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ECG Monitoring in Athletes

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Abstract*— Athletes and medical personnel need reliable methods to monitor vital signs and detect potentially life-threatening issues before they occur. Electrocardiograph (ECG) monitoring is currently the best method of detecting heart-related health issues. Current ECG monitors worn by athletes are difficult to use and pose many functional issues. Through research and interviews with various clinicians, further problems have been identified which include poor electrode contact during athletic events, and a lack of compatibility with the equipment worn by athletes. Our design team proposes to develop solutions which will improve performance and comfort associated with ECG monitors for athletic applications.

Keywords—electrocardiogram, electrode, athlete

I. Introduction

A. Background

Heart disease is the leading cause of death in Americans. Each year 655,000 people [1], of which 2,500 are under the age of 25 [2] die from heart related conditions. The most common method of diagnosing heart conditions is with an ECG, or a test conducted to monitor the electrical activity of the heart. Corrective actions from an ECG diagnosis range from surgical procedures to making lifestyle changes [3]. An ECG test is usually done in a lab in which a technician places 12 passive, adhesive silver/silver chloride (Ag/AgCl) electrodes on a patient over the course of a few minutes after which the results are printed out. Another form of test, which is the focus of this project, is continuous remote ECG monitoring. In this test a long-term device like a Holter Monitor or Event Recorder is given to the patient to be used continuously for a predetermined amount of time (usually a week to a month). More data offers greater opportunities to catch a cardiac abnormality, giving a cardiologist the ability to make an accurate diagnosis. Early diagnosis is crucial for preventing long term medical conditions.

B. User Needs

While the practice of reading an ECG signal has been greatly improved over the past few decades, there are still downsides. The adhesive Ag/AgCl electrodes are not ideal for long term monitoring. This project focuses on improving ECG monitoring for athletes. Many collegiate athletes are forced to overcome perspiration and precipitation, both of which can cause passive electrodes to lose their adhesion. Many sports, like football, also have uniforms with large padding that often interfere with adhesive electrodes. All of these factors interfere with retrieving an ECG signal from an athlete during practice or a game. Since the heart is under more stress during exercise, it is important to collect the ECG information in this state to make a proper diagnosis. This data is critical because some disorders are more visible under this kind of stress. Cardiologists and sports medicine directors require a device that athletes can wear when exercising that will not inhibit the athlete's ability to perform but will still gather critical information to detect irregular heart rhythms. This device will need to be sweat resistant, and compatible with uniforms and other equipment.

C. Competitive Products

Currently, sports directors and college athletes use cardiac monitoring devices that are not ideal. One major competitor is KardiaMobile made by ActiveCor. This device is a small metal bar that the patient touches with their pointer fingers which acquires an ECG and sends a report to an app on a phone. The downside is that KardiaMobile only works when the user is in direct contact with the bar. This device only conducts 30 second readings, so if the device does not pick up the cardiac episode in that time, the patient will have to try again. Another device frequently used by collegiate athletes is the Body Guardian® made by Boston Scientific. This is an adhesive device that is placed on the chest of the patient. The Body Guardian® suffers from the same adhesive issues as the passive electrodes, where

sweat and other athletic factors cause the device to fall off. This device does offer live remote recording, however, the patient needs to have a cell phone on them which is not possible for an athlete during a game or practice.

II. Methodology

A. User Needs

The first gate, User Needs, began on August 24, 2020 and ended on September 28, 2020. The primary purpose of this gate was to determine a clinical need that will be solved through background and patent research, interviews, and the development of user needs. The initial research conducted allowed us to understand the cardiac devices commonly used to treat different cardiovascular conditions. From here, each member of our group reached out to their personal connections to plan and conduct multiple interviews.

The first interviewee was Dr. Shaub, a cardiologist at Summa Health. He works with all of the athletes at The University of Akron that have heart conditions. Sharing his professional opinion, he expressed that the devices that are currently used to monitor the heart are not as beneficial as they could be. The main issues with current ECG devices include comfortability, lack of sustainable contact with the body, and difficulties detecting usable data that is uninterrupted by noise and motion. Another interview that provided more insight for our clinical need statement was with Bill Droddy, the Director of Sports Medicine at the University of Akron. The improvements he suggested based on his first-hand experiences were to create a device that is resistant to sweat, durable for contact sports, and can transmit a signal up to 120 yards. Taking the results from the interviews and the information found from further research into consideration, our group came up with a user need statement: medical professionals require a more accurate way to monitor the heart signals of young athletes that can withstand perspiration during physical activity. Our interviewees suggested that better electrode adhesion and better integration into the uniforms would decrease motion artifact. The following user needs were then developed: better electrode adhesion, longer transmission distance, better electrode comfort, electrode integration into different outfits and uniforms, and wireless device.

B. Design Inputs

The second gate termed Design Inputs, as labeled by the Food and Drug Administration (FDA) Medical Device Design Process diagram, began on October 5, 2020, culminating on November 2, 2020. The purpose of this gate was to translate user needs from gate one into engineering requirements. A Quality Functional Deployment (QFD) phase 1 was performed in this gate to rank the effectiveness of pre-existing products and procedures in meeting the engineering requirements. A key accomplishment achieved in this phase was acknowledgment of the importance that device integration played into our engineering and user needs. A device that can be worn, and accurately functions, in a myriad of sports is crucial for both the manufacturer and the customer. The QFD also emphasized the importance of improved electrode contact, compared to current devices on the market. This was a chief complaint from our gate one analysis, and has remained throughout the course of this project. During gate two, one of our engineering requirements was an adhesion metric of 0.56 N/m with the skin. This metric, along with a transmission distance of 120 yards through wireless transmission technology, were relevant during this stage in the design process. However, in later these requirements were deemed to be not feasible due to lack of time, funds and experience.

A preliminary risk assessment was performed in this gate of our project to identify any hazards or potential failure mechanisms prior to designing. At this stage in the medical device design process, the engineering requirement of cardiac data being transmitted 120 yards was still within the scope of our project.. Combining a relative lack of electrical engineering experience with transmission difficulties, the risk for hazard was deemed too great. As a result of our risk assessment using Failure Modes and Effects Analysis (FMEA), it was determined that achieving a transmission distance of at least 120 yards would most likely cause risks that would not outweigh the benefits. A second major alteration in our proposed design which originated from our risk assessment was the use of adhesive electrodes in our ECG monitor. Through our FMEA, it was determined that moisture, whether it originates from sweat or precipitation, could decrease the adhesion of a passive electrode to the skin. Current electrodes used on the market are passive, adhesive electrodes that require a conductive gel in order to transmit electrical signals. As a result of this potential failure mode, active electrodes were researched and selected for our design because they do not require adhesive elements.

As seen in Figure 1, the QFD for gate two assists in deriving engineering requirements from customer needs/requirements. Solutions to customer needs are analyzed and then ranked based upon their level of adequacy in meeting the engineering requirements. Competitive devices are also analyzed on the same diagram in an effort to illustrate the positive and negative aspects of existing products. For gate two, our competitive devices analyzed were Body Guardian, CardioMobile, and the Apple Watch.

C. Design Process

The third gate, Design Process, started on November 9, 2020 and concluded on November 30, 2020. The primary objective of this gate was to assess the engineering requirements derived in the second gate and develop design concepts. A brainstorming technique termed method 365 was used to brainstorm ideas for electrode material, number of electrodes, shape of wearable device, material of device, and integration of electrodes into device. The options for electrode material determined were silver coated nylon, stainless steel wire and copper wire. Two or three lead electrode configurations were derived as the options for the number of electrodes. The possible device shapes were a belt, double sash or vest. The possible materials of the wearable device could be Under Armour, polyester or spandex. The two ways determined for integrating the electrodes into the device were removable electrode pads or stitching the electrodes directly into the device. These options were evaluated using a phase two QFD by ranking each of them based on their ability to meet the engineering requirements derived previously.

A second phase risk assessment using an FMEA was also conducted during this gate. Specifically, a design FMEA was created which was used to evaluate the design approach being considered and improve the design, if needed. In this phase of the FMEA, the five design concepts were evaluated. Potential failure modes were identified for each concept and mitigations were proposed for those failures that weren't deemed acceptable. The second phase of the QFD and the design FMEA allowed preliminary specifications of the device to be solidified. These specifications include using silver coated nylon as the electrode material, a three lead electrode configuration, a vest shape, 90% polyester and 10% spandex as the material of the device and the electrodes to be integrated by stitching them directly into the material of the device.

D. Design Outputs

The fourth gate of this project began on January 11, 2021 and ended on February 15, 2021. The major goal of this gate was to evaluate the design outputs of the device and perform verification studies. During this gate many objectives were accomplished including: developing device specifications, creating a Three Dimensional (3D) model and corresponding drawings, determining a Bill of Materials (BOM), analytical modeling, verification, updating the FMEA, and creating a validation plan. The early alpha prototype was also developed, based on the available resources.

A small portion of the QFD was used to evaluate choices for component purchase. The three components used in this design that were evaluated consisted of the sports bra, conductive thread and ECG system. The most important requirements considered when searching for a sports bra to purchase included the material of the bra, the shape of the bra, water resistance, and elasticity. A bra that was made of polyester and spandex was desired as polyester is naturally hydrophobic. The bra had to be loose enough to ensure optimal comfort for the user, but not too restrictive that it would inhibit their movement. A simple shape was desired to ensure simplicity of the integration of the electrodes. The conductive thread required a decision matrix to compare the conductivity, resistivity and material of thread to optimize measurement of electrical activity being recorded. The components of the ECG system considered in the decision matrix were electrode configuration, weight and data storage. The system had to be compatible with a two lead electrode system as that is the configuration used in this device. An important aspect of the design is the device weight, so it does not hinder athletic performance.

SolidWorks software was used to create a virtual model of the device. For each individual part, a 3D model and corresponding drawing was created. These models provide insight into how the device should be assembled. The full assembly can be seen in Figure 2. Drawings as seen in Figure 3, show how components are to be assembled, i.e. four electrodes need to be sewn into a sports bra using regular thread following the given dimensions. Instruction for silver conductive thread show that it needs to be sewn into a cotton patch with a male snap connector sewed into the back to create the electrode subassembly seen in Figure 4. The Wellue can be connected to the sports bra device using the female snap connectors that come with the device.

Developing a BOM required determination of major components of the device, raw materials to be purchased, and components to be purchased from vendors. Raw materials for this device include silver conductive thread and cotton fabric. These materials have to be manipulated to become the needed component. Components, such as the Wellue monitor, could be purchased from a vendor without making alterations. Part and Assembly identification numbers were created as assigned during this gate. The final BOM can be seen in Table A6.

III. Design Results

A. Design Verification

Verification tests were used to confirm design outputs met design inputs. The device weight was verified to be 1.29 pounds, which falls into the acceptable range (0.7-1.3 lbs.). This weight was calculated by finding the sum of all the parts used to create the electrodes and device. The weights of each component were provided by each individual vendor. One of the most critical engineering requirements to be verified during this stage was the location of the electrodes on the sports bra design. These electrodes had to be placed in a specific orientation in order to correctly obtain accurate electrical activity of the heart, while simultaneously being lodged in the polyester material of the sports bra. The location of the electrodes lies 3 inches from the center of the ribcage. Anatomically speaking, referencing the body of the sternum as a midpoint, each electrode lies 3 inches horizontally adjacent to that point. Vertically speaking, the electrodes lie on the midclavicular line exactly 8 inches from one another. This orientation ensures that the electrodes are able to be sewn into the sports bra, while simultaneously providing an accurate image of the electrical activity of the heart. The engineering requirement of hydrophobicity of the conductive thread was tested by submerging the thread in water. Five 12-inch segments of thread were cut and massed. Next, the pieces of thread were submerged in water and their weights were re-evaluated. The difference in weights ranged from 5.35%-6.93%, with each of the five segments of thread remaining inside specification. The resistivity of the thread passes verification, as the vendor has included its resistive properties. The results from verification testing can be seen in Tables A1 and A2 in the appendix.

B. Medical Device

The fifth and final gate termed Medical Device, began on February 15, 2021 and ended on April 26, 2021. The major goal of this gate was to assemble a beta prototype by utilizing the design outputs from gate four. Once the materials for constructing the active electrodes were acquired, the electrodes were assembled according to the design specifications. Next, the electrodes were incorporated into the sports bra. Finally, the wiring was run from the Wellue to the respective electrodes. A picture of the beta prototype can be seen in Figures 5 and 6. The beta prototype was then used to perform validation testing where the device was tested against user requirements in clinical simulation.

Another important part of the Medical Device stage was the Risk Mitigation Summary. This document allowed the group to categorize all risks related to the final device. Once the risks were ranked, the group summarized how each risk was mitigated. An example of a residual risk that remained after risk mitigation activities is the operational temperature limitations. The device is currently rated to operate between 0-50 ℃. The lower limit of this rating may not be adequate for collegiate sports in cold regions. In order to mitigate this risk in the future, the device will incorporate optional thermal insulation to be used in cold weather events. This document allowed the group to explain how the overall benefits of the device would outweigh the residual risks. This risk summary also laid out how risks will be reevaluated in the future upon receiving complaints from users. In conclusion, this document allowed the group to visualize how important it is to recognize risks throughout the design process so that the final product could be designed while accounting for potential risks while also creating a plan that addresses any residual risks that remained.

C. Validation Process

The overall goal for the validation process is to ensure that the user needs are met with this prototype. For each customer requirement there is one validation procedure performed, and the majority were conducted outside in an area where the user could run and perform different exercises according to their sport.

The first customer requirement was to see if the device can be integrated into athletic uniforms while still transmitting a readable signal. This test was run by having the user put on the wearable ECG device, then their uniform and necessary equipment and perform three different exercises according to their sport. For this test we used a soccer player, they put on their uniform and ran, juggled the soccer ball, and kicked the ball. The results of the analyzed data showed that the ECG device can provide clear data for an athlete when their respective uniform is worn.

The second customer requirement was to confirm the electrodes will remain intact, pressed to the skin, and will make a good connection with the device. This test was conducted by visually inspecting the electrodes of the device while on the user to confirm total surface area contact with the skin. The results showed that the electrodes are firmly pressed against the skin, without irritation, intact and make a strong connection to the device.

The third customer requirement was to ensure that the electrodes produce a readable signal and can monitor and send data to a phone wirelessly by sending effective data to the app on the smartphone. This test was carried out by first downloading the app “ViHealth” onto a smartphone and pairing the device. The user then put on the wearable device, uniform, and necessary equipment and performed three different exercises according to their sport. The data was recorded and the app was opened. The data can be seen in Figure 7. This test resulted in clear data being sent automatically to the app.

The fourth customer requirement tested was to determine if the thread is sweat/water resistant. The user put on the device and began to sprint. Data was recorded and was compared to a second set of data where the user performed an activity until a noticeable amount of perspiration resulted. This test resulted in effective data both before and after perspiring.

The fifth customer requirement was to ensure the motion/physical contact doesn’t cause the electrode to change in shape or fall off while the user is partaking in their designated sport. This test was performed by having the user put on the device and record data while doing three exercises according to their sport. After the soccer player ran and kicked a soccer ball the Wellue device was connected to the electrodes. This test failed because the motion from the athlete’s heavy breathing caused significant motion artifact resulting in unclear data.

The last customer requirement was to determine if the device provides optimal comfort to the user. The user put on the device and was asked on a scale of 1 to 10, 10 being extremely comfortable and 1 being extremely uncomfortable, how comfortable the device was. The test resulted in the user providing us with a score of 9. The validation plan and the results of each test can be seen in Tables A3 and A4 in the appendix, respectively.

IV. Risk Mitigation Process

Throughout the course of the project, risk was identified and mitigated through FMEA. This process analyzed the possible risks associated with each gate of our project, and assisted in brainstorming creative mitigation solutions, along with verification techniques for those mitigation solutions. The FMEA was altered slightly in gates three and four to focus on risks associated with the design of our ECG monitoring device. For this reason, the term dFMEA will be seen throughout our documentation to emphasize the risk assessment process associated with the design process itself. One of the largest risks that had to be mitigated throughout our design process was associated with transferring personal health information through wireless transmission modalities. This risk was tracked all the way back to gate one, with a user need for wireless transmission of technology. In gate two, this was created into an engineering requirement of a wireless transmission distance of 120 yards. Although a large risk with this engineering requirement was not initially apparent, potential harm became evident following research. One potential genesis of risk was the transferring of patient sensitive information over such a large distance. The Federal Communications Commission (FCC) has a large number of guidelines, which were deemed to be outside the scope of this project. In addition to difficulties from FCC regulations, the electrical wiring of the sports bra design caused a large problem with regards to moisture from precipitation and perspiration. If patient-sensitive information were to be transferred over such a large distance, electrical and Bluetooth wiring through the sports bra design would be extensive.

Through multiple mitigation methods, some risks with our final design are imminent. One of the largest risks with the current design of our ECG device is related to the product weight. With a weight of approximately 1.29 pounds, as verified through the testing stage, the ECG device may negatively hinder their athletic performance. Many athletic clothing manufacturers aim to create clothing that is lightweight, for improved

performance, which is something we made a high priority. A possible risk of creating a device weighing more than one pound is present, however, it is difficult to remain under one pound with the combination of components. A risk summary table can be found in Table A5 in the appendix.

V. Marketing and Manufacturing Considerations

The intended market of this device is universities with sports programs. As stated earlier, a Division I school sees roughly one to two cases each year which means it would be expected that roughly 360 devices would be needed at the Division I level. There are almost 800 Division II and III schools in the country. Given that these schools have less athletes, it could be predicted that about 300 devices would be needed at these institutions. Currently devices often parched for collegiate athletes are around $100. To create this prototype the total cost was $287, however not all the materials were used on the one unit. When mass materials were bought in bulk this would bring down the cost significantly with the device costing about $180, which would make the selling price $576. At this price the device is not competitive with other devices on the market. The major cost of the unit would be the Wellue ECG device which is sold off the shelf at $110. To lower the cost, a business deal would have to be made in which the sports bra device would be sold by Wellue as an electrode option. In this situation the profit would have to be split, however, more devices would be sold because the price would decrease.

VI. Device Outcomes

A. Summary Feasibility Discussion

Two of the most critical needs identified at the beginning of the project were the ability for the electrode to stay in contact with the skin throughout performance of the sport, and the comfort of the ECG device. This design satisfies the need to stay in contact with the skin because the electrodes are stitched directly into the material, ensuring they will not fall off when exposed to factors such as sweat. Comfort was also addressed because the device will have enough elasticity to eliminate restriction of movement as the athlete is performing, but will be snug, ensuring the device will stay in place and work properly. On the other hand, this device did not satisfy other aspects of the needs identified in the beginning. Another identified need was a wireless device with a transmission distance of 120 yards. After performing risk assessments and conducting further research, it was concluded this need would present too many potential risks and would be outside the scope of the project.

It was determined the resulting product from this design would be categorized as a prototype because it addresses more than one aspect of the product. A proof of concept addresses one specific problem while a prototype addresses several aspects of the design. It is often difficult to test the design, usability and functionality using a proof of concept but not with a prototype. Therefore, this design would be categorized as a prototype because it meets these factors of a prototype.

B. Discussion, Lessons Learned and Conclusions

Throughout the project, many issues arose, resulting in a shift of the project focus. One of the most reoccurring issues was the requirement of having a wireless transmission distance of 120 yards. The group struggled with designing a circuit that could transmit such a great distance while also keeping the device lightweight, waterproof, within FCC regulations, and within NCAA regulations. This ultimately led the group to refocus the scope of the project. The new scope was to design a device that would be comfortable for athletes to wear and that incorporated electrodes that could withstand a moist environment and remain in place during athletic activity. The biggest challenge was acquiring a signal using active electrodes that were comparable to the standard 3M Ag/AgCl electrodes.

The next challenge was obtaining an affordable data acquisition system that allowed for integration into our electrode design while also providing the user with a platform to read the data on a mobile device. The Wellue system was chosen because it was affordable ($110) and packaged with an app that allowed the user to analyze the ECG data using a mobile device. The one downside with the Wellue device was that it only allowed for the recording of a two lead ECG test. Our device was designed to be able to conduct a three lead ECG test, however this compromise was necessary in order to satisfy the previously mentioned limitations.

The team could have used time more advantageously by focusing on the main scope of the project sooner. It was not until the late stages of gate four where the group realized the scope of the project was too large. Although the group had the knowledge on how to design an ECG circuit that acquired, filtered, and displayed the appropriate signals, we were not aware how involved incorporating wireless transmission would be in our circuit.

C. Future Work

Although the project satisfied many user needs, remain to be solved, such as a wireless data transmission of 120 yards. Our current device does incorporate wireless data transmission via the Wellue, however it does not satisfy the 120 yard distance requirement. This requirement is very challenging to complete, and through our research, cannot be completed via Bluetooth technology which has a limit of 30 feet (10 yards) [4]. Transmitting data via radio frequencies over a long distance is regulated by the FCC and requires further investigation.

Some recommended design changes would be to design a circuit that could wirelessly transmit data to the athletic trainer and immediately alert the trainer if an arrhythmia occurred to the player on the field. Our design requires the data to be analyzed after the fact which is not ideal in case a cardiac event occurs on the field and it requires immediate medical attention.

Additionally, with increased time and resources the design could be improved by making the electrodes interchangeable using a snap design. This would allow the electrodes to be removed so the sports bra can be washed. Furthermore, the sports bra used in the device could be designed to accommodate users of different sizes. An adjustable bra would make the design

more efficient. This device could also be incorporated into physical activity for anyone who needs ECG recordings.

D. *Abbreviations and Acronyms*

ECG- Electrocardiogram

FCC – Federal Communications Commission

FMEA – Failure Modes Effect Analysis

QFD – Quality Function Deployment

VII. RESPONSIBILITIES

A. *Annamarie Alfery*

My overall contributions to this project included attending all meetings while documenting meeting notes, and putting maximum effort into the requirements that were assigned to me. In gate one, I conducted initial research for our project, reached out to my connections and prepared for and scheduled interviews with people who have knowledge with cardiac care. In gates two and three, I helped create the QFDs and conducted research to aid with the engineering and design requirements. In gate four, I helped document purchase requisitions to gain the necessary parts for our prototype. I also created the validation plan that would be carried out in the final gate. Lastly, in gate five, I helped carry out the validation testing, and myself, along with another member, created the validation plan, procedure, and report. For this honors report, I was responsible for writing the user needs and validation testing sections.

B. *Kelly Purgason*

Throughout this semester I acted as a meeting facilitator to ensure everyone was on the same page and presented any roadblocks they ran into, as well as updates on their assigned tasks. At every stage I, along with the other members of my team conducted research at every gate to determine what the next steps of the project would need to be. This included but was not limited to, researching competitive products, materials, data acquisition systems, engineering designs, scientific reports, and general ECG information. During gate one I assisted with researching project ideas, conducting interviews and developing user needs. During gate two I was responsible for developing the QFD and assisted in developing the engineering requirements. In gate three I again developed a QFD and came up with design options. In gate four I created the device drawings and 3D models, and developed the BOM. In gate five I assisted in the validation process.

C. *Silvia Furman*

This semester I attended all meetings and contributed to the progress of the project in any way I was able. I created a new Gantt chart for this semester and have kept it up to date to aid with the organization of the project. The Gantt chart for each semester can be seen in Tables A7 and A8. In gate one I contributed to initial research, assisted with conducting stakeholder interviews and helped with developing user needs. During gate two, I was present in team discussions to develop engineering requirements. In addition, I, along with two other team members, performed a risk assessment using FMEA in this gate. During gate three, I had similar duties to gate two, as I again contributed to team discussions to develop design requirements and performed a second risk assessment using FMEA with two other team members. In gate four, I developed the decision matrices to optimize selection of parts to purchase and in gate five I was responsible for creating the beta prototype for the electrodes of the design.

D. *Joseph Linder*

Throughout the course of this project, I assisted in any manner which I was able. In gate one, I assisted in initial research and interviews of customers. In gates two, three, and four, I analyzed the risk associated with our project and design through Function Modes and Effects Analysis (FMEA). This was paired with contributions in gate four with circuit design and construction in the BME design lounge. In gate four I also assisted in creating the verification plan and testing the alpha prototype we created. In gate five, I assisted in further testing of our device. For this honors proposal, I was responsible for writing the abstract, design inputs, verification, and risk mitigation sections.

E. *Jalal Jwayyed*

My contributions to this project included attending all meetings and contributing in any way that best helped the project move forward. In gate one, I helped organize interviews and gather relevant information related to initial research. In gate two, I conducted in depth research in the current literature to help form the engineering and design requirements. In gates two, three, and four I assisted the team in risk assessment by contributing to the FMEA. In gate four, I helped design and construct the circuit used for testing the alpha prototype. I also was responsible for the analysis portion of gate four which included running the verification test plan and analyzing the data acquired. In gate five, I assisted in forming the risk mitigation summary and with the validation testing of the beta prototype. In this final report, I was responsible for writing the medical device, discussion, and future work sections.

F. *Professional and Ethical Responsibiilities*

The goal of this product in the grand scheme of the world is to produce a more efficient method of diagnosing heart conditions in order to prevent major catastrophic events like sudden cardiac death. As biomedical engineers it is our job to make the world a healthier place and for this project that means easing the diagnosis process for athletes. Over the past few years several cases of young, in shape people dying suddenly of heart attacks has brought to light the need to make cardiac diagnostics tools more prevalent and available. This device offers an easier and more comfortable ECG option, that athletes will be more likely to use. In the age of plastic and single use medical devices, this cloth based design offers a reusable option for cardiac diagnosing that is more environmentally friendly.

G. *Prototype Demonstrattion*

A video summary of the results of our project can be found using the following link: https://youtu.be/HJ8-ohdezzc.

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APPENDIX

Legend		
⊖	Strong Relationship	9
O	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
—	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
X	Objective Is To Hit Target	

Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Demanded Quality (a.k.a. "Customer Requirements" or "Whats") / Quality Characteristics (a.k.a. "Functional Requirements" or "Hows")	1 Adhesion to the body of 0.56 N/cm	2 Device Transmits signal 120 yards	3 30% Deformation Rate	4 Able to integrate into 80% of collegiate uniforms	5 Device uses bluetooth technology	6	Body Guardian	CardioMobile	Apple Watch
				Direction of Improvement: Minimize (▼), Maximize (▲), or Target (x)	X	▲	X	▲	X		Competitive Analysis (0=Worst, 5=Best)		
1	9	6.7	1.0	Better electrode adhesion	⊖	⊖	⊖	▲	▲		2	0	0
2	9	13.3	2.0	Longer Transmission Distance	▲	⊖	▲	⊖	⊖		3	1	1
3	9	33.3	5.0	Better electrode comfort	O	▲	⊖	⊖	▲		2	5	5
4	9	26.7	4.0	Electrode integration into different outfits and uniforms	▲	O	⊖	⊖	⊖		3	0	4
5	9	20.0	3.0	Wireless device	▲	O	▲	⊖	⊖		5	5	5
6													
				Target or Limit Value	0.56 N/cm	120 yards	30% deformation	80% integration success	Zero Wires connecting Device and electrodes				
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	2	5	4	3	1				
				Max Relationship Value in Column	9	9	9	9	9				
				Weight / Importance	220.0	353.3	633.3	846.7	580.0				
				Relative Weight	8.4	13.4	24.1	32.2	22.0				

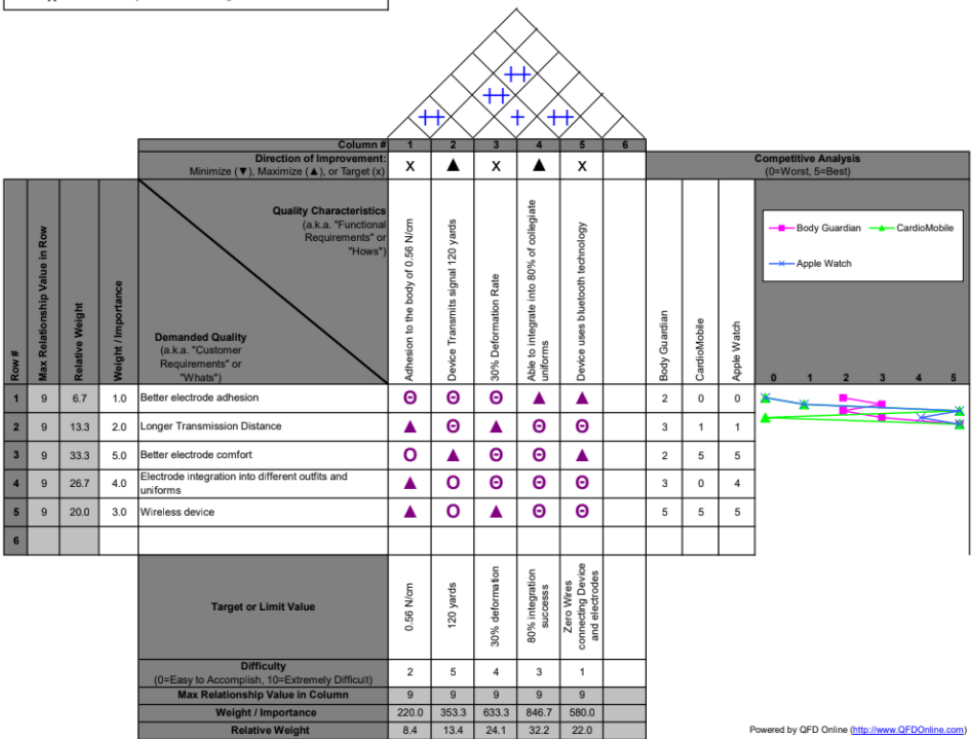


Figure 1: The QFD for Gate Two

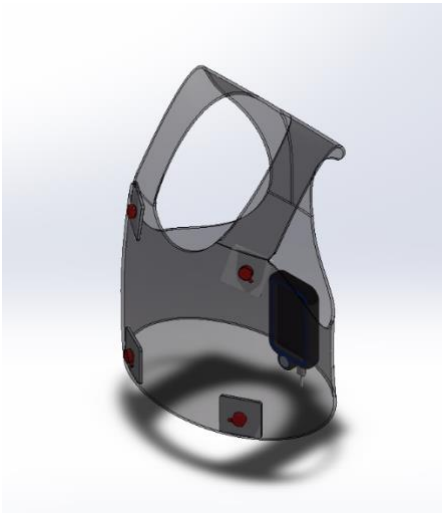


Figure 2: Full SolidWorks Assembly of Device

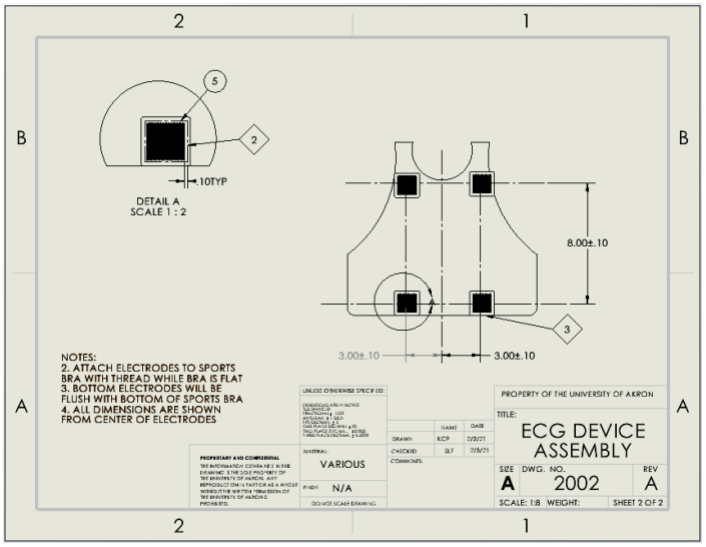
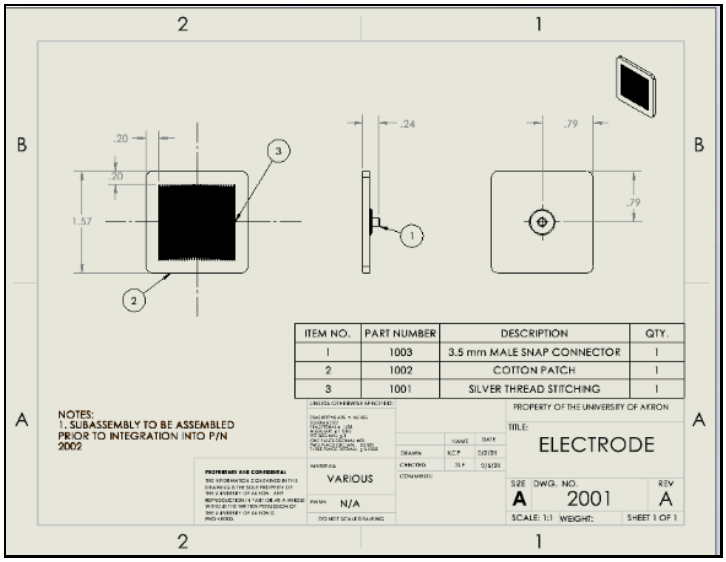


Figure 3: Device Drawing with Assembly Instructions



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1003	3.5 mm MALE SNAP CONNECTOR	1
2	1002	COTTON PATCH	1
3	1001	SILVER THREAD STITCHING	1

Figure 4: Electrode Subassembly

Figure 5: Beta Prototype of Electrodes

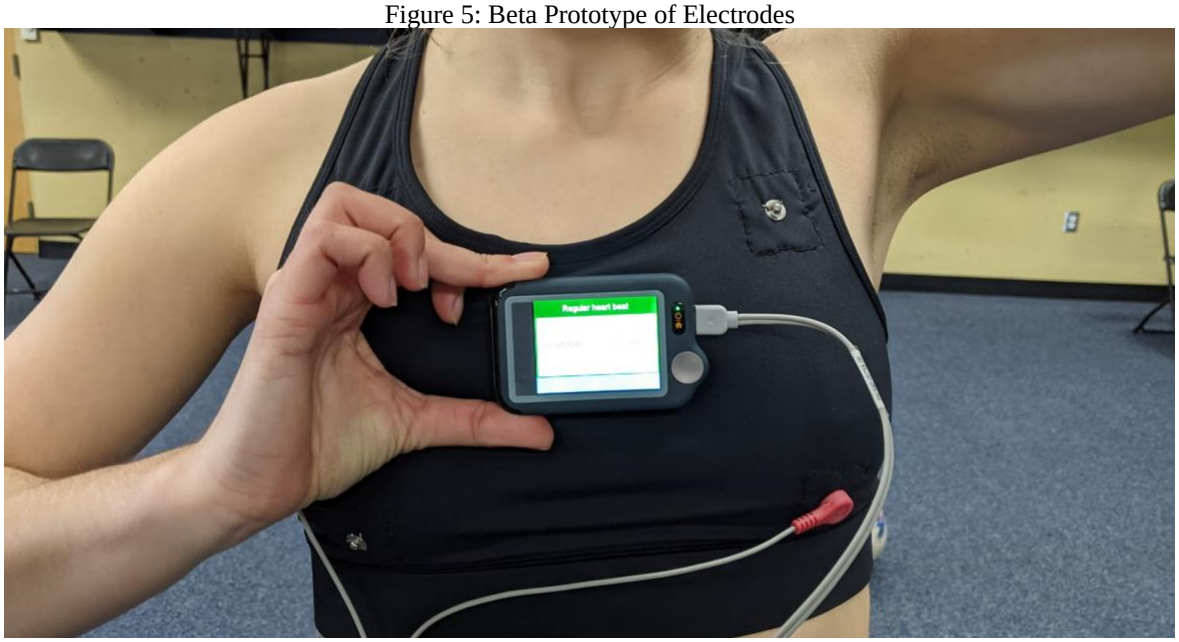


Figure 6: User Wearing Beta Prototype

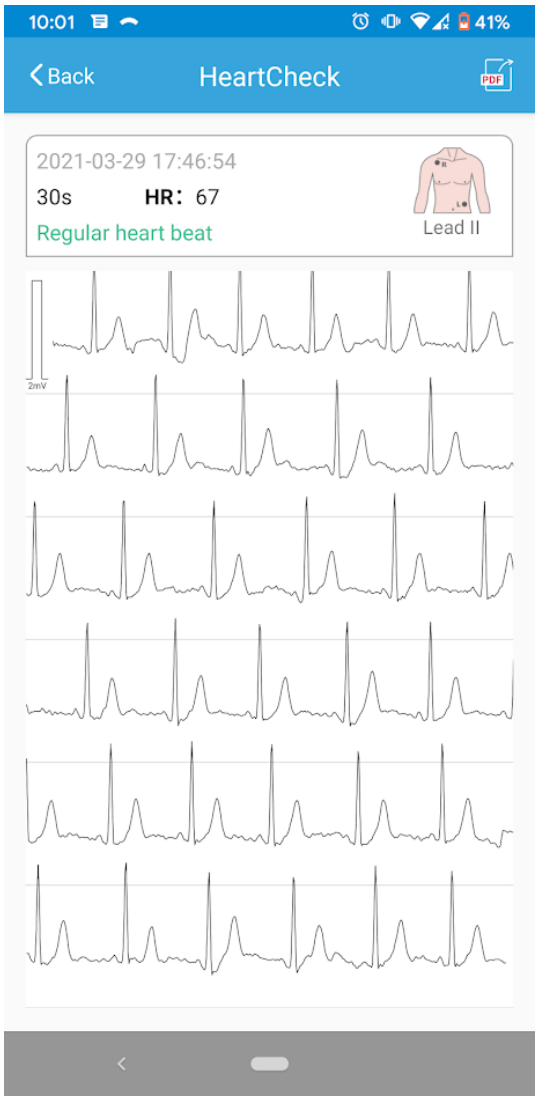


Figure 7: ECG Result from Prototype

Table A1: Verification Results

Engineering Requirement	**Test**	**Pass/Fail**
Weight (1+- 0.3lbs)	All device components weights (provided by vendor) were summed	Pass
A signal output size of at least 1mV	The signal outputs were verified by the vendor	Pass
Location of Electrodes	Measurement verification was conducted via SolidWorks	Pass
Conductive thread exhibits hydrophobic properties	The conductive thread was weighed before and after being exposed to water	Pass
Device operational temperature 0 to 50°C	Device components freezing/melting points were verified to be in range	Pass
Thread resistivity less than 50 ohm/m	45 ohm/m as verified by vendor	Pass

Table A2: Verification Testing

Design Spec	Test Method	Date	Name of Tester	Test Pass/Fail	If Fail, Improvement
Weight (1+- 0.3lbs)	All device components weights (provided by vendor) were summed	2/27/21	Jalal Jwayyed	Pass	N/A
A signal output size of at least 1mV	The signal outputs were verified by the vendor	2/23/21	Vendor	Pass	N/A
Location of Electrodes	Measurement verification was conducted via SolidWorks	2/25/21	Kelly Purgason	Pass	N/A
Conductive thread exhibits hydrophobic properties	The conductive thread was weighed before and after being exposed to water	2/22/21	Silvia Furman	Pass	N/A
Device operational temperature 0 to 50°C	Device components freezing/melting points were verified to be in range	2/23/21	Vendor	Pass	N/A
Thread resistivity less than 50 ohm/m	45 ohm/m as verified by vendor	2/23/21	Vendor	Pass	N/A

Table A3: Validation Plan

Customer Requirement Number	Customer Requirement	Validation Method	Validation Name	Validation Procedure Number
CR001	Device integrates with athletic uniforms	Test	Integration Test	51001
CR002	Electrode conforms to body	Inspection (visual)	Electrode Contact Test	51002
CR003	Electrodes produce a readable signal.	Inspection/Demonstration	Signal Inspection Test	51003
CR004	Thread is sweat resistant	Test/Analysis	Water Resistance Test	51004
CR005	Motion/physical contact does not change electrode location	Demonstration/Analysis	Movement Test	51005
CR006	Device does not cause discomfort to user	Analysis	User Comfort Survey	51006

Table A4: Validation Report

Validation Procedure Number	Validation Name	Passed	Failed	Comments
51001	Integration Test	X		Okay Data Shown
51002	Electrode Contact Test	X		okay fit, had to add additionally pressure via another sports bra, smaller size would be better
51003	Wireless Transmission Test	X		okay-clear data shown on app for all trials
51004	Water Resistance Test	X		clearer data after perspiring
51005	Movement Test		X	electrodes stayed intact, data did not continue transmitting when moving due to limitations of Wellue
51006	User Comfort Survey	X		User provided a score of 9

Table A5: Risk Summary Table

Name of Risk	Summary of Risk	Risk Priority Number (RPN) and Risk Level	Summary of How Risks were Mitigated
Incorrect electrode location	Electrodes are placed in incorrect locations	4, Justification Needed	Include directions (with diagrams) on each device to ensure that health professionals know the correct location of each electrode
Operational temperature lies between 0-50℃	Temperatures too high or too low for electrode to be operational	4, Justification Needed	If ambient (air) temperatures are close to electrode's limit, check device diligently
Signal output size of at least 1mV	The electrode does not obtain high enough electrical amplitude	2, Acceptable	Purchase conductive thread and research bra materials that will not decrease the amplitude of electrode signal capturing ability
Weight of the device is (1+/- 0.3lbs)	The weight of electrodes decreases the total weight of device too much	2, Acceptable	Weigh device with electrodes already stitched to ensure proper weight has been achieved
Material exhibits hydrophobic properties (Weight does not change by more than 10%)	Electrodes become so saturated that proper electrical signals are not captured	2, Acceptable	Coat the exterior surface of the electrode and the sports bra with a hydrophobic coating to protect against over saturation
Thread resistivity is less than 50ohm/m	Poor resistivity would decrease strength of electrical potential	1, Acceptable	Test thread resistivity that was provided by manufacturer
Weight of the device is (1+/- 0.3lbs)	The weight of electrodes increases total weight of device too much	1, Acceptable	Weigh device with electrodes already stitched to ensure proper weight has been achieved

Table A6: Bill of Materials

Bill of Materials								
Item Number	Part Number	Description	Quantity	Material	Procurement Type	Vendor	Price per 1 QTY (USD)	Lead Time
1	1001	Silver Thread	As Needed	Silver	OTS	Amazon	13.00	3 Days
2	1002	Cotton Patch	1	Cotton	OTS	Amazon	7.00	3 Days
3	1003	Male Snap Pin	4	Silver	OTS	R.S Hughes	14.00	1 Week
4	1004	Sports Bra	1	Polyester/Nylon Blend	OTS	Amazon	25.00	3 Days
5	1006	ECG Software	1	Plastic/ Metal	OTS	Wellue Pulsebit	120.00	1 Week
6	1008	Thread	As Needed	Textile	OTS	Amazon	4.00	3 Days
7	2001	Electrode Subassembly	4	-	Manufacture	-	-	
8	2002	Full Device Assembly	1	-	Manufacture	-	-	

Table A7: Gantt Chart for Fall 2020

TASK	ASSIGNED TO	PROGRESS	START	END
Phase 1 User Needs				
Research Clinical Problems	Everyone	100%	9/14/20	9/17/20
Contact Potential Stakeholders	Annamarie, Kelly, Joe	100%	9/14/20	9/17/20
Define User Needs/Problem Statement	Everyone	100%	9/17/20	9/18/20
Research Current Solutions	Kelly, Silvia, Jalal	100%	9/17/20	9/21/20
Prepare for Stakeholder Interviews	Everyone	100%	9/21/20	9/23/20
Conduct Holter Monitor Patient Interview	Kelly	100%	9/21/20	9/23/20
Make Presentation	Everyone	100%	9/21/20	9/27/20
Conduct Dr. Shaub Interview	Everyone	100%	9/23/20	9/23/20
Document Dr. Shaub Responses	Annamarie	100%	9/23/20	9/23/20
Finalize User Needs Statement	Kelly	100%	9/23/20	9/24/20
Write Honors Proposal Cover	Joe, Jalal	100%	9/23/20	9/24/20
Make Gantt Chart	Silvia	100%	9/24/20	9/27/20
Phase 2 Design Inputs				
Continue Conducting Interviews	Everyone	100%	9/28/20	11/2/20
Keep Gantt Chart Updated	Silvia	100%	10/5/20	11/2/20
Research Adhesive/Graphene Materials and Me	Everyone	100%	10/12/20	10/19/20
Write Honors Proposal	Everyone	100%	10/12/20	11/2/20
Generate QFD	Kelly and Annamarie	100%	10/14/20	11/2/20
Risk Assessment using FMEA	Silvia, Joe, Jalal	100%	10/15/20	11/2/20
Make Presentation	Everyone	100%	10/26/20	11/2/20
Phase 3 Design Process				
Make Presentation	Everyone	100%	11/23/20	11/29/20
Keep Gantt Chart Updated	Silvia	100%	11/9/20	11/30/20
Research (size/location of electrodes, materials, competitors, regulations)	Everyone	100%	11/9/20	11/13/20
QFD	Kelly and Annamarie	100%	11/16/20	11/29/20
Risk Assessment using FMEA	Silvia, Joe, Jalal	100%	11/16/20	11/29/20

Table A8: Gantt Chart for Spring 2021

Phase 4 Design Output and Verification				
Determine Device Specifications	Everyone	100%	1/11/21	1/25/21
Make SolidWorks/Drawings	Kelly	100%	1/18/21	2/1/21
Fill Out Expense Paperwork	Annamarie	100%	1/20/21	2/15/21
Create BOM	Kelly	100%	1/20/21	2/15/21
Decision Matrices	Silvia	100%	1/20/21	2/15/21
Build Prototype	Silvia - elctrodes; Jalal/Joe - circuit	100%	1/20/21	2/15/21
Verification Testing/Report	Joe/Jalal	100%	1/20/21	2/15/21
Risk Assessment with dFMEA - what has chai	Joe/Jalal	100%	1/20/21	2/15/21
Determine Validation Plans/Procedures	Annamarie	100%	1/20/21	2/15/21
Make Presentation	Everyone	100%	2/8/21	2/15/21
Make Gantt Chart	Silvia	100%	1/11/21	2/15/20
Phase 5 Medical Device				
Validation Plan	Annamarie	90%	3/1/21	3/15/21
Validation Procedure	Kelly/Annamarie	0%	3/1/21	3/15/21
Validation Report	Kelly/Annamarie	0%	3/15/21	4/5/21
Risk Summary	Joe/Jalal	0%	3/1/21	4/5/21
Sew Electrodes/Assemble Sports Bra	Silvia	50%	2/26/21	3/8/21
Complete Circuit	Joe/Jalal	60%	3/1/21	3/12/21
Assemble Whole Device	TBD	0%	3/12/21	3/15/21
Final Honors Report	Everyone	30%	2/15/21	3/15/21
Make Presentation	Everyone	0%	3/29/21	4/5/21
Keep Ghantt Chart Updated	Silvia	30%	3/1/21	4/5/21