FINAL REPORT

ELEC3117: ELECTRICAL ENGINEERING DESIGN

inTENS

A portable wireless TENS

(Transcutaneous Electrical Nerve Stimulation) device

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1. Executive Summary

This report provides an analysis on inTENS: a portable wireless, clothing integratable and customisable TENS (Transcutaneous Electrical Nerve Stimulation). inTENS allows users to relieve pain in a discrete fashion, whilst providing EMG (electromyography) data to provide a personalised experience for each user. Specifications of the device include 1-100Hz , 0-30mA stimulation along with EMG recording, both of which are controllable through a mobile application. Detailed in the report is an extensive summary of device needs, device concept and system design.

Market analysis results showed that investment in the development of inTENS would be strategically advantageous, as the product not only provides a solution to the problem of on-the-go TENS pain relief, but also allows for a unique user experience; features that competitors in the same market lack.

inTENS has an estimated market share of $2.94 million, attributed to it’s high large presence in the electrostimulation market as well as due to the few competitors that offer similar features at the low price point of $150AUD. Additionally, manufacturing costs total at $66.96AUD per unit, accounting for manufacturing, shipping, regulatory and engineering and development costs.

The report also includes a development timeline along with COVID-19 contingency and risk management plans, which ensures production and testing to be finalised no later than 16/11/2020. Main risks include: Block by barriers such as meeting medical device regulations, inability to implement working mobile interface and the inability to complete all planned tasks due to time constraints.However mitigation strategies are suggested in order to alleviate the severity and likelihood of these risks.

Overall, inTENS is a product that targets a niche, fast growing market, and is expected to have a positive net present value of 72,186.60 at the end of its product life cycle (2 years). Revenue is expected to be $96.55 AUD per unit and a gross profit margin of 280.6% and as a result, investment in the development of inTENS would be a strategic advantage. It provides a solution for a common issue, and allows for development of a new type of concealed pain relief wearable.

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2. Introduction

inTENS (Transcutaneous Electrical Nerve Stimulation) is a device focused on providing pain relief on the go. There is a growing demographic of people today who face muscle or nerve pain such as those with pre-existing medical conditions (such as arthritis), athletes (who repetitively stress their body by performing strenuous physical activity) and labourers and other people who experience muscle pain from their lifestyle or occupation where they may undertake work that can lead to muscle pain. There are a variety of types and areas of pain one can experience, and due to this, all TENS users will use the device differently - be it area of stimulation, or stimulation settings.

In saying this, TENS machines are required to be as functionally flexible as possible in order to accomodate for all users. Since the main use of this machine is primarily associated with pain relief while moving or performing day-to-day tasks, particularly in public, there is the need for a TENS device that is seamless, intuitive to use but most importantly concealable. The majority of current TENS products designed for this use case are not wireless and are quite large. Furthermore, few products provide the benefits of a mobile user interface and stimulation customization. Among these products, none are designed to be clothing integratable and concealable for public usage.

Thus, in this report an optimised solution for this specific usage is proposed; a TENS device that is miniature, wireless and clothing integratable. Additionally, a detailed market analysis is conducted to gain a better understanding of the current state of the market and what features need to be implemented to create a competitive product. This is paired with a business plan to glimpse at the financial performance and profitability of this product. Lastly, a development plan is established to effectively utilise time and resources while identifying and preparing for risk in order to ensure project completion.

3. Project Description

3.1 Needs Assessment

There are 3 main groups that this product is targeted towards:

- People with pre-existing medical conditions: Different medical conditions such as arthritis or a pinched nerve can experience muscle pain.
- Athletes: Athletes perform strenuous physical activity at regular intervals which can cause muscle pain and fatigue.
- Labourers and others: People who experience general muscle pain from their lifestyle or occupation from stressful work or being in repeated stress positions such as labourers.

All 3 target groups will use the device by attaching the electrodes in the correct configuration depending on where the muscle or nerve pain is located. The device can then be controlled using a mobile application where pulse width, frequency and amplitude (intensity) can be varied according to the user's preference.

inTENS addresses several key features which competitors lack or execute poorly which can be seen in our competitor analysis. These include:

- Mobile connectivity of up to 2m
- Modulation of both frequency, pulse width and amplitude
- Weight (<60g)
- Discrete (can be integrated into clothing)
- Portable - since the device is connected on the electrode, wiring is minimised so using the device doesn't restrict movement.
- Ability to set profiles with specific settings
- $50 Cheaper compared to closest alternative

TENS devices are a growing market in the pain management industry [#]. inTENS capitalises on this along with its growing demographic of users to capture as much of the market as possible.

3.2 Product Concept

A portable and discrete device that can provide relief from muscle and nerve pain. It is controlled by users through a mobile application which also relays key information back (e.g. battery life) to the user and provides them with the ability to control the properties of electrical stimulation (pulsewidth, frequency and intensity). The product is a device that is portable and discrete enough to be used without being noticed by others. Such a device would promote use as users would not worry about visibility and possible embarrassment.

The device will be self contained with a rechargeable battery and waterproof with rubber coverings on the openings for Input/Output (I/O) and user controls such as the On/Off switch and micro-usb charging port. inTENS will also possess an electromyographic (EMG) recording circuit to analyse the user's pain and provide a suggested pain relief stimulation profile.

inTENS will be used by connecting pads onto the user onto predetermined areas of the body for maximum efficiency as seen in appendix D.

3.3 Unique Selling Points

From our user needs and requirements as well as an analysis of our competitors, our unique selling points were found to be:

- Portability: Small form factor (4cmx4cm), and lightweight (<60g). Detachable electrodes and carry case make this device designed for on-the-go use.
- Tailored experience: The innovative EMG system detects muscle movement and provides information about irregular muscle twitches or pain caused by pinched nerves. This data is then used to suggest settings for stimulation, providing a unique experience for each user.
- Mobile application: This makes the device more user friendly and easier to integrate into daily life through the use of a smartphone. The app also provides more information than a standard remote.
- Customisation: Custom stimulation settings can be created using the mobile application. Preset modes are also available.

- Discrete TENS use: Lack of wires and seamless design allows the device to be integrated into clothing, giving a sleeker, more discrete solution for TENS stimulation in public.
- Large stimulation range: Stimulation can be modulated and output can be set up to 30mA, which makes it extremely versatile for its size.
- Rechargeable battery: the 3.7V LiPo battery that powers the device can be charged through a microUSB port.

3.4 Requirements

From the needs assessment and unique selling points, a list of key requirements was constructed to fulfil the needs of key users and act as a benchmark for the product design.

3.4.1 Functional Requirements:

1. The device must have a physical method to power on and off.
2. The device must be controlled wirelessly up to 2m via a mobile application.
3. The device must output a constant current, charge balanced, biphasic waveform. (0-30mA).
4. The device must be capable of frequency modulation. (1-150Hz).
5. Key information (such as battery life) must be wirelessly relayed to the user.
6. Devices must indicate to the user if the battery is being charged via an LED.
7. The device must be applicable to different body parts.

3.4.2 Customer Requirements:

8. The interface of the app shall be intuitive so first time users can utilise the device without instruction.
9. The system shall have power to last up to 20 hours with normal usage (20 hours of constant usage).
10. Total system mass shall be less than 60g.
11. The device shall have a top face area of less than 16cm^2.

3.4.3 Non Functional Requirements:

12. The system shall be rated to at least IP55
    a. Any dust ingress will not damage or impede performance of internal components
    b. Effective against directed water from any angle
13. The battery shall be replaceable

3.5 Design Concept

In order to achieve the above, the device will be designed as a rectangular prism (40mmx40mmx10mm) which will have fixed electrodes on the base. The electrodes will be used to secure the inTENS to the user's body as well as to stimulate/record data. The stimulation system will consist of a howland current pump constant current source that uses an input from the microcontroller to output a desired stimulation pattern. Additionally the recording system consists of multiple filters and amplifiers to record and analyse the EMG signals, which lie in the range of 50-150Hz with amplitudes spanning 0-10mA. The device will be powered using a 3.7V 1100mAh LiPo battery which is able to be recharged. Power management systems will be used in order to regulate and boost the voltages as required as well as recharge the LiPo battery when required. The entire system will be controlled using the ESP32WB55 module which has integrated BLE which the user can use to control the device via mobile or desktop user interfaces.

3.6 High Level Design

3.6.1 Functional Block Diagram

A high level block diagram of the inTENS system can be seen below in Fig 3.1

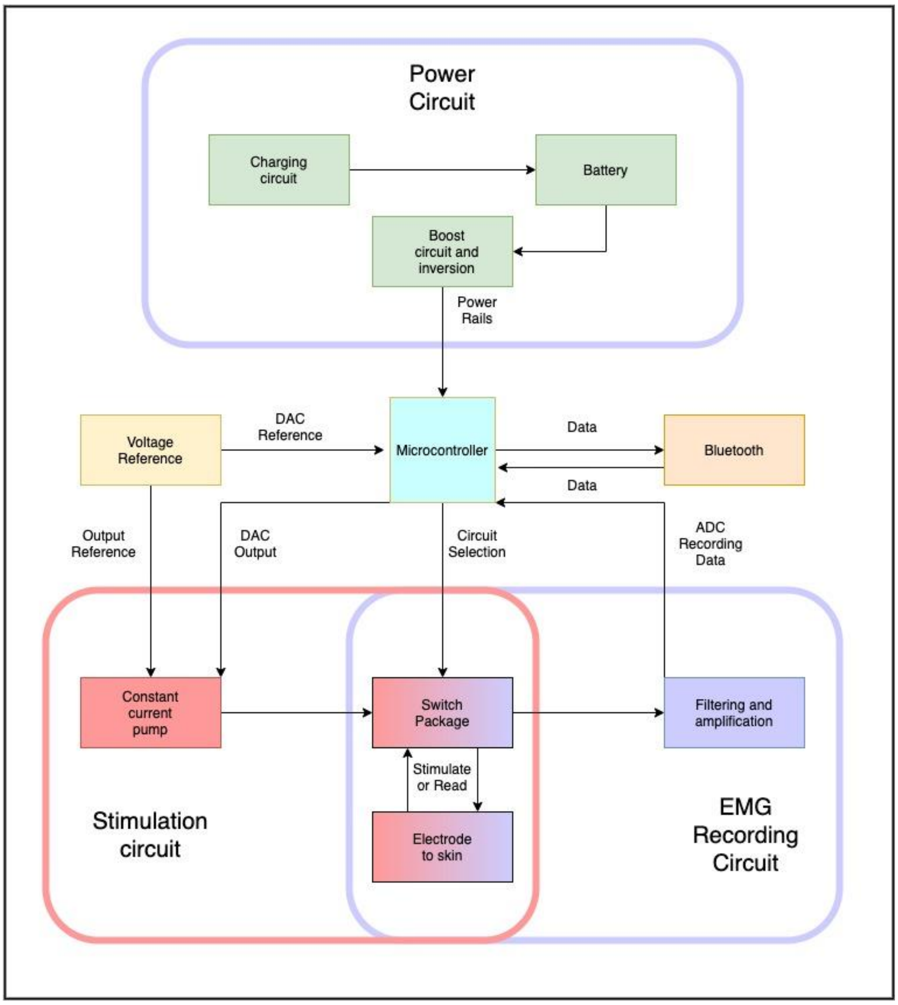

Figure 3.2: High Level Block Diagram

Function list:

1. Microcontroller: This will control the mode of operation- either recording or stimulation. Additionally it will control the stimulation output as well as process recording data and transmit data via Bluetooth to a mobile device.
2. Voltage reference: The voltage reference is used to supply a reference voltage to the Constant current charge pump in order for it to operate as desired.
3. Constant current charge pump: This is the mechanism for stimulation. It receives a DAC voltage and translates that into a constant current biphasic arbitrary wave. The voltage reference is used to produce this waveform.
4. Filtering and amplification circuit: This system filters and amplifies the EMG data from the electrode and sends it to the microcontroller for processing via ADC.
5. Switch package: This allows for selection between the stimulation circuit and the recording circuit. Only one can be selected at any given time.

6. Power supply: this system supplies power to the rest of the circuit by boosting the 3.7V LiPo battery to +-15V. It also charges the battery when a 5v USB is connected.
7. Electrode: This is the output electrode that gets stuck to the user's arm. It is used to stimulate muscle or to read EMG from muscles.

4. Market Analysis

4.1 Market Size and Potential Share

The pain management device market is valued closed to an estimated $4 Billion USD and is expected to grow at a compound annual growth rate (CAGR) of 9.4% from 2018-2026 to reach an estimated value of $8 Billion USD (fortunebusinessinsights, 2019) [1].

Out of all the pain management devices, there are 4 major categories, Electrical stimulation devices (ESD), RF Ablation Devices, Infusion Pumps and Neuromodulation Devices. Of these, neuromodulation devices hold a clear market dominance, comprising an estimated 73.6% (Fig 4.1) of the market. This is promising as our TENS unit is a type of neuromodulation device. Neuromodulation devices are also the most anticipated subsection of pain management devices in terms of growth, with the International Neuromodulation Society stating that regulatory approvals for neuromodulation devices grew by an estimated 35% in the past decade [1].

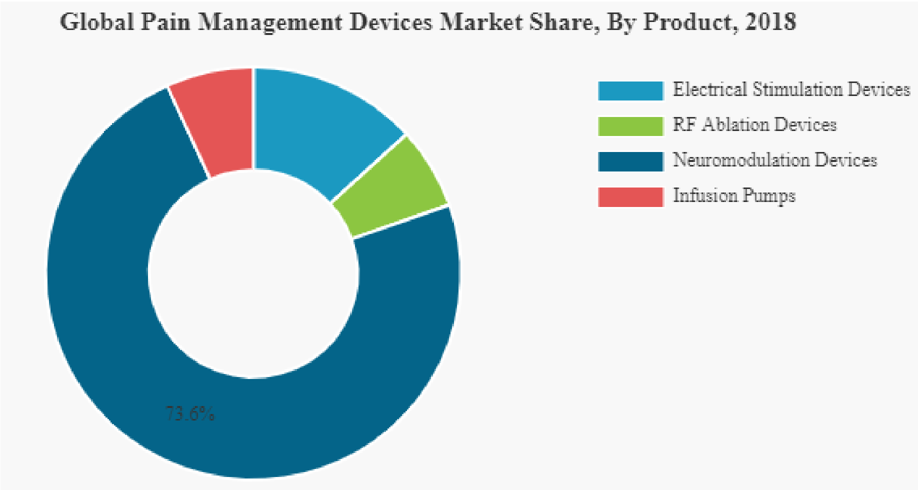

Figure 4.1: Market Share of Global Pain Management Devices [1]

TENS devices account for nearly 10% of the neuromodulation device market and of this, key companies such as Medtronic, Boston Scientific Corporation, DJO Global LLC and Nevro Corp account for nearly the entire market with a 95% market share [1]. Initially considering only the Asia Pacific market which accounts for roughly 20% of the global TENS market, this accounts for a total market share of $2.94 million dollars that is accessible to our product inTENS.

Our product also aligns with the increasing demand for a wireless and portable muscle stimulation and it's compatibility with smartphones places it in the fastest growing segment of the TENS market.

Our target market consists of:

- People with pre-existing medical conditions: Different medical conditions such as arthritis or a pinched nerve can experience muscle pain.
- Athletes: Athletes perform strenuous physical activity at regular intervals which can cause muscle pain and fatigue.
- Labourers and others: People who experience general muscle pain from their lifestyle or occupation from stressful work or being in repeated stress positions such as labourers.

This is an extremely large market with "the majority (60% to 80%) of the population [having] pain of muscular origin at some time or other". (Krismer, van Tulder, 2007) [17].

4.2 Possible Selling Price

Of the TENS market, pain management accounts for a market share of 54.5% [2], therefore, the target market of our product consists of:

- People with pre-existing medical conditions: Different medical conditions such as arthritis or a pinched nerve can experience muscle pain.
- Athletes: Athletes perform strenuous physical activity at regular intervals which can cause muscle pain and fatigue.
- Labourers and others: People who experience general muscle pain from their lifestyle or occupation from stressful work or being in repeated stress positions such as labourers.

One strategy to capture the market is through health professionals. For example in Australia alone, there are over 33,000 physiologists [3] and not counting other similar professions that may recommend this device such as exercise or sport physiologists, health professionals would provide a strong platform for promotion and awareness. They would initially be attracted by our product's superiority compared to existing TENS devices which would benefit their patients.

From this, existing TENS solutions range from $80 to $300. However, the closest related product, the Powerdot 2.0 Uno [4] is priced at $200. Thus, both from this and from primary market research in the form of interviews and surveys, our product will be priced at $150 AUD. This low price allows inTENS to remain a competitive product to those with a similar function while having superior portability and user interactivity. This also corresponds with our interview responses which showed 90% of users were willing to pay $150 or more. (Appendix A.a).

4.3 Marketing Data

4.3.1 Survey Responses

Survey responses were mainly elicited from people who either experienced chronic muscle pain or owned a TENS device since the responses gained from perfectly healthy people would not be representative of the TENS market. Since TENS is a relatively niche market, it is representative to have a smaller number of people surveyed. This was set at 15 users and 15 non-users. People who did not experience muscle pain were not excluded from the results since their view on features was important as injuries and stresses can lead to a healthy individual experiencing muscle pain.

The survey revealed a few key points:

- Over 70% of responders regularly experienced muscular or nerve pain.
- Over 80% of responders were likely or more to use a TENS device.
- 90% of responders found the portability of a TENS device to be important.

4.3.2 Interviews

Interviews were conducted with both individuals who have had experience utilising TENS devices and users who experience chronic muscle pain as well as a physiotherapist. All 3 interviewees stated that it was difficult to use existing TENS devices due to the “cords dangling that can catch and snag”. Interviewees also expressed a reluctance to use TENS devices in public due to the amount of wires that other people can see. Thus, portability and discreteness was prioritised in the design of inTENS.

Appendix A has a detailed view of survey responses and interviews.

4.4 Comparison to existing products

As identified through secondary research, surveys, interviews and a comparison with existing products, inTENS targets specific deficiencies that exist in existing solutions. These include eliminating connectivity issues in the form of wires, increasing portability, improving user interface with a mobile application and decreasing visibility by creating a seamless product [5].

Below are the main competitors for the inTENS. Most are catered to daily wear, however some are catered to athletes and muscular recovery rather than pain relief.

Table 4.4.1: Competitors in the TENS market

Product ($RRP USD)	**Features**	**Pros**	**Cons**	**Factors affecting their usability and/or marketability**
Withouch Pro Wireless TENS Machine [6] ($79.95) 	0 - 110mA output at 5-120Hz frequency with 120-400us pulse width. 5 intensity levels Remote control with increase/decrease button 136 g	Signals when you need to better place the UNIT with a yellow light turning on in the remote Uses a long-lasting flat type battery #2032 (lasts for about 40 treatments)	No degrees of freedom when placing electrode pads Somewhat bulky Lack of mobile compatibility for customisation Only 5 intensity levels with no modulation Auto shut off after 30 mins	Users may not wear the device depending on activity plans. Lack of stimulation settings may cause the device to lose effect Auto shut off may lead to less usage. Remote control may lead to device being worn less in public
iReliev ET-5050 ($179.95) [7] 	14 programs and intensity levels Wireless with a remote control 450g	One pad per channel Completely wireless	Sits quite tall - can be seen through fitted clothing Lack of mobile compatibility for customisation	Remote control may lead to device being worn less in public. Device may be used less in public due to

	0-80mA output	Intuitive remote function		appearance through clothes.
PlayMakar PRO Electrical Muscle Stimulator [8] ($249.95) 	Completely wireless. Electrodes attach directly to the pod unit. 70g 14 TENS & EMS programs and 25 intensity levels small enough to hide under clothes	Multiple pods can be used. 3-5 Hours of use per charge Variety of programs	Lack of mobile compatibility for customisation Sits quite tall - can be seen through fitted clothing Multiple pods needed in order to stimulate multiple areas. Controls are on the pod. Expensive	High price point affects purchases and marketability. Market segment catered to athletes and exercise rather than daily wear. Requirement of multiple pods makes the device not worth the money for stimulation of multiple areas
Powerdot 2.0 Uno [4] ($199) 	Custom application that tailors stimulation based on user input Lightweight and portable Mainly catered to athletes with the app interface and stimulation settings.	Small and portable Logs detailed usage and accepts user input Custom intensities and programs using a mobile app You can use the app to highlight your painful areas, pick the type of pain you’re experiencing, rate your current pain score and tolerance level.	Pad placement can be difficult to replicate from the application, leading to incorrect results Short wires used to connect to the head pod. Expensive Pads aren't as secure as other devices. Small stimulation area Difficult to integrate into clothing due to wires and separate electrodes.	Market segment catered to athletes and exercise rather than daily wear. Users may stop wearing the device due to the time and effort needed to apply the electrodes and pods Users may require a larger area of stimulation and may require a second unit. High price point affects purchases and marketability.

5. Detailed Design

5.1 Principle of Operation

inTENS is designed to be placed on the body of the user and secured through the detachable electrode pad. The device then uses bluetooth to allow the user to configure the stimulation and recording profiles. The main electrical system is based on a voltage controlled current source to achieve the stimulation output. When the user selects a stimulation profile on the mobile application, they essentially control the voltage output on the DAC of the ESP32. This DAC voltage is then used to generate a current output, which flows through the electrode pads. When the user switches the device operation mode to recording, an internal switch is toggled, which causes the electrodes to connect to the recording circuit rather than the stimulation circuitry. The electrodes then serve as the input signal, with the ESP32's ADC accepting the output signal from the recording circuit.

To operate the device, a mobile application will be used. A scanning feature will first be used to detect then connect to a nearby inTENS device wherein the mode of stimulation can be chosen between normal, acupuncture and hybrid mode. After selecting the mode, amplitude (mA) and frequency (Hz) can be changed. For acupuncture and hybrid mode, pulse width (μs) can also be varied. There is also a toggle button for the recording feature.

This principle of operation exemplifies the design concept requirements, by providing a discrete housing for the device that is easily concealable and lightweight. The ESP32 microprocessor is also utilised as the central control unit which gives the user control over the stimulation and recording systems. Lastly, the device is powered by a lithium polymer battery, which has a capacity of 1100mAh, and can be recharged via micro usb, enabling on the go stimulation.

5.2 Sub-system Design

5.2.1 Power System

The power system regulates power from the attached 1100mAh 3.7V lithium polymer battery and incorporates an effective recharging circuit that enables the safe use of a LiPO battery by preventing overcharging, whilst simultaneously notifying the user of the charge status. Figure 5.2.1 shows the power sub system and its components.

U1, the LP3947, is a USB/AC adaptor, single cell Li-Ion battery charger. It is a complete charge management system that is able to safely charge the battery from a 5V USB input, J1. If a voltage is detected at the input of the chip, and the undervoltage and overvoltage requirements of the chip are met [9], charging is initiated by passing a 70mA current through the battery, while the voltage across the battery terminals is continuously monitored. If the battery voltage exceeds 3V, then a fast charge cycle is implemented, in which a 500mA current is sent through the battery. This current can be controlled via the ISEL pin. The LED's indicate charge status. DS1 indicates that the battery is charged, as the chip is in maintenance mode (monitoring battery voltage once fully charged), and DS2 indicates that the battery is currently being charged.

The battery also directly connects to the 3.3V and +-15V regulator sub systems through a physical SPDT slide switch. This switch allows the user to turn off the device and enter charging mode when the device is idle, thus saving power. The 3.3V regulator system consists of U2, the TPS63031, which is a high efficiency 3.3V output buck-boost converter. It is an ideal solution when using a Li-Po battery, as it can output a current of up to 600mA, and discharge the battery from a peak of 4.2V down to 2.5V. For this circuit, the output voltage is fixed, and hence no passive components need to be used to configure this voltage. However inductor selection is affected by parameters such as inductor ripple, output voltage ripple as well as efficiency. An inductor with a low DCR was chosen in order to increase efficiency and minimise conduction loss. Additionally, an inductance of 1.5uH was chosen as recommended in the datasheet, in order to reduce ripple current and load transient response [10]. The feedback pin of this chip is used to sense the voltage at the output and regulate this voltage. Bypass capacitors are used at both the input and output stages in order to reduce ripple and smooth the voltages.

The 15V regulator circuit is similar to the 3.3V circuit, in that it is a switching regulator. The TPS55330 is an integrated 5A, 24V boost switching regulator that is configured to output 15V at 300mA, from a 2.5V to 4V input. The switching frequency of this regulator is 1.2MHz which allows for a lower valued inductor and capacitors to be used, resulting in a smaller footprint size, and an acceptable efficiency of 87%. Again, selection of the inductor is the most important consideration for this circuit, as the inductor value, DCR and saturation current all affect the steady state operation and loop stability of the system. The inductor value (4.7uH) was chosen so that the inductor can meet the worst case ripple current, which occurs at 50% duty cycle. The input and output capacitors were chosen for the same reasons as the 3.3V circuit. The output voltage and current formulas of this chip are provided in the data sheet [11], however the online WEBENCH Power designer application was used to customise the performance of this subsystem and automatically choose passive component values [12].

Finally, this 15V rail directly connects to U4, the LTC3261 inverting charge pump, that simply inverts the input voltage. The flying capacitor was chosen so as to output the full rated current of the IC (100mA). The input and output capacitors are low impedance ceramic capacitors that determine several important factors such as regulator control loop stability, output ripple, charge pump strength and minimum turn on time [13]. In order to reduce ripple, low equivalent series resistance capacitors were used (10uF) at the input and output. Additionally, the data sheet specifies that at least 2uF should be used over the operating temperature and bias voltage.

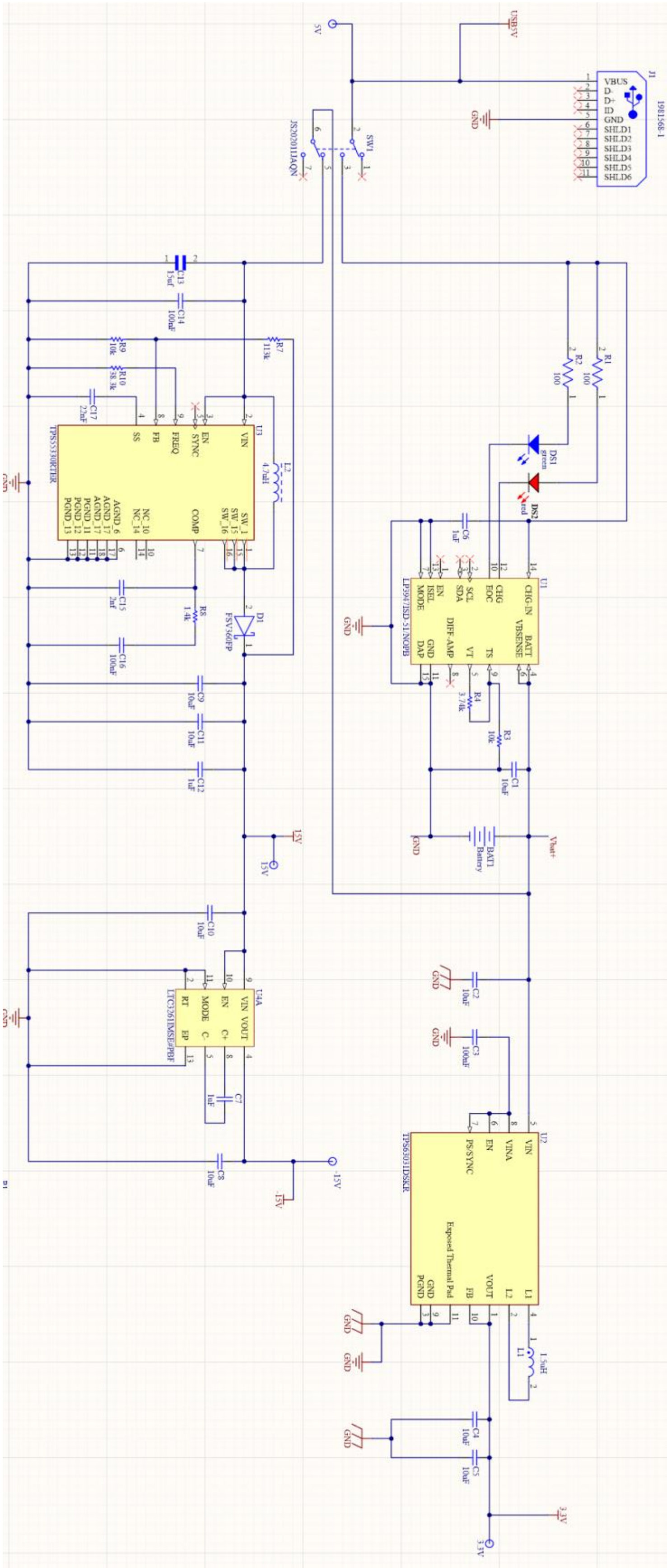

Figure 5.2.1. Power Sub System

5.2.2 Stimulation System

The stimulation system uses a voltage controlled current source in order to produce an arbitrary constant current waveform. There is a need for the output waveform to be charge balanced for safety measures, and thus an accurate current output is necessary. The topology used is the howland current pump. This system is powered using the +-15V rails generated in the previous section.

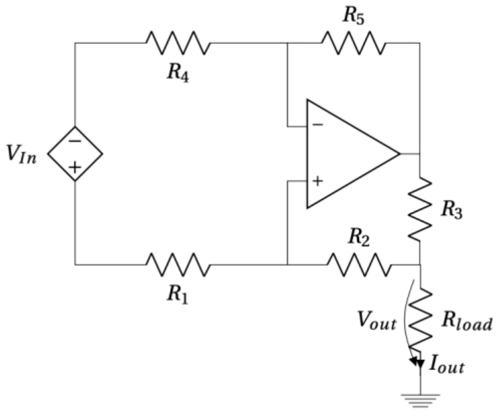

Figure 5.2.2. Howland Current pump

This system is sensitive to current changes at the inputs of the op amp, and hence a low input bias current op amp (OPA454) was used. This precision amplifier also has a high slew rate of 13V/us which allows it to produce high frequency, high voltage waveforms at a constant current as the load is increased. Additionally, due to the sensitivity at the op amps inputs, low tolerance resistors needed to be used in order to provide a high precision output, suitable for charge balancing. Additional topology requirements include having a high voltage compliance as well as driving a bipolar output with low noise. The howland current pump topology satisfies the above requirements whilst minimising component count, cost, and footprint size. By maintaining the resistor ratio

$$\frac{R_4}{R_5} = \frac{R_1}{R_2 + R_3} \qquad (5.2.1)$$

the output current can be determined by equation 5.2.2.

$$I_{out} = \frac{V_{in}}{R_3}\frac{R_4}{R_5} \qquad (5.2.2)$$

Thus by setting R4 = R5, the output current becomes:

$$I_{out} = \frac{V_{in}}{R_3} \qquad (5.2.3)$$

Thus to allow for enough voltage compliance, the resistors were selected as in Figure 5.2.3, allowing for a maximum current of 15mA at the output.

Since the ESP32 DAC provides the voltage Vin, no negative voltages and thus no bipolar output can be achieved. In order to overcome this, it is possible to offset the input signal by a constant value, whilst amplifying the DAC voltage to achieve a bipolar output that has a higher output swing. This is shown in Figure 5.2.3. U6 is the REF2030 which is a dual output voltage reference that is powered by the 3.3V power rail. This reference feeds into the inverting input of the OPA454, providing it with a 3V reference signal, rather than ground. Additionally, the DAC voltage labelled “DAC” is amplified by a non inverting amplifier U8, (a dual package that is shared with the recording circuit) with a gain of 2, before sending it to the Howland Current pump. These changes alter the output current as shown in equation 5.2.4.

$$I_{out} = \frac{2V_{in} - 3}{R_3} \qquad (5.2.4)$$

This now allows the output current to swing from -30mA to 30mA for the DAC’s 3.3V output range, with 1.51V as the equilibrium point corresponding to 0mA.

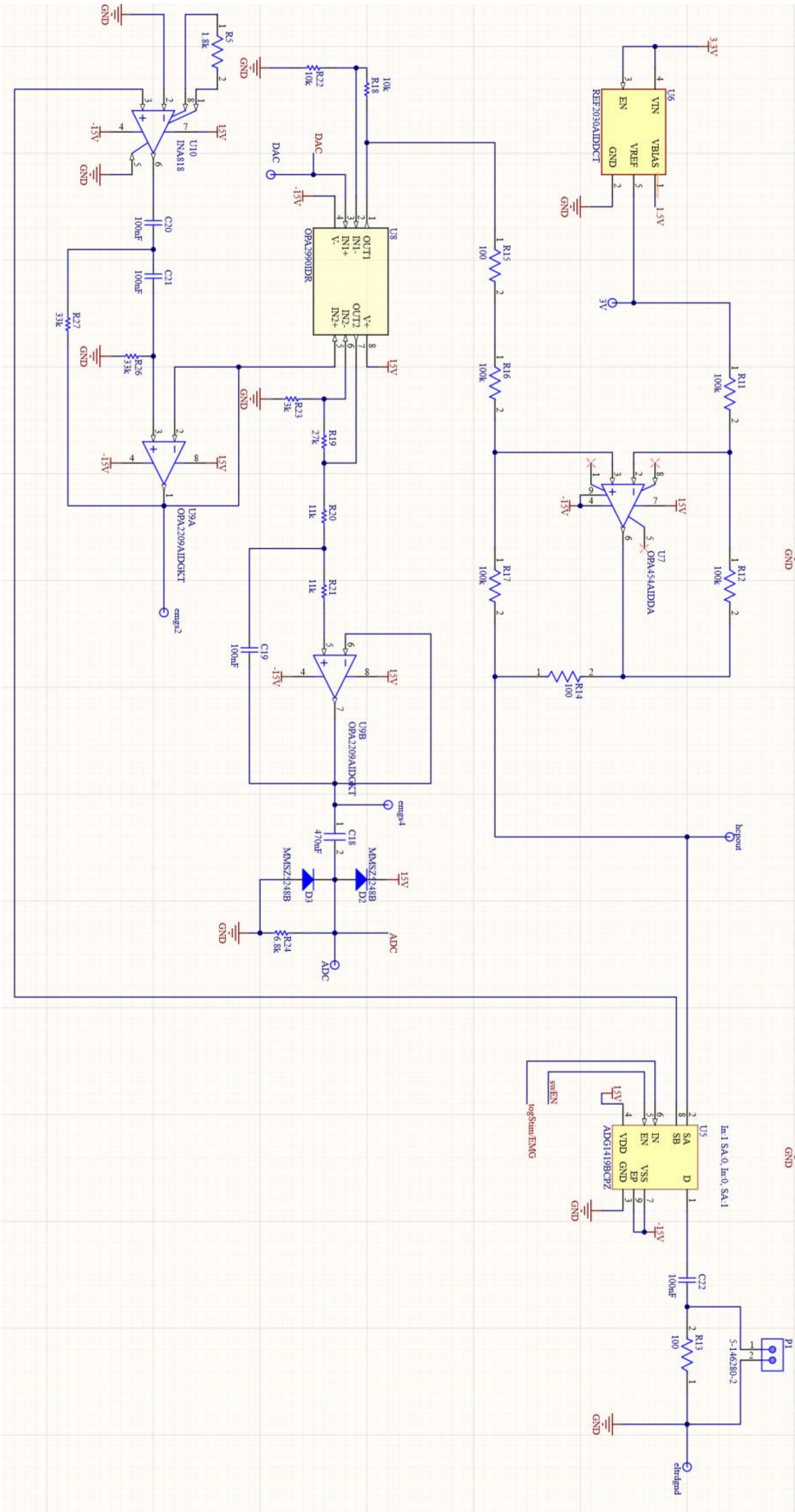

Figure 5.2.3 Simulator and Recording circuit

5.2.3 Recording System

In order to accurately acquire EMG data, filtering and amplification of the muscle response is required. The recording circuit is seen in Figure 5.2.3 and consists of two amplification stages and two filtering stages, this is needed to extract a signal in the 1-10mV, 50-150Hz range. The first amplification stage uses U10, an INA818 instrumentation amplifier with a gain of 28.7. An instrumentation amplifier is a good choice, as it has a high common mode rejection ratio, which helps reduce common mode signals with biopotentials such as EMG. Following this stage is a high pass filter which is a sallen key second order active filter, with a cutoff of 50Hz. A second order system has a higher rate of attenuation, and the OPA2209 used (U9) buffers the signal, eliminating any loading. Additionally, active filters also increase input impedance and decrease output impedance. Following this is the second amplification stage which consists of the OPA2990 acting as a standard non inverting amplifier with a gain of 10. The total amplification of the EMG signal is 287, sufficient for a recording range up to 50mV. The output thus ranges between 0-15V. The final stage is the low pass filter with a. cutoff of 150Hz, which is the same topology as the previous high pass filter. These cascaded filters create a bandpass filter with a passband of 50-150Hz. The coupling capacitor at the output removes any DC offset, and this signal is then sent to the ADC of the ESP32. Voltage clamping diodes were placed at the ADC input as a form of ESD protection. This redirects any large current away from the ADC pin and serves as a safety measure for any large signal artifacts. The ESP32's inputs and outputs can be seen in figure 5.2.4. The OPA2209 is a precision amplifier ideal for filtering due to its high slew rate and low THD. This reduces any group delay, or any phase shift that would normally occur when filtering high frequencies, thus producing a clean, non distorted output. The OPA2990 was chosen for its low offset voltage and bias current, which is necessary to produce a highly accurate output. Both op amps are capable of running +-15V rails, and have very low quiescent currents, that minimise power consumption.

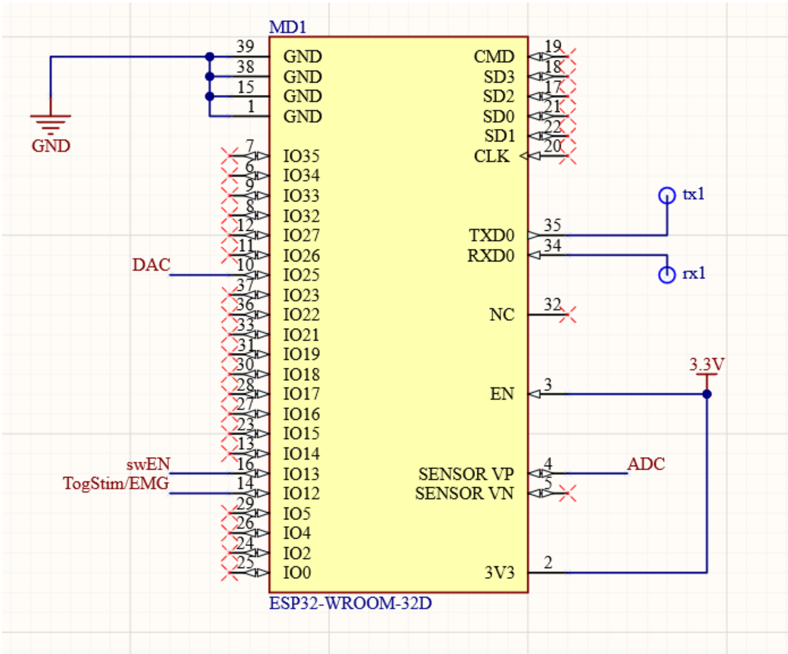

Figure 5.2.4. ESP32 schematic

5.2.4 Mechanical Design

The enclosure for this device was designed to have pads connected on the inside face and directly onto the body. It is also possible to connect short wires leading to pads that can reach parts that are further apart according to the diagram in appendix D. Having the smallest enclosure possible is important to allow for the ability to be worn under clothing or direct integration with clothing. It was also important for there to be openings for the switch and micro-USB port while retaining a certain degree of dust and water resistance.

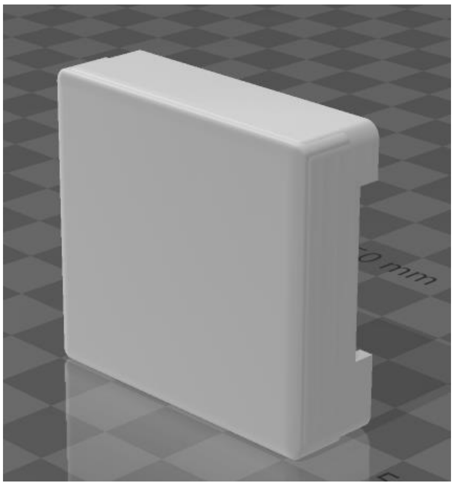

Figure 5.2.5: Outside view of top of enclosure

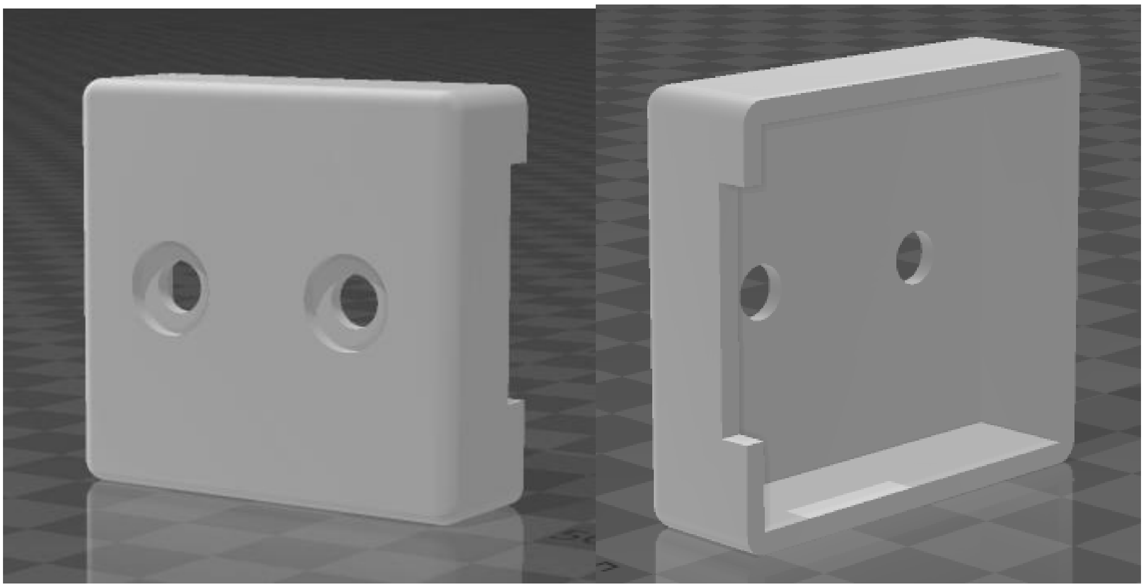

Figure 5.2.6: View of main part of enclosure with holes for output electrodes

The 2 halves of the enclosure as seen above connect together to encapsulate the PCB and battery. Female electrodes would be secured into the visible recesses where male electrodes can be connected for use.

5.2.4 Software Design

inTENS' microcontroller an ESP32 was programmed using Arduino and flashed using a USB-UART interface through the micro-USB port on the PCB. This code controlled the input and output of the device and allowed it to communicate with a mobile application. The mobile application was created using MIT app inventor, an online 'drag and drop' style app creator. The code changes the output of the DAC on the ESP32 which passes through the electrical circuit in the PCB to produce the desired output.

To output a square waveform, a simple equation was used to calculate the necessary amplitude, off/on time and interphase delay to generate a waveform with specified output amplitude, frequency and pulse width.

For the correct output voltage, the DAC output needed to be: V_DAC = ((Iout/10 + 3)/2)-1.5 Where Iout was the output current amplitude set by the user on the mobile application.

The output square waveform was done simply by specifying on/off times for the waveform corresponding to: frequency = 1/(time on + time off).

- Interval calculated on/off times for normal mode TENS: interval = million/(freq*2)
    - Million was used due to needing a value in microseconds
- Udelay calculated interphase delay corresponding to certain pulse width as specified by the user on the mobile application: udelay = (million / freq) - 2*pulseWidth
- Udelay2 calculated interphase delay for hybrid output:
  udelay2 = (million / freq) - 6*pulseWidth

The device passed all necessary information back to the mobile application through a callback function which was triggered every time a value was changed or button pressed passing back flags/values in an array which was then processed to separate the necessary flags and values. This code can be seen in Appendix E.

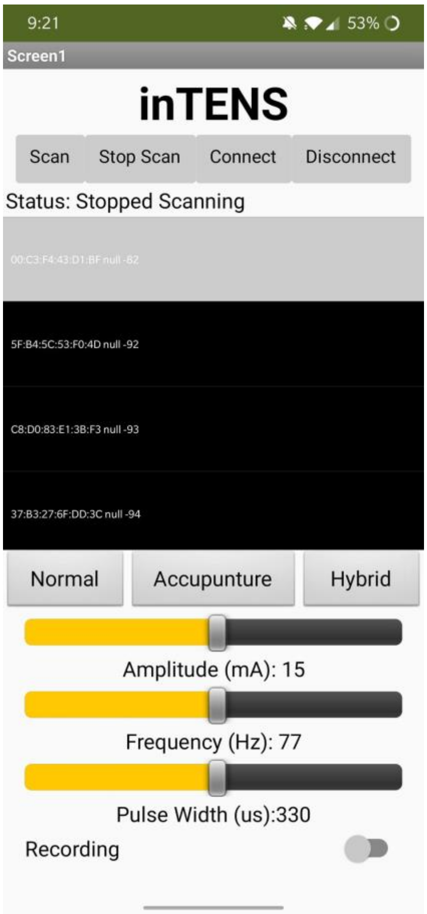

Fig 5.2.7: Screenshot of Mobile application for TENS device

5.3 Key design decisions and justification

5.3.1 Technical Factors

When designing a wearable electronic device, there are numerous design considerations and requirements that need to be met. Standards regarding medical device usage are among the most important requirements for the safe use of the device. Additionally, factors such as power and size contribute to the overall quality of the device, set by the design concept.

Power consumption and footprint

Device power is important as it influences the dependencies of all components on the final pcb. Input voltage is the key to choosing most components. In saying this, the battery was chosen to be the smallest suitable battery that had the highest capacity. The balance was struck by choosing a 1100mAh battery that fit the dimensions specified in the design concept. From this, components were chosen based on two main factors: quiescent current and footprint. All Op amps have very low quiescent current to minimise power draw, and were chosen for their small integrated package size (QFN, SOT23). Additionally, when choosing IC packages, dual packages were used where applicable. For instance, the OPA2209 and the OPA2990 are both dual package op amps. Lastly, passive components were chosen to be 0603 sizes or smaller, and minimum size PCB track widths and vias were used.

Standards and Stimulation output

<u>IEC 60529: Degrees of protection provided by enclosures (IP code)</u>

This standard, commonly referred to through an ‘IPXX’ rating (such as in mobile phones) describes the degree of protection provided by the enclosure of electrical equipment. Protection includes persons against access to hazardous parts inside the enclosure, protection of equipment inside the enclosure against ingress of solid foregin objects and the protection of the equipment inside the enclosure against harmful effects due to the ingress of water. The degree of protection and parts of equipment to which the protection applies are up to the manufacturer. This standard applies to the classification of devices where the rated voltage does not exceed 72.5kV.[X]

Our device is a wearable that aims to be concealed under clothing, and therefore it is necessary to be in close proximity to the user where they device may be exposed to solid foregin objects such as dirt and hair. The user can also sweat or may be exposed to weather conditions such as rain which would soak through clothing to the device. Therefore it is mainly in these 2 areas that the IEC 60529 standard apply, name in ingress protection against 'solid foregin objects' and 'against harmful effects due to the ingress of water'

ISO 60601: Medical electrical equipment

ISO 60601 contains requirements pertaining to the basic safety and essential performance that is applicable to medical electrical equipment such as nerve and muscle stimulators for use in the practice of physical medicine. This includes transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulators (EMS).[X]

Our product is a transcutaneous electrical nerve stimulator (TENS) machine and thus falls under the defined category of "medical electrical equipment" as outlined in ISO60601. From the title of the standard, it is necessary for our device to conform to the ISO60601 standard as it is classified underneath this standard which prescribes the basic design and operation safety a medical electrical device (TENS machine in our case) must exhibit in order to successfully be classified with this standard and thus be viable in international markets. This was achieved by ensuring sufficient output protection from the stimulator circuit. The first stage of consideration was in the +-15V power regulation stage, whereby the maximum output current was capped at 200mA. Secondly, short circuit protection was used in the stimulator circuit, where the OPA454 would be disabled if such a short is detected.

Furthermore, factors such as charge balancing, and arbitrary waveform generation were main considerations regarding the output of the device. Charge balancing is achieved by ensuring a biphasic output is supplied. This requires the topology of the stimulation to be able to output both positive and negative voltages. In saying this, an arbitrary waveform is most easily achieved through a topology that has a linear mapping of input voltage to output current. Ie. a voltage controlled current source. As a result of the above factors, the howland topology was used, and the last technical consideration for this design was to ensure the accuracy of the output, which was satisfied by choosing low tolerance passive components.

Recording outputs

As mentioned in section 5.2.3, distortion and saturation of the op amps were the main consideration for the recording circuit. These factors were accounted for by choosing components with high CMRR and low THD and high slew rates, along with low offset voltages and currents, in order to ensure a distortion free, precise signal output. Filter bandwidth and amplifier gain were obvious considerations that were also selected based on the desired output level from the input EMG. The output level was chosen in order to ensure saturation of the op amps does not occur if a stimulus artifact (≈50mV) is present at the input.

5.3.2 Component selection

Power circuit

- **3.7V 1100mAH LiPo battery**: This battery was chosen due to its small size (5cmx3cm) and rechargeable nature. Additionally, the capacity and discharge curve showed that it would last up to 8 hours under our application. This battery charging IC was made especially for LiPO batteries in the 3-4V range. It has desirable features such as undervoltage and overvoltage protection, power-path automatic charging, as well as pins to display the status of the battery. The use of this chip eliminates the need for any complex circuitry to recharge the battery, and thus minimises footprint as well as cost. It also retailed for a low price ($12)

- **TPS63031**: This chip is used to regulate the battery voltage to a fixed 3.3V output. This is necessary as a 3.3V output is needed to power the microcontroller. This chip was chosen as it is specifically designed for applications such as this, and therefore has a low power consumption and uses few components in order to build the regulator. As a result, footprint size and cost are minimised.

- **TPS55330**: This chip is used to boost the regulated 3.3V output to 15V. The. Maximum current output of this circuit is 200mA, which is an ample amount for our application. This chip was chosen due to the above specifications as well as due to its high efficiency and low quiescent current, which minimises its overall power draw. The footprint size was also a factor in this selection. Overall, the boost circuit occupies less than 120mm^2. As a result it costs less than $3AUD to build the whole circuit.

- **LTC3261**: This chip is used to invert the voltage from 15V to -15V. It was chosen due to its high efficiency as well as its small footprint size. Additionally, it is one of the few chips under $10 that can handle voltage inversion of > 12V.

- **LP3947ISD**: This chip is used to charge the LiPo battery. Its intended use is for mobile phones, however this made it the perfect choice for the inTENS stimulator. Due to its small footprint, specified usage for 3.7V LiPO batteries, and LED indicator features (green when full, red when charging), it not only provides a safe method for recharging the battery, but also a cost effective ($4AUD) and miniaturised implementation.

Microcontroller:

- **ESP32WROOM32E**: This module was chosen due to its small form factor, which saves both space on the PCB as well as power. The ESP32 has built in Bluetooth antennae and DAC, which means that no external circuitry is required. It also has 5 configurable power saving modes which align with the usage of our device. Lastly it is inexpensive at $4.32AUD.

Stimulator circuit:

- **OPA454**: This operational amplifier is ideal for a Howland current pump, due to its high slew rate, low input bias current as well as its low quiescent current. This allows for the output of fast waveforms (particularly square waves), with high accuracy. This results in the use of fewer components to preserve accuracy resulting in a smaller footprint and lower cost, despite the op amp being priced at $11 AUD. Lastly the low q current ensures that power draw is kept to a minimum.

- **REF2030**: This 3V voltage reference is necessary for the howland current pump to work. It produces a fixed 3V reference with extremely low output current, resulting in high accuracy and low power draw. Additionally no external circuitry is required, thus minimising footprint size. It is also very cheap at $4AUD.

- **OPA2990**: This op amp is used as a standard non inverting amplifier in order to provide a reference voltage from the DAC to the howland current pump. It has a low offset voltage which is beneficial for its application. Additionally, since it is a dual package op amp, the other package can be used in the recording circuit to reduce footprint size. ($6AUD)

Recording circuit:

- **INA818**: This instrumentation amplifier is used due to its high CMRR. This makes it better at amplifying biological signals such as EMG. However it is relatively expensive at $10AUD.
- **OPA2209**: These are used to filter the EMG signals through second order low pass and high pass filters. These have a low quiescent current as well as low THD which allow for zero phase distortion when analysing EMG signals. The dual package implementation also allows both filters to fit in one package at a low cost of $5AUD.

Switch package:

- **ADG1419**: This DPST switch package was used in order to select between the stimulator circuit and the EMG circuit. It uses a single input which can be controlled via GPIO from the esp32 and can accept current inputs of up to 30mA which is beyond the specification of the stimulator. Due to this it is suitable for use at a low cost and footprint size. ($6AUD)

Enclosure:

- Enclosure is a 3x3cm plastic, water and dust resistant container that is use to house the PCB and battery to complete the device.

5.3.3 PCB Design

Several considerations were made when constructing the PCB. Separation of analog and digital parts of the circuit was necessary in order to reduce noise and preserve the accuracy of the stimulation and recording circuits. Moreover, A 4 layer board was used in order to reduce the amount of tracks needed due to the 3 power rails used. Track widths were set to 10mil for the power rails and 5 mil for signal routing. These are the minimum track widths required for proper signal integrity and current flow along the power rails. Lastly, multiple test points were used in order to easily test the board post production.

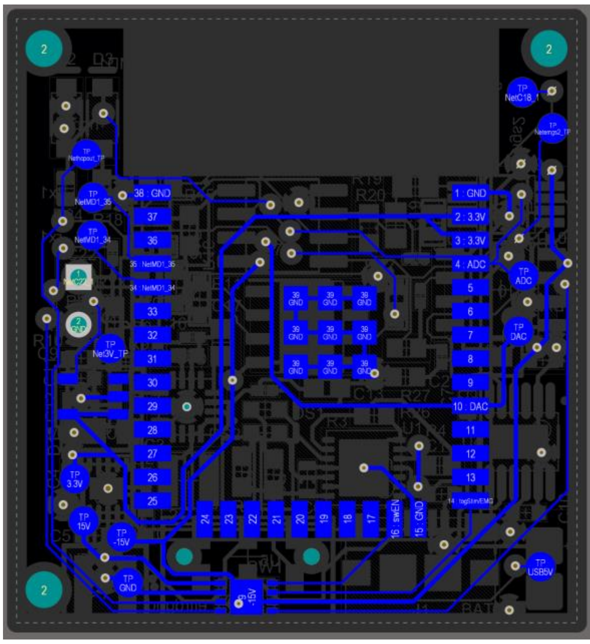

Figure 5.3.1. PCB routing (bottom layer)

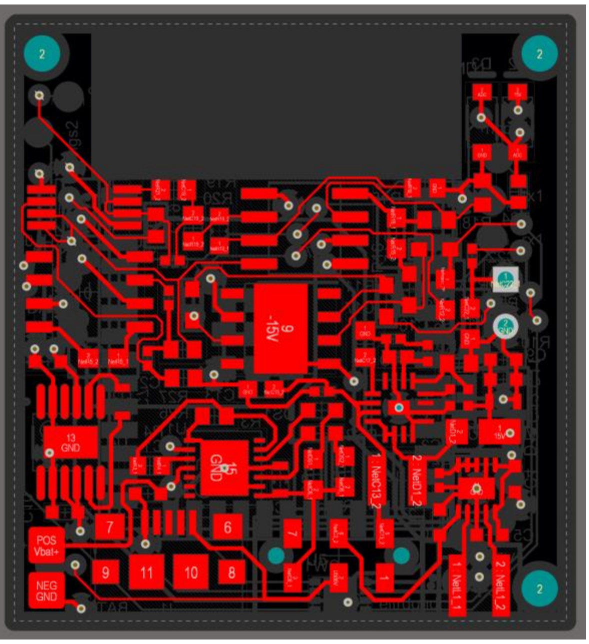

Figure 5.3.2. PCB routing (Top layer)

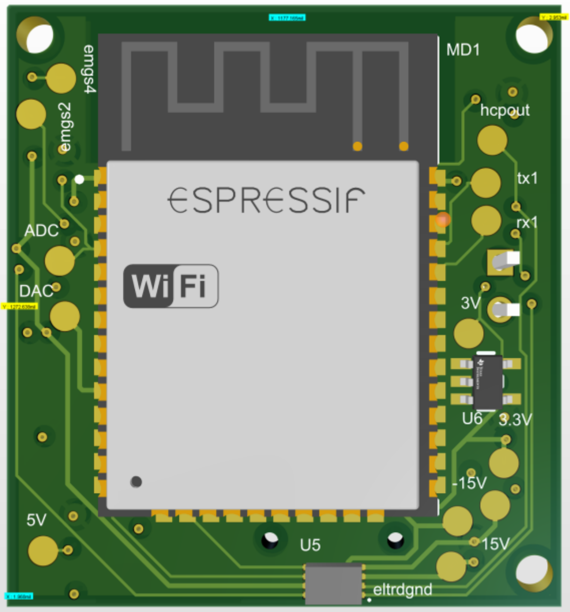

Figure 5.3.3. 3D PCB (bottom layer)

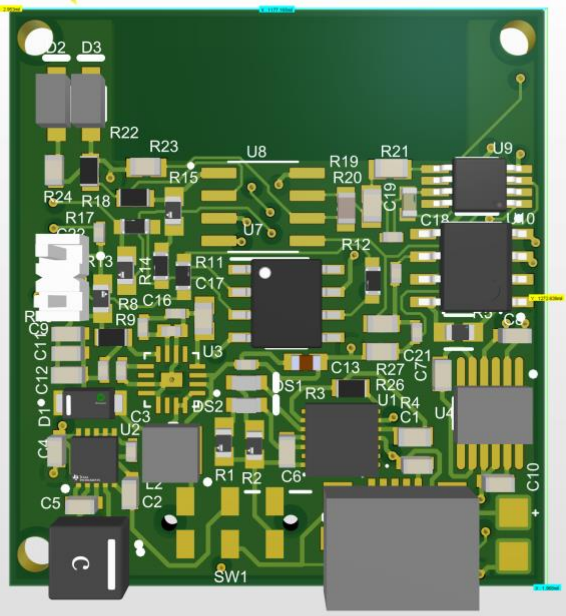

Figure 5.3.4. 3D PCB (top layer)

5.4 Specifications

The key specifications for inTENS are as follows:

Power: Either LiPO or LiION with a discharge range of 4V to 2.5V should be used for safety measures. 3.3V regulated output to the ESP32 microcontroller, +-15V, 200mA output to the remaining circuitry.

Stimulation Output: Biphasic, charge balanced arbitrary output in the range of -30mA to 30mA, with a voltage limit of -15V to 15V. The stimulation output is controlled by the mobile application. Frequency of stimulation ranges from 1 to 100Hz, with a customisable inter phase delay, inter stim delay, and pulse width (Figure 5.4.1).

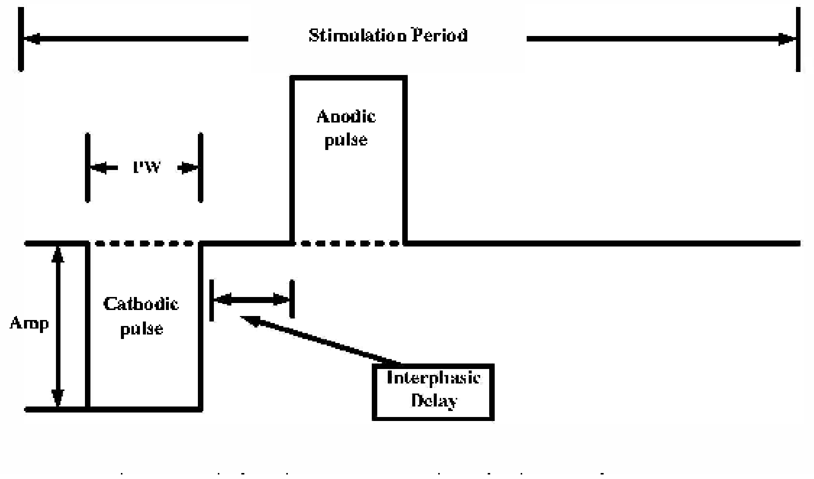

Figure 5.4.1 Charge balanced biphasic square wave

Additionally, preset modes are available to the user through the mobile application
Mode1: Normal Mode: Outputs charge balanced biphasic square wave
Mode2: Acupuncture Mode: Outputs short pulse of high amplitude
Mode3: Hybrid Mode: Outputs a short pulse train of moderate amplitude

Recording range: 50-150Hz signal ranging from 0 to 50mV, accounting for muscle artifacts.

Size and usage: The device is 37x41mm and 57g and uses the electrode pads to securely adhere to the user's skin. Placement on the back, along the centre of the spine (with a larger commercially available electrode pad) is a typical usage case in which users require a TENS machine to be concealed under clothes, yet light enough to use on the go. An example of typical usage is seen in Figure 5.4.2 below.

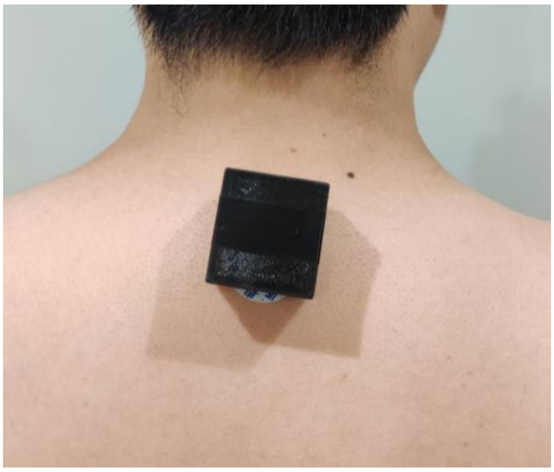

Figure 5.4.2 Typical usage case

5.5 Bill of Materials

The final bill of materials can be seen in table 5.5

Table 5.5 Bill of materials

#	QUANTITY	PART NUMBER	MANUFACTURER PART NUMBER	DESCRIPTION	BACKORDER	UNIT PRICE	EXTENDED PRICE
1	3	445-9117-1-ND	C1608X5R1A156M080AC	CAP CER 15UF 10V X5R 0603	0	0.74	2.22
2	3	P3.74KDBCT-ND	ERA-3AEB3741V	RES SMD 3.74KOHM 0.1% 1/10W 0603	0	0.45	1.35
3	2	FSV360FPCT-ND	FSV360FP	DIODE SCHOTTKY 60V 3A SOD123HE	0	0.62	1.24
4	1	CKN10722CT-ND	JS202011JAQN	SWITCH SLIDE DPDT 300MA 6V	0	0.84	0.84
5	3	541-38.3KLCT-ND	CRCW040238K3FKED	RES SMD 38.3K OHM 1% 1/16W 0402	0	0.14	0.42
6	3	399-9950-1-ND	C0402C202J3GAC7867	CAP CER 2000PF 25V C0G/NP0 0402	0	0.68	2.04
7	5	587-1438-1-ND	GMK212B7105KG-T	CAP CER 1UF 35V X7R 0805	0	0.3	1.50
8	1	LP3947ISD-51/NOPBCT-ND	LP3947ISD-51/NOPB	IC BATT CHARGE MGR LI-ION 14WSON	0	4.13	4.13
9	3	541-113KLCT-ND	CRCW0402113KFKED	RES SMD 113K OHM 1% 1/16W 0402	0	0.14	0.42
10	1	296-39425-1-ND	TPS55330RTER	IC REG MULTI CONFG ADJ 16WQFN	0	4.38	4.38
11	3	445-7468-1-ND	C1608X5R1H105K080AB	CAP CER 1UF 50V X5R 0603	0	0.29	0.87
12	10	541-10.0KHCT-ND	CRCW060310K0FKEA	RES SMD 10K OHM 1% 1/10W 0603	0	0.045	0.45
13	3	399-3476-1-ND	C0603C223K1RACTU	CAP CER 0.022UF 100V X7R 0603	0	0.14	0.42
14	2	445-7004-1-ND	CGA6P3X7S1H106K250AB	CAP CER 10UF 50V X7S 1210	0	1.43	2.86
15	1	296-39461-1-ND	TPS63031DSKR	IC REG BCK BST 3.3V 900MA 10SON	0	2.7	2.70
16	10	445-9015-1-ND	C1608X5R1E106M080AC	CAP CER 10UF 25V X5R 0603	0	0.779	7.79
17	1	LTC3261EMSE#PBF-ND	LTC3261EMSE#PBF	IC REG CHARG PUMP INV 12MSOP	0	10.35	10.35
18	3	541-1.40KLCT-ND	CRCW04021K40FKED	RES SMD 1.4K OHM 1% 1/16W 0402	0	0.14	0.42
19	3	490-11917-1-ND	GRM155R61H104KE19D	CAP CER 0.1UF 50V X5R 0402	0	0.16	0.48
20	1	541-1007-1-ND	IHLP2525CZER1R5M01	FIXED IND 1.5UH 9A 15 MOHM SMD	0	2.86	2.86
21	1	SRN3015-4R7MCT-ND	SRN3015-4R7M	FIXED IND 4.7UH 1.4A 136MOHM SMD	0	0.64	0.64
22	1	296-OPA2990IDSGRCT-ND	OPA2990IDSGR	IC OPAMP GP 2 CIRCUIT 8WSON	0	2.62	2.62
23	1	296-39109-1-ND	OPA2209AIDGKR	IC OPAMP GP 2 CIRCUIT 8VSSOP	0	5.57	5.57
24	10	541-33.0KHCT-ND	CRCW060333K0FKEA	RES SMD 33K OHM 1% 1/10W 0603	0	0.045	0.45
25	3	399-4922-1-ND	C0603C474K4RACTU	CAP CER 0.47UF 16V X7R 0603	0	0.26	0.78
26	10	541-6.80KHCT-ND	CRCW06036K80FKEA	RES SMD 6.8K OHM 1% 1/10W 0603	0	0.045	0.45
27	10	478-11877-1-ND	08053C104JAZ2A	CAP CER 0.1UF 25V X7R 0805	0	0.367	3.67
28	2	P11KDBCT-ND	ERA-3AEB113V	RES SMD 11K OHM 0.1% 1/10W 0603	0	0.45	0.90
29	10	541-3.00KHCT-ND	CRCW06033K00FKEA	RES SMD 3K OHM 1% 1/10W 0603	0	0.045	0.45
30	1	1965-ESP32-WROOM-32E(16MB)CT-ND	ESP32-WROOM-32E (16MB)	RX TXRX MOD WIFI TRACE ANT SMD	0	4.32	4.32
31	3	P122788CT-ND	ERJ-1GNF1801C	RES SMD 1.8K OHM 1% 1/20W 0201	0	0.14	0.42
32	1	ADG1419BCPZ-REEL7CT-ND	ADG1419BCPZ-REEL7	IC SWITCH SPDT 4.6OHM 8LFCSP	0	6.01	6.01
33	6	YAG1235CT-ND	RT0603BRD07100KL	RES SMD 100K OHM 0.1% 1/10W 0603	0	0.48	2.88
34	1	296-47351-1-ND	REF2030AIDDCR	IC VREF SERIES 0.05% SOT23-5	0	4.71	4.71
35	10	541-27.0KHCT-ND	CRCW060327K0FKEA	RES SMD 27K OHM 1% 1/10W 0603	0	0.045	0.45
36	5	749-1691-1-ND	MCT06030D1000DP500	RES SMD 100 OHM 0.5% 1/8W 0603	0	0.48	2.40
37	1	3.7V lipo battery					18.35
38	1	UART to USB board					7
				TOTAL	109.81		

5.6 Experimental results or performance analysis

Power circuit: The +-15V rail performs quite well with minimal ripple under load conditions. (Figure 5.6.1)

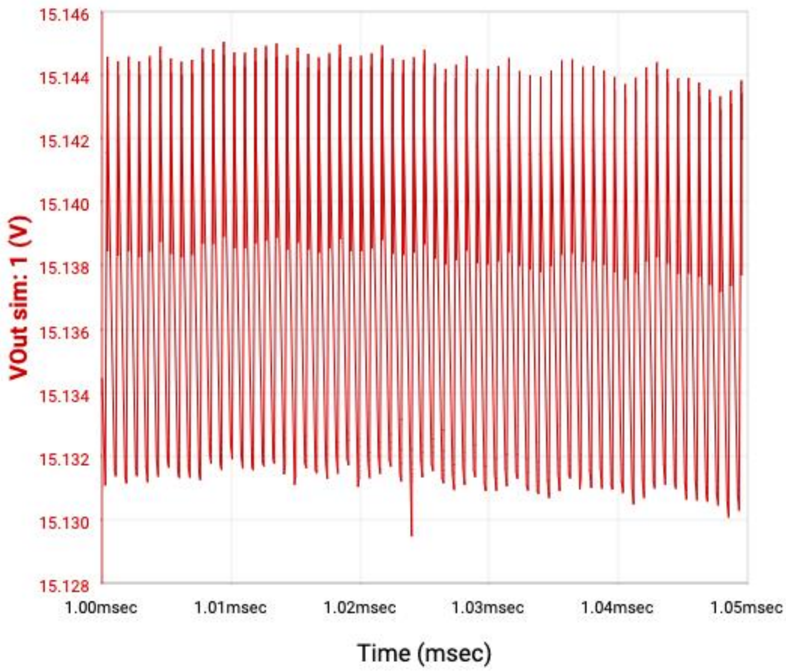

Figure 5.6.1. 15V rail ripple

Stimulator circuit: The following outputs are provided for the stimulator circuit. As shown in figures xx, the output is quite accurate, and the biphasic waveforms appear to be charge balanced, and safe for stimulation. Moreover the interface with the application performs nominally, with the output following the UI slider input. Any discrepancies in output are due to the DAC resolution as well as the lack of accuracy from the input UI. These are features to improve upon in further iterations.

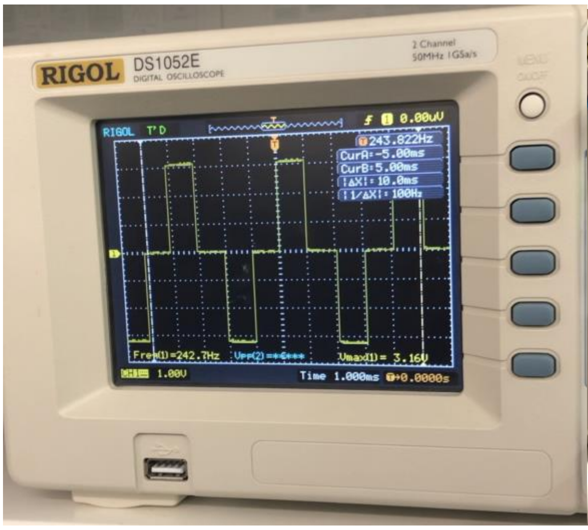

Figure 5.6.2 30mA output across a 120Ω load Figure 5.6.3 30mA output at 43Hz

Figure 5.6.3 30mA output at 86Hz Figure 5.6.3 17mA output at 86Hz

Overall, the electronics work soundly, as expected with minimal noise and distortion to the output signal. However further research can be conducted in order to produce a higher quality output that is more accurate.

6. Development Plan

6.1 Key Future Tasks

There are a number of key improvements that need to be made to transition inTENS from a prototype to a final product. These include:

Table 6.3.1: Future development breakdown

Key Task	Description	Time (hours)
Redesign enclosure for IP rating	While the enclosure was 3D printed and therefore made out of plastic, it wasn't designed with full water and dust resistance in mind. A cutout for a rubber o-ring needs to be added along with room for a rubber covering/protection around the opening for the switch and	12
Construct final enclosure	After redesigning the enclosure to meet an IP55 rating, it needs to be 3D printed and fit with O-rings and other rubber pieces to ensure it's waterproofing	10
Design a more robust battery management system	Currently the device is utilising the rudimentary inbuilt BMS system connected to the battery. However, this does not provide the necessary level of detail and protection that would come with designing our own BMS to ensure there is not excessive heat from current draw as well as to measure battery level. This battery level could then be displayed to the user fulfilling a requirement.	15
Software improvements	Current software does not reliably output a waveform for the acupuncture and hybrid modes. The code for those 2 waveforms needs to be rewritten to have a negative output. The code also needs the frequency and pulse width to limit each other. i.e. With a certain pulse width, frequency cannot be increased to a certain amount.	10
Reroute PCB	Problems in the prototype PCB led to a short when assembling and testing the prototype. Rerouting a specific part of the PCB would rectify this error	4
Order and Test final PCB	One the design error has been rectified, it is necessary to order another PCB to test that there are no lingering issues	8 + delivery

6.2 Task timeline

The tasks outlined above have been planned out over a 3 month period on the GANTT chart below. This is to accomodate for the summer holidays and festivities.They have been divided into design, manufacturing / procurement and testing stages.

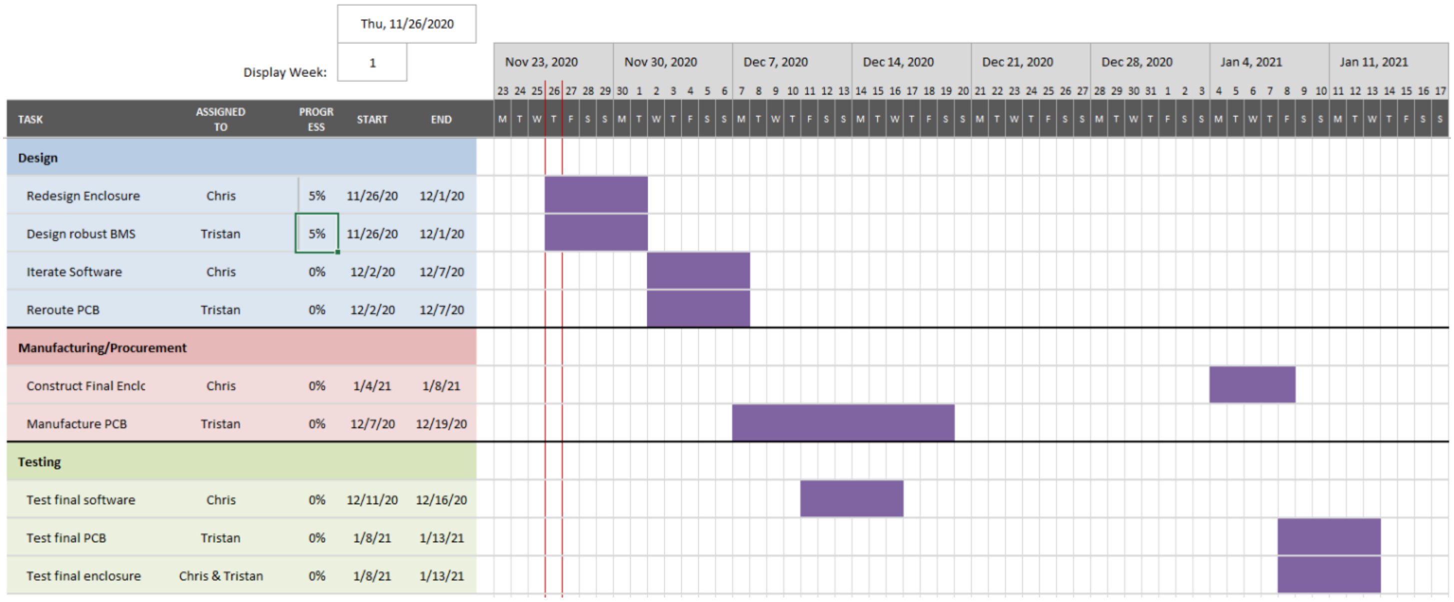

Figure 6.2.1: GANTT chart for future key tasks

6.3 Additional justifiable resources

As outlined in the previous section, the main resource that is needed is time in order to complete the required tasks. Money is also needed to ensure the completion of the tasks as outlined in the GANTT chart.

One main point of purchase that needs money is in the purchases of the necessary lab equipment and resources to complete the extensive tests that need to be done before commercialisation. This includes a small device environment tester which simulates different use temperatures and water conditions to mimic the real world. Other basics such as oscilloscopes, probes and power supplies will also be needed.

One possible alternative is to hire this equipment. In the long run, while this may be suitable for big machinery such as the environmental tester which can cost more than tens of thousands of dollars, it will be best to buy equipment such as the oscilloscopes and power supplies due to the heavy use required in the testing phase.

6.3 Development Risks

Many of the risks encountered here are similar to that as outlined in the original development proposal since many of the problems are the same in this stage of development. While the rate of COVID-19 has reduced, without a vaccine it is still important to plan for COVID risks in the event of another outbreak.

With the current state of the world and the prevalence of the COVID-19 epidemic, it is necessary to prepare a plan to mitigate the risks associated with it. This prepares the project managers to complete their tasks in the face of unforeseen circumstances.

For the successful completion of a project, it is necessary to identify and prepare for any risks that may occur in order to mitigate their impact. These risks can be split into technical and project management risks and are rated based on their likelihood and impact. These two metrics feed into a severity rating which project managers a measure of urgency.

Table 6.3.2: Covid risk management plan

COVID Risk	Mitigation Strategy
COVID resurgence causes university labs to close.	Have a plan to utilise alternative equipment (One of the team members has the necessary lab equipment at home). This would apply independent of the time period this occurs
Laboratory access is restricted due to COVID	Prepare a plan that prioritises the team member that needs the lab more. As mentioned in the previous strategy, one of the team members has the necessary lab equipment in his place of residence and thus this equipment could be used as an alternative.
Reemergence of COVID causes shipping times to blow-out.	Compile a list of domestic suppliers for any components or manufacturing as alternatives.
	This close to the deadline, the list of domestic suppliers would be utilised with a focus on speed of delivery and availability. (So suppliers such as digikey who have next day shipping within Australia).

Reimplementation of lockdown.	Have a plan established to maintain communication and collaboration with partner in the event of a lockdown. This would include assigning partner with lab equipment the manufacturing tasks and the other partner the software development.
	At this point, the project is nearing completion so just ensuring each member of the team has the necessary equipment to complete the product.
Team member contracts COVID	Have a strategy for implementing critical features only by the other member and apply for special consideration.
	Follow previously established strategies and apply for special consideration.

6.4.1 Technical

Table 6.4.3: Technical risks

Risk	**Likelihood**	**Impact**	**Severity**	**Mitigation Strategy**
Battery capacity insufficient to meet lifetime requirements	Low	Medium	Medium	Model power consumption from both base and peak current draws of different systems before making a decision on the battery. There is also an extensive range of LiPo so it is trivial to find an alternative battery with same specifications with a slightly higher capacity.
Unable to integrate desired subsystem	Low	High	Medium	Design of subsystems planned well in advance so their interaction can be verified.
Inability to design enclosure	High	High	High	Consult with mechanical engineer or other people experienced in this area
Enclosure does not meet Ingress Protection (IP) standards	Medium	Medium	Medium	Alternative methods of protection and types of enclosures identified.

Device outputs dangerous amount of current	Low	High	Medium	Circuit designed with maximum current outputs. There is also ESD protection which would divert an abnormal current spike to ground
Poor soldering resulting in damaged component or circuit malfunction	Low	High	Medium	Ensure team member soldering is well experienced with soldering. Explore the possibility of using a stencil and reflow oven. Have the PCB manufacturer solder the components as they can provide quality assurance. Order extra components.
Microcontroller issues (e.g. Not enough pins)	Low	High	Medium	Microcontroller with excess pins chosen in design to accommodate for additional features or overlooked sensors and components. Range of backup microcontrollers compiled.
Faulty Components	Low	Low	Low	Acquire components early in the design process and procure extra components
Inability to implement software features due to lack of experience	Medium	High	High	Begin working on software features early on in the design process to get familiarised with the development environment and constraints.Consult peers with extensive experience in programming microcontrollers and designing phone applications

6.4.2 Project Management

Table 6.4.4: Project management risks

Risk	Likelihood	Impact	Severity	Mitigation Strategy
Delays in delivery of components	Low	High	Medium	Add a buffer to expected delivery times and compile a list of alternative suppliers for components and manufacturers.
Conflict between team members	Low	Medium	Low	Establish a set of guidelines and methods of conflict resolution at the

				beginning of the project to refer to if there is any teamwork issues
Tasks not being completed within allocated time	Medium	High	Medium	Maintain regular communication with team members to ensure tasks are being complete. Buffer assigned to tasks above expected time for completion.
Too many features planned to be implemented	Medium	High	High	Have a strategy to implement critical features for operation in the beginning before adding additional features.

7. Business Plan

7.1 Estimate of Manufacturing Costs

The full BOM can be seen in section *5.5 Bill of materials* above which estimate each device to cost $102.81. (Exclude the USB-UART interface since over every single unit produced (1000+), the costs averages to 0).

Octopart which is an electrical component price aggregator was used which collects prices from multiple component suppliers such as Digikey, Mouser and RS components. Using Octopart, it was possible to estimate the cost of different components with a purchase of 1000+ units over a range of suppliers to prevent the case where a supplier may not have a specific component [14]. This places the component cost at **$33.19 AUD.**

Table 5.1.1: Summarised BOM

Subsystem	**Component**	**Price ($AUD)**	**Quantity**	**Total ($AUD)**
Power	3.7V 1100mAH LiPo Battery	12	1	4.73
Power	3.3V Linear Regulator TPS63031	2.70	1	2.70
Power	15V Linear Regulator TPS55330	4.38	1	4.38
Power	Inverter LTC3261	10.35	1	10.35
Power	Charge Management LP3947ISD	4.13	1	4.13
Microcontroller	ESP32WROOm32E	4.32	1	4.32
Stimulator	Op-Amp OPA454	9.27	1	9.27
Stimulator	Voltage Reference	4.71	1	4.71

	REF2030			
Stimulator	Non-inverting Op-Amp OPA2990	2.62	1	2.62
Recording	Instrumentation amplifier INA818	8.3	1	8.3
Recording	Op-Amp OPA2209	5.57	1	5.57
Switch Package	SPDT Switch ADG1419	6.01	1	6.01
Passive Components	Capacitors, Resistors, Inductors etc.			42.72
SUBTOTAL	109.81			

Manufacturing Costs:

PCB costs:
Cost for PCB manufacturing was approximately $5 AUD per unit. Extrapolating this for 1000+ units, PCB manufacturing would total $1.

With this, assembly and quality assurance would take place in China as the PCB is manufactured at approximately $0.007c per pad (From manufacturers such as JLCPCB & PCBWay) and for 80 pads, this would total $0.85 per unit.

Enclosure Costs:

Based on a similar sized enclosure, an ABS injection molded enclosure would costs 75c.

Shipping Costs:

With an estimated weight of 60g, shipping costs total $1.50 per unit including PCB and component costs.

Regulatory Costs:

Cost to obtain an IP (Ingress Protection) rating is set at $3 per unit based on known costs of existing mobile devices. Costs associated with ensuring the product meets specific medical device standards will be added to the engineering costs at a one time amount of $2,000.

Engineering and Developmental Costs:

From the 2 engineers it took to design this product, and the roughly 10 weeks duration of the project, using an industry average salary of $76,421 [15], it is possible to estimate $29,392 in developmental costs. Another 10 weeks is added for the further development of the product for a total $58,784. An initial $20,000 is also considered for the purchase and hire of necessary lab equipment. Adding the $2000 of medical regulatory costs and spread across an initial batch of 2000 units, this equates to $40.39 per unit.

Overall Costs:

Summing all of the above costs, manufacturing per unit totals **$77.68 AUD**. Adding an overhead of 20% to account for other indirect costs, this totals $93.22 AUD. Economies of scale suggest that as the manufacturing is increased, the total manufacturing costs would decrease.

7.2 Estimate of Profitability

From our market analysis which involved the comparison of competitors, the optimum price is set to be $150 AUD which is below our closest competitor. The cost of production was found to be $93.22 AUD or $52.83 per unit excluding developmental costs which brings a per unit profit of $97.17 AUD and a gross profit margin of 54.37%. In the future, it is estimated that as the product becomes streamlined and due to economies of scale, profit would increase further by up to 10%.

7.3 Net Present Value Calculations

Net Present Value (NPV) is calculated taking into account the assumptions below:

- Discount Rate: Due to the relatively risky nature of this product with a rather niche market and well established industry, a discount rate of 9% p.a was chosen. The risk however is mitigated by the competitive nature of the product in comparison to existing products and is hence why the discount rate is not too high. Using the effective rate for a period formula $DR = (1 + r)^{1/n} - 1$ where n is the number of compounding periods, the quarterly discount rate is equals 2.18%

- Marketing Costs: In order to penetrate a well established market, marketing costs of $10000 per quarter for the first year have been established starting in Q1.
- Manufacturing cost: As stated above, manufacturing cost excluding developmental costs is $52.83 per unit.
- Life cycle: There is an expected 2 quarter developmental life cycle and overall 5 year product life cycle.
- As outlined previously, developmental costs are set to be $29,392 per quarter for the first 2 quarters with an additional $20 000 for capital equipment (such as testing equipment) in the first quarter.
- Sales Volume: Projected to be 50 units per quarter in year 1, peaking at 300 units in year 3 before trending downwards towards 50 units again.

The formula $PV = FV/(1+r)^n$ is used to calculate NPV where PV - present value, FV - future value, r - discount rate, n - number of discounted periods [16].

Table 5.3.1: Year 1 NPV calculations

Quarter	**Q1**	**Q2**	**Q3**	**Q4**
Developmental costs ($)	49,392	29,392	0	0
Marketing ($)	10,000	10,000	10,000	10,000
Sales (Units)	0	0	50	50
Sales Revenue ($)	0	0	7,500	7,500
Manufacturing costs ($)	0	0	2,641.5	2,641.5
Profit ($)	-59,392	-39,392	4,858.50	4,858.50
Present Value ($)	-59,392	-36,139.45	4,089.30	3,751.65
Net Present Value ($)	-59,392	-95,531.45	-91,442.15	-87,690.49

Table 5.3.2: Year 2 NPV calculations

Quarter	**Q1**	**Q2**	**Q3**	**Q4**
Developmental costs ($)	0	0	0	0

Marketing ($)	0	0	0	0
Sales	100	100	200	200
Sales Revenue ($)	15,000	15,000	30,000	30,000
Manufacturing costs ($)	5,283	5,283	10,566	10,566
Profit ($)	9717	9717	19,434	19,434
Present Value ($)	6883.78	6315.38	11,587,86	10,631.06
Net Present Value ($)	-80,806.71	-74,491.33	-62,903.47	-52,272.41

Table 5.3.3: Year 3 NPV calculations

Quarter	**Q1**	**Q2**	**Q3**	**Q4**
Developmental costs ($)	0	0	0	0
Marketing ($)	0	0	0	0
Sales	250	300	300	300
Sales Revenue ($)	37,500	45,000	45,000	45,000
Manufacturing costs ($)	13,207.50	15,849	15,849	15,849
Profit ($)	24,292.50	29,151	29,151	29,151
Present Value ($)	12,191.59	13,421.93	12,313.70	11,296.97
Net Present Value ($)	-40,080.82	-26,658.89	-14345.19	-3,048.22

Table 5.3.4: Year 4 NPV calculations

Quarter	**Q1**	**Q2**	**Q3**	**Q4**
Developmental costs ($)	0	0	0	0
Marketing ($)	0	0	0	0
Sales	250	250	200	200
Sales Revenue ($)	37,500	37,500	30,000	30,000
Manufacturing costs ($)	13,207.50	13,207.50	10,566	10,566
Profit ($)	24,292.50	24,292.50	19,434	19,434
Present Value ($)	8,636.83	7,923.69	5,815.56	5,335.37
Net Present Value ($)	5,588.61	13,512.30	19,327.86	24,663.23

Table 5.3.5: Year 5 NPV calculations

Quarter	**Q1**	**Q2**	**Q3**	**Q4**
Developmental costs ($)	0	0	0	0
Marketing ($)	0	0	0	0
Sales	100	100	50	50
Sales Revenue ($)	15,000	15,000	7,500	7,500
Manufacturing costs ($)	5,283	5,283	2,641.5	2,641.5
Profit ($)	9717	9717	4,858.50	4,858.50
Present Value ($)	2,447.42	2,245.34	1,232.86	1,131.07
Net Present Value ($)	27,110.65	29,355.99	30,588.85	31,719.92

As seen above, inTENS has a NPV of $31,719.92 at the end of its product life cycle. The payback period is 3 years with a positive NPV in Q1 of year 4. The positive NPV and stable growth indicates a desirable investment. The Internal rate of return (IRR) from the above is 23% and return of investment (ROI) taking into account development and marketing costs is 39.68%. These are both high compared to the industry standard and thus cast a favourable light on the project in terms of financial performance.

8. Conclusion

inTENS is a portable wireless, clothing integratable and customisable TENS (Transcutaneous Electrical Nerve Stimulation). inTENS allows users to relieve pain in a discrete fashion, whilst providing EMG (electromyography) data to provide a personalised experience for each user.

The device will consist of a constant current source that serves as the stimulation source, and an EMG recording circuit that will be able to record user EMG data. The ESP32WROOM32E microprocessor will serve as the main control unit, allowing the user to transmit and receive data via wireless interface.

Market analysis showed that inTENS targets a very niche, fast growing market, and has few competitors that offer similar features at the low price point of $150AUD. As a result, investment in the development of inTENS would be a strategic advantage. Revenue is expected to be $96.55 AUD per unit and a gross profit margin of 280.6%.

The development plan included accounts for multiple risks of varying severity, thus production and testing of inTENS will commence at the recommended pace in order to finalise the design by 16/11/2020. Some further developments include redesigning the enclosure to adhere to IP standards, updating the mobile software and rerouting the PCB with no test points for a smaller design.

Overall, inTENS is a product that targets a niche, fast growing market, and is expected to have a positive net present value of 72,186.60 at the end of its conservative product life cycle (2 years). It provides a solution for a common issue, and allows for development of a new type of concealed pain relief wearable.

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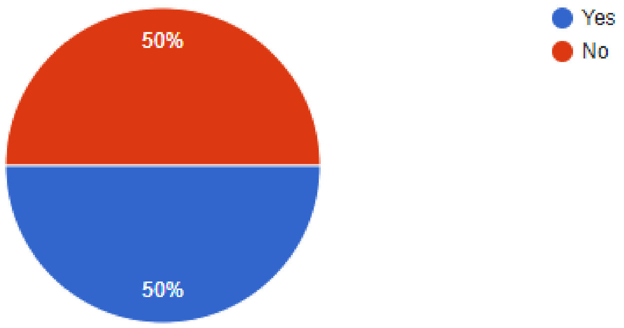
9. Appendix

A. Market Research

Do you own a TENS machine?

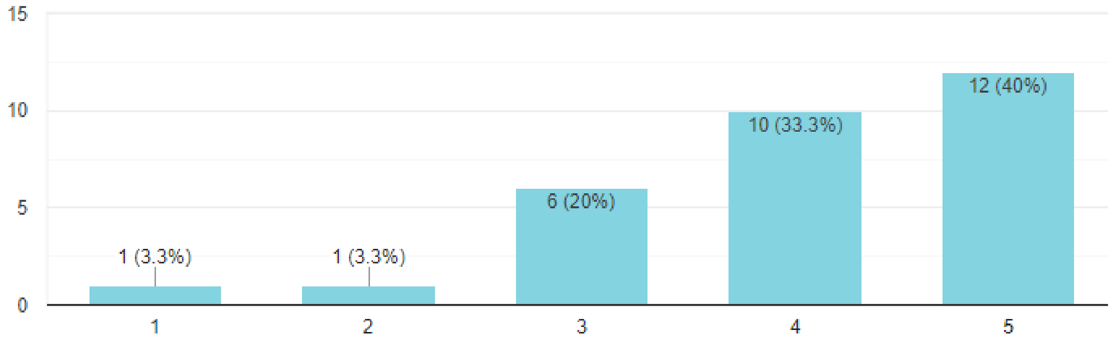
30 responses



a. Survey Results

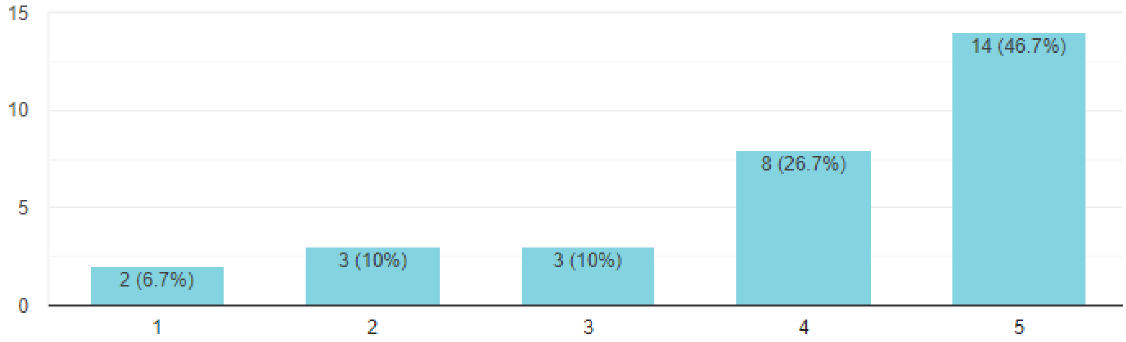
How often do you perform strenuous physical activity?

30 responses



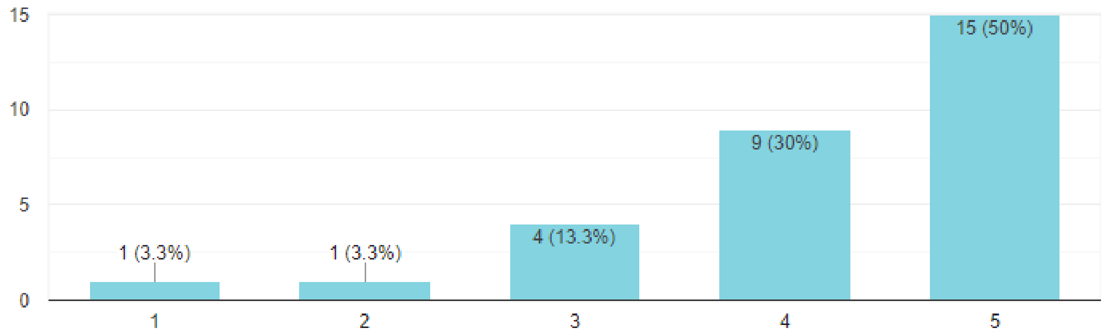
How often do you experience muscular or nerve pain?

30 responses



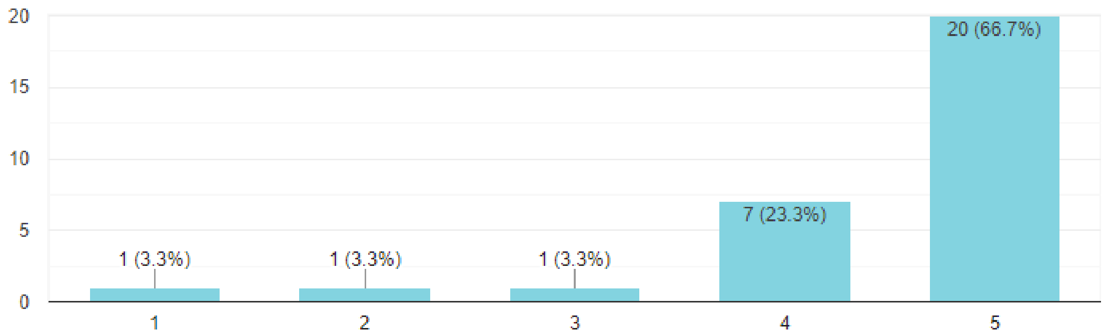
How often do you or would you use a TENS machine?

30 responses

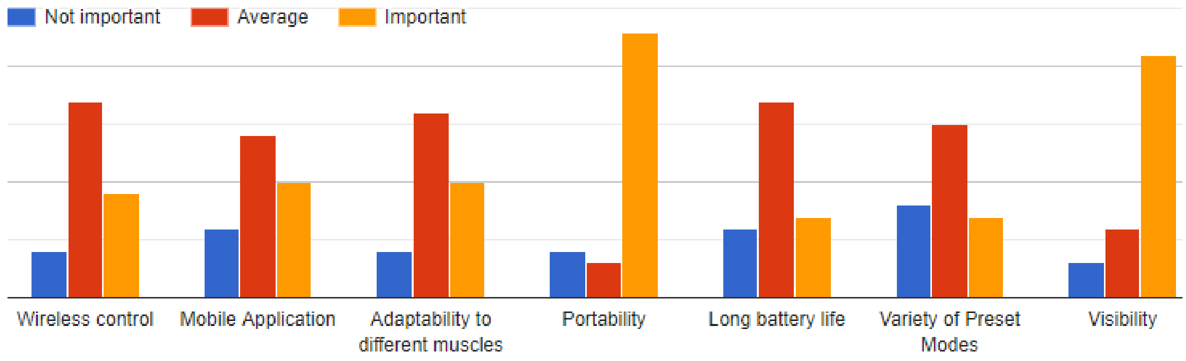


How important is the portability of a TENS machine?

30 responses



What features are important for a TENS machine?



What are some other desired features for a TENS unit?

4 responses

Other than how discreet and portable it can be? Nothing. Nothing is more desirable than those two things.

I wish my tens machine was more portable and not so visible - I don't like when people notice I am using one... As I use it at my desk when I'm in the office

It is a must for them to be easy to carry and as slim as possible

I would really like a tens unit that is more portable than my current.

What aspects of existing or similar devices do you dislike?

5 responses

The products i've seen are too bulky

10

How non portable and non discreet they are

5

How clunky they are!!! Too annoying to carry anywhere.

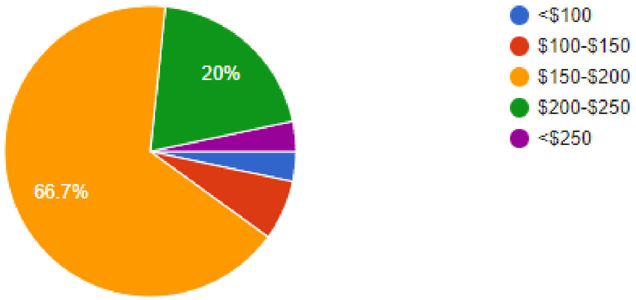
I really dislike when they are too bulky to fit in my pocket. I would like to be able to actually move around without having the burden of a bigger TENS Machine

0

They're ugly and are hard to make stylish

What price would you be willing to pay for an Ultra-portable TENS unit?

30 responses



b. Interviews

John - TENS user

- I bought one for my neuropathic pain
- It's a bit impractical because you have cords dangling that you can catch and snag
- It can be a little inconvenient especially if you need to be active.
- It's really only useful if I'm sitting or standing still at home

David - Physiotherapist

- I let my patients try our big TENS unit and they always ask if there is an option they can use on-the-go
- TENS machines clearly have limitations especially when movement is involved
- From my experience any twisting or movement causes the cords to tangle or pads to fall off

B. Meeting minutes

DATE	**Tuesday, 13th October 2020**
TIME START / FINISH	**10:00am - 11:00am**

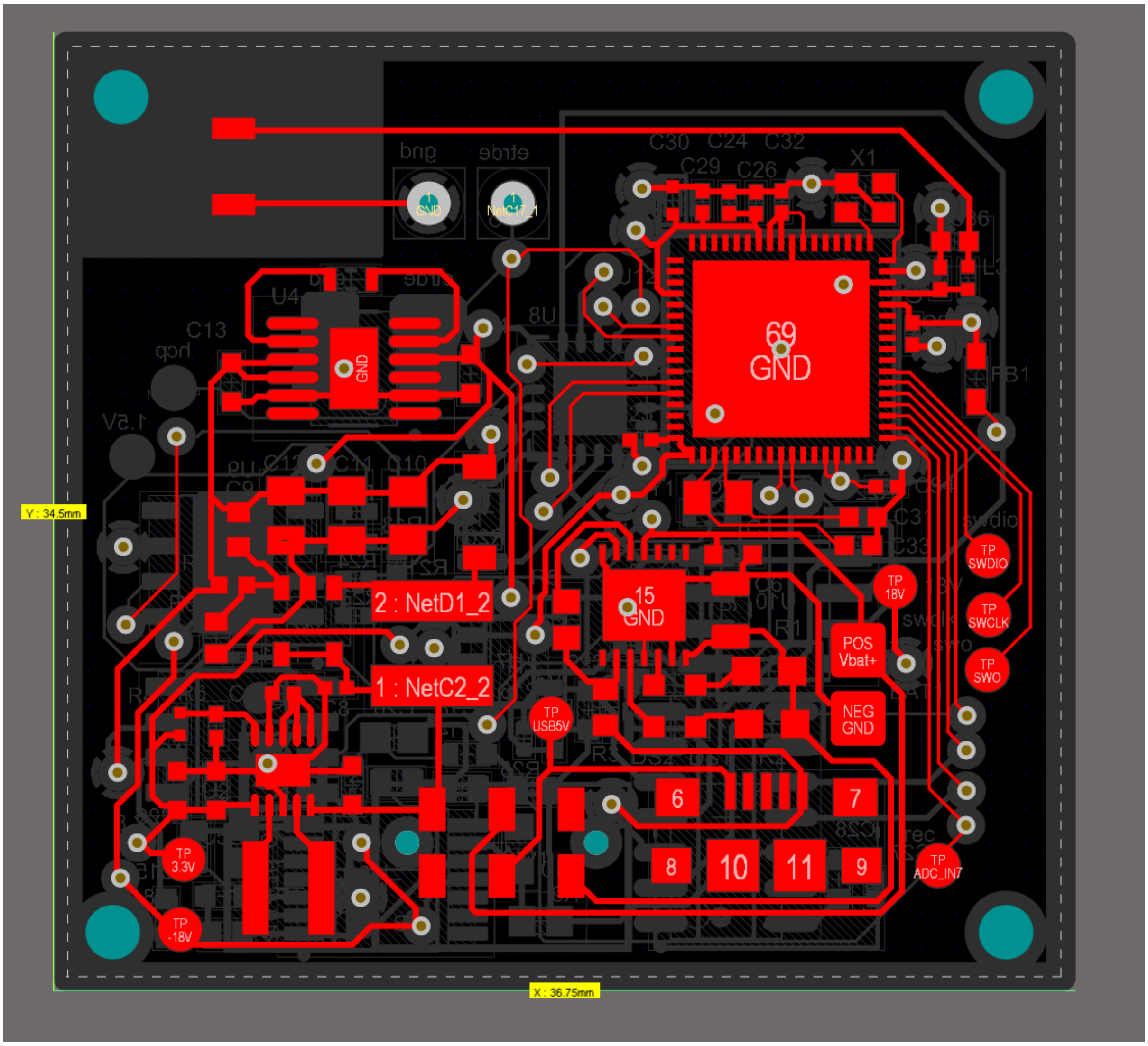
LOCATION	**Microsoft Teams**
ATTENDEES	**Adam Walker, Mina Nassief (H09A Group D)** **Jackson Sarcia, Eric Pullukaran (M13D Group E)**
APOLOGIES/ABSENT	

AGENDA ITEMS	DISCUSSION
Product Introduction	Wireless TENS unit → On the go pain relief Main things to address: ● Concealable in clothing ● Small form factor ● Controllable via app ● Etc. General plans ● Circuitry ● PCB ● Phone application
Thoughts & Advice	Adam - Does device have to sit where you're transmitting the pulse Mina - Sleeve would be good if it could be implemented - Look at heart rate monitors strapped on the back - What kind of testing are you going to implement before the product can be used on people? Eric - What is the battery life like Adam - Having it on your body is a benefit so having an extra part (e.g. some sort of strap) to keep it on your body would be good

DATE	**Wednesday, 25th November 2020**
TIME START / FINISH	**12:00pm - 12:20pm**
LOCATION	**Microsoft Teams**
ATTENDEES	**Adam Walker, Mina Nassief (H09A Group D)** **Jackson Sarcia, Eric Pullukaran (M13D Group E)**
APOLOGIES/ABSENT	**Tristan Chu (M13A Group D)**
RELEVANT LINKS	

AGENDA ITEMS	DISCUSSION
Product Introduction	•
Thoughts/Advice	•

C. Preliminary PCB layout



D. TENS placement

Figure D.1: Placement of TENS unit pads [13]

E. Code

ESP32_input_test§

```
/*
   ELEC3117 Code for a portable TENS machine
   Code implements a BLE server/client which is connected to
   using a mobile app acting as the server/client to control the device

   Code also implements function generator for sine/square wave with
   controllable frequency.
*/

// Libraries for BLE capability
#include <BLEDevice.h>
#include <BLEUtils.h>
#include <BLEServer.h>
#include <BLE2902.h>

// The remote service we wish to connect to.
#define SERVICE_UUID        "4fafc201-1fb5-459e-8fcc-c5c9c331914b"
// The characteristic of the remote service we are interested in.
#define CHARACTERISTIC_UUID "beb5483e-36e1-4688-b7f5-ea07361b26a8"

float freq = 3;                         // Frequency in Hz
float pulseWidth = 200;                 // Pulse width in microseconds
float holdtime = 0;

int switchPinEnable = 16;
int switchPinToggle = 14;

double PW;

double Iout = 15;
float million = 1000000;
float thousand = 1000;
double twofivefive = 255;
double sixsix = 6.6;
double interval = million / (freq*2);
double udelay = million / (freq) - 2*pulseWidth;
double udelay2 = (million/freq) - 6*pulseWidth;
double V_DAC = ((Iout / 10 + 3) / 2) - 1.5;
```

```
float step = 0.0125;
double N_DACH; double N_DACL;
double N_DAC = V_DAC/step;
unsigned long currentMicros = micros();
unsigned long previousMicros = micros();
unsigned long elapsedMicros;
int i = 0;
String input;
String SIout; String Sfreq;
String SPW; String SSW;
String Sb1; String Sb2; String Sb3;
int ind1; int ind2; int ind3; int ind4; int ind5; int ind6; int ind7;
int b1; int b2; int b3;
```

```
float step = 0.0125;
double N_DACH; double N_DACL;
double N_DAC = V_DAC/step;
unsigned long currentMicros = micros();
unsigned long previousMicros = micros();
unsigned long elapsedMicros;
int i = 0;
String input;
String SIout; String Sfreq;
String SPW; String SSW;
String Sb1; String Sb2; String Sb3;
int ind1; int ind2; int ind3; int ind4; int ind5; int ind6; int ind7;
int b1; int b2; int b3;
int SW;
```

```
class MyCallbacks: public BLECharacteristicCallbacks {
    void onWrite(BLECharacteristic *pCharacteristic) {
      std::string value = pCharacteristic->getValue();

      if (value.length() > 0) {
        input = "";
        for (int i = 0; i < value.length(); i++) {
          input = input + value[i];
        }

        ind1 = input.indexOf(',');
        SIout = input.substring(0, ind1);
        ind2 = input.indexOf(',', ind1+1 );
        Sfreq = input.substring(ind1+1, ind2);
        ind3 = input.indexOf(',', ind2+1 );
        SPW = input.substring(ind2+1, ind3);
        ind4 = input.indexOf(',', ind3+1 );
        SSW = input.substring(ind3+1, ind4);
        ind5 = input.indexOf(',', ind4+1 );
        Sb1 = input.substring(ind4+1, ind5);
        ind6 = input.indexOf(',', ind5+1 );
        Sb2 = input.substring(ind5+1, ind6);
        ind7 = input.indexOf(',', ind6+1 );
        Sb3 = input.substring(ind6+1, ind7);
```

```
        freq = Sfreq.toInt();
        Iout  = SIout.toInt();
        PW = SPW.toInt();
        SW = SSW.toInt();
        b1 = Sb1.toInt();
        b2 = Sb2.toInt();
        b3 = Sb3.toInt();

        interval = million/(freq*2);
        udelay = (million / freq) - 2*pulseWidth;
        udelay2 = (million / freq) - 6*pulseWidth;

        V_DAC = ((Iout/10 + 3)/2)-1.5;
        N_DACH = V_DAC/step;
        N_DACL = V_DAC/step;
        if (Iout == 30) {
          N_DACH = 120;
          N_DACL = 116;
        }

      }
    }
};
```

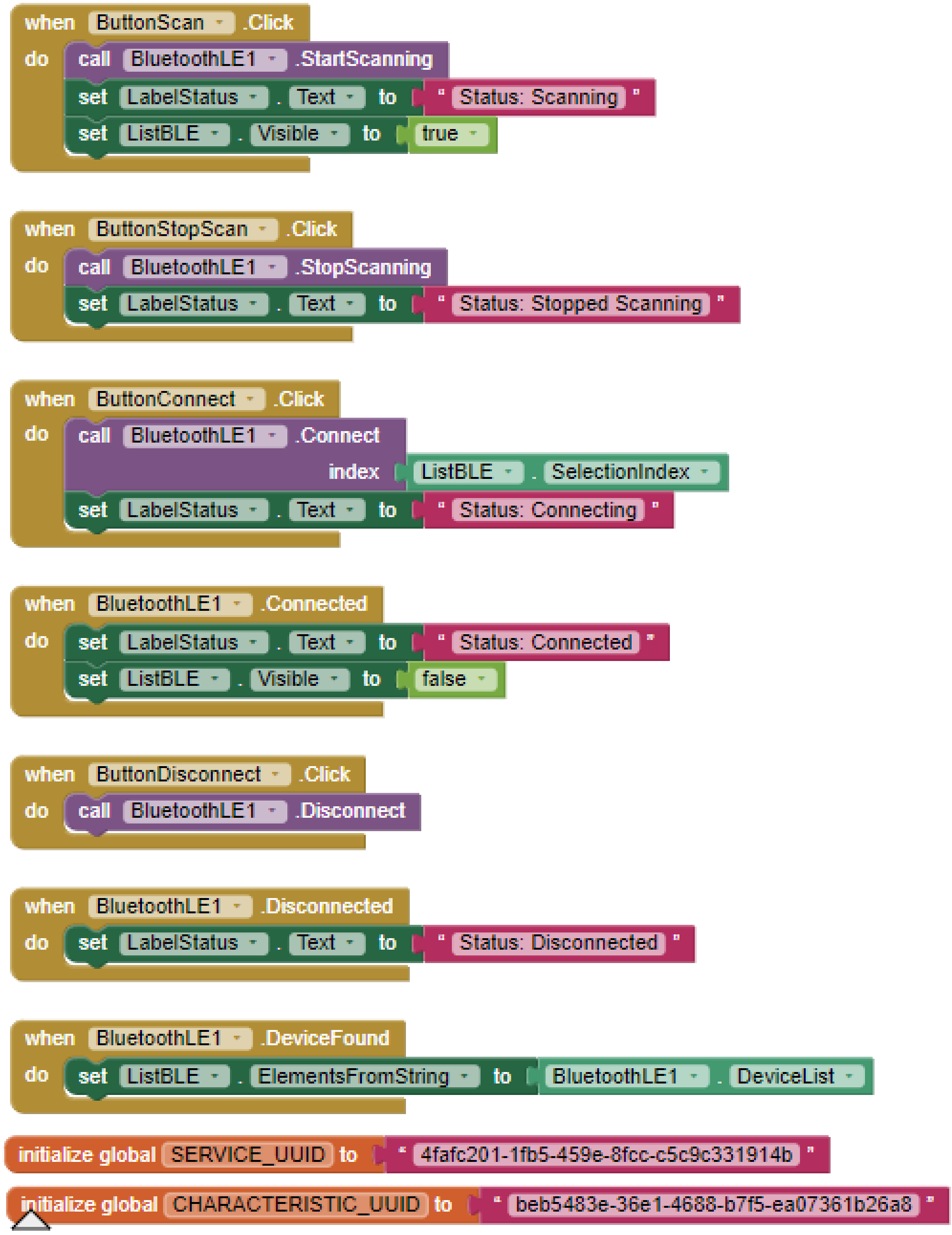
```
void setup() {
  pinMode(switchPinEnable, OUTPUT);
  pinMode(switchPinToggle, OUTPUT);

  Serial.begin(115200);

    BLEDevice::init("ESP32_TENS");
    BLEServer *pServer = BLEDevice::createServer();
    BLEService *pService = pServer->createService(SERVICE_UUID);
    BLECharacteristic *pCharacteristic = pService->createCharacteristic(
                                           CHARACTERISTIC_UUID,
                                           BLECharacteristic::PROPERTY_READ |
                                           BLECharacteristic::PROPERTY_WRITE
                                         );

    pCharacteristic->setCallbacks(new MyCallbacks());

    pCharacteristic->setValue("Hello World says Chris, Yo");
    pService->start();

    BLEAdvertising *pAdvertising = pServer->getAdvertising();
    pAdvertising->start();
}
```

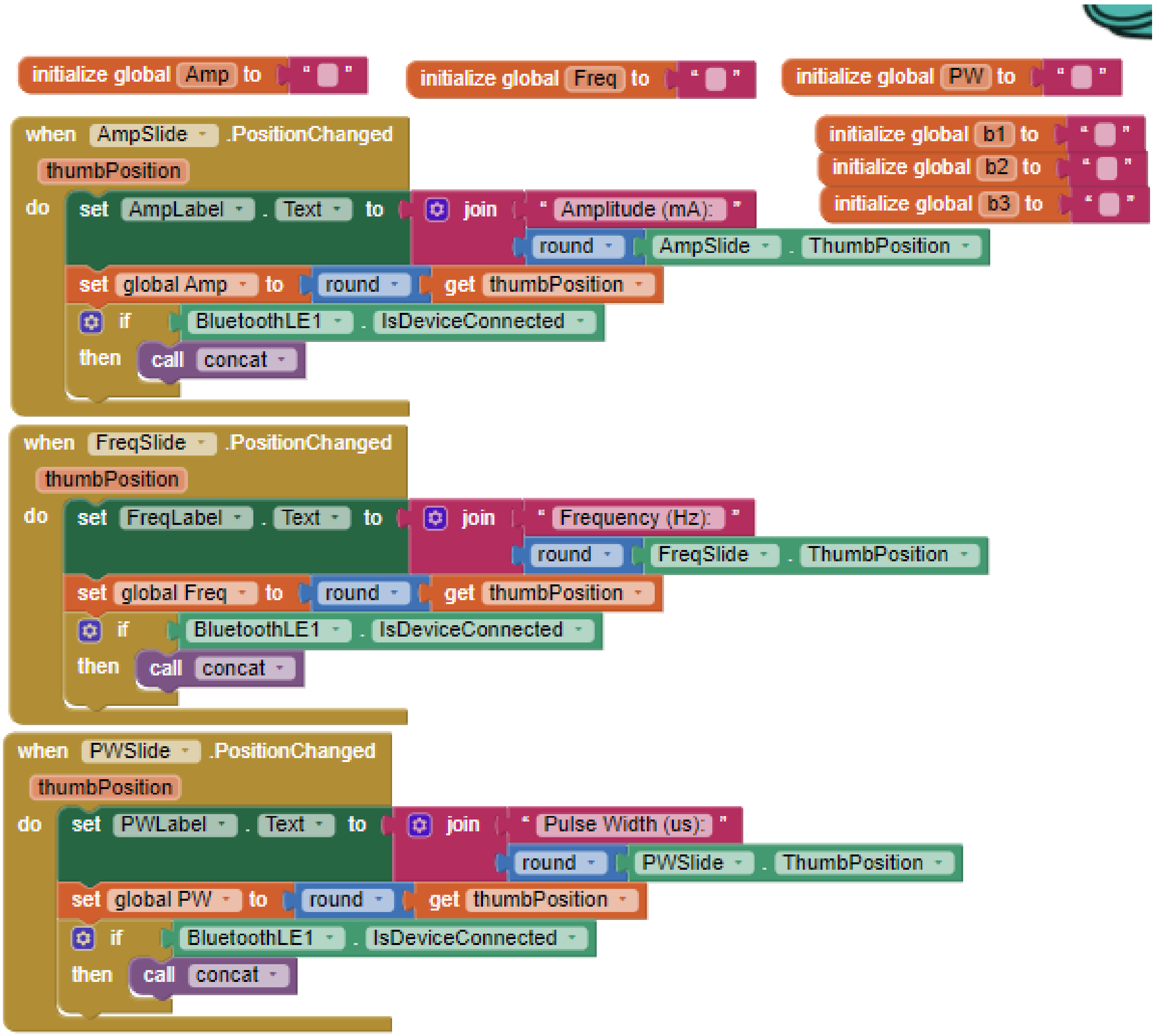
```
void loop() {

if (SW == 1) {
  digitalWrite(switchPinEnable, HIGH); // Pin 16
  digitalWrite(switchPinToggle, HIGH); // Pin 14 - High EMG input - Low for Stim
} else {
  digitalWrite(switchPinEnable, HIGH); // Pin 16
  digitalWrite(switchPinToggle, LOW); // Pin 14 - High EMG input - Low for Stim
}

// Normal output
while (b1 == 1 && b2 == 0 && b3 == 0 && SW == 0) { // Recording switched off
  elapsedMicros = 0;
  previousMicros = micros();
  while (elapsedMicros <= interval) {
    dacWrite(25, (116 + N_DACH)); // 117 is center
    currentMicros = micros();
    elapsedMicros = currentMicros - previousMicros;
  }

  elapsedMicros = 0;
  previousMicros = micros();
  while (elapsedMicros <= interval) {
    dacWrite(25, (116 - N_DACL));
    currentMicros = micros();
    elapsedMicros = currentMicros - previousMicros;
  }
}
```

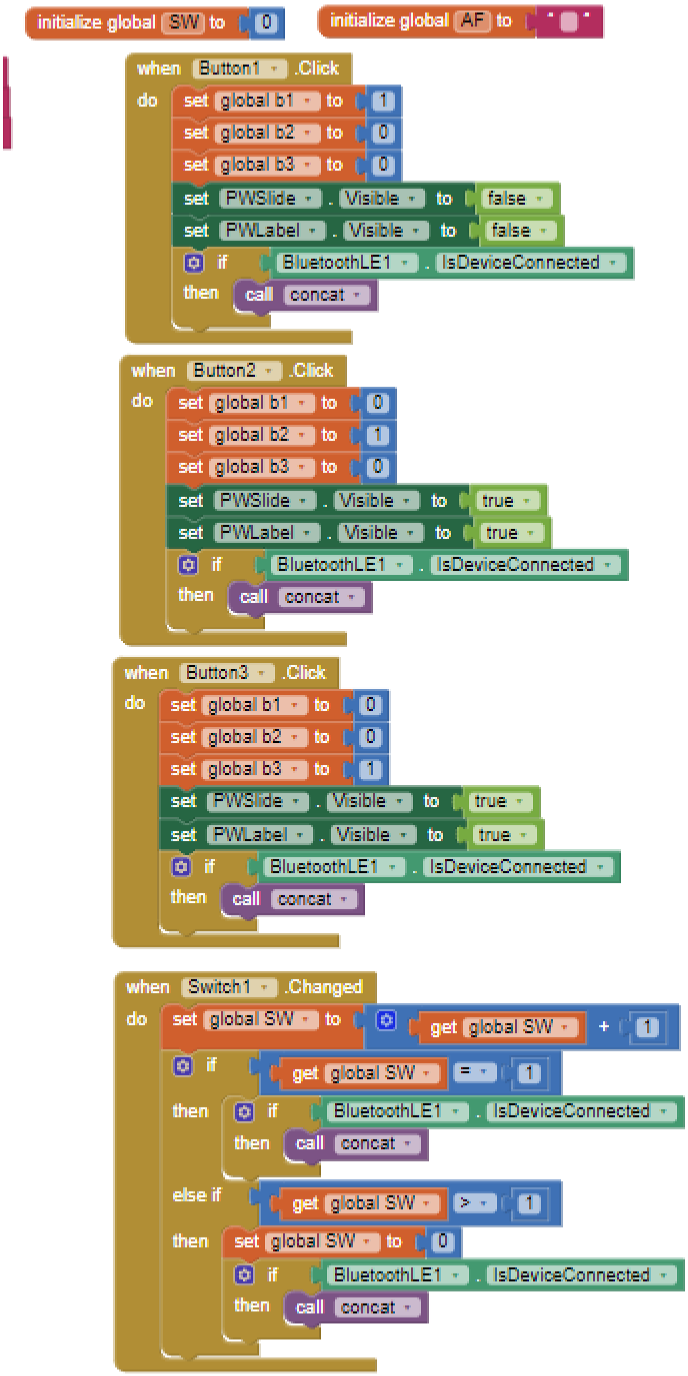
```
// Accupuncture output
while (b1 == 0 && b2 == 1 && b3 == 0 && SW == 0) {
  elapsedMicros = 0;
  previousMicros = micros();
  while (elapsedMicros <= PW) {
    dacWrite(25, (116 + N_DACH)); // 116 is center ata 1.5V
    currentMicros = micros();
    elapsedMicros = currentMicros - previousMicros;
  }

  currentMicros = micros();
  elapsedMicros = 0;
  previousMicros = micros();
  while (elapsedMicros <= PW) {
    dacWrite(25, (116 - N_DACL));
    currentMicros = micros();
    elapsedMicros = currentMicros - previousMicros;
  }
  delayMicroseconds(udelay);
}
```

```
// Hybrid output
while (b1 == 0 && b2 == 0 && b3 == 1 && SW == 0) {
  elapsedMicros = 0;
  previousMicros = micros();
  while (elapsedMicros <= PW) {
    dacWrite(25, (116 + N_DACH)); // 116 is center at 1.5V
    currentMicros = micros();
    elapsedMicros = currentMicros - previousMicros;
  }

  currentMicros = micros();
  elapsedMicros = 0;
  previousMicros = micros();
  while (elapsedMicros <= PW) {
    dacWrite(25, (116 - N_DACL)); // 116 is center at 1.5V
    currentMicros = micros();
    elapsedMicros = currentMicros - previousMicros;
  }
  i = i+1;
  if (i > 3) {
  delayMicroseconds(udelay2);
  }
}

}
```

Code for mobile application




initialize global Amp to " "
initialize global Freq to " "
initialize global PW to " "
initialize global b1 to " "
initialize global b2 to " "
initialize global b3 to " "
when AmpSlide .PositionChanged
thumbPosition
do set AmpLabel . Text to join " Amplitude (mA): "
round AmpSlide . ThumbPosition
set global Amp to round get thumbPosition
if BluetoothLE1 . IsDeviceConnected
then call concat
when FreqSlide .PositionChanged
thumbPosition
do set FreqLabel . Text to join " Frequency (Hz): "
round FreqSlide . ThumbPosition
set global Freq to round get thumbPosition
if BluetoothLE1 . IsDeviceConnected
then call concat
when PWSlide .PositionChanged
thumbPosition
do set PWLabel . Text to join " Pulse Width (us): "
round PWSlide . ThumbPosition
set global PW to round get thumbPosition
if BluetoothLE1 . IsDeviceConnected
then call concat


initialize global SW to 0
initialize global AF to " "
when Button1 .Click
do set global b1 to 1
set global b2 to 0
set global b3 to 0
set PWSlide . Visible to false
set PWLabel . Visible to false
if BluetoothLE1 . IsDeviceConnected
then call concat
when Button2 .Click
do set global b1 to 0
set global b2 to 1
set global b3 to 0
set PWSlide . Visible to true
set PWLabel . Visible to true
if BluetoothLE1 . IsDeviceConnected
then call concat
when Button3 .Click
do set global b1 to 0
set global b2 to 0
set global b3 to 1
set PWSlide . Visible to true
set PWLabel . Visible to true
if BluetoothLE1 . IsDeviceConnected
then call concat
when Switch1 .Changed
do set global SW to get global SW + 1
if get global SW = 1
then if BluetoothLE1 . IsDeviceConnected
then call concat
else if get global SW > 1
then set global SW to 0
if BluetoothLE1 . IsDeviceConnected
then call concat

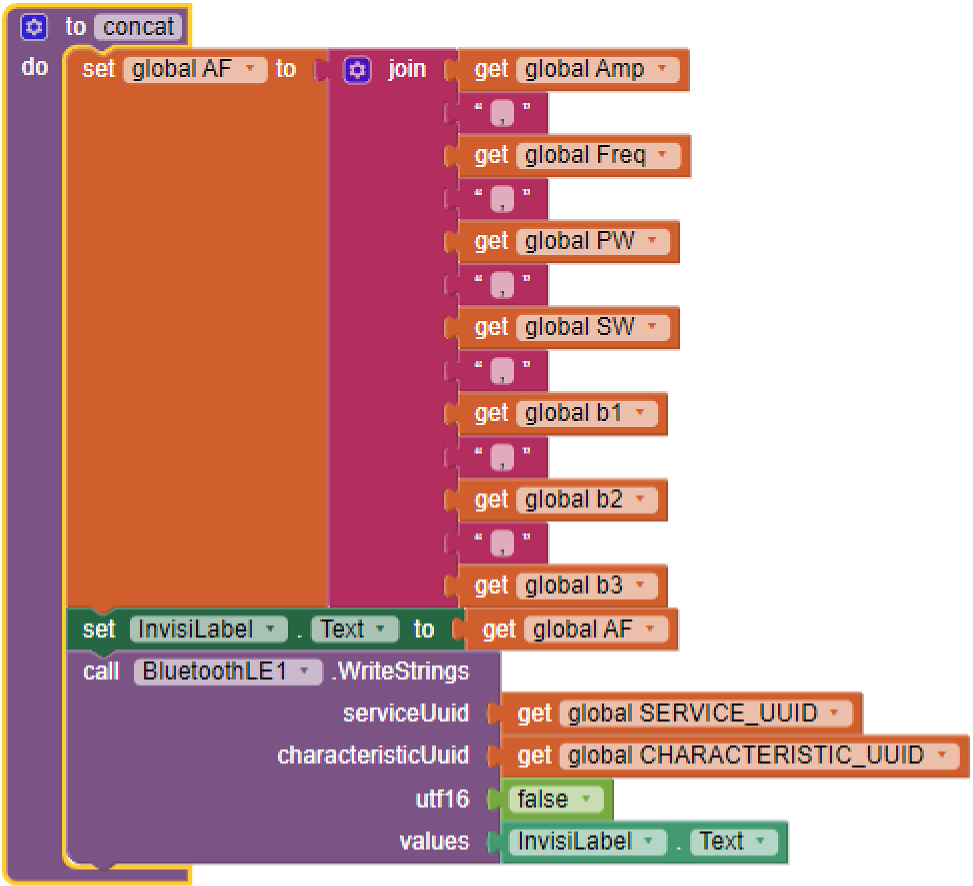


Figure 1.3 30mA output at 86Hz

Figure 1.4 17mA output at 86Hz