Infant Warmer

Product Design Specifications

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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. With the help of our client, Dr. Peter Popic, we hope to create an affordable, MRI-compatible device that will decrease the amount of infants that undergo hypothermia 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 37°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 heating ability for up to two hours
- System must be MRI-compatible
    - No metals
    - No frequencies that would alter the quality of the image
    - Specific chemicals are not allowed in the MRI
    - System cannot heat too much- can alter the quality of the image
- System must be disposable (one-time use)
- System must fit around or underneath head and abdominal contraptions that improve image quality
- System must allow for the insertion of breathing tubes and blood pressure tubing

Design Requirements:

1. **Physical and Operational Characteristics**

a. *Performance requirements:*

The designed system must be able to maintain an infant's temperature of exactly 37° 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. 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]. Maintaining an accurate and reliable temperature range for an infant is crucial to prevent excessive heating which can result in burn injuries, as well as hypothermia during an MRI [6].

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 (~5-6 lbs) up to age one (~20 lbs) [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:

Weight is not a problematic factor in this design, given that the MRI table can withstand great weights. The existing devices, the plastic bag and the heating pad, weigh under 2 lbs. 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

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