Project Objective

The objective of this project is to design and build a prototype that can reliably preserve and monitor a donor organ during transportation to the transplantation site, while serving as a platform for electrical, mechanical, and biomedical engineering education collaboration. The device must be able to perform a number of tasks, critical to the overall quality of the donor organ. These tasks include temperature monitoring and control, hypothermic perfusion of the organ, pressure monitoring, flow rate control, and global tracking capabilities.

Background

Research has shown that today there are approximately 120,000 people waiting for an organ transplant of some kind. However, only 28,000 transplants are performed in the US every year. Increasing the lifespan of organs for transplantation is key due to the continual lack of available organs.

A number of mobile preservation devices exist in clinical testing today. The LilePort Kidney Transporter is a specialized device that preserves kidney’s by hypothermic perfusion. The TransMedic Organ Care System is a warm perfusion device that preserves the heart, and in the future the lungs, during transportation. These devices are far superior to a cold static preservation solution, but are extremely costly and can only facilitate a specific organ.

The experimental design that is being implemented aims to have lower cost than current available models, be modular to facilitate transporting a variety of organs, and be able to efficiently monitor and control the organ environment. Maintaining a sanitary system is also imperative to the overall quality of the donor organ. The modules of the device have been tested individually and are currently being integrated into the final assembly.

Design Requirements

Using SolidWorks, the Tranplantation Donor Organ Preservation System (TDOPS) original concept design was modeled. This design features multiple modules including the control module, perfusion module, and containment module. Within the control module is the Raspberry Pi microcontroller which controls the whole system. The perfusion module features a peristaltic pump chosen primarily for sanitation reasons. The containment module is complex and features an organ specific interchangeable sleeve. The peristaltic pump perfuses the organ with UW solution and uses a heat exchanger to cool down the solution to the desired 4 degrees Celsius.

Figure 1: Expanded SolidWorks Model  Figure 2: Condensed SolidWorks Model

Containment Module of Donor Organ

The heat exchanger is designed such that the tube which UW solution flows through, sits in an ice reservoir consisting of a 50:50 ice and water mixture. Since an ice-water mixture is used for cooling, it is critical that the containment module is heavily insulated. The TDOPS system uses vacuum sealed walls as insulation resulting in an R-value of approximately 15, which is approximately three times greater than Styrofoam. Due to the vacuum pressured walls, the prototype was designed to be cylindrical to help disperse the negative pressure and prevent the walls from caving in. The organ specific sleeve rests on top of the ice reservoir and contains the organ which is submerged in the UW bath. All of these components are internal to the vacuum sealed walls of the organ module.

Hypothermic Organ Perfusion Module

In order to prevent unnecessary cellular death, and preserve the organ within the system for as long as possible, the organ must be preserved with a perfusion fluid created by the University of Wisconsin. In order to do this a peristaltic pump is used to draw water from the preservation fluid bath, in which the organ is submerged. The fluid then runs through the pump and either returns to the main artery of the organ, or passes through the heat exchanger before returning to the organ. The flow rate of perfusion is adjustable, up to 1000mL/min. This figure was established by the actual graph (Graph 1) shows the R-value and thermal conductivity based on vacuum pressure. The prototype is constructed out of schedule 40 PVC tubing and flat stock along with two part epoxy to ensure a complete vacuum seal.

Graph 1: Pressure vs Thermal Conductivity  Figure 3: Container during perfusion

Automated Control Module

At the core of the system is a Raspberry Pi Model B microcontroller shown below in Figure 4. The Raspberry Pi was selected for this design due to the convenience it provided. There was already one available to the team, and it accommodates all of the system’s needs.

The microcontroller pulls temperature data from five DS18B20 temperature sensors, which are used to determine whether or not the UW Solution should flow through the heat exchanger. The temperature sensors utilize 1-Wire technology which allows them to be connected in parallel. This allows for any practical number of sensors to be connected through only one pin of the microcontroller, which adds a great deal of flexibility to the system.

Figure 4: System Controller  Figure 5: Information Display

The Raspberry Pi is able to output a pulse-width modulation (PWM) signal to the servo which controls the fluid redirecting valve, thereby maintaining the appropriate temperature for the organ. The Raspberry Pi also uses PWM to control the peristaltic pump. The speed of the pump is determined by the program once the user indicates at startup which organ is in the device. This input comes from a keypad located on a small LCD screen, shown in Figure 6 below, which prompts the user to select the appropriate system.

The system also features GPS tracking capabilities. This is critical to the overall operation of the system, due to the fact that the transplantation team must be able to adequately prepare for the arrival of the organ. The GPS tracking system is currently being tested and optimized in order to provide the most accurate data possible.

Thermal Control

The temperature in the system must be precisely controlled in order to ensure the organ undergoes as little thermal stress as possible and it can be kept for extended periods of time. In order to do this a heat exchanger made of flexible PVC tubing was devised and submerged in the ice bath. The tubing is wrapped on a scaffold in order to keep it uniform throughout the ice bath. Research shows that the ideal temperature for organ preservation is above freezing, creating the need for a heat exchanger bypass. This prevents the temperature from dropping too low due to continuous flow of preservation fluid through the ice bath heat exchanger. Ordinary solenoids and pinch valves consume far too much power to be used as a bypass in this system. A new pinch valve was created by the team that uses a ratcheting system to hold the rotating paddle in place allowing the servo motor turning this flipper to power off once in place. The motor then powers back on when the flow to or around the heat exchanger needs to be changed as determined by the control system.

Discussion

The system was tested to ensure that it can bring the organ bath down to the set temperature in the system. Graph 2 demonstrates the system pumping fluid through the heat exchanger, while the system monitors the temperature in the organ, in the ice bath and the external environmental temperature. The system then would bypass the heat exchanger and continue to perfuse the organ until further cooling is needed. Graph 3 (TBA) shows the temperature of the ice bath over an extended period of time. This ensures the system will be able to maintain a hypothermic organ over 24 hours, as long as it is clinically feasible.

Future Work and Design Improvements

In order to improve the design, appropriate temperatures, pressures, and flow rates could be transmitted with the GPS location, in order to provide surgical teams with more information about the status of the organ as it approaches the receiving patient. Modular power packs would allow the user to swap out batteries as they needed on an extended trip. A means of adding ice without opening the seal on the organ could be incorporated to allow for additional ice to be added by the user in the event of an emergency when the volume of ice was decreasing too quickly.

Conclusion

This system is the product of a capstone, undergraduate research and design project. The interdisciplinary teams to this project underwent challenges and furthered the team’s understanding of electrical, mechanical, and biomedical engineering design methods. Once the testing phase is completed the appropriate changes are implemented, the system will be able to preserve a donor organ more effectively and efficiently, until arrival at the transplantation site, than current portable models.