

Pneumonia Diagnostic Aid for Use in Low Resource Settings

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Final Design Report

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Executive Summary

A recent study released by UNICEF, found that pneumonia causes 935,000 annual deaths in children under five, 70% of which occur in low-resource areas including Asia and Sub-Saharan Africa where there is limited access to medical healthcare. The primary health care provider in these low resource communities is the community health workers (CHW), whose training varies from a two week course to one year. CHWs are the first medical professionals to see children with pneumonia and in some cases administer the first round of antibiotics to combat the disease. Due to the variation in their levels of education, medical training, and access to medical infrastructure, there are many inaccuracies in the diagnosis process that can lead to more severe complications in the symptomatic children, including death. UNICEF and WHO have collaborated to produce the Integrated Management of Childhood Illness (IMCI), which publishes materials to train and guide CHWs to identify and treat pneumonia and other diseases. The IMCI's current recommended criterion for pneumonia diagnosis is fast breathing. However, the current methodology involves counting a child's breaths over one minute to calculate respiratory rate. This is then compared to age-based thresholds for fast breathing. This process is difficult to perform on a distress or restless child and invites many human errors into the diagnosis.

Our team was tasked with designing and prototyping an easy-to-use, reusable, cost effective, and accurate pneumonia diagnostic aid to accurately assist CHWs (and professional health workers) in diagnosing children under five years old in low-resource settings. The ideal device would accurately assess the child's respiratory rate in 15-20 seconds and could be taught by one CHW to another in 2 minutes or less.

Our proposed solution is to incorporate a sensor into a small housing unit that can be placed on the child to calculate breaths per minute. After testing several sensors, we settled on accelerometry for our device. We put together a benchtop prototype consisting of an Arduino Uno microcontroller, three-axis accelerometer, and small LED screen enclosed in an acrylic box, and an adjustable elastic band. We also developed a conceptual commercial model that incorporates a printed circuit board, drastically reducing the size, power consumption, and unit cost.

Our original breath detection algorithm was tested on a high-fidelity infant simulator at the University of Michigan's School of Nursing. This validation testing showed that the device is capable of accurate respiratory rate detection, but has limited repeatability. After validation testing, we developed a new detection algorithm that more directly tracks the motion caused by breathing. Efforts were also made to incorporate calibration procedures to further improve device robustness, but these calibration programs were never successfully implemented

Background and Problem Description

A recent study released by UNICEF found that 935,000 deaths are caused annually by pneumonia in children under five years old. This amount makes up 15% of all under-five deaths annually worldwide. 70% of these deaths occur in 15 countries in Asia and Sub-Saharan Africa where there are significant challenges in the provision of effective healthcare [1]. These challenges lead to misdiagnosis of pneumonia until the disease reaches a severe stage or the child dies.

Our team is addressing the problem of limited access to medical services regarding pneumonia. The World Health Organization (WHO) has recommended that the best indicator for assisting in the diagnosis of pneumonia is fast breathing [2]. However, the current methodology for doing so is inaccurate. Misdiagnosis from inaccurate readings has two severe outcomes; either a false negative is determined which can lead to a more severe stage of pneumonia, or a false positive is assumed leading to improper treatment. In false positive cases, the antibiotic, amoxicillin [3], could be prescribed leading to an immuno-resistance in the child. Medicinal treatments can also mask symptoms which could lead to the proper diagnosis. For example, if a child suffers from Malaria but is diagnosed and treated for pneumonia, the child could die in two days without receiving the proper treatment. These consequences for misdiagnosis reinforce the need for an easy-to use, accurate, and confidence building device to aid in the diagnosis of pneumonia.

Community Healthcare Worker

In order to design a technical solution to the problem, our team first needs to understand our end user, the community healthcare worker (CHW) [2]. There is a large variation in the function and responsibilities of the CHW depending on many contextual factors. Every country has a different job description for these workers, some allowing them to prescribe and administer medication, while others only allow the CHW to refer the patients to doctors [3].

There is a large variation in level of education CHWs have received, ranging from incomplete primary school to a completed high school education. Due to the inconsistency in levels of education, we can assume that many CHW's are often illiterate and sometimes innumerate. Because these community health workers are not pursuing medical degrees, they are often given basic or informal medical training ranging between two weeks to one year [2]. After their training, CHWs work at local health posts and often perform home consultations for families seeking medical attention.

It is important for our team to properly define and understand the CHW scope of responsibilities, skill, and work environment because it is pivotal to developing a device that adds value to the diagnostic process for our end user.

Mission Statement

Our team must design and prototype an easy-to-use, reusable, cost effective, and accurate pneumonia diagnostic aid to accurately assist CHWs (and professional health workers) in diagnosing children under five years old in low-resource settings.

Benchmarking

While designing a new pneumonia diagnostic aid, we researched the current devices to serve as comparable benchmarks to our device. Along with the past and present pneumonia diagnostic aid devices serving as benchmarks, we have consulted the Target Product Profile (TPP). The TPP was published by UNICEF in November of 2014 and is very specific guide, highlighting the design requirements of all future pneumonia diagnostic aids.

Several pneumonia diagnostic aids have already been designed and are currently used in the field. The most widely used device is the Acute Respiratory Infection timer, or ARI timer, shown in Figure 1. This device keeps track of time over 60 seconds, while the caregiver visually counts each breath the child takes [1]. Another current device is a string of colored counting beads, shown in Figure 2. The beads represent a single breath and the CHW counts the beads as the child breathes during a 60 second time frame. After one minute, if the bead count is in the different color zone, it indicates that the respiratory rate is too high [4]. On an even more basic level, a caregiver can simply use a wristwatch or sand timer to keep track of one minute while they count the breaths of the child. While these devices themselves are successful and have been proven in the field, the methodology leads to inaccuracy. None of these devices feature any automation, and rely on the accuracy of the community health worker to count the breaths of the child [3].



Figure 1: The Acute Respiratory Timer keeps track of time over 60 seconds, while the caregiver visually counts each breath the child takes [5].

The Breath Counter by Phillips, shown in Figure 3, is another device developed to assist in the diagnosis of pneumonia. Though this device was never put into field use, it featured solar power, a display of the breath count, and a necklace strap for portability. Though these features do offer advantages over the current devices that are in use, the Breath Counter still required the community health worker to visually count each breath of the child [6].

Understanding the success and shortcomings of these devices is crucial in order to design our device. However, given that these devices do not feature any automation, they provide a low benchmark for comparison.



Figure 2: Counting bead set used by community health worker for counting the breaths of a child. When the count reaches the red or green colored beads, the respiratory rate is above the threshold value and could indicate pneumonia [4].



Figure 3: Conceptual breath counter designed by Phillips featuring; an LCD screen which displays the count result and timer, solar cells, input button, and neck strap [6].

Target Product Profile

The Target Product Profile (TPP) for an Acute Respiratory Infection Diagnostic Aid (ARIDA), published by UNICEF on November 12, 2014, is a comprehensive description of the problem, background, working environment, and end users of an automated respiratory rate measurement device. The TPP also includes prioritized lists of the design constraints, requirements, and performance needs. This document is our main guide in developing our design, and will be the primary benchmark to compare our prototype against. We have developed our own list of design requirements and specifications and cross-referenced them with the list provided by UNICEF in this document to ensure that we are following the right path in our design process [2].

User Requirements and Engineering Specifications

We have developed our user requirements in conjunction with suggestions from our sponsors, key findings from our research, and from the TPP. The TPP presents a summary of the essential device requirements that would enable an effective diagnostic aid to assist CHW's as proposed by UNICEF and many collaborators (including our sponsors). Additionally, the World Health Organization and UNICEF have partnered to produce a strategy for childhood health care in low-resource settings called the Integrated Management for Childhood Illness (IMCI) [7], including manuals to help train and educate CHW's in treating illnesses such as pneumonia. The documents and manuals published about the IMCI are also pertinent to designing a device that can be integrated into the current environment and practices for childhood health care in the related low resource settings.

User Requirements

Our engineering specifications are shown in Table 1 with specific requirements and targets for each.

Table 1: Design specifications and values set to meet user requirements

<u>Design Specification</u>	<u>Target Value</u>	<u>Unit</u>
Minimize test time	30	Seconds
BPM Calculation Accuracy	2	BPM
Energy Requirement	240	mAh
Unit Cost	9.00	USD
Life Span	2	Years

The driving user requirement we developed with our sponsors was increasing the ease of use of the device for the CHW. This captures several design requirements outlined in the TPP and translates into the specification for minimizing test time. Minimizing testing time addresses the current difficulty for the CHW of performing breath counts over an entire minute to calculate the respiratory rate. A shorter test time can reduce error to the calculated respiratory rate.

A target for device automation and accuracy was also set to increase the ease of use of for the CHW. Our sponsors requested the device to be “as walk away as possible [3]” to assist the ease of use for the CHW as well as to reduce human influence and error on the test results [2, 8]. The accuracy of the respiratory rate was set as the metric for the effective automation of the respiratory rate calculation in response. The target of ± 2 BPM was pulled directly from the TPP. Overall, the decreased testing time and increased automation of the device allows for a more effective consultation between patient and CHW, as it was set and provides more attention from the CHW that distracts from the observation of other symptoms during diagnosis. It also allows a CHW to observe other symptoms that are essential factors to a holistic diagnosis [2]. The target for accuracy of respiratory rate is derived directly from the TPP and is a metric for the effective automation of our device. Our sponsors requested the device

Additional Requirement Considerations

Patient interaction is also an essential category for the user requirements. Most notably, the device must not “distress [3]” the child. Child movement or crying can influence respiratory measurements and even interrupt tests. To fulfill the requirement we aim to minimize pressure or force applied on the child for a contact device and minimize sensory engagement with the child as much as possible for a non-contact device. Data collection is a detailed category and will influence the role of the CHW in the diagnostic test, but the device must also report its results in a meaningful manner to the CHW. The current target for output information is to use symbols and numbers to convey threshold comparison and measured BPM.

Manufacturing and design is a category that captures the inherent requirements for the unit cost of the product as well as its physical characteristics. The device is being designed for a low-resource setting and is thus required to be cost effective, which is evaluated against two metrics: a unit cost and maximizing the cost-to-life span ratio. The current cost-to-life span ratio is approximately 1.8 (unit cost of \$3.65 and maximum lifespan of 2 years, round to one decimal point) [3]. We would target a maximum cost-to-lifespan of 1.8 (equal to ARI Timer that was introduced into the field by UNICEF) with a maximized life span of 5 years that yields a maximum unit cost of \$9. The design is required to be robust, durable, portable, and more specifically dimensioned to “fit in a pocket [3].” The associated specifications for

these characteristics will be measured against strength-to-mass and cost-to-mass ratios. Prototyped form factors may influence materials based on our manufacturing capabilities. Finally, the device is required to be reusable with no consumable materials and to require no maintenance [2]. Therefore we have determined that the end product will be one complete part that, for now, is likely to have no physical modularity.

The final requirement category pertains to medical and ethical standards. We must follow the IMCI guidelines, as stated previously, in order to implement an effective product. We want to make a device that is sanitary [2] (also related to non-consumable requirement) and we have confirmed that skin-contact and non-contact approaches are acceptable for testing methodology.

Concept Generation

Our team performed concept generation in three stages, each time considering methodology and technological integration separate from the physical design. Considering the functional decomposition, shown Figure 4, we were able to determine how the device should operate and begin developing concepts and designs. First, we worked individually to generate as many concepts as possible. Then we regrouped to share our individual designs with the goal of improving those designs and inspire new ones. At these stages we did not consider our design requirements, fearing that it would stifle our creativity. The last step involved critically analyzing each design housing and technology that would be incorporated in it. After several discussions and creating crude CAD models, mockups, and drawings, we were able to use the TPP and our generated user requirements to select our most viable concepts for testing.

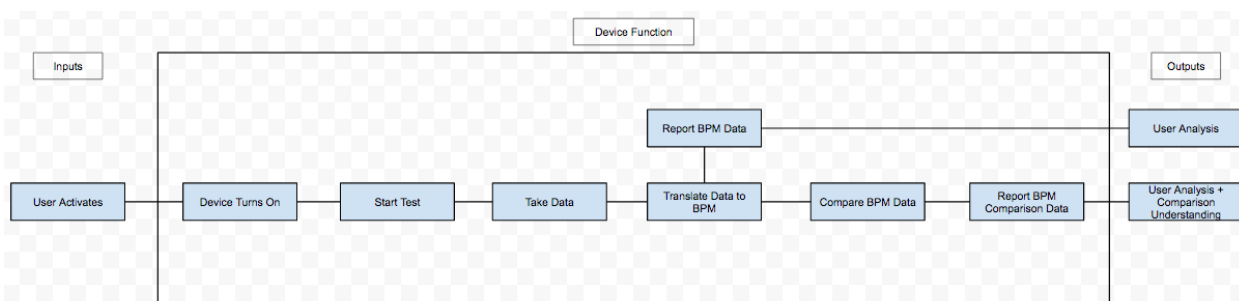


Figure 4: The functional decomposition for how the device will operate under ideal conditions.

Concept Selection

We based our concept selection process primarily on the user requirements we generated from discussion and research. It should be stated that more empirical data (in the form of methodological and technological testing) is required to produce a more objective quantitative comparison between concepts.

The key requirements we focused on in scoring concepts included ease of setup, minimizing required attention, repeatability, cost, minimizing energy consumption, robustness to noise factors, maximizing device lifespan, and portability. In assessing each concept, we considered the feasibility to work with certain methods, physical forms, and technologies within the short time frame given while maintaining low unit cost. We assigned weights to each set of criterion based on our ranking of importance as a user requirement and deviated from this in certain cases based on discussion.

Our designs were narrowed to two housings (a belted and a handheld device) and two technologies (a triple-axis accelerometer and hall-effect sensor). Given the scope of our project, we decided not to select one singular device at this time. Instead, we opted to let empirical testing and comparative analysis indicate the stronger design.

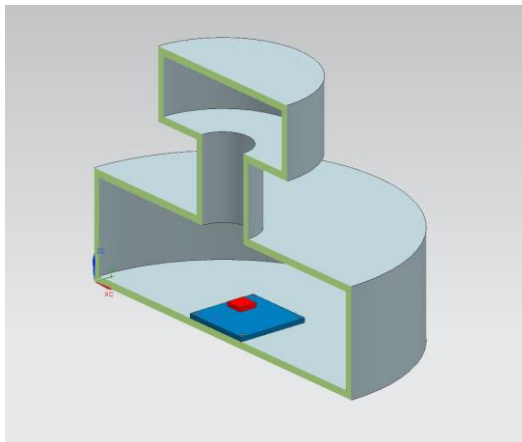


Figure 5: Handheld Concept CAD model with accelerometer

The handheld device, shown in Figure 5, can be placed anywhere on the child's abdomen to sense linear change and determine the respiratory rate. The advantages of this device are its robustness to variation due to the range of child ages and sizes and it functions in a variety of orientations so the child can be comfortable in any position. An inherent disadvantage to this concept is also the hand-held aspect, which makes it susceptible to human error during testing. A realistic measure of relative deflection of a child's abdomen or chest is still unquantified so a definite range of motion for this device is undetermined, which makes us question its feasibility without further empirical testing of the technology and physical configuration. Additionally, it could be difficult to package all the components we have considered into a compact hand-held design and this factor is still dependent on the technology module.

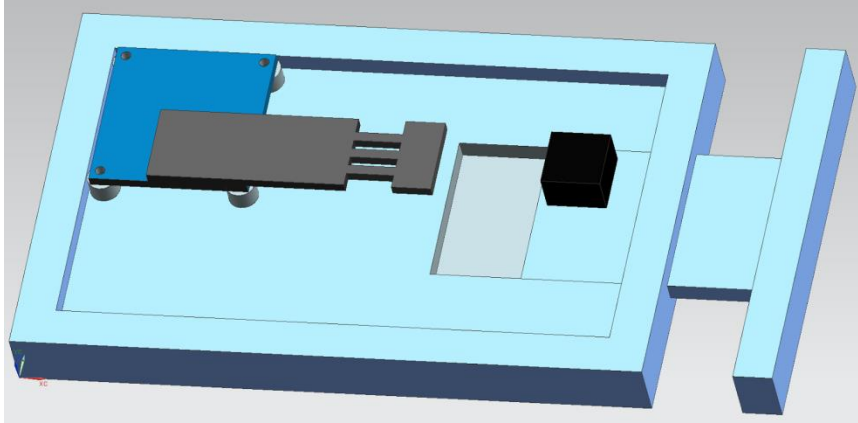


Figure 6: Belted Concept sketch (left) and CAD model with hall-effect sensor (right)

The belted concept, shown in Figure 6, involves strapping the device to the child's abdomen so a sensor can calculate the number respiratory rate. The device's primary mechanism will be constrained to the circumference of the child so that it moves in relation to the expansion and contraction of the abdomen or chest as the child breathes. One of the main advantages of the device is that it is secured to the child during the testing period which simultaneously reduces the chance of human interference, but also allows the CHW to observe other symptoms to make a holistic diagnosis. A disadvantage of the belt is that it must be adjusted for children of different sizes, which could lead to cyclical degradation of the product as well as variation in test methods. A similar concern with the belt is the unquantified circumferential expansion of a child's chest or abdomen with breathing, so we will be performing more research into this study specifically, as well as in the possible applicable ranges of the technology modules.

Engineering Analysis

For an initial breath counting algorithm using a single three-axis accelerometer, it was assumed that the primary motion caused by breathing would be in the direction normal to the abdomen. Due to the orientation of the accelerometer, this direction coincided with the z-axis of the accelerometer. A program was written for the Arduino Uno microcontroller to calculate the percent change in acceleration in the z-axis, using Eq. 1,

$$\Delta a_z = \frac{|a_{z,i} - a_{z,(i-1)}|}{a_{z,(i-1)}}, \quad (1)$$

where Δa_z is the normalized change in acceleration in the z-axis, $a_{z,i}$ is the current acceleration in the z-axis (in g's), and $a_{z,(i-1)}$ is the previous reading of acceleration in the z-axis. If the acceleration changed by a percentage greater than or equal to a certain threshold, then the breath count was incremented.

Although the breath count calculated by this algorithm showed some correspondence to actual breathing when empirically tested on members of the team, additional analysis was necessary to improve the tracking of motion. In particular, the z-axis assumption was based primarily on intuition in order to quickly develop a working model. To analyze the motion caused by breathing, the accelerometer data was converted to ASCII and transmitted through Simulink in real-time using the Serial port. This allowed for the data to be analyzed and plotted in MATLAB. Further tests were performed by fixing the device to a team member and collecting data while the team member breathed in a certain position. All 3 axes of acceleration over time could then be plotted, such as in Figure 4.

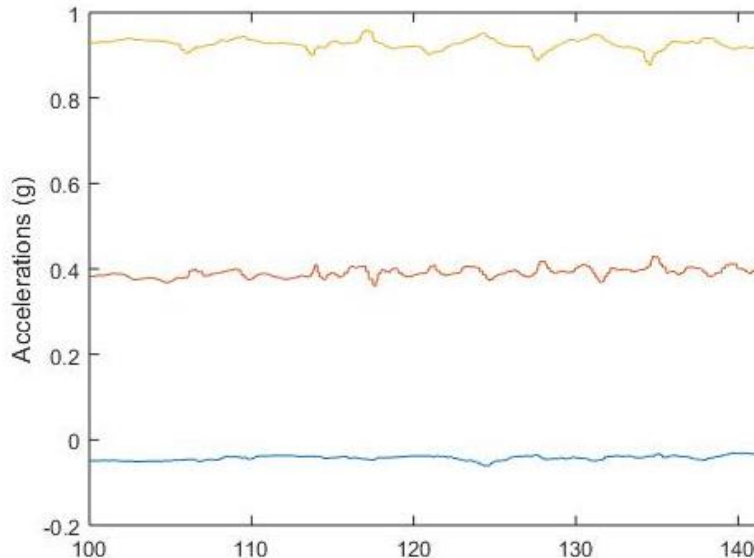


Figure 7: Plot of the measured accelerations in three axes (top:Z, middle:Y, bottom:X) vs. time, while team member was laying down. The z-axis was expected to produce the strongest signal, but was similar to the y-axis in amplitude.

This figure effectively shows the signal generated in each direction by breathing, while the team member was lying down. Although the z-axis signal was expected to be the strongest, it was actually close in amplitude to the other axes. This data showed that the primary axis of motion depended strongly on the position of the team member, and that the motion caused by breathing is not necessarily uniaxial.

In order to make the algorithm more robust to various positions of the patient, the Arduino program was adjusted to calculate percent changes in the overall magnitude of acceleration. The idea behind this change was that no matter what direction the breathing motion was in, the device would sense the changing signal. The magnitude was calculated for each reading, using Eq. 2, and percent change was calculated in a similar manner to Eq. 1.

$$a_{mag} = \sqrt{a_x^2 + a_y^2 + a_z^2}, \quad (2)$$

where a_{mag} is the overall magnitude of acceleration, and a_x , a_y , and a_z are the accelerations in the x, y, and z-axes, respectively.

In addition to altering the method to calculate the acceleration magnitude, a low-pass filter was implemented, using Eq. 3,

$$a_{i,filtr} = (1 - \alpha) * a_{(i-1),filtr} + \alpha * a_i, \quad (3)$$

where $a_{i,filtr}$ is the filtered current acceleration reading, $a_{(i-1),filtr}$ is the previous filtered value, a_i is the current raw acceleration value, and α is a coefficient where $0 \leq \alpha \leq 1$. This formula was used to filter the data from each of the three axes in real-time on the Arduino.

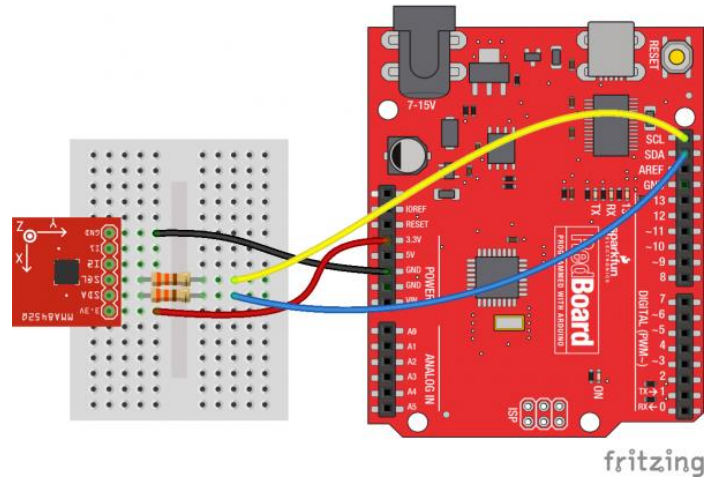


Figure 8 [10]: circuit diagram showing the connections between the Arduino Uno (shown here as Sparkfun RedBoard) and the Sparkfun MMA8452Q three-axis accelerometer. A 330-ohm pull-up resistor is hooked up to each of the i2c lines (SDA and SCL) for protection. Not shown on the diagram is the LCD screen, which uses the same inputs as the accelerometer (3.3v, GND, SDA, SCL).

Another design driver for this project is robustness to noise factors, including both user variation and signal noise coming from the Arduino channel. We will also attempt to simulate disturbances in the

testing process (auto-physical and infant simulators) such as child restlessness, coughing and other vocal disturbances, and device movement. We will evaluate the sensitivity to these disturbances and attempt to reject them through threshold tuning and additional coding to reset a test if device position change is determined. The current design incorporates countermeasures including an 'on' button that turns on the device and runs an automatic calibration program to set offsets along the accelerometer axes to determine any excessive change in orientation of the device during testing. This feature will account for test setup variation caused by changes in the device position and make it easier for the CHW to use the device properly. If the combined forces of gravity and breathing resolved onto the axes of the accelerometer produce a lot of noise, we will have to consider ways to reduce noise or read the accelerometer signals differently.

Failure Mode Effects and Analysis

After we began to understand how our device will operate, we then had to begin to understand how it could potentially fail. To do this, we quantified the types and effects of failures that the device could potentially have in the form of a failure mode effects and analysis chart, found in the Appendix. We found that the largest problems will most likely stem from the electronics and the mounting of the electronics. Loosening and breaking of soldered connections and electrical leads is a very big potential problem with the lifetime of an electromechanical device that will ultimately be used in low resource settings. Proper handling and transportation of the device will be key to maintaining operation and longevity. We plan to make our design very robust and overbuilt to ensure that it will have a very long lifetime, even in worse-than-ideal operating conditions.

Current Challenges

The design drivers we have mentioned are guiding our design of the device, and also represent two of our major challenges at this point in the design process. Further challenges include meeting all of the numerous requirements and design needs listed by the TPP. This document has helped us to form our idea of what this device needs to do and how it should interact with the end users and patients, but the number of requirements and constraints have had a limiting effect on our conceptual process.

We are also challenged by our inability to properly test a prototype in the target environment. Arguably, the most important factor of the device is end user interaction. We are having difficulty making design decisions without access to our end users or to the limited resource environments in which it will be used. Design decisions regarding packaging components, the power supply for the device, and ergonomic optimization would be significantly easier to make with feedback from the end user. Instead we are relying on research and sponsor input.

Finally, since the final device will be making a measurement based on chest or abdomen movement, the lack of anthropometric data on chest displacement during breathing in children with pneumonia is presenting a significant challenge.

Final Design

Throughout the design and testing phase of the project, both a benchtop display model and a final conceptual model were developed. The final benchtop prototype utilized an Arduino Uno microcontroller and MMA8452Q accelerometer enclosed in a laser-cut acrylic box, with an LED screen and an adjustable elastic band. The final CAD model is shown in Figure 5.

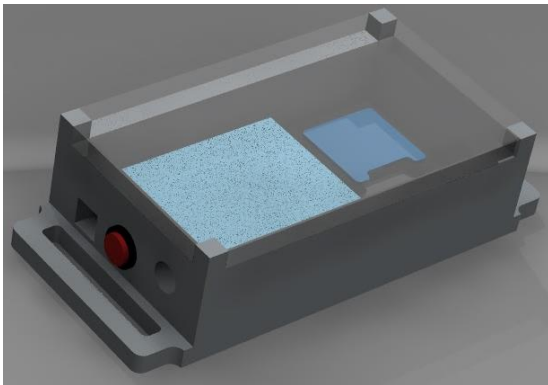


Figure 9: Final prototype CAD model, including Arduino Uno, accelerometer circuit, LED screen in acrylic enclosure.

The reason for developing a final conceptual model is that the prototype was tested with components that would not be used in the mass-produced final product. Most prominently, the Arduino microcontroller was necessary for prototyping and iterating the detection algorithm, but would be replaced with a printed circuit board (PCB) in the final design. This would drastically reduce the overall size, the cost per unit, and the power consumption of the device. The conceptual design was made mostly to show form factor and convey the ideal real-world use concept. This model is much smaller and uses less material and requires less power, making it more sustainable and easy to manufacture. The conceptual model would be manufactured in high volume using a PCB, a plastic injection molded housing, and elastic textile band. This would ideally be done in a single facility to reduce costs, and utilize recycled materials to reduce the carbon footprint of production. The final CAD model of the conceptual commercial model is shown in Figure 11.

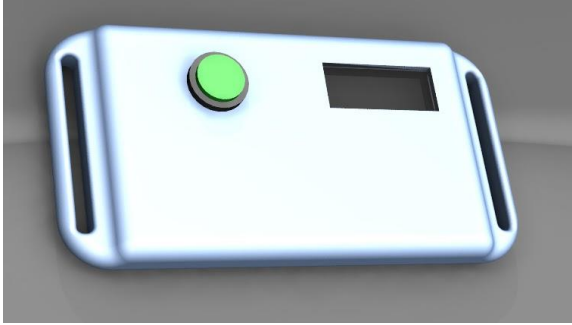


Figure 10: Final conceptual model showing a much size-reduced enclosure with small LCD screen for displaying the respiratory rate, and a power button.

Table 2 shows a comparison between the benchtop model and the commercial model, in regards to power consumption and unit cost. The commercial model was calculated to require 3 3V batteries, half that required by the benchtop model (though still well above the desired 1 battery). The benchtop model unit cost was over 5 times higher than the goal of \$9, while the commercial model could be produced for a unit cost of \$8.08, using a low-power Atmel ATtiny microcontroller unit and a lower cost LCD screen[11]. These unit cost calculations did not take into account manufacturing cost or the material costs of the elastic band and device enclosure.

	Benchtop Model		Commercial Model	
	Power Consumption (mW)	Unit Cost (\$)	Commercial Concept (mW)	Unit Cost (\$)
Accelerometer	<1	9.95	<1	2.95
Display Screen	40	11.99	45	2.70
Microprocessor	165	27.95	40	1.38
Total Power	205	-	85	-
mAh @ 3V, 20.3 operating hours	1387	-	576	-
Number of 3V batteries required	6	2.10	3	1.05
Total Cost	-	51.99	-	8.08

Validation

Validation testing was conducted on a high-fidelity infant mannequin provided by the University of Michigan's School of Nursing. The mannequin came equipped with an air bladder that could inflate and deflate to simulate breathing at a range of respiratory rates. The experimental setup is shown below, in Figure 7.



Figure 11: Validation testing was performed on a high-fidelity infant simulator. Respiratory rate was set and compared to the rate calculated by the device.

The testing primarily evaluated the quantitative accuracy of the percentage-acceleration-change method previously described over a 30 second trail. The results of these tests are shown below.

Table 3: Validation testing input respiratory rates and device-calculated rates

Input Rate	Device Calculation	Deviation
40	40	0
40	48	8
40	40	0
50	38	-12
50	40	-10
50	48	-2
60	58	-2
60	52	-8

Alternate detection method: Validation testing showed that the device and the percentage-acceleration-change method could produce accurate results, but with low repeatability. It was determined that the

detection method was not adjustable enough to reliably capture the breathing motion and correlate a breath count. As a result, raw acceleration data captured during validation testing was used to develop a second detection method using a counting mechanism based on changes in the angular orientation of the accelerometer. Inspiration was drawn from the work done by Bates, et al, who successfully tracked motion with a single three-axis accelerometer in part by calculating the angle of rotation between consecutive measurements [12]. As the results of prior analysis indicated that the motion caused by breathing is not necessarily uniaxial, it was decided that a more direct method of tracking this motion would be to follow a similar approach.

At each acceleration reading, the device calculated the angle of rotation between the previous acceleration vector and the current acceleration vector, using Eqs. 4 and 5.

$$\theta = \cos^{-1}(\vec{a}_i \cdot \vec{a}_{(i-1)}), \quad (4)$$

$$\vec{a}_i \cdot \vec{a}_{(i-1)} = a_{x,i} * a_{x,(i-1)} + a_{y,i} * a_{y,(i-1)} + a_{z,i} * a_{z,(i-1)}, \quad (5)$$

where θ is the angle between subsequent vectors (in radians), \vec{a}_i is the current acceleration vector, and $\vec{a}_{(i-1)}$ is the previous acceleration vector. Two thresholds were set on this rotation angle. The lower threshold, if exceeded, would cause the breath count to increment. The higher threshold would eliminate rotations too large to realistically be caused by breathing, and would this way help to filter out external movements.

This new breath detection algorithm was implemented in the Arduino program, as well as in a MATLAB program. Using MATLAB, the acceleration data measured during validation testing were used to run the new algorithm and compare the results to the original method. This comparison is illustrated in Figure 8.

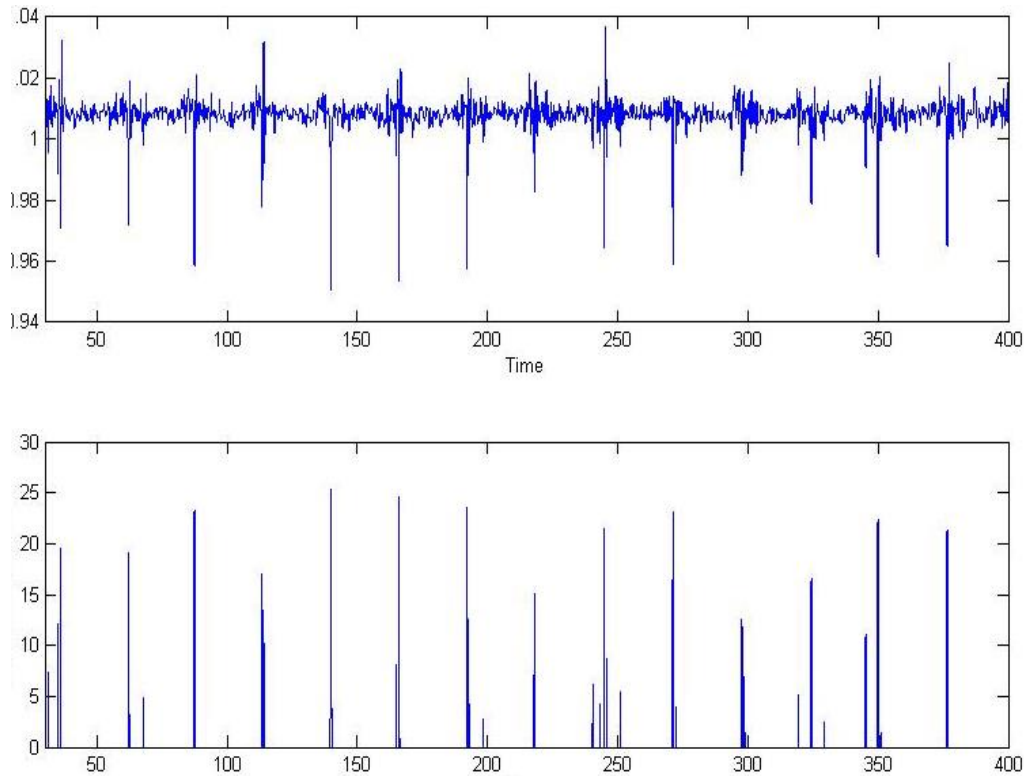


Figure 12: Comparison between the two breath detection methods, with a_{mag} vs. time (top), and θ vs. time (bottom) for the same acceleration data at 40 bpm. The magnitude threshold method (top) provided a noticeably more noisy signal, and had a_{mag} varying by 0.02-0.04g per peak, while θ was 10-20° per peak.

Comparing the two detection algorithms provided some indication that the rotation angle method was able to better track the motion caused by breathing, and produced a significantly clearer signal. Unfortunately, as the infant simulator was only available for use in a limited timeframe, the new algorithm was unable to be validated further than applying the method to pre-gathered acceleration data.

Threshold and directional calibration: Although testing on the infant simulator was crucial for validation of the developed prototype, the test was performed in a highly controlled environment. The respiratory rate was fixed, and external movements and disturbances were minimized to allow for an unhindered test of the device. However, in real use, disturbances are largely unavoidable, and must be selectively ignored for the device to function effectively. In order to increase robustness, calibration procedures were implemented.

First, due to breathing motion varying significantly among children, a peak-finding algorithm was used to attempt to find the average rotation angle per breath at the beginning of the test (assuming one breath would correspond with one complete period of the signal.) When this value was found, the threshold could be set as some percentage of that value.

Second, a directional calibration was designed to calculate the average unit vector of motion, using Eq. 6,

$$\hat{\delta} = \left\{ \begin{array}{l} \frac{(a_{x,i} - a_{x,(i-1)})}{\|(a_{x,i} - a_{x,(i-1)})\|}, \\ \frac{(a_{y,i} - a_{y,(i-1)})}{\|(a_{y,i} - a_{y,(i-1)})\|}, \\ \frac{(a_{z,i} - a_{z,(i-1)})}{\|(a_{z,i} - a_{z,(i-1)})\|} \end{array} \right\}, \quad (6)$$

where $\hat{\delta}$ is the unit vector between subsequent acceleration vectors \vec{a}_i and $\vec{a}_{(i-1)}$, and $\|\vec{a}_i\|$ represents the magnitude of \vec{a}_i . If the average unit vector, $\hat{\delta}$, were calculated over a calibration period of 1.5-2 seconds, then a threshold could be set on the angle between the current direction of motion and the calibrated direction, calculated using Eq. 7,

$$\varphi = \cos^{-1}(\hat{\delta}_i \cdot \hat{\delta}_{avg}), \quad (7)$$

where φ is the angle between the current direction of acceleration and the average calculated during calibration, $\hat{\delta}_i$ is the current unit vector between the current and previous acceleration vectors, and $\hat{\delta}_{avg}$ is the average unit vector calculated during calibration. Setting a threshold on φ would allow the device to exclude all acceleration that is not within a certain angle of the calibrated direction, thereby largely reducing the impact of disturbances and external movements.

Unfortunately, although both of these calibration procedures could have drastically increased the robustness of the prototype, neither was successfully implemented on the Arduino software and in the final prototype.

Design Critique

The nature of the project was very challenging because of the specific user requirements set, the intended low-resource environment, and the assumptions made about the end user. In summary, the prototype performed marginally and met some, but not all, of the user requirements and intended functionality.

The device was able to meet the requirement for a reduced test time of 30 seconds, which was extremely significant to the end-user ease of use and the accuracy of the holistic diagnosis. However, the device struggled to repeatedly perform respiratory calculations to within the targeted ± 2 BPM. More work needed to be done for the calibrated threshold used for breath detection, as it was determined that a fixed threshold could not capture the variance seen from test to test and patient to patient. The threshold was fixed due to difficulties with creating a dynamic threshold calibration program in the Arduino environment, so further development of calibration methods could improve the accuracy of the device.

The final conceptual design did not meet the energy requirements set for the device, which was linked to the lifespan of the device. It was estimated that 3 3V batteries would be required to power the device for the targeted two year lifespan, which was calculated assuming the device would perform 5 measurements per day. The trade-off between the lower energy requirement and large lifespan should have been investigated more, specifically by benchmark testing with more sensors and power sources.

The cost of the final conceptual model was anticipated to come just below the targeted \$9.00 unit cost, although this was calculated without factoring in manufacturing costs.

In regards to the conceptual model, a PCB model could have actually been designed, perhaps in partner with electrical or computer engineers, to develop a cheaper, more concisely integrated board that would meet the technical and financial needs of the project.

Despite the shortcomings of the device, it did effectively detect changes in acceleration and movement through the simulated breathing cycle, which showed the potential for further development and refinement to achieve superior results.

Future Work

With more time, the design could possibly be improved by implementing sensor fusion. Mostly simply, a second accelerometer could be used to find the relative changes between the two in an attempt to eliminate noise factors from patient movement and to isolate the breathing impulses to better detect and calculate respiratory rate. Additionally, a wider variety of sensors could be investigated for a sensor-fusion implementation and could serve as a passive, redundant checks or active factors in the calculation.

As previously stated, there were inherent constraints and trade-offs in the project that limited the scope of some technical solutions. An example a major limitation was that the device should not incorporate disposable materials and should preferably require no sterilization. Initial design concepts considered flow meters, turbines, gas sensors, and pressure sensors to detect the rate or consistency of expired air, which was believed to be a very robust mechanism for the analysis. However, the limitation on disposable elements in the design and inherent need for sanitation for a device covering or interacting with the mouth

deterred the investigation of such technologies. If a trade-off were made to allow cheap, disposable materials into the design and methodology, new technologies like flow meters could be explored that are inherently more related to the rate of respiration and that might produce far more accurate results.

Ultimately, an automated device that accurately and reliably calculates respiratory rate could be realizable, but more flexibility in unit cost and end-user assumptions is required. The proposed flow or gas sensors would likely increase the unit cost, but would also increase accuracy and repeatability. The intended end user influences constraints on the design and broadening the profile of the end user would invite additional solutions. For example, many mobile phones have gyroscopes or accelerometers that could be used in place of a physical product to perform the same intended function as the prototyped device, and at very little marginal cost. The design could also synthesize with other technologies including computers or cameras for various forms of analysis.

In conclusion, in order to better address the problem of pneumonia diagnosis methodology, a new approach should be taken with a broadened, less constraining set of criteria. If the accurate function can be achieved and it aids the CHW, the design could be considered a success, and then refinements can be made to reduce unit cost and increase lifespan from that point.

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Authors



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Scott Tweedy is a senior mechanical engineering student at the University of Michigan. He has worked on several research projects with professors and doctors throughout his years at the university and plans to start working with Kaydon, an SKF group, upon graduation. Scott has been a member of the Michigan Hybrid Racing team for three years, becoming Mechanical Lead for the 2015 season. He is also the president of the University of Michigan chapter of the Society of Automotive Engineers.



Stephen Ward is a senior mechanical engineering student at the University of Michigan. He worked for Pelico, LLC in the summer of 2014, helping to design a completely mechanical stair-climbing wheelchair. He is the Hulls & Systems team lead for UM::Autonomy, a student design team at the University that designs and build a fully autonomous robotic boat and competes in the AUVSI RoboBoat Competition.

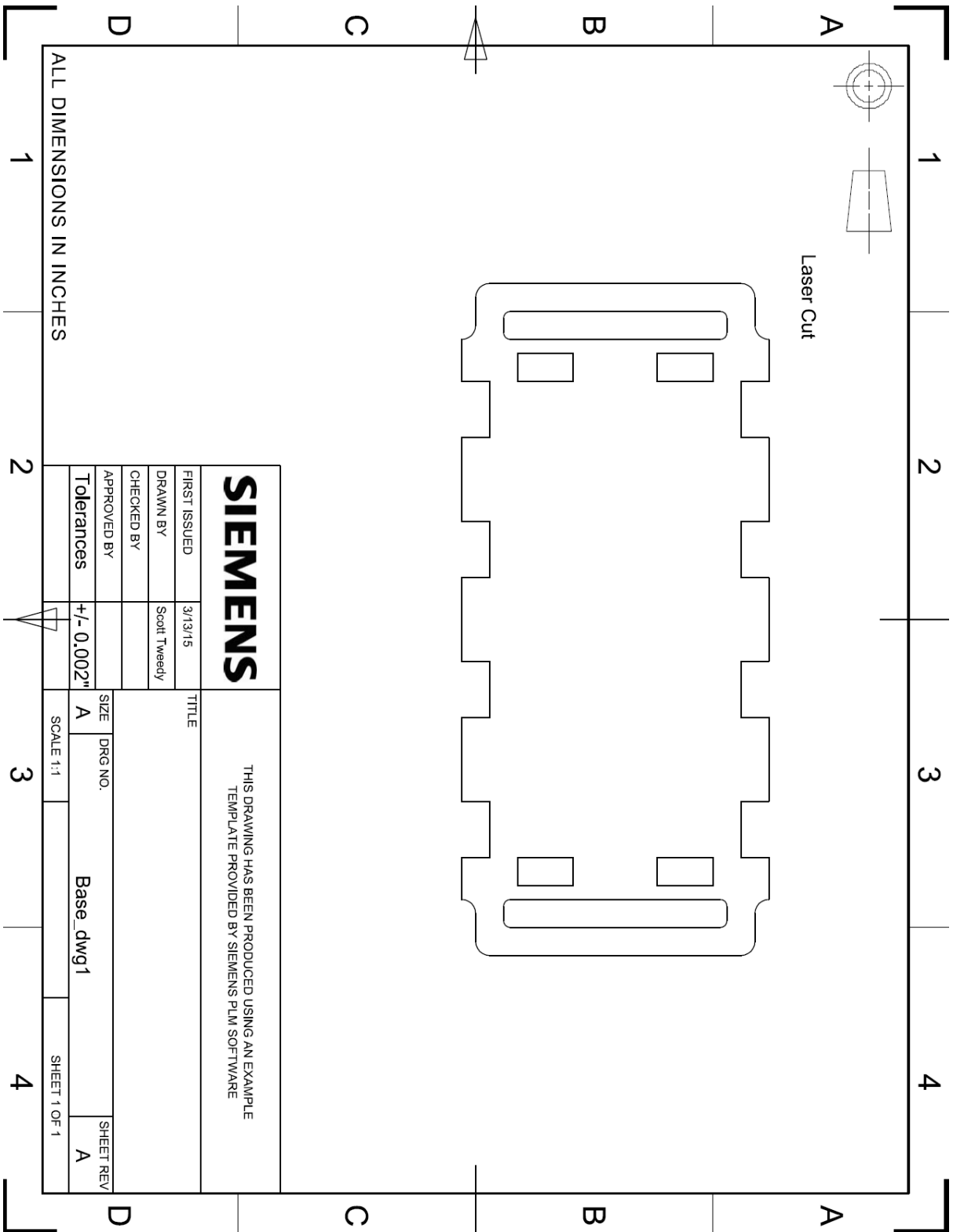
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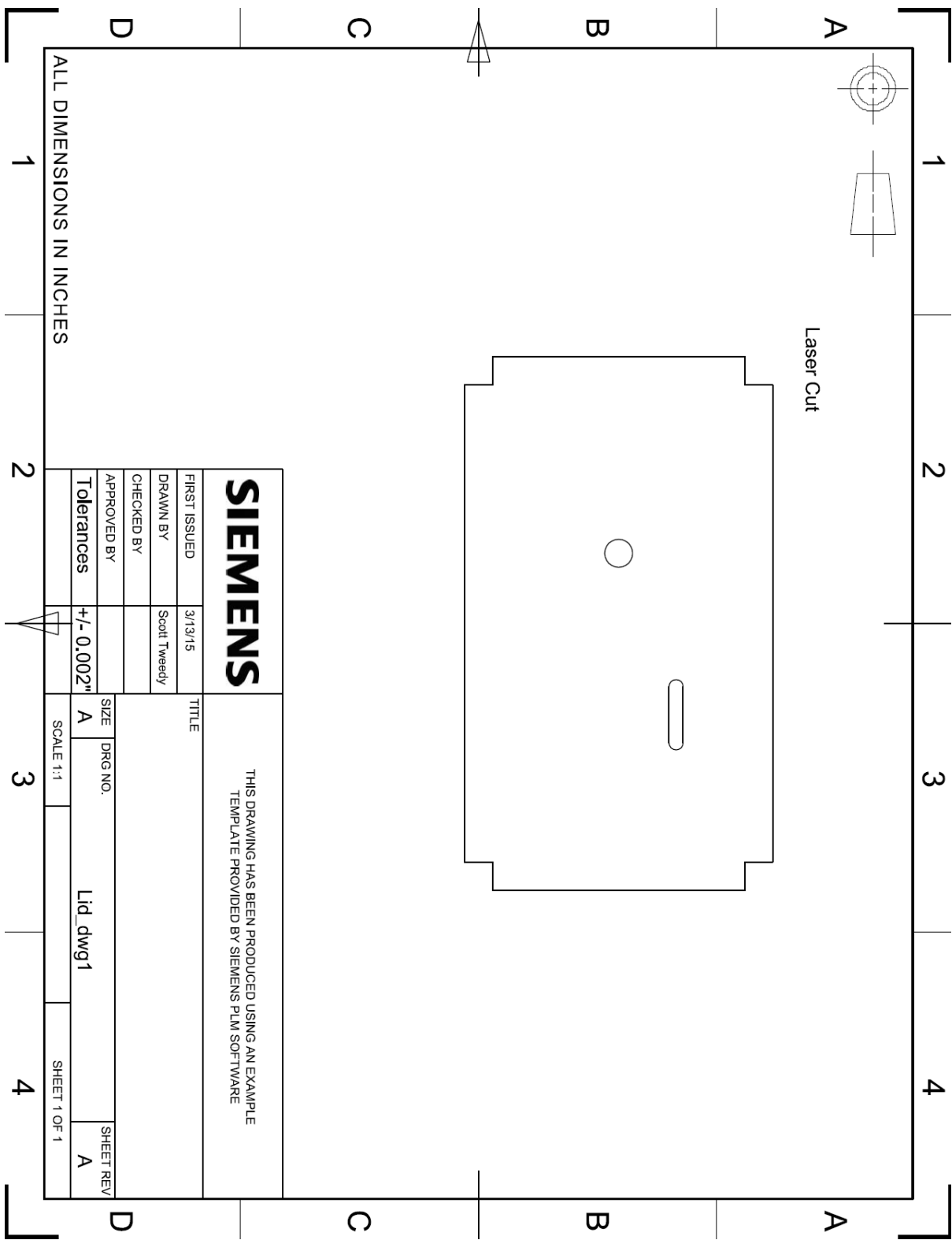
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Appendix

A.1: Engineering Drawings





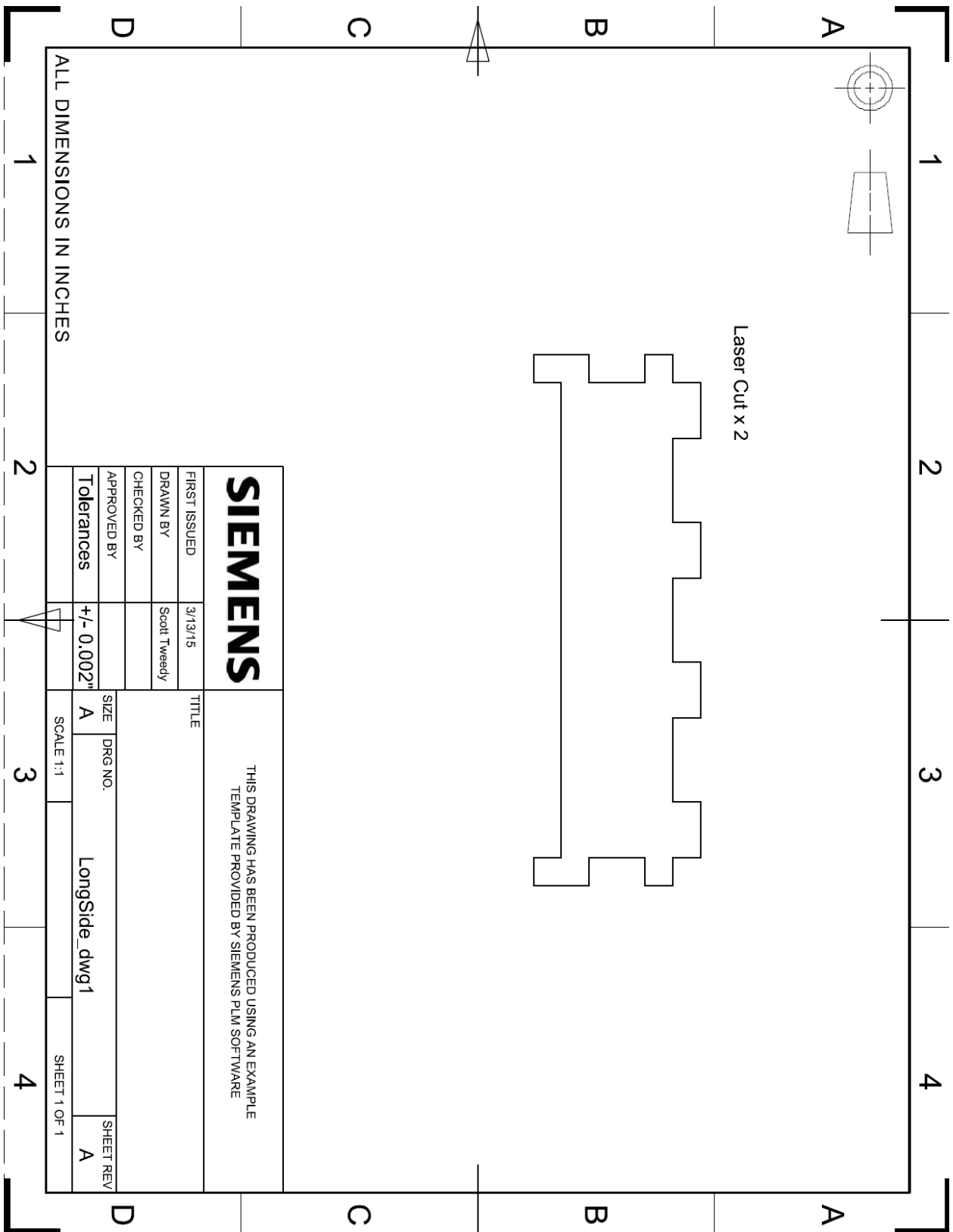
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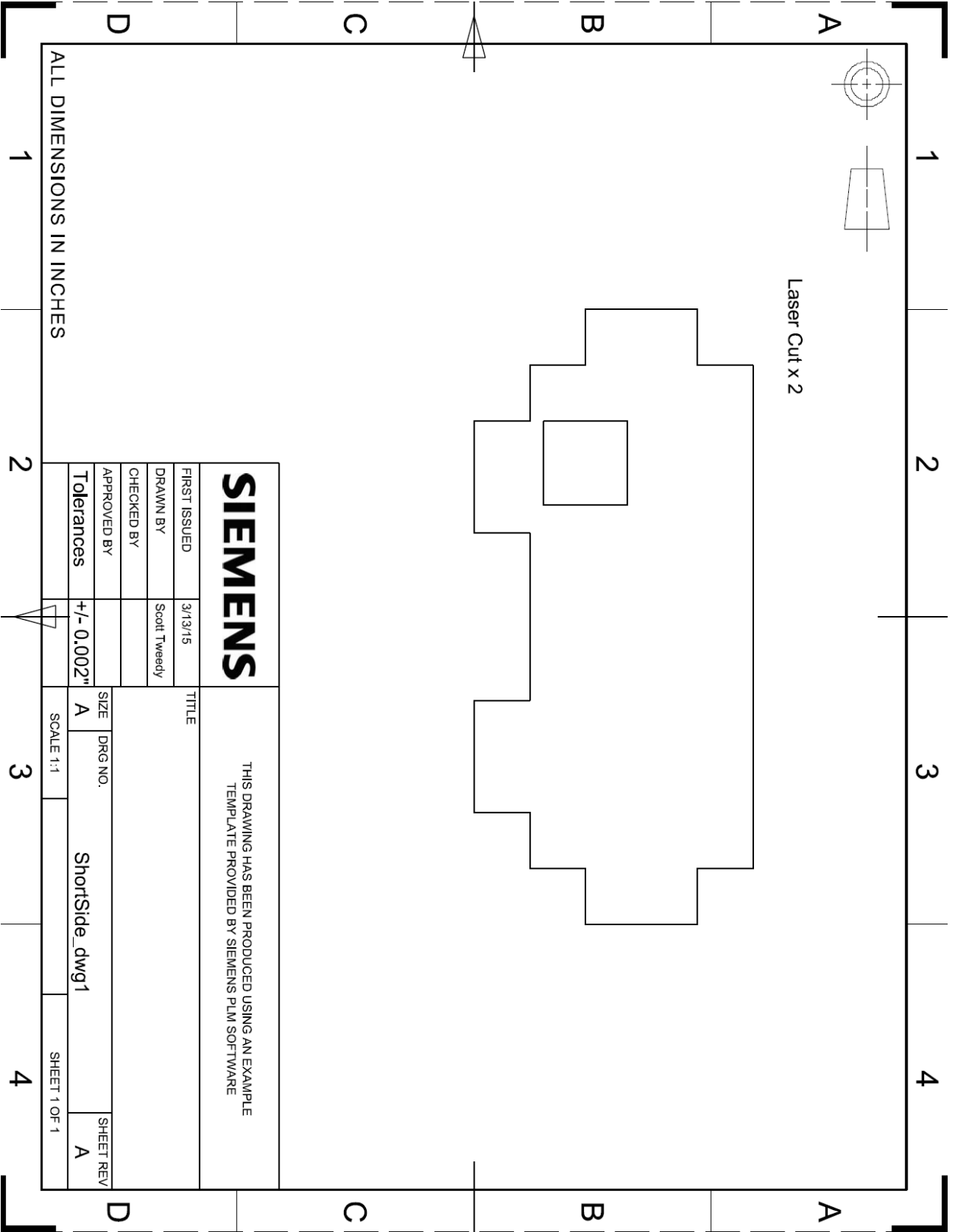
Laser Cut

SIEMENS

THIS DRAWING HAS BEEN PRODUCED USING AN EXAMPLE
TEMPLATE PROVIDED BY SIEMENS PLM SOFTWARE

FIRST ISSUED	3/13/15	TITLE		
DRAWN BY	Scott Tweedy	SIZE	DRG NO.	SHEET REV
CHECKED BY		A	Lid_dwg1	A
APPROVED BY		SCALE 1:1		SHEET 1 OF 1
Tolerances	+/- 0.002"			





A.2: Manufacturing Plans

Manufacturing Plan

Part Number: 001

Revision Date: 3/4/15

Part Name: Base

Team Name: Pneumonia Diagnostic Aid – Group 18

Raw Material Stock: Acrylic Plate 1/4" x 1' x 2'

Step #	Process Desc.	Machine	Fixtures	Tool(s)	Speed (RPM)
1	Load material into machine	Laser Cutter			
2	Load program into computer	Laser Cutter			
3	Cut material	Laser Cutter			
4	Remove pieces and leftover material from machine	Laser Cutter			

Manufacturing Plan

Part Number: 002

Revision Date: 3/4/15

Part Name: Lid

Team Name: Pneumonia Diagnostic Aid – Group 18

Raw Material Stock: Acrylic Plate 1/4" x 1' x 2'

Step #	Process Desc.	Machine	Fixtures	Tool(s)	Speed (RPM)
1	Load material into machine	Laser Cutter			
2	Load program into computer	Laser Cutter			
3	Cut material	Laser Cutter			
4	Remove pieces and leftover material from machine	Laser Cutter			

Manufacturing Plan

Part Number: 003

Revision Date: 3/4/15

Part Name: Long Side

Team Name: Pneumonia Diagnostic Aid – Group 18

Raw Material Stock: Acrylic Plate ¼” x 1’ x 2’

Step #	Process Desc.	Machine	Fixtures	Tool(s)	Speed (RPM)
1	Load material into machine	Laser Cutter			
2	Load program into computer	Laser Cutter			
3	Cut material	Laser Cutter			
4	Remove pieces and leftover material from machine	Laser Cutter			

Manufacturing Plan

Part Number: 004

Revision Date: 3/4/15

Part Name: Short Side

Team Name: Pneumonia Diagnostic Aid – Group 18

Raw Material Stock: Acrylic Plate ¼” x 1’ x 2’

Step #	Process Desc.	Machine	Fixtures	Tool(s)	Speed (RPM)
1	Load material into machine	Laser Cutter			
2	Load program into computer	Laser Cutter			
3	Cut material	Laser Cutter			
4	Remove pieces and leftover material from machine	Laser Cutter			

A.3: Bill of Materials

Item Purchased (QTY)	Spent	Supplier
Arduino Board (1)	\$27.95	Amazon
Arduino Screen (1)	\$11.99	Amazon
Hall Effect Sensor (3), Accelerometer (1)	\$28.92	Amazon
Breadboard (5)	\$6.79	Amazon
330 Ohm Resistors (20)	\$4.98	Amazon
Velcro (2)	\$32.93	Jo-Ann Fabric
Elastic (2)		
Strand Floss (2)		
Tacky Glue		
Fabric Samples (3)		
Buckle		
Allegro A1302 Hall Effect sensor (5)	\$23.00	Tayda Electronics
Flex sensor, 2.2" (1)	\$32.60	SparkFun
Flex sensor, 4.5" (1)		
USB cable, 6' (1)		
Momentary push button switch (2)	\$24.91	SparkFun
MM8452Q Accelerometer breakout (2)		
Total:		\$194.07
Remaining:		\$205.93

A.4: Failure Mode Effects and Analysis (FMEA)

Item	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Class	Potential Cause(s) / Mechanism(s) of Failure	Occur	Current Design Controls	Detect.	R.P.N.	Recommended Action(s)	Responsibility
Casing											
Houses electromechanical systems	Crack in the housing	Water leaking into device, circuit damage, battery damage	6		Dropping, sitting on, transportation error of the device	3	Strength and durability testing	2	36	Use tape or glue to fix crack. If not fixable, replace device or use in dry places only.	Scott, Forrest
	Crack in the screen	Possibility of loss of output data	2		Dropping, sitting on, transportation error of the device	3	Strength and durability testing	2	12	If screen still outputs, continue use. If screen no longer works, seek replacement.	Stephen
	Strap breaks	Device cannot be secured to child	4		Over-tightening, degradation	2	Strength and durability testing	1	8	Seek replacement	Scott
Electronics											
Carries out data collection and analysis	Solder breaks	Circuit will not work	4		Fatigue, mishandling	1	Proper soldering technique	4	16	Seek replacement	Stephen
	Battery cracks/leaks	Corrosion of casing and degradation of circuit	6		Improper installation, mishandling	1	Accurate assembly plan	4	24	Replace batteries. If device does not turn on after replacing batteries, seek replacement device.	Forrest, Scott, Stephanie, Stephen
	Dislodging of sensor	No data will be acquired	4		Dropping, mishandling device	2	Strength and durability testing	3	24	Seek replacement	Stephen, Scott

A.5: Ethical Design Statements

Forrest: Ethical design is significant to both the function of our device and the effective acceptance into the market (or user environment), so we gave consideration to ethical design and procedures throughout the design and testing of the device. A pivotal focus for the project was the understanding that the device was presented in the project brief as a ‘diagnostic tool’, implying that it should produce a diagnosis, but that sponsor expectations were for the device to be a diagnostic aid to assist in the diagnosis performed by a Community Health Worker. This nuance helped us to design a more ethical medical device with appropriate function and implementation. Ultimately, the device reports the calculated breaths per minute value and provides the health worker with a factor for consideration in the diagnosis, which can greatly assist the job of the CHW and meets legal medical requirements and ethical boundaries.

Our testing procedures were scrutinized for ethical flaws and to ensure the safety of all of our members. We were able to test the device on a high-fidelity infant test dummy in order to obtain respiratory patterns and test our current device. This testing method was not only ethical, but also extremely helpful to the understanding of how our device interacts with a patient and thus how we can refine and alter our design to create a more comfortable user experience. We persistently kept patient and user interaction at the front of our minds during design, so we are confident that we have made a safe and easy-to-use, ethically sound medical device to assist in the diagnosis.

Stephanie: Our design addresses diagnosing a medical condition as it affects children. There are many ethical dilemmas to consider when dealing with just health care, but when adding the needs of children into the equation, the problem becomes much more complex. When designing, we found that right away we were facing ethical problems just in the naming of the device. It was critical that we made the distinction that our design was a pneumonia diagnostic aid and that it did not replace other symptoms or a doctor’s inspection. It was also important that our device operate within a tight tolerance and be repeatable. Otherwise the respiratory rate displayed is untrustworthy, meaning we have provided an unethical device that does not perform the job it says it will.

We also needed to consider patient confidentiality, sanitation, and comfort when designing our device. When working on the final housing, we were debating on clasps for the belt. After viewing our two options, Velcro and a buckle, we quickly saw that a buckle had a chance of pinching. Knowing that we were working with children under 5 who may already be very ill, we knew that any potential for causing harm, no matter how minute, was not an option.

Our team was very lucky to work with a sponsor who had been considering the ethical impact of our device long before we joined the team. Working with both his advice, and the TPP guidelines, many of

the ethical dilemmas already had solutions presented to us. We just needed to follow the guide set for us and double check our work as we continued forward.

Scott: When it comes to designing a device that will be used on humans, young children especially, there are several ethical questions that need to be asked. Could this device cause harm or discomfort to the patient? Are there any potential liability issues that we may run in to when this device goes into use? How and where will the device be manufactured? One of the biggest things that we had to consider with this project was how the device should be used and labeled. At first, it was under our impression that it was a diagnostic device, but we were then corrected by one of our sponsors. He mentioned that there is a very large ethical dilemma with allowing this device to “diagnose” patients. It was made very clear to us that in order to be ethical, our device must be considered a “diagnostic aid,” in that it can only assist the community health worker or doctor using the device in diagnosing or not diagnosing the patient. There was a very distinct line drawn for us that we did not initially imagine would be such a big problem. Luckily for us, the crisis was averted and the device has been designed with the thought of aiding in diagnosis in mind. A few other things that needed to be considered as far as ethics were concerned were the comfort of the device while in use, potential health hazards, and sanitary and adjustability aspects of the design. We consider our device to be of ethically sound design and have taken significant steps to ensure this.

Stephen: In our design of an automated pneumonia diagnostic aid, ethical considerations are paramount to producing a successful device. The device will specifically be used on children (ages 5 and under), by people with little to no informal training. Ethics have driven every aspect of the design of our prototype, from appearance to technology.

First, we are aiming for the ultimate unit cost of the device to be under \$10. This is a crucial ethical decision because the target environment for the device is low-resource areas. If these communities cannot afford the device, then there is no purpose in doing the project at all. The appearance of the device is also more important than it may seem. As a medical device, it must inspire confidence in the community health worker, as in it must look like a medical device. On the other hand, the device must not appear dangerous or threatening, as this could dissuade the health care worker from using it, or frighten the child. In order to meet these criteria, we have designed our device to look professional, without deviating too much in appearance from the timers that are currently used.

In addition to appearance, the physical structure of the device also brings up ethical considerations. Since it will be contacting the skin of the child, our device has been designed to not have sharp edges, and we have chosen a material for the belt portion that will minimize skin irritation. Furthermore, in regards to

material choices, we have chosen materials that are non-absorbent, so as to minimize the spreading of germs and to make the device easily cleaned. Finally, the electronics of the device must be fully enclosed so as to eliminate any risk of electric shock.

Aside from the physical aspects, ethics have driven decisions related to the technological function of the device. Perhaps most importantly, we are emphasizing the fact that this device is not making a diagnosis, but is merely providing data that will be a factor in the diagnosis ultimately made by a health worker. This has dictated what we have chosen the device to output to the health worker during use. Our device will not tell the health worker that the child “has”, or even “may have” pneumonia. We have debated on having the device display whether or not the calculated respiratory is above or below the threshold, such as with a red LED indicating “too high.” Our sponsors have expressed differing points of view on this function, but we have chosen to just have the device display the respiratory rate, and offer no indication of “too high” or “all good”. Especially in dealing with minimally trained community health care workers, an indication compared to the threshold could end up being more of a diagnosis that we believe our device should be making.

A.6: Environmental Impact Statements

Forrest: The product is fundamentally designed to reduce both energy and waste throughout the device life cycle. Our environmental design goals were aimed primarily at requiring no additional materials or energy beyond the device itself (to power the device or perform the test, for example) and at producing no waste nor consumable materials. By creating a self-sustained (no additional material or energy required) device that produces no waste, there will be a small impact to the environment during the active life of the device.

However, because we designed a no maintenance device, the customer is likely to throw away the device at the end of the product life, which will produce waste. It could be possible for UNICEF to reclaim the devices and recycle the materials or even performance maintenance on devices that might still work, thus attempting to reduce waste.

Manufacturing and production will be the most energy and material intensive stage of the product life cycle. The conceptual form factor is designed for plastic injection molding and will consume high amounts of energy and requires large capital costs. Given the sizeable production volume (on the order of 100,000 to 200,000 units) and the small electrical components incorporated in the device, this process is desirable in terms of the energy consumption per unit produced.

Stephanie: The goal of the device is to leave as minimal of an environmental impact as possible. This was addressed in engineering requirements. Our goal was to create a device that had little to no disposable parts, that lasted 2-5 years, and that, when the device eventually died, could easily be disposed of. We considered materials that were robust yet easy to make so that the financial and environmental contributions used to make the product were minimized in the greater scheme of the device's life cycle. Since this diagnostic aid will be used in low resource areas of Sub-Saharan Africa and Asia, we wanted to make this device as long lasting as possible so that the end user did not have to worry about maintaining the device. This included considering the device's power source, by calculating the energy input needed, as well as the fabric used, by choosing strong, sturdy material.

Scott: One of the major things that our group has had to consider when designing this device has been its environmental impact, through its manufacturing and distribution. Trying to make the device with as few components and materials as possible has been a large part of the considerations that we have taken. Because of the potentially remote locations of use for the device, we have had to take into account the lifespan of the device and its power source. Replacing batteries is a big problem when there are no batteries to replace with. My idea for helping to reduce the environmental impact of the device was to generate our concept around the idea of using recycled plastics for the housing of the device and to incorporate a PCB in order to cut down on the power consumption from the batteries. We believe that we have taken the proper steps to make an environmentally friendly design.

Stephen: Throughout our design process of our automated pneumonia diagnostic aid, we have considered the potential impact of the environment due to its fabrication, use, and disposal. We have made design decisions to minimize the environmental impact, including minimizing the material required for each unit. Instead of an Arduino microcontroller, the ultimate device will have a printed circuit board which will vastly minimize the size of the device, which will also minimize the material required for the enclosure. In terms of power consumption, we have looked into both batteries (such as those found in wristwatches) and solar cells. These batteries would need to last for at least 2 years, at which point the device itself would be discarded. We have decided that replaceable batteries, such as AAA batteries, are not feasible due to the negative environmental impact created by their replacement and disposal. Due to these concerns related to power consumption, we have chosen to use a single three-axis accelerometer to reduce the power requirements of the device.