DEFIBRILLATION SAFETY

"A report submitted to the School of Engineering and Energy, Murdoch University in partial fulfillment of the requirements for the degree of Bachelor of Engineering."

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Executive Summary

In the past years, there has been a dramatic transition between the use of older monophasic defibrillators to newer, more sophisticated, biphasic types. As these biphasic defibrillators are more efficient, they require less energy and therefore create less of a risk to bystanders. Due to the lack of research around these new defibrillators, the current recommended procedures may not accurately reflect the safety of medical personnel. Because of this, the recommended “all clear” period may in fact become detrimental to the health of the patient as it causes the cessation of crucial activities of medical staff such as IV canalization and chest compressions. This thesis is aimed at assisting in a study to be performed by the Professor of Emergency Medicine at Royal Perth Hospital by designing a device capable of measuring, storing and analyzing the leakage voltages from a patient and their environment whilst undergoing defibrillation.

The device that was designed consisted of a data acquisition system that would measure the voltages using standard ECG leads, and then wirelessly transmit that data to a laptop for further processing. Throughout the entire design process, the focus was aimed at ensuring the device would meet all the criteria specified in the required standards and cause no detrimental effect to the patient being monitored. At the end of the thesis period, a functional schematic was designed and tested, ready for manufacture as well as a solid framework of the software component of the project.

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Acknowledgements

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Project Supervisor: Gregory Nicholls

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Terminology and Acronyms

AED – Automated External Defibrillator

AHA – American Heart Association

BMI – Body Mass Index

BOM – Bill of Materials

CAD – Computer Aided Design

CMRR – Common Mode Rejection Ratio

COTS – Commercial off the shelf

CTI – Comparative Track Index

DAQ – Data Acquisition

ECG – Electrocardiogram

ED – Emergency Department

ERC – European Resuscitation Council

GDT – Gas Discharge Tube

GMP – Good Manufacturing Practice

GUI – Graphical User Interface

IC – Integrated Circuit

IP (Rating) – Ingress Protection

IP (address) – Internet Protocol

IV - Intravenous

LED – Light Emitting Diode

(MOS)FET – Metal-oxide-semiconductor Field-effect Transistor

PCB – Printed Circuit Board

RMS – Root Mean Squared

RPH – Royal Perth Hospital

SQL – Structured Query Language

TGA – Therapeutic Goods Administration

TVS – Transient Voltage Suppressor

UMRN – Unique/Unit Medical Record Number

CHAPTER 1: Introduction

1.1. Project Motivation

The aim of this project is to perform an investigation of the hazardous potentials developed while defibrillating a patient during cardio version. As a result it will be determined whether or not it is safe while defibrillating for medical team personnel to continue activities such as IV canalization and resuscitation at the head etc. at patient extremities (reportedly done by some hospitals) or to break crucial Life saving treatment during defibrillator discharge (as currently practiced).

There have been a number of recorded incident cases at RPH of medical staff receiving minor shocks while performing defibrillation on patients. The logic and circumstances as to how these voltage potentials accumulate in staff are a bit of an engineering mystery. This is due to the fact that, according to the nature of electricity, the defibrillation pulse *should* travel the path of least resistance, through the chest cavity via the defibrillator electrodes (approximately 50-200ohms), yet the incidence reports show significant volumes of leakage current travelling through staff which, theoretically, have a much greater resistive path (approximately 15kΩ to 1MΩ).

Most reports of shocks from defibrillators are quite vague and have little to no details on how the individual was shocked, or any description of their environment. As well as this, it has been stated in studies that of most of injuries to medical personnel were mild, involving only mild shocks or burns. The rate of injury that has been predicted for paramedics is 1 per 1700 defibrillator shocks and 1 per 1000 for technician-defibrillator personnel (Gibbs, Eisenberg, Damon 1990). Although these studies are reputable, the effect of electrode-skin coupling and use of medical gloves has not been documented and in separate studies have shown to be quite important in determining the total rescuer impedance.

Up until 2010, defibrillation procedures around the world were not standardized as shown in Figure 1. The American Heart Association suggested that medical personnel cease chest compressions only while rhythm analysis was being

performed and when the shock occurred. This differs from the European Resuscitation Council who suggested that there be no chest compressions being done from the start of the rhythm analysis to the end of the post-shock pause. It is a reasonable assumption to make since such high voltages are being used, you should err on the side of caution to ensure the safety of the medical staff *yet* studies have shown there is a significant decrease in the likelihood of shock success with an increase of pre-shock pauses as shown in Figure 2 (Perkins and Lockey 2008) (Edelson, et al. 2006).

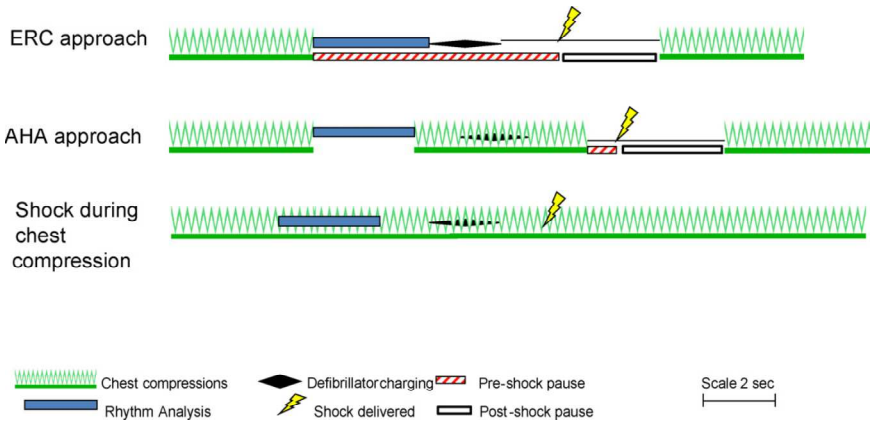


Figure 1 - Difference between defibrillation procedures of ERC and AHA (Perkins and Lockey 2008)

This pre-shock pause however has been decreased with the introduction of biphasic defibrillation waveforms as they have reduced the charge time from 8 seconds to approximately 2 seconds. These defibrillators also have increased efficacy and require less energy to provide ventricular defibrillation. As these are the most common type of defibrillators available today, these will be the basis of this thesis. These new defibrillators in conjunction with new self-adhesive pads and the use of gloves with high insulation properties should create extremely high impedance pathway to the medical staff in comparison to the trans-thoracic impedance of the patient. This should theoretically, allow safe contact with the patient while the shock occurs. These characteristics will all be explained in further detail later.

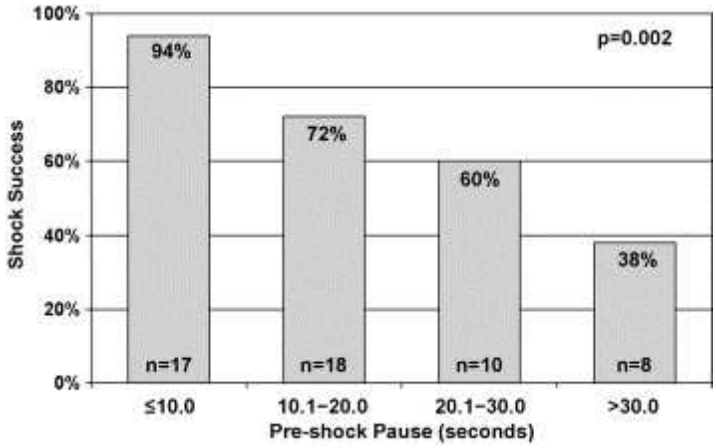


Figure 2 - Illustration of decrease in shock success with increase in pre-shock pause (Edelson, et al. 2006).

1.2. Project Scope

The main objective of this project is to engineer a device to use on a resistive test model of the human body and down the track in a clinical environment to prove/disprove the case of susceptibility of medical staff getting shocks from a defibrillator. It will also ascertain a quantifiable measure of the energy density's expected around the body under a variety of circumstances while defibrillating. This data will also be stored in a database, along with extensive information on the patient, rescuer and the environment. This should document any further shocks being exposed to medical staff at RPH and also give evidence to whether nursing practices should change. Below in Figure 3, shows the fundamental concept of how the proposed design should work.

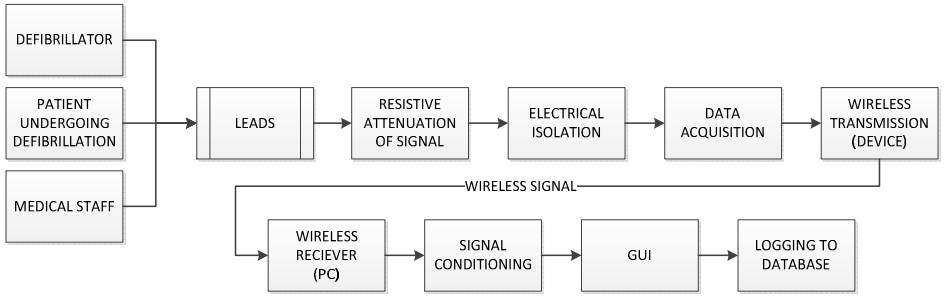


Figure 3 - Flow diagram of proposed device design.

1.3. Project Objectives

Design device

The device being designed will be able to record multiple differential voltages via a data acquisition module and wirelessly transmit the data to a laptop for analysis and storage.

A set of leads for each available DAQ channel will be placed on specified parts of the clinical environment whether it is on the patient, the rescuer or their surroundings. These leads will measure the leakage voltage of the defibrillator when in use. The (possibly) high voltage signal will then be attenuated to an appropriate input level to the DAQ module and then isolated. This isolation will allow for galvanic isolation between the patient and the hardware for patient and hardware safety.

This voltage signal will then be wirelessly transmitted to a Laptop by a Data Acquisition Module using IEEE802.11b/g protocol. The signal will then undergo various signal conditioning and will be displayed on a graphical user interface. The final step of the project will allow the set of data to be written to a database for future analysis via SQL queries. Figure 4 illustrates an in depth view of the segments of the device that must be designed.

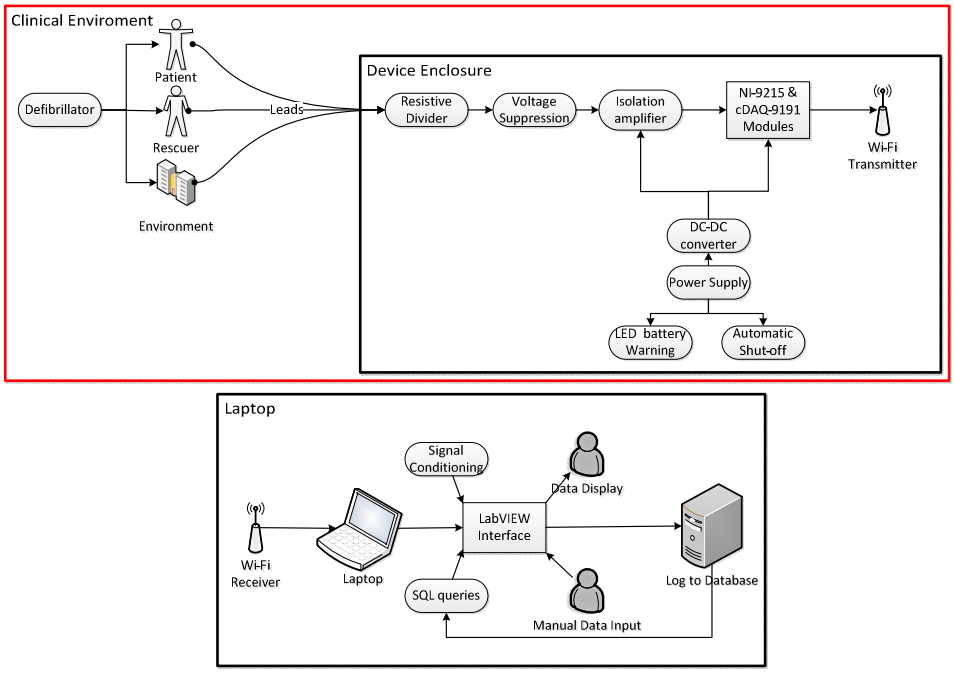


Figure 4 - Detailed Flow diagram of device.

Test device

The designed system will undergo a variety of testing and modifications to attempt to improve the overall working and efficiency of the functioning device. This will be in an attempt to ultimately have an end product that works with minimal interaction with medical staff and has a negligible impact on the quality of care to the patients. The main focus of the testing will be on the ability for the device to be safe, accurate and easy to use, and also that it requires the staff to input the minimum amount of information.

Test for electrical safety compliance (Verification)

This process of verification is required for any product that has been created by the medical engineering and physics department and Royal Perth Hospital. This is due to their quality assurance procedures that detail the who, how, when, where and why of a particular function or process undertaken by the division. These procedures ensure the department meets the requirements of the Australian Standard AS/NZS ISO9001:2008, “Quality management systems – Requirements”. This verification involves completing additional forms and tests to document that the device has been through the correct design process and conforms to appropriate safety standards.

1.4. Project Revisions

Since the project plan, it was deemed unnecessary to incorporate extra voltage suppression into the design. The testing done on these components will still be included as part of the design and research of the device.

1.5. Thesis Structure

Chapter 2: Technical review of hands on defibrillation

Chapter 3: Outlines the research and processes that went into the design

Chapter 4: Outlines the testing done on the design to ensure correct functionality.

Chapter 5: Outlines the software design, and various programming techniques

Chapter 6: Describes the extra documentation required to ensure good design process

Chapter 7: Summarizes completed objectives and discusses any future work.

CHAPTER 2: Technical Review of Hands-on Defibrillation

2.1. Overview of defibrillators and their interaction with the heart

2.1.1. Defibrillator Background

Defibrillators are a fundamentally simple device with regards to how they work. The main component of a defibrillator is a large capacitor that stores an electrical charge to be released as permitted. The auxiliary functions of modern defibrillators are what make them so complex. In older model defibrillators, the user specifies the energy they want to be discharged and the defibrillator will release an unspecified amount of voltage and current, depending on the physical characteristics of the patient. Modern defibrillators however have the ability to measure the real-time trans-thoracic impendence of the patient and alter the discharge characteristics of the defibrillator to ensure the patient's heart receives the appropriate average current (which is the parameter that causes defibrillation).

There are two main types of pulse waveforms which defibrillators output. The older types output a monophasic signal which has a peak voltage of around 8kV (40A) shown in Figure 5 (left). New defibrillators output what is called a biphasic (bipolar) rectilinear waveform shown in Figure 5 (right). These new defibrillators have been proven to be much more effective and require less energy. Some research has shown that triphasic waveforms are even more efficient to current biphasic waveforms (Huang, et al. 2000). The reason biphasic defibrillators are safer and more efficient is because by changing the polarity of the discharge mid-shock, there is no single reference point on the patient. As well as causing a reduced risk of burns to the patient skin, it is shown that serial shocks using a monophasic defibrillator can reduce impedance by aligning water molecules in the thorax creating reduced efficacy (Deakin, et al. 2010).

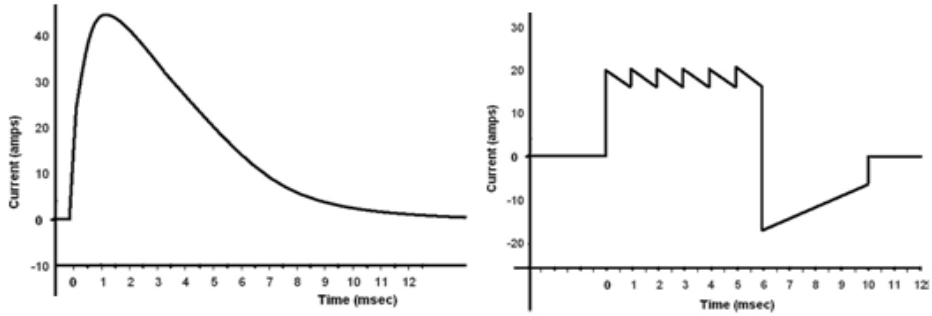


Figure 5 - (Left) Output of a monophasic defibrillator (Right) Output of a biphasic defibrillator (Deakin et al. 2010)

2.1.2. Fibrillation Background

The heart relies on electrical activity to contract and this electrical signal must occur in a specific sequence to allow the different chambers to push blood efficiently. When, for whatever reason, this electrical activity loses coordination, the heart chambers will contract out of sequence and problems can occur (e.g. chambers contracting before they have time to fill). (Bossaert 1997) This loss of coordination of the electrical activity is known as fibrillation. The purpose of a defibrillator is to essentially, reset the hearts natural electrical rhythm. This is done by sending enough current through the heart to depolarize all the myocardial cells and remove any electrical disturbances so the heart can start a fresh rhythm. There are a variety of electrode configurations used to administer this current pulse, each giving a different electrical pathway for the current to flow through the heart.

Eleven studies have shown that varying electrical pathways with regards to electrode placement has no effect of the efficacy of cardio version with the only significant difference being the change in trans-thoracic impedance (Australian Resuscitation Council; New Zealand Resuscitation Council 2010). The two major electrode configurations used are the anterior-apex placement and the anterior-posterior placement. Anterior-posterior placement is the preferred configuration with one electrode being placed over the left precordium and the other placed on the back, behind the heart. This is preferred because it's better for non-invasive pacing and gives generally lower impedance. Anterior-apex placement is used when anterior-posterior is inconvenient. One electrode is placed on the right, below the clavicle and the other on the left, just below and to the left of the pectoral muscle. (Procamed n.d.)

Although all defibrillators specify the amount of energy given to the patient in Joules (J) the parameter that really defibrillates a heart is current, more specifically, average current. The relationship between the two is shown below (Zelinka, Buic and Zelinka 2006):

$$W(Work) = V(Voltage)\ x\ I(Current) x\ t(Time)$$

By introducing the patient impedance (R) into the equation the above equation can be transformed into,

$$W = I^2.R.t$$

As the current from the defibrillator is changing over time, it can be said that the energy is a function of the integral of the current and resistance over time, as shown below:

$$W = \int RI^2(t)dt$$

This proves that the same amount of energy can be delivered to the patient with half the current if the shock lasts for four times as long. This is one way that biphasic defibrillators can use lower peak currents and voltages than their monophasic counterparts.

2.2. Biological Impedance

2.2.1. Human Resistive Properties

It is important for readers to understand the variability of the body's impedance in order to comprehend how the current discharged by the defibrillator may stray from its intended path. According to (Hoke et al. 2009) & (Olson 2008), the *internal* impedance of the human body can be approximated by a 500ohm resistor for high voltage capacitive discharges composed from 200ohm for each limb and about 100ohm for the trunk (assuming a limb-to-limb pathway). They also stated that the resistive pathway from hand to hand was relatively similar to the hand to foot pathway. This internal resistance can vary by things like haemoglobin levels, hydration and especially BMI as the specific resistivity of fat is higher than muscle.

In addition to this, the resistance of the skin must be factored in, which can be represented by another resistance in series. The majority of skin resistance comes from the outer, horny layer of the epidermis. The average skin resistance varies drastically with 1 cm² of electrical contact with dry, intact skin ranging from approximately 15kΩ to 1MΩ (Olson 2008). This value varies with such things as skin thickness, presence of sweat or hair, temperature and may be drastically lowered or may even be bypassed by skin incisions/abrasions and electrode gel (Olson 2008).This alternate pathway can be compared to the approximate impedance seen by a defibrillator which is generally between 50Ω and 200Ω. This value is significantly less due to the shorter pathway, the surface area of the electrode, and the ability for the electrodes to conductively couple with the skin via electrode gel.

2.2.2. Biopotential Electrodes

In the body, there is an abundance of electrical activity that affects a variety of biological functions. This electrical activity, however, is different to what one would find elsewhere. Normal electrical circuits rely in the flow of electrons to create current flow yet in the body these currents rely on the flow of ions (Lee and Kruse 2008). This is why we cannot simply place a voltmeter on the skin and measure a voltage and hence the need for Biopotential Electrodes.

A biopotential electrode is a transducer that detects ion distribution on the surface of tissue and converts that ion current to an electron current. This is done by having an electrolyte solution between the skin and a conductive metal where a chemical reaction occurs. “Current can pass from an electrolyte to a non-polarized electrode. Current crosses the interface as the atoms in the electrode oxidize to form cations and electrons. The cations are discharged into the electrolyte, and the electrodes carry charge through the lead wires to the measuring device. A voltage known as the half-cell potential develops across the interface due to an uneven distribution of anions and cations.” (Lee and Kruse 2008)

Electrodes are manufactured with a variety of compositions, with the most popular being Silver/Silver Chloride (Ag/AgCl) because of its low half cell potential (220mV) and its relatively low price (Lee and Kruse 2008). The reaction that takes between the electrolyte and the skin can be shown by the following equation:

$$Ag + Cl^- \rightarrow AgCl + e^-$$

This redox (oxidation-reduction) reaction is dictated by what is known as the Nernst equation:

$$E = -\frac{RT}{nF}\ln\left(\frac{a_1}{a_2}\right)$$

"Where a_1 and a_2 are the activities of the ions on either side of the membrane, R is the universal gas constant, T is the absolute temperature, n is the valence of the ion, and F is the faraday constant." (Neuman 2000)

This 220mV DC offset produced by the half cell potential can be removed with a differential amplifier assuming that the offset is the same on both electrodes. This DC offset will also increase over time as the electrolyte dries as well as with an increase in the impedance of the skin. When in use, these electrodes are also susceptible to motion artifacts in the form of low frequency noise which may be removed with a low-pass filter (Neuman 2000).

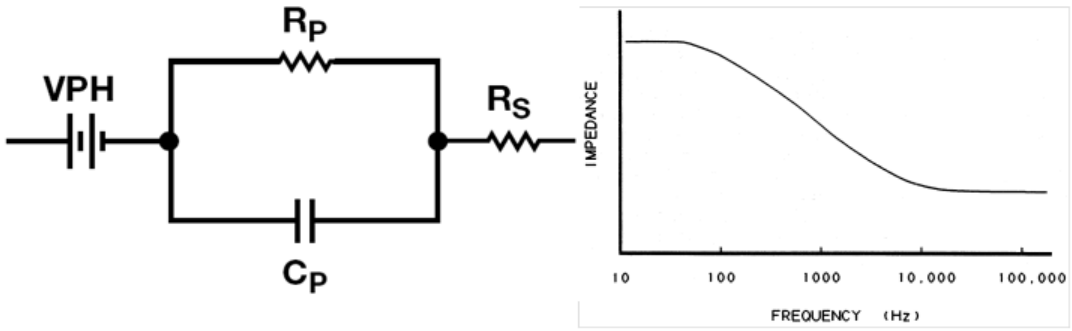


Figure 6 - (Left) Electrical equivalent circuit of a biopotential electrode (Lee and Kruse 2008) (Right) Plot of electrode impedance vs. signal frequency (Neuman 2000)

Biopotential Electrodes are electrically equivalent to that of the circuit shown in Figure 6 (left) where R_p and C_p represent the impedance of the electrode-electrolyte interface and polarization of the interface. R_s represents the series resistance of the electrode materials themselves and V_{PH} represents the half cell potential of the electrode. At low frequencies the electrode tends towards $R_p + R_s$ and at high frequencies the electrode tends towards R_s. This can be seen in the plot on Figure 6 (right)

With the information above, a defibrillator signal is shown to be around 100Hz; therefore it will be dominated by the resistance of $R_p + R_s$which can be compensated for.

2.2.3. Medical Gloves and other environmental factors

One of the major contributors to the electrical impedance of a rescuer in contact with a patient under defibrillation is their medical gloves. These gloves can add a considerable amount of resistance to the rescuer allowing for a significant reduction in the leakage current through them. Since most medical gloves are made from some type of plastic polymer or inorganic compound it can be easily deduced they have high impedance, but there is actually a large variation in the breakdown voltages of commercially available medical gloves. In a study (Sullivan and Chapman 2012) of four different types of medical gloves were tested for their breakdown voltages. The study showed that Latex and Chloroprene gloves have a considerably higher breakdown voltage than those made from nitrile and vinyl. This shows that the type of medical gloves used in 'hands-on' defibrillation may cause a significant effect on the safety of the individual performing chest compressions and other clinical activities. The results from the study are shown in Table 1.

Table 1 - Results of a study investigating the breakdown voltage of various medical gloves (Sullivan, Chapman 2012)

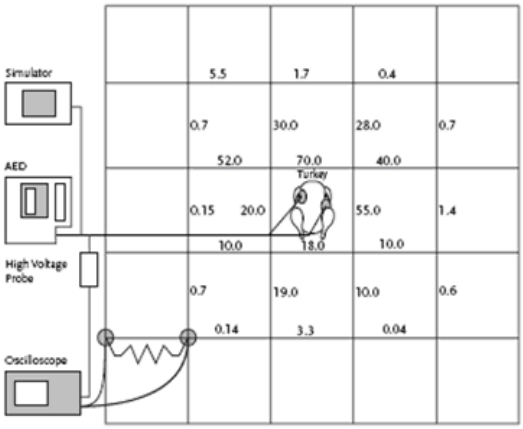
Glove breakdown voltages minimum, median, *n*			
Polymer	Single layer	Double layer	
	0.1 mA	10 mA	0.1 mA
Latex	3000 V, 5000 V, 40	2502 V, 4252 V, 20	–
Chloroprene	2250 V, 2986 V, 40	2998 V, 3321 V, 20	–
Nitrile	811 V, 1575 V, 40	1745 V, 3221 V, 20	2092 V, 2453 V, 40
Vinyl	604 V, 972 V, 40	1873 V, 3995 V, 20	789 V, 965 V, 40

Other environmental factors that may reduce the impedance of a rescuer are moisture on the patient from sources like excess sweating of the patient or spills of saline solution and other bodily fluids. Giving leakage current an alternate ground path will also theoretically reduce the rescuers impedance. This can occur by accidentally touching the patient with an unprotected body part or the cart that houses the defibrillator itself.

2.3. Previous Studies of Defibrillation Safety

2.3.1. ZOLL and LIFEPAK study

The manufacturers of the defibrillators have each performed their own testing with regards to leakage voltages under certain circumstances. Both ZOLL and LIFEPAK (ZOLL 2000)(Seguine 2000) (have investigated the leakage voltages while defibrillation is being performed on a wet surface. Although these were both done under very similar parameters, the results from the test completed by LIFEPAK measured voltages up to 10 times greater than those measured in the ZOLL test. The tests were done by measuring the leakage voltages around an area covered in fluid whilst an AED was used to defibrillate a raw turkey. The results of either study are shown in Figure 7.



1 0.0Vp	2 0.07Vp	3 0.34Vp	4 0.15Vp	5 0.14Vp
6 0.10Vp	7 0.22Vp	8 3.0Vp	9 0.68Vp	10 0.90Vp
11 0.0Vp	12 0.46Vp	13 Turkey	14 0.75Vp	15 0.24Vp
16 0.06Vp	17 0.24Vp	18 AED Plus 0.44Vp	19 0.36Vp	20 0.0Vp
21 0.0Vp	22 0.04Vp	23 0.06Vp	24 0.04Vp	25 0.0Vp

Figure 7 - Results from turkey tests (Left) LIFEPAK (Right) ZOLL

The inconsistencies in the results of these studies either show that there is a lack in the quality of the current studies about this topic or that small changes in the environmental factors in these situations can cause drastically different outcomes.

2.3.2. Lloyd - Hands on Defibrillation

The first extensive study on the effects of rescuer safety while performing hands-on defibrillation was only done in 2009 by Michael S. Lloyd of the American Heart Association. The study addressed the feasibility and safety of direct contact with a patient that is undergoing defibrillation by measuring the voltage and current through a volunteer simulating chest compression on patients receiving external

biphasic counter-shocks (Lloyd, et al. 2008). The study used a LIFEPAK 12 defibrillator, a predecessor of the newer LIFEPAK 20 used in the ED at Royal Perth Hospital today. In this study an oscilloscope was also used to capture the waveforms.

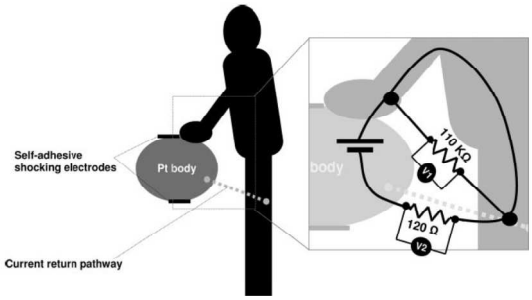


Figure 8 - Illustration of the setup used by Lloyd (Lloyd, et al. 2008).

Forty-three shocks were delivered to 39 different patients with 4 at 100J, 27 at 200J and 8 at 360J. During each shock, 1 of the 4 co-investigators simulated chest compressions with ~20lb of downwards force. The rescuers wore polyethylene gloves and were in contact with the patient bare skin. They also had an electrode connection between their thigh and the patients shoulder simulating inadvertent contact supplying a ground path. None of the 43 shocks were perceivable to the rescuers. Of the 43 shocks, 7 did not trigger the oscilloscope with only 36 shocks analyzed. The results are shown in Table 2. The study concludes with recommendations that chest compressions during shock delivery are feasible and rescuers are only exposed to low levels of leakage current.

Table 2- Results of the Lloyd Study (Lloyd, et al. 2008)

	Mean	SD	Range
Voltage across rescuer, V	5.80	5.77	0.280–14.1
Current through rescuer, μA	283	140	18.9–907
Energy through rescuer, μJ	24	12	0.070–95
Impedance through patient, Ω	60	15	36–87
Impedance through rescuer-patient circuit, Ω	2.27×10^4	1.40×10^4	1.09×10^3 to 1.00×10^5

This thesis is aimed to build upon Lloyd's study in the following ways:

- Increased flexibility, allowing a variety of different patient-rescuer configurations giving a variety of different possible pathways for leakage

current to travel. Lloyd's study can only confirm that this specific scenario is safe for rescuer.

- Having multiple channels to analyze multiple possible pathways at once giving more information about a single patient-rescuer configuration, signifying if there may be multiple possible ground pathways taken by the leakage current dispersing its effects.
- This device will store additional information about the environment that the defibrillation is delivered. This allows for analysis of the effects of additional variables like the presence of gloves, moisture and the BMI of the patient.
- As the device does not need any configuring and requires minimal interaction from medical staff, the lifetime of the project will improve. This will allow for more statistically significant data.

CHAPTER 3: Hardware Design

3.1. Resources

As the device will be used for research purposes, the cost of materials and manufacture was one of the main resource constraints. This required extensive research into components and ensuring they are not over specified for their purpose. As well as this, the use of existing stock at RPH was encouraged to minimize overall cost of the device.

Time was also a limitation for the project outcome. The project that was undertaken had a substantial workload associated with it. Along with that, components for the PCB had varying lead times as well as the lead time for manufacture of the PCB itself. This made time management difficult. The project could also not be seen to its final working stage as a submission for the use of the device to the ethics committee takes a few months on its own to be processed.

3.2. Determination of Device Functionality

As the staff and medical personnel at RPH will ultimately be operating the device after commissioning, the functionality of the device should be somewhat customized to the way they work. To do this, customer review meetings were organized with the Professor of Emergency Medicine. The suggestions taken from this meeting were analyzed and compared with the available resources and other limitations such as safety and electrical standards. From this analysis all feasible suggestions were integrated into the design.

The safety and electrical standards that were considered include the following:

- TGA standards
    - Good Manufacturing Practice (GMP) document
    - 12 essential principals
- Electrical safety standards

- Medical equipment standards
    - AS/NZS 2500 - ‘Guide to the safe use of electricity in patient care’
    - AS/NZS 3200.1 – ‘Medical electrical equipment General requirements for safety – Parent Standard’
    - AS/NZS CISPR 11 – Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement’
    - AS/NZS 3551- ‘Technical management programs for medical devices’
- Ethics committee limitations
    - E.g. cannot alter current clinical procedure whilst the device is being used.

Inspiration for the device was also taken from other similar medical devices such as ECG monitor front ends, defibrillator analyzers and other physiological monitors. This involved studying circuit diagrams and investigating other decommissioned devices. This research gave a good understanding of different types of electrical protection used to isolate patients from high voltage circuitry in devices.

3.3. Hardware Requirements

The design of the hardware was, by far, the most difficult part of the design process. Since the defibrillator gives such a high energy output pulse in such a short period, it was very difficult to find cost effective components to incorporate into the design. As this output is so unique, there were few options, by the way of purchasing any commercial off the shelf items.

The main design aspects that were considered were:

- High voltage applications
- Patient electrical isolation
- Signal Quality/conditioning
- Hardware surge protection

3.4. Electrical Design

3.4.1. Attenuation

There were two main options to be considered for the attenuation of the defibrillator signal. These were the use of a Commercial off the shelf 1000x Probe or a custom resistive divider network.

Probe

Various voltage probes, similar to that found on an oscilloscope, were pursued from a variety of manufacturers. There were probes available on the market that were suitable for our application yet they averaged from $1000-2000 per probe, and with the device requiring 4 probes, spending up to $8000 on probes was not a viable option for this level of project.

Resistive Divider Network

Once the option of using a commercial off the shelf probe was found unviable, the use of a resistive divider network was researched. For the resistive network to be appropriate it had to meet the following criteria:

- It must have a voltage rating equal to or greater than the maximum voltage deliverable by any defibrillator that it will be used with. In this case, only biphasic defibrillators will be used with a maximum deliverable voltage of ~3000V
- The overall network must be of significantly higher impedance than the patient's trans-thoracic impedance or rescuers impedance. This is to deter current from flowing into the device, rather than through the patient or rescuer to avoid interfering with the functionality of the defibrillator or results of the study, respectively.
- There must also be a limit to the tolerances of the resistors in the network to ensure accurate measurement of the signal.

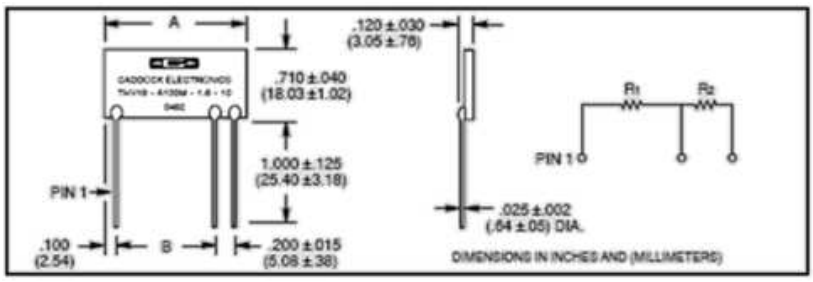


Figure 9 - Picture and circuit diagram of the resistor networks chosen (Caddock Electronics 2010)

A company called Caddock was contacted via their Australian distributor AJDM Distributors Pty. Ltd. with regards to a high precision film resistor network. Caddock are a reputable company that specializes in making precision resistors and resistive networks. A quote of $120.60 each was received for the THV10 type resistive network. This met all the required criteria with an impedance of 99.9Mohm: 100kohm resistance, 10kV voltage rating and a +-1% tolerance. This product was chosen as it was a much more cost efficient solution even though it created more work compared to the probe.

There was only one issue that came up while using the resistive network which was the difficulty in attenuating a differential, bipolar signal. It was initially thought that only a single network was needed for each channel but after testing, showed that a network was needed for both inverting and non-inverting inputs to the isolation amplifier for each channel. This unfortunately doubled the attenuation of the signal, giving a 2000:1 attenuation ratio.

3.4.2. Isolation

Electrical isolation was an integral part of the design process as the safety of the patient is paramount and must be protected from any potential created by the medical device. As well as this, protecting the hardware of the device from any potential created by any externally connected devices (defibrillator etc.) is also important. It was decided that an isolation amplifier was to be used as it provides full galvanic isolation to both patient and hardware. As a bonus, the use of isolation amplifiers also isolates each of the channels of the data acquisition module from each other as it does not have any kind of channel-to-channel isolation of its own. As the devices is battery operated, the emphasis of the isolation is to allow the appropriate signal to be passed from the environment to the DAQ while protecting the DAQ from any damage that may be done under any single fault condition.

An immense amount of time was allocated to researching the appropriate isolation amplifier for this application. The amplifier must be suitable to withstand the full power of a defibrillation pulse if the resistive network fails voiding any possible damage to the data acquisition module. Contrary to this, the isolation amplifier must have suitable precision to throughput high frequency, low voltage signals under normal operating conditions. This is only one criterion that must be met with a full detailed list of required criteria given below:

Isolation voltage - The isolation voltage must be equal to or greater than that of the maximum voltage output of the defibrillator. Most isolation amplifiers of this level have isolation voltages of 750V RMS, 1500V RMS or 2500V RMS. The ZOLL defibrillator has the highest maximum output voltage of any biphasic defibrillator on the market today with a peak voltage of 2220V (Procamed n.d.); therefore 2500V is the only suitable isolation amplifier. There *are* isolation amplifiers on the market with higher isolation voltages than the ones mentioned but there is a significant jump in cost.

Input voltage – As a biphasic defibrillator outputs a bipolar signal, the input to the isolation amplifier must also be bipolar. The signal could be given an offset to get around this but with the space limitations and the reduction in signal precision, this was not a viable option. The input voltage, combined with the gain of the amplifier should also give an output suitable to be input into the DAQ module (±10V). It is preferred to use a unity gain on the amplifier as the DAQ has its own, more precise, amplifier.

Single Supply – As the device is battery operated, it must be compact and light weight. Having a single power supply rail on the isolation amplifier removes the need for additional voltage inverting circuitry from the battery to power the isolation amplifier.

CMRR– the common mode rejection ratio is an extremely important characteristic of any differential amplifier. As the signal will be attenuated before it enters the isolation amplifier, it must be possible to distinguish between the low voltage, attenuated signal and the common mode voltage.

Bandwidth – The Isolation amplifier must have a high enough bandwidth to allow the defibrillator signal in its original form. Most biphasic defibrillators output a biphasic rectilinear waveform shown in Figure 5 (Right). As this waveform has properties similar to a square wave, which is made out of an infinite number of sinusoids the bandwidth must be high enough to avoid rounding of the edges by filtering the higher frequencies. For this application a frequency of 20-100kHz was required.

Voltage offset – As all signals that pass through the amplifier are attenuated by a ratio of 2000:1, the leakage voltage from the secondary circuits are also attenuated (e.g. a possible leakage voltage of 20V will be attenuated to 10mV). This requires the isolation amplifier to have a relatively low offset voltage in order to have accurate, low voltage signals.

Input Impedance – The amplifier requires a high Input impedance to stop it from loading the resistive networks. With low input impedance the amplifier will distort the attenuation ratio and also allow the entire device to draw current from the defibrillator (undesired). The input impedance should be in the range of magnitudes higher than the resistive networks.

The isolation amplifier chosen was the AD210BN. This was the only isolation amplifier on the market that satisfied all the criteria and was within the available price range.

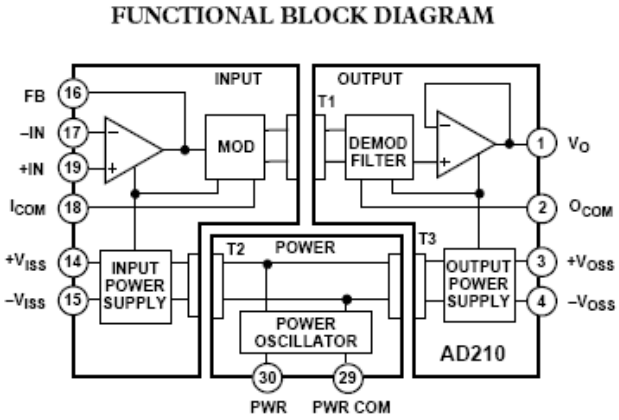


Figure 10 - Functional Block diagram of the AD210BN isolation amplifier (Analog Devices 2010)

Table 3- Analysis of commercially available isolation amplifiers

Model	Manufacturer	Supply Voltage (V)	Isolation Vrms (kV)	Isolation Vpeak (kV)	Input V	DigiKey price	RS Price	Element 14 price	Input Impedance (Ohms)	In Vos (mV)	Non-Linearity (%)	B/W (kHz)	CMR (dB)	Gain
Analog Devices	AD215AY	+-15	0.75		+-10V	80.34	134	NA	16^6	+/-2	+/-0.025	120	100	1-10
	AD215BY	+-15	1.5		+-10V	86.59	NA	NA	16^6	+/-2	+/-0.005	120	100	1-10
	AD210BN	+15	2.5	+/-3.5	+-10V	102.18	193	168	10^12	+/-20	+/-0.012	20	120	1-100
	AD202KY/KN	+15	1.5	+/-2	+-5V	61.23	100	100	10^12	+/-30	+/-0.025	2	130	1-100
Intronics (Legacy)	284J	+15	+/-2.5	+/-5	10V	NA	269.2	NA	10^9	+/-25	0.05	1	110	1-10
	IA296	+-15	+-3.5	6	+-0.5V	NA	NA	NA	30^8	+-5	0.10	1	170	10
Mornsun	T66550CP	+-12	2.5		+-5V	NA	NA	NA	10^6	???	0.10	???	???	1
Avago	ACPL-C78X	5	3.75	5K	+-2V	11.78	15.5	31.07	500^3	+-0.3	0.20	100	76	8
Texas Instruments	ISO121G	+-4.5-	3.5		+-10V	141.59	NA	NA	10^3	+-5	0.04	60	115	1
	ISO122P	+-4.5-	1.5kV	2.4	+-10V	26.43	38.3	50.85	10^3	+-20	0.02	50	140	1
	ISO107	+-15V	2.5	8	+-10V	NA	NA	NA	10^3	+-20	0.01	20	160	1

3.4.3. Surge Protection

Note: After appropriate testing, it was decided not to incorporate any additional surge protection into the design.

As a precautionary measure to ensure that the input of the isolation amplifier was safe from large transient voltages, an extra surge protection device was considered. Using a surge protection device would ensure that the input instrumentation amplifier in the isolation amplifier, which is only rated to the nominal input voltage, will not be damaged by the large voltages in the case of the resistive network failing. The main purpose for the use of these devices is because, although they do not give the same standard of safety as isolation amplifiers, they are inexpensive to replace compared to the isolation amplifiers.

There are many surge protection devices available in industry today including fuses, Tranzorbs, Metal oxide varistor's (MOV), Transient voltage Suppression diodes' (TVS), thyristor's, gas discharge tubes (GDT), neon lamps and spark gaps. Each of these devices has their own merits and limitations which give each device their own niche of applications. After extensive research the two most suitable devices were either a TVS or a GDT.

Transient Voltage Suppressor (TVS)

Transient Voltage suppressors are a type of Zener Diode, called a silicon avalanche diode. These components are the fastest acting surge protection devices available on the market today (usually in the range of picoseconds). They work by clamping the transient voltage spike at a nominal value while absorbing

and shunting the rest to ground. They also have an exceptionally long lifetime when they are used within their specifications and when they do fail, they revert to a permanent short circuit. The only limitation of the TVS is their low energy absorbing capabilities.

Figure 11 - Picture of the SMCJ6.0CA-E3 TVS (Semiconductor 2003)

The amount of energy that the TVS is designed to absorb is represented in Watts (W). Since the maximum normal defibrillator output is 360J released over ~10ms. This calculates to the nominal power dissipated by the defibrillator as ~18kW. Since the input of the isolation amplifier cannot exceed +-10V, the TVS must be specified to handle a power absorption of >18kW with a clamping voltage of <10V. There are currently no TVS's on the market today rated to these specifications.

Low voltage testing was done using the SMCJ6.0CA-E3 TVS on the test circuit shown in APPENDIX C with the results shown in Figure 12 (left). It was noted that there was a significant amount of rounding of the square wave when TVS was placed from the inverting input to the common input. This led to the discovery of the component having a rather large capacitive effect of approximately 2000pF at 10V Figure 12 (Right). This effect was amplified when attached to the inverting input of the isolation amplifier as it created large amounts of positive feedback.

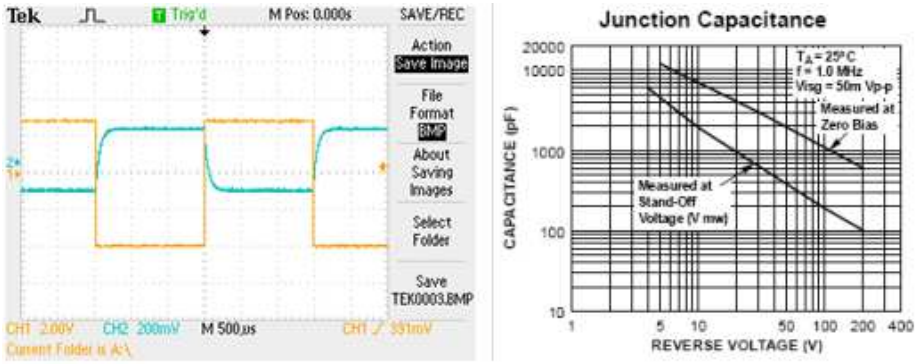


Figure 12 - (Left) Results from the testing of the TVS (Right) relationship between component capacitance and reverse voltage (Semiconductor 2003)

Gas Discharge Tube (GDT)

Gas discharge tubes consist of a specialized gas filled container between an anode and cathode. This device is a modified version of a *spark gap* where the air between the cathode and anode ionizes and conducts if the voltage potential is high enough causing a virtual short circuit. Instead of air, GDT's use gas, and isolates it in a container to give it a consistent composition and protects it from the effects of humidity. GDT's have extremely high surge current ratings and spark-over voltage values. The limitations of the GDT include relatively short life expectancy, and they have relatively slow activation times.

These limitations can be overlooked because if a possible surge is to occur, the user will be aware and fix the problem before it can happen again. As for the activation time, an average defibrillation pulse is approximately 10ms long giving it a 100Hz signal. This is far lower than that of what is expected by a lightning strike which is the primary use for GDT's. Using a GDT is deemed unsuitable as their spark-over voltages are far too high for the intended application.

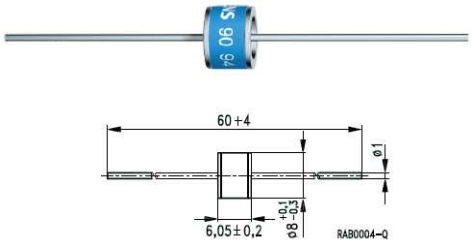


Figure 13 - Picture and diagram of the Siemens M51-C90 Gas Discharge tube that was tested (Siemens 1998)

As part of the research done into surge protection devices, some investigation was done into the mechanisms of medical devices that are classified as defibrillator proof. RPH supplied some example PCB's and circuit diagrams showing that ECG front ends use Gas discharge tubes as their primary surge protection. This however could not be used as ECG machines shunt over-voltages to ground instead of actually measuring them.

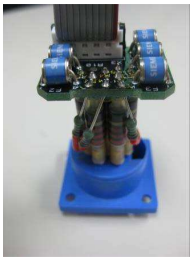


Figure 14 - Picture of the GDT in Figure 13 being used as an overvoltage protection device in an ECG front end.

3.4.4. Power Supply/Consumption

As the device will be battery powered, a suitable power source must be chosen that will satisfy the required criteria. These criteria were as follows:

Size – The batteries dimensions must match the space requirements specified by the size of the enclosure it will be housed in.

Weight – As the device is portable, the battery cannot be too heavy, since it will make the most significant contribution to the gross weight of the device. If the device is too heavy, it will be more inconvenient to move and will ultimately effect the centre of gravity of the device.

Capacity – the battery capacity must be enough to power all the components in the device for at least the duration of a single session of cardio-version. As the device will be in long term use, the battery must also be rechargeable.

The major decision to be made was the type of battery chemistry to be used. A comparison was done between lead acid batteries and lithium ion batteries. Although lithium ion batteries are more efficient with a higher capacity-to-weight ratio, they are considerably more expensive and are known to be volatile if not managed correctly. For these reasons lead acid batteries were chosen for their price-to-capacity ratio and their stability.

Warning LED and Automatic Cut-Off

Using a lead acid battery brings other consequences though, such as larger size and their inability to be deeply discharged. For this reason, a warning

mechanism was designed to flash an LED, signaling to the user that the battery charge is low and if necessary an automatic circuit isolation trigger. This was done with a COTS voltage supervisor IC and by exploiting the linear nature of the total voltage output of the battery as it discharges.

The voltage supervisor used was the LTC2960 made by Linear Technology. This COTS voltage supervisor was chosen for the following attributes.

- Low quiescent power consumption of 850nA ensuring that if the automatic cut-off was triggered, the device itself will not exhaust the battery.
- The device has a large operating range of 2.5-36V, allowing it to be powered by the same voltage input as it is monitoring.
- The ability for the IC to have two adjustable trigger voltages with two separate outputs that turn to a 36V open-drain upon triggering.

A trigger has been set at 11.5V so when the battery falls below this threshold, a red LED will start flashing, signifying to the user the battery is low and requires recharging. This is done inside the IC with a simple comparator, comparing the monitored voltage with a stable internal reference. The threshold is set with an simple external voltage divider.

A similar trigger has been made at 10.8V so when the battery falls below this threshold, the entire output to the device will be isolated, and therefore conserving the remaining charge in the battery. When this occurs, the voltage supervisor only powers itself which only draws 850nA. As this threshold is surpassed, the OUT pin drains, causing the P-type MOSFETS to turn off, consequently breaking the link between V_{OUT} and the positive battery terminal. It is assumed that the MOSFETS have an in-built Zener diode for correct current flow under normal operation. The application notes for this IC can be seen in Figure 15.

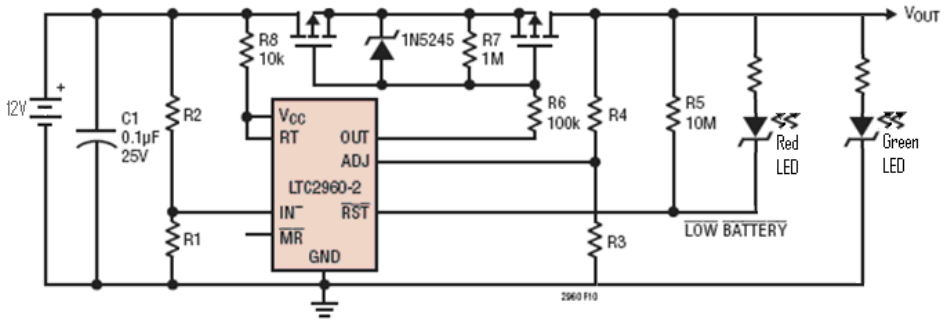


Figure 15 - Circuit diagram for Battery disconnection to protect against deep discharge (Linear Technology 2012)

DC-DC converter

There was another issue with the supply voltage that came with the choice of a lead acid battery. As most commercially available lead acid batteries come as a standard 6V, 12V or 24V, a DC-DC converter was required to regulate the batteries voltage to the correct input supply voltage of the Isolation amplifier of 15V. As 24V lead acid batteries are considerably larger and heavier than the 12V variety, a 12V Lead acid battery was chosen to use in combination with a Buck boost DC-DC converter.

Power Consumption

Before settling on a specific battery and DC-DC converter, a power consumption analysis was done to determine the overall power requirements of the all the components in the circuit. This is to ensure that the battery will allow the device to operate for the required amount of time and that the power output of the DC-DC converter is sufficient to run the circuit.

Table 4 – Analysis of the components in the device to determine overall power requirements and consumption

Component	Criteria	Power Consumption	Supply Voltage	Current
NI 9215 DAQ				
	Active mode (power)	560mW max	9-30V (15V)	37.3mA
	Sleep mode (power)	25uW max	9-30V (15V)	1.67uA
	Active mode (Thermal)	560mW max	9-30V (15V)	37.3mA
	Sleep mode (Thermal)	25uW max	9-30V (15V)	1.67uA
	Active Mode Total	1.12Wmax	9-30V (15V)	~75mA
	Sleep Mode Total	50uWmax	9-30V (15V)	~3.33uA
NI cDAQ-9191	Input power	6W	9-30V (15V)	400mA
AD210BN Amplifier	Full Load	1.2W	15V	80mA
	Quiescent	0.75W	15V	50mA
	4 Channel Total (Full Load)	4.8W	15V	320mA
	4 Channel Total (Quiescent)	3W	15V	200mA
Total	**Maximum**	11.92W	15V	795mA
	Minimum	9W	15V	600mA
DC-DC converter	Efficiency of 83%			
Device Total	**Maximum**	~14.36W	12V	1.20A

Table 4 shows that the power used by all components is 11.92W under full load conditions. This led to the Traco Power TEN 15-1213 DC-DC converter being chosen (Figure 16) with an input supply voltage of 8-18V, an output voltage of 15V and a power rating of 15W.

Figure 16 - Picture of the DC-DC converter used (Traco Power 2003)

Since the circuit will be running at 11.92W with 15V supply, using the formula P=VI the current can be deduced to be approximately 795mA under full load. As the DC-DC converter is powered by 12V with an efficiency of 83%, it was calculated that the overall device will draw approximately 14.36W at 1.2A. According to the representatives from the Emergency Department at RPH, a single session of cardio-version will last for approximately 1 hour. A battery with a 2.9Ah rating was chosen in the Yuasa NPH5-12V Deep cycle Lead acid battery.

3.4.5. Data Acquisition

NI-9215

The National instruments NI-9215 was chosen as the main data acquisition module. It has four analog input channels for strictly differential voltage measurements and a sampling rate of 100k samples per second per channel. It is also important to note that these measurements are taken simultaneously, compared to most DAQ modules that poll the measurements of each channel. This is made possible by the inclusion of a separate ADC for each channel. The NI-9215 takes an input voltage range of ± 10V with 16 bit digital resolution. It comes in both screw terminal and BNC configurations, yet for this application the screw terminal was chosen. A screw terminal diagram for the NI-9215 can be seen in Figure 17 (left). When using the screw terminal version, a 1Mohm resistor must be placed on each channel from the AI- input to the COM terminal as shown in Figure 17 (right).

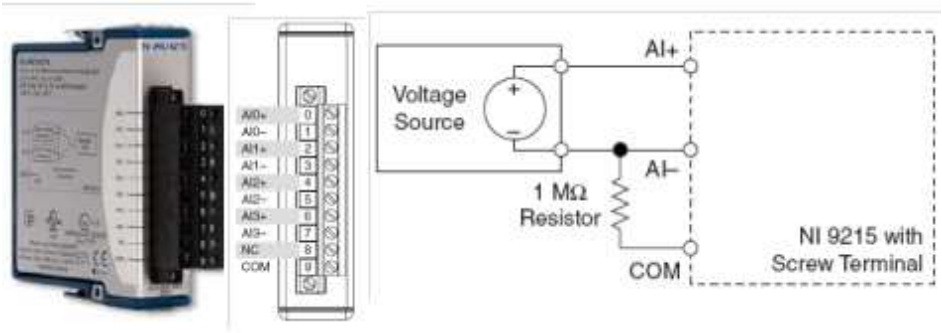


Figure 17 – (Left) Picture and Pin out diagram of the NI-9215 (Right) Required configuration for use for differential measurements (National Instruments 2010)

All of the four channels as been reserved for a specific purpose. AI0 is devoted to the trigger input which is done by having this channel located across the defibrillator paddles. Channels AI1, AI2 and AI3 are all to be used for various leakage voltage measurements.

NI cDAQ-9191

The CompactDAQ Wi-Fi chassis is the data transmission module that works in conjunction with the NI-9215. The chassis is compatible with more than 50 NI C series hot-swappable DAQ I/O modules that conveniently clip in, with a D-Sub DE-9 Serial plug link. The cDAQ-9191 uses either the IEEE 802.11b/g wireless protocols to transmit the data that the NI-9215 acquires to a host computer with LabVIEW installed. The NI device drivers were also installed with the DAQ modules. These are the means of how the DAQ communicates to the application program (LabVIEW) through the windows operating system.

In this situation, the Wi-Fi chassis and the Laptop were configured to connect in an Ad Hoc style network. The chassis has to be connected to the Laptop with an Ethernet cable for initial configuration where it was given a designated static wireless IP address. Once this was done, the Ethernet cable could be removed and a wireless network was broastcast by the DAQ for which the Laptop would connect. This process was done using NI Measurement and Automation Explorer (MAX) as shown in Figure 18(Right).

Figure 18 - (left) Picture of the cDAQ-9191 Wi-Fi module (Right) Network settings used to configure the connection (National Instruments 2010)

3.5. Enclosure Design

Figure 19 - Polycarbonate enclosure

An enclosure with the internal dimensions of 290mm x 220mm x 80mm was taken from existing stock at RPH. A picture of the enclosure is shown in Figure 19. The enclosure has a clear lid that can be used for visual indication of damage or debris and also to few the LED's on the PCB. The main design criteria that were focused on were as follows:

Inter device connections- optimizing the connections between the different components inside the device. This means decreasing the distance that low voltage signals travel to prevent excess interference, attenuation or crosstalk. The connectors should also be polarized, preventing misconnection of components

causing possible damage. Figure 20 shows the connections between the components in the device. The wiring diagram in APPENDIX K also shows the power distribution between the switching and recharge plug and the presence of the fuse on the power supply.

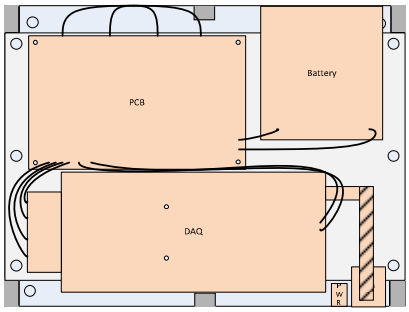


Figure 20 - Interconnections between all the elements in the enclosure

Overall IP rating

The enclosure was designed to be as fluid and dust resistant as possible. The device will be primarily used in the Emergency department, which is a fairly harsh and unpredictable environment so the device needs to be protected from damage by fluids as well as being easily cleanable for hygiene purposes. The enclosure itself has an ingress protection rating of IP66 but any alteration in its panels must be of equal or greater value in order to keep this rating. This is why the power switch, recharge plug and ECG lead input must match its IP rating. A base plate was also used in the enclosure to secure the elements in the device. This removed the need for screws to be drilled into the base of the enclosure, giving a possible route for moisture and dust. The full descriptions of the ingress protection ratings can be seen in APPENDIX A.

The following are a list of alterations made to the enclosure that may alter the ingress protection rating:

Table 5 - Inputs of the enclosures panels and their ingress protection ratings

Name	Description	IP Rating
Enclosure	The enclosure incorporates a sealed rubber edge between the two sections to stop any moisture from getting through. On top of this, the screws used to secure it have their own cavities to isolate them from the inner compartment.	IP66
Power	This double pole, single throw switch is used to turn	IP44(65)

Switch	the power to the PCB on, and off (connecting the battery to the charge outlet). Although the switch only has an IP rating of 44, it comes with an optional protective cover that increases the protection rating to IP65.	
Recharge plug	This plug is used to connect the device to mains for charging the 12V lead acid battery with a 300mA SLA battery charger.	IP67
Cable Gland	This gland houses the cables that connect the ECG leads to the PCB. It also acts as a form of strain relief for the connector.	IP68
Handle	This is used to transport the device. There is no specified IP rating which requires further investigation. However, protecting the opening with silicon should provide adequate protection.	(No rating given)

Input/outputs

Below is a list of all the inputs and outputs of the device and their functions:

Table 6 - List of all input and outputs of the device

Inputs	**Function**
ECG Leads	Experimental Data from environment
Rocker Switch	Power On/Off
Charge socket	For recharging the battery
Outputs	**Function**
Green LED	Indication of PCB Power
Red LED	Indication of low battery
Wi-Fi signal	Output of acquired data to PC

CAD Drawings

The final design was drawn in Microsoft Visio. The three CAD drawings were to document the dimensions of any modifications made. The three drawing created were as follows which can also be found in APPENDIX J:

Mounting plate – This drawing outlined the dimensions of the mounting plate to be manufactured. It also illustrates the co-ordinates of the screw holes required for mounting the various components.

Panel modifications – This drawing outlined the dimensions of the modifications that must be made to the original enclosure.

Labels – This drawing specifies the labels and tags required to each of the inputs and outputs of the enclosure. All significant plugs and switches must be labeled as a requirement for any medical device being designed in accordance to AS/NZS 3551:2012.

3.6. PCB Design

To draw the schematic of the circuitry and design the PCB, CadSoft EAGLE PCB Design Software was chosen as cheap and reliable option. However, one of the drawbacks of using this PCB design software is that it lacks the quantity of available libraries that more expensive packages offer. Because of this a portion of the components used on the PCB had to be manually input into the software. This was done by either modifying a component with a similar that already exists in the available libraries or by drawing an entirely new symbol and package. The dimension of the components and recommended pad sizes could be found on the manufacturer's website or datasheet. The final schematic of the boards can be seen in APPENDIX L.

Another drawback of using this PCB design software is that the maximum size the PCB could take was only 160mm x 100mm. Since the PCB relies heavily on spatial isolation and the sheer size of the isolation amplifiers and the resistive divider networks, the decision was made to space the circuit over two, stacked PCB's. The final design of the two PCB's can be found in APPENDIX B.

3.6.1. Board Configuration

The focus was placed on the following issues when designing the layout of the two PCB's:

- Isolating the high voltages from the low voltages
- Maximizing the efficiency of power distribution
- Gaining correct isolation for components by their creepage and clearance distances
- Minimizing the path that low voltage analog signals have to travel to reduce the effects of noise.
- Reducing the distance of connections between the elements inside the enclosure (e.g. distance between battery and connection to the PCB).

The final PCB design was configured to have a top board that consists only of the resistive divider networks shown in Figure 21 and the lower board has everything else as shown in Figure 22. This allows for two major issues to be satisfied, one being that the high voltage signals will be isolated to the top board and second, that the top board is entirely passive requiring no power. The only drawback to the configuration is that the low voltage signal must now travel further, possibly increasing the noise induced.

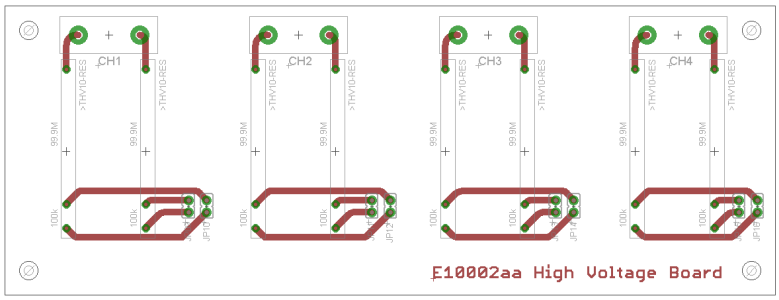


Figure 21 - Final design of the top, high voltage PCB

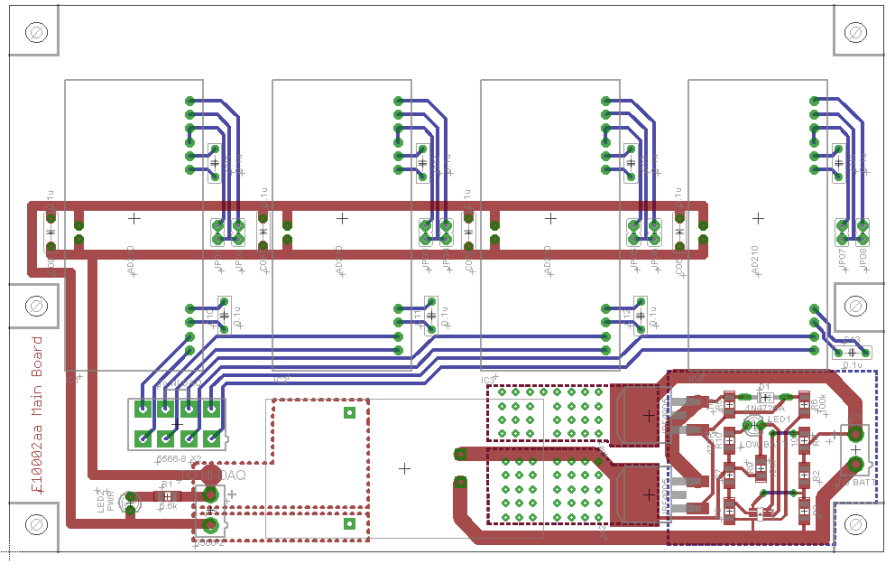


Figure 22 - Final Design of the bottom, low voltage PCB

3.6.2. Creepage and Clearance

When assessing the requirements of the creepage and clearance distances in any electronic device, normally one would refer to the IEC 60664 'Insulation coordination for equipment within low-voltage systems' or IEC 60601-1 'medical electrical equipment general requirements for basic safety and essential performance' for guidance. In this situation, 'clearance' is defined by the shortest distance between two conductive parts, measure through air. 'Creepage' is defined by the shortest distance between two conductive parts, measured across the surface of the insulation. The lack of these requirements may cause the device to arc and short components. The requirements for these distances are effected by three parameters; the degree of pollution of the environment that the circuit is in, the level of the power source used to power the device, known as the 'overvoltage category', and finally the nominal working voltage of the device. It is important to note that when referring to the working voltage it is described by "the highest RMS [root-mean-square] value of the ac or dc voltage that may occur locally across any insulation at rated supply voltage, transients being disregarded," Other factors that affect creepage and clearance distances include the comparative track index (CTI), the altitude that the device is installed and the type of insulation used.

The following categories were chosen to best fit the design of the PCB:

Pollution Degree 1 – As the enclosure of the device has been give a relatively high ingress protection rating, it is resistant against more forms of pollution.

Overvoltage Category I – As the device is powered by a single 12V battery, it will only be exposed to extra-low transient over-voltages. This is further compounded by the presents of the DC-DC converter which regulates the output power.

Working Voltage – although the maximum working voltage of the device is only 15V, the secondary circuit of the defibrillator pulse will be classified as being up to ±3kV.

Comparative track index – For the design of medical products, CTI is treated in accordance to IEC 60601-1. This PCB will have a class III(a) comparative track index.

Altitude – Altitude of the installation of this device is negligible.

Type of insulation – As required in AS/NZS 3200, the device requires does not require significant insulation to be classified as a safety extra-low voltage SELV equipment.

Full class descriptions of pollution degree, overvoltage category and comparative class index can be found in APPENDIX G.

3.6.3. Vertical spatial clearance

In order to achieve correct isolation, the two boards must have sufficient vertical clearance as well as the on-board isolation. As the vertical space is limited by the height of the enclosure and the resistive networks themselves have a significant height, the spatial clearance was carefully planned. Furthermore, a commercially available board stacker must be found with a height that will match that of the spacers.

As the spacers are a physical means of connection between the boards, nylon spacers were used as they are non-conductive. This again applies for the screws that are used to secure the board to the spacers. Figure 23 shows a diagram of the spatial separation between components in the enclosure.

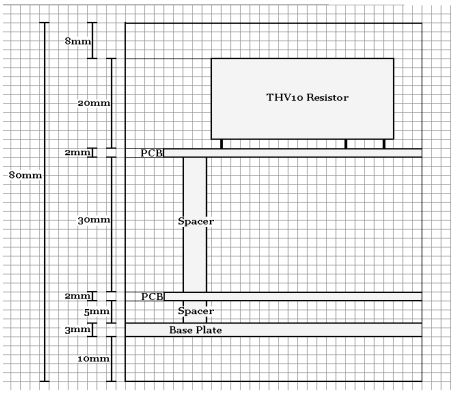


Figure 23 – Vertical spatial clearances between components

3.6.4. Onboard Isolation

Typical PCB's usually have a large ground plane that covers the empty space on the board as this helps with the reduction of noise and other anomalies. This PCB however cannot use this technique since all of the portions of the boards that are isolated from one another have their own ground reference. As well as this, there needs to be a certain distance between the isolated components where no conductors exist to decrease the risk of arching under fault conditions.

On the PCB there are a number of sections that require physical isolation from one another, they are listed below and shown in Figure 24:

Between pins of divider network – The resistor has a fixed distance between the 99.9M pins to accommodate for its large ±10kV rating. By placing tracks on the PCB between these pins will void this rating as this forms a path for the voltage to arc across. Note: a small portion of this distance is used by track as the device is not rated to the full ±10kV range.

Between networks of the same channel – The resistor networks must be placed a certain distance from each other as theoretically large voltage potentials may be formed between them if a channel of the device is exposed to a significant voltage.

Between channels – Similar to that state above, there must be separation between each collective 'channel' of dividers. This is due to the fact that arcing may occur if one channel sees a large voltage potential with respect to another.

The AD210BN Isolation amplifier also has 3-way isolation between the input, power and output sections. Due to space restrictions on the board, the isolation between power and input was forfeited. Although this was done, it was redundant anyway since the DC-DC converter which supplies the Isolation amplifier with power has galvanic isolation of its own.

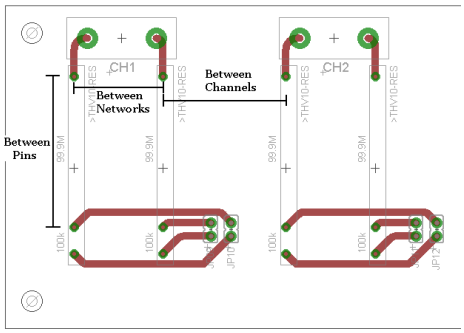


Figure 24 - Depiction of creepage isolation between high voltage pins

CHAPTER 4: Hardware Testing

4.1. Resistive Model

Purely for the purpose of testing, a mock resistive model circuit of the patient and rescuer impedance was designed, shown in Figure 25. This was done for two reasons: for testing with the device to ensure that it is safe before going on to implementation on live patients; and to ensure that if the device were to perceive significant results, that quality data is acquired.

A defibrillator analyzer, used for maintenance of defibrillators in the Technical Service Department at RPH was available which is used as a test patient load with the additional ability to output an ECG waveform to the defibrillator. This device was useful for the initial investigation of the defibrillators yet was not flexible enough to be used for testing. The resistive model was simply a network of high wattage resistors (around 100W for a 25ohm resistor) similar to that found in the defibrillator analyzer. Low impedance resistors were used as simulated patient impedance and larger impedance resistors were used as the rescuer impedance.

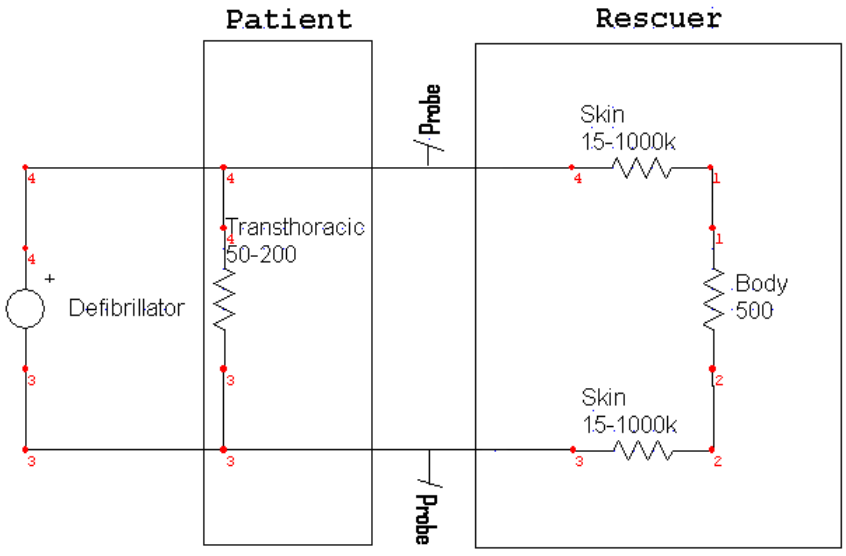


Figure 25 - Circuit diagram of the theoretical situation when a rescuer is touching a patient undergoing defibrillation

4.2. Isolation Circuit Prototype

The isolation circuit consists of the hardware that attenuates the signal from the high voltage signal to the input range of the DAQ. This circuit also makes the device intrinsically safe by providing galvanic isolation between the device and patient. A single channel prototype was created firstly on a breadboard using the AD215AY isolation amplifier to verify that the circuit had an appropriate attenuation ratio (AD210BN was on order). Another prototype was then made on Vero board with all the finalized components. This prototype was used for the rest of the testing.

4.2.1. Testing

The initial testing for attenuation ratio was done on AD215AY using a breadboard and signal generator. The attenuation ratio for a 99.9M: 100k resistive divider network on both the inverting and non-inverting input was 2000:1. Although this does not utilize the full range of the DAQ it is sufficient for the application of the device. Figure 26 displays the circuit diagram of the first prototype along with a picture of the circuit. Figure 27 shows the output of the prototype (blue) with a signal generator input (yellow) of +-10V. This input is a simulation of what the minimum significant result will be during the study and with software based filtering the output should be clearly visible. (See APPENDIX C)

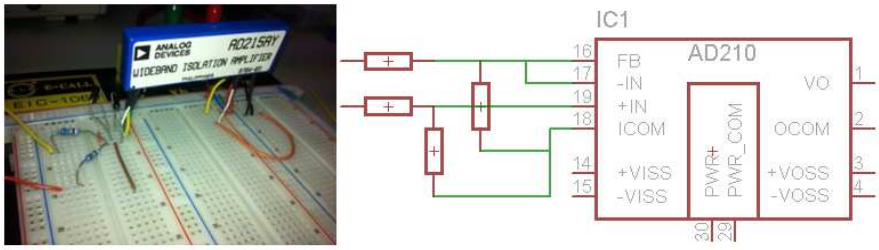


Figure 26 - Picture and circuit diagram of the testing circuit used to test attenuation

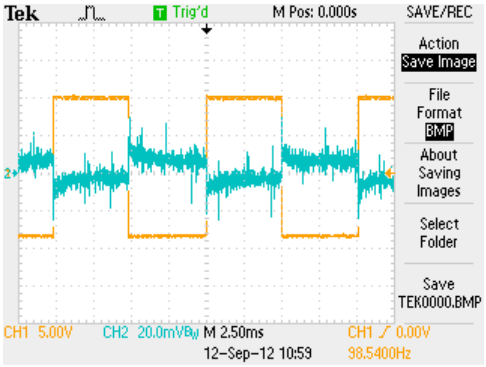


Figure 27 - Results from the test for attenuation

Further testing was done on Vero board using the AD210BN to ensure intrinsic safety and overall quality of the signal. This prototype consists of all the components that will be used in the final device. To achieve appropriate isolation between components, entire rows of copper on the Vero board were cut out. Figure 28 shows a picture of the prototype and an example of the results achieved. Yellow represents the actual defibrillator pulse at 3J and patient impedance of 50.7ohm and blue represents the attenuated and isolated signal. Again, it's assumed that the noise on the output of the prototype can be filtered out in software. The testing for this prototype was deemed to be successful. (See APPENDIX C)

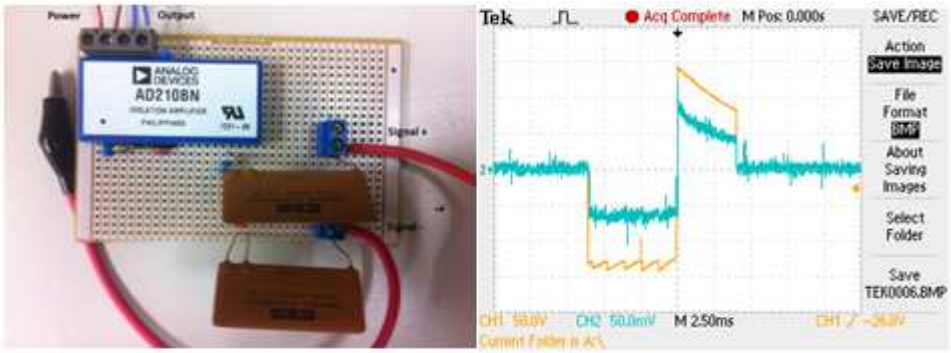
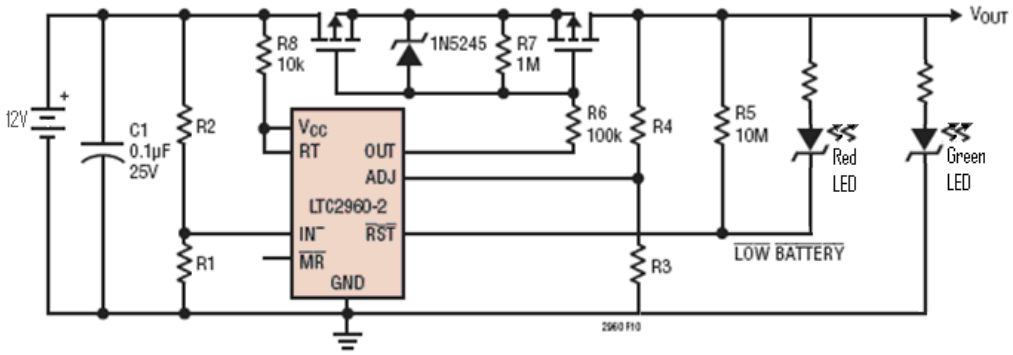


Figure 28 - (left) a picture of the single channel prototype that was made for use in testing (Right) typical example of the output of the defibrillator and its attenuated signal

4.3. Battery Management Prototype



Battery Disconnect to Protect Against Deep Discharge

Figure 29 - Modified application notes diagram of the battery management circuit to protect the battery against a deep discharge (Linear Technology 2012)

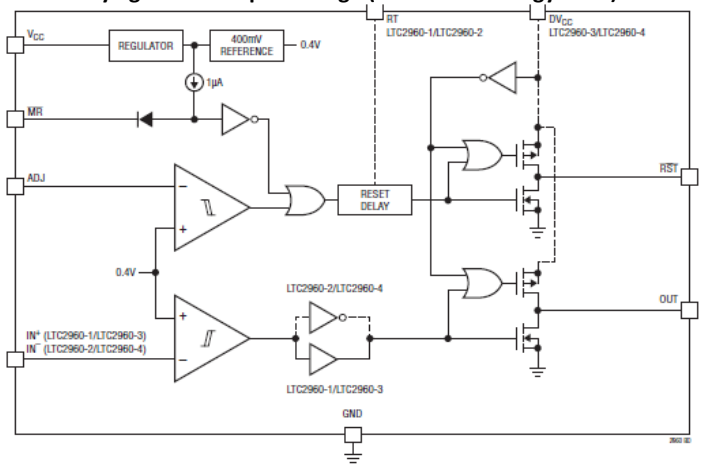


Figure 30 - Functional diagram of the LTC2960 (Linear Technology 2012)

4.3.1. Technical Analysis

Dividers

Figure 29 shows the circuit used for the battery management circuit. This design was a modified version of an example given in the voltage supervisors application notes. R1 and R2 are used as a reference for IN- to configure the trigger point for OUT. In a similar fashion, R3 and R4 are used to configure the trigger for RST. Figure 30 shows the functional diagram of how these voltages are compared and pins are triggered. The maximum resistor size for these dividers is governed by the maximum input leakage current which is 1nA when below 85ºC. For a maximum error of 1% the resistive divider should be at least 100 times the leakage currents, or 1uA. Therefore with cut-off voltages at 10.8V and 11.5V the resistive dividers were calculated as follows (resistor values were changed for standard values):

For ADJ pin:

$$\frac{R_1}{R_2} = \frac{V_{FT}}{V_{TH}} - 1 = \frac{11.5}{0.4} - 1 = 28.75$$

$$R_2 = \frac{8.2M}{28.75} = 285k\Omega$$

Resistor R_2 was exchange for 300kΩ recalculating for a cut-off of 11.27V.

For IN^- pin:

$$\frac{R_1}{R_2} = \frac{V_{FT}}{V_{TH}} - 1 = \frac{10.8}{0.4} - 1 = 27$$

$$R_2 = \frac{6.2M}{27} = 230k\Omega$$

Resistor R_2 was exchange for 220kΩ recalculating for a cut-off of 10.93V.

Auto cut-off

During normal operation, the OUT pin is held low, keeping the P-FET's switched on, and allowing power to flow from the battery to the device. When the voltage drops below the reference voltage at IN-, the OUT pin will pull high. Consequently, this pulls the gates of the P-Channel MOSFET's high, reducing the gate-to-drain voltage to 0, turning the MOSFET off and interrupting the power supply to the rest of the device.

LEDs

This test circuit incorporates both a green and a red (flashing) LED's. The green LED is powered between the output on the side controlled by the voltage supervisor and the common ground. This allows the LED to be on, showing that power is on, and to be turned off when the OUT pin interrupts the supply. This LED signifies that the entire PCB has power. The Red flashing LED is used to show that the battery has become sufficiently low. It is powered between the OUT pin controlled battery supply and the RST pin. When the reference voltage at ADJ falls below the threshold, the RST pin drains to ground. This creates a ground path through the LED, turning it on. As well as this, when the voltage falls below the OUT threshold the red LED will turn off as well.

4.3.2. Testing

As shown in APPENDIX C, three tests were done on the circuit. The first test was done to ensure that the correct voltage references were achieved for the resistor values calculated. The second test consisted of powering the circuit with the battery and actually testing to see if the Pins were pulling high and low as expected and the respective circuit reactions were gained. The final test was to time the intervals between these events under fully loaded conditions. Initially the time interval between the fully charged battery and the first low battery warning occurred was measured. This was done to ensure that the device will be able to operate for enough time before the battery charge depletes. The next time interval was measured between the occurrence of the low voltage event and the automatic cut-off event. This was to detect whether the user of the device has a reasonable amount of time to notice the flashing red LED and to get it to a charger. The results of this test are shown in Figure 31.

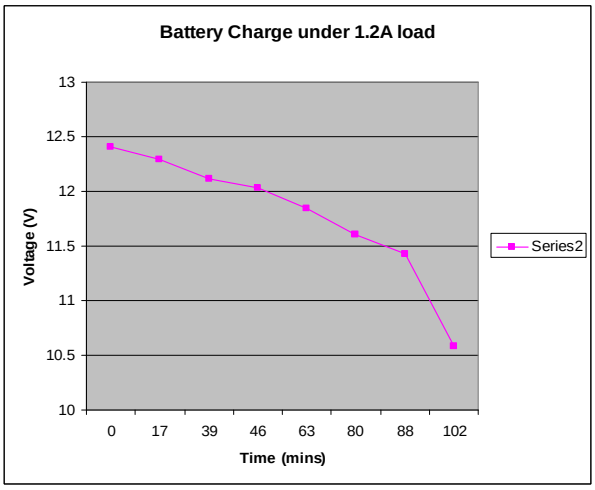


Figure 31 - Graph of Battery voltage over time when under a 1.2A load.

CHAPTER 5: Software Design

The software development package used to design the graphical user interface for this project was LabVIEW 2012. LabVIEW is an acronym for Laboratory Virtual Instrument Engineering Workbench. It is a graphical programming language that consists of two main windows, one being the block diagram where the user programs in a graphical language called 'G'. From this block diagram elements are linked to objects on the front panel, where the final program is executed and displays the data. It is assumed that the reader understands the basic fundamentals of the LabVIEW programming environment.

5.1. Graphical User Interface

Shown in Figure 32 is the graphical user interface designed for the data acquisition system. The front panel consists of multiple panes each with their own specific purpose as explained below:

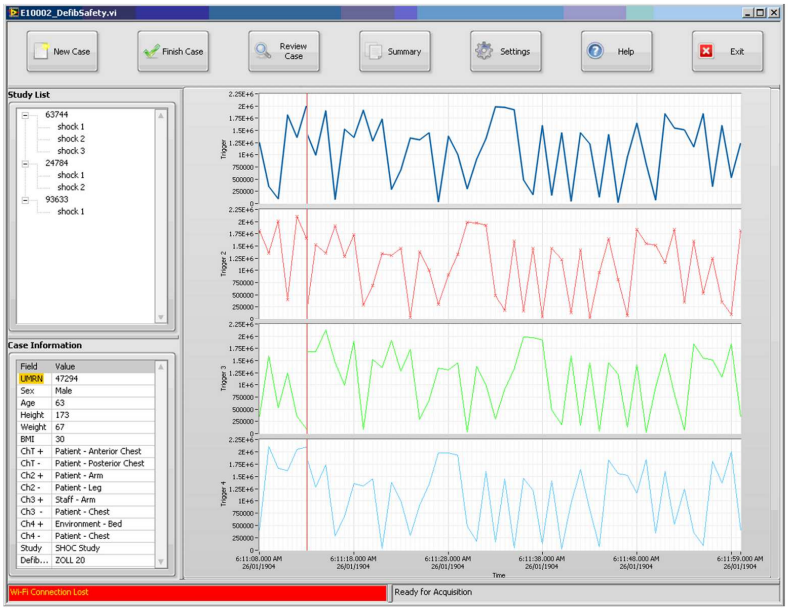


Figure 32 – Picture of the Final front panel of the graphical user interface.

Menu Bar Pane

The menu pane houses all the buttons the user needs to navigate through the study. At various points during the study, some of these buttons are disabled to control the flow of the program. The buttons are described below:

New Case – Launches ‘New Case’ SubVI

Finish Case – Launches ‘Finish Case’ SubVI

Summary – Launches ‘Summary’ SubVI

Review Case – Allows user to view logged data from previous shocks

Help – Link directly to operator manual

Exit – Shuts down program

Graph Pane

This pane solely consists of the graph used to display the acquired data. This pane has two functions; the first is to display the ‘real time’ data as it is being acquired and the second is display archived data when reviewing a previous case.

Status Pane

This pane shows the status of the Wi-Fi connection and the state of the DAQ device. As a Wi-Fi is a much less stable form of communication, it is important to boldly display its status as it may be unapparent to the user if the connection is lost. Therefore the pane is triggered to flash red if the connection is lost giving a clear indication to the user. The state of the DAQ is to indicate whether the program is acquiring data, logging data or whether it has been disabled.

Information Directory Pane

This pane is composed of a single tree control and a multicolumn list-box indicator. During a case, the tree indicator will inform the user about the number of shocks that the patient has received and once finished, if the user reviews a case, this tree control will display the data from that shock on the graph pane depending on which shock number is active. The multicolumn list box displays the patient’s information while the case is active as well as the locations of the leads as a reference for the user. When reviewing a case, this indicator will display the information on the activated UMRN in the tree control.

Software Flow Chart

Described below is a basic description of how the user may interact with the program over the course of logging data for the study. The entire software flow chart may be seen in APPENDIX I.

Pre/Post Study

During this phase, the user has full access to the settings menu and has the ability to view either a summary of the study so far, or look at the data from a particular shock. The summary SubVI queries the database for all case and shock data for some minor statistical processing to calculate the range, mean, standard deviation and inter-quartile range of specific fields.

Start Study

Once a user presses ‘new study’ he/she is prompted to input patient data and lead locations. For the sake of data integrity, the user will not be able to successfully submit this data unless all fields are entered. For the same reason, drop down menus are used wherever possible to avoid typos or incompatible data being entered. Once this data is successfully submitted, the information is displayed on the front panel in the information pane for the staff to use as a reference. After this, the data acquisition will commence automatically, logging the data when appropriate.

Mid-Study

Once the study has started, certain features are disabled to avoid interference with the data acquisition. These include the summary, review study, new study and a portion of the settings. As soon as the initial data has been submitted the DAQ immediately starts acquiring and searching for a trigger. When the trigger is met, the data is logged, written the database and then immediately returns to searching for a trigger. This process is repeated until the user activates the ‘finalize study’ button.

End Study

This is similar the start of the study as the user is prompted to input the shock data. This includes the patient impedance, current and energy of each shock that was performed. These are figures that are given out as a printout from the LIFEPAK and ZOLL defibrillators. Again, the data cannot be submitted unless all the appropriate fields are filled.

5.2. Structure and Programming Techniques

5.2.1. Structure

Once again, the structure of the program being developed was heavily influenced by the Professor of Emergency Medicine as his associated personnel will be using the system. There was many ways that the program could have been structured depending on how much interaction the user required while the study was in progress (e.g. did the user want to view statistics or logged data between shocks?). It was decided that the user was only required to interact with the program before and after the acquisition process. Therefore the need for a real-time capture of the logged data was unnecessary. The graph pane was still chosen to display the acquired data in real-time, purely for the purpose of showing that the program was executing.

5.2.2. JKI State Machine

JKI is a software design company that specializes in creating LabVIEW VI's and add-ons. They have designed a state machine VI that was utilized in controlling the transitions in the different phases of the program.

How it works?

The state machine essentially consists of an extensive case structure inside a while loop with a customized message queue system. Each case in the structure is classified as a state and the transition between states is controlled by the message queue system. The 'idle' state is the backbone of this programming technique. In the 'Idle' state lies an event structure with an infinite timeout period. The event structure contains all of the states that can be initiated by the user. The state machine will naturally proceed to the idle state when the message queue is empty and will stay there until the user initiates another state.

When a state is initiated, it may choose to add items to the queue, via the custom message queue system. This allows the items to be prioritized to be either placed at the front or back of the queue. Once a state has completed the next iteration of the main while loop will call the next item in the queue, and so on.

Advantages

This type of programming style has a variety of advantages. The main advantage is to reduce the repetition of code as a state can be called any number of times from any state in the program. This VI also consolidates the error handling in the program. By having the errors of all the states in a single shift register, the message queue system can detect an error and call the appropriate error handling state.

Another useful feature of the state machine is the ability to form macros. This essentially allows the programmer to split up large chunks of code into a number of different states, and then have a single 'macro' state that places all the previous states onto the queue. Not only does this make programming easier, it also allows each smaller function to be called individually. For example, a single 'Initialize' function can be split up into 'initialize GUI', 'initialize core data' and 'initialize variables'. As all of these have different purposes they all fall under the 'initialize' umbrella.

5.2.3. Guiding User Through Program

This was a simple technique used assist the user in navigating the program. By visually removing the options the user had in each phase of the program, it ensures they used the program efficiently. Doing this was a simple matter of graying out/disabling controls that were not necessary for the user to operate whilst in that state. For example, when a 'new case' has been initiated, all the controls are disabled except the 'finish case' control as the user shouldn't be reviewing other cases or changing settings whilst the DAQ is acquiring data. Not only does this help navigate the user thorough the program, it allows for easier programming.

5.2.4. Local/Global Variable Buffers

The local and global variables are used as a compilation of the settings that are required throughout the program. These are passed around the program in a cluster for various piece of code to read/write to. Some SubVI's in the program have been designed to have a simple 'transactional' relationships with these

variables (can alter the variable but unless the transaction is complete, the alteration is discarded). To enable this kind of functionality, buffers were created as temporary storage for these alterations until the transaction is complete. This allows the program to make changes to this buffer, and if the transaction is successful, this buffer is then written to the settings cluster. There is a buffer for both global and local variables as stated below.

Local Variables

Local variables are defined by those variables that need to be kept upon exiting the program. These are placed as a constant control made into a type definition; this allows them to be consistent over all instances throughout the program. These variables are saved in a type of text file called an '.ini' file in the programs directory. Upon exiting the program, the settings will be written to this file and then re-instated at the programs start-up. This ensures the continuity of all the settings. For example, if a new defibrillator is used, they must register it in the settings subVI which will the write it into the local settings. This will then be saved, so the user does not have to register the new defibrillator every time the program is run.

Global Variables

Global Variables are defined by the variables that are discarded once the program closes. For example, the acquired data from the DAQ is required throughout the program but is flushed once the program closes.

5.2.5. Data Acquisition/Logging

The acquisition of data into the LabVIEW VI is done using the DAQmx Data Acquisition Palette. From this palette, the data acquisition was done by simply specifying the channels on the DAQ, sampling mode, terminal configuration and the sampling rate. These variables were all kept in the Local settings.

Logging

The data logging was designed around a trigger voltage. As the data was acquiring, it was placed into a buffer and the data from the trigger channel was searched for an element that exceeded the trigger limit. When this trigger was exceeded, x amount of samples before and after that trigger were extracted and

logged (the amount of samples taken would correspond to 30ms before and after the trigger, depending on the sampling rate).

Queuing system

Each sample acquired from the DAQ, was written directly into a queue. This queue is a form of buffer that stores the values in sequence until they are de-queued elsewhere. By using the queuing system, it allows the queuing and dequeuing of elements to be use independantly of the while loops used elsewhere in the program therefore removing the need for passing the data in and out of the loops. This voids the risk of having the errors occur due to the speed of the loops.

This system works by storing the data independent to the program and simply feeding references to the queue inside the loops.

5.2.6. Signals Processing

Like many low level analog signals that are measured with data acquisition devices, a certain amount of processing is required to extract the useful information out from amongst the noise. As the measurement device measures low level signals from anywhere between 4V and 10mV (1/2000x the original signal) the data must be amplified back up to its original levels and also filtered to remove the high frequency noise from the PCB and also the low DC offset caused by motion artifacts.

After digitally amplifying the signal by 2000x, the signal was run through two digital filters. The first filter was a high-pass filter to remove high frequency noise, just still high enough to allow the majority of the signal through. The only problem with this is that the defibrillation pulse is essentially a square wave which is made up of an infinite amount of sine waves meaning it is inevitable for a portion of the signal to be lost. The second filter signal is put through is a low-pass filter with a cut-off of around 0.05Hz. This low-pass filter is used to remove two things, the DC offset created by any motion artifacts created by the patient moving and the slow DC creepage of the electrode as the electrolyte increases impedance.

5.2.7. Data Storage

The archiving of the data is an important issue when it comes to a research study, especially as the lifetime and quantity of data increase. The two main types of data storage considered: simple text files that can be opened straight into Microsoft Excel, or the more advanced option of using a SQL database. Both systems have their merits; therefore an analysis of the two was done, shown below.

Table 7 - Analysis of the use of text file against a database

	Database	Text file
Initialization	Requires setup of database and tables	Simply create .csv file in directory.
Write/Update applications	Simple SQL statement	Requires reading and splitting entire file to insert data.
Local Backup	?	Copy .csv file to external memory
Memory usage	Possibility for normalization	Possibility for normalization
Programming	Database Palette	File I/O palette
Format	Not human readable	Human readable
Querying	Simple SQL statement	Split and read all files or export to Excel. (double the work needed when accessing two tables and once)

The database was chosen on the grounds that its read/write functionality greatly outweighs the effort required to set up the database. Using text files, although simpler, require a great amount of effort to update existing files and search files for specific information.

It was chosen to use a single *un-normalized* table in the database. Although normalizing the data was considered, it would require the creation of three tables with their associated primary and foreign keys. Each of these three tables would then need to be queried upon updating information on the GUI and displaying data. As the overall size of the database will be relatively small, it was decided that the

benefits of querying a single un-normalized (increased processing speed) would outweigh the effects of having redundant data in the table.

The database was created using SQL server management studio and was run using Microsoft SQL server 2008 Express. Figure 33 shows the final structure of the table. It was deemed necessary to have all the data stored as strings as this will create a consistency throughout the data. Note: All of the physically acquired data were converted into comma separated values before being stored in a single element inside the table, hence why they are 'varchar (MAX)'.

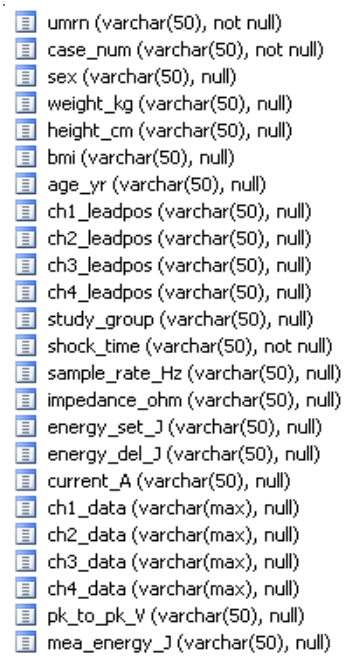


Figure 33 - Database table configuration from SQL Server Management Studio

CHAPTER 6: Documentation

Upon completion of this project, it was expected that certain documentation be complete with regards to the design process used whilst designing the device and software. This is strictly for the purpose of quality assurance (QA). By doing this it forces the designer to consider every outcome of the design process ensuring no aspects of the project was overlooked. It also makes it possible for others to check their work in the future if any problems occur with the project, voiding any viability.

The following documents were completed throughout the project timeline:

Essential Principals Checklist – This document is a checklist that must be complete with regards to the design of any piece of medical equipment in Australia. This document is designed around the Good Manufacturing Process Document created and upheld by the Therapeutic goods administration (TGA). Completing this document attempts to demonstrate the manufacturers compliance with Australian standards for medical devices.

BOM – A bill of materials was created for both the assembly of the PCB and the enclosure. These can be found in APPENDIX F.

Feasibility report & Risk analysis - These documents were completed upon starting the project to deem whether it is in the department's best interests to take up the project. This includes an analysis of the resources that are currently available.

Ethics Approval – In order for the device to be used in a clinical study, it must gain the approval of the ethics committee to ensure the device will not have any detrimental impact while in use. The professor of emergency medicine was in charge of putting forward a proposal for ethics approval.

CHAPTER 7: Concluding Remarks

7.1. Project Conclusions

Throughout this thesis, a device was designed and manufactured for the purpose of a research study to achieve better understanding of the safety of bystanders whilst a patient undergoes defibrillation. Included in this was the design and testing of a PCB, Device Enclosure and a Software program. Each of these elements required research planning into various electrical, mechanical and programming procedures and techniques.

At the end of the thesis period the following was completed:

- The PCB was designed, tested and sent out for manufacture.
- The Enclosure was designed and sent out for modification.
- An operational framework for the software program was completed. This includes final design of the GUI interface, Storage of local and global settings and the acquiring and logging of data from the DAQ.

During this time an abundance of knowledge was gained from a variety of different software packages including:

Eagle CAD software – This was used to create the schematics, PCB design and the overall enclosure wiring diagram.

LabVIEW 2012 – This was used to create the software program that would be used to analyze and log the acquired data to the database. Extra programming techniques learnt include JKI state machine system and message queue system.

Microsoft Visio – This program was used to create the enclosure layout and design. In future, a more suitable CAD software package should be used.

RPH Project Management system (Ace Projects) – This web-based project management system was learnt to coordinate all the projects taking place at the

Medical Engineering and Physics Department. This was useful in organizing the intern's workload and documentation linked to the project.

7.2. Proposed Future Works

Software

Although the framework of the software has been completed, there is a considerable amount of work that needs to be completed with regards to the manipulation of the data for analysis as well as the finer details in presenting a professional GUI. Another issue that may need to be considered is some form of automatic re-initialization for the DAQ in the situation where Wi-Fi signal were to be lost.

Documentation

Because of the sheer size of this project, not all the documentation could be completed. Some documents that need completing are the specification document, Project summary report, service manual and operator manual. These documents are essential to the project and must be completed before the final device can be handed over to the customer.

Verification testing and Commissioning

To ensure the device abides by certain criteria laid out in various standards (E.g. AS/NZS 3200, AS/NZS 2500, CISPR11, etc.) proper verification testing must be done. This includes testing of the physical integrity of the device as well as the electrical safety of the device. Some common tests include test for electromagnetic compatibility, mechanical strength test, leakage current test and protective earthing test. For an example of this test, see APPENDIX H.

Patient trials

Once the device has been fully commissioned it will then take part in live patient trials. This will be done by Representatives of the Emergency department at Royal Perth Hospital under the supervision of the Medical Engineering and Physics Department. The device will initially be used on two groups of participants, those requiring planned cardio versions and those requiring unplanned defibrillation.

Analysis of study data

Once the trials are complete the data collected can be analyzed and a conclusion may be formed about the dangers of hands on cardio version/defibrillation.

Incorporation of current sensing resistor

Plans may be made to incorporate a current sensing resistor into the device. This will allow the leakage current to be directly measure from the patient allowing for a more thorough analysis. The only drawback with this is it would decrease the overall amount of channels available on the device.

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APPENDIX

APPENDIX A – IP RATINGS

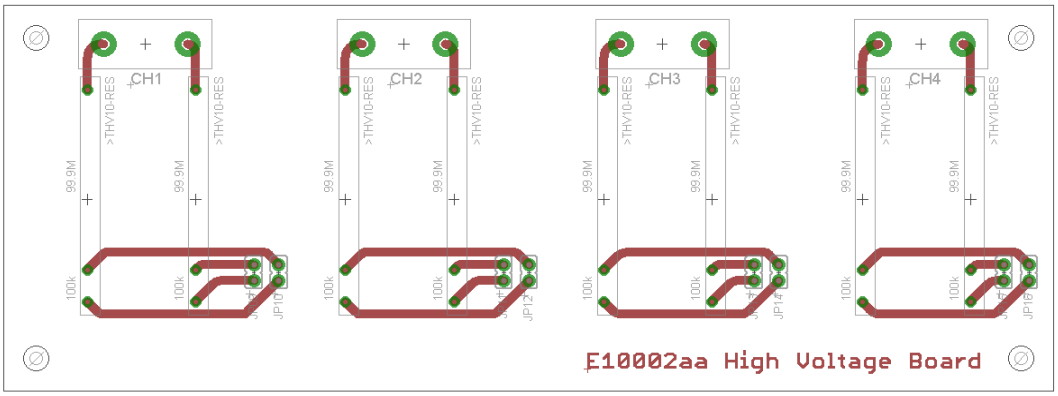
The following table describes the first and second figures of the ingress protection ratings specified by the EN/IEC 60529 standard.

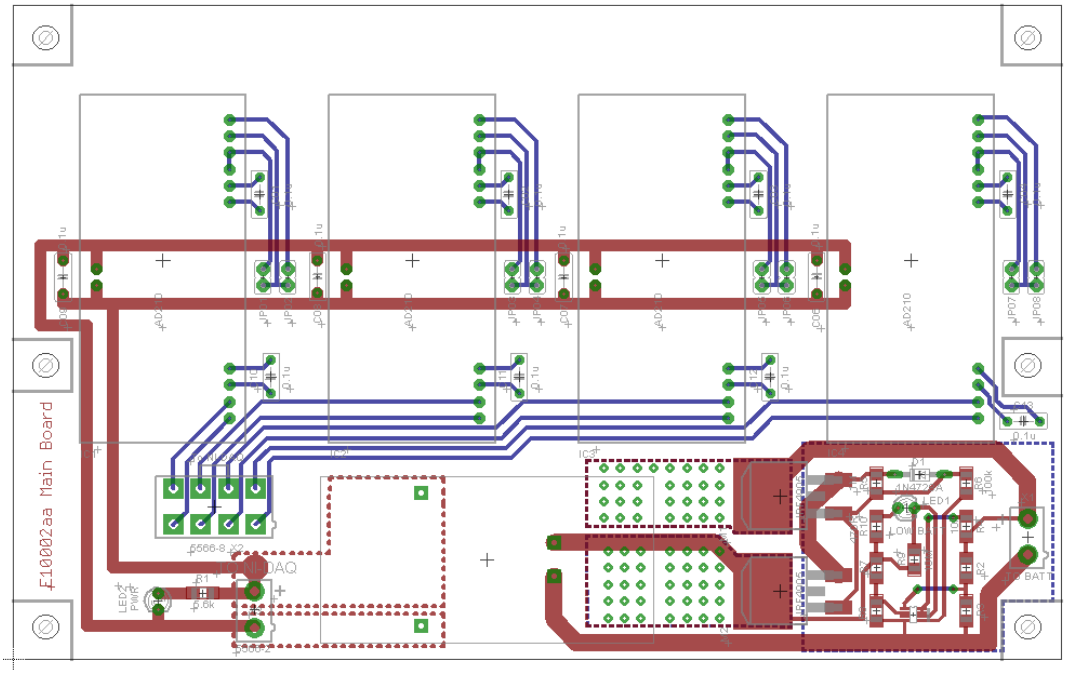
Table 8- Description of the IPXX figures (Electrical Engineering Portal n.d.)

First Figure		Second Figure	
0	No protection	0	No protection
1	Protected against a solid object 50 mm or greater	1	Protected against vertically dripping water
2	Protected against a solid object 12 mm or greater	2	Protected against vertically dripping water, when tilted 15 degrees
3	Protected against a solid object 2,5 mm or greater	3	Protected against water spraying at an angle up to 60 degree
4	Protected against a solid object 1 mm or greater	4	Protected against water splashing from any direction
5	Dust protected	5	Protected against jets of water from any directions
6	Dust tight	6	Protected against powerful jets of water from any directions
	-	7	Protected against immersion between a depth of 150 mm and 1000 mm
	-	8	Protected against submersion

APPENDIX B – FINAL PCB

The following diagrams are screenshots of the final PCB design. See attached DVD for the .sch and .brd files.





APPENDIX C – PROJECT DESIGN TEST FORM

TECHNICAL SERVICES
Medical Engineering & Physics Department

PROJECT TEST FORM

Certified System Quality ISO 9001 SAI GLOBAL

PROJECT No: A	**DATE:**
PROJECT TITLE: Defibrillation Safety	**TESTED by:** Matthew Oeding

SPECIAL PRECAUTIONS: High voltages used in tests.

AIM: Verify the design, components and tolerances of the overall design circuit.

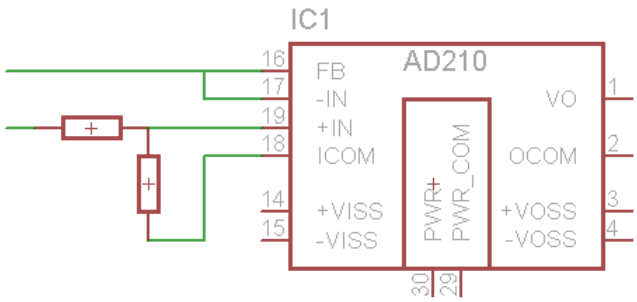
APPARATUS: Power supply, ZOLL/LIFEPAK defibrillator, Vishay bidirectional TVS SMCJ6.0CA-E3, CADDOCK HIGH PRECISION VOLTAGE DIVIDER NETWORK TYPE THV 1000:1 10kVDC 1% 25PPM, DMM, Tektronixs oscilloscope, patient impedance (FAR 187-8569, 155-7184, 155-9782, 107-3266), AD210BN Isolation amplifier, NI-9215/cDAQ-9191 DAQ module, bread board.

PROCEDURE:

ELECTRICAL SAFETY TESTS

1. Test the characteristics of the voltage divider network.

Equipment: Power supply, Voltage Divider network, Tektronixs oscilloscope



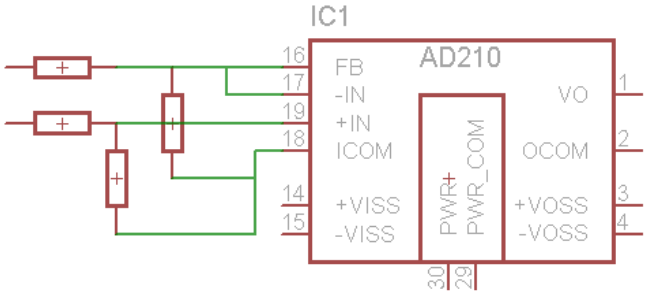
Criteria: a) Test with divider network on one leg of the differential input. Measure the differential voltage across the two terminals using a square wave signal and check for correct attenuation ratio.

Criteria: b) Measure the voltage potential between the inverting/non-inverting input and the common input with attenuation on both legs. This should not exceed the voltage potential between the inverting and non-inverting inputs.

Criteria: c) Test with divider network on both legs of the differential input. Measure the differential voltage across the two terminals using a square wave signal and check for a 1000:1 attenuation ratio.

2. Test the isolation amplifier

Equipment: Power supply, AD210BN Isolation amplifier, Tektronics oscilloscope, Voltage Divider network



Criteria: a) Apply voltage in the range from -10V to +10V and measure output to verify general quality.

Criteria: b) Apply voltages that exceed the specified input voltage and assess the response of the isolation amplifier. Assure that excess voltages will not pass that may interfere with DAQ module.

Criteria: c) Apply square wave across the isolation amplifier via the resistive attenuation network and measure the response. Compare the response with that of the expected response. This will be done to assess the quality of the frequency response and other characteristics of the amplifier in response to a defibrillator pulse.

3. Current offset voltage test

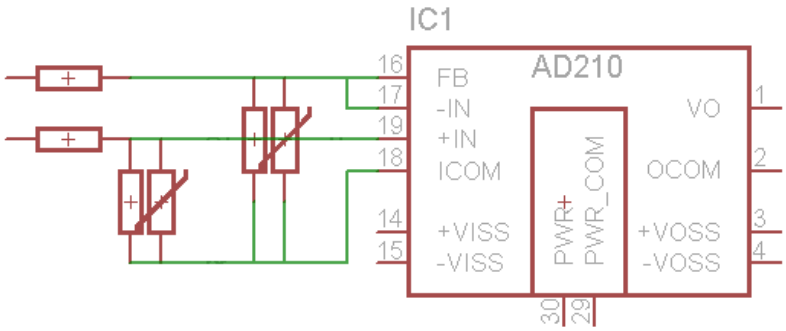
Equipment: Power supply, AD210BN Isolation amplifier, Tektronics oscilloscope, potentiometer

Criteria: a) Measure the voltage offset of the isolation amplifier. Using this, determine if small voltage signals can be discriminated from the offset voltage. From here determine whether a voltage offset bias is required in hardware or possibly software.

4. Test for breakdown voltages of voltage suppression components.

Equipment: Power supply, Tektronics oscilloscope, AD210BN Isolation amplifier, Voltage Divider network **,** bidirectional TVS

Apply a gradually increasing voltage to the voltage suppressor until it conducts and record this breakdown voltage. Then apply a defibrillation pulse to the voltage suppressor and test for its impulse breakdown voltage. Ensure that the speed of the suppression will avoid damage to the Isolation amplifier or DAQ. Once criteria a) are approved, repeat test with the voltage suppression components in conjunction with the isolation amplifier. Measure the output of the isolation amplifier. The output should be saturated at 10V but no damage to the isolation amplifier should be done.



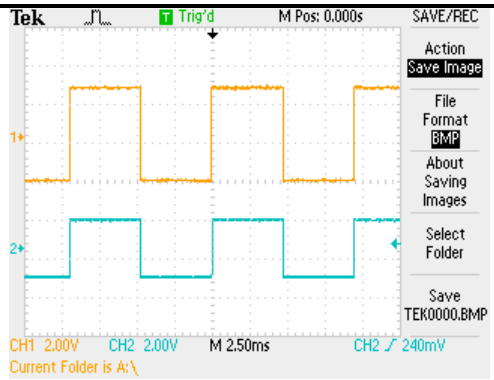
Criteria: a) Is the breakdown voltage and clamping voltage appropriate for the application?

Criteria: b) Ensure that the shunted voltage is suitable with the common rail and will not be damaged by high voltage spikes.

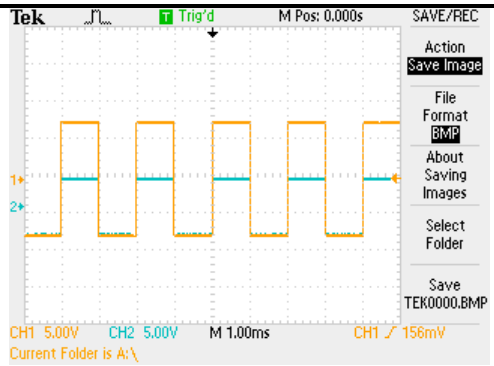
Criteria: c) Check that the use of the voltage suppression device does not affect the output of the amplifier.

RESULTS:

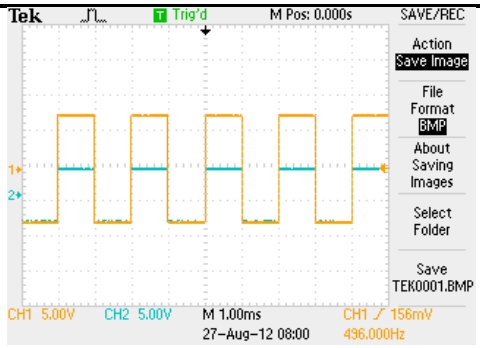
Test No.	a)	b)	c)	d)
1	(X)See Figure 1	(√)See figures 2,3,4	(√)See figure 5	
2	(√)See figure 6	(√)	(√)See Figure 7	
5	(√)			
6	(√)	(√)	(X)	



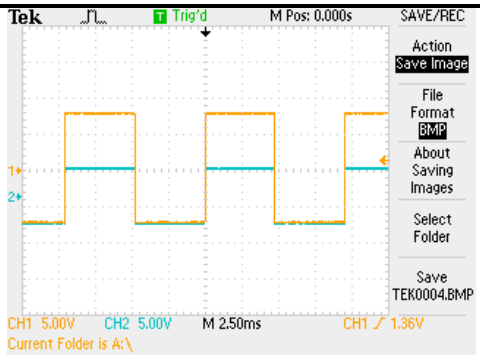
Single Leg attenuation with a 1k: 1k divider showing attenuation ratio of ~5:3 when it should be 2:1. Therefore Attenuation on a single input is unacceptable.



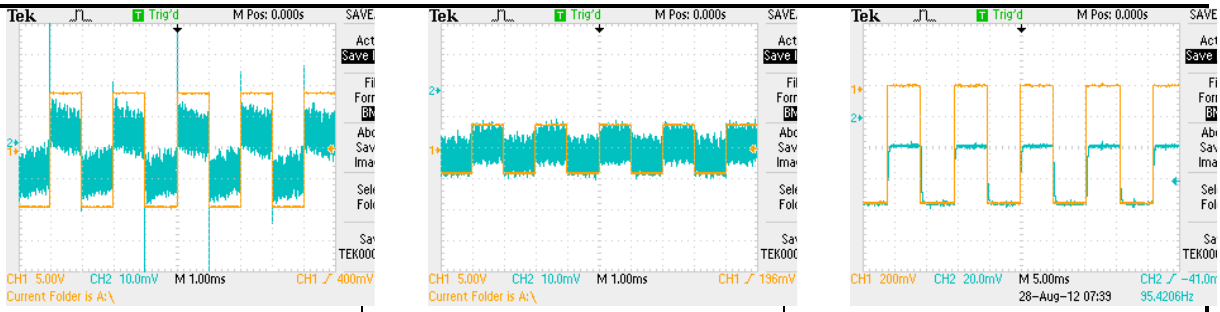
Double leg attenuation with a 1k: 1k divider. Referenced from Common input to non-inverting input.



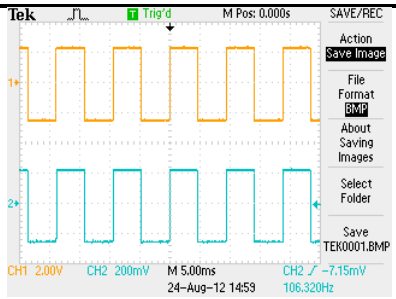
Double leg attenuation with a 1k: 1k divider. Referenced from Common input to inverting input



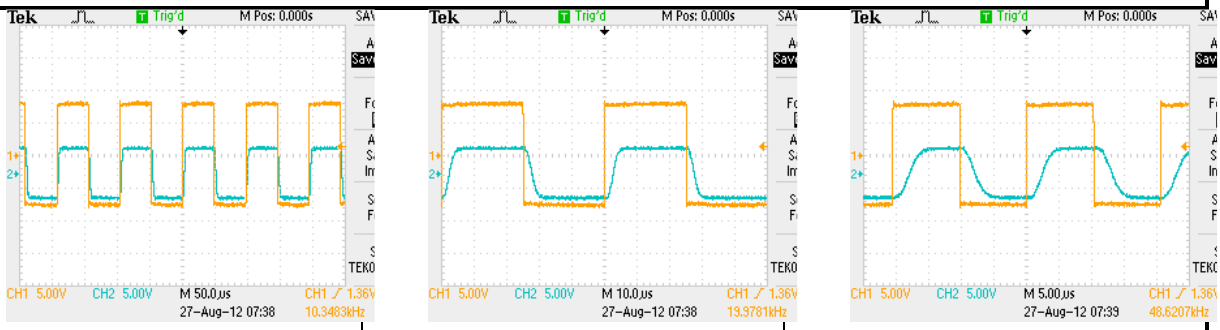
Double leg attenuation with a 1k: 1k divider. Referenced from inverting input to non-inverting input. This does not exceed figure two or three, therefore the common rail will not see voltages above the attenuated signal.



(Left) double leg attenuation with 100M: 100k dividers. Excessive noise present due to amplifier input impedance. (Middle) double leg attenuation with 100: 100k dividers. Insufficient evidence to show correct attenuation. (Right) Using a resistive network of 100k: 10k, a clear attenuation ratio of 20:1 can be seen. This shows that each resistive network attenuates the signal by 10:1. Although not preferred, this allows an acceptable overall attenuation of the network at 2000:1.



Output of Square wave signal of isolation amplifier.



Double leg attenuation with a 1k: 1k divider exposed to varying frequencies from ~10 kHz, ~20 kHz and ~50 kHz respectively. This shows little attenuation over frequencies that are far above that of a defibrillation pulse.

APPENDIX D – PROJECT RESISTIVE MODEL TEST FORM

TECHNICAL SERVICES
Medical Engineering & Physics Department

PROJECT TEST FORM

PROJECT No: A	**DATE:**
PROJECT TITLE: Defibrillation Safety	**TESTED by:** Matthew Oeding

SPECIAL PRECAUTIONS: High voltages used in tests.

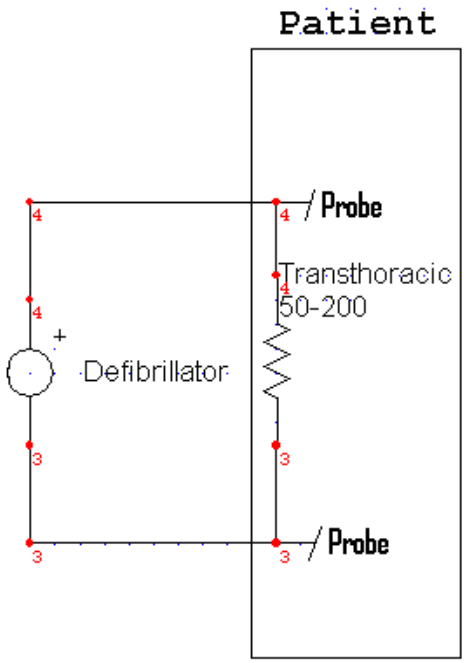
AIM: Verify the design, components and tolerances of the experimental resistive model.

APPARATUS: Trans-thoracic impedance circuit, rescuer impedance circuit, Signal generator, oscilloscope, Digital Multimeter, defibrillator.

PROCEDURE:

5. High Voltage patient Impedance test

Equipment: Trans-thoracic impedance circuit, Defibrillator, oscilloscope, Digital Multimeter.



Apply defibrillator pulse across the trans-thoracic impedance model. Measure the voltage across the resistor as well as the impedance and current. Ensure that it is an accurate representation of the patient. Resistance value can range from ~50-200ohms. The defibrillator should be set to output the minimum amount of joules it can to start off (approx. 1 joules.) This should also not exceed to recommendations of the oscilloscope or the Digital Multimeter. If this is successful, repeat the test with a higher energy output. The resistor used to simulate the trans-thoracic impedance must be able to withstand a defibrillator pulse which requires it to have a reasonably large power rating (~100W.)

Defibrillator Procedure (ZOLL):

1.) Turn on Defibrillator.
2.) Press Manual Mode
3.) Press Confirm
4.) Set joules via *Energy select* buttons
5.) Press charge
6.) When the Device beeps, press *shock* button.

Criteria: a) Investigate the change in defibrillator output with varying patient impedance. Ensure that the voltage drops and current flow through the resistor is an accurate representation of the patient.

Criteria: b) Ensure that the resistor is not radiating excessive amounts of heat.

6. High Voltage Resistive model and isolation circuit test

Equipment: Trans-thoracic impedance circuit, Signal generator, oscilloscope, Digital Multimeter, Prototype.

Run the signal from test 1 into the prototype circuit. Measure the output of the circuit to test for signal quality.

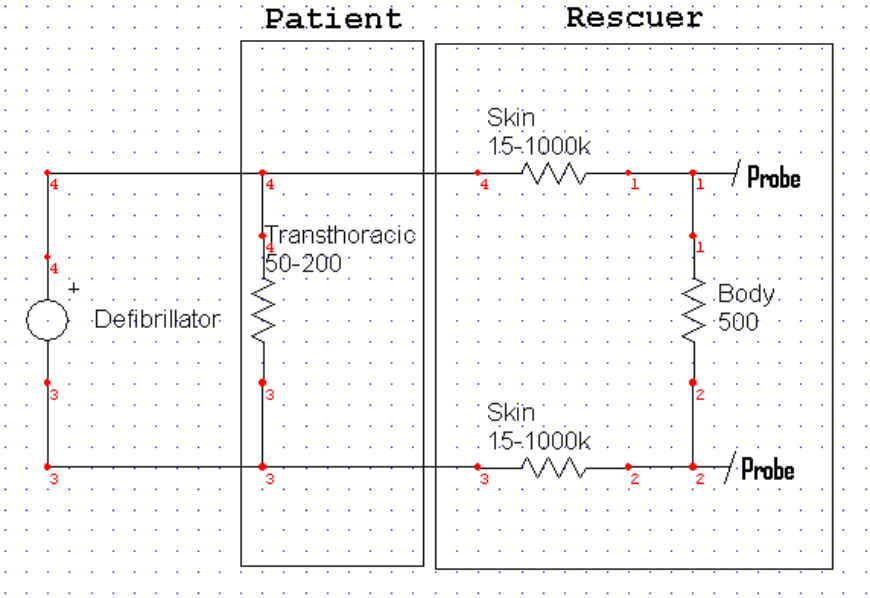
For defibrillator procedure, see test 1

Criteria: a) Ensure the output of the isolation circuit is correctly attenuated and gives a significant trigger. Repeat with different patient impedances.

Criteria: b) check that no damage has been done to the isolation circuit.

7. High Voltage Resistive model test

Equipment: Trans-thoracic impedance circuit, Defibrillator, oscilloscope, Digital Multimeter.



Apply a defibrillator pulse across the trans-thoracic impedance model with the secondary rescuer circuit attached in parallel. Measure the voltage drop across the trans-thoracic impedance resistor and use this to deduce the current. Also measure the voltage drop across the secondary patient circuit and calculate current. This should signify any leakage current though a rescuer and should be significantly less than that of the trans-thoracic impedance. Repeat the test varying the patient and rescuer impedance.

For defibrillator procedure, see test 1

Criteria: a) Ensure that this is an accurate representation of a patient and rescuer circuit.

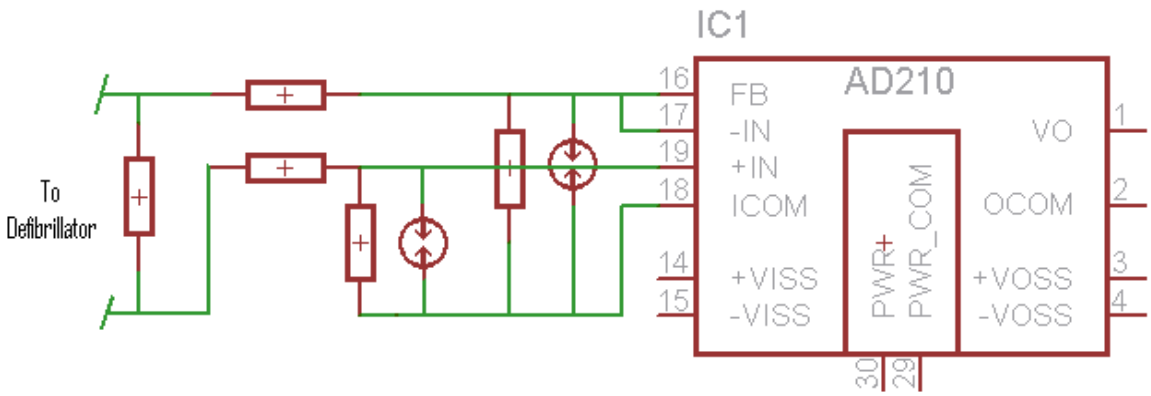
Criteria: b) Ensure that neither of the resistive networks is radiating excessive heat.

Criteria: c) Does the finding from the test support those found in similar literature?

8. Gas Discharge Tube test

Equipment: Trans-thoracic impedance circuit, Defibrillator, oscilloscope, Digital Multimeter GDT's.

Apply Defibrillator pulse across patient impedance resistor with resistive attenuation circuit in parallel. This circuit should also include the gas discharge tubes, similar to the test with the Transient voltage suppressors. This will be done to ensure that the GDT's have negligible effect on the overall quality of the signal. Once this is done, the resistive attenuation should be removed to represent a single fault condition of the failure of the resistor. In this situation, the GDT's should pass their spark-over voltage of 90V and conduct, protecting the isolation amplifier.



Criteria: a) Check that the GDT has a negligible effect on the quality of the signal.

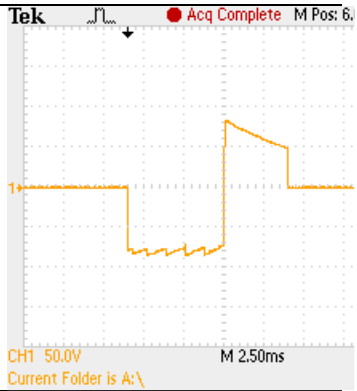
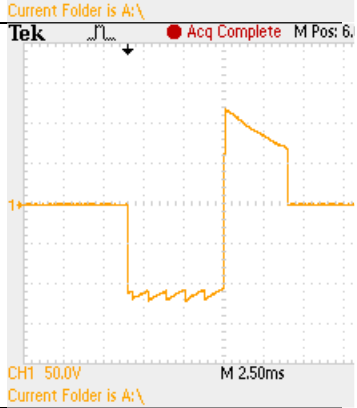
Criteria: b) Ensure that under single fault condition of resistive failure, the GDT's conduct appropriately and no damage to the Isolation amplifier is done.

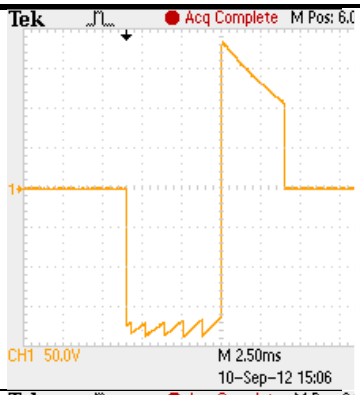
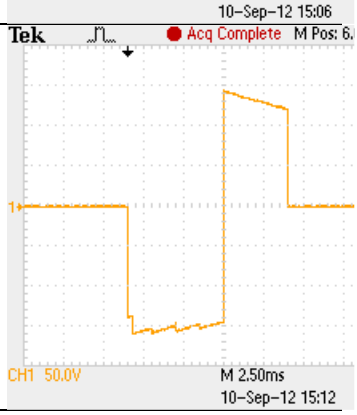
RESULTS:

Test No.	a)	b)	c)	d)
1	See table 1	(√)		
2	See table 2	(√)		
3	See table 3			
4	(√)	(DNF)		
5				
6				

COMMENTS:

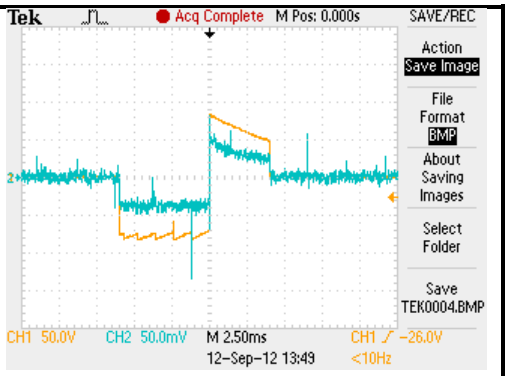
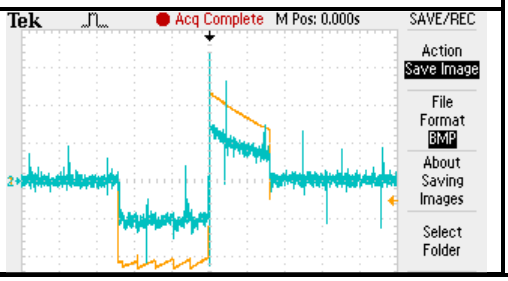
Table 1

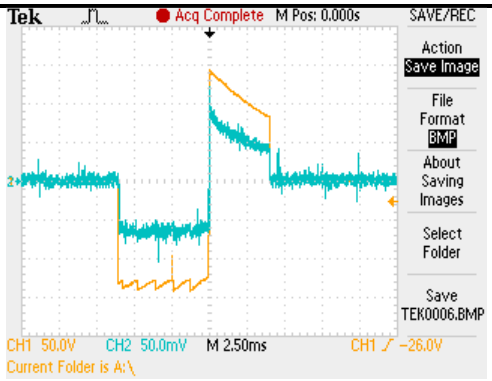
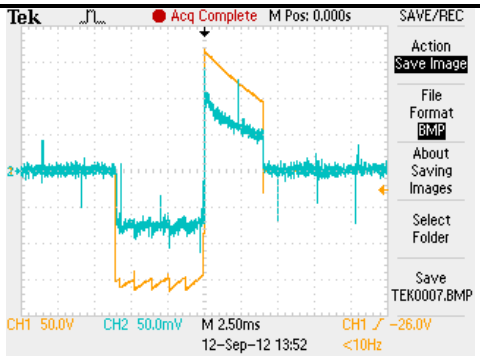
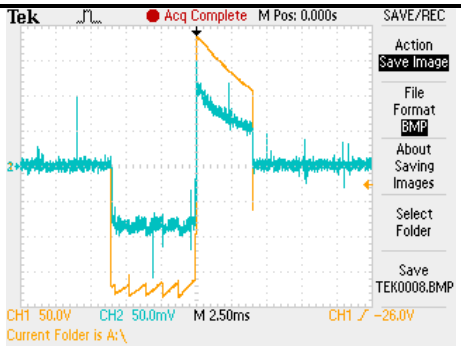
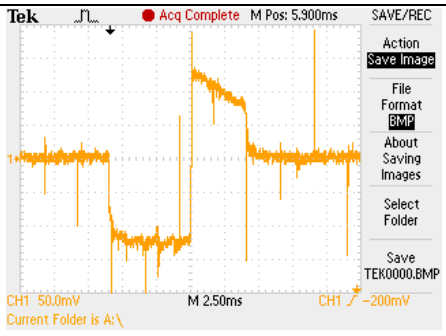
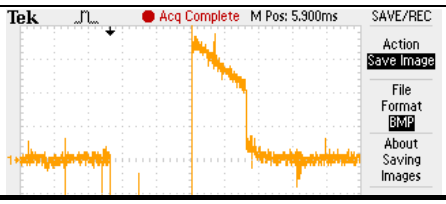
Impedance	44ohm	
Current	1A	
Energy	1.0J	
Impedance	47ohm	
Current	2A	
Energy	2.1J	

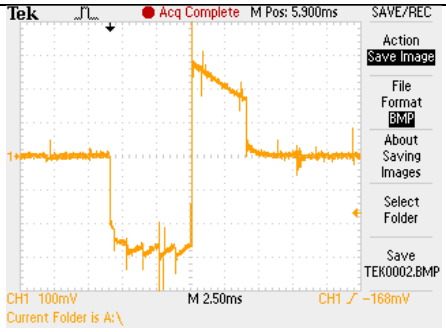
Impedance	48ohm	
Current	3A	
Energy	5.0J	
Impedance	187ohm	
Current	0A	
Energy	1.1A	

COMMENTS: As shown, the ZOLL has a fixed pulse length of 10ms. This requires the average voltage and current to increase with an increase in patient impedance. In the table it shows an output of 1J at 200ohm is similar to that of 5J at 50ohm. The pictures also show the unique biphasic rectilinear waveform that the defibrillator outputs.

Table 2 – yellow = defibrillator output, blue = prototype output

Patient Impedance (Seen)	50.7(42)ohm	
Energy Delivered (Set)	1.0(1)J	
Current	1A	
Pk-Pk (Defib)	166V	
Pk-Pk (Output)	~90mV	
Attenuation Ratio	~1844	
Patient Impedance (Seen)	50.7(45)ohm	
Energy Delivered (Set)	2.0(2)J	
Current	2A	
Pk-Pk (Defib)	234V	

Pk-Pk (Output)	~130mV	
Attenuation Ratio	~1800	
Patient Impedance (Seen)	50.7(45)ohm	
Energy Delivered (Set)	2.9(3)J	
Current	2A	
Pk-Pk (Defib)	286V	
Pk-Pk (Output)	~170mV	
Attenuation Ratio	~1682	
Patient Impedance (Seen)	50.7(49)ohm	
Energy Delivered (Set)	4.2(4)J	
Current	2A	
Pk-Pk (Defib)	334V	
Pk-Pk (Output)	~190mV	
Attenuation Ratio	~1758	
Patient Impedance (Seen)	50.7(49)ohm	
Energy Delivered (Set)	5.2(5)J	
Current	3A	
Pk-Pk (Defib)	374V	
Pk-Pk (Output)	~210mV	
Attenuation Ratio	~1781	
Patient Impedance (Seen)	50.7(49)ohm	
Energy Delivered (Set)	10.4(10)J	
Current	4A	
Pk-Pk (Output)	~260mV	
Pk-Pk (Defib) *Theoretical at x2000	520V	
Patient Impedance (Seen)	50.7(50)ohm	
Energy Delivered (Set)	20.5(20)J	
Current	6A	
Pk-Pk (Output)	~380mV	

Pk-Pk (Defib) ***Theoretical at x2000**	760V	
Patient Impedance (Seen)	50.7(51)ohm	
Energy Delivered (Set)	50.8(50)J	
Current	10A	
Pk-Pk (Output)	~580mV	
Pk-Pk (Defib) ***Theoretical at x2000**	1160V	

COMMENTS: This table shows the relationship the defibrillators output and the output from the isolation device. The attenuation is calculated to be approximately x2000, with the error probably due to human measurement error. In the last three tests do not have a defibrillator output since the oscilloscopes probe ratings are exceeded at higher energy outputs. There is also the presence of some high frequency noise at the output of the isolation amplifier that will be filtered out in software later in the design process.

APPENDIX E – PROJECT WI-FI TEST FORM

TECHNICAL SERVICES
Medical Engineering & Physics Department

Certified System Quality ISO 9001 SAI GLOBAL

PROJECT TEST FORM

PROJECT No: A	**DATE:**
PROJECT TITLE: Defibrillation Safety	**TESTED by:** Matthew Oeding

SPECIAL PRECAUTIONS: High voltages used in tests.

AIM: Verify the design, components and tolerances of the overall design circuit.

APPARATUS: ZOLL/LIFEPAK defibrillator, NI-9215/cDAQ-9191 DAQ module

PROCEDURE:

9. Test EMC between operational Defibrillator and cDAQ-9191 Wi-Fi transmission.

Equipment: ZOLL/LIFEPAK defibrillator, test circuit, NI-9215/cDAQ-9191 DAQ module

Criteria: a) While applying a 200J defibrillation pulse to a test circuit, vary the distance between the Wi-Fi transmitter and the defibrillator. Ensure that the EMI from the large defibrillation pulse does not cause the Wi-Fi signal to be lost.

RESULTS:				
Test No.	**a)**	**b)**	**c)**	**d)**
1	**From <30cm no interference was detected.**			
2				
3				
4				
5				
6				

APPENDIX F – BOM

Manufact Supplier Part Number	PCB ASSEMBLY ITEM DESCRIPTION	U.O.M	QTY	Cost Each	Cost Total	Item No.
THV10-A100M-1.0-25	CADDOCK HIGH PRECISION VOLTAGE DIVIDER NETWORK TYPE THV 1000:1 10kVDC 1% 25PPM	EA	8	$120.4	$963.20	R11, R12, R13, R14, R15, R16, R17, R18
FAR 318-2046	Analog Devices Isolation amplifier AD210BN	EA	4	$168.23	$672.92	IC1, IC2, IC3, IC4
RS 163-5585	MATURA POWER SOLUTIONS DC-DC converter UEP-15/1200-D12N-C 15W 1.2A	EA	1	$42.60	$42.60	DC1
FAR 158-1188	MULTICOMP - MCLF056SRD - LED, FLASHING, 5MM, SUPER-RED 20mA 5V 35mcd	EA	1	$0.94	$0.94	LED1
FAR 116-8554	DIALIGHT - 521-9327F - LED, 5MM, GREEN, 1.8MCD, 565NM	EA	1	$0.85	$0.85	LED2
FAR 182-6120	NXP- 1N4749A 113 ZENER DIODE, 1W, 24V, DO-41	EA	1	$3.23	$3.23	D1
FAR 209-7976	LINEAR TECHNOLOGY - LTC2960ITS8-2 #PBF – VOLTAGE MONITOR, 0.015/0.2 S RESET, 36V, 8TSOT	EA	1	$6.33	$6.33	IC5
	Caps	EA	2	$0.06	$0.12	
FAR 933-5765	MULTICOMP - MC 0.125W 1206 1% 10K - RESISTOR, 10K, 125MW, 1% (pk of 50)	EA	1	$0.132	$0.13	R4
FAR 912-839	MULTICOMP - MC 0.125W 1206 1% 1M - RESISTOR, 1206 1M (pk of 50)	EA	1	$0.08	$0.08	R5
FAR 933-6672	MULTICOMP - MC 0.125W 1206 1% 5K6 - RESISTOR, 1206 5K6 (pk of 50)	EA	1	$0.08	$0.08	R1
FAR 912-712	MULTICOMP - MC 0.125W 1206 1% 100K - RESISTOR, 1206 100K (pk of 50)	EA	1	$0.08	$0.08	R6
RS 223-2215	TE Connectivity Resistor precision chip SMT 1206 1% 470R (PK OF 50)	EA	1	$0.05	$0.05	R10
RS 722-0765	Panasonic Anti-Surge Resistor 1210 0.5W 5% 10M (PK OF 5)	EA	1	$0.11	$0.11	R9
RS 722-0747	Panasonic Anti-Surge Resistor 1210 0.5W 5% 6M2 (PK OF 5)	EA	1	$0.11	$0.11	R7
RS 722-0006	Panasonic Anti-Surge Resistor 1206 0.33W1% 220K (PK OF 5)	EA	1	$0.21	$0.21	R8
RS 722-0012	Panasonic Anti-Surge Resistor 1206 0.33W 1% 300K (PK OF 5)	EA	1	$0.21	$0.21	R3
RS 722-0753	Panasonic Anti-Surge Resistor 1210 0.5W 5% 8M2 (PK OF 5)	EA	1	$0.11	$0.11	R2
FAR 1298511 RS 650-3678	IRF4905SPBF P-Channel power MOSFET-55V 20mA -42A D2Pak	EA	2	$2.41	$4.82	M1, M2
RS 849007	TYCO Mate-N-Lock PCB Header 3 Pin20.3 x 7.6 x 14 mm	EA	4	$0.78	$3.12	X4, X5, X6, X7
RS 4841883	Molex MiniFit PCB header 2 Pin 11 x 12.8 x 5.8 mm(pk of 5)	EA	2	$0.57	$1.14	X1, X3
RS 6998540	Molex MiniFit PCB header 8 Pin					

	11 x 12.8 x 18.4 mm (pk of 5)	EA	1	$1.03	$1.03	X2
RS 2779736	SAMTEC PCB stacker 33.53mm 50 Pin (pk of 4)	EA	8	$6.20	$6.20	JP09, JP10, JP11, JP12, JP13, JP14, JP15, JP16
FAR 972-8910	FISCHER ELEKTRONIK BL5.36Z - HEADER SOCKET 2.54MM 36WAY	EA	1	$15.92	$15.92	JP01, JP02, JP03, JP04, JP05, JP06, JP07, JP08
				TOTAL	$1723.59	

Manufact/Supplier Part Number	ENCLOSURE ASSEMBLY ITEM DESCRIPTION	U.O.M	QTY	Cost Each	Cost Total	Item No.
ROSE RS 138-206	ENCLOSURE CLEAR LID 300mm (L) X 230mm (W) X 85mm (H) POLYCARBONATE IP65 (LID FASTENER M4 37/10 CYLINDER SCREWS x6)	EA	1	$159.50	$159.50	1
TSD	Enclosure mounting plate	EA	1	$0.00	$0.00	2
National Instruments NI-9215	NI-9215 4-Channel Differential Data Acquisition Module 100Kb/s/ch +-10V	EA	1	$693.00	$693.00	3
National Instruments cDAQ-9191	National Instruments cDAQ-9191 Wifi DAQ chassis IEEE802.11b/g	EA	1	$616.00	$616.00	4
RS 320-4508	YUASA NPH5-12 12V,5.1Ah Deep Cycle Lead Acid Battery ~1.3kg	EA	1	$64.00	$64.00	5
RS 3779743	Switch Rocker DPST 30x22mm cut-out 0/1 marking black IP44	EA	1	$3.11	$3.11	6
RS 468774	Connector circular sub-miniature 620 series 3-5mm cable diameter cable socket 3way	EA	1	$9.70	$9.70	7
RS 468813	Connector circular sub-miniature panel plug series 620 3 way	EA	1	$5.80	$5.80	8
ALT M8520	Charger Battery SLA 12V 300mA M 8520	EA	1	$13.08	$13.08	9
	Fuse	EA	1	$0.00	$0.00	10
FAR 3700690	COOPER BUSSMANN - BK/HHT - FUSE HOLDER 5 X 20MM IN LINE 32V 5A	EA	1	$5.26	$5.26	11
RS 382-961	Spacer nylon female-female hexagonal tapped thru M3x6mm (pk of 50)	EA	4	$0.32	$1.28	12
	Screws for mounting plate M3 thread	EA	6	$0.00	$0.00	13
FAR 1514409	DURATOOL - D00687 – NYLON SCREW PAN M3X6 PK of 25	EA	1	$4.48	$4.48	14
	Screws for DAQ mounting M4 thread	EA	2	$0.00	$0.00	15
	Screws for PCB mounting 12mm M3 stainless steel	EA	4	$0.00	$0.00	16
RS 325671	Spacer Nylon hexagonal type 2 M3x30mm (PK of 50)	EA	4	$0.72	$2.88	17
RS 848846	TYCO Connector PCB multi-pole MATENLOK free plug housing 3 way	EA	4	$0.39	$1.56	18
RS 4841748	MOLEX Connector PCB Mini-Fit Jr receptacle 2 way (pk of 5)	EA	2	$0.57	$1.14	19
RS 4841782	MOLEX Connector PCB Mini-Fit Jr receptacle 8 way (pk of 5)	EA	1	$1.50	$1.50	20
	Battery restraints	EA	0	$0.00	$0.00	21
MAQUET 0012-00-1155-02	Datascope ECG Trunk Cable	EA	1	$0.21	$0.00	23
MAQUET 0012-00-1156-02	Datascope General Use ECG Lead-wires	EA	1	$0.21	$0.00	24
RS 750-187	Plastic Strap Handle Black	EA	1	$19.90	$19.90	25
RS 444-2919	Cable gland w/o locknut polyamide liquid tight IP68 M12 grey (pk of 5)	EA	2	$1.70	$3.40	26
RS 444-2975	Cable gland locknut polyamide liquid tight IP68 M12 grey (pk of 5)	EA	2	$0.42	$0.84	27
				TOTAL	$1606.43	

APPENDIX G – CREEPAGE AND CLEARANCE CLASSIFICATIONS

Table 9 - Definitions of pollution degrees specified by IEC 60664-1:2002 (Lamothe n.d.)

Pollution Degree	Definition
1	*Pollution Degree 1* refers to a condition of no pollution or only dry, nonconductive pollution. Likely to be characteristic of clean-room equipment, this type of pollution has no influence. Only components or subassemblies that are adequately enclosed by enveloping or hermetic sealing to prevent ingress of dirt and moisture qualify to use Pollution Degree 1 spacing's.
2	*Pollution Degree 2* is nonconductive pollution of the sort where occasionally a temporary conductivity caused by condensation must be expected. This is the usual pollution degree used for equipment being evaluated to 60950 and is suitable for equipment employed in an office environment.
3	*Pollution Degree 3* covers conductive pollution and dry, nonconductive pollution that becomes conductive owing to condensation that can be expected. The local internal environment of the equipment is subject to conductive pollution because the device is permanently or temporarily exposed to the outdoors.
4	*Pollution Degree 4* refers to pollution that generates persistent conductivity caused, for instance, by conductive dust or by rain or snow. This category is not applicable to products covered in 60950.

Table 10 - Definitions of overvoltage categories specified by IEC 60664.1-2002 (Lamothe n.d.)

Overvoltage Category	Definition
I	*Overvoltage Category I* refers to the signal level and encompasses secondary circuits, special equipment or parts of equipment, telecommunications devices, and the like, which experience smaller transient over voltages than normal in Overvoltage Category II. Category I spacing's are usually employed for battery-powered or safety extra-low-voltage (SELV)—powered equipment where there are not likely to be power-source transients.
II	*Overvoltage Category II* is local level, covering appliances, portable equipment, etc., with smaller transient over voltages than those characteristic of Overvoltage Category III. This category applies from the wall plug to the power-supply isolation barrier (transformer). The typical office and small plant environment is Overvoltage Category II, so most equipment evaluated to the requirements of 60950 are considered to belong in that classification.
III	*Overvoltage Category III* refers to the distribution level, that is, building wiring and fixed installations. This level experiences smaller transient over voltages than occur in Overvoltage Category IV. A large industrial plant would be considered Overvoltage Category III. Equipment for use in this environment must receive special consideration for both pollution degree and overvoltage category. Many standards require that the environment be specified in the product manual.
IV	*Overvoltage Category IV* refers to the primary supply level: overhead lines, cable systems, and so on. This category is not relevant to most

	product standards.

Table 11 - Table of categories of comparative track indexes for medical equipment specified by IEC 60601-1:2005

Comparative Track index	Material Group
600 <= CTI	I
400 <= CTI < 600	II
175 <= CTI < 400	IIIa
100 <= CTI < 175	IIIb

APPENDIX H – EXAMPLE ELECTRICAL SAFETY TEST FORM

The following report is an Example given by the AS/NZS 3551:2004 standard to which any medical device must pass in order to be used in clinical practice.

ANYTOWN HOSPITAL
BIOMEDICAL ENGINEERING DEPARTMENT

(Page 1 of 2)

BME No: _____

WARD/DEPT: _____ SERIAL No: _____

EQUIPMENT: _____ MODEL: _____

MANUFACTURER ORDER NO: _____

AGENT: _____ VALUE: $ _____

TYPE TEST CERTIFICATE DETAILS: _____

DELIVERY DATE _____ INSTALLATION DATE: _____

PERFORMANCE VERTIFICATION DATE: _____

SAFETY TESTING DATE: _____

LIST OF ESSENTIAL SAFETY AND PERFORMANCE PARAMETERS TO BE CHECKED DURING SUBSEQUENT SAFETY AND PERFORMANCE TESTS INCLUDING PROPOSED TEST FREQUENCY. (Clause references relate to those in the Standard.)

ELECTRICAL SAFETY TEST:	Frequency (Clause 4.4)
Protective earthing test (5.3.3)	
Insulation resistance test (5.3.4)	
Earth leakage current test (5.3.5)	
Applied part leakage current test (5.3.6)	
Mains contact current test (5.3.7)	
ESSENTIAL SAFETY AND PERFORMANCE PARAMETER TESTS FOR THIS DEVICE	

WARRANTY PERIOD:

4.2	ACCEPTANCE CHECK AND INSPECTION	Pass/Fail
4.2.2	Packaging undamaged	
4.2.3	General acceptance inspection	
4.2.3a	Type test certificate applies to the equipment supplied	
4.2.3b	Appropriate documentation supplied	
4.2.3c	No access to live parts during operator maintenance	
4.2.3d	Liquids levels in tanks are satisfactory and there is no spillage	
4.2.4	**DEVICE MARKINGS**	
4.2.4a	Name or trademark of manufacturer	
4.2.4b	Supply voltage and frequency (a.c. or d.c.) and the current rating or power in watts or volt-amperes	
4.2.4c	For class II equipment, the symbol [box-in-box]	
4.2.4d	Type and rating of all operator-replaceable fuses	
4.2.4e	The voltage of any power supply outlets unless 3-pin outlets are used	
4.2.4f	Special purpose/controlled power outlets for special function e.g. 'BLOOD PUMP'	
4.2.4g	Function indicated on all operator controls and indicators	
4.2.4h	Warnings on equipment with potentially hazardous outputs.	
4.2.4i	Markings to confirm that the device and applied parts are consistent with type and classification in purchase contract. Type B, BF and CF Applied Parts to be identified by the appropriate symbols	
4.2.4j	Marking to indicate which piece of equipment the power pack belongs to, if it is detachable from the equipment	
4.2.4k	Marking to indicate if applied parts are protected against the output of a defibrillator	
4.2.5	**PERMANENTLY INSTALLED EQUIPMENT**	
4.2.5a	Operator removable covers or panels do not expose live parts	
4.2.5b	Correctness and security of the equipment mounting	
4.2.5c	Environmental requirements, e.g. exhaust extraction	
4.2.5d	Cables on moving parts secured	
4.2.6	**SUSPENDED MASSES**	
4.2.6a	Correct installation of equipment incorporating supported masses.	
4.2.6b	Motorized drives checked in the event of power failure. No hazardous situation shall result.	
4.2.6c	After power interruption or normal switch-off, equipment not to move in a dangerous fashion.	

ACCEPTANCE TEST SUMMARY (includes electrical safety test, if applicable)		
PASS ☐ **FAIL** ☐ **RE-SUBMIT** ☐		
Reason:		
Tests completed by.....	Date.....	

APPENDIX I- SOFTWARE FLOWCHART (INCOMPLETE)

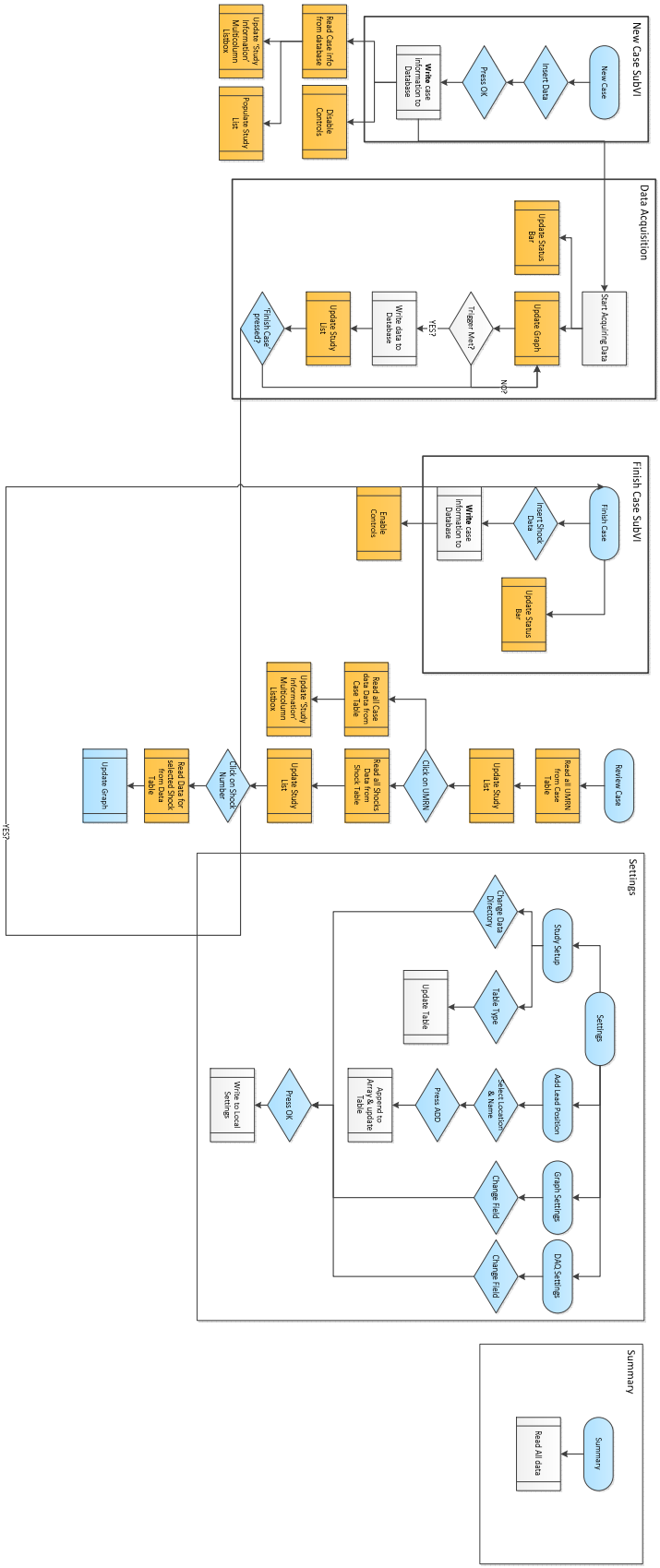


Figure 34 - Software Flow Chart (Incomplete)

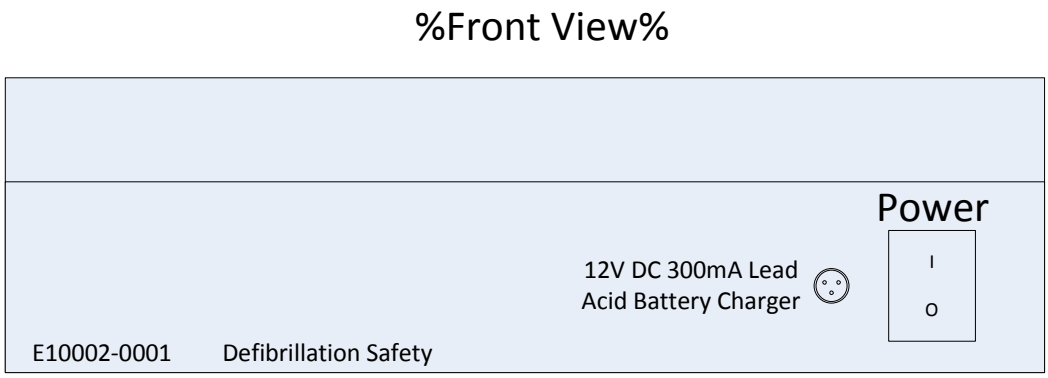


Figure 35 - Mechanical drawing of enclosure labels

D=M12 thread hole
E= M8 Thread hole
F= 21.1mmx30mm cutout
G = M4 Thread hole

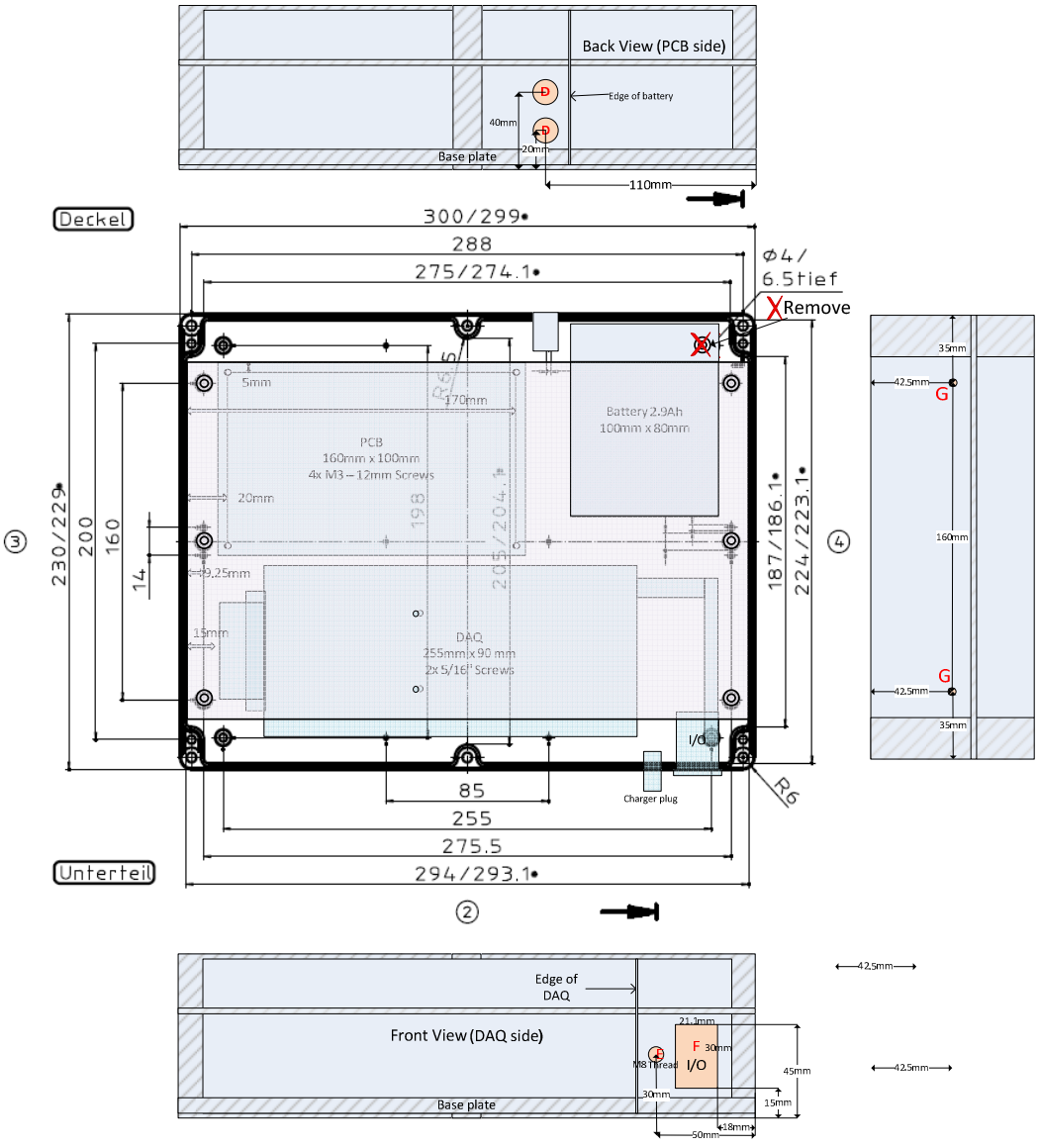


Figure 36 - Mechanical drawing of modifications required to enclosure panels

A=M3 Pan-head screws (4x)
B= FLH #6-32 x 5/16" screws (2x)
C= thread inserts with M3 Screws (6x)
NOTE: All measurements from centre of hole.

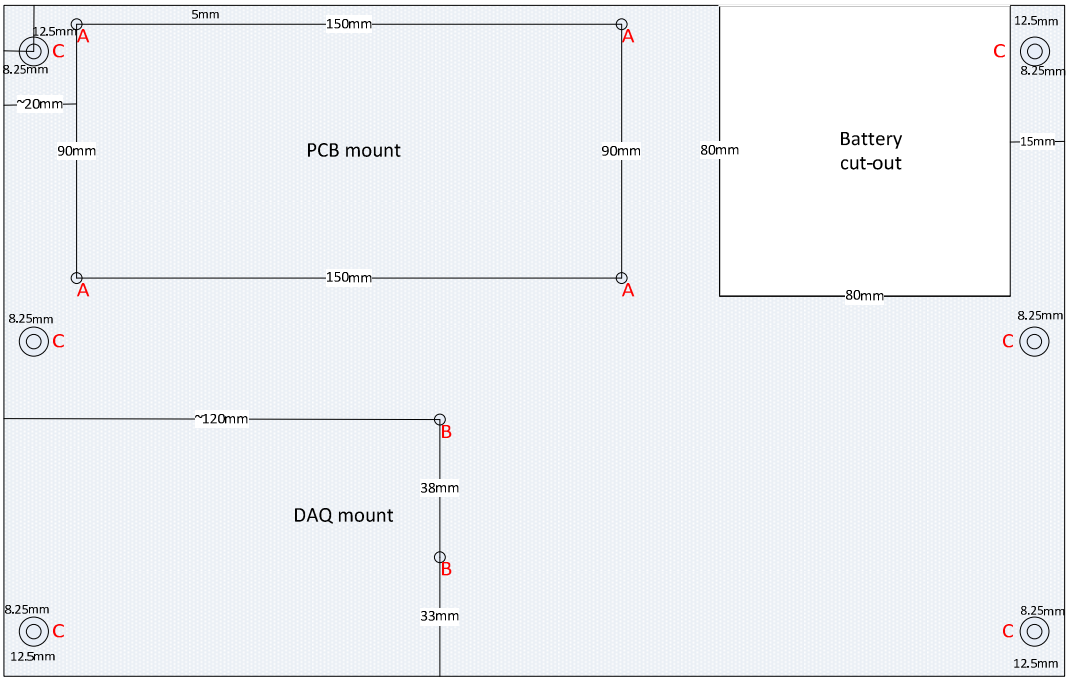


Figure 37 - Mechanical drawing of enclosure mounting plate and screw hole dimensions

APPENDIX K – WIRING DIAGRAM

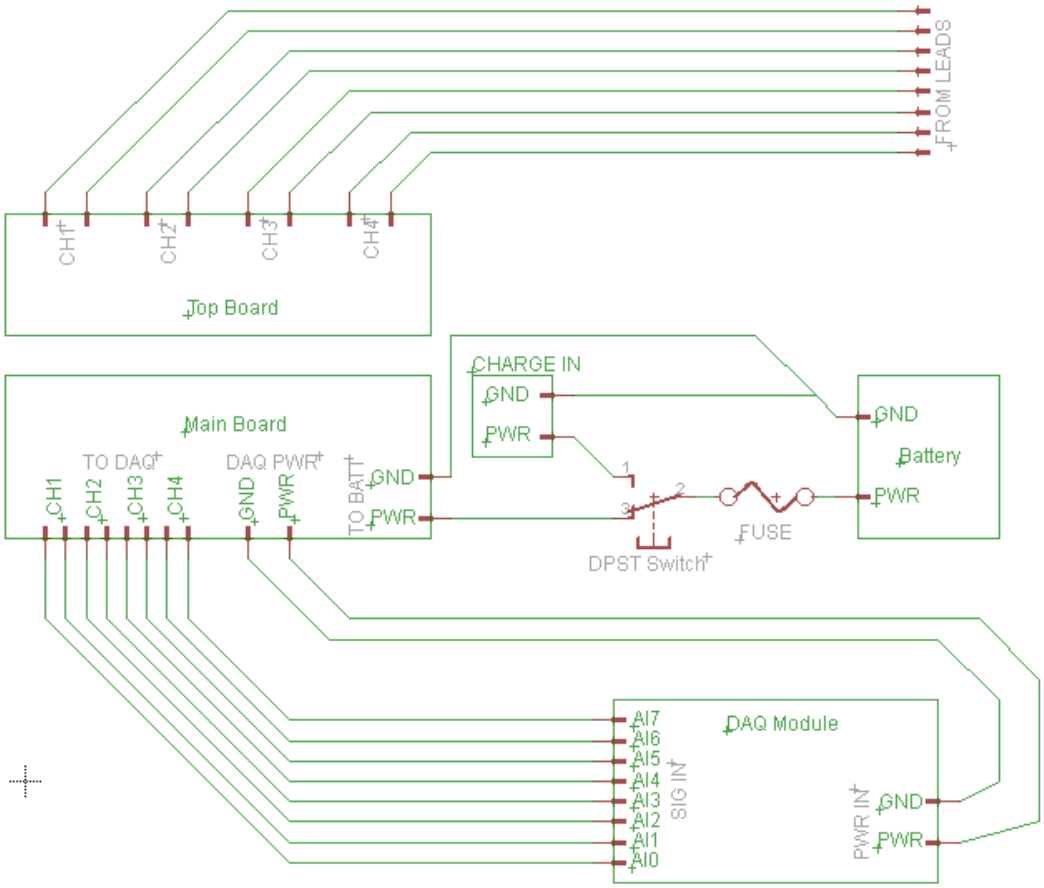


Figure 38 - Wiring diagram of the connections inside the enclosure

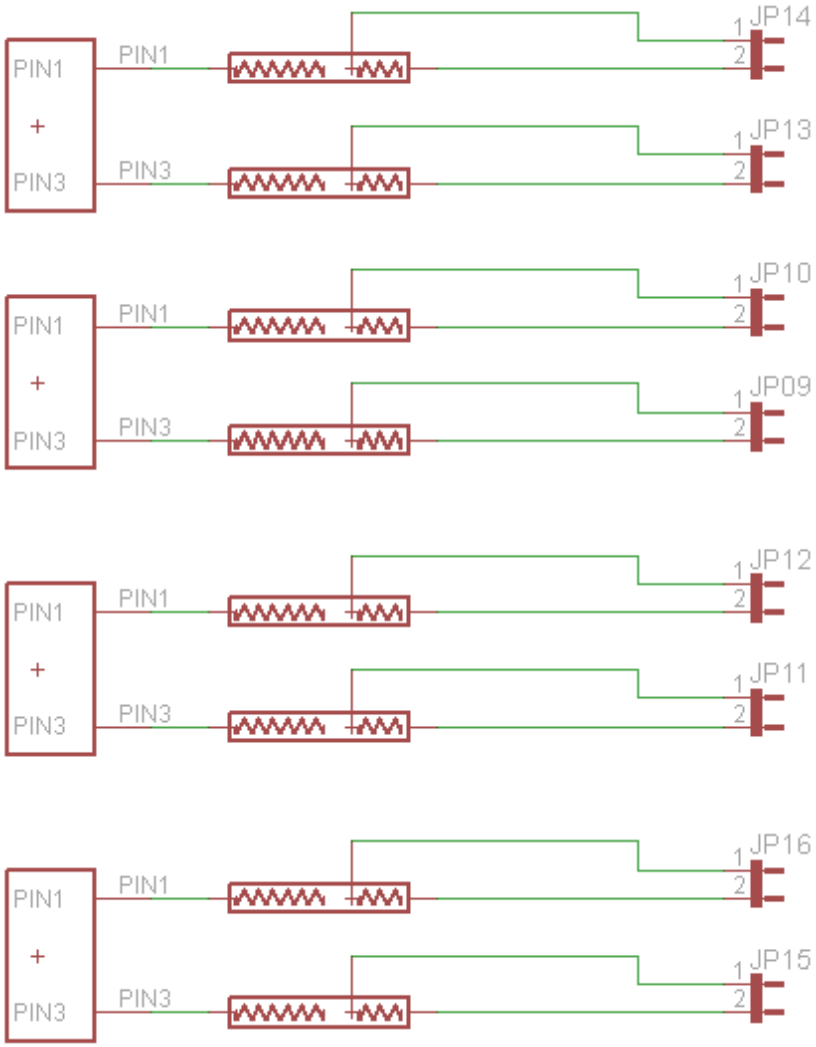


Figure 39 - Schematic of top, high voltage PCB

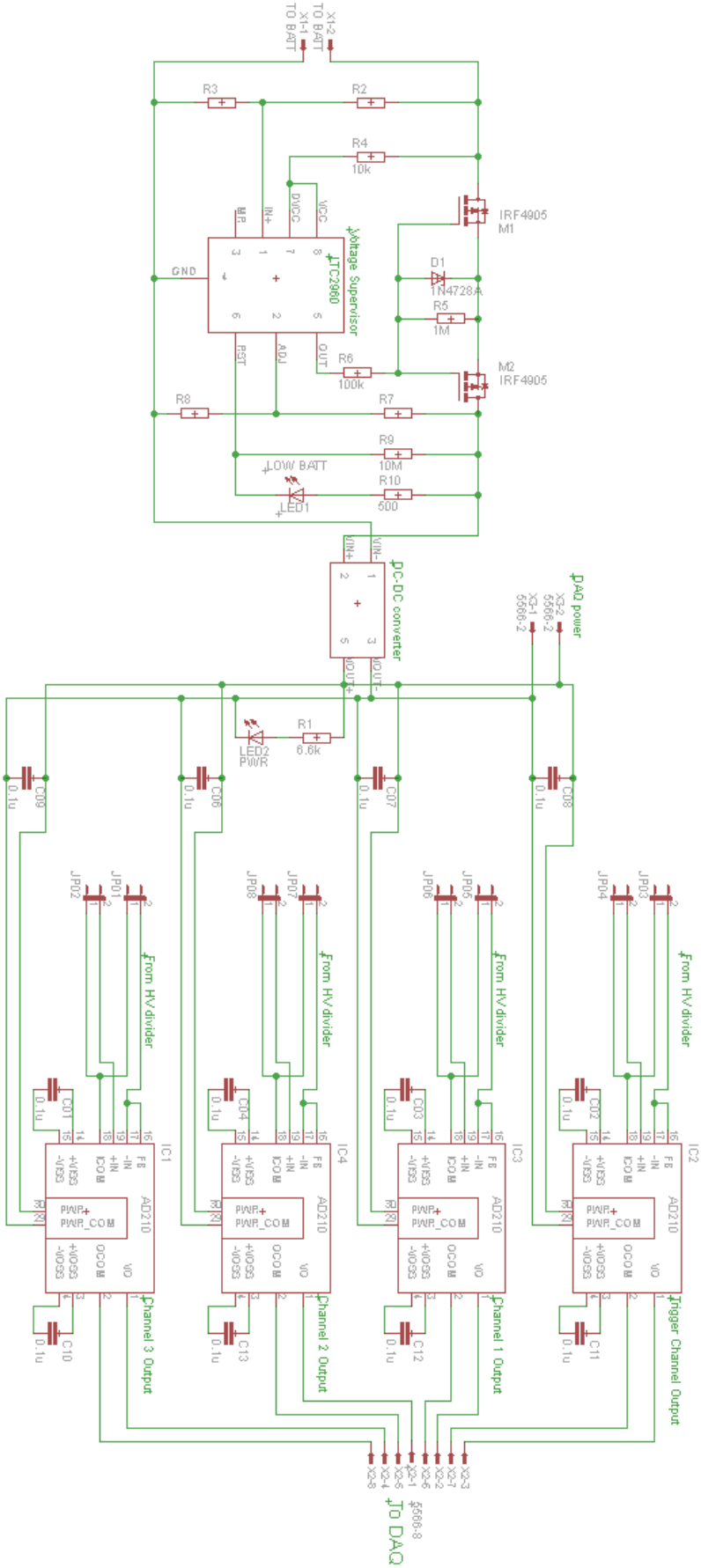


Figure 40 - Schematic of bottom, Low voltage PCB