System Requirements Document

Biomedical Sensor Board for Education

ENGR 498B - #24052

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REVISION PAGE

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1.0 INTRODUCTION AND SCOPE

1.1 BACKGROUND

This document contains the System Requirements Document for a Biomedical Sensor Board assigned by the University of Arizona's Department of Biomedical Engineering and sponsored by Dr. Urs Utzinger. Dr. Utzinger is an associate professor of the University of Arizona in the departments of Biomedical Engineering, Obstetrics and Gynecology, Electrical and Computer Engineering, Optical Sciences, and BIO5. Some of his experiences include, but are not limited to, clinical imaging instrumentation to evaluate gynecological and gastrointestinal cancer, spectral imaging techniques for the skin, and development of hands-on training courses on electro mechanical systems for BME undergraduates.

The main goal of this project is to create a safe and fully functional sensor array for BME students to use in their laboratory sessions. This sensor board has five physiological sensors: temperature, impedance, electrocardiogram (ECG), sound, and pulse oximeter. With these five sensors, users can measure their body temperature, body fat percentage, water composition, heart electrical impulses, arterial blood oxygenation, heart rate, and heart and lung sounds. All five sensors are modular and will communicate using ESP-32 microcontrollers. Since this project is geared toward students, a beginner-friendly GUI will be developed along with this device. This GUI will allow users to measure using any of the five physiological sensors, and it will also allow users to record all the data collected by this device. The GUI will also provide a graphical representation along with the quantitative result according to the physiological measurement selected by the user.

1.2 NEED

The Department of Biomedical Engineering at the University of Arizona has grown significantly in recent years, resulting in an annual increase in the number of admitted students. Therefore, an affordable, accurate, and easy-to-use physiological sensor board is currently necessary for biomedical engineering teachers and students. At the time this project was developed, affordable and functional multi-physiological sensors were not currently available on the market. Although commercial systems are available, no unified approach uses existing third-party hardware, allows for later expansion, and uses open-source software.

1.3 CONCEPT OF OPERATIONS

1.3.1 SYSTEM BOUNDARIES

The system boundaries are divided into two categories: physical materials and software interface. For physical materials, each sensor will be separated into its own modules. Each module will have a power supply, a microcontroller, and a sensor board. There will be a total of five separate modules that will communicate to one receiver microcontroller. This receiver microcontroller will then communicate to the software interface. Users will be able to read, save, and display data from one or more sensors in their computers using this software interface.

1.3.2 SYSTEM ENVIRONMENT

The biomedical sensor array is intended for usage in laboratory, educational, and research environments, which are dry and room-temperature operating settings. The part of the sensors that interface with the human body will be water-resistant, chemically inert, and have no electrical connection to power lines. Furthermore, the whole system should be able to recharge within the environment when not in use.

1.3.3 SYSTEM CONSTRAINTS

Each sensor module with its own microcontroller shall have the same size. The complete sensor array shall cost less than $200, be easily replicated by senior-standing engineering students, and last three years of light use. Additionally, the system must be powered without being plugged into a wall outlet. As for the overall size, this device shall be no larger than a standard shoe box.

1.3.4 SYSTEM USE

The system will be used to collect physiological signals chosen by the user. The system will have a total of six microcontrollers, where one microcontroller is assigned for each of the five sensors. These microcontrollers will then wirelessly communicate with the designated sixth microcontroller, acting as a receiver, which will then communicate with the GUI within the user's personal computer.

Skin Impedance: Students will attach electrodes to two distinct, predetermined spots on a participant to measure the impedance between the two

locations. Based on the user's body weight, the software will convert the recorded data to body fat and water content.

Electrocardiogram: Students will connect two electrodes to the right and left arm as well as right leg, as a ground reference, to measure electrical potential created by the beating heart.. The program will allow users to construct an ECG measurement chart. The program may incorporate a 60Hz noise suppression filter and a low pass filter to graphically show the QRS complex of the signal.

Blood Oxygenation: A typical nine-pin analog pulse oxygenation sensor will be used in this module. The sensor will connect to a participant's finger and use red and near-infrared LEDs to detect blood oxygenation. The software will allow users to view the resulting plethysmography data from the pulse oximeter sensor.

Sound: This sensor will be able to record heart sounds with the use of a stethoscope and microphone placed on the user's chest. Recordings from this sensor will range from 5-10 seconds with the ability to playback using the GUI as well as save the created file. This sensor will also be able to listen to lung sounds.

Temperature: Students will be able to accurately monitor temperature orally or by placing it between their armpits. To measure the temperature, a medical thermistor will be utilized as a sensor. The software will offer temperature readings to the user.

1.3.5 EXPECTED OUTPUT

We hope to build a sensor array, composed of carefully selected sensors and well-designed integrated circuits, to measure biological data and provide graphical interpretations of the parameters obtained. The product will include a software application for personal computers, and will be capable of receiving, displaying, and storing data from the sensor array in response to human input. The project will be successful if the product provides enough instruction for students in the Department of Biomedical Engineering to integrate and operate the sensor.

1.4 STAKEHOLDERS

The project's stakeholders are the team members of Team #24052, the University of Arizona's Department of Biomedical Engineering through the sponsor, Urs Utzinger, the College of Engineering, and the Senior Design Instructional Team. In addition, there are indirect stakeholders within the open-source community who are interested and enthusiasts in microcontrollers and single-board computers and their functionalities. Dr. Utzinger will act as the primary point of contact for the project, representing all other

stakeholders and users. Given his expertise in sensor integration with microcontrollers and single-board computers, Dr. Utzinger will validate the device's functionality. The sponsor will be present during all system verification tests.

2.0 APPLICABLE DOCUMENTS

2.1 STANDARDS

- **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.

2.2 DATASHEETS

- **ESP32-S3 Series Datasheet:** https://www.espressif.com/sites/default/files/documentation/esp32-s3_datasheet_en.pdf
- **Single-Lead, Heart Rate Monitor Front End (AD8232):** https://cdn.sparkfun.com/datasheets/Sensors/Biometric/AD8232.pdf
- **12-Bit Impedance Converter (AD5933):** https://www.analog.com/media/en/technical-documentation/data-sheets/AD5933.pdf
- **Biomedical Chip NTC Thermistors (MA100GG103AN):** https://www.mouser.com/datasheet/2/18/Amphenol_04022020_AAS_920_321E-1826352.pdf
- **Integrated Analog Front-End for Pulse Oximeters (AFE4490RHAT):** https://www.ti.com/lit/ds/symlink/afe4490.pdf?HQS=dis-dk-null-digikeymode-ds

f-pf-null-wwe&ts=1696122373646&ref_url=https%253A%252F%252Fwww.ti.com%252Fgeneral%252Fdocs%252Fsuppproductinfo.tsp%253FdistId%253D10%2526gotoUrl%253Dhttps%253A%252F%252Fwww.ti.com%252Flit%252Fgpn%252Fafe4490

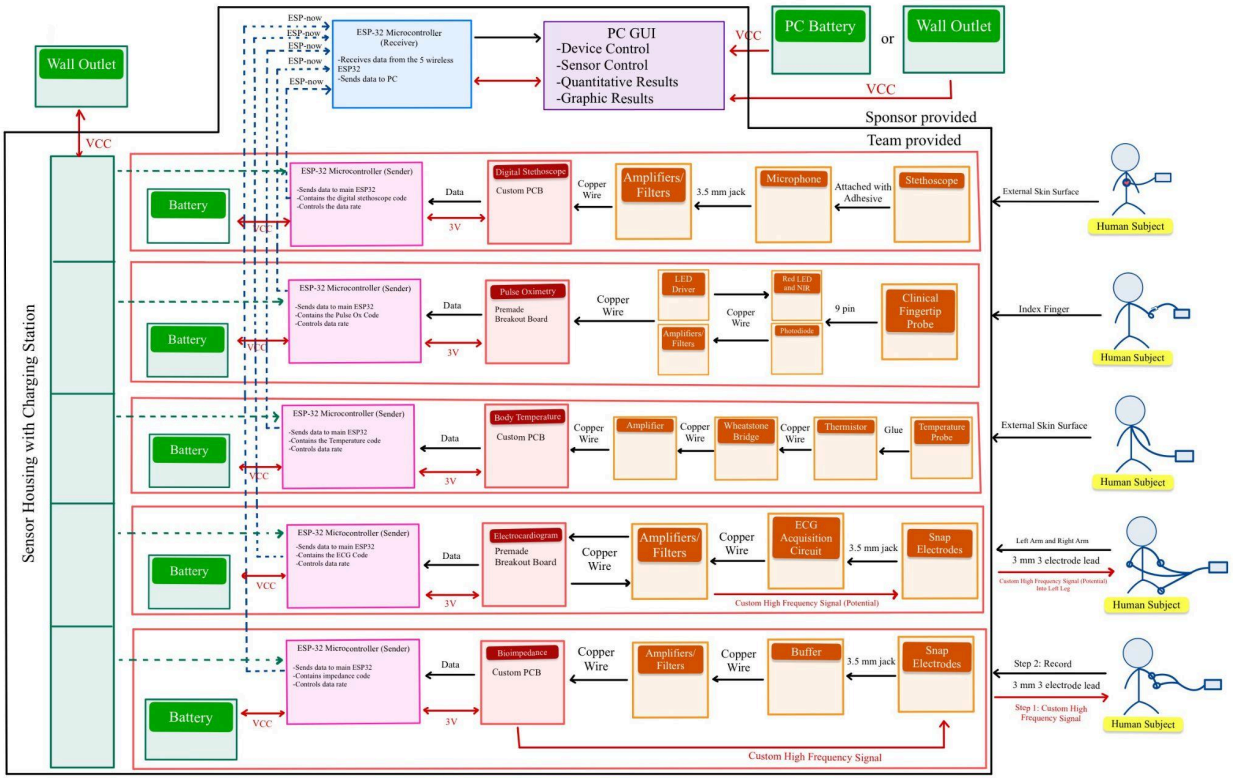
- **Low-Cost, Micropower, SC70/SOT23-8, Microphone Preamplifiers (MAX4466):** https://www.analog.com/media/en/technical-documentation/data-sheets/MAX4465-MAX4469.pdf

3.0 DEFINITIONS, ACRONYMS, AND ABBREVIATIONS

BPM	Beats per minute
BME	Biomedical Engineer/ Engineering
CFR	The Code of Federal Regulations
DMM	Digital Multimeter
ECG	Electrocardiogram/Electrocardiography
FFT	Fast Fourier Transform
GUI	Graphical User Interface
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
IEC	Internal Electrotechnical Commision
IP	Ingress Protection
ISO	International Organization for Standardization
SRD	System Requirements Document

4.0 REQUIREMENTS

4.1 SYSTEM BLOCK DIAGRAM



The team will be responsible for creating each sensor and integrating them into a modular wireless module. The team will also create a GUI for the device, as well as develop the housing with the device's charging station. They will also be responsible for updating each member's progress to the sponsor in the weekly meetings.

The sponsor, however, is responsible for providing necessary tools and equipment, such as 3D printers, soldering stations, electrical consumables, and last year's leftover equipment. The sponsor is also responsible for providing feedback on the team's plans and progress. Lastly, the sponsor is responsible for providing the team with any plans he would like to integrate into the device in a timely manner.

4.2 SYSTEM REQUIREMENTS

4.2.1 PERFORMANCE REQUIREMENTS

4.2.1.1 Temperature Sensor Range: The temperature sensor module shall measure temperature within the range of 20°C to 45°C.

4.2.1.2 Temperature Sensor Accuracy: The sensor shall return readings with an accuracy of 0.1°C of the true value.

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 20-800 Hz.

4.2.1.4 Stethoscope Audio: The digital stethoscope audio shall sound similar to the audio produced through a typical medical-grade stethoscope.

4.2.1.5 Pulse Oximeter Signal Noise: The amplitude changes returned from the pulse oximeter shall be at least 15 dB.

4.2.1.6 Pulse Oximeter Heart Rate: The pulse oximeter module shall be able to return a BPM value from 50 to 180.

4.2.1.7 Skin Impedance Range: The measurable body fat percentage range shall be 5%- 40%, while the water composition range shall be 45%-80%.

4.2.1.8 Skin Impedance Accuracy: The skin impedance sensor shall be able to return a value for the water content of the subject that is within 5% of the true value of the body fat content.

4.2.1.9 Electrocardiogram Accuracy: The ECG sensor shall return a signal with the QRS-complex intact along with the P-wave and T-wave. In order to do so, it shall have a signal-to-noise ratio (SNR) of at least 10 and that the power at 60Hz (power line interference) is less than 10% of the total power.

4.2.2 ENVIRONMENT

4.2.2.1 IP Rating: The system shall be compliant with an IP rating of 20.

4.2.2.2 Operational Temperature: The board shall function within a temperature range of 10 to 40 degrees Celsius.

4.2.2.3 Operational Humidity: The system shall function in areas with Relative Humidity lower than 50%.

4.2.3 DESIGN FEATURES

4.2.3.1 Weight: The system shall not exceed 15 pounds in weight.

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.

4.2.3.3 Inexpensive: The system’s final cost to manufacture one entire system shall not exceed $500.

4.2.3.4 Saved Data: The system will allow the user to save sensor readings as graphed data or in the case of the stethoscope, as an MP3 file.

4.2.3.5 Probe Chemical Resistance: Components exposed to the body fluids or exhaled gasses shall be able to withstand exposure to 70% isopropyl alcohol swabs.

4.2.4 SAFETY

4.2.4.1 Electrical Safety: The system shall not have any exposed electrical components.

4.2.4.2 Privacy Protection: Any reports generated from the board shall be compliant with HIPAA Privacy Rule, 45 CFR Part 160 Subparts A and E.

4.2.4.3 Maximum Bioimpedance Current: The electrodes connected to the skin for the bioimpedance sensor shall not exceed a maximum current of 10 μA.

4.2.4.4 Maximum ECG Current: The electrodes connected to the skin for the ECG sensor shall not exceed a maximum current of 10 μA.

4.2.4.5 Medical Device Standard: The system shall be compliant with IEC 60601-1.

4.2.4.6 Chemical Safety: Components in contact with the skin shall meet ACGIH TEL for surface chemical concentrations.

4.2.5 INTERFACES

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.

4.2.5.2 Computer Communication: The main board must be able to communicate with the user’s computer.

4.2.5.3 GUI: The system shall have a GUI that the user can open on their computer to display data.

4.2.5.4 External Power Supply: The system shall be able to function when provided with 15 amp and 120 V AC.

5.0 VERIFICATION REQUIREMENTS

5.1 PERFORMANCE REQUIREMENTS

5.1.1 Temperature Sensor Range: Fill a container with water and allow it to come to room temperature, roughly 21°C. Place an accurate, pre-calibrated thermometer in the water. Place the temperature sensor into the water. Allow both to come to equilibrium. Verify the pre-calibrated thermometer reads roughly 21°C and verify that the temperature sensor also returns a reading of 21°C. Repeat this process by heating the container to roughly 45°C and repeating the process of allowing the sensors to come to equilibrium and comparing their reading to the expected temperature.

5.1.2 Temperature Sensor Accuracy: Fill a container with water and allow it to come to room temperature, roughly 21°C. Place an accurate thermometer and the temperature sensor into the water and allow both to come to equilibrium. Note the values of both thermometers. Heat the water by roughly 5°C and repeat the measurements. Repeat this process until temperature measurements have been taken for 45°C. Verify that each temperature reading from the temperature sensor is within 0.1°C of the thermometer-measured values.

5.1.3 Stethoscope Sensitivity: Place the sensor probe on the chest over the heart of a healthy human adult. Verify that the digital stethoscope plays the audio of the heartbeat within a range of frequencies (20 Hz to 800 Hz).

5.1.4 Stethoscope Audio: Record sound through the digital stethoscope and analyze sound signals. Using signal processing software and FFT, compare the spectrum of the signal from the digital stethoscope to online stethoscope sound spectrums.

5.1.5 Pulse Oximeter Signal Noise: Connect the pulse oximeter to an individual and take measurements. Measure the amplitude of the noise in comparison to the desired signal and ensure the signal has an amplitude of at least 15 dB greater than the noise.

5.1.6 Pulse Oximeter Heart Rate: The pulse oximeter sensor shall be able to measure an individual's BPM under particular settings. The first shall need the subject to sit quiet and breathe deeply in order to reduce their heart rate. The second shall require the subject to perform one minute of jumping jacks. Both measurements must accord with those of a pre-built pulse oximeter.

5.1.7 Skin Impedance Range: Gather individuals with different physiques and test our device. Collect data and calculate the ranges.

5.1.8 Skin Impedance Accuracy: Rent an impedance device from the University of Arizona's Sensor Lab and compare both devices' outputs. If there are no impedance devices available, check whether any of the three recreational centers at the University of Arizona have any electronic scales with an impedance sensor.

5.1.9 Electrocardiogram Accuracy: Rent an ECG sensor from the University of Arizona's Sensor Lab and compare both devices' outputs. If an ECG is unavailable, gather a group of people and collect their data using the ECG sensor for this project. Find normal ECG results from the web and compare them with the collected data.

5.2 ENVIRONMENT

5.2.1 IP Rating: Place the system flat onto a surface, disconnected from any sources of power. Inspect the system to ensure that hands and fingers are unable to come into contact with exposed electrical components or can enter the internal volume of the system.

5.2.2 Operational Temperature: Place the system within a container cooled to roughly 10°C and allow the system to come to equilibrium. Verify the temperature of the system using an accurate thermometer. Operate the system, ensuring that all systems work within tolerances. Place the system within a container heated to roughly 40°C and repeat all steps to ensure the system works within tolerances.

5.2.3 Operational Humidity: Place the system within a container humidified to roughly 50% relative humidity. Verify that the system components work within tolerances.

5.3 DESIGN FEATURES

5.3.1 Weight: Place the system onto a scale and verify the total weight of the system is less than 15 pounds.

5.3.2 Dimensions: Using a tape measure, measure the length, width, and height of the system and verify that the system is less than or equal to 35.5 cm on one side, 25.4 cm on one side, and 20.7 cm on one side.

5.3.3 Inexpensive: Analyze the costs of parts and labor to verify the total cost of the system is less than $500.

5.3.4 Saved Data: Ask the system to export its saved data to the user's computer and open the data on the computer.

5.3.5 Probe Chemical Resistance: Place into a beaker 100 mL of 70% isopropyl alcohol. Place the sensor probe into the solution. After 1 hour, remove the probe

and inspect the probe for degradation. Activate the sensor probe and verify that the probe still reports normal values.

5.4 SAFETY

5.4.1 Electrical Safety: Inspect the system to ensure that the user does not have access to exposed electrical components without dismantling the system.

5.4.2 Privacy Protection: Inspect the GUI and saved data to ensure that identifying data, such as the user's name is not asked for or used.

5.4.3 Maximum Bioimpedance Current: Attach the electrodes of the bioimpedance module to a DMM and verify the output is less than 10 μA.

5.4.4 Maximum ECG Current: Attach the electrodes of the ECG module to a DMM and verify the output is less than 10 μA.

5.4.5 Medical Device Standard: Inspect all aspects of sensors to ensure they meet IEC 60601-1.

5.4.6 Chemical Safety: Demonstrate the system can be used within parameters set by ACGIH.

5.5 INTERFACES

5.5.1 Internal Power Supply: Measure the amperage of each auxiliary board using a DMM and compare the amperage to the amp hour rating of the battery used. To demonstrate battery life, activate each auxiliary board and enable measurements to be taken. Ensure that each board is active for at least 3 hours.

5.5.2 Computer Communication: Open the GUI on the user's laptop and receive data.

5.5.3 GUI: Open the GUI on the user's laptop and observe that measurements are being displayed.

5.5.4 External Power Supply: Analyze the voltage requirements of the components to ensure the system can function with the provided power.

6.0 SYSTEM REQUIREMENTS VERIFICATION MATRIX (SRVM)

	Verification Method **T = Test** **A = Analysis** **D = Demonstration**

	I = Inspection			
Requirements	**T**	**A**	**D**	**I**
4.2.1 Performance				
4.2.1.1: Temperature Sensor Range	**X**			
4.2.1.2: Temperature Sensor Accuracy	**X**			
4.2.1.3: Stethoscope Sensitivity	**X**	**X**		
4.2.1.4: Stethoscope Audio			**X**	
4.2.1.5: Pulse Oximeter Signal Noise	**X**	**X**		
4.2.1.6: Pulse Oximeter Heart Rate	**X**			
4.2.1.7: Skin Impedance Range	**X**			
4.2.1.8: Skin Impedance Accuracy	**X**			
4.2.1.9: Electrocardiogram Accuracy	**X**		**X**	
4.2.2 Environment				
4.2.2.1: IP Rating	**X**			
4.2.2.2: Operational Temperature			**X**	
4.2.2.3: Operational Humidity			**X**	
4.2.3 Design Features				
4.2.3.1: Weight		**X**		**X**
4.2.3.2: Dimensions		**X**		**X**
4.2.3.3: Inexpensive		**X**		
4.2.3.4: Saved Data			**X**	
4.2.3.5: Probe Chemical Resistance	**X**			
4.2.4 Safety				
4.2.4.1: Electrical Safety				**X**
4.2.4.2: Privacy Protection				**X**

4.2.4.3: Maximum Bioimpedance Current				**X**
4.2.4.4: Maximum ECG Current				**X**
4.2.4.5: Medical Device Standard				**X**
4.2.4.6: Chemical Safety			**X**	
4.2.5 Interfaces				
4.2.5.1: Internal Power Supply	**X**	**X**		
4.2.5.2: Computer Communication			**X**	
4.2.5.3: GUI			**X**	
4.2.5.4: External Power Supply		**X**		

7.0 NOTES

7.1 INEXPENSIVE / PROVIDED COMPONENTS FOR THE PROJECT

These components will not be part of our spent budget due to them being provided by the EDC and sponsor with no additional costs:

- **Electrical Components:**
    1. Copper wires
    2. Resistors
    3. Capacitors
    4. Inductors
    5. ECG wires
    6. Provided Impedance converters
    7. Pins
    8. 9 pin medical grade pulse ox sensor
    9. 9 pin rs232
- **Cleaning components:**
    1. Ethanol 70%
    2. Isopropyl Alcohol 99%
    3. Electronic components cleaner
- **Electrical connections and prototyping:**
    1. Breadboards
    2. Solder
    3. Flux
    4. 3D printing filament

There are other components that are provided by the sponsor from the previous year's team that we may utilize in our project.

7.2 PCB MANUFACTURING

Our PCBs will be manufactured and assembled collaboratively with (PCBWAY) to fulfill a project constraint regarding ease of reproduction and in house maintenance while still keeping costs at a minimum.

8.0 TEAM MEMBERS PRESENT DURING THE DEVELOPMENT OF THE SRD

- Maria Carmella Ocaya - Biomedical Engineer
- Muad Alsayar - Electrical Engineer
- Michael Chase Morrett - Biosystems Engineer
- Daniel Fabricio Campana Moscoso - Electrical Engineer
- William Alec Newman - Mechanical Engineer