

Product Design Specification

Centrifugal Pump Design for Neuroendoscopy

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Function

The centrifugal pump design for neuroendoscopy will provide a continuous (non-peristaltic) flow of saline to the surgical field to visualize and navigate throughout the brain. Because the pump was originally designed for cardiac surgery, it will be modified to include circuitry that will attenuate the maximum allowable saline flow and create a negative feedback system to control the saline flow when instruments are inserted and removed from the endoscope during the procedure.

Client Requirements

- An operational circuit for the pump within the next three months
- An optimized design within the next 8 months
- Intellectual property security measures and initiation
- Frequent communication in terms of our progress to date

Design Requirements

- Physical and Operational Characteristics

a) *Performance requirements*

The circuit must utilize the 120 VAC, 50-60 Hz, and 3 A power that is supplied to the Medtronic Bio-Pump and Bio-Console. A transistor is available to convert the supply to 5 VDC. The circuit must process a micro- to millivolt signal from the Bio-Pump while tolerating at least 9 V from the Bio-Console. Neuroendoscopic operations range in duration from 30 minutes to over 2 hours, requiring that the circuit be able to perform in excess of 4 hours per use and in multiple operations per day.

b) *Safety*

The circuit must be enclosed within the Bio-Console to eliminate the risk of electrical shock for patients and medical staff. The saline solution in the Bio-Pump must remain isolated from the electrical hardware, and the voltage utilized by the system should be no more than 10 volts so as not to present unnecessary risk.

Additionally, it is important that fluid flow be regulated well below a rate that may be harmful to the brain. Although the system prevents buildup of pressure on the brain, the flow rate must not exceed 150 mL/min, as this is the maximum irrigation rate necessary during the procedure. Rates that exceed 150 mL/min may induce damage to the internal

structures of the brain. An electrical switch or component could be incorporated within the design to act as a safety in the unlikely occurrence of an elevated flow rate.

c) *Accuracy and reliability*

The fluid flow rate control must provide fine resolution limited within a range of 0 to 600 rpm, which is equivalent to a flow rate of 0-150 mL/min and voltage range of 0-1.2903 V. Each was determined to be reliable based on the standard and relative deviations of 0.047V and 0.054 for V_c , 0.002 V and 0.324 for V_s , and 0.019 mL/min and 0.103 for flow rate. The signals were linearly related to Bio-Pump speed based on the R^2 values of 0.9999, 0.9978, and 0.9976, respectively.

d) *Life in service*

The system will be transported by cart within the hospital and must be resistant to small fluctuations in environmental conditions while in use.

e) *Shelf life*

The circuit will be housed adjacent to existing circuitry within the Bio-Console. Humidity and temperature of the laboratory and operating room will not be detrimental to the device operation or shelf life.

f) *Operating Environment*

As a component within the centrifugal pump system, the negative feedback circuitry will be subjected to the conditions of the operating room and surrounding vicinity of the hospital. As a consequence, the normal temperatures at which the device will be operating are lower than room temperature, on the order of 18.9 degrees Celsius and below. During usage, the exterior of the device may be subjected to fluid spatter, potentially from the saline being irrigated by the endoscope through the brain as well as blood or other bodily fluids from the remainder of the surgical procedure. Thus, the device should be designed with an exterior to encase all circuitry and working parts to allow for easy sterilization.

g) *Ergonomics*

In terms of ergonomics, the surgeon or operator will not directly handle the portion of the device to be designed. Thus, the device to be designed should not hinder or prevent usage of any of the measures designed within the endoscope to ensure the safety and health of the operator. Additionally, the device must be designed so that it can be implemented in a manner that is conducive to the safety of the user. For instance, the length of the tubing emerging from the pump must allow the surgeon to perform the surgical procedure with the capability to freely move the instrument to any orientation.

h) *Size*

For the most professional presentation of the device, the circuitry elements and components of the design should fit within a 5"x2.5"x2.5" exterior container that can be either attached or incorporated within the Medtronic Bio-Pump console.

i) *Weight*

The weight of the designed device will not be of great importance to the functionality and safety.

j) *Materials*

As the device will be utilized near an open body cavity during a surgical procedure, the exterior materials must be easily sterilized. Thus, they must be able to withstand repeated treatment with chemical cleaning sprays without degradation. Also, as the device will be used within the operating room setting, the materials utilized in the design should not be significantly magnetic so as not to interfere with any of the other devices being operated simultaneously.

k) *Aesthetic, Appearance, Finish*

The circuit component of this design will be mounted within a Medtronic Bio-console® System, therefore the device will not be visible to a user of the brain irrigation system. The device also needs to be compact, and it cannot have components that interfere with the electrical signals of the circuit design.

- Production Characteristics

a) *Quantity*

By the end of the semester we will have one functioning prototype to be integrated with our client's Bio-console®, Bio-pump® and flow sensor. We believe this product has market potential.

b) *Target Product Cost*

This design primarily consists of circuit elements (resistors, operational amplifiers, potentiometers, and connecting wires) that will modify the Medtronic Bio-Console® System. These components are projected to cost about \$25. In order to manufacture the product we will also need to purchase several bread boards (\$24).

- Miscellaneous

a) *Standards and Specifications*

FDA approval of this class III medical device would be required, as the material is intended to support life and failure could be life threatening. As a medical device, the material must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA.

b) *Customer*

Ease of use is required so that health professionals may effectively use the material. Ideally, the user will not have to interact with the device as it is within the Bio-Console® System.

c) *Patient-Related Concerns*

The circuitry of the centrifugal pump to be designed will be encased within the Bio-Console® System, and therefore has no immediate threat to the patient. All other parts of the centrifugal pump system will not be modified and will be used under the direction of the surgeon.

d) *Competition*

The current technology used for saline flow during neuroendoscopy is a pressurized saline bag that must be replaced several times during the procedure. Our client discovered the centrifugal pump to be modified for this application within the hospital; it is a Medtronic Bio-Pump used for cardiac surgery. Currently, there is no centrifugal pump device currently used for neuroendoscopy and would be the first of its kind.