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A method to synchronize an implantable Cardiac Compression Device with the heart

THESIS

submitted in partial satisfaction of the requirements
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MASTER OF SCIENCE

in Biomedical Engineering

by

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Professor Joshua Mauney
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DEDICATION

To

my family and friends

in recognition of their love, support, and worth

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ABSTRACT OF THE THESIS

A method to synchronize an implantable Cardiac Compression Device with the heart

By

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Master of Science in Biomedical Engineering

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Associate Professor Christine King, Chair

Cardiovascular diseases are among the world's leading causes of death. Therefore, it is important to define advanced heart failure using signs and symptoms, hemodynamics, exercise testing, biomarkers, and risk prediction models. However, most medical and device therapies fail to define stage-D heart failure. Therefore, there is a need to develop a method to synchronize Cardiac Compression Devices with the heart of those patients who suffer from Stage-D heart failure. Previous cardiac compression devices do not synchronize with cardiac contraction mechanics and their natural direction, and some cannot help with the diastolic phase of the cardiac cycle. Therefore, the devices were not synchronized with a pacemaker to compress the heart when the heart paces irregularly and slowly. The method discussed in this paper uses a synchronized rotation mechanism of a servo motor via a pacemaker to compress the heart. The servo motor is synchronized with the

pacemaker to help with this process and follows the heart's movement. For the purpose of this project, the servo motor was used to rotate clockwise and counter-clockwise at a set angle continuously to help compress the heart. A potentiometer was used to set the Pulse Width Modulation (PWM) to control the angular speed of the motor; in this case, the motor has the ability to rotate at different angular speeds to help compress the heart as needed based on the patient's heart conditions. This method aims to improve the quality of life and extend the life expectancy of patients with Stage-D heart failure since they do not currently have any other options than palliative care to alleviate their congestive heart failure symptoms. To improve the system in the future, the system should be built with higher quality motors, reducing the possibility of collecting noise. All systems including the required sensing of pacemaker and motor wiring should be checked for loose connections as any human error could cause a shift in the results. This biological system will have to undergo in vivo and vitro testing prior to clinical trials such as large animal testing such as pigs, sheep, and dogs to provide with safety information and activity of cellular products. For vitro testing, ideally, the hyperpolarization-activated cyclic nucleotide gene family is suited to function as a pacemaker when overexpressed. Finally, the synchronized system that compresses the heart can be used to help patients with stage-D heart failure by improving their cardiac output with no need for donors and open-heart surgery which is not safe due to their health conditions.

CHAPTER 1: Background and Significance

1.1 Stage D Heart failure

Cardiovascular diseases are one of the world's leading causes of death [1, 2, 3]. The United States experiences over 800,000 deaths per year due to cardiovascular disease conditions [1, 4]. There are many types of cardiovascular diseases, including arrhythmia, cardiomyopathy, valvular heart disease, and congestive heart failure (CHF) [5, 6]. Some of the common causes of these diseases are atherosclerosis, high blood pressure, smoking, and diabetes [1, 7].

Heart failure affects 5.7 million and is the most common cause of hospitalization for US citizens over the age of 65 years old [8, 9, 10]. The disease costs the country over $30 billion annually [8, 11]. Among heart failure patients, approximately 3-3.5 million people develop systolic heart failure annually [12]. Within systolic heart failure patients, 150,000-250,000 developed advanced heart failure with NYHA class IV symptoms that reach stage-D heart failure [12].

The presence of progressive and/or persistent severe signs and symptoms of heart failure despite optimized medical, surgical, and device therapy is called stage-D heart failure [12]. It is important to note that the progressive decline is primarily driven by heart failure syndrome [12]. It is also important to define advanced heart failure using signs, symptoms, hemodynamics, exercise testing, biomarkers, and risk prediction models. However, it is challenging when medical and device therapies fail to define stage-D heart

failure [12]. Since treatments are inherently limited, morbidity is typically progressive, and survival is often short; thus, identifying patients with stage-D heart failure is a clinically important task [12, 13, 14].

Different factors such as age, frailty, and psychosocial issues affect both outcomes and the selection of therapy for stage-D patients [12, 15, 16]. Potential treatment options in selected patients are heart transplants and mechanical circulatory support devices [12, 13, 14]. Additionally, when considering indications, contraindications, clinical status, and psychiatric co-morbidities, treatment selection for stage-D patients involve incorporating the patient's wishes for survival versus quality of life, while integrating palliative and hospice care into care plans [12, 17].

The current treatment for stage-D heart failure includes heart transplants and open-heart surgery; however, not all individuals have access to these treatments [18, 19]. Due to psychiatric co-morbidities and limited donors, most of these patients are not eligible to receive a heart transplant. For transplantation of a ventricular assist device (VAD) (Figure 1), patients must undergo an open-heart surgery [13, 14, 20]. Stage-D by definition has a poor health condition to undergo major surgery to receive a VAD or does not have access to current VADs alternatives due to existing limitations [21, 22, 23]. One limitation includes patient health issues such as psychiatric co-morbidities, and another is the unattainability of these devices [24, 25]. Other limitations include the side effects of transplanting the VADs into the body of ill patients which causes bleeding, infection, and blood clots [26]. Transplantation of VAD needs a continuous infusion of intravenous inotropic drugs [26, 27]. Therefore, having a system that improves the cardiac output can help stage- D heart

failure patients with no need for donors and open-heart surgery which is not safe due to their health conditions.

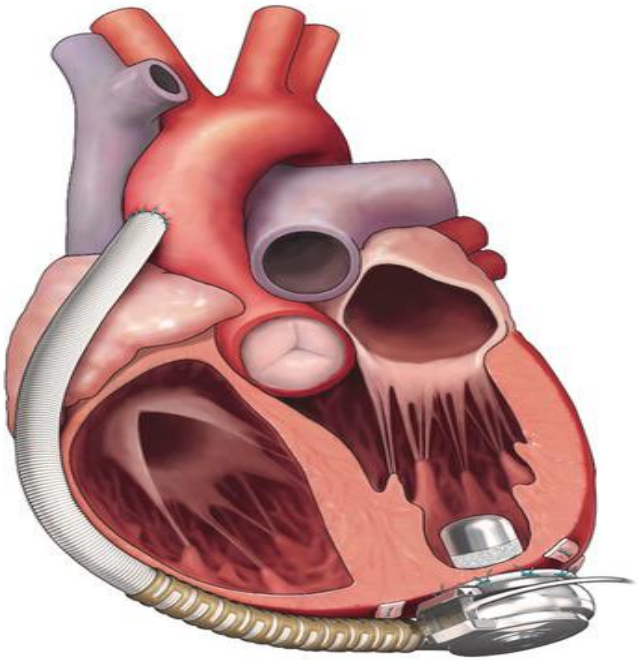

Figure 1: Transplanted magnetically levitated rotor VAD allows for the total elimination of bearings [20].

Transplantation of ventricular assist devices shown in figure 1 is a fully magnetically levitated rotor that allows for the total elimination of bearings and the subparts that are shown in Figure 2 [28, 29, 30]. This design improves the outcomes by refinements in patient selection and timing of VAD implant to reduce adverse events [31, 32, 33]. These improvements have led to expansion into all age groups and now many VADs are inserted as elective surgery [31, 32]. In addition, since this device is small and flat, and could be implanted within the pericardium, it eliminates the associated infection risk. However, existing limitations include patients' age, psychiatric comorbidities, and social and financial

constraints [28, 29, 30, 34]. The flat design of this system allows implantation on the diaphragmatic surface of the heart for both right-sided and left-sided long-term support.

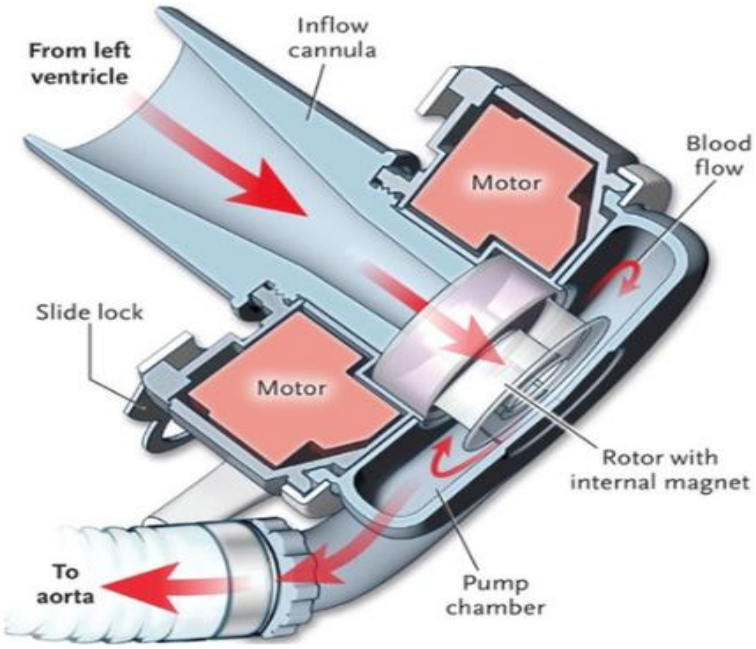

Figure 2: Transplanted magnetically levitated rotor VAD subparts include motor, rotor with internal magnet, inflow cannula, and pump chamber [20].

Among individuals who reach stage-D heart failure, approximately 2,500 patients receive a heart transplant, and another 2,500 who can tolerate major open-heart surgery will receive a VAD [14]. Therefore, most patients with Stage-D heart failure do not currently have any treatment options available for them to cure CHF symptoms.

1.2 Cardiac compression devices

Many cardiac compression devices do not synchronize with cardiac contraction mechanics and their natural direction, and others cannot help with the diastolic phase of the cardiac cycle [35]. For instance, one study discussed the interest of form-fitting, low-modulus, and implantable devices to assist the contraction of heart muscle [35, 36, 37, 38]. This device actively compresses and twists to act as a cardiac ventricular assist device and it is implanted around the heart [35, 36, 37]. It mimics the orientation of the outer two muscle layers of the mammalian heart. The sleeve can be customized to patient-specific needs and may be used as a transplant for patients with heart failure [35, 37, 38].

For clinical use in the future, the above design reduces the risk of complications from clotting, simplifies treatment, and reduces costs for anticoagulation therapy among patients receiving mechanical circulatory support [35, 37, 38]. Through the specific arrangement of the contractile elements and selective actuation, it achieved desired independent or simultaneous compression and twisting [35]. By applying pressure to pneumatic artificial muscles, it contracts, and by applying vacuum, it extends. The device could potentially be turned off when no longer required [35]. The study used a combination of mechanical, chemical, and suction strategies for acute device attachment [35, 38]. However, these approaches are not adequate for long-term implantation [35, 36, 38]. Although the improvements in design implemented with each generation of VADs have helped to decrease prothrombotic components, contact between blood and artificial surfaces remains; this issue makes it necessary for long-term blood-thinning medications for patients with VADs [35, 36, 37, 38]. Despite anticoagulation treatment, there still is a

20% risk of thromboembolic events such as stroke among patients who receive a VAD [35].

Furthermore, the heart's muscle layers are arranged in helical and circumferential patterns and simultaneously undergo twisting and compressive motions to help compress the heart [35, 39, 40]. The device was inspired by the architecture of the heart, which comprises a fully conformable sleeve with two biomimetic layers of contractile elements embedded in an elastomeric matrix with mechanical properties similar to those of cardiac tissue [35, 41, 42].

A different study by Markus A Horvath describes an assist device for efficient coupling of a cardiac compression sleeve to the external surface of the heart and various fixation strategies [43, 44, 45]. To this end, a cardiac compression sleeve for the heart is crucial for cardiac function. A suture and Velcro band combination adhered the strongest to epicardium for basal fixation [43].

A mesh-based sleeve coupled to the myocardium improves the function of augmenting cardiac output in acutely failing porcine hearts [35, 43, 44]. Therefore, further augmentation of cardiac output was possible with the coupling of the sleeve to the myocardium with adhesive, compared to when the sleeve is deliberately decoupled from the moving heart muscle using a gel liner [43, 44, 45]. The results of this study also suggest that exploiting the host response of an epicardially placed soft robotic sleeve could be advantageous in terms of mechanically coupling with the myocardium. The mesh will potentially integrate selectively with the diseased tissue and not the surrounding healthy tissue [43, 44, 45]. However, the device is implanted and is not synchronized with the

cardiac contraction mechanics of the heart. The other major limitation is a high mortality rate likely because the implanted patches imposed a significant load on the infarcted region of the murine heart leading to ventricular rupture [43, 46, 47].

Although the improvements in design implemented with each generation of VADs that were described above have helped to decrease prothrombotic components, contact issues between blood and the artificial surface remain problematic, as it makes it necessary for the use of long-term blood-thinning medications in these patients [35]. As outlined by the above studies [35, 43], the normal curvature of the heart is inverted by most of the external devices and acts as opposed to the remaining cardiac contraction mechanics; this results in predisposing these devices to reduced biomimicry and efficiency, another disadvantage of current VAD technologies. Therefore, many of these devices do not synchronize with cardiac contraction mechanics and their natural direction, and some cannot help with the diastolic phase of the cardiac cycle [35, 43]. As a result, patients with Stage-D heart failure do not currently have any other options than palliative care to alleviate their CHF symptoms.

1.3 Cardiac Pacing

The application of an artificial electrical stimulus to the heart in the hope of producing depolarization of cardiac cells is defined as cardiac pacing [48]. The Medtronic 5388 dual chamber temporary pacemaker (Medtronic, Dublin, Ireland) is used in conjunction with a cardiac pacing lead system for temporary single or dual-chamber pacing in clinical studies and procedures (Figure 3). The connecting cable is shown in Figure 4

which helps the pacemaker signal the heart to beat when the heart beats irregularly [48]. Post cardiac surgery, epicardial pacing via epicardial pacing wires are inserted into the endocardium and placed in the myocardium, which is located around the surface of the myocardium [49, 50]. The epicardial wires are positioned on the anterior cardiac surface [49]. The atrial leads are normally inserted on the right atrial appendage, and the right ventricular leads are inserted on the diaphragmatic surface of the right ventricle [49, 51]. The right atrial appendage is located in the anterior and medial of the right atrium, overlapping the root of the aorta [52]. The inferior or diaphragmatic surface of the heart forms a roughly straight plane or slight concavity that projects to the left and slightly inferiorly to the apex of the heart and senses the patient's intrinsic heart rate [49, 52]. Therefore, when the patient's intrinsic heart rate goes below the pacer rate of the pacemaker then ventricular pacing occurs which helps the patient's heart rate reach to normal pacing rate [49, 52, 53].

Figure 3: Medtronic 5388 dual chamber temporary pacemaker is to capture and pace heart rate [48].

Epicardial pacing has advantages and disadvantages, including endovascularly implanted leads to a risk of vascular injury and endocarditis. However, it can be difficult to locate in desired positions for LV pacing [50, 51]. The advantage of surgical epicardial LV lead positioning is that direct visualization helps to select the most suitable surface and avoid epicardial fat or fibrosis areas, which can cause changes in pacing thresholds [50]. However, concern for systemic infections and vascular injury have prompted the evolution of subcutaneous and epicardial systems [50, 51]. Lead failure includes the risk of surgical interventions because of a fracture, an insulation break, outgrowth, or an exit block [50].

Figure 4: Pacemaker connecting cable is to capture and pace heart rate [48].

Temporary epicardial pacing has other advantages as well. For instance, temporary epicardial pacing provides a mechanical advantage by preserving the physiological relationship of atrial to ventricular contraction [51, 52]. This, however, is at risk of asynchronous atrial pacing in which a pacing spike might be delivered during the repolarization phase of an endogenous beat, which may precipitate atrial fibrillation [52].

1.3.1 Ventricular pacing

Sensing and capture settings of Ventricular pacing are the main characteristics of pacemaker communication with cardiac compression devices and the heart when the heart paces irregularly and slowly, as explained in Table 1. The ventricular sensing setting of the pacemaker generator is used to see if the heart has an intrinsic rhythm [53]. The purpose of the sensing setting is to make sure the rate on the pacemaker is lower than the patient's intrinsic rate to prevent pacing by ensuring there is an atrial output of zero and a significantly low ventricular output [53, 54]. The sensitivity of the sensing setting should be low so as to not miss any ECG complexes, and the atrial output rate should equal to the patient's heart rate; therefore, it will generate a high sensitivity threshold until no QRS is detected, and then reduce ventricular sensitivity to half or the third of the previous sensitivity which then detects the QRS complex [54].

Pacemaker generators send out electrical currents that stimulate the heart to beat; therefore, the pacemaker is set to pace at least 20% above the patient's intrinsic heart rate [53, 54]. To ensure that reliable pacing occurs, pacemaker settings slowly increase the ventricular output current until continuous capture spikes, and the QRS complex is generated. The point at which this complex occurs is known as the "capture threshold" [53, 54]. Immediately after the pacemaker is on, the rate is still below the patient's intrinsic rate, which is known as the "backup rate" [53]. A backup rate is when the patient's intrinsic heart rate is below the sensing threshold and the voltage is set to maximum to cause pacing. The pacemaker "Lock" could be used to set the rate of atrial and ventricular output so it cannot be changed [54].

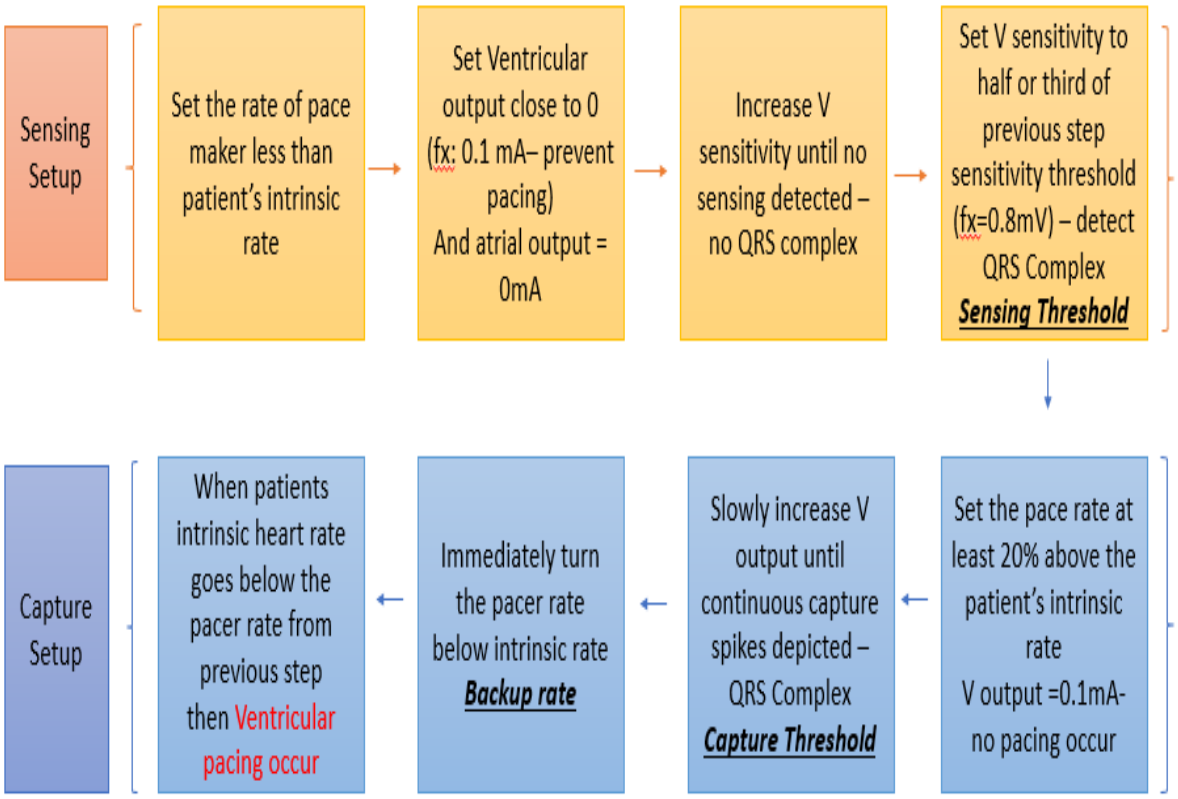

Table 1: Ventricular pacing - Sensing and Capture settings [53, 54]

1.3.2 Bipolar pacing

The alternative bipolar system involves a single wire with two conductors insulated from one another, which both run to the epicardial surface [55]. In bipolar pacing, pacing occurs when voltage differences are captured [55]. The negative anode is typically the more distal electrode. Therefore, the smaller current path of bipolar electrodes makes them less sensitive to electrical interference when performing the sensing function [55]. As shown in Figure 5, the curved myocardial needle is slimmer and has been reduced from 0.66 mm to 0.61 mm to minimize tissue perforation [56, 57]. Two discrete electrodes are

used for consistent pacing and sensing connecting via a single conduit, a selected subset of a plurality of individual electrodes; at least one electrode suitable for the pacing of a cardiac atrium and at least one electrode suitable for the pacing of the cardiac ventricle is needed for a pacemaker located outside the heart to initiate cardiac capture and pacing of multiple chambers of the heart [55, 56, 57].

A bipolar mode of electrode activation is used in which each individual lead is equipped with a second ring electrode (usually serving in an anode capacity) which may be spaced apart from the negative (cathode) electrode (Figure 5) [56, 57]. The ring electrode may or may not be in touch with the cardiac tissue, but still supports the activation of the central electrode via conduction through blood [57]. As previously mentioned, two discrete electrodes are used for consistent pacing and sensing [55, 56]. As bipolar electrodes require less energy, to begin with, they may have greater longevity in pacing compared to a unipolar system [55, 56].

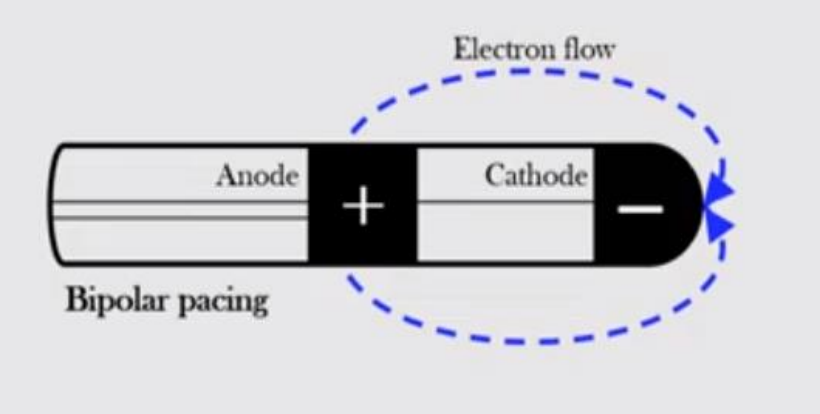

Figure 5: Bipolar pacing lead setup is used in which each individual lead is equipped with a second ring electrode to pace the heart [55].

Medtronic Model 6495 Bipolar Temporary Myocardial Pacing Lead (Medtronic, Dublin, Ireland) shown in Figure 6 contains a distal, discrete, ring electrode, discrete, tip electrode, and coaxial conductor lead body [56, 57]. Each discrete electrode is crimped onto a conductor and terminates in an atraumatic myocardial curved needle [57]. The curved needle creates a channel in the myocardium for embedding the electrodes [57]. A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue [57]. An atraumatic chest needle at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall [56, 57]. Terminated on the back of the chest needle are two breakaway connector pins, which provide an attachment to an external pulse generator [56, 57]. All parts of the Medtronic Model 6495 Bipolar Temporary Myocardial Pacing Lead are removed from the body by end of surgery [56, 57].

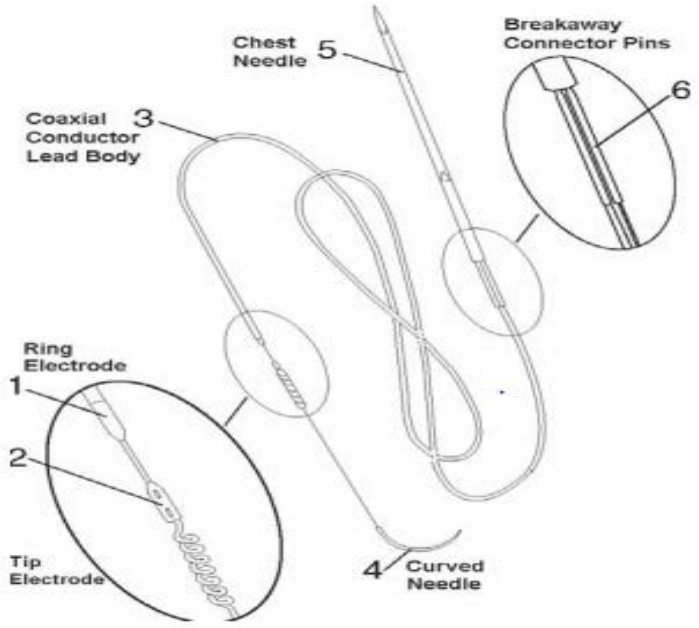

Figure 6: Medtronic Model 6495 Bipolar Temporary Myocardial Pacing lead contains a distal, discrete, ring electrode, discrete, tip electrode, and coaxial conductor lead body [56, 57].

As shown in Figure 6, at least one electrode is suitable for the pacing of a cardiac atrium, and at least one electrode is ideal for the pacing of the cardiac ventricle to a pacemaker located outside the heart [55, 57]. To initiate cardiac capture and pacing of multiple chambers of the heart, selected subsets of individual electrodes are used [57]. Dual chamber, the atrial and ventricular pacing, are both needed to sense the intrinsic heart rate to prevent atrial fibrillation and as a result, pacing the ventricle helps assist the heart to reach the normal heart rate in patients with heart failure [53, 55, 57].

CHAPTER 2: Synchronization of Cardiac Compression Device with Pacemaker

2.1 Methods and Strategies

Numerous studies and articles have brought up and discussed the different types of cardiac compression devices in use. Previous cardiac compression devices do not synchronize with cardiac contraction mechanics and their natural direction, and some cannot help with the diastolic phase of the cardiac cycle [35, 43]. Therefore, the devices were not synchronized with a pacemaker to compress the heart when the heart paces irregularly and slowly. As a result, there is a need to synchronize cardiac compression devices with the heart. One method to do this is that the heart rhythm is captured and sensed using a pacemaker and it is used to synchronize with cardiac compression devices for heart behavior purposes.

This project aims to develop a method to synchronize the assist function of an externally wrapped implantable Cardiac Compression Device (CCD) with the heart. Synchronization of the CCD - a group of whole heart assist devices that improve the quality of life of patients with Stage-D heart failure - is vital to their assist function. Proper synchronization ensures that the device assists in cardiac function (both systole and diastole) at proper timing.

2.1.1 Force, Torque, and Power Estimations

This research method includes using epicardial atrial leads that receive electrical signals from the atria, an external pacemaker that receives the atrial signals, and outputs signals to control the CCD in addition to a custom-designed circuit board that controls the CCD's magnitude of contraction and twists angle. The method used in this study uses a custom Arduino program and circuit system to communicate with a pacemaker and servo motor to synchronize the pacemaker and servo motor to control the servo motor so that it can compress and twist the heart with the same frequency captured from the pacemaker. Therefore, there is a need to calculate the required torque and force to compress the heart using a servo motor.

The heart measurements are needed to calculate the required torque and angle of twist. The load and power requirement of the pump at a given rpm is defined by the fluid motor torque [58]. Torque (τ) is defined as the product of force (F) and radius (R) of LV (Equation 2) [58]. To calculate the force fluid pressure (P) and area (A) of LV needed (Equation 1) [58]. Therefore, all the measurements are used to calculate the force and torque respectively to compress the LV of the heart. Equation 1 represents the fluid pressure passing through the LV. Equation 2 represents the torque required to compress the left ventricle. Finally, in Equation 3, the division of power (P) by torque (τ) calculates the angular speed (ω) needed to compress the left ventricle in the unit of rpm.

$$F = P \times A \quad \text{Eqn 1}$$

$$\tau = F \times R \quad \text{Eqn 2}$$

$$P = \tau \times \omega \quad \text{Eqn 3}$$

Taken from Mohammadi et. al 2016, the following measurement values were used to estimate the torque, force, and power (Equation 1-3): 9 cm for the mean circumference of the mitral valve in males and 7.2 cm in females, 10.8 cm for the tricuspid valve in females and 11.4 cm in males [59]. The length of the heart is from the base to the apex using a vernier caliper [59]. The greatest distance between the anterior and posterior surfaces of the heart was considered to be its thickness [59], which is shown in Figure 7. The circumference and area of tricuspid and mitral valves were measured using ImageJ software [58]. Therefore, as measured by Mohammadi et. al 2016, the heart length, width, and thickness are 12 cm, 8.5 cm, and 6 cm, respectively [59].

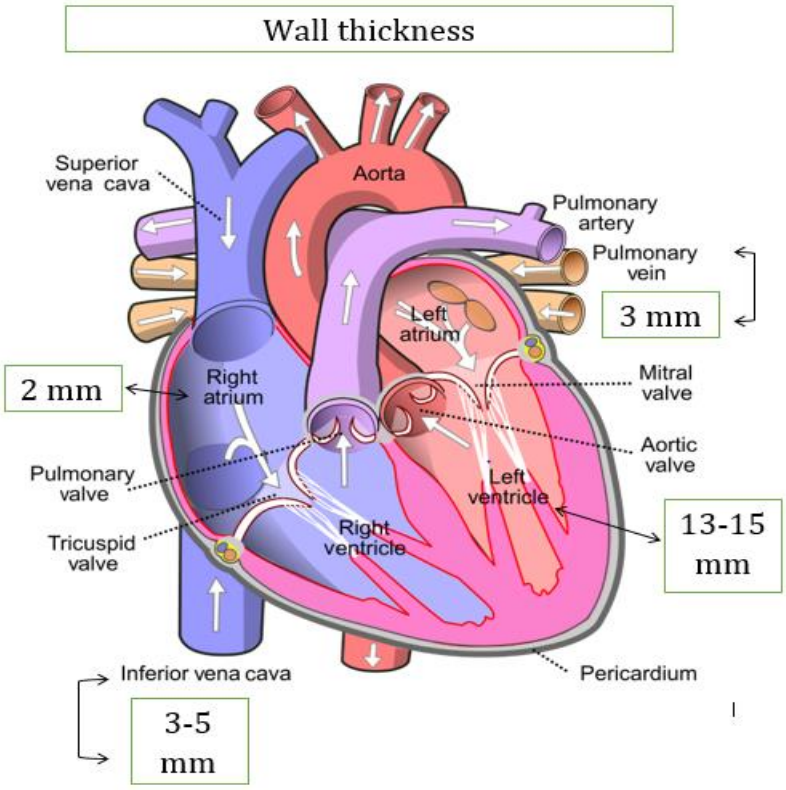

Figure 7: Heart measurements in normal stage of wall thickness include 2 mm for right atrium, 3 mm for pulmonary vein, 13-15 mm for left ventricle, and 3-5 mm for inferior vena cava [59].

The coronary sinus represents a prominent landmark in the right atrium. The anteromedial margin of the orifice of the coronary sinus defines the base [59]. Left ventricle (LV) twist was defined as the net difference in the rotation angles between apex and base along LV longitudinal axis; whereas, LV torsion is LV twist normalized to the distance between LV apex and LV base (LV length) expressed in degrees per centimeter [60]. The measurements are all presented in Table 2.

Variable	Men	Women	P-value
LV Twist (degree)	16.78 ± 1.83	20.95± 2.09	0.002
LV Torsion (degree)	5.49 ± 1.23	7.12± 1.38	0.000

Table 2: LV twist and torsion degree in Men and Women [60]

The left ventricle is thicker and more muscular than the right ventricle because it pumps blood at a higher pressure. Taken from Clay et. al 2006, the normal ranges for LV end-diastolic volume measurements after adjustment to body surface area (BSA) were 58-103 ml for females and 62-120 ml for males [61]. Therefore, the normal range for LV end-diastolic volume is between 58 to 120 ml [61]. An estimated stroke volume of 80, 90, and 30 ml for the normal, exercise, and CHF conditions, respectively are also recorded [61].

The mean LV end-diastolic pressure (LVEDP) for normal conditions is 23±9 mm Hg and patients with an LVEDP >30 mm Hg have the highest risk of death [62]. The average range of LV lateral length in patients is 39 mm to 69 mm, and the average range of LV internal diameter (LVIDD) is 39.1 mm to 67.6 mm presented by Narayanan et. al 2014 [63]. A left ventricle can be considered to have an intrinsic limited possible range of end-

diastolic volumes, with the lower end of the range at an LVEDP of 0 mmHg and the upper end of the normal range at an LVEDP of ~ 25 mmHg [62, 65].

To calculate the required force range, the area is calculated using the LV end-diastolic volume which is between 58 to 120 ml, and the LV lateral length of patients which is between 39 mm to 69 mm. The area range was found to be 0.0031 m^2 and 0.00084 m^2. Using equation 1, the required force range is 1.57 N to 13.23 N. Finally, the required torque range is measured using Equation 2. The average range of LV internal diameter (LVIDD) which is 39.1 mm to 67.6 mm is multiplied by calculated force and it results in 0.031 N.m - 0.4472 N.m. torque range.

The power of a healthy and normal heart is approximately 1.3 - 5 W depending on the patient's weight, height, gender, and activity [66]. Therefore, using equation 3, a maximum of 106 rpm is needed to compress the heart LV. Since under normal conditions, the heart beats 75 to 80 times per minute [66], the rpm of 80 is used to compress the heart in this research paper.

For this research purpose, a Servo Motor MG995 is used [67]. This motor has the ability to rotate within 270 degrees [67]. It has a power supply of 4.8 - 6 Volts with high torque and a 67 to 80 rpm range which is a well-desired motor for this project [49]. Servo motors including the Servo Motor MG995 has a built-in angle function which can show the accurate position of the motor to start and end with [67].

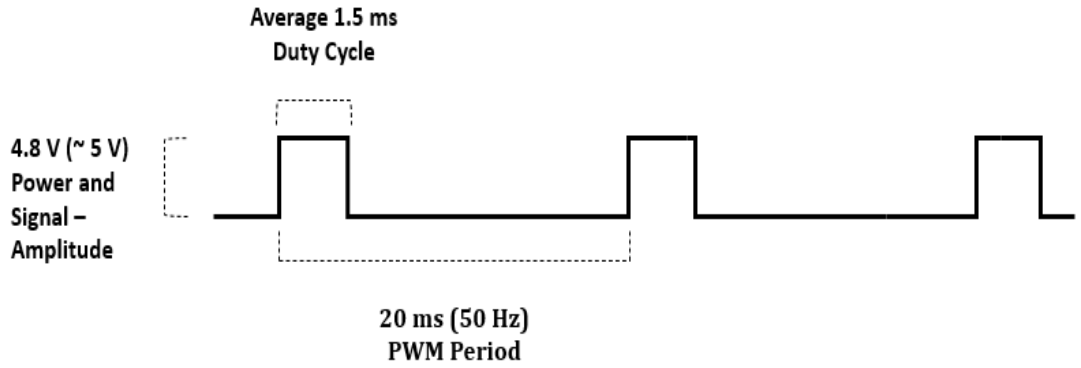

Figure 8: Servo motor setup describes the average duty cycle of 1.5 ms and pulse width modulation of 20 ms [67].

Servo motors are controlled by sending a digital electrical pulse of variable width, or pulse width modulation (PWM) [67, 68]. A servo motor system is a form of PWM in which the length of the pulses determines the angle of the servo itself. The average duty cycle for the servo motor is a 1.5 ms (millisecond) pulse, with a pulse width modulation of 20 ms (Figure 8) [67, 68].

The motor's neutral position is where the servo has the same amount of potential rotation in both the clockwise and counterclockwise directions [67, 68]. The position of the shaft is determined by the PWM sent to the motor, and also based on the duration of the pulse sent via the control wire which causes the rotor to turn to the desired position [68]. As previously mentioned, the servo motor receives a pulse every 20 milliseconds (ms), and the duration of the pulse determines how far the motor moves [67, 68]. For the purpose of this paper, an average of 1.5 ms pulse will turn the motor 90°, with a pulse width modulation of 20 ms.

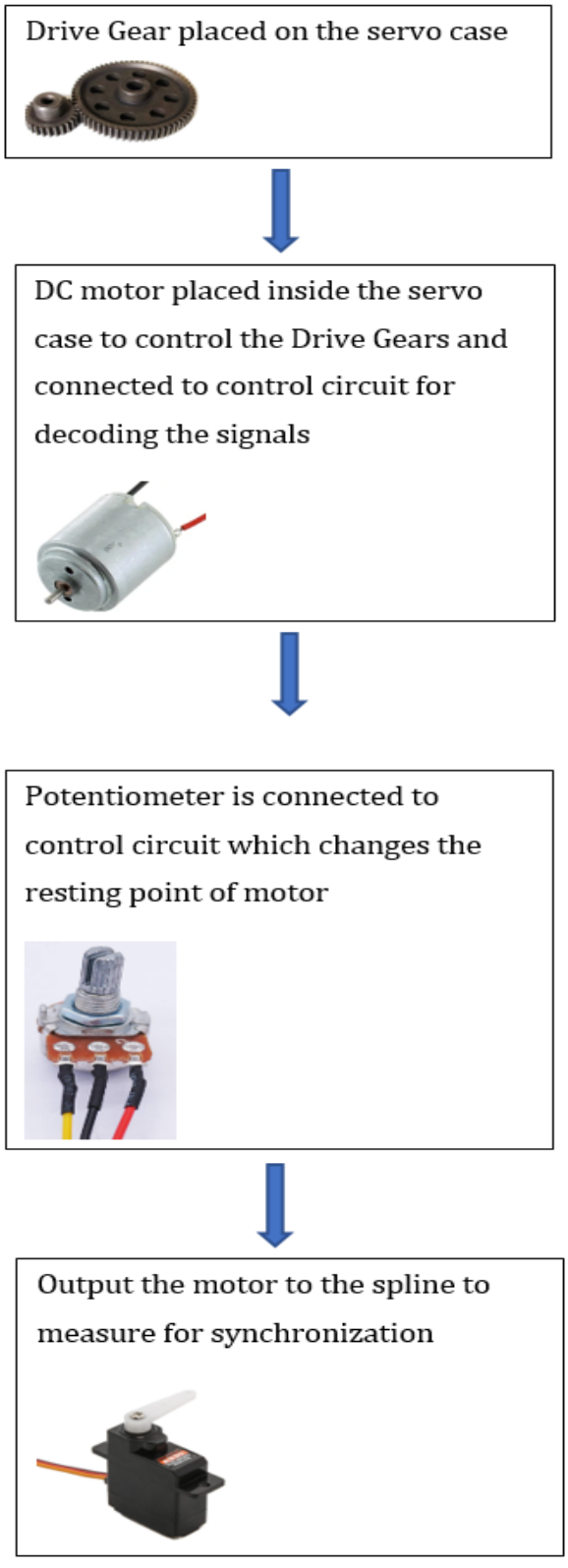

Figure 9: Flowchart describes the details of Servo motor setup.

Servo motors are built using drive gears, a control circuit, potentiometer, motor, and servo case [67, 68]. Figure 9 shows the details of the servo motor system connections and setup which are described below [67, 68]. Drive gears are all placed on the servo case and the motor controls the drive gears are placed inside the servo case [68, 69]. The PWM instructions delivered from the MCU control the resistance of the potentiometer, which controls the angular velocity of the motor [68, 70, 71]. The control circuit decodes the signals from the position sensor and then compares the actual position of the motors with the desired position [70, 71, 72]. Therefore, it controls the direction of rotation of the motor to get the required position. Finally, the servo motor outputs to the spline to measure for synchronization for the purpose of this paper. In addition, if an external force pushes against the servo while the servo is holding a position, the servo will resist moving out of that position [68]. Therefore, the torque rating of the servo is the maximum amount of force the servo can exert which is presented by Equation 2.

Servo motors have two ball bearings on the output shaft to reduce friction and make it easier to get to the potentiometer that changes the rest point [68]. For the purpose of this project, the servo motor was used to rotate clockwise and counter-clockwise at a set angle continuously. The motor rotates from zero to ninety degrees clockwise and vice versa from ninety degrees to zero counter-clockwise to help compress the heart. A potentiometer is used to set the PWM to control the angular speed of the motor; in this case, the motor has the ability to rotate at different angular speeds to help compress the heart as needed based on the patient's heart conditions. This has been done by using a hall effect sensor which captures the magnetic field generated via a pacemaker to estimate an appropriate pulse

width modulation value and therefore, to estimate the position. Based on the position, the velocity is being differentiated to determine the pulse width modulation values to help compress the heart.

The circuit outline and wiring to synchronize the motor with the pacemaker are shown in Figures 10 and 11. Pacemaker input is connected to pin 2 and servo motor input is connected to pin 9. Appendix A-F describes the code outline in detail. The magnetic field generated via a pacemaker is captured by the hall effect and is inputted to the servo motor. Therefore, the beat per minute generated by the pacemaker is captured by the servo motor and generated the same beat per minute to compress the heart as needed. If the pacemaker generates 80 beats per minute, the servo motor also captures and generates 80 beats per minute at the same time. Therefore, the cycles of the servo motor of 80 rpm compress the heart as needed at the same frequency.

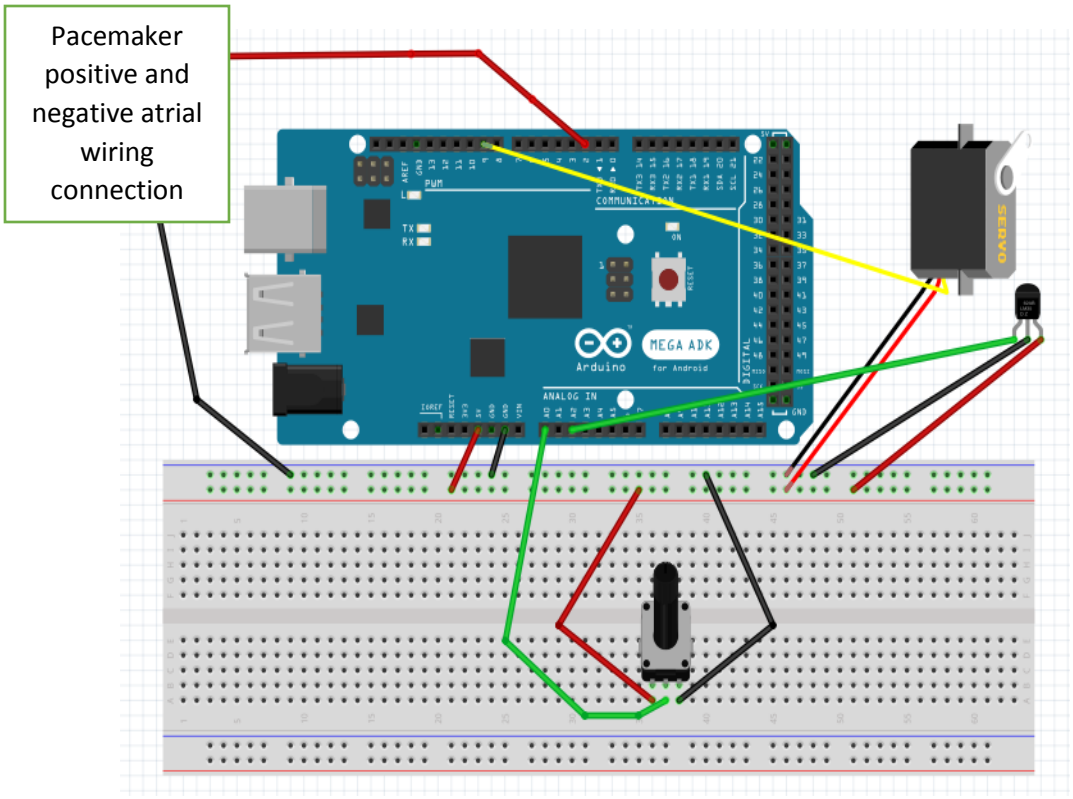

Figure 10: Servo motor, hall effect sensor, and potentiometer is used for the circuit and breadboard wiring (made using Fritzing (Fritzing, Berlin, Germany) of the synchronized system.

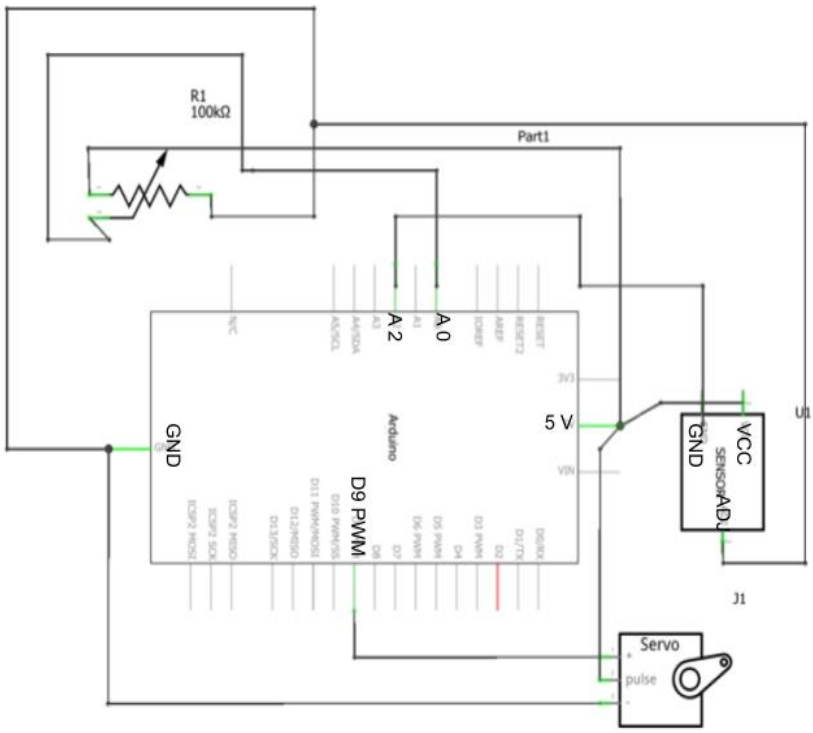

Figure 11: Servo motor, hall effect sensor, and potentiometer is used for the circuit diagram of the synchronized system.

Finally, the LCD screen pin is described as follows and is discussed in Appendix D which counts the motor's cycles: CD RS pin to digital pin 12, LCD Enable pin to digital pin 11, LCD D4 pin to digital pin 6, LCD D5 pin to digital pin 5, LCD D6 pin to digital pin 4, LCD D7 pin to digital pin 3, LCD R/W pin to GND, LCD VSS pin to GND, LCD VCC pin to 5V, LCD LED+ to 5V through a 220-ohm resistor, and finally, LCD LED- to GND which is shown in figure 12. Additionally, a 10k potentiometer is wired to +5V and GND, with its wiper (output) to LCD screens connected to a pin (pin3). Figure 12 and 13 shows detailed wiring and circuit diagrams of the LCD counting system.

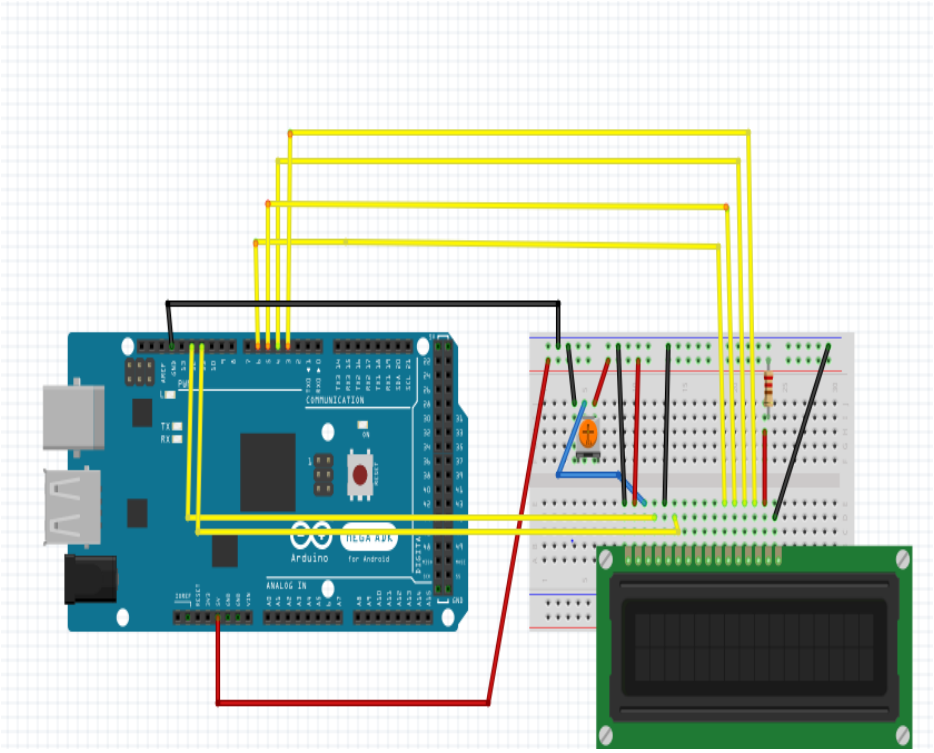

Figure 12: A potentiometer and LCD screen is used for the circuit and breadboard wiring (made using Fritzing (Fritzing, Berlin, Germany)) of LCD Screen for counting the motor's cycle.

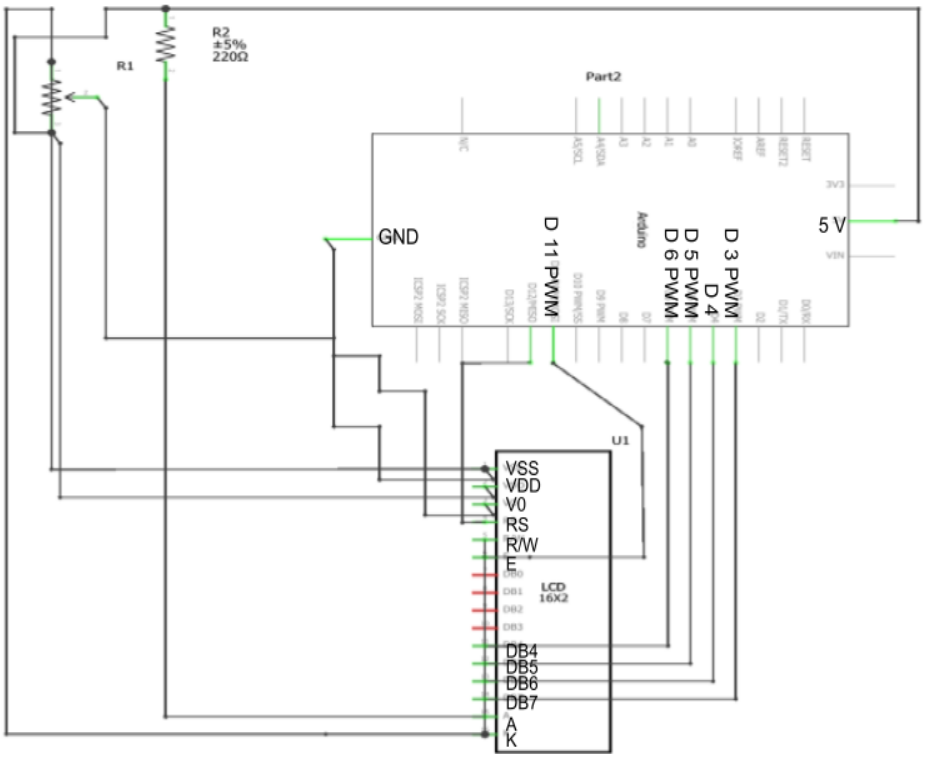

Figure 13: A potentiometer and LCD screen is used for the circuit diagram of LCD Screen for counting the motor's cycle.

In addition, the materials used for circuit setup and synchronization of pacemaker with servo motor include the following: Servo motor, Arduino, Potentiometer, Hall effect sensor, wires, pacemaker, and pacemaker connecting cables which are labeled in Figure 14; and Figure 15 shows the complete built system.

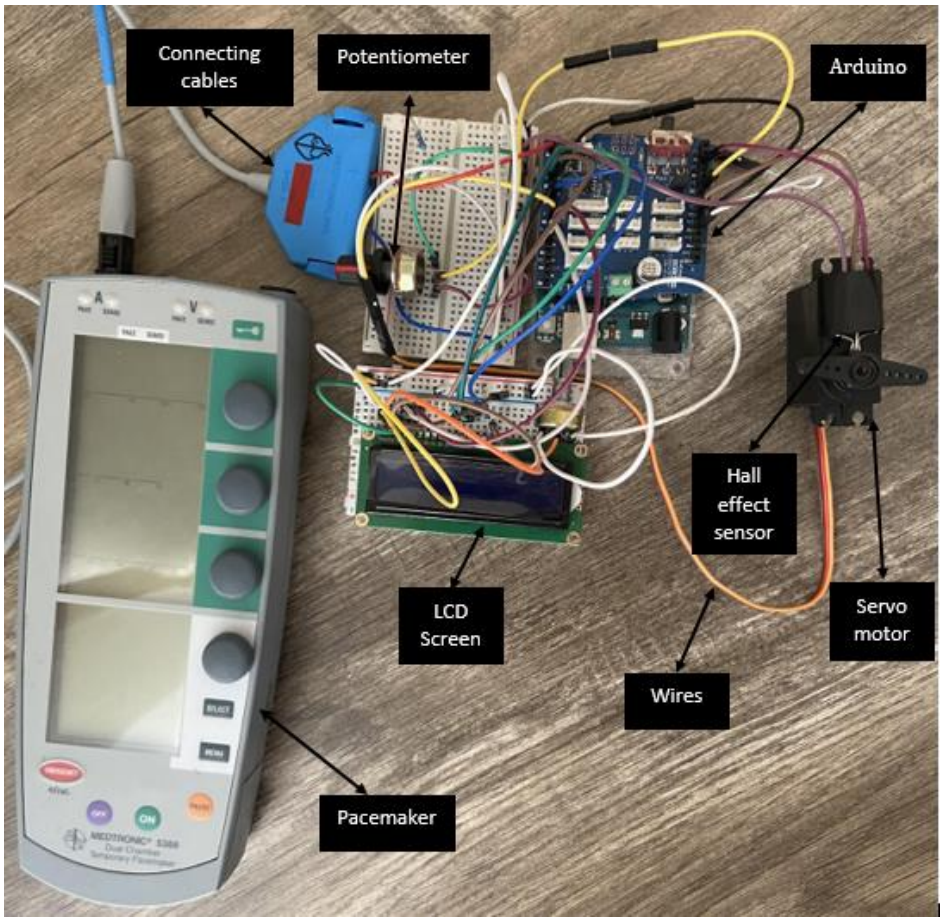

Figure 14: Circuit setup materials include servo motor, Arduino, potentiometer, hall effect sensor, wires, pacemaker, and pacemaker connecting cables.

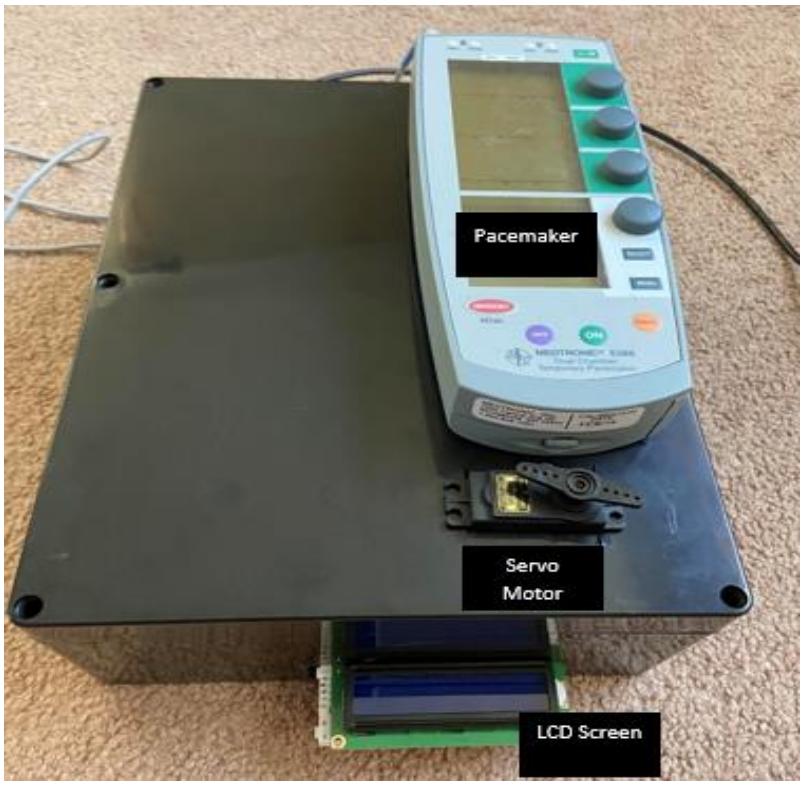

Figure 15: Completed build system of synchronized pacemaker with servo motor

CHAPTER 3: Validation and Discussion

To validate the system, the LCD counting screen is used. The LCD screen was installed to count the cycles of the motor, and the timer has been used to count the number of seconds in a minute. 30 to 80 rpm generated by the pacemaker, rotates and compresses any cardiac compression device attached to the motor in the same range of 30 to 80 rpm respectively. This would indicate the system is synchronized for any rpm generated by the pacemaker. Also, the system of pacemaker which has 80 rpm as default should count 80 cycles of the motor in a minute which gives the same frequency and rpm as the pacemaker. Figures 16-19 show the 4 trials of the synchronized system with 80 cycles of the motor in a minute with a slope of 1.33. The system is turned on and the LCD screen counts the cycles of the motor and the timer counts the seconds. Then, each data is plotted so there would be four different trials. Based on the plot's linear slope, which indicates the same ratio of 1.33 for each trial, the system is steady; therefore, it is synchronized with 80 cycles of the motor in 60 seconds. The trials are done on different dates and times to show that there was consistency across the usage of the device. Since the frequency of the system is the same and the system is synchronized, with the default setting of 80 rpm, and the timer counting the seconds, the results show the same slope of 1.33. Since the pacemaker was set at 80 rpm – the default setting - the ratio of cycle counts to time was theoretically calculated to be 1.33 rounds per second. Since the theoretical ratio was found, only a few experimental trials were needed to be done to validate and confirm the accuracy and precision of the system. Two trials were initially done and later two additional trials were done to confirm

the system was synchronized and was returning the same result of 80 rpm or 1.33 rounds per second every time it was running. 80 rpm is selected for validation since the pacemaker's range maxes out at 80 rpm. Since the maximum rpm is 80, the highest instability occurs at this rpm. By having a few numbers of trials on 80 rpm and showing the system is steady, it was proved that the motor is steady in the entirety of the rpm range and it will stay steady and will not lose precision and accuracy. In addition, the YouTube link of the 80 rpm pacemaker with timer and cycle counter is attached for reference to validate that the system is functioning accurately and spontaneously. A demonstration of the system working can be seen in the following YouTube video: https://youtu.be/3z6uCI6swgs.

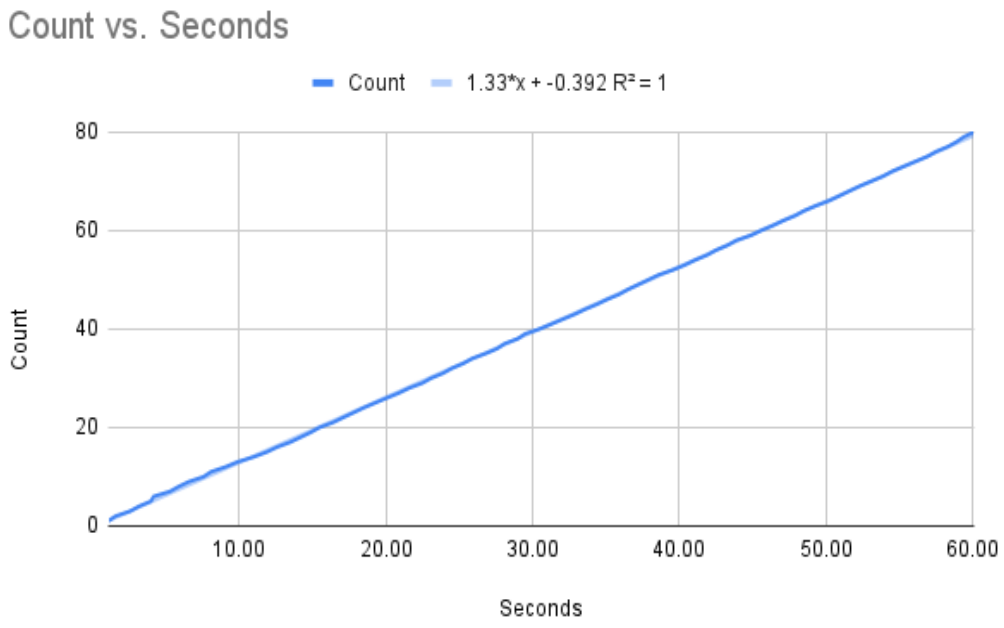

Figure 16: Trial 1 tests the synchronization of the pacemaker with the servo motor for 80 rpm.

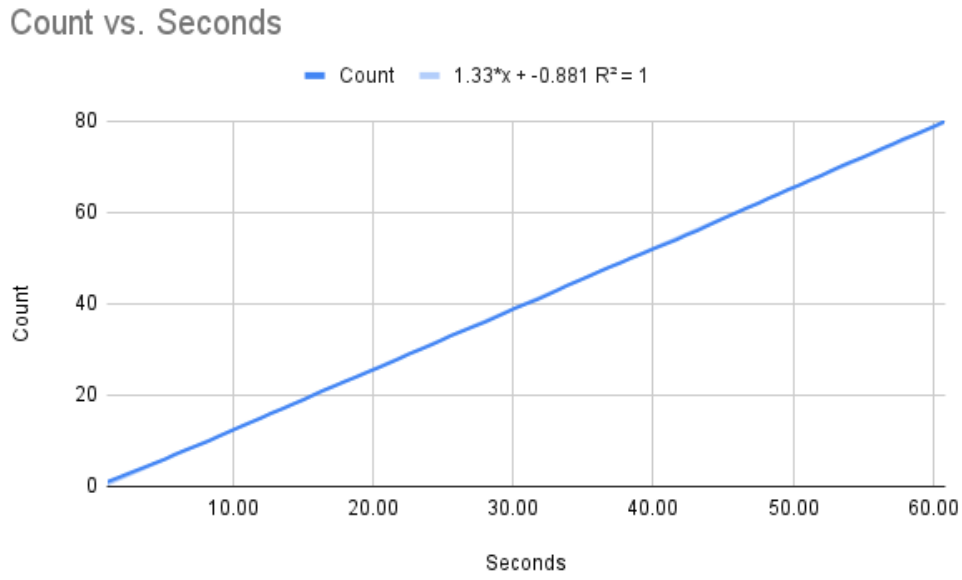

Figure 17: Trial 2 tests the synchronization of the pacemaker with the servo motor for 80 rpm.

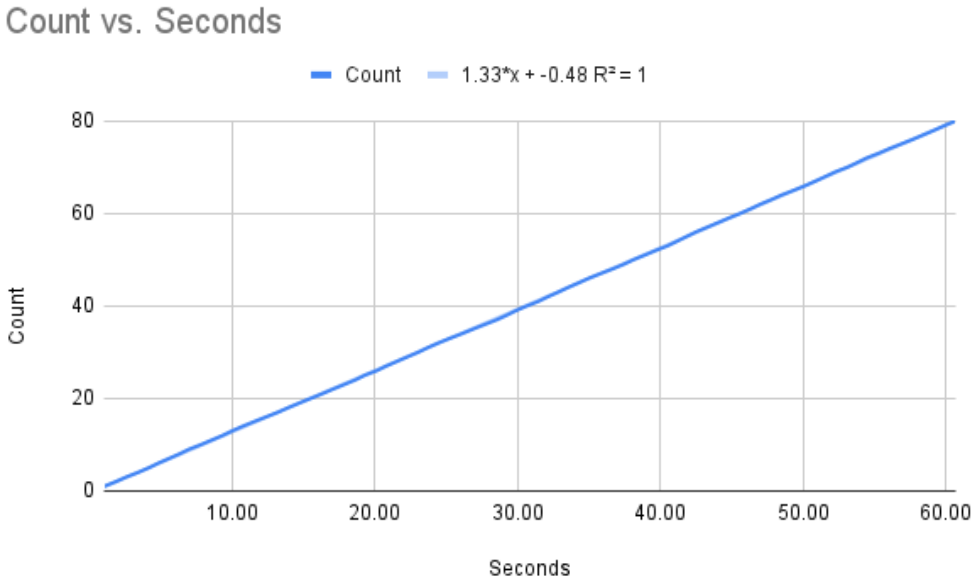

Figure 18: Trial 3 tests the synchronization of the pacemaker with the servo motor for 80 rpm.

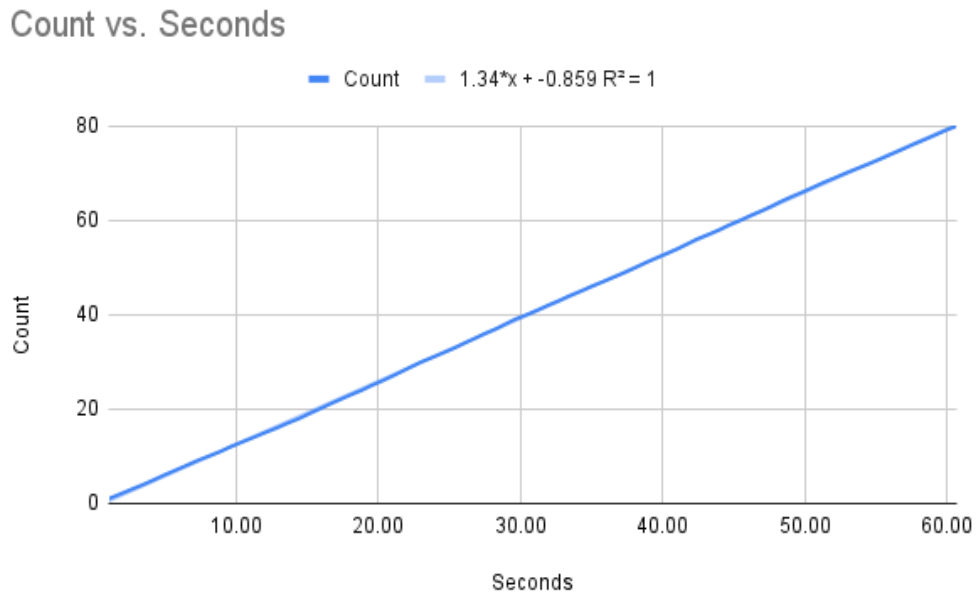

Figure 19: Trial 4 tests the synchronization of the pacemaker with the servo motor for 80 rpm.

The servo motor rotates clockwise and counter-clockwise at a set angle continuously. The motor rotates from zero to ninety degrees clockwise and vice versa from ninety degrees to zero counter-clockwise to help compress the heart. A protractor is used to test and validate the 90-degree angle of rotation in 80 trials. As a result, servo motor angular rotation has an average angle of rotation of 88 degrees with an average standard deviation of 0.89, and a percent error of 1.76 with a theoretical value of 90 degrees. As described above, an LCD counting screen and a protractor were used to validate the accuracy of the motor angular rotation and the synchronization of the pacemaker with the servo motor, which could be connected to any cardiac compression device to help with the assistance of the heart.

CHAPTER 4: Conclusions and Future Work

Previous cardiac compression devices do not synchronize with cardiac contraction mechanics and their natural direction, and some cannot help with the diastolic phase of the cardiac cycle. As a result, the devices were not synchronized with a pacemaker to compress the heart when the heart paces irregularly and slowly. Therefore, in this paper, a method is developed to synchronize the rotation mechanism of the servo motor with a pacemaker to help patients with stage-D heart failure. The servo motor is synchronized with the pacemaker to assist the patient's heart and its movement. Due to psychiatric co-morbidities and limited donors, most of these patients are not eligible to receive a heart transplant. Patients with Stage-D heart failure do not currently have any other options than palliative care to alleviate their CHF symptoms. Having a synchronized system that compresses the heart can help stage-D heart failure patients by improving their cardiac output with no need for donors and open-heart surgery which is not safe due to their health conditions. Therefore, this method aims to improve the quality of life and extend the life expectancy of patients with Stage-D heart failure.

In the future, the system should be built with higher quality motors, reducing the possibility of collecting noise. This biological system will have to undergo in vivo testing in an animal model prior to clinical trials. Similar to studies discussed above such as Ellen T. Roche's study and the FDA guidance on cell therapies for cardiac disease, large animal models such as pigs, sheeps, and dogs provide information on the safety and activity of cellular products and delivery systems which leads to the selection of a potentially safe

Phase 1 clinical trial [73]. In addition, for vitro testing, the hyperpolarization-activated cyclic nucleotide (HCN) gene family is ideally suited to function as a pacemaker when overexpressed [73, 74]. Finally, after multiple vivo and vitro testing and modeling, the system can be used to treat patients with stage-D heart failure in clinical trials. All systems, including the pacemaker and motor wiring, should be checked for loose connections as any human error could cause a shift in the results. The processor that runs and compiles the system should be stronger and be able to run more efficiently and quickly in order for the system to not experience any type of lag.

In conclusion, this paper successfully develops a system to compress the heart as needed using a pacemaker that is synchronized with a servo motor. This is important because prior to this study the patients with stage-D heart failure had to go the path that would require a donor and undergo open-heart surgery which is not safe due to their health conditions. This method could be used in future work to reduce the risk of treating patients with stage-D heart failure.

REFERENCES

1. Mozaffarian, D., Benjamin, E. J., Go, A. S., Arnett, D. K., Blaha, M. J., Cushman, M., ... & Howard, V. J. Executive summary: Heart Disease and Stroke Statistics-2016 update: A report from the American Heart Association. *Circulation*. 2016; 133(4), 447.

2. "Cardiovascular diseases," *World Health Organization*. https://www.who.int/health-topics/cardiovascular-diseases#tab=tab_1.

3. "Cardiovascular diseases (cvds)," *World Health Organization*, 11-Jun-2021. https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvd)

4. "Vital signs: Avoidable deaths from heart disease, stroke, and hypertensive disease - United States, 2001–2010," *Centers for Disease Control and Prevention.*

5. "Heart failure," *Mayo Clinic*, 10-Dec-2021. https://www.mayoclinic.org/diseases-conditions/heart-failure/symptoms-causes/syc-20373142.

6. "Cardiovascular disease: Heart disease causes and symptoms," *Cleveland Clinic*. https://my.clevelandclinic.org/health/diseases/21493-cardiovascular-disease.

7. Go, A. S., Mozaffarian, D., Roger, V. L., Benjamin, E. J., Berry, J. D., Blaha, M. J., ... & Fullerton, H. J. Heart disease and stroke statistics-2014 update. *Circulation*. 2014;129(3).

8. R. Nair, H. Lak, S. Hasan, D. Gunasekaran, A. Babar, and K. V. Gopalakrishna, "Reducing all-cause 30-day hospital readmissions for patients presenting with acute heart failure exacerbations: A Quality Improvement initiative," *Cureus*, 25-Mar-2020.

9. S. M. Dunlay and V. L. Roger, "Understanding the epidemic of heart failure: Past, present, and future," *Current heart failure reports*, Dec-2014.

10. Roger, V. L. (2013). Epidemiology of Heart Failure. *Circulation Research,* 113(6), 646–659.

11."Heart failure," *Centers for Disease Control and Prevention,* 08-Sep-2020. https://www.cdc.gov/heartdisease/heart_failure.htm.

12. Fang JC; Ewald GA; Allen LA; Butler J; Westlake Canary CA; Colvin-Adams M; Dickinson MG; Levy P; Stough WG; Sweitzer NK; Teerlink JR; Whellan DJ; Albert NM; Krishnamani R; Rich MW; Walsh MN; Bonnell MR; Carson PE; Chan MC; Dries DL; Hernandez AF; Hershberger RE; Katz SD; Moore. (n.d.). Advanced (stage D) heart

failure: A statement from the Heart Failure Society of America Guidelines Committee. *Journal of cardiac failure.* Retrieved June 24, 2022.

13. A. P. Kalogeropoulos, A. Samman-Tahhan, J. S. Hedley, A. A. McCue, J. B. Bjork, D. W. Markham, K. N. Bhatt, V. V. Georgiopoulou, A. L. Smith, and J. Butler, "Progression to stage D heart failure among outpatients with stage C heart failure and reduced ejection fraction," *JACC: Heart Failure,* 14-Jun-2017.

14. Gustafsson, F., & Rogers, J. G. (2017). Left ventricular assist device therapy in advanced heart failure: Patient selection and outcomes. *European Journal of Heart Failure,* 19(5), 595–602.

15. J. Walston, B. Buta, and Q.-L. Xue, "Frailty screening and interventions: Considerations for Clinical Practice," *Clinics in geriatric medicine,* Feb-2018.

16. G. Kojima, A. E. M. Liljas, and S. Iliffe, "Frailty syndrome: Implications and challenges for Health Care Policy," *Risk management and healthcare policy,* 14-Feb-2019.

17. J. C. Fang, G. A. Ewald, L. A. Allen, J. Butler, C. A. W. Canary, M. Colvin-Adams, M. G. Dickinson, P. Levy, W. G. Stough, N. K. Sweitzer, J. R. Teerlink, D. J. Whellan, N. M. Albert, R. Krishnamani, M. W. Rich, M. N. Walsh, M. R. Bonnell, P. E. Carson, and M. M. Givertz, "Advanced (stage D) heart failure: A statement from the Heart Failure Society of America Guidelines Committee," *Journal of Cardiac Failure,* 04-May-2015.

18. "Heart failure (congestive heart failure): Symptoms & treatment," *Cleveland Clinic.* https://my.clevelandclinic.org/health/diseases/17069-heart-failure-understanding-heart-failure.

19. Kirali, K., Yerlikhan, O. A., & Hancer, H. (2017). Invasive treatment in advanced (stage-D) heart failure. *Cardiomyopathies - Types and Treatments.*

20. L. Miller, Leslie Miller Correspondence to Leslie W. Miller, E. Birks, Emma Birks Division of Cardiology, M. Guglin, Maya Guglin Division of Cardiology, H. Lamba, Harveen Lamba From the Division of Cardiovascular Medicine, O. H. Frazier, O.H. Frazier From the Division of Cardiovascular Medicine, C. to L. W. Miller, and E. Al., "Use of ventricular assist devices and heart transplantation for advanced heart failure," *Circulation Research,* 23-May-2019.

21. S. Shehab and C. S. Hayward, "Choosing between left ventricular assist devices and biventricular assist devices," *Cardiac failure review,* Feb-2019.

22. L. W. Miller and M. Guglin, "Patient selection for ventricular assist devices: A moving target," *Journal of the American College of Cardiology,* 02-Jan-2013.

23. E. Cerier, B. C. Lampert, A. Kilic, A. McDavid, S. V. Deo, and A. Kilic, "To ventricular assist devices or not: When is implantation of a ventricular assist device appropriate in advanced ambulatory heart failure?," *World journal of cardiology,* 26-Dec-2016.

24. J. N. Katz, S. B. Waters, I. B. Hollis, and P. P. Chang, "Advanced therapies for end-stage heart failure," *Current cardiology reviews,* 2015.

25. Medical Advisory Secretariat, "Left ventricular assist devices: An evidence-based analysis," *Ontario health technology assessment series,* 2004.

26. "Ventricular assist device (VAD)," *Mayo Clinic,* 11-May-2022. https://www.mayoclinic.org/tests-procedures/ventricular-assist-device/about/pac-20384529.

27. "Ventricular assist devices as destination therapy," *CMS.gov Centers for Medicare & Medicaid Services.* https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=243&ver=9.

28. M. L. W. R. JG; "Evolution of left ventricular assist device therapy for Advanced Heart Failure: A Review," *JAMA cardiology.*

29. L. L. B. S. B; "Advances in mechanical circulatory support," *Current opinion in organ transplantation.*

30. Pinney SP; Anyanwu AC; Lala A; Teuteberg J J; Uriel N; Mehra MR; "Left ventricular assist devices for lifelong support," *Journal of the American College of Cardiology.*

31. Kirklin JK; Xie R; Cowger J; de By TMMH; Nakatani T; Schueler S; Taylor R; Lannon J; Mohacsi P; Gummert J; Goldstein D; Caliskan K; Hannan MM; "Second annual report from the ISHLT mechanically assisted circulatory support registry," *The Journal of heart and lung transplantation: the official publication of the International Society for Heart Transplantation.*

32. Ciarka A; Edwards L; Nilsson J; Stehlik J; Lund LH; "Trends in the use of mechanical circulatory support as a bridge to heart transplantation across different age groups," *International journal of cardiology.*

33. Kulkarni HS; Cherikh WS; Chambers DC; Garcia VC; Hachem RR; Kreisel D; Puri V; Kozower BD; Byers DE; Witt CA; Alexander-Brett J; Aguilar PR; Tague LK; Furuya Y; Patterson GA; Trulock EP; Yusen RD; "Bronchiolitis obliterans syndrome-free survival after Lung Transplantation: An international society for heart and lung transplantation thoracic transplant registry analysis," *The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation.*

34. Kormos RL; Cowger J; Pagani FD; Teuteberg JJ; Goldstein DJ; Jacobs JP; Higgins RS; Stevenson LW; Stehlik J; Atluri P; Grady KL; Kirklin JK; "The Society of Thoracic Surgeons Intermacs database annual report: Evolving Indications, outcomes, and scientific partnerships," *The Annals of thoracic surgery.*

35. Roche ET; Horvath MA; Wamala I; Alazmani A; Song SE; Whyte W; Machaidze Z; Payne CJ; Weaver JC; Fishbein G; Kuebler J; Vasilyev NV; Mooney DJ; Pigula FA; Walsh CJ; "Soft robotic sleeve supports heart function," *Science translational medicine.*

36. M. R. Moreno, S. Biswas, L. D. Harrison, G. Pernelle, M. W. Miller, T. W. Fossum, D. A. Nelson, and J. C. Criscione, "Assessment of minimally invasive device that provides simultaneous adjustable cardiac support and active synchronous assist in an acute heart failure model," *ASME Digital Collection,* 28-Nov-2011.

37. M. R. Moreno, S. Biswas, L. D. Harrison, G. Pernelle, M. W. Miller, T. W. Fossum, D. A. Nelson, and J. C. Criscione, "Development of a non-blood contacting cardiac assist and support device: An in vivo proof of concept study," *ASME Digital Collection,* 28-Nov-2011.

38. O. M. C. A. J. H. B. D; "Direct cardiac compression devices," *The Journal of heart and lung transplantation: the official publication of the International Society for Heart Transplantation.*

39. G. D. Buckberg, "Basic science review: The helix and the heart," *The Journal of Thoracic and Cardiovascular Surgery,* 23-Apr-2003.

40. Buckberg G; Hoffman JI; Mahajan A; Saleh S; Coghlan C; "Cardiac mechanics revisited: The relationship of cardiac architecture to ventricular function," *Circulation*.

41. P. P. Sengupta, B. K. Khandheria, and J. Narula, "Twist and untwist mechanics of the left ventricle," *Heart Failure Clinics,* 01-Jul-2008.

42. Sengupta PP; Korinek J; Belohlavek M; Narula J; Vannan MA; Jahangir A; Khandheria BK; "Left ventricular structure and function: Basic science for Cardiac Imaging," *Journal of the American College of Cardiology.*

43. M. Horvath, C. E. Varela, E. B. Dolan, and W. Whyte, "Towards Alternative Approaches for Coupling of a Soft Robotic Sleeve to the Heart," May-2018.

44. Anstadt MP; Bartlett RL; Malone JP; Brown GR; Martin S; Nolan DJ; Oberheu KH; Anstadt GL; "Direct mechanical ventricular actuation for cardiac arrest in humans. A clinical feasibility trial," *Chest.*

45. Chaudhry PA; Anagnostopouls PV; Mishima T; Suzuki G; Nair H; Morita H; Sharov VG; Alferness C; Sabbah HN; "Acute ventricular reduction with the ACORN cardiac

support device: Effect on progressive left ventricular dysfunction and dilation in dogs with chronic heart failure," *Journal of cardiac surgery.*

46. K. L. Fujimoto, K. Tobita, W. D. Merryman, J. Guan, N. Momoi, D. B. Stolz, M. S. Sacks, B. B. Keller, and W. R. Wagner, "An elastic, biodegradable cardiac patch induces contractile smooth muscle and improves cardiac remodeling and function in subacute myocardial infarction," *Journal of the American College of Cardiology*, 12-Jun-2007.

47. Park J; Choi S; Janardhan AH; Lee SY; Raut S; Soares J; Shin K; Yang S; Lee C; Kang KW; Cho HR; Kim SJ; Seo P; Hyun W; Jung S; Lee HJ; Lee N; Choi SH; Sacks M; Lu N; Josephson ME; Hyeon T; Kim DH; Hwang HJ; "Electromechanical cardioplasty using a wrapped elasto-conductive epicardial mesh," *Science translational medicine*.

48. University of ottawa, "Temporary Cardiac Pacing." https://www.ottawaheart.ca/sites/default/files/uploads/documents/user-communities/clinical-services-education/pdf/pacing-presentation-notes.pdf.

49. A. S. Batra and S. Balaji, "Post operative temporary epicardial pacing: When, how and why?," *Annals of pediatric cardiology,* Jul-2008.

50. R. MC; "Temporary epicardial pacing after cardiac surgery: A practical review: Part 1: General considerations in the management of epicardial pacing," *Anaesthesia.*

51. C. Richards, "CTSNet step-by-step series: Pacing wires," CTSNethttps://www.ctsnet.org/article/ctsnet-step-step-series-pacing-wires.

52. S. B. Malik, D. Kwan, and A. Shah, "The right atrium: Gateway to the heart-anatomic and pathologic imaging findings," *RadioGraphics,* 15-Jan-2015.

53. E. Burns and R. Buttner, "Pacemaker rhythms – normal patterns," *Life in the Fast Lane • LITFL*, 04-Jun-2021.

54. "Ventricular capture management feature," *Medtronic Academy,* 18-Aug-2016. https://www.medtronicacademy.com/features/ventricular-capture-management-feature.

55. R. MC; "Temporary epicardial pacing after cardiac surgery: A Practical Review. part 2: Selection of epicardial pacing modes and troubleshooting," *Anaesthesia.*

56. Medtronic, "Streamline temporary surgical pacing leads - surgical heart valves," *Medtronic.* https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/heart-valves-surgical/temporary-myocardial-pacing-leads.html.

57. A. S. Batra and S. Balaji, "Post operative temporary epicardial pacing: When, how and why?," *Annals of pediatric cardiology*, Jul-2008.

58. B. Y. Chang, S. P. Keller, S. S. Bhavsar, N. Josephy, and E. R. Edelman, "Mechanical circulatory support device-heart hysteretic interaction can predict left ventricular end diastolic pressure," *Science translational medicine*, 28-Feb-2018.

59. S. Mohammadi, A. Hedjazi, M. Sajjadian, N. Ghoroubi, M. Mohammadi, and S. Erfani, "Study of the normal heart size in northwest part of Iranian population: A cadaveric study," *Journal of cardiovascular and thoracic research*, 2016.

60. B. T. M H, Z. H, P. H, N. Sh, E. A, and G. A, "Sex-related left ventricle rotational and torsional mechanics by Block Matching Algorithm," *Journal of biomedical physics & engineering*, 01-Oct-2019.

61. S. Clay, K. Alfakih, A. Radjenovic, T. Jones, JP. Ridgway, MU. Sinvananthan, "Normal range of human left ventricular volumes and mass using steady state free precession MRI in the radial long axis orientation," *Magma (New York, N.Y.)*.

62. L. M. Mielniczuk, G. A. Lamas, G. C. Flaker, and G. Mitchell, "Left Ventricular End-Diastolic Pressure and Risk of Subsequent Heart Failure in Patients Following an Acute Myocardial Infarction - Wiley Online Library," 30-Jul-2007.

63. K. Narayanan, K. Reinier, C. Teodorescu, A. Uy-Evanado, R. Aleong, H. Chugh, G. A. Nichols, K. Gunson, B. London, J. Jui, and S. S. Chugh, "Left ventricular diameter and risk stratification for sudden cardiac death," *Journal of the American Heart Association*, 16-Sep-2014.

64. K. Narayanan, K. Reinier, C. Teodorescu, A. Uy-Evanado, R. Aleong, H. Chugh, G. A. Nichols, K. Gunson, B. London, J. Jui, and S. S. Chugh, "Left ventricular diameter and risk stratification for sudden cardiac death," *Journal of the American Heart Association*, 16-Sep-2014.

65. P. RE; "Understanding preload and preload reserve within the conceptual framework of a limited range of possible left ventricular end-diastolic volumes," *Advances in physiology education*.

66. G. Elert, "Power of a human heart," *Power of a Human Heart - The Physics Factbook*. https://hypertextbook.com/facts/2003/IradaMuslumova.shtml.

67. Molnár, Z., István Erdei, T., Obinna, N. C., & Husi, G. (2017). A novel design of an air-cushion vehicle and its implementation. *MATEC Web of Conferences*, 126, 2004.

68. "Pololu - Gettin' All up in Your Servos." *Pololu Robotics & Electronics*, https://www.pololu.com/blog/13/gettin-all-up-in-your-servos.

69. Collado, Edgar, et al. "How to Control Servo Motors with Arduino - Complete Guide." *How To Mechatronics*, 17-May-2022.

70. "Servo Motor," Servo Motor - an overview | ScienceDirect Topics. https://www.sciencedirect.com/topics/engineering/servo-

motor#:~:text=The%20function%20of%20the%20servo,of%20the%20motor%20output%20shaft.

71. H. Liu, “Rail Transit Collaborative Robot Systems,” *Robot Systems for Rail Transit Applications*, 24-Jul-2020. https://www.sciencedirect.com/science/article/pii/B9780128229682000036.

72. P. says: Tarun Agarwal says: at Hi PankajaYes, T. A. says: C. A. Says: and N. *, “Servo Motors - working principle, controlling and applications,” *ElProCus*, 28-Apr-2020.

73. R. B. Robinson, “Engineering a biological pacemaker: In vivo, in vitro and in silico models,” Drug discovery today*. Disease models*, 2009.

74. X. Zhao, A. Bucchi, R. V. Oren, Y. Kryukova, W. Dun, C. E. Clancy, and R. B. Robinson, “In vitro characterization of HCN channel kinetics and frequency dependence in myocytes predicts biological pacemaker functionality,” *The Journal of physiology*, 01-Apr-2009.

APPENDICES

A. Program open:

For the Arduino program to recognize the servo motor, <Servo.h> library is installed. For the Arduino program to recognize the LCD screen, <LiquidCrystal.h> library is installed. The parameter input is connected to pin 2 and it is recognized by the Arduino.

```
#include <Servo.h>

#include <LiquidCrystal.h>


/* global variables */


// Pacing

const byte pacemaker = 2;    // trigger pin representing pacemaker

volatile byte trigger = LOW; // state of pacing HIGH - triggered, LOW - reset


// Motor

const int pwm = 9; // connect the servo motor to pin 9

int potpin = 0;  // connect the potentiometer to pin 0

const int angle = A0; // connect angular position of motor to pin A0

float ms = 0;
```

```
int val;    //   the analog pin variable to read

Servo myservo;  // create servo object to control a servo

int pos = 0;    // variable to store the servo position

float counter = 0;

float sec = 0;


//Position

const int hall = A3;        // connect Hall effect sensor to A3


// LCD Screen

LiquidCrystal lcd(12, 11, 6, 5, 4, 3); // connect the LCD to pins of arduino for
communication
```

B. Pacemaker communication and Void pace_detect and setup function:

The trigger is detected when the function is interrupted. Therefore, the loop "setup" runs when the Arduino is powered to reset the system.

```
/* interrupt function to run if trigger is detected */

void pace_detect() {
```

```
trigger = HIGH; }

/* Setup Loop runs once with the Arduino is powered on */

void setup() {

Serial.begin(9600);

// https://www.arduino.cc/reference/en/language/functions/external-interrupts/attachinterrupt/

 attachInterrupt(digitalPinToInterrupt(pacemaker), pace_detect, RISING); // interrupt 0 is pin D2
```

C. Setting pinModes:

The pinModes are set to appropriate settings for communication.

```
 myservo.attach(pwm);  // pin 9 used to attach the servo to the servo object

 pinMode(pacemaker, INPUT_PULLUP); // set pin mode for pacemaker as input

 pinMode(pwm, OUTPUT); //  // set pin mode for motor as output

 pinMode(hall, INPUT);      // set pin mode for angle as input
```

D. LCD screen setup:

The LCD 16x3 is a 16-pin device that has 3 rows that can accommodate 16 characteristics each. lcd.begin starts the LCD screen. The 1000 second delay is generated to give LCD time to power and function by showing the comment “starting”. The LCD screen counts the cycles of the motor.

```
lcd.begin(16, 3);
lcd.print("starting");
delay(1000);
lcd.clear();
lcd.setCursor(0,1);
lcd.print(counter);
```

E. Void loop setup:

The loop “beat” is repeated indefinitely after the above setup is completed. If the pacemaker is on, the hall effect captures the magnetic field generated and completes the “beat” process in step F.

```
 // if the pacing mode is HIGH
 if (trigger == HIGH) {
```

trigger = LOW; // reset pace to LOW

beat(); // complete beat process }

F. Void beat setup:

The custom function is built to generate a “heart beat”. The magnetic field is generated by pacemaker, then it is captured by hall effect and inputted to the servo motor. The servo motor directions are defined with capability of maximum rotation of -90 to 90 which is the maximum angle of rotation needed to compress the heart.

ms = analogRead(angle);

for (pos = 0; pos <= 90; pos += 1) { // 0 degrees to 90 degrees position - in steps of 1 degree

myservo.write(pos); } // choose direction - servo goes to position in variable 'pos' - from 0 to 90 //To control the motor, use Pulse Width Modulation which has a specific resolution for servo motor - PPM, or "Pulse Position Modulation".

for (pos = 90; pos >= 0; pos -= 1) {// goes from 90 degrees to 0 degrees

myservo.write(pos); } // choose direction - servo goes to position in variable 'pos' - from 90 to 0

```
  //To control the motor, use Pulse Width Modulation which has a specific resolution for servo motor - PPM, or "Pulse Position Modulation".


 digitalWrite(pwm, HIGH);      // turn on motor

 while (digitalRead(hall) == HIGH) {

 digitalWrite(pwm, LOW);       // turn off motor

 if (digitalRead(hall) == LOW) {

  counter = ++counter; } }
```