Project Design Specification

Impedance/Tonometry System

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Contents

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 machines 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.

References

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