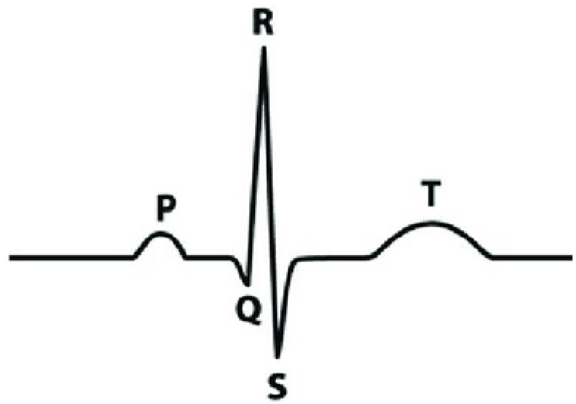
Portable Electrocardiogram Final Report

Hamza Abdul-Ghani habdulgh@caltech.edu
Grace Ding gding@caltech.edu
Saehui Hwang shwang@caltech.edu

Motivation

The electrocardiogram (ECG) is a tool that monitors the electrical activity of the heart. It can help detect various heart diseases and inspect heart performance. A typical ECG has features that are universal across humans.



(a)

P wave	Depolarization of the atria
Q wave	Activation of the anterioseptal region of the ventricular myocardium
R wave	Depolarization of the ventricular myocardium
S wave	Activation of the posteriobasal portion of the ventricles
T wave	Rapid ventricular repolarization

(b)

Figure Source: Savalia, Shalin & Emamian, Vahid. (2018). Cardiac Arrhythmia Classification by Multi-Layer Perceptron and Convolution Neural Networks. Bioengineering. 5. 35. 10.3390/bioengineering5020035.

The heart contracts and relaxes when the polarity of various muscle tissues of the heart switch. The polarity differences cause weak currents to flow in the body, which changes the relative electric potential between various points on the skin. By measuring the potential difference across the body, we can recover the heart's electrical signal known as the ECG.

An ECG can diagnose various issues of the heart, including myocardial infarctions, abnormal heart rhythms, enlargement of one side of the heart, and other abnormalities. As a result, an ECG is a useful tool for diagnosing various health issues associated with heart health. With over 600,000 deaths resulting from heart conditions a year in the USA (that's 1 in 4 deaths), an ECG is an integral part of diagnostic healthcare.

Despite being an essential non-invasive diagnostic tool, ECG instruments can cost upwards of $2000 with single clinical ECG checkups ranging from $80 to $1200.

Goals of Project

The goal of this project is to create an affordable ECG device that can be used regularly at home. To provide adequate data for medical diagnostics, we plan to design the ECG to compute Leads I/II/III and report the estimated angle of the heart. The user can view the trace on an integrated display, on a computer over USB, or on a smartphone application over Low Energy Bluetooth. CSV data to plot the measured trace will also be recorded on an SD card. An LED indicator will light with each heartbeat, and an optionally enabled speaker will beep with each heartbeat. To power the device while maintaining enforced isolation from mains electricity, a lithium polymer battery will supply the power rails to the system. The device will not function while the battery is charging.

If time permits and the chip shortage inflated prices are not too high, we would like to include a touch interface for the display as well as an audio amplifier to record stethoscope sounds.

Method

A typical ECG signal contains frequency components that fall between 0.3Hz and 250Hz. We will be using an instrumentation amplifier that amplifies the differential signal coming from the electrodes that are attached to the body. The resulting signal is expected to contain a 60Hz noise from the electrical grid, which will be filtered out using a notch filter. We will also use TVS diodes to protect the board from voltage spikes, originating from defibrillation or ESD. This circuit will be powered using a battery for safety, portability, and to minimize noise. The final design will consist of three separate PCBs – battery management, instrumentation amplifier, and microcontroller with display.

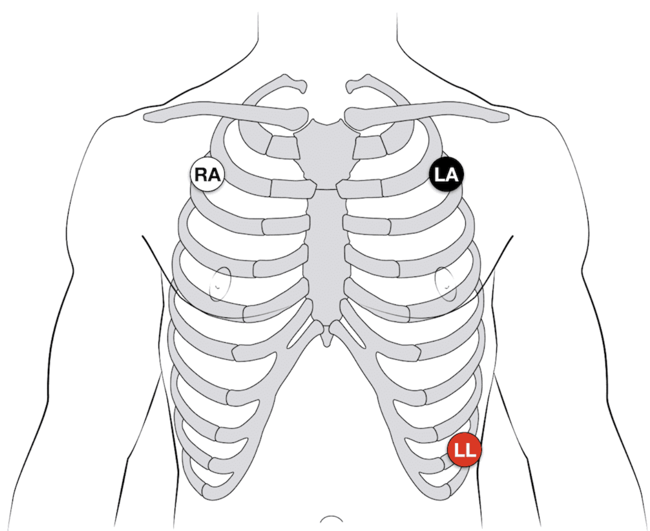
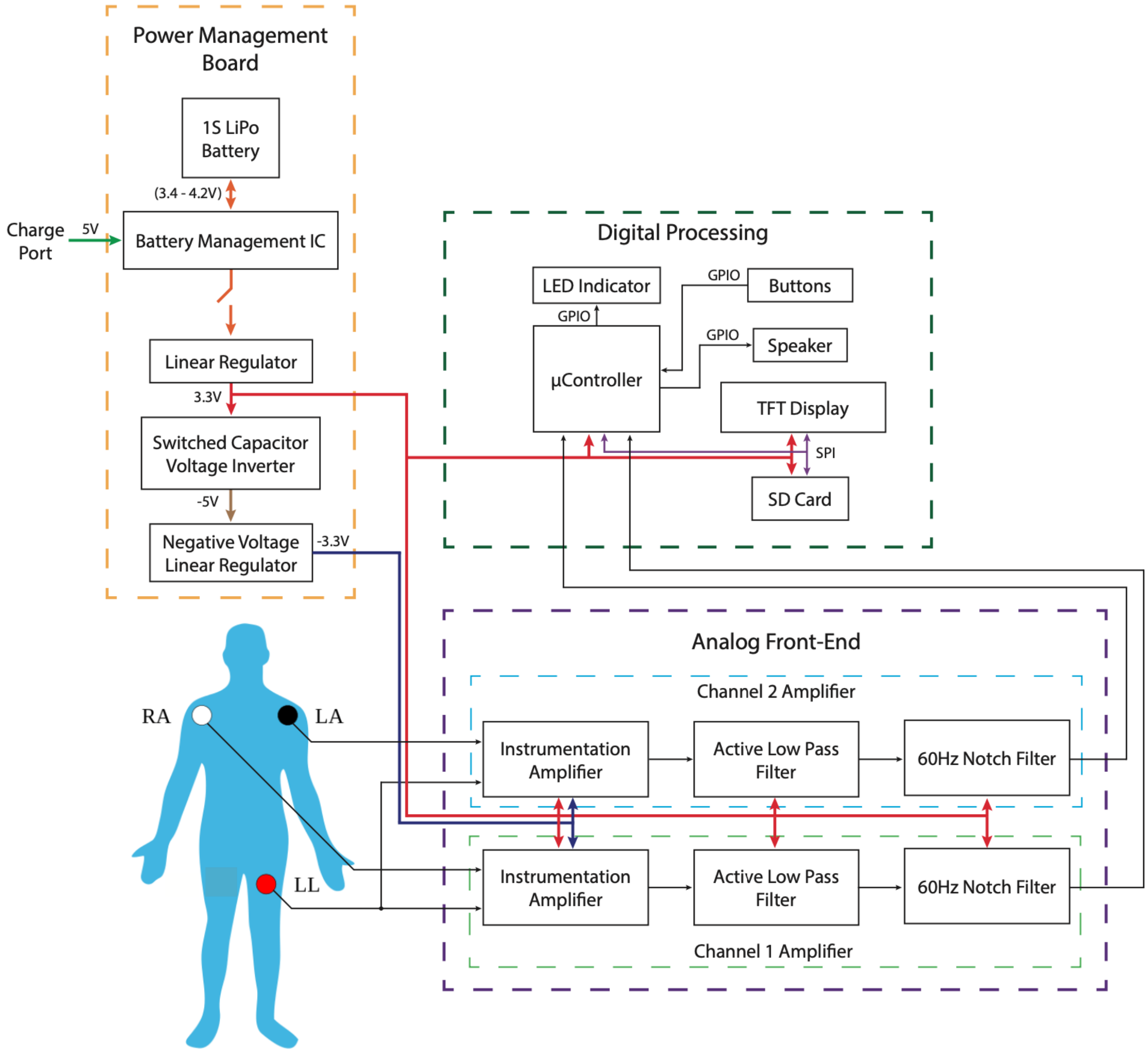


Figure 2: Electrode placement for 3 lead ECG measurement. Source: https://litfl.com/ecg-lead-positioning/

Requirements and V&V Table

Requirement	Verification/Validation
The ECG shall be electrically isolated from mains electricity.	**Verified + Validated - no sources of power outside of internal battery are used while operating the device.**
The ECG shall consist of three PCBs.	**Verified + Validated - visually verified, three PCBs consist of digital processing PCB (display screen + microcontroller), power management PCB (power rail generation and battery charging), and analog front end PCB (instrumentation amplifier + filters)**
The ECG shall have no less than 3 hours of battery life of continuous operation.	**Verified + Validated - bench tested current draw of the entire system to be 120 mA, and calculated based on the discharge capacity of the battery. Discharge capacity is about 1900 mAh, current draw is 120 mA, so total battery life is 15.8 hrs.**
The ECG machine shall record ECG data on a SD card.	**Verified + Validated - CSV file is present on SD card, records both voltage and time values and reconstructed graph matches ECG signal.**
The ECG machine shall contain protection against transient voltage spikes, and continue (or resume) normal operation without user input.	**Verified + Validated - Device continues function after ESD Gun test.**
The ECG shall fit in a container no more than 10 cm by 10 cm by 10 cm in size, excluding electrodes.	**Verified + Validated - enclosure size was measured using calipers to be 100mm x 56mm x 43mm.**
The ECG machine shall not pass a current exceeding 100 uA AC and 10 uA DC through the patient under standard operating conditions.	**Verified + Validated - input current and impedance were measured using resistor and ammeter.**
The ECG machine shall not pass current exceeding 500 uA AC and 50 uA DC through the patient under single fault conditions (i.e. component failure).	**Verified + Validated - UVLO and fuse as well as diode protection protects the patient under single fault conditions.**
The container for the electronics shall have no exposed conductive surfaces that are connected to electronics.	**Verified + Validated - enclosure is 3D printed with non-conductive material**

Block Diagram



Critical Component Selection

Analog Front-End:

Component	Part Number	Properties	Justification
Instrumentation Amplifier	AD8648	● 24MHz Bandwidth Product ● Slew Rate: 11V/µs ● 50uV max input offset ● 79dB min CMRR ● Supply Voltage: 2.7V to 5.5V ● Noise: 8nV/√Hz	● Low cost and easily obtainable. ● The specifications are sufficient for the post-amplified ECG signal.
Operational Amplifier	OP07CP	● 600kHz Gain Bandwidth Product ● Slew Rate: 300mV/µs ● Unity-gain stable ● Supply Voltage: ±3V to ±18V ● 150uV typical input offset ● Noise: 0.15nV/√Hz ● 94dB min CMRR	● Low cost and easily obtainable. ● The high CMRR is required since the patient's body can be coupled to sources of common-mode noise. ● Low input bias current ensures minimal current is passed through the patient and the device remains within the IEC60601 standards.

Digital Processing Board:

Component	Part Number	Properties	Justification
Microcontroller	ESP32-WROOM-32D	● 2.4GHz Wi-Fi and Bluetooth ● Small size (7mm x 7mm)	● Designed for wearables & IoT (low power, ideal for battery operation) ● Small size ensures portability
TFT Display	ILI9341	● Resolution: 240RGB x 320 ● Voltage: 1.65V - 3.3V ● Various color modes for power consumption ● Interface: SPI ● Integrated SD card slot	● Extensive Arduino library support ● Supports color display and touchscreen for enhanced user interface
Buzzer	CMI-9605-0580	● 2.7kHz ● Voltage range: 3 ~ 7V	● We need an internally driven speaker to avoid timer conflicts. ● Verified the frequency to mimic the buzzer sound from a commercial ECG
Button	KMR221G LFS	● SMD Push button	● Compact size

			● Inexpensive

Battery Management Board:

Component	**Part Number**	**Properties**	**Justification**
Battery	[Adafruit PN 2011]	● 2000 mAh 1S LiPo battery	● Small enough to fit within the box we plan on making ● 2000 mAh should be ample power to supply the device for up to 3 hours of use
Battery Management IC	[BQ24200DGN]	● Charge termination by minimum current and time ● 4.2V charge regulation voltage ● Max 500 mA output current ● Integrated voltage regulation with 0.5% accuracy	● Designed specifically for use with current limited wall supplies (i.e. cellphone charger) ● Charging scheme ideal for LiPo battery ● Charge status output allows easy connection of indicator LED ● Temperature monitor for fault mitigation
Switched Capacitor Voltage Inverter	[LTC1261IS8#PBF]	● Output voltage: -8V to -1.25V ● Input voltage: 3V to 8V ● Output current: 12 mA with guaranteed 5% regulation ● Supply Current: 600 uA typical	● Produces negative rail from a single positive supply (can produce -5V from a +3.3V supply) ● Adjustable output voltages ● Requires few external components (3-4 capacitors, fixed output voltage of -5V requires no additional external components)
Low Dropout Linear Regulator	[XC6222B331MR-G]	● Output voltage: 0.8V - 5.0V ● PSRR: 65dB (1kHz) ● Dropout: 0.12V @300mA ● Output current: 700mA (max)	● Input voltage/output voltage was in range we needed ● Dropout of 0.12V means that system will power off when battery is at 3.4V, preserving battery life
Negative Voltage Linear Regulator	[TPS72301DDCT]	● Output voltage: -1.2V to -10V adjustable ● PSRR: 65dB (1 kHz)	● Input voltage/output voltage was in range we needed

		• Dropout: 280 mV @200mA • Output current: 200mA (max)	• Output current should be more than enough to power negative rail for the amplifiers
Undervoltage Lockout Regulator	MIC2776L-YM5-TR	• Adjustable input, monitor supplies as low as 0.3V • +-1.5% threshold accuracy • Power on reset pulse (140 ms min) • Ultra-low supply current, 3.0 uA typical	• Manual reset input perfect for power switch • Can choose to be active high/active low/open drain active low reset out, so connected to a power switch can cut off power to rest of circuit • Threshold within values needed to shut off system below 3.4V
Power Switch	MIC94065YC6-TR	• 1.7V to 5.5V input voltage range • 2A continuous operating current • Low 2 uA quiescent current	• Input voltage matches with output of reset from UVLO regulator • Active high input matches with active low output from RST (if reset triggered, output value is low, so power switch is disabled)

Connectors & Headers:

Component	**Part Number**	**Properties**	**Justification**
JST	440055-2/4	• 2mm pitch • Male contact • Throughhole	• Low profile • Inexpensive • Inventory available
JST	4-103327-5	• 2.5mm pitch • Throughhole	• Inexpensive • Inventory available

Specifications

Features	Specification
Size	10cm x 10cm x 10cm
Weight	< 1 kg
Charger	0.5A @ 5V micro USB input
Peripherals	7cm diagonal, 240 x 320 RGB touchscreen display Touchscreen buttons for UI
Data Recording	CSV file to uSD card
Einthoven Leads	Leads I, Leads II, Leads III
Patient Leakage Current	<10 uA
Input Impedance	≥50 MΩ

Timeline

Week	Task	Deliverable
4/7	● Outline project goals and system requirements. ● Select critical components and finalize system architecture in block diagram. ● Order through-hole components for breadboard prototype.	Proposal & Requirements
4/14	● Simulate instrumentation amplifier and filter circuits in LTSpice using ECG WAV file. ● Begin constructing design on a breadboard. ● Write preliminary firmware for displaying analog waveforms on SPI display.	Preliminary Design Review
4/21	● Verify breadboard prototype of instrumentation amplifier works using oscilloscope. ● Finalize schematics in Altium and start component placement. ● Finalize Bill of Materials and order SMD components for final PCBs ● Add SD card recording and bluetooth transmittal capabilities to firmware.	Critical Circuits Simulations
4/28	● Complete PCB component placement and start layout. ● Add Lead I/II/III computation and ECG data analysis features to firmware.	Critical Circuits Breadboarding
5/5	● Review PCB and apply final touches.	Critical Design Review
5/12	● Design laser cut device enclosure. ● Finish Assembly & Packaging Plan. ● Finish Test Plan & Procedure. ● Order PCBs.	Parts Placement
5/19	● Assemble device and fabricate enclosure. ● Verify and validate the design against project requirements. ● Begin compiling the final report.	Layout
5/26		Assembly & Packaging Plan Test Plan & Procedure
6/3	● Present project.	Demonstration & Report

Fault Modes and Effects Analysis

The system components, assemblies, and subsystems have been analyzed to identify potential failure modes. The ECG will be directly connected to the human body, so it is important that there are no negative health consequences to the user in any scenario. Three fault modes have been identified and handled in the proposed schematic. The first failure mode occurs when the Li-Po battery experiences thermal runaway, which is mitigated by the battery management IC. The second possible failure mode occurs when the battery management IC experiences miscellaneous hardware failures and firmware bugs. To protect against overcurrent, a fuse is included in the schematic. The last failure mode occurs when the operational amplifier and linear regulator fail and short circuit the pads to the power rails. For this, no failure handling is required as 4.2V is the maximum at the power rails and it is a negligible amount of voltage and current.

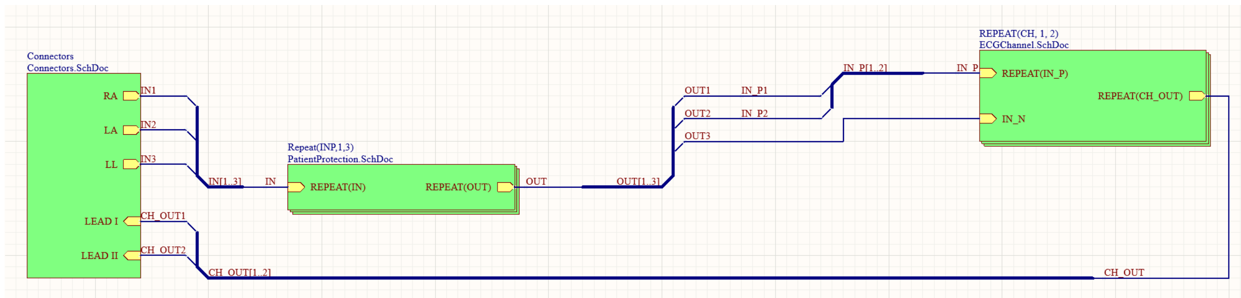
FMEA No.:	Component	Failure Mode	Failure Cause	Failure Effect	Severity	Failure Handling
1	Li-Po Battery	Thermal runaway	Manufacturing flaws, mechanical damage, internal short circuit, overcharge and over discharge are all causes for thermal runaway	Elevated cell temperature, thermal runaway	2	The Battery Management IC will conduct over & under voltage protection, over-current protection, and thermal protection
2	Battery Management IC		Hardware failures, firmware bugs	Thermal runaway	2	A fuse will be installed for overcurrent protection
3	Op Amp and linear regulator failure	The electrodes may be connected to the power rail, which is at most 4.2V	This failure is extremely unlikely. Multiple hardware failures must occur simultaneously for this failure to occur, if ever.	The user may be shocked by the electrodes	1	No handling is required, as 4.2V will not affect the user. Current limiting resistors will restrict the amount of current that can run through the body, and back to back diodes will limit the voltage at the electrodes. If the user feels unsafe while using the device, the user may, at any time, remove the electrodes from the body.

Key for Severity	
Rating	Severity
1	No injuries may be caused
2	Light injuries may be caused
3	Medium injuries may be caused

Schematics

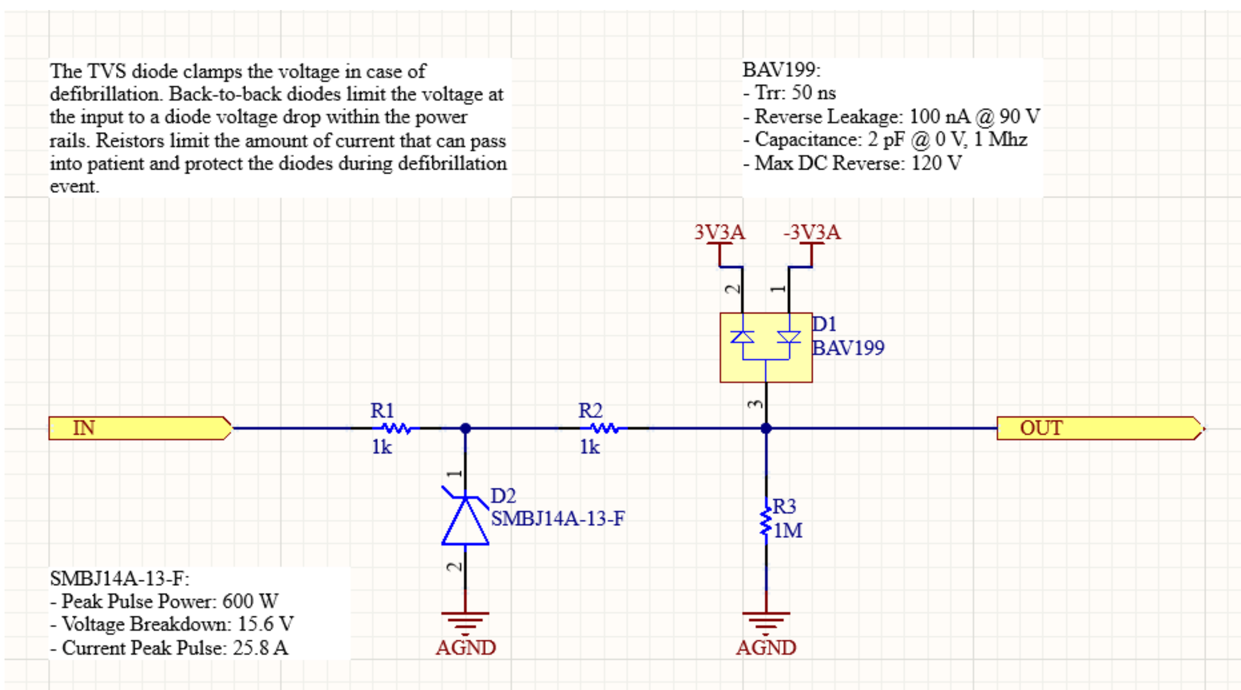
Analog Front End Board

TopLevel.SchDoc



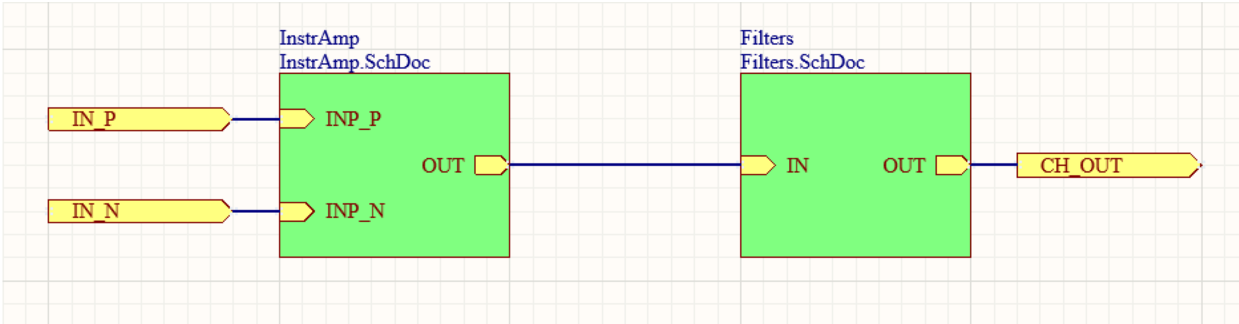
The top level is separated into several sheets and utilizes the multichannel Altium feature to avoid repetitive workflows and allow for better organization, readability, and routing. The right arm (RA), left arm (LA), and left leg (LL) electrode connector inputs pass through the patient protection components before being separated into pairs as inputs to the two instrumentation amplifier channels. Channel 1 and channel 2 receive the RA and LA signals at their non-inverting inputs respectively. Both channels take in the LL signal at their inverting inputs. This allows the channels to measure Lead I and Lead II.

PatientProtection.SchDoc



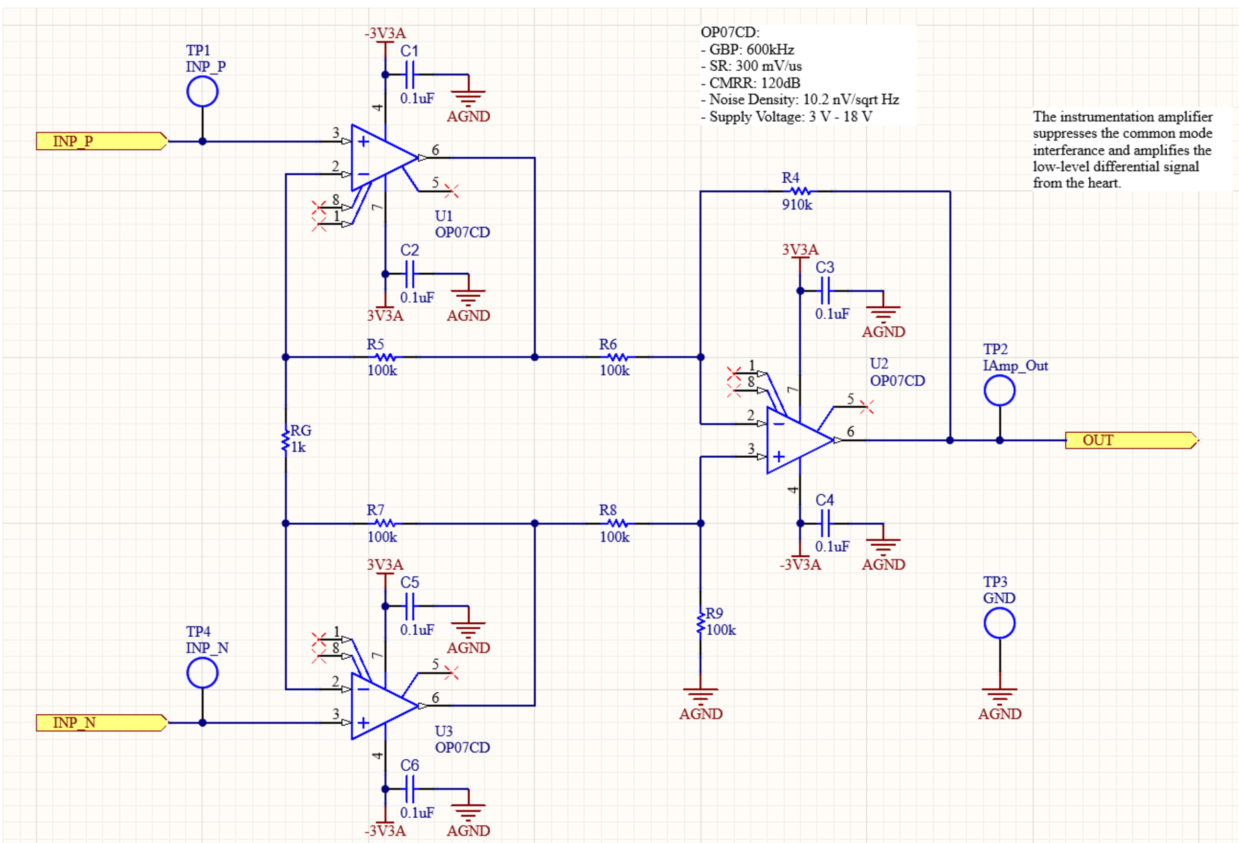
The patient protection components limit the voltage at the electrode as well as the input bias current to ensure the device remains within safe operating conditions. The function of the components are described in the schematic text frames above.

ECGChannel.SchDoc



The ECGChannel schematic document follows the block diagram closely. The output of the instrumentation amplifier is passed through cascaded filters before being passed to an output connector to interface with the digital processing board.

InstrAmp.SchDoc

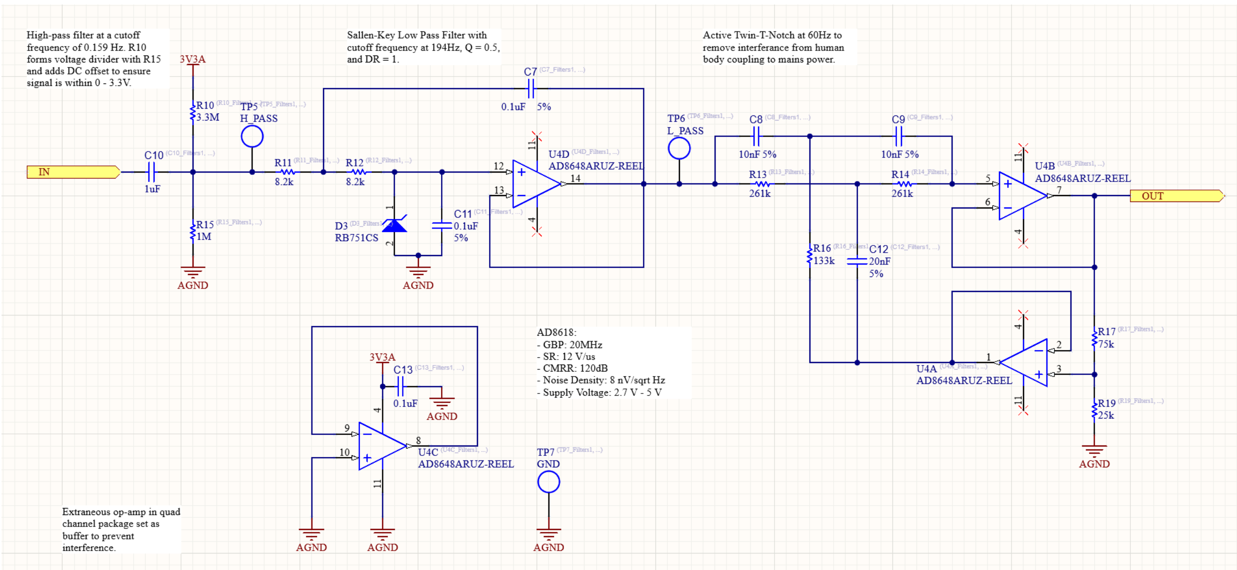


The instrumentation amplifier utilizes a buffered differential amplifier stage to allow the gain to be set using only one resistor, RG. Given U1 and U3 are in a negative feedback topology the voltage at their inverting inputs is equal to INP_P and INP_N respectively. The voltage across RG is thus given by (INP_P - INP_N). U2 acts as a standard differential amplifier. Therefore, since R8 = R9 and R5 = R7, the output voltage of the instrumentation amplifier is given by the expression below where INP_P = V1 and INP_N = V2.

$$V_{out} = \frac{R4}{R6}\left(1 + \frac{2R5}{RG}\right)(V2 - V1) = 1829.1\,(V2 - V1)$$

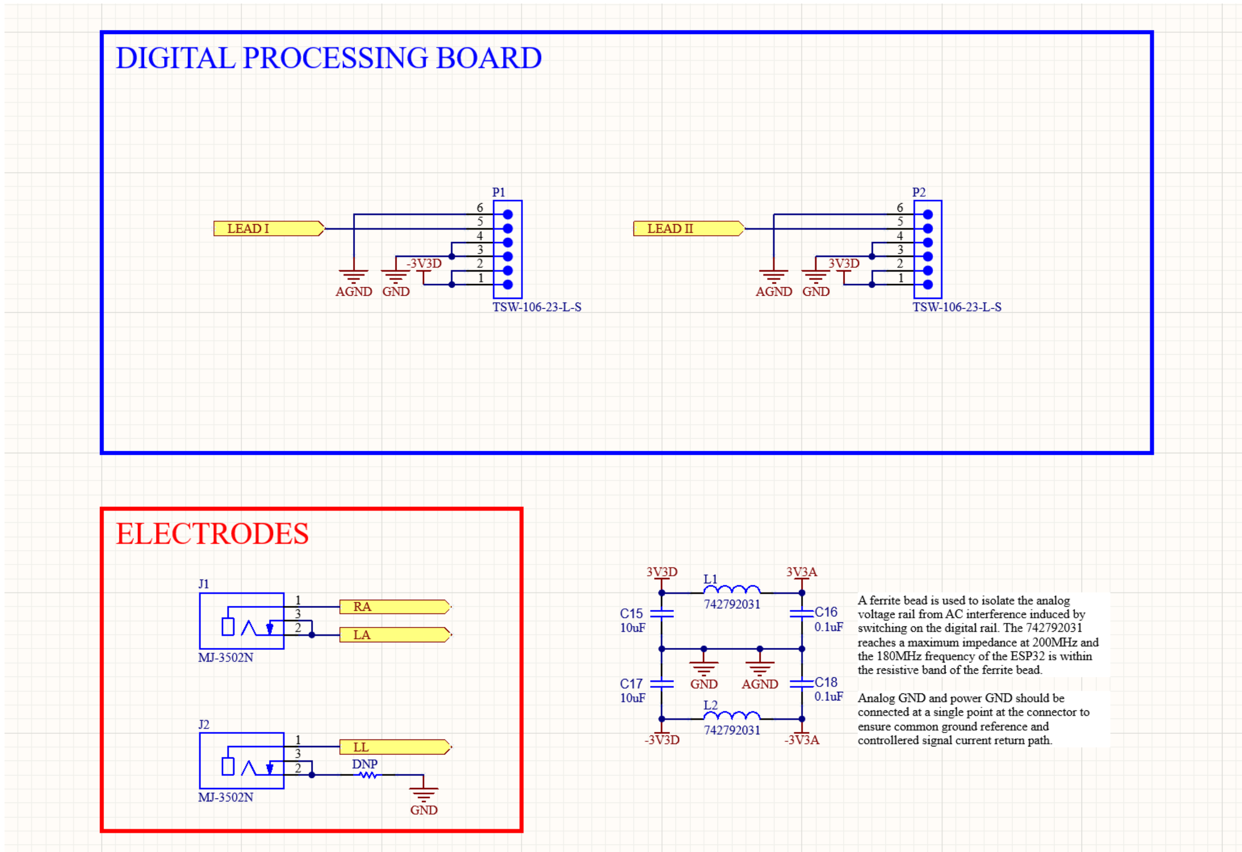
Sufficient test points are included to allow for testing of the instrumentation amplifiers without first passing the electrode signals through the patient protection components.

Filters.SchDoc



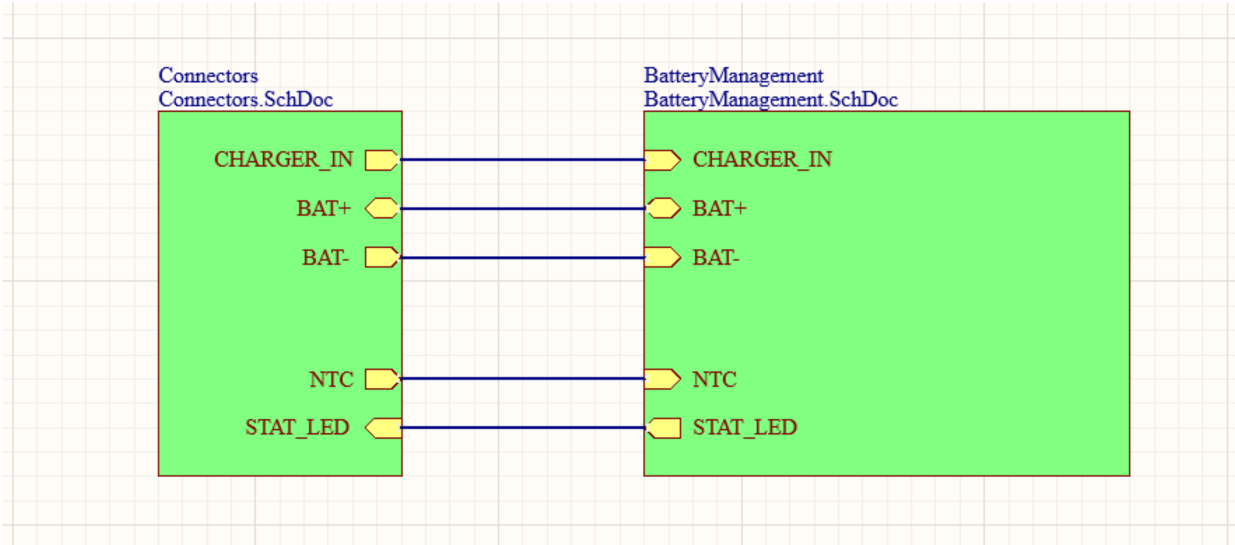
The filters consist of a cascaded high pass, Sallen-Key low pass, and an active twin t-notch filter. The high pass filter has a cutoff frequency of 0.159Hz set using R15 and C10. R10 forms a voltage divider with R15 to add a DC offset to ensure the signal is within 0V and 3.3V. D3 protects the input of the AD8648 quad channel operational amplifier. The Sallen-Key filter has a cutoff frequency of 194Hz with a quality factor of 0.5 and a damping ratio of 1. The active twin-t-notch filters signal components near 60Hz to reduce interference from mains electricity. U4C is placed in a buffer topology to prevent output swings from interfering with other signals in the package. A typical ECG has frequency components between 0.2 and 200Hz. These filters will . For a more detailed description of the filter performance, please refer to the Simulations section.

Connectors.SchDoc



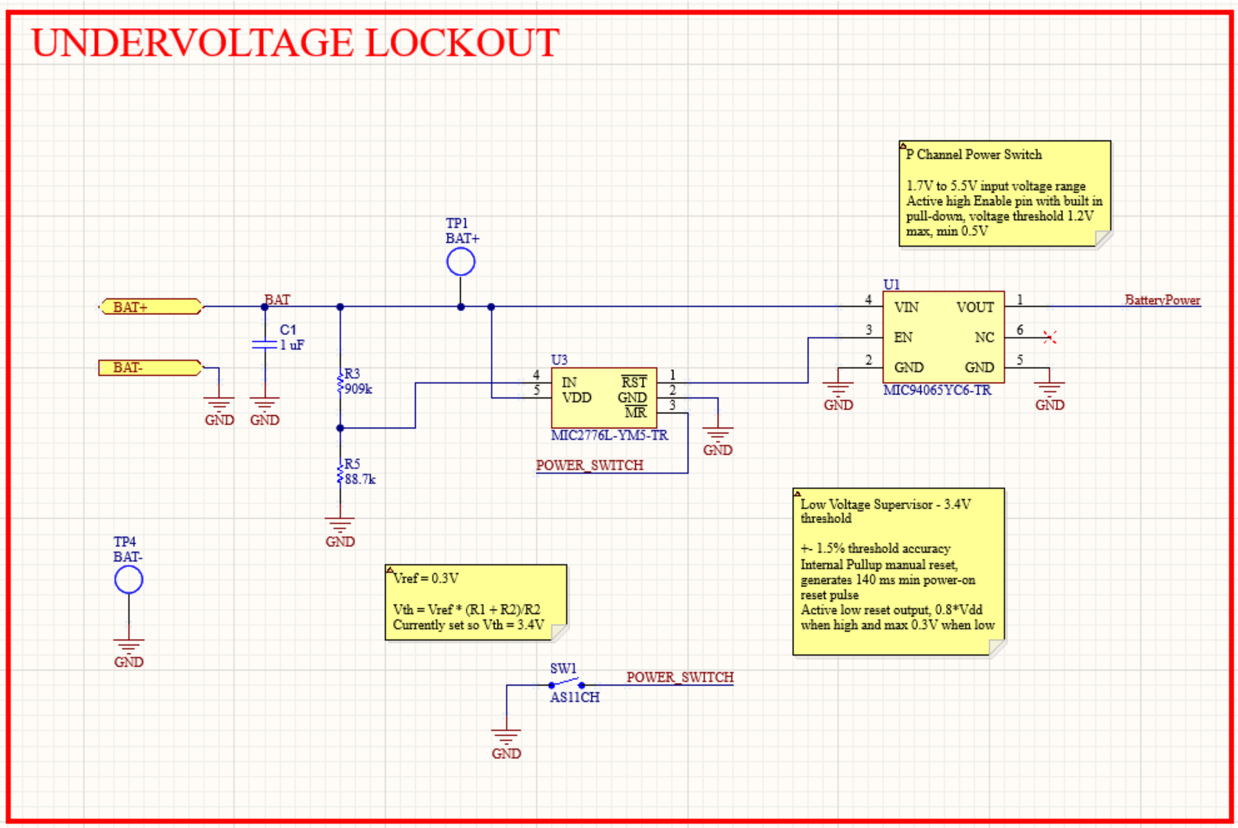
Standard 6-pos male header pins are used to connect the Analog Front End to the Digital Processing Board. Each signal and power pin has a corresponding ground pin to allow for optimal current return paths. Standard 3.5mm monopole jacks are used to connect to the electrode wires. As described above, a ferrite bead is included to isolate the analog voltage rail from the high frequency interference induced by switching on the digital rail. The inductors were selected such that the 180MHz frequency range of the ESP32 is within the resistive band of the ferrite bead. In case a channel fails, a Do Not Populate or DNP resistor pad is exposed to connect one of the electrodes to ground using a 0Ω resistor. This would allow the other channel to continue functioning with a ground referenced to the patient’s lower torso.

Battery Management Board



The top layer is separated into two schematic symbols for readability. The Connectors.SchDoc contains the JST connector symbols and the headers for interfacing with external boards. The JST connectors are used for external parts that will be fit into the enclosure/onto the battery, such as the LED indicator for charging status and the NTC for temperature sensing of the battery during charging. These signals are passed from the BatteryManagement.SchDoc, which manages the power rail generation as well as the charging management and protection circuits.

BatteryManagement.SchDoc
This schematic document is split into several different sections, covered below:



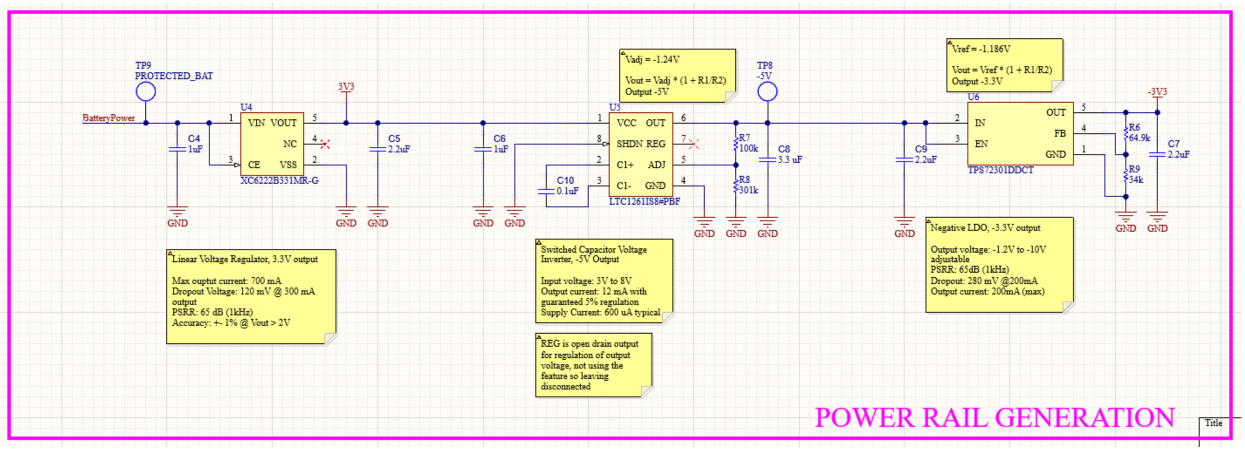
For the UVLO regulation/protection circuit, the two ports input are the positive and negative outputs of the LiPo battery. This battery has a range of voltages ranging from 2.7V to 4.2V at full charge; however, because of the presence of a 3.3V linear regulator with 120 mV dropout voltage in the power rail generation part of the schematic, the rest of the system will shut off at 3.4V (as the power rail will no longer generate 3.3V if the input to that IC decreases past the 120 mV dropout threshold). Thus, we implemented UVLO protection that will automatically shut off power to the rest of the system via a power switch (U1) if the voltage falls below 3.4V.

U3 is the UVLO regulation IC – Vdd is a supply voltage (acceptable range anywhere from -0.3V to 7V, and therefore can be powered directly off the battery), /MR is a manual reset that is internally pulled high – when externally connected to ground via an external switch, U3 will trigger a reset sequence. This will output low at /RST, therefore shutting off the P-Channel power switch U1, and cutting off battery power to the power rail generation subcircuit, and therefore power to the rest of the system. We can treat this switch (SW1) as a power switch for the user to turn off the system.

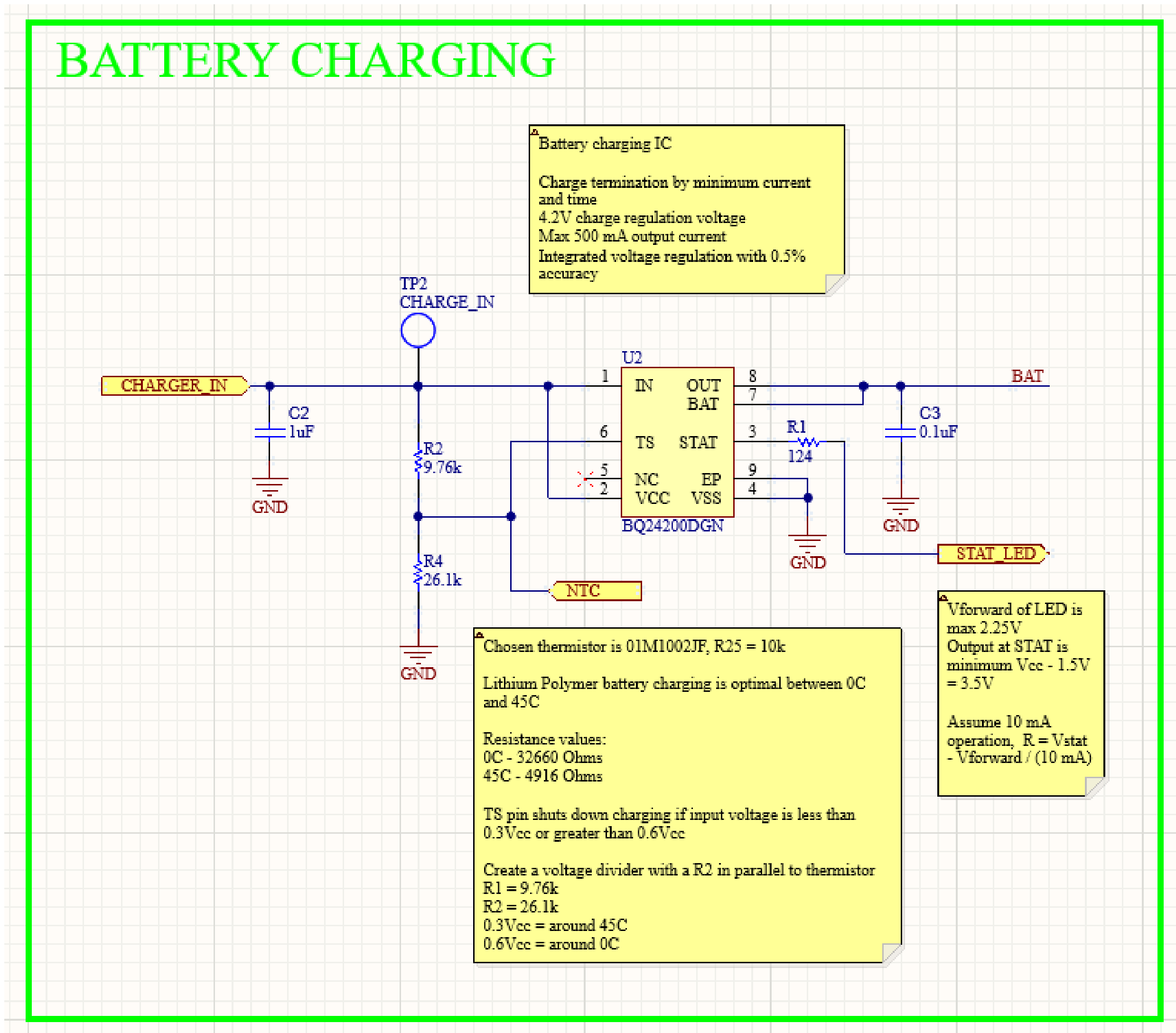
Additionally, pin 4 on U3 (IN) is compared to an internal voltage reference of 300 mV. Thus, we can calculate the threshold voltage Vth by using the voltage divider at IN, which gives the formula $V_{th} = V_{ref} * (R3 + R5)/R5$. $V_{th} = 0.3V * (909k + 88.7k) / 88.7k = 3.37V$, which is about

3.4V. If Vth falls below this value, /RST will go low, turning off the P-Channel power switch U1, which will then cut battery power to the power rail generation subcircuit, and therefore cut power off to the rest of the system.

Output of the /RST pin on U3 is minimum of 0.8*Vdd (0.8 * 3.4V minimum = 2.7V) when high, and max of 0.3V when low, while threshold for EN pin on U1 is max 1.2V. Thus, the power switch will always turn on when /RST is high and always turn off when /RST is low.



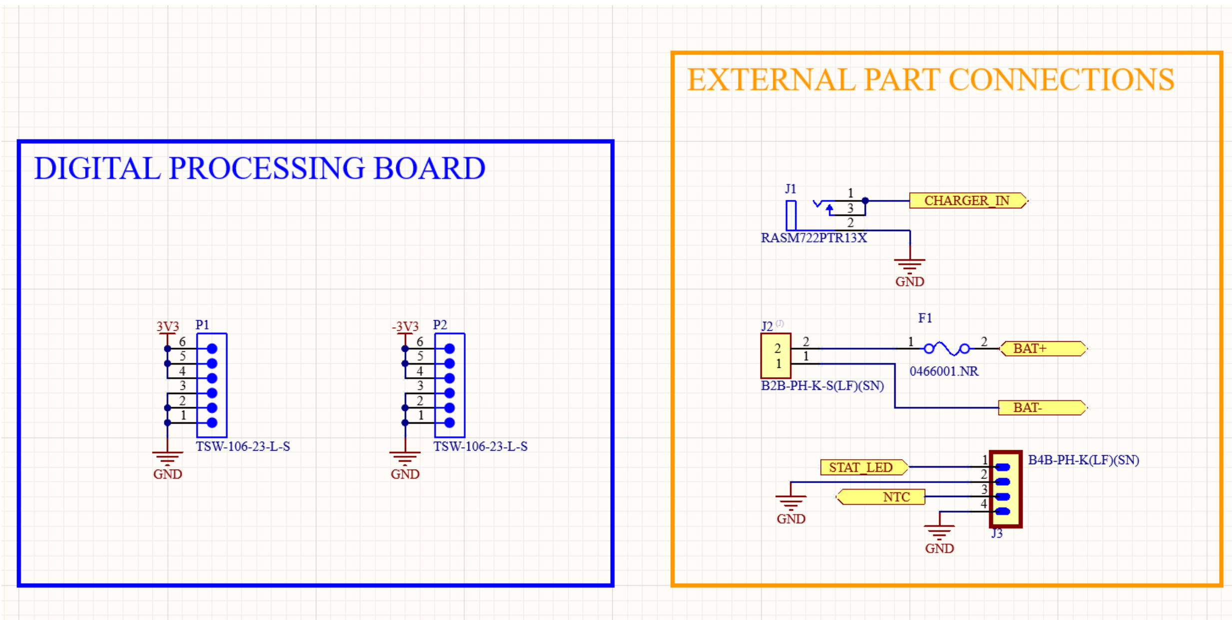
From the output of the P-Channel power switch in the undervoltage lockout subcircuit, we have the BatteryPower net. This net can vary from 3.4V (value of UVLO regulated voltage) to 4.2 V (fully charged LiPo battery). This value is input into U4, which is a 3.3V linear regulator. This LDO has a dropout of 120mV at 300 mA output. C4 and C5 are bypass caps, values are recommended by the datasheet. U5 is a switched capacitor voltage inverter – it takes in an input from 3V to 8V (so our input value of 3.3V will work). The REG pin is open drain output, which we will not be using so we can leave it open. We are also not using the SHDN (shutdown) capability, so we tie that to GND so that it is pulled low. C6 and C8 are bypass capacitors recommended by the datasheet. C10 is the capacitor recommended by the datasheet, and OUT outputs the negative voltage. Using the internal reference voltage at the ADJ pin (-1.24V), we can use the formula $V_{out} = V_{adj}$ * (1 + R8/R7) to get the output voltage - V_{out} = -1.24V * (1 + 301k / 100k) = -4.97V. We can then pass this -5V rail through a negative LDO (U5) to get a -3.3V rail, which is necessary for some of the dual supply amplifiers on the instrumental amplifier. U5 is also an adjustable output LDO, so we must use the internal reference voltage at the FB pin (-1.18V) to calculate the output value. $V_{out} = V_{ref}$ * (1 + R6/R9), so V_{out} = -1.18V * (1 + 64.9k/34k) = -3.4V. C6 and C7 are bypass caps recommended by the datasheet. From here, the 3.3V rail and the -3.3V rail are passed to the Connectors.SchDoc, where they are connected to header pins going to the digital processing PCB.



Finally, on the battery charging subcircuit, we have U2, which is a battery charging management IC. It contains temperature sensing and charging status LED output. C2 and C3 are bypass capacitors. IN takes an input from the charging port (on the Connectors.SchDoc), which will take an input from a 5V current limited wall charger. If voltage input at TS is less than 0.3*Vcc or more than 0.6*Vcc, the charging will stop. R2 and R4 form a resistive bridge which sets the threshold values for temperature sensing. Lithium polymer battery charging is optimal between 0C and 45C, so taking the resistance values of the NTC at those temperatures (32.66k and 4.916k respectively), we can calculate the values of R4 and R2 using a system of equations. The values we obtain from this are R4 = 26.1k and R1 = 9.76k. At the lower threshold, 0.3Vcc, the NTC should measure around 45C and at the higher threshold, 0.6Vcc, the NTC should measure around 0C.

Charge output is from OUT, and battery voltage sense input comes from BAT. Both are connected to the positive battery terminal. Finally, the STAT output powers an LED – this pin outputs a minimum value of Vcc - 1.5V, which is equal to 3.5V. Assuming an external battery takes 10 mA to drive and has a forward voltage of 2.25V, we can calculate the resistor in series with the LED to be R = $(V_{stat} - V_{forward})/(10\text{ mA})$ = 125 Ohms. This output is then connected to the Connectors.SchDoc document, where it is connected to a JST header connected to an external LED.

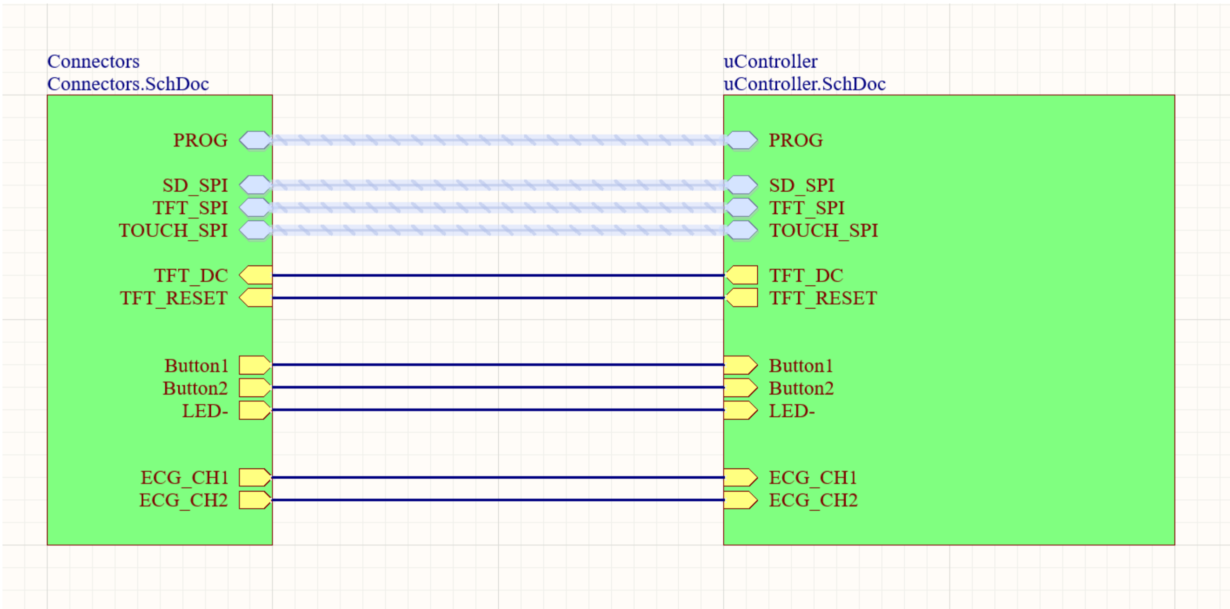
Connectors.SchDoc



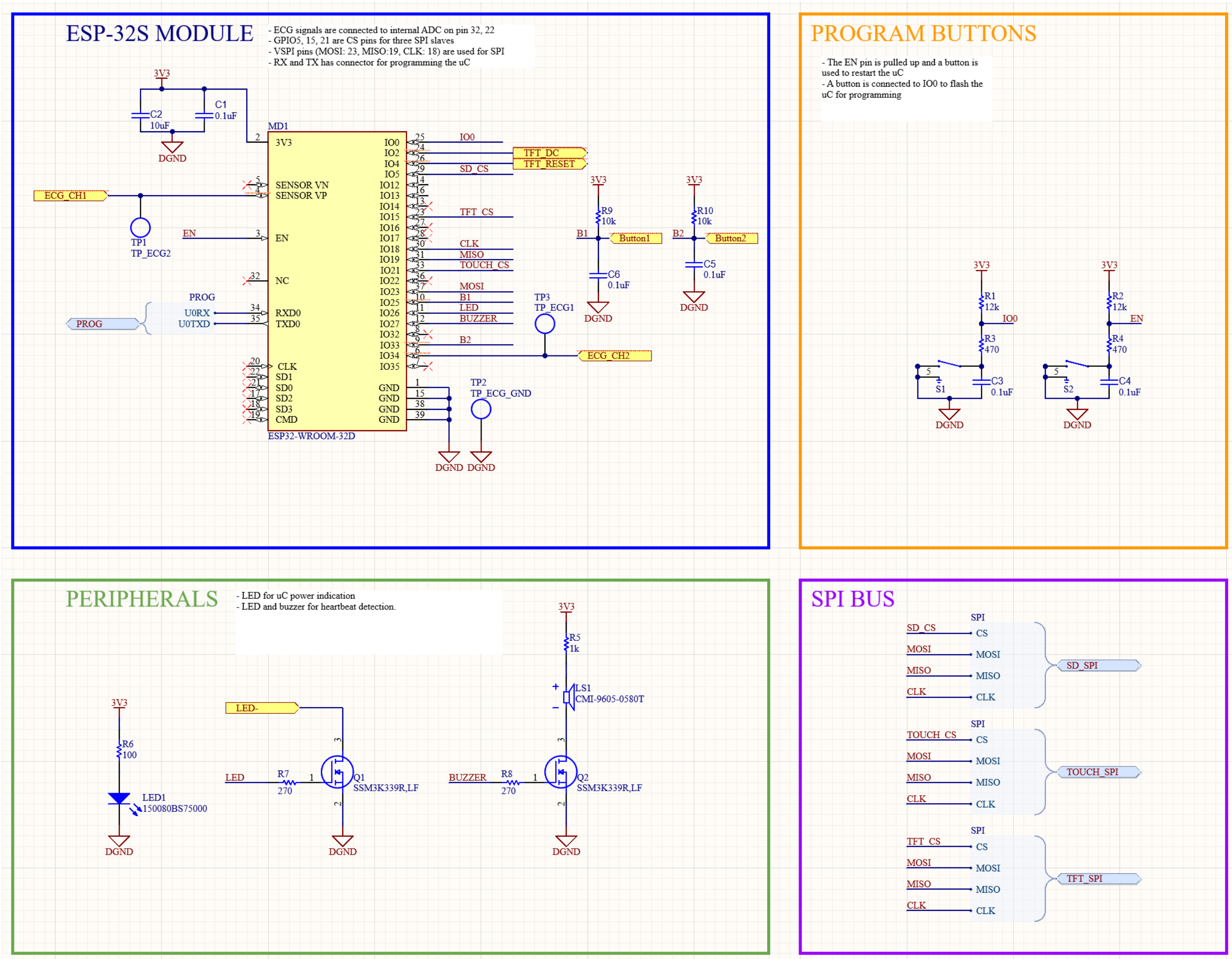
This is the document containing connectors to external boards and components. There are two sets of 6 header pins connecting to the digital processing board, which carries the 3V3 and -3V3 rails respectively. Then, there are external part connections – the status LED output and NTC input are connected to a four pin JST connector. The battery input/output is connected to a 2 pin JST connector, with a 1A fuse between the battery and the board – this is an extra failsafe, in case the battery charging IC fails. We know from the power budget that total current draw should not exceed 300 mA, so this is a reasonable value to set the fuse to be.

Finally, the charger input is connected to a barrel connector J1.

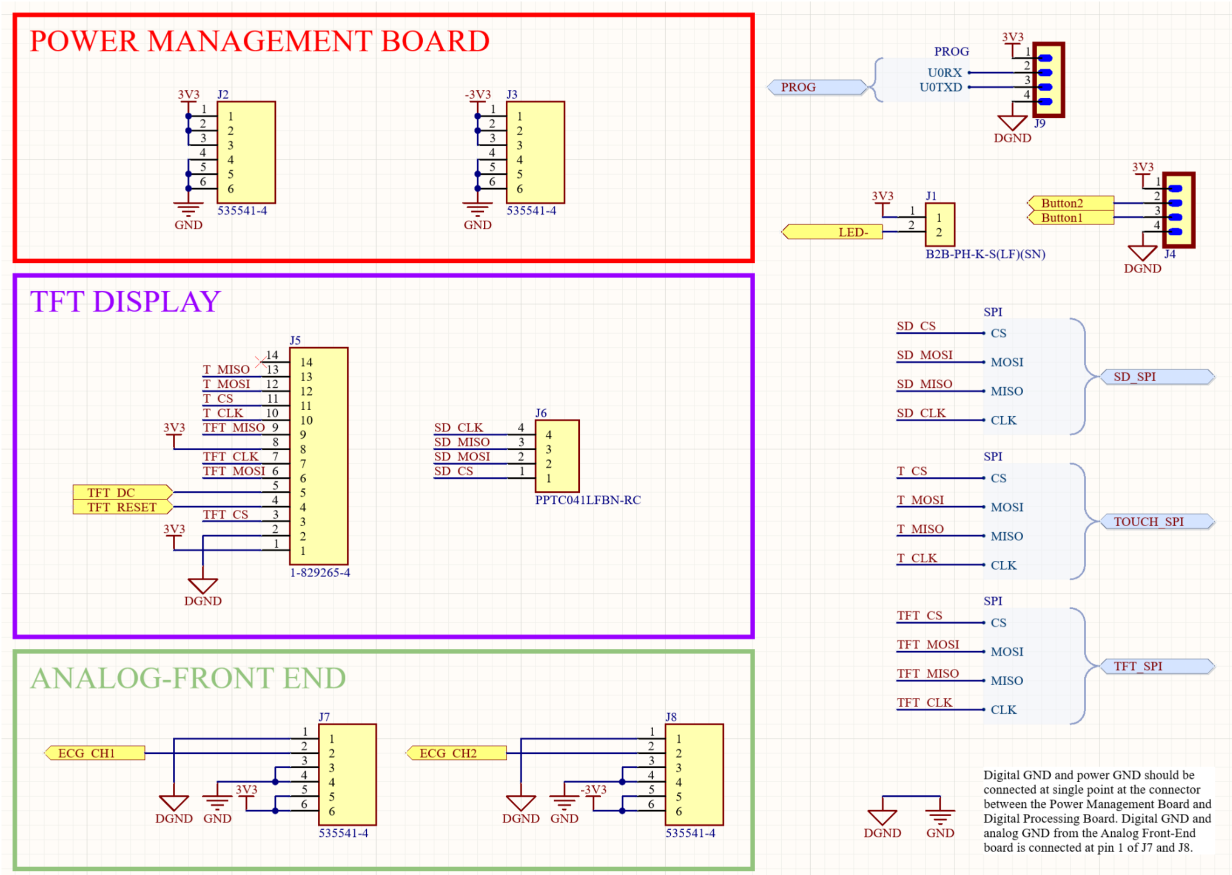
Digital Processing Board



The top level is separated into two sheets for readability. The signal harness feature in Altium has been used to group together the SPI signals to/from the three slave devices, and the program signals that is used to upload sketches to the microcontroller. The connector sheet contains all elements that interface with components that are not directly mounted on the digital processing board, such as display connectors, connectors for programming, user interface buttons/LEDs, and analog signals from the analog front end board. The microcontroller sheet takes the SPI signals from the SD card module, the display, and the touch module. It also takes in the user interface signals, and the analog signals from the analog front end board to process and display it accordingly.

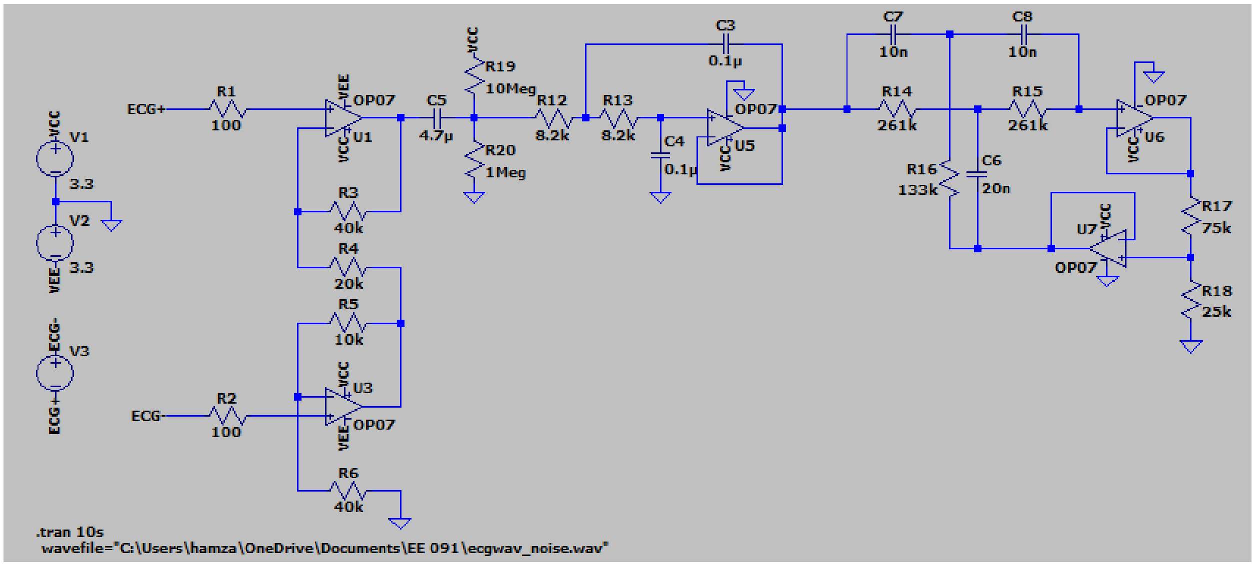


The *ESP32 module* controls three slave devices over SPI: the TFT display, the touch module, and the SD card module. Two ECG signals from the analog front end board are connected to the internal ADC on pin 4 and pin 34, as prototyped on the breadboard. These two traces have a test point pad to verify signal integrity. The RX and TX pins, along with the 3V and ground are exposed to the user through a JST connector, for programming purposes. There are two external buttons that can be installed in case the touch screen functionalities do not work after assembling. These buttons are debounced and connected to GPIO25 and GPIO33. Separate from these buttons, there are program buttons that are used for restarting and programming buttons. This design has been referenced from the ESP32 breakout board, in which two SMD push buttons are connected to IO0 and EN pins. Setting EN to ground via the push button will reset the module, and setting IO0 to ground will set the module in program state. There are three peripheral devices. One is a blue LED which indicates 3V power on the board. This allows for easy visual inspection of power during debugging processes. The second is a red LED that indicates the heartbeats. The third is a buzzer that will beep according to the detected heartbeats.

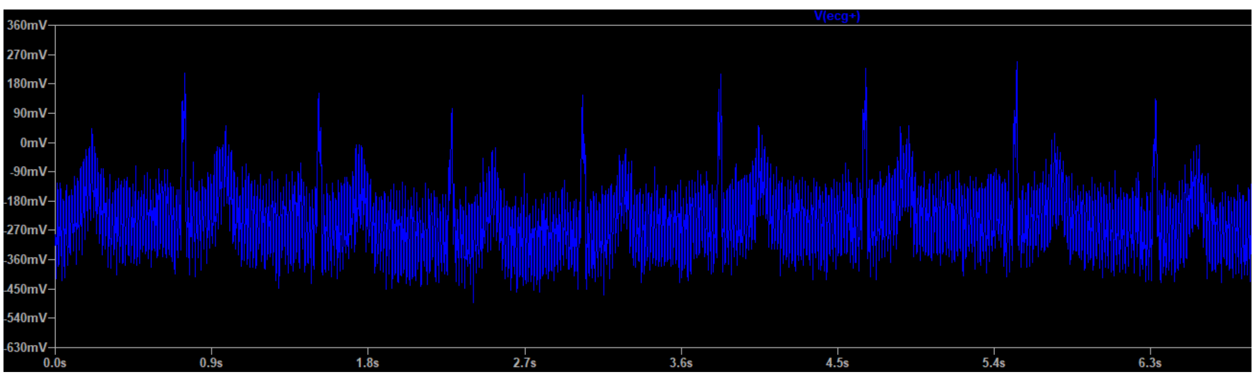


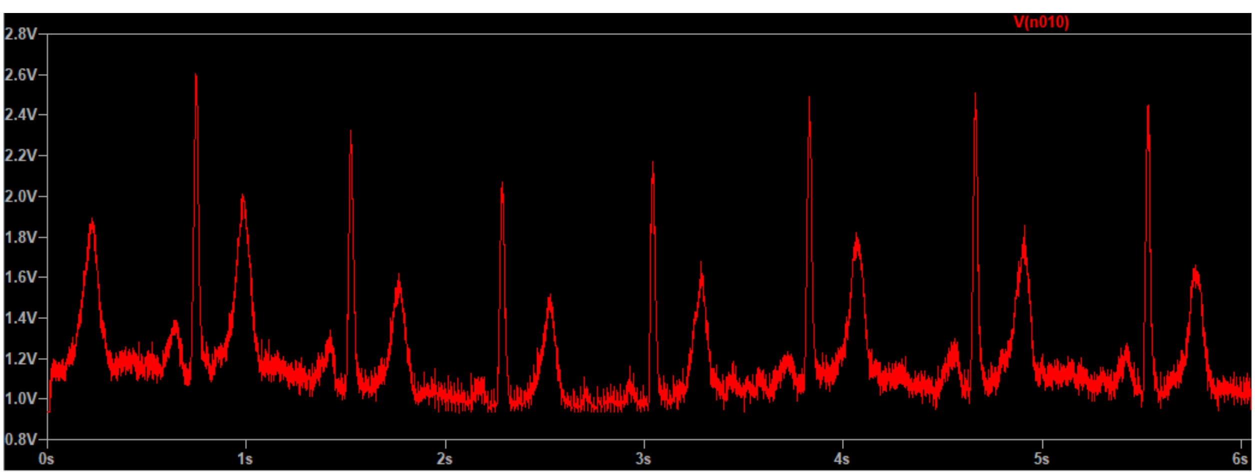
The connectors sheet contains the connectors that interface with components that are not directly on the digital processing board. There is a connector dedicated to receiving 3V power from the power management board, and a separate connector dedicated to receiving -3V power. A 14 pin header is used to connect to the ILI9341's display module and the touch module, and a 4 pin header is used to connect to the SD card module. Two separate connectors are used to receive the analog signals from the analog front end board. Lastly, there are three JST connectors for user buttons, program signals, and external LED.

Simulations

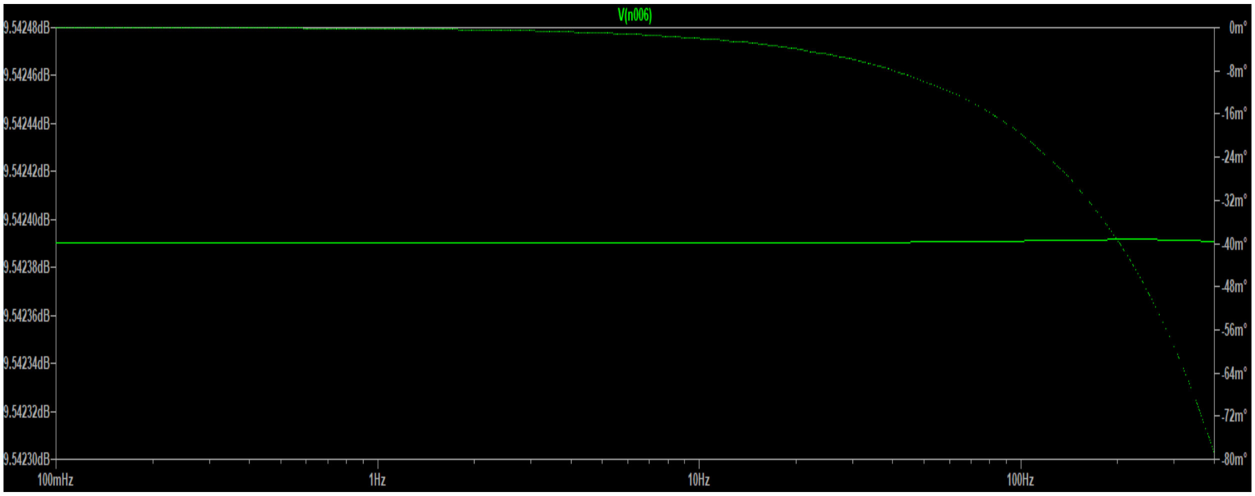


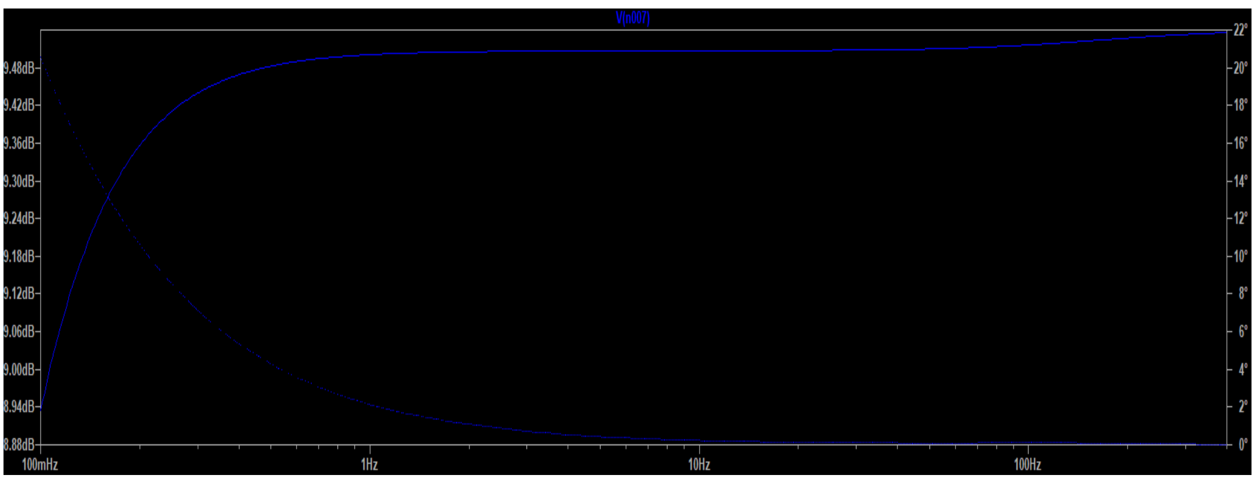
To evaluate the performance of the filters before ordering components, the Analog Front End was simulated in LTSpice. A noisy ECG file was obtained online and used to ensure the filters did not attenuate critical frequency components of the ECG waveform. The noisy ECG is shown below in blue and the output in red. As can be seen, the circuit accurately recovered the original ECG signal.

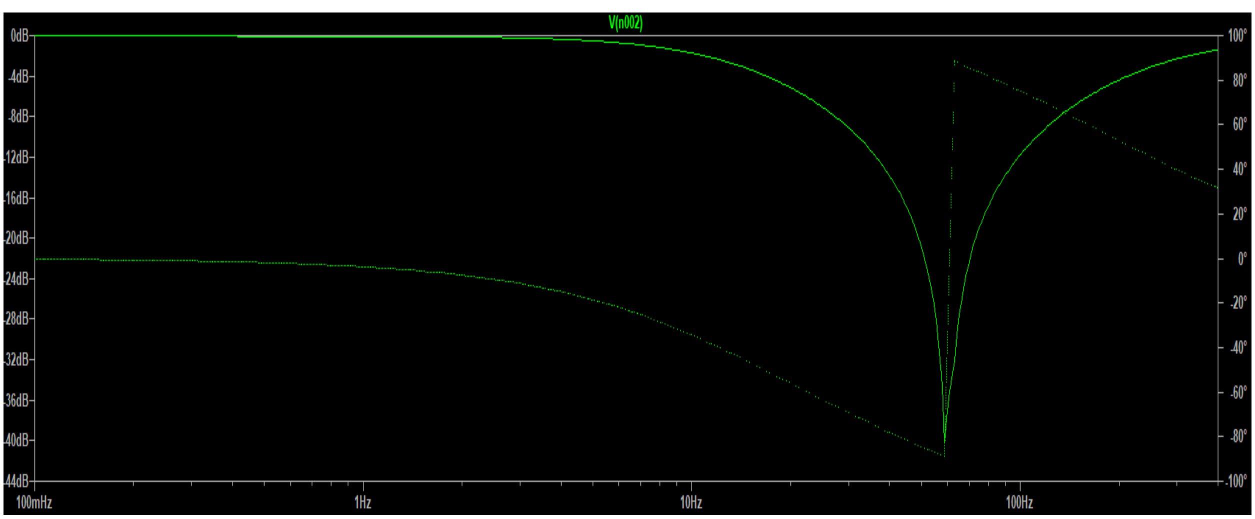




The following plots show the frequency response of the instrumentation amplifier, high pass filter, and active twin-t-notch filter respectively. The gain of the instrumentation amplifier is consistent across the pertinent frequencies. The high pass filter shows the correct cutoff frequency of 0.159Hz. The twin-t-notch filter has a depth of -40dB at 60Hz.



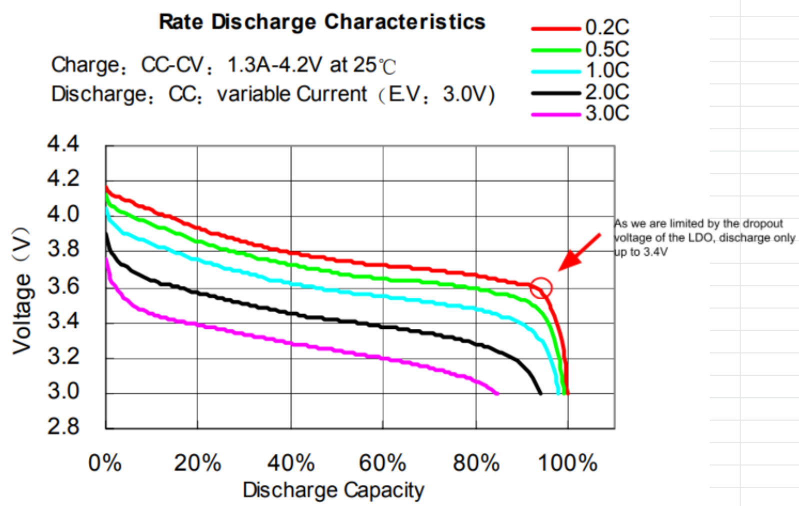




Power Budget

-5V Rail									
Part Number	Part Function	Number of Parts Needed	Supply Current Consumed per Part		Total Current Consumed				
TPS72301DDCT	Negative Voltage Linear Regulator	1	3.50E-04	A	3.50E-04	A			
							Total:	3.50E-04	A
- 3.3V Rail	Max -200 mA								
Part Number	Part Function	Number of Parts Needed	Supply Current Consumed per Part		Total Current Consumed				
OP07CP	Instrumentation Amplifier	6	2.00E-03	A	1.20E-02	A			
AD8618ARUZ	Filtering	2	2.00E-03	A	4.00E-03	A			
							Total:	1.60E-02	A
+ 3.3V Rail	Max 500 mA								
Part Number	Part Function	Number of Parts Needed	Supply Current Consumed per Part		Total Current Consumed				
ESP32	Microcontroller	1	1.00E-01	A	1.00E-01	A			
ILI9341	TFT Display	1	9.00E-02	A	9.00E-02	A			
OP07CD	Instrumentation Amplifier	6	2.00E-03	A	1.20E-02	A			
AD8618ARUZ	Filtering	2	2.00E-03	A	4.00E-03	A			
							Total:	2.06E-01	A
Directly from Battery									
Part Number	Part Function	Number of Parts Needed	Supply Current Consumed per Part		Total Current Consumed				
XC6222B331MR-G	Linear Dropout Regulator	1	1.00E-04	A	1.00E-04	A			
MIC2776L-YM5-TR	UVLO Voltage Supervisor	1	3.00E-06	A	3.00E-06	A			
MIC94065YC6-TR	P Channel Power Switch	1	2.00E-06	A	2.00E-06	A			
LED	LED	2	1.00E-02	A	2.00E-02	A			
							Total:	2.01E-02	A

Grand Total Current Consumption:	
2.42E-01	A
Discharge Rate:	
1.21E-01	C
Discharge Capacity:	
0.95	
Total Power Available:	
1900	mAh
Total Battery Life:	
7.84	hr



For the power budget, ICs were split into different power rails. Quiescent current for each IC was found through their datasheets, and multiplied by the number of ICs used. Then, all the currents were summed up per rail to ensure that the current outputs of the linear regulators would be enough to support all the ICs. Current draw for the microcontroller and display were also verified by bench tests.

From all the ICs, grand total current consumption comes to about 242 mA. This value was verified through bench testing – the actual value comes out to be about 120 mA instead. The rate discharge chart is from the datasheet of a comparable battery to the one we are using – a current consumption of 242 mA equates to a discharge rate of 0.121C for a 2000 mAh battery. Thus, from the graph, we can see that the discharge capacity is about 95% of the total (or 1900 mAh). This gives a total hypothetical battery life of about 7.84 hours, which fulfills our battery life requirement. Using our bench tests, it turns out that our actual battery life will be about 15.83 hrs based on current draw during operation, which also fulfills our battery life requirement.

Bill of Materials

Board components

Designator	Value	Manufacturer Part Number	Quantity
Analog Front End			
C1_InstrAmp1, C1_InstrAmp2, C2_InstrAmp1, C2_InstrAmp2, C3_InstrAmp1, C3_InstrAmp2, C4_InstrAmp1, C4_InstrAmp2, C5_InstrAmp1, C5_InstrAmp2, C6_InstrAmp1, C6_InstrAmp2, C13_Filters1, C13_Filters2, C14_Filters1, C14_Filters2, C16, C18	0.1uF	CL21B104KACNNNC	18
C7_Filters1, C7_Filters2, C11_Filters1, C11_Filters2	0.1uF	08055C104JAT4A	4
C8_Filters1, C8_Filters2, C9_Filters1, C9_Filters2	10nF	C2012C0G1H103J060AA	4
C10_Filters1, C10_Filters2	1uF	08053C105JAT2A	2
C12_Filters1, C12_Filters2	20nF	08051C203JAT4A	2
C15, C17	10uF	CL21A106KAYNNNE	2
D1_INP1, D1_INP2, D1_INP3		BAV199	3
D2_INP1, D2_INP2, D2_INP3		SMBJ14A-13-F	3
DNP, R1_INP1, R1_INP2, R1_INP3, R2_INP1, R2_INP2, R2_INP3, RG_InstrAmp1, RG_InstrAmp2	0, 1k	RT0805FRE101KL	9
J1, J2, P1, P2,	75k, 25k		34
R3_INP1, R3_INP2, R3_INP3	1M	CRG0805F1M0	5
R4_InstrAmp1, R4_InstrAmp2	470k	CRG0805F470K	2
R5_InstrAmp1, R5_InstrAmp2, R6_InstrAmp1, R6_InstrAmp2, R7_InstrAmp1, R7_InstrAmp2, R8_InstrAmp1, R8_InstrAmp2, R9_InstrAmp1, R9_InstrAmp2	100k	ERJ-6ENF1003V	10
R10_Filters1, R10_Filters2	3.3M	RC0805FR-073M3L	2
R11_Filters1, R11_Filters2, R12_Filters1, R12_Filters2	8.2k	CRCW08058K20JNEA	4

R13_Filters1, R13_Filters2, R14_Filters1, R14_Filters2	261k	ERJ-6ENF2613V	4
R15_Filters1, R15_Filters2	1M	ERJ-6GEYJ105V	2
R16_Filters1, R16_Filters2	133k	ERJ-6ENF1333V	2
U1_InstrAmp1, U1_InstrAmp2, U2_InstrAmp1, U2_InstrAmp2, U3_InstrAmp1, U3_InstrAmp2		OP07CD	6
R17_Filters1, R17_Filters2	75k	RMCf0805ft75k0	3
R19_Filters1, R19_Filters2,	25k	CPF-A-0805B25KE1	2
L1, L2,		742792031	
U4_Filters1, U4_Filters2		AD8648ARUZ	
Digital Processing			
C2, C5, C6	10uF	CL21A106KAYNNNE	3
C1, C3, C4	0.1uF	CL21B104KACNNNC	5
LED1		150080BS75000	1
LS1		CMI-9605-0580T	1
MD1		ESP32-WROOM-32D	1
Q1, Q2		AO3414	2
R1, R2	12k	ERJ-6ENF1202V	2
R3, R4	470	ERJ-6ENF4700V	2
R5	1k	RT0805FRE101KL	1
R6	100	RMCF0805FT100R	1
R7, R8	270	AC0805FR-10270RL	2
S1, S2		KMR221GLFS	2
J1, J9		S04B-PASK-2(LF)(SN)	2
R9, R10	10k	RMCF0805FT10K0	2
J4			
J2, J3, J5, J6, J7, J8			
Power Management			
C3, C6, C7, C9, C11	1 uF	CL21B105KAFNNNE	5
C4, C5, C12	0.1uF	CL21B104KACNNNC	3
C8	2.2 uF	CL21B225KOFNFNE	3
C10	3.3 uF	C2012X7R1A335K125AC	1
F2	0.075Ω	0466001.NR	1
R5	124	RC0805FR-07124RL	1
R6	9.76k	ERJ-6ENF9761V	1
R7	909k	CRCW0805909KFKEAHP	1
R8	26.1k	CRCW080526K1FKEAHP	1

R9	88.7k	RC0805FR-0788K7L	1
R11, R12	100k	ERJ-6ENF1003V	2
R13	301k	CRCW0805301KFKEA	1
SW1		AS11CH	1
TP1, TP2, TP3, TP4, TP5, TP6, TP7, TP8, TP9			9
U1		MIC94065YC6-TR	1
U2		BQ24200DGN	1
U3		MIC2776L-YM5-TR	1
U4		XC6222B331MR-G	1
U5		LTC1261IS8#PBF	1
U6		TPS72301DDCT	1
	61.9k	RC0805FR-0761K9L	1
	34k	RC0805FR-0734KL	1
J1		RASM722PTR13X	1
J2		620102131822	1
J3, J4		620102131822	2
P1, P2		TSW-106-23-L-S	2

Off-board Components and Materials

Part	Manufacturer Part Number	Quantity
4-48 0.25’’ Hex Standoff	2433	4
4-48 0.25’’ Phillips Head Screw	4072691	4
3m Red Dot Monitoring Electrode	3M 2560	1

Tools

CraftUnique Craftbobox Plus
Medium Phillips Screwdriver
JST crimp tool
Wire Stripper
FT232RL FTDI Programmer

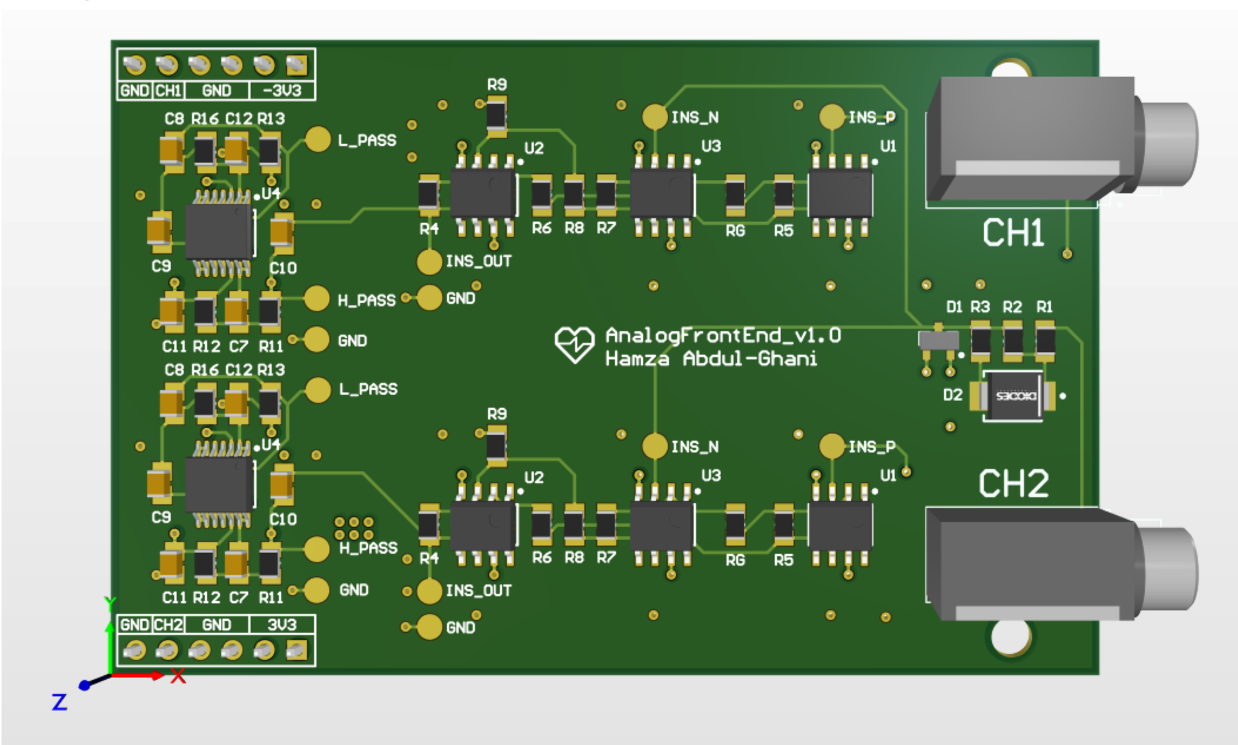
Parts were sourced from Digikey, Arrow Electronics, and Mouser. The PCBs were ordered from PCBWay. The overall cost of the project was roughly $440, however, more than twice the quantity of components were ordered in case of damages. This cost also included tooling, materials, and shipping. Due to the pandemic and the global short shortage, prices and shipping cost have been higher than normal. If this unit was to be mass manufactured and assembled, a single unit is estimated to cost around $76 accounting for reduced wholesale pricing.This achieves our goal of producing a portable, inexpensive and accessible ECG device.

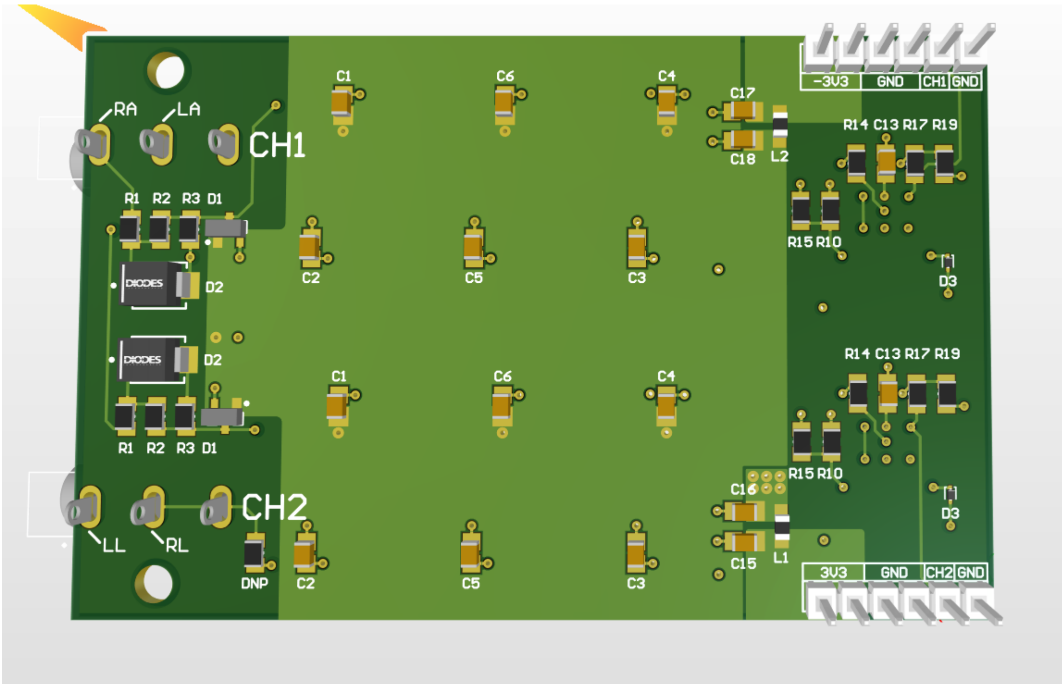
Layout and Routing

#	Name	Material	Type	Weight	Thickness	Dk	Df
	Top Overlay		Overlay				
	Top Solder	SM-001	Solder Mask		0.0254mm	4	0.03
	Top Surface Fini...	PbSn	Surface Finish		0.01999mm		
1	Top Layer	CF-004	Signal	1oz	0.035mm		
	Dielectric 1	PP-017	Prepreg		0.12954mm	4.3	0.02
	Dielectric 2	PP-017	Prepreg		0.12954mm	4.3	0.02
2	Int1 (GND)	CF-004	Plane	1oz	0.035mm		
	Dielectric 3	Core-039	Core		0.7112mm	4.8	0.02
3	Int2 (PWR)	CF-004	Plane	1oz	0.035mm		
	Dielectric 4	PP-017	Prepreg		0.12954mm	4.3	0.02
	Dielectric 5	PP-017	Prepreg		0.12954mm	4.3	0.02
4	Bottom Layer	CF-004	Signal	1oz	0.035mm		
	Bottom Surface...	PbSn	Surface Finish		0.01999mm		
	Bottom Solder	SM-001	Solder Mask		0.0254mm	4	0.03
	Bottom Overlay		Overlay				

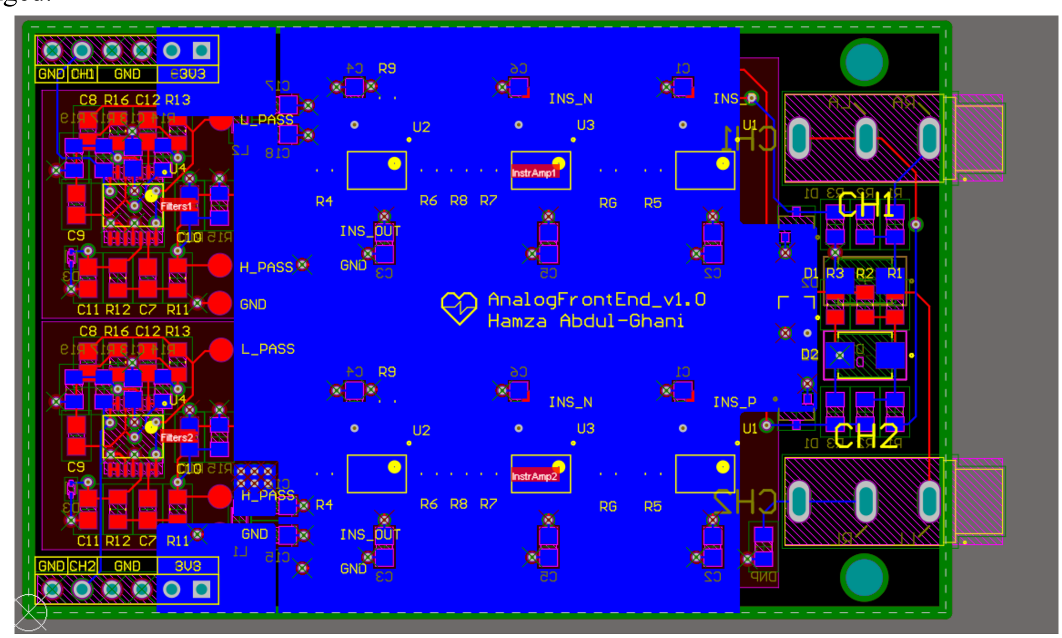
A four-layer stack up with 1oz. copper weights was utilized for all three boards to minimize fabrication costs while leaving enough room for adequate separation between the different components. Most components were placed on the top layer to allow us to use a reflow oven. Power ground and digital ground are tied together at a single point at the Digital Processing Board to adhere to a star grounding scheme.

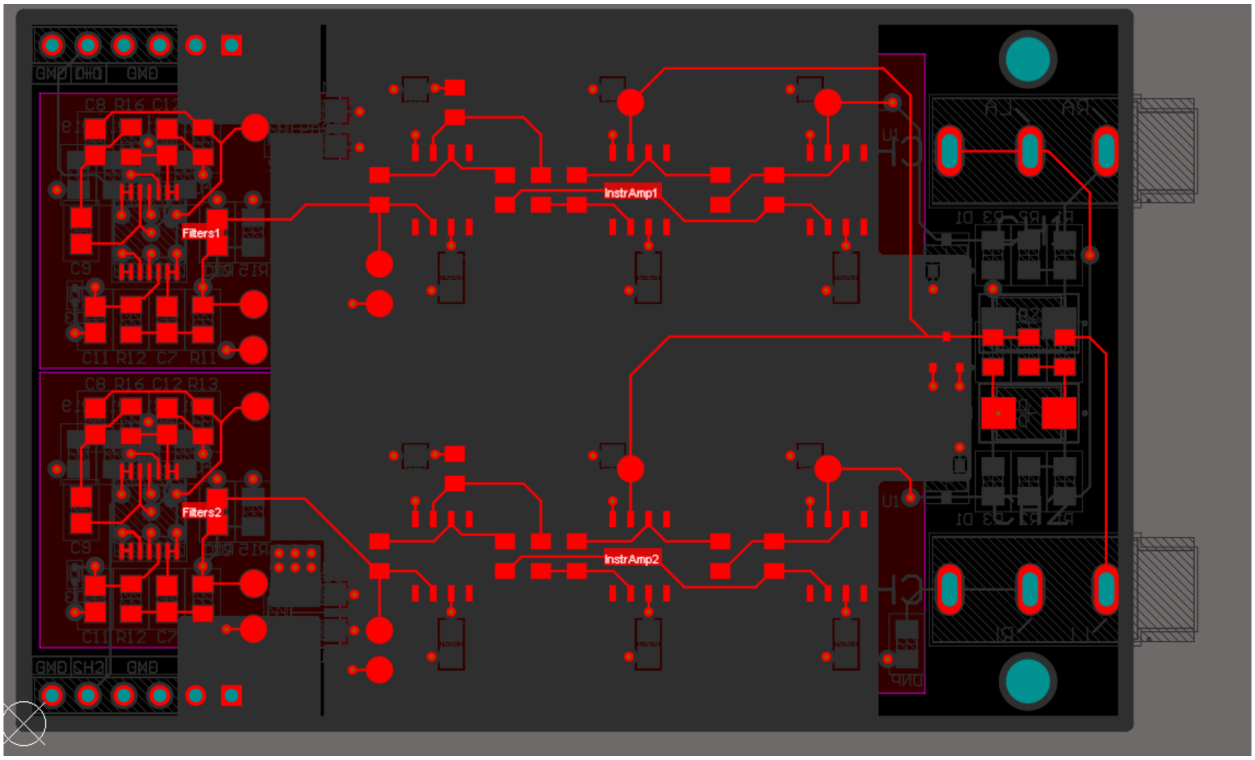
Analog Front-End Board

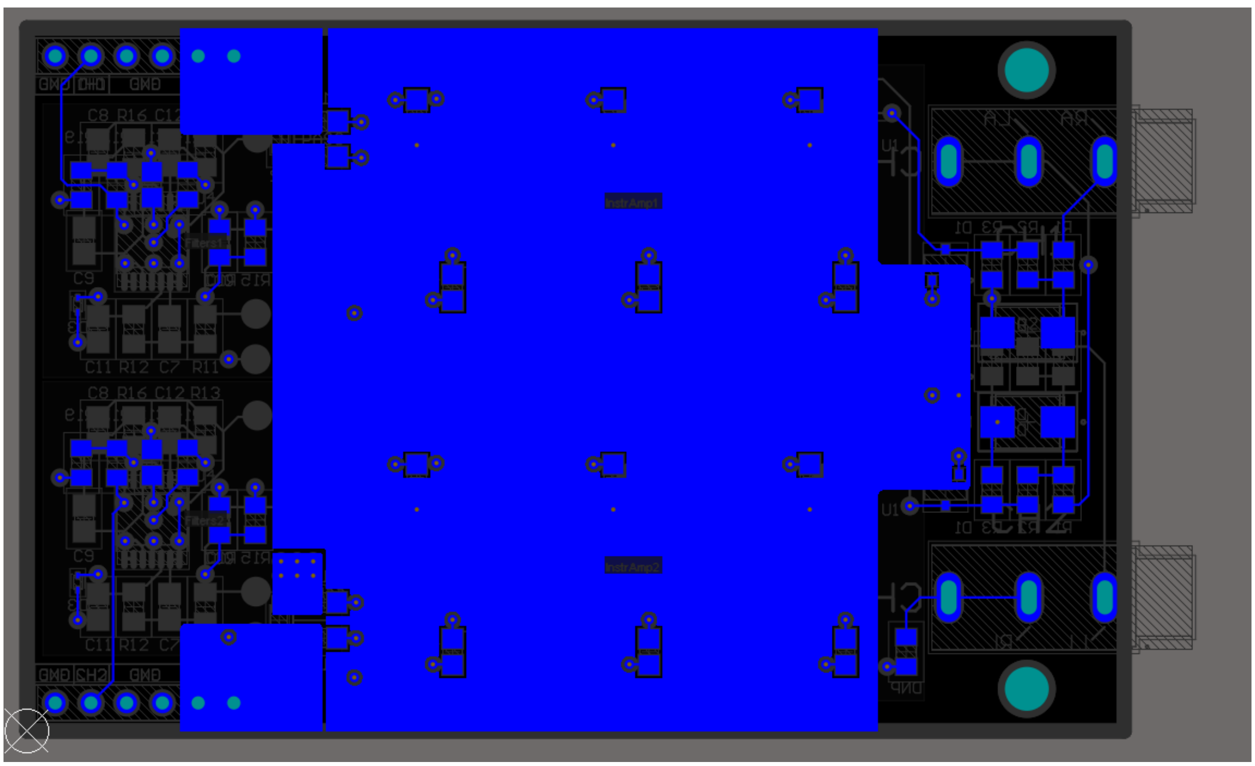




The design uses Altium's multichannel tool to allow for symmetric placement of channel 1 and channel 2 components. The 3.5mm electrode inputs extend beyond the board to be easily accessible from outside the enclosure. Decoupling capacitors are placed on the bottom layer along with a few of the filter components. Trace lengths were minimized by placing the instrumentation amplifier components in a linear fashion from left to right on the board. Test points and header pins are clearly labeled on the silkscreen for debugging purposes. Adequate space is provided around the gain resistor in case it needs to be changed.

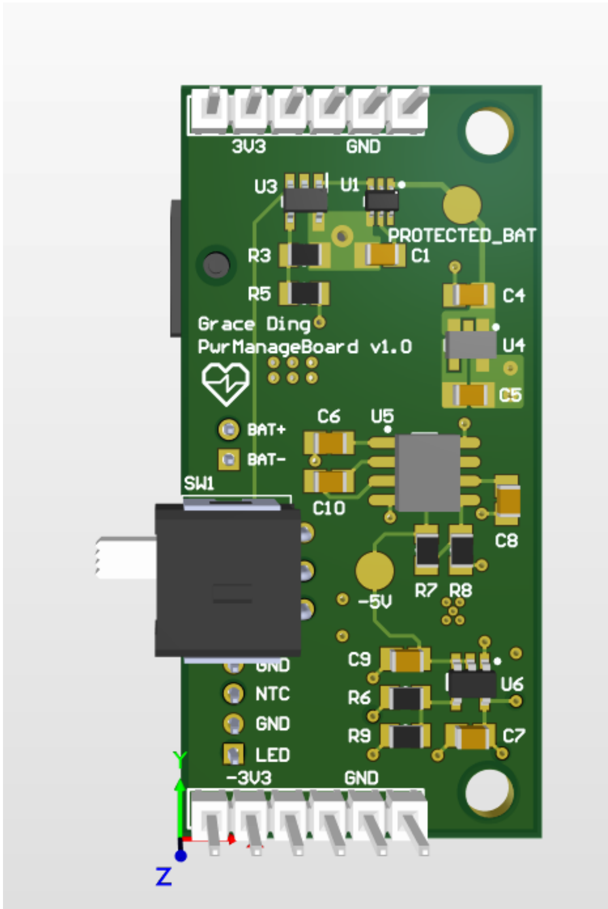


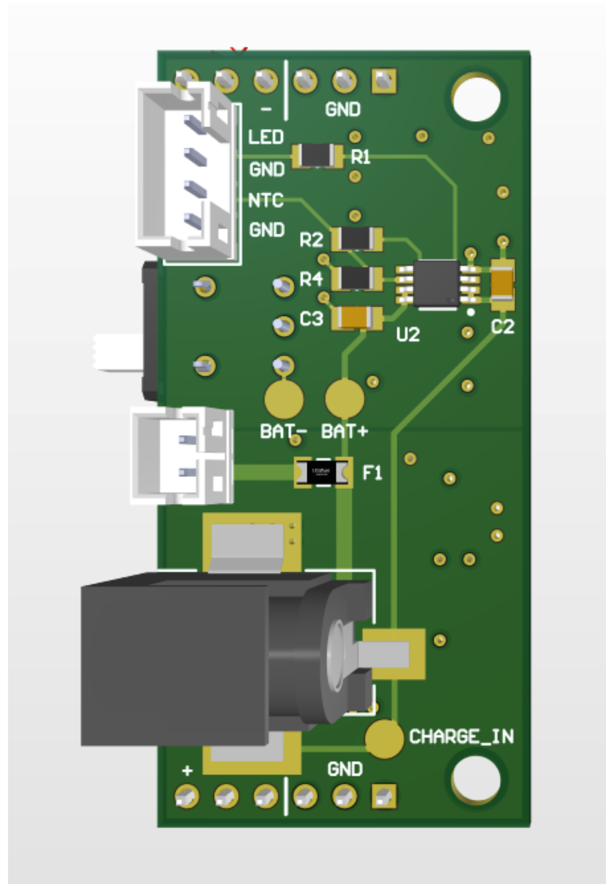




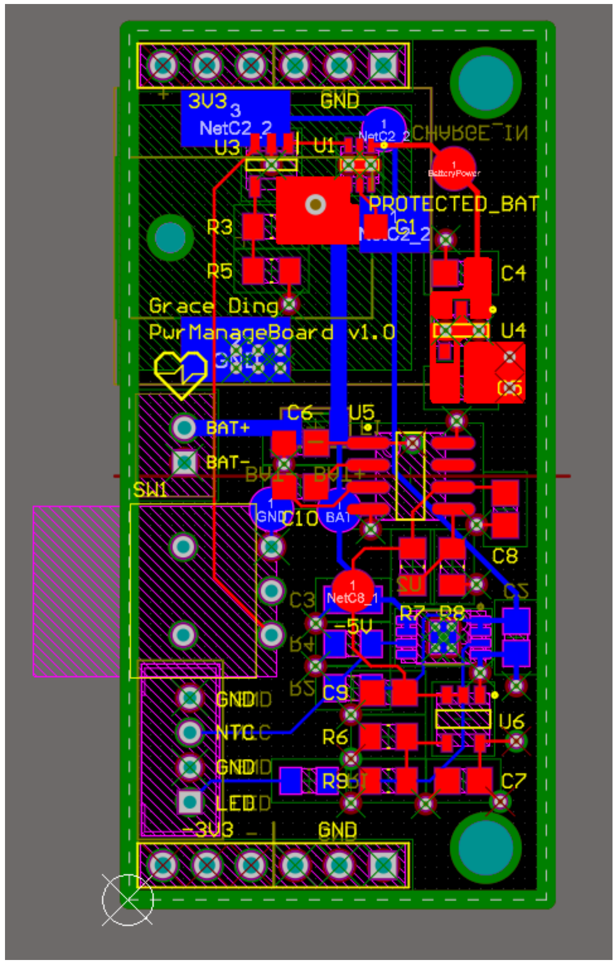
To power the instrumentation amplifier op-amps, a polygon pour on the bottom layer supplied -3.3V while the second internal layer supplied 3.3V. The ground plane was not segmented to ensure adequate short return paths and minimal parasitic inductances. Traces on the top layer were kept short and maintained a separation distance of at least 10mil to minimize crosstalk.

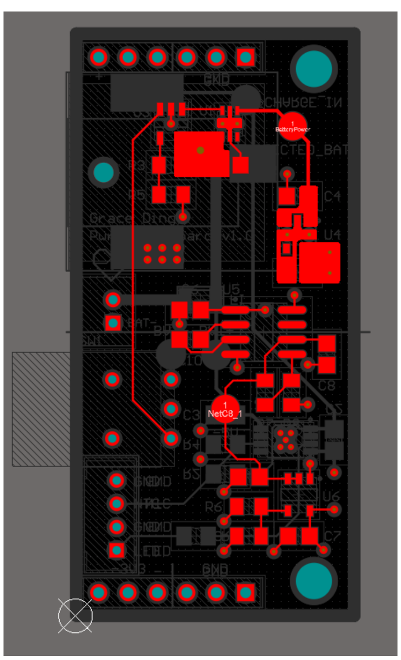
Battery Management Board

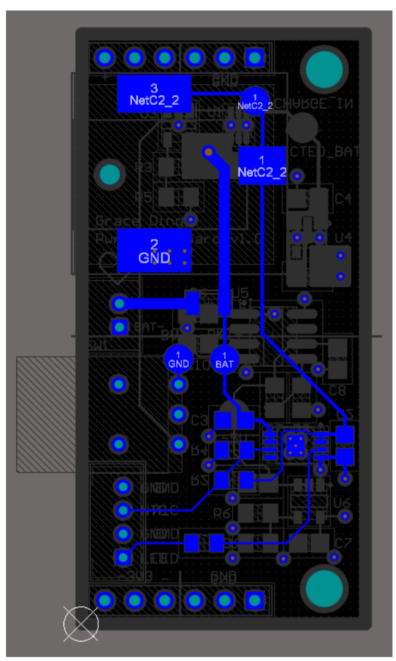


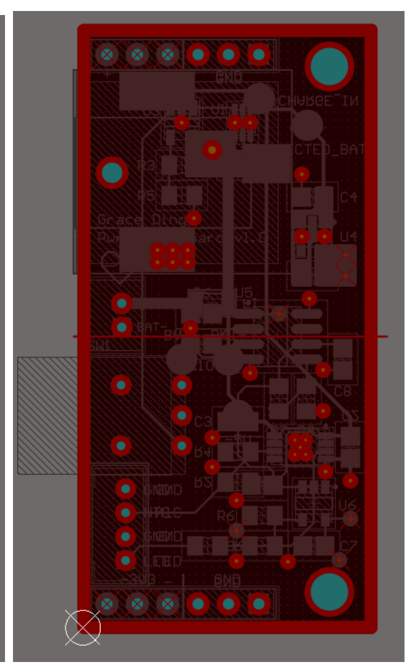


From the 3D view, we can clearly see the placement of headers, connectors, and switches. The power switch and the barrel connector both face the same side, which will be the right side of the final enclosure. These external parts will be pressed against holes made in the enclosure so that the user can toggle the switch or plug in the battery to be charged. The headers on the top and bottom of the board are placed to be aligned with the respective female headers on the digital processing board, and contain the 3V3 and -3V3 nets. Finally, the 2 pin JST connector on the "bottom" of the board will be connected to the LiPo battery, and the 4 pin JST connector will be connected to the LED and the NTC. These are placed on the side of the board because that is where most of the space is – because these are throughhole connectors, it makes sense to group them in an area where not a lot of components are placed.


3V3
GND
NetC2_2
U3
U1
CHARGE_IN
PROTECTED_BAT
R3
R5
C1
C4
Grace Ding
PwrManageBoard v1.0
U4
C6
U5
BAT+
BAT-
SW1
C10
C8
C3
R7
R8
-5V
C9
U6
GND
NTC
GND
LED
R6
R9
C7
3V3
GND







With respect to component placement and layout – due to the positioning of the headers, it made sense to split the top half of the board and bottom half of the board into two power planes. The top is then the +3V3 rail, and the bottom is the -3V3 rail. Then, components were placed such that -3V3 and +3V3 nets remained on the respective sides of the board such that traces carrying the other power rail never crossed over the split plane so that ground return paths remain short.

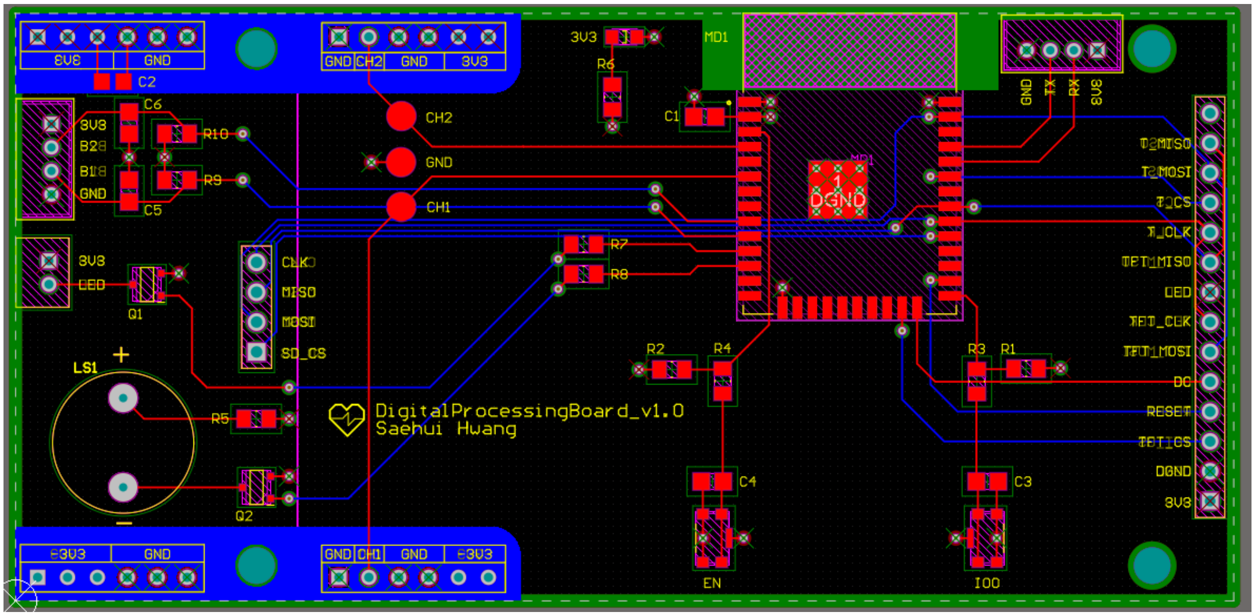
Thus, the positions of the power rail generation ICs (the positive and negative LDOs, and the switched capacitor voltage inverter) are dictated by the locations of the headers/power planes.

Because the battery charging IC is largely isolated from the rest of the circuitry that creates the two power rails, the components are placed at the back of the board, next to the battery charging barrel connector. This reduces the number of nets we have to pass through vias between the front and the back of the board.

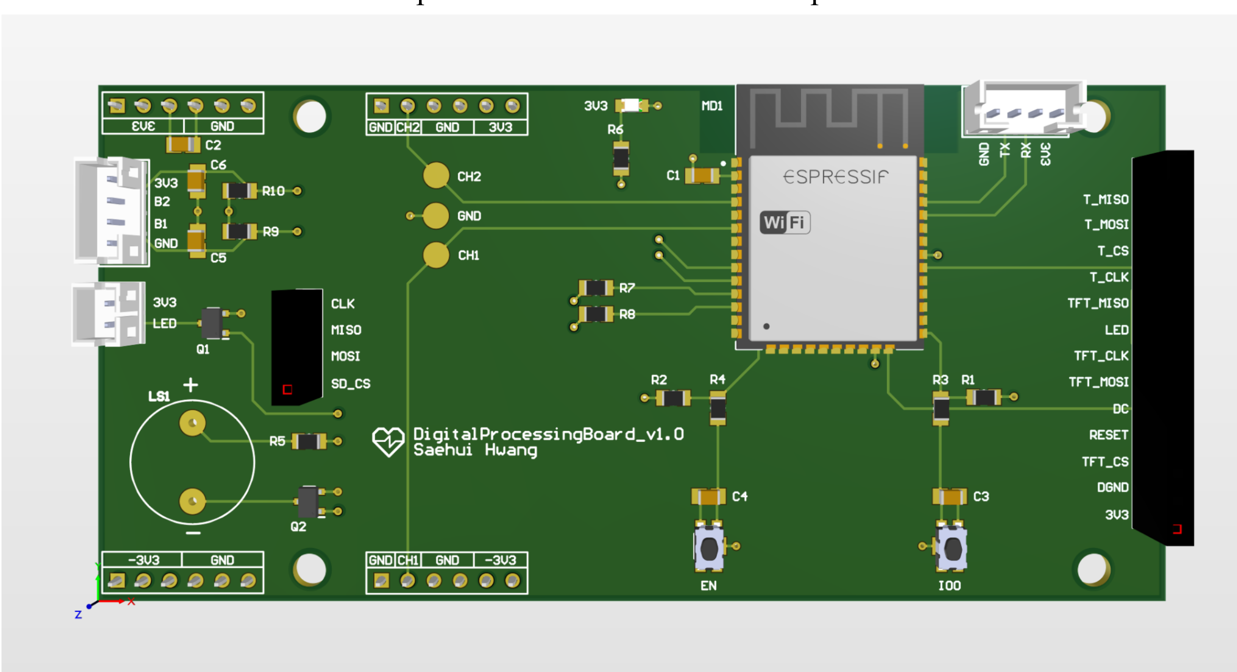
For the routing of the board, polygon pours were used where there were many pads of the same net. Large planes on both sides of the board (GND) were via stitched together. Thicker traces (40 mils, as opposed to 6 mil standard traces) were used on nets that carried higher current (so from battery to rest of the board and from the charging IC to the battery). These currents are still low (200-300 mA max), but are relatively high compared to the other nets; using wider traces ensures that the board will not overheat due to high resistance in the traces.

Digital Processing Board

The digital processing board does not require a negative power rail, so the power plane is not divided but instead reserved for the positive 3V power rail. The bypass capacitors are placed in proximity to the respective pins. There are two user interfacing JST connectors placed to the left side of the device for ease of assembly. The buzzer is also placed on this side of the board for maximal sound delivery. The EN and IO0 SMD buttons are placed close to the edge of the board for ease of access even when the ILI9341 is attached to the board. The 14 pin female header and the 4 pin female header have been placed exactly such that the ILI9341 will fit snug with the board.



Planes are used for the positive and negative rails to minimize heat. The ESP32 antennas are exposed by removing the copper layers on all three boards. Each part is labeled on the silkscreen for assembly and debugging.
As for routing, the analog signals are routed on the top layer of the board. The main source of concern for interference is between SPI and analog signals, so the SPI traces from the SD card module are routed on the bottom layer. This allows for the ground layer to act as a shield, minimizing cross talk and maintaining signal integrity. Via stitching is used on the ground plane of the ESP32 to maintain low impedance and shorten return loops.



Test Plan and Procedure

Construction and Test - Power Management Board

1. Before placing a component onto the PCB, a visual inspection should be conducted focusing on possible layer separation, cracks, plating voids, exposed traces, incomplete holes, and missing or improperly printed solder mask. The through-hole connectors can be test fit, and an operational amplifier, resistor, and capacitor may be placed against their corresponding pads to check alignment and size. A third pass using electronic calipers can also be carried out to further assess pad/hole size if necessary. If any problems are identified, the Altium project files should be checked to determine whether the cause is a designer or PCB fabrication error.
2. Begin with the MIC2776L-YM5-TR (U3) and MIC94065YC6-TR (U1). Confirm using a multimeter that pads are connected by nets as dictated by the routing document. Then, solder all related parts (including the switch AS11CH) to the PCB. Using a current limited power supply, set voltage to 3.6V and connect to TP1 or pin 4 of U3. Confirm that output of pin 1 on U3 is greater than 0.3V (around 2.9V). Then, measure pin 1 of U1 - output voltage should be equal to that of the power supply (in this case, 3.6V). Then, turn the switch AS11CH (SW1) into the "Off" position. The voltage output at pin 1 of U1 should be 0V. Then, set voltage to 3.2V on the power supply. Once again, perform measurements on pin 1 of U3 and pin 1 of U1. Output for both of these pins should be below 0.3V.
3. After disconnecting the PCB from the power supply, solder the XC6222B331MR-G (U4) linear regulator and associated passives. Connect the system once again using TP1 from the current regulated power supply with a voltage of 4.0V. Measure output of pin 5 on U4 – this value can be compared to the expected value of 3.3V. Confirm that +3.3V is present at all corresponding header pins.
4. With power disconnected, the LTC1261IS8#PBF (U5) and associated passives can be soldered into place. With the same power source as previous steps connected, an expected value of -5V should be measured from the output of pin 6 on U5 (TP8).
5. Disconnect all power from the board, and solder on parts associated with U6, the TPS72301DDCT. Once again connecting power to TP1, confirm that output of pin 5 on U6 is -3.3V.
6. Once again making sure power is disconnected, the headers and connectors can all be soldered onto the board. Use a multimeter to check continuity between the headers/switch pads and their corresponding nets. Connect the board to power (bench power supply) and confirm that the voltages at the header pins are indeed the values they are marked (+3.3V, -3.3V, and GND).
7. Once we have confirmed that all components are working, connect the battery to the battery header, and perform same checks as above on outputs of all ICs – output of U4

should be +3.3V, output of U5 should be -5V, and output of U6 should be -3.3V. Make sure that the switch is configured such that it is open.

8. Disconnect the battery, and solder on BQ24200DGN (U2) and all related parts. Make sure to solder the LED and NTC onto their corresponding JST connectors. Make sure that SW1 is in the open position. Connect the battery to the header, in series with a multimeter in current measurement mode. Use a current limited wall supply and connect to the female barrel connector on the PCB. Set the voltage to 5V, and limit current to 1A. Look for the LED to light up to indicate charging, and read the current passing to the battery – make sure this value is nonzero.
9. Once operation is confirmed, connect the barrel charger to the wall and to the female connector on the PCB instead of the current limited bench supply. Look for the LED to light up to indicate charging, and read the current passing to the battery – make sure this value is below 1A, but above 0A.
10. Once confirmed the battery is indeed charging, artificially heat the NTC using a heat gun – make sure the value exceeds 40C. Check the current flowing to the battery again – this value should now be 0A. Repeat this process, but artificially cool the NTC using dry ice to below 0C. The current flowing to the battery should once again be 0A.
11. If any of the preceding steps revealed possible issues, continuity may be checked against the topology of the BatteryManagement.SchDoc and Connectors.SchDoc documents under the ECG_PowerManagement project. The components may also be removed and tested individually using the same tools and a benchtop power supply.

<u>Construction and Test - Digital Processing Board</u>

1. The same methodology as before can be used to evaluate the digital processing board fabrication integrity. Continuity between all connected pads can be checked against the schematic as done before.
2. The headers interfacing with the power management board may be soldered on, as well as their respective capacitors. The blue LED and R6 can be soldered on. An external power supply can be connected to one of the 3V headers for the remaining sections, for testing purposes. Verify that power is delivered to the board by visually inspecting the blue LED.
3. After disconnecting the power supply, the ESP32 module can now be soldered on, as well as R[1-2], R[3-4], IO0 pin and the EN pin are grounded properly, thereby putting the microcontroller into program mode.
4. The JST connectors for TX and RX can now be soldered on, along with the buzzer circuit – LS1, R5, Q2, and R8. Upload a simple sketch of the buzzer beeping and verify the frequency of the buzzer.
5. R7, Q1 and LED connector may be soldered on. Upload a simple sketch of the LED blinking and verify the LED.

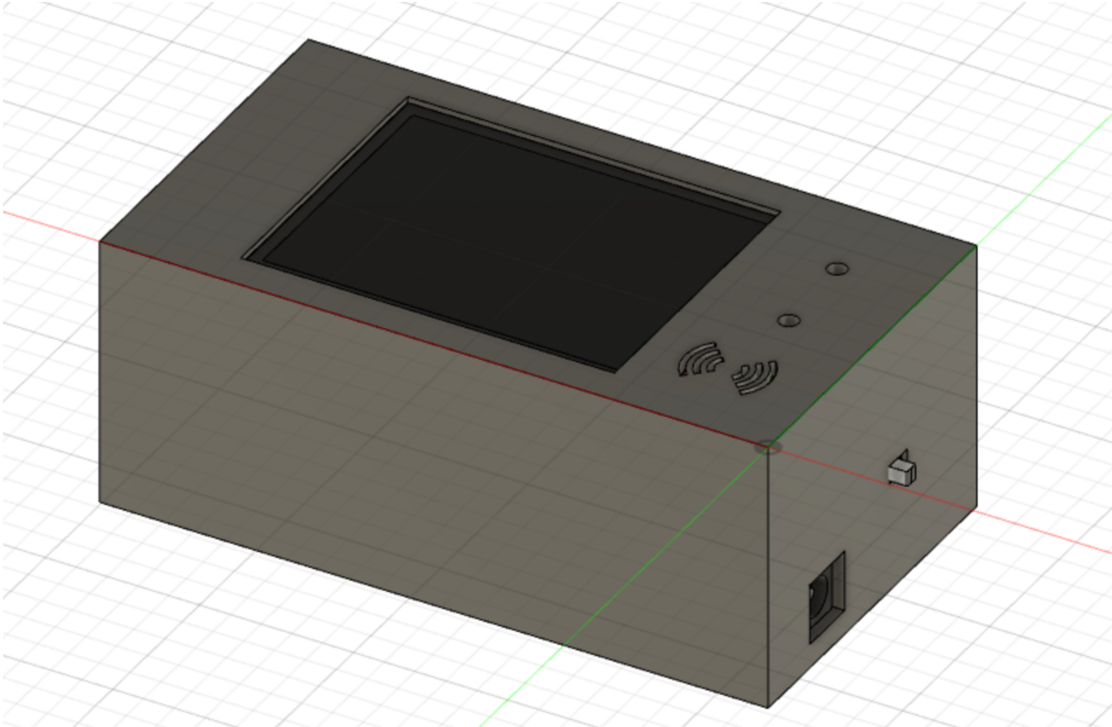
6. The rest of the headers can be soldered on. Mount the ILI9341, and visually verify that the screen turns on. Upload the full program sketch to the ESP32.
7. Using a jumper wire, connect the CH1 header and the CH2 header to an arbitrary low voltage function generator with 1Vpp 10Hz. Verify that the signal is recovered and displayed on screen properly.
8. If the assembler wishes to add physical buttons to the ECG, the JST connectors may be soldered on, as well as the capacitors C[5-6] and resistors R[10-9]. Upload a simple sketch that prints the buttons pressed to verify button functionality.
9. The digital processing board can be connected with the power management board and analog front end board

<u>Construction and Test - Analog Front-End</u>

1. The same methodology as before can be used to evaluate the analog front-end PCB fabrication integrity. Continuity between all connected pads can be checked against the schematic.
2. To verify the functionality of each channel and identify potential problems, the components of each ECG channel can be placed onto the PCB and tested separately. The three OP07CD operational amplifier ICs can be soldered to the U1, U2, and U3 pads of CH1 using 60/40 rosin core solder at an iron temperature of 300°C. Results should be inspected for cold solder joints using a microscope.
3. The complementary components of the CH1 instrumentation amplifier identified by designators RG, R[4-9] can be soldered onto their corresponding pads on the top layer.
4. Decoupling capacitors C[1-6] along with bulk capacitors C[15-18] and ferrite beads L[1-2] can be soldered onto their corresponding pads on the bottom layer.
5. The functionality of the CH1 instrumentation amplifier can be evaluated by powering the board using an external power supply and soldering jumper wires to the exposed 3V3/GND/-3V3 header pads. A function generator can be used to inject a 100mV 10Hz sinusoidal signal across the INS_P and INS_N test points of CH1. Using an oscilloscope to measure the CH1 INS_OUT test point with the nearest GND test point as reference, an expected 1Vpp 10Hz sine wave should be observed. Power and test equipment should be disconnected before soldering additional components.
6. Patient protection components D[1-2], R[1-3] can be soldered to the top and bottom of the PCB. The same test should be performed, this time injecting the sine wave across the RA and LL pads, to ensure parasitics introduced by the components did not significantly degrade performance.
7. The AD8648 quad channel operational amplifier can be soldered to the CH1 U4 pad using a Chip Quick solder paste, a solder wick, and flux.
8. The components of the CH1 filter identified by designators C[7-12], R[11-13], and R16 can be soldered to the top layer of the PCB.

9. The components of the CH1 filter identified by designators D3, R10, R14, R15, R17, R19 can be soldered to the bottom layer of the PCB.
10. The same tests in step 6 can be performed with measurements taken across the exposed CH1 header pad and nearest ground pad. A 1Vpp 10Hz sine wave with a 1.5V offset should be observed.
11. To evaluate the high pass, low pass, and notch filter performance, the output or corresponding test pads may be observed with higher frequency signals injected at the input of the board.
12. Steps 2-8 can be repeated with the CH2 components to solder them onto the board and test their functionality.
13. The 2.5mm pitch male headers and 3.5mm jacks can be soldered onto the board. The same testing procedure can be carried out with both channels functioning simultaneously. An ammeter can be used to verify current draw into the inputs is less than 10nA, and the overall power draw of the board is within the budget specifications.
14. Once the analog-front end board has been shown to work properly under the preceding conditions, it can be tested on human patients.

Assembly and Packaging Plan



1. Using a set of pliers or a crimping tool, crimp the wires of the charging status LED and the thermistor to the four pin JST female connector, making sure that wire length is sufficient for the LED to fit in the enclosure and the NTC to rest on the battery while the JST connector is connected to the power management board.
2. Then, crimp the wires of the heartbeat indicator LED to the two pin JST female connector, and ensure that the wire length is enough such that the LED can sit in the enclosure while the JST connector is connected to the digital processing board.
3. Insert the charging status and heartbeat LEDs into the hole at the top of the enclosure, securing them using hot glue. Connect the JST connectors to their respective boards.
4. Secure the ILI9341 display to 11mm standoffs.
5. Secure the digital processing board by aligning the mechanical holes to the 11mm standoffs.
6. Align the analog front end board header pins to the female headers on the digital processing board – make sure that the net labels are matching on the headers connected (3V3 to 3V3, -3V3 to -3V3)
7. Align the power management board header pins to the headers on the digital processing board. Make sure that the net labels are matching on the headers connected (3V3 to 3V3, -3V3 to -3V3)
8. Connect the battery's JST connector to the connector on the power management board, making sure that the black wire goes to BAT- and red wire goes to BAT+.

9. Secure the NTC to the battery using electrical or Kapton tape, making sure that the NTC makes contact with the battery itself
10. Secure the battery in place on the bottom of the enclosure using hot glue.
11. Close the bottom panel and secure it to the rest of the enclosure with 4 M2 screws.