

Technical Data Package

Biomedical Sensor Board for Education - MediBrick 2000

ENGR 498B - #24052

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TABLE OF CONTENTS

Page No.

1.0 PROJECT DESCRIPTION.....	7
2.0 SYSTEM DESCRIPTION & SYSTEM BLOCK DIAGRAM.....	7
2.1 SYSTEM DESCRIPTION.....	7
2.2 SYSTEM BLOCK DIAGRAM.....	8
2.3 MINIMUM VIABLE PRODUCT 1.....	9
2.4 MINIMUM VIABLE PRODUCT 2.....	9
2.5 IMPACTS.....	9
3.0 SYSTEM VERIFICATION PLAN.....	10
3.1 SYSTEM VERIFICATION OVERVIEW.....	10
3.2 SYSTEM VERIFICATION FLOW DIAGRAM.....	11
3.3 SYSTEM REQUIREMENT VERIFICATION MATRIX.....	11
3.4 EVIDENCE OF VERIFICATION.....	11
3.4.1 MVP1 VERIFICATION.....	11
3.4.2 MVP2 VERIFICATION.....	11
3.5 STANDARDS REFERENCED.....	12
4.0 DESIGN DOCUMENTATION.....	12
4.1 INDENTURED DOCUMENT LIST.....	12
4.2 SYSTEM REQUIREMENTS DOCUMENT.....	13
4.3 VERIFICATION DOCUMENTATION.....	14
4.4 HARDWARE DRAWING PACKAGE.....	16
4.4.1 HOUSING DRAWINGS.....	16
4.4.2 TEMPERATURE SENSOR DRAWINGS.....	17
4.4.3 DIGITAL STETHOSCOPE DRAWINGS.....	18
4.4.4 PULSE OXIMETER SENSOR DRAWINGS.....	18
4.4.5 BIOIMPEDANCE SENSOR DRAWINGS.....	19
4.4.6 ECG SENSOR DRAWINGS.....	19
4.5 SOFTWARE DESIGN DOCUMENT.....	19
4.6 MODELS.....	19
4.6.1 STETHOSCOPE SENSITIVITY MODEL.....	20
4.6.2 STETHOSCOPE AUDIO MODEL.....	20
4.6.3 PULSE OXIMETER SIGNAL NOISE MODEL.....	21
4.6.4 SYSTEM COST MODEL.....	22
4.6.5 SYSTEM WEIGHT MODEL.....	23
4.6.6 SYSTEM DIMENSIONS MODEL.....	24
4.6.7 INTERNAL POWER SUPPLY MODEL.....	24
4.6.8 EXTERNAL POWER SUPPLY MODEL.....	24

4.6.9 TEMPERATURE MODULE ERROR MODEL.....	25
4.6.10 BIOIMPEDANCE CURRENT MODEL.....	28
4.6.11 ECG CURRENT MODEL.....	28
5.0 APPENDIX.....	30
5.1 SYSTEM REQUIREMENTS DOCUMENT.....	31
5.2 ACCEPTANCE TEST PROCEDURES DOCUMENT.....	48
5.3 SOFTWARE DESIGN DOCUMENT.....	102
5.4 EXAMPLE ECG RESPONSE CURVE.....	199
5.5 EXAMPLE HEARTBEAT SIGNAL FREQUENCY RESPONSE.....	199
5.6 AMPHENOL ADVANCED SENSORS 10 KΩ THERMISTOR DATASHEET.....	199
5.7 SYSTEM REQUIREMENT VERIFICATION MATRIX.....	200
5.8 SYSTEM VERIFICATION FLOW DIAGRAM.....	1
5.9 MVP1 VERIFICATION DATASHEETS.....	1
5.10 STETHOSCOPE SOURCE.....	1
5.11 ECG CURRENT SOURCE.....	1
5.12 HARDWARE.....	1
5.12.1 SENSOR MODULE HOUSING DRAWINGS.....	1
5.12.2 CHARGING HOUSING DRAWINGS.....	1
5.12.3 TEMPERATURE MODULE CIRCUIT SCHEMATIC.....	1
5.12.4 TEMPERATURE MODULE PCB DIAGRAM.....	1
5.12.5 ECG MODULE SCHEMATIC.....	1
5.12.6 ECG MODULE PCB HOLDER.....	1
5.12.7 PULSE OXIMETER MODULE SCHEMATICS.....	1
5.12.8 PULSE OXIMETER MODULE PCB DIAGRAM.....	1
5.12.9 IMPEDANCE MODULE SCHEMATICS.....	1
5.12.10 IMPEDANCE MODULE PCB DIAGRAM.....	1
5.12.11 DIGITAL STETHOSCOPE MODULE SCHEMATIC.....	1
5.12.12 DIGITAL STETHOSCOPE PCB DIAGRAM.....	1
5.12.13 INSERT MODULE DRAWINGS.....	1
5.12.14 RECEIVER MODULE DRAWINGS.....	1
5.13 INDENTURED DOCUMENT LIST.....	1
5.14 SYSTEM ARCHITECTURE DIAGRAM.....	1
5.15 MVP2 VERIFICATION DATASHEETS.....	1
5.16 ENGINEERING CHANGE REQUEST DOCUMENTS.....	1
5.16.1 HOUSING DRAWING CHANGES.....	1
5.16.2 PCB DRAWING CHANGES.....	1
5.16.3 SYSTEM REQUIREMENTS ALTERATIONS.....	1
5.16.4 TEMPERATURE & IMPEDANCE SCHEMATICS CHANGES.....	1

5.16.5 HEIGHT SYSTEM REQUIREMENT ALTERATION.....	1
5.17 SUMMARY TABLE OF MODEL PREDICTIONS & MARGINS.....	1

1.0 PROJECT DESCRIPTION

This Technical Data Package details the design documentation of the MediBrick 2000. This device was created for the University of Arizona's Biomedical Engineering Department to provide a low-cost, open source device for students within the Biomedical Engineering Department of the University of Arizona and other colleges and universities to get acquainted with basic physiological sensors, measurement procedures, and data. The device contains a temperature sensor, a digital stethoscope, a pulse oximeter, an electrocardiogram, and a skin impedance sensor. This device is not designed for diagnostic purposes and is designed only to provide data for students to study and interpret in a classroom setting to further their education in a hands-on manner.

This project is designed to be released in an open source environment where any potential user can download the requisite files and construct this device. This project is also designed to be beginner-friendly allowing users to be able to follow the directions in the user manual to take live physiological measurements. Through these two main traits, this project completes its main purpose as an introductory device, allowing potential users to gain practice soldering the device, reading sensor outputs, and interpreting physiological data.

This is the second year of this project. The first team to attempt this project succeeded in getting the temperature sensor, the ECG, and the bioimpedance sensor to operate with a Raspberry Pi 4. For the second year of this project, design limitations of attempting to get all five sensors to be integrated into one HAT for the Raspberry Pi 4 has led to the project to shift to having each sensor be paired with its own microcontroller, specifically the Adafruit ESP32-S3. As such, the previous team's design documentation is being used as reference material for this project, but their material is not being used for any part of the final design.

For the purposes of testing and verifying this project and its progress, two Minimum Viable Products were established, MVP1 and MVP2. MVP1 and MVP2 are discussed below in TDP 2.3 and TDP 2.4, respectively. MVP1 was completed by CDR, and dealt with the basic function of each sensor in isolation to ensure that the basic approach to each sensor was going to meet the System Requirements. MVP2 deals with all of the System Requirements not included in MVP1.

2.0 SYSTEM DESCRIPTION & SYSTEM BLOCK DIAGRAM

2.1 SYSTEM DESCRIPTION

This project is designed to be a modular system where each sensor module can be separated from the central charging station for use. The System Block Diagram located below in TDP 2.2 shows the general overview of the system. Each system contains the following five sensor modules: a Temperature Module, a Digital Stethoscope Module, a Pulse Oximeter Module, an Electrocardiogram Module, and a Skin Impedance Module. Each sensor module contains within it an Adafruit ESP32-S3 Feather microcontroller outfitted with the code needed to operate, a battery to run the microcontroller and sensor, an OLED screen to display the battery status of the module, the sensor-specific PCB that contains the sensor circuitry connected to the microcontroller, and the sensor probe connected to the PCB required for that sensor module. The

requisite physical and digital filters for all of the sensors are located either on the PCB for the physical filters or within the code on the ESP32-S3 Feather for the digital filters.

Each sensor module has different probes in order to measure the necessary physiological signals. The Temperature Module uses a $10\text{ k}\Omega$ thermistor as the probe. The Digital Stethoscope Module uses a stethoscope bell connected to a microphone as the probe. The Pulse Oximeter Module uses a standard clip-on finger-based pulse oximeter with integrated red and infrared sensors as the probe. The ECG Module uses three electrodes as the probes. The Skin Impedance Module uses two electrodes as the probes.

As the sensors are operating, they send data wirelessly to the Receiver Module that is connected to the laptop of the user using a USB-C cable. The Receiver Module returns this data to the Graphical User Interface running on the laptop, allowing the user to read the data in real time and record the data. The GUI is designed to display and save the live data from one sensor at a time through dedicated pages made for each sensor.

The Charging Module contains the charging strip that will allow the batteries in each sensor module to recharge and acts as the central housing that the other modules will be attached to when not in use. The Charging Module has slots for each of the sensor modules to slot into while charging. Each slot has a magnetic charger embedded in the housing that connects to the charging strip; the magnetic charger lines up with a corresponding magnetic connector in the sensor housings, allowing the connection to be made easily and quickly without requiring the use of plugs or wires. The Charging Module is plugged into a standard 15-amp, 120-volt AC wall outlet using the cable of the charging strip.

2.2 SYSTEM BLOCK DIAGRAM

The System Block Diagram is located below in Figure 2.2.1, and is arranged as per the System Description in TDP 2.1.

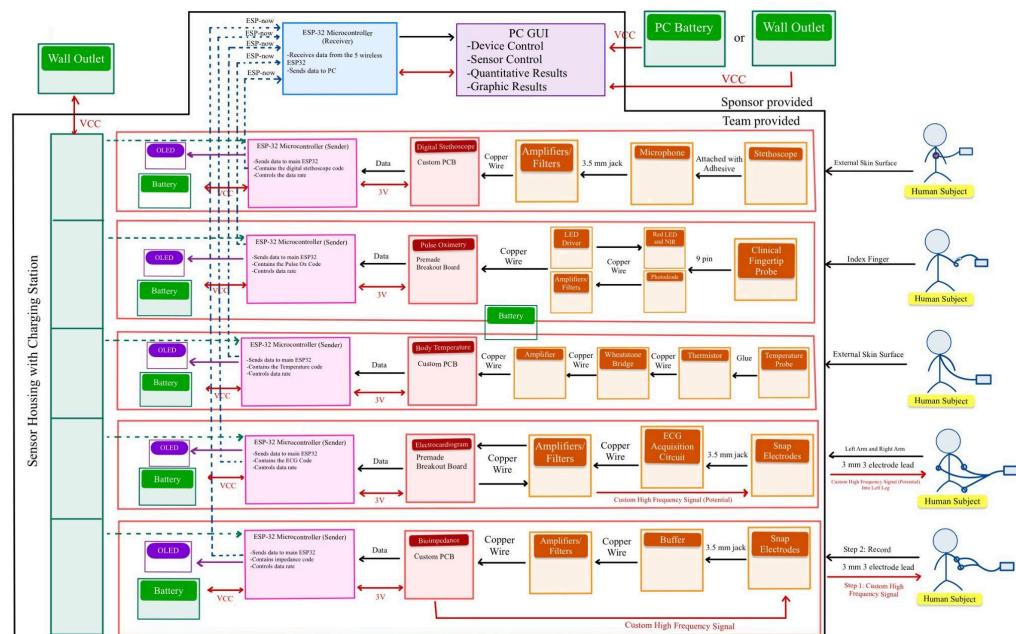


Figure 2.2.1: System Block Diagram for the MediBrick 2000.

2.3 MINIMUM VIABLE PRODUCT 1

The MVP1 for this project is described as the basic working function of each of the sensors. The goal of this MVP1 is not to have accurate sensors ready for implementation, but to prove the design of the sensor by receiving data that is generally correct from the sensors. This plan was agreed upon by the sponsor, who stated that above integration, usability, and accuracy, the sensors must be able to operate on a basic level. As such, the requirements put forth for MVP1 focus on the subsystem of each sensor module in isolation, and include the following System Requirements located in the System Requirement document in TDP 4.2: SR 4.2.1.1, SR 4.2.1.3, SR 4.2.1.4, SR 4.2.1.5, SR 4.2.1.6, SR 4.2.1.7, and SR 4.2.1.9. The datasheets verifying those requirements verified via Test or Inspection are located in TDP 3.4.1, while the requirements verified with Analysis are located in TDP 4.6.1, TDP 4.6.2, and TDP 4.6.3. As shown in the above mentioned sections, each requirement for MVP1 was met, proving that the general design of each sensor module was correct, with additional effort needing to be put forth to increase the accuracy of each module.

2.4 MINIMUM VIABLE PRODUCT 2

The MVP2 for this project has been identified as the rest of the functions of the system, including the improvement of sensor accuracy and response, the integration of sensor outputs and functions into a central Graphical User Interface, the integration of the physical systems into manufactured PCBs and housing units, and the demonstration of the ability of the system to safely operate within expected laboratory conditions.

The Tests and Inspections required to prove MVP2 that have been performed are displayed below in TDP 3.4.2. More will be added as this project progresses.

2.5 IMPACTS

The proposed biomedical sensor array has the potential to have a significant impact on various stakeholders and users including students, faculty and staff etc.

The primary beneficiaries of this project are the students in the medical laboratory classes within the college of biomedical engineering at the University of Arizona. They will gain access to the comprehensive and cost-effective sensor array that enables them to collect biological data in the hands-on learning environment. The system's user-friendly design and integrated software will make it accessible for students to measure and interpret data related to ECG, body fat and water composition, blood oxygen, sound and temperature. The hands-on experience contributes to their practical understanding of biomedical concepts.

Beyond educational purposes, researchers within the field of biomedical engineering can benefit from this sensor array for data collection in their studies. The integration of multiple sensors in a single package offers a versatile tool for various research applications. The

open-source nature of the project further promotes collaboration and customization, allowing researchers to adapt the system to suit their specific needs.

The department, represented by Dr. Urs Utzinger, serves as a key stakeholder and will benefit from the successful implementation of the sensor array. The project aligns with the department's goals of advancing education and research in biomedical engineering. The availability of such a sensor array enhances the department's capabilities and resources for teaching and research purposes.

The project indirectly impacts the open-source community interested in microcontrollers and single-board computers. By providing an open-source and open-hardware solution, the project contributes to the collective knowledge and resources available to the community. This may lead to further innovations and collaborations within the open-source hardware and software development space.

The emphasis on creating a cost-effective sensor array is noteworthy. By keeping the overall cost of the system under \$300, the project makes advanced biomedical sensors more accessible. This affordability can potentially extend the use of such systems to other educational institutions or settings with budget constraints, thereby democratizing access to healthcare education tools.

In summary, the impact of the proposed biomedical sensor array extends to students, researchers, the academic institution, and the broader open-source community, fostering education, research, and collaboration in the field of biomedical engineering. The project's success would contribute to advancements in healthcare education and research methodologies.

3.0 SYSTEM VERIFICATION PLAN

3.1 SYSTEM VERIFICATION OVERVIEW

The verification of the system requirements listed in TDP 4.2 will occur based on the Verification Flow Diagram in TDP 3.2. System Requirements have been assigned the verification methods shown in the System Requirement Verification Matrix in TDP 3.3. Four verification methods are possible, being Test, Analysis, Demonstration, and Inspection; a system requirement may be assigned any number of verification methods if the verification method logically fits with the requirement, though for this project, only two verification methods have been assigned to each system requirement. The Test verification method involves exposing the system under scrutiny to specific conditions to trigger a specific, known response, such as exposing the temperature sensor to a specific temperature and measuring the resulting reading. The Analysis verification method involves performing calculations and producing models to predict if the system will meet the requirement, such as calculating the weight of the system based on the weight of part, the volume of the system, and the density of the material it is made of. The Demonstration verification method involves demonstrating that the system can do a particular action, such as operate within certain temperature ranges and humidity levels. The Inspection verification method involves taking simple measurements of the system, such as measuring the

size of the overall system to ensure it is no larger than a particular size. The verification procedures of requirements listed with Test and Inspection verification methods in TDP 3.3 are located in the Acceptance Test Procedures document located in TDP 4.3, and includes the procedures of verification as well as the Test and Inspection datasheets; completed Test and Inspection datasheets are located in TDP 3.4. The verification of requirements listed with Analysis verification methods in TDP 3.3 is located in TDP 4.6, and includes the verification of requirements with a verification method of Analysis as well as any models that have informed the design of this project. The verification of requirements listed with Demonstration verification methods in TDP 3.3 is not included in this document due to the extreme simplicity of the verification and the rarity of the method in TDP 3.3.

3.2 SYSTEM VERIFICATION FLOW DIAGRAM

Below is the System Verification Flow Diagram, located in Appendix 5.8. This diagram shows the order of System Requirement verification that must occur for this project, as well as what verification has already occurred, and when incomplete verification is expected to be completed.

3.3 SYSTEM REQUIREMENT VERIFICATION MATRIX

The System Requirement Verification Matrix is shown below in Appendix 5.7. This table displays a condensed version of the System Requirements shown in TDP 4.2, as well as the Assy that needs to be verified for that requirement, what method of verification is required, what limit or condition needs to be met for verification, whether or not the verification has been passed and by what margin, and any important notes. For more details on each requirement and the verification method, refer to TDP 4.2 and TDP 4.3.

3.4 EVIDENCE OF VERIFICATION

3.4.1 MVP1 VERIFICATION

As stated in TDP 2.3, the MVP1 verification focused on testing basic sensor function to ensure that the basis for each sensor's design was correct. The verification proof for MVP1 is shown by the datasheets displayed in Appendix 5.9, where it is shown that the System Requirements under investigation for MVP1, listed in TDP 2.3, are passed.

3.4.2 MVP2 VERIFICATION

MVP2 verification focused on verifying the rest of the System Requirements. The verification proof for MVP2 is shown by the datasheets displayed in Appendix 5.15, where the System Requirements requiring Test or Inspection verification not proven for MVP1 are listed. For the Analysis that has been performed, refer to TDP 4.6.8.

3.5 STANDARDS REFERENCED

Various standards and guidelines were followed over the course of the project. Such standards were incorporated into the System Requirements of the project, and informed the engineering design created during the project. These standards and requirements are as follows:

- **ISO 13485 Compliance - Medical Devices:** This is the harmonized standard for the medical devices industry that contains a set of standard quality management systems that are internationally agreed upon. Due to the time restrictions of this project, the team will only focus on this standard's risk management and design control during product development.
- **IEC 60601-1:** This standard contains the essential performance and basic safety requirements for medical-related electrical equipment. This ensures that no failures relating to, but not limited to, electrical, thermal, or function will cause an unacceptable risk to its users.
- **45 CFR 46:** Also referred to as the “Common Rule”, this is the HHS standard for human subjects in research. This standard requires that all participants provide consent before getting tested, which in this case by the sensor board.
- **IP 21:** IP standards provide information relating to the ability of a system to be resistant to intrusion from objects and water.
- **ACGIH:** Organization that provides guidelines for the maximum concentration of chemicals in contact with an individual.

4.0 DESIGN DOCUMENTATION

Below in this section is the design documentation necessary to manufacture this project. Parts and documents are arranged within the IDL in TDP 4.1. Design requirements and verification are discussed in TDP 4.2 and TDP 4.3. The hardware designs, such as the housing schematics and PCB designs, are discussed in TDP 4.4. The software design is discussed in TDP 4.5. The analysis required to prove verification, as well as the analysis that informed design decisions, is located in TDP 4.6.

4.1 INDENTURED DOCUMENT LIST

The Indentured Document List in Appendix 5.13. This document includes a list of all the main components of the system. The IDL includes a dedicated section for each subsystem listed on the system architecture diagram, located in Appendix 5.14.

4.2 SYSTEM REQUIREMENTS DOCUMENT

The system requirements for the proposed biomedical sensor array encompass both hardware and software aspects. These requirements are crucial for the documentation to ensure clarity and facilitate successful implementation of the device.

In the domain of hardware, the system demands specific attributes for optimal functionality. The chosen microcontrollers or single-board computers must exhibit compatibility with widely used counterparts, ensuring a harmonious integration process. Equally important is the requirement for these platforms to feature appropriate interfaces, seamlessly connecting with sensor boards to establish a cohesive hardware framework.

The sensor boards, serving as the core of the system, are intricately designed to incorporate five distinct sensors: ECG, body fat and water composition, blood oxygen, sound, and temperature. Noteworthy features include the integration of a standard nine-pin clinical pulse oximeter for precise blood oxygen measurement, microphones for accurate sound measurement, and the utilization of thermistors, thermocouples, and an RLC circuit for temperature measurement. Additionally, electrodes are strategically positioned for skin impedance measurement, creating a comprehensive sensor suite.

Reliability in power supply is paramount for sustained functionality. Microcontrollers or single-board computers are expected to be equipped with dependable power supplies, seamlessly connecting to the sensor boards to ensure an uninterrupted flow of power throughout the system. To facilitate prototyping and testing, a development board or boards are deemed indispensable. These boards serve as secure mounting platforms for sensor components, providing a structured foundation for the iterative development of the electronic system.

In the realm of software, the system imposes specific criteria to ensure efficient operation. The user interface should be user-friendly, accessible via personal computers, with the ability to interface seamlessly with multiple sensors simultaneously. Clarity and intuitiveness in design are prioritized for ease of use. The software should be capable of activating, recording, and displaying data from each sensor. It should support graphical interpretations of measured parameters, enhancing the user's ability to comprehend and analyze the data effectively.

Connectivity requirements include the ability to connect to personal computers or laptops, facilitating seamless data transfer between the sensor array and external devices. Furthermore, the implementation of measurement algorithms is essential, converting raw sensor data into meaningful measurements. Specific algorithms tailored for each sensor type, such as impedance to body fat and water content or ECG signal filtering, contribute to the system's efficacy.

The delineation of system boundaries is crucial for defining the operational scope. Clear physical interfaces are specified, ensuring well-defined connections between the power supply, microcontrollers, and sensor boards. Standardized interfaces for each sensor type contribute to the system's cohesion. On the software front, user interaction is limited to personal computers, with designated data reading and display interfaces for one or multiple sensors.

The system's functional environment is expected to encompass laboratory, educational, and research settings, operating optimally in dry, room temperature conditions. Additionally, water resistance is mandated for sensor components, considering their interaction with the human body. Charging capability for sensor modules within the functional environment during non-use is also a prerequisite.

Several constraints govern the system's parameters. Size and cost considerations dictate that sensor modules fit within the footprint of microcontrollers or single-board computers. The complete sensor array is required to cost less than \$300. Ease of replication is emphasized, with the system organized to facilitate straightforward replication by students. Comprehensive instructions and documentation further support replication purposes. Durability is a key constraint, with the system expected to withstand three years of light use. Components are mandated to be durable and reliable. Power independence is specified, necessitating microcontrollers or single-board computers capable of operation without a direct connection to a wall outlet.

By documenting these comprehensive system requirements, stakeholders, developers, and users will have a clear understanding of the specifications and expectations for the successful implementation of the biomedical sensor array project.

For more details, the full System Requirements Document can be found in Appendix 5.1.

4.3 VERIFICATION DOCUMENTATION

The Verification Procedures as well as the datasheets needed for this project are located below in the Acceptance Test Procedures document in Appendix 5.2. The document outlines the procedures needed to verify the System Requirements verified via tests and inspections. The procedures outlined therein should be followed in the order described in TDP 3.2. Below are general descriptions of the tests and inspections.

The first five groups of tests outline procedures to verify the proper function and performance of the individual sensors, and are located in ATP 1.0, ATP 2.0, ATP 3.0, ATP 4.0, and ATP 5.0. The Temperature Module will be tested for range and accuracy, ensuring the sensor will be useful. The Sound Module will be tested for its accuracy and range, ensuring the microphone can pick up the sounds of a heart. The Pulse Oximeter Module will be tested for its accuracy when measuring heart rate and the signal to noise ratio of the signal, ensuring the sensor works accurately and with minimum disturbance. The Skin Impedance Module will be tested for its range and accuracy, ensuring it can measure the proper percentages of body fat and water content for the individual being tested. The ECG Module will be tested for its signal quality, ensuring that the graph returned by the sensor looks similar to the QRS-complex graph in Appendix 5.5 and that the signal is without excessive noise. Through these tests, the baseline function of the sensor modules will be verified, ensuring that the sensors themselves work as intended.

The second two groups of tests outline procedures to verify the durability of the system to the conditions it will operate in, and are located in ATP 6.0 and ATP 7.0. The first test is the IP Rating Test, where the housing will be tested to ensure that users are unable to stick their fingers

into the housing. This test is to test the safety of the device by ensuring the users cannot touch the electrical components when the case is closed. The second test is the Probe Chemical Resistance Test, where the temperature probe will be tested to see if it can withstand isopropyl alcohol exposure; only the temperature probe is being tested as only the temperature probe has the ability to enter the body of users. If the probe can withstand prolonged exposure without any physical damage or loss of signal quality, then the test is passed and the commonly used cleaner can be used on the probe.

The third group of tests outlines the procedures to verify the ability of each sensor module to operate independently of the Charging Module, and are located in ATP 8.0. These tests are important as the ability of the sensor to operate apart from the Charging Module is one of the ways in which the user will be protected. Several sensors utilize potentially dangerous electrodes, so to avoid unlikely catastrophes with those sensors, their circuits must operate physically isolated from all other electrical devices. These tests are simple, involving charging the batteries of each sensor module with the Charging Module, then disconnecting the sensor modules and monitoring the output data with the Receiver Module; if the sensor module being investigated continues transmitting data over the three hour test period, the test on that module is a success. The ability of the sensors to operate for the whole duration is supported through the analysis located in TDP 4.6.6, though an official test to ensure this is possible is still required to verify this ability.

The first two groups of inspections outline the procedures to verify that certain design parameters have been met, and are located in ATP 9.0 and ATP 10.0. These inspections verify that the design points of being easy to carry and roughly the size of a shoebox are met, two requirements posed by the sponsor. These inspections are simple, involving placing the completed system on a digital scale to ensure it does not exceed the limit of fifteen pounds, and measuring the sides of the completed system to ensure that it does not exceed the required 35.5-cm by 25.4-cm by 12.7-cm. The system passing these inspections are supported by the analysis located in TDP 4.6.4 and TDP 4.6.5, though the inspection is required to prove these requirements are met.

The second five groups of inspections outline the procedures to verify the user safety of the system, and are located in ATP 11.0, ATP 12.0, ATP 13.0, ATP 14.0, and ATP 15.0. These inspections include Electrical Safety, Privacy Protection, Maximum Bioimpedance Current, Maximum ECG Current, and Medical Device Standard inspections; they are required in order to ensure that the system is generally safe for users. The Electrical Safety Inspection involves inspecting the completed system to ensure that the system does not have any exposed and uninsulated components that could prove dangerous to users. The Privacy Protection Inspection involves inspecting the GUI and saved data to ensure that information that could identify an individual whose physiological data is being measured is not present. The Maximum Bioimpedance Current Inspection and the Maximum ECG Current Inspection involve measuring the current across the electrodes of the Skin Impedance Module and the ECG Module with a DMM to ensure that the current through the user will not exceed 10 μ A. The system passing these inspections is supported by the analysis located in TDP 4.6.9 and TDP 4.6.10, though with the danger of harming the user posed by these two sensors, passing this inspection is crucial towards proving the safety of the system. The Medical Device Standard Inspection is an inspection to ensure the system meets the safety standards outlined in IEC 60601-1, and due to

the many other safety standards of this project, amounts to ensuring all other safety standards have been met. All of these inspections are necessary to ensure that the system will be safe to use, with little risk of harming the user.

4.4 HARDWARE DRAWING PACKAGE

4.4.1 HOUSING DRAWINGS

The drawings consist of the general version of the module and the charging station, each are in two parts. The general module has a bottom half in which it houses the battery within the incomplete rectangle, the ESP which will rest on the elevated platform next to the charging port, the platform has an extended platform that the bottom of ESP rests on with velcro so as not to require soldering.. The openings on the bottom half are for the charging port, previously mentioned, the sensor port, and the OLED slot. Along the edge of the bottom half of the module, there is a ridge half the width of the wall and raised 2mm. In the ridge are four indentations, two on opposite sides of the OLED, one on the side with the charging port, and one on the side of the button slot, both of the latter two are near the middle of the ridges. Inside the hollow body of the module, against the ridges are angular bumps meant to diffuse force so the indentations do not crack as easily when used. The indentations match with protrusions on the top half of the module meant to lock the module together without another form of adhesion.

The plug port was fitted for a magnetic charger so we could have an easy break-away from the charger and the module. This limits the potential damage of the cables and ESP. The sensor slot was put on the opposite side to the OLED and takes up a majority of the side both top and bottom. The slot is universal to any sensor and a slide will be put in when the sensor's placement is determined by the set-up. The ESP platform was made so the ESP will meet near the center of the charging port. The battery slot is to prevent sliding from a battery of approximate size when it is held in place with an adhesive. The OLED slot was to house the OLED and keep it close to the ESP to minimize the amount of wiring inside for it. The button slot is opposite of the charging slot and has a platform inside to allow the button to remain mostly internal while still allowing use. A vent has been put between the button platform and the ESP platform to aid in heat dispersal. The drawing is in appendix 5.12.1.

The top half of the module is primarily for the PCB. This has the other halves of the sensor slot, the charging port, the OLED slot, and the button port previously mentioned. On the top half of the module, there are raised feet, this will elevate the PCB from the flat of the casing. The feet are rounded so there will not be sharp corners to scratch into or otherwise damage the PCB. The feet are stationed near a center-point closer to the sensor slot, equidistant from each other. Near the corners of the feet set up, equidistant from the feet and each other, there are four pilot holes, these holes will be used to melt in brass female knurled inserts as to screw in the PCB so it rests, unbent on the feet. The screws will prevent the PCB from falling from its position on the top half. The top half of the module has a cut in the inner half of the half 2mm deep, in the positions matching the indentations of the bottom half of the module are triangular protrusions that lock into the indentations of the bottom half of the module. From the button platform to the charging plug, a vent is placed to add in heat dispersal. The drawing is in appendix 5.12.1.

Each Sensor Module has an insert meant to seal the module from the outside. Each sensor has its own insert with a unique hole for the sensor probe and unique label to distinguish the modules from each other. The drawings for the inserts are located in Appendix 5.12.13.

The charger is split into two parts; the main body and the base. The base of the charging station has ridges near the edges that have angled protrusions meant to clip into the main body. The base has a sloped part of a port for the charging cable of the power strip/surge protector. The drawing is in appendix 5.12.2

The main body of the charging station has slots with holes in the center of the slots, the slots each hold a module with the holes for the magnetic charging cables to come up and connect with the plugs in the module. On the side of the main side is an open faced container, this container will hold the sensors so the sensors won't drag, snag, or be wrapped around the module or charging station. The main body is hollow inside to cover the power strip/surge protector, the inside has indents along the bottom with a few deeper indents for the base to clip into. The main body has the majority of a port for the cable of the power strip/surge protector. The drawing is in appendix 5.12.2

The Receiver Module is in two halves as all of the other modules. As with all of the other modules, it is designed to easily snap together to protect the microcontroller within. The bottom part of the module has two screw holes for an ESP32-S3 to be secured within, identical to the Sensor Module. The Receiver Module is smaller than the Sensor Module, designed to only contain the ESP32-S3, and has a port to allow a USB-A to USB-C cord to connect to the ESP housed within. The drawings for the module are located in Appendix 5.12.14.

4.4.2 TEMPERATURE SENSOR DRAWINGS

The Temperature Module has two drawings governing its manufacturing and assembly: the Temperature Module Circuit Schematic and the Temperature Module PCB Diagram. The Temperature Module Circuit Schematic shows the circuit diagram of the sensor; it is located in Appendix 5.12.3. The Temperature Module PCB Diagram shows the layout of the components on the PCB, along with the labels of the PCB and the holes that will be drilled in it for mounting; it is located in Appendix 5.12.4.

The circuit diagram for the Temperature Module is very simple as the sensor does not require physical filtering to condition the signal into a usable reading. The circuit is a simple wheatstone bridge connected to 3V DC power supply and GND. One branch of the wheatstone bridge contains R1 and R2, which are two 10 k Ω resistors; the other branch contains a 10 k Ω thermistor and a 10 k Ω resistor. A wire branches from between the two resistors of the first branch to allow for the voltage of that branch to be measured at A0. A similar branch is located between the thermistor and the resistor that leads to A1.

The circuit diagram was recently redesigned by the sponsor, resulting in the current circuit diagram. The previous design utilized a Two Pin Vertical Male Header to disconnect the circuit to measure the exact resistance values of the resistors. A Female Jumper could then be used to bridge the gap between the two pins, allowing for the circuit to be closed when the sensor was in operation. This is necessary because, as discussed in TDP 4.6.9, knowing the exact

resistance of each resistor is crucial. The aforementioned jumper system was discarded in the redesign, shifting to a series of Test Points to measure the resistance values and using Solder Jumpers to disconnect the circuit components from the leads. This shift was a suggestion of the sponsor, as he stated that because the calibration measurements would only need to be done a few times during the PCBs projected lifespan, Solder Jumpers would be easier to implement and less expensive, allowing the system cost to be reduced slightly in exchange for increased effort needed during calibration. Another change made at the sponsors request is that the thermistor now connects to the PCB via a 3.5 mm aux port. This was added as the sponsor wanted each sensor to be easily removed from their respective PCBs. Another change involves the addition of two decoupling capacitors, one $10\ \mu F$ and one $0.1\ \mu F$, linking the 3V power supply directly to the GND in order to filter out power line interference. The final change is that another circuit branch was added outside of the main sensor circuit; this branch contains an LED and a $1\ k\Omega$ resistor in order to indicate when the board is powered. ECRs were files for these changes, and are located in Appendix 5.16.2 and Appendix 5.16.4.

The PCB diagram for the Temperature Module contains the same circuit with the wiring placed for PCB creation. The important dimensions are listed on the diagram in Appendix 5.12.4 for inspection. The connections of the components to the board have shifted from through-hole solder joints to solder pad connections, allowing the smaller PCB components to be used. As thermal interference can be high within the housing with the ESP32-S3 and the battery located directly below the PCB, the resistors have been moved to be right next to each other to ensure that they are roughly the same temperature to mitigate a drift in the resistance due to temperature. The 3V hole, GND hole, A0 hole, and A1 hole are through-hole solder holes to allow for the PCB to be wired to the ESP32-S3. Four 3.5 mm diameter holes are placed in the corners of the PCB to secure the PCB to the lid of the Sensor Housing.

4.4.3 DIGITAL STETHOSCOPE DRAWINGS

The Digital Stethoscope module circuit was designed to pre-amplify and filter the audio signal, located in Appendix 5.12.10. The MAX9814 includes a customisable pre-amplification stage that goes up to 1000x and DC offset, which is 1.25 V. Then, the second stage is a second order Butterworth low pass filter with a cutoff frequency discussed in section 4.6.2. The output is sent to ES8388, where the analog signal is quantized. Finally, the digital signal is sent to the ESP32-S3.

4.4.4 PULSE OXIMETER SENSOR DRAWINGS

The pulse oximeter module is designed around the AFE4490 IC chip which is an Integrated Analog Front End (AFE) for Pulse Oximeter. By following the guidelines and examples of the datasheet of the AFE4490 the main schematic was created. One of the requirements for the pulse oxi sensor is for it to use the DB9 connector which is a standard in the industry. The schematic includes this type of connector so different standard pulse oxi sensors can be integrated through the connector. The AFE4490 chip is already low noise since it includes the necessary filters for the pulse oximeter to function accurately.

4.4.5 BIOIMPEDANCE SENSOR DRAWINGS

The bioimpedance sensor circuit for this project is heavily inspired by the evaluation board of the AD5933, which is the impedance converter, along with the impedance circuitry from an online tutorial. The drawings for this sensor can be seen in Appendix 5.12.8 and 5.12.9. However, this PCB is unique due to its ability to switch between using two 2-lead electrodes to only one 2-lead electrode. This can come in handy depending on what sample the user wants to test the impedance sensor on. This apparatus is done using jumpers within the PCB itself.

Not only can this PCB switch between using one or two electrodes, but it can also use a calibration resistor. This is done through an analog switch which the user can choose if desired. If the user would like to use a calibration resistance, an input will be needed in the GUI.

4.4.6 ECG SENSOR DRAWINGS

The ECG module that was decided to be used for this project is the ECG pre-amplifier board from SparkFun which takes advantage of the AD8232 ECG integrated circuit. The schematics for this board can be seen in Appendix 5.12.5. This ECG board is mainly inspired by the recommended circuitry in the datasheet of the AD8232. This board contains multiple hardware filters in order for the AD8232 to capture the extremely low frequencies of the heart. Another aspect of this board are the three large resistors in series with the pins that are connected to the electrode leads. Mentioned later on, these resistors serve a role of keeping the user safe from higher than recommended currents that may potentially be injected into the body.

4.5 SOFTWARE DESIGN DOCUMENT

The Software Design Document (SDD) seen in Appendix 5.3, is a crucial blueprint for this project, providing an in-depth exploration of the device's software purpose, functionality, architecture, interfaces, libraries, protocols, and assembly intricacies. Of particular importance in the SDD is the detailed breakdown of the ESP32-S3 Feather, a vital component that serves as the backbone of the device. Within the document, every aspect is thoroughly examined, including the intricacies of the Arduino codes specifically crafted for each sensor incorporated into the device. These codes are essential in ensuring the seamless integration and performance of the sensors, ultimately contributing to the device's overall effectiveness.

4.6 MODELS

The following sections contain explanations for the models and analysis performed towards the beginning of this project, as well as changes that have been made to the analysis on models as the project has progressed. Such analysis was performed on every System Requirement with the verification method of Analysis, as well as some additional analysis performed to inform some decisions during the project. A summary detailing the analysis

predictions and margins is located below in Appendix 5.17; such analysis that was performed but is not directly related to a System Requirement does not appear in the chart in Appendix 5.17.

4.6.1 STETHOSCOPE SENSITIVITY MODEL

The heartbeat sounds have a significantly low amplitude, which hinders their detection and further processing. For that reason, we base our analysis on, “Frequency responses of conventional and amplified stethoscopes for measuring heart sounds,” located in Appendix 5.10. Even though the paper does not fully explore the amplitude response of heartbeat signals, it provides a useful insight. Their results show that the minimum signal amplitude varies in the range of -40 to -80 dB. Therefore, the microphone utilized in this sensor must have a sensitivity within such range, and the circuitry should provide an amplification of at least 100x (40 dB).

4.6.2 STETHOSCOPE AUDIO MODEL

The audio signals are particularly fascinating and sometimes hard to analyze, because they are made of a wide range of frequencies that characterize the sound. In the process of digitization, the engineer needs to follow the Nyquist Sampling Theorem. This theorem states that the minimum sampling frequency for a digital signal should be at least double of the bandwidth of the signal, so it can be reconstructed with no aliasing nor distortion, shown in Figure 4.6.2.1. The industry standard for the digitization process of audio signals is a sample rate of 44100 Hz, which for this application seems more than enough. However, we intend to display a real-time audio recording while having hardware limitations such as ESP32-S3 Feather maximum baudrate, which limits the amount of information that can be sent in a transmission line. Therefore, we needed to investigate the frequency bandwidth of a typical heartbeat.

Relationship of Nyquist frequency & rate (example)

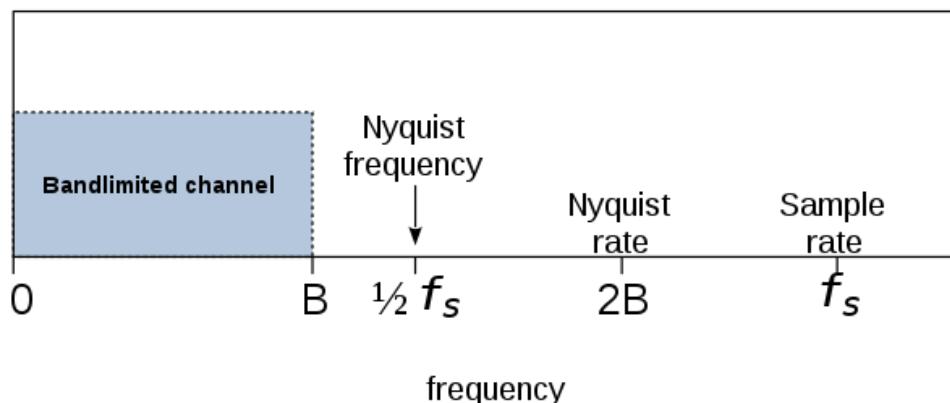


Figure 4.6.2.1. Nyquist Sampling Theorem.

We base our analysis on, “Frequency responses of conventional and amplified stethoscopes for measuring heart sounds,” located in Appendix 5.10. According to Alanazi, normal heartbeat sounds have a bandwidth of 200 Hz, while normal lung sounds have a bandwidth that goes up to 1050 Hz, shown in Figure 4.6.2.2. Therefore, we expect our signals to have a bandwidth of 1050 Hz. This value gives us a threshold for the cutoff frequency of both

analog and digital filters: A frequency within the range of 1050 and 1100 Hz. In a similar manner, our minimum sampling frequency should be 2200 Hz, which is in line with the technical limitations.

For frequency analysis and calibration, we use Fast Fourier Transform (FFT). This tool converts a digital signal in the time domain to frequency domain. We also refer to “Frequency responses of conventional and amplified stethoscopes for measuring heart sounds,” located in Appendix 5.10, for the spectrum of the signal.

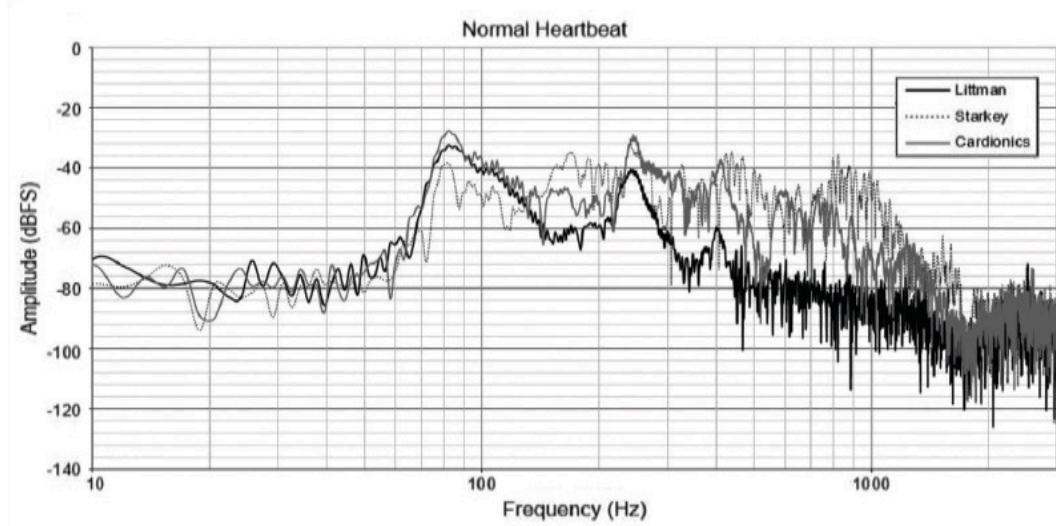


Figure 4.6.2.2. Frequency response of a normal human heartbeat. Figure 2 in “Frequency responses of conventional and amplified stethoscopes for measuring heart sounds.” (Appendix 5.10).

4.6.3 PULSE OXIMETER SIGNAL NOISE MODEL

The noise of the pulse oximeter signal is important for the accuracy of the sensor. The signal noise model is based on the SNR (signal to noise ratio). Where we observe the signal from the pulse oximeter and get the average of the signal and the standard deviation. Using the equation provided below in figure 4.6.3.1 we can calculate the SNR of the signal.

$$\text{SNR} = 20 \times \log_{10} \left(\frac{\text{Signal Average}}{\text{Standard Deviation of Signal}} \right)$$

Figure 4.6.3.1 SNR equation

Ten thousand samples are taken in order to have a consistent average reading of the signal and the standard deviation of the signal is used as the noise amplitude of the signal as shown a better visualization is displayed below on figure 4.6.3.2

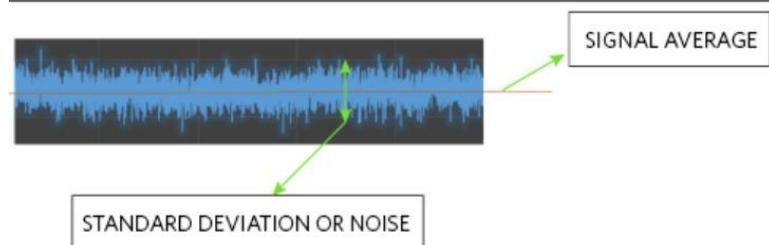


Figure 4.6.3.2 standard deviation and average of signal

With this method of measuring SNR different models of pulse oximeters can be compared and the higher the SNR is the more superior the signal will be and the sensor would have better results.

4.6.4 SYSTEM COST MODEL

When calculating the system cost model, the project sponsor has set guidelines on the total cost of replicating this device. The device's cost must align with the structure established by the Board of Regents for the three state universities in Arizona. Another factor that affects the system cost model is the product lifespan and amount of users. The sponsor and team, drawing on their experiences with sensor modules, have estimated a lifespan of three years for this project. As for the number of users, it is mandated that each device accommodates two users—one recording and the other being recorded.

With this information, we can calculate the cost. Over the course of three years, spanning six semesters with two users each, there will be a total of 12 users per device lifetime. Typically, an acceptable laboratory fee of \$50.00 to \$100.00 per student is established in the University of Arizona. However, only a percentage of this fee will be allocated to the device, as other expenses, such as laboratory supplies, also need consideration.

The initial calculation allocates 50% of the laboratory fees for covering the ongoing replacement cost of devices, with \$50 per student. This totals to an estimated cost of \$300 per device. However, a recent calculation shows that \$300 is not enough to cover one unit of the device. With this discovery, the calculations were redone with \$75 per student, and 60% of fees towards the devices. This totals to approximately \$540 towards building one unit of the device. Figure 4.6.4.1 shows the cost summary table for the completed system. An ECR was filed for this change, and is located in Appendix 5.16.3, where the final cost requirement was set at \$500 in a compromise between the sponsor and the team, as laboratory fees must also be used to pay for other materials within the class.

Total Estimated Cost for 1 Unit of the End Product

Name of Item	Quantity	Cost (\$)
Adafruit ESP32-S3 Feather	6	\$108.00
ECG Pre-Amplifier Board	1	\$21.00
Pulse Ox IC	1	\$23.00
Impedance IC	1	\$21.00
Thermistor	1	\$10.00
Microphone	1	\$8.00
Audio Codec	1	\$17.00
Stethoscope	1	\$35.00
Electrode Pads	40	\$20.00
3-Lead Snap Electrodes	1	\$7.00
2-Lead Snap Electrodes	2	\$9.00
Rechargeable Batteries	5	\$50.00
SMDs (Surface Mounted Devices) for PCBs		
dB 9-Pin Plug for Pulse Ox	1	\$2.00
0603 SMDs Pack	1	\$35.00
3.5 mm Audio Jack Connector	5	\$7.00
Housing		
PolyFlex TPU	1	\$30.00
USB Charging Station	1	\$16.00
USB-C Magnetic Wires	5	\$20.00
USB-C Magnetic Connectors	5	\$10.00
Services		
PCB Printing	N/A	\$25.00
Total Estimated Cost		\$474

Figure 4.6.4.1: Cost summary table for completed system.

4.6.5 SYSTEM WEIGHT MODEL

The model constraints, as given by the sponsor, are for weight was less than 15 lbs in totality. The density of ABS Plastic is generally $1.0 \text{ to } 1.05 \frac{\text{g}}{\text{cm}^3}$, the modules are about 0.145 kg or about 0.32 lbs each without circuitry. The charging station is about 0.503 kg or 1.11 lbs without the power strip/surge protector. This will have the system weight, without circuitry, at about 1.23 kg or 2.71 lbs. The final weight of the system with all electrical components was measured at 4.6 lbs, still meeting the required final weight limit of 15 lbs.

4.6.6 SYSTEM DIMENSIONS MODEL

The original model constraints, as given by the sponsor, are to fit within a size 14 men's shoebox, which is about 35.5 x 25.4 x 12.7 cm or 14 x 10 x 5 in inches, in totality. Originally, the maximum width was 10 cm or about 4 in, the maximum height was 14 cm or about 5.51 inches, and the maximum length was 20 cm or 7.9 inches. Several redesigns took place which altered the dimensions of the original design. The addition of a trough or bucket to hold the sensor probes increased the width from 10 cm to 19.05 cm. The length of the design was increased from 20 cm to 31.75 cm to accommodate the expansion of sensor modules. The size of the modules needed to be increased in order to accommodate the size of all of the sensor probes and the circuitry, which thus required the housing to be expanded to fit the larger sensor modules. Finally, during final assembly, it was found that the wires of the charging station could be accommodated with the current interior height of the space the wires went in. As such, the overall height of the design was increased from 14 cm to 19.05 cm to fit all of the wires. As this increase in height was beyond the original design specifications set by the sponsor, an ECR was filed by the team and approved by the sponsor, increasing the overall Dimensions System Requirement to 35.5 cm x 25.4 cm x 20.7 cm; the ECR is shown in Appendix 5.16.5.

4.6.7 INTERNAL POWER SUPPLY MODEL

The internal power supply depends on the battery consumption of one sensor module. Each module at worst case power consumption with it processing sensor data and wifi functionally is on the module would consume about 340mA. The module is required to last about 3 hours on a single charge. A 1200mAh battery will be used for each module. Calculating the hours (1200mAh/340mA) will result in battery life of 3.5hrs.

4.6.8 EXTERNAL POWER SUPPLY MODEL

Used on (Assy)					Current		
Use On		Part	part no.	Supplier	Volts	Amps (mA)	Watts
100300	Temperature Assy	ESP32 S3	5323	Adafruit	3.6	340	0.612
100400	Stethoscope Assy	ESP32 S3	5323	Adafruit	3.6	340	1.224
100500	Pulse Ox Assy	ESP32 S3	5323	Adafruit	3.6	340	1.224
100600	Bio Impedance Assy	ESP32 S3	5323	Adafruit	3.6	340	1.224

100700	ECG Assy	ESP32 S3	5323	Adafruit	3.6	340	1.224
100100	Main Housing Assy	ESP32 S3	5323	Adafruit	3.3	280	0.924
Total (Worst Case Scenario/Highest Power Consumption)					21.3	1980	6.5

Figure 4.6.8.1 Overall power consumption of system

As seen on figure 4.6.8.1 the overall power consumption of the whole system would be 6.5w. This was determined by assuming the worst case scenario that all sensors are actively processing data and wirelessly transmitting data. With these assumptions the consumption of the whole system is determined.

4.6.9 TEMPERATURE MODULE ERROR MODEL

This model did not serve the purpose of directly verifying a System Requirement is met, but instead served the purpose of informing certain design decisions of the Temperature Module circuit. This model was designed to determine some of the sources of error that will be present within the Temperature Module in order to determine their effects on the error of the system and ways that these error sources can be mitigated. Two main sources of error were identified for the Temperature Module, those being the error of the resistors and the error from the two equations relating thermistor resistance to thermistor temperature. Both models were made using an Excel sheet that compared the values given by the Amphenol Advanced Sensors MA100GG103AN 10 kΩ Thermistor datasheet, shown in Appendix 5.6, to the predicted value of the temperature reading for the test being performed across the range of temperatures the thermistor is rated for.

For the resistor error model, the datasheet temperature values were compared to temperature values calculated when the resistors of the wheatstone bridge had an error of 1% from their listed values, an error smaller than the listed error value of the resistors used for prototyping, which was 5%. The greatest possible error values were seen when the errors of R2 and R3 were opposite of each other; this occurs as R2 and R3 operate as the base of the wheatstone bridge against which the voltage of the two branches are compared, so if those two resistors are not equal to each other, a very large error is seen. The graph of this error is shown below in Figure 4.6.8.1, where the error from the unbalanced bridge averages 0.8 °C from the true value across the range of temperatures from 0 °C to 50 °C. For comparison, Figure 4.6.8.2 shows the graph of the errors with the same resistor error values, except the code knows what the exact resistance values are when calculating. The error there is negligible, meaning once the code knows the exact values, the system can easily compensate for the discrepancy. This fact informed the decision to include a detachable jumper and 2 Pin Male Header and use larger resistors connected with through-hole connections in the design of the Temperature PCB. This will allow users to disconnect the jumper, opening up the wheatstone bridge, and allowing the user to measure the exact resistance values of the resistors using a DMM. The Temperature Code then asks for the resistance values upon opening, allowing the user to calibrate the sensor outputs.

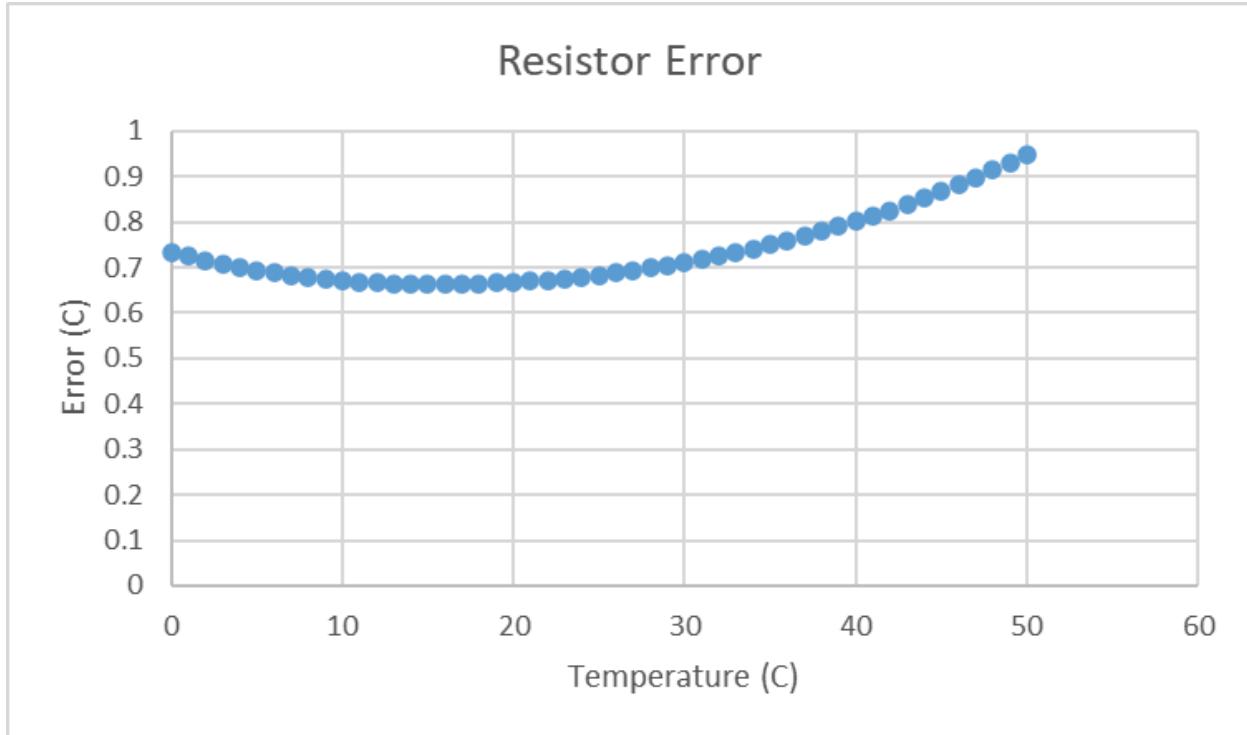


Figure 4.6.8.1: Graph of error from resistor error when $R1$ error = +1%, $R2$ error = -1%, and $R3$ error = +1%.

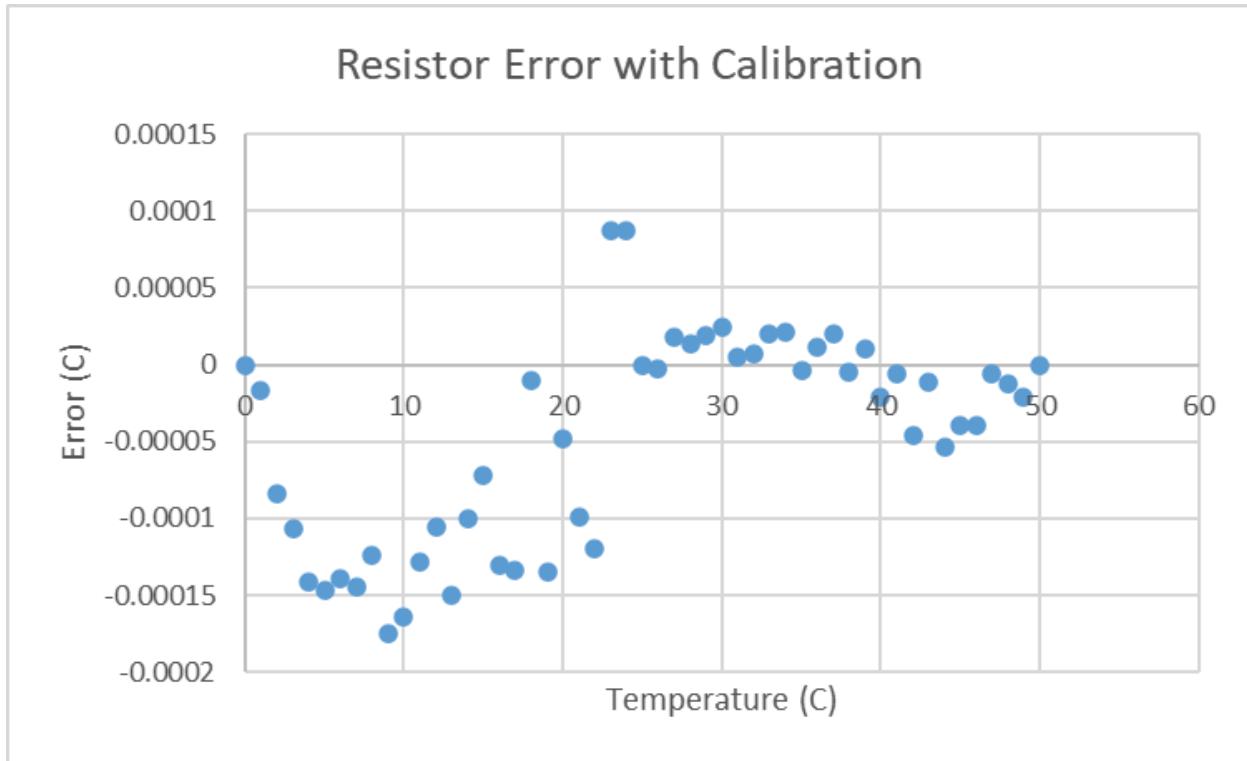


Figure 4.6.8.2: Graph of error from resistor error when code is calibrated with exact resistances.

As for the two equations that could be used to calculate temperature from thermistor resistance, the two models are called the Steinhart-Hart equation and the Beta equation, shown below:

$$T_{\text{Steinhart-Hart}} = \frac{1}{A + B * \ln(R) + C * \ln(R)^3}$$

$$T_{\text{Beta}} = \frac{1}{\frac{\ln\left(\frac{R}{R_0}\right)}{\beta} + \frac{1}{298.15}}$$

For the Steinhart-Hart equation, A, B, and C are all coefficients determined by the thermistor response curve, and R is the current resistance of the thermistor. For the Beta equation, β is determined by the thermistor response curve, R_0 is thermistor resistance at 25 °C, and R is the current resistance of the thermistor. The graphs of the resulting errors from the two equations are shown in Figure 4.6.8.3 and Figure 4.6.8.4. The Steinhart-Hart equation's error is random across the range of temperature values, but is extremely smaller, not exceeding +/- 0.0002 °C; in comparison, the error from the Beta equation is very predictable, but is much larger over the range, with the error fluctuating from - 0.5 °C at 20 °C to 2.5 °C at 40 °C. Because the error of the Beta equation was so much larger than that of the Steinhart-Hart equation, it was determined that the Steinhart-Hart equation would be used because it would not require another calibration factor to correct the temperature measurements after calculation.

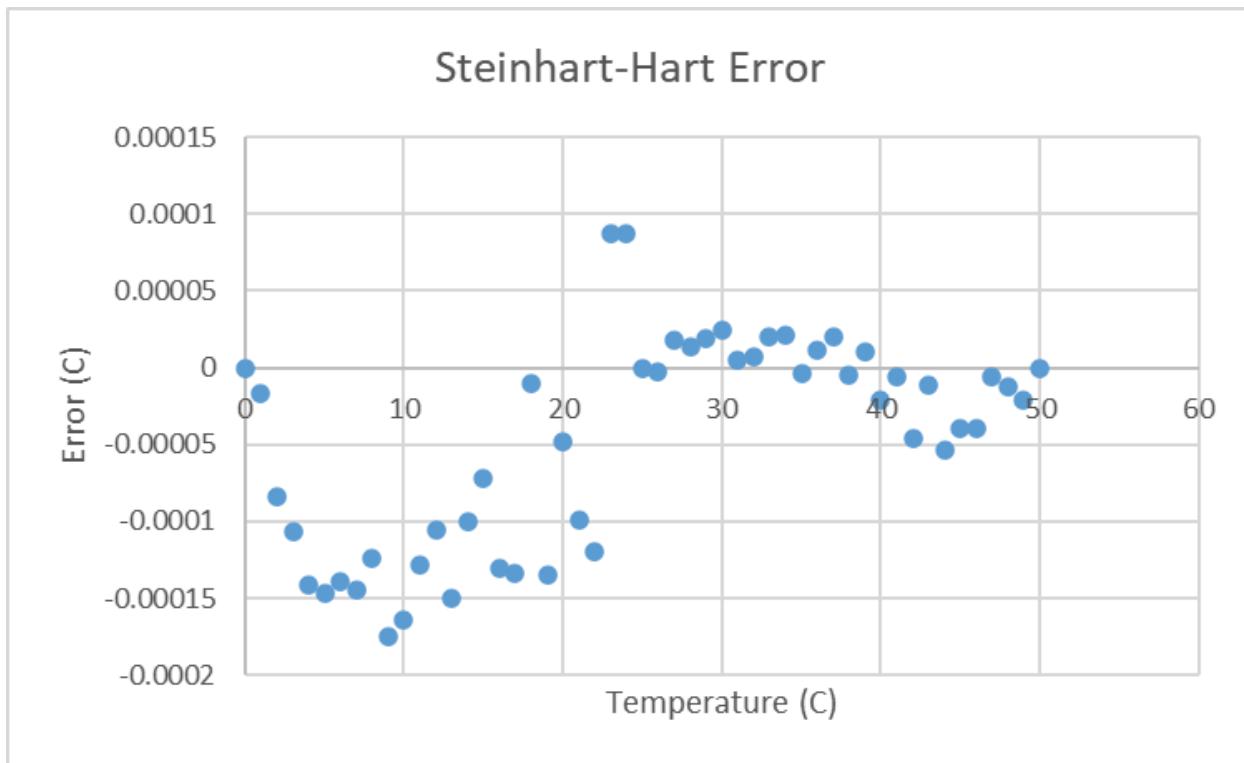


Figure 4.6.8.3: Graph of error from Steinhart-Hart equation.

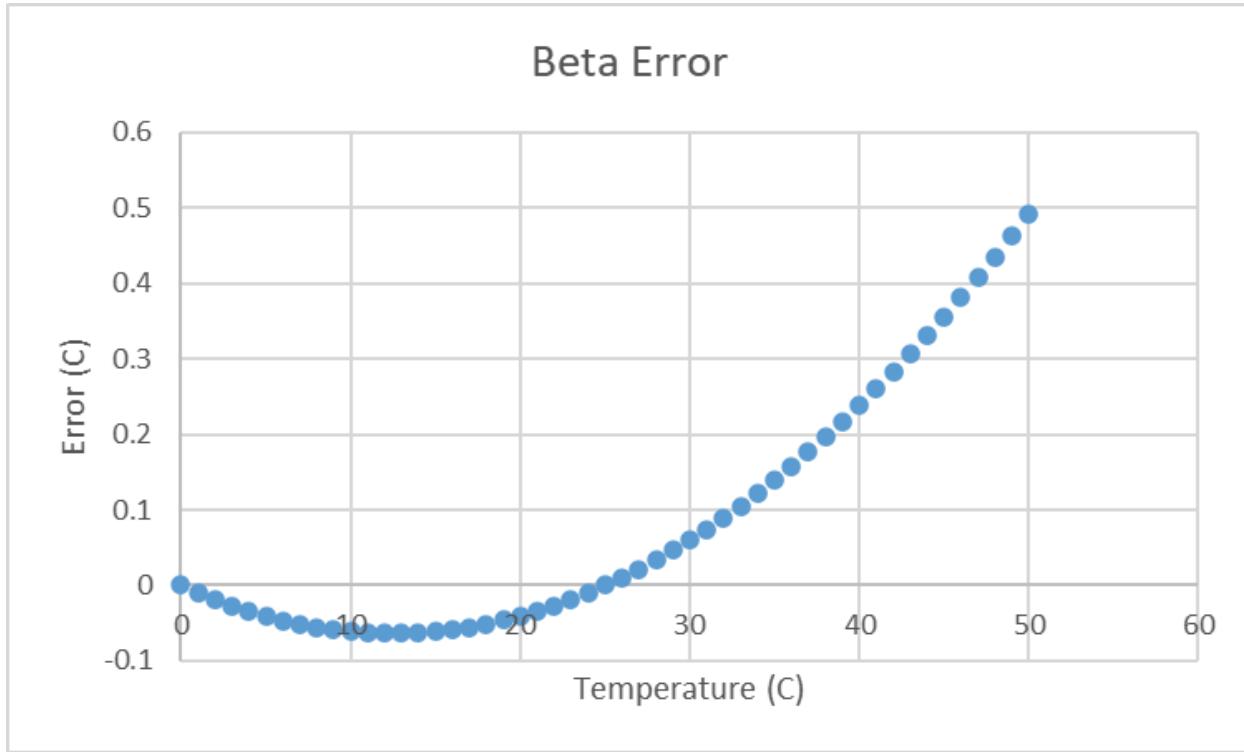


Figure 4.6.8.4: Graph of error from Beta error.

4.6.10 BIOIMPEDANCE CURRENT MODEL

The bioimpedance current model is based on the IEC 60601-1 standard, which states that for frequencies below 1kHz, the maximum AC current is 10 μ A. To follow this protocol, the impedance current is controlled through the schematics of the sensor. In the schematics, there will be a current setting resistor. It is important to pick a large enough resistor to set the current low enough to be safe. Another resistor is then connected as a feedback resistor that protects the body from excess current from the output of the op-amp. By adding these circuit designs to the bioimpedance circuitry, it assures that we comply with the industry standard for current limits.

4.6.11 ECG CURRENT MODEL

Cited in Appendix 5.11, in 1972, the AHA, in an amendment to its 1967 report, recommended an upper limit of 10 μ A for current between any patient electrode and either power line, ground, or the accessible part of the electrocardiograph. The AHA based its 1972 recommendation on the fact that the 10 μ A limit had been previously specified by the 1971 National Electrical Code, the 1971 National Fire Protection Association, the 1972 Underwriters' Laboratory, and the 1971 report of the Subcommittee on Electrical Safety of the Association for the Advancement of Medical Instrumentation (AAMI).

The maximum harmless current that the human body can withstand is 5 mA, which is significantly higher than 10 μ A. However, the AHA recommended that the 10 μ A limit not be

exceeded, even in the presence of a single fault, to address occurrences such as an insulation failure in a line-operated component, an incorrectly wired power line receptacle, a single failure in an electronic circuit, or a disconnected power line ground.

According to the datasheet of the AD8232 (ECG sensor), as a safety measure, it is best to place a resistor between the input pin and the electrode that is connected to the subject to ensure that the current flow never exceeds 10 μA .

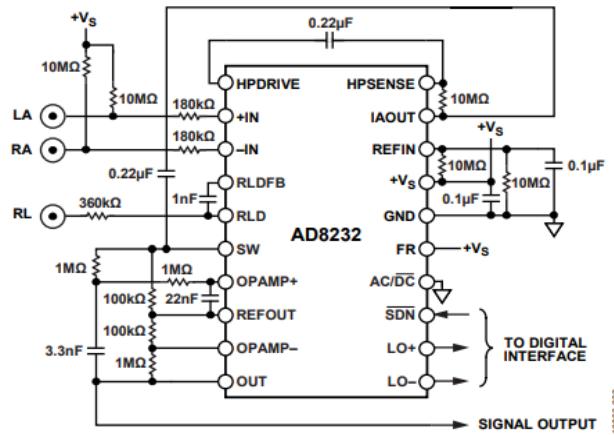


Figure 4.6.11 AD8232 Recommended Circuit

5.0 APPENDIX

5.1 SYSTEM REQUIREMENTS DOCUMENT

Refer to Other GitHub Documents:

<https://github.com/grender007/Modular-Biomedical-Sensor-Board-for-Education/tree/main/User%20Manual%20and%20Other%20Documents>

5.2 ACCEPTANCE TEST PROCEDURES DOCUMENT

Refer to Other GitHub Documents:

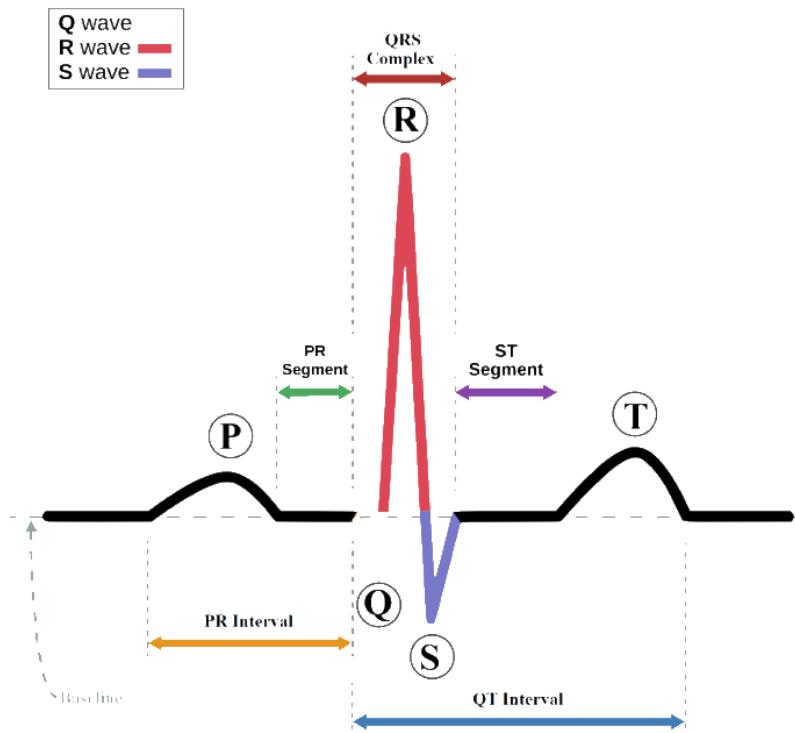
<https://github.com/grender007/Modular-Biomedical-Sensor-Board-for-Education/tree/main/User%20Manual%20and%20Other%20Documents>

5.3 SOFTWARE DESIGN DOCUMENT

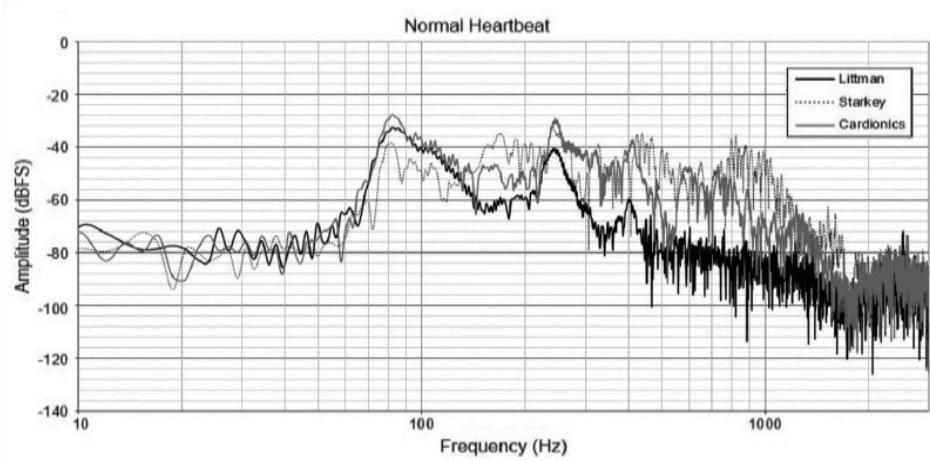
Refer to Other GitHub Documents:

<https://github.com/grender007/Modular-Biomedical-Sensor-Board-for-Education/tree/main/User%20Manual%20and%20Other%20Documents>

5.4 EXAMPLE ECG RESPONSE CURVE



5.5 EXAMPLE HEARTBEAT SIGNAL FREQUENCY RESPONSE



5.6 AMPHENOL ADVANCED SENSORS 10 KΩ THERMISTOR DATASHEET

https://www.mouser.com/datasheet/2/18/Amphenol_04022020_AAS_920_321E-1826352.pdf

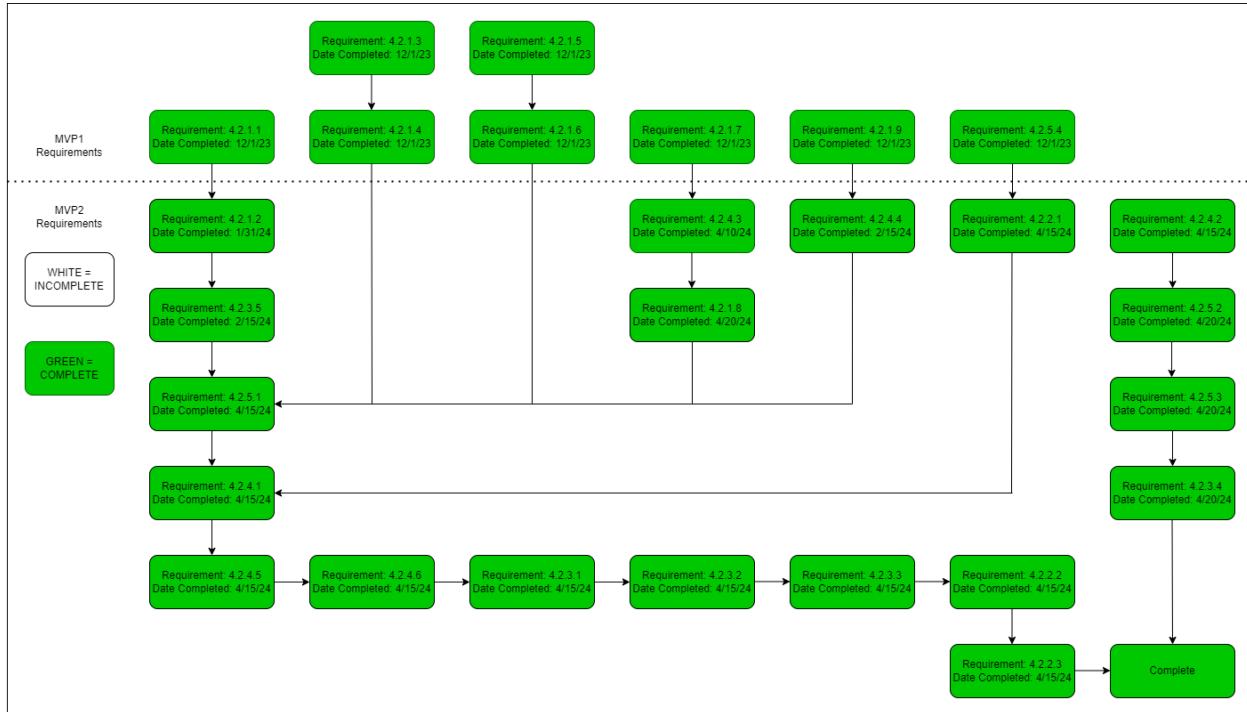
5.7 SYSTEM REQUIREMENT VERIFICATION MATRIX

System Requirement	Assy	Limit	Measured/Predicted Value	Margin	Pass/Fail	Notes
4.2.1.1: Temperature Sensor Range	Temperature Assy	(T) Limit = +/- 3.0 degrees Celsius from 20 to 45 degrees Celsius	+/- 0.4 degrees Celsius	2.6 degrees Celsius	Pass	
4.2.1.2: Temperature Sensor Accuracy	Temperature Assy	(T) Limit = +/- 0.1 degrees Celsius	+/- 0.0 degrees Celsius	0.1 degrees Celsius	Pass	Margin different than range test because correction factor from range test implemented
4.2.1.3: Stethoscope Sensitivity	Sound Assy	(T/A) Limit = +/- 10 Hz of noise from 20-800 Hz	+/-10 Hz	0 Hz	Pass	
4.2.1.4: Stethoscope Audio	Sound Assy	(A/D) Heartbeat audible, frequency spectrum similar to TDP 5.5	Heartbeat heard, frequency graph similar	N/A	Pass	
4.2.1.5: Pulse Oximeter Signal Noise	Pulse Oximeter Assy	(T/A) Limit = SNR > 15 dB	SNR > 27.9 dB	12.9 dB	Pass	

4.2.1.6: Pulse Oximeter Heart Rate	Pulse Oximeter Assy	(T) Limit = +/- 10 BPM from 50 to 180	+/- 10 BPM	0 BPM	Pass	
4.2.1.7: Skin Impedance Range	Skin Impedance Assy	(T) Limit = WC 45% to 80%, FC 5% to 40%	WC 45% to 80%, FC 5% to 40%	N/A	Pass	
4.2.1.8: Skin Impedance Accuracy	Skin Impedance Assy	(T) Limit = 5% accuracy	Accuracy = +/- 5%	0 %	Pass	
4.2.1.9: Electrocardiogram Accuracy	ECG Assy	(T/D) Limit = graph similar to TDP 5.4	Graph intact	N/A	Pass	
4.2.2.1: IP Rating	Housing Assy	(T) Limit = IP 20 standard	Protected from Intrusion of Objects >= 12.5 mm	N/A	Pass	
4.2.2.2: Operational Temperature	Complete System	(D) Limit = operates from 10 to 40 degrees Celsius	Operates in Temperature over the Range	N/A	Pass	
4.2.2.3: Operational Humidity	Complete System	(D) Limit = operates under 50% humidity	Operates in Humidities over the Range	N/A	Pass	
4.2.3.1: Weight	Complete System	(A/I) Limit <= 15 pounds	4.6 lbs	10.4 lbs	Pass	Analysis in TDP 4.6.5
4.2.3.2: Dimensions	Complete System	(A/I) Limit <= 31.75x19.05x 35.5x25.4x20.7 cm	31.75x19.05x 15.24 cm	3.75x6.35 x5.46 cm	Pass	Analysis in TDP 4.6.6
4.2.3.3: Inexpensive	Complete System	(A) Limit <= \$500	\$474	\$26	Pass	Analysis in TDP 4.6.4
4.2.3.4: Saved Data	Computer Assy	(D) Limit = can save data	Each sensor can save data with the GUI	N/A	Pass	Complete for 4/5 sensors, Awaiting Integration with Digital Stethoscope
4.2.3.5: Probe Chemical Resistance	Temperature Assy	(T) Limit = 1 hour without degradation in 70% ethanol	No physical or signal degradation	N/A	Pass	Datasheet in TDP 5.6 supports probe integrity
4.2.4.1: Electrical Safety	Complete System	(I) Limit = no uninsulated components	Meets Standard	N/A	Pass	Approval Supported by system design
4.2.4.2: Privacy Protection	Computer Assy	(I) Limit = no identifying data	No identifying data saved	N/A	Pass	Supported by current GUI function

		saved				
4.2.4.3: Maximum Bioimpedance Current	Skin Impedance Assy	(I) Limit = Electrode I <= 10 µA	8.8 µA	1.2 µA	Pass	Analysis in TDP 4.6.10
4.2.4.4: Maximum ECG Current	ECG Assy	(I) Limit = Electrode I <= 10 µA	0.25 µA	9.75 µA	Pass	Analysis in TDP 4.6.11
4.2.4.5: Medical Device Standard	Complete System	(I) Limit = IEC 60601-1 safety standards	Meets Standard	N/A	Pass	
4.2.4.6: Chemical Safety	Complete System	(D) Limit = ACGIH TLV-SL Guidelines for surface contaminants	No Hazardous Chemicals Used	N/A	Pass	
4.2.5.1: Internal Power Supply	Temperature Assy, Sound Assy, Pulse Oximeter Assy, Skin Impedance Assy, ECG Assy	(T/A) Limit = On for > 3 Hours	3.6 Hours	0.6 Hours	Pass	Analysis in TDP 4.6.7
4.2.5.2: Computer Communication	Computer Assy	(D) Limit = System can send data to user's laptop	Each sensor can communicate with the GUI	N/A	Pass	
4.2.5.3: GUI	Computer Assy	(D) Limit = GUI displays realtime data for each sensor	Each sensor can display data with the GUI	N/A	Pass	
4.2.5.4: External Power Supply	Complete System	(A) System works with 15 amp, 120 V AC power	1.98 A, 21.3 V	13.02 A, 98.7 V	Pass	Analysis in TDP 4.6.8

5.8 SYSTEM VERIFICATION FLOW DIAGRAM



5.9 MVP1 VERIFICATION DATASHEETS

Refer to Other GitHub Documents:

<https://github.com/grenger007/Modular-Biomedical-Sensor-Board-for-Education/tree/main/User%20Manual%20and%20Other%20Documents>

5.10 STETHOSCOPE SOURCE

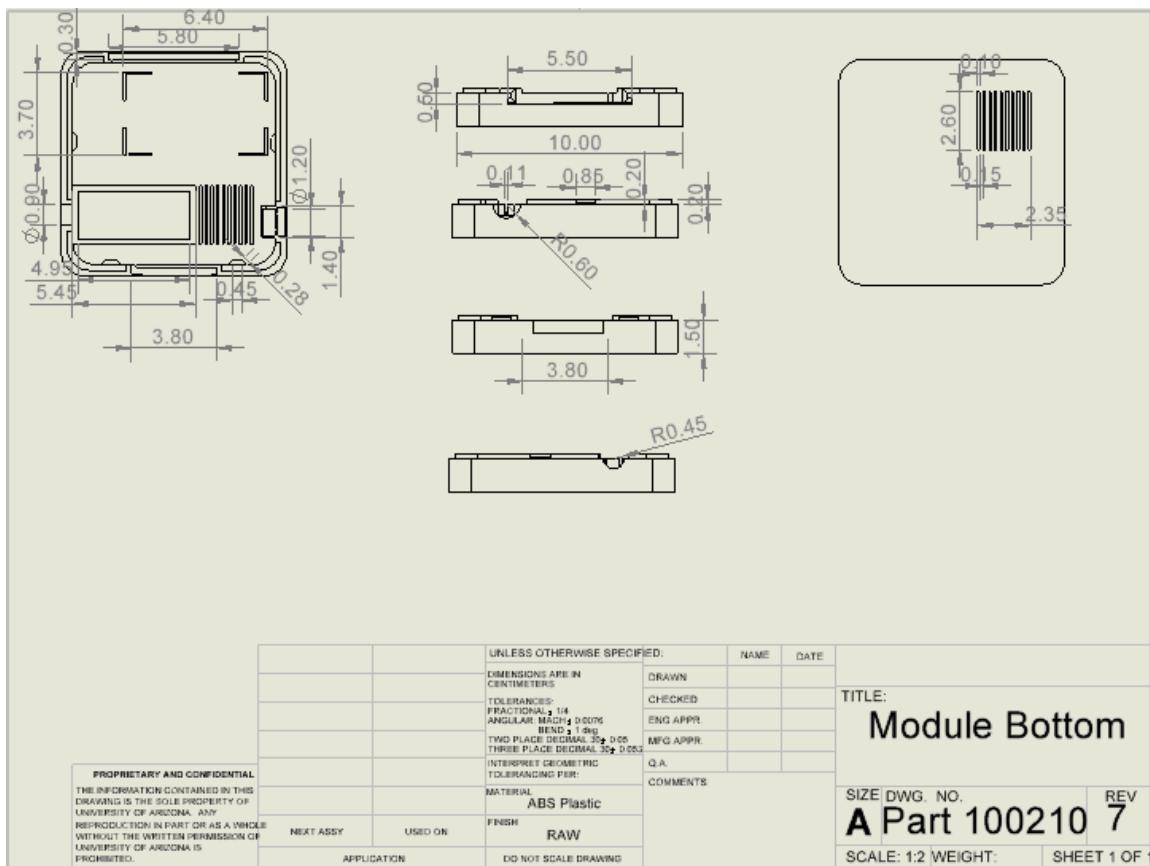
Alanazi, Ahmad A.; Atcherson, Samuel R.; Franklin, Clifford A.; Bryan, Melinda F.. *Frequency Responses of Conventional and Amplified Stethoscopes for Measuring Heart Sounds*. Saudi Journal of Medicine and Medical Sciences 8(2):p 112-117, May–Aug 2020. | DOI: 10.4103/sjmms.sjmms_118_19

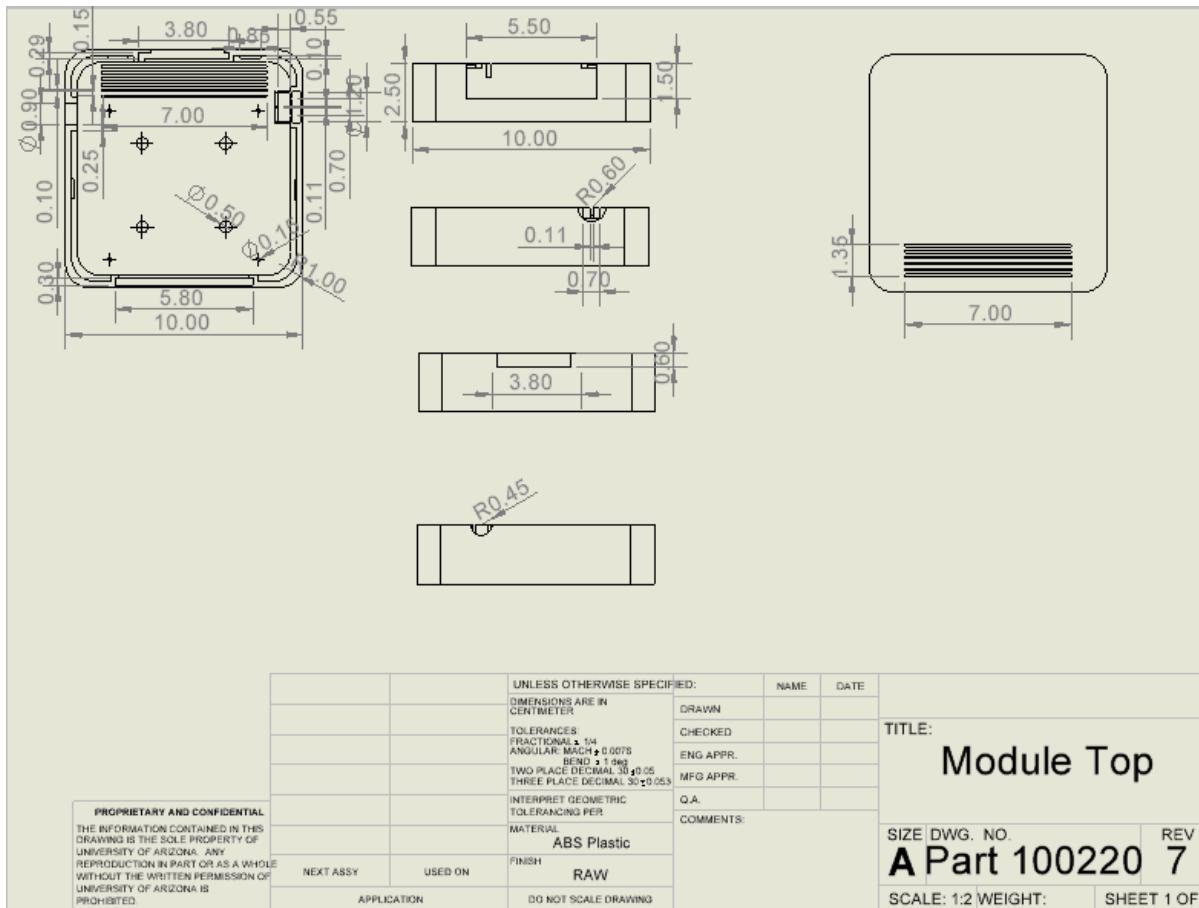
5.11 ECG CURRENT SOURCE

Laks, M. M., Arzbaecher, R., Bailey, J. R., Geselowitz, D. B., & Berson, A. S. (1996). Recommendations for safe current limits for electrocardiographs. Circulation, 93(4), 837–839. <https://doi.org/10.1161/01.cir.93.4.837>

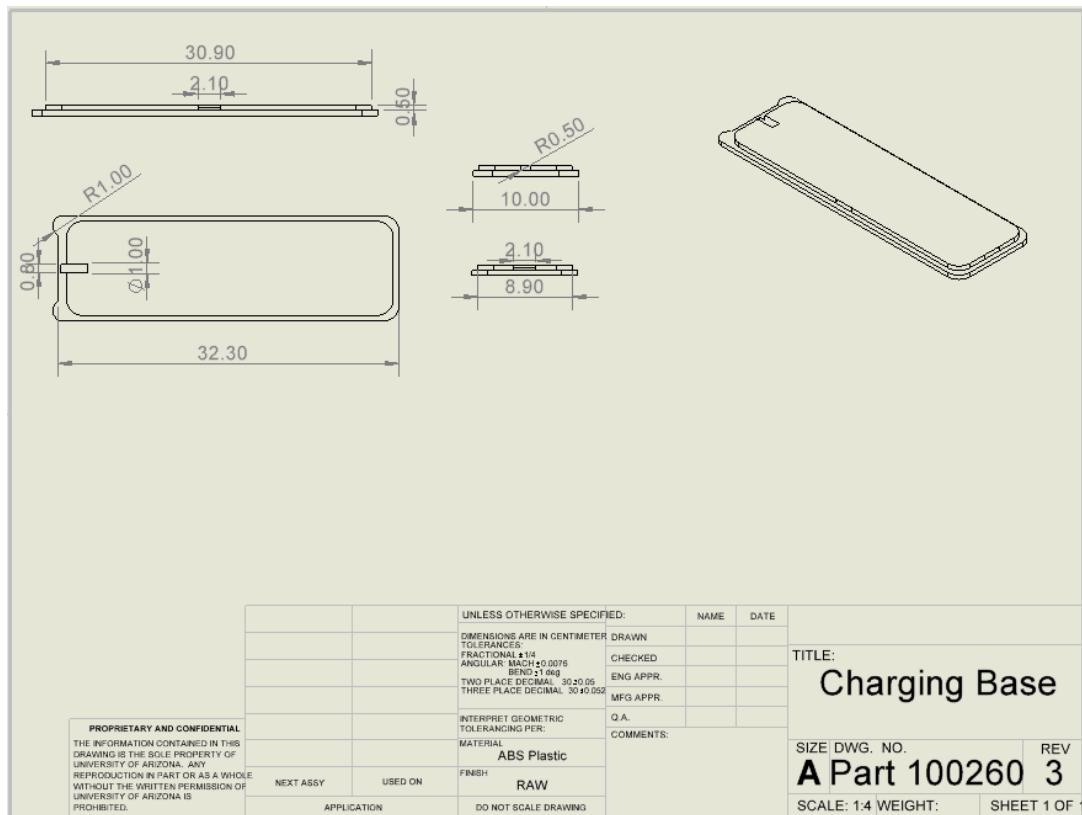
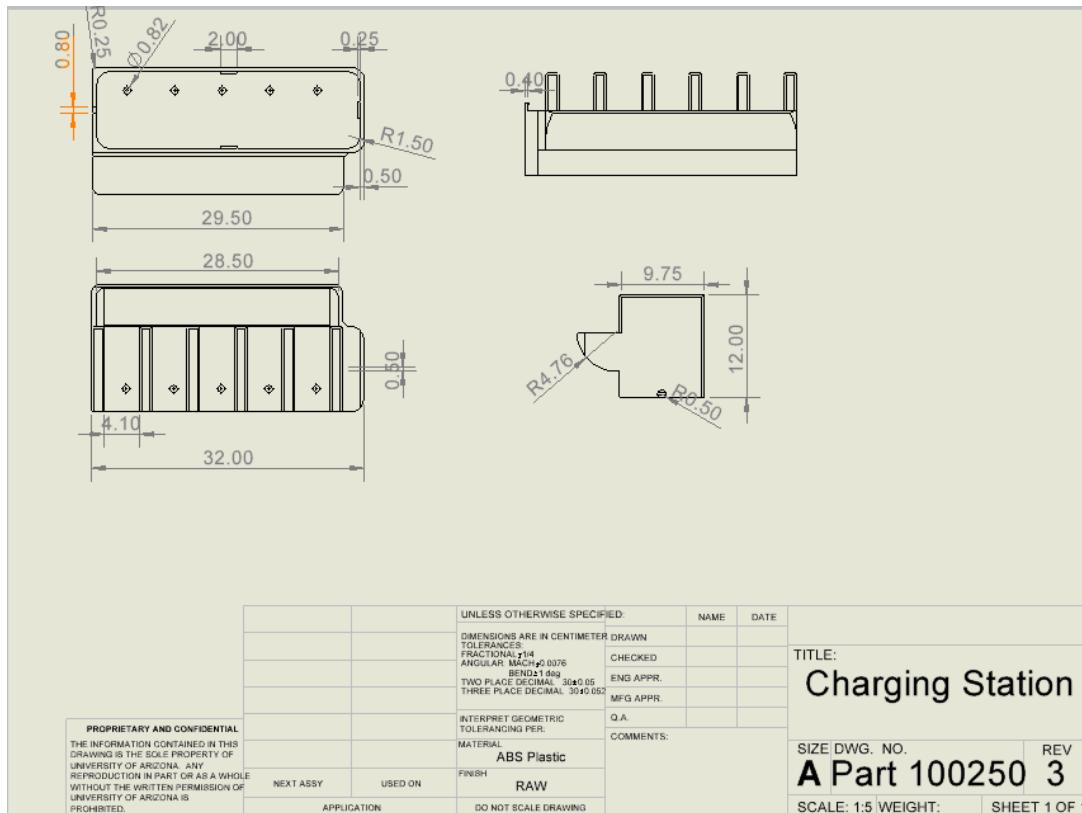
5.12 HARDWARE

5.12.1 SENSOR MODULE HOUSING DRAWINGS

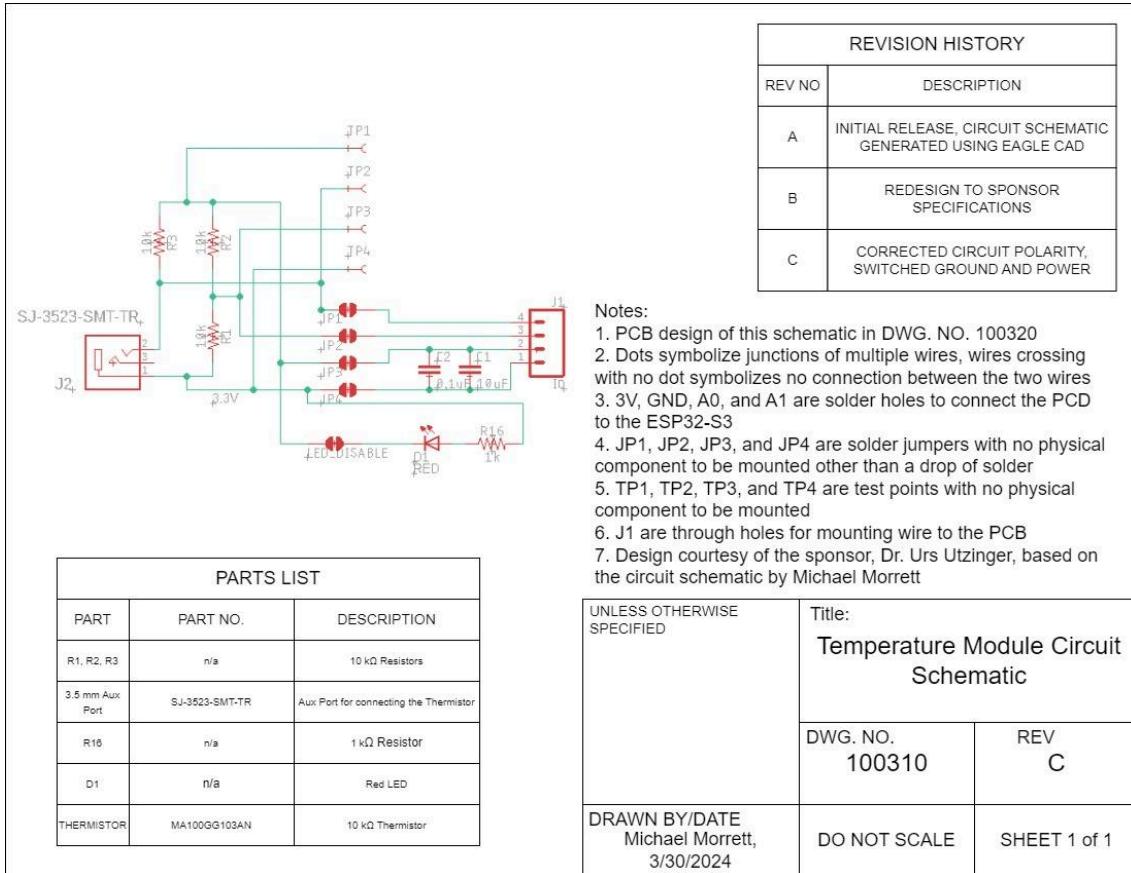




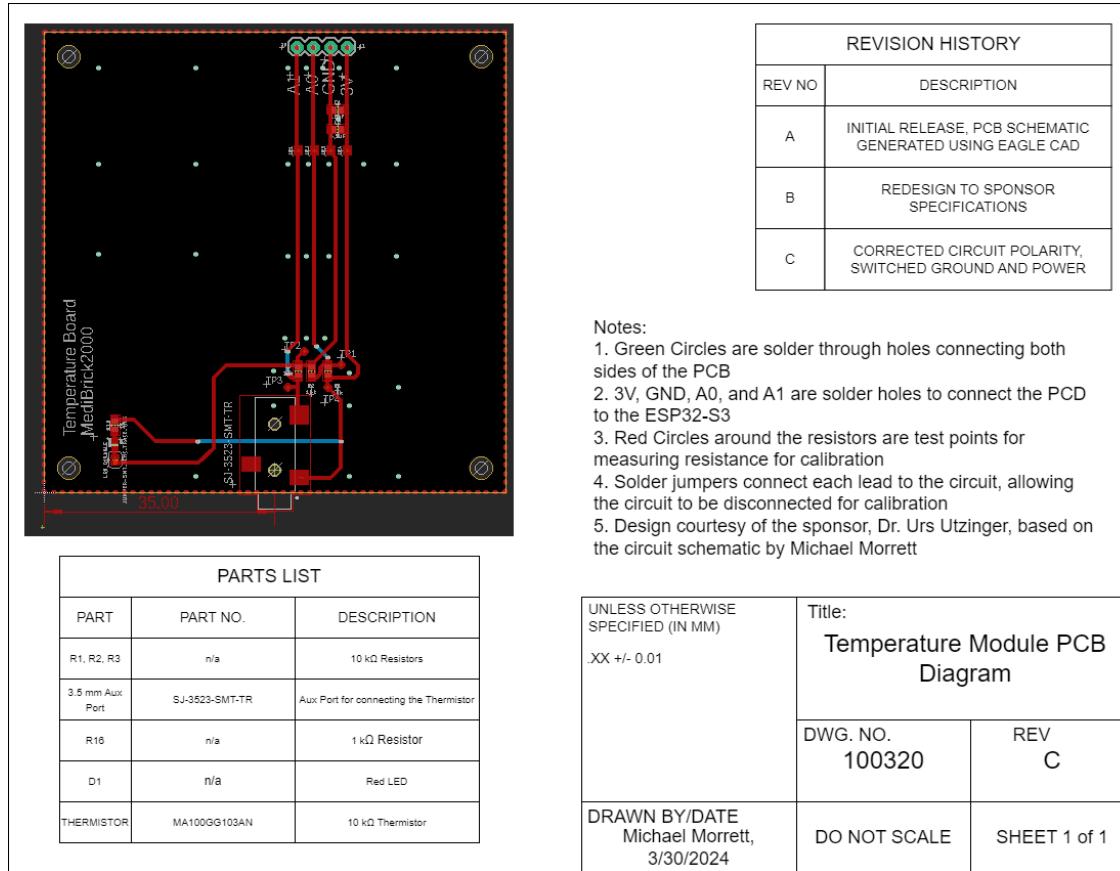
5.12.2 CHARGING HOUSING DRAWINGS



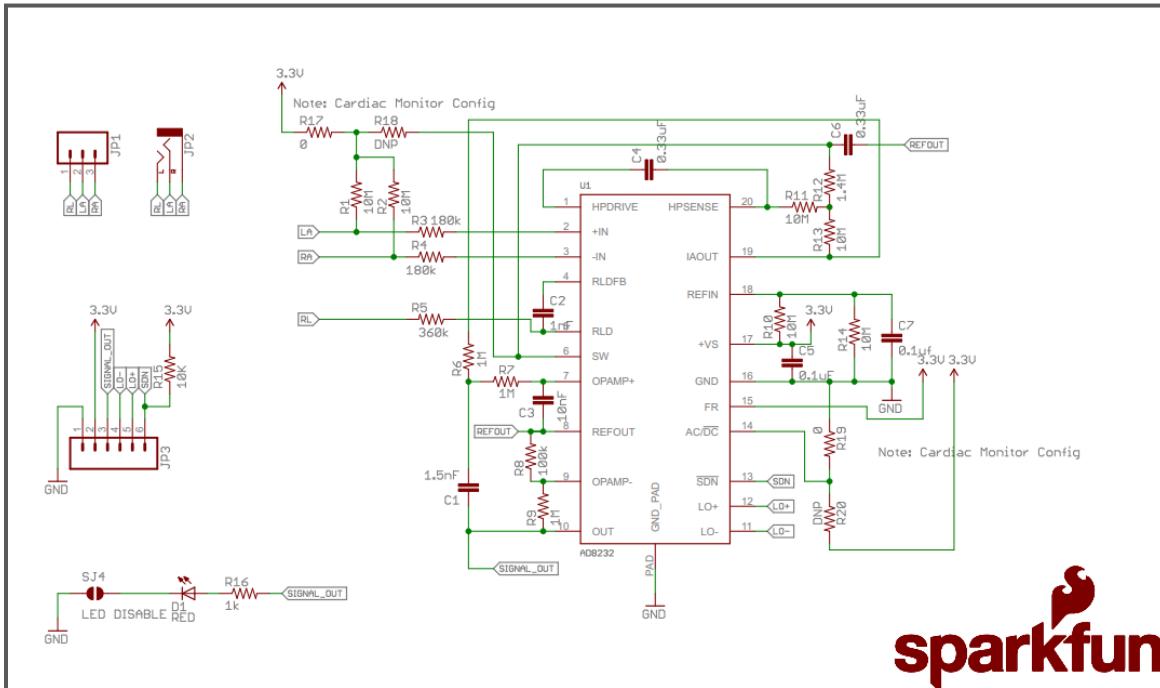
5.12.3 TEMPERATURE MODULE CIRCUIT SCHEMATIC



5.12.4 TEMPERATURE MODULE PCB DIAGRAM



5.12.5 ECG MODULE SCHEMATIC

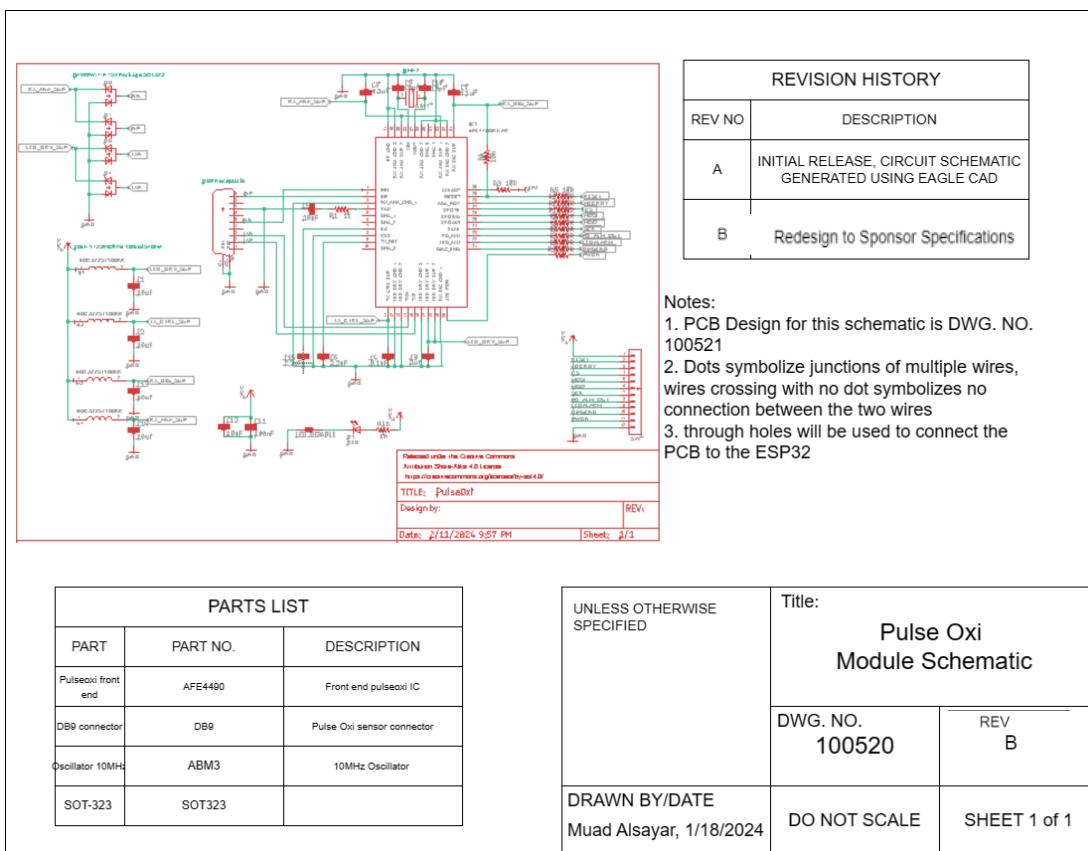


https://cdn.sparkfun.com/datasheets/Sensors/Biometric/AD8232_Heart_Rate_Monitor_v10.pdf

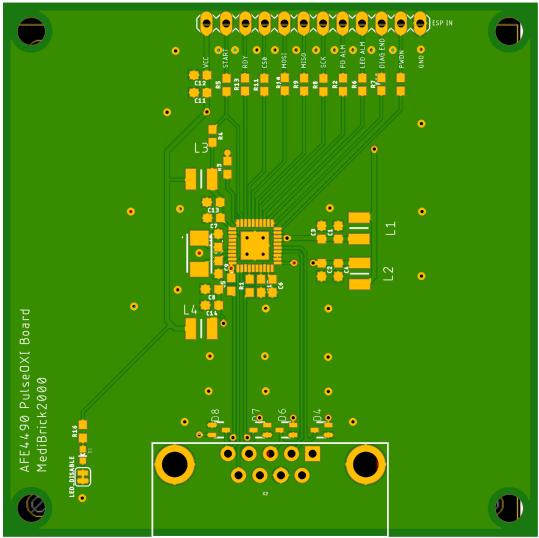
5.12.6 ECG MODULE PCB HOLDER

	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">REVISION HISTORY</th> </tr> <tr> <th style="text-align: center;">REV NO</th><th style="text-align: center;">DESCRIPTION</th></tr> </thead> <tbody> <tr> <td style="text-align: center;">A</td><td style="text-align: center;">INITIAL RELEASE, CIRCUIT SCHEMATIC GENERATED USING EAGLE CAD</td></tr> <tr> <td></td><td></td></tr> </tbody> </table> <p>Notes:</p> <ol style="list-style-type: none"> 1. PCB Design for this schematic is DWG. NO. 100750 2. Dots symbolize junctions of multiple wires, wires crossing with no dot symbolizes no connection between the two wires 3. through holes will be used to connect the PCB to the ESP32 	REVISION HISTORY		REV NO	DESCRIPTION	A	INITIAL RELEASE, CIRCUIT SCHEMATIC GENERATED USING EAGLE CAD																
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5.12.7 PULSE OXIMETER MODULE SCHEMATICS



5.12.8 PULSE OXIMETER MODULE PCB DIAGRAM

 <p>AFFE4490 PulsedOxi Board MedbrickZ2000</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. PCB Design for this schematic is DWG. NO. 100521 2. Dots symbolize junctions of multiple wires, wires crossing with no dot symbolizes no connection between the two wires 3. through holes will be used to connect the PCB to the ESP32 	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">REVISION HISTORY</th> </tr> <tr> <th style="text-align: center;">REV NO</th> <th style="text-align: center;">DESCRIPTION</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A</td> <td>INITIAL RELEASE, CIRCUIT SCHEMATIC GENERATED USING EAGLE CAD</td> </tr> <tr> <td style="text-align: center;">B</td> <td>Rearrange and improve wiring and orientation of components</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">PARTS LIST</th> </tr> <tr> <th>PART</th> <th>PART NO.</th> <th>DESCRIPTION</th> </tr> </thead> <tbody> <tr> <td>Pulseoxi front end</td> <td>AFE4490</td> <td>Front end pulseoxi IC</td> </tr> <tr> <td>DB9 connector</td> <td>DB9</td> <td>Pulse Oxi sensor connector</td> </tr> <tr> <td>Oscillator 10MHz</td> <td>ABM3</td> <td>10MHz Oscillator</td> </tr> <tr> <td>SOT-323</td> <td>SOT323</td> <td></td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td rowspan="2" style="width: 25%;">UNLESS OTHERWISE SPECIFIED</td><td colspan="2" style="text-align: center;">Title: Pulse Oxi Module PCB</td></tr> <tr> <td style="text-align: center;">DWG. NO. 100521</td><td style="text-align: center;">REV B</td></tr> <tr> <td style="width: 25%;">DRAWN BY/DATE Muad Alsayar, 1/18/2024</td><td style="width: 25%;">DO NOT SCALE</td><td style="width: 25%;">SHEET 1 of 1</td></tr> </table>	REVISION HISTORY		REV NO	DESCRIPTION	A	INITIAL RELEASE, CIRCUIT SCHEMATIC GENERATED USING EAGLE CAD	B	Rearrange and improve wiring and orientation of components	PARTS LIST			PART	PART NO.	DESCRIPTION	Pulseoxi front end	AFE4490	Front end pulseoxi IC	DB9 connector	DB9	Pulse Oxi sensor connector	Oscillator 10MHz	ABM3	10MHz Oscillator	SOT-323	SOT323		UNLESS OTHERWISE SPECIFIED	Title: Pulse Oxi Module PCB		DWG. NO. 100521	REV B	DRAWN BY/DATE Muad Alsayar, 1/18/2024	DO NOT SCALE	SHEET 1 of 1
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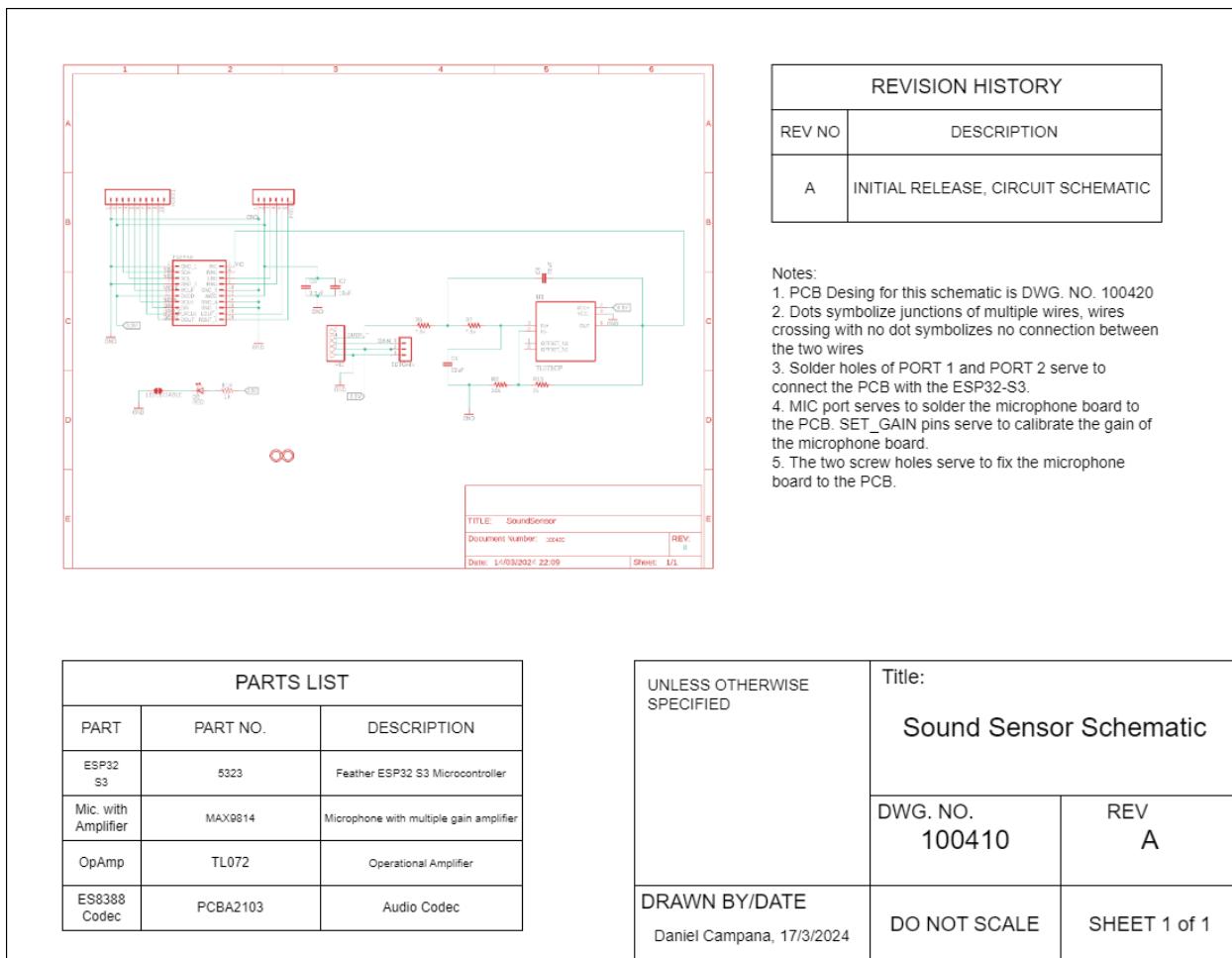
5.12.9 IMPEDANCE MODULE SCHEMATICS

	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th colspan="2">REVISION HISTORY</th> </tr> <tr> <th>REV NO</th> <th>DESCRIPTION</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>INITIAL RELEASE, CIRCUIT SCHEMATIC</td> </tr> <tr> <td>B</td> <td>ADDITIONAL ANALOG SWITCH FOR CALIBRATION</td> </tr> </tbody> </table> <p>Notes:</p> <ol style="list-style-type: none"> 1. PCB Design for this schematic is DWG. NO. 100621 2. Dots symbolize junctions of multiple wires, wires crossing with no dot symbolizes no connection between the two wires 3. through holes will be used to connect the PCB to the ESP32 	REVISION HISTORY		REV NO	DESCRIPTION	A	INITIAL RELEASE, CIRCUIT SCHEMATIC	B	ADDITIONAL ANALOG SWITCH FOR CALIBRATION																						
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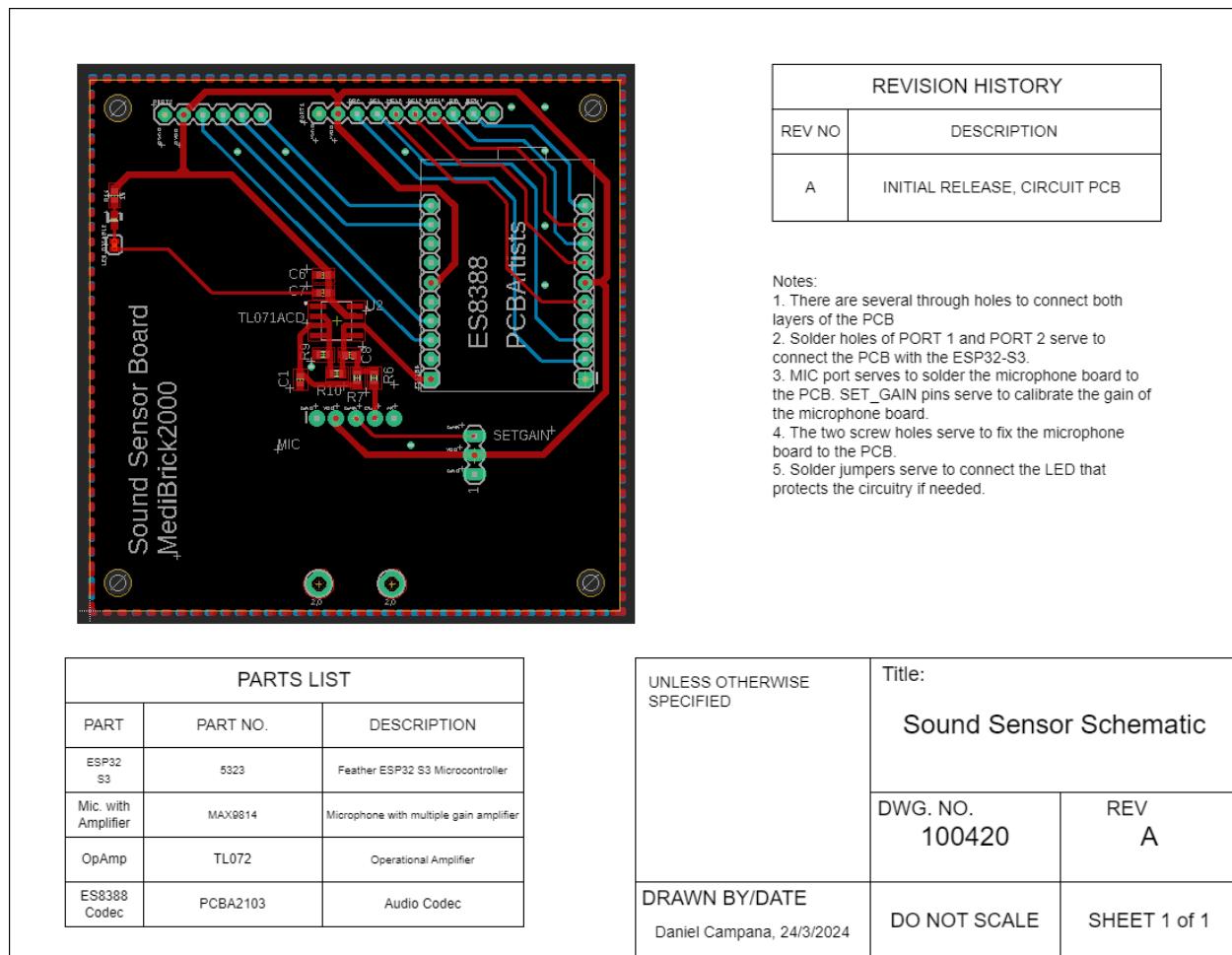
5.12.10 IMPEDANCE MODULE PCB DIAGRAM

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5.12.11 DIGITAL STETHOSCOPE MODULE SCHEMATIC



5.12.12 DIGITAL STETHOSCOPE PCB DIAGRAM



5.12.13 INSERT MODULE DRAWINGS

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN CENTIMETER TOLERANCES FRACTIONAL: $\pm\frac{1}{64}$ ANGULAR: MACH 3 BENDS BEND: $\pm 1^\circ$ deg TWO PLACE DECIMAL: ± 0.05 THREE PLACE DECIMAL: ± 0.005		DRAWN		
		INTERPRET GEOMETRIC TOLERANCING PER:		CHECKED		
		MATERIAL ABS Plastic		ENG APPR.		
		FINISH RAW		MFG APPR.		
		Q.A.		Q.A.		
		COMMENTS:				
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF UNIVERSITY OF ARIZONA. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF UNIVERSITY OF ARIZONA IS PROHIBITED.		NEXT ASSY	USED ON	SIZE DWG. NO. REV A Part 100340 1		
		APPLICATION	DO NOT SCALE DRAWING	SCALE: 1:1 WEIGHT: SHEET 1 OF 1		

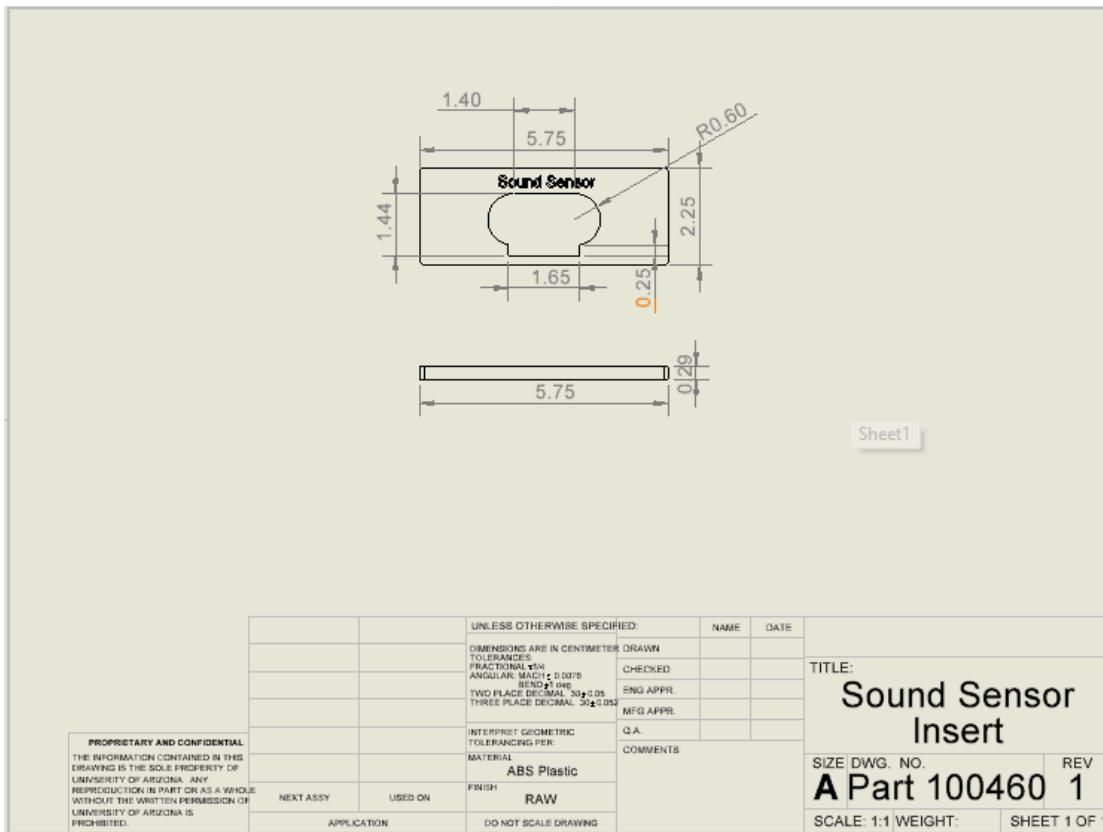
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		Q.A.		Q.A.		
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		APPLICATION	DO NOT SCALE DRAWING	SCALE: 1:1 WEIGHT: SHEET 1 OF 1		

		UNLESS OTHERWISE SPECIFIED:	NAME	DATE
		DIMENSIONS ARE IN CENTIMETER DRAWN TOLERANCES: FRACTIONAL: $\pm\frac{1}{16}$ ANGULAR: $\pm 1^\circ$ BEND: $\pm 1^\circ$ deg TWO PLACE DECIMAL: ± 0.02 THREE PLACE DECIMAL: ± 0.002		
		CHECKED	ENG APPR.	MFG APPR.
		Q.A.	COMMENTS:	
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF UNIVERSITY OF ARIZONA. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF UNIVERSITY OF ARIZONA IS PROHIBITED.		TITLE: Pulse Oxi Insert		
NEXT ASSY	USED ON	FINISH	SIZE DWG. NO. A Part 100540 1 REV	
		RAW	SCALE: 1:1 WEIGHT:	SHEET 1 OF 1
APPLICATION	DO NOT SCALE DRAWING			

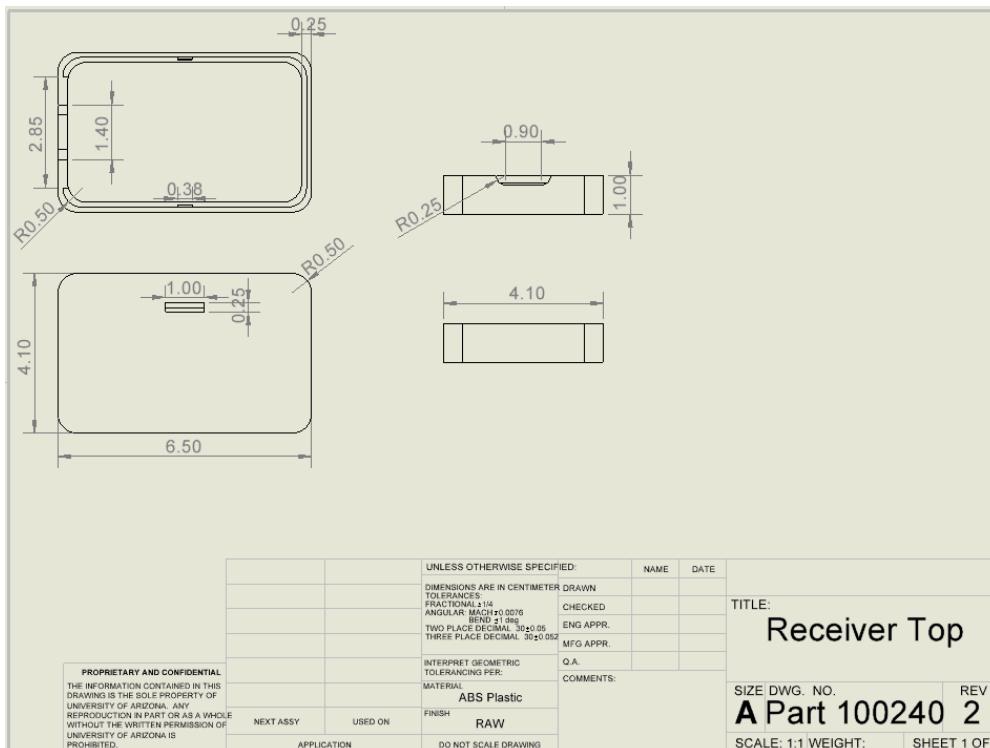
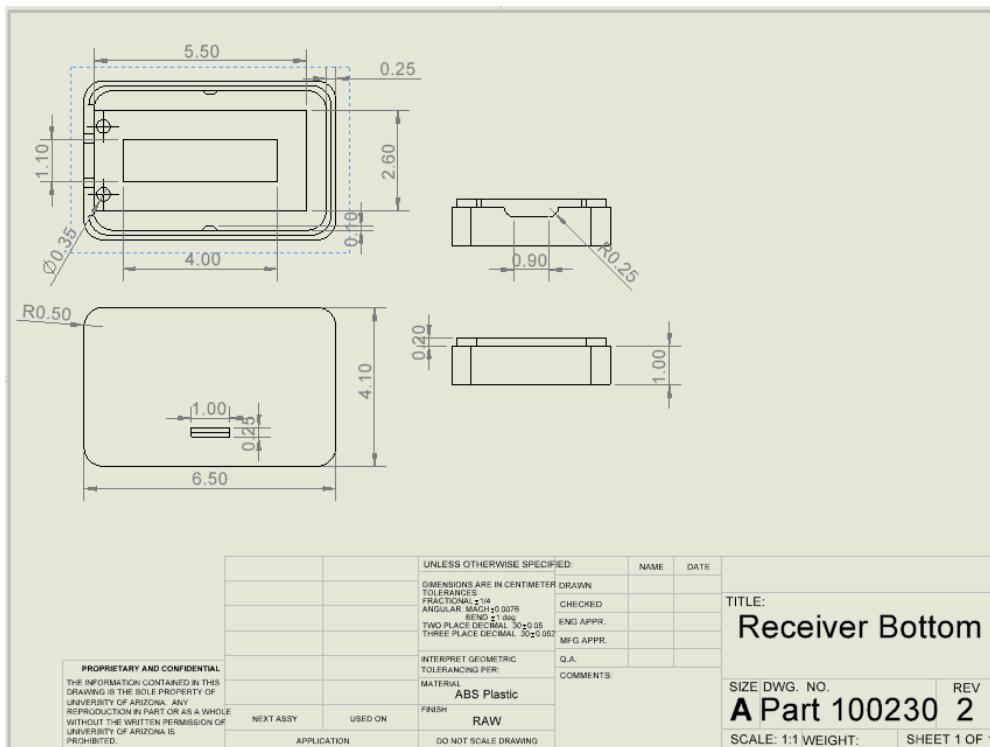
Technical drawing of the Pulse Oximeter housing. The top view shows a rectangular part with a central cutout. Dimensions are: width 5.75, height 1.20, depth 3.00, and a side wall thickness of 0.29. The side view shows the total height as 2.25.

		UNLESS OTHERWISE SPECIFIED:	NAME	DATE
		DIMENSIONS ARE IN CENTIMETER DRAWN TOLERANCES: FRACTIONAL: $\pm\frac{1}{16}$ ANGULAR: $\pm 1^\circ$ BEND: $\pm 1^\circ$ deg TWO PLACE DECIMAL: ± 0.02 THREE PLACE DECIMAL: ± 0.002		
		CHECKED	ENG APPR.	MFG APPR.
		Q.A.	COMMENTS:	
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF UNIVERSITY OF ARIZONA. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF UNIVERSITY OF ARIZONA IS PROHIBITED.		TITLE: Impedance Insert		
NEXT ASSY	USED ON	FINISH	SIZE DWG. NO. A Part 100660 1 REV	
		RAW	SCALE: 1:1 WEIGHT:	SHEET 1 OF 1
APPLICATION	DO NOT SCALE DRAWING			

Technical drawing of the Impedance insert. The top view shows a rectangular part with a central cutout and rounded corners (R0.40). Dimensions are: width 5.75, height 1.37, and a side wall thickness of 0.29. The side view shows the total height as 2.25.



5.12.14 RECEIVER MODULE DRAWINGS



5.13 INDENTURED DOCUMENT LIST

Part Number				Document			Revision
100000				Biomedical Sensor Board			A
	100100			Computer Assembly			A
		100110		GUI Python Code			B
		100120		GUI CSCI Diagram			A
		100130		Receiver Code			N
		5323		ESP32-S3 Feather			N/A
		B08FYNN55Z		USB-C to USB-A Wire			N/A
	100200			Housing and Accessories Assembly			
		100210		Sensor Module Case Bottom Half			G
		100220		Sensor Module Case Top Half			G
		100230		Receiver Bottom			B
		100240		Receiver Top			B

		100250		Charging Station Main Body (Solid Works)			C
		100260		Charging Station Base (Solid Words)			C
		B093GXLHNL		USB Surge Protector/ Power Strip			N/A
		B093R3XNR2		Magnetic Charging Wires (1ft)			N/A
		B07V9P5LGB		5-Magnetic Charging Tips			N/A
		B08L7QW7SR		I2C OLED Screens			N/A
		1009		Tactile Buttons			N/A
		258		3.3 V 1200 mAh Battery			N/A
	100300			Temperature Assembly			A
		100310		Temperature Module Circuit Schematic			C
		100320		Temperature Circuit PCB Diagram			C

		100330		Temperature Arduino Code			A
		100340		Temp Insert			A
		MA100GG103A N		Thermistor			N/A
	100400			Sound Sensor Assembly			B
		100410		Sound Sensor Circuit Schematic			B
		100420		Sound Sensor PCB Diagram			A
		100430		Sound Sensor sender Arduino Code			B
		100431		Sound Sensor receiver Arduino Code			A
		100440		Sound Sensor MATLAB Filter Creator Tool			B
		100450		Plug for Stethoscope Tube (Solid Works)			B

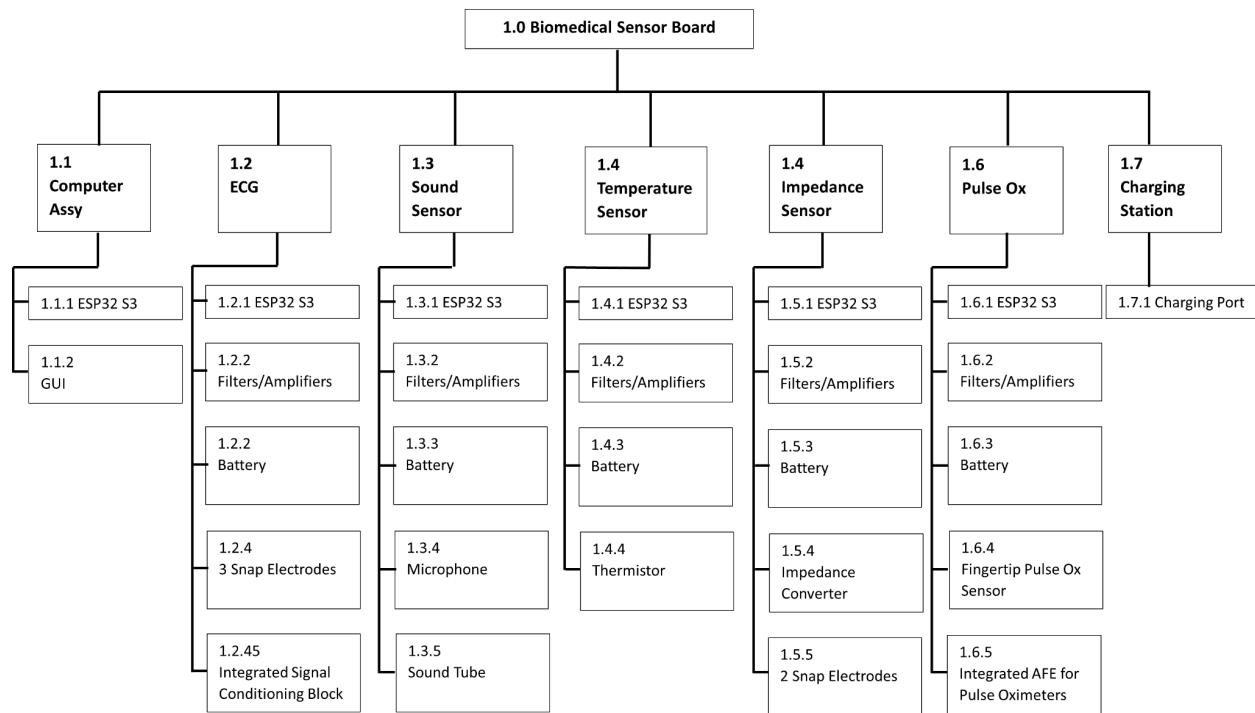
		100460		Sound Insert			A
		MAX9814		Electret Microphone with Amplifier			N/A
		B0011E4TJW		Stethoscope Tube (MDF10)			N/A
		B0011E4TJW		Stethoscope Diaphragm (MDF10)			N/A
		PCBA2103		Audio Codec Module ES8388			N/A
		TL071ACD		Operational Amplifier			N/A
	100500			Pulse Oximeter Assembly			A
		100510		Pulse Oximeter Schematic			A
		100520		Pulse Oximeter Circuit PCB Diagram			A
		100530		Pulse Oximeter Arduino Code			A
		100540		Pulse Ox Insert			A
		DS-100A		Oxygen Saturation Probe			N/A

				Adult Ear Clip			
		AFE4490		Integrated AFE for Pulse Oximeter			N/A
	100600			Skin Impedance Assembly			B
		100610		Skin Impedance Circuit Schematic			A
		100620		Skin Impedance Circuit PCB Diagram			B
		100630		Skin Impedance Arduino Code			A
		100640		2-Snap Electrode			N/A
		100650		Impedance Insert			A
		22850		Disposable Snap Electrode			N/A
		AD5933YRSZ-REEL7		AD 5933 Impedance Converter IC			N/A
	100700			Electrocardiogram Sensor			A

		100710		ECG Circuit Schematic			A
		100720		ECG Circuit PCB Diagram			A
		100730		ECG Arduino Code			A
		100740		ECG MATLAB Testing Code			A
		100750		ECG Insert			A
		22850		Disposable Snap Electrode			N/A
		CAB-12970		3-Snap Electrode			N/A
		AD8232		ECG Amplifier Board			N/A
	100800			System Documents			
		100810		Proposal			J
		100820		Statement of Work			F
		100830		System Requirements Document			P
		100840		Software Description Document			B

		100850		Acceptance Test Procedures			
		100860		System Models			B
		100870		Technical Data Package			AF
		100880		Final Report			F

5.14 SYSTEM ARCHITECTURE DIAGRAM



5.15 MVP2 VERIFICATION DATASHEETS

Refer to Other GitHub Documents:

<https://github.com/grender007/Modular-Biomedical-Sensor-Board-for-Education/tree/main/User%20Manual%20and%20Other%20Documents>

5.16 ENGINEERING CHANGE REQUEST DOCUMENTS

5.16.1 HOUSING DRAWING CHANGES

Engineering Change Request

Date: March 21, 2024

Team Number: 24052

Project Name: Modular Biomedical Sensor
Board for Education

Title of Change: Housing Drawing Changes
Documents Affected (check all that apply):

	Doc Type	Document Number	Document Name
<input type="checkbox"/>	SOW		
<input type="checkbox"/>	SRD		
<input type="checkbox"/>	SDD		
<input checked="" type="checkbox"/>	TP	100870	Technical Data Package rev. #23
<input type="checkbox"/>	EVMS		
<input checked="" type="checkbox"/>	Drawing	100210	Charging Station Main Body rev. A
<input checked="" type="checkbox"/>	Drawing	100220	Charging Station Base rev. A
<input checked="" type="checkbox"/>	Drawing	100230	Sensor Module Case Top Half rev. B
<input checked="" type="checkbox"/>	Drawing	100240	Sensor Module Case Bottom Half rev. B
<input type="checkbox"/>	Other		
<input type="checkbox"/>	Other		

Description of Change: The housing drawings have been altered incrementally to ensure that components fit snugly in their places of the housing and that that housings lock together firmly.

Need for Change: Slight alterations have been made to the housings, incrementally altering dimensions so that components fit well together.

Impact: The impact of these changes is that all of the housings lock firmly together, immobilize the components within, and protect them better.

Substantiation: Previous iterations did not lock together well and components could not fit. Current versions accommodate components well without issues.

Approvals:


Team Leader Signature


Sponsor Signature



A handwritten signature consisting of stylized letters, possibly 'M', 'Y', 'D', 'i', 'c', 'u', 'r', and 'e', written above a horizontal line. Below the line, the text 'Mentor Signature' is printed.

Mentor Signature

5.16.2 PCB DRAWING CHANGES

Engineering Change Request

Date: March 21, 2024

Team Number: 24052

Project Name: Modular Biomedical Sensor
Board for Education

Title of Change: PCB Drawing Changes

Documents Affected (check all that apply):

Doc Type	Document Number	Document Name
<input type="checkbox"/> SOW		
<input type="checkbox"/> SRD		
<input type="checkbox"/> SDD		
<input checked="" type="checkbox"/> TP	100870	Technical Data Package rev. #23
<input type="checkbox"/> EVMS		
<input checked="" type="checkbox"/> Drawing	100320	Temperature Circuit PCB Diagram rev. B
<input checked="" type="checkbox"/> Drawing	100520	Pulse Oximeter Circuit PCB Diagram rev. A
<input checked="" type="checkbox"/> Drawing	100620	Skin Impedance Circuit PCB Diagram rev. B
<input type="checkbox"/> Other		
<input type="checkbox"/> Other		

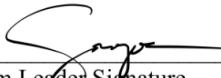
Description of Change: The PCBs have been changed following revisions from the sponsor to meet the sponsor's requirements. These changes are just in the placement and pathing of the PCBs.

Need for Change: The sponsor desired these changes to both look cleaner, and to move certain components around to better interface with the housings. In their current placement, said components are in the right place to access the necessary ports of the housings.

Impact: These changes make the PCBs look more appealing to the sponsor and to place components where they need to be to interact with the housings.

Substantiation: The sponsor helped design these PCBs, allowing him to design the PCBs how he would like them to be. As for the placement of components, for the plan of how the two will connect, the components will be lined up with the port of the housing.

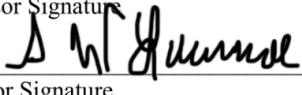
Approvals:



Team Leader Signature

TDP #24052



Sponsor Signature


Mentor Signature

5.16.3 SYSTEM REQUIREMENTS ALTERATIONS

Engineering Change Request

Date: March 21, 2024

Team Number: 24052

Project Name: Modular Biomedical Sensor

Board for Education

Title of Change: System Requirements Alterations

Documents Affected (check all that apply):

	Doc Type	Document Number	Document Name
<input type="checkbox"/>	SOW		
<input checked="" type="checkbox"/>	SRD	100830	System Requirements Document rev. #15
<input type="checkbox"/>	SDD		
<input checked="" type="checkbox"/>	TP	100870	Technical Data Package rev. #23
<input type="checkbox"/>	EVMS		
<input type="checkbox"/>	Drawing		
<input type="checkbox"/>	Drawing		
<input type="checkbox"/>	Other		
<input type="checkbox"/>	Other		

Description of Change: Two system requirements need to be changed. One is the total cost, SR 4.2.3.3, which needs to be increased from \$300 to \$500. The other change is that SR 4.2.1.6, the pulse oximeter signal count, needs to be removed from the System Requirements.

Need for Change: The total system cost requirement needs to be changed because the current total system cost is unachievable. By increasing the cost by \$200, all of the requirements of the sponsor can be met for the final system design.

For the pulse oximeter signal count, the team has not been able to develop a method to verify the requirement, and due to the fact that the pulse oximeter has passed all other requirements and functionality, the team has deemed this requirement unnecessary.

Impact: The system cost alteration will allow the team to fulfill all of the sponsor's requirements in terms of functionality. With a slight cost increase, the system will have full functionality and still be low cost in comparison to the tools this project is replacing.

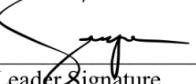
For the pulse oximeter signal count, if this requirement is removed, it will remove a needless requirement on a device that has already been proved to work with adequate accuracy and speed.

Substantiation: Proof the system cost alteration will work is found in TDP 4.6.4, where the total cost of \$500 is argued for and proven for current project plans.

As for the pulse oximeter signal count, current function of the Pulse Oximeter is shown in TDP 3.4.1 and TDP 3.4.2, where the other requirements on the Pulse Oximeter are proven. Removing

this requirement will not prevent the system from working, as that part of the system has been proven to work.

Approvals:


Team Leader Signature


Sponsor Signature


Mentor Signature

5.16.4 TEMPERATURE & IMPEDANCE SCHEMATICS CHANGES

Engineering Change Request

Date: March 21, 2024

Team Number: 24052

Project Name: Modular Biomedical Sensor
Board for Education

Title of Change: Temperature and Impedance Schematics Changes

Documents Affected (check all that apply):

	Doc Type	Document Number	Document Name
<input type="checkbox"/>	SOW		
<input type="checkbox"/>	SRD		
<input type="checkbox"/>	SDD		
<input checked="" type="checkbox"/>	TP	100870	Technical Data Package rev. #23
<input type="checkbox"/>	EVMS		
<input checked="" type="checkbox"/>	Drawing	100310	Temperature Module Circuit Schematic rev. B
<input checked="" type="checkbox"/>	Drawing	100610	Skin Impedance Circuit Schematic rev. A
<input type="checkbox"/>	Other		
<input type="checkbox"/>	Other		

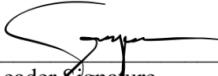
Description of Change: The Temperature and Impedance Schematics have both been changed, altering the configuration of components in the circuit and adding new components to meet the sponsor's desires.

Need for Change: The components have been added to both circuits to meet performance requirements desired by the sponsor. Such requirements include adding solder jumpers to be able to open and close circuits, using microcomponents for the PCBs, eliminating through-hole components, and altering component order and placement to enable the final PCB to function better.

Impact: The impact of these changes is that both PCBs will have a few extra low cost components, such as resistors, capacitors, and LEDs, that will increase the cost slightly and add new functionality to each PCB.

Substantiation: Cost analysis is present in TDP 4.6.4. Updated drawings projected to function the same way with added filtering and functionality. The core circuit to operate the system has not changed.

Approvals:

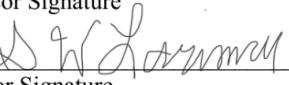


Team Leader Signature

TDP #24052



Sponsor Signature



Mentor Signature

5.16.5 HEIGHT SYSTEM REQUIREMENT ALTERATION

Engineering Change Request

Date: March 21, 2024

Team Number: 24052

Project Name: Modular Biomedical Sensor
Board for Education

Title of Change: Height System Requirement Alteration

Documents Affected (check all that apply):

	Doc Type	Document Number	Document Name
<input type="checkbox"/>	SOW		
<input checked="" type="checkbox"/>	SRD	100830	System Requirements Document rev. #15
<input type="checkbox"/>	SDD		
<input checked="" type="checkbox"/>	TP	100870	Technical Data Package rev. #23
<input type="checkbox"/>	EVMS		
<input type="checkbox"/>	Drawing		
<input type="checkbox"/>	Drawing		
<input type="checkbox"/>	Other		
<input type="checkbox"/>	Other		

Description of Change: The total allowable height requirement for the system needs to be increased by 8 cm from 12.7 cm to 20.7 cm.

Need for Change: The requirement needs to be changed because in order to accommodate the connectors to allow the sensor microcontrollers to charge, the charger housing needs to be slightly taller. This increase in height would cause the entire system to exceed the height requirement, necessitating the change.

Impact: The height requirement change will allow us to continue with our current design without needing to drastically change the current design or configuration of components.

Substantiation: The increase in height has already been measured to work by the team, measuring the clearance needed to allow the plug to fit within the housing. A margin of 2 cm has been added to this measurement to ensure that an additional ECR will not need to be filed if the measurements were incorrect. As it is a very slight increase in height and the system will still be sized to sit on a table and fit in a box “roughly the size of a shoebox,” we believe it is still in the spirit of what the sponsor has requested of us.

Approvals:



Team Leader Signature

TDP #24052


Sponsor Signature

Mentor Signature

5.17 SUMMARY TABLE OF MODEL PREDICTIONS & MARGINS

System Requirements	Models	Prediction	Margin
4.2.1.3 Stethoscope Sensitivity: The digital stethoscope shall be able to detect the sound of a human heartbeat, estimated to have a frequency from 20-600 Hz.	Discrete Fourier Transform	Bandwidth = ~800 Hz Minimum amplitude = ~ -80 dB	200 Hz -20 dB
	Nyquist Sampling Theorem	Sampling Frequency > 2000 Hz	-design point-
4.2.1.5 Pulse Oximeter Signal Noise: The amplitude changes returned from the pulse oximeter shall be at least 5 times larger than the noise of the signal.	Signal To Noise Ratio	SNR > 15 dB	-design point-
4.2.3.3 Inexpensive: The system's final cost to manufacture one entire system shall not exceed \$500.	Cost	\$474 for a unit of the final project	\$26
4.2.3.1 Weight: The system shall not exceed 15 pounds in weight.	Weight	7 pounds	8 pounds
4.2.3.2 Dimensions: The system shall fit within a volume of a box with a 35.5-cm side, and 25.4-cm side, and a 20.7-cm side.	Size	31.75-cm side, 19.05-cm side, 15.24-cm side	-design point-
4.2.5.1 Internal Power Supply: The auxiliary boards shall be able to perform their associated functions while only connected to internal battery sources without the aid of wall outlets for 3 hours.	Power	Max Current Consumption per Sensor: 340 mA	-design point-
4.2.5.4 External Power Supply: The system shall be able to function when provided with 15 amp and 120 V AC.	Power	Max Current Consumption of the five sensors connected to the Charging Station: 1700 mA	13.3 A