Product design from PRS to Prototype using Comsol Multiphysics

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Introduction

Dialysis acts as an artificial kidney. Dialysis patients receive hemodialysis, in which the blood is circulated outside the body and cleaned inside a machine before returning to the patient.

Blood flows into the dialysis machine to be cleaned. The machine has two parts, one side for blood and one for a fluid called dialysate. A thin, semipermeable membrane separates the two parts. As dialysate passes on one side of the membrane, and blood on the other, particles of waste from the blood pass through microscopic holes in the membrane and are washed away in the dialysate. Blood cells are too large to go through the membrane and are returned to the body. [1]

Blood Warmer

Blood Warmer is an accessory in dialysis machine intended to deliver the blood or fluids before to transfusion to a human body at 37°C which is the set temperature. Malfunctioning of the blood warmer device could lead to hypothermia. The blood warmer heats the blood to the desired temperature (37°C) that is nontoxic for infusion.

American standard defines ASTM F2172–02 titled as "Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers". The purpose of these specifications is to originate necessary quality conformance requirements for blood warmers devices. The standard actually decreases or eliminates risks of damages to subject and also the medical service provider and to stipulate testing by which fulfillment of requirements can be authenticated.

The resistance heating technology which has a silicone heater patch and aluminum plates between which the fluid tubing passes was selected based on the thermal efficiency results. In designing the heating plate in the blood warmer, the data needed are type of plate material, plate dimensions, the effective area of the heating plate, the upper and the lower temperature limits the heating plate, and the discharge of blood flow. [2]

Though current blood warmers can heat blood to the human body blood temperature, the challenges are Temperature management, heat mapping across plate, optimum sensor location and the determination of the right compensation factor for dynamic control algorithm. This study was performed to improve the performance and functional aspects of the blood warmer design.

The device manufacturer supplied the complete list of product requirement specifications which had all the details of constraints, functionalities and geometric details. The design and development of blood warmer subassembly involved a multi-disciplinary team which consisted of simulation, software, hardware, CAD, Electrical, testing, Industrial design and materials engineers.

However in this paper only the electro-thermo-fluid interaction of the multiphysics simulations are discussed. The multiphysics simulation procedure and the results are discussed.

Simulation procedure

The multiphysics simulations were performed to determine the power input required for 8 different flow rates to reach a desired set temperature of 37.6 °C from the inlet temperature of 30 °C. The range of flow rates used in the simulation are 100,150,200,250,300,350,400 and 450 ml/min. By varying the power input applied on the heating coils of heater plates, the power required to achieve the desired set temperature was determined. A convective heat transfer coefficient of 10W/m^2.K was assumed considering that the heating unit is placed in an enclosure. The operating fluid was assumed as water instead of blood to avoid the non linearities. Humidity effects were not considered in the simulation.

The voltage difference was applied on the coil path of the top plate and the bottom plate (to generate joule heating in the plates). A Perfect thermal contact was assumed between the disposable and heater plates.

The blood warmer assembly used in the dialysis machine consists of four components, the fluid domain, blood flow path, the heater coil and the two aluminum heater plates. The material properties of the different components used in the simulations are as listed in table 1.

Table 1 Material properties used

Component /Material	Property	Values	Unit
Fluid/Water	Specific heat	4181.8	J/kg*K
	Density	1000	Kg/m^3
	Dynamic viscosity	1.002	Pa-s x 10-3
	Kinematic viscosity	1.004	(m2/s) x 10-6
	Thermal conductivity	0.58	W/(m.K)
Blood flow path/ Polyethylene	Specific heat	1800	J/kg*K
	Density	1500	Kg/m^3
	Thermal conductivity	0.209	W/(m.K)
Heater plate/ Aluminum	Specific heat	956	J/kg*K
	Density	2699	Kg/m^3
	Thermal conductivity	165	W/(m.K)

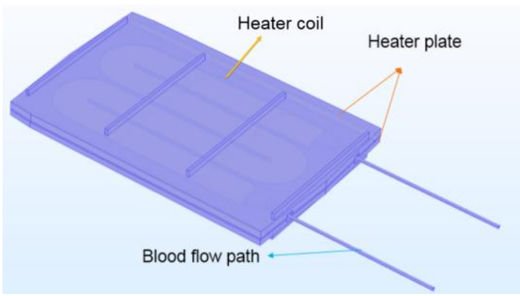

Figure 1 Blood warmer assembly

Simulation results

The power required for the flow rates 100, 150, 200, 250, 300, 350, 400, 450 (ml/min) are 60, 89,118,148,177,206,234,264 (Watts) respectively as listed in the table 2.

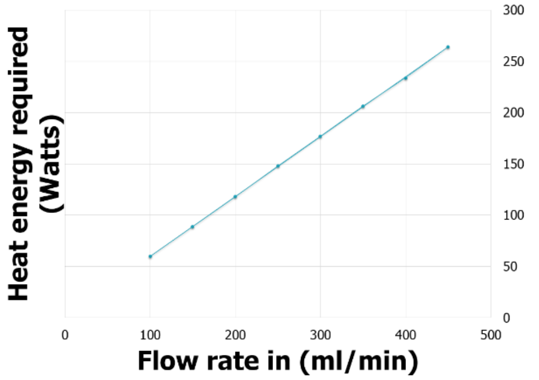

Figure 2 The relationship between Heat energy and flow rate

Table 2 Heat energy required vs Mass flow rate

Sl. No.	Mass Flow rate (ml/min)	Heat energy required(W)
1	100	60
2	150	89
3	200	118
4	250	148
5	300	177
6	350	206
7	400	234
8	450	264

There is a linear directly proportional relationship between the mass flow rate and heat energy required as depicted in the figure 2. The spatial thermal distribution of the blood flow path is depicted in the figure 3.The temperature of the fluid increases along the blood flow passage.

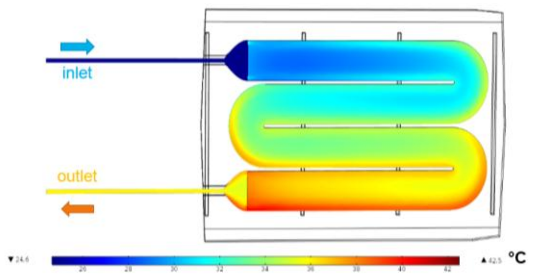

Figure 3 Temperature distribution along the blood flow passage

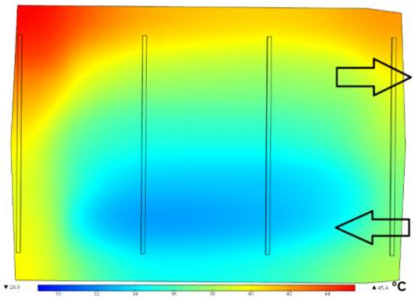

Figure 4 Temperature distribution in the heater plate

The temperature distribution is higher in the exit region of the blood warmer and lower at the entry region of the blood warmer. The spatial thermal variations on the heater plate is depicted in figure 4.

Conclusion

Based on the simulation results, the heat energy required at different flow rates to heat the blood to 37°C was obtained. This information was useful for the further developments in the product design cycle.
There is a linear relationship between the flow rate and heat energy required.
The temperature gradient is observed across flow passage as it gets heated up.
The correlation between testing and multiphysics simulation results was good. The multiphysics simulations results were used for creating the control algorithms softwares.
The product development process has been shortened in the concept and prototyping phase by effectively using multiphysics simulations.
The reports generated by using COMSOL multiphysics simulations were used as supporting documents for regulatory purposes.

References

1. **Book** [1] Living Day to Day with Kidney Dialysis: Quality Improvements Continue for Devices and Clinics

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3. **Website:** https://www.zazzle.co.uk/diagram_of_a_haemodialysis_medical_treatment_poster-228847818138128382