Chapter One: EML 4551C

1.1 Project Scope

Project Description

The objective of the *103* Senior Design (SD) project build a measurement device that measures manual inputs and evaluates those inputs against a 1:1 promise. Biosense Webster has recently altered the production of their catheter and have since implemented a new material into the fabrication of their product. Due to this, the current catheter that Biosense Webster currently is using and manufacturing has not validated if the deflection relationship from the proximal end is translating through the catheter and equal to the distal end. The *103* SD group will not be designing and prototyping a new catheter, for their project they will fabricate a device that can replicate the insertion of the catheter, act as a substitute for the venous system of the human body. This will allow the *103* SD team to accurately test their measuring device. In addition to this, the students will create a database of all measurements received to be analyzed and used for further validation.

Key Goals

The goals of this project will revolve entirely around the measuring device's ability to accurately detect output signals. The first goal of this project is to develop the testing arena that will be utilized for all proceeding manners. This testing arena will perform a similar role that the venous system of the human body serves. The *103* SD team will have to ensure that the fluid it is filled with is akin to the viscosity of human blood, have a rigid plastic tube (at least 106cm long) suspended within the fluid that is rigidly attached to the testing arena, and have an entrance diameter that is large enough to contain the French size of the catheter.

The measuring device is undeniably the most integral aspect of this project. To ensure success for the *103* SD group, the measuring device must fulfil the project description, to build a measurement device that measures manual inputs and evaluates those inputs against a 1:1 promise . This device will consist of a housing unit, sensors, and an interface that is able to be controlled by the used to extract output signals. The housing unit will be entirely outside of the human body and will more than likely be attached at the handle. The sensors will be inserted into the catheter at both the proximal end, which is rigidly connected to the testing arena, and another sensor will be attached at the distal end of the catheter.

Another goal that was outlined by the Senior Design team was to create the measuring device to be compartmentalizable yet constant. The Biosense Webster facilities in California deal with small spacing within the lab for the team to be able to work in. By creating the measuring device in a way that allows it to be storable, the *103* SD team can aid the team in California with their limited space. Additionally, the team aims to design the fasteners, which will be secured once the catheter is attached to the measuring device, to create as constant of a testing environment as possible. Collecting data is important but ensuring that all data can be compared to one another to validate findings more accurately is integral to both the California team and the *103* SD team.

Primary Markets

It is crucial to have established primary markets as they serve the purpose of defining a target audience. Primary markets are identified as markets, individuals, or centers that will be using the product. These parties can also provide comments to the original company for any comments or suggestions they may have.

Cardiac surgeons are identified as being a primary market. The 103 SD team intends to use the measuring device to meet the specific needs and challenges faced by cardiac surgeons that use catheters in their operations and are looking to improve their existing technologies.

Another primary market would be cardiology researchers such as Investigator Initiated Study (IIS). Biosense Webster, Inc. values the importance of partnering with global leaders in research to elevate the standard of treatment and has collaborated with over 150 research centers and investigators globally to fund more than 100 external research partnerships (J&J).

Cardiology centers are considered a primary market due to their ability to provide feedback to Biosense Webster regarding ways the catheter has malfunctioned or failed to perform certain tasks or aspects

Secondary Market

A secondary market is typically identified as those who will purchase the product with the intention of turning a profit on it. These secondary markets are typically removed from the actual synthetization and production of the product. These external parties will be involved in the distribution of the product but separate from the original company that manufactures the product.

One secondary market that has been identified is biotech resell companies, such as Grayline Medical. This vendor offers a multitude of different medical devices, including the Biosense Webster catheter. Another seller with the same intention is DOTmed. Both of these suppliers are considered secondary since they have no concrete interest in the product other than flipping a profit.

Assumptions

To save time, resources, and energy exhausted from the *103* SD team, assumptions that simplify the project must be established. These assumptions can range from prototype and

deliverable assumptions to assumptions regarding the demographic that this project is aimed towards. There will also be few assumptions on which action items will be delivered by.

The first assumption that has been identified by the *103* SD team revolves around the usage of the Biosense Webster catheter. The catheter's measuring device will only be designed and programmed to be applied to the catheter. This meaning, no external functions or abilities will be considered or implemented throughout the design, prototyping, and end performance of the catheter's measuring device.

Another assumption that has been declared is the demographic which will benefit from the success of the *103* SD project. Such as, those experiencing coronary artery disease, congenital heart disease, heart failure, heart valve disease, or damage to the walls and inner lining of tiny blood vessels in the heart (Mayo Clinic).

It is important to note that another assumption that the *103* SD team has noted is that the catheter's measuring device will not impact or disrupt the existing functions of the Biosense Webster catheter. The device will only have one sensor implanted at the distal end of the catheter and all other aspects of the measuring device will be outside of the body.

The final assumption that the *103* SD team has identified is the timeline of the project. The team is projecting to have a prototype designed and in-production by the end of the 2023 fall semester and a final working prototype by the week before senior design presentations.

Stakeholders

Stakeholders for the *103* SD team will consist of both individuals and parties that are investing monetary interest in the success of the project or those with a concern for the success and development of the end product. These stakeholders can range from the actual sponsor of the project to those that indirectly fund the project, such as Johnson & Johnson.

The main stakeholder for the Biosense Webster catheter measuring device is Dr. Charles Lindholm, the senior regional business director of Biosense Webster's Advanced R&D department. Dr. Lindholm. He is most invested in the measuring system that the *103* SD team will be designing and producing. His involvement in the project will be more akin to a manager as he will expect certain milestones to be complete by certain dates. He will also provide direction and clarity when needed. In addition to the previously stated involvement, Dr. Lindholm will also be providing existing catheters for the SD team to handle as well as monetary supplements for the project and any prototypes.

Another stakeholder in the project will be Dr. Arce. Dr. Arce is acting as the **functional** manager of the project. Since this SD team is originating from the biomedical engineering department at the FAMU-FSU College of Engineer, any problem areas that would be inappropriate to address with Dr. Lindholm will be redirected to Dr. Arce. He will also act as an aid for more general confusion points, specifically around the biomedical aspect and implantation of the measuring system.

Two additional stakeholders for the Biosense Webster catheter measuring device will be Dr. Hooker and Dr. McConomy. The *103* Senior Design team consists of biomedical, electrical, and mechanical engineering students. These two professors, though acting more as **functional** managers. Because of this, they will be secondary points of contact that will assist in assigning grades to the electrical and mechanical students, as well as provide guidance in the areas which Dr. Arce cannot provide.

The last stakeholder identified by the *103* SD team is the parent company of Biosense Webster, Johnson & Johnson. Since Johnson & Johnson has acquired Biosense Webster, all products are in turn a reflection of Johnson & Johnson. To maintain their praised public

perception, Johnson & Johnson is considered a stakeholder in the *103* SD team and their success with the catheter's measuring system.