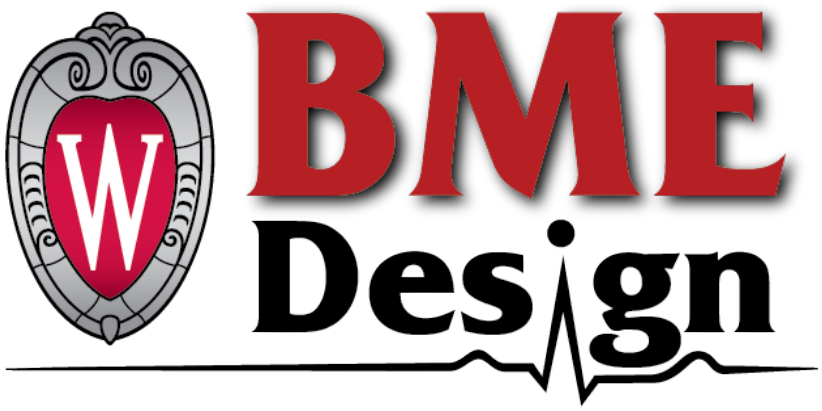

Specialized Pads for Dual Sequential Defibrillation

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BME 200/300 Design Project

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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 200 joules of shock and sequentially deliver another 200 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 198J and 202J when the setting is at 200J. 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, a capacitor, a battery, a resistor, a transistor, a latch, and an Arduino. The pads will consist of Zoll's defibrillation pads [3]. The design will be compatible with the two most popular cardiac machines, Zoll's X-Series Cardiac Monitor and 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 [15].

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

References

[1] “Advanced cardiovascular life support (ACLS),” cpr.heart.org, https://cpr.heart.org/en/cpr-courses-and-kits/healthcare-professional/acls (accessed Sep. 17, 2023).

[2] “Lifepak 15 V4+ monitor/defibrillator,” Stryker, https://www.stryker.com/us/en/emergency-care/products/lifepak-15.html (accessed Sep. 17, 2023).

[3] “Zoll Medical Corporation,” X Series Monitor/Defibrillator for EMS - ZOLL Medical, https://www.zoll.com/products/defibrillators/x-series-for-ems (accessed Sep. 17, 2023).

[4] Hoch DH;Batsford WP;Greenberg SM;McPherson CM;Rosenfeld LE;Marieb M;Levine JH;, “Double sequential external shocks for refractory ventricular fibrillation,” Journal of the American College of Cardiology, https://pubmed.ncbi.nlm.nih.gov/8144780/#:~:text=Double%20sequential%20shocks%20were%20delivered,with%20separate%20pairs%20of%20electrodes. (accessed Sep. 17, 2023).

[5] “AED Frequently Asked Questions,” *www.altramedical.com*. https://www.altramedical.com/aed-faq/#:~:text=Philips%20defibrillator%20batteries%20will%20give (accessed Sep. 20, 2023).

[6] V. Padmavathi, P. Kundra, P. Vishnu Prasad, and T. Siva, “Defibrillator maintenance policy,” *Indian Journal of Anaesthesia*, vol. 59, no. 10, p. 685, 2015, doi: https://doi.org/10.4103/0019-5049.167478.

[7] B. J. Cross and M. S. Link, “Erroneous shock by an AED: Importance of obtaining AED tracing to prevent inappropriate ICD implantation,” HeartRhythm case reports, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5418544/#:~:text=Although%20automated%20external%20defibrillators%20(AEDs,99%25%20but%20not%20100%25. (accessed Sep. 17, 2023).

[8] “How many times can you use a defibrillator on a person?,” Risk Assessment Products. https://risk-assessment-products.co.uk/blog/how-many-times-can-you-use-a-defibrillator-on-a-person/#:~:text=Thankfully%2C%20defibrillators%20have%20been%20designed (accessed Sep. 17, 2023).

[9] “Why do aed defibrillator pads expire?,” AED Brands, https://www.aedbrands.com/resources/maintain/why-do-aed-pads-expire/ (accessed Sep. 17, 2023).

[10] AED.com, “Do AED Batteries and Pads Expire?,” *AED.com*. https://www.aed.com/blog/do-aed-batteries-and-pads-expire/ (accessed Sep. 20, 2023).

[11] “Automated external defibrillator (AED): Environmental Health & Safety: University of Missouri,” Automated External Defibrillator (AED) | Environmental Health & Safety | University of Missouri, https://ehs.missouri.edu/work/aed (accessed Sep. 17, 2023).

[12] “Weather conditions and your AED,” *AED Superstore Blog*, Jul. 13, 2017. https://www.aedsuperstore.com/blogs/weather-conditions-aed/#:~:text=The%20majority%20of%20AED%20manufacturers (accessed Sep. 20, 2023).

[13] “Resuscitation,” Resuscitation | European Resuscitation Council Guidelines for Resuscitation 2021 | ScienceDirect.com by Elsevier, https://www.sciencedirect.com/journal/resuscitation/vol/161/suppl/C (accessed Sep. 9, 2023).

[14] “How to use an AED,” HealthyChildren.org, https://www.healthychildren.org/English/health-issues/injuries-emergencies/Pages/Using-an-AED.aspx#:~:text=While%20all%20AEDS%20are%20made,children%208%20years%20and%20older. (accessed Sep. 17, 2023).

[15] “Zoll Aed plus replacement pads,” AEDs, AED Pads, and AED Batteries by AEDLand, https://aedland.com/product-category/aed-supplies/zoll-aed-plus-pads/?orderby=price (accessed Sep. 17, 2023).

[16] Edition 4.0 2014-02 international standard norme internationale - IEC, https://webstore.iec.ch/preview/info_iec60601-1-2%7Bed4.0%7Db.pdf (accessed Sep. 17, 2023).

[17] “Advanced cardiovascular life support (ACLS),” cpr.heart.org, https://cpr.heart.org/en/cpr-courses-and-kits/healthcare-professional/acls (accessed Sep. 17, 2023).

[18] Edition 4.0 2014-02 international standard norme internationale - IEC, https://webstore.iec.ch/preview/info_iec60601-1-2%7Bed4.0%7Db.pdf (accessed Sep. 17, 2023).

[19] “ISO 80601-2-61:2011,” ISO, https://www.iso.org/standard/51847.html (accessed Sep. 18, 2023).

[20] “IEC,” IEC 60068-2-27:2008 | IEC Webstore | rural electrification, https://webstore.iec.ch/publication/514 (accessed Sep. 18, 2023).

[21] A. C. Emmerson, M. Whitbread, and R. T. Fothergill, “Double sequential defibrillation therapy for out-of-hospital cardiac arrests: The London experience,” Resuscitation, vol. 117, pp. 97–101, 2017. doi:10.1016/j.resuscitation.2017.06.011

[22] A. Goyal, L. Chhabra, J. C. Sciammarella, and J. S. Cooper, “Defibrillation,” National Library of Medicine, https://www.ncbi.nlm.nih.gov/books/NBK499899/ (accessed Sep. 17, 2023).

[23] M. Ramzy and P. G. Hughes, “Double defibrillation,” National Library of Medicine, https://www.ncbi.nlm.nih.gov/books/NBK544231/ (accessed Sep. 13, 2023).

[24] R. Maraj et al., “Iatrogenic cardiovascular complications: Part I. semi-noninvasive procedures and diagnostic invasive procedures,” Journal of Interventional Cardiology, vol. 12, no. 2, pp. 145–162, 1999. doi:10.1111/j.1540-8183.1999.tb00224.x

[25] “Zoll Medical Corporation,” ECG Electrodes for AEDs & Defibrillators - ZOLL Medical, https://www.zoll.com/medical-products/defibrillator-electrodes/cpr-stat-padz (accessed Sep. 17, 2023).

[26] “Stryker Physio control quick combo pads with Redi-Pak for Lifepak defibrillators and aeds,” Avobus Medical Equipment, https://avobus.com/product/physio-control-quik-combo-defibrillator-electrodes (accessed Sep. 17, 2023).

[27] “Zoll Medical Corporation,” Electrodes for AEDs - ZOLL Medical, https://www.zoll.com/medical-products/defibrillator-electrodes/cpr-d-padz-aed (accessed Sep. 17, 2023).

[28] A. Badnjević and D. Vuković, “Chapter 109 - Improving the accuracy and efficiency of medical devices in the legal metrology system of Bosnia and Herzegovina,” ScienceDirect, Jan. 01, 2020. https://www.sciencedirect.com/science/article/pii/B9780128134672001103#:~:text=The%20percentage%20of%20accurate%20devices%20varies%20between%2080.3%25%20in%20neonatal (accessed Sep. 21, 2023).