ICP Monitor

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Function

The device should be implanted into the frontal section of a patient's brain to monitor the intracranial fluid pressure (ICP) in order to troubleshoot problems with failed shunts. Patients presenting with headache, nausea and various other symptoms need to be able to use the device to test their ICP. The device should also output data to be interpreted by trained professional to diagnose shunt failure or abnormalities in the ICP.

Client requirements

- transcutaneous pressure to be measured outside lumen
- non invasive
- produce logical output
- telemetry unit so data can be interpreted from their homes
- Small
- User friendly
- MRI compatible
- Low power need
- Use available technology

Design requirements

1. **Physical and Operational Characteristics**

a. *Performance requirements*: It needs to measure changes in pressure, it is going to measure those changes and the direct reading is going to be read in differences in voltage but it needs to be output in pressure (mmHg). The output should be displayed graphically to be interpreted by the physician. The pressure should be able to be measured continuously

b. *Safety*: Since it's implanted into the brain, it needs to be biocompatible. To be MRI compatible it needs to be durable to large voltages and currents (120V?) caused by the MRI it also needs to be made of non-ferrous materials. Our goal is to use 100 to 120 mA and 10 to 15 V to power the implantable device in order to not interfere with brain function. It should have encased electrical components to avoid electrical shock to the patient. It should not produce an excess of heat relative to internal body temperature 98.6 degrees.

c. *Accuracy and Reliability:* The normal ICP is about 15 mmHg so it needs to measure pressures in this range. It should be able to interpret measurements on the range of -10 to 50 mmHg. It should be accurate to 1 mmHg. Repeated measurements in quick succession (5 minutes) should produce consistent results.

d. *Life in Service*: Since it will require surgery to implant the pressure sensor, this part of the device should have a long life span (~2 years). The external device does not need to be as durable since external batteries are more easily replaced. It needs to have low drift (less than 1% degrading of accuracy per year).
e. *Shelf Life*: The external power source's batteries should last through at least 50 uses.
f. *Operating Environment:* The implantable device will be exposed to brain fluid and elements the brain is exposed to including magnetism and radiation. The external part will be used in a home environment and possible subject to patient abuse and household villains like dust and mold.
g. *Ergonomics:* Holding onto the device should be comfortable.
h. *Size:* The internal device should be minimized to be non-invasive (1 cc max). The external device needs to be small enough to hold in one hand (the size of a grapefruit.)
i. *Weight:* The external device should be light enough to hold over your head for a few minutes with one hand (1 lb or less).
j. *Materials:* It could be exposed to an MRI so no ferrous materials. Other than that, bio-friendly materials are required.
k. *Aesthetics, Appearance, and Finish*: The internal device needs to be finished in a way to avoid deterioration being exposed to the body's internal environment.
2. **Production Characteristics**
a. *Quantity:* Initially one working prototype, eventually enough to accommodate population of patients with cerebrospinal fluid shunts.
b. *Target Product Cost:* manufacturing cost under $300, eventual patient about $3000 or covered by insurance.
3. **Miscellaneous**
a. *Standards and Specifications*: FDA approval
b. *Patient-related concerns*: sterile, stored at home
c. *Competition*: Medtronic InSync Sentry CRT-D Device has similar application for intrathoracic fluid with OptiVol fluid status monitoring.