1.4 Target

Targets and Metrics allows the *103 SD* team to best assess the tasks of the Biosense Webster Catheter's measuring device that was declared as part of the functional decomposition. A metric is how one plans to validate a function. This can be seen in the form of size, pressure, opinions, etc. After the metric is identified, it is imperative to pair it with a target, the specific value used to design around. If no specific value is assigned, then concentration on a viable and effective product is no longer feasible. Having a target allows the team to get a better idea of how to most accurately produce designs and allows the stakeholders, advisors, and the team alike to see that concrete answers to the problem at hand have been identified.

Critical Targets

Although the team was able to identify multiple functions and outcomes from the customer's statements, it is more efficient to focus on a select few that the customer placed emphasis on. These functions or needs will have equally particular targets, known as critical targets. For instance, the sponsor expressed interest in designing and using materials and instruments to allow the product to be used more than just once, in this case, sterile. Accordingly, the *103* SD team decided to focus on the subsystem "Reproducibility", from the function "Environment Simulation". Another concern was the ability to detect the rotation of the catheter. Knowing this, it was imperative that the team designated the subsystem "Detects Rotation" as a critical function, since the product must be able to track these types of changes. Similar to "Detects Rotation", it is also critical that the team designs and develops their measuring system to also "Detect Translation" and "Detects Deflection", all three of which are nested underneath the major function of "Sensibility". The last critical target that was identified was "Stabilization", this falling under the "Environment Simulation" major function. This was

designated as a critical function due a meeting the SD team had with the R&D testing team based in California. The team in California had mentioned issues seen with stabilizing their prototyped measuring device, creating the mind space within the SD team to set a metric for this target.

Table 2

Critical Targets Tables

Major Function	Minor Function	Metric	Target
Sensibility	Detect Translation	Size, displacement Test various lengths of product and product within various common environments.	Product can detect translation of the distal end inside the testing arena within **0.5 mm**.
Sensibility	Detect Rotation	Angular Position The amount at which the product will be able to turn.	Product will detect the distal end output rotation and puller wire orientation with an accuracy of **0.5 degrees**.
Sensibility	Detect Deflection	Deflection Position Amount at which the product will be able to deflect.	Product will detect the distal end output translation and puller wire orientation with an accuracy of **0.5 degrees**.
Environment Simulation	Reproducibility	Reuse/Lifespan	Product will be able to be used **more than once**.

		Research which material will be able to be used more than once or singularly.	
Environment Simulation	Stabilization	Material of Testing Arena Develop various options for the testing area to be made from.	Product will be made of either **metal or wood** to ensure a firm foundation to test within.

Detects Translation

One of the *103 SD*'s major functions is sensibility, along with this key outline, several minor functions are derived, including one described as "detecting translation". With this critical target in mind, developing a rule of thumb for how much the distal tip of the catheter can translate within the heart is essential to the success of the project. Fortunately for the SD team, these metrics were outlined by the project scope. The group's target will be to detect translation within the heart up to 0.5mm, this is a strict limit that the team will attempt to achieve.

Detects Rotation

Another critical target that was outlined by the team was another sensibility-based function that the team is "detects rotation". The Biosense Webster Catheter is mobile within the heart and needs to rotate in order to reach different areas of the heart. This function is critical, and the sponsor has continuously expressed extreme interest in being able to measure/detect the catheter's position in terms of rotation. This led the team to 0-90 degrees with a 0.5-degree tolerance.

Detects Deflection

Another critical target that was outlined by the team was another sensibility-based function that the team is “detects deflection”. As stated previously, the catheter moves within the heart and deflects to certain degrees based on the user’s desire. This function is critical, and just like the previous critical target, the sponsor has continuously expressed extreme interest in being able to measure/detect the catheter’s position at all times within the heart in terms of deflection. This led the team to 0-90 degrees with a 0.5-degree tolerance.

Reproducibility

The product will be set up to be reproduced feasibly by those who want to recreate this product. All dimensions and materials will be included in the Evidence Manual once the product is considered successful. Not only will it be able to be reproduced but the product will allow multiple different styles of catheters to be inserted and tested for an extended number of times. Results from the testing method should have a variance of less than 5% across multiple trials conducted by different operators using the same equipment and conditions.

Stabilization

The platform on which the product will be mounted will be made of a solid material such as metal or wood to ensure sturdiness. This robust foundation will be easily stored in an office workspace, such as an office cabinet, to not take up much space that is needed for other supplies. Wood and metal are considerable options for this platform because they allow screws and hinges to be easily added, which grants the team to have more creativity and flexibility when designing a compact product.

Derivation of Targets/Metrics

The critical target metrics were determined primarily from the advice of the team sponsor. The precision in determining the location and orientation of the catheter is the basis of the team's design. After discussion with the members of the team, it was decided that these must be the critical targets of the design.

Method of Validation

To validate the catheter's design metrics, a series of tests will be conducted. Dynamic testing will evaluate translation, rotation, and deflection using motion tracking systems. Data integrity will be assessed through stress tests, ensuring accurate data capture under varying conditions. The catheter will be subjected to simulated blood conditions using thermocouples and viscometers for environmental fidelity. Post-sterilization, its functionality will be reviewed. Sensor accuracy will be confirmed through calibration tests, while reproducibility is ascertained through repeated trials. Stability will be gauged using laser sensors, electronic emissions will be monitored for EMI compliance, and durability will be tested under continuous operation cycles, ensuring a robust and reliable design.

Discussion of Measurement

The senior design team will need to employ a systematic approach using precision tools. Motion tracking systems and rotary encoders can measure translation and rotation, while flex sensors assess deflection. Data integrity in acquisition and manipulation can be tested using software platforms like MATLAB. For venial replication, thermometers and viscometers ensure accurate temperature and viscosity. Sterilization effectiveness can be checked using functionality testing post-sterilization. Calibrated gauges evaluate sensor adjustability, statistical software determines reproducibility and laser sensors monitor catheter stabilization. Lastly, electromagnetic interference (EMI) meters ensure non-invasive electronic standards are met, and

durability machines paired with functionality checklists ensure longevity and consistent performance.

Critical Targets Without Metric

There are targets that can be drawn from the functional decomposition performed that are just as critical as the ones that were listed in *Table 2*. However, these targets come without a strict metric that is easily applied. For instance, the *103 SD* team had identified that the means of which data is acquisitioned and manipulated is critical to the success of the measuring device that is actively being designed, listed underneath the "Data Collection" major function. Though, these functions are typically executed through singular medium, and cannot be assigned any true metric. Due to this, come critical targets of the group are not outlined in the table, but will be described within the concepts that have been generated.