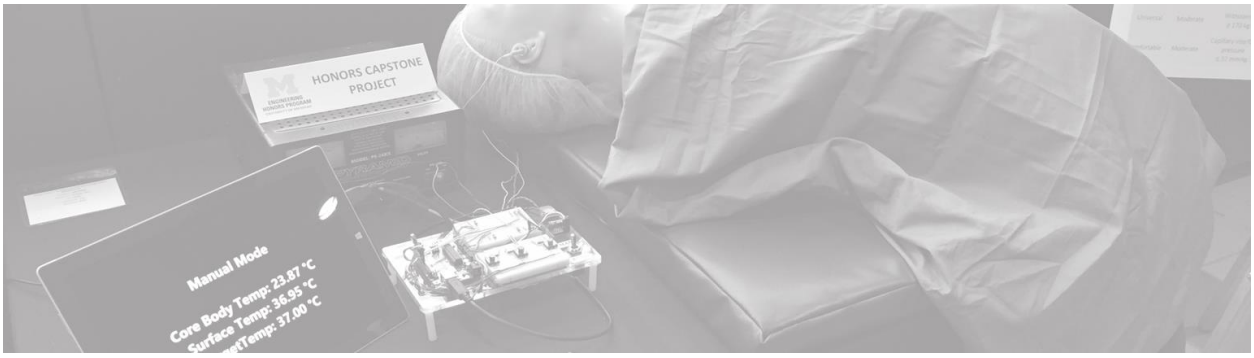
COLLEGE OF ENGINEERING
MECHANICAL ENGINEERING
UNIVERSITY OF MICHIGAN

MECHENG 450 | Design & Manufacturing III | Fall 2015

Device to perioperatively regulate patient temperature for low-resource settings

Team 6: Sam Dion | Ben Lewis | Kerstin Nilsson | Ryan Thomas



Sponsors

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Phi Kappa Phi Project Grant
The Honor Society of Phi Kappa Phi
Chapter 39, University of Michigan

Executive Summary

Perioperative hypothermia, or a reduction in core temperature due to anesthesia, occurs in 50 - 90% of patients undergoing surgery [1, 2] and can result in adverse outcomes for the patient, including reduced wound healing, increased risk of infection, prolonged hospitalization, increased cost, and discomfort [1, 3, 4, 5]. Based on observations collected in the Dominican Republic during summer 2015, there is a need for an active warming method for low-resource settings to prevent perioperative hypothermia [6] .

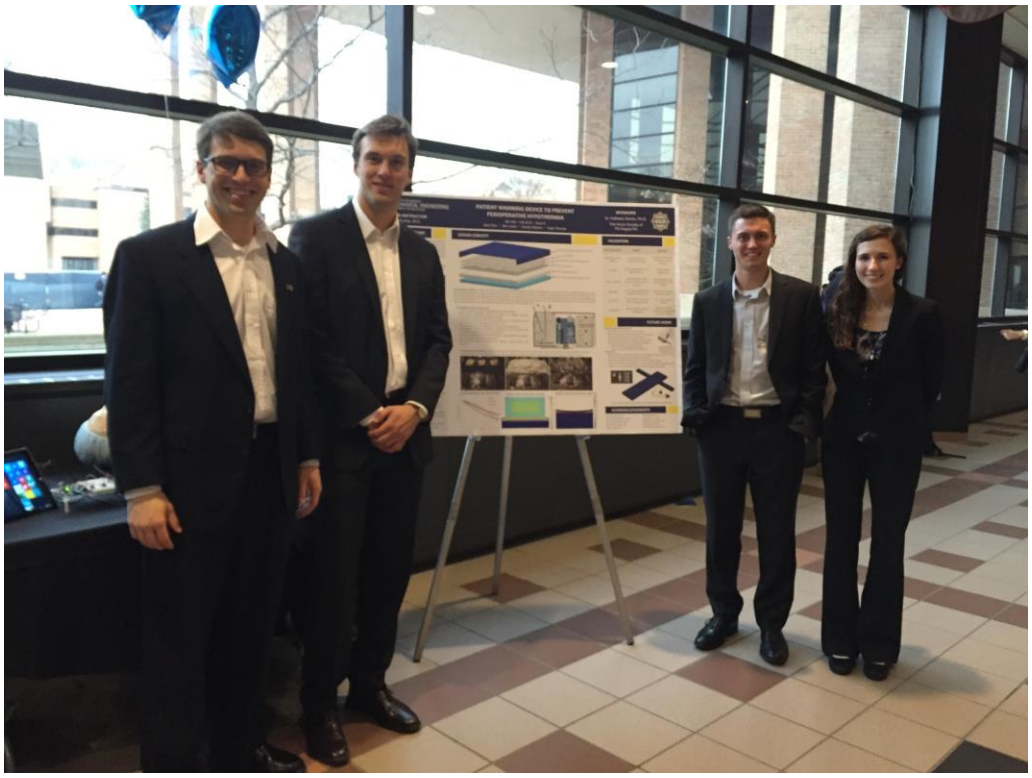
Products on the market used to prevent perioperative hypothermia range from forced air to convective water flow to infrared warming but fall short in that they lack feedback systems and require manual operation, are not reusable and require expensive disposables, and are often designed for specific surgeries. The main requirements we have been asked to meet by our stakeholders include minimizing cost and accommodating most surgeries and patients, and our design is driven by its ability to effectively transfer heat to the patient, be cleaned by 1:10 bleach solution, and require minimal user input.

Our engineering analysis involved both theoretical and experimental tests. We tested resistances and power outputs of heat-generating materials, reviewed literature and performed experiments to determine the bleach resistance of materials, performed thermal conductivity testing and theoretical heat transfer calculations, and reviewed the accuracy and precision of non-invasive thermometry techniques compared to gold standards. We also performed experimental heat depletion tests for the selection of our over body design and modeled the system in COMSOL to determine power output needed from the heating element.

Our design is a system that includes the following components: underbody resistive heating mattress to be placed over the operating bed to provide radiant and conductive heat to the patient, insulating surgical drapes to prevent radiant and convective heat loss, tympanic membrane thermistor for non-invasive thermometry, and temperature control unit with internal sensors as fail-safes. The mattress incorporates open cell polyurethane foam for support, viscoelastic foam for pressure distribution and comfort, a radiant heat deflector to direct heat upward, insulated resistive wire, a polyester fill to diffuse heat to the surface, and a polyurethane coated nylon fabric covering for washing and avoiding contamination. The surgical drape is made of cotton linen to absorb fluid and PET coated Mylar® to prevent radiant heat loss. The PID temperature controller consists of an automatic mode driven by core temperature measurement with the tympanic membrane thermistor and includes fail-safe temperature readings and a manual mode featuring three adjustable temperature buttons.

We manufactured a 2’ by 2’ section of the mattress for proof-of-concept and to perform validation testing. A COMSOL model simulated heat transfer between our device and metabolically active patient under surgery to verify our heat transfer requirement, qualitative assessments were administered to gather data from a small random sample to validate our requirements of ease-of-use, comfort and aesthetics, costs for the full-scale prototype were verified, and another COMSOL model was used to calculate cycles to failure and deflection of our device under load. Future validation will primarily involve clinical trials evaluating the prototype's performance (heat transfer) in surgeries and expanding the qualitative user study for validation of patient mobility, durability, ease of use, comfort, and aesthetics requirements.

Our primary goals in moving forward with this project are optimizing materials, reducing material costs, scaling the heating element, designing the infrared tympanic membrane thermometer, developing the attachment mechanism for securing the mattress to the operating bed, transferring the control circuit to a PCB, and designing the control unit housing before manufacturing the full-scale prototype.



Team #6 at Design Expo (from left to right: Sam Dion, Ben Lewis, Ryan Thomas, and Kerstin Nilsson)

Prototype of patient warming device at Design Expo (December 10, 2015)

Contents

1 Introduction

1.1 Project Background

During the eleven-week period between May 20th and August 7th, 2015, team member Ryan Thomas conducted needs assessment in primary and secondary medical facilities in the Dominican Republic, specifically in the cities of Jarabacoa and Cabrera. The project was arranged independently as part of Ryan's College of Engineering Honors Program capstone experience, supervised by Dr. Kathleen Sienko, Associate Professor of Mechanical and Biomedical Engineering, along with teammates Sam Dion, Ben Lewis and Kerstin Nilsson who engaged in teleconference meetings during topic selection. The project aimed to identify challenges in emergency care, transportation and surgery in the Dominican Republic.

Ryan conducted interviews with physicians and clinicians as well as documented observations for the first four weeks in the public hospitals and private clinics in Jarabacoa and Cabrera. Most research during this time was focused in the emergency departments, and the goals were to establish relationships with the hospital administration, physicians, staff and local interpreters, familiarize himself with the health care system, and begin compiling need statements with associated problem statements.

With the needs identified from the first month, Ryan spent 3.5 weeks in both Jarabacoa and Cabrera to filter down the list of need statements based on impact on the patient and community, feasibility, scalability, expert opinion and team interest. Most research was conducted in the surgery department and in the operating room (Figure 1, 2), and significant time was spent collecting data to determine user requirements for potential solutions and forming relationships with stakeholders who could be contacted to assist project development back at the University of Michigan.

Figure 1: Entrance to operating room in Jarabacoa, D.R. [*Personal Photograph by Rvan Thomas. 3 Jun 2015.*l

Figure 2: Operating room in Cabrera, D.R. [*Personal Photograph by Ryan Thomas. 4 Aug 2015.*].

Upon return to the University campus, our team selected our project topic to address the need for a method to regulate patient temperature during surgery to prevent a significant drop in patient temperature and the complications that can arise. Dr. Kathleen Sienko assumed the role of our project mentor during our fall coursework in MECHENG 450, Design & Manufacturing III to develop a functional prototype of our device solution.

1.2 Problem Description

Core body temperature is typically regulated in a tight range, but, when under general anesthesia or neuraxial anesthesia, the body's ability to control temperature is impaired. This results in a core-to-peripheral redistribution of body heat and a reduction in core temperature; this temperature drop is escalated by exposure to a cool surgical environment, administration of unwarmed intravenous fluids, and evaporation from surgical incisions [1, 2]. In fact, core-to-peripheral redistribution of body temperature accounts for 89% of heat loss during the first hour of surgery and 62% in the time after that; the rest of this heat loss from the body during surgery is due to other heat loss mechanisms [7]. Consequently, a patient can become hypothermic during a surgical operation, known as perioperative hypothermia, which occurs in 50 - 90% of patients undergoing surgery [1, 2].

Perioperative hypothermia can result in adverse outcomes, such as cardiac complications, infection of the surgical site, impaired blood clotting, more frequent blood transfusions, negative nitrogen balance, delayed wound healing, delayed recovery from anesthesia, prolonged hospitalization, shivering, and patient discomfort [1, 3, 4, 5]. In fact, a 2 ^{o}C drop in core body temperature in surgery triples the incidence of wound infection and prolongs hospitalization by around 20 percent, or roughly two additional days of hospitalization [5]. A 2012 study estimates the average cost per inpatient day to be $1,629 US, so just one extra day of hospitalization adds up [8]. Additional evidence shows that hospital costs can be reduced by $2,500 to $7,000 US per surgical patient by maintaining normothermia during operation [2, 9]; since maintaining normothermia reduces the risk for surgical wound infection, savings could be as much as $25,000 US (the average cost to treat a surgical site infection) [10].

Active and passive warming methods are used to treat and/or prevent perioperative hypothermia; passive methods include the use of linen or aluminum blankets and head covers, while active warming methods include the use of forced-air warming devices, fluid warmers and radiant heaters [2]. Prewarmed surgical patients need to be actively warmed during the operation if it lasts longer than one hour, and those without prewarming need to be actively warmed during surgery if it is to last longer than thirty minutes [1, 9]. However, methods for actively warming patients to prevent perioperative hypothermia in the Dominican Republic and other low- and middle-income countries are either lacking or non-existent, and only passive methods, such as the use of warmed solutions or linen sheets to cover the patient's body (Figure 3), are available [6, 11].

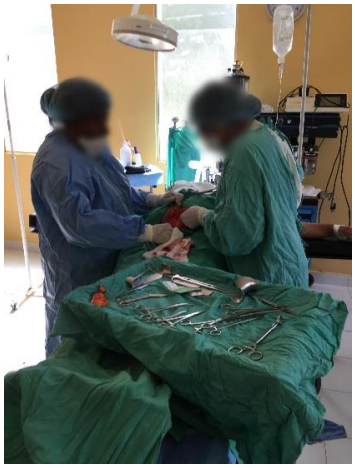


Figure 3: Gynecologist and nurse performing cesarean section; linen sheets cover the patient and wall-mounted air conditioning unit is running (in the background). [*Personal Photograph by Ryan Thomas. 29 Jul 2015.*]

Based on observations of surgeries (cesarean sections, appendectomies, gall bladder removals) collected in the Dominican Republic during summer 2015, there is a need for an active warming method for low-resource settings to prevent perioperative hypothermia; surgical patients experience uncomfortable episodes of shivering perioperatively and/or postoperatively, indicating cases of hypothermia during surgery [6]. This drop in core temperature is not only uncomfortable for the patient, but can negatively influence surgical outcomes, can prolong hospitalization and increase cost [9].

1.3 Project Scope

Based on eleven weeks of needs assessment and immersion in the Dominican Republic and reports from physicians and surgeons based in San Pedro Sula, Honduras, secondary facilities lack methods to actively warm patients during surgery; only passive methods by covering the patient with cotton sheets or warming intravenous solutions are available (with the exception of some private hospitals in Honduras having warming blankets and one having a forced air warming device) [6, 11]. Observations by the University of Michigan cohort in Ethiopia, under supervision of Dr. Kathleen Sienko and her Design for Maternal Health Program, suggest that active warming methods during surgery are lacking or inadequate, since patients left the operating room shivering [6]. Although user requirements for our current design are driven by stakeholders in the Dominican Republic and partly by those in Honduras and in the University of Michigan medical school, our design has the potential to scale to low-resource settings around the world where active warming methods during surgery are lacking or inadequate. In the context of the Mechanical Engineering 450 course, our project's scope will be limited to secondary hospitals in the Dominican Republic; we will strategize design decisions this semester to allow for future pivoting and scope expansion.

1.4 Project Mentors

This project is sponsored under the Global Health Design Specialization by Kathleen Sienko, Associate Professor of Mechanical and Biomedical Engineering. The Honor Society of Phi Kappa Phi financially sponsored the project with a Phi Kappa Phi Project Grant awarded in March of 2015.

Both Dra. Maria Plasencia, a general physician at the Hospital Municipal Octavia Gautier de Vidal in Jarabacoa, and Lucila Santana, the Director of Nursing at the Hospital Municipal Dr. Virgilio Garcia in Cabrera, serve as our primary stakeholders and contacts in the Dominican Republic. They are available by phone call and WhatsApp messaging.

Our team’s mentors on campus include Dr. Paul Reynolds, Pediatric Anesthesiologist in C.S. Mott Children's Hospital, and Dr. James Geiger, Pediatric Surgeon in C.S. Mott Children's Hospital. Additionally, we consulted with Dr. Shanna Daly, Josh Bishop-Moser, Michael Deininger, and Dr. Grant Kruger through Insitu. We received support from John Pitre, Jr., Dr. Roland Chen and Dr. Xudong Fan. We also maintain communication with Mirna Hernandez, a graduated medical student working in San Pedro Sula, Honduras, by email and WhatsApp; she has connected us with Tannia Calix, a graduated medical student, and Dr. Marcial Zuniga, a general surgeon, who both work in San Pedro Sula.

1.5 Benchmarking

There are numerous solutions and products currently in use that attempt to minimize the risk of perioperative hypothermia. Both passive and active warming methods are utilized throughout the world to

provide warmth for surgical patients. The secondary hospitals visited in the Dominican Republic relied solely on the use of passive warming through the use of linens. Patient body temperatures cool during preoperative care and drop further during operation; the surgical team uses linen sheets to cover the patient's body in attempt to keep to maintain the patient's body heat [6]. Any solution we provide must compete with the ease of use, convenience, and affordability of current products.

1.5.1 Existing Products and Patents

On the other end of the spectrum, forced air warming is widely considered the gold standard in patient warming. The 3M Bair Hugger (Figure 4), Stryker Mistral-Air Forced Air Warming System, and other forced air devices attempt to keep patient's body temperature steady by circulating heated air through disposable sheets [12, 13]. The sheets are laid under, over, and around the patient during surgery, covering varying amounts of the body. This method distributes heat over the body well through conduction and provides comfort for the patients. These devices have been criticized for the large volume they encompass when fully inflated and for the potential to blow contaminants and bacteria around the operating room.

Figure 4: Bair Hugger, over body forced air warming. Image retrieved from [12].

Other methods of active, over body warming come in the form of liquid (EasyWarm) or resistive heating (Hot Dog) blankets [14, 15]. These blankets can either be placed beneath the patient or be easily be molded to the contours of the body. Conduction transfers heat from the devices to the patients in a closed loop feedback system.

Underbody warming is also a popular method to regulate body temperature. Warming mats, like the Gelli-Roll, effectively provide patient comfort and warming exclusively through conduction on the backside of the patient [16]. PerfecTemp (Figure 5) utilizes similar resistive heating technology to other blankets on the market while integrating the heating elements into the bed cushions [17]. This solution provides a closed loop system that is enclosed in the bed and eliminates the need for further cleaning beyond current practices. Other unique solutions exist beyond heated blankets and pads. Intravenous devices work to warm IV fluids before entering the body, and specialized lamps can be used to produce infrared warming around the patient.

Figure 5: PerfecTemp, underbody resistive heating. Image retrieved from [17].

When conducting a search for research and modern innovations through patents, additional functionality and needs are discovered. One patent attempts to explore how customizable a forced air system can be. The proposed device would include flaps that may be easily added/removed based on the surgery location and patient size [18]. This customization helps limit the need to purchase numerous blankets of varying size and design. Another patent develops a closed loop feedback system that automatically turns off the device if a high temperature is sustained for a set amount of time [19]. This safety feature limits the chance for burns and discomfort. Heated mattresses can be made more effective by examining different materials to deflect and transmit heat in a directed manner [20]. Infrared warming lamps may also become more efficient as bulb design concentrates more heat over a small area [21]. These innovations should be considered as we attempt to increase the functionality of our product beyond current ability. There are few novel solutions/improvements that have appeared in this industry allowing us to think small while looking to make a huge impact.

The KOALA Warming System by NOVAMED is a conductive, underbody warming system designed for reuse. The product is advertised for its ability to conform to different beds and warm patients much more efficiently than forced air or water-based warmers. The X-ray and radio translucent mattress straps directly around the bed and utilizes an external control system. The mattress promotes complete patient access with silent operation to minimize impact on current surgical procedures. The system requires 75 Watts for operation [22].

This system mirrors many of the same features we had previously identified for our product. The temperature settings are 99°F, 100°F, 102°F, and 104°F and incorporates a thermistor to constantly measure the temperature of the mattress [22]. The mattress is covered in polyurethane coated nylon with welded seams for infection control. The warmer contains three internal layers as shown in Figure 6: the bottom layer is a pressure-relief memory foam that conforms to the patient's body and distributes weight and warmth, the middle layer is a patented carbon polymer sheet that provides consistent warming, and the top layer is cotton for enhanced comfort and pressure-relief [23]. We are looking to incorporate many of these features in our device and this new benchmark validates many of the design decisions we had previously made. Although this device fulfills our requirement for reuse, the device still requires outside input to function (no feedback loop), does not satisfy the aesthetic or attachment modes desired by or stakeholders, and does not fulfill our low cost goal (the KOALA system base cost is $6,000) [24].

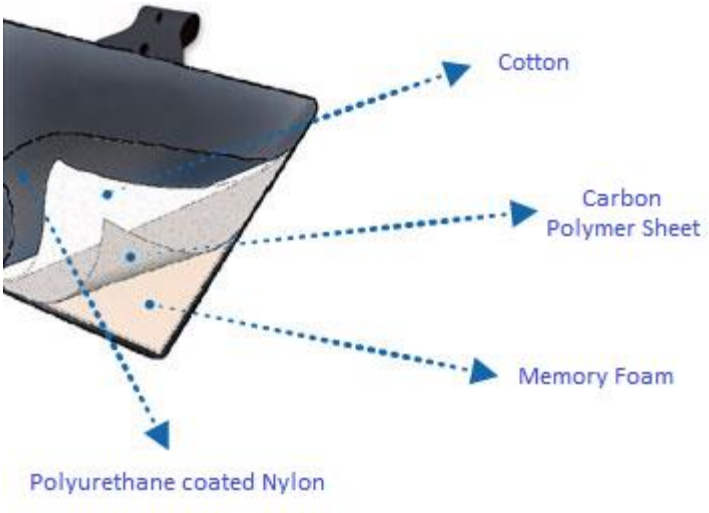


Figure 6: The KOALA warming system contains four layers to provide heat and comfort to the patient. Image reprinted from [23].

1.5.2 Insufficiencies of Current Solutions

Current solutions on the market are insufficient due to high cost, field failures, and impracticality. While benchmarking current products on the market, we found that the lowest price starts at $1,000 US for the Bair Hugger over body warming unit (without inflatable materials) and the highest price runs at $18,000 US for the PerfecTemp underbody warming cushions [17, 13]. Low-resource settings are unable to pay these steep prices and prefer to cover a patient with a linen blanket, but this passive method doesn't effectively prevent perioperative hypothermia. Products that warm patients via conduction are known to cause burns if improperly designed [25]. The resistive heating devices are less expensive than forced air devices but are known to have more issues with cases of second-degree burns [26]. Forced air has become a recent issue, though, because it has been found to cause infections in the patient, specific to the type of surgery being performed [27, 28].

Over body devices can cause patient discomfort due to pressure and can block the surgeon from accessing abdominal areas to operate on. Underbody devices, on the other hand, are more comfortable and durable for both the patient and surgeon. With that being said, over body devices like the Bair Hugger still seem to dominate the market today. Additionally, we discovered that heated IV fluids cannot actively warm a patient and infrared lamps warm the surgeon to a point of discomfort [26]. We researched randomized controlled trials with different devices, such as warming techniques during Cesarean birth, and found that favorable techniques can vary from patient to patient and the trial essentially talks about how there isn't one specific warming technique on the market that is beating all others [29]. Benchmarking all of these warming devices allowed us to better form our user requirements and engineering specifications for the settings were are focusing on.

In summary, existing solutions for active patient warming fall short because they are too expensive, are not reusable, rely on user control, and do not monitor patient core body temperature.

2 Project Plan

A RACI chart (Figure 6) organizes the project deliverables our team must meet throughout the course of this semester. RACI allows us to effectively view project tasks, due dates, and how we'd like to divide up work. A quick scan of the chart easily shows the amount of involvement each member has per task and when we should plan on consulting our sponsors or professors.

RACI Chart (Roles and Responsibilities Matrix)

Project Name / Description:	*ME 450 project: Device to perioperatively regulate patient temperature for low-resource settings*
Created On:	*9/15/15* Revision: *9/22/15*
Created by:	*Kerstin Nilsson (safety officer), Sam Dion (portfolio manager), Ben Lewis (facilitator), Ryan Thomas (sponsor contact & treasurer)*

	Due by	Kerstin	Sam	Ben	Ryan	Sponsors/Profs
Form project team structure, begin background research, develop QSD, form user needs and engr specs	9/17/15	R	R	R	R	C
Meet with UMHS physicians to discuss warming methods	9/22/15	A	A	A	A	-
Conference call Dominican physicians to present design options and gather more background information	9/22/15	A	A	A	R	I
Use books, articles, databases to gather further research	9/22/15	R	R	R	R	-
Compile user needs	9/22/15	R	R	R	R	C
Design Review #1 - background and presentation	9/22/15	R	R	R	R	-
Rough draft of functional decomposition for class	9/24/15	R	R	R	R	-
Discuss the ranking of user requirements with Stakeholders and UM physicians if any changes are made	9/29/15	R	R	R	R	C
Generate design concepts: each teammate produces at least 3 drawings each	9/29/15	R	R	R	R	-
Using a Pugh chart, choose best concept from the 12 choices	10/1/15	R	R	R	R	-
Discuss top concept with project mentors and Dominican contacts	10/2/15	R	R	R	R	C
Outline design drivers of chosen concept, describe how concept represents a solution to perioperative hypothermia in low-resource settings	10/6/15	A	A	A	R	I
Produce physical, 3D mockup of design that illustrates shape and key features - small scale and possible 3D printed plastic	10/6/15	R	R	R	A	-
Indentify design challenges, prepare ppt presentation and project report for DR 2	10/6/15	R	R	R	R	C
Design Review #2 - concept selection	10/6/15	R	R	R	R	-

R = Responsible, A = Accountable, C = Consulted, I = Informed

Figure 6: RACI chart, a responsibility assignment matrix, for Design Reviews 1 & 2

In order to properly plan for Design Review 3 and 4, our team produced a RACI chart (Figure 7) organizing our project deliverables. Because Design Review 3 and 4 have multiple forms of engineering analysis for us to complete, the RACI allows us to effectively view project tasks, due dates, and how we'd like to divide up work.

RACI Chart (Roles and Responsibilities Matrix)

Project Name / Description:	*ME 450 project: Device to perioperatively regulate patient temperature for low-resource settings*
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	Due by	Kerstin	Sam	Ben	Ryan	Sponsors/Profs
Detailed CAD model of prototype	10/12/2015	R	R	R	A	C
Make instructional video of how final design will work and send to Dominican contacts for feedback	10/12/2015	A	A	A	R	C
Analysis of design drivers utilizing theoretical modeling, heat transfer, force analysis	10/12/2015	R	R	R	R	I
Discuss updated reqs and specs with Stakeholders and UM physicians if any changes are made	10/12/2015	R	R	R	R	-
Controls and mechatronics plans	10/13/2015	R	R	R	R	-
Safety plan	10/13/2015	R	A	A	A	I
FMEA and Risk Analysis	10/13/2015	R	R	R	R	-
Meet with heat transfer professor	10/13/2015	R	R	R	R	I
Make refined and final mockup	10/15/2015	R	R	R	R	C
Initial manufacturing plans	10/20/2015	R	R	R	R	I
Updates in report	10/22/2015	R	R	R	R	-
Design Review #3 - engineering analysis presentation	10/22/2015	R	R	R	R	-
Continued engineering analysis to choose final underbody and overbody materials & heat transfer	10/30/2012	R	A	A	A	I
Call with Stakeholders to discuss overbody solution	10/30/2012	A	A	A	R	C
Complete any modeling and a detailed overall assembly view	11/2/2015	A	A	R	A	-
Proof-of-concept fabrication plan	11/3/2015	A	R	A	A	C
Proof-of-concept safety plan	11/3/2015	R	A	A	A	I
Meet with professors about Arduino and tympanic sensor setup	11/5/2015	R	R	R	R	C
Design validation plan	11/5/2015	R	R	R	R	C
Updates in report	11/12/2015	R	R	R	R	-
Design Review #4 - Prototype, Design & Manufacturing presentation	11/12/2015	R	R	R	R	-
Incorporate resistive heating into "mattress"	11/19/2015	R	R	R	R	-
Use heat sealer in art or engineering school	11/20/2015	R	R	R	R	-
Incorporate controls system into device, completing our manufacturing	11/24/2015	R	R	R	R	I
Validation protocall	11/24/2015	R	R	R	R	C
Evaluate device for ethical design	11/24/2015	R	R	R	R	C
Updates in report and powerpoint	12/1/2015	R	R	R	R	-
Design Review #5 - finished prototype	12/1/2015	R	R	R	R	-

R = Responsible, A = Accountable, C = Consulted, I = Informed

Figure 7: RACI Chart for Design Review 3 – 5

3 User Requirements & Engineering Specifications

3.1 Obtaining User Requirements

The process to obtain user requirements began with team member Ryan Thomas visiting two public hospitals (secondary facilities) in the Dominican Republic: Hospital Municipal Octavia Gautier de Vidal in Jarabacoa, La Vega, and Hospital Municipal Dr. Virgilio Garcia in Cabrera, Maria Trinidad Sanchez. He spent the entire summer compiling a list of various problems and needs that could be addressed with engineering solutions. Once our team narrowed the list of need statements to three using our selection rubric, Ryan collected data that would help generate user requirements and design specifications. He interviewed a surgeon, nurse and community member, observed procedures and took measurements related to the three topics in order to begin forming user requirements.

The next step in the process was to consult with our project sponsor, Dr. Kathleen Sienko, our in-country stakeholders and other medical professionals. Dr. Sienko helped by critiquing our drafted requirements and providing guidance on how to transform those requirements into quantifiable and testable design specifications. We met with Dr. James Geiger, a pediatric surgeon at C.S. Mott Children's Hospital, to get his opinion on current solutions and his experiences with patient warming methods. We also interviewed Dra. Maria Plasencia and Lucila Santana, our Dominican stakeholders, over the phone. All of the information gathered throughout these interviews and consultations helped form an initial list of user requirements that we later refined into the finalized list.

3.2 Generating Engineering Specifications

Specifications (including numbers and units) were supplied both by medical professionals during in-person and over the phone interviews as well as through literature review and standards. User requirements communicated by our stakeholders were sometimes difficult to quantify, so we asked follow-up questions during our interviews to better understand the context of their need to help us capture the appropriate engineering specification. Literature and standards were used both to supplement requirements of our stakeholders as well as generate requirements a patient warming device should meet.

3.3 Ranking User Requirements and Engineering Specifications

Once all of our user requirements and engineering specifications were determined, we ranked each one in order of importance; prioritization of each requirement was first based on the frequency of stakeholder feedback. In other words, the more frequent the requirement was communicated by the same and/or multiple stakeholders, the higher the priority it was assigned. This ranking was then further refined based on benchmarking of current solutions and review of medical standards. We were able to confidently rank all user requirements and engineering specifications by combining research with our stakeholders' needs. This prioritized list of user requirements will allow us to focus on what is most important to consider as we make any design decisions.

Table 1: User Requirements and Engineering Specifications

Priority	User Requirement	Engineering Specification	Source
1	Warms the patient effectively	Maintains patient core temperature within 37°C ± 1°C	[1, 30, 11]
2	Avoids contamination	Does not absorb bodily fluids and other liquids; components must sit ≥ 82 cm off the ground or ≥ 61 cm from bed on if on the floor	[6, 31, 30, 32]
3	Does not burn patient's skin	Surface temperature of device shall not exceed 40°C	[13, 33]
4	Can be cleaned by current methods	Withstands wash with 1:10 bleach solution ≥ 60 s and washed in < 5 minutes	[6, 31, 30, 34]
5	Is easy to operate	Manual control limited to power on/off and 3-level heat adjustment	[31]
6	Does not damage easily	Resists cuts from scalpel applied with force-cut pressure	[6, 31, 33, 35]
7	Can accommodate all surgical patients	Withstands up to 170 kg	[31, 30, 36, 37]
8	Allows mobility of the patient's body	Frictional force between device and skin ≤ 333 N	[6, 31, 36]
9	Is comfortable for the patient	Device maintains normal capillary interface pressure ≤ 32 mmHg; pressure on chest ≤ 5 cmH_2O; materials in contact with patient skin meet hypoallergenic standards	[31, 30, 33, 32, 13, 38]
10	Compatible with the surgical bed in use	Does not exceed 1.867 m x 51.435 cm nor 65.405 cm x 15.24 cm for arm attachments 38.735 cm from edge of headrest	[6, 31, 30]
11	Must tolerate frequent power outages	Operates at 110-120 Volts and without a power supply for at least 4.5 mins	[6, 39]
12	Is inexpensive	Production costs less than $250 US	[11, 13]
13	Can be used for all surgeries in secondary hospitals	Device extends < 12 cm from operating bed surface	[31, 30, 40]

14	Does not warm the surgical team	Temperature 6 cm away from device remains ≤ 36°C	[1, 6, 33, 40]
15	Does not interfere with patient monitoring or anesthesia administration	Measures ≥ 23 cm from edge of O.R. bed headrest and ≥ 48 cm from edge of O.R. bed armrests	[6, 40]
16	Functions under variable ambient temperatures	Performs within ambient temperature range of 25°C ± 18.8°C	[6, 41]
17	Does not interfere with medical monitoring systems	Materials are anti-static according to ANSI.S20.20 standards	[32, 42]
18	Is aesthetically appealing	Outer (dark blue) material RGB color range: (B102-B204)*	[31, 30]

3.4 Detailing Requirements & Specifications

Warms the patient effectively:

During an interview, Dominican nurse Lucila Santana stated that the device must warm the patient effectively [30]. In engineering specifications, this means that our device must maintain patient core temperature within the normothermic range of 37°C ± 1°C [1]. Equations for calculating heat losses and gains of the human body by convection and radiation as well as total human body heat exchange will allow us to theoretically evaluate the efficacy of our patient warming device [43]. To test the efficacy of our device, we will simulate a patient's body with a mannequin (or other representative object) that has been cooled to temperatures below 36°C and record (core) temperature readings with multiple devices, such as a thermocouple, thermometer, or coolant temperature sensor.

Avoids contamination:

This device must be able to resist the absorption of bodily fluids such as blood, bile, vomit, and embryonic fluids, or other liquids such as iodine, hydrogen peroxide, alcohol, and hand sanitizer [6, 31, 32]. If any infectious fluids are absorbed by the device, it becomes contaminated and increases the risk for infection, especially if the patient and/or surgical equipment is to be in direct contact with the device. Any reusable medical device that comes into contact with the patient and bodily fluids is subject to bio-burden, or the buildup of biological waste products even after cleaning [44]. Furthermore, our stakeholders desire a device that resists stains to preserve a clean appearance, which is also important to the patients. The device should not have noticeably visible stains from previous surgeries [31, 30]. Along with our project mentor, we determined that testing will not be necessary this semester to validate this requirement and that materials will be selected on the basis of fluid absorption, stain resistance, and antimicrobial properties. Dra. Maria Plasencia stated that the warming device we design must avoid contamination during surgery because fluids spill onto the floor of the operating room [6, 31]. As an engineering spec, we determined that the components that make up our device must be no lower than the height of the operating bed, which is 82 cm from the ground. If a component of our device must be on the floor, it needs to be at least 61 cm away from the edge of the bed, where blood and fluid spills do not reach. We determined these measurements from the Needs Assessment Data sheet, as observations in fluid spread during surgery were measured and

documented [6]. After designing our device, we can measure the height in which it sits on a hospital bed or lays on the floor from the center of the bed, which will allow us to validate this user requirement.

Does not burn patient's skin:

When dealing with heating elements or a device providing heat at a temperature greater than the temperature of the body, burns are a major concern. Extended and consistent exposure to high temperatures poses a high risk for complications [9, 44]. Forty degrees Celsius (40°C) is temperature at which one could bathe in water for an indefinite period of time without risk of burning [45, 46]. The burn threshold for skin – when necrosis of epithelial cells begins – is 44°C, so our device ensures we do not approach that temperature [94]. Therefore, the surface temperature of the patient must not exceed this 40°C threshold to maintain patient safety. This requirement will be satisfied through design intent ensuring there is a safety control system in place that does not allow the system to reach a temperature higher than the threshold.

Can be cleaned by current methods:

Material must withstand wash with 1:10 bleach solution for a period of at least 60 seconds, since that is the accepted standard by the CDC for semi-critical items and blood spills. In many cases, a 1:100 bleach solution can be used to clean and disinfect [34]. Our stakeholders in the Dominican Republic confirmed observational data from the needs assessment that cleaning staff use wet rags with bleach solution to clean the operating room, equipment and bed [6, 31, 30]. After consulting with our project mentor, Dr. Kathleen Sienko, we determined that we will intend to meet this specification for our design in material choice and that no testing will be necessary this semester to evaluate this requirement. In addition, the quickest turnaround observed for operating rooms in the Dominican Republic was five minutes between operations (back-to-back cesarean sections) [6]. Because of this, the device must be able to be properly cleaned in less than five minutes by janitorial staff [6, 30]. This will ensure that the device can be reused immediately and operating schedules will not be interrupted. To test this specification, we will time subjects while they clean the device, using a dye solution to measure the surface area that was cleaned. The recommended time for using bleach solution on the device is 30-60 seconds, which allows enough time for the janitorial staff to entirely and appropriately clean the device [34].

Is easy to operate:

One of our primary stakeholders, Dra. Maria Plasencia, strongly communicated to us that the device must not require much monitoring and manual operation, since the surgical team has a routine and would not be willing to deviate much from that routine. They are usually too preoccupied with the surgery at hand to operate additional equipment. To better understand what this requirement meant to her, we showed her our concept of obtaining feedback from a temperature sensor and having the device automatically control the heating elements accordingly and the device's operation without requirement manual input, and she thought that would be excellent [31]. In the event the temperature sensor was not able to be used, our design would have manual control limited to powering the device on and off and buttons to adjust the heat between three settings: low, medium and high.

Does not damage easily:

During our interview with Dr. James Geiger, we were told that devices such as the Bair Hugger were susceptible to being punctured or tearing in the presence of hemostats, sutures, needles, and electric cauterizers [33]. Since this is an issue that has potential to delay surgeries and decommission the warming device, this device must resist punctures, tears, and cuts from hemostats, sutures, needles, and electric cauterizers that may come in contact with the device [6]. Eliminating the risk of puncturing, tearing, or cutting of the device will improve the surgical experience and ensure that no complications arise mid-

surgery. To test this requirement, we will make contact with various surfaces on the device using tools such a hemostats, sutures, needles, and electric cauterizers. The device must resist cuts or punctures when subject to force-cut pressure using a scalpel on the device surface [35].

Can accommodate all surgical patients:

The device cannot fail due to patient weight, since patients could be resting on the device or sitting upright; this requirement developed from the concern our stakeholder in Jarabacoa has with some current devices we had showed her, particularly the Bair Hugger by 3M and Gelli-Roll by CSZ Medical, which she perceives as weak and unable to support a patient's weight [31]. Therefore, the device must withstand at least 67.9 kg (149.7 lb), or the average body mass of people in Latin America and the Caribbean. We will include a safety factor of 2.5, since roughly 58% of the (regional) population is overweight (BMI > 25) [36]; this safety factor would ensure our device would withstand patient weights of up to 170 kg, or those with a BMI >> 35 (for a 6'3" adult) [37]. We will test this requirement by performing mechanical (axial) loading on our device and analysis of any deformation or failure.

Allows mobility of the patient's body:

Upon completion of the surgical operation and cleaning the patient, at least two members of the surgical team transfer the patient, still under anesthesia, to the wheeled cot to transport the patient to an inpatient bed; the team must lift and slide the patient from the operating bed to the cot, which is kept slightly lower than the surgical bed [6]. The surgical team will occasionally need to shift the patient's body on the table to adjust the position of the surgical site [31]. In quantifiable terms, the frictional force between the patient's skin and device cannot exceed the force applied by two people to lift the patient's body (333 N = 0.5*9.81[m/s^2]*67.9[kg]), if the device is to make contact with patient skin. This force was determined using the average body mass in Latin America and the Caribbean [36]. We can test if our device meets this requirement by measuring the horizontal force required to just begin moving the patient's body, simulated by our team members and additional random samples.

Is comfortable for the patient:

During a phone call to the Dominican Republic, surgeon Dra. Maria Plasencia and Nurse Lucila Santana stated that the warming device cannot cause patient discomfort, while breathing or while lying on the operating bed [31, 30]. To translate this user requirement into an engineering specification, we determined that this meant a pressure of 5 cmH_2O should not be exceeded if our device were to lay over a patient's chest. This spec was verified through a medical resource, University of Washington School of Medicine, which states the pressure on the chest must be minimal to provide standard comfort and safety while breathing [38]. As another engineering specification to test for comfort while laying down, our device must maintain a normal capillary interface pressure of 32 mmHg or less, which we found through benchmarking the standards in which the PerfecTemp Warming System follows to prevent pressure ulcers [17]. We will test these specifications with a pressure gauge. Whenever dealing with the medical industry, it is important to realize the solution will be used by a client base with a wide variety of medical situations. One concern established when speaking with Dr. Geiger was the material of any device that would come into contact with a patient's skin. Specifically, our design must ensure all materials in contact with a patient's skin meet hypoallergenic standards. An allergic reaction in the middle of a surgery would cause substantial danger to the patient and could jeopardize the surgery [33]. This will be verified through material selection and utilizing materials approved as hypoallergenic by the manufacturer [32].

Compatible with the surgical bed in use:

If the device is to attach or in some way interact with the surgical bed, it must be compatible with the current operating bed in use [6, 31]. Specifically, the device must not exceed the current surgical bed

dimensions, 1.867 m long by 51.435 cm wide (for an AMSCO Surgical 9030M model). The armrest attachments measure 65.405 cm long by 15.24 cm wide, located 38.735 cm from the edge of the headrest. These measurements were taken on-site in the public hospital in Cabrera, Dominican Republic [6]. This requirement and specification will likely adapt, as it does not include a constraint related to volume of the device or space in the operating room; it also could restrict the device's functionality to the public hospital in Cabrera, since operating bed sizes vary from hospital to hospital.

Must tolerate frequent power outages:

This device must be able to withstand power outages of at least 4.5 minutes, which is the maximum amount of time it took for a backup generator to restore power, determined by measurements collected in the summer needs assessment; although power outages can last for longer time periods, generators or inverters in the hospitals most often restore power within a few minutes [6]. The device must also operate at 110-120 V, since the Dominican Republic's electric grid operates at this voltage range [39]. To test this specification, we will cut off power to the supply while the device is in operation and measure the time from supplied power loss until the surface temperature of the device falls below 37 C; this will allow us to determine the functional time window our device operates without power.

Is inexpensive:

There are many viable solutions for patient warming currently on the market with one exception - price. The need for active patient warming goes unsolved in the Dominican Republic and other low-resource settings because there is no economical solution readily available [6, 11]. Our solution must be innovative by design to deliver at a price affordable to hospitals with low financial resources. The device (materials and production costs) must cost less than $250 US; this price is the estimated manufacturing cost of the Bair Hugger, which is the most affordable active warming method available (for control unit alone), assuming medical device retail mark-up is 3-4 times the manufacturing cost (for noninvasive devices) [6, 12]. The total cost of materials and estimated labor must not exceed this amount. We hope to find out budget information from the Ministry of Health in the Dominican Republic to better define a cost that would be affordable for secondary hospitals, since purchasing of medical equipment is done through the Ministry of Health and not the hospitals or directors [6].

Can be used for all surgeries performed in the hospital:

Our stakeholders in the Dominican Republic, Dra. Maria Plasencia and Nurse Lucila Santana, both expressed that a device would ideally be used for all of the surgeries they perform in the secondary hospitals they work in Jarabacoa and Cabrera, respectively; they would not find a device specific to a particular surgery as useful since they lack the resources to purchase multiple units and/or devices [31, 30]. The surgeries performed at those secondary hospitals include cesarean sections, appendectomies, gall bladder removals, hernias, broken limbs, amputation of limbs, hysterectomies, exploratory laparotomies, and surgeries of the skull, heart, kidney and prostate [6, 31, 30]. A warming device could not interfere with the surgical team's ability to access those various locations of the body to make incisions and operate; they desire full access to the top of the patient. Therefore, the device cannot extend into the anterior coronal plane of the patient, meaning it must measure < 12 cm (4.75 inches) high when in use, measured from the operating bed surface; this number was determined as half the average human coronal height, or average human girth [40]. Restricting the dimensions of our device to the posterior coronal plane of the patient should prevent the device from interfering with most surgical operations.

Does not warm the surgical team:

The warming effects of the device must be isolated to the patient's body and not warm the surgical team, as it is uncomfortable for the surgeon and team [33]. It was noticed from comments made by the surgical

team and behaviors of running the air conditioning unit during operations that the surgical team is uncomfortable working in a warm environment [6]. We will meet this requirement of not warming the surgical team by ensuring the temperature 6 cm (the gap between the widest part of the patient's body and edge of the operating bed, where the surgeon and assistant operate) away from the device (laterally and vertically) does not exceed 36°C [1, 6, 40].

Does not interfere with patient monitoring or anesthesia:

During operations, the surgical team (primarily the anesthesiologist) is monitoring the patient's IV drip (inserted into the wrist) as well as oxygen and beats-per-minute (BPM) with a pulse oximeter on the forefinger. The anesthesiologist also helps turn a patient's head in the event the patient needs to vomit, and occasionally the anesthesiologist will need to use the manual resuscitator over the patient's mouth and nose if the patient experiences difficulty breathing [6]. Neuraxial anesthesia (epidural) is almost always used, but when supplies of needles are in shortage, general anesthesia is administered and the patient's breathing is maintained by the anesthesia machine and trachea tube [31]. Therefore, our design cannot obstruct the patient's head, forearm, wrist or hand; this means that our device must measure ≥ 23 cm from the edge of the OR bed headrest and ≥ 48 cm from the edge of the operating bed armrests [40].

Functions under variable ambient temperatures:

The average annual temperature in the Dominican Republic is around 25°C, with lows around 15°C and highs around 40°C throughout the course of the year [41]. Operating rooms have air conditioning units and can be open-air or lack sealing to the outside environment, so the temperature in the operating room can fluctuate considerably [6]. To ensure our device functions in a wide temperature range, we will incorporate a safety factor of 1.5 to the variance of annual temperature (± 12.5°C); this means our device must operate in an ambient temperature range of 25°C ± 18.8°C. This range should account for any extremes in temperature. We will test our device for this specification by subjecting the device to ambient temperatures at both extremes and making sure it still functions correctly, meaning it will maintain the patient's core temperature at 37°C ± 1°C (as tested for the requirement of "warms the patient effectively").

Does not interfere with medical monitoring systems:

According to standards outlined in the document "Choosing the Ideal Fabrics by Application," our device must not interfere with medical monitoring systems [32]. We translated this user requirement into the engineering spec: our materials must be anti-static. ESD stands for electrostatic discharge, which happens when a two electrically charged objects close in contact create a static build up, resulting in a static event or a small enough static spark that damages electrical components. To prevent this buildup, sensitive materials must be properly grounded according to ANSI.S20.20 standards. In other words, to make our product ESD-protected, we must be aware of a number of different protective methods: ESD-safe chemical coating, copper grounding tape running to earth ground, or other conductive materials placed over insulators [42]. We can use a static meter to test if our device is generating static or improperly grounded. But for the purposes of this course, we determined with our project sponsor that this requirement does not require testing this semester and can be met by selecting approved materials meeting the ANSI.S20.20 standards.

Is aesthetically appealing:

In order for the product to be accepted and used, it must be aesthetically appealing to our stakeholders (primarily the hospital staff and patients). To understand what our stakeholders meant by aesthetics, we asked questions to gather more context and found that it is important that the color of the device be a dark color so that blood and other fluids are better hidden. We selected the color palate by displaying a series of devices to two medical personnel in the Dominican Republic and receiving feedback based on their

preferences [31, 30]. From this data, we have narrowed the allowable color to be between B102 and B204 on an RGB scale.

4 Concept Generation and Selection

4.1 Exploration of Concept Space

Each one of us individually generated a minimum of 20 design concepts, ranging from full systems to specific components. We created a functional decomposition diagram (Figure 8) before we began concept generation to help us appropriately explore our concept space. Along with our functional tree (Figure 8), we generated a structure diagram for our controls design (Figure 9) to assist us in the future prototyping of our control unit.

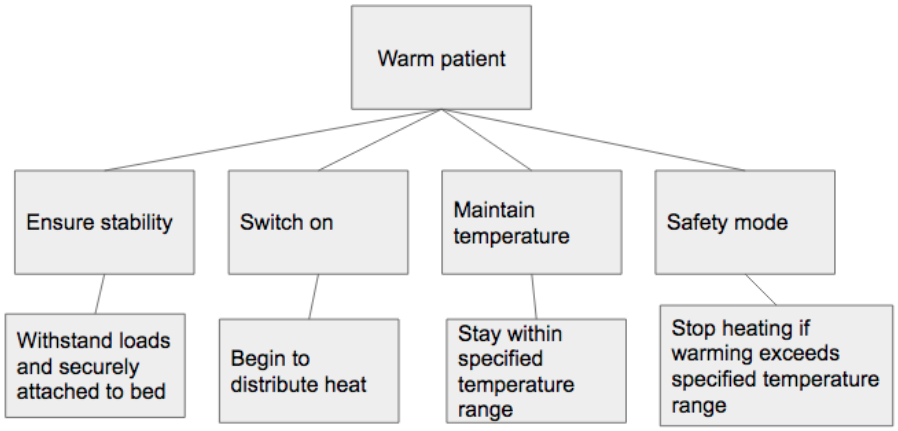

Figure 8: Functional Decomposition Step 1, Creating a Functional Tree

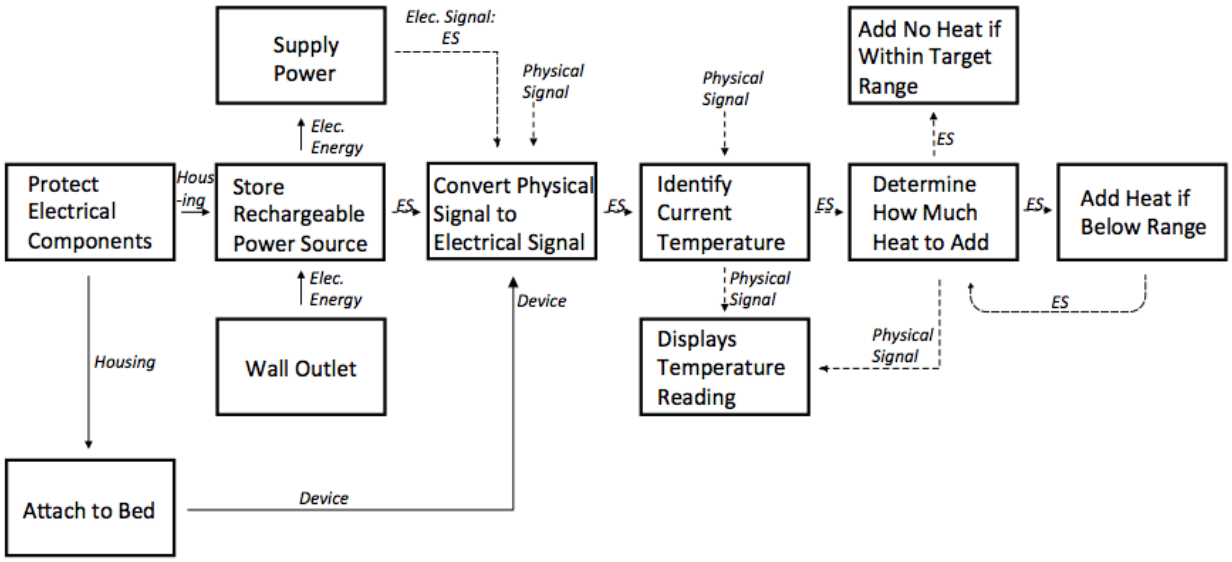

Figure 9: Functional Decomposition Step 2, Creating a Structure Diagram for Controls Design

We used various brainstorming methods, including design heuristics and brain writing, to generate unique concepts and help ensure that our team fully explored the entire solution space. Time spent in the surgery department of the C.S. Mott Children's Hospital was invaluable in furthering our knowledge of the product environment and familiarizing ourselves with current warming methods and standards.

These methods of using design heuristics, brain writing, and observations in the surgery department of C.S. Mott Children's Hospital resulted in generation of diverse concepts that ranged from incremental changes to revolutionary ideas. We sat down and utilized the brain writing methodology. Each of us began by sketching a design solution. Each solution then worked its way around the table with members of the team adding to the idea, asking a constructive question, or developing a new idea based on the concept to stimulate a creativity exchange. This method produced a control unit that could be stored under the bed as shown in Figure 10. The location is minimally invasive to the room layout and hits requirements regarding ease of use for the surgeon, aesthetics, and safety.

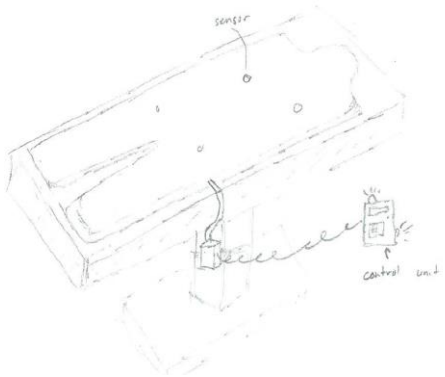

Figure 10: The control unit is stored under the bed to limit effect on room layout while allowing easy access to make adjustments. [*Sketch by Sam Dion. Oct 2015.*]

We met with Professor Shanna Daly to discuss divergence and convergence of our concepts. This meeting led to using the 77 Design Heuristics for Inspiring Ideas cards to generate further concepts. One card prompted us to "make it wearable." We expanded this idea to integrate our conductive heating methods in a suit that can be put on before surgery, shown in Figure 11. The patient would put on the full body clothing that could be used for preheating and perioperative heating. This methodology increases surface area for conductive heating while limiting losses due to radiative heat transfer.

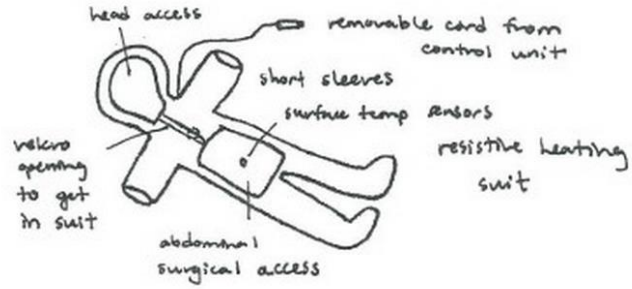

Figure 11: A full body suit increases the conductive surface area while maintaining patient comfort. [*Sketch by Ryan Thomas. Oct 2015.*]

Further novel ideas were generated when combining cards like "utilize the environment" and "use it for another purpose." This combination resulted in an idea to repurpose the heat from the A/C unit and transfer this heat to the patient, shown in Figure 12. The air would need to be filtered, but this reuse could increase the thermodynamic efficiency of the unit while utilizing the available natural resources.

Figure 12: Heat rejected by the A/C unit can be repurposed to heat the patient. [*Sketch by Sam Dion. Oct 2015.*]

A Morphological Matrix was created to identify different combinations of solutions. Functions such as points of warming and safe to prevent burns can be identified alongside energy sources and stability to create varying concepts. Table 2 shows the functions and various design solutions. Random solutions can be chosen for each function which are later combined into a complete solution.

Table 2: Chart of functions with brainstormed concepts for selection

Function	1	2	3	4	5	6
Appropriate aesthetics	Dark blue color	Completely underbody	Can be formed into multiple chair shapes	Follows precise shape of chair	Limited buttons, simplistic	Various (organized) buttons for more options
Stable device	Latches onto chair with velcro	Magnetic pieces latch onto chair	Cushions to replace original cair cushions	Heavy enough, no attachment to chair needed		
Sterilizable, flexible, comfortable material used	Plastic reusedable heating pad with Dartex slip cover	Thick cushion of Dartex material	Other branded puncture and stain resistant material	Possibility: polyester nonwoven geotextile fabric	Plastic material cover?	Material on bed detachable from wires
Convenient warming method	Conduction via underbody device, many sensors spread underbody	Conduction via various contact points under or over body	Radiation via heat lamp	Convection via blowing	Reusable heating pads via exothermic sodium acetate reaction	
Effective points of warming	Along entire underbody	Underbody plus some optional overbody flaps	Underbody plus comes up on sides of patient	Accessories system (wraps around portion of torso, arms, legs, forehead)	Attached to chair but contact with patient not needed for specific convection or radiation methods	
Convient energy sources	Thermal energy from boiling	Wall outlet power with backup batteries	Runs only on rechargeable batteries	Compressed air stored		
Well-designed controls box	Placed above head of patient, on chair	Wireless capabilties to move anywhere	Side table style with controls attached	Attached at IV stand	Current temperature of blanket and patient displayed	
Safe to prevent burns	Automatically powers off when overheated	Cool down fan can kick in if needed	Temp display flashes and beeps for doctor to push safety/off button			

Further design concepts will be explored as we narrow the scope and enter the converging phase of design. The SCAMPER model is one that we will use to implement incremental changes by helping us generate new ideas and encouraging us to think about how we can improve existing ones; it is a mnemonic that stands for "Substitute, Combine, Adapt, Modify, Put to another use, Eliminate, Reverse [47]." All concepts generated are shown as sketches and briefly described in Appendix A.

4.2 Ranking of Concepts

We organized our design concepts into four categories: warming unit, warming technique, control unit, and temperature monitoring. The Pugh Charts in this section (Figures 13 – 16) compare our top generated concepts to these four specific components of our device. We created Pugh Charts for each category to organize our design concepts against a list of desired functions; we compared each concept against a current 'gold standard' solution that we determined from benchmarking. We utilized a simple +1/0/-1 scoring system; a concept is assigned a "-1" if it would serve the function worse than the standard, "0" if it would serve the function similar to the standard, and "+1" if it would serve the function better than the standard. Finally, a weighting scale was applied to the functions, ranging in weight from 1 to 4; 1 corresponded to a non-essential function, 2 a desired function, 3 an important function, and 4 a critical function. These weights (1-4) were multiplied by the scores (-1, 0, or +1) for each concept and function, and those scores were then tallied to provide a numeric score to assist in selecting design concepts that best meet the desired functions. The highlighted columns in the Pugh Charts below correspond to the highest scoring designs for each concept category.

PUGH MATRIX: WARMING UNIT					
Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)					
Benchmark/Datum receiving all 0s: Bair Hugger over body forced air blanket					
Key Criteria	Weight	Design 1: Under body mat with conductive metallic beads	Design 2: Conformable radiant heating bedside modules	Design 3: Resistive heating sleeping bag with removable sections	Design 4: Resistive heating cushions
Effective	4	-1	1	1	-1
Ease of Use	3	1	1	0	1
Safety	4	0	-1	0	1
Durability	3	1	1	1	1
Aesthetics	1	1	0	0	1
Reliability	2	1	0	1	1
Patient Comfort	2	-1	1	0	1
Provider Comfort	2	1	-1	0	1
Cost / Affordability	3	1	0	1	-1
Manufacturability	1	-1	0	0	1
Portability	1	0	-1	0	-1
Reusable	4	1	1	1	1
Compatibility	2	0	-1	0	-1
Maintenance	3	-1	-1	-1	-1
Efficiency	2	1	0	1	1
Invasiveness	2	1	1	0	1
Environmental impact	1	1	1	1	1
Noise	1	1	1	1	1
Sterilizable	4	-1	0	-1	-1
	+1	11	8	8	13
	0	3	6	9	0
	-1	5	5	2	6
Totals	Score	10	8	13	11

Figure 13: Warming Unit Pugh Chart

PUGH MATRIX: WARMING TECHNIQUE					
Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)					
Benchmark/Datum receiving all 0s: Bair Hugger over body forced air					
Key Criteria	Weight	Design 1: Resistive heating	Design 2: Forced air	Design 3: Radiant heat	Design 4: Insulation
Effective	4	-1	0	1	-1
Ease of Use	3	1	0	0	0
Safety	4	0	0	-1	1
Reliability	2	1	0	-1	0
Patient Comfort	2	0	0	1	1
Provider Comfort	2	1	0	-1	1
Cost / Affordability	3	0	0	0	1
Reusable	3	0	0	0	0
Maintenance	3	0	0	0	0
Efficiency	2	1	0	0	1
Environmental impact	1	0	0	0	1
Noise	1	1	0	1	1
	+1	5	0	3	7
	0	6	12	6	4
	-1	1	0	3	1
Totals	Score	6	0	-1	11

Figure 14: Warming Technique Pugh Chart

PUGH MATRIX: CONTROL UNIT						
Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)						
Benchmark/Datum receiving all 0s: Bair Hugger control unit (3 temperature buttons, power button, air temperature display)						
Key Criteria	Weight	Design 1: Feedback display	Design 2: Power button with indicator light	Design 3: Battery power backup	Design 4: Detachable remote under bed	Design 5: Panel slides under bed
Effective	3	1	1	1	0	0
Ease of Use	3	1	1	0	1	1
Safety	2	1	1	1	1	1
Durability	3	0	1	1	0	0
Aesthetics	3	1	1	0	1	1
Reliability	3	0	1	1	0	0
Patient Comfort	1	0	0	1	0	0
Provider Comfort	4	0	0	1	1	1
Cost / Affordability	2	-1	0	-1	0	0
Manufacturability	2	-1	0	-1	0	0
Portability	2	0	0	0	-1	-1
Reusable	3	1	0	1	0	0
Compatibility	2	1	0	0	0	0
Maintenance	2	0	0	-1	-1	-1
Efficiency	2	0	0	0	1	1
Invasiveness	1	0	0	1	1	1
Environmental impact	2	0	0	0	0	0
Noise	2	0	0	1	0	0
	+1	6	6	9	6	6
	0	10	12	6	10	10
	-1	2	0	3	2	2
Totals	Score	12	17	16	11	11

Figure 15: Control Unit Pugh Chart

PUGH MATRIX: TEMPERATURE MONITORING					
Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)					
Benchmark/Datum receiving all 0s: PerfecTemp surface temp monitoring (2 sensors under patient's back)					
Key Criteria	Weight	Design 1: Nasopharyngeal sensor	Design 2: Surface sensor on forehead	Design 3: Band-style surface sensor on axillary artery	Design 4: Pacifier-like sensor underneath
Effective	4	1	0	0	1
Ease of Use	3	0	1	0	0
Safety	4	0	1	1	0
Durability	2	0	-1	1	0
Aesthetics	1	0	0	1	-1
Reliability	2	1	-1	0	1
Patient Comfort	3	-1	1	1	-1
Provider Comfort	1	0	1	1	-1
Cost / Affordability	2	0	1	0	0
Manufacturability	1	0	0	-1	-1
Portability	2	0	0	0	0
Reusable	3	0	-1	1	1
Compatibility	2	0	0	0	0
Maintenance	2	0	0	0	0
Efficiency	1	1	1	0	1
Invasiveness	3	-1	1	1	-1
Sterilizable	4	-1	0	0	-1
	+1	3	7	7	4
	0	11	7	9	7
	-1	3	3	1	6
Totals	Score	-3	10	16	-3

Figure 16: Temperature Monitoring Pugh Chart

4.3 Preliminary Concept Mockup

To better demonstrate some of our key concepts, we created two physical concept mockups. We were supplied with various materials in the assembly room such as Styrofoam, clear plastic, polystyrene beads, velcro, fabric glue, and various fabrics. A scaled-down human model was also provided to us and we were able to scale our concepts to fit this model. The purpose of these mockups was to demonstrate the key functionalities of our key designs as well as to give our stakeholders a better idea of what the final design will look like. The following will discuss the purpose of each mock up as well as what we learned from the process of creating them. Our mockups of both resistive and conductive-bead heating methods are shown in Figure 17, page 25.

Figure 17: Mockups of both resistive (left) and conductive-bead (right) heating methods. [*Personal photograph by Ben Lewis. 1 Oct 2015.*]

The first concept mockup we created was the resistive heating device with over-body flaps. This is shown on the left in Figure 17, and a sketch of the concept with all of the over-body flaps extended is pictured in Figure 18 in Section 5.6 below. We began by cutting the fabric to shape and making slits for each of the flaps. Next, we made a cut-out for the head and attached Velcro with fabric glue at each of the connection points for the flaps.

From the process of creating this mockup of the resistive heating device with over-body flaps, we learned about some of the complications that will arise when we scale up the device to accommodate a human. First, we realized that there must be more adjustability with the connection points to allow for different sizes of patients. For example, the size and location of the cut-out for a patient's head is important because patients can vary in not only weight but also height. The current model was fitted only to the wooden human model shown above. We will address this challenge by consulting with Dr. Matthew Reed and utilizing his anthropometry data from human measurements. Furthermore, we recognized that the placement and amount of the over-body flaps will be crucial to the design; our design must allow surgeons and the surgical team to adjust these flaps for any type of surgery they may perform to meet that user requirement. The current mockup slightly overlaps with sections of the torso and abdomen that will need to remain unobstructed during certain procedures. We also considered what will happen to certain pieces of Velcro when a flap is opened. If one piece relies on another for a seal, how will we take this into account when that other piece is pulled back. Finally, we thought about the material of the flaps. One of the key requirements conveyed by our stakeholders is that the device should not be obstructive to surgeons or uncomfortable to patients if there are over-body portions. We have since explored lighter insulative materials for the flaps instead of bulkier active heating elements.

The second concept mockup we created was the underbody, conductive-bead heating device which is shown in Figure 17. We began by cutting a rectangular piece of Styrofoam to fit the size of the operating bed we created for our mockups. Next, we added a gray, plastic layer to represent a conductive sheet which will serve as the heating mechanism for the beads. We then added a clear plastic layer on top of the first two to serve as a pocket to put the beads in to as well as a way to visualize the inner layers of the device for the purpose of demonstrating functionality with our mockup. Finally, we poured beads into the pocket and sealed it to ensure they would not fall out.

Again, we learned from this mock-up of the underbody, conductive bead heating device and have new design considerations moving forward. The first thing we realized was that it may be difficult to keep the beads in a position that will be beneficial for both uniform heating and patient comfort. As it is now, the beads are free to move around the entire surface of the device. We will need to consider consolidating the beads into sections to minimize movement and ensure even distribution. Next, we realized that the top-layer material we select will be very important. It will not only need to allow for heat transfer, be sterilizable, and not melt or burn, but it must also allow for comfort of the patient. An idea that was generated from this is that we put a layer of steel wool on top of the beads to add a layer of cushioning and also help with distribution of heat. Finally, we concluded that an underbody heating method alone will not be enough to keep the patient warm. Adding an over-body portion to the device will help insulate the heat generated by the under-body portion and prevent heat loss from the patient's body. Our final concept selection was based on a combination of ideas generated during the mockup process.

4.4 Preliminary Concept Selection

Our selected concepts for Design Review 2 were based on the scores from our Pugh Charts with weighted criteria, fulfillment of existing user requirements, feedback from medical professionals at C.S. Mott Children's Hospital, and feasibility in the context of the Mechanical Engineering 450 course. Although these selected concepts are our proposed designs, we will not finalize our design until we receive feedback on these selected concepts from our primary stakeholders in the Dominican Republic.

Our proposed design for our patient warming device is shown as a sketch in Figure 18. It utilizes resistive heating through an underbody mat and insulative flaps that can fold over the body of the patient; the resistive mat will be covered in polyurethane-coated nylon fabric since it is highly durable, puncture-resistant, does not absorb fluids and can be cleaned with bleach [48]. The flaps will utilize Mylar material (the same that is used in marathon blankets) for effective retention of the body's radiant heat to prevent heat loss from the upper half of the patient's body not in direct contact with the patient; Mylar material for the flaps will also allow flexibility for placement over and contact with the patient [49]. The method for flap attachment will either be Velcro or mimic the locking mechanism of Ziploc bags, or press-fit technology [48]; we have yet to generate a mockup of the press-fit technology to see if it is feasible for our design. As the design is currently conceptualized, it would meet all of our user requirements, pending validation and testing of our future prototype.

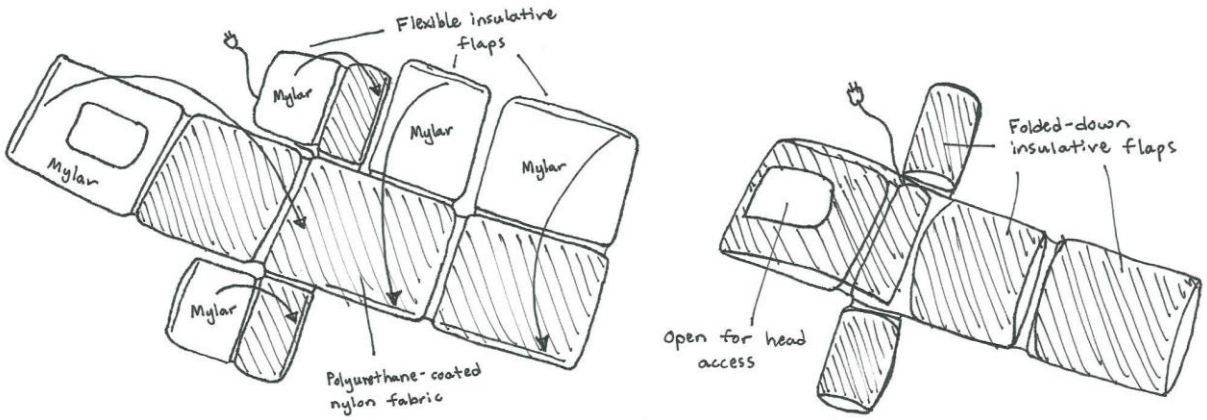

Figure 18: Conformable underbody resistive heating mat with insulative over body flaps. [*Sketch by Ryan Thomas. 5 Oct 2015.*]

The advantages of this selected concept are that it incorporates active conductive warming via resistive heating in the mattress underneath the body as well as passive insulation to prevent loss of heat by radiation from the upper body to prevent heat loss from the body to the environment. Additionally, it can be used for all surgeries performed in the secondary hospitals since it allows the surgical team to use the over body flaps as desired to ensure full and comfortable access to the surgical site; also, this device integrates well into the existing operating room space and bed, since it fits right on top of the operating bed, with the flaps folding away underneath the bed when not in use; the entire units folds up to be stored when it is not used on the operating bed.

There are several disadvantages of this concept. It does not utilized forced-air warming, which is currently the method of choice in hospitals in the United States due to its efficacy of warming the patient, since forced-air warming incorporates both radiant and convective heating. The surface area of the device is very large, so it could potentially be more difficult for janitorial staff to clean quickly and appropriately. This concept does not currently involve resistive heating in the flaps that come over the patient's body, so the flaps currently serve to insulate the patient and prevent radiant heat loss. We may find that to increase efficacy of patient warming that we will need to incorporate resistive heating elements into the flaps, but we would need to balance that potential design change against the added weight and potential increase in patient discomfort it would cause.

We have selected a concept to monitor patient core temperature via an axillary artery surface temperature sensor band (Figure 19). The band will be made of polyurethane-coated nylon fabric or other soft material to be cleaned by bleach. The sensor will be surrounded by an insulative gel or other material to mimic a closed-arm axillary artery temperature reading, since the arms of patients for most surgeries are spread out to their sides [6, 48]. The surface sensor will come in direct contact with the armpit to effectively read the temperature of blood passing through the axillary artery.

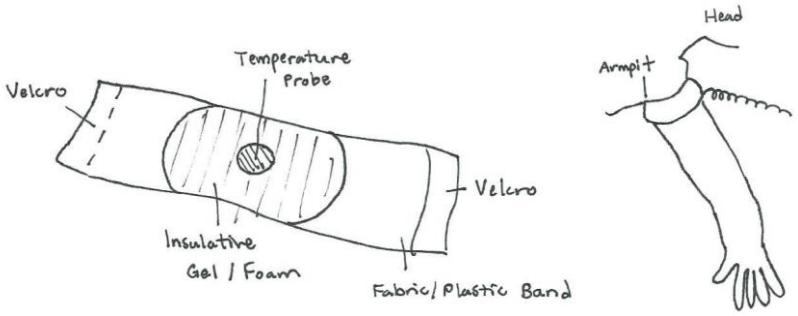

Figure 19: Surface temperature probe on band to measure temperature of axillary artery. [*Sketch by Ryan Thomas. 5 Oct 2015.*]

The advantages of measuring core temperature with a surface temperature probe at the axillary artery is that it provides an accurate reading of core body temperature, relative to other surface temperature probes, and is non-invasive. Additionally, the axillary artery is a good location to measure temperature since the surface reading is largely unaffected by body fat content and physical variations in patients [44]. This

element of our design distinguishes our product from others on the market, since no other current solution from our benchmarking utilizes core temperature feedback into a control system.

This device concepts does not come without disadvantages. First, temperature measurements of the axillary artery are considered representative temperatures of the core body temperature, but they are not equivalent to the body's core temperature, which can only be most accurately measured with invasive methods [44]. Additionally, temperature measurements at the axillary artery are currently done while the patient arm is rested at the patient's side (the armpit is closed), so there will be difficulty in insulating the sensor to recreate that environment while the patient's arms are stretched out (the armpit is open), which is the case for many surgical procedures in secondary facilities in the Dominican Republic [6].

Finally, our team has selected the concept of the control unit (Figure 20), which receives feedback from the temperature sensors and controls the operation of the warming unit, to be a unit which displays core body temperature and surface temperature and features a power button with three indicator lights (green, yellow, and red) of the state of the device's operation. The core temperature reading will receive input from the temperature sensor at the axillary artery, and the surface temperature reading will be the highest reading from the two surface sensors underneath the patient's body on the mat. The green indicator light will be displayed while the unit is functioning normally and warming the patient, the yellow light appears when the device is shut off or cooling because the core temperature reading exceeded the normothermic range and/or the surface temperature reading exceeded the limit for risk of burning, and the red light appears when the device experienced an error or problem, such as overheating. The control unit is intended to be our power supply, so it must incorporate a circuit breaker so the device is not damaged during power outages or surges.

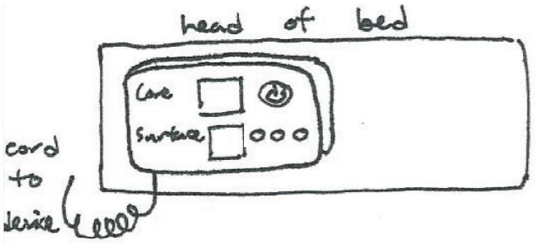

Figure 20: Control unit with feedback displays, power button, indicator lights and temperature controls. [*Sketch by Ryan Thomas. 5 Oct 2015.*]

The advantages of a control unit as pictured in Figure 20 are that it is simplistic and requires minimal user control and input so that the surgical team can focus on the current routine for patient monitoring. Its placement at the head of the bed puts it in close proximity to the anesthesiologist who monitors the patient and is out of the way of the surgeon and assistant that operates on the patient.

Some disadvantages of this control unit concept are that it does not allow for manual user input to increase or decrease the temperature of the warming device, nor does it currently have words to show what the corresponding indicator lights represent, especially for those users who are color blind.

Before we begin modeling and analysis of our selected concept, we will gather feedback from our stakeholders in the Dominican Republic to identify any potential design changes that would need to be made to ensure we have captured all of our user requirements, especially our primary design drivers, through our design. Although we will move forward with a design to produce a final prototype for the Mechanical Engineering 450 course this semester, we will continue involving our stakeholders in the Dominican Republic in our design decisions so that our product will continue to iterate to a design that will ultimately be implemented in secondary hospitals in the Dominican Republic and potentially scale to other low-resource settings.

5 Design Drivers

Due the constraints on time and resources our team has this semester with our work through Design and Manufacturing III, our team has compiled the following primary design drivers: 1) Effectively transfers heat to the patient, 2) Fully cleaned by 1:10 bleach solution, and 3) Requires minimal user input. These primary drivers for our design were determined by a combination of stakeholder feedback, mentors on campus, literature review and benchmarking. These design drivers will assist our selection of a design concept and focus the goals our prototype should meet by the end of the Fall 2015 semester; these drivers are essentially the requirements that will "make or break" our design.

Effectively transfers heat to the patient:

The purpose of our device is to regulate a patient's temperature during surgery to prevent perioperative hypothermia; if our device fails to effectively transfer heat to the patient to maintain normothermia, our design is useless. The body and environment exchange heat by means of four mechanisms; radiation accounts for roughly 50 – 70% of the body's heat loss, convection accounts for about 15 – 25%, evaporation accounts for 5 – 20%, and conduction accounts for about 3 – 5% [9]. We will be dealing with a temperature gradient of relatively warm peripheral body temperature and relatively cool core body temperature, so we must analyze the steady-state distribution of heat while the device has transferred heat to the patient, and the time it takes to reach that steady state, to understand the efficacy of our warming device design. In addition to transferring heat to the patient, our device must prevent radiant and conductive heat loss from the patient's upper body through either insulating or warming the patient (or both). This design driver must be evaluated on the fundamentals of heat transfer, using governing equations of conduction and radiation and computer models as well as empirical testing.

Fully cleaned by 1:10 bleach solution:

Our design aims to prevent all complications of perioperative hypothermia, including reducing the risk of infection. Our device must have the ability to be cleaned by 1:10 Clorox bleach solution (the current method of cleaning in secondary hospitals in the Dominican Republic) to remove all undesired pathogens and buildup of biological wastes [31, 30]. The design cannot absorb bodily fluids, like blood, that could transmit infectious diseases and/or encourage the growth of harmful microorganisms. From review of literature, bleach solution is proven to be effective in killing blood-borne pathogens (including viruses) and emerging pathogens, like Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Rotavirus, Human Papilloma Virus, Norovirus, Severe Acute Respiratory Syndrome [SARS] Coronavirus [34]. Literature noting the effects of bleach solution on the materials to be used (polyurethane coated nylon fabric, Mylar, ABS plastic) was also reviewed.

Requires minimal user input:
Our stakeholders have made it clear to us that the device would likely not be used if it required much manual input from the surgical team or anesthesiologist; the surgical team would not be willing to go much beyond their current protocol for surgery which involves covering the patient's body (all except the surgical site) in linen sheets [6, 14]; the surgical team does not currently monitor patients' temperature, so it would be inconvenient for them to have to adjust the warming device accordingly. Therefore, it is absolutely necessary that our design utilize a feedback system; temperature measurements from probes provide information to the controls which respond by increasing or decreasing the intensity of the warming unit or shutting it off.

6 Risk Analysis

The failure risk assessment chart is ranked based on several factors regarding each possible failure. These factors include probability of failure, probability of detection, and severity of consequences. Failures with the most severe consequences were reviewed first in terms of risk assessment. This is because when these failures occur there can be irreversible damage, and so these need to have priority when it comes to prevention, regardless of likelihood. These absolutely need to be prevented due to the possible serious damage or harm that can occur. The next factor that was taken into account was probability of detection. Regardless of how likely a failure is, the ability to detect the failure in order to prevent its consequences is what determines if consequences can be prevented. If a failure is particularly difficult to detect when it is occurring, these need to take next priority to invent new means to catch these failures before any damage or harm is done. Lastly, the likelihood of a failure occurring was also taken into account in the risk assessment. The more likely a failure is to occur, the more often it needs to be screened for prevention. If detection or screening is not performed at a high enough frequency, these failures will happen much more often without any preparedness.

We found the highest risk associated with the FMEA to be “temperature exceeds highest range” because this could burns or blisters on the patient. This risk would be associated with our underbody-heating unit and has a high likelihood of happening and a severity rating of 9. To prevent this from happening, we need real-time sensors (tympanic, in-ear) to monitor the temperature throughout the surgery. In addition, we will incorporate an LED into our control system to notify the surgeon if the blanket or patient is in a dangerous temperature range, which will act as a manual backup to power down the warming device into safety mode. These preventative methods will reduce our overall risk associated with our device to an acceptable level.

Item	Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Causes of Failure	Occur	Current Design Controls	Detection	RPN	Recommended Action
Blanket	Warms patient with resistive heating via conduction and controls radiant heat loss	Temperature exceeds target range	Burns/blisters	9	Programming defect/circuitry defect/eqipment damage/malfunction	4	Probes and sensors for constant monitoring / Testing prior to each use	2	10	Need: real-time sensors for strict monitoring of blanket and patient temperature throughout each use, heat trasnfer analysis on system as well
		Puncture in material	Bodily fluids may contaminate/faster radiant body heat loss/misfunction	7	Accident during procedure/Accident in storage/Repeated use (wear and tear)	5	Full blanket check for any abnormal marks or damages directly prior and after each use/Concise date stamps for when blanket was first added to stock	4	30	Healthcare workers physically assess the blanket before and after use. Marking date of restocking of blankets can help assess how long the blanket has been in use and when to replace. Use of heat transfer calculations to ensure proper material selection (thickness, emissivity, etc.)
		Improperly cleaned	Higher risk of infection/transmission of diseases between patients	10	Inadequate cleaning protocols/Failure to follow cleaning protocols/Outside contamination source	2	Proper cleaning protocol, such as thorough washing, bleaching, antibacterials, heating, etc.	5	20	Proper cleaning should avoid contamination of blankets
		Pressure concentrations with patient	Development of pressure ulcers	9	Accumumlation of moisture between patient and material, insufficient cushioning and load distribution	3	Use of cushioned foam in blanket to distribute pressure and conform to body	2	20	Incorporate moisture-wicking material and utilize memory foam-like cushioning
		Slips from the operating bed	Trauma/ blood loss/ rug burn	10	Combination of large force and moisture between patient and bed decreasing the coefficient of friction	1	Cushioned foam and blanket material selection with high static coefficient of friction	1	10	Carefully select materials to prevent failure mode from ever occurring
		Catches on fire	Severe burns/blisters	9	Programming defect/circuitry defect/malfunction	1	Automatic shut down if open circuit occurs/temperature sensor feedback prevents added heat	1	10	Utilize non-flammable materials where possible and incorporate automatic shut down mechanism
		Resistive heating elements and/or wires inside cushion break	Hypothermia	6	Break/cut of wires/accident during procedure	2	Open loop system initiates shut down	5	10	Ensure controller shuts system down when the system is not functioning properly
		Seams on cushion tear open	Bodily fluids may contaminate/faster radiant body heat loss/misfunction	7	Accident during procedure/Accident in storage/Repeated use (wear and tear)	3	Full blanket check for any abnormal marks or damages directly prior and after each use/Concise date stamps for when blanket was first added to stock	4	20	Healthcare workers physically assess the blanket before and after use. Marking date of restocking of blankets can help assess how long the blanket has been in use and when to replace.

Table 3: FMEA for the underbody resistive heating mattress

Item	Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Causes of Failure	Occur	Current Design Controls	Detection	RPN	Recommended Action
Controls	Controls temperature	Does not turn on	Device rendered useless	8	Damage/Uneducation (clinician was not properly trained to use device)/Faulty manufacturing	2	Regular diagnostic testing of device/Proper clinical training	2	5	Diagnostic testing of the device regularly can determine which models are defective and which are working proplery
		Buttons or remote broken	Device is unable to be changed or modified once turned on = danger to patient and clinician	7	Damage/Uneducation (clinician was not properly trained to use device)/Faulty manufacturing	3	Regular diagnostic testing of device/Proper clinical training	2	5	Diagnostic testing of the device regularly can determine which models are defective and which are working proplery
		Safety mode disfunctional	Product no longer has any necessary safeguards = danger to patient and clinician	10	Damage/Uneducation (clinician was not properly trained to use device)/Faulty manufacturing	2	Regular diagnostic testing of device/Proper clinical training	2	5	Diagnostic testing of the device regularly can determine which models are defective and which are working proplery
		Electrical surge destroys circuit elements	Device rendered useless	8	Natural disaster/Faulty manufacturing	2	Regular diagnostic testing of device/Proper clinical training	2	5	Diagnostic testing of the device regularly can determine which models are defective and which are working proplery

Table 4: FMEA for the control unit

Item	Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Causes of Failure	Occur	Current Design Controls	Detection	RPN	Recommended Action
Tympanic sensor	Measures patient's temp for feedback	Not properly aligned to body	Renders device useless/Dysregulation of temperature due to lack of measurement = danger to patient and clinician	9	Manufacturing defect/Uneducation (clinician was not properly trained)/Body type of patient/Excessive patient sweating	5	Be sure manufactured product ergonomics are effective before clinical use/Proper clinical training/Multiple sensor sizes or customizations	3	10	Effective design of sensors will eliminate most of these issues
		Inaccurate reading	Renders device useless/Dysregulation of temperature due to lack of measurement = danger to patient and clinician	10	Damage/Defective product	3	Regular diagnostic testing	2	10	Diagnostic testing of the device regularly can determine which models are defective and which are working proplery
		Falls off during procedure	Renders device useless/Dysregulation of temperature due to lack of measurement = danger to patient and clinician	8	Damage/Defective product/Patient movement/Unsecure grip	5	Be sure manufactured product ergonomics are effective before clinical use/Multiple sensor sizes or customizations/ Periodic checking for sensor security during procedure	1	30	Checking periodically throughout a procedure will ensure sensor is securely on. Physical assessment of sensors can also determine which sensors need to be repaired or replaced
		Becomes contaminated and/or is not properly sterilized	Increased risk of infection	4	Inadequate cleaning protocols/Failure to follow cleaning protocols/Outside contamination source	2	Proper cleaning protocol, such as thorough washing, bleaching, antibacterials, heating, etc.	5	10	Proper cleaning should avoid contamination of blankets
		Connection to control breaks or comes loose	Renders device useless/Dysregulation of temperature due to lack of measurement = danger to patient and clinician	8	Damage/Defective product/Patient movement	5	Ensure design compatability between control unit and sensor	1	10	Checking periodically throughout a procedure will ensure sensor is functioning properly.
		Scratches patient's skin	Increased risk of infection	4	Defective product/misuse/mechanical failure	4	Remove sharp edges from design	3	20	Visually inspect unit before each use.

Table 5: FMEA for infrared tympanic membrane thermometer ear bud

Item	Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Causes of Failure	Occur	Current Design Controls	Detection	RPN	Recommended Action
Housing	Contains electrical parts	Overheats	Danger to patient or clinician/Damage to device itself/Causes malfunction	7	Repeated use/Accidental damage during use or during storage	2	Full device check for any abnormal marks or damages directly prior and after each use/Concise date stamps for when device was first added to stock/Device monitoring during procedures to check for damages	2	10	If a physical assessment of the device is followed through with (thoroughly, both before and after use), healthcare workers can relatively easily check for damage. Also, marking date of restocking of device can help assess how long the device has been in use and when to replace
		Physical Damage	Causes malfunction/Require repairment or replacement/Inaccurate readings/Could render device useless	7	Repeated use/Accidental damage during use or during storage	2	Full device check for any abnormal marks or damages directly prior and after each use/Concise date stamps for when device was first added to stock/Device monitoring during procedures to check for damages	2	5	If a physical assessment of the device is followed through with (thoroughly, both before and after use), healthcare workers can relatively easily check for damage. Also, marking date of restocking of device can help assess how long the device has been in use and when to replace
		Pieces come apart/separate	Causes malfunction/Require repairment or replacement/Inaccurate readings/Could render device useless	7	Repeated use/Accidental damage during use or during storage	2	Full device check for any abnormal marks or damages directly prior and after each use/Concise date stamps for when device was first added to stock/Device monitoring during procedures to check for damages	2	5	If a physical assessment of the device is followed through with (thoroughly, both before and after use), healthcare workers can relatively easily check for damage. Also, marking date of restocking of device can help assess how long the device has been in use and when to replace
		Becomes wet with bleach solution	Malfunction of the control unit likely causing catastrophic failure	8	Accidental spill during cleaning	5	Separate control unit from the bed	3	30	Design the unit to be resistant to bleach and water eliminating the risk.

Table 6: FMEA for the control unit housing

7 Engineering Analysis

We consider two spectrums for our engineering analysis: 1) Theoretical and 2) Experimental; the spectrum spans from the simplest way in which we could accomplish the analysis to the most complex. Without a prototype and inventory of all of the materials and components we need for our selected concept, we performed mostly theoretical analysis and some experimentation.

Once we have a prototype, we will test our concept for fulfillment of our primary design drivers and remaining user requirements through a number of simulations and physical testing. We have established a partnership with the Clinical Simulation Center in the University of Michigan Hospital and have access to its resources, including full- and partial-mannequin models, silicone material models, vital reading simulations, and operating room staging.

7.1 Material properties and testing

7.1.1 Bleach solution testing

Every component of our device is considered a noncritical patient care item or instrument, since it only comes in contact with intact patient skin and not with mucous membranes; the sterility of items coming in contact with intact skin is considered not critical, in which there is virtually no risk for transmission of infectious agents and pathogens.

Sodium hypochlorite, or household bleach, is widely used as a cleaning method and is the method used in hospitals in the Dominican Republic [31, 30]; it has a broad spectrum of antimicrobial activity, does not leave toxic residue, is inexpensive and fast-acting, removes dried or fixed microorganisms and biofilms from surfaces, and has a low incidence of serious toxicity [34]. In fact, a 1:10 bleach solution is known to kill blood-borne pathogens (including viruses) and emerging pathogens, including Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Rotavirus, Human Papilloma Virus, Norovirus, Severe Acute Respiratory Syndrome [SARS] Coronavirus [34].

First, we reviewed literature to determine the ability of our selected materials to withstand wash by sodium hypochlorite (bleach) solution. Resistance to bleach was defined as only a slight change in weight, dimension and/or property (swelling or degradation, for example). All of the following materials were found to be resistant to bleach: ABS (acrylonitrile-butadiene-styrene) plastic [50], polyurethane [51], nylon [52], and Mylar (polyethylene terephthalate, or PET) [53, 54]. However, the tensile strength in both polyurethane and nylon were found to decline with bleach [55].

Since literature was not found for the resistance of polyurethane coated nylon fabric to bleach and some literature showed that bleach can attack nylon and some types of polyesters, we performed an experimental test [56]. We used a plastic bucket, liquid measuring cup, lukewarm city tap water and household bleach to prepare a 1:10 bleach-water solution. With a wet cotton cloth, we applied the bleach solution to two 2" by 2" sections of both the polyurethane coated nylon fabric and Mylar marathon blanket and let the bleach solution, pooled on the sample, stand for 1 minute and 5 minutes before wiping dry (Figure 21). Additionally, we submerged another 2" by 2" section of the samples in the bleach solution. We assessed the condition of the materials after application with and submersion in bleach solution, looking for signs of color fading, corrosion, mechanical or chemical deformation, and other reactivity (Table 7).

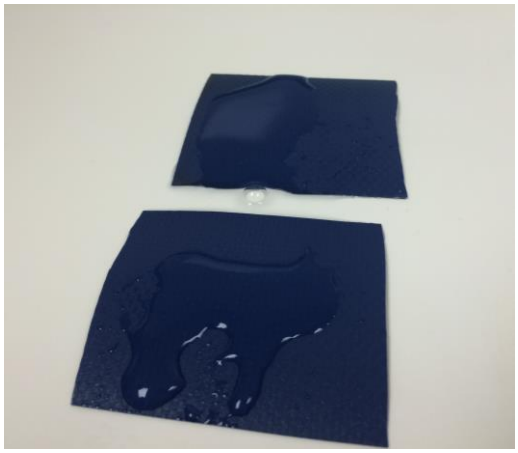

Figure 21: Polyurethane coated nylon fabric samples with 1:10 bleach solution pooled on surface. [*Personal photograph by Ben Lewis. 20 Oct 2015.*]

Table 7: Observations from tests subjecting materials to bleach solution

Material	Surface puddle, 1 minute	Surface puddle, 5 minutes	Submersion
PU-coated nylon	No change	No change	No change
Mylar	No change	No change	Grains formed at 10 minutes; lost metallic coating at 12 minutes

As a result of our testing, we can support the literature that the polyurethane coated nylon fabric is resistant to bleach and can safely be used in our design in areas that would be subject to wash by bleach solution. Although topical application of bleach solution to Mylar appeared to have no effect on the material, submersion in bleach solution caused the dissolution of the metallic coating beginning around 10 minutes; this metallic coating is essential to the function of the Mylar material in preventing radiant heat loss. Therefore, although a study in the literature found Mylar to resist bleach, the findings from our test indicate that we must ensure that any Mylar material to be incorporated into our design avoid any contact with bleach; it must be protected by a resistant coating or encased by another material, such as PET.

7.1.2 Properties of heating material elements

Literature was reviewed to determine the properties of materials under consideration for incorporation into the heating element of our design. We did not find any printed circuit boards (PCBs) that were designed for heat generation (and instead, designed for high conductivity and insulation resistance). Table 8 shows the materials and their corresponding properties relevant to heat production.

Table 8: Properties of materials under consideration for use in heating element

Material	Composition	Dimension	Property	Source
Carbon tape	Carbon-boron alloy	3 mm (t) x 90 mm (w)	29.5 kΩ/m	[57]

Conductive yarn	Stainless steel alloy fibers	0.5 – 35 µm (d)	0.1 – 395 Ω/m	[58]
Kapton®	Polyimide insulated film	25.4 mm (t) max.	2.5 – 10 W/in^2	[59]
Ultra heating fabric	Metal polymer fiber composite	0.7 mm (t)	58 – 89 Ω/m	[60]
Conductive fabric	Electrolycra, silver plated	Varying	72 – 273 Ω/m	[61]
Polymer thick film heating sheets	Polyester substrate & conductive inks	25.4 mm (t)	1.25 W/in^2	[62]
Heatflex®	Fiberglass reinforced silicone rubber	1.0 mm (t)	12 W/in^2	[63]

The ultra heating fabric heats quickly; in fact, with an input voltage of 9 V, the fabric produced a temperature of 38°C in just 1 minute. Due to its light weight, flexibility and heat generation capacity, ultra heating fabric may be a good option for us to incorporate into our design as the resistive heating element [60].

However, to appropriately compare each material under consideration for the heating element of our device, we must find further information on the watt density of the materials for which it is currently unknown from literature review or perform theoretical calculations with known information. On the basis of the materials for which the wattage density is known, however, our findings suggest that Heatflex®, Kapton® polyimide insulated flexible film, and polymer thick film heating sheets are good options for our heating element of our device, as they display desirable watt densities [59, 62, 63].

7.1.3 Conductive metallic beads

Conductive metallic beads were considered as a concept to use in an underbody mattress to effectively transfer heat to the patient while conforming to the body's contours to increase contact surface area. However, analysis was first done on the theoretical weight of the beads that would be needed inside of the mattress to determine if it would be feasible just by weight limit.

Every liter of beads weighs roughly 3.65 pounds [64]; our mattress would require a volume of about 0.0582 m^3, or 58.2 L, assuming an area of 1.16 m^2 and depth of 5 cm [6]. To fill this volume, the mattress would weigh around 212 pounds due to the beads alone; due to the extreme load this would place on the operating table and on the team moving and placing the mattress, conductive metallic beads will not be incorporated into our prototype.

7.1.4 Properties of polyurethane coated nylon fabric

Literature was reviewed to understand the material properties of the polyurethane nylon fabric to be used in covering the cushions of the underbody warming mattress. Testing of applied force in both the warp and fill directions of the fabric determined the relationship of Poisson's ratio to the applied load for the fabric; in the warp direction, Poisson's ratio is around 0.25, and in the fill direction, Poisson's ratio is around 0.20. Polyurethane coated nylon fabric exhibits both stress- and strain-relaxation under axial tensile cyclic loading. In the warp direction, or the direction of the lengthwise fibers held in tension, cyclic loading testing

found an average load and average stress at failure to be 452 N and 59.8 MPa, respectively. In the fill, or weft, direction, cyclic loading testing determined the average load and average stress at failure to be 563 N and 73.9 MPa.

This suggests that this fabric will be durable for long use in continued loading of surgical patients. Further analysis must be performed on the properties of this material; specifically, we need to understand the tension that would exist between the material and skin for both a resting and sliding patient, as this information would allow us to better understand how our device might cause pressure ulcers of the patient's skin and how we can improve the device and/or material to reduce to risk of pressure ulcers.

7.2 Thermal testing

7.2.1 Polyurethane coated nylon thermal conductivity test

Before we could create theoretical models to simulate our solution, we had to discover the thermal properties of our materials. After research failed to provide conclusive numbers for the thermal conductivity of our blanket materials, we decided to run an empirical test to experimentally discover the properties. Specifically, we needed to determine the thermal conductivity of polyurethane coated nylon. Conductive heat transfer is governed by equation 1 [65]:

$$\dot{Q} = \frac{\kappa A \Delta T}{d} \qquad \text{Eq. 1}$$

Where Q is heat flux, $\boldsymbol{\kappa}$ is thermal conductivity, A is the cross sectional area, ΔT is the temperature difference between the hot and cold sides of the material, and d is the thickness of the material. If we are able to apply a known heat flux through a specific thickness and area of our material, we can solve for the thermal conductivity by measuring the change in temperature across our sample. Heat flux is a difficult and expensive to quantify directly. In order to solve for heat flux, we decided to utilize a second sample of a known material. We know the thermal conductivity of aluminum, can measure the size of the sample, and can experimentally measure a temperature difference across the material allowing us to solve for heat flux. This heat flux value can be substituted back into our original equation to provide us an experimental value for the thermal conductivity of polyurethane coated nylon as shown in Equation 2.

$$\kappa_2 = \dot{\kappa}_1 \frac{d_2 \Delta T_1}{d_1 \Delta T_2} \qquad \text{Eq. 2}$$

If the areas of the two materials are the same, then Eq. 2 characterizes the unknown thermal conductivity as a ratio of thicknesses and temperature differences scaled by the known material thermal conductivity.

With the experimental theory verified, we began setting up the experiment. We utilized a hot plate to generate a constant heat flow. We cut matching pieces of 6061 T6 aluminum and polyurethane coated nylon into 1.5" by 4" segments. The aluminum had a thickness of 3.175 mm and a known thermal conductivity of 205 W/mK. The thickness of polyurethane coated nylon was 0.2 mm. Temperature measurements were taken redundantly with K-type thermocouples and an infrared thermometer at the interface points between the hot plate and material samples. The hot plate was warmed and reached a steady state value of approximately 80°C. The experimental set up is shown in Figures 22 and 23.

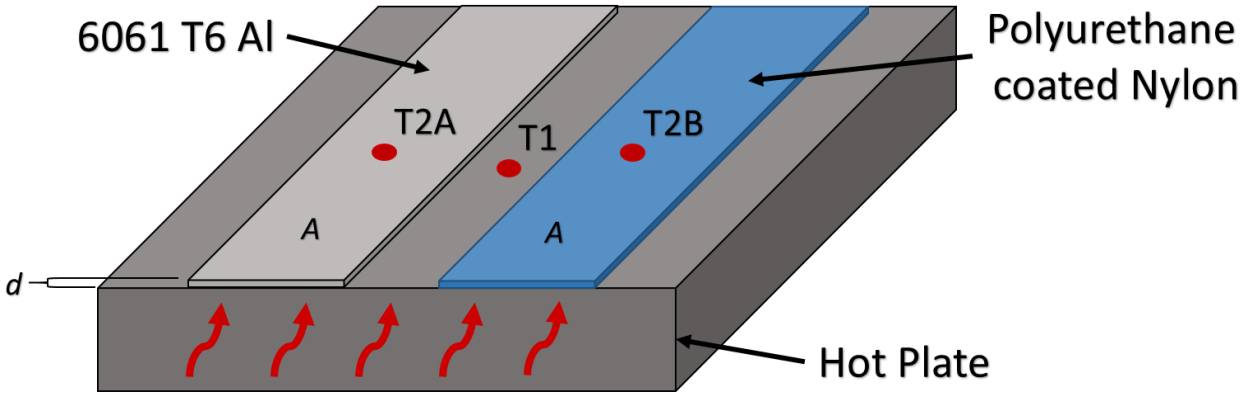

Figure 22: The experimental set up. The hot plate provided constant heat to samples of aluminum and polyurethane coated nylon. Temperature measurements were taken at the surface of the hot plate and at the top of each material shown in Table 9.

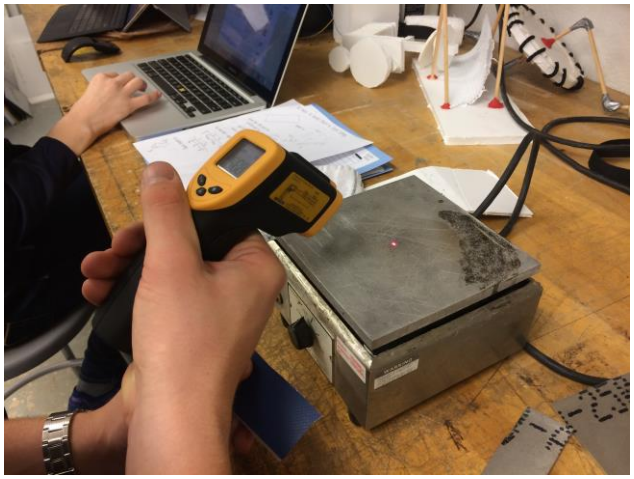

Figure 23: Experimental test using hot plate, Al sheet and polyurethane coated nylon fabric. [*Personal photograph by Ben Lewis. 20 Oct 2015.*]

Table 9: Temperatures taken with a thermocouple at each interface of the experiment outlined in Figure 22.

Material	Hot Plate: T1 (°C)	Material Interface: T2 (°C)	Thermal Conductivity (W/mK)
6061 T6 Al	82	78	205
Polyurethane coated Nylon	82	60	61.5

Our results concluded that the temperature measurements from both the thermocouples and the infrared thermometer were inconclusive. The infrared thermometer proved to be inaccurate when used on metallic surfaces, a known weakness of the device. Temperatures were consistently shown to be higher on the cold side of the non-reflective polyurethane coated nylon when compared to the reflective hot plate. This

measurement method was disregarded. The thermocouples gave seemingly accurate readings. However, as discussed below, the thermal conductivity calculated from this methodology was orders of magnitude off from the theoretical values for thermal conductivity for polyurethane and nylon separately. We concluded that the thermocouples used were not gathering proper readings due to poor contact with the surface. Furthermore, the hot plate seemed to be distributing heat unevenly across the material with a hot spot in the center of the plate.

This mode of analysis is the simplest way to calculate the thermal conductivity of a material. This methodology and level of detail would be sufficient to gather baseline theoretical values for the heat transfer through our blanket. However, the results were not within our anticipated range for the material, so we failed to verify thermally the polyurethane coated nylon for our use. This test could be repeated multiple times to increase the certainty of our values and to increase the confidence in our temperature measurement units. Professional thermal analysis or calculations would have been preferred in our setting. Further lab tests are required to minimize outside factors and ensure proper temperature readings at the interfaces.

7.2.2 Heat transfer calculations

To prioritize our design driver, "effectively transfers heat to the patient", we knew it was essential to perform theoretical modeling through heat transfer analysis. The heat transfer calculations below allowed us to obtain certain parameters that would impact the quality and functionality of our design. Preventing burns and ensuring that the patient does not enter a hypothermic state could be analyzed by finding important quantities such as heat flux and insulator material thickness.

Heat loss through cotton linen surgical sheets

Currently in the Dominican Republic, simple cotton linens of thread count 270-280 are placed over the patient during surgery [31]. Our team wanted to simulate an environment where we could calculate how much heat is lost when only placing sheets over a patient during surgery. Because the Simulation Center at UMHS did not have a heat-emulating mannequin for us to conduct measurements for heat loss, we were able to find a study of heat loss in an appropriate OR environment with cotton linens.

The Department of Aesthesia at the University of California, San Francisco, conducted the study “Heat loss in humans covered with cotton hospital blankets.” The study was conducted in simulated OR environment with 6 patients. A range of 1-3 unwarmed cotton linens were placed over each patient for 60 minutes. The department found that cotton linens only reduced heat loss by average 33% +- 5%, which is ineffective in providing a comfortable or safe body temperature. The Bair Hugger, in comparison, reduces heat loss by ~80% +- 5% [66]. This information allowed us to move forward in finding a better insulating material to place over patients and use with our underbody heating system.

Heat flux through underbody warmer of polyurethane-coated nylon

Our team purchased polyurethane-coated nylon to understand if this material was effective in using under the patient during surgery. The details of this testing was outline in the previous test section. We used the following model, in Figure 24, to understand the material and how the coating affects the thermal resistivity of the unit.

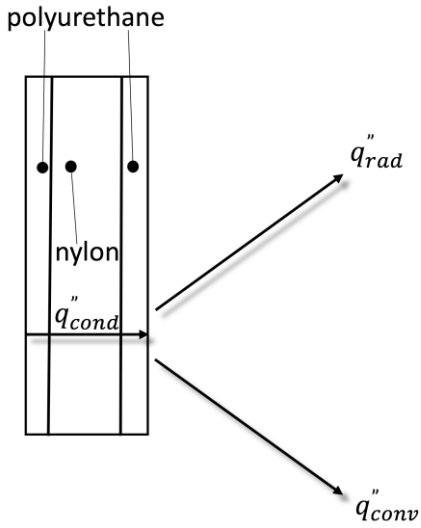

Figure 24: Polyurethane-coated nylon

After finding that the tests we ran we not accurate enough the find the thermal conductivity of the unit, we decided to find literature values of polyurethane and nylon to and than calculate the total thermal resistance of the material. We know the governing equations of conduction, convection, and radiation from the textbook Fundamentals of Heat and Mass Transfer [65](Eq. 3-5). Using this textbook allowed us to perform a heat transfer analysis (essentially a thermal circuit in series) to better understand how to calculate the total effective thermal resistance. We would use this value to then perform a heat flux analysis and energy balance to evaluate the amount of heat delivered to our patient at certain temperatures we set our device to during simulation (Eq. 6,7).

Governing equations:

$$q''_{cond} = \frac{-k(T_1 - T_2)}{t} \qquad [W/m^2] \tag{Eq. 3}$$

$$q''_{conv} = h(T_2 - T_\infty) \tag{Eq. 4}$$

$$q''_{rad} = \varepsilon\sigma({T_2}^4 - {T_\infty}^4) \tag{Eq. 5}$$

Heat flux analysis:

$$q'' = \frac{\Delta T}{R''_{tot}} \tag{Eq. 6}$$

Energy balance:

$$\dot{E}_{in} - \dot{E}_{out} = q''_{cond} - q''_{conv} - q''_{rad} = 0 \tag{Eq. 7}$$

Where q'' = heat flux in Watts for meter squared, T = temperature in Kelvin, E = energy in Joules, R'' = material thermal resistance in Kelvins per Watt meters squared, t = material thickness in meters, σ = Boltzman's constant in kilogram meters squared per Kelvin seconds squared, ε = emissivity which is unitless, k = thermal conductivity in Watts per Kelvin meters, and h = convection coefficient in Watts per Kelvin meters.

Minimum thickness for insulation above 95th percentile human

Since our design incorporates placing an insulated material above the patient, we wanted to understand how thick to make the material. In order to calculate this, we first made a schematic of the skin/fat and insulation over the body (Figure 25) and translated this into a thermal circuit diagram (Figure 26).

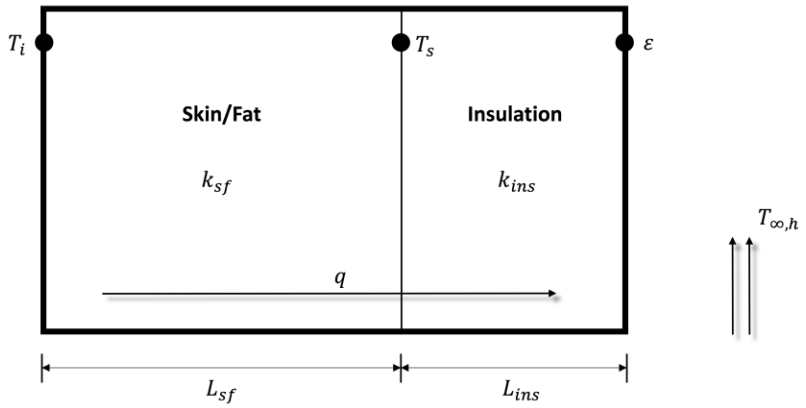

Figure 25: Model of the Skin/Fat and Insulation over the body

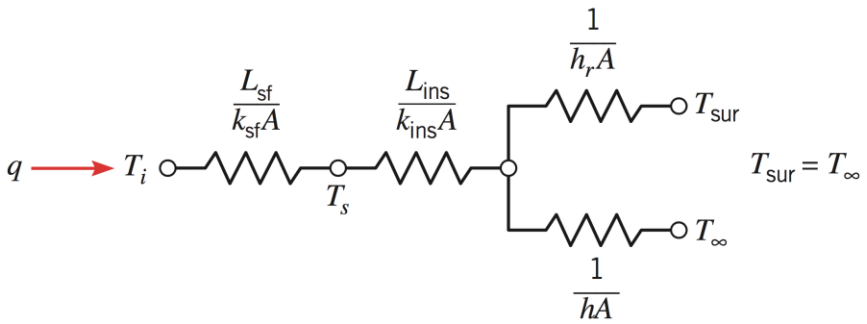

Figure 26: Circuit diagram of patient skin/fat layer with overlaying insulator material

We were able to obtain equations 8-10 using this model. We then took the surface area of a 95th percentile human in a low-ended non-hypothermic heat range (q = 100 W) and calculated that we needed a minimum thickness of 4.5 mm of insulator material to ensure our patient stays within the allowable non-hypothermic range. The insulator alone will keep the patient safely warm for 10 minutes if the power were to go out in a Dominican Republic hospital.

Radiation heat transfer coefficient:

$$h_r = \varepsilon\sigma(T_{s,o} + T_{sur})(T_{s,o}^2 + T_{sur}^2) \quad \text{(Eq. 8)}$$

Outer surface temperature of the insulation layer:

$$T_{s,o} = T_i - q\left[\frac{L_{sf}}{k_{sf}A} + \frac{L_{ins}}{k_{ins}A}\right] \quad \text{(Eq. 9)}$$

Insulation thickness:

$$L_{ins} = k_{ins}\left(AR_{tot} - \frac{L_{sf}}{k_{sf}} - \frac{1}{h+h_r}\right) \quad \text{(Eq. 10)}$$

Where q= heat loss in Watts , T = temperature in Kelvin, A = surface area in meters squared, R = material thermal resistance in Kelvins per Watt, L = material thickness in meters, σ = Boltzman's constant in in kilogram meters squared per Kelvin seconds squared, ε = emissivity which is unitless, k = thermal conductivity, and h = convection coefficient.

7.3 Temperature monitoring

There are a number of current methods for measuring patient core temperature non-invasively, including the use of mercury, electronic and/or infrared thermometers (and probes) at the axillary artery (armpit), nasopharynx, deep lingual vein (under tongue), tympanic membrane (inner ear), and temporal artery (forehead). Due to the invasiveness of measuring temperature in the nasopharynx and under the tongue and the discomfort it would cause to a patient under neuraxial anesthesia (the most commonly administered anesthesia in secondary hospitals in the Dominican Republic), we removed those methods from consideration into our design [14, 42].

We reviewed literature of testing comparing the three temperature measurement techniques (axillary, tympanic and temporal) to compare and contrast their accuracy and precision to temperature measurements from the pulmonary artery, since the blood nearest the heart is the most accurate representation of true core body temperature [61].

Axillary artery:

This measurement technique requires placement of a mercury thermometer or electronic sensor into the armpit where the axillary artery lies close to the skin surface. Medical studies have shown readings from probes near the axillary artery to deviate from the pulmonary artery temperature by 1.3°C ± 1.3°C [67] [68]. This deviation occurred under a controlled environment where the patient held the temperature probe (such as Hi-Lo Temp probes, Mallinckrodt Critical Care) tightly between their arm and body [67]. For our scope in the Dominican Republic, patient orientation consists of arm placement outstretched horizontally, leaving the armpit in a 90° angle [11]. Furthermore, the open arm scenario introduces uncertainty into the insulation of the sensor. Body heat will penetrate the sensor from only one angle, leaving approximately 2/3 the probe exposed to the environment. This additional variance to the measurement causes concerns for accuracy when our device may respond to changes in temperature up to half a degree.

Temporal artery:

This measurement technique requires a sweeping motion by a sensor across the forehead into the hairline to ensure that the sensor passes over the temporal artery, where it is closest to the skin. Since one of our primary design drivers is that our device requires minimal user input, this temperature measurement technique is not a good option for our design.

Tympanic membrane:

This measurement technique requires insertion of an infrared sensor into the ear. Studies have shown tympanic temperature measurements to be the most accurate non-invasive way to monitor core body temperature [69]. In a study of over 100 adults, tympanic thermometers showed a mean difference of 0.8°C ± 1.0°C when compared to the temperature in the pulmonary artery [67]. This method has proved effective even against external thermal stimulus, such as sweating, decreased head temperature, and cooling the skin [70]. This method is both non-invasive and common in the industry. However, no method currently exists to provide continuous temperature feedback to our system (current methods supply a one-time reading after manually taking the temperature). This technology has been proven in the use of a

football helmet, the Therma Tracker, but is not currently available on the market [71]. We will be developing a sensor to be used in a continuous feedback loop.

Due to the study, we now understand what average error and standard deviation will be acceptable for our design.

7.4 Wattage and temperature output

InfraFloor WarmFilm®

The InfraFloor WarmFilm® underfloor warming device came with two leads and is meant to connect to 120V AC. To test this system, we connected the leads to a standard 3-prong plug to be connected to a wall outlet. We tested it both with and without wooden block layers above and below to help insulate heat and reduce outward radiation. First, without the wooden layers, it took 20 minutes to change from 22°C to 30°C. With the wooden layers, it took 20 minutes to change from 22°C to 31°C. We determined that this will not supply enough heat for our device.

STEP Warmfloor

The STEP Warmfloor underfloor warming device was also connected to a 3-prong plug, exactly like the InfraFloor device was. We tested it both with and without tin foil on its surface, which was used to disperse the heat evenly. Without the tin foil, it took 30 seconds to change from 22°C to 36°C, but then it dropped to 34°C. It also would not heat up nearly as much as this the second or third times, and would only behave the same way if we left it untouched for over a half hour. With the tin foil, it took 30 seconds for the surface of the tin foil to change from 22°C to 25°C, and then it would decrease soon after. We have determined that this will not supply enough heat and it decreases quickly as well.

Magnetic Wire

We acquired magnetic wire from the mechatronics lab to test how it compares to resistive heating wire. Two lengths of wire were compared to test how fast the wire heated and how hot it got. The lengths were 10 feet and 50 feet. We tested the wire using a 5V DC power supply. The 10 foot length wire changed from 22°C to 247°C in about 20 seconds. The 50 foot length wire changed from 22°C to 180°C in about 40 seconds. We determined that this amount of heat will be too dangerous for our application, and it heats up far too quickly to control.

Carbon tape

We Tested Carbon tape because of its flexibility and potential for placing it directly under the top surface without causing discomfort for the patient. There were doubts about this material because its common use is not to produce heat, but we wanted to make sure. During our test, we supplied 20V from a power supply to 2 different lengths of the carbon tape, corresponding to different resistances. The first length was 3 feet, which changed from 22°C to 40°C in 50 seconds. The longer length, 10 feet, changed from 22°C to 37°C in 50 seconds. We determined this was not enough heat for our application. The carbon tape also seemed to not radiate any heat at all from just placing our hands directly over it while heating.

Electric blanket wire w/ and w/out limiters

Our most promising heating method was resistive wires without limiters. We took the resistive wires out of an electric blanket and tested it with and without current limiters that were included in the circuit. With the current limiters, the temperature changed from 22°C to 34°C after 10 minutes of heating. Without the limiters, the temperature changed from 22°C to 42°C in 3 minutes. We then tested the wires without limiters when it was sandwiched between our foam/nylon layers. In this test, the wires retained heat and were able to change from 22°C to 48°C in 3 minutes. Figure 27 below shows the temperature of the wire and surface of the device vs time.

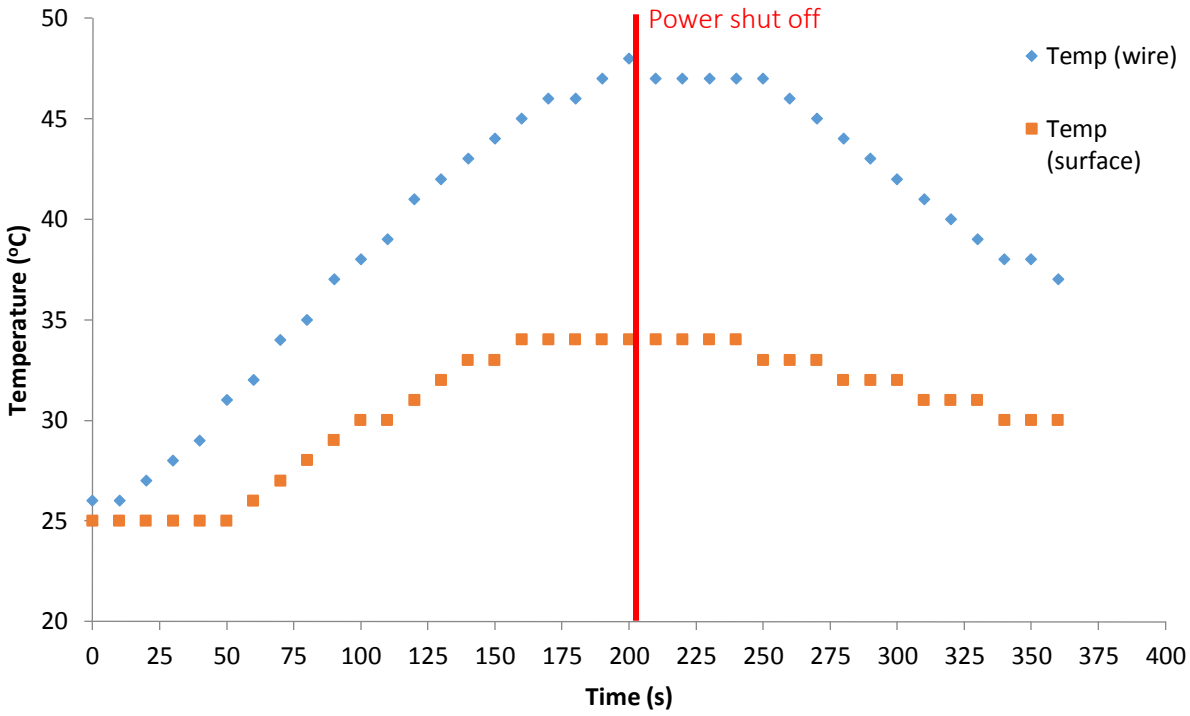

Figure 27: Temperature vs time plot of resistive heating wire and surface temperature vs time

7.5 Patient heat loss simulation

The purpose of this test is to determine the time constants (RC) from plots of temperature versus time for the representation of core body temperature of a raw chicken for the following over-body insulating methods: 1) open air, 2) cotton linen, and 3) Mylar® marathon blanket. These scenarios, shown in Figure 28, will allow us to quantify the heat loss in each scenario and make objective comparisons to the effectiveness of each.

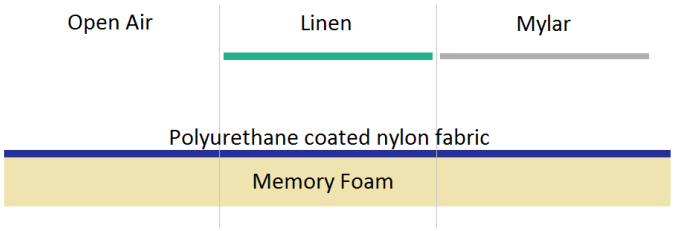

Figure 28: Simulation of body temperature loss as a function of time for various over-body insulation types

This test required three ~4 lb whole chickens, three 5 L cooking pots filled with water and a stove top to bring the chickens to temperature. We measured temperature with a Thermapen® digital food thermometer, Nubee™ infrared heat gun, thermocouples and multimeters. To create the testing scenarios, we used a 3" thick memory foam mattress topper, Mylar® marathon blankets, polyurethane coated nylon fabric, and a 100% cotton sheet.

To prepare for testing, we brought the ~4 lb chickens to 40 - 49 °C in a pot of warm water heated on the stove-top, monitoring temperature of the water and chicken with a Thermapen® digital food thermometer. Temperature of the chicken was measured ~1 in into the upper chest just to the left of the sternum. For each of the three tests, we collected data simultaneously from three samples, placing the chickens on an unheated mattress, composed of 3" thick memory foam covered in a layer of Mylar® sheeting then by a layer of polyurethane coated nylon fabric to recreate the basic composition of our mattress. The chickens were left exposed to open air in the first test, covered directly by Mylar® in the second, and covered directly by a cotton linen in the last test (Figure 29). We measured the "core" temperature of the chicken with thermocouples buried ~1 in into the upper chest of the chicken just to the left of the sternum; this allowed us to collect temperature measurements from the same location for each sample to reduce error due to measurement location.

Figure 29: Open air (left), cotton linen (middle) and Mylar(R) (right) testing set-up. [*Personal photographs by Ryan Thomas. 4 Nov 2015.*]

We collected temperature readings every 2-4 minutes from the multimeters (with connected thermocouples) for a 30 minute time period, and ambient temperature was maintained by the household thermostat at 21.8 °C with 57% humidity. The results are shown in Figures 30-32.

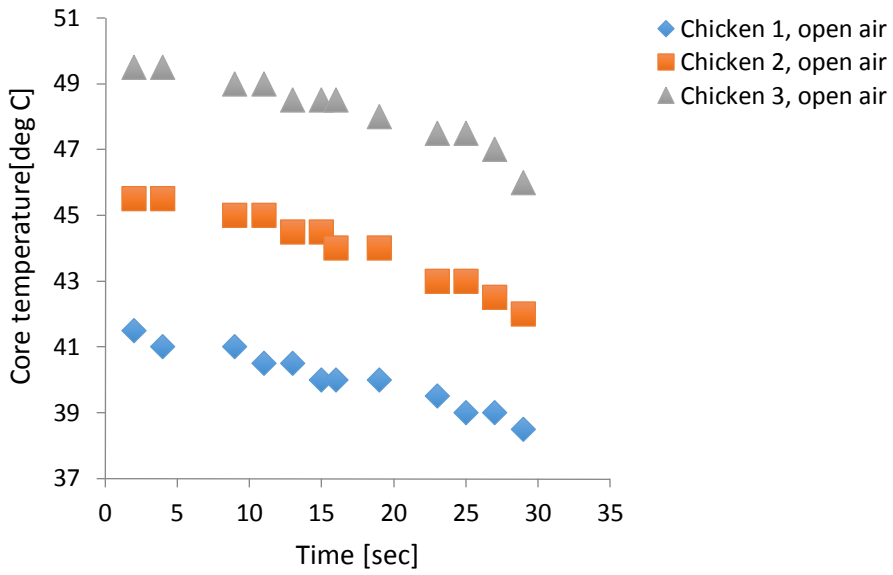

Figure 30: Temperature vs time plot for open air

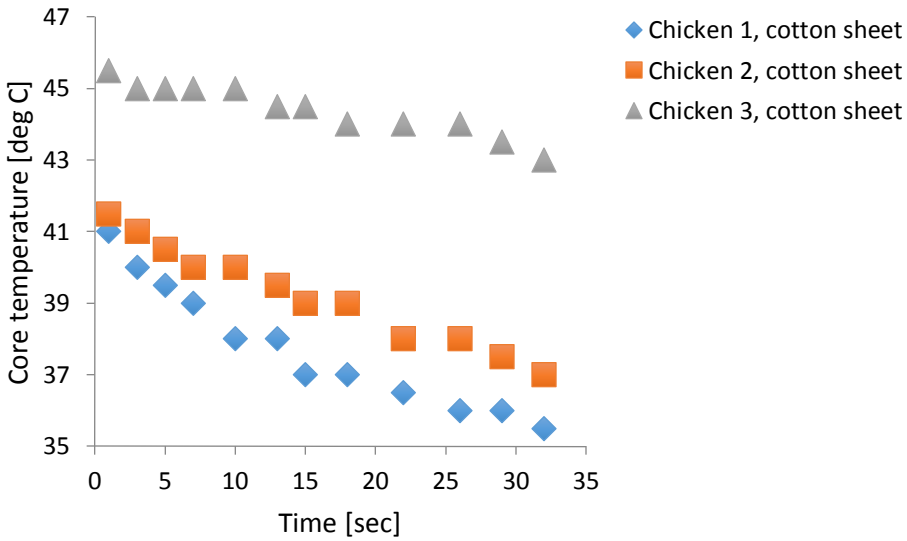

Figure 31: Temperature vs time plot with use of cotton linen drape

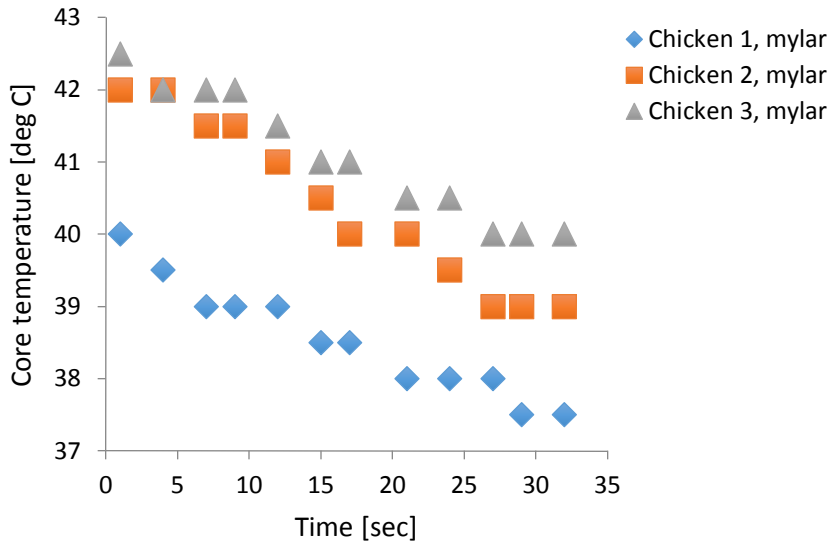

Figure 32: Temperature vs time plot with use of Mylar® drape

For a visual representation of the averaged behavior of heat loss for the three situations on the same plot, we averaged the coefficients of the second and first order coefficients to the polynomial lines of best fit and determined the intercept to be 44 °C, assuming that a starting temperature within +/- 5 °C does not significantly affect the rate of heat loss (and shape of the heat loss curve). Heat loss behavior for the three situations are shown in Figure 33.

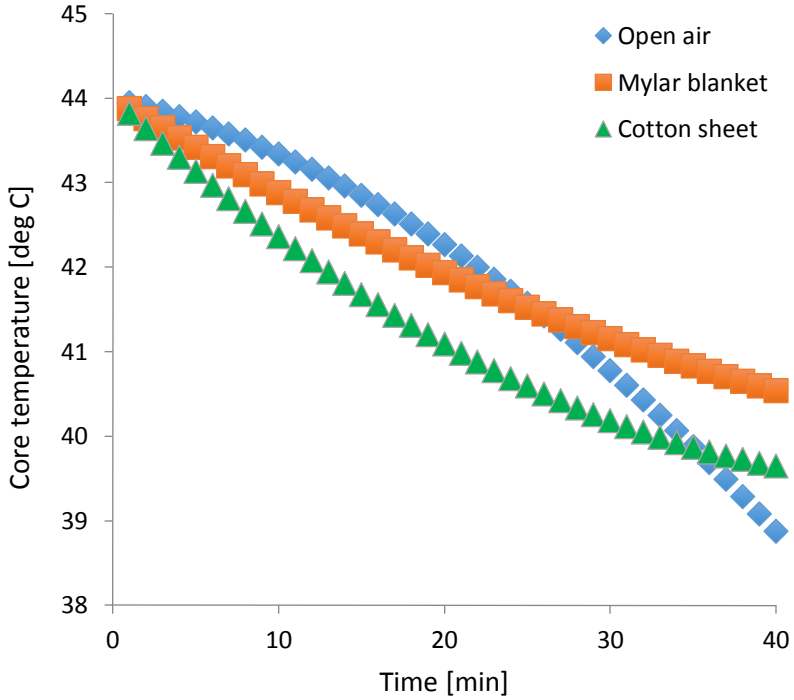

Figure 33: Averaged rate of heat loss in chicken (patient model) open-air and with coverings of cotton linen or Mylar®

We performed paired t-tests to determine the significance of the differences in rate of temperature decrease among the situations using the data we collected from each of the chickens for the three tests. The p-values for our one-tailed, paired t-tests for rate of temperature decline are given in Table 10.

Table 10: Statistical testing of rate of temperature decline with one-tailed, paired t-test

$H_o: \left\|{}^{\Delta T}/_{\Delta t\ air}\right\| \leq \left\|{}^{\Delta T}/_{\Delta t_{Mylar}}\right\|$	$H_A: \left\|{}^{\Delta T}/_{\Delta t_{air}}\right\| > \left\|{}^{\Delta T}/_{\Delta t_{Mylar}}\right\|$	*p = 0.0548*
$H_o: \left\|{}^{\Delta T}/_{\Delta t_{air}}\right\| \geq \left\|{}^{\Delta T}/_{\Delta t_{linen}}\right\|$	$H_A: \left\|{}^{\Delta T}/_{\Delta t_{air}}\right\| < \left\|{}^{\Delta T}/_{\Delta t_{linen}}\right\|$	*p = 0.310*
$H_o: \left\|{}^{\Delta T}/_{\Delta t_{Mylar}}\right\| \geq \left\|{}^{\Delta T}/_{\Delta t_{linen}}\right\|$	$H_A: \left\|{}^{\Delta T}/_{\Delta t_{Mylar}}\right\| < \left\|{}^{\Delta T}/_{\Delta t_{linen}}\right\|$	*p = 0.0173*

Due to the results of our testing, we can with 94% confidence support our hypotheses that the rate of temperature decline in open air is greater than that with Mylar®, but we cannot confidently support that the temperature decline in open air is less than that for cotton linen. We can support with 98% confidence that the rate of temperature decline with cotton linens is greater than that for Mylar®. To obtain more accurate results, however, we would need to collect a larger sample to gather additional confidence in our statistical test.

This test has led us to the conclusion that Mylar® is most effective in retaining heat loss from the body due to its relative ability to slow initial heat loss and reach a relatively high plateau. However, we learned from our stakeholders that Mylar® should not be the sole over-body component since it cannot serve the purpose of absorbing fluids during surgical procedures to maintain a sterile surgical site like cotton linens (currently used as surgical drapes in secondary hospitals in the Dominican Republic). Therefore, our design will contain both Mylar® and cotton linen components to effectively prevent heat loss while also serving the primary purpose that surgical drapes are used for in soaking up blood and other fluids during an operation to keep the surgical site sterile.

8 Design Description

8.1 Underbody resistive heating mattress

The primary function our device is to effectively warm patients during surgery, which we will accomplish with an underbody resistive heating mattress. The mattress must warm the patient using conduction and radiation, resist bodily fluids, resist puncturing and tearing, and not interfere with the surgical procedure. For proof-of-concept, we have decided to make a 2 foot by 2 foot small-scale model of our mattress. This will be the width of the OR bed and just under the length of a section that the regular OR bed is made of. Our model will allow us to effectively evaluate the functionality of our device, without having to spend money on building the full scale when there may be future iterations of our design. In our validation and verification section, will prove how this small-scale model will still fulfill our requirements this semester.

There will be multiple layers within the mattress that serve various purposes. The bottom layer will consist of light blue mini-cell luxury firm foam, which will act as a sturdy base for the device. Above this will be a layer of soft memory foam that will help distribute a patient's weight and reduce pressure. The next layer will consist of our deflector, to prevent heat loss through the bottom of the device, which is a piece of reflective material lying over the foam. The deflector is secured to the foam with a spray adhesive made for use with foam. Next, a resistive heating system will be above the deflector, which will consist of one of the specific-gauge insulated wire shown in the Bill of Materials and embedded in porous fabric. Then, on top of our resistive heating system, a diffuser will be used to evenly dispense heat across the surface of the mattress. The diffuser being used in our scale system is a piece of loosely wound cotton. Surrounding the entire device will be polyurethane-coated nylon fabric, which allows for heat transfer while resisting absorption of bodily fluids and prevents puncturing or tearing. Our model device is sewn together with Kevlar string (Figure 34).

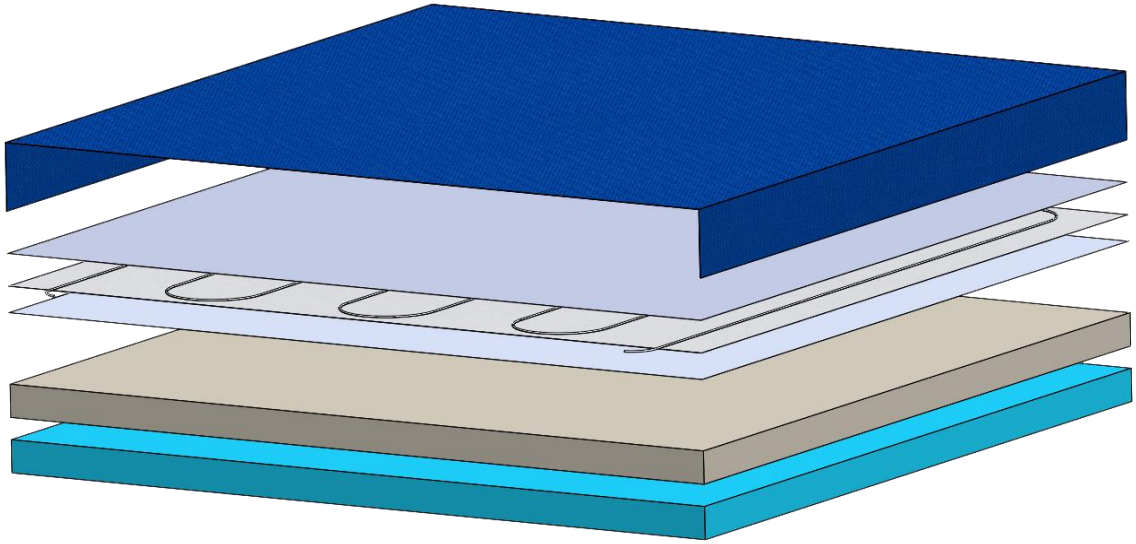

Figure 34: Cross-sectional, exploded view of the layers for our 2'x2' mattress design. Materials from bottom to top include: firm foam, memory foam, reflective deflector, resistive wire heating element embedded in porous fabric, cotton diffuser, and outermost covering of polyurethane-coated nylon.

In the future, we would like to implement design changes into the full scale version of our product. In order to eliminate any fluids leaking into the device and streamline manufacturing, we would like to heat seal the edges of the polyurethane coated nylon covering (this was not completed in the scale model due to lack of available equipment). After receiving feedback from our stakeholders, we have decided to utilize clips to attach the device to the bed. Adjustable elastic straps allow for the device to fit snuggly on any style of bed while providing quick and convenient set up and tear down. Also, we are continuing to investigate conductive memory foam for use as a diffuser and pressure distributer. This second layer of conductive memory foam infused with graphite would eliminate the memory foam in the scale model and replace the current diffuser (Figures 35 and 36) [72].

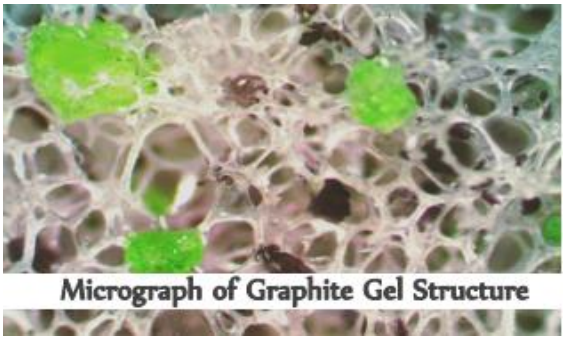

Figure 35: Micrograph of conductive foam used above our heating element, HC-95 graphite-infused viscoelastic foam produced by Peterson Chemical Technology. Image retrieved from [72].

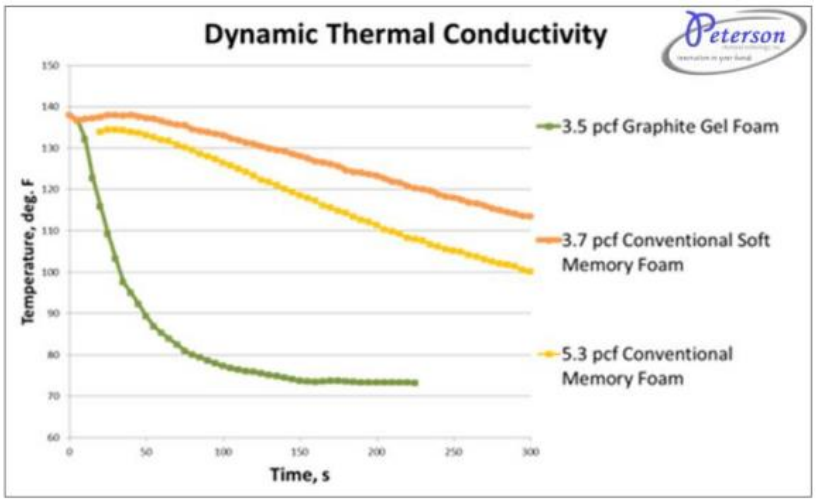

Figure 36: Thermal conductivity comparison between conventional memory foams and HC-95 graphite-infused viscoelastic foam, produced by Peterson Chemical Technology. Image retrieved from [72].

8.2 Over body insulating surgical drape

Confirmed with testing with chickens to model heat loss through air, cotton linen, and Mylar® as insulators (see Section 7.5), our design incorporates insulating over-body sheets (surgical drapes), shown in Figure 37, in place of the hospitals' existing cotton linens (proved to be insufficient in preventing radiant heat loss in our analysis in Section 7.2.2), to prevent radiant and convective heat loss. We changed our over-body design from the attached conformable panels to these insulating over-body sheets to accommodate the needs of our stakeholders; this system would replace current sterile sheets that are used during operations to cover the patient's body to both serve their current function of absorbing blood and bodily fluids to keep the patient and surgical site clean as well as enhance their thermal insulation capacity. We are currently investigating materials that can be effectively embedded in the linens to provide insulation while maintaining performance of the sheets. For Mylar to be effectively deployed, we would need to coat the current Mylar sheets with a PET coating to attain resistance to bleach.

Figure 37: Insulating over-body surgical drape; insulating material in the center (PET-coated Mylar®) surrounded on each side by cotton linen (270 thread count) sheets.

8.3 Tympanic membrane thermometer

To effectively prevent perioperative hypothermia, we must continuously measure the patient's core body temperature. In section 7.3, we identified the tympanic membrane as the most accurate non-invasive location to measure core body temperature. We have identified the NOVAMed 400 Series Adult Tympanic Sensor as our sensor of choice [73]. This sensor utilizes a 400 series thermistor to measure the temperature of the ear canal with an accuracy of ±0.2°C. An ear bud made from a latex-free material restricts air or heat from escaping the canal where measurements are taken (Figure 38).

Figure 38: NOVAMed 400 Series Adult Tympanic Sensor [X1].

Although this system provides use of a reliable industry device, the NOVAMed sensor is not ideal for our system. The sensor is designed for single use and does not meet our reusability requirement. We have identified a prototype sensor developed by a previous University of Michigan team to be the optimal sensor for our final product [74]. This device, developed for monitoring core body temperature at the University of Michigan Sleep Center, utilizes a Melexis MLX90615 infrared thermometer to measure the temperature of the tympanic membrane within an accuracy of ±0.1°C. The team developed a custom ear bud and clip to maintain a steady reading of the membrane temperature (Figure 39). The ear bud is made from molded silicone rubber room temperature vulcanization (RTV) material that is safe for use inside the body and can be easily sterilized. The clip is also reusable and made from Acrylonitrile Butadiene Styrene (ABS) plastic. Although validation revealed some variation in measurements due to movement and the product is not available on the market, this innovative system fulfills our reusability requirement while accurately

measuring core body temperature. The progress of this device will be closely monitored for possible integration into our final design.

Figure 39: Exploded view of the ear clip, ear bud, and infrared thermometer used to measure core body temperature at the tympanic membrane [74].

8.4 Feedback control system

Temperature sensor conversion

For our scale model, we are utilizing 400 series thermistors to measure temperature in three separate locations: on the heating wire, at the surface of the bed, and in the patient's ear to represent core body temperature. Thermistors are characterized by a change in resistance of the wire due to a change in temperature. After the sensor has been calibrated (our 400 series thermistor follows a standard curve of resistance against temperature with a base resistance of 2252 Ohms at 25°C), the change in resistance can be measured and converted to temperature using the Steinhart-Hart equation, Equation 11 [75] [76].

$$\frac{1}{T} = a + b\ln(R) + c(\ln(R))^3 \qquad \text{Eq. 11}$$

The temperature can be calculated based on the resistance of the wire and three constants: *a, b,* and *c*. The constants vary for each type of thermistor, but the values are clearly established for 400 series thermistors ($a = 1.4678 \times 10^{-3}$,$b = 2.3827 \times 10^{-4}$, and $c = 1.0188 \times 10^{-7}$) [76]. With this equation, we can calculate the temperatures at the three locations of our system and adapt the heat being supplied accordingly.

Max temperature fail safes

We have two temperature fail safes to go along with our feedback system. The first fail safe ensures that the temperature of the heating wires does not exceed 60 °C, which is the lowest melting temperature of PBC wire coating [77]. A 400 Series thermistor is placed on the heating wire and is constantly monitored by the Arduino board. When the wire temperature exceeds its limit, the system cuts off the power to the wire until its temperature lowers to a safe level. The second fail safe ensures that the temperature of the surface

of the mattress does not exceed 40 °C, which is the temperature that wet skin can be at for an indefinite amount of time without burning [45]. It also cuts off the power to the device until the temperature returns to a safe level. If either of these limits are reached, the Arduino sends a message to the output screen saying that the temperature is at an unsafe level.

PID controller and coefficients

Our device utilizes a standard Proportional-Integral-Derivative (PID) controller to adjust the heat being emitted by the device. The model system is limited by the amount of power we can supply with a 15 Volt power supply. Since the thermal capacitance of the system is large (it takes a long time for the pad to heat up or cool down), the power initially required by the system remains high while heating and fluctuates once the temperature is initially reached. The controller utilizes a sum of three terms to control the system. First, the proportional gain of the system controls how quickly our device warms and reacts to stimulus. We set the coefficient of our system high for gain to quickly heat and maintain temperature even if some overshoot results (K_p) [78]. Second, the integral term utilizes time stamps taken in the code and previous readings to control for error over time. The coefficient of the integral term, K_i, is an order of magnitude smaller than the proportional term but is still effective in accelerating the system towards the final value and eliminating steady-state error [78]. The derivative term is calculated based on how the readings have changed since the last measurements were taken. By adjusting the derivative coefficient, K_D, we can improve the settling time and stability of the system [79]. For our system, we began with base parameters and adjusted our values based on system performance. The values that we are utilizing in our system are $K_P = 40$, $K_I = 0.1$, $K_D = 0.1$ and input into Equation 12.

$$F(t) = K_P \times P(t) + K_I \times I(t) + K_D \times D(t) \qquad \text{Eq. 12}$$

In the future, the coefficients could be better adjusted empirically if we could accurately model our system as a plant. If we could experimentally determine the thermal resistance and capacitance of the materials in our design, we could optimize the response to follow a specified curve with little overshoot, quick settling time, and no steady state error [78].

Switches (on/off; manual 1, 2, 3 / automatic)

Our control system incorporates two switches (on/off and auto/manual) and three buttons (to switch between manual mode temperatures). The on/off switch is turned to off, the system does not go into the main loop and an output message saying that the system is off is sent to the screen. Once the on/off switch is turned to on, the system enters the main feedback loop. The next step is determining automatic or manual mode. There is another switch that determines which mode the system is in. Within these modes, there are different variables for different functions. When the system is in automatic mode, the target temperature is set to 37 °C, which is the ideal patient core temperature. The tympanic membrane thermometer constantly measures core temperature and adjusts the temperature of the mattress accordingly. When the system is switched to manual mode, the target temperature is set to one of three mattress surface temperatures (26 °C, 38 °C, and 40 °C. There are three buttons that correspond to these three temperatures. When one of the buttons is pressed, the target mattress surface temperature is set to the corresponding temperature for that button.

Pulse Width Modulation (PWM) & H-bridge (electronic relay)

To ensure that our feedback system does not overshoot the target temperatures for core body and mattress surface temperature, we implemented pulse width modulation (PWM). PWM utilizes the methods described in the PID control section above to determine what voltage should be applied to the wires. By applying lower voltages, we are better able to approach desired temperature and maintain it in steady state so that there is no overshoot. We are using an H-bridge as an electronic relay, which is necessary for PWM because it must be able to send very quick pulses. A mechanical relay cannot be used because it the time it takes to discharge current between cycles is too long to be able to support these pulses The Arduino has a PWM range of 0 to 255. When a signal of 255 is sent to the H-bridge, it tells it to supply the maximum voltage to the heating wires. When a signal of 0 is sent to the H-bridge, it tells it to not supply any voltage to the heating wires. The PID control calculates values between 0 and 255 which are used to supply less voltage. For example, if a signal of 128 is sent to the H-bridge, half of the maximum voltage will be supplied. As the current temperature approaches the target temperature, the system will send smaller values to make the wires heat more slowly, which ensures that there is no overshoot. Once the target temperature is reached, the PWM value will be constantly calculated so that the target temperature is maintained.

Output to screen

The Arduino sends information to an LCD screen on the control unit. Output to the screen includes which mode the system is in (auto/manual), patient core body temperature and mattress surface temperature, as well as the target temperature (either target core body temperature or target surface temperature).

Housing

The electronics will be contained in a housing that is placed at the head of the bed in our final design. The ABS plastic box utilizes clips for external mounting and provides a platform for the control unit to be secured while supplying access to the controls. The on/off switch, automatic/manual switch, and manual temperature buttons are placed on the surface next to a screen that displays the current patient temperature, bed temperature, and device setting.

9 Manufacturing Plan

9.1 Bill of Materials

Table 11: Small-scale (2'x2') prototype bill of materials

Description	*Dimensions*	*Supplier*	*Qty.*	*Cost*	*Unit Cost*
Polyurethane-coated nylon fabric, dark blue	0.022 x 61 x 120 in	McMaster-Carr	1	$50.20	$12.97*
Heating element, wires coated with insulation film	Thin gauge	Amazon	1	$29.99	$29.99
Open cell polyurethane foam, light blue	1x24x24 in	Foam N' More	1	$17.00	$17.00
Memory foam, 5.3 LB	1x24x24 in	Foam N' More	1	$17.00	$17.00
Bed clip	--	Amazon	2	$3.49	$3.49
Arduino Kit	--	Amazon	1	$35.99	$35.99
			Total	**$153.67**	**$116.44**

**31 inches of 61 inch wide fabric needed for small-scale prototype*

9.2 Fabrication and assembly plan

The following manufacturing steps outline how to assemble our device. For proof-of-concept, we have decided to make a 2 foot by 2 foot small-scale model of our mattress. This is the width of the OR bed and just under the length of a section that the regular OR bed is made up of. The manufacturing plans below include steps to build the full-scale model (outside the scope of this class).

Steps for Assembly

1. Assembling the heat source: Begin by using a sewing machine to stitch thin pieces of fabric over the insulating wires, which will attach to the cotton beneath (Figure 40). The layout of the wires should finish in a snake-like, even pattern as shown in Figure 41.

Figure 40: Stitching the wires into the cotton/porous-fabric.

Figure 41: Completion of the evenly sewn heat source (snake-like pattern).

2. Creating the proper layering: Next attach the embedded wires onto the deflector (Figure 42). To do this, spray the deflector with Loctite adhesive spray then lay the wires on top of the deflector, pressing firmly into place (Figure 43).

Figure 42: The deflector, used to prevent heat loss the bottom of the OR bed.

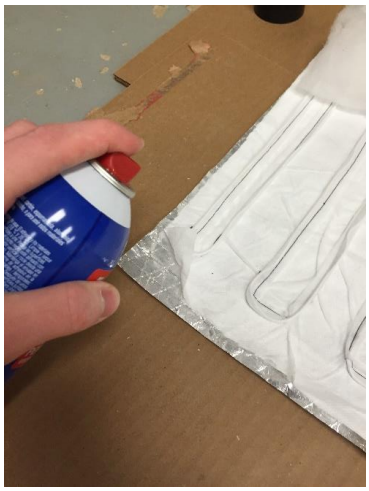

Figure 43: Using Loctite adhesive spray to adhere the wires to the deflector.

We have multiple layers to assemble in a particular order, so it is important to study Figure 44 before moving forward.

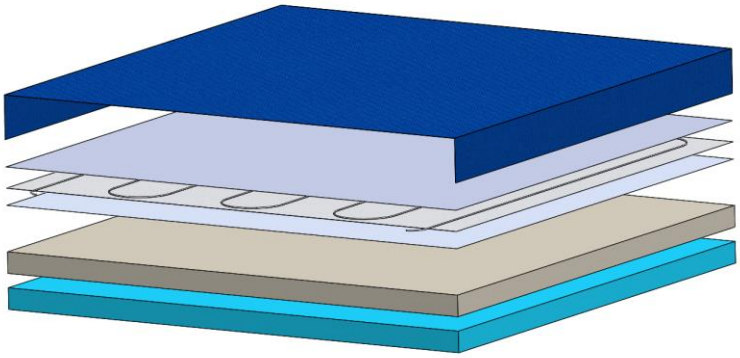

Figure 44: Cross-sectional, exploded view of the layers for our 2'x2' mattress design. Materials from top to bottom include: firm memory foam, softer memory foam, deflector, wire heating element embedded in porous fabric, thin cotton overlay, and outermost covering of polyurethane-coated nylon.

Start your layering process by lying down the foams: the firmer blue polyurethane foam on the bottom and then the softer white memory foam on top of it (Figure 45).

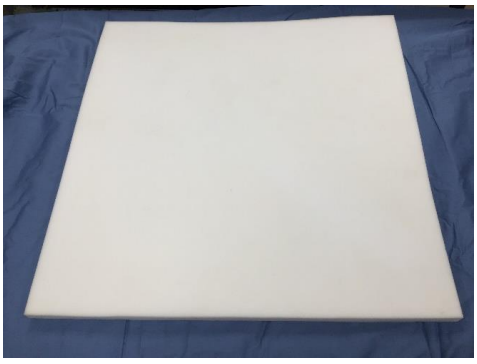

Figure 45: The two foam layers set in place.

Next, lay your deflector with attached wires on top of the foams. Additionally, lay the thin cotton layer over the embedded wires (Figure 46).

Figure 46: From bottom to this top view: two foams, deflector, embedded wires, and thin cotton overlay.

Finally you will have to use the sewing machine to form the outermost material: the dark blue polyurethane-coated nylon. After sewing to shape, inside-out the material to create a cleaner look. Be sure to leave a flap open on the end so you can put your layered device in the interior before completely sealing (Figure 47).

Figure 47: Cross section of device before completely sealing.

3. Forming the full-scale base: build multiple mattress sections to size of the OR bed. Stitch together the body sections, then stitch the two arm pieces to the body section. Eight thermocouples will be stitched into the top surface of the diffuser, just underneath the polyurethane coated nylon fabric with flame-resistant thread (i.e. conductive thread or yarn). One thermocouple will be stitched into the center of the head and foot mattresses, one thermocouple will be stitched into the center of the arm mattresses, and four thermocouples will be stitched into the center of each of the four quadrants of the middle mattress (Figure 48). These multiple sections throughout the full-scale foam mattress that will be connected in parallel with the resistive wires. This is important because it will allow us to shut of certain section of the device. It will also ensure that the entire device does not stop working if one of the sections breaks, allowing for easier repairs.

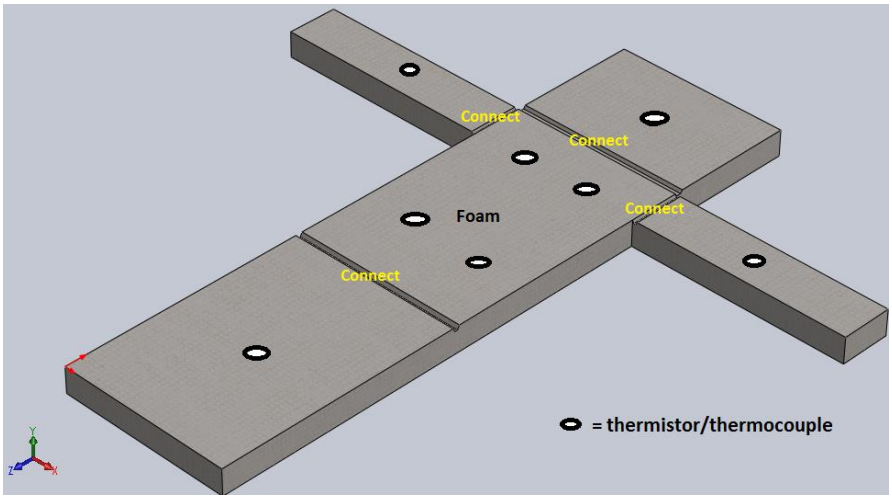

Figure 48: Image of thermocouples embedded just beneath the outermost layer (i.e. the diffusive thin-cotton layer).

4. Securing: We will clip the device to the sides of the operating bed using a plastic clip with straps so that it can be adjusted. Similar devices that have mattress components use straps that go underneath the operating bed, but our stakeholders in the Dominican Republic conveyed to us that they would prefer something that would clip to the sides of the bed instead of a strap. There are metal sidings on the operating bed that we will clip onto. This will function similarly to a car clip and should be attached to the middle of the device before sealing completely. To construct, simply stitch elastic looped over your clips, as shown in Figure 49.

Figure 49: Clips to secure our device to an OR bed.

5. Using a heat sealer, finish sealing the perimeter of the polyurethane-coated nylon so no other material is visible (Figure 50, Figure 52). Be sure to leave a small opening to bring together the wire that goes throughout the entire foam mattress, which you will later connect to the control unit. Be sure to calibrate the thermocouples, underneath the polyurethane-coated nylon, to output a reading above the polyurethane-coated nylon. This surface temperature will be visible on the control unit. As we did not have a heat sealer accessible this semester, we hand-sewed our last side together (Figure 51).

Figure 50: Last side-flap to seal once the layering is set in place.

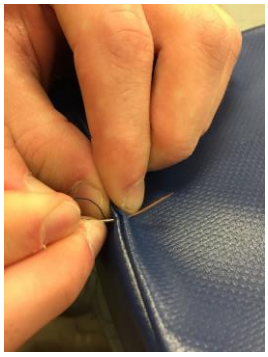

Figure 51: Hand-sewing the last side together.

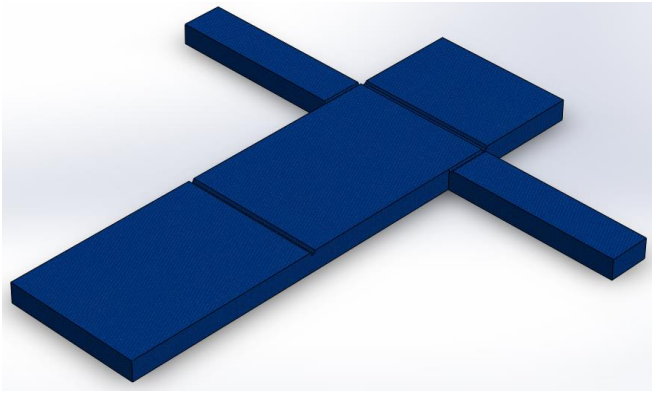

Figure 52: Entire device covered in polyurethane-coated nylon via a heat sealer.

6. Construction of controls: Follow the wiring diagram below (Figure 53). We will attach our circuit to a relay (H-bridge) connecting to the mattress and the power supply. Lastly, attach the system to an acrylic plate. The breadboards attaches via adhesive on the backsides. The Arduino Uno and H-bridge attach by putting screws and nuts through pre-drilled holes in the acrylic plate.

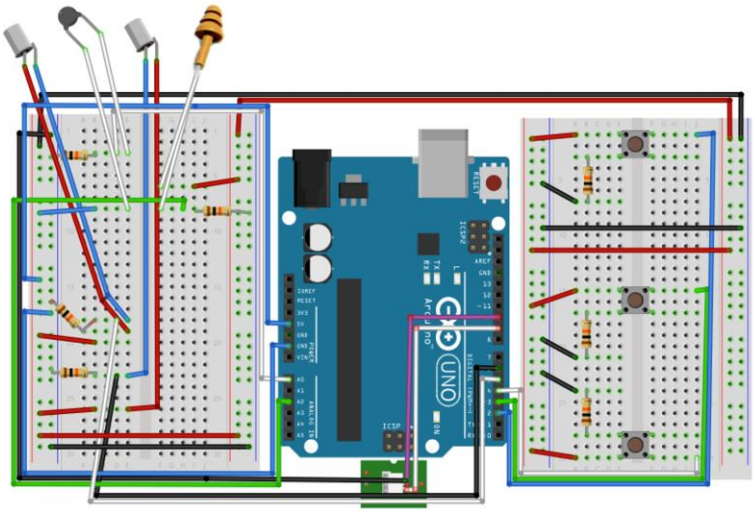

Figure 53: Circuit diagram including: Arduino Uno, Push Buttons, Switches, and Thermistors.

7. Tympanic sensor: We have purchased a thermistor tympanic membrane sensor from NovaMed (Figure 54). We will cut the manufactured 7-pin connector and expose the two wires to connect into the Arduino. Calibrate the thermistor against the clinically-valid Equaline ear thermometer.

Figure 54: NovaMed tympanic sensor, which is a thermistor.

8. Programming of feedback system (a PID controller): The code for the feedback loop will include a While() loop that will call for a temperature reading every one second. The temperature value will be recorded in Volts, and will be converted to degrees Celsius. If the temperature is too low, the heat supplied will increase, and vice versa. There will also be an option to switch to manual mode. This will disable the infrared temperature sensor and enable the GPIO ports allocated to the control buttons on the front of the unit. The system will then take input from buttons telling it to increase or decrease temperature. Refer to section 8.4.

9.3 Final manufactured prototype

Our final prototype, as shown in Figure 54.5, was displayed and demonstrated at the Design Expo. Our warming unit consists of the small-scale resistive mattress, insulated sheets, PID control unit, and tablet display, all of which was staged with a hospital mannequin.

Figure 54.5: Prototype of warming unit at Design Expo

10 Validation & Verification Testing

Our validation and verification testing and protocols are not all able to be completed this semester. Our validation testing and protocols for future tests are detailed in this section and categorized by each requirement our design must meet or exceed.

10.1 Warms the patient effectively

In order to validate the ability of our device to warm the patient effectively, we would need to conduct pre-clinical and clinical studies with animal models, followed by human patients, under neuraxial anesthesia to recreate the surgical procedure and operating room setting. We would need to measure the core body temperature continuously, which would be measured with our non-invasive tympanic membrane thermometer as well as with a rectal thermometer to compare an invasive technique against our tympanic membrane measurements. We would generate a plot of core body temperature over the time of the procedure, ensuring that the core body temperature remained in the 36°C – 38°C normothermic range. This test would also generate data to determine the error of our tympanic membrane thermometer (thermistor) in measuring core body temperature. We would work with the regulatory bodies on campus, including the IRB and Tech Transfer office, to form our test protocols. Testing would be performed at the University of Michigan hospital with surgeries performed in secondary hospitals in the Dominican Republic

(i.e. gall bladder removal, appendectomy, minor trauma, cesarean section, minor cardiac surgeries), and we would work with regulatory bodies in the Dominican Republic to ensure the results of the clinical study would be accepted even if not performed in-country.

We created a COMSOL model to simulate heat transfer of the simplified system of the surgical bed, underbody mattress, and patient. The goal of the model was to understand how heat would flow through the mattress and warm the patient as well as monitor the temperatures of the core body, surface of the mattress and heating element. This model would allow us to calculate the wattage needed from the heating element to warm the patient's core body temperature in the normothermic range (near 37°C) within the first 10 minutes of operation and monitor the device's ability to maintain temperature in that normothermic range.

This COMSOL model was created with the following assumptions:

- All materials, except for the patient, begin at room temperature (22°C).
- The core body temperature of the patient begins at 36°C and peripheral body temperature begins at 34°C [80].
- The patient can be modeled as a system of concentric rectangle, the outer of which is constrained to the dimensions of anthropometric measurements by Harvard University and the inner of which fills 42% of the larger rectangle's volume.
- Convective heat flux from the surrounding air is 10 W/m^2 with a low speed of moving air over a surface (the outer exposed surfaces of the patient and mattress) [81].
- The core body's metabolic heat production is 50 kcal/h and cutaneous heat loss is 80 kcal/h [80].
- The thicknesses of the heating element and deflector are 0.01 in and 0.02 in, respectively.

The material properties that were used in the model, outside of those stored in the material library of COMSOL, are shown in Table 12.

Table 12: Material properties used in COMSOL heat transfer model

	Open cell polyurethane foam	Mylar®	Viscoelastic polyurethane foam	Thermoplastic polyurethane (coating)	Human skin
Density	2.80 lb/ft^3 [82]	1.39 g/cm^3 [83]	5.3 lb/ft^3 [82]	1.18 g/cm^3 [84]	COMSOL
Young's Modulus	49 $lbs/$ 50 in^2 [82]	490 $kg/$ mm^2 [83]	13 $lbs/$ 50 in^2 [82]	60 MPa [85]	101.2 kPa [86]
Heat capacity	0.005 $J/g°C$ [87]	1.17 $J/g°C$ [88]	0.003 $J/g°C$ [87]	1.514 $J/g°C$ [84]	COMSOL
Thermal conductivity	0.020 $W/$ mK [89]	3.7×10^{-4} $(cal \cdot cm)/$ $(cm^2 s°C)$ [83]	0.049 $W/$ $m°C$ [84]	0.202 $W/$ $m°C$ [84]	COMSOL
Poisson's ratio	0.5 [90]	0.38 – 0.58 [83]	0.30 [91]	0.48 [92]	0.50 [86]
Specific heat	N/A	0.28 $cal/g°C$ [83]	N/A	N/A	COMSOL
Melting point	N/A	254°C [83]	N/A	N/A	N/A

Porosity	95% [93]	N/A	95% [93]	N/A	N/A

Our model, shown in Figure 55, allowed us to determine the wattage of the heat source necessary to warm the core body temperature into the normothermic range. The model also shows a heat-map of the temperature distributions throughout the patient, mattress and operating bed.

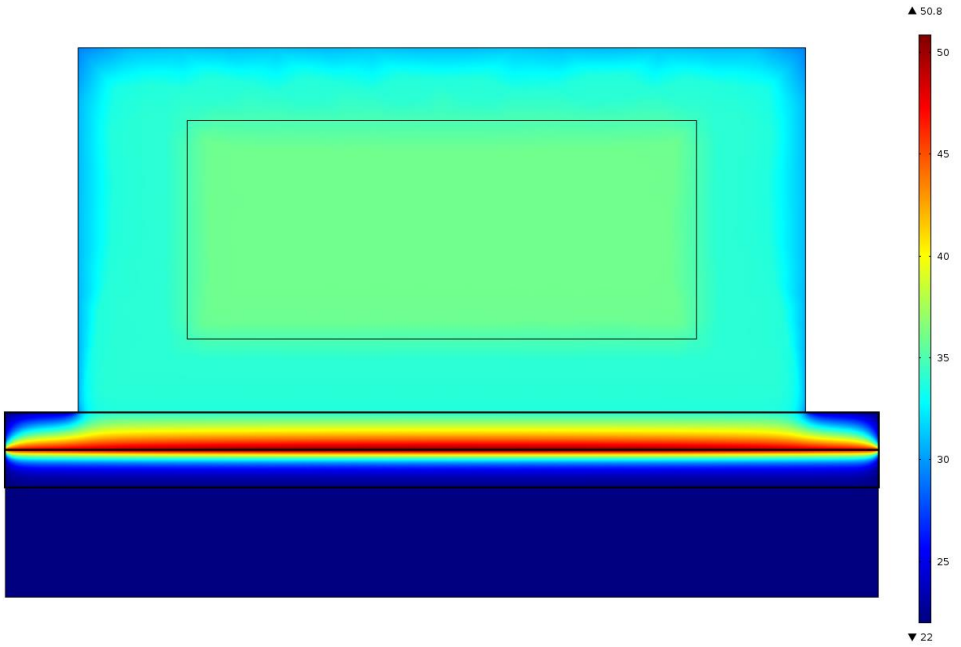

Figure 55: Heat distribution at t = 10 min in degrees Celsius; heat source Q = 15 W/m^2

To understand how our mattress would warm the patient's core body temperature, we generated a plot in COMSOL, shown in Figure 56, to observe this temperature increase. We are confident that our device will be able to effectively warm the patient, as the temperature of the core body continues to increase linearly over time.

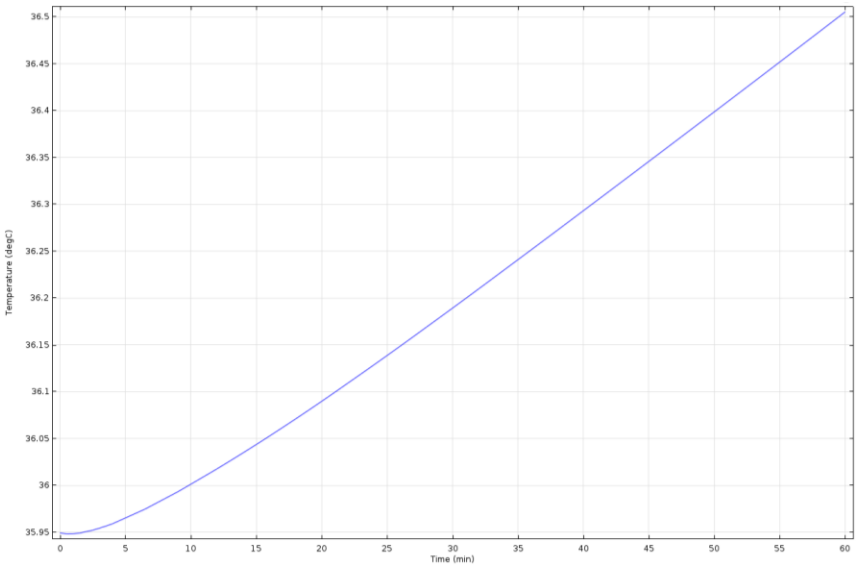

Figure 56: Core body temperature increase over time with heating mattress (no over body insulation)

To experimentally verify our prototype meets the user requirement of warming the patient effectively, we will operate the device with a chunk of medical-grade silicone (lent from the Clinical Simulation Center) placed on top of the mattress after cooling it to ~35°C in cold water. Temperature of the heating element and fabric surface will be monitored with thermocouples connected to our control system, and temperature of the silicone will be measured at two places: one with a 400 series thermistor embedded into the center of the slab and another at the top surface of the slab. We will plot the fluctuations in temperature (of the device and of the silicone slab) over time as the device operates to evaluate the product's effectiveness in warming the silicone slab from a hypothermic state.

Although outside of our scope this semester, a test we need to do in the future is experimentally measure the heat flux produced by our device at the surface of the mattress when fully expanded and compressed. In a temperature-controlled environment, we would measure the temperatures (using thermocouples or thermistors with a tight window of error) of the heating element, the internal surface of the mattress fabric, and the outside surface of the mattress fabric as well as the thicknesses of all components of the mattress (using calipers). This data would provide us with enough information do then, using heat transfer principles and equations, calculate the thermal conductivity of the material as well as the heat flux through the material. This information would enable us to better evaluate the net heat flux entering the patient and compare to experimental values from existing large-sample studies for total metabolic heat loss for patients under anesthesia.

10.2 Avoids contamination and can be cleaned by current methods

We designed our device such that it avoids contamination and can be cleaned by current methods by selecting materials that are resistant to bleach and resist absorption of fluid (heat sealed polyurethane coated nylon fabric covering the mattress, ABS plastic covering the control unit components, and a PET coating on the Mylar blanket in the cotton surgical linen). To further verify our product meets this requirement, we conducted a test with 1:10 bleach solution with polyurethane coated nylon fabric and Mylar to observe the effect and verified the need for a PET coating on the outside of the Mylar blanket. The protocol and results of that test are described in Section 7.1.1.

Future validation will be performed after the full-scale prototype is manufactured that will include a random sample study where subjects will perform cleaning of the device. Using a solution dye, subjects will use rags wet with the dye solution to wipe down the mattress and control unit. We will record time-stamps for completion of checkpoints and document observations during the simulation and follow up with a questionnaire gathering information on the ease of cleaning, challenges and inefficiencies as well as overall thoughts and suggestions.

10.3 Does not burn patient's skin

We designed our device such that the polyurethane coated nylon fabric at the surface of the device in potential contact with a patient's skin does not exceed 40°C – the temperature at which it is safe to bathe for an indefinite period of time without risk of burning [45]. The burn threshold for skin – when necrosis of epithelial cells begins – is 44°C, so our device ensures we do not approach that temperature [94]. The surface temperature is measured with a 400 series thermistor, which is on the inside surface of the fabric; we calibrated this surface temperature thermistor by measuring against a thermocouple on the external surface of the mattress fabric while the device is turned on and operates until reaching its maximum temperature output. Those temperature readings were plotted against time and shown in Figure 57. Since the plots were linear, we took the temperature difference of the intercept and used that offset to calibrate our surface temperature thermistor.

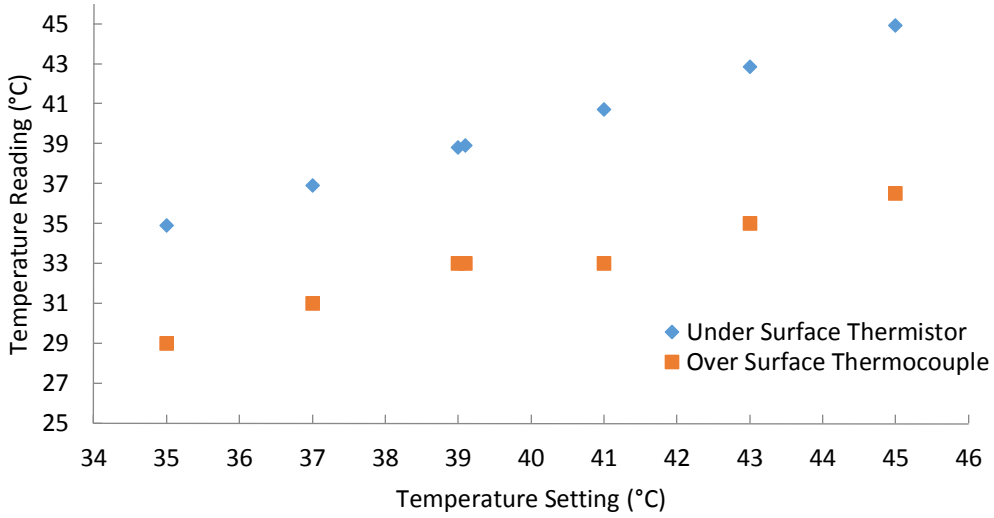

Figure 57: Internal vs external surface temperature difference

We do not have access to a power supply that provides enough voltage to produce the power we need to supply to the resistive circuit and produce the desired surface temperature of 40°C. With the 15-V power supply we have, the maximum temperature the wires can achieve is 39°C. Accordingly, our control code is set to shut off the power supply upon reaching a surface temperature of 38°C so that we can simulate the function of our feedback control system, since setting it to our 40°C target would defeat the function of our fail-safe control as our device is powered with this 15-V supply. We will record the surface temperatures (measured with a 400 series thermistor) for which the power supply shuts off to determine our tolerance for our fail-safe control.

10.4 Is easy to operate

We have designed our product to limit the user input to powering the device on and off and, when in manual mode, a 3-level temperature adjustment (35°C, 37°C and 39°C). This minimal amount of complexity in the device's operation was what is desired by our stakeholders in the Dominican Republic to ensure it would integrate into their current routine without interruption.

To validate our product's ease of operation, we administered a qualitative assessment to a small sample population. The assessment required each subject to perform three tasks: turning on the device, controlling the temperature with manual adjustment, and feeling and pressing down on the device. For each task, the subject responded to the following three questions: 1) Describe what it felt like to complete the task, 2) Why/what made it feel that way? and 3) Is there anything that would make this easier for you? Please explain. See Appendix C for our questionnaire.

With a random five-sample study, we found that 90% of subjects responded that the use and operation of the prototype was easy or intuitive. Much of the reasoning was that our prototype included descriptive labels and intuitive layout of the switches and buttons. It was suggested that we color code the manual and automatic controls when we design the control housing. Moving forward, we will perform the same qualitative assessment with a larger random sample. We also hope to collect data while in the Dominican Republic with our full-scale, refined prototype.

10.5 Can accommodate most surgical patients

We have designed our device with both viscoelastic and open cell polyurethane foams to distribute pressures exerted on the mattress to both protect the materials and components inside the mattress as well as prevent the risk of patients developing pressure ulcers. Using a COMSOL two-dimensional model of our mattress, we simulated fatigue from a cyclic 170 kg point load in the center of the mattress to verify its ability to withstand loads of all the patients it would be used with. This load was determined by the upper percentile of overweight patients whose BMI is much greater than 35 (extremely obese or bariatric patients). The fatigue model was created with the additional assumptions that the endurance limit (S_e), endurance life (N_e), transition stress (S_t), and transition life (N_t) were 96.5 MPa, 1×10^8, 180 MPa, and 2×10^6, respectively [95]. Figure 58 shows the deflection of the mattress, Figure 59 shows the stress gradient exerted on the copper wire at the center of the mattress, and Figure 60 shows the plot of von Mises stress for each horizontal position across the mattress. Each figure shows the results under the extreme case of a 170 kg point load applied at the center of the small-scale mattress.

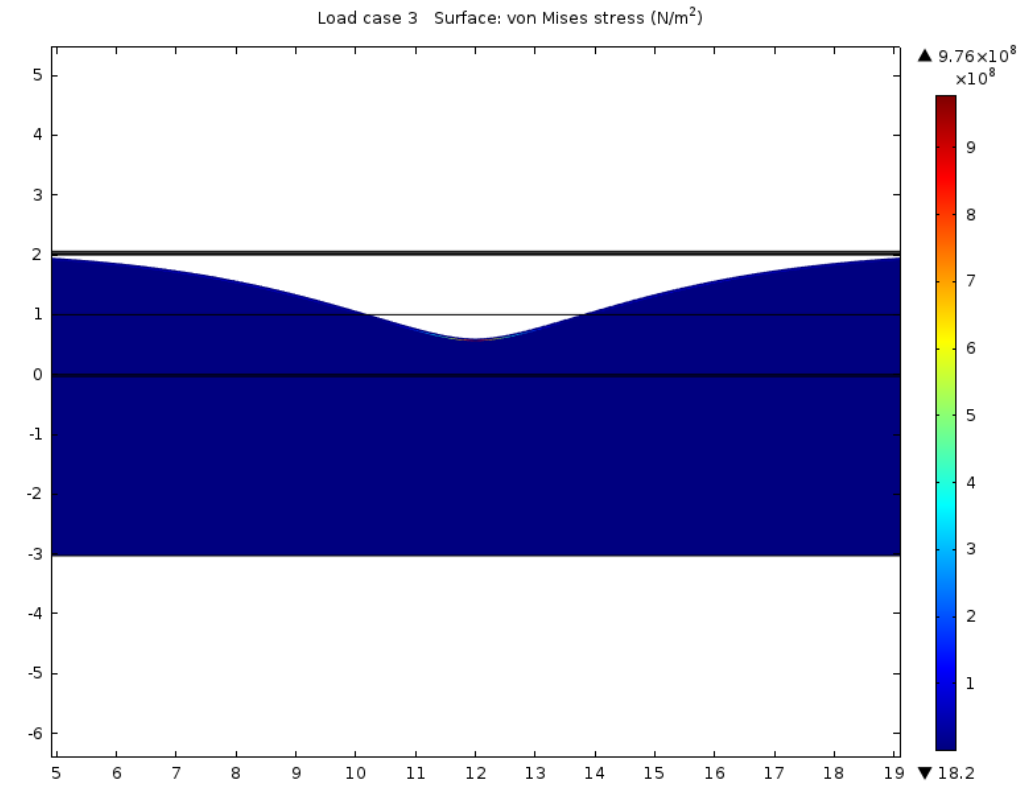

Figure 58: Deflection of the resistive heating mattress under static compression from 170 kg point load

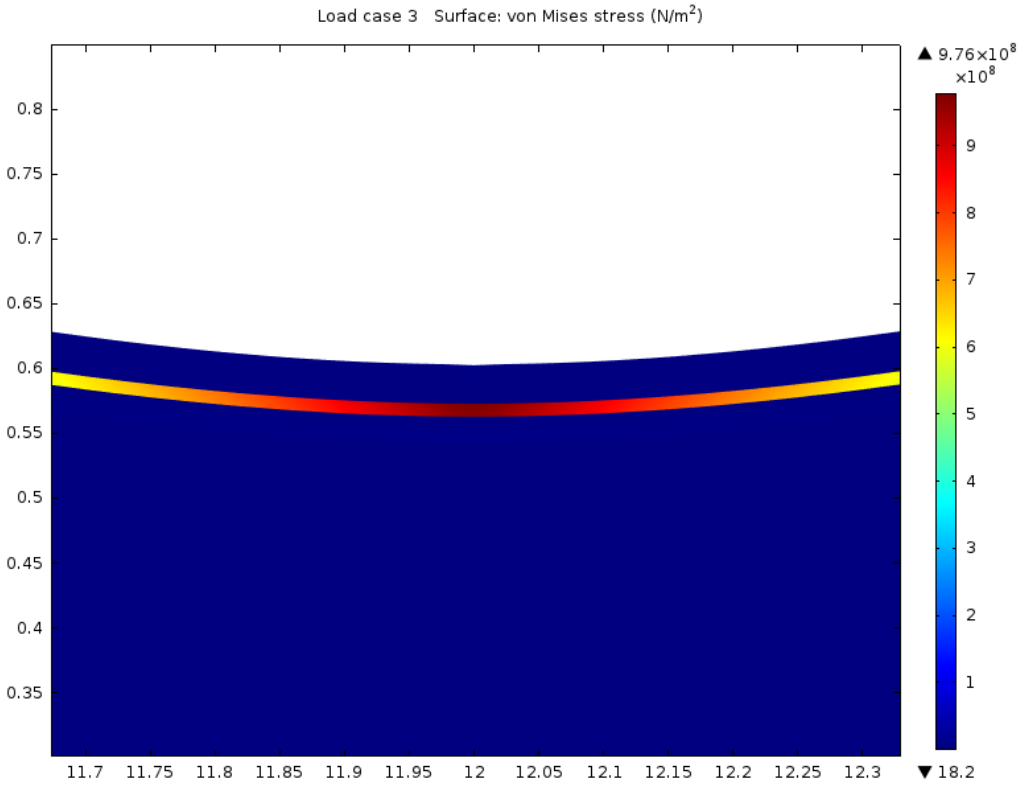

Figure 59: Stress distribution of copper wire at center of mattress from 170 kg point load

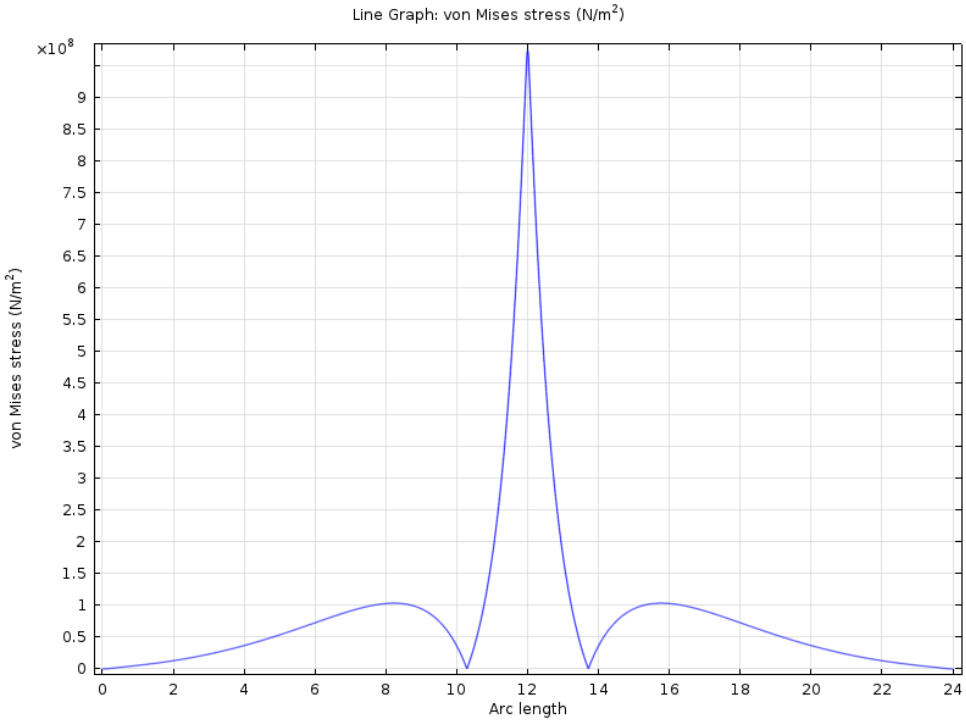

Figure 60: Stress of copper wire versus distance from end of mattress with 170 kg static point load

The simulation computed the number of cycles to failure of the copper heating element, which dramatically exceeded the lifetime of the materials used in our mattress, particularly the viscoelastic foam which has a lifetime of about 10-15 years [96]. We will have to adapt this fatigue model to accommodate the layering of our final mattress design (with polyester cotton lining above the heating element above the two foam types) and compute the cycles to failure to re-evaluate our product's lifetime. In that simulation, we will add a distributed load instead of a point load with a smoothing function to compute more representative results. Our current results show the extreme case with the weight of a bariatric patient applied at the center point. COMSOL does experience difficulty in running partial differential equations with point loads, so our current validation results could exhibit some error.

In the future, we will need to experimentally validate our product's satisfaction of this requirement by loading the full-scale mattress with a mannequin patient model that is loaded with incremental weights (lead bean-bag weights) up to the 95th percentile of patient weights (on the bariatric end) and measuring the deflection of the mattress. This deflection would provide us data to calculate the stress and strain exerted on the components of the mattress as well as the mattress' ability to support the weight of patients on the 95th percentile of weight.

10.6 Allows mobility of the patient's body

We will not conduct testing of this requirement this semester, but in the future we will need to administer a qualitative assessment, like that in Appendix C, for a sample population both on campus and in the Dominican Republic on transferring a patient (with human subject) from the full-scale mattress. We will submit applications to the Health Sciences and Behavioral Sciences (HSBS) IRB for study approval. This assessment would quantify the experience of transferring a patient from the mattress on the operating bed to a wheeled cot with 5-point scales, looking at areas such as any irritation or discomfort experienced by

the patient (subject) during the transfer related to the product as well as any resistance or disturbance of the transfer related to the product experienced by the two subjects transferring the patient. Three subjects would be required for each experiment, with one staged as the patient and two as the hospital staff responsible for transferring the patient to the cot (with a combination of lifting and sliding) as is done in secondary hospitals in the Dominican Republic.

To further verify our product's satisfaction of this requirement, we would use a frictional force gage that we would use to measure the frictional force of sliding a patient (subject) on the mattress under two situations: bare skin exposed to the mattress and bare skin exposed to a vinyl plastic sheet placed between the patient and mattress. With these values from a small study, we would compare to experimental values for skin shear force limitations/thresholds before irritation or damage to ensure our product would allow mobility of a patient's body without damaging their skin.

10.7 Is comfortable for the patient

Using the questionnaire in Appendix C, we evaluated the product's level of comfort with a five-subject sample population with subjects performing the task of feeling and pressing against the device with their hands and arms (2'x2' mattress section) and posing the following questions: 1) Describe what it felt like to sit on the mattress, 2) Why or what made it feel that way, and 3) Is there anything that would make this easier or more comfortable for you (and explain). We processed the responses of this qualitative assessment in Microsoft Excel and categorized responses to generate basic statistics on the response to the product's comfort. We found that 80% of subjects rated the prototype as comfortable, and those that did not give it this comfort rating stated that it was comfortable enough for a hospital setting. Improvements to be made would be pursuing designs that included a thicker diffuser above the resistive wires that would maintain or increase the current prototype's heat transfer ability. We will expand this study in the future during a trip to the Dominican Republic as well as increase the sample size on campus.

In the future, we will verify our product's comfort level by creating a pressure map using a flexible fabric pressure sensor placed over the mattress or multiple pressure sensors placed at regular intervals on the mattress surface. With that pressure map, we will calculate the capillary interface pressure with experimental values of capillary pressure from literature for the hot points of the pressure map and compare to the threshold for formation of pressure ulcers. We would also determine the tolerance of the pressure map to ensure an appropriate operating limitation was included with our device so that risk of pressure ulcer formation was mitigated.

10.8 Compatible with the surgical bed in use

We are unable to validate or verify this requirement with our proof-of-concept (small-scale) prototype, as we need the full-scale mattress design to perform testing and analysis; this user requirement would be fulfilled by design. We will design the full-scale mattress to the dimensions of the operating beds in use. Since operating beds differ slightly in dimension and significantly in design (i.e. separated legs versus solid leg panel, various hinge points), we will most likely have to design our product for make-to-order instead of a universal (one-size-fits-all) design. With our full-scale prototype(s), we validate this requirement with a qualitative assessment with stakeholders and a sample population of performing the task of placing the mattress onto the operating bed and securing it in place. Additionally, we would measure the range of shifting the device could experience by sliding against the operating bed which may inspire design changes related to the friction of the bottom surface of the mattress in contact with the operating bed.

10.9 Is inexpensive

We will validate this requirement in the future by contacting the Ministry of Health in the Dominican Republic, as well as other low- and middle-income countries (or the appropriate purchasing bodies), to determine the cost at which the purchasing body would be willing and able to pay for this product both through conversation with the relevant officials as well as data from purchasing records.

We will verify our product's satisfaction of this requirement by adding the material costs of our assembled prototype as well as the estimated cost for the full-scale model. Our target manufacturing cost is 250 USD. We will also contact suppliers of the materials our product requires to obtain a more accurate estimate of the cost of the product when manufactured at a large scale (approximately 200 units to supply every secondary hospital with a device).

Table 13: Bill of Materials for full-scale prototype

Description	*Dimensions*	*Supplier*	*Qty.*	*Cost*
Control Unit Housing	--	Mouser Electronics	1	$6.78
Customized PCB	1x3x2 in	BatchPCB	1	$10.00
Mini LCD Screen	1x3x1.5in	oddWires	1	$3.85
Resistive Wires	Thin gauge	Pelican	1	$20.00
Polyester cotton blend to embed wires	5 yards	Amazon	1	$10.00
Polyurethane-coated nylon fabric, dark blue	0.022 x 61 x 69 in	McMaster-Carr	1	$28.87
Open cell poly foam, light blue	1x24x24 in	Foam NMore	1	$31.20
Viscoelasticfoam, 5.3 lb, white	1x24x24 in	Peterson Chemical	1	$64.00
Bed clips (2 packs of 4)	--	Amazon	1	$27.90
Elastic band	1 in	Amazon	1	$4.36
Thermocouples (3 packs of 2)	--	Amazon	1	$19.50
400 series thermistor	--	NovaMed	1	$3.50
			Total	**$229.96**

10.10 Is aesthetically pleasing

The user requirement of aesthetics was satisfied by the design of our product with a dark blue color scheme as specified by our stakeholders in the Dominican Republic. To validate this requirement, we used a questionnaire (Appendix C) that posed several questions to gather qualitative data on our product, which we categorized to perform basic statistics. Questions the assessment include: what descriptive words or thoughts come to mind when you see this product, what does this product remind you of, what would you imagine this product would be used for, and is your perception of the product changed knowing what the device actually does and in what way(s). The assessment also includes scales for subjects to respond to the perceived quality, technology, and professionalism of the product. We found that 60% of subjects perceived the current proof-of-concept prototype as high quality, with 100% of the subjects rating the

proposed final design as high or very high quality. Without knowing what the product was used for, subjects perceived the device as something they might see in seating at a doctor's office, as a smart cushion, and something that incorporates temperature measurements. Again, we will conduct this qualitative assessment with our full-scale prototype with a large, random sample to gather results more representative of the population.

11 Future Work

Our primary goals in moving forward with this project are optimizing materials, reducing cost, and manufacturing the full-scale prototype.

Specific design work we will complete in the future include optimizing the materials in the design (particularly the viscoelastic foam, diffuser and resistive wire), reducing material costs, scaling the heating element to the full-scale prototype, refining the design of the infrared tympanic membrane thermometer and packaging it into a wireless earbud, developing the attachment (clip) mechanism for securing the mattress to the operating bed, transferring the control circuit to a printed circuit board (PCB), and designing the control unit housing to be bleach-safe and water resistant.

Upon completion of these design changes and enhancements, we will manufacture the full-scale prototype (full-size, heat-sealed mattress with attachment mechanism, tympanic membrane thermometer, control unit and power supply). We will have to iterate our risk analysis (FMEA) and validation tests for this refined prototype, including those tests outlined in Section 10.

We will work with the IRB on campus, specifically the IRB-HSBS and IRB-MED, for support and approval of protocol for user feedback and clinical studies, respectively. We will determine the regulatory pathway this device would be required to follow according to FDA guidelines, and we will work with the Tech Transfer office on identifying any design components that should be patent-protected and developing a business model and market strategy. We will explore whether this product would best fit in a model where a medical device company would purchase the rights to produce and sell the product or if we would hand off the product to a local technology development company.

We will enter the project into Michigan Health Engineered for All Lives, or M-HEAL, to ensure its sustainability. We plan to travel to the Dominican Republic to conduct user feedback studies on our prototype and expand our stakeholder network, including the Ministry of Health, medical device distributors, and other public hospitals.

12 Team Biographies

Sam Dion

Sam was born and raised in Caledonia, MI, a small town just south of Grand Rapids. He is the second oldest of six boys. Sam grew up outside doing anything from camping to sailing to playing sports (in a big family there is always someone looking to play). He is in the first generation of his family to attend college. Sam has used his time in college to explore interests and discover his passions. He is an active member of the Engineering Honors Program in the Engineering Global Leadership specialization. He is currently on the EGL board as community chair and serves as a peer advisor in the honors and engagement office. Sam is also a co-founder of a start-up company, Daedalus Design, created to produce sports training equipment. In addition to his mechanical engineering education, Sam is completing the Multidisciplinary Design Minor (team leader redesigning a quick disconnect coupling for Eaton Aerospace) and the International Minor for Engineers (study abroad in Berlin, Germany, over the 2014 summer). Sam has spent his summers at M-STEM and working at Westshore Design and Lockheed Martin Space Systems; he will complete a project through the Tauber Institute for Global Operations next summer.

Ben Lewis

Ben was born in Chicago, Illinois, where he spent the first ten years of his life. He then moved to Traverse City, Michigan, a beach town in northwest Michigan. He is an active participant in anything related to sports. As a freshman, he was on the University of Michigan Men's Rowing Team. He currently is a part of the Engineering Global Leadership Honors Program, in which he is the membership chair. Ben is very interested in German language and culture, and has spent time living in Berlin, Germany. He plans to go back to work in Germany someday. In addition to Germany, he also has spent time in Quito, Ecuador. There, he volunteered with a group called UBELONG teaching students English. Ben is a senior studying mechanical engineering with a focus on international business. He was also admitted into the Tauber Institute for Global Operations, where he will be taking business classes at the Stephen M. Ross School of Business. He plans on pursuing a graduate degree in industrial and operations engineering which will lead into a career in operations.

Kerstin Nilsson

Kerstin grew up in Cincinnati, Ohio, and Stockholm, Sweden. Her interests in math and science led her to a position on the INTERalliance Leadership Council, where she aimed to introduce opportunities in STEM (Science, Technology, Engineering, and Mathematics) to young students in Cincinnati. Kerstin moved to Grand Rapids, Michigan after graduating high school and shortly thereafter began her undergraduate studies in Mechanical Engineering and Music Performance at the University of Michigan. Kerstin became involved in the Campus Orchestra Board, Music Matters, and M-HEAL's Medical Device Repair Collaborative because of her passions for both global health and music. In her spare time, Kerstin enjoys figure skating, rock climbing, traveling, viola composition, and volunteering at the hospital as a music therapist. After her graduation in the spring of 2016, Kerstin will begin work as a Manufacturing Engineer for Stryker Instruments in Portage/Kalamazoo, Michigan.

Ryan Thomas

Ryan grew up in Menominee, Michigan, a small town in Michigan's Upper Peninsula right on the border with Marinette, Wisconsin. He lives on the Menominee River and enjoys any adventure involving water: swimming, kayaking, snorkeling and SCUBA diving. He has cared for a variety of pets since he was little, from rodents to chameleons to sea horses to saltwater reef systems. Now serving as the President of M-HEAL, Ryan is passionate about developing healthcare solutions for low-resource settings, creating new and meaningful learning experiences for M-HEAL members, and building the M-HEAL network and community. He has had a number of curricular and service-related international experiences in Spanish-speaking environments - the most recent of which he lived in the Dominican Republic for eleven weeks conducting needs assessment as part of his Honors capstone experience and assisting with a health research and immersion program. Ryan is in his final year of undergrad studying biomedical engineering with an international minor and plans to pursue graduate school in BME to prepare him for a career in biomedical industry (or elsewhere) where he can contribute to global health efforts and engage in work to improve the quality of life of others.

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Appendix A: Drafted Design Concepts

The following numbered concept descriptions correspond to the numbered concept sketches at the end of Appendix A.

1. **Forced-air resistive heating blanket:** This blanket uses resistive (electrical) heating to surround the patient's upper chest and arms in heat and opens up for easy removal from the patient by Velcro strips.
2. **Conformable resistive heating mat:** This mat uses resistive heating to heat the patient from underneath with insulative flaps that swing over areas of the body (arms, legs, abdomen, and torso) and attach by Velcro to prevent heat loss by radiation.
3. **Conformable sleeping bag:** This sleeping bag-like device uses resistive heating surrounding the patient's body with Velcro-removable panels for access to areas of the patient's body for surgeries, such as the abdomen and torso.
4. **Zippered sleeping bag:** This concept is additive to #3 in that it uses a zipper to fully open the sleeping bag warmer for easy transfer of the patient to and from the operating bed. It also ensures a sealed connection to prevent heat loss from the patient's body.
5. **Rigid forced-air dome:** This clear plastic dome is placed over the upper body of the patient with soft plastic seals around the contact points with the patient's body: neck, arms, and chest. Hot air is blown inside the dome by a hose, which comes directly in contact with the patient's body to provide both radiant, conductive and convective heat transfer.
6. **Forced-air IV stand control unit:** Since contamination is a concern for any unit on the floor and space around the operating bed is limited, this control unit for a forced-air system would attach directly to the IV stand which is in close proximity to the patient and where the warm air would be fed into a forced-air system.
7. **Forced-air hose connection:** The hose connector to a forced-air system could incorporate a simple twist and locking mechanism to make it easy for the surgical team to connect and disconnect the forced-air hose. This would resemble a pinch-to-open design to remove the connector and hose from the forced-air unit.
8. **Anti-microbial filter:** A major concern with using forced air is that it has the potential to blow particles onto the sterile surgical site which could increase the risk of infection. Therefore, this antimicrobial filter would be installed at the control unit so that only clean air, free of microbes, would pass through the hose to the forced-air warming unit.
9. **Collapsible air hose:** This hose is corrugated to allow expansion from the control unit and collapse onto the control unit for easy storage. This also ensures the hose doesn't collapse as it bends.
10. **Secure snaps for rigid dome:** These simple snaps click into place on the sides of the surgical bed to ensure that a forced-air dome or tent would be able to be placed securely over the patient and onto the bed, preventing the unit from shifting or coming loose from the operating bed.
11. **Rigid arm attachments for forced-air dome:** These rigid, clear plastic domes would be attachable to the main torso dome to cover the arms and armpits with warm air, helping to both supply heat and prevent heat loss.

12. Control unit air IV warmer: This feature would be an extension of the force-air system hose, which allows placement of the IV tubing into an insert on the side of the hose to allow the warm air passing through the hose to warm the IV fluid. If it would be heated quickly enough depending on the rate of IV fluid flow, this could add the benefits of internal patient warming.
13. Rigid dome bed attachment: The forced-air, clear plastic rigid dome could incorporate Velcro or magnets to attach the unit securely to the operating bed where the edges of the dome unit come into contact with the operating bed.
14. Forced-air soft tent: This clear, soft plastic tent traps forced air over the patient's upper body for use in abdominal surgeries. Its shape and integrity is maintained by tent-like poles forming the frame of the structure. It is collapsible for storage and would exert little pressure over the patient, since its only contact points are with the patient's neck, arms and chest.
15. Wired controller IV stand attachment: The anesthesiologist monitors patient vitals near the patient's head and IV stand. A controller would be most convenient in that area for easy use by the anesthesiologist and appropriate monitoring and control. Attachment to the IV stand reduces any extra space used in the operating room and avoids cluttering of extra equipment around the operating bed.
16. Pacifier under-tongue thermometer: Temperature readings under the tongue produce fairly accurate readings of core body temperature, so this design incorporates that temperature
17. Remote control unit IV stand attachment: The anesthesiologist monitors patient vitals near the patient's head and IV stand. A controller would be most convenient in that area for easy use by the anesthesiologist and appropriate monitoring and control. This remote allows for increased ease-of-operation since it may be detached from the control unit on the IV stand.
18. Axillary artery band thermometer: This novel surface temperature sensor measures core temperature at the axillary artery (in the armpit) for continuous temperature readings. The band is wrapped around the patient's arm with the sensor, surrounded by insulative material to ensure accurate temperature readings when the patient's arms are outstretched.
19. Operating bed control unit attachment: The anesthesiologist monitors patient vitals near the patient's head. A controller would be most convenient in that area for easy use by the anesthesiologist and appropriate monitoring and control. Attachment to the head of the operating bed reduces any extra space used in the operating room, ensures stability of the unit and avoids cluttering of extra equipment around the operating bed.
20. Zippered torso jacket: This resistive heating jacket is placed directly onto the patient but features zippers for removal so that the surgical team can unzip the jacket and easily transfer the patient from the operating bed to the cot they are wheeled out of the operating room on.
21. Conductive metallic bead underbody mat: This underbody heating method utilizes conductive metallic beads, similar to those that are used in research laboratories in place of a water bath for thawing and warming solutions, which are placed inside a mat on top of resistive heating elements to quickly transfer heat to the patient's body via conduction. The beads also serve the purpose of conforming to the patient's contours, much like a bean bag chair, maximizing the surface area of contact with the patient and reducing interface pressure.
22. Underbody water mat: This underbody mat uses warm water pumped through the cushion to transfer heat to the patient via conduction and convection. It uses an alternating tube arrangement to maximize the area within the mat where warm water is flowing, with an inlet and outlet port to a pump.

23. Water pump around IV stand: This pump minimizes the extra space taken up in the operating room by its placement around the base of the IV stand, which keeps it off of the floor to avoid contamination. Its circular design assists in the circulation of water through the internal pumps and features user controls.
24. Underbody resistive heating foldable mat: This underbody resistive heating mat consists of heating sections at the head, thorax, arms, and legs connected by flexible material so that it can be folded up when not in use and not resting on the operating bed. It serves to increase surface area of contact to the patient.
25. Resistive heating jumpsuit: This resistive heating method comes in the form of a full-body suit so that heat loss is minimized and surface area for heat transfer is maximized. It features openings for full access to the face and abdomen for surgeries and has Velcro at junctions so it can be removed easily from the patient while lying on the operating bed.
26. Resistive heating piece-able suit: This resistive heating method resembles #25 but covers less surface area and includes a torso suit and booties, allowing enhanced access to the full head, forearms, and abdomen (including access for cesarean surgeries).
27. Resistive heating bed cushion replacement: This resistive heating concept replaces the current operating bed cushions with heated cushions. This concept makes next to no changes to the current operating room by integrating the heating elements into the cushions and doesn't interfere with any of the current surgeries performed.
28. Conformable radiant bedside modules: These rigid bedside modules stand over the patient in sections of the body (torso, arms and legs) to provide radiant heat to the patient through radiant heat lamps. They are easily adjustable by the surgical team and do not contact the patient's body.
29. Resistive heating roll-up mat: This resistive heating concept comes in the form of a simplistic, flexible mat that can be rolled up for storage and is similar to #24.
30. Adjustable radiant module connection: This concept specifies the design of the connection of the radiant heating modules in #28 that allows the modules to move and be adjusted.
31. Radiant module slide-rail: This metal rail along the bedside is attached underneath the operating bed and is hollow to run electrical wiring and features slots to allow for sliding of the radiant heating modules in #28 to be adjusted by the surgical team.
32. Radiant module swivel mechanism: This concept describes the mechanism of the motion of the radiant heating modules in #28 that allows the modules to swivel away from the bed and swivel down against the side of the bed when not in use.
33. Radiant heat conductive mat: This concept could be paired with #28 and consists of a mat of particular material that would conduct radiant heat to transfer to the underside of the patient's body to allow for more thermal insulation that would be lost to the cool operating bed.
34. Surgical tool table radiant module: This feature would be paired with #28 in that the surgical tool metal table could be placed on top of the radiant module for easier access to sterile surgical tools the team uses during operations, which are currently placed on a bedside table and farther away from the surgical site.
35. Electric Blanket: This underbody heating method utilizes resistive heating like typical electric blankets. The blanket is modified to vibrate to reduce pressure on the back of the patient and further stimulate muscle movement.

36. Controlled Shivering: Bands are placed on major muscles and stimulate reaction via electronic pulses. When attached to a control unit, this device acts to create a shivering like phenomena in the body to utilize biological heating.
37. Grooved Surface Convection: Warm air generated at the base of the bed is blown up grooves placed in the surface of the bed. This allows the heat to travel the length of the bed and warm the patient from the bottom side. Direct convection to the skin limits losses due to a containing material.
38. Modular Mat: By incorporating a modular design you can optimize the material and electricity used in the system. This design contains a base piece which uses stackable pieces to build arms, legs, and a head to match the size of the patient. This decreases the size of the warmed area and decreases the cleaning solution necessary.
39. Stackable: A stackable design helps optimize the heat produced by a single unit. The heating and insulating layers may be adjusted to match the environmental conditions and needs for specific surgery.
40. Wearable Display: Moving the display to a wearable piece places the readout of temperature directly in the line of sight of the surgeon. Alerts are quickly displayed in the field of vision of the operators stimulating a quick response.
41. Cover-all: Radiation from the body is the main source of heat loss from the body. A cover all that leaves access for IV fluids in the arms and a face mask helps trap as much of the heat as possible while not interfering with current operations.
42. Wearable Warmer: A wearable suit may be used to warm the patient preoperatively and perioperatively. The design traps heat radiating from the body while using resistive heating to conduct more heat into the body. The large surface area created by the wearable is highly desired. Access to the body to perform the surgery can be created via design intent.
43. Control Panel Under Bed: The underside of the bed currently is open real estate in the operating room. By placing the panel underneath the surgeons keep all functionality that they currently have during operation while having the ability to make adjustments before and after the operation.
44. Flipped Function: The device can perform a different function based on orientation. When the panel is on side A, the table acts like a normal operating table that uses conduction to heat the patient from under the body. When flipped to side B the device expands to accommodate forced air warming around the patient.
45. Foot Pedal Adjustment: The operating room holds limited technicians. The surgeon's hands are full during operation. The device could be adjusted despite these limitations by implementing foot pedal adjustments on the floor to change the operation of the device.
46. A/C Heat Reuse: Air conditioners in the room reduce the operating room temperature significantly compared to the environmental temperature. During the cooling process some heat is rejected to the environment. This concept aims to reuse this rejected heat to heat the patient warming device. This increases the efficiency of the device by utilizing a currently available heat source.
47. Back of Knee Sensor: One area that may help measure temperature non-invasively is the area behind the knee. This sensitive area of the body contains many blood arteries/vessels and should provide an ample reading of body temperature.
48. Control Panel Attached to Bed: The front of the bed is currently used to house anesthesia and other limited equipment. By placing our panel close to other devices it will likely be seen in the current routine

of the doctors. Also, when visiting Mott's Children's Hospital we observed the current unit at the head of the bed next to body monitoring devices.

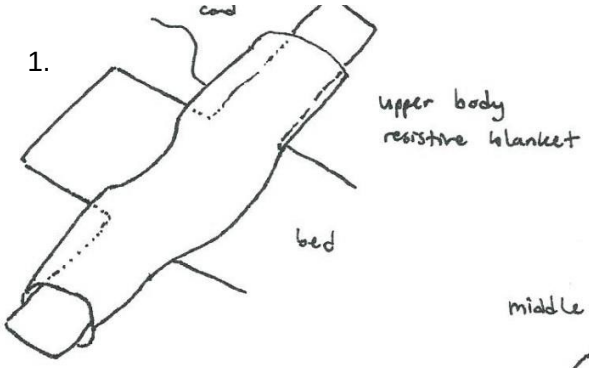
49. Control Remote Under the Bed: Areas under the patient are currently unused. A remote could be strapped to the main bed support so that it can easily be removed to make adjustments. Also, alerts will be near the operator when to stimulate a quick response.
50. Control Unit on Cart: A move-able cart that holds the adjustment interface and warming unit optimizes the footprint of the system. The system may be moved and adjusted to fit the needs of the operating team in a non-invasive way.
51. Patient Adjustment: By allowing the semi-conscious patient to adjust the temperature the surgeon may retain his/her current operating routine. The patient will experienced increased comfort through adjustable preferences. One main concern is burning, thus, a control/safety mechanism must be implemented with this design.
52. Draw String Attachment: Draw string bags hold a certain volume of items and is cinched tight to close the opening. This methodology could be used to place a bed or sanitation unit over the bed and/or the patient to secure the device in place.
53. Suction Cup Attachment: The device may be able to suction onto the bed to hold the device in place. Depending on material selection, this design could increase stability and ensure the patient remains in contact with the heating device.
54. Bagged Storage: Just as the top of the bed is available to mount the control unit, the base of the bed is available to store the heating unit when not in use. A bag secured to the end of the bed allows for the unit to be rolled up and stowed away when not needed.
55. Sanitary Sheets: Also at the base of the bed, a box of sanitary sheets may be pulled out and over the device to ensure a sanitary surface before use. Sheets could be disposed of after each use.
56. Chemical Reaction Resetting Hot Box: If a chemical reaction is used to decrease the heat loss of the patient, the device may need to be reset in a hot box between uses. This particular box is placed at the foot of the bed for easy storage and use.
57. Outside Air: Air conditioners are used to cool the rooms on hot days in the Dominican Republic. The hot air from outside may be insulated, filtered, and pulled inside the room to heat the patient. No electricity is needed to heat the body (only a pump to transfer the air from the environment to specified locations on the patient).
58. Audible Alerts: The surgeon may not always be aware of visual alerts when focused on surgery. By implementing an audio alert (similar to a fire alarm) the room will quickly be notified of any issues and be prompted to take immediate action.
59. Friction Heating: When you come inside after a cold day outside it is common to rub your arms or legs with your hands to generate heat. This methodology may be applied to a bed that vibrates and rubs the back of the patient to create friction heating between the bed and patient. Further development could ensure the patient remains stationary during the surgery.
60. Brain Writing: Closed Loop Feedback: A closed loop feedback system is developed between the human body and the control unit. Sensors on the bed take the surface temperature of the person and relay the information to the unit. The control system then outputs a voltage to warm the patient through resistive heating. Adjustments and alerts may be sent to the control unit that is located with a remote beneath the bed.

61. Intelligent Room Temperature Control: Having the ability to sense various temperatures throughout the operating room will allow for smarter air conditioning and air warming. The system will have the ability to sense if the operating bed is a different temperature than the area the surgeons are standing and will warm that part of the room separately from the others.
62. Resistive Heating Pad: This is a basic design that fits to the standard size of the operating beds. It uses resistive heating to warm the patient from under the body. The control unit is integrated into the side of the device. This will allow for easy access to controls for the surgeons.
63. Warming Lamp: Radiation is one of the most effective forms of heat transfer. Because of this, having a lamp that concentrates heat directly onto the patient will have the ability to effectively warm patients. It will not use as much energy as a blowing system used for forced-air warming.
64. Battery Power Backup: Power outages occur very frequently in the Dominican Republic so we need to incorporate a backup power source in case of an outage. This system will monitor if the power coming from an outlet is turned off, and the batteries will start supplying power. It will work in parallel with the outlet power so that it can be charged while not being utilized.
65. Microcontroller Device: To power our device, we will need a microcontroller which is does not use a lot of energy and has the capability to control every sensor. This microcontroller should be able to supply a feedback loop for temperature controller as well as monitor the power supplies so that it can enable battery power when necessary.
66. Device with Arm Flaps: This device utilizes hinges so that the arm extensions do no interfere with surgeries where the arms lay by the patient's side. This will allow for the arm portions of the device to fold down to the sides of the bed.
67. Head and Lower Extremity Hinges: This device will be able to fold at the point where the head is and where the lower extremities are. The ability to fold will allow the device to be easily foldable so that medical assistants can store the device away easily when not in use.
68. Foldable Underbody Device: This is an underbody warming unit that has creases which will allow the device to be able to be easily folded. Having creases allows for the device to be efficiently folded in a pattern that will minimize volume for storing when not in use.
69. Underbody Unit with Multiple Sensors: Having the ability to measure surface temperature at multiple locations on the body will allow us to better monitor patient temperature and provide a better feedback loop based on differing temperatures throughout the body.
70. Ventilation System on Side of Device: Overheating will be a concern for our device. Hence, this ventilation system will allow the device to breath without allowing heat from the patient to escape. It will have small openings on the sides of the device to allow for air flow.
71. Compressible Underbody System Patient comfort and height of patient off the ground are two important considerations while designing our device. If a patient is larger, the device may need to compress so that the patient's highest part is at a standard height. It also will conform to the patient's body shape.
72. Puncture-Proof Material: The material we choose for the exterior of our device must resist puncturing and tearing. This material will use advanced technology to resist poking from medical equipment such as needles and tearing from cutting devices all while remaining lightweight.

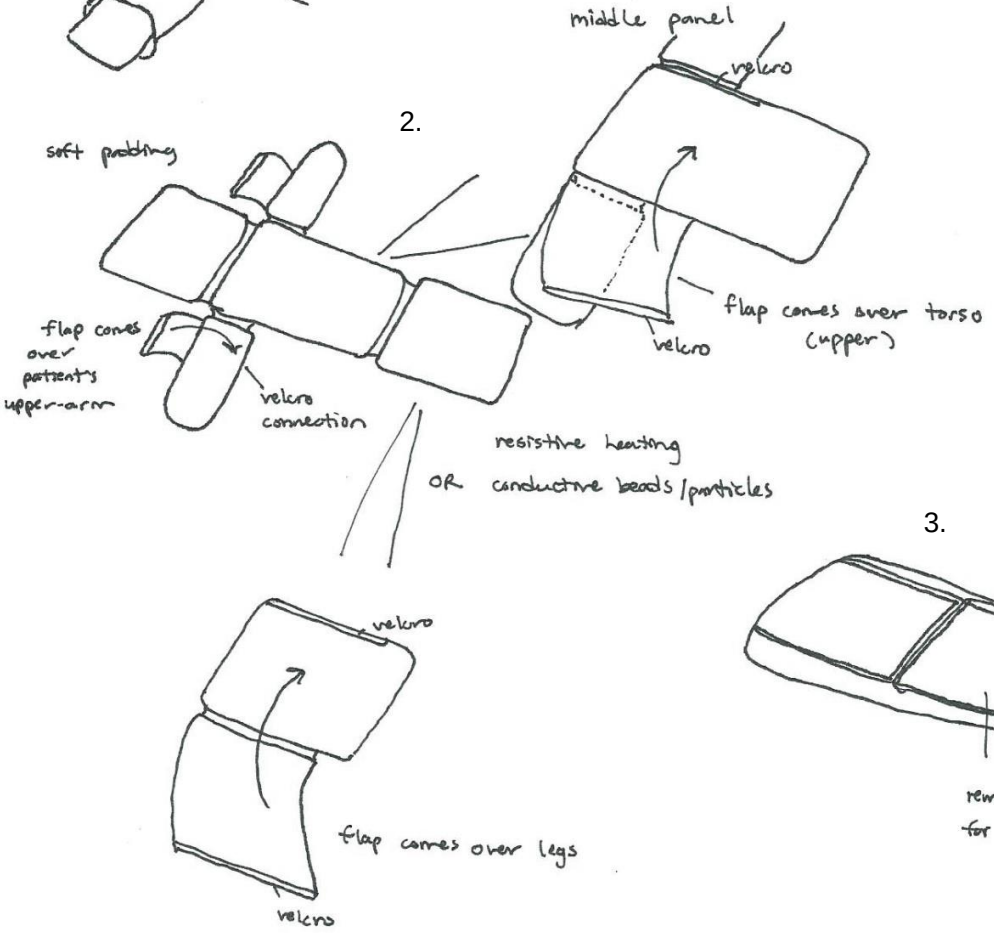
73. Control Unit with Numbers: This device will have an advanced control unit with a number pad and plus/minus buttons to allow surgeons to exactly control patient temperature. They may need to very precisely set the temperature for specific purposes, so having a number pad will help.
74. Integrated Microcontroller within Device: A microcontroller will be embedded within the underbody device so that it does not take up valuable space within the control unit. This will allow for a small display with mini buttons to be placed in a convenient place for the doctors and will make the device much more portable/less invasive.
75. Heating covers for OR bed: Dartex is a stain-resistant, non-absorbent material that the PerfecTemp bed uses on their cushions. This concept would use the same material, but as a thin slip cover to go over existing OR beds in the Dominican Republic. The material would have two layers with resistive heating and sensors embedded to properly provide heat to the patient through conduction and monitor the patient's core temperature. We also could consider reusable heating pads between the slipcovers.
76. Accessories system: Surgeons needs to access various parts of the body depending on who they are working on and what surgery they are performing. This accessories system would allow the surgeon to pick and choose where the patient could be warmed via conduction (i.e. around arms, legs, wrist, or torso).
77. Resistive heating bed cushions: Given the exact dimensions of the OR bed in the Dominican Republic, we would create removable heating cushions to replace the existing cushions. The heating style would be resistive.
78. Attachment to bed: Attaching heating units to the OR bed is essential for stability of the patient. Magnets may interfere with other medical devices, so Velcro seems to be the best method of attachment. Velcro can also be sterilized with bleach.
79. Reusable heating pad: There are heating pads that produce heat through chemical reactions. They can then be reheated through boiling. These types of heating pads could be covered with a stain-resistant and non-absorbent slipcover and used under or over the patient to provide heat through contact.
80. Controls display: The ideal controls display would have a simplistic on/off switch, display of the device temperature, display of the heat flow, display of the skin and core temperature of the patient, and a safety-flashing signal when the patient becomes too hot. Our feedback loop would update this control system in real-time.
81. Rechargeable batteries: Because the Dominican Republic is subject to frequent power outages, rechargeable batteries would be an ideal power source or back-up power source. The batteries would be closely packed in a sturdy housing to provide enough power to our heating unit.
82. Convective dome with sliding panels: This dome would be sturdy enough to not come into direct contact with the patient. The patient would be warmed via convection from air blowing and circulation into the dome. The tight enclosure would not allow radiant heat to escape easily. There would also be a sliding panel, which would allow the surgeon to access multiple areas of the body but still have the entire warming unit in one piece.
83. Forced air covering: This unit would function like the Bair Hugger, except that it would be made of non-disposable material, such as a flexible PVC material. The forced air would be filtered before arriving into the unit. The unit could also be placed either over or under the patient.
84. Resistive underbody blanket: This blanket would be made to size of the OR bed with arms outstretched. There would be a bit of extra material draped over the side to allow some adjustability for coverage on the bed or on the patient. Sensors would be placed throughout the underbody blanket to ensure a proper reading of the patient’s core temperature.

85. Temperature display at head of bed: After speaking with surgeons and observing surgery, the optimal place to include the temperature display would be at the head of the OR bed. This would allow the surgeon or anesthesiologist to quickly check on the patient's temperature throughout the surgery. It will not be in the way of other devices being used and would detach to clean easily.
86. Housing and cord design: The ideal housing would have an option to be used wirelessly by having the cord detach when fully charged. The cord can also detach from the heating unit to allow for easier cleaning (i.e. the blanket material can be cleaned separately from the controls components).

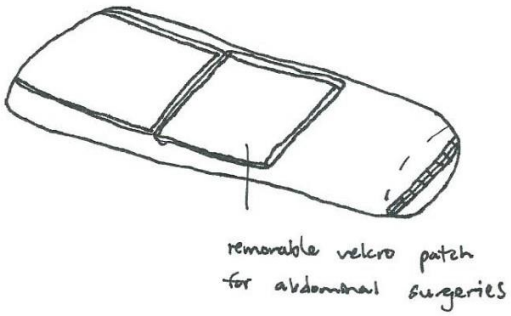
1.


cord
upper body
resistive blanket
bed

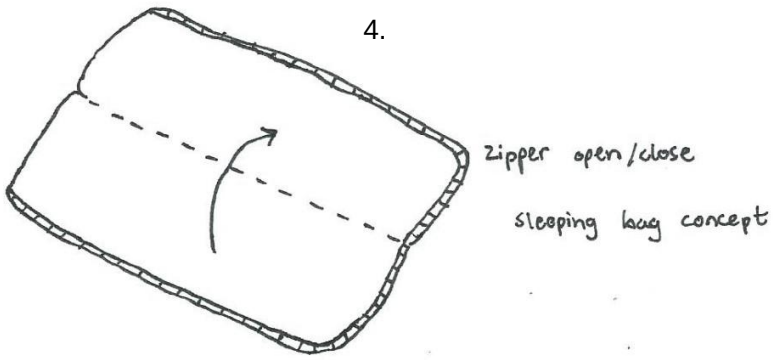
2.

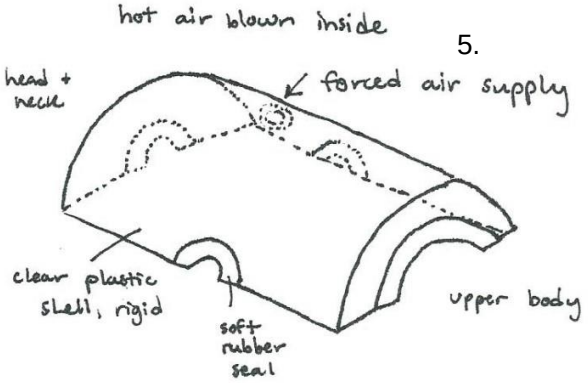

middle panel
velcro
soft padding
flap comes over torso
(upper)
velcro
flap comes
over
patient's
upper-arm
velcro
connection
resistive heating
OR conductive beads/particles
velcro
flap comes over legs
velcro

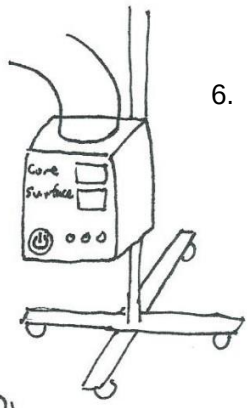
3.

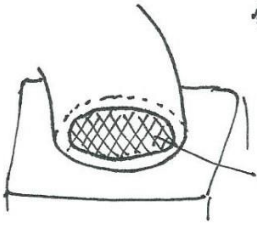

removable velcro patch
for abdominal surgeries

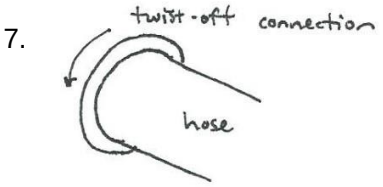
4.

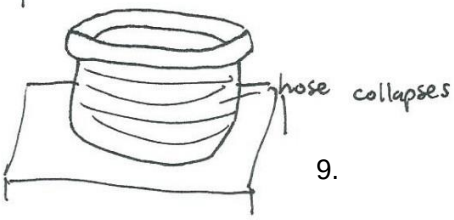

zipper open/close
sleeping bag concept

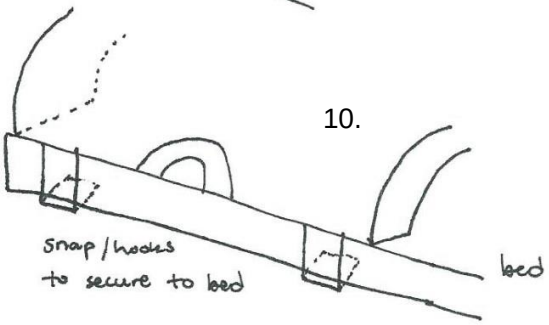

hot air blown inside
5.
head + neck
forced air supply
clear plastic shell, rigid
upper body
soft rubber seal

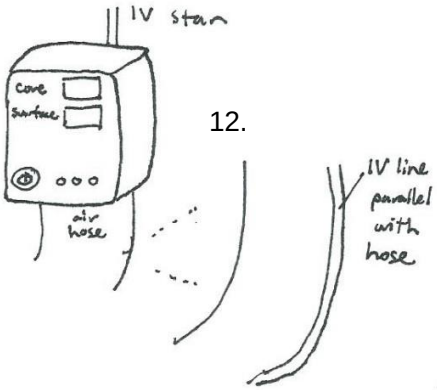

6.
Core
Surface

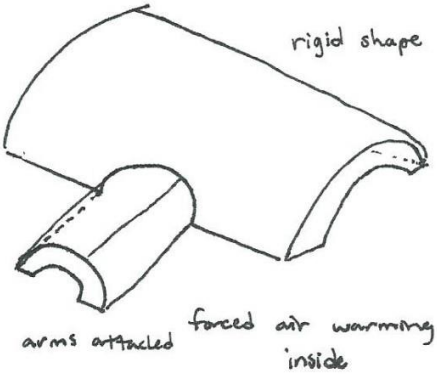

anti-microbial filter

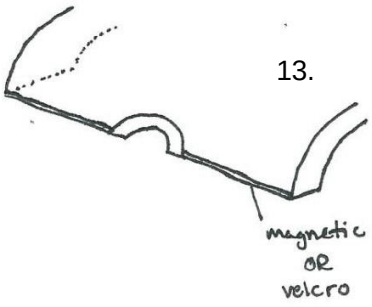

7.
twist-off connection
hose

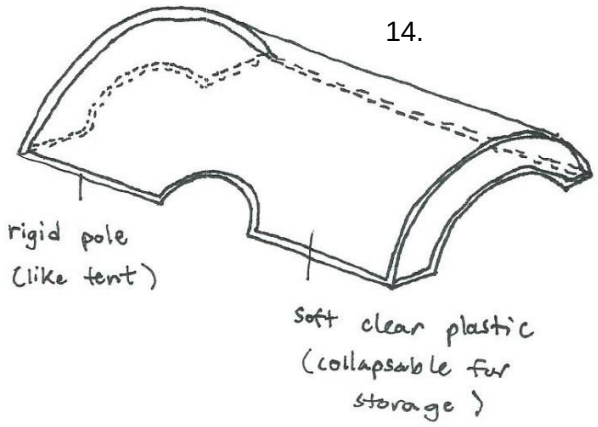

8.
hose collapses
9.

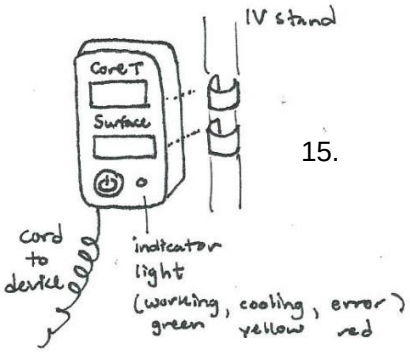

10.
snap/hooks to secure to bed
bed


IV stan
Core
Surface
air hose
12.
IV line parallel with hose

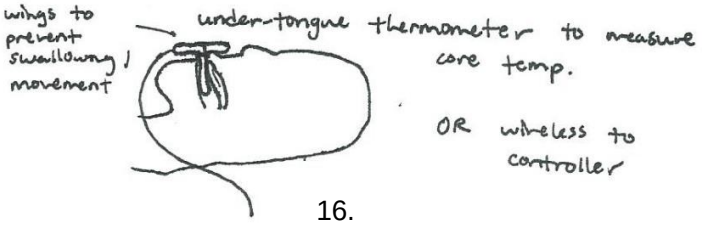

rigid shape
11.
arms attached
forced air warming inside


13.
magnetic OR velcro

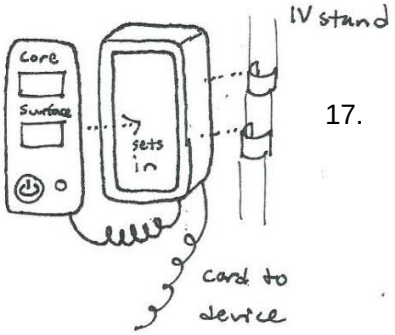

14.
rigid pole (like tent)
Soft clear plastic (collapsable for storage)



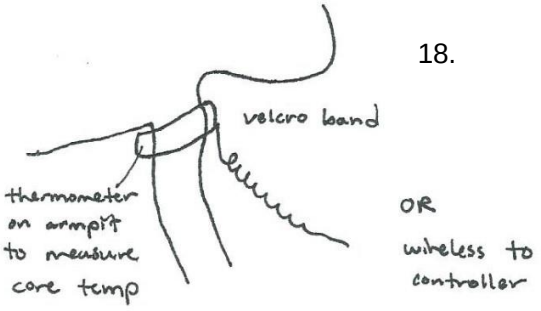
15.



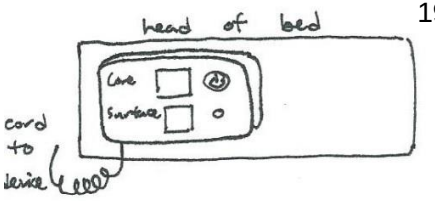
16.



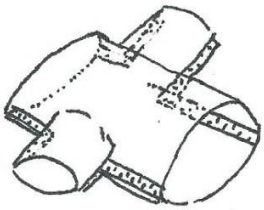
17.



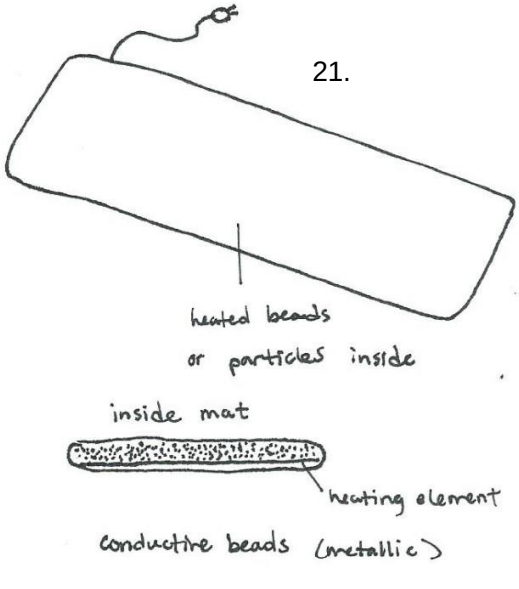
18.



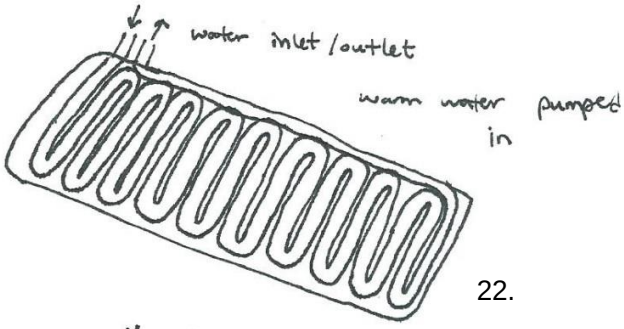
19.



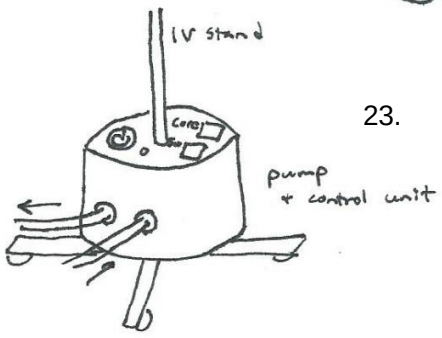
20.



21.

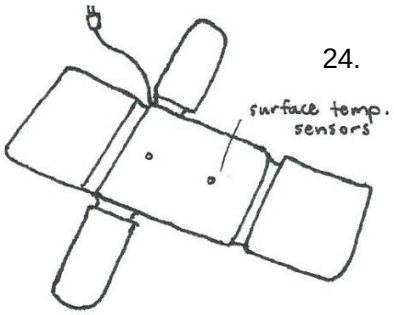


22.



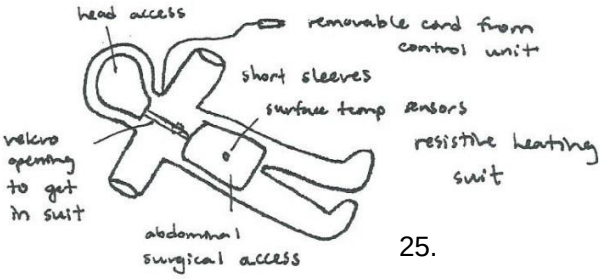
23.

24.



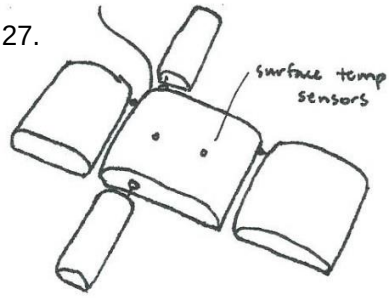
resistive heating pad
folds up into one rectangular piece

25.



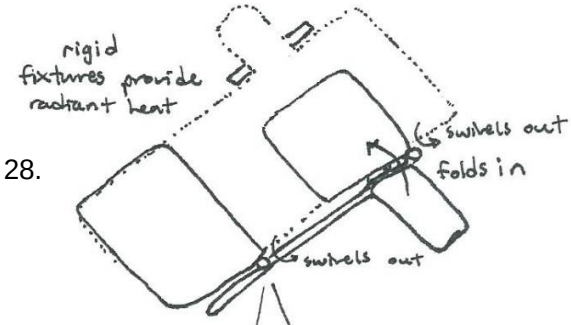
26.

27.

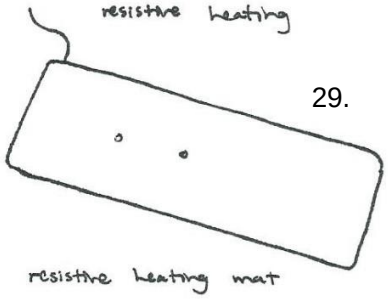


removable (velcro) cushions
resistive heating

28.



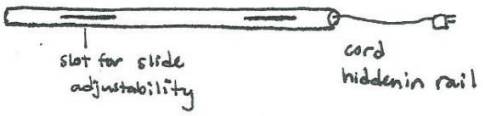
29.



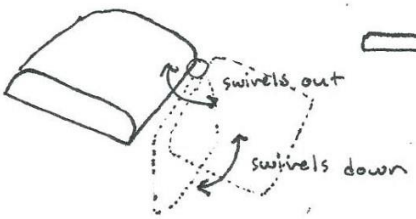
resistive heating mat
rolls up

30.

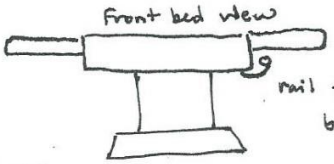
31.



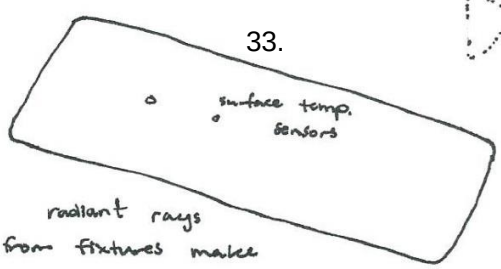
32.



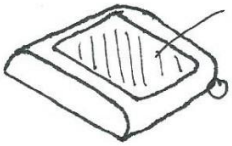
sheet / film on bed



33.



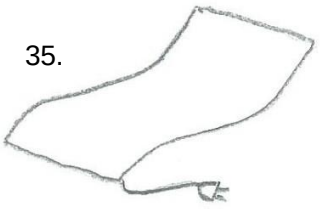
radiant rays from fixtures make conduct or reflect heat



34.

Electric Blanket

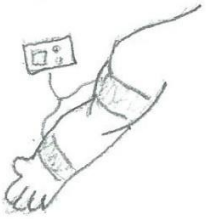
35.



- Vibrates to reduce pressure

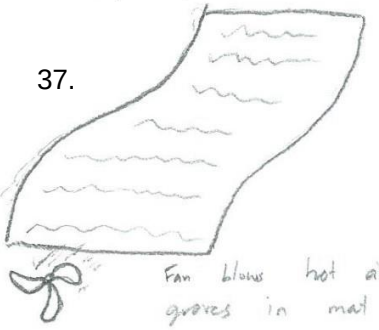
Unit stimulates controlled "shivering"

36.



Bumpy surface

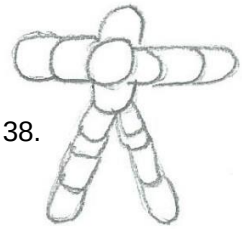
37.



Fan blows hot air up grooves in mat

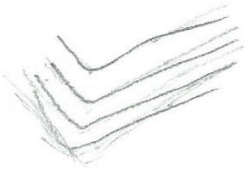
- Modular pieces to customize size

38.



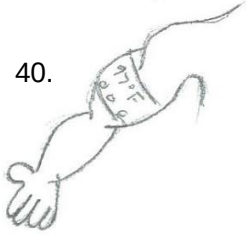
Many thin, stackable

39.

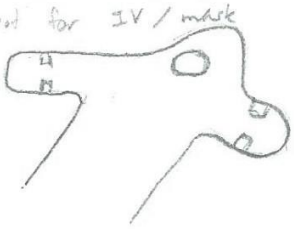


Wearable display

40.



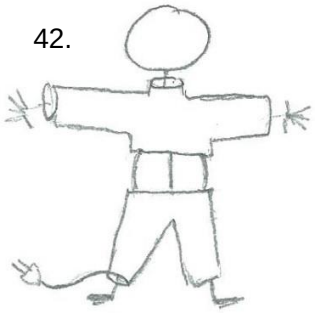
Covers all, but leaves spot for IV / mask



41.

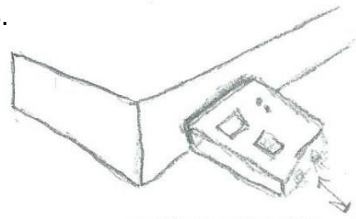
Wearable warmer

42.



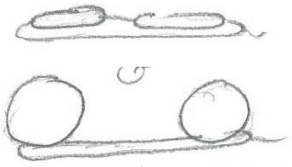
Control panel slides under bed

43.



44.

Flat table ↺ FLIP

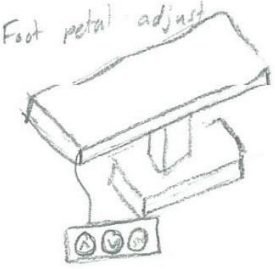


Forced air warmer

(different function on each side)

Foot petal adjust

45.



46.

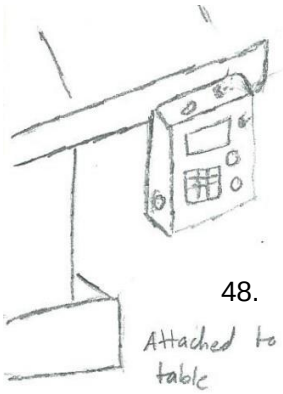
Use A/C heat rejected to warm

Armpit sensor

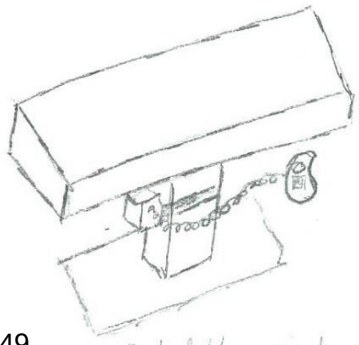
Sensor behind knee

Neck sensor

47.

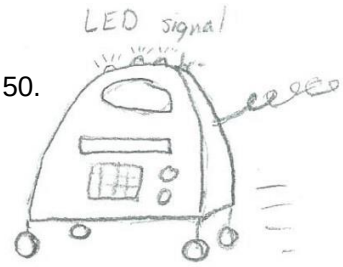


48.

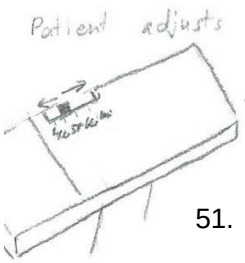


49.

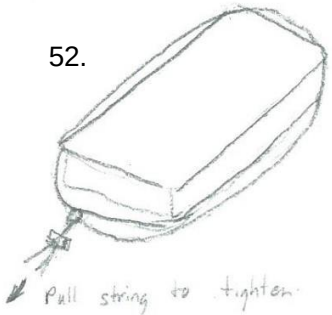
- Detachable remote
- Unit protected under bed



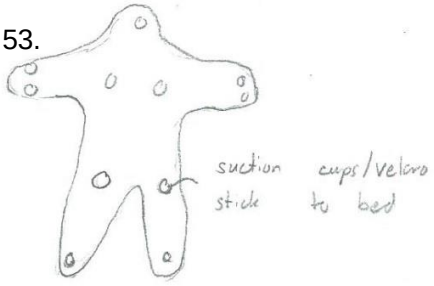
50.



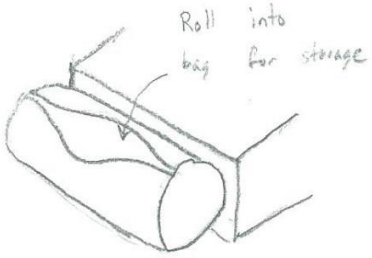
51.



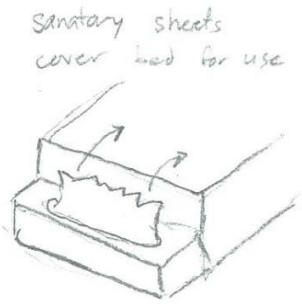
52.



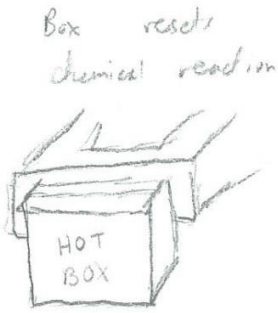
53.



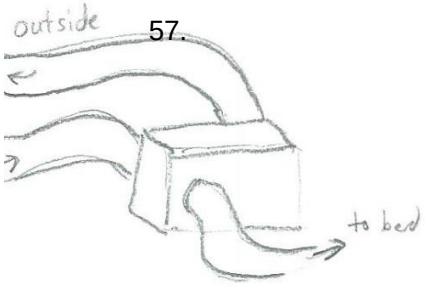
54.



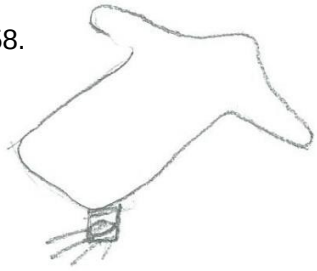
55.



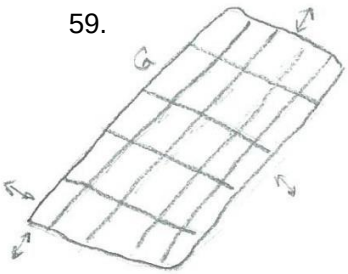
56.



57.

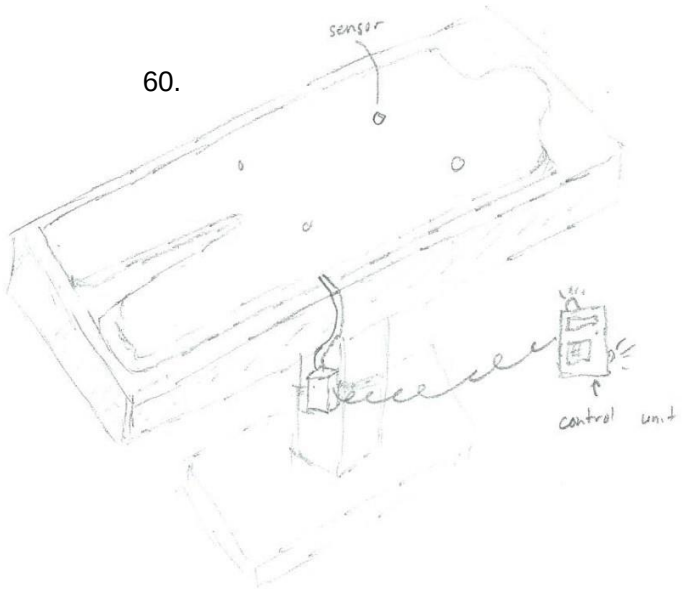


58.



59.

60.



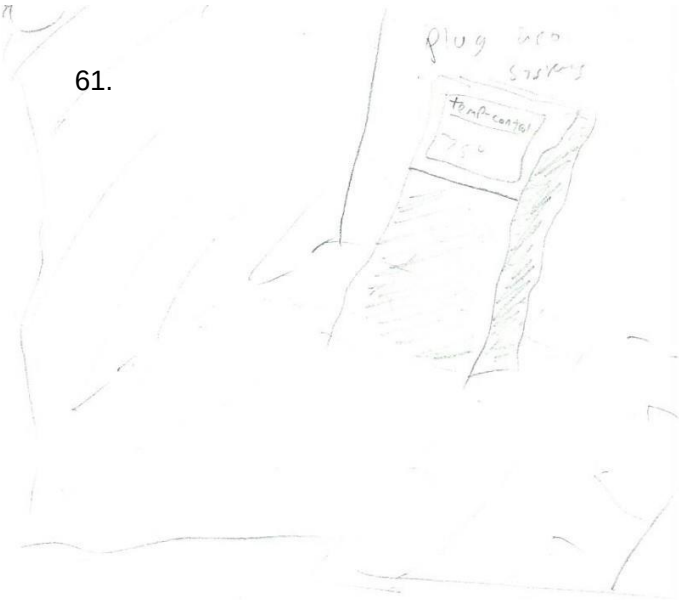
- Add in arms
- control unit on IV stand by anesthesiologist

form fitting: will it accomadate patients of all sizes?
how does it attach to bed? sturdy?
how high does it sit/thickness?

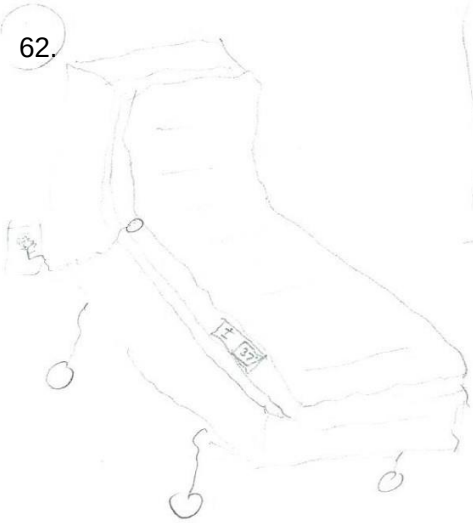
- how many sensors will we need / will be feasible?
- how thick does it NEED to be?
- accessible control unit

Where / how many sensors? Under arm?

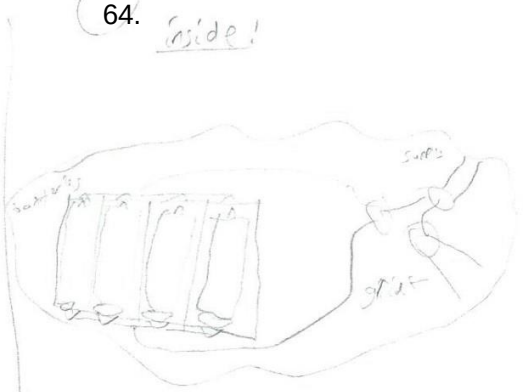
61.



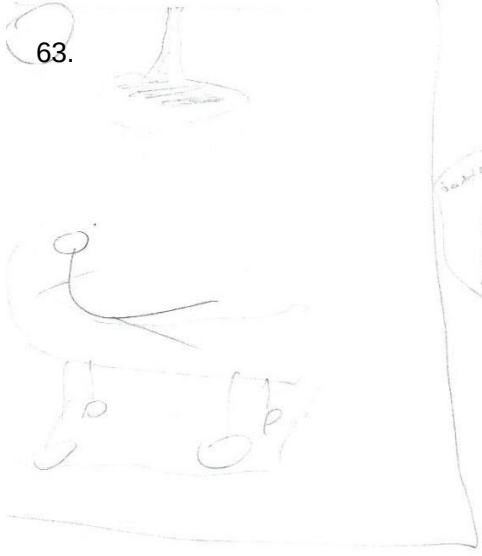
62.



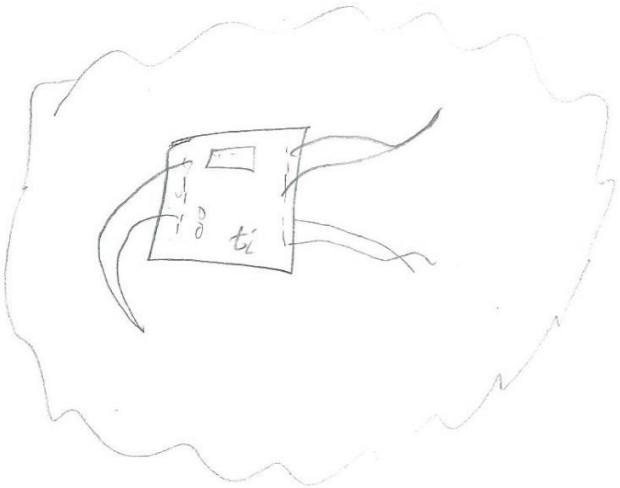
64.



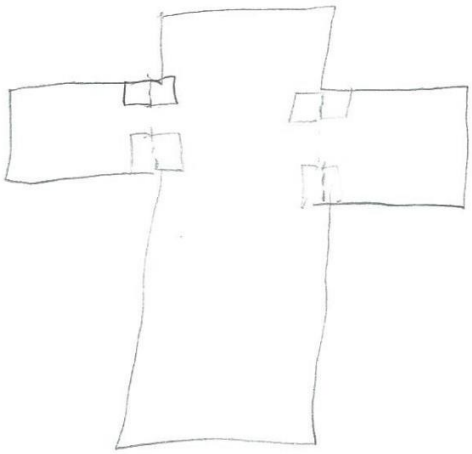
63.



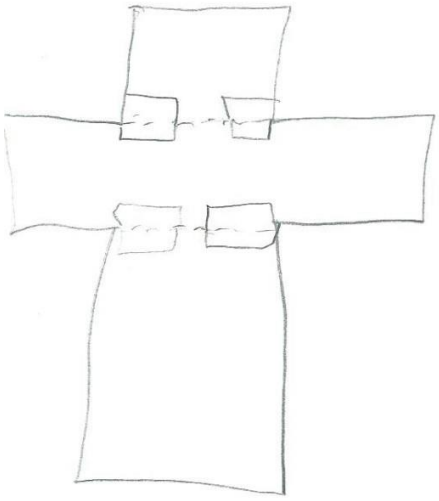
65. inside:



66.



67.



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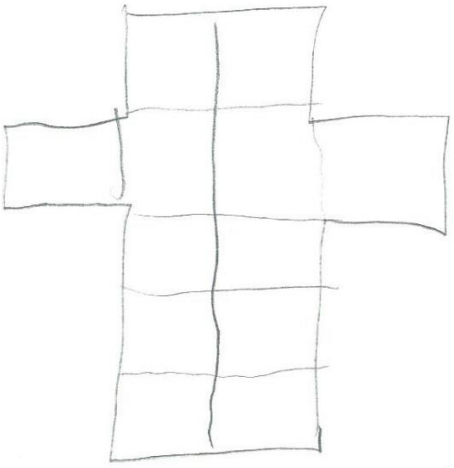

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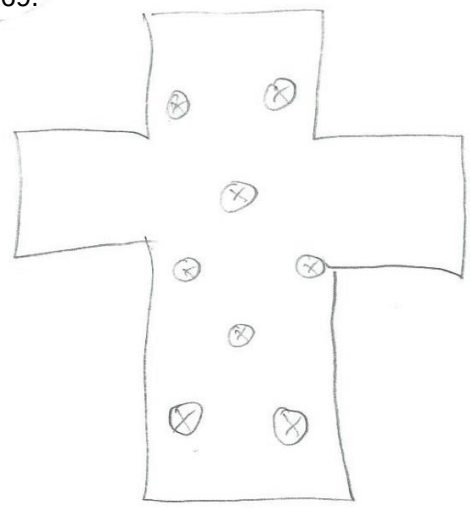

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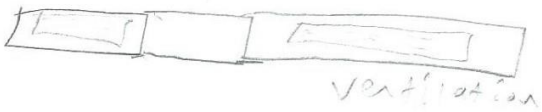

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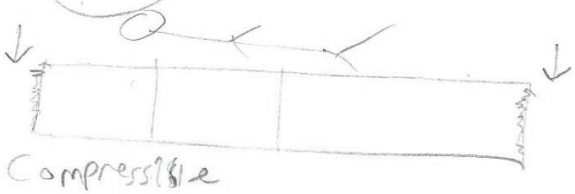

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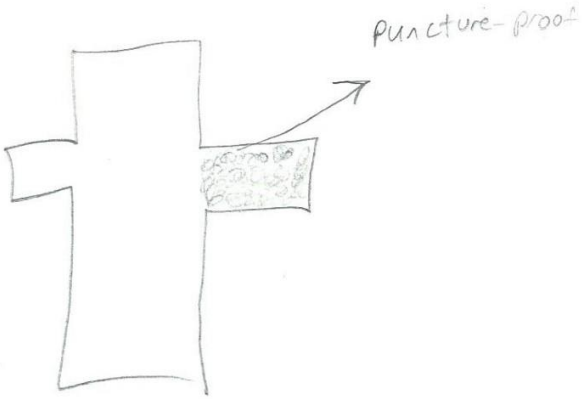
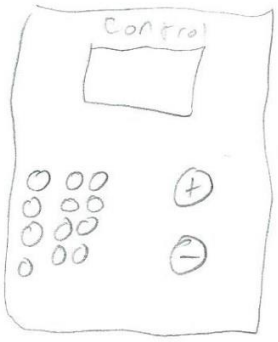
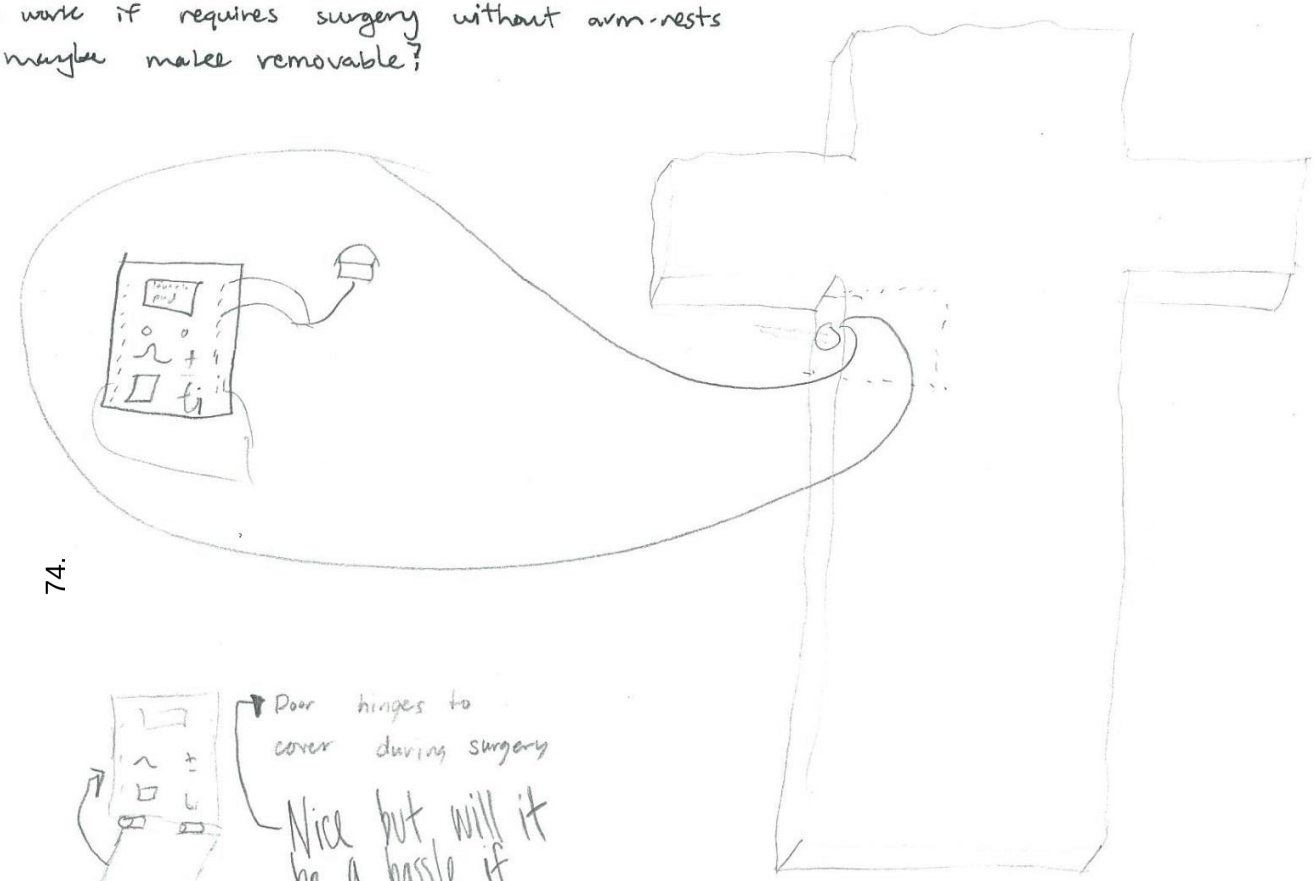


73.



What happens if the surgeon leans on it?

Warming gels inside? Or water more effective?
Won't work if requires surgery without arm-rests
so maybe make removable?

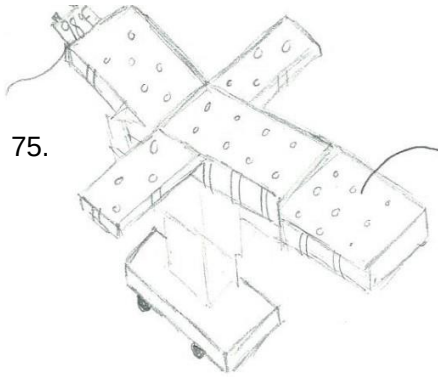


74.

Door hinges to cover during surgery

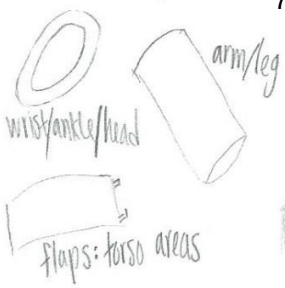
Nice but will it be a hassle if surgeons want to quickly check temp during surgery?

75.

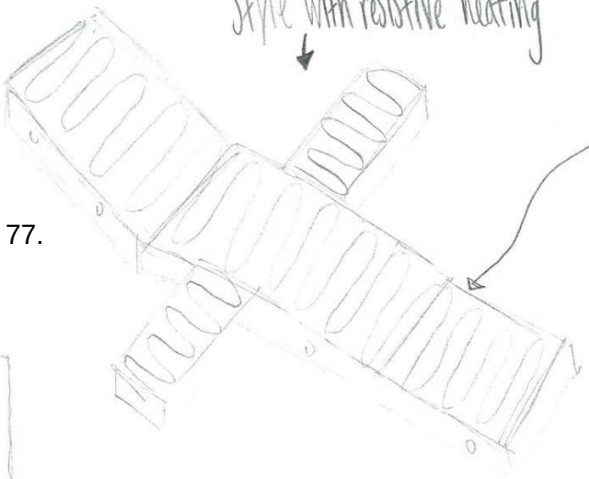


Accessories system:

76.

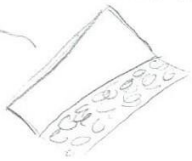


77.



attaches: magnetically or with velcrow

78.



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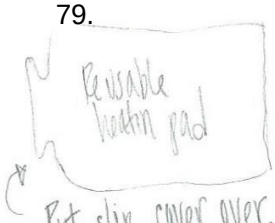
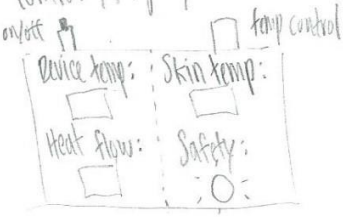


Put slip cover over, a puncture and stain resistant one

80.

Controls/Display:

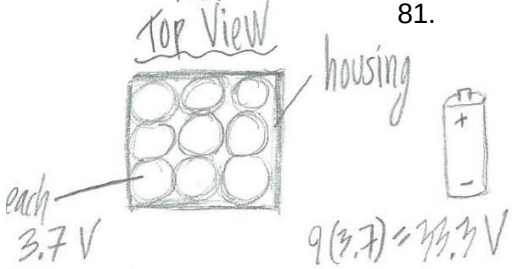


Rechargeable lithium-ion AA batteries

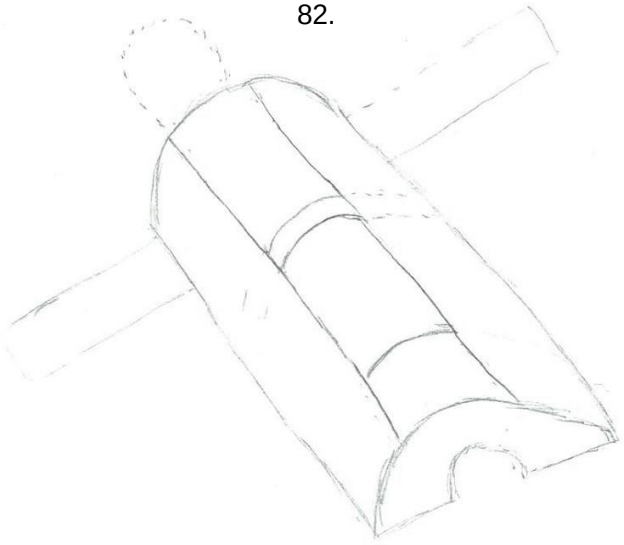
3.7V

Top View

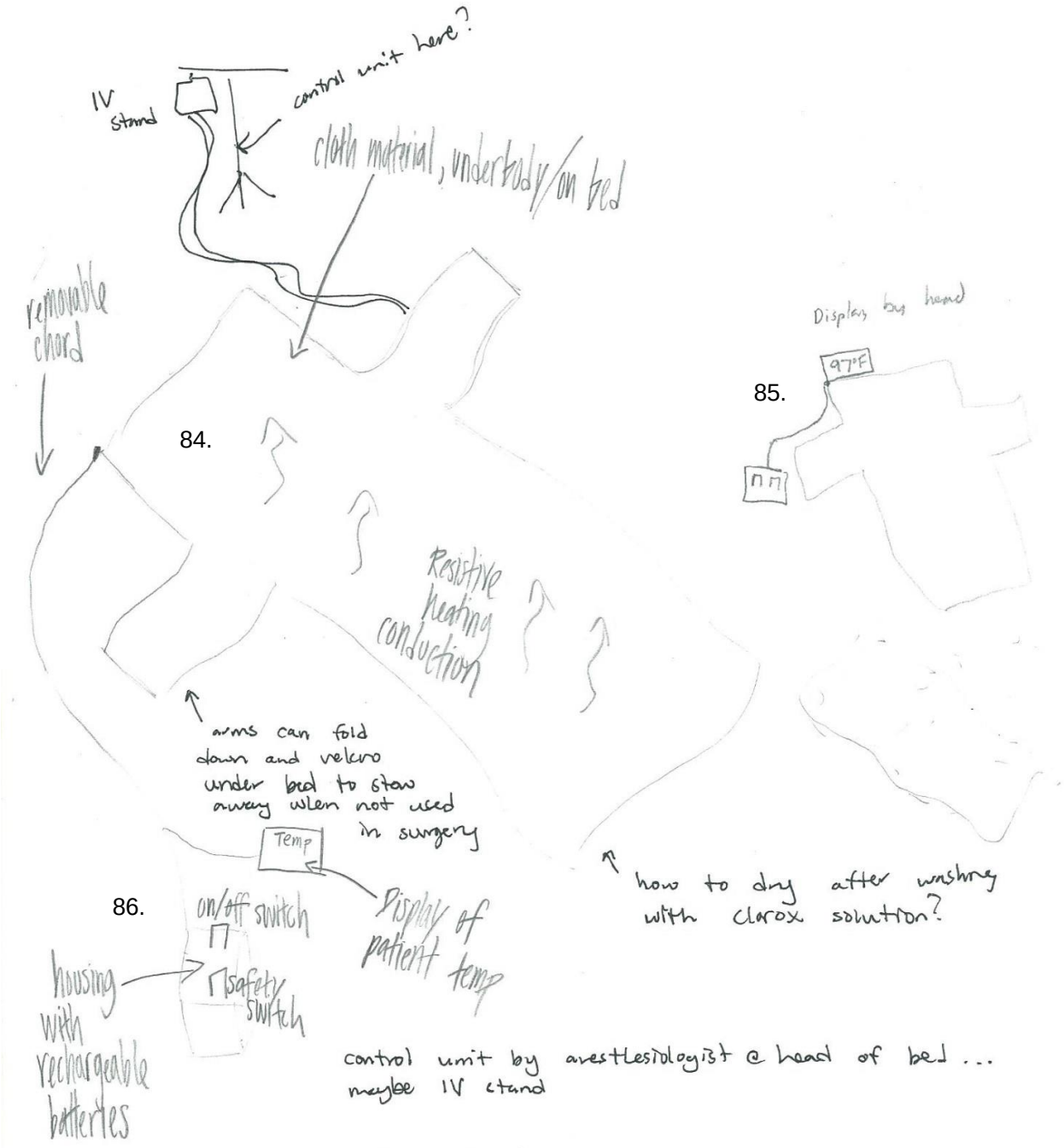
81.



82.



83.


IV stand
control unit here?
cloth material, underbody/on bed
removable chord
84.
Resistive heating conduction
arms can fold down and velcro under bed to stow away when not used in surgery
Temp
86.
on/off switch
Display of patient temp
housing with rechargeable batteries
safety switch
85.
Display by head
97°F
how to dry after washing with clorox solution?
control unit by anesthesiologist @ head of bed ... maybe IV stand
• do we want controls inside the unit, where it plugs into the wall, or in between/on the cord?
• where does the unit sit? When is it removed?
Need sensors to check multiple body locations

Appendix B: Complete Pugh Charts

The following Pugh Charts allowed us to assess our many generated concepts of four specific components to our device: warming unit, warming technique, control unit, and temperature monitoring.

PUGH MATRIX: WARMING UNIT

Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)

Benchmark/Datum receiving all 0s: Bair Hugger over body forced air blanket

Key Criteria	Weight	Accessories system	Forced-air over body rigid torso dome	Under body mat with conductive metallic beads	Conformable radiant heating bedside modules	Forced-air over body soft torso tent	Warming suit with removable patches	Resistive heating sleeping bag with removable sections	Resistive heating cushions
Effective	4	-1	0	-1	1	0	-1	1	-1
Ease of Use	3	-1	0	1	1	0	0	0	1
Safety	4	1	-1	0	-1	-1	-1	0	1
Durability	3	1	1	1	1	0	1	1	1
Aesthetics	1	0	1	1	0	1	-1	0	1
Reliability	2	-1	0	1	0	0	1	1	1
Patient Comfort	2	-1	0	-1	1	0	-1	0	1
Provider Comfort	2	1	-1	1	-1	0	-1	0	1
Cost / Affordability	3	1	1	1	0	1	0	1	-1
Manufacturability	1	-1	1	-1	0	1	0	0	1
Portability	1	1	-1	0	-1	0	0	0	-1
Reusable	4	1	1	1	1	1	1	1	1
Compatibility	2	-1	0	0	-1	0	0	0	-1
Maintenance	3	-1	-1	-1	-1	-1	-1	-1	-1
Efficiency	2	1	-1	1	0	0	0	1	1
Invasiveness	2	0	0	1	1	0	-1	0	1
Environmental impact	1	0	0	1	1	1	0	1	1
Noise	1	1	0	1	1	0	1	1	1
Sterilizable	4	-1	-1	-1	0	-1	-1	-1	-1
	+1	8	5	11	8	5	4	8	13
	0	3	8	3	6	11	7	9	0
	-1	8	6	5	5	3	8	2	6
Totals	Score	-1	-4	10	8	-1	-12	13	11

PUGH MATRIX: WARMING TECHNIQUE

Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)

Benchmark/Datum receiving all 0s: Bair Hugger over body forced air

Key Criteria	Weight	Resistive heating	Forced air	Reusable heating pads, chemical reaction	Conductive beads	Radiant heat	Convection - water	Insulation	Filter air from outside	Hot box at end of bed to reset chemical reaction	Controlled shivering	Fan blows through channels in bed for convection against body	Repurpose rejected heat from A/C unit
Effective	4	-1	0	-1	-1	1	-1	-1	0	-1	-1	-1	1
Ease of Use	3	1	0	-1	1	0	0	0	-1	-1	-1	-1	-1
Safety	4	0	0	-1	0	-1	0	1	-1	0	-1	-1	-1
Reliability	2	1	0	-1	-1	-1	-1	0	-1	-1	-1	-1	-1
Patient Comfort	2	0	0	-1	-1	1	-1	1	0	0	-1	0	0
Provider Comfort	2	1	0	1	1	-1	0	1	0	0	-1	-1	0
Cost / Affordability	3	0	0	0	0	0	-1	1	1	1	1	1	1
Reusable	3	0	0	-1	0	0	1	0	-1	1	-1	1	-1
Maintenance	3	0	0	-1	-1	0	-1	0	-1	-1	-1	1	-1
Efficiency	2	1	0	-1	0	0	-1	1	1	1	1	-1	1
Environmental impact	1	0	0	-1	1	0	0	1	1	1	1	1	1
Noise	1	1	0	1	1	1	0	1	0	1	1	-1	0
	+1	5	0	2	4	3	1	7	3	5	4	4	4
	0	6	12	1	4	6	5	4	4	3	0	1	3
	-1	1	0	9	4	3	6	1	5	4	8	7	5
Totals	Score	6	0	-21	-4	-1	-13	11	-9	-2	-16	-8	-5

PUGH MATRIX: CONTROL UNIT

Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)

Benchmark/Datum receiving all 0s: Bair Hugger control unit (3 temperature buttons, power button, air temperature display)

Key Criteria	Weight	Feedback display	Attachment to IV stand	Display core and surface temperature	Power button with indicator light	Battery power backup	Attachment to head of operating bed	Detachable remote under bed	Adjusted by patient	Speaker for audible alerts	Wearable display	Panel slides under bed	Foot petals on ground to adjust
Effective	3	1	0	1	1	1	1	0	0	1	1	0	1
Ease of Use	3	1	1	1	1	0	1	1	1	1	1	1	1
Safety	2	1	-1	1	1	1	1	1	-1	-1	1	1	-1
Durability	3	0	0	0	1	1	0	0	-1	0	-1	0	-1
Aesthetics	3	1	1	1	1	0	0	1	0	0	-1	1	0
Reliability	3	0	-1	0	1	1	0	0	0	-1	0	0	0
Patient Comfort	1	0	0	-1	0	1	0	0	1	-1	-1	0	0
Provider Comfort	4	0	0	0	0	1	1	1	-1	-1	1	1	1
Cost / Affordability	2	-1	0	-1	0	-1	0	0	0	0	1	0	0
Manufacturability	2	-1	-1	-1	0	-1	0	0	-1	0	-1	0	0
Portability	2	0	-1	0	0	0	-1	-1	-1	0	0	-1	0
Reusable	3	1	0	0	0	1	0	0	0	0	-1	0	0
Compatibility	2	1	0	0	0	0	0	0	0	-1	0	0	0
Maintenance	2	0	-1	-1	0	-1	0	-1	-1	0	0	-1	-1
Efficiency	2	0	0	0	0	0	0	1	0	0	1	1	1
Invasiveness	1	0	0	-1	0	1	0	1	1	0	0	1	0
Environmental impact	2	0	0	0	0	0	0	0	0	0	0	0	0
Noise	2	0	0	0	0	1	0	0	0	-1	1	0	0
	+1	6	2	4	6	9	4	6	3	2	7	6	4
	0	10	11	9	12	6	13	10	9	10	6	10	11
	-1	2	5	5	0	3	1	2	6	6	5	2	3
Totals	Score	12	-5	3	17	16	10	11	-10	-8	6	11	5

PUGH MATRIX: TEMPERATURE MONITORING

Weight: 1 (non-essential), 2 (desired), 3 (important), 4 (critical)

Benchmark/Datum receiving all 0s: PerfecTemp surface temp monitoring (2 sensors under patient's back)

Key Criteria	Weight	Nasopharyngeal sensor	Surface sensor on forehead	Wristband surface sensor on axillary artery	Pacifier-like sensor underneath tongue	Behind the knee
Effective	4	1	0	0	1	-1
Ease of Use	3	0	1	0	0	0
Safety	4	0	1	1	0	0
Durability	2	0	-1	1	0	0
Aesthetics	1	0	0	1	-1	-1
Reliability	2	1	-1	0	1	-1
Patient Comfort	3	-1	1	1	-1	-1
Provider Comfort	1	0	1	1	-1	0
Cost / Affordability	2	0	1	0	0	0
Manufacturability	1	0	0	-1	-1	0
Portability	2	0	0	0	0	0
Reusable	3	0	-1	1	1	0
Compatibility	2	0	0	0	0	0
Maintenance	2	0	0	0	0	0
Efficiency	1	1	1	0	1	0
Invasiveness	3	-1	1	1	-1	0
Sterilizable	4	-1	0	0	-1	0
	+1	3	7	7	4	0
	0	11	7	9	7	13
	-1	3	3	1	6	4
Totals	Score	-3	10	16	-3	-10

Appendix C: Questionnaire – Aesthetics, Ease of Use, Comfort

Device to perioperatively regulate patient temperature for low-resource settings

Aesthetics

1) When you first look at the product what are the first descriptive words or thoughts that come to mind?

2) Is there anything that this product reminds you of when you first see it?

3) What would you imagine this product to be used for?

   Explain its actual use.

4) Now that I told you what this product is meant to do does it change your perception of it in any way? How so?

5) How would you describe the look from the standpoint of "quality"? Please explain why you say this.
   a. Very high quality
   b. High quality
   c. Somewhat high quality
   d. Not very high quality
   e. Very low quality

6) How would you describe the look in terms of "being high tech"? Please explain why you say this.
   a. Very high tech
   b. High tech
   c. Somewhat high tech
   d. Not very high tech
   e. Very low tech

7) How would you describe it in terms of being "professional"? Please explain why you say this.
   a. Very professional
   b. Professional
   c. Somewhat professional
   d. Not very professional
   e. Very unprofessional

Product Testing - Ease of Use and Comfort

Now I'd like you to actually try out the product.

(Use this series of questions for each moment you want them to experience.)

Please X (action), where X is turning on the device, controlling the temperature with manual adjustment, and sitting in a relaxed position on the device.

8) Describe what it felt like to do X.

9) Why/what made it feel that way?

10) Is there anything that would make this easier for you? Please explain.

After all questions, ask:

11) Lastly, how would you describe how you feel about this product taking into account the look, feel and experience testing it out?
    a. I feel positive
    b. I feel somewhat positive
    c. I feel neither positive nor negative
    d. I feel somewhat negative
    e. I feel very negative

12) Please tell me why you gave it this rating.