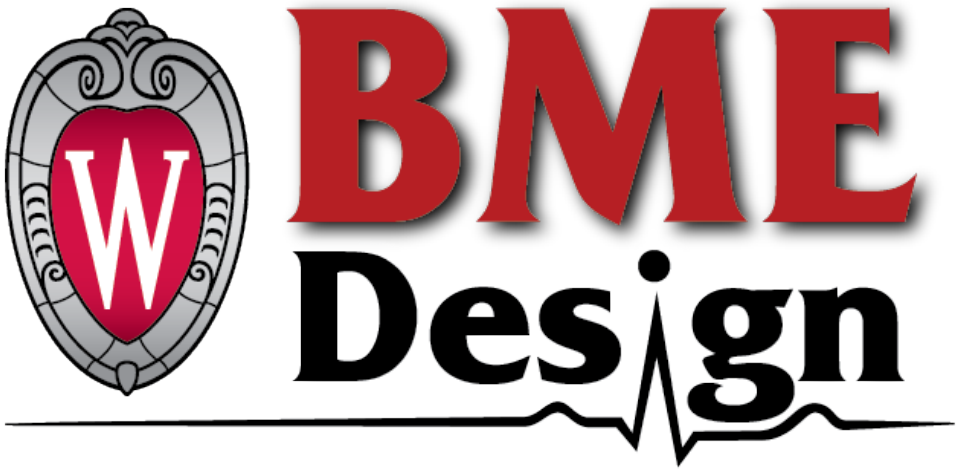

Reutilization of Pulse Pressure and Tonometry Equipment

BME 200/300
University of Wisconsin-Madison
Department of Biomedical Engineering
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ABSTRACT

System vascular impedance is a mathematically derived spectrum of data that indicates opposition to pulsatile blood flow. Impedance cannot be directly measured. Rather, it is calculated using data from pulsatile waveforms and blood volume flow waveforms. Three years ago, Dr. Nancy Sweitzer conducted research on impedance to blood flow using tonometry and blood flow equipment. The owner of the leftover equipment, Dr. Naomi Chesler, has tasked this biomedical team with reassembling the instruments with the ultimate goal of measuring impedance data in healthy individuals. In the process of reassembly, it is the task of the team to take inventory of which devices work and which don't, which devices have missing or incomplete parts, and which instruments can be reutilized for further use in future research. As of now, there are four identified instruments that are used to gather impedance data. The electromagnetic blood flowmeter is used to measure blood velocity through the blood vessels by creating a magnetic field through the vessel and measuring the movement of charged particles through the vessels. Second is the Acuson Sequoia machine which also measured blood flow velocity but does so by measuring the difference in outgoing and ingoing ultrasound frequencies. Third is the rapid cuff inflator, which inflates an arm cuff to measure systolic and diastolic blood pressure. Fourth is the NIHem instrument, which is a customized data analysis instrument. It is likely that the NIHem performs the necessary calculations acquire impedance data.

Contents

1 INTRODUCTION

1.1 Motivation

Ventricular failure is the number one cause of death in people with cardiovascular disease [8]. By utilizing mechanical engineering, vascular biology, and imaging tools, a noninvasive assessment of cardiovascular health can be performed which is critical in order to avoid poor vascular health [8] [9]. An important biomarker for good cardiovascular health is systemic vascular impedance which is calculated by measuring pulse pressure via tonometry and blood flow via echocardiography [10].

The instruments used to measure impedance were provided by the client, Dr. Naomi Chesler. Dr. Chesler, a professor and active researcher at the University of Wisconsin-Madison, is requesting an assessment and reutilization of medical instruments leftover from a former professor and researcher, Dr. Nancy Sweitzer. Dr. Sweitzer had used the instruments in past research but have been unutilized since her departure in 2014 [7]. The usage history of the instruments were analyzed via Dr. Sweitzer's literature that was published during her time in UW-Madison. The conditions of the instruments have been unknown until an inventory of the components was performed. These instruments are to be integrated into a working system that accurately measures systemic vascular impedance, as requested by Dr. Chesler, as well as a schematic outlining the integration of the different components and how they operate. A protocol for using the system for human testing will also be created if time permits.

1.2 Problem Statement

There are medical instruments in the lab of Dr. Chesler that need to be assembled into a working system that noninvasively assesses systemic vascular impedance by measuring the pulse pressure with tonometry and blood flow with echocardiography . The system needs to be assembled to do so with healthy volunteers [11].

2 BACKGROUND

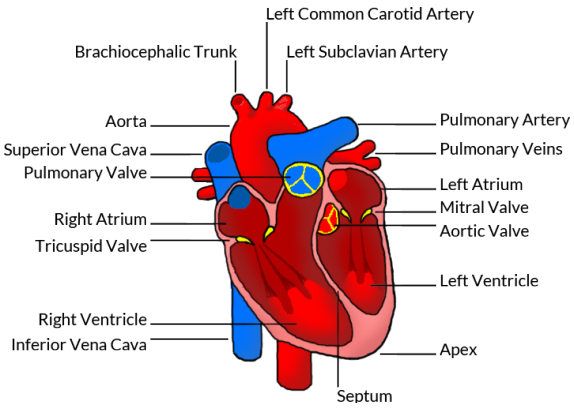

Figure 1. Heart Anatomy

Knowledge of the anatomy and physiology of the heart and vascular system is required in order to interpret the data gathered from the tonometry pulse pressure equipment. Understanding of the relevant information begins with the biology of the heart. Figure: 1 on the left depicts the anatomy of the human heart. For the purposes of this project, the left ventricle is responsible for the measured pulse pressure and impedance data. This is because the left ventricle pumps blood into the body and arteries [1]. The right ventricle pumps the un-oxygenated blood

to the lungs where gas exchange can occur [1]. For this reason, blood that exits the left ventricle is pumped through the *systemic vascular system* [1].

Since systemic vascular data is easier to gather than pulmonary data (measurements of pulmonary data require tampering with the organs in the chest cavity), doctors and scientists have created ways to gauge biomarkers for cardiovascular health simply by measuring systemic cardiovascular data [2]. An important measure of cardiovascular health is vascular impedance which is defined as the ratio of the frequencies of the local blood pressure waveform and the local blood volume flow waveform [3]. However, these measurements are not easy to obtain noninvasively. Usually, pressure waveforms are replaced with distension (changes in diameter of the vessels) so as to make the calculation easier.

An important distinction to make here is the difference between vascular impedance and vascular resistance. Vascular resistance is a single value that conveys the instantaneous resistance to blood flow whereas vascular impedance is reported as a ratio of two functions [4]. Impedance is reported as a spectrum with frequencies on the x axis and the corresponding modulus ratios associated with each frequency value. On the right in Figure: 2 is an example of the way vascular impedance is reported. Modulus is defined as the amplitude of the harmonic. A harmonic is a mathematically derived sinusoidal wave taken from the pulsatile waveform [4].

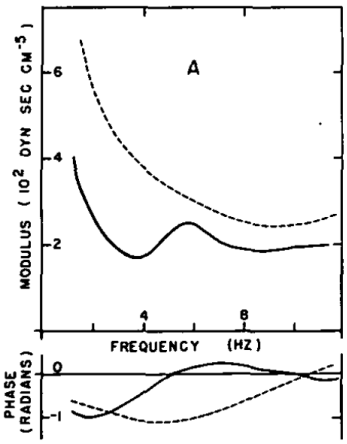

Figure 2. Impedance Modulus vs Frequency [4]

Knowing the above information, research can be performed to assess different components of impedance. Relevant to our work is Nancy K. Sweitzer M.D., Ph.D. Sweitzer is currently working as chief of the cardiology department at the University of Arizona College of Medicine- Tucson. However, three years ago she conducted several experiments using the pulse pressure and tonometric instruments the team must reutilize. Two of these studies include studying left ventricular responses to acute changes in late systolic pressure augmentation, and effects of the HeartMate II[8] left ventricular assist device as observed by serial echocardiography. A short summary of the instrument use in each of these studies gives information needed to further understand instrument function and may give the team ideas for conduction of future experiments.

When studying the left ventricular responses to acute changes in late systolic pressure augmentation in 2013, Sweitzer used the *cuff inflator* to obtain a base systolic and diastolic blood pressure. Using these readings, the calibration of the tonometric wave functions was performed. The transducer was then used to measure arterial tonometry from the brachial, radial, femoral, and carotid arteries. An electrocardiogram (*Acuson Sequoia)* was then used to measure the mitral flow, mitral relaxation, left ventricular out flow. Results were then digitized via CD-ROM and sent to a cardiovascular engineering lab for analysis [5]. In summary, the semi-automated computer-controlled cuff calibrated the system and the transducer and electrocardiogram

collected experimental data. Together, these instruments produced digitized results for analysis and figures such as Figure 3 below.

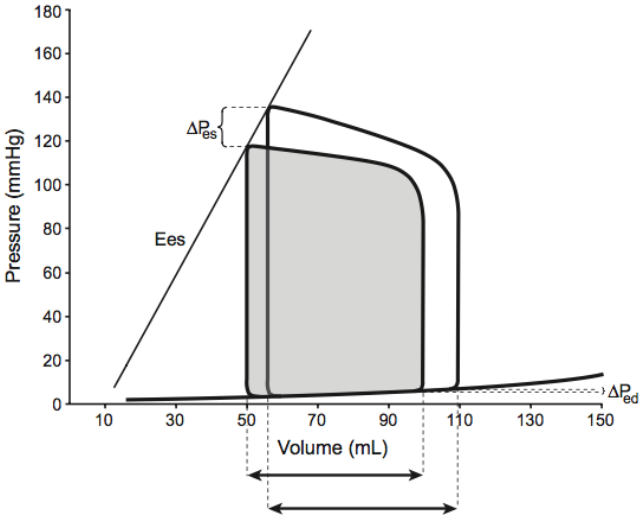

Figure 3. Tonometric Data [5]

When studying the effects of the HeartMate II in 2013, Sweitzer, Chapman, and Allana used serial echocardiography. Along with the instruments used when studying left ventricular responses to changes in systolic pressure augmentation, they used an echocardiography system called *NIHem*[8]. In the research methods and results, the explanation of the function of the *NIHem* device is brief, but includes measuring based off of the Doppler readings. This same technology was used, but not mentioned in the left ventricular response article[6]. In summary, the NIHem along with the Acuson Sequoia are used in real studies to measure ventricle size, ejection fraction, aortic valve thickening, and tricuspid regurgitation.

Dr. Naomi Chesler has a BS in general engineering as well as an MS in mechanical engineering, a PhD in medical engineering and a post-doctoral fellowship with Georgia Tech and Emory University. At UW-Madison, Dr. Chesler has been heavily involved with research in vascular biomechanics and hemodynamics.

3 DEVELOPMENT PROCESS

3.1 Methods

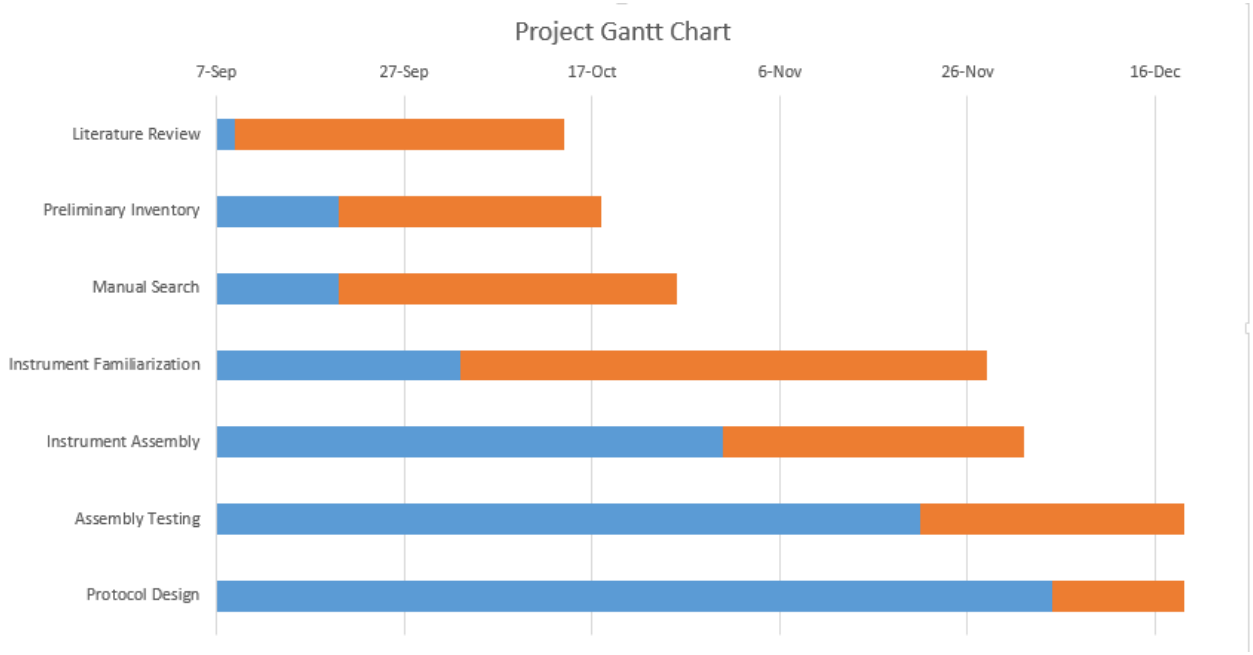

Figure 4. Gantt Chart

To set a road map for the project, the team created a Gantt chart (Figure 4) of seven project phases. The blue sections of the bar indicate time from project start to phase start and the orange sections indicate phase duration. A literature review was started on the first day of the project to gain information about the cardiovascular system, impedance, and Dr. Sweitzer's research. Once the team gained access to the lab, an inventory of the instruments and components (Table 1) was made in order to locate missing components and better understand the connectivity of the assembly. A paper-copy manual for one of the instruments was provided by Dr. Chesler, and the team conducted an online manual search, all of which returned three more manuals [12,13]. The team then began the process of familiarizing themselves with the instruments. This section included visual investigation, troubleshooting, and testing different connectivity of the instruments. The team projected that assembly of the instruments will begin in the third week of October, assembly testing will begin in mid-November, and protocol design will begin in the beginning of December. Using this schedule, the team has developed an inventory and instrument descriptions, the first steps in the reutilization process.

4 RESULTS

4.1 Inventory

Manufacturer	Part	Description	Serial Number	Notes
Hokanson	E20 Rapid cuff inflator	Controls amount of pressure delivered to the cuff	8180623	Missing one power cord (found)
Hokanson	AG101 Cuff Inflator Air Source	Provides source of air	9290613	Missing an air tube to connect the air source and the inflator
Cardiovascular Engineering	NIHem	A custom-made computer for data acquisition. Has ports for inputs and outputs.	P017 (not sure because it is custom-made)	Missing power cord and monitor
Acuson	Sequoia	Collecting tonometric data		Don't know the password
Tronics		Appears to be an air blower	456873	Missing power cord. Don't know the function
N/A		No idea	01684-1 or 12OVACRMS	Missing power cord. Don't know the function
Carolina Medical Electronics Inc.	Cliniflow II	Model FM701D Electromagnetic Blood Flowmeter	004801A	Manual found

Table 1. Inventory

4.2 Instruments

4.2.1 Acuson Sequoia

The Acuson Sequoia (Figure 5,6,7), often referred to as the “Echo Machine” in lab documents, is a sonographic instrument used in the lab to measure blood flow with ultrasound technology. The ultrasound measurement uses the Doppler Effect to derive flow velocity from the difference in outgoing and incoming ultrasonic frequency. There are extensive protocols in the lab documentation regarding how to run various experiments. Most of these protocols focus on flow measurements in the heart, including such values as mitral inflow and left ventricular outflow.

4.2.2 Cliniflow II Blood Flowmeter

The Cliniflow II Blood Flowmeter (Figure 8), manufactured by Carolina Medical Electronics Inc., is an electromagnetic flowmeter that measures blood flow. The electromagnetic flowmeter uses Faraday's law to derive flow velocity from the induced voltage caused by a conducting fluid flowing through a magnetic field. The Cliniflow is the least mentioned instrument in the lab documentation, but does not have missing components.

4.2.3 Cuff Inflator

The Rapid Cuff Inflator (Figure 9), manufactured by Hokanson Inc., is a cuff inflator used to measure systolic and diastolic blood pressure using conventional methods. The apparatus consists of an inflator and an air supply connected by an air hose. A second air hose exits the cuff inflator and leads to an arm cuff. The cuff inflator is mentioned in some protocols in the lab documentation.

4.2.4 NIHem

The NIHem instrument, manufactured by Cardiovascular Engineering Inc., is a custom-made system for the acquisition of tonometric data and possibly the integration of data from the previously mentioned instruments. The instrument currently lacks a power cord, but protocols found in the lab documents confirm its use as an acquisition system for tonometry. Ports labeled "Cliniflow" and "Echo Machine", referring to the Cliniflow II Blood Flowmeter and Acuson Sequoia respectively, suggest that it could be the integration point for calculations in which data from all three instruments are needed. The manual for this was provided at the start of the project by the client.

5 DISCUSSION

5.1 Analysis of Instrument Conditions

Summarizing Table 1 above, the NIHem and the Tronics component are missing power cords. The cuff inflator is missing one of the tubes that connect to the air source. The NIHem is missing the monitor and the Acuson cannot be opened because the password has been forgotten. Instruments that have power chords are able to be turned on. This is a good sign for predicting the conditions of the other instruments; meaning, if all of the instruments were in the same place for the same amount of time, they should respond the same way to power once connected.

5.2 Ethical Considerations

If the team reaches a stage of performing examinations on patients using the system, a protocol involving invasive examinations may be produced. These examinations may include probing of the body's arteries including the radial, brachial, and carotid. Consent must be given by the patient in order to carry out these procedures and if conducted wrong, could lead to arterial damage.

5.3 Potential Sources of Error

5.3.1 Conditions of the Instruments:

Most of the instruments have been left unused in the lab for an extensive amount of time, possibly without maintenance. Therefore, the instruments may not be in their best working conditions, which can potentially impact the accuracy of the data collected.

5.3.2 Non-compatible Parts:

Some instruments are missing parts, which will have to be purchased in the near future. However, due to the old ages of the instruments, some original parts may not be available now. If the team has to decide to use non-original parts for the instruments, the instruments may not have been calibrated for these parts, so re-calibration may be needed for accurate data acquisition.

6 CONCLUSIONS

Medical instruments in the lab of Dr. Chesler need to be assembled into a working system that noninvasively assesses systemic vascular impedance by measuring the pulse pressure with tonometry and blood flow with echocardiography [11]. The system needs to be assembled and ready to conduct tests on healthy volunteers.

So far, inventory of separate instruments and their components has been taken, along with careful notation of missing or damaged parts. The functions of the instruments have been uncovered through manuals found on web databases, hard-copied manuals found in the lab, and the research of Dr. Sweitzer. Methods of web based data search and literature review has worked well for finding information about various instruments; however, contacting individuals such as Dr. Sweitzer and Dr. Hacker, the director of Cardiovascular Physiology Core lab at UW Madison, has not been successful in gathering useful information. Nevertheless, the team predicts that once the instruments get in working condition, these sources may provide more information on data collection.

The next step the team must do is obtain missing/damaged parts. To obtain these parts, future meetings with the client must occur in order to gain permission and funding. Once purchased, the team must incorporate each individual instrument into a working system. A schematic can then be made to further explain the working system. This task will be completed by retrieving information from the manuals.

In the future, the team will assemble all instruments into a system that collects data that will be used to measure systemic vascular impedance. Once adequate data can be collected, healthy volunteers may be called in and testing can occur. Realistically, this testing will be based off of the ability of our working instruments. For example, if the team cannot get the echocardiography instrument to work, we may focus exclusively on cuff measurements with the rapid cuff inflator.

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8 APPENDIX

8.1 Product Design Specification

Function

The primary goal of this project is to reassemble a system of instruments previously used for research, but have since been unused and their procedures forgotten. The instruments screen for specific indicators of poor cardiovascular health. A secondary goal is to subsequently develop a protocol to use these instruments to measure impedance and other cardiovascular metrics. The instruments collectively determine pulsatile pressure for systemic vascular impedance only (pulmonary impedance requires a more invasive procedure). The instruments have to produce an accurate reading of the impedance to systemic blood flow.

Client Requirements

The client, Professor Chesler, wants the leftover equipment from Dr. Nancy Sweitzer's experiments to be assessed and reutilized for use in further experimentation, the goal of which is unknown at this time. It is safe to assume that the instruments will be used to measure systemic vascular impedance as it was earlier experiments. Assessment of the instruments includes:

- An inventory of the components of each device and the devices themselves
- A schematic outlining the integration of the components and how they operate
- An assessment of the accuracy of data the devices collect

Professor Chesler has minimal information to provide regarding the quantity, quality, and age of each of the devices. A manual was provided that describes the function of the catheters for insertion in the aorta but little else was known. Any equipment provided must have a surface or surfaces that can be wiped down easily.

Design Requirements

1. Physical and Operational Characteristics

A. Performance Requirements

The instruments will be involved with measure impedance of the systemic vascular system. Based on literature research on Nancy Sweitzer, described later in this document, as well as independent research, the team will be able to determine the frequency of device use and the loading/unloading patterns.

B. Safety

Until it is determined how to safely use each instrument by finding and reviewing each device's instruction manual, the team will use utmost precaution when handling each device. Gloves will be warn and all electromagnetic sensitive equipment (e.g. pacemakers) will be kept away from radiological equipment such as the Doppler ultrasound until exact dangers can be assessed in instruction manuals.

C. Accuracy and Reliability

There are not yet available sample data for the instruments. The team will try to obtain sample data and communicate with the client for an acceptable range of error. The system to be designed will be strictly for screening purposes only, and will not serve as a diagnostic device. Therefore, slightly larger error margins will be tolerated.

D. Life in Service

This system must be able to withstand testing and data collection 8 hours a day anywhere from 1-7 days per week. There is no distance this system needs to travel at the present time. This system has been in use already for an unknown amount of time.

E. Shelf Life

The shelf life conditions include a lab setting. While in storage dust and dirt may collect. The batteries of this device may eventually corrode, however the amount of time of this occurring is unknown. Note, the batteries, wiring, and circuitry to some components of this system may already be damaged.

F. Operating Environment

The system must be able to handle lab conditions. This includes standard room temperature, pressure, and humidity. It also must endure sanitation by means of spray and cloth or sanitation wipes.

G. Ergonomics

The system must be easy to operate, requiring no strain or discomfort. The instruments will be assembled on carts so that all necessary buttons, switches, instruments, etc. are easily within reach from a standing position and do not require bending or heavy lifting to access.

H. Size

The intended size of the device will be/ should be the same as outlined in the blueprints of the original device. Based on observation of the devices, most of the instruments are large enough to require carts to be transported. Once an inventory of the lab is complete, more information will be provided in this category.

I. Weight

The devices are heavy enough to require carts to transport. Modern ECHO instruments are typically portable and require little maintenance[(1)]. However, close examination of the ECHO instrument in the lab revealed that it required multiple separate components, all of which were loaded on a cart. Information on the identity of the other devices wasn't provided by the client.

J. Materials

All the parts for the instruments either already exist or need to be replaced with the original model. Therefore we do not need to determine whether a material can be used in the design, as long as the existing parts work or the replacement parts are the same as the original ones.

2. Production Characteristics

A. Target Project Cost

The entire system reassembly should not cost no more than the price of replacement parts. Dr. Chesler has not set a budget, but it is the objective of the project to repair rather than replace as many components as possible. Some components will inevitably need to be replaced, which should be the only cost associated with the project.

3. Miscellaneous

A. Standards and Specifications

For this project U.S. regulations regarding electrical equipment standards as well as medical equipment standards will need to be considered. The electrical equipment standards that will be followed fall under Occupational Safety and Health Administration (OSHA) regulations Subpart S[(2)]. Regarding medical equipment regulation, the project is

subject to the U.S. Food and Drug Administration's (FDA) Code of Federal Regulation (CFR) Title 21 Subchapters H[3] and J[4]. Each instrument in the assembly will be verified against recall and obsolescence. The course of this project will unlikely require any modifications to any of the instruments, which would require much more in-depth evaluation of these standards. Regulations for human subject testing are also to be considered when developing a protocol for using these instruments. CFR Title 45 Part 46[5] and 690[6] and must be approved by an Institutional Review Board before studies may commence. Patient information must be stored securely vis a vis HIPAA Privacy Rule and Security Rule delineated in CFR Title 45 Parts 160[7] and 164[8].

B. Patient Related Concerns

The device will need to meet the standard requirements for sterility before each test vis a vis CFR[3,4]. The comfort of the patient during potential testing is also important, but patient testing, but patient procedures are outlined in one of Dr. Sweitzer's research publications noted below. If there is human testing within this project, the collected data will need to be stored in a secure database that comply with HIPAA regulations regarding patient privacy[7,8].

C. Background

Previous research with these instruments had been conducted by Nancy Sweitzer, M.D., who left the University of Wisconsin in 2014. A review of her publications[9,10,11] has revealed some information about the methods used by Dr. Sweitzer. One particularly enlightening publication[9] aims to determine a causative relationship between late systolic aortic pressure augmentation, measured by central augmentation index (AI), and myocardial diastolic performance, measured by lateral annular mitral velocity. In *Methods,* the procedure includes measuring blood pressure using a cuff apparatus, measuring arterial tonometric waveforms using a custom transducer, possibly one of the instruments in Dr. Chesler's lab, as well as using a Doppler electrocardiogram to measure mitral inflow. AI and lateral annular mitral velocity can be calculated using these three measurements as described in *Data/statistical Analysis*. The conclusions from the study determine that AI is not a strong determinant for poor heart health and that other metrics should be explored. Though this article does not provide immediate direction for the protocol design, it does indicate which instruments were used in Dr. Sweitzer's research.

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8.2 Instrument Visual Aides

Figure 5. Acuson Sequoia

1 Monitor and Speakers
2 Monitor Controls
3 MO Disk Drive
4 Transducer Holders
5 Cable Holder
6 Storage Compartment
7 Wheel Lock/Steering Controller
8 Footswitch Connector
9 MP Transducer Ports
10 MP Storage Port
11 Control Panel/Keyboard
12 Power Button
13 Soft Keys (4)

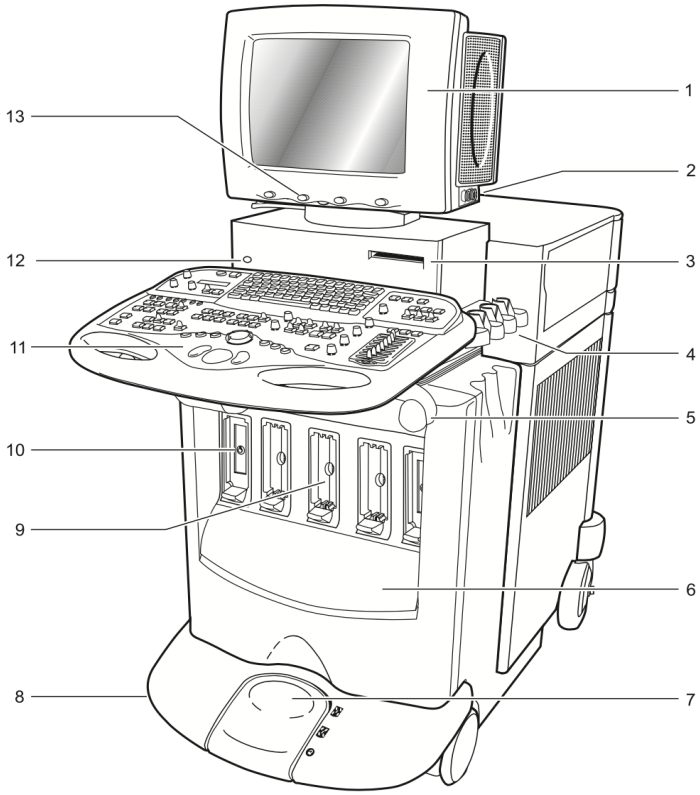

Figure 6. Acuson Sequoia Diagram [12]

Figure 7. Acuson Sequoia Components

Figure 8. Cliniflow II

Figure 9. Rapid Cuff Inflator