Bicep PPG and Accelerometer Wearable

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Table of Contents

Market Analysis & Customer Need

There currently exist very few wearable devices that can accurately measure localized internal body temperature, heart rate, and movement of the wearer. We were approached by our client, Dr. Ali Roghanizad of the Duke University “Big Ideas Lab”, to develop a companion device to his extremely accurate internal body temperature monitoring wearable. This companion device would accurately measure body movement and heart rate, and it would communicate this data to the temperature sensor component. We transformed this problem into a needs statement: to support the current internal temperature device, intended for high school football athletes, with an additional wearable device capable of sensing heart activity and movement and communicating with the existing form factor in real time.

In addition to the original intended recipient of the device (United States high school football athletes), we performed a market analysis on several other potential market segments. These included professional soccer players worldwide, firefighters and construction workers in the US, pregnant women in the US, and children (6-17 years-old) in the US.

Annually, there are approximately 10 million children in the 6-17 year-old age range who are hospitalized in the United States (Witt et al., 2014). During their hospital stay, children are monitored by biometric devices to track their state of health. A wide variety of pediatric devices exist from Philips, Welch Allyn, and an even broader supply exists in the field of commercial wearables, such as those from Apple, Samsung, and Garmin. Most hospitalized children suffer from poisoning, physical injury, or nervous system problems (Witt et al., 2014), and so parents/legal guardians will end up paying at least $50 for treatment - the cost is even greater for the uninsured. For a device that can accurately monitor biometric information and provide useful health information at a moment’s notice to help prevent these ailments, parents would be willing to make a one-time payment of $50. Thus, the total addressable market amounts to about 200 million dollars a year.

Given that there are around 11.4 births for every 1000 Americans (Centers for Disease Control and Prevention, 2022), there are approximately 3.5 million pregnant women in the US annually, accounting for multiple births and pregnancies. Because 8% of pregnancies involve some sort of complication, families or mothers usually purchase a baby monitor device for $70-$80 or rent one from clinics for $20-$30 (*4 common pregnancy complications)*. Current solutions to infant monitoring include fetal dopplers, temperature/blood pressure/heart rate sensors. Given that handheld fetal Dopplers cost around $50, we believe families would seriously consider purchasing a biometric monitoring device at around the same price point. Thus, the total addressable market for the pregnant women segment would be approximately 70 million dollars a year.

In the United States, there are approximately 1 million firefighters and 900,000 construction workers (Fahy et al., 2021), combining for a total of 1.9 million participants in the workforce who work in physically exhausting conditions (Mycomply, 2021). There are currently very few products on the market designed to monitor body temperature in firefighting temperatures, but some exist for construction workers who do not work in as extreme of a temperature. This includes CORE body temp, standard smart watches, and simple temperature sensors. Standard protective equipment for construction workers can cost on the order of hundreds of dollars (helmets, gloves, vests, work boots), and that for firefighters will cost even more due to the extreme conditions they work in. Because of this, we believe that a firefighter/construction worker or their public/private representative will be willing to make a one-time purchase of at least $40 per temperature monitoring device. Thus, we estimate that the total addressable market for the firefighter/construction worker market segment is 80 million dollars. This does not account for worker turnover/employment growth, so the actual market cap may be even larger.

Worldwide, there are about 130,000 professional soccer athletes (*Professional Football Report*, 2019). These athletes undergo extreme physical exertion during training and competing, so despite their elite degree of cardiovascular conditioning, it is essential that their vitals are monitored in the event of unexpected disaster: heat-exhaustion-related injuries and fatalities have garnered increasingly more media attention in recent years. There are a wide variety of smartwatches on the market that monitor basic vitals, such as those from Apple, FitBit, and Garmin. There are also higher fidelity wearables, like those from CORE Body Temp and Kenzen, that produce more accurate readings. Because soccer balls cost upwards of one-hundred US dollars (and many soccer clubs will purchase more than one soccer ball for every player), we assume that it would be reasonable for a soccer club to purchase a biometric-monitoring device for at least $100. As a result, the total addressable market amounts to approximately 322 million dollars. This is an underestimate considering young athletes are constantly being contracted.

Finally, the market segment that we initially intended to design the device for is US high school football athletes. They number approximately 1.25 million, knowing that there are an average of 50 players on a football team and that there are about 25,000 high schools in the US (*Educational institutions*, 2021). These athletes experience strenuous training for extended periods of time, so they are vulnerable to dehydration and heat exhaustion if they are not vigilant about their condition. Some solutions that address this include sports drinks, industrial fans, digital thermometers, and commercial wearables like the FitBit. Since the price of an entry-level FitBit, a device that provides similar (but lower fidelity) biometric information, costs $80, we believe that student athletes (or their team/school/district sponsor) will be willing to pay as much for each device. These can be reused if they are purchased by the sponsor. The total addressable market then becomes about 100 million dollars.

We have analyzed five different market segments and have realized the broad applicability of the device we intend to design and produce. To optimize productivity, we decided to target the most practical market segment in terms of accessibility and regulation: United States high school football athletes.

Functional Specifications and Functional Decomposition

Essential Functional Specifications:

Drop/Impact resistance:

We initially wanted our device to have an extent of drop resistance given the possibility of fall damage; however, after doing more research we have made slight modifications to the drop-resistant specification for our device. We realized that, since the product is intended for use by athletes playing sports involving forceful contact (like football), it would be more appropriate to optimize the resistance of the device to sudden impact. We decided that the impact-resistance standard for medical-grade electronic equipment determined by IEC 60601-1 would be sufficient. Specifically, this standard involves dropping a 0.5 kg ball on all sides of the device from a height of 1.3m. One trial of our test will consist of a ball drop on each outward facing side of the device. The percent of those drops that do not induce the breaking open of the enclosure will be calculated for each trial. A minimum of ten trials will be conducted. Ideally, we would want all ten trials to have 100% of the drops not lead to breakage. This is also the case for existing wearables on the market. Marginally, we would want all ten trials to have an average of 80% success. The results will be reported as a confidence interval of percent success.

Low cost:

We also want our device to be priced appropriately and low cost for schools to purchase them in bulk. The specification for low-cost stays the same, but we would like to add some nuance to the measurement of cost of our device. We are aiming for the sum of all the components to manufacture the device to be under $100.00 for the ideal value and under $300.00 for the marginal value. It is hard to find statistical tests for how we meet the specification because the test is binary: pass or fail. However, it is possible to compare the cost of our devices parts to the part cost of other wearables on the market (assuming they have the same functionality). It is also possible to model total cost based on the market's fluctuation. From gathering information on other wearables on the market, we can also create a distribution of mean value and standard deviations so that we can gauge our cost to the average. In short, we will sum of the cost of our parts and attach a plus or minus depending on the market analysis, and we will compare the total to the ideal and marginal values for a pass or fail. It is important to note that we did not account for shipping or distribution costs in our calculation.

Accuracy:

One of the key specifications is that the PPG reading that the device records is accurate. From the original, we have a change to the measurement and testing protocol for the specification for PPG accuracy. We are striving for the Polar Heart Band mean heart rate to fall within the 95% confidence interval of our device. The Polar Chest strap heart rate values will be taken in increments of 20 consecutive data points. Data points from our wearable ppg heart rate monitor will be used to identify the 95% CI and to identify if the mean heart rate from the polar strap falls in this range. The results will be graphed using a line graph. The mean and 95% CI bounds will be plotted for various mean heart rates. In addition to checking the 95% CI bounds, a t-test comparison will be performed to identify if there is a significant difference between the two PPG sensors. Therefore, the 95% CI bonds will also be displayed for the Polar Heart Rate Data.

Compatibility:

Our device needs to be compatible to the client's internal temperature device. To test for this compatibility, a verification will be conducted that the Adafruit nrf52840 board can send information to a second microcontroller within 5 ft before sending information to the Bluefruit connect app. This specification involves a sample size of 5 as we will check this binary functionality under jumping jacks, light jogging, rest, stretching, and sprinting. Data will be visualized with a table indicating whether the test passed or failed for each case.

Battery life:

Our device needs to exhibit a degree of battery life. Our battery life specification has not changed and the sample size is one battery for now. By taking current measurements across several time points as well as running till the battery dies several times and taking the statistical mean of run times across 10 tests (full to drained), we can establish that our run time either falls within a 95% confidence interval of our specifications, or exceeds them by a statistically significant amount. The results can best be displayed in a distribution curve and showing that our battery life is statistically within 95% of the spec.

Functional Decomposition:

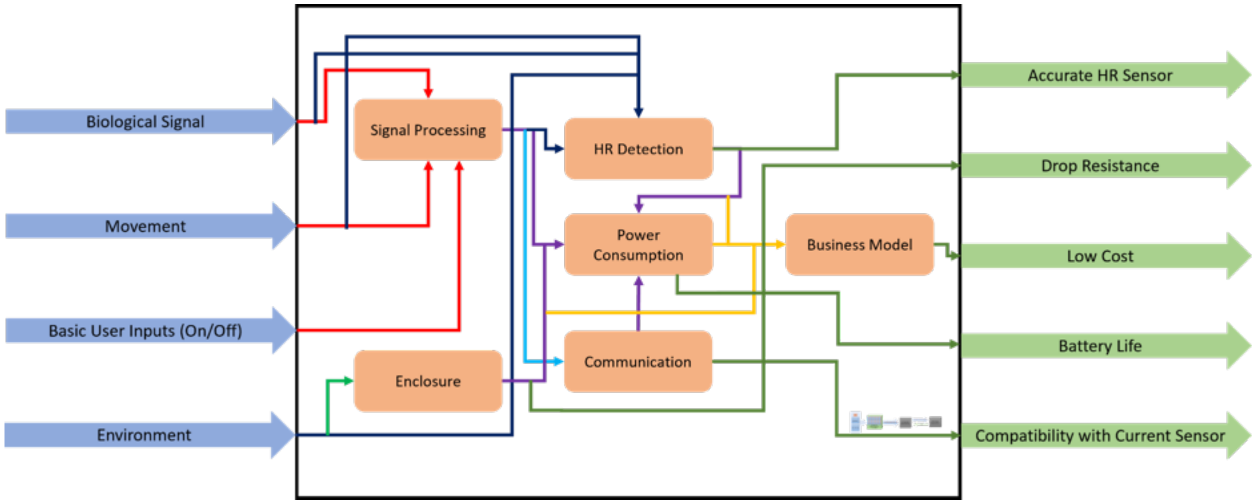
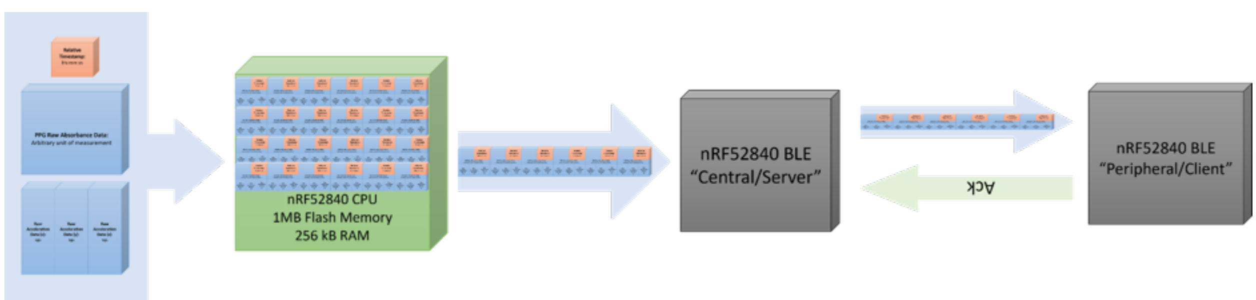
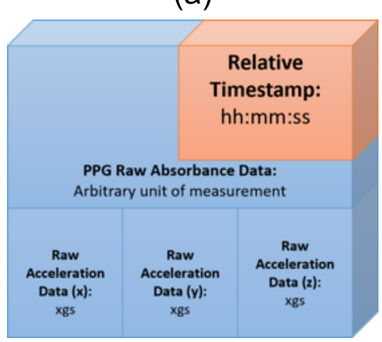


Figure 1. Black box functional decomposition of device.

The above, Figure 1, is a diagram mapping out how some of our specifications will be reached through our device.We will be taking inputs such as biological signal, human movement, basic user inputs, and the environment to output an accurate HR sensor, device drop resistance, low overall cost, battery life, and compatibility with current sensor. By having blocks such as signal processing, power consumption, communication, etc. we can accomplish the specifications.



(a)



(b)

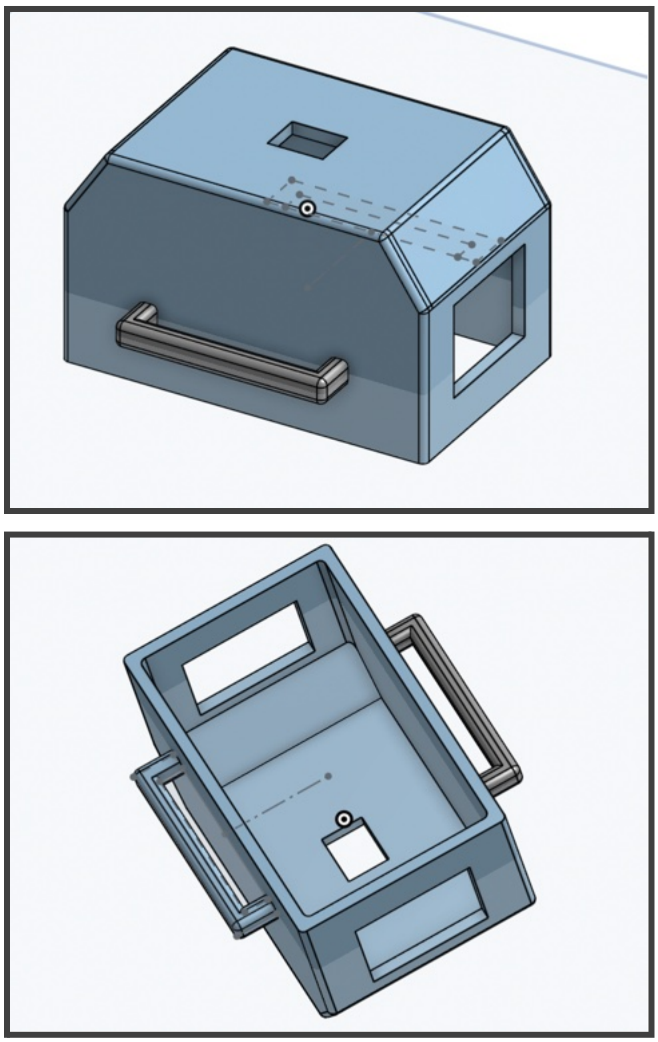
Figure 2. (a) Overall flow diagram of data collection, processing, and transfer. (b) Detailed representation of data structure.

To better illustrate the nature of the communication aspect of the device, we designed a data structure for each packet of information being transported. At one instance in time, the external RTC will send a time stamp, the accelerometer will send 3 acceleration values (one for each 3D axis), and the PPG will send one absorbance reading to the microcontroller. The microcontroller will then package all three categories of information together into one packet and ideally store it to non volatile memory. Simultaneously, the microcontroller will build sequences of packets in chronological order based on timestamp. Once a discreet number of packets accumulates, the microcontroller will send it to the Bluetooth chip onboard, which will then send it to a receiving Bluetooth chip. This receiver will send a signal back to the onboard chip to acknowledge data reception. This process, shown in Figure 2, then repeats while data collection occurs.

<u>Proof of Concept/Proof of Principle</u>

<u>Proof of Concept</u>

Shown below in Figure 3 are the CAD design drawings created for the enclosure. The housing for the enclosure had to be made taller due to the height of the final circuit board including the real time clock and all the wire connections needed to be made. The final product would be a consolidated circuit board, however, since the shipping times for these PCB’s extended out into June, the reasonable and cost effective way to prove that the device works was to heat shrink open connections.



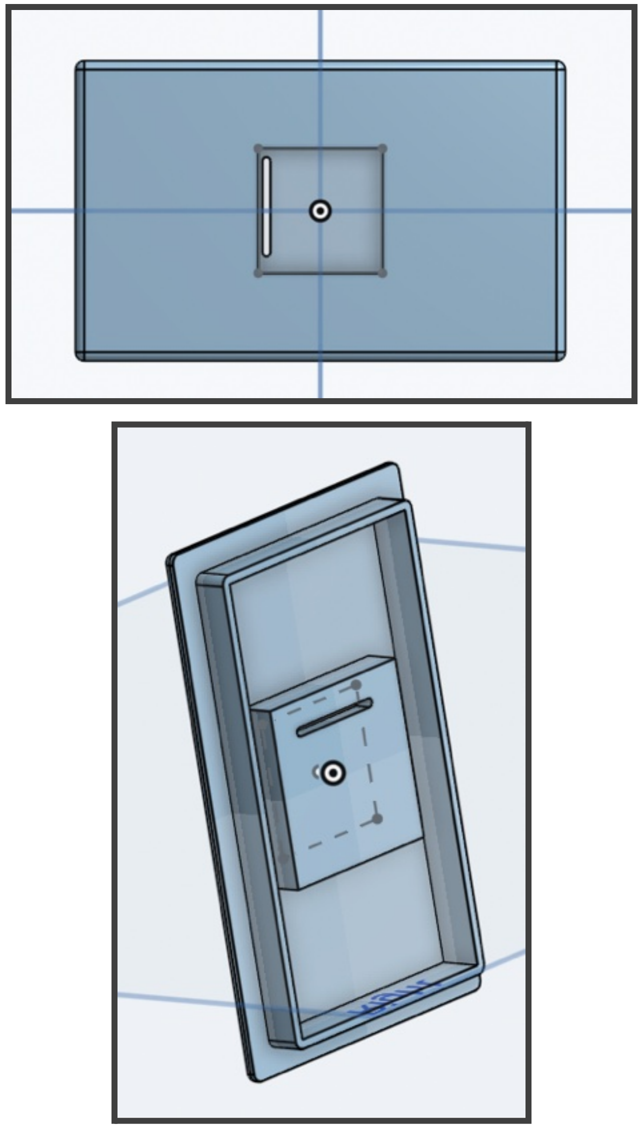


Figure 3. CAD Design of Enclosure

The design was centered around housing the entire unit while also allowing for the PPG to have the best contact with the flesh where it measures the signal. One of the issues with this project was to ensure that the sensor had a secure signal to measure at the bicep which is achieved by a deep skin to sensor connection which is achieved, by the protruding sensor which allows for a comfortable yet fidel signal front he bicep. The working prototype is shown below in Figure 4. Here, you can see a signal that is reliably received front the device which shows the heart beat signal received from the PPG.

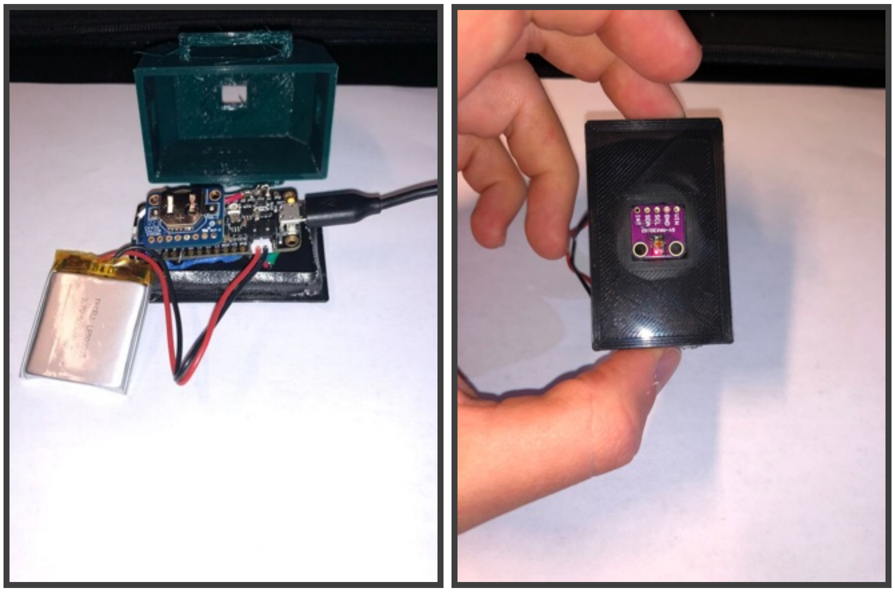


Figure 4. Final Printed Enclosure

After working out some of the issues with the enclosure and the microcontroller itself, the resulting prototype is shown above. The circuitry sits inside the top half of the enclosure while the PPG sensor is on the “bottom”, the side that faces the skin, with the PPG sensor sitting 4mm above the rest of the enclosure to ensure a good skin to sensor contact point. The final product has the ability to detect whether there is a surface contact to skin or not, as well as the ability to plot and send live raw data to any bluetooth connected device.

Proof of Principle

In order to show that the device works as is, a demonstration video was created specifying how to use the device. The videos can be found at two different links: https://youtu.be/kzwhJoWzDFI and https://duke.zoom.us/rec/play/jDqXWfT8bGnHnQoWww6mOmrO6VhOeBKo7WkfhoYHJN9GkiUt6jIELuIsFcBIrRJPsbomMGeb9a6-64Ie.Y_mnOo95YqShGHz2?continueMode=true&_x_zm_rtaid=xZg4cwgpSousM3NKITfXrw.1650336080633.a737d56522b754bf35faf630d64c71c7&_x_zm_rhtaid=301. In the first link, Ben demonstrates how to put the device on the bicep individually using the strap with the device positioned on the inner bicep. The second link displays the information that is gained by the device as well as the GUI interface information from the Bluefruit Connect app on the computer which mimics the interface used by the app on the phone. When the device is powered on, and the app is running, the user is able to connect to the bluetooth signal sent out by the microcontroller. The device is then able to tell the user whether there is good skin contact with the sensor. If there is a connection, the plotter will show the raw signal received by the sensor. The image of the raw data plotted is shown below in Figure 5. The yellow trace shows the PPG signal while the other three traces show the accelerometer data. The areas with great amounts of movement can describe the behavior of the PPG signal trace. PPG signal is very fickle and depends on the movement of the user and can be as sensitive as sending high noise signal when the user is talking.

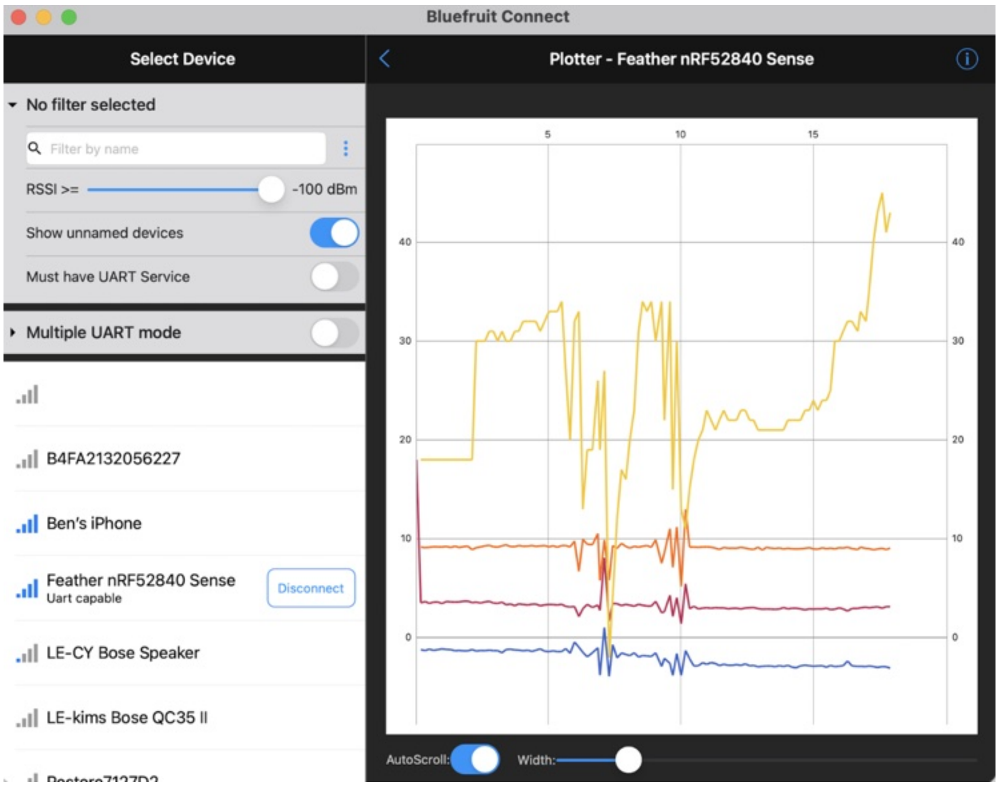


Figure 5. Fully integrated device output.

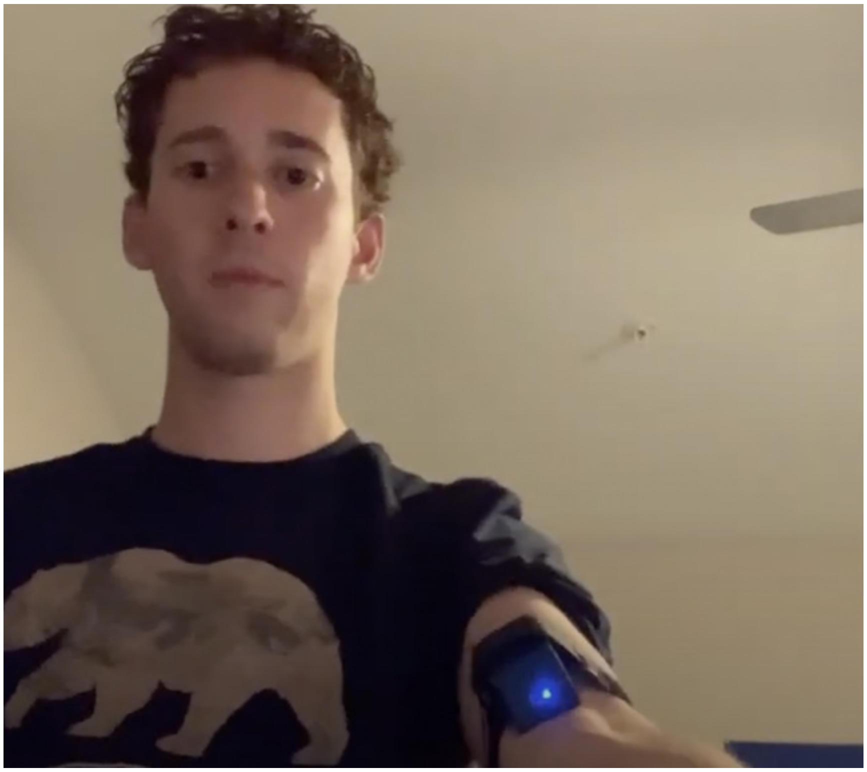


Figure 6. Device on the sample user, Ben, with the device on the arm working using a battery and bluetooth.

Figure 6 shows a screenshot captured from the demonstration video that displays the working device on Ben's arm. The device is fully powered by the battery and can be charged using the ports on the side. The strap secures the device in the area that is desired to be measured (in this case the bicep but it can support measurement as long as there are blood vessels, such as the finger).

Testing Results to V & V Plan

Enclosure Impact Testing

Several modifications were made to the testing plan to accommodate for the resources we had at our disposal. Firstly, it was difficult to procure a ball that had a mass of exactly 0.5 kg, so we combined objects together to create one with a final weight of 0.5 kg. This object is a combination of two rolls of tape, shown below in Figure 7.

Figure 7. Droppable makeshift 500g weight.

Additionally, to simulate the wearing of the device, the enclosure was placed on the band and then wrapped around a foam cylinder with a 3 inch diameter. This arrangement is shown in Figure 8.

Figure 8. Device arrangement for impact testing.

Impact testing was moderately successful. The average success rate was 91.7% with a standard deviation of 11.8%. This means that the device will survive 91.7% of impacts that produce an impulse similar to that of a 500g object impacting the enclosure from 1.3m above the enclosure. One thing to note is that all failures occurred when the weight was dropped onto the side of the enclosure with the greater surface area (the longer side). This may be due to the greater degree of flexing the longer surface will experience upon impact. The confidence interval is (80.0%, 103%), which exceeds the marginal value of 80% success, but barely encapsulates the ideal value of 100% success. The raw data will be included in Appendix D.

<u>Battery Testing</u>

The batteries implemented in the final design were 500 mAh. The specification for battery life desired at least a 50 % battery life after 4 days or 96 hours. To test the current draw from the battery when plugged into the Adafruit nrf52840 Sense microcontroller, a multimeter was connected to the ground and the 3.7 voltage output to determine the current draw out of the battery. This current draw allowed calculation of the estimated battery life. To meet the ideal specification, the current draw would need to be less than 2.6 mA. After 10 Trials of measuring the current draw as observed in Table 1, the average current draw was 60.87 μA. Extrapolating the mean current draw of 0.06087 mA, the wearable would reach a battery life of 50 % after 4 days. Figure 9 illustrates the measured current draw from the Lipo battery.

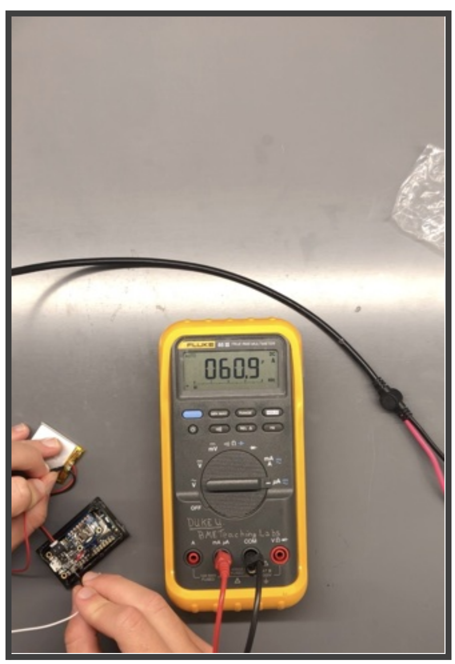


Figure 9. Measuring Framework for Battery Life Testing

Table 1. Current Draw from LiPo Battery during Wearable Operation

Trial	Current Draw (μA)
1	60.9
2	60.8
3	60.9
4	60.9
5	60.9
6	60.8
7	60.9
8	60.9
9	60.8
10	60.9
Average	60.87
Standard Deviation	0.048

The team recognized this would result in a battery life of hundreds of days. Therefore, the testing was redone with a separate multimeter. The second multimeter in Figure 10 illustrates a current draw of 0.097 A for the first measurement. This would result in a battery life of slightly more than 2 hours. This is significantly less than the design specification our team set out to achieve. Additional testing should be performed with the device being fully charged and then left on as long as possible to have a more realistic sense of the battery life of the 500 mAh battery.

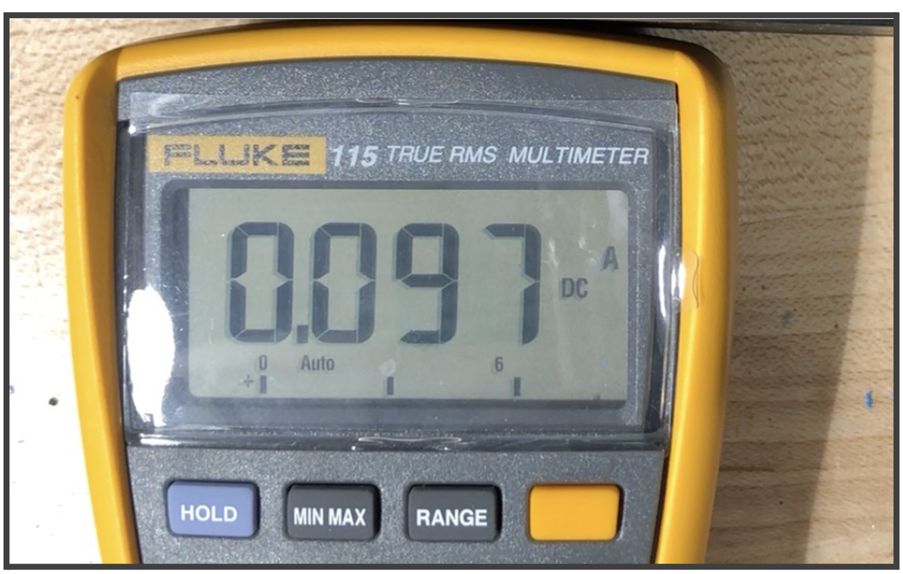


Figure 10. The Current Draw of the Lipo Battery

Compatibility Testing

The compatibility of the novel wearable with the existing internal temperature sensor wearable was investigated by coding an Adafruit Feather ItsyBitsy. The ItsyBitsy featured an nrf52840 chip that resembles that on the existing wearable temperature sensor. Therefore, a binary test was performed by running the novel wearable as a peripheral and the ItsyBitsy as a dual role central and peripheral. Then, if the data was plotted from the ItsyBitsy to the Bluefruit connect app, a binary successful rating was provided. Each trail started with both devices powered off. The Battery was inserted into the novel wearable and the ItsyBitsy was connected to a computer power source. The ItsyBitsy was connected to the Bluefruit connect app to identify the plotted PPG data. The boards were then both powered off. For the compatibility testing, all five trials conducted were successful. Therefore, the current board is compatible with the existing wearable and can provide information to a separate microcontroller with an nrf52840 chip.

Cost Testing

In order to hit our marginal value for the low-cost specification, we summed up the total market price of the raw materials needed to construct our device. The specification for low-cost stays the same, but we would like to add some nuance to the measurement of cost of our device. We are aiming for the sum of all the components to manufacture the device to be under $100.00 for the ideal value and under $300.00 for the marginal value. It is hard to find statistical tests for how we meet the specification because the test is binary: pass or fail. It is also possible to model total cost based on the market's fluctuation. In short, we summed up the cost of our parts and attached a plus or minus depending on the market analysis, and we will compare the total to the ideal and marginal values for a pass or fail. We took our testing and cost values from the LBM documentation referenced below. With the sum of the processes adding to $120.78 ± 12.00, our final device does pass the marginal value specification of being low cost. Unless overwhelming adjustments such as high market price for labor or extremely high raw materials to the costs would be unreasonable for the cost of our device.

PPG Accuracy Testing

The accuracy of the PPG sensor was quantified through comparison with the Polar H10 Heart Rate Sensor. For each trial, a subject would first place the Polar H10 Heart Rate Sensor around their torso. Subsequently, the subject would place the novel bicep wearable around their bicep. The subject would then either walk for one minute or jog up and down the hallways for one minute. The subject would then stop and the first ten heart rate readings would be recorded for the individual. These ten readings would be averaged to make up a single data point. Ten walking and jogging trials were conducted. Additionally, ten walking and jogging trials were conducted where the novel wearable device was not on the patient during movement and used to record heart rate at the fingertip following the minute of movement. All averages for each of the 10 trials may be observed in Table 2. Figure 11 depicts the wearable device sensing data at the fingertip and bicep. Additionally, Figure 12 demonstrates example signals from the wearable device at the finger and bicep respectively.

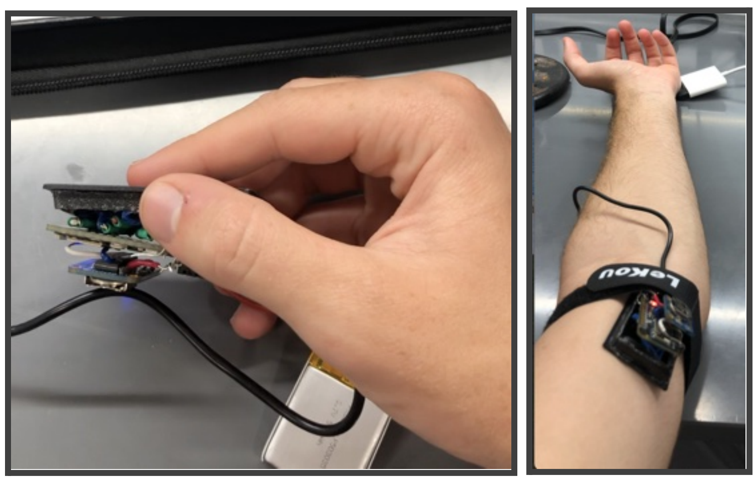


Figure 11. The Setup of the Novel Wearable Device Sensing at the Fingertip and Bicep

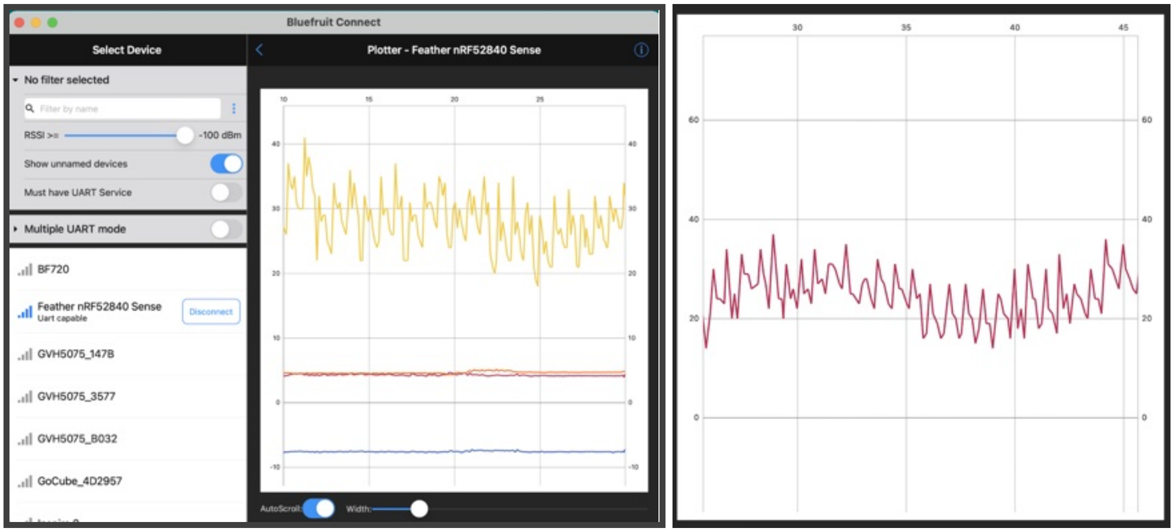


Figure 12. Example PPG Data Collected at the Fingertip and Bicep

The ideal specification for the heart rate functionality of the device is to achieve a heart rate signal mean within the 95 % confidence interval of the Polar H10 Heart Rate Sensor. The 95 % confidence interval for the Polar H10 Sensor during walking and jogging was identified as 81.3 ± 4.9 bpm and 111.7 ± 16.0 bpm. The novel wearable device demonstrated mean walking heart rates of 85.9 bpm and 95.2 bpm at the finger tip and bicep respectively. Therefore, the specification was met when the device is measuring PPG signal at the fingertip, but the specification was not met when the device was measuring data at the bicep. The novel wearable device demonstrated mean jogging heart rates of 100.6 bpm and 82.8 bpm at the finger tip and bicep respectively. Similarly, the wearable device met the functional spec at the fingertip but was not accurate at the bicep. The heart rate mean decreased, demonstrating the lack of reliable signal being obtained at the bicep.

Additional statistical analysis was performed using a paired t-test. After confirming normality and equality of variances with the Shapiro-Wilks and Levene's tests, significant differences between the data were investigated. Significant differences were observed between the walking and jogging data sets of the wearable at the bicep and the Polar H10. This further supports the identification that the wearable device is accurate with a reliable signal at the fingertip, but the device is unable to obtain a signal reliably at the bicep. All statistical analyses were conducted in Microsoft Excel using the Real Statistics Macro.

Table 2. Raw Heart Rate Averages from Specification V&V Testing

	Polar H10 HR (bpm)		Novel Wearable HR at Fingertip (bpm)		Novel Wearable HR at Bicep	
Trial	Walking (1 min)	Jogging (1 min)	Walking (1 min)	Jogging (1 min)	Walking (1 min)	Jogging (1 min)
1	81	105	82	110	93	35
2	78	99	93	128	82	82
3	82	115	106	95	93	93
4	81	109	74	65	93	149
5	85	106	93	102	105	106
6	79	110	67	104	149	82
7	85	123	82	93	106	67
8	83	117	82	119	82	41
9	79	124	74	102	67	67
10	80	109	106	88	82	106
Mean	81.3	111.7	85.9	100.6	95.2	82.8
Standard Deviation	2.5	8.0	13.3	17.3	22.2	33.5

FMEA

After careful consideration, the following risks were deemed the most significant for the user: the risk of electrocution, the band falling off, the band being too tight, water seeping into the device, the battery exploding, and the device being paired to the wrong receiver. Each risk was scored in Appendix A1 to quantify the risk index and corresponding acceptability of the risk. The mitigation plan for each risk may be observed in Appendix A2.

Band Tightness

The two outstanding failure modes include the risk of the bicep band being too tight and the risk of electrocution. The risk of the bicep band being too tight received a risk index of 9, which falls in the undesirable range. Several factors may play a role in the band being too tight, such as the band fit not being optimized for a wide range of bicep diameters and the band material stiffening after repeated stress. A tight band poses health risks to the user, ranging from slight discomfort to loss of circulation at the arm. Due to the limited fabrication methods and materials we have available, it is challenging to develop an ideal fit. Discomfort and loss of circulation are reversible effects and are thus slight annoyances, granting a severity level of III. One method to help mitigate this risk is to develop a different size band for each range of bicep diameters. Another method to address this risk earlier in the product development pipeline is to further research existing one-size-fits-all bands used in wearables already on the market and borrow their techniques. The current prototype implements a band that is adjustable velcro to minimize undesired band tightness.

<u>Electrocution</u>

The risk of electrocution received a risk index of 10. Because we are only dealing with data recording and transmission, it is unlikely that a significant amount of electrical current will be discharged due to failure. In the worst-case-scenario, a large electrical discharge could cause the burning of skin, which may be irreversible and leave scarring. Mitigation efforts will include ensuring proper electrical insulation of the internal components from the outer housing, checking all connections for unintentional short-circuits, and programming current/voltage monitoring so that the microcontroller can force-quit if abnormal levels of current draw are detected. The current device implements heat shrink to minimize exposed wires and connections. Additionally, the enclosure is tightly secured around the PPG sensor to avoid internal components contacting the user.

The following failure modes are worth noting despite not being one of the two most pressing concerns.

<u>Explosion</u>

Explosion of the wearable device is the most extreme failure a user would experience. Explosion may occur if the integrity of the circuitry was destroyed or if the device was subject to extreme temperature. At extreme temperatures, the Lipo battery would be the most likely component to smoke, catch fire, or explode. Fortunately, the complete explosion of the wearable is unlikely in everyday use. Explosion was assigned a severity of I and is improbable; therefore, the risk index was identified as 12. In addition to the necessary quality assurance review, our team plans to mitigate potential for explosion by ensuring there are warning labels for the user indicating to avoid using the device at extreme temperature. We also maintain circuit integrity and safety by applying heat shrink to soldered connections. Finally, we hope to investigate code blocks that would shut down the device at the microcontroller should the battery exhibit erratic power distribution. Nonetheless, the battery could still explode; therefore warnings and safety instructions will be detailed for consumers.

Water Damage

The wearable device may also experience water damage from its interaction with its constant interaction with the environment. Profuse sweat, water, or any excess amount of liquid coming in contact with the electrical components may result in permanent damage to the device and render it unusable. While the probability of water damage is categorized as occasional, the user should not experience any pain. The mild discomfort of having the damaged wearable attached to the bicep nets a severity level III. With the probability of occurrence as occasional and severity level III, the water damage is identified as 11. Water damage likely only alters the device functionality and the design is acceptable after quality assurance. Keeping this failure mode in mind; however, it is possible to mitigate the frequency of this failure mode. The physical casing of the electrical components can be altered to include internal channels that guide any incoming water outside the device. This design would require extra CAD modification for effective use. Another implementable design is to use water resistant material for some of the outer casing of the wearable. Water resistant polymers such as polyethylene or polystyrene could be used to seal the device, thereby completely minimizing the effects of excess liquid. Both options are feasible and effective in handling potential water damage hazards. Such modifications may be implemented in future iterations.

Band Removal

The band falling off would result in no data being recorded, and the device may fall to the ground and break. Depending on how the user implements the device, the movements can cause the band to slip off the length of the arm causing the device to come loose and hit the nearest low point around. Another cause of failure could be in the band itself breaking due to multiple different reasons including: bicep flex circumference is past the elastic limit of the band, poor band construction, and day to day wear and tear. Because the band coming off the arm could potentially fly into a bystander or even the wearer, there is a possibility of inconvenience in the form of bruises, surface lacerations, and in very very rare cases, minor head trauma. Nonetheless, the issue can pass risk analysis as long as there is review. Ideas to help mitigate the problem are as follows: introduce a rubber liner that can catch the device against the skin as it begins to slip. By doing so, this can act as a preventative measure to ensure the band does not slip off the length of the arm. Second, if the device does come off, there would be an insulated bungee wire that would clip on to another place or clothing item to ensure that if the device falls off, it will not smash on the ground and break. A third more complicated idea is to use a version of an automated garrote to self tighten the band to a certain degree before shutting off. An issue with this solution is the addition of several more risks that could occur including but not limited to over tightening to the point of amputation, garrote device failure that makes the band impossible to remove. The final design implements a velcro strap that would stick to itself upon failure. The absence of elastic character in the velcro prevents damage from the band as a projectile.

LBM

Burdened Labor Rate:	$ 40.00	*per hour*				
Process Step	*Material*	Quantity	Cost at Full Scale	*# of people*	*Duration of Task (hrs)*	*Cost*
3D-printing the enclosure	PLA printer filament (grams)	25	$ 0.02	1	0.5	$ 20.50
PCB Milling	Copper & etc	1	$ 20.00	1	0	$ 20.00
Assembly of internal components	Injection molding plastics (grams)	5	$ 0.05	1	0.5	$ 20.25
Microcontroller	Adafruit nRF52840 Feather Sense	1	$ 37.50	0	0	$ 37.50
PPG	Maxim integrated PPG sensor module	1	$ 7.83	0	0	$ 7.83
RTC	DS3231 RTC Module	1	$ 13.95	0	0	$ 13.95
Band	Lekou loop and cable straps	1	$ 0.75	0	0	$ 0.75
Assembly of entire device	Assembled enclosure with integrated components inside	1	$ -	1	0.5	$ 20.00
TOTAL						**$ 120.78**

Above is the table for the estimated LBM for the entire manufacturing of the device. In addition to the raw materials for the device, there is included PCB milling, injection molding, assembly, and even 3D printing of the enclosure. In total, the overall cost would be around $120.

Regulation Discussion

The wearable device in question claims to provide raw PPG data, raw accelerometer data, and a heart rate quantity to an existing wearable. No part of these claims attempts to diagnose disease as the information is merely being provided. Any potential diagnosis would be at the discretion of user interpretation. Additionally, the device does not alter the structure or function of the “body of man.” Therefore, our device does not meet the criteria detailed by the FDA for a medical device. We understand that the distinction between wearable devices and medical devices is obscure. In our product, we have also considered the existing temperature sensor module. This module is also capable of sensing information and providing this to the user. In the current state of the device, no diagnostic information is provided beyond the formatted data. Therefore, the total wearable is not deemed a medical device.

According to the FDA, a predicate device is defined as “a legally marketed device to which equivalence is drawn” to our device with respect to “intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics”. While we do not consider our device a medical device and will not be seeking any approval through the FDA, we still value comparing our device with existing ones already on the market. There are several categories of devices that can be considered predicate to our device: pedometers, blood pressure pumps, sweat bands, “dumb” watches, and smart watches. Pedometers and blood pressure pumps are examples of primitive forms of human bio-information gatherers. For a pedometer, a small lever inside the device acts as a sensor to track up and down motion at the hips. Sphygmomanometers use an inflatable cuff, pump, and a mercury scale that are used in conjunction to manually measure the systolic and diastolic pressure. While pedometers and blood pressure systems might not necessarily diagnose or treat the users of any particular disease, they do allow users to gain more data about their health through their device mechanisms. Similarly, our wearable device is an advanced form of the former devices. Sweat bands are comparable to our device because both are/can be worn around the bicep and must have a snug enough fit to ensure they neither slip off the bicep nor constrict circulation and cause discomfort to the wearer. “Dumb” watches are comparable to our device because they are worn on the arm and display useful information. Smart watches are comparable to our device because they are worn on the arm and can measure and display useful information about our short-term health.

All research was conducted using FDA Code of Federal Regulations and FDA Device Database. The device we are designing is a PPG that is intended for non-medical use only. We would refer to Title 21 CFR xxx.9 where xxx is parts 862-892 to determine if our device falls under the purview of the FDA in terms of regulation. Since our device is not intended for medical use, Title 21 Chapter H referring to medical devices does not apply. As of now, the FDA lists a PPG as an unclassified device which means that only a premarket review would be required prior to market release if a premarket review has not been submitted under exemption section CFR 807.85. The PPG is listed under product code QOA and falls under the purview of the Office of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A). Here it would go through regulatory review and after approval be allowed on the market. However, if we had classified the device as a medical device, it would fall under Title 21 CFR 890.5360 which is titled Measuring exercise equipment. Here the PPG wearable device would be classified as a class II (special controls) device which is not exempt from premarket notification as outlined by Title 21 CFR 807.85 as it is a custom device NOT being used by a physician with named patients. Here a premarket notification would go through regulatory review and then pushed into market if a 510(k) is deemed unnecessary.

Ethics and Design Considerations

An important design consideration is the influence of the wearable device on the mental state of the public. It is paramount to market the device without false claims. Any misinformation may develop a false sense of security within the community. Subsequently, individuals may remain in hot environments longer than expected if the device does not promote them to go indoors. Within medical ethics, there exists the principle of nonmaleficence. Therefore, it is a priority to ensure the device is brought to market only following rigorous testing.

An important economic consideration is who will take on the financial burden. In the case of the wearable device, it is most likely that teams, school districts, and sponsor organizations would provide funds to supply teams with the device. However, there is also potential for an individual consumer market. However, at a price point nearing one-hundred dollars, it is not a device that can readily be purchased by everyone. Considering who will fund the consumers buying the device, it is apparent that socioeconomic status would prevent someone from obtaining a device. With novel, expensive medical technology, an important consideration is not creating cultural segregation due to the device. For example, the iPhone initially represented a form of status due to the luxurious nature of the product. It would be important to work with organizations and school districts to make the product affordable and accessible to all in need. Similarly, the problem of heat stroke and elevated internal body temperature may vary geographically based on climate. However, certain regions of the world that are less resourceful may not be able to access the product as readily. A consideration with high priority is making the device easy to ship and package to be affordable and readily distributed to global populations.

An important environmental consideration is the implementation of heavy metals in the form of a wire. If the device is improperly disposed of, the metals would pollute the environment. Additionally, the presence of a lithium polymer battery raises the concern for hazard should the device be disposed of without care. The Lipo battery could overheat, explode, or start a fire in certain cases. Therefore, this may be a concern worth noting on the west coast of the United States or other areas susceptible to wildfires. Furthermore, the presence of a Lipo battery complicates the distribution of the device. If mass quantities of the device are shipped globally, the Lipo batteries may require some form of pressurization for shipment. This could raise the cost burden of the device when considering spreading the device into the global market.

From product design ethics to environmental awareness, all of these considerations have significant implications if they are improperly addressed. Throughout the designing and prototyping processes of our final device, we have carefully discussed these issues and attempted to mitigate them to the best of our ability.

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Appendix

Appendix A1 - FMEA Risk Index Scoring

	Potential Failure Mode	Cause(s)	Effect(s)	Probability of Occurance	Severity (Catastrophic	Risk Index
1	Electrocution	Faulty insulation between internals and housing, improperly regulated voltage/current, wiring/soldering errors, unintentional short circuits	Ranges from slight discomfort (stinging/pinching sensation) to burns	Remote	Severity II	10
2	Band falls off	Vigorous movement can cause the band to slip/The bicep flex volume is past the allowable elastic limit of the band/Wear and tear/Poor quality control	Device no longer measures anything/the device falls and breaks	Remote	Severity III	14
3	Water damage	If the user is sweating heavily, there is a potential for the sweat to seep into the internal compartment housing the electronics	Damaged Circuit or Electrical Components, Potential for device breaking	Occasional	Severity III	11
4	Battery explodes	Heat, broken device, improper wiring, build up of gas/heat in closed enclosure	Shrapnel, burns, law suits,	Improbable	Severity I	12
5	Band is too tight	Band is not one-size-fits-all, elasticity of the material is not ideal, the material hardens after repeated stress	Circulation being cut-off, loss of sensation, constant discomfort, obstruction of mobility	Probable	Severity III	9
6	Bluetooth Pairs to Wrong Device	Poor bluetooth code structure, crowded number of bluetooth devices in area	Data leak, frustration with user	Occaisional	Severity III	11
7	Low Quality PPG Signal	Improper skin contact, insufficient hardware, movement artifacts	Uninterpretable data, inaccurate readings	Occasional	Severity III	11
8	Insufficient Impact Resistance	Poor material quality of enclosure, stress concentration points on enclosure, weak seal between base and top of enclosure	Improperly functioning device/not working at all	Remote	Severity III	14

Appendix A2 - FMEA Risk Mitigation Plan

	Potential Failure Mode	Risk Index	Acceptable?	Mitigation Plan
1	Electrocution	10	(Borderline) acceptable upon completion of quality assurance review	Proper electrical insulation, checking for unintentional short circuits, high-current draw detection software
2	Band falls off	14	Acceptable upon Quality Assurance Review	Use a safety clip that acts as a catch mechanism/use different liner material for better surface to skin adhesion
3	Water damage	11	Acceptable upon Quality Assurance Review	Water channels to guide water away from components/ water resistant polymer seal
4	Battery explodes	12	Acceptable upon Quality Assurance Review	Ensure not loose wires or soldered connections. Use heat shrink. Consider code block to prevent device functionality if battery supply is erratic.
5	Band is too tight	9	Undesirable	Make a small, medium, and large size band to fit a wider range of bicep diameters. Look into what existing wearables have done
6	Bluetooth Pairs to Wrong Device	11	Acceptable upon Quality Assurance Review	Provide Code to nt search for new bluetooth connections unless a pairing button is pressed. This should minimize random disconnections.
7	Poor Signal	11	Acceptable upon Quality Assurance Review	Improve skin contact with optimized enclosure design, optimize electrical hardware onboard the PPG sensor to remove sufficient noise, write software to either account for movement or negate data during movement
8	Insufficient Impact Resistance	14	Acceptable upon Quality Assurance Review	Create grooves on the inside of the enclosure to which electrical components can be attached and secured better, Consolidate all components onto one PCB

Appendix B - PPG/Heart Rate Sensor Accuracy Testing Example Statistical Analyses

T Test: Two Paired Samples								
SUMMARY			Alpha	0.05		Hyp Mean Diff	0	
Groups	*Count*	*Mean*	*Std Dev*	*Std Err*	*t*	*df*	*Cohen d*	*Effect r*
Walking (1 min)	10	81.3	2.45175674					
Walking (1 min)	10	85.9	13.31206637					
Difference	10	-4.6	13.15885844	4.16119641	-1.1054513	9	0.349574397	0.34575717
T TEST								
	p-value	*t-crit*	*lower*	*upper*	*sig*			
One Tail	0.1488189	1.833112933			no			
Two Tail	0.297637801	2.262157163	-14.01328026	4.81328026	no			

Appendix C - Final Code for Novel Wearable Device

The final code and videos of the functional final product may be found on in the git repository with <ssh> = git@github.com:achen1776/BME-474-Internal-Temperature-Team.git

The code may also bee noted below

```
/*********************************************************************
 This is an example for our nRF52 based Bluefruit LE modules

 Pick one up today in the adafruit shop!

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 please support Adafruit and open-source hardware by purchasing
 products from Adafruit!

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 All text above, and the splash screen below must be included in
 any redistribution
*********************************************************************/
#define VBATPIN A6
#include <bluefruit.h>
#include <Adafruit_LittleFS.h>
#include <InternalFileSystem.h>
#include <Adafruit_LSM6DS33.h>

#include <Wire.h>
#include <MAX30105.h>
#include "PeakDetection.h"
```

```
//// OLED libraries
#include <Adafruit_GFX.h>
MAX30105 particleSensor;

// BLE Service
BLEDfu  bledfu;  // OTA DFU service
BLEDis  bledis;  // device information
BLEUart bleuart; // uart over ble
BLEBas  blebas;  // battery

Adafruit_LSM6DS33 lsm6ds33; // accelerometer, gyroscope

float accel_x, accel_y, accel_z;


PeakDetection peakDetection; // create PeakDetection object
int prevBeat = 0;
// SPO2 variables
float average_red_AC = 0;
float average_IR_AC = 0;
float spo2 = 0;
byte x;
byte y;
byte z;
byte lastx;
byte lasty;
long baseValue = 0;
long lastMin=2200000;
long lastMax=0;
long rollingMin = 2200000;
long rollingMax=0;
int tcount = 0;
int beatCount = 0;
bool cleard = false;

//RTC globals
// Date and time functions using a DS3231 RTC connected via I2C and Wire lib
#include "RTClib.h"

RTC_DS3231 rtc;
```

```
char daysOfTheWeek[7][12] = {"Sunday", "Monday", "Tuesday", "Wednesday",
"Thursday", "Friday", "Saturday"};

void setup()
{
  Serial.begin(115200);

  lsm6ds33.begin_I2C(); // Initialize Acc Sensors

#if CFG_DEBUG
  // Blocking wait for connection when debug mode is enabled via IDE
  while ( !Serial ) yield();
#endif

  Serial.println("Bluefruit52 BLEUART Example");
  Serial.println("---------------------------\n");

  // Setup the BLE LED to be enabled on CONNECT
  // Note: This is actually the default behavior, but provided
  // here in case you want to control this LED manually via PIN 19
  Bluefruit.autoConnLed(true);

  // Config the peripheral connection with maximum bandwidth
  // more SRAM required by SoftDevice
  // Note: All config***() function must be called before begin()
  Bluefruit.configPrphBandwidth(BANDWIDTH_MAX);

  Bluefruit.begin();
  Bluefruit.setTxPower(4);    // Check bluefruit.h for supported values
  //Bluefruit.setName(getMcuUniqueID()); // useful testing with multiple central
connections
  Bluefruit.Periph.setConnectCallback(connect_callback);
  Bluefruit.Periph.setDisconnectCallback(disconnect_callback);

  // To be consistent OTA DFU should be added first if it exists
  bledfu.begin();

  // Configure and Start Device Information Service
  bledis.setManufacturer("Adafruit Industries");
```

```
  bledis.setModel("Bluefruit Feather52");
  bledis.begin();

  // Configure and Start BLE Uart Service
  bleuart.begin();

  // Start BLE Battery Service
  blebas.begin();
  blebas.write(50);

  // Set up and start advertising
  startAdv();

  Serial.println("Please use Adafruit's Bluefruit LE app to connect in UART mode");
  Serial.println("Once connected, enter character(s) that you wish to send");


  particleSensor.begin(Wire, I2C_SPEED_STANDARD);
  //Setup to sense a nice looking saw tooth on the plotter
  byte ledBrightness = 0x1F; //Options: 0=Off to 255=50mA
  byte sampleAverage = 8; //Options: 1, 2, 4, 8, 16, 32
  byte ledMode = 3; //Options: 1 = Red only, 2 = Red + IR, 3 = Red + IR + Green
  int sampleRate = 3200; //Options: 50, 100, 200, 400, 800, 1000, 1600, 3200
  int pulseWidth = 411; //Options: 69, 118, 215, 411
  int adcRange = 4096; //Options: 2048, 4096, 8192, 16384
  particleSensor.setup(ledBrightness, sampleAverage, ledMode, sampleRate,
pulseWidth, adcRange); //Configure sensor with these settings
  //Take an average of IR readings at power up; this allows us to center the plot on start
up

  const byte avgAmount = 30;
  long reading;
  for (byte x = 0 ; x < avgAmount ; x++){
    reading = particleSensor.getIR();
    // Find max IR reading in sample
    if (reading > lastMax){
      lastMax = reading;
    }
    // Find min IR reading in sample
    if (reading < lastMin){
```

```
    lastMin = reading;
   }
  }
  x = 0;
  y = 0;
  lastx = 0;
  lasty = 0;

  // Peak detection
  peakDetection.begin(6, 0.8, 0.6); // sets the lag, threshold and influence
  pinMode(LED_BUILTIN, OUTPUT);


/* #ifndef ESP8266
  while (!Serial); // wait for serial port to connect. Needed for native USB
#endif
*/
  if (! rtc.begin()) {
    Serial.println("Couldn't find RTC");
    Serial.flush();
    while (1) delay(10);
  }

  if (rtc.lostPower()) {
    Serial.println("RTC lost power, let's set the time!");
    // When time needs to be set on a new device, or after a power loss, the
    // following line sets the RTC to the date & time this sketch was compiled
    rtc.adjust(DateTime(F(__DATE__), F(__TIME__)));
    // This line sets the RTC with an explicit date & time, for example to set
    // January 21, 2014 at 3am you would call:
    // rtc.adjust(DateTime(2014, 1, 21, 3, 0, 0));
  }

  // When time needs to be re-set on a previously configured device, the
  // following line sets the RTC to the date & time this sketch was compiled
  // rtc.adjust(DateTime(F(__DATE__), F(__TIME__)));
  // This line sets the RTC with an explicit date & time, for example to set
  // January 21, 2014 at 3am you would call:
  // rtc.adjust(DateTime(2014, 1, 21, 3, 0, 0));
```

```
  blebas.write(20);
  delay(2000);

}

void startAdv(void)
{
  // Advertising packet

Bluefruit.Advertising.addFlags(BLE_GAP_ADV_FLAGS_LE_ONLY_GENERAL_DISC_
MODE);
  Bluefruit.Advertising.addTxPower();

  // Include bleuart 128-bit uuid
  Bluefruit.Advertising.addService(bleuart);

  // Secondary Scan Response packet (optional)
  // Since there is no room for 'Name' in Advertising packet
  Bluefruit.ScanResponse.addName();

  /* Start Advertising
   * - Enable auto advertising if disconnected
   * - Interval:  fast mode = 20 ms, slow mode = 152.5 ms
   * - Timeout for fast mode is 30 seconds
   * - Start(timeout) with timeout = 0 will advertise forever (until connected)
   *
   * For recommended advertising interval
   * https://developer.apple.com/library/content/qa/qa1931/_index.html
   */
  Bluefruit.Advertising.restartOnDisconnect(true);
  Bluefruit.Advertising.setInterval(32, 244);    // in unit of 0.625 ms
  Bluefruit.Advertising.setFastTimeout(30);      // number of seconds in fast mode
  Bluefruit.Advertising.start(0);                // 0 = Don't stop advertising after n seconds
}

float time1 = millis();
float time2 = 0.0;

void loop()
{
```

```
// Forward data from HW Serial to BLEUART
while (Serial.available())
{
  // Delay to wait for enough input, since we have a limited transmission buffer
  delay(2);

  uint8_t buf[64];
  int count = Serial.readBytes(buf, sizeof(buf));
  bleuart.write( buf, count );
}

// Forward from BLEUART to HW Serial
while ( bleuart.available() )
{
  uint8_t ch;
  ch = (uint8_t) bleuart.read();
  Serial.write(ch);
}

sensors_event_t accel;
sensors_event_t gyro;
sensors_event_t temp;

lsm6ds33.getEvent(&accel, &gyro, &temp);
accel_x = accel.acceleration.x;
accel_y = accel.acceleration.y;
accel_z = accel.acceleration.z;

//bleuart.print("Acceleration: ");
bleuart.print(accel_x);
bleuart.print(",");
bleuart.print(accel_y);
bleuart.print(",");
bleuart.print(accel_z);
bleuart.print(",");
//bleuart.println(" m/s^2");


float measuredvbat = analogRead(VBATPIN);
measuredvbat *= 2;    // we divided by 2, so multiply back
```

```
  measuredvbat *= 3.3;  // Multiply by 3.3V, our reference voltage
  measuredvbat /= 1024; // convert to voltage
  //bleuart.print("VBat: " );
  float vbat_adjust = 0.73242188 * measuredvbat * 1000;
  float battery_percent = mvToPercent(vbat_adjust);

  //bleuart.print(measuredvbat);
  //bleuart.print(",");
  blebas.write(battery_percent);
  //bleuart.print(battery_percent);




  long irValue = particleSensor.getIR();
  if (irValue < 20000)
  {
   //50000
   //bleuart.print(",");
   bleuart.println(" No finger?");
   tcount = 0;
   beatCount = 0;
   cleard = false;
  }
  else
  {
   if(!cleard)
   {
    cleard = true;
   }

   //if has been reading for 20s, then report value
   int numSamples = 0;

    //SHOW PPG WHILE READING
    tcount++;
    // Display is only 128 pixels wide, so if we're add the end of the display, clear the
display and start back over
    if(x>127)
    {
```

```
  x=0;
  lastx=x;
}

// Even though we're keeping track of min/max on a rolling basis, periodically reset the min/max so we don't end up with a loss of waveform amplitude
if (z > 20)
{
  z = 0;
  lastMax = rollingMax;
  lastMin = rollingMin;
  rollingMin = 2200000;
  rollingMax = 0;
}

//Get data
long irValue = particleSensor.getIR();    // Read pulse ox sensor; since this is a pulse pleth, we're really only after the IR component
peakDetection.add(irValue); // adds a new data point
average_IR_AC += irValue;
long redValue = particleSensor.getRed();
average_red_AC += redValue;

//Count beats
int peak = peakDetection.getPeak(); // returns 0, 1 or -1
double filtered = peakDetection.getFilt(); // moving average
if( (prevBeat == 0 or prevBeat == -1) and (peak == 1) and (filtered > 10000) )
{
  beatCount++;
  digitalWrite(LED_BUILTIN, HIGH);
  if ((beatCount != 0) && (beatCount % 2 == 0))
  {
    time2 = millis();
    float timediff = time2 - time1;
    int heartRate = 2/timediff * 1000 * 60;
    Serial.println(heartRate);

    time2 = 0.0;
    time1 = millis();
  }
```

```
    }
    prevBeat = peak;
    digitalWrite(LED_BUILTIN, LOW);
    //Plot PPG
    int y=40-(map(irValue, lastMin, lastMax, 10, 25));   // Normalize the pleth waveform
against the rolling IR min/max to keep waveform centered
    //bleuart.print(",");
    bleuart.println(y);
    float raw = particleSensor.getIR();
    // Serial.println(raw);
    // Keep track of min/max IR readings to keep waveform centered
    if (irValue > rollingMax){
      rollingMax = irValue;
    }
    if (irValue < rollingMin){
      rollingMin = irValue;
    }
    // Keep track of this IR reading so we can draw a line from it on the next reading
    lasty=y;
    lastx=x;
    digitalWrite(LED_BUILTIN, LOW);
    x += 3; //scale x-axis
    z++;

   if( tcount >= numSamples )
    {
//       int hr = int(beatCount / 40.0 * 60);
//       Serial.print(beatCount);
//       Serial.print(",");
//       Serial.println(hr);
//       bleuart.print(",");
//       bleuart.print(hr);
      average_red_AC = average_red_AC / numSamples;
      average_IR_AC = average_IR_AC / numSamples;
      spo2 = average_red_AC/ average_IR_AC / 2.0; //dividing by 2 for calibration
purposes
      //exit(0);
    }
```

```
//    DateTime now = rtc.now();
//    bleuart.print(",");
//    bleuart.print(now.year(), DEC);
//    bleuart.print('/');
//    bleuart.print(now.month(), DEC);
//    bleuart.print('/');
//    bleuart.print(now.day(), DEC);
//    bleuart.print(" (");
//    bleuart.print(daysOfTheWeek[now.dayOfTheWeek()]);
//    bleuart.print(") ");
//    bleuart.print(now.hour(), DEC);
//    bleuart.print(':');
//    bleuart.print(now.minute(), DEC);
//    bleuart.print(':');
//    bleuart.println(now.second(), DEC);

  }
}

// callback invoked when central connects
void connect_callback(uint16_t conn_handle)
{
  // Get the reference to current connection
  BLEConnection* connection = Bluefruit.Connection(conn_handle);

  char central_name[32] = { 0 };
  connection->getPeerName(central_name, sizeof(central_name));

  Serial.print("Connected to ");
  Serial.println(central_name);
}

/**
 * Callback invoked when a connection is dropped
 * @param conn_handle connection where this event happens
 * @param reason is a BLE_HCI_STATUS_CODE which can be found in ble_hci.h
 */
void disconnect_callback(uint16_t conn_handle, uint8_t reason)
{
```

```
  (void) conn_handle;
  (void) reason;

  Serial.println();
  Serial.print("Disconnected, reason = 0x"); Serial.println(reason, HEX);
}


uint8_t mvToPercent(float mvolts)
{
  uint8_t battery_level;

  if (mvolts >= 3000) {
    battery_level = 100;
  } else if (mvolts > 2900) {
    battery_level = 100 - ((3000 - mvolts) * 58) / 100;
  } else if (mvolts > 2740) {
    battery_level = 42 - ((2900 - mvolts) * 24) / 160;
  } else if (mvolts > 2440) {
    battery_level = 18 - ((2740 - mvolts) * 12) / 300;
  } else if (mvolts > 2100) {
    battery_level = 6 - ((2440 - mvolts) * 6) / 340;
  } else {
    battery_level = 0;
  }

  //blebas.write(battery_level);
  return battery_level;

}
**********************************************************************
```

Appendix D - Raw Data and Analysis Calculations for Impact Testing

Trial	Side	Result	Percent Success	
1	Top	Success	0.8333333333	
1	Long Side 1	Fail	0.8333333333	
1	Long Side 2	Success	0.8333333333	
1	Short Side 1	Success	0.8333333333	
				0.8333333333

1	Short Side 2	Success	0.8333333333	
2	Top	Success	1	
2	Long Side 1	Success	1	
2	Long Side 2	Success	1	
2	Short Side 1	Success	1	
2	Short Side 2	Success	1	1
3	Top	Success	0.8333333333	
3	Long Side 1	Success	0.8333333333	
3	Long Side 2	Fail	0.8333333333	
3	Short Side 1	Success	0.8333333333	
3	Short Side 2	Success	0.8333333333	0.8333333333
4	Top	Success	1	
4	Long Side 1	Success	1	
4	Long Side 2	Success	1	
4	Short Side 1	Success	1	
4	Short Side 2	Success	1	1
5	Top	Success	0.8333333333	
5	Long Side 1	Success	0.8333333333	
5	Long Side 2	Fail	0.8333333333	
5	Short Side 1	Success	0.8333333333	
5	Short Side 2	Success	0.8333333333	0.8333333333
6	Top	Success	1	
6	Long Side 1	Success	1	
6	Long Side 2	Success	1	
6	Short Side 1	Success	1	
6	Short Side 2	Success	1	1
7	Top	Success	1	
7	Long Side 1	Success	1	
7	Long Side 2	Success	1	
7	Short Side 1	Success	1	
7	Short Side 2	Success	1	1
8	Top	Success	1	
8	Long Side 1	Success	1	
8	Long Side 2	Success	1	
8	Short Side 1	Success	1	

1

8	Short Side 2	Success	1	
9	Top	Success	0.6666666667	
9	Long Side 1	Fail	0.6666666667	
9	Long Side 2	Fail	0.6666666667	
9	Short Side 1	Success	0.6666666667	
9	Short Side 2	Success	0.6666666667	0.6666666667
10	Top	Success	1	
10	Long Side 1	Success	1	
10	Long Side 2	Success	1	
10	Short Side 1	Success	1	
10	Short Side 2	Success	1	1
			Std Dev	0.1178511302
			Mean	0.9166666667
			Mean - Std Dev	0.7988155365
			Mean + Std Dev	1.034517797