Appendix A

The Product Design Specifications

Function:

The overall function of the intracranial pressure monitor is to accurately measure the pressure in the skull using an internal MEMS device and transmit it to an external power supply to be displayed as a pressure reading. This semester focused on designing a biocompatible casing for the internal portion of the intracranial pressure monitor. The casing would house the MEMS device and must incorporate a flexible membrane to transmit intracranial pressure changes to a fluid filled chamber which then alters the MEMS capacitor plate distance. Two inductor coils located on opposing sides of the MEMS circuit allow the device to be inductively powered, requiring no exposure through the skin.

Client Requirements:

- No ferromagnetic materials can be used in the circuit located on the skull (must be MRI compatible).
- The component located on the skull must be covered in biocompatible materials.
- Nothing located on the skull can be protruding from the skin (so as to eliminate the possibility of infections)
- Device on skull must have a constant current/voltage so as to achieve accurate results.
- The upper portion that will rest on top of the skull just below the skin will be approximately 2.5 cm in diameter and no more then 6 mm thick, allowing it to remain discrete.
- The long cylindrical portion will need to be 3 cm long in order to reach the correct portion of the brain to measure pressure accurately.
- The diameter of this portion will be 2 mm to allow it to fit through a hole drilled by a typical neurosurgical drill.

Design Requirements:

1. **Physical and Operational Characteristics**

a. *Performance requirements:*

The internal component of the ICP monitor will have a portion that rests on top of the skull underneath the skin and a portion that penetrates through the skull and into the intracranial fluid. The device used to power the ICP monitor will be a hand-held device that when held up to the head with inductively power the internal component. The device will be used only when there is suspicion that the patient's shunt has failed.

b. *Safety:*

The portion of the device implanted inside the head will need to be completely biocompatible and cannot contain any ferrous materials that would disrupt MRI scans.

c. Accuracy and Reliability:

The internal pressure gauge will need to measure a pressure range of -30 mmHg to 100 mmHg. The accuracy of the pressure measurement needs to be within ± 1 mmHg. Drift in the pressure measurement should not exceed 1 mm Hg per 5 year period.

d. *Life in Service:*

Given that the device will be implanted inside of the body, it should work as long as the patient is alive with altering requirements at a maximum of once every 20 years.

e. Shelf Life:

Storage of the device will occur at approximately room temperature. The internal component should be able to last up to 20 years. The external portion should be rechargeable or replaceable.

f. *Operating Environment:*

The external component of this device should be able to be placed against an individual's skull as well as be stored at room temperature around the home and in hospitals. Part of the internal portion of the device will be located outside the skull and underneath the skin, while the other portion will have to penetrate through the skull and into the brain. Biocompatibility is therefore an important factor for the internal component and it will need to withstand average human body temperatures of approximately 98 °F. We will need to ensure that the device does not corrode or suffer from considerable drift when exposed to the body fluids. The device will also need to withstand a regular pressure change due to the heart rate of approximately 5 mmHg in both directions.

g. Ergonomics:

The external portion of the device should not exert an electric field that would cause any adverse effects on any other portion of the individuals head. The internal portion should be able to fit underneath the skin and outside of the skull. The portion that is inserted in the skull should be able to reach a depth within the brain to measure

pressure accurately. The upper portion that will rest on top of the skull just below the skin will be approximately 2.5 cm in diameter and no more then 5 mm thick, allowing it to remain discrete. The long cylindrical portion will need to be 3 cm long in order to reach the correct portion of the brain to measure pressure accurately. The diameter of this portion will be 2 mm to allow it to fit through a hole drilled by a typical neurosurgical drill.

h. *Size:*

The size of the external portion of the device should be able to be held in an individual's hand. It should be less then 2.5 cm in diameter and no more than 3.5 cm in height. The internal portion that is placed on the exterior of the skull should be no more than 5 mm thick and no more than 2.5 cm in diameter. The cylindrical portion that penetrates through the skull and into the intracranial fluid should be 2 mm in diameter and 3 cm in length.

i. *Weight*:

The weight of the internal portion should be less than 0.25 lbs. The external portion should not weigh more than 5 lbs.

j. *Materials*:

Material restrictions: Any ferrous material, or metallic material. Patients need to be free of these materials for MRI scans. Since this is a permanent implant, we must make certain the product is composed of non-ferrous material, removing the implant for an MRI scan it not an option. The product should be enclosed in a biocompatible material, such that the body does not reject the implant. The external portion should be enclosed to cover all circuitry.

k. *Aesthetics, Appearance, and Finish*:

The internal transmitter of the device currently has no preferences of appearance of color. The external receiving device should be covered to enclose circuitry.

2. Production Characteristics

a. *Quantity*

One prototype. Hydrocephalus prevalence- 1-1.5% of population (6.46 per 10,000 births, approx 1 in 105,263 or 0.00% or 2,584 people in USA)

b. *Target Product Cost:*

The product should be under $3,000.00 market value and have a production cost of less then $1,000.00.

3. Miscellaneous

a. *Standards and Specifications:*

FDA approval is needed before the device can be used on patients.

b. *Customer*:
Used in conjunction with patients who have shunts.

c. Patient –related concerns:
The device needs to be sterile and completely inside the head so there is no risk for infection. The power supply must be stored in a safe place, most likely at home. The internal portion should be able to withstand forces that are applied to the head. The lifespan should be greater than 20 year in order to prevent additional surgeries.

d. Competition:
Radionics makes a device that has a solenoid that moves with pressure changes. Medtronic also makes an Insite Monitor that is more accurate and capable of recording trends but was very expensive. It also requires a large battery that has to be implanted to chest and has finite power supply