

1.2 Customer Needs

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Customer needs are certain needs, attributes, and requirements that can be best described more as “wants” than “needs”. These needs are not typically tied to a concept and are more vague or general interpretations of items that may be hidden within the project scope. These needs, although not explicit, are crucial to the success of the project. By sitting down with the Biosense Webster sponsor, the 103 SD team was able to extract certain needs that are desired from the customer to be completed.

Compatibility

One desire for the measuring device is for it to be compatible with Biosense Webster catheters ranging from 1-8 mm. Compatibility of these parts is crucial for the success of the measuring device’s ability to perform on different types of catheters that BSW uses. Compatible components will make integrating various catheters easier and faster to test. This integration of the various catheters will contribute to reduced costs, time, and effort for BSW.

1:1 Rotational Promise

During a meeting with the sponsor, the question “What is the goal of the project?” was asked. From the sponsor’s response it was uncovered the 103 SD team had to create a catheter that had to determine the “1:1 relationship” between proximal inputs and distal inputs (Appendix. D). When the catheter is in use during a heart procedure, puller wires control the distal end deflection. By attaching sensors to the catheter, the 103 SD team will be able to measure 1:1 rotation from proximal to distal catheter end for 0-degree, 45-degree, and 90-degree deflections.

Measures Translation

An important goal is to be able to measure translation from the proximal end to the distal end to 0.5mm in XYZ directions. The sponsor was asked “What is the goal of the project?” He responded “The goals include testing the 1-1 promise of translation as well as the deflection inputs. New materials have made the catheter crowded and there has not been time to check the 1-1 relationship, the outputs translating, and if there is lag. We want both ends to turn at the same time and same rate.” In order to ensure that the customer is satisfied with the measuring device for the catheters, the device must be able to also track translation.

Simulated Environment of Human Heart

Another desire that was communicated to the 103 SD group from the sponsor is to create a testing arena that is akin to the human heart. When asked “What other devices are used in addition to the catheter”, the sponsor detailed a “[replication of the] venous system” (Appendix D). This will allow the 103 SD team to be able to test their measuring system in an environment that can simulate the fluids and barriers that will be exhibited if the product is implemented by Biosense Webster.

Measuring arena can be replicated in production

In order to be able to properly test the catheter and the measuring devices for use in a human, a measuring arena will be produced to gather the most accurate results resembling a human's internal organs. When the sponsor was asked “What other devices are used in addition to the catheter and CARTO?” The sponsor described that “The testing arena needs be able to replicate venous system (hose and plastic tube) and then can use the sheath to put inside the

venous systems (catheter, sheath, tube)”. One goal of the 103 SD team will be to figure out how to replicate blood flow including lubrication from blood and the constriction.

Develop a procedure for collecting measurements

A well-defined procedure for collecting measurements is important for many reasons. By establishing a routine that is followed with each data collection, more consistency and reliability can be credited towards each trial. A valid procedure ensures precise and accurate measurements that can be used in reference for sound decision making, consistency in the measurements recorded, reproducibility for others to be able to replicate the procedure to ensure validity, and for analysis to draw informed conclusions.

Sensor Interchangeability

Since the primary project focus is to design and implement a testing arena to measure the rotation of the catheter, it is crucial that all measurement sensors can be removed from the catheter without disrupting any of its functionality. BSW has made it clear to the SD team that the catheter testing arena is intended to be implemented for future catheter integration, and that the sensors used for collecting data cannot remain on any catheters used by BSW.

Non-invasive Electronics

The success of the SD team on this project relies on minimizing the number of devices that will be implemented by BSW in the field. Considering the many factors involved with these surgeries, BSW has indicated that no electronics are needed to monitor the orientation of the catheter within the human body. The testing arena will be designed so that the electronic monitoring of the catheter will take place outside of the pseudo “human heart.”

Methods to Collect and Analyze Data

BSW maintains that the SD is not responsible for designing a new catheter, however a means to monitor and verify that the existing catheters are functioning as intended. To prove this, the SD team will implement a means to collect data that is verifiable to be accurate. This is a main point of emphasis for BSW, since the SD team working on this project previously was unable to show that their data was accurate.

Maintain functionality

Any additions to the catheter for the purpose of measurement will not affect the performance of the catheter as well as complying with all F.D.A rules and regulations. For the data collected in the testing arena to be accurate the catheter will retain complete functionality within a reasonable degree of error.

Sensor durability

Since BSW plans to use their catheters inside the human body the measurement tools will be able to withstand the internal forces of the human body. The sensor also has to be reusable and be able to survive multiple rounds of testing.