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January 31, 2017

Steve Whitmore
School of Engineering Science
Simon Fraser University
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Re: ENSC 405W Project Requirements for ThinkUp EZG

Dear Mr. Whitmore:

Please find our ENSC405W/ENSC 440 requirements specification, *ThinkUp: The EZG Requirements Specification* attached. This document outlines the necessary deliverables for the development of our product. We will be developing a portable, adaptable EEG device, with a focus on versatility and affordability.

This document will outline the project requirements that define the deliverables of our product, with software, hardware, and economic requirements. As well, we outline safety measures to be taken and provide a comprehensive list of relevant standards.

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

ENCLOSED : Requirement Specification for ThinkUp EZG

SFU SIMON FRASER UNIVERSITY
ENGAGING THE WORLD

School of Engineering Science

ENSC 405W

ThinkUp: The EZG Requirements Specification

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Abstract

The EZG is a portable and easy to use electroencephalography (EEG) device that allows users to pick up their brain signals during a wide variety of activities. The EZG is placed on the user's forehead and temple using an adhesive and wirelessly transfers data to the user's phone or laptop. To this end, the EZG must be small and lightweight, with electronics and software capable of detecting brainwaves and then transmitting them over a secure wireless connection. As well, the EZG must be safe for the user and conform to all relevant standards. The quantitative requirements to achieve these overall goals are outlined in this document.

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List of Figures & Tables

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.

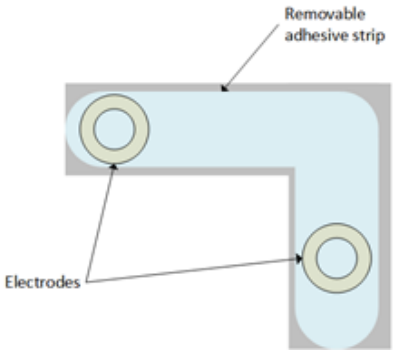

Figure 1: Basic design of EZG, bottom view

2 Background

2.1 EEG & EOG

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 [4]. A chart of common medical imaging devices sorted by relative spatial and temporal resolutions is shown below.

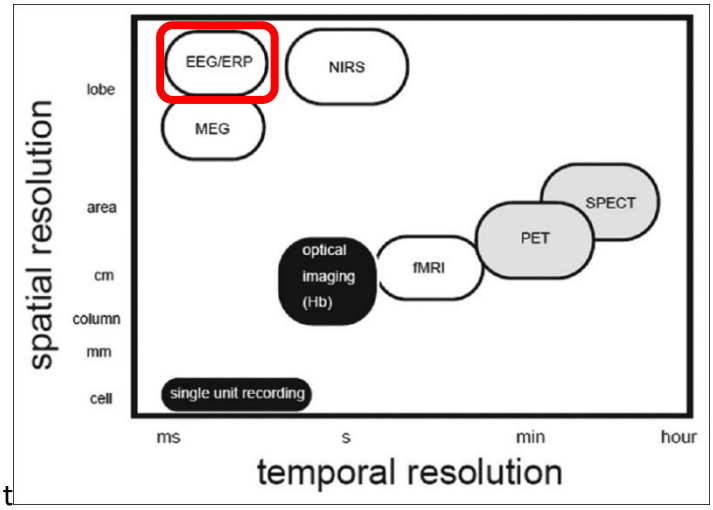

Figure 2: Relative temporal and spatial resolutions of common medical imaging devices [5]

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 [6]. The computer will filter and sort this data to display the information that is recognized as brainwaves.

Hand in hand with EEG collection is EOG collection. EOG, or electrooculography, is the collection of electrical potentials elicited by movement of the eyes. Because the magnitude of these electrical potentials is much greater than the potentials elicited by the brain, EOG data - commonly referred to as 'blink data' in EEG analysis - is recorded and can be used to filter out the eye movement from the EEG signal in post processing.

2.2 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. [7]

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 [8].

2.3 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 back of the neck.

3 Process Details

The EZG will consist of three major components: a sealed plastic weatherproof electronics container, a detachable electrode ear clip that will serve as a bias, and a disposable adhesive and electrode component. The primary goal of this device is to create an EEG that occupies the middle ground between a full cap EEG and a dry electrode system.

The EZG will measure the data via the electrodes on the adhesive. The electrodes will be connected to the plastic via snap leads, and the ear clip electrode connects to the plastic container through a jack. Each of these will transmit the measurements to the amplifier and filter. Next, the data is sent to an ADC which converts the signal from an analog signal to digital, so the microcontroller can process it. This data transmission pipeline is the highest risk element of the EZG. It must be able to withstand the stress of continual use, and not be sensitive to sweat or weather conditions. Some potential design problems will be creating proper electrode contact and fit on the user. This will be addressed by using a flexible material that can conform to the users face.

The microcontroller will act as an intermediary between the data collected from the electrodes on the device and the software endpoint to which the data is delivered. The microcontroller will be powered by the battery inside of the EZG that also provides power to the rest of the device. The software endpoint will either be any device that is able to connect to a Wi-Fi network and view a webpage, or an app on an Android/iPhone smartphone which connects via Bluetooth. Once connected a user will initiate data recording after giving a proper password and the device will send that data back to the user through either Bluetooth Classic, Bluetooth Low Energy (LE), and/or Wi-Fi.

The requirements for the EZG are listed below; these requirements encompass the scope of the problem and list the quantitative limits that the product must meet. They are separated into five main sections: Physical, hardware, software, economics, and documentation; each section has been further divided into subsections for clarity where necessary. Each section is prefaced by a short explanation to give more detail on the requirements.

Requirements are listed in the following format:

[ReqX.Z-i] Requirement Information

In this format, **X** represents the section where the requirement is in the document, **Z** represents the requirement number and **i** represents the design stage at which the requirement is expected to be met. The design stage has been split into 3 sections: **a** for alpha prototype, which will serve as proof of concept, **g** for gamma prototype which is the pre-production stage or **p** for production which will be part of the finalized product.

An example of a requirement for this section would be [Req3.1-a]; this means it is in section 3 of the document, is the first requirement in this section, and is to be complete for the alpha stage.

3.1 Physical Requirements

The physical requirements detail the structure of the device, including the breakdown into different components and the requirements of each. The general characteristics of the device, including a limit on the weight and the overall dimensions, are also outlined. The focus here is on creating a device that will be lightweight and portable, and that will therefore allow the EZG to be used in sports or other activities requiring freedom of movement.

[Req3.1.1-b] The device will be made of three discrete components, the ear clip, the electronics component, and the adhesive and electrode component

[Req3.1.2-b] The adhesive and electrode component will be user friendly, simple to connect with the electronics and easy to apply to the forehead

[Reb3.1.3-b] The adhesive and electrode component will be single use

[Req3.1.4-b] The adhesive will support the weight of the electronics and maintain adhesion to the user's forehead for a maximum of 12 hours

[Req3.1.5-b] The adhesive will support the weight of the electronics and maintain adhesion to the user's forehead for a minimum of 4 hours

[Req3.1.6-g] The weight will be no greater than 100 grams

[Req3.1.7-g] The device will not cause discomfort for a wearing period of 12 hours

[Req3.1.8-b] The connecting wire from the ear clip to the electronics compartment will be 15 cm

[Req3.1.9-b] The electronics component will be encased in weatherproof plastic

[Reb3.1.10-b] The electronics component will withstand sanitization by being wiped down with cleansing liquid but not full submersion or heat treatment

[Req3.1.11-b] The connections to the weatherproof electronics component will be made by snap leads embedded in the plastic

[Req3.1.12-b] The physical dimensions of the EZG will be as shown in Figure 3

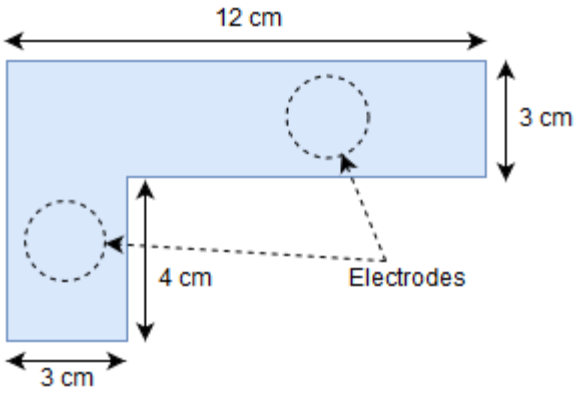

Figure 3: Physical Dimensions of the EZG, Front View

[Req3.1.13-a] The electrodes will have a maximum radius of 3 cm

[Req3.1.14-a] The electrodes will be pre-gelled, disposable electrodes

[Req3.1.15-b] The structure will be able to flex enough to conform to the forehead

3.2 Hardware

The hardware section outlines the components that we will need to pick up the brain signals and do light processing on them to provide useable data. This includes all the components that will be present in the adhesive and the plastic.

3.2.1 Electrodes

[Req3.2.1-a] The electrodes will be Ag AgCl type wet electrodes

3.2.2 Amplifiers

[Req3.2.2-a] EZG will use differential amplifiers connected to the electrodes

[Req3.2.3-a] Differential amplifiers will use the ear electrode in the common reference configuration

[Req3.2.4-g] Differential amplifiers will have a gain of at least 1000 or 60dB

[Req3.2.5-a] Differential amplifiers will be able to amplify signals as small as 1µV

[Req3.2.6-a] The amplifiers will have a Common Mode Rejection Ratio of at least 100dB [9]

[Req3.2.7-g] The high-gain amplifiers will draw no more than 0.2mA at 3.6V

3.2.3 Filters

[Req3.2.8-a] EZG will use a band-stop filter with center frequency of 60Hz for North American power line noise filtering

[Req3.2.9-a] The band-stop filter will draw no more than 1.5mA at 3.6V

[Req3.2.10-a] EZG will use a lowpass filter with cutoff frequency of 500Hz to remove high frequency noise and pass the desired 300Hz signal

[Req3.2.11-a] The lowpass filter will draw no more than 1.5mA at 3.6V

3.2.4 ADC

[Req3.2.12-a] The device will use an ADC with at least 12 bit precision

[Req3.2.13-a] The sample rate of the ADC will be 256 Hz

[Req3.2.14-a] The ADC will have to support either SPI or I2C output interface

3.2.5 Chip

[Req3.2.15-g] The microcontroller will draw no more than 500mA of current

[Req3.2.16-a] The microcontroller will operate at a voltage range between 2.3V to 3.6V

[Req3.2.17-a] The EZG will transmit Wi-Fi data using WPA2 encryption

[Req3.2.18-g] The EZG shall provide Bluetooth Classic and LE standards of at least version 4.0

[Req3.2.19-a] The microcontroller must be able to communicate via SPI or I2C to peripherals

[Req23.2.20-a] The microcontroller must have a minimum 8Mb of on board flash storage

[Req3.2.21-g] The microcontroller firmware code shall be updated via over-the-air programming (OTA)

3.2.6 Battery

[Req3.2.22-a] The battery will be a rechargeable lithium ion cell

[Req3.2.23-g] The battery will have capacity to support at least a 12-hour runtime

[Req3.2.24-a] The battery will have an output voltage of at most 3.6V

[Req3.2.25-g] The EZG will display power on/battery charge status through multicolour lighting on the front of the device

[Req3.2.26-g] The EZG will have an easily accessible charging port

3.3 Software

There are two main software components involved for the EZG device. The first is the software of the EZG, and the second a browser or smartphone app with which the user interacts with. The browser is used when connecting to the Wi-Fi being hosted by the EZG device, while the smartphone app connects to the EZG via Bluetooth.

The algorithm flow chart from the point of view of the EZG software is shown below, in Figure 4. The different colours of the blocks represent what type of method was used to communicate with the device, either the web browser via Wi-Fi, or the smartphone app via Bluetooth. It is important that access is password protected, as this would limit who can view the information for user safety and security reasons. Since the board will be hosting a web page, it will be accessible by all devices that are able to connect to a Wi-Fi network, which in today's world is very common. Likewise, nearly all new smartphones have Bluetooth which would allow the data to be stored directly on the phone.

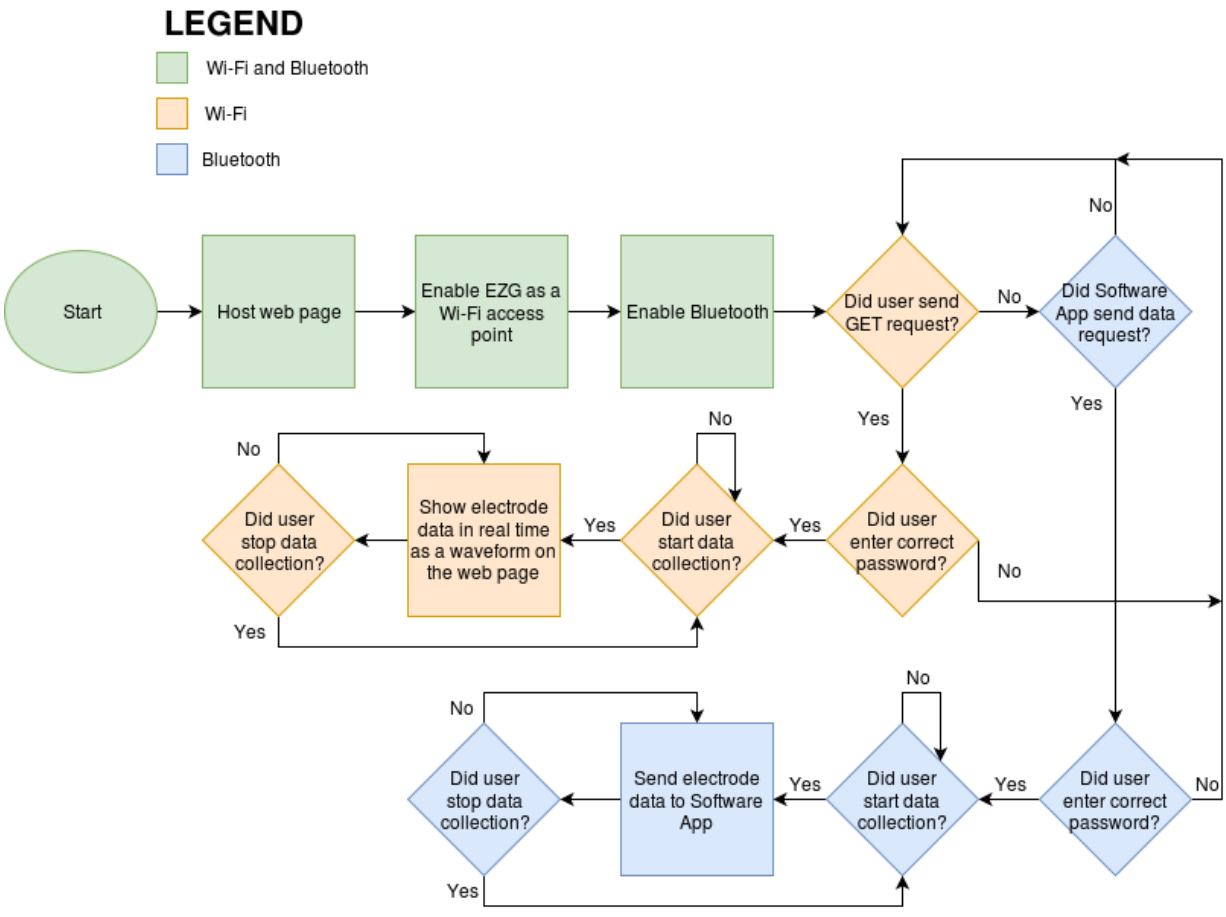

Figure 4: Flowchart of the data streaming algorithm for the microcontroller

The steps for communicating with the EZG device via web browser or smartphone app is shown below in Figure 5. To be as intuitive as possible, the number of actions that a user can perform

is minimized to the fewest possible. This will limit the number of potential issues that may arise while also being able to collect/view data in just a few seconds. Starting and stopping data collection is done by the press of a "collect data" and "stop collecting data" button that will be available to the user on both the webpage as well as the smartphone app.

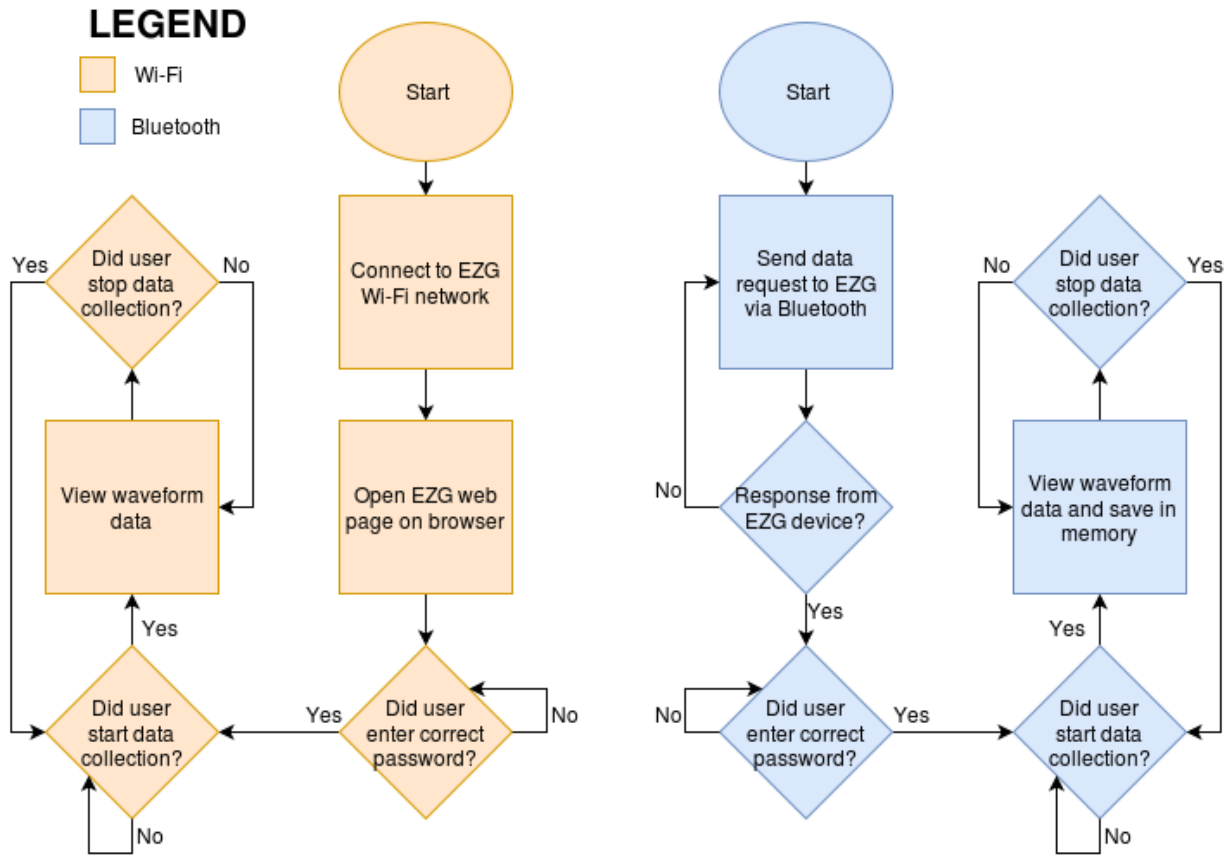

Figure 5: User interaction to communicate with to the EZG device

3.3.1 Chip

[Req3.3.1-a] The EZG will host a Wi-Fi soft access point (AP)

[Req3.3.2-a] The EZG will host a webpage asking users to type in the password to proceed

[Req3.3.3-a] The EZG will host a webpage allowing the user to start/stop data collection

[Req3.3.4-a] The chip shall stream data from the electrodes to the webpage, showing real time data in a waveform viewer

[Req3.3.5-g] The device will support a minimum of 2 connections to be maintained at any time

[Req3.3.6-g] The device will support a maximum of 5 device to be connected to it via Wi-Fi or Bluetooth at any time

[Req3.3.7-g] The EZG shall be available as a Bluetooth pairable device

[Req3.3.8-g] The EZG shall send data to the software app once a proper password is submitted

[Req3.3.9-g] The EZG will start/stop collecting data when it receives the command to do so from the software app

[Req3.3.10-g] The microcontroller will use only one processing core

[Req3.3.11-g] The microcontroller will run in a low power mode when waiting for a connection to the software app

3.3.2 App

[Req3.3.11-g] The software app will be available for Android devices

[Req3.3.12-g] The software app will attempt to connect to an EZG device via Bluetooth

[Req3.3.13-g] The software app will prompt the user to input a password to connect to the EZG device

[Req3.3.14-g] The software app shall allow the user to start/stop data collecting once connected to the EZG via Bluetooth

[Req3.3.15-g] The software app will show live data as a waveform from the EZG and store it in local memory on the device, if there is any available

[Req3.3.16-p] The software app will be extended to include iPhone devices with the same capabilities as the Android version

3.4 Economic Requirements

[Req3.4.1-p] The final product will cost no more than $80 USD

3.5 Documentation Requirements

It is important for every medical device to come with a manual, including an intended use statement, because many people may be unfamiliar with how to operate the device and/or setup procedure. The EZG will come with such a user manual, and it will be an opportunity to notify the user of the proper procedure to safely handle and clean the device.

[Req3.5.1-p] The EZG manual will depict an image of where the electrodes should be placed

[Req3.5.2-p] The EZG manual will explain how to turn the device on and off

[Req3.5.3-p] The EZG manual shall provide instructions on how to remove or place the adhesive on the plastic

[Req3.5.4-p] The EZG manual will how the user can connect to the device and start/stop collecting data

[Req3.5.5-p] The EZG manual will notify the user of all parts that should have been included in the packaging

[Req3.5.6-p] The EZG manual shall contain an intended use and indication for use statement

4 Engineering Standards

4.1 Overview

As a medical device, the EZG will need to conform many strict regulations and standards. To ensure this device meets global standards, we will primarily focus on the international standards governed out by the International Organization for Standardization (ISO), and the international Electrotechnical Commission (IEC) [10]. As this device will initially be marketed in Canada, we will also focus on the Canadian Standards Authority (CSA), and its adaptions of the international standards. Following the standards laid out by these governing bodies makes scalability quite simple, as the standards of most other markets deviate very little from the international standards. [11]

Medical devices face another constraint as they must be classified based on the risk they present. In Canada, devices are classified by Health Canada, and are divided as Class I, II, III, or IV; In the United States, devices are classified by the Food and Drug Administration (FDA), and are classified by Class I, II or III. Each of these classifications will have stricter or more lenient regulations [11]. To ensure that the product meets the required standards and regulations the designer of the product must assign a preliminary classification. Based on the guidance documents provided by Health Canada, the EZG would be subject to Rule 10(1) and be considered a Class II device. In the United States, the EZG would also be a Class II device, as per the FDA classification strategies [11], [12], [13].

Ensuring that our device is aligned with the following standards will permit the EZG to be sold on the North American market and provide consumers with confidence in the efficiency and safety of the device.

4.1.1 Safety and Essential Performance Standards

ISO 60601-1-11:2015 - Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance [14]

CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (Adopted IEC 60601-1-11:2015, second edition, 2015-01, with Canadian deviations) [15]

IEC 62353:2014 - Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment [16]

IEC 82304-1:2016 - Health software - Part 1: General requirements for product safety [17]

4.1.2 Sterilization Standards:

ISO 14937 - Sterilization of health care products [18]

ISO 17664:2017 - Processing of health care products [19]

4.1.3 Home Healthcare Environment Standards

CAN/CSA – C22.2 NO. 60601-1-11:15 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – includes Canadian deviations [20]

4.1.4 Usability

CAN/CSA-C22.2 NO. 60601-1-6:11 (R2016) - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability [21]

IEC 62366-2:2016 - Medical devices — Part 2: Guidance on the application of usability engineering to medical devices [22]

4.1.5 Environmental Conscious Design Standards

CAN/CSA-C22.2 NO. 60601-1-9:15 - Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design (Adopted IEC 60601-1-9:2007, edition 1:2007 consolidated with amendment 1:2013, with Canadian deviations) [23]

4.1.6 Medical Device Software

IEC 62304 :2006 - Defines the life cycle requirements for medical device software. [24]

IEC TR 80001-2-3:2012 - Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks [25]

4.1.7 Quality Management & Risk Management Standards

ISO 13485 :2016 - specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements [26]

ISO 14971 - Application of risk management to medical devices [27]

IEC 60529:2001 - Degrees of protection provided by enclosures (IP Code) [28]

4.1.8 EEG Specific Standards

ISO 22077-1:2015 - Health informatics -- Medical waveform format -- Part 1: Encoding rules [29]

4.1.9 Battery Standards

IEEE 1625 - IEEE Standard for Rechargeable Batteries for Multi-Cell Mobile Computing Devices [30]

4.1.10 Electronics Standards

CISPR 22: EN 55022 EMC Standard - information for information technology equipment, ITE for the radio disturbance characteristics for electromagnetic compatibility compliance [31]

4.1.11 Wireless Communication Standards

IEEE 802.11 – IEEE Standard for implementing wireless local area networks between computers in the 2.4GHz and 5GHz range [32]

IEEE 802.15.1 – IEEE Standard specification based on Bluetooth technology for portable devices [33]

5 Sustainability and Safety

5.1 Sustainability

Reusability of the system will be of high priority for the EZG, this reduces the amount of medical waste sent for disposal. This not only reduces costs for the medical facility but also reduces the EZG's environmental impact. The electrodes and adhesive will be the only single-use component of the EZG, with the intent that the rest of the EZG is reused until the end of its usable life. Incorporating recyclability as a major factor in designing the EZG will allow the decommissioning process to be as simple as recycling current electronic waste.

Listed below are parts of the EZG and the materials and sustainability concerns that could be encountered.

Table 1: EZG materials & sustainability concerns

Part	Material	Source	End of Life
Battery	Lithium Ion Polymer	Conflict-Free Lithium Sources	Return to Battery Recycler
Electrodes and Adhesive	Silver Chloride	Medical Consumables Supplier	Medical Waste Processing
PCBA	Fiberglass, Solder, ICs	Lead Free Solder, RoHS	Return to Electronics Recycler
EZG Casing	Medical Grade ABS	Recycled Plastics	Plastics Recycling

5.2 Safety Requirements

The EZG is intended to be used for detecting electrical potential differences of the brain; due to its proximity with the user, the EZG must adhere to strict safety guidelines.

The EZG will have to satisfy the safety requirements listed below.

5.2.1 Physical

[Req5.2.1-g] The EZG enclosure shall not have sharp burrs or edges to reduce risk of injuries and be made of an insulated plastic to prevent shorts.

[Req5.2.2-p] The EZG enclosure shall conform to IEC 60529:2001, (Degrees of Protection Provided by Enclosures (IP Code) [28]

[Req5.2.3-g] The EZG battery shall be in an enclosure that resists puncturing.

[Req5.2.4-p] The EZG will be made up of parts that conform to the RoHS directive [34]

[Req5.2.5-p] The EZG shall be able to withstand drops from 2m onto hard surfaces and remain functional.

5.2.2 Electrical

[Req5.2.6-g] The EZG battery shall conform to IEEE 1625 (Rechargeable Batteries for Multi-Cell Mobile Computing Devices) [30]

[Req5.2.7-p] The leakage current of the EZG should conform to IEC 60601-1 [20]

[Req5.2.8-g] The EZG should conform to FCC Part 15 or EN55022/CISPR 22 EMI Standards (EMI Standards) [31]

[Req5.2.9-p] Electrical components used in the design of the EZG will conform to CAN/CSA-C22.2 NO. 60601 [23]

5.2.3 Biomedical

[Req5.2.10-g] The EZG adhesive shall not cause irritation to the skin.

[Req5.2.11-g] The users of the EZG will have to undergo orientation and training before using the EZG.

By considering these safety requirements, the risk that the device poses will be significantly reduced.

6 Conclusion

This document presents the functional requirements of the EZG device. These requirements provide an in-depth synopsis of the electronic, mechanical, and software functionality that are necessary for the EZG to perform its intended purpose. Also included are the relevant engineering standards regarding the design and use of medical devices. Compliance with these standards is undertaken to ensure that the device is high quality, is safe for human use, and adheres currently accepted sustainability practices. The EZG is intended to augment existing research apparatus while remaining suitable for personal use.

The EZG development will occur in two stages: An alpha prototype, proof of concept, to be completed April 2018, and a gamma, or design prototype, to be completed August 2018. A test plan for the alpha prototype is included in the appendix at the end of this document. It details how the alpha device will be tested and demonstrated; both on a human subject, and via simulated signals should ethics approval for human testing be delayed.

7 Glossary

AP – Access Point, a station that transmits and receives data that allows wireless devices to connect to it as a network

ADC – Analog to Digital Converter

FCC – Federal Communications Commission

EEG – Electroencephalography

EOG – Electrooculography

IEC – International Electrotechnical Committee

ISO – International organization for standardization

I2C – Inter Integrated Circuit

LE – Low Energy

RoHS – Restriction of Hazardous Substances

SPI – Serial Peripheral Interface

WPA2 – Wi-Fi Protected Access 2

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9 Appendix

9.1 Alpha Prototype Test Plan

While there are many small electronic components used in the EZG, the testing of the device will be a straight forward process. Testing of the ESP2 controller and the individual amplifiers, filters, and electrode snap leads will take place as the prototype is constructed. This is part of the natural design and build process of any electronic device.

The alpha prototype testing will not entail the measurement of brain signals. Testing will take place using an EOG “blink test”. This test will be used as the signals are similar to encephalography signals; but, are several orders of magnitude larger in amplitude (mV instead of µV). This will ensure that the EZG is functioning correctly, without requiring the use of the high gain amplifiers intended for the gamma prototype.

For the alpha prototype testing, the electrodes will be directly attached to the subject. One electrode will be placed on the midline of the forehead, above the brow line. The second will be placed on the temple (right or left). The ear electrode will be attached to the ear on the same side as the temple electrode. The subjects natural eye movement and blink response will then be sufficient to ensure a successful test.

Should the ethics approval required for human testing not be obtained in time for the alpha test, a function generator will be used to simulate signals for testing. For this setup, the function generator signal is routed through voltage dividers to bring the resulting signal into the correct voltage range. The output of the dividers will then be connected to the ends of the snap leads that connect the electrodes to the device.

Once the EZG is properly setup, a phone, tablet, or other electronic device can be connected to a password protected Wi-Fi network called “EZG_POC”. Once connected to the network, navigating to the URL “192.168.2.1” will bring the user to the home page of the EZG web app. There will be a “Start” button that the user will press to start taking EEG data from the subject. The web app will then display a waveform showing the data collected from the electrodes in real time. The user will then be able to press the “Stop” button at any time. If the user disconnects from the network for more than two minutes without pressing the stop button, the device will stop collecting data.

These tests will be duplicated in a live demonstration to show the ease of use of the device. On display will be the browser based interface used to initiate data collection and view the raw data stream from the device. The device will also run on battery power to demonstrate the low power consumption.