# *Final Report - BMEG 257*

**Group 5**

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# *DHF 1: Needs Finding and Specifications*

**Introduction**

Sepsis in infants (0-1 years of age), also known as neonatal sepsis, continues to be one of the leading causes of death for infants worldwide, accounting for 400,000 - 700,000 deaths and affecting between 1.3-3.9 million infants per year (1). There are three critical stages in neonatal sepsis, the first being sepsis itself. Sepsis is classified as the immune response of the body to external pathogens in which normal responses such as a fever, inflammation, fast heart rate and breathing become exaggerated and begin to compromise the health of the infant. This can move into the second stage of sepsis known as severe sepsis in which the body's response causes organ dysfunction. This can progress further into septic shock in which organs begin to fail, and the pulse becomes faint as blood vessels are damaged and begin to leak blood into the surrounding areas. The mortality rate of infants with septic shock is about 40% (2). Approximately one third of the babies that recover from septic shock experience a change in cognitive skills as well as other detrimental long term effects (3). Our objective is to create a sepsis monitor that will detect the very earliest symptoms of sepsis so they can be addressed before any permanent or long-lasting damage occurs.

**Methods of Data Collection**

Preliminary research was conducted to build an understanding of current monitoring devices on the market, symptoms of sepsis, and common practices used for diagnosis. Needs were developed open-endedly, keeping in mind the large range of wearable, portable and non-portable options available on the market in order to keep options open. Further research was performed based on the standards of wearable devices, materials currently on the market for infants, and how these are being used to monitor medical illnesses. It was critical for us to determine the demographic of infants typically affected by sepsis so that our monitoring device could be tailored towards them and their families. This research was supplemented with a question and answer session with Dr. Calvin Kuo to discuss what a caregiver with a newborn infant would desire for a sepsis monitoring device. This allowed us to gauge his personal comfortability and concerns with the topic. We conducted further interviews with a nurse in the field at the Calgary Children’s Hospital, in order to refine design specifications, and obtain a better definition of sepsis and sepsis symptoms in infants, in order to ensure that sepsis cases are caught as often as possible, with minimal false alarms. Our conclusions from this conversation were that infants are very difficult to diagnose, especially under the age of 3 months, as they typically are not able to show symptoms of illnesses. Due to this, infants admitted to hospitals with fevers and any sepsis symptoms are automatically diagnosed with sepsis until proven otherwise. Practitioners also advise that guardians come to the hospital if they feel their infant is showing any symptoms of illness. This is strictly because studies have shown that infants have a better chance of survival when parents catch the warning signals early, even if excess hospital resources are used (4).

**Results and Findings**

The most common sepsis symptoms found in infants are presence of a fever (greater than 38 degrees), hypothermia (less than 36 degrees), abnormal pulse (fast, diminished, weak or bounding), abnormally rapid breathing (tachypnea), slow capillary refill especially in limb extremities, low blood pressure (hypotension) and low blood oxygenation (5). Rapid heart rate and rapid breathing are commonly found in infants from 0-12 months for a multitude of reasons, and would likely not constitute enough to diagnose sepsis, unless occurring for a prolonged period of time and with other sepsis symptoms (5). Heart rate observation (HeRO) monitoring is another assistive technology that has been used in the NICU in many U.S. hospitals to combat premature sepsis. This technique uses ECG monitors to detect standard deviation of the inter-heartbeat, sample asymmetry, and sample entropy, in order to detect early symptoms of sepsis so they can be addressed before they become detrimental (5). This unfortunately would not be feasible for long term monitoring of an infant due to the size of the ECG monitor, and because it does not provide all of the evident data needed to diagnose sepsis without additional medical tests. The Kaiser Neonatal Sepsis Calculator is an additional tool that is used by practitioners to determine the risk of early onset sepsis for infants based on baseline statistical criteria (6). This tool could alleviate some anxiety for parents and could warn those whose infants might be more susceptible to sepsis. However, it lacks in its ability to track real time data that could alert a parent immediately if their infant is showing symptoms of sepsis. Through the sources previously cited, and consultation with stakeholders in the project, we determined three overarching topics which should be addressed are: User/Stakeholder, Function, and Safety-related objectives. During the Q&A session, Dr. Kuo stated that a caregiver would prefer a device that makes decisions for them and can detect symptoms of sepsis whenever and wherever sepsis can take place. Research on safety requirements for infant's products has also revealed tolerable dimensions and noise level of the device. Through discussion with Dr. Teressa Wu, a pediatric physician at the Alberta Children's Hospital, we determined clear needs for a sepsis monitoring device. Firstly, Dr. Wu clarified how the diagnosis, as discussed previously, is a labor intensive and emotionally strenuous task. As the symptoms of sepsis are comorbid with a plethora of other illnesses, practitioners will immediately diagnose infants with sepsis if they display any of the symptoms. This is very strenuous for both practitioners and guardians, as guardians are immediately alarmed by the worst case scenario and practitioners rush to do clinical tests that are time and resource consuming. Although the survival rate of infants with sepsis is 83% (7), of those that survive 1 in 3 experience an impact in cognitive ability (8). This impact is greatly lowered when symptoms are caught early, again adding stress to parents and practitioners to catch the symptoms and find a diagnosis quickly (9). These statistics clearly show why a monitoring device would be beneficial within this process, as it would provide practitioners with extremely valuable data that can be used as a tool to diagnose sepsis. Additionally, this gives guardians peace of mind, as they can be confident that initial symptoms will be detected as early as possible, with real time rapid results.

**Identified needs**

| Need Number | Type | Need and Details | Source |
|---|---|---|---|
| **1.** | **User/ Safety** | The device must provide clear, direct, and efficient instructions that outline the next steps of action if symptoms of sepsis are detected. This will aim to relieve the guardian from having to make an informed decision on their infant's health. The device must notify the guardian if symptoms of sepsis are detected. | (10) |
| **2.** | **User** | The device is easy to set up in a short amount of time and once it is set up it is easy to interface with. | (10), (11) |
| **3.** | **Function** | The device will determine symptomology of sepsis based on data collected from the infant over an extended period of time. The device should be able to monitor the symptoms of sepsis at minimum when guardians are not in close proximity to the infant (out of the house, while the infant is sleeping, or if the infant is out of view for more than 10 minutes). | (12) |
| **4.** | **Function** | The device must measure the most critical symptoms of sepsis. The device should also be able to differentiate signs of sepsis from healthy conditions. | (13) |
| **5.** | **Function** | The device is lightweight and compact, and portable. | (10) |
| **6.** | **Function** | The device is adjustable and the size changes throughout the development of the infant. The device must fit the infant and be functional for at least one year. | (10) |
| **7.** | **Safety** | The device should not interfere with the infant's mobility or safety. This implies that the device should not inadvertently or unnecessarily inhibit the infant's movement. The device should not be easily removed/rendered nonfunctional by the infant. It must operate at a safe noise level. Parts must be large enough so as to not be a choking hazard. | (14), (15) |
| **8.** | **Safety** | The device should be durable, waterproof, and biocompatible. It must not have exposed wiring and the device should use materials that are comfortable and safe. | (16), (10) |

# *DHF 2: Setting requirements*

**Statement of Need**

A device to continuously monitor and report early signs and symptoms characteristic of sepsis in infants up to 1-years old.

*This statement of need was revised to be more concise and to focus on the "one need". Based on our needs finding (DHF 1), we have determined this need to be the identification of signs and symptoms of sepsis in infants. (DHF 1, need 3).

**Requirements**

| Number | Associated Need Number | Property | Requirements | Justification |
|---|---|---|---|---|
| **1** | **3** | **Battery life (How long can the device monitor the infant)** | Portable devices should be able to function >= 8 hours on one full charge of a brand new, unused battery. | While unlikely with an infant, if there are no interruptions, the average adult can be expected to sleep for 7-8 hours every night (17). During this time, parents are not able to watch over a sleeping infant, hence a portable device should at least be able to function during that time. |
| **2** | **3** | **Detection frequency** | The device's sensor data is collected at least once every 5 seconds. (Refers to rate of measurement)<br><br>*Fixed typo (minutes -> seconds) and clarified that sensor data is collected every 5 seconds. | On the ecg companion app for the apple watch, the data collection rate for heart rate is once every 5 seconds by default (18). This will be assumed as the industry standard for wearable, consumer-grade vital monitors. |
| **3** | **8** | **Waterproofing** | The device should at least be rated at ip-x4 after testing | On the ingress protection (IP) marking system, there is a scale for durability and waterproofing. The 4 signifies that the device is protected against splashes of water which would be the most common form of getting wet (19). |

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| **4** | **8** | **Biocompatibility** | Wearable material must not irritate or cause discomfort to the skin of at least 85% of infants.<br><br>*Made requirement more quantifiable; expanded justification. | Around 17% of infants are affected by atopic dermatitis (eczema) in the first 6 months of life (20). The wearable device must at least be non-irritative to infants who do not suffer from a skin condition.<br><br>Infants' skin is very sensitive and prone to rashes (21). |
| **5** | **8** | **Durability** | The device's rate of correctly identifying signs of sepsis (sensitivity) must be at least 75% after being dropped from a height of 37.5 cm.<br><br>*Added a quantifiable explanation to what a "functioning device" is post-drop. Expanded requirement justification to satisfy quantities. | 37.5 cm is half of the average height of a 1 year old infant (22). Being dropped from this height simulates the infant falling or dropping the wearable device. The percentage was chosen according to (23), where over 4 years, the sensitivity value of EMS assessed cardiac symptoms for the diagnosis of acute myocardial infarction (AMI) was 75%. The accuracy rate of AMI diagnosis was chosen due to it being best diagnosed by a medical monitor (ECG) like this device. (24) |
| **6** | **4** | **Accuracy in detecting symptoms of sepsis** | Any sensors used should have an accuracy rate equal to the industry standard.<br><br>For body temperature sensors, the accuracy rate is 57%.<br><br>*Changed "Accuracy in detecting sepsis" to a requirement which specifies sensor accuracy. This is much easier to quantify and still reflects the need to accurately detect the warning signs of sepsis.<br><br>Note: the ability of our device to differentiate the infant's conditions as a whole (sensors, software, notification system) is still covered by the following requirement, false positives. | All sensors used must at least meet the industry standard accuracy rate. Not meeting this threshold would impair our solution to our statement of need. Having a sensor with a lower accuracy is not acceptable because this device is monitoring for life-threatening symptoms, and therefore it should be at least as accurate as any regularly available sensor.<br><br>For body temperature sensors, the "industry standard" was chosen to be contactless digital thermometers because they have the lowest accuracy of commonly relied-on body temperature sensors. (25) This accuracy rate was found to be 57%. (26) |

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| **7** | 4 | **False Positives**<br><br>*Updated definition for what defines a healthy condition, including the applicable sources. | Under healthy conditions, the device does not generate false alarms more than 38% of the time from a total testing pool of 50 trials within the span of a year. Healthy conditions are defined as a body temperature below 38 degrees celsius (27), heart rate below 160 bpm (28), and blood pressure above 71/36 (27). | False positives may lead to 'alarm fatigue'; when signs of sepsis are actually found, the guardian is less likely to take action. This could create a major health concern for the infant.<br><br>Previous studies have shown that false positives can occur in up to 38% of cases in the emergency room, so this requirement will allow false positives to occur up to 38% of the time in emergency situations (29).<br><br>"Healthy conditions" have been derived from the following sources:<br>Heart and Respiratory Rate: (28)<br>Body Temperature and Blood Pressure: (27)<br>Blood Pressure: (30) |
| **8** | **2** | **Separate Components** | The final functioning device after assembly does not contain more than 3 physically separate components. | While some separable components are okay, more than 3 individual parts will make the device hard to deal with and potentially not worth the effort to the guardian.<br><br>A maximum of 3 was chosen as the threshold value by analysis of current infant monitor solutions, which may for example utilize a camera, screen monitor, and remote. |
| **9** | **7** | **Removability or deconstruction by the infant.** | The device must be able to function completely (all sensors and systems hold accuracy to industry standard) if 50N of pushing or pulling force is applied. | If the device can be removed or stopped by the infant there is a health concern if sepsis is developed when the device is turned off. This also poses a safety concern to the infantas deconstruction of the device could expose electrical components or lead to choking.<br><br>Some designs may allow for the device to be placed out of reach of the infant which fulfills the need. In the case of a wearable, the approximate weight of a 12-month infant is 10kg (22). To simulate forces of squirming and pulling off the device, approximately half of this average weight (5kg ~ 50N) was chosen as a threshold value. |

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| **10** | **1** | **Emergency instructions** | When the device detects emergency vital signs (which can be precursors to sepsis), it sends a notification to the guardian to go to the hospital in the case of an emergency.<br><br>Emergency vital signs in infants are defined as a fever of 38C or higher, blood pressure below 71/36 (27) and heart rate above 160 bpm (28) | When humans are faced with stress, a physiological response occurs in which prefrontal cortex signaling is impaired. This can result in an inability to think clearly and make logical decisions. The knowledge that an infant may be gravely ill would most likely produce an intense stress response, so it is important to give parents or caregivers clear directions for what to do next when an infant is at risk of sepsis (31). |
| **11** | **2** | **Easy setup** | Large devices should take at most 75 minutes to set up. | Taking too long to set up a device may lead to frustration in caregivers, and could result in the device not being set up.<br><br>Maximum time to set up a device was decided based on average time to set up various furniture items (32). This should be the maximum amount of time needed to set up any device. Including both physical and digital setup. |
| **12** | **2** | **Understandable Notifications** | Device text/notifications should be written in simple English with instructions that are understandable by individuals with IELTS reading score >4. | This device should be accessible to all people regardless of language gaps. This means that it should be accessible to people with limited english. Notifications must be grammatically correct and not use jargons (33). An IELTS reading score of 4 is defined as someone with "a very basic understanding of English and [they] are more comfortable communicating in familiar situations." (34) |
| **13** | **5** | **Weight** | Devices should weigh less than 7kg. | This is a common weight restriction for carry-on baggage on planes (35). |

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| **15** | **5** | **Length** | Length should be less than 55cm | Length will be defined as the object's longest measurement, width will be the second, height will be last<br><br>These are the maximum dimensions of the baggage that can be carried on board an Air Canada plane (36). These are the bare minimum for a device to be portable and are used here to indicate compactness. |
| **16** | **5** | **Width** | Width should be less than 40 cm | |
| **17** | **5** | **Height** | Height should be less than 10 cm | |
| **18** | **7** | **Background noise** | The device should produce background noise quieter than 45 dB. | This is the normal noise inside an incubator in the NICU (14). |
| **19** | **7** | **Alert volume, safety** | Emergency alert noise should remain below 120 dB | Noise louder than this can cause gradual or even permanent hearing loss (37).<br>120 dB is the loudest volume fire alarms reach, and though long-term exposure may be damaging, the short-term risk has been deemed safe (38). |
| **20** | **7** | **Dimensions, safety** | The device must conform to 16 C.F.R. § 1501, 1500.18 (a)(9), and 1500.50, 51, 52. | These are sections from the Code of Federal Regulations outlining the minimum size of small parts in infant's products; the device should not choke the infant (39). |
| **21** | **6** | **Dimensions, adjustability** | The device is usable on a 50th percentile newborn infant up to a 50th percentile 1-year old infant. | This is the anthropomorphic table for infants that are newborns to 1 years of age (40). These dimensions are determined by the lowest measurement of a newborn to the largest percentile dimension of a 1 year old to encapsulate all sizes from 0-1. |

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| **22** | **1** | **Sensory Notifications** | Urgent notifications should have notification in two sensory cues. | Notifications that require immediate attention should have two methods of reaching the guardian. This allows room for a “failsafe” notification method if the main method does not work. |

## Evaluation Criteria

| Criteria Number | Associated Requirement Number | Property | Evaluation Criteria | Justification |
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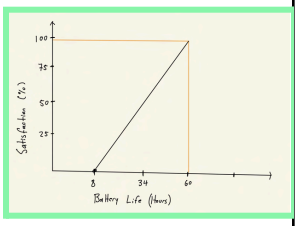
| **1** | **2** | **Battery life** | On a single charge, how long does the monitor run?<br>- Linear curve<br>- 8 hour = 0%<br>- 60 hour = 100%<br>  <br>See Appendix B for larger image of graph | Under these assumptions:<br>- Portable devices runs on rechargeable batteries<br>- There are 2 sets of batteries<br>- 1 set is in the device, while the other is charging<br><br>These assumptions allow for the time between charges to be negligible. Criteria is for frequency of battery change (convenience)<br><br>A linear curve was chosen so that no difference in satisfaction would occur if the device functioned for 9-10 hours, vs if the device functioned for 10-11 hours.<br><br>Maximum satisfaction is achieved at at least 60 hours per charge, allowing for constant monitoring with minimal battery changes (41), based on the gold standard for apple watch recharging.<br><br>Minimum satisfaction is at 8 hours as the average adult sleeps 7-8 hours per night and this would allow the device to monitor the infant while the guardian sleeps (17). |
| **2** | **2** | **Waterproofing** | On 2nd number of Ingress Protection scale<br>- Discretized S-Curve<br>- Min IP-x4<br>- Max IP-x9<br>- Steepest increase (inflection point) present at IP-x7 | The Ingress Protection (IP) scale is generally used when designing water-resistant/proof devices. The number refers to the level of protection the device has against unique tests. IP-x4 is the lowest rating to be considered water-resistant (can still function after a splash of water), while IP-x9 is the highest, still functioning after high pressure, close range spraying. The scale depends on passing tests, so a discrete satisfaction curve is used.<br><br>We chose IP-x7 as the inflection |

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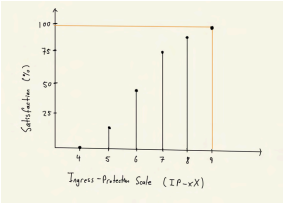
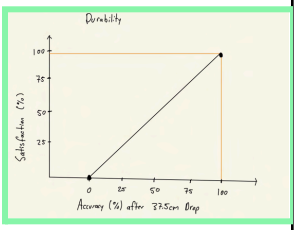
| | | |  <br>See Appendix B for larger image of graph | point on the satisfaction curve as it represents submersion in water, which is likely the highest water resistance that would be needed in everyday life (42). |
| **3** | **6** | **Durability** | How will device sensitivity be affected after a 37.5 cm drop?<br><br>- Linear<br>- Min at 75% accuracy<br>- Max at 100% accuracy<br><br>  <br>See Appendix B for larger image of graph | A linear satisfaction curve was used so that the difference in satisfaction between 2 sets of 2 points would be proportional.<br><br>There would be no diminishing returns if the device were to reach 100% sensitivity.<br><br>The minimum sensitivity comes from requirement 5. The maximum sensitivity is 100% as it is the highest accuracy a device could have, which would yield the most satisfaction.<br><br>The height of 37.5 cm was chosen as it is the shoulder height of a 50th percentile male (43). This is to simulate falls, and ensure durability. |
| **4** | **7** | **Accuracy in detecting symptoms** | Sensor accuracy<br><br>Linear graph<br>Minimum: Industry standard accuracy for sensor (different for each type of sensor)<br>Maximum: Gold Standard (26)<br><br>Because this evaluation criteria depends on the sensors we decide to use, it will have different bounds depending on the sensor. We have decided to make the below graph for a temperature sensor.<br><br>Lower Bound: 57%<br>Upper Bound: 85% | It is of critical importance that sensors accurately measure the infant's physical characteristics such as heart rate, temperature, or blood pressure at all times.<br><br>A linear curve was chosen for the satisfaction graph as industry standard is already good enough to pass legal tests, so increasing the accuracy above industry standard would only linearly increase satisfaction.<br><br>For temperature sensors:<br>The "industry standard" thermometer is a contactless digital thermometer, as these have the lowest-accuracy readings while still being commonly relied on for body temperature measurements (25).<br>The accuracy rate was found to be 57%. |

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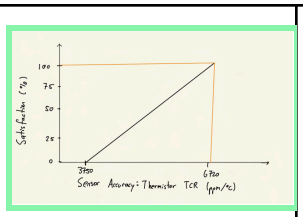
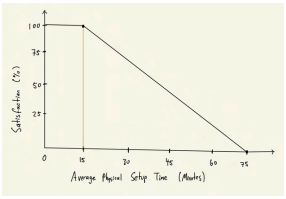
| | | |  <br>See Appendix B for larger image of graph | (26) The “gold standard” is a mercury rectal thermometer. (25) The accuracy rate was found to be 85%. (26) |
| **5** | **11** | **Easy device setup** | Linear<br>Range [15-75]<br><br>Max satisfaction at time = 15 min or below<br>0 satisfaction at time = 75 min or above<br><br>These times would ideally be evaluated based on the average setup time taken for a test group of users (determined when the product is complete).<br><br>  <br>See Appendix B for larger image of graph | These curves are linear as initial satisfaction with a device is typically correlated with less time spent setting it up.<br><br>Devices should take less time to set up, as they should arrive without much assembly needed (smaller parts are harder to assemble).<br><br>Maximum satisfaction occurs at 15 minutes which is the average time taken to set up an iPhone (44).<br><br>The minimum satisfaction occurs at 75 minutes (or the maximum time allowed for setup, which is our requirement 5). Maximum time to set up a device was decided based on average time to set up various furniture items (32). This should be the maximum amount of time needed to set up any device. Including both physical and digital setup. |

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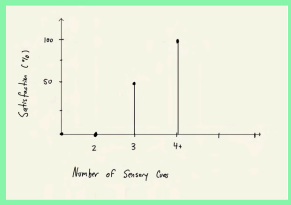
| **6** | **22** | **Emergency Notification** | The device sends notifications using multiple sensory cues or methods:<br><br>Discrete:<br>2 Forms : 0%<br>3 Forms: 50%<br>4 Forms: 100%<br><br>  <br><br>See Appendix B for larger image of graph | More methods of notification will correlate with a higher success rate in alerting the guardian. This allows for immediate action on the guardian's part when symptoms of sepsis are detected in the infant.<br><br>A discrete function reflects the nature of this criteria. The minimum of 2 forms of notification is the base requirement as it allows for a backup in case one method fails. The maximum of 4 forms reflects the ways in which an Apple watch (industry standard) alerts users in life-threatening situations such as when crash detection is triggered (45).<br><br>Notifications can be visual (phone notification), auditory (alarm), sensory (vibration) and visual (flashing light) |

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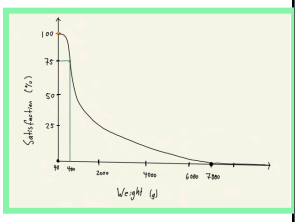
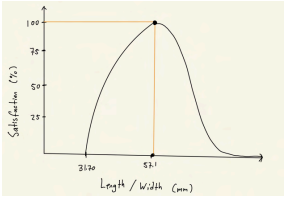
| **7** | **16** | **Weight** | Asymmetric S-shaped curve<br>Range [40 g , 7000 g]<br>Max satisfaction at 40 g<br>Min satisfaction at 7000 g<br>Inflection point: 400 g<br><br>  <br><br><br>See Appendix B for larger image of graph | In this requirement, we wanted to ensure that non-wearable devices were not eliminated. However, wearable devices would be ideal as these would be able to monitor the infant more regularly.<br><br>Due to this, we decided on an S-shaped curve, where lighter devices score higher. We selected 400g as the inflection point as devices lighter than this will likely be wearable and will score exponentially higher than heavier devices. This was determined as Holter monitors typically weigh 1 pound which is approximately 400 grams (46).<br><br>Maximum satisfaction is achieved at 40 g when the device is about the same weight as one layer of clothing (47). This would be a comfortable weight for an infant as it is a weight that they comfortably bear on a daily basis, and going lighter would not serve much purpose.<br><br>Minimum satisfaction is achieved at 7000 g as our requirement specifies a weight of 7000 g or less. |
| **8** | **17, 20** | **Length** | Asymmetric optimum<br>Range [3.17cm, 55 cm]<br>Max satisfaction at 5.71cm<br><br>  <br><br><br>See Appendix B for larger image of graph | Here we define the length as the longest dimension of the device.<br><br>We chose the optimum curve for length because although smaller devices are more favorable, due to Federal Regulations on small parts in children's products, there is a limit to how small they can be. The maximum is chosen as such because with at least one dimension greater than 57.10 mm, the device is unlikely to choke the infant (39).<br><br>The two end points are the minimum and maximum size outlined in the requirement. |

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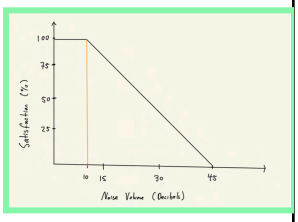
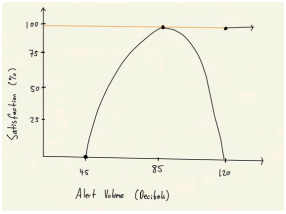
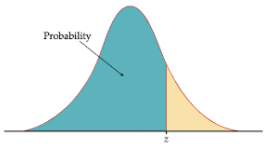
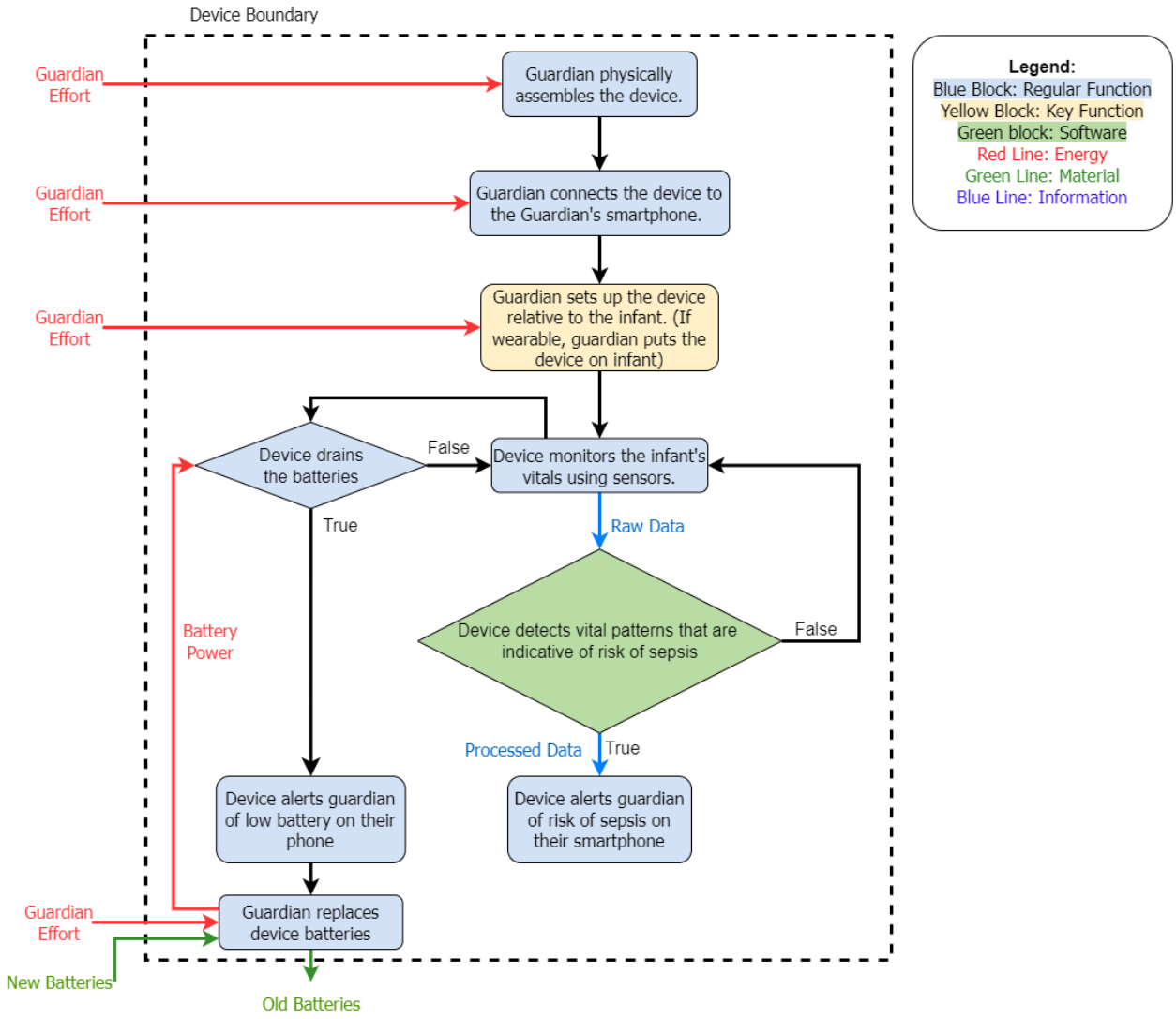
| **9** | **18** | **Maximum background noise** | Linear<br>Range [10, 45]<br>Max satisfaction at 10 dB<br>Min satisfaction at 45 dB<br>  <br>See Appendix B for larger image of graph | A linear curve was chosen because the difference in satisfaction between values does not vary much between the upper and lower bounds.<br><br>Maximum satisfaction occurs at 10 decibels. This is the average sound level produced by someone breathing (48)<br><br>Minimum satisfaction occurs at 45 decibels. This is the average sound of an incubator inside the NICU (14) |
| **10** | **19** | **Alert volume** | Optimum<br>Range [45, 120]<br>Max satisfaction at 85 dB<br>  <br>See Appendix B for larger image of graph | We have chosen a concave curve with maximum satisfaction occurring at 85 dB<br><br>45 dB is chosen as the lower bound because at the bare minimum, the alarm must be louder than its background noise. This is minimum satisfaction<br><br>120 dB is chosen as the upper bound as this is the loudest volume fire alarms reach, and though long-term exposure may be damaging, the short-term risk has been deemed small enough when balanced with the potential consequences (38).<br><br>Maximum satisfaction occurs at 85 decibels as long-term exposure to sounds above 85 decibels can begin to cause hearing loss (49). We want the alarm to be as loud as it can get without the potential for hearing loss. |
| **11** | **21** | **Adjustability** | Gaussian distribution curve<br>Range [0-100]<br>Max satisfaction at 100% population | Was assumed infant size across population can be modeled by a gaussian distribution curve. This curve was used to generate our satisfaction curve (Appendix C).<br><br>See appendix C for exact calculations.<br><br>Our graph is based on a gaussian distribution curve from infant |

| | | | | |
|---|---|---|---|---|
| | | |  <br>Standard Normal Distribution<br><br>See Appendix C for more details on graph. | measurements from ages 0-1 years old.<br><br>0% satisfaction is achieved for devices usable only by 50th percentile infants.<br><br>66% satisfaction is reached at the inflection point which represents 66% of the population<br><br>100% satisfaction at reaching 100% of the population. |

# *DHF 3: Concept selection*

## Part 1: Function Structure




**Function Structure Diagram***

**Link:**

**[https://drive.google.com/file/d/1rMe9ZBrD3Vy_4GqB4z69PF58YgnseMJ9/view?usp=sharing]**

*This function structure was updated to improve the clarity of our diagram. Firstly, the functions are rearranged to highlight which of them are in sequence and which are in parallel. Secondly, some of the functions are split or simplified, so each box contains only one function. An example of this is the “Device monitors the infant’s vitals”; additional information describing requirements for this function were removed. Another example would be “Device alert guardians

if risk of sepsis is detected by the sensors". This function was split into a diamond box and subsequent functions for different scenarios. Thirdly, some functions were deleted because we later decided they were not a function of our device. Finally, the color code was altered as we no longer have functional requirements.

Key Function**:** Guardian sets up the device relative to the infant. (If wearable, the guardian puts the device on the infant).

# Part 2: Concept Generation

Putting the device in close proximity to the infant is the selected key function for this project. We chose this because device interface with the infant ultimately dictates the safety of the infant. Additionally this function is critical to determining major design decisions for future development, as the device's end requirement is noticing and alerting symptoms of sepsis.

**Concept Generation Process**

Our team started with a concept sketch session in which each individual was tasked with sketching a design that would satisfy function 1. A 10 minute period was set for each individual to draw their ideas. We then discussed these ideas, attained feedback and underwent another ten minutes sketching period to add to each design. This allowed us to attain fruitful results, which can be seen in appendix D. We then collaborated upon these devices to determine 10 final designs, inspired by the concepts generated in the sketching period. These designs are detailed below.

# Half Tank

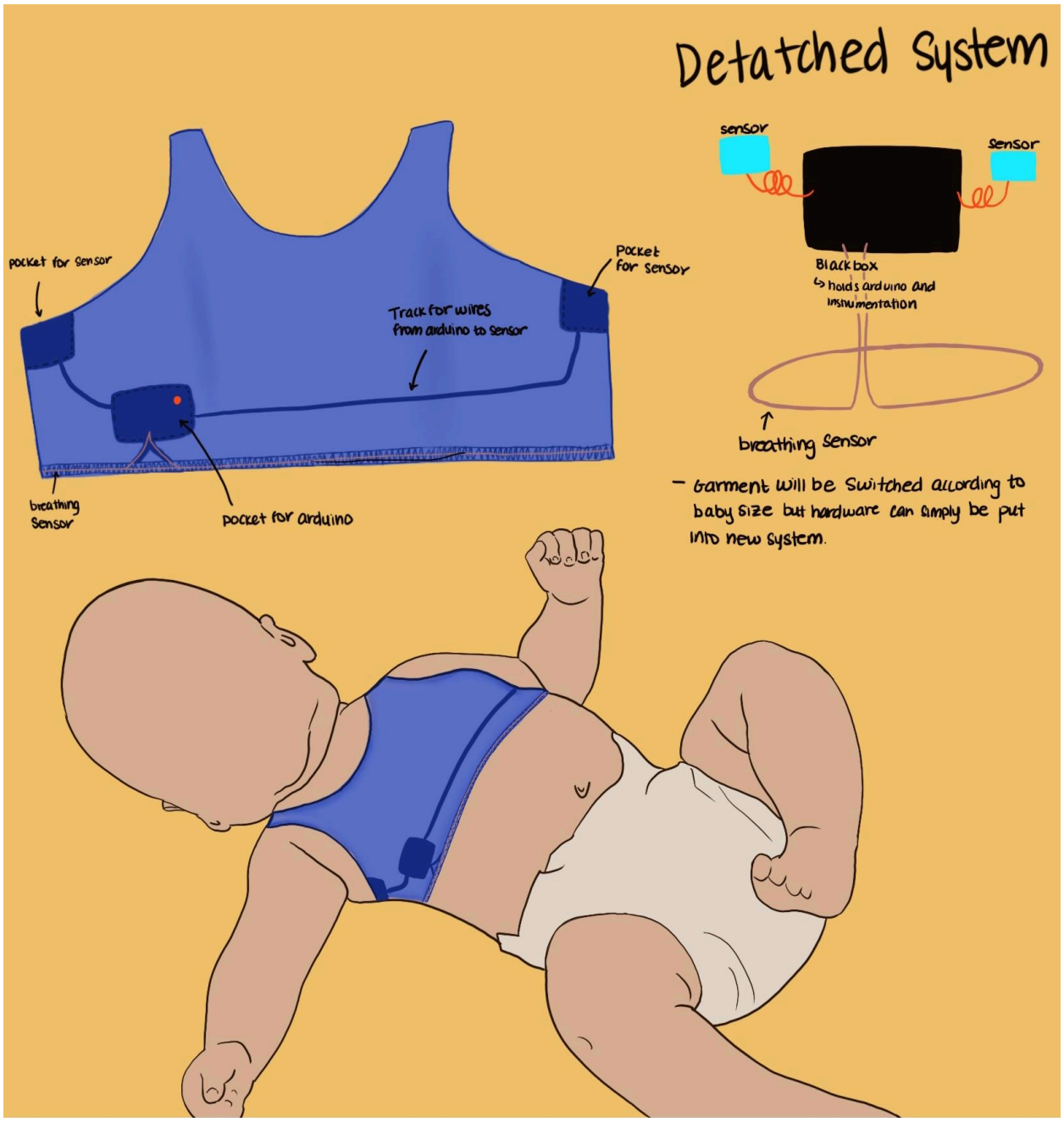



**Figure 1:** Involves a bandeau top with pockets to hold hardware. The sensors and hardware can be easily removed so that the top can be washed and all electronic components would be encased for safety. This satisfies need 7 and 8 as the concept includes means to ensure safety. Additionally, different sizes of top could be purchased as the infant grows, and the hardware can be easily placed into the newly sized top, satisfying need 6 “the size changes throughout the development of the infant”. Sensors are placed under the armpits and around the belly, to account for need 4 “The device must measure the most critical symptoms of sepsis” . The arduino and other instrumentation (black box) is placed on the front of the body also enclosed in a pocket so that the infant is not bothered by them. This satisfies need 7 “The device should not interfere with the infant's mobility or safety”. This concept also addresses need 5 as it is lightweight and compact.  This concept was inspired by concept A1, in appendix A.

# Chest Band

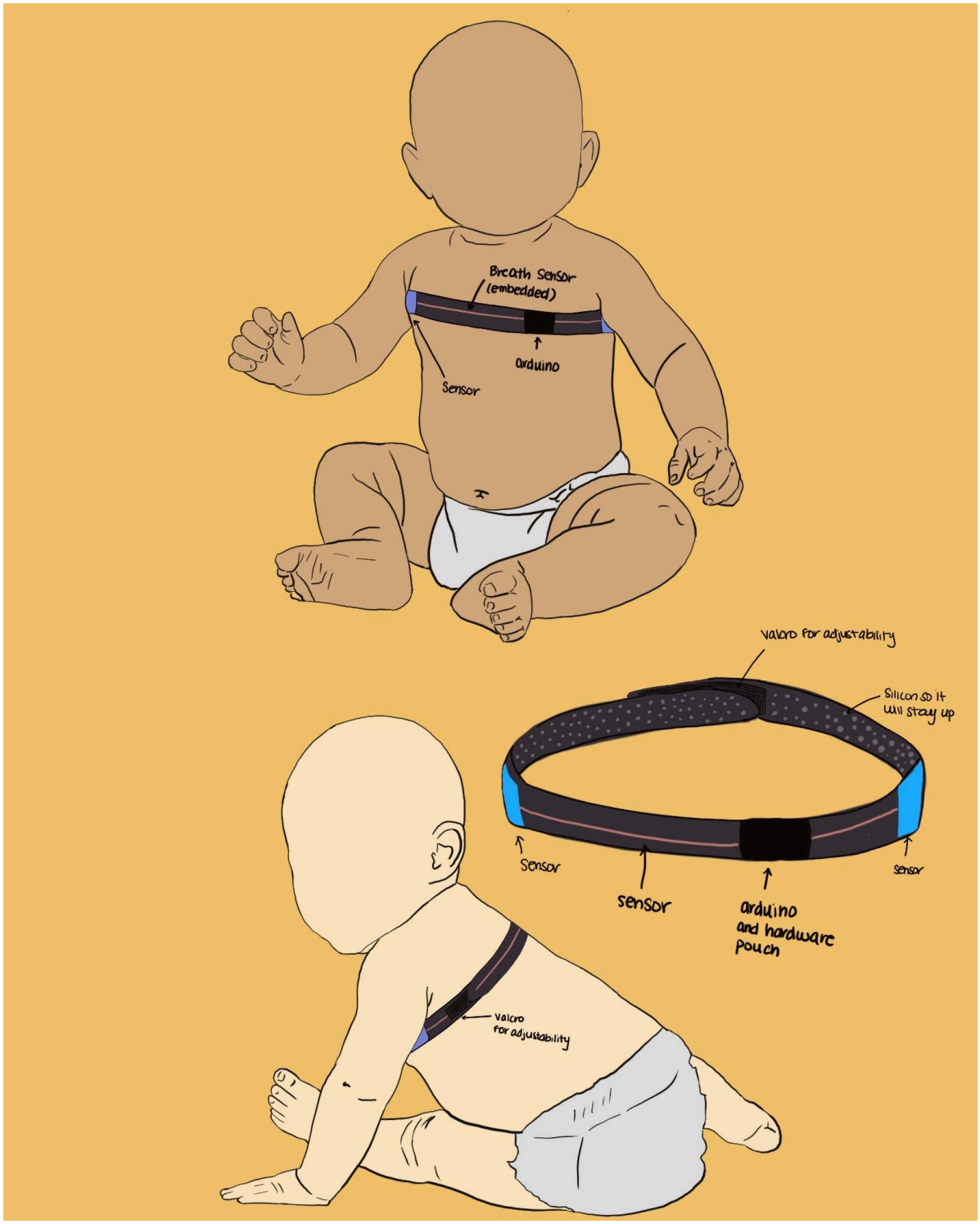



**Figure 2:** Slightly compresses the chest with sensors under the armpit and around the chest. This is to address need 5 “device is lightweight and compact” but may sacrifice elements of need 7 “should not interfere with infant's mobility”. Sensor placement is specific to satisfy need 4 “determine symptomology of sepsis”. Arduino and hardware are placed in a pouch on the front, again to try and meet need 7. Includes velcro for adjustability and silicon beads to keep the sensor in place, to meet need 6. This design was inspired by concept A4 in appendix D.

# Chip

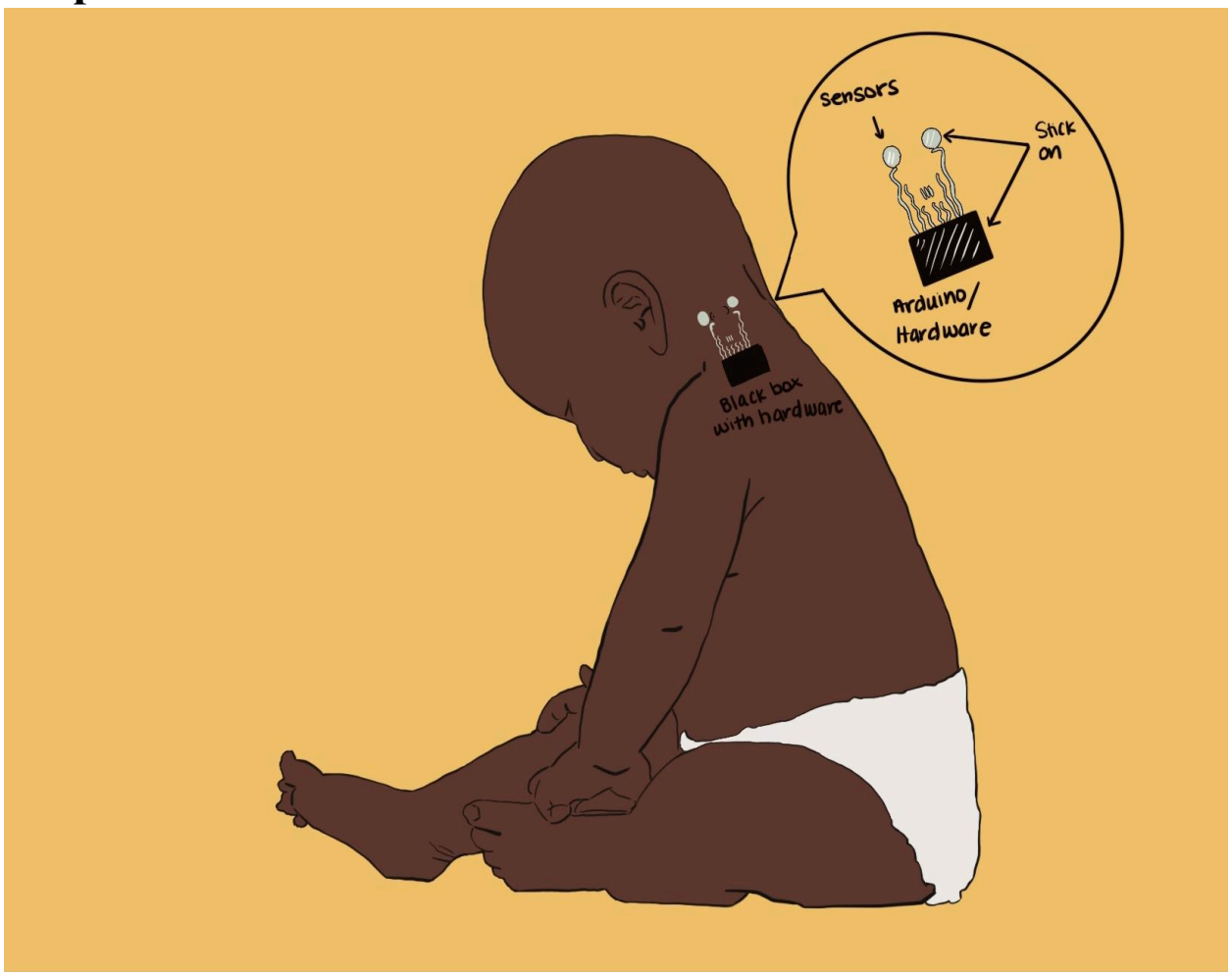



**Figure 3:** The chip is a stick-on device that has a sensor placed across the neck. This is placed directly on the skin and would be biocompatible to fit need 8: “device should be durable, waterproof, and biocompatible”. Arduino and hardware would be placed below the sensors and also stick onto the skin. The placement would ensure that need 4 be met “The device must measure the most critical symptoms of sepsis”. The device should also be able to differentiate signs of sepsis from healthy conditions. Due to the device being small and independent of the growth of the infant, need 6 would also be met. There are however elements of need 7 “The device should not be easily removed/rendered nonfunctional by the infant. It must operate at a safe noise level. Parts must be large enough so as to not be a choking hazard.” that are not met by this device. There is potential that this device is not safe for infants as it may pose a choking risk. Additionally it could easily be rendered nonfunctional if not designed correctly.

# Wristband

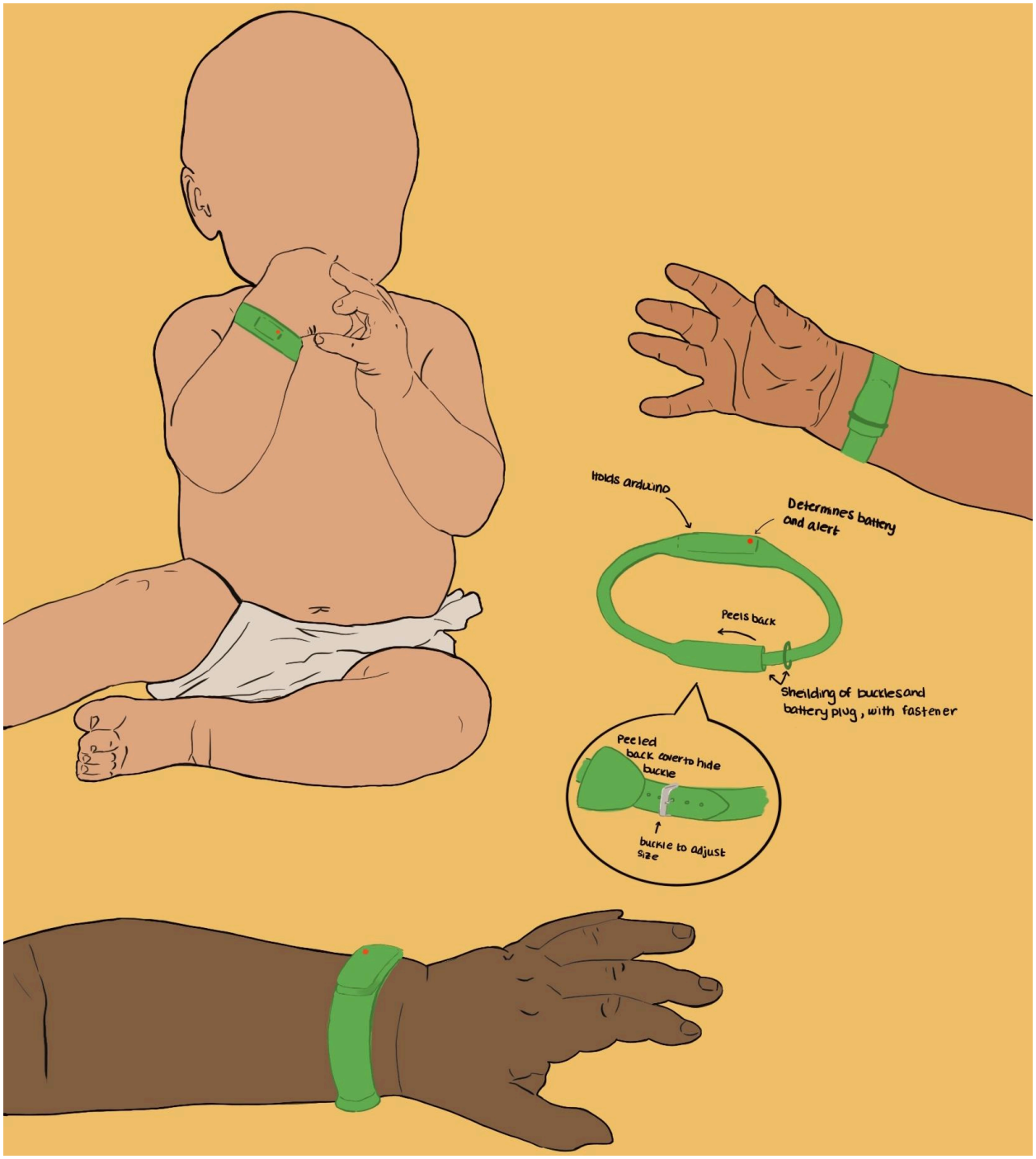



**Figure 4:** A device that is placed on the wrist with sensors that could be placed anywhere along the band. This provides freedom to satisfy need 4 “The device must measure the most critical symptoms of sepsis” as sensors could be placed anywhere on the wrist. Arduino and hardware are placed at the top of the wrist (to meet need 7 “The device should not interfere with the infant's mobility”) and adjustment mechanisms are on the bottom (to meet need 6 “The device is adjustable and the size changes throughout the development of the infant”). Adjustment mechanisms have a cover to shield removal and provide comfort (for need 7). This design was inspired by concept A2 and A7 in appendix A.

# Leg Band

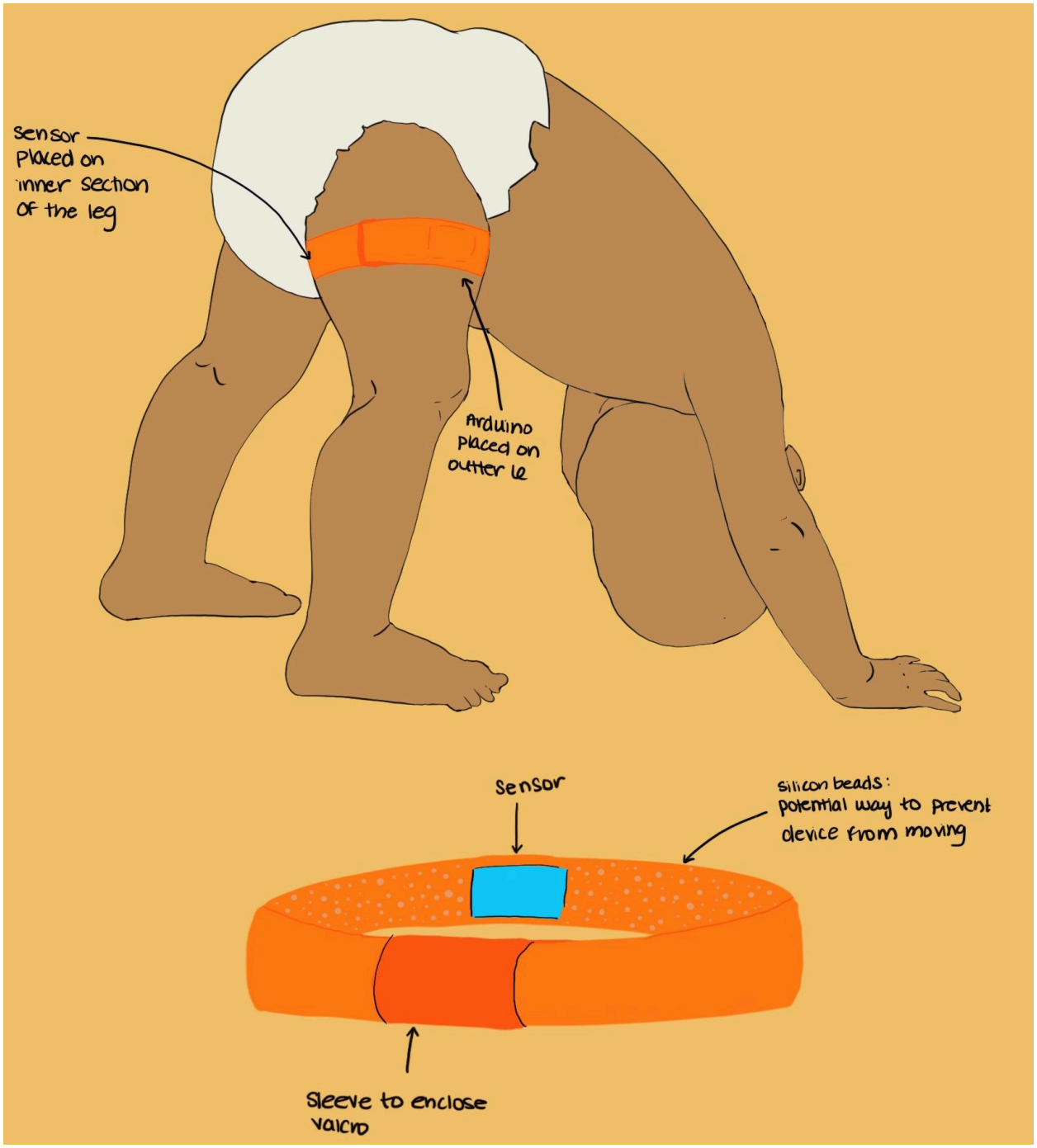



**Figure 5**: Sensor placed on the inner leg with adjustable mechanism on the outer leg. This is to satisfy needs 4,6, and 7 “The device must measure the most critical symptoms of sepsis”, “The device is adjustable and the size changes throughout the development of the infant” and “The device should not interfere with the infant's mobility or safety.” respectively. This design has a sleeve to cover velcro so that it is adjustable, comfortable, and sleek to meet need 7. Silicon beading would also be placed on this device to keep it in the same location. This design was inspired by the Chest Band and concept A4 in appendix D. Again this device may interfere slightly with need 7 as it could irritate or cause mobility impairments to the infant.

# Arm Band

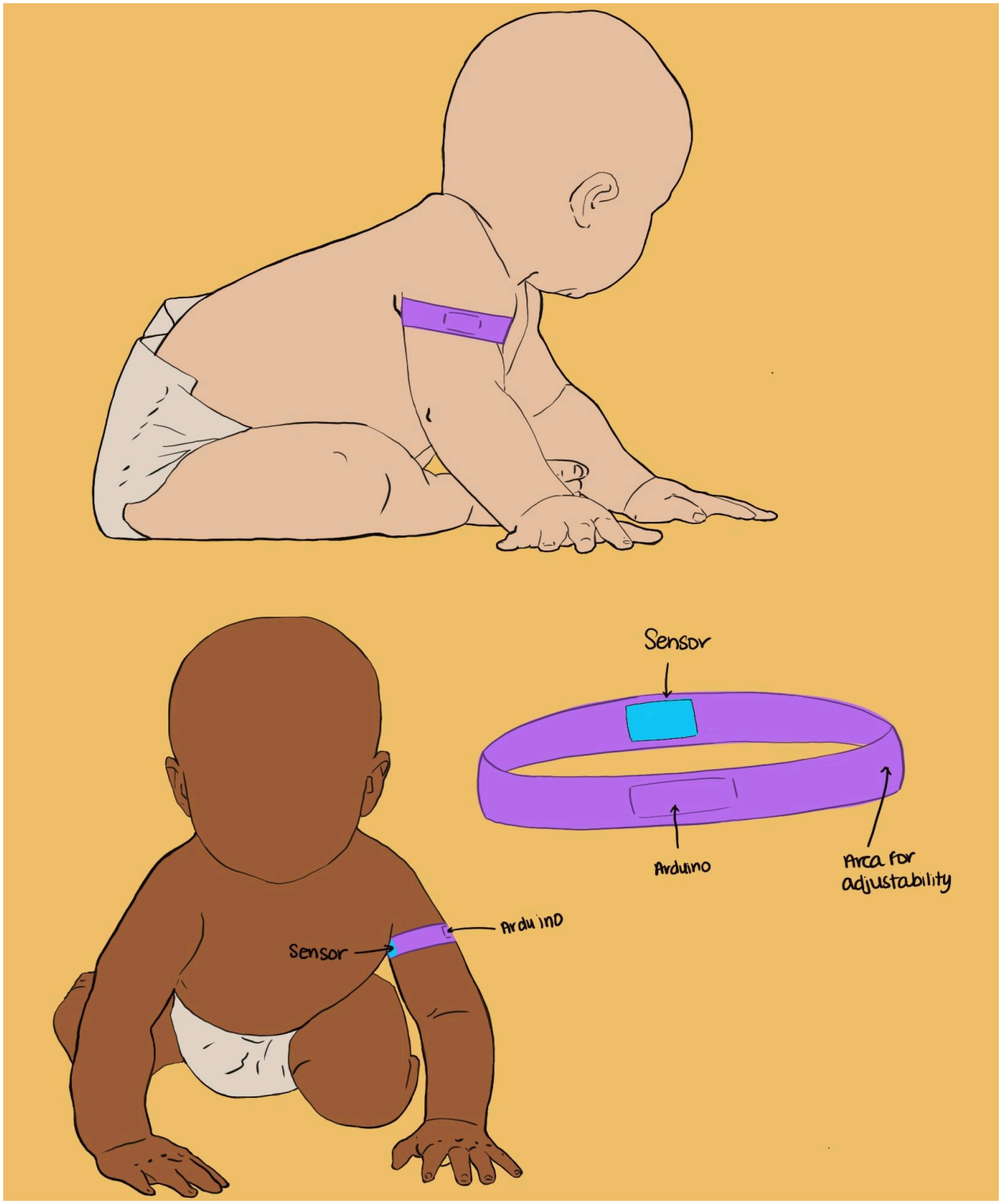



**Figure 6:** This device has the exact same mechanism as figure 5 but is instead placed on the upper arm with sensors placed in the armpit. This is critical for the ability to measure an accurate temperature. This was modified slightly from design 5, and would therefore have the same pros and cons.This design was inspired by the Chest Band and concept A4 in appendix D.

# Diaper Clip


**Figure 7:** Although subject to change, the general idea for this concept is a clip that is locked onto the diaper. The device holds the hardware and arduino within the device with a sensor that would lie flush on the abdomen or back of the infant. This was done to meet needs 5 “The device is lightweight and compact”, and 7 “The device should not interfere with the infant's mobility or safety”. Additionally, the device completely satisfies need 6 “The device is adjustable and the size changes throughout the development of the infant” as it will clip on to any garment as the infant grows. One con of this design is it may not satisfy need 4 “The device must measure the most critical symptoms of sepsis” and need 7 “The device should not be easily removed/rendered nonfunctional by the infant”. Due to the placement being slightly wavering, and sensors potentially not being in contact with the skin at all times, need 4 may not be satisfied all of the time. Additionally, its placement may allow the infant to easily remove it, if not designed well. This design was a slight modification on design A3 in appendix A.

# Helmet

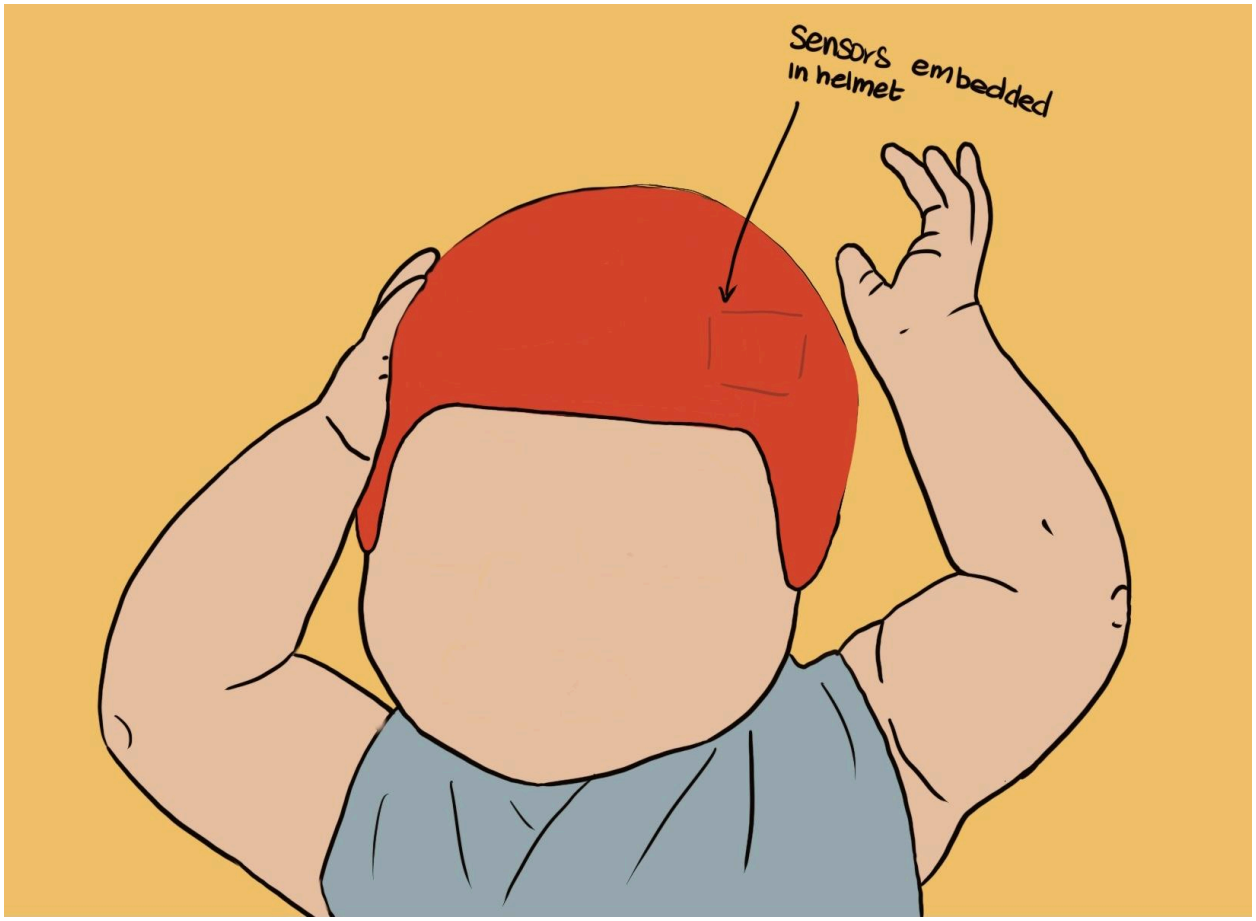



**Figure 8:** This design is very simple. Sensors would be placed within a helmet with hardware integrated inside. ECG's could potentially be placed within this device for further measurements. A knob on the back of the helmet is included to tighten or loosen a plastic strip inside, which molds the helmet to the shape of the infant's head (not pictured). This design satisfies need 4 "The device must measure the most critical symptoms of sepsis" with great certainty. Many helmet like devices are currently on the market to measure vitals of infants, similar to the ones we would need to monitor to detect sepsis. This device also meets need 8 "The device should be durable, waterproof, and biocompatible". The cons of this device however, are seen in its inability to fully satisfy needs 5, and 7 "The device is lightweight and compact", and "The device should not interfere with the infant's mobility or safety" respectively. It would take a lot of technical design to create a helmet that includes all of the sensors necessary and is also lightweight, this is a con related to need 5. The device may also impact the infant's mobility due to this factor.

# Crib Clamp

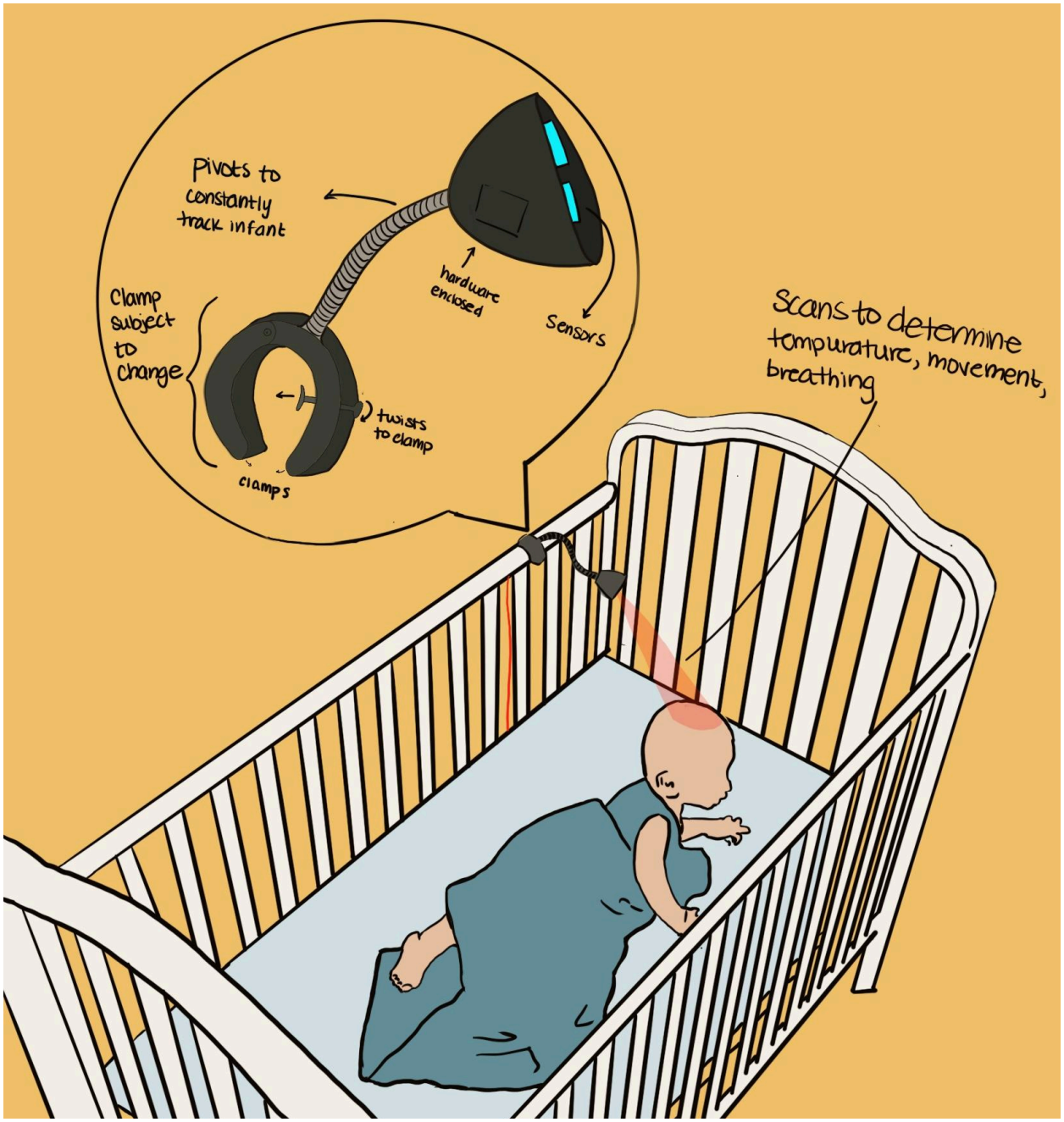



**Figure 9**: This is the only design that we determined for a non wearable. This design includes a clamp that could be adjusted to any crib side. The design would include a pivot system that tracks the infant. Sensors would monitor breath rate and temperature (as visualized by the red highlight on the infant's head). This satisfies needs 4 "The device must measure the most critical symptoms of sepsis" and 5 "The device is lightweight and compact". The non wearable has no need to satisfy need 7. The cons of this device are found in needs 7 "The device should not interfere with the infant's mobility or safety" and 8 "The device should be durable, waterproof, and biocompatible". Due to the device being clipped onto the crib, there could be a risk of it falling onto the infant if not secured properly. Additionally it would not be waterproof and if subject to any water it could also be harmful to the infant. This design was inspired by design A3 in appendix D.

# Sticker

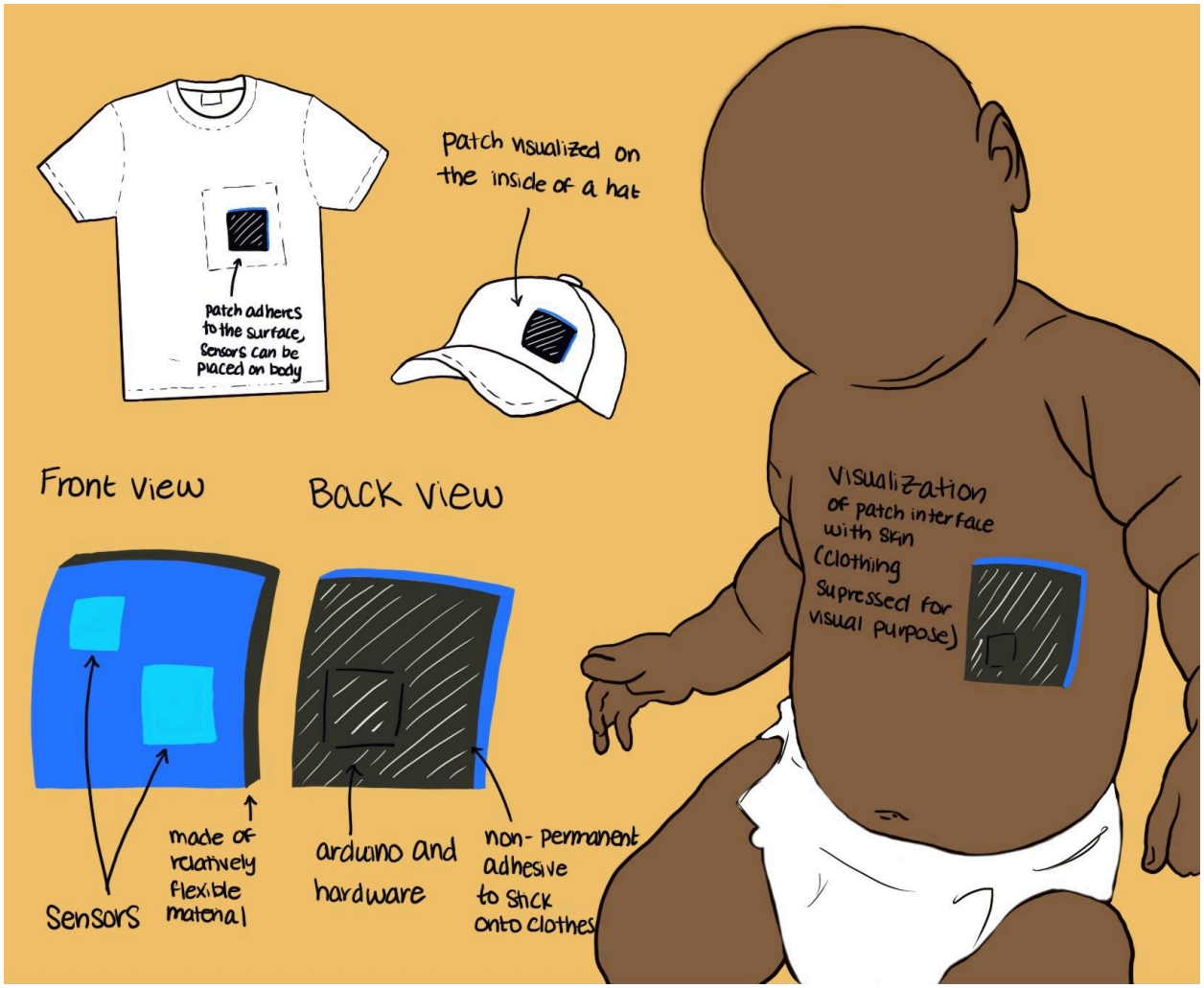



**Figure 10:** This design is a sticker that has the hardware and sensors enclosed for safety to satisfy need 8. Optimally this sticker would have an adhesive that could attach to any clothes and be removed and reused at the guardians convenience. This would completely satisfy need 6 as it would be able to adhere to any garment, similar to the Diaper Clip. The sensors would be placed so that the adhesive is on the clothes and the sensor is flush to the skin. Similarly to the Diaper Clip this device has the same number of cons related to need 4 “The device must measure the most critical symptoms of sepsis” and need 7 “The device should not be easily removed/rendered nonfunctional by the infant”. Due to the placement being slightly wavering, as it would be attached to clothes, and sensors potentially not being in contact with the skin at all times, need 4 may not be satisfied all of the time. Additionally, its placement may allow the infant to easily remove it, if not designed well. This design was a more intensive sketch of design A1 in appendix A.

# Part 3: Concept Selection

**Concept Elimination:**
6 concepts were eliminated as a result of not meeting our baseline requirements.

**The Chip**

- Failed requirement 3: Waterproofing:
  The chip is not designed with a housing as the electronics would directly be stuck onto the infant. Hence, it would fail the waterproofing test.
- Failed requirement 4: Biocompatibility:
  Adhesives stuck directly onto skin would irritate the infant's skin and cause discomfort and pain during removal for baths.
- Failed requirement 9: Removability:
  The Chip would likely not be adhesive enough to prevent removal by the infant with an applied force of 50N.
- Failed requirement 20: Choking hazard (size)
  The Chip would be made up of small electrical components that when removed, could pose a choking hazard to the infant.

**The Leg Band**

- Failed requirement 9: Removability:
  We believe that the Leg Band could be slid off of the thigh, and fully off the infant's leg with less than 50 N of pushing force. This is because the device is in a fairly accessible location, allowing the infant to remove the device with relative ease. This would prevent the band's sensors from monitoring symptoms of sepsis, posing significant risk to the infant.

**The Arm Band**

- Failed requirement 9: Removability:
  The Arm Band could be removed in a similar manner to the Leg Band, as 50N of force would be enough to render it useless.
    - Note: the Wristband was not eliminated, as the hand would prevent the band from being slid off of the infant's wrist.

**The Sticker**

- Failed requirement 9: Removability:
  The Sticker was eliminated because, although the sticker might not be able to be taken off the clothing with 50 N of force, it is very likely that the clothing can.

**The Diaper Clip**

- Failed requirement 9: Removability:
  The Diaper Clip, positioned in a location that is very accessible to the infant, has been estimated as removable by 50 N of pushing or pulling force.

**The Chest Band**

- While the Chest Band met all the necessary requirements, we have decided to incorporate its main design component (sensors around the chest area) with that of the Half Tank. As a result, the Chest Band has been removed from consideration.

**Evaluation Criteria:**

**Battery life:**

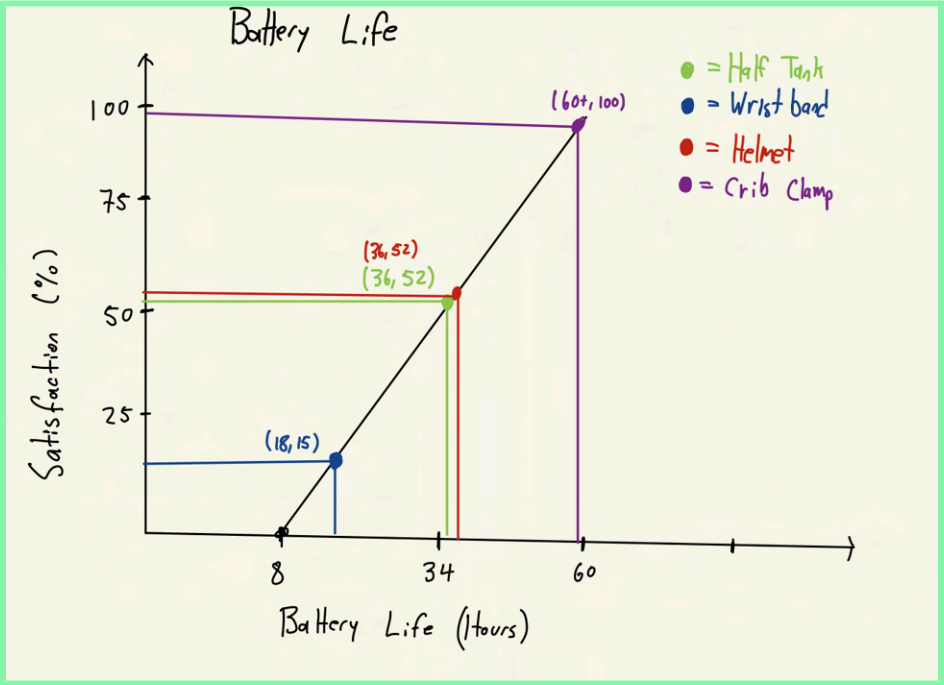



**Figure 11:** Battery Life Concept Evaluation

It was assumed all devices would be pulling the same load because they are all supporting the same sensors. This is exempting the crib clamp, as this design would be plugged in.

- We assumed that the Wristbands would support a battery equivalent to a single lithium-ion battery used in a 44mm Apple Watch. According to Apple, Apple Watch batteries are advertised to last up to 18 hours on one charge, operating with bluetooth and app functionality (41), which we assume that our sensors would take the place of. This produced a satisfaction rate of 15% for the wristband.
- Through the same logic it was assumed that the Half Tank battery pack would support two Apple Watch batteries thus providing 36 hours of charge giving 52% satisfaction.

- The Helmet was assumed to be of generally similar size (able to fit two Apple Watch batteries) thus its rank was the same as that of the Half Tank (52% satisfaction).
- The Crib Clamp design can be plugged into the wall and therefore it was assumed to have the longest lasting battery life as it never has to be "recharged" but it always needs to be plugged in. Additionally, even if it is not plugged in it is a much bigger device than a wrist band therefore giving more room for a greater power supply. Thus yielding 100% satisfaction.
    - Note: See appendix F for  measurements and size justifications for using Apple Watch batteries.
    - Note: future DHFs will use 9V batteries as it is what we initially thought to use, this change will not be propagated

**Waterproofing:**

- This evaluation criteria is not being evaluated as it primarily concerns the housing of the electronic components of our designs which is not very relevant to the key function we identified (i.e., how the device physically interfaces with the infant). Waterproofing tests rely heavily on the specific housing of each device, and it is difficult to accurately predict their performance based on the information available to us. For instance, the waterproofness of a crib clamp is largely determined by its electronic housing rather than the features of the clamp design itself. Therefore, it is not feasible to compare the waterproofing performance of the crib clamp to, say, a helmet, which has a different design and housing.

**Durability:**

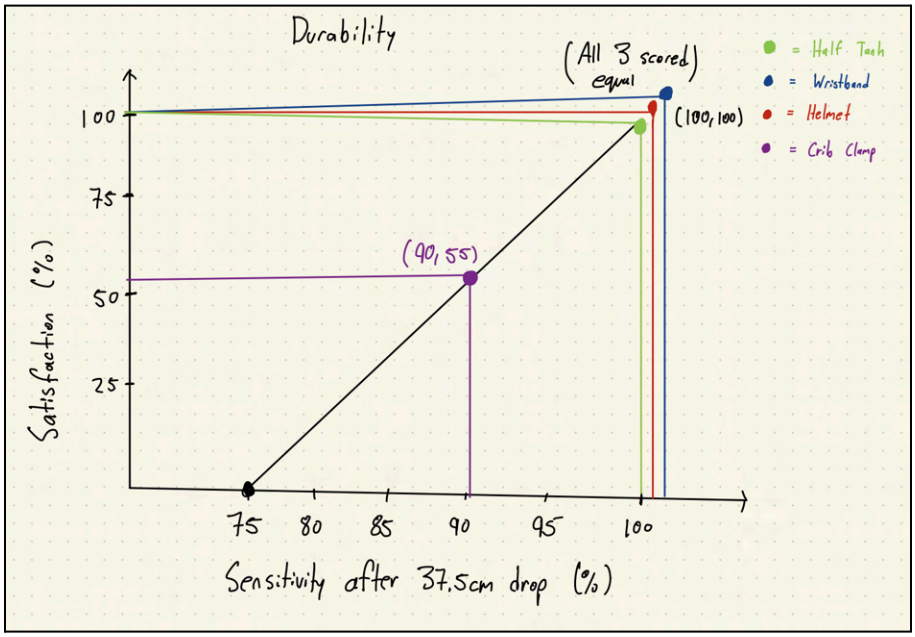



**Figure 12:** Durability Concept Evaluation

- Wearable designs were all considered to reach max satisfaction as they are enclosed by some sort of fabric or flexible material which is assumed to completely break the device's fall.
    - Since the devices (except the crib clamp) are all estimated to be under 200 grams and padding is in place to absorb the force of the fall, we believe that any sensitivity issues would be negligible following a fall, if present at all
    - 37.5 cm was chosen in the first DHF and is the shoulder height of a 50th percentile male adult, to account for if the adult ever drops the device.
    - Note: infant helmets are generally not rigid and are assumed to be made of a similar material to the wristband.
- The Crib Clamp was ranked lower as it does not have any padding on it, such as fabric, to cushion the fall. Due to this, and the fact that its additional sensors would increase its mass, it was assumed that it would sustain more damage under durability testing.
    - The clamp does not have padding because the initial concept does not include padding

**Accuracy rate:**

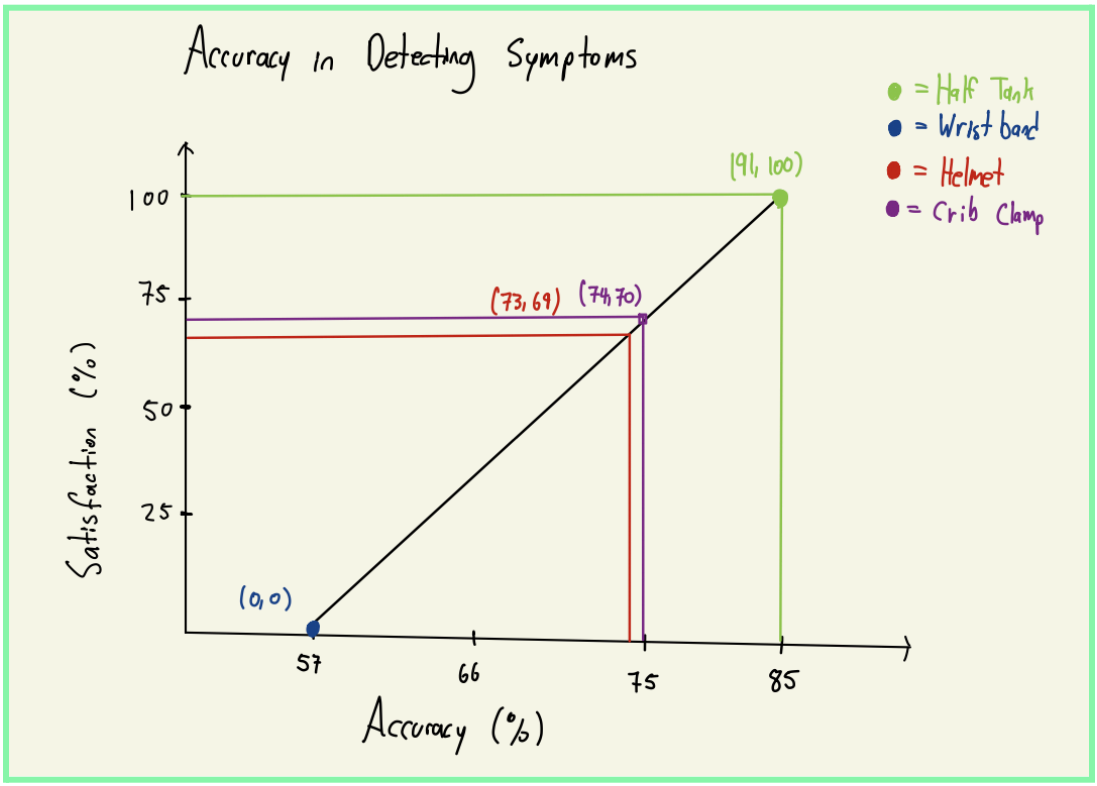


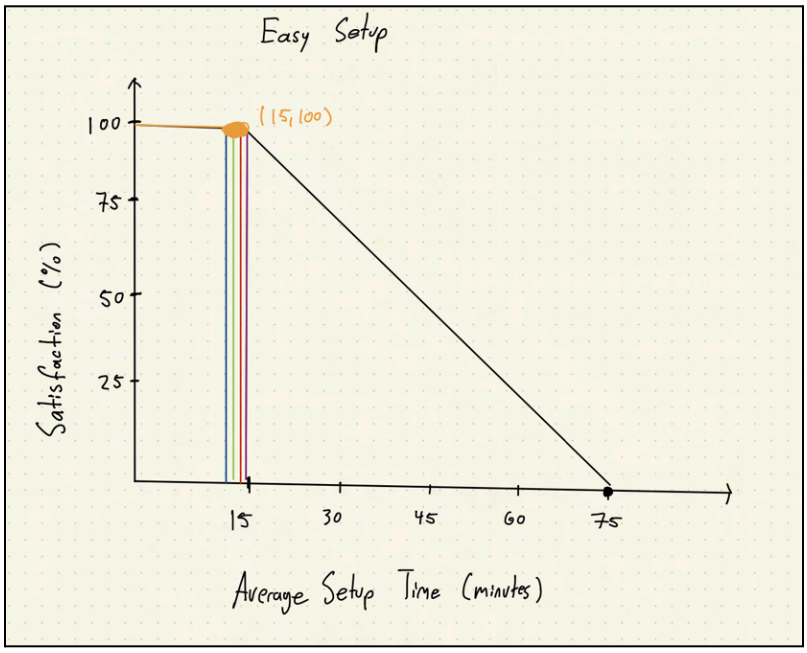

**Figure 13:** Accuracy rate in Detecting Symptoms Concept Evaluation

The accuracy rate is defined as the % of time that a sensor reading is true at a 95% confidence interval (50). Industry standard is what is being used on the market currently (industry standard

for thermometers is 57%), gold standard is equivalent to what would be used in an emergency room (gold standard for thermometers is 85%). Bounds justified in previous DHF.

- The Crib Clamp would use an IR thermometer to measure temperature at a distance away from the infant. A study in China evaluated the accuracy of a non-contact infrared thermometer (NCIT) in determining fever temperatures (51). The study found specificity and sensitivity values that can be used to calculate accuracy (see appendix G for calculations). The calculated accuracy rate was **74%**. Which translates to a satisfaction score of. 70%.
- As there are few contact thermometers that are typically employed for the head area, we will assess the performance of a head-contact thermometer based on the same study cited in the Crib Clamp justification. In that study (51), researchers measured forehead and wrist temperatures using an NCIT, so we will rely on the recorded accuracy rate of forehead temperature measurements. This accuracy rate for the helmet is **73%**, which translates to a satisfaction score of 69%.
- One study used a digital thermometer to evaluate the accuracy rate of axillary (armpit) temperature screening using rectal temperature readings as a baseline (52). The study found the sensitivity and specificity of axillary readings that we used to determine accuracy rate of temperature readings taken at the armpit (see appendix G). This ended up being **91%**, which translates to a satisfaction score of 100%  assigned to the halftank whose sensors would be near the armpit. Note that this accuracy score is larger than what we found to be the gold standard for health monitoring thermometers. While in real life this may or may not be true, it is what our sources and calculations have provided.
- The Wristband temperature reading accuracy rate was found by looking at on the market smart watches and devices that recorded your temperature. This led us to the AVA fertility tracker, a bracelet that uses temperature alongside other vital signs to track ovulation. One study done using the AVA tracker evaluated the accuracy of AVA in determining ovulation based on a participant's temperature shifts (53). This leads us to believe that we could use the accuracy rate found in this study as the accuracy rate of wrist-based thermometers as they are evaluating the ability to detect shifts in temperature. The true diagnostic numbers in determining ovulation were determined in the study, using urine luteinizing hormone tests as standard reference, which we have used to calculate accuracy rate (see appendix G). The accuracy rate was found to be **55%**.
    - As this accuracy rate would actually fail our accuracy requirement, the Wristband should not have passed into evaluation. However, since this part was added late, we did not know when we evaluated it earlier. Thus it will still be kept in the other evaluation criteria, but disregarded at the end when we compare each design. Additionally, because it is so close to passing this requirement, the error between our assigned value and actual value is large enough that the wristband may pass this requirement in real trials. **Regardless, in our final WDM calculations the wristband has been removed (strikethrough) because it technically fails the accuracy requirement.**

**Easy setup:**




- Each concept would take a similar amount of time to set up, leading to a very similar score. This was assumed because the devices are rather small and would come pre-assembled without requiring complex physical setup. On top of this, under the assumption that all software is already downloaded and that all devices communicate alerts using the same method, digital setup would take the same amount of time for each device. Because of this, we determined each device could feasibly be set up in under 15 minutes, giving each concept a satisfaction rating of 100%.
    - 15 minute bound justified in previous DHF

**Emergency instructions:**

- This criteria is not being evaluated because emergency instructions provided will depend on the developed device software, and software interface with users is assumed to be the same regardless of device (e.g. if we were to use a phone application, the clarity of emergency instructions does not depend on the physical device that interfaces with the infant).

**Weight:**

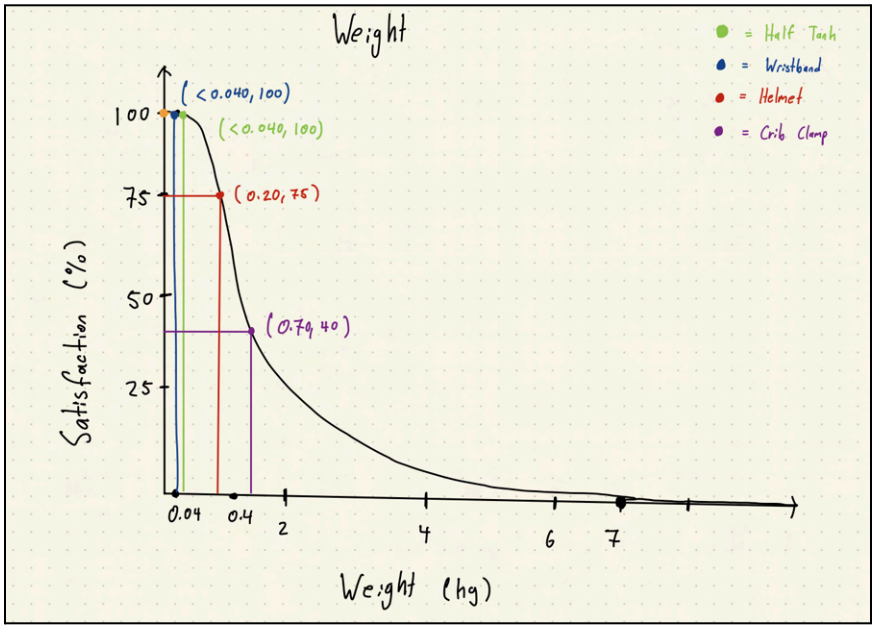



**Figure 14:** Weight Concept Evaluation

Given that the circuit and electronics used in devices will be approximately the same, designs will be evaluated excluding the circuit weight.

- The weight of the Wristband was estimated using the weight of an apple watch (53), which has an average weight of nearly 40 grams (~39 grams). This predicts a satisfaction of 100%.
- A layer of infant clothes and diapers was found to be approximately 40 grams (47), assuming that the Half Tank weighs the same amount, this predicts a satisfaction score of 100%.
- The average infant helmet weighs 200 grams (54) which gives a rating of 75% satisfaction.
- The weight of our crib clamp design was estimated to be similar to the weight of a market infant monitor, which was found to be approximately 0.7 kilograms (55). This gives a satisfaction of around 40%. (Note: this infant monitor was chosen due to it having the most ratings on Amazon)

Since the weight of the clamp falls within the upper bound of the common weight restriction for carry-on baggage on airlines, it is important to consider its weight when it comes to customer satisfaction. This is because most customers would want to take the monitoring device with them throughout their day without having to carry a heavy item, thus ensuring its portability.

**Length:**

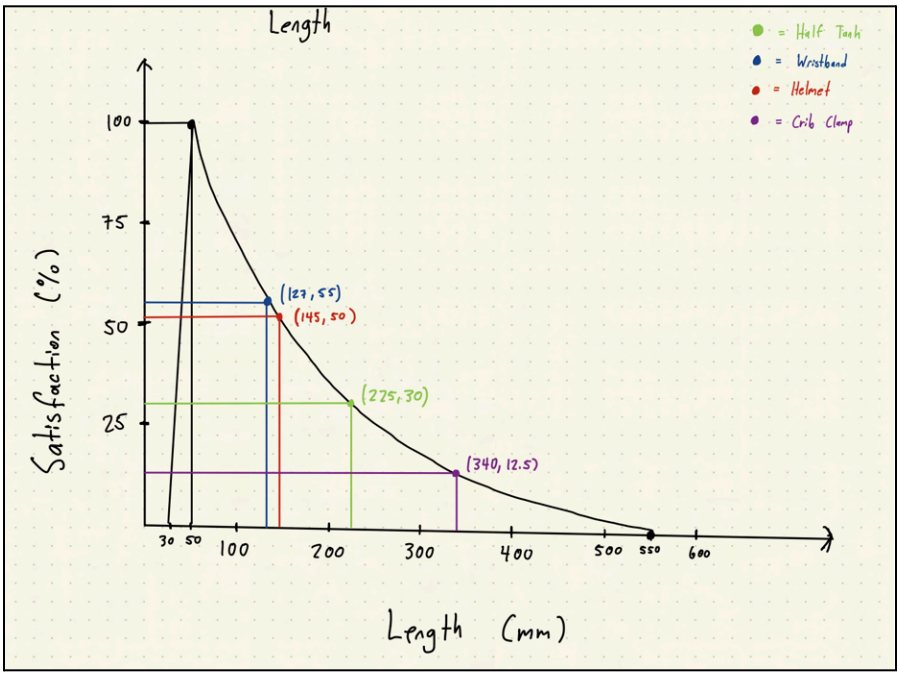



**Figure 15:** Length Concept Evaluation

- The longest dimension of the Half Tank was assumed to be the chest diameter of a 100th percentile 1 year old infant (145 mm). The measurement for a 100th percentile infant was used because it is the largest our design could possibly be. This was predicted to score 30% satisfaction. The diameter was found by dividing the infant's chest circumference by 2pi (40).
- For the helmet we assumed that an infant's head is a perfect circle, which gives a calculated head diameter of 147mm according to the anthropometric table (40). This was assigned 50% satisfaction. The infant's head diameter was found in a similar fashion to the chest diameter.
- The circumference of the average infant's wrist was found to be 127mm (56), which is the maximum length of the device when it is not on the infant's wrist. This was assigned 55% satisfaction.
- The length of the Crib Clamp was estimated to be similar to the length of an IKEA clamp spotlight, which was found to be 340mm (57). This was because the Crib Clamp design was inspired by the spotlight, and will likely be similar in size and dimension. This is the longest design, and has the least satisfaction at 12.5%.

Note:
This indicates that the clothing article possesses the ability to fit snugly on a child who ranks in the 100th percentile, thereby indicating that it can also be adjusted to be secured onto a child who ranks in the 1st percentile. For example, a shirt that happens to be excessively large for a child, can still be easily adjusted to fit a smaller child. However, if a shirt is too small, it cannot be made to fit a larger child. This evaluation criterion serves as an indicator of the maximum level of adjustability.

**Maximum background noise:**

- This evaluation criteria is not being evaluated as the main source of noise is the electronic components of the devices, which are not the main concern of this document. We understand that this would affect customer satisfaction, but without knowing what components each device would use, we cannot in good faith make accurate assumptions of each device's performance in this metric. Hence why we relegated this to be a requirement for our circuit.

**Alert volume:**

- This evaluation criteria will not be evaluated as notification of guardians is not considered in our key function.

**Adjustability:**

- This evaluation criteria is not being evaluated because every one of our designs can be hypothetically designed to be able to adjust to a growing infant in some way. Therefore it is very difficult to score the device on a scale of satisfaction.

**Uncertainty Analysis:**

The uncertainty analysis was chosen to be performed on the **length** evaluation criteria. This evaluation criteria was chosen as it is hard to accurately determine the actual length of each concept. The final length will likely depend on the size of the infant, or choices in the design of the final product. The error in length measurements for each concept is explained below:

- For the Half Tank, the standard deviation of a one-year-old's chest diameter is 7.28mm (40). 2 standard deviations of error includes approximately 95% of infants, so an error of 14.55mm was calculated.
- For the Wristband, we found that most commercial infants' bracelets varied by half an inch, or ~13mm of error.
- For the Helmet, the head circumference has a standard deviation of 4.85mm (40). 2 standard deviations of error should include 95% of infants, so an error of 9.70mm was calculated.

- The Crib Clamp has the most uncertainty, as there is no data on the average length and standard deviation of an infant monitor. Additionally, this design is the most open ended. By searching for other designs similar to IKEA's clamp light, many seem to vary within 5 inches or 127mm. Therefore, 127mm was chosen as the uncertainty (57).

The quantities of error were applied to both sides of the given parameter (assuming a symmetric distribution of error), which was used to calculate the uncertainty in satisfaction for each design.

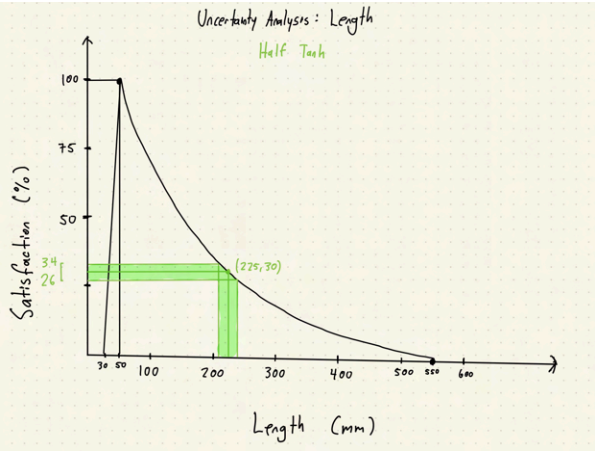



**Figure 16(a):** Half Tank Uncertainty Analysis

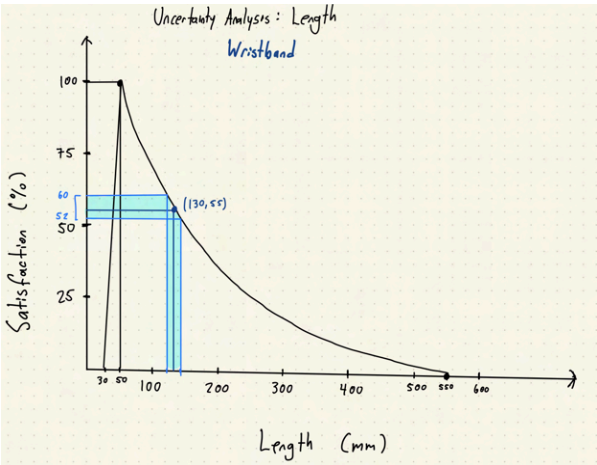



**Figure 16(b):** Wristband Uncertainty Analysis

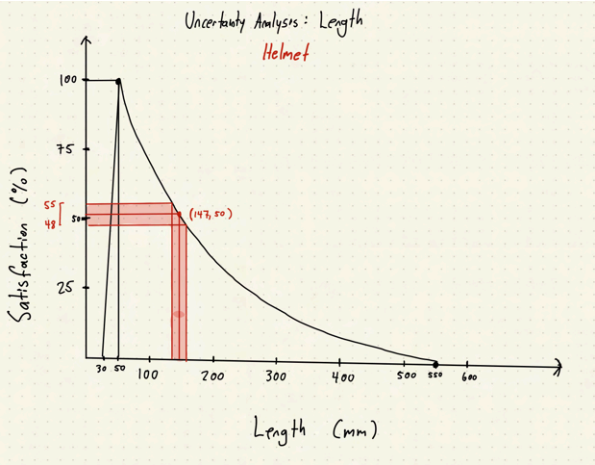



**Figure 16(c):** Helmet Uncertainty Analysis

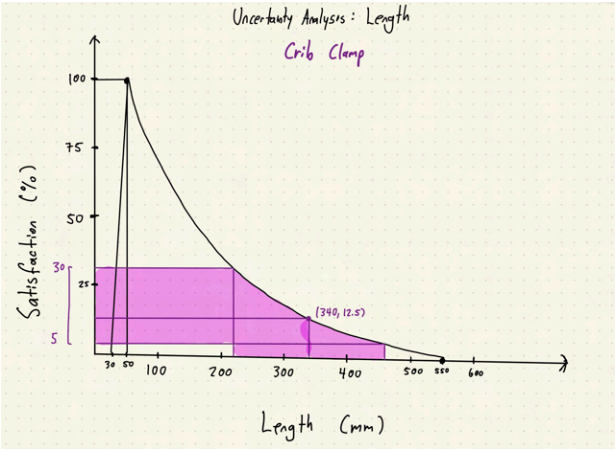



**Figure 16(d):** Crib Clamp Uncertainty Analysis

- The Half Tank had a satisfaction uncertainty range of 26 - 34%.
- The Wristband had a satisfaction uncertainty range of 52 - 60%.
- The Helmet had a satisfaction uncertainty range of 48 - 55%.
- The Crib Clamp has a satisfaction uncertainty range of 5 - 30%

Note that the error in each length parameter does not correlate to a proportional error range in satisfaction. This is due to the non-linear nature of the evaluation curve.

**Weighted Decision Matrix:**

| Evaluation Criteria | Weighting (out of 100%) |
|---|---|
| 1. Battery Life | 21% |
| 2. Durability | 16% |
| 3. Accuracy | 25% |
| 4. Easy Setup | 10% |
| 5. Weight | 14% |
| 6. Length | 14% |

(removed unevaluated criteria)

**Justifications:**
Initially, after referring to the needs section of Report 1, it is clear that the function of the device (detecting symptoms) along with safety are essential. Therefore, weighting must be shifted to reflect this, specifically towards battery life, accuracy, and adjustability. It is assumed that these criteria are nearly equally important, as the device cannot function without one of them. Notably our key function refers to the setup and interface of the device with the child. This in turn means we must ensure to evaluate the criteria involved with this function, those being easy setup, weight, length and adjustability.

**1. Battery life:**
This criterion has a high weight because the device's battery life will determine the likelihood of parents using it. If the device requires constant charging, it may become more of a hassle for parents, leading to discontinued use. Furthermore, having a larger battery life overall improves or maintains the quality of life for the caregivers. If the device battery life is low and the caregivers plan to travel for extended periods of time, the device will need to be charged regularly, which will impose significant constraints on these activities. In addition, having a larger battery life allows for a larger window of time where the parent or guardian can charge a potential backup battery to replace the used battery when necessary. This allows for reduced stress for the parent or guardian and increases the likelihood of our device catching early sepsis symptoms.

**2. Durability:**
This criteria has a reasonable weighting associated with it as it is not considered as essential as battery life or accuracy. However, it is important to consider this criteria since the device must be able to function until the infant reaches one year of age. During this time, our device should

ideally not need to be replaced due to damage, so it is important for it to be durable enough to maintain a standard level of accuracy while being subjected to everyday life. Despite this, it is still far more essential for the device to be accurate, have good dimensions, and have a long battery life, as those criteria determine whether the device will be used out of the box initially (before it has a chance to break). Therefore, durability accounts for 10% of the weight.

**3. Accuracy:**
This criteria holds the most weight due to the fact that it addresses two needs directly: the safety of the user and the function of the device. It is essential for our device to accurately detect early symptoms of sepsis, which would allow for the highest likelihood of survival for the infant. If our device is inaccurate in any way, it may detect sepsis late, if at all. If the device is made super sensitive in an attempt to combat this issue, it could lead to a large amount of false positives, which is also a big red flag. As a result, it is critical that this criterion has the highest weighting associated with it.

**4. Easy setup:**
This criteria is not essential to the long-term function of our device; therefore, it has a minimal weight associated with it. Furthermore, the majority of devices have a very similar hypothesised setup time, leading to very little difference in their scores. Additionally, all our devices already meet the minimum requirement for setup time, which is reasonable and validated. Thus, it is not as important for us to evaluate the miniscule differences in setup time in comparison to other criteria such as accuracy or battery life. Hence, this criteria has a low weight.

**5. Weight and 8. Length:**
Both of these criteria have the same weight, as it is crucial for the infant to be comfortable wearing our device (this is also one of our needs). Therefore, the combined weighting of these criteria is on the same level as that of adjustability and battery life. It is important for the infant to not be uncomfortable while wearing our device, as that could lead to them trying to take off the device or impair their movement abilities. Therefore, it is important for the weight and length of the device to be optimised as much as possible. However, this criteria ranks below accuracy, as it is more important for the device to accurately be able to detect symptoms of sepsis, even if it means a slight sacrifice of comfort for the infant.

| Evaluation Criteria | The Half Tank | ~~The Wristband~~ | The Helmet | The Crib Clamp |
|---|---|---|---|---|
| **1** | 52% | ~~15%~~ | 52% | 100% |
| **3** | 100% | ~~100%~~ | 100% | 55% |
| **4** | 100% | ~~0%~~ | 69% | 70% |
| **5** | 100% | ~~100%~~ | 100% | 100% |
| **7** | 100% | ~~100%~~ | 75% | 40% |
| **8** | 30% (26% - 34%) | ~~55% (52% - 60%)~~ | 50% (48% - 55%) | 12.5% (5% - 30%) |
| **Total** | 80.12% (79.56% - 80.68%) | ~~50.95% (50.53% - 51.65%)~~ | 71.67% (71.39% - 72.37%) | 64.65% (63.6% - 67.10%) |

(Numbers changed, wristband failed: see explanation in evaluation criteria: accuracy rate)

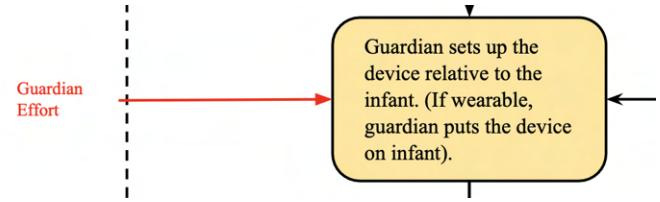
After conducting the scoring process using our generated WDM the Half Tank design outweighed the other designs and was chosen as our final design to move forward. This was due to its superiority in battery life, durability and accuracy in detecting symptoms of sepsis. The uncertainties have a limited impact on our final decision because the upper bound of the second-best concept is lower than the lower bound of the best concept. Note that the final overall satisfaction scores are not reflections of total satisfaction as many criteria were chosen to not be evaluated.

# *DHF 4.1: Detailed CAD Design*

## Part 1: Iterated Function Structure

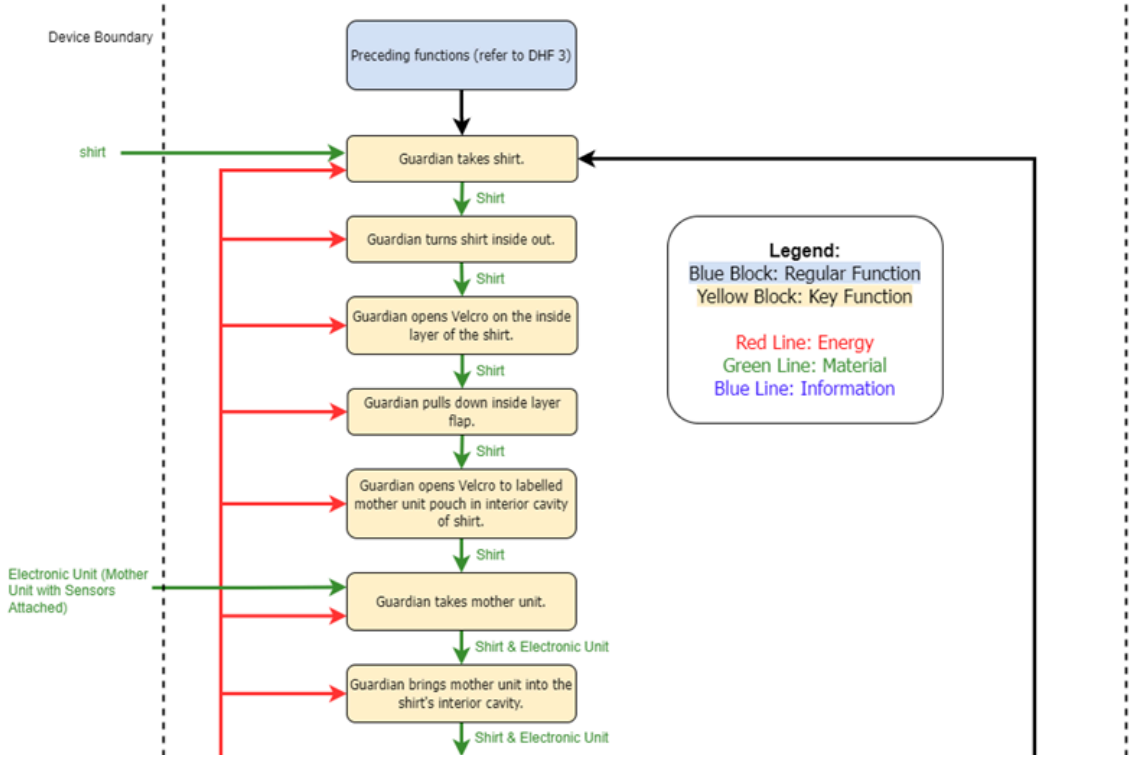
We chose to iterate on the "Guardian sets up device relative to the infant (if wearable, guardian puts device on the infant)". We felt this was the most significant mechanical function, as it requires complex interactions with both the guardian and the infant and also includes the most moving parts. Additionally, we felt it was important to further detail the process of setting up the device to make sure the process is comprehensive but also easy for the guardian to understand. Note that ease of setup is important because of the "easy setup" requirement that we outlined in DHF2.

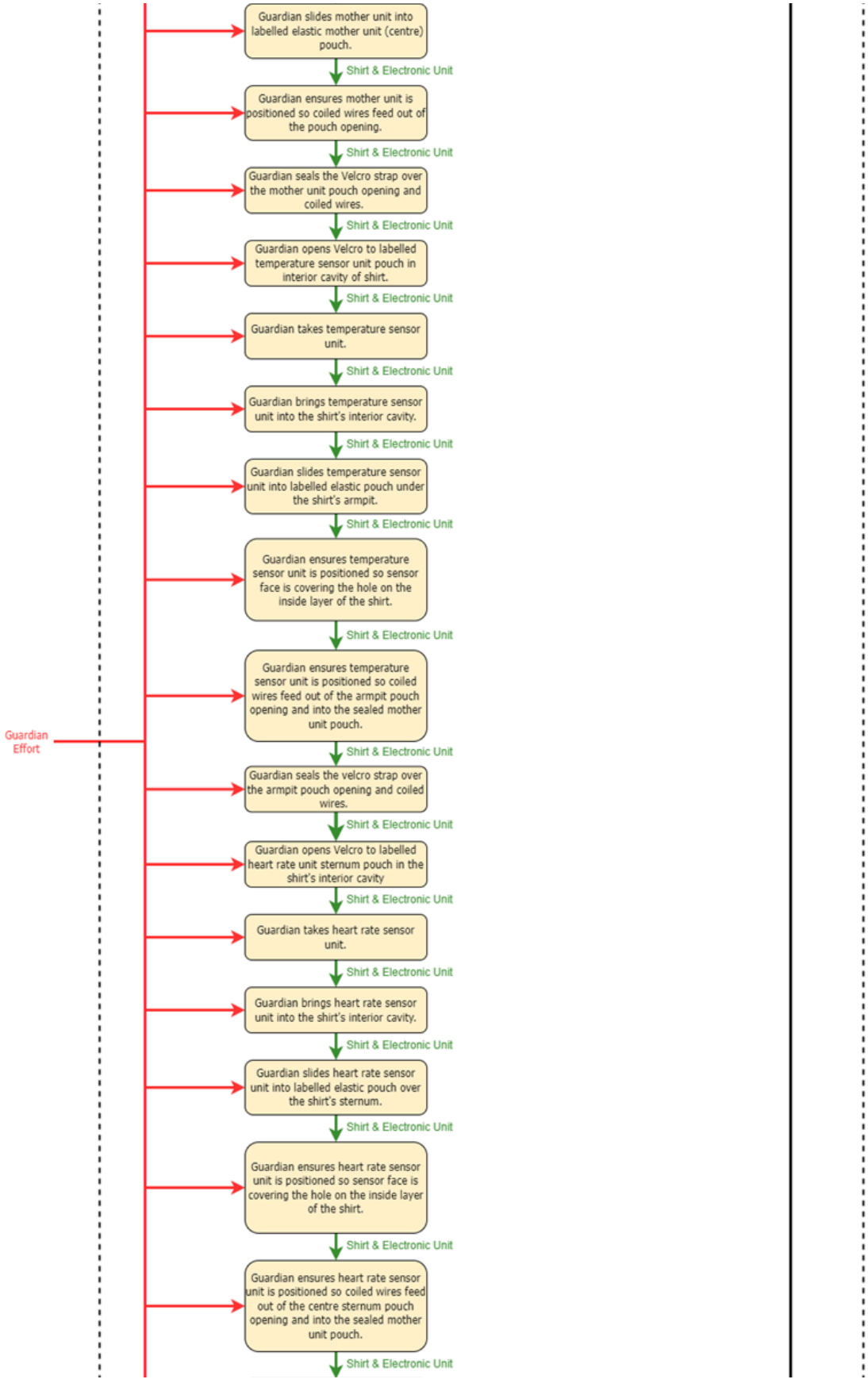
**Original Function:**

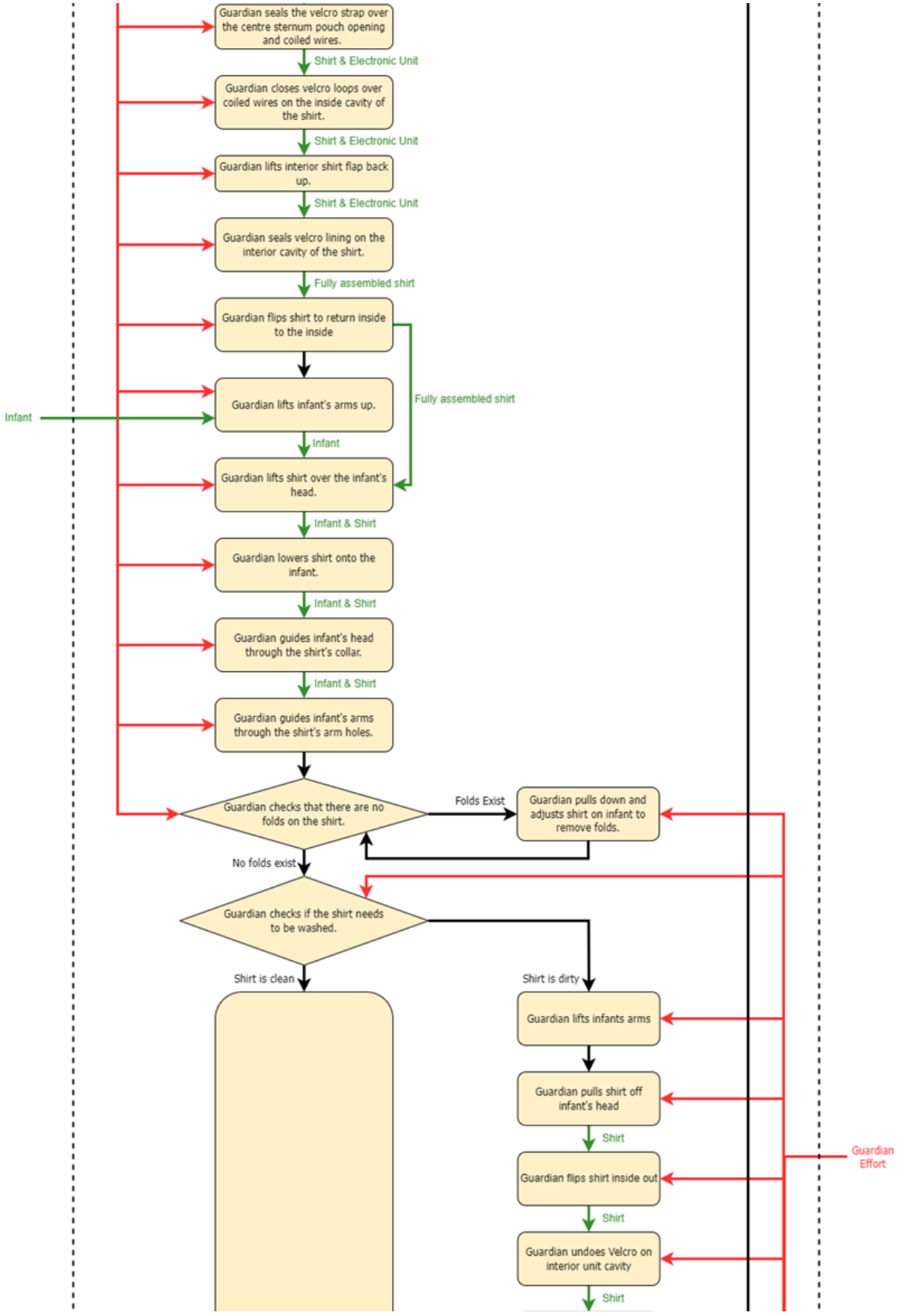


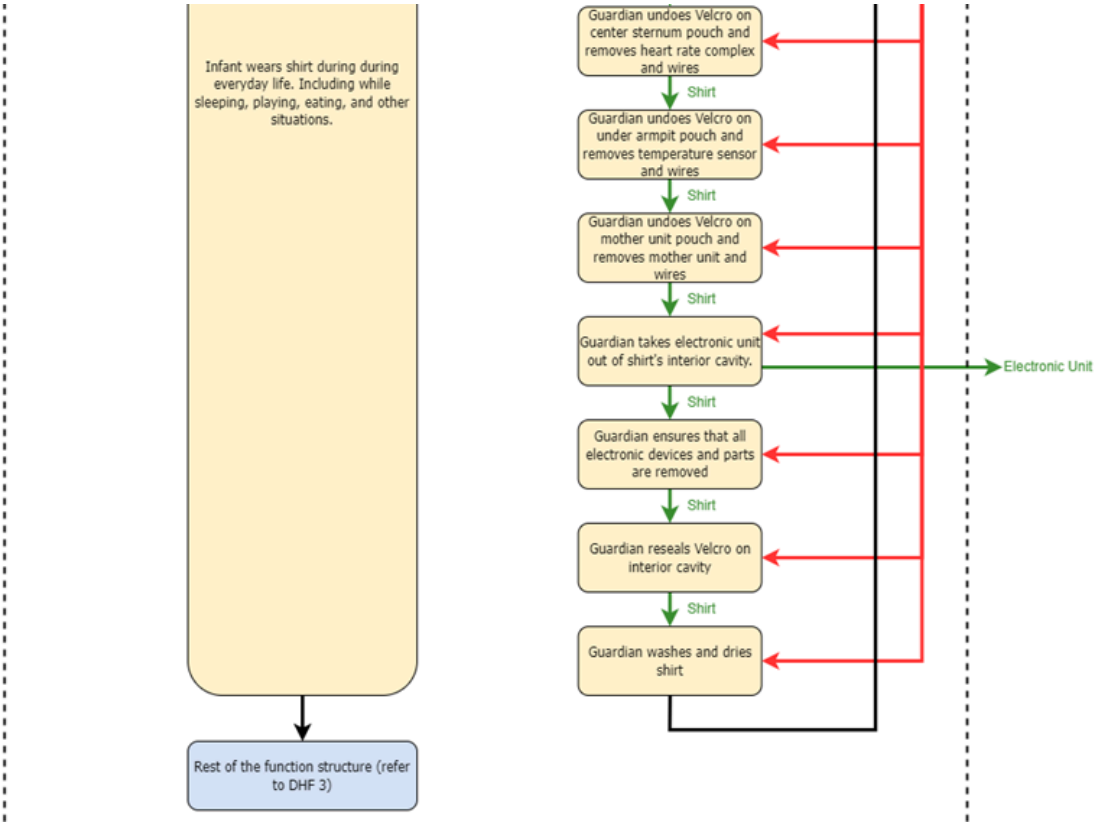

**Iterated Function (updated):**
**Link:**
**[https://drive.google.com/file/d/1x8pC4QggRRguvuSj1x41R8kEys9L-HdH/view?usp=sharing]**

****Apologies for the broken formatting, we could not find a continuous way to format the diagram while including a high enough resolution.****




Guardian slides mother unit into labelled elastic mother unit (centre) pouch.
Shirt & Electronic Unit
Guardian ensures mother unit is positioned so coiled wires feed out of the pouch opening.
Shirt & Electronic Unit
Guardian seals the Velcro strap over the mother unit pouch opening and coiled wires.
Shirt & Electronic Unit
Guardian opens Velcro to labelled temperature sensor unit pouch in interior cavity of shirt.
Shirt & Electronic Unit
Guardian takes temperature sensor unit.
Shirt & Electronic Unit
Guardian brings temperature sensor unit into the shirt's interior cavity.
Shirt & Electronic Unit
Guardian slides temperature sensor unit into labelled elastic pouch under the shirt's armpit.
Shirt & Electronic Unit
Guardian ensures temperature sensor unit is positioned so sensor face is covering the hole on the inside layer of the shirt.
Shirt & Electronic Unit
Guardian ensures temperature sensor unit is positioned so coiled wires feed out of the armpit pouch opening and into the sealed mother unit pouch.
Guardian Effort
Shirt & Electronic Unit
Guardian seals the velcro strap over the armpit pouch opening and coiled wires.
Shirt & Electronic Unit
Guardian opens Velcro to labelled heart rate unit sternum pouch in the shirt's interior cavity
Shirt & Electronic Unit
Guardian takes heart rate sensor unit.
Shirt & Electronic Unit
Guardian brings heart rate sensor unit into the shirt's interior cavity.
Shirt & Electronic Unit
Guardian slides heart rate sensor unit into labelled elastic pouch over the shirt's sternum.
Shirt & Electronic Unit
Guardian ensures heart rate sensor unit is positioned so sensor face is covering the hole on the inside layer of the shirt.
Shirt & Electronic Unit
Guardian ensures heart rate sensor unit is positioned so coiled wires feed out of the centre sternum pouch opening and into the sealed mother unit pouch.
Shirt & Electronic Unit


Guardian seals the velcro strap over the centre sternum pouch opening and coiled wires.
Shirt & Electronic Unit
Guardian closes velcro loops over coiled wires on the inside cavity of the shirt.
Shirt & Electronic Unit
Guardian lifts interior shirt flap back up.
Shirt & Electronic Unit
Guardian seals velcro lining on the interior cavity of the shirt.
Fully assembled shirt
Guardian flips shirt to return inside to the inside
Fully assembled shirt
Infant
Guardian lifts infant's arms up.
Infant
Guardian lifts shirt over the infant's head.
Infant & Shirt
Guardian lowers shirt onto the infant.
Infant & Shirt
Guardian guides infant's head through the shirt's collar.
Infant & Shirt
Guardian guides infant's arms through the shirt's arm holes.
Guardian checks that there are no folds on the shirt.
Folds Exist
Guardian pulls down and adjusts shirt on infant to remove folds.
No folds exist
Guardian checks if the shirt needs to be washed.
Shirt is clean
Shirt is dirty
Guardian lifts infants arms
Guardian pulls shirt off infant's head
Shirt
Guardian flips shirt inside out
Shirt
Guardian undoes Velcro on interior unit cavity
Shirt
Guardian Effort




To ensure the "ease of setup" requirement (DHF 2) is satisfied, each function outlines explicit, easy-to-follow instructions that the guardian can complete without any outside help. Note that this diagram is not an instruction manual; however, it outlines the steps that are necessary to setting up the device.

This function structure diagram was updated. Material transfers were added to clarify when different components of the device (such as the electronic uint) are brought into the device boundary and what is being passed between different functions. Despite the fact that the different components all belong to the same device system, we are convinced that showing components transferred into the boundary can better illustrate the “ready-to-assemble” nature of our device. Some functions are rearranged to clarify their sequentiality.

# Part 2: Computer Aided Design Parts

## Solidworks Part 1: Temperature Sensor Casing

- Made to fit a waterproof DS18B20 digital temperature sensor for Arduino.
- Sensor to be placed within the case has a 6mm stainless steel tube diameter with a length of 35mm.
- The cable diameter of this sensor is 4mm.
- Only one of these casings is present in the final design.
- Material of this part will be made of PLA because it is biocompatible and durable (58). Biocompatible implies that the device does not irritate the infant's skin. PLA, although it can cause reactions, typically does not cause issues with skin to skin contact (59). In addition, this would need to be durable as the sensor casing would have to protect the sensor from the infant's body weight and more. It would need to keep the sensor intact throughout everyday activities and protect the infant if the sensor were to fail in any way.

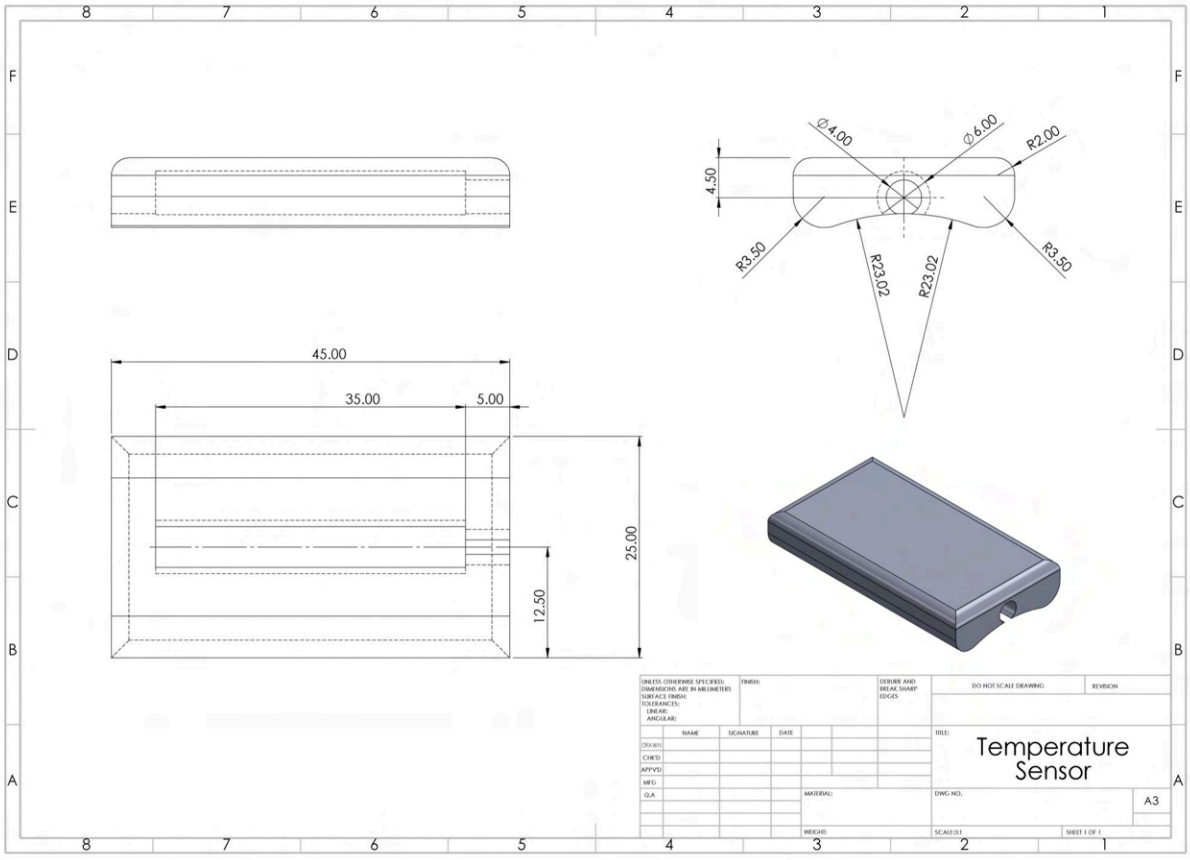



**Figure 1:** Temperature Sensor Casing. Dimensions shown in mm.

## Solidworks Part 2: Photoplethysmography (PPG) Sensor Case Lid

- This part represents the lid of the case for the PPG sensor. It is designed to enclose the sensor inside the case to protect the sensor from damage. The pins on the lid shall fit into the holes of the case to hold the two parts in place.
- This part will be made of PLA for its durability and bio-compatibility.
- The lid is 22 mm in diameter and 1 mm in thickness. The pins are 1.5 mm in diameter and 2 mm in length.
- Only one of these parts is utilized in our design.

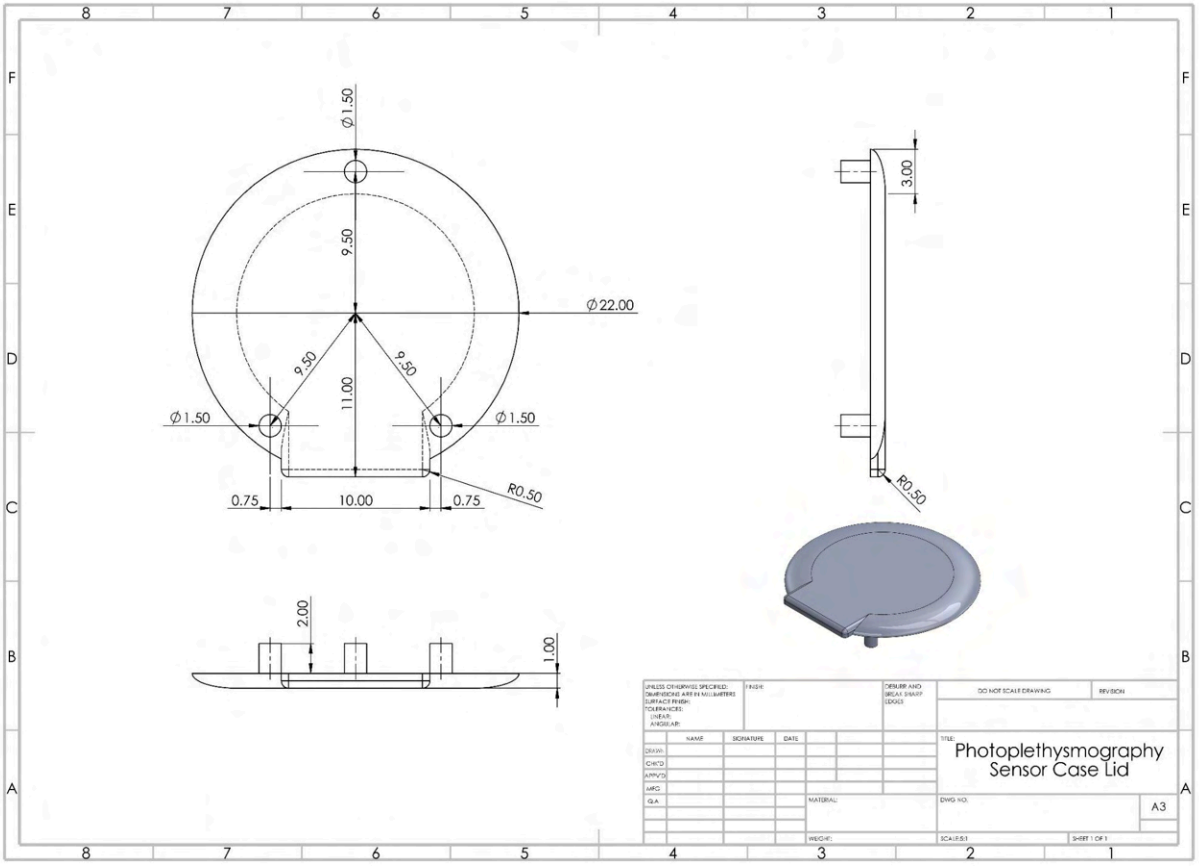



**Figure 2:** PPG lid. The dimensions in this figure are in mm. A symmetric filet is used on the edge of the lid; the two radii are 1 mm and 3 mm (as labeled in the bottom and side views).

## Solidworks Part 3: PPG Case

- This part represents the case that contains and protects the PPG sensor. The PPG sensor will be placed within this casing. The sensor will be in contact with the infant's skin through the central hole. The wires of the sensor can go through the opening on the side. There are three holes on the edge for the pins on the lid.
- The material of this part will be PLA for bio-compatibility and durability.
- The case is 22 mm wide and 4.2 mm thick. The inside is 3.2 mm deep. The diameter of the central hole is 12 mm. The three holes on the edge are 1.5 mm in diameter and 2 mm in depth.
- One of these parts is included in our device.

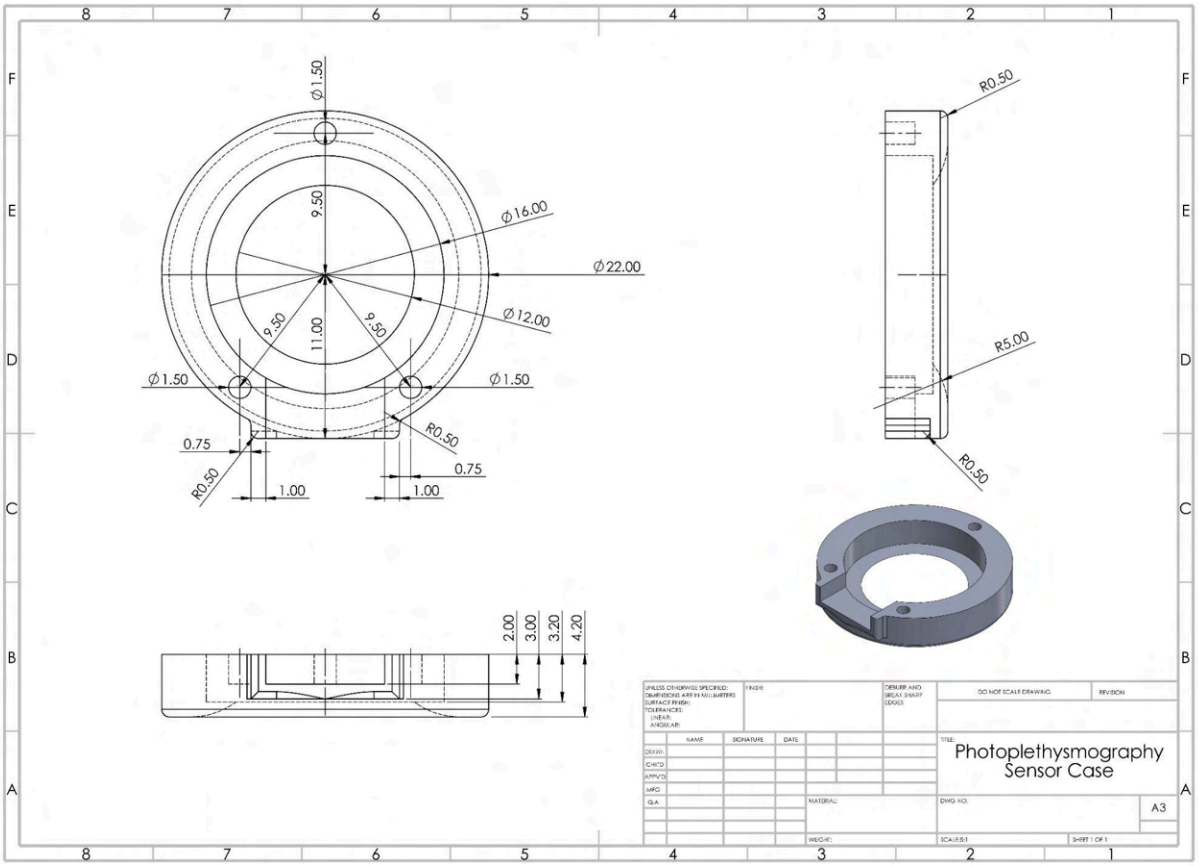



**Figure 3:** PPG case lid. The dimensions are in mm. (added dimension to “butterfly-loooking segment”, bottom left figure was not able to be dimensioned, so changes were made to the top left)

## Solidworks Part 4: Mother Housing

- This part represents the housing in which the microcontroller, batteries and breakout boards will rest. The Mother Housing will rest in a pocket located right above the naval, in between the layers of clothing. There are holes cut out of the sides of the Mother Housing to allow for any breakout board or Arduino cables to run out of the Mother Housing.
- The material of this part will be PLA for biocompatibility and durability.
- The Mother housing is 175 mm in length, ~134 mm in width, and 25 mm in height. The cutouts for the electronic components are ~16.3 mm in depth, allowing for the entire component to be covered by the case lid.
- There is 1 of this part in our device
- **Note:** The housing modeled here is indicative of a housing for our benchtop prototype, meaning that the final housing (as shown in the final assembly) would be much smaller.

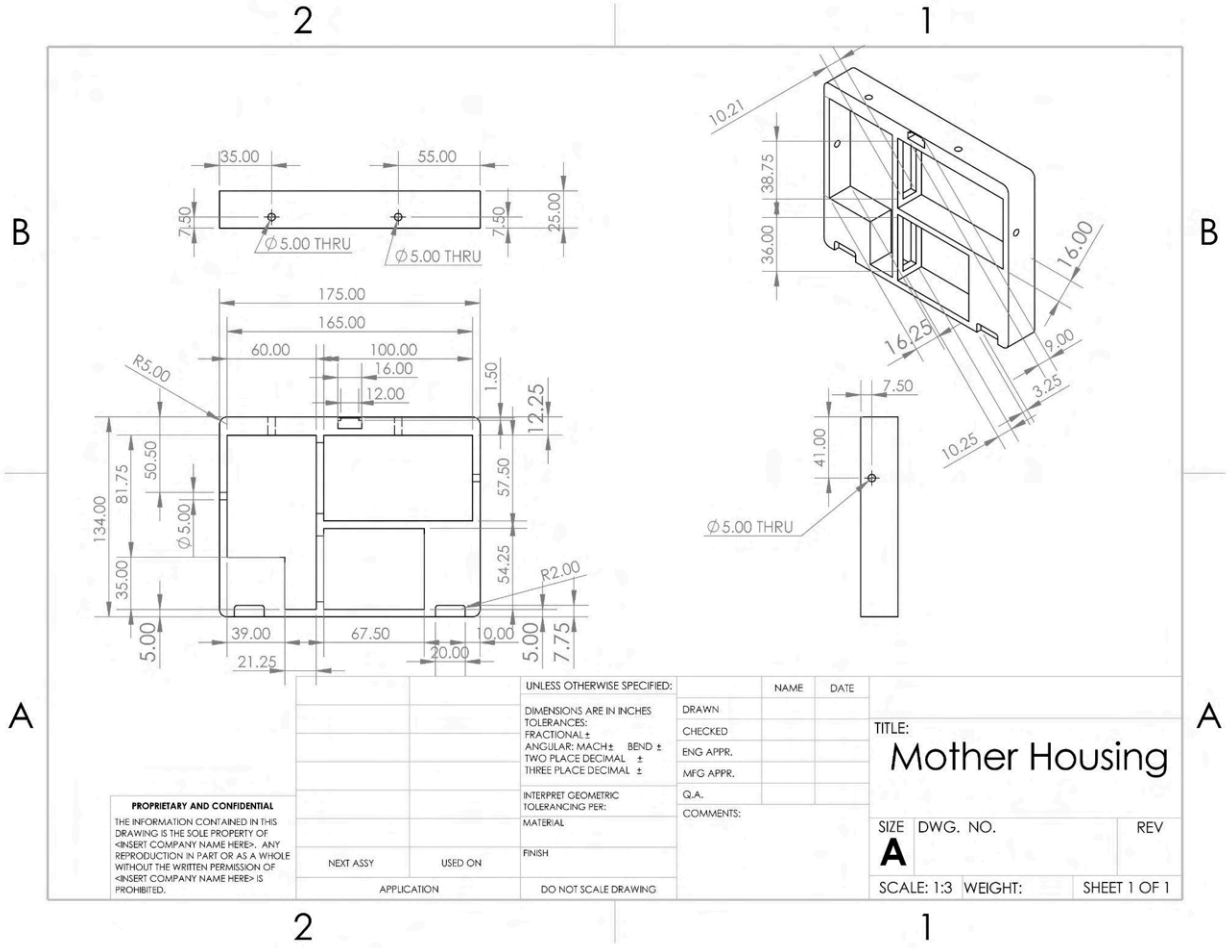



**Figure 4:** Mother Housing. The dimensions are in mm, not inches. (added dimensions)

## Solidworks Part 5: Mother Housing Lid

- This part represents the lid for the housing in which the microcontroller, batteries and breakout boards will rest. The Mother Housing Lid will be attached to the Mother Housing using hinges and screws. The Mother Housing Lid has a latch that can clip into an opening made in the Mother Housing, ensuring that the entire container stays closed, similarly to the battery cover of a television remote.
- The material of this part will be PLA for biocompatibility and durability.
- The Mother Housing Lid is 175 mm in length, ~127 mm in width, and 5 mm in height. The latch is 14 mm in width and is meant to bend slightly to fit into a 9 mm deep opening in the Mother Housing.
- There is 1 of this part in our device
- **Note:** The housing modeled here is indicative of a housing for our benchtop prototype, meaning that the final housing (as shown in the final assembly) would be much smaller.

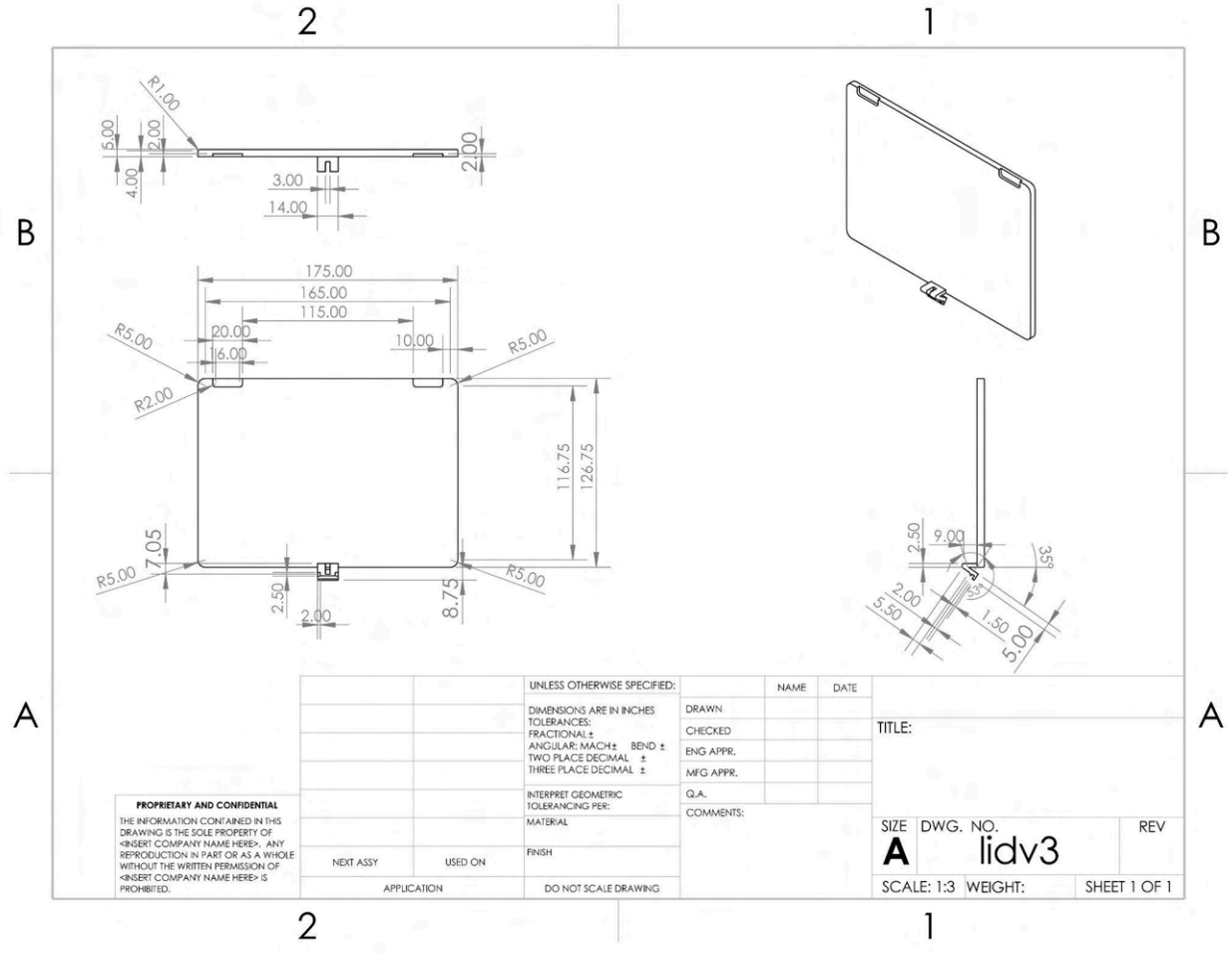



**Figure 5:** Mother Housing lid. Dimensions in mm. (added dimensions)

## Solidworks Part 6: Hinge Leaf 1

- This is a representative part for a hinge we would buy. 2 of these are used in the final assembly. Made of stainless steel because it is a common material hinges are made out of, thus they are easier to source, as well as the fact that stainless steel is biocompatible.

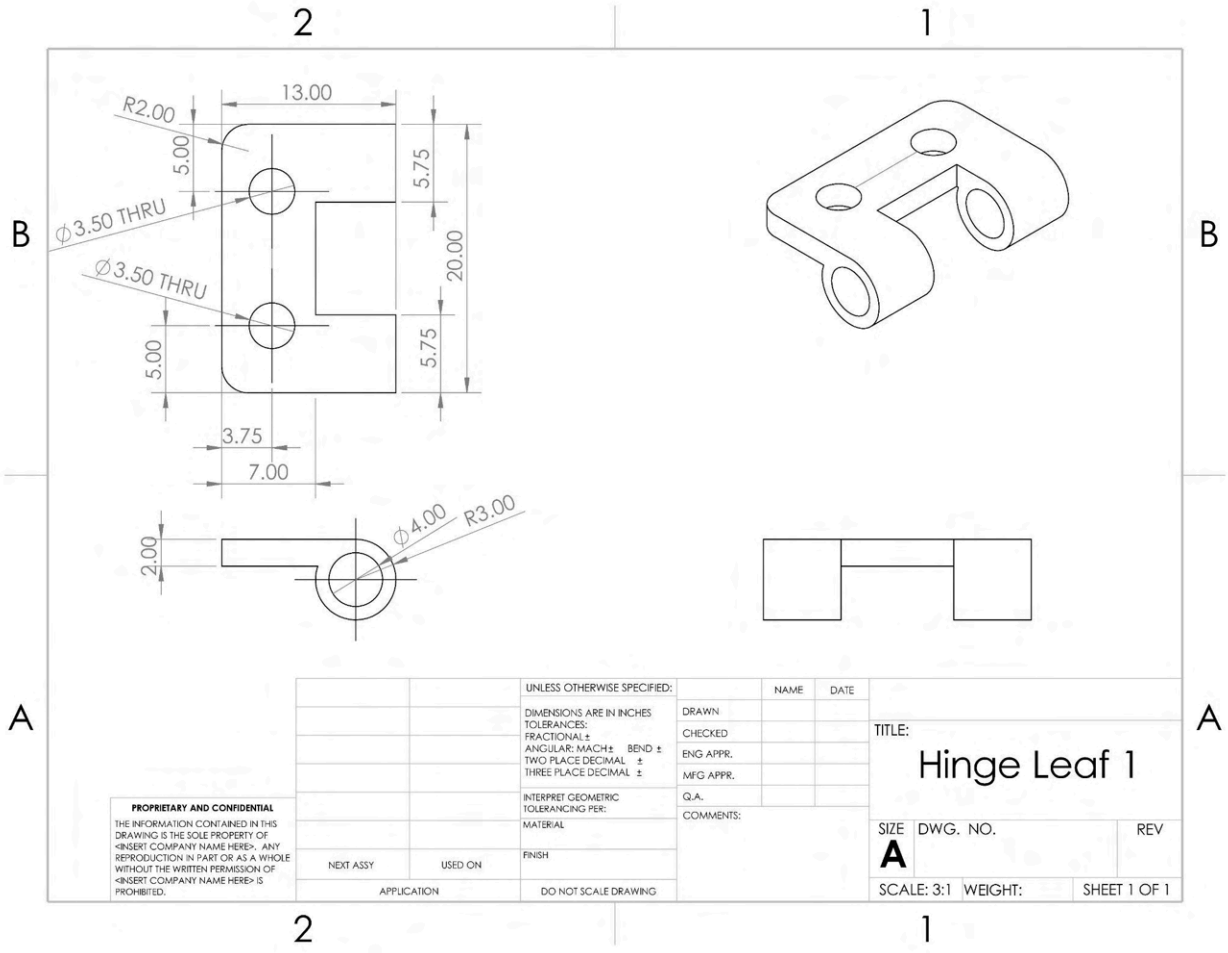



**Figure 6:** Hingle Leaf 1. Dimensions in mm. (added dimensions)

## Solidworks Part 7: Hinge Leaf 2

- This is a representative part for a hinge we would buy. 2 of these are used in the final assembly. Made of stainless steel because it is a common material hinges are made out of, thus they are easier to source, as well as the fact that stainless steel is biocompatible.

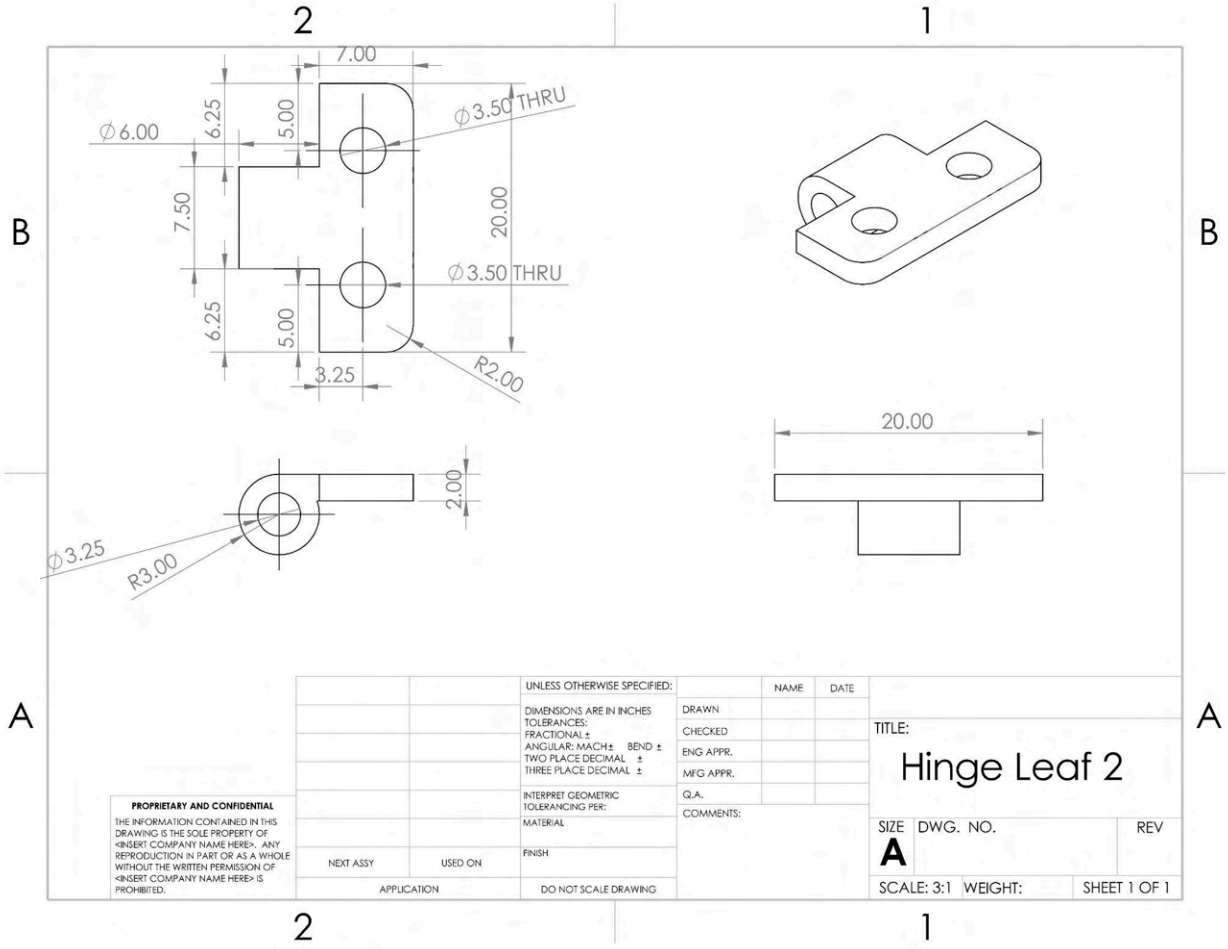



**Figure 7:** Hingle Leaf 2. Dimensions in mm. (added dimensions)

## Solidworks Part 8: Pin

- This part represents a pin that holds the two leaves of the hinge together.
- This part will be made of stainless steel as this is common in similar products (60).
- The pin is 20 mm in length and 3.25 mm in diameter.
- Two of these are used in our design.

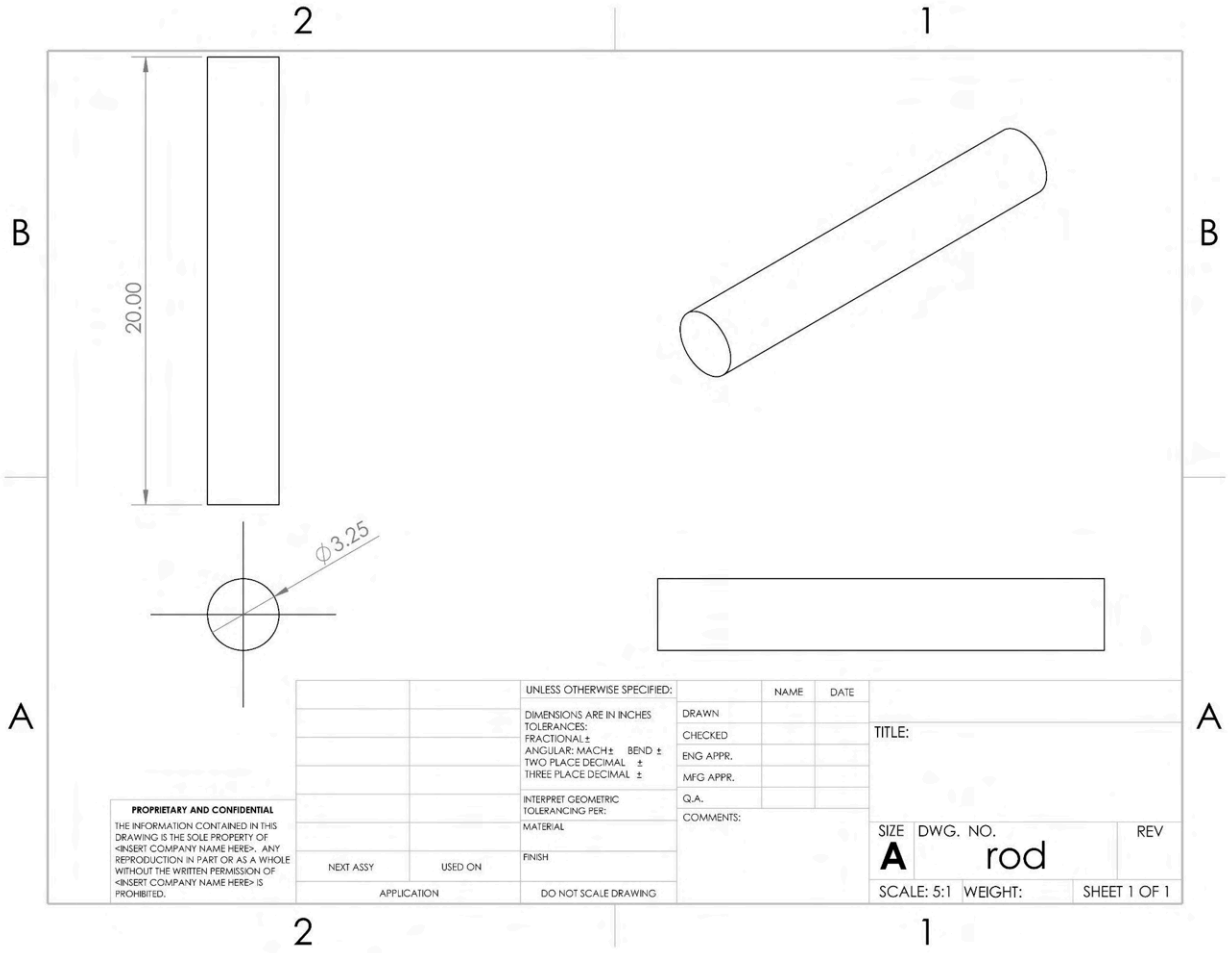



**Figure 8:** Pin. The dimensions are in mm, not inches. (updated dimensions)

## Solidworks Part 9: Screws

- This part represents a screw that is used to secure the hinges onto the mother housing and lid.
- The material will be stainless steel since it is commonly used in similar products.
- The head has a diameter of 6.4 mm and is 1 mm thick. The body has a diameter of 3.4 mm. The entire screw is 5 mm long.
- 8 of these are used in our design.
    - We plan on sourcing #6 gauge wood screws (61), length does not matter as much as we could always cut them to our desired length

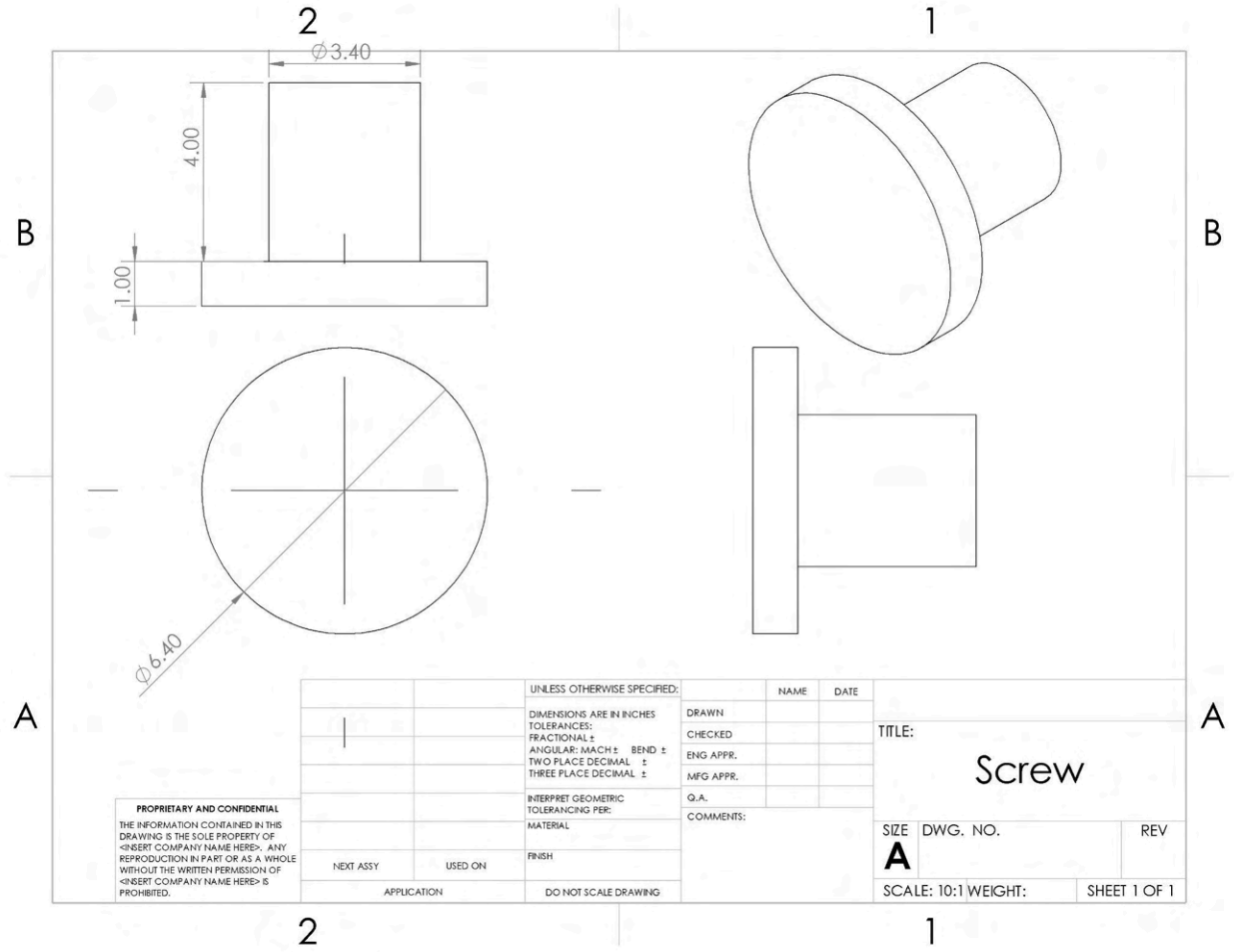



**Figure 9:** Screw. The dimensions are in mm instead of inches.

## Solidworks Part 10: Coiled Coil

- This part represents a coiled coil that covers the wires connecting the sensors and the Mother unit. This part is based directly off of a Philmore retractable cable (62).
- The material of the coil will be PVC, the same as the retractable cable mentioned above.
    - We plan on sourcing the retractable cable for our project, and this model is representative.
    - The retractable cable is too large for what we plan on using it for (25 ft), so this model is a representative model of a cut version of the cable.
- The coil has a mean diameter of 5 mm. The diameter of the wire with the covering is 2.5 mm.
    - The wire itself is not shown in the image below, below is a representative model of the wire jacket.(2.5 mm diameter of jacket is shown in bottom left model in the figure below)
    - The diameter of the spiral is 5 mm
    - The angle of the spiral is not given on the website, but is estimated to be approximately 13.25° with the horizontal
    - Jacket thickness would be 0.05 mm (62)
- Two of these coiled coils are used in our design.

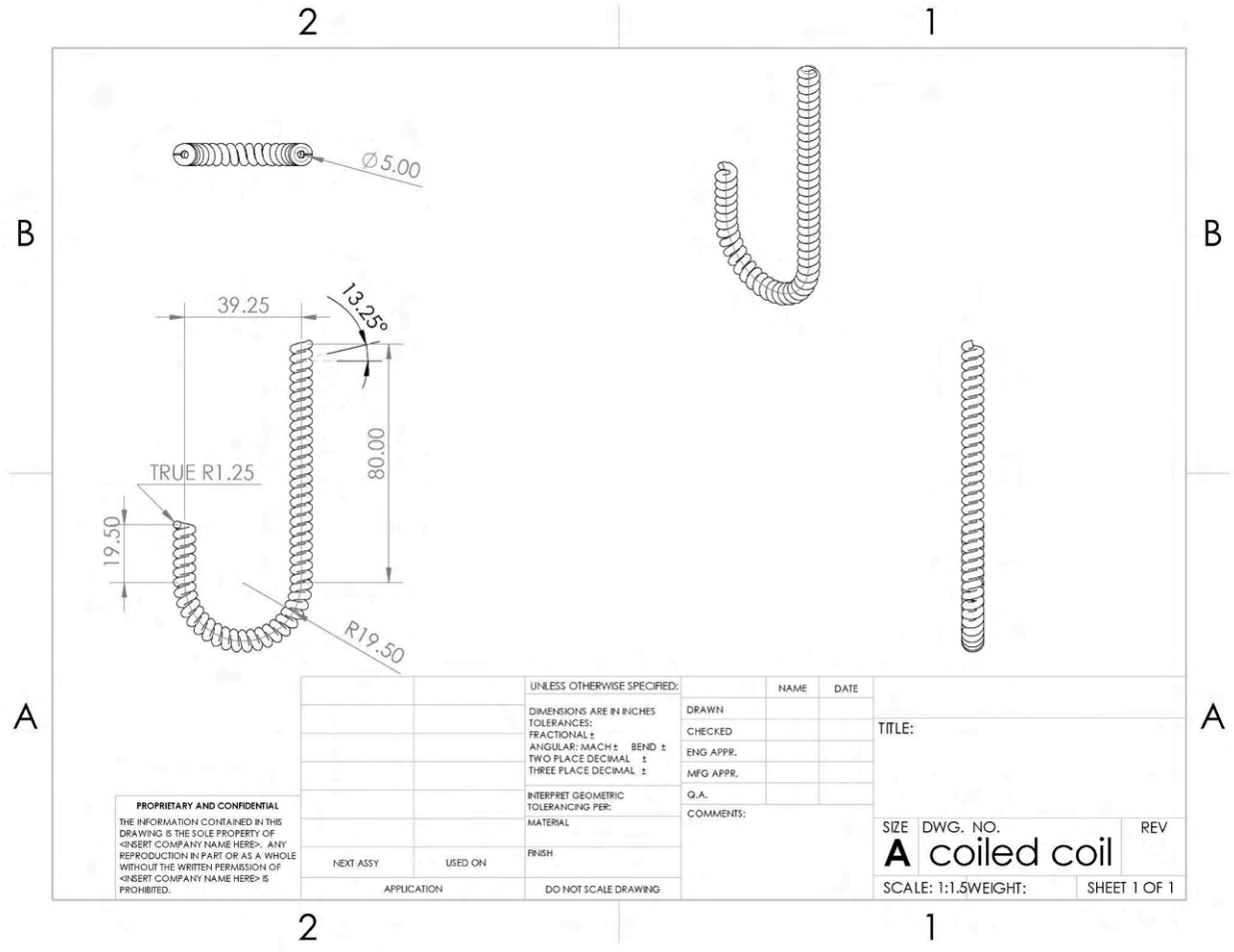



**Figure 10:** Coiled Coil. Dimensions in mm. (edited dimensions, added angle)

## Solidworks Part 11: Half Tank

- Used purely for schematic purposes as this model would be made out of cotton due to its hypoallergenic properties, addressing need 8 from DHF 1: Biocompatibility.
- Visualization of half of the shirt. The flap hanging down is the inner flap of the shirt: this part will flip up to attach to the inner layer of the shirt.

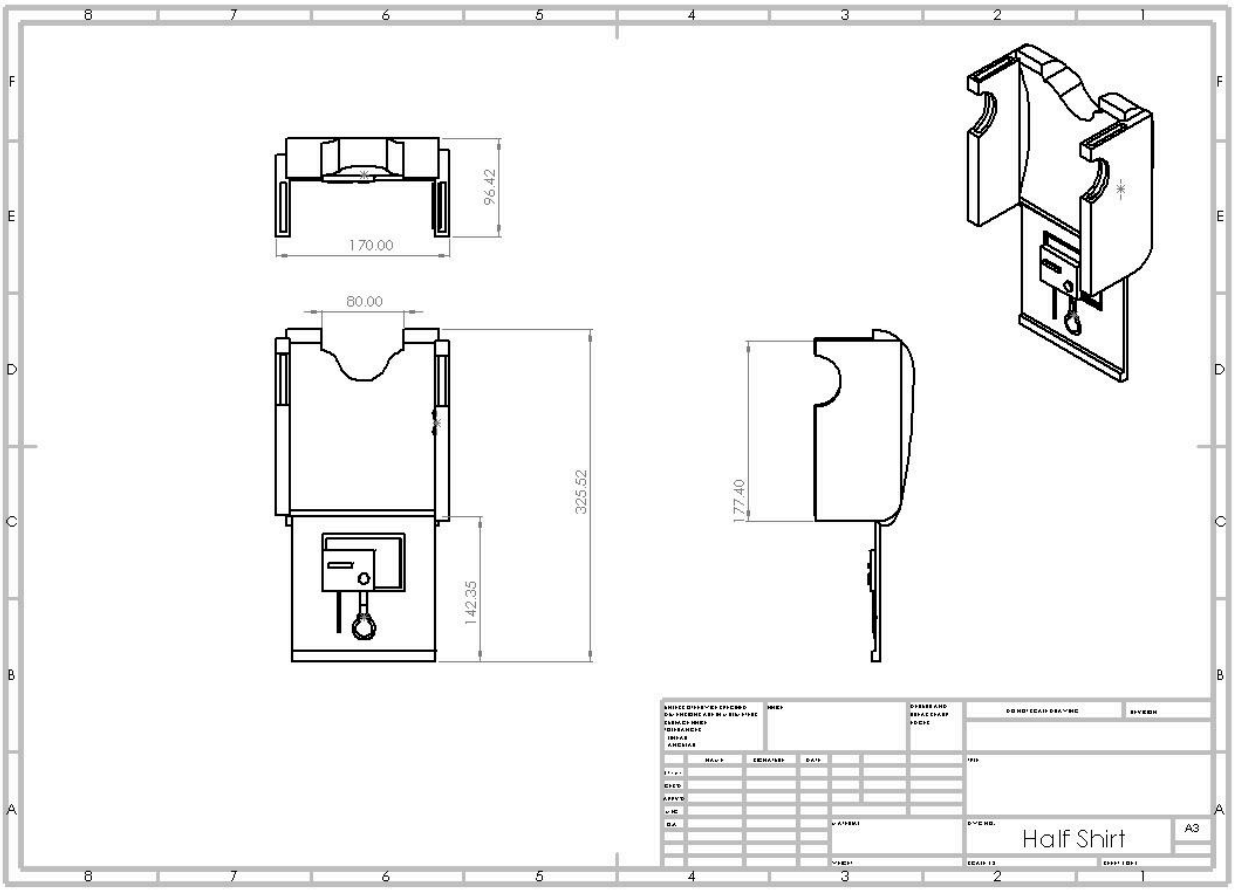



**Figure 11:** Half tank. Dimensions in mm. This is not exactly to scale. Used purely as a schematic. The clothing portion of the Half Tank is meant to be single sized, with additional sizes purchasable, allowing the parent to reuse the electronic component, but resize their infant's clothes.

## Justifications for shirt

The measurements used for the shirt model are directly based on the child model (on the next page). More generally this shirt prototype was designed to model a shirt to fit a 90th percentile 1 year old child. In this design the neck cut out and the main circumference of the shirt were directly based on the measurements from the anthropometric table (40). Due to difficulty in making a shirt in CAD other dimensions of the shirt, such as the sides and front of the shirt are non indicative of an actual shirt for an infant. The main goal with the shirt model was to convey the general shape of the design and to create a housing for the different sensors and electrical components. This was done to see how everything would fit together. This shirt model design is able to be adjusted for an infant between the ages of 0-12 months in the following ways: the shirt will need to be replaced every time the infant grows out of it, however the electronics of the device will never "outgrow" the infant as the wires connecting the sensors to the motherboard are adjustable in length. The electronics are connected with a coiled wire that can be stretched out if needed, allowing it to compensate for growth of the infant. As previously stated the shirt will be designed in different sizes (like normal children's clothing), which parents will order as the child grows out of previous shirts. These shirts will already have all the pockets sewn into them, with the inner flap.

## Solidworks Part 12: Infant Torso

- Part is used as a schematic to represent an infant's torso. Measurements follow anthropomorphic tables (40). Note this model is based on a 90th percentile 1 year old infant (main torso). This was done to help us design an upper bound for our half tank. The half tank was then based on this design. It is important to emphasize that this model is in no way indicative of an actual infant and it is solely meant as a visualization device to help us understand how the half tank will interact with the infant.

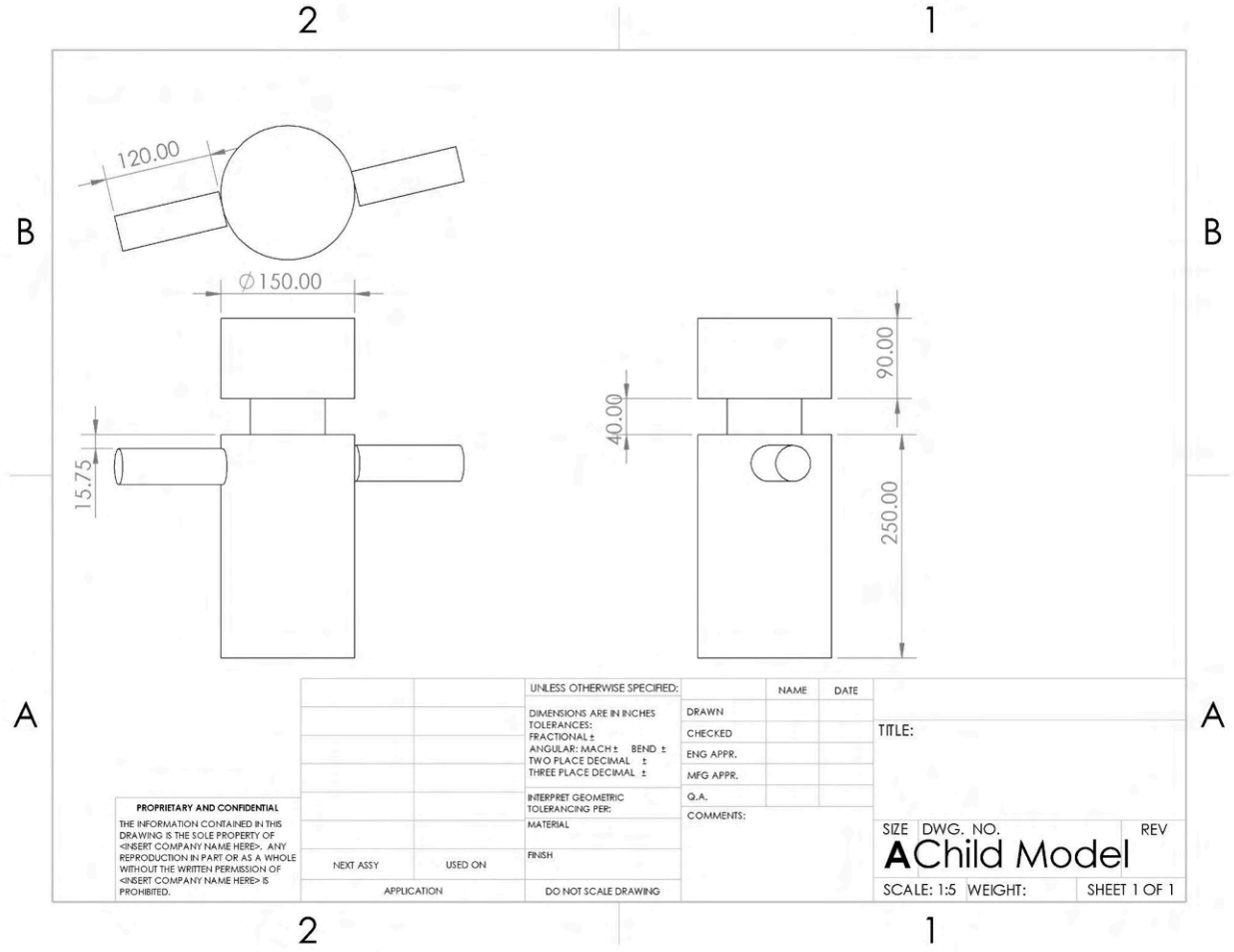



**Figure 12:** Infant Torso. Dimensions in mm. Build to scale the general torso diameter of an infant. (Updated dimensions to infant model)

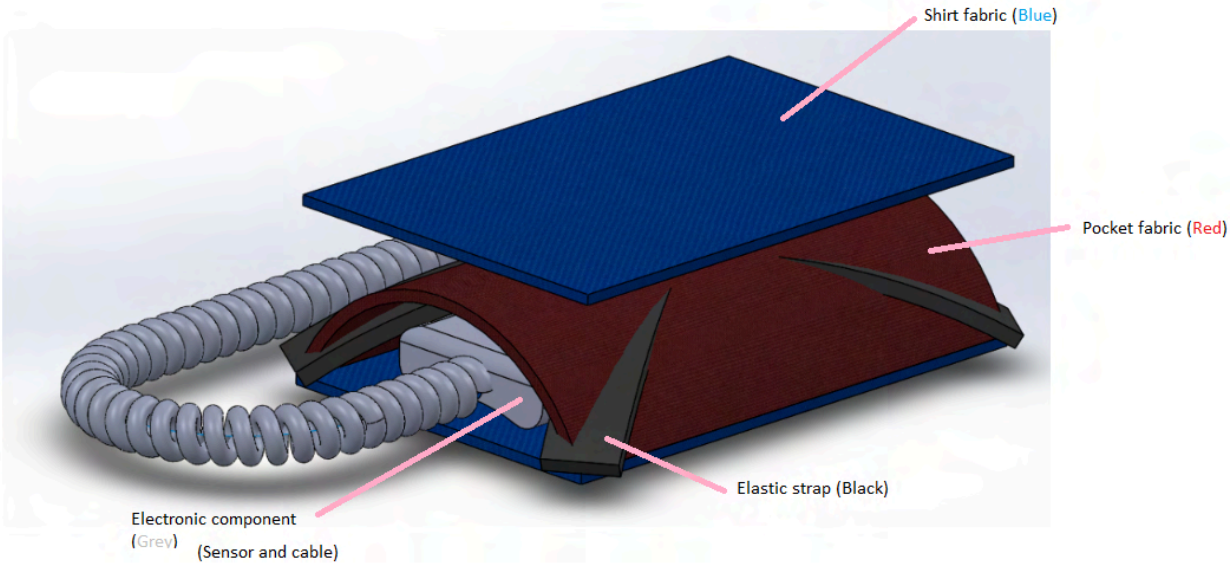



**Figure 13:** Example sensor pocket (temperature, isometric view), made to aid in visualization during part 3, not dimensioned, but generally would be dimensioned individually and large enough to fit each sensor enclosure and Mother Housing

- In real life, the straps would obviously not be clipping into the pocket fabric, and would press against the sensor housing, but in the images do not reflect this because of our inexperience with SolidWorks.

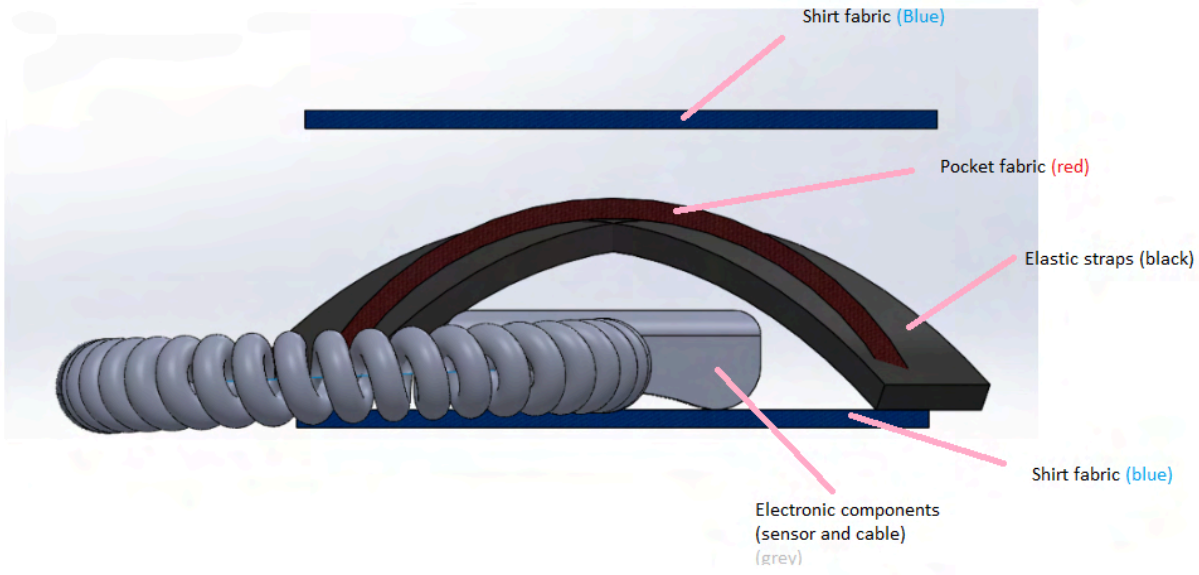



**Figure 14:** Example sensor pocket (temperature, side view), same as 13

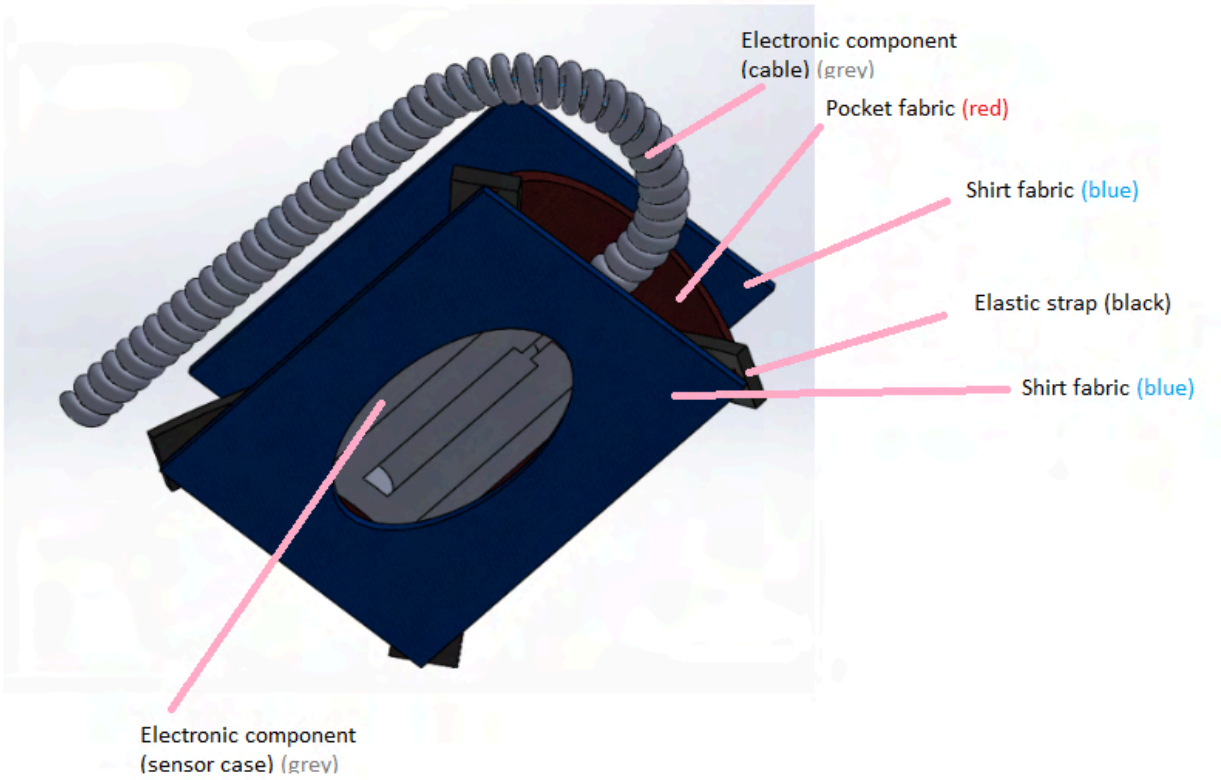



**Figure 15:** Example sensor pocket (temperature, bottom view), same as 13

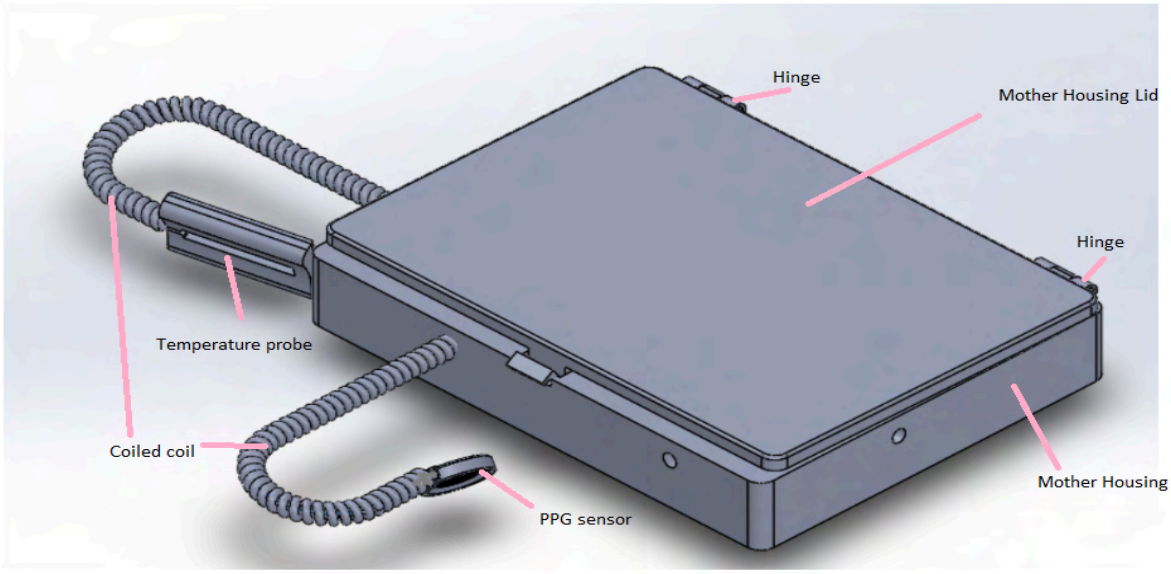



**Figure 16:** complete Mother unit, made to add visual clarity for electronic components

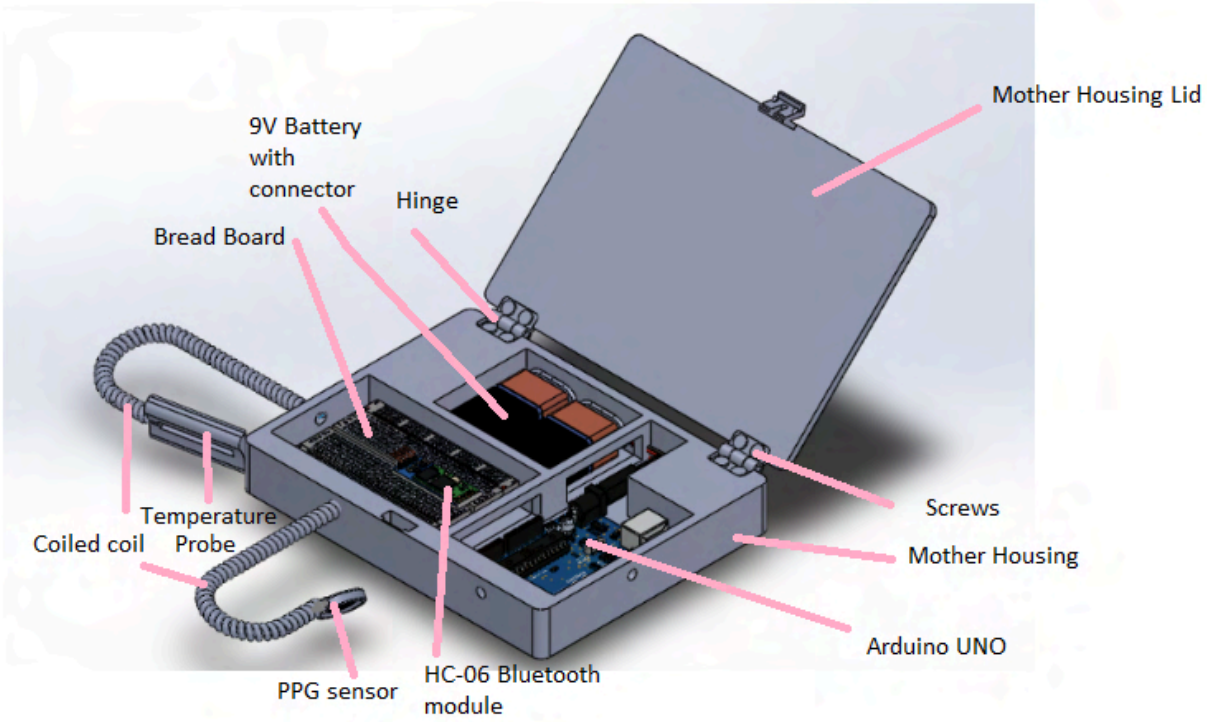



**Figure 17:** Full sized benchtop prototype, open Mother unit

- Externally sourced CAD models:
  - 9V battery with connector (63, 64)
  - HC-06 bluetooth module (65)
  - Arduino UNO (66)
  - Breadboard (67)

# Part 3 - CAD Assembly

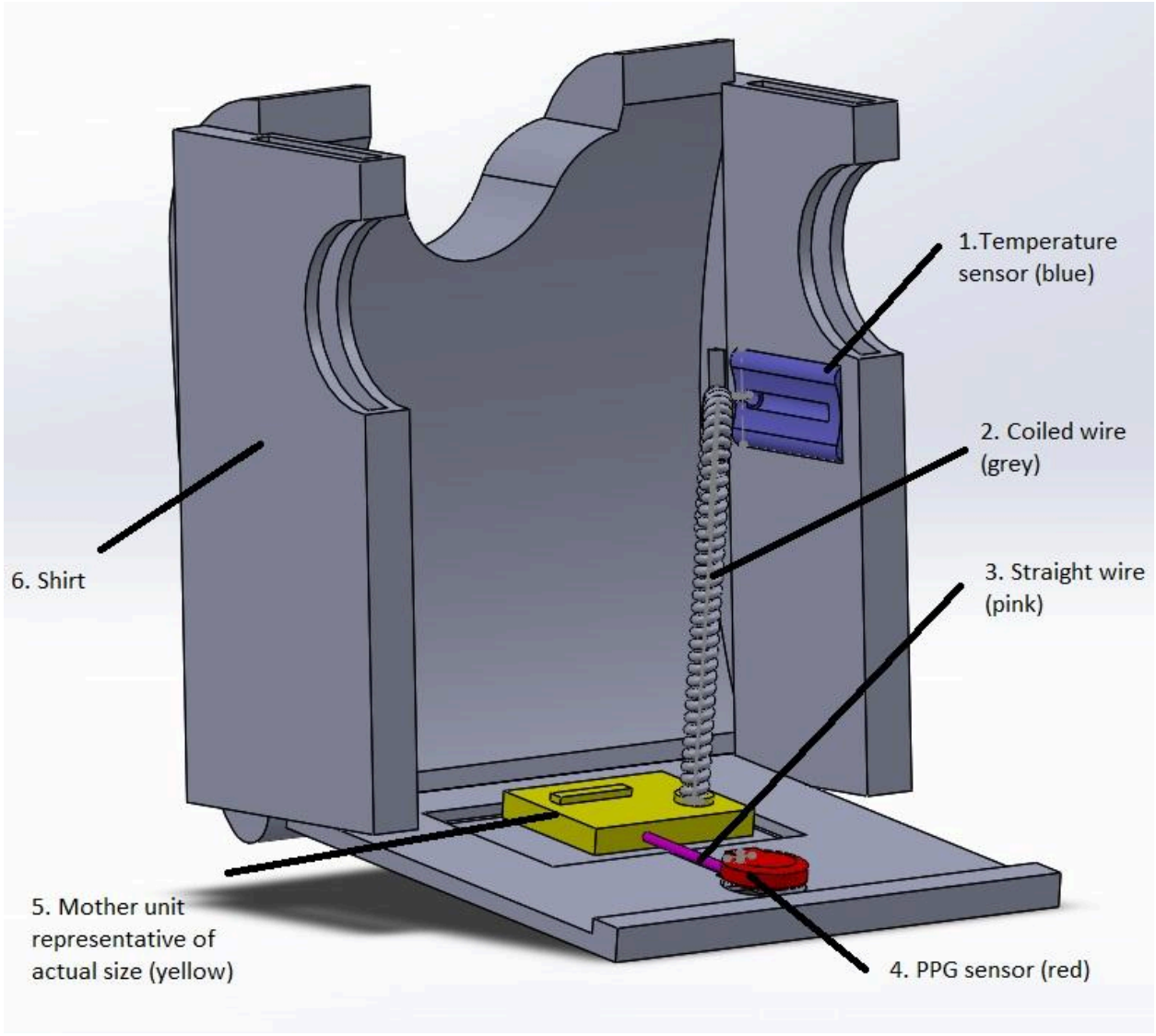



**Figure 18:** Full assembly showing smaller Mother Housing, heart rate sensor and temperature sensor casings.

1. Temperature sensor was placed specifically in the location under the child's armpit. This was chosen in order to get the most accurate readings from the temperature sensor. This is one of the advantages of this design as it allows for more accurate measurements, thereby reducing risk of false positives and increasing the chance of detecting sepsis
2. The coiled wire was chosen since it would likely be stretched during assembly of the shirt or during regular movements by the child. The use of a coiled wire allows it to stretch as needed without unplugging any sensors. This implementation allows the electronic parts of our device to be adjustable with the growth of the infant.
3. Straight wire was used in this location as there is no need for it to move, as both the Mother unit (part 5) and PPG (part 4) sensors are fixed.

4. The PPG sensor is placed through the inside shirt covering that the red sensor rests on in the picture above. This allows it to have direct contact with the child's sternum in order to measure accurate heart rate. (68)
5. This Mother unit is a representative design of a Mother Housing built to house an Arduino Nano, which would ideally be used in the design with a larger budget.
6. Shirt is made to have velcro attached inside the flap that contains all electronics to easily place the shirt onto the child.

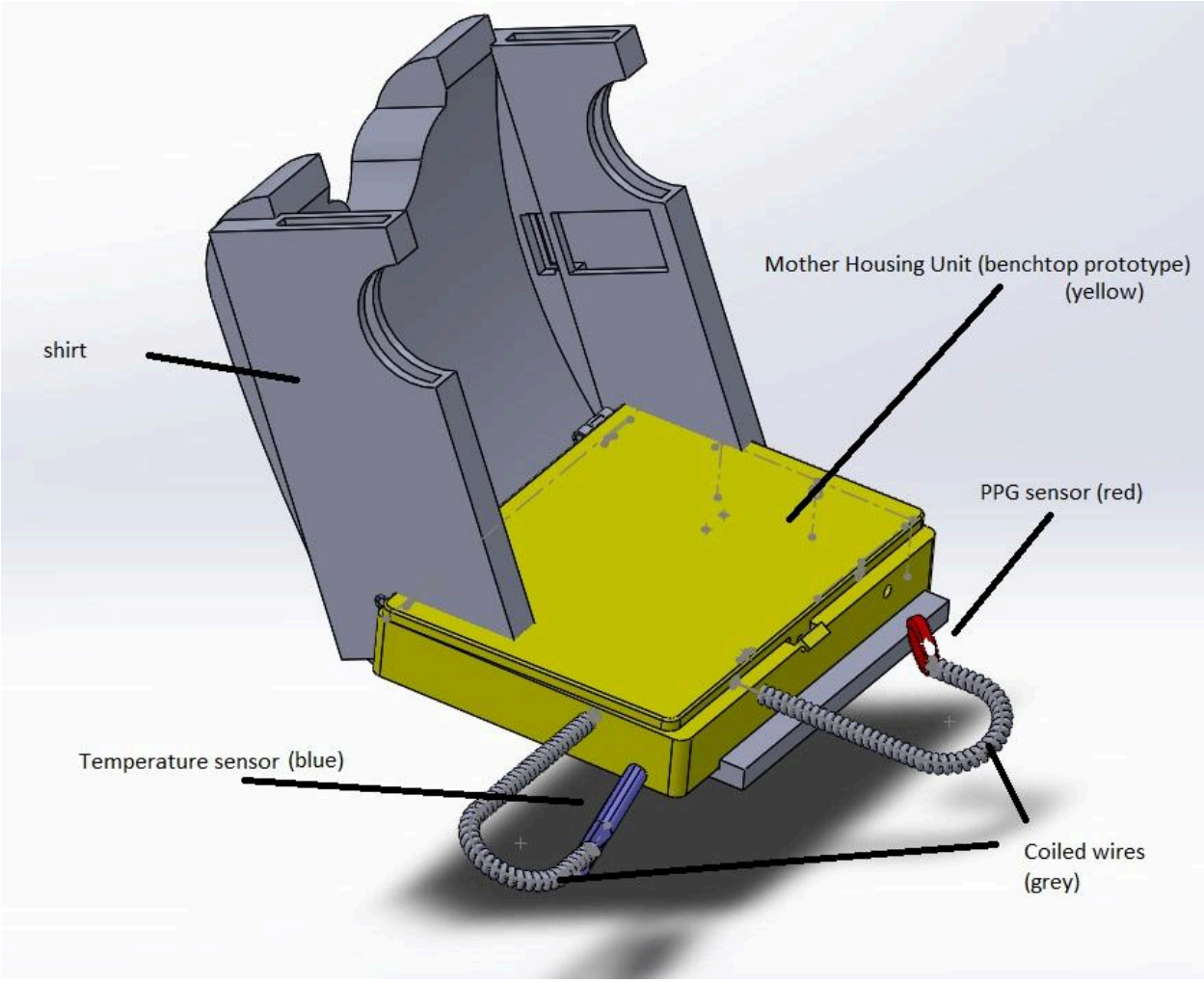



**Figure 19:** This assembly shows the model with a version of the Mother Housing using an Arduino UNO (Figs. 4,5). This is why we chose to create an alternate version of the Mother Housing in Fig. 18 and Part 4, using alternate dimensions in which we would use an Arduino Nano instead. This is because the benchtop prototype using an Arduino UNO that we initially modeled is too bulky and would be a very difficult prototype to build instructions for. We want to acknowledge that the currently dimensioned Mother Housing (Figs. 4 and 5) is too large to fit in the shirt, but also that this is currently the development we are able to realistically achieve in this class. Nonetheless, this also provided insight into how we will have to work around this issue to further prototype our model.

## Instruction Manual

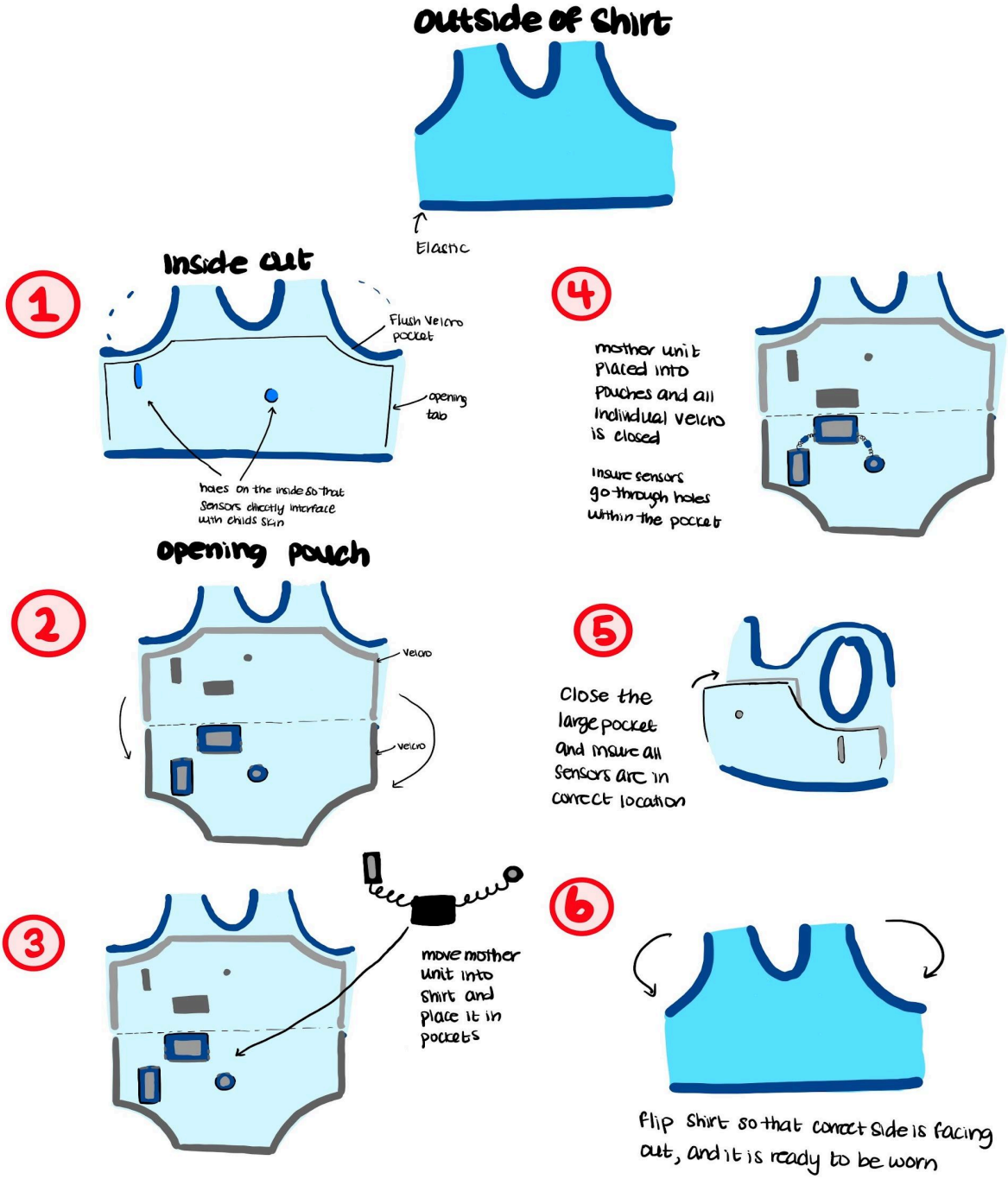



**Figure 20:** Represents a drawn diagram to supplement the functions structure and following CAD model diagrams. This was added purely to give a future representation of the way the fabric will interact. It is very difficult to model turning fabric inside out on solid works.

## Mother Unit assembly

### Step 1 - Insert hinges (Mother Housing)

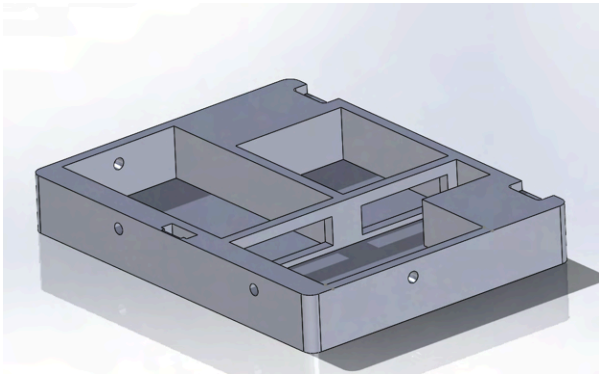


**Figure 21:** Mother Housing

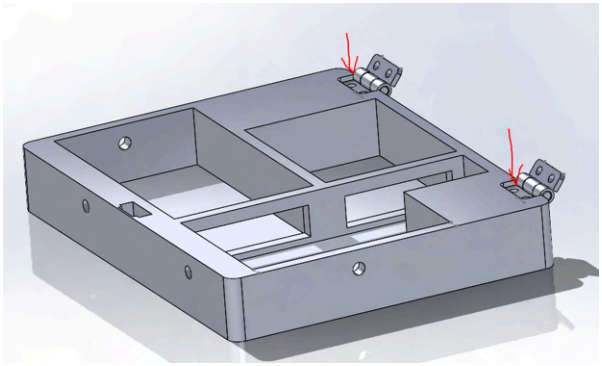


**Figure 22:** Mother Housing with hinges

**1.1**: Insert preassembled, bought hinges into hinge divots in Mother Housing.

### Step 2 - Drill screws into hinges (Mother Housing)

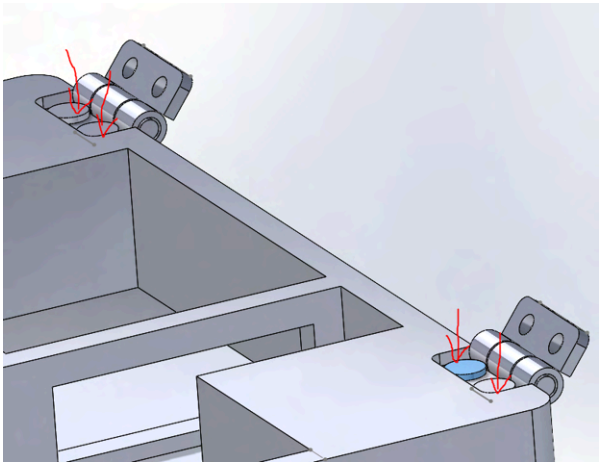


**Figure 23:** Mother Housing with screwed in hinges

**2.1**: Drill screws into hole provided by hinge, into the Mother Housing, securing the hinges to the Mother Housing. Each hinge should have 2 screws being drilled into the Mother Housing, totalling 4 in this step.

## Step 3 - Insert hinges (Mother Housing Lid)

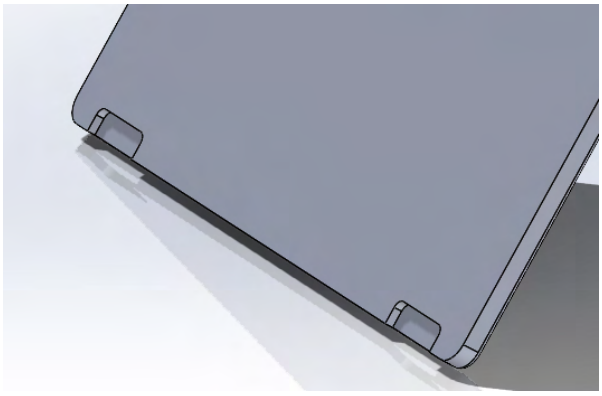


**Figure 24:** Mother Housing Lid

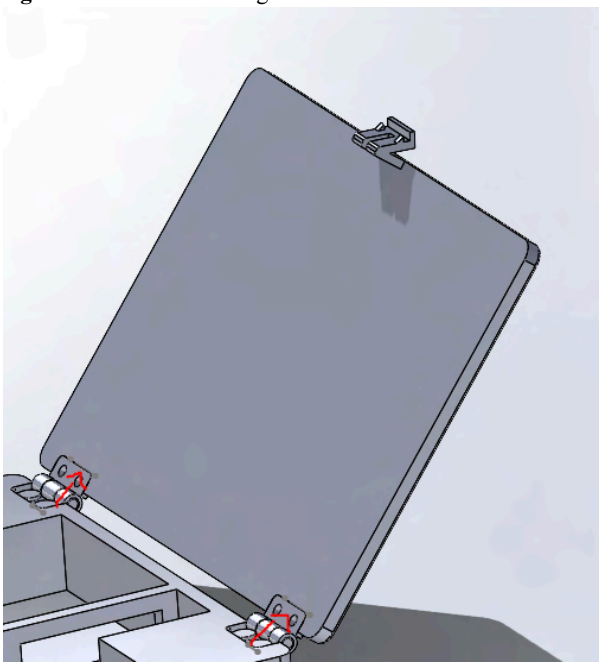


**Figure 25:** Mother Housing Lid with hinges

**3.1**: Like for the Mother Housing, insert the top half of the hinge into the divots made in the Mother Housing Lid.

## Step 4 - Drill screws into hinges (Mother Housing Lid)

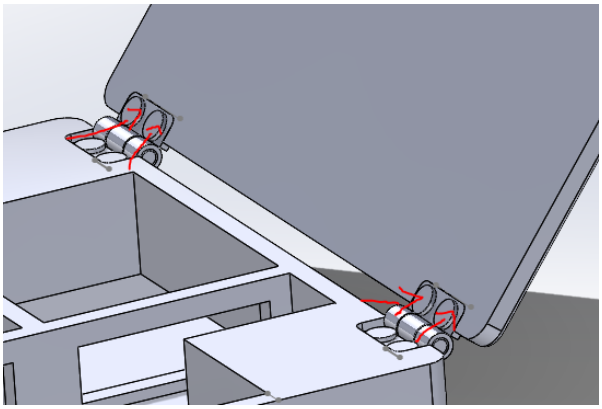


**Figure 26:** Mother Housing Lid with hinges screwed in

**4.1**: Drill screws into hole provided by hinge, into the Mother Housing Lid, securing the hinges to the Mother Housing Lid. Each hinge should have 2 screws being drilled into the Mother Housing Lid, totalling 4 in this step.

## Step 5 - Insert electronic components

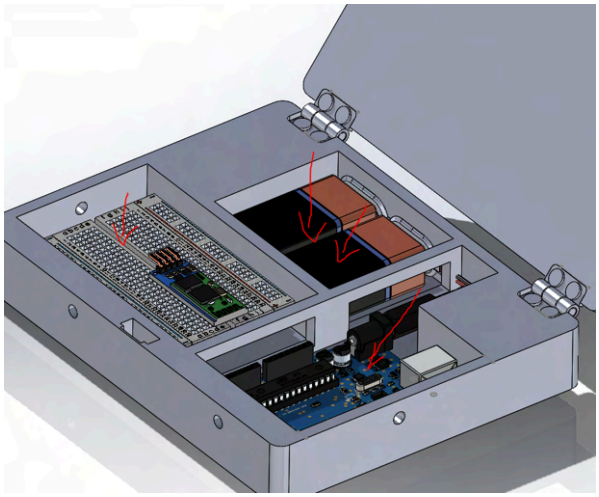


**Figure 27:** Electronic components inserted into Mother Housing

**5.1**: Place each electronic component into their respective compartments, ideally these would be labeled, however, they are not in this image. (Note these are the electronics used in a benchtop prototype).

**5.2**: Connect all circuitry (circutry not shown).

## Step 6 - Assemble PPG sensor case

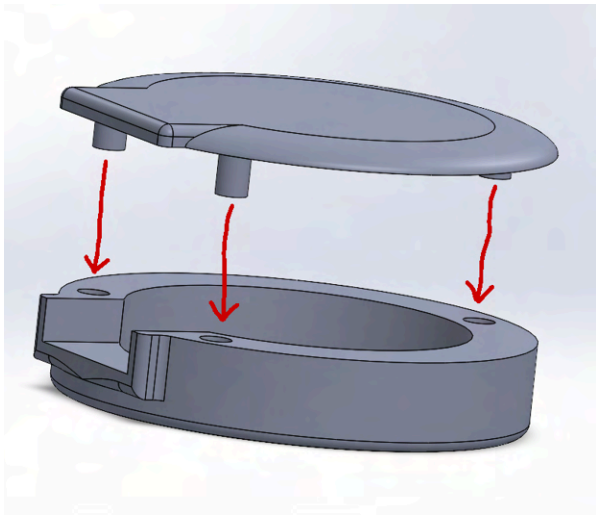


**Figure 28:** Lid aligned with PPG sensor case

**6.1**: Attach the lid to the PPG sensor case by inserting the pins into the holes. The PPG sensor (not shown) would be enclosed with the sensor facing downward.

## Step 7 - Connect sensors to wires in coils

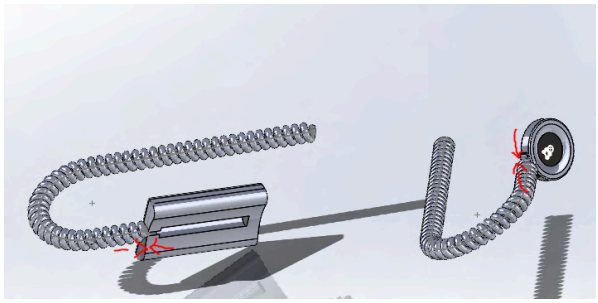


**Figure 29:** Sensors connected to coiled wire (coiled coils)

**7.1**: Connect the temperature sensor (already placed in housing (temperature probe not shown)) to the coiled wire.

**7.2**: Repeat the same with the PPG sensor.

## Step 8 - Connect wires to Mother Housing

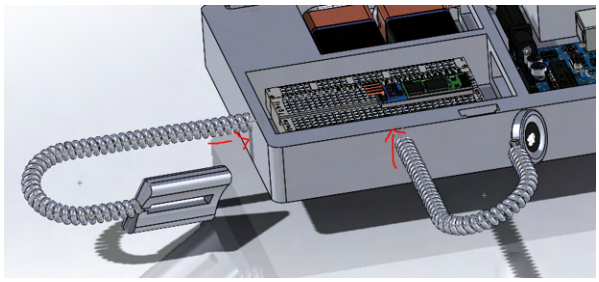


**Figure 30:** Coiled wires connected to breadboard in Mother Housing (connections not shown)

**8.1**: Connect wires to breakout board in Mother Housing (breakout board connection not shown).

## Step 9 - Finish

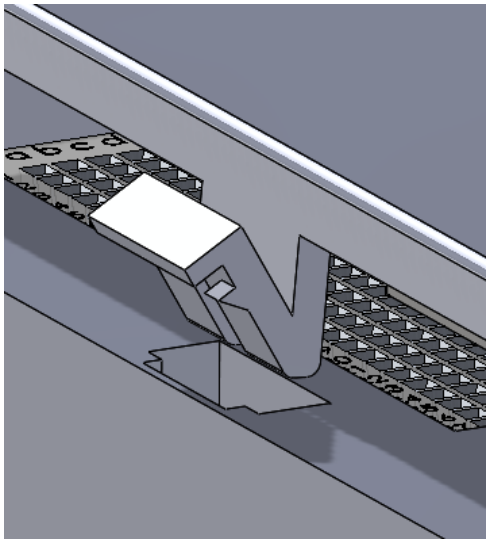


**Figure 31:** Mother Housing Lid latch (unlatched)

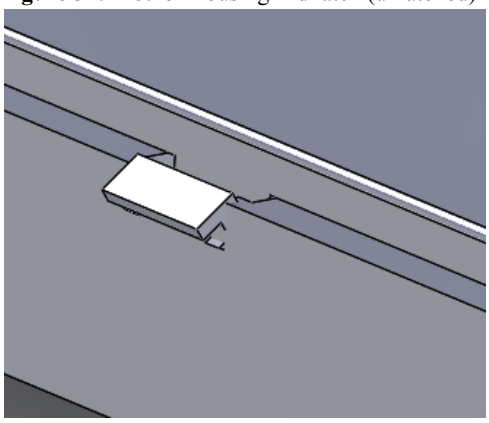


**Figure 32:** Mother Housing Lid latch (latched) (would bend in real life, not clip through Mother Housing)

**9.1**: Complete the Mother unit by closing the lid on the Mother Housing and securing it using the premade latch.

Completed Mother Unit can be seen in Figs. 15, 16.

## Mother Unit insertion

Note: These would be example steps for how the guardian of the infant would insert the sensors and Mother unit after washing the shirt. As the Mother unit would already come preassembled, these steps come after the previous steps outlined.

### Step 1 - Turn Shirt Inside Out

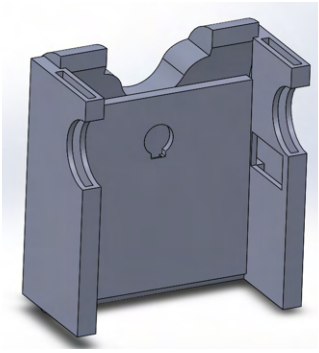


**Figure 33:** Half shirt

**1.1**: Turn the shirt inside out. In this schematic the shirt is viewed as cut in half. This is used purely for visual representation.

**1.2**: Begin to detach velcro on the inner lining panel.

### Step 2 - Open Pouch

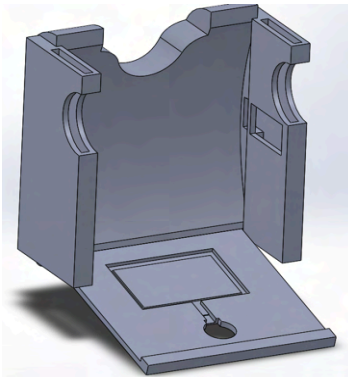


**Figure 34:** Opening of inner shirt layer

**2.1**: After velcro has been loosened, fully pull away the pouch from the outside lining of the shirt. This will expose the placement for sensors.

## Step 3 - Place the Electronic System Into Their Marked Areas

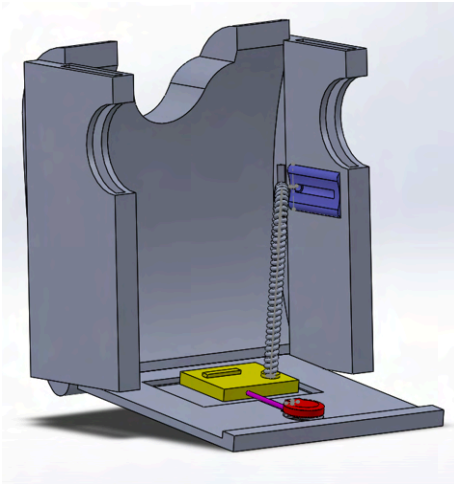


**Figure 35:** Inner shirt layer with sensors embedded

**3.1:** Position the sensors, seen in red and blue, and the Mother unit in yellow into their respective positions.

**3.2**: Tuck each enclosed sensor into their respective pocket (not seen on this diagram). Schematic of this is viewed in figure 13/14.

**3.3**: Ensure that sensors are facing outwards and correctly positioned into the slots within the shirt. This step is critical so that sensors directly interface with the infant's skin. See figure 15 for a clear diagram.

*note: In our real model, and in the representative diagram as seen in figure 20, these components would be as a singular unit that would be easily placed into pockets. Additionally the Mother Unit is not the same as the one modeled in figure 19. A smaller, more compact model was used to simulate what future prototypes would ultimately look like.

## Step 4 - Close the Pouch

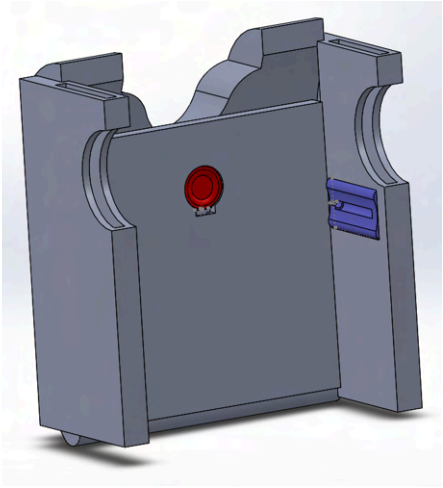


**Figure 36:** Inner shirt pouch with sensors, closed. Shows the areas where the sensors will interface with the skin.

**4.1**: Once all sensors are correctly in place, close the large pouch.

**4.2**: Secure the pouch in place with the velcro.

**4.3**: Flip the shirt so that the outside is correctly facing.

## Step 5 - Place the Shirt Onto Infant

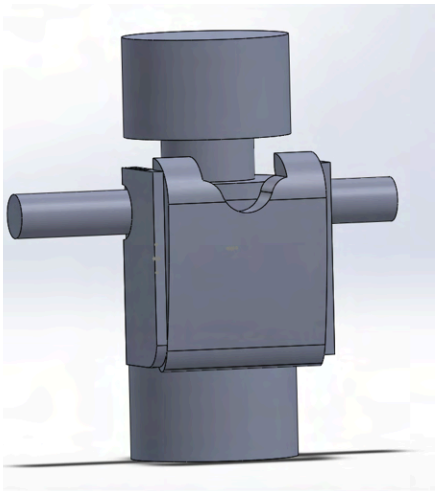


**Figure 37:** Shirt placed on a very rough anatomical model of an infant.

**5.1**: Place the shirt onto the infant.

# Part 4: Building a Part

We printed a few parts. To ensure the safety of the temperature and heart rate sensors that we'll be using, we printed enclosures for them. This is because the sensors are not fixed in a rigid housing and may be subjected to jostling during use, which increases the risk of damage. So by manufacturing the enclosures and dealing with any obvious issues, we can make sure that the sensors are safe and secure. We chose to 3D print these parts as some aspects of these components require a degree of precision that hand tools are unable to fulfil (ex: lid pin holes). We chose to 3D print over CNC machining because we do not know how to use a CNC mill.

- Of the things that did go well, the lid and enclosure were designed to be 22 mm in diameter and came out fairly accurate (within 5% tolerance). On the other hand, the heart rate sensor enclosure holes for the lid pins ended up being printed too small, which made it near impossible for us to clip the lid into it. This was most likely due to the 3D printer's lack of precision in printing. In the future, we will design our parts with significantly more tolerance to account for this. The holes and pins were meant to both be 1 mm in diameter; however, due to the PLA melting over the hole during printing, the holes became uneven and slightly closed up, blocking the pins.
- We chose to 3D print the lid on the flat surface rather than the side with the pins as it is much more stable and requires less material (no supports) to print due to there being no overhangs. Similarly for the enclosure that the lid clips onto, this part was printed on its flat side facing the printer bed, as there is a divot on the other side that would leave an overhang if printed on that side. The infill pattern used was a general cubic pattern as the enclosure would take force from every direction.


**Figure 38:** Printed PPG (heart rate sensor) enclosure lid.

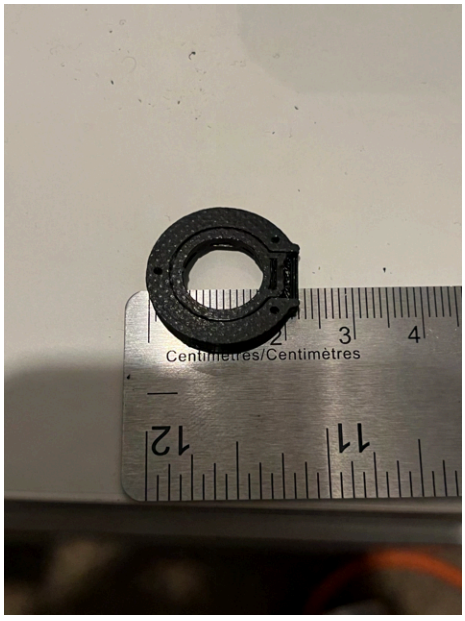



**Figure 39:** Printed PPG (heart rate sensor) enclosure.

- The temperature sensor enclosure, like the PPG enclosure, was printed with the flat end facing the print bed to prevent the sensor compartment from overhanging during printing. This allows us to print without supports, which uses less material.
- The temperature sensor enclosure did come out quite nice. However, the hole where the temperature probe would actually slot in came out oval-shaped, which would make it quite hard for us to insert the rigid circular probe. The compartment for the sensor and cable was designed to be 6 mm and 4 mm in diameter, respectively; however, due to a slight unsupported overhang in the design of the compartment, it cooled in an oval shape rather than a perfectly circular one.
    - The width and length of the temperature sensor enclosure were designed to be 25 and 45 mm respectively, and did end up printing faithful to its dimensions.
- Like the PPG sensor enclosures, the infill pattern chosen was cubic, as the enclosure would take force from every direction.

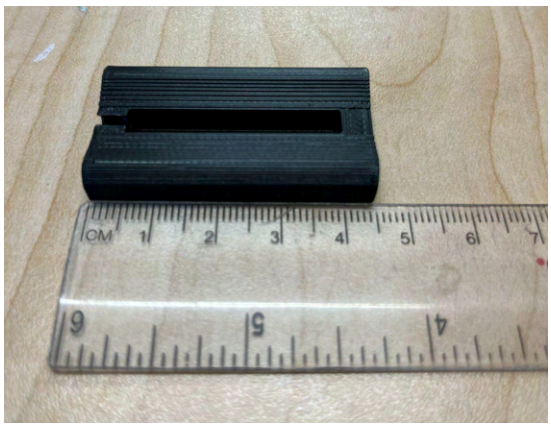


**Figure 40:** Printed temperature sensor enclosure.

It is worth noting for future reference that filament-based 3D printers may have limits when printing materials with detailed millimeter-scale details. In such circumstances, we should consider using CNC machining as an alternative option. Furthermore, we should consider including a reasonable degree of tolerance to assist the manufacturing process.

# *DHF 4.2: Detailed Circuits and Software Design*

## Part 1: Selecting Resistance Sensor

To measure changes in temperature, we needed to select a resistance-based sensor for our design. The resistor will predictably change in response to the temperature, which can then be used in a resistance-based circuit which the Arduino's analog voltage pin will measure.

First, we chose three evaluation criteria to evaluate different resistance-based sensor candidates. The justification for why each criteria was chosen is below.

1. Cost
    a. The cost refers to the money (in Canadian dollars) that we need to spend in order to purchase a single sensor. Sensors that cost more will make our final product more expensive, so ideally the sensor cost will be minimized. To increase overall user satisfaction, a lower price correlates to a higher user satisfaction.
2. Thermal Sensitivity: Temperature coefficient of resistance
    a. The sensitivity of the sensor reading is immensely important to the ability of our design in detecting signs of sepsis. The sensitivity of the sensor determines the fluctuations in temperature that our device will be able to differentiate. This is of utmost importance as the difference between normal body temperature (36-38℃) and a critical fever (warning for sepsis) body temperature (38+℃) is only one or two degrees of difference. Therefore, a more sensitive sensor offers performance benefits in regards to detecting signs of sepsis, which results in a large impact in overall user satisfaction.
    b. The temperature coefficient was found in the respective sensor's dataset.
3. Accuracy
    a. Sensor accuracy is a measure of the uncertainty of a temperature reading at any given temperature. If the device's sensors are not accurate, they may underestimate the infant's actual temperature and miss critical signs of sepsis. If the sensor is overestimating the infant's temperature, false alarms may constantly occur. Sensor accuracy has a direct impact on the ability of our device in detecting sepsis, and therefore impacts the overall user satisfaction of the device.
    b. The accuracy score was found in the respective sensor's dataset.

The evaluation function for each criterion is described in the table below.

**Table 1: Evaluation Criteria**

| Number | Associated Requirement | Property (Weight) | Evaluation Criteria | Justification for criteria ranges |
|---|---|---|---|---|
| 1 | NA | Cost (20%) | S-curve<br>Max satisfaction = $5<br><br>Min satisfaction = $50<br><br>Inflexion point = $12 | We chose the S-curve for this criterion because the change in cost of a sensor that is already very cheap or expensive will not matter as much as that in the ones with a moderate price. We chose $5 for maximum satisfaction because the cheapest physical thermometers (those that require physical contact) on the market right now cost around 5 - 6 dollars (69). And our thought process was that, if guardians are willing to pay $5 for a single thermometer, the temperature sensor we use in our device can also be $5.<br>Along the same lines as the bound for maximum satisfaction, we chose $50 for our minimum satisfaction (70). We chose the inflection point at $12, as it corresponds to the price of the most reviewed physical thermometer on Amazon (71). Since this product has the highest number of reviews, it suggests that it is also the most purchased, making it a relevant and meaningful price point to consider. The number of reviews shows that consumers are more willing to pay for a thermometer at this price, which indicates that their satisfaction at this price is likely to be the most sensitive to change. |
| 2 | Accuracy | Thermal Sensitivity (40%) | S curve, inflection point at 3850 ppm/°C<br><br>Lower bound: TCR of 3750 ppm/°C<br><br>Upper TCR of around 6720 | The lower bound was decided by choosing the lowest available TCR value available on Digi-Key. The upper bound was chosen using the same but with the highest value.<br><br>Platinum is the most common material used for manufacturing RTDs, and the inflection point for the temperature coefficient of resistance (TCR) was chosen to be 3850 ppm/°C. This value is the calibration point for most platinum RTDs |

| | | | | |
|---|---|---|---|---|
| | | | ppm/°C | due to the requirements set by IEC 60751, which mandates that all platinum RTDs must have a TCR within the range of 3850 to 3915 ppm/°C.<br><br>We chose an S-curve to incentivize sensors for achieving higher accuracy than the standard, while still rewarding sensors that meet the standard accuracy. However, the reward for exceeding the standard decreases after reaching 3850 ppm/°C as the final satisfaction declines after meeting the standard sensor sensitivity. |
| 3 | Accuracy | Sensor Accuracy (40%) | Linear:<br><br>Lower bound: ±0.485℃<br><br>Upper bound: ±0.163℃ | The lower bound is the industry standard of temperature sensor accuracies. It is specified as “Class B” accuracy by IEC-751. This is our lower bound as our accuracy requirement states all sensors must have a baseline accuracy equal to or greater than the industry standard.<br><br>The upper bound is considered “Class AA” accuracy by IEC-751. Having this level of accuracy is commonly considered exceptional, and therefore results in maximal user satisfaction.<br><br>A linear relationship was chosen as every increase in sensor accuracy has a direct and proportional relationship with the increase in the ability of our sensor in detecting sepsis, and therefore the overall user satisfaction. |

*Please note, in accordance with our biocompatibility requirement, sensors must be compliant with RoHS. RoHS compliance is not an evaluation criteria but rather is a requirement for the temperature sensor to be chosen.

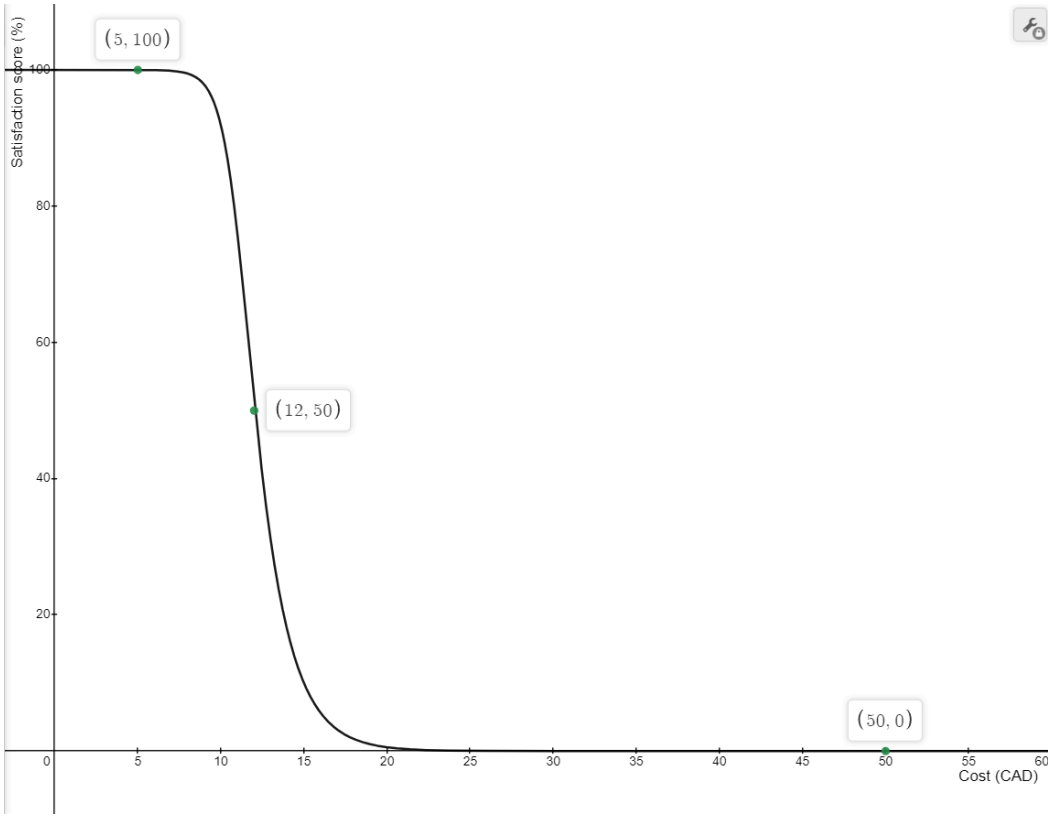



**Figure 1:** Evaluation curve for cost (changed graph)

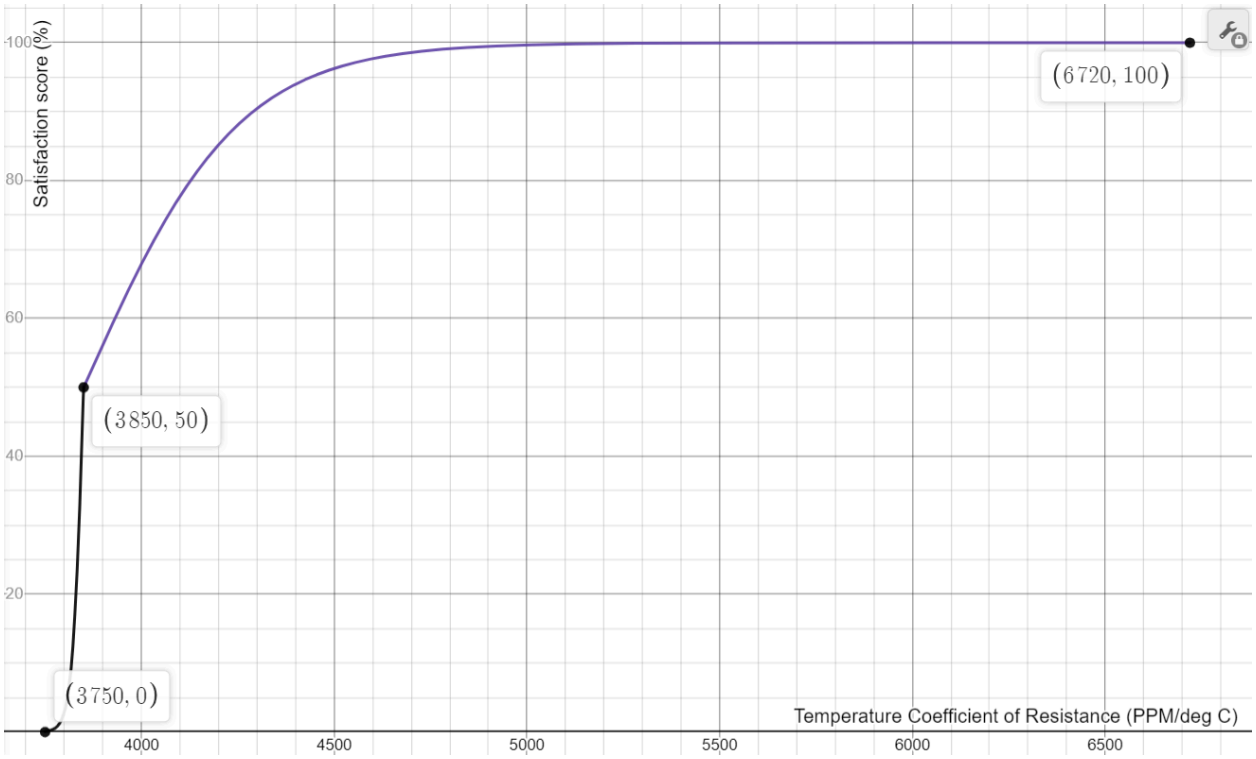



**Figure 2:** Evaluation curve for thermal sensitivity

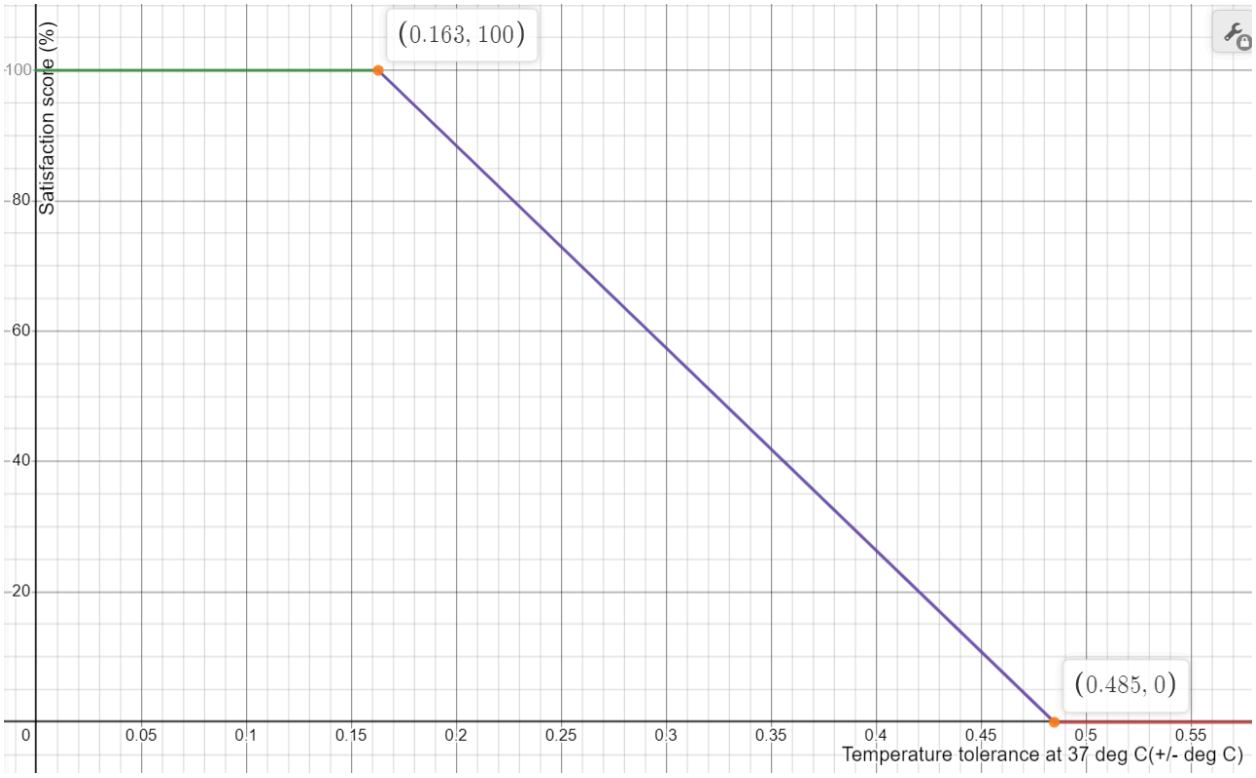



**Figure 3:** Evaluation curve for accuracy

**Table 2:** Evaluation Criteria Weightings

| Evaluation Criteria | Weighting (out of 100%) |
|---|---|
| 1. Cost | 20% |
| 2. Thermal Sensitivity | 40% |
| 3. Accuracy | 40% |

The sensitivity and accuracy were given equally large weightings because they both have a large effect on the accuracy and precision of our final design in detecting signs of sepsis. These criterions are weighted heavily because they are directly influential in properly addressing our statement of need (DHF 1). The cost evaluation criteria was given a 20% weighting. This is because our design must stay within our designated budget, however the cost of the sensor does not have an impact on the ability of our sensors to detect signs of sepsis.

The parameters relevant to each evaluation criteria were found on each sensor's datasheets. These parameters are summarized in the table below.

**Table 3:** Sensor Parameters

| **Parameter** | 32208439 | PTFC102 A1G0 | 32208550 | P0K1.281. 6W.B.007. R | HEL-705- U-0-12-00 | ND1K0.5 20.2FW.B .007 | R-8203 |
|---|---|---|---|---|---|---|---|
| **Sensor #** | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| |  | | | | | | |
| **Cost (CAD)** | 13.49 | 5.26 | 8.13 | 7.23 | 51.77 | 4.52 | 119 |
| **Thermal Sensitivity (ppm/C)** | 3850 | 3850 | 3850 | 3850 | 3750 | 6180 | 4270 |
| **Accuracy** (±℃) (all sensitivities are at 37℃ unless specified otherwise) | 0.224 | 0.224 | 0.224 | 0.485 | 0.5 **(from 0 - 100℃)** | 0.485 | 0.2 |

Each parameter was then converted into an evaluation satisfaction score using the evaluation functions described. The final scores for each sensor was computed in the weighted decision matrix below.

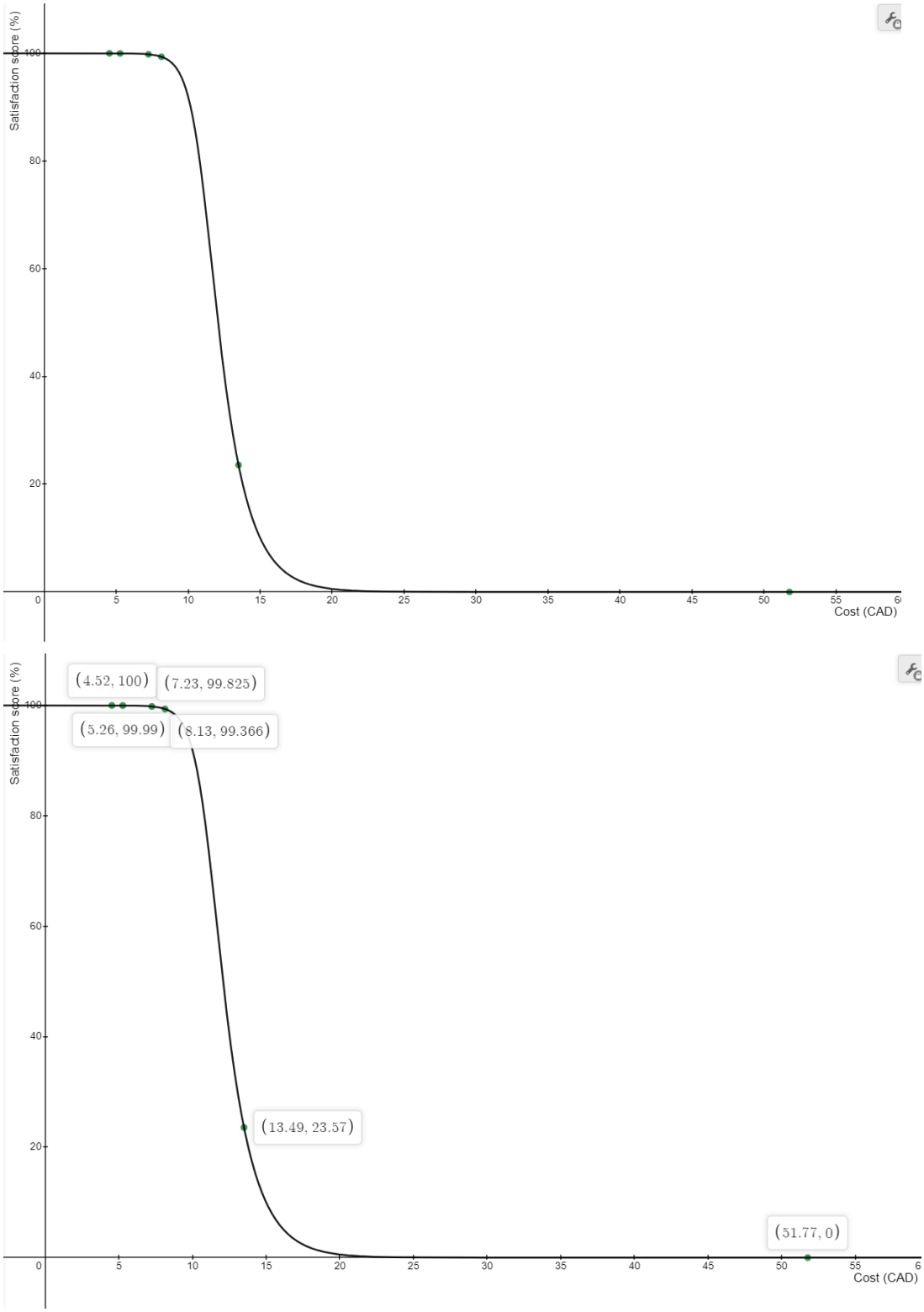



**Figure 4:** Evaluation Curve for cost with sensor scores without $119 module. Unlabeled (top) and labelled (bottom) [Desmos link]

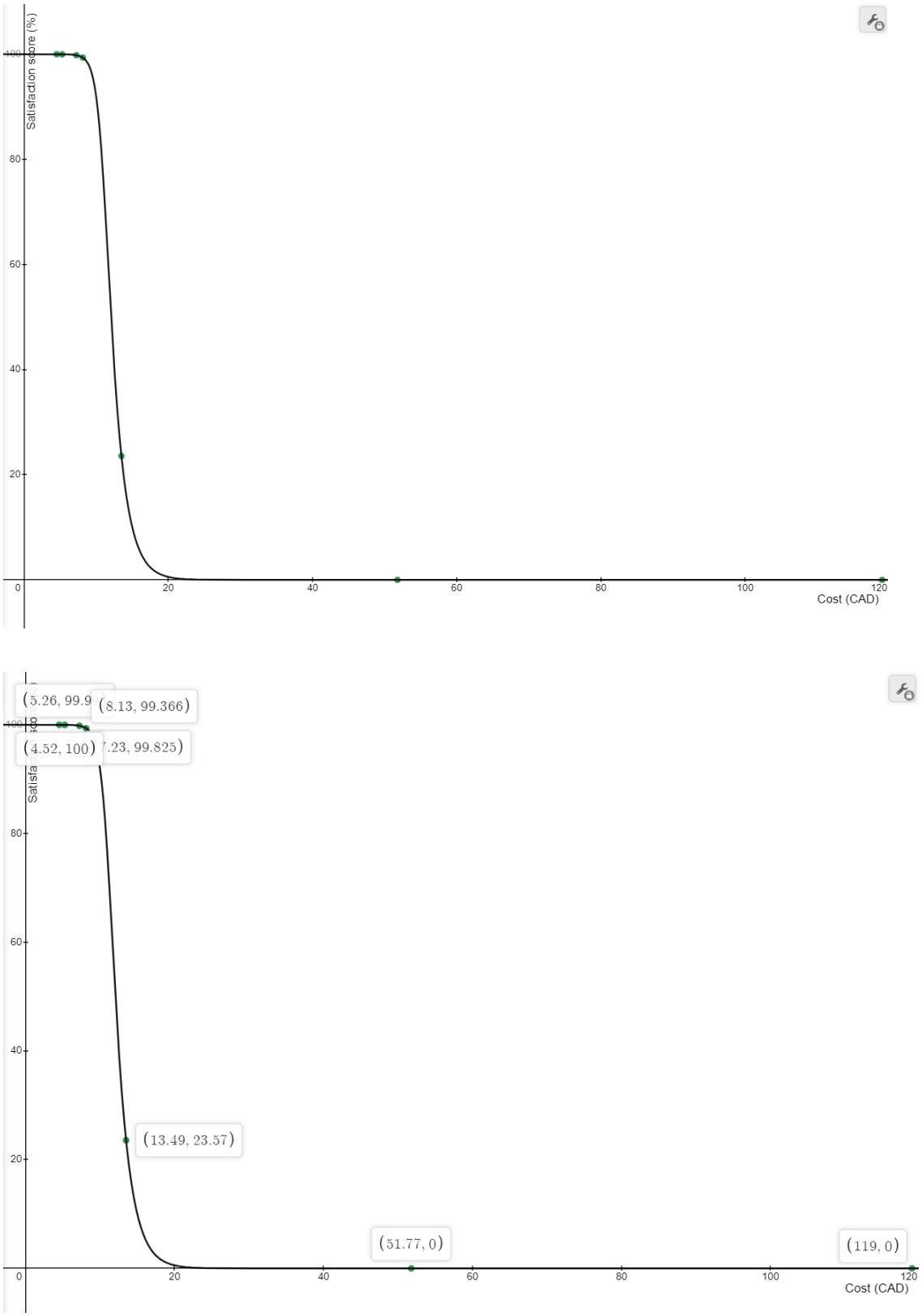



**Figure 5:** Evaluation Curve for cost with sensor scores with $119 module. Unlabeled (top) and labeled (bottom)

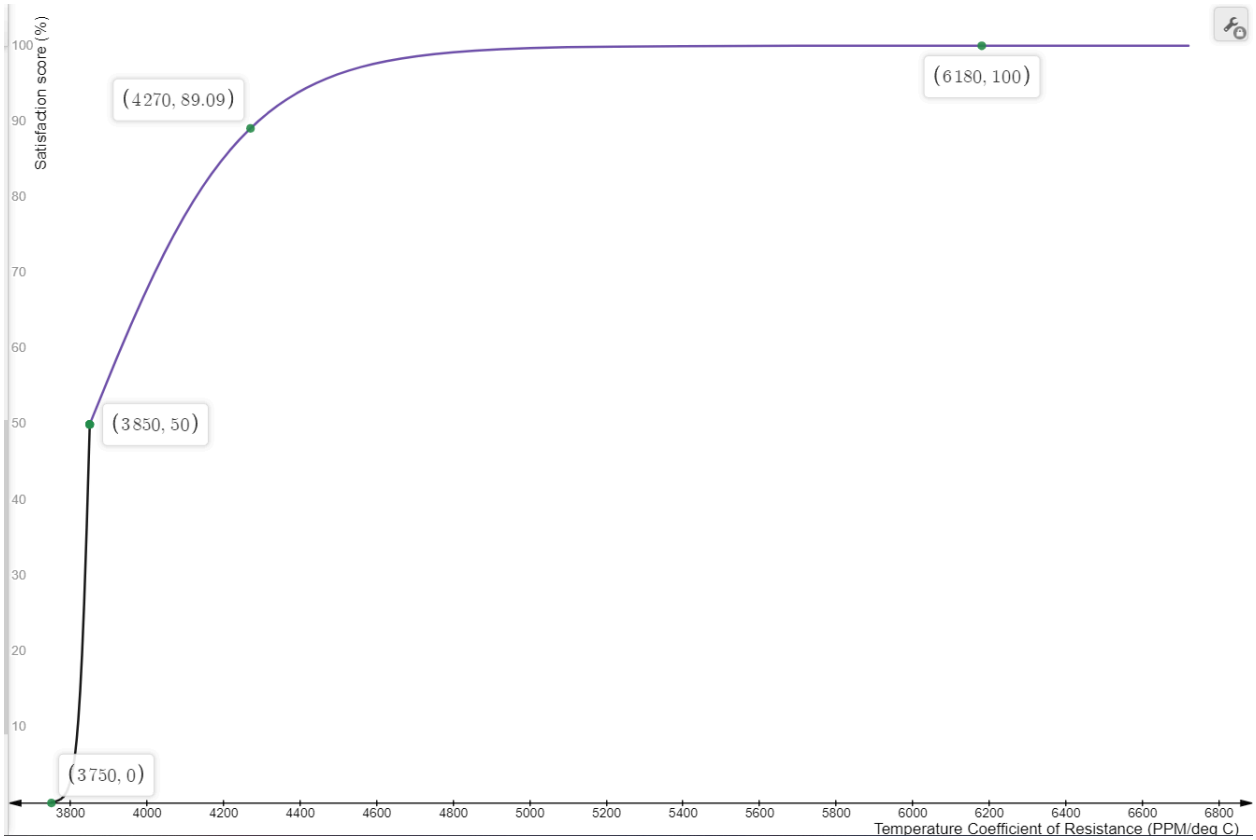



**Figure 6:** Evaluation Curve for temperature coefficient of resistance (labeled) (updated graph)
Desmos link

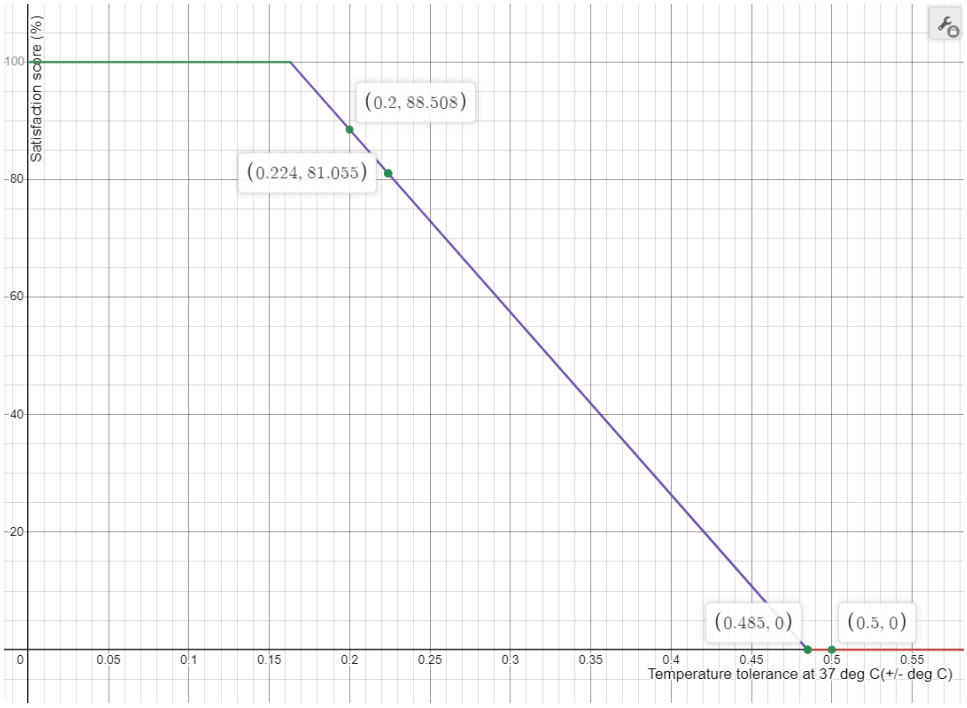



**Figure 7:** Evaluation curve for temperature tolerance (labelled) (updated graph)
Desmos link

**Table 4: Satisfaction scores and module performance**

| Sensor | | Cost | | Temperature coefficient of resistance | | Temperature tolerance | |
|---|---|---|---|---|---|---|---|
| # | Part | Performance (CAD) | Satisfaction (%) | Performance (PPM/deg C) | Satisfaction (%) | Performance (+/- deg C) | Satisfaction (%) |
| 1 | 32208439 | 13.49 | 23.57 | 3850 | 50 | 0.224 | 81.06 |
| 2 | PTFC102A1G0 | 5.26 | 99.99 | 3850 | 50 | 0.224 | 81.06 |
| 3 | 32208550 | 8.13 | 99.37 | 3850 | 50 | 0.224 | 81.06 |
| 4 | P0K1.281.6W.B.007.R | 7.23 | 99.83 | 3850 | 50 | 0.485 | 0 |
| 5 | HEL-705-U-0-12-00 | 51.77 | 0 | 3750 | 0 | 0.5 | 0 |
| 6 | ND1K0.520.2FW.B.007 | 4.52 | 100 | 6180 | 100 | 0.485 | 0 |
| 7 | R-8203 | 119 | 0 | 4270 | 89.09 | 0.2 | 88.51 |

**Table 5: Weighted Decision Matrix:**

| Evaluation Criteria | Criteria Weight | 32208439 | PTFC102A1G0 | 32208550 | P0K1.281.6W.B.007.R | HEL-705-U-0-12-00 | ND1K0.520.2FW.B.007 | R-8203 |
|---|---|---|---|---|---|---|---|---|
| | |  |  |  |  |  |  |  |
| **1** | 20% | 23.57 | 99.99 | 99.37 | 99.83 | 0 | 100 | 0 |
| **2** | 40% | 50 | 50 | 50 | 50 | 0 | 100 | 89.09 |
| **3** | 40% | 81.0 | 81.06 | 81.06 | 0 | 0 | 0 | 88.51 |
| **Total** | **100%** | 57.114 | 72.398 | 72.298 | 39.966 | 0 | 60 | 0 |

The second sensor (PTFC102A1G0) scored the highest in our WDM, however, at the time, it was shown to have a long lead time, thus we will use the runner up, the third sensor (32208550), which we will use in our circuit design.

# Part 2: Sensor Circuit Design

The design of our circuit features:

- A single-bridge wheatstone bridge module
- Resistor models for long sections of wire
- A differential amplifier module to take the difference between the two sides of the wheatstone bridge and amplify the voltage output

We chose to use a wheatstone bridge for our circuit design because measuring the voltage difference between the rungs of the two voltage dividers gives us a range of voltages from 0 Volts to some value. In comparison, a regular voltage divider would provide some range of voltage that doesn't start at exactly 0 Volts. This offset makes it much harder to accurately and precisely measure voltage. This is especially relevant when it comes to electrical noise. By measuring the voltage difference between two rungs, most electrical noise will be negated as the noise will presumably affect both rungs. Therefore, the wheatstone bridge is a more reliable and precise sensing circuit compared to a voltage divider, which is why we decided to use it in our design.

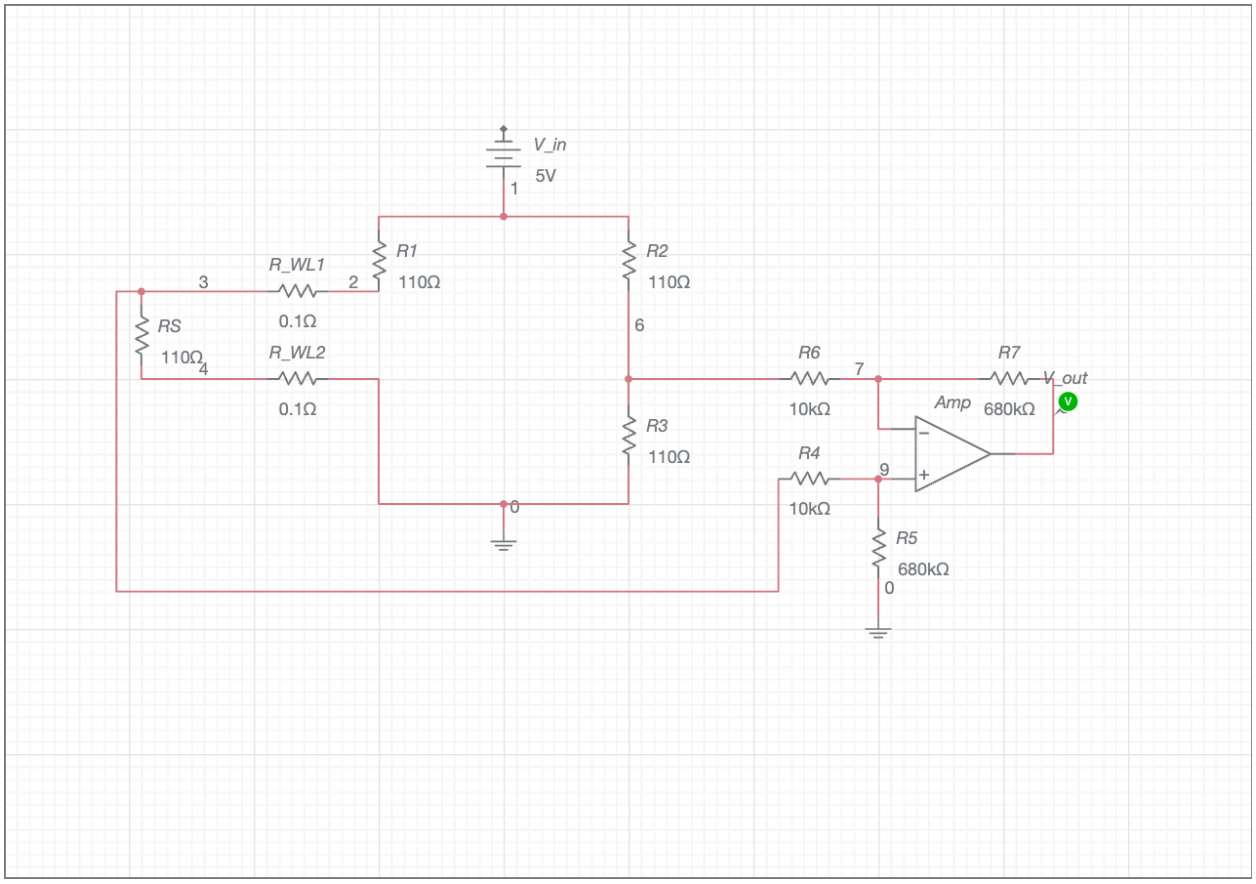


**Figure 8:** Schematic of final circuit design

Legend:

| **Component Name** | **Description** |
|---|---|
| V_in | The input voltage from the Arduino Uno (5V) |
| R1, R2, R3 | Static resistors in the wheatstone bridge module |
| R_WL1, R_WL2 | Resistors to model the resistance in long sections of wire. |
| RS | The temperature-dependent variable resistor. |
| R4, R5, R6, R7 | Static resistors in the differential amplifier module |
| Amp | The differential amplifier |
| V_out | The output voltage which is sent to the Arduino Uno analog input. |

First, the resistance bounds of the sensor were calculated. We chose our resistance bounds using the temperature bounds of [35, 42]℃. These values are the temperature bounds of a standard clinical thermometer. (72)

Sensor Parameters:
RTC = 0.00385 Ω/Ω/℃
$R_{Sensor}$ (T = 0℃) = 100Ω

$$RTC = \frac{R_{100} - R_0}{R_0 \cdot 100℃}$$

$$R_{100} = R_0[1 + RTC(100℃)] \Rightarrow R_T = R_0[1 + RTC(T)]$$

$$R_T = (100Ω)[1 + (0.00385\ Ω/Ω/℃)T]$$

$$R_{35℃} = (100Ω)[1 + (0.00385\ Ω/Ω/℃)(35℃)] = 113.5Ω$$
$$R_{42℃} = (100Ω)[1 + (0.00385\ Ω/Ω/℃)(42℃)] = 116.2Ω$$

For the circuit, we need to use common resistor values. The 110Ω resistor will therefore be used as our base value.

Calculating the temperature corresponding to 110Ω of resistance:

$$110\Omega = (100\Omega)[1 + (0.00385\,\Omega/\Omega/°\text{C})(T)]$$

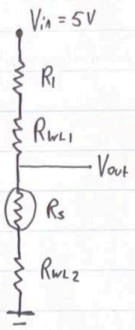
$$T = \frac{\frac{110\Omega}{100\Omega} - 1}{0.00385\frac{\Omega}{\Omega°\text{C}}} = 25.97°\text{C}$$

The working temperature range of our sensing circuit is [26, 42]℃ and the corresponding resistance range of the resistance sensor is [110, 116.2]Ω.

Next, a value for R1 must be found which maximizes the voltage range of the left side of the wheatstone bridge. Ideally, over the previously calculated resistance range a value of R1 can be found such that the change in voltage of the left voltage divider is 5V. This would allow the Arduino Uno to detect smaller changes in temperature.

However, this change of 5V is not feasible because the input voltage V_in = 5V. Instead, a value of R1 must be found that maximizes this voltage change. To do this, Wolfram Alpha was used to maximize $\Delta V(R_1)$:

Left Side Voltage Divider:




We want $\Delta V = 5\,V$

$$V_{out} = \left(\frac{R_s + R_{WL2}}{R_1 + R_{WL1} + R_s + R_{WL2}}\right)(5V), \quad R_s(T=26°C) = 110\,\Omega \quad R_s(T=42°C) = 116.2\,\Omega$$

$$\Delta V = V_{out}(T=42°C) - V_{out}(T=26°C)$$

$$= (5V)\left(\frac{R_s(T=42°C) + R_{WL2}}{R_1 + R_{WL1} + R_s(42°C) + R_{WL2}} - \frac{R_s(26°C) + R_{WL2}}{R_1 + R_{WL1} + R_s(26°C) + R_{WL2}}\right)$$

Approximate: $R_{WL2}$ terms approximately cancel out.

$R_{WL1}, R_{WL2} << R_1, R_s$

$$\Delta V \approx \left(\frac{R_s(42°C)}{R_1 + R_s(42°C)} - \frac{R_s(26°C)}{R_1 + R_s(26°C)}\right)(5V)$$

$$\Delta V = (5V)\left[\frac{(116.2\,\Omega)}{R_1 + (116.2\,\Omega)} - \frac{(110\,\Omega)}{R_1 + (110\,\Omega)}\right]$$

→ Solving $\Delta V = 5V$ for $R_1$ has no real solutions.

→ Maximizing $\Delta V$ gives $R_1 = 113\,\Omega$

↳ Using common resistor values: $R_1 = 110\,\Omega$

- $R_1 = 110\,\Omega$ gives on a voltage range of $\Delta V = 0.0685V$ or $68.5\,mV$.

**Calculations showing $\Delta V(R_1)$**

**Wolfram Alpha Critical Points and Plots:**

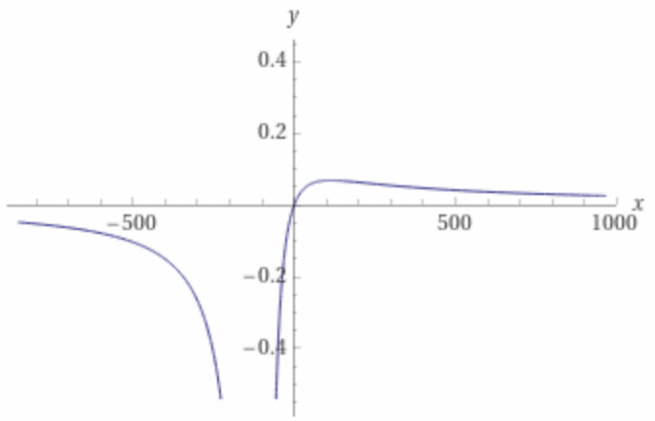
critical points $5\left(\frac{116.2}{x+116.2}-\frac{110}{x+110}\right)$

Results — Approximate forms

$x=-\frac{581}{5}$

$x=-\sqrt{12782}$

$x=\sqrt{12782}$




So a local maximum of ΔV occurs at R1 ≈ 113Ω. To make R1 a common resistance value, R1 = 110Ω was chosen.

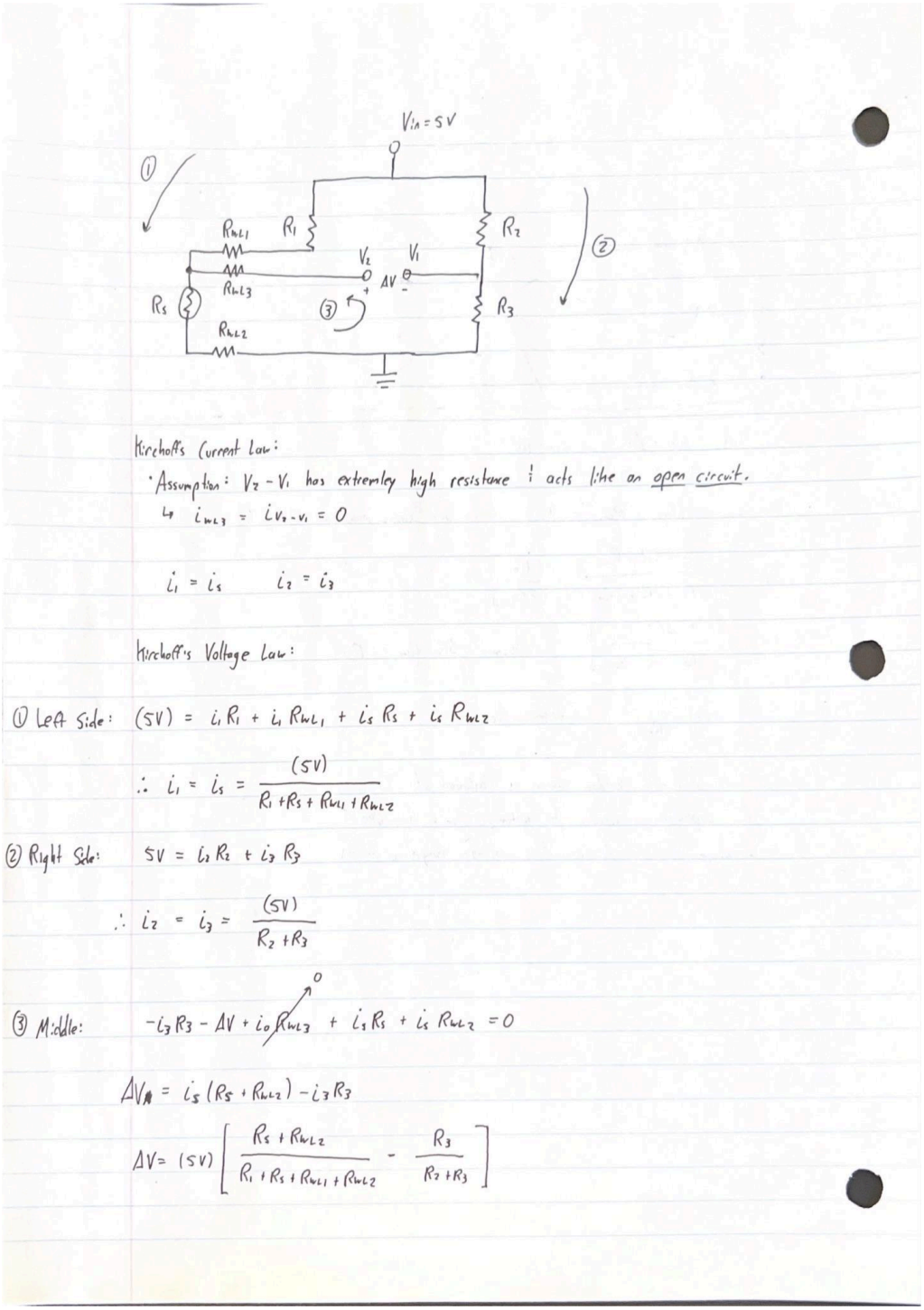
Calculating the voltage range at R1 = 110Ω:

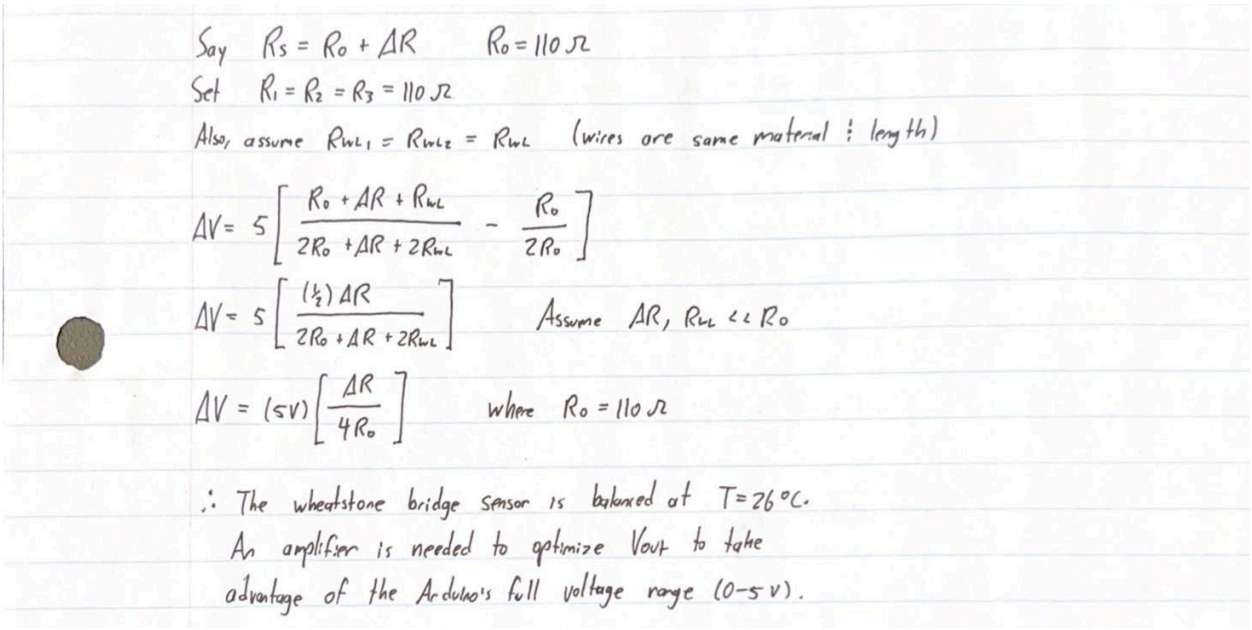
$\Delta V = (5V)\left(\frac{(116.2)}{(110)+(116.2)} - \frac{(110)}{(110)+(110)}\right) = 0.0685\,V = 68.5\,mV$

The expected output voltage range of the wheatstone bridge is 68.5 mV.

So the output voltage range of the wheatstone bridge will be **68.5mV**.

R2 and R3 must next be chosen to balance the wheatstone bridge. As we learned in class, we set R1 = R2 = 110Ω, and R3 = RS(T=26℃) = 110Ω. Below the wheatstone bridge is analyzed to verify these resistance values balance the circuit:





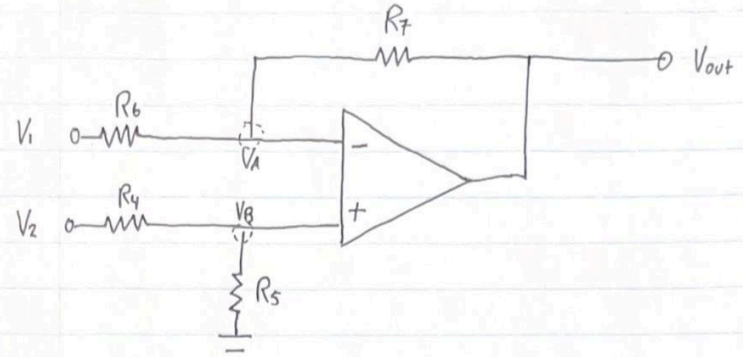

**Calculations deriving wheatstone bridge circuit equation**

Ideally the entire (0-5V) range of the Arduino will be used, so this output voltage of 68.5mV will be amplified to 5V. A differential amplifier is used to take the difference between the two sides of the wheatstone bridge and amplify the output signal. The outputs of the wheatstone bridge are the two inputs to the next section of the circuit, the differential (non-inverting) amplifier.

For our physical prototype, we chose a standard MCP6002-I/MS operational amplifier. We chose this specific operational amplifier because the voltage supply span covers our input voltage (5V) and the output type is rail-to-rail, meaning the amplifier's voltage output can be within the full 5V range that it is powered with. Additionally, it falls within our operational temperature range.

For the circuit calculations and simulations below, the operational amplifier is assumed to be ideal.

# Op Amp: Non-Inverting Amplifier




Node A: $\frac{V_A - V_1}{R_6} + \frac{V_A - V_{out}}{R_7} = 0$ (1)

node B: $\frac{V_B - V_2}{R_4} + \frac{V_B - 0}{R_5} = 0$ (2)

Assuming ideal op-amp: $V_A = V_B$ (3)

Solve for $V_{out}$ in terms of $V_1, V_2$:

(2): $V_B = \frac{V_2}{R_4}\left(\frac{1}{R_4} + \frac{1}{R_5}\right)^{-1} = V_2\left(\frac{R_5}{R_4 + R_5}\right) = V_A$ (3)

(1): $V_{out} = R_7\left(\frac{V_A}{R_7} + \frac{V_A}{R_6} - \frac{V_1}{R_6}\right)$

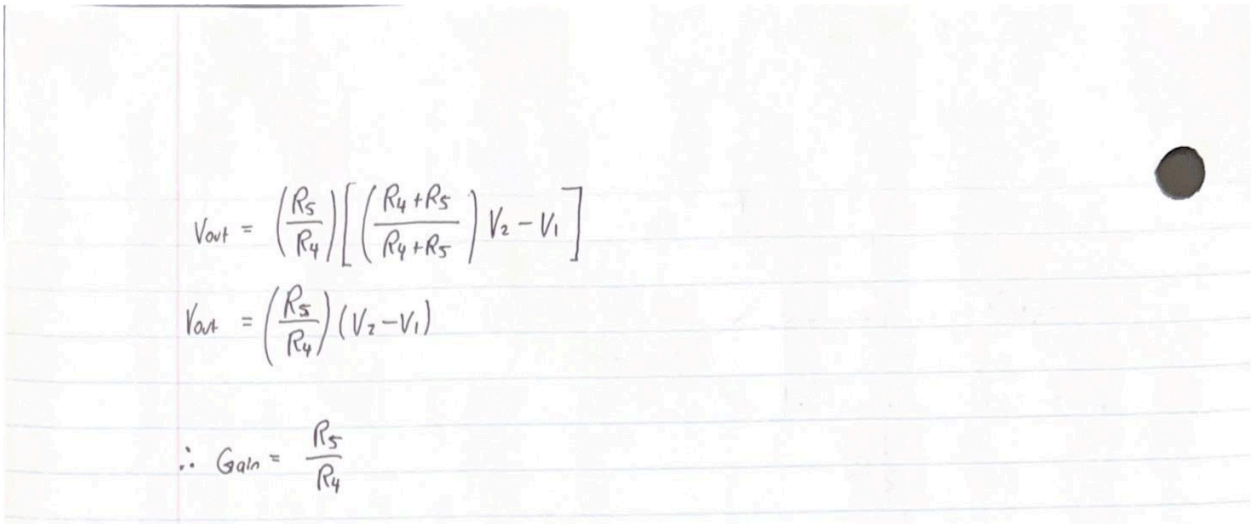
$V_{out} = V_A\left(1 + \frac{1}{R_6}\right) - \frac{R_7}{R_6}V_1$

$V_{out} = \left(V_2\left(\frac{R_5}{R_4 + R_5}\right)\right)\left(1 + \frac{1}{R_6}\right) - \left(\frac{R_7}{R_6}V_1\right)$

To simplify: restrict! $\frac{R_7}{R_6} = \frac{R_5}{R_4}$

$\therefore V_{out} = \left(\frac{R_5}{R_5 + R_4}\right)\left(1 + \frac{R_5}{R_4}\right)V_2 - \left(\frac{R_5}{R_4}\right)V_1$

$V_{out} = \left(\frac{R_5}{R_4}\right)\left[\left(\frac{R_4}{R_5}\right)\left(\frac{R_5}{R_4 + R_5}\right)\left(1 + \frac{R_5}{R_4}\right)V_2 - V_1\right]$



$$V_{out} = \left(\frac{R_5}{R_4}\right)\left[\left(\frac{R_4+R_5}{R_4+R_5}\right)V_2 - V_1\right]$$

$$V_{out} = \left(\frac{R_5}{R_4}\right)(V_2 - V_1)$$

$$\therefore Gain = \frac{R_5}{R_4}$$

**Operational amplifier gain calculations.**

To choose values for $R_4$ and $R_5$, two considerations are necessary:

1) They will produce a gain which amplifies the output voltage to 5V
2) $R_4$ and $R_5$ are much greater than the resistance values in the wheatstone bridge (100Ω). This is to ensure the assumption that no current passes through V_out holds.

$$Gain = \frac{R_5}{R_4} = \frac{V_{out}}{V_A} = \frac{(5V)}{(0.0682V)} = 72.31$$

To produce this gain, any set of resistors R4 and R5 which satisfy this ratio will work. R4 = 10kΩ and R5 = 680kΩ resistors were chosen. These values are commonly available resistance values which are also ~100x larger than the resistors in the wheatstone bridge.

Because to simplify the gain equation we made the assumption $\frac{R_5}{R_4} = \frac{R_7}{R_6}$, we set R6 = R4 = 10kΩ and R5 = R7 = 680kΩ.

A summary table of the chosen resistance values is provided below:

**Table 5:** Final resistance values for sensing circuit

| **Resistor** | **Value** |
|---|---|
| R1, R2, R3 | 110Ω |
| R4, R6 | 10kΩ |
| R5, R7 | 680kΩ |

The final relationship between V_out and the temperature T of the final circuit can be expressed in a single equation:

Find $V_{out}$ Equation Final

① $V_1 = (5V)\left(\frac{R_5 + R_{WL2}}{R_1 + R_{WL1} + R_5 + R_{WL2}}\right)$

② $V_2 = (5V)\left(\frac{R_3}{R_2 + R_3}\right)$

③ $V_{out} = \left(\frac{R_5}{R_4}\right)(V_2 - V_1)$

Sub ①,② into ③: $V_{out} = \left(\frac{R_5}{R_4}\right)\left[(5V)\left(\frac{R_5 + R_{WL2}}{R_1 + R_{WL1} + R_5 + R_{WL2}}\right) - (5V)\left(\frac{R_3}{R_2 + R_3}\right)\right]$

Simplify: $R_1 = R_2 = R_3 = R_0$, $R_{WL1} = R_{WL2} = R_{WL}$, $R_{WL} << R_0$ | $R_5 = R_0 + \Delta R$

$V_{out} = \left(\frac{R_5}{R_4}\right)(5V)\left[\frac{R_0 + \Delta R + R_{WL}}{2R_0 + 2R_{WL} + \Delta R} - \frac{1}{2}\right]$

$V_{out} = \left(\frac{R_5}{R_4}\right)(5V)\left[\frac{(\frac{1}{2})\Delta R}{2R_0 + 2R_{WL} + \Delta R}\right]$ $R_{WL}, \Delta R << R_0$

④ $V_{out} = \left(\frac{R_5}{R_4}\right)(5V)\left(\frac{\Delta R}{4R_0}\right)$

Find $\Delta R$ in terms of T:

$R_{@\,110} = 110\Omega$ at $T = 26°C$

$R_{116} = 116.2\Omega$ at $T = 42°C$

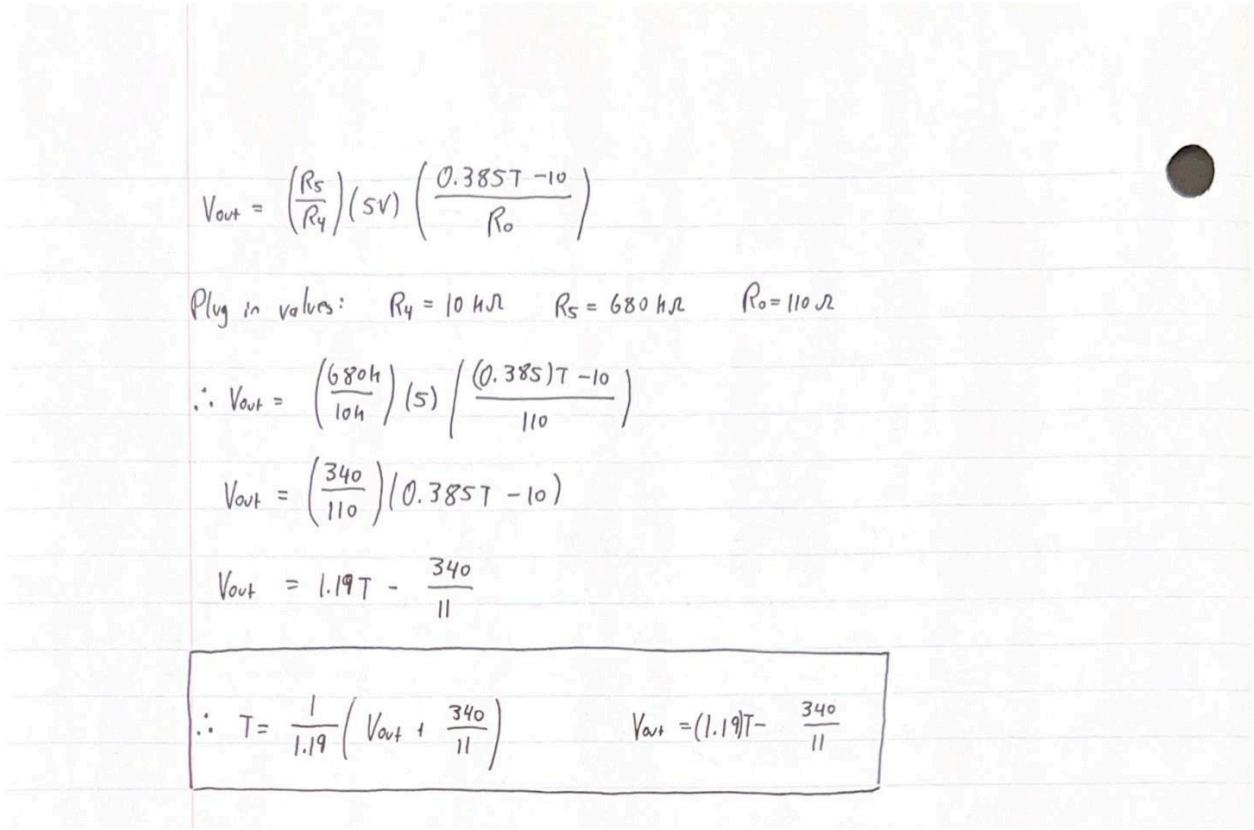
$m = \frac{(116.2\Omega) - (110\Omega)}{(42°C) - (26°C)} = 0.3875\ \frac{\Omega}{°C}$

From Earlier... $R(T) = R_{0t}[1 + (RTC)T] = (100\Omega)[1 + (0.00385\ \frac{\Omega}{\Omega\,°C})T]$

$\Delta R = R(T) - R_{110} = 100\Omega + (0.385\ \frac{\Omega}{°C})T - (110\Omega)$

⑤ $\Delta R = (0.385)T - 10$

Plug ⑤ into ④: $V_{out} = \left(\frac{R_5}{R_4}\right)(5V)\left(\frac{0.385T - 10}{4R_0}\right)$ * This $R_0$ refers to $R(T=26°C) = 110\Omega$




**Final relationship between the voltage output of the circuit and measured temperature.**

The calculated circuit was then entered into MultiSim to simulate and verify the circuit design.

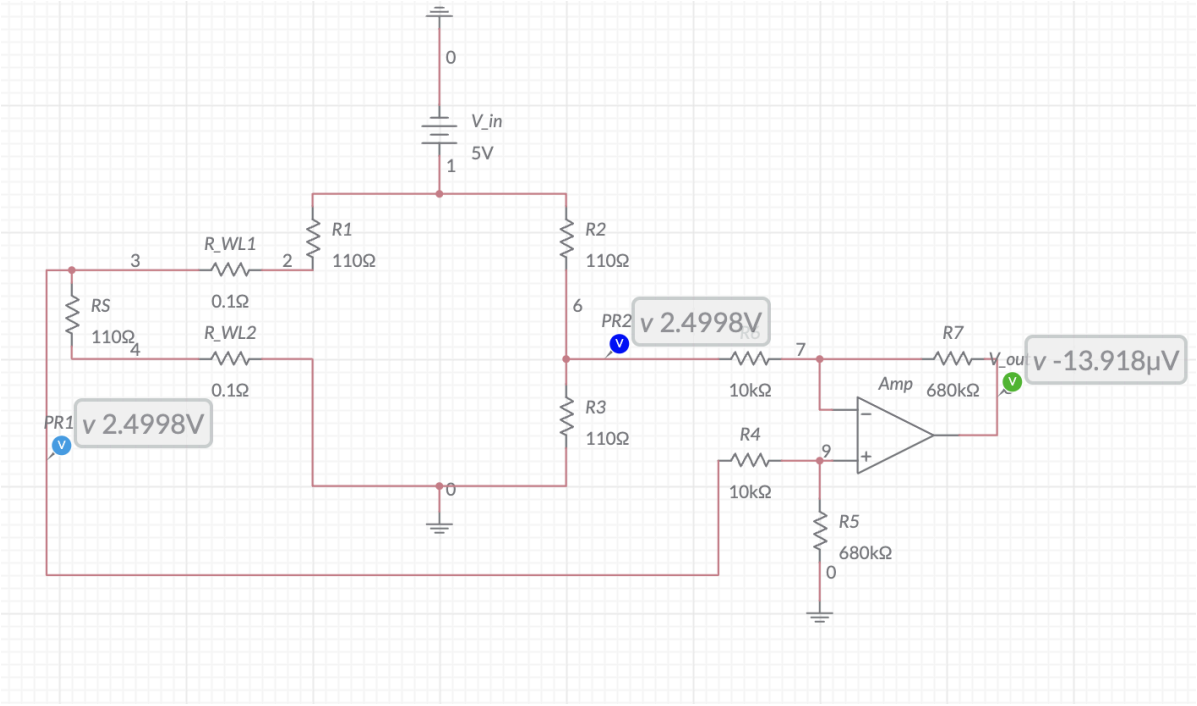



**Figure 9:** Verification of circuit design at T = 26℃

When RS = 110Ω (which corresponds with the lower temperature bound of 26℃) the output voltage is ~0V.

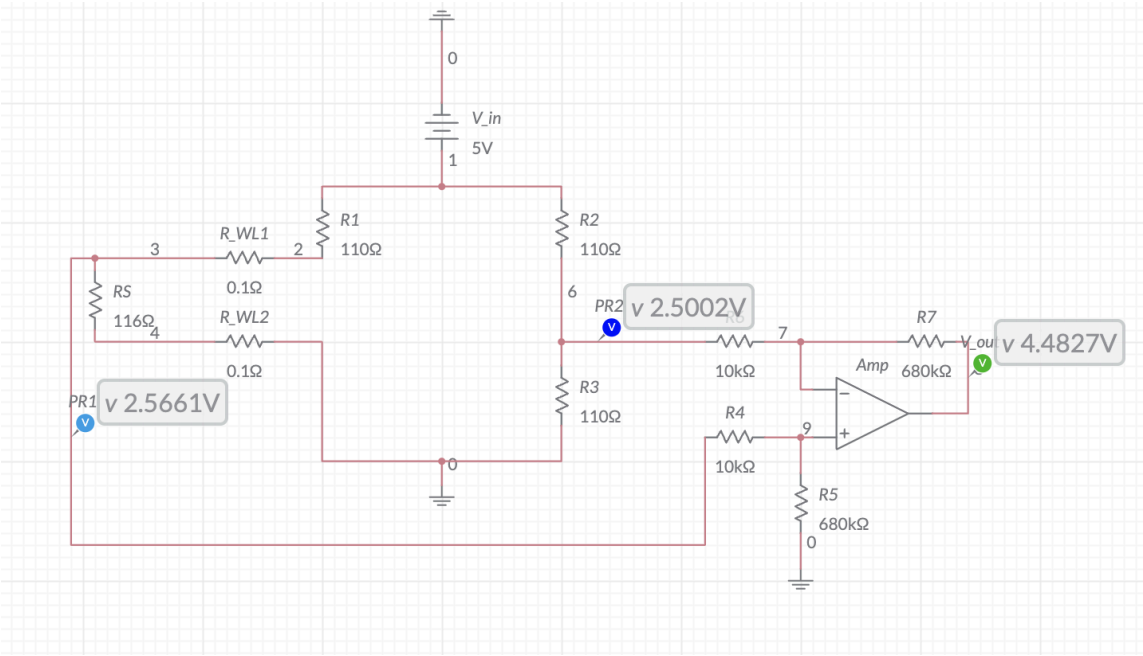



**Figure 10:** Verification of circuit design at T = 42℃

When RS = 116Ω (which approximately corresponds to the upper temperature bound of 42℃) the output voltage is ~4.48V.

This value of 4.48V isn't exactly 5V which is expected because of the various assumptions that were made, as well as how common resistance values were chosen. However, 4.48V is close enough to 5V which does a good job optimizing the sensitivity of the Arduino.

This output voltage will finally be fed into an analog pin of the Arduino Uno for signal processing. Below is our prototype wired in Tinkercad.

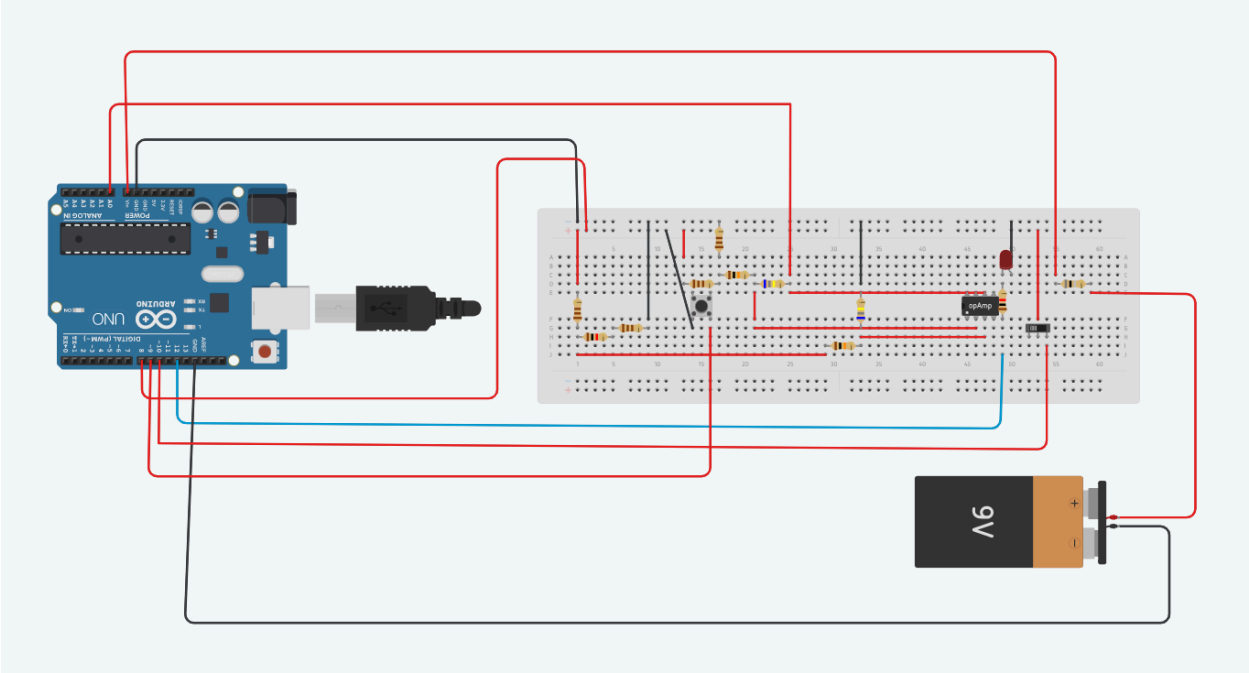
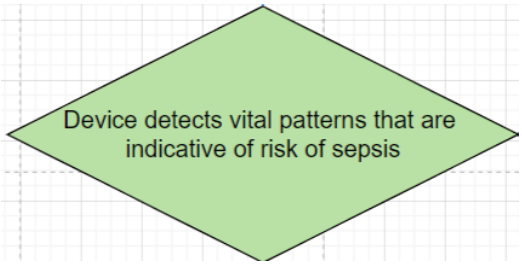



**Figure 11:** Circuit created in Tinkercad to demonstrate the prototyping setup for our device.

# Part 3: Iterated Software Function Structure

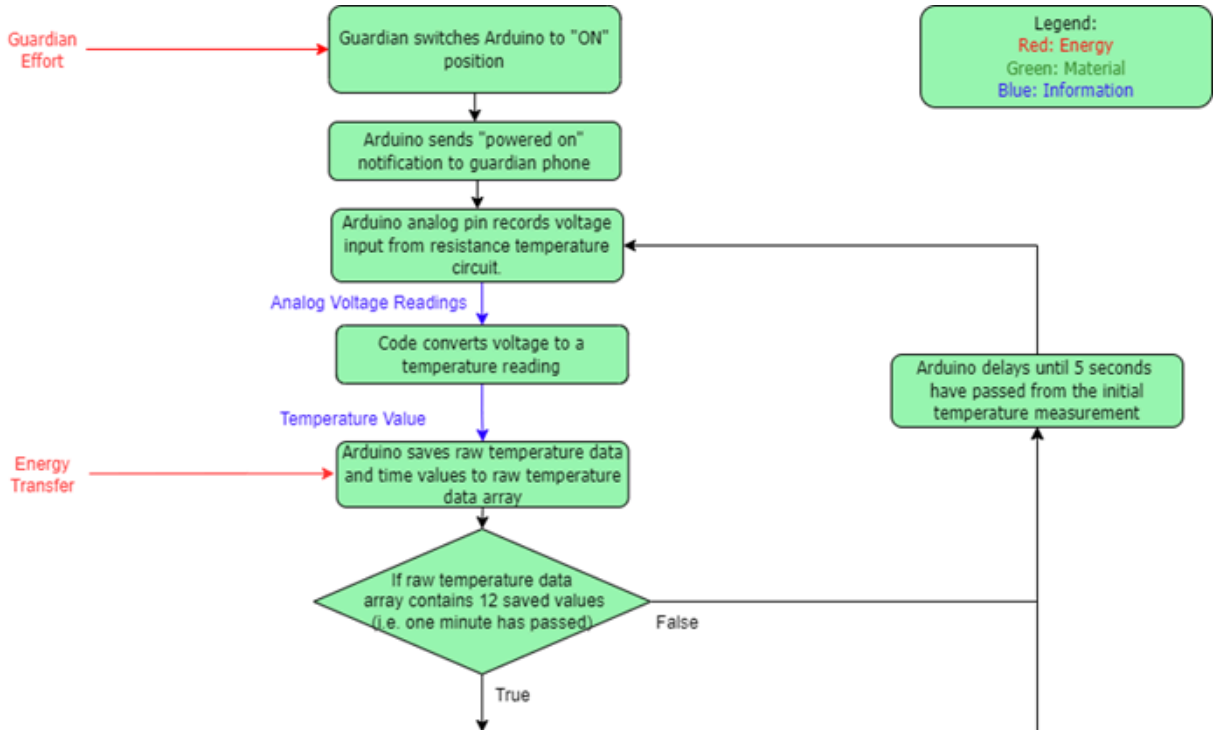
Per the course instructions, we are creating an iterated function structure diagram for one of the key functions related to software. Specifically, we have chosen to iterate on the "Device detects vital patterns that are indicative of risk of sepsis" function. For this assignment, we specifically focused on code that would interpret the temperature sensor readings for signs of sepsis. We chose this function to further iterate because the algorithm will need to be able to interpret temperature data to determine the risk of sepsis, which is the most important part of our project. The interpretation of temperature data was specifically chosen because this assignment is focused on the development of a circuit using a resistance-based sensor.

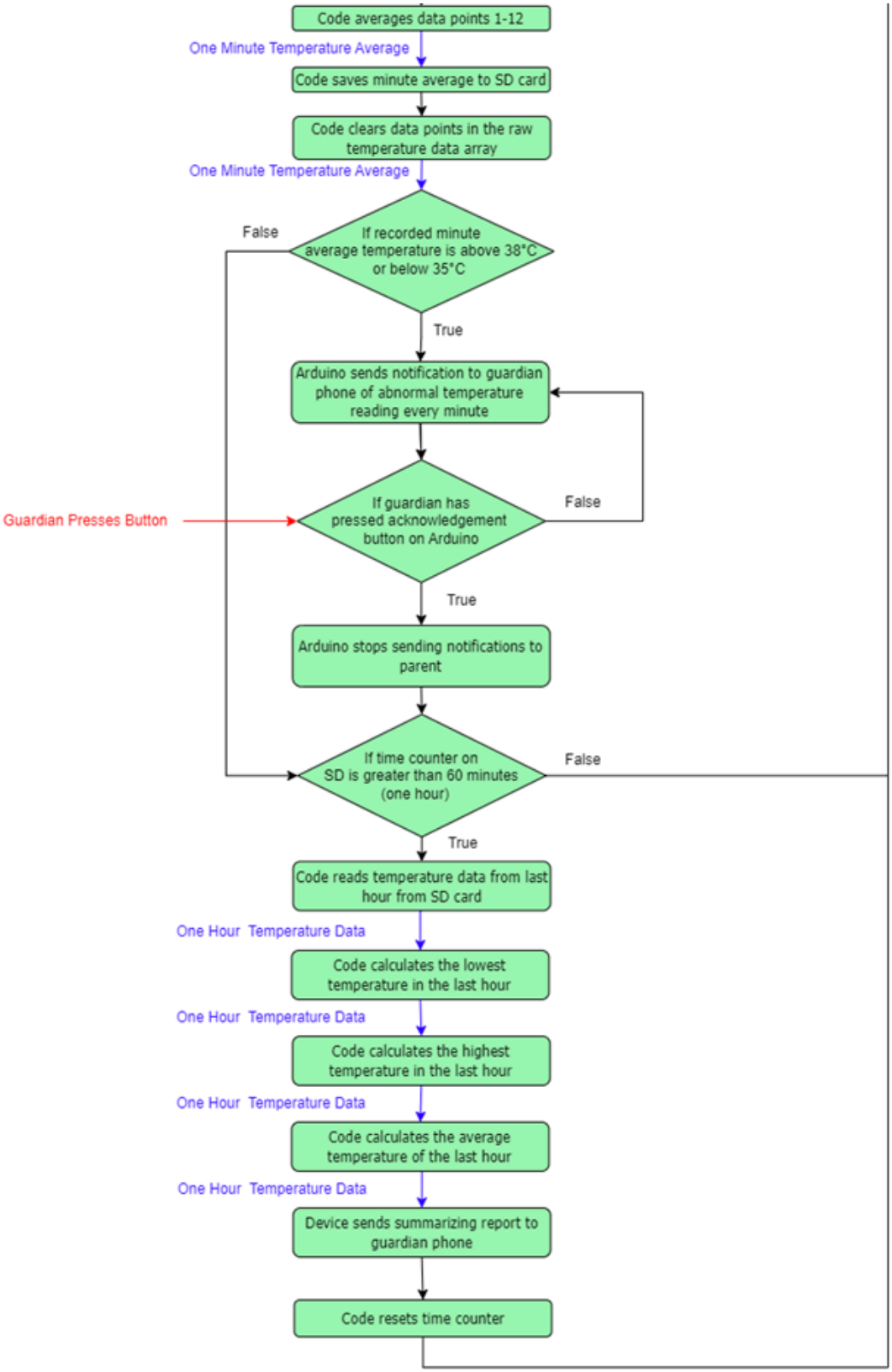
**Original function** (*rephased with the rest of the function structure; refer to DHF 3)




**Iterated function structure (below)**

Link:
[https://drive.google.com/file/d/1toDLiWYGzja4DwLOvjZ_J8oA92xN6kS7/view?usp=sharing]




Code averages data points 1-12
One Minute Temperature Average
Code saves minute average to SD card
Code clears data points in the raw temperature data array
One Minute Temperature Average
False
If recorded minute average temperature is above 38°C or below 35°C
True
Arduino sends notification to guardian phone of abnormal temperature reading every minute
Guardian Presses Button
If guardian has pressed acknowledgement button on Arduino
False
True
Arduino stops sending notifications to parent
If time counter on SD is greater than 60 minutes (one hour)
False
True
Code reads temperature data from last hour from SD card
One Hour Temperature Data
Code calculates the lowest temperature in the last hour
One Hour Temperature Data
Code calculates the highest temperature in the last hour
One Hour Temperature Data
Code calculates the average temperature of the last hour
One Hour Temperature Data
Device sends summarizing report to guardian phone
Code resets time counter

# Part 4: Software Implementation

For this section we have included snippets of our code. Each function from our function structure is coupled with its relative code block. The global constants, function signatures, and main loop are first shown below.

**The following screenshots of our code were updated because we have added comments and fixed errors since the last submission of this document. Please note that some functions have not been fully implemented yet. Certain modules (outside of this DHF's assigned tasks) such as the SD module require future design implementations that have not yet been determined.**

```
//Defining constants
const int TEMP_INTERVAL = 5000; //temperature sensor collects data every 5 seconds
const double RTC = 0.00385; //RTC of temperature sensor

const int R_0 = 100; //R of sensor at 0 degree celsius
const int R_26 = 110; //R of sensor at 26 degrees celsius
const int GAIN = 68; //Gain of the sensing circuit
const int V_in = 5; //Input voltage of the sensing circuit

const int V_OUT = A0;
const int POWER_CIRCUIT = 8;
const int OUTPUT_SOURCE = 7;
const int OP_AMP_VOLTAGE = 2;
const int SWITCH = 10;
const int ACKNOWLEDGE_SWITCH = 9;

//bluetooth
// create a new software serial port on pins 0 (RX) and 1 (TX)
SoftwareSerial bluetooth(0, 1);


//SD pins;
//no need to define MOSI, MISO, CLK.
//They are pin 11, , 12, 13 by default
const int CS = 4;

//subject to change
const double TEMP_UPPER_BOUND = 38.0;
const double TEMP_LOWER_BOUND = 35.0;

const int RAW_DATA_ROW = 12;
const int RAW_DATA_COL = 2;
const int timeCol = 0;
const int tempCol = 1;
const int heartCol = 2;
```

**Global Constants**

```
//Defining variables

//Number of milliseconds elapsed since the program started
unsigned long time;

//Whether guardian has been notified that the device is turned on/off
bool notifiedOnOff = false;

//a 2d array which saves raw temperature readings per time (max one minute).
//first column: time, second column: temperature
//all entries = NULL when empty
double rawTempData[RAW_DATA_ROW][RAW_DATA_COL];

//record the number of time rawTempData has been updated
int count = 0;

//the time of last alert
unsigned long lastAlert;

//status of alert: false = off, true = on
bool alertStatus = true;

//files on SD card
//note in this file there are currently two columns
//column 0 = time
//column 1 = temp
String mainDataFile = "dataFile.txt";
//etc

//start reading data from line ...
int lineBegin = 0;
```

**Global Variables**

```
//function signatures
//SD functions
bool writeToSD(unsigned long time, double temp, String fileName);
String readFromSD(File file); //TODO: what is the return type?
void clearSD();
void removeSDFile(String fileName);
double extractData(String line, int col);

//analytical functions
double calculateMinTemp(double arr[]);
double calculateMaxTemp(double arr[]);
double calculateAverageTemp(double arr[]);
double findAverageOfMinute();

//time functions
bool oneMinutePassed();
bool oneHourPassed();

//guardian interface
void notifyParentPowerOn();
void notifyParentPowerOff();
bool acknowledgeParentInput();
void alertAbnormalTemp(double temp);
void hourlyNotification();


//housekeeping functions
bool isOn();
void turnOffAlert();
void wait(int interval);
void saveTempReading(double temp);
void clearRawTempData();
bool tempWithinRange(double temp);

//voltage readgs
void powerOPAMP();
double readVoltage();
double convertVoltageToTemp(double v);

//detailed documentations can be found below, under "functions"
```

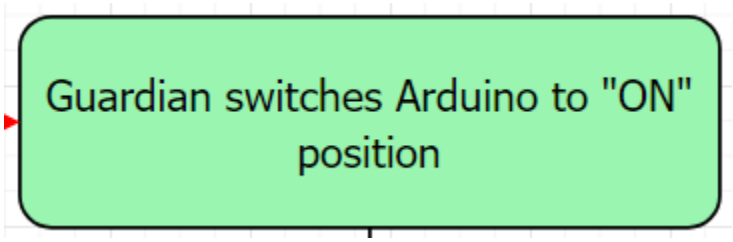
**Function signatures**

```
void setup() {
    Serial.begin(9600);

    pinMode(POWER_CIRCUIT, OUTPUT);

    pinMode(V_OUT, INPUT);

    pinMode(SWITCH, INPUT);

    pinMode(ACKNOWLEDGE_SWITCH, INPUT);

    pinMode(OUTPUT_SOURCE, OUTPUT);

    pinMode(OP_AMP_VOLTAGE, OUTPUT);

    bluetooth.begin(9600); // initialize the software serial port at 9600 baud

}
```

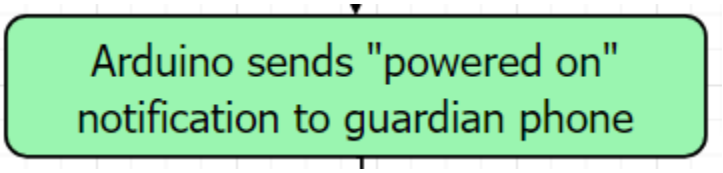
**Arduino Pin Setup**

```
//Main function
void loop() {
    if (isOn()) {
        time = millis();

        notifyParentPowerOn();
        double volts = readVoltage();
        double temp = convertVoltageToTemp(volts);
        saveTempReading(temp);

        if (oneMinutePassed()) {
            double average = findAverageOfMinute();
            writeToSD(time, average, mainDataFile);
            clearRawTempData();

            if (!tempWithinRange(average)) {
                if (!acknowledgeParentInput()) {
                    turnOffAlert();
                }
                alertAbnormalTemp(average);
            }
        }

        if (oneHourPassed()) {
            hourlyNotification();
        }

        wait(TEMP_INTERVAL);

    }
    else {
        notifyParentPowerOff();
    }

}
```

**Main Loop Function**




```
//checks if the power switch is on
//return true if on, false otherwise
bool isOn() {
    if (digitalRead(SWITCH) == HIGH) {
        return true;
    }

    return false;
}
```




```
//notifies parent when the sensor is turned on
void notifyParentPowerOn() {
    if (!notifiedOnOff) {
        //assuming that our notification system is connected
        //to this pin
        digitalWrite(OUTPUT_SOURCE, HIGH);//turns on the device

        String message = "Sepsis monitor is on; you have turned "
          + String(alertStatus) + "mobile notification";
        bluetooth.println(message);

        notifiedOnOff = true;
    }

    return;
}
```

Arduino analog pin records voltage input from resistance temperature circuit.

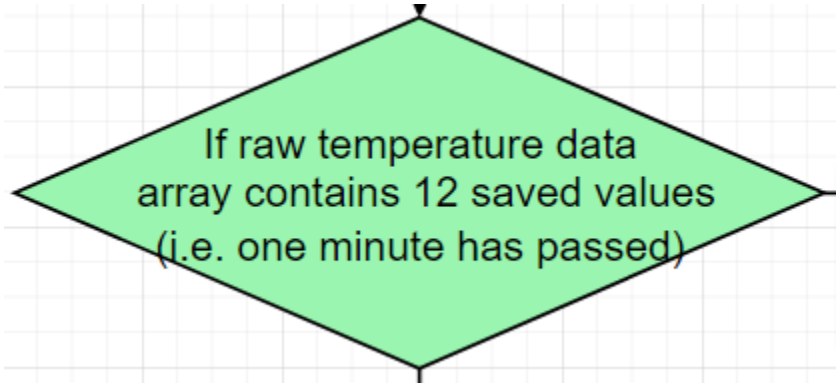
```
//read temperature of the infant and add the value to rawTempData[][]
//input: time when reading is taken
double readVoltage() {
    //convert analog read to voltage
    double v = (double)5 / 1023 * analogRead(V_OUT);
    return v;
}
```

Code converts voltage to a temperature reading

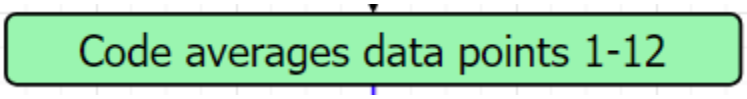
```
//output: temperature reading
double convertVoltageToTemp(double v) {
    //find temperature from voltage
    double temp = (double)1 / 1.19 * (4 * v + 340.0 / 11.0);
    return temp;
}
```

Arduino saves raw temperature data and time values to raw temperature data array

```
//stores temperature
void saveTempReading(double temp) {
    //put temperature data into rawTempData
    int i = 0;
    while (rawTempData[i][tempCol] != NULL) {
        i++;
    }

    rawTempData[i][0] = time;
    rawTempData[i][tempCol] = temp;

    return;
}
```




```
//check if a minute has passed (i.e. rawTempData is full)
bool oneMinutePassed(){
  if(rawTempData[RAW_DATA_ROW][RAW_DATA_COL] != NULL){
    return true;
  }

  return false;
}
```



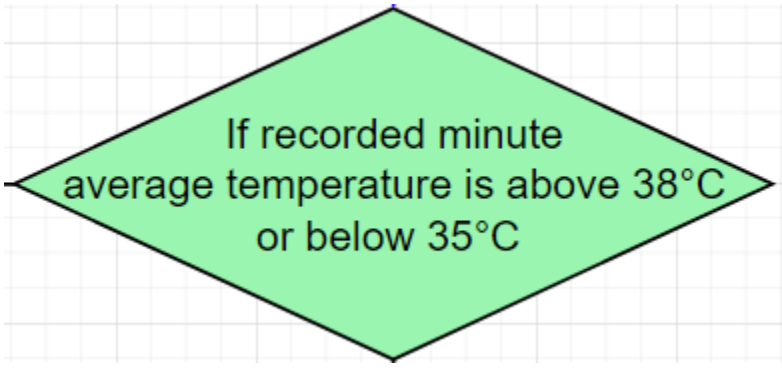

```
//find average of temperature readings over a minute
double findAverageOfMinute() {
    double sum = 0.0;
    for (int i = 0; i < 12; i++) {
        sum = +rawTempData[i][2];
    }

    return sum / RAW_DATA_ROW;
}
```

Code saves minute average to SD card

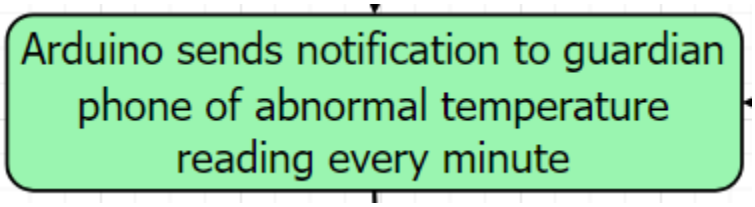
```
//parameter: temperature & time to enter to SD
//return: true if succesful write to SD
//false otherwise
bool writeToSD(unsigned long time, double temp, String fileName) {
    //check if write was succesful
    if (!SD.begin(CS)) {
        //Serial.println("initialization failed!");
        return false;
    }
    //Serial.println("initialization done.");

    // open the file. note that only one file can be open at a time,
    // so you have to close this one before opening another.
    File file;
    file = SD.open(fileName, FILE_WRITE);

    // if the file opened okay, write to it:
    if (file) {
        String dataString = String(time) + "," + String(temp);
        //Serial.print("Writing to %s...", filename);
        file.println(dataString);
        // close the file:
        file.close();
        //Serial.println("done.");
        return true;
    }
    else {
        // if the file didn't open, print an error:
        //Serial.println("error opening test.txt");
        return false;
    }
}
```

Code clears data points in the raw temperature data array

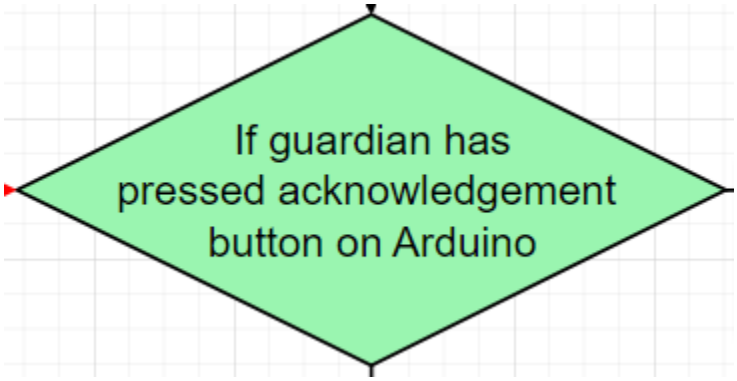
```
//clear the rawTempData array; reset all entries to NULL
void clearRawTempData(){
  for(int i = 0; i < RAW_DATA_ROW; i++){
    for(int j = 0; j < RAW_DATA_COL; j++){
      rawTempData[i][j]= NULL;
    }
  }

  count++;

  return;
}
```



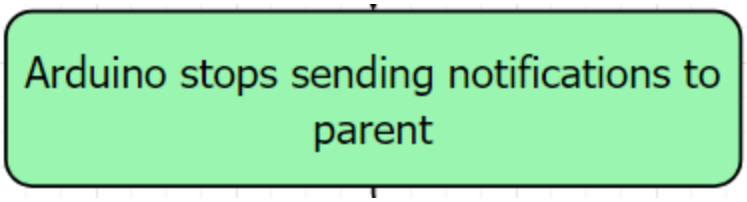

```
//parameter: average temp for minute
//return true if temp is within normal bounds
//false otherwise
bool tempWithinRange(double temp){
  double upperBound = TEMP_UPPER_BOUND;
  double lowerBound = TEMP_LOWER_BOUND;

  if(temp <= upperBound && temp >= lowerBound){
    //temp is in normal range
    return true;
  }

  return false;
}
```



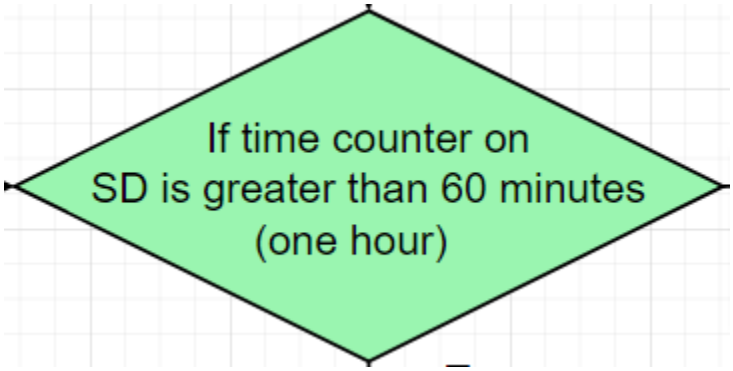

```
//notify guardian of abnormal temperature reading
//input: temperature reading
void alertAbnormalTemp(double temp) {
    if (!alertStatus) {//alert is off
        return;
    }

    double upperBound = TEMP_UPPER_BOUND;
    double lowerBound = TEMP_LOWER_BOUND;
    if (temp < lowerBound) {
        //tell guardian temperature is too low
        String message = "INFANT TEMPERATURE DANGEROUSLY LOW. CHECK ON INFANT";
        bluetooth.println(message);
    }
    else if (temp > upperBound) {
        //tell guardian temperature is too high
        String message = "INFANT TEMPERATURE DANGEROUSLY WARM. CHECK ON INFANT";
        bluetooth.println(message);
    }

    return;
}
```




```
//checks if parent has ackoweldged alert
//return false to turn off the alert afetr parent has acknowledged it
bool acknowledgeParentInput() {
    if (digitalRead(ACKNOWLEDGE_SWITCH) == HIGH) {
        return false;
    }
    return true;
}
```




```
//turn off alert
void turnOffAlert(){
  alertStatus = false;

  return;
}
```




```
//check if an hour has past since last check
bool oneHourPassed(){
  if(count >= 60){
    count = 0;
    return true;
  }

  return false;
}
```

Code reads temperature data from last hour from SD card

```
//reads from SD card;
//***need to open/close the file before/after calling this mathod
//inputs: the file to read from and the column
//outputs:
String readFromSD(File file) {
    //read an entire line
    String line = "";
    for (int i = 0; !line.endsWith("\n") && file.available(); i++) {
        line += file.read();
    }

    return line;
}
```

Code calculates the lowest temperature in the last hour

```
//calculates min value in 2D array
double calculateMinTemp(double arr[]) {
    int i;
    double min = arr[0][tempCol];
    for (int i = 0; i < 60; i++) {
        if (arr[i][tempCol] < min) {
            min = arr[i][tempCol];
        }
    }
    return min;
}
```

Code calculates the highest temperature in the last hour

```
//calculates max value in 2D array
double calculateMaxTemp(double arr[]) {
    int i;
    double max = arr[0][tempCol];
    for (i = 0; i < 60; i++) {
        if (arr[i][tempCol] > max) {
            max = arr[i][tempCol];
        }
    }
    return max;
}
```

Code calculates the average temperature of the last hour

```
double calculateAverageTemp(double arr[]) {
    int i;
    int sum = 0;
    for (i = 0; i < 60; i++) {
        sum = sum + arr[i][tempCol];
    }
    double average = sum / 60;
    return average;
}
```

Device sends summarizing report to guardian phone

```
//send hourly notification
void hourlyNotification() {
    //read last 60 measurements (from SD card perhaps?)
    //report: lowest temp
    //      highest temp
    //        average temp

    //array for storing reads from SD card
    double temperatureForHourData[60];
    //open file
    File file = SD.open("dataFile.txt", FILE_READ);
    int currLine = 0;
    //skips until last read position
    while (currLine < lineBegin) {
        readFromSD(file);
        currLine++;
    }
    //read actual data that we want for hour
    int i = 0;
    while (currLine < lineBegin + 60) {
        //call to read dataFile temperature column
        double data = extractData(readFromSD(file), 1);
        temperatureForHourData[i] = data;
    }
    file.close();

    lineBegin += 60;
```

```
    //now we have an array of our hourly data
    double avgTemp = calculateAverageTemp(temperatureForHourData);
    double maxTemp = calculateMaxTemp(temperatureForHourData);
    double minTemp = calculateMinTemp(temperatureForHourData);

    //report above values to the parent

    //the message we are sending the parent
    String message = String("Hourly summary:\n")
        + "* Temperature:\n"
        + " - Average: " + String(avgTemp) + " degrees Celsius\n"
        + " - Maximum: " + String(maxTemp) + " degrees Celsius\n"
        + " - Minimum: " + String(minTemp) + " degrees Celsius\n";

    bluetooth.println(message); // send the message to the HC-06 module
}
```

Code resets time counter

```
//resets time variable of arduino
void resetTimeCounter() {
    //this is the algorithm
    //reset the arduino
    time = 0;
}
```

Arduino delays until 5 seconds have passed from the initial temperature measurement

```
//wait for given time interval in milliseconds
void wait(int interval){
  while (millis() < time + interval){

  }

  return;
}
```

**Miscellaneous Functions:**

```
//notify parent when the sensor is turned off
void notifyParentPowerOff() {
    if (notifiedOnOff) {
        //assuming that our notification system is connected
        //to this pin
        digitalWrite(OUTPUT_SOURCE, LOW);

        String message = "Sepsis monitor is off";
        bluetooth.println(message);

        notifiedOnOff = false;
    }

    return;
}



//power op amp
void powerOPAMP(){
  digitalWrite(OP_AMP_VOLTAGE, HIGH);
}


//extract value from a line of deliminated file reading
//input: string representing one row in a deliminated file
//output: data on the desired column; use zero based indexing
double extractData(String line, int col) {
    int commaCount = 0;

    String dataString = "";

    for (int i = 0; i < line.length() && commaCount <= col; i++) {
        if (line[i] == ',') {
            commaCount++;
        }

        if (commaCount == col) {
            dataString.concat(line[i]);
        }
    }

    double data = dataString.toDouble();

    return data;
}
```

# *DHF 5: Validation and Verification*

## Part 1: Verification

We verified our design against our updated requirements. Table 1 lists these requirements, our device's performance, and whether the requirement was passed or failed.

We used various simulation and physical prototypes to test most of our requirements. A short description of our physical prototype is detailed below:

Figure 1: Half Tank as viewed worn.

**Details:**
The following image details how the device would look on the infant. Here, the 'mother board', PPG casing, and thermistor casing are all visible. This image shows all of these components within the Half Tank.

**Limitations:**
This Image details the limitation of this prototype as it is clear that the mother board is much larger than it would be for a later generation prototype.

Figure 2: Half Tank turned inside out.

**Details:**
This image details the Half Tank when it is turned inside out. In this image, one can see the large pocket, intended to shield all circuit components as well as create comfort.

**Limitations:**
Because the mother board is much larger than it would be in a later generation prototype the PPG sensor is not placed in the correct area. This leads to the exposed wiring and larger gaps within the velcro, seen in this image.

Figure 3: Inside of device exposed.

**Details:**
In this image the larger pocket has been undone to show the inner circuitry. This would be a step required to perform by the guardian to set up the device. This image clearly details the pockets that each sensor would be placed.

**Limitations:**
This more clearly shows the gaps in the velcro on the larger pocket. Additionally, the exposed wire is something that would be cased in a later generation prototype.

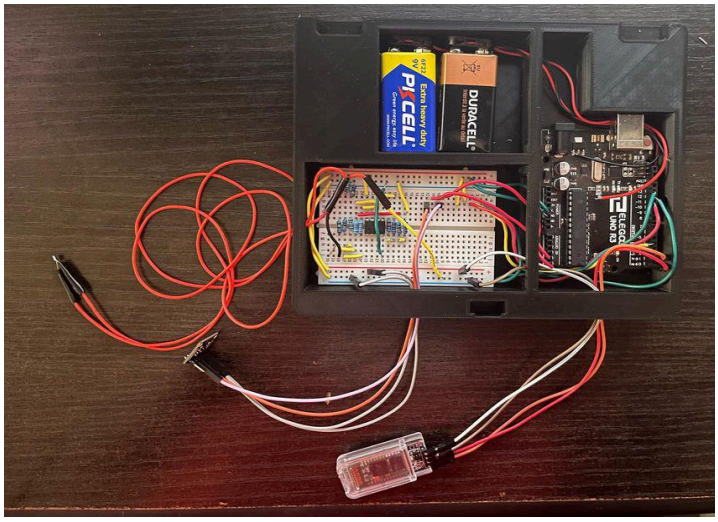



**Figure 4:** Motherboard, Enclosing, and Sensors

The electrical prototype was developed using a breadboard, Arduino Uno, two 9V batteries, our chosen thermistor, a pulse oximeter, and a bluetooth module. All of these components are housed within a large 3D-printed box, collectively dubbed “The Motherboard”.

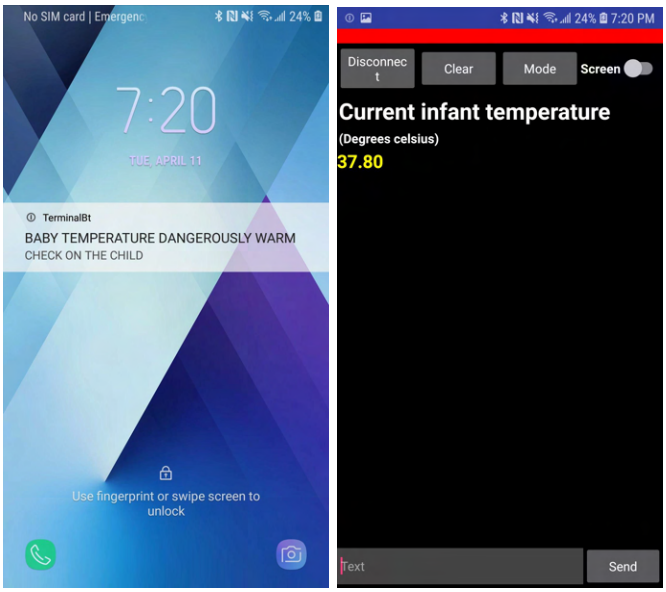



**Figure 5.1 and 5.2 :** Bluetooth Phone Notification System, lock-screen and app interface respectively

Our final physical prototype piece is a phone which wirelessly communicates with the bluetooth chip in the motherboard.

Note about verifications: Due to device prototyping limitations, not all of these requirements are able to be thoroughly tested. In these cases, estimations were included where appropriate, and justifications are supplied for cases where an exact quantitative measurement was not obtained.

**Table 1:** Requirements and Verification Results

| Requirement Number | Property | Requirements | Performance | Pass / Fail |
|---|---|---|---|---|
| **1** | **Battery life (How long can the device monitor the infant)** | Portable devices should be able to function >= 8 hours on one full charge of a brand new, unused battery. | Calculated battery life of each 9V battery is 2.64 hours (using max draw rates of all components). **Verification calculations are included below the table, labeled (1): Battery Life.** | Not tested, Likely would fail based on calculations<br><br>*A potential solution to remedy this would be to use rechargeable lithium batteries. Ultimately, we would have to perform tests on lithium batteries as well as see how to minimize how much power is drawn. |
| **2** | **Detection frequency** | The device's sensor data is collected at least once every 5 seconds. (Refers to rate of measurement) | Running the software, the Arduino takes and reports sensor measurements every 5 seconds. Our testing protocol to determine that the 5 seconds interval was functioning properly was through observations. When the temperature went into the critical range, the phone was notified every 1 minute. This 1 minute interval encoded 12 temperature readings and would not notify the phone if these readings were not taken. This 1 minute notification occurs consistently, leading up to justify that this detection frequency requirement is fulfilled. To determine that these were perfect 1 minute intervals we recorded the time using a timer. This was repeated for 15 minutes worth of intervals and confirmed that perfect 1 minute intervals were indeed verified. | Pass |

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| **3** | **Waterproofing** | The device should at least be rated at ip-x4 after testing | Plastic encasing makes the device durable to small splashes of water.<br><br>This was not quantitatively tested, for the sake of our precious prototype!<br><br>Additionally, the exposed wires, seen in figure 3, are also waterproofed. Although these would absolutely not be exposed in a later generation prototype all circuitry is waterproofed using electrical tape and plastic encasings. | Not tested, Likely would pass in later stage prototypes |
| **4** | **Biocompatibility** | Wearable material must not irritate or cause discomfort to the skin of at least 85% of infants. | The wearable shirt is designed with 100% cotton. This material is extremely common and popular in infant clothes and does not irritate the skin of most infants. Therefore, we can safely assume that this test is passed. Additionally, any sensor that interfaces with the skin is made of silicone which is renown for its biocompatibility (73). | Not tested, Likely to pass<br><br>All material used (cotton, PLA, rubber, polyester) are all biocompatible (refer to DHF 4.1) |
| **5** | **Durability** | The device's rate of correctly identifying signs of sepsis (sensitivity) must be at least 75% after being dropped from a height of 37.5 cm. Although these are not negatively proportional this is the main concern that must be determined to pass a durability test. The device should also be intact and continue to be wearable, comfortably. | This requirement was not tested, as we were unsure of the product's durability, and within budget constraints did not want to risk destruction of our only prototype.<br><br>However, we predict that with the hard plastic container that securely fits the electronic components, this requirement would likely pass. As a laptop, encased in a hard exterior is only able to handle a 40 cm fall, we are making the assumption that a pass would be from the height of the average infant which is approximately 45.7-70cm (74). For this reason we are not certain that the device would pass. However, as there are less components that can be damaged, and they are padded by many layers of foam, we believe this would likely pass. | Not tested |
| **6** | **Accuracy in detecting symptoms of sepsis** | Any sensors used should have an accuracy rate equal to the industry standard. | The temperature sensor is rated IEC class A (±0.15℃) according to its datasheet (89), which is above industry standard (IEC class B). | Pass |

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| **7** | **False Positives** | Under healthy conditions, the device does not generate false alarms more than 38% of the time from a total testing pool of 50 trials within the span of a year. Healthy conditions are defined as the infant's breathing rate is between 30-45 breaths per minute, temperature is between 35-38 degrees celsius, and blood pressure has not exceeded 130/85.<br><br>(Note that the 'healthy conditions' temperature range was updated from our previous DHF 2). | To test this requirement, the thermistor circuit design and software must both be verified. This is because the infant's body temperature is encoded by a changing resistance in the thermistor, which results in a change in voltage in the circuit output, which is processed by the software to determine whether or not to alert the guardian. Therefore, to test this requirement we have chosen to test:<br><br>(1) The circuit outputs a correct, predictable voltage that corresponds to the infant's body temperature (as defined by the derived circuit equation in DHF 4). **Verification for (1) is included below the table, labeled (7.1: Circuit Verification).**<br><br>(2) The software correctly calculates the infant's body temperature given a voltage value from [0, 5]V, and does not notify guardians when temperature values are within normal, healthy conditions. **Verification for (2) is included below the table, labeled (7.2: Software Verification).** | Pass |
| **8** | **Separate Components** | The final functioning device after assembly does not contain more than 3 physically separate components. | The device has two physical components, the shirt and the electronics (which are continuous and act as a single component). | Pass |
| **9** | **Removability or deconstruction by the infant.** | The device must be able to function completely (all sensors and systems hold accuracy to industry standard) if 50N of pushing or pulling force is applied. | The shirt was designed to fit snugly on the user. Upon testing our prototype, it is very hard to remove the shirt off with only pushing or pulling force, let alone only 50N of this force. While this is not an exact quantitative measurement, we can assume that this requirement passes.<br><br>As the motherboard is encased within a plastic casing, we can assume that it would not experience any issue with an applied force of 50N to the protective casing. Also, it is contained within the shirt and cannot be accessed by the infant unless the shirt is removed first. | Pass |

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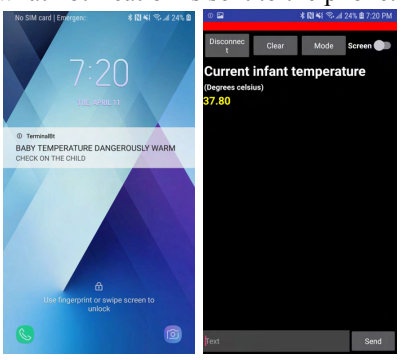
| **10** | **Emergency instructions** | When the device detects emergency vital signs (which can be precursors to sepsis), it sends a notification to the guardian to go to the hospital in the case of an emergency.<br><br>Emergency vital signs in infants are defined as a fever of 38C or higher, blood pressure below 71/36 and heart rate above 200 bpm. | Device sends an alert to the phone via bluetooth when the circuit is tested with synthetic environmental conditions meant to monitor signs of sepsis. The alert suggests that the guardian takes the infant to the emergency room.<br><br>(We applied a voltage to the arduino using a potentiometer which simulates a proper and consistent temperature sensing circuit. Setting the potentiometer to 5V simulates emergency conditions (>38C). | Pass |
| | **Sensory Notifications** | Urgent notifications should have notification in two sensory cues. | Both audio (beeping) and visual notification are sent to the phone. This has been proven by the physical prototype.<br><br>Here a picture is provided to show what notification is sent to the phone:<br>  <br>The picture on the right shows the notification that is sent when the temperature sensor reads a temperature that is too warm. There is also an audible notification that occurs when this notification is displayed. On the right you can see the bare bones of the app, where more information is displayed and the red bar visually shows that something is wrong. This would be much more developed in a future prototype. | Pass |

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| **11** | **Easy setup** | Large devices should take at most 75 minutes to physically set up.<br>Small devices should take at most 15 minutes to set up. (Common sense).<br>Both large and small devices should take =<30 minutes to connect to caregiver devices (less is better). | In physical demonstrations, the device took less than a minute to set up and insert sensors.<br><br>This being said, our group member was well versed with an understanding of the device and how to assemble it. Despite this, it can be assumed that individuals, not previously exposed to the device, would still be able to set it up within 30 minutes as our time was well within the limit. Further confirmation could be attained by testing on groups of subjects to see how long average setup time would take.<br><br>Digital setup took less than a minute as well, and it can be assumed that the same time value would apply for individuals not well versed with the product. This is because our digital setup uses bluetooth to connect, and any individual who has set up bluetooth devices in the past would not experience any challenges. For people not experienced with bluetooth, this may take slightly longer, but again should fall within the 30 minute time limit, as long as the instruction for use manual is well written and descriptive. | Not tested<br><br>*This can not pass or fail until a test group, that does not know how the device works, attempts to use it. Unfortunately, due to everyone's very crammed schedules and us being antisocial engineers this was not tested. |
| **12** | **Understandable Notifications** | Device text/notifications should be written in simple English with instructions that are understandable by individuals with IELTS reading score >4. | Message displayed: "INFANT TEMPERATURE DANGEROUSLY WARM. CHECK ON INFANT".<br><br>This text is simple and concise in plain English. Unfortunately we cannot quantitatively verify that this text is understandable by individuals with an IELTS reading score equal to 4. However, we believe that in combination with the audio notification this alert will be understandable. | Not tested<br><br>*This can not be assessed for the same reason as the above justification. |
| **13** | **Weight** | Devices should weigh less than 7kg. | Device weights <1kg<br><br>This was physically determined using a physical scale. Because it is much larger than what an infant would wear, this test is most definitely | Pass |

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|---|---|---|---|---|
| | | | passed. | |
| **15** | **Length** | Length should be less than 55cm | Device is 22cm x 22cm x 8cm.<br><br>Note that these values are approximate, and can change depending on how the device is folded. However, every conformation fits our requirements. Additionally, this prototype is constrained by the large dimensions of the motherboard. With a later generation prototype these requirements would be much more satisfied.<br><br>**(See (15) under detailed verification explanations for photos of physical dimensions).** | Pass |
| **16** | **Width** | Width should be less than 40 cm | | |
| **17** | **Height** | Height should be less than 10 cm | | |
| **18** | **Background noise** | The device should produce background noise quieter than 45 dB. | The device does not create any audible noise. | Pass |
| **19** | **Alert volume, safety** | Emergency alert noise should remain below 90 dB | The device we are using to notify is a Samsung Galaxy S5 which<br><br>Device sends a regular phone notification sound, which is less than 90 dB. | Pass |
| **20** | **Dimensions, safety** | The device must conform to 16 C.F.R. § 1501, 1500.18 (a)(9), and 1500.50, 51, 52. | The device does not fit into a 57.1 mm long and 31.7 mm wide cylinder. As the infant would never have access to the device without it being fully constructed, they would have to swallow a 22cm x 22cm x 8cm device. This is not physically possible, and still would not be possible in a later generation prototype with a smaller size. | Pass |
| **21** | **Dimensions, adjustability** | The device is usable on a 50th percentile newborn infant up to a 50th percentile 1-year old infant. | Our prototype was not designed for a 50th percentile newborn, but instead it was scaled up to fit one of our team members (for prototyping purposes).<br><br>Therefore, we are not able to quantitatively test this requirement, however we predict that a final prototype scaled to the infant would pass. | Not tested |

**Detailed Verification Explanations:**

**(1): Battery Life**

From sources (75-79) we obtained the following draw rates for all components:
Bluetooth module: 40mA
Arduino Board: ~50mA
Pulse Oximeter : 5mA
Thermistor  (Temp sensor): 50mA (Found via MultiSim circuit simulation)
SD module interface: SPI
SD card draw rate assumed to be maxed at 80mA
mAh of 9v battery: assumed to be 595 mAh

Total current consumption is 225mA
Thus the battery life can be calculated by mAh/mA: 595/225 = 2.644 hours per battery.

**(7.1): False Positives: Circuit Verification:**

The circuit design detailed in DHF 4 was first verified in MultiSim:

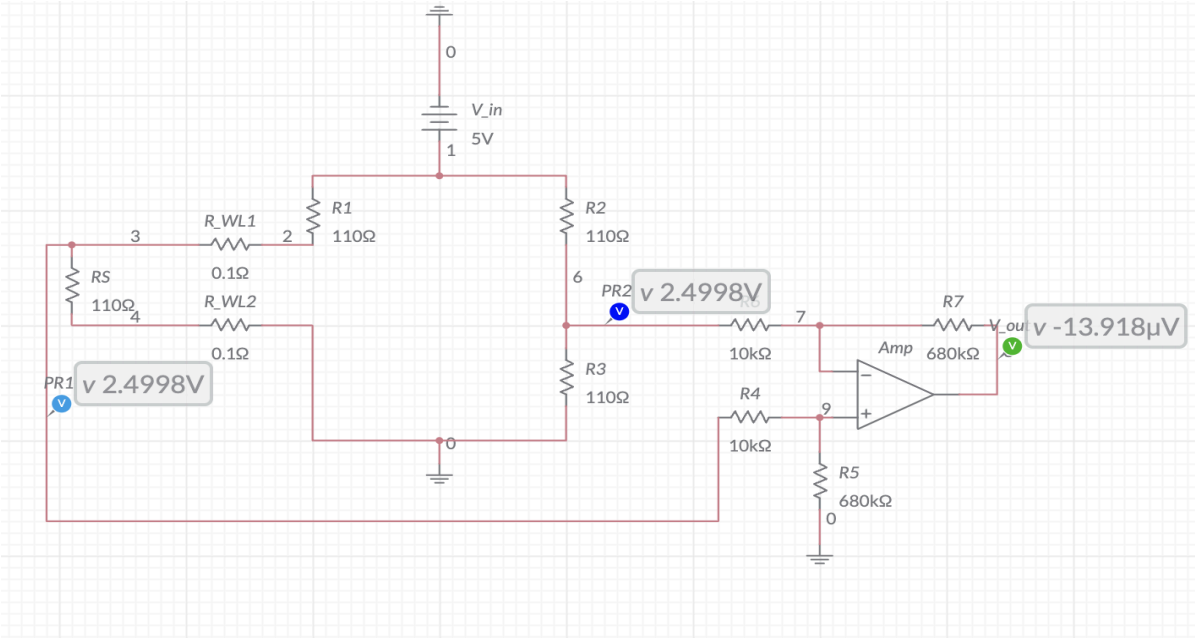


**Figure 6:** Verification of circuit design at T = 26℃

When RS = 110Ω (which corresponds with the lower temperature bound of 26℃) the output voltage is ~0V.

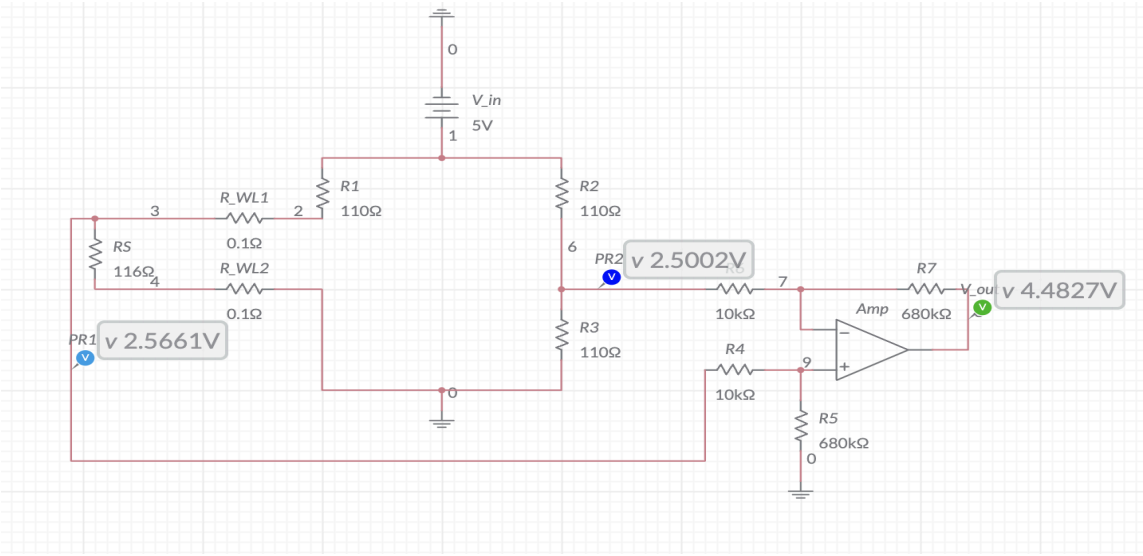


**Figure 7:** Verification of circuit design at T = 42℃

When RS = 116Ω (which approximately corresponds to the upper temperature bound of 42℃) the output voltage is ~4.48V.

An output voltage of 4.48V is expected here because of the various assumptions that were made, as well as how common resistance values were chosen. 4.48V is close enough to 5V that it does a good job of optimizing the sensitivity of the Arduino.

To review, this circuit was simulated in MultiSim at both the resistance lower and upper bounds which correspond to a body temperature of 26℃ to 42℃. The circuit design correctly responds to this temperature range by outputting voltage values ranging from [0, 4.48]V (respective to the temperature bounds).

**(7.2): False Positives: Software Verification:**

The circuit above is reproduced in Tinkercad (figure 8) to verify if the software can compute the correct temperature from the varying resistance and only alerts the guardian when abnormal temperature is detected. This primarily verifies the code segments corresponding to the functions

- Arduino pin records voltage input from resistance temperature circuit,
- Code converts voltage to a temperature reading, and
- Arduino sends notification to the guardian phone of abnormal temperature reading every minute.

The circuit and code setup was slightly altered for testing purposes (e.g., the temperature sensor was replaced by a resistor of set resistance), and a few minor mistakes in the previous DHF were corrected (such as code syntax etc.).

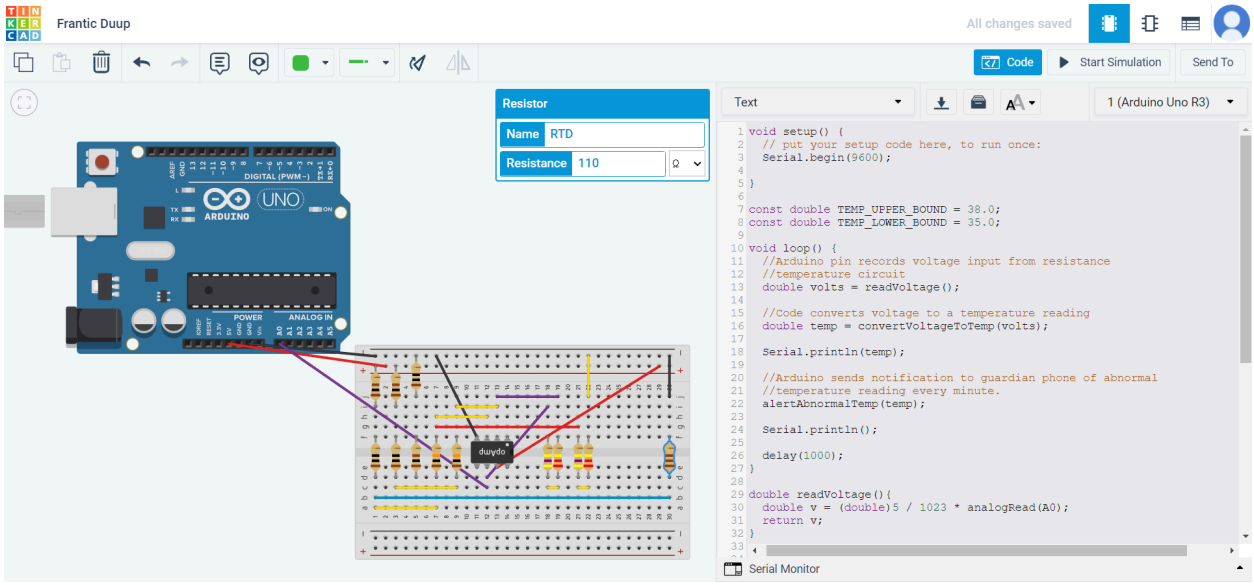


**Figure 8:** Simulation Setup

Table 2 shows the expected temperature and the actual temperature measured and computed by our software. Several different resistances are chosen for this verification. They all correspond to temperature within the functioning range of our device as specified in DHF 4, but are primarily centered around the threshold temperatures 35 ℃ and 38 ℃ outlined in the requirement. The expected temperature is calculated from the resistance and the formula $R_T = R_0[1 + RTC(T)]$ (derived in DHF 4). The measured temperature is collected from the serial monitor in the Tinkercad simulation.

**Table 2.** Expected Temperature vs Measured Temperature

| Resistance (Ω) | Expected Temperature (℃) | Measured Temperature (℃) | Guardian Notified? |
|---|---|---|---|
| 110 (lower bound) | 25.97 | 25.99 | Yes |
| 113.4 | 34.81 | 34.75 | Yes |
| 113.5 | 35.06 | 35.01 | No |
| 114 | 36.36 | 36.27 | No |
| 114.6 | 37.92 | 37.79 | No |
| 114.7 | 38.18 | 38.03 | Yes |
| 116.2 (upper bound) | 42.08 | 41.78 | Yes |

Table 2 has demonstrated that the software is able to compute the infant's temperature with sufficient accuracy and only report to guardians when the temperature is out of bound. The small discrepancies between the expected and measured values might stem from the rounding errors in deriving the equation relating temperature to voltage (which is used in the software to convert the measured voltage back to temperature). These inaccuracies are not significant since the largest of them (0.3 ℃) still complies with IEC class B accuracy (requirement 6).

However, we are unable to test how well the device processes data with noises because, without experimental data, it is difficult to generate a data set with the appropriate level of noises that offers practical insight into how our system functions in real life. So far, we did not implement any filters in either the circuit nor the software. The only measure to reduce random errors in collected data is to average the data every minute. This might be ineffective when there are spontaneous very large or very small readings.

**(15): Physical Dimensions**

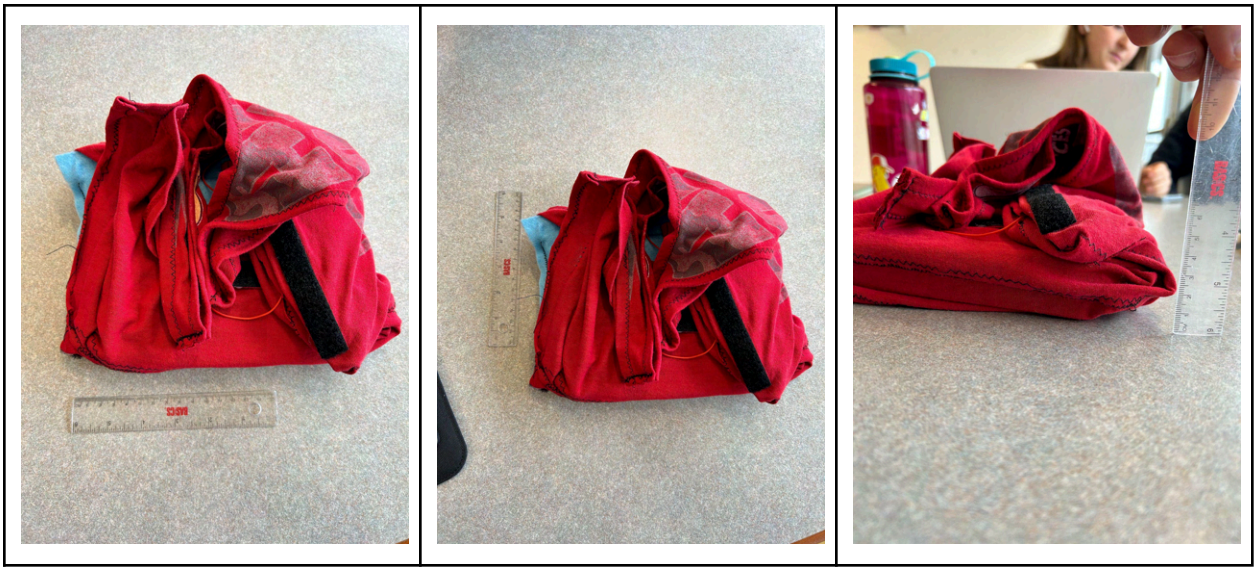

**Figure 9:** Length, Width, and Height (From left to right) (Values (Approximately): 22cm, 22cm, 8cm)

# Part 2: Failure Mode Analysis

**Table 3:** Failure Mode Analysis

| Failure number | Hazard (cause) | Mode | Harm (effect) |
|---|---|---|---|
| **1** | Device shuts off without notifying guardian | Device battery dies and no notification is sent to the guardian | If the device shuts off without the guardian knowing, notifications will not be sent, and the infant could begin showing signs of sepsis. This could progress into septic shock without the guardian being warned. |
| **2** | Heart Rate and/or temperature sensor failure | Sensor modules slip out of designated shirt pockets | The sensors no longer give accurate readings. This may either result in false positives or false negatives. A false negative is a potentially life-threatening error as signs of septic shock may be missed. This would impact the infant, as they could begin showing symptoms that the device would not detect and may progress into shock without warning, resulting in potential injury or even death.<br><br>A false positive is a less major error, as a notification will be sent to the guardian to check on the infant. Assuming the notification instructions are followed, the guardian will check on the infant to either discover that the sensor was dislodged or that the infant is healthy and is not displaying symptoms of sepsis. This has the effect of wasting the guardian's time. |
| **3** | Notification failure | Guardian walks out of range of the bluetooth transceiver and disconnects, or their phone dies and disconnects. We have tested this with our device, and the phone | Once disconnected, the device will not communicate with the phone. If this happens, the device is rendered useless, as there is no notification system currently in place to alert the guardian.<br><br>This has the potential to affect the |

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| | | permanently disconnects from the device when the range is approximately greater than 50ft. Ideally, the guardian would be made aware of this limitation and it would be kept in mind during daily activities. | infant and the guardian. The guardian is affected because they will no longer have access to a summary of the infant's vital information (this is a minor effect). The infant is affected because they may begin showing symptoms and progress into sepsis and septic shock without warning to the guardian. This has the potential to cause injury or even death to the infant.<br><br>However, if the phone goes back into bluetooth connect range, it will reconnect with the device and start communicating again. |
| **4** | Wires are disconnected | If incorrectly set up, or if exposed to significant movement, long wires may become exposed and could be pulled by the infant, or get caught on objects in the environment. This could cause the wires to disconnect.<br><br>In our current prototype, multiple wires connect between the different pockets of the shirt. These wires are long enough that the infant could feasibly pull on the wires and disconnect them. | If the wires are disconnected, the device will stop working. This means the guardians will not be notified if the infant develops sepsis, which is a critical error that has the potential to cause injury or death to the infant (as justified in the failures above).<br><br>An additional effect is the open wires, which have the potential to shock the infant. This could result in burns or numbness, tingling or vision, hearing, and/or speech problems. This low of a shock would not be strong enough to cause death (80). |
| **5** | Resistor sensor overheats | In prior testing we have seen the resistor sensor overheat, albeit not unbearably hot, however this | The overheating of the resistor can cause damage to the infant's skin, as they are in physical contact with one another. This could also cause damage to the shirt. If they overheat |

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| | | could still be a potential hazard. This is likely due to the current being driven through the resistor as they dissipate heat based on the current flow. Therefore it could be a result of the current we are sending through the circuit. | excessively, it could also potentially damage the sensors. These effects could lead to the device not being able to properly function. |
| **6** | Software failure | Undetected bugs in code cause the software to malfunction | Malfunctioning software might not detect telling symptoms of sepsis, or it might not notify the guardian of such symptoms. This may lead to the septic infant missing the optimal time for treatment and thus suffering from the more severe outcomes of sepsis.<br><br>On the other hand, the malfunctioning software might alert the guardian when no signs of sepsis are detected. This might cause unnecessary anxiety in the guardian and add to the burden on the medical system. |

# Part 3: Risk Assessment

Table 4 shows our risk assessment table for calculating the risk scores of certain device failures. Below is justification for the creation of the table.

For levels of likelihood, we quantified different tiers by how likely the failure is to occur within 1 ideal battery life of our device. One ideal battery life is 8 hours (as specified by requirement 1). We decided to use battery life because it is an easily quantifiable unit of time for our device. Certain guardians may choose to use 1 battery life's worth of charge per day, but others may choose to use 2. This distinction ensures consistency in our likelihood scale, because choosing "days of use" is ambiguous. Additionally, 8 hours of charge is a reasonable time scale for this likelihood rating. The highest likelihood would be an occurrence of multiple times during a single battery life (multiple failures every 8 hour period). Next would be one failure in a battery life (1 failure in 8 hours), then once in 7 battery lives (56 hours) because this represents a full week of usage if an 8-hour battery charge is used once every day. The last two levels are 30 battery lives (240 hours) and 365 battery lives (2920 hours), using the same justification but with months and years respectively. Note that our device is intended to be used from birth to about 1 year of age, so this final likelihood level reflects 1 failure per device's lifetime. This final likelihood level does not reflect extremely rare failures (such as failures that might only occur in 1 out of 100 devices). We justified using this smaller range for likelihood because our brainstormed failures all occur relatively many times per a single device.

For levels of severity, we primarily used the trauma chart for the Abbreviated Injury Scale (AIS) (81) to define the severity of the injuries related to our device. Specifically, a minor injury in the trauma chart corresponds with severity 2 in our table, a moderate injury corresponds with severity 3, a major but non-life threatening severe injury corresponds with severity 4, and a life threatening severe injury corresponds with severity 5. For severity 1, we defined it as inconvenience caused to the user with no injuries involved. **Importantly, a failure of our device that results in the loss in the ability to detect sepsis has been assigned to a severity level of 2.** This decision was made because the likelihood of sepsis developing and progressing to septic shock during the short period in which the device is not monitoring the infant is very unlikely, as the most aggressive infections take over one hour to enter the bloodstream, and longer to progress to septic shock (82). Additionally, our device does not cause direct harm to the infant if there are small gaps in monitoring. We do recognize that a failure to detect sepsis is a critical issue, however, for this portion of the assignment, we are only considering ways in which our device could directly harm or injure the infant. Even though there is a chance that the infant will develop sepsis during a period of device inactivity, which could lead to serious health complications, we have assigned severity level 2 to all failures that prevent the device from detecting sepsis. This is because, unlike an exposed wire, failing to detect sepsis would not directly harm the infant. In comparison, a severity level of 5 would correspond to a direct and certain cause of infant death which is caused by a mode of failure in our device.

By rating each failure with a severity and likelihood score, we then quantified the risk by calculating Risk (R) = Severity (S) * Likelihood (L). We have set three thresholds for levels of risk:

1. Safe is <= 3 (Green)
2. Requires attention and future mitigation is >3 and <8 (Orange)
3. Requires urgent mitigation is >= 9 (Red)

These levels of risk were chosen by examining the potential impact of each level of risk. Certain exceptions were made for highly severe but low-likelihood risks. This is because our likelihood range is quite small; a risk that happens once a year is still extremely likely to happen and should require mitigation if the severity is even moderate.

We defined safe risk as less than or equal to 3 because at most: minor inconveniences will happen once a week or minor injuries once a year. A moderate injury once a year was excluded from the safe category because any moderate injury that our device may cause to a newborn should be mitigated.

A risk level that requires attention and future mitigation is between 4 and 7 (inclusive). These risks can at most cause a severe injury in an unlikely case or many minor inconveniences multiple times a day. These risks will have to be considered in future iterations of our design and will hopefully receive some form of mitigation. A severity 5 but likelihood 1 risk has been excluded from this category, as any directly life-threatening risk requires immediate attention and mitigation.

Finally, any risk level of 8 or greater will require urgent mitigation. These risks can cause death or have a high likelihood of causing lesser injuries. Future iterations of our design must consider and mitigate these risks.

**Table 4:** Risk Assessment

| | **Severity 1 Inconvenience (inconvenience caused to guardian, and need for device attention)** | **Severity 2 Minor injury (superficial abrasion, unspecified laceration or first degree burn. No injury to subcutaneous tissue)<br><br>AND / OR: Chance of sepsis not being detected** | **Severity 3 Moderate injury (major abrasion, laceration to subcutaneous tissue, non life threatening burn of second or third degree)** | **Severity 4 Severe injury (potential for loss of limb or organ, or negative impact to long-term function)** | **Severity 5 Loss of life (critical and life-threatening injury)** |
|---|---|---|---|---|---|
| **Likelihood 1<br><br>1 in 2920 hours** | **1** | **2** | **3<br>THIS BEING ORANGE IS JUSTIFIED ABOVE** | **4** | **5<br>THIS BEING RED IS JUSTIFIED ABOVE** |
| **Likelihood 2<br><br>1 in 240 hours** | **2** | **4** | **6** | **8** | **10** |
| **Likelihood 3<br><br>1 in 56 hours** | **3** | **6<br><br>Failure 2** | **9<br><br>Failure 4** | **12** | **15** |
| **Likelihood 4<br><br>1 in 8 hours** | **4** | **8<br><br>Failure 1<br>Failure 3** | **12** | **16** | **20** |
| **Likelihood 5<br><br>>1 in 8 hours** | **5** | **10<br><br>Failure 5<br>Failure 6** | **15** | **20** | **25** |

**Failures assessed:**

| Failure | Risk Score |
|---|---|
| 1: Device shuts off without notifying guardian | 8 |
| 2: Sensor failure | 6 |
| 3: Notification failure | 8 |
| 4: Disconnected wires | 9 |
| 5: Electronic overheating | 10 |
| 6: Software failure | 10 |

**Justification for failure risks:**

1.This is a very flexible issue and a failure of our early-stage prototype. A notification could easily be sent to the phone indicating low battery. Ideally, the late-stage prototype would send a notification if the battery was running low. However, our current prototype fails to send a notification to the guardian if the battery is not fully charged. This would be added during the next stages of iteration. For these reasons, we assigned it a likelihood score of 4 and a severity score of 2. The prototype was given a likelihood score of 4 as it would occur once every charge, with a severity score of 2. This would likely not cause any severe harm to the infant, however, this clearly poses a risk, as sepsis symptoms cannot be detected if the device does not have power. We plan on fixing this by adding more robust code as well as working with circuits that draw less power. This will ultimately fix the battery issues and allow a notification to be useful.

2. A sensor falling out of the shirt pocket is unlikely given our pocket design. This secure pocket design is implemented in both the prototype and our final design. However, due to improper use, sensor placement may not be ideal as it could fall out of the pocket; therefore, it is expected that this would occur once every few days (48–72 hours), giving it a likelihood score of 3. In this case improper use is considered to be: not using the pocket, not closing the pocket, or manipulating shirt pockets in any way. In the case of a sensor falling out of a pocket, our device may still be able to detect sepsis due to the fact that it uses several different sensors. However, the worst possible case results in the inability to accurately detect sepsis if multiple sensors fall out or stop working. Thus, the severity is mild (severity level 2) if not dealt with.

3. Notification Failure. Walking out of range of the device would likely happen once a day (likelihood level 4), because our device has a maximum bluetooth range of 50ft (which we

tested) which is not an extremely large distance. The main harm is not detecting sepsis, which is a severity score of 2. In our ideal design, an application on the guardian's device would warn them of a disconnected or weakening signal, which would lead to them dealing with the issue and therefore there being no risk for the infant. However, in our prototype, our system does not implement such a mechanism, so the guardian would not be notified of any disconnects that would hinder the function of our device.

4. Wires Disconnected. This mode of failure has two potential risks: not detecting sepsis symptoms and minor electrocution (Minor shocks can result in burns or numbness, tingling or vision, hearing, and/or speech problems (80)). Not detecting sepsis symptoms is assigned a severity level of 2, and for the various health concerns of minor shock we assigned an overall severity level of 3. Our device will only cause up to minor shock because it is powered by a 9V battery. The final severity level was chosen as 3. For all likelihood, in our current prototype, the wires are fairly easy to access and could feasibly be removed a couple times in a week. Therefore, we assigned a likelihood level of 3. In our final iterated design, this issue would be addressed through proper encasing of the wires.

5. Resistor overheating. Through building our physical prototype, we found that our prototype's temperature sensor became uncomfortably hot every time it was used for longer than a minute. This has been converted to a likelihood score of 5, as it occurred every time we powered on the device. We did not measure the exact temperature that the temperature sensor would achieve; however, we believe that because infant skin is usually very sensitive, the sensor heating up would likely cause a heat rash or a first-degree burn at most, both minor injuries (severity 2). (Note that the sensor never became extremely hot, just warm enough to potentially cause a light burn to sensitive skin). Because this failure's risk rating is considered to require urgent mitigation, this issue will be addressed in a future prototype. We plan to adjust the circuit so that the sensor sees a more appropriate voltage and current so that it doesn't heat up as dramatically. Using another type of sensor (non-resistance based) that does not see an electrical current is another option for risk mitigation.

6. Software failure. Commercial software typically has 20 to 30 bugs for every 1000 lines of code (83). These undetected bugs might either cause the device to fail to notify the guardian when there is sepsis (severity 2) or notify the guardian when there is no sepsis, which is an inconvenience to the guardian (severity 1). Therefore, the overall severity level is 2. For likelihood, since it is quantified in terms of battery life, assuming every line of code is covered during each use between two charges, a device with critical bugs will fail every time it runs, thus giving a likelihood of level 5. For further iterations, we will implement code that catches errors and notifies the guardian to mitigate this risk. We will also write more comprehensive test cases to detect and eliminate as many bugs as possible.

# *Presentation Reflection:*

Our own design process:

Overall, our design process went without much note. Following the design process allowed us to clearly flesh out our ideas, concepts and path going forward before jumping headfirst into a potential dead-end idea. There were not many notable roadblocks in the design process, save for some technical issues during DHF 4.1, most notably attempting to share SolidWorks files over drive. This was not a great solution as some of us would work on the same file concurrently, making several changes individually and then ending up with 2 completely different CAD files. Paired alongside having to manually select each file and uploading it to drive, which would take a long time, only to find out that you forgot to upload one of the parts of the assembly a few hours later, made this part of the project a little bit of a nightmare. As a result, we hope to explore alternative file-sharing systems in the future to avoid similar issues.

Day 1:

Group 17 “DiapAlert”: This group’s solution to our design problem was very interesting, as they stated they wanted to ensure they made a product that would take the least amount of time for guardians to learn to use, and that using a diaper (a task new parents do regularly) would be the easiest adjustment for new users. On top of this, their device was non-invasive, and nonrestrictive of the infant's movements. Of all devices, group 17’s device would most likely be the easiest to learn to use as a new parent, and the most comfortable for the infant. Despite this, however, it would be much more difficult to ensure proper function of the sensors on the DiapAlert, as based on the proposed design they would not have very much stability. This design represents the balance between comfort and accuracy, which was one of the main challenges of this project. It contrasts ours, which may be less comfortable to the infant, but more accurate in the symptom detection. To improve the usability of our device, we can take inspiration from Group 17 by designing the assembly process to mimic actions that caregivers already perform. For instance, we could make the electronics of our device compatible with different types of baby clothes, not just the tank top, to make it easier for caregivers to put the device on the baby. This could be achieved by adding user-friendly features like adjustable straps and snap-on fasteners to simplify the process for caregivers.

Day 1:

Group 4 “The Sepsis Sentinel”: Group four decided to make a wristband designed to monitor heart rate, blood oxygenation, breathing rate and skin temperature monitors. This was interesting as they selected many more symptoms to monitor. Although our team decided not to measure breathing rate due to the complexity associated with distinguishing breathing rate from other movements, they offered an interesting solution which was the use of artificial intelligence to determine breathing rate. Another interesting aspect of group 4’s project was that rather than detect symptoms of sepsis and transmit these directly to the device, they decided to use sensor

readings to calculate the % chance of sepsis. This would help ensure less false alarms occur, and would ensure that outliers (within symptoms) are not immediately labeled as sepsis, thus reducing guardian stress. Our group could take after group 4 and potentially add more sensors with an algorithm to ensure that outliers within the sensors are not immediately labeled as sepsis symptoms.

Day 2:

Group 7: We thought that it was beneficial that this group examined their top scoring designs from the evaluation phase instead of defaulting to the highest-scoring solution. This allowed them to meticulously combine the best aspects of the top 2 designs, resulting in an overall better solution. Compared to our design process, while we did spend time combining designs, we could have been more critical between the top-scoring designs to integrate them together. With group 7, this resulted in a velcro-adjustable shirt which could be used to fit many different sizes of infants. In comparison, our design is only for a single shirt size (however we had multiple concepts with adjustable aspects that didn't make it through the evaluation phase). By integrating an adjustability function like a velcro strap our device would work for more infants, resulting in an overall higher user satisfaction.

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# *Appendices*

# Appendix A: Q&A Questions (DHF 1)

**Q&A Questions (Our prepared questions)**

- How much time do you spend with your child? Do you spend a lot of time in the same room as your child? How long do you feel comfortable leaving your child alone?

- Do you feel safe having devices on your child? Would your child be likely to chew/suck on the device if it were an external device or remove it?

- Does your child remain in your bedroom at night or do you keep them in a separate room?

- Would your child try to remove a small wearable device, such as a bracelet?

- Would your child be likely to chew/suck on the device if it were an external device (wearable accessory)?

- Would you take the time to fix, adjust, or maintain a solution for some time everyday? (Ex. would you be okay changing the device every day, if it takes about 5 minutes)

- Do you have health insurance? Does it cover infant monitoring devices?

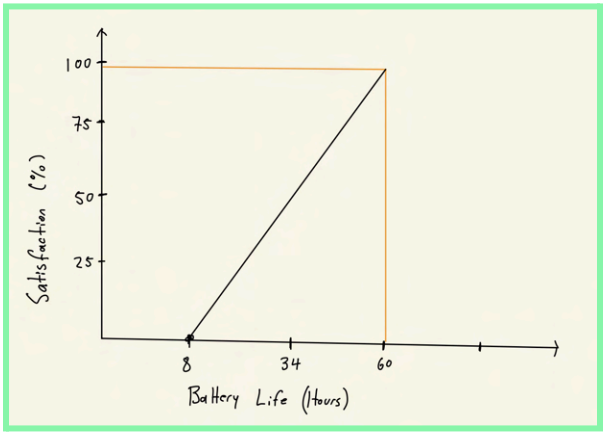
- What price range would you be comfortable spending on a device?

- Would you like the device to be portable?

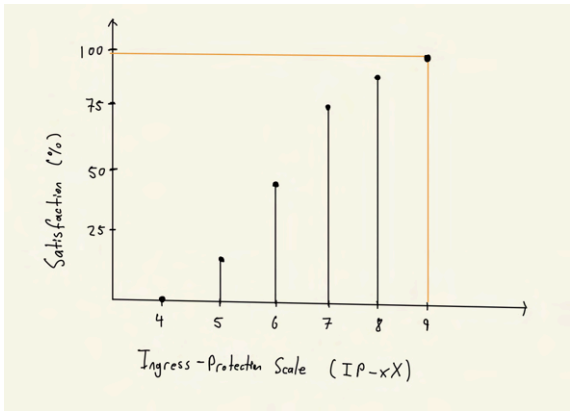
- Are you familiar with the symptoms of sepsis and if you are aware how often do you worry about sepsis in your infant?

# Appendix B: Satisfaction Curves (DHF 2)

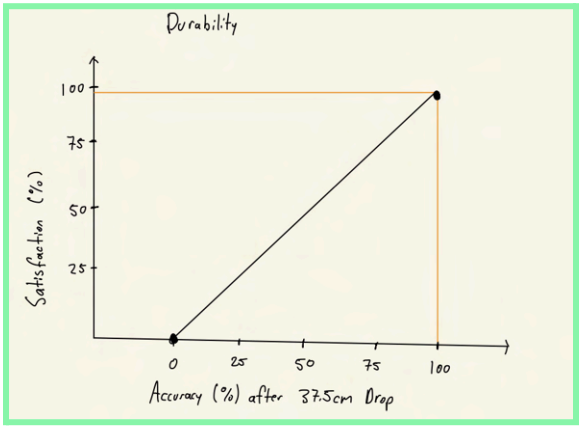
### Satisfaction Curves



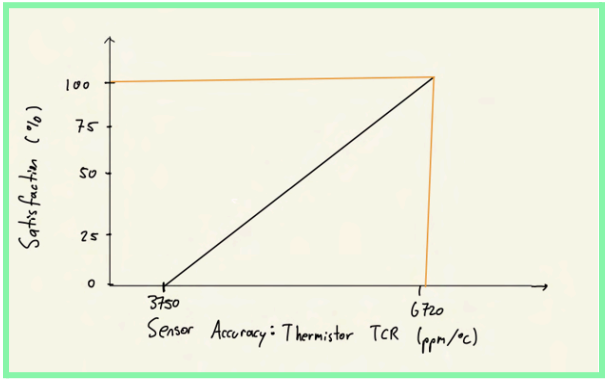

1: Battery Life



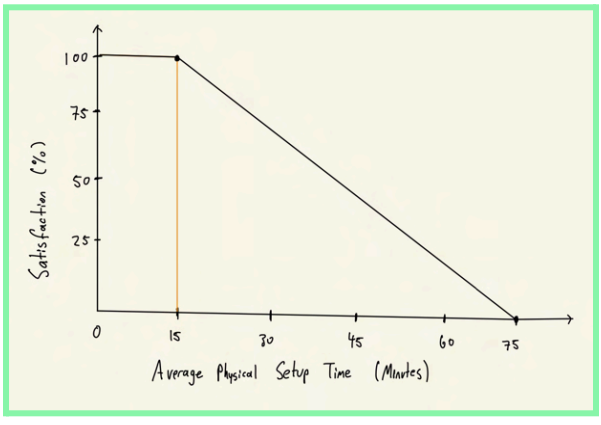

2: Waterproofing



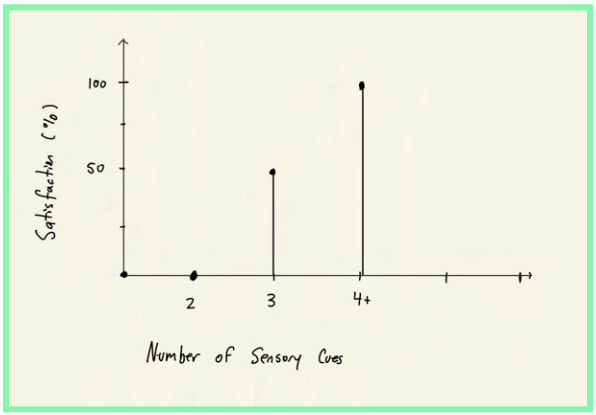

3: Durability



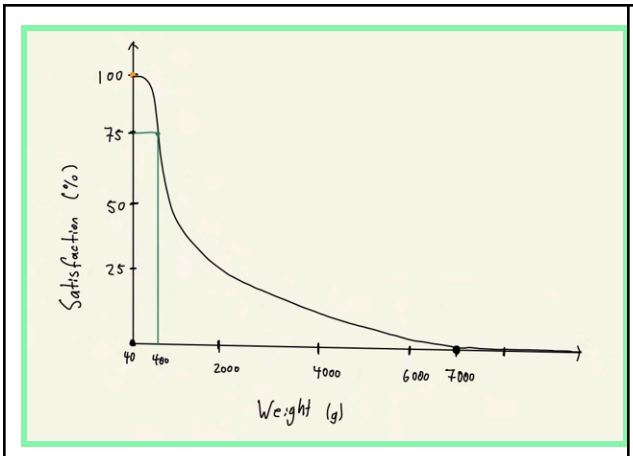

4: Accuracy in detecting symptoms: thermistor example



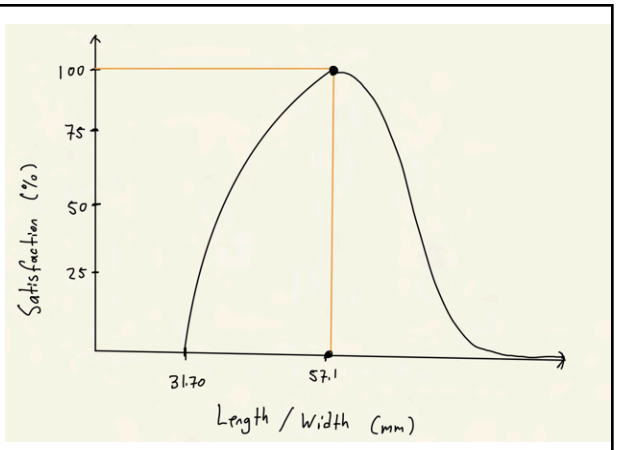

5: Easy Device Setup



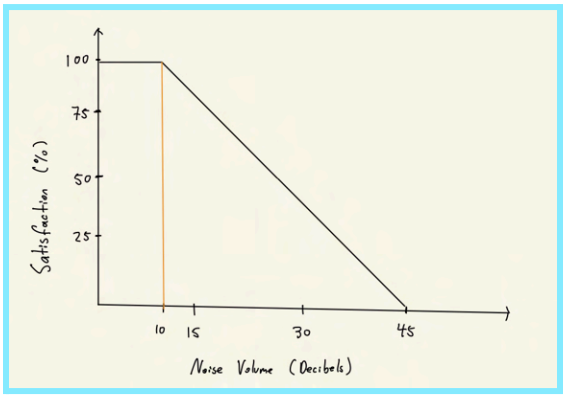

6: Emergency Notification: Number of sensory cues



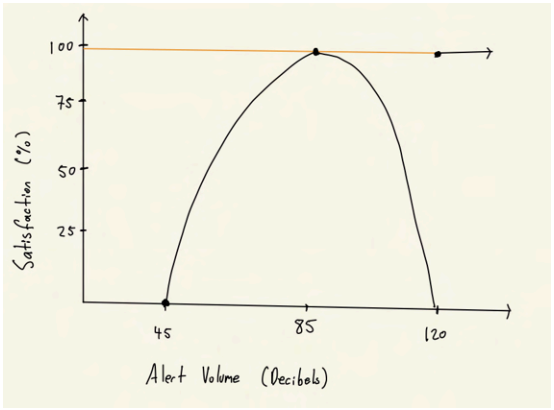

7: Weight




8: Length




9: Maximum Background Noise




10: Alert Volume

# Appendix C: Adjustability Evaluation Criteria (DHF 2)

**Adjustability Math:**

Mean Infant Length: 75cm
Standard Deviation: 2.5cm
Source: World Health Organization
(Averaged Boys and Girls data from z-score tables)

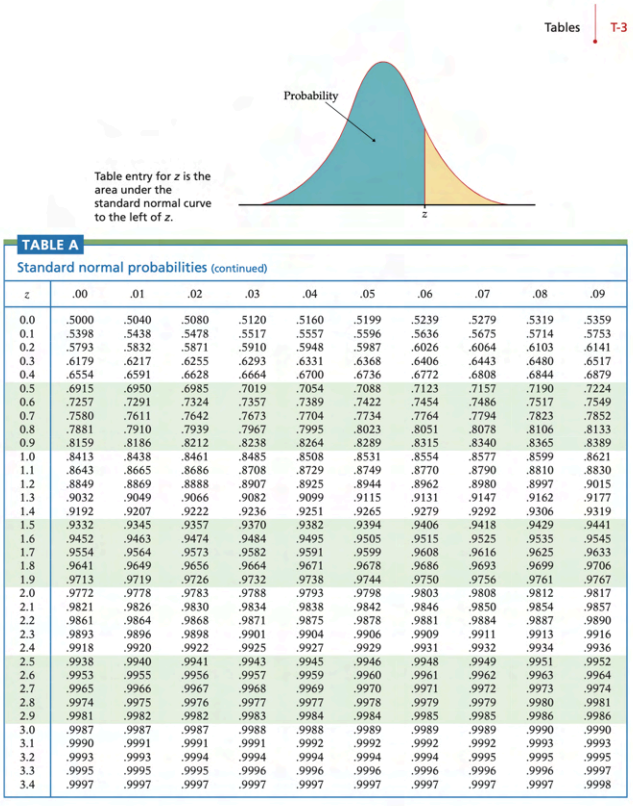
We will assume that the distribution of infant length's is close to normal.

The next step is to normalize the distribution to create a **standard normal distribution**. We do this by converting the infants's length into a **z-score**. The formula for z-score is quite simple:

$$Z = \frac{x - \mu}{\sigma}$$

Where x is the infant's length, μ is the mean infant length, and $\boldsymbol{\sigma}$ is the standard deviation.

The reason we normalize this data is because tables exist which tell us standard normal probabilities (i.e. the area underneath the normal distribution graph), and therefore we don't have to calculate or do any weird integrals ourselves!



Tables T-3

Probability

Table entry for $z$ is the area under the standard normal curve to the left of $z$.

z

**TABLE A**

Standard normal probabilities (continued)

| z | .00 | .01 | .02 | .03 | .04 | .05 | .06 | .07 | .08 | .09 |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.0 | .5000 | .5040 | .5080 | .5120 | .5160 | .5199 | .5239 | .5279 | .5319 | .5359 |
| 0.1 | .5398 | .5438 | .5478 | .5517 | .5557 | .5596 | .5636 | .5675 | .5714 | .5753 |
| 0.2 | .5793 | .5832 | .5871 | .5910 | .5948 | .5987 | .6026 | .6064 | .6103 | .6141 |
| 0.3 | .6179 | .6217 | .6255 | .6293 | .6331 | .6368 | .6406 | .6443 | .6480 | .6517 |
| 0.4 | .6554 | .6591 | .6628 | .6664 | .6700 | .6736 | .6772 | .6808 | .6844 | .6879 |
| 0.5 | .6915 | .6950 | .6985 | .7019 | .7054 | .7088 | .7123 | .7157 | .7190 | .7224 |
| 0.6 | .7257 | .7291 | .7324 | .7357 | .7389 | .7422 | .7454 | .7486 | .7517 | .7549 |
| 0.7 | .7580 | .7611 | .7642 | .7673 | .7704 | .7734 | .7764 | .7794 | .7823 | .7852 |
| 0.8 | .7881 | .7910 | .7939 | .7967 | .7995 | .8023 | .8051 | .8078 | .8106 | .8133 |
| 0.9 | .8159 | .8186 | .8212 | .8238 | .8264 | .8289 | .8315 | .8340 | .8365 | .8389 |
| 1.0 | .8413 | .8438 | .8461 | .8485 | .8508 | .8531 | .8554 | .8577 | .8599 | .8621 |
| 1.1 | .8643 | .8665 | .8686 | .8708 | .8729 | .8749 | .8770 | .8790 | .8810 | .8830 |
| 1.2 | .8849 | .8869 | .8888 | .8907 | .8925 | .8944 | .8962 | .8980 | .8997 | .9015 |
| 1.3 | .9032 | .9049 | .9066 | .9082 | .9099 | .9115 | .9131 | .9147 | .9162 | .9177 |
| 1.4 | .9192 | .9207 | .9222 | .9236 | .9251 | .9265 | .9279 | .9292 | .9306 | .9319 |
| 1.5 | .9332 | .9345 | .9357 | .9370 | .9382 | .9394 | .9406 | .9418 | .9429 | .9441 |
| 1.6 | .9452 | .9463 | .9474 | .9484 | .9495 | .9505 | .9515 | .9525 | .9535 | .9545 |
| 1.7 | .9554 | .9564 | .9573 | .9582 | .9591 | .9599 | .9608 | .9616 | .9625 | .9633 |
| 1.8 | .9641 | .9649 | .9656 | .9664 | .9671 | .9678 | .9686 | .9693 | .9699 | .9706 |
| 1.9 | .9713 | .9719 | .9726 | .9732 | .9738 | .9744 | .9750 | .9756 | .9761 | .9767 |
| 2.0 | .9772 | .9778 | .9783 | .9788 | .9793 | .9798 | .9803 | .9808 | .9812 | .9817 |
| 2.1 | .9821 | .9826 | .9830 | .9834 | .9838 | .9842 | .9846 | .9850 | .9854 | .9857 |
| 2.2 | .9861 | .9864 | .9868 | .9871 | .9875 | .9878 | .9881 | .9884 | .9887 | .9890 |
| 2.3 | .9893 | .9896 | .9898 | .9901 | .9904 | .9906 | .9909 | .9911 | .9913 | .9916 |
| 2.4 | .9918 | .9920 | .9922 | .9925 | .9927 | .9929 | .9931 | .9932 | .9934 | .9936 |
| 2.5 | .9938 | .9940 | .9941 | .9943 | .9945 | .9946 | .9948 | .9949 | .9951 | .9952 |
| 2.6 | .9953 | .9955 | .9956 | .9957 | .9959 | .9960 | .9961 | .9962 | .9963 | .9964 |
| 2.7 | .9965 | .9966 | .9967 | .9968 | .9969 | .9970 | .9971 | .9972 | .9973 | .9974 |
| 2.8 | .9974 | .9975 | .9976 | .9977 | .9977 | .9978 | .9979 | .9979 | .9980 | .9981 |
| 2.9 | .9981 | .9982 | .9982 | .9983 | .9984 | .9984 | .9985 | .9985 | .9986 | .9986 |
| 3.0 | .9987 | .9987 | .9987 | .9988 | .9988 | .9989 | .9989 | .9989 | .9990 | .9990 |
| 3.1 | .9990 | .9991 | .9991 | .9991 | .9992 | .9992 | .9992 | .9992 | .9993 | .9993 |
| 3.2 | .9993 | .9993 | .9994 | .9994 | .9994 | .9994 | .9994 | .9995 | .9995 | .9995 |
| 3.3 | .9995 | .9995 | .9995 | .9996 | .9996 | .9996 | .9996 | .9996 | .9996 | .9997 |
| 3.4 | .9997 | .9997 | .9997 | .9997 | .9997 | .9997 | .9997 | .9997 | .9997 | .9998 |

Now, you may be wondering: why does a z-score of 0.00 give a standard normal probability of 0.5? Oh, do I have a fascinating answer for you! You see, the standard normal distribution is centered around a z-score of 0. Because the distribution is symmetrical, and the total area under the curve is 1, the total area to the left of z = 0 is half the total area, i.e. an area of 0.5!

Here is a sample calculation. Say one concept is adjustable from 70 cm - 78 cm in length. Calculating the z scores yields:

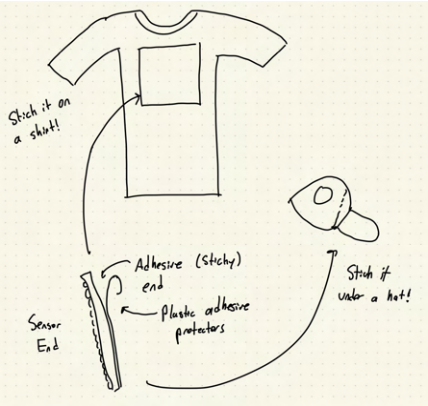
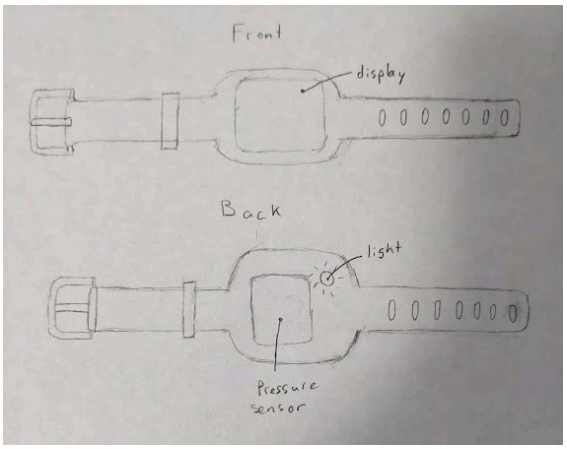
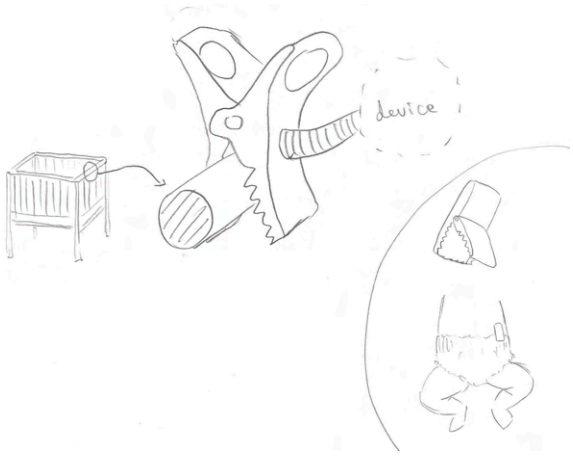
78 cm -> z = 1.2
70 cm -> z = -2

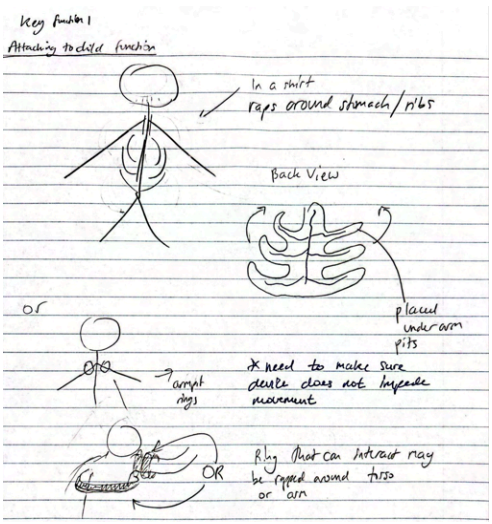
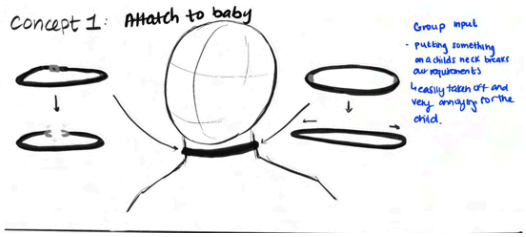
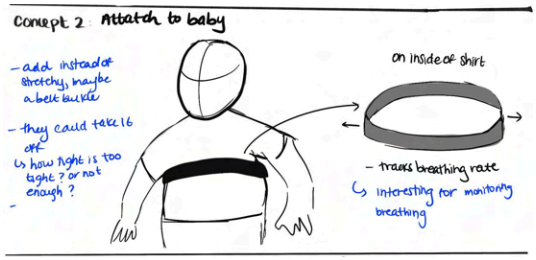
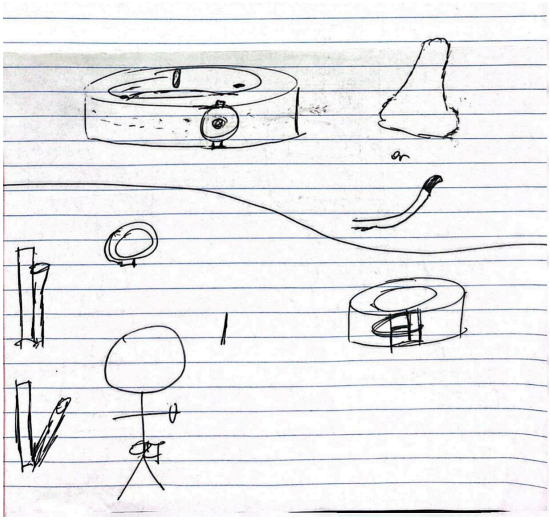
Calculating the total score, we take the upper bound and subtract the lower bound. This, in essence, is taking the area under the graph to the left of $z = 1.2$ and subtracting the area under the graph to the left of $z = -2$.

Using the table:
Area = 0.88 - (1 - 0.97) = 0.85
Satisfaction = 85%

This satisfaction is quite high, even considering that the range of the adjustability does not vary by an extreme amount. This can be attributed to the relatively low standard deviation (meaning, most babies 1 year old are quite a similar length. In fact, nearly 100% of babies range from 65cm - 85cm.)

# Appendix D: Original Concept Generation Sketches (DHF 3)

| Appendix Number | Concept Name & General Description | Concept Sketch |
|---|---|---|
| **A1** | "Adhesive Patch": Sensors and a micro-computing chip are packaged into a flat, flexible material. The sensor is located on one side, and the other side is adhesive. This allows for the parents to place the sensor in an area that is the most appropriate for their own infant, and allows the device to be moved / modified as fit.<br><br>For example, the sensor could be attached to the inside of a shirt or pants. |  |
| **A2** | "Wristwatch": Includes a screen display on the front, providing up-to-date vital signs for the infant. The back contains a light-sensor to monitor blood oxygenation and a pressure sensor to keep track of blood pressure. A typical watch wrist strap allows for size adjustments for different infants, and as the infants grow, and a small band allows the excess watch material to be tucked away from the infant's attention. The display and sensors would also be covered in the rubber watch casing, to keep any hard materials away from the infant, and to protect electronic elements from water and damage. |  |
| **A3** | "Clip": The sensors are connected to a clip that can be placed on a crib, a stroller, or any furniture or objects that are close to the infant. This design allows for quick setup and removal of the device. A bendable connection between the sensors and the clip would allow the user to adjust the position of the sensors.<br><br>Alternative: smaller clip that can be attached to the infant's clothing |  |

| | | |
|---|---|---|
| **A4** | A design that would mimic a rib cage. This wearable would be able to determine breathing rate and temperature. Sensors would be placed throughout the ribs of the device for multiple places of measurement.<br><br>Alternatively, another design was sketched in which a band is placed around the chest and leg. This would be another option for sensor placement. |  |
| **A5** | Neck sensor that is stretchable. This concept was immediately discarded as it posed a safety risk to the infant. |  |
| **A6** | This concept is a stretchable chest strap specifically for measuring breath rate. |  |
| **A7** | This design incorporates both an adjustability mechanism as well as sensors. The infant would place this wristband, with sensors under the interface, on the wrist so that vitals could be read. A belt mechanism would be used for adjustability. |  |

# Appendix E.1: Old changes to Requirements for DHF 3 (DHF 3)

* Please note: Only major criteria changes are reflected in this table. Minor changes to grammar, definitions, etc. are not recorded in this report.

| **Change** | **Justification** |
|---|---|
| Removed requirement: “Detection time frame” | Redundant with detection frequency and accuracy in detection requirements. Additionally, this requirement was not testable as specified. |
| Changed requirement: “Biocompatibility” to:<br>“Wearable material must not irritate or cause discomfort to the skin of at least 85% of infantren.” | Updated requirement is quantifiable. |
| Change to requirement: “Durability” to:<br>“The device’s rate of correctly identifying signs of sepsis (sensitivity) must be at least 75% after being dropped from a height of 37.5 cm.” | Updated requirement is more descriptive than “device still works after being dropped”. Requirement is now more easily quantified. |
| Changed requirement: “Accuracy in detecting sepsis” to:<br>“Accuracy in detecting symptoms”:<br>“Each sensor used in the device is accurate up to the industry standard of that sensor” | Updated requirement is much more specific. If a design fails, the problem is now diagnosable to the specific sensor. |
| Changed requirement: “False positives” to:<br>“Under healthy conditions, the device does not generate false alarms more than 38% of the time from a total testing pool of 50 trials within the span of a year. This means that the device does not alert when the infant's breathing rate is between 30-45 breaths per minute, temperature is between 36.4-37.5 degrees celsius, and blood pressure has not exceeded 130/85 " | Added a definition of what is considered “healthy conditions” so the requirement is quantifiable. |
| Removed requirement: “Range of motion” | Redundant; this is covered by size and weight requirements. Leaving this requirement as it stood would also fail valid wearable ideas. |
| Changed requirement: “Removability or deconstruction by the infant” to:<br><br>“The device must be able to function completely (all sensors and systems hold accuracy to industry standard) if 50N of pushing or pulling force is applied.” | Requirement is now generalised to every concept and can be easily quantified. |
| Changed requirement: “Emergency instructions” to:<br><br>“When the device detects emergency abnormal vital signs (which can be precursors to sepsis), it notifies the guardian to go to the hospital in the case of an emergency. | The requirement is now more specific and quantifiable. It is no longer redundant with other requirements. Emergency vital signs have been specified. Additionally, notifications have been specified to 2 different sensory cues. |

| | |
|---|---|
| Emergency vital signs in infants are defined as a fever of 38C or higher, blood pressure below 71/36 and heart rate above 200 bpm<br><br>Urgent notifications should have notification in two sensory cues."<br><br>Combined requirement with parts of requirement 13 about sensory notifications. | |
| Combined requirements "Easy Physical Setup" and "Easy Digital Setup" into a single requirement: "Easy setup" | Requirement is now easy and non-redundant. |
| Changed requirement: "Easy interface" to:<br>"Understandable Notifications":<br>"Device text/notifications should be written in simple English with instructions that are understandable by individuals with IELTS reading score >4. " | Requirement is now precise and quantifiable. |
| Changed requirement: "Weight" to:<br>"Devices should weight less than 7 kg" | This was changed due to safety precautions. A device on the side of a crib could be pulled down and harm the infant.<br><br>The requirement is now generalised to all concepts, regardless of whether they are wearable. |
| Split up "Dimensions" requirement into multiple dimensions: "Length", "Height", and "Width". | This was made to abolish ambiguity as much as possible. |
| Changed requirement: "Dimensions, safety" to:<br>"The device must conform to 16 C.F.R. 1501, 1500.18 (a)(9), and 1500.50, 51, 52." | The requirement is now quantifiable and precise. |
| Changed requirement: "Dimensions, adjustability" to:<br>"The device is usable on and works for percentile newborn infants up to a 50th percentile 1-year old infant." | This was changed from originally being split up into different measurements. However, we did not want to constrain any wearable or non wearable concepts to anthropomorphic dimensions that may not be applicable. (Ex. A wristwatch did not meet the old requirement of chest circumference).<br><br>The requirement can now be generalised to all concepts. |
| Removed requirement: Diagnostics accuracy | Requirement was redundant and imposed design implications. |
| Removed requirement 23: Pattern detection, accuracy. | Requirement was a design implementation feature, once again imposing design implications that were not absolutely necessary. |

# Appendix E.2: Old changes to Evaluation Criteria For DHF 3 (DHF 3)

* Please note: Only major criteria changes which affect our evaluation are reflected in this table. Minor changes to grammar, definitions, etc. are not recorded in this report.

| **Change** | **Justification** |
|---|---|
| "Charge Life" changed to:<br>Linear Curve: 8 hours to 60 hours. | The new maximum value of 60 hours reflects the gold standard charge life (charge of an apple watch). |
| "Durability": changed to:<br>"How will device sensitivity be affected after a 37.5cm drop<br>Linear Curve: 75% to 100%" | This change reflects the change made to the associated requirement. The new terminology indicates sensitivity which defines its accuracy in detecting sepsis after impact. |
| "Accuracy in Detecting Sepsis" changed to: "Accuracy in Detecting Symptoms"<br><br>Linear Curve<br>Minimum: Sensor Industry Standard<br>For temperature thermometers: 57% (8)<br><br>Maximum: Sensor Gold Standard<br>For temperature thermometers: 85% (8)<br>*Note, unfortunately this source is in French, but Canada is a Bilingual nation! (Nadege is fluent in French). | The criteria is now directly quantifiable and diagnosable.<br><br>Note, that the evaluation criteria bounds should change depending on the sensor being measured. The bounds for temperature are given as an initial basis for comparison. |
| Removed Criteria 5: "False Positives" | The sensor accuracy is covered by 'Accuracy of Sensors' and the device's algorithm is a design implication. These are the two important deciding factors of False Positives, making it redundant and also non-diagnosable. |
| Changed Criteria 6: Emergency Instructions to:<br>"The device sends notifications in multiple sensory cues or forms:<br><br>Discrete:<br>2 Forms : 0%<br>3 Forms: 50%<br>4 Forms: 100%" | Changed to reflect the updated "Emergency Instructions" requirement. A maximum of 4 forms notification reflects the industry standard (apple watch alert system). |
| Removed Criteria 12, 13: Width and Height | Height and Width are less than the length, so these evaluation criteria are redundant and covered by the Length criteria. |
| Changed Criteria 16: Adjustability to:<br><br>"The device is adjustable to XX% of the population. | This evaluation criteria was created in order to better reflect how well the concept adjusts to the target population (infants). It is more specific, diagnosable, and reflective of our target population. |

| | |
|---|---|
| The score for each concept is calculated by providing the percentile range that the concept is adjustable to. This range is then used to calculate the standard normal probability, which is the satisfaction score." **See Appendix D for more information on scoring this evaluation criteria.** | |

# Appendix F: Battery measurements and size justification for wristband (DHF 3)

**(new appendix added)**

From this website (84), the wrist of a newborn to 6 month old is ~ 4”, which translates to 101.60 mm, approximating the shape of the wrist of a newborn as a perfect circle, the diameter of the wrist would be ~32 mm. Let’s say that if the longest dimension of the battery is smaller than the diameter of the infant’s wrist, it is a valid size for a wristband battery.

For our battery, we’ll use a common smart watch battery, the lithium ion Apple Watch battery. The display dimensions of the 44 mm Apple Watch are 44 x 38 mm (85). The dimensions for the battery itself is not publicly available information that Apple provides, so we’re going to have to do some estimations. Through a “teardown” of the 44 mm Apple Watch series 6 on ifixit.com (86), we are provided with an image of the lithium ion battery sitting in the Apple Watch, and with some pixel measurements, and proportion math, we are able to estimate the dimensions of the Apple Watch battery.

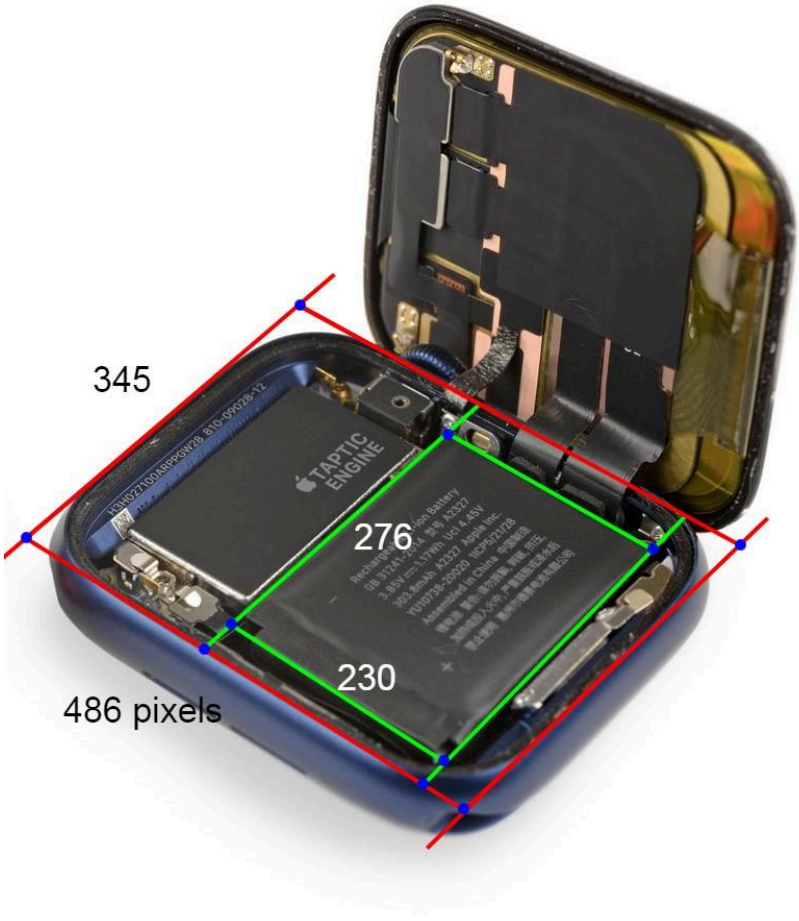



**Figure F1: open Apple Watch with battery exposed, length and width pixel measurements annotated**

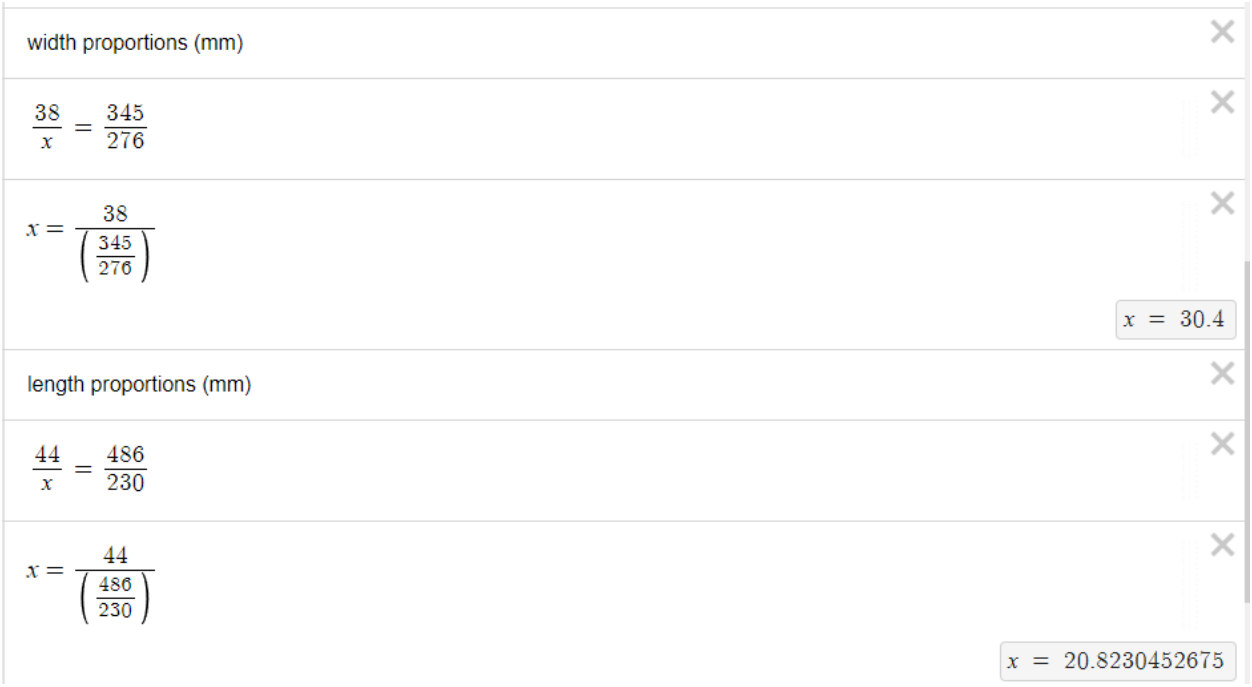



**Figure F2: proportion math**

As we can see here, even the longest dimension is shorter than the diameter of the infant's wrist, thus using an Apple Watch battery is a valid model for the wristband battery. Even if 30 mm seems too large to fit across the child's wrist, we could orient it the other direction, where the long edge is parallel to the arm.

Desmos link

# Appendix G: Accuracy rate calculations (DHF 3)

**(new appendix added)**

Crib Clamp:

To find accuracy rate given sensitivity and specificity I referenced this article (50). Which details can be found using those values alongside prevalence. Now the prevalence of fever among the studied population wasn't explicitly given in the referenced study above (51), but we can determine this by finding the prevalence of fever among those diagnosed with COVID-19 (87).

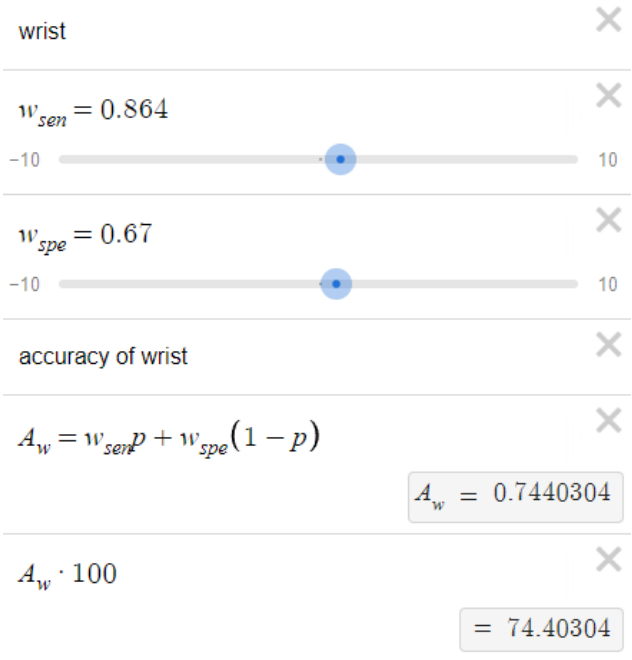
- COVID-19 was chosen because the accuracy study for NCITs was to evaluate temperature screening for COVID-19.
- The chosen prevalence of fever was that of a low-grade fever (38.1–39°C) (88) because the accuracy study was evaluating NCITs for temperatures around that range.

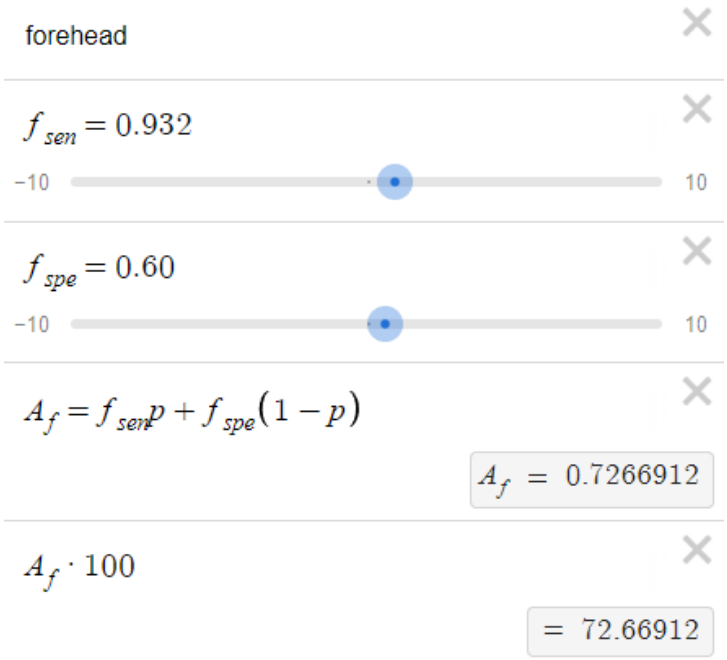
The prevalence found was **38.16%.** Both sensitivity and specificity were found for an NCIT to measuring the temperature of the forehead and wrist (51). These are listed below.

| | Wrist | Forehead |
|---|---|---|
| Sensitivity (%) | 86.4 | 67.0 |
| Specificity (%) | 93.2 | 60.0 |

Using this reference (50), we determined the accuracy rate for the wrist and forehead measurements using:

Accuracy = (sensitivity)(prevalence) + (specificity)(1 - prevalence)




The rates for wrist and forehead turn out to be 74.4% and 72.7% respectively. Taking the average gives **~74%** which we will take as our Crib Clamp accuracy rate. Desmos Link

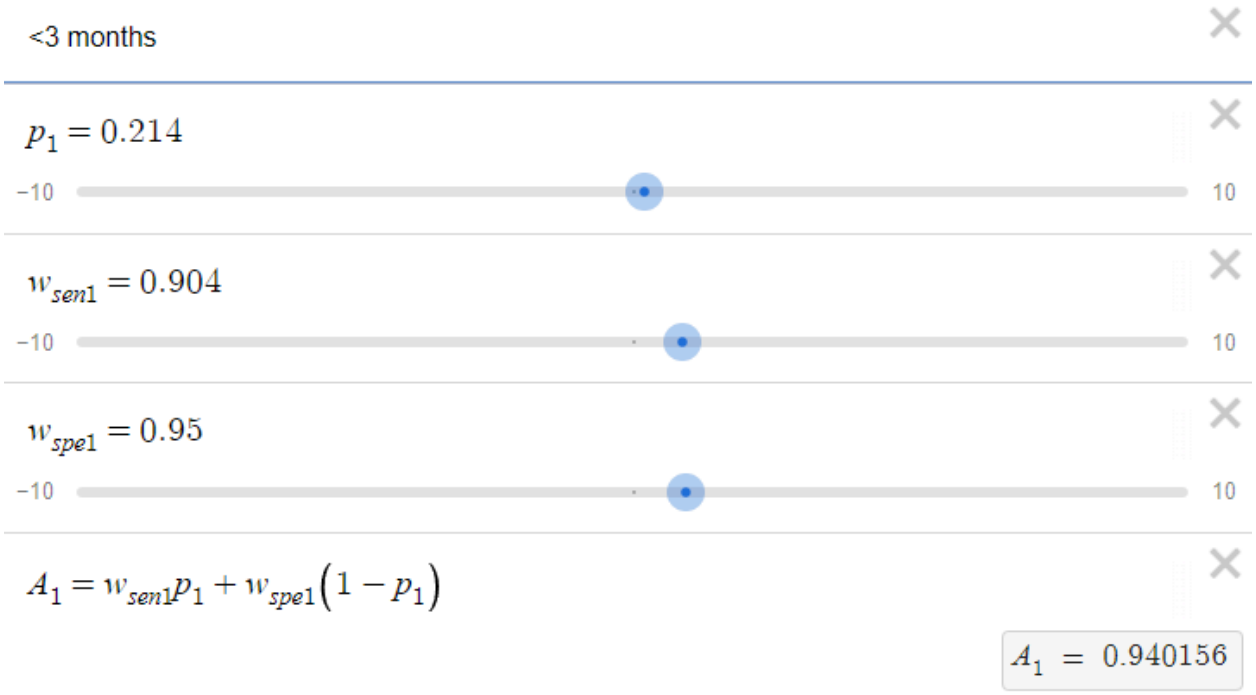
Half Tank:

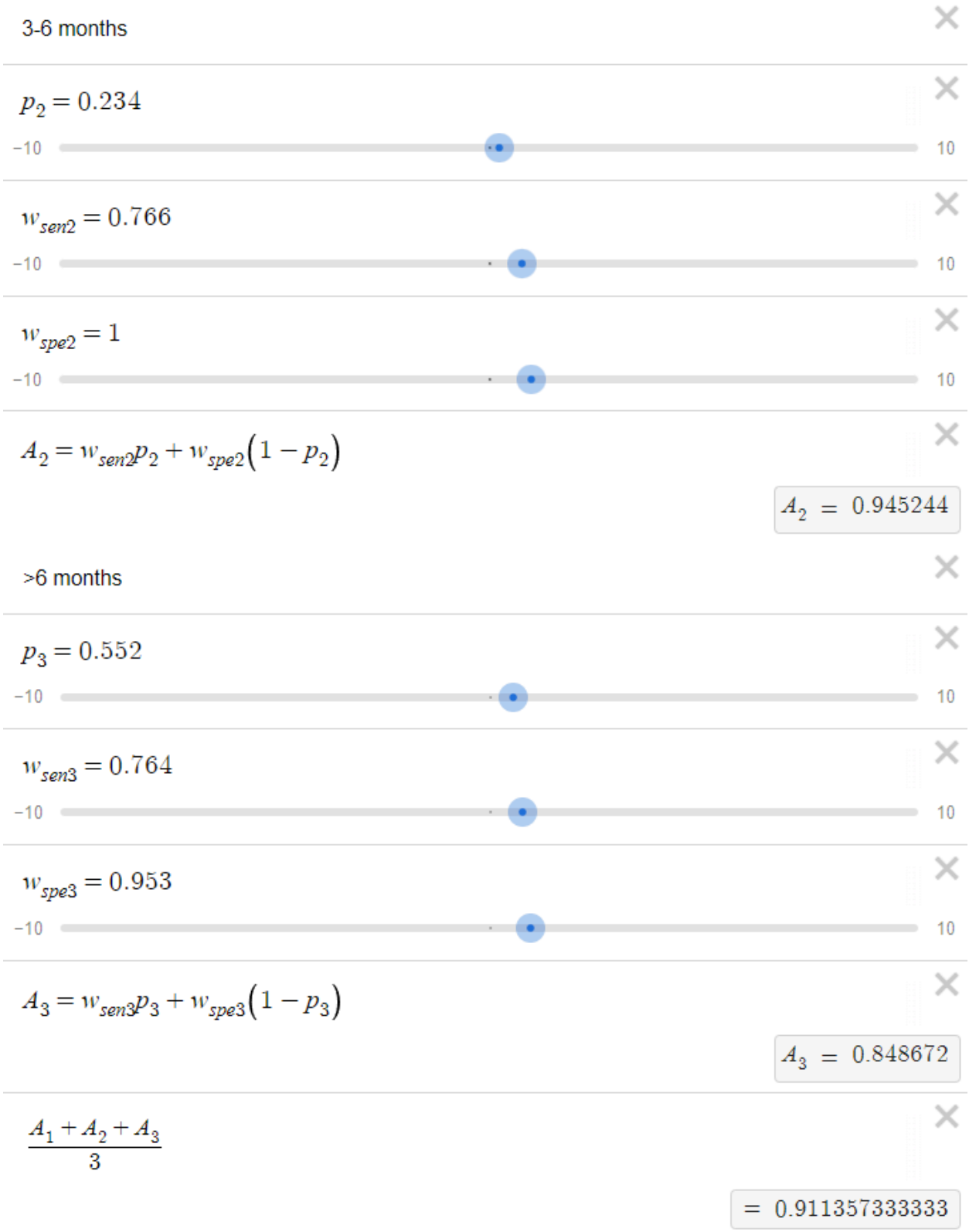
Similarly to the Crib Clamp, we used a reference (50) to find out how to find accuracy rate given sensitivity and specificity. The sensitivity and specificity of axillary temperature measurements relative to rectal measurements for each age group are provided by this article (52), and are listed below.

- Fever prevalence for each population is also provided in the article.

| | <3 months | 3 - 6 months | > 6 months |
|---|---|---|---|
| Sensitivity (%) | 90.4 | 76.6 | 76.4 |
| Specificity (%) | 95.0 | 100 | 95.3 |
| Prevalence (%) | 21.4 | 23.4 | 55.2 |

Using the same method to find the accuracy of the crib clamp:






The end result giving us a rate of accuracy of **91%** for the Half Tank.
[Desmos link]

Wristband:

The method to find the wristband accuracy is even simpler than the last two we found. The true numbers for diagnosis were shared in the article (53). Using the reference (50), I'm able to determine the accuracy rate.

- The true numbers are as following:
    - True positives (TP): 106
    - True negatives (TN): 6
    - False positives (FP): 17
    - False negatives (FN): 64

To find accuracy the true positives and negatives were added up, and then divided by the total amount of trials.

$$\frac{TP + TN}{TP+TN+FN+FP}$$

$$\frac{106 + 6}{106+6+17+64} = 0.55$$

Therefore the accuracy rate of the Wristband thermometer would be 55%.