Infant Warmer

BME 200/300: Biomedical Engineering Design
October 10, 2018

Client: Dr. Peter Popic, American Family Children's Hospital

Advisor: Dr. John Puccinelli, Biomedical Engineering

Team Members:
Sara Jorgensen (Team Leader)
Margaret Edman (Communicator)
Maggie Freking (BSAC)
Johanna Ellefson (BWIG)
Olivia P'ng (BPAG)

Abstract

While infants undergo MRI scans, they are often anesthetized to keep them still, ultimately optimizing the image quality. However, anesthetizing babies is risky because they are unable to regulate their own body temperature while under anesthetics, causing them to cool. To avoid the extremely expensive MRI compatible infant warmers on the market, Dr. Peter Popic at the American Family Children's Hospital uses crude methods for retaining an anesthetized infant's body temperature while undergoing an MRI scan, including putting the infant in a plastic bag. Dr. Popic challenged a team of biomedical engineering students at the University of Wisconsin-Madison to design an affordable, effective, MRI compatible infant warmer. Three preliminary designs were generated and evaluated, and "The Sleeping Bag" was chosen as the final design. "The Sleeping Bag" 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 will contain two pockets in which Cardinal Health Porta-Mattresses can be placed. Additionally, the hood of the blanket will be made out of thermochromic fabric, allowing for the anesthesiologist to visually monitor the temperature of the baby. In the future, research will be done to determine the best fabrication method and material selection. Fabrication and testing protocols will be developed to create and evaluate the trial prototypes. The final prototype will be delivered at the BME 200/300 poster session at the end of the semester.

Table of Contents

Introduction

1.1 Motivation

Premature babies and infants with medical issues will have numerous tests done on them, including MRI scans. 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 arises such that infants are unable to regulate their own body temperature while anesthetized. This drop in body temperature that infants face is extremely dangerous, for they risk the chance of becoming hypothermic. 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-Warm Mattress and a medium sized plastic bag.

The Cardinal Health Porta-Warm Mattress 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 bent, it begins to heat up.

The plastic bag used is simply a medium sized garbage bag. The infant is put inside the bag, it is tied shut, and necessary holes for medical tubing are made in the bag. This device retains the infant's own body heat in attempt to keep the patient warm.

Figure 1: Image depiction of the Cardinal Health Porta-Warm Mattress

These two devices can be used individually, as well as simultaneously. However, these methods do not keep the baby warm enough and do not maintain heating for the maximum two hour scan time. A current device on the market is the Bair Hugger which uses an active heat source to warm an inflatable piece that wraps around the baby. This device would be beneficial in warming infants; however, the Bair Hugger heating unit is not MRI compatible [4].

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*. 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.

Figure 2: Image depiction of the current Bair Hugger in use during an operation

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

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 scans. 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. Dr. Popic currently uses two devices, both of which are unable to achieve high enough temperatures to heat the infant for the maximum scan time of two hours. While there are multiple devices on the market, they are extremely expensive. Our 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.

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 [3]. Infants, in particular, tend to lose heat 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 [8]. The dry anesthesia gases and small weight-to-surface-area ratio contribute to this temperature decrease as well. In some instances, infants lose so much heat that they undergo hypothermia. Hypothermia is defined as when an infant's temperature drops below 36.0°C. However, moderate hypothermia is stated to be when the baby's temperature is between 32-35.5°C. This drop in temperature causes the heart rate to slow, and even stop if left undiagnosed for too long [9].

Conversely, if the body temperature increases too much, the infant may undergo hyperthermia. Hyperthermia is defined as a body temperature above 38°C while mild hyperthermia is 38-38.8°C, and extreme hyperthermia is any temperature over 38.8°C [9]. Since the central nervous system controls the

body's reaction to temperature, it is especially vulnerable to overheating [7]. Due to this high vulnerability, hyperthermia of infants can lead to lasting neurological damage. Furthermore, hyperthermia has the potential to cause neuroleptic malignant syndrome and has been shown to adversely affect attention, memory, and acute information processing [5].

2.2 Research for Building Designs

Evaluating materials for the design is crucial, for they have to meet the requirements of the MRI. Ferromagnetic materials cannot be used inside the MRI room, eliminating the option of using oxygen tanks and certain metals.

The size of the design must fit the MRI patient table without being larger than 6.0 cm wide. It also must fit inside of the additional head cage that can be used during scans. According to Dr. Popic, the head coil is a half oval shape that is 20 cm wide and 20 cm high. The coil is necessary to develop a high quality scan [6].

This device must also be fairly 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.

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.

The baby must be kept at a temperature of 36.5°C ± 0.5°C to keep them from entering hypothermia. This specific temperature range needs to be maintained for a maximum of 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 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 20cm 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.

Finally, it is important that the design can either be cleaned with simple sterilization methods or is disposable. Sterility is crucial with an infant's weakened immune system. All current methods of warming are disposable; therefore, the new design must not be any less sterile.

Preliminary Designs

3.1 “The Tent”

Three preliminary designs of a regulated warming system were created. The first design was “The Tent”, as depicted in Figure 4.

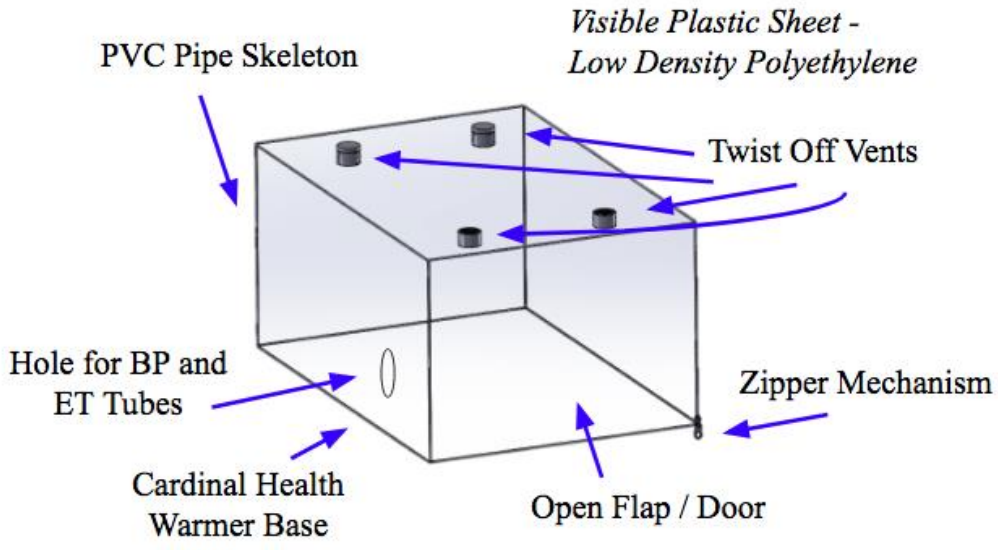


Figure 4: “The Tent” Design; isometric view.

“The Tent” was originally inspired by the cruder methods the client currently uses to regulate an infant’s temperature: The Cardinal Health Porta-Warm Mattress, the plastic bag, and external 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 surrounding material would be a visible and flexible plastic sheet which would function as insulation. The plastic would need to be non-toxic as compatible with 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-Warm Mattress as the base for this design. This would function as an additional heat source to the system.

3.2 “The Glamper”

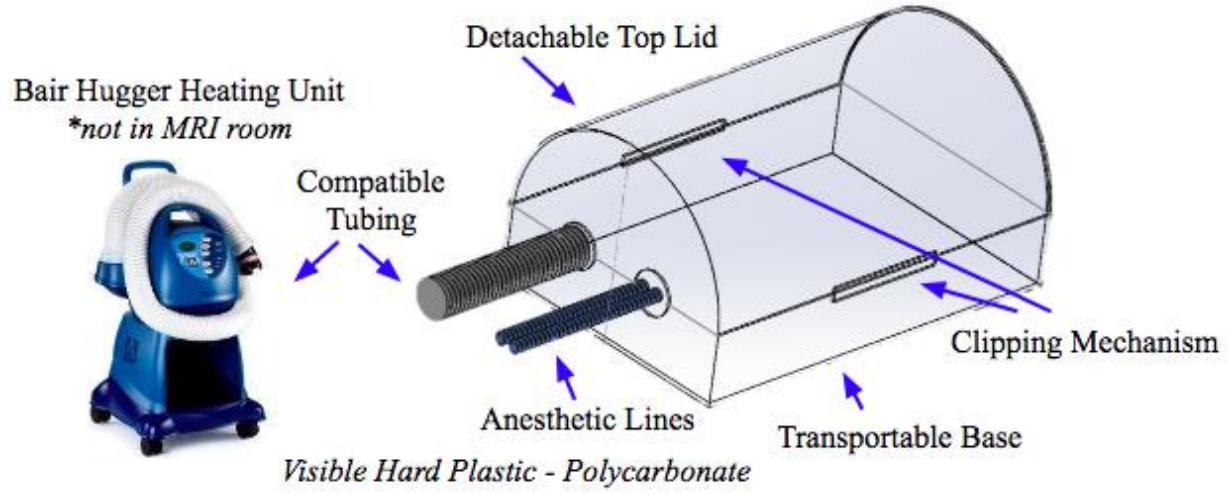


Figure 5: “The Glamper”; isometric view (right) alongside the Bair Hugger Heating Unit (left)

“The Glamper” was inspired by an infant incubator for premature babies. Rather than rely on body heat and heating pads, this system uses an active heating source 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”

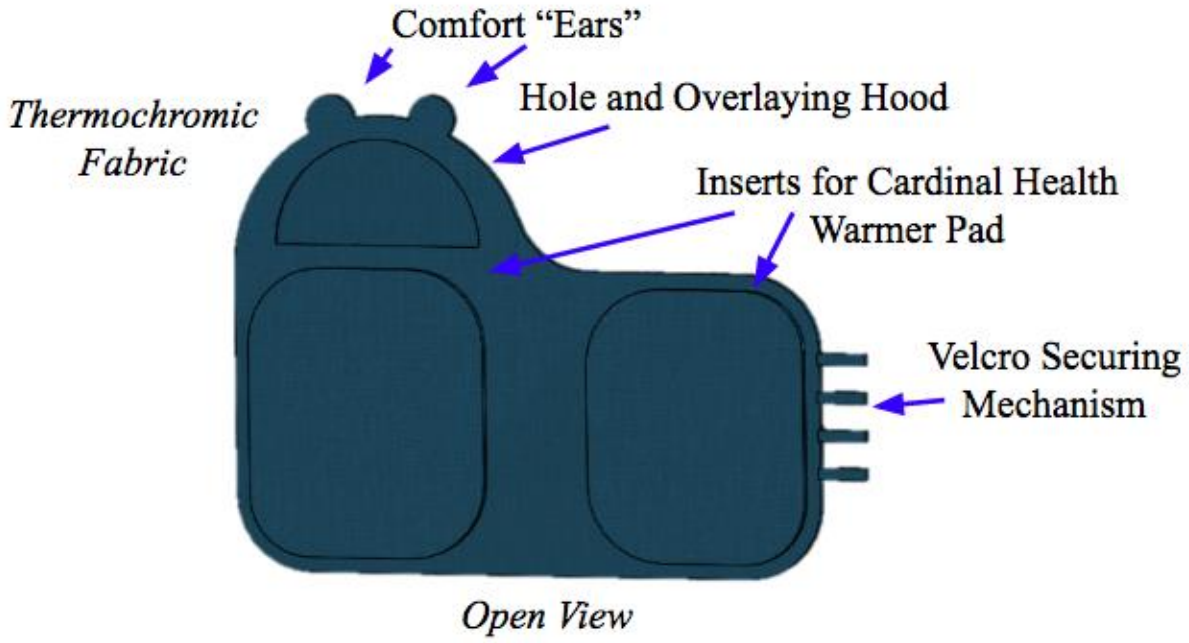


Figure 6: “The Sleeping Bag”; front view

“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 [2]. Therefore, “The Sleeping Bag” highlights the importance of parent comfort when a child goes through an MRI scan. Furthermore, “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. And, 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.

Preliminary Design Evaluation

4.1 Design Matrix

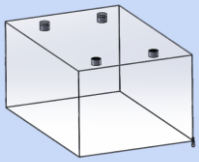
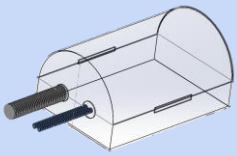
	The Tent 		The Glamper 		The Sleeping Bag 	
Safety (20)	**3/5**	**12**	**5/5**	**20**	**4/5**	**16**
Effectiveness (20)	**2/5**	**8**	**5/5**	**20**	**4/5**	**16**
Precision (15)	**1/5**	**3**	**5/5**	**15**	**4/5**	**12**
Sterility (15)	**4/5**	**12**	**3/5**	**9**	**5/5**	**15**
Assembly Time (10)	**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 7: Design matrix including criteria for the device and scores of the three preliminary designs

The design matrix 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, bacterial infection, hypothermia, and inaccessibility. The category effectiveness evaluates how well the device maintains heat, methods of cooling if the baby gets too warm and ways 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 keep 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. Sterility is crucial when working with young babies. Next on the design

matrix 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 procedure, which ultimately decreases the risk of the baby undergoing hypothermia. Aesthetics refers to how appealing the device is to look at. Since this device is used on infants, it is important that the parents feel safe and comfortable with their child using it, and aesthetics is key to making this happen. 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 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-Warm Mattress. If machine-washed, it is certain that there were no 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.

4.3 Proposed 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 is able to 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-Warm 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.

Future Works

The next step in the design process is to research materials that will be incorporated into the prototype. In the case of "The Sleeping Bag" (Figure 6), research must be done to determine the cloth

used in the swaddling wrap and also the thermochromic, or color indicating, material. It is predicted that either paint [1] or actual fabric would be the indicator of choice. In the case of "The Glamper" (Figure 5), the type of hard plastic encasing the infant which was initially proposed as polycarbonate, must be further researched and finalized as well as Bair Hugger compatible tubing. For "The Tent", finding the cheapest, easiest, and safest materials would be the next steps. For "The Tent" and "The Sleeping Bag", a preliminary test will be done on the Cardinal Health Porta-Warm Mattress to evaluate the heat distribution and effectiveness over time. In order to accomplish this, a thermal camera will be directed at the mattress for a two hour time period and take photos every five minutes. Furthermore, each design will be evaluated using an event related sterility standard to determine its approximate shelf-life. Doing so would take into consideration microbial contamination of the environment, air movement, traffic, location, temperature and humidity factors [10]. After this final research and preliminary testing is done, the design matrix may need to be reevaluated in order to finalize the design that will be constructed moving forward.

Although "The Sleeping Bag" won the design matrix and was proposed as the final design, "The Glamper" may be the final design pursued after recent advice and information on fabrication and safety was noted. The above final research will be able to help the team distinguish what will work best to fit the clients needs.

After the design is finalized, fabrication and testing protocol will be established and a prototype will be developed. Testing will follow the first prototype and will continue on until the design has reached a level of effectiveness deemed suitable for this semester. The prototype will have to first be tested in a room kept at around the same temperature as an MRI room (21.0℃) [11]. A simulated baby will serve in place of an infant patient. Possibly, after this testing, there will be another test set up in an MRI room to see if the conditions in an actual room affect how the design works.

Conclusions

Dr. Peter M Popic from the American Family Children's Hospital is looking for an affordable, easy to use, and MRI compatible device that will keep an infant's core body temperature in the healthy range of 36.5 ± 0.5℃. Currently, there are no warming systems for infants that meet all three of these criteria. There is a demand for such a device because when infants undergo general anesthetics, they become hypothermic due to vasodilation caused by the anesthesia induction.

After brainstorming three initial designs: "The Sleeping Bag", "The Tent", and "The Glamper", a design matrix with important criteria was developed and the three designs were evaluated. "The Sleeping Bag" was proposed as a final design. This design consists of two Cardinal Health Porta-Warm Mattresses inserted into the pockets of a swaddling blanket wrap, ultimately avoiding direct skin contact to the heat source to increase the infant's safety. 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. Moreover, velcro straps are put in place to secure the baby within the swaddle to further enhance the systemic warming.

After the final design has been picked, the next step is to finish materials and pricing research. Before the prototype is created, a test will be done on the Cardinal Health Porta-Warm Mattress to evaluate the ability of the mattress to create and retain heat. Briefly following this, ordering materials and fabrication will begin. The design will be edited throughout testing, which will be done first in an

appropriately cooled room with a simulated baby. Final testing may be permitted in an MRI machine. By developing the prototypes as such, this process will optimize the final design to best fit the client's requirements.

References

[1] Atlanta Chemical Engineering, “Thermochromic Fabric Paints,” 2018. [Online]. Available: http://www.atlantachemical.com/tfp/tfp.html

[2] BabyCentre Medical Advisory Board, “Swaddling: what are the risks and benefits?,” BabyCentre UK. [Online]. Available: https://www.babycentre.co.uk/a125/swaddling-what-are-the-risks-and-benefits. [Accessed: 05-Oct-2018].

[3] “Child Development,” *Centers for Disease Control and Prevention*, 23-May-2018. [Online]. Available: https://www.cdc.gov/ncbddd/childdevelopment/positiveparenting/infants.html. [Accessed: 09-Oct-2018].

[4] Díaz M, Becker DE. “Thermoregulation: physiological and clinical considerations during sedation and general anesthesia.” Anesth Prog. 2010. [Online]. Available: https://clinicaltrials.gov/ct2/show/NCT03150953. [Accessed: 9-Oct-2018]

[5] E. J. Walter and M. Carraretto, “The neurological and cognitive consequences of hyperthermia,” *Current neurology and neuroscience reports.*, 14-Jul-2016. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4944502/. [Accessed: 09-Oct-2018].

[6] “I'm Getting an MRI, so What's a Coil?,” *Center for Diagnostic Imaging*, 13-Jan-2016. [Online]. Available: https://www.mycdi.com/viewpoints/im_getting_an_mri_so_whats_a_coil_103. [Accessed: 09-Oct-2018].

[7] R. S. Pozos, “http://ljournal.ru/wp-content/uploads/2017/03/a-2017-023.pdf,” *Human Physiological Responses to Cold Stress and Hypothermia*, 2017.

[8] T. Bergstrom, “The science behind patient warming and the benefits of normothermia,” Infection Prevention News, 03-Sep-2015. [Online]. Available: http://infection-prevention-news.3m.com/the-science-behind-patient-warming-and-the-benefits-of-normothermia/. [Accessed: 11-Sep-2018].

[9] “Thermal Protection of the Newborn: a practical guide,” *Healthy Newborn Network*. [Online]. Available: https://www.healthynewbornnetwork.org/resource/thermal-protection-of-the-newborn-a-practical-guide/. [Accessed: 09-Oct-2018].

[10] Urmc.rochester.edu. (2017). *Event-Related Sterility - Sterile & Materials Processing Department - University of Rochester Medical Center*. [online] Available at: https://www.urmc.rochester.edu/sterile/event.aspx [Accessed 17 Sep. 2018].

[11] Working Safely GE Medical Systems, *GE Medical Systems MR 3.0T Signa ExciteTM Learning and Reference Guide*, Ch 2, 2003.

Appendix

8.1: Project Design Specifications

Infant Warmer
Product Design Specifications
September 20, 2018

Client: Dr. Peter Popic
Advisor: Dr. John Puccinelli
Team Members:

Sara Jorgensen	sjorgensen3@wisc.edu	Team Leader
Margaret Edman	medman@wisc.edu	Communicator
Maggie Freking	mafreking@wisc.edu	BSAC
Johanna Ellefson	jlellefson@wisc.edu	BWIG
Olivia P'ng	opng@wisc.edu	BPAG

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. Our 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 (one-time use)
- 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°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°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 our 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 will 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. As soon as it is used in the MRI with a patient, it will not be used on another patient. 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.

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 our 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°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, our 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 our device by avoiding touching the sides of the bore. If our 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 our 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 our 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, our client 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-Warm 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 our device must follow similar regulations as this device.

b. Customer:

The customer would primarily be children's hospitals. We would target the pediatric anesthesia faculty, as they understand the problem the most. Our client, 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 our client's needs; however, the client is not using either product due to their high costs and MRI-incompatibility. Currently, our 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-Warm Mattress.

Works Cited

[1] A. Kurz and M. Tryba, "Safe patient warming," Warming is Important | Bair Hugger Safe Patient Warming. [Online]. Available: http://safepatientwarming.com/spw/warmingisimportant/index.html. [Accessed: 11-Sep-2018].

[2] Bound Tree, "Porta-Warm Infant Mattress, 9 ¼ inch x 19 inch" *Cardinal Health, www.boundtree .com,* 2015. [Online]. Available: "https://www.boundtree.com/porta-warm-infant-mattress-951475-product-9199-334.aspx

[3] Devine Medical, “3M 55501 Bair Hugger Forced Air Warming Pediatric Underbody Blanket,” *3M*, 2018. [Online]. Available: https://www.devinemedical.com/3M-55501-p/mck-348286.htm?gclid=EAIaIQobChMI-8DQ-vjH3QIVzLbACh0Lhg5SEAkYCCABEgJWyfD_BwE

[4] L. updated: O. 2016, “Your child's size and growth timeline,” *BabyCenter*, 03-Aug-2018. [Online]. Available: https://www.babycenter.com/0_your-childs-size-and-growth-timeline_10357633.bc#articlesection2. [Accessed: 19-Sep-2018].

[5] Medicines and Healthcare Products Regulatory Agency, “Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use,” *MHRA*, 2014. [Online]. Available: http://www.ismrm.org/smrt/files/con2033065.pdf

[7] T. Bergstrom, “The science behind patient warming and the benefits of normothermia,” Infection Prevention News, 03-Sep-2015. [Online]. Available: http://infection-prevention-news.3m.com/the-science-behind-patient-warming-and-the-benefits-of-normothermia/. [Accessed: 11-Sep-2018].

[8] Urmc.rochester.edu. (2017). *Event-Related Sterility - Sterile & Materials Processing Department - University of Rochester Medical Center*. [online] Available at: https://www.urmc.rochester.edu/sterile/event.aspx [Accessed 17 Sep. 2018].

[9] “3.0T,” *GE Healthcare*. [Online]. Available: https://www.gehealthcare.com/products/magnetic-resonance-imaging/3-0t. [Accessed: 19-Sep-2018].