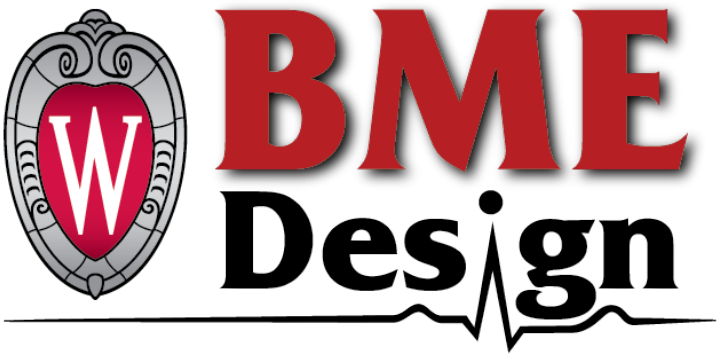

Specialized Pads for Dual Sequential Defibrillation

BME 200/300
University of Wisconsin-Madison
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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 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 be tested by first simulating the circuit using a software application such as LTspice, then by hand to test the output current through each set of pads. Once a physical device is created, it 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.

Table of Contents

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.

1.3 Existing Devices & Current Methods

Currently there are no existing devices that execute dual sequential defibrillation (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 if they want to use DSD. As a result, doing 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 defibrillator

could implement DSD. 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 the desired energy of the medical professionals as seen in Figure 1 [6].

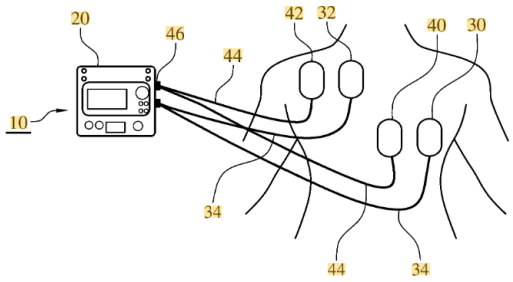


Figure 1: South Korean patent for Dual Sequential Defibrillation

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.

Figure 2: Example of current DSD setup on a mannequin using a Zoll monitor

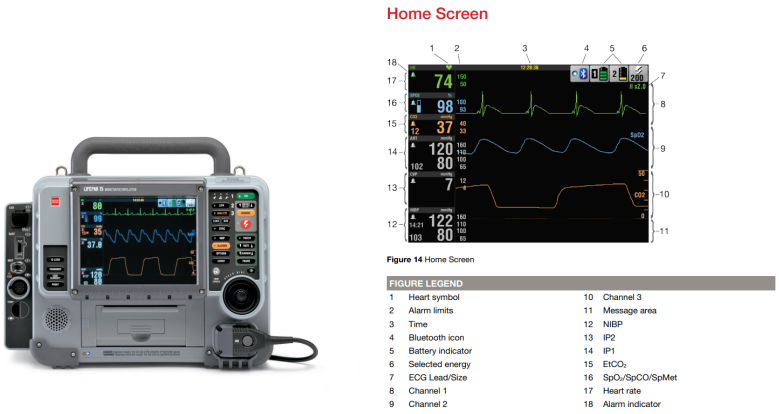


Figure 3: LIFEPAK Monitor and home screen with descriptions

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 [8]. 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 [9].

The focus of this device is to rectify these two problems by adapting defibrillation pads so they can be applied to the patient without the removal of the LUCAS. It will do this by creating a circuit to divide 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 at the incorrect time, limiting the effectiveness of each heart beat. Eventually, heart beats cannot even be discerned on an electrocardiogram (ECG) and the heart no longer provides effective blood flow to the body. VF is one of four types of arrhythmias that can cause a heart attack [10]. The other three include pulseless ventricular tachycardia (VTach), pulseless electrical activity (PEA), and asystole. Refractory ventricular fibrillation (RVF) is the most common heart arrhythmia in which DSD is indicated [11]. A picture of RVF compared to a standard heart rhythm and their associated ECGs are pictured below in Figure 4.

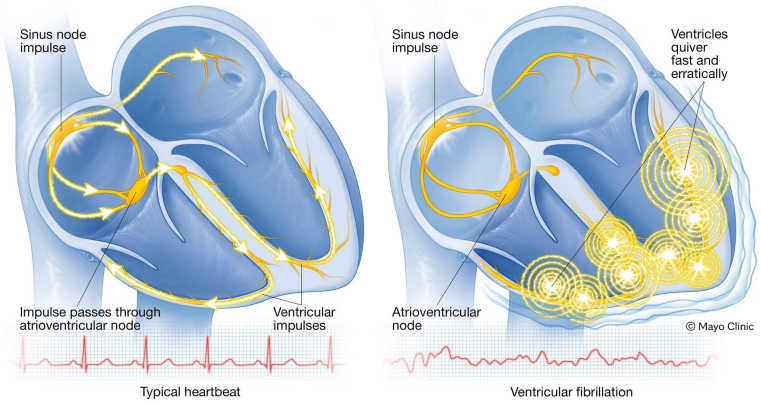


Figure 4: Diagram showing electrical signals in a standard heart rhythm and RVF along with the associated ECGs

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 [12] and Zoll X-Series [13]) 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 they are still shockable. If the rhythm is determined to be shockable, the device charges and prepares to deliver a shock. Electrodes in the form of cardiac pads (or hospitals sometimes use metal paddles that look like a steaming iron) send an electric current through the body and because of the electrode placement, through the heart as well. 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.

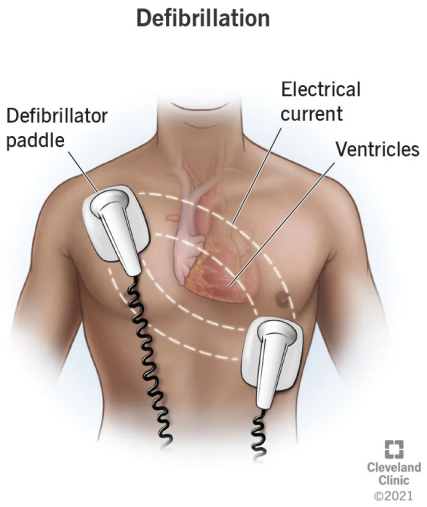


Figure 5: Diagram of electrode placement and electrical circuit created during defibrillation

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 to decrease the barrier to access that this device will have in hospitals or EMS services. 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 [14]. 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 [15]. All existing defibrillator monitors must deliver energy with 96% accuracy, so the proposed device must match this reliability standard as well [16]. 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

[17]. The circuit element will be contained in a plastic box that is 12 x 12 x 6 cm and weigh no more than 3 kg in total. This portion of the device must be able to be held with one hand, so this is the driving factor behind its dimensions.

The adapted defibrillator pads must be able to fit a patient ages 8 years old and up or 25 kg pounds and heavier [18]. 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 8.1.

3 PRELIMINARY DESIGNS

3.1 Design 1 - Light Sensor

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 [15]. 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 with 4 leads 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.

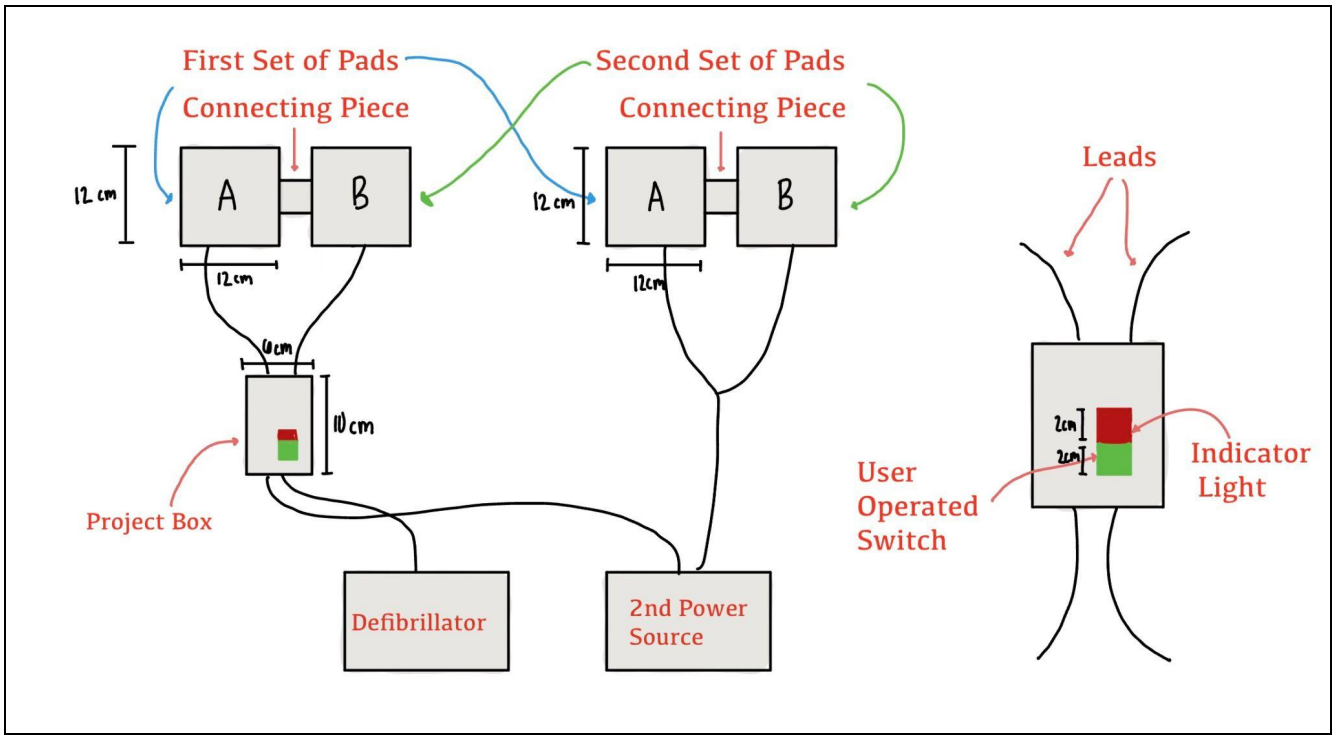


Figure 6: Light Sensor Design Sketch

3.2 Design 2 - Layered Electrode

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, if in DSD the circuit will have a current divider 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 [15]. In conjunction with the current divider is an internal time delay that will delay the shock of the secondary pads by the specified 0.5 to 2 seconds when delivering a DSD shock [15]. 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.

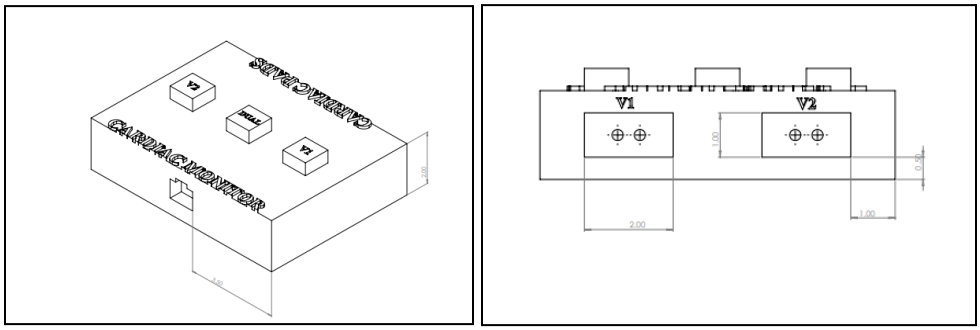


Figure 7: Layered Electrode and Modular Shock Pack Circuit Box Design Sketch from Top and Side view

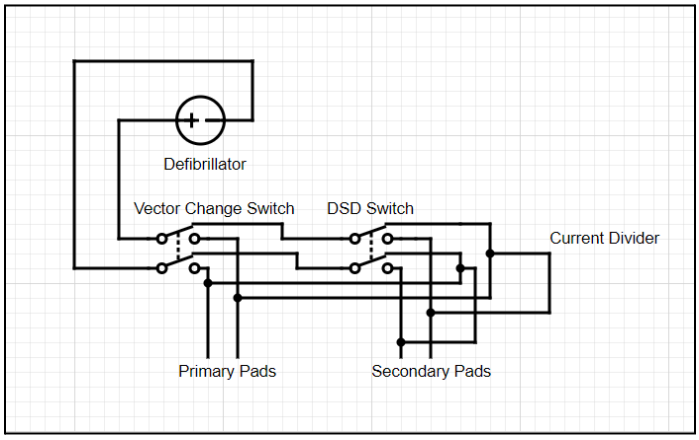


Figure 8: The Layered Electrode Circuit Design

3.3 Design 3 - Modular Shock Pack

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 7, 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. The design for this circuit is shown in Figure 9. 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 [19] 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.

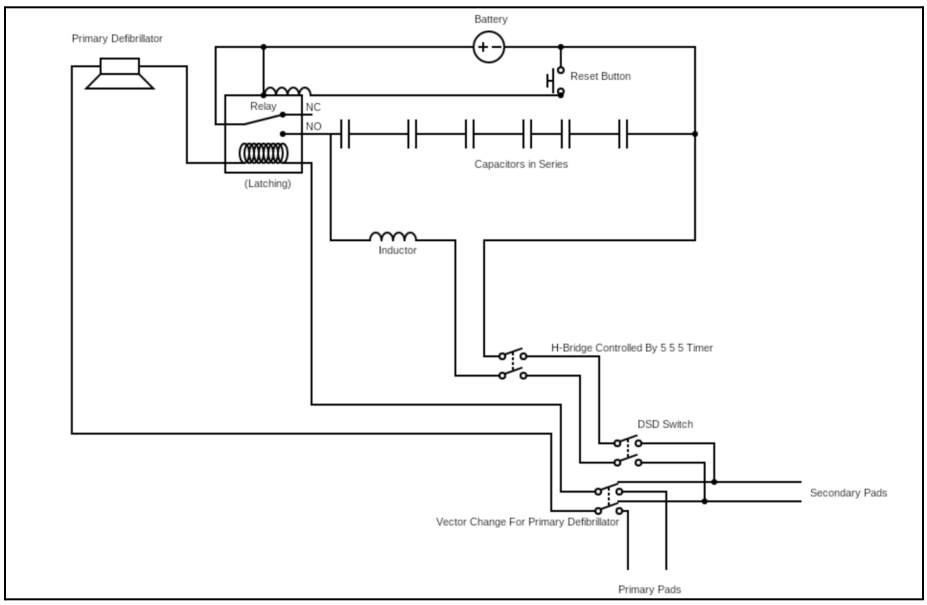


Figure 9: The Modular Shock Pack preliminary circuit design sketch

4 PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

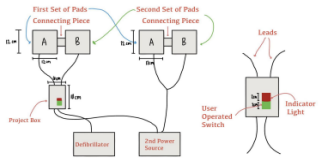
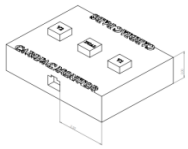
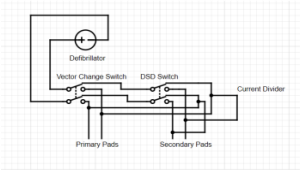
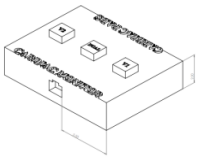
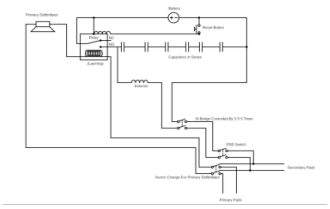
Design Criteria	Light Sensor Design		Layered Electrode Design		Modular Shock Pack Design	
			 		 
Feasibility (25)	**5/5**	25	**4/5**	20	**2/5**	10
Efficiency (20)	**2/5**	8	**4/5**	16	**2/5**	8
Reliability (20)	**3/5**	12	**4/5**	16	**2/5**	8
Ease of Use (15)	**2/5**	6	**4/5**	12	**5/5**	15
Safety of 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 designs' 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 Materials

The device will be composed of a plastic polymer project box that is waterproof to limit the danger of electrocution to users or bystanders. The plug and cords that connect the project box to the defibrillator will be harvested from a set of current LIFEPAK pads. The connected pads will be created using two sets of LIFEPAK pads which already work effectively to allow defibrillation in a diverse set of environments [20]. The electrical components that will be housed inside the project box will be composed of two switches (one for vector change and the second for DSD), a current divider, and a time delay relay. There will be a parallel circuit that will be opened when the DSD switch is activated. The circuit will also contain an alternate pathway for the second vector that will be accessed when the vector change switch is activated. The circuit will be constructed using a custom printed circuit board (PCB) which electrical components will be added to. See appendix 8.2 for a more detailed list of materials and budget.

5.2 Methods

The exterior designs for the Modular Shock Pack and the Layered Electrode Design were constructed using SolidWorks. The electrical circuit preliminary designs were drawn using circuit-design.org. The Light Sensor Design was drawn using Notability software on a tablet. Future fabrication of the circuit will be done using online electrical simulation software such as LT-Spice. The project will then be fabricated using a circuit board, insulated copper wires, and plastic connectors inside a plastic project box. The plastic connectors will be attempted to be harvested from expired defibrillator pads. However, it is likely that one or more of the connectors integrated into the project box will need to be 3D printed using software such as SolidWorks.

5.3 Testing

The device will be tested in three separate ways throughout fabrication. One test will measure the feasibility of splitting the power supply from the LIFEPAK monitor. The second test will simulate the voltage outputs of our circuit design and test the power output reliability. The last test will measure the time between defibrillation shocks received by a testing manikin. For each test, five trials will be performed. This number was chosen based on the limited access to the LIFEPAK monitor through the UW Hospital. The number of trials is subject to change and depends on how many tests the UW Hospital will allow.

In the first test, a circuit will be developed to test the feasibility of dividing the power generated by the LIFEPAK monitor. To do this, a circuit will be created with a 750 ohm resistor to replicate the resistance of the heart [21]. This circuit will be attached to the LIFEPAK monitor and an oscilloscope will be integrated to measure the output voltage after the resistor. Then, an additional 750 ohm resistor will be added to the circuit in parallel with the original resistor. Another oscilloscope measuring point will be attached to the circuit and the output voltage after both of the resistors will be recorded. This test is designed to test the hypothesis that the output voltage at both points will be the same. This test will be performed five times and if both output voltages are within 2 J of each other in all five tests, the design will be labeled as feasible and will move into the next phase of fabrication and testing [22].

In the second test, the proposed circuit for the device will be assembled in a digital circuitry software, such as LTspice. Within LTspice, the voltage outputs and current amplitudes of the circuit will be measured to see if they match the desired values. In this test, the desired power output from both circuit elements is a power value of 180 J. The power output of the proposed circuit elements will be calculated using the equation for power, as shown in Equation 1. If the power output matches the desired value, the circuit will be assembled and tested in the same fashion, but using a smaller power supply than the LIFEPAK. A small power supply will be used in order to minimize the risk of damaging the measuring tools in the event that there is an error in the circuit. The circuit will be tested multiple times with a varying number of power supplies. Each the predicted voltage and current outputs will be calculated and compared to the measured values. This will measure the reliability of our circuit. The circuit will be labeled as reliable if it can deliver the correct power through each element of the circuit with 96% accuracy [16].

Equation 1: Power = Voltage x Current

In the final phase of testing, the assembled circuit will be attached to the LIFEPAK monitor. The entire defibrillation device will be connected to a testing manikin located at the UW Emergency Education Center. A shock will be delivered to the manikin and the monitors installed within the manikin will show if a shock was delivered and the time between the shocks. The manikin is unable to detect the magnitude of the shock delivered, so this test will only be able to test the ability of the device to deliver two sequential defibrillation shocks. This is why the circuit reliability will be tested prior to testing on the manikin. The timing between the two

shocks must fall within 0.5-2.0 seconds [15]. If the circuit is able to meet this requirement over the course of five tests on the mannequin, it will be deemed reliable within the domain of the circuit delay.

6 CONCLUSION

The difference between life and death when it comes to VF or VTack can be as small as a brief pause of chest compressions or a delay in administering a defibrillation shock. With these considerations the design will integrate seamlessly with the LUCAS CPR device as well as have the ability to deliver normal defibrillation, vector change defibrillation, or dual sequential defibrillation through a single defibrillator based on the needs of the medical professional. The design moving forward will have a button layout to toggle between the options listed above and contain circuitry to split the current from the defibrillator during DSD. The design will also incorporate an internal time delay with regards to DSD as well so the shocks are sequential instead of simultaneous, limiting the possibility of damaging the defibrillator being used.

Future work on the project will include simulating circuitry within software such as LTspice to ensure the current is being split correctly before building the physical circuit. Once built, the circuit will be housed in a project box that will be modified to allow for both the defibrillator and two sets of pads to be plugged into the circuit box. Further testing will be done to ensure that each set of pads administers 180 J and that the secondary set has the correct delay during DSD. As the device is a novel design integrated with defibrillators, considerations into patenting should be investigated further.

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8 APPENDIX

8.1 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. There are two major limitations to DSD in the clinical setting. First, the Lund University Cardiopulmonary Assist System (LUCAS), a device used to perform mechanical chest compressions, makes it difficult for healthcare providers to add an additional set of pads to a patient without removing the LUCAS device. Removing the LUCAS means interrupting chest compressions, which would stop blood flow in the patient. Additionally, 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. The goal of this project is to create a circuit device that can perform DSD from one defibrillator monitor and adapt already existing defibrillation pads so that they can be placed on the patient without removing the LUCAS. This device will increase the feasibility of DSD and make it easy for healthcare providers to implement DSD during chaotic cardiac arrest cases.

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 LIFEPAK defibrillator monitors and the LUCAS chest compression device[2][3].
- The final prototype must have a similar user interface, operation options, and command buttons to current designs on the market to ensure 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 J of shock and sequentially deliver another 180 J worth of shock through a separate vector within 0.5-2.0 sec [4]. This must be repeatable for up to 200 shocks per battery [5]. The product must also be able perform standard single defibrillation, meaning the DSD capabilities of the device must be able to be turned on and off. 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: Existing defibrillator monitors must deliver energy with 96% accuracy, so the proposed device must match this reliability level as well [7][28]. The timing between the shocks must also be accurate to 99%, meaning that the shocks must be delivered within 0.5-2.0 seconds 99% of the time. 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 its life in service, the product has the potential to be used in 1 of every 200,000 cardiac arrest eventes, 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 will 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: One of the two main goals of the product is to make it easier for the healthcare provider to place the defibrillation pads on the patient without removing the LUCAS device. 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 ages 8 years old and up or 25 kg pounds and heavier [14]. The product will have two separate designs: 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 circuit element will be contained in a plastic box that is 12 x 12 x 6 cm. The length of the cords connecting the pads to the circuit box will be 120 cm. The measurements of the plastic box and cords are subject to change as the project is developed further. Both the pads and circuit box must be handheld, so this is the driving factor behind their proposed dimensions.

i. Weight: The circuit device should be less than 3 kg so it is light enough to transport around the field and hospital without great difficulty. The pads will be 0.5 kg in weight so that they do 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, a capacitor (50 uF), a battery, a resistor (750 ohm), a transistor, a latch, and an Arduino. The proposed values of the capacitor and resistor are estimated based on impedance of the heart [16]. All circuit element values are subject to change as the project progresses. The circuit component will be contained in a plastic box. The pads will consist of Zoll defibrillator pads which will be adapted so two sets of pads can be placed on a patient without removing the LUCAS. The pads must not touch, so a foam insulating material will be used to separate connected pads. The design will be compatible with 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. The goal is to create the pads at a similar price to pads that are on the market currently. Defibrillation pads range in price from $60 to $190 [17].

3. Miscellaneous

a. Standards and Specifications:
   i. IEC 60601-1-2:2014: Collateral Standard: Electromagnetic disturbances [18]
      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 [19]
      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 [20]
      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 [21]
    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 [22]
    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 [23].

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 [24]. The total shock that the pads deliver will be under 720 J to remain in a shock range that research has shown safe [25]. Another patient concern could be burns or allergic reactions. The most common complication of defibrillation is burns at the site of the pads [26]. 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 [27]
        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 [28]

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 [29]

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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8.2 Expense Spreadsheet

Item	Description	Manuf acturer	Part Number	#	Cost of Each	Total	Link
LIFEPAK Pads	Defibrillator Pads	Stryker -Physio	11996-00 0017	3	62.48	187.44	https://www.grainger.com/product/454L63?gucid=N:N:PS:Paid:GGL:CSM-2295:4P7A1P:20501231&gclid=CjwKCAjwyY6pBhA9EiwAMzmfwe6T-Q54rhCe8M9RccHpmirG-EX8fEPYpZpH1e5FFZnNtM2Drf116BoC5jIQAvD_BwE&gclsrc=aw.ds
Project Box	Waterproof box to house electrical components	Otdor- atio	B08N6P- 4HPH	1	9.99	9.99	https://www.amazon.com/dp/B08N6P4HPH/ref=twister_B08N1DYTKP?

							_encoding=UTF8&th=1
PCB	Circuit board	OSH Park	-	1	Price will be determined after circuit board layout is finalized	-	https://docs.oshpark.com/services/
Other Electrical Compone-nts	Will be described in greater detail after circuit is modelled with software and necessary components are identified.	-	-	-	-	-	-