An Alternative Scaled-Down Surgical Heat Exchanger for use in Cardiopulmonary Bypass Instruments

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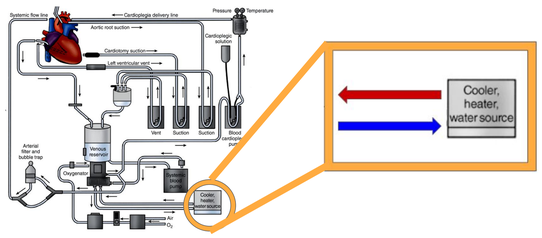
Introduction

A **Cardiopulmonary Bypass** mimics the **function of the heart**, including **maintaining the temperature** of the blood as it is passed back into the patient[1].



Above: A cardiopulmonary bypass machine with the heater-cooler unit highlighted. **Heater-Cooler Units** are the specific instrument that **maintains** the **blood's temperature**.

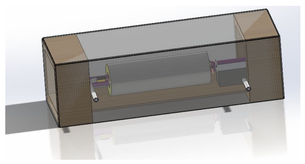
Background

Three Fundamental issues exist within **Heater-Cooler Units** in hospitals.

Size	Current Heat Exchangers are about **16 ft^3**, making them **too obstructive** in the **operating room**.
Bacterial Infection	A Hot/Cold **water reservoir** allows for **bacterial growth**. **Bubble formation** and **aerosolization** allows for **bacterial proliferation**.
Poor Design	**Perfusionists** find several **ergonomic issues** with current CPB machines and **heater-cooler units**.[2]

Proposed Solution

Our solution proposes **improving the HCU** by **scaling down** a typical HCU, as well as **eliminating** the need for a **water reservoir**.



The design **focus** is primarily on the **decreasing size** and of **Bacterial Infection**.

Left: A CAD model of the proposed design.

Methodology

Design Considerations

Size
Pipe Geometry
Heating Elements
Pump Selection

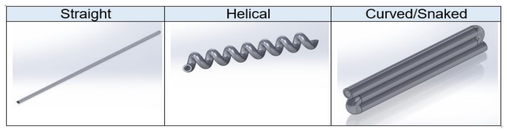
Bacterial Infection
Material Selection for Antimicrobial properties
Removing Water Reservoir
Disinfectants

Above: The table lists factors that were examined to help solve issues in both size and bacterial infection.

Simulations

ANSYS Fluent was used to **simulate** and **predict** the **optimal geometry** in piping. **Three** different variations were examined.

1. Pipe Shape
2. Pipe Length
3. Number of Tubes



Above: Different geometries of pipe evaluated.

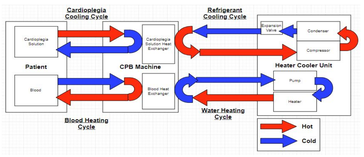
Pump selection was found through examining simulations for **pressure differentials**.

Manufacturing

Various **pipe bending** techniques were tested to produce the desired **coiled pipe geometry**.

Electrical controls utilized **Arduino** microcontrollers and were designed for **temperature regulation** and **user interface**.

Cooling Circuit



Left: A theoretical cooling circuit was designed for future manufacturing and testing.

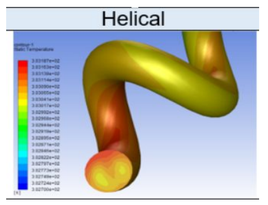
Patentability and Regulatory Analysis

- An extensive patent search and search of current US Clinical trials yields no device similar to ours suggesting our idea to be unique and patentable
- HCU is classified by the FDA as a Class II medical device[3,4]
- Though our HCU is novel, it is likely sufficiently similar to current HCU's to be considered for a Premarket Notification 510(k) clearance pathway

Results

Size

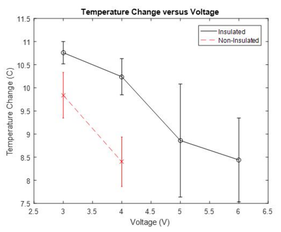
The size of the HCU was **reduced to 2.4 ft^3**, a reduction by a **factor of 7**.



Helical pipes found optimal for **heating**. They:

- **Increased heat transfer** compared to other shapes
- **Decreased length of tube** required for desired heating leading to smaller size

Functionality



Water was found to have a **desirable change** in temperature of 10.7°C at its lowest flow rate.

Temperature change of the water in the heater **varied with voltage** and, thus, **flow rate**

Economic Impact

The estimated cost for our heater-cooler unit design is around **$5,048**, which is **similar if not less** than what was found for current models

Acknowledgements

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