



Polytechnic University of Puerto Rico  
Biomedical Engineering Department  
WI-20

**Capstone Project:**  
**Ventricular Assist Device with Telemonitoring Capabilities**  
Bachelor of Science in Biomedical Engineering

**Alexander M. Martínez Lopez #113832**  
**Carlos Francisco Gonzalez Rivera #117052**  
**Stephanie Muñiz Mercado #91245**

Due Date: March 26, 2021  
**Advisor:** Dr. Carlos Alvarado

## **ACKNOWLEDGEMENTS**

As undergraduate students we feel privileged and thankful in taking this opportunity to express our gratitude to the many people who have contributed to this project.

Firstly, we would like to express our deepest gratitude to Dr. Carlos Alvarado and Prof. Yaelia Pacheco for their motivating and valuable guidance during the project.

We would also like to offer special thanks to Abigail Velazquez Perez for her poster editing guidance and assistance during the project. Her willingness to give her time so generously has been very much appreciated.

At last, we would like to thank Alexander Martinez parents, Anivluz Lopez and Alejandro Martinez, for their love and unconditional support that they gave him. Not only during his academic education but also throughout life, who have been the most important reason for who he is today.

## **ABSTRACT**

Heart failure (HF) is a complex clinical disease associated with enormous healthcare costs because of its high morbidity and mortality rates. Left ventricular assist devices (LVADs) are known to be acceptable cardiac therapy for patients with advanced heart failure for their clinically meaningful survival benefit and improved quality of life. However, their cost-effectiveness is often questioned since they substantially increase lifetime costs because of frequent readmissions and costly follow-up care. This project aims to design and fabricate a feasible yet cost-effective continuous-flow LVAD with telemonitoring capacity for patients with advanced heart failure. Focusing on a design that can support patient's heart function by maintaining a cardiac output of 5.5 L/min and provide continuous telemonitoring of parameters concerning the health of LVAD patients through a mobile app. Such design was achieved through a Computer-Aided Design (CAD) of the heart pump, a PID control system and, WIFI parameter transmission. Physical simulation of the device achieved a regulated volume flow of 5.5 L/min, and both blood flow and rotor velocity were able to be monitored continuously through the app. Obtained results state the project objectives were met satisfactorily and reflect the feasibility of the design and functioning of our cost-effective continuous-flow LVAD.

## TABLE OF CONTENTS

<i>Acknowledgements</i> .....	<i>ii</i>
<i>Abstract</i> .....	<i>iii</i>
<i>List of Figures</i> .....	<i>viii</i>
<i>List of Tables</i> .....	<i>xiii</i>
<i>List of Symbols &amp; Acronyms</i> .....	<i>xvii</i>
<b>Pre-Phase A: Concept Studies.....</b>	<b>1</b>
<b>Users &amp; Stakeholders .....</b>	<b>1</b>
<b>Project Description &amp; Objectives.....</b>	<b>2</b>
<b>Project Significance .....</b>	<b>4</b>
<b>System Level Requirements and Constraints.....</b>	<b>6</b>
<b>Resource Budget.....</b>	<b>12</b>
<b>Risk estimates .....</b>	<b>15</b>
<b>Phase A: Concept &amp; Technology Development.....</b>	<b>17</b>
<b>Technology Assessment .....</b>	<b>17</b>
<b>Project/Mission Architecture and Interfaces .....</b>	<b>20</b>
<b>Project Planning for System and Subsystems .....</b>	<b>22</b>
<b>Sub-System Level Requirements and Constraints .....</b>	<b>25</b>
<b>Heart Pump Subsystem .....</b>	<b>25</b>
<b>Controls Subsystem .....</b>	<b>26</b>

<b>Monitoring Subsystem.....</b>	<b>27</b>
<b>Sub-System Risk Assessment.....</b>	<b>28</b>
<b>Heart Pump Subsystem .....</b>	<b>29</b>
<b>Controls Subsystem .....</b>	<b>30</b>
<b>Monitoring Subsystem.....</b>	<b>31</b>
<b><i>Phase B: Preliminary Design and Technology Completion .....</i></b>	<b><i>33</i></b>
<b>Technology Development .....</b>	<b>33</b>
<b>Heart Pump Subsystem .....</b>	<b>33</b>
<b>Controls Subsystem .....</b>	<b>37</b>
<b>Monitoring Subsystem.....</b>	<b>42</b>
<b>Subsystem Architecture into Components .....</b>	<b>47</b>
<b>Heart Pump Subsystem .....</b>	<b>47</b>
<b>Controls Subsystem .....</b>	<b>58</b>
<b>Monitoring Subsystem.....</b>	<b>68</b>
<b><i>Phase C.1: Design of Parts and Components.....</i></b>	<b><i>77</i></b>
<b>Detail Design Studies .....</b>	<b>77</b>
<b>Heart Pump Subsystem .....</b>	<b>77</b>
<b>Controls Subsystem .....</b>	<b>86</b>
<b>Monitoring Subsystem.....</b>	<b>102</b>
<b><i>Phase C.2: Integration.....</i></b>	<b><i>111</i></b>
<b>System Integration.....</b>	<b>111</b>
<b>Manufacturing.....</b>	<b>115</b>

<b><i>Phase D: System Demonstration &amp; Verification</i></b> .....	<b>127</b>
<b>System Verification Plan</b> .....	<b>127</b>
<b>Physical Prototype</b> .....	127
<b>Maintaining Budget Assessment</b> .....	128
<b>Rotor Measurement Assessment</b> .....	128
<b>Maximum Motor Voltage Measurement</b> .....	129
<b>LVAD Device Mass Measurement</b> .....	130
<b>Fluid Flow Physical Simulation Loop</b> .....	131
<b>LVAD Temperature Assessment</b> .....	133
<b>Real-time Monitoring Verification</b> .....	134
<b>System Demonstration</b> .....	135
<b>System Verification</b> .....	140
<b><i>Discussion</i></b> .....	<b>146</b>
<b><i>Conclusion</i></b> .....	156
<b><i>Recommendations</i></b> .....	157
<b><i>References</i></b> .....	158
<b><i>Appendix A: Presentations</i></b> .....	160
<b><i>Appendix B: Timeline of Activities</i></b> .....	191
<b><i>Appendix C: Calculations</i></b> .....	193
<b>Heart Pump Subsystem</b> .....	193
<b>Controls Subsystem</b> .....	193

<i>Appendix D: Bill of Materials .....</i>	<i>197</i>
<i>Appendix E: Detail Drawings.....</i>	<i>200</i>
<i>Appendix E: Manufacturing Sheets.....</i>	<i>209</i>
<i>Appendix F: Schematics &amp; Interfaces .....</i>	<i>213</i>
<i>Appendix F: Code .....</i>	<i>218</i>
<i>Appendix G: User's Manual.....</i>	<i>228</i>

## LIST OF FIGURES

Figure 1: Patient using a left ventricular assist device.....	1
Figure 2: Biomedical Engineering Students responsible for device development .....	1
Figure 3: Heart Failure Statistics .....	2
Figure 4: Current Treatments used to address patients with Heart Failure (CONOPS) ....	3
Figure 5: Lvad Components & Functioning (CONOPS).....	4
Figure 6: System-Level QFD.....	12
Figure 7: Rehabilitation Engineering and Industrial Automation Laboratory.....	13
Figure 8: Technology Asseesment CONOPS .....	19
Figure 9: System Hierarchy Diagram for the TLVAD .....	20
Figure 10: TLVAD system <i>N2</i> diagram.....	21
Figure 11: TLVAD Capstone Project WBS.....	22
Figure 12: Capstone I Timeline .....	23
Figure 13: Capstone II Timeline .....	23
Figure 14: Budget Allocation by subsystems .....	25
Figure 15: Axial continuous flow pump Model.....	34
Figure 16: Ventrifugal flow pump Model.....	35
Figure 17: Pulsatile continuous flow pump Model.....	36
Figure 18: Open loop LVAD Model.....	38
Figure 19: PID feedback control system LVAD Model .....	39
Figure 20: ON/OFF feedback control system LVAD Model .....	41
Figure 21: Bluetooth Connection Model .....	43
Figure 22: Wi-Fi Implemented module's Schematics.....	44

Figure 23: Both module's Schematics.....	45
Figure 24: Pump subsystem PBS .....	47
Figure 25: Motor Alternatives Figure .....	48
Figure 26: Rotor Alternatives .....	51
Figure 27: Heart pump subsystem risk assessment matrix .....	58
Figure 28: Controls subsystem PBS .....	59
Figure 29: Microcontroller Alternatives .....	60
Figure 30: Battery Alternatives.....	62
Figure 31:Flow sensor Alternatives .....	65
Figure 32: Controls Subsystem Risk Assesment Matrix .....	68
Figure 33: Monitoring System arquitecture .....	69
Figure 34: Liquid Cristal Display Alternatives.....	70
Figure 35: Wi-FI Module Options .....	72
Figure 36: Monitoring Subsystem Risk Assesment Matrix .....	76
Figure 37: Pump Flow Diagram .....	78
Figure 38: Heart pump Drawing .....	79
Figure 39: Motor Detail Drawing .....	80
Figure 40: Open-end rotor Detail Drawing.....	81
Figure 41: pump Subsystem working Principal.....	84
Figure 42: Pump subsystem exploded drawing .....	84
Figure 43: Ejection Fraction Diagram .....	87
Figure 44: Motor Circuit Diagram.....	90
Figure 45: PID Block Diagram .....	91

Figure 46: Closed Loop Block Diagram .....	91
Figure 47: PID Programming Flowchart .....	94
Figure 48: Arduino Detail Drawing .....	95
Figure 49: Li-Ion Battery Detail Drawing .....	96
Figure 50: YF-B6 Flowmeter Detail Drawing.....	97
Figure 51: Parts of the Controls susbsystem.....	98
Figure 52: L298N motor driver Detail Drawing.....	99
Figure 53: L298N motor driver Internal circuit Diagram.....	99
Figure 54: Control Subsystem working Principal.....	100
Figure 55: Controls subsystem Schematics .....	100
Figure 56: Visual Studio GUI Program .....	103
Figure 57: Main code Architecture .....	105
Figure 58: Main Page of TLVAD APP.....	106
Figure 59: Alarms Notification GUI.....	106
Figure 60: Monitoring Subsystem working Principal.....	109
Figure 61: Monitoring Subsystem Shematics .....	110
Figure 62: System-level Interfaces .....	112
Figure 63: Quantified Interface diagram.....	113
Figure 64: Tolerance Interface Diagram.....	114
Figure 65: System-Level Detail Drawing .....	115
Figure 66: Control Box Assembly detail drawng with BOM .....	117
Figure 67: Control Box Manufacturing Sheet .....	117
Figure 68: Heart Pump Detail Drawing .....	118

Figure 69: Heart Pump Cap Detail Drawing.....	118
Figure 70: Heart Pump Rotor Detail Drawing .....	119
Figure 71: Heart Pump Manufacturing Sheet .....	120
Figure 72: Inflow Graft Detail Drawings.....	121
Figure 73: Inflow Graft Manufacturing Sheet .....	122
Figure 74: Outflow Graft Detail Drawing .....	122
Figure 75: Outflow Graft Manufacturong Sheet.....	123
Figure 76: Heart Pump Assembly Drawings .....	124
Figure 77: Rotor measurement assesment tools.....	129
Figure 78: Motor Voltage measurement assesment tools.....	130
Figure 79: Device Mass measurement assesment tools.....	131
Figure 80: Fluid Flow Physical Simulation Loop tools.....	132
Figure 81: Fluid Flow Physical Simulation Loop.....	133
Figure 82: Temperature Assesment tools .....	134
Figure 83: Monitoring Assesment tools.....	135
Figure 84: Printing Process and final heart pump Print.....	136
Figure 85: Printing Process and final Inflow pipe Print .....	136
Figure 86: Printing Process and final Outflow Pipe Print.....	137
Figure 87: Control Box Printing Process .....	137
Figure 88: Early Hardware integration .....	138
Figure 89: Pump and Sensor Assembly .....	139
Figure 90: Final Prototype .....	139
Figure 91: Rotor length Measurement .....	141

Figure 92: Motor Voltage Measurement.....	142
Figure 93: Device Weight Measurement .....	143
Figure 94: Device Testing.....	143
Figure 95: Monitored Parameters .....	144
Figure 96: Device Weight Measurement .....	144

## LIST OF TABLES

Table 1: Average LVAD implantation related costs (Shreibati et al., 2016).....	5
Table 2: Specifications for MOE and MOP establishments .....	7
Table 3: System Level MOE's .....	8
Table 4: System Level MOP's .....	10
Table 5: Standards of MOP's.....	11
Table 6: Preliminary system-level cost analysis.....	14
Table 7: Devices in Market Comparisson.....	14
Table 8: Financial project Plan .....	14
Table 9: Potential risks involved that would affect the project's completion.....	16
Table 10: Technology Assesment.....	17
Table 11: Rating Weighting Decision Matrix for Technology Assessment.....	20
Table 12: Budget Allocation based on materials .....	24
Table 13: Heart pump subsystem-level Mop's with standards.....	26
Table 14: Controls subsystem-level Mop's with standards .....	27
Table 15: Monitoring Subsystem-level MOP's with standards.....	28
Table 16:Heart pump subsystem risks and mitigation strategies.....	30
Table 17: Controls subsystem risks and mitigation strategies .....	31
Table 18: Monitoring subsystem risks and mitigation strategies.....	32
Table 19: Axial Continuous Flow Pump Assesment Values .....	34
Table 20: Centrifugal Flow Pump Assesment Values .....	35
Table 21:Pulastile Flow Pump Assesment Values.....	37
Table 22: Rating Weighting decision Matrix for Pump selection .....	37

Table 23: Open Loop Assesment Values.....	39
Table 24: PID Feedback control Loop Assesment Values .....	40
Table 25: ON/OFF Feedback control Loop Assesment Values.....	41
Table 26: Rating Weighting for Control System Selection .....	42
Table 27: Bluetooth Connection Criteria.....	43
Table 28: Wi-Fi Connection Criteria .....	44
Table 29: Bluetooth & wi-Fi Connection Criteria .....	45
Table 30: Rating Weighting Decision Matrix for Monitoring System Selection .....	46
Table 31: Linear motor Values for motor Selection Criteria.....	49
Table 32: BLDC motor Values for motor Selection Criteria.....	49
Table 33: Axial self-bearing motor Values for motor Selection Criteria .....	50
Table 34: Rating Weighting Decision Matrix for motor Selection.....	50
Table 35: Salient pole rotor Values for rotor Selection Criteria.....	51
Table 36: Cylindrical pole rotor Values for rotor Selection Criteria .....	52
Table 37: Open-end rotor Values for rotor Selection Criteria .....	53
Table 38: Rating Weighting decision Matrix for rotor selection.....	53
Table 39: Silicone Tubing Values for tubing material Selection Criteria .....	54
Table 40: Teflon Tubbing Values for tubing material Selection Criteria.....	55
Table 41: Titanium Alloy Tubing Values for tubing material Selection Criteria.....	56
Table 42: Rating Wheighting decision Matrix forTubing Material SELECTION .....	57
Table 43: Lists of Risks in the Heart pump subsystem.....	58
Table 44: Arduino Uno Values for Microcontroller Selection Criteria.....	60
Table 45: Arduino Mega Values for Microcontroller Selection Criteria.....	61

Table 46: MSP430 Launchpad Values for Microcontroller Selection .....	61
Table 47: Rating Weighting Decision Matrix for microcontroller Selection .....	62
Table 48: Li-ion Battery Values for Battery Alternatives .....	63
Table 49: NiMH Battery Values for Battery Alternatives .....	63
Table 50: Alkaline Battery Values for Battery Alternatives.....	64
Table 51: Rating Weighting Decision Matrix for Battery Selection .....	64
Table 52: Silicone YF-S201C Value for Sensor Alternatives .....	65
Table 53: YF-B6 Value for Sensor Alternatives.....	65
Table 54: Plastic YF-S201C Value for Sensor Alternatives.....	66
Table 55: Rating Weighting Decision Matrix for Sensor Selection .....	67
Table 56: List of Risks in the Controls Subsystem.....	68
Table 57: Asiawill COLOR TFT touch lcd for LCD Alternatives.....	70
Table 58: Huhushop White OLED Display For LCD alternatives .....	71
Table 59: Arduino DOT Matrix Display for LCD Alternatives.....	71
Table 60: Rating Weighting decision Matrix FOR Liquid Cristal Display Selection .....	72
Table 61: Arduino Uno Wi-Fi Criteria .....	73
Table 62: ESP8266 Wi-Fi Module Criteria .....	73
Table 63: Sp32 Wi-Fi & Bluetooth Module Criteria .....	74
Table 64: Rating Weighting decision Matrix FOR Wi-Fi Module Selection .....	75
Table 65: List of Risks in tje monitoring Subsystem.....	75
Table 66: Motor Specifications.....	78
Table 67: Motor Compliance Assessment .....	81
Table 68: Rotor Compliance Assessment .....	82

Table 69: tubing material Compliance Assessment .....	83
Table 70: Tubing Connections of the Heart Pump Subsystem.....	84
Table 71: pump subsystem performance Compliance Assessment.....	85
Table 72: Given Measurements/Parameters in Writeup .....	87
Table 73: Microcontroller Compliance Assessment .....	95
Table 74: Battery Compliance Assessment .....	97
Table 75: Flow Sensor Compliance Assessment .....	98
Table 76: Wiring Connections of The Controls Subsystem .....	101
Table 77: Controls subsystem performance Compliance Assessment.....	102
Table 78: Monitoring subsystem LCD performance .....	108
Table 79: WIFI module Performance .....	109
Table 80: Monitoring subsystem Performance Verification .....	110
Table 81: System-level performance Compliance Assessment .....	115
Table 82: System BOM with Costs .....	116
Table 83: Budget estimates before manufacturing .....	124
Table 84: Financial project Plan .....	125
Table 85: Budget estimates before manufacturing .....	126
Table 86: Budget Verification .....	140
Table 87: System-level Verification Compliance.....	145

## LIST OF SYMBOLS & ACRONYMS

<b>Abbreviations</b>	<b>Meaning</b>
1. AAMI	Association Advancement of Medical Instrumentation
2. ANSI	American National Standards Institute
3. BLDC	Brushless Direct Current
4. BOM	Bill of Materials
5. CAD	Computer Aided Drafting
6. CAGR	Compound Annual Growth Rate
7. CFR	Code of Federal Regulations
8. CNC	Computer Numerical Control
9. CO	Cardiac Output
10. ConOps	Concept of Operations
11. DIS	Distributed Interactive Simulations
12. EDV	End-diastolic Volume
13. EF	Ejection Fraction
14. FDA	Food and Drug Agency's
15. HF	Heart Failure
16. IEC	International Electrotechnical Commission
17. ISO	International Organization of Standardization
18. LCD	Liquid Crystal Display
19. LVAD	Left Ventricular Assist Device
20. MOE	Measures of Effectiveness
21. MOP	Measures of Performance
22. PBS	Product Breakdown Structure
23. PEG	Polyethylene Glycol
24. PLA	Polylactic Acid
25. PMA	Premarket Approval
26. PTFE	Polytetrafluoroethylene
27. QFD	Quality Function Deployment
28. ROI	Return of Investment
29. SV	Stroke Volume
30. TLVAD	Telemonitoring Left Ventricular Assist Device
31. WBS	Work Breakdown structure

Symbols	Meaning
1. n	Rotational Speed
2. p	Power
3. $K_I$	Integrative Constant
4. $K_P$	Proportional Constant
5. $K_D$	Derivative Constant
6. K	Back-EMF constant
7. R	Internal Resistance
8. L	Internal Inductance
9. J	Rotor Moment of Inertia
10. $N_t$	Efficiency
11. V	Voltage

## PRE-PHASE A: CONCEPT STUDIES

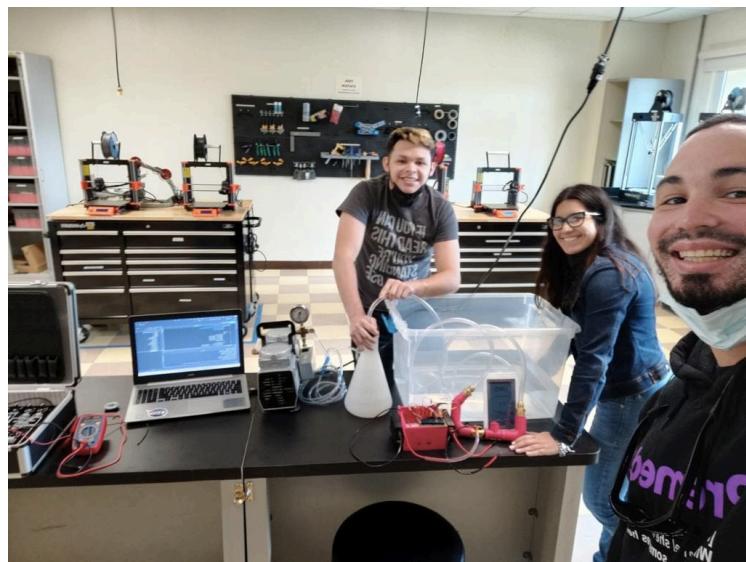
### USERS & STAKEHOLDERS

The left ventricular assist device is an implanted device designed for Patients with advanced Heart Failure, who's heart is unable to pump enough blood to meet the body's demands. **Figure 1** represents a patient using a left ventricular device.



**FIGURE 1: PATIENT USING A LEFT VENTRICULAR ASSIST DEVICE**

The students from the Biomedical Engineering Department at the Polytechnic University of Puerto Rico, who developed this device were their own stakeholders. These students can be seen on **Figure 2** with their finished left ventricular assist device prototype.



**FIGURE 2: BIOMEDICAL ENGINEERING STUDENTS RESPONSIBLE FOR DEVICE DEVELOPMENT**

## PROJECT DESCRIPTION & OBJECTIVES

Heart failure (HF) currently affects nearly 5 million Americans and contributes to approximately 287,000 deaths a year [1,2]. HF doesn't mean that the heart has stopped or is about to stop working. Rather it is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen. This disease is often particularized by having a low ejection fraction. Which is the percentage of blood leaving your heart each time it contracts. Overall, it is a serious condition that requires medical care, **Figure 3** illustrates several eye-opening statistics that show the high prevalence of HF.

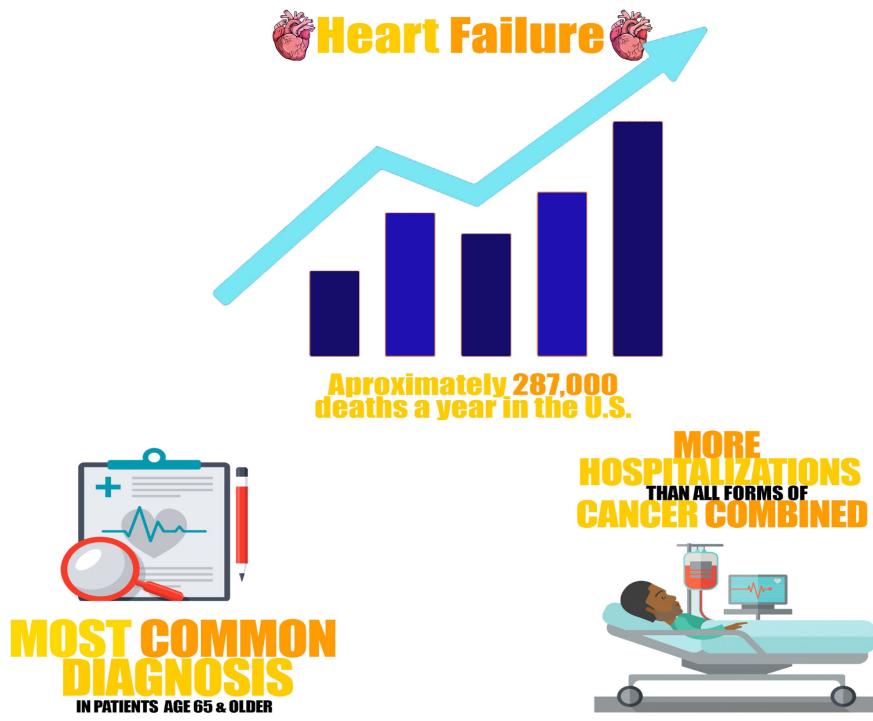
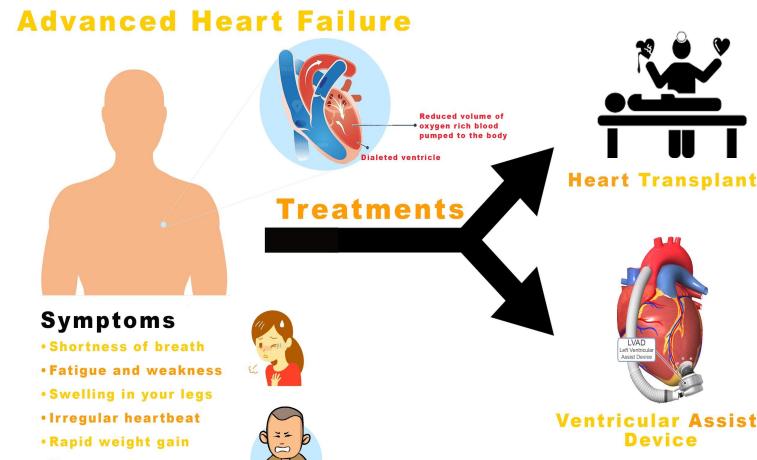


FIGURE 3: HEART FAILURE STATISTICS

Most treatments for people who suffer from HF involve a balance of the right medications and, in some cases, use of devices that help the heartbeat and contract properly. A left ventricular assist device (LVAD) is an implantable, battery-operated mechanical pump that helps pump blood from the left ventricle pump blood to the rest of the body [3].

This surgically implanted cardiac therapy device is usually used in patients who have reached end-stage heart failure. **Figure 4** illustrates the Concept of Operations (ConOps) of how HF is addressed demonstrating its current treatments. Error! Reference source not found.

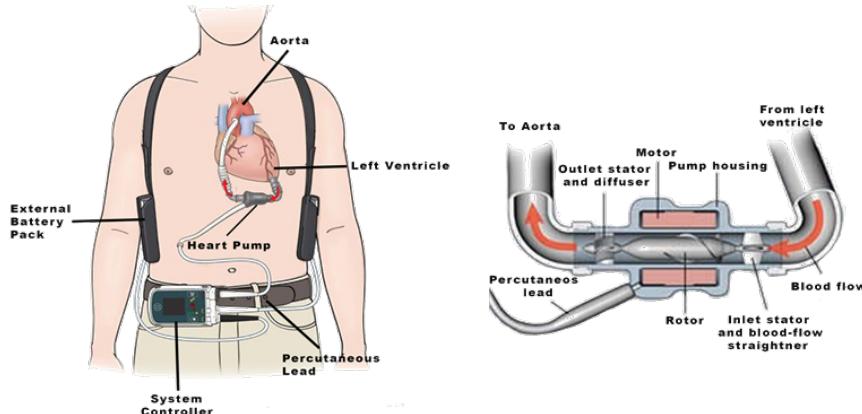


**FIGURE 4: CURRENT TREATMENTS USED TO ADDRESS PATIENTS WITH HEART FAILURE (CONOPS)**

LVADs can be used as temporal or long-term treatments. Temporal implantation of LVADs is utilized while patients wait for a heart donor to become available for a heart transplant and in some cases, the LVAD can restore the failing heart, eliminating the need for a transplant. This is usually referred as bridge-to-transplant therapy. Long-term or destination therapy is utilized when patients are not candidates for heart transplants [3,4]. In this case, patients can receive long-term treatment using an LVAD, which can prolong and improve patients' lives. A ConOps is shown in **Figure 5** that illustrates the LVAD components and how it functions.

LVADs are known to be an acceptable cardiac therapy for patients with advanced heart failure and patients who are not candidates for cardiac transplantation. Mainly because of their clinically meaningful survival benefit and improved quality of life. However, LVADs possess many opportunities to reduce cost if adverse events and outpatient costs can be

reduced. Such cost reduction can be achieved by improving device mechanics to reduce risks of device thrombosis and the incorporation of telemonitoring. Telemonitoring LVAD patients holds a great potential due to the importance of continual monitoring for this patient group because of the complexity of its aftercare, requiring steady control of various parameters [5].



**FIGURE 5: LVAD COMPONENTS & FUNCTIONING (CONOPS)**

The aim for this capstone project is to design and fabricate a feasible and cost-effective continuous-flow LVAD with telemonitoring capacity for patients with advanced heart failure. The main objective for this device is to support patient's heart function by maintaining ejection fraction above 40% or a cardiac output of 5.5 L/min and provide continual and significant monitoring during the complex aftercare. The latter addressed by implementing a mobile app for continuous monitoring of parameters and data concerning the health of LVAD patients.

## PROJECT SIGNIFICANCE

Even though LVADs are lifesaving surgical implants for the management of end-stage heart failure, their cost-effectiveness is often questioned. Since they substantially increased lifetime costs because of frequent readmissions and costly follow-up care

estimated to cost patients \$726,200 over a six-year period [7]. These costs regarding before and after the LVAD implantation are very high. With increased risks due to stroke cases, device malfunctions, among other costs can potentially increase even more. **Table 1** shows the average costs related to LVAD implantation.

These cost issues related to LVAD implantation are of upmost significance since HF affecting more than 11 million people in the U.S. and Europe. The high prevalence of HF patients has caused a growing demand for heart transplant that cannot meet due to the lack of donor organs, thus triggering a constant growth in the ventricular assist market. The global ventricular assist device market size was valued at USD 1.7 billion in 2019 with an expected market size growth at a compound annual growth rate (CAGR) of 11.7% from 2020 to 20278].

**TABLE 1: AVERAGE LVAD IMPLANTATION RELATED COSTS (SHREIBATI ET AL., 2016)**

Resource category	Average cost (SD) (US\$)	% of total cost
LVAD (HeartMate)	67,085	48%
Professional payment	23,935 ± 10,897	17%
Special care days	14,765 ± 10,874	10%
Regular floor days	7,071 ± 7,376	5%
Operating room	10,818 ± 1,725	8%
Diagnostics	3,900 ± 3,574	3%
Laboratory	3,407 ± 1,767	2%
Blood products	2,873 ± 2,562	2%
Drugs	3,257 ± 3,229	2%
Miscellaneous	3,235 ± 1,695	2%
Rehabilitation	670 ± 423	0%
Total	141,016	

<sup>a</sup> Initial hospitalisation costs only, based on 'clinically sufficient' LOS of 17.5 days.

Capitalizing on the demand for LVAD's along with providing a cost-effective design that can be more affordable for clients is of great significance and relevancy in the biomedical engineering field.

## SYSTEM LEVEL REQUIREMENTS AND CONSTRAINTS

Measures of Effectiveness (MOE) are measures designed to correspond to the accomplishment of mission objectives and the achievement of desired results. They quantify the results to be obtained by a system ensuring it will perform as required. Time and resource constraints will prohibit the precise verification procedures required for the compliance of the MOE's as proper functionality, biocompatibility, implantation and monitoring capacities evaluated from all global regulation agencies. For instance, most guidelines assessed from the International Organization of Standardization resembled in the ISO 10993 standard for the Biological Evaluation of Medical Devices in addition to the Title 21 Code of Federal Regulations part 870 from the Food & Drug Agency will not be entirely accomplished. As a categorical ventricular bypass or assist device (870.3545) for use in heart failure patients, every class III device requires either a pre-market approval or a completion notice of a product development protocol. Both requirements entail clinical testing with certain patients; any PMA application involves many volumes of material to be submitted to the FDA. The material may include device design, clinical studies, case report forms, manufacturing methods, even sterilization, packaging, and labeling at once. Considering these numerous constraints, customer expectations and objectives, as seen on **Table 2**, the team discussed the resulting MOE's for the consumer. These include cost, durability, portability, pyrogenicity, comfortability, and hemocompatibility. The cost factor was considered most important as research highlights the expensive prices for similar products found in the system's trade studies. This factor influences the patient's means of subsistence and their deep necessity for very much demanding this solution. Moreover, the hemocompatibility and pyrogenicity were regarded equally as important

because of their rehabilitative urgency. These needs are more concerned for the user's preemptive safety and healthy rehabilitation regarding the materials' implanted as their compatibility of the interaction with blood and potential release of pyrogens as substances that trigger a fever response when they make their way into the organism, respectively.

**TABLE 2: SPECIFICATIONS FOR MOE AND MOP ESTABLISHMENTS**

<b>Internal Clients</b>	Stakeholders, Polytechnic University of Puerto Rico
<b>External Clients</b>	HF patients, FDA, potential third-party companies, hospitals, and cardiologists
<b>Define Problem</b>	HF incidence has increased the demand for heart transplants and cannot meet its demand due to the lack of organ donors
<b>Objective</b>	Support patient's heart function with a short-term LVAD cost-effectively
<b>Customer Expectations</b>	Provide continual, yet easy real-time monitoring during the complex aftercare

On the other hand, comfortability, durability, and portability were observed as the less essential MOE's. These reflect an internal desire for the consumer to be fulfilled as a result of their lesser basic needs, interests, and motivations. For example, the weight of the final manufactured device will influence all these factors until rendering the load as unimportant due to satisfying their needs for a cheap, secure, and portable device. It is worth mentioning that the comfortability encompasses many degrees and activities of physiologically relaxing considerations. The importance of this factor was then deemed as critical for the effectiveness of this device contemplating the adequate consumption upon its physical and mental complacency; every type of client expects this device to provide a continual, yet simple cardiovascular monitoring during the complex aftercare of this surgical implant.

Finally, the durability and portability become essential as the patient needs to perform most of the activities of daily life practiced during the rehabilitation process and afterwards. More crucially, maintaining a certain monitoring capacity, device functionality

and biocompatibility for a predicted time is incredibly vital to every level of client from the stakeholders to the hospitals, patients, and their surgical physicians. Therefore, the portable potential to monitor the specific requirements supplied to the user through the external application will provide the necessary effectiveness to the customer's expectations. All MOE's along with their descriptions are listed at Error! Not a valid bookmark self-reference..

TABLE 3: SYSTEM LEVEL MOE'S

MOE's	
<b>Cost</b>	Must be cheap
<b>Comfortability</b>	Must be comfortable for user while wearing the device
<b>Durability</b>	Must be durable (withstand one year functionality)
<b>Portability</b>	Must be portable
<b>Pyrogenicity</b>	Must withstand capacity to work through pyrogenetic fever
<b>Hemocompatibility</b>	Must be easy interaction between device and blood

By weighing the MOE's evaluated by the different levels of clients beforehand, almost a dozen requirements or features were independently assessed as measurements of performance according to several regulation agencies, their respective guidelines and codes, environmental laws, and manufacturing/design protocols. The following governmental or public organizations utilized as guides for the compliance of the system's distinct performance categories were mainly the Food and Drug Agency's (FDA) code of federal regulations (CFR) title 21 part 820 and 870, a wide range of International Organization of Standardization (ISO) standards mainly for the testing of medical devices and their biological evaluation, and even some of the International Electrotechnical Commission (IEC) guidelines for embedded electronic controls. Other regulations and standards were also considered in conjuncture with the aforementioned organizations, such as: Distributed Interactive Simulations (DIS) as an IEEE standard used globally for

conducting real-time platform-level programming across multiple host computers and the Association for the Advancement of Medical Instrumentation (AAMI).

The DIS and AAMI served as focal points for many of the design, verification, and interphase procedures conducted during the course of the project. On the other hand, the last organization to submerge into the performance conditions was the American National Standards Institute (ANSI) for dimension requirements in the constructed drawings that served for many of the system's assemblies and components. Moreover, most of the future packaging, labeling, and manufacturing of the device will be gauged through the hinged evaluation from ANSI, AAMI, DIS, FDA, ISO, and IEC.

Measures of performance (MOP's) are measures design to quantify the accomplishment of mission performances and the achievement of desired results. The specific MOP's accorded will be categorized into three general clusters of compliance: functionality, biocompatibility & operability, and telemonitoring implantation capabilities. A list of all MOP's can be seen on **Table 4**. Some of the functional requirements included many dimensional technicalities and appropriate executions of base or derived quantities. The MOP's by functionality associated to the system's durability, portability, and comfortability from the aforesaid MOE's were the following: the rotor's length will be no more than 100 millimeters, the rotor's shaft will have a circumference of no more than 40 millimeters, the implanted pump will weigh less than 250 grams, and even the cost should be less than \$600 to manufacture.

Furthermore, other MOP's by functionality more connected to the pyrogenicity and hemocompatibility as the pump's motor should use a voltage of no more than 6 volts and the blood's volume flow should be optimal at 5.5 Liters/minute, respectively. All of these

functional MOP's can be fulfilled by following the protocols already discussed in the FDA Title 21 CFR 820.30, ISO 9001:1994, ANSI Y14, and even additionally in the subsection ISO/DIS 13485 for more modeling validation protocols in future analysis. **Table 5** lists all standards each MOP must comply.

TABLE 4: SYSTEM LEVEL MOP'S

MOP's	
<b>Functional Requirements</b>	Useful life expectancy will be one year of shelf life
	Rotor length will be no more than 100 mm
	Rotor will have a circumference of no more than 40 mm
	Volume flow should be optimal at 5.5 L/min
	Pump motor should use a voltage of no more than 6 V
	Implanted product will weigh less than 250 grams
<b>Biocompatibility</b>	Implanted product shall be water resistant
	Will withstand several temperature assessments for set periods of time
<b>Implantability</b>	Cost should be less than \$600
	Will monitor blood flow through external app
	Will monitor rotor speed (velocity) through external app

On the other hand, the biocompatibility category features a range of testing procedures to assess the adequate use for biological consumption after implantation, particularly in animals and humans. The prototype's weight and respective material were to be analyzed in this section for their strongest connections to all of the MOE's. The subsequent requirements for the biocompatibility assessment were that the system must withstand several temperature assessments for set periods of time and the implanted subassembly shall be water resistant. The system-level MOE's and MOP's relationships are further established in a Quality Function Deployment (QFD), as seen on **Figure 6**.

It is important to mention that the constraint of the material manufacturing limited the thorough analysis of this section into a proper clinical trial testing as phase I. Therefore, the proper qualification for approval by the appropriate organization were not required to be comprehensively performed. To properly complete the requirements for biocompatibility of certain medical devices that require Class III approval by PMA, HDE,

IDE, or PDP from the FDA, it is important to mention that both the FDA and ISO provide guidance documents for the International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Finally, the telemonitoring implantability classification will monitor any electrical and computational capability that the system must provide to the user.

**TABLE 5: STANDARDS OF MOP'S**

Standards (PMAs within FDA 21 CFR 820.30 Quality parameters)	MOP's
ASTDM D4169-09 and AAMI ANSI ISO 11607-1: 2006	Useful life expectancy will be one year of shelf life
FDA 21 CFR 820.30, SO 9001:1994 and ISO/DIS 13485	Rotor length will be no more than 100 mm
FDA 21 CFR 820.30, SO 9001:1994 and ISO/DIS 13485	Rotor will have a circumference of no more than 40 mm
ISO Biological evaluation of medical devices Part 1: Evaluation and Testing	Volume flow should be optimal at 5.5 L/min
ISO Biological evaluation of medical devices Part 1: Evaluation and Testing	Pump motor should use a voltage of no more than 6 V
FDA 21 CFR 820.30, SO 9001:1994 and ISO/DIS 13485	Implanted product will weigh less than 250 grams
ISO Biological evaluation of medical devices Part 1: Evaluation and Testing	Implanted product shall be water resistant
ISO Biological evaluation of medical devices Part 1: Evaluation and Testing	Will withstand several temperature assessments for set periods of time
FDA 21 CFR 820.30, SO 9001:1994 and ISO/DIS 13485	Cost should be less than \$600
AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1	Will monitor blood flow through external app
AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1	Will monitor rotor speed (velocity) through external app

Although the simple monitoring post-implantation is deeply linked to the cost and biocompatible factors, these features present a great influence to the patients monitoring this system. Consequently, the system will simply monitor blood flow and the motor's working voltage (indirect rotor velocity and power) through an external application viewed by a smart device. To comply with these specific programming codes and electrical circuitry controls, follow AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012.

Cost	6	9	3	3	1	1	3	1	3	144
Hemocompatibility	5	1	3	3	9	3	1	3	3	130
Pyrogenicity	4	3	1	1	3	9	3	9	3	128
Comfortability	3	3	3	3	3	1	9	3	9	102
Durability	2	3	9	9	1	3	3	9	9	92
Portability	1	3	9	9		1	9	3	9	43
UNITS	#	\$	mm	mm	L/min	V	g	°C	L/min & V	
			22	28	28	17	18	28	28	36

FIGURE 6: SYSTEM-LEVEL QFD

## RESOURCE BUDGET

Project resources are of great significance in the execution and completion of the LVAD with telemonitoring capabilities. The required resources include personnel, available time, equipment, and facilities. The main personnel ensuring the completion of the project are the Biomedical Engineering students/stakeholders shown on **Figure 2**. All required equipment and facilities were provided by the Biomedical Engineering Department at the Polytechnic University of Puerto Rico, as well as additional assistance and guidance from their staff. **Figure 7** showcase the main facility and equipment utilized

thought the project. Furthermore, the timeline for completion of the device was throughout the 2020-2021 academic year.



**FIGURE 7: REHABILITATION ENGINEERING AND INDUSTRIAL AUTOMATION LABORATORY**

No funding was provided for the completion of the device, the students working on the project were responsible to pay in full for all materials, software, or equipment the University did not provide. A preliminary cost analysis was done in order to establish the budget needed for the project execution. The approach for said cost analysis was to gather cost information on essential materials and equipment needed for project completion. Essential system-level materials at this point of the project include a microcontroller to automatically controlled the actions and features of the implantable medical devices, and the material for the LVAD pipes such as Titanium alloy or Polylactic acid (PLA). Table 6:**Table 6** provides a summary of the preliminary system-level cost analysis.

The unit cost for the design and manufacturing of the LVAD, according to the preliminary cost analysis, came at around \$600. Considering the low manufacturing cost and the expected large market size growth the project not only provides significance for clients but can potentially provide a large monetary gain for the stakeholders.

**TABLE 6: PRELIMINARY SYSTEM-LEVEL COST ANALYSIS**

<b>Material/ Other</b>	<b>Unit cost</b>	<b>Model, Brand</b>	<b>Description</b>
Microchip	\$50	Nano, Arduino	Smallest available motherboard
DC Motor	\$50	Brushless	Used for Fluid Flow
Battery	\$50	Li-Ion	Energy reservoir charged externally
Wiring	\$10	Male to Male	Used for circuit building
Filament	\$50-80/kg	PLA	3D printed material for pump pipes
Metal	\$75-100/kg	Titanium alloy	Material for pump pipes
Electronic components	\$50	Modules and Others	Used for circuit building
Software	\$0	Arduino	Programming, computational techniques
Workforce	\$0	Student provided	Design, Safety Analysis, Reports and Presentations
Equipment	\$0	University provided	3D printers, Soldering device, Laboratory tools
<b>Total Cost</b>	<b>\$600</b>		

To provide a cost-effective design that can be more affordable for clients, but at the same time provide a large monetary gain for stakeholders, a comparison between current devices on the market is needed. **Table 7** provides that comparison and shows in order to provide affordability the device should cost less than \$10,000. Even with a cost that low, the gain at a \$600 manufacturing investment possesses a very substantial monetary gain. A financial project plan as seen on

**Table 8**, was elaborated to project the gains based on an investment of \$600 and an initial selling price of \$5,000. Estimated earnings by 2025 are \$42,000,000 by selling 5000 units scaling its selling cost to \$9,000.

**TABLE 7: DEVICES IN MARKET COMPARISON**

<b>Model Name</b>	<b>Unit cost</b>	<b>Duration</b>
Duraheart	\$100,000	Long Term
Heartmate II	\$150,000	Long Term
Heartmate III	\$95,000	Long Term
Heartware	\$80,000	Long Term
CentriMag	\$10,000	Short Term

**TABLE 8: FINANCIAL PROJECT PLAN**

<b>Time Period</b>	<b>2021-2022</b>	<b>2023-2024</b>	<b>2025+</b>
<b>Unit cost</b>	\$600	\$600	\$600
<b>Selling Cost</b>	\$5,000	\$7,000	\$9,000
<b>Units Sold</b>	500	2000	5000
<b>Total Gross Income</b>	\$2,200,000	\$12,800,000	\$42,000,000

## RISK ESTIMATES

Risks potentially impact project's timeline, performance, or budget, and if they become realities, then they become classified as "issues" that must be addressed. Thus, it is important to go through the process of identifying, categorizing, prioritizing and planning for risks before they become issues in any engineering project. The team working on the LVAD with Telemonitoring capabilities identified and listed the risks involved that would affect the project's completion along with strategies to mitigate those risks, **Table 9** summarizes said list. Initial concerns were risks related to costs and planning, where the team was worried to spend more money than the allocated budget and that project tasks would take longer to complete than estimated. However, planning and applying mitigation strategies could minimize the occurrence or impact of these uncertainties, improving the chance of successful project completion. The strategies to reduce costs and scheduling risks include to accurately cost estimate, choose the most cost-effective materials and to carefully perform project planning for each Phase. Other potential risks relate to performance and governance. To mitigate said risks, in Phase A, a team member will be assigned the role of Systems Engineer. This team member will be tasked with managing and monitoring all installed systems and infrastructure. Furthermore, possibly the biggest risk that would affect the project's completion would be the ongoing COVID-19 pandemic due to the diverse restrictions and complications it could impose during the project development. Mitigating any uncertainties related to COVID-19 were established to be addressed by carefully performing project planning and following Safety and Quarantine Guidelines.

**TABLE 9: POTENTIAL RISKS INVOLVED THAT WOULD AFFECT THE PROJECT'S COMPLETION**

<b>Potential Risks</b>	<b>Mitigation Strategies</b>
1. Going Over Budget	Accurately Cost Estimate. Choose the Most Cost-Effective Materials.
2. Failing to Meet Schedule	Carefully Perform Project Planning for Each Phase.
3. Unable to Meet Wanted Performance	A Team Member must Have Role of Systems Engineer.
4. Governance Related Risks	A Team Member must Have Role of Systems Engineer. Follow MOP's Standards.
5. External Risks: COVID-19	Carefully Perform Project Planning Throughout Project Completion. Follow Safety and Quarantine Guidelines.

# PHASE A: CONCEPT & TECHNOLOGY DEVELOPMENT

## TECHNOLOGY ASSESSMENT

A systematic review of the technology requirements and solutions currently out there is needed to address the design and fabrication of a feasible, yet cost-effective continuous-flow LVAD with telemonitoring capacity for patients with advanced heart failure. Essentially, the technology of LVAD's found in the current literature was assessed to find a solution that's best suited for the project's requirements and environment. Diverse LVAD models were addressed for specific requirements or MOP's the Telemonitoring LVAD (TLVAD) highly valued. The models evaluated were the HeartMate III, Duraheart and Heartware, these models are listed along with their references in **Table 10**. The HeartMate III is a fully magnetically levitated centrifugal blood pump that allows for full hemodynamic support, possessing several important features that significantly improve its hemocompatibility. Furthermore, both the Duraheart and HeartWare models also possess a centrifugal pump with a magnetically levitated impeller or rotor that take advantage of a combination of magnetic and hydrodynamic forces. Even though all these models follow the same principles they differ in key specific requirements or MOP's relevant for the TLVAD.

TABLE 10: TECHNOLOGY ASSESMENT

Technology Assessed	Reference
HeartMate III	Pfister, R., Tozzi, P., Hullin, R., Verly, P., Jahns, F., Prêtre, R., & Kirsch, M. (2018, April 25). HeartMate 3 implantation via left antero-lateral thoracotomy to avoid resternotomy in high risk patients. <sup>8</sup>
Duraheart	Nishinaka, T., Schima, H., Roethy, W., Rajek, A., Nojiri, C., Wolner, E., & Wieselthaler, G. (2006). The DuraHeart VAD, a magnetically levitated centrifugal pump: The University of Vienna bridge-to-transplant experience. <sup>9</sup>
HeartWare	Carrel, T., Englberger, L., Kadner, A., & Mohacsi, P. (2013). Implantation of the continuous flow HeartWare® left ventricular assist device. Multimedia manual of cardiothoracic surgery. <sup>10</sup>

The addressed parameters in relation to the TLVAD's requirements or MOP's ranged from dimensionalities to function related requirements to maintain hemodynamic support. For instance, the pump dimensions and device weight were assessed to find solutions that complied with the project's MOE's of comfortability and portability. Ensuring patients with supported heart function while being able to resume their daily normal activities until a heart donor is made available. In terms of ideal values for the TLVAD system pump height and diameter are considered ideal at 50 mm and 45 mm, respectively. Ideal weight

Selling cost was also evaluated between the LVAD technologies addressing the project's cost and budget related requirements, ideally a selling cost of \$5,000 would fulfill the system's needs. The evaluated requirements for sustaining hemodynamic support were related to pump velocity, volume flow and the amount of monitored performance parameters via an external app or software. The pump velocity and volume flow are intrinsically related as the blood gains velocity and pressure via rotational energy from the blood passes through the rotor. The adequate range values for pump velocity and volume flow for the TLVAD system are 1,000 to 6,500 RPM and 4 to 8 L/min, respectively. Lastly, the amount of monitored performance parameters was heavily addressed since it is an essential component of the TLVAD system. Minimum two parameters should be monitored to comply with the system's MOP's. The technology assessment is illustrated on **Figure 8**, showing the different requirements along with their respective values per model.

<b>HeartMate 3</b>	<b>Duraheart</b>	<b>Heartware</b>
		
<b>Description</b>	<b>Description</b>	<b>Description</b>
<ul style="list-style-type: none"> <li>• Weight: 200g</li> <li>• Pump Height: 33.8 mm</li> <li>• Pump Diameter: 50.3 mm</li> <li>• Volume flow: 2 to 10 L/m</li> <li>• Pump Velocity: 3000-9000 rpm</li> <li>• Cost: \$95,000</li> <li>• Monitored Parameters: 5</li> </ul>	<ul style="list-style-type: none"> <li>• Weight: 540g</li> <li>• Pump Height: 45mm</li> <li>• Pump Diameter: 72mm</li> <li>• Volume flow: 2-10L/min.</li> <li>• Pump Velocity: 1200 to 2600 rpm</li> <li>• Cost: \$100,000</li> <li>• Monitored Parameters : 0</li> </ul>	<ul style="list-style-type: none"> <li>• Weight: 140g</li> <li>• Pump Height :33 mm</li> <li>• Pump Diameter: 49 mm</li> <li>• Volume flow: 1 to 10 L/m</li> <li>• Pump Velocity: 1000-2500 rpm</li> <li>• Cost: 80,000</li> <li>• Monitored Parameters: 0</li> </ul>

FIGURE 8: TECHNOLOGY ASSESSMENT CONOPS

In order to assess the different solutions, we have for our problem and choose the best one to match the TLVAD system-level requirements and MOP's the rating/weighting method was utilized as a decision matrix. The rating/weighting methodology relies on weighting the criteria based on their importance and then score the range of options from best solution (3) to worse solution (1) while intermediate values were obtained using interpolation. The full decision matrix can be seen on **Table 11**. The requirements described earlier served as a criterion for the decision. The most important criteria were the selling cost, volume flow and the amount of monitored parameters as each of them were weighted to 20%. The technologies weight and pump velocity were also deemed as of great importance, being weighted to 18% and 12%, respectively. Finally, the criteria considered less important were the pump's height and diameter dimensions as they were weighted to 5% each. Based on the decision matrix calculations, the best technology presently in the market to provide a solution best suited for the projects requirements and environment is the Heartmate III.

TABLE 11: RATING WEIGHTING DECISION MATRIX FOR TECHNOLOGY ASSESSMENT

Technology Assessment Decision Matrix					
Criteria	Value	Weight	Heartmate 3	Duraheart	HeartWare
Device Weight	250g	0.18	2.7	1	3
Pump Height	50 mm	0.05	2.9	1	3
Pump Diameter	45 mm	0.05	2.9	1	3
Pump Velocity	1,000 to 6,500 RPM	0.12	1	3	3
Volume Flow	4 to 8 L/min	0.20	3	3	1
Cost	\$5,000	0.20	1.5	1	3
Monitored Parameters	2	0.20	3	1	1
Total		1	<b>2.396</b>	<b>1.64</b>	<b>2.2</b>

## PROJECT/MISSION ARCHITECTURE AND INTERFACES

Engineering systems consist of elements or subsystems that interact with each other to accomplish an objective. The relations between the system and subsystems can be illustrated using a System Hierarchy Diagram. Represented on a block diagram, the System Hierarchy Diagram starts with the system as a whole and below its subsystem, then assemblies, subassemblies, components, and parts until reaching the lowest level of identifiable items. The TLVAD project consists of three subsystems: the heart pump, the controls, and the monitoring. During Phase A the System Hierarchy Diagram only possess two tiers, however it will become more detailed by adding more tiers as progress advances through the phases. The System Hierarchy Diagram for the TLVAD can be seen on **Figure 9.**

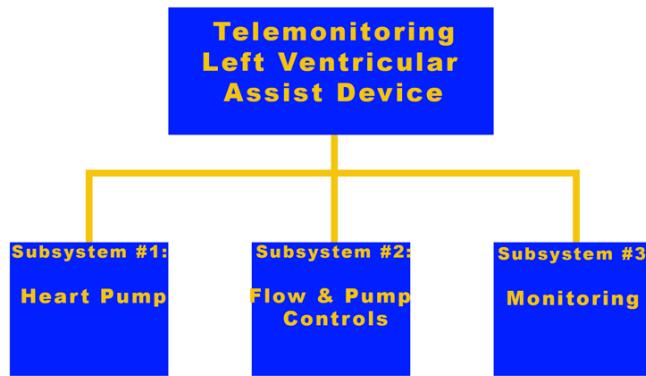


FIGURE 9: SYSTEM HIERARCHY DIAGRAM FOR THE TLVAD

After establishing the main subsystem for the TLVAD system it is important to establish the systems interfaces or interactions between subsystems and their main components. The  $N^2$  diagram is utilized to represent these functional or physical interfaces between the subsystems. The main interacting components in the TLVAD system are set to be the patients, microcontroller, pump, sensors and mobile app. Interaction will commence once the patient is implanted and connected to the LVAD device. Once device is connected, the microcontroller will signal the pump to move blood at a required flow rate and adjust the rotor speed according to its needs. This will commence the pump to start the blood flow from the left ventricle to the body. The sensor will then read the flow rate, which will register in the microcontroller, serving as a feedback input to adjust the rotor speed accordingly until ideal flow rate is achieved. If any high or low flow risks arise, the control system will inform patients via auditory and visual alarms. Pump performance parameters such as power and speed will be read by the microcontroller which will be transmitted along with the flow rate to the mobile app. These parameters will then be received and displayed in the mobile app for patient monitoring. Representation of the systems interfaces can be seen on the  $N^2$  diagram in **Figure 10**.

Patient	$o_1 \rightarrow$ Connection to System $I_2 \downarrow$			
$I_1 \uparrow$ Risk Alarms $\leftarrow o_2$	Microcontroller	$o_2 \rightarrow$ Signal Pump Move blood at X flow rate (L/min) $I_3 \downarrow$		
$I_1 \uparrow$ Flow blood to the body $\leftarrow o_3$	$I_2 \uparrow$ Pump Performance Reading $\leftarrow o_3$	Pump	$o_3 \rightarrow$ Blood Flow Rate $I_4 \downarrow$	
	$I_2 \uparrow$ Blood Flow Rate Reading $\leftarrow o_4$		Sensors	$o_4 \rightarrow$ Blood Flow Rate Reading (L/min) $I_5 \downarrow$
$I_1 \uparrow$ Performance Information $\leftarrow o_5$				Mobile App

FIGURE 10: TLVAD SYSTEM  $N^2$  DIAGRAM

## PROJECT PLANNING FOR SYSTEM AND SUBSYSTEMS

The execution and completion of the TLVAD project relied heavily on the project planning done throughout the academic year. Certain project management and system engineering techniques were applied for the team to achieve goals and meet success criteria at a specified time. A work-breakdown structure (WBS) was utilized to illustrate the total scope of work to be carried out by the team to accomplish the project objectives. This hierarchical decomposition of the project into phases can be seen on **Figure 11**.

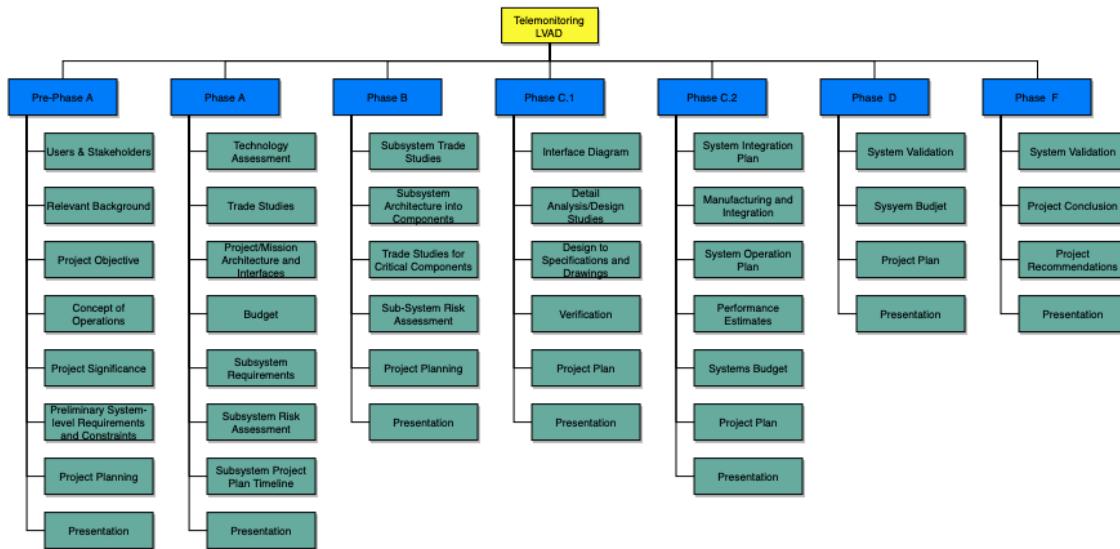


FIGURE 11: TLVAD CAPSTONE PROJECT WBS

Another project management tool that the team heavily relied on to complete the TLVAD project were Gantt charts. Planning and scheduling utilizing these tools were useful for simplifying the complexity of the project. The scheduling of key tasks is divided into two Gantt charts for the Capstone I and Capstone II portions of the project. These charts can be seen in both **Figure 12** and **Figure 13**, respectively. Both Project management timelines include key tasks for each phase, show the start and end dates, as well as dependencies, and who is the task owner.

	ACTIVITIES	ASSIGNEE	START	DUe	DPD	Aug 2020 03 10 17 24 31 07 14 21 28 05 12 19 26 02 09 16 23 30	Sep 2020	Oct 2020	Nov 2020
	<b>Pre-Phase A:</b>		10/Aug	03/Sep					
1	✓ Users and Stakeholders	Group	10/Aug	12/Aug					
2	✓ Background Information	Alexander M. M...	13/Aug	18/Aug					
3	✓ Project Objectives	Alexander M. M...	18/Aug	21/Aug	2				
4	✓ Concept of Operations	Alexander M. M...	23/Aug	27/Aug	3				
5	✓ Project Significance	Stephanie Muñiz	27/Aug	27/Aug	4,3				
6	✓ Preliminary System-level Requirements	Carlos F. Gonzalez	27/Aug	02/Sep	3				
7	✓ Project Planning	Group	02/Sep	02/Sep					
8	✓ Presentation	Group	03/Sep	03/Sep					
	<b>Phase A:</b>		07/Sep	18/Sep					
	<b>Phase B:</b>		24/Sep	09/Oct					
24	✓ Subsystem Trade Studies	Group	24/Sep	29/Sep	-1, 6				
25	✓ Subsystem Architecture into Components	Group	29/Sep	30/Sep	24, 6				
26	✓ Sub-System Risk Assessment	Group	02/Oct	06/Oct	25				
27	✓ Project Planning	Group	08/Oct	08/Oct	26				
28	✓ Presentation	Group	09/Oct	09/Oct					
	<b>Phase C.1:</b>		11/Oct	24/Oct					
30	✓ Interface Diagram	Group	11/Oct	15/Oct	6				
31	✓ Detail Analysis/Design Studies	Group	15/Oct	17/Oct					
32	✓ Design to Specifications and Drawings	Group	17/Oct	22/Oct	31, 30				
33	✓ Verification	Group	23/Oct	23/Oct	32, 31				
34	✓ Project Plan	Group	23/Oct	23/Oct					
35	✓ Presentation	Group	24/Oct	24/Oct					

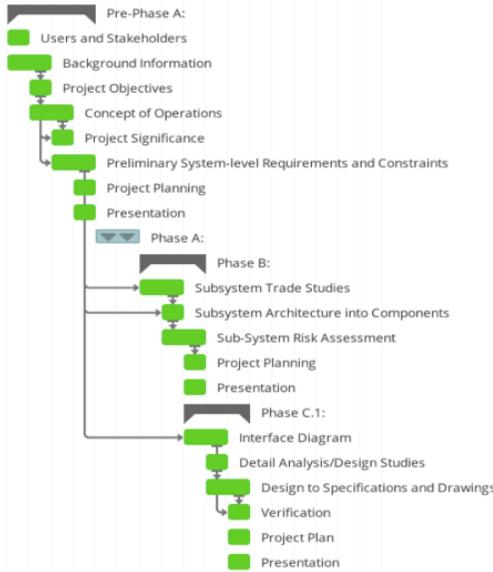


FIGURE 12: CAPSTONE I TIMELINE

Phases C.2 through phase D encompass lots of verification and validation processes on the end product. Where procedures must demonstrate the end product satisfies its MOE's and MOP's. A team member must take the role of a systems engineer, to ensure the TLVAD complies with its required performances. The student taking this role was Alexander M. Martinez Lopez and was tasked with installing, configuring, testing, and monitoring all installed systems and infrastructure.

	ACTIVITIES	ASSIGNEE	START	DUe	DPD	Nov 2020 09 16 23 30 07 14 21 28 04 11 18 25 01 08 15 22 01 08 15 22 29 05 12 19 26	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021
	<b>Phase C.2:</b>		21/Nov	11/Dec							
1	✓ System Integration Plan	Alexander M. M...	21/Nov	24/Nov							
2	✓ System Operation Plan	Alexander M. M...	24/Nov	29/Nov	1						
3	✓ Manufacturing and Integration	Stephanie Muñiz	30/Nov	03/Dec	1						
4	✓ Performance Estimates	Carlos F. Gonzalez	04/Dec	06/Dec	2,1						
5	✓ Systems Budget	Carlos F. Gonzalez	07/Dec	08/Dec	3,1						
6	✓ Project Plan	Group	10/Dec	10/Dec							
7	✓ Presentation	Group	11/Dec	11/Dec							
	<b>Phase D:</b>		15/Dec	16/Feb							
9	✓ System Validation Plan	Alexander M. M...	15/Dec	10/Feb	-1,5						
10	✓ Prototype Construction	Group	15/Jan	10/Feb	9						
11	✓ System Budget	Group	13/feb	13/feb	10						
12	✓ Project Plan	Group	15/feb	15/feb							
13	✓ Presentation	Group	16/feb	16/feb							
	<b>Phase E:</b>		27/Feb	15/Mar							
15	✓ System Validation	Group	27/Feb	03/Mar	9						
16	✓ Project Conclusion	Group	04/Mar	07/Mar	15						
17	✓ Project Recommendations	Group	07/Mar	07/Mar	15						
18	✓ Presentation	Group	15/Mar	15/Mar							

FIGURE 13: CAPSTONE II TIMELINE

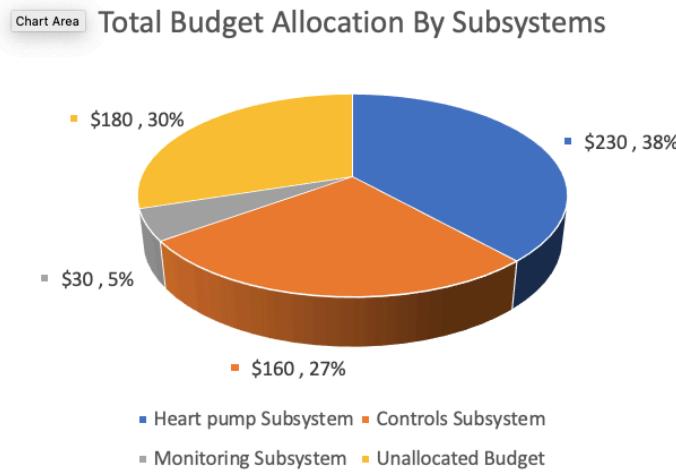
Any resources relating to materials, software, or equipment the University did not provide, the students working on the project were responsible to pay in full using their \$600 budget. Important components or materials were assessed through diverse trade studies to find the best cost-effective solutions (**Subsystem Architecture into Components**). Due to the COVID-19 restrictions most materials were obtained through online shopping.

With an estimated budget and preliminary system-level cost analysis in place, the TLVAD team allocated their budget designated to each subsystem. Based on the preliminary system-level cost analysis the subsystem with most budget allocation should be the heart pump, followed by the controls and then monitoring. **Table 12** relates each preliminary set of materials for each subsystem.

**TABLE 12: BUDGET ALLOCATION BASED ON MATERIALS**

Material/ Other	Cost	Subsystem
Microchip	\$30	Controls
DC Motor	\$50	Heart Pump
Battery	\$50	Controls
Wiring	\$10	Controls/Monitoring
Filament	\$80	Heart Pump
Metal	\$100	Heart Pump
Electronic Modules	\$20	Controls
Monitoring Modules	\$20	Monitoring
Flow Sensor	\$20	Controls
Testing Equipment	\$30	Controls
Software	\$0	Controls/Monitoring
Workforce	\$0	All
Manufacturing Equipment	\$0	Heart Pump
<b>Total Cost</b>	<b>\$420</b>	

The heart pump subsystem was allocated \$230 or 38.33% of investment, since the materials for the design are the most expensive materials. The control system was allocated \$160 or \$26.66% of investment, due to it containing several electronic modules, batteries and the microchip. Finally, the monitoring subsystem was allocated \$30 or 5.5% of investment, for monitoring modules and their wiring. **Figure 14** illustrates the budget allocation by subsystem.



**FIGURE 14: BUDGET ALLOCATION BY SUBSYSTEMS**

## **SUB-SYSTEM LEVEL REQUIREMENTS AND CONSTRAINTS**

### **HEART PUMP SUBSYSTEM**

**Table 13** accurately depicts the necessary standards for compliance of a working heart pump sub-assembly. The most important standards for evaluation for this sub-system were the pre-market approval (PMA) by FDA 21 CFR 820 as Quality parameters in design and manufacturing and ISO 10993-1 as the Biological Evaluation of Medical Devices. For example, the pump's dimensions were evaluated with the FDA 21 CFR 820 and the ISO 9001:1994, and ISO/DIS 13485. It is already known that the ISO/DIS standard is for physiological modeling verification procedures. On the other hand, the ISO 9001:1994 is another standard for comparison of the FDA 21 CFR 820 Quality parameters in system designs. Nevertheless, every other measurement of performance was evaluated using the standard ISO 10993-1 to assess the adequate rate of the blood flow, motor velocity and voltage, heart pump weight, and even the overall cost or water resistance.

**TABLE 13: HEART PUMP SUBSYSTEM-LEVEL MOP'S WITH STANDARDS**

Standards (PMAs within FDA 21 CFR 820.30 Quality parameters)	MOP'S
FDA 21 CFR 820.30 and ISO 9001:1994 and ISO/DIS 13485	Pump height will be about 50mm and pump diameter will be about 45mm
FDA 21 CFR 820.70; ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	The blood flow should be 4 to 8 L/min L/min
FDA 21 CFR 820.70;ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	Pump velocity should be no more than 1,000 to 6,500 RPM
FDA 21 CFR 820.70;FDA 21 CFR 820.30 and ISO 9001:1994 and ISO/DIS 13485	Weight should be less than 250g
FDA 21 CFR 820.70;FDA 21 CFR 820.30 and ISO 9001:1994 and ISO/DIS 13485	Pump cost should be around the \$300.00
ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	Pump will be water resistant

## CONTROLS SUBSYSTEM

**Table 14** precisely illustrates the required standards for compliance of an electronic control subsystem in a working ventricular assist device. The most important standards for evaluation for this sub-system were the pre-market approval (PMA) by FDA 21 CFR 820 as Quality parameters in design and manufacturing of an electronic controls for a medical device. On the other hand, the embedded assessment from the standards of AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012 also evaluated every measurement of performance discussed for this subsystem. For example, the pump's calculations of blood flow, rotor speed, pump power were designed with these compliance standards in mind. Conversely, it is already known that the AAMI ANSI IEC 62304:2006 and FDA 21 CFR Sec. 820.70 were the main standards assessed for the regulation of the motor's voltage and the pump's blood flow output. It is important to mention that the AAMI ANSI IEC 62304:2006 general standard gauges medical device software compliance with their own rules and guidelines for performance.

**TABLE 14: CONTROLS SUBSYSTEM-LEVEL MOP'S WITH STANDARDS**

Standards (PMAs within FDA 21 CFR 820.30 Quality parameters)	MOP'S
AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012, FDA 21 CFR Sec. 820.70	Will measure blood flow output (L/min)
AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012, FDA 21 CFR Sec. 820.70	Will calculate pump rotor speed (rpm)
AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012, FDA 21 CFR Sec. 820.70	Will calculate pump power (W)
AAMI ANSI IEC 62304:2006, FDA 21 CFR Sec. 820.70	Must regulate motor voltage (V)
AAMI ANSI IEC 62304:2006, FDA 21 CFR Sec. 820.70	Must regulate pump blood flow output (L/min)

## MONITORING SUBSYSTEM

**Table 15** specifically explains the mandatory benchmarks for the adequate fulfillment of a telemonitoring subsystem through an external application in a working ventricular assist device. The most important standards for evaluation for this sub-system were the pre-market approval (PMA) by FDA 21 CFR 820 as Quality parameters in design and manufacturing of a telemonitoring application for a medical device. Conversely, the embedded assessment from the standards of AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012 also measured the pump's discussed for this subsystem with its own electronic controls. For example, the pump's power, changes in pump velocity, and continuous blood flow output were designed with these compliance standards in mind. It is readily recognized that the AAMI ANSI IEC 62304:2006 and FDA 21 CFR Sec. 820.70 were the main standards assessed for the regulation of the motor's voltage and the pump's blood flow output.

It is important to mention that the AAMI ANSI IEC 62304:2006 general standard gauges medical device software compliance with their own rules and guidelines for

performance that are profoundly intertwined with the subsystem of electronic controls. On the other hand, the FDA Class I (General Controls) Title 21 CFR Section 880.6310 particularly evaluates the computing power stored, converted, transferred, and displayed from electronical medical device data to another general device like a smartphone.

**TABLE 15: MONITORING SUBSYSTEM-LEVEL MOP'S WITH STANDARDS**

Standards <small>(PMAs within FDA 21 CFR 820.30 Quality parameters)</small>	MOP'S
FDA Title 21 CFR Sec. 820.70(i) Production and Process Controls: Automated Processes & FDA Title 21 CFR Sec. 820.30(a) Design Controls: Verification (f)	Shall validate computer software for its intended use according to an established protocol. Shall establish and maintain procedures for verifying the device design.
FDA Class I (General Controls) Title 21 CFR Sec. 880.6310	Will transfer and display of electronic medical device data to smartphone (Mbps)
FDA Class I (General Controls) Title 21 CFR Sec. 880.6310	Will electronically convert medical device data from one format to another format in accordance with preset specifications and store medical device data from one device to another (GB)
AAMI ANSI IEC 62304:2006, AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, c1:2009/(R)2012 and A2:2010/(R)2012, FDA 21 CFR Sec. 820.70	Will monitor pump power (W)
AAMI ANSI IEC 62304:2006, FDA 21 CFR Sec. 820.70	Must monitor changes in pump velocity (rpm)
AAMI ANSI IEC 62304:2006, FDA 21 CFR Sec. 820.70	Must monitor continuous pump blood flow output (L/min)

## SUB-SYSTEM RISK ASSESSMENT

Risk assessments are a valuable and integral part of systems engineering, especially in the biomedical engineering field. The following chapter focuses on identifying, evaluating hazards and determine appropriate ways to mitigate the risks at a subsystem-level. The risk assessment matrix will be found on **Subsystem Architecture into Components**.

## HEART PUMP SUBSYSTEM

As with any surgical procedure, especially with implantable devices, LVAD implantation is associated with adverse events. Such complications of LVAD therapy include bleeding, infection, pump thrombosis, right heart failure, device malfunction, and stroke. Infections occur most frequently around driveline exit sites because they create an ideal environment for the formation of bacterial biofilms [11]. Formation of blood clots or hemolysis occur due to abnormal blood flow caused pump malfunctions which can ultimately lead to heart stroke. Device malfunctions can also lead to right heart failure, as the right ventricle is forced to pump blood and becomes weak. All aforementioned risks are assessed on their likelihood of occurrence and the severity of their consequences using a risk assessment matrix found on **Figure 27**: Heart pump subsystem risk assessment matrix.

Among all the mentioned risks, the formation of blood clots, and occurrence of hemolysis or heart stroke are considered high risks. They all possess a high severity of permanent heart damage and even death if symptoms are aggravated. The three risks are also considered likely or near certain to occur. However, there are potential mitigation strategies patients can take to reduce the adverse effects of these risks. Blood clot formation and hemolysis can be treated using anticoagulant drugs, which slow down these processes. Furthermore, heart stroke prevention therapies include the use of anticoagulant drugs and antiplatelet agents. The latter reduces the occurrence of platelet aggregation in the bloodstream. Other potential hazards are considered low risks due to their low likelihood and severity. Driveline infections can easily be treated with antibiotics to prevent adverse effects. In addition, risks related to power failure can be reduced by using backup

rechargeable lithium-ion batteries. Finally, right heart dysfunction can be reduced by maintaining and monitoring the device produces the optimal blood flow. A list of mitigation strategies for each risk can be seen on **Table 16**.

TABLE 16:HEART PUMP SUBSYSTEM RISKS AND MITIGATION STRATEGIES

Risks	Mitigation Strategies
Driveline infections	Can be treated with antibiotics
Blood clots (caused by a circulatory failure)	Can be treated with anticoagulants drugs (Doctor's discretion)
Power failure (factors related with physical hardware)	Use Lithium Rechargeable Batteries that Posses 2 to 3 years of Battery Life
Internal Bleeding (caused after the LVAD implantation)	Treatment involves the administration of intravenous vitamin K, fresh frozen plasma, blood, and platelets
Right Heart Dysfunction	Monitor blood flow constantly
Heart Stroke	Anticoagulant drugs and antiplatelet agents.
Hemolysis (damage to blood cells due to the pump)	Coagulant drugs (Ex. Ibuprofen, Naproxen) and blood transfusion

## CONTROLS SUBSYSTEM

The control system in the TLVAD provides critical function to the product by providing the desired response by controlling the output. Therefore, risk assessment is crucial to ensure patients safety. Complications of control systems in LVAD's include controller failure, power issues and device malfunctions. The latter can happen due to incorrect readings, erroneous regulation or incorrect cable connection. Failed power supplies and discharged batteries are common in LVAD devices due to their portable nature. Hardware and software issues can also occur. Microcontrollers with low reliability or with imperfections from manufacturing can fail proving to be catastrophic for patients, because the device will cease to function. Furthermore, the implanted sensor can read incorrect flow rates leading to erroneous of the heart pump. All risks are assessed on their likelihood of occurrence and the severity of their consequences using a risk assessment matrix found on **Figure 32**.

Other potential hazards are considered medium risks due to their low likelihood and high severity. Most hazards in the control subsystem risk assessment are deemed high risks because if the controls fail the whole system will as well. Incorrect sensor readings or erroneous regulation of pump parameters can cause severe damage through pump thrombosis. To mitigate those risks accurate sensors will be utilized and an alarm system will be implemented. On the other hand, there is a low risk of alarm fatigue, which is the desensitization of patients towards alarms. It is unlikely to happen and does not present major danger. However, as a mitigation strategy the alarm system will use a small threshold of alarming parameter range. A list of risks and their mitigation strategies for each risk can be seen on **Table 17**.

**TABLE 17: CONTROLS SUBSYSTEM RISKS AND MITIGATION STRATEGIES**

Risks	Mitigation Strategies
Failed Power Supply	Use a Backup Battery and Microcontroller as Power Supply
Batteries Discharged	Use Lithium Rechargeable Batteries that Posses 2 to 3 years or 300 to 500 Charge Cycles of Battery Life
Incorrect Sensor Readings	Use Accurate and Reliable Flow Sensor
Alarm Fatigue (Patient Desensitization Towards Alarms)	Use Small Threshold of Alarming parameter Range
Incorrect Connection of Modular Cable	Provide Correct Orientation for Electrical Connection
Microcontroller Failure	Use a Microcontroller with High Reliability, such as Arduino
Erroneous Regulation of Pump Parameters (Pump Thrombosis)	Implement Failure Alerts for Patient Safety

## MONITORING SUBSYSTEM

The monitoring aspect of the TLVAD allows continuous assessment of device parameters by patients, family, or caregivers at home, which mitigates certain risks associated to the heart pump subsystem. However, the monitoring subsystem holds potential hazards as well. Complications that can arise from the monitoring aspect are failed power supplies, controller failure, alarm fatigue, unsynchronized monitoring along

with hardware or software errors can lead to adverse effects. Most of these have already been covered, since they are heavily tied into the control's subsystem. See **Controls Subsystem** for detailed explanations on hardware or software errors from power failures, incorrect sensor readings, alarm fatigue and incorrect cable connection. On the other hand, exclusive risks on the monitoring subsystem include hacking into application interphase and providing an unsynchronized monitoring of pump parameters. All aforementioned risks are assessed on their likelihood of occurrence and the severity of their consequences using a risk assessment matrix found on **Figure 36**.

Mitigation strategies can also be implemented to reduce the risks related to the monitoring subsystem. In order to reduce unsynchronized monitoring, verification procedures will be followed to test optimal monitoring is achieved. Firewall protection will be added to the software to minimize any hazards related to hacking, therefore improving patient safety. A list of mitigation strategies for each risk can be seen on **Table 18**.

TABLE 18: MONITORING SUBSYSTEM RISKS AND MITIGATION STRATEGIES

Risks	Mitigation Strategies
Failed Power Supply	Use a Backup Battery and Microcontroller as Power Supply
Crashing from hardware problems or software errors (operating system failure)	Use accurate yet reliable resolution parameters
Incorrect Sensor Readings	Use minute threshold of Alarming Range
Alarm Fatigue (Desensitization towards alarms)	Provide Correct Orientation for Electrical Connections
Incorrect connection in cables or wiring of telemonitoring system	Use a Microcontroller with High Reliability like an Arduino
Hacking into application interphase	Implement Firewall protection for Patient Safety
Unsynchronized Monitoring of Pump Parameters (by complications or offset of usage)	Verify Optimal Monitoring is Achieved Before Implantation.

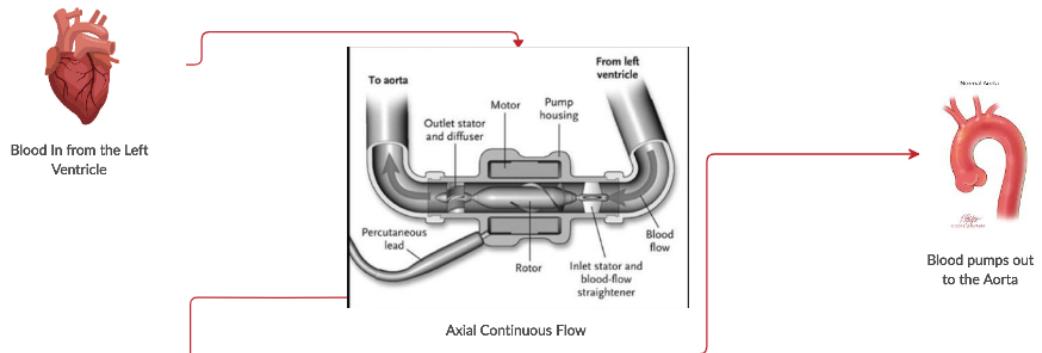
## **PHASE B: PRELIMINARY DESIGN AND TECHNOLOGY COMPLETION**

### **TECHNOLOGY DEVELOPMENT**

Systematic reviews of the technology requirements and solutions currently out there is needed to comply with the MOP's at the subsystem-level. Essentially, the technology found in the current literature was assessed to find a solution that is best suited for each subsystem requirements and environment.

### **HEART PUMP SUBSYSTEM**

The heart pump is the figurative heart of the entire system. An essential medical device, such as LVADs, require a motorized rotor to move the blood flow at a controlled state. The pump's system in the TLVAD physically pushes the blood optimally. Therefore, it is critical to utilize the adequate components that will be best suited for the consumer's requirements from their own anatomy. The heart pump systems gauge for the TLVAD and serves as the sensor for feedback control. A plethora of pumps were evaluated according to the changes they caused in blood according with their particular working mechanisms, such as: axial continuous flow, centrifugal-flow, and even pulsatile flow systems. For most TLVADs, a continuous flow pump system, sometimes with an appropriate electromagnetic suspension, will maintain a fixed, yet optimal motor voltage to provide a stable output as the blood flow and heart rate. According to Cheng (2014), continuous-flow VADs have demonstrated improved reliability and durability compared to the first generation pulsatile-flow left ventricular assist devices. **Figure 15** represents an axial continuous flow pump model for the TLVAD. The input will be the blood entering the pump and the output will be the adjusted blood flow that exits through the connection of the Aorta artery.



**FIGURE 15: AXIAL CONTINUOUS FLOW PUMP MODEL**

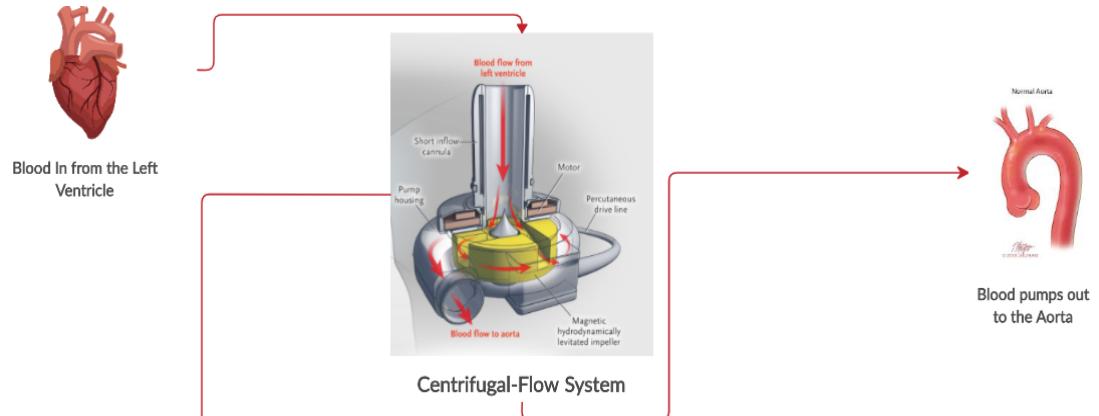
Assessment of the axial continuous flow pump in terms of the subsystem requirements or MOPs discussed in **Controls Subsystem** can be seen in **Table 19**. Axial continuous flow pumps permit constant rotor speed and simple calculation changes through the voltage applied to the motor. The pump speed can be set to the working range of approximately to 3000 RPM. Moreover, the pump's dimensions like weight, rotor length, motor diameter, working voltage, volume flow, and even water resistance were also evaluated. However, a set operating fix does not make automated blood flow regulation possible and will not possess any dead time.

**TABLE 19: AXIAL CONTINUOUS FLOW PUMP ASSESSMENT VALUES**

Axial continuous flow pump	
Weight (g)	180 g
Investment cost (\$)	\$150.00
Motor Diameter (mm)	50.3 mm
Motor Velocity (rpm)	3000 rpm
Volume Flow (L/min)	2-10 L/min
Length (mm)	50 mm
Water resistance	Yes

Other assessed heart pump systems were the centrifugal flow system and pulsatile flow system. Centrifugal flow is similar to axial flow in regard to the continuous delivery of blood flow throughout the body. On the other hand, most pulsatile flow is a first generation VAD that intend to mimic the heart mechanism for pumping blood into the body by using rhythmic pulses to push the blood out of the heart. For the TLVAD mechanism,

a continuous flow pump will allow more durability and reliability for the one-year functionality. Continuous pumping and constant regulation should in theory reduce ventricular suction. **Figure 16** represents a centrifugal flow model for the possible TLVAD pump. The input will be the blood flow rate entering the pump and then the pump will adjust the working voltage to reach the needed speed that best provides the blood flowrate setpoint. This will happen continuously and will depend on the sensors feedback.



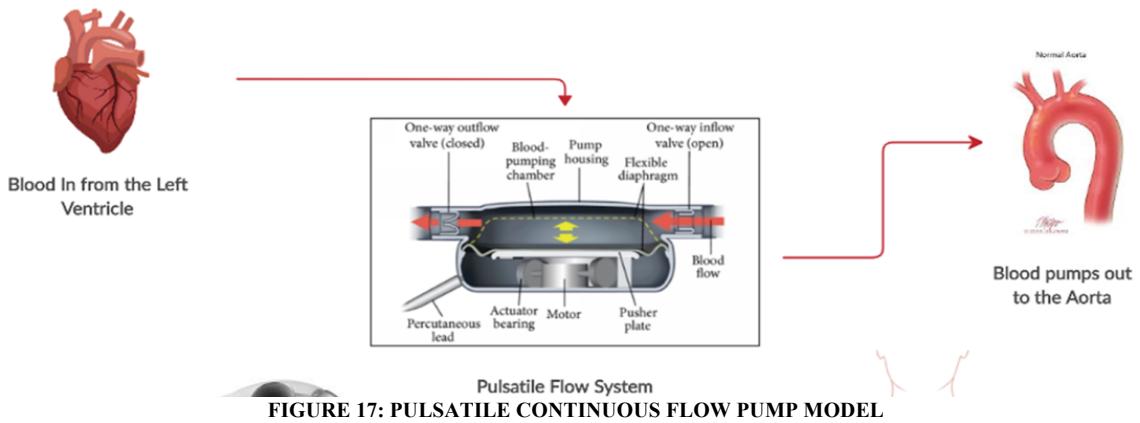
**FIGURE 16: VENTRIFUGAL FLOW PUMP MODEL**

Assessment of the centrifugal flow pump systems in terms of the subsystem requirements or MOP's can be seen in **Table 20**. Just like the previous control system, the centrifugal flow permits pump speed calculation through the voltage applied to the motor. The pump speed can also be regulated between the working range at approximately 2600 RPM. In comparison, this model presents a lower range of volume flow and is heavier, longer, and more expensive than its continuous flow counterpart. However, this option also presents water resistance.

**TABLE 20: CENTRIFUGAL FLOW PUMP ASSESSMENT VALUES**

Centrifugal flow pump	
Weight (g)	210 g
Investment cost (\$)	\$250.00
Motor Diameter (mm)	48 mm
Motor Velocity (rpm)	2600 rpm
Volume Flow (L/min)	1-8 L/min
Length (mm)	95.5 mm
Water resistance	Yes

The final solution assessment for the heart pump subsystem is based on the original blood pumping technique of pulsatile flow pump systems. Pulsatile flow is the simplest method for fluid volume changes. These set of controls simply push the incoming blood out of a pusher plate into a desirable state regulated by the motor which is operated by the controls' subsystem. A pulsatile flow pump, see **Figure 17**, does not have intermediate states, but only fully ON or fully OFF states by activating the pusher plate or staying in rest mode, respectively.



Assessment of the pulsatile flow pump systems in terms of the subsystem requirements or MOP's can be seen in **Table 21**. Just like the all the previous control systems, the pulsatile flow pump permits pump speed calculation through the voltage applied to the motor. The pump speed can also vary between the working range of 2000 RPM depending on the amount of voltage the motor receives. It cannot provide adequate regulation as it reaches close to its setpoint even though it will not stay consistently there. Moreover, the pump diameter, weight, and investment cost were significantly larger than the axial continuous flow pump. In comparison with this preferable option, the pulsatile flow pump system renders a similar pump length, volume flow, and positive water resistance.

TABLE 21:PULASTILE FLOW PUMP ASSESSMENT VALUES

Pulsatile flow pump	
Weight (g)	210 g
Investment cost (\$)	\$250.00
Motor Diameter (mm)	48 mm
Motor Velocity (rpm)	2600 rpm
Volume Flow (L/min)	1-8 L/min
Length (mm)	95.5 mm
Water resistance	Yes

Pump subsystem selection was performed utilizing the rating/weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were all weighed to 20% from the capabilities of the system to be lightweight, inexpensive, and cover the readings or adjustments of blood flow and pump velocity. On the other hand, the possible water resistance and pump diameter were each accounted for 5% of the weight due. Finally, the pump's height weighed in at 10. The full decision matrix can be seen on **Table 22**. Based on the decision matrix calculations, the best pump system presently in the market for our patient's needs to provide a solution best suited for the projects requirements and environment is the axial continuous flow pump system.

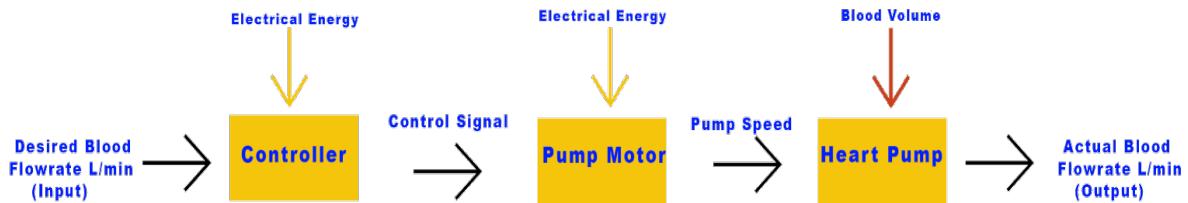
TABLE 22: RATING WEIGHTING DECISION MATRIX FOR PUMP SELECTION

Control System Selection Decision Matrix					
Criteria	Value	Weight	Axial continuous flow pump	Pulsatile flow pump	Centrifugal flow pump
Weight (g)	150 g	0.20	3	2	1
Height (mm)	45 mm	0.10	2.6	1	3
Diameter (mm)	50 mm	0.05	2.76	3	1
Pump Speed (RPM)	2000 RPM	0.20	1.9	1	3
Volume Flow (L/min)	5.5 L/min	0.20	3	1	3
Cost (\$)	\$200.00	0.20	2.33	1	3
Water Resistance	Yes	0.05	3	3	3
	Total	1	2.655714	1.714286	2.428571

## CONTROLS SUBSYSTEM

Control systems are essential in medical devices, such as LVADs, that require to regulate or obtain certain outputs. The control system in the TLVAD controls the heart

pump, monitoring and alarm systems. Hence, it is critical to utilize an adequate system of controls best suited for the application and its requirements. The control systems asses for the TLVAD were open loop control systems, PID feedback control system and ON/OFF feedback control system. Open loop control systems possess no feedback; therefore, the output will have no effect on the control action. For the TLVAD controls, an open loop system will maintain a fixed speed to provide a fixed output. Most LVAD technologies in the market operate using this principle. However, they increase risks of ventricular since they keep the same speed even with low end diastolic volumes. **Figure 18** represents an open loop control model for the TLVAD application. The input will be the desired blood flow rate or rotor speed, then the controller will signal the motor or apply the needed voltage to reach the fixed pump speed.



**FIGURE 18: OPEN LOOP LVAD MODEL**

Assessment of the open loop control systems in terms of the subsystem requirements or MOP's discussed in **Controls Subsystem** can be seen in **Table 23**. Open loop controls permit pump speed calculation through the voltage applied to the motor. The pump speed can be set to the MOP requirement range of 1,000 to 6,500 RPM. However, this system will not measure the blood flow as there is no feedback, therefore utilizing only two major components (Controller and Motor). A set operating fix does not make blood flow regulation possible and will not possess any dead time.

TABLE 23: OPEN LOOP ASSESSMENT VALUES

Open Loop Control Values	
Pump Speed Calculation (RPM)	Yes
Blood Flow Measurement (L/min)	N/A
Set Pump Speed (RPM)	1,000 to 6,500 RPM
Blood Flow Regulation	No
Dead time	N/A
Major Components	2
Calculate other Pump Parameters	Yes

Other assessed control systems were PID feedback control system and ON/OFF feedback control systems. PID control drives a system towards a target position or level. Automation or regulation is achieved using closed-loop control feedback to keep the actual output from a process as close to the target or setpoint output as possible. For the TLVAD controls, a closed loop system will allow regulation of the blood flow by regulating the voltage applied to the motor. Continuous regulation should in theory reduce ventricular suction. **Figure 19** represents an PID feedback control model for the TLVAD application. The input will be the desired blood flow rate, then the controller will signal the motor or apply the needed voltage to reach the needed speed that best provides the blood flowrate setpoint. This will happen continuously and will depend on the sensors feedback signal.

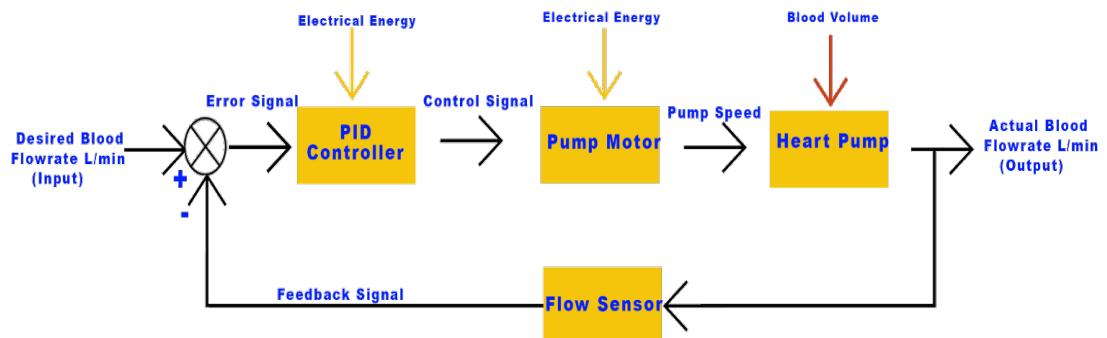


FIGURE 19: PID FEEDBACK CONTROL SYSTEM LVAD MODEL

Assessment of the PID closed loop control systems in terms of the subsystem requirements or MOP's can be seen in **Table 24**. Just like the previous control system, the PID controls permits pump speed calculation through the voltage applied to the motor. The

pump speed can also be regulated between the MOP requirement range of 1,000 to 6,500 RPM. This set of controls allows blood flow regulation, using the blood flow measurements as feedback signals. Hence, it utilizes the controller, motor and sensor as major components. The dead time in these set of controls is usually very low.

**TABLE 24: PID FEEDBACK CONTROL LOOP ASSESSMENT VALUES**

<b>PID Controls</b>	
Pump Speed Calculations (RPM)	Yes
Blood Flow Measurement (L/min)	2 to 8 L/min
Pump Speed (RPM)	1,000 to 6,500 RPM
Blood Flow Regulation	Yes
Dead time	Low
Major Components	2
Calculate other Pump Parameters	Yes

The final solution assessment for the control subsystem is based on the ON/OFF feedback control systems. On-Off control is the simplest form of feedback control. These set of controls simply drive the manipulated variable from fully closed to fully open depending on the position of the controlled variable relative to the setpoint. An on-off controller does not have intermediate states but only fully ON or fully OFF states. For the TLVAD controls, a closed loop feedback system like this one will not allow regulation of the blood flow. However, it will allow the system to reach close to its setpoint even though it will not stay consistently there. **Figure 20** represents an PID feedback control model for the TLVAD application. The input will be the desired blood flow rate, then the controller will signal the motor to turn ON until it reaches the blood flowrate setpoint. When it reaches the setpoint it will turn OFF. This will happen continuously and will depend on the sensors feedback signal.

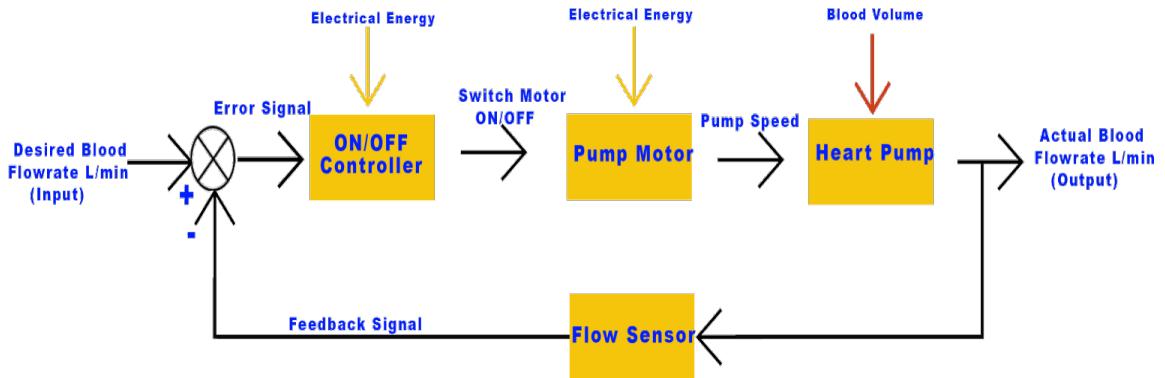


FIGURE 20: ON/OFF FEEDBACK CONTROL SYSTEM LVAD MODEL

Assessment of the ON/OFF closed loop control systems in terms of the subsystem requirements or MOP's can be seen in **Table 25**. Just like the all the previous control systems, the ON/OFF controls permit pump speed calculation through the voltage applied to the motor. The pump speed can also vary between the MOP requirement range of 1,000 to 6,500 RPM depending on the amount of voltage the motor receives. It cannot provide regulation but reach close to its setpoint even though it will not stay consistently there. Therefore, it utilizes the controller, motor, and sensor as major components. The dead time in these set of controls is usually remarkably high.

TABLE 25: ON/OFF FEEDBACK CONTROL LOOP ASSESSMENT VALUES

ON/OFF Controls	
Pump Speed Calculations (RPM)	Yes
Blood Flow Measurement (L/min)	2 to 8 L/min
Pump Speed (RPM)	1,000 to 6,500 RPM
Blood Flow Regulation	No
Dead time	High
Major Components	3
Calculate other Pump Parameters	Yes

Control system selection was performed utilizing the rating/weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were the ability of the system to provide measurement and regulation of blood flow weighted to 20% and 25%, respectively. Being able to calculate pump speed and other parameters accounted for 15% of the weight each. Reaching pump speed at a

required range of 1,000 to 6,500 RPM and possessing a low dead time accounted for 10% of the weight each. Finally, the least prioritized requirement was the number of major components weighted at 5%. The full decision matrix can be seen on

. Based on the decision matrix calculations, the best control system presently in the market to provide a solution best suited for the projects requirements and environment is the PID controls.

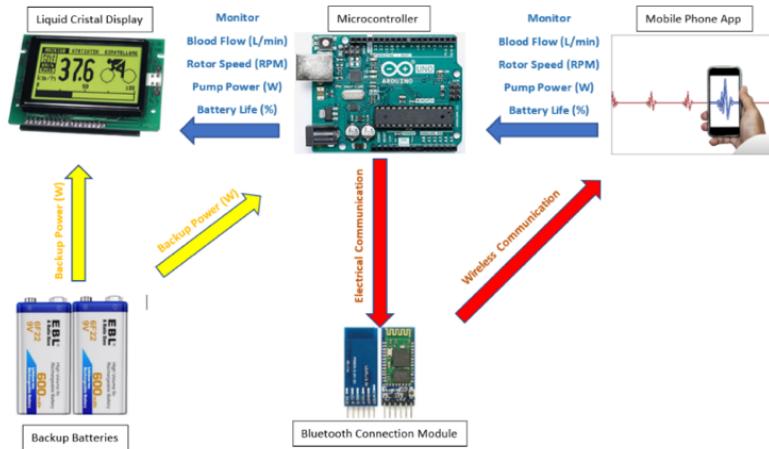
**TABLE 26: RATING WEIGHTING FOR CONTROL SYSTEM SELECTION**

<b>Control System Selection Decision Matrix</b>					
<b>Criteria</b>	<b>Value</b>	<b>Weight</b>	<b>Open Loop Controls</b>	<b>PID Controls</b>	<b>ON/OFF Controls</b>
Pump Speed Calculations (RPM)	Yes	0.15	3	3	3
Blood Flow Measurement (L/min)	4 to 8 L/min	0.20	1	3	3
Pump Speed (RPM)	1,000 to 6,500 RPM	0.10	3	3	3
Blood Flow Regulation	Yes	0.25	1	3	1
Dead time	Low	0.10	1	3	2
Major Components	3	0.05	3	1	1
Calculate other Pump Parameters	Yes	0.15	3	3	3
<b>Total</b>		1	<b>1.9</b>	<b>2.8</b>	<b>2.2</b>

## MONITORING SUBSYSTEM

To develop a system that can monitor the work of the pump, appropriate instruments must be considered that are in accordance with current technology. The mobile application will be working on the blood flow in L / min, the rotor speed in RPM, the pump power in W and it should also show the status of the batteries that will be used for the LVAD. For the application to work, several parameters must be considered, first an application can be developed where it works with a connection via Bluetooth. Bluetooth technology is used for point-to-point, connection-oriented or point-to-point transfer of voice and data between two different digital devices. The main objective of this technology is to replace cable connections, that is, to make them obsolete, which is an advantage,

especially for mobile devices such as smartphones or tablets. As a solution, the Bluetooth module would be in charge of sending the information to the APP. In that case, the batteries provide the power (W) to the LCD and the microcontroller, these ensure that the Bluetooth module receives the data and this is sent to the APP, then the APP monitors the Blood Flow (L / min), the Pump power (W) and the Rotor Speed (RPM), **Figure 21**.



**FIGURE 21: BLUETOOTH CONNECTION MODEL**

Being a connection application via Bluetooth, it can be operated by two people, it consists of a mode, the type of power source is through batteries, it consists of 4 main components and this type of connection can be economical, with an approximate cost of \$

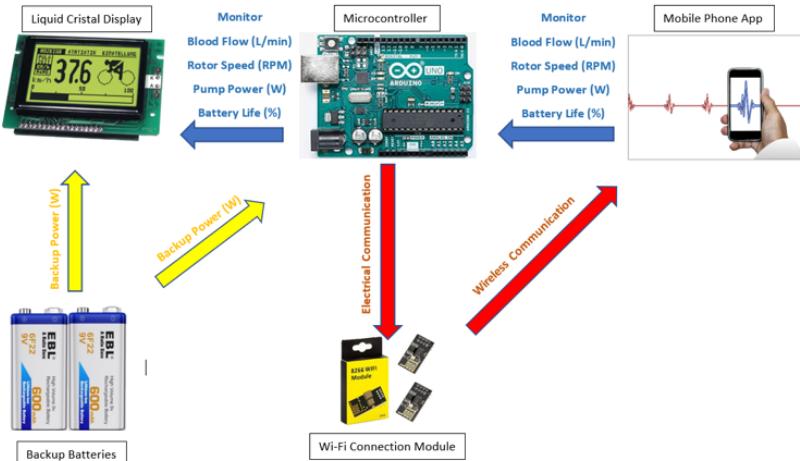
5. **Table 27** discusses a summary about the Bluetooth module.

**TABLE 27: BLUETOOTH CONNECTION CRITERIA**

Bluetooth Module	
Operability	2 persons
Modes	1
Connection type	Bluetooth
Power Source type	Battery
Major Components	4
Additional Components	0
Cost (\$)	\$5

Another parameter to consider when working with the application aimed at LVAD is the Wi-Fi, a mechanism that allows different devices to access the Internet wirelessly when connecting to a certain network. This technology, while offering the entrance to the

large network of networks, links different equipment with each other without the need for cables. The alternative can be seen on **Figure 22**.



**FIGURE 22: WI-FI IMPLEMENTED MODULE'S SCHEMATICS**

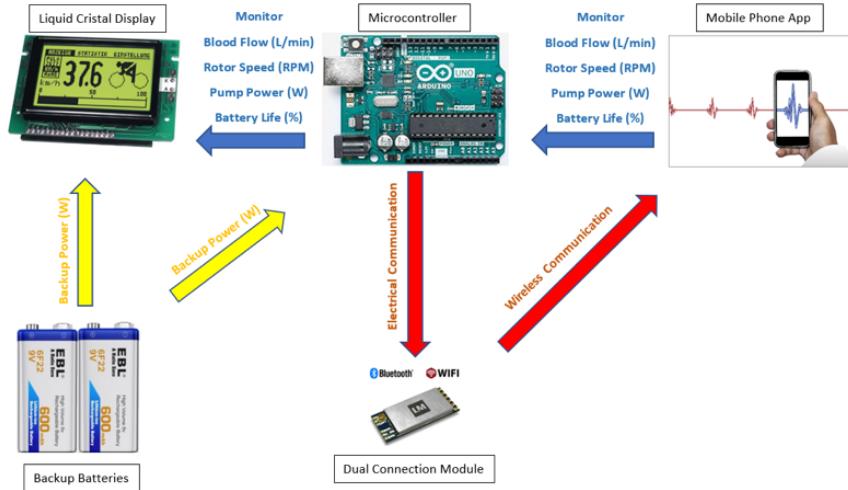
For the LVAD application, the Wi-Fi can be operated in one person, it consists of 2 modes, the type of power source will be with batteries, it contains 4 components, and this can have an approximate cost of \$ 10, refer to **Table 28**.

**TABLE 28: WI-FI CONNECTION CRITERIA**

Wi-Fi Module	
Operability	1 person
Modes	2
Connection type	Wi-Fi
Power Source type	Battery
Major Components	4
Additional Components	0
Cost (\$)	\$10

Another criterion to consider is the module that includes both. Wi-Fi and Bluetooth combination modules incorporate special periodic antenna switching so that they both operate on the same module and efficiently at the same time. This is known as Bluetooth coexistence, **Figure 23**. Its purpose is to achieve the best RF power and performance, and it shows robustness, versatility and reliability in a wide variety of applications and power scenarios. Designed for mobile applications, portable electronics and the Internet. This

module consists of an operability mode for one person, it has 2 modes, its main components can be 4 or 5 and it has a cost of \$ 10, **Table 29**.



**FIGURE 23: BOTH MODULE'S SCHEMATICS**

For both modules, either the Bluetooth or Wi-Fi type, must be programmed with the microcontroller that will be in charge of controlling the LVAD pump, once the data found in the microcontroller, the module is in charge of transmitting the information to the mobile application.

**TABLE 29: BLUETOOTH & WI-FI CONNECTION CRITERIA**

Bluetooth & Wi-Fi Module	
Operability	1 person
Modes	2
Connection type	Both
Power Source type	Battery
Major Components	4 or 5
Additional Components	1
Cost (\$)	\$10

In order operate the mobile application, the appropriate parameter must be selected that can transmit the data without any problem. It is essential to create a trade study, comparing the different modes that can transmit data wirelessly, **Table 30**. The mode of operability must be one person (patient), it must comply with 2 modes, the efficient connection must have Wi-Fi in case any of them fail or cause any problem the patient

should visit the doctor or configure the Wi-Fi module. It must comply with 3 or 4 main components and of course the most economical module that can operate efficiently and safely. Mentioning the previous characteristics, the appropriate module is the one that includes Wi-Fi, this either for its security and for complying with the greater of the components and operability.

TABLE 30: RATING WEIGHTING DECISION MATRIX FOR MONITORING SYSTEM SELECTION

Control System Selection Decision Matrix					
Criteria	Value	Weight	Wi-Fi Module	Bluetooth Module	Both
Operability	1 person	0.2	2.8	2	3
Modes	2 modes	0.15	3	1	3
Connection type	Wi-Fi	0.2	3	1	1.5
Power Source type	Battery	0.1	2	2	2
Major Components	3 or 4	0.1	2	2	3
Additional Components	0	0.1	3	3	1.5
Additional Cost (\$)	\$0	0.15	2.2	3	1.5
	Total	1	2.43	2.07	2.4

To establish an application, its constituents must be created in an organized manner found on **Figure 22**. The application must be linked to the microcontroller, connection module and the liquid crystal display, where the operation of the LVAD will be shown. The microcontroller is divided into what is the monitoring model, the GUI type software and the programming code, which in this case will be Arduino and Visual Studio. As previously discuss the connection module consists of Wi-Fi type. For the liquid crystal display, the cables that will be linked to the pump and the percentage of the battery are subdivided.

## SUBSYSTEM ARCHITECTURE INTO COMPONENTS

A system hierarchy diagram was defined previously on **Project/Mission Architecture and Interfaces**, this diagram possesses only two tiers. Where below the end product, its main subsystems were established. This chapter will make the system hierarchy diagram more detailed as each subsystem will add its main components and parts.

### HEART PUMP SUBSYSTEM

The product breakdown structure (PBS) of the pump's subsystem subdivides into components or a self-contained combination of items performing a function necessary for subsystem operation. The main components of the pump's subsystem are considered to be the motor, rotor, and tubing as well as the customized drafted parts attached to the heart, aorta, and main pump component for each specific patient. They provide the main functions the subsystem needs: weight, size, function durability and reliability, respectively. These elements are fostered and subdivided into key hardware parts that are not subject to further subdivision or disassembly without destruction of designated use. For example, the pump's housing as the main component hosts the motor, rotor, and sensor in one same space.

**Figure 24** graphically showcases de PBS structure of the pump's subsystem.

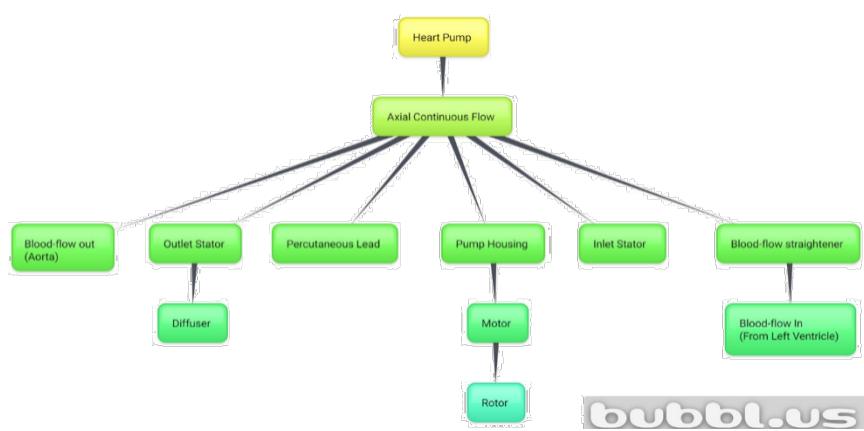


FIGURE 24: PUMP SUBSYSTEM PBS

The three main components (motor, rotor, and bearings) were addressed using the same trade study's methodology followed throughout the project. Component selection would commence looking for current products that could potentially suffice criteria for subsystem requirements or MOP's. Afterwards, the products would be assessed through a decision matrix to find best solution tailored for the subsystem requirements and environment.

Motors should be able to work on the task at hand efficiently and effectively. Consequently, several motors were assessed on a variety of criteria to ensure adequate selection. The main reviewed models were the linear motor, BLDC Motor and the specialized axial self-bearing motor. The aforesaid motors were selected for review due to their widespread commercial accessibility, known information about them, and simple development environment. It is important to mention that the axial self-bearing motor was the most adequate for the project. Nevertheless, the axial self-bearing motor was the most appropriate although the materials to execute with this option were improbable due to huge manufacturing limitations on a first prototype. Therefore, the BLDC motor was conventionally used on the prototype to simulate analogous performance verifications and validations. **Figure 25** illustrates the three motor selection alternatives.



FIGURE 25: MOTOR ALTERNATIVES FIGURE

The linear motor is lightweight and inexpensive at a listed weight of approximately 32 g and a cost of less than \$50.00. It is also relative compact as its unit diameter is around 25 mm, even though its length is more than 35 mm. In addition, the linear motor does not

present an adequate life expectancy, operating flow, or motor velocity for the system's requirements. **Table 31** lists the values of the linear motor for the motor selection criteria.

**TABLE 31: LINEAR MOTOR VALUES FOR MOTOR SELECTION CRITERIA**

Criteria	Linear Motor value
Weight (g)	25g
Length (mm)	70 mm
Diameter (mm)	30 mm
Motor velocity (RPM)	1500 RPM
Operating flow (L/min)	~5 L/min
Cost (\$)	\$30.00
Life expectancy	< 1 year

The brushless direct current (BLDC) motor is a bulkier version weighting more than 40 g and having an overreaching length of about 50 mm depending on the model acquired. It is the most expensive out of all of the options as its unit cost range from \$10 to \$100 depending on motor specifications. However, more important criteria like the motor diameter, operating flow, and working velocity were optimal in the BLDC motor option. It is important to note that it can operate using 3.3-24V supply. **Table 32** lists the values of the BLDC motor for the motor selection criteria.

**TABLE 32: BLDC MOTOR VALUES FOR MOTOR SELECTION CRITERIA**

Criteria	BLDC Motor value
Weight (g)	40 g
Length (mm)	50 mm
Diameter (mm)	25 mm
Motor velocity (RPM)	2500 RPM
Operating flow (L/min)	10 L/min
Cost (\$)	\$50.00
Life expectancy	> 2 year

Finally, the Axial self-bearing motor is a small sized motor weighing little over 30g and having a length lesser than 35 mm. It is the as inexpensive as the linear motor option as its unit cost is directly related to the unique manufacturing of each pump system; there are no commercial alternatives available. In addition, the self-bearing motor possesses the ideal life expectancy for over 10 years, the ideal operating flow for up to 10 L/min, and its respective pump velocity for approximately 1000-7000 RPM. It is important to mention

that, even though the motor's diameter is larger than 25 mm, this choice's criteria is declared non-essential as the diameter can be displaced inside of the pump system per se and serve as a maximum diameter for the tubing. **Table 33** lists the aforementioned values of the Axial self-bearing motor for the motor selection criteria.

TABLE 33: AXIAL SELF-BEARING MOTOR VALUES FOR MOTOR SELECTION CRITERIA

Criteria	Axial self-bearing Motor value
Weight (g)	40 g
Length (mm)	50 mm
Diameter (mm)	25 mm
Motor velocity (RPM)	2500 RPM
Operating flow (L/min)	10 L/min
Cost (\$)	\$50.00
Life expectancy	> 2 year

Motor selection was performed utilizing the rating weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were the weight, cost, and motor working voltage (velocity) weighted to 20% each. The operating flow and life expectancy were given high priorities as well as they were weighed to 15% each. Finally, the least prioritized requirements were the motor's length and diameter weighed at 5% each as well. The full decision matrix can be seen on **Table 34**. Based on the decision matrix calculations, the best motor currently in the market to provide a solution best suited for the projects requirements and environment is the BLDC motor.

TABLE 34: RATING WEIGHTING DECISION MATRIX FOR MOTOR SELECTION

Motor Selection Decision Matrix					
Criteria	Value	Weight	Linear motor	Axial bearing motor	BLDC motor
Weight (g)	32g	0.2	3	2	1
Length (mm)	35 mm	0.05	1.5	3	3
Diameter (mm)	25 mm	0.05	2.1	1	3
Motor velocity (RPM)	2000 RPM	0.2	1.8	3	3
Operating flow (L/min)	5 L/min	0.15	1.3	2.5	3
Cost (\$)	< \$50.00	0.2	3	3	1
Life Expectancy	2 years	0.15	1	2.8	3
	Total	1	1.6171429	2.471429	2.828571

Specific rotor selection is profoundly important as they provide intrinsic durability and a sense of comfortability. Moreover, they affect cost, pyrogenicity, and hemocompatibility of the LVAD devices implemented into the patient. Therefore, several rotor types were assessed on a variety of criteria to ensure adequate selection. The main reviewed types were salient pole, cylindrical, and open-end rotors. **Figure 26** illustrates the three rotor selection alternatives.

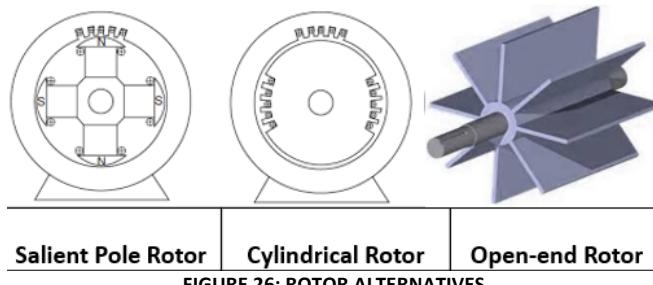


FIGURE 26: ROTOR ALTERNATIVES

Salient pole rotors are rotors commonly used in power plants that are short in length yet have a huge diameter proportional to their length. Their working principal is based on lower speed electrical machines that range from 100 RPM to 1500 RPM. The salient pole rotor model was assessed and measured more than 50 mm in diameter for a sufficiently short length lesser than 25 mm. It is important to mention that the low noise level was not achieved with this model and its respective cost was more than \$50.00 to attain the proportional frequency worked in the rotor. **Table 35** lists the values of the salient pole rotor for its selection criteria.

TABLE 35: SALIENT POLE ROTOR VALUES FOR ROTOR SELECTION CRITERIA

Criteria	Salient pole rotor value
Speed	1500 RPM
Length (mm)	50 mm
Diameter (mm)	25 mm
Poles	4
Frequency	Proportional
Cost (\$)	\$50.00
Noise	High

Non-salient pole rotors, better known as cylindrical rotors, are easy to work rotors typically used in applications with high energy consumption and demand like turbogenerators. The cylindrical pole rotor model assessed their speed on electrical machines that usually go over 1500 RPM. This non-salient pole rotor model measured more than 30 mm in length due to its incredibly diminutive diameter for proportional work at less than 30 mm. It is important to mention that the low noise level was not achieved with this model and its respective cost was about \$40.00 to attain the proportional frequency with still some noise worked in the rotor because of its overall small size. **Table 36** lists the aforementioned values of the cylindrical pole rotor for its selection criteria.

TABLE 36: CYLINDRICAL POLE ROTOR VALUES FOR ROTOR SELECTION CRITERIA

Criteria	Cylindrical pole rotor value
Speed	3000 RPM
Length (mm)	30 mm
Diameter (mm)	30 mm
Poles	4
Frequency	Semi-Proportional
Cost (\$)	\$40.00
Noise	High

Open-end rotors are generic 4-pole rotors typically used in small devices. The open-end rotor model possessed dimensions of 2.5 inches and 2 inches for length and diameter, respectively. A continuous flow LVAD device will consume this type of rotor rapidly due to constant friction of use and that will provide an exceptionally low life expectancy. It is important to mention that the proportional frequency output is ideal due to little noise observance. **Table 37** lists the values of the open-end rotor for its selection criteria. The selection of rotors was performed utilizing the rating/weighting methodology.

The requirements described earlier served as a criterion for the decision. The most important criteria were of the rotor's cost and working speed weighed to 20% each. The

diameter, length, output frequency, and number poles were given relative high priorities as they were weighted to 18%, 15%, 12%, and 10%, respectively.

TABLE 37: OPEN-END ROTOR VALUES FOR ROTOR SELECTION CRITERIA

Criteria	Open-end rotor value
Speed	1500 RPM
Length (mm)	30 mm
Diameter (mm)	25 mm
Poles	4
Frequency	Proportional
Cost (\$)	Varies on size
Noise	Low

Finally, the least prioritized requirement was the noise level and its corresponding reduction or cancellation weighed at 5%. The full decision matrix can be seen on **Table 38**. Based on the decision matrix calculations, the best rotor currently in the market to provide a solution best suited for the projects requirements and environment is the open-end rotor.

TABLE 38: RATING WEIGHTING DECISION MATRIX FOR ROTOR SELECTION

Rotor Selection Decision Matrix					
Criteria	Value	Weight	Salient Pole Rotor	Cylindrical Rotor	Open-End Rotor
Diameter (mm)	25 mm	0.18	1	3	3
Length (mm)	30 mm	0.15	3	1	3
Speed (RPM)	3000 RPM	0.2	1	3	1
Poles (#)	4	0.1	3	3	3
Frequency (output flow)	Proportional	0.12	3	2	3
Cost (\$)	\$40.00	0.2	2	2.5	1
Noise (Level)	Low	0.05	1	1	3
	Total	1	1.894	2.214286	2.57143

Finally, the tubing material selection gives the pump system a backbone support feedback response to the constant friction done in heart pumps to maintain the desired input and output conditions. Consequently, several biocompatible materials were assessed on a variety of criteria to ensure adequate selection.

The traditional silicone tubing design is an easy-to-use hardware that can weigh usually only 150 g for the estimated heart pump casing volume of approximately 146.5 cubic cm. It provides proper visceral comfortability, high temperature functionality up to 500 degrees Celsius, flexible blood movement, and sufficient seal for the manufactured parts in a heart pump subsystem. Sets of 10 feet tubing are also priced approximately at \$10 and all are naturally water resistant as they present natural hydrophobicity. They provide some friction control and over time tend to lose this ability due to their constant wear and tear with the visceral tissue surrounding the implanted device. It is generally a good alternative, but the low control for tolerance and friction rate presents deep problems for the long-term heart pump stability after implantation. Buodot (2016) concluded that several bulk and surface modifications of the silicone elastomers with polyethylene glycol (PEG) induced long-term (2 months) stable wettability of the surface, no cytotoxicity, and an overall better hemocompatibility. Moreover, it is readily known that silicone has long been used for medical tubing as it meets the medical industry's requirements for cleanliness, general non-toxicity, and resistance to extreme temperature variations. **Table 39** lists the abovementioned values of the silicone tubing material for its selection criteria.

**TABLE 39: SILICONE TUBING VALUES FOR TUBING MATERIAL SELECTION CRITERIA**

Criteria	Silicone Tubing Value
Weight (g)	150 g
Friction (levels)	Medium high
Water resistance (compliance)	Yes
Stability (levels)	Medium
Tolerance (levels)	Medium
Cost (\$)	\$10.00 for 10 ft
Malleable (Compliance)	Yes

The medical grade ePTEE, readily known as expanded Teflon, tubing material is an assimilated silicone concept with a more malleable property that can usually weigh 300 g for the estimated heart pump casing. This material type also presents water resistance, high tolerance levels to fluids, low friction, and high temperature functionality up to 300

to 500 degrees Celsius depending on the porosity. Even though regular polytetrafluoroethylene presents a general low cost, expanded PTFE can present a slighter larger cost of manufacturing due to post-processing. They provide some friction control and over time tend to lose this ability due to their constant wear and tear with the visceral tissue surrounding the implanted device. It is generally a good alternative, but the normal control for tolerance and stability rate presents some problems for the long-term heart pump stability after implantation. Multifunctional coating and cross-linking are also suggested for this material tubing option. **Table 40** lists the previously mentioned values of the Teflon tubing for its selection criteria.

**TABLE 40: TEFLON TUBING VALUES FOR TUBING MATERIAL SELECTION CRITERIA**

Criteria	Teflon Tubing Value
Weight (g)	300 g
Friction (levels)	Low
Water resistance (compliance)	Yes
Stability (levels)	Medium
Tolerance (levels)	Medium
Cost (\$)	\$10.00 for 10 ft
Malleable (compliance)	Yes

The titanium alloy tubing material is a very different concept to its traditional counterparts by providing a stronger support and effective seal to the pump without excessive friction. The high cost of manufacturing as well can range with the specific alloys attached to the titanium base. By delivering low friction junctures, the tolerance levels increase in very particular ranges that offer adequate safety. The specifications mostly differ in weight, malleability and stability, and tolerance levels, and even its respective cost. Most of these models are heavier and larger than their polymer and non-metallic equivalents at more than 500 g.

Moreover, the model unit is priced at more than \$20 for the entire heart pump casing. It is important to mention that these metallic materials also possess the ability to

resist water and other fluids like blood. It is largely a good quality option; however, this alternative is too heavy, and its already low-level tolerance is too much of a risk. **Table 41** lists the aforementioned values of the magnetic bearing for its selection criteria.

**TABLE 41: TITANIUM ALLOY TUBING VALUES FOR TUBING MATERIAL SELECTION CRITERIA**

Criteria	Titanium Alloy Tubing Value
Weight (g)	20 g
Friction (levels)	Medium Low
Water resistance (compliance)	Yes
Stability (levels)	High
Tolerance (levels)	Medium high
Cost (\$)	\$20.00 for 10 ft
Malleable (compliance)	No

The selection of the tubes' material was performed utilizing the rating/weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were the weight, cost, and overall stability level which were weighted to 20% individually. The tubing material friction coefficient with red blood cells and their tolerance levels were heavily prioritized as well, being weighted to 15% each. Finally, the least prioritized requirements were the possible water resistance of the tubing and its malleability inside the body at 5% independently. The full decision matrix can be seen on **Table 42**. Based on the decision matrix calculations, the best bearing currently in the market to provide a solution best suited for the projects requirements and environment is the ePFTE material (medical grade expanded Teflon). It is important to mention that no bearing was yet used in the initial constructed prototype: the three options were rated, and their total weight were spontaneously similar. Nowadays, some ceramics and polymers are used to their excellent biocompatibility and biofunctionality. However, for implants which require high strength, toughness and durability, they are still made of metals.

TABLE 42: RATING WEIGHTING DECISION MATRIX FOR TUBING MATERIAL SELECTION

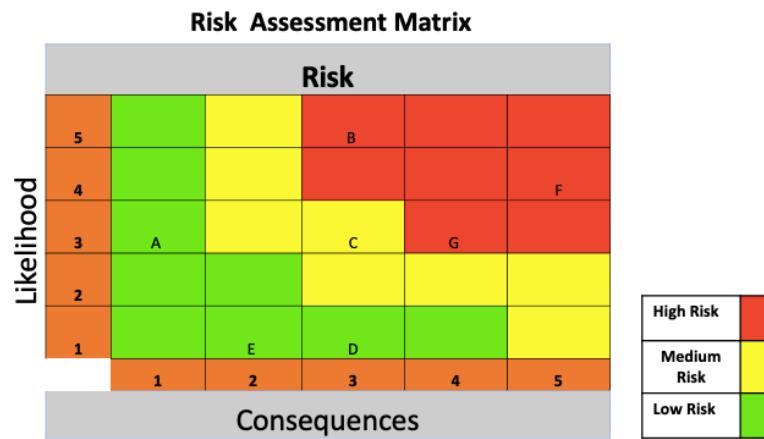
Tubing Material Selection Decision Matrix					
Criteria	Value	Weight	Silicone Tubing	ePTFE Tubing	Titanium Tubing
Weight (g)	10 g	0.2	2.5	2	1
Friction (levels)	Low	0.15	1.5	3	2
Water resistance (compliance)	Yes	0.05	3	3	3
Stability (levels)	High	0.2	2	2	3
Tolerance (levels)	High	0.15	2	2	2.5
Cost (\$)	\$10.00	0.2	3	3	1.5
Malleable (compliance)	Yes	0.05	3	3	1
Total		1	2.325	2.45	1.975

With the selection of main components established, the next course of action was developing a risk assessment matrix tool to analyze risk. Risks regarding the heart pump with their mitigation strategies were listed on **Table 16**. Among all the listed risks, the formation of blood clots, and occurrence of hemolysis or heart stroke are considered high risks. They all possess a high severity of permanent heart damage and even death if symptoms are aggravated. The three risks are also considered likely or near certain to occur. However, there are potential mitigation strategies patients can take to reduce the adverse effects of these risks. Blood clot formation and hemolysis can be treated using anticoagulant drugs, which slow down these processes. Furthermore, heart stroke prevention therapies include the use of anticoagulant drugs and antiplatelet agents. The latter reduces the occurrence of platelet aggregation in the bloodstream. Other potential hazards are considered low risks due to their low likelihood and severity. Driveline infections can easily be treated with antibiotics to prevent adverse effects. In addition, risks related to power failure can be reduced by using backup rechargeable lithium-ion batteries. Finally, right heart dysfunction can be reduced by maintaining and monitoring the device produces the optimal blood flow. All aforementioned risks are listed on **Table 43** and

assessed on their likelihood of occurrence and the severity of their consequences using a risk assessment matrix found on **Figure 27**.

**TABLE 43: LISTS OF RISKS IN THE HEART PUMP SUBSYSTEM**

List of Risks						
A. Driveline Infections						
B. Blood clots (caused by a circulatory failure)						
C. Power failure (factors related with physical hardware)						
D. Internal Bleeding (caused after the LVAD implantation)						
E. Right Heart Dysfunction						
F. Heart Stroke						
G. Hemolysis (damage to blood cells due to the pump)						



**FIGURE 27: HEART PUMP SUBSYSTEM RISK ASSESSMENT MATRIX**

## CONTROLS SUBSYSTEM

The pbs of the control's subsystem subdivides into components or a self-contained combination of items performing a function necessary for subsystem operation. The main components of the control's subsystem are considered to be the microcontroller, electronics, flow sensor and power supplies. They provide the main functions the subsystems needs; controlling, measuring and power, respectively. These elements are furthered subdivided into key hardware parts that are not subject to further subdivision or disassembly without destruction of designated use. The microcontroller parts consist of the model, software, and the code. The electronic components parts include a liquid crystal display (lcd), led lights, buzzer, motor driver, motor, and electrical wires. The flow sensor

component parts include wires, and the power supply includes batteries and driveline.

**Figure 28** graphically showcases de pbs structure of the control's subsystem.

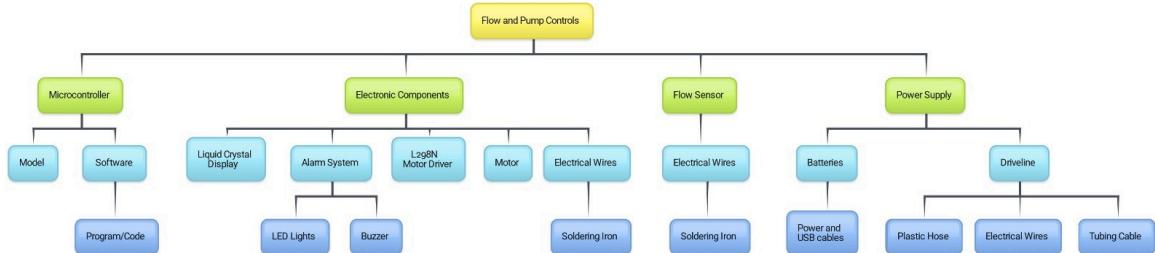


FIGURE 28: CONTROLS SUBSYSTEM PBS

The three main components (microcontroller, flow sensor and power supply) were addressed using the same trade study's methodology followed throughout the project. Component selection would commence looking for current products that could potentially suffice criteria for subsystem requirements or MOP's. Then products would be assessed through a decision matrix to find best solution tailored for the subsystem requirements and environment.

Microcontrollers should be able to fit the task at hand efficiently and cost effectively. Consequently, several microcontrollers were assessed on a variety of criteria to ensure adequate selection. The main reviewed models were the Arduino uno, Arduino Mega and the MSP 430 Launchpad. The Arduino microcontrollers were selected for review due to their open-source physical computing platform based on a simple I/O board and a development environment. The Arduino Uno is based on the ATmega328P and the Arduino Mega is based on the ATmega2560. The MSP430 Launchpad is a hardware development tool for MSP430 Value Line series of microcontrollers and is developed on TI MSP430 microcontrollers. The Launchpad board is similar to Arduino's in terms of their easy usability. **Figure 29** illustrates the three microcontroller selection alternatives.



Arduino Uno



Arduino Mega



MSP430 Launch Pad

FIGURE 29: MICROCONTROLLER ALTERNATIVES

The Uno board is lightweight and compact at a listed weight of 25g and an area of  $5.67 \text{ in}^2$ . It is also very inexpensive as its unit cost is \$23 and its software is free. In addition, the Uno board possesses 14 I/O ports and a 2kbyte RAM, both very adequate for the application. It can operate using a 7-12 V supply but also supply 5 and 3 V to any other electronic components. **Table 44** lists the values of the Arduino Uno for the microcontroller selection criteria.

TABLE 44: ARDUINO UNO VALUES FOR MICROCONTROLLER SELECTION CRITERIA

Criteria	Arduino Uno Value
Weight (g)	25g
Dimensions ( $\text{in}^2$ )	$5.67 \text{ in}^2$
Cost	\$23
Software Cost	\$0
I/O Ports	14
RAM	2k bytes
Power Supply	5V
Operating Voltage	7 to 12

The Arduino Mega is a bulkier board weighting at 37g and having an area of  $8.38 \text{ in}^2$ . It is more expensive than the other options as its unit cost is \$40 but, its software is free. In addition, the Mega board possesses 54 I/O ports and a 8kbyte RAM, both more than adequate for the application. It can operate using a 7-12 V supply but also supply 5 and 3 V to any other electronic components. **Table 45** lists the aforementioned values of the Arduino Mega for the microcontroller selection criteria.

**TABLE 45: ARDUINO MEGA VALUES FOR MICROCONTROLLER SELECTION CRITERIA**

<b>Criteria</b>	<b>Arduino Mega Value</b>
Weight (g)	37g
Dimensions ( $in^2$ )	8.38 $in^2$
Cost	\$40
Software Cost	\$0
I/O Ports	54
RAM	8k bytes
Power Supply	5V
Operating Voltage	7 to 12

The MSP430 Launchpad is a medium sized board weighting at 25g and having an area of 7  $in^2$ . It is the less expensive option as its unit cost is \$5 and its software is free. In addition, the Launchpad board possesses 10 I/O ports and a 512-byte RAM, which are less than what is needed for the application. It can operate using a 5 V supply but also supply 3 V to any other electronic components. **Table 46** lists the aforementioned values of the MSP430 Launchpad for the microcontroller selection criteria.

**TABLE 46: MSP430 LAUNCHPAD VALUES FOR MICROCONTROLLER SELECTION CRITERIA**

<b>Criteria</b>	<b>MSP430 Launchpad Value</b>
Weight (g)	25g
Dimensions ( $in^2$ )	7 $in^2$
Cost	\$5
Software Cost	\$0
I/O Ports	10
RAM	512 bytes
Power Supply	3.3
Operating Voltage	5

Microcontroller selection was performed utilizing the rating/weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were the amount of memory and I/O ports the controller possessed weighted to 17% each. The weight and voltage supplied were given high priorities as they were weighted to 14% and 13%, respectively. Both the unit and software costs were prioritized as well, being weighted to 12% each. Finally, the least prioritized requirements were the operating voltage and area dimensions weighted at 10% and 5%, respectively. The full decision matrix can be seen on **Table 47**. Based on the decision matrix calculations,

the best microcontroller currently in the market to provide a solution best suited for the projects requirements and environment is the Arduino Uno.

**TABLE 47: RATING WEIGHTING DECISION MATRIX FOR MICROCONTROLLER SELECTION**

Microcontroller Selection Decision Matrix					
Criteria	Value	Weight	Arduino Uno	Arduino Mega	MSP430 Launchpad
Weight (g)	30g	0.14	3	1	3
Dimensions ( $in^2$ )	6 $in^2$	0.05	2.94	1	3
Cost	\$50	0.12	1.97	1	3
Software Cost	\$0	0.12	3	3	3
I/O Ports	15	0.17	1.18	3	1
RAM	3k bytes	0.17	1.4	3	1
Power Supply	5V	0.13	3	3	1
Operating Voltage	5V	0.10	1	1	3
	Total	1	<b>2.092</b>	<b>2.18</b>	<b>2.06</b>

Battery selection is important as they provide portability to the LVAD devices. Therefore, several battery types were assessed on a variety of criteria to ensure adequate selection. The main reviewed types were Lithium-Ion (Li-ion), Nickel-metal hydride (NiMH) and Alkaline batteries. **Figure 30** illustrate the three battery selection alternatives.



**FIGURE 30: BATTERY ALTERNATIVES**

Li-ion batteries are rechargeable batteries commonly used in portable devices. Their working principle is based on lithium ions moving from the negative electrode to the positive electrode when in use and back when charging. The Li-ion battery model assessed weighted 190g and possessed dimensions of 4.13 in and 2.48 in for height and width, respectively. The battery supplied both 12V and 5V. In addition, had a life battery of 500

charged cycles. The unit cost was priced at \$25. **Table 48** lists the values of the Lithium-ion battery for its selection criteria.

**TABLE 48: LI-ION BATTERY VALUES FOR BATTERY ALTERNATIVES**

Criteria	Li-ion Battery Value
Weight (g)	190g
Height (in)	4.13 in
Width (in)	2.48 in
Cost	\$25
Voltage (V)	12 V
Life (Charge Cycles)	500 Charge Cycles

NiMH batteries are rechargeable batteries typically used in applications with high energy consumption and demand. The NiMH battery model assessed weighted 255g and possessed dimensions of 2.9 in and 2.1 in for height and width, respectively. Even though it is relatively compact it is very heavy for a portable device application. The battery supplied 12V and had a life battery of 500 charged cycles. The unit cost was priced at \$40.

**Table 49** lists the aforementioned values of the Nickel-metal hydride battery for its selection criteria.

**TABLE 49: NIMH BATTERY VALUES FOR BATTERY ALTERNATIVES**

Criteria	NiMH Battery Value
Weight (g)	255g
Height (in)	2.9 in
Width (in)	2.1 in
Cost	\$40
Voltage (V)	12 V
Life (Charge Cycles)	500 Charge Cycles

Alkaline batteries are rechargeable batteries typically used in small electronic devices. The Alkaline battery model assessed weighted 8g and possessed dimensions of 2.5 in and 2.1 in for height and width, respectively. The battery only supplied 9V and had a low life battery of 30 charged cycles. The LVAD device will consume these batteries rapidly and provide exceptionally low life. The unit cost was priced at \$15.

**Table 50** lists the values of the Alkaline battery for its selection criteria.

TABLE 50: ALKALINE BATTERY VALUES FOR BATTERY ALTERNATIVES

Criteria	Alkaline Battery Value
Weight (g)	8g
Height (in)	2.5 in
Width (in)	2.1 in
Cost	\$15
Voltage (V)	9 V
Life (Charge Cycles)	30 Charge Cycles

The selection of batteries was performed utilizing the rating/weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were of battery life or charge cycles the battery possessed weighted to 35%. The cost and voltage supplied were given high priorities as they were weighted to 20% each. The unit weight was heavily prioritized as well, being weighted to 15%. Finally, the least prioritized requirements were the height and width dimensions weighted at 5% each. The full decision matrix can be seen on **Table 51**. Based on the decision matrix calculations, the best battery currently in the market to provide a solution best suited for the projects requirements and environment is the Lithium-ion battery.

TABLE 51: RATING WEIGHTING DECISION MATRIX FOR BATTERY SELECTION

Battery Selection Decision Matrix					
Criteria	Value	Weight	Li-ion	NiMH	Alkaline
Weight (g)	50 g	0.15	1.5	1	3
Height (in)	6 in	0.05	1	1.8	3
Width (in)	4 in	0.05	1	1.3	3
Cost	\$45	0.2	2.2	1	3
Voltage (V)	12 V	0.2	3	3	1
Life (Charge Cycles)	500 Charge cycles	0.35	3	3	1
	Total	1	2.415	2.2	1.9

Flow sensor selection gives the control system a feedback response to automatically achieve and maintain the desired output condition. Consequently, several flow sensors were assessed on a variety of criteria to ensure adequate selection. The main reviewed models were the YF-S201C made from silicone, the YF-S201C made from plastic and the YF-B6. **Figure 31** illustrate the three sensor selection alternatives.



Silicone YF-S201C



YF-B6



Plastic YF-S201C

FIGURE 31: FLOW SENSOR ALTERNATIVES

The silicone YF-S201C is an easy-to-use flowmeter, that weighs 51g and measures 60 mm in length. It provides flow measurements in a range of 1 to 30 L/min. It operates at a 5 V supply and a 25 to 80 °C temperature range. The models were priced at around \$25. Overall a good alternative but, overbudget and too long for the application. **Table 52** lists the aforementioned values of the silicone YF-S201C for its selection criteria.

TABLE 52: SILICONE YF-S201C VALUE FOR SENSOR ALTERNATIVES

Criteria	Silicone YF-S201C Value
Weight	51g
Length	60 mm
Cost	\$25
Flow Range	1 to 30
Operating Voltage	5V
Operating Temperature	25 to 80 °C

The YF-B6 is an easy to install, copper flow sensor that weighs 79g and measures 44 mm in length. It provides flow measurements in a range of 1 to 30 L/min. It operates at a 5 V supply and a 25 to 80 °C temperature range. The models were priced at around \$15. The downside of this alternative it is too heavy for the application, considering one of the system MOP's is for the implanted device to weigh under 250g. **Table 53** lists the previously mentioned values of the silicone YF-S201C for its selection criteria.

TABLE 53: YF-B6 VALUE FOR SENSOR ALTERNATIVES

Criteria	YF-B6 Value
Weight	79g
Length	44mm
Cost	\$15
Flow Range	1 to 30
Operating Voltage	5V
Operating Temperature	25 to 80 °C

The plastic YF-S201C is similar to its silicon counterpart, providing flow measurements in a range of 1 to 30 L/min and operating at a 5 V supply. However, its specifications differ in weight, length, and operating temperature. It is more lightweight at weighs 35g and measures 44 mm in length and at 0 to 35 °C temperature range. The models were priced at around \$22. Overall a good alternative but, overbudget and its operating temperature is too low. **Table 54** lists the aforementioned values of the silicone YF-S201C for its selection criteria.

**TABLE 54: PLASTIC YF-S201C VALUE FOR SENSOR ALTERNATIVES**

Criteria	Plastic YF-S201C Value
Weight	35g
Length	44mm
Cost	\$22
Flow Range	1 to 30
Operating Voltage	5V
Operating Temperature	25 to 35 °C

The selection of the sensor was performed utilizing the rating/weighting methodology. The requirements described earlier served as a criterion for the decision. The most important criteria were the weight and the cost of the unit, which were weighted to 23%. The sensor length was heavily prioritized as well, being weighted to 22%. The range of measurement and operating voltage were given high priorities as they were weighted to 11% each. Finally, the least prioritized requirement was the operating temperature weighted at 10%. The full decision matrix can be seen on **Table 55**. Based on the decision matrix calculations, the best battery currently in the market to provide a solution best suited for the projects requirements and environment is the YF-B6 flow sensor.

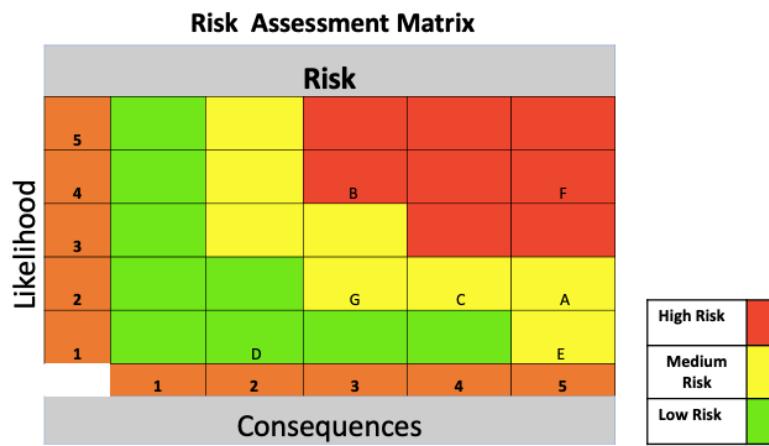
TABLE 55: RATING WEIGHTING DECISION MATRIX FOR SENSOR SELECTION

Flow Sensor Selection Decision Matrix					
Criteria	Value	Weight	Silicone YF-S201C	YF-B6	Plastic YF-S201C
Weight	20g	0.23	2.27	1	3
Length	44mm	0.22	1	3	3
Cost	\$15	0.23	1	3	1.25
Flow Range	1 to 10 L/min	0.11	3	3	3
Operating Voltage	5V	0.11	3	3	3
Operating Temperature	25 to 80 °C	0.1	3	3	1
Total		1	1.71	2.54	2.31

With the selection of main components established, the next course of action was developing a risk assessment matrix tool to analyze risk. Risks regarding the controls with their mitigation strategies were listed on **Table 17**. Among all the listed risks, dischargement of batteries and microcontroller failure are considered high risks. They both possess a high severity of permanent heart damage and even death if not resolved quickly. They are also considered likely to occur. Addressing these hazards poorly can be deadly for patients that suffer from advanced HF, since these issues will make the device cease to function. Causing major injuries or even death. However, there are potential mitigation strategies patients can take to reduce the adverse effects of these risks. To reduce potential microcontroller failure, a microcontroller with high reliability must be utilized or manufactured for this application. As for battery dischargement, using lithium rechargeable batteries that possess 2 to 3 years of battery life can mitigate such adverse risks. All previously mentioned risks are listed on **Table 56** and assessed on their likelihood of occurrence and the severity of their consequences using a risk assessment matrix found on **Figure 32**.

**TABLE 56: LIST OF RISKS IN THE CONTROLS SUBSYSTEM**

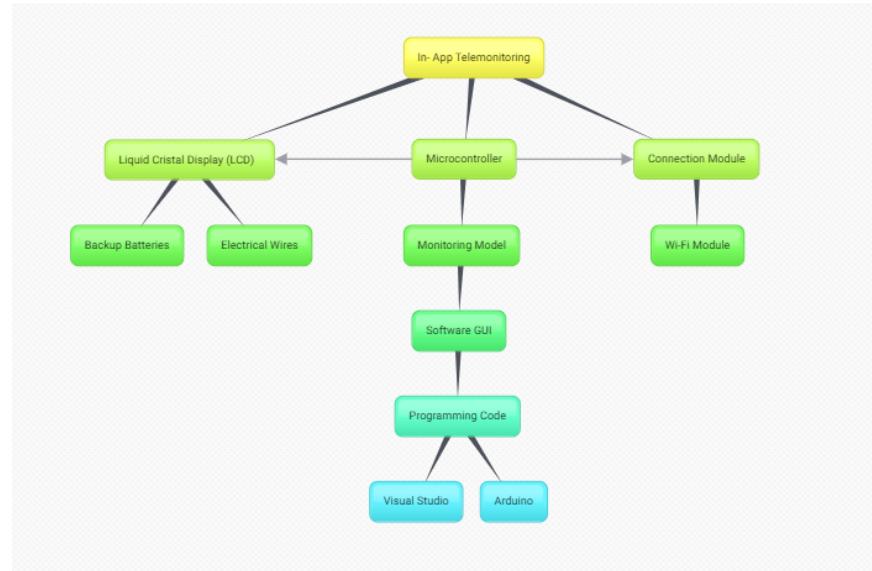
List of Risks						
A – Failed Power Supply						
B – Batteries Discharged						
C – Incorrect Sensor Readings						
D – Alarm Fatigue (Patient Desensitization Towards Alarms)						
E – Incorrect Connection of Modular Cable						
F – Microcontroller Failure						
G – Erroneous Regulation of Pump Parameters (Pump Thrombosis)						

**FIGURE 32: CONTROLS SUBSYSTEM RISK ASSESSMENT MATRIX**

## MONITORING SUBSYSTEM

For telemonitoring it is essential to have the control system, since according to how the microcontroller works, it is how the App will be working. However, the telemonitoring App is divided into three main components: Microcontroller, Connection Module and Liquid Cristal Display. The main components are responsible for transmitting the information produced or worked on in the Heart Pump. Liquid Cristal Display (LCD) will have the batteries and electrical cables connected, that is, it will ensure that the system can work. The microcontroller is linked to the pump, since it will monitor its parameters. The other component known as the connection module, will be linking with the aforementioned Wi-Fi, it will be in charge of being able to send and receive the information from both the

microcontroller and the App. **Figure 33** graphically showcases de PBS structure of the control's subsystem.



**FIGURE 33: MONITORING SYSTEM ARQUITECTURE**

For the system to be optimal, the benefit microcontroller is sought for both the APP and the patient. Microcontrollers include the Arduino Uno, the Arduino Mega, and the MSP430 LaunchPad. Among these microcontrollers, the Arduino Uno complies with the weight of 30 grams, the dimensions of 140 square inches, this is considered since the smaller it is, the more comfortable it is for the patient. In addition, the Arduino complies with an affordable cost of the software and the 7V power supply. However, the MSP430 LaunchPad meets the same qualities as the Arduino Uno but, does not meet the 7V power supply which is what would be working in this case. As for the Arduino Mega, it is much larger, which can cause discomfort problems for the patient, it is more expensive and it weighs more than 30g, which including the wiring would be an additional problem for the patient. In short, after the comparison between microcontrollers, the Arduino Uno is the most accessible and economical to work with, both the LVAD and the telemonitoring system. The complete decision matrix can be found on **Table 47**.

Having the Arduino Uno, a suitable liquid crystal display (LCD) must be selected, which directs the LVAD parameters. The main reviewed models were the Asiawill color TFT Touch LCD Screen Module, the Huhushop White OLED LCD LED Display Module and the Arduino Dot Matrix LCD. **Figure 34** illustrate the three LCD selection alternatives.



Asiawill Color TFT Touch Screen Module | Huhushop White OLED LCD Display Module | Arduino Dot Matrix LCD

**FIGURE 34: LIQUID CRYSTAL DISPLAY ALTERNATIVES**

It must comply with the dimension of 1”, be economically priced, that does not generate so much consumption (0.5W), that it is composed of TFT, that it has a good resolution of approximately 320 \* 240 and that it has an accessible and easy text to visualize. The display is driven based on an 8-bit data truck, and a 4-Bit ili9323ds display to control truck interface, which can 65K colors. **Table 57** demonstrates all values associates to this type of LCD.

**TABLE 57: ASIAWILL COLOR TFT TOUCH LCD FOR LCD ALTERNATIVES**

Criteria	Asiawill Color TFT Value
Dimensions	72.0mm x 71mm x 1.6mm
Cost (\$)	\$10
Power Consumption	0.5W
Material	TFT
Display Resolution	320x240
Text Characters	15x3

The Huhushop White OLED LCD LED Display Module is another alternative for the selection of the Liquid Cristal Display. **Table 58** demonstrates all values associates to this type of LCD.

**TABLE 58: HUHUSHOP WHITE OLED DISPLAY FOR LCD ALTERNATIVES**

Criteria	Huhushop White OLED Display Value
Dimensions	1.8 x 1 x 0.8 inches
Cost (\$)	\$7
Power Consumption	0.65W
Material	OLED
Display Resolution	128x64
Text Characters	20X4

Arduino Dot Matrix LCD consists of a dot matrix of lights or mechanical indicators arranged in a rectangular configuration (other shapes are also possible, although not common) such that by switching on or off selected lights, text or graphics can be displayed. A dot matrix controller converts instructions from a processor into signals that turn on or off indicator elements in the matrix so that the required display is produced. **Table 59** demonstrates all values associates to this type of LCD.

**TABLE 59: ARDUINO DOT MATRIX DISPLAY FOR LCD ALTERNATIVES**

Criteria	Arduino Dot Matrix Display Value
Dimensions	4.92 x 1.7 x 0.4 inches
Cost (\$)	\$12
Power Consumption	0.5W
Material	Dot Matrix LCD
Display Resolution	128x64
Text Characters	20x4

LCD comparison between the Asiawill color TFT Touch LCD Screen Module, the Huhushop White OLED LCD LED Display Module and the Arduino Dot Matrix LCD is needed to determine which model fits best the projects criteria. The Asiawill color TFT

Touch LCD Screen Module meets all the requirements to be used as a display of the LVAD parameters. However, the article was not the most economical and it was decided to use the Arduino Dot Matrix LCD. It is the one with the greatest accessibility and is the least that consumes energy for the project, which is ideal.

TABLE 60: RATING WEIGHTING DECISION MATRIX FOR LIQUID CRYSTAL DISPLAY SELECTION

Liquid Crystal Display Selection Decision Matrix					
Criteria	Value	Weight	Asiawill Color TFT Touch Screen Module	Huhushop White OLED LCD LED Display Module	Arduino Dot Matrix LCD
Dimensions	1"	0.1	1.8	3	1.4
Cost	\$15	0.15	1.5	3	2.8
Software Cost	\$0	0.15	2	2	3
Power Consumption	0.5 W	0.05	3	2	3
Material	TFT	0.15	3	1.4	2
Display Resolution	320x240	0.2	3	1.4	2
Text Characters/ Rows	20x4	0.2	2	2.8	2
Total	1		<b>2.58</b>	<b>2.23</b>	<b>2.61</b>

A connection module is needed for the telemonitoring app to work. Several alternatives were assessed to carry out this task, see **Figure 35**.



FIGURE 35: WI-FI MODULE OPTIONS

The Wi-Fi Module is a self-contained SoC with integrated TCP/IP protocol stack that can provide access to a Wi-Fi network, or act as an access point. The Arduino UNO WIFI Rev.2 has 14 digital input/output pins—5 can be used as PWM outputs—6 analog inputs, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller. Simply connect it to a computer with a

USB cable or power it with an AC adapter or battery to get started. **Table 61** demonstrates all values associates to this type of LCD.

**TABLE 61: ARDUINO UNO WI-FI CRITERIA**

Criteria	Arduino Uno Wi-Fi Rev2- ABX00021
Dimensions	68.6mm x 53.4mm
Cost (\$)	\$12
Weight	25g
Ports	11
Clock speed	16 MHz
Power Consumption	Low

The ESP8266 WIFI Module is a self-contained SOC with integrated TCP/IP protocol stack that can give any microcontroller access to your WIFI network. The ESP8266 is capable of either hosting an application or offloading all WIFI networking functions from another application processor. Each ESP8266 module comes pre-programmed with an AT command set firmware, meaning, you can simply hook this up to your Arduino device and get about as much WIFI-ability as a WIFI Shield offers. This module has a powerful enough on-board processing and storage capability that allows it to be integrated with the sensors and other application specific devices through its GPIOs with minimal development up-front and minimal loading during runtime. **Table 62** demonstrates all values associates to this type of LCD.

**TABLE 62: ESP8266 WI-FI MODULE CRITERIA**

Criteria	ESP8266 Wi-Fi
Dimensions	58 mm x 48.9 mm
Cost (\$)	\$7
Weight	20g
Ports	17
Clock speed	80 MHz
Power Consumption	Low

The ESP32 WIFI and Bluetooth chip is the latest generation of Espressif products. It has a dual-core 32-bit MCU, which integrates WIFI HT40 and Bluetooth/BLE 4.2 technology inside. The ESP32 WIFI and Bluetooth chip has a significant performance improvement. It is equipped with a high-performance dual-core Ten silica LX6 MCU. One core handle high speed connection and the other for standalone application development. The ESP32 has 32 achieves ultra-low power consumption with a combination of several proprietary software applications. The state-of-the-art power saving features include fine resolution clock gating, power modes, and dynamic power scaling.

TABLE 63: SP32 WI-FI & BLUETOOTH MODULE CRITERIA

Criteria	SP32 Wi-Fi & Bluetooth Module
Dimensions	18 mm x 25 mm x 3mm
Cost (\$)	\$10
Weight	22g
Ports	18
Clock speed	240 MHz
Power Consumption	Low

A decision matrix, see **Table 64**, was carried out to evaluate all options and select the most convenient one to work with the program. For this case, the ESP8266 Wi-Fi is chosen since it is the most convenient and economical to be able to meet the budget and the established requirements.

With the selection of main components established, the next course of action was developing a risk assessment matrix tool to analyze risk. Risks regarding the controls with their mitigation strategies were listed on **Table 18**. The exclusive risks of the monitoring subsystem are considered medium risk and low risk.

TABLE 64: RATING WEIGHTING DECISION MATRIX FOR WI-FI MODULE SELECTION

Wi-Fi Module Selection Decision Matrix					
Criteria	Value	Weight	Arduino Uno Wi-Fi Rev2- ABX00021	ESP8266 Wi-Fi	SP32 Wi-Fi & Bluetooth Dual-Core Module
Dimensions	1''x1''	0.15	1.8	2	2
Hardware Cost	\$10	0.10	1.1	3	2.8
Additional Software Cost	\$0	0.10	3	3	2.8
Weight	10g	0.2	1.2	3	3
Clock speed	240 MHz	0.2	1	2	3
Channel Ports	16	0.1	1.4	1.4	2
Power Consumption	Low	0.15	2	2.8	2.8
Total		1	1.64	2.82	2.43

Providing an unsynchronized monitoring of pump parameters is deemed as a low risk even due to their low likelihood and medium severity. If unaddressed, the monitor system can feed patients false monitoring which can lead to stressful situations that worsen their heart health. On the other hand, hacking into the application interphase is deemed as a medium risk due to their low likelihood and high severity. This can be extremely dangerous as any malicious hacking can reprogram the device purpose causing injuries or even death. All aforementioned risks are listed on **Table 65** and assessed on their likelihood of occurrence and the severity of their consequences using a risk assessment matrix found on **Figure 36**.

TABLE 65: LIST OF RISKS IN TJE MONITORING SUBSYSTEM

List of Risks
A – Failed Power Supply
B – Crashing from hardware problems or software errors (operating system failure)
C – Incorrect Sensor Readings
D – Alarm Fatigue (Desensitization towards alarms)
E – Incorrect connection in cables or wiring of telemonitoring system
F – Hacking into application interphase
G – Unsynchronized Monitoring of Pump Parameters (by complications or offset of usage)

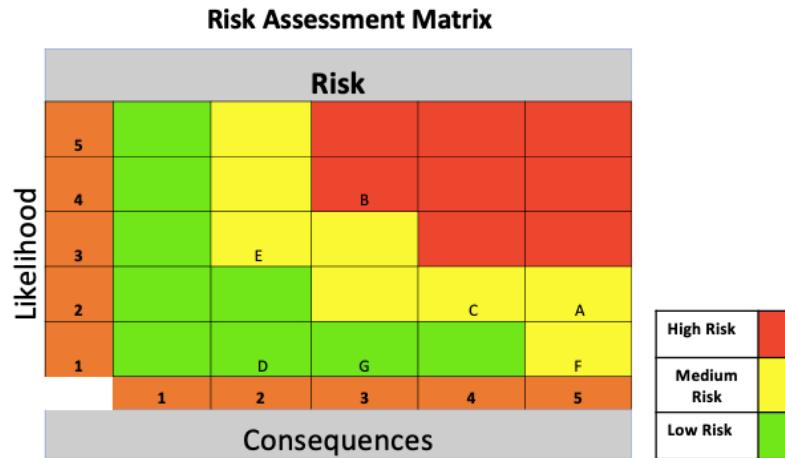


FIGURE 36: MONITORING SUBSYSTEM RISK ASSESSMENT MATRIX

## **PHASE C.1: DESIGN OF PARTS AND COMPONENTS**

### **DETAIL DESIGN STUDIES**

During detail design studies refines and plans, the design, specifications and estimates at subsystem-level. This chapter will demonstrate each of the subsystem engineering analysis and designs performed.

#### **HEART PUMP SUBSYSTEM**

Engineering analysis of the heart pump subsystem was developed based on a writeup that established the interface requirements of the heart pump subsystem and other subsystems in relation to it. The writeup states the following:

**Individuals who suffer from heart failure (HF), possess a heart that is unable to pump enough blood to meet the body's demands. Patients with HF typically possess an end-diastolic volume of 150 ml per beat, a stroke volume of 50ml per beat and a heartbeat of 70 beats per minute. Design a pump and pipeline unit for an electromechanical circulatory support device for a patient diagnosed with HF that can maintain its ejection fraction (EF) above 40%. Perform the following using their designated figures to establish interface requirements:**

- a)** Calculate the pump power at an CO of 5.5 L/min
- b)** Determine the motor specifications
- c)** Computer-Aided Design (CAD) of the motor enclosure, rotor and pipeline unit
- d)** Find the tolerances between each pipeline component

The physiological parameters of major importance for the functionality of this medical device are the ejection fraction (EF) and Cardiac Output (CO). However, the calculation of such parameters is handled in the controls design to specification section for accurate PID regulation program establishment. Motor selection was appropriate for the

heart pump subsystem and from the trade studies realized on Phase B: **Controls Subsystem** the best solution was a Brushless DC motor. A motor was selected for appropriate size fitting in the motor enclosure. The motor specifications can be seen on **Table 66**.

TABLE 66: MOTOR SPECIFICATIONS

Specification/Parameter	Value
Back-EMF constant (K)	0.028 V.s/rad
Internal Resistance (R)	0.66 Ω
Internal Inductance (L)	11mH
Rotor Moment of Inertia (J)	0.06 Kg · m <sup>2</sup>
Efficiency (N <sub>t</sub> )	0.49
Max Voltage (V)	5V
No Load Speed	6,100 RPM

The dynamic pump power specification of the motor and rotor are obtained from the ideal CO of 5.5 L/min and the height difference between outlet and inlet elevations evaluated at 2.2 in found in **Figure 37**.

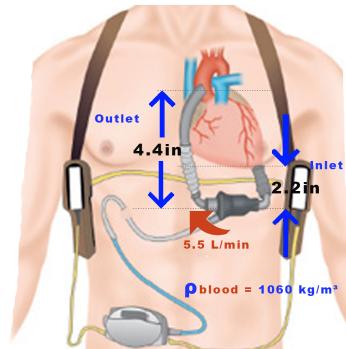
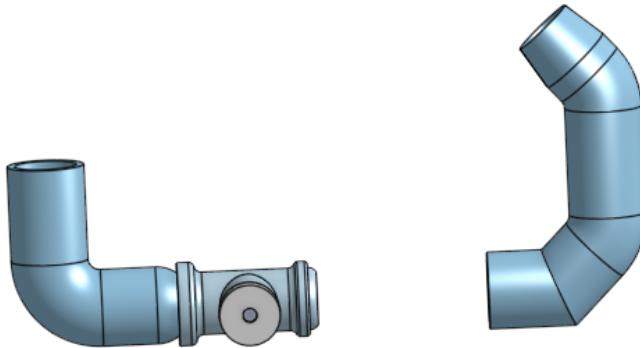


FIGURE 37: PUMP FLOW DIAGRAM

By evaluating **Equation (1)** an average working pump power will be at 0.11 W well around the pump subsystem compliance assessment due to the proportional flow carried in the pump system from the tubing elevations. Therefore, no significant prolonged heat transfer from the pump's work will be assessed as a risk because of the proper transport phenomena capable for the pump during the phase C1 evaluation of that particular subsystem. Step-by-step calculations can be found in **Appendix C: Calculations**.

$$P_{pump} = (CO_{ideal} * g * \rho_{atm} * h_{outlet-inlet}) / N_t \quad (1)$$

Afterwards, the tubing system moves the blood from the left ventricle and bypasses the aorta with help from the adjustments in the rotor speed from the motor voltage changes with the required pump parameters and PID tuning parameters established in a program that can maintain a continuous modulated control. With the motor specifications established in **Table 66**, the next step in constructing the pump subsystem is a Computer-Aided Design (CAD) of the motor enclosure, rotor and pipeline unit. The three tubing sections (main component, inlet, and outlet) can be observed in the tubing CAD found on **Figure 38**. All detail drawings can be found on **Appendix E: Detail Drawings**.



**FIGURE 38: HEART PUMP DRAWING**

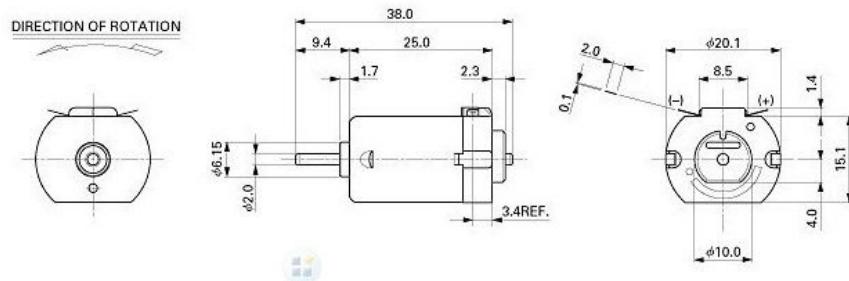
Safety factors for the tolerance levels in the blood transport are evaluated for each constructed tubing component from the System integration plan instructed from the later phases of the Capstone Design. The Tolerance calculation, **Equation (2)** is simply assessed by the difference between upper limit and lower limit with for each tubing component.

$$\text{Tolerance} = \text{Upper Limit} - \text{Lower Limit} \quad (2)$$

For example, the outflow pipe presents a heart pump connection safety factor of 0.56 while the aorta connection has a safety factor of 0.30 accounting for a tolerance level of 0.26. On the other hand, the inflow pipe produces a safety factor of 0.55 at the heart pump connection while the left ventricle connection offers a 0.36 safety factor. The

resultant is a 0.19 tolerance level for the inflow pipe. Finally, the heart pump accounts for a tolerance level of 0.25. This is because, at the main connection, the outflow side offers a safety factor of 1 and the inflow side provides a 0.75 safety factor.

The trade studies realized on Phase B: **Controls Subsystem** focused the selection of the subsystem's main components: motor, rotor, and tubing material. Based on the decision matrix, it was concluded that the most suitable motor for the projects requirements and implanted environment was the Brushless DC version. The model is can easily fit small enclosure for the tubing components. It's simple design and small size flexibility provide a straightforward layout that reliefs the handmade construction of several magnetically axial self-bearing motors. A detail drawing, as seen on **Figure 39**, provides complete and precise descriptions of the components.



**FIGURE 39: MOTOR DETAIL DRAWING**

Even though the Brushless DC Motor was deemed as the best solution and complied with most requirements, it did not meet one of those requirements. The ideal weight and length for the motor was less than 40 g and 40 mm, respectively, to make the patient feel less of a one-and-a-half-inch protruding motor pumping. However, the BLDC Motor failed compliance will not affect the completion or performance of the system as minute adjustments from low working voltage can be implemented to make up for this. All requirements and compliances can be seen on

**Table 67.**

TABLE 67: MOTOR COMPLIANCE ASSESSMENT

Motor Compliance Assessment			
Criteria	Desired Value	BLDC Motor Value	Compliance
Weight (g)	32g	40g	No
Length (mm)	35 mm	50mm	No
Diameter (mm)	25 mm	25mm	Yes
Velocity (RPM)	2000 RPM	2500RPM	Yes
Operating Flow (L/min)	5 L/min	10L/min	Yes
Cost (\$)	< \$50.00	\$50.00	Yes
Life Expectancy	2 years	> 2 year	Yes

Rotors served as the second assessed main component of the pump subsystem.

Based on the decision matrix it was concluded that the most suitable rotor type for the projects requirements and environment were the open-end rotors. They are frequently used on devices to provide portability and comfortability aspects like the TLVAD product. Their small and simple frame, along with its straightforward mechanics with calculated usability and durability, make it a great selection for this particular project. A detail drawing, as seen on **Figure 40**, provides complete and precise descriptions of the purchased component's dimensions and shape. All detail drawings can be found on **Appendix E: Detail Drawings**.

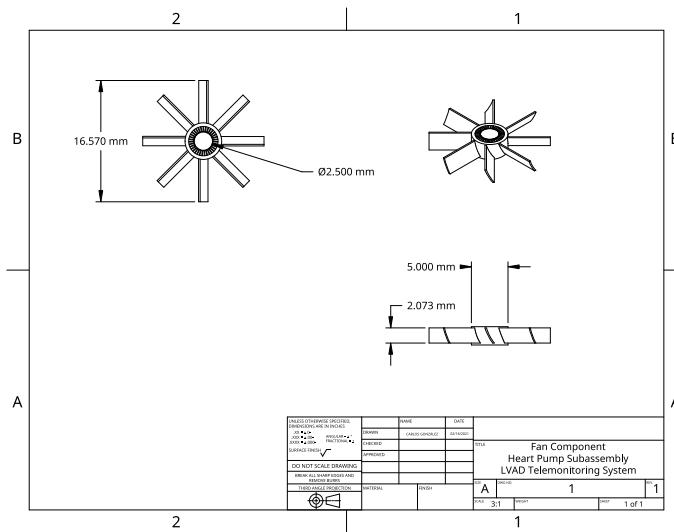


FIGURE 40: OPEN-END ROTOR DETAIL DRAWING

Even though the open-end rotors were deemed as the best solution and complied with most requirements, it did not meet one of those requirements. Ideally the rotors should

work at a speed around 2000 RPM to move more easily the blood through the body constantly, however the purchased models weigh around 1500 RPM without regarding friction from wear and tear. This failed compliance will not affect the completion or performance of the system as MOEs and MOPs at a system-level related speed did not include the pump section and only applied to control subsystem along with its telemonitoring communication app. All requirements and compliances regarding the rotor selection can be seen on **Table 68**.

TABLE 68: ROTOR COMPLIANCE ASSESSMENT

Rotor Compliance Assessment			
Criteria	Desired Value	Open-end Rotor Value	Compliance
Speed (RPM)	2000 RPM	1500 RPM	No
Length (mm)	60 mm	63 mm	Yes
Diameter (mm)	25 mm	30 mm	Yes
Poles (#)	4	4	Yes
Frequency (output flow)	Proportional	Proportional	Yes
Cost (\$)	\$40.00	Varies on size	Yes

The final main component of the controls' subsystem was the tubing and respective manufactured material. Based on the decision matrix it was concluded that the most suitable material for the projects requirements and environment was the ePTFE. A durable Teflon coating can be out of simple commercial tape or clinically expanded polytetrafluoroethylene; therefore, it is always more resistant to pressure and corrosion. Even though the ePTFE tubing material was deemed as the best solution and complied with most requirements, it did not meet one of those requirements. Ideally the tubing system should weigh around 20g, however the designed model weighs around 30g. This failed compliance could affect the completion or performance of the system as system-level MOE's and MOP's related weight since this component is part of the implanted product. To reduce risk of not complying with MOE's and MOP's, the motor and rotor will be

designed to be lightweight. All requirements and compliances regarding the battery selection can be seen on **Table 69**.

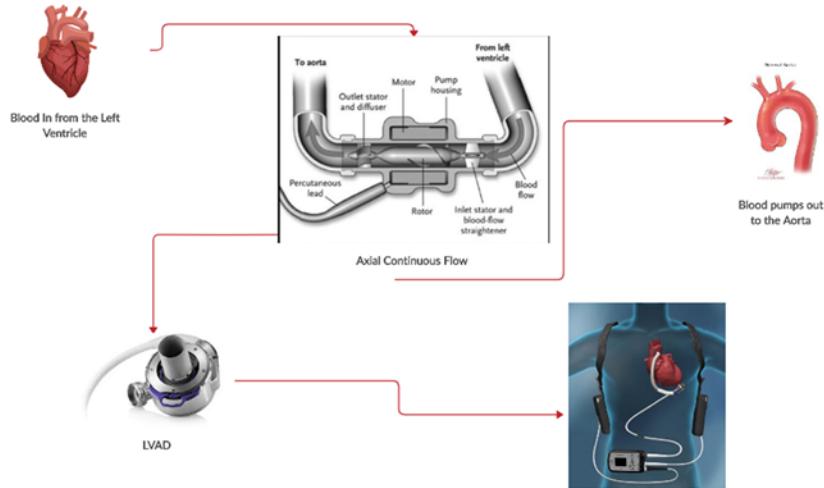
TABLE 69: TUBING MATERIAL COMPLIANCE ASSESSMENT

Tubing Material Compliance Assessment			
Criteria	Desired Value	ePTFE Tubing Value	Compliance
Weight (g)	20 g	30 g	No
Friction (levels)	Low	Low	Yes
Water resistance (compliance)	Yes	Yes	Yes
Stability (levels)	High	Medium High	Yes
Tolerance (levels)	High	Medium	Yes
Cost (\$)	\$10.00	\$10.00 for 10 feet	Yes

Other relevant parts of the pump subsystem include the motor top and bottom caps, the connected flow sensor (which is an intricate component of the control subsystem), and the driveline where the silicone tube connects from the pump cables to the control system outside the body. The flow sensor integration and functionalities regarding the TLVAD control will be discussed further in this chapter in the **Monitoring Subsystem** section. However, the bottom and bottom caps will be designed particularly for the motor worked with for this project.

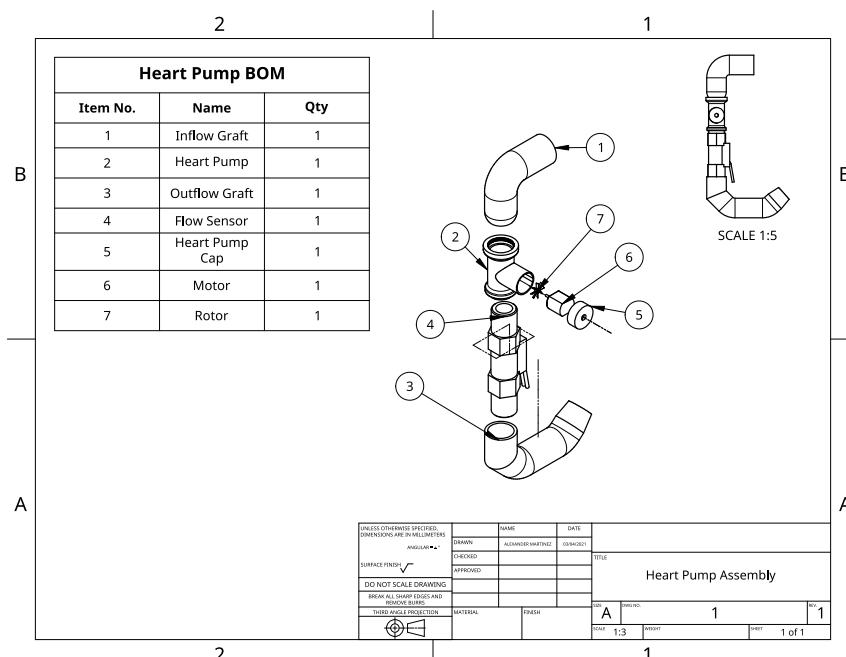
With all the main components and parts established of the pump subsystem, the hardware must be connected accordingly to comply with both subsystem and system-level requirements and interfaces. **Figure 41** illustrates the working principal, both the mechanical and electronic aspects of the subsystem will work cohesively towards. Essentially, this working principal states that power will be provided from the batteries to both the microcontroller and pump motor. Conversely, the microcontroller will provide modulation of the voltage supplied to the motor. This modulation will provide blood flow regulation via the rotor speed, this process will continue continuously while the sensor provides the feedback on current blood flow rate to the microcontroller. Using the

feedback, the microcontroller can indirectly regulate blood flow until it achieves a desired setpoint.



**FIGURE 41: PUMP SUBSYSTEM WORKING PRINCIPAL**

The complete structure of the pump subsystem can be seen on the exploded drawings of the tubing system shown on **Figure 41**. Below on **ng Table 70 70** the schematics each connection is stated in so it can be easily understood. All system BOM's can be seen on **Appendix D: Bill of Materials**.



**FIGURE 42: PUMP SUBSYSTEM EXPLODED DRAWING**

**TABLE 70: TUBING CONNECTIONS OF THE HEART PUMP SUBSYSTEM**

Tubing Connections of the Pump Subsystem	
Main Connector	Inlet Connector
Connected to Inlet to receive blood	Receives blood from heart through left ventricle
Contains motor to modulate the working voltage	Transports blood to main connector
Motor attached to rotor inside to modulate speed	Sends blood smoothly to the adjustment period
Connected to flow sensor to detect changes in output	<b>Inlet Connector</b>
Contains bottom and top caps to protect motor from spillage	Receives blood from flow sensor through main connector
Connected to Outlet from flow sensor to transport output	Transports blood to entire body
Driveline attached to the top cap and flow sensor	Sends blood transitionally through the ascending aorta

Now that the pump system has been under detail analysis and designed to comply with the specifications at both subsystem and system-level, performance estimates should be addressed to prove compliance with subsystem MOP's. These subsystem-level MOPs are stated on **Table 13**. The requirement for the subsystem should meet a suitable diameter of maximum 50 mm was met on Phase B with the tubing drawings. The other requirements were met at Phase C.1 as they are assessed with the performance estimates based on patient specific parameters given in writeup. The subsystem is able to measure the motor voltage using PID tuning parameters and the feedback response of the blood flow measurements from the sensor. Estimated performance is a range of 3.44 V to maintain an average of 5.5 L/min flow rate and 3000 RPM. This voltage regulation intrinsically and indirectly achieves regulation of the pump blood flow output, estimating a performance of ideal 5.5 L/min by proportionally measuring the rotor speed from the motor working voltage. In addition, utilizing the voltage supplied to the motor the program is able to calculate both pump rotor speed as well as the pump power. Their performance estimates are 2672.70 to 3499.96 RPM and 0.084 to 0.11 W, respectively. Based on estimates full compliance of the controls' subsystem MOPs was achieved. A full list of MOPs and their performance estimates can be found on **Table 71**.

TABLE 71: PUMP SUBSYSTEM PERFORMANCE COMPLIANCE ASSESSMENT

MOP'S	Performance	Phase	Compliance
Should meet a suitable max diameter (mm)	50 mm	B	Yes
Motor must maintain speed range (RPM)*	1309 RPM	C.1	Yes
Pump must maintain flow range (L/min)*	5.5 L/min	C.1	Yes
Pump must work with a max power (W)*	0.2 W	C.1	Yes
Blood flow should be directly proportional to rotor speed	Proportional	C.1	Yes

\*Performance values are patient specific (writeup) and range for optimal values.

## CONTROLS SUBSYSTEM

Engineering analysis of the control's subsystem was developed based on a writeup that established the interface requirements of the control's subsystem and other subsystems in relation to it. The writeup states the following:

**Individuals who suffer from heart failure (HF), possess a heart that is unable to pump enough blood to meet the body's demands. Patients with HF typically possess an end-diastolic volume of 150 ml per beat, a stroke volume of 50ml per beat and a heartbeat of 70 beats per minute. Design a control unit for an electromechanical circulatory support device for a patient diagnosed with HF that can maintain its ejection fraction (EF) above 40%. The use the specifications of the motor utilized for the application, referenced on Error! Reference source not found.. Perform the following using their designated figures to establish interface requirements:**

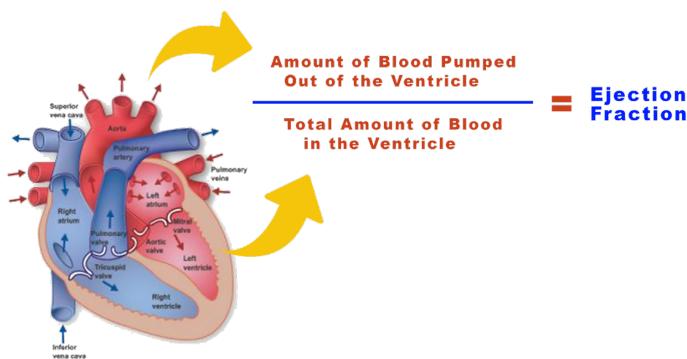
- a) Calculate the patients current EF. Use **Figure 43**.
- b) Calculate the patients current Cardiac Output (CO).
- c) Calculate the stroke volume needed to achieve an EF above 40%.
- d) Calculate the stroke volume needed to achieve an CO of 5.5 L/min
- e) Determine the pump speed needed to achieve an CO of 5.5 L/min.
- f) Determine the voltage needed to apply to achieve desired pump speed.
- g) Find the system transfer function and PID tuning parameters. Use **Figure 44**, **Figure 45**, and **Figure 46**.
- h) Write a program that can maintain a continuous modulated control of pump speed through voltage.

The engineering analysis starts by identifying the given values on the writeup and evaluating certain physiological parameters to determine if a patient requires an LVAD device. All given parameters can be seen in **Table 72**.

**TABLE 72: GIVEN MEASUREMENTS/PARAMETERS IN WRITEUP**

Measurement/Parameter	Value
End diastolic Volume (EDV)	150 $\frac{ml}{beat}$
Stroke Volume (SV)	50 $\frac{ml}{beat}$
Heart Rate (HR)	70 $\frac{beat}{min}$
Ideal Cardiac Output (CO)	5.5 L/min
Desired Volume Displaced	78.57 $\frac{ml}{beat}$ at 0.04 $\frac{beat}{rev}$
Minimum Ejection Fraction (EF)	40 %

Such physiological parameters are the ejection fraction (EF) and Cardiac Output (CO). The EF represents how much blood the left ventricle pumps out with each contraction. An EF measurement under 40 percent may be evidence of heart failure. Hence, it is important for this value to be calculated to determine if that particular patient requires an LVAD device. EF calculation requires the stroke volume (SV) and end-diastolic volume (EDV). The SV is the amount of blood that is expelled from the heart with each contraction. On the other hand, the EDV is the amount of blood that is in the ventricles before the heart contracts. The relationship between these parameters is illustrated on **Figure 43** and seen on **Equation (3)**.



**FIGURE 43: EJECTION FRACTION DIAGRAM**

$$EF = \frac{SV}{EDV} \quad (3)$$

Solving this equation using the patient specific parameters yields an EF of 33.33%. This value suggests the patients is in need of an LVAD technology. Furthermore, the CO value of a patient can also indicate HF incidence, as this value represents how much blood your heart pumps per beat. A CO below 4 L/min can indicate HF. Even though CO can be measured diverse ways, utilizing the patient's heart rate (HR) and SV will suffice for an accurate estimation. Making use of **Equation (4)** it is determined the patient's CO is 3.5 L/min, further indicating HF diagnosis. However, physicians determine HF diagnosis depending on a plethora of additional factors not included in this analysis as they are more medical oriented. Step-by-step calculations can be found in **Appendix C: Calculations**.

$$\text{CO} = \text{HR} \times \text{SV} \quad (4)$$

Once patient is deemed approval of LVAD implantation, it is required to analyze and calculate the SV needed to achieve a minimal normal EF of 40% and optimal CO of 5.5 L/min. The latter can be subject to change by the physician depending on the severity of other risk factors associated to HF, an optimal value will be set accordingly for each patient's needs. Solving for SV using **Equation (3)** provides the minimum amount of blood that should be expelled from the heart with each contraction, which in this case is 60 ml/beat. On the other hand, solving for SV using **Equation (4)** provides the optimal amount of blood that should be expelled from the heart with each contraction, a value calculated to 78.57 ml/beat. These set of parameters indicate the range of SV (60 ml/beat to 78.57 ml/beat) the TLVAD must provide, in order to comply with both its system-level and subsystem-level MOP's regarding blood flow regulation. Step-by-step calculations can be found in **Appendix C: Calculations**.

Fulfilling the system-level MOP of maintaining a CO of 5.5 L/min requires a determination pump parameter related to the rotor speed and voltage applied to the motor. The pump rotor will displace or propel the blood through the pipeline unit and into the Aorta. However, this blood displacement depends on the speed the rotor is rotating, and the type of motor utilized. Since, the optimal SV of  $78.57 \frac{ml}{beat}$  should be displaced at  $0.02 \frac{beat}{rev}$  for this application, **Equation (5)** can be utilized to determine the appropriate rotor speed for maintaining a CO of 5.5 L/min, using a DC motor. This formula utilizes the desired pump output or CO, and the volume displacement. The equation is readily available in many engineering textbooks, fluid power design guides, and hydraulic handbooks. Step-by-step calculations can be found in **Appendix C: Calculations**.

$$N = \frac{231(CO)}{D} \quad (5)$$

When utilizing **Equation (5)** with the appropriate units for each parameter it is determined that for the system to comply with MOP of maintaining a 5.5 L/min flow, a speed of 3,499.96 RPM should be mostly maintained. However, since the controls subsystem focuses on continuously modulating the pump speed through voltage, the voltage that should be mostly applied to the motor must be calculated. Assuming a linear relation between the input voltage and motor velocity, the voltage needed to reach a 3,499.96 RPM rotor speed can be calculated. Using the motor parameters seen on Error! Reference source not found. and standard linear equation, their relationship can be established on **Equation (6)**.

$$V_{applied} = 0.00098(N) \quad (6)$$

Evaluating Equation (6) a value is established for the system to comply with MOP of maintaining a 5.5 L/min flow, a 3.44V supply to the motor should be mostly maintained. Thus, maintaining a 3,499.96 RPM rotor speed.

With the motor specifications established in Error! Reference source not found. and parameters for motor controls computed, the next step in constructing the controls subsystem is find the system transfer function and PID tuning parameters. Firstly, the dynamic equations of the motors circuit and rotor are established using the motor circuit diagram found in **Figure 44**.

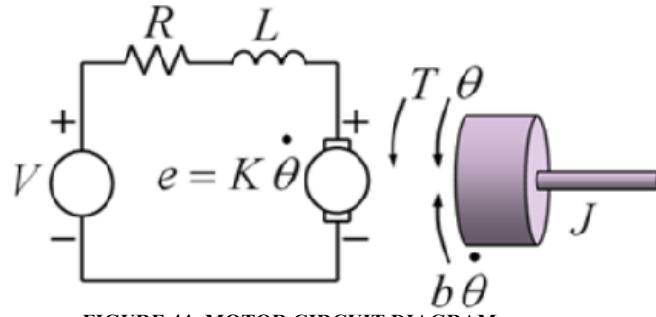


FIGURE 44: MOTOR CIRCUIT DIAGRAM

The dynamic equations of the motors circuit and rotor can be seen by **Equation (7)** and **Equation (8)**, respectively.

$$V(T) = I(T) \cdot R + L \cdot \frac{d}{dt} i(t) + k\omega(t) \quad (7)$$

$$K \cdot (t) = J \cdot \frac{d}{dt} k\omega(t) + b \cdot \omega(t) \quad (8)$$

These equations are converted into their Laplace transforms and combined. Then its transfer functions is found and evaluated using the specifications leaving **Equation (9)**.

$$G_M = \frac{K}{(J \cdot L) \cdot s^2 + ((J \cdot R) + (b \cdot L)) \cdot s + (R \cdot b + K^2)} \quad (9)$$

The PID equation is established using the PID block diagram found in **Figure 45** and can be seen on **Equation (10)**.

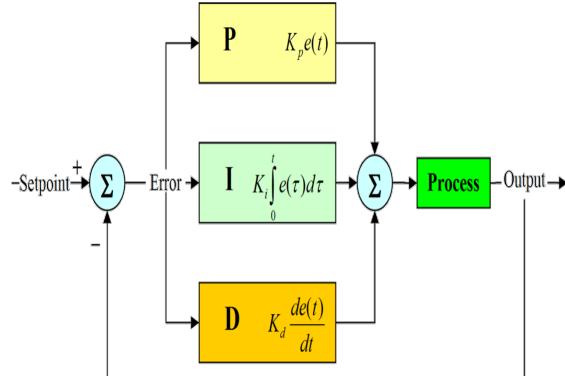


FIGURE 45: PID BLOCK DIAGRAM

$$u(t) = K_p e + K_d \frac{de}{dt} + K_i \int_0^t e(t) dt \quad (10)$$

The PID equation can be seen on and after finding its Laplace transform, the closed loop transfer function can be calculated using the control block diagram found in **Figure 46**.

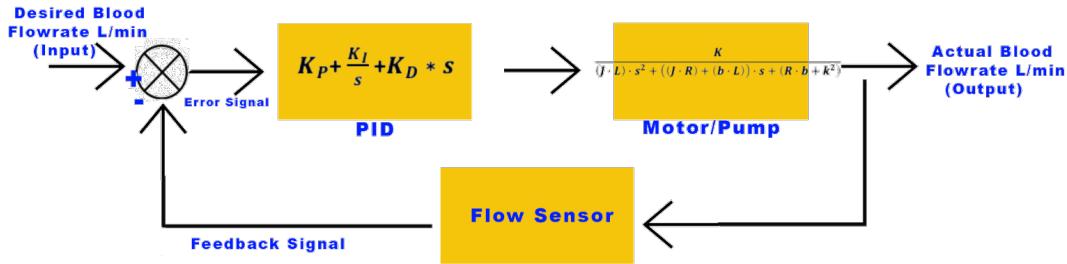


FIGURE 46: CLOSED LOOP BLOCK DIAGRAM

The closed loop transfer function represents the relationship between the output signal of a control system and the input signal. The controls subsystem transfer function is given by **Equation (11)**

$$G = \frac{K_D s^2 + K_P s + K_I}{0.066 s^3 + (K_D + 4.51) s^2 + (K_P + 33.96) s + K_I} \quad (11)$$

The PID portion of these control circuit is a series of numbers that are used as adjustments in order to achieve your objective, these are called tuning parameters. The proportional, integral and derivative terms of these controls calculate a correction factor applied to the input. Proportional tuning involves correcting a target proportional to the

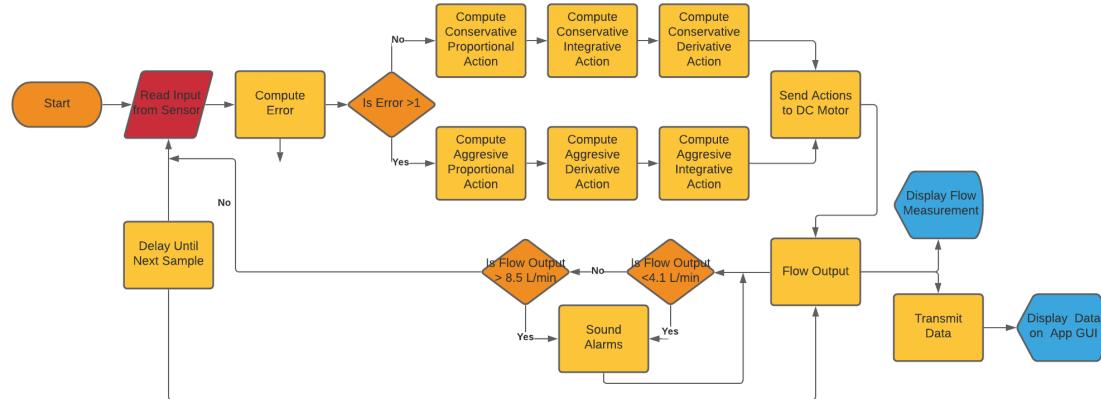
difference. Integral tuning attempts to remedy this by effectively cumulating the error result from the proportional action to increase the correction factor. Derivative tuning attempts to minimize any overshoot by slowing the correction factor applied as the target is approached. The closed loop transfer function makes the calculation of the PID tuning parameters possible. However, initial assumptions were made to calculate these tuning parameters. A max overshoot of 1% was assumed to minimize deviation in the final (steady state) value of the response. Assumption that the difference between the desired value and the actual value of a system output in the limit as time goes to infinity (step response steady-state error) would be equal to zero. An ideal rise time of 0.04 was assumed, to have rapid and constant parameter modulation. The final assumption made was initially making  $K_I$  equal to zero, in order to solve for  $K_P$  and  $K_D$  in the closed loop transfer function. The computed values for  $K_P$  and  $K_D$  were 8.77 and 5.54, respectively. It is important to mention  $K_I$ ,  $K_P$ ,  $K_D$  would be later adjusted accordingly through trial and error. Step-by-step calculations can be found in **Appendix C: Calculations**.

With the required pump parameters and PID tuning parameters established a program that can maintain a continuous modulated control of pump speed through voltage can be developed. The algorithm's the flow of information and processing or PID programming flowchart found on **Figure 47**.

Essentially, the algorithm starts by reading the input or actual blood flow rate from the sensor and calculates the error or distance from its desired value of 5.5 L/min. Then it decides if the error is higher or lower than the number one. If the error value is lower than one, it will compute the derivative, integrative and proportional actions conservatively based on the calculated tuning parameters. However, if the error value is higher than one

then derivative, integrative and proportional actions will be calculated more aggressively, using the tuning parameters incremented by three. This will provide a more rapid response. Once the PID actions are calculated, no matter if it used aggressive or conservative parameters, the voltage that will be supplied to the motor will be regulated accordingly. The voltage supplied serves as a signal, the higher the signal the faster will rotate the rotor. This leads to the flow output which is then read again by the sensor on a loop. Once voltage is calculated and signaled, the program calculates the rotor speed and pump power based on the supplied voltage and current flowrate. In addition to the main controls, the algorithm provides an alarm system. If the flow output is too low, at 4.0 L/min or lower it will provide both visual and auditory alarms. Conversely, if the flow output is too high, at 8.0 L/min or higher it will also provide both visual and auditory alarms. Even though the algorithm instructions are thoroughly explained in both the text and programming flowchart, **Appendix F: Code** contains all the code utilized for both controls and monitoring subsystem with a functional description.

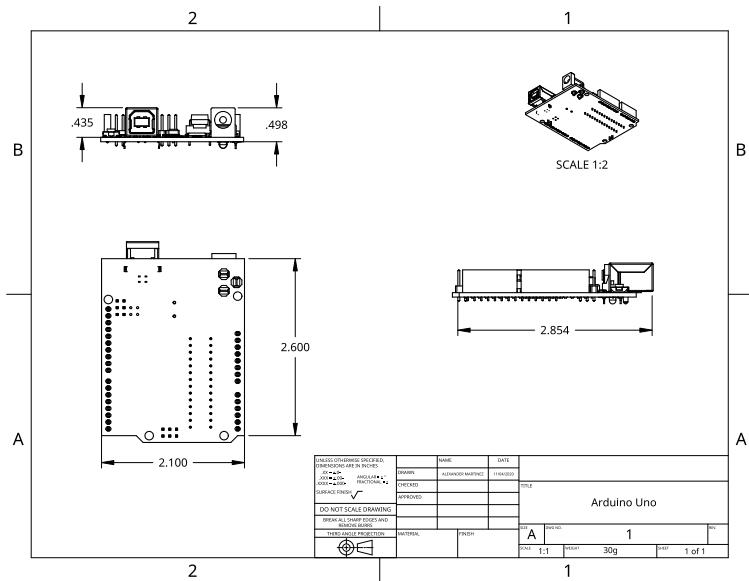
The software aspects of the control's subsystem have been established; hence the hardware aspects must be further developed to achieve the subsystems requirements. The trade studies realized on Phase B: **Controls Subsystem** focused the selection of the subsystem's main components: microcontroller, batteries, and flow sensor.



**FIGURE 47: PID PROGRAMMING FLOWCHART**

Based on the decision matrix it was concluded that the most suitable microcontroller for the projects requirements and environment was the Arduino Uno. Its flexibility and easy to use software and hardware provide a straightforward design that reliefs the handmade construction of several electronic controls on a 6-month time constraint. The model is compact and can easily fit small enclosure for the electronic components. A detail drawing, as seen on **Figure 48**, provides complete and precise descriptions of the component's dimensions and shape. All detail drawings can be found on **Appendix E: Detail Drawings**.

Even though the Arduino Uno was deemed as the best solution and complied with most requirements, it did not meet one of those requirements. The ideal operating voltage for the microcontroller was 5V, however the Arduino operates at a 7 to 20 V range. This failed compliance will not affect the completion or performance of the system as it can be worked around. A second power supply can be implemented to make up for this unmet compliance. All requirements and compliances can be seen on **Table 73**.



**FIGURE 48: ARDUINO DETAIL DRAWING**

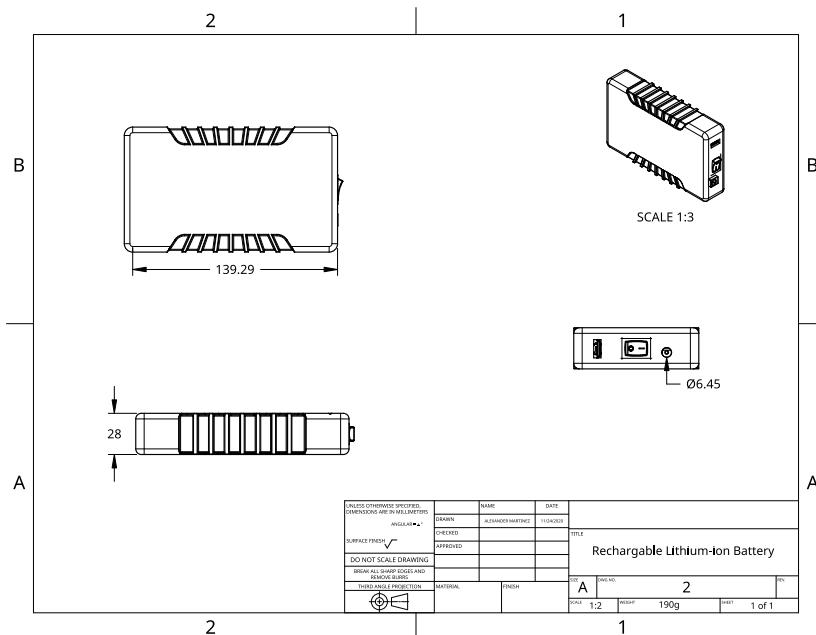
Batteries served as the second assessed main component of the control's subsystem.

Based on the decision matrix it was concluded that the most suitable batteries for the projects requirements and environment were the lithium-ion batteries. They are frequently used on devices to provide portability and telecommunication aspects like the TLVAD product. Their small and thin frame, along with its fast-charge and durability make it a great selection for this particular project. A detail drawing, as seen on **Figure 48**, provides complete and precise descriptions of the purchased component's dimensions and shape. All detail drawings can be found on **Appendix E: Detail Drawings**.

**TABLE 73: MICROCONTROLLER COMPLIANCE ASSESSMENT**

Microcontroller Compliance Assessment			
Criteria	Desired Value	Arduino Uno Value	Compliance
Weight (g)	30g	25g	Yes
Dimensions ( $in^2$ )	$6\ in^2$	$5.67\ in^2$	Yes
Cost	\$50	\$23	Yes
Software Cost	\$0	\$0	Yes
I/O Ports	14	14	Yes
RAM	3k bytes	2k bytes	Yes
Power Supply	5V	5V	Yes
Operating Voltage	5V	7 to 12	No

Even though the lithium-ion batteries were deemed as the best solution and complied with most requirements, it did not meet one of those requirements. Ideally the batteries should weight around 50g, however the purchased models weigh around 190g. This failed compliance will not affect the completion or performance of the system as system-level MOE's and MOP's related weight did not include the controls section and only applied to implanted product. All requirements and compliances regarding the battery selection can be seen on **Table 74**.



**FIGURE 49: LI-ION BATTERY DETAIL DRAWING**

The final main component of the control's subsystem was the flow sensor. Based on the decision matrix it was concluded that the most suitable flowmeter for the projects requirements and environment was the YF-B6. A durable flowmeter made out of copper; hence it is more resistant to pressure and corrosion. A detail drawing, as seen on **Figure 50** provides complete and precise descriptions of the purchased component's dimensions and shape.

TABLE 74: BATTERY COMPLIANCE ASSESSMENT

Battery Compliance Assessment			
Criteria	Desired Value	Li-ion Value	Compliance
Weight (g)	50 g	190g	No
Height (in)	6 in	4.13 in	Yes
Width (in)	4 in	2.48 in	Yes
Cost	\$45	\$25	Yes
Voltage (V)	12 V	12 V	Yes
Life (Charge Cycles)	500 Charge cycles	500 Charge Cycles	Yes

The final main component of the control's subsystem was the flow sensor. Based on the decision matrix it was concluded that the most suitable flowmeter for the projects requirements and environment was the YF-B6. A durable flowmeter made out of copper; hence it is more resistant to pressure and corrosion. A detail drawing, as seen on **Figure 50** provides complete and precise descriptions of the purchased component's dimensions and shape.

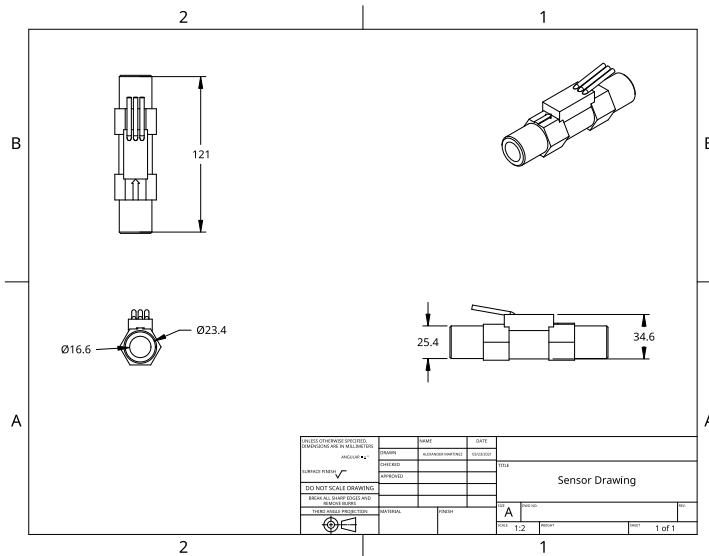


FIGURE 50: YF-B6 FLOWMETER DETAIL DRAWING

Even though the YF-B6 flowmeter was deemed as the best solution and complied with most requirements, it did not meet one of those requirements. Ideally the sensor should weight around 20g, however the purchased model weighs around 79g. This failed compliance could affect the completion or performance of the system as system-level MOE's and MOP's related weight since this component is part of the implanted product.

To reduce risk of not complying with MOE's and MOP's, the pump and pipelines will be designed to be lightweight. All requirements and compliances regarding the battery selection can be seen on **Table 75**.

TABLE 75: FLOW SENSOR COMPLIANCE ASSESSMENT

Battery Compliance Assessment			
Criteria	Desired Value	YF-B6 Value	Compliance
Weight	20g	79g	No
Length	44mm	44mm	Yes
Cost	\$15	\$15	Yes
Flow Range	1 to 10 L/min	1 to 30	Yes
Operating Voltage	5V	5V	Yes
Operating Temperature	25 to 80 °C	25 to 80 °C	Yes

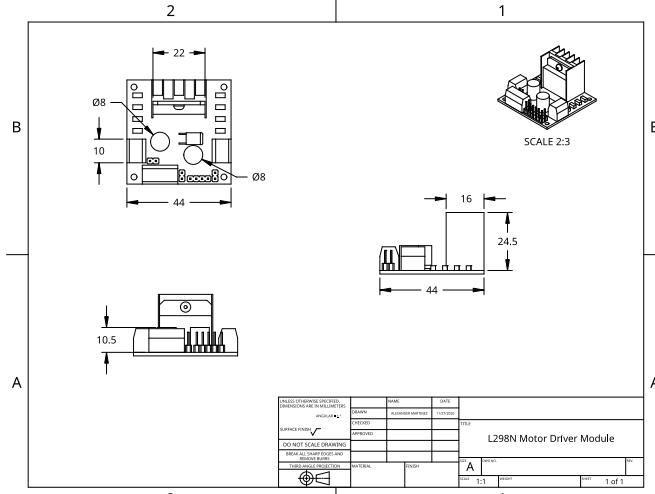
Other relevant parts of the control's subsystem include the LCD, L289N motor driver, and LED's and a buzzer for the alarms. The LCD's integration and functionalities regarding the TLVAD will be discussed further in this chapter in the **Monitoring Subsystem** section. **Figure 51** illustrates these other parts of the control's subsystem.



FIGURE 51: PARTS OF THE CONTROLS SUBSYSTEM

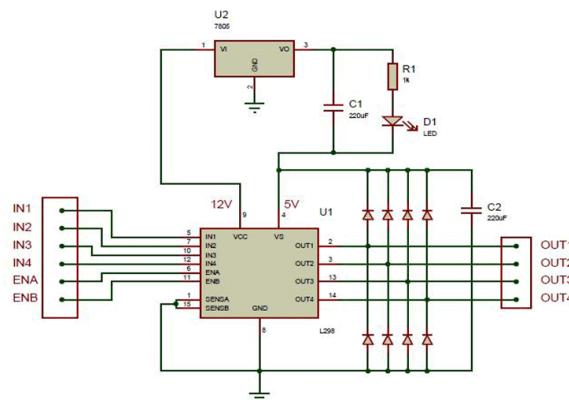
As for the L298N motor driver module, it is a dual-channel H-Bridge motor driver which allows speed and direction control. The module consists of an L298N motor driver chip (IC), 78M05 Voltage Regulator, resistors, capacitor, Power LED, 5V jumper in an integrated circuit. A detail drawing, as seen on **Figure 52** provides complete and precise

descriptions of the purchased component's dimensions and shape. All detail drawings can be found on **Appendix E: Detail Drawings**.



**FIGURE 52: L298N MOTOR DRIVER DETAIL DRAWING**

The L298N motor driver was brought into the project due to its easy usability that could provide a straightforward design that reliefs the handmade construction of several electronic controls on a 6-month time constraint. **Figure 53** illustrates the module's internal circuit diagram.



**FIGURE 53: L298N MOTOR DRIVER INTERNAL CIRCUIT DIAGRAM**

With all the main components and parts established of the controls subsystem, the hardware must be wired accordingly to comply with both subsystem and system-level requirements and interfaces. **Figure 54** illustrates the working principal, both the hardware and software aspects of the subsystem will work cohesively towards. Essentially, this

working principal sates that power will be provided to both the microcontroller and pumps motor. Conversely, the microcontroller will provide modulation of the voltage supplied to the motor. This modulation will provide blood flow regulation via the rotor speed, this process will continue continuously while the sensor provides the feedback on current blood flow rate to the microcontroller. Using the feedback, the microcontroller can indirectly regulate blood flow until it achieves a desired setpoint.

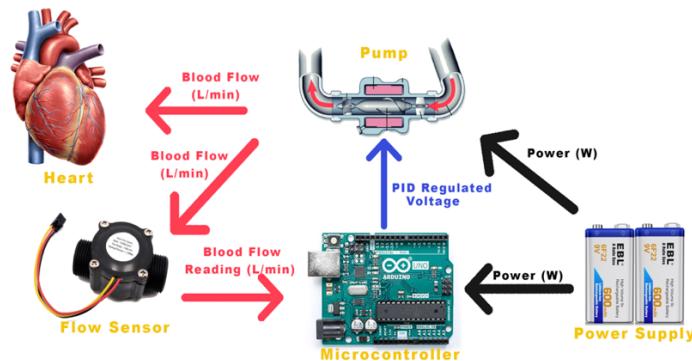


FIGURE 54: CONTROL SUBSYSTEM WORKING PRINCIPAL

The complete wiring of the control's subsystem can be seen on the wiring schematics shown on **Figure 55**. Below the schematics each connection is stated in **Table 76** so it can be easily understood.

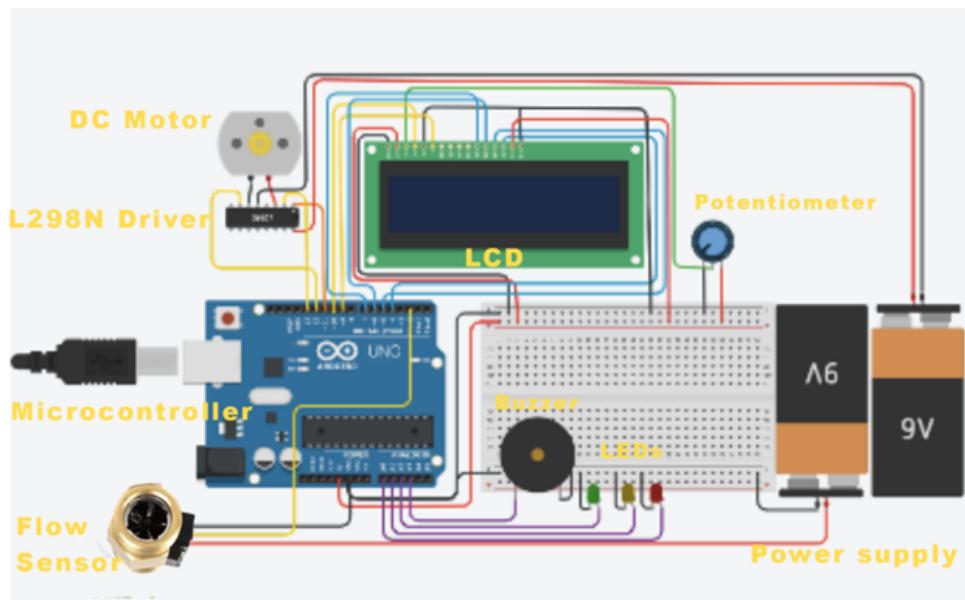


FIGURE 55: CONTROLS SUBSYSTEM SCHEMATIC

TABLE 76: WIRING CONNECTIONS OF THE CONTROLS SUBSYSTEM

Wiring Connections of the Controls Subsystem		
Arduino – LCD	Arduino – Alarms	
LCD RS pin to digital pin 10	LED's cathode and Buzzer's negative to ground	
LCD Enable pin to digital pin 9	Analog pin A0 to Red LED anode	
LCD D4 pin to digital pin 7	Analog pin A1 to Red Yellow anode	
LCD D5 pin to digital pin 6	Analog pin A2 to Red Green anode	
LCD D6 pin to digital pin 5	Analog pin A3 to Buzzer Positive	
LCD D7 pin to digital pin 4	Arduino – L298N Module	
LCD R/W, LCD VSS, and LCD LED- pins to GND	Digital pin 11 to ENA	
LCD VCC and LCD LED+ pin to 5V	Digital pin 12 to IN1	
LCD VO to 10K potentiometer signal	Digital pin 13 to IN2	
10K potentiometer to 5V and GND	Module to 12V battery supply and common GND	
Arduino – Sensor	L298N Module – DC Motor	
Digital pin 2 to Sensor's output	Out1 to Motor Positive	
Sensor to 5V battery supply and common GND	Out2 to Motor Negative	

Now that the control system has been under detail analysis and designed to comply with the specifications at both subsystem and system-level, performance estimates should be addressed to prove compliance with subsystem MOP's. These subsystem-level MOP's are stated on **Table 14**. The requirement for the subsystem to measure blood flow output met and exceeded compliance being able to measure 2 to 25 L/min, this was met on Phase B with flow sensor selection. The other requirements were met at Phase C.1 as they are calculated performance estimates based on patient specific parameters given in writeup. The subsystem is able to regulate the motor voltage using PID tunning parameters and the feedback response of the blood flow measurements. Estimated performance is a range of 2.62 to 3.44 V to maintain a 5.5 L/min flow rate. This voltage regulation intrinsically and indirectly achieves regulation of the pump blood flow output, estimating a performance of ideal 5.5 L/min. In addition, utilizing the voltage supplied to the motor the program is able to calculate both pump rotor speed and pump power. Their performance estimates are 2672.70 to 3499.96 RPM and 0.084 to 0.11 W, respectively. Based on estimates full compliance of the control's subsystem MOP's was achieved. A full list of MOP's and their performance estimates can be found on **Table 77**.

**TABLE 77: CONTROLS SUBSYSTEM PERFORMANCE COMPLIANCE ASSESSMENT**

MOP'S	Performance	Phase	Compliance
Will measure blood flow output (L/min)	2 to 25 L/min	B	Yes
Will calculate pump rotor speed (RPM)*	2672.70 to 3499.96 RPM	C.1	Yes
Will calculate pump power (W)*	0.084 to 0.11 W	C.1	Yes
Must regulate motor voltage (V)*	2.62 to 3.44 V	C.1	Yes
Must regulate pump blood flow output (L/min)*	4.2 L/min to 5.5 L/min (Setpoint)	C.1	Yes

\*Performance values are patient specific (writeup) and range for optimal values

## MONITORING SUBSYSTEM

Engineering analysis of the monitoring subsystem was developed based on a writeup that established the interface requirements of the monitoring subsystem and other subsystems in relation to it. The writeup states the following:

**One way to adequately display Heart Failure's progress is to design a heart pump for an electromechanical circulatory support device for a patient diagnosed with HF that can telemonitor many purposeful parameters. The interphase design would monitor the cardiac output in the range of 4 - 6.5 L / min, end-diastolic volume of approx. 140 ml per beat, a stroke volume of approx. 70ml per beat and a heartbeat of 70 average BPM. Moreover, it will overwatch the pump speed and blood flow at a frequency of 20 kHz.**

- A. Develop a Graphical User Interface application that can display pump parameters
- B. Develop a program that can communicate the acquired or calculated parameters to the GUI

As explained previously, the Arduino Uno will be used as the main microcontroller, which will direct the program and send signals to the LVAD device. From the microcontroller, it is linked to the Arduino Dot Matrix LCD, where the running data will be displayed, either the RPM of the motor and the blood flow (L/min) that goes through the sensor that is located inside the pump. Also, the WIFI connection module and the battery are presented, who will be responsible for making the system work. It is important

to emphasize that everything is connected to the microcontroller, since it is the one who directs the data and transmits the instruction signal.

The monitoring system essentially is a graphical user interface (GUI) or an interactive system of visual components for the mobile software. The GUI will display the patients pump information. Several icons will be utilizing to represent actions. Making the patient aware of how device is functioning in its body. Visual Studios was utilized to develop the GUI mobile application code. It is important, once the program is being developed, it is determined whether it will work via Android or IOS, in this case it was determined to work for the Android operating system, since it is the most accessible. Visual Studio begins with the design of the program that will be reflected on the Tablet. Error! Reference source not found. shows how's the program designed, as explained above.

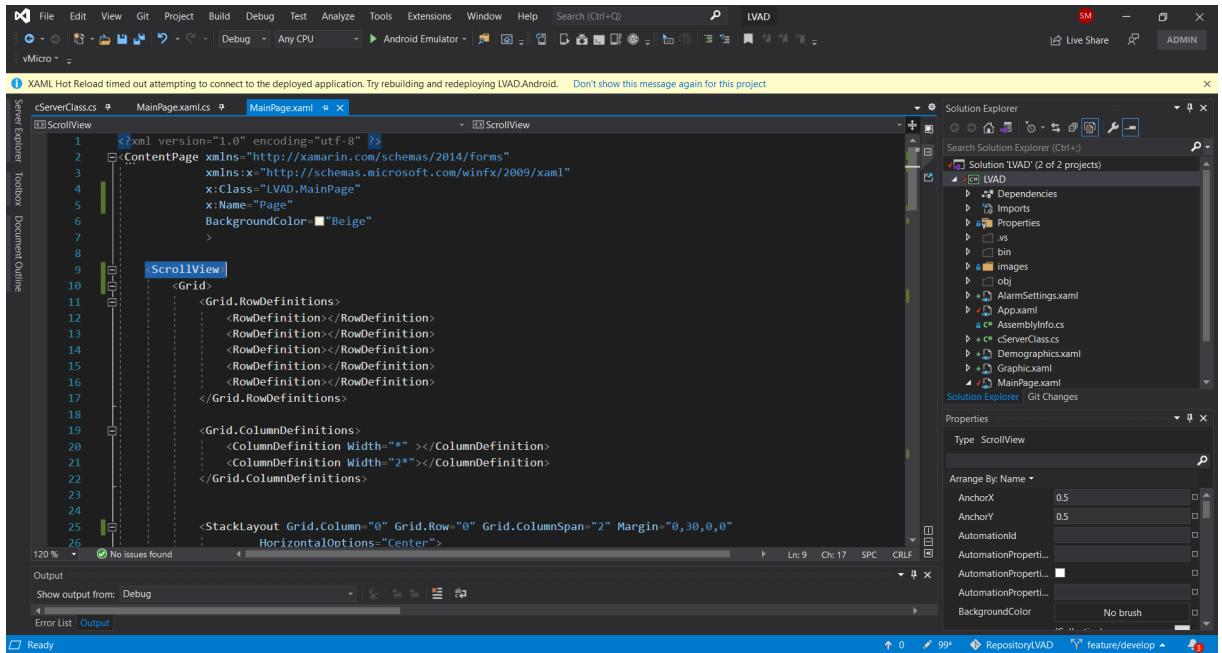


FIGURE 56: VISUAL STUDIO GUI PROGRAM

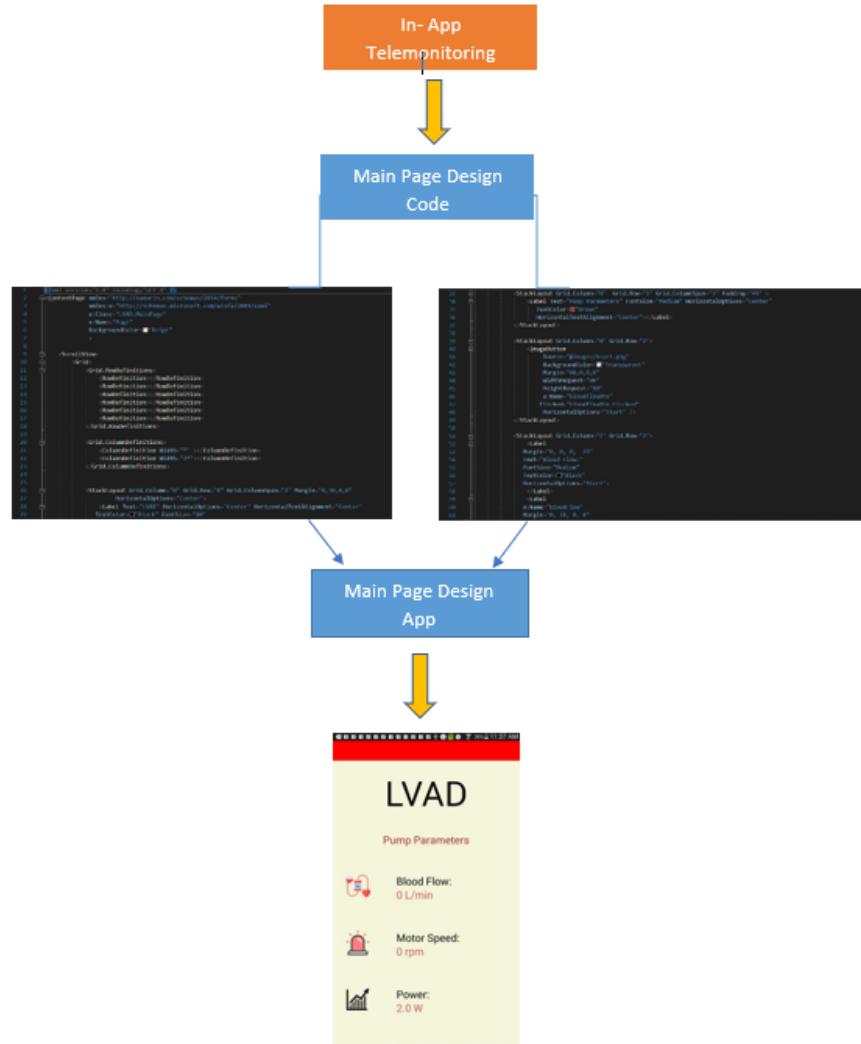
In the following architecture, (Figure 57) it can be shown in more detail how the program is being created, starting with the main page of the App, structuring how the patient will be seeing it. Once the default program such as Visual Studio and the Arduino

program is established to work with the application, which will be reading all the information based on what the behavior of the LVAD device is and how it will send the information through the module. Wi-Fi to the tablet that will be used.

In Visual Studio, the design of the APP is worked on, establishing a main menu known as "Pump Parameters". There is the Blood Flow reading, which will be read in L / min according to what the microcontroller transmits, the speed motor reading in rpm and the patient information will be displayed. Within the Visual Studio program, another page is established that will be managing the Arduino server. The function of the microcontroller server is to be able to receive the information directly from the Arduino program so that it can be read in the APP. This section collects the parameters of the blood flow (L / min) and motor speed (rpm) that will be passing through the Heart Pump. Inside the Arduino Server it is important to establish the same IP Address and Port in both programs (Arduino and Visual Studio) so that the information can be transmitted. If not configure the IP Address and the Port, the data will not be transmitted and therefore the application will be affected since it would not be receiving any reading. To view the code referring to the APP design and to establish the alternative of receiving the information from the Arduino program, you can refer to the **Appendix F: Code**.

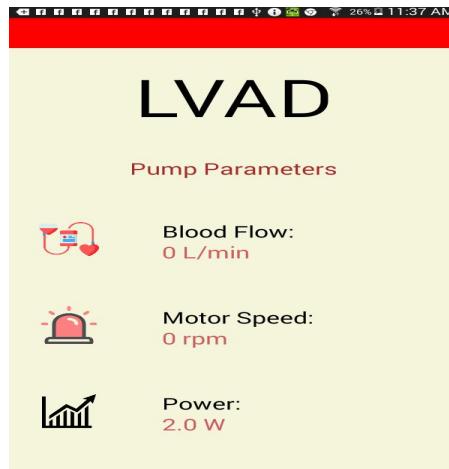
Another section is also integrated which will be working with the Wi-Fi module. This is necessary to receive the information of the program, if it is not configured in both Arduino and Visual Studio, the module will not be able to transmit the reading and in any case, no matter how much the Arduino Server is configured with Visual Studio, it will not be working in it. APP. In the Arduino program, the router will be configured as the following: ssid [] = "iPhone" and pass [] = "alanis04"; so that it can receive, have a

connection established and thus be able to receive the data, **Appendix F: Code**. In the same way, the App is displayed directly on the Android tablet. It is where the patient will be viewing the Blood Flow parameters, the motor speed and the power of the device. In addition, a section is included where the parameters of the alarms are established, whether when the blood flow is less than 5L / min or greater than 8 L / min. In that case, the App will be warning the patient of an increase or when the flow decreases, in the same way when the motor is not complying with the established rpm that is approximately 6000rpm. To observe the App format, refer to the **Appendix F: Code**.



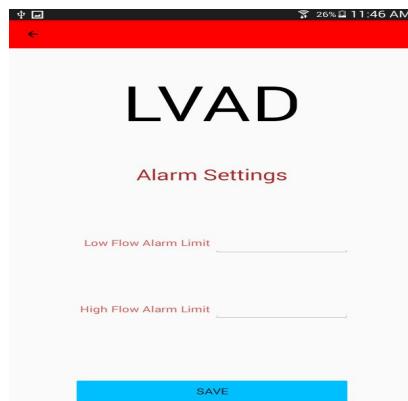
**FIGURE 57: MAIN CODE ARCHITECTURE**

The main functionality of the mobile's app GUI is to essentially showcase these important pump parameters to the patient, seen in **Figure 58**. Optimal blood flow values and motor speed should be around 5.5 L/min and 3,000 RPM, respectively. Providing this continual monitoring would be very significant for LVAD patients because of the complexity of its aftercare, requiring steady control of these pump parameters.



**FIGURE 58: MAIN PAGE OF TLVAD APP**

In addition to the main GUI, the app possesses two additional GUI's. The first one is accessed using the alarm icon, and this allows patients to set the low and high alarm threshold. If a value is found outside this threshold, then the patient will be notified. Finally, a display of historical trends for blood flow and motor speed is provided to patients by using the trends icon. Both can be seen on **Figure 59**.



**FIGURE 59: ALARMS NOTIFICATION GUI**

It is important to consider the LCD will be used to directly present the behavior of the blood flow (L/min), the behavior of the sensor when the blood passes through the pump and in the same way it will show the motor rpm. The LCD would be the main

LCD Components Specifications	
Design Requirements (MOP's)	Design Performance
Shall validate computer software for its intended use according to an established protocol. Shall establish and maintain procedures for verifying the device design.	<b>Yes.</b> Proven to work adequately from previous projects worked on
Will transfer and display of electronic medical device data to smartphone (Mbps)	<b>Yes.</b> Proven to work adequately in transfer and display of electronic data from previous applications
Will electronically convert medical device data from one format to another format in accordance with preset specifications and store medical device data from one device to another (GB)	<b>Yes.</b> Proven to work adequately in conversion of electronic data from previous systems
Will monitor pump power (W)	<b>No.</b> Only two lines of data are provided for the LCD (speed and flow)
Must monitor changes in pump velocity (rpm)	<b>Yes.</b> Second line of code will read pump velocity
Must monitor continuous pump blood flow output (L/min)	<b>Yes.</b> First line of code will read pump blood flow

screen since it is the direct way of being able to observe externally the behavior of the device within the patient.

Table 78 explains each of the functionalities and whether or not those mentioned meet the requirements provided by the device through its validation.

**TABLE 78: MONITORING SUBSYSTEM LCD PERFORMANCE**

The ESP8266 Wi-Fi Module is a self-contained SOC with integrated TCP/IP protocol stack that can give any microcontroller access to the Wi-Fi network. Is capable

LCD Components Specifications	
Design Requirements (MOP's)	Design Performance
Shall validate computer software for its intended use according to an established protocol. Shall establish and maintain procedures for verifying the device design.	<b>Yes.</b> Proven to work adequately from previous projects worked on
Will transfer and display of electronic medical device data to smartphone (Mbps)	<b>Yes.</b> Proven to work adequately in transfer and display of electronic data from previous applications
Will electronically convert medical device data from one format to another format in accordance with preset specifications and store medical device data from one device to another (GB)	<b>Yes.</b> Proven to work adequately in conversion of electronic data from previous systems
Will monitor pump power (W)	<b>No.</b> Only two lines of data are provided for the LCD (speed and flow)
Must monitor changes in pump velocity (rpm)	<b>Yes.</b> Second line of code will read pump velocity
Must monitor continuous pump blood flow output (L/min)	<b>Yes.</b> First line of code will read pump blood flow

of either hosting an application or offloading all Wi-Fi networking functions from another application processor. This module has a powerful enough on-board processing and storage capability that allows it to be integrated with the sensors and other application specific devices through its GPIOs with minimal development up-front and minimal loading during runtime. The ESP8266 Wi-Fi Module has certain requirements to be able to handle the data that will be transferred from the microcontroller that directs the system to the telemonitoring application. **Table 79** shows the design requirements and its performances.

TABLE 79: WIFI MODULE PERFORMANCE

Wi-Fi Module Specifications	
Design Requirements (MOP's)	Design Validation
Shall validate computer software for its intended use according to an established protocol. Shall establish and maintain procedures for verifying the device design.	Yes. Proven to work adequately from previous projects worked on
Will transfer and display of electronic medical device data to smartphone (Mbps)	Yes. Proven to work adequately in transfer and display of electronic data from previous applications
Will electronically convert medical device data from one format to another format in accordance with preset specifications and store medical device data from one device to another (GB)	Yes. Proven to work adequately in conversion of electronic data from previous systems
Will monitor pump power (W)	Yes
Must monitor changes in pump velocity (rpm)	Yes
Must monitor continuous pump blood flow output (L/min)	Yes

With all the main components and parts established of the controls subsystem, the hardware must be wired accordingly to comply with both subsystem and system-level requirements and interfaces. **Figure 60** illustrates the working principal, both the hardware and software aspects of the subsystem will work cohesively towards.

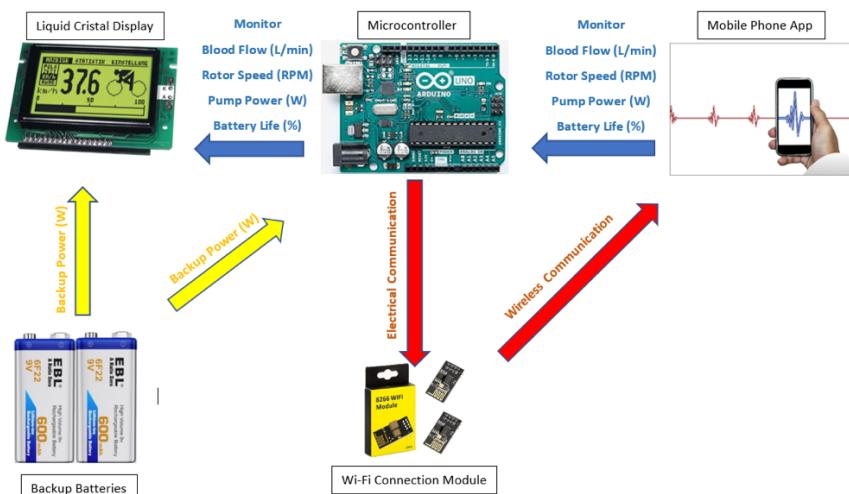
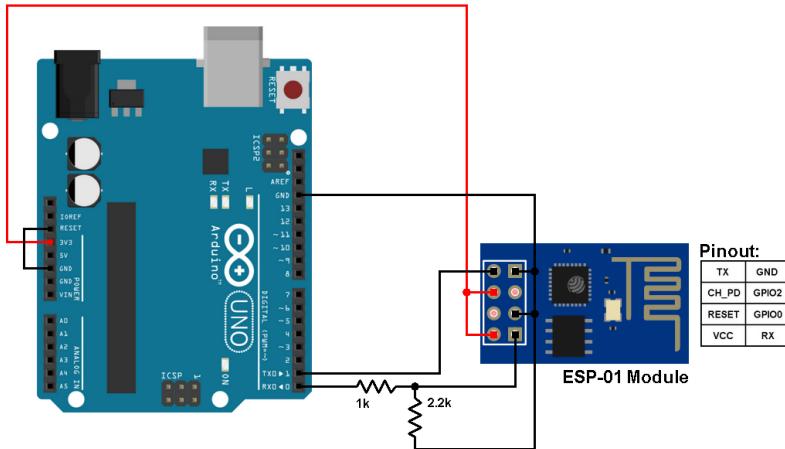


FIGURE 60: MONITORING SUBSYSTEM WORKING PRINCIPAL

The complete wiring of the control's subsystem can be seen on the wiring schematics shown on **Figure 61**.



**FIGURE 61: MONITORING SUBSYSTEM SHEMACTICS**

After establishing performance of the previous components, the subsystem must go through a verification where it would be compared with the phases. Once it goes through the verification, it must meet all the aforementioned requirements and be able to run all the information processed by the microcontroller, both the LCD and the Wi-Fi module. **Table 80** summarizes the MOPs: the design's requirements, the MOP Compliance: comparison of the actual performance of the design and the phase complied.

**TABLE 80: MONITORING SUBSYSTEM PERFORMANCE VERIFICATION**

MOP'S	Performance	Phase	Compliance
Shall validate computer software for its intended use according to an established protocol. Shall establish and maintain procedures for verifying the device design.	Verified with the final programming code.	C.1	Yes
Will transfer and display of electronic medical device data to smartphone (Mbps)	Code has been established to verify the code as an app.	B	Yes
Will electronically convert medical device data from one format to another format in accordance with preset specifications and store medical device data from one device to another (GB)	Verified with the final programming code.	C.1	Yes
Will monitor pump power (W)	Verified in Visual Studio and Arduino program	C.1	Yes
Must monitor changes in pump velocity (rpm)	Verified in Visual Studio	C.1	Yes
Must monitor continuous pump blood flow output (L/min)	Verified in Visual Studio	C.1	Yes

## PHASE C.2: INTEGRATION

### SYSTEM INTEGRATION

The TLVAD system integration plan will define the integration strategies for the project's interface. The plan is structured to bring the elements together to assemble each subsystem and bring all subsystems together to assemble the end product. The system integration plan commences with the controls subsystem, where circuit building utilizing the essential hardware, shown in **Figure 55**, is required for project integration. Consequently, the heart pump subsystem must be manufactured and assembled for project integration, as it provides important physical performance. Finally, application development and integration of the monitoring subsystem hardware must be performed for successful system level MOP and MOE compliance.

The interfaces between subsystems were initially described on Phase A and illustrated in the  $N^2$  diagram, **Figure 10**. However, with the design and analysis performed at the subsystem level these interfaces can now be represented graphically, as seen on **Figure 62**. The heart pump subsystem, represented in red, is essentially most of the implanted part of the product. It possesses the motor enclosure, motor, rotor and the inflow and outflow grafts. Furthermore, the controls subsystem is represented in green and consists of the sensor and control box. The latter consists of the sensor, microcontroller, batteries, LCD and the alarms. Finally, the monitoring subsystem is represented in yellow. It consists of the WIFI module and the TLVAD APP. Interaction between these subsystems is provided by the driveline. The driveline permits communication from the sensor to the controller, sending its flowrate readings. Communication between the motor

and controller is also permitted by the driveline. With the flow measurement feedback, the microcontroller computes the required voltage the motor needs and then provides it to the motor through the driveline. The WIFI module is also an important component in the integration as it permits the communication between the app and microcontroller. Utilizing this module makes access to the flowrate, rotor speed and pump power accessible through a device.

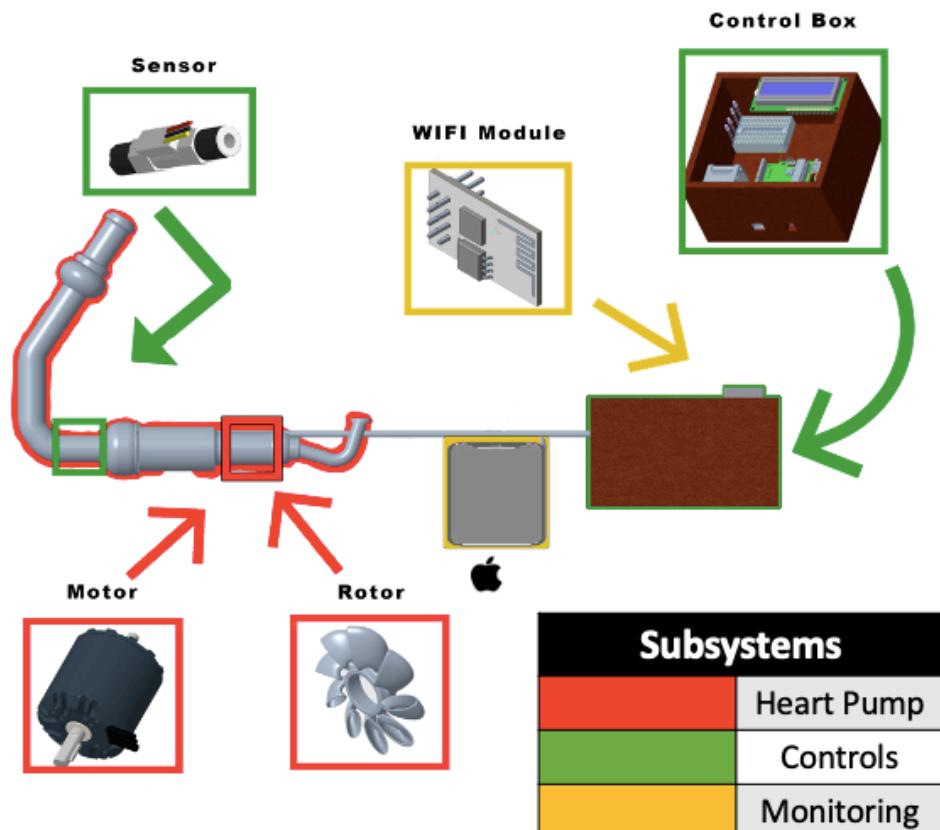
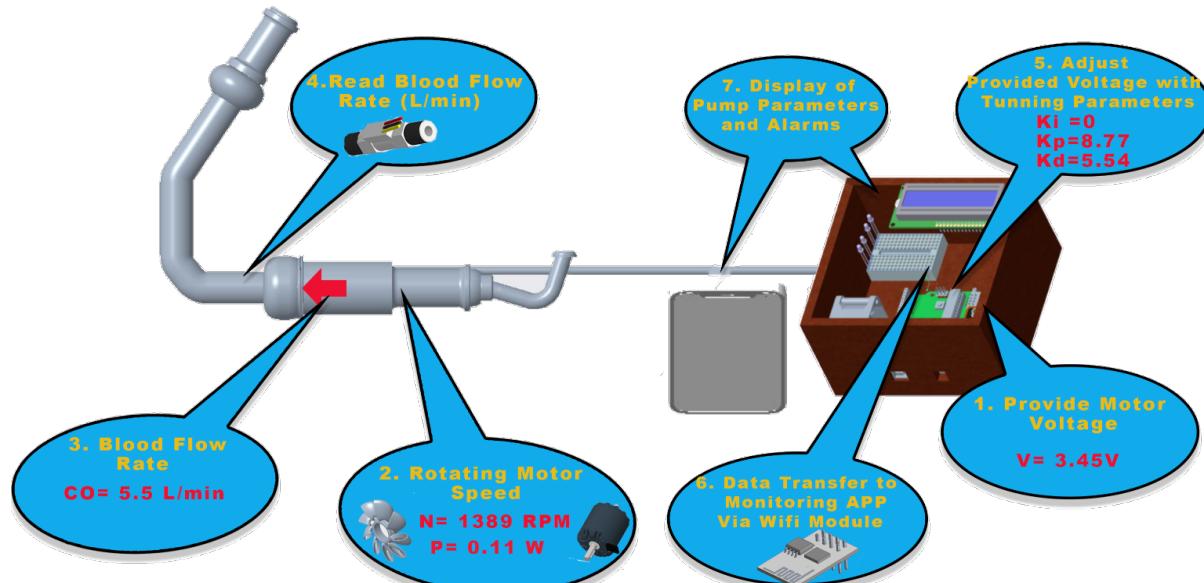


FIGURE 62: SYSTEM-LEVEL INTERFACES

Compliance with the interfaces established on the  $N^2$  diagram is essential for ensuring the system-level MOE's and MOP's are obtained in the end product. Once device is implanted and connected, the microcontroller will provide the motor a voltage of 3.45V. With said voltage the motor will be able to rotate at RPM and giving a power output of 0.11 W This will commence the pump to start the blood flow from the left ventricle to the

body. The sensor will then read the flow rate, which will register in the microcontroller, serving as a feedback input to adjust the rotor speed accordingly until ideal flow rate of 5.5 L/min is achieved. The regulation is attributed through the PID tuning parameters of  $K_p$  and  $K_d$ . These parameters hold values of 8.77 and 5.54, respectively. Maintaining a CO of 5.5 L/min might require a supplied voltage range of 2.62 to 3.44 V. Nevertheless, MOP's will still be accomplished. If any high or low flow risks arise, the control system will inform patients via auditory and visual alarms found in the control box. Pump power and rotor speed will be calculated by the microcontroller which will be transmitted along with the flow rate to the mobile app. These parameters will then be received and displayed in the mobile app for patient monitoring. Achieving compliance of the systems interfaces. Compliance of the interfaces based on estimates of engineering analysis is graphically represented on **Figure 63**.



**FIGURE 63: QUANTIFIED INTERFACE DIAGRAM**

In addition to verifying the interface requirements, tolerance in the TLVAD system is analyzed since the pipeline will be manufactured in parts and will not be made in one go. Tolerance allows parts to fit rightly with each other enabling the machine to work

properly. In detail engineering analysis of the tolerances is provided at **Heart Pump Subsystem**. However, these tolerances are illustrated in **Figure 64** as part of the system-level interface compliance.

With the establishment of the designs compliance with the system-level interface requirements, performance estimates should be addressed to prove compliance with system-level MOP's. These MOP's were sated on **Table 4**. The requirement for the system a rotor length of 100 mm with a 40 mm circumference was met on Phase C.1 with the rotor design. Based on the performance estimates the MOP of the pump motor using a voltage of no more than 6 V is also met.

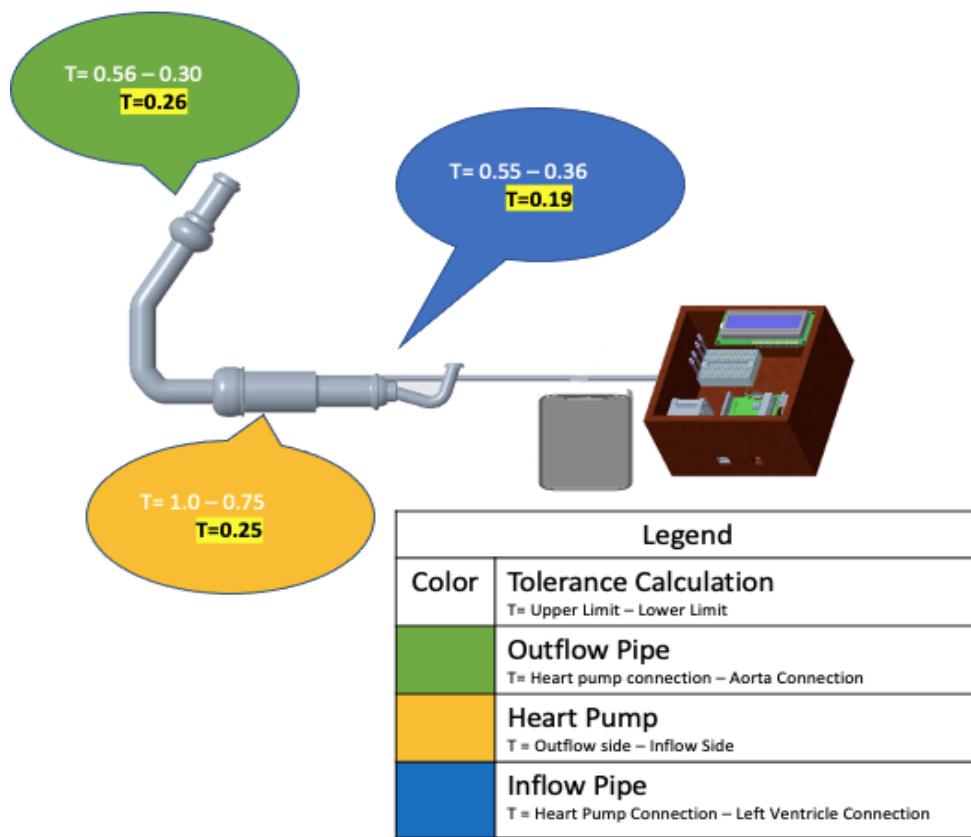


FIGURE 64: TOLERANCE INTERFACE DIAGRAM

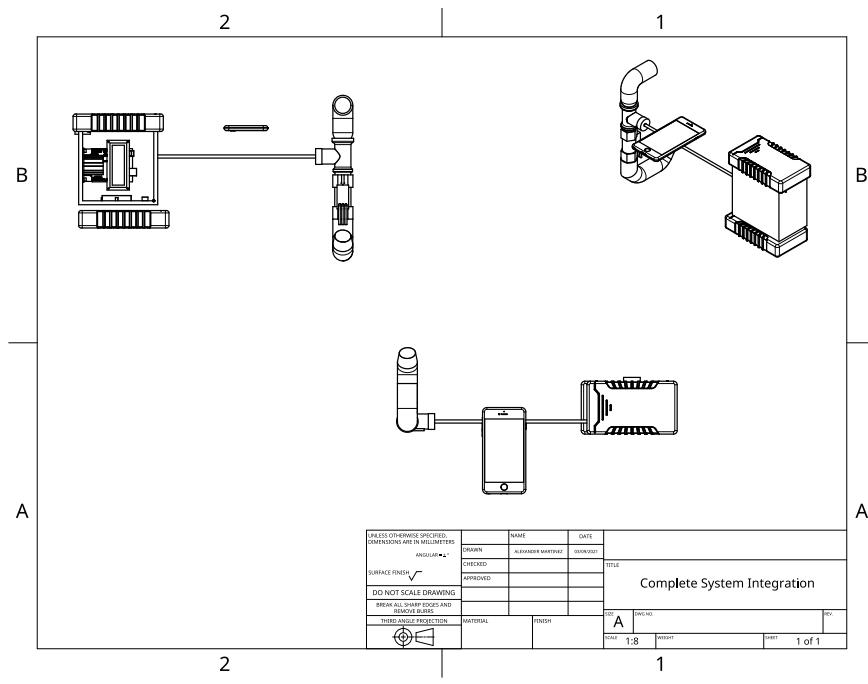
The controls subsystem is able to regulate the motor voltage using PID tunning parameters and the feedback response of the blood flow measurements. Estimated

performance is a range of 2.62 to 3.44 V to maintain a 5.5 L/min flow rate. A full list of MOP's and their performance estimates can be found on **Table 81**.

**TABLE 81: SYSTEM-LEVEL PERFORMANCE COMPLIANCE ASSESSMENT**

MOP'S	Performance	Phase	Compliance
Rotor length will be no more than 100 mm	17 mm	C.1	Yes
Rotor will have a circumference of no more than 40 mm	3 mm	C.1	Yes
Pump motor should use a voltage of no more than 6 V	6V	C.1	Yes

After continual refinement, the final system assembly designs can be seen on **Figure 65**. These are the designs and components that will be manufactured or implemented on the prototype or end product.



**FIGURE 65: SYSTEM-LEVEL DETAIL DRAWING**

## MANUFACTURING

Manufacturing is an essential process in the design and operation of integrated systems for the production of high-quality, economically competitive products. Creating an accurate bill of materials (BOM) is vital because it ensures that parts are available when

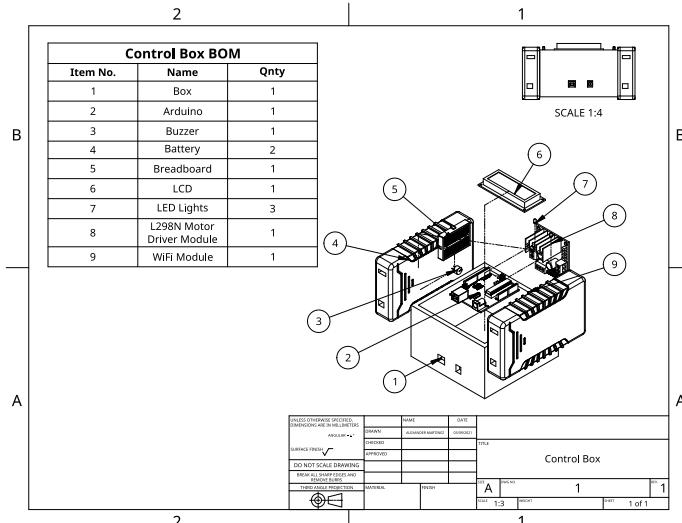
needed as well as ensuring that the assembly process is as efficient as possible. A BOM essentially serve as the foundation of production planning systems, the BOM for the TLVAD can be found on **Table 82**. All system BOM's can be seen on **Appendix D: Bill of Materials.**

**TABLE 82: SYSTEM BOM WITH COSTS**

Component/Part	Subsystem	Qty	Cost	Total
Flow Sensor (G1/2" Thread Hall Effect Liquid Sensor)	Controls	1	\$17.99	\$17.99
Lithium-Ion Researchable Batteries	Controls	2	\$23.99	\$47.98
Microcontroller, Driver Module, LCD and Cables (Pack)	Controls	1	\$52.99	\$52.99
WIFI Module	Monitoring	1	\$5.99	\$5.99
5V DC Brushless Motor	Heart Pump	1	\$7.50	\$7.50
Pump (Materia)	Heart Pump	1	\$25	\$25
Inflow Graft (Material)	Heart Pump	1	\$50	\$50
Outflow Graft (Material )	Heart Pump	1	\$100	\$100
Adapters	Heart Pump	4	\$4.50	\$18
Hose	Heart Pump	2	\$4.99	\$9.98

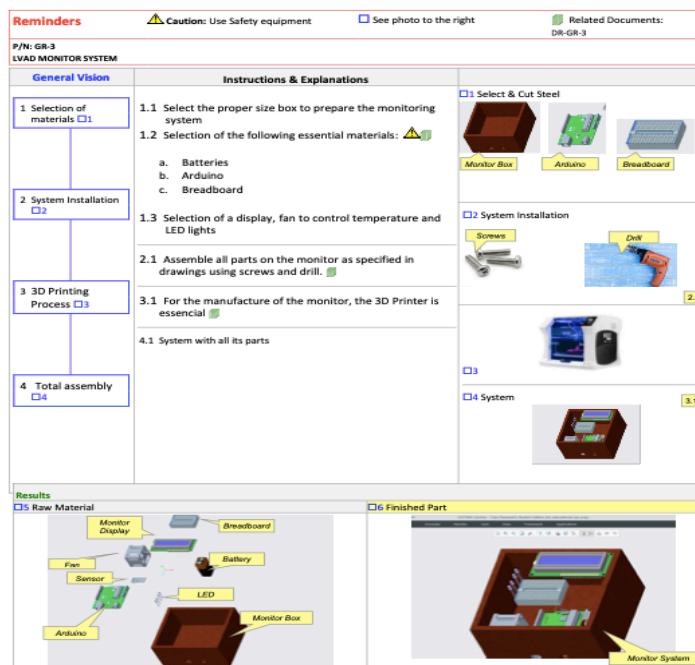
The manufacturing of the TLVAD will be divided into two main components: pipeline unit and control box. The latter is essentially where all electronic components will be held. The batteries, controller, alarms and modules will be hidden in said control box providing mobility and portability to patients. **Figure 66** gives a detailed assembly drawing of the control box with all of its components. All BOM's can be seen on **Appendix D: Bill of Materials.**

This control box will be made out of PLA and will go through a 3D printing manufacturing process. Where after it is printed assembly of all electronic devices will take place. The use of screws and drilling will take place to have the LCD on top of the control box and to provide visibility to the LEDs.



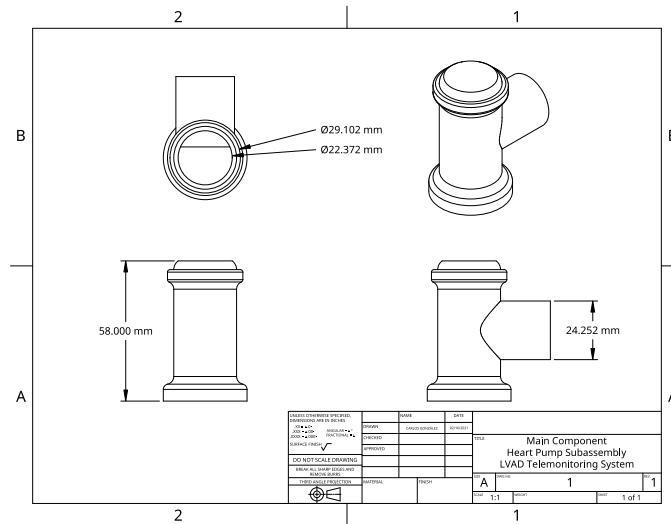
**FIGURE 66: CONTROL BOX ASSEMBLY DETAIL DRAWNG WITH BOM**

This manufacturing process will take place at the facilities of the Department of Biomedical Engineering in the Polytechnic University of Puerto Rico. The use of all materials and equipment, like drills and 3D printers, will be provided by the University. Therefore, manufacturing of the control box will be free of cost. A manufacturing sheet is provided on **Figure 67** for a detailed manufacturing process. All manufacturing sheets can be found on **Appendix E: Manufacturing Sheets**.



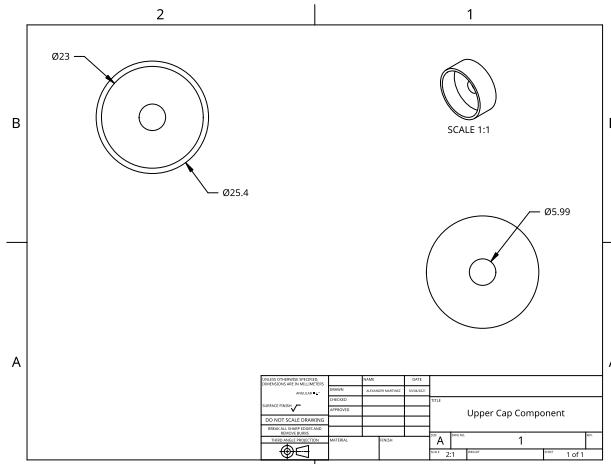
**FIGURE 67: CONTROL BOX MANUFACTURING SHEET**

Manufacturing and assembly of the implanted aspect of the TLVAD, the pump subsystem, requires individual manufacturing for each pipeline unit: heart pump, rotor, inflow graft, and outflow graft. The hurt pump part design is essentially an enclosure for the motor, separating it from any contact with the blood. The hurt pump detail drawing can be seen on **Figure 68**. All detail drawings can be found on **Appendix E: Detail Drawings**.



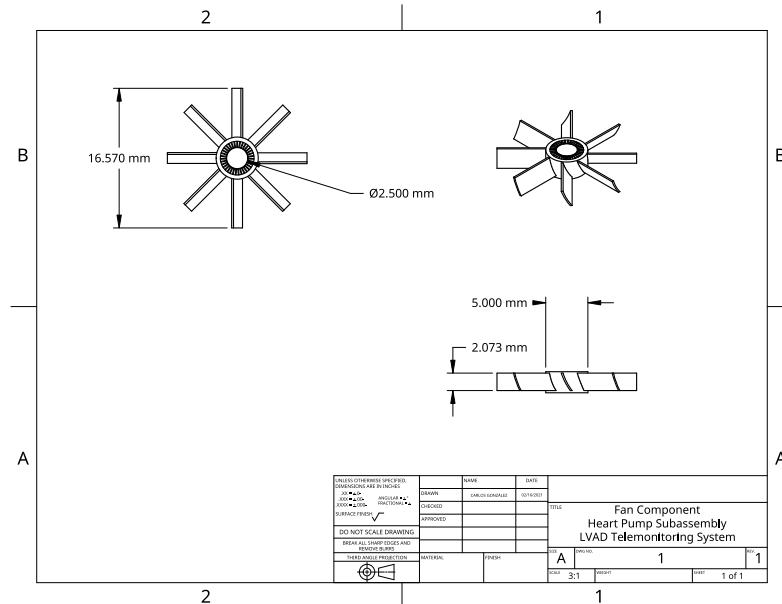
**FIGURE 68: HEART PUMP DETAIL DRAWING**

The heart pump also possesses a cap to keep the motor sealed off from coming into any contact with biological material and provide easy access to the driveline. The caps detail drawing can be seen on **Figure 69**. All detail drawings can be found on **Appendix E: Detail Drawings**.



**FIGURE 69: HEART PUMP CAP DETAIL DRAWING**

The rotor is also an important component of the heart pump and its design was tailored to comply with several system-level MOP's. The designs dimensions needed to be precise to ensure compatibility with the motor's stator. The rotor's detail drawing can be seen on **Figure 70**. All detail drawings can be found on **Appendix E: Detail Drawings**.



**FIGURE 70: HEART PUMP ROTOR DETAIL DRAWING**

The heart pump will be set to be manufactured using a CNC machining. CNC uses computers to control the motion of the tool being used. While computer numerical control can be used for a variety of manufacturing processes, CNC machining is specific to the subtractive process that is performed when a tool is used to remove material from a blank or other type of unfinished part. This process is usually performed on metal pipes such as the heart pump part. With the bending and drilling aspects of the design covered by the CNC machine, assembly with the other components and sterilization would be the final manufacturing stages. A manufacturing sheet is provided on **Figure 71** for a detailed manufacturing process. All manufacturing sheets can be found on **Appendix E: Manufacturing Sheets**.

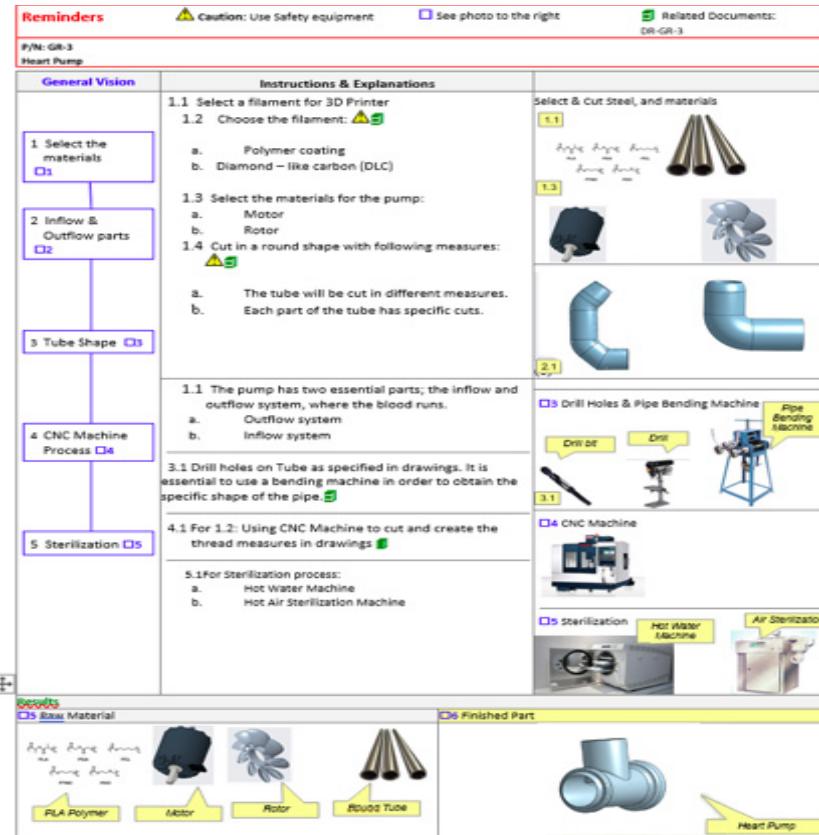
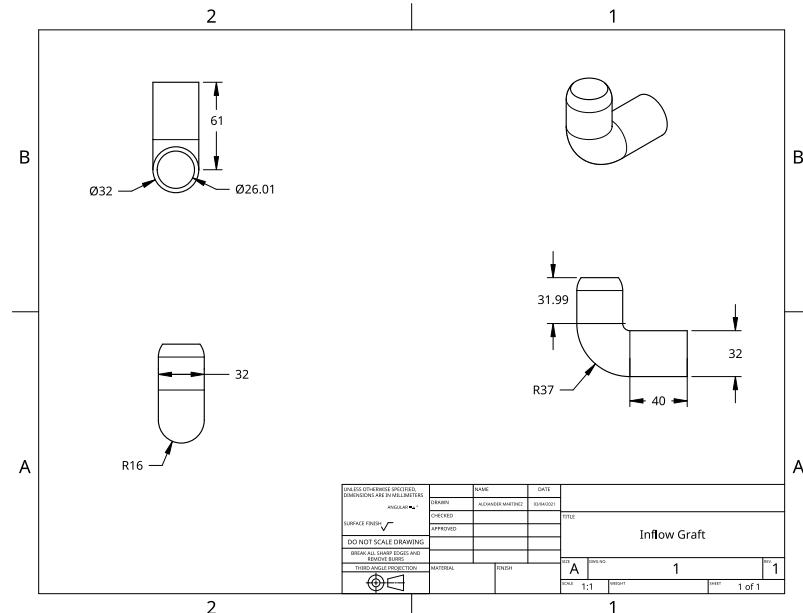


FIGURE 71: HEART PUMP MANUFACTURING SHEET

The inflow graft, **Figure 72**, provides a path for the blood to flow from the left ventricle to the heart pump. The design allows easy flow from left ventricle due to the force of gravity and assembly to the heart pump. The assembly between the TLVAD parts should be fairly easy because each part is designed to be fitted with its connecting pipe. All detail drawings can be found on **Appendix E: Detail Drawings**.

CNC machining will also be the manufacturing process for the inflow pipe part. Titanium allows will be bent and formed into the desired design using CNC machine. Titanium is a strong and light material in weight compared to stainless steel. Titanium has a large resistance to repeated loads making it ideal for its application as an implant. It also has great strength under repeated load stresses, making this metal capable of withstanding strain during internal fixation. A manufacturing sheet is provided on **Figure 73** for a

detailed manufacturing process. All manufacturing sheets can be found on **Appendix E: Manufacturing Sheets**.



**FIGURE 72: INFLOW GRAFT DETAIL DRAWINGS**

Finally, the outflow graft will provide a path for the impulse blood to reach the aorta. The design allows this part to be assembled to the sensor and attached to the ascending aorta. outflow graft's detail drawing can be seen on **Figure 74**. All detail drawings can be found on **Appendix E: Detail Drawings**. All manufacturing sheets can be found on **Appendix E: Manufacturing Sheets**.

The outflow graft will follow the same manufacturing process as the inflow graft using a CNC machine. However, it will be tailored to this specific design ant it will be attached to the sensor. A manufacturing sheet is provided on **Figure 75** for a detailed manufacturing process.

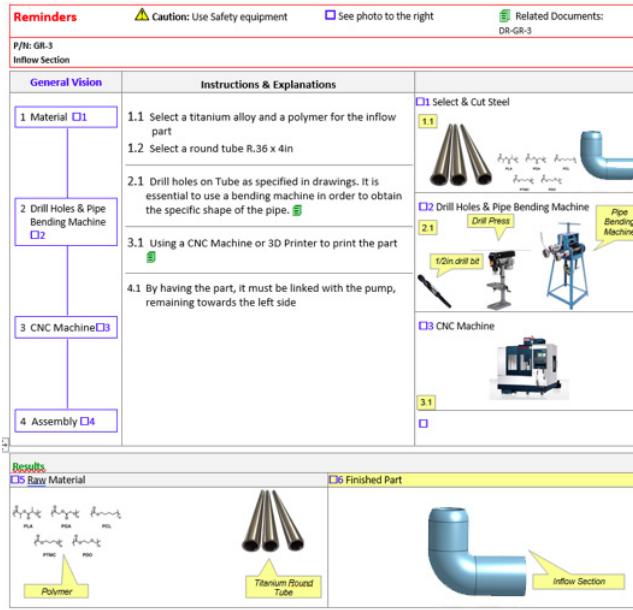


FIGURE 73: INFLOW GRAFT MANUFACTURING SHEET

As previously stated, the design between parts allows for easy assembly as each part is specifically fitted and threaded to facilitate connection between them, full heart pump assembly with BOM can be seen on the detail drawing found in **Figure 76**. However, performing such manufacturing processes requires expensive materials and equipment, such as titanium alloys and CNC machines, which were not at disposal of the students.

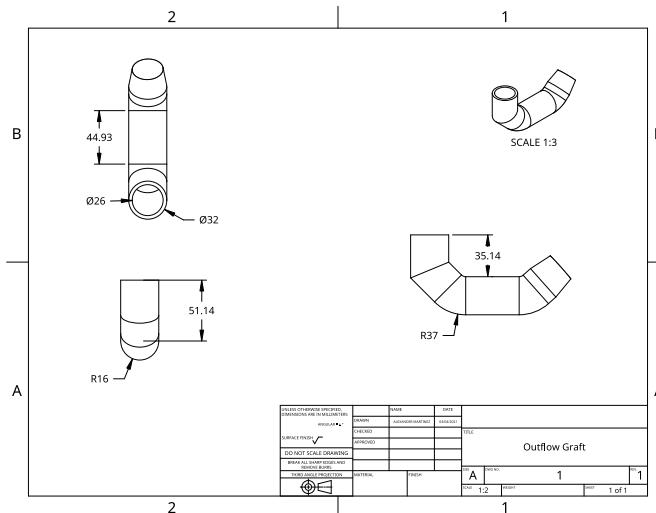


FIGURE 74: OUTFLOW GRAFT DETAIL DRAWING

Therefore, a company in Puerto Rico that possessed high quality machinery to manufacture said parts with precision and quality was contacted. Pricing and timeline for

each part to be manufactured was discussed. Unfortunately, the manufacturing of such detailed designs was priced much higher than anticipated.

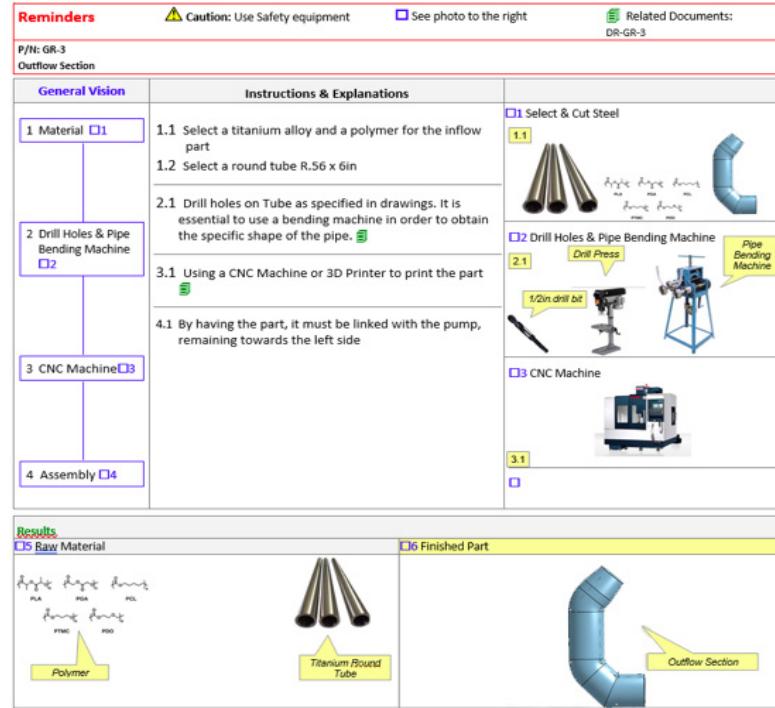
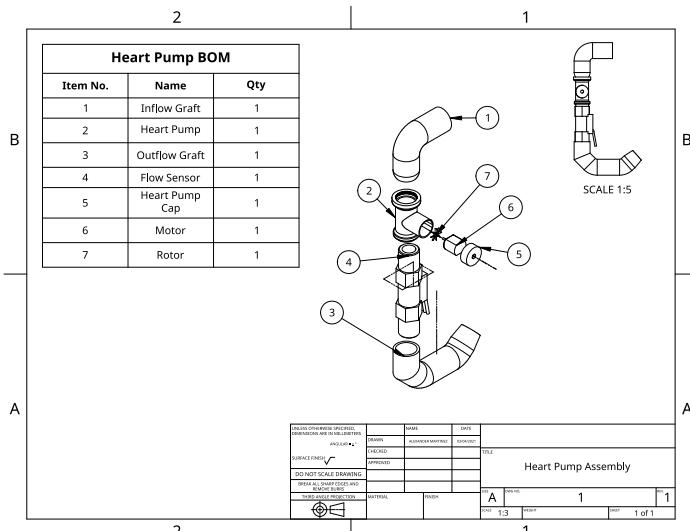


FIGURE 75: OUTFLOW GRAFT MANUFACTURONG SHEET

The manufacturing of the heart pump, inflow graft and outflow graft would have costed around \$125, \$150 and \$200, for each one respectively. These costs exceeded the preliminary estimations for the heart pump subsystem and along with the COVID-19 restrictions the part manufacturing will not permit project completion in its six-month timeline.

Taking into consideration that the heart pump subsystem exceeded its allocated budget due to its expensive manufacturing processes, the system as a whole did not meet the budget requirements for ideal product construction, see **Table 83**. However, even going over budget, the return investment (ROI) is still very substantial for the device. All detail drawings can be found on **Appendix E: Detail Drawings** and All BOM's can be seen on **Appendix D: Bill of Materials**.



**FIGURE 76: HEART PUMP ASSEMBLY DRAWINGS**

The efficiency or profitability of the investment will still be around 670% as costs only exceeded by about \$50. The implemented design can still provide a cost-effective device that can be affordable for clients, but at the same time provide a large monetary gain for stakeholders. Compared to the designs on the market, the proposed unit price for the TLVAD, at \$5,000, is very low. However, based on an investment of \$650 it holds a great potential for substantial monetary gain.

**TABLE 83: BUDGET ESTIMATES BEFORE MANUFACTURING**

Component/Part	Subsystem	Qty	Estimated Cost	Expected
Flow Sensor (G1/2" Thread Hall Effect Liquid Sensor)	Controls	1	\$17.99	\$15
Lithium-Ion Researchable Batteries	Controls	2	\$47.98	\$50
Microcontroller, Driver Module, LCD and Cables (Pack)	Controls	1	\$52.99	\$60
WIFI Module	Monitoring	1	\$5.99	\$15
5V DC Brushless Motor	Heart Pump	1	\$7.50	\$50
Pump (Material& Manufacturing)	Heart Pump	1	\$125	\$60
Inflow Graft (Material& Manufacturing)	Heart Pump	1	\$150	\$70
Outflow Graft (Material & Manufacturing)	Heart Pump	1	\$200	\$90
Adapters	Heart Pump	4	\$18	\$20
Hose	Heart Pump	2	\$9.98	\$15
	Total	15	\$635.43	\$600

A financial project plan, as seen on **Table 84**, was elaborated to project the gains based on an investment of \$650 and an initial selling price of \$5,000. Estimated earnings by 2025 are \$41,750,000 by selling 5000 units scaling its selling cost to \$9,000. With the increased investment due to manufacturing costs, new ROI estimates is \$250 less than initially stated. Capitalizing on the demand for LVAD's along with providing a cost-effective design, like the TLVAD, that can be more affordable for clients is of great significance and relevancy in the biomedical engineering field.

**TABLE 84: FINANCIAL PROJECT PLAN**

Time Period	2021-2022	2023-2024	2025+
<b>Unit cost</b>	\$650	\$650	\$650
<b>Selling Cost</b>	\$5,000	\$7,000	\$9,000
<b>Units Sold</b>	500	2000	5000
<b>Total Gross Income</b>	\$2,175,000	\$12,700,000	\$41,750,000

Even though the end product will not be able to be manufactured as it is intended to due to budget and COVID-19 restrictions, a prototype will still be manufactured. Alternatively, the prototype will be manufactured using 3D printing and will still be able to be tested in order to verify MOE and MOP compliance. Furthermore, since the prototype budget or investment is relevant the system MOP's, budget estimates must be performed again for prototype manufacturing. **Table 85** represents the budget for building the TLVAD prototype using 3D printing technologies. All systems are under their allocated budget; therefore, budget related requirements are still being met.

TABLE 85: BUDGET ESTIMATES BEFORE MANUFACTURING

Component/Part	Subsystem	Qty	Estimated Cost	Expected
Flow Sensor (G1/2" Thread Hall Effect Liquid Sensor)	Controls	1	\$17.99	\$15
Lithium-Ion Researchable Batteries	Controls	2	\$47.98	\$50
Microcontroller, Driver Module, LCD and Cables (Pack)	Controls	1	\$52.99	\$60
WIFI Module	Monitoring	1	\$5.99	\$15
5V DC Brushless Motor	Heart Pump	1	\$7.50	\$50
Pump (Material& Manufacturing)	Heart Pump	1	\$5	\$60
Inflow Graft (Material & Manufacturing)	Heart Pump	1	\$5	\$70
Outflow Graft (Material & Manufacturing)	Heart Pump	1	\$5	\$90
Adapters	Heart Pump	4	\$18	\$20
Hose	Heart Pump	2	\$9.98	\$15
	Total	15	\$175.43	\$600

## **PHASE D: SYSTEM DEMONSTRATION & VERIFICATION**

### **SYSTEM VERIFICATION PLAN**

The main objective for the TLVAD project is to support patient's heart function by maintaining ejection fraction above 40% or a cardiac output of 5.5 L/min and provide continual and significant monitoring during the complex aftercare. Rigorous engineering analysis and design has been applied throughout the planning and development phases of this project, to achieve compliance with said objectives. Several MOE's and MOP's were defined to quantify the compliance of these objectives under certain governance standards and regulations. The purpose of the system verification plan is to verify the design and performance of a Left Ventricular Assist Device prototype, which certifies the fulfilment of its design, controls, and monitoring requirements. Thorough this section a series of verification experiments will be established, these procedures will test the end product on the compliance of its MOE's and MOP's.

### **PHYSICAL PROTOTYPE**

As previously mentioned, the intended manufacturing the TLVAD was unable to be followed due to budget and COVID-19 limitations. The final prototype will be manufactured in 3D printing using PLA as its material. The change in material and manufacturing will not impact the verification of MOE's and MOP's compliance, all testing procedures will remain unaffected. Both the controls and monitoring subsystems will continue their established construction and integration procedures.

## MAINTAINING BUDGET ASSESSMENT

The requirement or MOP of the TLVAD system related to budget established that prototype cost should be less than \$600. Ensuring compliance of this particular MOP lets stakeholders provide more interest and investment in the product. Clients are heavily benefited as producing a cost-effective device improves patients' quality of life. Therefore, assessment of budget militainment is essential for device functionality requirements. The **tools** to be utilized for the budget assessment is the budget documentation found on **Table 85**. A comparison between the expected and actual budget will determine if the prototype cost was less than \$600.

## ROTOR MEASUREMENT ASSESSMENT

Other MOP's were related to the design of the rotor, as it was established the rotor will have a length and shaft circumference of no more 100 mm and 40 mm, respectively. Proving compliance of both these MOP's is essential as the rotating blades adds energy to the blood by converting the rotational kinetic energy into mechanical energy. Thus, an important design for the completion of the project's objectives. The **tools** needed for the measurement assessment include a digital caliper and the rotor itself, seen on **Figure 77**. The **Safety precautions** for this assessment include keeping the area clean and carefully handle and align the measuring tools for accurate measurements. The procedure to follow for assessing the rotor measurements can be found below:

### Procedure Steps

1. Using a digital caliper measure the length of the rotor
2. Using a digital caliper measure the shaft diameter
3. Calculate circumference using diameter



**Rotor**



**Digital Caliper**

**FIGURE 77: ROTOR MEASUREMENT ASSESSMENT TOOLS**

Following the provided verification procedure will ensure the MOP's are verified accurately and accordingly.

### **MAXIMUM MOTOR VOLTAGE MEASUREMENT**

Most of the stated MOP's cover functionality requirements, where their implementation is key to enable users to accomplish their tasks. Establishing that the pump motor should use a voltage of no more than 6 V as an MOP, attempts to provide low power consumption in the entire system. Therefore, ensuring long duration of the stored energy and improving its cost effectiveness. The **tools** needed for the motor voltage measurement assessment include a multimeter, the motor and the assembled TLVAD controls, as seen on **Figure 78**. The **Safety precautions** for this assessment include keeping the area clean and carefully handle and align the measuring tools for accurate measurements. In addition, any testing or use of electronics in this setting must follow OSHA standards for any electrical hazards. The procedure to follow for assessing the motor voltage measurement can be found below:

#### **Procedure Steps**

1. Wire a multimeter to the output voltage of the L298N DC Motor Driver Module.
2. Start the LVAD. Make sure there is no fluid flow.
3. Using the multimeter verify the max output voltage being delivered to the motor.



**FIGURE 78: MOTOR VOLTAGE MEASUREMENT ASSESSMENT TOOLS**

Following the provided verification procedure will ensure the MOP is verified accurately and accordingly. Essentially, this procedure verifies the control system. If there is no fluid flow the controls will signal the motor to increase the motors speed. If this value does not exceed 6 V then the verification is successful. The multimeter will provide an accurate real time measurement of the output voltage provided to the motor.

### **LVAD DEVICE MASS MEASUREMENT**

The weight of the device is a functionality associated to the system's durability, portability, and comfortability from the established MOE's. Consequently, an MOP was established for the implanted prototype product to weigh less than 250 grams. Complying with lightweight device requirements ensures less energy consumption and comfortability for patients. The **tools** needed for the device mass measurement assessment include an analytic balance and the assembled implantable prototype, as seen on **Figure 79**. The **Safety precautions** for this assessment include keeping the area clean and carefully handle and align the measuring tools for accurate measurements. The procedure to follow for assessing the device mass measurement can be found below:

#### **Procedure Steps**

1. Use the analytic balance to measure the mass of the LVAD Device

2. Make sure to tare the balance before the measurement

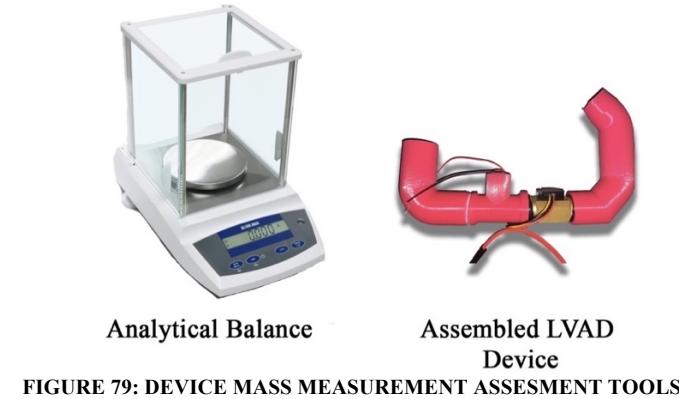


FIGURE 79: DEVICE MASS MEASUREMENT ASSESSMENT TOOLS

Following the provided verification procedure will ensure the MOP is verified accurately and accordingly.

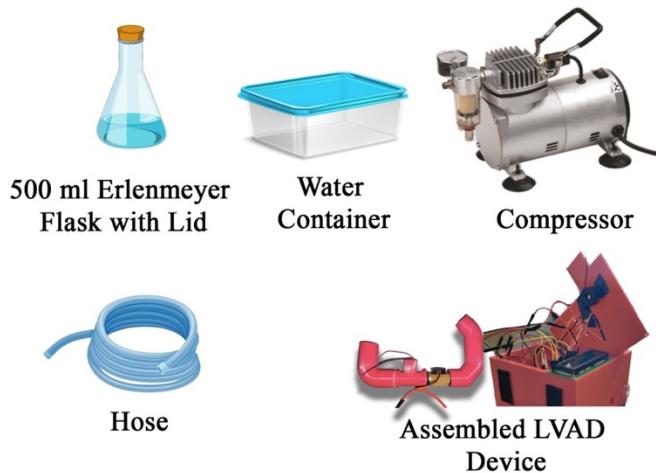
### FLUID FLOW PHYSICAL SIMULATION LOOP

The Fluid Flow Physical Simulation Loop (FFPSL) will be utilized to verify the remaining MOP's. The FFPSL tests the TLVAD device under similar physiological conditions it would be after implantation. The system MOP's this physical simulation are: will monitor both blood flow and rotor velocity through external app, will withstand several temperature assessments for set periods of time and volume flow should be optimal at 5.5 L/min. Only the latter will be discussed in this section and the others will be explained on the sections to follow. Providing an optimal volume flow at 5.5 L/min is essential, as the device purpose is to support patient's heart function. Therefore, complying with this MOP is a way of achieving one of the projects objectives. The **tools** needed for the FFPSL include water, the assembled TLVAD, water container, a 500ml Erlenmeyer Flask with Lid, compressor and hoses, as seen on **Figure 80**. The **Safety precautions** for this assessment include keeping the area clean and carefully handle and align the measuring tools for accurate measurements. In addition, any testing or use of electronics in this setting

must follow OSHA standards for any electrical hazards. The procedure to follow for assessing the flow regulation can be found below:

### Procedure Steps

1. Fill a water container with water
2. Submerge a hose in water and connect it to inlet of LVAD device.
3. Connect one end of a hose to the outlet of LVAD device and other end to the flasks lid.
4. Connect the Flask's inlet portion to a compressor
5. Set the compressor's pressure to 1 PSI (mimicking aortic pressure)
6. Turn compressor and LVAD ON.
7. Verify if flow is regulated to 5.5 L/min.



**FIGURE 80: FLUID FLOW PHYSICAL SIMULATION LOOP TOOLS**

Following the provided verification procedure will ensure the MOP is verified accurately and accordingly. Essentially, this procedure verifies the controls and heart pump system integration, the full set-up can be seen on **Figure 81**. The water will replace the blood as the fluid in motion, their densities are very close to each other's. The compressor will mimic the aortic pressure initiating fluid flow. However, the TLVAD device will

impulse the flow at a higher rate. If such task is achieved, then device will comply with requirements.

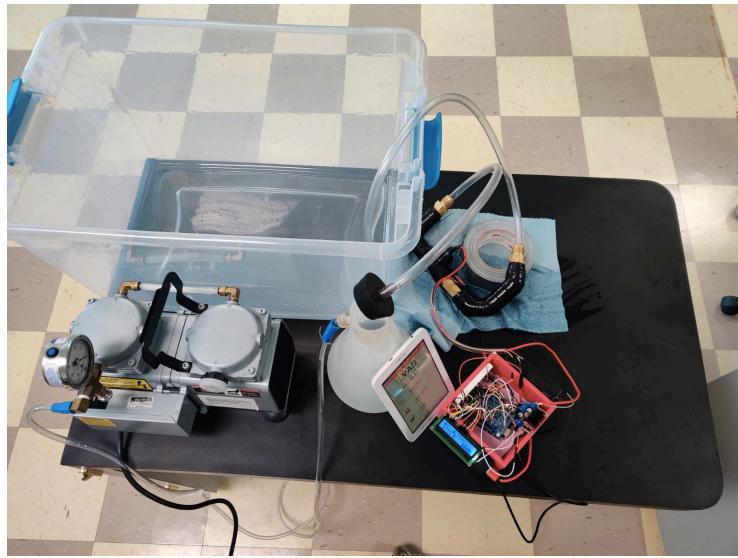


FIGURE 81: FLUID FLOW PHYSICAL SIMULATION LOOP

## LVAD TEMPERATURE ASSESSMENT

The requirements for the biocompatibility assessment were that the system must withstand several temperature assessments for set periods of time and the prototype for implanted subassembly shall be water resistant. The FFPSL will also be utilized to verify this set of MOP's. The **tools** needed for the temperature assessment include the FFPSL tools and a thermometer, as seen on **Figure 82**. The **Safety precautions** for this assessment include keeping the area clean and carefully handle and align the measuring tools for accurate measurements. In addition, any testing or use of electronics in this setting must follow OSHA standards for any electrical hazards. The procedure to follow for assessing the temperature withstanding can be found below:

### Procedure Steps

1. Run the Fluid Flow Physical Simulation Loop at 25° C
2. Verify if flow is regulated to 5.5 L/min.

3. Run the Fluid Flow Physical Simulation Loop at 32° C
4. Verify if flow is regulated to 5.5 L/min.



**FIGURE 82: TEMPERATURE ASSESSMENT TOOLS**

Following the provided verification procedure will ensure the MOP's is verified accurately and accordingly, the full loop is illustrated. Essentially, this procedure is the same as the FFPSL but, done at different temperatures. Verifying the biocompatibility requirements and the controls and heart pump system integration.

### **REAL-TIME MONITORING VERIFICATION**

The final verification procedure verifies the requirements for the implantability assessment. Established MOP's stated that will monitor both blood flow and rotor velocity through an external app. The FFPSL will also be utilized to verify this set of MOP's. The tools needed for the temperature assessment include the FFPSL tools, LCD and the app, as seen on **Figure 83**. The **Safety precautions** for this assessment include keeping the area clean and carefully handle and align the measuring tools for accurate measurements. In addition, any testing or use of electronics in this setting must follow OSHA standards for

any electrical hazards. The procedure to follow for assessing the monitoring can be found below:

### Procedure Steps

1. Run the Fluid Flow Physical Simulation Loop
2. Open the APP
3. See if the APP is giving the same measurement information as the LCD.



FIGURE 83: MONITORING ASSESSMENT TOOLS

Following the provided verification procedure will ensure the MOP's is verified accurately and accordingly, the full loop is illustrated. Essentially, this procedure is the same as the FFPSL but, with additional steps of monitoring verification. The procedures ensure verifying the implantability requirements and the whole system integration and functioning.

### SYSTEM DEMONSTRATION

Prototype construction followed the procedures of 3D printing established on Phase C.2. The heart pump, control box, and inflow and outflow pipes were all 3D printed on the Rehabilitation engineering laboratory at the Polytechnic University campus, using the Original Prusa i3 3D printer. The heart pump or motor enclosure part was scaled to size

accordingly using Ultimaker Cura and then proceeded to be printed, which lasted around two hours. **Figure 84** illustrates the printing process and the final printed heart pump part.

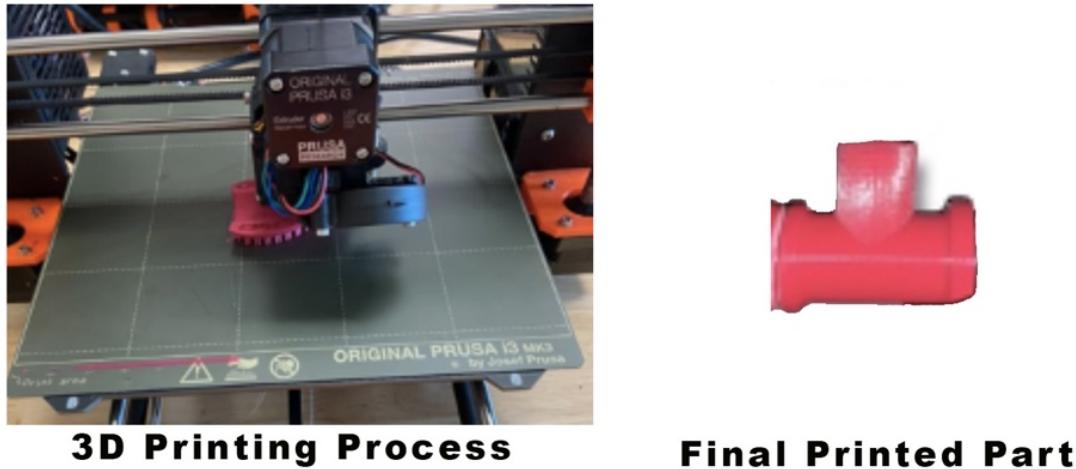


FIGURE 84: PRINTING PROCESS AND FINAL HEART PUMP PRINT

The inflow pipe followed the same procedure as the heart pump. It was scaled to size accordingly using Ultimaker Cura and then proceeded to be printed, which lasted around four and a half hours. **Figure 85** illustrates the printing process and the final printed inflow pipe part.

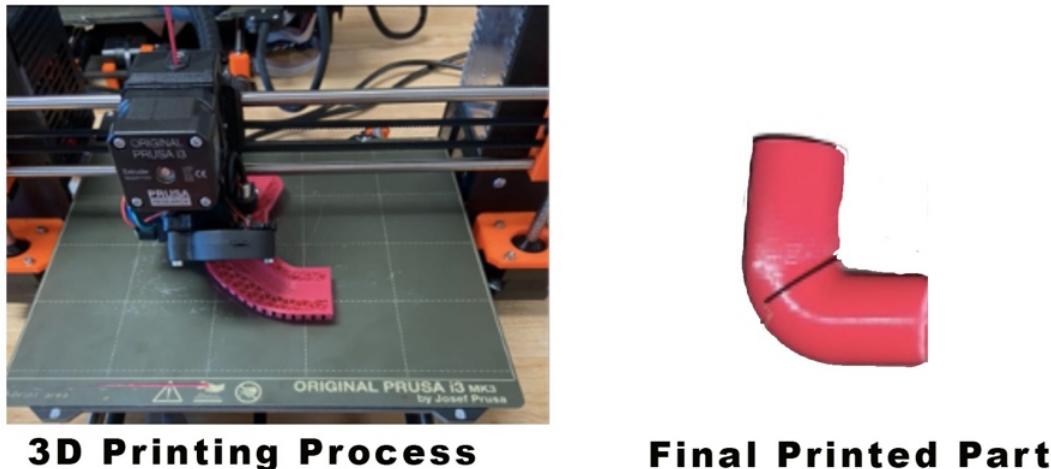
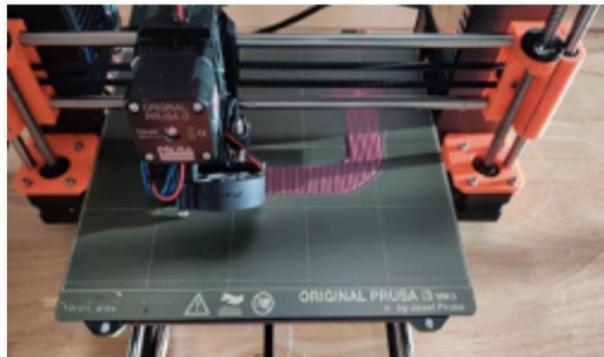


FIGURE 85: PRINTING PROCESS AND FINAL INFLOW PIPE PRINT

The standard printing and scaling process was also followed for the outflow pipe. However, initial designs held a very thin wall thickness that damaged the printing product.

After adjusting and troubleshooting the design printing process lasted around six hours.

**Figure 86** illustrates the printing process and the final printed outflow pipe part.



**3D Printing Process**



**Final Printed Part**

FIGURE 86: PRINTING PROCESS AND FINAL OUTFLOW PIPE PRINT

The next step in prototype construction was the hardware assembly of the controls and monitoring. However, the control box was printed first to provide easy assembly on it.

**Figure 87** illustrates the printing process and the final printed outflow pipe part.

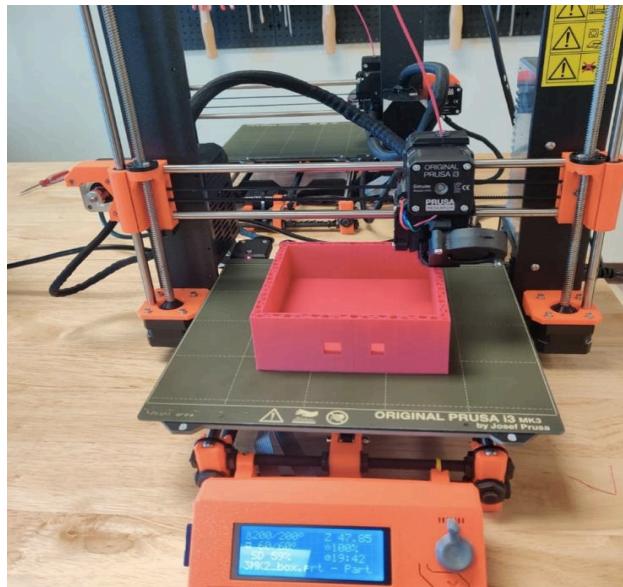


FIGURE 87: CONTROL BOX PRINTING PROCESS

Each hardware component was tested individually to ensure their functioning. After ensuring the sensor, LCD, the WIFI module, and motor components were functioning individually they were integrated one by one following the schematics described on **Figure**

55. The sensor, alarms and motor components were initially integrated and after troubleshooting the LCD followed in this hardware integration, early integration can be seen on **Figure 88**.

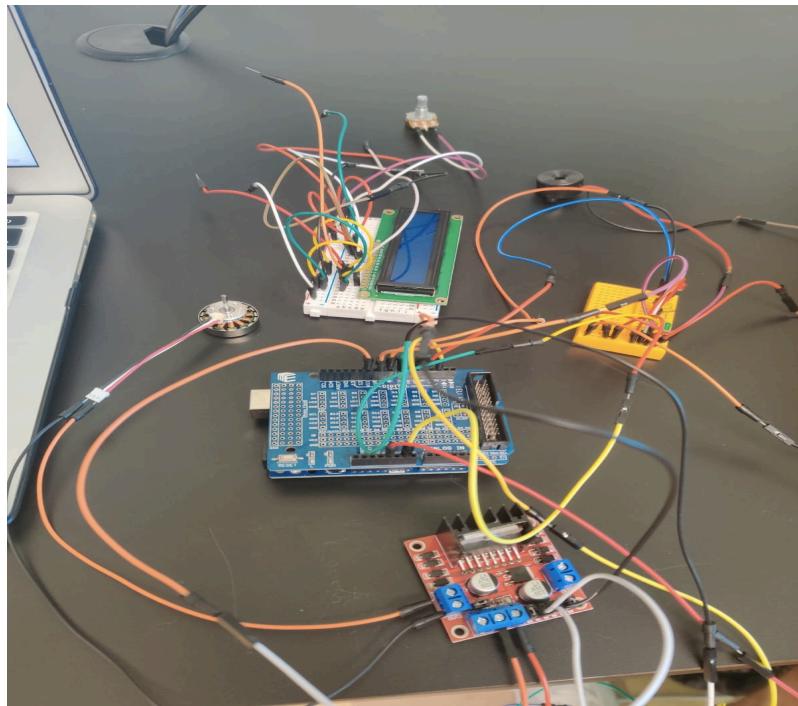
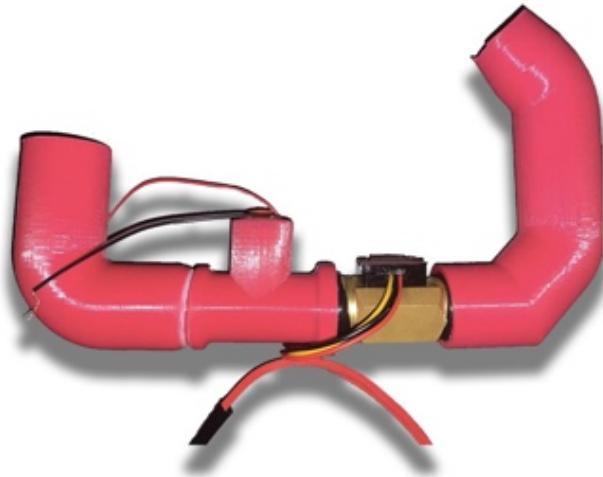


FIGURE 88: EARLY HARDWARE INTEGRATION

Finally, after ensuring the controls were functioning appropriately the WIFI module was integrated to the system as well as the code. Both controls and monitoring programs were developed throughout Phase C.1, no major adjustments were made during the prototype construction.

After hardware connection, the assembly between the pump parts and sensor was followed. The assembly between the pump parts was fairly easy because each was specifically designed to be fitted with its connecting pipe or the sensor. However, to prevent any leaking between the pipes and sensor Teflon tape was utilized, sealing pipe threads. The assembly between pipes and sensors can be seen on **Figure 89**.



**FIGURE 89: PUMP AND SENSOR ASSEMBLY**

Finally, to conclude prototype construction, the implantable component must be connected to the control box via the driveline. A silicone hose was utilized as the tubing for the driveline, due to its biocompatibility. After all, connecting cables were passed through the hose and connected to the sensor, motor and control box the prototype was finalized. The final system prototype with all subsystems integrated can be seen on **Figure 90**.



**FIGURE 90: FINAL PROTOTYPE**

## SYSTEM VERIFICATION

The system verification plan was followed exactly as established before to verify the design and performance of a Telemonitoring Left Ventricular Assist Device prototype based on a plethora of MOE's and MOP's that confirm the fulfilment of the projects objectives. Such verification procedures were established to verify the realization of accurate design, controls, and monitoring requirements for the TLVAD system.

System verification commenced addressing the MOP of the TLVAD system related to budget established that prototype cost should be less than \$600. A comparison of the sum of the expected and actual budget determined if the prototype cost was less than \$600. **Table 86** holds all costs related to components and manufacturing, essentially the budget documentation. Using this documentation, the first MOP can be verified. Complete cost of prototype construction was \$175.43. The cost was well under the expected value, therefore the TLVAD passed the MOP stating that prototype cost should be less than \$600.

TABLE 86: BUDGET VERIFICATION

Component/Part	Subsystem	Qty	Cost	Expected
Flow Sensor (G1/2" Thread Hall Effect Liquid Sensor)	Controls	1	\$17.99	\$15
Lithium-Ion Researchable Batteries	Controls	2	\$47.98	\$50
Microcontroller, Driver Module, LCD and Cables (Pack)	Controls	1	\$52.99	\$60
WIFI Module	Monitoring	1	\$5.99	\$15
5V DC Brushless Motor	Heart Pump	1	\$7.50	\$50
Pump (Material& Manufacturing)	Heart Pump	1	\$5	\$60
Inflow Graft (Material& Manufacturing)	Heart Pump	1	\$5	\$70
Outflow Graft (Material & Manufacturing)	Heart Pump	1	\$5	\$90
Adapters	Heart Pump	4	\$18	\$20
Hose	Heart Pump	2	\$9.98	\$15
	Total	15	\$175.43	\$600

After addressing the budget, the verification of the MOP's related to rotor measurements commenced. Those functional requirements established that the rotor would have a length and shaft circumference of no more 100 mm and 40 mm, respectively. Utilizing the procedure, tools and safety precautions established for this particular test, it was concluded that the performance of the rotor design achieved compliance. The achieved rotor length after manufacturing was 12.04 mm, well under than the maximum expected length of 100 mm. Furthermore, the circumference of the rotor was measured to be at 3 mm. A value that proved compliance with the functional requirements and fitted the motor perfectly. **Figure 91** demonstrates the rotor length measurements.



FIGURE 91: ROTOR LENGTH MEASUREMENT

The verification of the functional requirement that the pump motor should use a voltage of no more than 6 V was also successful. Utilizing the procedure, tools and safety precautions established for this particular test, it was measured that the maximum voltage applied to the motor would be 6 V. Potentially providing low power consumption in the entire system. Therefore, ensuring long duration of the stored energy and improving its cost effectiveness. **Figure 92** demonstrates the motor voltage measurements.



FIGURE 92: MOTOR VOLTAGE MEASUREMENT

The weight of the device is a functionality associated to the system's durability, portability, and comfortability from the established MOE's. Consequently, an MOP was established for the implanted prototype product to weigh less than 250 grams. Complying with lightweight device requirements ensures less energy consumption and comfortability for patients. Once all implantable manufactured components were integrated, the end product was weighted under an analytic balance. The measured weight was 196.913g, a value that complies with the established requirement of 250g. Even though systematic errors could vary this measurement, since the balance was left open due to the size of the device, it would still comply with the MOP. The measured and desired value are far enough that the variation won't affect compliance verification. **Figure 93** demonstrates the device weight measurement.

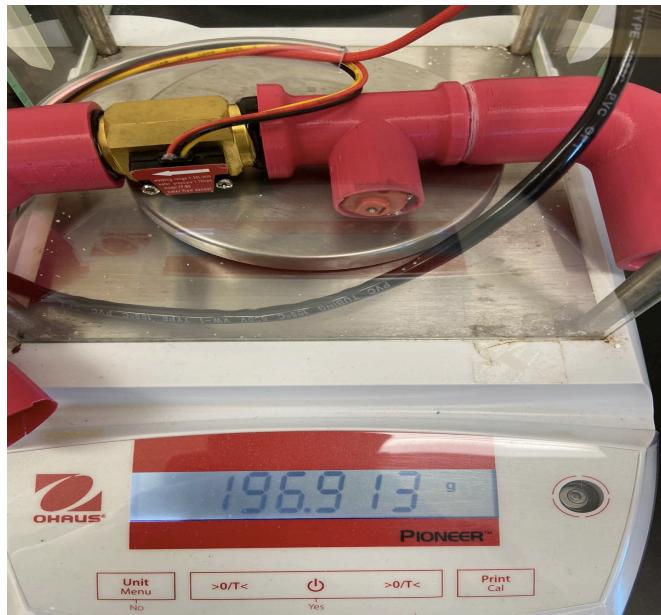


FIGURE 93: DEVICE WEIGHT MEASUREMENT

The Fluid Flow Physical Simulation Loop (FFPSL) was utilized to verify the remaining MOP's. The FFPSL tested the TLVAD device under similar physiological conditions (see **Figure 94**) it would be after implantation. The system MOP's this physical simulation tests are: will monitor both blood flow and rotor velocity through external app, will withstand several temperature assessments for set periods of time and volume flow should be optimal at 5.5 L/min. Firstly, the FFPSL was ran for 45 seconds at 22°C. The time limitation was attributed to the rapid filling of the available Erlenmeyer flask.



FIGURE 94: DEVICE TESTING

However, the physical simulation ran smoothly as volume flow was regulated and optimal at 5.5 L/min, both blood flow and rotor velocity were able to be monitored through the external app, **Figure 95**. In addition, device was able to withstand the temperature as everything functioned to its specifications.

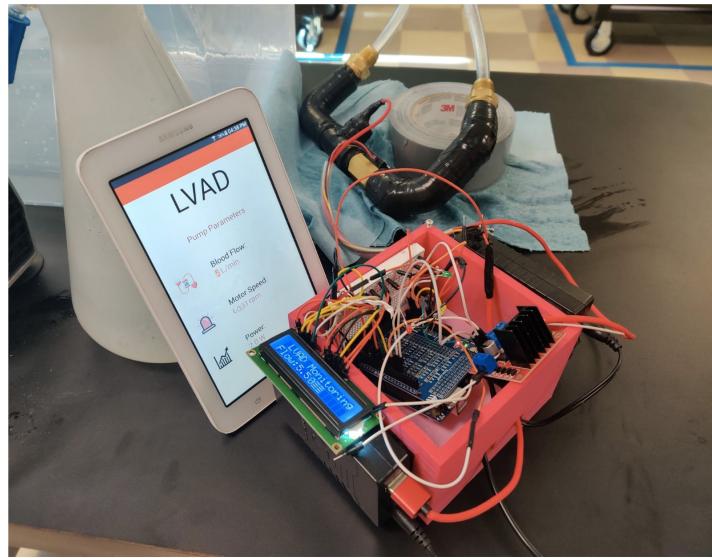


FIGURE 95: MONITORED PARAMETERS

The FFPSL was also ran for 45 seconds at 30°C, see **Figure 96**. Same results followed, therefore establishing compliance for the following MOP's: system will monitor both blood flow and rotor velocity through external app, will withstand several temperature assessments for set periods of time and volume flow should be optimal at 5.5 L/min.



FIGURE 96: DEVICE WEIGHT MEASUREMENT

It is worth mentioning several issues were faced at the testing of the device since a long time passed since the manufacturing and device developed porosity, therefore leaking occurred. Since final end product would be manufactured using titanium allow, prototype was sealed for testing purposes. **Table 87** summarizes all MOP's with their verification procedure performances and phases of compliance.

**TABLE 87: SYSTEM-LEVEL VERIFICATION COMPLIANCE**

MOP'S	Performance	Phase	Procedure	Pass/Fail
Cost should be less than \$600	\$175.43	B	Verification	Pass
Rotor length will be no more than 100 mm	12.04 mm	C.1	Verification	Pass
Rotor will have a circumference of no more than 40 mm	3 mm	C.1	Verification	Pass
Pump motor should use a voltage of no more than 6 V	6V	F	Verification	Pass
Implanted product will weigh less than 250 grams	196.913g	C.1	Verification	Pass
Implanted product shall be water resistant	Yes	C.2	Verification	Pass
Will withstand several temperature assessments for set periods of time	Yes 22-30°C for 45 seconds	F	Verification	Pass
Volume flow should be optimal at 5.5 L/min	5.5 L/min	F	Verification	Pass
Will monitor blood flow through external app	Yes	F	Verification	Pass
Will monitor rotor speed (velocity) through external app	Yes	F	Verification	Pass

## **DISCUSSION**

Heart failure (HF) is a complex clinical disease associated with enormous healthcare costs due to its high morbidity and mortality rates. Most treatments for people who suffer from HF involve a balance of the right medications and, in some cases, use of devices that help the heartbeat and contract properly. Left ventricular assist devices (LVADs) are known to be an acceptable cardiac therapy for patients with advanced heart failure and patients who are not candidates for cardiac transplantation. Mainly because of their clinically meaningful survival benefit and improved quality of life. Even though LVADs are lifesaving surgical implants for the management of end-stage heart failure, their cost-effectiveness is often questioned. Since they substantially increase lifetime costs because of frequent readmissions and costly follow-up care, therefor proving to be a socio-economic burden for patients. With increased risks due to stroke cases, device malfunctions, among other costs can potentially increase even more. Cost issues related to LVAD implantation are of upmost significance since HF affects more than 11 million people in the U.S. and Europe. The high prevalence of HF patients has caused a growing demand for heart transplant that cannot meet due to the lack of donor organs, thus triggering a constant growth in the ventricular assist market. Furthermore, with the opportunities LVADs possess to reduce cost if adverse events and outpatient costs can be reduced. Such cost reduction can be achieved by improving device mechanics to reduce risks of device thrombosis and the incorporation of telemonitoring. Telemonitoring LVAD patients holds a great potential due to the importance of continual monitoring for this patient group because of the complexity of its aftercare, requiring steady control of various parameters

Capitalizing on the demand for LVAD's along with providing a cost-effective design that can be more affordable for clients is of great significance and relevancy in the biomedical engineering field. Therefore, this capstone project was aimed at designing and fabricating a feasible and cost-effective continuous-flow LVAD with telemonitoring capacity for patients with advanced heart failure. The main objective for this device is to support patient's heart function by maintaining ejection fraction above 40% or a cardiac output of 5.5 L/min and provide continual and significant monitoring during the complex aftercare. The latter addressed by implementing a mobile app for continuous monitoring of parameters and data concerning the health of LVAD patients.

The plan for the completion of both the project and its objectives, a system engineering methodology was followed. Firstly, several Measures of Effectiveness (MOE) needed to be established to quantify the accomplishment of mission objectives and the achievement of desired results. Unfortunately, time and resource constraints prohibited the precise verification procedures required for the compliance of the MOE's as proper functionality, biocompatibility, implantation and monitoring capacities evaluated from all global regulation agencies. For instance, most guidelines assessed from the International Organization of Standardization resembled in the ISO 10993 standard for the Biological Evaluation of Medical Devices in addition to the Title 21 Code of Federal Regulations part 870 from the Food & Drug Agency will not be entirely accomplished. As a categorical ventricular bypass or assist device (870.3545) for use in heart failure patients, every class III device requires either a pre-market approval or a completion notice of a product development protocol. Both requirements entail clinical testing with certain patients; any PMA application involves many volumes of material to be submitted to the FDA. The

material may include device design, clinical studies, case report forms, manufacturing methods, even sterilization, packaging, and labeling at once. Considering these numerous constraints, customer expectations and objectives. Even with such constraints a feasible list, that could work with the limitations present, of MOE's was established. These would include cost, durability, portability, pyrogenicity, comfortability, and hemocompatibility. The cost factor was considered most important as research highlights the expensive prices for similar products found in the system's trade studies. Comfortability encompasses many degrees and activities of physiologically relaxing considerations. The importance of this factor was then deemed as critical for the effectiveness of this device contemplating the adequate consumption upon its physical and mental complacency; every type of client expects this device to provide a continual, yet simple cardiovascular monitoring during the complex aftercare of this surgical implant. The durability and portability also were deemed essential as the patient needs to perform most of the activities of daily life practiced during the rehabilitation process and afterwards. More crucially, maintaining a certain monitoring capacity, device functionality and biocompatibility for a predicted time is incredibly vital to every level of client from the stakeholders to the hospitals, patients, and their surgical physicians. Therefore, the portable potential to monitor the specific requirements supplied to the user through the external application will provide the necessary effectiveness to the customer's expectations.

Furthermore, measures of performance (MOP's) were also established to quantify the accomplishment of mission performances and the achievement of desired results. The specific MOP's established were categorized into three general clusters of compliance: functionality, biocompatibility & operability, and telemonitoring implantation capabilities.

Some of the functional requirements included many dimensional technicalities and appropriate executions of base or derived quantities. The MOP's by functionality associated to the system's durability, portability, and comfortability from the aforesaid MOE's were the following: the rotor's length will be no more than 100 millimeters, the rotor's shaft will have a circumference of no more than 40 millimeters, the implanted pump will weigh less than 250 grams, and even the cost should be less than \$600 to manufacture. Additionally, the telemonitoring implantability classification established that it would monitor any electrical and computational capability that the system must provide to the user. Although the simple monitoring post-implantation is deeply linked to the cost and biocompatible factors, these features present great influence on the patients monitoring this system.

After MOE and MOP establishment project planning techniques were implemented to ensure project objective completion. However, no funding was provided for the completion of the device, the students working on the project were responsible to pay in full for all materials, software, or equipment the University did not provide. This would force device manufacturing to be completed under a different set of materials. This was expected as risk estimates were taken into account, the low budget and the ongoing COVID-19 pandemic would impose diverse restrictions and complications during the project development. Nevertheless, the goal would still be to provide a cost-effective design that can be more affordable for clients, but at the same time provide a large monetary gain for stakeholders.

To achieve the mission objectives a systematic review was conducted. The systematic review of the technology requirements and solutions currently out there was done to address the design and fabrication of a feasible, yet cost-effective continuous-flow LVAD

with telemonitoring capacity for patients with advanced heart failure. Diverse LVAD models were addressed for specific requirements or MOP's the Telemonitoring LVAD (TLVAD) highly valued. The models evaluated were the HeartMate III, Duraheart and Heartware. Based on the decision matrix calculations, the best technology presently in the market to provide a solution best suited for the projects requirements and environment is the Heartmate III. With a model to base off a System Hierarchy Diagram was established to define the system as a whole and below its subsystems. The TLVAD project was determined to consist of three subsystems: the heart pump, the controls, and the monitoring. An  $N^2$  diagram was utilized to represent these functional or physical interfaces between the subsystems. The main interacting components in the TLVAD system are the patients, microcontroller, pump, sensors and mobile app. Consequently, to comply with these interfaces the mandatory benchmarks or requirements for the adequate fulfillment of a telemonitoring, controls and heart pump system were established. Following requirement establishment, an identification and evaluation of hazards along with determination of appropriate ways to mitigate the risks at a subsystem-level was rigorously performed to achieve patient safety.

Trade studies were then performed to assess the technology found in the current literature to find a solution that is best suited for each subsystem requirements and environment. The selected approach for the heart pump subsystem was a continuous flow working principal and for the controls it was selected a PID closed Loop control system. As for the monitoring, a WIFI communication principal was selected. After establishing the working principal for each subsystem, component selection of each subsystem commenced. Looking for current products that could potentially suffice criteria for

subsystem requirements or MOP's. Afterwards, the products were assessed through a decision matrix to find best solution tailored for the subsystem requirements and environment.

Refinement and planning, the design, specifications and estimates at subsystem-level using engineering analysis for each subsystem followed. Using a writeup that established the interface requirements of the specific subsystem and other subsystems in relation to it, several designs and estimates were performed. The work related to the heart pump subsystem centered on the Computer-Aided Design (CAD) of the motor enclosure, rotor and pipeline unit. Taking into account pipeline tolerances and the diverse specifications needed for the TLVAD design. On the other hand, the control subsystem analysis was centered on the system transfer function and PID tuning parameters that could provide accurate development of a program that can maintain a continuous modulated control of pump speed through voltage. Once those were established, the hardware connections were designed for compliance of the TLVAD's specifications. Finally, the monitoring system's analysis was focused on designing a graphical user interface for easy pump monitoring for patients and the hardware connections to achieve such specifications.

The system integration was structured to bring the elements together to assemble each subsystem and bring all subsystems together to assemble the end product. Compliance with the interfaces established on the  $N^2$  diagram is essential for ensuring the system-level MOE's and MOP's are obtained in the end product. Estimates were calculated to verify this system interface compliance. Once device is implanted and connected, the microcontroller will provide the motor a voltage of 3.45V. With said voltage the motor will be able to rotate at RPM and giving a power output of 0.11 W This will commence the

pump to start the blood flow from the left ventricle to the body. The sensor will then read the flow rate, which will register in the microcontroller, serving as a feedback input to adjust the rotor speed accordingly until ideal flow rate of 5.5 L/min is achieved. The regulation is attributed through the PID tuning parameters of  $K_P$  and  $K_D$ . These parameters hold values of 8.77 and 5.54, respectively. Maintaining a CO of 5.5 L/min might require a supplied voltage range of 2.62 to 3.44 V. Nevertheless, MOP's will still be accomplished. If any high or low flow risks arise, the control system will inform patients via auditory and visual alarms found in the control box. Pump power and rotor speed will be calculated by the microcontroller which will be transmitted along with the flow rate to the mobile app. These parameters will then be received and displayed in the mobile app for patient monitoring. Achieving compliance of the systems interfaces.

The system integration plan commenced with the controls subsystem, where circuit building utilizing the essential hardware was performed. Consequently, the heart pump subsystem was to be manufactured and assembled for project integration, as it provides important physical performance. Finally, application development and integration of the monitoring subsystem hardware must be performed for successful system level MOP and MOE compliance. Manufacturing and assembly of the implanted aspect of the TLVAD, the pump subsystem, requires individual manufacturing for each pipeline unit: heart pump, rotor, inflow graft, and outflow graft. Unfortunately, the cost for manufacturing these parts exceeded the preliminary estimations for the heart pump subsystem, along with the COVID-19 restrictions the part manufacturing would not be completed if the procedure was followed as stated. Manufacturing capabilities are limited due to the heavy restrictions imposed from regulation agencies, such as the FDA, for the ultimate approval of different

medical devices like Heart Pump Telemonitoring systems. For example, the materials needed for the final prototype include titanium for the rotor and the main connector component as well as 3D-printed polytetrafluoroethylene (PTFE) used for the general tubing assembled within the heart pump. Furthermore, the project's approximate 6-month time constraint prevented the handmade construction of several electronic controls, such as the Liquid Crystal Display (LCD), the flowmeter, DC motor driver, and the microcontroller. Consequently, these components were acquired by open-source hardware like Arduino that provide a straightforward design. Even though the end product was not manufactured as it was intended to due to budget and COVID-19 restrictions, a prototype was still manufactured. Alternatively, the prototype was manufactured using 3D printing and will still be able to be tested in order to verify MOE and MOP compliance. Both the controls and monitoring subsystems were constructed and integrated as established.

As a way to verify the design and performance of a Left Ventricular Assist Device prototype a system verification plan was established, that could certify the fulfilment of its design, controls, and monitoring requirements. The system verification plan was followed exactly as established before to verify the performance of the TLVAD prototype based on a plethora of MOE's and MOP's that confirm the fulfilment of the projects objectives. It is important to mention the constraint of the material manufacturing limited the thorough analysis of this section into a proper clinical trial testing as phase I. Therefore, the proper qualification for approval by the appropriate organization were not required to be comprehensively performed. To properly complete the requirements for biocompatibility of certain medical devices that require Class III approval by PMA, HDE, IDE, or PDP from the FDA, it is important to mention that both the FDA and ISO provide guidance

documents for the International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

System verification commenced addressing the MOP of the TLVAD system related to budget established that prototype cost should be less than \$600. A comparison of the sum of the expected and actual budget determined if the prototype cost was less than \$600. Using the budget documentation, the first MOP can be verified. Complete cost of prototype construction was \$175.43. The cost was well under the expected value, therefore the TLVAD passed the MOP stating that prototype cost should be less than \$600. After addressing the budget, the verification of the MOP's related to rotor measurements commenced. Those functional requirements established that the rotor would have a length and shaft circumference of no more 100 mm and 40 mm, respectively. Utilizing the procedure, tools and safety precautions established for this particular test, it was concluded that the performance of the rotor design achieved compliance. The achieved rotor length after manufacturing was 12.04 mm, well under than the maximum expected length of 100 mm. Furthermore, the circumference of the rotor was measured to be at 3 mm. A value that proved compliance with the functional requirements and fitted the motor perfectly.

Furthermore, the verification of the functional requirement that the pump motor should use a voltage of no more than 6 V was also successful. Utilizing the procedure, tools and safety precautions established for this particular test, it was measured that the maximum voltage applied to the motor would be 6 V. Potentially providing low power consumption in the entire system. Therefore, ensuring long duration of the stored energy and improving its cost effectiveness. Complying with lightweight device requirements ensures less energy consumption and comfortability for patients. Once all implantable manufactured

components were integrated, the end product was weighted under an analytic balance. The measured weight was 196.913g, a value that complies with the established requirement of 250g.

Finally, the Fluid Flow Physical Simulation Loop (FFPSL) was utilized to verify the remaining MOP's. The FFPSL tested the TLVAD device under similar physiological conditions it would be after implantation. The system MOP's tested were: will monitor both blood flow and rotor velocity through external app, will withstand several temperature assessments for set periods of time and volume flow should be optimal at 5.5 L/min. Firstly, the FFPSL was ran for 45 seconds at 22°C. The physical simulation ran smoothly as volume flow was regulated and optimal at 5.5 L/min, both blood flow and rotor velocity were able to be monitored through the external app. In addition, device was able to withstand the temperature as everything functioned to its specifications. The FFPSL was also ran for 45 seconds at 30°C. Same results followed, therefore establishing compliance for the tested MOP's for the TLVAD system.

## **CONCLUSION**

In efforts of reducing the high mortality rates, enormous healthcare costs, and the demand for cardiovascular devices caused by heart failure, a Telemonitoring Left Ventricular Assist Device Prototype was designed and tested. Such device was designed to specifications to support patient's heart function by maintaining ejection fraction above 40% or a cardiac output of 5.5 L/min and provide continual and significant monitoring during the complex aftercare. As a result of compliance regarding the measures of performance during the verification procedure, it was concluded that the stated project objectives were met satisfactorily. Obtained results reflect that the design and fabrication of a cost-effective continuous-flow LVAD with telemonitoring capacity for patients with advanced heart failure is feasible.

## **RECOMMENDATIONS**

The prototype experimentation verified the accuracy of device's working principal. Future directions should include the handmade construction of several electronic controls in order to increase the systems compactness. Consequently, manufacture the implantable device utilizing titanium alloys for biocompatibility. In addition, device should go through a validation process to validate the blood flow regulation over long periods of time, before going through clinical trials or medical device market.

## REFERENCES

1. Heart & Vascular: Conditions & Treatments. Retrieved July 19, 2020, from <https://www.emoryhealthcare.org/heart-vascular/wellness/heart-failure-statistics.html>
2. Heart Failure. (n.d.). Retrieved July 19, 2020, from <https://www.heart.org/en/health-topics/heart-failure>
3. Left Ventricular Assist Device. (2019, February 19). Retrieved July 19, 2020, from <https://stanfordhealthcare.org/medical-treatments/l/lvad.html>
4. Oz, M., Glijns, A., Miller, L., Wang, C., Nickens, P., Arons, R., . . . Moskowitz, A. (2003, October). Left ventricular assist devices as permanent heart failure therapy: The price of progress. Retrieved July 19, 2020, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1360116/>
5. Reiss, N., Schmidt, T., Boeckelmann, M., Schulte-Eistrup, S., Hoffmann, J., Feldmann, C., & Schmitto, J. (2018, June). Telemonitoring of left-ventricular assist device patients-current status and future challenges. Retrieved July 19, 2020, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6035944/>
6. Rose, E., Al., E., For the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group\*, Author AffiliationsFrom the College of Physicians and Surgeons (E.A.R., Jessup, M., L. A. Jackson and Others, . . . Heaton, P. (2001, November 15). Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure: NEJM. Retrieved July 19, 2020, from <https://www.nejm.org/doi/full/10.1056/nejmoa012175>
7. Shreibati, J., Goldhaber-Fiebert, J., Banerjee, D., Owens, D., & Hlatky, M. (2017, February 01). Cost-Effectiveness of Left Ventricular Assist Devices in Ambulatory Patients With Advanced Heart Failure. Retrieved July 19, 2020, from <https://heartfailure.onlinejacc.org/content/5/2/110>
8. Pfister, R., Tozzi, P., Hullin, R., Yerly, P., Jahns, F., Prêtre, R., & Kirsch, M. (2018, April 25). HeartMate 3 implantation via left antero-lateral thoracotomy to avoid sternotomy in high-risk patients.

9. Nishinaka, T., Schima, H., Roethy, W., Rajek, A., Nojiri, C., Wolner, E., & Wieselthaler, G. (2006). The DuraHeart VAD, a magnetically levitated centrifugal pump: The University of Vienna bridge-to-transplant experience.
10. Carrel, T., Englberger, L., Kadner, A., & Mohacsi, P. (2013). Implantation of the continuous flow HeartWare® left ventricular assist device. Multimedia manual of cardiothoracic surgery.
11. Leuck, A. (2015, December). Left ventricular assist device driveline infections: Recent advances and future goals. Retrieved December 08, 2020, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4703684/>
12. Boudot, C., Burkhardt, S., & Haerst, M. (2016, September 01). Long-term stable modifications of silicone elastomer for improved hemocompatibility. Retrieved from <https://www.degruyter.com/document/doi/10.1515/cdbme-2016-0008/html>
13. Hermawan, H., Ramdan, D., & Djuansjah, J. R. (2011, August 29). Metals for Biomedical Applications. Retrieved from <https://www.intechopen.com/books/biomedical-engineering-from-theory-to-applications/metals-for-biomedical-applications>
14. Roque-Malherbe, R. M. (2017). The physical chemistry of materials: Energy and environmental applications. Boca Raton: CRC Press.

# APPENDIX A: PRESENTATIONS

## Pre-Phase A

**Capstone I Pre-Phase A:  
Ventricular Assist Device  
With Telemonitoring  
Capabilities**

Stephanie Molla-Morales  
Alexander Martinez-Lopez  
Carina Gonzalez-Rivera  
Dr. Carlos Arevalo  
Due Date: September 8, 2020

The slide features the Polytechnic University of Puerto Rico logo at the top left. The title is centered in a large, bold font. Below the title is a list of team members and the due date. To the right is a graphic of three blue stylized human figures inside a hexagonal frame.

1

2

**Users**

**Stakeholders**  
Carina Gonzalez, Stephanie Molla, Alexander Martinez

Polytechnic University of Puerto Rico, Biomedical Engineering Department Students.

This slide details the users (patients with advanced heart failure) and stakeholders (team members and students).

3

**Background Information**

- Heart Failure, often called a "weak heart", prevents the heart's ability to pump enough blood to meet the body's demand.
- Ejection fraction (EF) is the percentage of blood leaving your heart each time it contracts.
- Patients with advanced heart failure often possess an EF of less than 40%.
- Approximately 550,000 new cases of Heart Failure are diagnosed a year in the U.S.
- Heart failure is responsible for 9.4% of deaths attributed to cardiovascular disease in the U.S.

**Infographic:** Heart Failure is the most common diagnosis in the U.S., with nearly 550,000 new cases diagnosed each year. It is also the leading cause of hospitalization for seniors.

4

**Project Description & Objectives**

**Description**

- Electromechanical circulatory support device that can help pump blood from the left ventricle to the rest of your body, as well as monitor its own pump parameters.

**Objective**

- Support patient's heart function by maintaining ejection fraction above 40% or a cardiac output of 5.5 L/min
- Provide continual and significant monitoring during the complex aftercare.

This slide describes the project as an electromechanical circulatory support device and outlines the objective to support patient heart function and provide monitoring.

5

**Concept of Operations**

**Advanced Heart Failure**

**Treatments**  
Heart Transplant, Ventricular Assist Device

**Symptoms**  
- Shortness of breath  
- Swelling and edema  
- Coughing or pain when breathing  
- Rapid heart rate  
- Fluid retention in legs and ankles

**Operational Objectives**  
Current and most common treatments used to address patients with advanced heart failure.

This slide illustrates the concept of operations for advanced heart failure, showing the progression from symptoms to treatments like heart transplant and VAD.

6

## Concept of Operations

**Operational Objective:**  
LVAD's increase blood flow from the left ventricle towards the body.

7

## Project Significance

**Heart LVADS**  
The heart-lung bypass pump is a pump that replaces the failing heart during surgery or until a heart transplant can be performed.

**Heart Failure**

- Heart failure affects more than 22 million people in the U.S. and Europe, with an incidence of 2.2 million per year.
- Problem: Growing demand for heart transplant cannot meet, owing to the lack of donor organs.
- The average cost of LVAD device implants is US\$ 85,000 to US\$ 100,000. The high cost of devices makes it unaffordable for patient to undergo treatment, which is likely to target the heart pumps market.
- Device price need to reduce substantially to make it a widely acceptable and cost-effective treatment option.
- Why this device is vital need - the number of people heart need for replacement is the sum of the number of patients who require transplantation + the number of people who die on the waiting list + the number of transplants performed.

8

## Project Significance

**Heart Pumps Market 2019-2027**

- High prevalence of heart failure patients in the U.S. has triggered constant growth in the ventricular assist market.
- The global ventricular assist device market size was valued at USD 1.7 billion in 2019.
- The market size is expected to grow with compound annual growth rate (CAGR) of 11.7% from 2020 to 2027.

9

## Project Significance

**Market Categories**

Market Category	Average cost (US\$ 1,000)	% of total cost
LVAD implants	47,861	85%
Prosthetic heart valves	13,491 ± 1,080	17%
Stents	2,701 ± 2,736	2%
Biologics	1,091 ± 173	2%
Diagnosis	2,959 ± 1,216	2%
Drugs	1,267 ± 362	2%
Other products	3,337 ± 1,249	2%
Services	2,335 ± 1,049	2%
Rehabilitation	2,215 ± 1,049	2%
Total	84,294	100%

Market categories costs are based on estimates derived from 104 of 111 sites.

10

## Cost Analysis

Material	Unit cost	Model, Brand	Description
Mediflex	\$200	Mediflex	Mediflex is the best implant.
Elc-Med	\$200	Elc-Med	Used for heart flow.
Battery	\$200	Lilium	Battery source charged recently.
Welding	\$10	Weld	Weld source charged recently.
Threads	\$0.004kg	P.L.A.	3D printed material for heart tube.
Mediflex	\$100	Mediflex	Mediflex is the best implant.
Electrodes	\$100	Mediflex and Others	Used for heart flow.
Surgeon	\$80	Surgeon	Professional cardiovascular surgeon.
Surgeon	\$80	Anesthesiologist	Professional cardiovascular anesthesiologist.
Nursing	\$80	Medical personnel	Medical personnel.
Nursing	\$80	Medical personnel	Medical personnel.
Transport	\$100	Transport	Transportation services.
<b>Total Cost</b>	<b>\$1000</b>		

Model Name	Unit cost	Duration
Transportation [1]	\$170,000	Long Term
Transportation [2]	\$170,000	Long Term
Transportation [3]	\$170,000	Long Term
Transportation [4]	\$170,000	Short Term
<b>Total Cost</b>	<b>\$2,140,000</b>	

11

External Clients	Internal Clients
• External clients: USA, general clinical practice, hospitals, and medical facilities.	• Internal clients: All patients, USA, general clinical practice, hospitals, and medical facilities have increased the number of heart transplants and heart pumps.
• External providers	• External providers: All patients, USA, general clinical practice, hospitals, and medical facilities have increased the number of heart transplants and heart pumps.
• External partners	• External partners: Physician patient's heart function is a main issue.
• External stakeholders	• External stakeholders: you may need more resources during the implementation.

**MOP's**

Objectives	Process
• Lead life independently and live a normal life.	• Lead life independently and live a normal life.
• Be able to exercise for over one year without any issues.	• Be able to exercise for over one year without any issues.
• Be able to work for over one year without any issues.	• Be able to work for over one year without any issues.
• Participate in social activities.	• Participate in social activities.
• Be able to travel without any issues.	• Be able to travel without any issues.
• Be able to live independently.	• Be able to live independently.
• Be able to live independently.	• Be able to live independently.
• Be able to live independently.	• Be able to live independently.
• Be able to live independently.	• Be able to live independently.

**MOF's & MOP's**

12

Standards of MOPs	
ARTC100-0410-01 and AAMI/AAMI/ISO1-1077-0 2000 FDA 21 CFR 820.38, SDI, MIL-1794 and DOD-ORS 1990 FDA 21 CFR 820.38, SDI, MIL-1794 and DOD-ORS 1990 FDA Biological evaluation of medical device Part 1: Evaluation and Testing FDA Biological evaluation of medical device Part 1: Evaluation and Testing FDA 21 CFR 820.38, SDI, MIL-1794 and DOD-ORS 1990 FDA Biological evaluation of medical device Part 1: Evaluation and Testing FDA Biological evaluation of medical device Part 1: Evaluation and Testing FDA 21 CFR 820.38, SDI, MIL-1794 and DOD-ORS 1990 FDA 21 CFR 820.38, SDI, MIL-1794 and DOD-ORS 1990 AAMI/AAMI/IEC 62664-2004, AAMI/ANSI/ES 1997 AAMI/AAMI/IEC 62664-2004, AAMI/ANSI/IEC 1997	SDMOP's  Usable-life expectancy will be one year of shelf-life Rate length will be no more than 1.00 mm Rate will have a clearance rate of no more than 40 mm Volume flow should be optimal of 2.1 Units 1. Evaluation and Testing Pump motor should use a voltage of no more than 240VAC Implanted product will weight less than 250 grams Implanted product shall be water resistant Will withstand several temperature variations for an article of 10°C Can stand in an air flow 5000 Will measure blood flow through external app Will measure return speed (velocity) through external app

13

QFD	Customer requirements	Design requirements	Product requirements
Customer requirements	Customer requirements	Design requirements	Product requirements
Design requirements	Design requirements	Design requirements	Product requirements
Product requirements	Design requirements	Design requirements	Product requirements
Customer requirements	Customer requirements	Design requirements	Product requirements

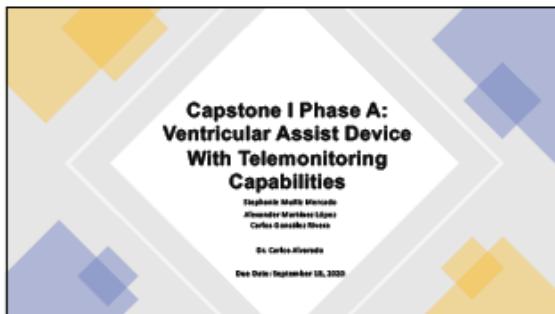
14

Preliminary Project Planning										
Timeline for the Cardiopulmonary System										
Activity	Responsible	WBS Category I			Week	Month	WBS Category II			January
		W2	W3	W4			W5	W6	W7	
Technological Assessment	Group	X								
Market Analysis	Group		X							
Task Breakdown	Individual			X						
Budget	Central				X					
Subsystems: Power Supply Design & Manufacturing	Individual					X				
Subsystems: Personnel Modeling & Maintenance Programming	Individual						X			
Subsystems: Data Transmission and Monitoring Development	Central						X			
Final Presentation	Group				X					

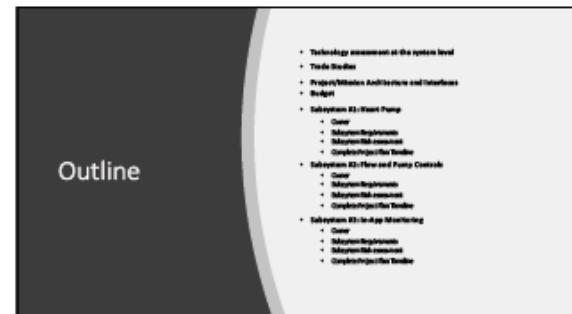
\*\*Each Subsystems will establish sub-system requirements, risk assessment and project plan timeline.

15

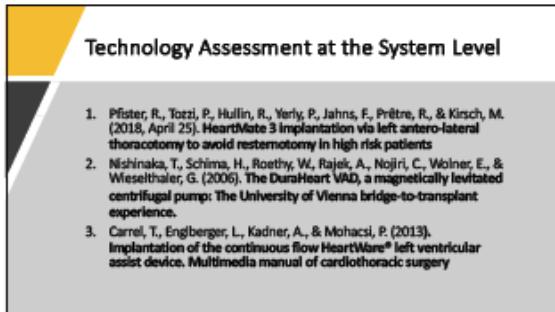
## Phase A



1



2



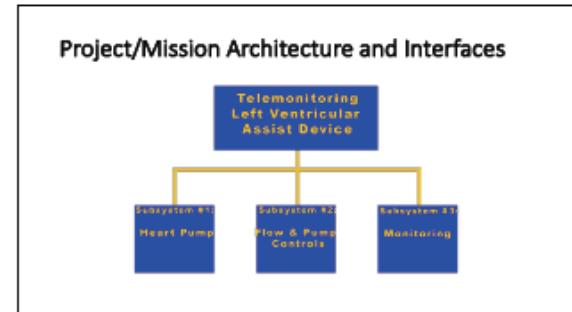
3



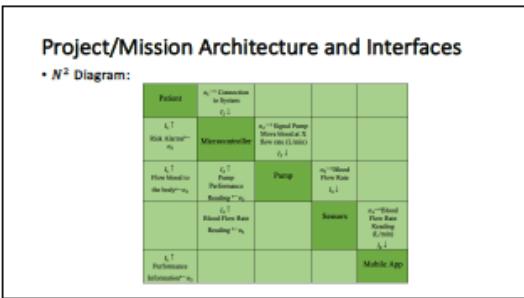
4

Rating Weighting Decision Matrix					
Criteria	Value	Weight	Heartmate 3	Duraheart	Heartware
Weight	100g	0.18	2.7	1	3
Pump Height	50 mm	0.05	2.9	1	3
Pump Diameter	45 mm	0.05	2.9	1	3
Pump Velocity	1,000 to 2,500 rpm	0.12	1	3	3
Volume Flow	2 to 50 L/min	0.2	3	3	1
Cost	\$5,000	0.2	1.5	1	3
Monitored parameters	4	0.2	3	1	1
Total		1	2.396	1.64	2.2

5



6

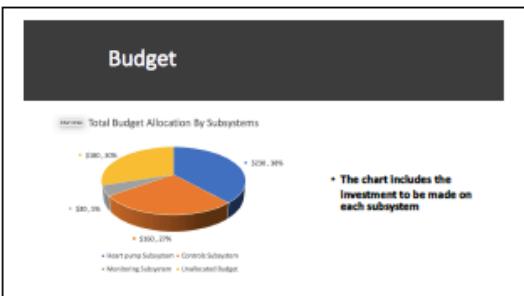


7

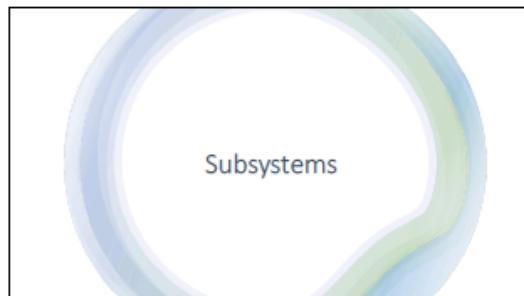
**Budget**

Material/Offer	Cost	Subsystem
Motor	\$10	Control
DC Motor	\$10	Heart Pump
Battery	\$10	Controls
Wiring	\$10	Control/Monitoring
Filament	\$20	Heart Pump
Microcontroller	\$20	Control
Electronic Modules	\$20	Controls
Monitoring Modules	\$20	Monitoring
Flow Sensor	\$20	Controls
Testing Equipment	\$20	Controls
Tool Box	\$5	Control/Monitoring
Workforce	\$5	All
Manufacturing	\$5	Heart Pump
Logistics	\$5	Heart Pump
<b>Total Cost</b>	<b>\$420</b>	

8



9



10

**Subsystem #1: Heart Pump**  
Owner: Stephanie Muñiz

**Standards**

FDG 21 CFR 820.30 and ISO 9001:1994 and IEC60601-1:2005

**MOPS**

Pump height will be about 50mm and pump diameter will be about 45mm

ISO 21 CFR 820.30, ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

The blood flow should be 4 to 8 L/min 1/min

FDG 21 CFR 820.70 ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Pump velocity should be no more than 1,000 to 4,500 RPM

ISO 21 CFR 820.70/FG 21 CFR 820.30 and ISO 9001:1994 and IEC60601-1:2005

Weight should be less than 250g

ISO 21 CFR 820.70/FG 21 CFR 820.30 and ISO 9001:1994 and IEC60601-1:2005

Pump cost should be around the \$300.00

ISO 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Pump will be water resistant

11

**Subsystem #1: Heart Pump Risk Assessment**

**Risks**

- A – Device Infections
- B – Blood clots (caused by a circulatory failure)
- C – Power failure (failure related with physical hardware)
- D – Internal Bleeding (caused after the DMD Implantation)
- E – Right Heart Dysfunction
- F – Heart Stroke
- G – Hemolysis (damage to blood cells due to the pump)

**Soft Risk Matrix**

Likelihood	Risk					
	Very Low	Low	Medium	High	Very High	Extremely High
Very Low	Green	Yellow	Orange	Red	Dark Red	Black
Low	Light Green	Yellow	Orange	Red	Dark Red	Black
Medium	Light Green	Yellow	Orange	Red	Dark Red	Black
High	Light Green	Yellow	Orange	Red	Dark Red	Black
Very High	Light Green	Yellow	Orange	Red	Dark Red	Black
Extremely High	Light Green	Yellow	Orange	Red	Dark Red	Black

**Consequences**

Very Low, Low, Medium, High, Very High, Extremely High

12

## Subsystem #1: Heart Pump Mitigation Strategies

REASNS	STRATEGIES
Driveline infections	Can be treated with antibiotics
Blood clots (caused by a circulatory failure)	Can be treated with anticoagulants drugs (Doctor's discretion)
Power failure [factors related with physical hardware]	Use Lithium rechargeable Batteries that Posses 2 to 3 years of Battery Life
Internal bleeding [caused after the LVAD implantation]	Treatment involves the administration of intravenous vitamin K, fresh frozen plasma, blood, and platelets
Right Heart Dysfunction	Monitor blood flow constantly
Heart Stroke	Anticoagulant drugs and antiplatelet agents.
Hemolysis [damage to blood cells due to the pump]	Coagulant drugs (Ex: Ibuprofen, Naproxen) and blood transfusion

13

## Subsystem #1: Heart Pump Project Plan Timeline



14

## Subsystem #2: Flow and Pump Controls Owner: Alexander Martínez

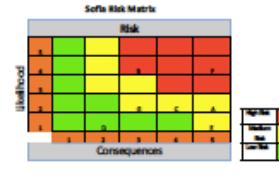
### Subsystem Requirements

Standards	MOP'S
PMA-2004-0101-0001-0000-A000-B1-A0001	Will measure blood flow output (L/min)
AAMI-AMS-BC-A0100-A000-B1-A0001 A2-2010/FM-2011, PMA-21 CFR Sec. A200-70	
AAMI-AMS-BC-A0100-A000-B1-A0001 A2-2010/FM-2011, PMA-21 CFR Sec. A200-70 and A2-2010/FM-2011, PMA-21 CFR Sec. A200-70	Will calculate pump motor speed (rpm)
AAMI-AMS-BC-A0100-A000-B1-A0001 A2-2010/FM-2011, PMA-21 CFR Sec. A200-70 and A2-2010/FM-2011, PMA-21 CFR Sec. A200-70	Will calculate pump power (W)
AAMI-AMS-BC-A0100-A000-B1-A0001 A2-2010/FM-2011, PMA-21 CFR Sec. A200-70	Must regulate motor voltage (%)
AAMI-AMS-BC-A0100-A000-B1-A0001 A2-2010/FM-2011, PMA-21 CFR Sec. A200-70	Must regulate pump blood flow output (L/min)

15

## Subsystem #2: Flow and Pump Controls Risk Assessment

Index	Risk
A – Failed Power Supply	High
B – Batteries Discharged	Medium
C – Incorrect Sensor Readings	Medium
D – Alarm Fatigue (Patient Desensitization Towards Alarms)	Medium
E – Incorrect Connection of Modular Cable	Medium
F – Microcontroller Failure	Medium
G – Erroneous Regulation of Pump Parameters (Pump Thrombosis)	Medium



16

## Subsystem #2: Flow and Pump Controls

### Mitigation strategies

Mitigation strategies
A – Use a Backup Battery and Microcontroller as Power Supply
B – Use Lithium Rechargeable Batteries that Posses 2 to 3 years or 300 to 500 Charge Cycles of Battery life
C – Use Accurate and Reliable Flow Sensor
D – Use Small Threshold of Alarming parameter Range
E – Provide Correct Orientation for Electrical Connection
F – Use a Microcontroller with High Reliability; such as Arduino
G – Implement Failure Alerts for Patient Safety

17

## Subsystem #2: Flow and Pump Controls

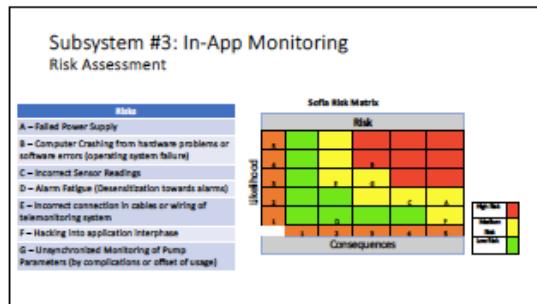
### Project Plan Timeline



18

Subsystem #3: In-App Monitoring Owner: Carlos González	
Standards (PAEs within 21 CFR 820.40 Quality Parameters)	MOPs
FDA Title 21 CFR Sec. 820.70(l) Production and Process Controls: Automated Processes	Shall validate computer software for its intended use according to an established protocol. Shall establish and maintain procedures for verifying the device design.
ii) FDA Title 21 CFR Sec. 820.30(a) Design Controls: Verification (f)	Will transfer and display of electronic medical device data to smartphone (Mop)
FDA Class I (General Controls) Title 21 CFR Sec. 880.6310	Will electronically convert medical device data from one format to another format in accordance with preset specifications and store medical device data from one device to another (G)
AMMI ANSI / IEC 62304-2006, AMMI ANSI ES 60601-1:2005/ES 60601-1:2011, cl.2006/R0312 and A2-2013/V2013, FDA 21 CFR Sec. 820.70	Will monitor pump power (M)
AMMI ANSI / IEC 62304-2006, FDA 21 CFR Sec. 820.70	Must monitor changes in pump velocity (pm)
AMMI ANSI / IEC 62304-2006, FDA 21 CFR Sec. 820.70	Must monitor continuous pump blood flow output (l/min)

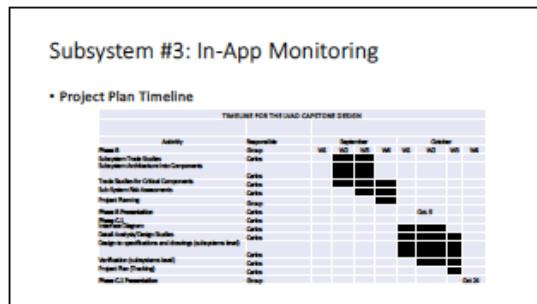
19



20

Subsystem #3: In-App Monitoring	
▪ Mitigation strategies	
Mitigation strategies	
A – Use a Backup Battery and Microcontroller as Power Supply	
B – Use accurate yet reliable resolution parameters	
C – Use minutes threshold of Alarming Range	
D – Provide Correct Orientation for Electrical Connections	
E – Use a Microcontroller with High Reliability like an Arduino	
F – Implement Firewall protection for Patient Safety	

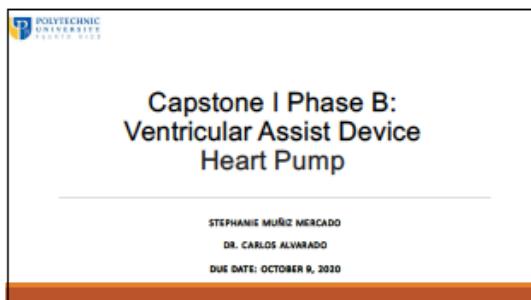
21



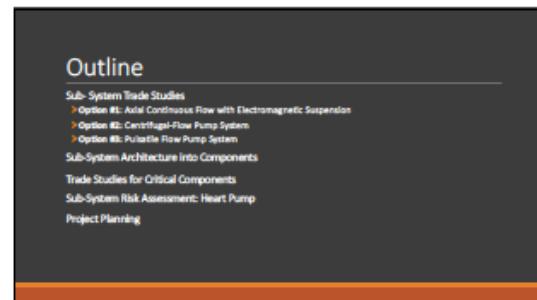
22

## Phase B

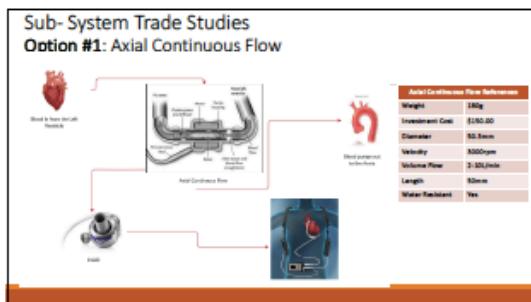
### Heart Pump



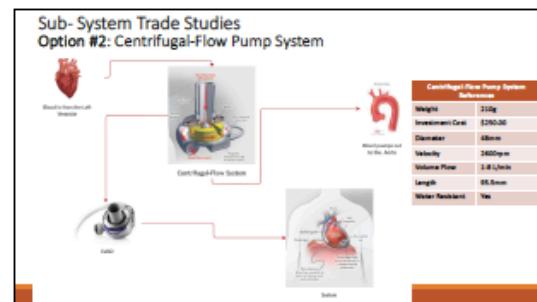
1



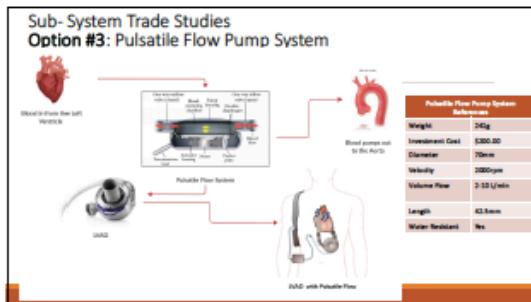
2



3



4

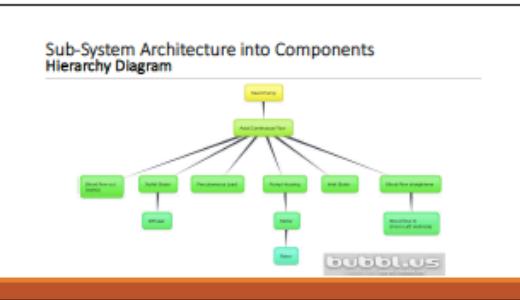


5

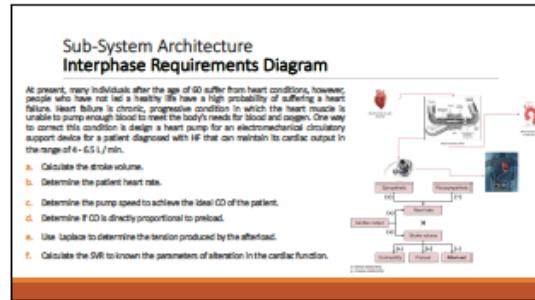
**Sub-System Trade Studies**

Criteria	Value	Weight	Rating Weighting Decision Matrix		
			Axial Continuous Flow	Centrifugal Flow Pump System	Pulsatile Flow Pump System
Weight	0.33	0.33	1.00	0.00	0.00
Height	0.33	0.33	0.00	1.00	0.00
Width	0.33	0.33	0.00	0.00	1.00
Depth	0.33	0.33	1.00	0.00	0.00
Velocity	0.33	0.33	0.00	1.00	0.00
Volume Flow	0.33	0.33	0.00	0.00	1.00
Length	0.33	0.33	0.00	0.00	1.00
Water Resistant	0.33	0.33	0.00	0.00	1.00
Total	1.00	1.00	2.888754	0.112442	0.112442

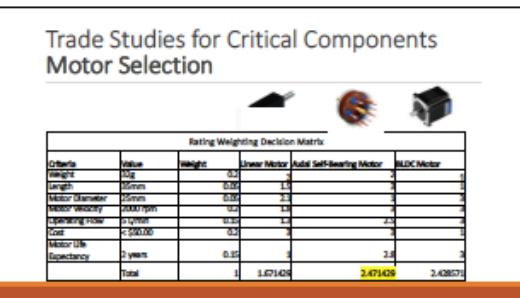
6



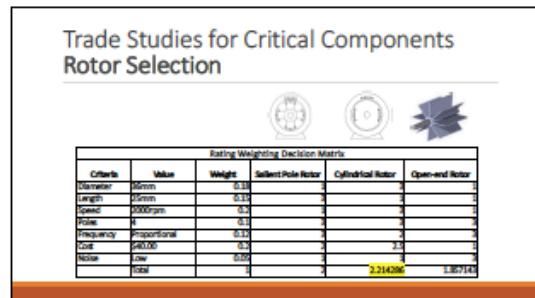
7



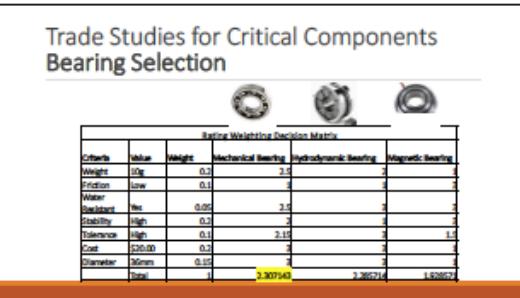
8



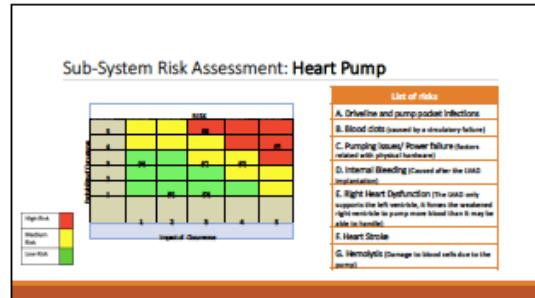
9



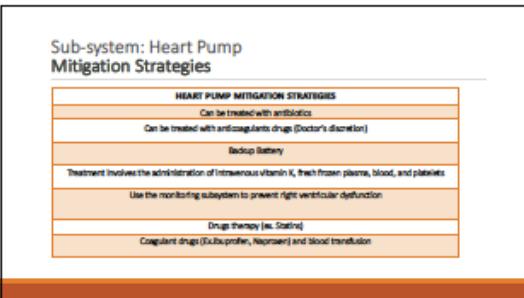
10



11



12



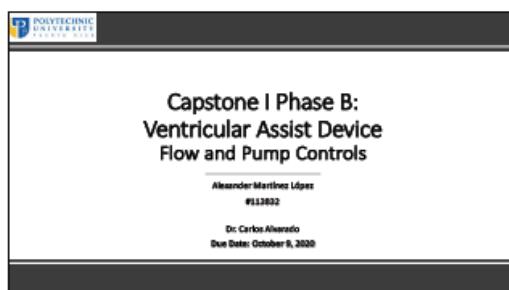
13

**Project Planning**

TIMELINE FOR THE VAD CAPSTONE DESIGN									
Activity	Responsible	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
PWRS C	Group	Replace							
Initial Design	Replace								
Design Analysis Design Studies (Mayo Clinic)	Replace								
Design Specifications and Drawing	Replace								
Verification (Autodesk Inventor)	Replace								
Project Plan Planning	Replace								
Final Submission	Group								

14

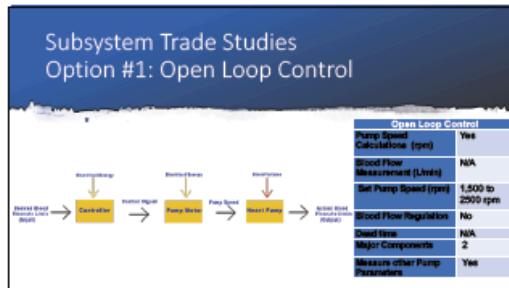
## Controls



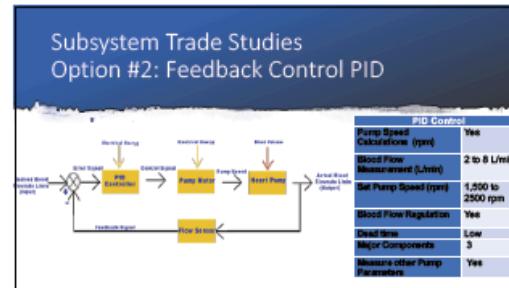
1

- Outline**
- Subsystem Trade Studies
  - Subsystem Architecture into Components
  - Trade Studies for Critical Components
  - Sub-System Risk Assessment
  - Project Planning

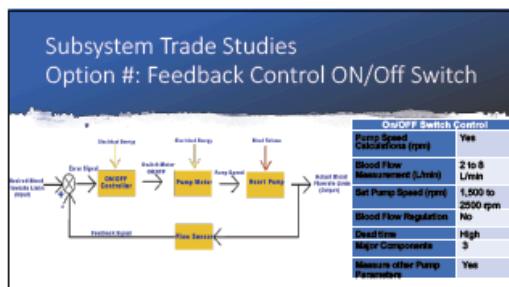
2



3



4

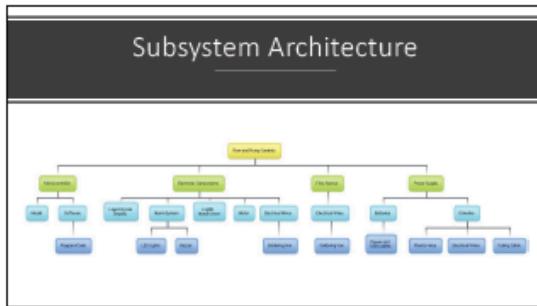


5

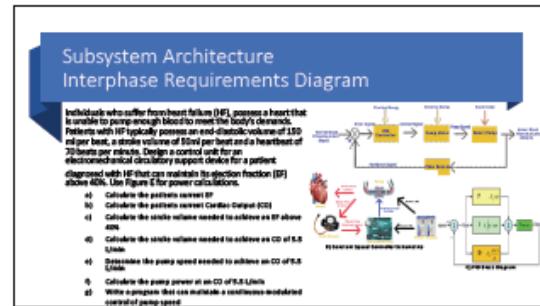
**Trade Studies**

Criteria	Control System Selection Decision Matrix				
	Value	Weight	Open Loop Control	PID Control	ON/OFF Control
Pump Speed Calculations (KPM)	Yes	0.15	3	3	3
Blood Flow Measurement (Litres)	4 to 8 Litres	0.28	1	3	3
Set Pump Speed (rpm)	1,500 to 2,000 rpm	0.18	3	3	3
Blood Flow Regulation	Yes	0.35	1	3	1
Dead Time	Low	0.18	1	3	2
Major Components	3	0.05	3	3	1
Measure other Pump Parameters	Yes	0.13	3	2	3
Total		1	8.5	2.8	3.2

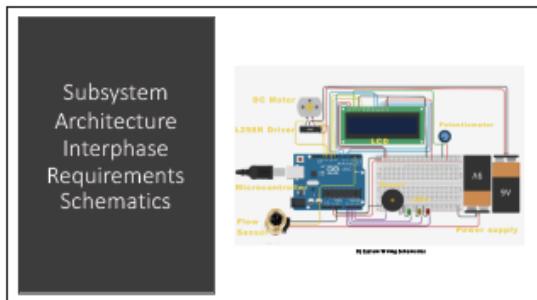
6



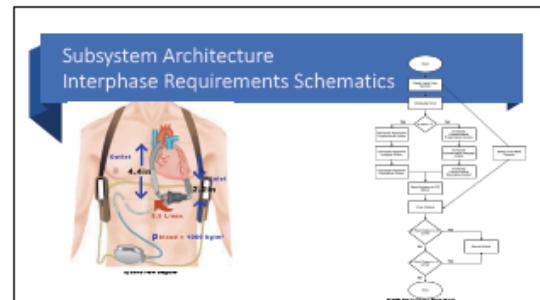
7



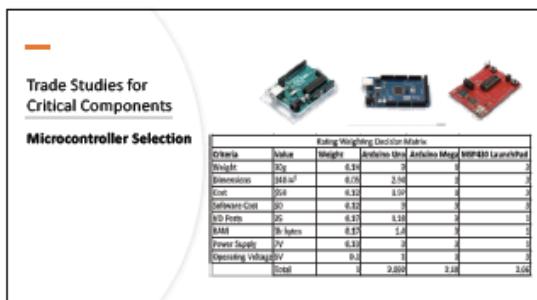
8



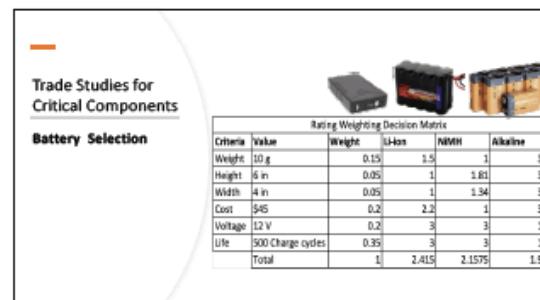
9



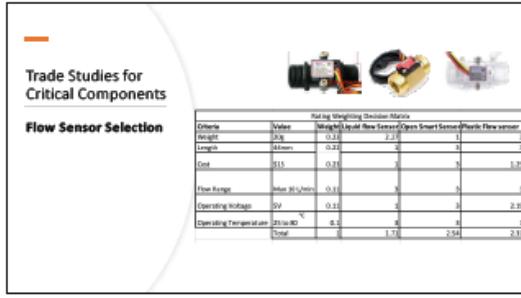
10



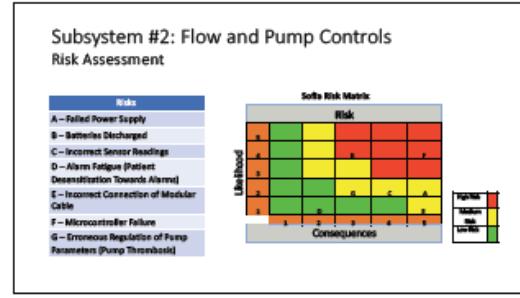
11



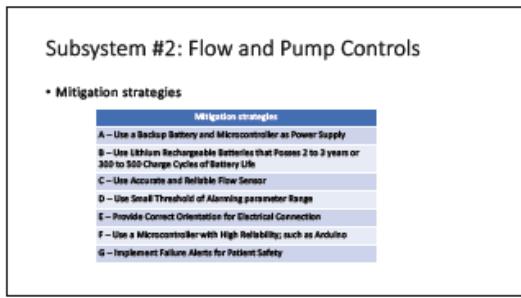
12



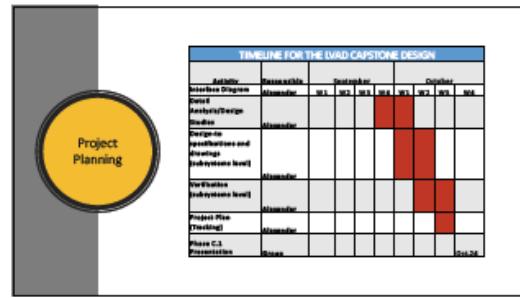
13



14

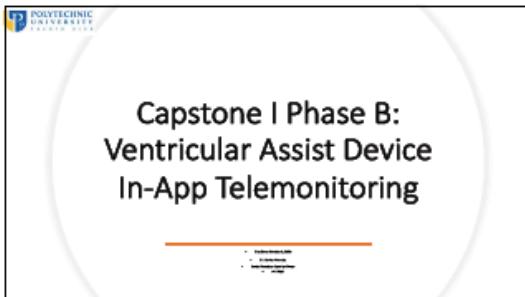


15

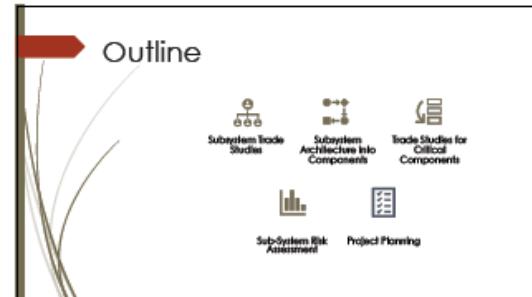


16

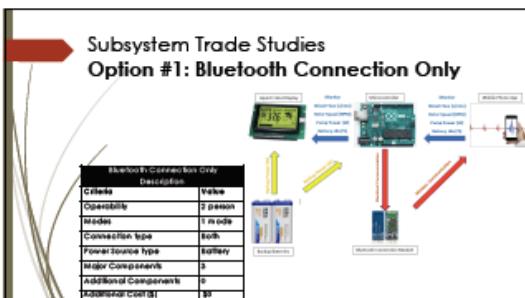
## Monitoring



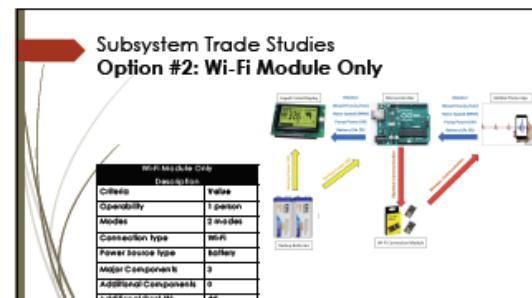
1



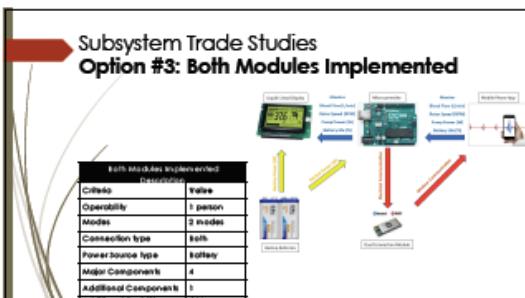
2



3



4

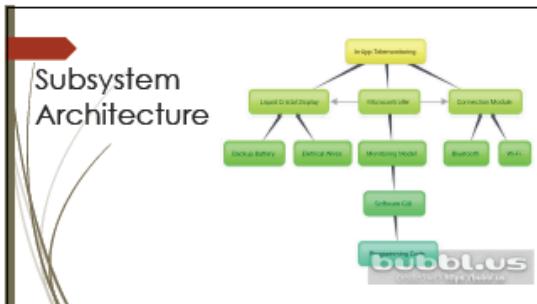


5

A summary table comparing the three options based on various criteria. The columns include Operability, Modes, Connection type, Power source type, Major Components, Additional Components, and Additional Cost (\$). The table also includes a Weight column and a Total row.

Criteria	Value	Weight	Wi-Fi Module	Bluetooth only	Both
Operability	1 person	0.2	2.8	2	3
Modes	2 modes	0.15	3	1	3
Connection type	both	0.2	1.8	1.5	3
Power source type	battery	0.1	2	2	2
Major Components	3 or 4	0.1	2	2	3
Additional Components	0	0.1	3	3	1.5
Additional Cost (\$)	\$0	0.15	2.2	3	1.5
Total		1	2.4	2.07	2.43

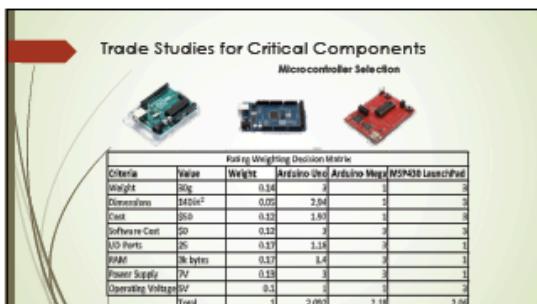
6



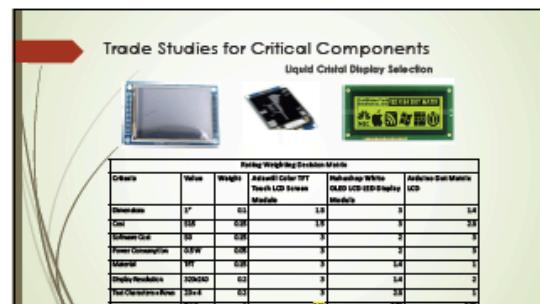
7



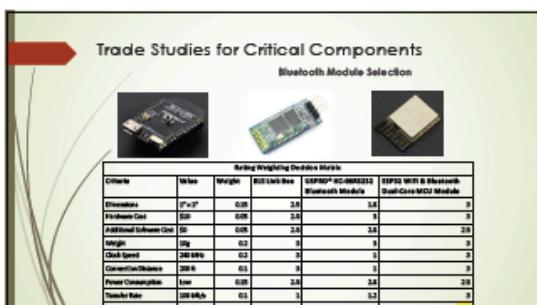
8



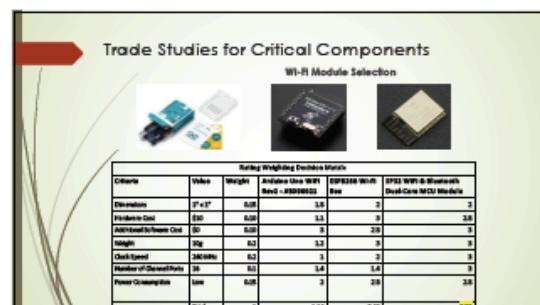
9



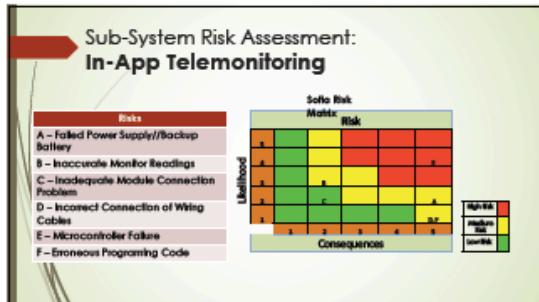
10



11



12

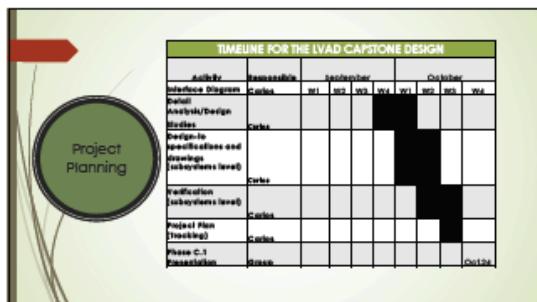


13

**Sub-System Risk Assessment: Mitigation strategies**

Mitigation strategies
A - Use a Backup Battery as extra Power Supply in LCD Display
B - Monitor the Blood Flow Output Just Below Physiologically Required
C - Use Efficient and Dependable Bluetooth and Wi-Fi modules
D - Provide Correct Orientation for Electrical Connections
E - Use a Microcontroller with High Reliability like Arduino
F - Program Code Validation Before Implantation

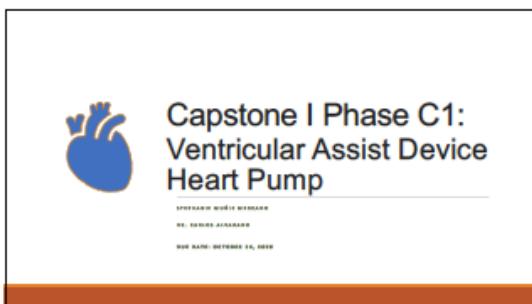
14



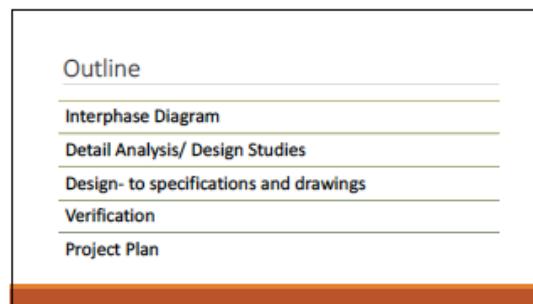
15

# Phase C.1

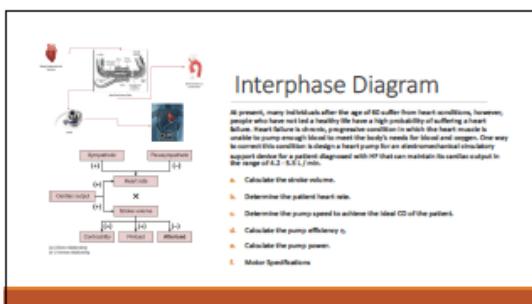
## Heart Pump



1



2



3

**Detail Analysis/ Design Studies**

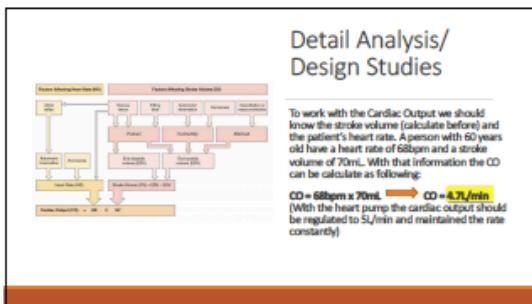
The stroke volume is the volume of the blood pumped from the left ventricle per beat. Stroke volume is an important determinant of cardiac output. The value of the stroke volume is obtained by subtracting the end-systolic volume (ESV) from end-diastolic volume (EDV) for a given ventricle. In this case, a 70kg person of 60 years old, the ESV is about 50ml, while the EDV is about 120ml.

$SV = EDV - ESV$        $SV = \frac{EDV}{EDV}$

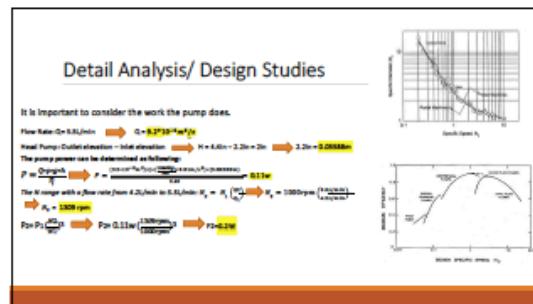
**1 Preload  $\rightarrow$  T EDV  $\rightarrow$  1 SV**  
**2 Afterload  $\rightarrow$  T ESV  $\rightarrow$  1 SV**  
**3 Ttensity  $\rightarrow$  1 EDV  $\rightarrow$  1 SV**

$SV = 120ml - 50ml$   $\rightarrow$   $SV = 70ml$ . This is the stroke vol. obtained from a person with the data mentioned before, helping to determine the CO and know how much blood could pass around the heart pump!

4



5

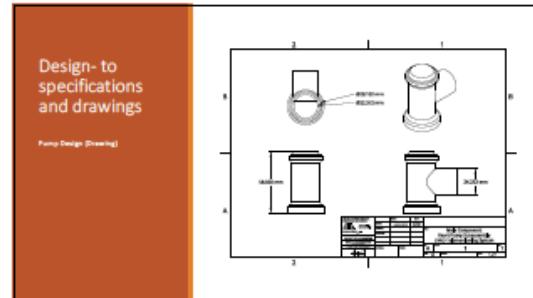


6

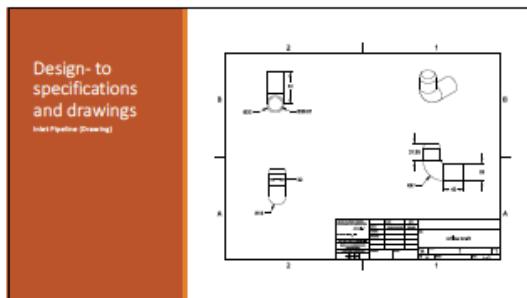
**Detail Analysis/  
Design Studies**

Brushless Motor Specifications	Value
Resistance Torque	26.8 N.m
Efficiency	49%
Resistance current	1.28A
Voltage	5V
Internal Resistance	0.66Ω
Rotor moment of inertia	0.06kg*m <sup>2</sup>
Internal Inductance	11mH

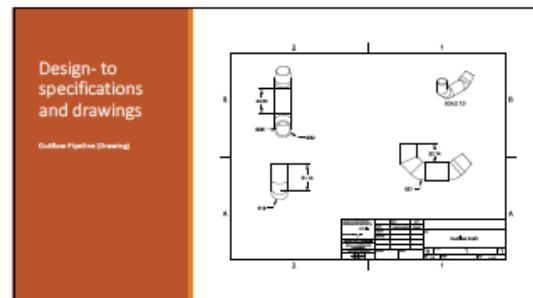
7



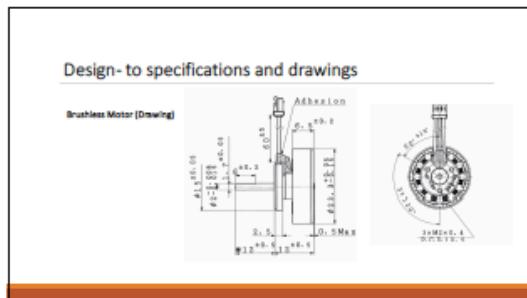
8



9



10



11

**Verification**

MOPs for Heart Pump	Performance	Compliance	Phase
Should meet the suitable diameter of 50mm.	50mm	Yes	B
Motor must have a speed from 1000 rpm to 5000 rpm.	1300 rpm	Yes	B
Pump must have a flow estimate of 5.5L/min	5.5L/min	Yes	C.1
Pump needs to work with a power of 0.32W	0.2W	Yes	B
Device flow should be directly proportional to rotor speed	Proportional	Yes	C.1

12

**Verification**

Verification Budget			
Components	Qty	Cost	Total
DC Brushless Motor	Heart Pump	1	\$22.49
Pump (Manufacturing)	Heart Pump	1	\$30.00
Valve (Manufacturing)	Heart Pump	1	\$18.00
Outflow Check Valve (Manufacturing)	Heart Pump	1	\$30.00
Adapters	Heart Pump	4	\$18.00
Hour	Heart Pump	2	\$30.00
Total Cost			\$137.49

13

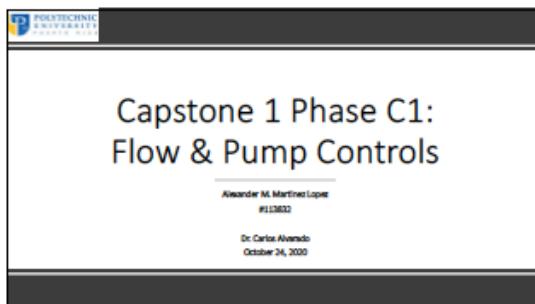
**Project Plan**

TIMELINE FOR THE IAND CAPSTONE DESIGN

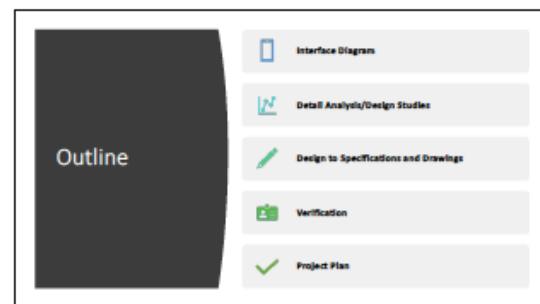
Activity	Responsible	Start Date	End Date	Duration
Phase 01				
System Requirements	Group	08/01/2023	08/15/2023	14 days
System Architecture	Group	08/15/2023	08/20/2023	5 days
System Design	Group	08/20/2023	08/25/2023	5 days
Implementation	Group	08/25/2023	09/05/2023	11 days
Testing	Group	09/05/2023	09/10/2023	5 days
Deployment	Group	09/10/2023	09/15/2023	5 days
Phase 02				
Phase 03				

14

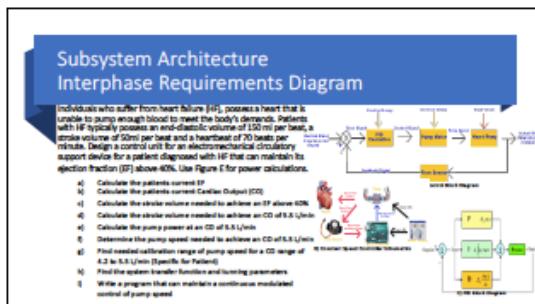
## Controls



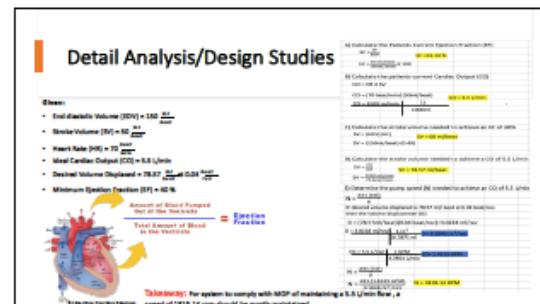
1



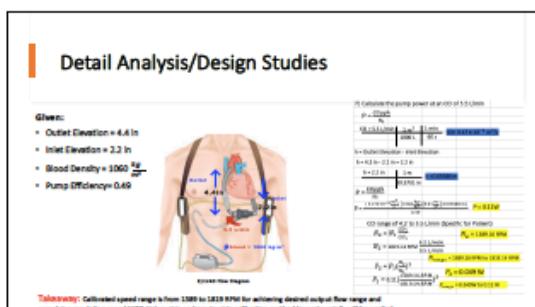
2



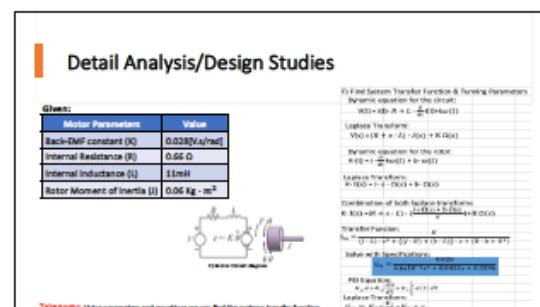
3



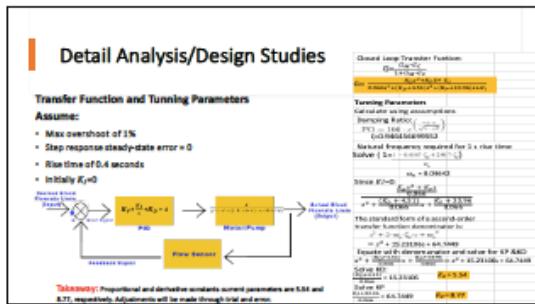
4



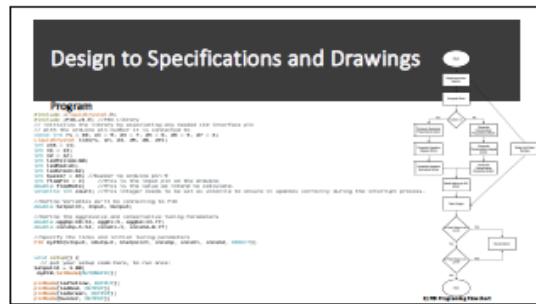
5



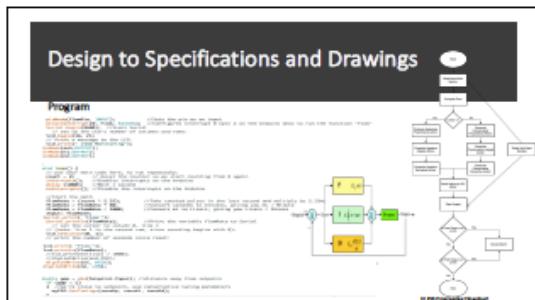
6



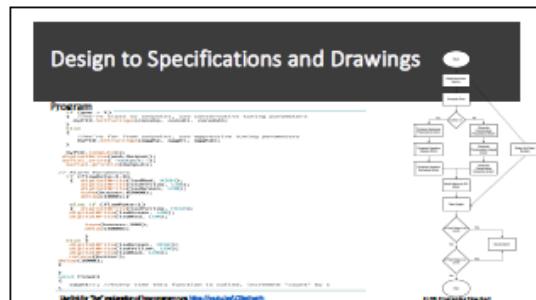
7



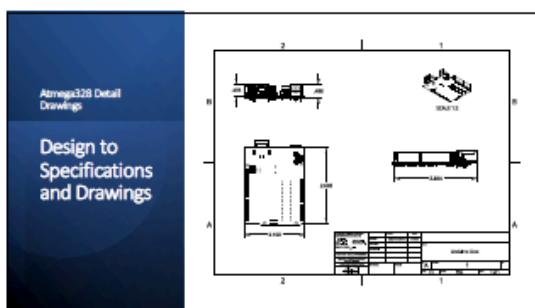
8



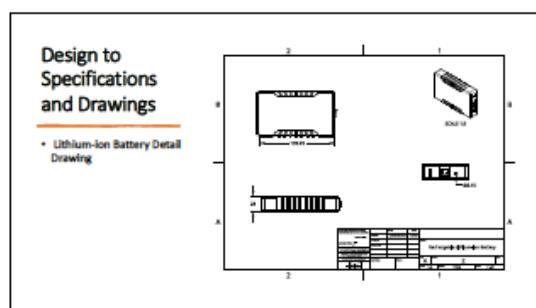
9



10



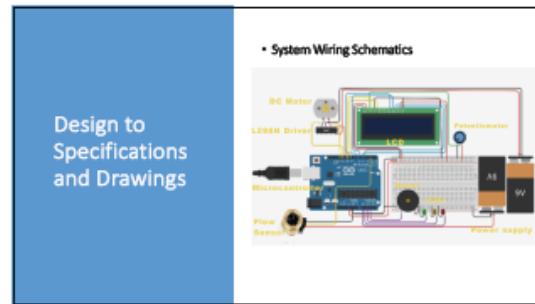
11



12



13



14

Verification	
Standards	MOP's
ASAM MSA-IEC 62366-2006, ASAM MSA-ES 62365-1-2008/MS2012, AS-302, IEC 60601-2-21 and IEC 60601-2-22, PON-21-076 Rev. 623-70	Will measure blood flow output (L/min)
ASAM MSA-IEC 62366-2006, ASAM MSA-ES 62365-1-2008/MS2012, AS-302, IEC 60601-2-21 and IEC 60601-2-22, PON-21-076 Rev. 623-70	Will calculate pump motor speed (RPM)*
ASAM MSA-IEC 62366-2006, ASAM MSA-ES 62365-1-2008/MS2012, AS-302, IEC 60601-2-21 and IEC 60601-2-22, PON-21-076 Rev. 623-70	Will calculate pump motor power (W)
ASAM MSA-IEC 62366-2006, ASAM MSA-ES 62365-1-2008/MS2012, AS-302, IEC 60601-2-21 and IEC 60601-2-22, PON-21-076 Rev. 623-70	Will regulate motor voltage (V)
ASAM MSA-IEC 62366-2006, PON-21-076 Rev. 623-70	Will regulate pump blood flow output (L/min)

15

Verification			
MOP'S	Performance	Phase	Compliance
Will measure blood flow output (L/min)	2 to 25 L/min	B	Yes
Will calculate pump motor speed (RPM)*	3672.70 to 3480.06 RPM	C1	Yes
Will calculate pump power (W)*	0.096 to 0.11 W	C1	Yes
Must regulate motor voltage (V)*	2.63 to 2.66 V	C1	Yes
Must regulate pump blood flow output (L/min)*	4.2 L/min to 5.5 L/min	C1	Yes

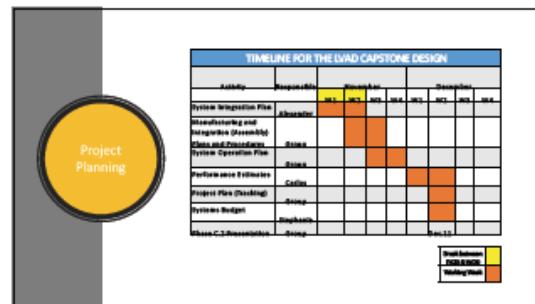
\*Specific to patient described in Interphase diagram.

16

Verification				
Budget Verification				
Component	Qty	Cost	Total	Estimated Total
Flow Sensor (1/2" Thread Hall Effect Liquid Sensor)	1	\$17.99	\$17.99	\$15
Lithium-Ion Rechargeable Batteries	2	\$23.99	\$47.98	\$50
Microcontroller, Motor Driver, LCD and Cables (Pack)	1	\$52.99	\$52.99	\$60
<b>Total</b>			<b>\$118.96</b>	<b>\$125</b>

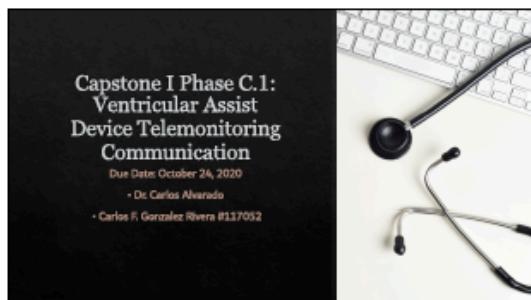
**Takeaway:** Total Cost of Flow & Pump Controls Subsystem is on budget.

17

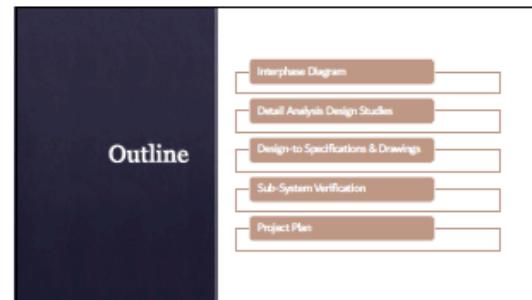


18

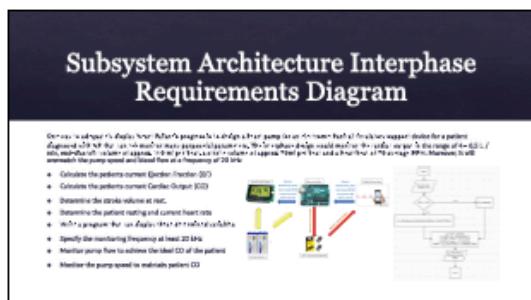
## Monitoring



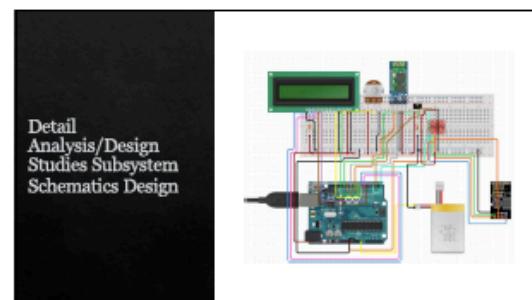
1



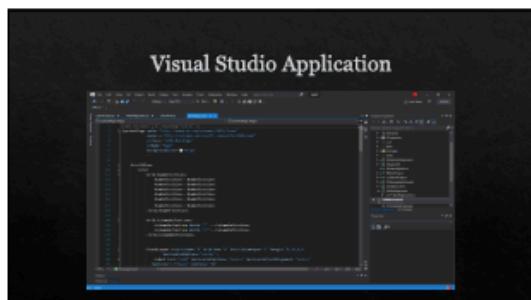
2



3



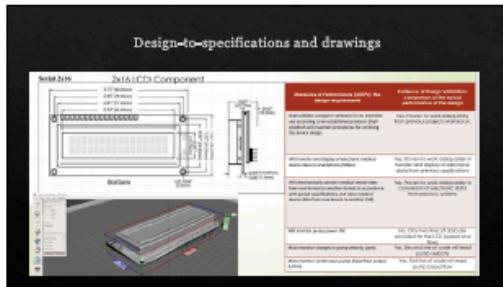
4



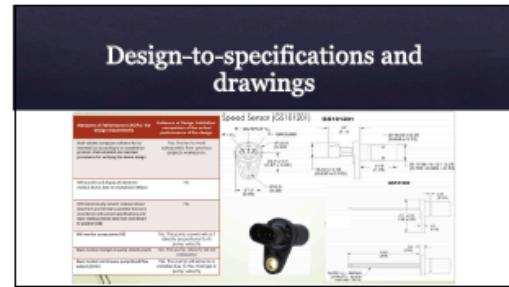
5

A code snippet titled "Programming Logic – Monitoring Function" showing C# code for monitoring functions.

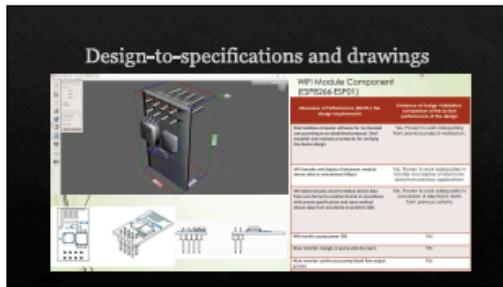
6



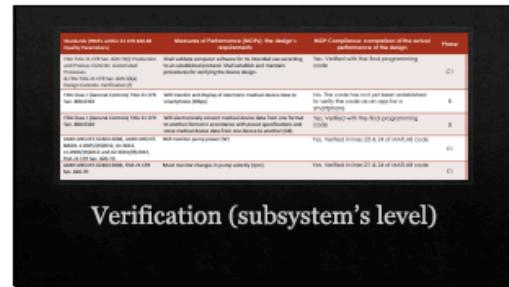
7



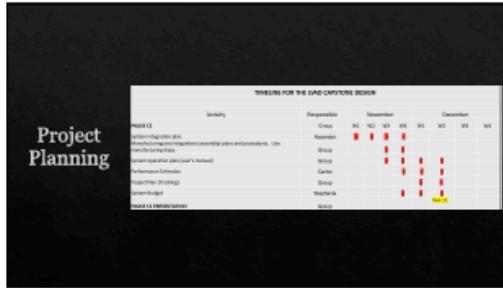
8



9



10

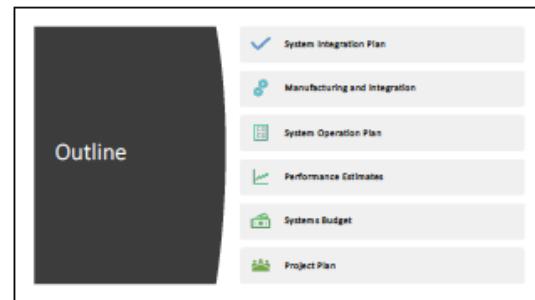


11

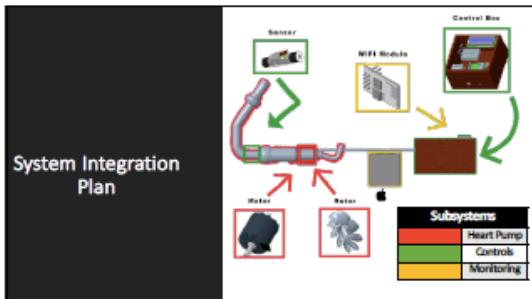
## Phase C.2



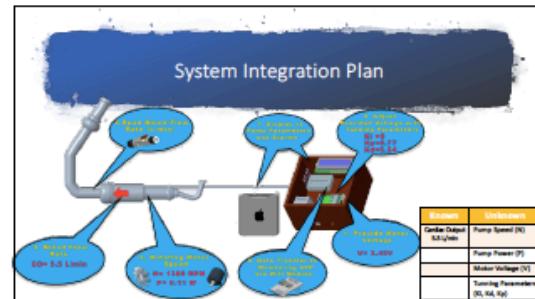
1



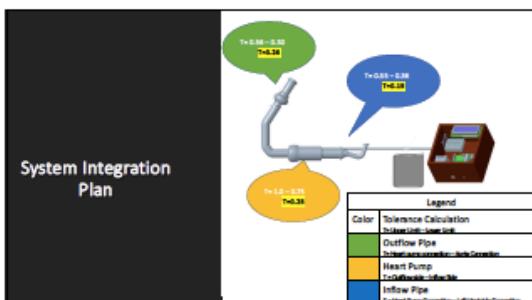
2



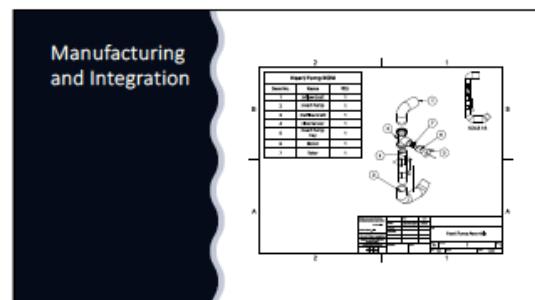
3



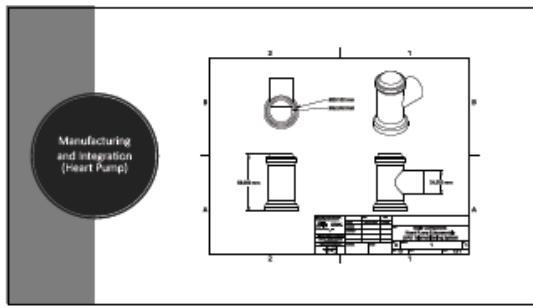
4



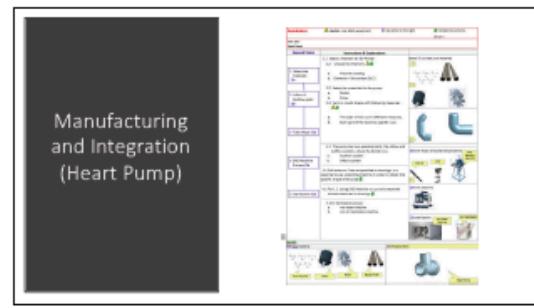
5



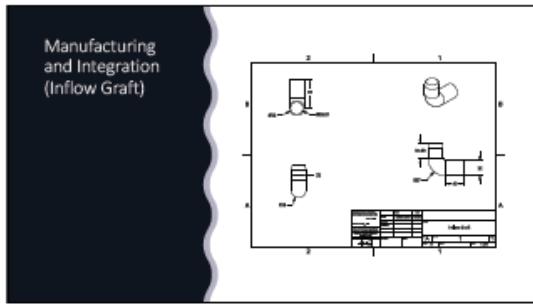
6



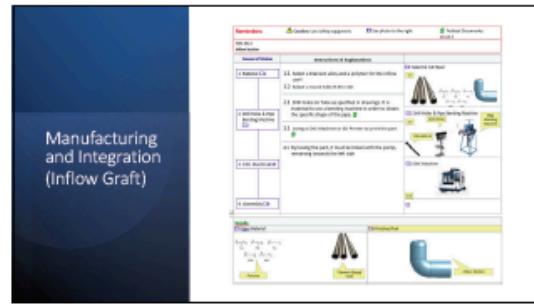
7



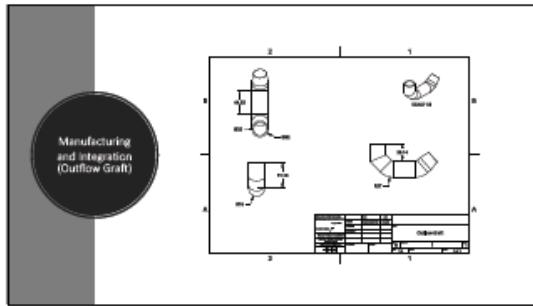
8



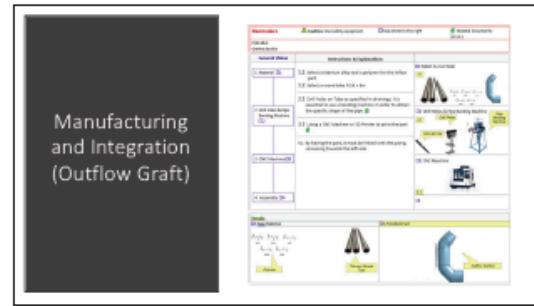
9



10



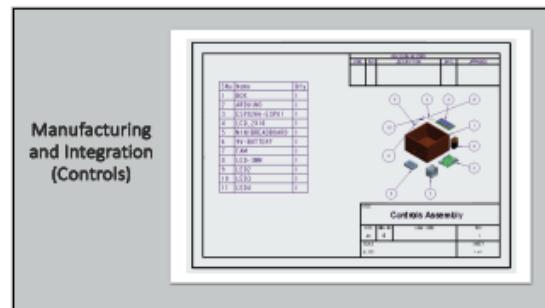
11



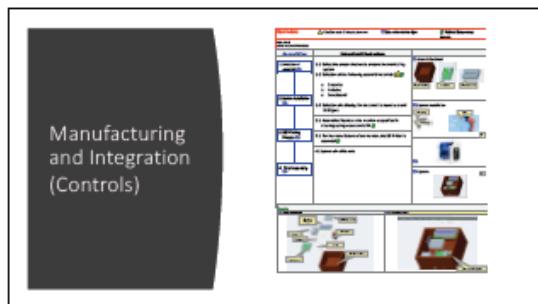
12



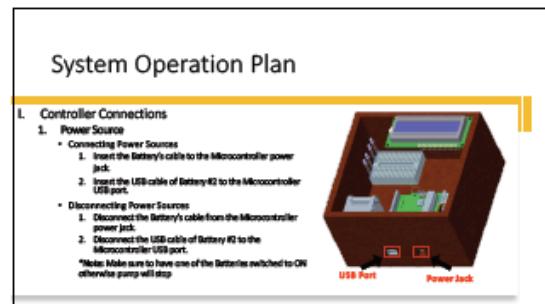
13



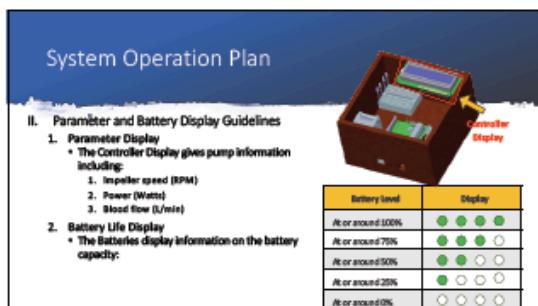
14



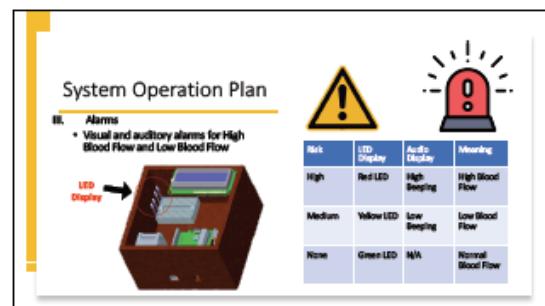
15



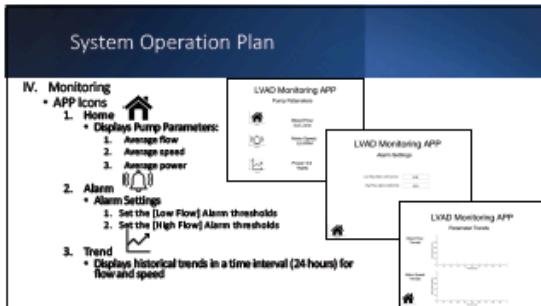
16



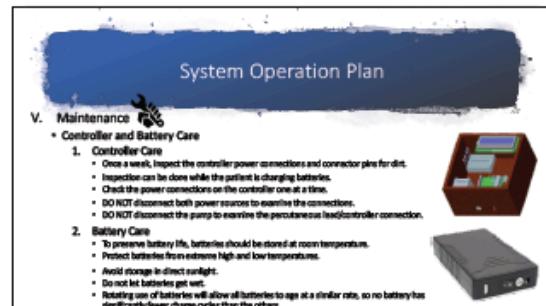
17



18



19



20

**Performance Estimates**

MOP'S	Desired Value	Obtained Value	Phase	Compliance
Rotor length will be no more than 100 mm	20 mm	17 mm	C.1	Yes
Rotor will have a circumference of no more than 40 mm	10 mm	3 mm	C.1	Yes
Pump motor should use a voltage of no more than 6V	6V	6V	C.1	Yes

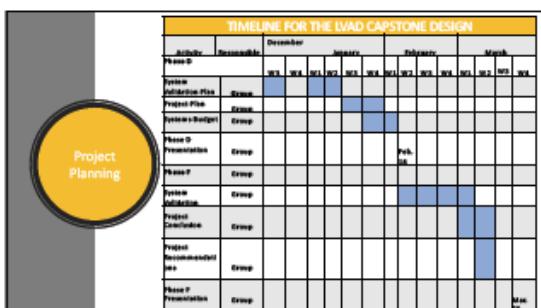
21

**Systems Budget**

Component	Subsystem	Qty	Cost	Total	Released
New Sterile SCL™ Reservoir Filter	Cartridge	1	\$17.00	\$17.00	0%
100mmx100mmx10mm	Cartridge	2	\$21.00	\$42.00	0%
Microcontroller Board and Cables (Proto)	Cartridge	1	\$93.00	\$93.00	0%
3D Printed Housing	Housing	1	\$8.00	\$8.00	0%
LVDC Brushless Motor	HeartPump	1	\$18.00	\$18.00	0%
LVDC Brushless Motor	HeartPump	1	\$8.00	\$8.00	0%
LVDC Brushless Motor	HeartPump	1	\$8.00	\$8.00	0%
LVDC Brushless Motor	HeartPump	1	\$8.00	\$8.00	0%
LVDC Brushless Motor	HeartPump	1	\$8.00	\$8.00	0%
Adapters	HeartPump	4	\$4.00	\$16.00	0%
Base	HeartPump	2	\$4.00	\$8.00	0%
<b>Total</b>			<b>\$794.00</b>	<b>\$794.00</b>	

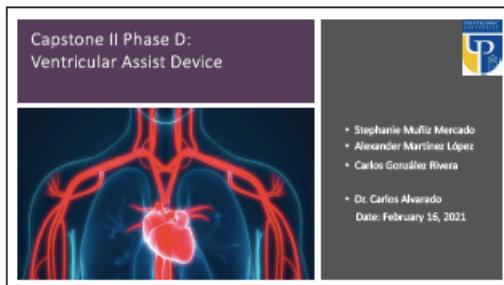
\*Budget for Prototype Construction By 3D Printing

22

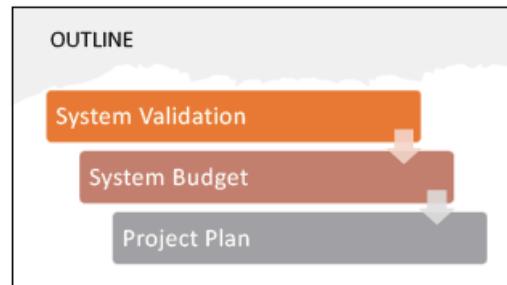


23

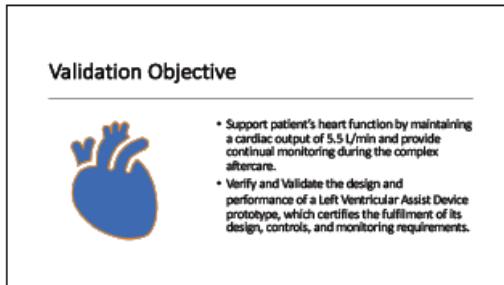
## Phase D



1



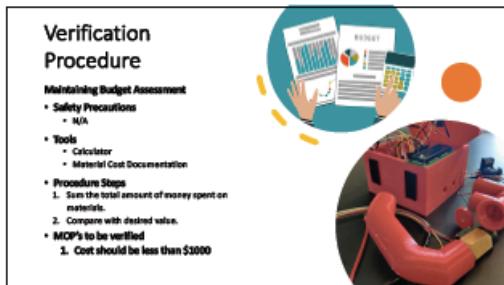
2



3

System Level MOP's to Verify/Validate				
MOP #	MOP	Phase Compliance	Procedure Type	Pass/Failed
1	Cost should be less than \$3000	N	Verification	Pass
2	Rotor length will be no more than 120 mm	C1	Verification	Pass
3	Rotor will have a circumference of no more than 40 mm	C1	Verification	Pass
4	Pump motor shoulders voltage of no more than 4 V	C1	Verification	Pass
5	Implanted product will weigh less than 200 grams	C1	Verification	Pass
6	Implanted product must pass impedance assessments for 100% of time	F	Verification	To Be Verified
7	Implanted product shall be water resistant	F	Verification	To Be Verified
8	Volume flow should be optimal at 5.5 L/min	F	Verification	To Be Verified
9	Will monitor blood flow through external app	F	Verification	To Be Verified
10	Will monitor rotor speed (optional) through external app	F	Verification	To Be Verified

4



5



6

## Verification Procedure

**Medium Motor Voltage Measurement**

- Safety Precautions**
  - Keep area clean.
  - Carefully handle and align the measuring tools.
  - Follow OSHA standards for any electrical hazards.
- Tools**
  - Multimeter
  - Motor
  - Assembled LVAD Controls
- Procedure Steps**
  - Take a multimeter to the output voltage of the C2504 DC Motor Driver Module.
  - Turn on the pump. Make sure there is no fluid flow.
  - Using the multimeter verify the no current reading being delivered to the motor.
  - MOP's to be verified**
    - Pump motor should see a voltage of no more than 6V

7

## Verification Procedure

**LVAD Device Mass Measurement**

- Safety Precautions**
  - Keep area clean.
  - Carefully handle and align the measuring tools.
  - Follow OSHA standards for any electrical hazards.
- Tools**
  - Analytic Balance
  - Assembled LVAD device
- Procedure Steps**
  - Use the analytic balance to measure the mass of the LVAD Device.
  - Make sure to turn your balance before the measurement.
  - MOP's to be verified**
    - Implied product will weigh less than 200 grams.

8

## Verification Procedure

**Fluid Flow Physical Verification Loop**

- Safety Precautions**
  - Keep area clean.
  - Avoid direct exposure to chemicals or without tools.
  - Follow OSHA standards for any chemical hazards.
- Tools**
  - Water
  - Water Container
  - Flowmeter
  - Small Diameter Bell-Jet Mass Flowmeter
- Procedure Steps**
  - Fill water container with water.
  - Connect one end of the water container to the fluid loop.
  - Turn the pump on and verify the pump is pumping correctly.
  - Verify flow rate is equal to 0.5 L/min.
  - MOP's to be verified**
    - Implied product shall be water resistant.
    - Water resistance is required at 0.5 L/min.

9

## Validation Procedure

**IMD Temperature Assessment**

- Safety Precautions**
  - Keep area clean.
  - Carefully handle and align the measuring tools.
  - Follow OSHA standards for any electrical hazards.
- Tools**
  - Fluid Flow Physical Verification Loop
  - Thermometer
- Procedure Steps**
  - Turn the pump on and place the thermometer loop at 37°C.
  - Verify F/F is equal to 0.5 L/min.
  - Turn the pump on and place the thermometer loop at 32°C.
  - Verify F/F is equal to 0.5 L/min.
  - MOP's to be verified**
    - W/H validated sensor temperature measurements for set points of three

10

## Verification Procedure

**Real-time Monitoring Verification**

- Safety Precautions**
  - Keep area clean.
  - Carefully handle and align the measuring tools.
  - Follow OSHA standards for any electrical hazards.
- Tools**
  - Fluid Flow Physical Verification Loop
  - PC
  - USB-Cordless Multimeter (DC20)
- Procedure Steps**
  - Run the Fluid Flow Physical Verification Loop.
  - Open the app.
  - Verify the app is displaying the same measurement information as the LCD.
  - MOP's to be verified**
    - W/H monitor fluid flow through external app.
    - W/H monitor pump speed (velocity) through external app.

11

## System Budget

Component	Subsystem	Qty	Cost	Total	Budgeted Total
Pump Driver (0.5L/min Pump Driver)	Control	1	\$17.00	\$17.00	\$17.00
Ultimate Air Removal Check Valve	Control	2	\$10.00	\$20.00	\$20.00
Microcontroller (CC3221EF001) (Part)	Control	1	\$50.00	\$50.00	\$50.00
HPI Module	Monitoring	1	\$20.00	\$20.00	\$20.00
RV DC Brushless Motor	Heart Pump	1	\$210.00	\$210.00	\$210.00
Pump Drive Coupling	Heart Pump	1	\$5.00	\$5.00	\$5.00
Diffuser (Silicone)	Heart Pump	1	\$5.00	\$5.00	\$5.00
Adapters	Heart Pump	4	\$2.00	\$8.00	\$8.00
Heel	Heart Pump	2	\$20.00	\$40.00	\$40.00
<b>Total</b>			<b>\$376.00</b>		

\*Budget for Prototype Construction By 3D Printing

12

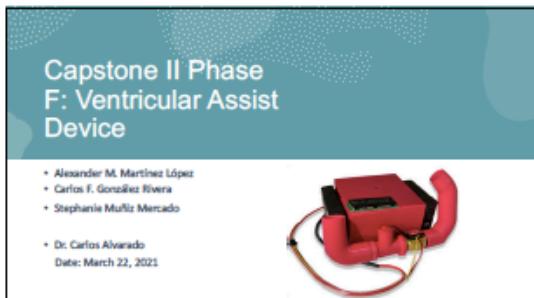
## Project Plan

**TIMELINE FOR THE LVAD CAPSTONE DESIGN**

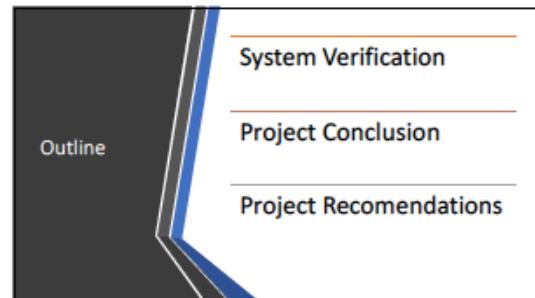
Phase	Responsible	February				March			
		W1	W2	W3	W4	W1	W2	W3	W4
System Validation	Group			X	X	X			
Project Conclusion	Group					X	X		
Project Recommendations	Group					X	X		
Phase F Presentation	Group							Mar. 26	

13

## Phase F



1



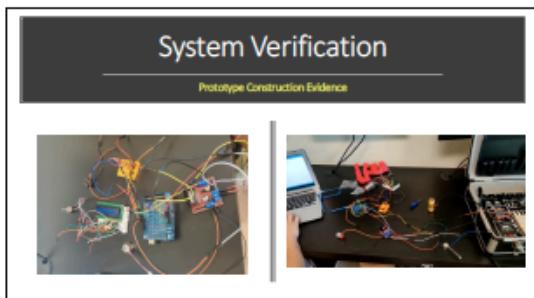
2



3



4



5



6

Verified System Level MOP's				
MOP #	MOP	Phase Compliance	Procedure Type	Spec/Thold
1.	Cord should be less than 3000	R	Verification	Pass
2.	Rotor length will be no more than 100 mm	C2	Verification	Pass
3.	Rotor shaft will have a circumference of no more than 30 mm	C2	Verification	Pass
4.	Pump motor should use a voltage of no more than 6V	C2	Verification	Pass
5.	Implanted product will weigh less than 250 grams	C2	Verification	Pass
6.	Will withstand several temperature assessments for set periods of time	F	Verification	Pass
7.	Implanted product shall be water resistant	F	Verification	Pass
8.	Volume flow should be optimal at 5.3 L/min	F	Verification	Pass
9.	Will monitor blood flow through external app	F	Verification	Pass
10.	Will monitor rotor speed (velocity) through external app	F	Verification	Pass

7

System Verification				
Budget Verification Assessment				
Component/Part	Subsystem	Qty	Cost	Expected
Flow Sensor (SL-27 Channel Hall Effect Liquid Sensor)	Canards	1	\$17.99	\$13
Lithium-Ion Rechargeable Battery	Controls	2	\$47.99	\$10
Microcontroller, Driver Module, LCD and Canbus Print	Controls	1	\$52.99	\$60
TB6612HGR Stepper Motor	Monitoring	1	\$5.99	\$15
2V DC Brushless Motor Pump (Material & Manufacturing)	Motor Pump	1	\$7.89	\$10
12V DC Brushless Motor Monitoring	Motor Pump	1	\$5	\$78
Orbital Grit (Material & Manufacturing)	Motor Pump	1	\$5	\$99
Heatsink	Motor Pump	4	\$16	\$20
Heatsink	Motor Pump	2	\$9.99	\$15
Total		15	\$115.43	\$600

8



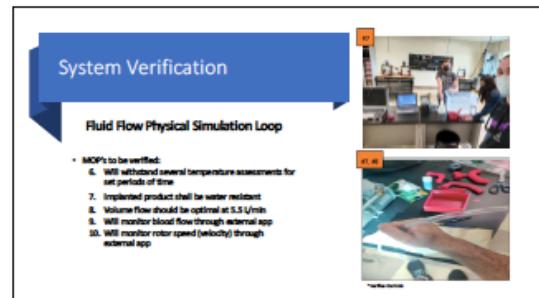
9



10



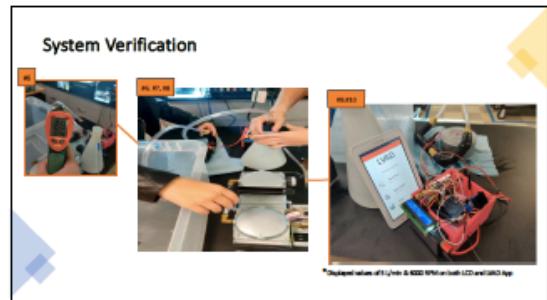
11



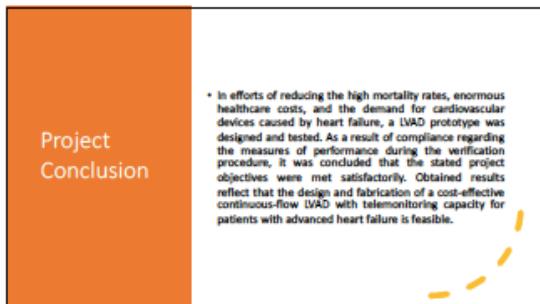
12



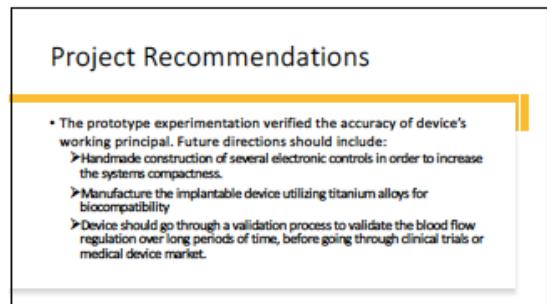
13



14



15



16

## **APPENDIX B: TIMELINE OF ACTIVITIES**

TLVAD Project Planning		Capstone I								Capstone II											
		Aug.		Sept.		Oct.		Nov.		Dec.		Jan.		Feb.		Mar.					
Phase	Tasks	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W4	W1	W2	W3	W1	W2
Pre-Phase A: Concept Studies	Users & Stakeholders		■																		
	Background Information			■																	
	Project Objectives				■																
	Concept of Operations					■															
	Project Significance						■														
	Presentation							■													
Phase A: Concept & Technology Development	Technological Assessment					■															
	Mission Architecture						■														
	Trade Studies							■													
	Budget								■												
	Subsystem Requirements									■											
	Subsystem Risk Assessment										■										
Phase B: Preliminary Design & Technology Completion	Presentation									■											
	Subsystem Trade Studies									■											
	Subsystem Architecture										■										
	Subsystem Risk Assessment											■									
	Presentation											■									
Phase C.1: Design of Parts & Components	Interface Diagram										■										
	Detail Analysis/Design Studies											■									
	Design to Specifications												■								
	Drawings												■								
	Presentation													■							
Phase C.2: Integration	System Integration Plan													■							
	System Operation Plan														■						
	Manufacturing & Integration															■					
	Performance Estimates															■					
	System Budget																■				
	Presentation																	■			
Phase D: System Demonstration	System Validation Plan																■				
	Prototype Construction																	■			
	System Budget																	■			
	Presentation																		■		
Phase F: System Verification	System Verification																		■		
	Project Conclusion																			■	
	Project Recommendations																				■
	Presentation																				■

## APPENDIX C: CALCULATIONS

### HEART PUMP SUBSYSTEM

**Calculate the pump power at an CO of 5.5 L/min**

**Given:**  $CO = 5.5 \text{ L/ml}$        $p = 1060 \frac{\text{kg}}{\text{m}^3}$        $g = 9.81 \frac{\text{m}}{\text{s}^2}$

**Calculate:** The pump power at an CO of 5.5 L/ml

$$CO = 5.5 \text{ L/min} \left( \frac{1 \text{ m}^3}{1000 \text{ L}} \right) \left( \frac{1 \text{ min}}{60 \text{ s}} \right) \quad CO = 9.17 \times 10^{-5} \text{ m}^3/\text{s}$$

$h$  = Outlet Elevation - Intel Elevation

$$h = 4.4 \text{ in} - 2.2 \text{ in} = 2.2 \text{ in}$$

$$h = 2.2 \text{ in} \left( \frac{1 \text{ m}}{30.3701 \text{ in}} \right) \quad h = 0.05588 \text{ m}$$

$$P = \frac{CO \cdot pg \cdot h}{N_t}$$

$$P = \frac{\left( 9.17 \times 10^{-5} \text{ m}^3/\text{s} \right) \left( 1060 \frac{\text{kg}}{\text{m}^3} \right) \left( 9.81 \frac{\text{m}}{\text{s}^2} \right) \left( 0.05588 \text{ m} \right)}{0.49} \quad P = 0.11 \text{ W}$$

CO range of 4.2 to 5.5 L/min (Specific for patient)

$$N_2 = N_1 \frac{CO_2}{CO_1} \quad N_2 = 2672.70 \text{ RPM}$$

$$N_2 = 3,499.96 \text{ RPM} \frac{4.2 \text{ L/min}}{5.5 \text{ L/min}}$$

$$N_{range} = 2672.70 \text{ RPM to } 3,499.96 \text{ RPM}$$

$$P_2 = P_1 \left( \frac{N_2}{N_1} \right)^3$$

$$P_2 = 0.11 \left( \frac{2672.70 \text{ RPM}}{3,499.96 \text{ RPM}} \right)^3 \quad P_2 = 0.084$$

$$P_{range} = 0.084 \text{ W to } 0.11 \text{ W}$$

### CONTROLS SUBSYSTEM

**Calculation of the Patient's Current Ejection Fraction (EF)**

**Given:**  $SV = 50 \frac{\text{ml}}{\text{beat}}$        $EDV = 150 \frac{\text{ml}}{\text{beat}}$

**Calculate:** Patients Current Ejection Fraction

$$EF = \frac{SV}{EDV}$$

$$EF = \frac{50 \text{ ml/beat}}{150 \text{ ml/beat}} \times 100$$

$$EF = 33.33\%$$

**Calculation of the Patient's current Cardiac Output**

**Given:**  $SV = 50 \frac{\text{ml}}{\text{beat}}$        $HR = 70 \frac{\text{beat}}{\text{min}}$

**Calculate:** Patient's current Cardiac Output

$$CO = HR \times SV$$

$$CO = (70 \text{ beat/min}) (50 \text{ ml/beat}) \left( \frac{1 \text{ L}}{1000 \text{ ml}} \right)$$

$$CO = 3.5 \text{ L/min}$$

**Calculating the Stroke Volume Needed to Achieve an EF 40%**

**Given:**  $EDV = 150 \frac{\text{ml}}{\text{beat}}$        $EF = 40\%$

**Calculate:** The stroke volume needed to achieve an EF 40%

$$\begin{aligned} \text{SV} &= (\text{EDV}) (\text{EF}) \\ \text{SV} &= (150 \text{ ml/beat}) (0.40) \\ \text{SV} &= 60 \text{ ml/beat} \end{aligned}$$

### Calculating the Stroke Volume Needed to Achieve a CO of 5.5 L/min

Given:  $\text{CO} = 5.5 \frac{\text{L}}{\text{min}}$        $\text{HR} = 70 \frac{\text{beat}}{\text{min}}$

Calculate: The stroke volume needed to achieve a CO of 5.5 L/min

$$\begin{aligned} \text{SV} &= \frac{\text{CO}}{\text{HR}} \\ \text{SV} &= \frac{5500 \text{ ml/min}}{70 \text{ beat/min}} \\ \text{SV} &= 78.57 \text{ ml/beat} \end{aligned}$$

### Determine the Pump Speed (N) Needed to Achieve an CO of 5.5 L/min

Given:  $\text{CO} = 5.5 \frac{\text{L}}{\text{min}}$

Assumption: Desired volume displaced is  $78.57 \frac{\text{ml}}{\text{beat}}$  at  $0.40 \frac{\text{beat}}{\text{rev}}$

Calculate: The pump speed (N) needed to achieve an CO of 5.5 L/min

If desired volume displaced is  $78.57 \frac{\text{ml}}{\text{beat}}$  at  $0.40 \frac{\text{beat}}{\text{rev}}$  then the volume displacement (D):

$$D = (78.57 \text{ ml/rev}) (0.02 \text{ beat/rev}) = 1.5714 \text{ ml/rev}$$

$$D = 1.5714 \text{ ml/rev} \left( \frac{1 \text{ in}^3}{16.3871 \text{ ml}} \right) \quad D = 0.1845 \text{ in}^3/\text{rev}$$

$$\text{CO} = 5.5 \text{ L/min} \left( \frac{1 \text{ GPM}}{3.7854 \text{ L/min}} \right) \quad \text{CO} = 1.4529 \text{ GPM}$$

$$N = \frac{231(CO)}{D}$$

$$N = \frac{231(1.4529 \text{ GPM})}{0.09589 \text{ in}^3/\text{rev}}$$

$$N = 3,499.96 \text{ RPM}$$

### Determine the voltage needed to apply to achieve desired pump speed.

Given:  $V_{max} = 6 \text{ V}$        $N_{max} = 6100 \text{ RPM}$

Assumption: Linear relationship

Calculate: The voltage supplied (V) needed to achieve an CO of 5.5 L/min

$$V_{needed} = 0.00098(N)$$

$$V_{needed} = 0.00098(3,499.96 \text{ RPM}) \quad V_{needed} = 3.44 \text{ V}$$

### Calculate the System Transfer Function & Tuning Parameters Dynamic equation for the Circuit:

Given:  $K = 0.028 \text{ V.s/rad}$        $R = 0.66\Omega$        $L = 11mH$        $J = 0.06 \text{ Kg}\cdot\text{m}^2$

Assumptions: Figure 44 and Figure 45 for dynamic equations, Max overshoot of 1%, Step response steady-state error = 0, Rise time of 0.4 seconds, initially  $K_I=0$

Calculate: System transfer function & tuning parameters dynamic equation for the Circuit:

$$V(t) = i(t) \cdot R + L \cdot \frac{d}{dt} i(t) + k\omega(t)$$

**Laplace Transform:**

$$V(s) = (R + s \cdot L) \cdot I(s) + K\Omega(S)$$

**Dynamic equation for the rotor:**

$$K \cdot (t) = J \cdot \frac{d}{dt} k \omega(t) + b \cdot \omega(t)$$

**Laplace Transform:**

$$K \cdot I(s) = J \cdot s \cdot \Omega(s) + b \cdot \Omega(s)$$

**Combination of both Laplace transforms**

$$K \cdot I(s) = (R + s \cdot L) \cdot \left( \frac{J \cdot \Omega(s) + b \cdot \Omega(s)}{k} \right) + K \cdot \Omega(s)$$

Transfer Function:

$$G_m = \frac{K}{(J \cdot L) \cdot s^2 + ((J \cdot R) + (b \cdot L)) \cdot s + (R \cdot b + K^2)}$$

**Solve with Specifications:**

$$G_m = \frac{0.028}{6.6 \times 10^{-4} s^2 + 0.0451 s + 0.3396}$$

PID Equation:

$$u(t) = K_p e + K_d \frac{de}{dt} + K_i \int_0^t e(t) dt$$

**Laplace Transformation:**

$$G_C = K_p + \frac{K_I}{s} + K_D * s$$

Closed loop Transfer Function:

$$G = \frac{G_M \cdot G_C}{1 + G_M \cdot G_C}$$

$$G = \frac{K_D s^2 + K_P s + K_I}{0.066 s^3 + (K_D + 4.51) s^2 + (K_P + 33.96) s + K_I}$$

### Tunning Parameters

Calculate using assumptions

**Damping Ratio**

$$PO = 100 \cdot e \left( \frac{-\zeta \cdot \pi}{\sqrt{1 - \zeta^2}} \right)$$

$$\zeta = 0.946456699552$$

**Natural Frequency required for 1 s rise time**

$$\text{Solve } (1 - \frac{1 - 0.4167 \cdot \zeta_d + 2.917 \cdot \zeta_d}{\omega_n})^2$$

$$\omega_n = 8.04642$$

Since  $KI=0$ :

$$\frac{\frac{K_D s^2 + K_P s}{0.066}}{s^2 + \frac{(K_D + 4.51)}{0.066} s + \frac{K_P + 33.96}{0.066}}$$

**The standard form of a second-order transfer function denominator is:**

$$\begin{aligned} & S^2 + 2 \cdot \omega_n \cdot \zeta_d \cdot s + \omega_n^2 \\ & = s^2 + 15.23106s + 64.7449 \end{aligned}$$

**Equate with denominator and solve for KP & KD**

$$s^2 + \frac{(K_D+4.51)}{0.066} s + \frac{K_P+33.96}{0.066} = s^2 + 15.23106s + 64.7449$$

Solve KD

$$\frac{(K_D+4.51)}{0.066} = 15.23106 \quad K_D = 5.54$$

Solve for KP

$$\frac{K_P+33.96}{0.066} = 64.7449 \quad K_P = 8.77$$

## APPENDIX D: BILL OF MATERIALS

### System-Level BOM:

Component/Part	Subsystem	Qty	Cost	Total
Flow Sensor (G1/2” Thread Hall Effect Liquid Sensor)	Controls	1	\$17.99	\$17.99
Lithium-Ion Researchable Batteries	Controls	2	\$23.99	\$47.98
Microcontroller, Driver Module, LCD and Cables (Pack)	Controls	1	\$52.99	\$52.99
WIFI Module	Monitoring	1	\$5.99	\$5.99
5V DC Brushless Motor	Heart Pump	1	\$7.50	\$7.50
Pump (Materia)	Heart Pump	1	\$25	\$25
Inflow Graft (Material)	Heart Pump	1	\$50	\$50
Outflow Graft (Material )	Heart Pump	1	\$100	\$100
Adapters	Heart Pump	4	\$4.50	\$18
Hose	Heart Pump	2	\$4.99	\$9.98

# Heart Pump

2

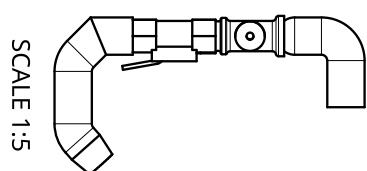
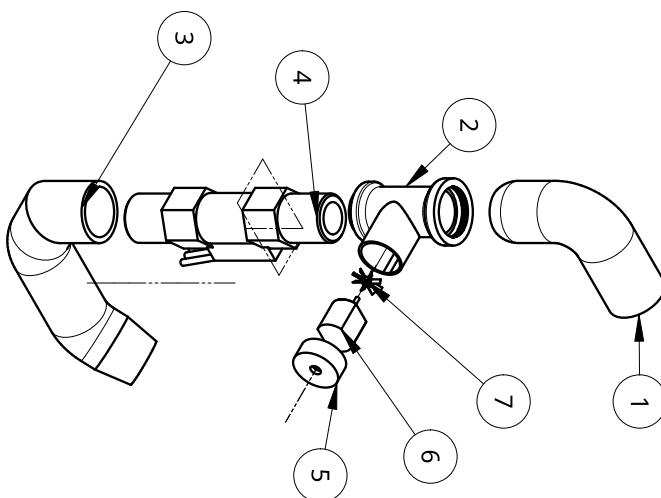
1

B

## Heart Pump BOM

Item No.	Name	Qty
1	Inflow Graft	1
2	Heart Pump	1
3	Outflow Graft	1
4	Flow Sensor	1
5	Heart Pump Cap	1
6	Motor	1
7	Rotor	1

A



SCALE 1:5

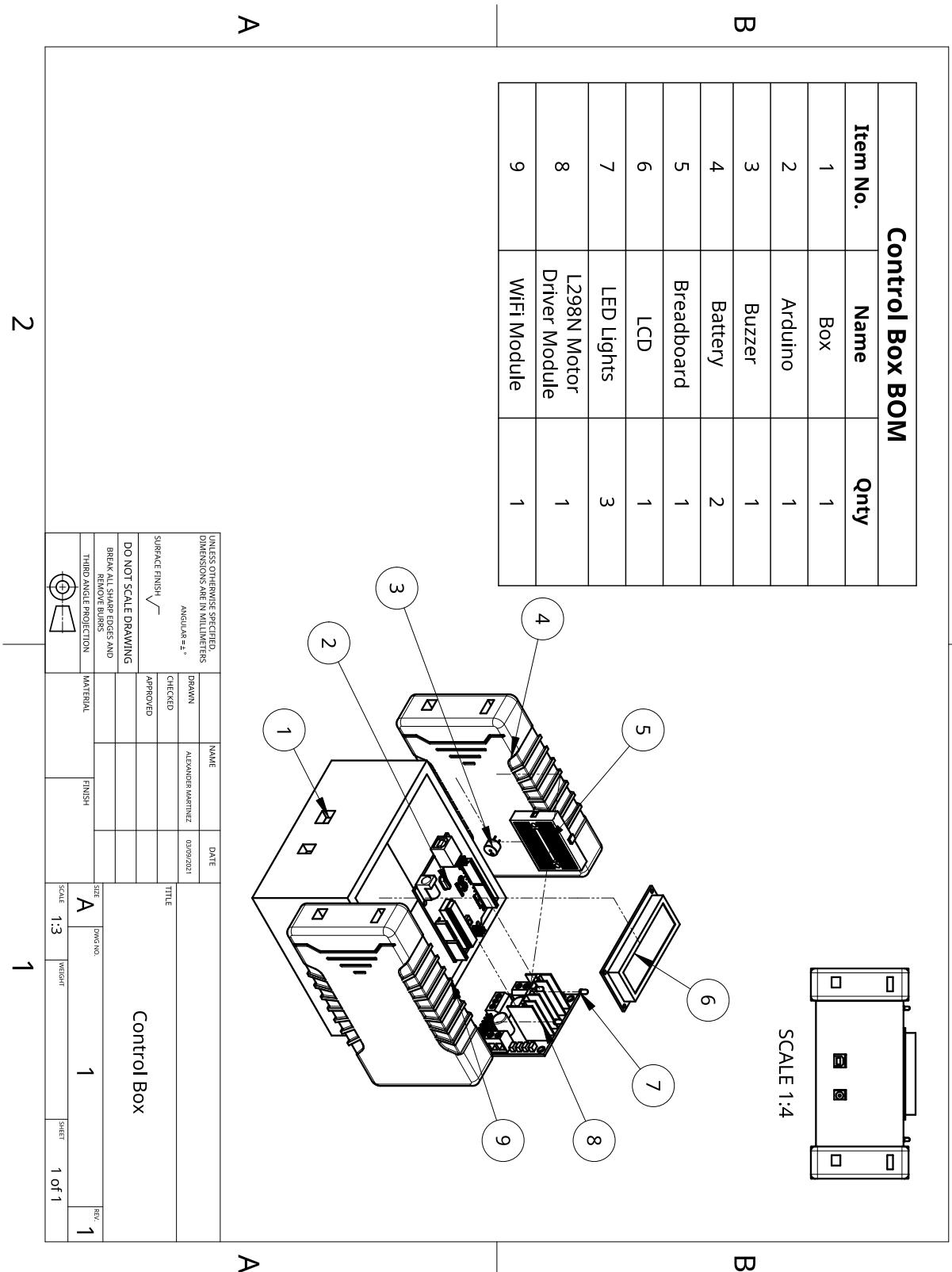
A

UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN MILLIMETERS			NAME DRAWN CHECKED APPROVED	DATE 03/04/2021 TITLE
SURFACE FINISH ✓	ANGULAR = 2°			
DO NOT SCALE DRAWING				Heart Pump Assembly
BREAK ALL SHARP EDGES AND REMOVE BURRS				
THREE ANGLE PROJECTION	MATERIAL	FINISH	SIZE A	DWG NO. 1
			SCALE 1:3	WEIGHT 1 of 1
				REV. 1

2

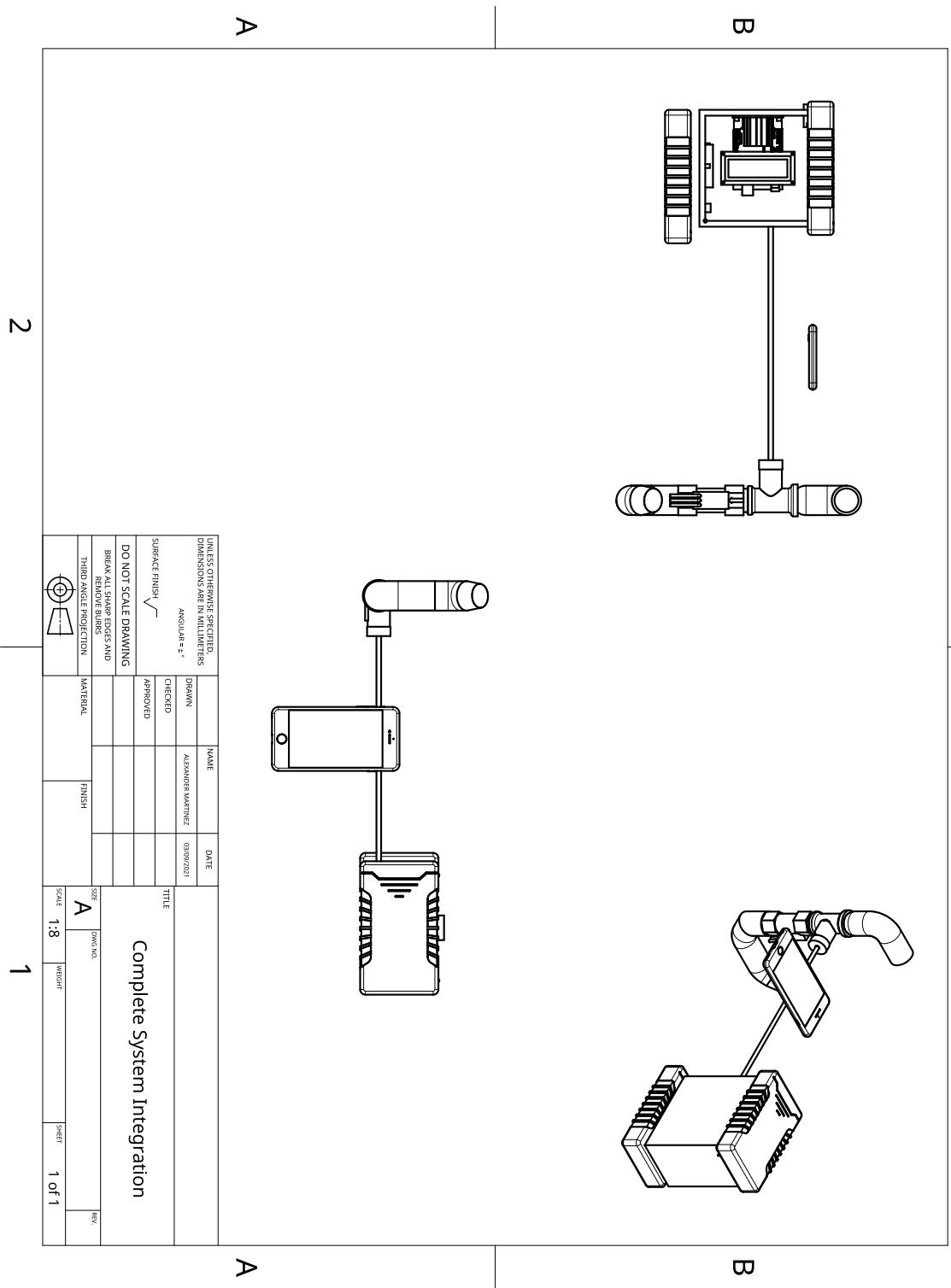
1

# Control Box

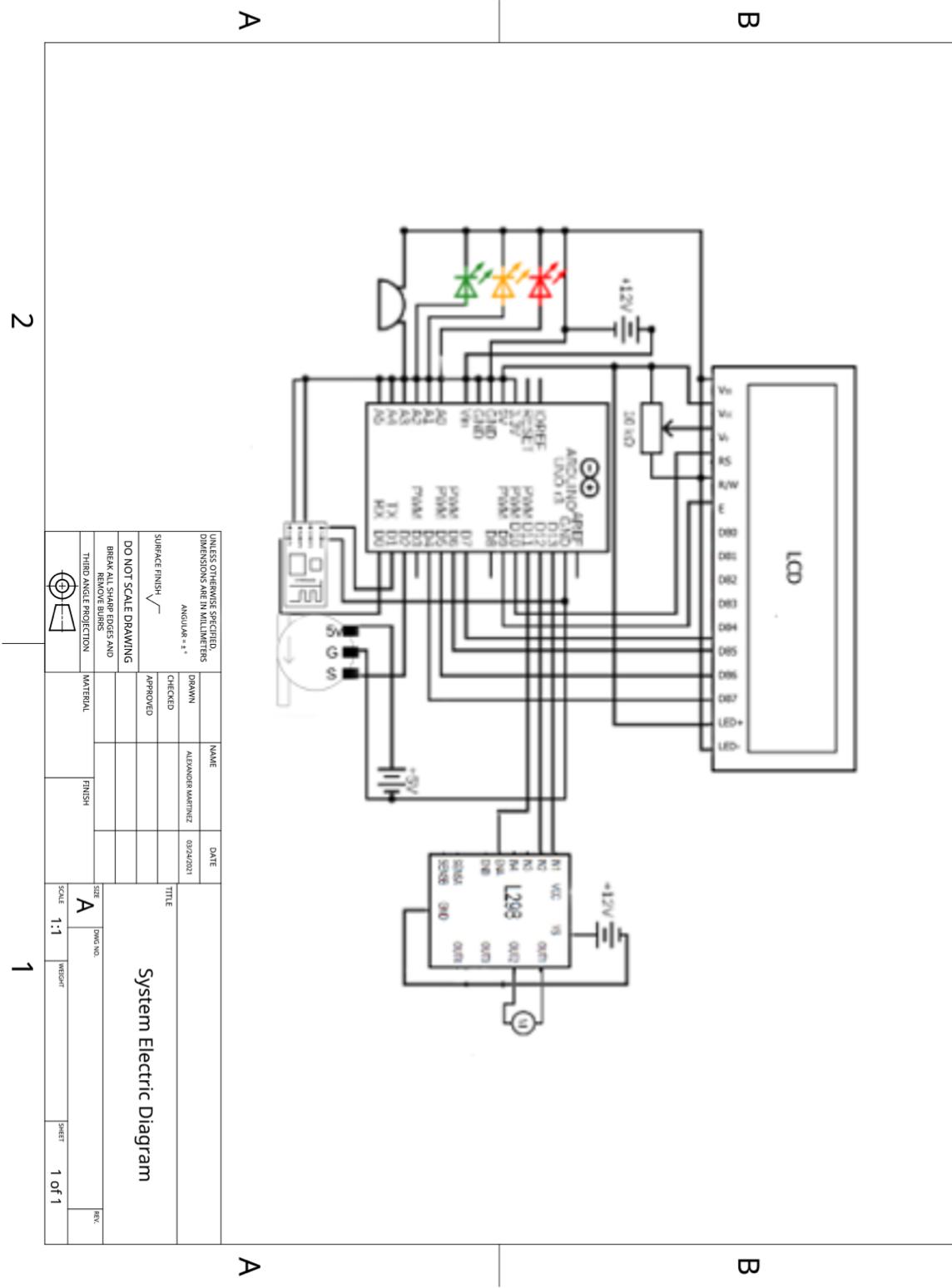


## APPENDIX E: DETAIL DRAWINGS

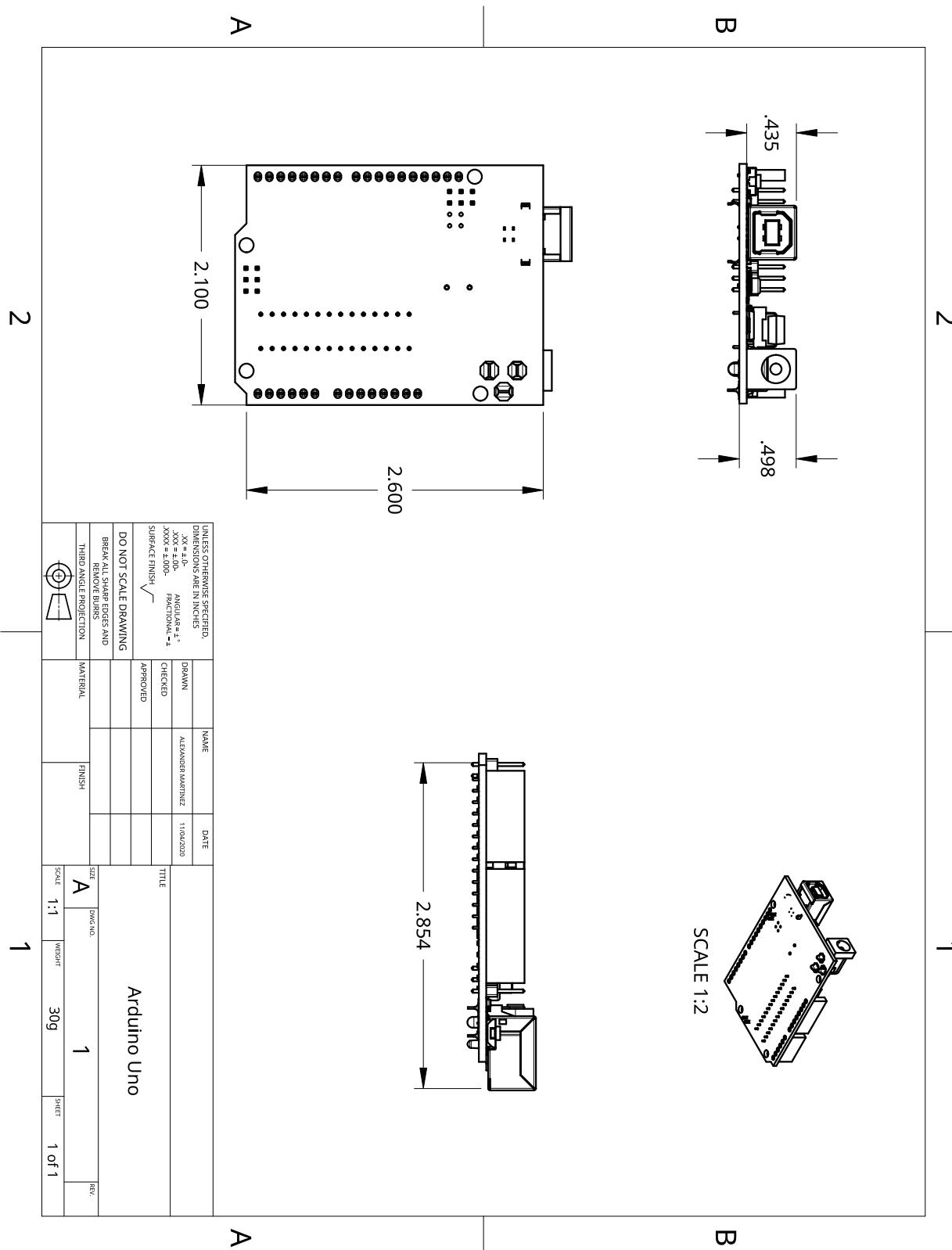
### System Drawing



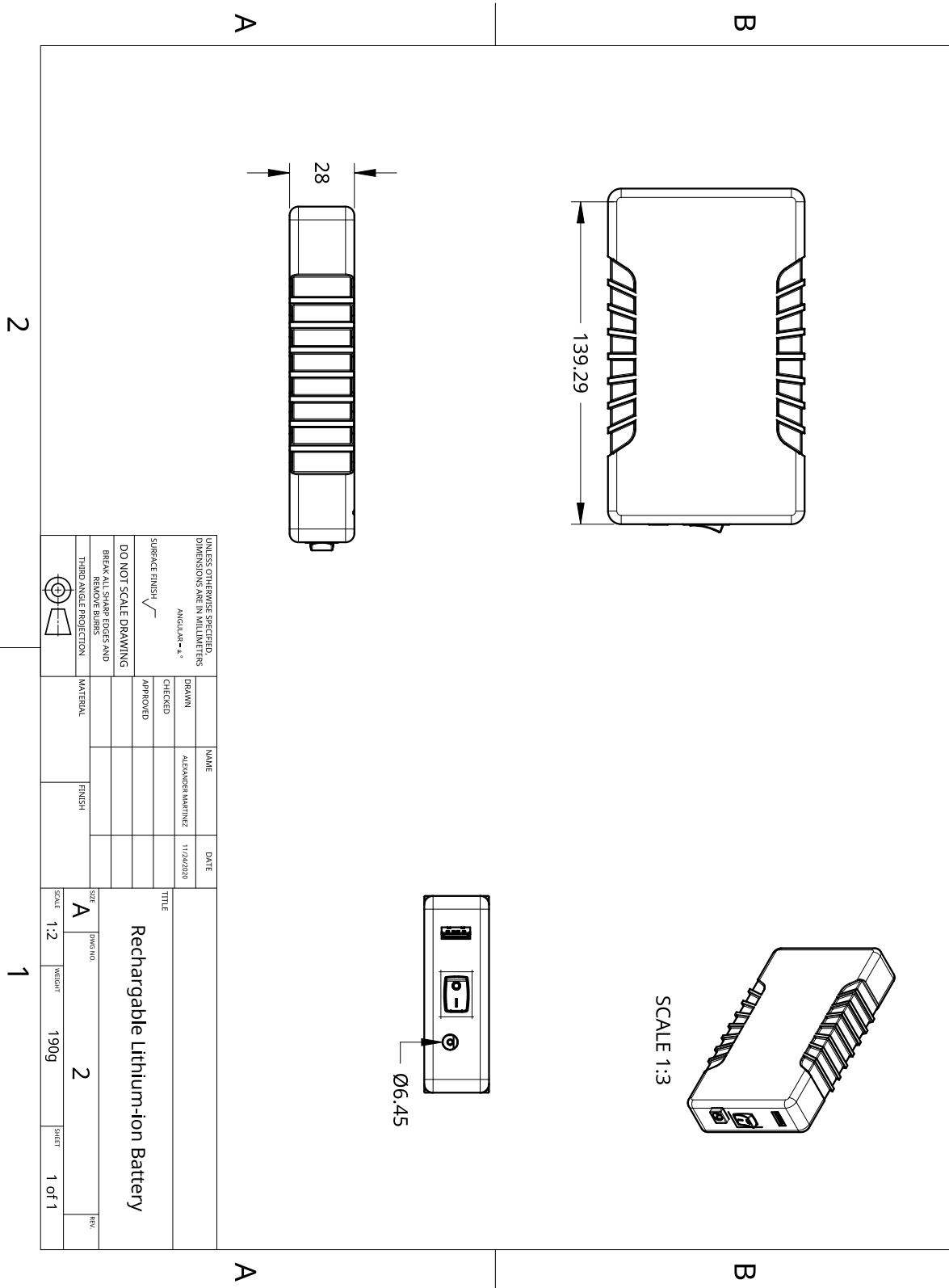
# System Level Electronic Diagram



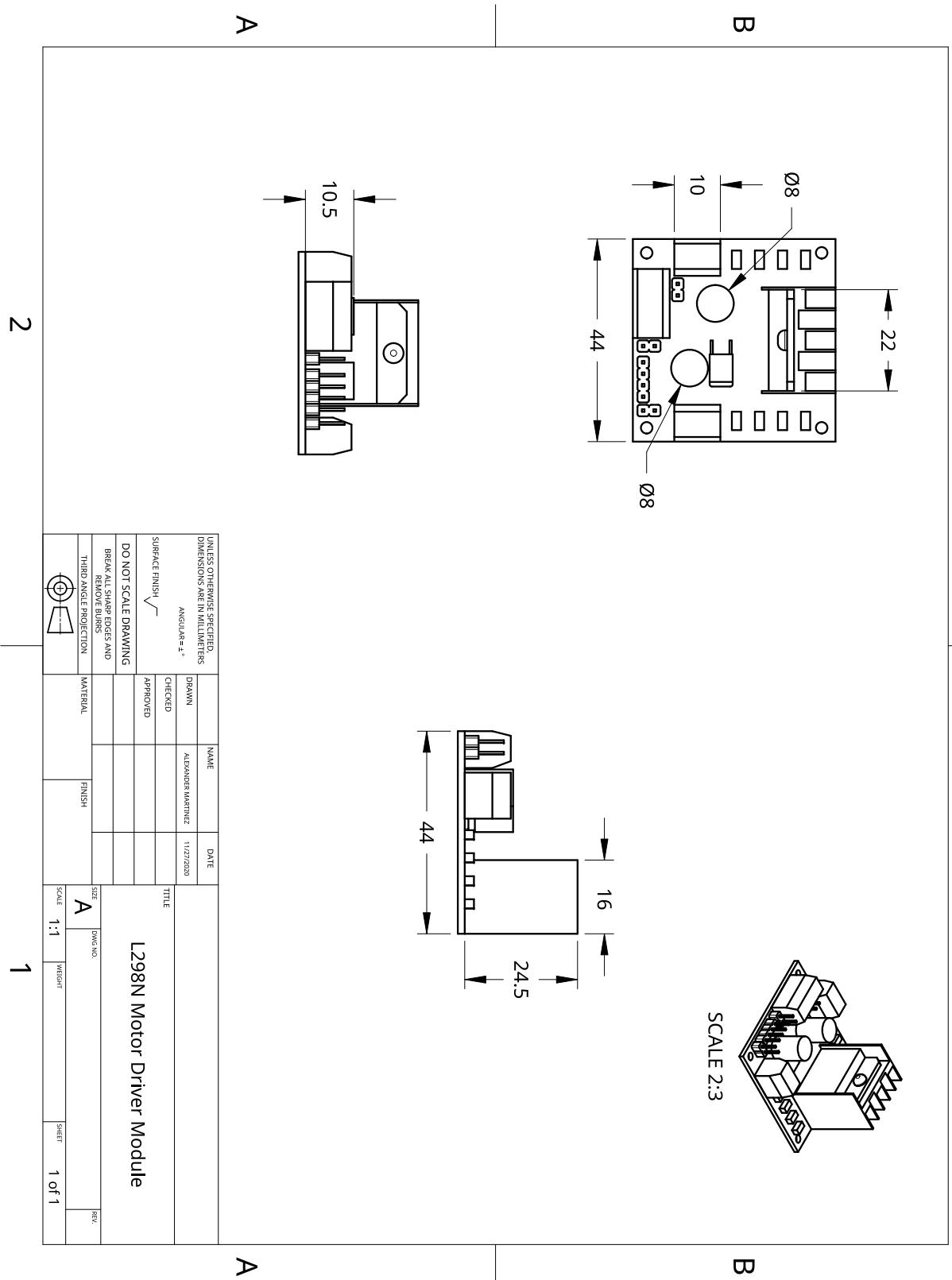
# Arduino



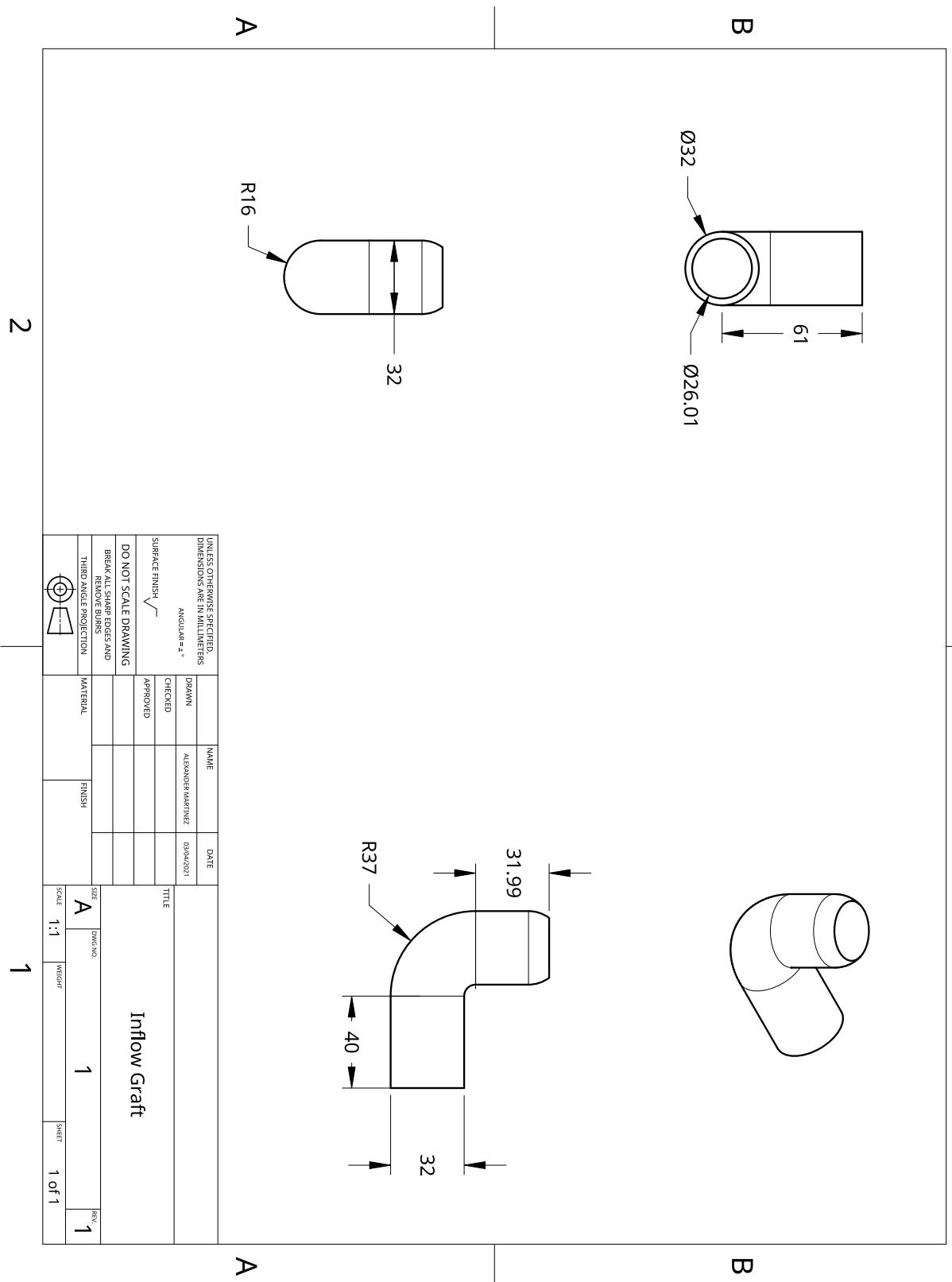
# Battery



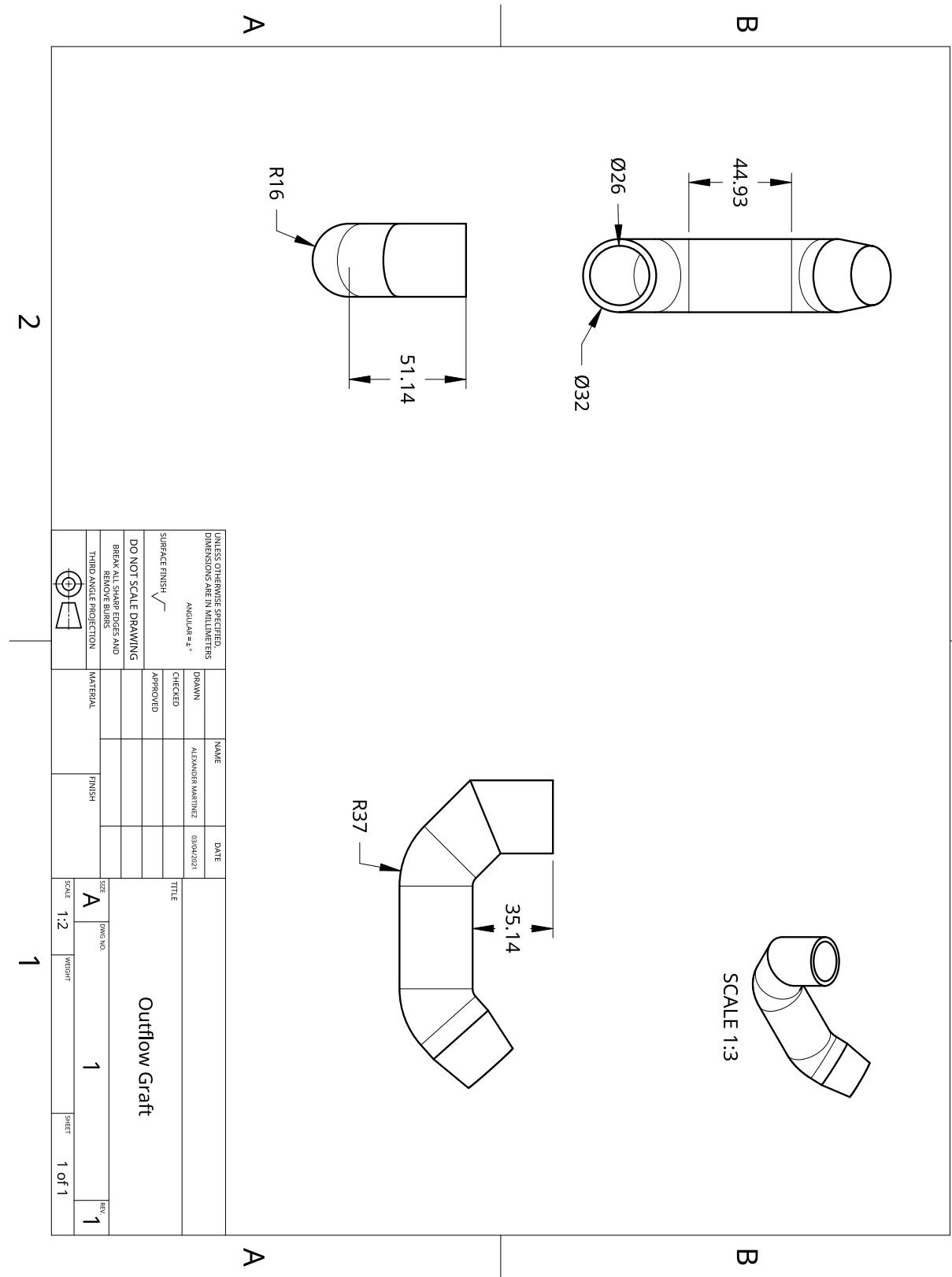
# Motor Driver Module



# Inflow Pipe



# Outflow Pipe



# Heart Pump

2

1

B

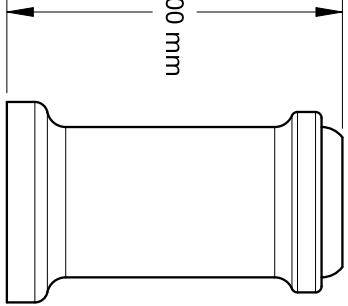
B

2

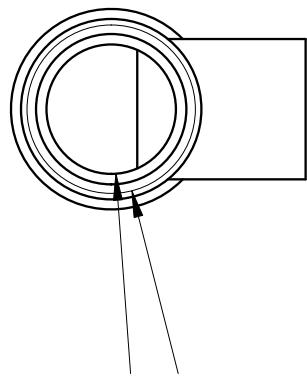
A

A

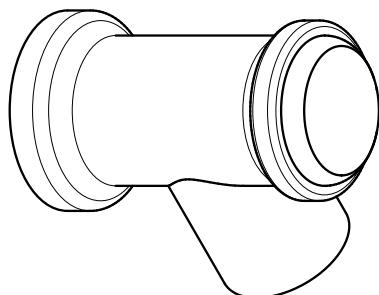
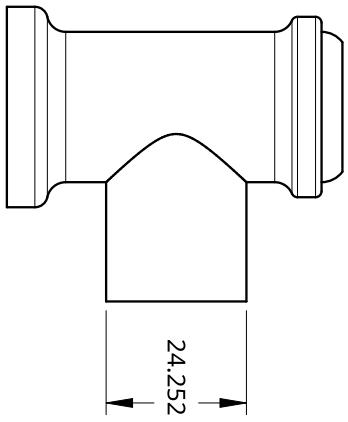
58.00 mm



$\varnothing 29.102$  mm  
 $\varnothing 22.372$  mm



24.252 mm



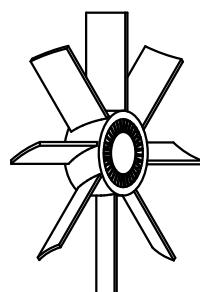
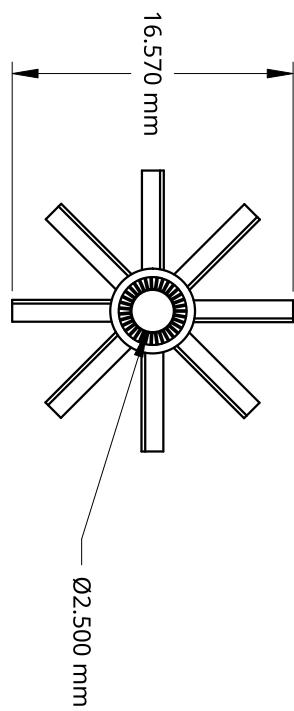
UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES		
XX = 0-	DRAWN	NAME CARLOS GONZALEZ
.XXX = 00-	CHECKED	DATE 02/16/2021
.XXXX = 000-	APPROVED	TITLE Main Component
SURFACE FINISH ✓		LVAD Telemonitoring System
DO NOT SCALE DRAWING		SIZE A
BREAK ALL SHARP EDGES AND REMOVE BURRS		DWG NO. 1
THIRD ANGLE PROJECTION	MATERIAL	REV. 1
	FINISH	SCALE 1:1
		WEIGHT
		SHEET 1 of 1

# Rotor Drawing

2

1

B



A

A

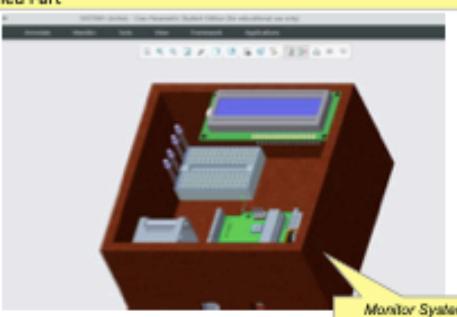
UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES XXX = $\Delta$ , XXXX = $\pm$ , ANGULAR = $\pm$ FRACTIONAL = $\frac{1}{2}$			NAME	DATE
DRAWN BY	CARLOS GONZALEZ	02/16/2022		
CHECKED				
APPROVED				
DO NOT SCALE DRAWING				
BREAK ALL SHARP EDGES AND REMOVE BURRS.				
THIRD ANGLE PROJECTION				
	MATERIAL	FINISH	SIZE A	REQ 1
			SCALE 3:1	WEIGHT
			SHEET 1 of 1	REV 1

2

1

## APPENDIX E: MANUFACTURING SHEETS

### Control Box

Reminders	⚠ Caution: Use Safety equipment	☐ See photo to the right	Related Documents: DIR-GR-3
P/N: GR-3 <b>LVAD MONITOR SYSTEM</b>			
<p><b>General Vision</b></p> <ul style="list-style-type: none"> <li><b>1 Selection of materials ☐1</b></li> <li><b>2 System Installation ☐2</b></li> <li><b>3 3D Printing Process ☐3</b></li> <li><b>4 Total assembly ☐4</b></li> </ul>	<p><b>Instructions &amp; Explanations</b></p> <p>1.1 Select the proper size box to prepare the monitoring system</p> <p>1.2 Selection of the following essential materials: ⚠            a. Batteries            b. Arduino            c. Breadboard</p> <p>1.3 Selection of a display, fan to control temperature and LED lights</p> <p>2.1 Assemble all parts on the monitor as specified in drawings using screws and drill. ☐</p> <p>3.1 For the manufacture of the monitor, the 3D Printer is essential ☐</p> <p>4.1 System with all its parts</p>	<p>☐1 Select &amp; Cut Steel</p>  <p>Monitor Box      Arduino      Breadboard</p> <p>☐2 System Installation</p>  <p>Screws      Drill</p> <p>☐3</p>  <p>2.1</p> <p>☐4 System</p>  <p>3.1</p>	
<p><b>Results</b></p> <p>☐5 Raw Material</p>  <p>☐6 Finished Part</p> 			

# Heart Pump

Reminders		Caution: Use Safety equipment	<input type="checkbox"/> See photo to the right	Related Documents: DR-GR-3	
Pm: GR-3 Heart Pump					
<b>General Vision</b> 	<b>Instructions &amp; Explanations</b>				
	1.1 Select a filament for 3D Printer 1.2 Choose the filament: <ul style="list-style-type: none"> <li>a. Polymer coating</li> <li>b. Diamond – like carbon (DLC)</li> </ul>				
	1.3 Select the materials for the pump: <ul style="list-style-type: none"> <li>a. Motor</li> <li>b. Rotor</li> </ul>				
	1.4 Cut in a round shape with following measures: <ul style="list-style-type: none"> <li>a. The tube will be cut in different measures.</li> <li>b. Each part of the tube has specific cuts.</li> </ul>				
<b>1 Select the materials </b>  <b>2 Inflow &amp; Outflow parts </b>  <b>3 Tube Shape </b>  <b>4 CNC Machine Process </b>  <b>5 Sterilization </b>	1.1 The pump has two essential parts; the inflow and outflow system, where the blood runs. <ul style="list-style-type: none"> <li>a. Outflow system</li> <li>b. Inflow system</li> </ul>				
	3.1 Drill holes on Tube as specified in drawings. It is essential to use a bending machine in order to obtain the specific shape of the pipe.				
	4.1 For 1.2: Using CNC Machine to cut and create the thread measures in drawings				
	5.1 For Sterilization process: <ul style="list-style-type: none"> <li>a. Hot Water Machine</li> <li>b. Hot Air Sterilization Machine</li> </ul>				
<b>Results</b> <b>05 Raw Material</b>		<b>06 Finished Part</b>			

# Inflow Pipe

Reminders	Caution: Use Safety equipment	<input type="checkbox"/> See photo to the right	Related Documents: DR-GR-3
P/N: GR-3	Inflow Section		
General Vision	Instructions & Explanations		
1 Material <input type="checkbox"/> 1	<p>1.1 Select a titanium alloy and a polymer for the inflow part</p> <p>1.2 Select a round tube R.36 x 4in</p>		<input type="checkbox"/> 1 Select & Cut Steel  
2 Drill Holes & Pipe Bending Machine <input type="checkbox"/> 2	<p>2.1 Drill holes on Tube as specified in drawings. It is essential to use a bending machine in order to obtain the specific shape of the pipe. </p> <p>3.1 Using a CNC Machine or 3D Printer to print the part </p>		<input type="checkbox"/> 2 Drill Holes & Pipe Bending Machine    
3 CNC Machine <input type="checkbox"/> 3	<p>4.1 By having the part, it must be linked with the pump, remaining towards the left side</p>		<input type="checkbox"/> 3 CNC Machine  
4 Assembly <input type="checkbox"/> 4			
Results	<p><input type="checkbox"/> 5 Raw Material</p> <p><input type="checkbox"/> 6 Finished Part</p>		

# Outflow Pipe

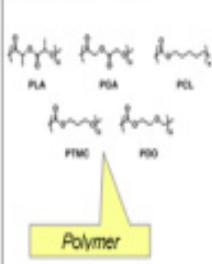
**Reminders****⚠ Caution: Use Safety equipment****▢ See photo to the right****Related Documents:**  
DR-GR-3

P/N: GR-3

Outflow Section

General Vision	Instructions & Explanations	
1 Material <b>▢1</b>	<p>1.1 Select a titanium alloy and a polymer for the inflow part</p> <p>1.2 Select a round tube R.56 x 6in</p>	<b>▢1</b> Select & Cut Steel  
2 Drill Holes & Pipe Bending Machine <b>▢2</b>	<p>2.1 Drill holes on Tube as specified in drawings. It is essential to use a bending machine in order to obtain the specific shape of the pipe. <b>▢</b></p>	<b>▢2</b> Drill Holes & Pipe Bending Machine   
3 CNC Machine <b>▢3</b>	<p>3.1 Using a CNC Machine or 3D Printer to print the part <b>▢</b></p>	<b>▢3</b> CNC Machine 
4 Assembly <b>▢4</b>		<b>▢</b>

**Results**

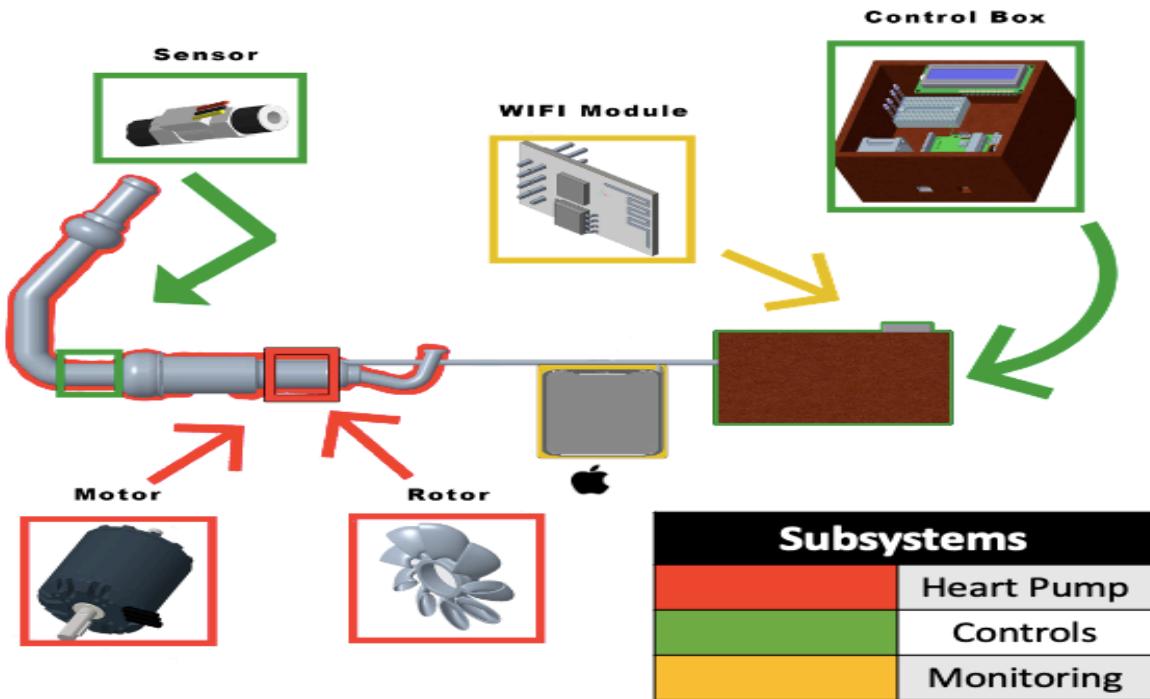
<b>▢5 Raw Material</b>	<b>▢6 Finished Part</b>
	

## APPENDIX F: SCHEMATICS & INTERFACES

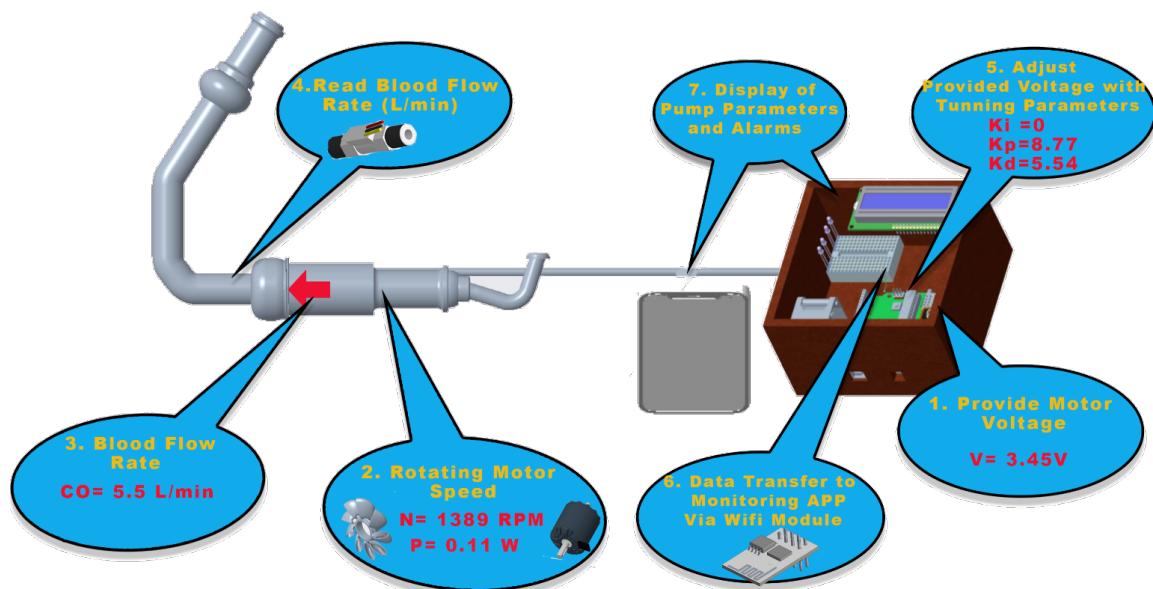
### $N^2$ Diagram

Patient	$o_1 \rightarrow$ Connection to System $I_2 \downarrow$			
$I_1 \uparrow$ Risk Alarms $\leftarrow o_2$	Microcontroller	$o_2 \rightarrow$ Signal Pump Move blood at X flow rate (L/min) $I_3 \downarrow$		
$I_1 \uparrow$ Flow blood to the body $\leftarrow o_3$	$I_2 \uparrow$ Pump Performance Reading $\leftarrow o_3$	Pump	$o_3 \rightarrow$ Blood Flow Rate $I_4 \downarrow$	
	$I_2 \uparrow$ Blood Flow Rate Reading $\leftarrow o_4$		Sensors	$o_4 \rightarrow$ Blood Flow Rate Reading (L/min) $I_5 \downarrow$
$I_1 \uparrow$ Performance Information $\leftarrow o_5$				Mobile App

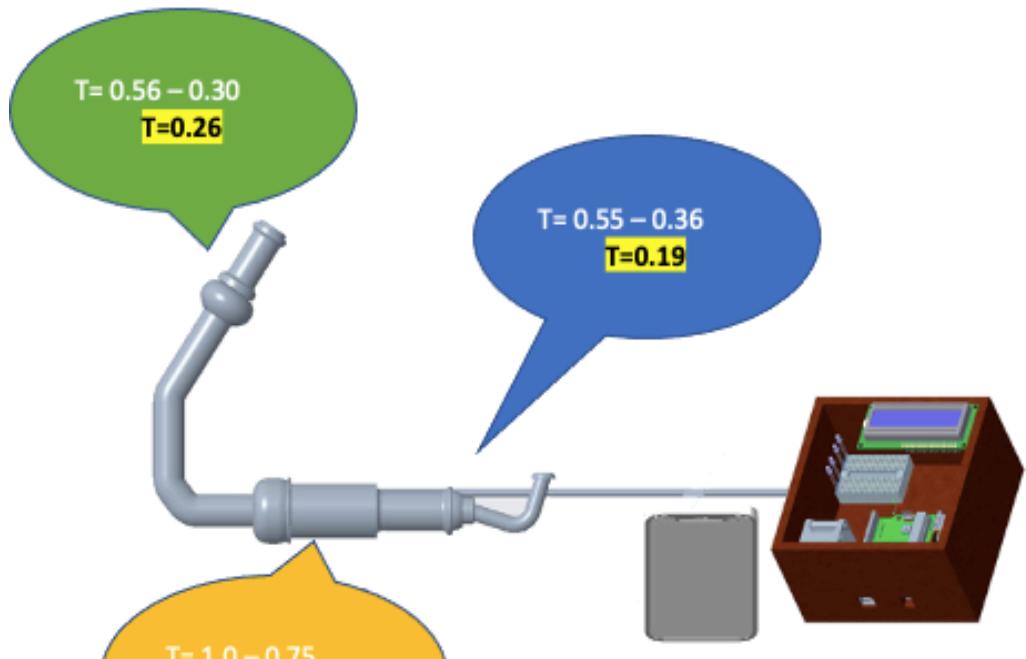
## Component Interface Representation



## Interface Performance

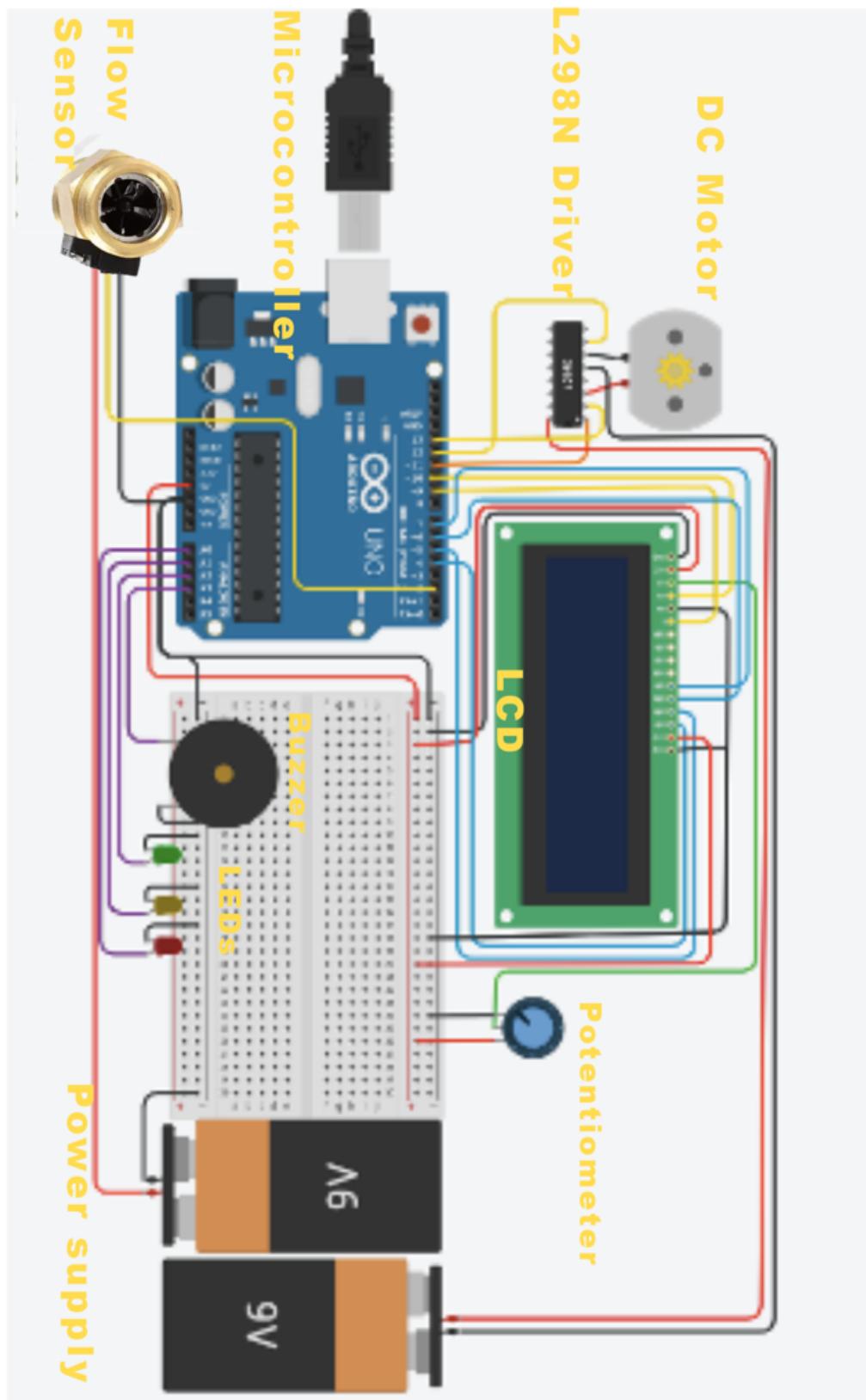


## Interface Tolerances

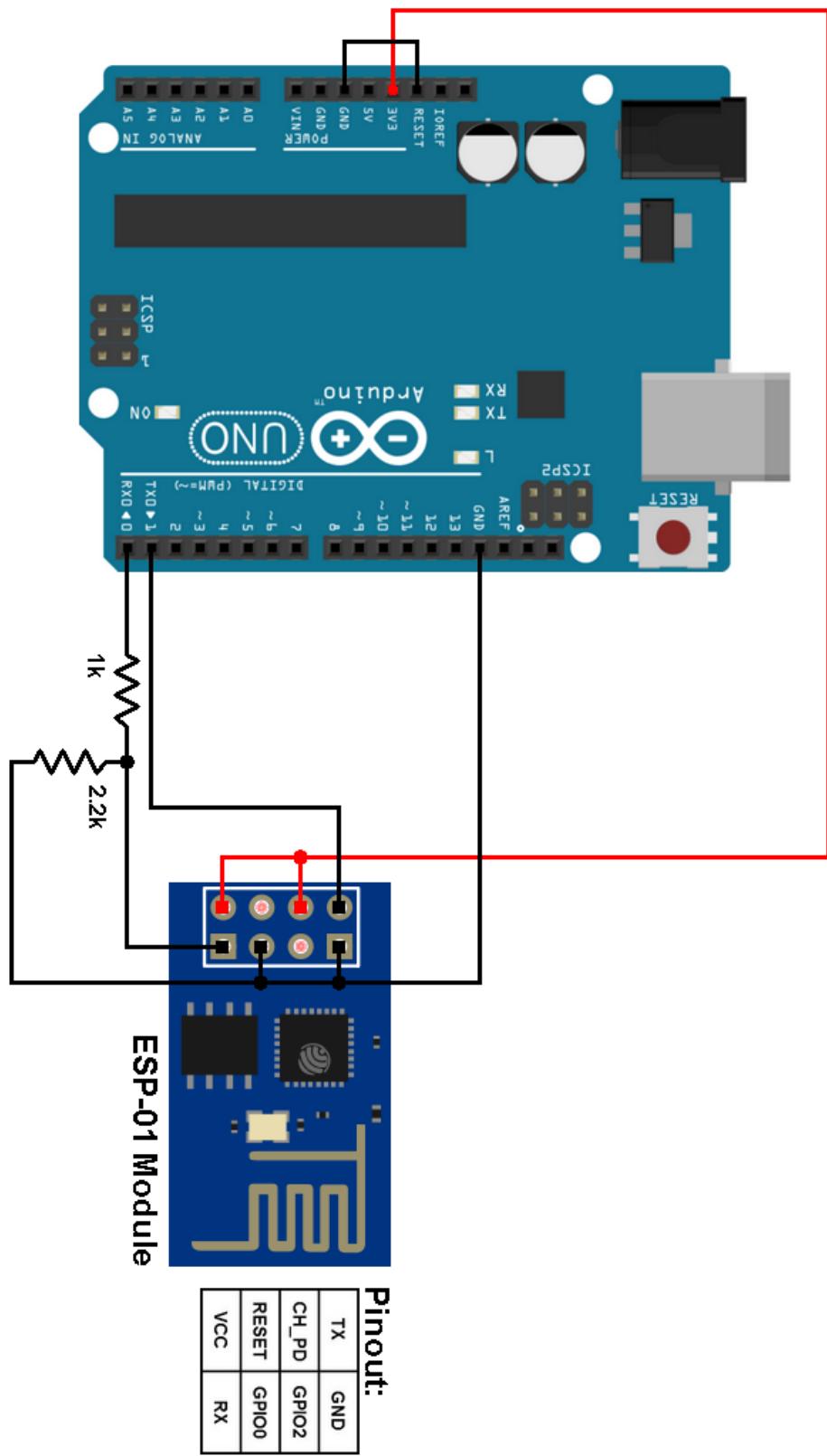


Legend	
Color	Tolerance Calculation $T = \text{Upper Limit} - \text{Lower Limit}$
Green	<b>Outflow Pipe</b> $T = \text{Heart pump connection} - \text{Aorta Connection}$
Yellow	<b>Heart Pump</b> $T = \text{Outflow side} - \text{Inflow Side}$
Blue	<b>Inflow Pipe</b> $T = \text{Heart Pump Connection} - \text{Left Ventricle Connection}$

## Controls Subsystem Schematics



## Monitoring Subsystem Schematics



## APPENDIX F: CODE

### TLVAD APP GUI (Visual Studios)

```
<?xml version="1.0" encoding="utf-8" ?>
<ContentPage xmlns="http://xamarin.com/schemas/2014/forms"
    xmlns:x="http://schemas.microsoft.com/winfx/2009/xaml"
    x:Class="LVAD.MainPage"
    x:Name="Page"
    BackgroundColor="Beige"
>

<ScrollView>
<Grid>
    <Grid.RowDefinitions>
        <RowDefinition></RowDefinition>
        <RowDefinition></RowDefinition>
        <RowDefinition></RowDefinition>
        <RowDefinition></RowDefinition>
        <RowDefinition></RowDefinition>
        <RowDefinition></RowDefinition>
    </Grid.RowDefinitions>

    <Grid.ColumnDefinitions>
        <ColumnDefinition Width="*" />
        <ColumnDefinition Width="2*" />
    </Grid.ColumnDefinitions>

    <StackLayout Grid.Column="0" Grid.Row="0" Grid.ColumnSpan="2" Margin="0,30,0,0"
        HorizontalOptions="Center">
        <Label Text="LVAD" HorizontalOptions="Center" HorizontalTextAlignment="Center"
            TextColor="Black" FontSize="80"
        ></Label>
    </StackLayout>

    <StackLayout Grid.Column="0" Grid.Row="1" Grid.ColumnSpan="2" Padding="49" >
        <Label Text="Pump Parameters" FontSize="Medium" HorizontalOptions="Center"
            TextColor="Brown"
            HorizontalTextAlignment="Center"></Label>
    </StackLayout>

    <StackLayout Grid.Column="0" Grid.Row="2">
        <ImageButton
```

```

Source="@images/heart.png"
BackgroundColor="Transparent"
Margin="40,0,0,0"
WidthRequest="80"
HeightRequest="80"
x:Name="bloodFlowBtn"
Clicked="bloodFlowBtn_Clicked"
HorizontalOptions="Start" />
</StackLayout>

<StackLayout Grid.Column="1" Grid.Row="2">
<Label
Margin="0, 0, 0, -29"
Text="Blood Flow:"
FontSize="Medium"
TextColor="Black"
HorizontalOptions="Start">
</Label>
<Label
x:Name="bloodFlow"
Margin="0, 20, 0, 0"
Text="1 L/min"
FontSize="Medium"
TextColor="IndianRed">
</Label>
</StackLayout>

<StackLayout Grid.Column="0" Grid.Row="3">
<ImageButton
Source="@images/alarm.png"
BackgroundColor="Transparent"
Margin="40,0,0,0"
Clicked="ImageButton_Clicked_1"
WidthRequest="80"
HeightRequest="80"
HorizontalOptions="Start" />
</StackLayout>

<StackLayout Grid.Column="1" Grid.Row="3">
<Label
Margin="0, 0, 0, -29"
Text="Motor Speed:"
FontSize="Medium"
TextColor="Black"

```

```

HorizontalOptions="Start">
</Label>
<Label
Margin="0, 20, 0, 0"
Text="2000 rpm"
FontSize="Medium"
TextColor="IndianRed">
</Label>
</StackLayout>

<StackLayout Grid.Column="0" Grid.Row="4">
<ImageButton
BackgroundColor="Transparent"
Source="@images/graphic.png"
HorizontalOptions="Start"
Margin="40,0,0,0"
WidthRequest="80"
Clicked="ImageButton_Clicked"
HeightRequest="80"/>
</StackLayout>

<StackLayout Grid.Column="1" Grid.Row="4">

<Label
Margin="0, 0, 0, -29"
Text="Power:"
FontSize="Medium"
TextColor="Black"
HorizontalOptions="Start">
</Label>
<Label
Margin="0, 20, 0, 0"
Text="2.0 W"
FontSize="Medium"
TextColor="IndianRed">
</Label>
</StackLayout>
</Grid>
</ScrollView>
</ContentPage>

```

### TLVAD App Arduino Communication (Visual Studios)

using ArduinoCServer;

```

using DocumentFormat.OpenXml.Spreadsheet;
using Java.IO;
using Java.Net;
using System;
using System.IO.Ports;
using System.Net;
using System.Net.Sockets;
using System.Text;
using System.Threading;
using System.Threading.Tasks;
using Xamarin.Forms;

namespace LVAD
{
    public partial class MainPage : ContentPage
    {

        public MainPage()
        {
            InitializeComponent();
        }

        protected override async void OnAppearing()
        {
            await WaitAndExecute(1000, () =>
            {
                StartListening1();
            });
        }

        protected async Task WaitAndExecute(int milisec, Action actionToExecute)
        {
            await Task.Delay(milisec);
            actionToExecute();
        }

        private cServerClass Server;

        public void StartListening1()
        {
            var count = 1;
            do
            {

```

```

        this.bloodFlow.Text = count.ToString() + " L/min";
        Thread.Sleep(2000);

    }

    while (count < 11);
}

public void StartListening()
{
    string StringHost;
    string StrIP;

    try
    {
        StringHost = System.Net.Dns.GetHostName();
        StrIP = Dns.GetHostByName(StringHost).AddressList[0].ToString();
        var z = "Host Name:" + StringHost + "IP Address:" + StrIP;
    }
    catch (Exception ex)
    {

    }
}

Server = new cServerClass();

Server.Message += RecInfo;

}

private void RecInfo(cServerClass sender, string data)
{
}

private void ImageButton_Clicked(object sender, EventArgs e)
{
    Navigation.PushAsync(new Graphic());
}

private void ImageButton_Clicked_1(object sender, EventArgs e)
{
    Navigation.PushAsync(new Demographics());
}

```

```

private void bloodFlowBtn_Clicked(object sender, EventArgs e)
{
    Navigation.PushAsync(new AlarmSettings());
}
}
}

```

## WIFI Server (Visual Studios)

```

using System;
using System.IO;
using System.Net;
using System.Net.Sockets;
using System.Threading;
namespace ArduinoCServer
{
    class cServerClass
    {
        public event MessageEventHandler Message;

        public delegate void MessageEventHandler(cServerClass sender, string Data);

        //Server Control
        public IPAddress ServerIP = IPAddress.Parse("172.20.10.6");
        public int ServerPort = 139;
        public TcpListener myserver;

        public Thread Comthread;
        public bool IsLiserning = true;

        //Clients
        private TcpClient client;
        private StreamReader clientdata;

        public cServerClass()
        {
            myserver = new TcpListener(ServerIP, ServerPort);
            myserver.Start();

            Comthread = new Thread(new ThreadStart(Hearing));
            Comthread.Start();
        }

        private void Hearing()

```

```

{
    while (!IsListening == false)
    {
        if (myserver.Pending() == true)
        {
            client = myserver.AcceptTcpClient();
            clientdata = new StreamReader(client.GetStream());
        }

        try
        {
            Message?.Invoke(this, clientdata.ReadLine());
        }
        catch (Exception ex)
        {

        }
        Thread.Sleep(10);

    }
}
}

```

## PID Controls & Monitoring (Arduino)

```

#include <WiFi101.h>
#include <LiquidCrystal.h>
// connect to server, send message and display response
#include <Ethernet.h>
#include <SPI.h>
#include <PID_v1.h> //PID Library
// connect to server, send message and display response
// initialize the library by associating any needed LCD interface pins
// with the arduino pin number it is connected to
const int rs = 10, en = 9, d4 = 7, d5 = 6, d6 = 5, d7 = 4;
LiquidCrystal lcd(rs, en, d4, d5, d6, d7); //LCD Inputs
// Wifi
char ssid[] = "iPhone";
char pass[] = "alanis04";
int keyIndex = 0;
int status = WL_IDLE_STATUS;
WiFiServer server(139);
int enA = 11; // Motor Driver Enable Input
int n1 = 13; // Motor Driver Pin
int n2 = 12; // Motor Driver Pin

```

```

int ledYellow=A0; //Yellow LED Pin
int ledRed=A1;//Red LED Pin
int ledGreen=A2;//Green LED Pin
int buzzer = A3; //buzzer to arduino pin 9
int flowPin = 2; //This is the input pin on the Arduino
double flowRate; //This is the value we intend to calculate.
volatile int count; //This integer needs to be set as volatile to ensure it updates correctly during the
interrupt process.
int Power; // This is the value of power we intend to calculate based on measurements
int Conversion;
int voltage;
int RPM;
//Define Variables we'll be connecting to PID
double Setpoint, Input, Output;
//Define the aggressive and conservative Tuning Parameters
double aggKp=10.54, aggKi=5, aggKd=13.77;
double consKp=5.54, consKi=1, consKd=8.77;
//Specify the links and initial tuning parameters
PID myPID(&Input, &Output, &Setpoint, consKp, consKi, consKd, DIRECT);
void setup() {
    // put your setup code here, to run once:
    Setpoint = 5.5; // Idial Blood flow
    myPID.SetMode(AUTOMATIC);
    //Alarms Pinmode
    pinMode(ledYellow, OUTPUT);
    pinMode(ledRed, OUTPUT);
    pinMode(ledGreen, OUTPUT);
    pinMode(buzzer, OUTPUT);
    pinMode(flowPin, INPUT); //Sets the pin as an input
    attachInterrupt(0, Flow, RISING); //Configures interrupt 0 (pin 2 on the Arduino Uno) to run the
    function "Flow"
    Serial.begin(9600); //Start Serial
    // set up the LCD's number of columns and rows:
    lcd.begin(16, 2);
    // Print a message to the LCD.
    lcd.print(" LVAD Monitoring");
    pinMode(enA,OUTPUT);
    pinMode(n1,OUTPUT);
    pinMode(n2,OUTPUT);
    if(WiFi.status() == WL_NO_SHIELD){
        while(true);
    }
    while( status!= WL_CONNECTED){
        status = WiFi.begin(ssid, pass);
}

```

```

        delay(10000);
    }
    server.begin();
}
void loop() {
    // put your main code here, to run repeatedly:
    count = 0;      // Reset the counter so we start counting from 0 again
    interrupts();  //Enables interrupts on the Arduino
    delay (1000); //Wait 1 second
    noInterrupts(); //Disable the interrupts on the Arduino
    //Start the math
    flowRate = (count * 2.25);      //Take counted pulses in the last second and multiply by 2.25mL
    flowRate = flowRate * 60;        //Convert seconds to minutes, giving you mL / Minute
    flowRate = flowRate / 1000;      //Convert mL to Liters, giving you Liters / Minute
    Input= flowRate;
    Conversion = flowRate/60000; // Convert L/min to m^3/s
    Power= (Conversion * 9.81 *1060 *0.0588) / 0.49; // Power Calculation
    Serial.print( "Flow:");
    Serial.println(flowRate);      //Print the variable flowRate to Serial
    // set the cursor to column 0, line 1
    // (note: line 1 is the second row, since counting begins with 0):
    lcd.setCursor(0, 1);
    // print the number of seconds since reset:
    lcd.print( "Flow: ");
    lcd.println(flowRate);
    //lcd.print(millis() / 1000);
    //digitalWrite(enA,255);
    digitalWrite(n1, HIGH);
    digitalWrite(n2, LOW);
}

```

```

double gap = abs(Setpoint-Input); //distance away from setpoint
if (gap < 1)
{
    //we're close to setpoint, use conservative tuning parameters
    myPID.SetTunings(consKp, consKi, consKd);
}
else
{
    //we're far from setpoint, use aggressive tuning parameters
    myPID.SetTunings(aggKp, aggKi, aggKd);
}
myPID.Compute();
voltage=Output*0.024;
RPM=voltage*1016.7; //Rotor Speed Calculation

```

```

digitalWrite(enA,Output);
Serial.print( "Output:");
Serial.println(Output);
// Alarm Parameters
if (flowRate>3.0)
{
  digitalWrite(ledRed, HIGH);
  digitalWrite(ledYellow, LOW);
  digitalWrite(ledGreen, LOW);
  tone(buzzer,65000);
  delay(1000);}

else if (flowRate<1)
{
  digitalWrite(ledYellow, HIGH);
  digitalWrite(ledGreen, LOW);
  digitalWrite(ledRed, LOW);

  tone(buzzer,500);
  delay(5000);

}

else {
  digitalWrite(ledGreen, HIGH);
  digitalWrite(ledYellow, LOW);
  digitalWrite(ledRed, LOW);
  noTone(buzzer);
  delay(1000);
}

WiFiClient client = server.available();

if(client){

  while(client.connected()){

    if(client.available()){

  }

void Flow()
{
  count++; //Every time this function is called, increment "count" by 1
}

```

## **APPENDIX G: USER'S MANUAL**



# **Telemonitoring Left Ventricular Assist Device**

User's Manual





**TABLE OF CONTENTS**

<i>Preface</i> .....	1
<i>Introduction</i> .....	2
Overview .....	2
Indications for use .....	2
Contradictions .....	2
Warnings .....	3
Precautions.....	4
Adverse Events .....	6
<i>Telemonitoring Left Ventricular Assist Device System Overview</i> .....	7
LVAD .....	7
Control System .....	7
Driveline .....	8
TLVAD App .....	8
Controller Power Sources .....	8
<i>TLVAD System Pump</i> .....	9
Principles of Operation .....	9
Physiologic Control Algorithms .....	9
<i>Controller Connections</i> .....	10
<i>Parameter and Battery Display Guidelines</i> .....	11
<i>Alarms</i> .....	12
<i>Monitoring App</i> .....	12
<i>Patient Management</i> .....	14
Anticoagulation .....	14
Right Heart .....	14
Arrhythmias.....	14
<i>Maintenance</i> .....	15
Controller Care .....	15
Battery Care .....	15
Driveline Care .....	15

## PREFACE

This manual contains information needed to operate the Telemonitoring Left Ventricular Assist System properly and safely. Users of the Telemonitoring Left Ventricular Assist System should have a practical knowledge of the principles of mechanical circulatory support and should be aware of the physiological and psychological needs of a patient undergoing mechanical heart function support. New users should read this document in its entirety before system operation. This manual may serve as a reference for detailed information including specific information on device function, system setup, and maintenance. As with all prescription medical devices, clinical procedures should be conducted under the direction of the prescribing physician. This manual is not intended to replace comprehensive educational programs or to supersede acquired knowledge or proper medical judgment.

## INTRODUCTION

### OVERVIEW

The Telemonitoring Left Ventricular Assist Device is a set of equipment and materials that together comprise a medical device designed to assist a weakened, poorly functioning left ventricle. Its design is intended for out-of-hospital settings, providing portability for users and significant monitoring during the complex aftercare. The complete system features a Left Ventricular Assist Device (LVAD), a blood pump intended for short-term implantation in such patients, an extracorporeal Controller, plus all of the telemonitoring features, controls, attachments, interfaces, power sources, supporting equipment, labeling, and tools required to achieve the desired therapeutic benefit. The controller, powered by two batteries, regulates pump function, and monitors the system. The TLVAD mobile app provides for continuous monitoring of parameters and data concerning the health of LVAD patients. All components of the TLVAD System are designed to be used only in conjunction with each other. They are neither compatible nor intended to be used with other manufacturer's devices.

### INDICATIONS FOR USE

The Telemonitoring Left Ventricular Assist Device System is indicated for hemodynamic support in patients with advanced left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

### CONTRADICTIONS

The Telemonitoring Left Ventricular Assist Device System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

## WARNINGS

- ⚠️ WARNING!** A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using the Telemonitoring Left Ventricular Assist Device System. Read this entire manual before caring for TLVAD patients.
- ⚠️ WARNING!** Understanding the operating and safety aspects of the Telemonitoring Left Ventricular Assist Device System is critical for safe and successful use.
- ⚠️ WARNING!** All users, including clinicians, patients, and caregivers, must be trained on system operation and safety before use.
- ⚠️ WARNING!** Do not use the Telemonitoring Left Ventricular Assist Device System in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy.
- ⚠️ WARNING!** Do not modify this equipment without authorization.
- ⚠️ WARNING!** NEVER disconnect both power sources at the same time since this will stop the pump. At least one power source must be connected at all times.
- ⚠️ WARNING!** DO NOT allow patients to shower until they have received permission from their clinician to do so.
- ⚠️ WARNING!** DO NOT allow patients to take a bath or swim, as this may damage Telemonitoring Left Ventricular Assist Device System components and/or result in driveline exit site infection.
- ⚠️ WARNING!** DO NOT submerge Telemonitoring Left Ventricular Assist Device components in water or other fluid as this may damage them.
- ⚠️ WARNING!** DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors, as this may damage Telemonitoring Left Ventricular Assist Device System components.

- ⚠️ WARNING!** DO NOT use any components other than those supplied, as this may affect operation.
- ⚠️ WARNING!** DO NOT grasp the driveline cable as this may damage the driveline. To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector.
- ⚠️ WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
- ⚠️ WARNING!** Avoid devices and conditions that may induce strong static discharges (e.g., television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the VAD to perform improperly or stop.
- ⚠️ WARNING!** DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump.
- ⚠️ WARNING!** DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
- ⚠️ WARNING!** NEVER clean the battery charger with the power on, as this may lead to an electrical shock.

## PRECAUTIONS

- ⚠️ CAUTION:** Clinical procedures should be conducted under the direction of the prescribing physician (Authorized Personnel) only.
- ⚠️ CAUTION:** Do not try to repair any of the TLVAD system components. If components need service, contact appropriate personnel.
- ⚠️ CAUTION:** Notify appropriate personnel if there is a change in how the pump works, sounds, or feels.
- ⚠️ CAUTION:** Counsel the patient to avoid contact sports and jumping activities while implanted with the pump. Contact sports or jumping can cause bleeding or damage the pump.
- ⚠️ CAUTION:** Care should be taken when small children or pets are present. There is a potential for strangulation from the system's cables.

- ⚠ **CAUTION:** DO NOT pull, kink or twist the driveline or the power cables, as these may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources.
- ⚠ **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the Telemonitoring Left Ventricular Assist Device System may not function as intended.
- ⚠ **CAUTION:** ALWAYS recharge fully depleted batteries within 24 hours to avoid permanent battery damage.
- ⚠ **CAUTION:** DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.
- ⚠ **CAUTION:** ALWAYS recharge fully depleted batteries within 24 hours to avoid permanent battery damage.
- ⚠ **CAUTION:** DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.
- ⚠ **CAUTION:** ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.
- ⚠ **CAUTION:** DO NOT disassemble, crush, or puncture a battery.
- ⚠ **CAUTION:** DO NOT use a damaged battery. Battery function is unknown if the battery is damaged.
- ⚠ **CAUTION:** DO NOT short circuit the external contacts on a battery since this may result in battery damage

## ADVERSE EVENTS

Implantation of a VAD is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. These surgical procedures are associated with numerous risks. Risks associated with the implant procedure and use of the device may include, but are not limited to, the following:

- |   |   |
|---|---|
|  Death                 |  Stroke                                    |
|  Bleeding              |  Psychiatric Episode                       |
|  Cardiac Arrhythmia    |  Venous Thromboembolism                    |
|  Localized Infection   |  Hypertension                              |
|  Right Heart Failure   |  Arterial Non-Central Nervous System (CNS) |
|  Respiratory Failure   |  Thromboembolism                           |
|  Device Malfunctions   |  Pericardial Fluid Collection              |
|  Driveline Infection |  Pump Pocket or Pseudo Pocket Infection  |
|  Renal Dysfunction   |   |
|  Sepsis              |   |

## TELEMONITORING LEFT VENTRICULAR ASSIST DEVICE SYSTEM OVERVIEW

The primary components of Telemonitoring Left Ventricular Assist System (excluding the TLVAD app) are intended for single patient use.

### LVAD

The Telemonitoring Left Ventricular Assist Device is implanted in the chest below the heart. One end is inserted into the apex of the left ventricle; the other end connects to the ascending aorta. The pump diverts blood from the weakened left ventricle and pumps it to the aorta.

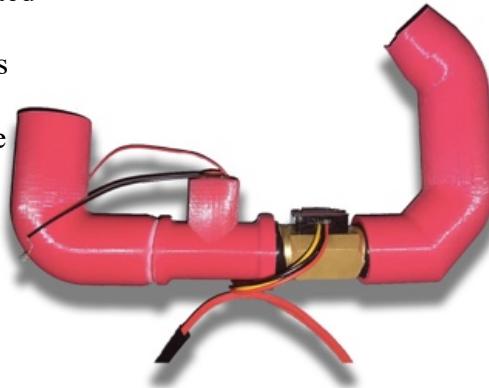
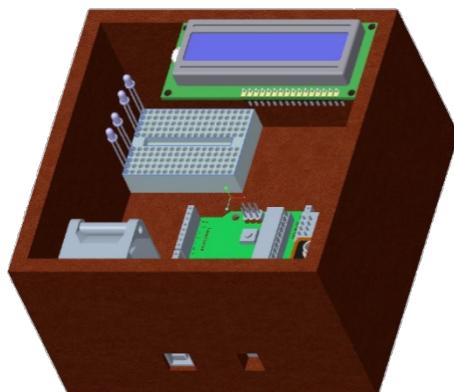


FIGURE 97: TLVAD DEVICE

### CONTROL SYSTEM



98: CONTROL BOX

FIGURE

The control system is a box that contains microprocessor unit and other electronics that controls and manages the Telemonitoring Left Ventricular Assist Device operation. It sends power and operating signals to the blood pump and collects information from the sensor. The percutaneous driveline is connected to the controller, which must always be connected to two power sources (rechargeable batteries). The controller interfaces with the monitor through a WIFI Module.

## DRIVELINE

The Driveline consists of two cables: the Pump Cable and the Sensor Cable. One end of the Pump Cable connects to the pump implanted in the patient's abdomen. The other end of that cable exits the patient's body. One end of the Sensor Cable is connected to the battery and the other end connects to the System Controller.

## TLVAD APP

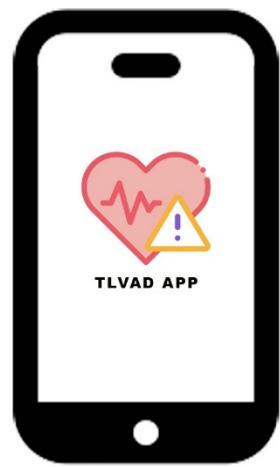


FIGURE 99: TLVAD APP ICON

## CONTROLLER POWER SOURCES

The controller requires two power sources for safe operation: two rechargeable batteries.



FIGURE 100: TLVAD RECHARGEABLE BATTERY

## TLVAD SYSTEM PUMP

### PRINCIPLES OF OPERATION

The TLVAD pump is a continuous flow pump. It contains a rotor that adds energy to the blood by converting the rotational kinetic energy into mechanical energy. Impeller blades push the fluid through the pump using hydrodynamic and centrifugal forces. Essentially, produces flow in the patient's circulatory system by angularly accelerating and expelling blood.

### PHYSIOLOGIC CONTROL ALGORITHMS

The TLVAD Pump control algorithms provide patients information about device performance.

The control system will provide modulation of the voltage supplied to the motor. This modulation will provide blood flow regulation via the rotor speed, this process will continue continuously while the sensor provides the feedback on current blood flow rate to the microcontroller. Accurate and reliable blood flow measurements are given by flow sensor.

The VAD power and speed are calculated based on the blood flow measurements provided by the sensor and the voltage provided to the rotor. The control system will provide modulation of the voltage supplied to the motor. This modulation will provide blood flow regulation via the rotor speed, this process will continue continuously while the sensor provides the feedback on current blood flow rate to the microcontroller.

## CONTROLLER CONNECTIONS

### Power Source

#### Connecting Power Sources

- Insert the Battery's cable to the Microcontroller power jack.
- Insert the USB cable of Battery #2 to the Microcontroller USB port.

#### Disconnecting Power Sources

- Disconnect the Battery's cable from the Microcontroller power jack.
- Disconnect the USB cable of Battery #2 to the Microcontroller USB port.

**\*Note:** Make sure to have one of the Batteries switched to ON otherwise pump will stop.

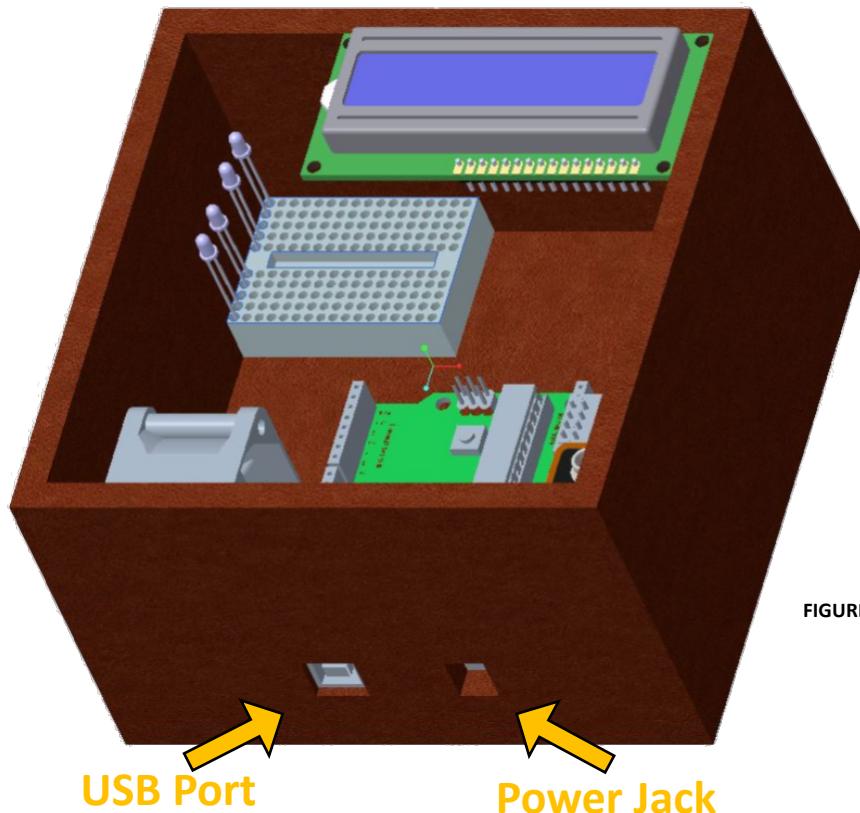


FIGURE 101: POWER CONNECTIONS

## PARAMETER AND BATTERY DISPLAY GUIDELINES

### Parameter Display

The Controller Display gives pump information including:

- Rotor speed (RPM)
- Power (Watts)
- Blood flow (L/min)

\*Note: Parameter display will cycle continuously.

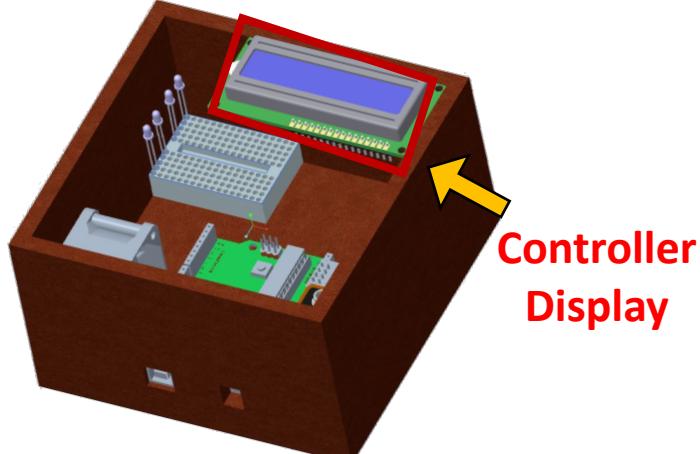


FIGURE 102: CONTROLLER DISPLAY

### Battery Life Display

- The Batteries display information on the battery capacity:

Battery Level	Display
At or around 100%	● ● ● ●
At or around 75%	● ● ● ○
At or around 50%	● ● ○ ○
At or around 25%	● ○ ○ ○
At or around 0%	○ ○ ○ ○

FIGURE 103: BATTERY LIFE DISPLAY

## ALARMS

- Visual and auditory alarms for High Blood Flow and Low Blood Flow.

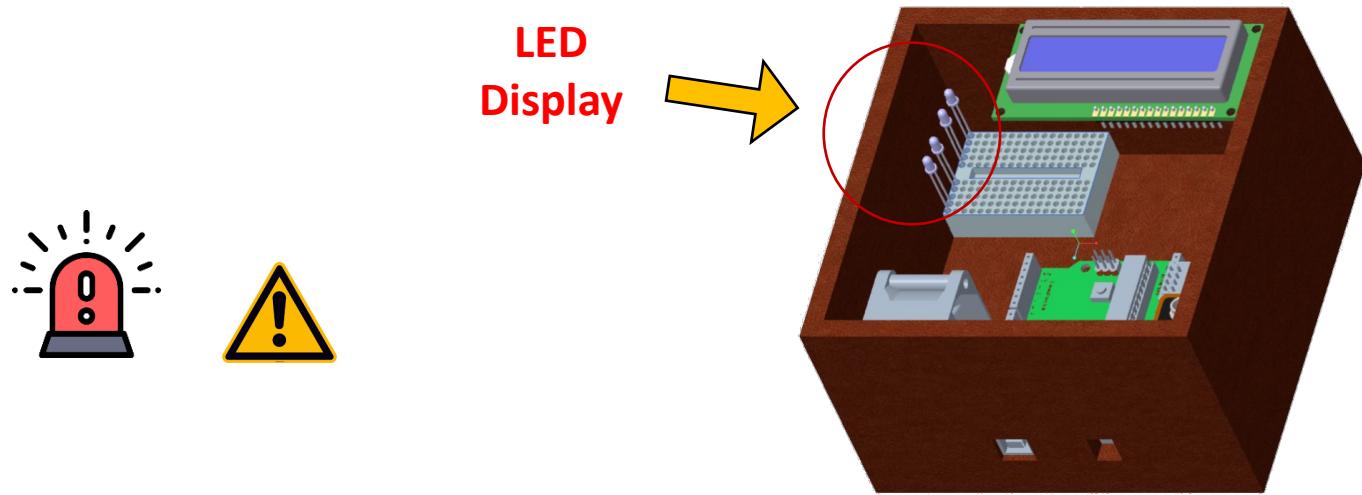


FIGURE 104: VISUAL ALARM DISPLAY

Risk	LED Display	Audio Display	Meaning	
High	Red LED	High Beeping	High Blood Flow	High blood flow can result in high blood pressure, causing the left ventricle to thicken. Increasing risk of heart attack, worsen heart failure and sudden cardiac death.
Medium	Yellow LED	Low Beeping	Low Blood Flow	Reduced blood flow can cause the heart muscle to receive enough oxygen. Leading to myocardial ischemia,
None	Green LED	N/A	Normal Blood Flow	

## MONITORING APP

## APP Icons

**Home**



**Displays Pump Parameters:**

Average flow

Average speed

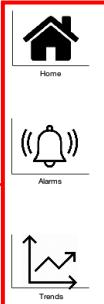
Average power

Touch Screen  
Icons

Pump Parameters

**LVAD Monitoring APP**

Pump Parameters



Blood Flow:  
0.0 L/min

Motor Speed:  
0.0 RPM

Power: 0.0  
Watts

FIGURE 105: PUMP PARAMETER APP GUI

**Alarm**



**Alarm Settings**

Set the [Low Flow] Alarm thresholds

Set the [High Flow] Alarm thresholds

Alarm Notification  
Thresholds

**LVAD Monitoring APP**

Alarm Settings

Low Flow Alarm Limit (L/min)

2.0

High Flow Alarm Limit(L/min)

6.5

FIGURE 106: ALARM SETTINGS APP GUI

**Trend**



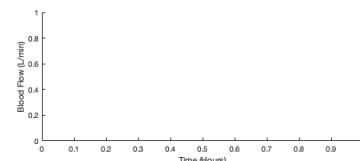
Displays historical trends in a time interval (24 hours) for flow and speed.

Blood flow & Motor Speed Waveforms

**LVAD Monitoring APP**

Parameter Trends

Blood Flow Trends:



Motor Speed Trends:

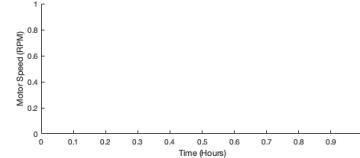


FIGURE 107: PARAMETER TRENDS APP GUI

## PATIENT MANAGEMENT

After implantation, the patient is returned to the intensive care unit. Some vasopressor and/or vasodilatory pharmacologic assistance can be used as required to adjust vasomotor tone. Patients may require inotropic assistance to improve right ventricular function. Additional precautions must be taken to reduce adverse events.

## ANTICOAGULATION

Patients supported with implantable left ventricular assist devices have a significant risk of bleeding and thromboembolic complications. All patients require anticoagulation with warfarin, aiming for a target international normalized ratio of 2.5 and most patients also receive antiplatelet therapy.

## RIGHT HEART

Some patients suddenly develop right ventricular failure during or shortly after pump implantation. The onset of right ventricular dysfunction in patients is often accompanied by the inability of the LVAD to fill, and drastically reduced flow rates. Treatment for patients in right heart failure typically consists of inotropes to augment right ventricular contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance.

## ARRHYTHMIAS

The TLVAD functions most effectively when adequate and stable amounts of preload are available. A stable supraventricular rhythm helps to optimize right heart performance and provide the TLVAD with preload.

## MAINTENANCE

### CONTROLLER CARE

- Once a week, inspect the controller power connections and connector pins for dirt.
- Inspection can be done while the patient is changing batteries.
- Check the power connections on the controller one at a time.
- DO NOT disconnect both power sources to examine the connections.
- DO NOT disconnect the pump to examine the percutaneous lead/controller connection.

### BATTERY CARE

- To preserve battery life, batteries should be stored at room temperature.
- Protect batteries from extreme high and low temperatures.
- Avoid storage in direct sunlight.
- Do not let batteries get wet.
- Rotating use of batteries will allow all batteries to age at a similar rate, so no battery has significantly fewer charge cycles than the others.

### DRIVELINE CARE

To minimize the risk of infection, driveline exit site dressings should routinely be changed.

Routine driveline/exit site care is the responsibility of the patient and the primary caregiver. For proper HVAD® Pump driveline and exit site care, please ensure the following:

1. Use good hand-washing technique before and after dressing changes.
2. Always use aseptic technique.
3. Change dressings per institutional protocol/guidelines.

4. Once the exit site dressing is removed, the driveline should be visually inspected for kinks, tears, or other damage. If blood is seen within the lumen of the driveline, the implanting center should be notified immediately.