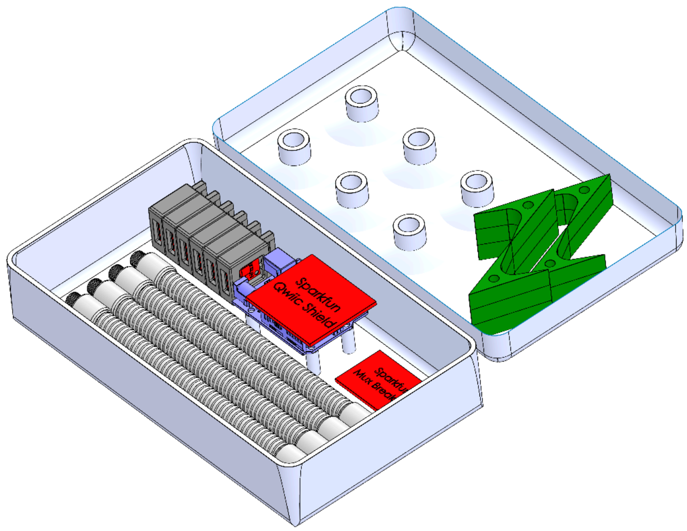

MECHENG 450
Winter 2024
Final Report

Team 018: IncuCheck | Section 007 | Professor Kathleen Sienko
Sponsor: M-HEAL Initiative, Dhiya Krupashankar

April 29, 2024

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Executive Summary

Studies show that neonatal hypothermia in low-resource communities has a significant contribution to the global burden of neonatal deaths [1]. This global health issue is currently being tackled by M-HEAL, a project team working to develop an affordable, non-electric neonatal incubator. The need for design validation drives our ME450 design, the IncuCheck. To evaluate the effectiveness of the incubator, our objective is to develop a device capable of assessing the thermoregulation abilities of the incubator design.

In order to guide the device design and future verification, we identified six "must have" requirements: (1) Measure ambient and contact temperature accurately within incubator (2) Be safe (3) Have user controlled functional capabilities (4) Be durable (5) Be user-friendly and (6) Meet ME450 standard budget.

After conducting initial concept generation, we narrowed our device to three main subfunctions: (1) temperature sensing (2) device housing and (3) user interface. From there, we took ideas from each sub function and combined them to make complete concepts. After conducting a pro con analysis on each of the concepts and analyzing tradeoffs between cost, feasibility and efficacy, we then narrowed down to our final selected concept, which we iterated on by testing the most relevant design "worries."

Our final design consists of two main parts: electromechanical components and mechanical components. The electromechanical components consist of the Arduino as the controller, the SparkFun sensors, and additional breakout boards necessary to make the Arduino compatible with the SparkFun sensors. The mechanical components consist of a suction cup and adjustable arms to attach the sensors to the walls of the incubator, as well as a Pelican case and 3D printed sensor housing to protect the sensitive components of the design and enable easy transport and packaging.

In order to verify the project, we created and conducted verification testing plans to ensure that our final design meets the necessary requirements and specifications outlined during the project's initial scope. The accuracy of the temperature sensors was verified using temperature probes and controlled environments with known accuracy and readings. The safety was verified through the use of a multimeter, to check voltage and current at critical electromechanical components. User controlled functional capabilities were verified by nature of the design itself. Durability was verified theoretically, using the rated specifications of the SparkFun sensors and Arduino. User- friendliness was verified through the use of the System Usability Scale (SUS) and finally, adherence to the budget was verified using our internal finance tracking system, to a total spend of just under $400. Finally, to validate the device as a system, we began preliminary testing to screen for three main design necessities: safety, efficacy and usability, and have outlined ideal testing procedures for each, for future iterations of the project.

Looking ahead, we recommend that M-HEAL continue this project by using the existing user interface and electromechanical setup to continue adding SparkFun sensors that measure additional incubator parameters, such as humidity, sound and air flow.

Abstract

To combat neonatal hypothermia, our sponsor, M-HEAL, has created a low-cost, non-electric bassinet incubator designed specifically for low-resource hospitals. Prior to clinical trials, it is necessary to run rigorous testing to ensure the safety and accuracy of the incubator's thermoregulation functionalities. However, current incubator analyzers have a price point that is prohibitive to the M-HEAL team. Therefore, our objective is to develop an affordable device capable of assessing the thermoregulation functionalities of the incubator. Our device aims to gather accurate ambient and surface temperature data in varying locations within the incubator, with a user-friendly interface.

Project Introduction, Background, and Information Sources

Sponsor Mission

In today's medical landscape, the prevalence of neonatal mortality is unequally distributed around the globe and skewed heavily toward developing nations. The neonatal period is defined as the first four weeks of a newborn's life [2]. In 2022 alone, neonatal mortality increased by 3%, to 3.58 deaths per 1000 live births [3]. Of these, more than 99% of all deaths occur in developing countries, where the average neonatal mortality rate is 33 per 1,000, compared with four per 1,000 in high-income countries [4]. In the period immediately following birth, maintaining a normal body temperature is critical for newborn survival. However, in premature and low birth-weight infants, thermoregulatory mechanisms are easily overwhelmed, leading to the onset of neonatal hypothermia.

A neonate is an infant in the first 28 days of life, and hypothermia is a state of decreased body temperature, and results when the newborn falls below 36.5 °C [3]. Beyond overwhelming their bodily functions, hypothermia is a significant comorbidity for infants, meaning in tandem with other factors such as neonatal infections or preterm birth, can often result in neonatal death [4]. In fact, studies have shown that a high prevalence of neonatal hypothermia was correlated with countries with the highest neonatal mortality rates. Therefore, reducing neonatal hypothermia in low-resource communities will significantly contribute to reducing the global burden of neonatal deaths [1]. This is the issue that is currently being tackled by M-HEAL, a co-curricular project team affiliated with the College of Engineering at the University of Michigan. Along with its community partners in Ghana, this group is working to develop a low-cost, non-electric neonatal incubator.

ME450 Design Challenge

The need for validation of this design is where our ME450 design challenge originates. In order to evaluate the effectiveness of the incubator, our objective is to develop a device capable of assessing the thermoregulation abilities of the incubator design. By gathering accurate and comprehensive data at an affordable cost, we aspire to equip the M-HEAL testing engineers with valuable insights for refining the design in subsequent iterations. In regards to testing, the current team has only conducted simulations and no physical testing has taken place, so our prototype will initiate the first round of testing to validate the efficacy and safety of the design.

Background on M-HEAL Device

Figure 1 below shows a CAD rendering of the most recent M-HEAL bassinet incubator prototype. Most notably, it is made up of acrylic sheets with ventilation holes lining the perimeter of the base to allow for passive airflow and to filter out any carbon dioxide that is exhaled by a neonate to ensure no suffocation. The front doors contain integrated portholes that allow the nurses and caregivers access to the neonate. Depending on the relative position of the portholes, given that they can be opened and closed, it introduces the possibility of different environments in which heat is emitted at different rates. This means it is imperative that our team creates a device whose tests are able to be repeated and replicated under different conditions to ensure it is safe for the neonate at all possible operating states.

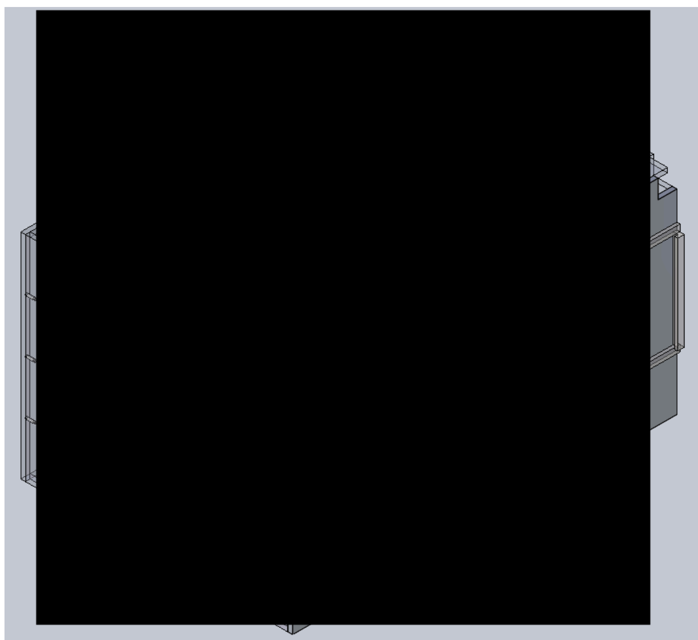


Figure 1: V2 Prototype CAD Model

As for the heat source, the bassinet is heated by a Warmilu Instawarmer pack, as seen in Figure 2. The Warmilu is a company based out of Ann Arbor, Michigan, that has developed an FDA-approved chemical warming pack. This heat pack warms itself up through chemical reaction and is therefore not reliant on electricity. It can also stay hot for up to 8 hours and be reset by simply placing the pack into a microwave or pot of boiling water. Finally, it can be reused up to 100 times. For these reasons, it is currently the standard of care for neonatal thermoregulation in third-world countries. In practice, the M-HEAL team places this mattress on the floor of the bassinet, atop which the neonate can lay to be cared for. While the pack itself is FDA-approved for safe temperature use, the need for validation is still necessary to see how it interacts with the environment of the bassinet, ensure that all parts of the bassinet are heated uniformly, and ensure that the materials in the bassinet are maintaining heat the way it was originally intended.

Figure 2: Warmilu Instawarmer Pack [5]

Background on Heat Transfer

The underlying challenge that our project seeks to solve is related to testing and validation through designing a device that can verify the heat transfer abilities of the M-HEAL bassinet incubator device. Heat transfer is the study of mechanisms that convert energy from one location to another [6], thereby facilitating a change in temperature through the movement of molecules. Specifically within heat transfer, there are three possible modes: (1) conduction (2) convection and (3) radiation [7]. Conduction is heating through a solid material and transfers energy between adjacent molecules. Convection is heat flowing through any fluid, where energy is transferred between either air or liquid molecules. Finally, radiation refers to the transmission of energy as electromagnetic radiation from a heated surface to another surface, which requires no medium of energy transfer [6].

In looking at the M-HEAL device, all three modes of heat transfer can be observed. First and foremost, given that the bassinet is heated via a neonate lying in direct contact with a mattress, there is conduction occurring between the heated molecules in the mattress and the neonate. Any residual heat that rises from the mattress and heats the air around it does so by convection, thereby changing the temperature of the ambient air inside the bassinet incubator. Finally, radiation exists from several sources, including the body of the neonate itself, the sun, and the surrounding environment [8]. Therefore, our device must measure the temperature inside multiple areas of the bassinet, both in contact with and in the ambient air surrounding the mattress, to ensure the device is adequately and safely heated at a consistently safe and effective temperature for the neonate.

Design Constraints and Drivers

The first constraint driving this project is the need for low-cost testing equipment. Current incubators in the United States can cost up to $35,000 [9]. However, when speaking with community partners in Ghana and Africa, the M-HEAL team found that hospitals only have a willingness to pay up to $2500 per incubator (Donnelly, Erin). In order to keep overall costs as low as possible, it is necessary to create a low-cost tester as well. As outlined above, all available incubator testing products in the market are upwards of $10,000, making purchasing a device unfeasible for the M-HEAL team.

The second driving factor for this device is the importance of validating effective thermoregulation. In order to be considered healthy, a neonate's core body temperature must be between 36.5 and 37.4°C [10]. With an optimal range that totals less than one degree celsius, even small variations in temperature can have big medical implications. Therefore, a device is necessary to confirm the safety of the bassinet, in conjunction with the Warmilu Instawarmer Pack.

The third and final motivation for this project is in regard to M-HEAL's position in the design process. They currently have multiple iterations of the product complete, and have received feedback from their community partners. However, in order to move to clinical trials, they need to validate the safety of the device for a potential infant. Therefore, collecting data from a testing device would allow them to create a proof of concept, to reasonably demonstrate their product's efficacy before taking it to a hospital to be fully tested.

Project Scope

As shown above, current devices on the market also contain metrics for airflow and humidity, but we have deemed those out of the initial scope of this project. Airflow refers to the movement of air within the incubator. This metric is typically tested in traditional incubators because they contain an active airflow system that regulates airflow to make sure there is adequate ventilation for the neonate. However, the M-HEAL bassinet incubator does not have any air flow regulation system, and relies on passive air flow that occurs naturally through the ventilation holes which are largely a function of the surrounding environment. Therefore, we removed this functionality from the scope of our initial prototype. Secondly, humidity refers to the moisture content in the air surrounding the neonate inside the incubator. Similarly to airflow, traditional incubators enable nurses or caregivers to regulate humidity levels in the bassinet. However, the M-HEAL device does not have any humidity regulation, and once again, the humidity is a function of the surrounding environment, which is why this functionality was also removed from the scope of the initial prototype.

In order to accurately scope our project, we relied on two primary drivers to determine the necessary features. First, the M-HEAL device, given its low-cost nature, necessitates a low-cost testing device as a proof of concept prior to applying for clinical trials. Therefore, our sponsor felt it was best to begin with thermoregulation ability, given that is the primary purpose of the incubator. Secondly, our budget, as given by the UM ME Capstone Design Specs document, is $400. Given the cost of sensors and the tradeoff between price and accuracy, we opted to design around sensors that would be optimal for measuring temperature alone, given that this is the most important requirement for this semester's initial prototype, as outlined by our sponsor.

All in all, we measured success over the course of this project by being able to accurately and thoroughly test the heating ability of the bassinet, and ultimately identify whether or not the non-electric mattress along with the incubator is able to safely thermoregulate an infant, as the WarmiLu specifications outline [5].

Existing Incubator Testing Devices

As it currently stands, the market has only a handful of incubator-testing products. The first product, shown below, is known as the INCU™ II Incubator Tester [11] (Figure 3a). This device is manufactured by Fluke Biomedical, at a selling price of $11,650. According to their website, this tester is "an all-in-one Incubator/radiant neonatal warmer analyzer that simplifies testing and ensures proper performance and safety of infant incubators, transport incubators, and radiant neonatal warmers" [11]. This device allows for the measurement of temperature, humidity, air flow, and sound. The second product is the vPad-IN (~$10,000), shown below. It is a device that can be used to test both infant incubators and radiant warmers (Figure 3b). Similar to the INCU Incubator Tester, this tester measures humidity, airflow, sound, and temperature, with an external tablet for users to collect and interpret data [12].

Figure 3a: INCU™ II Incubator Tester

Figure 3b: vPad-IN

To analyze their features in relation to one another, these two products are benchmarked against one another in Table 1 below.

Table 1: Benchmarking Table for Commercial Market Incubator Testing Devices

	Price ($)	Number of Temperature Sensors	Air Flow Sensor Accuracy	Temperature Sensor Accuracy	Relative Humidity Sensor Accuracy	Measures Instantaneous and Average Period Temperatures	Graphical Use Interface
INCU II Incubator Radiant Warmer Analyzer	11,650.00	5 sensors	± 0.1 m/s	± 0.05 °C	± 3 % RH	Yes	Built in Unit Display
vPad-IN The Next Generation Infant Incubator & Radiant Warmer Analyzer	>10,000	5 sensors	± 0.1 m/s	± 0.05 °C	± 3 % RH	Yes	Android Table

Table 1 displays the important key features of commercially available incubator testing devices such as abiding by standards for the number of temperature sensors and accuracy specifications of all airflow, temperature, and relative humidity sensors. The devices measure numerous environmental factors including temperature, airflow, relative humidity, and more. Understanding that within the scope of the semester we have limited time and cost constraints, our prototype will be a first-stage proof of concept. This means that our device may not meet all commercial benchmarks on sensor variety but have benchmarked nonetheless to fully understand market presence and commercial device specifications. Holistically, the products abide by all global standards for incubator requirements and performance. The devices measure the instantaneous temperature of all sensors as well as display averaged temperatures through the form of a graphical user interface. Understanding the current market allows us to establish and identify the needs and requirements of our product. These benchmarking statistics are sourced from each device's specification sheets and user manuals respectively [11], [12]. We have provided a summarized benchmark in Table 2 below that summarizes market benchmarks against our device within the scope of this semester.

Table 2: Summarized Benchmarking Table Against Project Goals

	Low Cost	Meets 5 Sensor Measurement Locations Standard	Meets Range and Accuracy Standards	Verifies Incubator Effectiveness and Safety Status
INCU II Incubator Radiant Warmer Analyzer	✖	✔	✔	✔
vPad-IN The Next Generation Infant Incubator & Radiant Warmer Analyzer	✖	✔	✔	✔
ME 450 Incubator Testing Device	✔	✔	✔	✔

Table 2 summarizes the key points of how we aim for our prototype to be benchmarked against the current devices in the market. The prototype will aim to measure temperature from 5 standard different locations to a certain accuracy standard and by using collected data and accepted standards, report whether or not the incubator is considered safe for neonatal use. Within this semester, our device aims to act as a proof of concept, to first meet standards of sensor measurement location, meet sensor accuracy requirements, and verify the safety status of the incubator but not necessarily meet all benchmarks of commercially available incubator analyzers. All in all, the benchmarking allowed us to understand the functionality of existing incubator testing devices, see what the value proposition of our ME450 device is, and identify how it compares in functionality and scope to other devices on the market.

Information Sources

In order to gather relevant information, we divided our research into two categories: primary and secondary sources. For primary sources, we had a network of individuals with whom we met over the course of the semester that have been able to provide insights about various aspects of the project. To understand the heat transfer and theoretical components of the design problem, our technical mentors were Dr. Solomon Adera and Dr. Julia Kramer. They each gave us a roadmap for conducting our engineering analysis and verification, creating requirements and specifications, and building our simulation studies. Regarding the global health and clinical aspects of testing a neonatal device, we spoke to two doctors at Michigan Medicine, Dr. Tim Johnson and Dr. Dhanu Thiyag, as well as a NICU Nurse. Additionally, we have conducted several interviews with the team lead of M-HEAL, Erin Donnelly, and met with various other members of the M-HEAL verification and validation team to get feedback as the end users of the device. Finally, we visited Dr. Deb Rooney at the Simulation Center at Michigan Medicine to get an idea of the current industry standards in warming beds and bassinets. In addition, she provided valuable input about building a testing device intended for a medical device, given that they have similar products at the Simulation Center.

As for secondary sources, in order to fill in gaps in industry research, relevant engineering standards, and other journal articles on proper neonatal device testing, we have made use of the ME450 library resources, specifically the Knovel and Access Engineering databases. We also met with the Biomedical Engineering librarian, to give us additional resources to use to supplement our research.

The final information source that will inform the project specifications are the engineering standards outlined by the International Electrotechnical Commission (IEC). Specifically, these standards are IEC 60601-2-19, IEC 60601-2-20, and IEC 60601-2-21, all of which relate to the basic safety and performance standards for a neonatal incubator [13], [14], [15]. Essentially, each standard outlines what a proper incubator testing device must have the ability to do. While it is out of the scope of the project to replicate the complexity of a device that abides by these standards, we are using them as a benchmark for our engineering specifications for the aspects of the device that we do hope to include.

Throughout the process, the first hand interviews we conducted were certainly the most beneficial part of the design process. By being able to talk through our design, assumptions, and hear live feedback, we made significant progress towards the final design during each of these meetings. On the other hand, the most difficult part of the process was finding appropriate benchmarks to use as the basis of our engineering requirements and specifications. Given that there are so few devices on the market that align with what we are trying to build, we were restricted to only a handful of sources that allowed us to pull out quantitative metrics to use for our engineering specifications.

Stakeholder Engagement

The incubator testing device encompasses many different stakeholders at different levels of interaction, intervention, and influence. Looking at the device from an initial prototype framework, we have broken up the stakeholders into three different high-level groups: Primary, Secondary, and Tertiary. We have provided a stakeholder map to act as a visual guide in categorizing stakeholders in Figure 4.

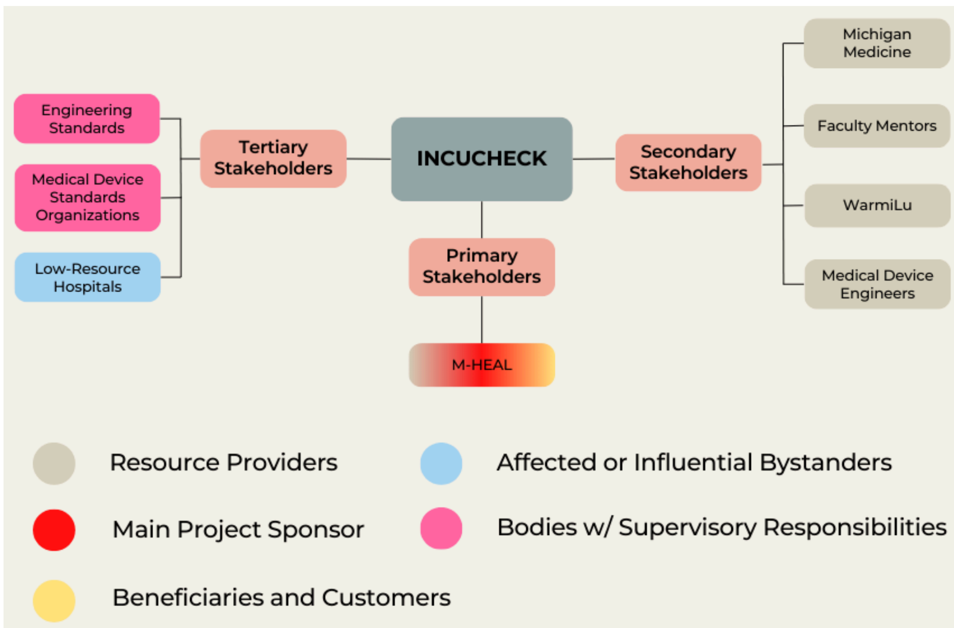


Figure 4: IncuCheck Prototype Stakeholder Map

Looking at primary stakeholders, M-HEAL has not only directly provided material that must be tested using the prototype IncuCheck but also is willing to provide other materials like sensors in their project workspace. Simultaneously, M-HEAL is acting as the main stakeholder and sponsor for the project as well as the main customer because we have framed this prototype solely to verify M-HEAL's incubator in terms of safety and effectiveness.

In regards to secondary stakeholders, numerous faculty mentors, Michigan Medicine medical professionals, and Michigan medical device engineers have graciously provided expertise in the form of interviews and feedback.Their input and knowledge have had a significant effect on the design choices made but they did not dictate themselves the prototype's requirements and design. WarmiLu is another key resource provider who has provided materials that are to be tested and expertise from their experience with creating and verifying a product that is used with neonates.

Looking at our tertiary stakeholders, medical device standards organizations and engineering standards have been identified as having a common role as bodies with supervisory responsibilities whose standards and protocols will influence the solution's design process despite not having a direct role in the immediate problem. Furthermore, within the scope of the semester, the prototype may not be sent directly to low-resource hospitals in Ghana, but still will indirectly affect them as an affected or influential bystander because the IncuCheck device will help verify the incubator that they wish to use. Their input from a medical perspective is also extremely valuable as they are a customer not of this IncuCheck prototype but the M-HEAL incubator. In regards to any stakeholders that may be negatively affected, within the current scope of the project we have not identified clear stakeholders who match this categorization.

In the context of a future commercial version, other non-profit medical organizations aiming to aid under-resourced hospitals could be identified as complementary organizations. This is due to their support towards the same cause, they would be affected by this project in a positive way as it would be helping advance towards the similar goal of decreasing neonatal hypothermia in under-resourced communities. The device would also positively affect general hospitals and researchers, as beneficiaries and customers, as it would allow a low-tier-cost incubator test option. Similarly, medical device engineers and researchers may utilize the device as well in their testing projects similar to the M-HEAL neonatal incubator. Clinical testing centers are another customer, who may use the device to test current or new incubators.

We may further identify secondary consumers as affected or influential bystanders, such that training centers, certification bodies, and caregivers may use future commercial iterations of the device in incubator training. Government regulation, engineering standards, and any medical regulatory bodies have been identified as general tertiary stakeholders, with a common role as bodies with supervisory responsibilities whose standards and protocols will influence the solution's design process despite not having a direct role in the immediate problem. The concept of a cheaper alternative to incubator testing devices would generally positively affect the population, as creating more accessible resources serves the common greater good. However, stakeholders who may be negatively affected or be opponents of the solution entering the market include profit-incentivized organizations such as insurance companies or biomedical product companies.

Project Intellectual Property

Currently, intellectual property logistics or concerns are playing little to no role within the scope of the project as this project is an initial proof of concept and first-round prototype. The M-HEAL incubator utilizes a Warmilu infant instawarmer pack, which is the only protected intellectual property being utilized within the incubator. Our sponsor does not foresee any requirements for obtaining intellectual property protections on our solution unless commercializing the product in the far future, which will not be done on the current ME450 version of the device. In the event that they do so, however, the ME450 team will own any intellectual property on design components that were adapted from our original idea.

Initial Design Approach

Initially, we unintentionally used somewhat of a solution-based approach by viewing the project as a need to create a thermodynamically accurate neonate simulator rather than a need to create a device and procedure which can verify the safety and effectiveness of the incubator. While this process did not abide by the Capstone Design Process, that was the model we had intended to follow from the start. Through realigning our design process with the Capstone Design Process (depicted in Figure 5) we have been able to view our project from a broader perspective and alter the project to better suit the needs of our sponsors. For this reason, we have chosen to follow the Capstone Design Process. The Capstone Design Process also offers a model that is reasonably abstract, iterative, and problem-oriented which we believe best suits our project.

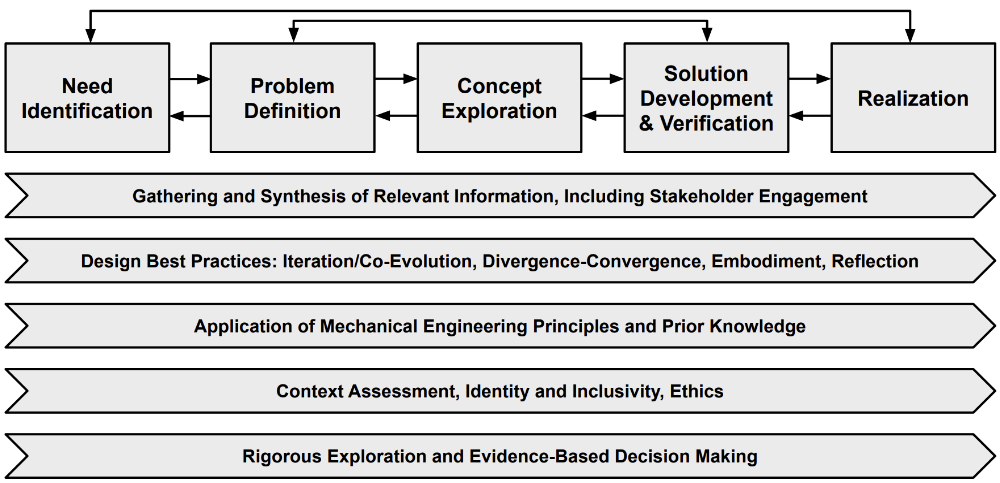


Figure 5: Capstone Design process and associated principals [16].

Looking at the current progress of the project, we have dedicated time to continually iterating on our design process. Regarding our initial scoping, we have already seen a shift in our project's main goal, which helped in realigning our focus before DR1. Specifically, this caused a shift in focus from developing a device that can accurately reflect the thermodynamic properties of a neonate to a focus on incubator testing procedures and the relevant equipment needed. Due to these drastic changes in our project, we have decided that an iterative design process that allows for movement between design stages is necessary. Based on these needs, we believe that a combined model design process which is problem-oriented and reasonably abstract will suit our project best. Despite the fact that "models with a stage-based component are more useful in practice than their purely activity-based counterparts" [17] we believe that an over-structured process will do more harm than good. Our project will require a large amount of research throughout all stages, which will likely continue to alter the design ideas we have created thus far. This has resulted in a lack of clearly defined steps along with a desire to avoid over-defining the process - hence the use of an abstract process. We have also chosen to use a problem-based approach as the end goal of this project is to verify the low-cost incubator which has been designed by M-Heal along with the fact that "emphasis is placed upon abstraction and thorough analysis of the problem structure before generating a range of possible solutions," [17] in problem-based models.

As of the completion of our final report, we have continued to abide by the Capstone Design Process as it has proved useful insight and was well aligned with the needs of our project. We have not needed to significantly revisit the need identification or problem definition phases as of the completion of DR2. Between DR2 and DR3, we primarily moved between concept exploration and solutions development and verification as we find issues or improvements to be made within our system. By moving between these phases we were able to ensure that our changes are backed by additional sources, allowing us to better evaluate the effectiveness of these alterations prior to committing to them. We have also found that some aspects of our design such as the user interface have not had a large amount of focus placed on them before DR3, leading to a need to explore the associated concepts to make up for a lack of prior analysis. Between DR3 and the final report we have utilized some concept exploration in the creation of our user interface, but have primarily focused on verification and realization.

User Requirements and Engineering Specifications

This section describes the project requirements and engineering targets associated with the IncuCheck device being developed for use in testing neonatal incubators. The development of these requirements, relevancy, priority, and specification quantization are all presented in this section.

Background

To determine engineering targets, benchmarking was conducted through technical specification sheets on existing related products. Thorough analysis was also done to evaluate the standards of current state-of-the-art incubator technologies. This enabled us to develop a series of targets based on current state-of-the-art incubator testing devices such as the INCU™ II Incubator Tester manufactured by Fluke Biomedical and the vPad-IN The Next Generation Infant Incubator & Radiant Warmer Analyzer. Simultaneously, we ensured the relevant standards of current, technologically advanced incubators are also considered. The state-of-the-art devices both cost more than $10,000 and are described as "all-in-one Incubator/radiant neonatal warmer analyzer that simplifies testing and ensures proper performance and safety of infant incubators." [11] The INCU™ II and vPad-IN contain many features, including wireless functionality, automated test procedures, fully customized test sequences, and 24-hour battery Life [11]. These luxury features are unnecessary and irrelevant to the type of testing required by M-HEAL, so specifications analyzed focused on the key features such as simultaneous measurement of temperature, humidity, airflow, and sound that the INCU™ II can provide [11]. Using the specifications of the INCU™ II and additional resources dedicated to providing neonatal incubator normal operation, a table of user requirements, Table 3, was developed [11], [18]

All of the requirements were then translated into engineering specifications to quantify the performance of the IncuCheck device. These specifications were also evaluated and based upon findings from the INCU™ II and vPad-IN technical specifications, in addition to relevant neonatal incubator standards.

Table 3: Requirements and associated engineering specifications.

Priority	Reference	IncuCheck Requirement	Specification	Sources
Must Have	1	Measure ambient and contact temperature accurately within incubator	- Temperature sensor readings are within ±0.1°C of actual ambient and contact temperature - Data evaluated from ≥ 5 separate zones within incubator (see Figure 6 below)	[11], [19], [20]
Must Have	2	Be safe	IncuCheck beta design conforms to IEC 60601-2-19:2020 Standard	[11] [15]
Must Have	3	Have user controlled functional capabilities	- Contains ≥ 1 user accessible component - Able to control ≥ 3 functions of the device. Minimum functions include: (Start, Stop, View Log)	[21, p. 5] M-HEAL Interview
Must Have	4	Be durable	- Can withstand ≥ 120 uses - Able to be operated for 6 hours continuously (each use)	[22] M-HEAL Interview
Must Have	5	Be user-friendly	System Usability Score > 68 (Average "Usability Score")	[23] [24]
Must Have	6	Meet ME 450 standard budget	-All costs of prototyping the build design ≤ $400	[21] [25] M-HEAL Interview
Nice to Have	7	Have easily replaceable sensors	- Need ≤ 2 tools to completely change out sensors if a user desires	[11] [26]

Nice to Have	8	Measure air velocity accurately	- Air Velocity sensor readings are within ±0.1 m/s of actual temperature	[11], [18]
Nice to Have	9	Measure humidity data accurately	- Humidity sensor readings are within ±0.1% of actual humidity	[11], [26]

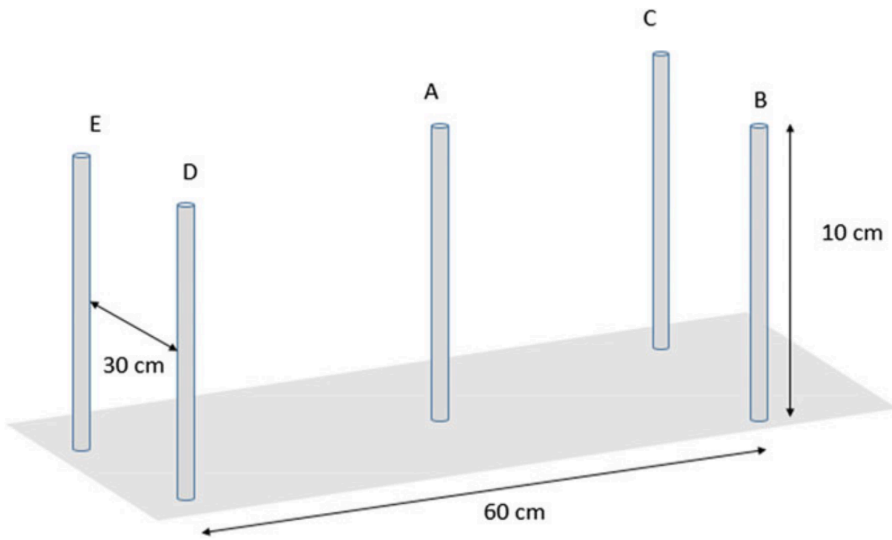


Figure 6: Placement of five sensors in the mock infant incubator [20]

Requirement Priority Level

The relative importance of each requirement was determined based on the desirability of each requirement and the overall project specifications defined by the M-HEAL team. Requirements one through six are all important and considered vital to the success of the IncuCheck device. The priority column in Table 3 denotes the importance of each requirement, broken down into either "Must Have" or "Nice to Have." The "Must Have" priority level means the requirement and associated engineering specification must be integrated into the design. The "Nice to Have" priority level associates the relevant requirement and engineering specification as a possible addition, but not necessary to include in the design. All "Must Have" device requirements are of high relative importance to the design of the IncuCheck.

Temperature Sensor Accuracy

The IncuCheck device's first requirement is to collect accurate ambient and contact temperature data from sensors within the incubator. A necessary and must-have component, the specification includes having contact and ambient temperature sensor readings within ±0.1°C of the actual contact and ambient temperature. In addition, data must be collected from more than five separate zones within the incubator. These specifications were driven directly from the

INCU™ II technical specifications sheet in addition to the National Library of Medicine and a biomedical engineering book on the testing of neonatal incubators [11], [19], [26]. The INCU™ II technical specifications provide information for what a current market solution utilizes in the resolution of its temperature sensors. The National Library of Medicine and supporting research on the testing of neonatal incubators incorporate additional data into the decision of temperature sensor accuracy. All three sources in tandem contain valuable information in regard to collecting temperature readings of a neonatal incubator. The current plan to evaluate the sensor's accuracy is to run the sensor's calibration test provided by the manufacturer of the sensor.

Durability, Usability, and Safety

The second requirement is for the device to have safe features. The associated specification is to conform to the IEC 60601-2-19:2020 standard, which applies to the basic safety and essential performance of infant incubators [13], [14], [15]. Although this requirement is considered a must, we fully expect to be unable to rigorously test our device against this standard. For our use cases this semester, we can internally evaluate the safety of the IncuCheck prototype against the standard instead of undergoing a rigorous testing campaign. Further explanations on the planned testing of the IncuCheck prototype can be found in the Problem Analysis and Iteration section.

The fourth requirement is to ensure the testing device is durable. The specification to match the requirement is withstanding at least 120 uses and having the ability to operate for 6 hours continuously. The specification was derived from the interview with the M-HEAL team lead and the specification of the WarmiLu mattress [5]. The WarmiLu mattress has the capacity for up to 100 uses. Initially, the minimum was set at this value to match the capabilities of the mattress. However, after consulting with M-HEAL the decision to increase the durability specification by twenty percent was made. This ensures M-HEAL is happy and that the testing device will always outlast the span of one WarmiLu mattress. By having the IncuCheck device outlast the WarmiLu, M-HEAL can run a full-cycle durability test on their incubator with the embedded WarmiLu mattress. While it will be difficult to replicate the 120-use cycle, we plan on incorporating a durability test plan into the evaluation process of the device after it completes production.

Our fifth requirement is for the device to be user-friendly, or specifically have a system usability score (SUS) of more than 68 [27]. The requirement is also a must, with the SUS scale being a robust and industry-standard scale that has been referenced in more than 600 publications [27], [28]. The SUS test consists of ten standardized questions with five responses that range from strongly agree to strongly disagree. Using this scale to validate the user-friendliness of the IncuCheck device enables our team to have a baseline evaluation of the device. Furthermore, it ensures the device is user-friendly and able to be used by any member of the M-HEAL team. The SUS test will be conducted with members of M-HEAL to validate this requirement (using the ten questions listed in Appendix B).

Device Development Cost

The sixth requirement, ensuring the IncuCheck is low cost, is specified to have the final product cost of less than or equal to $400. This requirement stemmed from the UM ME Capstone Design Specs document in addition to an interview with the M-HEAL team, making this requirement a must-have [29]. As of this design report, the M-HEAL project team is not providing any additional funding to the IncuCheck project. Additional funding is plausible if future iterations of the IncuCheck design gain M-HEAL's confidence and further financial support is required to continue the development of the device.

Device Capabilities

Our third requirement, also a must-have, is to ensure the IncuCheck has functional capabilities that are able to be controlled by the user. The corresponding specifications for this requirement are to contain more than 1 user-accessible component and have the ability to control more than three functions of the device. Basic functionalities like starting a test, stopping a test, and having the ability to view the logs of each temperature sensor are possible and reasonable features. This requirement was driven by the interview with the M-HEAL team lead, Erin Donnelly. Erin wanted to ensure that the IncuCheck would provide enough capability to run a simple test using the device, while also having the ability to go through the raw data if deemed necessary. To assess this requirement, our initial testing trials will incorporate feedback from M-HEAL team members in relation to the functional capacities of the IncuCheck device (Donnelly, Erin).

"Nice to Have" Requirements

Requirements seven, eight, and nine are all listed as nice to haves, which means they are not necessary to the success of the device but would be beneficial additions for the robustness of the device. The first nice to have is that the sensors would be replaceable, needing no more than two tools to change out the sensors. The specification for this requirement was developed with consideration from Dr. Randy Johnson and the probabilities of sensors malfunctioning and needing replacement [24]. Dr. Johnson noted that there is always a possibility of sensors failing. Without having the ability to replace the failed sensor, that would render the entire device useless. This is something that would be very beneficial to avoid, especially in early prototyping stages. The validation for this requirement is to try and swap a sensor in and out of the device. By successfully interchanging a sensor with less than two tools, this requirement will have been satisfied.

Requirement number eight is for the IncuCheck device to be able to collect accurate air velocity data from sensors varying in location within the incubator, with the related specification being to ensure the sensor readings are within ±0.1 m/s of actual air velocity and to have data from at least 5 separate zones within the incubator. This specification comes from the INCU™ II technical specifications sheet in addition to a biomedical engineering book on the testing of neonatal incubators [11], [26]. Both of these sources of information provide insight into the air velocity sensors used in testing neonatal incubators. However, the additional sensing is not a priority for the M-HEAL team, which is why the requirement stands at a nice-to-have. The current plan to evaluate the sensor air velocity sensor accuracy is to run the sensor's calibration test provided by the manufacturer of the sensor.

Requirement number nine is to be able to collect accurate humidity data from sensors varying in location within the incubator, with the related specification being to ensure the sensor readings are within ±0.1 m/s of the actual humidity and to have data from at least 5 separate zones within the incubator. This specification also comes from the INCU™ II technical specifications sheet in addition to a biomedical engineering book written about the testing of neonatal incubators [11], [26]. Similar to the air velocity, the humidity sensor is also not a priority for the M-HEAL team. Tying the last two requirements to the first, having the additional sensors would also dramatically raise the cost of the product. This direct trade-off also points us toward the air velocity and humidity sensor additions to be nice-to-haves. The current plan to evaluate the humidity sensor's accuracy is to run the sensor's calibration test provided by the manufacturer of the sensor.

Evolution of Requirements and Specifications

Our requirements and specifications evolved quite significantly from the start of our project. Initially, the scope of the project that we determined was to create a "baby simulator" type of device that would emulate the thermodynamic properties of a neonate. Thus, our first version of requirements and specifications included references to this type of device. This included such requirements as: "correct geometry," "thermal properties of skin," "thermal properties of internals," and "precise heating method." However, there were other requirements in the first version that were carried through the rest of the requirements and specification versions such as having "low development costs," and being "reusable and durable." Overall, four separate versions of the requirements and specifications were completed for our project. The final two versions are evolutions of the second, which is where we switched the scope of the project from the baby simulator device to an incubator testing type of device. Additionally, we included the priority of each requirement and specification and added how important each one was to incorporate into our device.

Concept Generation Methods

Looking at our concept generation process from a high-level, we began with over 150 individual ideas and as a team, narrowed them down to about 20. We then organized and decomposed these ideas into subfunctions and created four distinct prototype concepts. We proceeded to then conduct an analysis on each of the concepts, which led us to our final selected concept. A high level view of this process can be seen below in Figure 7.

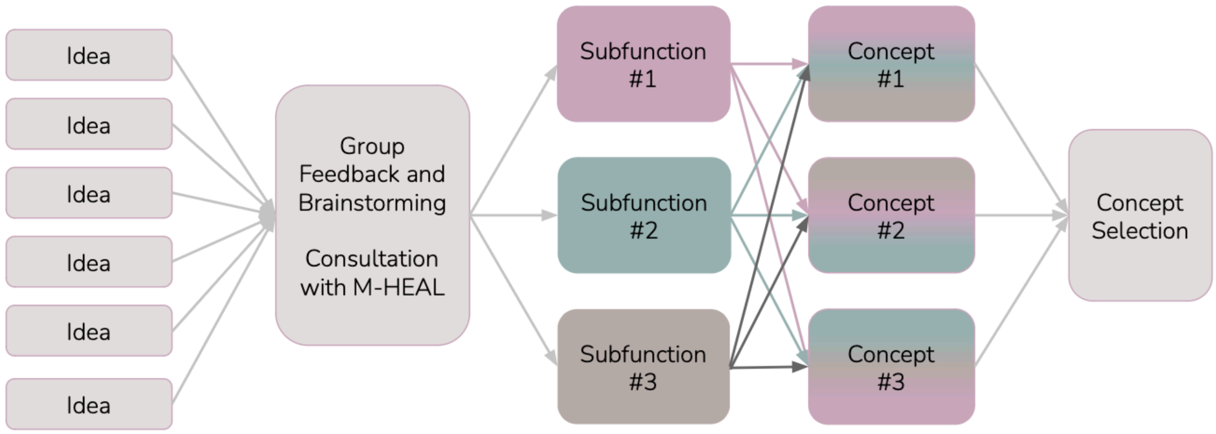


Figure 7: High-Level Design Process Overview

Our team began the concept generation phase with an individual concept generation assignment, where each team member came up with 40 distinct ideas using a multitude of concept generation methods as outlined in the ME450 learning block [30], which yielded over 150 unique ideas. Our next step was to come together as a team and share our ideas to increase the scope of concept generation and help us work towards capturing the entire solution set. Some best practices of this brainstorming session included a focus on quantity over quality, not fixating on any one solution, and welcoming any and all ideas, no matter how feasible. After achieving a significant quantity of ideas, we had to narrow the scope down to roughly 20 ideas. In order to do this, we evaluated the initial set of ideas among 3 dimensions: feasibility, effectiveness at addressing the design challenge, and openness to future iteration by M-HEAL.

In doing a feasibility check, we thought about what we could realistically achieve based on our limited budget, time constraint of one semester, and level of experience as seniors in ME. During the feasibility check, we were able to eliminate ideas such as the creation of an "analog baby," with a built-in temperature sensing device. This initial idea involved the recreation of our human bodily processes to simulate a baby's response to its environment, which had significant time, money and expertise constraints. During the evaluation of effectiveness, we eliminated ideas such as the warm avocado. When reading several blogs and speaking to doctors, we learned that a common, low-cost way to test an incubator is to heat up an avocado and place a temperature probe inside, to test how well it retains heat over a set period of time. However, when thinking about the needs of the M-HEAL team to eventually take the device to clinical testing, we decided that this idea did not produce a nuanced enough result that would effectively solve their design challenge. Finally, when looking at the final factor of ease of iteration, we wanted to stay cognizant of the fact that our project de-scoped several components that will eventually need to be tested to validate the incubator device. Therefore, we knew our end design would need to be amenable to adding humidity sensors, air flow sensors, more accurate temperature sensors, etc. These 40 ideas can be seen in Figure 8 below.

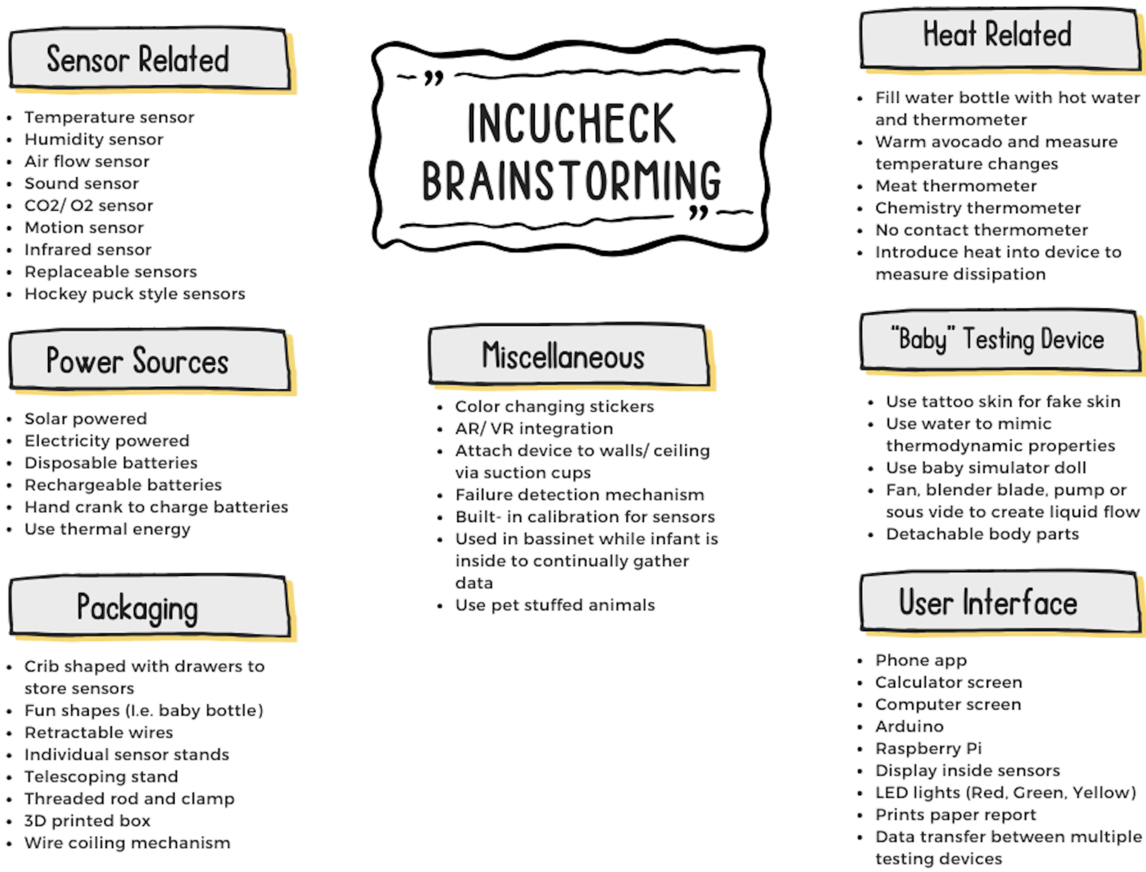


Figure 8: Initial 40 Concepts

With these three factors in mind, we narrowed our group set ideas down to 20, which were then organized and decomposed these ideas into subfunctions and created four distinct prototype concepts. In order to add organization to the ideas, we opted to conduct functional decomposition, displayed with a morphological chart [31]. For our project in particular, we thought this would be a useful way to tackle the solution set because there are several sub functions that the device must accomplish to comply with our outlined requirements and specifications. Therefore, tackling each requirement ensures that our designated categories fill the entire solution space.

Our brainstormed sub functions are as follows: (1) data collection and interface (2) temperature measurement and (3) device and sensor housing. A mapping of how each requirement is represented within each sub function can be found below in Figure 9.

Requirement	Subfunction
Have user controlled functional capabilities	Data Collection and User Interface
Have user friendly features	
Have accurate ambient temperature data from sensors	Measure Temperature
Have accurate contact temperature data from sensors	
Have numerous sensors varying in location within incubator	
Have durability	Device and Sensor Housing
Have safe features	
Have low cost	This requirement will inform the material choice and concept selection, but does not yield its own subfunction.

Figure 9: Mapping of Requirements to Subfunctions

In order to build out the complete morphological chart, we listed out multiple ideas for each sub function of the device, with the goal of being able to pick out combinations of ideas from each sub function to generate complete concepts. A summary of the morphological chart can be found below in Figure 10.

Sub Functions	Solutions				
Data Collection and User Interface	*SparkFun* Data Logger	*Arduino* Board	Raspberry Pi	Interactive Phone App	Calculator Screen
Measure Temperature	Thermistor	Temperature Sensor (Thermocouple)	Infrared Sensor	*SparkFun* Sensor	Meat Thermometer
Device and Sensor Housing	Scissor Lift	Clamp and Stand	Retractable Wire and Custom Box	Mini Stands for Each Sensor	Detachable Wall Sensor System

Figure 10: Morphological Chart

In the process of collecting ideas for each sub function and in order to fill out the solution space, we employed two additional brainstorming strategies: design heuristics and SCAMPER. These played a large role specifically in generating ideas for sub functions that previously had little variation or were largely one idea in multiple forms. Examples of heuristics used include: substitute way of achieving function (#63), synthesize function (#64), use common base to hold components (#68) and use packaging as functional component (#73) [32]. The use of these heuristics ultimately expanded the scope of our morphological chart analysis. For example, where we had previously imagined a scissor lift being compressed to fit inside a 3D printed box, we employed heuristic #64 and #68 to make the scissor lift collapse onto itself, for easy storage while reducing materials and number of design components. Additionally, we used SCAMPER categories such as Adapt (A) and Eliminate (E) [33]. This allowed us to unlock ideas such as using alternative power sources for energy, and eliminating the need for multiple sensors by using one highly-accurate sensor.

By selecting components of each sub function that worked well with one another, we were able to come up with four distinct ideas. Given the differing methods of temperature, user interface, and housing used in each idea, the concept solution set has variation in temperature accuracy and resolution, physical footprint, cost, usability, and durability. A breakdown of each sub function is indicated below, and a full analysis of each is included in Appendices G-I.

Sub Function 1: Data Collection and User Interface

The first subfunction, data collection, and user interface, addresses the requirements for the device to have a user controlled interface with user friendly design features. Ranging from most simple to most complex, there are three primary options to accomplish this: *SparkFun* Data Logger, *Arduino*, and Raspberry Pi.

The *SparkFun* Data Logger is an open-source data logger that can be connected to a sensor and MicroSD card to receive and store data from the sensor [34]. It is part of the *SparkFun* ecosystem, whose curated kits offer temperature and humidity sensors, cables and wiring, and several other add-ons. The second option is an *Arduino* board, which is a single-board microcontroller with a full suite of compatible hardware and software that is open-source and widely used for many applications [35]. With its own integrated development environment (IDE) and hardware add-ons, it is a customizable way to receive various modes of data and send results to a user-facing interface. The final option is a Raspberry Pi, which serves as a mini computer, with all the processing power and capabilities of a normal computer. A user is able to add a USB cable, SD card insert or any other functionality they desire by soldering it to the board [36]. In order to become fully functional and user-accessible the only required components are a power source, display and a method of inputting commands. The data can be summarized below in Figure 11.

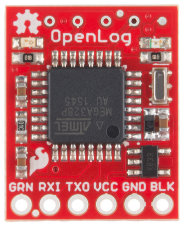
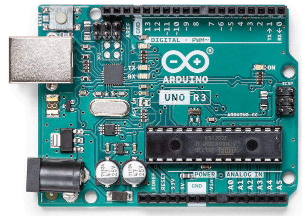
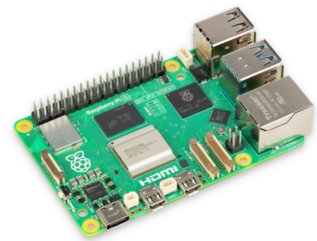
	SparkFun Data Logger	*Arduino* Board	Raspberry Pi
			
	Monitors and collects data overtime	Single-board microcontroller	Single-board computer with native operating system
+	❖ Integration with *SparkFun* environmental sensors ❖ Affordable (~$17) ❖ Significant data storage	❖ Availability of documentation ❖ Affordable (~$27) ❖ Offers compatible software ❖ Exposure to use in ME350	❖ Acts as a "mini computer" ❖ Extensive compatibility with operating systems, devices ❖ Can handle various data types
-	❖ Restricted to *SparkFun* components ❖ Limited functionality beyond data collection	❖ Limited memory capacity for large scale data collection ❖ Limited input/ output ports	❖ Expensive (~$102) ❖ Not beginner friendly

Figure 11: User Interface (Sub Function 1) Breakdown

Sub Function 2: Temperature Measurement

The second subfunction, temperature measurement, addresses the three requirements involving the accurate and thorough capture of both ambient and surface temperature data from the incubator. The three primary options are a thermistor, a thermocouple, and an infrared sensor.

A thermistor acts as a semiconductor whose resistance is dependent on temperature. To establish a measurement, the measured electrical resistance can be correlated to the temperature of the environment from which the thermistor gathers data [37]. The second option, a thermocouple, is a type of temperature sensor that provides temperature readings via electrical signals. Specifically, these sensors are composed of two metals that generate an electrical voltage or resistance when a temperature change occurs and produce a value by measuring the voltage across the terminals. When the voltage increases, the temperature also increases [38]. Finally, an infrared sensor focuses infrared light at an object to measure radiation coming from its surface. The amount of electricity generated by the rays will provide a reading that is displayed on the thermometer [39]. The data can be summarized below in Figure 12.

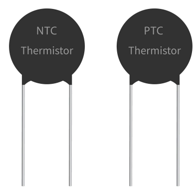
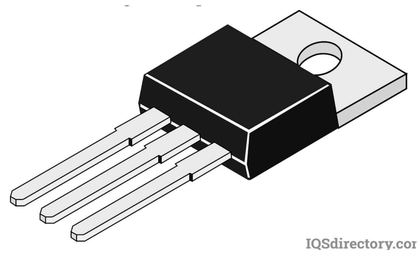
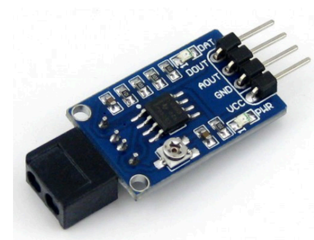
	Thermistor	Temperature Sensor	Infrared Sensor
			
	Acts as a semiconductor whose resistance is strongly dependent on temperature	Provides temperature readings via electrical signals	Focuses infrared light at an object to measure radiation coming from its surface
+	❖ High sensitivity ideal for low temperature range ❖ Highly accurate ❖ Easily interfaced to electronics with two-wire system	❖ Durable ❖ Fast response times ❖ Self-powered ❖ Cost effective	❖ Fastest response times ❖ Highly repeatable results ❖ Good stability over time ❖ No contact required with object
-	❖ Narrow working temperature range ❖ Fragile	❖ Temperature drift can cause inaccuracy over time ❖ Lower accuracy ❖ Vulnerable to corrosion	❖ Must be within certain distance of object ❖ Does not work through obstacles

Figure 12: Temperature Measurement (Sub Function 2) Breakdown

Sub Function 3: Device Housing

For the final subfunction, device housing, we aim to address the durability and safety requirements, by ensuring that the electromechanical components of the device are protected and able to withstand numerous uses. For these ideas, we generated multiple mechanisms that can fulfill our requirements, the top three of which are outlined below.

The first mechanism is a scissor lift, that can be expanded and contracted to allow the user to set a custom height for the sensors at different points within the incubator. Secondly, we envisioned a vertical stand, with double spring clamps to attach a sensor and enable the user to move the device up and down to their desired height. The stand can also be telescoped to enable easy storage. The final design concept was mini sensor stands, that allow each sensor to stand upright independently and collapse inward if necessary to stay compact. The data can be summarized below in Figure 13.

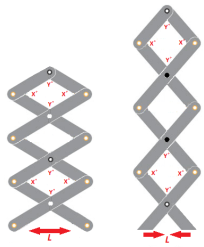
	Scissor Lift	Clamp and Stand	Retractable Wire and Custom Box
			
+	❖ Customization of height by user ❖ Compressible for easy storage ❖ Robust	❖ Customization of height by user ❖ Lightweight and simple ❖ Affordable	❖ Compact and easy to pack ❖ Durable ❖ Each sensor is independent
-	❖ Liable to mechanical failure ❖ Complicated to implement ❖ Expensive	❖ Bulky and not portable ❖ Clamp can damage electromechanical elements	❖ No height customization ❖ Does not protect design electronics

Figure 13: Device Housing (Sub function 3) Breakdown

Concept Selection Process

Concept Generation and Screening

The following concepts use components from each of the above subfunctions, to ensure all the design requirements and specifications are met. For each concept, the selection of components from each sub-function was intentionally completed based on which components work best together electrically, the feasibility of the housing relative to the temperature measurement device, and other considerations that ensured the components of the concept work together cohesively. In particular, we considered the pros and cons of each individual subfunction, and tried to identify which components from other sub functions would work well with the selected components. Additionally, we considered technical compatibility, cost and rigor of each selected component, and the relative size of each component.

Because our concepts were mainly generated based on different combinations of varying subfunction solutions, our team utilized pros and cons lists to first identify the highlights and shortcomings of each design and how well the selected sub function components were technically compatible. These pros and cons lists would further identify shortcomings against our requirements and engineering specifications. Because of this interwoven relationship between components, there is feasibility judgment threaded throughout our concept screening process based on research conducted by the team on any very possible technical roadblocks. These technical roadblocks would only be able to be identified if we created whole generated designs, further highlighting how one subfunction component may not be suitable under conditions with one or more certain components.

We strayed away from numerically weighted decision matrices because of the influence numerical scores may have towards convincing our team members to automatically choose one design over another. These decision matrices analyze the design as a whole numerically subjectively, and we wanted to analyze the design as a whole therefore we decided to begin the screening process by utilizing pros and cons lists and in a very detailed oriented manner.

The following pros and cons lists analyze the highlights and shortcomings of each design based on the design's ability to meet engineering specifications and requirements and any other technical roadblocks that our team may foresee in the future. These lists were generated within full team discussion over a long period of time.

Concept #1

The first concept uses a thermistor, which allows us to measure both ambient and surface temperature with accuracies that fall within our provided specifications. Given that the sensor has no output of its own, it must be connected to an external electronic device in order to present data and be interpretable by the user. Therefore, we aim to connect this to a breadboard and Arduino via wiring, to form the main electromechanical component of the device. For the sensor housing, we envisioned a 3D printed case that protects the electronic components of the sensor, with holes for the probes to collect data. Given that we need to measure temperature at different heights, this housing will be attached to a scissor lift mechanism, that the user can adjust to their desired height. A sketch of this design can be seen in Figure 14.

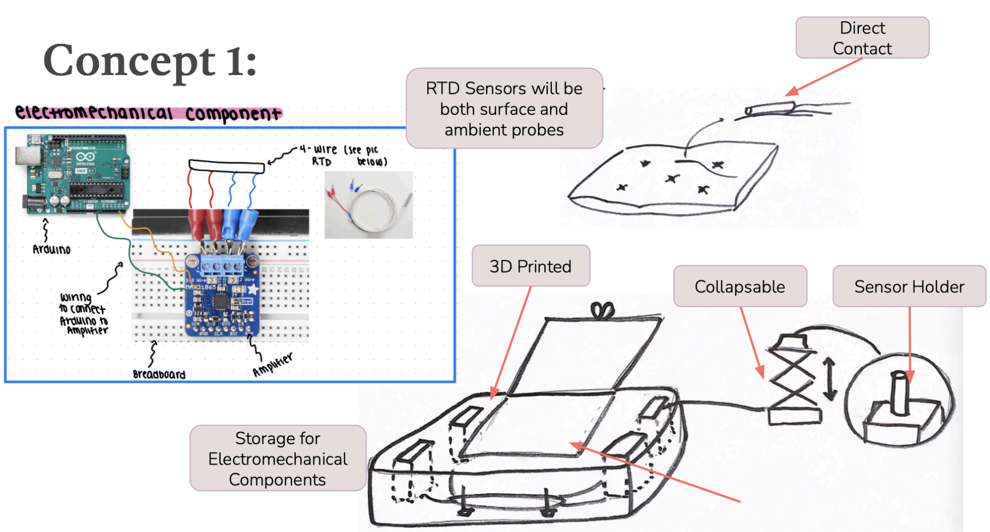


Figure 14: Concept #1 Sketch

Table 4: Pros and Cons List for Concept #1

Pros	Cons
Adjustable height → allows for evaluating different areas	Scissor lift → may be difficult to manufacture
Sensor housing is collapsible → Portable	Scissor lift → Subject to breakage
Arduino → Well documented and cheap	Scissor Lift → Subject to wire entanglement
RTD sensors → Cheap	Learning curve with *Arduino*
Easily compatible to accessible laptops	Learning curve with Calibrating Sensor
RTD Tolerance: ± 0.13°C	Temperature Accuracy: ±0.5°C

There are some key highlights and shortcomings within this design. Within this concept, the RTD sensors are compatible with our *Arduino* as the form of the data logger. However, the temperature accuracy of the sensor is out of the range that we have defined in our specifications, at ±0.1°C where the sensor accuracy is at ±0.5°C. The RTD sensor is relatively cheap at $14.95. The scissor lift design allows us to adjust the height at which we are analyzing the ambient temperature. However, it may be difficult to manufacture if we use cost effective materials such as wood based on members' previous experience with these types of assemblies. Further, the scissor lift if using cost effective materials would be subject to breakage, as pointed out by team members and their own experience in creating scissor lifts in robotics teams. Lastly, the scissor lift would be subject to wire management issues due to the ability of the scissor legs to collapse.

Concept #2

The second concept uses a pre-existing *SparkFun* kit that comes with a data logger, temperature and humidity sensors, and cable kit. The data is collected via sensor, logged via a data logger, and saved on a microSD card. For the user interface, the SD card can be plugged into a computer for a user to view and manipulate the results at their convenience. Together, the *SparkFun* components form the electromechanical part of the concept. For the sensor housing, we aimed to embed the sensor into mini clips, with a backing that can be placed upright, similar to that of a picture frame. With each sensor attached to its own clip, the user can place it at their desired height and location within the incubator. Given the affordability and memory capacity of the *SparkFun* sensor, it is feasible to purchase multiple sensors to collect data at once. A sketch of this design can be seen in Figure 15.

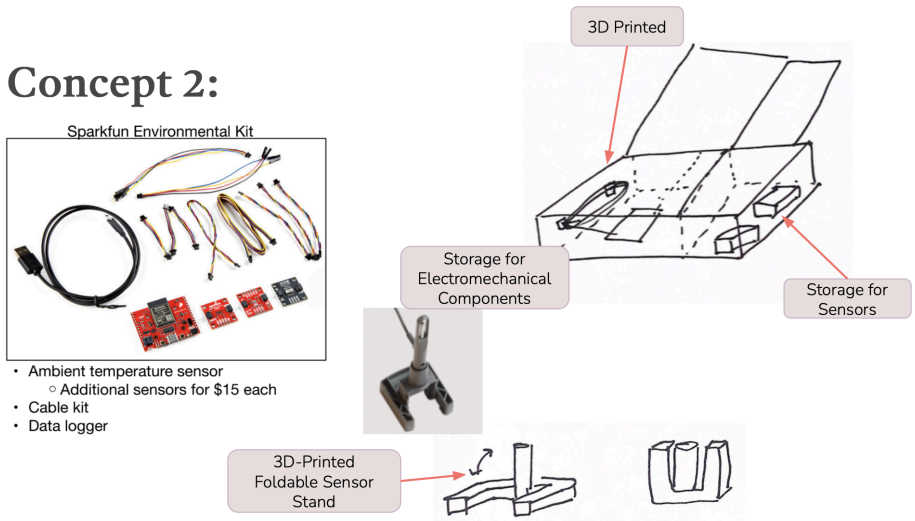


Figure 15: Concept #2 Sketch

Table 5: Pros and Cons List for Concept #2

Pros	Cons
Contains high precision temperature sensor and environmental sensor	*SparkFun* kit is not compatible with OTC contact sensors
Sparkfun kit → Smaller learning curve	*Sparkfun* contact sensors have poor accuracy, only ±0.5°C
Ambient Temperature Precision: ±0.1°C	Non-adjustable sensor height
Ambient Temperature Range: -55°C to 150°C	Less customizability → Lower number of pins
Kit contains temperature, humidity and barometric pressure sensor	
Ambient Temp Sensors → Easy Plug & Play	
Ambient Temperature Accuracy: ±0.1°C	
Low power consumption: 3.5µA (1-Hz conversion cycle)	
Sensor housing → fully collapsible	

There are some key highlights and shortcomings within this design. The *Sparkfun* kit contains many components that have many benefits including the ambient temperature sensor that has satisfactory accuracy specifications and functions via a plug and play structure. The data logger that is included in the kit is affordable (~$17) and monitors and collects data overtime.

However, the Sparkfun data logger has less customization and constrains the arrangement of sensors we would be able to include. The kit does also contain a humidity sensor with an absolute accuracy of ±3%RH which is out of the scope of our specification but is not too expensive at around $22. The collapsible mini clips are portable but have no way of adjusting in height to measure at different heights without switching the sensor stand for a varying set of heights.

Concept #3

The third concept uses an infrared thermometer as the primary method of temperature data collection. The sensor itself is integrated into a circuit board, which we planned to connect to a Raspberry Pi. In order to make it accessible to the user, we will connect a display, power source and a way to enable the user to input commands [36] to serve as the user interface. To obtain height variation, we wanted to use a stand with a double spring clamp interference fit onto the base of the clamp that can be moved up and down. The 3D printed plate can then be placed onto the stand, to expose the temperature sensor to any height the user desires. A sketch of this design can be seen in Figure 16.

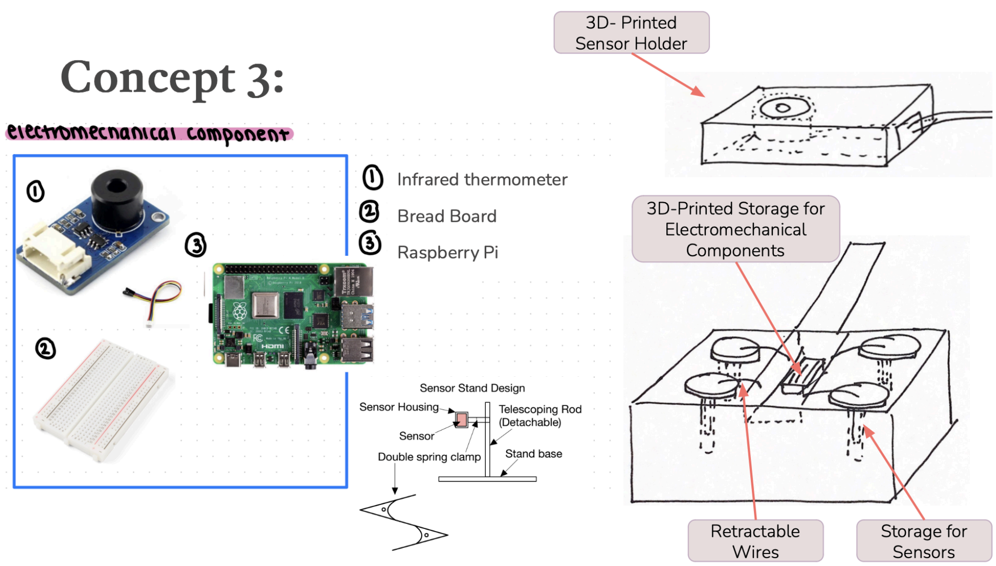


Figure 16: Concept #3 Sketch

Table 6: Pros and Cons List for Concept #3

Pros	Cons
Full contact with mattress	Infrared sensors may accidentally record incubator wall temperature
Raspberry Pi → Well documented	Infrared Accuracy: ±0.5°C
Sensor Housing → Can disassemble	Learning curve w/ Raspberry Pi
Infrared sensors → Cheap	Raspberry Pi → Expensive
Easily compatible to accessible laptops	
Sensor stand → Adjustable in height	
Temperature measurement range: -70℃～382.2℃	
Temperature Accuracy: ±0.14°C	

There are some key highlights and shortcomings within this design. The infrared sensor has the ability to detect the mattress temperature both via direct contact or from a distance. The infrared sensor we researched and discussed has an accuracy of ±0.5°C which is out of the scope of our specification. Infrared sensors with an accuracy abiding by our specification average a very high cost. The sensor, however, does meet within low cost specifications and is small in size. The data collection method for this design is the Raspberry Pi which leans on the expensive side (~$80) and has a larger learning curve due to the complex nature of the computer, which may be outside of the capabilities we require our data collection method to be. The Raspberry Pi does have a large degree of customization with it. The sensor stand within this design would allow us to adjust the sensor height and based on materials used can be disassembled for portability.

Concept #4

The fourth concept uses a thermocouple to measure and collect temperature data. For the user-facing component, we felt that a thermocouple was best integrated with an *Arduino*, for the user facing component of the concept. For the housing, we can create a 3D printed box, with a separate section to house the electronic components, and a separate section for the sensors and wiring. The side of the box, shaped like a tissue box, has holes the size of the sensors for users to pull out the sensors and place it wherever they see fit on the incubator. However, the wires themselves can retract into the box when the sensors are not in use. This makes pack up and transport easy and keeps the wires clean and organized. A sketch of this design can be seen in Figure 17.

Concept 4:

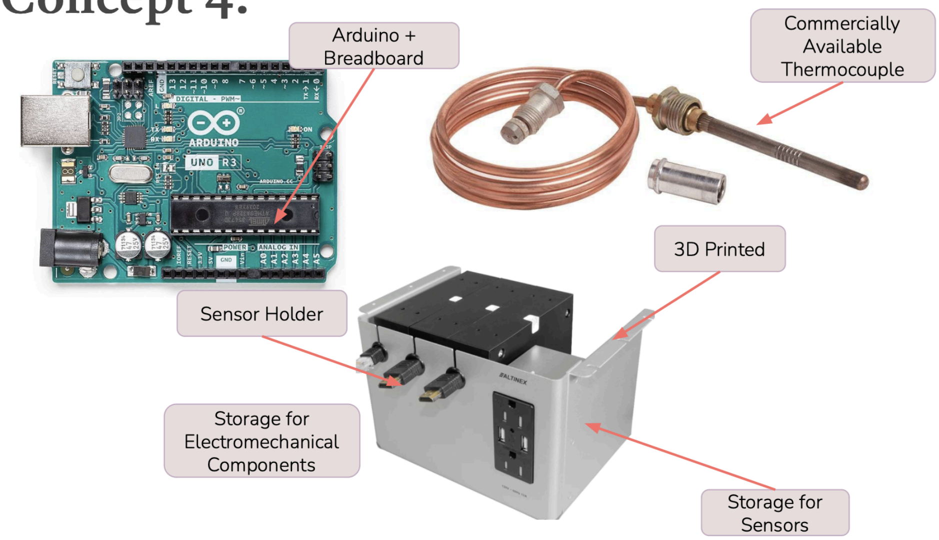


Figure 17: Concept #4 Sketch

Table 7: Pros and Cons List for Concept #4

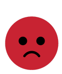
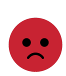
Pros	Cons
Industry thermocouple: Resistance to high-temperature	Large Size → Affect Portability and Compactness
High-temperature range: 0℃ to 400℃.	Market thermocouple not compatible with directly attaching to data logger
Compatible with *Arduino* through only adaptor boards	Retractable wire and custom box may be difficult to manufacture
	Temp Accuracy: ±0.25°C
	Retractable mechanism may damage sensors
	Learning curve with *Arduino*
	High Accuracy → Expensive

There are some key highlights and shortcomings within this design. The thermocouples that are available on the market are primarily used for professional industrial processes and are very large in size which would affect the portability aspect of the design. The sensor does have a high temperature range but has an accuracy outside of the scope of the specification for ambient temperature. Due to the tube nature of the sensor it would be able to also act as a contact temperature sensor. The compatibility between the *Arduino* however requires an additional component to make it compatible. Furthermore, the custom retractable wire box will be difficult to manufacture considering the larger size of the sensors and we will have to utilize other forms of manufacturing as 3D printing will require a lot of material and time.

Summarizing Key Highlights and Shortcomings

These pros and cons lists summarize different shortcomings and highlights of each design and give our team great insight of the interaction between different components. Certain combinations of components affect the design as a whole and this process helped our team identify how to conceptualize a design that can build upon these concepts based on each design's pros and cons lists. After analyzing the pros and cons of each design, we decided to summarize each design's ability to meet our requirements and engineering specifications based on technical compatibility within the design within Table 8 below.

Table 8: Key Design Highlights and Shortcomings

	Data Collection and User Interface		Measures Temperature		Device and Sensor Housing	
Concept 1		*Arduino* - Good Compatibility and Documentation		RTD Sensor - Satisfies Accuracy and Compatibility but Difficult Integration Compared to *Sparkfun* Sensors		Difficulties w/ Manufacturing, Wire Management, and Durability
Concept 2		*Sparkfun* Data Logger - Lack of Customization		*Sparkfun* - High Accuracy Ambient Temp Sensor but Low Accuracy Contact Sensor and Easy Compatibility with *Arduino* and *Sparkfun*		Non Adjustable Height Sensor Height but is Collapsable
Concept 3		Raspberry Pi - Overcomplexity and Expensive		Infrared Sensor - Insufficient Ambient Temp Measurement → Only Contact		Adjustable Height and Can Disassemble
Concept 4		*Arduino* - Good Compatibility and Documentation		Thermocouple Sensor - Insufficient Ambient Temp Accuracy, Size, and Difficult Compatibility		Difficulties w/ Manufacturing and Feasibility with Intricacies

This table evaluates the concept's ability to meet our requirements and specifications and in conjunction with our M-HEAL sponsor, the satisfaction from their perspective after meeting and discussing each concept. This table summarizes the smaller set of solutions and their advantages and disadvantages. Some key points from the table include the conclusion that the *Arduino* is compatible with most systems and considered cost restraint. Various sensors such as the thermocouple are not suitable for this project but the infrared sensors, RTD sensors, and infrared sensors all are somewhat suitable with certain caveats. Mainly, our ambient temperature sensors that we aim to use are within the accuracy specification that we have within our specifications. However, the accuracy of the infrared temperature sensor does not meet our specification; however, we will utilize these sensors as a starting point as infrared temperature sensors within our specifications on accuracy tend to be expensive and will move towards that point if the budget allows for further iterations. The telescoping stand that acts as our sensor housing was deemed satisfactory by both the team and the M-HEAL sponsor due to portability and height adjustability.

First Solution Concepts versus Final Generated Concepts

It is important to note that our first generated solutions during the team's concept generation block consisted of ideas that aligned by a differently defined scope of the project. Initially, our team discussed the possibility of creating a device that would simulate the thermoregulation properties of a neonate to determine if the incubator was deemed a safe environment for the neonate. These initial ideas are very different in overall concept and direction of how to accomplish the problem of incubator verification. By analyzing the current market for incubator verification analyzers, we were able to explore other solution methods for our problem. Furthermore, after discussing the project and our initial solution to many different professors and medical professionals, our initial solution method would be extremely difficult to execute as the thermoregulation of a neonate is based on many different bodily functions that are difficult to represent.

Our team has explored many different solution pathways in an effort to explore the entire possible solution set and justify an alpha design that we deem the most efficient and best way to tackle the problem.

Determining the Alpha Design

After evaluating our solution set, we understood that not one concept completely satisfies all requirements and specifications. We considered the possibility of reevaluating the combination of certain design elements based on technical compatibility after now understanding how certain components would interact within a design space. Based on comments from our M-HEAL sponsor about each concept's ability to meet requirements and specifications and feasibility judgment from the team, our team decided to create an alpha design that encompasses the highlights from each design to make a system that would best meet the requirements and specifications.

Our team decided to utilize the *Arduino* as our device for data collection based on how it performs in cost and customizability compared to other subfunction solutions. Furthermore, based on our analysis of sensor stands, the telescoping sensor housing satisfies more requirements and specifications compared to other solutions within the solution space such as retractable custom housing units or foldable compact sensor housing components. Lastly, we have evaluated that the *SparkFun* ambient temperature sensors are able to satisfy many of the requirements for measuring ambient temperature, both in cost, temperature accuracy, and technical compatibility with the *Arduino* as they are in a plug and play design structure. In regards to measuring mattress temperature, our team decided to utilize the infrared sensor. It is important to note that the infrared sensor and RTD sensor both are able to measure object temperature but the infrared sensor performs in a more plug and play structure compared to the RTD sensor, and is a more efficient method to integrate into our electrical system. The infrared sensor that satisfies our cost constraint has an accuracy of ±0.5°C which does not satisfy the contact temperature specification. This infrared sensor would most likely be utilized within a build design to demonstrate proof of concept. In our ideal case, the infrared sensor that would meet our specification of ±0.1°C, would be out of the cost scope of the project but in an all encompassing best case design, the more expensive version of the infrared sensor be our main choice for contact temperature sensing

After many rounds of discussion, research, screening and evaluation, we have come to an initial alpha design which we have arrived at after considering and evaluating all generated concepts. Any slight modifications made by refining certain minor design elements to establish compatibility such as the telescoping stand and the *sparkfun* temperature sensor, and how it would attach to the clamp. This will be explored further in the following section.

The Alpha Design

The alpha design we have selected is a combination of our highest evaluated potential design solutions. We have chosen to design a 3D CAD model that is customized for the individual components within the IncuCheck device. The housing that the device operates out of is shown in Figure 18 both with its lid on and removed. The layout displayed in Figure 20 shows the different subsystems of the IncuCheck alpha design. The overall assembly consists of four main subsystems: the electronics board and breadboard, the sensor components, the stand components, and the box used to house the three previously mentioned subsystems.

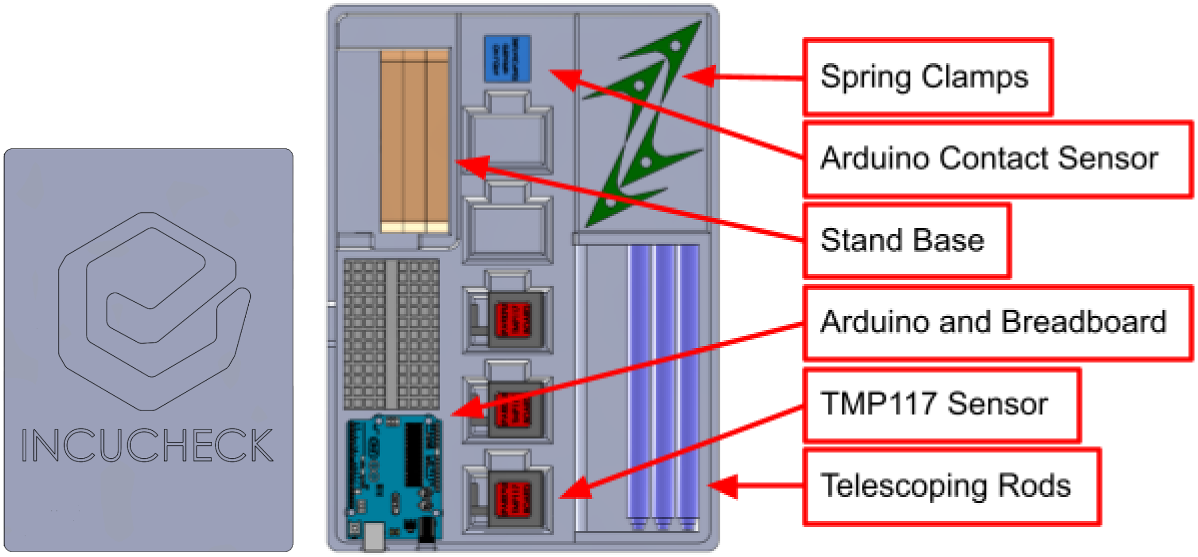


Figure 18: Left: Top-down of the IncuCheck alpha prototype with the lid on. The IncuCheck logo is engraved into the lid which neatly covers the entire box in one piece. Right: Top-down of the IncuCheck alpha prototype with the lid off, simulating the use of two sensors/stands.

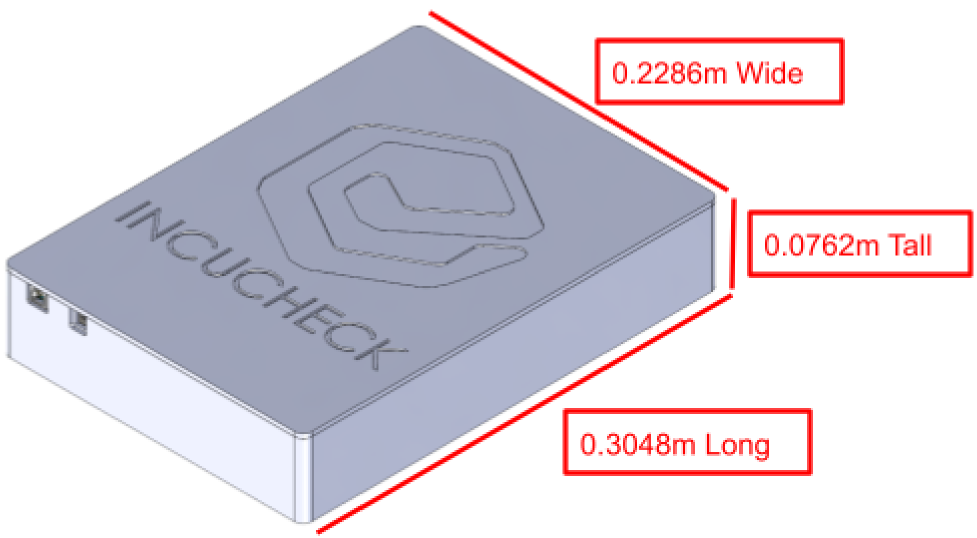


Figure 19: Dimensionalized drawing of the alpha concept. The total height of the box is 0.0762m, the length of the box is 0.3048m, and the width of the box is 0.2286m. We expect the box to decrease in size as the design evolves.

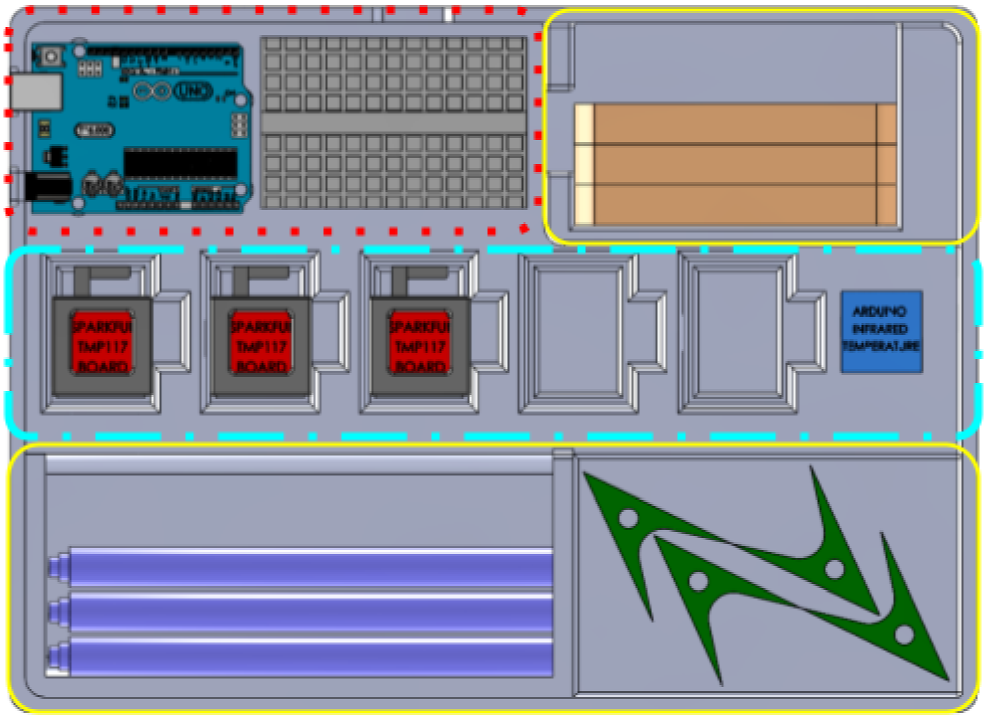


Figure 20: Top-down of the alpha prototype's interior. The area circled in red dots contains the electronics board and breadboard. The area circled in the light blue dashes and dots contains the sensor components. The areas highlighted in solid yellow lines contain the stand components.

Electronics Board and Breadboard

The first subsystem, the electronics board and breadboard, consists of an *Arduino* board with a *Pololu* 400 point breadboard shown in Figure 21. The *Arduino* board sits on four 3D printed plastic stand-offs that enable airflow around the entire board. Four nuts sit flush with the bottom of the box, enabling small screws to fasten through the *Arduino* and the standoffs into the nuts. Ventilation holes are also placed on the side of the box to prevent the *Arduino* from overheating. There are also openings to allow the power and data cable connectors access to the outside of the box, shown in Figure 19 above. This enables the *Arduino* to be used and connected to while being covered completely with the lid closed. The ventilation holes and wire openings can be seen in Figure 14 within problem analysis and iteration. The *Pololu* breadboard is also neatly tucked directly opposite of the *Arduino*, making wire management much easier. The breadboard comes with a provided double-sided tape which can be used to fasten the breadboard to the bottom of the box.

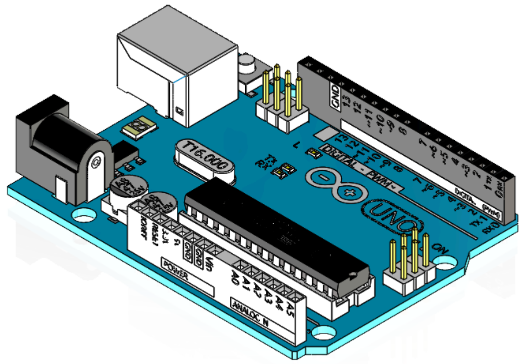


Figure 21: *Arduino* board. The sensors are wired through the *Pololu* breadboard and into the *Arduino* board.

Sensor Components

Sitting right next to the *Arduino* and *Pololu* breadboard are the sensor measurement devices highlighted in the light blue dashes and dots on Figure 11. The ambient air temperature sensors manufactured by *SparkFun* are enclosed in a custom, 3D printed case. The case includes openings for airflow, wiring, and also includes a small handle used to wrap the wire connections neatly and conveniently. The 3D printed cases shown in Figure 12 sit flush with the bottom of the box, with all five in a row. Next to the *SparkFun* ambient sensors there is an additional infrared temperature sensor manufactured by *Arduino*. Unfortunately there are no CAD models available of the device, and even pictures have been quite hard to come by. For the initial alpha design we blocked off extra space in the box to prevent packaging issues in the future. We expect the sensor to arrive within the next week and will create an accurate CAD model and design a housing, if necessary.

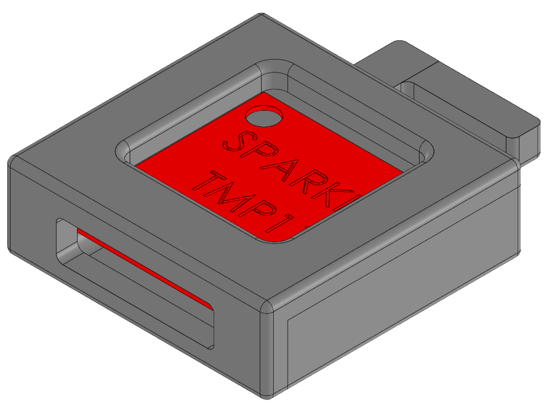


Figure 22: Isometric view of enclosed *SparkFun* ambient temperature sensor 3D printed case.

Stand Components

Sitting on either side of the sensor measurement devices are the components that make up the sensor stands, highlighted in the solid yellow line in Figure 11. The stand can be broken down into its own subassemblies, with the base, telescoping rod, and the clamp mechanism. The base consists of a ¾” thick plywood with a ½” diameter hole for the telescoping rod. The telescoping rod is an off-the-shelf component supplied by Amazon Basics that attaches to a back scratching claw. The claw will be removed from the rest of the body, leaving an extendable metal rod that can easily be placed inside of the plywood base. The third and final component of the stand is the clamping mechanism for the sensors. The chosen clamping method utilizes two spring clamps that are joined through the use of an adhesive to form a double spring clamp. One end of the clamp will attach to the extendable rod at a desired height, while the other end will attach to the sensor chosen for the specific stand. The stand, now with all components attached, can be placed inside of the incubator as shown in Figure 13. Figure 14, on page 35, shows the entire IncuCheck assembly in tandem with the M-HEAL Bassinet.

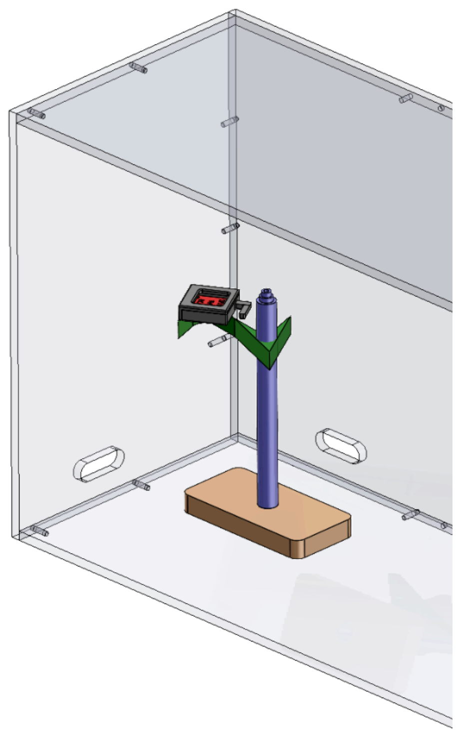


Figure 23: Isometric section view of the InchuCheck stand within the M-HEAL Bassinet CAD.

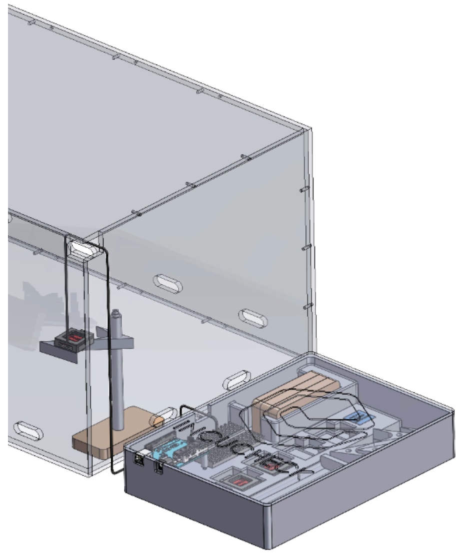


Figure 24: Isometric view of the IncuCheck assembly with the M-HEAL Bassinet CAD. A mock wire was placed into the model to show an example of device operation.

Housing

The final subassembly is the box that holds all of the components inside of it, shown in Figure 15. The housing is a purchased box from ZKHOB, an outside vendor. The part number for the product is B0CCDDZM37. The inside of the box contains laser-cut foam that conforms to the specific shape needed to the individual components placed inside of the box. The combination of the purchased box and laser-cut foam creates a much lower cost than the alternatives such as 3D printing an entire box or custom-molding a box out of plastic. The box and foam combination is easier to manufacture while still achieving a high level of customization. The total height of the box is 0.0762m, the length of the box is 0.3048m, and the width of the box is 0.2286m. The dimensionalized drawing of the box can be seen in Figure 19 above. Additionally, using the box and foam method also enables high levels of cable management to be considered. Channels can be cut into the foam to designate wiring paths that neatly tuck away to avoid entanglement issues.

Due to the box being purchased, we would have to make modifications to it which enable further *Arduino* integration. To be able to power the device and maintain a constant data flow, the Arduino must be plugged in. We want to ensure the device can be used whether the lid is open or closed. Therefore, there must be holes made for the two Arduino ports, in addition to holes for the mounting screws. To address the cooling of the board, additional holes will have to be placed into the side of the box. Without proper cooling the board might overheat and cause the entire device to be rendered unusable. Cooling is imperative and we wanted to ensure we accommodated for that in our design.

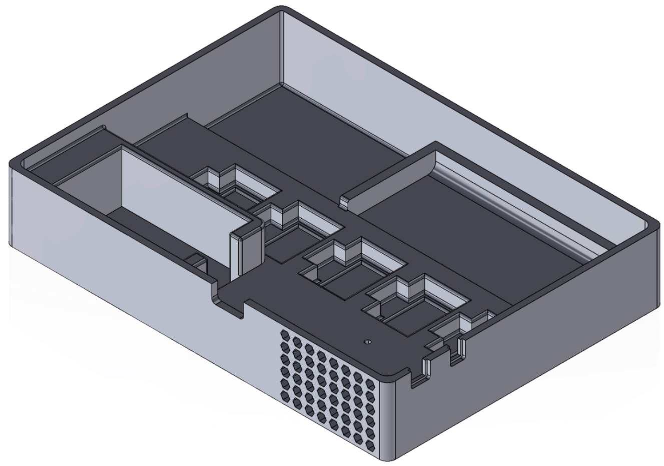


Figure 25: Isometric view of the bottom section of the IncuCheck box. The box is empty in this image, showing what the box would look like before all of the components are installed inside.

Mock-Ups of Alpha Design

Following the 3D CAD modeling of the alpha design, we initiated the build of very high level concepts from the alpha design. We created a cardboard prototype that is roughly the same dimensions as the alpha design model. Using cardboard found in the X50 lab in addition to some leftover styrofoam in CSED enabled us to make the cardboard mockup. We also decided to create a mockup of our stand design from the alpha concept. This involved using a similar foam material for the base, a wooden dowel rod found in the X50 lab, and some organization clips also found in the X50 lab. We also started to write our only Sparkfun TMP117 sensor to our Arduino Uno. The very early build prototypes we created gave us valuable insight into the design and engineering analysis process. We were able to physically visualize the prototypes and really get to understand how the design would exist in space. This helped us inform many of our engineering analysis decisions and where our worries would be moving forward.

Engineering Analysis

Our team conducted multiple methods of engineering analysis to evaluate our alpha design in an effort to refine and optimize it with respect to our requirements and specifications. We conducted multiple different methods of analysis with certain reasoning for each method and assumptions. We acknowledged the limitations of each method, but ultimately used the results from each method to guide us in solving our current worries about our Alpha design to develop a Beta design that is more refined than our Alpha Design. The table below displays the design worries our team generated based on discussion about what worried us the most about our alpha design.

Table 9: Generated Alpha Design Worries

Are we able to develop a design user interface with the Arduino data analoging capability in an organized manner?	**High Priority**	Would the alpha design introduce thermal air flow variations that stray away from base case incubator behavior?	**High Priority**
Where must the user place the sensors to analyze areas of concern?	**High Priority**	Are we able to use six TMP117 sensors with only one Arduino Uno?	**High Priority**
Will we receive accurate ambient temperature readings from SparkFun sensor TMP117 with Arduino?	**High Priority**	Is there potential for breaking sensor and other mechanical components?	**Medium Priority**
Will our power source be accessible?	**Low Priority**	Is the device customizable for every user's intended usage for analysis?	**Low Priority**
Is the device not portable or too bulky?	**Low Priority**		

Our team discussed many different worries based on potential functionality worries we have about the design, as well as worries related to accurately sensing ambient temperature and whether or not the design would be contributing to temperature variations in the incubator. We ranked the worries based on prioritization and to what degree they should be prioritized, in the context of which worry is most important to analyze to build our confidence in our Alpha Design. We ultimately concluded that the set of five main high-priority worries were more instrumental in analyzing and evaluating our alpha design and the confidence level of the design. The table below summarizes the worries, each with a reference number along with the exact design worry question we explore through engineering analysis.

Table 10: Key Alpha Design Worries

Worry 1	Will we receive accurate ambient temperature readings from SparkFun sensor TMP117 with Arduino?	**High Priority**
Worry 2	Where must the user place the sensors to analyze areas of concern?	**High Priority**
Worry 3	Would the alpha design introduce thermal air flow variations that stray away from base case incubator behavior?	**High Priority**
Worry 4	Are we able to use six TMP117 sensors with only one Arduino Uno?	**High Priority**
Worry 5	Are we able to develop a design user interface with the Arduino data analoging capability in an organized manner?	**High Priority**

The following sections will discuss each worry in more detail, the methods chosen for each worry, and the justification for the method. Each worry is explored in detail in terms of the form of analysis chosen, parameter analysis, and what the results from each analysis will imply about moving forward in improving our design.

Engineering Analysis: Worry 1

Our first worry was if we will receive accurate ambient temperature readings from the SparkFun sensor TMP117 when connected to an Arduino Uno. This concern needed to be addressed as the primary functional purpose of our prototype is to provide M-HEAL with temperature readings in order to allow for incubator verification. If our prototype does not provide accurate readings, M-HEAL will not be able to benefit from it. In order to evaluate this concern we came up with three different ways of testing as shown in Table 11.

Table 11: Potential Methods of Testing Worry One

Method	Type/Rigor	Pros	Cons	Assumptions
Comparing Multiple Sensors	Empirical/ Low	Affordable, Verifies reading from Arduino	Does not verify sensor accuracy to ± 0.1°C	Uniform temperature, Additional sensors are correct
CFD Analysis/ Comparison	Both/High	Affordable, Verifies reading from Arduino	High level of CFD knowledge	Model is extremely accurate (unreasonable)
Point-to-Point Testing	Empirical/High	Verifies sensor accuracy to ± 0.1°C	Not accessible, No Arduino verification	Arduino is accurately relaying sensor data

Within this table we compare the methods of point-to-point testing, CFD analysis along with a comparison to the temperature sensor within the incubator, and comparing multiple sensors. In order to utilize point to point testing we needed access to expensive and specialized testing equipment which is not available to us or within our budget [40]. Additionally, point-to-point testing would only verify the accuracy of the sensor itself with no consideration given to the Arduino; this could be problematic as we would have no idea if the sensor is properly connected (assuming that the Arduino is displaying values from the sensor) to the Arduino and/or if the Arduino and sensor are working together properly to relay the temperature that the sensor is actually measuring.

Another option would be CFD analysis and comparison, this would entail the creation of a CFD simulation of the incubator that is accurate enough to represent the temperature within the incubator with an accuracy of well under a degree. We would then place the sensor within the incubator and compare the temperature values displayed from the Arduino with the temperature values received from the CFD analysis. While this could verify the sensor from the values displayed by the Arduino to a high degree of accuracy (based on accuracy of the CFD analysis), the necessary assumption that the simulation is “correct” is not a realistic assumption to make. We have no way of knowing how accurate that CFD analysis is without additional physical testing on the incubator. If additional testing was done with more accurate sensors in order to verify the simulation, it would likely be better to simply compare those values with our sensors instead of adding an additional level of error between the more accurate sensors and the CFD analysis. In order to create a model that is capable of this it will also require an extremely high level of CFD knowledge and thermodynamics. This is not something that we currently had within our team as only one member has completed a heat transfer course which the other three members are currently enrolled in, this is also a relatively introductory heat transfer course. While we had access to and were utilizing CFD to address other worries, this was primarily being compared with other CFD simulations to provide a better understanding of what is occurring within the incubator and the deviations caused by our design choices, not to directly compare quantitative values from simulation to real life measurements.

Chosen Testing Method

Out of the three methods shown we elected to proceed with comparing multiple sensors. This method entailed the use of multiple sensors being operated at the same time and in roughly the same location as ours in order to compare the resulting values. This method was very affordable as we were able to borrow various temperature sensors from the school, and reasonably easy as it simply involved operating the given sensors along with ours. We borrowed an Arduino along with one TMP117 which allowed us to hook the sensor up to the Arduino and receive values from a connected computer. While this method did not verify the accuracy of the TMP117 to ±0.1°C it provided us with enough information to understand if the sensor was providing us with reasonable results. We also planned on incorporating more accurate sensors in order to verify the sensor's accuracy to a greater degree. This test was being run under the assumption of constant temperature within the testing area as it was a relatively small space within a temperature controlled room, we also assumed that the additional sensors were correct per their associated specs.

Procedure

In order to run this test we connected the TMP117 sensor to an Arduino and that Arduino to a computer, we utilized Arduino IDE software along with code provided by Sparkfun which was intended to be used with our sensor and Arduino combination [41]. While this sensor was running we also monitored the same space with an IR thermometer and a Klein Tools K-Type Thermocouple. The TMP117 and K-Type sensors were not moved throughout these test runs and the IR sensor was held at a relatively constant distance from the measuring point. We decided to use the center of the TMP117 as the measuring point for the IR sensor as this is the exact point where the TMP117 is evaluating the temperature of the room. We conducted three test runs with each run lasting three minutes and the temperature of all devices recorded simultaneously every 15 seconds, the setup for the procedure can be seen in Figure 26.

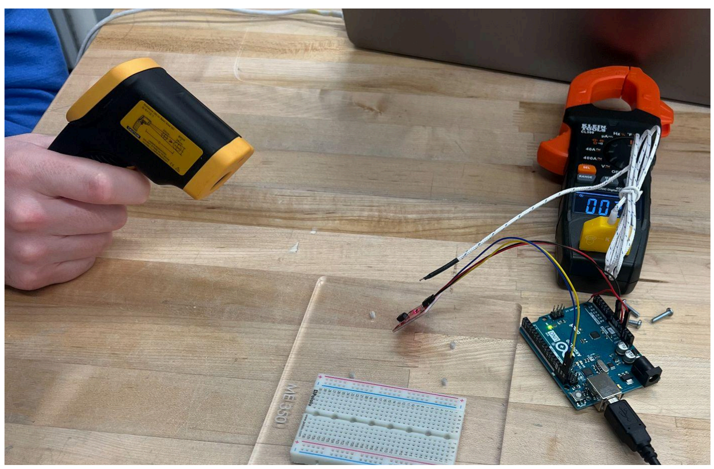


Figure 26: Sensor testing procedure setup

Results and Limitations

The sensor testing procedure described above has provided us with 13 comparable data points for each sensor across each test run, this data can be seen in Table 12 and Figure 27.

Table 12: Sensor Comparison Test Results

	Control Device: SparkFun Sensor (Accuracy: 0.1°C)			Verification 1: Infrared Thermometer (Accuracy: ± 1% OR 1°C)			Verification 2: Klein Tools AC/DC Digital Clamp Meter (Accuracy: ± 2°C)		
Time (sec)	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
0	23.05	23.27	23.41	22.1	22.3	22.2	23	24	24
15	23.01	23.33	23.45	22.4	22.3	22.2	23	24	24
30	23.02	23.32	23.47	22.4	22.4	22.3	23	24	24
45	23.09	23.35	23.5	22.4	22.7	22.2	23	24	24
60	23.12	23.39	23.49	22.4	22.6	22.3	23	24	24
75	23.14	23.36	23.52	22.4	22.5	22.1	23	24	24
90	23.05	23.39	23.52	22.4	22.2	22.1	23	24	24
105	23.05	23.41	23.57	22.4	22	22.1	23	24	24
120	23.09	23.43	23.53	22.3	22.5	22.1	23	24	24
135	23.02	23.42	23.45	22.3	22	22	23	24	24
150	23.11	23.45	23.51	22.3	22	22.1	23	24	24
165	23.03	23.44	23.51	22.3	21.8	22	23	24	24
180	23.12	23.48	23.51	22.2	22.9	22.2	23	24	24
AVG	23.069	23.388	23.495	22.331	22.323	22.146	23	24	24
error	0.100	0.100	0.100	1.005	1.005	1.005	2.236	2.236	2.236
Delta				0.738	1.065	1.349	0.069	-0.612	-0.505
STDEV	0.044	0.059	0.042	0.095	0.319	0.097	0.000	0.000	0.000

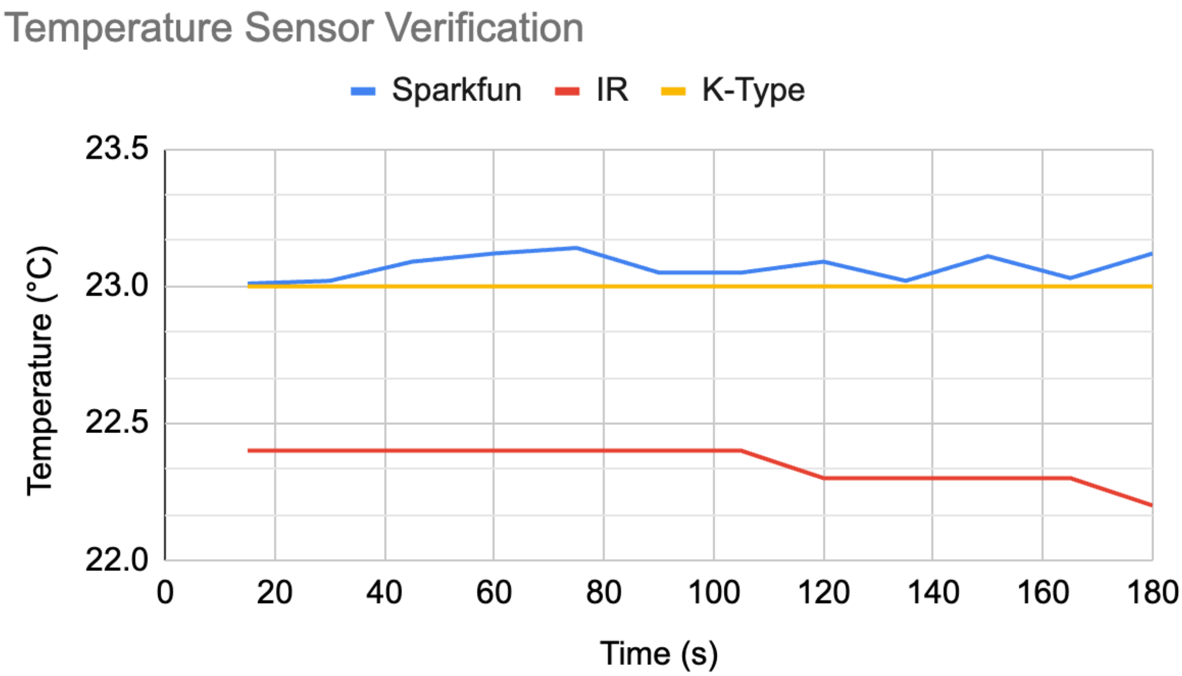


Figure 27: Sensor comparison graph, trial 1 results.

The results of this data inform us on the accuracy of the TMP117 and if it is providing reasonable measurements. The deltas across each test are within the combined error of the respective sensor and the TMP117 sensor with the exception of trial three between the TMP117 and the IR sensor by a margin of greater than 0.5°C, and trial two between the TMP117 and the IR sensor by a very small margin. While we are making the assumption of constant temperature within the testing area, we do understand that there will be small deviations within this temperature which will slightly alter the results. The IR sensor is also prone to user error as the distance at which it is measuring from will alter the results along with the exact point which the laser is being aimed at. As the measuring point on the TMP117 is relatively small and is surrounded by openings, some laser measurements may have been slightly off per our desired testing procedure. This deviation can be seen though the standard deviation of all recorded temperatures within each test, the IR sensor has significantly greater standard deviation within the temperatures recorded relative to the TMP117 with test two of the IR sensor having a standard deviation that is three times greater than any other test run.

Based on the results from this experiment we are able to conclude that the TMP117 sensor and arduino combo is providing reasonable results however we are not able to effectively evaluate the accuracy of the sensor as a result of this test. The most accurate sensor used to compare has an accuracy of ± 1% or 1°C, this is the highest degree of accuracy that would be ensured from this test. However, this sensor appeared to encounter some user error within the test which resulted in some test runs not providing evidence that the TMP117 sensor is accurate to this degree. In order to overcome this lack of definitive accuracy verification we will either incorporate point-to-point testing, or utilize more accurate sensors for comparison. As point-to-point testing is not accessible to us we will be utilizing more accurate sensors, we have currently spoken to professors and found a source which we can borrow these sensors from. Despite our constant temperature assumption we do understand that this room will have airflow and small temperature variations which limit the level of accuracy that can be verified from this test, for this reason we plan on finding a more consistent environment that will not introduce additional heat sources such as radiation which may be interpreted differently depending on the type of sensor being utilized. Finally, this test was not completed within a temperature range that would be considered reasonable for an incubator, as these sensors have varying levels of accuracy within different temperature ranges, we plan on conducting this test within an active incubator or a space that is at a similar temperature to what can be expected from an incubator. In conclusion, we now know that the TMP117 and Arduino is relaying reasonable temperature data but more intensive testing is needed to verify the accuracy of this sensor to the degree which is needed by our project. As a result of this analysis we will continue to move forward with the TMP117 and Arduino combination unless further testing yields results that lead us to believe that this combination does not effectively meet the needs of this project.

Engineering Analysis: Worry 2

Worry 2 states “Where must the user place the sensors to analyze areas of concern?” and is listed as a high priority. This worry stemmed from the fact that the M-HEAL incubator is a non-standard design and is the first of its kind. We worried that the IEC standard for where to place the sensors would be insufficient to analyze the incubator as a whole and that there would be potential cold spots that the IEC standard placement would be insufficient to detect. Therefore, we wanted to determine the potential areas of concern within the incubator and where exactly the user should place sensors within the incubator, in an effort to come to a conclusion of safety level for the incubator. In order to evaluate this concern, we considered multiple different methods of analysis as shown in Table 13.

Table 13: Potential Methods of Testing Worry Two

Method	Type/Rigor	Pros	Cons	Assumptions
Using Sensors to Map Temperature Gradient	Empirical Testing/High	Uses device actual sensors within real world incubator	Limitations of # of sensors and time to analyze every single point within the incubator	Accuracy error of the sensors is present
Simulation Software (ANSYS Discovery)	Theoretical Testing/Med	Creates very detailed visual temperature gradient	Mathematical approximations vs real world behavior	Where inflows and outflows are, room temperature etc.
First Principles Analysis	Theoretical/Med	Time efficient	Not detailed enough to generate a temp gradient representative of all points	Mathematical approximations

We considered multiple different methods of analysis to address this worry. We considered using sensors to create a temperature gradient by physically mapping the incubator over a number of tests. We would place sensors at numerous spots within the incubator, map their temperature at the point, and repeat the process. This is a form of empirical testing at a very high level of rigor. The method has an advantage because it measures the real world scenario compared to mathematical approximations. However, this is a very high rigor level method. However, we have limitations on budget and therefore the number of sensors we currently have. Therefore, we would most likely not have the budget to afford both a build design proof of concept and a separate device to create a map to determine where the INCUCheck sensors should be placed by the user. We would also have to assume that the accuracy error of the sensors would need to be taken into account for the temperature map. Because we have limitations on time as well, we deemed this method inefficient of our time and costly.

We considered using first principles analysis, a theoretical method that is medium level of rigor, to determine a theoretical map of temperature within the incubator. The method would be time efficient due to the fact that we would need to base the temperature map based on a set of mathematical equations. However, mathematical approximations would not be detailed enough to generate a temperature map that is truly representative of all points within the incubator. We would have to use certain assumptions about material and boundary conditions if using first principle analysis.

Lastly, we considered 3D simulation and analysis software to create an incubator temperature gradient. This is a theoretical method of medium level rigor. The software would be using mathematical approximations to calculate steady state streamlines based on whatever inputs the software is given. Similar to the first principles analysis, simulation software can also take into account the materials of the incubator, where the flows of fluids would be assumed to be coming from, and more.

Chosen Testing Method: ANSYS Discovery

We went with the theoretical method of analysis of simulation software because of how time and cost efficient the method was and that it satisfied the level of detail needed. It was detailed enough to provide specific information on the expected temperature in certain areas of the incubator. Most software is free and available for university students through the university app resources. We require a detailed 3D model of how temperature flows within the incubator as close as possible to the real world scenario and how the air would flow from inflows to outflows within the incubator. We specifically chose ANSYS Discovery because it has an easy to use interface, has the ability to analyze detailed CADs, and has multiple simulation capabilities including thermal and fluid flow. ANSYS Discovery is not a traditional very complex CFD software but essentially contains the key functionalities of CFD software in an easy to use package. Further, one of our members has previous experience with ANSYS Discovery, and would be a great use of already existing resources. We believe simulation software would be the best method to address this worry as we will not be using this simulation to check our sensors against but to help address overall temperature flow behavior.

ANSYS Discovery Procedure

We first began analysis by identifying certain boundary conditions and parameters that the software would run under. By discussing with the M-HEAL team about how the incubator was designed, we were able to identify the theoretical inflows and outflows of the incubator. The incubator was designed with the intention that air would flow through the upper corners of the incubator and would flow out of the ventilation holes at the bottom of the incubator and the portholes if opened by the user. These inflow and outflow assumptions were also confirmed with Professor Adera, an expert in heat transfer and fluid dynamics. The images below show the identification of inflows and outflows within the simulation.

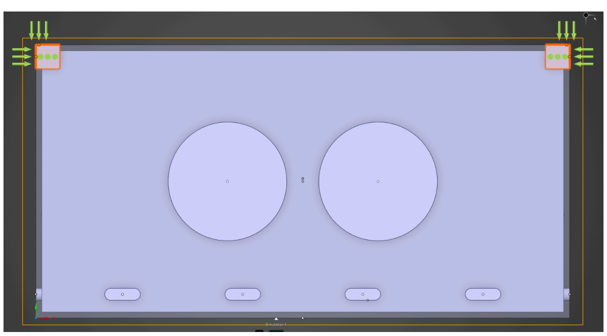


Figure 28a: Inflow Parameters

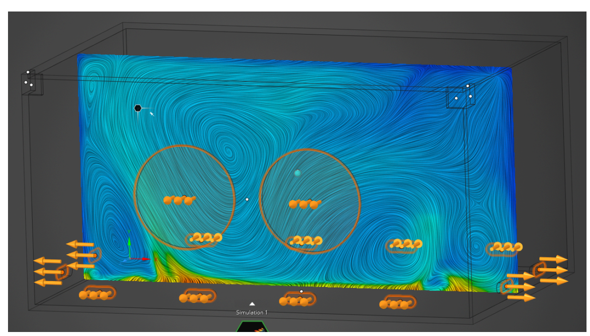


Figure 28b: Inflow Parameters

Next we determined how we were going to simulate the Warmilu within the software. We discussed with the M-HEAL Team about the incubator and how the Warmilu would be placed upon a layer of insulated material. The WarmiLu mattress averages at a temperature of 102.2 ℉ for 3 hours [42]. Therefore we identified the incubator bottom plane would be set at a constant temperature of 102.2 ℉. Further, we discussed with Professor Adera about further boundary conditions and parameters including the incubator having convection coefficient of 3 W/m^2 ℃ and at 22℃. The selected material for the incubator was set to Acrylic Plastic (PMMA). At all inflows, we determined that air velocity would be 0.1 m/s. This parameter comes from the ANSI/ASHRAE Standard for Thermal Environmental Conditions for Human Occupancy and the average internal air velocity at a comfortable indoor environment [43]. The inflow air temperature would be at 22℃, average room temperature. The outflows were set at a pressure of 0 Pa. From discussion with Professor Adera, these parameters had all been checked in regards to their validity based on his previous experience. Gravity was also included in the simulation.

After all parameters were set, the simulation was run and mathematical approximations were run on a steady state case. We took points along the central axis and points of temperature to obtain quantitative data along with visual qualitative data from the visual direction field of the incubator. Figure 29 below shows the approximate locations of the points at which temperature was measured.

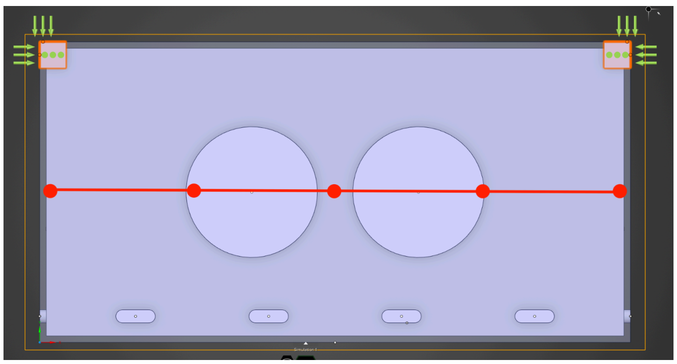


Figure 29: Points for Measurement of Temperature in Direction Field

This method of measuring temperature in the direction field was repeated for the worst case scenario with the portholes open. This system for recording temperature is used in an effort to analyze the incubator at different scenarios that are likely to happen, such as someone leaving the portholes open by accident. Figure 30 below displays the temperature direction field for both analysis cases. ANSYS Discovery displays a temperature gradient color scale to show how the air flows vary with temperature for either case. The figure below shows the temperature gradient and the associated colors with flows.

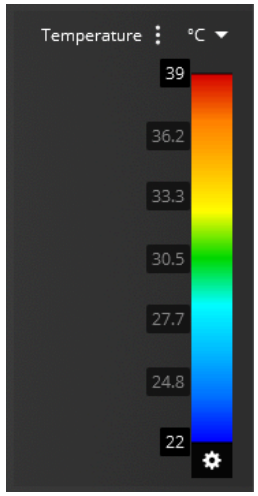


Figure 30: Temperature Gradient Color Scale

Worry 2 ANSYS Discovery Results

The Figure 31a, 31b, 32a, and 32b below show the direction field for both cases of analysis: Base Case 1 with portholes closed and Case 2 with portholes open as well as the streamlines for both cases.

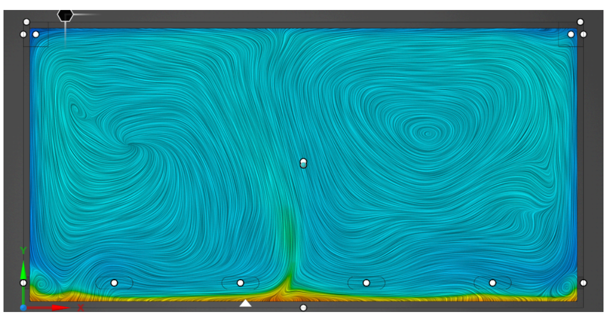


Figure 31a: Portholes Closed

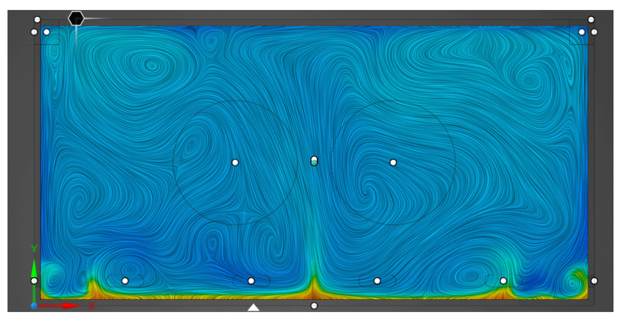
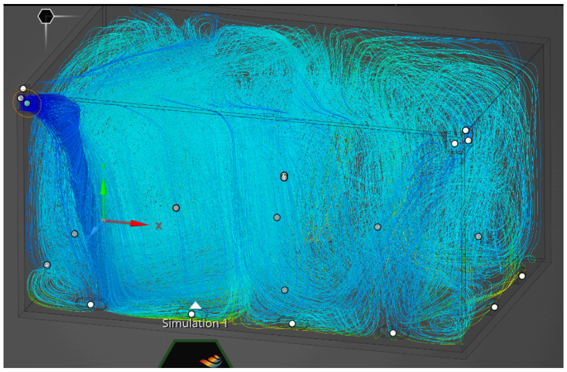


Figure 31b: Porthole Open

Figure 31(a) and 31(b): ANSYS Discovery Fluid Flow Analysis Direction Field for case of portholes closed (left) and open (right)



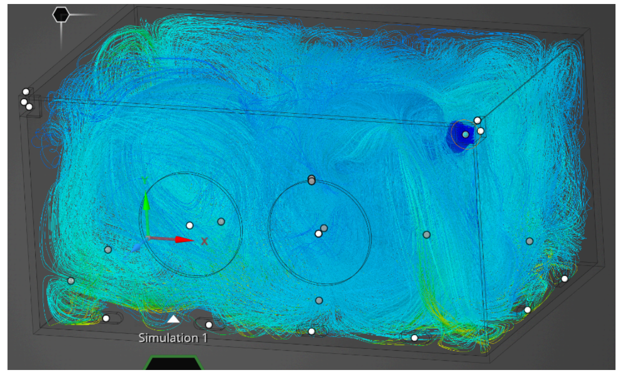


Figure 32a: Portholes Closed **Figure 32b:** Porthole Open

Figure 32(a) an 32(b): ANSYS Discovery Fluid Flow Analysis Streamlines for case of portholes closed (left) and open (right)

From the analysis, it was clear that in the case where the portholes are open, the average temperature of the incubator is higher than when the incubator has the portholes open, which is behavior that is expected. This analysis was discussed with Professor Adera, an expert in heat transfer, who confirmed the behavior of the direction fields, that the analysis was accurate and the direction fields presented are very much expected under the conditions we put within the simulation. From this discussion, we have a higher level of confidence that this analysis is presenting accurate simulations similar to expected real world scenarios. This behavior was also represented in the collected data from the five points within the incubator which is summarized in the table below.

Table 14: Recorded Temperatures From Ansys Simulation for Base and Portholes Open Case

	Temp 1 (℃)	Temp 2 (℃)	Temp 3 (℃)	Temp 4 (℃)	Temp 5 (℃)	Average Temperature (℃)
Base	28	27.7	27.8	27.9	27.9	27.9
Portholes	27	27.5	25.8	26.5	26.8	26.7

The numerical data confirmed the average temperature of each case matches the visual inspection of the simulation. From a visual standpoint, the coldest spots within the incubator were along the corners of the incubator and walls of the incubator. Our Alpha design due to the telescoping aspect of the does have the ability to reach the high ceilings of the incubator. This analysis confirmed that our design has the ability to reach high ceiling points but there was concern if the large boards could reach very tight corners according to the IEC standard as the standard restricts the sensors to essentially be touching the corner walls. This was taken into account into further development in the Beta design. The limitations of ANSYS Discovery do include the fact that the simulation was all based on mathematical calculations (that ANSYS does not explicitly display what equations it is solving) and by nature would not always accurately represent the real world simulation. But our high level of confidence allowed us to go forward with accepting this mode of analysis and concluding that the outer walls and corners (specifically the open corners) were the biggest areas of concern.

Engineering Analysis: Worry 3

Worry 3 states “Would the alpha design introduce thermal air flow variations that stray away from base case incubator behavior?” and is listed as a high priority. This worry stemmed from the fact that we were concerned that the presence of the stands within the incubator would cause different air flow variations in the incubator. We wanted to ensure that the incubator is going to sense temperature data that is representative of the case where the device would not be present within the incubator and therefore the data collected from the device would have a confidence level to inform towards the safety of the incubator. In order to evaluate this concern, we considered multiple different methods of analysis as shown in Table 15.

Table 15: Potential Methods of Testing Worry Three

Method	Type/Rigor	Pros	Cons	Assumptions
Using 3rd Party Device to Compare To	Empirical Testing/High	Would know exact contribution of device (spec sheet)	Limitations of budget and time to analyze every single point within the incubator	Accuracy error of the sensors is present
Simulation Software (ANSYS Discovery)	Theoretical Testing/Med	Creates very detailed visual temperature gradient	Mathematical approximations vs real world behavior	Where inflows and outflows are, room temperature etc.
First Principles Analysis	Theoretical/Med	Time efficient	Not detailed enough to generate a temp gradient representative of all points	Mathematical approximations

We considered multiple different methods of analysis to address this worry. We considered using a third party device that already has a known correction factor or known calibration curve. This third party device method is a form of empirical testing at a very high level of rigor. The method has an advantage because it already has a known contribution of temperature variation according to the spec sheet. However, we have limitations on budget and time and did not need the necessity to spend the budget on a third party device to verify one single worry of our design. Furthermore, it would take a lot of empirical tests and time to determine a quantifiable factor of how our design, which is not fully built and most likely will not be completed until design expo, affects the base case temperature of the incubator. We would also have to assume that the accuracy error of the sensors would need to be taken into account.

We considered using first principles analysis, a theoretical method that is medium level of rigor, to determine the effect of the alpha design. The method would be time efficient due to the fact that we would need to use a set of mathematical equations and assumptions. However, mathematical approximations would not be detailed enough to generate a temperature map that is truly representative of all points within the incubator that could compare to the base case. We would also have to use certain assumptions about material and boundary conditions if using first principle analysis.

Lastly, we considered 3D simulation and analysis software to create an incubator temperature gradient with a CAD that includes our device to compare it to the base case. This is a theoretical method of medium level rigor. The software would be using mathematical approximations to calculate steady state streamlines based on whatever inputs the software is given. Similar to the first principles analysis, simulation software can also take into account the materials of the incubator, where the flows of fluids would be assumed to be coming from, and more.

Chosen Testing Method: ANSYS Discovery

We went with the theoretical method of analysis of simulation software because of how time efficient the method is, it satisfies our level of detail needed, and how cost efficient the method is. Most software is free and available for university students through the university app resources. We require a detailed 3D model of how temperature flows within the incubator in reaction to the device being present and be as close as possible to the real world scenario and how the air would flow from flows to outflows within the incubator. Due to similar reasons as stated before, we specifically chose ANSYS Discovery because it has an easy to use interface, has the ability to analyze detailed CADs, and has multiple simulation capabilities including thermal and fluid flow. We believe simulation software would be the best method to address this worry with already existing resources.

ANSYS Discovery Procedure

We first began analysis by identifying certain boundary conditions and parameters that the software would run under. We chose to set the standard position at which the device stands would be evaluated to be according to IEC standard in an effort to keep a control. The exact same conditions and parameters used when evaluating worry two. The same inflow and outflows were used, according to Figure 28a and 28b. The the incubator bottom plane would be set at a constant temperature of 102.2 ℉. According to Professor Adera's advice, the incubator was set to the same convection coefficient as before of 3 W/m^2 ℃ and at 22℃. The air velocity again would be set to 0.1 m/s [43]. Inflow air temperature would be at 22 ℃ and outflows were set at a pressure of 0 Pa. Gravity was included in the simulation as expected to real work conditions against the center of gravity of the incubator. The selected material for the incubator was set to Acrylic Plastic (PMMA). One limitation of this analysis was that the program allows the CAD geometry set in the program to only be set to one material therefore the program thinks the device stands are also made of acrylic plastic. This was a far assumption as the stand assemblies would consist of wood and metal. We inputted a CAD of the incubator with the Alpha design stands set at the IEC standard positions. The IEC Standard for sensor placement applies to all market incubators, however the M-HEAL incubator is smaller than many standard incubators. Therefore we scaled the IEC standard down to the size of the M-HEAL Incubator. These scaled down measurements can be seen in the figure below.

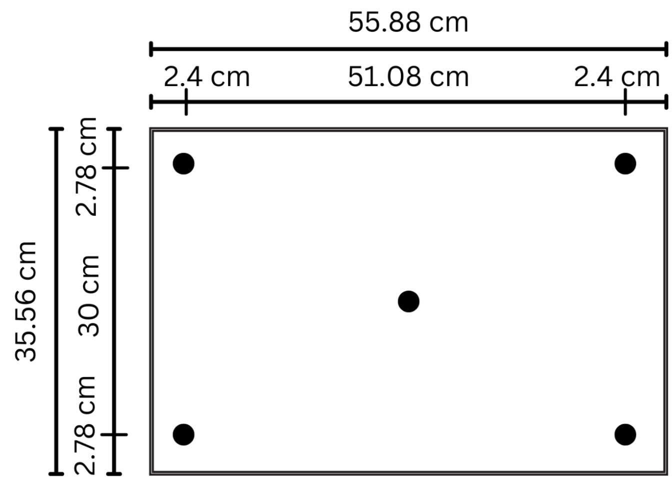


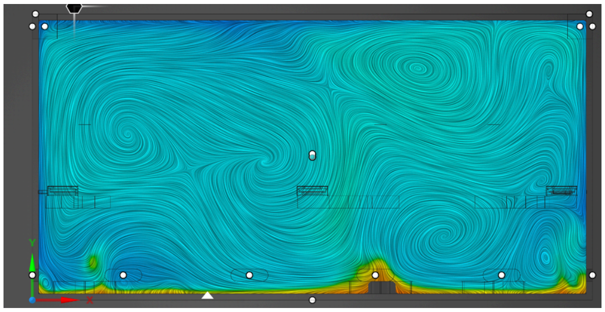
Figure 33: Scaled Down IEC Stand Placement for M-HEAL Incubator

In an effort to set the sensors in the correct spot, which is in a very tight position against the corners, we reduced the board stand size to 5.08x5.08 cm for the simulation as the majority of the variation of air flows should be coming from the poles according to discussion with Professor Adera. After all parameters were set, the simulation was run and mathematical approximations were run on a steady state case. We took points along the central axis and points of temperature to obtain quantitative data along with visual qualitative data from the visual direction field of the incubator according to Figure 31. We also ran simulations with floating sensors in the scaled down IEC positions to identify how the sensors themselves may affect the thermal air flows.

This was repeated for the worst case scenario with the portholes open. This is in an effort to analyze the incubator at different scenarios that are likely to happen, such as someone leaving the portholes open by accident. The same temperature gradient color scale was used by the program when analyzing worry 2 as shown in Figure 30.

Worry 3 ANSYS Discovery Results

The Figures 34a, 34b, 35a, and 35b below show the direction field for both cases of analysis: Base Case 1 with portholes closed (device stands present) and Case 2 with portholes open as well as the streamlines for both cases present (device stands present).



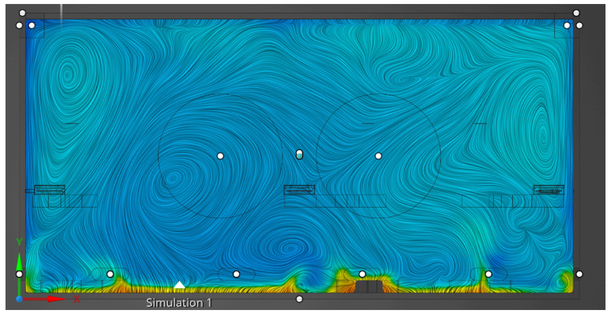
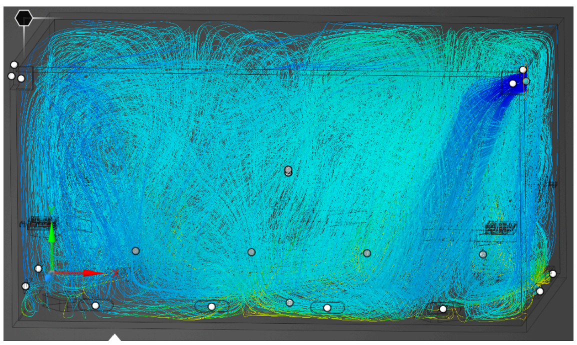


Figure 34a: Portholes Closed **Figure 34b:** Porthole Open

Figure 34(a) an 34(b): ANSYS Discovery Fluid Flow Analysis Direction Field for case of portholes closed (left) and open (right) (floating sensors present)



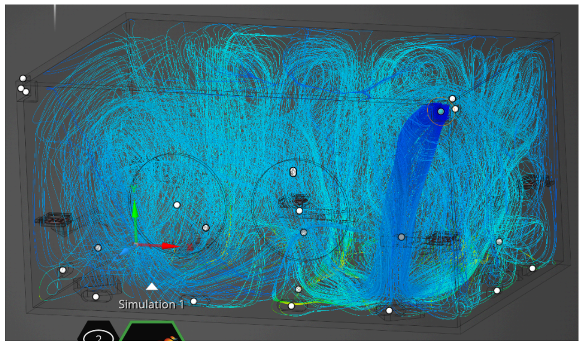


Figure 35a: Portholes Closed **Figure 35b:** Porthole Open

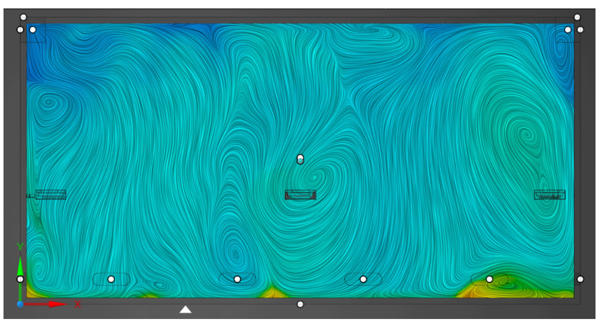
Figure 35(a) an 35(b): ANSYS Discovery Fluid Flow Analysis Streamlines for case of portholes closed (left) and open (right) (floating sensors present)

From the analysis, it was clear that in the case where the portholes are open, the average temperature of the incubator was still higher than when the incubator has the portholes open, which is behavior that was expected. However, there were many different variations in consistent circular flow within the incubator with the portholes closed. This analysis was discussed with Professor Adera who confirmed the behavior of the direction fields; that these direction fields were very much expected under the conditions we put within the simulation. We discussed how for a stand to have no physical impact on the air flows within the incubator, the diameter of the stand would have to be zero. Professor Adera showed us his own experiments in his lab where he was utilizing thermocouples. He began to point out how the extremely thin thermocouples still will affect the air flows despite having a very small physical footprint. Table 16 below shows the quantitative points from the stand analysis in ANSYS.

Table 16: Recorded Temperatures From Ansys Simulation for Base and Portholes Open Case with Stand

	Temp 1 (℃)	Temp 2 (℃)	Temp 3 (℃)	Temp 4 (℃)	Temp 5 (℃)	Average Temperature (℃)
Base (Stand)	28	27.9	28	28.2	27.7	28.0
Base	28	27.7	27.8	27.9	27.9	27.9
Portholes (Stand)	27.1	26.9	26.7	27.3	26.4	26.9
Portholes	27	27.5	25.8	26.5	26.8	26.7

On average the centerline temperature in the base case, varies by 0.1 ℃ such that the case with the stands varies by 0.1 ℃. On average the centerline temperature for when the portholes are open, varies by 0.2 ℃. We also analyzed the CAD with just sensors floating in their position to analyze the impact of the rods themselves. The Figures 36a, 36b, 37a, and 37b below show the direction field for both cases of analysis: Base Case 1 with portholes closed (floating sensors present) and Case 2 with portholes open as well as the streamlines for both cases present in the figures below.



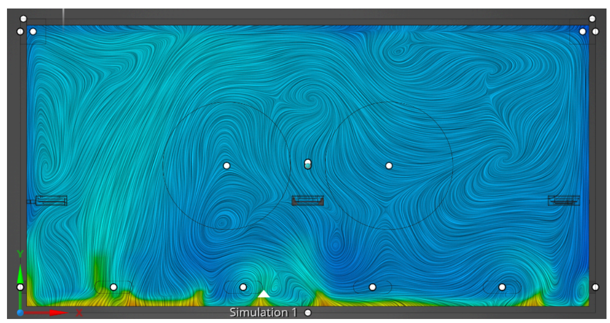
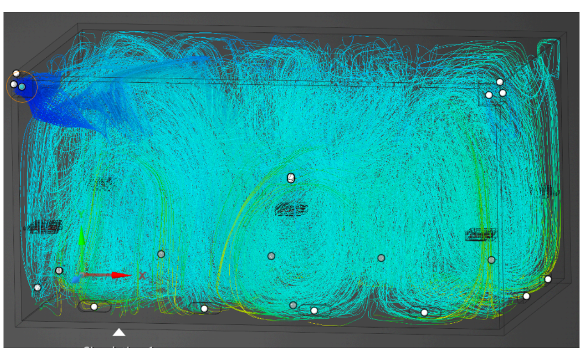


Figure 36a: Portholes Closed **Figure 36b:** Porthole Open

Figure 36(a) an 36(b): ANSYS Discovery Fluid Flow Analysis Direction Field for case of portholes closed and open (device standards present)



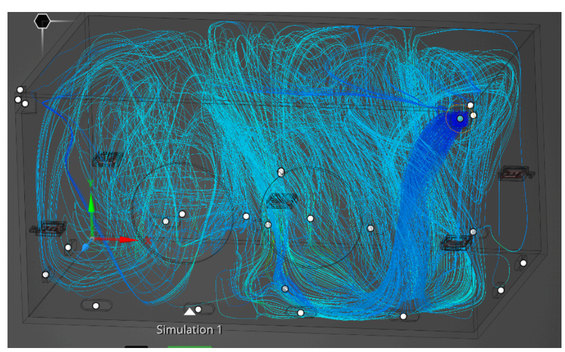


Figure 37a: Portholes Closed **Figure 37b:** Porthole Open

Figure 37(a) an 37(b): ANSYS Discovery Fluid Flow Analysis Direction Field for case of portholes closed and open (device standards present)

From the analysis, it was clear that in the case where the portholes are open, the average temperature of the incubator was still higher than when the incubator has the portholes open, which was behavior that was expected. There were expected variations in the air flows surrounding the sensors. The table below shows the quantitative points from the floating sensor analysis in ANSYS.

Table 17: Recorded Temperatures From Ansys Simulation for Base and Portholes Open Case with Floating Sensors

	Temp 1 (℃)	Temp 2 (℃)	Temp 3 (℃)	Temp 4 (℃)	Temp 5 (℃)	Average Temperature (℃)
Base (Float)	28.4	28	27.8	27.4	28.2	28.0
Base (Stand)	28	27.9	28	28.2	27.7	28.0
Base	28	27.7	27.8	27.9	27.9	27.9
Portholes (Float)	27.1	26	25.6	27	27.8	26.7
Portholes (Stand)	27.1	26.9	26.7	27.3	26.4	26.9
Portholes	27	27.5	25.8	26.5	26.8	26.7

On average the centerline temperature in the base case varied by 0.1 ℃ such that the case with the floating sensors varied by 0.1 ℃. On average the centerline temperature for when the portholes are open varies by 0 ℃ between the float sensor case and base portholes case. From all the ANSYS analysis the presence of stands and sensors caused temperature variations from 0.1 to 0.2 ℃. We discussed with Dr. Johnson from Michigan Medicine on the issue of varying degrees in temperature and what was considered significant enough to alter the neonate's environment from a safe one to an unsafe one. He deemed that a 0.1 ℃ difference would not be significant enough of a drop in temperature to alert the environment of the incubator as unsafe. As the portholes open case is a worse case scenario, in a more likely case the portholes will be closed it is more probable that the 0.1 ℃ difference would occur.

It is important to note that the analysis is based on the assumption that the material of the stands and or floating sensors is set as Acrylic Plastic (PMMA) so the approximations may vary. However, in the scope of the current project, the device is aimed to be used by M-HEAL to start initial tests to further advance towards clinical trials and to see how to improve their design. It is the objective of M-HEAL to use the device to see in the real world application temperature of the incubator, so it would not be deemed a significant worry based on the data presented. We have a high level of confidence that the simulation addresses the concerns we want to address with this detailed level of analysis.

One important factor to take away from this analysis is that it seems from the ANSYS stand analysis that some temperature variations may have stemmed from the fact that the program believes that the bottom stands would heat up slightly. According to the averaged temperature data, this increase in temperature of the boards would not act as a significant heat source in the system. But this aspect of the Alpha design is one major thing we want to address. From this analysis, we will edit our Alpha design to aim towards a design that does not introduce potential heat sources other than the WarmiLu like physical objects in contact with the WarmiLu.

Engineering Analysis: Worry 4

Worry 4 states "Are we able to use six TMP117 sensors with only one Arduino Uno?" and is listed as a high priority. This worry stems from our concern about only having one Arduino Uno that must be able to provide power to and receive data from six individual *Sparkfun* TMP117 ambient temperature sensors. We want to ensure that the IncuCheck device can reliably and effectively produce the results of the temperature inside of the M-HEAL incubator. In order to evaluate this concern, we considered two different methods of analysis as shown in Table 18.

Table 18: Potential Methods of Testing Worry Four

Method	Type/Rigor	Pros	Cons	Assumptions
Experimental Trials	Empirical Testing/ High	Hands-on If it works no further effort required	Very little electro-mechanical knowledge right now Safety issues Potentially break a sensor/Arduino if wired improperly	We have 5 or 6 sensors on hand
Research Evaluation	Theoretical/ Med	Time efficient	Not making physical connections Might not yield results we are looking for	We will be able to find something online that helps us/matches what we need to do

The first of the two different testing methods, running experimental trials, is an empirical test of high rigor. The potential positives for this method included hands-on work of the physical prototype in addition to requiring no further work if the method succeeds. The downsides of this method started with the fact that none of the members of our group have deep levels of understanding in the electro-mechanical field. We all took EECS 314 which introduced us to this topic, however none of us have worked with *Arduino* and *Sparkfun* in the past. Because of this, running experimental trials could also potentially break a sensor or the Arduino we have if wired improperly. When the analysis was done we only had a single *Adruino* and *Sparkfun* sensor, which meant if we broke either one we would be without any devices to continue to prototype our design with. In addition, safety was a large concern of ours since we didn't really know what we were doing. The voltages are not high enough to seriously injure us, however we wanted to ensure that we considered this when taking into consideration the entire analysis process. The assumptions made included having more than one sensor on hand to test with.

The second potential testing method considered was research evaluation. This is a highly theoretical approach and has a medium in rigor. The major pro for this method of analysis is that it is very time efficient. Quick searches on the web can yield very helpful results. The two potential negatives for this analysis method include not making any physical progress with the actual devices and potentially not finding any information on the topic. Our assumptions made for this analysis included the fact that people have done this before and documented their process. Without this, we would not be able to find anything related to this unless *Arduino* or *Sparkfun* had written anything about the connections.

Chosen Testing Method: Research Evaluation

The research evaluation analysis method was chosen because it had more potential for success than the experimental trials while also having less potential downsides. The analysis method also satisfies our level of detail needed and is not a time consuming process. The research evaluation avoided us breaking any sensors or the *Arduino* that we have. We also were able to understand how other people worked out the same problem. This enabled us to learn from other people's mistakes and be able to save ourselves time. Learning from others also helps us with our own electro-mechanical knowledge of the *Arduino* and *Sparkfun* systems.

Research Evaluation Procedure

The procedure for the research analysis was very simple. We made some quick google searches to see if there were any hits from the forums on either the *Arduino* or the *Sparkfun* side. We also browsed the Arduino and Sparkfun websites for the specific product information pages of the products we are using in our design. These quick searches yielded an immense amount of results that closely matched what we were looking for.

Worry 4 Research Analysis Results

The results of the research analysis were extremely positive. We were able to find plenty of documentation in regards to the connection between *Sparkfun* sensors and an *Arduino* board. More importantly, we were also able to find information on connecting multiple sensors to our single *Arduino* uno board [44], [45], [46], [47], [48], [49]. An example of information we found was in the *Sparkfun* forums. The form is titled "multiple sensors on Arduino" and contains a question from a user about connecting multiple sensors to a single *Arduino*. Another user responds with information on writing the correct code for multiple *Sparkfun* sensors connected to an *Arduino* board. In addition to forums like this one, *Sparkfun* and *Arduino* both have information available on their respective websites on how to connect *Sparkfun* sensors to *Arduino* boards.

We have been able to gather example code, wiring diagrams, and potential alternative methods to wire multiple *Sparkfun* TMP117 sensors to our *Arduino Uno*. The best potential alternative to using our current setup with a breadboard is called the Sparkfun Qwiic Mux Breakout [49]. This board, when connected to a Qwiic enabled system, can process information from up to eight separate channels. This means that from the single board, up to eight separate TMP117 sensors can be wired into it. The board, using the Qwiic system, can be connected to the eight sensors while also connected to the Arduino board, supplying all of the sensors with power and a place to send data. The potential for the Qwiic Mux system is very high and we have already purchased one to potentially use in the beta/build design. Using our information gathered through the research analysis will help aid us when setting up the Qwiic Mux and the six TMP117 sensors in our beta design.

Engineering Analysis: Worry 5

This worry is related to whether or not we are able to develop a design user interface compatible with the Arduino data logger, and how complex the resulting interface will be. This worry was the result of our limited technical knowledge in computer science, and whether or not we have the capability to create a user interface that collects data from the Arduino, and presents it in a way that is easy for the user to interact with and interpret. Currently, the Arduino outputs data from the SparkFun temperature sensor into the serial monitor, and lists out values one after the other, in one second increments. This visualization method makes it difficult for users to see any patterns in the data, or read the numbers quick enough to draw any conclusions. Therefore, a secondary interface is necessary for an engineer's use case.

Table 19: Potential Methods of Testing Worry Five

Method	Type/Rigor	Pros	Cons
Finding Relevant Documentation	Theoretical Testing/ Low	Wide and extensive availability of Arduino documentation	More difficult to find documentation relevant to our specific use case
Building out an Initial Application	Empirical Testing/ High	Allows us to see technical capabilities of Python first hand	More technically complex and time consuming

To design this test, we considered two primary options: theoretically planning out the user interface, and empirically testing out ways of building it out. While the theoretical collection of documentation would allow us to see if this is technically feasible, we found that there was less documentation available regarding our specific use case, for translating the output from an Arduino serial monitor to a web application for users to interpret. Therefore, we would have to make several assumptions to fill in the gaps in data, to determine whether or not our specific use case is possible. For the empirical testing option, however, we can apply the available documentation to our own code, and attempt to build out a portion of the user- facing web application. While this is significantly more time consuming, building our own code allows us to customize it for our specific application, and understand whether or not it is feasible to translate Arduino data to a web application.

Chosen Testing Method and Procedure

Given the two options outlined above, we opted to begin building out our application using Python as the backend language, Flask as the web development framework, and Matplotlib as the Python visualization library. While it presented difficulty in terms of the implementation, we were able to use online resources to troubleshoot the code logic, and follow tutorials for building a basic web application. The creation of the user interface is a two part process: (1) downloading a program, puTTY, to translate the Arduino serial monitor output into a .csv file and [50] (2) take in the readings from the .csv file and translate it into a time vs. temperature graph on the web application. Using our initial research, we deemed both of these functions to be within scope of the project, because it only involves roughly 100 lines of code, using a language that is broadly documented and relatively intuitive from a coding perspective. Therefore, this testing method, despite being more rigorous, did a better job at answering the worry and allowing us to verify whether it was possible.

Empirical Testing Results and Limitations

The initial version of the interface can be seen in Figure 38 below. When the user opens the web application, they are then taken to a page where they can view the temperature data as a function of time. Using documentation, we determined that puTTY allows the user to export data from the Arduino serial monitor, as a .csv file. Therefore, our code picks up from this step, and reads in a .csv file and graphs the resulting data, allowing the user to see trends in temperature changes as a function of time. While our initial mockup does not represent the full functionality of the final design, it allowed us to determine that the combination of Flask, Python and Matplotlib was in fact able to generate a plot that would allow a user to read data beyond the list form produced in the Arduino serial monitor. The data shown in the figure below is a list of randomly generated data points, which were used for the purposes of testing the code and do not represent actual outputs from the temperature sensors.

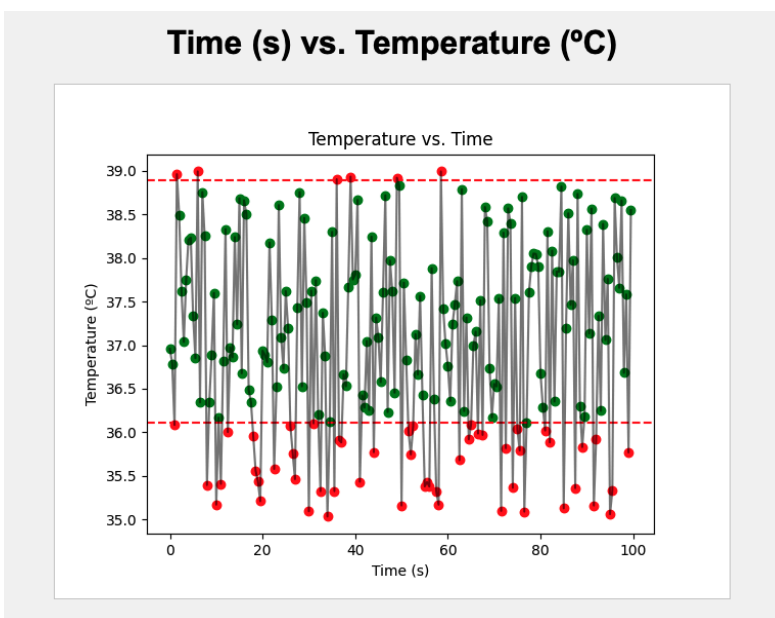


Figure 38: Visualization of Temperature Data

The major limitation of this method of user interface creation is the inability of the web application to actually interface with the Arduino itself. Therefore, while this web application can be used for data visualization and pattern recognition, it cannot actually start or stop the sensor from logging data. However, for the purposes of the build design, we determined this functionality to be out of the scope of the ME450 semester, given that it necessitates the use of more complex computer science principles which would take time and resources away from the core mechanical components of the project. Additionally, considering that our primary stakeholder is M-HEAL engineers, we can assume that they are familiar with the use of an Arduino, and can therefore collect the data using Arduino, and analyze it via our supplemental ME450 application, with puTTY as an intermediary between the two steps.

Moving forward, we are looking to add additional functionality, as well as stylistic components of the project to create a more fleshed out user interface. Specifically, we are looking to add a zone on the graph that shows the optimal temperature for the incubator, so a testing engineer can quickly identify whether or not the incubator is operating in the necessary conditions. Additionally, we can also add error bars and color coding, to show when the incubator goes in and out of the ideal temperature range. Overall, the results of this analysis can help inform how complex our user interface can be, and what features are and are not attainable as we move into the final beta and build design.

Key Takeaways from Engineering Analysis

Take Away from Worry 1

Based on the results from this experiment we are able to conclude that the TMP117 sensor and arduino combo is providing reasonable results however we are not able to effectively evaluate the accuracy of the sensor to the degree needed as a result of this test. The most accurate sensor used to compare has an accuracy of ± 1% or 1°C, this is the highest degree of accuracy that could potentially be verified from this test. However, his sensor appeared to encounter some user error within the test which resulted in some test runs not providing evidence that the TMP117 sensor is accurate to this degree. In order to overcome this lack of verified accuracy we will utilize more accurate sensors for comparison in a future test along with using an enclosed space to avoid the effects of radiation and airflow on the sensors.

Take Away from Worry 2

The coldest spots within the incubator are along the corners of the incubator and walls of the incubator based on our analysis from ANSYS Discovery. This confirms that our design has the ability to reach high ceiling points but the large boards can not reach very tight corners according to the IEC standard as the standard restricts the sensors to essentially be touching the corner walls. Our Beta design must take into consideration the scaled down IEC standard for sensor placement and allow for very tight orientation.

Take Away from Worry 3

Our design introduces variations in thermal air flows within the incubator on multiple steady state scenarios. However, a 0.1 ℃ difference in temperature variations would not be significant enough of a drop in temperature to alert the environment of the incubator as unsafe. It is the objective of M-HEAL to use the device to see in the real world application temperature of the incubator, so it would not be deemed a significant worry based on presented data. Another important factor to take away from this analysis is that it seems from the ANSYS stand analysis that some temperature variations may also be stemming from the fact that the program believes that the bottom stands would heat up slightly. From this analysis, our Alpha design should be revisited to make sure to not introduce potential heat sources other than the WarmiLu like physical objects in contact with the WarmiLu. Thus, a design needs to be pursued where there is no contact with teh WarmiLu such that the device itself becomes a heat source within the incubator.

Take Away from Worry 4

The main takeaway from worry four is that we have high confidence in our ability to wire multiple Sparkfun TMP117 sensors to a single Arduino Uno. We have gathered information from Arduino and Sparkfun forums in addition to direct manufacture directions/wiring diagrams on attaching the components together. We also found multiple ways to wire the setup together and we ultimately chose the easiest and simplest way to implement the sensors, using the Qwiic Mux. Although we found great instructions and examples on how to connect multiple Sparkfun sensors to the Arduino Uno, we never were able to physically wire the sensors to the Arduino. This is the only major downside for this worry, however we are confident in our ability to be able to wire the Sparkfun sensors to the Arduino. To achieve this we have purchased additional sensors, PCBs, and wires from Sparkfun. Once we receive these items we can start connecting everything together to create the web of interconnected sensors.

Take Away from Worry 5

Given the complexity of the Python code necessary to create an interface where the user is able to directly interface with the Arduino, we deemed this out of the scope of our build design. Instead, the build design will allow a user to enter into the output from the Arduino serial monitor and identify patterns in the data. However, the final ME450 design will include an interface that allows the user to select start, stop and view log, and interact directly with the functions of the Arduino.

Concept Description

The final design concept we created is the third evolution of our IncuCheck design after taking into consideration the results of engineering analysis. The 3D CAD model built in Solidworks is designed to meet the requirements and associated engineering specifications we wrote for the incubator testing device. An overall, isometric view of the entire model can be seen in Figure 39 below. Figure 40, also below, shows a layout drawing of the IncuCheck system and Figure 41 shows an operational diagram on how each of the subsystems work together. The four main subsystems include the housing, the controller, the stand components, and the sensors.

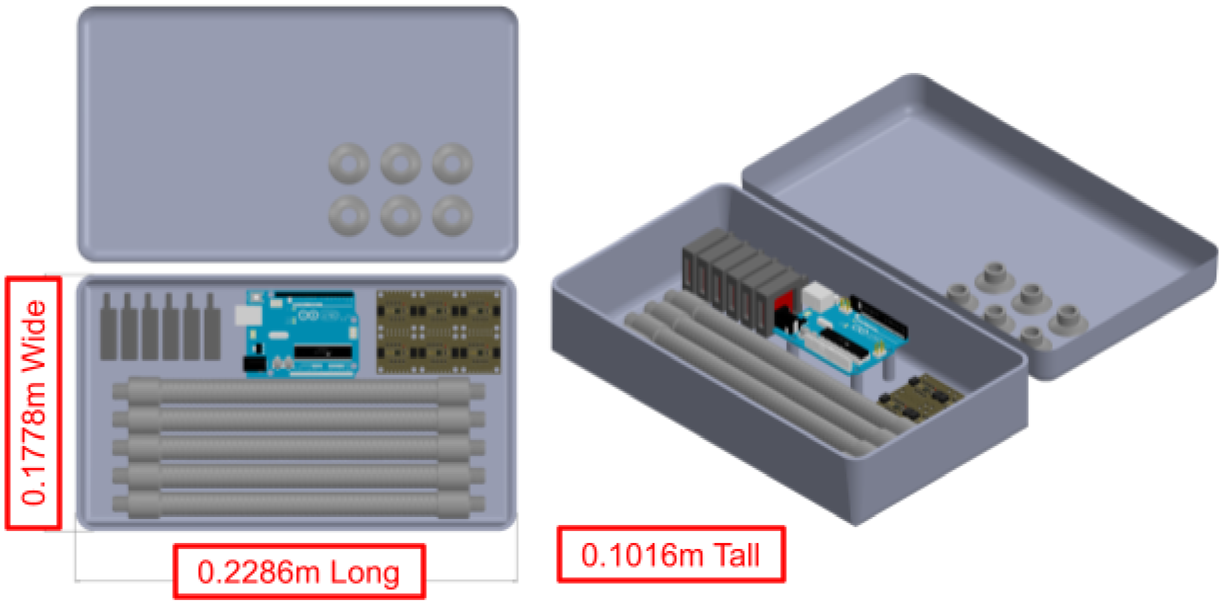


Figure 39: isometric view of CAD model

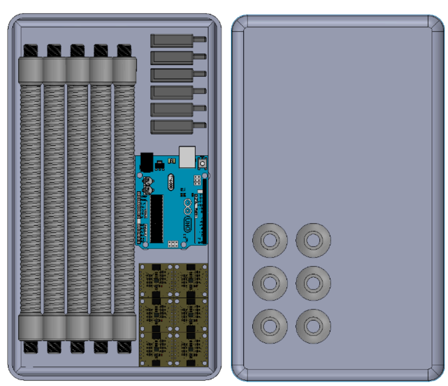


Figure 40: top down view of inside of the pelican case

Device Operation

There is only one stage of operation for the device: when it is fully set up with all components in their correct position. The sensors must be connected to the Arduino, which must be connected to the provided computer. The stands must be in the M-HEAL incubator and attached to the walls. The case must be outside of the incubator and not affecting the thermodynamic properties of the incubator.

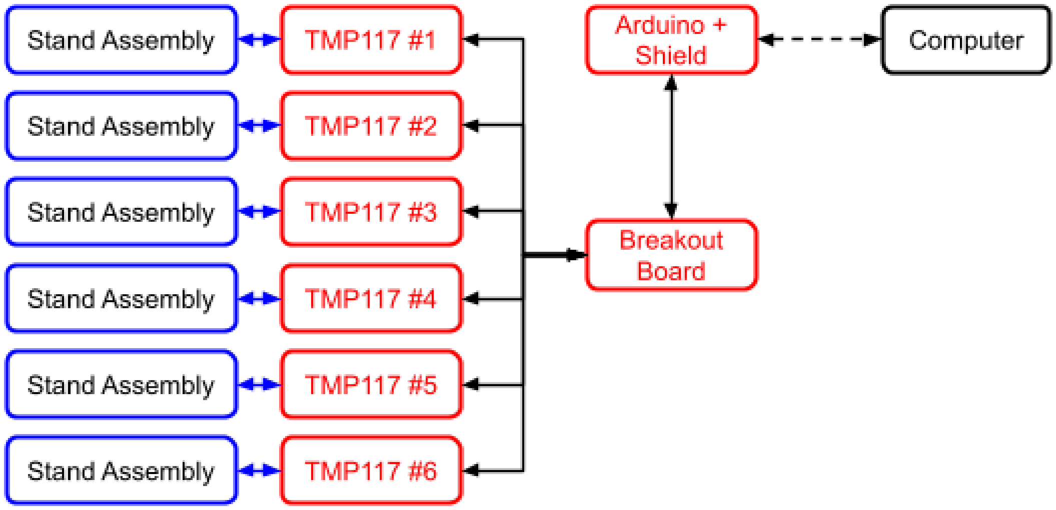


Figure 41: Operational diagram of the IncuCheck device.

Housing

The housing, shown in Figure 42, is a purchased, off-the-shelf case made by Pelican. Its main purpose is to ensure the other subassemblies are contained safely and are unharmed during travel. The case is crushproof, vibration and shock resistant, and waterproof. This robust foundation provides safety for the entire device while not in use. The housing contains the three other subassemblies and is also modular. The integrated yet removable block foam sections enable full customization to the exact dimensions of the devices housed within the case. This also enables the interior to accommodate different components if the device were to be upgraded or changed in any way.

Figure 42: plain, empty pelican case

Controller

The controller subassembly is the brains behind our device, with the three components shown in Figure 43. The Arduino, Sparkfun Shield, and Sparkfun Mux Breakout devices are all contained within the controller subassembly. The Arduino and attached Sparkfun Shield are connected to the sensors via the Sparkfun Mux Breakout board. The breakout board can handle information from up to eight different Sparkfun sensors. The Arduino is powered by an outside computer that the user must provide to run the IncuCheck device.

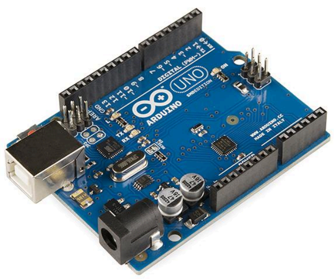


Figure 43a: Arduino

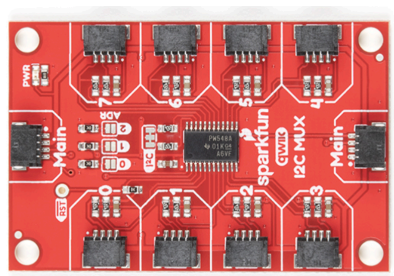


Figure 43b: Shield

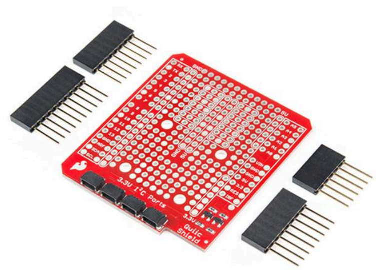


Figure 43c: Mux board

Stand Components

The stand components consist of three parts: the suction cup mount, the any-which-way positioning arm, and the double spring clamp. These three components come together to enable the stand to be attached to the walls of the M-HEAL incubator in addition to holding the sensors in the correct position and orientation. All three components are bought from third-party suppliers. A 3D model depicting each component can be seen in Figure 44 below.

Figure 44: 3D model of double spring clamp, arm, and suction cup

Sensor Components

The final subassembly contains the sensors, which are Sparkfun's TMP 117 high-accuracy temperature sensors, and the housing for the sensors. The Sparkfun board is housed within a custom, 3D printed case that we designed to enable easy setup for users of the IncuCheck device. The case has two parts which slide together to house the sensors. The sensors are connected to the arduino which powers them and reads the data the sensors are outputting. The 6 different sensors include 1 contact temperature sensor and 5 ambient temperature sensors. Figure 45 shows a Sparkfun TMP 117 sensor inside of our custom-designed 3D printed case.

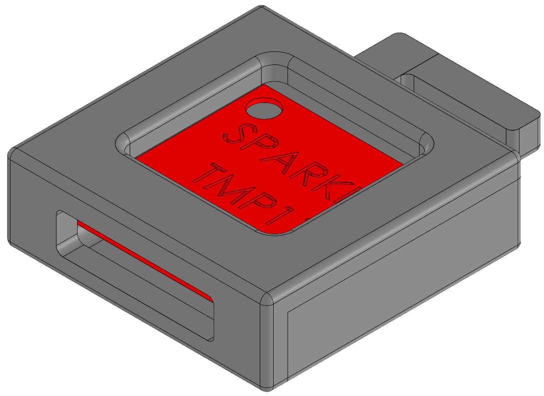


Figure 45: 3D model of sparkfun TMP 117 sensor inside of custom designed case

Final Design Description

The final design for the IncuCheck device is largely the same device described in the final concept section above. The final design is a prototype of the IncuCheck device that is intended for M-HEAL's in-house testing uses only. A detailed layout drawing of the final Incucheck design can be seen in Figure 46 below. The device in operation can be seen in Figure 47 below.

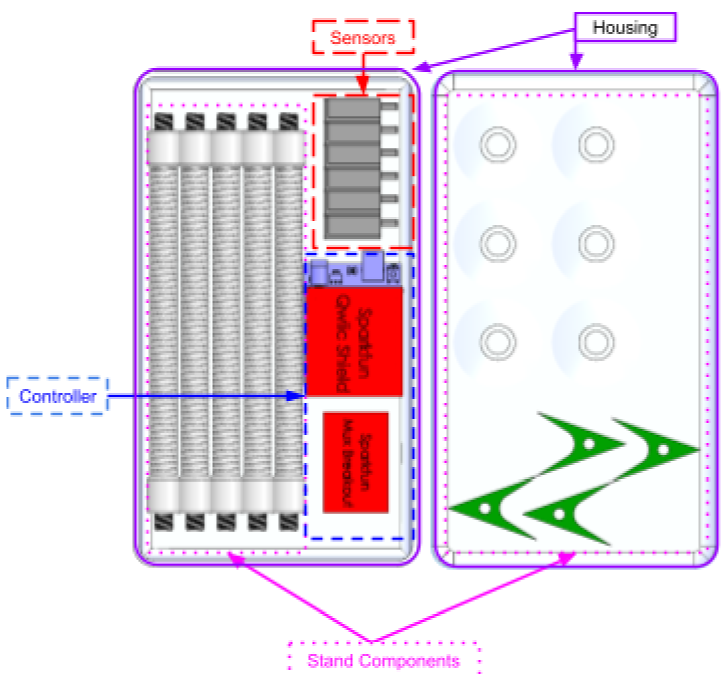


Figure 46: Detailed layout drawing of the IncuCheck device in a 3D Solidworks model. The four subassemblies are present in this image. All wiring components are not in Solidworks.

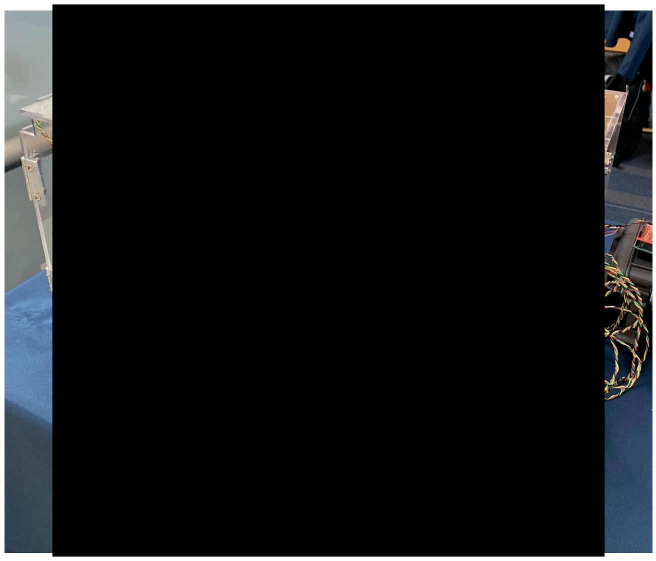


Figure 47: IncuCheck device in operation

The device consists of four major subsystems, the same as described above in the final concept section: the housing, the controllers, the stands, and the sensors. The housing contains all of the other subsystems while the device is not in use. The controllers are connected to the user-provided computer and the temperature sensors that are inside of the incubator. The sensors are held in place by the stands, which are placed inside of the incubator and can be positioned anywhere the user desires. The temperature sensor relays the information back to the computer, which is programmed to output the temperature each sensor is reporting in the Arduino serial monitor. An example image of the outputs generated by the Arduino code can be seen in Figure 48.

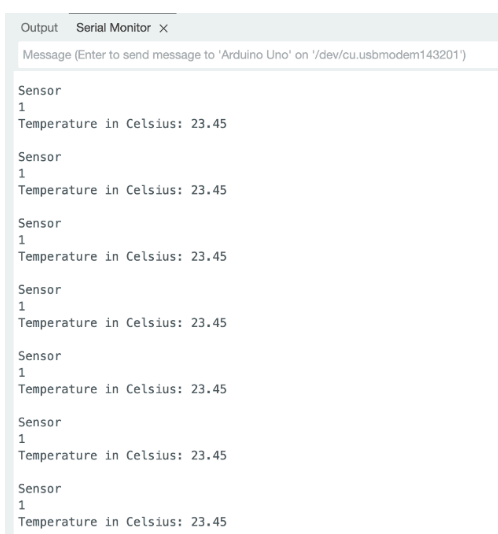


Figure 48: Example output from our Arduino code. This example only shows one sensor outputting temperature measurements.

Housing Subassembly

Starting with the housing, we selected the Pelican 1170 case for use in our device. This off-the-shelf component was suggested to us by Professor Shorter, who saw our initial design which consisted of a large, 3D printed case. The Pelican case, seen in Figure 49, offers major advantages over a custom, 3D printed housing. Pelican cases are more durable, offer locking and pressure stabilization capabilities, already exist on the market so there is no need to create additional tooling, and offer flexible interiors using their trademarked pick and pluck foam technology. The manufacturing of this product is already underway, meaning that to mass produce the IncuCheck device M-HEAL would likely place a large quantity order through Pelican for a discounted price on each unit. The 1170 case is 11.64” wide by 3.78” tall by 8.34” long and includes pick and pluck foam, also shown in Figure 49, which enables full customization of the interior of the case. The top of the case also has removable foam, enabling even further storage space if needed. Potential future design iterations of the IncuCheck device may use larger versions of the Pelican 1170 case, such as the Pelican 1200 case. This case offers more interior width and height, however it is around a 20% increase in cost as compared to the 1170. The Pelican cases are a great base for the IncuCheck design, enabling the device to travel anywhere knowing it will still function regardless of how harsh the environment is.

Figure 49: Pelican case with pick and pluck foam. The small cubes can be separated from each other, creating a customizable and snug fit for each component housed in the case. The top foam is also removable, enabling even further storage capacity.

Controller Subassembly

For the controllers, we have three separate devices. The main brain of the IncuCheck device is an Arduino Uno Rev 3. An engineering drawing of the Arduino can be seen in Figure 50.

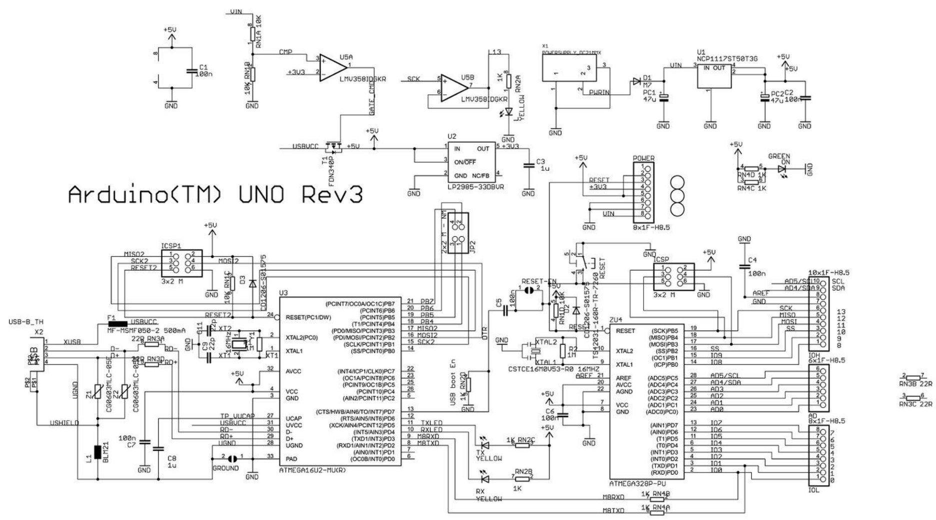


Figure 50: Arduino Uno Rev 3 electrical diagram schematic. This schematic shows how all of the pins are connected in addition to the controlling logic the Arduino employs.

One of the main reasons we chose to use an Arduino board was because the software that Arduino boards run is extremely intuitive and has copious amounts of free documentation. It also is great for connecting almost any kind of sensor. When we chose to use multiple Sparkfun TMP 117 sensors for the IncuCheck device we knew we had to add additional, intermediate devices to enable the Arduino to talk to multiple Sparkfun sensors. At first, we thought that all we would need is a Sparkfun Mux Breakout board, which contains the ability to read information from up to eight sparkfun sensors at once. The engineering diagram for this device can be seen in Figure 51.

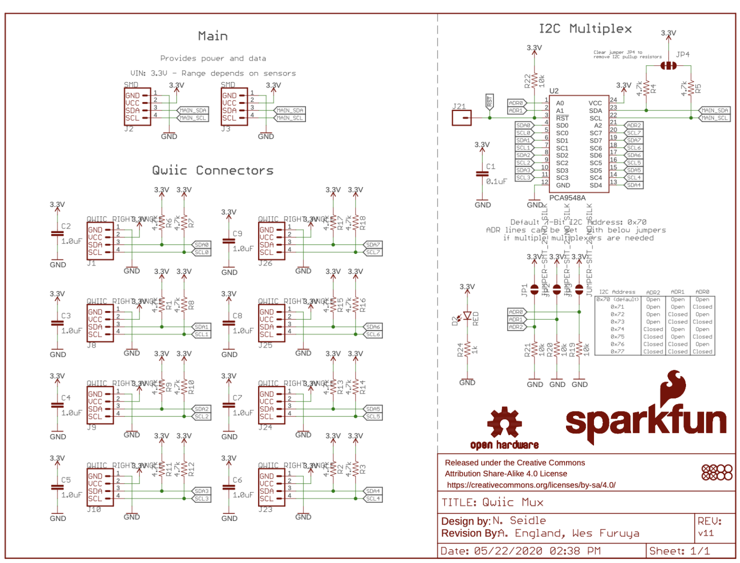


Figure 51: Engineering wiring diagram for the Sparkfun Mux Breakout board. This diagram shows how all of the main pins are connected in addition to labeling the specific pin on each Qwiic connector.

These eight ports are all diverted into one input and one output port, which can be connected to an Arduino Uno. We tried using just this breakout board and the Arduino Uno with some example code Sparkfun engineers had written. However, the code was not running correctly and we were unable to see that multiple sensors were connected to the breakout board. This led us to further research the Qwiic connection system developed by Sparkfun. This connection was what we were using between the breakout board and the TMP 117 sensors. However, we were connecting the breakout board to the Arduino via just regular pin wires and not using the Qwiic system. When looking at the code further we realized that we needed to add an additional board, called the SParkfun Arduino Shield, to enable the correct connection between the Arduino board and the TMP 117 sensors. The Shield, whose engineering diagram is shown in Figure 52, connects to all pins on the Arduino board and comes with a built-in Qwiic port.

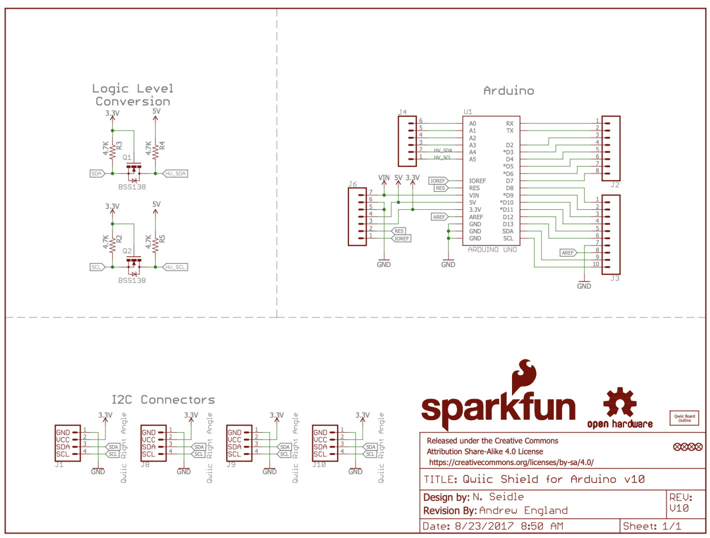
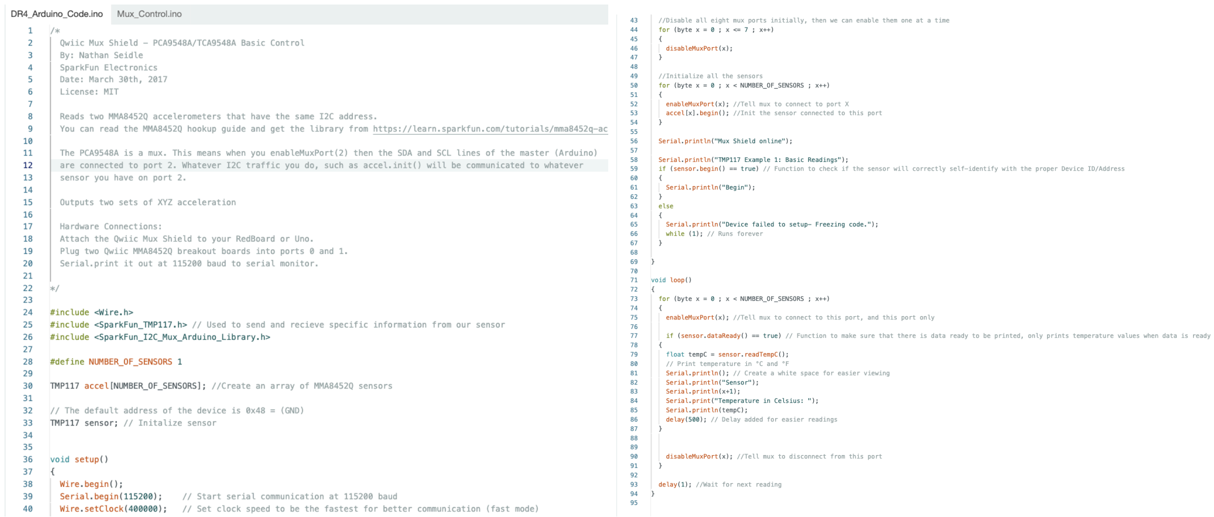


Figure 52: Engineering wiring schematic for the Sparkfun Qwiic Shield device. This schematic shows the connectors, labels all of the pin locations, and shows a high-level overview of the control logic.

So, when we connected the Shield to the Arduino we were able to use the Qwiic connection all the way from the Arduino board to each TMP 117 sensor. With some small adjustments to our code, we were able to create a device that has variable sensor inputs. An image of the code can be seen in Figure 53.



DR4_Arduino_Code.ino   Mux_Control.ino

```
/*
  Qwiic Mux Shield - PCA9548A/TCA9548A Basic Control
  By: Nathan Seidle
  SparkFun Electronics
  Date: March 30th, 2017
  License: MIT

  Reads two MMA8452Q accelerometers that have the same I2C address.
  You can read the MMA8452Q hookup guide and get the library from https://learn.sparkfun.com/tutorials/mma8452q-ac

  The PCA9548A is a mux. This means when you enableMuxPort(2) then the SDA and SCL lines of the master (Arduino)
  are connected to port 2. Whatever I2C traffic you do, such as accel.init() will be communicated to whatever
  sensor you have on port 2.

  Outputs two sets of XYZ acceleration

  Hardware Connections:
  Attach the Qwiic Mux Shield to your RedBoard or Uno.
  Plug two Qwiic MMA8452Q breakout boards into ports 0 and 1.
  Serial.print it out at 115200 baud to serial monitor.

*/

#include <Wire.h>
#include <SparkFun_TMP117.h> // Used to send and recieve specific information from our sensor
#include <SparkFun_I2C_Mux_Arduino_Library.h>

#define NUMBER_OF_SENSORS 1

TMP117 accel[NUMBER_OF_SENSORS]; //Create an array of MMA8452Q sensors

// The default address of the device is 0x48 = (GND)
TMP117 sensor; // Initalize sensor


void setup()
{
  Wire.begin();
  Serial.begin(115200);    // Start serial communication at 115200 baud
  Wire.setClock(400000);   // Set clock speed to be the fastest for better communication (fast mode)
```

```
  //Disable all eight mux ports initially, then we can enable them one at a time
  for (byte x = 0 ; x <= 7 ; x++)
  {
    disableMuxPort(x);
  }

  //Initialize all the sensors
  for (byte x = 0 ; x < NUMBER_OF_SENSORS ; x++)
  {
    enableMuxPort(x); //Tell mux to connect to port X
    accel[x].begin(); //Init the sensor connected to this port
  }

  Serial.println("Mux Shield online");

  Serial.println("TMP117 Example 1: Basic Readings");
  if (sensor.begin() == true) // Function to check if the sensor will correctly self-identify with the proper Device ID/Address
  {
    Serial.println("Begin");
  }
  else
  {
    Serial.println("Device failed to setup- Freezing code.");
    while (1); // Runs forever
  }

}

void loop()
{
  for (byte x = 0 ; x < NUMBER_OF_SENSORS ; x++)
  {
    enableMuxPort(x); //Tell mux to connect to this port, and this port only

    if (sensor.dataReady() == true) // Function to make sure that there is data ready to be printed, only prints temperature values when data is ready
  {
    float tempC = sensor.readTempC();
    // Print temperature in °C and °F
    Serial.println(); // Create a white space for easier viewing
    Serial.println("Sensor");
    Serial.println(x+1);
    Serial.print("Temperature in Celsius: ");
    Serial.println(tempC);
    delay(500); // Delay added for easier readings
  }


    disableMuxPort(x); //Tell mux to disconnect from this port
  }

  delay(1); //Wait for next reading
}
```

Figure 53: Arduino code that enables the IncuCheck device to output temperature data from up to eight separate Sparkfun TMP117 temperature sensors.

Using the Arduino as a controller, the IncuCheck device can take in temperature measurements not just from one sensor, but up to eight sensors. The number eight is defined by a hardware limit of the Sparkfun Breakout board. However, if more than eight sensors are required in the future, the Sparkfun Breakout boards can be daisy chained to add another eight Qwiic ports to the system. The controller system is the backbone of the IncuCheck device's operational capabilities and is an integral part of the overall device design. A figure describing the functionality of the controller subassembly is shown in Figure 54 below.

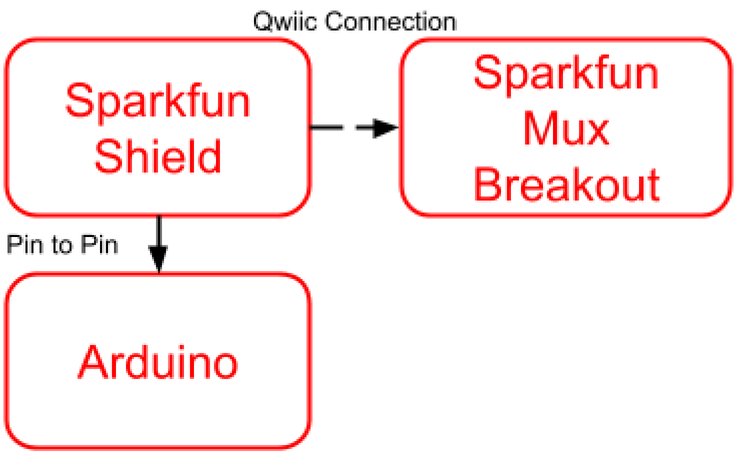


Figure 54: Block diagram for controller connections. The Sparkfun Shield connects to the Arduino through the pin receptacles on the Arduino. This enables the Mux Breakout board to connect to the Arduino, as the breakout board can connect to the shield via the Sparkfun Qwiic connector.

In terms of manufacturing, all of these devices are already produced in large scales. The Sparkfun sensors are purchased directly from Sparkfun while the Arduino was purchased from

Amazon. Similar to the Pelican case, M-HEAL can enter into agreements with suppliers for potential discounts on a large quantity order of any of these components. This would drive the cost of the IncuCheck device down.

Stand Subassembly

The stand components used in the final IncuCheck device design were quite different from the first version of the device concept. Initially, we wanted to use a very simple stand that rested on top of the WarmiLu heating pack, which is secured on the bottom of the M-HEAL incubator. This design, shown in Figure 55, used a small wood block, a press-fit telescoping rod, and a double spring clamp to enable the temperature sensors to be placed anywhere on the inside of the M-HEAL incubator.

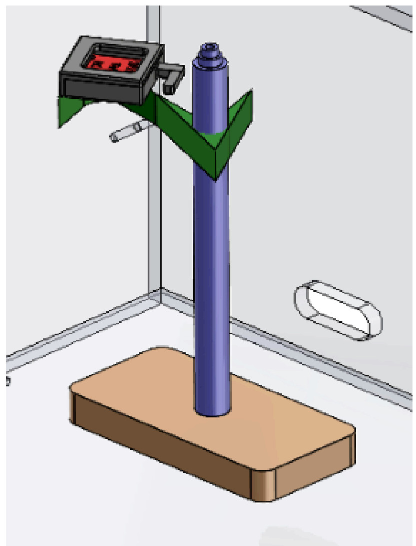


Figure 55: Initial temperature sensor stand concept. The blue, vertical rod would be connected to the wood block, while the double spring clamps would be connected to the rod and the sensor case.

Through further engineering analysis and verification described in the engineering analysis section above, we realized that the initial design would impact the M-HEAL incubator's thermodynamic properties. This is an important thing to avoid, especially when the entire goal of the IncuCheck device is to ensure the M-HEAL incubator is adequate in keeping neonates from becoming too hot or too cold. So, using further analysis on ANSYS Discovery, a fluid flow simulation tool, we discovered that the best place to mount the temperature sensor stands would be on the walls and ceiling of the M-HEAL incubator. This presented some interesting challenges, due to the fact that one of our requirements is that the device must be able to last for 6 hours continuously while also being able to go through 120 of these cycles. Thus, we decided to go with high-strength suction cups as our mounting method, shown in Figure 56.

Figure 56: High-strength suction cups used in the IncuCheck design. The small protrusion fits right into the female threaded end of the positioning arm. The built-in tab enables easy removal from any surface the suction cup is attached to.

We also considered using magnets, but we were concerned that they would interfere with the electrical signals the IncuCheck device needs to function in addition to not being strong enough to go through ¼” acrylic. Using different types of magnets could potentially be a nice upgrade in the future, especially since suction cups have a much shorter lifespan. Attached to the suction cups are purchased, “any-which-way” positioning arms. These arms from Mcmaster-Carr, part number 50035A691, have a male and female threaded rod as shown in the engineering drawing in Figure 57.

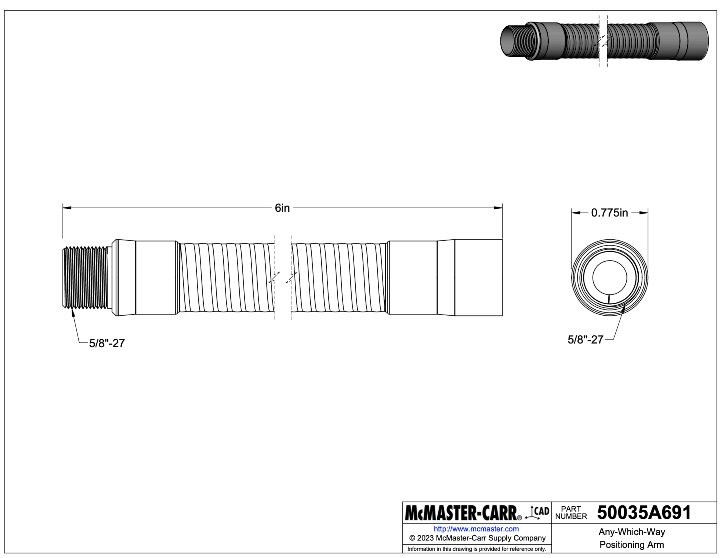


Figure 57: Engineering drawing from Mcmaster-Carr of the “any-which-way” positioning arm. The arm is six inches long overall and contains one male threaded end and one female threaded end. This enables easy connection to the suction cups in addition to plenty of surface area for the double spring clamps to attach to.

The non-suction end of the suction cups fits right into the female threaded end of the rod and is adhered in place using Plexus MA200 epoxy adhesive. This creates a strong bond between the plastic suction cups and the interior metal rod of the positioning arm. This arm is flexible and can be positioned in any way desired. The male threaded rod is perfect for the double spring clamps, which was a design carried through from the first, initial concept of the temperature sensor stand. This simple yet effective design contains two spring clamps zip-tied together. This enables one of the clamps to be attached to the male threaded end of the positioning rod, while the other clamp can attach to the 3D printed temperature sensor housing case. Using the double spring clamps offers a lot of flexibility, as each clamp can be positioned in different ways to achieve a reach that extends to any position within the M-HEAL incubator. The double spring clamps are shown in a CAD drawing in Figure 58 and in the prototype design in Figure 59.

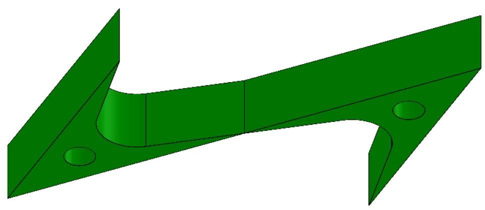


Figure 58: CAD design for the double spring clamp. The CAD does not include the zip ties used to connect the two clamps together. They were modeled for dimensional and display purposes only.

Figure 59: Image of double spring clamp connected together via a zip tie. The image also shows how the clamp connects to the male threaded rod end of the positioning arm.

Manufacturing many of these would be quite simple. The hardest part is ensuring a good bond between the suction cup and the positioning arm. The Plexus MA200 is a bit expensive, as is the positioning arm. Tying the two clamps together to create a double spring clamp is also simple and requires a minimal amount of effort to create. All of the components can be purchased in bulk and will be quite a bit less expensive if done so. The Plexus adhesive has been used to bond metal to metal, metal to composites, and metal to plastics for quite some time now. The bond between the suction cup and the positioning arm will exceed the amount of uses required out of the entire device. The double spring clamps and the suction cups will certainly wear down over time. Alternative methods to using these types of clamps can be explored in future versions of this device. Given more time, we would have certainly explored other options to compare the spring clamps and the suction cups to.

Sensor Subassembly

The last subassembly is arguably the most important, which contains the temperature sensors used to measure the temperature inside of the M-HEAL incubator. We chose to use the Sparkfun TMP 117 high-accuracy temperature sensor as it met our temperature accuracy specification, is very affordable, and the Sparkfun system has great integration with Arduino. Sparkfun also offers an entire ecosystem of sensors and boards which can be added onto our existing architecture, which is great for M-HEAL's testing needs. The engineering drawing for the TMP 117 sensor can be seen in Figure 60.

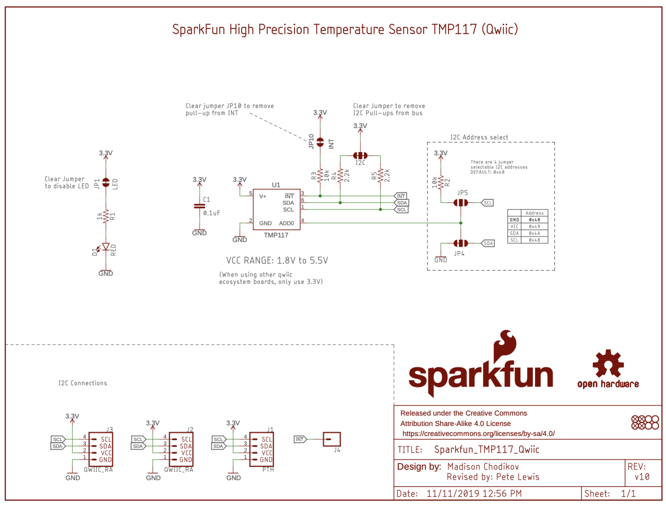


Figure 60: Engineering wiring schematic for the Sparkfun TMP 117 high-precision temperature sensor. This schematic shows the connectors, labels all of the pin locations, and shows a high-level overview of the control logic.

The TMP 117 sensor is housed within our custom-designed 3D printed case. This case contains two parts, one that the sensor rests on, and one that the slides over the top to cover. Figure 61 shows the two different parts of the cover.

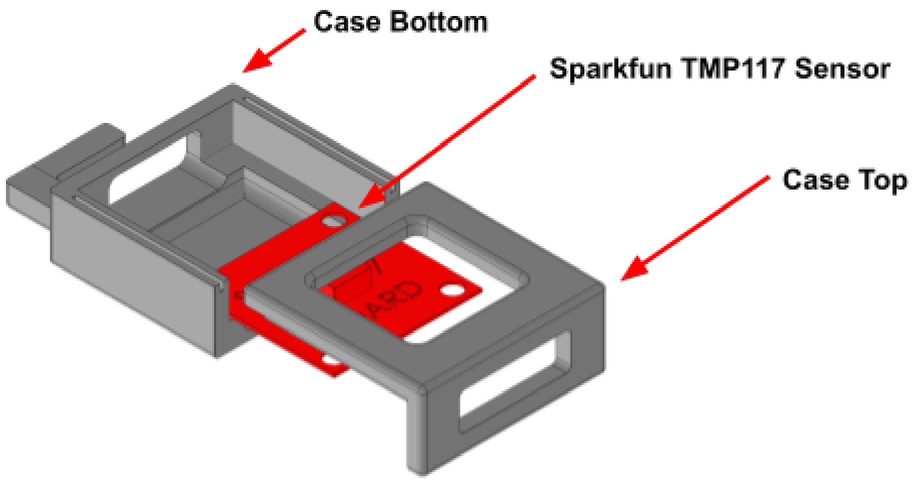


Figure 61: Exploded view of the 3D printed Sparkfun TMP117 temperature sensor housing. The two halves slide together to cover most of the chip, with openings for electrical connections and to enable enough airflow to the sensor.

The bottom section has a small shelf for the sensor to sit on, while also including an opening for airflow and electrical connections. The bottom half of the cover also has an integrated clamping section, which enables the double spring clamp to hold the case without interfering with any temperature readings the sensor is taking. The bottom of the case also contains grooves for the top half to slide into place. The top half contains the other set of grooves, in addition to more openings for adequate airflow and necessary electrical connection points. Further exploration into this case design should consider using injection-molded parts. The design was intended for 3D printing as we have access to many of them and they enable rapid prototyping of our designs. The initial design was too small, which forced us to redesign the cases. This was easy with 3D printing as we just made small adjustments in the CAD model and sent the new design to the printer. Once we were happy with the adjusted design we printed 6 sets of the cases.

The wiring components that stretched between the Arduino and the temperature sensors used Sparkfun's Qwiic system, shown in Figure 62.

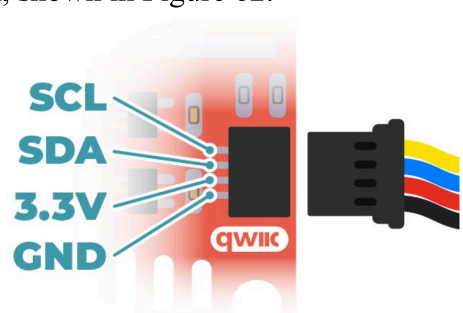


Figure 62: Sparkfun Qwiic connector pins. Each connector uses the SCL, SCA, 3.3V, and GND connections to send the data through the wires.

We purchased the longest possible cables Sparkfun produced, however they were nowhere near the length we needed for the IncuCheck device. The Qwiic system uses a four-pin connection. Luckily, we were able to find plenty of four-wire cables in the X50 laboratory that were not being used in any project. We cut the existing connectors off of the four-wire cables and cut the Qwiic connectors off of the purchased cables from Sparkfun. We then spliced a Qwiic connector on each end of the long cables that we cut to a length of 40 in. This length was determined by the distance between the case and the furthest possible sensor location in the Incubator. We connected the Qwiic connectors to the appropriate colored cables and used shrink wrap to protect the connections. We built six wires for each of the temperature sensors used in the current IncuCheck design.

For future manufacturing of the temperature sensor cases, we suggest looking into injection molded parts. With the high tooling cost and long lead time we were unable to viably look into injection molding any parts. However, injection molding is great for high-manufacturing quantities and enables further design integration such as additional fastening clips that will ensure the sensor does not escape the housing. Due to the current method of 3D printing we were unable to add in these desired features. The current wiring solution works well, however it is a very laborious and time consuming process. Although it would be great to employ automation in manufacturing these wires, the best way to manufacture these wires would be just doing it by hand. Our team broke it down into an “assembly line” approach, where we all worked together to create the six extended wires.

User Interface

Due to constraints in time we were unable to create an all-in-one user interface for the IncuCheck device. Although this has not been fully completed, we developed an alternative way for users to view the data gathered by the device. An image of an example graph generated by the user interface is shown in Figure 63 below.

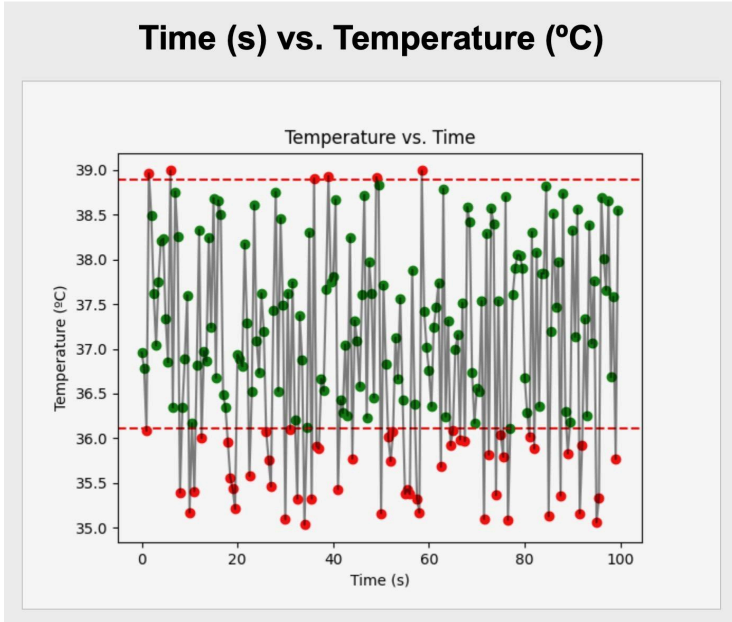


Figure 63: Example image of the graphical user interface that was developed for use in conjunction with the IncuCheck device. This data represents made-up results to show an example of what the interface would output with the raw .csv data input.

Currently, the Arduino serial monitor captures all of the incoming data from the temperature sensors. The serial monitor can be downloaded as a .csv file, which is a raw text file format which can be read into other programs. To get the .csv file from the serial monitor an application called puTTY is used. Once the .csv file is downloaded it can be uploaded to our private website where the application will graph the data in the .csv file. Although there are a few steps to the process, the M-HEAL engineers will still have access to the raw data and will also be able to view a graph if they prefer that. They can also use additional software services like Matlab, which will read in a .csv file and be able to plot the numbers just like our web application. In the future, it would be great to be able to build a feature in the Arduino code or integrate the Arduino code into another application. This would enable the Arduino to run while also live-streaming the data into a graphical user interface so that the M-HEAL engineers can actively see what the incubator environment is like.

Build Design

The build design for the Mechanical Engineering Design Expo was only slightly different from the final design concept. We aimed to have a graphical user interface that displays the live temperature of all six sensors, however we understood that this was quite a large challenge. Therefore we did not have the final version of that interface working in time for the build design. We were also unsure of the ability to have a working contact temperature sensor based on the TMP117 platform. The difficulties associated with the transformation led it to not being included in our build design.

Considering that our primary stakeholder is M-HEAL engineers, we have assumed they are familiar with the use of an Arduino. Therefore, in our build design, we did not include any portions of our graphical user interface. We were still able to view the data from the sensors, however the IncuCheck device must be used via our supplemental ME450 application, with puTTY as an intermediary between the two steps.

Although the build design did not have the final, most complete design, we are confident that the solution we showed will work for the M-HEAL team. Overall, these changes from the build design to the final design are quite minor. However, the consistency of the device, robustness, and full functionality were not as far along in our build design as the final design. All materials and components selected for use in the build design reflect the same materials and components in the final design concept. A list of the materials and parts used in the final build are below in Figure 64. The only part produced in-house and not contained on this list were the 3D printed sensor housing cases. These six cases were produced using PLA filament on a printer that a team member, Erik Wahr, owns.

Part No.	Part Title (hyperlink)	Supplier	Quantity	Price/ Unit	Total Cost
1	Heavy Duty Suction Cups for Glass Surfaces	Window Garden (Amazon)	1	$9.99	$10.59
2	32-Piece 2" inch Small Spring Clamp, Spring Metal Spring Clamps,	HORUSDY (Amazon)	1 pack	$12.99	$13.77
3	Any-Which-Way Positioning Arm, Threaded Stud Base with Threaded Hole End, 6" Projection	McMaster Carr	2	$9.38	$28.17
3	Any-Which-Way Positioning Arm, Threaded Stud Base with Threaded Hole End, 6" Projection	McMaster Carr	2	$9.38	
4	Suction Cup 0.96 lbs. @ 10 in. of Hg	McMaster Carr	2	$10.09	$49.56
5	SparkFun Qwiic Shield for Arduino	SparkFun	1	$7.50	
6	Flexible Qwiic Cable - 50mm	SparkFun	4	$1.05	$27.83
6	Qwiic Cable - Breadboard Jumper (4-pin)	SparkFun (Amazon)	6	$2.95	$23.85
7	SparkFun Qwiic Mux Breakout - 8 Channel (TCA9548A)	SparkFun	1	$12.95	
8	Flexible Qwiic Cable - Breadboard Jumper (4-pin)	SparkFun	8	$1.60	
9	SparkFun High Precision Temperature Sensor - TMP117 (Qwiic)	SparkFun	5	$14.95	$119.97
9	SparkFun High Precision Temperature Sensor - TMP117 (Qwiic)	SparkFun (Amazon)	1	$15.86	$16.81
10	Pelican™ 1170 Case	Pelican	1	$65.00	$79.46
11	Arduino Uno REV3 [A000066]	Arduino (Amazon)	1	$27.60	$29.26
					$399.27

Figure 64: List of materials, supplier, quantity, and price for the components used in the build design of the IncuCheck device.

Verification and Validation Plans and Results

Requirement 1: Have accurate ambient and contact temperature data from sensors within incubator

Specification:

- *Temperature sensor readings are within ±0.1°C of actual ambient and contact temperature*
- *Data evaluated from ≥ 5 separate zones within incubator*

The primary verification of the accuracy specification is simply cross-referencing the given or known contact and ambient temperature measurement device accuracies with our own outlined specifications, and ensuring they are aligned. However, as a secondary measurement, we have performed empirical testing. Specifically, to test the accuracy of the ambient temperature measurements, we used a controlled environment with a known temperature and placed our sensors inside of that environment. Once the entire system reached steady-state, we measured the temperature using our ambient temperature sensors, and verified whether it accurately reflects the known temperature. An example of a known environment is the X50 room, we utilized two additional sensors that are known to be accurate per the accuracy ranges provided within their specs in order to ensure that our sensors are providing reasonable data through the values reported from the Arduino. Comparing these measurements allowed us to determine that the accuracy of the ambient temperature sensor falls within its rated amount. Given our time and budget constraints, we believe that this test is sufficient for the scope of ME 450, to ensure that the temperature measurement device is operating in the ballpark of its expected temperature. For a more ideal, rigorous test, we can use a heat chamber, whose temperature can be controlled to the nearest ±0.05°C, and set at the upper and lower limits of the sensor's operating temperature. We can then use this apparatus to verify the accuracy, and operating conditions of the selected sensor.

Results from Sensor Accuracy Testing

The results of our testing are shown within Figure 65 and Table 20. Based on the results from this experiment we are able to conclude that the TMP117 sensor and arduino combo is providing reasonable results. A more in depth analysis of this testing is shown within Worry 1 on page 43.

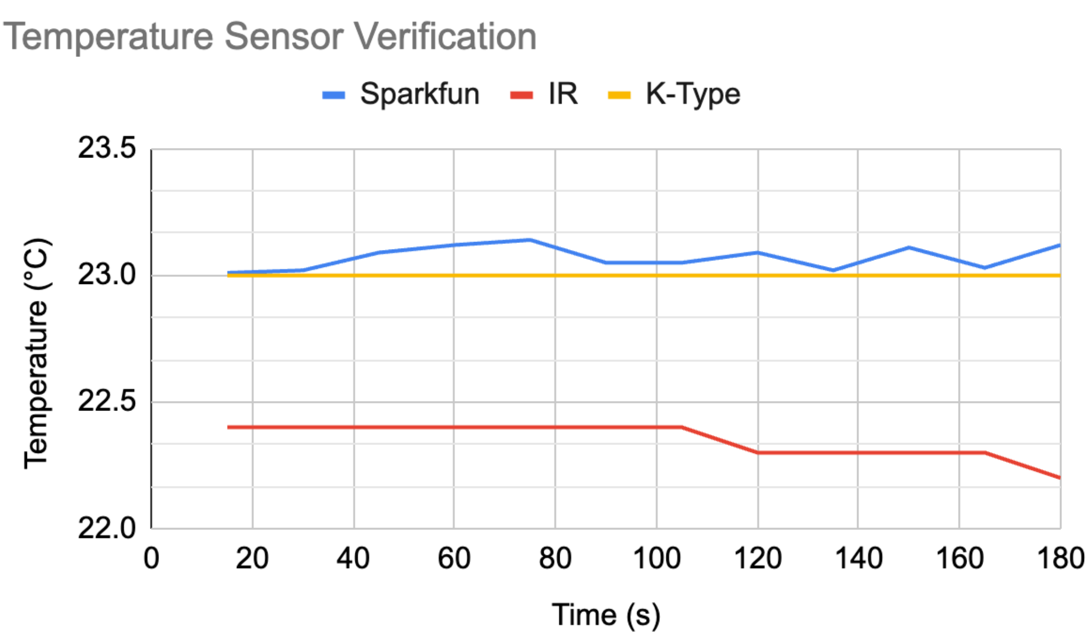


Figure 65: Sensor comparison results, test 1

Table 20: Sensor Comparison Test Results

	Control Device: SparkFun Sensor (Accuracy: 0.1°C)			Verification 1: Infrared Thermometer (Accuracy: ± 1% OR 1°C)			Verification 2: Klein Tools AC/DC Digital Clamp Meter (Accuracy: ± 2°C)		
Time (sec)	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
0	23.05	23.27	23.41	22.1	22.3	22.2	23	24	24
15	23.01	23.33	23.45	22.4	22.3	22.2	23	24	24
30	23.02	23.32	23.47	22.4	22.4	22.3	23	24	24
45	23.09	23.35	23.5	22.4	22.7	22.2	23	24	24
60	23.12	23.39	23.49	22.4	22.6	22.3	23	24	24
75	23.14	23.36	23.52	22.4	22.5	22.1	23	24	24
90	23.05	23.39	23.52	22.4	22.2	22.1	23	24	24
105	23.05	23.41	23.57	22.4	22	22.1	23	24	24
120	23.09	23.43	23.53	22.3	22.5	22.1	23	24	24
135	23.02	23.42	23.45	22.3	22	22	23	24	24
150	23.11	23.45	23.51	22.3	22	22.1	23	24	24
165	23.03	23.44	23.51	22.3	21.8	22	23	24	24
180	23.12	23.48	23.51	22.2	22.9	22.2	23	24	24
AVG	23.069	23.388	23.495	22.331	22.323	22.146	23	24	24
error	0.100	0.100	0.100	1.005	1.005	1.005	2.236	2.236	2.236
Delta				0.738	1.065	1.349	0.069	-0.612	-0.505
STDEV	0.044	0.059	0.042	0.095	0.319	0.097	0.000	0.000	0.000

Secondly, to test the contact temperature sensor, we can replicate the above procedure using a second temperature measurement device instead of a controlled environment. For the purposes of ME450, the second temperature measurement device must have the same or greater accuracy than ±0.1 °C, such as a Precision Analog Temperature Sensor from Texas Instruments [51], which has a rated accuracy of ±0.05 °C, and can be purchased for $1 each. We can then measure the same object using both sensors, and check the values against one another. A more rigorous version of this test can be run with a temperature device whose accuracy is ±0.01 °C. Overall, these testing methods are the most straightforward way of comparing the measured temperature values to the actual values. By selecting a thermometer and environment with a known resolution and accuracy outlined, we can accurately determine whether our ambient and contact measurement devices are reading within an acceptable range. Additionally, this only requires the purchase of one additional device, which is relatively cost- effective and well within our $400 budget, and therefore feasible in terms of cost and rigor. Our final design did not include a contact temperature sensor, therefore this testing was not conducted.

To test the second specification, we determined whether or not five distinct data points are being collected at any given time, from five different points within the incubator. This was evaluated empirically, and was relatively simple and non-rigorous. Five ambient sensors were placed within the incubator and connected to the Arduino, we were able to receive data from all five sensors which appeared to be reasonable as the Warmilu was not activated and all recorded temperatures were within room temperature range and ±1°C of each other.

Requirement 2: Have safe features

Specification: Conform to IEC 60601-2-19:2020 Standard

To test the safety of the device, we primarily need to verify that the electromechanical components of the device are safe for use, and do not have any incorrect wiring, leaking voltage/current or short circuits. First, we conducted a visual inspection, ensured that all wires were properly stripped, undamaged, not crossed over one another, and coiled to reduce tangling. Once this was complete, we used a digital multimeter to ensure that the voltages and currents were moving as expected and indicated by the wiring diagram [52]. This device was checked out at the ME450 shop, which means we did not need to purchase any additional materials or tooling in order to conduct this test, this made empirical testing favorable by cost and rigor.

The specific IEC standard from which the specification was derived states that strong safety is indicated if "the manufacturer has demonstrated in his risk management file that the risk presented by the hazard has been found to be of an acceptable level when weighed against the benefit of treatment from the device" [15]. We believe that the above test has allowed us to accomplish this, while remaining feasible given our time and cost constraints.

Results of Safety Testing

In order to evaluate the safety of this system, we first inspected it visually. We found that some wires had minor damage to the insulation as they were cut out of old harnesses, damaged sections were wrapped with electrical tape to ensure safety. Based on our testing with a multimeter, all currents and voltages are within acceptable ranges of what is expected based on the specs of our electrical components and our wiring diagrams as shown within our final design description. The currents and voltages within this system are generally not high enough to cause significant harm or death to the user outside of the Arduinos power source. The Arduino and power wire is tested to the necessary safety standards and this is not something that we are tampering with in any way. Using the SparkFun documentation for the sensor, we found that it consumes an extremely small amount of power, and has a shutdown current of 150 nA, which is well within the 0.001 A threshold [44], [53]. Based on this testing and analysis we are able to conclude that our system is safe.

Requirement 3: Have user controlled functional capabilities

Specification:

- *Contains ≥ 1 User Accessible Component*
- *Able to control ≥ 3 functions of device (Minimum Functions Include: (Start, Stop, View Log)*

Given the nature of this requirement and its corresponding specifications, it was verified by simply evaluating the final design and noting whether or not it had a user accessible component, and contained the necessary three subfunctions. Given that the build design differed from the final design, this test was completed using the idealized CAD model, given that the physical build design did not have all the necessary functionalities to verify.

In the future, we also propose an additional test where the final design is given to a third- party, who has little to no exposure to the project and any of its design components or iterations. From there, we can ask them to use the device, and see if they are able to successfully control the stop, start and view log functions. If they are able to do so, we can verify that the device does in fact have user controlled capabilities, even when the user is not someone closely connected to the project.

Results of User Controlled Capabilities Studies

When verifying the final design against the above specifications, we concluded that our final design passes the first specification, and fails the second. The first specification is the ability to control at least one component of the data collection process. This is met by the ability of the user to upload and run the Arduino code, which begins the data collection process through the SparkFun sensors. This allows the user to start and stop the data collection process, and is thus a user accessible component.

The second specification, on the other hand, is failed by our final design, because the user can only control two functions of the device. As mentioned above, the first function is the ability to start the data collection via uploading and running the code and the second function is the ability to stop running code by exiting the Arduino serial monitor. On the other hand, in order to view the log, the user must use an external application, puTTY, in order to export the serial monitor data as a .csv file, prior to uploading it into our web application. Therefore, the view log functionality is not readily available to the user, hence the specification is failed.

Requirement 4: Have durability

Specification:

- *Can withstand ≥ 120 uses*
- *Able to be operated for 6 hours continuously (each use)*

Within the scope of ME450, we have tested the former specification by simply running the device for 6 hours straight, and verified the resulting output to ensure that data was being collected for the entirety of the 6 hours. Additionally, we made sure to run the device in an environment with little temperature variation, to ensure that no drift occurred during the 6 hour period. To test the latter specification, however, we do not believe the necessary rigor to conduct durability testing justifies the time and funding required to do so. Therefore, we decided to rely on the theoretical ratings of our selected temperature device. Typically, device specifications will indicate the number of life cycles it is projected to last for, either in units of time or uses. Using data provided in the specification, we can calculate the maximum number of uses for the sensor, and make sure it is greater than 720 hours or 120 uses.

For a more rigorous option, the most common way to conduct durability testing is to simply test the device until failure. To do so, we can run it for 720 hours (120 uses*6 hours for each use) straight, and verify that data is being collected and stored for the entire time. By collecting the data in a controlled temperature environment with little variation in the surroundings, we can also watch for drift in the data points, and ensure that the sensors do not become less accurate as time goes on. If the device is able to run for 720 hours straight and experience a drift that still complies with our temperature accuracy requirement, we can successfully verify that it's durable enough to collect accurate data for its entire life cycle. Given that 720 hours is equivalent to 30 days, this is not feasible for the scope of ME450, but can be completed in later iterations of the prototype to fully verify this specification.

Results of Durability Tests

In order to test the second specification, we have allowed the device to run for 6 hours straight. All data appeared reasonable and the only issue encountered was with the computers auto sleep setting, once fixed we encountered no further issues, this test was only completed once. The TMP117 has a long term drift of ±0.03°C per 300 hours of use at 150°C. Per the spec sheet “Long term stability is determined using accelerated operational life testing at a junction temperature of 150°C,” [44]. As this testing is accelerated and our device will be operating within significantly lower temperatures we can reasonably expect to see less than ±0.03°C of drift over the course of 300 hours, for this reason we would recommend replacing the sensors after 300 hours, or 50 “standard uses” of six hours each, in order to ensure that deviations in accuracy as a result of drift remain minimal. Once a sensor has exceeded 300 hours of use, additional testing can also be performed in order to evaluate the drift that has occurred and determine if it is reasonable to continue using this sensor.

Requirement 5: Have user friendly features

Specification: System Usability Score > 68 (Average "Usability Score")

This specification required verification testing, specifically because it involved conducting user testing to determine the usability score of our prototype. The System Usability

Scale (SUS) is a series of 10 questions with 5 response options. Using a set of predetermined mathematical rules, the SUS score from a single questionnaire can fall in the range of 0-100. A score of 68 is considered "average" which is how we arrived at the corresponding specification for this requirement.

In regards to our testing methods, we wanted to give our device to a variety of users (doctors, engineers, M-HEAL sponsors, other 450 students, etc), along with any training materials that we would realistically give an end user, such as training pamphlets or diagrams. In doing so, we planned to ask a minimum of 10 participants, but recognized that the more we ask, the better our results would be. From there, we allowed each user to use the device for 5-10 minutes, so they can get a feel for its functionality, as outlined by the training materials, which are shown in Figure 66 below.

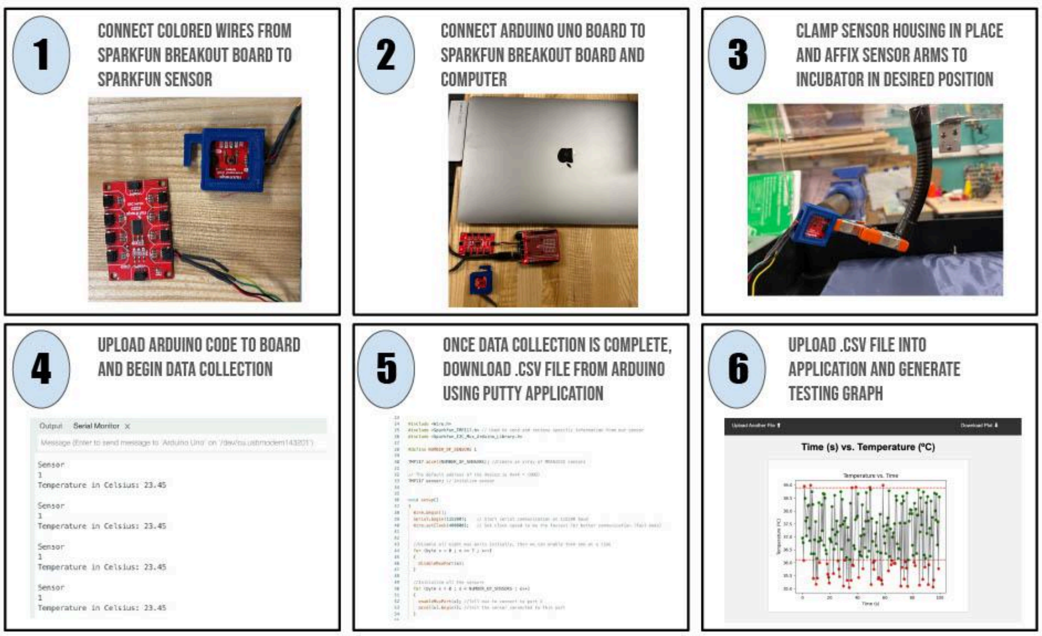


Figure 66: Instructional Guide For SUS Usability Tests

Following their real time interaction with the device, we gave each user a SUS questionnaire, allowing them to rank each question on the questionnaire on a scale from 1-5. After collecting these results, we applied their individual scores to the SUS score mathematical model, to determine a final usability score from 0 to 100. After averaging the usability scores across all participants, we can verify whether or not our design passed the specification based on the final score, where a 68 or above is a pass.

The use of a System Usability Score (SUS) is an industry standard for measuring a device's user friendliness, and attributing quantitative values to a qualitative metric. Therefore, conducting user testing followed by a survey is a common procedure, as outlined by many journals and engineering websites. Additionally, giving the completed device to users was cost-effective, and did not require the purchase of any extra materials. Finally, given our group's network of stakeholders that we have built over the course of this project, getting 10 volunteers is well within our capabilities, making it a feasible testing method.

However, despite having the appropriate network, due to time constraints within ME450, we found it most efficient to run the usability tests with the real end users of the device, M-HEAL. The initial plan of running these tests with industry doctors and engineers, etc. is an ideal that would help in verifying the usability of the device across a larger sample size to ensure the device is usable by all professions. However, due to time constraints and understanding the final end user of the device this semester is M-HEAL we conducted usability testing with the three main leaders of M-HEAL Initiative who will be using this device the most among team members in the coming semester.

Results of Usability Tests

After the tests were conducted across the 3 users individually, the data from the questionnaires was transferred into a spreadsheet that calculated the score of each question based on the individual's response. Those score calculations were summed together and multiplied by the respective constant according to the SUS standard to get the total score. The SUS score calculation method used in finding the SUS score can be within the following steps:

1. For each of the odd numbered questions, subtract 1 from the score.
2. For each of the even numbered questions, subtract their value from 5.
3. Take these new values which you have found, and add up the total score. Then multiply this by 2.5.

This method of calculating the score is implemented in the following table and displays the raw data from the questionnaire, the score calculation for each question, and the total score from each user.

Table 21: SUS Score Raw Questionnaire Data and Score Calculations

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Sum	Total Score
User A Score (1-5)	3	1	4	2	4	2	3	1	4	4		
Score Calculation	2	4	3	3	3	3	2	4	3	1	28	70
User B Score (1-5)	3	1	5	1	3	1	2	3	4	4		
Score Calculation	2	4	4	4	2	4	1	2	3	1	27	67.5
User C Score (1-5)	3	1	4	2	3	2	3	1	4	3		
Score Calculation	2	4	3	3	2	3	2	4	3	2	28	70
AVERAGE SUS SCORE												69.17

The average SUS Score from the trials is 69.17 with a standard deviation of 1.44. This score is above the average 68 indicating that we are above the 50th percentile and that our device has a B or "Good" adjective description of usability for the device. The M-HEAL was satisfied with the functionality of the device and were excited to use it in the coming future. Because this is a testing device that involves using Arduino code, there was feedback that not many people have had exposure to this unless they had done previous projects with it, but because the way we outlined the Arduino code and had an instructional manual, the learning curve in using the device was small. From feedback, we need to further specify the kind of application and settings that are needed for each person's computer if they'd like to run the code on their computer. We further anticipate that through further validation testing we will be able to conclude on the specifics of how to improve the device in terms of usability in the set up process. However, overall feedback suggested positivity with the device from end users, excitement on using for future testing, and no present complexities in setting up and using the device that hinder the users' ability to utilize the device.

Requirement 6: Meet ME 450 standard budget

Specification: Total prototyping expenses are ≤ $400

To verify this specification, we referred to our bill of materials and budget, where we tracked all our purchased items over the course of the semester. This includes both items that were used in the prototyping process, as well as items that are intended to be included in our final prototype for the ME450 design expo. The creation of this budget made it relatively easy to verify this specification, as we just compared the total amount spent against the ME450 budget of $400, and verified whether or not we stayed below the intended budget.

Results from Budget Adherence

The final budget for the semester can be found below, in Table 22. Given that it totals less than the ME450 standard budget of $400, we deemed this specification to be passed.

Table 22: ME450 Budget

Part No.	Part Title (hyperlink)	Supplier	Quantity	Price/ Unit	Total Cost
1	Heavy Duty Suction Cups for Glass Surfaces	Window Garden (Amazon)	1	$9.99	$10.59
2	32-Piece 2" inch Small Spring Clamp, Spring Metal Spring Clamps,	HORUSDY (Amazon)	1 pack	$12.99	$13.77
3	Any-Which-Way Positioning Arm, Threaded Stud Base with Threaded Hole End, 6" Projection	McMaster Carr	2	$9.38	$28.17
3	Any-Which-Way Positioning Arm, Threaded Stud Base with Threaded Hole End, 6" Projection	McMaster Carr	2	$9.38	
4	Suction Cup 0.96 lbs. @ 10 in. of Hg	McMaster Carr	2	$10.09	$49.56
5	SparkFun Qwiic Shield for Arduino	SparkFun	1	$7.50	
6	Flexible Qwiic Cable - 50mm	SparkFun	4	$1.05	$27.83
6	Qwiic Cable - Breadboard Jumper (4-pin)	SparkFun (Amazon)	6	$2.95	$23.85
7	SparkFun Qwiic Mux Breakout - 8 Channel (TCA9548A)	SparkFun	1	$12.95	
8	Flexible Qwiic Cable - Breadboard Jumper (4-pin)	SparkFun	8	$1.60	
9	SparkFun High Precision Temperature Sensor - TMP117 (Qwiic)	SparkFun	5	$14.95	$119.97
9	SparkFun High Precision Temperature Sensor - TMP117 (Qwiic)	SparkFun (Amazon)	1	$15.86	$16.81
10	Pelican™ 1170 Case	Pelican	1	$65.00	$79.46
11	Arduino Uno REV3 [A000066]	Arduino (Amazon)	1	$27.60	$29.26
					$399.27

Validation Plan

In regards to our device validation, we want to evaluate it across three primary dimensions: safety, efficacy and usability. In the following section, we will outline the most ideal study design based on existing FDA standards, a study feasible for the time and resources available in ME450, as well as preliminary results for each of the completed validation studies.

Safety: Is the device safe for the end user?

In an ideal study, the device would be run for the entirety of its rated lifetime: six hours at a time over 120 cycles, which totals 720 hours of usage. By running it for its entire life cycle, we can spot the areas of most degradation, which also have a high probability of creating an unsafe user environment. In order to conduct this test, we can set up an automated testing sequence that performs certain motions of the device, turns the sensor on and off between uses and adjusts the height at which the sensor is placed. By replicating a typical usage pattern, we can determine how well the electrical and mechanical components of the design hold up against time and wear, and see if any safety concerns arise as a result. Specifically, to verify safety at periodic intervals over its lifetime, we can make use of tests recommended by the IEC to test electromechanical components of medical devices.

Specifically, we can purchase an electrical safety analyzer (ESA) [54]. This device adheres to the IEC standards for testing medical devices, and includes all functions necessary to complete testing. This includes (1) line (mains) voltage (2) ground wire (or protective earth) resistance (3) equipment current (4) ground wire (earth) leakage (5) chassis (enclosure) leakage (6) direct equipment leakage (7) point to point leakage and resistance [55]. By using this device, we can validate that our device does not have any electromechanical failures, adheres to IEC standards and is therefore safe for a potential end user.

For the purposes of ME450, we can supplement the use of an electrical safety analyzer with the use of a multimeter, which will enable us to get current, voltage and resistance readings at various points along the system. This will enable us to ensure that there is no current or voltage leakage, and that the current flowing through the device matches the rated power as per the SparkFun and Arduino specifications.

Initial Safety Results

Using literature and documentation, we were able to successfully validate that the current running through the major electromechanical components of the device fall well within the acceptable safety range. When looking at safety, research has shown that the amount of current running through a human's body is what determines the intensity of the shock, not the amount of voltage. For this reason, we sought to determine the amount of current running through the SparkFun TMP117 sensor. Using literature, we determined that it is generally recommended that the threshold be around 0.001 A, which marks the amount of current required to give a human being mild sensation [53]. Using the SparkFun documentation for the sensor, we found that it consumes an extremely small amount of power, and has a shutdown current of 150 nA, which is well within the 0.001 A threshold [44]. Therefore, for our initial results, we were able to validate the safety of the device.

Efficacy: Is an engineer able to draw conclusions about overall incubator safety?

Given that the goal of this device is to allow a testing engineer to take away data about the safety of the incubator, it is imperative that the device allows the engineers to draw conclusions based on broader incubator testing standards. Fluke Biomedical has laid out some necessary best practices for infant incubator and radiant warmer testing, which we can check against the capabilities of our incubator tester to ensure they meet certain criteria [18].

1. Always test to the standards and/or manufacturers' service manual.
    a. The IEC standards reflect the best experience of the industry, researchers, consumers, and regulators worldwide
    b. Specifically, The IEC 60601-2-19, 60601-2-20, and 60601-2-21 standards recommend basic safety and essential performance requirements for infant incubator, transport incubator, and radiant warmer testing.
2. Adopt a consistent inspection frequency
    a. Check the manufacturer's service manual for frequency recommendations; most manufacturers recommend a minimum inspection frequency of once per year.
3. Adopt a formal standardized test procedure
    a. If the service manual and inspection procedure from the manufacturer is not available, it is still the responsibility of the medical facility to choose and standardize on a test procedure.

b. It is important that the infant incubator and radiant warmer functionality be quantitatively evaluated by comparing it to the applicable medical device standard or manufacturer's specifications.

4. Be mindful of probe placement while testing—especially for temperature and airflow.

a. See Figure 67 below

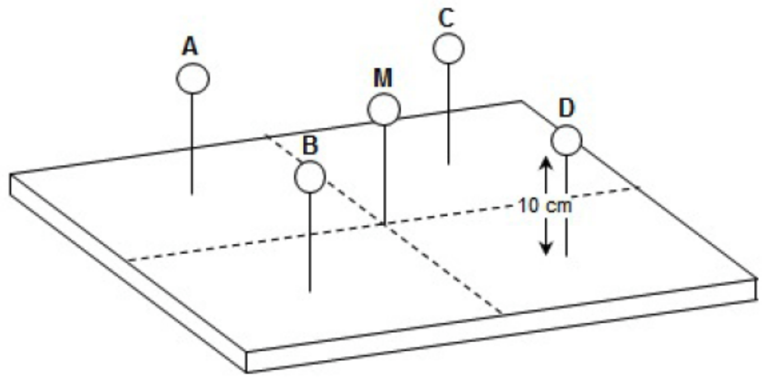


Figure 67: Air Temperature Probe Height and Placement on Mattress

5. The warm up time of the incubator to a steady temperature condition (STC) should be measured, and measurements should be taken both during and after the incubator reaches STC.

a. Warm-up time is the time it takes for the incubator to rise 11 °C from ambient temperature.

b. Manufacturers' manuals will specify the warm-up time, and testing should be carried out to ensure the incubator is within the acceptable range of ±20 % the specified warm up time. This is very important, as incubators are often turned on right before use.

6. Pair additional test equipment with your incubator/radiant warmer analyzer for comprehensive testing

a. Most manufacturer performance inspection procedures require electrical safety tests, including ground wire resistance and chassis leakage.

b. Keep an electrical safety analyzer close by to complete the electrical safety portion of the performance inspection easily.

7. Perform all tests necessary to ensure proper performance

a. Basic Tests: Temperature, Humidity, Airflow, Sound, Oxygen/ Weighing Scale

8. Use test automation to quickly perform tests, document measurements, and archive data

9. Always archive test results

10. Choose to test with an analyzer that you can depend on for complete preventive maintenance and safety testing.

This validation strategy was selected specifically to help the M-HEAL team reach their next goal of creating a device ready for clinical testing. By using a procedure outlined by a company whose device complies with all standards for incubator testing, Fluke Biomedical, we can confidently determine whether the M-HEAL incubator produces results that satisfy these strict requirements, therefore verifying whether the IncuCheck device produces reliable results. For the scope of our final prototype in ME450, we are able to implement the majority of the above best practices, with the exception of collecting data regarding humidity, air flow, sound, etc. In passing this list onto M-HEAL for use in their testing protocol, we feel confident that they are well equipped as the end user to make conclusions about the safety of the incubator.

Initial Efficacy Results

In order to validate the initial efficacy of the device, we created the below table to determine whether or not our device adheres to the outlined best practices as stated above.

Table 23: Initial Efficacy Results

Step	**Validated? (Y/N)**
1. Test to IEC Standards	Y: Our device's temperature measurement accuracy adheres to IEC standards
2. Adopt a consistent inspection frequency	Y: The device enables the M-HEAL team to control the start and stop functionalities of data collection, and therefore allows them to take measurements at equal time intervals
3. Adopt a formal standardized test procedure	Y: Figure 66 above outlines a standardized testing procedure that can be repeated as the user sees fit
4. Be mindful of probe placement while testing—especially for temperature and airflow.	Y: The results of our CFD analysis show the initial cold spots and general temperature dynamics within the incubator, giving the team a place to begin when placing the sensors
5. The warm up time of the incubator to a steady temperature condition (STC) should be measured, and measurements should be taken both during and after the incubator reaches STC.	Y: The team can use the contact temperature sensors placed on top of the Warmilu to measure how long it takes to heat up
6. Pair additional test equipment with your incubator/radiant warmer analyzer for comprehensive testing	N: As of right now, our final design does not have additional functionality beyond temperature measurement. However, the use of the Arduino and SparkFun sensors was intentional to allow for additional sensors to be added with no major changes to the overall design

7. Perform all tests necessary to ensure proper performance	N: The team is currently only able to perform temperature testing, which is not sufficient to ensure proper performance.
8. Use test automation to quickly perform tests, document measurements, and archive data	Y: The data gathering process does not need to be monitored, and can therefore be automated by the team to collect data using the Arduino
9. Always archive test results	Y: The use of puTTY allows the team to export the serial monitor data from Arduino and save it as a .csv file
10. Choose to test with an analyzer that you can depend on for complete preventive maintenance and safety testing	N: As of right now, our device does not have the ability to test safety and maintenance of the incubator device

Usability: How easy is it for a potential end user to operate the device?

While the initial scope of the project is intended for engineers, future iterations have the potential to be used by doctors, nurses and caregivers, to verify the incubator in the hospital prior to using it for a neonate. With this in mind, one goal of the design was to lay the foundation for a user- friendly prototype, beyond the immediate audience of engineers and technical individuals. In order to do so, we can make use of the following plan:

Testing Method/ Plan:

1. Give the device to at least 30 stakeholders (industry professional engineers, ME450 engineers, researching engineers, doctors, nurses, caregivers etc) along with any necessary user documentation. This range of people represents all potential end users of the device, across several industries and functions.
2. Allow them to use the device for 1 week and collect data as needed
3. After 7 days, issue an open- ended survey, in which recipients can indicate which components of the design were intuitive to use, and what they found difficult
4. Use the corresponding feedback to iterate on the design and address any outstanding usability concerns

This method aligns with the FDA human factors guidance for medical devices, given that usability testing is required by the FDA for new or modified medical devices. According to the FDA, there are four requirements that must be met by the test: (1) Test participants represent the intended (actual users) of the device (2) All critical tasks are performed during the test (3) The device user interface represents the final design and (4) The test conditions are sufficiently realistic to represent actual conditions of use [56].

This validation method not only allows us to test whether a stakeholder is able to effectively use the device, but also get feedback from across different skill levels and backgrounds. Additionally, by taking input from stakeholders starting from new grads all the way through professionals, we can ensure that we are getting a wide range of opinions and make sure the device is truly intuitive. Given that M-HEAL has built relationships with several engineers, doctors and nurses within the industry, this validation method is also feasible for them to complete as well.

Within the scope of ME450, we can run a smaller version of the above plan, by giving the device to M-HEAL engineers to represent the end user, and following the outlined steps above. While the scale of the experiment and number of end users is smaller, we can use the best practices outlined above to gain meaningful data about the overall usability of the device to someone who is not immediately familiar with its design.

Initial Usability Results

In order to conduct the above tests on a smaller scale, we gave our device to three members of the M-HEAL team, to use for 30 min each and give us feedback. We selected these members because they are all part of the mechanical subteam of the M-HEAL team, and will be the ultimate end users of the testing device. We also selected members who had very little background about the device or its design, beyond the fact that it is meant to collect temperature data from the incubator. We also provided them with a copy of the instruction manual (Figure 66), to see how effective the pictures and descriptions were at steering them through the entire data collection process.

Aggregating the general feedback, all three members were able to successfully collect temperature data using one sensor and the Arduino. However, we did receive critiques regarding the clarity of the wiring photos, and some uncertainty regarding where to plug things in, especially if more than one sensor was necessary. For this reason, we included a more detailed wiring diagram in the Manufacturing and Fabrication Plan section of this report, to make it more clear to the end user. Additionally, some positive feedback we got included the ability to suction and point the arm anywhere in the device to increase flexibility of data collection, the ability to run the device on a computer off an Arduino to decrease the purchase of additional testing equipment, and the use of the Pelican case to hold all the sensitive electromechanical components for safe transport, especially given that the team often travels overseas to present their prototype.

Design Adherence to Requirements and Specifications

In looking at the final design, we successfully verified that the design meets all but one of the originally outlined specifications. Additionally, we have shown through preliminary validation studies that the design performs on the dimensions of usability, safety and efficacy. Based on the results of the engineering verification and the updates made to the beta design, we are confident that our final design will successfully allow the M-HEAL engineers to successfully test and verify the safety of their neonatal incubator, as the project scope initially intended.

Discussion

The following section will discuss our design and design process and give an overview of critique.

Problem Definition

If our team had more time and resources to collect data and better define the problem, our team would want to further research similar projects to M-HEAL's non-standard incubator. There are many projects similar to M-HEAL, aiming to create ways of fighting neonatal hypothermia, where that may be turning a room into an incubator or creating collapsible portable incubator. Because our scope settled within only looking at a solution for M-HEAL, we did not research heavily into other existing non-profit organizations who are also aiming to combat neonatal hypothermia. We researched standard procedures to verify M-HEAL's incubator against hospital and national standards. If we had more time, we'd like to research and contact other non-profit organizations and ask about their testing methods. Many of these non-profit organizations are in a similar situation, looking for an accurate way to verify the safety of their incubator in a cost-effective manner. We'd interview these organizations and gather information on their own procedures, which may be a lengthy process but a useful one in refining a testing device used in conjunction with clinical trials for future plans of the device for M-HEAL. Within the scope of ME 450, it would open the scope of testing methods that are well tested and have already been run by similar organizations.

Design Critique

Our design has many strengths and weaknesses, and outnumbers weaknesses by strengths which is why we are confident that M-HEAL will benefit well from this design. Our design has a very large degree of flexibility in analyzing the environment of the incubator. Because our design utilizes a sensor standard with a flexible arm, the device can reach tight to reach corners if M-HEAL decides that there is a need to have that area analyzed for their testing. The device also is designed in a manner that makes it easy for the end user to understand how the recorded data stands against current standards of temperature and safety for the neonate, whether or not the incubator is operating properly against incubator standard conditions. The graph that the user automatically creates after uploading the Arduino data has strong visual color indicators that signals to the user, what if the data verifies safety of the incubator.

Some weaknesses of the design include that the user interface is not creating a graph in real time and not letting the user know if the incubator is operating within safe temperature ranges at that specific moment in time. Real time data graph reading can be very helpful to the M-HEAL engineers in identifying what occurred during the timespan if something peaked and users could visually inspect the incubator while monitoring the graph. Because our design lacks this aspect, M-HEAL engineers, if wanting to run very long tests, may have to set up a camera monitoring system to synchronize with the data collection. The M-HEAL engineers do have the ability to read the incoming raw numbers from the Arduino home screen.

The design user interface can be improved by either changing the data collection method from an Arduino to a more complex one that can allow for real time graphing. The Ardiuno was chosen because of its well documented usability with SparkFun sensors and is a commonly used microcontroller across M-HEAL members, a factor that would aid in high ratings for usability and intuitiveness for the project team. The current graph system would then have to be implemented for real time graphing, and be able to be stopped and exported. This system would also have to include a stop, start, and view log user interface as well, which is one of our must have requirements for the user interface. The Arduino home page does have a stop, start, and view window for the data, but this is in reference to the visual data graphing for the temperature data. Overall, a simple switch in user interface to a real time logging system could further enhance the ease and efficiency of data collection for M-HEAL.

It is important to note that the real time graphing user interface could have been implemented in this semester's design process, if our team had a much larger background in computer science and the inner workings of how to process raw data between Sparkfun and microcontrollers. In order to meet the deadlines of the ME450, our team decided to work with the most commercially available electronics for the M-HEAL team, so that they could iterate on the design for their future plans, but at the cost of real time data graphing. If time allowed, our team could have been able to dive into the much lengthier process of developing a web application that somehow can take raw data from the microcontroller in real time and graph it. However, we are confident that the switch to real time data logging can be integrated into the device with ease, with the help of other M-HEAL engineers with differing majors and background knowledge in the future.

Risks

We encountered many different challenges within the design process. These challenges included understanding the integration of different electronic components from varying vendors and the attached documentation, and in turn piecing them together to create a functioning electronic system for our needs. Our team members do not have background in computer science or electrical engineering, so we felt that we had a large learning curve ahead of us. We addressed these issues by attempting to learn as much as we could about available market options and how they can be easily integrated with others to create an entire system and then identify the strengths and weaknesses. This process was completed especially because we wanted to cross check electronic components compatibility with one another, because we ran into the issue such that some electronic components were compatible with one another on certain conditions, ie a separate component acting as a converter or needing another board connecting sensors, etc. Because there is a lot of fine print within the sea of information about market option electronics for this device we were designing, it was common to come to a place of having to research small line items for compatibility. However, this main challenge that we encountered was minor in the grand scheme of our design as it did not overtly affect our stand design, sensor choice, etc. Any converters or additional electronic components would be small in scale.

Risks associated with the final design include that because the device does not track data real time graphically, it may be easier for the user to miss incorrect readings that the sensors may be reading, i.e. the sensor may not be functioning properly. The sensor output data can be small to read and increases the chances that the user might not act on investing that sensor and its faulty operation. The device does not have any self diagnostics system or self calibration system. The device operates under the assumption that the sensors were calibrated at the manufacturer according to the specification sheet and that they read temperature correctly. Verification of these sensors has to be manually checked via the usage of other sensors. This lack of self diagnostics may be an issue if the end user collects data during a verification trial and the device's lack of real time graphing does not indicate an issue early on. This is why we have created an instruction manual for the setup of the device and intend to communicate a document that has a list of potential issues and ways to fix them. The intent is that the document is a living document that keeps track of past issues that have occurred in our usage and M-HEAL's usage, and how they have been addressed, in an effort to aid other testing engineers in how to diagnose a situation with the device.

Reflection

Public Health, Safety, and Welfare Factors

Public health, safety, and the well-being of the end-users of our device must all be considered throughout the design process. Given that the IncuCheck is a medical device, there are many concerns related to the safety and welfare of the individuals using the device. The device will carry many electrical wires and must be plugged into a power source providing current and voltage to the device. If the device is not grounded properly or wires are exposed, handlers of the device may possibly be shocked. By wiring everything correctly, taping any exposed wires, and properly grounding the device will ensure the IncuCheck is safe to operate. In addition, since the device is intended to provide information critical to the conditions a neonatal infant will be placed in, the data the device provides must be an accurate presentation of the conditions within the incubator. If the information is incorrect, the neonate may not be in the ideal conditions the hospital is trying to provide, or worst case scenario severely harm the neonate. Therefore, it is imperative that we ensure the IncuCheck device is accurate and correctly displays information. We must also ensure the device is being used in the proper conditions. Providing operation guides and instruction manuals are integral to the operational success of the device. In addition, maintaining proper procedures and device integrity ensures the device will operate properly in the defined conditions.

Global and Cultural Implications

Given that the M-HEAL device is ultimately intended for hospitals and clinics in Sub-Saharan Africa, taking into account a global context is especially relevant for our project and prototype. While the first iteration is going to be used by M-HEAL engineers here at the University of Michigan, future iterations of the project are intended to create a testing device that can be used on-site in Sub-Saharan Africa to continually test the safety of the M-HEAL incubator prior to use. If this is the case, future designs must consider available materials in the region for repairability purposes, intuitive setup and usage that can be reasonably understood by a non-technical, non-American audience, and the features that are most relevant to the specific hospitals and stakeholders for which our prototype is intended.

This device has the potential to impact the global marketplace by enabling access to low-cost, accessible medical device solutions to treat conditions which historically yield high rates of mortality. In particular, this device can reduce the instances of neonatal mortality, 99% of which is concentrated in developing countries due to a lack of proper medical devices.

Social Impacts of Manufacturing, Use, and Disposal

First and foremost, the social impact of using this device is in bridging the gap between the standard of care in developed versus developing countries. This device can enhance the safety and functionality of neonatal incubators, and enable engineers to create a safe device at a fraction of the cost, thus improving the reach of the device and creating more positive outcomes for preterm infants. Additionally, it has the potential to bring awareness to the issue of unequal access to medical devices, and encourage more engineers to create low-cost solutions to long standing healthcare disparities. Finally, given that the device is built to be durable and reusable, it has positive environmental implications, throughout its lifetime.

Economic Impacts of Manufacturing and Disposal

Given that this device was intended to substitute a device whose market cost is over $10K, the primary incentive to use it is economic. It enables M-HEAL testing engineers to check the safety of the device without compromising their budget, which keeps their overall costs down and allows them to get the incubator to their end user at a reasonable cost. Additionally, given that we stayed well within their willingness to pay for testing equipment, it creates additional economic value that can be redirected elsewhere, to adding additional features to the incubator or subsidizing the cost of the final product to the end user.

Characterization of Societal Impact

In order to understand the impacts of our design, we primarily made use of stakeholder mapping. In identifying primary, secondary and tertiary stakeholders, we were able to prioritize how we met each of their needs, in order of how important their influence was on the project. For additional details on the stakeholders, reference Figure 4.

Influence of Variety in Team Member Identities in Design Process

Throughout the design process this semester, each team member brought a unique view of perspectives and background knowledge and skill to the table. Each team member, from their own unique identity in terms of gender, race, and more brought unique ideas about how different varieties of people will interact with the device, whether that was thinking about how much force the stands needed in order to change the orientation or bend them or how much force was needed to attach the arm to the interior of the incubator. Many members of our team came with no background knowledge on electronics, which led into a path towards designing a device with easy to use electronics and set up for all end users, which in the end was a unanimous design choice between members.

Many members came with different skill sets, such that we decided to delegate tasks to each member where they felt most comfortable and confident in, in an effort to produce high quality work and output at a lesser learning curve and in an efficient manner. We believed that because of the fast pace of the class, all outputs and deliverables needed to be of high quality but also done in a very efficient manner, thus the use of team members with their own strengths whether that be in CAD, logistics management, organization of deadlines reports and analysis with simulation software, etc. Cultural and privilege differences affected the way we interacted with one another, in how we approached solutions and had conversations, but never created internal negative conflicts as all team members acted in a very professional manner. All team members acted with decorum and bonded with each other, to great a well functioning and fun team dynamic.

Influence of Varying Identities with Sponsor in Design Process

The influence of the differences of identity and culture between our sponsor M-HEAL and our own team members played a significant role in the design process and the final design. Because M-HEAL team members share a similar identity with the ME450 team, as we are all students at the University of Michigan and have a similar perspective on the role of project teams and how much little time there is with busy schedules, which influences the design for the incubator analyzer. This aspect influences how the device must be easy plug and play and easy to use in regards to setting up a testing environment and gathering data in an efficient manner.
M-HEAL also had significant input in regards to what the device was supposed to achieve at the beginning of the year. Therefore there is a power dynamic such that M-HEAL is the main head of direction, and the ME 450 team acts as a “contractor” hired by M-HEAL to create this device to meet their needs and their objectives in an effort to verify the safety of the incubator.
However, due to the nature of M-HEAL acting as a head partner but also in a student to student relationship, there was a smooth flow in communication and was never a power struggle between

the two parties. Each party came at the problem from the perspective of an engineer and how to objectively achieve the overall goal for the semester and both parties were aware of the other parties' role, differences in identity, and acted in very professional manners. Both parties approached the problem understanding that M-HEAL themselves don't have many resources in terms of financials and aimed to create an objective of a device that is cheap but easy to use in operating and gathering data for verification.

Present Power Dynamics and Implications

Being that one of our four team members is directly involved with M-HEAL, this project is based on full collaboration between the ME 450 engineering students and the project team. The relationship is reliant on full and clear communication between both parties in addition to the exchange of ideas, comments, and thoughts on the current design process. The team aims to identify all possible inclusivity implications and problems that should be addressed to create a more holistic design process. This is to be achieved through engaging in discussions with all stakeholders involved, identifying all varying social identities in an organized manner, expressions of power by different stakeholders, and their associated level of influence. From this, all inclusivity implications will be woven into every step of the design process, ensuring that the device is designed within a socially conscious framework by all members of the team. There will be a heavy emphasis on the needs that are expressed by M-HEAL, acting as representatives of Kenyan medical professionals.

The relationship with our sponsor and their stakeholders also created interesting power dynamics, wherein we as ME450 wanted to fulfill their requirements, but also wanted to exert creativity and take liberties in the way we approached the problem. As we became subject matter experts in the world of incubator testing, the power shifted away from the sponsors and towards ME450, as we established credibility for our understanding of the problem, which thereby created trust between us and the sponsors and gave us more freedom to interpret the problem as we saw fit. This was especially important given that M-HEAL was our primary stakeholder, sponsor and end user, in addition to communicating the needs of their community partners.

On a broader scale, it is important to note that there would be prominent power dynamics in the context of a commercial product such that historically there has always been a trade-off between abiding by regulatory bodies and the value of time. Regulatory bodies often have slower reaction times to new and upcoming technology, without regard for the prevalent time issue for which the technology is needed. Their role as a regulatory body constrains our team in a position where we must abide by their regulations and navigate their own timed process of approval despite our device's stakeholders. There are public costs in terms of public health associated with loss of time in the development process towards our technology.

Further, there exists power relations that may not be balanced between developed and developing partners in the context of partnerships and patterns of varying degrees of economic development. The differences between the historic development of global developed and developing economies, affects the way developed partners may have a lack of knowledge on the everyday local stakeholders of the developing partners they may be working with. There has also historically been impacts of colonization and a colonial mindset when engaging with developing partners. This sometimes impacts the way developed partners' unconscious biases towards developing partners. The way to address this is to adopt a habit of open communication about how to respectfully and properly integrate technology in developing regions with local partners in the context of the social, economical, and environmental sustainability for all local stakeholders.

In order to ensure that our team's scope was not too narrow or heavily influenced by our own biases, we also interviewed a large number of stakeholders, each of whom brought a different perspective. For example, Dr. Solomon Adera, an expert at heat transfer, was very helpful in identifying the feasibility of the idea, and ensuring that it was technically sound. On the other hand, Dr. Tim Johnson approached his feedback from a more clinical lens, given his experience in maternal care. He was able to speak more practically about the impacts of an incubator that is too hot or too cold, and therefore influenced specifications such as accuracy of the temperature sensor. Finally, Dr. Julia Kramer had a unique third perspective, wherein she combined her engineering expertise with her role in leading a medical device nonprofit, which enabled her to speak on the low cost dimension, and help us decipher what components of our project were most important to implement. While these are only a few examples of all the interviews we collected, our team prioritized gaining broad opinions, to ensure that we were understanding the problem across all dimensions, and exploring the entire solution set.

With our team members, there are power dynamics that arose given our differences in background, ethnicity, gender and general life experiences. Myles is currently working at a job that necessitates strong Solidworks skills, so he primarily took the lead on the 3D modeling component of the project. Becca has previously worked on CFD modeling and analysis, which equipped her to run a lot of our simulations during the verification and validation phase. Erik has also had previous engineering experience, which enabled him to create testing plans and help with the physical development of the prototype. Finally, Dhiya, having sponsored the project, was the primary communicator between ME450 and M-HEAL, and helped build the project requirements and specifications based on what was most beneficial to the team. Together, each member brought a unique point of view, and contributed significantly to the final product.

Given the diversity of our viewpoints, we established norms such as weekly check-ins to gauge project progress and updating other members, prioritized teaching members of the team about parts of the project to which they had not had previous exposure, and having certain checks in place where multiple team members reviewed all major deliverables to ensure high quality of work. We also tried to be aware of imbalances in influence or dominance of personalities, and made it a priority to address each other as equals, and make sure everyone had equal say in our final decisions, during the presentation and in general during group meetings. If there was a major decision in which multiple team members disagreed, we put it to a vote, after allowing both parties to explain their side of the argument. This way, regardless of which way the group voted, both sides would feel equally seen and heard, and thereby increase buy-in to the final group decision.

Culturally, given that our team had a variety of ethnic backgrounds, each member of the team valued a different component of the project, and had differing viewpoints regarding what should be prioritized. For example, having worked with M-HEAL for two years, Dhiya wanted to prioritize the ability of the product to be used in third world countries, which was partly influenced by her recent travels to India and seeing first hand how their medical system is underserved and requires additional resources. On the other hand, Myles, who has spent a significant amount of time in industry, wanted to prioritize usability for the initial end user, M-HEAL, in order to make the prototyping process more efficient and establish a more narrow, feasible scope. While both approaches had merit, the cultural influences of each team member ultimately influenced how they approached the project over the course of the semester.

Ethics

Ethical Implications of Sustainability

Regarding sustainability in the design of the IncuCheck, the nature of the device itself may call for the use of batteries (rechargeable or single-use), varying sensors that may likely be manufactured with emitted pollutants and hard-to-dispose materials, and other sources of non-renewable energy. These aspects may affect M-HEAL's priorities as the disposal of the project, dependent on design considerations, can have negative long-term effects regarding environmental sustainability.

To abide by M-HEAL's core foundational principles, our team will continue to investigate materials that push towards a more sustainable design overall in future iterations. Realistically, if striving toward sustainable design is only attainable at the expense of functionality and affordability, the latter two shall be prioritized to expedite the implementation of M-HEAL's incubators in Kenya and plan to move forward with incubator development toward clinical trials. The lack of emphasis on sustainability must still be investigated if the product's emissions, power consumption, or disposal will negatively harm surrounding communities and produce more harm than good if future iterations of the IncuCheck device were commercially sold to Ghanaian hospitals and medical professionals. Further, M-HEAL designated that our team should aim to overall design towards sustainability because the sustainability footprint of the IncuCheck device is taken into account of the sustainability footprint of the M-HEAL incubator. Thus, M-HEAL aims to reduce the negative environmental impact of the incubator as a whole, including all forms of testing and validity.

In practice, given that we are currently optimizing for cost, not all of our products are optimal in their environmental impact, or their end of life treatment. However, having weighed the pros and cons of this decision, we ultimately decided to make the tradeoff, given that the purpose of our device is to be used by one group and is built to be durable and used for multiple years. Given that the prototype is a one off design, the environmental impact of using more unsustainable products is not as far-reaching as a design that necessitates the commercialization of mass manufacturing.

Ethical Implications of Affordability

Looking at the prototype's cost constraint, it was difficult to meet the accuracy standards of the higher cost incubator verification devices that are currently on the market. Therefore, there must be consideration of what standards are reasonably possible for our device to meet in order to confidently validate the safety and effectiveness of M-HEAL's incubator and how these standards can be met with a significantly lower cost device. For example, the necessary accuracy of the contact sensor as defined by the IEC standards was roughly ±0.1°C. However, a single contact sensor that met this specification would have put us significantly over the $400 prototyping budget, so we instead opted to convert a SparkFun ambient sensor with an accuracy of ±0.1°C into a contact sensor for our final design. In doing so, we took the tradeoff in cost and accuracy and used engineering design to split the difference and find a way to adhere to both in a way that was most beneficial to our sponsor. Using a similar method, we analyzed which of the remaining IEC standards need to be met and how to design within the cost constraint to confidently verify incubator safety.

The final design is not able to measure all incubator environmental factors (relative humidity, temperature, and airflow) as those additional sensors will result in a significant impact on our budget. Our current final design only looks at ambient temperature and contact temperature due to cost constraints in an effort to make sure that the temperature is accurately measured before focusing on other environmental factors. From an ethical standpoint, our first round prototype only focuses on temperature, relative humidity and airflow are ignored solely because of cost constraints. However, in the context of the neonates who desperately need access to M-HEAL's incubator, the lack of verification of these two aspects within this prototype further complicates the safety readiness for future verification testing. Thus, it is a social cost at neonates' expense in lower-income communities. Further iterations of the device may include the ability to verify relative humidity and airflow at the cost of an increase in book value cost. This could have a negative impact on the accessibility of our incubator due to increasing verification costs. Further iterations beyond our project and first-round prototypes may build upon this, expanding the capabilities of the device and increasing the number of incubator environmental factors that can be measured accurately in order to abide by global and/or specific United States standards.

These ethical dilemmas have been discussed with multiple stakeholders to find what best suits the needs of M-HEAL. As students of the University of Michigan in collaboration with M-HEAL, a student organization, we uphold similar professional standards and ethics according to university protocol.

Recommendations

In order to make the most effective use of our incubator analyzer we have a series of recommendations. The first recommendation is to add a contact temperature sensor. This device is intended to utilize five ambient temperature sensors; we have included six TMP117 sensors as they are capable of being converted to contact temperature sensors, an explanation is linked within the Sparkfun TMP117's documentation, and source [57]. Through the provided documentation and additional sensor included this should be a relatively simple and low cost solution. Our next recommendation is to establish procedures around sensor testing. The TMP117 sensor has a long term drift of ±0.03°C per 300 hours of use at 150°C (source), after 300 hours the sensor needs to be evaluated through a method that will allow sensor accuracy to be tested to a very high degree, or replaced in order to avoid excess drift in accuracy. It will also be necessary to properly track sensor usage in order to ensure that this limit is not exceeded, a spreadsheet should be created in order to document each use of the system as well as the amount of time it was used for. Tests are expected to be six hours each in order to evaluate the incubator through the entire use span of the Warmilu, this will allow for the sensors to conduct 50 tests, but tests may be shorter depending on what is being tested.

We would also recommend creating an improved user interface. The current interface does not live graph the data being collected and requires the user to export a CSV file from the Arduinos code and import it into another code which we created in order to graph and provide information on if the temperature of the incubator is safe at specific times. Being able to see the data being graphed in real time will make analysis much easier and more effective, modifying the code which we created to automatically load the information from the Arduino will likely be sufficient for this task. A notation system should be implemented in order to add notes within the data surrounding the specific conditions of the incubator as the doors being opened or any change in the environment surrounding the incubator will likely impact the data being recorded and could potentially result in a false failure or acceptance. Due to the concern around any changes in environment impacting the data from the incubator it will currently be necessary to have a person supervising the device at all times, as tests are six hours each, this may be unreasonable. We recommend utilizing a camera along with a timer being displayed to the camera at all times in order to conduct the test without constant supervision. If any deviations are seen in the data the camera can be used to see if the incubator was tampered with or if anything within the room was altered, the timer will allow the user to see exactly when this change occurred and treat the data accordingly.

Our final recommendation would be to implement an automatic sensor failure detection system into this software. While procedures will be developed around the sensor's accuracy drift specs, the sensors could still fail for other reasons. For this reason we recommend implementing auto failure detection into the updated user interface, this can be done through comparing the sensors within the incubator with each other along with past data, once a few trials have been ran, find the max deviation that occurs between the sensors within the incubator, and apply a safety factor. If a sensor falls out of that range relative to the others it should be inspected and tested to ensure that it is still properly functioning. Utilizing the recommendations above, we believe that M-Heal will be able to utilize this device in the most effective way possible to verify the thermodynamic properties of their incubator.

Conclusion

The end goal of this project was to provide M-Heal with a prototype incubator testing device in order to conduct testing on the low-cost incubator which they have/are designing in order to combat neonatal hypothermia in low resource communities. This device is intended to allow them to evaluate the thermodynamic properties of their incubator design in order to ensure that it is safe prior to pursuing clinical trials. We have created a device which is affordable and capable of accurately measuring the temperature within five locations in the incubator in accordance with incubator testing standards. This device primarily utilizes off the shelf components including an Arduino as the controller, five Sparkfun TMP117 sensors to measure temperature, adjustable stands through suction cups and flexible arms, a case in order to safely store and transport the sensitive electronic components, and some additional electronic components that were needed to properly utilize the Sparkfun sensors with an Arduino. As the final design is intended to be a prototype, our build and final design are very similar to the final design, with the primary difference coming from the inclusion of a contact temperature sensor.

We believe that we have been successful in solving the issues brought to our attention by M-Heal when taking the recommendations explained above into consideration. The current final design meets all but one of our specifications which were created in collaboration with M-Heal's needs and wants for this device. This specification that was not met is primarily related to usability, and will not cause the resulting data to be inaccurate or negate the primary purpose of the device, but will provide a minor inconvenience in the use of our device. This can be easily remedied in a low cost way through the addition of an improved user interface, despite this issue our device still met the system usability score which was desired. Our device is capable of analyzing the incubator's temperature to an accuracy of ±0.1°C along with analyzing five points at the same time. This device was built around the current incubator designs but is also very adaptable to different designs, the suction cups allow the stands to be mounted to any flat surface within an incubator along with the flexible arms allowing small areas and corners to be effectively analyzed. This device also met a specification that was not a primary design focus of being able to switch out the sensors with ≤ 2 tools. Our device does not require any tools to change the sensors, this will allow for rapid changing of sensors if needed. Overall we are confident that our device will be very useful to M-Heal and will be able to effectively meet their needs in addressing the problem that was given to us.

Acknowledgements

We'd like to thank M-HEAL for sponsoring this project and their continual support. M-HEAL strives to create a global impact within the world and create positive change within people's lives and we were honored to be a part of this. We'd also like to thank Professor Adera for his continued support and advice throughout the process in regards to heat transfer and logistics of how to manage a project like this. We'd like to thank Professor Sienko and Professor Shorter for providing insight and guidance throughout all of ME450. We'd also like to thank Dr. Johnson from Michigan Medicine, Dr. Rooney from U of M Clinical Simulation Center, and all other ME 450 staff, professors, and lab mentors who guided us throughout the entire process.

Team 018 Biographies

Myles Burchill is a current Undergraduate Senior in the Mechanical Engineering Department at The University of Michigan, where he plans to graduate in May 2024. Myles was born and raised in New York City where he resided from 2002 - 2020 with his two younger siblings Marcus and Maclen. His parents, Randee and Andrew, are both lawyers and have been living in New York City since the 1990's. Growing up in NYC made Myles interested in vehicles, construction, and generally how things worked the way they did. As a child Lego's were very popular in his life and thus started the interest in building/designing everything from fake buildings to actual computers. Myles always loved to help fix small things around his house and never stepped down from the opportunity to help his parents with mechanical issues. Math and science were the subjects Myles enjoyed most and combining this with his interest in how objects moved and worked, Mechanical Engineering was the obvious choice. Myles has been involved in sports since the age of four, and most recently became an endurance athlete. He has completed both the 2022 and 2023 Chicago Marathon (with plans to run every year) while also completing the 2023 Ironman 70.3 Steelhead. Following his expected graduation in May, Myles will be working for a company called EAVX. EAVX is the internal innovation hub for the J.B. Poindexter and Co. Corporation which is headquartered in Houston, Texas. EAVX operates out of two facilities located in Ann Arbor and Ypsilanti, with the latter where Myles is currently working part time to help both the Mechanical Engineering and Fabrication teams complete prototype UPS delivery vans.

Dhiya Krupashankar is currently a fourth-year student at The University of Michigan, studying Mechanical Engineering and Business Administration, with a concentration in Business Law and Strategy. Dhiya is originally from West Bloomfield, MI, and lives with her parents, Rohini and Krupa. Dhiya originally became interested in engineering through her elementary school magnet program, where she competed in the World in Motion national engineering competition. Through this program, she learned the fundamentals of design and iteration, tackled engineering problems, and worked with industry mentors to gain their insights into engineering as a career. This continued through high school in the enrollment of their STEAM Engineering Academy, and further through her coursework and internships at the University of Michigan. Outside of the classroom, she is the President of a Ross School of Business student-run investment portfolio, known as the Global Investments Committee. Additionally, she is the prototype lead for M-HEAL, a club focused on biomedical device creation for low resource communities, which is where she initially became interested in global health. Additionally, she works as an undergraduate researcher in the Soft Tissue and Biomechanics lab under Professor Ellen Arruda, understanding the anatomy of an ACL and what causes them to tear. In her free time, she enjoys running and playing tennis. Regarding work experience, she has previously held roles in research engineering, product management and business strategy. This summer, she will be interning at the D.E. Shaw Group in their investment strategy group, working to expand the portfolio and identify future investment strategies.

Rebecca Lara is a Junior at the University of Michigan, studying Mechanical Engineering with a minor in Economics. Rebecca was born and grew up in Los Angeles, CA, and as a kid would always find enjoyment in designing and building dollhouses. It was the realization that she found more enjoyment in creating and designing than playing with the dolls themselves that drove her to further investigate engineering. Her interest in engineering expanded in middle school and high school when she was enrolled in advanced mathematics and science courses. After joining her all-girls high school robotics team and competing for 3 full years, one as Build Lead, Rebecca set herself to further study Mechanical Engineering at the University of Michigan. Outside of the classroom, she has been the Business Lead of a university project team called Supermileage for 2 years, which builds and competes fuel-efficient vehicles at the annual Shell Eco-Marathon. Rebecca is also interested in engineering economics in the context of corporate finance, strategy, and project management. She is also involved in Pi Tau Sigma, the Mechanical Engineering Honors Society, and works at the University of Michigan Museum of Natural History as a store clerk and museum docent. In her spare time, she enjoys cooking and trying new restaurants. In an alternate universe, Rebecca states that she'd be enrolled in culinary school. She also loves to read and collect books. In past work experiences, Rebecca has worked as a Summer Lego Camp STEM Instructor and interned at Nissan Technical Center North America as a Vehicle Program Management Intern. Rebecca intends to return to Nissan this following summer to intern in User Experience Research and Test.

Erik Wahr is a senior in the Mechanical Engineering Department at The University of Michigan. Erik Was born in New York City in January of 2002 where he lived for two years, he then moved to Charlotte, North Carolina, where he resided until he started college at The University of Michigan. Erik's family consists of his father, who was born in Green Bay, Wisconsin, and works at US Bank along with his mother, Kristine, who was born in Texas and worked as an accountant until she retired to stay at home as a mother. Erik also has a younger sister, Katherine, who is currently a Freshman at The University of Wisconsin. As a child, Erik enjoyed playing with legos, watching construction sites, and playing with relevant toys, along with disassembling any unused piece of technology despite typically not being able to reassemble them. While Erik was very interested in design and engineering-related tasks as a child, in middle school he became more interested in coding and video game development. This was somewhat of a short-lived interest, as towards the end of middle school he became more interested in cars and automotive racing. From that point, Erik knew that he wanted to go down the engineering path in order to have a career that aligned with his passion. Erik's automotive and engineering interest was also furthered by the programs provided by his high school which included engineering-specific classes which introduced him to the basics of design and CAD software. Erik also enjoyed the auto tech classes offered in high school along with the automotive club which entered the 24 hours of lemons every year with a Merkur XR4Ti. Erik has completed three internships in the automotive racing industry including Richard Childress Racing (NASCAR), Joe Gibbs Racing (NASCAR), and Aston Martin (Formula 1). Erik is currently searching for internships for next summer and looking forward to a career in the automotive racing industry.

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Appendices

Appendix A: Project Plan

DESIGN					
Obtain M-HEAL Sensors	Dhiya Krupashankar	100%	2/2/24	2/6/24	-48
Obtain Arduino Kit from x50 Lab	Myles Burchill	100%	2/2/24	2/6/24	-48
Revise Design Requirements and Specifications (Final Round)!	All Members	100%	2/2/24	2/6/24	-48
Interview with NICU Nurses	All Members	100%	1/30/24	2/7/24	-47
List of Potential Ideal Constraints and Practical Constraints	All Members	100%	2/2/24	2/8/24	-46
Concept Exploration Meeting w/ Activities	All Members	100%	2/2/24	2/8/24	-46
Conceive 5+ Well Drafted Concept Ideas Before Class	All Members	100%	2/2/24	2/7/24	-47
Conceive Subfunction Requirements List for Subsystems	All Members	100%	2/8/24	2/13/24	-41
List of Potential Sensors and Materials	All Members	100%	2/8/24	2/13/24	-41
Create list of Final 5 Concepts	All Members	100%	2/10/24	2/15/24	-39
Consultation with M-HEAL Board	All Members	100%	2/10/24	2/15/24	-39
Select FINAL Concept	All Members	100%	2/10/24	2/17/24	-37
Draft #1 of Potential Materials	Myles Burchill	100%	2/10/24	2/17/24	-37
Draft #1 of Electrical Wiring Diagram	Myles Burchill	80%	2/12/24	2/24/24	-30
Draft #1 of Financial Budget Sheet	Rebecca Lara	100%	2/8/24	2/22/24	-32
Create Draft CAD Mockup of Subsystems	Erik Wahr	100%	2/17/24	2/25/24	-29
Consultation with M-HEAL Board	Dhiya Krupashankar	100%	2/14/24	2/17/24	-37
All Hands on Deck Evaluation Meeting of "Alpha Design"	All Members	100%	2/25/24	2/27/24	-27

MANUFACTURING					
Session for Wiring to Contact Temperature	All Members	100%	2/25/24	3/21/24	-5
Gather Test Data for Contact Temp	All Members	100%	2/25/24	3/20/24	-6
Final Plan for Engineering Analysis on Contact Temp System	All Members	100%	2/25/24	3/20/24	-6
Discussion on Beta Design	All Members	100%	2/25/24	3/22/24	-4
Meeting with Professor Adera about Material and Incubator Contact Temp	All Members	100%	2/25/24	3/19/24	-7
Discussion on Device Housing Case	All Members	50%	2/25/24	3/19/24	-7
Order SparkFun Sensors (1)	All Members	100%	2/25/24	3/1/24	-25
Prototype Device Housing and Organizer CardBoard	All Members	100%	2/25/24	3/5/24	-21
Wiring Session	All Members	100%	2/25/24	3/7/24	-19
Test Written Program to Obtain 1st Round Temp Data	All Members	100%	2/25/24	3/8/24	-18
3D Print Sensor Housing First Round	Erik Wahr	0%	2/25/24	3/5/24	-21
Final CAD for Beta Design	Myles Burchill	100%	2/26/24	3/22/24	-4
Design Review for Beta Design	All Members	50%	2/27/24	3/22/24	-4
Sparkfun Sensor to Arduino Diagram	All Members	100%	2/25/24	3/5/24	-21
Proof of Concept Build Completed	All Members	30%	2/25/24	3/30/24	4
First Round Testing w/ M-HEAL Incubator	All Members	0%	2/25/24	3/25/24	-1
Plan for Graphical User Interface	All Members	100%	2/25/24	3/10/24	-16
All Materials Ordered for Manufacturing	Rebecca Lara	80%	2/26/24	2/27/24	-28
Order QWIIC Connecters	Rebecca Lara	0%	3/25/24	3/28/24	2
Finish Black Box	Erik Wahr	50%	3/25/24	3/28/24	2
Order McMaster Carr Tubing	Rebecca Lara	0%	3/25/24	3/28/24	2
Engineering Drawings for all Part Drafted	Dhiya Krupashankar	0%	3/1/24	3/5/24	-21
Engineering Drawings Finalized	Dhiya Krupashankar	0%	3/5/24	3/7/24	-19
Wiring and Electrical Systems for 1st Prototype Build Finalized	Myles Burchill	0%	2/27/24	3/7/24	-19
Diagram for Data Collection Draft	Erik Wahr	50%	3/7/24	3/12/24	-14
Consultation with Dr. Johnson	All Members	0%	3/11/24	3/12/24	-14
Consultation with Dr. Adera	All Members	0%	3/11/24	3/12/24	-14
Consultation with M-HEAL Board	All Members	0%	3/11/24	3/13/24	-13
Deadline for 1st Prototype Build	All Members	0%	3/1/24	3/21/24	-5
Sensors and Electrical Wiring Subsystems to be Ready for Testing	All Members	0%	3/20/24	3/26/24	0
Data Collection System Prototype Ready for Testing	All Members	0%	3/20/24	3/26/24	0
Bill of Materials Finalized	Rebecca Lara	0%	3/23/24	3/26/24	0

TESTING					
Testing of Sensors and Electrical Wiring	All Members	0%	3/20/24	3/28/24	3
Data Collection Hookup to Sensors	All Members	0%	3/28/24	4/2/24	8
Testing Rounds for Sensor Verification	All Members	0%	3/30/24	4/4/24	10
Consultation with Dr. Johnson	All Members	0%	4/4/24	4/5/24	11
Consultation with Dr. Adera	All Members	0%	4/4/24	4/5/24	11
Consultation with M-HEAL Board	All Members	0%	4/4/24	4/5/24	11
Testing with M-HEAL Incubator	All Members	0%	4/5/24	4/15/24	21
Data Verification against Industry Standards	Rebecca Lara	0%	4/5/24	4/15/24	21
Summary if Valid Against Collected Data	Rebecca Lara	0%	4/5/24	4/15/24	21

OVERALL ME 450 SCHEDULE					
Design Review #1 Report	All Members	100%	1/15/24	2/8/24	-47
Design Review #2 Presentation	All Members	100%	2/8/24	2/22/24	-33
Team Health Assessment #1	All Members	100%	2/8/24	2/23/24	-32
Design Review #2 Report	All Members	100%	2/8/24	3/7/24	-19
Design Review #3 Presentation	All Members	80%	3/7/24	3/19/24	-7
Design Review #3 Report	All Members	90%	3/7/24	3/26/24	0
Team Health Assessment #2	All Members	100%	3/7/24	3/29/24	3
Design Expo Poster Abstract	All Members	100%	3/29/24	4/2/24	7
Design Review 4 Presentation	All Members	0%	3/29/24	4/11/24	16
Deadline for Design Expo Poster Printing	All Members	0%	4/11/24	4/16/24	21
Design Expo Presentation: 12 pm - 4 pm	All Members	0%	4/11/24	4/18/24	23
Final Report	All Members	0%	4/11/24	4/29/24	34
Final Team Peer Evaluation	All Members	0%	4/11/24	4/29/24	34
Project Handoff Agreement	All Members	0%	4/11/24	4/29/24	34

For Full Plan: ME 450 Incubator Project Plan

Appendix B: System Usability Scale (SUS) Questions

When a SUS is used, participants are asked to score the following 10 items with one of five responses that range from Strongly Agree to Strongly disagree:

1. I think that I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.
5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system.

The questionnaire and scoring are outlined in the System Usability Scale (SUS) Template

Appendix C: DR3 Obstacles and Lessons Learned

To analyze the engineering specifications that are considered to assess the incubator testing device's design, it is important to be knowledgeable about many subjects within both mechanical and electrical engineering. The integration of electro-mechanical components is integral to the success of our project. The state of knowledge for all group members is quite low in electrical engineering, however, we have a large combined knowledge of mechanical engineering due to our previous internship experiences and our education through The University of Michigan mechanical engineering undergraduate program. Even though our group does not possess immense skill related to electrical engineering, there are plenty of resources available to us to be able to effectively translate our design into an actual product. YouTube has many informational videos, we have friends who are studying electrical engineering, and the library has immense resources on educational content related to electrical engineering. We have also taken classes such as ME 360 that taught us the basic, general concepts of how controls work in electro-mechanical systems. Using that prior knowledge and notes from class can help us with the design of the IncuCheck device.

Based on our current evaluation of our design we have found some associated potential challenges. The first challenge is verifying the accuracy of our sensors to a higher degree, the test we have conducted in order to address this concern was able to prove that our system provided reasonable temperature measurements but was not able to verify the accuracy of the sensor to a high degree. We also understand that factors such as airflow and radiation can affect different sensor types in unique ways along with the room not being a truly consistent temperature. In order to overcome this issue we plan on borrowing more accurate sensors and finding an environment that is better controlled than a large room in order to repeat the test described in worry one. As we do not have access to a research quality temperature controlled box we are considering the idea of placing all sensors within a black box in order to decrease temperature variation from airflow and block radiation from entering the testing space. We are also considering conducting this test within M-HEAL's low cost incubator in order to better analyze the sensors at temperatures where precision is most important as sensor accuracy varies based on the temperature being measured.

Our next challenge involves the user interface and usability of this device. As of now our device is capable of doing data visualization through exporting a CSV file which is created by our Arduino code, along with being able to see real time temperature measurements within the Arduino code's output while the test is being run. As this process requires the user to export a file into an additional program in order to visualize the data, we do not believe that it is ideal for usability. We have found examples online for live plotting within the Arduino coding which we are planning to incorporate. With the use of this code, the user will be able to use the Arduino software to start tests, stop tests, log data, see the temperature values as they are read, and have life graphing/visualization of this data as it is being recorded.

Our final concern is related to our redesign of the sensor stand. Our alpha design slightly alters the thermodynamic properties of the incubator, primarily as a result of the large base that stands on the heated mattress. Despite this change being small, this is still something we would like to avoid and will therefore alter the stand design to avoid contact with the heated mattress. We currently plan to attach the sensor to the roof of the incubator through the use of suction cups and a flexible arm. We expect this design to reduce the impact on the incubators base case thermodynamic properties, however, we will need to conduct tests in order to evaluate the effectiveness of this design. We have already begun to develop potential solutions for these problems and we believe that these challenges are reasonable for us to overcome.

Appendix D: DR3 Anticipated Problems

Over the course of this part of the project we have encountered a series of obstacles which we had to overcome, the first of these obstacles is having not wired more than a single sensor to the Arduino. As the TMP117 sensor has proven to work well with the Arduino and provide reasonable readings we are confident that we want to move forward with it. We have conducted extensive research within worry four of engineering analysis in order to understand what must be done to properly connect multiple sensors to one arduino and have currently ordered more sensors along with the described breakout board in order to empirically evaluate this previous concern.

Based on our results from worry three and four of engineering analysis we have found that the sensor stand used within the alpha design interferes with the ability of the device to effectively measure the temperature within the incubator. We have altered this design to avoid contact with the heated mattress within the incubator through the use of suction cups and a flexible arm. This will allow us to attach the sensor stands to the roof of the incubator in order to reduce their impact on the thermodynamic properties of the incubator. We still need to repeat CFD simulations with these new sensor stands in order to evaluate their effectiveness.

The final lesson was a result of our testing associated with worry one of engineering analysis. This test used low accuracy sensors to compare against our high-accuracy sensor, while this was a useful test to ensure that the Arduino and TMP117 setup was providing reasonable results but did not effectively verify the accuracy of our sensor to a high degree. We have also considered the assumptions made within this test and what can be done to make them more reasonable. We have learned that this test procedure should be altered to include a dark enclosed space and more accurate sensors in order to verify the sensor's accuracy to a greater degree.

Appendix E: DR2 Obstacles and Lessons Learned

Over the course of our concept generation process, the first major obstacle we faced was creating distinct ideas that had creativity beyond small variations of a previous idea. Given how our device deals with testing and the existence of several products that complete the exact functions that we require, we initially found it quite difficult to think beyond the idea of a box and sensor concept. However, as we learned in class, the first five to ten ideas that are generated are often the most “obvious” ideas. With this in mind, we continued to brainstorm and iterate to push for a large quantity of ideas, ensuring that we captured the full solution set without fixating on one idea too soon.

The second major obstacle we faced was after crafting the initial list of concepts, and narrowing it down to one concept to pursue for our first round of prototyping. Going in, we qualitatively selected our “favorite” idea which, in reality, was the one we had spent the most amount of time iterating and thus was top of mind. However, when we created a more formalized evaluation system to objectively evaluate the pros and cons of each idea, we could clearly see that there were elements of each concept that stood out. Combining them to create one alpha concept yielded the strongest outcome that addressed all of our requirements. The lesson learned was to establish formal processes when necessary for evaluation.

The third issue we came across was in the creation of our alpha concept. Given the customized nature of our idea, we initially opted to create a 3D printed box for our sensor holder. This ensured we would have full control over the features and functionality. However, when we gave our DR2 presentation, the feedback we received was to purchase as many pre-made items as possible so long as they serve our purpose. This not only lessens costs, but also increases the feasibility of the design. This taught us to simplify wherever possible, and ask ourselves whether we selected the most simple approach prior to taking a more complex path.

Appendix F: DR2 Anticipated Problems

Throughout this project, we expect to run into a few difficulties including the balance between the number, cost, and accuracy of the temperature sensors used along with the lack of electrical engineering knowledge within our team. We have currently found ambient temperature sensors that are capable of the desired accuracy, however, contact sensors that meet our specifications without exceeding or putting an extreme strain on our budget has proved difficult. We will need to continue to monitor our budget in order to see if we will have enough money left in order to purchase a sensor that meets our needs, in the event that this is not possible we may need to sacrifice accuracy in the name of our budget. Despite this issue, we are currently looking to create a proof of concept that does not need to perfectly match all medical device testing standards. In order to better understand the electrical side of this project we are planning on learning with rented devices from the school along with using library research. As of now we have rented an *Arduino* from the school and ordered one ambient temperature sensor in order to begin an initial prototype and further our electronics development. Throughout the course of this project, we have developed a better understanding of how to reasonably scope a project in order to provide a reasonably achievable result within the given time span. Initially, we misunderstood the problem statement and attempted to create an accurate thermodynamic simulator of a neonate, we then shifted towards creating a product more similar to what is currently used to test incubators along with setting the goal of a proof of concept prototype by the end of the semester.

Appendix G: Build Design Bill of Materials

The bill of materials for the build design is shown below in Table G.1. This includes all of the materials used in the build of the IncuCheck device.

Table G.1: Bill of materials for the build design of the IncuCheck device.

Part No.	Part Title (hyperlink)	Supplier	Quantity
1	Heavy Duty Suction Cups for Glass Surfaces	Window Garden (Amazon)	5
2	2" inch Small Spring Clamp, Spring Metal Spring Clamps	HORUSDY (Amazon)	10
3	Any-Which-Way Positioning Arm, Threaded Stud Base with Threaded Hole End, 6" Projection	McMaster Carr	5
4	SparkFun Qwiic Shield for Arduino	SparkFun	1
5	SparkFun Qwiic Mux Breakout - 8 Channel (TCA9548A)	SparkFun	1
6	Flexible Qwiic Cable - Breadboard Jumper (4-pin)	SparkFun	14
7	SparkFun High Precision Temperature Sensor - TMP117 (Qwiic)	SparkFun	6
9	Pelican™ 1170 Case	Pelican	1
10	Arduino Uno REV3 [A000066]	Arduino (Amazon)	1
11	3D Printed TMP 117 Sensor Case Housing	Erik Wahr	6

Appendix H: Manufacturing/ Fabrication Plan

Controller

The first step of the fabrication plan is to install the Sparkfun Qwiic shield onto the Arduino Uno, which are the main parts of the controller subassembly. This is done by soldering the pins included with the Sparkfun Qwiic shield onto the shield board. Once the pins are all soldered in the correct position, they can be inserted into the receiving end of the Arduino Uno board. The board will look like Figure H.1.

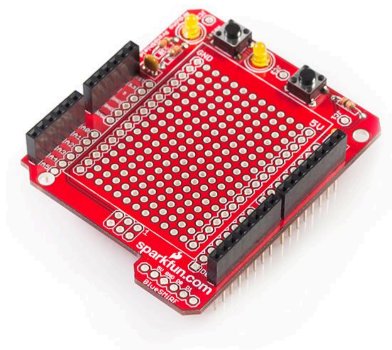

Figure H.1: Sparkfun Qwiic Shield with provided fins soldered to the board.

Sparkfun has additional documentation on how to connect the devices if there is any uncertainty moving forward. After the shield is connected to the Arduino Uno, the Sparkfun Mux Breakout board can be connected to the shield using a Qwiic to Qwiic connector. This connection can be seen in Figure H.2 below. Connecting the Mux board enables up to eight different Sparkfun Qwiic enabled sensors to connect to the Arduino. It is extremely important to ensure that the Qwiic connectors are fully pushed into the receiving pins. Sometimes it is difficult to tell if the pin is pushed in all the way. The pin is also not reversible, meaning it only goes in one direction - just like a USB type A port.

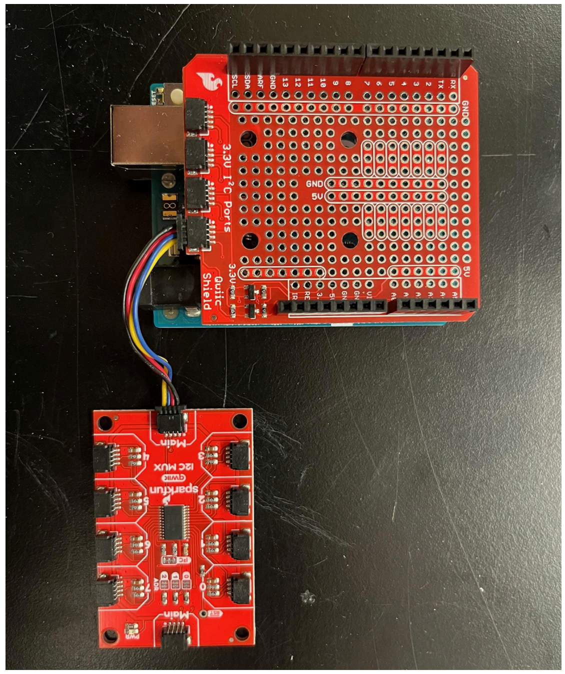

Figure H.2: Top down view of the connection between the Qwiic Shield and the Mux Breakout boards. The Qwiic is placed on top of the Arduino, with all of the pins lining up between the Arduino and the Shield.

Temperature Sensors

The first step for putting together the temperature sensors is to 3D print the two halves of the temperature sensor case. The .stl files used to print the current cases will be provided. To produce more of the cases using the same material, the .stl file will need to be sliced in a 3D printing slicing software. The fabrication underground studio will do this for you if you submit them a file. CSED also has 3D printers that are available for use. Ensure that the cases are printed in PLA, as that is the easiest material to work with and will ensure a smooth, consistent case that works right off the printer. You also want to make sure that all support material is removed from the case prior to assembling it together with the sensor. After the two halves of the case are printed, the sensor can be placed inside. The view shown in Figure H.3 below shows the two case components and the TMP 117 temperature sensor.

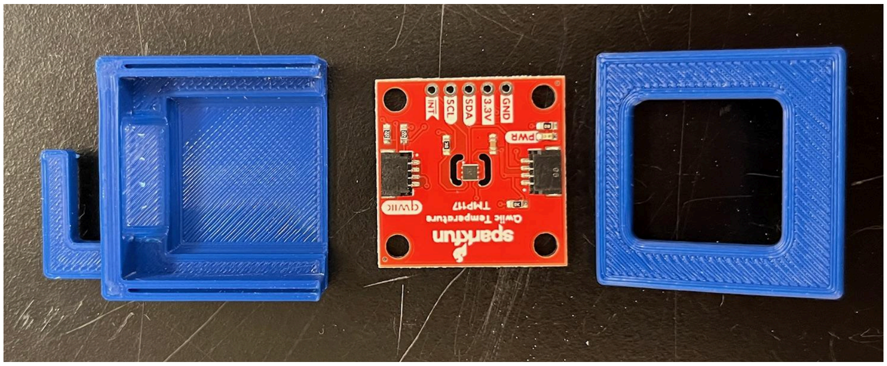

Figure H.3: From left to right: The bottom of the case, the Sparkfun TMP 117 sensor, and the top of the case.

First, you will want to place the bottom of the case, which is the side that has the small grab handle, on the ground. This is the component all the way on the left of Figure H.3. You will want the case to be bottom side down, with the small grooves on the sides facing up. Next, place the Sparkfun sensor with the top side facing up. The top side will have all of the writing on it, in addition to the small black box in the center of the board. Also ensure that the Qwiic connectors are facing towards the openings in the top and bottom of the case. This will enable the wires to successfully connect to the sensor. Finally, the top of the case will be slid onto the bottom of the case using the interlocking grooves on each of the parts. These two halves then lock together to create the casing, with the complete assembly shown in Figure H.4 below.

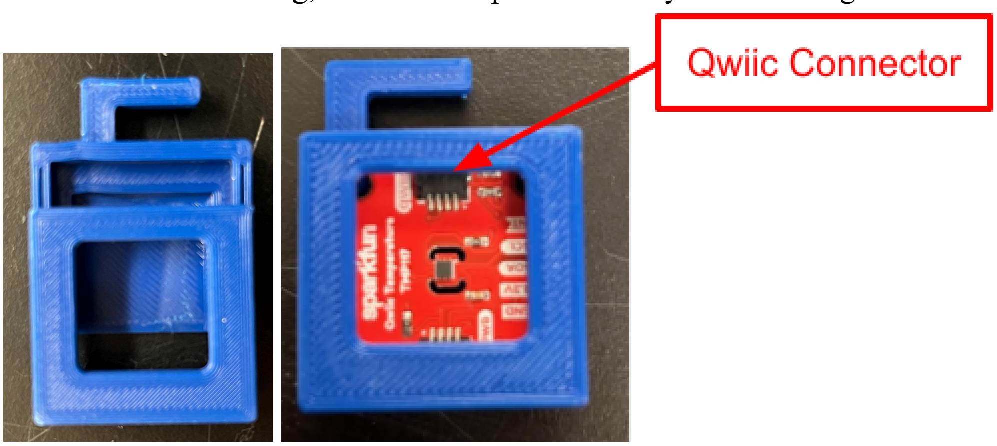

Figure H.4: Complete and assembled temperature sensor within its case. The Qwiic connectors, called out in this image, should be facing towards the openings in the case.

<u>Temperature Sensor Wiring</u>

After the case has been placed over the sensor, the wires can then be run from the Sparkfun temperature sensors to the Mux Breakout board. To create the long wires necessary for the device to reach all corners of the incubator you must secure long extension cables that contain four separate wires. Additional Qwiic connectors must also be purchased. Once you have the Qwiic connectors, they must be cut off of the existing, smaller wire and spliced into the longer cables. The best practice for splicing is to first remove any protective coverings on the ends of each of the wires. This can be done using a wire stripping tool. Once all of the wires are stripped, the cables can be connected and wound together. Finally, shrink wrap or electrical tape should be used to cover the bare cables and protect the cables and any person from being harmed. This is an extremely important step that must be followed. Once one end has been completed, repeat the same process on the other end. This will complete the necessary cable to connect the temperature sensors to the Mux Breakout board. An image of the connection can be seen in Figure H.5 below. The only cable that does not contain Qwiic connectors on both ends of the IncuCheck system is the cable that connects the Arduino to the user-provided computer.

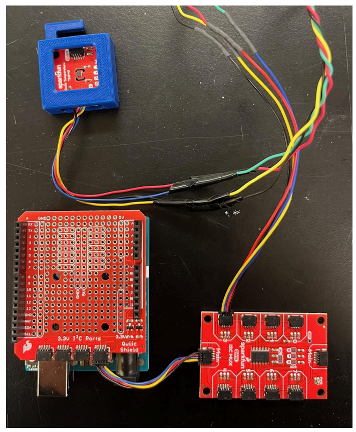

Figure H.5: Controllers connected to a single sensor through the extended Qwiic cable

Stand Components

After connecting the temperature sensors to the breakout board and connecting the computer to the arduino via the provided Arduino USB 2.0 Cable Type A/B cable, the stands must be constructed. The stand consists of three separate parts: the suction cups, the positioning arms, and the double spring clamps. These are shown in Figure H.6 below.

Figure H.6: Left to right: Suction cup, suction cup and positioning rod, and the double spring clamps.

Suction Cups and Positioning Arms. First, the suction cups should be connected to the positioning arms. To complete this process you will need an adhesive, such as Plexus MA200. This adhesive can be purchased from Mcmaster-Carr. Any other metal to plastic adhesive or superglue type of glue can be used in this process. To start the adhering process, liberally clean both the suction cup and the female threaded end of the positioning arm with alcohol wipes. This ensures there is a nice, clean surface for the bond to adhere to. After this step, place the suction cup so that it is suctioning onto the table this step is being performed on. Then, liberally douse both the suction cup nub and the inside of the female threaded end of the positioning arm with the preferred adhesive of choice. After the adhesive is on both surfaces, place the female threaded end of the positioning arm onto the nub of the suction cup. Hold the positing arm straight onto the suction cup for at least five minutes. The curing time depends on the type of adhesive used, however five minutes will be enough for most high-strength bonding agents. Once the adhesive has dried the suction cups will successfully be attached to the position arms, as shown in Figure H.7 below.

Figure H.7: The positing arm attached to the suction cup. The black tape is covering the excess adhesive from the bonding of the suction cup to the positioning arm.

Double Spring Clamps. To connect the two spring clamps together to create a double clamp, a small zip tie is used. The zip tie should be placed on the clamps such that the openings face opposite ways. Once the spring clamps are in the correct position, tighten the zip ties and cut off the remaining plastic from the zip tie. After this step is completed the double spring clamp assembly has been successfully created. An image of the double spring clamps connected to the positioning arm and suction cup assembly is shown in Figure H.8 below.

Figure H.8: Double spring clamps connected to the positioning arm and suction cup.

<u>*Final Assembly and Case Placement*</u>

Final Assembly. To complete the fabrication/setup of the IncuCheck device, the stands must be placed on the inside of the incubator. The double spring clamps are to be attached to the positioning arms on one end while the other end is attached to the temperature sensor housing, shown in Figure H.9 below.

Figure H.9: Positioning arm and suction cup with the double spring clamp connected to the male end of the positioning rod and the clip of the sensor housing case.

The temperature sensors should be connected to the Mux Breakout board through the fabricated Qwiic extended wires. The Breakout board should be connected to the Arduino through the Qwiic Shield, which should be connected to the user-provided computer through the USb Type A/B cable shown in Figure H.10 below.

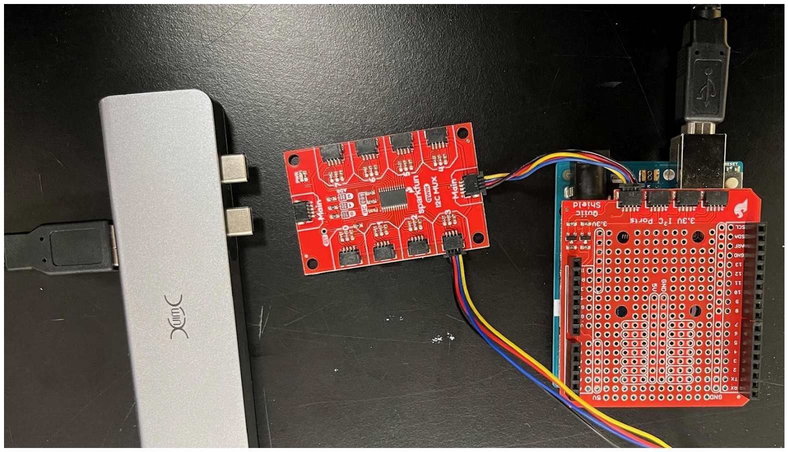

Figure H.10: Sparkfun Breakout board connected to the Arduino Uno and Sparkfun Qwiic Shield. The Arduino Uno is also connected to the USB-C adapter used to connect the user-provided computer to the Arduino.

Once that has been done, all of the lights on each of the Sparkfun and Arduino boards should be lit up. This means that all of the devices are receiving power and are ready to be used. If any of the devices are not receiving power, check to ensure the Qwiic cables are fully connected to the connector. There also may be issues with the custom wires in addition to possible faulty connectors on the Sparkfun boards.

After the connections are validated, the Arduino IDE application, which controls the Arduino, can be opened. The provided Arduino code can be uploaded to the Arduino, which will start receiving data from the temperature sensors. Once this step has been completed, the device is fully set up and operational.

Case Placement

The provided Pelican case will already have missing foam in it for the components our team integrated into the IncuCheck design, shown in Figure H.11.

Figure H.11: Empty Pelican case with Pick and Pluck foam taken out of spots where components rest.

However, if a new Pelican case is ever purchased it needs to be ensured that the foam inside of the case is removable or of the Pick and Pluck kind. The Pick and Pluck will enable full customization of the interior of the case, which is great for the purposes of the IncuCheck device. It is designed to be modular and evolve over time, meaning that an upgraded, larger version of the current Pelican case is very possible quite quickly after M-HEAL starts using the device. The Pick and Pluck foam can be changed and moved around to set up the inside of the case as needed. There is no set way the device has to be stored. However, it must be ensured that all of the sensitive electronic components are properly and securely stored in the foam such that they will not be harmed by any movement of the case.

A full electrical wiring diagram for the device is shown below in Figure H.12. The solid line connection denotes the use of a Qwiic to Qwiic wire. The use of a dashed line denotes the use of a USB Type A/B cable.

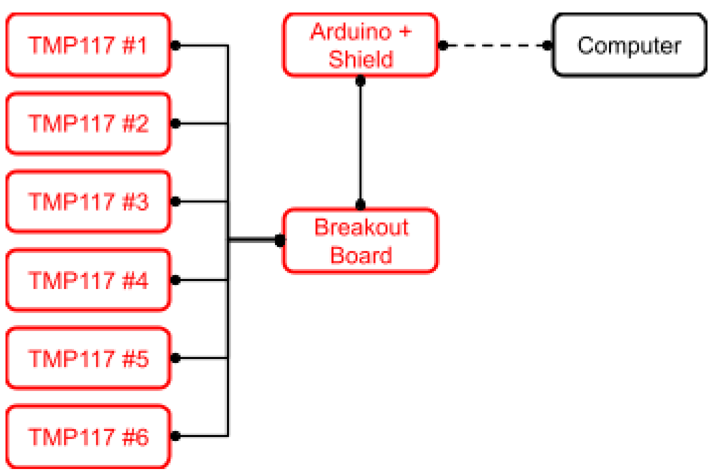

Figure H.12: Wiring diagram for the IncuCheck Device. Six sensors are connected to the breakout board, which connects to the Arduino. The Arduino then connects to the computer, which powers the whole device. Information is gathered from each temperature sensor and is sent to the computer through the use of the Arduino IDE software.