

# **Product Design Specifications: Intracranial Pressure Sensor**

## **Team Roles:**

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**Function:** Shunt failure in hydrocephalus patients is difficult to detect. The current pressure sensor system is complex and bulky. Other detection methods can be inaccurate. Our client needs a more simple, inexpensive, and reliable implantable intracranial pressure monitor for patient care. The first step to developing this product is to design it on a large scale. Our goal is to develop a phantom testing protocol in order to properly calibrate the sensor.

## **Client Requirements:**

- Must not interfere with sensor telemetry
- Must apply proper range of pressure (-30 to 100 mmHg)
- Must apply constant pressure over a long period of time
- Must be able to apply a known and accurate pressure
- Must be able to test drift-stability
- Testing protocol must be standardized and accurate

## **Design Requirements:**

### **1. Physical and Operational Characteristics**

**a. Performance Requirements:** The phantom tester must provide adequate conditions to test the newly developed intracranial pressure sensor. This includes supplying appropriate pressure (-30 to 100 mmHg), conditions to test drift stability, and a leak proof environment.

**b. Safety:** All components should be water proof or able to interact with water. The device should not be too heavy or cumbersome for one person to handle.

**c. Accuracy and Reliability:** The testing device must be able to apply many different pressures (over 100 points).

**d. Life in Service:** Components should have a life span of 20 years.

**e. Shelf Life:** Storing the product will have no effect on its ability to perform

**f. Operating Environment:** This device will be used in a traditional lab setting, but should be operable under the final product environment of the intracranial region.

**g. Ergonomics:** There should be a low learning curve, but interpretation should be done by licensed professionals. Final implanted product should cause no discomfort to the patient or disrupt daily activities.

**h. Size:** The sensing device should be a maximum of 12" x 6" x 4". The phantom tester has no size requirement, but should not unreasonably large, under 5' tall.

**i. Weight:** The phantom tester has no weight requirements, but a person should be able to transport by lifting. (Under 35 pounds)

**j. Materials:** All outer interface should be waterproof.

**k. Aesthetics, Appearance, and Finish:** The intracranial pressure sensor should appear safe and operable. The product should also look professional.

## **2. Product Characteristics**

**a. Quantity:** Our team will be developing the one phantom tester used in calibrating the pressure sensor.

**b. Production Cost:** The cost should be reasonable in comparison with technologies and materials used. The phantom tester should cost less than \$500.

## **3. Miscellaneous**

**a. Standards and Specifications:** Electrical components should be compatible with data scanner device and inductive power source.

**b. Customer:** The client would like a sensing device that is operational on a large scale compared to the final product.

**c. Patient-related concerns:** The final product will require multiple patient related concerns, including: out-growing device, infection, replacement or recalibration of device, comfort, and interaction on daily use. However, this product has no interaction with the patient.

**d. Competition:** Currently there are other devices on the market that have the same relative use. However, these devices are inaccurate and prone to failure.