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14. ABSTRACT Many patients become hypothermic after severe injury due to environmental exposure during transport. These patients also have decreased thermoregulation due to blood loss. Normal core body temperature is defined as 37°C and core body temperature below 35°C and above 40°C is defined as hypothermia and hyperthermia respectively. Studies have shown much better outcomes for patients with either trauma or hypothermia compared to patients with both trauma and hypothermia. Additionally, studies have shown that decreasing the hyperthermic patient's core body temperature rapidly to 38°C lowers the incidence of complications and the risk of death. Currently, one of the most effective treatments for dysthermic patients involves the use of active convective/conductive heating/cooling devices. However, current devices require heavy or bulky equipment not suitable for military applications. This study focuses on developing a portable battery operated body temperature conditioning system. The heating/cooling system has been designed to maximize efficiency allowing for a reduction in component and battery weight. Additionally, rechargeable lithium-ion batteries are being utilized to allow for military use during medical evacuations in the absence of a reliable power source. To evaluate the heating/cooling capacity of the device, patient simulation testing will be performed through the use of a thermal manikin. This research will identify specific design improvements to be implemented in a reiterative process, ultimately leading to an efficient portable body temperature conditioning device suitable for military applications.

15. SUBJECT TERMS
Hypothermia, Circulating Water-blanket, Trauma, Hyperthermia, Military, Thermal Manikin

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Portable Body Temperature Conditioner

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INTRODUCTION:

Many patients become hypothermic after severe injury due to environmental exposure during transport and decreased ability of thermoregulation due to blood loss. Normal core body temperature is defined at 37°C and hypothermia occurs at a core body temperature below 35°C. Studies have shown much better outcomes for patients with either trauma or hypothermia compared to patients with both trauma and hypothermia [1-6]. Additionally, hyperthermia occurs at core body temperatures above 40°C. Hyperthermia can progress quickly and occurs as the result of excessive heat exposure or strenuous physical activity in hot environmental conditions. Studies have shown that lowering the patient's core body temperature rapidly to 38°C improves complications and lowers the risk of death [7-8]. Currently, one of the most effective treatments for hypo-hyperthermia patients involves the use of active convective/conductive heating/cooling devices [1,3-8]. However, these methods require heavy or bulky equipment and are not practical for military applications in the field. The evidence for active heating/cooling treatments for trauma patients prompted this study to develop a portable battery operated body temperature conditioning device for military use under extreme thermal conditions. This portable device will promote normothermic conditions in injured or ill patients during medical evacuation. The body warmer consists of two elements: the heating/cooling module and a full body water circulating blanket. The circulating water blanket is composed of multiple layers including a heat exchanger with circulating passageways, insulation, and a contact surface allowing direct surface contact with the patient's body. The heating/cooling module comprises an ultra-high efficiency vapor compression cooler/heat pump with advanced viable speed drive. The heating/cooling system also utilizes advanced refrigerant flow control for variable speed operation yielding maximum energy efficiency. By designing the heating/cooling system for maximum energy efficiency, smaller batteries are able to be used for equivalent operating periods while reducing the overall weight of the device. Additionally, the variable speed vapor compression system can be powered from either DC/AC power systems or operated via battery power. Rechargeable lithium-ion batteries will be used to minimize additional accessories. Overall, the heating/cooling module of the body warmer is designed to allow for controlled heating or cooling of a patient in an extremely efficient manner while minimizing battery weight. Additionally, upon completion of the prototype for the portable body temperature conditioner, patient simulation testing will be performed to measure the heating/cooling capacity of the device. A thermal manikin has been purchased to simulate various conditions as part of the patient simulation testing. Quality system regulation (QSR) is required for 510(k) submission and Food and Drug Administration (FDA) clearance of medical device. University of Nevada School of Medicine (UNSOM) department of Surgery Research Laboratory has begun to implement QSR Standard Operating Procedures (SOP's) which will be ongoing throughout the duration of the project.

KEYWORDS:

Hypothermia, Hyperthermia, Circulating Water-blanket, Trauma, Military, Thermal Mankin

OVERALL PROJECT SUMMARY:

Gantt Chart (Outlining current progress and current schedule of proposed project)
[Gantt chart. Green when task is completed. Light green for task that is on schedule and active. Yellow when it is delayed; a red line showing when it is to start and when anticipate it to be completed. Blue for task that is yet to start.]

Task	Y1Q1	Y1Q2	Y1Q3	Y1Q4	Y2Q1	Y2Q2	Y2Q3	Y2Q4	Y3Q1	Y3Q2	Y3Q3	Y3Q4	Status
1 Design of the System													**Completed**
2a Breadboard Fabrication													**Completed**
2b Breadboard Testing													**Completed**
3a Functional Testing													**Completed**
3b Performance Testing (Manual Control)													**On Schedule**
3c Control Logic & Testing													**Yet to Start**
3d Prototype Fabrication													**Yet to Start**
3e Modifications as necessary and retest													**Yet to Start**
4a Write test and validation methods													**On Schedule**
4b Receive/training on thermal manikin & software													**Completed**
4c Validation of thermal manikin													**On Schedule**
4d Patient Simulation Testing													**Yet to Start**

Administrative or Logistic Matters

In the Y1Q1 and Y1Q2 report, UNSOM attempts to hire a second bioengineer researcher were unsuccessful. In lieu of further attempts to hire a second technician, during the past year (Year 2) UNSOM began the process of hiring a bio-heat transfer engineering expert to help with the patient simulation testing. UNSOM had previously hired a FDA consultant to assist with quality systems regulation. In addition to the current FDA consultant, UNSOM also began the process of hiring a consultant with expertise in risk management and FDA project development planning.

During the Y2Q1 quarter, UNSOM began working on a budget revision, which included the hiring of a bio-heat transfer expert and an additional FDA consultant to assist with project plan development and risk management assessment. Input from the bio-heat transfer expert will be integral in developing the testing methods for the patient simulation testing. Also, the additional FDA consultant's expertise will help align the project with appropriate regulatory standards in preparation for 510(k) submission and future FDA clearance of the medical device. The revised budget was submitted for approval; however, additional clarification was required regarding effort increases due to technical adjustments in the patient simulation testing. Clarification of the technical adjustments was submitted by UNSOM during Y2Q2. Additionally, Rocky Research and UNSOM submitted a no-cost extension of one year to extend the project completion date to October 2014. The no-cost extension and budget revision have been approved by the Army, and the appropriate paperwork was started to begin the hiring process for the bio-heat transfer expert and additional FDA consultant. The no-cost extension has allowed the project to get back on schedule.

Summary of Work Performed by Rocky Research

The primary focus of Rocky Research during the first quarter of the reporting year was directed towards evaluating the performance of portable body temperature conditioner (PBTC) on Newton, the thermal manikin. Time was spent learning how to utilize the thermal manikin, along with its corresponding ThermDac software. A significant effort has been spent developing methods for effectively exploiting the manikin to gauge system capabilities. Several system modifications were implemented based on discoveries found during functional and performance assessments. A heat sink has been added to the compressor in order to mitigate concerns of overheating. Testing methods have been established for properly quantifying the cooling capacity of the PBTC. The procedure consists of monitoring the additional heat flux of each zone required to maintain a constant surface temperature. Then, by multiplying the additional heat flux of each zone with its corresponding area and summing the products, the total effective cooling capacity on the manikin can be ascertained. In evaluating the PBTC on the thermal manikin diminishing system performance was observed in comparison to initial bench top testing. The culprit was pinpointed to deterioration of thermal expansion valve (TXV) capabilities. A manual regulating valve was temporarily installed in replace of the TXV in order to evaluate a solution to the problem.

In the second quarter further effort were targeted towards performance testing and improvements of the PBTC. The TXV orifices on both the heating and cooling sides were modified to better modulate refrigerant flow into the evaporator at an optimal proportion to the evaporation rate of the refrigerant in the evaporator. A concern in regards to the control board utilized to drive the compressor was identified and a solution addressed. A heat sink has been designed and developed to mitigate concerns of overheating. Furthermore, Underwriters Laboratories (UL) approved boards were acquired from the manufacturer of the compressor that have been developed to resolve this known outstanding issue. Cooling and heating performance test matrices were established and implemented to evaluate the cooling and heating capacities under different ambient and operating conditions. A discrepancy in the required refrigerant charge between optimal performance of the heating and cooling cycles was identified. In order to accommodate the additional charge required for the heating cycle a separate refrigerant reservoir was designed and sized. A water reservoir was also sized and integrated into the PBTC breadboard for filling the blanket and plumbing of the system. The water reservoir was assimilated into the case design. Vibration dampers have been integrated into the design of the PBTC at the suction and discharge lines of the compressor to mitigate concerns of mechanical failure, an observed malfunction during performance testing of the appliance.

The prominent emphasis of Rocky Research during the third quarter was focused on constructing and evaluating performance and design enhancements required to maintain mechanical integrity over long-term operation of the PBTC. An accumulator was designed, assembled, and integrated into the system implementation in order to eliminate liquid refrigerant droplets from flooding the compressor. A reservoir required to accommodate the additional charge for the heating cycle was constructed then evaluated for effectiveness in both the heating and cooling cycles to ensure optimum performance for both operating modes at various ambient conditions. Previously sized vibration dampers were additionally acquired and installed on the system. The heat sink designed and implemented for temperature management of the compressor control board continued to be evaluated for effectiveness and long term operation of the compressor. System performance testing ensued with all additional components installed and operating simultaneously. Peak heating and cooling capacities were demonstrated for both operational modes with a single system charge. Since a solitary environmental chamber was available for system performance testing, allowable time for appliance evaluation in the environmental chamber had to be balanced with the efforts required for manikin validation and calibration.

The fourth quarter was directed towards control development, case finalization, and user interface design. The control logic diagram was constructed to identify the operating modes of the appliance. Furthermore, the boolean logic expressions were defined for each operating mode based on the decision tree hierarchy of the logic diagram. Safeties and system defaults were also identified and integrated into the control logic design. A keypad design has been developed based on the user inputs require to guide the user through properly selecting an operating mode. An LCD display has also been specified and acquired for the system. An actuator valve was identified, sized, and retrofit in order to automate the process of switching between heating and cooling modes. Temperature probes were identified, attained, and assimilated into the system design for monitoring patient body temperature. A flowmeter was sized and acquired to be utilized in the control scheme for optimal temperature maintenance by allowing the heat transfer rate to be monitored in and out of the system. Furthermore, the flow sensor will be exploited as a safety indicator to ensure the presence of fluid flow. The case was modified and updated to accommodate the additional components and specified keypad. Stability analysis has been implemented on the case to gauge how easily the appliance can tip over. Preliminary comprehensive performance testing of the previously designed test matrices was also completed in the fourth quarter.

Task 1: Design of the System (Months 1-6). Completed

Rocky Research has completed the overall design and the 3-D solid modeling and engineering drawings of the portable body temperature conditioner. UNSOM continues to work with an FDA consultant on implementing a Quality System Regulation (QSR). The QSR will be ongoing throughout the duration of the project and is required for 510(k) submission and FDA clearance of the medical device.

Implementing QSR

The following QSR Quality Assurance SOPs are in progress and in various stages of completion. An FDA consultant has been hired to assist with QSR compliance. During the previous quarter (Y2Q2), UNSOM began drafting the SOP's for the PQ testing procedures and fluidics calibration as part of periodic maintenance. UNSOM still requires input from the bio-heat transfer expert and the following SOP's are pending final review.

- "Procedure for thermal manikin performance qualification"– Describes the standard testing methods for performing and documenting the performance qualification of the thermal manikin. The procedure includes testing conditions to mimic a patient in a cold, neutral, and hot environment.

- "Procedure for thermal manikin fluidics calibration" – Describes the standard procedure for performing the fluidics calibration on the thermal manikin's sweating system. This is an integral part of routine maintenance for the thermal manikin to ensure consistent and repeatable results.

- "Newton thermal manikin use and maintenance" – Describes the general procedures for the use and maintenance of the thermal manikin "Newton".

Additionally, UNSOM has finalized two other SOPs. One of the SOPs pertains to the installation qualification (IQ) and operational qualification (OQ) as part of the thermal manikin validation. Another SOP is in regards to the integrity and security of data collected.

- "Equipment Validation Procedure" – Describes the procedure for developing and performing IQ/OQ equipment validation to ensure that the equipment is fit for the intended use. IQ is intended to ensure that the equipment is installed to meet manufactures specifications. The OQ is intended to ensure that the equipment meets the specifications of intended use.

- "Data Integrity" – Describes the procedure for developing and using passwords and backing up data to external hard drives to secure computerized data.

Task 2: Breadboard Design and Fabrication (Months 7 – 12). Completed

Rocky Research has completed testing to evaluate the performance of different components of the portable body temperature conditioner breadboard. Extensive analysis has been implemented to optimize component selection based on size and performance characteristics. Testing of designated components on the breadboard has identified essential components. The primary components evaluated included compressors, battery packs, power supplies, chargers, pumps, and fittings. Current prototype design has been based on the results found from the breadboard testing data. All testing analysis was performed using an open loop with a water bath simulating the load.

Task 3: Prototype Fabrication and Testing (Months 10 -36). In Progress

3a. Functional Testing

Functional testing was accomplished in an iterative process with performance testing in order to enhance the capacity, robustness, mechanical integrity, and operational longevity of the PBTC. In order to demonstrate the development process of the appliance system enhancements are reported in the order that they were implemented. All enhancements, modifications, and alterations required additional functional testing before performance testing could ensue. Functional testing reporting in this section consists of the initial testing required to get the system fully operational so that performance testing could ensue. Modifications and enhancements identified and implemented during performance testing of the appliance, requiring additional functional testing, are reported under performance testing results.

Functional testing of all system components was first manifested while cycling the unit in a cooling mode with a Cincinnati Sub-Zero (CSZ) adult sized Maxi-Therm® blanket measuring 60" L x 24" W on the thermal manikin, Newton. Ambient temperatures were controlled at approximately 20°C by implementing the test configuration in an environmental chamber. The Aspen compressor was maintained at a control voltage of 4.1 V, equating to a speed of 6,000 rpm. Such a speed is the maximum analyzed for the individual performance component testing of the compressor, and was therefore deemed appropriate for initial functional analysis while operating the PBTC on the thermal manikin. Furthermore, higher compressor speeds result in larger quantities of heat generation, allowing for long term operational durability of the compressor to be investigated. The following figure, figure 1, depicts the initial functional and performance testing configuration of the PBTC in the environmental chamber utilizing the thermal manikin.

Figure 1. Initial functional & performance testing configuration

While operating the PBTC for extended periods of time, on the thermal manikin, the compressor was found to consistently approach overheating conditions. The practical operating temperature limit for the Aspen compressor is 135°C before damage can occur. Functional testing of the unit revealed that the compressor was uncomfortably close to that sensible limit. Since for breadboard functional testing the prototype was not enclosed in a casing, concerns of overheating the compressor required being addressed. The following performance plot, figure 2, depicts the PBTC component temperatures as a function of time while testing the unit on the thermal manikin. The heat generation load from the manikin was that necessary to maintain a surface temperature of 35°C. The compressor, operating at a maximum speed of 6,000 rpm, is the top curve represented in blue.

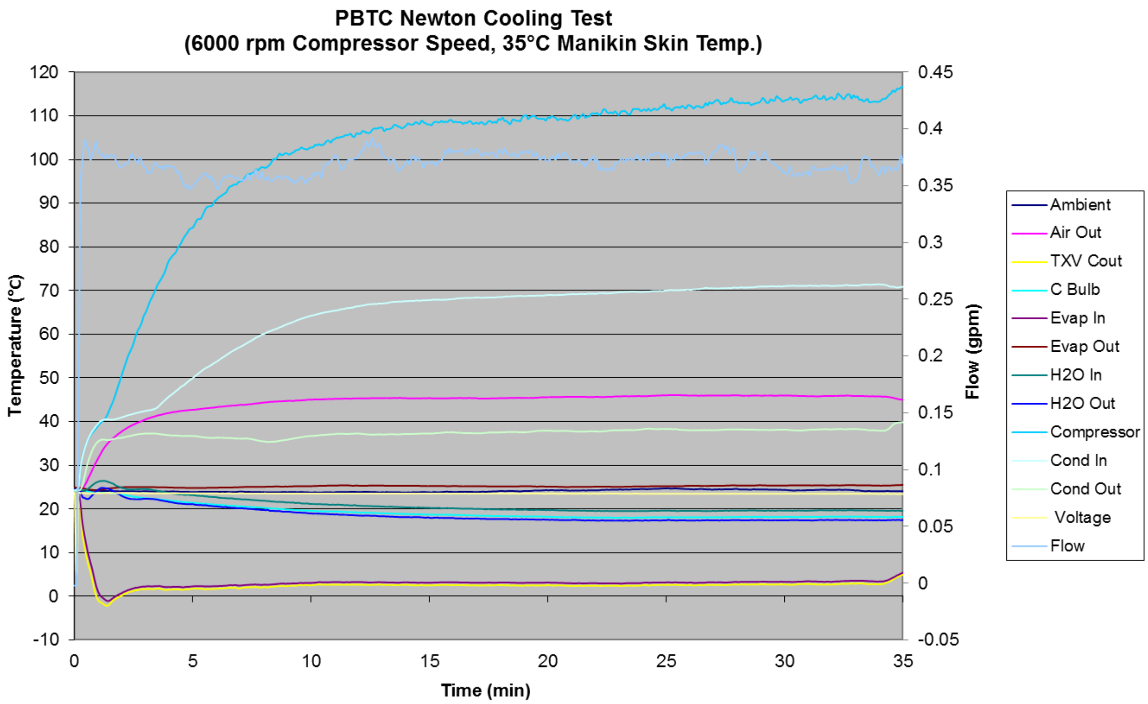

Figure 2. PBTC functional testing operating temperature characteristics

As can be observed, compressor temperatures exceeded 110 °C within 25 minutes of operation under the presented operating conditions. At such a temperature the performance of the compressor began to degrade, and the cooling capacity of the unit was limited. The overheating quandary was resolved by adding fins to the compressor in order to more effectively dissipate heat. Figure 3 presents a new layout of the prototype at the developmental stage in which the finned heat sink was added to the compressor. As can be observed, the finned compressor is still containable within the current PBTC casing design. It is essential that the fins on the compressor are exposed to adequate cross-sectional air flow in order for them to be effective. Resultantly, the case ventilation has been designed such that inlet airflow is drawn across the compressor. Furthermore, an additional 40mm fan has been added to aid in airflow across the fined heat sink of the compressor.

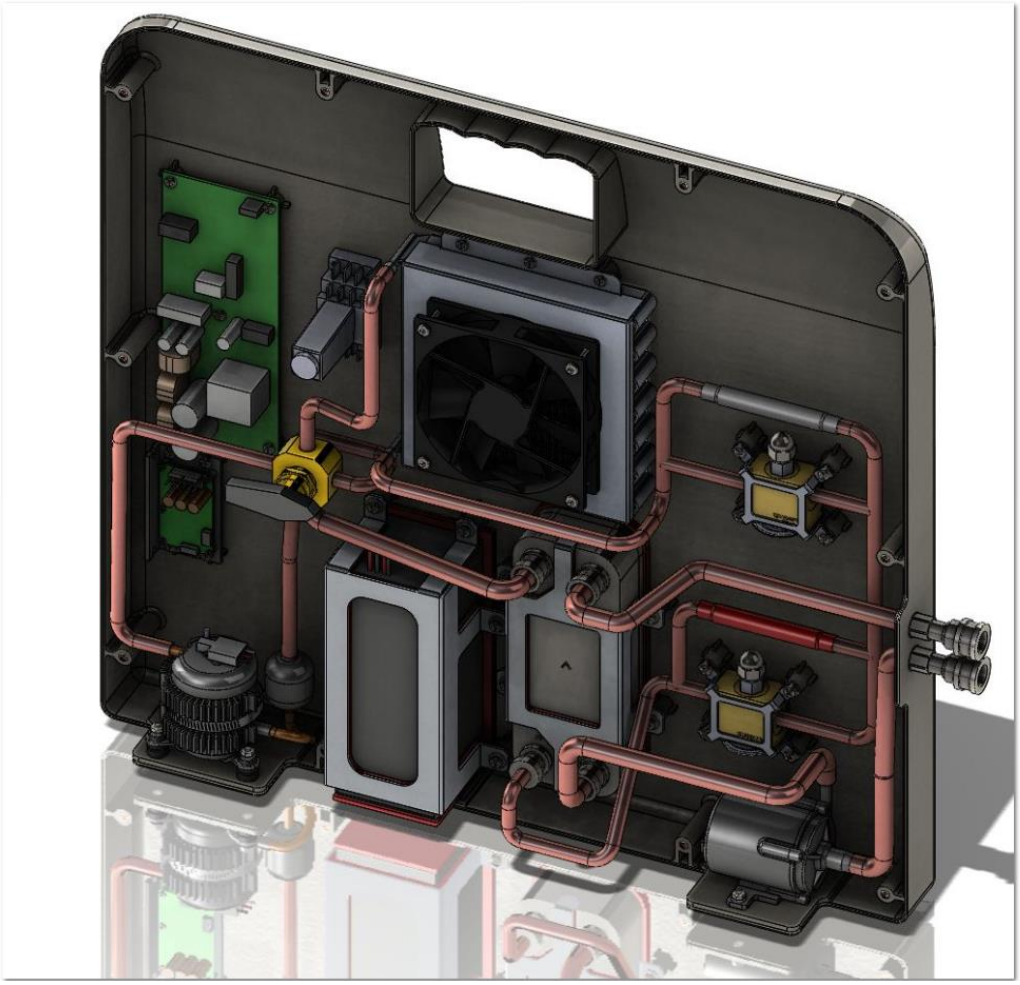

Figure 3. PBTC at developmental stage of adding heat sink to compressor

Functional testing of the pump on the breadboard prototype was also investigated before performance testing of the appliance initiated. The fluid volumetric flow rate vs. pump voltage was analyzed over the entire operating range of the pump. First, the pump was configured in-line with a bath in order to circulate water through the PBTC unit as well as the blanket. The blanket was oriented horizontally, on a flat lab bench at a similar height as the pump, in order to eliminate the restriction of flow and the effects of pressure head. A voltage of 24 V was then applied to the pump and decreased in 0.5 V increments every minute until the pump shut off. The testing approach allowed for a generalized curve of signal voltage vs. flow rate to be developed for the system in a typical operating configuration. The results from the test are presented in figure 4.

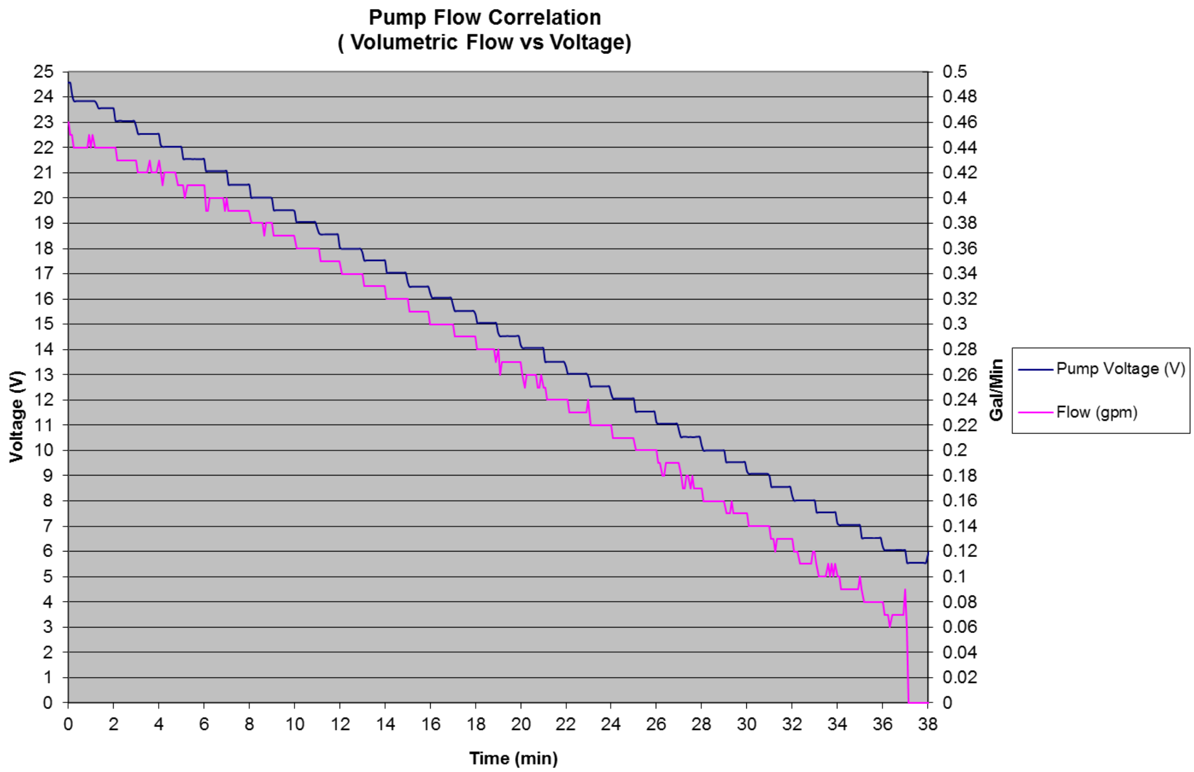

Figure 4. Pump voltage & volumetric flow comparison

As can be observed from the figure, the pump was able to maintain a volumetric flow rate of approximately 0.5 gpm at 24 V for the specified testing conditions. Furthermore, the pump voltage was reducible to 5.5 V before shutting down entirely. At this voltage a flow rate of 0.07 gpm was achieved. Flow analysis was then analyzed while operating the PBTC on the thermal manikin. It was immediately observed that the flow rate of 0.5 gpm was not attainable. Depending on how the blanket was positioned on the manikin, flow rates ranged from 0.28 gpm to 0.4 gpm. The process of forming the blanket to fit the contour of the manikin in order to allow for decent surface contact explains the additional flow restriction, and subsequent pressure drop. Consequently, the blanket was not entirely flat as in the case of the bench top testing. The loss of volumetric flow rate is not detrimental to system design as long as similar heating and cooling capacities can be obtained. Such analysis was further investigated and is presented under the performance testing results, section 3b.

3b. Performance Testing

Initial performance testing was also implemented utilizing the thermal manikin. Cooling capacity was first investigated utilizing a circulating bath in conjunction with the CSZ adult size Maxi-Therm® blanket. Bath temperatures were set to 30°C, 15°C, and 10°C respectively. In order to develop a testing procedure for quantifying the effective cooling capacity of the blanket, the additional heat input required by the manikin in maintaining a surface temperate at 35°C was monitored. The testing process was to first set a constant skin temperature for the manikin at 35°C in the environmental chamber held close to 20°C. The heat flux from each zone required to maintain the 35°C surface temperature was allowed to come to steady state. Once equilibrium was achieved the Maxi-Therm® blanket was then placed over the thermal manikin and the zone heat fluxes were again allowed to achieve steady state conditions. The blanket was centered on top of the manikin to allow good contact with the chest, hip, and leg regions. The blanket was not forced to make ideal contact with the manikin, nor was it insulated by an additional garment to mitigate heat transfer with the ambient environment. The motivation was to simulate performance of a user just placing the blanket on the patient and operating the unit. The bath was then turned on and allowed to circulate at approximately 0.5 gpm through the blanket at the specified temperature while the spike in individual zone heat flux was monitored until steady-state conditions were obtained. By multiplying the surface area of each zone by the additional heat flux, the cooling capacity of the blanket on the individual zones was calculated. As expected, the cooling capacity is minimal for the 30°C bath temperature and resultantly those results are not depicted. Presented in figure 5 is the additional heat input required by the manikin for each individual zone with an input temperature of 15°C from the bath.

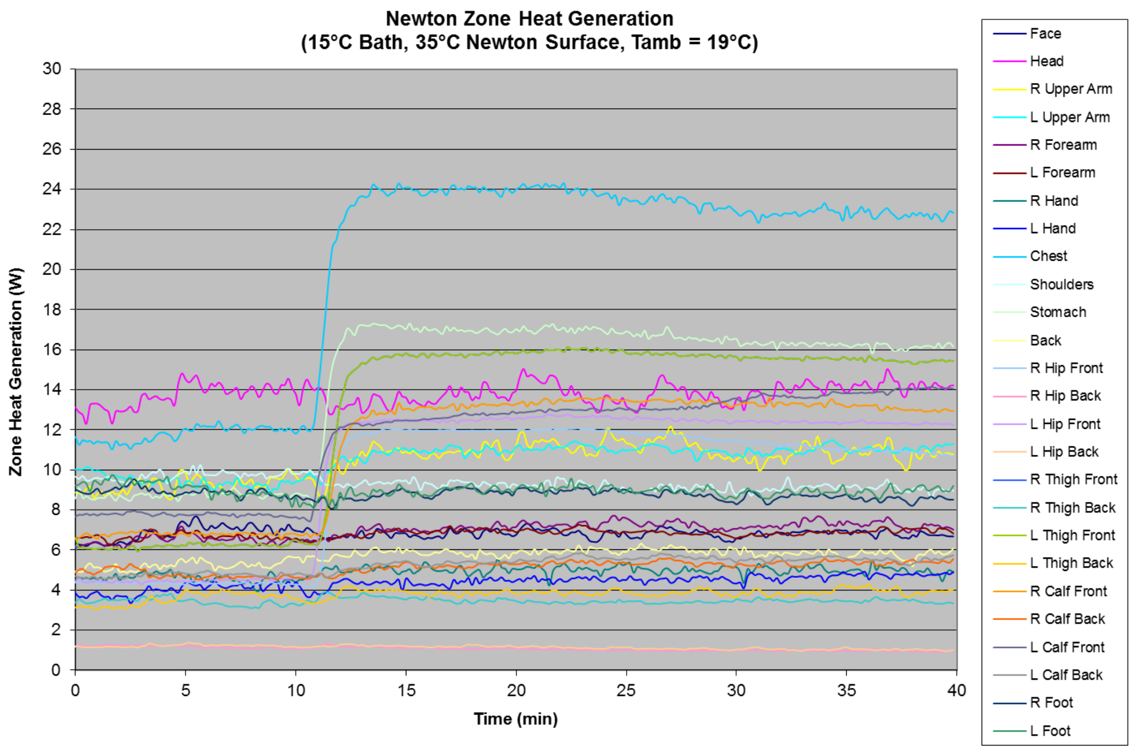

Figure 5. Individual zone heat generation rate (15°C bath)

The plot depicts which zones are most substantially impacted by the placement of the blanket. As can be observed, there is a significant increase in heat input from the chest, stomach, hip, and leg zones. Expectantly, there is no cooling provided by the blanket on the head, feet, hands, or back regions. In order to quantify the overall effective cooling capacity on the manikin the sum of the increase in each zone heat input was compiled. The heat removal rate, as measured by the total additional power required from each zone of the manikin, was analyzed against the heat transfer rate into the water of the blanket. Presented in the following figure are the results for the 15°C bath.

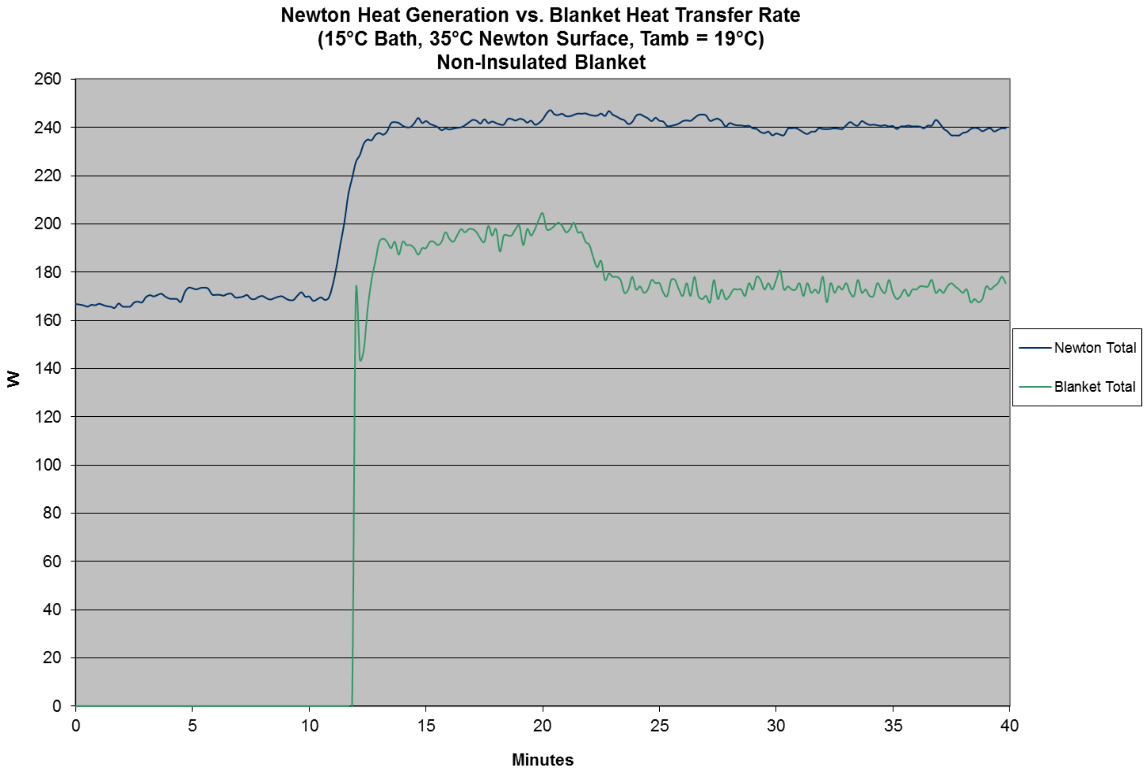

Figure 6. Accumulated increased heat generation & heat transfer rate (15°C bath)

As can be ascertained from the figure, a total increased heat generation rate of approximately 80 W is required for the manikin to maintain a surface temperature of 35°C for the given testing conditions. Consequently, from an energy balance analysis, the blanket is providing an effective cooling capacity of approximately 80 W. A total of approximately 160 W is being input into the water based on the mass flow rate and temperature change as the water circulates through the blanket. The water was at a temperature of about 15.5°C by the time it entered the blanket from the bath and in the range of 16°C and 17°C by the time it had completely traversed through the blanket. In figure 7 the accumulated results are also presented for the 10°C blanket inlet temperature, as provided by the bath.

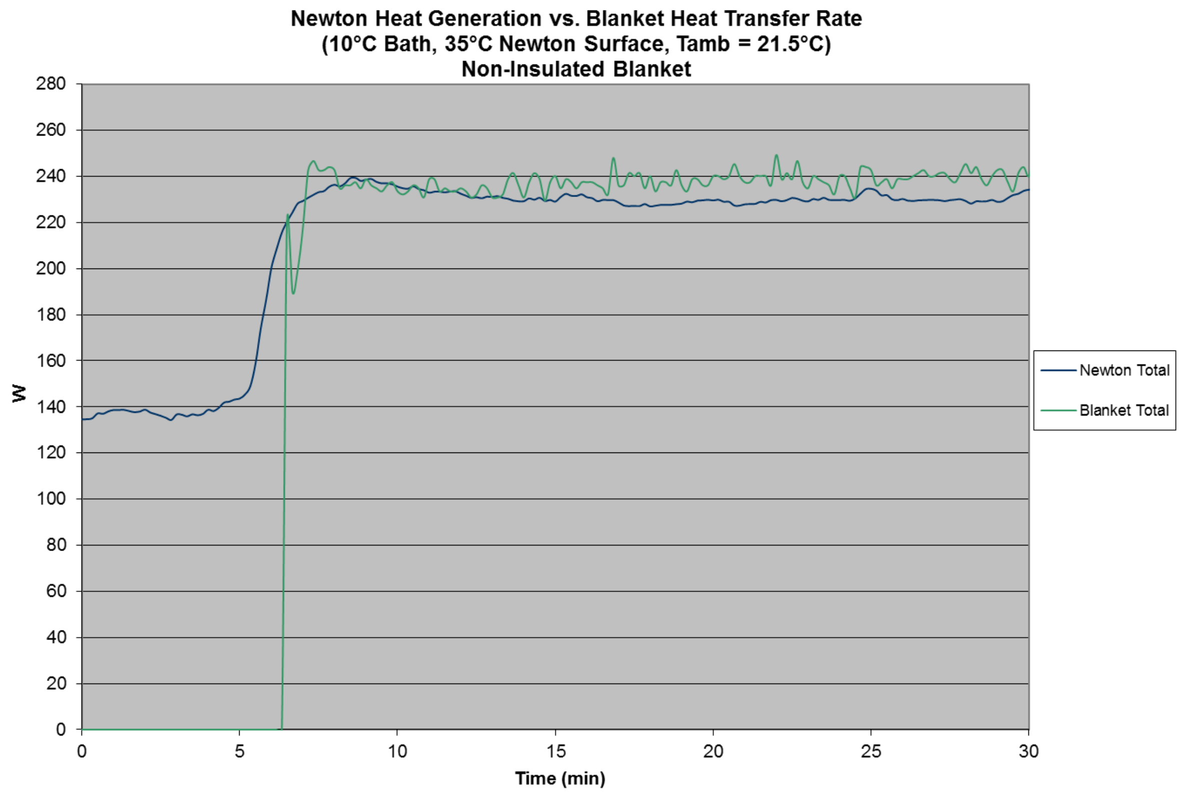

Figure 7. Accumulated increased heat generation & heat transfer rate (1°C bath)

The plot depicts an increased heat generation rate of approximately 100 W for the 10°C bath temperature. Therefore, the effective cooling capacity of the blanket for the specified testing conditions is in the range of 100 W. In analyzing the heat transfer rate into the blanket, based on the mass flow rate and increased water temperature, nearly 240 W is present. From an energy balance, the higher heat input rate is a result of the slightly higher ambient temperature as well as the significantly larger temperature gradient between the water and the ambient air. Consequently, there is a substantial heat input from the ambient to the water justifying the significantly higher heat input rate to the water than the additional rate being lost from the manikin. The manifestation is depicted above in figure 7.

With a general understanding of the available effective cooling capacity performance of the Maxi-Therm® blanket operating at different conditions on the thermal manikin, performance testing was redirected towards the PBTC. A similar procedure was implemented for system cooling capacity analysis as with the circulating bath configuration. Initially, the manikin surface temperature was set be maintained at 35°C in the environmental chamber held at approximately 20°C. The heat flux from each zone required to maintain that 35°C temperature was monitored at steady state conditions. Once equilibrium was achieved the Maxi-Therm® blanket was then placed over the thermal manikin and the zone heat fluxes were again allowed to achieve equilibrium. Yet again, the blanket was not insulated. The PBTC was then turned on and allowed to circulate water at the maximum capacity of the pump, approximately 0.32 gpm. The increase in each zone heat flux was then monitored until steady-state conditions were obtained. The heat input rate and cooling capacity were then analyzed in comparison to the bath results.

In analyzing the data it was immediately realized that the performance was poor in comparison to initial testing of the compressor with a bath simulating the load instead of the manikin. The problem was identified as an issue with the TXV limiting adequate refrigerant flow into the evaporator. Upon further investigations it was thought the issue may be traced back to swelling of the seals, due to compatibility problems with the refrigerant, restricting the flow path through the valve. The seals initially utilized are comprised of ethylene propylene rubber (EPR) and the refrigerant is R134a. The seals were replaced with neoprene and the bulb of the TXV was recharged and installed on the PBTC unit. The refrigerant charge was also re-adjusted on the prototype in order to optimize superheat in the evaporator and subcooling in the condenser. Although system performance improved, it was still significantly less than anticipated based on initial performance testing of the compressor. Instead of the nearly 200 W at a 5°C inlet temperature only 100 W was attained, a nearly 50% degradation in performance.

A manual regulating valve was replaced in lieu of the TXV in order to manually control the flow coefficient (C_V) through the valve and further pin-point the problem. The orifice size of the valve was adjusted to optimize performance of the system and the unit was allowed to stabilize. The process was implemented without a load from the manikin in order to quantify the cooling capacity of the PBTC in relation to the inlet water temperature into the unit. The results are transient since the cooling capacity varies as a function of inlet temperature. The volumetric flow rate was maintained constant at approximately 0.32 gpm. A graphical depiction of the results is presented in figure 8.

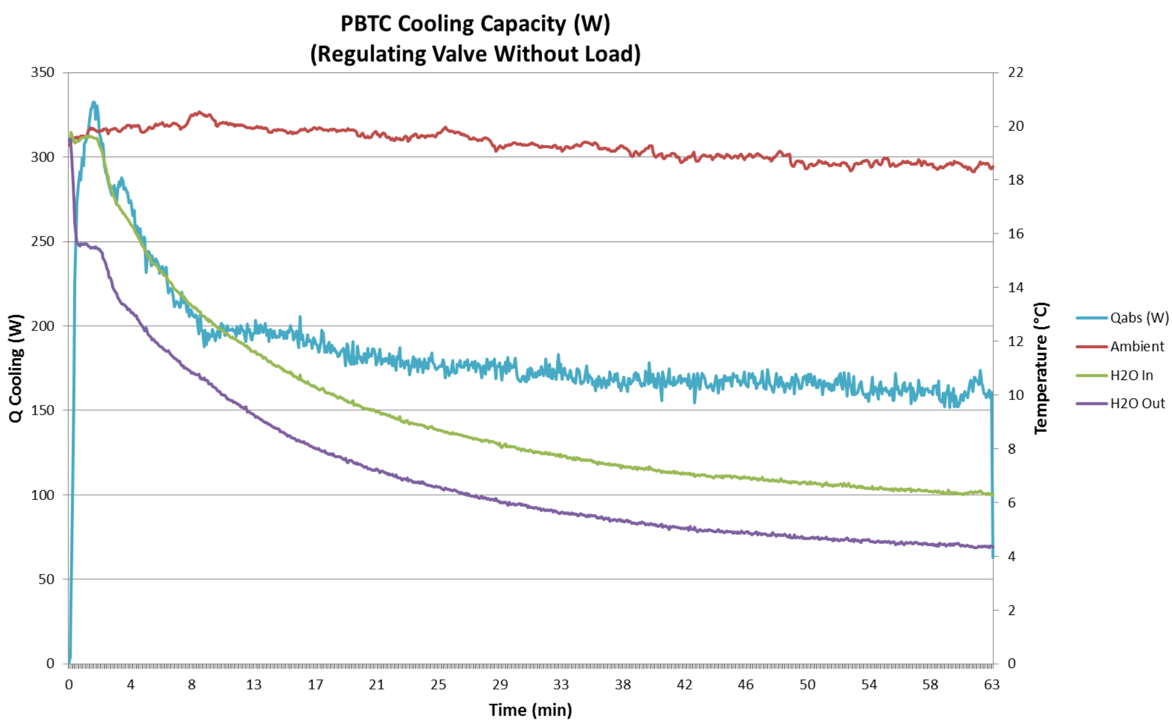

Figure 8. PBTC performance curve with regulating valve

The results demonstrate that even at an inlet water temperature of 6°C the PBTC with the regulating valve is able to maintain well above 150 W of cooling based strictly on the heat transfer rate from the water. That is not to say that all 150 W would be effective on the manikin, as was the case demonstrated in figures 6 and 7 based on the total increased heat flux required to maintain a surface temperature of 35°C.

Based on the orifice size of the regulating valve, and corresponding flow coefficient, the TXV was adapted and optimized to implement similar performance.
The regulating valve was then replaced with a TXV of the correct orifice diameter. The adaptation allows for refrigerant flow into the evaporator at an optimal proportion to the evaporation rate of the refrigerant in the evaporator. As a result, better superheat is obtained in the evaporator and sub-cooling in the condenser, improving overall system performance. The impact of adjusting the TXV orifice has been compared against the cooling capacity obtained from manually tuning the regulating valve. The

comparison was implemented without a load from Newton to better assess PBTC system behavior. Presented in figure 9 is the performance plot for the cooling test with the adjusted TXV orifice at a 20°C ambient temperature.

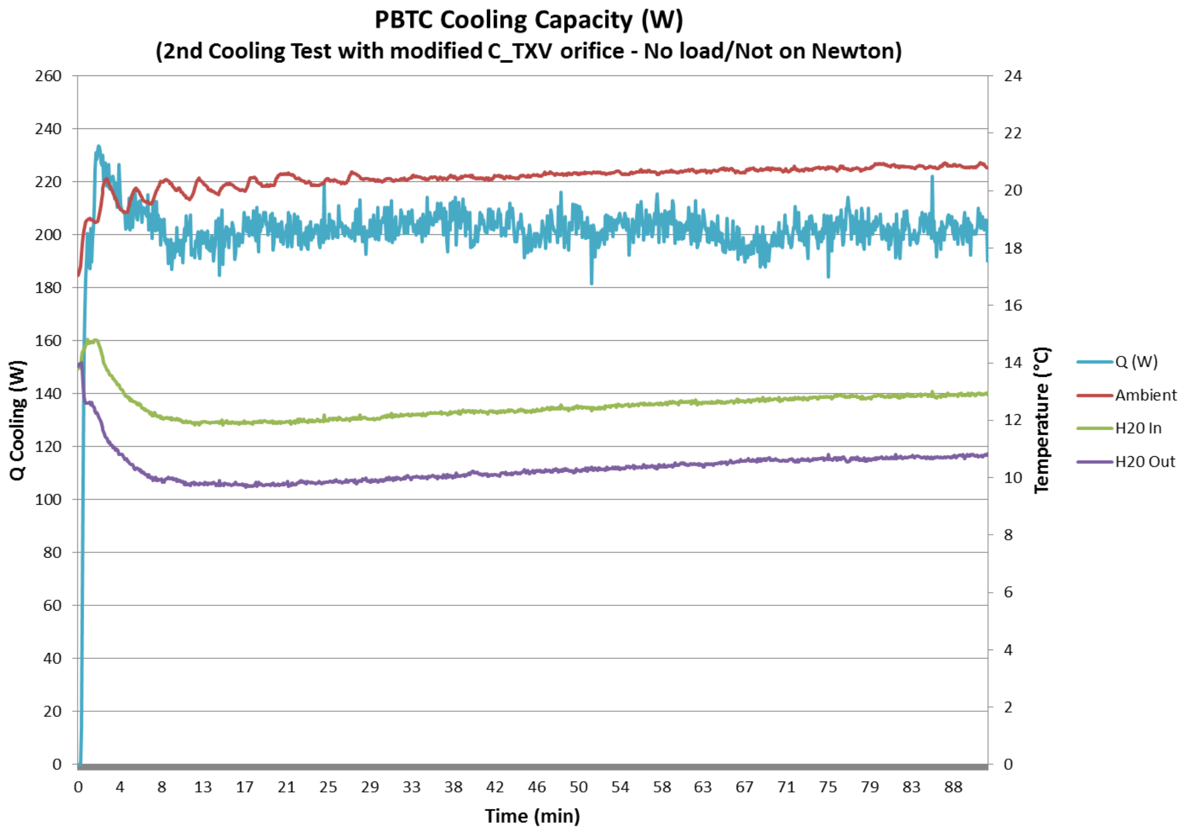

Figure 9. Modified TXV orifice cooling performance plot

As presented in the figure, the PBTC was able to maintain a cooling capacity of 200 W under steady state conditions, an improvement over the 160 W steady state capacity obtainable with the regulating valve. Adjusting refrigerant charge and spring force of the TXV, optimized superheat in the evaporator was obtained. The TXV was adjusted to obtain approximately 8°C superheat in the evaporator. A comprehensive testing matrix was then executed with a thermal load provided by Newton, the thermal manikin.

Cooling tests were implemented for varying ambient and operating conditions, while maintaining the surface temperature of Newton, the thermal manikin, at 35°C. The increased heat flux required to maintain the 35°C surface temperature was monitored while operating the PBTC along with the cooling capacity of the unit. The tests were performed for compressor speeds of 4,000 rpm, 5,000 rpm, and 6,000 rpm each at ambient temperatures of 10°C, 20°C, 30°C, and 35°C. The tests were limited to the range of operating ambient temperatures because below 10°C the water would approach freezing conditions and above 35°C the heat flux from the manikin was not required to maintain the desired surface temperatures. Consequently, the impact of the blanket on the manikin could not be quantified. All tests were implemented as dry tests, implying no simulated perspiring from the thermal manikin. Through testing, it was demonstrated that the PBTC was able to maintain a cooling capacity in the range of 285 W to 425 W depending on testing conditions. With concerns of running the compressor for extended periods of time at the high 6,000 rpm speed, risks of overheating and mechanical vibration failure lend to the requirement of being capable to achieve good heating and cooling capacities at lower compressor speeds. Resultantly, the cooling capacity performance plot for the 35°C ambient, 5,000 rpm compressor speed is presented in figure 10.

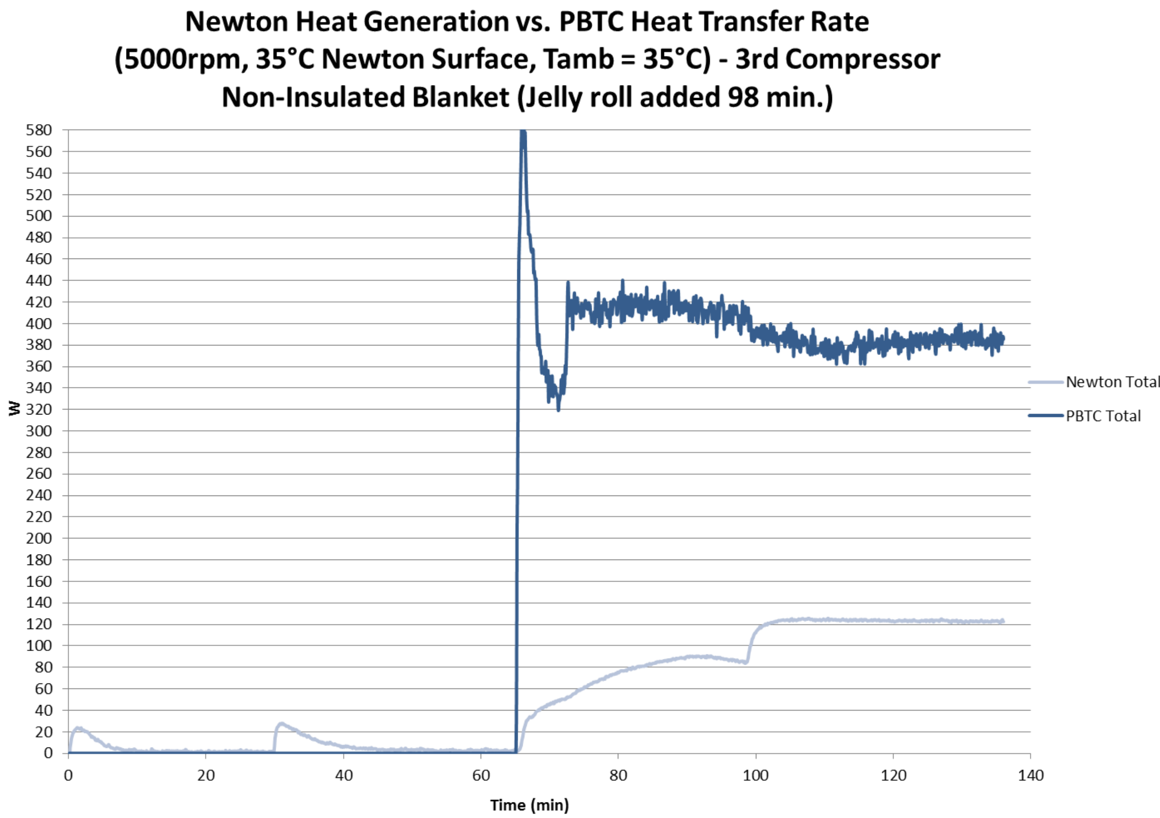

Figure 10. PBTC cooling capacity evaluation

As depicted in figure 10, the PBTC was able to maintain approximately 420 W of cooling while operating under the specified conditions. At the 98 minute mark a large Gelli-Roll® blanket was placed on top of the Maxi-Therm® blanket to increase skin surface contact with Newton. The plot presents an additional 40 W of cooling provided to Newton by increasing the surface contact utilizing the Gelli-Roll® blanket.

With a comprehensive evaluation of cooling capacities, testing was direct towards the heating cycle performance of the PBTC. When running the heating cycle the evaporator and condenser become opposite components within the system in comparison to the cooling cycle. Switching from cooling to heating, the evaporator becomes the condenser and the condenser becomes the evaporator. The incongruity in volume between the two components leads to a discrepancy in optimal refrigerant charge for each cycle. Resultantly, for peak heating and cooling capacities, the heating cycle requires approximately 70g of additional R134a refrigerant in comparison to the cooling cycle. A refrigerant storage reservoir has been designed and sized to accommodate the additional charge during the cooling cycle. The refrigerant reservoir is located within the system at the outlet of the air coil, the condenser during the cooling cycle and the evaporator during the heating cycle. The sizing and placement of the reservoir allows the additional charge to be available during the heating cycle and stored in the reservoir during the cooling cycle. Figure 13 below depicts the reservoir geometry and placement within the system.

A specific instance of operating the compressor at the maximum speed of 6,000 rpm for an extended period of time, exceeding 3 hours, resulted in mechanical failure of the compressor. It was observed that vibrations from the higher threshold of the compressor speed appeared to have caused the failure at the interface between the compressor and the discharge line. In order to alleviate the possibility of a similar occurrence within an operating prototype, a vibration damper has been integrated into the design on both the suction and discharge lines of the compressor. The vibration dampers consist of flexible refrigeration hose, and their effectiveness has been evaluated over long term operation of the PBTC. The flexible hoses preserve the mechanical integrity of the compressor, and are displayed in the model of the prototype in figure 13.

Operating the PBTC and high compressor speeds and elevated ambient temperatures resulted in the compressor ceasing. A heat sink had previously been designed and tested to prevent the compressor from overheating. Furthermore, it was found that the compressor was always well below the practical operating temperature limit of 135°C when experiencing the problem. Upon further examination, it was determined that the control board driving the compressor was the actual component overheating. The heat sink provided with the compressor was not capable of effectively dissipating enough heat for the drive to maintain full functionality consistently. Rocky Research has designed, implemented, and tested a new finned heat sink capable of dissipating enough heat to prevent the problem from occurring over long-term operation of the PBTC. Furthermore, an additional fan has been incorporated into the design to allow for direct air circulation over the finned heat exchanger. Figure 13 also portrays the additional heat exchanger along with the fan and how they are each integrated into the system.

Rocky Research has been in contact with the design team of the Aspen compressor to express a concern with overheating of the control board utilized to drive the compressor. Upon doing so it was found that a new UL approved control board has been developed by Aspen to address the issue of the control board overheating. The UL approved board has a finned heat exchanger very similar in design to the one implemented by Rocky Research. Rocky Research has acquired a couple of the UL approved boards for evaluation comparisons to the in house developed heat sink. Figure 11 portrays the performance of the PBTC without the Rocky Research implemented heat sink on the compressor control board while figure 12 portrays the same test with the heat exchanger intact. Both tests were implemented at the higher end capacity of the compressor in terms of speed, 6000 rpm.

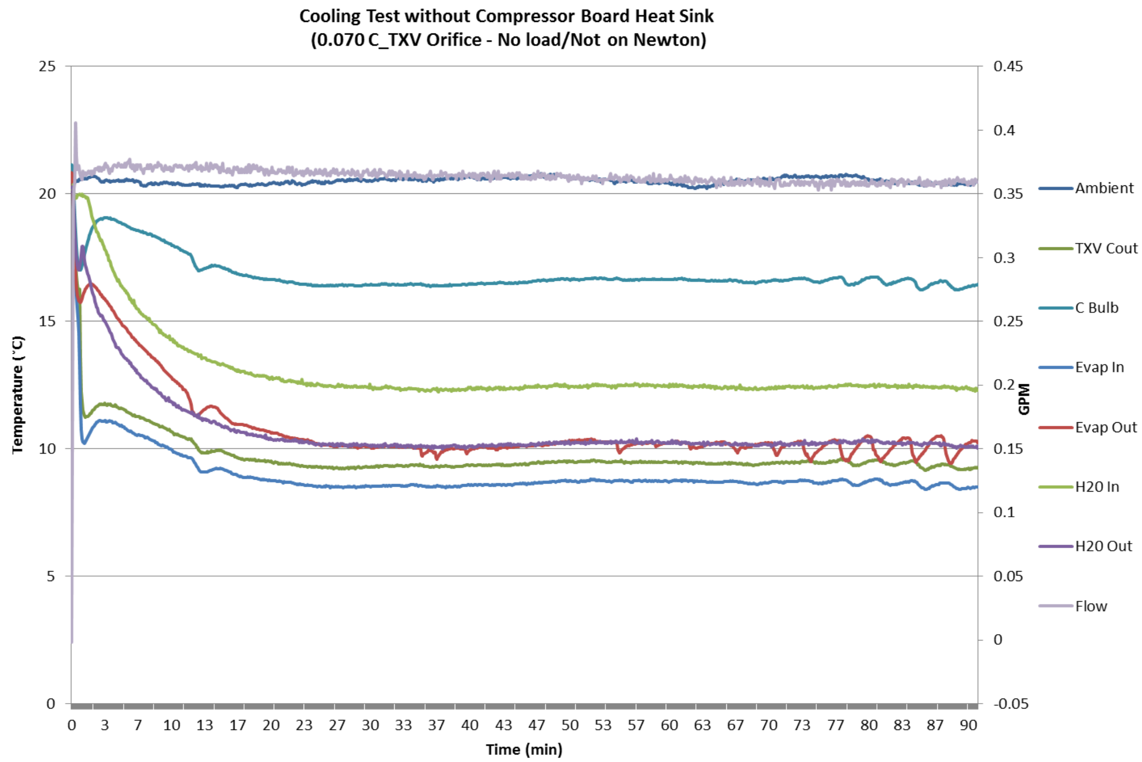

Figure 11. Performance without compressor board heat sink

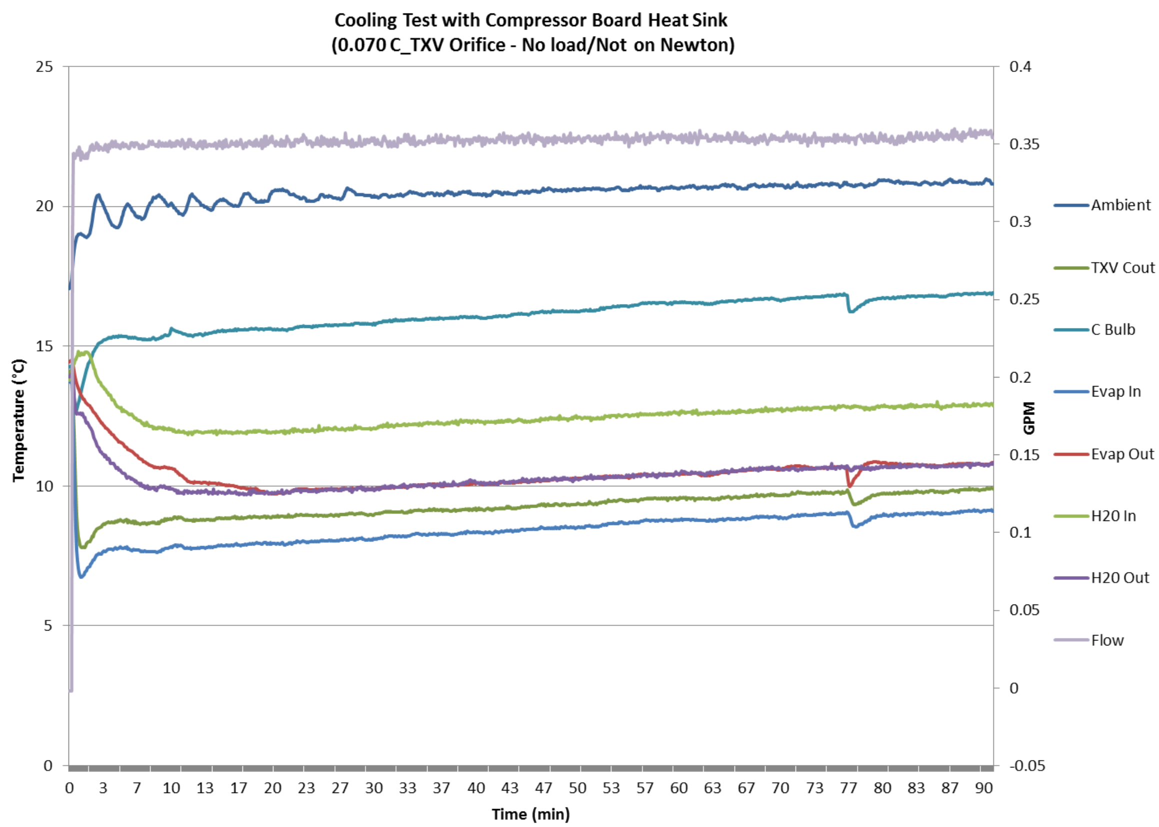

Figure 12. Performance with compressor board heat sink

In analyzing the data depicted in figure 11, around the 70 minute mark, instability in the evaporator outlet temperature is observed. The fluctuation directly corresponds to the compressor cycling on and off as the compressor board began to overheat. Figure 12 shows the same testing conditions with the heat sink for the board installed as implemented by Rocky Research. The system ran considerably more stable, and is able to maintain long-term operational performance of the compressor with the heat sink intact and direct forced convection air flow available.

A reservoir for filling the blanket has also been integrated into the design of the case of the PBTC along with a charge port for filling the blanket. The reservoir is designed to accommodate enough water to fill a large CSZ adult size Maxi-Therm® blanket along with the connection hoses and plumbing of the PBTC. A graphical depiction of the reservoir, along with all other described design component enhancements at that development state of the prototype is presented in figure 13.

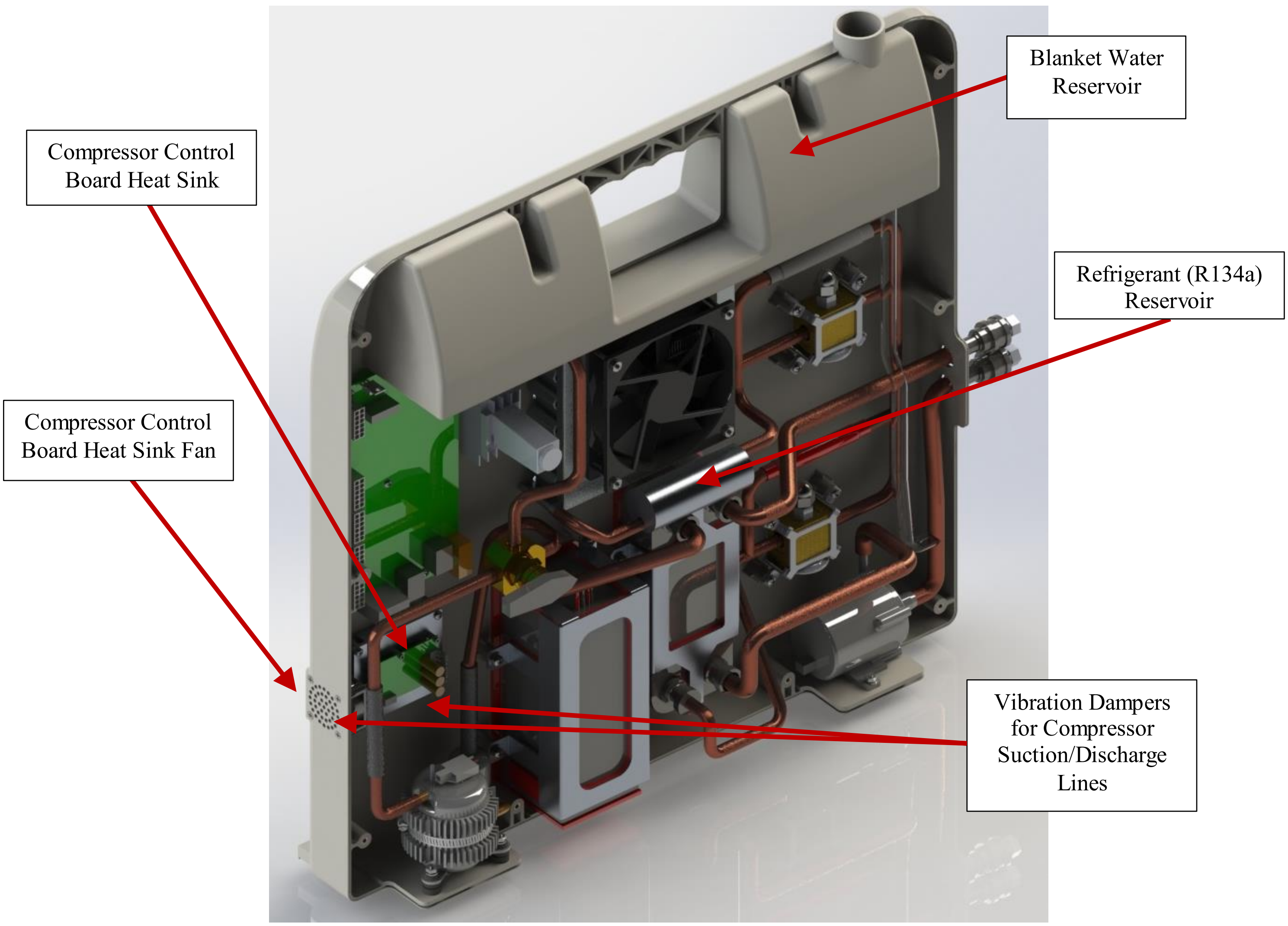

Figure 13. PBTC system component design enhancements

Similar to the cooling performance evaluations, heating tests were also implemented at compressor speeds of 4,000 rpm, 5,000 rpm, and 6,000 rpm with ambient conditions of 10°C, 20°C, 30°C, and 35°C. Since Newton is not capable of providing a cooling load, which is a necessity to perform the heating analysis in the same manner as the cooling tests, the testing procedure varied for evaluating the heating capacity.

The initial heating capability analysis of the PBTC consisted of first placing the Maxi-Therm® blanket on top of the thermal manikin. The blanket was not forced to make ideal contact with the manikin, nor was it insulated by an additional garment to mitigate heat transfer with the ambient environment. The ambient temperature in the environmental chamber was set, and the manikin was calibrated to allow the manikin zone heat flux's to achieve a surface temperature of 35°C. Once the chamber and manikin reached steady state conditions, a new test was ran forcing the manikin heat flux to 0 W/m^2 while simultaneously starting the PBTC. Consequently, it is significant to recognize that the manikin does not provide a load during the heat pump evaluation of the PBTC utilizing this procedure. All tests reflect the performance of the PBTC after optimizing the charge for the heating cycle. The heat input into the water was then documented along with the temperature profiles of the water in and out of the blanket. Furthermore, the surface temperatures of each zone and the average surface temperature of Newton were recorded. The individual Newton surface temperatures are presented in figure 14. Similar to the cooling tests, the compressor speed for the plots presented was set to 5,000 rpm at an ambient temperature of 35°C to evaluate performance of the system. Again, this was to allow system performance to be evaluated at less than maximum compressor speed where overheating and mechanical vibration complications occurred.

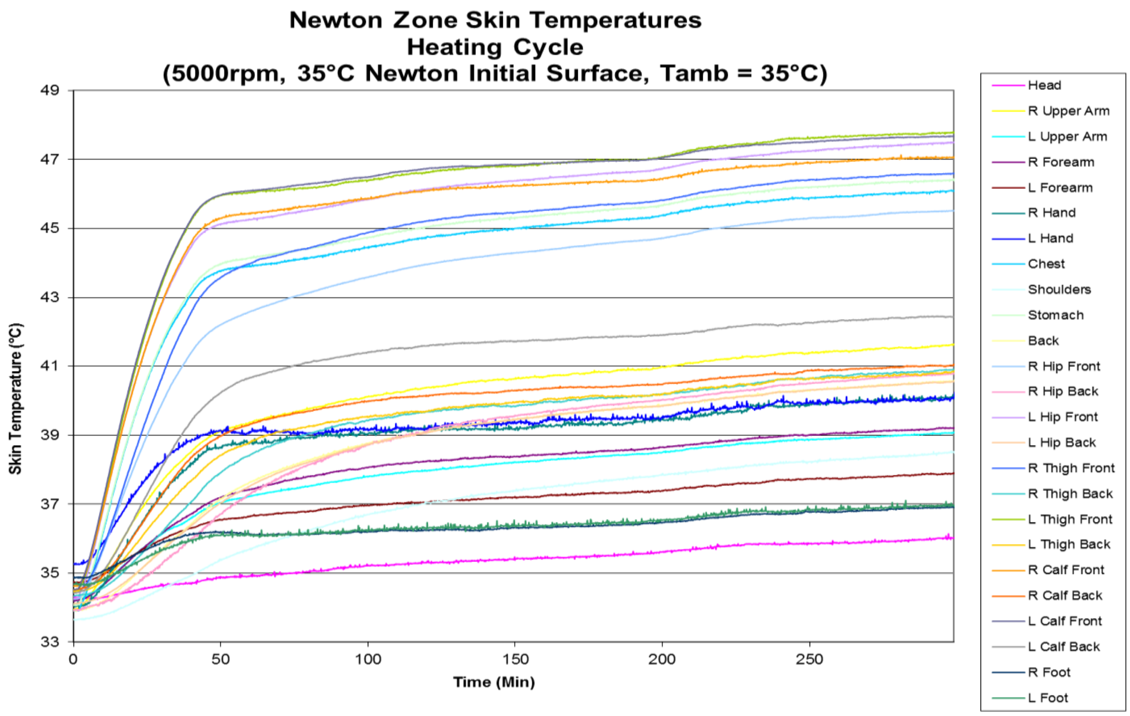

Figure 14. Newton heating test skin temperatures

Analogous to the cooling evaluations, the plot demonstrates good contact with the hips, thighs and chest. The PBTC was capable of increasing the surface temperature of several Newton zones to well above 42°C within 30 minutes, a 7°C increase in temperature. Heating surface temperatures much hotter initiates the risk of skin damage to the patient. The figure also establishes that after about 4 hours of continuous operation the PBTC was proficient in bringing the surface temperature of highly impacted zones up to 48°C. Zones not in contact with the blanket show a much slower increase in surface temperature, and the impact is primarily due to lateral heat transfer from the affected areas. The average Newton surface temperature is plotted against the heat transfer rate provided by the PBTC to the blanket water in figure 15.

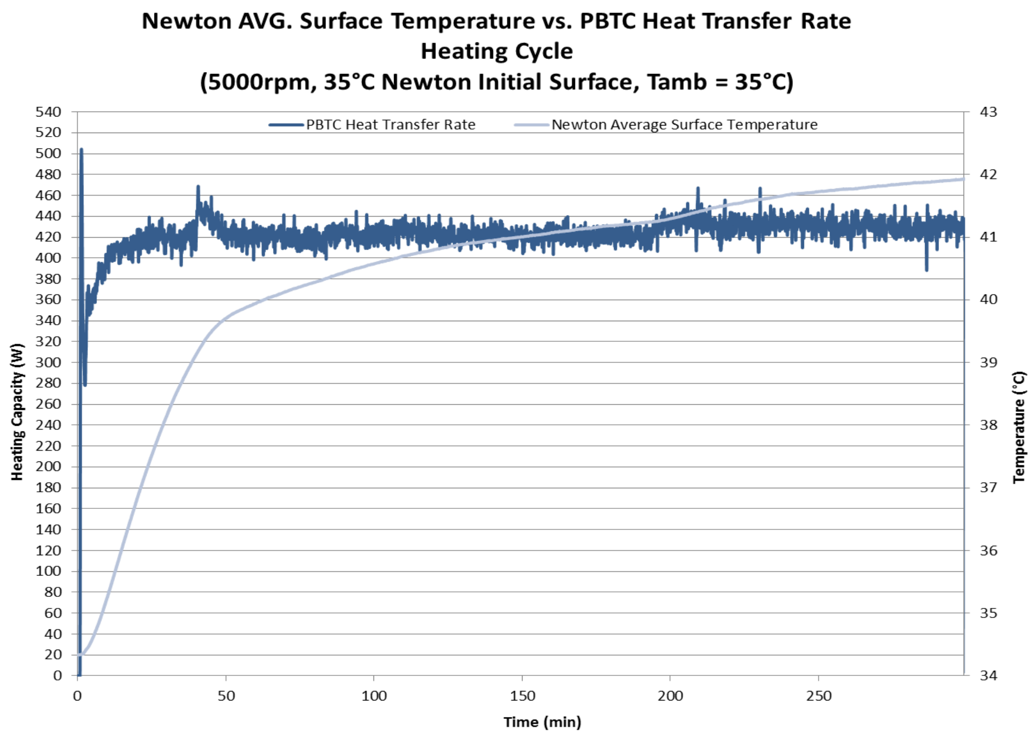

Figure 15. Heating performance & average Newton surface temperature

As can be ascertained from the figure, the majority of the PBTC heating impact on the manikin for the demonstrated testing conditions occurs within the first 45 minutes. There is, however, still a significant influence on Newton after that time frame. The average temperature is lower than many of the surface temperatures presented in figure 14 due to the fact that the blanket is not in contact with several manikin zones, specifically the entire backside of Newton. Steady state capacity reflects 430 W of heating for the presented evaluation. Similar to the cooling capacity, the heating capacity of the PBTC has been demonstrated to be within the targeted performance capabilities of the unit.

Compressor failure during system evaluation due to a surge of liquid refrigerant droplets entering the compressor, specifically when cycling between heating and cooling modes at startup, resulted in the requirement of an additional component for maintaining reliable compressor functionality. The component, an accumulator, was designed specifically for the refrigerant charge requirement of the PBTC. Accumulators work by vaporizing liquid slugging in the suction line, in order to prevent damage to the compressor. Harmful liquid refrigerant is trapped in the accumulator until it can evaporate. Traditional off the shelf accumulators are designed for much larger refrigeration systems then that applicable for the PBTC. Resultantly, a custom accumulator was designed, sized, implemented, and tested for the application at hand. The accumulator was also developed with a metering orifice such that oil required by the compressor is not confined in the accumulator. Fabricated accumulator geometry was oriented towards providing minimum system pressure drop to accommodate the maximum refrigerant flow rate required. The accumulator has been installed directly at the inlet suction line of the compressor to prevent mechanical damage and failure of the compressor. The suction line, along with the accumulator shell, have been fabricated from copper. Figure 16 is a depiction of the geometry of the accumulator along with corresponding dimensions in units of inches, while figure 17 is a picture of the prototyped accumulator installed on the system breadboard along with a cross-sectional view of the 3D model.

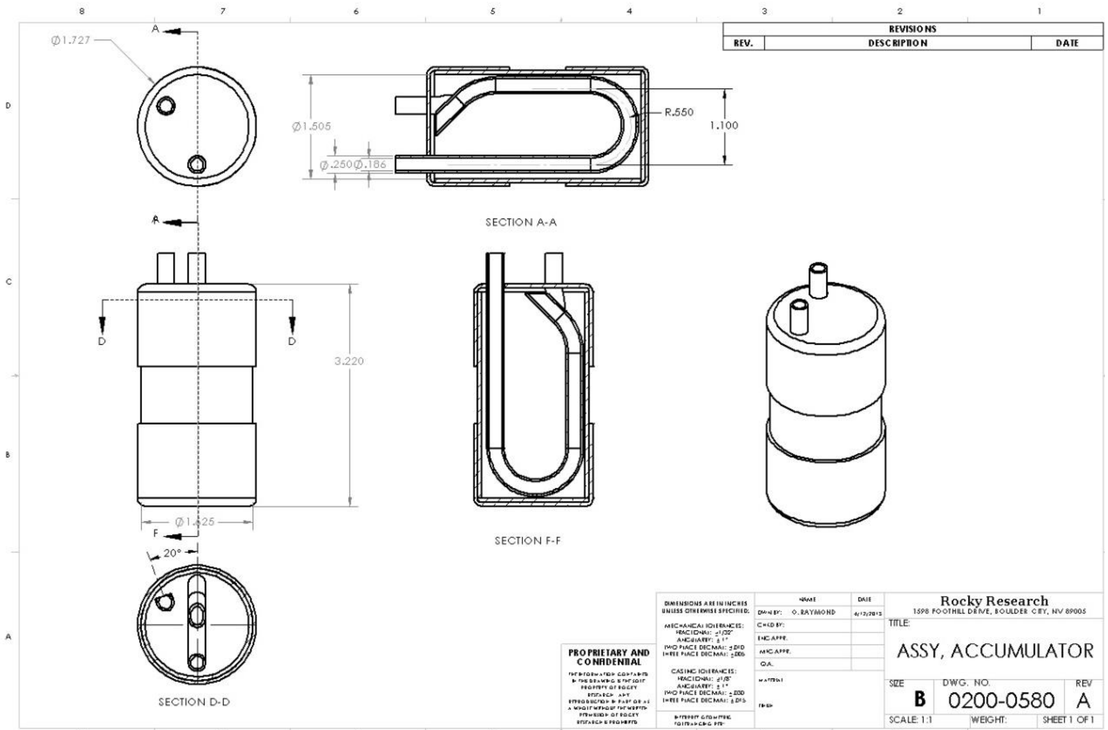

Figure 16. PBTC accumulator geometry drawing

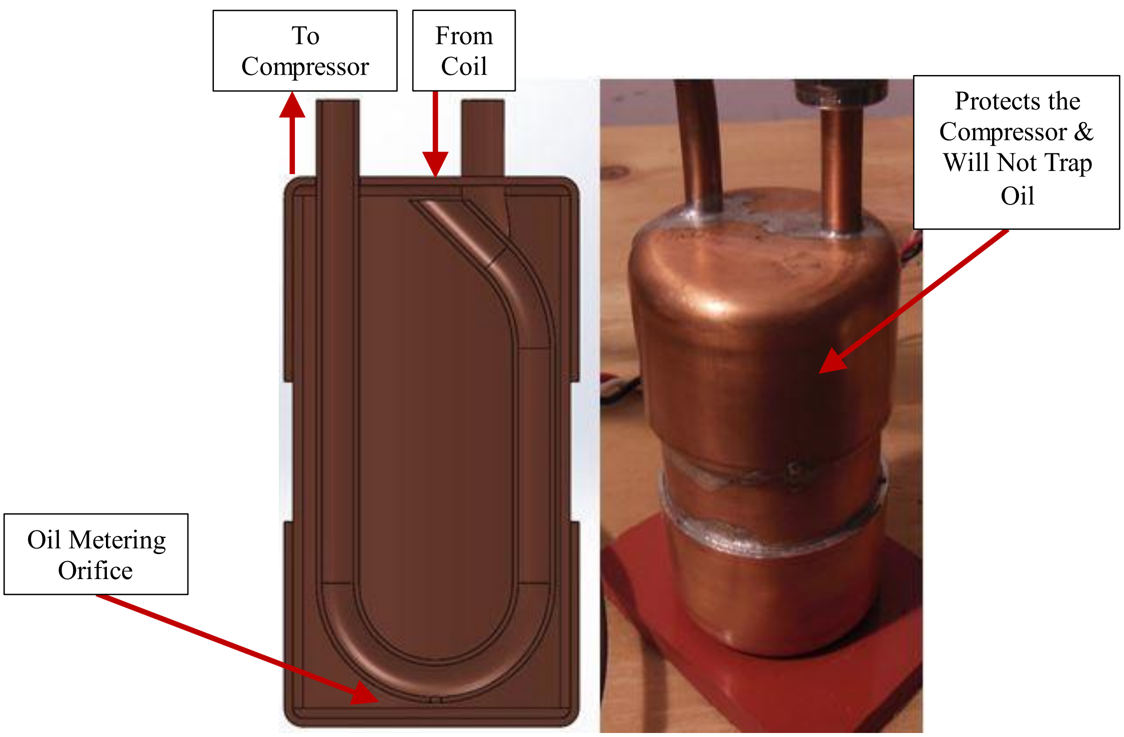

Figure 17. PBTC accumulator cross-section & fabricated prototype

The effectiveness of the accumulator was evaluated by operating the system and analyzing for symptoms of liquid slugging in the compressor. Without the accumulator installed, liquid slugging into the compressor was substantially apparent, specifically at system startup. Large fluctuations in system low side pressure along with a corresponding instability in compressor operating tone was indicative of liquid slugging. On several instances the liquid flooding resulted in permanent damage of the compressor leading to complete system failure. With the accumulator installed, however, there were no indications of liquid refrigerant slugging into the compressor, including when cycling between heating and cooling modes at startup. Resultantly, the system was able to operate reliably for long durations of time, cycling between heating and cooling modes, so that performance testing could ensue.

With the accumulator ensuring the operational integrity of the compressor, focus was directed towards evaluating the effectiveness of the refrigerant storage reservoir. The refrigerant reservoir was assessed by first optimizing the refrigerant charge for the lower required refrigerant system capacity of the cooling cycle, 134g of R134a, and then adding refrigerant in 10g increments to the optimal heating cycle charge while monitoring superheat, subcooling, and overall system cooling capacity. Once the full charge demand was ascertained for the heating capacity requirement the appliance was ran in the cooling mode until steady state conditions were achieved, ensuring that the compressor was not being overloaded and that refrigerant was collecting in the reservoir as desired. The appliance was then altered from the cooling to heating cycle and the system performance analyzed for optimal heating capacity under the same operating conditions. With previous concerns of running the compressor for extended periods of time at the high 6,000 rpm speed, risks of overheating and mechanical vibration failure led to the requirement of being capable to achieve good heating and cooling capacities at lower compressor speeds. Resultantly, the cooling capacity performance plot for the 30°C ambient, 5,000 rpm compressor speed is presented in figure 18, and the heating capacity performance in figure 19. The temperature profiles for the inlet and outlet water temperatures of the PBTC are also demonstrated in both figures. Again, both tests are with the accumulator and reservoir installed and a single system refrigerant charge for operating in either mode.

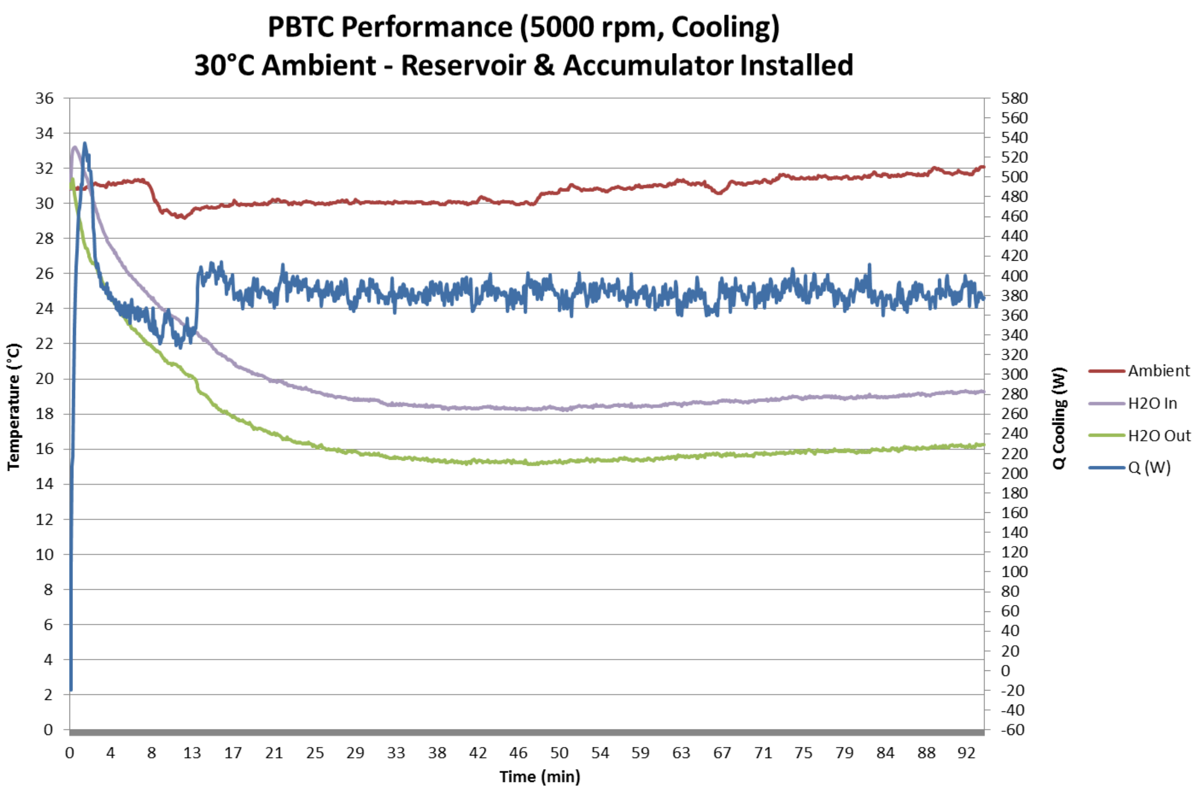

Figure 18. PBTC cooling performance plot with accumulator and reservoir

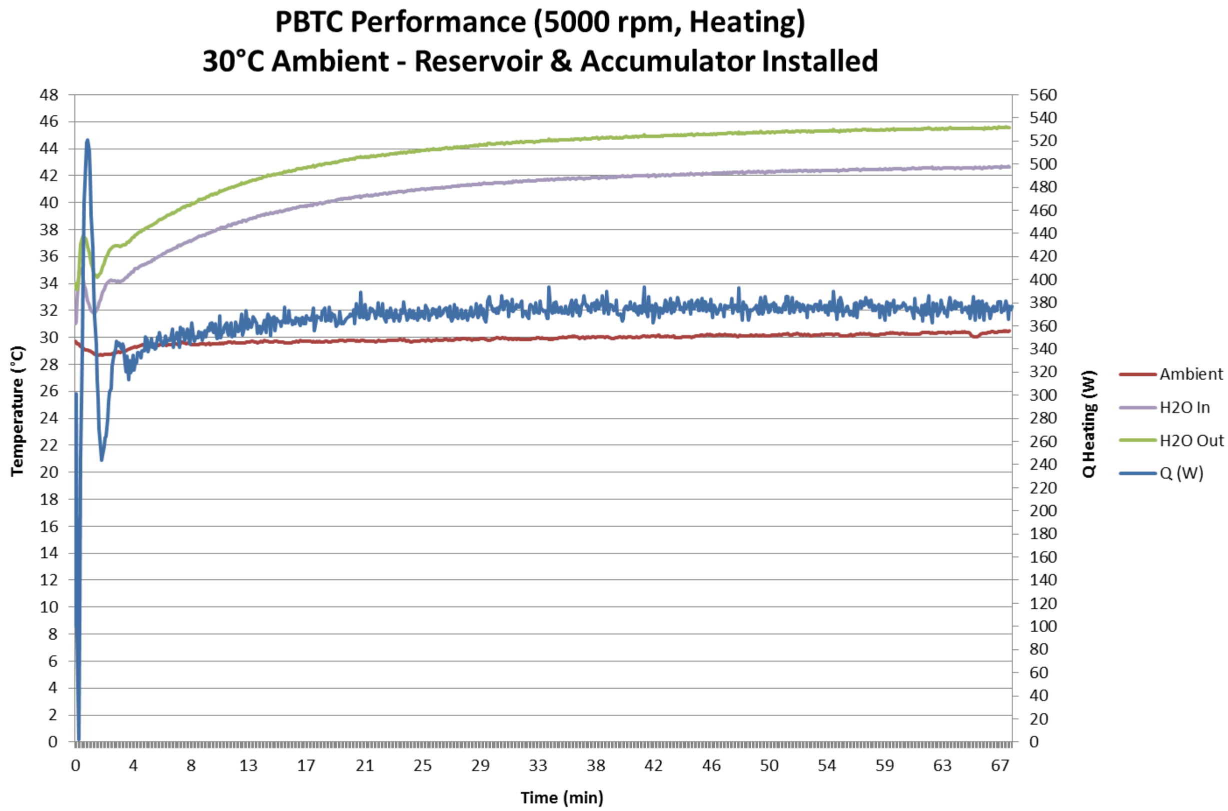

Figure 19. PBTC heating performance plot with accumulator and reservoir

As presented in the figure 18, the PBTC was able to maintain a steady state cooling capacity of approximately 390 W under the demonstrated operating conditions, nearly identical performance without the reservoir installed and the system optimized strictly for cooling mode operation at the same conditions. Such results exhibit the effectiveness of the reservoir in storing liquid refrigerant as desired. Without the reservoir installed, and an equivalent system refrigerant charge as necessary for heating, operating the appliance in the cooling cycle gave rise to flooding of the compressor. The results in figure 19 portray a similar heating capacity of the PBTC under equivalent operating conditions with the reservoir installed. Resultantly, the entire refrigerant charge becomes available as desired when operating in the heating mode. A steady state heating capacity of approximately 380 W is subsequently achieved as portrayed in figure 19. Adjusting refrigerant charge and spring force of the TXV was optimized for superheat in the evaporator and subcooling in the condenser. Depending on the operating conditions, superheat was targeted between 8°C to 15°C while subcooling was targeted at 3°C to 6°C.

System geometry and plumbing of the PBTC has been modified and incorporated in a 3D model to support the additional required components. Figure 20 is a model depicting how the accumulator, reservoir, and vibration dampers are integrated into the system design.

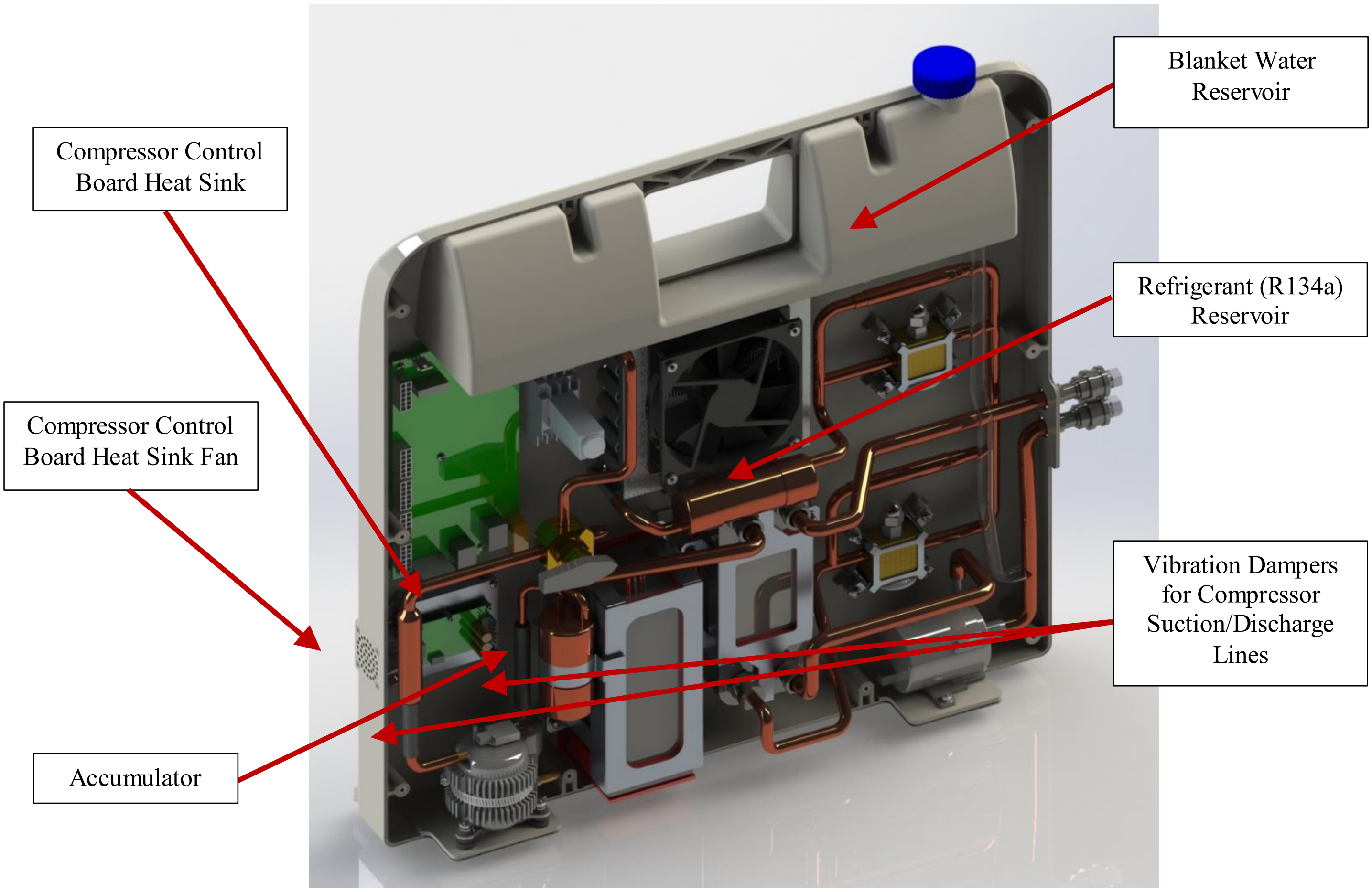

Figure 20. PBTC system component design enhancements

The requirement for the additional components necessary for stable and continuous operation of the PBTC resulted in confined space availability within the designed case of the appliance. Resultantly, the plumbing and component layout of the device had to be modified to utilize available space most efficiently. Figure 20 portrays how the plumbing and orientation of the components is intended to be utilized within the case of the PBTC. Fortunately, the supplementary components have been sized and oriented within the system layout such that the case geometry did not have to be altered. However, the additional components do result in a subsidiary weight increase of the appliance. The refrigerant reservoir weighs approximately 198g, the accumulator approximately 315g, and the flexible hose vibration dampers approximately 166g. Consequently, the accumulated total weight increase of the additional components is approximately 679g (1.5lbs).

Once the reservoir was integrated into the system, functional and performance evaluations of the reservoir effectiveness were implemented. Analogous to performance testing without the accumulator and reservoir installed, cooling tests were implemented for varying ambient and operating conditions, while maintaining the surface temperature of Newton, the thermal manikin, at 35°C. The increased heat flux required to maintain the 35°C surface temperature was monitored while operating the PBTC along with the cooling capacity of the unit. The tests have been implemented for a compressor speed of 4000 rpm, 5000 rpm, and 6000 rpm at ambient temperatures of 10°C, 20°C, 30°C, and 35°C. All tests were implemented as dry tests, implying no simulated sweating from the thermal manikin. Through initial testing, with the accumulator and reservoir installed operating at a compressor speed of 5000 rpm, it was demonstrated that the PBTC was able to maintain a cooling capacity in the range of 320 W – 420 W depending on testing conditions. Again, apprehensions of operating the compressor for significant lengths of time at maximum speed led to the requirement of being capable to achieve good heating and cooling capacities at lower compressor speeds. Resultantly, the cooling capacity performance plot for the 30°C ambient, 5,000 rpm compressor speed is presented in figure 21.

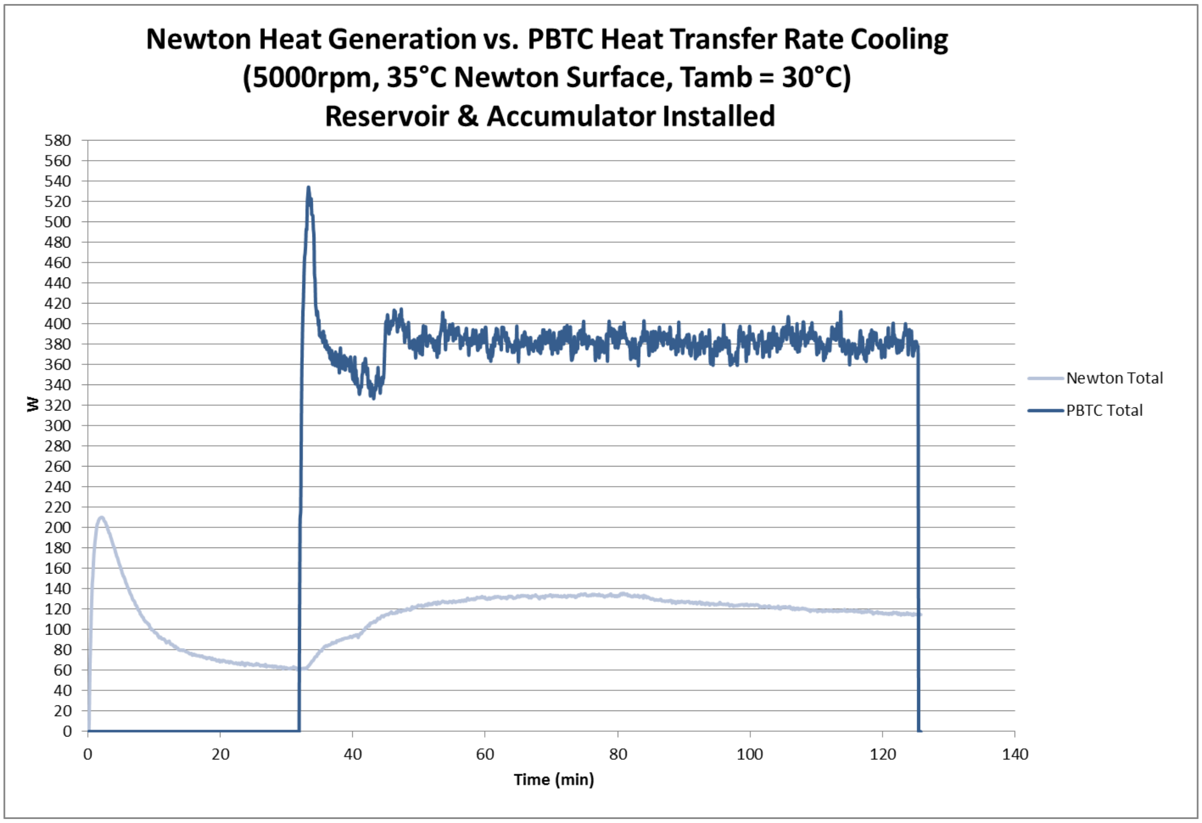

Figure 21. PBTC cooling capacity evaluation with reservoir & accumulator

As depicted in figure 21, the PBTC is able to maintain approximately 380 W – 400 W of cooling while operating under the specified conditions on the thermal manikin. The performance is very similar to that demonstrated with the optimal refrigerant charge just for the cooling cycle without the reservoir or accumulator installed and is well above the minimum target cooling capacity of the system at 200 W – 500 W. Correspondingly, the 140 W heat flux from the thermal manikin require to maintain zone surface temperatures at 35°C is also nearly identical without the additional charge and reservoir. Figure 22 portrays the heat flux of each zone, corresponding to which areas of the manikin are most significantly affected by the PBTC under the current testing procedures. Nearly identical to what was demonstrated in previous performance tests; the blanket of the PBTC has the most significant impact on the chest, stomach, arm, thigh, and hip zones.

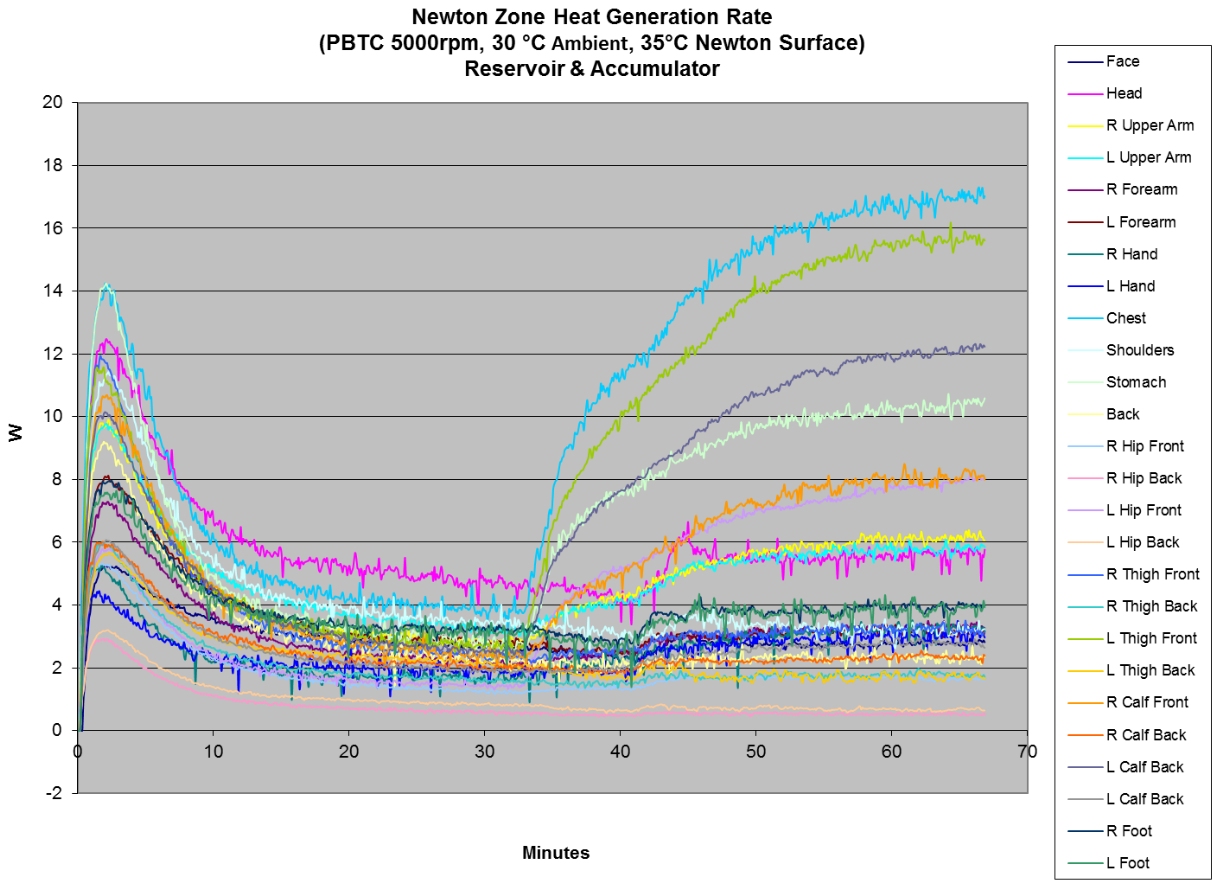

Figure 22. PBTC cooling cycle zone heat generation rate

With a comprehensive evaluation of cooling capacities, the heating capability for the PBTC was also evaluated for the 4000 rpm, 5000 rpm, and 6000 rpm compressor speeds at ambient temperatures of 10°C, 20°C, 30°C, and 35°C with the accumulator and reservoir installed. As with previous testing procedures of the heating cycle, the capability analysis of the PBTC consisted of first placing the Maxi-Therm® blanket on top of the thermal manikin. The ambient temperature in the environmental chamber was set, and the manikin was calibrated to allow the zone heat flux's to achieve a surface temperature of 35°C. Upon reaching steady state conditions, a test was implemented forcing the manikin heat flux to 0 W/m^2 while simultaneously starting the PBTC. All tests reflect the performance of the PBTC with one system charge for both heating and cooling modes and both the accumulator and reservoir installed. The heat input into the water was then documented along with the temperature profiles of the water in and out of the blanket. Furthermore, the surface temperatures of each zone and the average surface temperature of Newton were measured. Similar to the cooling tests, the compressor speed for the plots presented was set to 5,000 rpm at an ambient temperature of 30°C to evaluate performance of the system. Again, this was to allow system performance to be assessed at less than maximum compressor speed. The average Newton surface temperature is plotted against the heat transfer rate provided by the PBTC to the blanket water in figure 23.

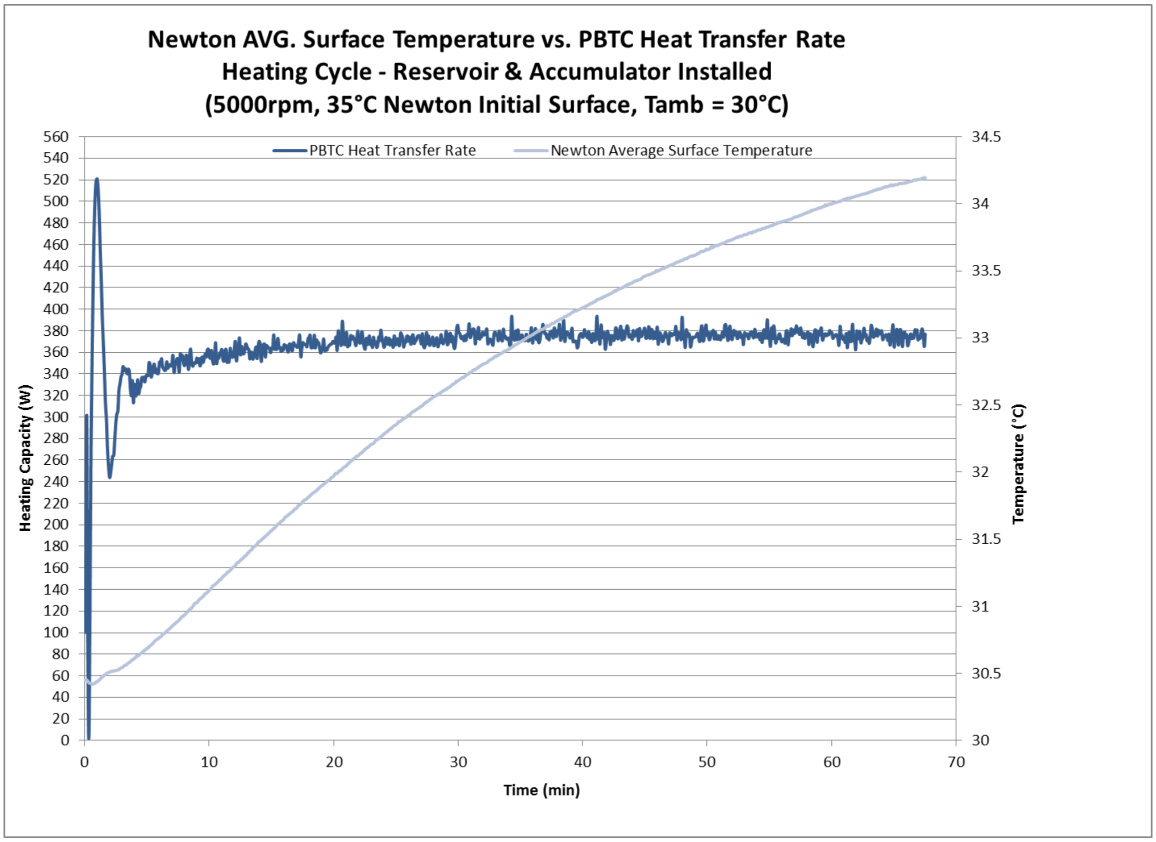

Figure 23. Heating performance & average Newton surface temperature

As can be ascertained from the figure, steady state heating capacity is achieved after approximately 10 minutes of continuous operation. The average temperature is lower than many of the surface temperatures due to the fact that the blanket is not in contact with several manikin zones, specifically the entire backside of Newton. Steady state capacity reflects 380 W of heating for the presented evaluation. Therefore, by incorporating the refrigerant reservoir and accumulator, and optimizing the system refrigerant storage capacity for the larger cycle, a heat transfer rate of approximately 400 W is nearly achievable for both operational modes. Similar to the cooling capacity, the heating capacity of the PBTC has been demonstrated to be within the targeted performance capabilities of the unit at 300 W – 800 W.

Preliminary comprehensive cooling and heating test matrices, along with their corresponding performance curves, have been constructed for the PBTC and different operating compressor speeds and ambient temperatures. Test were implemented, according to the previously defined procedure, at ambient temperatures of 10°C, 20°C, 30°C, and 35°C and compressor speeds of 4000 rpm, 5000 rpm, and 6000 rpm. Capacities were measured after steady-state conditions were achieved. Maintaining target ambient temperatures in the environmental chamber was held to a tolerance of ±1°C. Figure 24 depicts the cooling results for the entire test matrices.

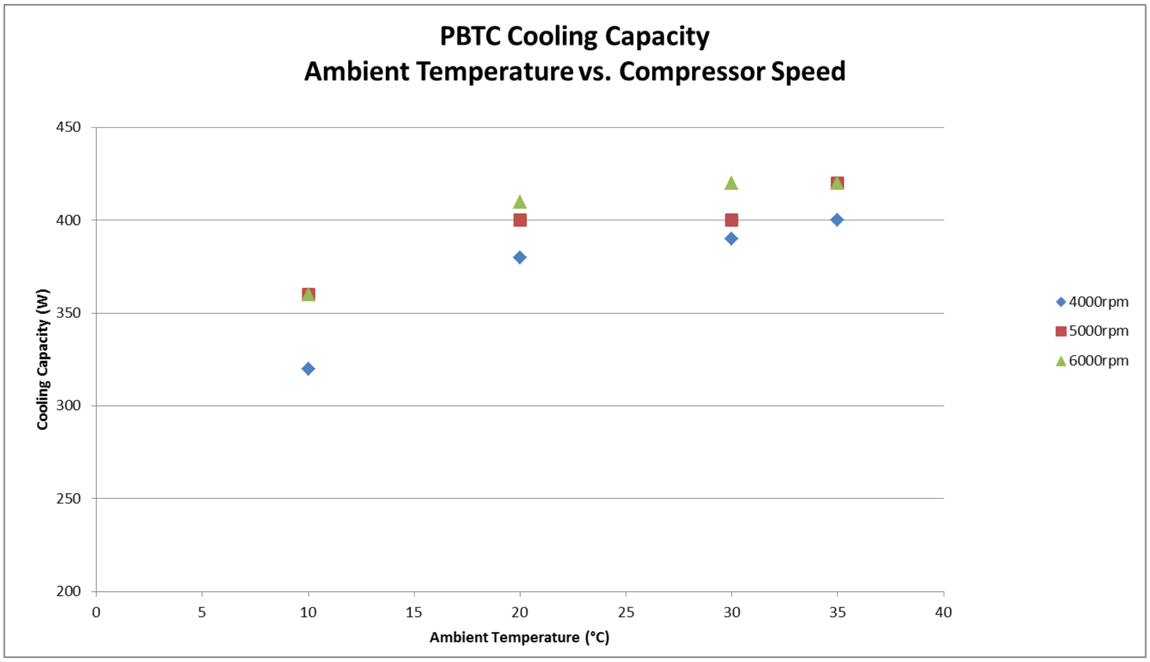

Figure 24. PBTC cooling capacities for varying ambient temperatures and compressor speeds

The figure demonstrates cooling capacities achieved between 320 W– 420 W. It also demonstrates that at higher ambient temperatures it is less impactful to run the compressor at higher operating speeds in the cooling mode. System coefficient of performance (COP) needs to be evaluated for the entire test matrices. In figure 25 the data for the same testing conditions, in terms of compressor speed and ambient temperatures, is presented for the heating mode.

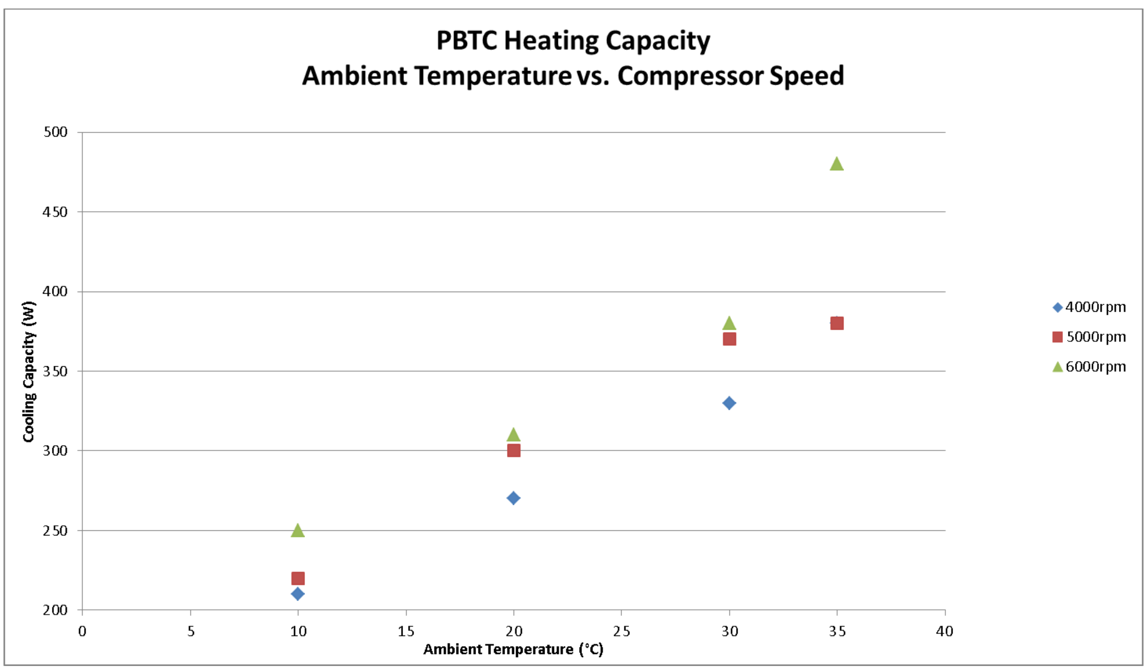

Figure 25. PBTC heating capacities for varying ambient temperatures and compressor speeds

The heating tests demonstrate a larger range of capacities than the cooling test for the same operating conditions, ranging from 210 W – 480 W. System COP needs to be evaluated for the heating test matrices as well.

An actuator valve has been integrated into the system design in order to automate the process of switching from heating to cooling modes and vice-versa. The actuator will allow system operators to seamlessly transition between operating modes with the selection of a button instead of manually having to turn the valve. The actuator is a GM part initially designed and utilized in the automotive industry. In the design of the PBTC it has been retrofit and mounted to the existing manual valve utilizing a custom bracket. The actuator requires an input voltage of 12 V and a varying signal voltage is then utilized to control the position of the valve for cooling and heating modes. The valve has been oriented on the mounting bracket such that a signal voltage of 0 V corresponds to the heating mode and 8.66 V corresponds to the cooling mode. The actuator has been extensively evaluated to ensure it supplies sufficient torque and is capable of transitioning the system between heating and cooling modes effectively. Presented in figure 26 is a depiction of the actuator mounted to the valve on the breadboard.

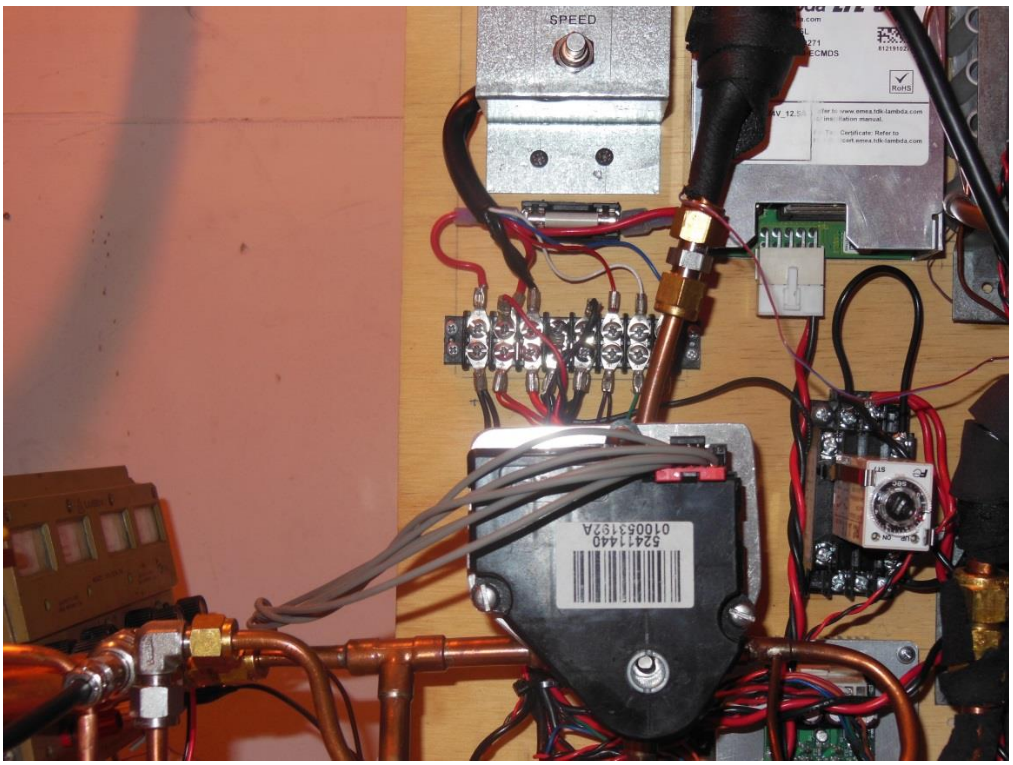

Figure 26. Actuator valve for PBTC installed on system breadboard

A flow meter has been integrated into the system design to both protect system operational integrity as well as assist in the control scheme of the appliance. The sensor is a disposable PVDF turbine flowmeter that is compact in size and capable of accommodating a volumetric flow rate from 0.03 L/min to 2.0 L/min of water. The meter is manufactured by Equflow® sensors and is specifically intended for medical and bio-technological applications. Having a flow sensor is a much more reliable method to controlling water flow rate through the blanket than curve fitting pump flow rate vs. signal voltage. Presented is pictorial representation of the flowmeter along with a dimensional drawing.

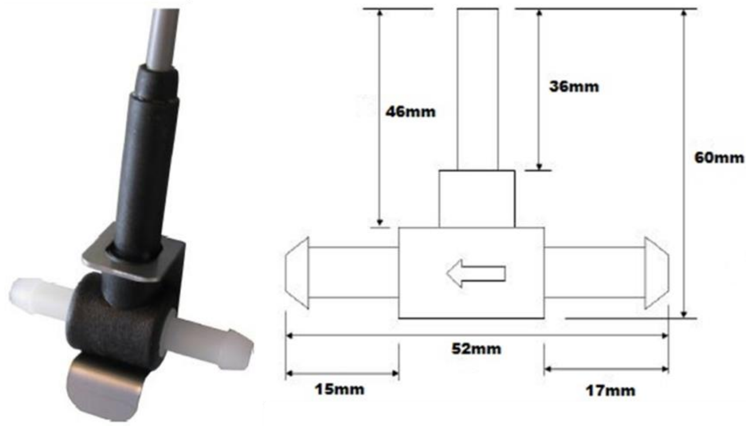

Figure 27. Water flowmeter for PBTC

As displayed in the dimensional drawing, the geometry of the flow meter is small, especially in comparison to similar devices. Additionally, the sensor is light in weight making it ideal for portable applications. All identified and specified system components have been fully integrated into the model of the PBTC. A model of the prototype, fully updated with all system components at its current state, is presented in figure 28. The actuator valve and flowmeter are specifically identified.

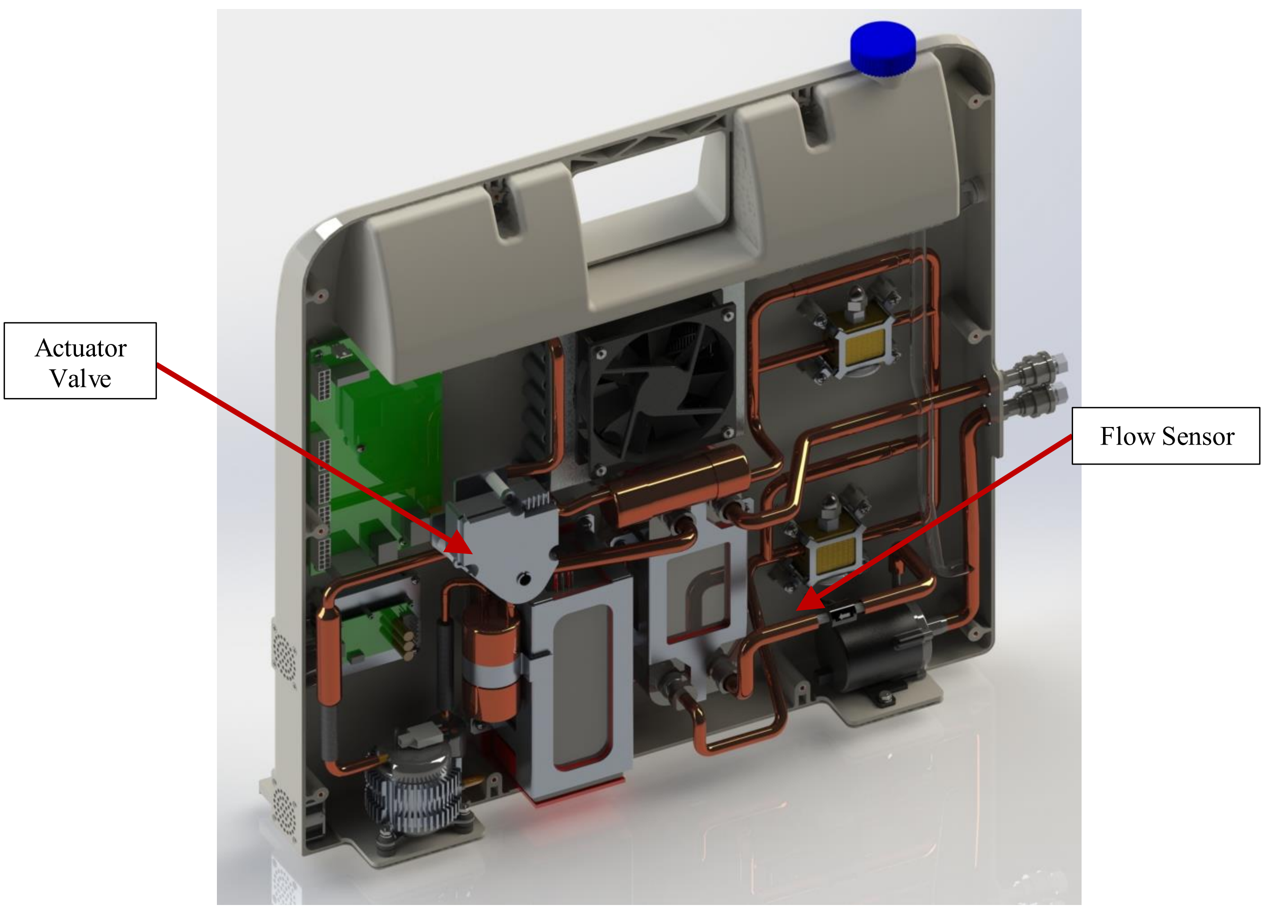

Figure 28. PBTC layout with all functioning system components

System power consumption has been broken down and analyzed on an individual component basis. The power utilization breakdown was based on maximum power consumption of each system component. Presented in figure 29 is a pie chart depicting the comparison in power consumption for all electrical system components. For each section of the chart the individual component power consumption is presented in watts along with the fractional percentage of system power utilization.

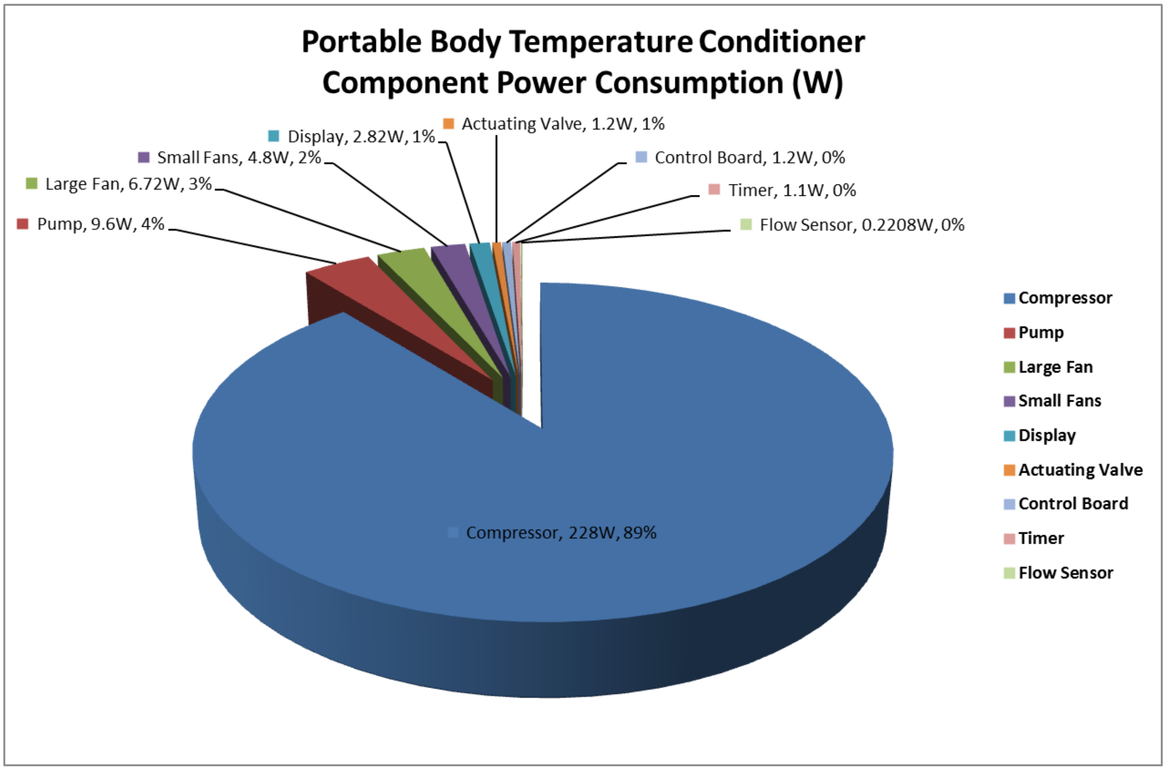

Figure 29. PBTC power consumption breakdown of electrical components

As demonstrated from the figure, the majority of the power consumption is attributed to the compressor at over 89% and 228 W. The second largest draw comes from the pump at 9.6 W and only 4% of overall power consumption. Again, it is important to recognize that these are worst case operating conditions. The actuating valve, for example, only has a current draw when switching between heating and cooling modes. The time frame required switching between heating and cooling is minimal, approximately 10 seconds, and otherwise the actuator consumes no power. Furthermore, the power consumption for the compressor, pump, and fans are all calculated assuming maximum operating speeds.

3c. Control Logic and Testing

The control logic flow diagram has been developed for the PBTC. The diagram has been structured in a decision tree hierarchy format resulting in fourteen different operation modes. Presented is a list of the defined operating modes along with a brief description of each:

1) **Off Mode** – The appliance is off and non-operational
2) **Idle Mode** – The appliance is on, displaying system temperatures, but not operational
3) **Gradient Heating Mode** – The appliance is heating according to the gradient heating algorithm
4) **Gradient Maintain Mode** – The appliance is maintaining temperature according to the gradient maintain algorithm

5) **Gradient Cooling Mode** – The appliance is cooling according to the gradient cooling algorithm
6) **Auto Heating Mode** – The appliance is heating according to the auto heating algorithm
7) **Auto Maintain Mode** – The appliance is maintaining temperature according to the auto maintain algorithm
8) **Auto Cooling Mode** – The appliance is cooling according to the auto cooling algorithm
9) **Manual Heating Mode** – The appliance is heating according to the manual heating algorithm
10) **Manual Maintain Mode** – The appliance is maintaining temperature according to the manual maintain algorithm
11) **Manual Cooling Mode** – The appliance is cooling according to the manual cooling algorithm
12) **Safety Default Mode** – The appliance is non-operation due to a safety default
13) **Connection Default Mode** – The appliance is non-operational due to a connection default
14) **Flow Default Mode** – The appliance is non-operation due to a lack of water flow through the system

The operating modes for the control logic diagram have been developed such that they are suitable for boolean logic implementation. The boolean expressions for the different operating modes has also been defined. Control algorithms for the heating, cooling, and temperature maintenance modes still need to be constructed and evaluated for performance integrity and reliability. Proportional-integral-derivative (PID) controls need to be defined for each control mode and will need to be optimized for premium temperature maintenance under all operating conditions.

Preliminary design of the keypad utilized to operate the PBTC has been implemented. Button design was employed to strategically guide the user through selecting one of the appropriate user specified operating modes as described above. Feedback from qualified medical personnel may result in modifications to the keypad. Presented is a model representation of how the keypad of the PBTC is intended to appear.

Figure 30. User interface keypad for PBTC

As presented in the figure, the keypad consists of buttons and indicator LEDs. The "AUTO" button allows the user to achieve auto control modes. The user is then required to select either traditional auto control or gradient auto control. The up and down arrows can be utilized to scroll through available set point temperatures and chose the desired temperature with the "SELECT" button. Once a set point temperature is specified the control logic automatically determines an operating mode based on the set point temperature relative to the measured temperature. The "MANUAL" button allows the user to specify set point temperature for the water circulating through the blanket utilizing the up and down arrows along with the "SELECT" button. The "C°/F°" button allows the user to switch between the depicted units of temperature on the display. The "SAFETY TEST" button is to ensure that the safety indicators and LEDs are effective and operating correctly. The "BLACKOUT" button allows the LCD backlight of the display to be dimmed and shutoff for discreteness when operating the device in the field. The "STOP" button shuts off heating or cooling of the appliance and puts the device in an idle mode where the temperatures are still displayed. LEDs serve as indicators for varying system functionality. The blue LED implies the unit is cooling, the green that the unit is maintaining target temperature, and the orange that the unit is heating. The red LED is a visual safety alert indicator.

The temperature probe utilized to measure patient body temperature has been identified, acquired, and assimilated into the system design. The sensor is a YSI 400 series reusable probe that has been approved by the FDA for applications such as that of the PBTC. Furthermore, the sensor is currently utilized in comparable patient thermal management devices to that of the PBTC. The YSI 400 has an operation temperature range of 0°C to 60°C with an accuracy ±0.2°C from 0°C to 60°C and an accuracy of ±0.1°C from 25°C to 45°C. The probes are considered to be dependable, repeatable, and interchangeable making them ideal for utilization in the PBTC. The YSI 400 supports the utilization of disposable skin, esophageal, oral, and rectal probes. Currently, Measurement Specialties MEAS 4400 series surface temperature sensors have been acquired for initial system evaluation. Figure 31 is a model portraying the probe configuration integrated into the case design.

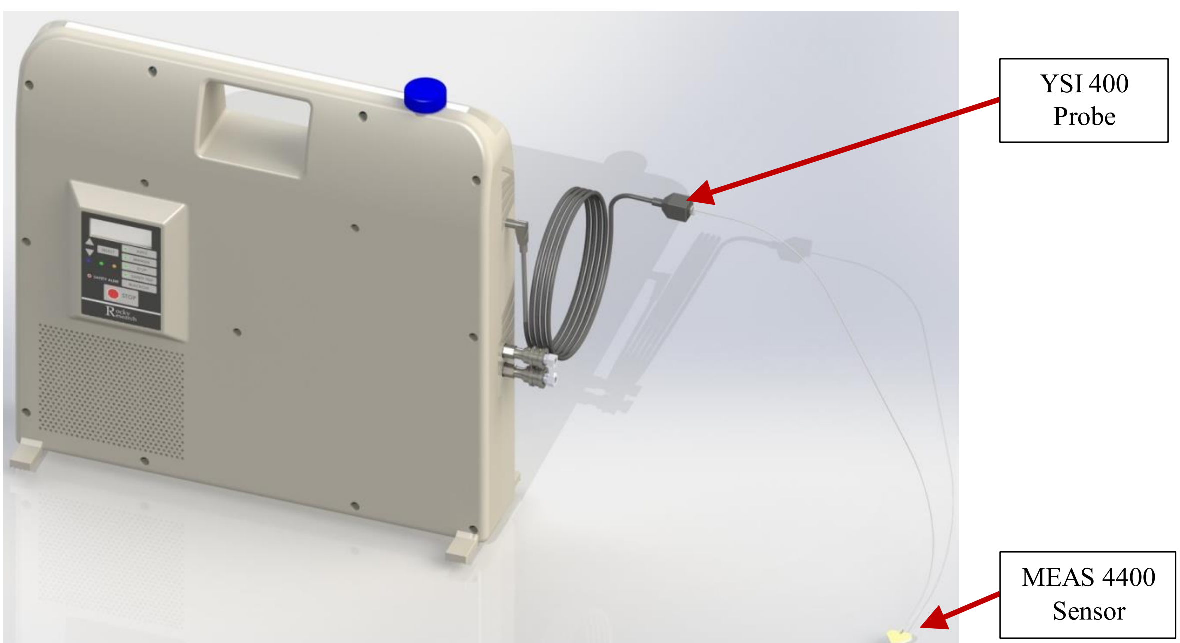

Figure 31. Comprehensive case design with keypad and temperature probes

Stability analysis on the PBTC prototype has been investigated to evaluate the steadiness of the appliance. Currently, feet have been sized to allow the device to tilt 15° before the center of gravity of the PBTC surpasses its base, the point at which the device will tip over. Since the center of gravity is skewed slightly towards rear of the appliance it is more susceptible to tipping backwards than forwards. The feet support tipping 15° backwards, not forwards. Presented in figure 32 is a drawing showing the tilt perspective of the point at which the appliance will tip over. The center of gravity is clearly indicated on the drawing along with a line that shows at the 15° tilt angle the center of gravity is vertically in line with the base edge of the foot. Units of length are depicted in inches.

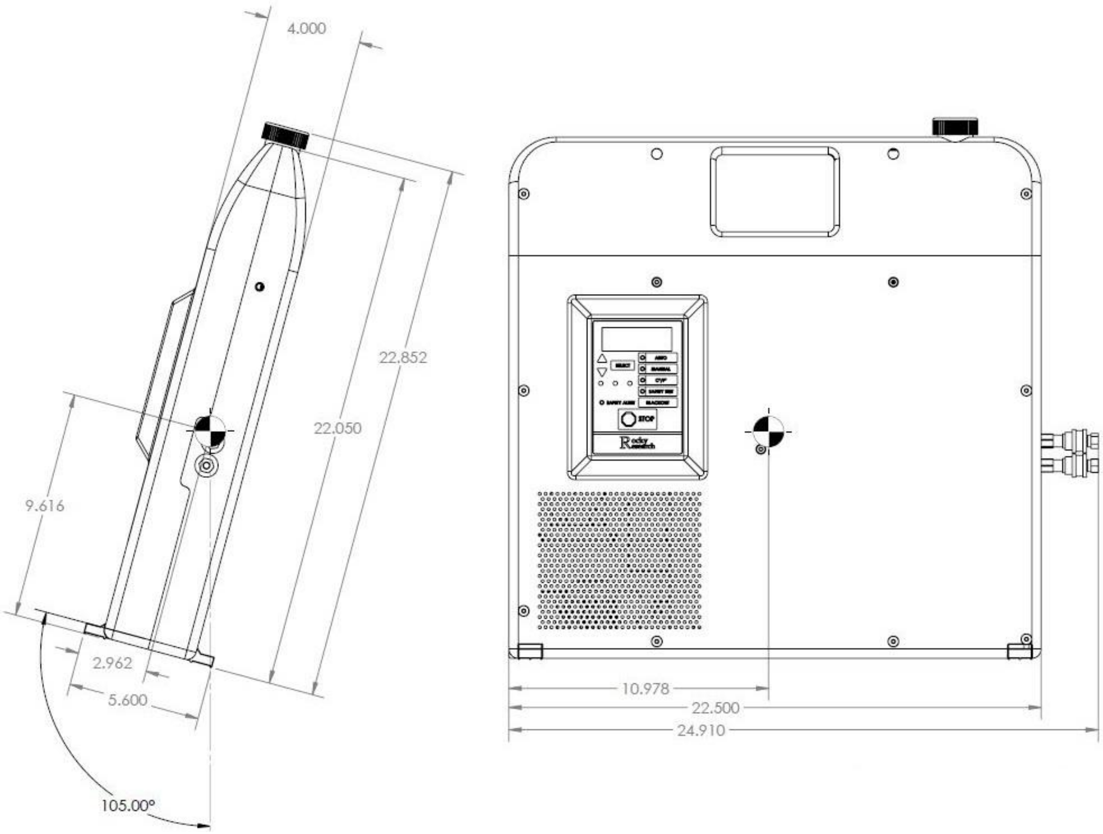

Figure 32. PBTC tipping diagram

The PBTC prototype is currently predicted to weigh approximately 31lbs. The feet length required to accommodate a 15° tilt is 0.8in. Free body diagram analysis leads to a required force of approximately 3.6lbs in the plane normal to the front display at the top of the fill cap in order to tip over the appliance. The current case design will be fabricated with removal and interchangeable feet of different lengths. Such an approach will allow final system design to be employed with an optimal balance between stability, transportability, and aesthetics.

Summary of Work Performed by UNSOM

Over the past project year, UNSOM has focused on hiring additional consultants to aid in the completion of the patient simulation testing. This includes a bio-heat transfer engineering expert and a consultant with expertise in risk management and FDA project development planning. This additional expertise will aid in the development and performance of a sound scientific study, as well as maintain the necessary regulatory standards/steps toward eventual 510(k) submission and FDA clearance of the medical device.

Additionally, UNSOM has focused its efforts on writing and testing the thermal manikin validation methods.

Task 4: Patient Load Simulation Testing (Months 9 – 24). In Progress

4a. Write the Test and Validation Methods

UNSOM has begun to develop the testing methods for the patient simulation testing. The addition of a bio-heat transfer expert to the team was a necessary asset in finalizing the patient simulation testing methods. This individual has experience in thermal fluids and bio-heat transfer and has published in medical journals for his work with continuous arteriovenous patient warming methods. The test methods for the patient simulation testing are expected to be completed within the upcoming quarter.

UNSOM has completed writing the protocols for the thermal manikin validation methods, and the SOP for the "Equipment Validation Procedure" has been finalized. This SOP describes the procedure for the Installation Qualification and Operational Qualification portion of the thermal manikin validation. This procedure ensures that the thermal manikin is installed and operating according to its intended use as outlined by the manufacturer. The Performance Qualification portion of the manikin validation has been drafted and the procedure tested by UNSOM personnel. However, the Performance Qualification protocol's finalization is pending the approval by the bio-heat transfer/engineering expert. This precaution is necessary to ensure a sound scientific study and will benefit the study in its entirety.

4b. Receive/Training on Thermal Manikin/Software

The thermal manikin "Newton" was purchased from Measurement Technology Northwest (MTNW), which is a Seattle based company specializing in the manufacture of thermal manikins and associated accessories. The manikin was originally scheduled to be delivered at the end of August; however there was a slight delay in fabrication by MTNW. Fabrication of the manikin was completed and shipped from MTNW on 07-Sep-2012. UNSOM received the thermal manikin and associated accessories on 11-Sep-2012.

UNSOM and Rocky Research have completed training on the thermal manikin and software provided by Measurement Technology Northwest (MTNW). Training on the use and maintenance of the thermal manikin was completed over two days, from September 26-27, 2012. Personnel from MTNW personally trained UNSOM and pertinent Rocky Research staff on the general use and maintenance of the thermal manikin and associated software. This included system set-up and startup procedures, operation of the various control modes, basic safety precautions/procedures, and general maintenance/calibration procedures. Also included with the training session, MTNW personnel assembled and tested the thermal manikin "Newton" and the associated accessories/software. This testing was a part of the installation and operational qualification portion of the manikin validation.

4c. Validation of Thermal Manikin

Procedure for Manikin Validation

Measurement Technology Northwest performed part of the validation procedure for the thermal manikin during the assembly/training session held in September 2012. The installation qualification (IQ) included documentation of the activities necessary to establish that the manikin was received and functions as was designed and specified. The operational qualification (OQ) included the documentation of the testing necessary to establish that the manikin will function according to its operational specifications.

Additionally, MTNW trained UNSOM and Rocky Research personnel on how to do performance checks/calibration during routine maintenance, which will encompass performance qualification (PQ). PQ is the documentation of activities necessary to establish that the manikin consistently performs according to defined user specifications. Currently, the performance of IQ and OQ have been completed, however, final documentation is pending on the completion of the PQ. The testing procedures for PQ are currently drafted and were designed to test the thermal manikin's performance simulating a patient in cold, neutral, and hot environments. Additionally, a testing procedure for the calibration of the thermal manikin's sweating fluidics has been drafted as part of periodic maintenance protocols. However, finalization of the PQ testing methods is pending on the hiring of a bio-heat transfer expert. The completed documentation of IQ, OQ, and PQ will be finished as part of the thermal manikin validation.

Optimization of Performance Qualification Procedure

UNSOM has begun to test the performance qualification procedures as part of the thermal manikin validation. The experiment is being performed within a temperature controlled environmental chamber at cold, neutral, and hot ambient temperatures. These experiments were performed to optimize the specified ambient temperatures and duration time. The following steps outline the current performance qualification validation procedure. The results of these experiments will be reviewed by the contracted bio-heat transfer expert, and adjustments may be made prior to the finalization of the Performance Qualification testing method.

- Instrument Preparation
  - The thermal manikin is appropriately dressed and all necessary connections made between the manikin, power supply, and fluid reservoir. The power enclosure and fluid pump are powered on.

- Experimental Procedure
  - The thermal manikin is simply dressed in the sweating skin only and placed supine on a table within the environmental chamber.
  - Prior to the experiment start, the environmental chamber is set to the specified temperature (cold, neutral, or hot) and allowed to reach steady state.
  - After the chamber has reached temperature, the thermal manikin is powered on and allowed to acclimate to the ambient conditions.
  - Once the thermal manikin has acclimated to the ambient conditions, the physiological software "Manikin PC2" is started and the experiment "Model Control" run.
  - The manikin is now running under the control of the physiological software which accounts for conditions such as; vasodilation, vasoconstriction, sweating, metabolic activity, circulation, and conduction/convection/radiation heat loss. The physiological software simulates the thermoregulatory response of a healthy individual based on the environmental conditions.
  - The experiment was allowed to run for approximately 2 hours and repeated over multiple days.

The data collected was compared over multiple days for simulated core body temperature and body average skin temperature. The data is depicted in figures 33-38 for cold, neutral, and hot ambient conditions.

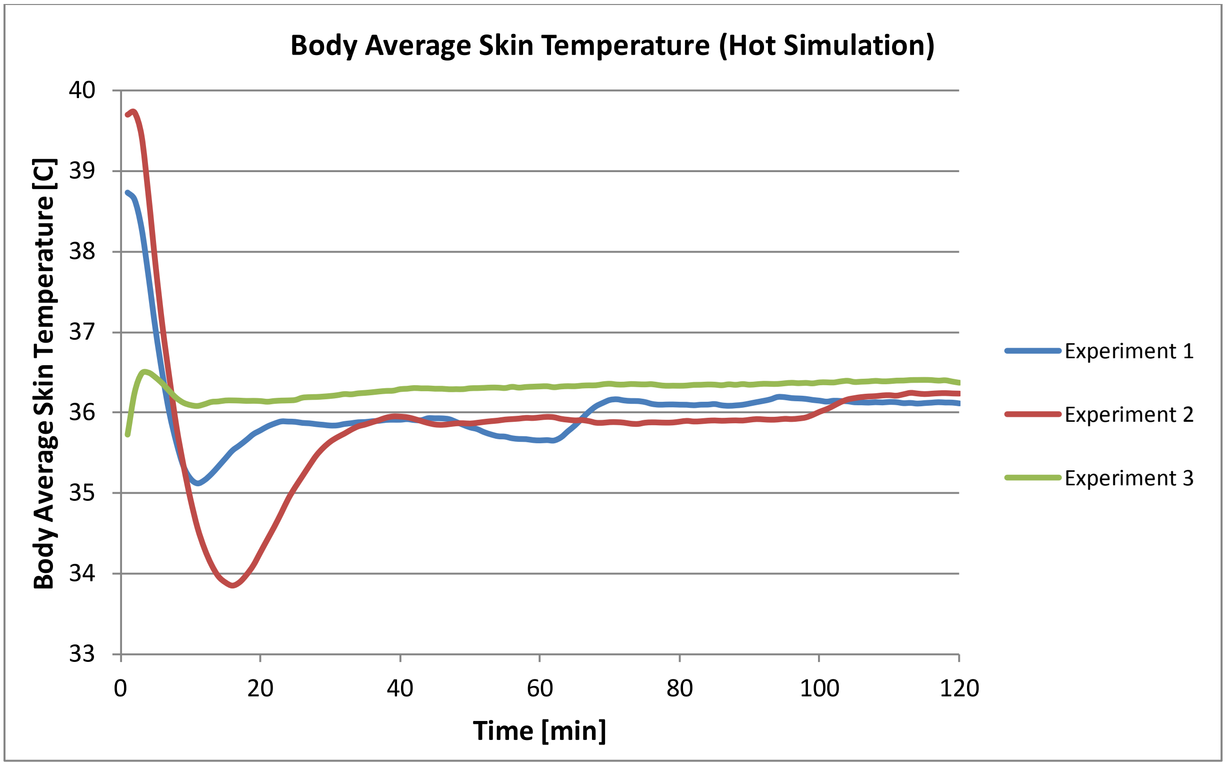

Figure 33. Comparison of body average skin temperature of thermal manikin in hot ambient conditions

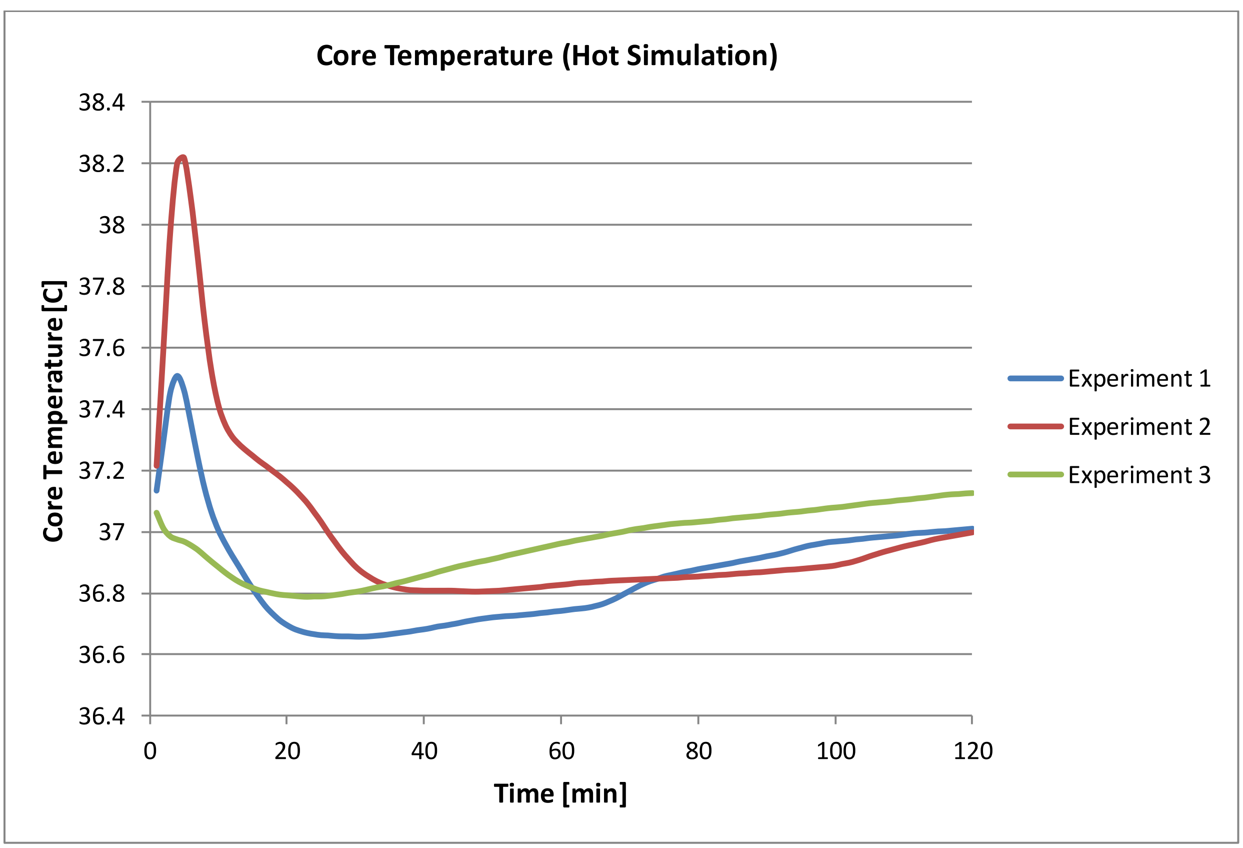

Figure 34. Comparison of core temperature of thermal manikin in hot ambient conditions

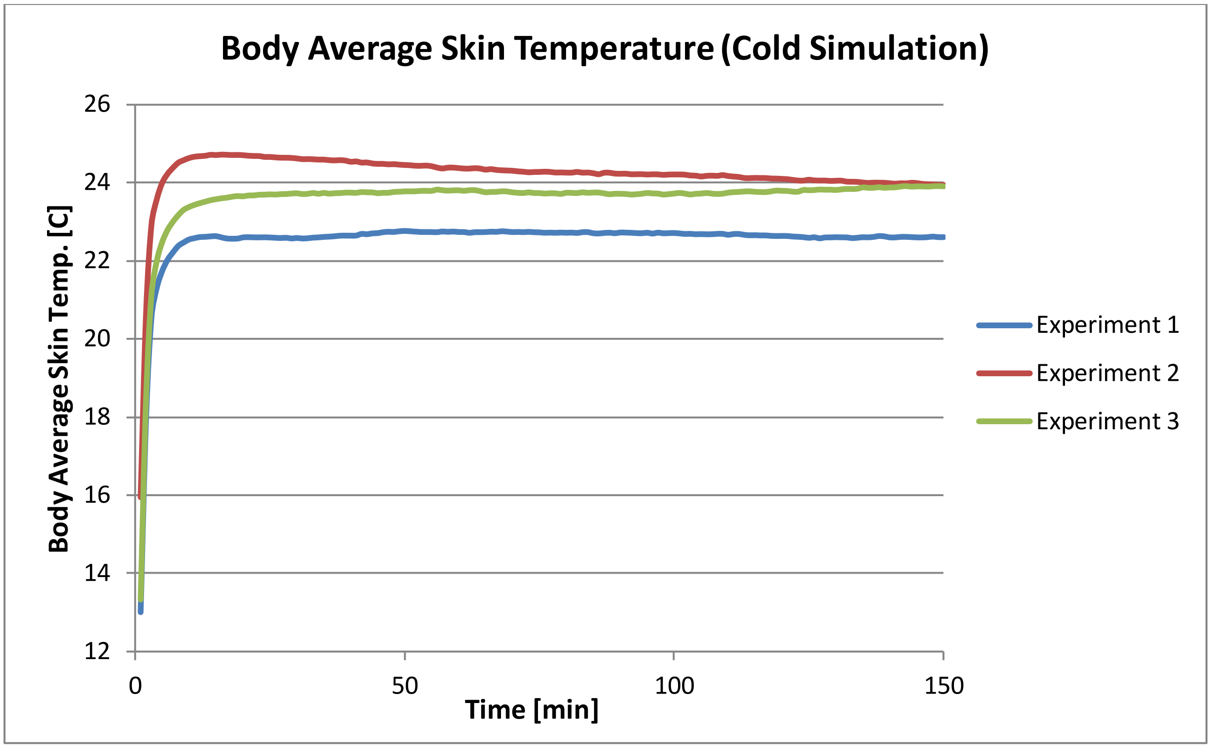

Figure 35. Comparison of body average skin temperature of thermal manikin in cold ambient conditions

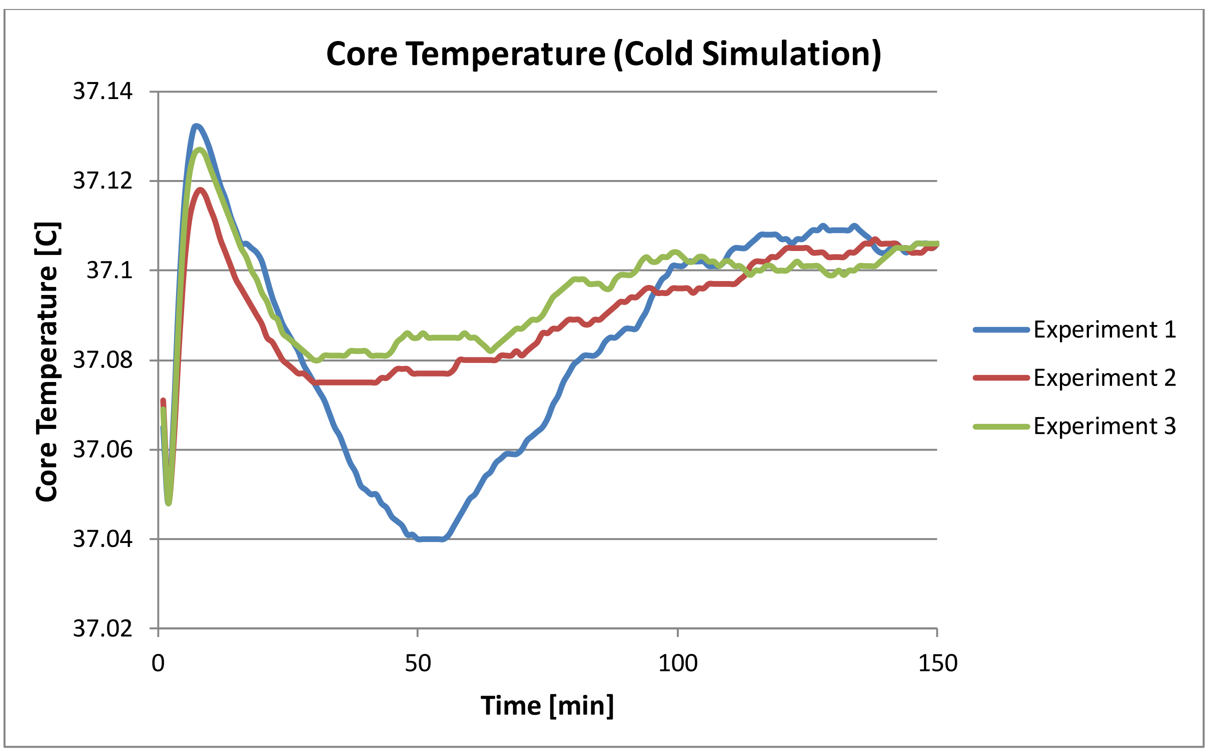

Figure 36. Comparison of core temperature of thermal manikin in cold ambient conditions

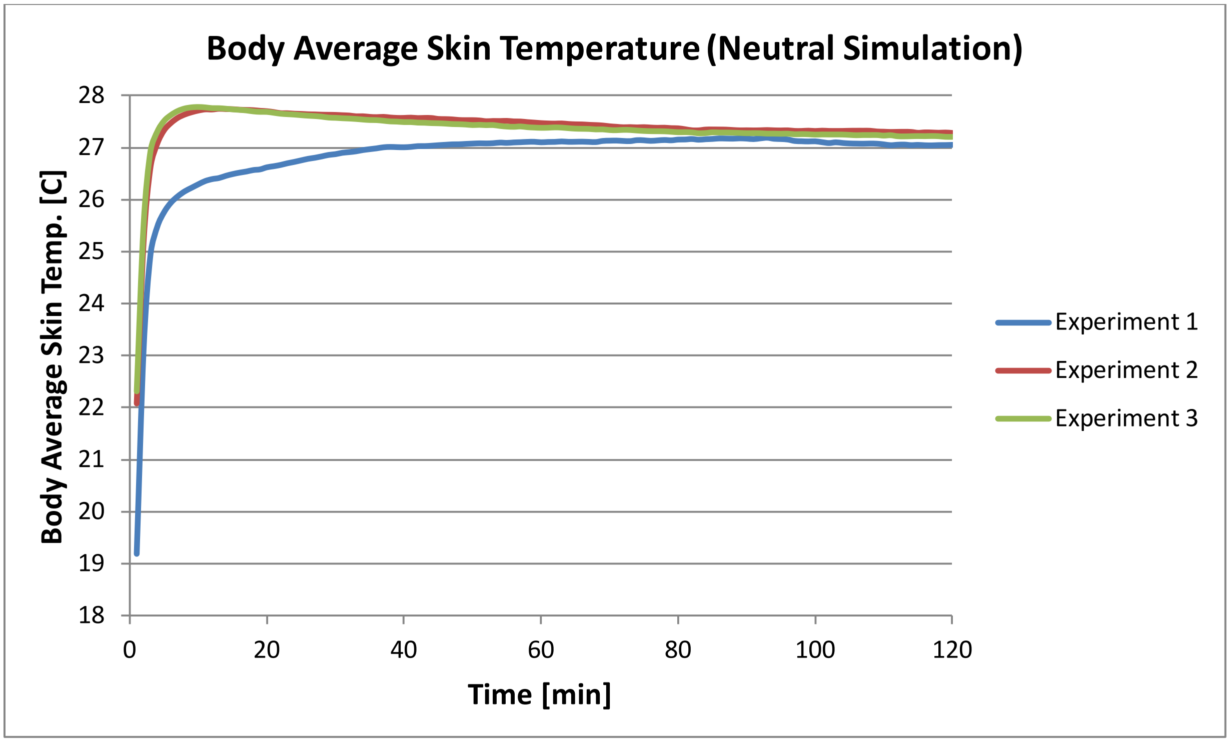

Figure 37. Comparison of body average skin temperature of thermal manikin in neutral ambient conditions

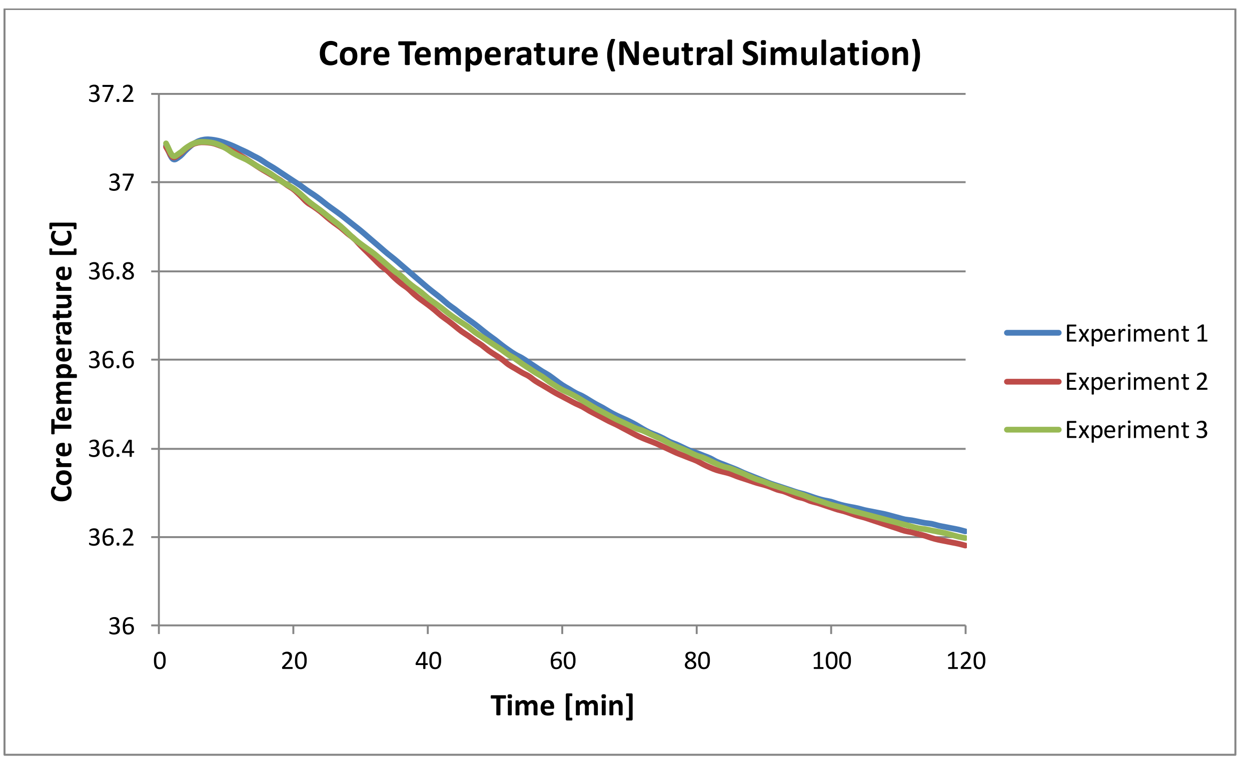

Figure 38. Comparison of core temperature of thermal manikin in neutral ambient conditions

KEY RESEARCH ACCOMPLISHMENTS:

The following were accomplished in the past year:

- Methods were developed for utilizing Newton, the thermal manikin, to gauge and quantify PBTC heating and cooling capabilities. System analysis was implemented utilizing these testing procedures to quantify capacities and different ambient and operating conditions.

- Heat sinks for the compressor and compressor control board have been designed, sized, fabricated, and tested for effectiveness in order to mitigate concerns of overheating. The compressor has been operated for extended periods of time to ensure long term functional integrity of system.

- The TXV orifices on both the heating and cooling sides were modified to better modulate refrigerant flow into the evaporator at an optimal proportion to the evaporation rate of the refrigerant in the evaporator.

- A discrepancy in the required refrigerant charge between optimal performance of the heating and cooling cycles was identified. In order to accommodate the additional charge required for the heating cycle a separate refrigerant reservoir was designed and sized to allow the additional charge to be available during the heating cycle and stored in the reservoir during the cooling cycle.

- An accumulator was designed, assembled, and integrated into the system implementation in order to eliminate liquid refrigerant droplets from flooding the compressor. The accumulator is a custom fabrication specifically designed and tested for the PBTC.

- Vibration dampers have been incorporated into the design of the PBTC at the suction and discharge lines of the compressor to mitigate concerns of mechanical failure.

- A control logic diagram was constructed to identify the operating modes of the appliance. Furthermore, the boolean logic expressions were defined for each operating mode based on the decision tree hierarchy of the logic diagram. Safeties and system defaults were also identified and integrated into the control logic design.

- A keypad design has been developed based on the user inputs require to guide the user through properly selecting an operating mode. An LCD display has also been specified and acquired for the system.

- An actuator valve was identified, sized, and retrofit in order to automate the process of switching between heating and cooling modes.

- Temperature probes were identified, attained, and assimilated into the system design for monitoring patient body temperature. A flowmeter was sized and acquired to be utilized in the control scheme for optimal temperature maintenance by allowing the heat transfer rate to be monitored in and out of the system. It will also be utilized to ensure water flow is present when operating the device.

- Several modifications were made to the case design of the PBTC to accommodate additional system components such as the accumulator, actuator, and refrigerant reservoir. Additionally, a water storage reservoir has been integrated directly into the case design and stability analysis was implemented on the case to evaluate how easily the case may tip over.

- Patient Simulation Testing: UNSOM and Rocky Research personnel were trained by MTNW staff on the basic use and maintenance of the thermal manikin and associated software. Additionally, UNSOM began the hiring process for a bio-heat transfer engineering expert and an additional FDA consultant with expertise in risk management and FDA project development planning.

- Implementing QSR: Currently, twenty SOP's have been implemented. UNSOM continues to work with an FDA consultant as part of QSR compliance, and has hired an additional consultant as part of a focus on meeting necessary regulatory standards/steps towards eventual 510 (k) submission and FDA clearance of the medical device.

CONCLUSIONS:

Defense medical installations require efficient and reliable equipment for the thermoregulation of either injured or ill patients. However, effective methods for warming/cooling injured patients during medical evacuations in the absence of a reliable power source are currently unavailable. The current research will yield a portable, reliable, intuitive device that will effectively maintain normal core body temperature during transport between various levels of combat casualty care. Similarly, the portable body temperature conditioner will also translate to civilian use as an essential tool for Emergency Medical Service (EMS) crews in response to emergency situations within the general public.

A custom built thermal manikin was purchased from Measurement Technology Northwest during the second year of the project. A training/installation session was held with personnel from MTNW during September 26^{th} and 27^{th} of 2012. UNSOM and pertinent Rocky Research personnel were trained on the basic use and maintenance of the thermal manikin. Additionally, Installation and Operational qualification procedures were completed during the scheduled training session with MTNW as part of the validation procedure. Utilizing the thermal manikin preliminary testing was implemented to analyze system heating and cooling capabilities at varying ambient and operating conditions. Several system adaptations were instigated based on results found during performance testing. Additional components were incorporated into the system design in order to ensure operational integrity, longevity, and performance. Each component was then extensively evaluated for effectiveness within the nominal operational regime of the appliance. The additional components include an accumulator, refrigerant reservoir, heat sinks, vibration dampers, and an actuator valve to automate the process of cycling between heating and cooling. Furthermore, modifications were made to existing system components, such as the TXVs, to enhance system capacities. A control logic diagram was constructed to identify and allocate the operating modes of the appliance. Safeties and system defaults were also identified and integrated into the control logic design. A keypad design has been developed based on the inputs require to guide the user through properly selecting a desired operating mode. A flowmeter was sized and acquired to ensure the presence of fluid flow. Patient temperature probes were identified, attained, and assimilated into the system scheme. The case design was updated and modified to accommodate the additional components as well as the specified LCD display and keypad design. A water reservoir was incorporated into the case design and initial stability analysis was implemented on the case.

UNSOM began the hiring process for a bio-heat transfer engineering expert, and an additional FDA consultant with expertise in risk management and FDA project development planning. The engineering expert has been assisting UNSOM with the development of the validation and patient simulation testing methods. Additionally, UNSOM continues to work with a FDA consultant as part of QSR compliance, and has hired an additional FDA consultant as part of a focus on meeting necessary regulatory standards/steps towards eventual 510 (k) submission and FDA clearance of the medical device.

PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

The project is still in the fabrication phase of the prototype and patient simulation testing of the device has not yet begun. As such, no abstracts, presentations, publications or other equivalent reportable outcomes have been produced from this research at this time.

INVENTIONS, PATENTS AND LICENSES:

No inventions, patents, or licenses have been produced or issued for this reporting period.

REPORTABLE OUTCOMES:

Currently, the project is still in the fabrication phase of the prototype and patient simulation testing of the device has not yet begun. As such, no commercialized products have been produced during this reporting period.

OTHER ACHIEVEMENTS:

Not Applicable

AWARD PARTICIPANTS:

The number of individuals participating on this project and receiving salary support from this USAMRAA award during this reporting period is listed below.

Organization	Number of Supported Individuals
UNSOM	3
Med-School Associates South	2
Rocky Research	8
Total Number of Supported Individuals	**13**

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