MRI-Compatible Infant Warmer

BME 200/300: Biomedical Engineering Design
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Abstract

When anesthetized, infants are unable to regulate their own body temperature. Under some circumstances, infants may become hypothermic. Therefore, physicians must use devices during operations to help the infants retain their body temperature; however, most of these devices are not MRI-compatible. Current MRI-compatible infant warmers on the market are extremely expensive, leading to many physicians to use crude and/or insufficient methods to retain an anesthetized infant's body temperature during an MRI scan. Therefore, the "Sleeping Bag" was developed. It was inspired by the swaddling of the baby, as it is made out of a soft, fabric material in which the baby will be wrapped. The inside of the blanket is lined with an insulating fabric, allowing for the retainment of heat and the posterior contains a pocket in which a Cardinal Health Porta-Warming Mattress is placed. A venting system was put in place by installing side zippers that can be adjusted between scans. The results of the various tests done show that the device retained heat for at least a two hour duration. Improvements can still be made to enhance the functionality and the aesthetics of the device.

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I. Introduction

1.1 Motivation

Since the mid-1990's, the number of MRI machines in the U.S. has more than doubled from 12 per million population to 35 per million population in 2013 [1]. With this increase, the U.S. has the highest number of MRI exams performed per 1,000 population per year in comparison with other developed countries [1]. This popularity trend of MRI usage could be attributed to the arising discoveries of the advantages MRI's have over other imaging techniques such as X-rays and CTs. An MRI is particularly advantageous for revealing abnormalities in soft tissues, the brain and heart, as well as for early diagnosis of diseases by detecting any molecular changes in the patient [2]. Lastly, and most importantly, MRIs do not expose patients to ionizing radiation [2]. Thus, this makes MRI's particularly attractive for infants who are more susceptible to the harmful side effects.

To optimize the quality of the images of the MRI scan, infants have to be anesthetized to ensure they remain still. However, a major concern that arises for infants is their inability to regulate their own body temperature while anesthetized. This possible drop in body temperature is extremely dangerous, for infants risk the chance of becoming hypothermic [3]. In fact, up to 20% of patients experience unintended perioperative hypothermia when under anesthesia and not treated nor warmed appropriately [4]. In the past year Dr. Popic, a pediatric anesthesiologist in Madison, WI, has had two cases in which MRI scans had to be stopped in order to warm infants with low body temperatures. Stopping the MRI scans elongates the total procedure time, keeping the baby under anesthetics for longer and increasing the chance of developing hypothermia.

1.2 Current Methods

Currently at the American Family Children's Hospital, Dr. Popic is using two devices in attempt to warm up the anesthetized infants - the Cardinal Health Porta-Warming Mattress and a medium sized plastic bag. The Cardinal Health Porta-Warming Mattress (Figure 1) is a disposable pad that lays under the infant and heats up in a similar fashion as hand warmers. When the pad is removed from its plastic wrap and folded, pockets filled with a gel like viscosity are broken and begin to heat up rapidly. The mattress requires no electricity or wires and contains only warming chemicals which are certified food grade and nontoxic to the infant [5]. The plastic bag used is simply a medium sized garbage bag. The infant is put inside the bag, tied shut, and necessary holes for medical tubing are made in the bag. Advantages to this methodology is that it requires minimal equipment and is very cheap. However, these methods alone do not keep the baby warm enough and do not maintain appropriate heating for the maximum two-hour scan time.

Figure 1: Image depiction of the Cardinal Health Porta-Warming Mattress [5]

A current device on the market is the Bair Hugger (Figures 2 and 3) which primarily uses an forced air heat source to warm an inflatable blanket that wraps underneath and on the sides of the infant. This device would work to warm infants; however, the Bair Hugger heating unit is not MRI-compatible [3]. Additionally, the Sree Medical Neonatal MRI Transport Incubator is an attractive device for

physicians to warm infants during an MRI; however, one unit costs over $500K [6]. Thus, many physicians, including Dr. Popic, shy away from devices as expensive as this.

Medical devices that are designed for warming infants follow the standard titled: *Sec 880.5130 Infant Radiant Warmer, Sec. 880. 5400 Neonatal Incubator, Sec. 880.5410 Neonatal Transport Incubator, Sec. 880. 5560 Temperature Regulated Water Mattress* [7]. They are all from the same Title and Volume (Title 21, Volume 8) within the Code of Federal Regulations. The design is an infant warming device, falling under this category; therefore, it should meet these standards. The FDA database describes an infant incubator to be a box-like structure in which the infant may be kept in a controlled environment that can have an AC powered heat source with a fan to circulate the warm air [8]. Additionally, an infant radiant warmer may contain an infrared heating device above the infant with the addition of a temperature monitoring sensor, a heat output control mechanism, and an alarm system. The device may be constructed on the patient's bed or placed above the bed [9]. A device similar to the Cardinal Health Porta-Warming Mattress, a Temperature Regulated Water Mattress, contains a mattress filled with water that may be warmed or cooled by an electrical component to heat and circulate the water [10]. Other infant warmers fall under a Class II medical device. Before reaching the market, Class II devices must satisfy the FDA's regulatory requirements (special controls). These requirements include performance standards, post-market surveillance, patient registries, special labeling requirements, premarket data requirements, and guidelines [11].

Figure 2: Image depiction of the current Bair Hugger Device in use on a patient [12]

Figure 3: Image depiction of the current Bair Hugger Heating Unit [13]

1.3 Problem Statement

While anesthetized, infants are unable to regulate their body temperature. This creates a demand for a device to ensure they stay warm while in an MRI scan. If a child gets too cold, the scan needs to be stopped in order to warm them back up. This device will increase efficiency of scans by eliminating the need to stop scans. Currently, there is no infant warmer on the market that is both cost effective and MRI-compatible; thus, Dr. Popic must rely on cruder and cheaper methods to warm an infant. However, the Cardinal Health Porta-Warming Mattress and the plastic bag are unable to achieve high enough

temperatures to heat the infant for the maximum scan time of two hours and are not attractive to parent or patient due to its rudimentary methodology. While there are multiple devices on the market, they are extremely expensive. The device needs to be MRI-compatible and able to maintain an infant's body temperature for up to two hours, all while being under a budget of $500.00.

II. Background

2.1 Relevant Physiology and Biology

The device must be designed to suit an infant. By definition, an "infant" is a human being under one year of age [14]. Infants, in particular, tend to lose heat while anesthetized primarily due to vasodilation caused by the anesthesia induction. Under normal conditions, heat is centrally concentrated in the core region of the body around the head and truncal areas, while the body's periphery remains about 2.0˚C - 4.0˚C cooler [3]. However, when anesthetized, vasodilation combined with a lowered cold threshold in the hypothalamus allows warmer blood from the body's core to flow freely and mix with the blood from the cooler periphery, thus lowering the core body temperature (see Figure 4) [3][15]. In addition, the dry anesthesia gases and small weight-to-surface-area ratio contribute to this temperature decrease as well. In some instances where this loss of thermoregulation is left unattended, infants can become hypothermic. Hypothermia is defined as when an infant's temperature drops below 36.0°C. This drop in temperature causes the heart rate to slow, and even stop if left untreated for too long [16].

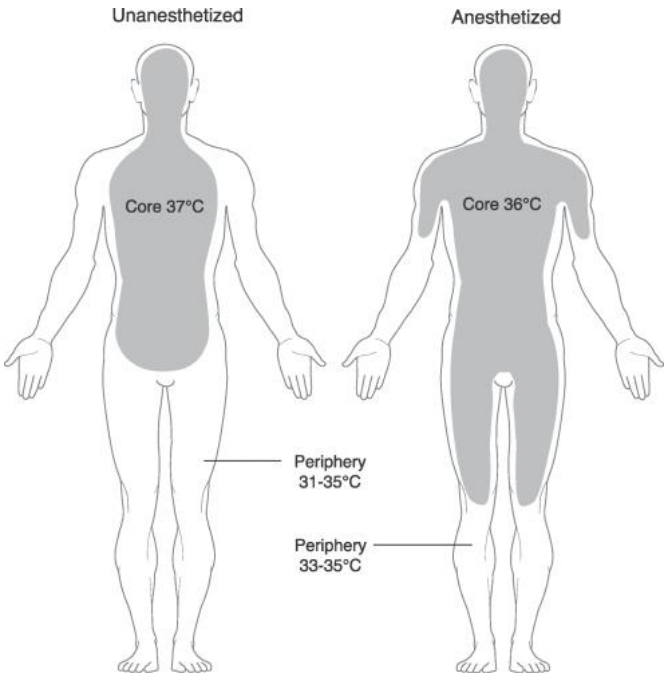


Figure 4: Visual representation of the side effects anesthesia induction has on the body's ability to maintain adequate core body temperature. This diagram displays the effects on an adult human; however, this phenomenon occurs in infants as well, and even more severely [4]

Conversely, if the body temperature increases too much, the infant may undergo hyperthermia. Hyperthermia is defined as a body temperature above 38.0°C [16]. Since the central nervous system controls the body's reaction to temperature, it is especially vulnerable to overheating [17]. Due to this high vulnerability, hyperthermia of infants can lead to lasting neurological damage. A few examples of neurological damage include adverse effects to attention, memory, acute information processing, and a development of neuroleptic malignant syndrome. [18]. One study of induced hyperthermia showed that memory was impaired at a core temperature of 38.8°C. The study also showed that artificially induced hyperthermia may induce cognitive impairment after only one to two hours of temperature elevation [18].

2.2 Research for Building Designs

Due to the magnetic field generated by the MRI machine (Figure 5), the MRI room has many material restrictions on what can be present in the room during a scan. Ferromagnetic materials cannot be used inside the MRI room, eliminating the option of certain metals such as iron, nickel, and cobalt [7]. The ferromagnetic materials are attracted to the magnetic field of the MRI machine, causing the object in which they are contained to disintegrate as the ferromagnetic materials accelerate to the bore of the MRI scanner and align themselves with the magnetic field [19]. Additionally, the magnetic field also prevents the use of a forced-air warming device, due to skewing of image quality [20]. This limitation must be taken into consideration while designing the device.

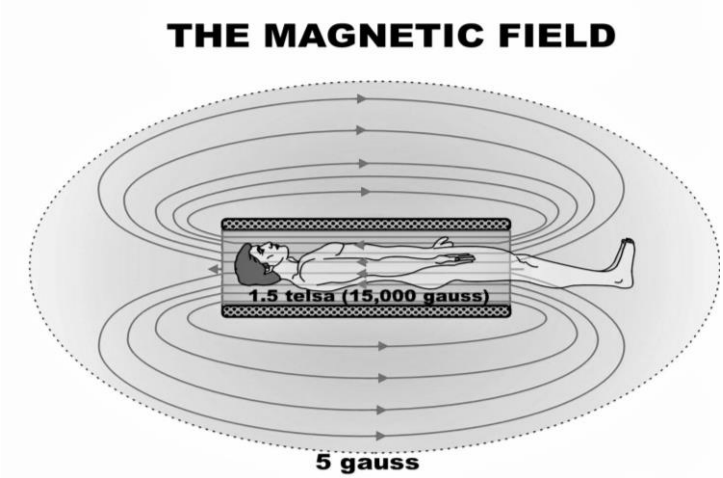


Figure 5: Visual representation of how the magnetic field forms within the MRI [21]

The size of the design must fit the MRI patient table which has a maximum width of 70.0 cm [22]. It also must fit inside of the additional head shield (Figure 6) that can be used during scans. This head coil is a half oval shape that is 20.0 x 20.0 cm. The coil is necessary to develop a high-quality scan [23].

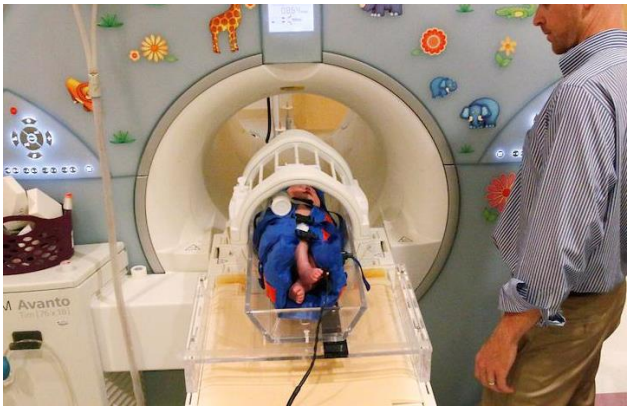


Figure 6: Visual depiction of the bore of an MRI scanner, as well as the head shield the infant warmer must accommodate [24]

This device must also be simple to assemble in order to decrease the amount of time the infant has to remain anesthetized. The device should be easy for the MRI staff to install as well as be able to heat up to its optimal temperature quickly. Currently this process takes five minutes, so the device's installment should fit in this time restraint.

The MRI room environment must be below 22.0°C. If the temperature exceeds 22.0°C, the quality of the images produced from the MRI scan lessens significantly due to loss of signal [20]. Thus, the design must be operative and effective at this temperature.

2.3 Client Information

The client for this project, Dr. Peter M Popic, is a pediatric anesthesiologist who works at American Family Children's Hospital in Madison, Wisconsin.

2.4 Product Design Specifications

Most importantly, the design must be MRI-compatible and cost effective. Currently, an affordable MRI-compatible infant warming device does not exist, and the client requested the team uses $500 or less to fabricate such a device. When considering MRI-compatibility, only specific materials can be used in the MRI. Metals such as copper and titanium can be used in the MRI environment while ferromagnetic metals such as iron and steel cannot [7].

The baby must be kept at a temperature of 36.5 ± 0.5°C to keep them from entering either hypo- or hyperthermia. This specific temperature range needs to be maintained for two hours. To avoid overheating, the design needs to have a method of ventilation or cooling as well. While the device must provide heat to the baby, the device cannot increase the temperature of the MRI room over 22.0°C, or it could risk having distorted images.

The design must accommodate for additional medical devices used during the procedure, such as head coils and breathing tubes. The design must be able to fit underneath or above a 20.0 cm head coil. Additionally, there must be holes in the device towards the posterior of the infant to allow for insertion of accessory tubing i.e. breathing tubes, blood pressure tubes.

Sterility is crucial with infant-related devices since infants have a weakened immune system. For this reason, all current warming devices used are disposable. To ensure sterility and maintain ease of use,

the new design must also be disposable or easily sterilized. See the complete design specifications in Appendix 11.1.

III. Preliminary Designs

3.1 "The Tent"

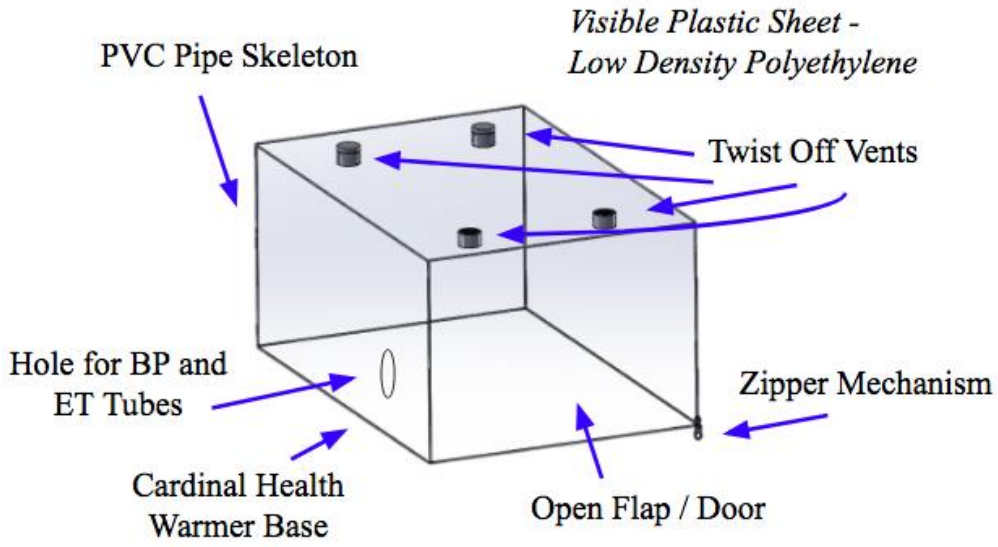


Figure 7: "The Tent" Design; isometric view.

"The Tent" (Figure 7) was inspired by the cruder methods the client currently uses to regulate an infant's temperature: The Cardinal Health Porta-Warming Mattress, the plastic bag, and body heat. "The Tent" consists of a few main components, the first being the skeleton. The skeleton would ideally be made from polyvinyl chloride (PVC) pipes, as the material is sturdy enough to support any additional weight, as well as being easy to fabricate into the desired shape of a hollow box. The second material would be a transparent vinyl sheet which would function as insulation. The vinyl would need to be non-toxic when used in warmer temperatures, and a low-density polyethylene plastic would satisfy both these criteria. Attached to the plastic sheet would be four threaded, circular openings to serve as vents, which can be closed or opened in case the infant gets too warm during an MRI scan. Furthermore, "The Tent" has a large flap which would be used as a functional door so the user can safely place the infant inside the warming system with ease, ideally in a feet first position. Since "The Tent" was inspired by current methods for thermoregulation, this design also requires the use of the Cardinal Health Porta-Warming Mattress as the base for this design. This would function as an additional heat source to the system.

3.2 “The Glamper”

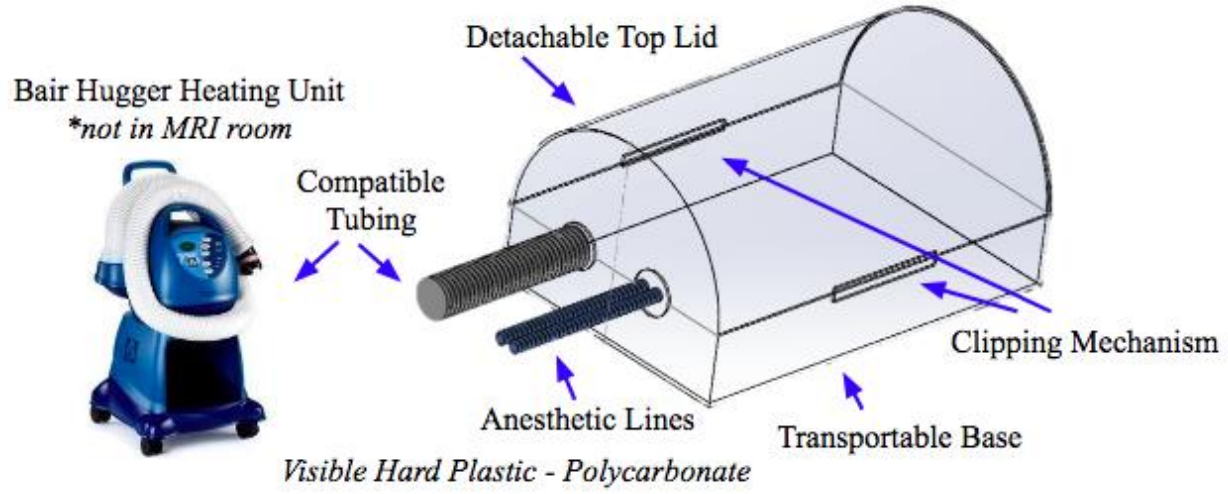


Figure 8: “The Glamper”; isometric view (right) alongside the Bair Hugger Heating Unit (left) [13]

“The Glamper” was inspired by an infant incubator for premature babies. Rather than rely on body heat and heating pads, this system uses warmed forced air to thermoregulate the patient’s temperature. In order to prevent any additional and unnecessary costs to the client, “The Glamper” reuses the heating unit from The Bair Hugger as its primary heat source. Extended tubing would connect the heating unit, which would be placed in the control room, to the “The Glamper” through an existing hole in the wall. This hole allows wires and tubes to travel from the control room to the MRI room. Therefore, “The Glamper” would take advantage of an already existing adaption to the room. The two main components of this design consist of a detachable top lid and a transportable base, ideally fabricated from a non-toxic plastic such as polycarbonate. These two components would be connected with a clipping mechanism on both left and right side in order to prevent any leakage from the system. Lastly, a unique element to both components is a compatible divit that fits both anesthetic lines connected to the patient, as well as the heated air tubing.

3.3 The “Sleeping Bag”

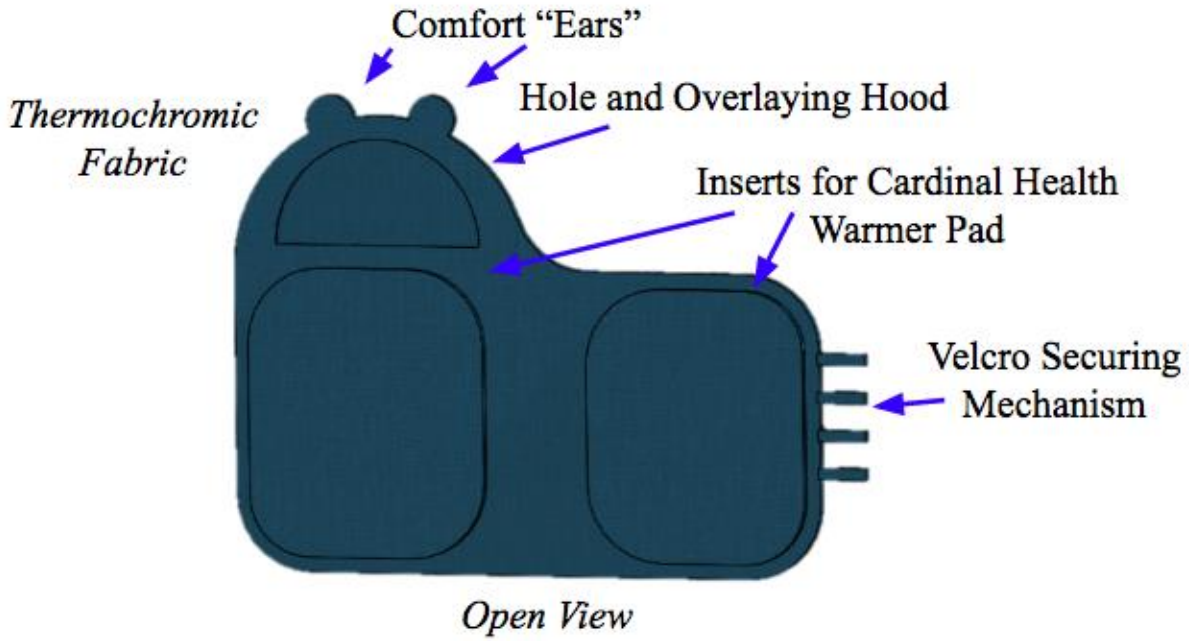


Figure 9: The “Sleeping Bag”; front view

The “Sleeping Bag” was inspired by the comforting feeling swaddling engenders in infants. Swaddling helps to recreate the feeling of security that a baby had in its mother’s womb [25]. Therefore, the “Sleeping Bag” highlights the importance of parent comfort when a child goes through an MRI scan. The “Sleeping Bag” design consists of two inserts for the Cardinal Health Warmer Mattress, which can be removed and replaced as needed. The mattresses function as heat sources for the infant during the scan. To ensure the mattresses are at adequate temperatures, the design would be made from thermochromic fabric, which visually shows the temperature environment through changing colors. In addition, a hood is included in order to prevent heat loss from the infant’s head. Comfort ears are also added to the hood for an aesthetically pleasing appearance. Lastly, velcro straps secure the baby within the swaddle to further enhance the systemic warming.

IV. Preliminary Design Evaluation

4.1 Design Matrices

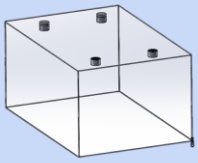
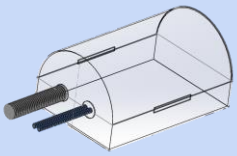
	The Tent		The Glamper		The Sleeping Bag	
						
Safety (20)	**3/5**	**12**	**5/5**	**20**	**4/5**	**16**
Effectiveness (20)	**2/5**	**8**	**5/5**	**20**	**4/5**	**16**
Precision (15)	**1/5**	**3**	**5/5**	**15**	**4/5**	**12**
Sterility (15)	**4/5**	**12**	**3/5**	**9**	**5/5**	**15**
Assembly Time (10)	**2/5**	**4**	**2/5**	**4**	**3/5**	**6**
Aesthetics (10)	**3/5**	**6**	**3/5**	**6**	**5/5**	**10**
Ease of Manufacturing (5)	**5/5**	**5**	**1/5**	**1**	**3/5**	**3**
Cost (5)	**5/5**	**5**	**2/5**	**2**	**3/5**	**3**
Total (100)	**55**		**77**		**81**	

Figure 10: Design matrix including criteria for the device and scores of the three preliminary designs

Figure 10 consists of eight categories that are all weighted according to importance when considering the final design. The top two categories, weighted at 20 points each, are safety and effectiveness. Safety refers to the well-being of both the patient and the user. Some considerations that were accounted for when evaluating this category include burns from direct heat, hypothermia, and inaccessibility. The effectiveness category evaluates how well the device maintains heat, methods of cooling if the baby gets too warm, and techniques of rapidly heating to avoid hypothermic situations. The following two categories are precision and sterility, each worth 15 points. Precision represents how well the device is able to maintain the temperature of the baby at 36.5 ± 0.5°C, as well as methods of determining the temperature while an MRI scan is underway. When considering sterility, it is important that the device is either a one-time-use or can be sterilized with standard decontamination equipment

found in hospitals, as sterility is crucial when working with young babies. Weighted next are assembly time and aesthetics at 10 points each. A short assembly time is desired with this device; the shorter the assembly time, the shorter the infant is under anesthesia, which ultimately decreases the risk of the baby undergoing hypothermia. Aesthetics refers to how appealing the device is visually. Since this device is used on infants, it is important to consider the concerns of the parents. By designing a device that is physically appealing and safe for their child, parents will feel more comfortable and less intimidated by the strict and cold MRI environment. The last two categories on the design matrix are ease of manufacturing and cost. They simply refer to how easy the device is to manufacture and how much it would cost to manufacture, respectively.

4.2 Material Matrices

4.2.1 Inner Layer Matrix

	Insul-Bright		Wool		Clear Vinyl		Quilted Cover Fabric (Cotton)	
MRI-Compatibility (30)	0/5	0	5/5	30	5/5	30	5/5	30
Heat Retention (25)	5/5	25	5/5	25	4/5	20	5/5	25
Durability (20)	2/5	8	5/5	20	2/5	8	4/5	16
Softness (15)	3/5	9	1/5	3	0/5	0	5/5	15
Cost (10)	3/5	6	1/5	2	3/5	6	4/5	8
Total (100)	48		80		64		94	

Figure 11: Inner layer material matrix including criteria for the materials and scores of the four possible fabric choices

4.2.2 Outer Layer Matrix

	Fleece (Polyester)		Cotton		Nylon		Wool	
MRI-Compatibility (30)	5/5	30	5/5	30	5/5	30	5/5	30
Durability (25)	5/5	25	3/5	15	1/5	5	4/5	20
Heat Retention (20)	5/5	20	4/5	16	1/5	4	5/5	20
Softness (15)	5/5	15	5/5	15	4/5	12	1/5	3
Cost (10)	4/5	8	5/5	10	2/5	4	1/5	2
Total (100)	98		86		55		75	

Figure 12: Outer layer material matrix including criteria for the materials and scores of the four possible fabric choices

Once the final design was decided, the material that would be used for the final product needed to be considered. Both an outer and inner layer fabric was determined with design matrices (Figure 9 and Figure 10) using the same criteria, but with different weightings. The most important category, MRI-compatibility, is weighed at 30 points for both inner and outer. Materials that are compatible received a score of 5/5, while materials that are not compatible earned no points. Heat retention ranked second for the inner layer, at 25 points, while it ranked third for the outer layer, at 20 points. This difference is because the inner layer rests closer to the infant, and is necessary to retain the heat of the infant and the Cardinal Health Porta-Warming Mattress. While it is also important for the outer layer to not let heat escape, it is not as crucial as the inner component. Durability, weighted at 20 for the inner layer and 25 for the outer, pertains to the ability to withstand wear and multiple machine washes. Softness, weighed at 15, ranked fourth for both layers. Materials should be soft and not itchy for the comfort of the infant. Lastly, cost weighted both at 10 points, simply refers to how much the material costs.

4.3 Design Evaluations

The winning score in the safety category was “The Glamper”. This design was rated high in safety due to the Bair Hugger Heating Unit controlling the heat, which prevents burning and hypothermia of the patient. “The Glamper” is also safe for the user. It does not become too hot to touch and is easily controlled. “The Glamper” also received the highest marks in effectiveness and precision. Since the Bair Hugger Heating Unit is controlling the heat, it can be said with confidence, that it will maintain heat for at

least two hours. Since the anesthesiologists control the unit, a precise temperature of 36.5 ± 0.5°C will be maintained with the help of the display on the heating unit. Although “The Glamper” received the highest marks in these three categories, the “Sleeping Bag” had similar scores. In the sterility category, the “Sleeping Bag” received the highest score. This is due to the material of the device being machine-washable and the disposable Cardinal Health Porta-Warming Mattress. If machine-washed, it is less likely that there were any shortcuts taken when sterilizing the device. In regards to assembly time, each device scored roughly average. The assembly times of each of the devices would be comparable to the assembly time of the plastic bag, making the operation no more or less efficient. When it comes to aesthetics, The “Sleeping Bag” received the highest score. The score reflects the approachability of the material, visibility of the face, and the fun aspect of the “comfort ears”. “The Tent” won the final two categories of ease of manufacturing and cost. Since the materials are cheap and easy to modify in the shop, this design would be ideal for both manufacturing and cost standpoints.

4.4 Material Evaluations

For the inner layer, all the materials earned a perfect score for MRI-compatibility except the Insul-Bright material, which contains bits of metal. This category, alone, eliminates the possibility of the Insul-Bright being the chosen material. The heat retention of the remaining three fabrics are very comparable. While wool is a more insulated material, the quilted cover fabric is a very thick cotton, making it an extremely good insulator. The wool earned the best scores for durability as its ability to bend without breaking supersedes the competing materials greatly [26]. Cotton is also relatively durable, and especially so with this fabric being very thick. The clear vinyl has a more rigid shape and could easily be damaged. The quilted cover fabric is the only material earning an impressive score for softness and the fact that hospital linens and gowns are made of a cotton-polyester mix ensures the material’s performance [27]. Vinyl is not a wearable material by humans, and while wool is a wearable material, it is itchy. The least expensive option is the quilted cover fabric listed at $6.50/yd at JOANN Fabrics [28] and second is the clear vinyl at $8.99/yd [29].

All of the outer materials are MRI-compatible as they contain no ferromagnetic metal remnants. Fleece, which is composed of polyester, is the most durable material and outperforms wool in this category [30]. The standard cotton material considered for the outer layer is not as durable as the cover fabric, for it is much thinner. As for insulators, wool and fleece earn the highest ratings, but fleece provides a more lightweight option. Again, this thinner cotton does not perform as well in heat retainment as the thick cover fabric. Fleece and cotton are most comfortable materials, earning 15/15. While the outer layer may not be directly touching the infant's skin, it may come in contact with the infant, so the itchy wool material is not ideal. The cheapest option is cotton at $2.99/yd [31], with fleece being the second listed at $5.99/yd at JOANN Fabrics [32].

4.4.1 Material Sterilization

The chosen materials of polyester (fleece) and cotton are found in common hospital linens such as scrubs, gowns, and drapes [33]. Therefore, it was expected that the “Sleeping Bag” would withstand common hospital sterilization practices for linens such as those. One common practice used widely among hospitals consist of a pre-wash, main wash, and rinse [33]. The pre-wash removes larger particles of soiling matter with common detergent at a temperature below 38˚C and at a low alkalinity. The main wash removes the remaining adherent soils and stains by holding the water temperature at the minimum

disinfection temperature time combinations (71˚C for 3 minutes or at 65˚C for 10 minutes) [33]. Lastly, the linens will endure a rinse which removes alkali, detergent and other additives. Following a rinse, heat, and pressure are applied via heated rollers rotating in a bed and then sent off to be re-used throughout the hospital. Another test of durability for the chosen materials is seen in Figure 13, which displays properties of both cotton and polyester (laminated), and their response to a hospital sterilization [33].

	Cotton	Barrier type fabrics	Laminated polyester
Withstands laundering at 73°C	Yes	Yes	Yes
Withstands autoclaving	Yes	Yes	Yes
Permeability to bacteria	High	Moderate/low	Very low
Permeability to fluids	High	Moderate/low	Very low
Linting	High/ moderate	Low	Low
Cost	Low	Moderate/high*	High*
Comfort	High	High	Low†
Draping quality	Good	Good	Moderate

*Barrier fabrics are more expensive than cotton or cotton/polyester mixtures. Surgeons' gowns, for instance, are between two and almost five times dearer than cotton. Laminated gowns are approximately five times the cost of cotton.
†As laminated fabric does not 'breathe' it is used for the front and sleeves of gowns and polyester/cotton or barrier material used for the rest of the garment.

Figure 13: Table displaying fabric response to a common hospital sterilization practice, as well as cost, comfort and draping quality; both cotton and polyester and materials were chosen to be used in the design [33]

4.5 Final Design

Based on the outcome of the design matrix, it was decided that the "Sleeping Bag" will be the design to pursue. The "Sleeping Bag" effectively provides heat to the patient while the anesthesiologist can monitor the temperature via the thermochromic fabric paint surrounding the face. The design is safe for both the patient and user, as the Cardinal Health Porta-Warming Mattress are inserted in pockets, ultimately avoiding direct skin contact to the heat source. The "Sleeping Bag" is also the most sterile of the designs as well as the most aesthetically-appealing. Since the device is machine-washable, it can be ensured that it is clean for the next patient to use. With the cute "comfort ears" and blanket-like design, parents of the patient will feel more at ease while their child is undergoing an MRI scan. Although the design may be more challenging to fabricate and more expensive to produce, the benefits of the functionality, aesthetics, and sterility of the device outweigh the negatives.

4.6 Final Material

The winning materials of the two material matrices were the quilted cover fabric for the inner layer and fleece for the outer layer. The quilted cover fabric most importantly retains heat very well and is MRI-compatible. In addition, the fabric should be able to withstand wear and multiple washes. The quilted cover fabric surpasses the competing materials in softness and cost. Cotton, which the quilted cover fabric is made of, is a comfortable, wearable material, unlike the other materials. The quilted cover fabric is also the least expensive of the options, adding another favorable component.

For the outer layer design matrix, fleece was the decided material. Fleece excels in all of the material criteria. It is MRI-compatible and also has great heat retention. Also, it is primarily composed of

polyester which can withstand standard hospital sterilization techniques (see Figure 13), and while typically wool is more breathable than polyester, polyester fleece is the exception [21]. Furthermore, fleece is a very soft material, inexpensive, and comes in a multitude of colors and patterns, making it very aesthetically pleasing. The aesthetics of this device are important to ensure the well-being of the infants.

V. Fabrication and Development Process

5.1 Methods

The main fabrication method for this project was standard sewing. A sewing machine, needles, and thread were used via the UW Makerspace. The UW Makerspace was chosen because they offered all equipment needed to successfully fabricate a prototype at little cost. It was also in a desirable location, on campus and open for engineering students to use. For the final prototype, dimensions were mapped on the whiteboard and then drawn out with a graphite pencil on the fabric before any cuts were made.

To begin, the body of the "Sleeping Bag" was fabricated (see fabrication protocol in Appendix 11.2). The main materials, which consisted of yellow fleece fabric and quilted cover fabric, were folded, cut with a fabric shears from the UW Makerspace, and sewn into the dimensions described in Appendix 11.2. Plastic zippers of lengths 46.0 cm and 23.0 cm were also sewn in for ease of use and ventilation (Figure 14 and 15). The sewing machine was incorporated in order to complete the stitching and attachment. A forward backward stitching method was used while prototyping. This method involves reversing the stitch at the end of a length of fabric and backstitching to finish off a stitch. This locks the end of the stitch into place and prevents fraying. On the sewing machine, the lockstitch method was used because of its increased durability and cost effectiveness (Figure 16) [34].

Following this fabrication, the hood of the "Sleeping Bag" was created using much of the same techniques as the body. The hood consisted only of the the yellow fleece fabric and thread provided by the UW Makerspace. Two pieces of fleece were cut and placed on top of eachother; dimensions from Appendix 11.2 were once again used when cutting and sewing. Finally, the back flap of the hood was sewn onto the back side of the body creating the final product.

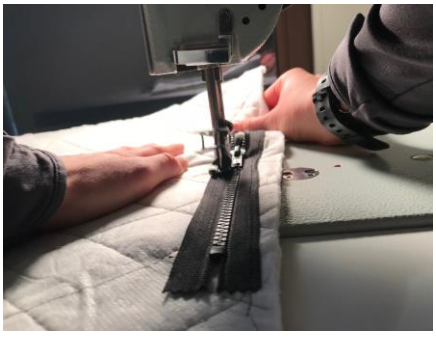


Figure 14: Team members sewing zippers to insulating fabric during fabrication

Figure 15: Photo of zippers sewn onto insulating layer showing progress during fabrication

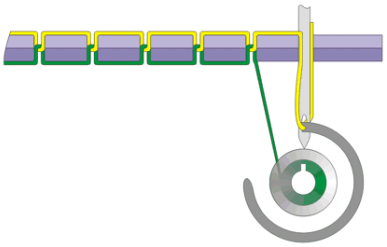


Figure 16: A Representation of the Mechanism of the Forward Backward Stitch Used in Sewing Machines [35]

5.2 Materials

All material used was purchased at a local craft store JOANN Fabrics, and each given name correlates to those in JOANN's inventory. In order to produce one prototype, two yards of fleece was used. The purchased fleece was the "Skyr Pale Banana Anti Pill" fleece. This specific fabric could easily be replaced with any other anti-pill fleece. Also, two yards of the quilted cover fabric or "Quilted Ironing Board Cover Fabric" were needed. For the three zippers on the sleeping bag, "Coat & Clark All Purpose Zippers" were used: the 23 cm version for the two side zippers and a 46 cm zipper for the middle. These zippers are composed of 100% polyester [36], ensuring the ability to perform within the MRI. Simple thread was used in accompaniment with the sewing machine. The overall cost of the prototype was $42.65 including taxes.

5.3 Final Prototype

The final prototype was an iteration of, rather than identical to, the final design first proposed. Instead of including two Porta-Warming Mattress inserts, the team chose to design only one insert behind the infant. If an additional Porta-Warming Mattress was included in front, concern for patient safety arose as the potential for thermal burns and extra weight on the infant's chest increased. Additionally, the final design utilizes zippers instead of Velcro for a closing mechanism. This was an implemented change due to its ease and effectiveness to release heat. Lastly, the use of thermochromic paint was a redundant mechanism to monitor the patient's temperature since a fiber optic temperature probe is regularly used instead to accomplish the same task. Thus, thermochromic paint was not added to the device.

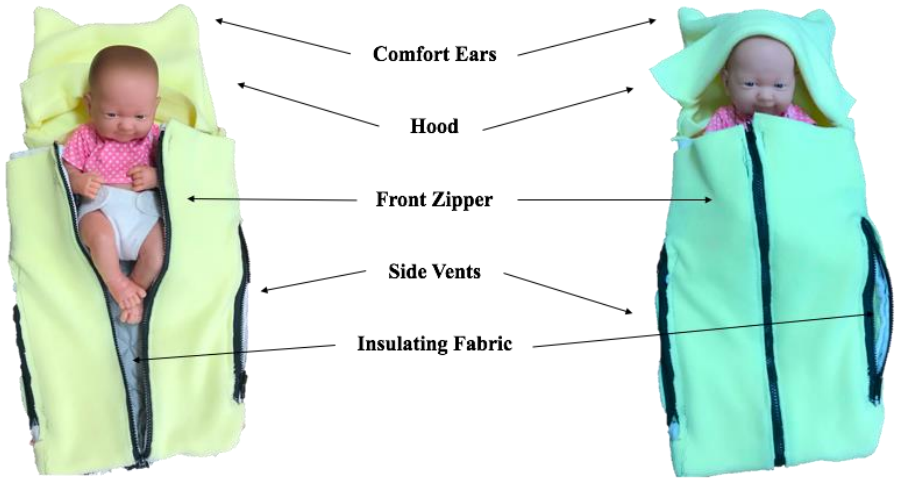


Figure 17: Front View of the "Sleeping Bag" with front zipper and side vents open (left) and front zipper closed and side vents open (right) with significant features of aesthetically pleasing comfort ears, hood, plastic front zipper, plastic side vents, and the insulating fabric identified

Figure 18: Visual representation of the "Sleeping Bag" with top-front view (left) displaying the pocket for the Cardinal Health Porta-Warming Mattress. The pocket is located between the fleece and insulating layers to hold a single Cardinal Health Porta-Warming Mattress which allows for active heat application to the baby without direct contact to the baby's skin. The side-front view (right) displays the side vents for the removal of heat in case the infant becomes to warm. The vents can easily be activated in between scans and the zippers can be put at any desired position.

5.4 Testing

5.4.1 Analysis of Heat Distribution of the Cardinal Health Porta-Warming Mattress

The first test was conducted on the Cardinal Health Porta-Warming Mattress alone. This test was conducted to have baseline data on the temperature that the Cardinal Health Porta-Warming Mattress reached and retained throughout a two-hour period (full testing protocol can be found in Appendix 11.3). Photos were taken (Figure 22) 0.6 m away from the mattress by the FLIR Thermal Camera every 5 minutes following mattress activation to ensure enough data was gathered for appropriate assumptions to be made. The FLIR camera was held in place by a ring stand and was not moved throughout the duration of testing (Figure 19). The test was conducted in a temperature regulated office in the Biomedical Engineering Department of UW Madison. The temperature of the office was set to 20.0°C. This allowed for +/- 2.0°C within the regulated temperature of an AFCH MRI room (kept between 18.0°C and 22.0°C).

Figure 19: Testing set up with FLIR Thermal Camera fixed by a ring stand and heating pad below.

5.4.2 Analysis of Heat Retainment within the "Sleeping Bag"

The second test was conducted on the "Sleeping Bag" with the Cardinal Health Porta-Warming Mattress placed inside of its appropriate pocket between the outside fleece and the cotton inner fabric. The purpose of this test was to determine if the temperature and amount of the heat delivered to the infant was greater inside the "Sleeping Bag" compared to the Cardinal Health Porta-Warming Mattress alone. The environment that the test was conducted in was nearly identical to the first test. The same office in the Biomedical Engineering Department of UW Madison was set to 20.0°C, once again allowing for +/- 2.0°C within the regulated temperature of an AFCH MRI room. The "Sleeping Bag" was placed on a surface that simulated a patient table, and a textbook of mass 1.7 kg was used as a source of pressure to account for any potential increase in heat transfer due to the pressure of the infant's weight. This textbook was chosen because its weight was around the same of a premature infant. Premature infants range from 1.5 kg (very low birth weight) and 2.5 kg (low birth weight), so the textbook was an appropriate simulator [37]. The RTech IR Thermometer was used to detect the temperature inside the "Sleeping Bag" at a centrally marked point every five minutes over a two hour period, which is the length of the longest scan time.

5.4.3 Analysis of Performance of the "Sleeping Bag" Under Various Circumstances

In order to increase the accuracy of the temperature values during the testing of the "Sleeping Bag", a more infant-like object was desired to be placed inside of the prototype for testing. It was also ideal for the testing to occur in a hospital setting, so the final test conducted was located at AFCH in an MRI waiting room. This room was used due to the large amount of traffic in the MRI rooms on the night that the testing occurred. A fiber optic temperature probe was connected to a Philips Expression MR400 (Figure 21) and placed inside the "Sleeping Bag". The Philips Expression MR400 is the temperature monitoring system used in actual MRIs. The temperature was recorded every 5 minutes throughout this testing. The Cardinal Health Porta-Warming Mattress was placed inside the "Sleeping Bag" and activated, and temperature was first taken with just this setup. Then, a room temperature saline bag was placed inside of the "Sleeping Bag" with the fiber optic sensor underneath; temperature was recorded. After expressing concern for the fluid bag being the inaccurate temperature, a 39.0°C saline bag was placed inside the prototype and temperatures were recorded (Figure 20). This saline bag was considered an accurate simulation of an infant because of its temperature and due to the fact that water can account for 70% to 83% of body weight in premature and non-premature infants [38]. The zippers on the side of the "Sleeping Bag" were then opened to observe if there was any change in exterior temperature, and then subsequently closed to observe the overall change in temperature after opening the zippers.

Figure 20: Sleeping Bag (right) with Fiber Optic Temperature Probe (left)

Figure 21: Philips Expression MR400

Figure 22: Representation of the warmer entering the MRI machine at AFCH

VI. Results

6.1 Analysis of Heat Distribution of the Cardinal Health Porta-Warming Mattress Results

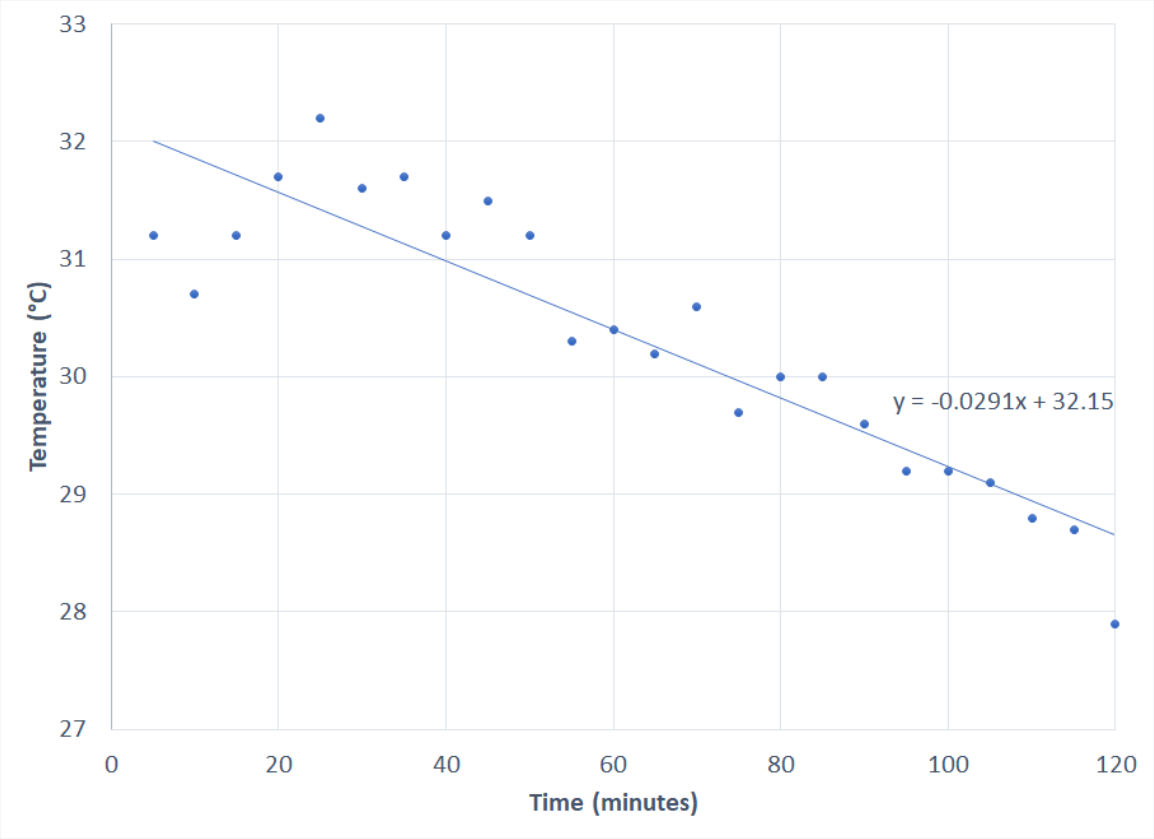


Figure 23: Graph of temperature data from FLIR Thermal Camera

Figure 23 shows the data of the temperature taken over a two hour duration. On average, the temperature of the heating pad decreased by 0.03°C per minute. The maximum temperature reached was 32.2°C while the minimum temperature reached was 27.9°C. The mean temperature was 30.33°C with a standard deviation of 1.135°C.

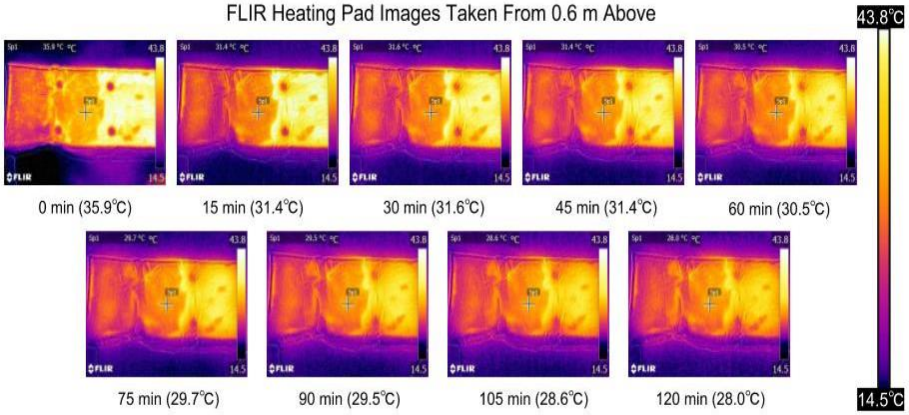


Figure 24: Photos of Heat Distribution Thermal Images over Two Hours in ~20.0°C Temperature Controlled Environment with Colors Scaled Between 14.5°C and 43.8°C

Figure 24 shows the photos of the heat distribution among the Cardinal Health Porta-Warming Mattress. The images show the warmest areas of the pad (yellow) and the coolest areas of the pad (purple). Most of the heat is consolidated around the center of each pocket of the pad.

Rate of Heat Transfer Through Conduction of Plastic Bag

$$Rate = (K)(A)(T1 - T2) / (d)$$

K = the thermal conductivity of the material
A = the surface area of the heated surface
T1 = the temperature of the heated object
T2 = the temperature of the surrounding area
d = the thickness of the material we're interested in

Equation 1: Heat is transferred from hot surfaces to colder locations via conduction. The transfer of heat will continue as long as there exists a difference in the two environmental temperatures. However, once the two locations have reached the same temperature, heat transfer then halts as thermal equilibrium is established. Thus, this rate of heat transfer through conduction can accurately portray expected heat loss for the plastic bag and the outer layer in comparison to one another [39].

$$Rate = (0.2\,W/mK)(0.1394\,m^2)(309.15\,K - 293.15\,K) / (0.005\,m)$$
$$Rate = 892.16\,W$$

6.2 Analysis of Heat Retainment within the "Sleeping Bag" Results

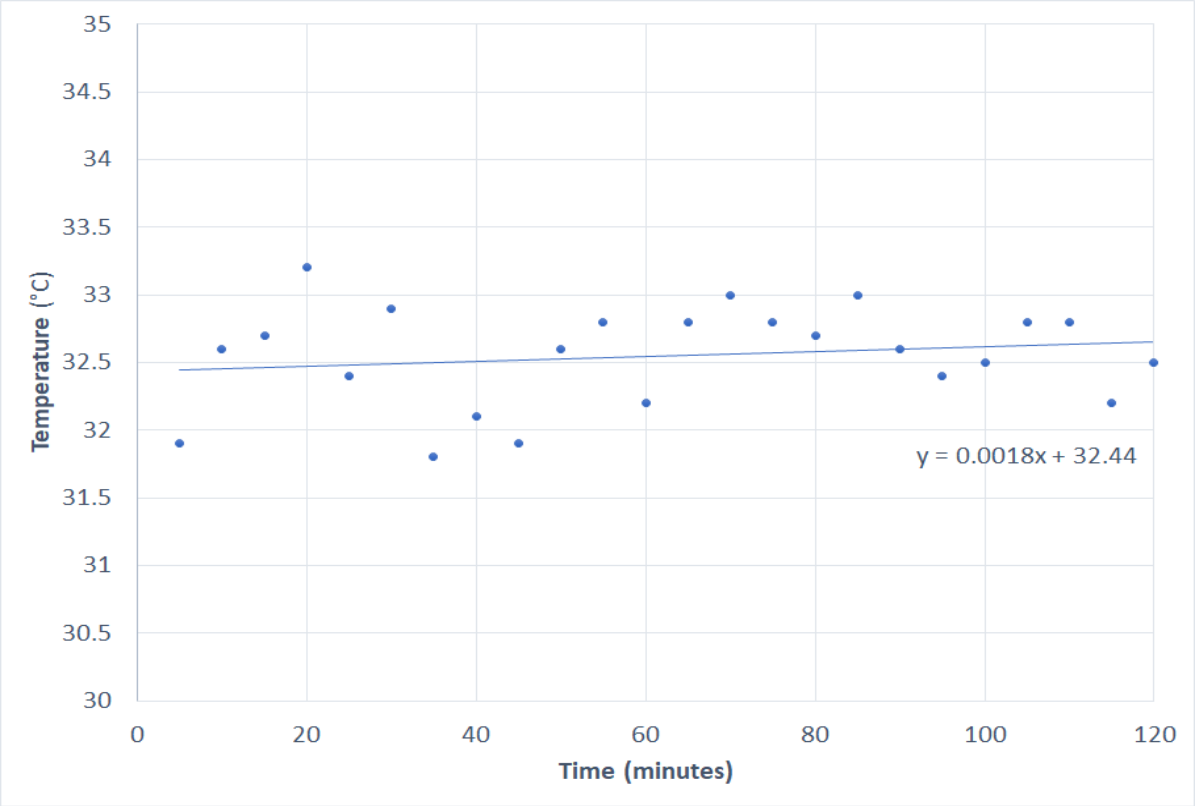


Figure 25: Graph of temperature data from temperature gun

Figure 25 shows the data of the temperature taken over a two hour duration. The line of best fit shows that on average the interior temperature of the "Sleeping Bag" increased by 0.0018°C per minute. The lowest temperature of 31.8°C was reached at the beginning of data collection while the maximum temperature was 33.2°C. The average temperature of the interior of the "Sleeping Bag" was 32.55°C with a low standard deviation of 0.374°C.

Rate of Heat Transfer Through Conduction of Polyester Fleece

(see Equation 1)

$$Rate = (0.05\,W/mK)(0.1394\,m^2)(309.15\,K - 293.15\,K) / (0.005\,m)$$

$$Rate = 22.304\,W$$

6.3 Analysis of Performance of the "Sleeping Bag" Under Various Circumstances Results

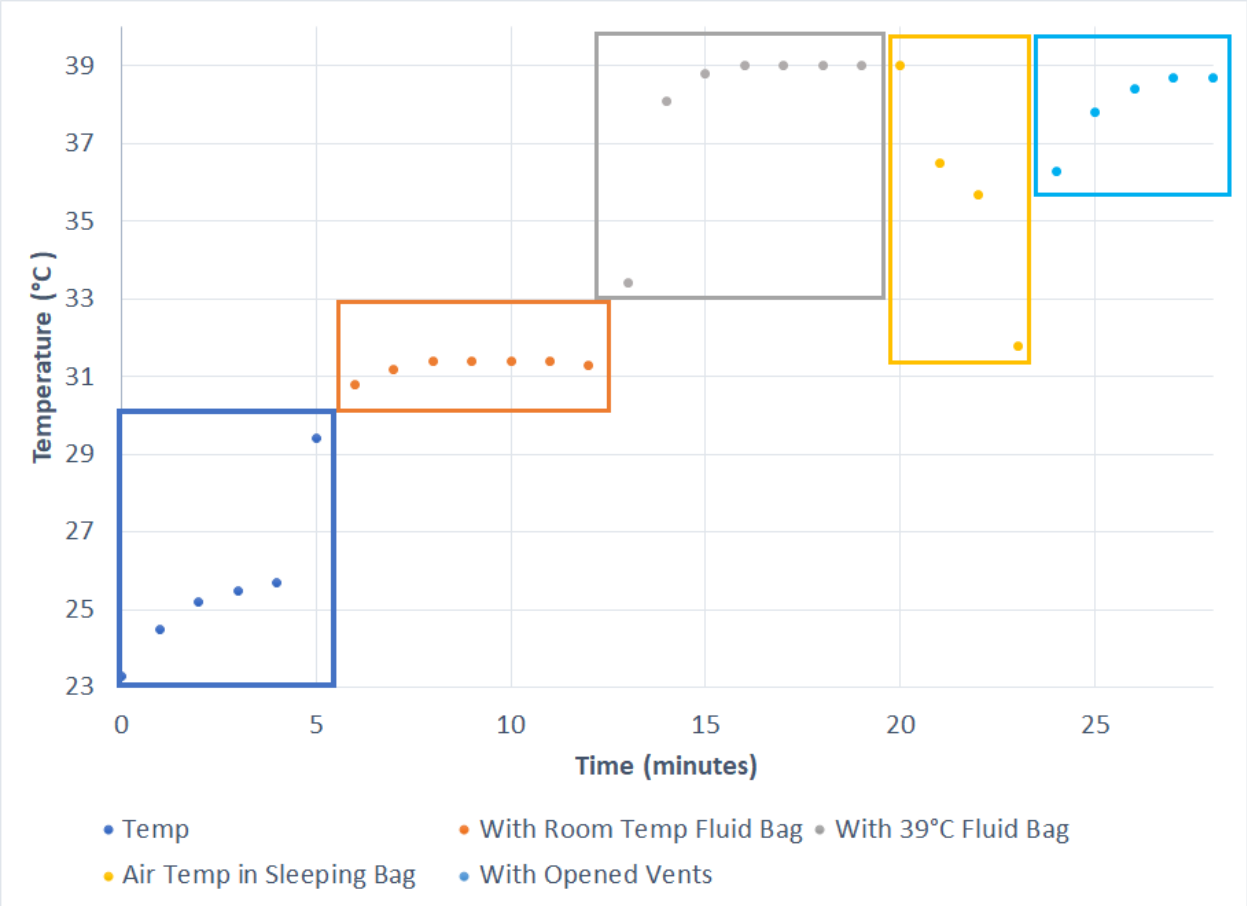


Figure 26: Graph of temperature data from fiber optic temperature probe

Figure 26 shows the data of temperature taken over the course of 30 minutes under various circumstances at the American Family Children's Hospital. Under each of the circumstances, the data suggests a steady retainment of heat.

VII. Discussion

The results of the Analysis of Heat Distribution of the Cardinal Health Porta-Warming Mattress were as expected. Dr. Peter Popic expressed that the heating pad simply did not give off enough heat to maintain an infant's temperature. With the pad losing an average of 0.03°C per minute, it was clear that the pad alone is an insufficient method of retaining an infant's body temperature. Furthermore, 892.16W of thermal energy is lost based on the heat transfer through conduction from the plastic (k-value = 0.2 W/mK) and the environment [40]. Shown in Figure 24, the FLIR thermal images show that the majority of the heat is consolidated among the center of each of the pockets of the pad. This shows that the pad is being used optimally when the infant is positioned in the center of the pad. To optimize the design, it

should be known to users that the pad should be centered in the “Sleeping Bag” along with the infant. To improve the results of this test, a fully functioning Cardinal Health Porta-Warming Mattress should be used. Prior to testing, it was noticed that one of the outer pockets of the pad had already been activated, leaving the interior elements to be solid. This may have skewed the data. Due to shortage of pads provided, the team was unable to redo the test as the other pads were needed for the following tests.

The results of the Analysis of Heat Retainment within the “Sleeping Bag” were satisfactory. With an average increase in temperature of 0.0018°C per minute, it can be concluded that the “Sleeping Bag” along with the Cardinal Health Porta-Warming Mattress is able to retain the temperature of the interior environment for at least two hours. Furthermore, based on the given thermal conductivity value for the outer layer of polyester (k-value = 0.05 W/mK), the device will only loose 22.304W of thermal energy due to heat transfer through conduction; whereas mentioned previously, the plastic bag would loose 892.16W of thermal energy [40]. This gave the team confidence that the “Sleeping Bag” would perform well in a live MRI scan. To improve the results of this test, it would be desirable to use a more accurate representation of the infant. As the textbook was of similar weight, it was not of similar size of an infant. This misrepresentation may have affected the results slightly, but not enough to change the conclusion of the test.

The results of the Analysis of Performance of the “Sleeping Bag” Under Various Circumstances were adequate as well. From the shape of the navy data points in Figure 26, it can be concluded that the “Sleeping Bag” does a sufficient job at retaining the interior temperature when the Cardinal Health Porta-Warming Mattress is inserted. The asymptote-like shape of the orange data points shows also that the “Sleeping Bag” can retain the temperature of the interior environment when an object of infant-like shape and weight is inserted. The gray data points also have an asymptote-like shape with the maximum at a temperature of 39.0°C (the temperature of the saline bag), showing that the “Sleeping Bag” retains the temperature of an infant-like object while not increasing the temperature past the critical point. It is safe to assume that a 39.0°C saline bag can be used to model an infant for testing purposes because infants are 70% water and are of similar weight and size of a saline bag. After the side zippers were opened for venting (bright blue data points), the data points were about 0.5°C lower than the gray data points just after a few minutes of ventilation. This ensured that the venting mechanism was sufficient for decreasing the interior temperature rapidly. From the results from this test, it can be concluded that the components as well as the general functionality of the device, works adequately with infant-like objects; therefore, it can be said with confidence that the “Sleeping Bag” would function similarly with an infant inside. If the test were repeated, it would be desired to test each of the categories for a two hour duration. This would give a better representation how the temperature of the “Sleeping Bag” behaves during a full two hour MRI scan.

VIII. Future Works

Although the team created an effective design, further testing will need to be done on more realistic infant-like models inside the “Sleeping Bag”. In previous testing, the team had limited time to complete the testing in the hospital due to strict schedules for patients using the MRI rooms and machines. In the future, testing will need to be done for the full two hours in the MRI in order to prove that the device does indeed maintain the correct temperature of the infant for the maximum scan time. Furthermore, the team will need a more controlled environment for the testing. The first testing of the Cardinal Health-Porta Warming Mattress was conducted in a semi-controlled room in which the team set

the temperature to 20℃, but the temperature may have fluctuated during the testing time. To solve this, testing would be ideal in the actual MRI room in order to have the exact environment the device would be used in. However, utilizing the MRI equipment, while it may be necessary/required for patient-use, presents a challenge in obtaining more testing results. Moreover, additional testing will need to be done with the ventilation system to prove that if the infant does become hyperthermic, opening of the zippers will be sufficient to decrease the temperature of the infant without causing any neurological damage. A testing protocol will need to be written for such testing. All further testing will need to be repeated multiple times to illustrate the accuracy of the device.

There is a multitude of regulations and codes from the FDA that the design will have to meet in order to be put on the market. To pass the Class II special controls of the FDA, the "Sleeping Bag" will have to meet the premarket data requirements as well as performance standards. With future testing mentioned above, an adequate data set can be put together to fulfill the premarket data requirements. Edits can then be made to the device to satisfy the performance standards and allow the device to go to market.

In order to increase the quality of the device, collaboration with the School of Human Ecology at UW-Madison would be beneficial. The team will discuss fabric choices and methods of fabrication. After hearing their suggestions, a new fabrication protocol will need to be written. Additionally, a new materials matrix will need to be constructed and analyzed.

IX. Conclusions

When infants need to have an MRI scan, they are anesthetized in order to improve image quality of the scans. However, undergoing anesthesia causes the infant to lose thermal regulation ability. Vasodilation along with a small weight to surface area ratio and the dry anesthetic gases causes the infant's temperature to drop. This change can cause the infant to become hypothermic, thus leading to other health complications. The current methods include putting the baby in a plastic bag once he/she is anesthetized and the use of the Cardinal Health Porta-Warming Mattress underneath the baby. These methods provide both an active and passive heat sources; however, physicians are still encountering the problem of infants' temperatures dropping too low. When the temperature drops below 36℃, the baby becomes hypothermic and the MRI scan needs to be stopped to allow the physician to warm the baby.

To solve this, the "Sleeping Bag" was developed which consists of dual-layered fabric with a hood and plastic zippers along both sides. First, the fleece outer layer provides an aesthetically pleasing element to the design along with another layer of insulation for the infant. The inner quilted material is a cotton fabric designed for insulation, soft to the touch, and adds a passive heat source element to the design. Secondly, the hood is an additional aesthetically pleasing part of the design via the comfort ears, while it contributes to ensuring the warmth of the cranial region on the patient. The hood may also be taken off the baby in the case of overheating the infant. Next, the back pocket provides a space for the Cardinal Health Porta-Warming Mattress to be inserted and used as an active heat source. Finally, the zippers allow for both easy placement of the baby in the device and a ventilation system. It was imperative that the design had a method of ventilation, because if the infant temperature rises above the critical temperature of 39℃, hyperthermic conditions can cause neurological damage. The side zippers allow for easy ventilation as the cooler air from the MRI room can instantly enter the device and cool the baby's temperature. Long MRI scans are conducted in multiple shorter time increments, which provides time where the zippers could be partially or fully opened depending on the extent of the overheating of

the infant and how quickly the temperature of the baby drops. Additionally, the zippers are plastic to ensure that they can be placed in the MRI environment without causing damage.

Through the testing it was found that the Cardinal Health Porta-Warming mattress loses heat too rapidly to retain an infant's temperature alone. Further testing proved that the "Sleeping Bag" with the Cardinal Health Porta-Warming mattress does in fact maintain the correct temperature inside the device for the full two hour maximum scan time. When the prototype was brought into the hospital and the fiber optic temperature probe was used, it was observed that opening the vents caused a immediate drop in temperature within the device. Additionally, when the vents were closed after being open the temperature had dropped but was not below the critical temperature of 36℃. This testing proved that the final prototype met the functionality criteria that was previously determined. Dr. Popic was pleased with the results of the prototype and agreed that it was an effective device for the issue at hand. After testing the prototype and analyzing the results, it was concluded that no changes were necessary for the final prototype.

For the device to be manufactured, sold, and used in hospitals, various steps will have to be taken. First, the team would like to meet with a faculty member from the School of Human Ecology at UW-Madison to discuss improving methods of manufacturing. Next, the team will have to conduct extensive testing in the MRI environment with a more realistic baby simulator. These tests must be repeated to ensure the effectiveness of the design and foresee possible complications. Finally, the team will need to do patent research and the device will have to pass FDA regulations.

X. References

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XI. Appendix

11.1: Product Design Specifications

Infant Warmer
Product Design Specifications
September 20, 2018

Client: Dr. Peter Popic
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Function:

There is a current need for an MRI-compatible warming system for infants while they are under general anesthetics. In the past year, there has been at least two cases at the American Family Children's Hospital in which infants cooled drastically during an MRI screening. Many infants undergo hypothermia while anesthetized due to vasodilation caused by the anesthesia induction. Vasodilation allows warmer blood from the body's core to flow freely and mix with the blood from the cooler periphery, lowering the core body temperature. The dry anesthesia gases and small weight-to-surface-area ratio contribute to this temperature decrease as well. There are currently many existing products on the market; however, most are not MRI-compatible. Those that are MRI-compatible are so expensive that most hospitals choose not to purchase them. The goal is to create an affordable, MRI-compatible device that will maintain an infant's core body temperature during an MRI screening.

Client Requirements:

- Design a warming system that will maintain an infant's temperature while undergoing an MRI screening
- System must maintain the baby's temperature at 36.5°C +/- 0.5°C
    - 35° C is too cold to wake the baby; breathing begins to slow
    - 38° C is too warm and can have lasting neurological damage
- System must have cooling capabilities as well (venting, circulation)
- System must maintain constant temperature for two hours
- System must be MRI-compatible
    - No metals except titanium, cobalt-chromium, copper, and stainless steel
    - No frequencies that would alter the quality of the images
- System must be disposable or easily sterilized
- System must fit around or underneath head and abdominal shields that improve image quality
- System must allow for the insertion of breathing tubes and blood pressure tubing

- System cannot increase the temperature of the surrounding environment to over 22.0°C

Design Requirements:

1. **Physical and Operational Characteristics**

a. *Performance requirements:*

The designed system must be able to maintain an infant's temperature at 36.5°C +/- 0.5°C during an MRI screening. To do this, the device must be able to warm and cool the baby in such a manner that is MRI-compatible and does not heat the surrounding area to over 22.0°C (temperature of MRI room). The warming system can be used from a few minutes up to two hours; the system must operate at an optimal level for this entire duration. The device must include access to the breathing tubes and the blood pressure tubing. This device will be used each time an infant undergoes anesthesia gases and needs an MRI scan. The device cannot take long to assemble, as this is more time that the infant is losing heat. After use, the device must be disposed of due to sterility issues.

b. *Safety:*

The primary safety concern is maintaining the patient's normothermia in order to prevent unintended perioperative hypothermia. Normothermia is defined as a condition of normal body temperature, ranging from 36.1°C to 37.2°C [7]. When a patient's body temperature drops below this normothermia range, they undergo a state of hypothermia. Perioperative hypothermia has consequences such as an increased rate of wound infections and higher mortality rates, especially in infants [1]. Therefore, any interruption to the warming can have severe ramifications on the safety of the patient. Possible failures in the device that could potentially lead to hypothermia involve seal brakes, material strength and temperature resistance, and a disruption in the heating source. Contrarily, the device cannot overheat to a point that overheat and potentially burn the baby. Applying a safe amount of heat is essential to the baby's safety.

c. *Accuracy and Reliability:*

The device must be able to produce and maintain a constant temperature range of 36.1°C to 37.2°C [7] for up to two hours [1].

d. *Life in Service:*

The device will be a one time use per person due to sterility issues. However, the device can be reused for multiple scans on the same patient, as long as it is in use for no longer than two hours. As soon as it is used in the MRI with a single patient, it will then be considered a hospital linen and sterilized per standard hospital protocol. Once after three patients, the device can no longer be used due to the tougher washing methods and lower durability of polyester and cotton.

e. *Shelf Life:*

Many hospitals consider a standard 30 day shelf life for all wrapped sterile supplies [8]. However, current hospitals have begun using an event-related sterility standard. It considers factors such as microbial contamination of the environment, air movement, traffic, location, temperature, and humidity [8]. Since an MRI environment has specific standards for use, an event-related sterility shelf life will be considered for the infant warmer.

f. Operating Environment:

The operating environment for this device is within MRI scanners and MRI rooms. Since sterility is crucial with newborns, this device will not be installed until within the MRI room. The temperature of the MRI room is always kept under 22.0°C. The temperature of the scanner increases with use, causing

the surrounding environment to warm as well. The bore of the MRI scanner is a different environment. With the MRI scanner heating up as the scan progresses, the inside of the scanner gets hotter than the surrounding area. For this reason, the device must avoid touching the inside of the machine. The device can be stored in the MRI room or in a separate storage room.

g. Ergonomics:

The primary person handling this device will be an anesthesiologist's assistant. While a scan is in progress, the assistant cannot enter the room to make any adjustments, making the effectiveness of the installation of the device to be crucial. If a baby's temperature begins to drop, the scan must be paused before hypothermia sets in. To maximize efficiency, the device needs to ensure the infant will stay warm for the entire duration of the scan. The assistant also needs to be cautious in installing the device by avoiding touching the sides of the bore. If the device is made small enough so that it does not come near the sides, installation time will decrease.

h. Size:

This device will be used on infants ranging from small neonates (~2.3 kg) up to age one (~9 kg) [4]. The device must be approximately the same size of the infant so that it retains the child's heat effectively, avoids touching the sides of the scanner, and fits inside of the MRI head shield. Infants are not placed into any additional guards in the scanner, so the device can be dimensionally the same as the patient table. The primary MRI used, the GE 3.0T, has a 70 cm bore, so the device must fit in these constraints [9].

i. Weight:

When designing this product weight has to be considered. For one, if the device is in any way resting on the infant then it needs to be light enough so the baby is comfortable. It also needs to be considered that this device will be regularly moved on and off of the patient table. The weight needs to be able to be lifted by a person. The existing devices, the plastic bag and the heating pad, weigh under 2 kg. Therefore, it is expected this device will be around the same weight.

j. Materials:

MRI-compatibility is crucial when deciding materials in this design. Materials that should be avoided in the design include all ferrous materials; this can include oxygen tanks and certain metals that might be implemented in the design [5]. Additionally, no materials should be used that are electrically conductive, metallic, or magnetic [5]. Other metals, coils, coil leads, ECG connectors, and oxygen monitor probes must be placed away from the patient's body to avoid possible burns [5].

k. Aesthetics, Appearance, and Finish:

The main focus of this project is its functionality; allowing infants and premature infants to retain heat. A clear plastic lightweight design might be desirable so the infant inside is visible; however, once the infant is in the MRI visibility is already limited. The color and texture are not required to be anything specific. The device's shape must fit inside the MRI and around the infant. The device must be relatively small and close to the infant for easier heat retention. In cases where additional devices are placed on the infant for MRI imaging, the design must be able to fit either under these or enclose them.

2. Production Characteristics

a. Quantity:

For the purposes of this project, only one prototype is needed. If testing is completed thoroughly and the design is implemented in a hospital, multiple copies could be made to meet the needs of the client.

b. Target Product Cost:

As long as the device stays within the current project budget of $500.00, it will be competitive with other warming techniques. The 3M Bair Hugger Normothermia System, a commonly used device for infant warming, is priced at $282.85 [3]. If the design can be created under this price budget, it could be easily implemented into hospital settings. Currently, Dr. Popic uses a plastic bag to cover the infant with holes in it for a breathing tube, which is an essentially disposable price. They also use the Cardinal Health Porta-Warming Mattress on occasion that is priced at $80.99 [2]. A goal price that would be competitive would be somewhere between $80.99 and $282.85.

3. Miscellaneous

a. *Standards and Specifications:*

Currently, the Codes of Federal Regulations in the FDA database for medical devices that are designed for warming infants are titled as follows: *Sec 880.5130 Infant Radiant Warmer, Sec. 880. 5400 Neonatal Incubator, Sec. 880.5410 Neonatal Transport Incubator, Sec. 880. 5560 Temperature Regulated Water Mattress.* They are all from the same Title and Volume (Title 21, Volume 8) within the Code of Federal Regulations. The 3M Bair Hugger Normothermia System is considered to be a class II device via the FDA; therefore, it can be assumed that the device must follow similar regulations as this device.

b. Customer:

The customer would primarily be children's hospitals. The team would target the pediatric anesthesia faculty, as they understand the problem the most. Dr. Peter Popic, expressed that many pediatric anesthesiologists encounter this problem and are constantly thinking of new, often crude ways to warm the baby. A successful design would help decrease their stress-level exponentially.

c. Patient-related concerns:

The device will be designed for one-time use and should be disposed of after use. It cannot touch the sides of the MRI machine. The patients need to remain within the specified temperature range of 36.1°C to 37.2°C [7].

d. Competition:

Products such as the 3M Bair Hugger Normothermia System and the FilteredFlo Infant exist to meet the client's needs; however, the client is not using either product due to their high costs and MRI-incompatibility. Currently, the client uses two different devices. The first is a plastic bag to cover the infant with holes in it for a breathing tube and other necessary equipment. The second is the Cardinal Health Porta-Warming Mattress.

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11.2 Fabrication Plan

Fabrication Plan

Materials
Fleece Fabric (1 yard)
Quilted Ironing Board Cover Fabric (1 yard)
45.7 cm plastic zipper (x2)
22.9 cm plastic zipper (x1)
Thread
Sewing Machine

Body of "Sleeping Bag"

1. Fold fleece fabric in half
2. Cut a 30.5 cm by 46 cm rectangle from the fleece fabric with the fold at the bottom
3. Cut a .64 cm wide slit that is 2.5 cm from each side of the fleece fabric and 5 cm from the bottom
4. Cut a .64 cm wide slit that is 46 cm long down the middle of the fabric
5. Repeat steps #1-4 for Quilted Ironing Board Cover Fabric
6. Unfold the fabrics
7. Pin the 23 cm plastic zipper on one of the side slits on the Quilted Ironing Board Cover Fabric; sew each side of the zipper to the fabric
8. Repeat step #6 with the other side slit and another 23 cm plastic zipper
9. Place the unfolded Quilted Ironing Board Cover Fabric underneath the unfolded fleece fabric
10. Sew the side panels of the side zippers on both sides to the fleece fabric
11. Place the 46 cm zipper behind both the fabrics, with middle of the zipper centered in the middle slit of the fabrics; pin in place
12. Sew the zipper in place
13. Flip both fabrics inside out, fold in half
14. Sew the fabrics together on each side less than .64 cm from the edges
15. Flip the fabrics again with the fleece fabric on the exterior

Hood of "Sleeping Bag"

1. Put two pieces of fleece fabric on top of each other
2. Cut a 25.5 cm by 30.5 cm square of fabric out of the fleece
3. Measure halfway distance between the 30.5 cm fabric (mark at 15.2 cm)
4. Place a circle cardboard cutout with radius .64 cm on each of the corners and trace around, keeping the distance between the two cutouts 10 cm apart on top
5. Trace a wide circle around the top of the fabric with the edge on the beginning of the ears to form the top curve
6. Cut around the exterior of the traces
7. Sew the two cut outs together leaving the bottom and two inches along the side near the bottom unsewn
8. Turn inside out
9. Sew the back layer to the body of the "Sleeping Bag"

Radii of ears - .64 cm
Height - ears 21.6 cm
Between ears - 10 cm

11.3 Analysis of Heat Distribution of Cardinal Health Porta-Warming Mattress Protocol

Testing Protocol (Pad Outside "Sleeping Bag")

1. The environment that the test will take place in has to be set up:
    a. Start off in a room set to 20.0°C. This allows for +/- 2.0°C of error and will still be a reasonable MRI room temperature
    b. Place the warming pad on a surface similar to one in an MRI room (according to Dr. Popic, a flat table will be sufficient)
2. Set up camera 24 inches directly above the heating pad with a stand
    a. Camera will be held by a stand in a fixed position
    b. Photos will be taken by pulling the trigger on the camera
3. Pop the three chambers of the heating pad to activate it
4. Take photo every 5 minutes for a span of 2 hours (photo will be taken of the entire pad, while the temperature is taken from the center of pad)
5. Data will be analyzed using an excel spreadsheet and graphs, FLIR software, and RStudio
6. Plan on only doing this test once, will do a second time if needed

11.4 Analysis of Heat Retainment Within the "Sleeping Bag" Protocol

Testing Protocol (Pad Inside "Sleeping Bag")

1. The environment that the test will take place in has to be set up:
    a. Start off in a room set to 20.0°C. This allows for +/- 2.0°C of error and will still be a reasonable MRI room temperature
    b. Place the "Sleeping Bag" on a surface similar to one in an MRI room (according to Dr. Popic, a flat table will be sufficient)
2. Place an item around the same size and weight of an infant inside the bag (textbook). This will help to see if pressure affects the heat transferred or not
3. Place the activated Cardinal Health Porta warming mattress in its designated pocket within the "Sleeping Bag"
4. Slightly open the "Sleeping Bag" to use the RTech IR Thermometer to take readings at a site where the infant-like item touches the pad. Temperature readings could also be taken at other important sites like near zippers and the head opening
5. The position where the temperature was recorded from should be marked to ensure all readings will taken from the same location
6. Take temperature readings once every 5 minutes for a duration of 2 hours (the maximum MRI test time)
7. Finish gathering data, and end the test with data analysis
    a. Analyze data with graphs using Excel Spreadsheets and RStudio
8. Depending on the results of the first test, repeated testing may be useful to gain more accurate results or if the prototype is changed. Findings may lead to the prototype needing alterations, and these changes should be tested

11.5 Analysis of Performance of "Sleeping Bag" Under Various Circumstances

Testing Protocol ("Sleeping Bag" at Hospital)

1. Activate Cardinal Health Porta-Warming Mattress and place inside pocket of "Sleeping Bag"
2. Connect fiber optic temperature probe to Philips Expression MR400 and place inside "Sleeping Bag"
3. Record temperature every minute for 5 minutes
4. Place room temperature fluid bag inside of "Sleeping Bag" with fiber optic sensor underneath, record temperature every minute for 7 minutes
5. Replace room temperature fluid bag for a 39.0°C fluid bag, record temperature every minute for 7 minutes
6. Move fiber optic temperature probe above fluid bag, measuring the temperature of the surrounding environment. Record temperature every minute for 4 minutes
7. Fully open both side zippers and move temperature probe underneath the fluid bag, record temperature every minute for 5 minutes
8. Repeat testing as needed
9. Analyze data with graphs using Excel Spreadsheet and RStudio