Specialized Pads for Dual Sequential Defibrillation

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ABSTRACT

In a very small number of cardiac arrest cases, a patient may present with a refractory dysrhythmia such as refractory ventricular fibrillation (RVF) or refractory ventricular tachycardia. In these cases, the healthcare provider can elect to perform Dual Sequential Defibrillation (DSD) on the patient. Unfortunately, the current method to perform DSD requires two defibrillation monitors and a second set of defibrillation pads to be placed on the patient. This current method makes it difficult for DSD to be implemented in standard practice, as many ambulance services do not have access to a second defibrillator monitor due to their high price. It is also impossible to add an additional set of pads to a patient when a mechanical cardiopulmonary resusituation (CPR) machine is in use. The goal of this project is to develop a device that can perform DSD from one defibrillator monitor and adapt defibrillation pads so they can be placed on a patient prior to a mechanical CPR device being implemented. This project proposes a device that will split the power from one defibrillation monitor into two separate pad connections, sending half of the supplied power to each set of pads. Additionally, the device will allow the operator to switch between standard defibrillation and DSD through a switch that opens and closes the DSD circuit pathway. The device will first be tested over a range of low negative and positive and negative voltages to determine how the polarity of the input voltage impacts the output of the device. If this test is successful, a second test will be performed where the device will be connected to the defibrillator monitor and attached to a testing manikin. A shock will be sent through the manikin and the output received by the manikin will be recorded.

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1 INTRODUCTION

1.1 Motivation

Cardiac arrest occurs when there is a disturbance to the electrical rhythm of the heart [1]. There are many distinct causes for cardiac arrest, two of the most common being Ventricular Fibrillation (VF) and Ventricular Tachycardia (VTach). Both VF and VTach can be treated with transthoracic defibrillation [1]. In defibrillation, an electrical shock of current is sent through the heart, causing depolarization of the myocardial cells in the heart and giving the heart a chance to regain its normal spontaneous circulatory rhythm [1]. In a very small number of cases, a patient in VF or VTach can present with a refractory rhythm. Refractory VF and VTach are defined as the heart's failure to return to its normal rhythm despite three standard defibrillation attempts [2]. These refractory rhythms are extremely rare and only occur in roughly 1 in 200,000 VF or VTach cardiac arrests [3]. Due to their rare incident of occurrence, it is extremely difficult to predict which patients will present with a refractory rhythm. Additionally, the mortality rate for these refractory rhythms is estimated to be between 85-97%, making them extremely dangerous to the patient [3].

One proposed method to treat refractory VF or VTach is Dual Sequential Defibrillation (DSD). In DSD, two shocks of electrical current are sent through the heart sequentially [4]. The two sequential shocks increase myocardial cell response within the heart [3]. Currently, there is very little evidence to support DSD as a viable technique for treating refractory rhythms, due to the rare occurrence of refractory rhythms and the lack of a device that can perform DSD [5]. Additionally, there is currently no device designed to implement DSD. If a provider wishes to perform DSD, they must obtain an additional defibrillation monitor, defibrillation pads, and designate another person to operate the second monitor. These obstacles to DSD are often difficult to overcome given the high-stress environment of cardiac arrest treatment. The goal of this project is to create a device that can condense the equipment needed for DSD into one device, making it easier to initiate DSD when a patient presents with a refractory rhythm.

1.2 Existing Devices & Current Methods

Currently there are no existing devices that execute DSD through a single defibrillator monitor. Due to the novel nature of DSD and no current devices on the market, medical professionals need access to two monitors in order to perform DSD. As a result, performing DSD outside of a hospital setting is difficult because of the high cost of defibrillators. However, there is a South Korean patent that demonstrates how a single defibrillator could implement DSD [6]. This design idea has two sets of pads plugged directly into the monitor and would send a separate shock through each set of pads. The shock is sent at an energy level set by the medical professionals, as seen in Figure 1 [6].

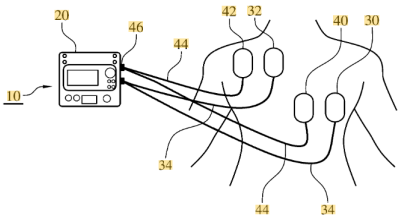


Figure 1: South Korean patent for Dual Sequential Defibrillation [6]

Figure 2 demonstrates the current method of using two monitors. One such monitor is the LIFEPAK 15 Monitor [7]. This monitor differentiates itself from other monitors such as Zoll or Philips because instead of using 200 J for shocking, the LIFEPAK Monitor uses 360 J [7]. The access to a higher energy output device allows for a greater ability to adapt the monitor for DSD. In Figure 3, the LIFEPAK Monitor is shown along with a view of the display. There are two important aspects of defibrillator monitors that must be taken into consideration for this project. First, the monitors will deliver a biphasic shock to the patient, meaning that the shock contains a negative and positive portion [7]. Secondly, the defibrillator monitors use a short pulse of current to measure the impedance of a patient prior to delivering the electrical shock. The DSD device created for this project must not impact the monitor's ability to calculate this impedance value.

Figure 2: Example of current DSD setup on a mannequin using a Zoll Monitor [8]

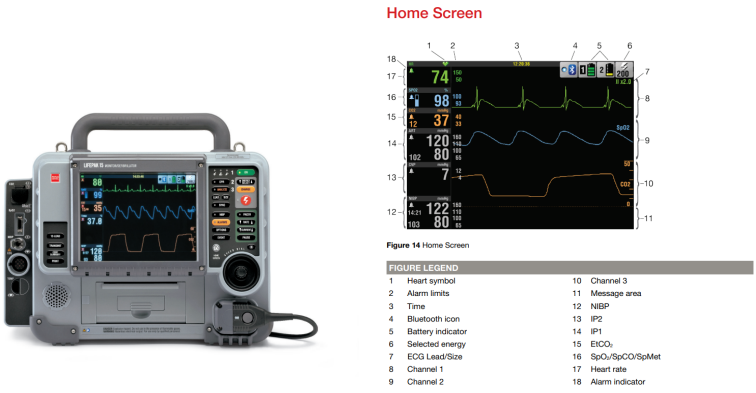


Figure 3: LIFEPAK Monitor and home screen with descriptions [9]

1.3 Problem Statement

The current method for DSD requires two defibrillation monitors and an additional set of defibrillation pads to be added to the patient [3]. This is a problem for two main reasons. First, during cardiac arrest, a new technology called the Lund University Cardiopulmonary Assist System (LUCAS) is used to provide mechanical chest compressions to the patient. This device is widely used as it provides consistent CPR to a patient in cardiac arrest, which is the best way to improve patient survival [10]. However, when the LUCAS is in place, it is impossible to add an additional set of defibrillation pads to the patient without removing the LUCAS device and interrupting CPR. Secondly, the current way to perform DSD is by utilizing two defibrillation monitors. This makes DSD widely unavailable as most ambulance services do not have access to two monitors given their high cost. This means that DSD is usually only performed once a patient arrives at the Emergency Room, and at this point, the patient has an extremely low survival rate as permanent brain damage starts to occur only after five minutes of oxygen deprivation [11].

The focus of this device is to rectify these two problems by creating a device that can be placed on the patient and allow the healthcare provider to perform normal defibrillation or DSD without the removal of the LUCAS. The proposed device will include a circuit that directs the shock from one defibrillator monitor into two sets of pads. This will make DSD more widely available to healthcare providers and allow it to be easily implemented in the rare cases of refractory rhythms. Additionally, a device designed to perform DSD will make field studies that assess the effectiveness of DSD more feasible and allow for further study on how to best treat refractory rhythms.

2 BACKGROUND

2.1 Anatomy and Physiology

Ventricular fibrillation, also known as VF, occurs when muscles in the heart are no longer contracting in an orderly fashion. Rather, they begin to quiver and contract irregularly, limiting the effectiveness of each heart beat. Eventually, heart beats cannot be discerned on an electrocardiogram (ECG) and the heart cannot provide effective blood flow to the body. VF is one of four types of arrhythmias that can cause cardiac arrest [12]. The other three include VTach, pulseless electrical activity (PEA), and asystole. Refractory ventricular fibrillation (RVF) is the most common heart arrhythmia in which DSD is indicated [13]. A representation of RVF compared to a standard heart rhythm and their associated ECGs are pictured below in Figure 4.

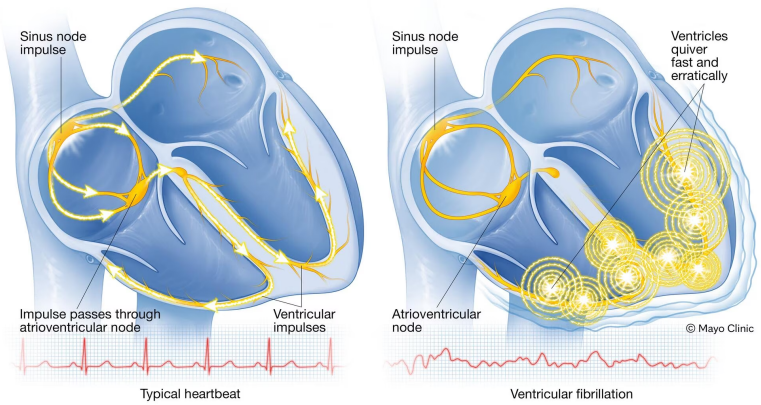


Figure 4: Diagram showing electrical signals in a standard heart rhythm and RVF along with the associated ECGs [8]

When a patient's heart begins to beat in a shockable heart rhythm (VF or VTach), a defibrillator can be used to shock it back into sinus rhythm. Automated external defibrillators (AEDs) and cardiac monitors (such as the LIFEPAK 15 Monitor [14] and Zoll X-Series [15]) both provide sufficient energy to do this procedure. In conventional VF or VTach, either a medical professional or the device interprets the cardiac rhythm elicited by the patient and determines if it is a shockable rhythm. If the rhythm is determined to be shockable, the device charges and prepares to deliver a shock. Electrodes in the form of cardiac pads send an electric current through the body and heart. Figure 5 shows the current path of standard defibrillation using the anterior/anterior electrode positions and manual paddles. This electrical current contracts all the cardiac muscles at once, allowing the sino atrial node to restart organized electrical activity, thus supplying sufficient blood flow to the rest of the body. The theory of DSD aims to contract a larger portion of the heart from different vector paths through two sets of pads when the sinoatrial node does not respond to a standard defibrillation attempt.

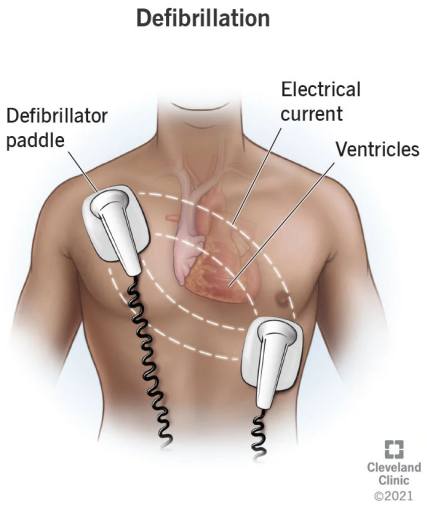


Figure 5: Diagram of electrode placement and electrical circuit created during defibrillation [16]

2.2 Client Information

Dr. Michael Lohmeier is an Associate Professor, Board Certified Emergency Medicine Physician, and serves as part of the Medical Direction team for multiple Dane County EMS services.

2.3 Product Design Specification

Information combined from client requirements, research, and present standards for similar devices culminated to create the Project Design Specifications for this project. Per client request, the device must allow for easier initiation of DSD during complex resuscitations and not interfere with resuscitation efforts in place prior to the start of DSD. The proposed device must have a similar user interface, operation options, and command buttons to the already existing defibrillation devices to ensure that users are able to operate the device with very little additional training. This will reduce barriers to implementation of the device in emergency care settings. The entire project must fit within a $500 budget.

The circuitry element of the device must be compatible with the LIFEPAK 15 monitor and deliver a shock within the range of 120 - 200 J through two attached sets of defibrillation pads [17]. All electrical components of the device must be graded to withstand a maximum voltage of 2600 V and a maximum current of 30 A [18]. Additionally, the components cannot interfere with the defibrillator monitor's ability to calculate the impedance of the patient.

The circuit element must also have standardized connectors so it can work with Zoll defibrillation pads. Additionally, the shocks coming through the circuit element must be delivered between 0.5-2.0 sec apart from each other 99% of the time [19]. All existing defibrillator monitors must deliver energy with 96% accuracy, so the proposed device must also match this reliability standard [20]. All components of the device must be kept between 0 and 50

degrees Celsius and near standard atmospheric pressure, and have a shelf life of 4-6 years [21]. The circuit element will be contained in a plastic box that is 20 x 20 x 10 cm and weigh no more than 2 kg in total. This portion of the device must be able to be held with one hand, so this is the driving factor behind these dimensions.

The adapted defibrillator pads must be able to fit a patient ages 8 years old and up or 25 kg pounds and heavier [22]. The product will have two separate sets of pads: pediatric pads for patients weighing 25 kg to 45 kg and adult pads for patients weighing 46 kg and up. The pediatric pads will be 8 x 8 cm in size and the adult pads will be 12 x 12 cm [15]. The pads must not touch, so a foam insulating material will be used to separate connected pads.

The full, unabridged version of the PDS can be found in Appendix 11.1.

3 PRELIMINARY DESIGNS

3.1 Design 1 - Light Sensor

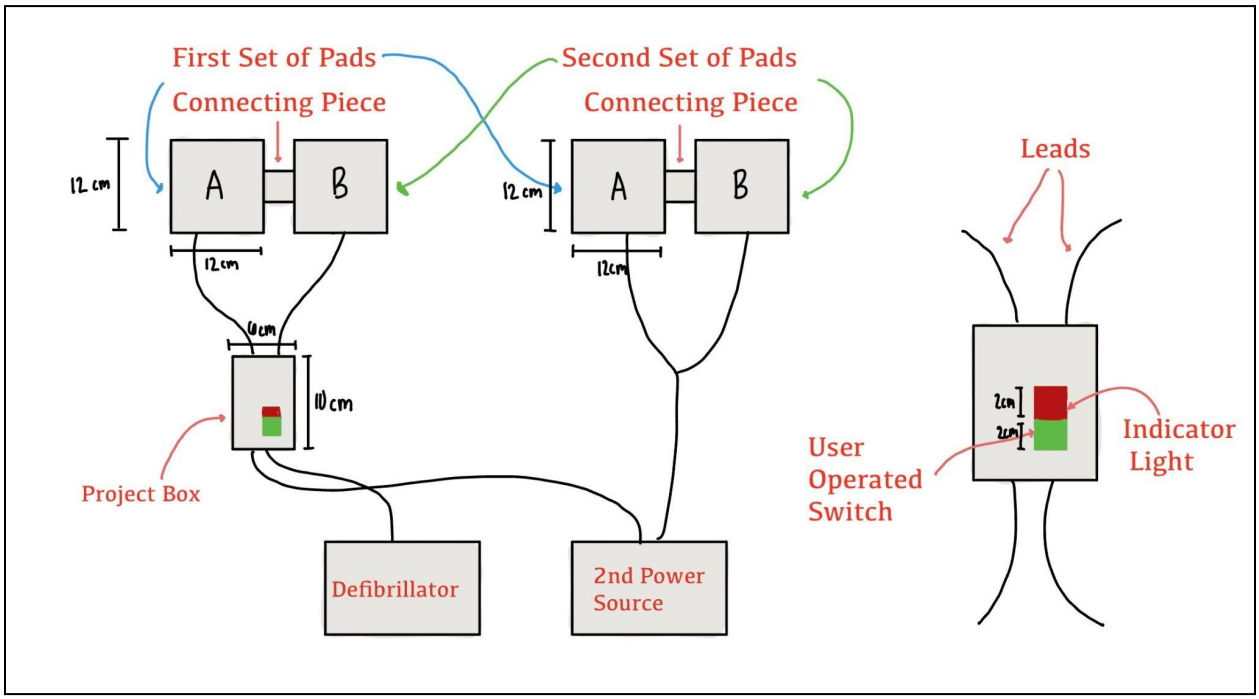


Figure 6: Light Sensor Design Sketch

The light sensor is the first preliminary design idea. This design is displayed in Figure 6. It is the simplest of the three designs because it focuses on leading the user through the process of DSD and does not interact or alter any of the electrical components of the pads or process of defibrillation. This design contains a few main aspects to consider. The most distinct component is a circuit box which the two connections leading to the front two pads run through. The circuit detects the initial shock then turns on a light on the outside of the box for 0.5 to 2 seconds after the initial shock [19]. This light indicates to the user that DSD is a viable option. While the light is on, the user can activate a switch to send the second shock. Another component of this design is that it contains 4 pads that can plug into up to 2 defibrillators. This feature allows for the user to easily change the vector of the initial shock by switching which leads are plugged into the defibrillator sending the initial shock. The front two pads and side two pads will be connected for easy placement that doesn't require removal of the LUCAS device.

3.2 Design 2 - Layered Electrode

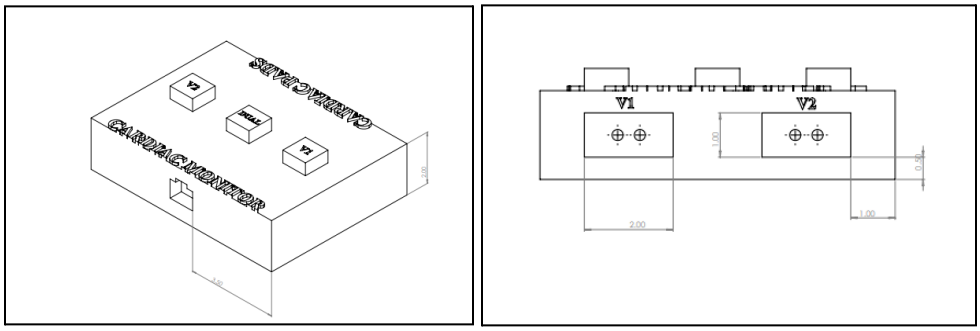


Figure 7: Layered Electrode and Modular Shock Pack Circuit Box Design Sketch from Top and Side view

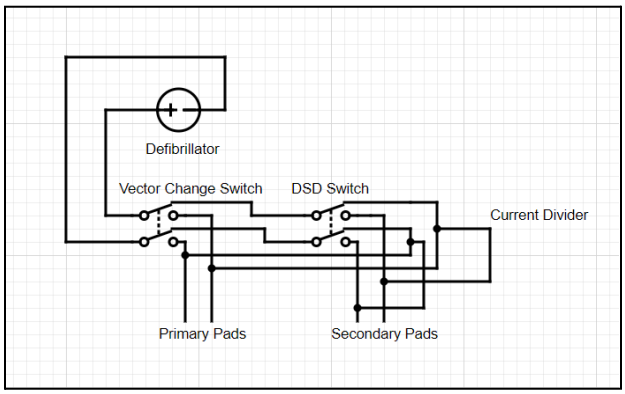


Figure 8: The Layered Electrode Circuit Design

The Layered Electrode design consists of a circuit box that connects to the LIFEPAK monitor, as shown in Figure 7. The shock from the LIFEPAK will travel into the circuit where there are multiple options depending on the button that is pressed down. There are three buttons to choose from, Vector 1, Vector 2, or DSD. The switches within the circuit then direct the current to either the primary or secondary pads. While in the DSD mode, the circuit will have a current director to split the current in half to allow for equal energy distribution between the two pads. This then ensures that the 360 J of energy from the LIFEPAK is split into 180 J in each set of pads. The 180 J still gives an effective shock as the minimum effective shock is 120 J [19]. In conjunction with the current divider, an internal time delay that will be implemented to delay the shock sent from the secondary pads by the specified 0.5 to 2 seconds when delivering a DSD shock [19]. The proposed circuit for this design is shown in Figure 8. The ability to connect two sets of pads to the circuit box simplifies integrating DSD with the LUCAS device as the pads can already be pre-placed prior to the LUCAS being implemented for CPR. The situations in which DSD is used can be highly stressful and chaotic so having a simple button layout is an integral part of the design that makes the circuit box easily adaptable and trainable for medical professionals.

3.3 Design 3 - Modular Shock Pack

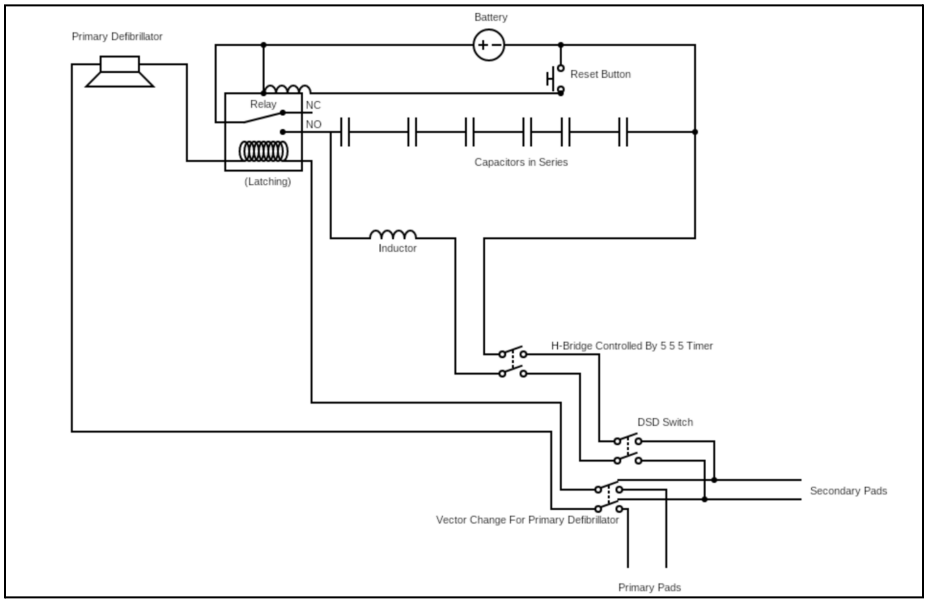


Figure 9: The Modular Shock Pack preliminary circuit design sketch

The Modular Shock Pack is the only design that involves creating a circuit capable of delivering a shock to the patient. The exterior includes the same project box as the Layered Electrode Design. As shown in Figure 9, the defibrillator connector plugs into one side of the project box. Three buttons on the top allow for vector change between two different vectors and dual sequential defibrillation between both vectors.

The circuit design within the box allows for circuit to circuit communication via a latching relay. When the defibrillator discharges a shock during traditional defibrillation the latching relay is tripped. This closes the circuit connecting the power source and capacitors in series. The capacitors begin to charge preparing for dual sequential defibrillation.

At this point the healthcare professional can choose to switch vectors via the vector change switch or select dual sequential defibrillation. If the healthcare professional selects dual sequential defibrillation, a time delay component controlling the dual sequential switch will become active. When the healthcare professional discharges a shock from the primary defibrillator the time delay component will now recognize the shock through a latching relay and discharge the capacitors after an adjustable amount of time (0.5-2 seconds). The capacitors are then discharged over 4 milliseconds [23] and then an H-bridge component within the circuit controlled by a 5 5 5 timer will flip. This causes the polarity to be reversed causing the current to travel in the opposite direction through the patient.

This design is incapable of calculating impedance within the patient and adjusting the voltage in order to deliver the correct number of joules. It would require preset voltages based on preset impedances. This would leave it up to healthcare professionals to estimate the impedance of a patient and adjust accordingly in order to deliver the correct range of joules.

4 PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

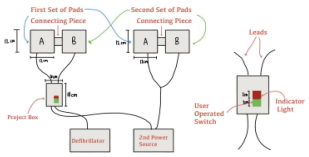
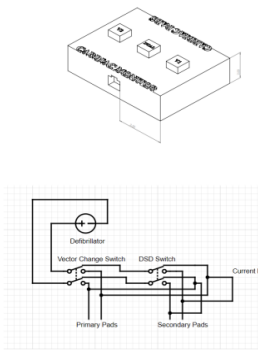
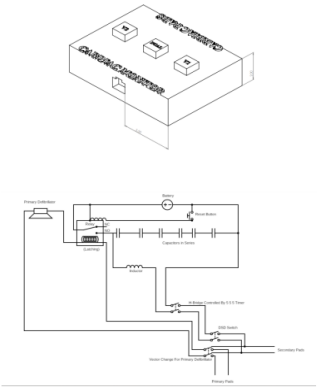
Design Criteria	Light Sensor Design		Layered Electrode Design		Modular Shock Pack Design	
						
Feasibility (25)	**5/5**	25	**4/5**	20	**2/5**	10
Efficiency (20)	**2/5**	8	**4/5**	16	**2/5**	8
Reliability (20)	**3/5**	12	**4/5**	16	**2/5**	8
Ease of Use (15)	**2/5**	6	**4/5**	12	**5/5**	15
Safety of Operator (10)	**5/5**	10	**4/5**	8	**2/5**	4
Cost (10)	**1/5**	2	**5/5**	10	**1/5**	2
Total (100)	**63/100**		**82/100**		**47/100**	

Table 1: A design matrix created by the team used to rank the three preliminary designs. Each category is rated by importance and is used to determine an overall score for each design.

Reasonings for Scores

Feasibility

The feasibility of the design is measured as the complexity of the construction and knowledge to be able to produce the design. A higher score represents a less complex design that

is easier to execute and produce. Feasibility was weighted the highest because it is a direct measurement of the ability of our team to produce a working version of the design.

Efficiency

The efficiency of the design was defined as the maximum amount of energy in the shock with the minimum amount of resources utilized. This received a relatively high score as well due to the importance of the shock energy and limited resources some healthcare centers don't have.

Reliability

Reliability defines the design's ability to repeat the function of the product. It is important that the amount of shock delivered during each use or the time between shocks when performing DSD is the same during each use. This is a crucial criteria because if a consistent amount of energy is not released each shock or the timing between the shocks is not consistently within the range then there is a risk the patient may not return to normal rhythm.

Ease of Use

Ease of use defines how easily an operator can use the design. For this project it is important that the operator, who is a medical professional, can quickly and efficiently connect the defibrillation pads to the patient, the device to the defibrillation pads, and the device to the monitor releasing the shock. In the design matrix, ease of use was given a weight of 15/100 as it is key that operators can utilize the device without confusion and quickly. This will also allow the device to be implemented in the care plan of Emergency Services and further minimize the risk of user error.

Safety of Operator

Safety of the operator quantifies the risk that the medical professional is experiencing while using the product. Medical professionals take many standard precautions to limit their exposure to existing risks using defibrillators, such as not using the device while it is submerged in water and ensuring all medical providers are not touching the patient when the shock is delivered. As the devices are altering, creating, or sending a shock there is an increased risk, but at a low level.

Cost

The device should be created within the $500 dollar budget allocated by the client, however, ideally the device will be as cost efficient as possible, so when manufacturing it will be at a lower cost for the healthcare industry. Cost was given the lowest weight as it is not a significantly important portion of the design for the client. Furthermore, based on preliminary calculations, the chosen design will fit well within the allocated budget.

4.2 Proposed Final Design

The Layered Electrode Design received the highest score overall in the design matrix based on the criteria and the weights that were assigned to the criteria. One main advantage to this device is that it only uses one monitor and does not create a shock itself. This allows the device to maximize efficiency and be more cost effective. Also, the Layered Electrode Design splits the shock from a patented defibrillator during dual sequential defibrillation, the shock energy and time is extremely reliable. One of the major drawbacks of the design is its inability to work with all defibrillators currently on the market; It is only compatible with LIFEPAK monitors. Furthermore, the circuit components, project box, and wiring will all be under $500, which is within the budget allocated by the client.

5 DEVELOPMENT PROCESS

5.1 Design Updates and Design Remodels

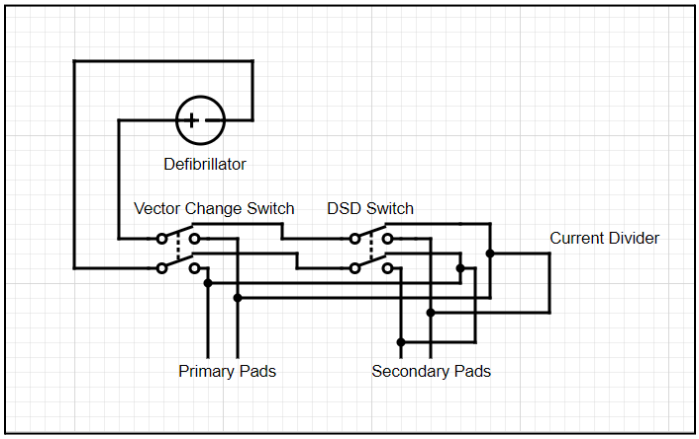


Figure 10: Preliminary DSD Design

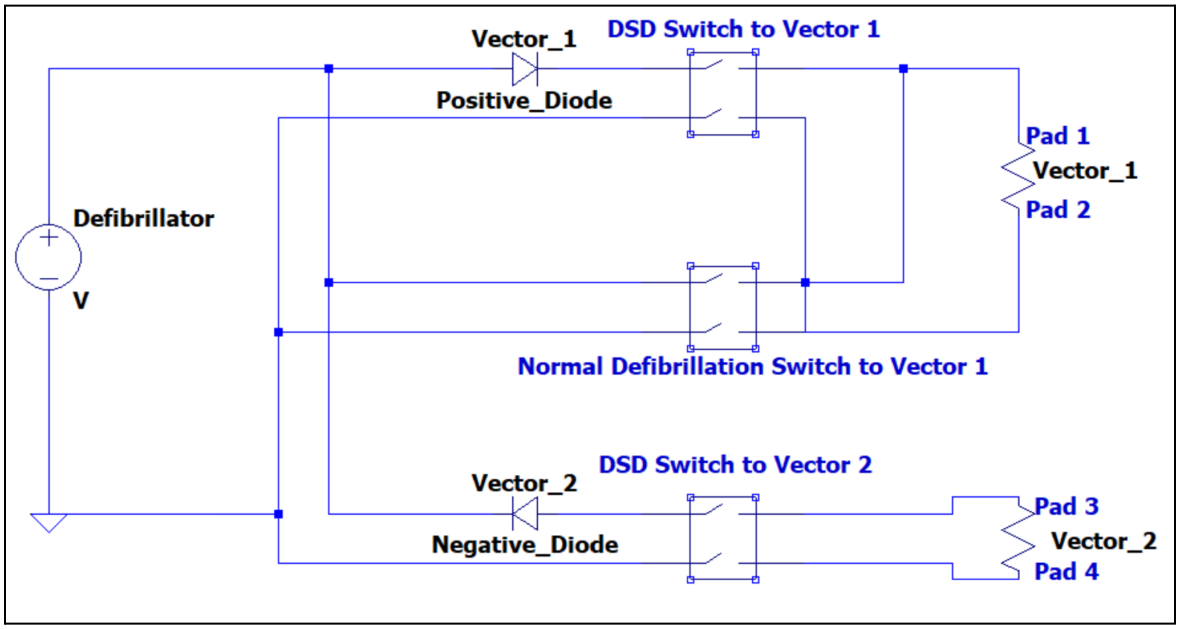


Figure 11: Final DSD Circuit Design

There were significant changes between the preliminary design and the final design due to design and fabrication difficulties and constraints. Figures 10 and 11 show the differences between the preliminary design and the final design of the circuitry respectively. The first major difference between the two is the addition of diodes to the final design. Based on further research and consultations with industry professionals it was determined that the manner in which the current was split in the preliminary circuit will do more harm than good to the patient. This is due to the fact that the circuit divides the current but the voltage going through the pads stays the

same. This combination of a lower current and no change in voltage results in a shock that will fail to depolarize the myocardial cells, leading to the patient's death. The diodes of the final design allow the shock from the defibrillator to be diverted instead of split. The LIFEPAK 15 Monitor delivers a biphasic shock, meaning the shock being delivered has a positive and negative portion to its waveform. In the final design the diodes are positioned so one set of pads receives the positive portion of the shock and the negative portion of the shock will be diverted to the second set of pads. This solves the original problem of an ineffective shock as the current and voltages are not being affected.

Another change to the original design is an addition of a third switch in the final design. The third switch was a result of a third pathway being added to allow for a bypass to do normal defibrillation through vector one. Without the third switch, only DSD would be possible with the device.

The last change to the design was the adapters. The adapters will allow the user to plug the two pads into the box and complete the circuit. The original design was to adapt and implement current defibrillator adapters on the market. This proved to be an ineffective solution as all defibrillator adapters have been discontinued due to the lack of FDA approval. 3-D scanning of the Zoll male pad adapter at the Makerspace was attempted, however, the complexity and size of the adapter being scanned failed due to the deep cavities. The final design for the adapter was created by measuring each aspect of the adapter then 3-D printing the negative of the SolidWorks model as seen in figure 12. This provides a simple and cheap solution to the adapter that can also be quickly modified due to the speed of 3-D printing.

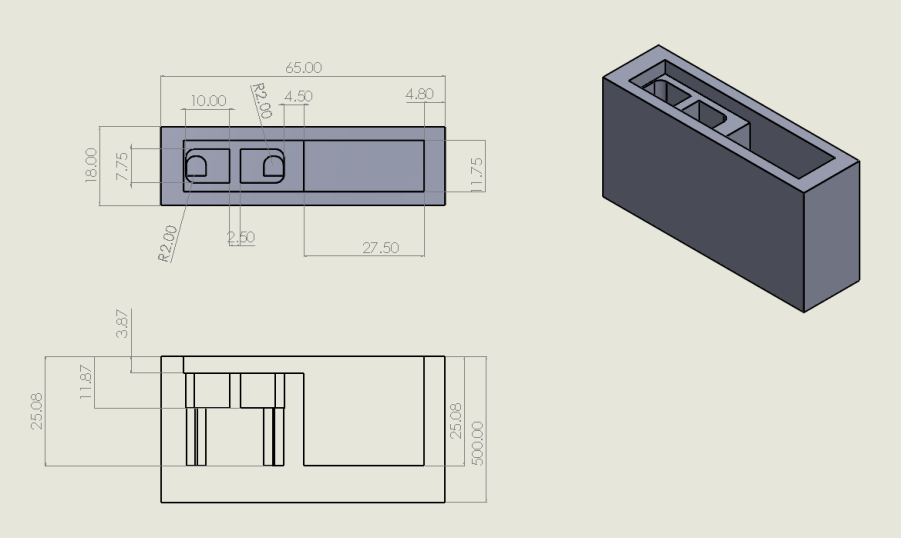


Figure 12: Final adapter for pad connection to circuit

5.2 Materials

All materials used in the device must be compatible with the maximum voltage of 2600 V that will flow through the device from the defibrillator. This specification was the driving force behind all material selection. All of the wires used in the device were 14 gauge and were harvested directly from LIFEPAK defibrillator pads. These wires were harvested from the pads as opposed to purchasing wires as they are proven to withstand the high voltage and current from a defibrillator monitor. To create the connection between the device and the LIFEPAK monitor, the connector piece that connects the pads and monitor was harvested from the LIFEPAK pads and resoldered to the wires in the circuit. This allowed the LIFEPAK monitor to connect directly to the device. The connector piece was harvested rather than created from scratch as its use in the field rendered it the safest method to connect the device and monitor [24].

Multiple attempts were made to create a custom female adapter that allows the Zoll brand cardiac pads to connect to the device, but none were successful. The commercially available adapters that can convert LIFEPAK male connectors to Zoll female are no longer available due to a lack of FDA approval. Therefore, to allow the prototype to connect to the two sets of pads required for DSD, two additional LIFEPAK brand male connectors were harvested from expired pads. The plastic was stripped from around the metal prongs inside the connection and served as a make-shift method of connecting the prototype's output to the input of the two Zoll cardiac pad sets.

The three switches used in the device were the NKK S21AWB [25]. These switches were chosen due to their ability to withstand the high current and voltage that comprises the cardiac shock. These three switches were attached to a plastic project box and soldered to the harvested wires. The diodes within the circuit are IXYS DNA30E2200PA, and are rated to handle over 2200 V, which is approximately equal to the average voltage that will be output by the LIFEPAK 15 Monitor [26]. These were chosen for their rated performance and relatively low cost The project box was selected due to its compact size as well as its ability to be modified as needed. This box was a budget-friendly option and easy to replace if necessary.

The modified cardiac pads were created from two sets of Zoll CPR-STAT pads [27]. No modifications to the inside, wiring, or electrical circuit of these pads occurred. The pads were simply oriented in a way to allow for the placement of four pads at one time. These pads were chosen for their long-term reliability and the frequency by which they are used in the prehospital environment.

5.3 Methods

The first portion of fabrication was the modification of the project box to accommodate the switches. The box was modified by creating rectangular holes on the lid of the box to place the three switches. These holes were cut with a jigsaw to accommodate the mounting hardware of the switches including 2 hinges and 4 screws to each switch. The switches were then super glued to the mounting hardware and to the lid of the box so that they do not move during use.

Once the switches were attached adequately to the top of the project box, four small leads of wire were soldered to each of the three switches. The switches are single pull double throw and connect two pathways. The first pathway will be referred to as the outgoing pathway and connect the power from the defibrillator to the pads. The second pathway will be referred to as the incoming pathway and connect the pads back to ground in the defibrillator. The incoming pathway for all three switches were soldered together to have a common "ground" wire that led back to the LIFEPAK Monitor. The first switch will be referred to as the Bypass Switch and has an output path connected directly to the power line coming from the defibrillator. The other two switches were connected to a perfboard and have output pathways that connect to the power from the defibrillator and then run through a diode. This limited each switch to only receiving the shock's positive or negative waveform. The path containing the positive diode and allows positive voltage to reach Pads 1 and 2 will be referred to as Vector 1 DSD. The path containing the negative diode and allows negative voltage to reach Pads 3 and 4 will be referred to as Vector 2 DSD. The remaining outgoing and incoming wires for the Bypass Switch and the Vector 1 DSD switch were soldered to the connector for Pads 1 and 2. The remaining outgoing and incoming wires of the Vector 2 DSD switch were soldered to the connector for Pads 3 and 4. This allows for the full shock to be sent to Pads 1 and 2 when the Bypass Switch is closed and the Vector 1 and 2 DSD switches are open. To switch to DSD, the Bypass Switch is turned off and the Vector 1 and Vector 2 DSD switches are turned on, allowing only the positive waveform of the shock to be transferred through Vector 1 while the negative waveform is transmitted through Vector 2.

The input terminals were soldered directly into the circuit and connected to the LIFEPAK Monitor via an unmodified LIFEPAK cable. The two output adapters that connect to the Zoll cardiac pad sets were modified by cutting their plastic shroud in half lengthwise. Additionally, excess plastic was stripped away from the metal prong connections to allow them to be inserted into the female Zoll brand pads. Throughout the fabrication process, measures were taken to limit the potential of short-circuiting and grounding through the project box. Electrical tape and heat shrink insulation were used on all possible solder joints during the soldering process. After the circuit was created and assembled in the project box, the modified output adapters were connected to the modified set of Zoll cardiac pads and the input to the prototype was connected to the LIFEPAK Monitor.

In addition to the modified output adapters, a custom female Zoll adapter was created so the Zoll branded cardiac pads can seamlessly plug into the device. These were created by first measuring the male Zoll plug using calipers and then creating the model in SolidWorks to then

3D print the negative of the designed model. These adapters were not integrated into the device by the end of fabrication this semester.

6 TESTING

6.1 Switch Test

The three switches that are used in the device were tested to eliminate concern of current arching over an open switch. It is essential that the switches prevent current from traveling down a pathway that is meant to be turned off, as this could lead to the current being split across two unintended paths, disrupt the shock, and potentially harm the patient.

In order to test the switches, the switch was placed in the open position and each side of one of the pathways in the switch was connected to a GwINSTEK GPT-9804 AC/DC Withstanding Voltage/ Insulation Resistance / Ground Bond Tester. This device can supply a very large amount of voltage and current to the switch while also measuring the amount of current that arcs across the open switch. Using the GwINSTEK, a voltage of 1000 V, 2000 V, and 2600 V were sent to the switch. These voltage values were selected as they encompass the maximum, minimum, and average amount of current that could flow through the circuit. These values were calculated based on current and impedance values published in a study by Zoll Medical Corporation [15]. For each test voltage, 5 tests were performed that lasted 2 seconds each. The duration of 2 seconds was chosen in an attempt to mimic the 16 millisecond duration of the defibrillation shock and was the smallest possible test duration allowed by the machine. The ramp time on the machine was set to 0.10 seconds. The switch was placed on a rubber mat and in a plastic box during each test to prevent harm to the operator. After each test, the value of the current that arced across the switch was recorded and compared to the value of current that was calculated to be running through the device at that given test voltage.

6.2 Normal Defibrillation Connection/Impedance Test

The connections between the defibrillator, the device, and the two sets of pads were tested to ensure that the shock would be able to pass through accurately and that the adapters were compatible with current devices on the market. The device was plugged into the LIFEPAK 15 Monitor using the LIFEPAK plug attached to the project box. The single vector output was plugged into the heart rate simulator with a Zoll pad adapter. To ensure that any shock value could be sent through the device, shock values of 50 J, 100 J, 125 J, 200 J, 275 J, and 360 J were tested. The heart rate simulator can simulate an array of heart arrhythmias. The heart rate simulator was set to replicate an RVF arrhythmia as it is the most common arrhythmia DSD is utilized for [3]. Each shock value was sent through the device to the heart rate simulator. As the shock was received a light would flash on the heart rate simulator signaling a shock was received and complete. This process was completed for all 6 shock values to ensure the connection was sufficient at all power standards.

The normal defibrillation impedance test was conducted to evaluate how the device affects the impedance value and the overall shock value, if at all. The connections between the

device and the LIFEPAK Monitor were duplicated from the normal defibrillation connections test. For this test the single vector output from the device was attached to simulator pads on a test manikin. Using the test manikin allows data points to be taken regarding the shock level received by the manikin compared to the shock level sent from the defibrillator. The manikin also simulates impedance values allowing the test to analyze the device's effect on impedance. Due to testing constraints 150 J was the tested shock value sent from the LIFEPAK monitor. Before the shock was run through the device the LIFEPAK Monitor was directly connected to the manikin to receive baseline data. Then the device was connected between the LIFEPAK Monitor and the manikin and the shock was repeated. If there is no difference in received shock with the device compared to baseline data this proves the connections are sufficient. The second portion of the test is analyzing if impedance is altered by the device. An increase in received shock proves impedance capabilities of monitor and circuit connections are not altered by the device.

6.3 DSD Test

The final test that was performed on the device was the DSD Functionality Test. The goal of this test was to determine if the polarity of the voltage inputted into the circuit impacts the voltage drop across the pads at the end of each vector. In order to evaluate this, the defibrillator connector of the device was switched into the DSD mode and connected to a DC power supply. A 1 Mohm resistor was used to connect the prongs of the pad adapter at the end of each vector path. A voltage meter was then connected in parallel to the resistor, and was used to measure the voltage drop across both sets of pads. In this test, a DC voltage was supplied to the device ranging from -5 V to 5 V with a step of 1 V. At each of these test voltages, the value of the voltage drop across the pads was measured. Three trials were performed at each of the test voltages. If there is no voltage drop across a set of pads this signifies no voltage flowing through that vector path. It is expected that when a negative voltage is applied to the device, Vector 1 will show a positive voltage measurement across Pads 1 and 2, and Vector 2 will show no voltage drop across Pads 3 and 4. Similarly, when a positive voltage is applied to the device, Vector 1 is expected to show no voltage drop across Pads 1 and 2, and Vector 2 is expected to show a negative voltage measurement across Pads 3 and 4. The results of this test will determine if the device is able to accurately direct the current through the circuit based on the polarity of the input voltage. The test was performed at lower voltages than the actual voltage that will flow through the circuit during defibrillation due to safety concerns for operators during this initial test. In the future, more testing following the same protocol at higher voltages will be needed.

7 RESULTS

7.1 Switch Results

For each of the trial voltages in the switch test, the value of the current arc was compared to the magnitude of current that will flow through the circuit component of the device at the given test voltage. The current flowing through the circuit is expected to be 11.5 A, 15.9 A, and 27.5 A for 100 V, 2000 V, and 3000 V respectively [15]. For each of the 5 trials within each test voltage, there was no variation in the measured current arc magnitude across trials. For each trial, an arc current was expected to be measured; the test values were at the maximum end of the switch grade, but the magnitude of the expected arc current was unknown. The magnitude of the current arc was 0.012 mA for 1000 V, 0.019 mA, for 2000V, and 0.023 mA for 2600 V. The magnitude of the current arc scales with increasing current through the circuit. This was expected as more current flow in the circuit will lead to a higher arc current. On average between the three test voltages, the arc current was 0.0005% of the current expected to flow through the circuit. This is an extremely small value, and can be regarded as negligible as this small amount of current leak is not expected to impact the patient when traveling through the path. Further testing is needed to confirm this assumption. Additionally, the arc current could be attributed to the current traveling through the air particles between the switch ends rather than through the switch itself. This is possible due to the humidity of the testing environment and the close proximity of the switch ends. More testing at a variety of different humidities can help confirm or disprove this hypothesis.

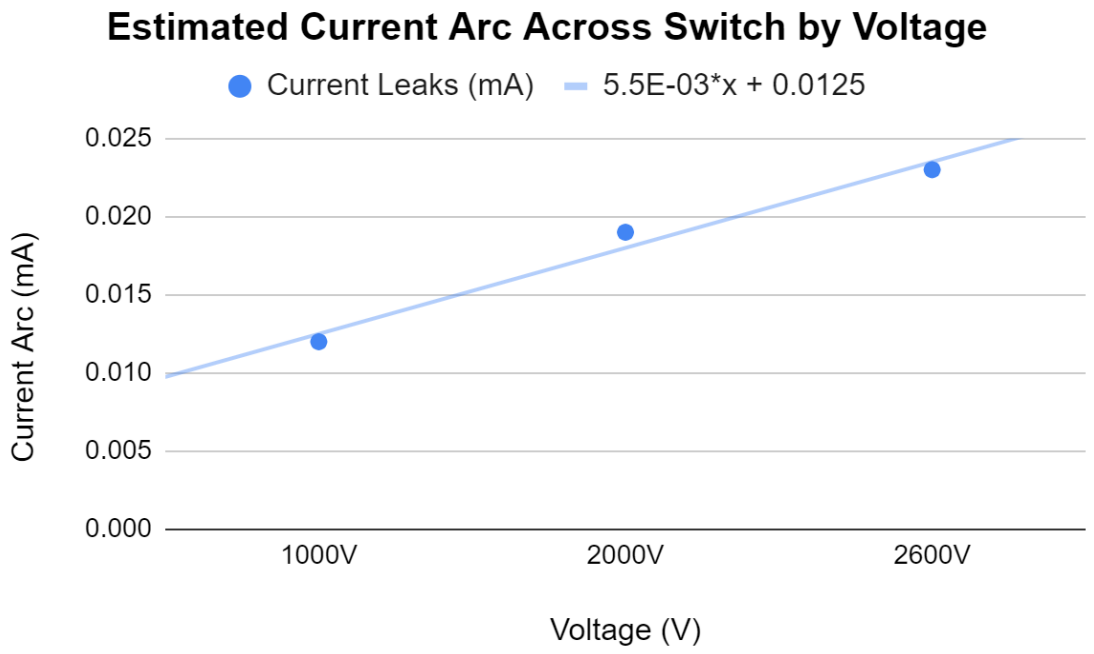


Figure 13: Arc Current Magnitude Across Switch for Given Test Voltage

$$\text{Arc Current (mA)} = 5.5\text{x}10^{-3}[\text{Test Voltage (V)}] + 0.0125$$

Equation 1: Estimation of arc current magnitude based on voltage through circuit

In Figure 13, the arc current values were graphed against the test voltages and a calibration curve was created using a linear line of best fit, Equation 1. Using Equation 1, it is possible to estimate the magnitude of the arc current at any voltage through the circuit. There was no variation in the arc current magnitude across the 5 trials of each test voltage, so the standard deviation of arc values within the test voltage is zero and no error bars can be included within the graph. The raw data from the switch testing can be found in Appendix 11.5B.

7.2 Normal Defibrillation Connection/Impedance Results

The first portion of the normal defibrillation connection/impedance test was used to ensure that the connections were complete between the circuit, the pads, and the defibrillator. Testing results indicated that the circuit was complete at shock values of 50 J, 100 J, 125 J, 200 J, 275 J, and 360 J. The maximum shock value possible from devices currently on the market and compatible with the device is 360 J. Shown in table 2, the device can successfully send a 360 J shock through one vector which is the maximum value that can be sent through the device. If the shock was delivered, it passed. If the shock was not delivered, it failed. Based on the results, there was a 100% pass rate with the device in shock deliverance. Using this analysis there is high confidence that the device connections are complete in the normal defibrillation circuitry.

Joule Value	50 J	100 J	125 J	200 J	275 J	360 J
Shock Delivered	Yes	Yes	Yes	Yes	Yes	Yes

Table 2: Table Recording the Delivery of the Shock at Varying Shock Values

The second portion of the normal defibrillation connection/impedance test was used to test if the manikin affected the patient impedance read by the defibrillator. Based on the test manikin the known impedance value equates to 25 J. The shock value from the defibrillator was 150 J and the manikin received a shock value of 175 J proving that the device did not alter impedance. The difference between the shock sent and the shock received was 25 J which equals the predicted impedance value created by the manikin. The increase in received shock proves impedance capabilities of the monitor are unchanged even with the use of the device's normal defibrillation function.

7.3 DSD Functionality Results

The DSD Functionality test yielded two important findings. First, the results showed that the circuit in the device can accurately direct the current through either Vector 1 or Vector 2 when in DSD Mode. When the voltage input into the circuit was positive, only Vector 1 was measured to have a voltage drop across its associated pads. The opposite was proven true for a negative input voltage as only Vector 2 was measured to have a voltage drop across its pads. These results are displayed in Figure 14. There was very little variation in the measured voltage drop across the pads over the three trials for each test voltage. For Vector 1, there was no variation between trials for test voltages of -5, -4, -3, -2, -1, 0, 1, 2, or 3 V and for Vector 2, there was no variation for the test voltages for -2, -1, 0, 1, 2, 3, 4, or 5 V. For the test voltages with variation across the trials, the average deviation from the mean for the three trials was 0.02 V. The raw test results from the DSD test can be found in Appendix 11.5B.

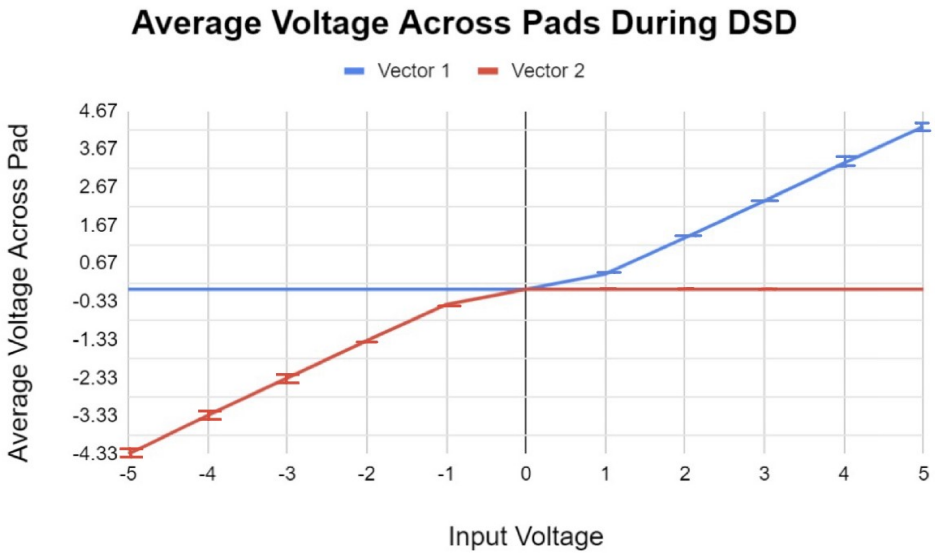


Figure 14: Measured Voltage Drop Across Pads for Vector 1 and 2 for Positive and Negative Input Voltages

The second important finding from the DSD Functionality test was analyzed from the magnitude of the voltage drop across the pads. It was expected that the voltage drop measured across the pads would be exactly equal to the voltage input into the circuit, but this was not the case. For every input voltage, the voltage drop measured across the pads was on average 0.64 V less than the absolute value of the input voltage. The magnitude of this difference between the input and measured voltage drop did not scale with increasing input voltage. At any magnitude of input voltage, the measured voltage drop across the pads was approximately 0.64 V less than the input voltage.

Five Student T tests were performed to determine if the difference between the expected and measured voltage drop was significantly different. For these tests, groups were made based on the absolute value of the input voltage, because the magnitude of the voltage drop should not change based on the polarity of the input voltage. One test was run for each absolute magnitude of the input voltage and compared the expected voltage drop versus the average of the 6 measured voltage drops across the trials. The values used to complete this test can be seen in Table 3. Using a p value of 0.05, it was found that the difference between the expected and the average measured voltage drop was significant, as seen by the p values in Table 3. It was also observed that as the magnitude of the input voltage increased, the p value increased as well. It is hypothesized that the difference between expected and measured voltage drop across the pads is due to the resistance of the diodes. The resistance of the diodes is a static property and will not change with increasing voltage, so it is reasonable to assume that the diodes are the reason for the discrepancies between expected and measured drop. It is hypothesized that when the device is tested at higher input voltage such as 2000 V, a loss of 0.64 V due to the diodes will be insignificant. This would prove that the diodes do not significantly disrupt the current or voltage sent from the defibrillator. Further testing at higher input voltages must be performed to confirm this hypothesis.

Group	Expected Voltage Drop Across Pads	Average Measured Voltage Drop Across Pads	P Value
1 and -1 V	1 V	0.4 V	3.6×10^{-160}
2 and -2 V	2 V	1.35 V	1.7×10^{-154}
3 and -3 V	3 V	2.32 V	3.4×10^{-17}
4 and -4 V	4 V	3.32 V	1.9×0^{-18}
5 and -5 V	5 V	4.3 V	5.5×10^{-17}

Table 3: P Values from Student T-Test on Measured Voltage Drop Across Pads During DSD

8 DISCUSSION

The testing results show the design's ability to conduct an electric shock through the normal single vector defibrillation path and the DSD path of the circuit. Despite this, possible errors and implications need to be considered. Exploring the effectiveness and functionality of this device further is an important next step, as this device is aimed to be used in high-risk emergencies. Research on the effectiveness of DSD suggests that it is a successful intervention for patients in RVF, but research is limited and more must be done to elucidate the effects of DSD [4]. Therefore, limiting interference with current standard medical interventions is of utmost importance when considering the use of this device. There are two ways this was accounted for. First, the pads are designed to be easily placed by medical professionals and are compatible with the use of the LUCAS device. Second, the functionality of normal defibrillation was tested by the normal defibrillation connection/impedance test to confirm that the device does not interfere with any normal defibrillation attempts.

While maintaining the capability of following standard medical interventions is important, the device's focus is to expand the defibrillator's function to include the performance of safe and efficient DSD. The results of the DSD functionality test showed that at low levels of voltage, electricity was successfully diverted, depending on a negative or positive charge, with a constant voltage drop of 0.64 V. At the high voltage of a defibrillation shock, this drop is negligible. This means that during a defibrillation shock, it would be reasonable to expect that the shock would be diverted and delivered to the patient without a significant loss of voltage, yet there are other implications to consider regarding this loss in voltage. To deliver the full defibrillation shock to a patient, the monitor must be able to read both the patient's rhythm and impedance. Measuring impedance is commonly done through the monitor by delivering a small test shock to the patient. Therefore, the voltage drop may interfere with accurate measurements of impedance. This must be addressed in the future by testing the DSD function with a defibrillator, similar to the normal defibrillation/impedance testing. If testing proves that further action is needed, a method to measure impedance and rhythm while using the DSD function must be implemented.

Keeping both medical professionals and patients safe when the device is in use is another consideration. One way safety is accounted for is through the switch test. This test ensured that the switches used in the device were capable of properly conducting shocks equivalent to those sent by a defibrillator. This test showed it is reasonable to assume arc by the switches is negligible. To further confirm this assumption, this test should also be run using a control to account for environmental factors, such as humidity, that could contribute to small amounts of current arc. A future method to increase safety and correct use of the device would also include fewer switches and clearer labeling, making the device more user-friendly. This is an important consideration due to the high-stress situations where the efficiency and simplicity of the device can be the difference between life and death.

9 CONCLUSION

A device was created to separate the positive and negative portions of a biphasic shock from a defibrillator monitor. By dividing the shock into its two portions, the device creates two smaller defibrillation shocks that can be delivered to a patient in sequence and accomplish DSD. This diversion of the shock is accomplished by a circuit that contains two diodes oriented in opposite directions. Initial testing regarding the DSD functionality of the device showed the device was able to correctly direct the voltage to either Vector 1 or 2 based on its polarity. Additionally, this test found that a significant amount of voltage is lost due to the resistance of the diodes when tested with small input voltages. It was also observed that the magnitude of the voltages lost did not scale with increasing input voltage, so it is hypothesized that the voltage lost due to the diode resistance will be insignificant at higher voltages. More testing will need to be performed at higher voltages to confirm this hypothesis.

A key specification for the device is that it must not interfere with the impedance calculations of the defibrillator monitor. If continual impedance within the circuit is not detected, then the release of current will stop and a shock will not be delivered. Future testing on the DSD function with the diodes must be implemented to ensure a shock is properly delivered while not interfering with the impedance. There are also implications that creating a shock that gets diverted could be extremely dangerous to the patient because of the delicate ratio required between voltage and current to achieve an effective shock. Therefore, testing must be done to ensure the current and voltage are only being diverted by the diodes and not intrinsically affecting these values.

In terms of improvements that must be made to the user interface of the design, the three-switch system should be turned into a one-switch system. This can be accomplished by reorienting the switches and connecting them via a metal bar so that while the Bypass Switch is closed, the Vector 1 and Vector 2 DSD switches can only be open. The three connected switches can be enclosed so they appear as one switch. This not only simplifies the user interface but also increases the safety factor of the device by preventing the Bypass Switch and DSD Switches from being open simultaneously.

The overall end goal for a DSD device includes sending two biphasic shocks. The circuit would need to be altered to integrate two h-bridges, one for vector 1 and one for vector 2. This would ensure that during DSD each monophasic shock created by the diodes would be broken up into two biphasic shocks. This would also require a ring sensor to detect the current sent by the defibrillator via the hall effect. This signal then could be sent to a microcontroller which is used to control both h-bridges. The h-bridges would be controlled by “power transistors” due to the extremely high voltage. The preliminary design iterations originally had incorporated h-bridges into the design but found controlling h-bridges at extremely high voltages is expensive and would require more time and expertise to develop a working prototype.

Overall, the first prototype of this device was successful in proving that DSD can be accomplished via division of the biphasic shock. The further development of this device will lead

the way for increased accessibility to DSD treatment and potentially facilitate field studies to assess the impacts of DSD in refractory cardiac arrest patients.

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11 APPENDIX

11.1 Product Design Specification

Project Function: Cardiac arrest is a sudden loss of heart function that can be attributed to an abnormal electrical signal in the heart. Defibrillation is a technique used to deliver an electrical shock to the heart and revert it back to a sinus rhythm. During a cardiac arrest in which the patient is in ventricular fibrillation or ventricular tachycardia and has not responded to three standard defibrillation attempts or medication, Dual-Sequential Defibrillation (DSD) is a last resort method that can be used by healthcare providers to reset the patient's cardiac rhythm. In DSD, two electrical shocks are delivered to the heart in sequence and require the addition of a second set of defibrillation pads to the patient. Unfortunately, the Lund University Cardiopulmonary Assist System (LUCAS), a device used to provide high-quality cardiopulmonary resuscitation, makes it difficult to access multiple vector positions for additional defibrillation pad placement. Currently, healthcare professionals must remove the LUCAS device in order to place an additional set of pads. This project is focused on creating cardiac pads that allow for two shocks to be delivered to the patient through one defibrillation system. This product will eliminate the need for additional cardiac pads to be placed on the patient in the event that DSD is needed. By creating this new system for DSD implementation, medical providers will be able to easily initiate DSD during resuscitation efforts in which the LUCAS is in use.

Client Requirements:

- Create a novel system to allow easier initiation of DSD during complex resuscitations
- Allow medical professionals to adequately provide Advanced Cardiac Life Support (ACLS) care and not interfere with current protocols [1].
- Improve the current system for DSD implementation during a cardiac arrest to increase chances of utilization by emergency services.
- The final prototype must be compatible with most commonly used cardiac monitors (LIFEPAK 15 and Zoll X-Series monitors) in addition to a LUCAS device being placed on the patient [2][3].
- The function of the final prototype must be similar enough to current designs that users are able to utilize the product safely with minimal training requirements.

Design Requirements

1. **Physical and Operational Characteristics**

a. Performance Requirements: The requirements of this product are to deliver 180 joules of shock and sequentially deliver another 180 joules worth of shock through a separate vector within 0.5 seconds [4]. This must be repeatable for up to 200 shocks per battery [5]. The product must also be able to switch vectors without doing DSD. The product must also be water-resistant to avoid complications with performance in poor weather conditions.

b. Safety: The design needs to be entirely insulated from users and water resistant to prevent electrical harm to users. Warnings should be posted on the specific buttons of the design and what they do to prevent user error. The IEC 60601-2-4:2010 Medical electrical equipment - part 2-4 requirement creates a safety protocol for the basic safety and performance of cardiac defibrillators [6]. The design must follow the outline put in place by the IEC safety protocols.

c. Accuracy and Reliability: The product needs to be at least 96% accurate and reliable due to its use on humans in critical condition [7][28]. This figure comes from surrounding literature corresponding to defibrillator accuracy in the current market[28]. However, we would like our device to be 99% accurate meaning it must deliver between 178.2 J and 181.8 J when the setting is at 360 J. The timing between the shocks must also be accurate to 99%. This product will be used in life-threatening situations and without accuracy and reliability the product will not be able to be used by medical professionals.

d. Life in Service: The connector portion of the design is needed for a minimum of 200 shocks which is comparable to the minimum lifespan of a manual defibrillator's battery. The pads portion of the design will be used a single time, each time the design is used even when DSD is not utilized [8]. Over the course of this product in service, the team estimates that this product could be used on 1 of every 200,000 people based on Refractory Ventricular Fibrillation statistics [4].

e. Shelf Life: The manufacturing date to the expiration date is 18-30 months for defibrillator pads [9]. The circuit component should be tested in accordance with Zoll's recommendation of a self-circuit test daily [6]. Shelf life for AEDs is currently two to four years [10]. If a battery is included in the design it would follow the same shelf life requirements listed above.

f. Operating Environment: Defibrillator pads can be used in almost all environments that do not involve standing water. Especially hairy or wet patients must be dried or shaved before use [11]. All components of the device must be kept between 0 and 50 degrees Celsius and near standard atmospheric pressure [12]. Circuit

components will be sealed from humidity and the pads, from the manufacturer, are designed for humid conditions.

g. Ergonomics: The product will make it easier for the physician to switch vectors on the patient without being forced to remove LUCAS. Eliminating the need to remove the LUCAS saves the physician time between compressions and defibrillator shocks. It creates a sequential shock on the patient resulting in an increased chance of return to normal rhythm for the patient's heart when in refractory ventricular fibrillation [13].

h. Size: The defibrillator pads must be able to fit a patient aged 8 and up or 55 pounds and heavier [14]. The product will have two separate designs: a set of pads for patients weighing 55 pounds to 100 pounds and one for patients weighing 101 pounds and up. This is to ensure that the pads don't touch each other on the patient's body. The pads must also be portable so that they can be transported in the field.

i. Weight: The device should be light enough to transport around the field and hospital without great difficulty. The pads will be made of material that is light so that it does not weigh down the patient when applied.

j. Materials: A major part of the design consists of the circuit performing dual sequential defibrillation. The circuit will consist of wire, diodes, switches, perf board, and a project box. The pads will be adaptable to fit with Zoll's defibrillation pads [3]. The design will be compatible with the LIFEPAK 15 Cardiac Monitor [2].

k. Aesthetics, Appearance, and Finish: The product will look professional and high quality. The design will include clear instructions of how to place the pad and switch between vectors. The circuit will be contained within a sleek-looking project box.

2. Production Characteristics

a. Quantity: The current goal set by the client is to produce one set of four pads that have the ability to deliver a defibrillation shock including the ability of DSD. If required for future use, the design could be easily replicated and manufactured for widespread use.

b. Target Product Cost: The client provided the team with a budget of $500. Defibrillation pads range in price from $60 to $190 [15]. The ideal range for the device cost is around $200 excluding the pads and defibrillator.

3. Miscellaneous

a. Standards and Specifications:
   i. IEC 60601-1-2:2014: Collateral Standard: Electromagnetic disturbances [16]
      1. Specifies general requirements and tests for basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions of ME equipment and ME systems. They are in addition to the requirements of the general standard IEC 60601-1 and serve as the basis for particular standards.
   ii. American Heart Association: Advanced Cardiovascular Life Support [17]
      1. Highlights the importance of high-performance team dynamics and communication, systems of care, recognition, intervention of cardiopulmonary arrest, immediate post-cardiac arrest, acute dysrhythmia, stroke, and acute coronary syndromes (ACS).
   iii. ANSI/AAMI DF39-1993: Automatic External Defibrillators and Remote-Control Defibrillators [18]
      1. This standard covers minimum labeling, performance, and safety requirements for automatic or semi-automatic (advisory) external defibrillators (AED), remote control defibrillators (RCD), and self-adhesive combination electrodes.
   iv. ISO 80601-2-61:2011: requirements for basic safety and essential performance of pulse oximeter equipment [19]
      1. Applies to the basic safety and essential performance of pulse oximeter equipment intended for use on humans. This includes any part necessary for normal use, including the pulse oximeter monitor, pulse oximeter probe, and probe cable extender.
   v. IEC 68-2-27: Environmental Testing [20]
      1. Provides a standard procedure for determining the ability of a specimen to withstand specified severities of non-repetitive or repetitive shocks. The purpose of this test is to reveal mechanical weakness and/or degradation in specified performances, or accumulated damage or degradation caused by shocks.

b. Customer: The customers for this product will be research facilities, hospitals, and first responders. Due to the novel nature of dual sequential defibrillation, it will

need to be more heavily researched before reaching markets such as hospitals or emergency services [21].

c. Patient-related concerns: The device will aim to be an emergency life-saving device. The main concern for the patient is unsuccessful treatment of ventricular tachycardia or fibrillation and subsequently, death. The device will deliver an appropriate shock in order to provide the proper treatment with minimal complications. A biphasic defibrillator pad will deliver a minimum shock of 120 J to remain effective with a standard shock being 200 J [22]. The total shock that the pads deliver will be under 720 J to remain in a shock range that research has shown safe [23]. Another patient concern could be burns or allergic reactions. The most common complication of defibrillation is burns at the site of the pads [24]. To minimize this, the pads will remain in the standard shock range. Using known common allergens, like latex, they will be avoided to prevent allergic reactions to the product.

d. Competition:
    i. Zoll CPR Stat-padz [25]
        1. Standard Zoll cardiac pads for use with their X-series monitor with real-time CPR feedback to be integrated into the monitor
        2. Only provides 1 vector of cardiac shocking and difficult to reposition due to adhesive
    ii. Stryker Physio-Control Cardiac Pads [26]
        1. Standard Stryker Physio-Control Cardiac Pads that are used with LIFEPACK 15 cardiac monitors
        2. Only provides 1 vector of cardiac shocking and is difficult to reposition due to adhesive
    iii. Zoll CPR-D-Pads [27]
        1. Combined set of pads for apex/lateral-sternum placement combined with real-time CPR feedback device in 1 adhesive S-shaped pad to simplify placement for medical professionals
        2. Only provides 1 vector of cardiac shocking and is not useful to reposition because the geometry of the product created for apex/lateral-sternum and apex/front-back

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11.2 Expense Spreadsheet

Order Number	Item To Order	Purpose	Amount	Price Individual	Total Price
1	Adult "Leads-Out" Defib Pads for Physio Quik Combo for LifePak	TO harvest male lifepak leads	2	38.44	76.88
2	DIODE GEN PURP 2.2KV 30A TO220AC	To create two seperate shocks for DSD	4	4.55	18.2
3	ZOLL® Electrode to Physio QUIK-COMBO Adaptor	Adapter to get female end of zoll pads	3	49	147
4	Hinges	Connect Swtiches to Box	6	1.75	10.5
5	Screws and Nuts	Connect Swtiches to Box	24	0.1	2.4
6	Hot Glue	Connect Swtiches to Box	1	1.15	1.15
7	Heat Shrink	Protect wires inside circuit box	1	2.25	2.25
8	Printed Circuit Board	Solder diodes to	1	1	1
9	Black Project Box	Project Circuit from Users	1	9	9
10	Toggle Switch DPST Panel Mount	3 Switches for the design	3	29.56	88.68
			Total Price:		357.06

11.3 Fabrication Protocol

11.3A Circuit Fabrication

1. Take the LIFEPAK pads and using the wire cutter, remove the pads from the wires.
2. Separate the wires from each other into a wire wire and blue wire, leaving the defibrator plug-in intact.
3. Using the wire cutter, cut 8, 3 inch long pieces of both white and blue wire.
4. Using the 14 guage wire stipping tool, strip off .25 in of the plastic coating on each end of the wire.
5. Using the 14 gauge wire stripping tool, strip off .25 in of the plastic coating off the blue and white wires that are still attached to the defibrillator connector.
6. CONNECTING THE CENTRAL GROUND WIRES:
    1. Collect three of the 3 inch blue wires and the blue wire that is connected to the defibrillator connector.
    2. Fan out the exposed wires ends on one end of each of the small blue wires and the defibrillator connector wire.
    3. Mesh the fanned ends together and twist them.
    4. Using the solder wand and solder, solder together the new wire connection.
    5. Slide a 1 cm diameter heat shrink tube up the wire and use the heat gun to seal the heat shrink around the wire you just soldered.
7. CONNECTING THE CENTRAL POWER WIRES AND POSITIVE DIODE:
    1. Take the white wire that is connected to the defibrillator connector and separate the exposed end into three sections.
    2. Twist each section and slide the three sections through the three holes on the second to last row on the left end of the perf board (this step is only needed if you do not have 14 gauge wire perf board)

3. On the bottom side of the perf board, twist the ends of the wire together and lie them flat on the surface of the perf board.
4. Solder the ends of the wire flat to the bottom of the perf board.
5. In the same line that you just added the white wire, place the first diode in the positive orientation.
6. Bend the end of the diode so that it lays flat on the perf board.
7. Take 2 pieces of the 3 in white wire and follow steps 2-3 to add one end of each of these wires to the lines directly adjacent to the wire from the defibrillator connector.
8. Use the solder wire to solder together the wire from the defibrillator connector, the diode, and the two short wires that have been added to the solder board.

8. ADDING THE NEGATIVE DIODE:
    1. Take the second diode and add it to the right side of the board and in the opposite orientation to the first diode.
    2. Fold the prongs of the diode flat onto the back side of the perf board.
    3. Take one of the short white wires that is connected to the power line and twist the end into three sections.
    4. Feed the three sections of the wire through the perf board in the line adjacent to the negative diode and solder the ends of the wire to the diode.
9. ADDING THE OUTGOING POWER WIRES TO THE DIODES:
    1. If you have not already, fold the second prong on both of the diodes down so it lays flat against the perf board.
    2. Take two 3 inch white wires and twist them into three pieces and slide them into the board (one in each line adjacent to the diode prong that you just folded down).
    3. Solder the wire to the end of the diode prong, should have both diodes soldered to your board and three short wires coming out from the board.
10. CONNECTING THE SWITCHES:
    1. Take the three switches and line them up so they are in the same orientation (on/off are facing in the same direction)
    2. The switches connect paths across their long side
    3. For each switch, connect one of the white wires coming out from the board to the prong on the left side of the switch, on the side closest to the perf board using solder.
    4. For each switch, take one of the blue wires from the ground connection and connect it to the prong on the right side of the switch, on the side closest to the perf board using solder.
11. CONNECTING THE NEGATIVE DIODE TO PAD 2:
    1. Taking the switch that is connected to the negative diode, solder a 3 in white wire to the left side of the switch on the side further away from the perf board.
    2. Follow step 1 for a 3 in blue wire on the right side.

3. On the switch, the white wires will be on the same side and the blue wires will be on the other side.
4. Solder the ends of the wires leaving the switch to the metal prongs in the adapters.

12. CONNECTING THE NORMAL DEFIB AND POSITIVE DIODE PATH TO PAD 1:
    1. For both the switches, follow steps 1 and 2 in step 11 to attach the outgoing wires.
    2. Take the outgoing white wires, fan out the wires on their exposed end.
    3. Take the last 3 on the white wire and fan out the wire in one of the exposed ends.
    4. Twist the three white wires together and solder.
    5. Add heat shrink over the connection and melt it using the heat gun.
    6. Follow steps 2-5 but for the blue wires.
    7. Now the outputs of both of the switches should be connected.
    8. Solder the blue and white wires to the adapter to pad 1.

11.3B Project Box Fabrication

1. Place the project box on the side that is longest with the lid removed.
2. Find the middle of the box from left to right and then go to the top portion of that side in the center.
3. Drill two holes .1 inches in diameter from the top of the box down .25 inches, the holes should be .2 inches apart.
4. Flip the box over to the opposite side.
5. Find the center of the left quadrant of that side.
6. Drill two holes .1 inches in diameter from the top of the box down .25 inches, the holes should be .2 inches apart.
7. Find the center of the right quadrant of that side.
8. Drill two holes .1 inches in diameter from the top of the box down .25 inches, the holes should be .2 inches apart.
9. Find the center of the lid.
10. Cut .710 inch width and 1.230 height out from the exact center of the box.
11. To the left and right of the center switch hole in the longest direction cut out .710 inches wide, 1.230 inches high, with .5 inches between them.
12. Drill 1/3 inch diameter holes with ½ inch distance away from the switch, with ½ inch distance between the two holes on one side of the switch.
13. Follow step 12 for the other side of the switch.
14. Follow steps 12-13 for the other two switches.
15. Glue the hinge to either long side of the switch with the hinge facing upwards.
16. Follow step 15 for the side of the switch.
17. Follow step 15-16 for all three switches.
18. Place the switches in the cutouts in the top of the project box with the hinges resting on the top of the box with their holes lining up with the holes in the project box.
19. Place 8-32 screw in the hole through the project box and hinge.

20. Follow step 19 for all 12 holes.
21. Place a 8-32 nut on the backside of the lid and screw on tight to the screw to ensure nothing moves.
22. Follow step 21 for all 12 nuts.
23. Place the circuit within the box and string the wires through the cutouts on the side of the box.

** In the future there will be 3D printed adapters attached to the box to simplify the connecting of the pads to the device

11.3C Pads Fabrication

1. Place the front pads together, when looking at the pads, the pad on the left should be horizontal in direction and the second pad to the right should be vertical.
2. Place the pad on the right (the vertical pad) one inch overlap on the horizontal pad so that only the foam is overlapping.
3. Take superglue and combine the pads together by placing glue on the back of the vertical pad and sticking to the top of the pad on the left.
4. Take each wire that is coming out of each pad and hold them together till reaching the base of the connections.
5. Super glue the wires together from where the wire starts at the pads and until where they combine with other wires, 2 ft from the pads.
6. Grab each pad plug adapter and stack them on top of each other so that the horizontal faces are on top of each other.
7. Go down the wires 6 inches from where they connect to the plug in and place some glue at this point so that the wider portions of the wires are on top of each other and connected.
8. From that point and towards the pads glue together the two wires till they meet the junction where they split apart.

11.3D Adapter Fabrication

1. Obtain a caliper and take measurements on the Zoll pad plug.
2. Using the measurements taken on the Zoll pads, design the simplified plug within software such as solidworks using the dimensions measured.
3. To ensure the pad adapter will fit in the plug being created, a tolerance should be added. This tolerance was in the range of 2-5 mm in each of the dimensions measured.\
4. Once the adapter is created, the negative will have to be created.
5. This can be done by creating a box that is dimensionally larger than the adapter by 5-10 mm in each dimension.

6. With both the box and the adapter created, start an assembly and add the two parts into the assembly.
7. Click on the box and edit the part. Go to the features tab and select cavity.
8. Drag the adapter into the box where you want the cavity to be and click the green check mark to create the cavity within the box.
9. Now you have the negative that will act as the plug that the pads will be plugged into in solidworks.
10. Convert the file to a stl file that can be 3-D printed.
11. The material used was PETG with carbon fiber embedded. This allows for a strong plug that is much less likely to be damaged.
12. Multiple iterations may be needed to get the desired connection between plug and pads.
13. The last portion of the fabrication is adding the electrode prongs that allow electricity to flow from the circuit to the pads.
14. Holes are to be drilled and prongs placed in the drill holes. These prongs will be super glued to the plug and soldered to wiring from the circuitry.

11.4 Experimental Protocol

11.4A Switch Protocol

1. Connect the power end and the ground coming from the testing machine to the one the longitudinal pathways on the switch.
2. Place the switch on the rubber mat and place the plastic covering box on top to protect the user from accidentally touching the switch.
3. Make sure the switch is in the off position (make sure the path is open).
4. On the testing machine, set the ramp time to .1 seconds and the testing time to 2 seconds. These are the lowest values on the machine and the closest we can get to simulating the 16 ms pulse that will be sent through the circuit from the defibrillator.
5. Set the reference value to 0.100 mA. This means that if the machine senses an arch value of greater than .100 mA, the switch will fail the test.
6. Set the voltage to 2000 V.
7. Once the machine has been configured and the switch is safely in the box, press start on the testing machine. The test will run for 2 seconds then turn off and display the results.
8. Record the arc value displayed on the machine. If it is less than .100 mA, the circuit passes the test.
9. Repeat this 4 more times for the 2000 V.
10. Repeat this test at voltages of 1000 V and 2600 V.

11.4B Single Vector Connection Protocol

1. Connect the device to the LIFEPAK 15 monitor.

2. Connect the device to the heart simulator through the single vector wire.
3. Flip the switches so the DSD function is off and the single vector switch is ON.
4. Turn on RVF on the heart simulator.
5. Read the value shown on the defibrillator to ensure the device is properly passing the rhythm.
6. Set the monitor to run 50 J through the circuit.
7. Send the shock from the defibrillator.
8. Ensure the shock was delivered to the heart simulator.
9. Run step 6-8 with Joule values of 100 J, 125 J, 200 J, 275 J, 360 J.

11.4C Single Vector Impedance Protocol

1. Connect the device to the LIFEPAK 15 monitor.
2. Connect the device to the manikin through the single vector wire.
3. Flip the switches so the DSD function is off and the single vector switch is ON.
4. Read the value shown on the defibrillator to ensure the device is properly passing the rhythm from the manikin to the defibrillator.
5. Set the monitor to 150 J (Max amount).
6. Send the shock through the manikin.
7. Record the measured Joules the manikin received.

11.4D DSD Functionality Protocol

1. Using alligator clips, take the defibrillator plug in and connect the pin corresponding to the blue wire to ground on the voltage supply and the pin corresponding to the white wire to the positive power supply.
2. Take the pads attached to vector one and wrap 100 ohm resistors around the plug in pins to connect them.
3. Attach one of the alligator clips from the voltage meter to each pad plug in pin.
4. Starting at 0V, increase the voltage from the power supply to 1V, 2V, 3V, 4V, and 5V, and record the value on the voltage for each voltage.
5. Perform step 4 three times.
6. Switch the alligator clip connecting the defibrator plug in to the negative power supply and perform steps 4 and 5 but this time using 0, -1V, -2V, -3V, -4V and -5V.
7. Repeat this procedure for the pad ending for vector 2.

11.5 Testing Raw Data

11.5A Switch Testing Data

Voltage Level	Voltage Value	Current	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Allowable Leaks
Low	1000V	27.5 A	0.012 mA	0.012 mA	0.012 mA	0.012 mA	0.012 mA	0.1375 mA
Average	2000V	15.9 A	0.019 mA	0.019 mA	0.019 mA	0.019 mA	0.019 mA	0.0795 mA
High	2600V	11.5 A	0.023 mA	0.023 mA	0.023 mA	0.023 mA	0.023 mA	0.0575 mA

11.5B DSD Functionality Testing Data

Vector 1					Vector 2			
Voltage Input(V)	Trial 1 (V)	Trial 2 (V)	Trial 3 (V)	Average (V)	Trial 1 (V)	Trial 2 (V)	Trial 3 (V)	Average (V)
-5	0	0	0	0	-4.30	-4.29	-4.30	-4.30
-4	0	0	0	0	-3.31	-3.32	-3.31	-3.31
-3	0	0	0	0	-2.33	-2.33	-2.33	-2.33
-2	0	0	0	0	-1.35	-1.35	-1.35	-1.35
-1	0	0	0	0	-0.40	-0.40	-0.40	-0.40
0	0	0	0	0	0	0	0	0
1	0.40	0.40	0.40	0.40	0	0	0	0
2	1.35	1.35	1.35	1.35	0	0	0	0
3	2.32	2.32	2.32	2.32	0	0	0	0
4	3.33	3.30	3.31	3.31	0	0	0	0
5	4.28	4.29	4.26	4.28	0	0	0	0