June 14, 2020

Professor Craig Scratchley
School of Engineering Science
Simon Fraser University
British Columbia, V5A 1S6

RE: ENSC 405W/ 440 Requirement Specification

Dear Professor Scratchley,

As part of Sleep Glory Technologies Inc., we have created the requirement specification document as a means of documentation for ENSC 405W/ 440. We intend to build a fully functional smart headband, called Medeor, that is targeted as a health tracker, towards the general public. With the help of Medeor, each individual is able to track their brain activity, pulse, temperature, etc., which could be used to improve their lifestyle.

By implementing a robust, small, and reliable EEG monitoring system that is interfaced with a pulse sensor, accelerometer and snoring detection, each individual can keep track of their sleep cycle and find solutions to better their routine. With additional features such as relaxing music and up to date notifications of their health data via the app, members of the community will find it easier to improve their daily routine.

Through this documentation, we will provide the necessary requirements needed to achieve the final product. By listing the software and hardware requirements needed for each stage, which is from the Proof Of Concept to the final product, we will provide a timeline of deliverables needed to achieve a fully functioning product. To add to that, we have included safety requirements.

On behalf of the team, we would like to thank you for taking the time to review our product's requirements. You can contact us at aromaniv@sfu.ca for further inquiries.

Yours sincerely,

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Requirement Specification: Medeor

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Abstract

Medeor is a smart headband that is to act as a health tracker by monitoring an individual's sleep cycle, pulse, and snoring. The documentation elaborates on the functionalities of Medeor by listing the core requirements, that is what is required from the product as a whole to each specific components' requirements. The purpose of this document is to inform the reader of what is expected of delievarable during the different stages: Proof Of Concept, Prototype, Final Product. Furthermore, the safety requirements and Engineering standards are included to further inform the reader as to how the product abides by the law.

The document analyzes the hardware and software requirements of the product. Firstly, we will look at the components that make the hardware system, namely the pulse sensor, EEG, microphone (to detect snoring), and the microcontroller system. We will then elaborate on what the software requirements are such as signal processing and application development to create an environment for the user to receive their health data. To add onto that, we discuss how the hardware and software systems are to interact and the requirements needed to enable the communication between them.

1. Introduction

Medeor is a cost-effective tool that can be used as a daily health monitor by tracking an individual's sleep cycle via electroencephalogram (EEG), pulse and breathing. The system will be able to collect the user's sleep patterns, analyze them, and recommend the solution. The input data are compared against pre-set values to determine the sleeping behavior of the user. If an irregularity has been detected the user or any caretaker will receive a notification to inform them of any possible abnormalities.

Medeor is targeted towards people suffering from insomnia due to anxiety, stress, etc. However, with the additional built in features such as the pulse sensor and snoring detector, Medeor is made for the general public interested in maintaining their health through a cost-effective and robust system.

1.1 Background

The market for sleep associated technology is expected to cross $27 Billion by 2025 [1]. Studies show that about 33% of the world population suffer from insomnia and 10% of them are in chronic stage [2].Furthermore, 40% and 24% of male and female identified individuals are habitual snorers, respectively [3]. This allows the sleep tech industry to grow at a rapid pace.

1.2 Scope

The document provides information to the reader regarding technical and functional requirements of the Medeor product. By elaborating and listing the specifications of each component and the system as a whole, the reader will be able to understand the product's expected functionality. To add onto that, the document will set Engineering and Safety Standards for the product. Furthermore, the sustainability aspect of the product will be discussed. All of the requirements will be categorized according to each stage of production (proof of concept, prototype and finished product).

1.3 Intended Audience

The requirements specification document informs the developers, testers, and executives of the expected functional requirements of the product during each stage of production.

1.4 Requirement Classification

The stages of product development are summarized and listed in the table below:

Table 1: List of stages of development

No	*Stage Of Production*	*Encoding*
#	Proof Of Concept	POC
#	Prototype	PT
#	Final Product	FP

To allow the reader to better understand the acronyms used in the documentation. The following format will be adapted to list all the requirements of the documentation:

Req {Section}.{Sub-Section} - {Stage Of Production}:{Item No}

Once requirements are set they are propagated over next stages, unless redefined.

2. Product Overview

Medeor has been designed as a cost-effective, robust and user friendly health monitoring system to help each user track their health parameters and improve sleep quality. This product will consist of two main parts: headband and mobile application.The Headband will be worn by the user overnight, and it will collect various sleeping data including brain activity, heart pulse and position of the head. The EEG will be responsible for monitoring electrical activity of the brain. The above data will indicate at what stage of the sleep cycle the user is in and detect any abnormal behaviour. Based on that information, Medeor will be able to play calming noises to keep users in deep sleep. In addition, new sleeping schedules will be suggested.
The figure below describes how the entire system is expected to work and the expected design, respectively:

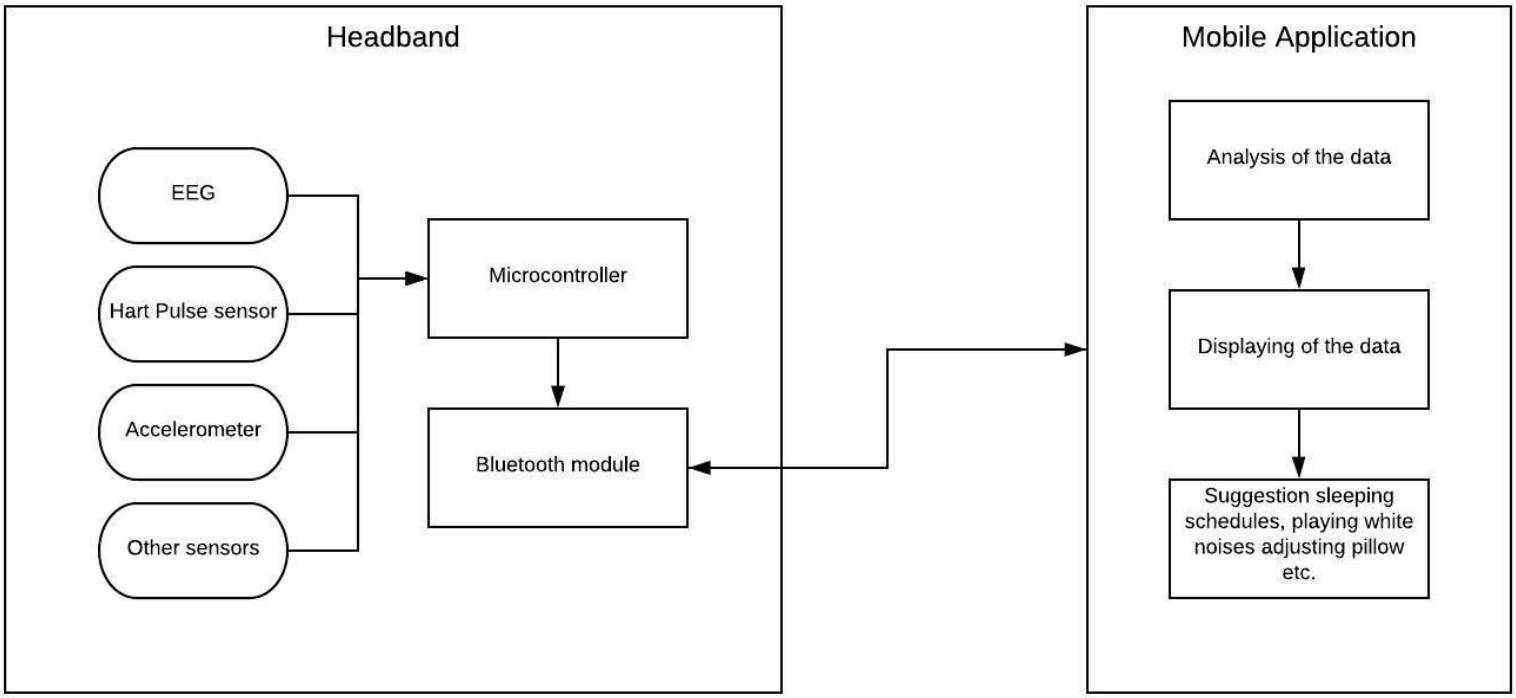

Figure 1: Medeor System Block Diagram

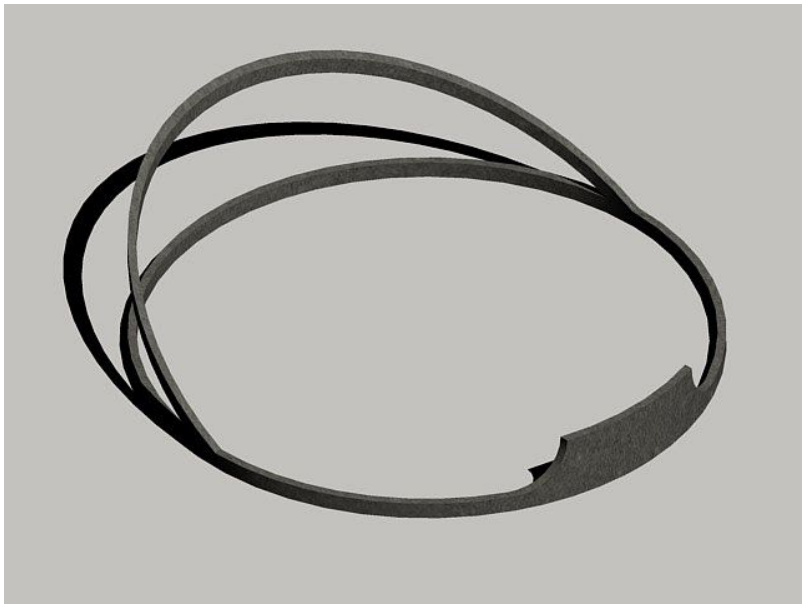

Figure 2: Model of Medeor

Figure 2 shows the sample design of the headband. It will include an embedded EEG monitoring system, pulse sensor, accelerometer, microphone, Bluetooth module and power supply. The EEG used in conjunction with the pulse sensor would provide a more reliable analysis of the user's sleep. The embedded microphone will help to detect the user's snoring pattern and can be used to reveal the causes of spikes in brain activity.

The data collected from the sensors will be amplified & filtered. It is then transferred to a microcontroller and stored to be sent to the phone. The microcontroller will connect to a mobile device via Bluetooth , after which the data is transferred. The transferred data will be analyzed and the results will be displayed.

The analyzed data will be stored, so it could be compared against other historic data.

3. Requirements:

This section will outline general requirements to the Medeor product. The following subsections describe the requirements for the product as a whole and for each individual component.

3.1 System requirements

System requirements are the high-level overview of the main functionality of Medeor product.

Table 2: POC Requirements for the System

No	*Requirement ID*	*Description of the requirement*
1.	**Req 3.1 - POC: 1**	The product shall have working EEG monitoring system
2.	**Req 3.1 - POC: 2**	The product shall have working accelerometer sensor
3.	**Req 3.1 - POC: 3**	The microcontroller shall record and store EEG data
4.	**Req 3.1 - POC: 4**	The microcontroller shall record and store accelerometer data
5.	**Req 3.1 - POC: 5**	The microcontroller & application shall be able to establish Bluetooth connection
6.	**Req 3.1 - POC: 6**	The microcontroller & application shall transfer data via Bluetooth
7.	**Req 3.1 - POC: 7**	The application shall have user friendly user interface (UI)
8.	**Req 3.1 - POC: 8**	The application UI shall have night color palette
9.	**Req 3.1 - POC: 9**	The application shall analyze sleeping data
10.	**Req 3.1 - POC: 10**	The application shall detect and report abnormal sleeping data
11.	**Req 3.1 - POC: 11**	The application shall play calming sound to keep user in deep sleep

Table 3: PT Requirements for the System

No	*Requirement ID*	*Description of the requirement*
12.	**Req 3.1 - PT: 1**	The headband shall have functional Heart Pulse monitoring system
13.	**Req 3.1 - PT: 2**	The microcontroller shall record and store Heart Pulse data
14.	**Req 3.1 - PT: 3**	The headband shall be comfortable for overnight use
15.	**Req 3.1 - PT: 4**	The headband shall be autonomous for at least 12 hours
16.	**Req 3.1 - PT: 5**	The application shall visualize additional sleeping data
17.	**Req 3.1 - PT: 6**	The application shall suggest how to improve sleep quality

Table 4: FP Requirements for the System

No	*Requirement ID*	*Description of the requirement*
18.	**Req 3.1 - FP: 1**	The headband shall cost less than $350
19.	**Req 3.1 - FP: 2**	The headband shall weight less than 300 grams
20.	**Req 3.1 - FP: 3**	The headband shall play calming sound to keep user in deep sleep
21.	**Req 3.1 - FP: 4**	The application shall have general information about the product
22.	**Req 3.1 - FP: 5**	Shall have the following operation range: +15 to +45°C
23.	**Req 3.1 - FP: 6**	User manual shall be available in English

3.2 Physical requirements

Medeor should have the following physical requirements:

Table 5: PT Requirements for the Headband

No	*Requirement ID*	*Description of the requirement*
24.	**Req 3.2 - PT: 1**	The headband shall have the mean circumference about 55cm
25.	**Req 3.2 - PT: 2**	The headband shall be adjustable within 6cm range
26.	**Req 3.2 - PT: 3**	The headband shall be flexible
27.	**Req 3.2 - PT: 4**	The headband shall be soft
28.	**Req 3.2 - PT: 5**	The headband shall have enlargement on the forehead (or higher).
29.	**Req 3.2 - PT: 6**	The enlargement shall have the maximum following dimensions: 5.5 cm width & 7.5 cm length
30.	**Req 3.2 - PT: 7**	The headband shall have tough plate in the enlargement

Table 6: FP Requirements for the Headband

No	*Requirement ID*	*Description of the requirement*
18.	**Req 3.2 - FP: 1**	The headband shall cost less than $350
19.	**Req 3.2 - FP: 2**	The headband shall weight less than 300 grams
31.	**Req 3.2 - FP: 3**	The headband shall be cleanable

3.3 Hardware requirements

This section includes hardware requirements for the following sections:sensors, Bluetooth module, microcontroller, power supply, speaker, and wireless connectivity.

3.3.1 Sensor requirements

3.3.1.1 EEG

Background on EEG:
EEG is a method for measuring the Electrical signals of the brain [4]. This is possible because the neurons communicate with each other using electrical impulses. An EEG is therefore useful in determining if there are any spikes in electrical activity as it indicates some kind of brain disorder.

Electrodes:
There are two types of non invasive electrodes, Wet and Dry. Wet electrodes are most commonly used in clinical settings while Dry electrodes have been developed for specific products in home use, they are also being developed for performing faster EEG in clinics as deployment of 10 -20 EEG international system takes time [5].

While we continue to search for a good dry electrode to use in our product, a gold plated electrode has been selected as a potential electrode for the final product. It has been considered it will be good to make our own electrode as it is just a piece of metal which can conduct well. By making our own flat electrode, we can save money and change its shape as required by our product when we go into the manufacturing stage.
For the prototype, we can use the gel electrodes which we can easily buy in bulk online.

Measurements:
The waves in the brain can be differentiated on the bases of frequency. Different wavelengths characterize the stages of the brain from awake to deep sleep [5]. To detect these waves, we

need a circuit which can amplify the input and reasonably filter out the noise. The Diagram for Layout of amplification circuit is shown below:

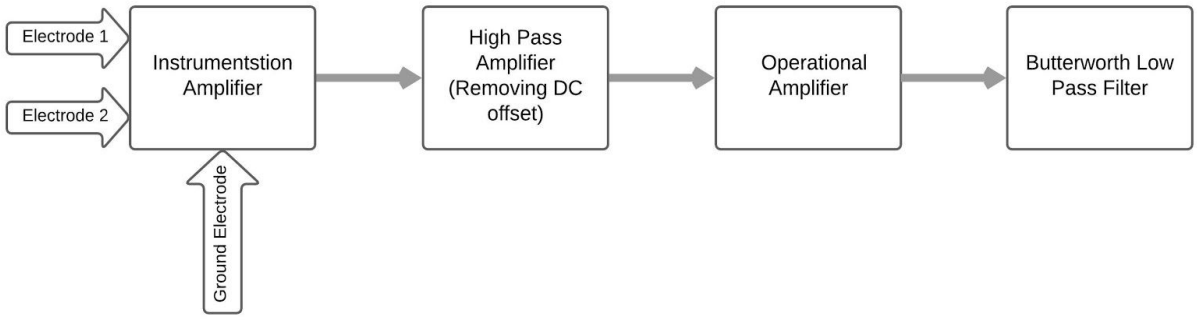

Figure 3: Layout of Amplification Circuit

Table 7: POC Requirements for Amplification Circuit

No	*Requirement ID*	*Description of the requirement*
32.	**Req 3.3.1.1.1 - POC: 1**	Amplifier shall have gain of at least 1000 or 60dB, so that 1uV input = 1mV output [5]
33.	**Req 3.3.1.1.1 - POC: 2**	Amplifier shall work on low voltage to reduce power consumption and heat release
34.	**Req 3.3.1.1.1 - POC: 3**	Low Pass Filter shall suppress the high frequency noise of anything larger than 50Hz
35.	**Req 3.3.1.1.1 - POC: 4**	High Pass Filter shall suppress the low frequency noise of anything smaller than 1Hz
36.	**Req 3.3.1.1.1 - POC: 5**	Differential Op-Amp shall have CMRR of about 100dB
37.	**Req 3.3.1.1.1 - POC: 6**	Shall output signal to Microcontroller

Table 8: FP Requirements for EEG For Amplification Circuit

No	*Requirement ID*	*Description of the requirement*
38.	**Req 3.3.1.1.1 - FP: 1**	Circuit shall operate on 3.3/3.7V supply
39.	**Req 3.3.1.1.1 - FP: 2**	Circuit has Gain of 3000 or higher
40.	**Req 3.3.1.1.1 - FP: 3**	Bandwidth filtering of 1 to 60-Hz Effectively
41.	**Req 3.3.1.1.1 - FP: 4**	Shall have the following operation range: +15 to +45°C

The table below lists the requirements for electrodes

Table 9: POC Requirements for EEG For Electrodes

No	*Requirement ID*	*Description of the requirement*
42.	**Req 3.3.1.1.2 - POC: 1**	The electrodes shall be highly conductive
43.	**Req 3.3.1.1.2 - POC: 2**	The electrodes shall cost less than 5$
44.	**Req 3.3.1.1.2 - POC: 3**	The electrode shall have reasonable contact area with the skin

3.3.1.2 Heart Pulse sensor

The pulse sensor acts as a heart rate detector by monitoring the blood flow. The circuitry consists of a Light Emitting Diode and a Light Detecting Resistor [6]. The sensor should be placed directly on top of the vein to detect the blood flow more easily. The blood flow reflects the emitted light which is then passed as electrical signals. The amount of blood flow is proportional to the heart rate and therefore the change in blood flow corresponds to the heart rate [7]. To add onto that, the configuration consists of 2 OP-AMPS, one for noise reduction and the other signal amplification. Based on the information, the requirements pertaining to a pulse sensor are listed below [8]:

Table 10: POC Requirements for Pulse sensor

No	*Requirement ID*	*Description of the requirement*
45.	**Req 3.3.1.2 - POC: 1**	Shall be able to work from 3.3 V
46.	**Req 3.3.1.2 - POC: 2**	Shall have a current of about 4mA
47.	**Req 3.3.1.2 - POC: 3**	Shall detect pulse in head or ear lobe
48.	**Req 3.3.1.2 - POC: 4**	Diameter shall be less then 20 mm
49.	**Req 3.3.1.2 - POC: 5**	Thickness shall be less than 4 mm
50.	**Req 3.3.1.2 - POC: 6**	Shall perform noise reduction within sensor
51.	**Req 3.3.1.2 - POC: 7**	Shall output signal to Microcontroller

Table 11: FP Requirements for Pulse sensor

No	*Requirement ID*	*Description of the requirement*
52.	**Req 3.3.1.2 - FP: 1**	Should be cost effective
53.	**Req 3.3.1.2 - FP: 2**	Shall have the following operation range: +15 to +45°C

3.3.1.3 Snoring detection sensor

According to the research [9], the snoring can be caused by: Sleeping position; Nasal obstruction;Bad habits (alcohol, cigarettes, drugs); Cold temperature and dry atmosphere; Overweight; Dust & Allergies; Aging.

The snoring causes people to wake up, so it diminishes sleep quality. Detecting the snoring with a microphone will allow us to suggest a possible solution & provide better understanding of EEG readings. Snoring frequency is up to 1500Hz & power < 100 dB therefore the microphone should be able to determine such bandwidth [10].

Table 12: PT Requirements for Microphone sensor

No	*Requirement ID*	*Description of the requirement*
54.	**Req 3.3.1.3 - PT: 1**	Sensor shall be able to operate from 3.3 V
55.	**Req 3.3.1.3 - PT: 2**	Sensor shall record 1500 Hz sound waves
56.	**Req 3.3.1.3 - PT: 3**	Sensor shall record 100 dB sound waves

57.	**Req 3.3.1.3 - PT: 4**	Sensor shall have fixed-gain, built-in amplification
58.	**Req 3.3.1.3 - PT: 5**	Sensor shall be small (3mm x 3mm or less)
59.	**Req 3.3.1.3 - PT: 6**	Sensor shall output signal to Microcontroller

Table 13: FP Requirements for Microphone sensor

No	*Requirement ID*	*Description of the requirement*
60.	**Req 3.3.1.3 - FP: 1**	Shall be relatively cheap
61.	**Req 3.3.1.3 - FP: 2**	Shall have the following operation range: +15 to +45°C

3.3.1.4 Accelerometer

There are 3 commonly used commercial devices [11]: piezoelectric, piezoresistive and capacitive.

Piezoelectric Devices:
They are lightweight and have high-frequency response.Piezoelectric transducers are inherently high output impedance devices and require special impedance-transforming amplifiers.

Piezoresistive Devices:
They use strain as a mechanical input to produce voltage.The change in signal due to strain is usually a small fraction of the total signal level in the circuit output and temperature variations also produce error

Capacitive Devices:
They are non contacting devices and high resolution measurements can be made with them. Relatively less costly and small linear, with straightforward compensation. The tradeoffs are low-sensitivity & need in a clean environment. Amplification is required, but most accelerometer circuitry comes with integrated amplification..

We have selected a capacitive accelerometer which is the best for motion sensing applications (relatively low frequency); piezoelectric is best for vibration; and piezoresistive is best for shock testing.

Table 14: POC Requirements for Accelerometer sensor

No	*Requirement ID*	*Description of the requirement*
62.	**Req 3.3.1.4 - POC: 1**	Accelerometer shall have amplification circuit
63.	**Req 3.3.1.4 - POC: 2**	Accelerometer shall operate on 3.3 V

64.	**Req 3.3.1.4 - POC: 3**	Accelerometer shall have the following operation range: +15 to +45°C
65.	**Req 3.3.1.4 - POC: 4**	Accelerometer shall output signal to microcontroller

3.3.2 Microcontroller requirements:

Medeor will require a processing unit to be located on the headband. Limited space will restrict the size of the microprocessor. According to our market research [12], and requirements considered earlier, we defined the dimensions to be 45x20mm. Furthermore, the controller should operate on 3.3V due to minimizing the power consumption (by 2.3 times lower than 5V), which will lead to longer operating life and will minimize power-supply dimensions.

Based on our research [12], Arduino has a simple topology making it the most feasible for our project. We did consider Raspberry Pi with its additional functionality, however the functionality was not necessary for this project, as such the additional cost and size was avoided. Arduino has real-time and analog capabilities, which increases the sensor compatibility. Whereas, Pi requires additional software or hardware to be installed. The tradeoff between the two is “Multitasking”, fortunately, this problem can be solved using Protothreading.

The board that has the lowest power consumption and relatively small size was chosen. This board is an Arduino Pro Mini which operates at 3.3V, 23µA (without load) and 8Mhz [13]. The maximum current draw is 200mA.

Table 15: POC Requirements for Microcontroller System

No	*Requirement ID*	*Description of the requirement*
66.	**Req 3.3.2 - POC: 1**	Microcontroller's dimensions shall be less than 45x20mm
67.	**Req 3.3.2 - POC: 2**	Microcontroller shall operate at 3V to 5V
68.	**Req 3.3.2 - POC: 3**	Microcontroller shall supply 3.3V
69.	**Req 3.3.2 - POC: 4**	Microcontroller shall collect data from the sensors
70.	**Req 3.3.2 - POC: 5**	Microcontroller shall have 6+ analog input terminals
71.	**Req 3.3.2 - POC: 6**	Microcontroller shall to store data in the internal storage (32 Kb)
72.	**Req 3.3.2 - POC: 7**	Microcontroller shall connect to Mobile device via Bluetooth
73.	**Req 3.3.2 - POC: 8**	Arduino microcontroller shall be used in the POC prototype

74.	**Req 3.3.2 - POC: 9**	Microcontroller shall have the following operation range: +15 to +45°C

Table 16: Prototype Requirements for Microcontroller System

No.	*Requirement ID*	*Description of the requirement*
75.	**Req 3.3.2 - PT: 1**	Microcontroller shall be powered with a battery in headband, 3.3V
76.	**Req 3.3.2 - PT: 2**	Hard restart functionality shall be implemented
77.	**Req 3.3.2 - PT: 3**	Arduino Pro Mini microcontroller shall be used in the POC prototype

3.3.3 Power supply requirements

Considering the maximum current draw for Arduino Pro Mini (200mA) [12] and minimum 10 working hours we can estimate the capacity for the power supply:

200mA * 10h = 2000 mAh

Therefore, the product should have at least 2000 mAh battery to last for 10 hours (over night) with a maximum current consumption. However, we expect the drain to be way lower, so this will extend the operating time & reserve some capacity for degradation & efficiency boost.

Table 17: POC Requirements for Power Supply

No.	*Requirement ID*	*Description of the requirement*
78.	**Req 3.3.3 - POC: 1**	The PC shall power the Arduino Board
79.	**Req 3.3.3 - POC: 2**	The battery (or pair) of 9 V shall power the EEG Circuit

Table 18: Prototype Requirements for Power Supply

No.	*Requirement ID*	*Description of the requirement*
80.	**Req 3.3.3 - PT: 1**	The battery shall have max discharging current > 0.2 A
81.	**Req 3.3.3 - PT: 2**	The battery shall be rechargeable
82.	**Req 3.3.3 - PT: 3**	The battery shall have charging time at least 180min

83.	**Req 3.3.3 - PT: 4**	The battery shall have voltage = 3.3 - 3.7 V
84.	**Req 3.3.3 - PT: 5**	The battery shall be Lithium-Ion battery
85.	**Req 3.3.3 - PT: 6**	The battery shall have capacity should be high enough (2000mAh) to power the head bandage overnight or longer
86.	**Req 3.3.3 - PT: 7**	Battery life shall be 300 cycles or longer at room temperature
87.	**Req 3.3.3 - PT: 8**	The battery shall be thin and flat, so the user's sleeping won't be affected about: 6.2 * 50.5 * 70mm (Thickness * width * length)
88.	**Req 3.3.3 - PT: 9**	The battery shall be replaceable

3.3.4 Speaker requirements

The headband should have a speaker, which will play a sound and stabilize the brain activity. The sound should not interfere with anyone's sleep. This speaker should be small, so it can be easily placed close to the ear. Speaker's quality is good enough to not produce any noises (signal to noise ratio) [14]. The extreme quality is unnecessary due to functionality (playing background noises over night), so the price can be minimized.

Table 19: Prototype Requirements for Speaker

No.	*Requirement ID*	*Description of the requirement*
89.	**Req 3.3.4 - PT: 1**	The speaker shall operate on low voltage (3.3V - 3.7V)
90.	**Req 3.3.4 - PT: 2**	The speaker shall be less than 50 mm in diameter
91.	**Req 3.3.4 - PT: 3**	The speaker shall have height less than 3mm
92.	**Req 3.3.4 - PT: 4**	The speaker shall have SNR at least 20dB
93.	**Req 3.3.4 - PT: 5**	The speaker shall have an amplifier
94.	**Req 3.3.4 - PT: 6**	The speaker shall have the following operation range: +15 to +45°C

3.3.5 Wireless connectivity requirements

There are 2 commonly used types of wireless connectivity. The first one is WiFi connection, which is not suited for our purposes since users might travel and will have to establish new connections to LAN every time they change location. The second type of connection is via Bluetooth. which depends on its profile capabilities.

There are two types of profiles: SPP (Serial Port Profile) and BLE (Bluetooth Low Energy) [15]. SSP usually requires you to pair the operating system with the host, then with the individual application. Also, Bluetooth SPP is not supported by iOS devices. Bluetooth Low Energy (BLE) only requires you to pair with the individual application and it has the same pairing process on iOS and Android. BLE is a preferred option for this project since it is designed to provide a significantly lower power consumption (8mA for BLE vs 30mA for SPP). The drawback is that BLE is not useful for transferring large files and it is most ideal to transmit a small amount of data at higher speeds,up to 10 times faster than other Bluetooth profiles [15]. Fortunately this is exactly the type of data the product will send. Moreover, BLE covers longer distances around 1,000m but SPP only covers around 100m. Both SPP and BLE BLE operate at the same 2.4 GHz ISM band [15].

Table 20: POC Requirements for Wireless Connectivity

No.	*Requirement ID*	*Description of the requirement*
95.	**Req 3.3.5 - POC: 1**	The modem shall powered from 3.3V to 5V
96.	**Req 3.3.5 - POC: 2**	The modem shall have a low power consumption (less than 10 mA) for BLE
97.	**Req 3.3.5 - POC: 3**	The modem circuit shall include UART [17]
98.	**Req 3.3.5 - POC: 4**	The modem shall have built-in antenna
99.	**Req 3.3.5 - POC: 5**	The Android device shall supports BLE

3.4 Software requirements

Software will play a significant part in the product, as it is important that the user has a smooth and user-friendly experience. Users will be able to track their sleeping cycles, level of sleep and any abnormalities on a screen of their cell phones. The requirements in this section focus on two separate software programs: on microcontroller and on mobile device. It is important that high quality code and optimized algorithms are used.

3.4.1 Microcontroller software requirements

The software of the microcontroller shall be able to collect the data from all of the available sensors. As the signal is received as an analog input (voltage), it must be formatted into a consumable form. The next step will be to save the data in the internal storage for later use. It is also important to check and maintain Bluetooth connection with the phone to transfer data. Basic logic of the data flow is described below:

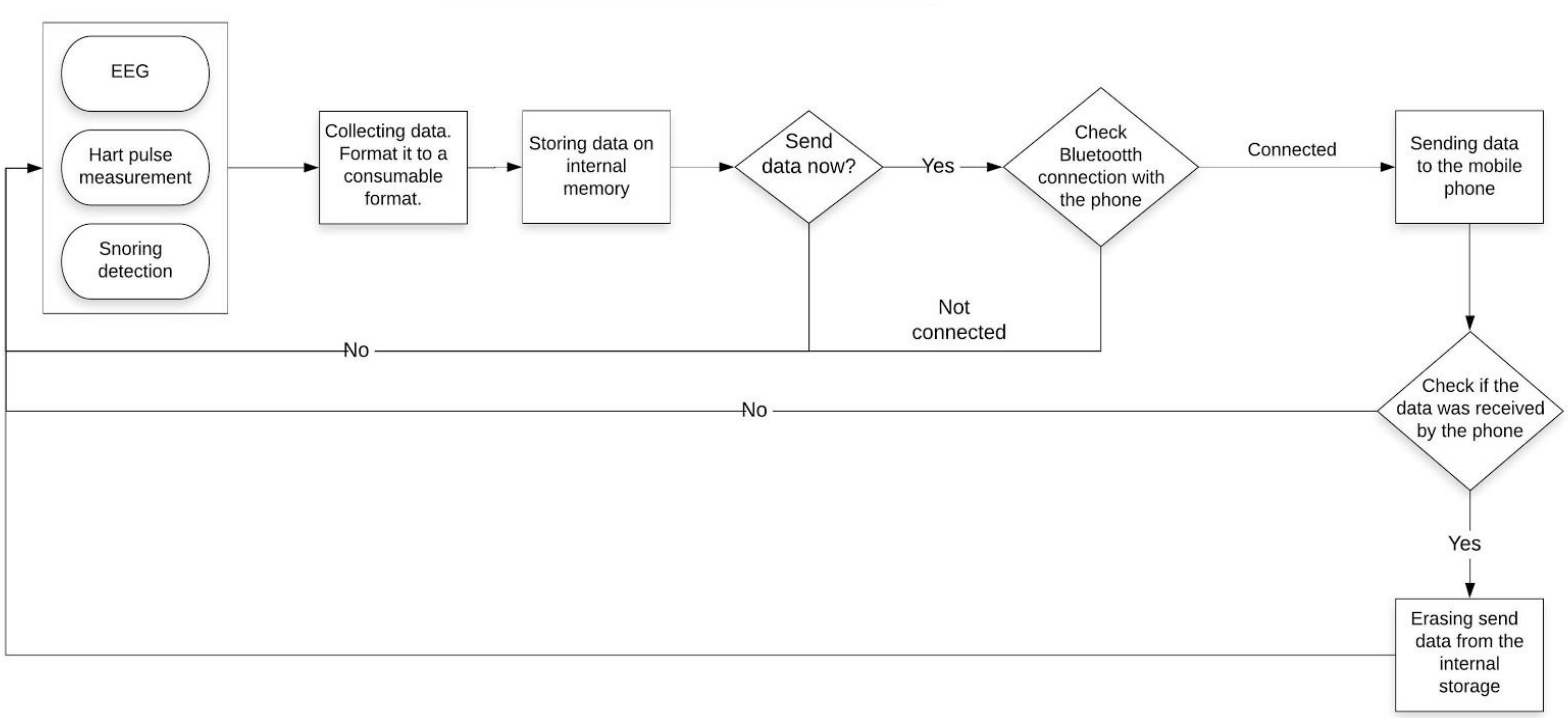

Figure 4: Data Flow in a Microcontroller System

According to the workflow above, below requirements have been selected for various stages of the product development.

Table 21: POC Requirements for Microcontroller Software

No.	*Requirement ID*	*Description of the requirement*
100.	**Req 3.4.1 - POC: 1**	Microcontroller shall collect and process data from the sensors
101.	**Req 3.4.1 - POC: 2**	Collected data shall be formatted into a consumable form
102.	**Req 3.4.1 - POC: 3**	Microcontroller shall be able to establish Bluetooth connection

The tables below lists the requirements expected from the prototype and final product:

Table 22: Prototype Requirements for Microcontroller Software

No.	*Requirement ID*	*Description of the requirement*
103.	**Req 3.4.1 - PT: 1**	Microcontroller shall be able to store data in internal storage
104.	**Req 3.4.1 - PT: 2**	Handshake protocol shall be implemented to check if data was delivered to the phone

Table 23: Final Product Requirements for Microcontroller Software

No.	*Requirement ID*	*Description of the requirement*
105.	**Req 3.4.1 - FP: 1**	Storing data shall be memory efficient
106.	**Req 3.4.1 - FP: 2**	Microcontroller shall be able to check if sensor is non responsive (broken)
107.	**Req 3.4.1 - FP: 3**	Microcontroller shall be updated over-the-air programming (OTA)

3.4.2 Mobile application software requirements

The mobile side of software is an application. For the scope of this project we decided to implement a native Android application and exclude cross-platform support. The diagram below shows the expected basic workflow for the application. Application receives data via Bluetooth, stores it locally, and analyzes. Then the data will be displayed to the user in different forms. The application will adopt under the user's preferences, give some recommendations, and suggest a sleeping schedule. The future development expects interaction with a user in sleep. Such as playing the background sound to interfere with brain activity.

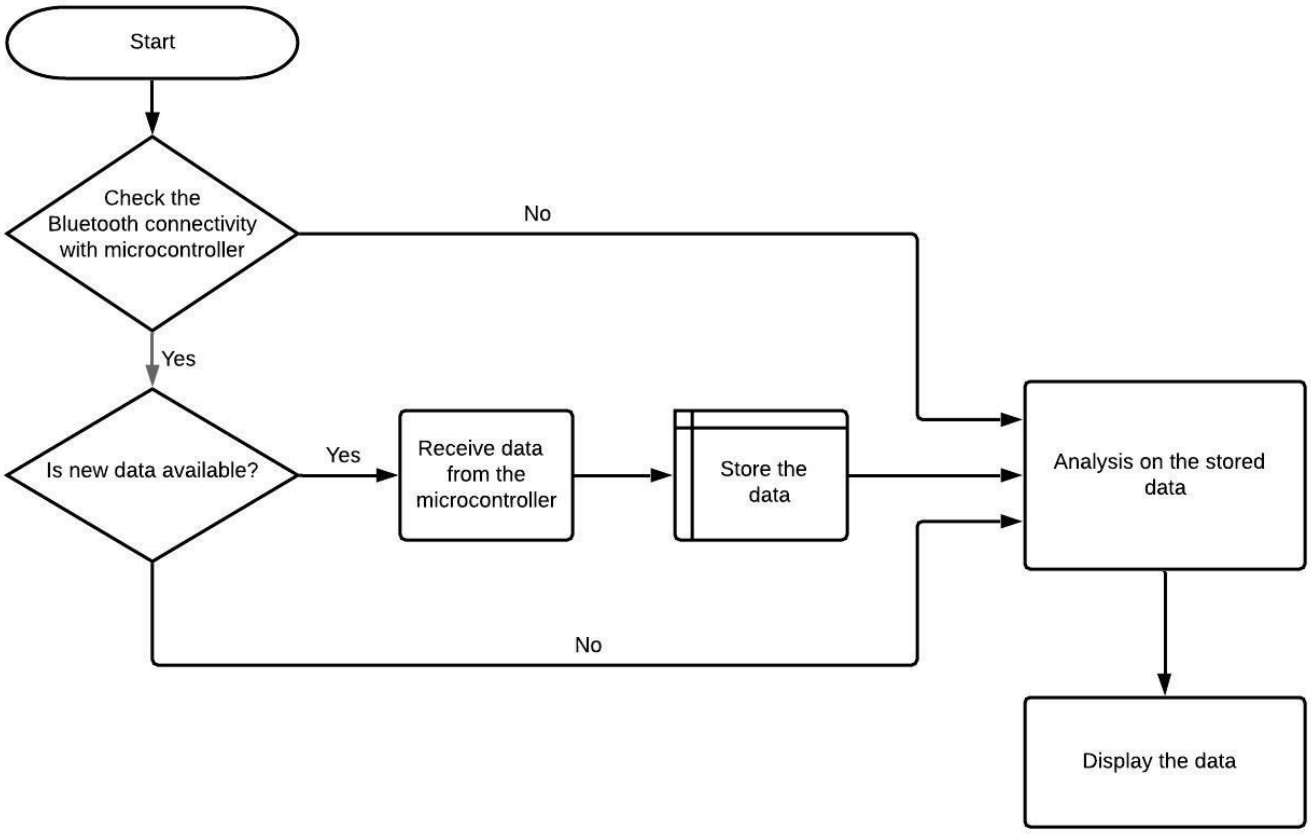

Figure 5: Layout for Mobile Software

Table 24: POC requirements for Mobile Application Software

No.	***Requirement ID***	***Description of the requirement***
108.	**Req 3.4.2 - POC: 1**	The application shall be available for devices with Android version 8.0 and higher.
109.	**Req 3.4.2 - POC: 2**	The application shall connect to Arduino via Bluetooth
110.	**Req 3.4.2 - POC: 3**	The application shall read & display received data
111.	**Req 3.4.2 - POC: 4**	The application shall distinguish types of brain waves

Table 25: Prototype Requirements for Mobile Application

No.	*Requirement ID*	*Description of the requirement*
112.	**Req 3.4.2 - PT: 1**	The application shall detect sleeping cycles based on data
113.	**Req 3.4.2 - PT: 2**	The application shall analyze the data that has been sent to discover any unusual pulse/breathing/brain activity.
114.	**Req 3.4.2 - PT: 3**	The application shall store data, so that historical charts can be build
115.	**Req 3.4.2 - PT: 4**	The application shall suggest the sleeping schedule based on recorded data.
116.	**Req 3.4.2 - PT: 5**	The application shall play calming music

Table 26: Final Product Requirements for Mobile Application

No.	*Requirement ID*	*Description of the requirement*
117.	**Req 3.4.2 - FP: 1**	The application shall data consistently over the night when it is prompted by a user
118.	**Req 3.4.2 - FP: 2**	The app will call 911 / close relative in case of emergency
119.	**Req 3.4.2 - FP: 3**	The profile page shall have a radial chart or any other graph that displays the progress of the patients

4. Engineering Standards:

Every electronic device must satisfy the certain standards set up by international or national Institutions.There are many certifications that a product can apply for but for our product we can focus on International Organizations for Standardization (ISO), The International Electrotechnical Commission (IEC) and Canadian Standards Authority (CSA), Institute of Electrical and Electronics Engineers (IEEE), Transportation of Dangerous Goods (TDG).

4.1 Safety and essential engineering standards

The following table lists the medical device software standards:

Table 27: List of Safety and Engineering Standards

Standard	*Description*
ISO 14971:2019	Medical devices - Application of risk management to medical devices[18]
IEC 62366:2007	Medical devices - Application of usability engineering to medical devices[19]
CAN/CSA-IEC 62366:14	Medical devices - Application of usability engineering to medical devices (Adopted IEC 62366:2007, first edition, 2007-10) [20]
CAN/CSA-C22.2 NO. 60601-2-47:14 (R2018)	Medical electrical equipment — Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems(IEC 60601-2-47:2012, MOD) [21]
IEC TR 62809:2019	Summary of requirements and tests for products in the scope of IEC 60601-2-66 [22]
IEC 62353:2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment [23]
IEC 82304-1:2016	Health software — Part 1: General requirements for product safety [24]
CAN/CSA-C22.2 No. 60601-1-9:15	Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design (IEC 60601-1-9:2013, MOD) [25]
CSA C22.2 No. 0.23-15	General requirements for battery-powered appliances [26]

4.2 Medical Device Software:

The following table lists the medical device software standards:

Table 28: List of Medical Device Software Standards

Standard	*Description*
IEC 62304:2006	Medical device software - Software life cycle processes [27]
CAN/CSA-CEI/IEC 62304:14	Medical device software - Software life cycle processes (Adopted CEI/IEC 62304:2006, first edition, 2006-05) [28]
IEC/TR 80001-2-9:2017	Application of risk management for IT-networks incorporating medical devices — Part 2-9: Application guidance — Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities [29]

4.3 Quality and Risk Management Standards:

The following table lists the quality and risk management standards:

Table 29: List of Quality and Risk Management Standards

Standard	*Description*
CAN/CSA-ISO/TR 14969:05 (R2010)	Medical Devices - Quality Management Systems - Guidance on the Application of ISO 13485:2003 [30]
CAN/CSA-ISO 13485:16	Medical devices — Quality management systems — Requirements for regulatory purposes [31]
ISO 14971:2019	Medical devices — Application of risk management to medical devices [32]
CAN/CSA-C22.2 No. 60529:16	Degrees of protection provided by enclosures (IP Code) [33]

4.4 EEG Specific Standards:

The following table lists the EEG specific standards:

Table 30: List of EEG Specific Standards

Standard	*Description*
ISO 22077-1:2015	Medical waveform format - Part 1: Encoding rules [34]
IEC 80601-2-26:2019	Particular requirements for the basic safety and essential performance of electroencephalographs [35]

4.5 Battery standards:

The following table lists the battery standards:

Table 31: List of Battery Standards

Standard	*Description*
CSA C22.2 No. 60086-4:19	Primary batteries — Part 4: Safety of lithium batteries [36]
IEC 62281	Safety of primary & secondary lithium cells and batteries during transport [37]
IEC 60086-4	Primary Batteries - Safety of Lithium Batteries [38]
IEEE 1625	Rechargeable Batteries for Multi-cell Mobile Computing Devices [39]
TDG Act	Transportation of Dangerous Goods [40]

5. Safety and Sustainability

Our product contains a number of electrical components and wiring. As a result, certain safety and sustainability requirements must be met to ensure the longevity of the product. The final product will ensure that the electrical components are not visible to the end user and will operate safely under normal conditions. Also, we have to consider some extreme cases, such as cold or hot environments (despite the fact that it is enough for the product to operate in +15 to +45 °C).

Table 32: List of Safety and Sustainability Requirements

No	*Requirement ID*	*Description*
120.	**Req 5.1 - FP: 1**	The product will be made from recyclable materials
121.	**Req 5.2 - FP: 2**	Product shall visibly display a recycling logo due to the usage of lithium ion batteries
122.	**Req 5.3 - FP: 3**	User shall be cautioned of Safety hazards
123.	**Req 5.4 - FP: 4**	The product shall handle extreme temperature -20 to +60°C
124.	**Req 5.5 - FP: 5**	The battery life cycle of the product shall be 300 - 500 charge cycles.
125.	**Req 5.6 - FP: 6**	Packaging shall come with manual instructions on maintaining cleanliness of the product
126.	**Req 5.8 - FP: 7**	During usage of product, user shall not be exposed to any toxins
127.	**Req 5.8 - FP: 8**	During usage of product, the effect of EMW shall be minimized

6. Acceptance Test Plan

For the proof of concept stage, our team will require to prove and benchmark the main concepts of the project.

The goal of the proof of concept is to :

- Collect the brain activity data using EEG
- Collect hart pulse data
- Collect position data with accelerometer
- Store collected data on microcontroller
- Transfer data from microcontroller to mobile app
- Mobile app shall be able to analyze data from the sensors
- Mobile app shall be able to display data from the sensors

In order to fulfill the above test plan, the following POC requirements must be satisfied.

Table 33: POC requirements for Test Plan

Requirement Type	***Acceptance Criteria***	***Requirement ID***
System	Must satisfy the requirements	**Req 3.1:** 1, 2, 3, 4, 5, 6, 9,
Physical	Must satisfy the requirements	Not applicable for POC
Hardware	Must satisfy the requirements	**Req 3.3.1.1.1:** 6 **Req 3.3.1.1.2:** 3 **Req 3.3.1.2:** 3, 7 **Req 3.3.1.3:** 2, 3, 6 **Req 3.3.1.4:** 4 **Req 3.3.2:** 4, 5, 6 **Req 3.3.5:** 5
Software	Must satisfy the requirements	**Req 3.4.1:** 1, 2 **Req 3.4.2:** 3

Satisfying the above requirements will allow us to prove that the main concepts of the product are functioning correctly and that the Prototyping stage can be started. Our team shall include all of the requirements in the planning under corresponding milestones. GitLab environment will help the team to maintain the specifications and deadlines.

7. Conclusion

Medeor is aimed to be a health tracker for individuals aiming to improve their daily routine by monitoring their sleep cycle and other health parameters. Our product is a cost-effective, robust and user friendly system designed to help those struggling with insomnia. To provide a safe and comfortable headband, we have listed the requirements needed to achieve as such.
By implementing up to date technology and efficient algorithms, Medeor aims to provide a reliable method to help monitor the user's health. The electrical components used in the final product have been carefully designed to provide all the necessary features in a space confined configuration. To add onto that, safety and sustainability requirements have been listed to further improve the efficiency of the expected product.
As part of Sleep Glory Technologies Inc. we strive to provide a reliable, safe and eco-friendly product to our consumers through innovative and efficient design requirements and features, as outlined in this document.

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