ENSC 405W Grading Rubric for Design Specification

Criteria	Details	Marks
Introduction/Background	Introduces basic purpose of the project.	**/05%**
Content	Document explains the design specifications with appropriate justification for the design approach chosen. Includes descriptions of the physics (or chemistry, biology, geology, meteorology, etc.) underlying the choices.	**/20%**
Technical Correctness	Ideas presented represent design specifications that are expected to be met. Specifications are presented using tables, graphs, and figures where possible (rather than over-reliance upon text). Equations and graphs are used to back up/illustrate the science/engineering underlying the design.	**/25%**
Process Details	Specification distinguishes between design details for present project version and later stages of project (i.e., proof-of-concept, prototype, and production versions). Numbering of design specs matches up with numbering for requirements specs (as necessary and possible).	**/15%**
Test Plan Appendix	Provides a test plan outlining the requirements for the final project version. Project success for ENSC 405W will be measured against this test plan.	**/10%**
User Interface Appendix	Summarizes requirements for the User Interface (based upon the lectures and the concepts outlined in the Donald Norman textbook).	**Graded Separately**
440 Plan Appendix	Analyses progress in 405W and outlines development plans for 440. Includes an updated timeline, budget, market analysis, and changes in scope. Analyses ongoing problems and proposes solutions.	**Graded Separately**
Conclusion/References	Summarizes functionality. Includes references for information sources.	**/05%**
Presentation/Organization	Document looks like a professional specification. Ideas follow logically.	**/05%**
Format/Correctness/Style	Includes letter of transmittal, title page, abstract, table of contents, list of figures and tables, glossary, and references. Pages are numbered, figures and tables are introduced, headings are numbered, etc. References and citations are properly formatted. Correct spelling, grammar, and punctuation. Style is clear, concise, and coherent. Uses passive voice judiciously.	**/15%**
Comments		

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March 28, 2018

Steve Whitmore
School of Engineering Science
Simon Fraser University
Burnaby, BC
V5A 1S6

Re: ENSC 405W Design Specifications for ThinkUp EZG

Dear Mr. Whitmore:

Please find our ENSC405W/ENSC 440 design specifications, *ThinkUp: The EZG Design Specifications* attached. This document contains the design approach we have taken and explains the rationale behind each decision. Also outlined are the final steps to complete the EZG, which will be a portable, adaptable EEG device, with a focus on versatility and affordability.

In addition to the design specifications, this document includes two detailed appendices. The first, the *User Interface Design Appendix*, focuses on the interaction between the EZG and the user, and the design elements in place to ensure that the EZG is intuitive and enjoyable to use. The second, the *440 Planning Appendix*, is a projection of the timeline, detailing the tasks to be completed next semester, when the EZG will be brought to a prototype stage.

ThinkUp is comprised of a diverse range of upper year engineering students, in a variety of specialties: Michael Chyziak, Isaac Cheng Hui Tan, Chloe Hill, Elizabeth Pieters and Nathan Zavaglia. If you have any questions or concerns, please contact chloe_hill@sfu.ca

Regards,

Chloe Hill

Chloe Hill

ENCLOSED: Design Specification for ThinkUp EZG

SIMON FRASER UNIVERSITY
ENGAGING THE WORLD

School of Engineering Science

ENSC 405W

ThinkUp: The EZG
Design Specifications

Team 5:

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Abstract

The EZG is a new electroencephalography (EEG) device with capabilities that lie in a middle ground between existing technologies. Lightweight and portable, the EZG will be more versatile than traditional EEGs that involve a full head cap. The EZG will be mounted on the forehead with adhesive, and the information is beamed via Bluetooth to a nearby laptop or phone. However, compared to other portable EEG systems such as the Muse, the EZG provides a better signal to noise ratio due to its use of wet electrodes; these are electrodes that come pre-gelled and create a better contact with the skin. Further, the use of preamplifiers right at the electrodes help to reduce noise from the leads. On the software side, Bluetooth was chosen as it has a low power mode that allows the EZG to have a much longer battery life. This expands the EZG's possible applications into longer timed studies such as sleep studies. Modularity will also be implemented to reuse expensive electronics but throw away cheaper components, such as adhesives, which are no longer sterile. In the end, the EZG provides a safe, portable, and versatile EEG with a good signal to noise ratio and expanded applications.

The design specifications outlined below detail the specifics of the design elements for the EZG. This includes the specifications of the current alpha Proof-of-Concept (PoC) prototype as well as the functional gamma prototype (prototype) to be developed in the coming months. These specifications are designed to meet the requirements as presented in the previously submitted Requirements Specifications document.

Two additional appendices are included at the end of this document. The first is the User Interface Design Appendix which details the specific user knowledge required to operate the EZG device as well as a detailed analysis of the hardware and software interfaces. The second is the 440 Planning Appendix which outlines the intended development timeline and task assignment breakdown for the development of the gamma prototype.

The targeted completion time for the PoC is April 9th, 2018. The development of the prototype is slated to be completed on August 3rd, 2018 after a four-month development cycle. This is outlined in the 440 Planning Appendix, as mentioned above.

Table of Contents

List of Tables and Figures

1 Introduction

Electroencephalography, or EEG, is a medical device that allows monitoring and recording of electrical activity in the brain. Discovered in 1929 by German psychiatrist Hans Berger [1], EEG was regarded as a breakthrough technology of its time, as it was one of the first imaging techniques to be developed. Today, EEGs are a standard device that most hospitals and many research centers consider an invaluable tool. These signals can be used to help diagnose many brain disorders, establish a baseline for brain activity, and perform alertness detection [2].

The current EEG products on the market have a huge limitation, as most marketed EEG devices (ABM, ANT Neuro, G.tec [3]) have their electrodes embedded in a mesh or plastic cap, and these are connected via wiring to either a heavy battery pack or directly to a computer. Additionally, a conductive medium is required to ensure a good connection between the electrodes and the scalp. This brings some obvious problems to light including the discomfort of wearing a cap for long term, the risk of allergic reaction to the conductive medium, and needing to wash your hair following the scan. Finally, fitting the cap and prepping the electrodes can be a very time-consuming process. At ThinkUp, we challenged ourselves to come up with an affordable, intuitive system that overcomes these problems, without changing the fundamental technology in the EEG; we are not aiming to redesign the wheel, but simply to find a better way to mount it. EZG will eliminate inconveniences by creating a portable, adhesive system that records data on a mobile phone or forwards the data to a processing computer. This small size and long battery life will also allow the user to move, exercise, or sleep without fear of the device shifting or shutting off, ruining the signal collection.

The inspiration of our product is the wearable ECG (electrocardiogram) system. Based on the same principles as the EEG, an ECG records electrical signals from the heart. A portable, adhesive, unobtrusive ECG system has been a marketed device for a long time and the EZG intends to mimic these properties. Using adhesive will ensure signal integrity, while a smaller set of electrodes will reduce device weight. A rudimentary schematic of EZG is shown in Figure 1. Our end goal is to create a portable, comfortable product, that collects high quality signals and is suitable for long-term wear.

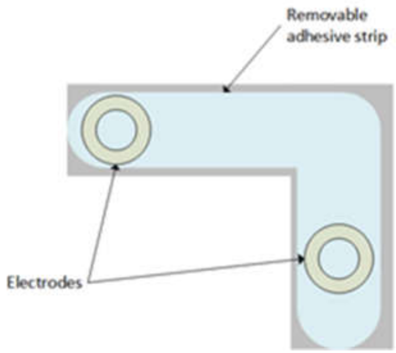


Figure 1: Basic design of EZG, bottom view

1.1 Intended use of the EZG

At this stage, the EZG is not intended to serve as a replacement for EEGs used in hospital settings. Because of its limitations on placement and few electrodes, the EZG is much more applicable in a personal or research setting; especially because of its quick preparation and take down time, and its ability to be used for longer term/movement studies. Future versions of the EZG may be expanded to include more electrodes that may be placed behind the ear or on the back of the neck.

2 Design Overview

2.1 Hardware and Software Overview

The design of the EZG is broken down into two overall components: the hardware and the software. The hardware includes the physical components such as the casing, adhesive, and electrodes, as well as the circuitry leading up to and including the System on Chip (SoC). The software components include the app that controls the EZG device, as well as the software on the SoC that provides the Bluetooth communication.

For hardware, human safety and usability is our top priority, and the design has to work around the constraints of weight and battery life. As well, a high signal to noise ratio is important to provide high quality data to end users. For software, the design aims to provide an intuitive, simple interface for the user to control the EZG, as well as providing low power communication.

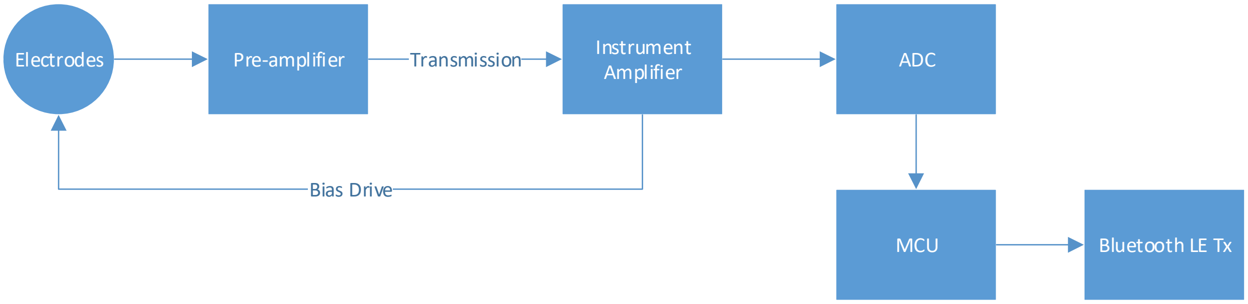


Figure 2: Functional block diagram of the EZG

2.2 Structure & Connection Points

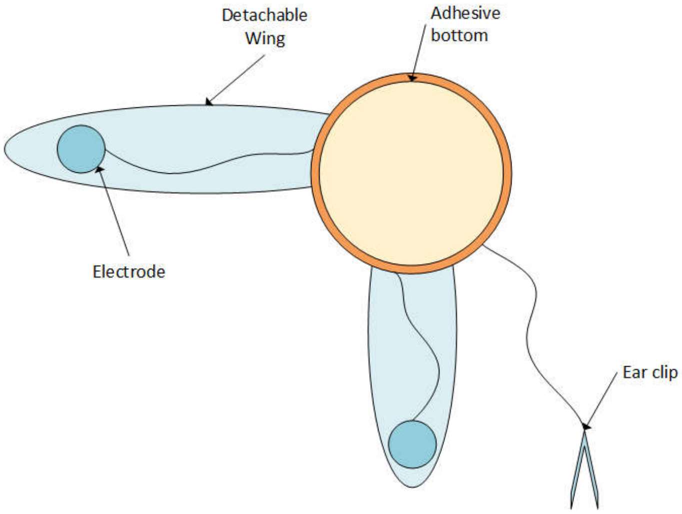


Figure 3: Schematic of EZG structure

There are three types of electrical connections between the various components of the EZG. Each of these connections corresponds to a specific part to reduce confusion for the user. The ear clip connects to the main electronics component via a jack, similar to a headphone jack. The wings attach to the main electronics component using a magnetic connector, and the electrodes connect to the wings using snap leads. The rationale behind having different connections is included in the User Interface Appendix, along with a figure of each connection.

The shape of the EZG was selected to reduce sharp edges that may harm the users, as well as increase the surface area of the device, allowing more adhesive to be placed and ensure a secure connection to the user.

2.3 Hardware Specifications

2.3.1 Amplifiers

The EZG uses several different amplifiers in its design. Figure 4 shows the main differential amplifier used for common mode (noise) rejection. This amplifier uses the ear clip electrode on the bias drive is as per requirements [Req3.2.2-a] and [Req3.2.3-a] of the technical requirements given in [4]. The PoC will omit the bias drive sub-circuit seen below. These amplifiers are intended to have Common Mode Rejection Ratio (CMRR) of 100dB in accordance with [Req3.2.6-a].

For the prototype, the differential amplifiers are also used as the high gain amplifiers in order to boost the relatively small (microvolt, µV) EEG signals, in accordance with [Req3.2.4-g] of the requirement specification.

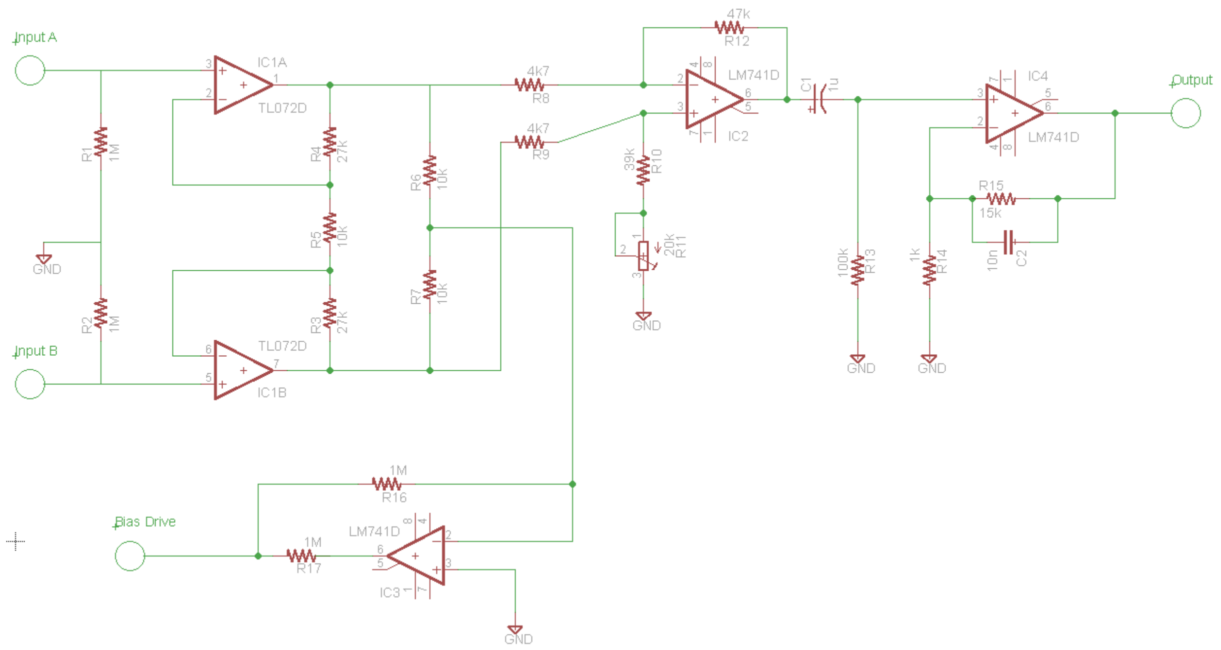


Figure 4: Differential amplifier used for common mode rejection

In addition to the amplification from the differential amplifiers, the EZG prototype will make use of amplifiers as part of the snap lead configuration as seen in Figure 5. These are used to pre-amplify the signal prior to common mode rejection to boost the signals prior to noise cancellation in the differential amplifier. This design modification will reduce the impact of noise picked up by the electrode wiring, and therefore increase the signal to noise ratio (SNR).

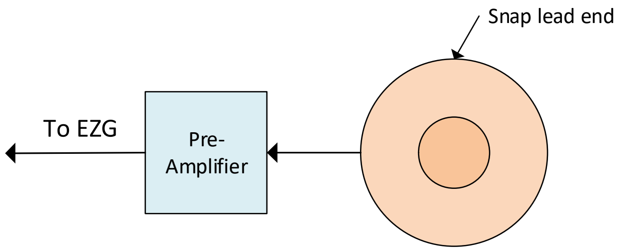


Figure 5: EZG snap lead with pre-amp arrangement

2.3.2 Filters

The hardware filtering used in the EZG is intended to remove the 60Hz interference introduced by nearby equipment, such as fluorescent lights, computers, and other electronic equipment.

The filter will be a band-reject, or notch, filter centered on 60Hz, as per [Req3.2.8-a] found in the requirements document [4].

Additionally, a lowpass filter will be used in the prototype in order to filter out high frequency noise above 300Hz. Again, this is specified in the requirements document under requirement [Req3.2.10-a]. The PoC omits the low pass filter as it is not required to demonstrate functionality.

2.3.3 System on Chip

The System on Chip (SoC) specifications vary between the Proof of Concept (PoC) and the Prototype builds. The reason for the large discrepancy is that the PoC uses just the bare minimum to get the data and do some calculations on it. The current part chosen also has Wi-Fi [Req3.2.17-a] and Bluetooth, and it was expected to use the same microcontroller for the prototype, but unfortunately the device consumes more power than we had wished. As such we continue to use it for the PoC but will not for the prototype.

For the PoC we only require having an ADC that takes the output from the filter stage, transforms it to a digital signal, and sends that to the microcontroller.

The prototype, however, will not only need an ADC but will be able to transmit data over Bluetooth Classic or Bluetooth Low Energy (BLE). It will also conform to the specific power and size requirements outlined in the requirements document.

2.3.3.1 Proof of Concept

The SoC used for the PoC is the ESP32 Development Board [1]. The board will be connected via the micro USB on the board to a laptop. This allows the laptop to flash the software to the board, as well as providing the proper power to the board.

There are wires connected to the pins of the SoC [2] such as to pin GPIO36 and GPIO34, which provides the input analog data from the filter. The data is expected to range from 0 to 3.3V. GPIO36 corresponds to Channel 0 and GPIO 34 corresponds to Channel 1 on the 12-bit ADC in the SoC. Another wire will also be used to go to the ground pin on the SoC.

2.3.3.2 Prototype

The SoC that will be used for the prototype will be Nordic Semiconductors nRF52832. This SoC provides the required specifications of having a 12-bit ADC [Req3.2.12-a] and provides Bluetooth support with the latest Bluetooth 5 protocol [Req3.2.18-g]. This SoC is similar to the PoC version in that the input to the 12-bit ADC will be between 0 and 3.3V after the filter stage. The power supply will be between 1.6 and 3.6V (optimally 3V) which will easily take our battery voltage [Req3.2.16-a].

The SoC will transmit using BLE and as such needs to meet the 256 Hz sampling rate needed for EEG devices. Due to this requirement [Req3.2.13-a] it will have to be able to send 256 12-bit packets per second. For a conservative estimate, we will assume each piece of data will be 16-bits or 2 bytes of data, which gives a total of 512 bytes to send per second. Therefore, to measure the throughput of our device we use the following equation:

$$\text{Throughput} = \text{Packets Per Second} * \text{Data Per Packet}$$

Expanding the above equation gives us:

$$\text{Throughput} = \frac{1000\text{mSecs} * \text{Number of Packets in a Connection Interval} * \text{Data Per Packet}}{\text{Connection Interval (mSecs)}}$$

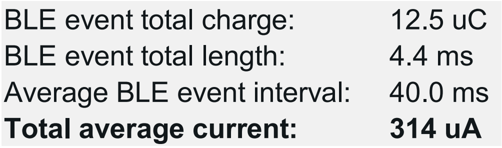
A conservative estimate of the values in the above equation would be:

- a packet connection interval of 30ms (iPhone 6)
- a Bluetooth 4 protocol connection [Req3.3.7-g], which has 20 bytes of data per connection
- 4 packets of data per interval

Using these values with the equation gives 2667 bytes per second, which is much more than needed. It is important to note this would be over continuous data communication, which doesn't always occur. Therefore, a good estimate is divide our number by 5, giving 533 bytes per second, which is enough to meet our needs.

To meet power requirements, the SoC will need to power down all unneeded peripherals and clocks [Req3.3.10-g, Req3.3.11-g]. As previously mentioned, we will need to send 512 bytes of data through 20-byte intervals, which will require a conservative interval of 35ms. Nordic provides a nice power estimate calculator for this series of chip [5], and using that gives Table 1, below:

Table 1: Power consumption for SoC Bluetooth low energy transmission



BLE event total charge:	12.5 uC
BLE event total length:	4.4 ms
Average BLE event interval:	40.0 ms
Total average current:	**314 uA**

We can also view the exact power consumption as seen in the Figure 6 below, which shows precisely our data transaction for the 4.4ms of the BLE event. The rest of the time is spent in a lower power state waiting until we are sending the next event [Req3.2.15-g].

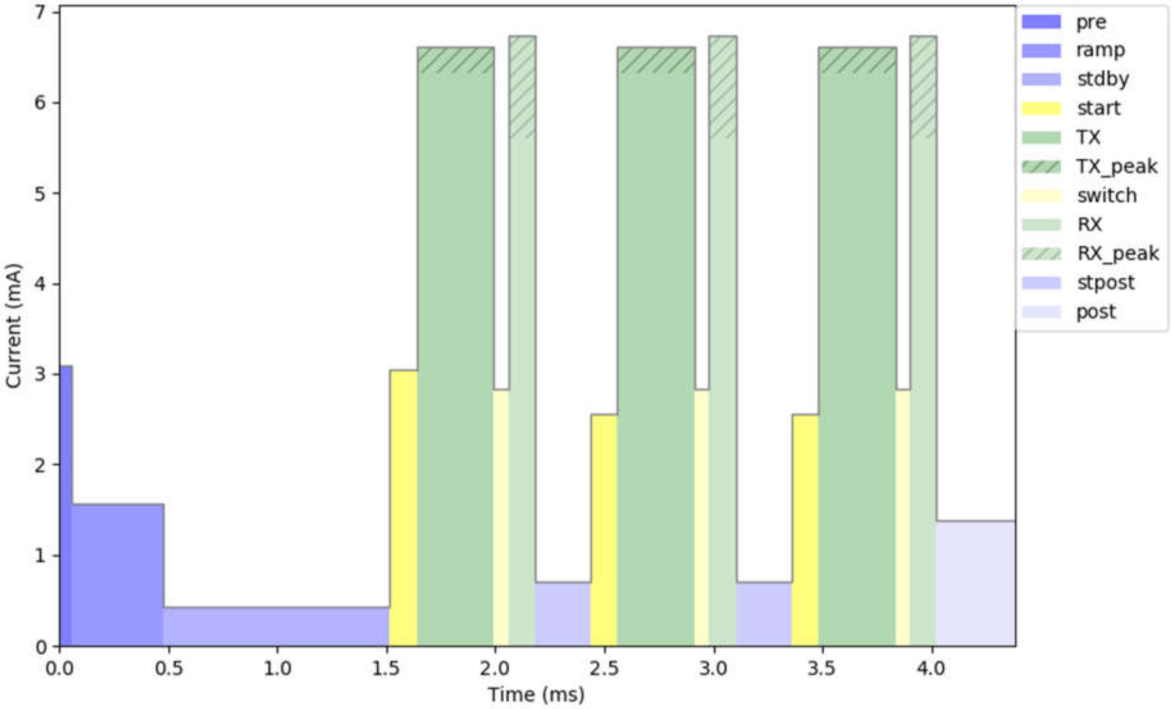


Figure 6: Power consumption from 0 to 4.4ms

2.3.4 Battery and Power

The power requirements for the EZG are quite straightforward. The power requirements for the PoC are omitted as it will be powered directly from a USB connection and will not require a battery.

The prototype will make use of a coin type lithium ion rechargeable cell, similar to that in Figure 7. This choice was made in order to dramatically reduce the weight of the device. The cell will maintain a battery life of up to 12 hours in accordance with requirement [Req3.2.23-g]. The expected battery life is almost exclusively dependent on the power draw of the SoC as it is by far the largest draw. The amplifiers used will be surface mounted IC's with a current draw of less than 0.1mA, whereas the SoC has an average current draw during data transmission of approximately 4mA.

Figure 7: Lithium ion rechargeable coin cell

With a lithium ion cell at 3.6V and 200mAh capacity, the expected battery life is $200mA \div 4.0mA = 50$ hours or approximately 2 days. The real-world performance is expected to be somewhat less; however, this is well beyond the requirement of up to 12 hours as specified in [Req3.2.23-g] in the requirements document in [4]. Should the current draw of the EZG go as high as 20-30mA, this is still within the specification.

Simple LEDs will be used on the front of the EZG prototype device to indicate battery/power on status as per [Req3.2.25-g].

2.3.5 Materials Specifications

2.3.5.1 Adhesive

2.3.5.1.1 Primary Adhesive

The primary adhesive used for adhering the EZG to the patient will be the 3M™ 1587 Two-in-One Polyester Double Sided Medical Tape, 60 # Liner [6]. This was chosen as the 3M™ 1587 was created for device-to-skin contact in mind, thus being safe for biomedical applications. It fulfills the requirements from the requirements specs [4].

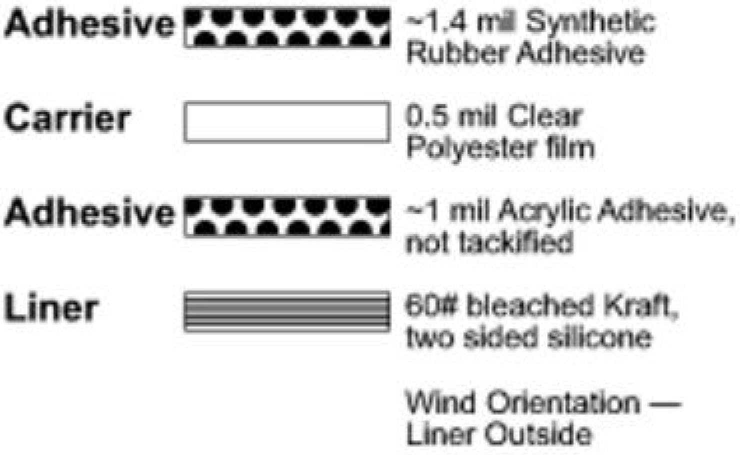


Figure 8: Components of the 3M™ 1587 two-in-one polyester double sided medical tape, 60 # liner

The Acrylic side will be used for skin contact with the patient, whereas the synthetic rubber side will be the side that will contact the EZG enclosure.

The 3M™ 1587 Two-in-One Polyester Double Sided Medical Tape, 60 # Liner is to be processed by a die cutter to cut out one-time use adhesive strips for the EZG.

The die cut adhesive strips will then be assembled together with the electrodes to form the disposable strip that will adhere the EZG to the patient.

2.3.5.1.2 Secondary Adhesive

If we are unable to acquire the primary adhesive, the 3M™ 9874 Transparent Polyethylene Double Sided Medical Tape, 60 # Liner [7] will be used to adhere the EZG to the patient.

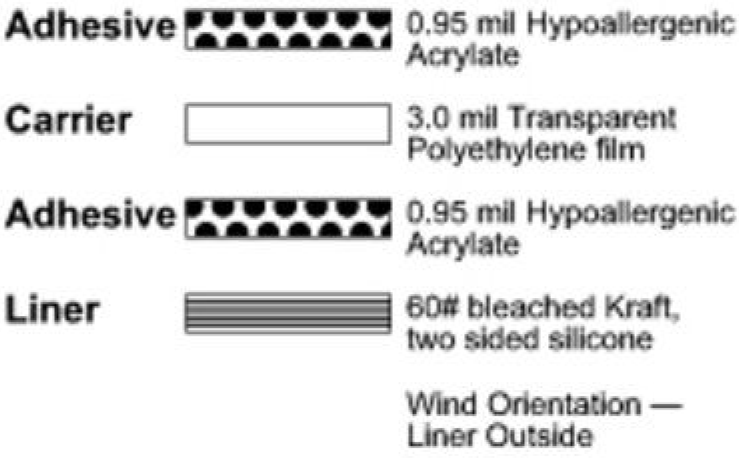


Figure 9: Components of the 3M™ 9874 transparent polyethylene double sided medical tape, 60 # liner

This adhesive will also be processed by a die cutter to create one-time use adhesive strips for the EZG

2.3.5.2 Enclosure

The enclosure will be made of flexible Polylactic Acid (PLA) 3D printed with a printing temperature of 190°C. The print bed will be set between 60°C - 80°C. It will be printed with a resolution of 0.02mm [8].

The walls of the enclosure will be at least 2mm in thickness for structural integrity yet still retain its flexibility.

PLA was chosen as it is biodegradable, which reduces its environmental impact. There are also medical grades of PLA available that are compatible with skin contact. Flexible PLA allows the EZG chassis to absorb shocks if dropped as well as conform to the facial shapes of different users.

2.4 Software Specifications

There are two distinct pieces of software that will be necessary for the EZG to function properly, one running on the SoC and one running on an Android phone app. The functionality of the software on the SoC will be to simply read the ADC data at a sampling rate of 256 Hz and send that data via BLE to the phone app. The functionality of the software running on the phone app will be to display all the incoming data coming from the EZG device (SoC specifically), and to display the waveform on the screen. It will also allow the user to record the data and save it for later viewing/use.

2.4.1 SoC Software

The SoC will follow the algorithm flow chart seen in the Figure 10 below. It is necessary to reach a sampling rate of 256 Hz, as that is required for EEG devices, while using the 12-bit ADC available on the nRF52832. The software is also in charge of disabling all other unused peripherals (GPIO, memories, LEDs), and turning off all unused clocks so that the power consumption of the SoC is reduced as much as possible.

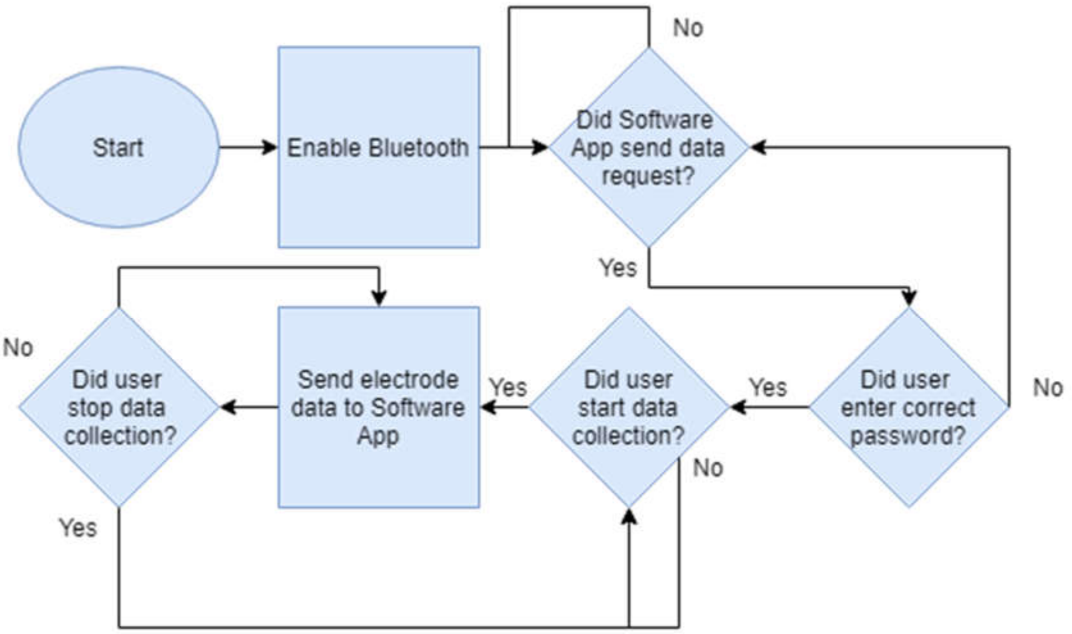


Figure 10: Algorithm flow chart for SoC device

For the PoC, the SoC reads the ADC data, then does some simple math that helps reduce the noise of the signal, which results in a reading with approximately 1-2% accuracy. After this the data can be shown using the Arduino Serial Plotter. The algorithm will convert the data from 0-4096 to appropriate voltage values between 0 and 3.3V. The PoC will deal with the -1.7 to 1.7V signal from the filter by reading the filter output from channel 0 and reading the inverse of the filter output from channel 1. Then the software will inverse the already inversed signal and add that to the channel 0 reading to get the actual output.

The prototype will have similar ADC reading software to the PoC with the exception that the entire signal will be read through a single ADC channel. The PoC, however, will have a large software component dealing with sending BLE signals to the android app, as well as being able to setup as a beacon. The beacon setup will be done by instantiating the Bluetooth driver on the SoC with the name “EZG”, and a hardware timer will send an interrupt every time enough data is collected from the ADC to send to the phone app.

Android App

The Android phone app [Req3.3.11-g] is important to get the software working correctly, since it is the only way that a user can view the incoming EEG data collected for the prototype and then final product. When the user opens the app the first time, it will connect to the EZG and ask for the default password provided in the user manual [Req3.3.8-g]. Once entered, they will reset the password so that no other users can monitor the data without the new password [Req3.3.13-g, Req3.3.12-g]. Once the password is entered, they will enter a simple screen that shows an empty waveform and two buttons, located as seen in Figure 11 below; one of these buttons will display live waveform data to the screen, and the other displays the waveforms and saves the collected data [Req3.3.14-g, Req3.3.9-g] in a preset user location.

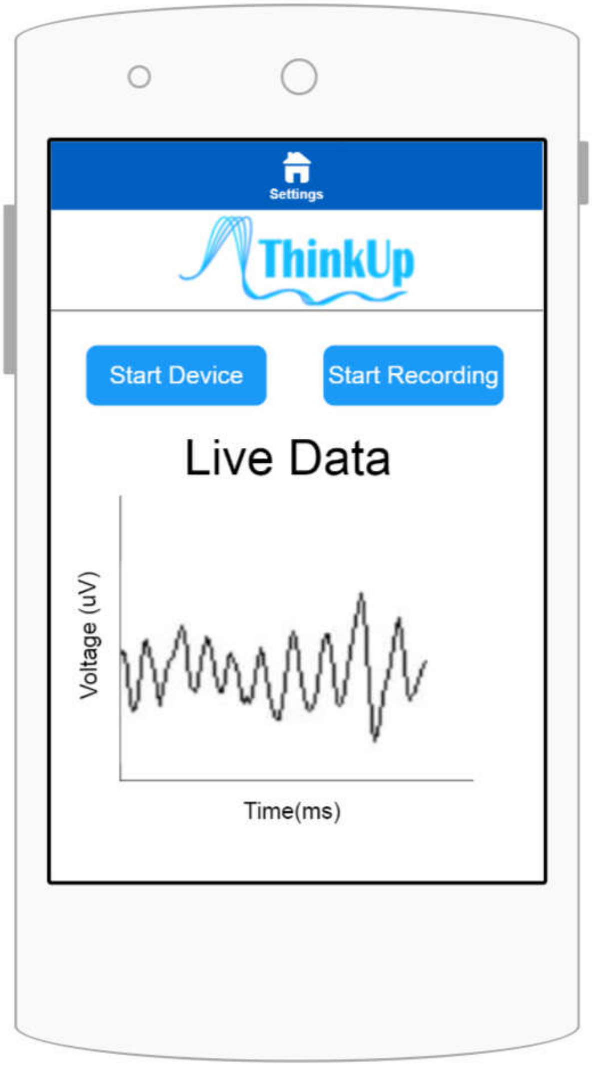


Figure 11: Android app data observation page

The user will be able to load stored data live or be able to save it to the cloud and view it on some other workstation PC that can analyze it using tools such as Matlab. The user interaction needed to communicate with the EZG device is shown in the Figure 12 below.

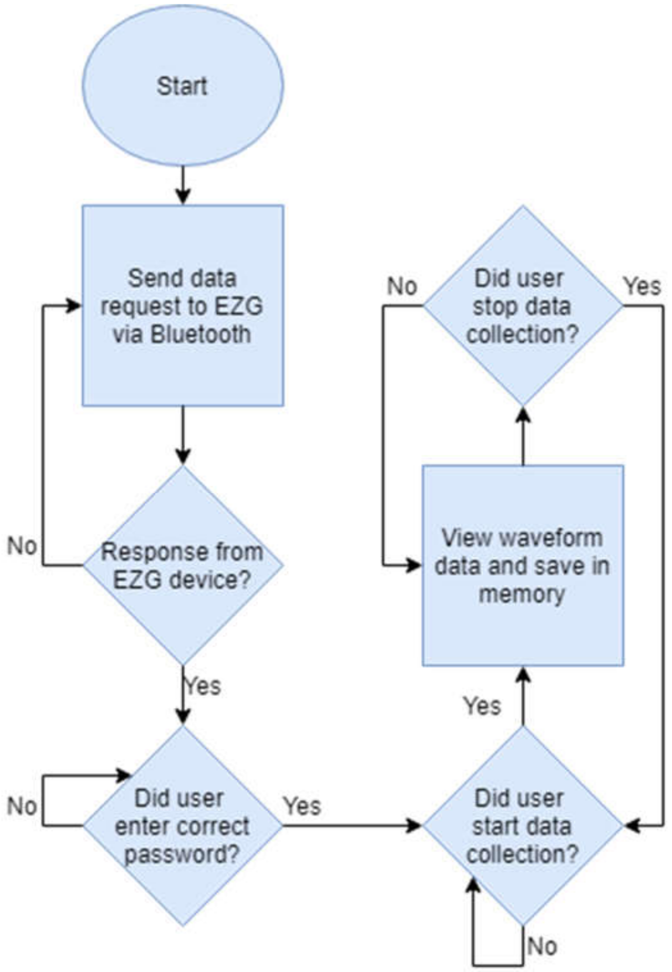


Figure 12: Algorithm flow chart for user software interface

3 Design Verification Test Plans

Design verification will be executed on the gamma prototype to ensure efficacy, safety and ease of use of the device. These test plans which are outlined in Appendix A, detail the procedures and acceptance criteria for to verify the device behaves as intended.

4 Conclusion

The preceding document lays out the design choices and specifications that enable the EZG to meet, or exceed, the requirements as detailed in the Requirements Specification document [4]. The design choices detailed above also include design changes that were decided upon after development of the proof-of-concept (PoC, alpha prototype) and that will be implemented in the prototype (gamma prototype) as development moves forward.

While the PoC will make use of an ESP32 development board – chosen due to its compatibility with Arduino and inclusion of a 12bit ADC. The prototype will make use of a Nordic Semiconductors nRF52832. This SoC also includes a 12-bit ADC but operates at significantly reduced power consumption, particularly with low power Bluetooth communications. This will allow a much smaller and lighter battery to be used, while still providing ample battery life for extended use.

A second design change that was decided upon was to change from a fixed shape device to one that makes use of modular "wing" attachments. The wings will contain the electrodes and pre-amplifiers and will be made available in a wide range of shapes and sizes to accommodate different EEG measurement paradigms for researchers. The wings will also enable personal users to quickly and easily set up the EZG, making the device accessible to the consumer market. Again, this will be implemented in the prototype device and is part of the User Interface specification.

The User Interface includes both the user's interaction with the physical device and with the software. An Android app, with a simple interface, is being developed to provide data collection and feedback for the prototyping stage. The interface also includes the use of LEDs to indicate battery charge and power on status on the device itself.

To verify functionality of the EZG design a test plan, detailed in Appendix A, has been developed that tests the major design factors such as power on/off, software functionality and security, comfort, and electrical safety.

The EZG incorporates the portability and low weight, of the consumer dry-contact EEGs and the greater signal quality of the research devices. This combined with increased comfort over both, and a long battery life, enables the EZG to fill the gap between the two alternative systems. This makes the EZG more than simply a niche device as it covers a wide range of usability, from researchers to consumers alike.

5 References

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[7] 3M, "the 3M™ 9874 Transparent Polyethylene Double Sided Medical Tape, 60 # Liner | 3M United States," 3M, [Online]. Available: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-9874-Transparent-Polyethylene-Double-Sided-Medical-Tape-60-Liner/?N=5002385+3294739708&rt=rud. [Accessed 25 03 2018].

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6 Appendix A: Design Verification Test Plan

6.1 TC–HW-001 On/Off Testing

Objective: Test the on/off usability of the device. Verify that the process is intuitive.

Test setup: EZG is charged and ready to record data. Device does not need to be attached. Receiving device is charged and within 10 feet of the EZG.

Operator Name: ________________________________

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Instructions	*Acceptance Criteria*	*Outcome*
1. Press the Power button	Red power LED glows on the device.	☐ PASS / ☐ FAIL
2. Check receiving application	App indicates that device is attempting to connect.	☐ PASS / ☐ FAIL
3. Wait for device to connect. Check receiving application	Application indicates that device is connected and ready to be set up.	☐ PASS / ☐ FAIL
4. Start Scan	Blue LED glows, red LED turns off.	☐ PASS / ☐ FAIL
5. End scan.	Blue LED turns off and red LED turns on.	☐ PASS / ☐ FAIL
6. Press and hold Power button on device. Check application	Application indicates that device is no longer connected.	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: ________________________________

6.2 TC–SW-00 Software and Security

Objective: Test efficacy and security of data in browser application.

Test setup: EZG is charged and ready to record data. Device is attached to either test subject or equivalent simulator. Receiving device is charged and within 10 feet of the EZG.

Operator Name: ________________________________

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Instructions	*Acceptance Criteria*	*Outcome*
1. Power up EZG	Device powers up without issues. Red power LED glows on device.	☐ PASS / ☐ FAIL
2. Turn on receiving device and navigate to receiving application	No secure information is displayed. Prompt to enter security info is present.	☐ PASS / ☐ FAIL
3. Enter security credentials	Smooth transition into setup screen. The following user options are available: START, STOP, SCAN DURATION	☐ PASS / ☐ FAIL
4. Select START	Scan begins, and app indicates data is being recorded. Red power LED turns off and blue transmission LED glows indicating data transmission.	☐ PASS / ☐ FAIL
5. Select SHOW LIVE DATA	Live data is being displayed to the app.	☐ PASS / ☐ FAIL
6. Select HIDE LIVE DATA	App returns to basic data collection page.	☐ PASS / ☐ FAIL
7. Select STOP	Scan ends gracefully and performs data processing, displaying data to screen within 1 min. Loading icon is displayed to screen informing user that processing is occurring. Blue transmitting LED turns off and red power LED glows.	☐ PASS / ☐ FAIL
8. Wait for processing to complete	Entire waveform recording is displayed. User is prompted to SAVE or DISCARD data.	☐ PASS / ☐ FAIL
9. Select SAVE. Navigate to file storage	Saved file is present.	☐ PASS / ☐ FAIL
10. Return to home screen and select SCAN DURATION of 30s (TEST SCAN). Press start	Scan runs for requested duration and stops gracefully. Entire waveform is displayed and user is prompted to SAVE or DISCARD data.	☐ PASS / ☐ FAIL

11. Select DISCARD and navigate to file storage	Most recent file is not saved.	☐ PASS / ☐ FAIL
12. Exit application.	Information is not accessible without logging in again.	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: ________________________________

6.3 TC–HW-002 Comfort Over Extended Periods and Long-Term Battery Usage

Objective: Test the comfort and battery of wearing the device over an extended period of time.

Test setup: EZG is charged and ready to record data. Device is attached to either test subject. Receiving device is charged and within 10 feet of the EZG.

Operator Name: ________________________________

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Instructions	*Acceptance Criteria*	*Outcome*
1. Power up EZG. Set up for undefined scan time. Press START	Device powers up without issues, Scan starts smoothly.	☐ PASS / ☐ FAIL
2. Wear device for 6 hours	Device remains firmly attached to the user.	☐ PASS / ☐ FAIL
3. Check battery life	Battery remains viable for the duration of the scan. Predicted remaining time is displayed on the app.	☐ PASS / ☐ FAIL
4. Examine the predicted remaining time	This number is greater than 50% remaining.	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: ________________________________

6.4 TC–HW-002 Electrical Safety: Leakage Current

Objective: Ensure that the electrodes do not exceed max leakage current, as defined by IEC 60601-1 standard. Will be tested in normal conditions and single fault conditions.

Test setup: EZG is charged and ready to record data. Device does not need to be attached. Receiving device is not necessary. Will make use of a measuring device. Connect the measuring device to the EZG, attaching the ground connection to the ground electrode and the other electrodes per measurement device instructions

Operator Name: ________________________________

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Instructions	*Acceptance Criteria*	*Outcome*
1. Patient Leakage Current Test (Normal Conditions)	Leakage current is < 0.5μA per electrode	☐ PASS / ☐ FAIL
2. Patient Leakage Current Test (Single Fault Condition)	Leakage current is < 0.5μA per electrode	☐ PASS / ☐ FAIL
3. Ground Leakage Current (Normal Conditions)	Leakage current is < 1μA per electrode	☐ PASS / ☐ FAIL
4. Ground Leakage Current (Single Fault Condition)	Leakage current is < 1μA per electrode	☐ PASS / ☐ FAIL
5. Enclosure Leakage Current (Normal Conditions)	Leakage current is < 0.8μA per electrode	☐ PASS / ☐ FAIL
6. Enclosure Leakage Current (Single Fault Condition)	Leakage current is < 0.8μA per electrode	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): ________________________________

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: ________________________________

ENSC 405W Grading Rubric for User Interface Design

(5-10 Page Appendix in Design Specifications)

Criteria	Details	Marks
Introduction/Background	Appendix introduces the purpose and scope of the User Interface Design.	**/05%**
User Analysis	Outlines the required user knowledge and restrictions with respect to the users' prior experience with similar systems or devices and with their physical abilities to use the proposed system or device.	**/10%**
Technical Analysis	Analysis in the appendix takes into account the "Seven Elements of UI Interaction" (discoverability, feedback, conceptual models, affordances, signifiers, mappings, constraints) outlined in the ENSC 405W lectures and Don Norman's text (*The Design of Everyday Things*). Analysis encompasses both hardware interfaces and software interfaces.	**/20%**
Engineering Standards	Appendix outlines specific engineering standards that apply to the proposed user interfaces for the device or system.	**/10%**
Analytical Usability Testing	Appendix details the analytical usability testing undertaken by the designers.	**/10%**
Empirical Usability Testing	Appendix details completed empirical usability testing with users and/or outlines the methods of testing required for future implementations. Addresses safe and reliable use of the device or system by eliminating or minimizing potential error (slips and mistakes) and enabling error recovery.	**/20%**
Graphical Presentation	Appendix illustrates concepts and proposed designs using graphics.	**/10%**
Correctness/Style	Correct spelling, grammar, and punctuation. Style is clear concise, and coherent. Uses passive voice judiciously.	**/05%**
Conclusion/References	Appendix conclusion succinctly summarizes the current state of the user interfaces and notes what work remains to be undertaken for the prototype. References are provided with respect to standards and other sources of information.	**/10%**
CEAB Outcomes: Below Standards, Marginal, Meets, Exceeds	1.3 Engineering Science Knowledge: 4.1 Requirement and Constraint Identification: 5.4 Documents and Graphic Generation: 8.2 Responsibilities of an Engineer:	

7 Appendix B: User Interface Design

7.1 Introduction

7.1.1 Purpose

The purpose of this Appendix is to provide the readers with a more in-depth understanding of user interactions with the EZG. This document will go over the considerations taken by our design team as we developed the EZG in both the hardware and software.

7.1.2 Scope

In this document we will discuss the various considerations taken when designing the EZG. We will start by discussing our target users and the knowledge that they need to have to properly operate the device. Following this, we will provide a technical analysis of the UI, breaking it down into the seven elements of UI interaction. This will provide detailed insight on the considerations which were taken when designing our device; this includes: interface components, discoverability, feedback, conceptual model, affordances, signifiers, mappings and constraints.

Additionally, we will discuss the engineering standards which have been considered for safe and intuitive operation. We will also provide an in-depth discussion of the analytical testing undertaken, which is focused on the theoretical analysis of the UIs of marketed devices. This research allowed us to make design choices to eliminate these issues. Also discussed is the empirical testing we plan to undertake, which will also serve as a verification test: does the device work well for the user?

7.2 User Analysis

The EZG has two main target markets: research institutes and personal users. As these are two very different demographics, one of the major challenges is creating a device that can be useful to both markets. To simplify the ease of use, we will include a simple user manual, detailing operation procedures, as well as a simple guide on electrode placement. As the EZG is not intended to provide users with a diagnosis, we do not expect the users to have any professional medical knowledge.

7.2.1 Researchers and Medical Professionals

Researchers and medical professionals that use our device will possess an understanding of EEG operation. Our intention, then, is to make the use of our product fall closely in line with existing devices by featuring similar graphical user interfaces (GUI), and, order of operation to facilitate its ease of use. As researchers will not necessarily need to use the same electrode placement between trials, we hope to cater to these needs by creating various available electrode layouts. We do not expect any research teams to require any extra knowledge of EEG electrode placement.

7.2.2 Personal Users

The biggest difference we expect between researchers and personal users is their knowledge of electrode placement, for this reason we will include an explanation of electrode placement in the user manual. Our goal is for the GUI to be accessible to the widest range of users. In addition to the information in the manual, we intend to create a mobile platform – one that does not require the user to purchase extra, specialized equipment. We do not expect many personal users to make use of our extra wing models, as they will likely use the device in a manner similar to the expected applications of existing dry contact devices. However, the extra wings will be made available should consumers wish to expand the range of usability, or to experiment with other applications.

7.3 Technical Analysis

7.3.1 Hardware and Software Interface Components

Users of the ThinkUp EZG will interact with both hardware and software components of the prototype device. Specifically, the hardware interface will focus on the physical setup of the EZG, whereas the software interface will focus on runtime control of the EZG.

During the physical hardware setup, the user will connect the electrodes to the wings using simple snap leads, connect the wings to the main EZG electronics component with magnetic contacts, and then use adhesive to securely attach the whole device to their forehead – see Figure 13. As well, the ear clip will require plugging into the main electronics component of the EZG with a jack. When the user wishes to remove the EZG, they will detach the entire component from their forehead, then remove and discard the adhesive and electrodes.

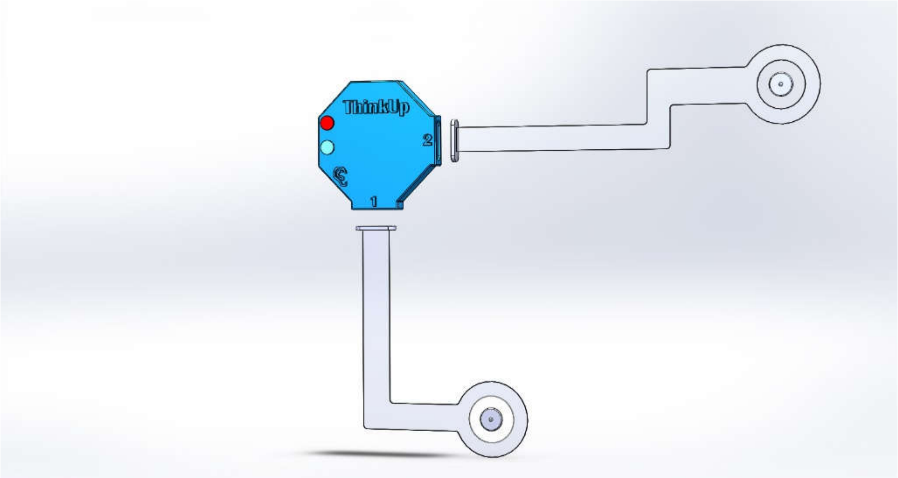

Figure 13: Rudimentary 3D model of EZG attachments

The software interface is the app which allows the users to view the data from the EZG. Not only will they be able to view the data on their phone, but will also be able to save the data as a spreadsheet. The data can then be offloaded to another platform and viewed in any program that can work with spreadsheets (e.g. Microsoft Word, MATLAB).

A user manual will be provided to walk the user through both the physical setup and the app to provide a high level of clarity and to assist those who have never used an EEG before. However, the user manual does not replace the need to have an intuitive, straightforward design that follows the "Seven Elements of UI Integration" [9]. The steps we will take to address each of these seven elements in both hardware and software is outlined below.

7.3.2 Discoverability

Hardware: The setup of the device is designed to be as intuitive as possible, so that the necessary steps are clear from a glance at the components. To minimize confusion and ensure that the components are connected to the proper location, each connection is the only one of its kind; examples of each are shown in Figure 14 below. The connection between the ear clip and the EZG is done using a jack. The electrodes, which are identical and therefore interchangeable with each other, are the only components that use snap leads. The connection between the wings and the main EZG electronics component is done using magnets to secure electrical contacts. Finally, the adhesive will have the same shape as the component (main electronics component or wing) it is meant to secure, and therefore is clear where it is meant to be applied. Failing these, the user manual can be consulted for further clarification.

Figure 14: Left to right: ear clip and jack, electrode snap lead, magnetic connector [10], [11], [12]

For determining the state of the device, one red and one blue LED will be placed at the front of the device. While the EZG is off, both LEDs will also be off. When the EZG is powered on, but not transmitting any information, the red LED will glow. When transmission of data begins, the red LED will switch off and be replaced by a blue LED, which signifies that the device is on and transmitting. This hardware will allow the user to determine the current state without having to consult the app. Placing their hand close to their forehead, they will be able to see the reflection of the LED on their hand, or they can have a friend or colleague continuously monitoring the colour.

Software: Once a user opens the app it will display any local EZG devices and the user will pick the device they wish to monitor/use. If they have already connected to it once, it will be shown as a “recommended” suggestion. The user will also have to enter a password if it is their first time connecting to the device or if the password of the device has changed. The Figure 15 [13] below shows a proof of concept sketch of what the aforementioned page will look like.

Device Name

EZG-A12J893 ●

EZG-8AI92N1 ○

Password

••••••••••••

Figure 15: Android app connect to device page

7.3.3 Feedback

Hardware: The EZG setup is simple to verify by checking the user's manual and making sure that the built device matches the one shown. Part of the reason there is a user's manual is to provide this kind of feedback.

During operation, the glowing LEDs on the exterior of the device will be constantly updated to reflect the current state of the EZG. This makes it simple for the user to determine that their actions have taken immediate effect.

Software: For the phone app there are a few features that provide feedback. These include providing feedback to user selections/presses, providing feedback on the state of the EZG device, and providing feedback in terms of data recorded.

First off is when a user presses a button or selection, it should provide a small vibration if the user has that enabled on their device. Second is that each button press should either change 40% of the screen interface or provide a message that covers 40% of the screen. The reason for this is that each selection is completely evident to the user, and it will also minimize accidental input.

Second is providing feedback via notifications. This would be sent when the user does not have the app open and has it running in the background. The notifications provided will tell the user if for some reason an error has occurred (e.g. Bluetooth connection is lost), when a recording is finished, to notify them every 30 minutes that the EZG device is still running to ensure they do not accidentally leave it on, and to provide low battery information of the EZG device.

Lastly is the data recording feedback. It will simply show on the waveform as previously explained and shown previously. However, for any data recording, the latest recording file location will be shown to the user. If they forget where they have saved it, they will be notified just by looking at the app.

7.3.4 Conceptual model

Hardware and software: The design of the EZG exists in two parts, with a hardware component reading signals and sending them via Bluetooth to a software app. These two components are completely separate and so help the user understand that they have separate roles: the user only needs to setup the hardware, but during runtime controls the overall device using the software.

7.3.5 Affordances.

Hardware: As mentioned earlier in the discoverability section, the parts that need to be connected are the only ones that will afford being put together. Parts that are not meant to connect have different mechanisms, such as a jack or snap lead, or will only fit in a particular orientation, such as the adhesive which will be the same shape as the back of the EZG.

The circuitry is set up to read potential differences on the skin and act as an EEG. This it will do, but it cannot be used as anything other than a potential difference reader.

Software: The Android app will give users many buttons and options to select that control the functionality of both the app and the EZG device itself. All the buttons will be formatted to properly fill the screen in a manner which makes them large enough so that they can be easily pressed.

7.3.6 Signifiers

Hardware: Various markings on the physical components of the EZG will aid in the setup. Markings on the adhesive will indicate whether it is to be applied to the forehead or to the back of the EZG. A small mark shaped like an ear next to the ear clip jack (Figure 13) and numbered magnetic connections for the wings will also indicate what components are meant to be connected.

The LEDs are also useful signifiers that provide instant feedback as to the state of the system.

Software: All buttons and waveforms will be labelled to notify users what each object they are looking at on the app does or displays. The signifiers are similar to what was mentioned for the feedback, where they will be done in a manner that will grab the user's attention. This ensures that all actions are intentional, or at the very least conveyed to the user without any confusion.

7.3.7 Mappings

Hardware: The hardware components do not feature any controls; the only mapping is during the physical setup where the pieces that are meant to go together are the only ones that fit together.

Software: The menu will be located on the top of the app that will change how it looks depending on the device being used. If the screen is big enough it will show the menu options horizontally. If the screen is too small, it will show a widget that will open the menu vertically only once pressed.

Any buttons will be located below the menu and below any headings of the current page. Any other information that the user must enter (passwords) or view (waveforms) will be shown below that and will be stretched to match the aspect ratio of the screen accordingly. If the screen is more vertical than horizontal, then the page will be scrollable in order to view all of the contents that might not have fit otherwise.

7.3.8 Constraints

Hardware: The physical constraints imposed on the pieces during the setup, namely that what goes together fits together, and what should not be connected would be very difficult to force together, is what allows for the discoverability of the setup. It allows an intuitive setup even without use of the user's manual.

Software: The main constraint of the Android app is for the recording of data since the memory on a device is limited. However, this will be handled by the user by selecting a length of time that they want the EZG device to record for which then will correspond to an file length estimate. This estimate will then be matched up with the memory available in the storage unit that the user has selected [Req3.3.15-g]. If the memory is insufficient the user will be notified with an error and recording will not begin.

7.4 Engineering Standards

As a biomedical device, the EZG must adhere to strict standards to ensure safety and efficacy of the device. The proposed user interface features two entities: the hardware which makes up the actual device, and the software which serves as a point of communication and control for the user. Both components must adhere to their own set of standards. As the software is split up between signal collection via chip on the hardware and signal processing in an android application, this inter-device communication must also conform to its own standards. As a complete system, the EZG must conform to several medical usability standards: IEC 62366, which discusses the application of usability engineering to Medical Devices [14], as well as CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016), which is the Canadian adaption. Meeting these standards demonstrates that the UI is safe and is a vital step in getting approval to bring the device to market.

7.4.1 Hardware

The hardware serves as the main point of contact for the user; it must adhere to the most safety standards. To ensure safety and reduce the risk to the user from leakage current, the device must conform to IEC 606061-1-11:2015 [15]. As this device also has the potential to be used in a home healthcare environment, it must also conform to CAN/CSA-C22.2 NO 60601-1:14 [16]. Additionally, it must conform to ISO 17664:2017 [17], which pertains to the sterilization of health care products. Following these standards ensures that the device will be safe to be handled by a user, which is a key part of interface. As an enclosed device, it must conform to IEC 60529:2001 [18], which is the IP code. Finally, it will be constructed of a material that conforms to the RoHS directive [19]

7.4.2 Software

As this software qualifies as medical device software, since it controls the operation of a medical device, it must follow several specific standards: IEC 62304 :2006 [20], which defines the lifecycle of the software and ensures that is has been built in a testable and traceable manner, and decreases the likelihood of use error.

7.4.3 Interoperability

As part of this system involves device communication via Bluetooth, it must meet the following IEEE standard which applies to Bluetooth in portable devices: IEEE 802.15.1 [21]. Meeting this standard will ensure smooth communication between the chip and the application.

7.5 Analytical Usability Testing

Analytical usability testing is used to address the inefficiencies and major usability issues prior to receiving user feedback. To accomplish this, we examined similar EEG devices which are already present on the market. To get industry feedback, we established contact with HealthTech Connex, a biotech company which focuses on data collection via EEG. Drawing from our teams' own experience in working with EEG devices and the conversation with HealthTech Connex, we were able to draw conclusions about the existing usability issues, and incorporate solutions into our device.

7.5.1 Wet Electrode EEG Systems

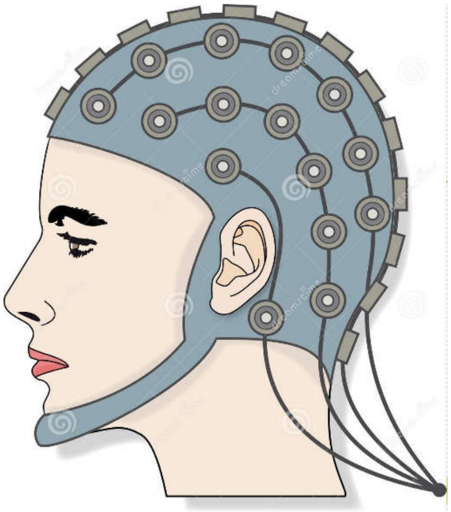

Figure 16: Sample of a cap and gel wet electrode EEG system [22]

The majority of research markets use wet electrode EEG systems for their superior signal quality. They feature a high signal to noise ratio, and are currently the only available device suitable for research.

Pros: These devices do not feature many UI benefits. Their main draw is the high-quality signal collection.

Cons: These systems feature intensive user interfaces, as they often feature a full cap system. This cap system requires the use of gel to ensure proper connections, which is an excess cost and deterrent for trial subjects. They also require a longer set up and take down time, which reduces turnover period for researchers. They require two people to setup and are completely unsuitable for personal use. Additionally, these set-ups can be quite cumbersome to clean and often quite bulky.

Design Choices: The overwhelming list of cons was the inspiration for the product – we wanted to eliminate the complexity of the cap and gel system while maintaining the signal integrity of the wet EEG system. By choosing an adhesive connection, we eliminate the need for gel and greatly reduce the setup and takedown time. Additionally, we aimed to improve the sterilization process by separating reusable parts and single use electrodes.

7.5.2 Dry electrode EEG systems

Figure 17: A Muse device, a personal EEG system using dry electrodes [23]

Dry electrode systems are mainly targeted to personal use and are often not suitable for research due to a lower SNR. We were interested in applying the ease of use and portability of these systems

Pros: Dry electrode systems are geared toward personal use, allowing them to be more portable and feature a less intensive set up. They allow users to set up the system without requiring additional help.

Cons: Most dry electrode systems are attached to the user through friction and pressure, or by resting on facial/head features. This makes them also quite bulky and uncomfortable to wear for long periods of time. They are also unsuitable for vigorous movement, as they fall off quite easily, and any shift in electrode placement will greatly distort the signal.

Design Choices: From the dry EEG system, we incorporated the features geared toward personal use: greater portability and simplified setup. The drawbacks of the dry system motivated us to use an adhesive connection point. We wanted to eliminate the risks of electrode movement to ensure signal integrity. We also wanted to increase the comfort of the system, eliminating pressure points on the users' head, allowing it to be worn for longer periods of time.

7.6 Empirical Usability Testing

Testing of the usability of the EZG will be of paramount importance as the adoption of the EZG will greatly depend on the user's impressions on ease of use. As such, the following usability testing procedures will be followed to create a user interface from the testing procedures.

7.6.1 Hardware/Material Testing

The hardware testing required for the PoC is simple since we are only using a function generator to create our signal, as we are still awaiting ethics approval. As such all the hardware is testing in functionality by probing the circuit in multiple places to ensure that the signal is working as expecting by getting properly amplified by the amplifier stage and filtering out a 60 Hz signal.

The prototype will also use probing of our circuit on the PCB to ensure that it works the same way that our PoC worked. Once packaged in our material we will no longer be able to probe it; however, this can still be tested by connecting the signals we would normally probe to the other channels of the ADC on the SoC and then reading those values in our software and comparing them to ensure they are appropriate working.

The material of the EZG plastic, adhesive, and electrodes will be tested for their wide range of use cases. The plastic will be tested for its weatherproof features by sinking the device in a pre-measured container of water and then pulling the device out after only 1 second in the water. This will simulate extreme weather conditions of the plastic and the container's volume will be measured once the device is pulled out to test the displacement of water which should be marginal, meaning that our device is weather resistant up to the extreme case of being submerged in water. The adhesive will be tested by placing the device with the adhesive on all the developers calculating the mean time for adhesive failure. Testing the electrodes will be done in isolation as we just must ensure that they are able to acquire a clean signal. For this we will reuse our PoC circuit to ensure the electrodes properly pick up signals from a developer’s forehead (if we are able to obtain ethics approval) or by using an EEG simulator device.

7.6.2 Stage 1 - Internal Testing

Employees of ThinkUp and members of the design team will be conducting stage 1 testing.

7.6.2.1 Bluetooth Messaging Testing

Wireshark [24] will be used to make sure that all of the messages sent from the EZG are properly sent out in terms of signal integrity and data. Wireshark enables monitoring of network data such as Bluetooth so that we can make sure that the distance and strength of the signal is strong enough for a few meters and can be easily advertised to a phone.

7.6.2.2 Android App Testing

The testing of the android app will be fairly simple. Since we have ensured via Wireshark that the Bluetooth data being sent is accurate, all that will be left to test is making sure that the user interface on the phone will work without stalling or any bugs. In order to test these, we will use an agile programming methodology for testing the android app which consists of creating tests first before starting any programming. Then once all the tests are written (examples of which are is 256 sample points collected every second, does pressing a button cause the intended effect, does the waveform update properly, etc.), we will start writing the minimal amount of code to pass the test. Tests can be added as seen fit, but every time a new feature is added it is checked against all the tests to ensure no software will cause any unexpected bugs or errors.

7.6.2.3 Adhesive Testing

The adhesive used to attach the EZG to the person will have to be easily removed after the testing period while still having good adhesion during the usage period. Design parameters that will be tested will be the shape and size of the adhesive pads as well as how long the adhesive remains strongly attached to the user.

7.6.2.4 Physical Testing

The EZG enclosure will be applied onto the testers and they should proceed through a walk-test, the enclosure should not hinder the testers are they conduct the walk-test.

7.6.3 Stage 2 – External Testing

Stage 2 testing will consist of a focus group of users with experience with conducting an EEG who represent the end users of the device. In this stage of testing, feedback will be obtained from the focus group to further refine the design of the EZG and to increase ease of use.

7.6.3.1 Ease of Application Testing

The focus group will be asked to prepare and apply the EZG to a patient. This will include the turning on of the unit, any battery changes or charging, application of the adhesive strip and so on. Feedback will be obtained on their opinions on how the EZG is attached to the patient and if there were any difficulties on attaching the EZG.

7.6.3.2 Ease of Control Testing

The focus group will then be asked to initiate use of the EZG in obtaining data from the patient. They will be using the UI created to start and stop the collection of the data. They will also be viewing the data obtained. Feedback will be obtained on the procedure of data collection as well as the viewing of the data.

7.6.3.3 Ease of Take Down Testing

The focus group will be asked to remove the EZG from the patient, as well as to perform the necessary wipe-down procedures to prepare the device for the next patient. Feedback will be obtained on the protocols used in taking down the EZG.

7.7 Conclusion

This appendix outlines the UI Design for both the proof of concept and the prototype EZG. Currently, the EZG is nearing completion on its proof of concept phase. This involves the underlying circuitry of an EEG combined with an app that provides basic functionality.

In terms of hardware, this means that the individual circuit components have been built, but that none of the encapsulating EZG components (main electronics component, wings) have been created. Therefore, the hardware side of the user interface, which deals mostly with the setup of the EZG, is currently only the electrodes. However, even these are being mimicked with a function generator until our pending ethics approval has been granted. Therefore, almost the entire hardware user interface will need to be created over the next semester.

The current software user interface is further developed. The user is able to connect with the EZG in order to read and display data for the user to view. However, next semester a new SoC that deals solely with a low power Bluetooth connection will be purchased, and the app will essentially have to be rebuilt.

Essentially, what currently exists is a working proof of concept version of the EZG, with bare circuitry rather than a physical shell, and a rudimentary app. Added on next semester will be the necessary encapsulation to provide a seamless user interface, and a rebuilt app that will be the basis for an intuitive and simple to use EZG.

7.8 References

References for the User Interface Design Appendix are combined with the references for the overall Design Specifications document.

ENSC 405W Grading Rubric for ENSC 440 Planning Appendix

(5-10 Page Appendix in Design Specifications)

Criteria	Details	Marks
Introduction/Background	Introduces basic purpose of the project. Includes clear project background.	**/05%**
Scope/Risks/Benefits	Clearly outlines 440 project scope. Details both potential risks involved in project and potential benefits flowing from it.	**/10%**
Market/Competition/ Research Rationale	Describes the market for the proposed commercial project and details the current competition. For a research project, the need for the proposed system or device is outlined and current solutions are detailed.	**/10%**
Personnel Management	Details which team members will be assigned to the various tasks in ENSC 440. Also specifically details external resources who will be consulted.	**/15%**
Time Management	Details major processes and milestones of the project. Includes both Gantt and Milestone charts and/or PERT charts as necessary for ENSC 440 (MS Project). Includes contingency planning.	**/15%**
Budgetary Management	Includes a realistic estimate of project costs for ENSC 440. Includes potential funding sources. Allows for contingencies.	**/15%**
Conclusion/References	Summarizes project and motivates readers. Includes references for information from other sources.	**/10%**
Rhetorical Issues	Document is persuasive and demonstrates that the project will be on time and within budget. Clearly considers audience expertise and interests.	**/10%**
Format/Correctness/Style	Pages are numbered, figures and tables are introduced, headings are numbered, etc. References and citations are properly formatted. Correct spelling, grammar, and punctuation. Style is clear, concise, and coherent.	**/10%**
Comments:		

8 Appendix C: 440 Planning

8.1 Introduction

The following is excerpted and modified from the original EZG proposal in [25].

The prototype development plan that follows uses the proof of concept device discussed in the previous documentation, [25] and [4], and extends the development to a functional prototype. The intent is to not only demonstrate that such a device is feasible; but, that it can provide the promised high-quality results found in the larger, non-portable, EEG devices used in research settings while still maintaining suitability for the consumer market.

As development switches from proof of concept to full design prototype, several factors become important. Where the proof of concept stressed the electronic circuitry and development of the low power system, the prototype stresses the design elements that were the inspiration for the EZG. The wet electrode systems used in research [3] have a much higher signal to noise ratio (SNR) than the dry electrode systems found in consumer devices, such as the Muse or Mindwave. The prototype development phase will pull together the low power electronics with the smaller, more portable size of the consumer devices. In addition, the EZG addresses several issues with the consumer devices, most notably the means of attaching, or connecting, with the user. Rather than a pressure and friction fit that creates pressure points on the user's head and restricts the user's motion (or the system falls off) the EZG will use adhesive contact. This, coupled with a long battery life will make the EZG a versatile device for both research and consumer uses.

The EZG is inspired by a portable, adhesive, unobtrusive ECG system that has been a marketed device for a long time. The EZG will mimic some of these properties in order to be a competitive and useful device. A rudimentary schematic of the EZG is shown in Figure 18. This design has been modified from the original proposal as per the preceding document.

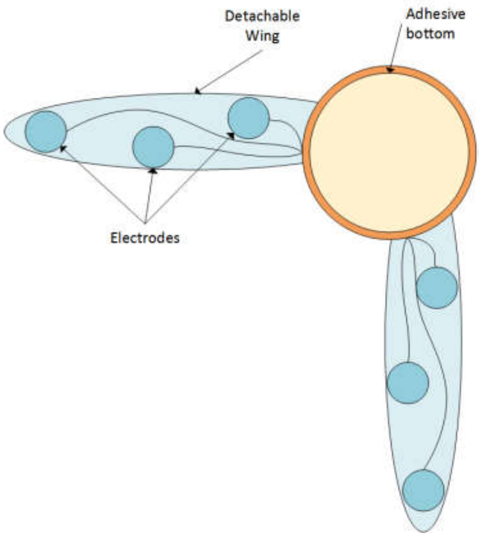

Figure 18: Basic design of EZG, modified from initial proposal

8.1.1 Background

The following is an excerpt from the original EZG proposal given in [25]. The background is unchanged from the original proposal and this excerpt is included for information purposes.

As discussed, the EEG is a method that allows the user to monitor electrical signals elicited by action and graded potentials in the brain. EEG is beneficial as it has very high temporal resolution, meaning that it is has very accurate time detection. It is also a non-invasive and nonradiative device, rendering it very safe for users. However, it suffers a trade-off in the form of very low spatial resolution, meaning that it is very difficult to tell where the signals were elicited [26]. A chart of common medical imaging devices sorted by relative spatial and temporal resolutions is shown below.

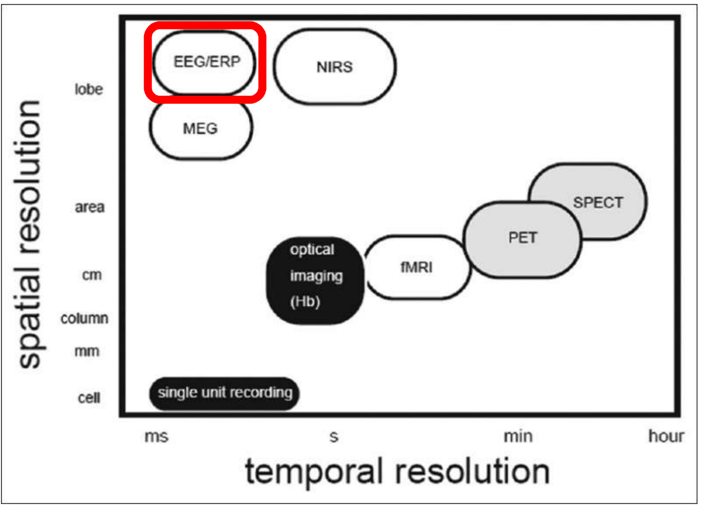

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Figure 19: Relative temporal and spatial resolutions of common medical imaging devices [27]

To complete a traditional EEG, between 4 and 256 electrodes are placed against the scalp using a gel medium to ensure minimal impedance, and the electrical signal is then sent to and analyzed on a computer [28]. The computer will filter and sort this data to display the information that is recognized as brainwaves.

8.1.1.1 Electrodes

Electrodes are the collection point of EEG data; they maintain contact with the subjects' scalp. Using a proper electrode can vastly change the quality of recorded data. There are multiple types of electrodes, but they can be classified into two main categories: surface and needle electrodes. Needle electrodes are single use needles that are placed under the skin while surface electrodes include EEG caps with disk electrodes and adhesive gel electrodes. These surface electrodes require a gel medium, which can be pre-applied; the requirement of the conductive medium classifies them as wet electrodes. [29]

As EEG's have evolved, a new surface electrode has arisen: dry electrodes. This contrasts the traditional wet electrodes, as it does not require a conductive medium. Dry electrodes require a much more complicated mechanism as they do not have guaranteed contact with the subject; this means they must tolerate high impedances (100-200x more than the wet). Additionally, dry electrodes need an apparatus that limits sensor movement, which would otherwise introduce noise into the system [30].

8.2 Scope

8.2.1 Project Goal and Benefits

The main goal of this project is to create an EEG that occupies the middle ground between a full gel cap EEG and a dry electrode EEG. Specifically, we want to achieve a higher Signal to Noise Ratio (SNR) and provide better data than the dry EEG, but to have a more portable system than the gel cap. The EZG system is a lightweight system located on the forehead and right temple and attached using hypoallergenic adhesive. This adhesive contact, in combination with wet electrodes will provide better signals than a dry EEG, while the small size, and lack of gel and head cap allows the EZG to be portable and versatile [25].

There will be some signal processing necessary for the EZG, for instance to remove the 60 Hz noise inherent in electrical connections; however, the goal of the project is to create the device and not to analyze the signals. Other than a simple blink test to verify that the EZG is functioning correctly, the in-depth processing and analysis will be left to the consumer and done on a computer after the EZG has successfully captured and transmitted the signal [25].

8.2.2 Structure

The EZG is designed as a modular system, to balance cost with the necessary sterilization required by biomedical systems. The central component is comprised of the electronics sealed in a weatherproof container to allow for cleaning. These electronics include the amplifiers, analog to digital converters (ADCs), and a microcontroller with Bluetooth and Wi-Fi. These are necessary to take the signal from the electrodes, do some simple filtering, and send it to a computer or phone, detailed in Figure 3.

Attached to the central component by magnetic connections are one to two wings. These wings contain the leads that will connect the electrodes to the main electronics component. As well, they have preamplifiers that sit directly above snap leads that will connect to the electrodes, reducing noise in the leads and increasing our signal to noise ratio (SNR). Users wanting to collect data on different brainwaves can choose to use differently shaped wings that will allow for electrodes placed on different areas of the forehead.

The wings and main electronics component are secured to the forehead using a throwaway adhesive strip. There will be one adhesive strip for each component, and individual adhesive strips will match the shape of the main electronics component and the desired wings. The adhesive components on the wings will also include the electrode, which will connect to the wing using a snap lead. Because of the adhesive and contamination due to contact with the skin, it is unrealistic for this component to be reusable, so it is single use but low cost.

The final component is an extension that connects the electronics to a clip on the ear which provides a ground for the signals on the forehead. Our system is a dual channel EEG; this means that although the device is composed of three physical electrodes, there is one electrode for data collection. The second electrode provides the potential difference across the forehead, and the third electrode provides biasing and virtual ground, which will be clipped to the patient’s earlobe.

8.3 Benefits

The benefits of the EZG include portability, a higher SNR, comfort, and affordability. Portability is important as having a lightweight, securely attached device opens up a whole new range of possible studies, such as sports, music, or even sleep studies. A higher SNR is always an important goal for an EEG, and with wet electrodes and preamplifiers directly on the electrodes, the EZG will have a higher SNR than its portable competitors. As well, the weight distribution across the forehead will be more comfortable than competitors such as the Muse, where the weight bears heavily down on the ears. Finally, having an affordable EEG device opens up the market to include not only researchers but also recreational users. A more complete analysis of each benefit can be found in [25] Sections 3.3 to 3.6.

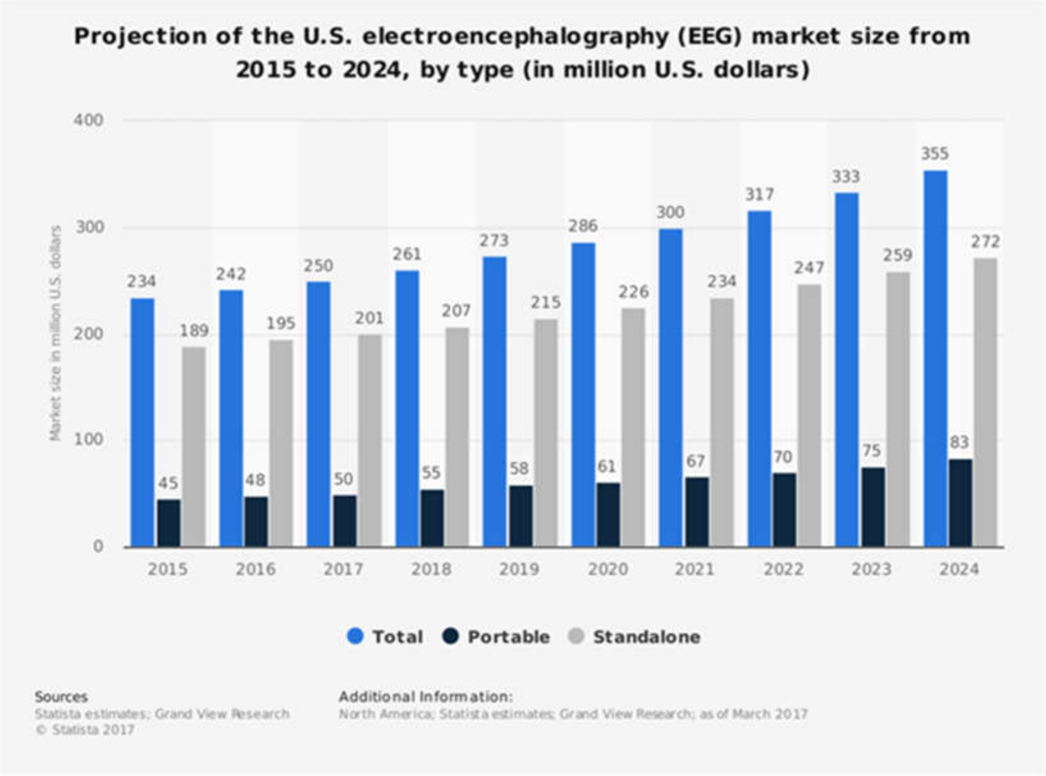
8.4 Risks

In biomedical applications, safety for the user is the primary concern. Certain risks to the user must be considered for the EZG, especially since it is in close physical contact with the user. The major risk is electric shock, or sudden fires due to electrical shorts in the device. However, having the electronics encapsulated in non-conductive plastic mitigates this risk, as do the lower power requirements of a portable device. Adhesive must also be selected carefully to ensure that it is hypoallergenic and will not cause skin irritation after being worn for the full battery lifetime of twelve hours. An additional concern is the possibility of water, or sweat, leaking into the casing and shorting out the electrical components. This is alleviated by ensuring that the casing is weather proof. See the original proposal, [25], for a full analysis of project risks.

8.5 Market

This section is an excerpt from the original EZG proposal in [25]. The market research is unchanged between the proof of concept and prototype development phases. This excerpt is included for informational purposes.

The global market for EEG devices in 2015 was valued at $687.6 million USD and is expected to rise to almost $1.4 billion USD by 2024. In the U.S alone, the expected growth for EEG devices will rise to $355 million USD, as shown in Figure 20 [31]. Our device, EZG, competes primarily with the portable subdivision of the EEG market.



Sources
Statista estimates; Grand View Research
© Statista 2017

Additional Information:
North America; Statista estimates; Grand View Research; as of March 2017

Figure 20: US Market EEG Projections [32]

The EEG market is primarily driven by its demand as a medical device, followed by commercial and academic use, all of which the EZG targets. Standalone EEG devices are used primarily in all the above-mentioned markets whereas portable devices mostly exclude the medical field.

Some uses of the EZG in the medical field may be to help diagnose dementia, sleep problems, epilepsy and seizures, and head injuries. Both dementia and epilepsy affect 50 million people worldwide each [33] [34] making them some of the most common neurological diseases. The EZG would likely not be used in testing facilities such as hospitals to diagnose patients, but out in the field where it is either too difficult or too costly to transport or a standalone EEG device.

One of the main target markets of the EZG is research centers. Much EEG research focuses on analyzing the state and reactions of the brain when the subject is exposed to a variety of stimuli. Recording and analyzing this data allows researchers to understand how the brain processes information. Another active research area is brain computer interfacing (BCI) which is the act of taking signals from the user and using them to control or manipulate a device or object. Since the EZG has a much quicker and simpler set-up process, as well as less messy clean-up, it will encourage greater participation in research studies, as well as a quicker turnaround time between subjects.

Commercially, the EZG can compete with or outperform existing EEG headsets being used for meditation, blink detection, or measuring alertness [23]. As previously mentioned, BCI's are not only used in research, but they also have existing commercial applications such as allowing people to control implanted body parts, playing video games, and controlling vehicles. The EZG could also allow for a new market to emerge in sports due to its increased comfort and reduced size; additionally, the use of an adhesive would allow sport users to move quickly without fear of the device falling off.

8.5.1 Competition

The competition that EZG will have in the market can be simplified into three categories: standard (standalone), ambulatory (standalone), and personal (portable) [22]. Standard EEG devices are set up in a testing facility and can require the user to be wired for up to a few hours at a time. Ambulatory EEG devices are like standard devices, except that the data is stored on a portable device that is usually carried in a backpack. Lastly, the personal devices are lightweight headsets that use dry electrodes; these allow for wireless data acquisition.

EZG has an advantage over standard and ambulatory devices by being portable, comfortable, and lightweight. The adhesive on the EZG also means that a test administrator will no longer need to prepare the electrodes with either a conductive gel or scalp cleaning which can take upwards of 40 minutes [35].

The main competitors to our device come in the form of other EEG headset devices which are all bigger, more expensive, and less comfortable than the EZG. These include the products listed in Table 1 below such as the Muse, Neurosky, Mindwave, and Insight to name a few. All the headsets from our competitors use dry electrodes in comparison to Ag-AgCl electrodes in our device, which are adhered to the skin and give a more consistent and higher quality signal than the dry electrodes [29]. Another unique advantage of EZG versus the competition is it can be washed, which allows our device to be used by multiple clients in a safe manner. Listed below are a few of the major players in the EEG headset market and how EZG stacks up against them. Some values are estimates since they may vary for our final prototype.

Table 2: Comparison of specifications of EZG and competitors [36]

Device	Channels	ADC Bits	Sample Rate (Hz)	Battery Length (Hours)	Cost ($USD)
EZG	2	12	256	12	80
Muse	4	12	256	5	200
Epoc	14	16	256	6	799
Insight	5	15	2048	4	300

OpenBCI	16	24	250	26	949
Neurosky Mindwave	1	12	512	8	100

8.6 Budget

(Excerpted from original EZG proposal in [25].)

The Budget has been reviewed based on current expenditure and new knowledge of how best to design and construct the prototype. Table 3 shows the initial costs of the Proof of Concept to provide baseline comparison with the projected cost of the full prototype, shown in Table 4.

8.6.1 Proof of Concept Budget

Table 3: Prototype/Proof of Concept costs (Est.)

Part	Description	Current Expenditure (CAD)	Budgeted Cost (CAD)
MCU w/ Wireless Tx, ADC	Arduino Mega, Raspberry Pi or similar	50	140
Electronic Components	Voltage Reg, Resistors, Capacitors and auxiliary parts	30	30
EEG Electrodes (10pk)	Adhesive backed EEG Electrodes	15	15
Battery, Lithium	Power Source	10	15
Shipping	Cost of purchases components online	24	24
PCB	Protoboard or copper etching	0	20
Chassis	3D Printing (Rapid Prototyping)	0	30
Total		129	274

Seeing as we have hit the maximum allocation of our budget for electronic components, it would be appropriate to revise the prototype budget to consider the increased spending on electronic components. Hence, we have increased the budget for electronic components for the prototype.

8.6.2 Final Prototype Budget

Table 4: Final functional prototype design costs (Est.)

Part	Description	Previous Budgeted Cost (CAD)	Revised Budgeted Cost (CAD)
MCU w/ Wireless Tx, ADC	ESP32 or similar, I2C ADC	280	280
Electronic Components	Voltage Reg, Resistors, Capacitors and auxiliary parts to support MCU	60	80
EEG Electrodes (10pk)	Adhesive backed EEG Electrodes	15	15
Battery, Lithium	Power Source	30	30
Shipping	Cost of purchases components online	48	48
PCB	PCB Manufacturing by CM	50	50
Chassis	3D Printing (Rapid Prototyping)	100	100
Total		583	603

8.7 Personnel and Task Assignments

The prototype development will be divided up between the team members in order to maximize productivity. The different aspects of the project are assigned base on a combination of personal preference, experience, and specific knowledge.

8.7.1 Printed Circuit Board Design

Personnel assigned: Chloe Hill, Elizabeth Pieters, Isaac Tan

The electronics for the EZG require a custom designed printed circuit board (PCB) in order to accommodate the shape of the device. The PCB will be configured using the Eagle PCB design software by AutoDesk. Three team members are assigned to this task as this requires selection of components, theoretical circuit design, and soldering in addition to the layout of the PCB in the software tool. The aspect of the project also requires laying out the circuitry for the wings and electrodes of the EZG.

8.7.2 Physical Design

Personnel assigned: Chloe Hill, Nathan Zavaglia

The physical design of the device involves the design of the outer casing that contains the PCB as well as the wings that contain the electrodes, the way in which the wings physically connect with the main device. These elements will be designed using the SolidWorks 3D CAD (Computer

Aided Design) software by Dassault Systems. Upon completion, these designs will be 3D printed.

8.7.3 Software

Personnel assigned: Michael Chyziak, Nathan Zavaglia

The software for the EZG is divided into two main modules. The first is the firmware used on the embedded microcontroller that manages the analog-to-digital (ADC) conversion of the EEG signals and the Bluetooth communications. The second module is the Android application used for interaction and control of the EZG and viewing the streaming data via the Bluetooth connection.

8.7.4 Materials

Personnel assigned: Isaac Tan, Chloe Hill

The material selection pertains to both the 3D printed parts and the adhesives. The shell material will be a medical grade plastic that can withstand the necessary sterilization and cleaning procedures required for medical devices. The adhesive will also be of medical grade and intended for long wear times. The adhesive must also be of hypoallergenic as it will be in prolonged contact with human skin. See the preceding document and previous documentation for more details [25], [4].

8.7.5 Testing

Personnel assigned: Various, whole team

Testing of the prototype includes fitting the physical casing of and wings together, fitting the PCB and other components inside the casing, and ensuring proper fit for human subjects. Testing also includes verification of circuit design; PCB testing and verification, before and after soldering of components; performance testing including, signal-to-noise analysis, impedance testing of electrodes, ADC verification, and battery life; and in situ testing of the device on a test subject (pending ethics approval). This is a lengthy process involving multiple iterations of testing and redesign. As such the entire project team will be involved in this task. Individual component testing will be performed according to the task assignments outlined above.

8.8 Timeline

The timeline for the gamma prototype development is deliberately left as general as possible. This is to accomplish two main goals: to allow for time slippage due to unforeseen delays; and to take into account the iterative nature of physical design and the necessary trouble shooting that occurs during prototype testing. Development of the gamma prototype is broken down into three main stages, physical design, prototype testing, and demonstration. The following sections outline the particulars of each stage and include partial Gantt charts illustrating the development timeline breakdown. The full Gantt chart is included at the end of this appendix.

Milestones for prototype development are taken to be the completion of the physical design (beginning of July), and the final demonstration at the beginning of August. There are no testing milestones as the testing of the device is an ongoing process that never completes even after the device has moved from prototype to production. Testing only completes when the production of the device ends (device is discontinued).

At the time of writing, the project deliverables are unknown, and as such this timeline is preliminary. Adjustments will be made to incorporate any deliverables as necessary arises.

8.8.1 Physical Design

The first stage is the physical design. As per the preceding document, the physical design parameters have been developed during the alpha (proof of concept) stage; however, the 3D models and CAD drawings of the device casing will need to be refined and 3D printed. They are then tested for fit with the necessary electronic components and the overall fit on the subject’s head, adjustments are made, then the process repeats.

The time allocation for this stage is 45 days, starting from May 7th and ending on July 6th. Though it is expected that this will require less time, with the extra included for the reasons mentioned above. The partial Gantt chart in Figure 21 shows the approximate breakdown of the physical design stage.

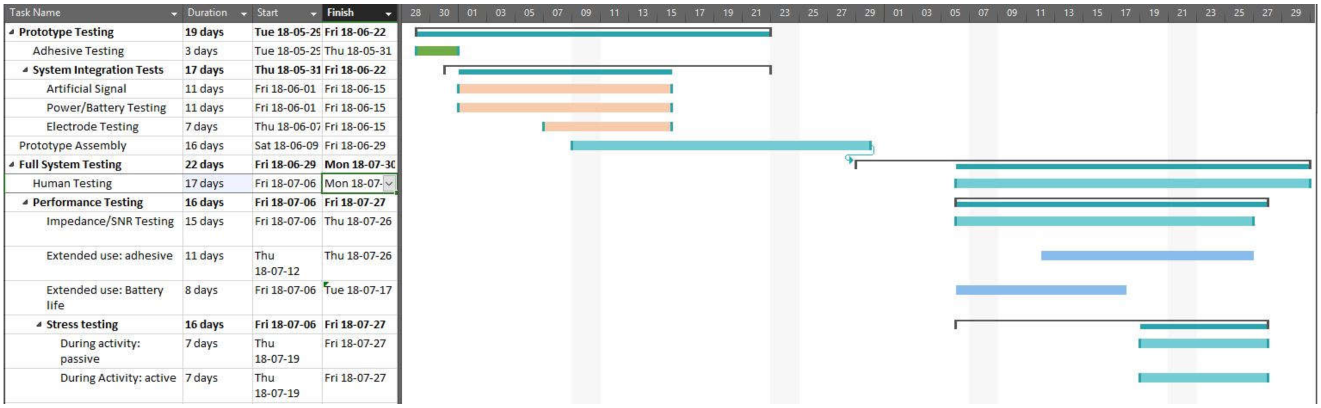
Task Name	Duration	Start	Finish
Physical Design	**45 days**	**Mon 18-05-0**	**Fri 18-07-06**
3D Modelling/Solidworks	40 days	Mon 18-05-07	Fri 18-06-29
3D Printing	34 days	Tue 18-05-15	Fri 18-06-29
PCB Design	30 days	Mon 18-05-07	Fri 18-06-15
PCB/Board Assembly	15 days	Mon 18-05-28	Fri 18-06-15
Physical Design Finished	0 days	Fri 18-07-06	Fri 18-07-06

Figure 21: Physical design stage

8.8.2 Prototype Testing

Prototype testing will commence before the expected completion of the physical design stage. This is due to the electronics and physical casing being semi-independent. The functionality of the electronics can be tested without need of the device casing and without the EEG electrodes.

A total of 41 days has been allocated for this stage. It is expected that this will be sufficient time to complete the testing. Figure 22 below shows the timeline breakdown. It should be noted that this phase may start earlier than indicated depending on how the physical design progresses. This stage runs from May 29th until July 30th and is broken into two parts. The initial testing of the electronics (Prototype Testing) and testing of the fully assembled prototype (Full System Testing).



Task Name	Duration	Start	Finish
Prototype Testing	**19 days**	**Tue 18-05-29**	**Fri 18-06-22**
Adhesive Testing	3 days	Tue 18-05-29	Thu 18-05-31
System Integration Tests	**17 days**	**Thu 18-05-31**	**Fri 18-06-22**
Artificial Signal	11 days	Fri 18-06-01	Fri 18-06-15
Power/Battery Testing	11 days	Fri 18-06-01	Fri 18-06-15
Electrode Testing	7 days	Thu 18-06-07	Fri 18-06-15
Prototype Assembly	16 days	Sat 18-06-09	Fri 18-06-29
Full System Testing	**22 days**	**Fri 18-06-29**	**Mon 18-07-30**
Human Testing	17 days	Fri 18-07-06	Mon 18-07-
Performance Testing	**16 days**	**Fri 18-07-06**	**Fri 18-07-27**
Impedance/SNR Testing	15 days	Fri 18-07-06	Thu 18-07-26
Extended use: adhesive	11 days	Thu 18-07-12	Thu 18-07-26
Extended use: Battery life	8 days	Fri 18-07-06	Tue 18-07-17
Stress testing	**16 days**	**Fri 18-07-06**	**Fri 18-07-27**
During activity: passive	7 days	Thu 18-07-19	Fri 18-07-27
During Activity: active	7 days	Thu 18-07-19	Fri 18-07-27

Figure 22: System testing

The task entitled "Human Testing" is performed as part of the other tests, and depends on receipt of ethics approval from Simon Fraser University. Should approval not be forthcoming, this will be omitted.

8.8.3 Demonstration and Wrap-up

This stage is the shortest running from approximately July 7th until the demonstration scheduled for August 3rd. This stage includes the preparation of the final project report and preparation of the demonstration details and any relevant imagery, posters, etc.

The final report preparation is set to start well before the demonstration, on July 7th, while the testing is still ongoing. Portions of the document can be written as the testing progresses with the remaining parts completed during the lead up to the demonstration. It is included here as it is part of the final wrap-up of the project.

Task Name	Duration	Start	Finish
Demonstration	**10 days**	**Mon 18-07-2**	**Fri 18-08-03**
Final Report Preparation	21 days	Sat 18-07-07	Fri 18-08-03
Prepare Demo	5 days	Sun 18-07-29	Thu 18-08-02
Demo Day	0 days	Fri 18-08-03	Fri 18-08-03

Figure 23: Demonstration and reporting

8.9 Conclusion

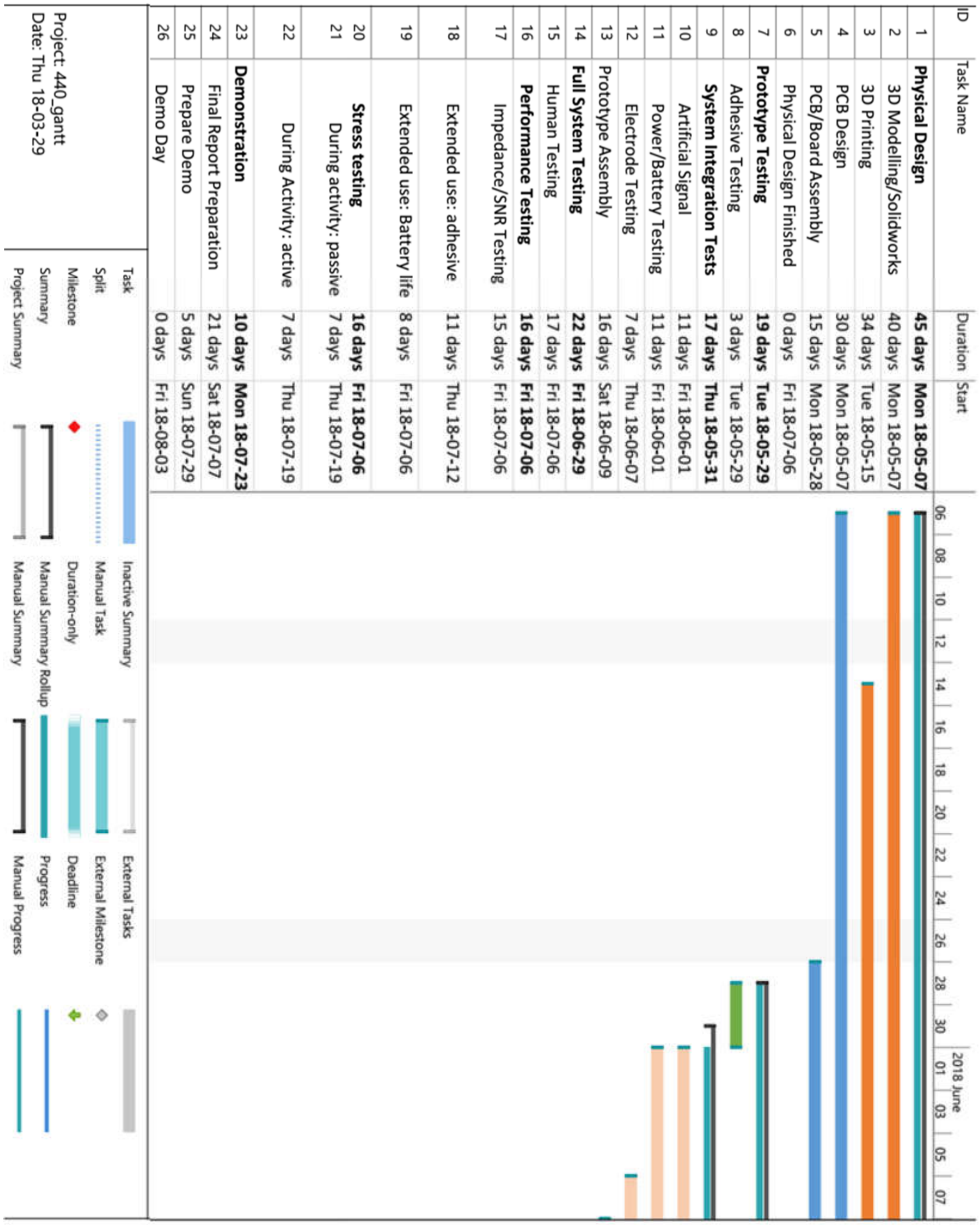
The design plan above provides the outline for the development of a working prototype (the gamma prototype) of the EZG. The EZG uses wet electrodes for their superior electrical contact properties. The adhesive attachment also improves the setup time and increases the user's comfort, particularly for long term wear. There are no conductive gels used, making clean up much simpler than with a traditional EEG.

The market for EEG devices, both for research and commercial use is growing. With the EZG moving into the prototype stage we feel confident that the system under development will fill the gap left between full cap wet electrode systems used in research settings and the more portable dry electrode devices found in commercial systems. The EZG combines the best of both.

8.10 References

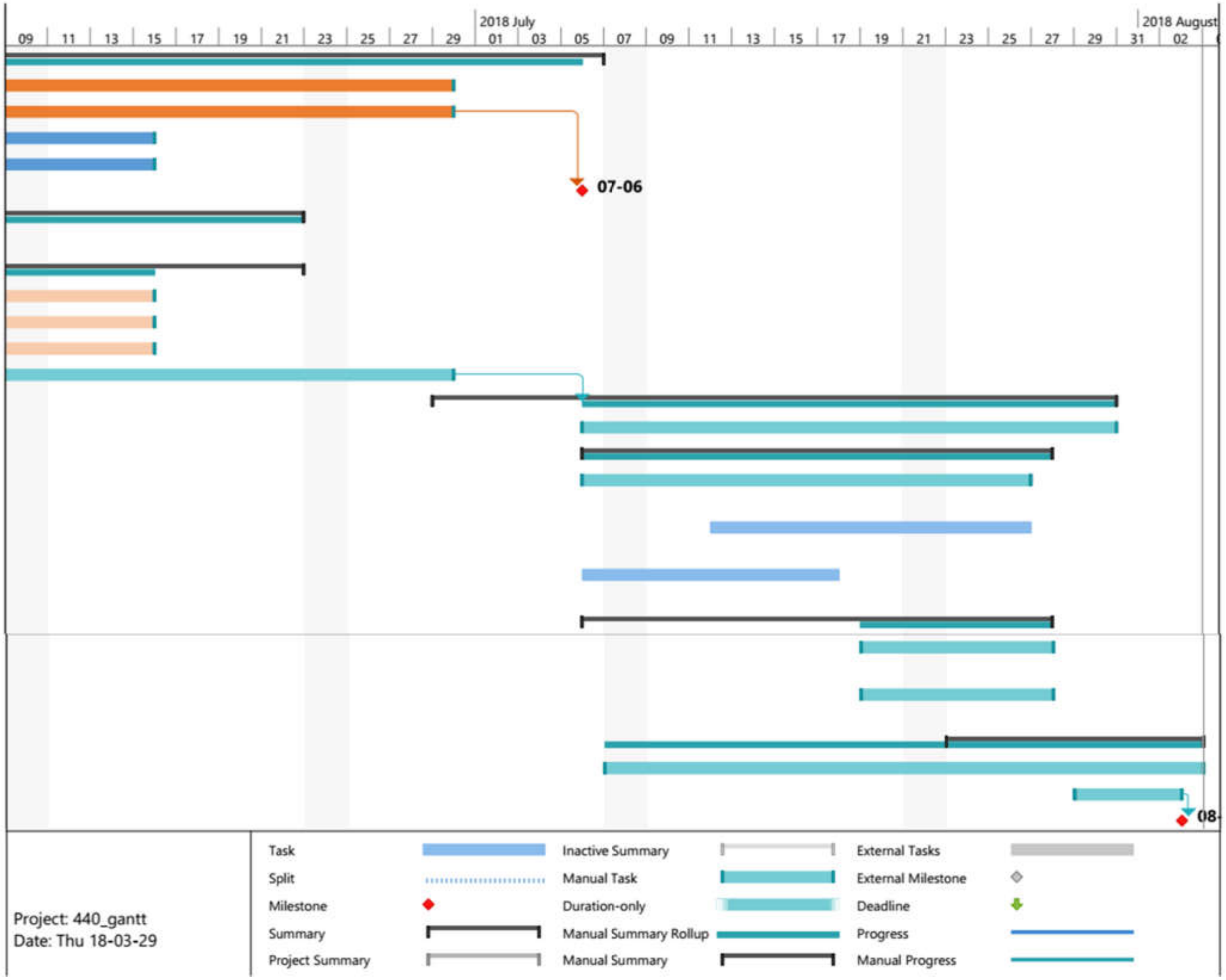
References for this appendix are the same as those in the Design Specification main document references.

8.11 Project Gantt Chart



ID	Task Name	Duration	Start
1	**Physical Design**	**45 days**	**Mon 18-05-07**
2	3D Modelling/Solidworks	40 days	Mon 18-05-07
3	3D Printing	34 days	Tue 18-05-15
4	PCB Design	30 days	Mon 18-05-07
5	PCB/Board Assembly	15 days	Mon 18-05-28
6	Physical Design Finished	0 days	Fri 18-07-06
7	**Prototype Testing**	**19 days**	**Tue 18-05-29**
8	Adhesive Testing	3 days	Tue 18-05-29
9	**System Integration Tests**	**17 days**	**Thu 18-05-31**
10	Artificial Signal	11 days	Fri 18-06-01
11	Power/Battery Testing	11 days	Fri 18-06-01
12	Electrode Testing	7 days	Thu 18-06-07
13	Prototype Assembly	16 days	Sat 18-06-09
14	**Full System Testing**	**22 days**	**Fri 18-06-29**
15	Human Testing	17 days	Fri 18-07-06
16	**Performance Testing**	**16 days**	**Fri 18-07-06**
17	Impedance/SNR Testing	15 days	Fri 18-07-06
18	Extended use: adhesive	11 days	Thu 18-07-12
19	Extended use: Battery life	8 days	Fri 18-07-06
20	**Stress testing**	**16 days**	**Fri 18-07-06**
21	During activity: passive	7 days	Thu 18-07-19
22	During Activity: active	7 days	Thu 18-07-19
23	**Demonstration**	**10 days**	**Mon 18-07-23**
24	Final Report Preparation	21 days	Sat 18-07-07
25	Prepare Demo	5 days	Sun 18-07-29
26	Demo Day	0 days	Fri 18-08-03

Project: 440_gantt
Date: Thu 18-03-29


2018 July
2018 August
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Project: 440_gantt
Date: Thu 18-03-29
Task
Split
Milestone
Summary
Project Summary
Inactive Summary
Manual Task
Duration-only
Manual Summary Rollup
Manual Summary
External Tasks
External Milestone
Deadline
Progress
Manual Progress