Positioning and Thermoregulation of Surgical Patients

Volume II

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1.1 Annotated Bibliography

As the field currently stands, there is no single device being utilized to both position and thermally regulate a patient during surgical procedures under general anesthesia. This leaves us room to generate a new product that can fill in the gap. Thorough research of the product market was performed in order to understand the products that are available, as well as to understand what people and companies have tried to do, and will try to do in the future to improve the patient experience while under the knife. Current positioning devices range in size and shape from pillows and blankets to large mechanical systems designed to limit the motion of the body. The most widely used positioning device is the surgical vacuum beanbag. Heating systems include forced air warmers, IV fluid warmers, and electric resistance blankets. Currently, the most widely used warmer is the forced air warmer.

The team gained valuable insight into the methods of positioning currently in use by observing several videos of the patient positioning process. All aspects of the problem were considered while performing research. This is important because by understanding all nuances of the problem the team was able to more clearly approach an appropriate solution. Topics researched include hypothermia, operating room temperatures and humidities, surgical positions, anesthesia and temperature control, as well as a host of other topics.

1.2 Patent Search

Objective
A thorough search was performed using Google patent in order to better understand the current technology in the market that catered to both surgical thermoregulation and positioning, as well as to establish the boundaries for the creation of new intellectual property. Searches were performed for surgical thermoregulation devices, patient positioning devices, as well as devices that combined the two. Research was also performed to understand the fundamental technologies associated with heating and positioning devices. For example, the design team looked into the elements of current surgical thermoregulatory devices such as the feedback control systems used to regulate the temperature of the devices and the heating elements in the devices (e.g. electrical resistance heating).

After a thorough and extensive patent search, there was a noticeable lack of devices which could both safely and securely position a patient for surgery while providing thermoregulation for the patient. In order to fill the existing market need for such a device, the design team came up with a design that reconfigures existing surgical beanbags used for surgical positioning with memory foam on the surface while incorporating a resistive heating element within the structure. The heating system is controlled using patient feedback, relying upon the preexisting body core temperature sensors already in use during all operations that require general anesthesia.

When the entire system is taken into consideration, the device, as well as the control systems used in tandem can potentially be patented.

Search Criteria
Table 1 provides the search criteria of the different patents used to describe major and minor risks related to the position team’s design.

<table>
<thead>
<tr>
<th>Patent</th>
<th>Publication #</th>
<th>Classification #</th>
<th>Search Word</th>
<th>Search Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heating Device for heating patient’s body</td>
<td>US7709770</td>
<td>H05B 1/02; 3/34; 3/56 A61F 7/02</td>
<td>Patient Heating</td>
<td>Google</td>
</tr>
<tr>
<td>Surface pad system for a surgical table</td>
<td>US6401283</td>
<td>5/740; 5/503.1; 5/600; 5/694; 5/731; 5/737</td>
<td>Thermoregulation surgical</td>
<td>Google</td>
</tr>
<tr>
<td>Electric warming blanket having optimized temperature zones</td>
<td>7851729</td>
<td>: 219/549; 219/212; 219/217; 219/528; 219/545; 219/548</td>
<td>Scott Augustine</td>
<td>Google</td>
</tr>
<tr>
<td>Heating pad system for patient warming</td>
<td>US6924467</td>
<td>219/528; 5/421; 219/212; 219/217; 219/218; 219/521; 607/96</td>
<td>Patient Heating</td>
<td>Google</td>
</tr>
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Major Findings

A major concern to the patentability for the position team’s design is the Surgical Positioning System patent application (US2011/0047706 A1). The system is made from a flexible air-impermeable shell, filled with beads, which can be wrapped against a patient and hold the patient in position when air is vacuumed out of the device. The bag is about 1.5 to 2.5 inches thick, made of a polyvinyl waterbed film, and has joined together walls for extra strength and airtightness. The bag is secured by attaching straps to the operating table, which helps prevent sliding. The main issue of concern is from the additional support structures, a laterally extending midline around the patient’s torso and a shoulder supporting region. The claims have a significant number of strengthened supports that could interfere with improving the position team’s design.

Minor Findings

The heating device for heating a patient’s body (US7709770) is a concern since it can heat the surface of a patient’s body. The device is made of an electrical heating element powered by an external source. The heating element constructed using two conductors. The conductors are placed in a parallel circuit using the first conductor as the heat source and the second conductor as the heat diffuser, which allows for a temperature gradient between the surface of the conductors and the body. The first and second conductors are made of relatively high and low specific resistivity, respectively. The concern is that a very low temperature gradient can be produced and controlled. This system could be a cause of concern because a low temperature gradient might be desirable and this is a simple way of creating it.

The surface pad system for a surgical table (US6401283) is a minor concern to the patentability for the position team’s design. The surface pad is made of two electrical heating elements. The first elements is connected to the power and provides the heating source, the second element has a lower resistivity and a larger surface area than the first to operate as the heat-diffuser. The concern here is that the system can provide a uniform distribution and transfer of heat to the area touching the patient.

The heating pad system (US6924467) for patient warming applies a foam layer of pads with a thermal-electric heating element between the layers. The system has two layers of foam pad and an electric heating element between the two layers, with an external power unit. The foam is covered by a waterproof antimicrobial cover and sealed to secure the cover. The main issues that could arise from this patent are the foams that are being used to transfer the thermal energy from the electrical circuit, and the cover that is secured over the design. Foam could be used as a material to convert the desired thermal energy for farming a body from an electrical circuit. The cover is also an issue since the material for the cover could conflict with the cover in the position team’s design.

The Electric warming blanket having optimized temperature zones (7851729) uses a temperature sensor that is in contact with the body. The system uses a flexible sheet-like heating element with uniform electrical resistance per unit area. The temperature sensor system has two sides, the first side has a temperature sensor coupled to a defined first temperature zone heating
element and the second side maintains the temperature of the first side. The temperature sensor could be a problem because of the way it is arranged to both sense the temperature change and maintain a heat.

### 1.3 User Needs Research

User needs are critical to consider during concept selection and product design. They enable the design team to create design specifications on which potential concepts can be evaluated. They are the guidelines for creating a new product that will have a meaningful impact. User needs were obtained through interviews and meetings with various surgical staff, including trained anesthesiologists, post-anesthesia care unit (PACU) nurses, and project advisors.

Ratings were chosen for each need on a 1-5 scale, with 5 being “very important”. For this project, the highest ratings were awarded to the needs associated with safety and surgical access. Current devices are very effective in these categories, and it is important that the new concept is competitive. Low ratings were given to the needs that are possible nice to have, but not required. An example of a 1 is being compatible with multiple surgical positions. While this property would be nice to have from a business standpoint, it does not affect the patient and is therefore given a low rating.

<table>
<thead>
<tr>
<th>#</th>
<th>User Need</th>
<th>Importance Rating (1-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Positioning needs to be faster than with current technology</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>Heating is more effective than with current technology</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>The cost of this system must be competitive in the device market</td>
<td>5</td>
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<tr>
<td>4</td>
<td>Has a disposable component</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>Allows access to airway</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>Allows access to surgical site</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>Easy to transport</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>Cleaning is easier or comparable to current technology</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>Compatible with multiple surgical positions</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>Has variable settings for patient warming temperature</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>Stable enough to hold the patient in place</td>
<td>5</td>
</tr>
<tr>
<td>12</td>
<td>Safe to use on an unconscious patient</td>
<td>5</td>
</tr>
<tr>
<td>13</td>
<td>Generates limited waste(^1)</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>Useful for many patient sizes(^1, 3)</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>Compatible with the lateral position(^1, 2)</td>
<td>5</td>
</tr>
</tbody>
</table>

Sources
\(^1\) Informal interviews and meetings with project advisor Jesus M. Cabrera, MD PhD.
\(^2\) Informal interviews and meetings with project advisor James Krocak.
\(^3\) Interview with University of Minnesota hospital anesthesiologist Dr. Barbara Gold and PACU nurses.
\(^4\) Interview with Anesthesiologist Resident Nick Sanborn, MD.

Customer Interview Transcripts

Nick Sanborn, MD
Anesthesiology Resident
2/13/13
Interviewer: TS

Interview Questions
a. How long does it take to set up a patient for operation?

Once asleep, 1-5 minutes to position. Usually doesn’t take very long. Patients usually start at a normal temp., so you just keep them from losing heat. Don’t normally heat patient until surgical drapes are up and the surgeons are ready to start. About 10-15 minutes when patients are not heated, unless they’re on a heat pad, which is turned on right away. Would also turn the Bair Hugger on once drapes were up.

b. What would you say could be important to take note of during the set-up procedure?

Make sure the patient is well padded, so there are no pressure points. You want to avoid a nerve injury. Make sure to pad any hard bony areas. The patient could be lying for 6+ hours.

c. How long does it take to clean the operation set-up?

1-2 min. It’s usually very fast. Don’t know what is disposed of. Wiping down the pads and machine is very quick. Unless things are all bloody, they are just wiped down.

d. How long does it take to get the patient out of the OR?
You usually wait until the patient is awake enough to breathe on his own, unless moving the patient to the ICU. Patients usually wake up 5-20 min. after surgery is completed.

e. What do you like about the positioning devices you are currently using? What don’t you like?

A lot of positioning is with foam padding and blankets. He likes the vacuum ban bag—it’s fast and easy to use. It seems to not hurt patients as much as the peg board. He thinks the Bair Hugger works well. It keeps patient warm, and is easy to use.

f. How often do patients come out shivering due to being cold? Did you notice any common trends in the setup, operation type, heating methods used?

Patients usually complain of being cold going in, not usually going out. The operating room is kept 65-70 deg. Shivering would be more a reaction to the drugs than being cold. Blankets from a warmer are provided to patients who complain of being cold going in or after waking up. Shivering is not a common experience. Patients are usually more concerned about pain than temperature.

g. Do you find the price of current technology reasonable?

He is not sure about the prices.

h. How often have you noticed burns on patients? Where do they typically occur?

He has never seen a burn on a patient. He has heard of the pad from a cauterizing device causing burns, but not a heating device.

i. How long does it take patients who are cold to get back to 36.9°C

It all depends on surface area exposed, temp. of room, and how the patient is warmed. It could take a couple of hours, or it could take 20 min. Some people with the Bair Hugger alone don’t warm up.

Dr. Barbara Gold and PACU nurses
2/14/13
Interviewer: Group

   o The nurse provided a demonstration of the Bair Hugger and Bair Paw technology.
   o The Bair Hugger went up to a maximum temperature of 43°C.
   o She also mentioned that it took at most 30 minutes to clean the operating room after a surgery.
   o When questioned on how long it took patients to get back to their regular temperatures while in the PACU she said it took about 1½ hours.
She also added that incorporating a positioning device that was capable of moving the patient’s limbs slightly during an operation would be very helpful.

Meetings with Advisors

Relevant Portions of Meeting Minutes
Jesus Cabrera, James Krocak
1/31/13
Interviewer: Group

Pros and Cons of Product History

- Positioning
  - Discussed importance of keeping airway channel protected at all times as well as IV, ECG, etc.
    - Care should be given to watching the extremities
  - Most challenging position to consider: lateral or prone position surgery
- Thermoregulation
  - A lot of the heating isn’t optimally distributed to the patient
  - Current products do not create an ideal situation for both heating and thermoregulation
  - Discussed chemical warming- might not possess a consistent temperature distribution and heat dissipation rate
    - Ideally we want circumferential heating, light, and easy to integrate into existing systems if necessary

Open Discussion

- How important is a feedback mechanism for heating?
  - Advisors mentioned that feedback was not very critical as the maximum allowable temperature was 40ºC and it would be hard to control temperature of the air directly.
  - Suggested using a water reservoir at a set temperature to maintain patient temperature.
- How common are heating devices (using circulatory water) used to cool the patient?
  - Not very common.
  - Suggested using circulatory water for heating instead of cooling
- What were the disadvantages of the Bair Hugger?
  - Not circumferential
  - There could be a better system
  - Not warm enough
  - Air and gasses in general have poor thermal capacities and can only transfer limited amounts of heat to the patient
• Inventor of the Bair Hugger using different heating technology now suggesting better possibilities
  o Another heating option discussed was to keep heat in using thermally reflective material (eg: OMNIHEAT technology by Columbia)
  o While thinking about positioning, consider ease of cleaning apparatus
  o Focus on prone/lateral position, considering both heating and positioning

Relevant Portions of Meeting Minutes
Jesus Cabrera, James Kroca
2/7/13
Interviewer: Group

Concept Selection

• Bair Hugger demo-made from paper. Paper also absorbs sweat.
• Beanbags used to position since it can conform to patient position.
• Suck out air from the Styrofoam and then it conforms to patient’s body.
• Concept: create a beanbag with heating abilities.
  o Could be heated using resistive heating or fluid flow.
  o With resistive heating, a fluid/thermal reflector could be used to line the beanbag. This component will be disposable.
  o With water, need pressurized and circulating flow.
  o Consideration will need to be given to the materials used to make the beanbag if we are using resistive heating.
  o Beanbag should still be at a similar weight and price with current products.
  o There should be a way to securely attach the disposable part of the beanbag.
  o The max/min range of the heating element should be clearly defined and controlled in other to avoid burns.
1.4 Concept Alternatives

Several concepts for the design were considered, encompassing three heating methods: electrical resistance, infrared, and water heating. Concept alternatives that were considered are as follows:

**Electrical Resistance Heating**

**Beanbag with Electrical Resistance Heating**
The beanbag is airtight and filled with fine granules. It can be wrapped around a patient to position him or her for surgery. When a vacuum pump is used to remove the air from the beanbag it becomes rigid and holds the patient in place. The electrical resistance heating element is embedded in a layer of foam which distributes the heat.

**Inflatable Device with Electrical Resistance Heating**
This device is shaped to fit around the patient’s body and can be inflated to secure the patient in place. Similar to the beanbag, it uses an electrical resistance heating element on the surface to warm the patient. A sketch of this concept is appended to this section.

**Foam Mattress with Electrical Resistance Heating**
In this device the heating element is embedded within the mattress. The softness of the foam causes the patient to sink into the mattress which helps to hold the patient in position. A sketch of this concept is appended to this section.

**Infrared Heating**

**Beanbag with Infrared Heating**
The beanbag, as described above, can be wrapped around the patient and the air vacuumed out to hold the patient in place. This device has a heating element embedded within the device which uses infrared radiation to warm the patient.

**Water Heating**

**Beanbag with Water Heating**
The beanbag is as described above. It uses water, heated in an external reservoir, flowing through flexible tubing to provide warmth to the patient. The water tubing is positioned on the surface of the beanbag nearest the patient.

**Wedge with Water Heating**
A solid foam wedge is used to support the patient in a lateral position. Tubing with warm flowing water is embedded within the wedge to warm the patient. Again, the water is heated in an external reservoir and circulated through the device. A sketch of this concept is appended to this section.
INFLATABLE DEVICE
WITH ELECTRICAL RESISTANCE
HEATING

- Air is pumped in and sealed to maintain tight grip on position.
- Insulating material.
- Electrical resistance heater.
- Temperature sensor for feedback control.
Foam Mattress with Electrical Resistance

Front View

Electrical heating element

Power Supply
1.5 Concept Selection

To evaluate eight different concepts in a systematic manner, a concept selection chart was utilized. By comparing each concept against a set of twelve key criteria, each concept’s strengths and weaknesses were assessed using a plus, minus and zero scoring system. All eight concepts were assessed relative to a baseline product on the market today—a beanbag with a Bair Hugger. After evaluating all concepts, they were ranked according to the net score obtained. Four concepts stood out as potentially superior to the others. These four were then considered in turn to determine if a redesign of the original concept could make it even stronger. Three concepts were redesigned. One original concept and the three redesigned concepts were then ranked against the baseline product using a concept scoring matrix with ten of the same criteria. This matrix included a weighting factor for each criterion. Also, the concepts were scored using a value from one to five for each criterion, with five being the strongest. The weighting factors were adjusted three times to determine the sensitivity of the weighting factor on the concept ranking. In all three resultant matrices, the same concept received the number one ranking.

The twelve criteria used in the concept screening matrix are as follows:

- **Maximum Patient Weight to Failure** measured the patient’s weight at which a concept would stop functioning. For instance, the weight at which a plastic tube would collapse and water would no longer flow through it is the maximum patient weight. This criterion ensured the sturdiness of the selected concept.
- **Device Lateral Stability** gauged the lateral force at which the concept would deform or tip. Since the concept must support a patient in the lateral position, this criterion ensured a patient would not tip over from the lateral position.
- **Safe Pressure Distribution on Patient** determined whether the concept would produce any localized pressure points. An uneven pressure distribution could lead to pressure sores or nerve damage on a patient. This criterion guarded against these risks.
- **Low Burn Risk** estimated the likelihood the concept could burn a patient. A concept with an even surface temperature and easily controllable maximum temperature received a high score.
- **Heat Transfer Rate** gauged the ability of the concept to quickly move heat from the concept to the patient. A higher transfer rate is better, as it would allow a patient to be warmed quickly if needed.
- **Contact Surface Area** measured the size of the concept that would be in direct physical contact with the patient. A larger surface area was better, as it would allow more heat to be transferred to the patient.
- **Temperature Responsiveness** determined the speed at which the actual temperature of the concept (not the control input) could be changed. If a patient’s temperature were to fall quickly, a fast change in the temperature output would be important.
- **Feedback Control** gauged the ease with which the temperature output from the concept could be measured and controlled in order to maintain a set patient temperature.
- **Manufacturing Cost** estimated the price of materials and the construction of the concept. A low cost was preferable, as this would ensure the retail price of the concept would be similar to current market technology.
• Ease of Use gauged the difficulty in using the concept during patient surgery. This criterion included setup of the concept prior to surgery, operation of the concept during surgery, clean up of the concept after surgery, and stowage of the concept.
• Low Risk of Sterile Field Contamination determined the danger the device would pose if inadvertently cut open during surgery.
• Configurability for Access to Surgical Site gauged the number of shapes the concept could assume. Lateral positioning from patient to patient is slightly different each time, as no two bodies are the same. A more versatile concept received a higher score.

All concepts included both a heating and a positioning element. The concepts varied by heating mode, shape and material. The heating modes considered were electrical resistance, infrared, and flowing water (heated in a separate reservoir and passed through plastic tubing). Three concepts used a beanbag, each of which was matched with a different heating mode. The beanbag contained a vacuum port, used to remove the air from the beanbag and make it rigid after a patient was moved into the lateral position. Two concepts used a memory foam base with either electrical resistance or water and electrical resistance heating. As the foam compressed under the weight of a patient, the foam would provide lateral support. A sixth concept used electrical resistance heating with an inflatable component. The concept would wrap around a patient when inflated and become rigid when sealed. A seventh concept contained electrical resistance heating with a mechanical clamping mechanism. The mechanism applied a normal force on the patient’s front and back in order to provide lateral stability. The final concept consisted of two wedges with water heating. The wedges provided lateral stability by being placed on either side of a patient in the lateral position. Figure 1 (appended) shows the results of the first selection matrix evaluating all eight concepts.

The beanbag with electrical resistance heating, memory foam with electrical resistance heating, contoured inflatable with electrical resistance heating, and clamping mechanism received the highest ranking. Concepts with infrared or water heating fell out of considerations as a result of the matrix. The memory foam concept proved difficult to redesign, as its weaknesses (lateral stability, contact area, and cost) could not easily be improved upon. The other concepts were all changed. To add more lateral stability to the contoured inflatable, rigid sides were included. To improve the pressure distribution of the clamping mechanism, a foam surface was added. Finally, foam was also added to the beanbag with electrical resistance heating to potentially improve the pressure distribution and decrease the burn risk. These three redesigned concepts were then carried forward to the concept scoring matrix, along with the original bean-bag-with-electrical-resistance-heating concept. In the concept scoring matrix, the ‘Feedback Control’ and ‘Low Risk of Sterile Field Contamination’ criteria were removed, as they provided no differentiation among the remaining concepts. Using knowledge of heat transfer, fluid dynamics, and solid mechanics as well as general engineering knowledge, a rating was determined for each criterion for all concepts. Figure 2 (appended) presents the concept scoring matrix.

After adjusting the weighting factors in the concept scoring matrix, the weighting factor sensitivity was determined to be negligible: The beanbag with foam and electrical resistance heating received the number one ranking each time, and no other concept came close to its total score in the matrix. The clamping mechanism received the lowest non-reference ranking. An uneven pressure distribution from the clamping force on either side of the patient and a relatively difficult setup relegated this concept to its low ranking. The contoured inflatable device suffered
from a reduced overall lateral stability and maximum patient weight. Also, it was determined that it would be difficult to design the device to both cover a large surface area and be configurable to multiple different patients.

The beanbag with foam and electrical resistance heating was the clear top choice. A sketch of this concept is shown in Figure 3. Adding the foam to the surface of the concept that contacted the patient both decreased the burn risk to the patient and provided a more even pressure distribution for the patient. The lateral stability and maximum patient weight are the same as the reference product (beanbag with Bair Hugger), which works very well for providing lateral support. The reference product only provides heating to the top surface of the patient. The reference product also uses air to transfer heat, which is much less effective than electrical resistance heating. The concept improves upon the reference product considerably. The concept has the ability to heat the patient from the bottom and sides (a much larger surface area) with a better rate of heat transfer while still providing lateral support.

Figure 3: Selected Concept-Beanbag with Foam and Electrical Resistance Heating
<table>
<thead>
<tr>
<th>Selection Criteria</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
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<td>Max Patient Weight to failure</td>
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<td>Low Burn Risk</td>
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<td>-</td>
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<td>Contamination</td>
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<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Configurability for access to Surgical Site</td>
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<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sum +’s</td>
<td>0</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>9</td>
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<td>6</td>
</tr>
<tr>
<td>Sum 0’s</td>
<td>12</td>
<td>8</td>
<td>5</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Sum -’s</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>7</td>
<td>3</td>
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<td>3</td>
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<td>Net Score</td>
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<td>5</td>
<td>-1</td>
<td>0</td>
<td>0</td>
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<td>4</td>
<td>-3</td>
<td>3</td>
</tr>
<tr>
<td>Rankways</td>
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<td>1</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Continue?</td>
<td>Yes</td>
<td>Yes, Revise</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Revise</td>
<td>Revise</td>
<td>No</td>
<td>No</td>
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Figure 1: Concept Selection Matrix
<table>
<thead>
<tr>
<th>Concept</th>
<th>A</th>
<th>B</th>
<th>B+</th>
<th>F+</th>
<th>G+</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Reference) Beanbag with Bair Hugger</td>
<td>Beanbag with Electrical Resistance Heating</td>
<td>Beanbag with Foam and Electrical Resistance Heating</td>
<td>Clamping Mechanism with Foam Surface and Resistance Heating</td>
<td>Contoured Inflatable with Rigid Sides and Electrical Resistance Heating</td>
<td></td>
</tr>
<tr>
<td><strong>Selection Criteria</strong></td>
<td><strong>Weight (%)</strong></td>
<td><strong>Rating</strong></td>
<td><strong>Weighted Score</strong></td>
<td><strong>Rating</strong></td>
<td><strong>Weighted Score</strong></td>
</tr>
<tr>
<td>Max Patient Weight to failure</td>
<td>4</td>
<td>4</td>
<td>0.16</td>
<td>4</td>
<td>0.16</td>
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<tr>
<td>Device lateral stability</td>
<td>4</td>
<td>3</td>
<td>0.12</td>
<td>3</td>
<td>0.12</td>
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<tr>
<td>Safe Pressure Distribution on patient</td>
<td>18</td>
<td>3</td>
<td>0.54</td>
<td>3</td>
<td>0.54</td>
</tr>
<tr>
<td>Low Burn Risk</td>
<td>18</td>
<td>3</td>
<td>0.54</td>
<td>3</td>
<td>0.54</td>
</tr>
<tr>
<td>Heat Transfer Rate</td>
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<td>0.26</td>
<td>5</td>
<td>0.65</td>
</tr>
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<td>2</td>
<td>0.26</td>
<td>5</td>
<td>0.65</td>
</tr>
<tr>
<td>Manufacturing Cost</td>
<td>2</td>
<td>4</td>
<td>0.08</td>
<td>4</td>
<td>0.08</td>
</tr>
<tr>
<td>Ease of Use</td>
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<td>3</td>
<td>0.24</td>
<td>5</td>
<td>0.4</td>
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<tr>
<td>Temperature Responsiveness</td>
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<td>0.4</td>
<td>4</td>
<td>0.4</td>
</tr>
<tr>
<td>Configurability for access to Surgical Site</td>
<td>10</td>
<td>4</td>
<td>0.4</td>
<td>4</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Total Score</strong></td>
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<td>3.94</td>
<td>4.3</td>
<td>3.27</td>
<td>3.74</td>
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<td>2</td>
<td>1</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>Continue?</strong></td>
<td>No</td>
<td>No</td>
<td>Develop</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Figure 2: Concept Scoring Matrix
2.1 Manufacturing Plan

2.1.1 Manufacturing Overview

In manufacturing the device, polystyrene beads are inserted in a pocket in a urethane case to form the beanbag. A valve is installed which will allow the air to be evacuated from the device. A layer of flexible foam is mounted on top of the beanbag, with the electrical resistance heating element on top of that. These layers are sealed inside the urethane case so the device is a single unit. A disposable cover made from a thermoreflective material is manufactured separately.

2.1.2 Part Drawings

Drawings of each part from a CAD model of the design are included in the following pages.
2.1.3 Bill of Materials

Table 2: Bill of Materials

<table>
<thead>
<tr>
<th>Part Name</th>
<th>Quantity</th>
<th>Thickness (mm)</th>
<th>Width (mm)</th>
<th>Length (mm)</th>
<th>Manufacturer</th>
<th>Cost ($/Quantity)</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyurethane</td>
<td>2</td>
<td>14</td>
<td>1008</td>
<td>928</td>
<td>Dongguan Tianyi Film Material Co., Ltd.</td>
<td>1.00</td>
<td>1</td>
</tr>
<tr>
<td>Electric Heater</td>
<td>8</td>
<td>0.2</td>
<td>203.2</td>
<td>457.2</td>
<td>Omega</td>
<td>57.5</td>
<td>2</td>
</tr>
<tr>
<td>Foam Layer</td>
<td>1</td>
<td>15</td>
<td>980</td>
<td>900</td>
<td>Hangzhou Xiaoshan Huafeng Feather &amp; Down Products Co. Ltd</td>
<td>10.56</td>
<td>3</td>
</tr>
<tr>
<td>Polystyrene</td>
<td>2 ft³</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Bluesea Dream LTD</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Vacuum Valve</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Shenzhen Homefun Plastic Co., Ltd.</td>
<td>0.50</td>
<td>5</td>
</tr>
<tr>
<td>Pyrolytic Graphite Sheet</td>
<td>1</td>
<td>0.2</td>
<td>980</td>
<td>900</td>
<td>Panasonic</td>
<td>174</td>
<td>6</td>
</tr>
</tbody>
</table>

Total Cost=$667.06

2.1.4 Manufacturing Procedure

As shown in figure 3, the final concept for the device will consist of a series of different layers, superimposed on top of each other to meet the product design specifications. The final product will be manufactured according to the procedure outlined below:

- Spherical beads used in conventional beanbags are inserted into a urethane case which will be manufactured to the design team’s geometrical specifications. This will form the beanbag layer of the design team’s concept. The casing will be heat sealed on both the shorter edges and one of the longer edges, leaving the 4th edge open for inserting the beads and vacuum pump valve. After the required amount of beads (according to the calculated volume) has been inserted into the casing, a valve is inserted into the casing with one end clearly protruding out of the bag. The valve will allow for a vacuum pump to be connected to the beanbag. A sieve is installed on the end of the valve that will be located within the beanbag in order to prevent the beads from being lodged in the valve. The 4th side of the urethane casing is then heat sealed.

- 15 mm thick Polyurethane foam is then inserted into the casing, resting on top of the beanbag. Subsequently, the flexible resistive heating elements are placed on top of it with the pyrolytic graphite layer on top of that. The electrical power wires of the flexible resistive heating elements run through the foam layer and protrude adjacent to the vacuum valve.

- Once step the preceding step is completed, the main urethane casing is heat sealed. Both the vacuum tube and electrical power wires should be protruding from the body of the device.
3.1 Evaluation Reports

Safe Temperature Distribution Report

Introduction

In order to determine the temperature profile of the heating elements used in the surface of the device an experiment involving an infrared camera was set up. The camera took temperature profile images of a representative 8” by 8” electrical resistance heater under representative, but unloaded, conditions. This was compared to a small 2” by 2” heater of the same type. Hot spots are areas of the heating element that are significantly above the average temperature of the element. Hot spots are important to avoid because it is a critical design requirement that this device be safe to use. Burn risk must be minimized.

Methods

The heater was set up in one of two conditions. Under condition one, each of the heaters was set up like they would be in the device. A layer of foam was placed on the table, followed by the heating element. On top of the heating element was the vinyl surface covering of the device. Condition two involved placing a layer of aluminum foil between the heating element and the vinyl to see how this affects the evenness of the surface temperature. A thermal imaging IR camera was used to take a picture of each heater under conditions 1 and 2 for each voltage setting. The results were images of the temperature profile over a range of settings. The results from each setup were compared for each voltage setting.

Results

The temperature profiles for each case for both the small and large heaters are shown below. The voltage setting shown is 20V. The element that is the most evenly heated is the small element in condition 2, which includes a layer of foil to disperse the heat. The large heater performed worse than the small heaters.

Small heater with foil

Small heater without foil
Discussion

The results show that the smaller heating element has less of a hot spot issue, and adding a heat-dispersing layer between the outer cover and the heating element helps even more. Adding many small heaters to the device instead of one large heater will help reduce hot spots, and by controlling each heater individually, the surface temperature of the device will be effectively controlled. The cost effectiveness of adding many small heating elements must also be examined. Adding more control circuits to the system to control each element also adds cost. A balance between too few and too many heating elements must be struck. Based on the results of this experiment, and a cost analysis of the heating elements it is suggested to use 8 heating elements for the final design. In order to fully test the heating of the device larger heating elements should be acquired and tested using this procedure to get a wider spectrum of data.
Effective Warming Report

Introduction
During surgery, a patient loses heat to the surrounding atmosphere thereby lowering their core body temperature. Thus, it is necessary that a heating device provides enough energy to overcome the amount of heat lost in order to warm and maintain a safe core body temperature. This experiment was performed to test the effectiveness of the heating element by warming a bag of water from ambient temperature to normal body temperature.

Methods
The human body is comprised of 50-70% water, therefore this experiment approximated a patient as a bag of water. The heating apparatus consisted of a layer of polyurethane foam, an electric resistance heating element, and a vinyl cover which simulates the final product design. The electric resistance heating element cannot be seen, but is sandwiched between the foam and vinyl layers (the foam layer contacts the table). The experimental setup is shown in Figure 4.

Using a Type-T thermocouple, the initial temperature of the water was measured. It was then placed on the vinyl layer, which was positioned squarely on top of the heating element. During the heating process, a foam cover was placed on top of the water bag to prevent convective losses. In addition, the bag was agitated periodically to simulate blood flow in the body. After approximately six minutes, the water bag was removed from the heater and the final temperature was measured.

Figure 4: Experimental Setup
In addition, theoretical values were found using the finite element analysis software, ANSYS.

**Results**
To determine the amount of heat that was gained by the water, the heat equation was used as shown in Equation 1.

$$ q = \frac{mc\Delta T}{t} $$

Equation 1

Where $q$ is the energy gained or lost by the water, $m$ is the mass of the water, $C$ is the specific heat of the water, $\Delta T$ is the change in temperature of the water, and $t$ is the time of the overall process.

The net amount of heat transferred into the bag was found. These results are shown in Table 3.

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$m$ (kg)</td>
<td>0.355</td>
</tr>
<tr>
<td>$C$ (J/kg·K)</td>
<td>4181</td>
</tr>
<tr>
<td>$T_i$ (°C)</td>
<td>21.9</td>
</tr>
<tr>
<td>$T_f$ (°C)</td>
<td>31.9</td>
</tr>
<tr>
<td>$t$ (s)</td>
<td>375</td>
</tr>
<tr>
<td>$q$ (W)</td>
<td>39.58</td>
</tr>
</tbody>
</table>

As shown in Table 3, the resulting heat into the water was 39.58 W. This value indicates that a heating element will provide at least 39.58 W into the body.

**Discussion**
The body produces approximately 86 W through metabolism. Using some basic heat transfer equations, the losses due to radiation, convection, and natural convection were found to be approximately 175 W. Note that the assumptions used to find this value are for the most extreme cases, thus this value denotes the maximum possible losses. Therefore, the maximum amount of input heat needed to counteract the heat loss is 89 W.

The amount of heated surface area is important for any heating device that is used on a patient. Obviously the amount of heat provided by the heating element in this experiment is smaller than the requirement. By using a larger heating element, and thus increasing the heated surface area, there would be a larger heat input into the body. With a larger heater and the fact that the actual required input heat would be smaller, it can be concluded that the design team’s device will provide enough heat to warm a patient.
ANSYS Report

Introduction
To determine the ideal temperature distribution of prototype ANSYS was used to model the temperature profiles when in contact with convection and conduction heat sources. The models represented ideal cases when using ANSYS. The free convection used for air, to simulate the operating room environment, is a high end value because it will represent lower operating room temperatures.

Methods
The model used in ANSYS represents the Water Experiment model used in the previous evaluation. This model takes into account all the different material that will be used in the final concept. The model is equivalent to the Water Experiment because the layers that are between the heating element and the water are the same for both the ANSYS and Water Experiment. An assumption was made that the only energy lose to the outside edge of the modal was due to air. The free air convection was calculated using equation 2.

\[ q = h_c A \Delta T \]

Equation 2

q is the heat transfer, A is the heat transfer area of the surface, \( h_c \) is the heat transfer coefficient, and \( \Delta T \) is the temperature difference. The heat transfer was put into ANSYS to demonstrate the heat loss due to air. The heating element is controlled by an expression that sets the amount of energy inputted into the system based on a limiting temperature which was 42 Celsius. 40 watts per volume of the heating element was put into the system, this was determined using equation 3.

\[ P = \frac{V^2}{R} \]

Equation 3

P is the power, V is the voltage, and R is the resistance of the heating element. The first test was conducted with a starting temperature for water of 34 Celsius. The 34 Celsius is picked because this is a very low human body temperature. This analysis is done to show the amount of time required to reach normal body temperature, 37 Celsius. The next test was done to see how what temperature the water will arrive at after 200 seconds. 200 seconds is a limiting factor because ANSYS could not solve for longer time periods. This test was compared to the actual data for water experiment to see the difference between ideal and experimental values.

Results
Figures 5 and 6 show the temperature change between the water and materials for 20 seconds and 200 seconds respectively. Figure 7 shows the temperature change within the water at 200 sec. Figures 5, 6, and 7 have the water temperature at 34 Celsius. Figure 8 shows a graph of the temperature change when the initial temperature was set to 34 Celsius. Three points were measured, the hottest point and the two lowest points of the surface temperature of the water in contact with the heating element. Figure 9 shows the temperature that the water achieves after 200 seconds. The same three points were used for measuring the temperature. Figure 10 shows
the experimental data for 375 obtained from the water experiment. At 375 sec the surface temperature reaches 31.9 Celsius, and at 200 it is at 30 Celsius.

Figure 5: Temperature at 20 sec

Figure 6: Temperature at 200 sec

Figure 7: Temperature of water at 200 sec

Figure 8: Hypothermic Temperature

Figure 8
Discussion
Figures 5, 6 and 7 show that the water is increasing in temperature even with the convection air lose. The temperature distribution of Figure 8 at max time is 35 Celsius at low and 37 Celsius at high. The temperature range is too high between the hot and cold spots that were measure in ANSYS. The variance between the hot and cold need to be lower, this might be accomplished using a higher power input from the power source. The energy lose around the edges of the heating element are going to be greater than the energy lose at eh center of the heating element. Comparing the data from Figures 9 and 10, the ideal is at a lower temperature than the experimental temperature after 200 seconds. The experimental temperature is at 30 Celsius and the hot spot for the ideal is only at 28 Celsius. A few different problems might have caused the
difference between the two experiments. The power used for ANSYS is an ideal model where the experimental data might have been had greater variances of power input over time. The energy lose comes from the convection with air and conduction of the fluid and materials inside the system, the ANSYS model might have had large values for convection and conduction heat loss. The set up for the ANSYS model might not have been created correctly. More analysis and data needs to be done before determining that the ANSYS simulation was faulty.

**Effective Positioning Report**

**Introduction**
A standard surgical beanbag consists of polystyrene beads covered by a thin layer of vinyl or urethane. Adding a layer of memory foam on top of a standard beanbag might affect its overall stability. If adding a layer of foam increases the lateral deflection of a folded beanbag subjected to an external force, the current heating and positioning design will be unusable. To test the lateral stability of the current design relative to a surgical beanbag, a torque versus lateral deflection curve will be created for each. If the deflection of the current design is within 2cm of the deflection of a surgical beanbag subjected to the same loading, the device will be deemed effective at positioning. 2cm was selected as a conservative estimate above which a device would start to become unstable.

**Methods**
The positioning effectiveness test was conducted using a single surgical beanbag and a 2.5cm memory-foam layer. For the test of the surgical beanbag, a person was wrapped in the beanbag in the supine position. Next, air was removed from the beanbag, making it rigid. A rope was then wrapped around side of the beanbag, forming a loop. The rope was placed 152mm above the base of the beanbag. A force transducer was then attached to the rope, and a smart phone was placed on top of the beanbag to measure angular deflection using an application. Figure 11 shows the general test setup, with the force transducer out of the frame on the right side. A tensile force up to 90N was applied to the rope, in 10N increments, and the angular deflection was recorded at each increment.

![Figure 11: Test Setup](image)
The same procedure was repeated with the memory foam layer placed on top of the surgical beanbag. The force transducer measurements were converted to a torque on the beanbag using Eq. 4.

\[ \tau = r \times F \]
Equation 4

\( F \) is the force applied to the beanbag via the rope, measured by the force transducer; \( r \) is the lever arm, the distance from the beanbag base to the point of application of the force at the rope; and \( \tau \) is the torque on the beanbag. The lateral deflection of the beanbag was calculated using Eq. 5.

\[ \delta = y \tan \theta \]
Equation 5

\( \delta \) is the lateral deflection, \( y \) is the height from the base to the top of the beanbag, and \( \theta \) is the displacement angle measured by the smart phone. Using the results from Eqs. 4 and 5, a torque versus displacement plot was produced.

Results
Figure 12 shows the torque vs. deflection curve developed from the force and angular displacement data.

Over the entire torque range of the test, the beanbag with the foam deflected no more than 1.8mm beyond the deflection of the beanbag without the foam. Above 14N, the beanbag with foam actually deflected less than the beanbag without foam. Due to the uncertainty in the torque measurements, it cannot be concluded that one beanbag provides more lateral stability than another.

Discussion
There was no significant difference between the deflection of the beanbag with the foam and without it. Over the entire torque range measured, the foam-beanbag device only deflected an
additional 1.8mm past the deflection of the beanbag without foam. Once uncertainty is factored in, this difference is even more negligible. The only significant uncertainty in the measurement arose from the person applying a load to the side of the beanbag. It proved very difficult to manually apply a discrete load (10N, 20N, etc.) to the beanbag. At each applied force, the force-transducer readout varied ±2N from the discrete load desired. If repeating the test in the future, a mechanical device with a load cell would be constructed to apply the known load. Nonetheless, the measured data showed that there is no significant difference in the lateral deflection between the two devices. As a result, the foam-beanbag device is as effective at positioning as the beanbag without foam.

Ease of Use Report

Introduction

One of the design requirements is that be easy for healthcare professionals to use; hence the concept was designed to be user-friendly and intuitive. However, the measure of the concept’s ease of use is subjective as it varies from person to person and was evaluated qualitatively.

Methods

Using a prototype to demonstrate how the concept would be used as well as explaining its key differences when compared to existing beanbag and heating technologies, the design team asked a small panel of doctors to rate the concept on a scale of 1-5 to obtain feedback on its ease of use relative to the standard practice of using a beanbag in conjunction with a Bair Hugger.

Results

From the surveys, the panel unanimously agreed that the concept was no harder to use when compared to the existing Bair Hugger and surgical beanbag technologies, as no major structural changes were implemented. On a scale of 1-5 (3 being comparable to the standard beanbag and Bair Hugger, 1 being much worse and 5 being much better), the concept averaged a 3.25 in terms of ease of use. This score corresponded to the concept being generally as easy to use as the Bair Hugger and beanbag combination.

Discussion

The results indicate that the concept is as easy to use as the existing Bair Hugger and surgical beanbag technologies with no immediately obvious difficulties observed by the panel of healthcare professionals. The evaluation also provided insight for the design team for possible future work. For example, one of the panel members commented that “it was difficult to displace the Bair Hugger as it is cheap and versatile.” Future work could possibly involve finding cheaper materials to address this issue while still being able to compete with the Bair Hugger and beanbag in terms of warming and positioning capabilities.
### 3.2 Cost Analysis

The total cost of the materials/components necessary to make the design is $667.06 (see the Bill of Materials in section 2.1.3 of this document). In estimating the manufacturing cost an assumption is being made that the fixed cost of purchasing the manufacturing equipment does not contribute significantly to the cost per beanbag due to the fact that a very large number of beanbags could be produced without need to replace the equipment. With labor and maintenance of the machines, the estimated manufacturing cost is $20 per beanbag. The total cost to produce one beanbag according to our design is $687.06 including material and production costs. It should be noted that the heating elements are listed as being purchased at retail price. A contract for a bulk supply of heating elements would likely reduce the cost. In the future it may be wise to consider manufacturing the heating elements as well, instead of purchasing them.

There are approximately 45 million surgeries performed under general anesthesia in the US each year. If 20% of these (9 million surgeries) use a beanbag for positioning, and a beanbag can be used for approximately 1000 procedures before needing to be replaced, 9,000 devices could be sold each year. Furthermore, a disposable component will need to be purchased each time the beanbag is used. It is reasonable for this to be priced similarly to the gown for the Bair Hugger at approximately $50. If used for 9 million surgeries each year this would generate $450 million of revenue.

This device would appeal to hospitals because it saves valuable time of surgical staff. It is not uncommon for up to three people to be needed in the OR just to keep the patient warm. A device that warms the patient with very little effort from surgical staff would reduce or eliminate the need for extra personnel in the operating room which is expensive for the hospital. Additionally, patients are not discharged from the Post-Anesthesia Care Unit (PACU) unless they are at normal body temperature. If the PACU is full, patients cannot be moved there from the operating rooms which in turn cannot be used for another procedure. If patients do not need to be warmed up after surgery the hospital system runs more efficiently, allowing for more procedures to be performed. Every additional procedure performed means thousands of dollars in revenue for the hospital.
3.3 Environmental Impact Statement

As stated in the problem scope, there is an existing need to simultaneously both effectively position and keep a patient warm during surgery. The design team’s concept will greatly improve the patient experience during surgical procedures as it caters to both these needs.

Due to the clean environment required during surgery the concept will be designed with a disposable component that will be used to line the upper surface of the concept as well as wrap around the patient. The disposable component is made out of both high-density-polyethylene (HDPE) and Mylar, a thermally reflective material which functions as a means of passive warming for the patient. After a surgical procedure has been completed, the disposable lining can be discarded easily thus increasing efficiency and improving operating room turnaround times while still maintaining the necessary clean levels. Although this creates a viable business model as the sale of the disposable lining to clients would provide a flow of steady revenue, both HDPE and Mylar are not biodegradable and could potentially pollute the environment. Even though both these materials are recyclable, safety and cleanliness standards required in operating theatres require that all materials which have been contaminated with bodily fluids be labeled as a biohazard and subsequently, sent for incineration.

In terms of the manufacturing process and logistics for transporting the product, there are no outstanding, major environmental concerns involved with the design team’s concept. The final concept (excluding the disposable lining) consists of base materials such as polyurethane foam and surgical grade polyurethane which can be easily recycled at the end of the product’s life.

There are two alternatives considered in order to create a more environmentally friendly design:

1) Replacing the Mylar component with a biodegradable, thermal insulator. There are existing cellulosic based thermal insulators which are biodegradable and can be used to replace the Mylar lining [2]. The HDPE layer can also be substituted with existing biodegradable plastics with similar properties.

2) Completely eliminating the use of Mylar from the design. If (1) is an unviable option, the used of Mylar in the design can be completely eliminated to produce a more environmentally friendly design.

With the proposed alternatives, additional cost and tradeoffs should be taken into account. For alternative (1), although the cellulosic based thermal insulator is biodegradable, it lacks the thermally reflective properties of Mylar. This results in it being slightly less effective at providing passive warming for the patient. Similarly, alternative number (2) which has no Mylar lining at all will result in a greater inability to keep the patient warm. Also, due to the lack of a disposable lining, the design will have to be decontaminated with strong chemical agents in order to refit it for further use in the operating room. However, the design will be no worse than the Bair Hugger (which also has a disposable component) in terms of environmental impact.

It should be noted that with the use of Mylar, the required heat input from the electrical resistance heaters will be significantly less after achieving steady state. This indirectly reduces electrical power consumption and throughout the concept’s life cycle would reduce the environmental impact of the concept.
The design could be improved further in future by designing a biodegradable thermal insulator which is also capable of reflecting heat back to the patient. This would enable the implementation of alternative 1) without having to compromise on patient comfort.

### 3.4 Regulatory and Safety Considerations

There are a few regulations found in 21 Code of Federal Regulations which apply to the device. First, the device must be registered electronically with the FDA on an annual basis. Additionally, the device must be listed with the FDA. This listing must include items like the name of all manufacturers, specification developers, and device distributors. On the device itself, all labels must adhere to FDA labeling requirements. If the device should ever injure someone, a report must be filed with the FDA. [3]

The main safety concern for the device is burning the patient. If the surface temperature of the beanbag exceeds 42°C, there is a burn risk to the patient. This risk is mitigated by incorporating both a fuse and control system. The fuse trips the heater circuit if excessive current is detected. This would shut off all electrical resistance heaters in the device until the system was reset. The control system continually polls all device thermocouples and shuts off any area of the device at or above 42°C. With both the fuse and control system in place, it is very unlikely the device would burn a patient.

A secondary concern is pressure points on the beanbag. Folding a beanbag creates multiple ridges along the beanbag surface which could act as pressure points on a patient. To reduce this risk, a foam layer was added to more evenly distribute pressure from the beanbag to the patient. The foam also protects the resistance heaters from the same ridges. Visual inspection of a folded beanbag with and without the foam confirmed that adding the foam significantly increased the radius of curvature of each ridge. With an increased radius of curvature, pressure is more evenly distributed. Because of this, there is little risk that the beanbag will create pressure points on a patient or damage the heaters.
References

