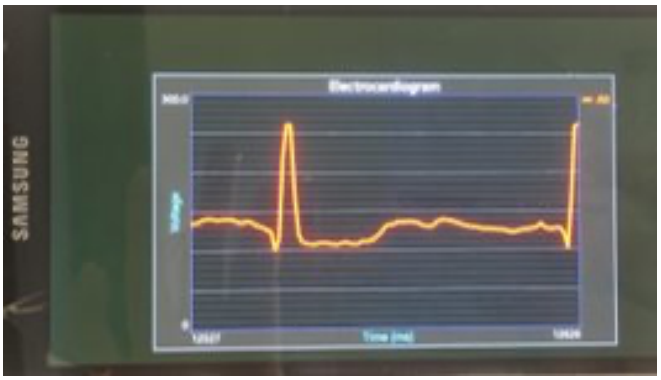

PORTABLE ELECTROCARDIOGRAPH MACHINE

BIOM1010 TEAM 17

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ABSTRACT

In this project, the design team developed a prototype electrocardiogram device that can take patient readings and output signals via Bluetooth to a mobile device. This process involved the physical construction of an ECG using an Arduino Uno board, the AD8232 ECG Module and the HM-10 Bluetooth module. It also required the implementation of software using Python code in Arduino to enable the correct communication between the heart monitor taking readings, the Arduino processing the readings and the Bluetooth module sending the readings to the Bluetooth Electronics android app. The project addressed the clinical need that developing nations require more durable and sustainable apparatus for patient monitoring, as the screens of their hospital patient monitors often break and become unusable. Design specifications were given, and as such the team's design process was guided by the objectives and constraints highlighted in these guidelines. The team followed the design process through from ideation to prototyping, leaving the implementation and commercialisation stages of product design for future endeavours. This was achieved by considering clinical needs, ethics involved, relevant regulations, methods of device assessment and future directions of the project.

INTRODUCTION

Cardiovascular diseases (CVD) are one of the leading causes of death worldwide. In Australia alone, an estimated 4.2 million (22%) people were hospitalised due to CVD in 2015-2016 alone [1]. Worldwide, CVD is the leading cause of death, and an estimated 17.9 million people died from CVD in 2016 [2]. Examining the epidemiology of CVD in third-world countries shows that 78% of global deaths due to CVD come from developing countries [3]. Thus, it is clear that there exists a clinical need to prevent and treat these diseases to improve the overall mortality and morbidity rates of the population, in particular that of the developing world.

In order to detect and test for cardiovascular pathologies, the initial screening involves an electrocardiogram (ECG). The ECG is a medical device that measures the electrical activity of the heart as it contracts. Specifically, it detects the various stages of depolarisation and repolarisation of cardiac chambers, which involves positive and negative ions moving in and out of cells. This process of depolarisation and repolarisation is what generates the upward and downward deflection of the voltage/time ECG graph *(see fig. 1).* The purpose of an ECG is to record and detect any anomalies in the heart it may potentially help in the diagnosis of certain cardiovascular pathologies. The most widely used existing technology is the standard medical-grade ECG machine *(see fig. 2).* These machines consist of a 30 x 30cm display screen and 12 ECG leads that are attached to the patient's extremities to measure their cardiac activity and plot it as a graph on the screen.

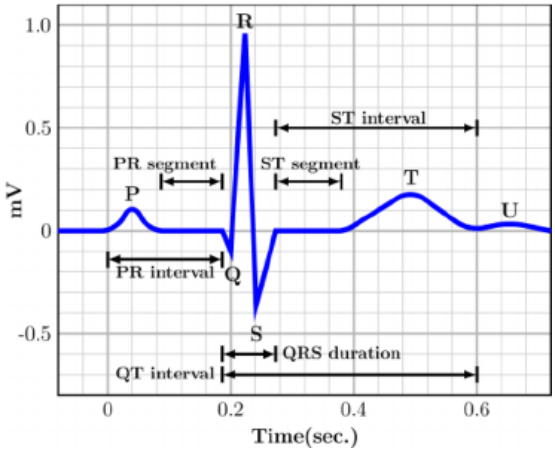


Figure 1 – Singular ECG graph wave complex

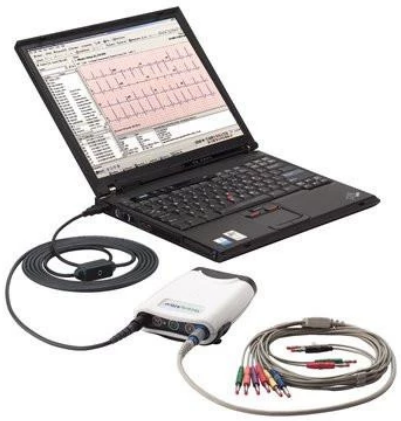


Figure 2 – Standard ECG machine

Medical devices found in the developing world are especially vulnerable to damage, as 95% of developing countries' medical equipment is sourced second-hand from developed countries [4]. Due to

their previous use and age, 96% of these devices break within 5 years [4]. A major problem arises from the lack of spare parts in developing countries, due to logistical issues and lack of local production. Devices in a developing country using components with replacement parts such as filters will often only have a working lifetime of said component due to this deficiency. Additionally, there is a lack of incentive and/or action to repair broken medical devices, with a recent study from EWH [1] identifying that only 120 out of 975 of the examined equipment required additional parts, where it is often cheaper for the target hospitals to request a new device from a sponsor than to repair it. Furthermore, affected hospitals lacked skilled technicians, device manuals and tools, which compounded with corruption and rudimentary logistics often leads to a buildup of unrepaired machinery. This creates excessive electronic waste and ultimately a greater cost burden on all involved parties. Furthermore, it weakens the overall state of the healthcare system in developing countries, due to a technological deficit and resultant inability to adequately provide for all patients.

ECGs face similar design barriers, especially regarding the monitoring component. One of the most cited broken devices from hospitals examined by the EWH are displays, due to the difficulty to repair the fragile glass. However, smartphones are quickly become one of the most produced and used electronic devices with IDC [5] reporting that 1.375 billion smartphones being shipped in the year 2019. Economies of scale drive down the costs, and a PEW study reports that a median of 45% of people own a smart device in emerging economies. Integrating smartphones into current technologies could potentially overcome design barriers of lacking repair components, as smartphones can be more readily repaired or replaced, and are widely distributed throughout the population.

In response to contextual information, the design team formulated the following problem statement: In third world countries, patient monitors are often damaged and are not able to display the graph traces from the ECG equipment. To address this, a prototype is to be created for a portable ECG machine that forgoes discrete monitoring screens and outputs an ECG reading onto a smartphone device via Bluetooth. It is to be capable of taking ECG readings through leads, processing the voltage data received and correctly outputting the data to be plotted as a graph on a smartphone app.

This project aims to improve the overall quality of the developing world's healthcare systems. By implementing this device, lives could potentially be saved, as medical professionals would be able to attend to more patients than would be possible with the small number of traditional ECG machines in third-world hospitals. It aims to combat technological inequality and make diagnostic tools more accessible and widely distributed throughout the world. The goal is to enable earlier and more accurate diagnoses of cardiac pathologies, and thus improve treatments and outcomes for patients.

DESIGN SPECIFICATIONS

Client Requirements

The device must:

1. have the functionality equivalent or innovative in comparison to currently marketed ECG machines.
2. be affordable for hospitals in developing countries.
3. contain 4 components:
    - The ECG module – reusable.
    - Electrode lead - reusable and replaceable if need be.
    - Electrodes – replaceable.
    - Smartphone - reusable and replaceable.
4. be able to transmit accurate readings through Bluetooth in the form of a graph, which is able to be interpreted by health care professionals.
5. be easy to repair.
6. be transportable and compact.

Design Requirements

1. Performance Requirements
    - The device must be able to perform at the level of or greater than a standard ECG. It must be light and portable for easy use. Inputs and outputs must be easy to interface and have a simple configuration. The device should be able to be operated by one person and generate an accurate electrocardiogram then transmit this through Bluetooth to a wide range of smartphones.
2. Safety
    - The ECG must be electrically safe to prevent potential harm to the patient. The leads must not be able to short circuit as the electrodes span across the chest of a patient, having a direct route through the heart which can be fatal. The electrodes must be tested for cytotoxicity and irritation and should be latex free to reduce potential allergic reactions. The device should be comfortable and compatible with all patients.

3. Accuracy and Reliability
    - The device must have at least a sensitivity of +-300mv, with a notch filter to generate a clean and accurate electrocardiogram.
4. Life in Service
    - The ECG must be able to potentially run for over twenty-hour cycles but will typically only be used for fifteen to thirty minutes at a time. The electrodes must be replaced every cycle for hygiene purposes, as they are disposable. The main lead is modular and replaceable and should be replaced every two years. The main unit should last over five years with batteries or power pack being replaceable as well. The smartphone component should last to their manufacturing specification's and be replaceable as needed.
5. Shelf Life
    - Theoretically, the main unit should be able to be stored indefinitely in a sealed environment. The electrodes should last at least twelve months in dry storage.
6. Operating Environment
    - The device should be able to function in a wide range of temperatures and humidity (-20°C to 40°C), allowing it to be used in both cold and warm climates and indoors and outside. The device should be resistant to water splashes and dust.
7. Size
    - The electrocardiogram leads should be long enough to account for a large range of body sizes. The main unit should be small enough to fit in first aid kits and shelves.
8. Materials
    - The device would be made of ABS plastic from 3d Printing, this reduces cost and simplifies production.

DESIGN DESCRIPTION

The ECG device contains multiple parts that all work together to create a functioning prototype. The hardware of the device is safely and securely attached to the breadboard using pins and solder *(see fig. 3)*. Pictures of the wiring can be seen below *(see fig. 4 and 5)*. It is designed to be compact and safe for transportation around different areas of need in a developing country, particularly in hospitals. This has been achieved through the creation of a casing that hold all parts of the device. This case has been designed using CAD software (Fusion 360) and has been 3D printed. A detailed blueprint of the design for the casing can also be seen below *(see fig. 6)*.

The utilisation procedure of the device is as follows:

1. The ECG electrodes are placed onto the patient's torso in order to receive the information by recording any potential difference between the electrodes on the patient.
2. These leads carry this information (in the form of electrical signals) into the ECG module, where these electrical signals are read, and sent to the Arduino.
3. This information is passed into the Arduino, which is being supplied with power by a power bank. The Arduino is embedded with notch, high pass and low pass filters. These filters only transmit the information within certain threshold conditions and will only take a certain number of data points that are within the range. The filtered data is then added to a string in the form of '**GDATAPOINT**', where 'G' is the receive character of the smartphone application.
4. This data string is sent to the HM-10 Bluetooth module. This module communicates to the desired smartphone device via Bluetooth BLE 4.0.
5. The Bluetooth Electronics android application then interprets the string of data and plots as a live feed onto a rolling graph, displaying a smooth PQRST complex.

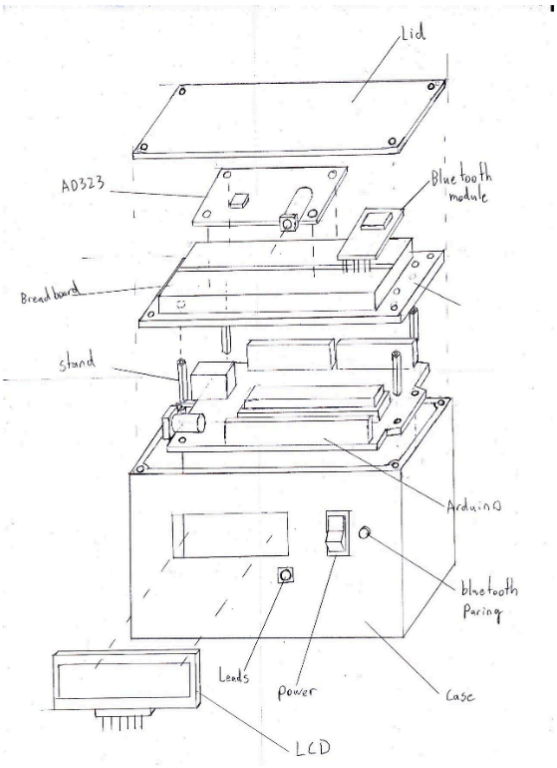


Figure 3 – Early design of outer casing of device

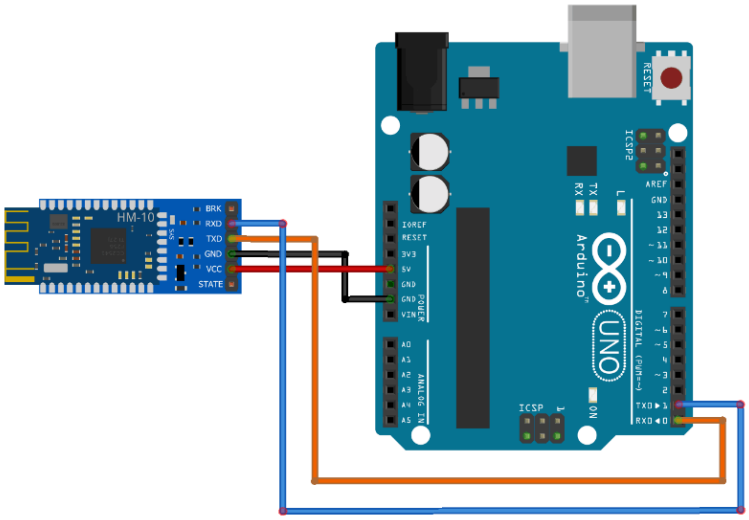


Figure 4 – Circuit diagram of connections between Arduino UNO and HM-10 Bluetooth Module

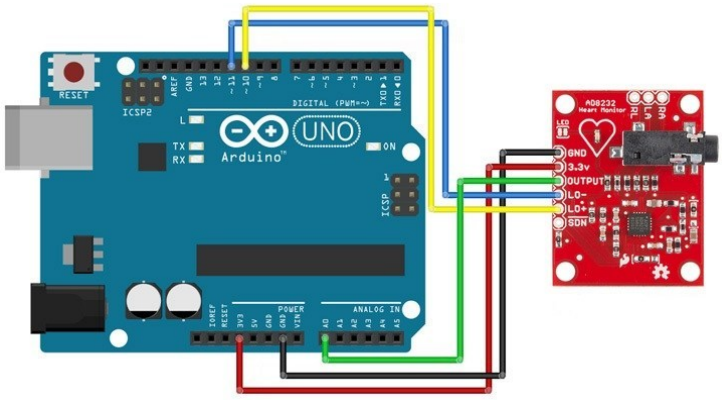


Figure 5 – Circuit diagram of connections between Arduino UNO and AD8232 ECG Module

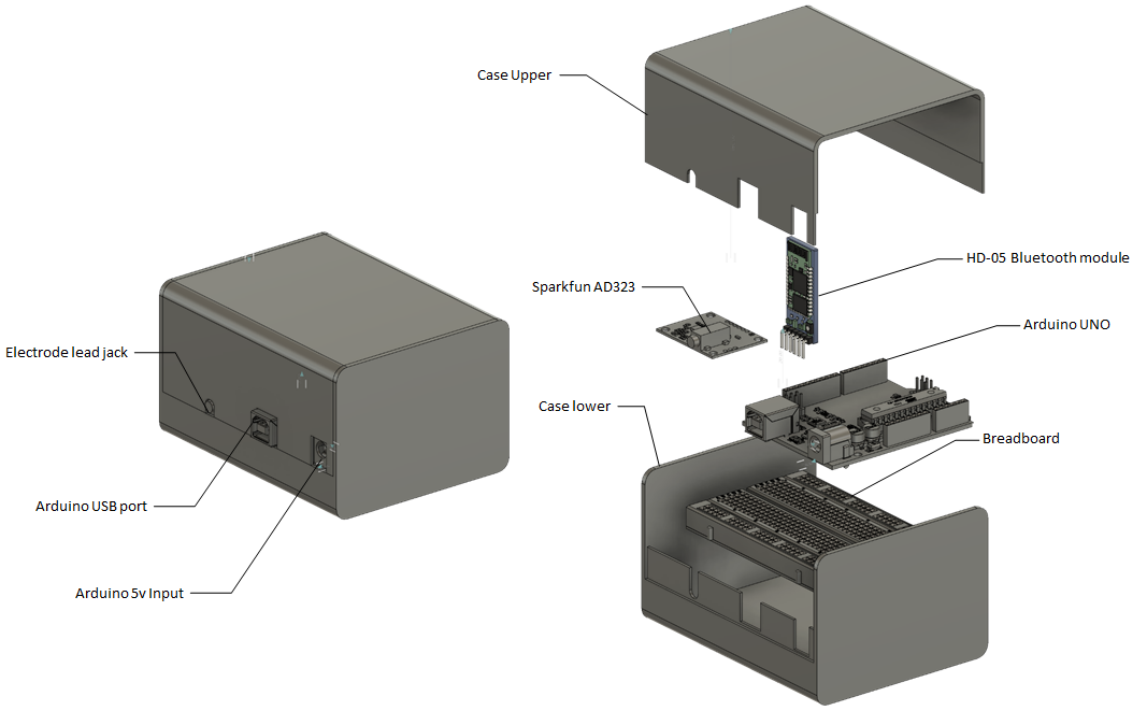


Figure 6 – Final Fusion 360 CAD design of outer casing of device

ETHICS

The device aims to provide a more effective, reliable and sustainable method of displaying an ECG reading for hospitalised patients in developing countries. In the current state of developing nations' health care system, the ECG machines and other equipment is mostly donated second-hand from developed countries. This results in equipment that is easily broken beyond the repair of the abilities of people in these countries as there is a lack of teachings resources and spare parts for the repair of the devices. A common problem that arises with the use of these second-hand machines is the display screens becoming damaged, and therefore unusable. The device aims to negate this issue by using an ECG machine that can be displayed on a smart phone in order to fill the resource gap in the current system. This is also achieved through the efficient manufacture and distribution of the device, using components that can be easily repaired.

If the product is used on a wider scale, more people would be able to access ECG monitoring, which would aim to allow for faster recovery time and a decrease in preventable deaths. This is due to the ability for health care professionals to identify any irregularities sooner. Another aspect of the health care system that the device aims to assist is the time strain that is put on health-care professionals. Part of their duties can be taken over by the ECG machine, allowing for more time and focus to be placed on other patients.

The environmental impact of ECG machines would also decrease with the integration of the prototype. The model would allow for hospital monitoring to become more efficient and more sustainable, as less landfill would be generated from constantly discarding large patient monitoring systems.

The primary ethical concern for the device is the safety of the components. As the device is not medical grade standard, the components of the device are less reliable and therefore may lead to harm. The elements such as the ECG module have the potential to short circuit or malfunction. This risk is minor and rare, though should be known to all health care professionals and patients that use the device.

Another concern that the device could potentially create is through the untrained administration of the device onto the patient. As the device is portable and inexpensive, patients may misunderstand the importance of the machine and try to take their own ECG reading, compromising the device. Through the education and training of the functioning of the device, this problem could be negated, with the regular monitoring and replacing of all components, to ensure that the ethical concerns are not experienced.

The coding makeup of the device may allow for people to hack into the system, altering the code and thus changing the results with or without the patient's knowledge. This would compromise the integrity of the device, potentially leading to false readings and diagnosis. Hacking also presents a privacy threat and could compromise patient confidentiality.

In the designing process of the prototype the perspectives of the potential market such as those of the health care professionals in developing countries, have not been considered. The design of the device is created from the perspective of engineers and technicians who are not aware of the conditions and equipment that is available in these developing countries. As the designers are not using, repairing or replacing the current devices this aspect may be overlooked, potentially causing greater issues in resources.

There is also a potential power imbalance that is established in the usage of the device is between those with and without smart phones. The readings are displayed on a smartphone, therefore patients and health care professionals without a smartphone will not have access to the device, limiting its effectiveness. Thus, preferences develop as patients with smartphones may be favoured for treatment in hospitals, further contributing to the inequality of technological accessibility.

Before the device is to be tested-on people in trials, ethical considerations in terms of the safety and reliability of the prototype need to be further assessed to ensure that no short circuiting of the device occurs. The testing on people will assess the reliability and accuracy of the results that are encoded in the device.

In order for the device to become marketable, further ethical considerations need to take place. These include the input provided from the health care professionals that aim to use the device. This would allow for a final device that would perform all necessary functions and be more useable and sustainable for the target market. This also includes the integration of a mobile phone within the ECG machine, which may limit the effectiveness of the device. Another major consideration and approval that needs to be put in place is towards the security of the code and the administration of the recordings.

DEVICE MANUFACTURE

In order to build this device, the design team was tasked to come up with a few design plans (as outlined in previous sections) by brainstorming models, drawing circuit diagrams and CAD models. Subsequently, regarding the materials required, the team researched online designs and previous designs to gain inspiration. A consolidated group design and further parts list was then produced. As the Arduino, a breadboard and some cables were provided, the only sourced items were the Bluetooth module (HM-10) and the ECG Module (AD8232). Other equipment includes 3x 1kΩ resistors to create a simple voltage divider, a single core breadboard wiring kit, a soldering iron and solder to solder pins to the ECG Module. The team also decided to design a casing for the device, using Fusion 360 and using a 3D printer to print.

The electrical circuit design was researched through various forums and YouTube videos, which discussed similar prototypes and how to assemble the Arduino UNO [6][7], the HM-10 [8] and the AD8232[9].

The first step was to assemble to AD8232 ECG Module. The team initially didn't anticipate the need to solder any components as it was assumed that the breadboard could act as a sufficient prototyping platform. However, to ensure a reliable constant connection occurred, the team decided to solder the AD8232 to some pins to insert into the breadboard, to secure it in place.

Next was to connect the HM-10 Bluetooth Module. After much research [10], the team realised the need for a simple voltage divider from the transmitter pin (TX) on the Arduino UNO to the receiver pin (RXD) on the HM-10. This was needed due to the transmitter pin being 5V on the Arduino Uno and the receiver pin being 3.3V on the Bluetooth module. Hence to ensure the extended health of the Bluetooth module the team decided to implement a 5V to 3.3V voltage divider using 3 1kΩ resistors.

The final step in assembling the electrical circuit involved testing the connections. To do this the team connected the Arduino Uno to a laptop to upload some basic code. The LED's on the ECG and the Bluetooth modules were observed to indicate proper functionality.

The software implementation of the device initially started with developing skeleton code in which the team could begin adding and implementing functions and filters that were believed necessary for optimal functionality of the prototype. The skeleton code was developed/inspired by previous Arduino code that was used to program a heart rate sensor [11] as well as Bluetooth transmission through a HM-10 Bluetooth Module [8]. All the functions inside this code were removed except for the main function (Serial.begin(9600)) which allowed the writing of code that was specifically designed for serial communication.

Throughout the code implementation process, the design team encountered some difficulties however these were slowly surmounted.

The notch filter is a function that essentially filters out 50Hz in order to make the resulting ECG heartrate function cleaner and less noisy. The mains power is drawn at 50Hz and therefore creates background noise at this frequency It is necessary to remove the 50Hz from the signal to produce a smooth wave. This waveform allows for a more accurate and easier to read ECG signal and hence a valid diagnosis, if the device is to be commercialised.

To implement the notch filter the design team needed to develop coefficients for the filtering function. A previous creator's bandwidth and notch location was used to develop these coefficients [12]. These numbers, along with others were put into the iirnotch function in MATLAB, to output coefficients for the notch filter. However, these resulting coefficients filtered out 60Hz and as a result, the graph was too smooth, not allowing for the peak of the QRS complex of a PQRST wave to be clearly defined. Hence, the input numbers into the iirnotch function in MATLAB needed to be changed. These new numbers were altered so only 50Hz was filtered out.

In addition, a low pass filter was used. A low pass filter is a function that was also developed on MATLAB, which passes signals with a frequency lower than a selected cut off frequency and attenuates signals with frequencies higher than the cut off frequency. In this case the cut off frequency was made to 100Hz as the coefficients used were from a previous creator [12].

However, after developing all these coefficients for the filters and testing the code several times, the design team observed that the resulting graph was too smooth. To rectify this problem, the team removed both filters. The team then came to know that the ECG module included both a notch filter and a low pass filter. Hence, in the final version of the code used (*see appendix D)*, the team disregarded both notch and low pass filters.

A difficulty also arose in coding for successful communication between the Arduino, the Bluetooth module and the Bluetooth graphing app. Once the correct command was decided upon to output values to the Bluetooth module, the correct syntax for the output value string was found in the Bluetooth Electronics application. It was discovered that the data was to be input as a string with an asterisk '*', followed by a data character which was 'G' in this case, followed by the data point, followed by another asterisk, i.e. "*G1.22*" would plot a value of 1.22 on the phone [7].

After discovering this, team had trouble testing a transmission of data to the application. After examining and determining that the code was correct, the assumption was made that the Bluetooth module was faulty. The design team decided to discard the previous HC-05 module and purchase

another type of Bluetooth module, the HM-10, to examine whether this was the problem. After, this new module was attached to the breadboard, the code was run again and data was coming through to the phone, graphing a smooth PQRST complex via Bluetooth.

The team also decided to create a cover for the device to keep it compact and portable. This involved the use of Fusion 360, a CAD software in order to create a design for the case. It was ensured that it fit all parts of the device and had accommodating extra space for the wiring. Once the design was finalised, it was sent to a 3D printer to print. Whilst printing, the 3D printer recalibrated, ruining the design and functionality of the case, and hence needed a reprint. Although the process was time consuming, it resulted in a portable, streamlined and effective case.

It is evident that the device manufacturing process required the design team to undergo a series of testing, changes and decision making. Although the team was presented with challenges, they were able to overcome these, resulting in a fully functioning Bluetooth ECG Machine that met the device requirements.

DESIGN PERFORMANCE

The ECG device must complete several different functions for the objective of large-scale manufacture and commercialisation to be realised. As the intention of the device is to be able to safely measure and monitor patients' cardiac health in developing hospitals, the device must maintain and deliver a constant and safe voltage to the body. This can be tested by attaching the device to a voltmeter/ammeter for an extended period to analyse and measure the potential difference and current flowing through the device. The device must also be analysed for a certain period to ensure that there aren't any fluctuations or malfunctioning of the device's voltage.

The next design parameter that needs to be fulfilled is the accurate measurement of data. The prototype includes a notch filter and low-pass filter in order to filter out measurements within a small range of around 50Hz that is delivered to the Arduino. By filtering out this frequency, it is ensured that the main power does not interfere with the readings. The following code interprets the data by averaging out these measurements to convert the data into points for graph which is then able to be understood by health care professionals. To test that the notch filter is working the prototype will be supplied with a constant 50Hz signal without the filter, with an expected sine wave produced as a result. The notch filter will then be applied to ideally convert the graph into a straight line. The next step to test this design parameter is to attach a subject to the machine to record. The graph that is delivered to the phone/laptop will be compared to a medical-grade ECG machine, to ensure that the prototype data is somewhat correct. If the desired result is not achieved than the code will need to be checked and potentially rewritten.

In order for the device to run, all components must be able to interact and transfer information between them. This includes the ECG electrodes, Arduino, Bluetooth module and mobile app. To ensure all modules work together the code is modular so each component can be tested separately, for example the signal could be sent from the Bluetooth module to the app to test the Bluetooth capabilities of the device. The device can also be tested by placing a finger on the ECG electrode, which should produce a signal spike to ensure that the ECG module and Arduino are interacting. To ensure that the Bluetooth module is functioning a code is sent from the laptop to the module. A signal/response from the module should then be sent back to the laptop. LED's were also connected to the breadboard to check that the Bluetooth and ECG modules were working respectively.

After all components have been separately tested, the leads should be connected between the modules and the ECG electrodes should be attached to a test subject to form a definite signal. By individually

testing each component and keeping the code modular for the prototype, any problems in connection or code can be identified and fixed.

As the device is needed for monitoring for a long period of time, it must be able to deliver constant power from an inbuilt power bank or a connected laptop. To test this function, the length of time that the power bank can deliver charge can be researched to determine the length of time that the prototype can safely and reliably run for.

FAILURE MODE AND EFFECT ANALYSIS (FMEA)

The FMEA is a tool used in projects in order to identify and analyse the problems associated with the prototype and the potential impacts of these problems. By brainstorming any solutions to potential problems, these issues can be mitigated, and a lesser impact of the problem can be expressed. The failures can therefore be prioritised based on the impact, frequency and ease of detection [13]. The following most severe modes of failure of the prototype have been analysed and potential solutions have been conceptualised *(see appendix E for an overview of other failures)*.

The most severe potential failure refers to the electrodes of the design. As the electrodes are directly applied to the skin there is potential for irritation or discomfort caused by this interaction. This is as a result of solvents, allergens and other impurities being trapped between the skin and the electrode for an extended period. The occurrence of this issue is uncommon due to the one-use electrodes, though has the potential to become a greater issue, depending on the storage of the electrodes and the cleaning of the area of the patient's skin prior to being attached to the machine. This issue can become more prevalent with the use of lotions and skin care products which can make the adhesion of the electrode difficult, allowing for these impurities to build up underneath. This build-up between the skin and electrodes may also result in lack of adhesion to the device and incorrect readings, which could potentially result in misdiagnosis. The irritation should be clear to the health care professionals, therefore the RPN is ranked at a 90. This issue is controlled during the manufacture by testing for cytotoxicity and sensitization and by sterilising the patient's skin prior to measurement [14].

Another potential mode of failure that could occur is out-of-date electrodes being used on the patients for ECG monitoring. The lack of adhesion that would be caused by the misuse of the electrodes may result in incorrect readings. Therefore, this is a high impact mode of failure due to the potentially disastrous results, though the risk is remote due to the controls in place. The electrodes should have the storage instructions placed on the packaging to prevent the risk from occurring, therefore rating the risk at an RPN of 48 [14].

The malfunctioning of the hardware could also be a potential mode of failure. This may be caused by the short circuiting of the equipment as a result of inexpensive components or the components being overworked. The impact of this failure is incorrect readings, or a voltage being delivered to people in contact with the device. The risk is severe, but uncommon, and can be avoided through the constant maintenance and replacing of the parts in the device. This potential failure is therefore at a risk priority number of 180.

INTELLECTUAL PROPERTY

This device is not patentable, as it relies heavily on existing techniques and technologies and no new ground is broken. One of the most basic requirements to obtain a patent is that its use or function can't merely be a straightforward iteration of an already patented invention. The team's device fails this criterion as many of its major utilities are off the shelf components of already patented devices. Furthermore, the Arduino components and software are open source, allowing adopters royalty-free use of technologies with the condition that development and improvements must be licenced under the same open source patent.

All parts of the design have been patented before, as the ECG machine is not a new machine and there have been others prior to our design which have patented each of the separate components.

There may be potential infringements of current patents, which would impede the process of applying for any new patents. For example, in the AusPat database for current patents, prior ECG patents were found upon which the device may potentially infringe *(see table 1)*.

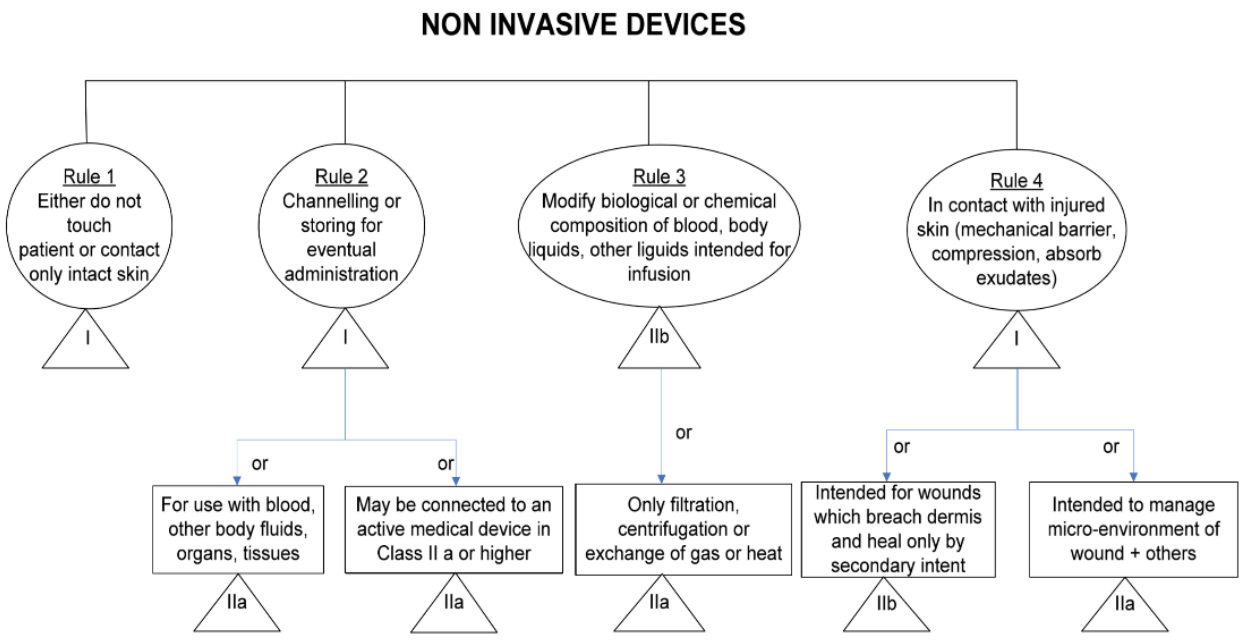
Table 1 – Current patents relating to project

Patent application number	Patent application name
2003256121	Mobile communication terminal with an electrocardiograph
2000030577	Wireless electrocardiograph system
2000024340	Portable electrocardiograph and central processing module
2018202207	ECG machine including filter for feature detection.
2002321833	Method and apparatus for analysing an electrocardiogram

PROJECT REGULATIONS AND STANDARDS

The ECG device is considered a medical device and therefore there are certain regulations for which it must comply with under different 'Standards Australia'. This is involved in the steps for premarket approval and the production stages of the device.

The class of the device differs between the U.S. Food and Drug Administration (FDA) and the European standards. This is due to the different systems by which medical devices are categorised, which therefore differs the regulations that are applied to the device. The FDA (category-based system) categorises the device as a class 2 due to the manufacturing of the electrodes and the direct skin contact that needs to take place in order for a reading to occur [14]. Under the rule-based European system, which most similar to the Australian standards the device is classed under Rule 1 and Rule 10, as the device only comes into contact with intact skin and holds an electrical current *(see fig.7)*. The difference in the classes of the device dictate the different regulations that the medical device must comply with before it is marketed [15].



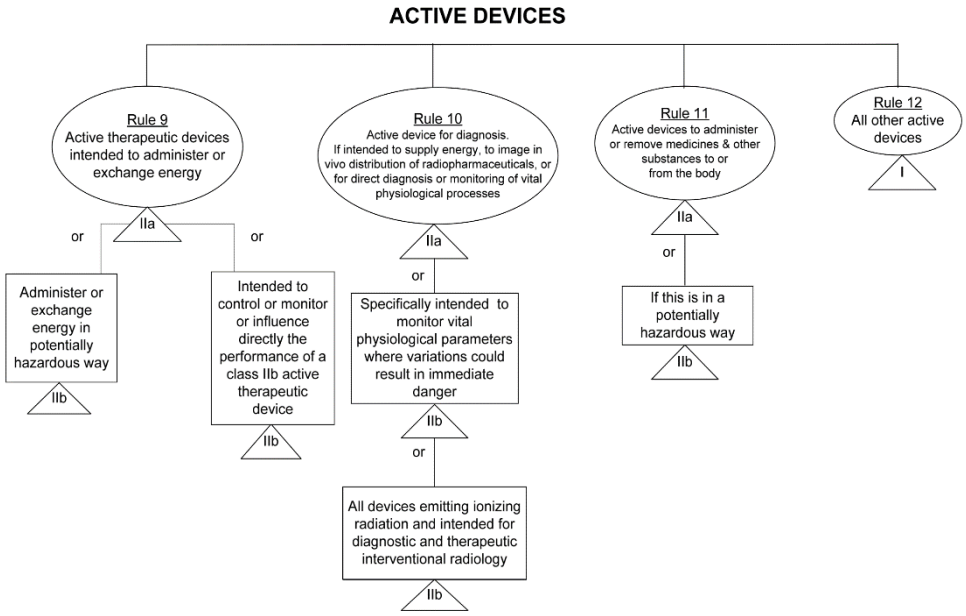


Figure 7 – European Rule-based system on Medical Devices [15]

Under Standards Australia the device must comply with the following current regulations [16]:

I. "AS/NZS IEC 60601.2.25:2016: Medical electrical equipment – Part 2.25: Particular requirements for the basic safety and essential performance of electrocardiographs"
II. "AS/NZS IEC 60601.2.27:2016: Medical electrical equipment – Part 2.27: Particular requirements for the basic safety and essential performance of electrocardiographs"
III. "IEC 60601-2-47:2012: Medical electrical equipment – Part 2-47 : Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems"
IV. "AS/NZS 3200.2.25-1993: Approval and test specification – Medical electrical equipment – particular requirements for safety – Electrocardiographs"

All these current regulations need to be met in order for the safety, effectiveness, truthfulness and accuracy of the device to be optimised. They must be adhered to prior to the distribution of the device in Australia.

The device is categorised as a Class 2 device under the Australian rule-based system. The electrodes are places on the surface of intact skin in order to measure the potential difference throughout the body. This therefore does not send a voltage throughout the body, so there is no risk of fibrillation as a result of the device. Though the device does contain at most five volts of power those this is not sent through the body, making it a Class 2 device. The electrodes may cause slight irritation to the skin, which may require clinical testing and approval throughout the manufacture of the electrodes, but in terms of clinical trials this factor is trivial.

HEALTH TECHNOLOGY ASSESSMENT (HTA)

In order to understand the economic benefit that our device has to the community, the team may first need to conduct a Health Technology Assessment (HTA), which involves studying the device's safety, health outcomes and cost-effectiveness. In terms of safety, Section 7 (FMEA, page 20) discussed this in detail, which covers the potential downfalls of the device and how they could be overcome. Regarding health outcomes, this relates mostly to effectiveness and efficacy of the product. All of these aspects constitute the HTA, which under the broad umbrella term of 'clinical effectiveness', consists of studying the added benefit this device has compared to current devices, the economic impact of making this device available, and what social and ethical implications there might be when making this device available. To assess these, clinical trials would be required to test the safety and efficacy of the device. These clinical trials will involve testing the device on patients with known ECG abnormalities. This will have to be compared against the graph achieved from a hospital-grade ECG machine. This information will tell us how close this device is to being clinically effective, which would give us an idea of how much economic benefit we can provide to hospitals. Also, an assessment of the socioeconomic situation of the country to be targeted for device distribution would be necessary. This would lead to a better understanding of the country as well as the policies involved in medical devices.

This device has the potential to provide huge economic benefit to the target community. First, it is to be manufactured at a low cost, which will maximise affordability of this device in the community. Second, as discussed in the clinical needs section, this device has a very clear purpose and could potentially save many lives if it works appropriately. Its potential benefit clearly outweighs the harms. However, there are still various obstacles in terms of developing a reliable and effective device that fulfils its true potential. Some of which include supply chain issues or manufacturing processes.

For proposed pricing, an average ECG device costs around AUD$2600. Our device should be priced lower than these devices to suit the market of third-world countries. Based on our budget of $70, the device could potentially be priced at $99 to account for manufacturing and labour costs. Although this will produce some profit, which is necessary for future growth and development, the cost is still kept affordable and suitable for distribution in developing countries.

FUTURE DIRECTIONS

For this device to be implemented clinically, it must be able to detect cardiac pathologies accurately and efficiently. While being mobile and transportable, it still needs to be accurate and reliable. It will have to undergo rigorous testing and clinical trials, in order to show that it can handle the workload of a normal hospital requirement. Furthermore, it needs to be easily reproducible, especially from a third-world country perspective, so that these countries can benefit from this product. A sustainable and replaceable power source must be implemented as well, and materials need to be reliable.

From a clinical standpoint, the device also needs to be able to detect cardiac pathologies. This would have to be tested rigorously against current hospital-grade devices, in order to guarantee that our device would meet the requirements of diagnosing patients. Also, its reliability of taking multiple readings over a long period of time will have to be tested, to match the demands of such a device in a hospital.

The prototype was made at under $70, using non-wholesale parts, not bought in bulk. Therefore, if the prototype is to be reproduced the cost of production would be well under $100. This would give the team the ability to sell the product to developing countries for a fraction of the cost of the current ECG machines, which currently cost thousands of dollars. However, there would also be various concerns to consider, such as manufacturing processes, supply chain issues and distribution strategies. These will all have to be developed if we were to successfully implement this device in a clinical setting.

In the prototyping of the device the team was able to discover the many different regulations and standards that must be adhered to and the length of time that a device takes from the initial bench testing to getting it onto the market. This ensures that all medical devices are safe and reliable before they are used in a widespread scale. The team was also able to learn about all the setbacks and redesigns that take place during the bench testing process, in order to determine the most efficient and reliable way the device can be built and run in order to fulfil the project aim.

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APPENDIX

APPENDIX A - Budget table

ITEM	QUANTITY	COST
Arduino	1	None, Supplied
Bread board	1	None, Supplied
Wires	70	$13.50
Power Source	1	None, Laptop/Portable charger
Resistors	4	$1.00
ECG module and leads	1 module, 3 leads	$20.35
ECG electrode pads	20	$3.35
HM-10 Bluetooth module	1	$29.95
TOTAL COST		**$68.15**

APPENDIX B - Group Contract

BIOM1010 Group 17 Project Contract

We, **Charlotte Stanwix, Navya Thokala, Peter Louka, Kevin Sun, Sabena Bhadri and Ryan Chee**, agree to uphold the following contract conditions:

- All group members must complete their individually assigned work on time.
- If a group member requires help on an individual task, they should ask other group members for assistance before the task is to be completed.
- The group must voice out any disagreements and discuss professionally to resolve any conflict.
- Any changes that an individual feels should be made during the project should be communicated respectfully and in a sensible amount of time before due dates.
- If there is a dispute between members, at the earliest convenience try and settle the dispute as a group and then if it isn't resolved within a week involve Lucy (tutor) or Antonia (mentor).
- Attendance at group meetings is mandatory, unless reasonable circumstances arise that prevent members from attending.
- All group members should be responsive and contactable, and the main channel of communication will be Facebook messenger.
- No plagiarism will be tolerated, in alignment with the UNSW policy.
- All costs associated with the project are to be recorded in the budget and the total cost split equally amongst the group members at the end of the project.

Signed:

Sabena Bhadri

Ryan Chee

Peter Louka

Charlotte Stanwix

Kevin Sun

Navya Thokala

Date: 18 June 2019

APPENDIX C - Minutes

Week 2 – MEETING MINUTES

Meeting/Project Name:	BIOM1010 – Team 17, ECG Machine		
Date of Meeting: (MM/DD/YYYY)	13/06/19	Time:	2pm
Minutes Prepared By:	Charlotte Stanwix	Location:	Mathews 104

1. Meeting Objective

To be introduced to our project and understand the objectives and ethics behind what we are trying to accomplish. This will allow us to have a basic understanding of the timeline of the term ahead and to begin to plan out the steps we must undertake in order to achieve our goals.

2. Attendance at Meeting

Name	Department/Division	E-mail
Antonia Workman	Tutor	a.workman@unsw.edu.au
Charlotte Stanwix	Group 17	c.stanwix@ student.unsw.edu.au
Sabena Bhadri		s.bhadri@student.unsw.edu.au
Ryan Chee		r.chee@student.unsw.edu.au
Peter Louka		p.louka@student.unsw.edu.au
Navya Thokala		n.thokala@student.unsw.edu.au
Kevin Sun		k.sun@ student.unsw.edu.au

Meeting/Project Name:	BIOM1010 – Team 17, ECG Machine		
Date of Meeting: (MM/DD/YYYY)	13/06/19	Time:	2pm
Minutes Prepared By:	Charlotte Stanwix	Location:	Mathews 104

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
General introduction to the task - We have to write up a final report to hand in with the design - The budget is $100 - The project is being designed for people in 3rd world countries with limited access to ECG machines, or to replace broken ECG machines - The project is very independent, with lots of research to be taken place and Antonia to serve only as a guide - The project is designed for first years, no background knowledge is required - The differences between the projects will come from the coding element	Antonia	2pm
What we need to do - Create physical connections between the hardware - Source all the equipment - Write an arduino code to run the device	Antonia	3pm
Ethics behind the project - To help those in 3rd world countries to access medical devices. Most of the current equipment is second hand from first world countries nad therefore breaks quickly and is unable to be repaired. With this device it is hoped that they will be able ot access an accurate ECG machine with a smart phone and a small bluetooth device. - The device will be made out of plastics and wires - The device will allow for less waste as the wires and other parts can be replaced and are small in comparison to the large machines that are currently in use	Antonia	3pm
Schdule for the term – Aim to finish coding by week 8 – Write report and presentation as you go	Antonia	3:30pm

4. Action Items

Action	Owner	Due Date
Make an equipment list / research all components	Team 17	20/06
Make a budget		13/06
Make a goals list / schedule for the term		13/06
Decide where to purchase each component		20/06
Find out the max safe voltage for your device		13/06

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	20/06/19	Time:	2pm	Location:	Mathews 104
Objective:	To learn more about the project and understand what we must accomplish.				

Week 3 – MEETING MINUTES

Meeting/Project Name:	BIOM1010 Team 17 ECG Machine		
Date of Meeting: (MM/DD/YYYY)	20/05/19	Time:	2:00-4:00pm
Minutes Prepared By:	Navya Thokala	Location:	MAT104, SAM318

1. Meeting Objective

Clinical needs

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Navya Thokala	Student		
Peter Louka	Student		
Charlotte Stanwix	Student		
Kevin Sun	Student		
Ryan Chee	Student		

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Looked at everyone's P3 submissions and gave feedback - 20 mins. 20 mins – group concensus to make clinical needs statement. Power point slide on clinical needs was made as well. Each group did a 3 minute presentation on their clinical needs.	All	2-3pm
Rest of time was used to work on our group project – we started to discuss where to source our materials from.	All	3-4pm

Meeting/Project Name:	BIOM1010 Team 17 ECG Machine		
Date of Meeting: (MM/DD/YYYY)	20/05/19	**Time:**	2:00-4:00pm
Minutes Prepared By:	Navya Thokala	**Location:**	MAT104, SAM318

4. Action Items

Action	**Owner**	**Due Date**
Source some of our materials – electrodes, ECG sensor, bluetooth module	Peter	30/05/19

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	25/5/19	**Time:**		**Location:**	
Objective:					

Week 4 – MEETING MINUTES

Meeting/Project Name:	Discussion of project and coming up with new ideas		
Date of Meeting: (MM/DD/YYYY)	06/27/2019	**Time:**	2.00 – 4.00pm
Minutes Prepared By:	Ryan Chee	**Location:**	MATS104

1. Meeting Objective

Discussing how our project should be designed – coming up with final design
Planning our project (weekly tasks)

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Peter Louka	Student		
Ryan Chee	Student		
Navya Thokala	Student		
Charlotte Stanwix	Student		
Kevin Sun	Student		

Meeting/Project Name:	Discussion of project and coming up with new ideas		
Date of Meeting: (MM/DD/YYYY)	06/27/2019	**Time:**	2.00 – 4.00pm
Minutes Prepared By:	Ryan Chee	**Location:**	MATS104

3. Agenda and Notes, Decisions, Issues

Topic	**Owner**	**Time**
Coming up with Final design for project	Everyone	
Writing a term timeline for weekly tasks	Charlotte, Ryan	
Look at everyone's P4 and discuss pros and cons	Everyone	

4. Action Items

Action	**Owner**	**Due Date**

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	07/04/2019	**Time:**	2.00pm	**Location:**	

Objective:	Discuss project ethics Complete p6

Meeting/Project Name:	BIOM1010 Team 17 ECG Machine		
Date of Meeting: (MM/DD/YYYY)	04/07/19	Time:	2:00-4:00pm
Minutes Prepared By:	Peter Louka	Location:	MAT104, SAM318

1. Meeting Objective

To have a consolidated document discussing the ethics of the project, including the reason for the device, any consequences of designing the device, the net benefit and the fairness of designing the ECG.

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Navya Thokala	Student		
Peter Louka	Student		
Charlotte Stanwix	Student		
Kevin Sun	Student		
Ryan Chee	Student		

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Looked at everyone's P6 submissions and gave feedback – 20 mins. 20 mins – Group consolidated document for Project Ethics Power point slide on Ethics was made as well.	All	2-3pm
Rest of time was used to work on our group project. Wiring up the device and researching notch filters and diagrams for AD8232 ECG module as well as HC-05 Bluetooth Module.	All	3-4pm

4. Action Items

Action	Owner	Due Date
Finished Wiring	Peter	
Final design for box	Peter	
Basic Code	Navya, Sabena	
Working on report	Charlotte, Ryan, Kevin	

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	09/07/2019	Time:	2-4pm	Location:	518 Samuels

Objective:	Device Assessment

Week 6 – MEETING MINUTES

Meeting/Project Name:	BIOM1010 week 6 tutorial 2		
Date of Meeting: (MM/DD/YYYY)	11/07/19	Time:	2:00pm
Minutes Prepared By:	Sabena Bhadri	Location:	MAT104, SAM318

1. Meeting Objective

Device prototyping
Parameters testing

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Navya Thokala	Student		
Peter Louka	Student		
Charlotte Stanwix	Student		
Kevin Sun	Student		

Meeting/Project Name:	BIOM1010 week 6 tutorial 2		
Date of Meeting: (MM/DD/YYYY)	11/07/19	Time:	2:00pm
Minutes Prepared By:	Sabena Bhadri	Location:	MAT104, SAM318

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Discussed each group members' individual ideas then came up with a group consensus about which design parameters we would use to test our device	All	2-2:30pm
Came up with a comprehensive testing procedure/method to test the device against these parameters by combining all group members' individual ideas	All	2:30-3pm
Spent the rest of the time on delegated tasks: • Report writing – ethics section finished, introduction started • Device assembling – all hardware connections were made but unsure whether Bluetooth module actually works/outputs signals as ECG readings were only tested and displayed via USB port on the laptop • Arduino coding – started trying to use Matlab to find the coefficients for the notch filter, and continuing to research the correct functions to use to input/output data correctly	Ryan and Charlotte (report) Peter and Kevin (device assembly) Sabena and Navya (code)	3-4pm

4. Action Items

Action	Owner	Due Date
Finalise assembly of the hardware connections of device	Peter Louka	18/7/19
Have a skeleton code structure finished	Navya, Sabena	18/7/19
Have all group report sections thus far written up	All	18/7/19

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	18/7/19	Time:	2:00pm	Location:	MAT104

Objective:	Continue working on prototype Discuss project clinical trials

Week 7 – MEETING MINUTES

Meeting/Project Name:	BIOM1010 week 7 tutorial 2		
Date of Meeting: (MM/DD/YYYY)	18/07/19	**Time:**	2:00pm
Minutes Prepared By:	Kevin Sun	**Location:**	MAT104, SAM318

1. Meeting Objective

Device prototyping
Parameters testing

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Navya Thokala	Student		
Peter Louka	Student		
Charlotte Stanwix	Student		
Kevin Sun	Student		

Meeting/Project Name:	BIOM1010 week 7 tutorial 2		
Date of Meeting: (MM/DD/YYYY)	18/07/19	Time:	2:00pm
Minutes Prepared By:	Kevin Sun	Location:	MAT104, SAM318

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Compilation and discussion of clinical trials prework	All	2-2:30pm
Determine that clinical trial testing was unrequired for our device	All	2:30-3pm
During the second half of the tutorial: • Report writing • Device assembly • Arduino coding	Ryan, Kevin and Charlotte – (Report) Peter – (device assembly) Sabena and Navya – (code)	2-4pm

4. Action Items

Action	Owner	Due Date
Assembling of device and debug bluetooth component	Peter Louka	25/7/19
Finish notch filter code	Navya, Sabena	25/7/19
Continue writing group report sections	All	25/7/19

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	25/7/19	Time:	2:00pm	Location:	MAT104

Objective:	Review project progress Review code

Week 8 – MEETING MINUTES

Meeting/Project Name:	BIOM1010 – Team 17, ECG Machine		
Date of Meeting: (MM/DD/YYYY)	25/07/2019	Time:	2pm
Minutes Prepared By:	Charlotte Stanwix	Location:	Mathews 104

1. Meeting Objective

To understand where we are in the project, and if we are on track with all parts of the report, presentation and coding of the device. To assign people for different parts of the report to be completed. To write the notch filter and bluetooth signal in the code and test the code in a modular format.

2. Attendance at Meeting

Name	Department/Division	E-mail
Peter Louka	Student	p.louka@student.unsw.edu.au
Charlotte Stanwix	Student	c.stanwix@student.unsw.edu.au
Ryan Chee	Student	r.chee@student.unsw.edu.au
Sabena Bhadri	Student	s.bhadri@student.unsw.edu.au

Apologies

Navya Thokala, Kevin Sun

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Review of the report writing Ethics, device performance have been written Project Regulations needs to be written from the notes in tutorial 1	Charlotte	2:00pm
Review of code written: The notch filter has been written but needs to be tested for the device with the bluetooth code and graphing code The notch filter needs to be further integrated into the code to create a smooth and accurate graph	Sabena	2:10pm
Plans for the next week Finish the project regulations (Charlotte) Integrate all code together, testing the device next week Write and proofread other parts of the report	Charlotte	3:55pm

4. Action Items

Action	Owner	Due Date
Notch filter written and integrated	Navya and Sabena	01/08
Project Regulations report part written	Charlotte	01/08
Drawings for the device design report section	Kevin	01/08
CAD of device casing	Peter	26/07

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	**01/08/2019**	**Time:**	**2pm**	**Location:**	**Mathews 104**

Objective:	To finalise the code for the device and to continue with the writing of the report and presentation.

Week 9 – MEETING MINUTES

Meeting/Project Name:	BIOM1010 – Team Seventeen ECG Machine		
Date of Meeting: (MM/DD/YYYY)	01/08/19	Time:	2:00-4:00pm
Minutes Prepared By:	Navya Thokala	Location:	MAT104

1. Meeting Objective

Implement and run code on prototype.
Continue assmebling parts of the report that were assigned to team members.

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Navya Thokala	Student		
Charlotte Stanwix	Student		
Ryan Chee	Student		
Kevin Sun, Peter Louka	Student		

Meeting/Project Name:	BIOM1010 – Team Seventeen ECG Machine		
Date of Meeting: (MM/DD/YYYY)	01/08/19	Time:	2:00-4:00pm
Minutes Prepared By:	Navya Thokala	Location:	MAT104

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Working on allocated sections of the report.	Charlotte, Ryan, Kevin	2-4pm
Changed coefficients of notch filer, howver could not get code to run/work.	Navya,Sabena	2-4pm
Finalise hardware connections of the prototype, also help in running code.	Peter	2-4pm

4. Action Items

Action	Owner	Due Date
Finalise and make finishing adjustments to prototype.	Peter	06/08/19
Work on allocated sections of report.	All	06/08/19
Attempt to run code again and make sure it works.	Sabena, Navya	07/08/19

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)	06/08/19	Time:	2:00-4:00pm	Location:	SAM513
Objective:	Finalize code, make sure it works.				

Week 10 – MEETING MINUTES

Meeting/Project Name:	Discussion for final project and presentation		
Date of Meeting: (MM/DD/YYYY)	08/06/2019	Time:	2.00-4.00pm
Minutes Prepared By:	Ryan	Location:	SAMS518

1. Meeting Objective

Work on final presentation slides – confirm who is presenting which part
Discuss final report and which part needs editing
Fixing/Troubleshooting final code
Printing case for device

2. Attendance at Meeting

Name	Department/Division	E-mail	Phone
Sabena Bhadri	Student		
Peter Louka	Student		
Ryan Chee	Student		
Navya Thokala	Student		
Charlotte Stanwix	Student		
Kevin Sun	Student		

Meeting/Project Name:	Discussion for final project and presentation		
Date of Meeting: (MM/DD/YYYY)	08/06/2019	Time:	2.00-4.00pm
Minutes Prepared By:	Ryan	Location:	SAMS518

3. Agenda and Notes, Decisions, Issues

Topic	Owner	Time
Disussion as to whether bluetooth module is faulty • Code seems right, but not outputting signals	Peter, Navya, Sabena	
Presentations slides were discussed and sections allocated	Everyone	
Discuss which part of final report needs editing		

4. Action Items

Action	Owner	Due Date
Finalise presention parts and practice individual sections • Get ready for presentation on thurs (08/08) • Charlotte will create the slides but everyone will look at their individual sections and prepare their slides	Everyone	08/08/2019
Continue work on report – finalise meeting minutes, appendix, references • Divide up sections of report to read and edit • Get everyone to check their own section • Align references	Everyone	11/08/2019

5. Next Meeting (if applicable)

Date: (MM/DD/YYYY)		Time:		Location:	
Objective:	**NA – things to be discussed on fb messenger chat if necessary**				

APPENDIX D – Arduino code for device

```
// ECG final code

// Pin usage
#define LOminus 11
#define LOplus 10
#define ecg_read_pin A0

// Variables
float x, output;
String colors[]={"R0G0B0","R0G150B0"}; // App light colours for LOW and HIGH

void setup() {
  // Initialize the serial communication:
  Serial.begin(9600);
  pinMode(LOminus, INPUT); // Setup for leads off detection LO -
  pinMode(LOplus, INPUT); // Setup for leads off detection LO +
}

void loop() {

    // Read digital pins and send results over Bluetooth
    // This tells app which stream to expect data from
    Serial.print(""+String("a")+colors[digitalRead(2)]+"");

    // Read in a value from the ECG sensors
    x = analogRead(ecg_read_pin);
    output = x * 0.3;

    // Output the correctly formatted string to Bluetooth module
    Serial.print("*G" + (String)output + "," + "*");
    //Serial.println(output); // only for laptop communication

    // Wait for a bit to keep serial data from saturating
    delay(50);

}
```

APPENDIX E – FMEA table

Mode and cause of failure	**What is the effect on the customer?**	**How severe is the effect on the customer?**	**How frequently is it likely to occur?**	**What are the existing controls to prevent it occurring?**	**Risk Priority number (RPN)**
Irritation to skin due to trapped solvents, allergens and other impurities under ECG electrodes, caused by lotions and other fluids becoming trapped between the two layers.	Irritation of discomfort to skin where the electrodes are placed. There is also a risk of incorrect diagnosis.	High impact – severe	Uncommon	During the manufacture all ECG electrodes are tested for cytotoxicity and sensitisation. The skin should also be cleaned at the site where the electrodes are placed.	90
A different voltage delivered to the ECG to power the device then it is accustomed too. This could overheat and damage the internal parts of the device.	The internal parts of the design would stop working, which would cause the breakage of the device.	Low impact to customer, high impact to device	Remote	The boxed device can be opened and inspected for signs of damage.	72
Malfunctioning of the hardware due to overworking and short circuiting of the device.	Possible voltage being delivered to the person in contact with the device.	High impact – severe	Uncommon	The constant maintenance and replacing of parts can reduce the risk of malfunctioning.	180
Out-of-date electrodes used on patients.	The lack of adhesion of the electrode can result in inaccurate readings.	High impact – severe	Remote	The storage conditions or shelf life for the electrodes should be shown on the packaging and adhere to.	48
Heating up of the electrodes due to transfer of heat from the device and overworking of the device.	The hot electrodes may cause first, or second degree burns to patient.	High impact – severe	Remote	A voltage divider in the hardware of the device is placed to prevent too much excess heat from building up, the box also able to be open to let out excess heat.	42