

Pulsatile pump

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*Cardiovascular Simulator
with Pulsatile Blood Pump*

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July 2024

Abstract

Biomedical engineering has always been a crucial pillar in the medical field. The integration between mechanical applications and hemodynamics is constantly growing more essential for the biomedical applications, with the continuous search for the perfect simulation methods and software that can serve the medical field at a rapid pace of research and medical products design.

In this documentation we discuss a thoroughly detailed work of maintenance of the pulsatile blood pump and manufacturing of the setup that simulates the aorta in the human body, and we will show different types and development of the pulsatile pump that simulates the left ventricle of the heart.

Acknowledgments

Since the early beginning of this project, we had a major support from a group of insightful and outstanding intellectuals that helped us through profound guidance and leadership; we would like to thank each one of them, even though our words won't be enough.

We would like to firstly give our greatest thanks and gratitude to our beloved supervisor

Prof. Dr. Hassan Warda.

For the absolute effort represented in insightful guidance, motivation, technical and scientific consultations, and huge help and support they provided us in our project to fulfil what we have accomplished.

We would like to also thank a group of great academics that helped us along the way:

Dr. Robert,

Prof. Dr. Essam Salem,

Prof. Dr. Ihab Atia,

Eng. Amr Emam,

Eng. Ali Ghalab.

for a collection of extremely helpful technical guidance through the project.

Partners

Lastly, we wanted to express our appreciation for some corporates and organizations that took part in our technical and financial aspects of our project, all along with our beloved college Faculty of Engineering, Alexandria University:

- *Academy of Scientific Research and Technology*
- *KINCO Egyptian Industrial Solution*
- *Dassault Systems (SOLIDWORKS®)*

Kinco



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1 Biology

1.1 Introduction

The cardiovascular system provides blood supply throughout the body. Responding to various stimuli can control the velocity and amount of blood carried through the vessels. The cardiovascular system comprises the heart, arteries, veins, and capillaries. The heart and vessels work intricately to provide adequate blood flow to all body parts. The regulation of the cardiovascular system occurs via a myriad of stimuli, including changing blood volume, hormones, electrolytes, osmolarity, medications, adrenal glands, kidneys, and much more. The parasympathetic and sympathetic nervous systems also play a key role in regulating the cardiovascular system.

The heart is the organ that pumps blood through the vessels. It pumps blood directly into arteries, specifically the aorta or the pulmonary artery. Blood vessels are critical because they control the amount of blood flow to specific parts of the body. Blood vessels include arteries, capillaries, and veins. Arteries carry blood away from the heart and can divide into large and small arteries. Large arteries receive the highest blood flow pressure and are thicker and more elastic to accommodate the high pressures. Smaller arteries, such as arterioles, have more smooth muscle, which contracts or relaxes to regulate blood flow to specific body portions. Arterioles face a smaller blood pressure, meaning they don't need to be as elastic. Arterioles account for most of the resistance in the pulmonary circulation because they are more rigid than larger arteries. Furthermore, the capillaries branch off of arterioles and are a single-cell layer. This thin layer exchanges nutrients, gases, and waste with tissues and organs. Also, the veins transport blood back to the heart. They contain valves to prevent the backflow of blood.

The cardiovascular system consists of 2 main loops: systemic circulation and pulmonary circulation. Its purpose is to provide adequate blood circulation through the body. Pulmonary circulation allows for the oxygenation of the blood, and systemic circulation allows oxygenated blood and nutrients to reach the rest of the body.

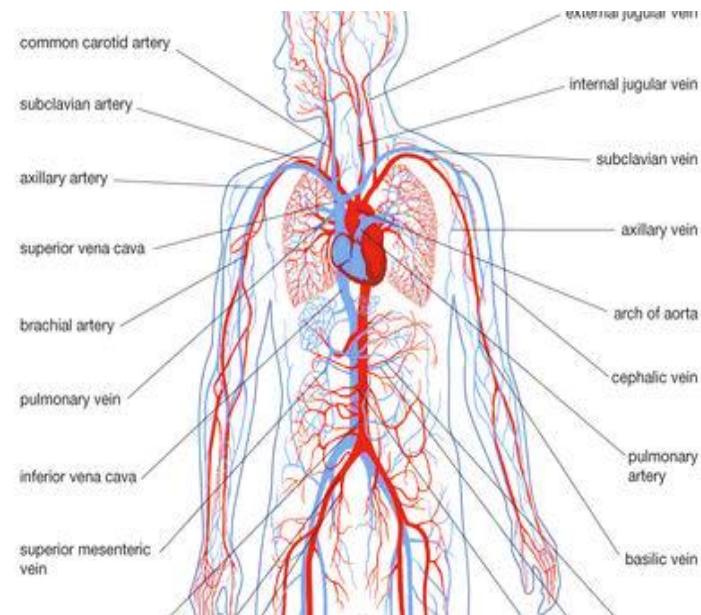


Figure 1-1 cardiovascular system

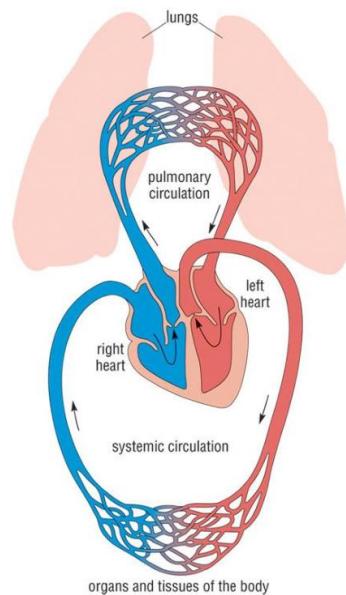


Figure 1-2 circulatory system

The human circulatory system is a closed loop system comprised of two circulations that are in series: pulmonary and systemic. The heart supports this circulation (upper section (pulmonary), lower section (systemic)).

The heart is a positive displacement pulsatile pump; fluid flow is created by a moving physical boundary and occurs at intervals. The geometry of the left and right structures reflects the characteristics of the circulations they are serving.

The pressure from ejection of the right ventricle into the lungs is roughly **15-30 mmHg** and the return pressure to the left atrium is on the order of **3-14 mmHg**. The flow through the lungs is low pressure and the tissues in this region are highly elastic. These characteristics almost completely dampen the pressure pulse from the right ventricle ejection. This enables the pulmonary system to have a large flow capacity at low pressures. Due to the larger network and geometries of the vessels, this system is under higher pressure and is less elastic in nature.

The systemic circulation's arterial pressures (SCAP)

- For healthy people: **SCAP systole (100-120 / 140 mmHg)**, **SCAP diastole (60-80 / 90 mmHg)**.
- The return pressure from the systemic circulation, via the vena cava, to the right atrium is roughly (3-8 mmHg).

1.2 Cardiovascular system

To understand the physiology of the heart, it is important to understand the cardiac output, stroke volume, preload, Frank-Starling law, afterload, and ejection fraction.

Cardiac Output

The cardiac output (CO) is the amount of blood ejected from the left ventricle; normally, it equals the venous return. The calculation is $CO = \text{stroke volume (SV)} \times \text{heart rate (HR)}$. CO also equals the rate of oxygen consumption divided by the difference in arterial and venous oxygen content.

SV

The SV is the amount of blood pumped out of the heart after 1 contraction. It is the difference between end-diastolic (EDV) and end-systolic (ESV) volume. It increases with increased contractility, increased preload, and decreased afterload. Also, the left ventricle's contractility increases with catecholamines by increasing intracellular calcium ions and lowering extracellular sodium.

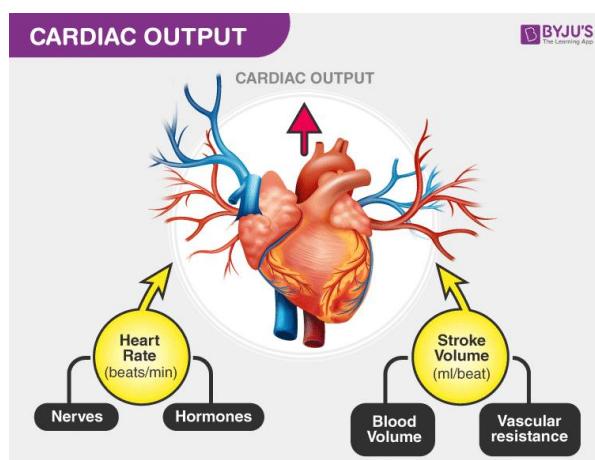


Figure 1-3 Cardiac Output

Preload

The preload is the pressure on the ventricular muscle by the ventricular EDV.

Frank-Starling Law

Frank-Starling law describes the relationship between EDV and SV. This law states that the heart attempts to equalize CO with venous return. As venous return increases, a larger EDV in the left ventricle leads to further stretching of the ventricle, leading to a larger contraction force and a larger SV. A larger SV leads to a larger CO, thus equalizing CO with venous return.

Afterload

Afterload is the pressure the left ventricular must exceed to push blood forward. Mean arterial pressure best estimates this. Also, afterload can be estimated by the minimum pressure needed to open the aortic valve, equivalent to the diastolic pressure. Thus, diastolic blood pressure is one of the better ways to index afterload.

Ejection Fraction

The ejection fraction (EF) equals SV/EDV. EF of the left ventricle is an index for contractility. A normal EF is greater than 55%. A low EF indicates heart failure.

Cardiac Cycle

The cardiac cycle describes the path of the blood through the heart. It runs in the following order:

- Atrial contraction closure of the mitral valve
- Isovolumetric phase
- Opening of the aortic valve
- Ejection phase (rapid and reduced ejection), emptying of the left ventricle
- Closure of the aortic valve
- Isovolumetric relaxation
- The opening of the mitral valve
- The filling phase (rapid and reduced filling) of the left ventricle

Vasculature plays a significant role in regulating blood flow throughout the body. In general, blood pressure decreases from arteries to veins, and this is because of the pressure overcoming the resistance of the vessels. The greater the change in resistance at any point in the vasculature, the greater the pressure loss. Arterioles have the most increase in resistance and cause the largest decrease in blood pressure. The constriction of arterioles increases resistance, which causes a decrease in blood flow to downstream capillaries and a larger decrease in blood

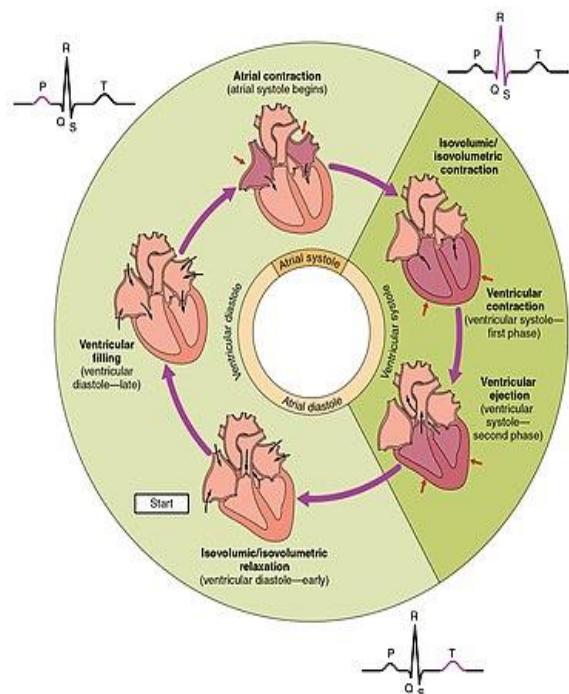


Figure 1-4 Cardiac Cycle

pressure. Dilation of arterioles causes a decrease in resistance, increasing blood flow to downstream capillaries and a smaller decrease in blood pressure.

Diastolic Blood Pressure

Diastolic blood pressure (DP) is the lowest pressure in an artery at the beginning of the cardiac cycle while the ventricles are relaxing and filling. DP is directly proportional to total peripheral resistance (TPR). Also, the energy stored in the compliant aorta during systole is now released by the recoil of the aortic wall during diastole, thus increasing diastolic pressure.

Systolic Blood Pressure

Systolic blood pressure (SP) is the peak pressure in an artery at the end of the cardiac cycle while the ventricles contract. It is directly related to stroke volume; as stroke volume increases, SP also increases. SP is also affected by aortic compliance. Because the aorta is elastic, it stretches and stores the energy caused by ventricular contraction, decreasing the SP.

Pulse Pressure

Pulse pressure is the difference between SP and DP. Pulse pressure is proportional to SV and inversely proportional to arterial compliance. Thus, the stiffer the artery, the larger the pulse pressure.

Mean Arterial Pressure

Mean arterial pressure (MAP) is the average pressure in the arteries throughout the cardiac cycle. The MAP is always closer to DP. MAP is calculated by $MAP = DP + \frac{1}{3} (pulse\ pressure)$. Also, $MAP = CO \times TPR$. This value is significant because whenever CO decreases, the TPR increases to maintain the MAP, which is relevant in many pathophysiology problems.

Velocity

Systemic veins have a lower decrease in pressure because they have low resistance. The venous system is very compliant and contains up to 70% of the circulating blood. A small change in venous pressure can mobilize the blood stored in the venous system. The velocity of blood in the vasculature has an inverse relationship with the cross-sectional area: volumetric flow rate (Q) = flow velocity (v) \times cross-sectional area (A).

As the cross-sectional area increases, velocity decreases. Arteries and veins have smaller cross-sectional areas and the highest velocities, whereas capillaries have the most cross-sectional and lowest velocities. The vasculature also gives resistance; resistance is $R = (8 * viscosity * length) / (\pi r^4)$. Viscosity depends on hematocrit and increases in multiple myeloma or polycythemia. As tube length increases, the resistance increases. As the tube radius increases, the resistance decreases. The fact that the radius is to the power of 4 means that slight changes in the radius profoundly affect resistance. The total resistance of vessels in a series is $R_1 + R_2 + R_3$, and so on, and the total resistance of arteries in parallel is $1/TR = 1/R_1 + 1/R_2 + 1/R$ and so on, where TR is the total resistance.

Poiseuille Equation

The Poiseuille equation measures the flow of blood through a vessel. It is measured by the change in pressure divided by resistance: $\text{Flow} = (P_1 - P_2)/R$, where P is pressure, and R is resistance. Increasing resistance in a vessel, such as the constriction of an arteriole, causes a decrease in blood flow across the arteriole. At the same time, there is a larger decrease in pressure across this point because the pressure is lost by overcoming the resistance. Increasing the resistance at any point increases upstream pressure but decreases downstream pressure. The Poiseuille equation applies to the systemic circulation such that F is the cardiac output (CO), P_1 is the mean arterial pressure (MAP), P_2 is the right atrial pressure (RAP), and R is the total peripheral resistance (TPR). Because RAP is close to 0 and very small compared to MAP, the equation approximates $F=P_1/R$ or $\text{CO}=\text{MAP}/\text{TPR}$, where $\text{MAP}=\text{CO}*\text{TPR}$ means cardiac output and total peripheral resistance control MAP. Its application is important because in trauma situations with hemorrhage, there is also a decrease in cardiac output, but at times, the blood pressure is near normal. This is because the TPR at the level of the arterioles has increased. As applied to the pulmonary vasculature, this equation determines the cause of pulmonary hypertension. As related to the pulmonary vasculature, F represents CO, P_1 represents pulmonary artery pressure (PAP), P_2 represents left atrial pressure (LAP), and R is pulmonary vascular resistance (PR); $\text{CO}=(\text{PAP}-\text{LAP})/\text{PR}$. A Swan-Ganz catheter helps to measure both PAP and LAP, allowing for the measurement of PR and, thus, the etiology of pulmonary hypertension.

Baroreceptors and Chemoreceptors

The nervous system regulates the cardiovascular system with the help of baroreceptors and chemoreceptors. Both receptors are located in the carotid and aortic arch. Also, both have afferent signals through the vagus nerve from the aortic arch and afferent signals through the glossopharyngeal nerve from the carotids.

Baroreceptors are more specifically located in the carotid sinus and aortic arch. They respond quickly to changes in blood pressure. A decrease in blood pressure or blood volume causes hypotension, which leads to a decrease in arterial pressure. This decrease in arterial pressure decreases the baroreceptors' stretch and decreases afferent baroreceptor signaling. This decrease in afferent signaling from the baroreceptor causes an increase in efferent sympathetic activity and a reduction in parasympathetic activity, which leads to vasoconstriction, increased heart rate, increased contractility, and an increase in BP. The vasoconstriction increases TPR in the equation $\text{MAP}=\text{CO}*\text{TPR}$ to increase pressure (MAP). An increase in blood pressure or blood volume causes hypertension, increasing the baroreceptors' stretch.

Chemoreceptors come in 2 types: peripheral and central. Peripheral chemoreceptors are specifically located in the carotid body and aortic arch. They respond to oxygen levels, carbon dioxide levels, and the pH of the blood. They become stimulated when oxygen decreases, carbon dioxide increases and the pH decreases. Central chemoreceptors are located in the medulla oblongata and measure the cerebral spinal fluid's pH and carbon dioxide changes.

Autoregulation

Autoregulation is how an organ or tissue maintains blood flow despite a change in perfusion pressure. When blood flow decreases to an organ, arterioles dilate to reduce resistance.

- **Myogenic theory:** Myogenic regulation is intrinsic to the vascular smooth muscle. When there is an increase in perfusion, the vascular smooth muscle is stretched. This causes it to constrict the artery. If there is a decrease in perfusion to the arteriole, then there is decreased stretching of the smooth muscle. This leads to the smooth muscles' relaxation and arteriole dilation.
- **Metabolic theory:** Blood flow is closely related to metabolic activity. When there is an increase in metabolism to muscle or any tissue, there is an increase in blood flow to that location. Metabolic activity creates substances that are vasoactive and stimulate vasodilation. The increase or decrease in metabolism leads to increased or decreased metabolic byproducts that cause vasodilation. Increased adenosine, carbon dioxide, potassium, hydrogen ions, lactic acid levels, decreased oxygen levels, and increased oxygen demand all lead to vasodilation. Adenosine is from AMP, which derives from the hydrolysis of ATP and increases during hypoxia or increased oxygen consumption. Potassium is increased extracellularly during metabolic activity (muscle contraction) and directly affects the relaxing of smooth muscles. Carbon dioxide is produced as a byproduct of the oxidative pathway and increases with metabolic activity. Carbon dioxide diffuses to the smooth vascular muscle and triggers an intracellular relaxing pathway.
- **Heart:** Metabolites that cause coronary vasodilation include adenosine, NO, carbon dioxide, and low oxygen.
- **Brain:** The primary metabolite controlling cerebral blood flow is..... carbon dioxide. An increase in arterial carbon dioxide causes vasodilation of cerebral vasculature. A decrease in arterial carbon dioxide causes vasoconstriction of the cerebral vasculature. Hydrogen ions do not cross the blood-brain barrier and thus are not a factor in regulating cerebral blood flow. A decrease in oxygen pressure in arteries causes vasodilation of the cerebral arteries; however, an increase in oxygen pressure in arteries does not cause vasoconstriction.
- **Kidneys:** Autoregulation of the kidneys is myogenic and with tubuloglomerular feedback. In severe cases of hypotension, kidney arterioles constrict, and renal function is lost.
- **Lungs:** Hypoxia of the lungs causes vasoconstriction, creating a shunt away from poorly ventilated areas of the lung and redirecting perfusion to ventilated portions of the lung.
- **Skeletal muscle:** Adenosine, potassium, hydrogen ion, lactate, and carbon dioxide all increase during exercise and cause vasodilation. When resting, the skeletal muscle is controlled extrinsically by sympathetic activity, not metabolites.
- **Skin:** Skin regulation occurs through sympathetic stimulation. The purpose of regulating blood flow in the skin is to regulate body temperature. In a warm environment, skin vasculature dilates due to decreased sympathetic stimulation. In cold

environments, skin vasculature constricts due to increased sympathetic activity. During fever, body temperature regulation is at a higher setpoint.

The starling equation can explain the capillary fluid exchange. This equation describes oncotic and hydrostatic pressure forces on fluid movement across the capillary membrane. Edema can result from increased capillary pressure (heart failure), decreased plasma proteins (liver failure), increased interstitial fluid due to lymphatic blockage, or increased capillary permeability due to infections or burns.

1.3 Heart mechanism

Each day, your heart beats around 100,000 times. This continuously pumps about five liters (eight pints) of blood around your body through a network of blood vessels called your circulatory system. This blood delivers oxygen and nutrients to all parts of your body to help your organs and muscles work properly. Your blood also carries away unwanted carbon dioxide and waste products.

1.3.1 Structure of the heart

Your heart has a left side and a right side, they are separated by a thin muscular wall called the Septum. Both sides of your heart have an upper chamber and a lower chamber.

- The upper chambers are called the **left atrium** and the **right atrium** (or the atria)
- The lower chambers are called the **left ventricle** and the **right ventricle**.

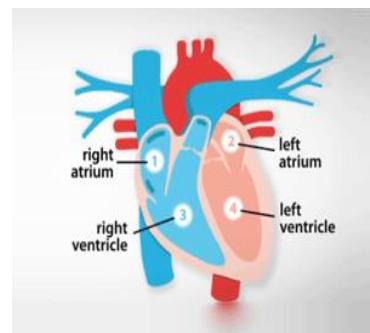


Figure 1-5 Heart

The right side of your heart receives the de-oxygenated blood that has just travelled round your body. It pumps the blood to your lungs to collect a fresh supply of oxygen. The left side of your heart pumps the re-oxygenated blood round your body again.

Your heart muscle is made up of three layers of tissue:

- **Pericardium** – a thin, outer lining that protects and surrounds your heart.
- **Myocardium** – a thick, muscular middle layer that contracts and relaxes to pump blood around your heart.
- **Endocardium** – a thin, inner layer that makes up the lining of the four chambers and the valves in your heart.

1.3.2 Heart's electrical system

Your heart's electrical system tells your heart when to contract and when to relax to keep your blood pumping regularly. The instructions to contract and relax are carried by electrical signals.

The electrical signals are sent from the sinus node which is known as your heart's natural pacemaker. Usually, the sinus node will send the electrical signals at a steady pace, but the

pace can change depending on your emotions and if you are active or resting – this is your heart rate.

1.3.3 How does blood flow around the heart and the body

Your heart is linked to the rest of the circulatory system with blood vessels called arteries and veins.

- Your arteries deliver oxygen-rich blood from the heart to other areas of your body
- Your veins return the de-oxygenated blood from your organs back to your heart
- Your arteries and veins are connected by even smaller blood vessels called capillaries.

Your blood flows around your heart and the rest of your body in one direction, like a one-way traffic system. Your heart valves control the direction of your blood flow, they act like doors that open and close with every heartbeat. There are four valves in your heart, they are:

- The **tricuspid valve** and the **pulmonary valve** on the right side of the heart.
- The **mitral valve** and the **aortic valve** on the left side of your heart.

Like the rest of your body, your heart needs to be supplied with oxygen-rich blood to work properly too. The coronary arteries are the arteries responsible for supplying the heart with oxygenated blood. The coronary arteries are spread across the outside of the heart to deliver the blood.

1.3.4 How to add oxygen to the blood

Your blood flows through your heart and your lungs to become re-oxygenated before being pumped to the rest of your body. Oxygen is added to your blood in four main steps, they are:

- ⇒ The right atrium receives the low-oxygen blood that has just travelled round the body. The right atrium pumps the blood to the right ventricle.
- ⇒ The right ventricle pumps the low-oxygen blood to the lungs to pick up a fresh supply of oxygen.
- ⇒ The left atrium receives high-oxygen blood from the lungs and pumps it to the left ventricle.
- ⇒ The left ventricle pumps the high-oxygen blood to the rest of the body.

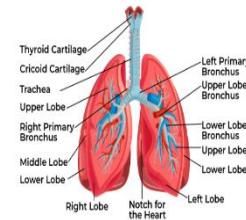


Figure 1-6 Lung

1.4 Heart diseases

Heart diseases, also known as cardiovascular diseases (CVDs), encompass a range of conditions affecting the heart and blood vessels. These diseases are the leading cause of death globally, with multiple underlying causes contributing to their development. Here is an in-depth look at various types of heart diseases and their causes:

1.4.1 Types of Heart Diseases

1.4.1.1 Coronary Artery Disease (CAD)

Description: The most common type of heart disease, CAD occurs when the coronary arteries, which supply blood to the heart muscle, become narrowed or blocked due to atherosclerosis (buildup of plaque).

Causes:

- **Atherosclerosis:** Plaque buildup (cholesterol, fat, and other substances) on artery walls.
- **Risk Factors:** High blood pressure, high cholesterol, smoking, diabetes, sedentary lifestyle, unhealthy diet, obesity, and genetic factors.

1.4.1.2 Heart Attack (Myocardial Infarction)

Description: A heart attack occurs when blood flow to a part of the heart is blocked for a long enough time that part of the heart muscle is damaged or dies.

Causes:

- **Blockage:** Usually caused by a blood clot in a coronary artery, often due to a ruptured plaque.
- **Risk Factors:** Similar to those of CAD, including smoking, high blood pressure, high cholesterol, diabetes, obesity, and stress.

1.4.1.3 Heart Failure

Description: A condition where the heart is unable to pump blood efficiently to meet the body's needs.

Causes:

- **Coronary Artery Disease:** Leading to weakened heart muscle.
- **High Blood Pressure:** Forces the heart to work harder, eventually weakening it.

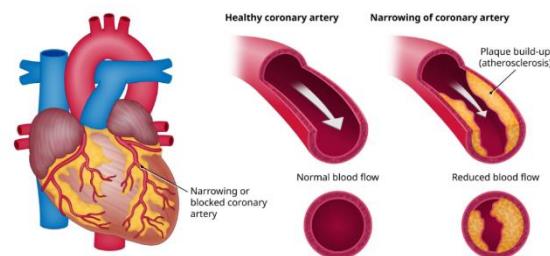


Figure 1-7 Coronary Artery Disease

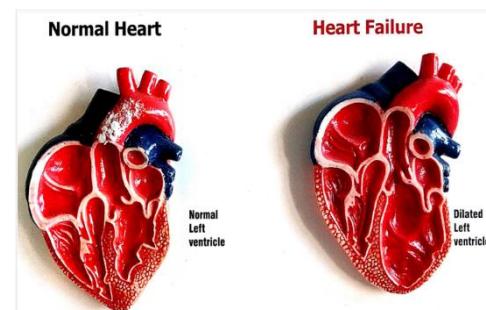
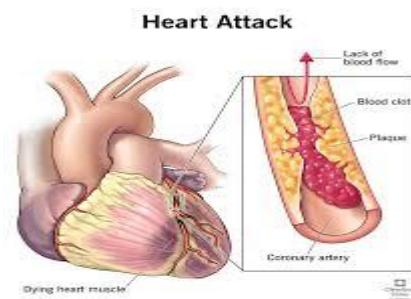


Figure 1-8 Heart Attack

- **Cardiomyopathy:** Diseases of the heart muscle (genetic, alcohol abuse, infections).
- **Valvular Heart Disease:** Malfunctioning heart valves.
- **Arrhythmias:** Abnormal heart rhythms.

1.4.1.4 Arrhythmias

Description: Abnormal heart rhythms, which can be too fast (tachycardia), too slow (bradycardia), or irregular.

Causes:

- **Electrical Conduction Issues:** Problems in the heart's electrical system.
- **Heart Damage:** From heart attack, CAD, or other heart diseases.
- **Electrolyte Imbalances:** In the blood.
- **Substances:** Caffeine, alcohol, drugs, and certain medications.

1.4.1.5 Valvular Heart Disease

Description: Damage to or defect in one of the four heart valves.

Causes:

- **Rheumatic Fever:** Resulting from untreated strep throat.
- **Congenital Defects:** Valve abnormalities present at birth.
- **Degenerative Changes:** Due to aging.
- **Infections:** Such as infective endocarditis.

1.4.1.6 Congenital Heart Disease

Description: Malformations of heart structures present from birth.

Causes:

- **Genetic Factors:** Inherited conditions.
- **Environmental Factors:** Infections, alcohol or drug use during pregnancy.

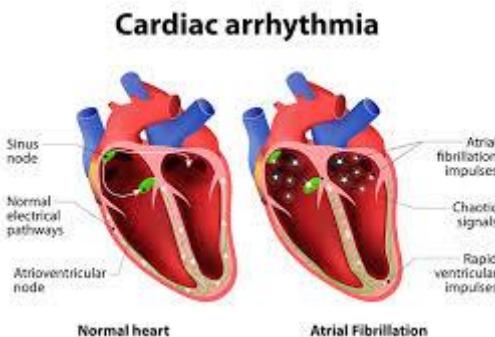


Figure 1-9 Cardiac Arrhythmias

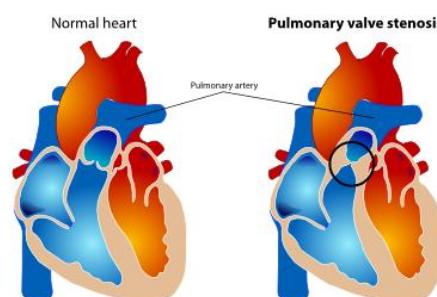
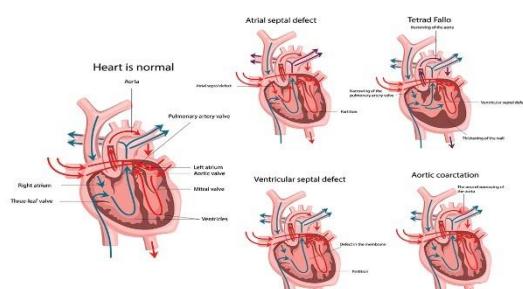


Figure 1-10 Valvular Heart Disease

Congenital heart disease



1.4.1.7 Cardiomyopathy

Description: Diseases of the heart muscle that can lead to heart failure.

Causes:

- **Genetic Factors:** Inherited conditions.
- **Chronic High Blood Pressure:** Leading to hypertrophic cardiomyopathy.
- **Infections:** Viral myocarditis.
- **Toxins:** Alcohol, drugs, chemotherapy.

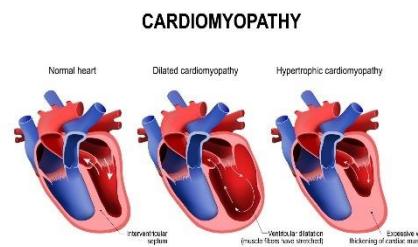


Figure 1-11 Cardiomyopathy

1.4.2 Causes and Risk Factors in Detail

1.4.2.1 Atherosclerosis

Mechanism: Cholesterol and fatty deposits build up on the inner walls of arteries, leading to hardening and narrowing, which restricts blood flow.

Risk Factors:

- **High LDL Cholesterol:** Low-density lipoprotein, often called "bad" cholesterol.
- **Low HDL Cholesterol:** High-density lipoprotein, known as "good" cholesterol.
- **High Triglycerides:** A type of fat in the blood.
- **High Blood Pressure:** Damages artery walls, making them more susceptible to plaque buildup.
- **Smoking:** Contributes to atherosclerosis and increases heart disease risk.

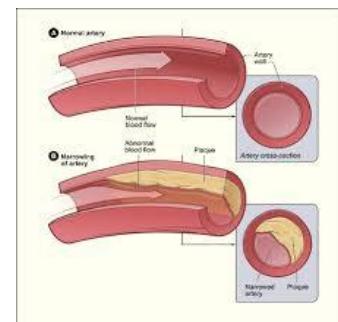


Figure 1-12 Atherosclerosis

1.4.2.2 High Blood Pressure (Hypertension)

Mechanism: Persistent high pressure in the arteries can damage the heart and arteries, leading to heart disease.

Risk Factors:

- **Excessive Salt Intake:** Can increase blood pressure.
- **Obesity:** Leads to increased blood pressure.
- **Sedentary Lifestyle:** Lack of physical activity contributes to high blood pressure.
- **Alcohol:** Excessive consumption can raise blood pressure.
- **Stress:** Chronic stress can contribute to hypertension.

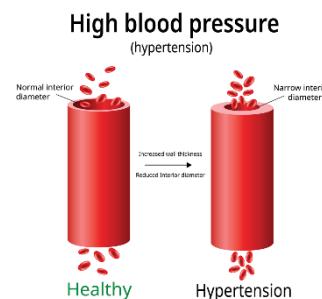


Figure 1-13 High Blood Pressure (Hypertension)

1.4.2.3 Diabetes

Mechanism: High blood glucose levels can damage blood vessels and the nerves that control the heart.

Risk Factors:

- **Type 1 Diabetes:** Usually diagnosed in childhood; the body cannot produce insulin.
- **Type 2 Diabetes:** Often linked to obesity and a sedentary lifestyle; the body becomes resistant to insulin.

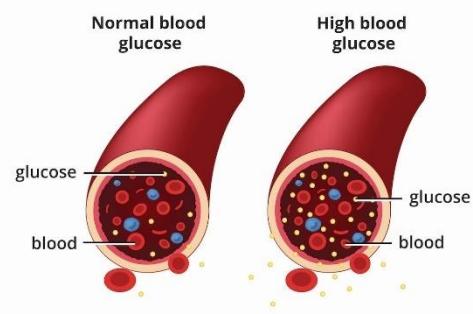


Figure 1-14 Diabetes

1.4.2.4 Lifestyle Factors

Poor Diet: Diets high in saturated fats, trans fats, cholesterol, and sodium can contribute to heart disease.

Lack of Exercise: Physical inactivity can lead to obesity, high blood pressure, and poor heart health.

Smoking: Damages blood vessels and heart tissue, increases blood pressure, and reduces oxygen in the blood.

1.4.2.5 Genetic Factors

Family History: A family history of heart disease can increase risk, indicating a genetic predisposition.

Inherited Disorders: Certain genetic conditions, such as familial hypercholesterolemia, increase the risk of heart disease.

1.4.2.6 Other Factors

Age: Risk of heart disease increases with age.

Gender: Men are generally at higher risk at a younger age, but the risk for women increases and equals that of men after menopause.

Chronic Stress: Long-term stress may increase the risk of heart disease.

Alcohol: Moderate alcohol consumption may have some benefits, but excessive drinking is harmful.

Heart diseases are complex and multifactorial conditions with numerous contributing factors, ranging from lifestyle choices to genetic predispositions. Prevention strategies involve managing risk factors through healthy lifestyle changes, regular medical check-ups, and medications when necessary. Understanding these causes and risk factors is crucial in reducing the global burden of cardiovascular diseases.

1.5 Cardiac Assist Devices

Congestive heart failure (CHF) is a debilitating condition that afflicts tens of millions of people worldwide and is responsible for more deaths each year than all cancers combined. Because donor hearts for transplantation are in short supply, a safe and durable means of mechanical circulatory support could extend the lives and reduce the suffering of millions. But while the profusion of blood pumps available to clinicians in 2019 tend to work extremely well in the short term (hours to weeks/months), every long-term cardiac assist device on the market today is limited by the same two problems: infections caused by percutaneous drivelines and thrombotic events associated with the use of blood-contacting surfaces. A fundamental change in device design is needed to address both these problems and ultimately make a device that can support the heart indefinitely. Toward that end, several groups are currently developing devices without blood-contacting surfaces and/or extracorporeal power sources with the aim of providing a safe, tether-free means to support the failing heart over extended periods of time.

1.5.1 The need for Mechanical Circulatory Support

Congestive heart failure (CHF) is a progressive condition in which cardiac function deteriorates over time. It is most common among people 65 years or older, but practically anyone can be at risk as the causes of heart failure include everything from coronary artery disease, high blood pressure, and congenital heart defects to myocarditis, abnormal heart rhythms, valve disease, diabetes, and obesity. The most common symptoms of the disease include shortness of breath and fatigue, and it is often diagnosed via blood tests, electrocardiograms, echocardiograms, stress tests, coronary angiograms, and chest x-rays CHF remains one of the most costly diseases in the industrialized world, both in terms of healthcare dollars and the loss of human life. It is estimated that 26 million people currently suffer from CHF worldwide, including 5.8 million people in the United States where the economic impact exceeds \$40 billion per year in medical costs and lost productivity. Worse still, roughly half of all people who develop CHF die within five years of diagnosis due to the limitations of current long-term treatment strategies. Cardiac transplantation is generally considered to be the best recourse for end-stage CHF patients, but this treatment option is not available to most patients as the number of donated hearts is restricted by roughly 2200 hearts per year in the U.S. Pharmacologic therapies can improve heart function in the short term and relieve the symptoms associated with CHF, but are unable to restore and maintain normal heart function over the long term. Therefore, decades of development work have focused on cardiac assist devices (CADs) as an alternate solution for end-stage CHF patients.

1.5.2 The Types of Cardiac Assist Devices

1.5.2.1 Bridge devices

CADs are often categorized according to duration of support. If a device lasts from hours to weeks as a means to stabilize patients until longer-term mechanical support can be implemented, it is considered to be a ‘bridge-to-device (BTD)’. BTDs were commonly used for myocardial recovery and mitral valve replacement from the 1970s through early 1980s. Nowadays, only about 25% of cases use this temporary treatment option, typically for one to four weeks post-operation.

CADs may also be used to provide circulatory support to patients on the waiting list for heart transplantation, in which case they are considered to be ‘bridge-to-transplant (BTT)’ devices. While BTT devices do not last longer than 2 years on average, the longevity of CADs is much better today compared to that of the mid-80s where the typical working life of these devices was only about a month. Yet, this improvement does not increase the total number of patients who can receive a transplanted heart, but rather increases the chances of receiving a transplanted heart for patients receiving CAD treatment while proportionally reducing the odds for those who do not.

In rare instances that are difficult to predict, some patients recover cardiac function while under CAD support and no longer need heart transplantation. These cases are categorized—more often in retrospect than by design—as ‘bridge-to-recovery (BTR).

1.5.2.2 Destination therapy

Currently, the most ambitious unmet goal in the CAD field is to develop a cardiac support system for long-term or permanent use. A safe, reliable, durable, implantable support mechanism leading to the preservation, or even restoration, of cardiac competence and coronary flow that completely frees patients from the need for heart transplantation would be considered an effective device for ‘destination therapy (DT). In order to achieve this goal, researchers have focused on overcoming several major failure modes associated with extended circulatory support. In this paper, we review the historical efforts, contemporary technologies, and up-to-date cutting-edge innovations that have been made to develop durable and reliable devices that both support cardiac function for long-term survival and also provide for better patient quality-of-life.

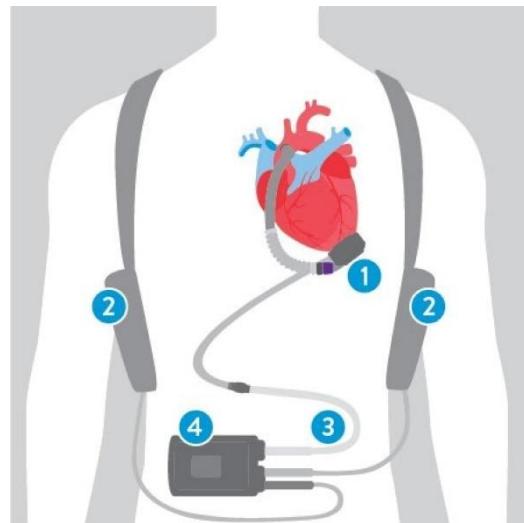


Figure 1-15 Bridge devices



Figure 1-16 Destination therapy

1.5.3 History of Cardiac Assist Devices

1.5.3.1 The beginning

The concept of artificial blood pumps can be traced as far back as 1813 when Le Gallios first performed the task by squeezing rubberized pumping chambers between pairs of wooden planks. But it was not until the 1960s when cardiac assist devices finally began to replace cardiopulmonary bypass circuits as a means to support the failing heart. The earliest mechanical assist devices were pneumatically driven. The first implantable artificial ventricles in clinical use was reported by Liotta in 1963 and it consisted of a pneumatically-compressed valved tubular conduit that connected the left atrium to the descending aorta. A double-lined restraint cup that wrapped around the ventricles and alternately inflated and deflated to displace blood from both ventricles (reported by G. Anstadt and P. Schiff in 1966) was also a pneumatic device. An air-powered balloon pump that provides effective left ventricular unloading and systemic circulatory support by displacing blood from the descending aorta during the diastolic phase of the cardiac cycle was first used clinically in 1968. Around the same time, the idea of complete replacement of the entire heart using a pneumatic total artificial heart (TAH) emerged and the implantation procedure was first performed clinically in 1969. However, because these early attempts risked a high rate of fatality from sudden device failures, focus shifted toward the use of simpler single-chambered mechanical blood pumps for univentricular support, known as ventricular assist devices or VADs.

1.5.3.2 First generation: Pulsatile Pumps

When VADs were first developed, they were designed to replicate the native cardiac cycle and generate pulsatile flow using a diaphragm and unidirectional artificial heart valves (Figure 4-3). The first generation VADs were either pneumatically or electrically driven and included larger pulsatile VADs like HeartMate XVE (Thoratec, Pleasanton, CA, USA) and Berlin Heart EXCOR (Berlin Heart, Berlin, Germany) that were used to support patients awaiting cardiac transplantation. These earlier pulsatile pumps were characterized by their large size, heavy weight, and an external driving unit that seriously limited patients' mobility. These first generation pulsatile VADs could be used either as a left ventricular assist device (LVAD), a right ventricular assist device (RVAD), or as a biventricular assist device (BiVAD).

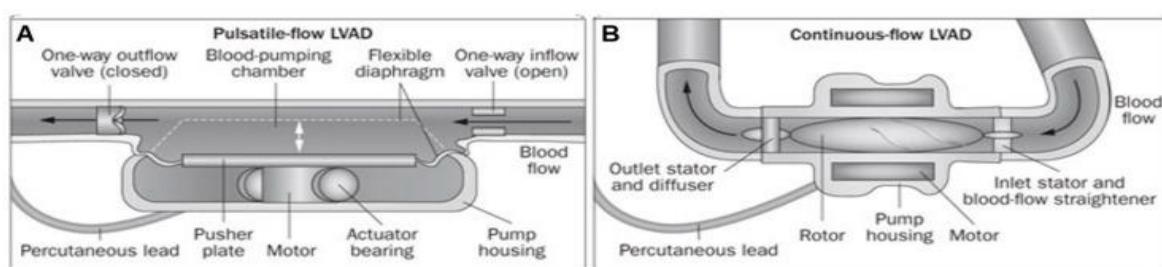


Figure 4-1-17 The first generation pulsatile-flow pumps (A) replicated the native cardiac cycle using a diaphragm and unidirectional artificial heart valves, while the second generation continuous-flow pumps (B) integrated a valveless axial pump designed to rapidly spin a single impeller.

1.5.3.2.1 LVAD

Because the left ventricle (LV) and right ventricle (RV) can be supported either separately or in unison, ventricular assistance is commonly separated into LVAD, RVAD, and BiVAD categories. With isolated LVAD therapy, the systemic circulation is typically supported by drawing blood from the left ventricular apex and pumping it into the ascending aorta. This not only restores perfusion to all organs and tissues outside the pulmonary circulation (including the heart itself), but also unloads the LV, which may prevent or even reverse pathologic LV remodeling caused by chronic pressure overload. Subsequent effects on RV function are complex however, as right-side improvements resulting from lower pulmonary pressures are offset by several factors that could lead to RV failure, including: increased preload, leftward shift and reduced contractility of the interventricular septum, increased work demand to match LVAD output, and tricuspid valvular distortions. The first successful LVAD implantation was completed by De Bakey in 1966, and the majority of cardiac support research has been dominated by LVAD developments for clinical practice ever since. Some first generation pulsatile LVADs include Novacor LVAS (Baxter Healthcare, Oakland, CA, USA), HeartMate I (Thoratec), and Thoratec PVAD (Thoratec).

1.5.3.2.2 RVAD

The clinical settings in which RVAD therapy are most commonly employed include acute myocardial infarction, pulmonary embolism, pulmonary hypertension, myocarditis, post-cardiotomy shock, cardiac transplantation, and LVAD implantation. As the frequency of LVAD use continues to rise, this last scenario is becoming increasingly common as nearly half of all CHF patients show right heart failure after LVAD implantation and 4% require RV support within the first two weeks post-operation. Because RV complications after LVAD surgery are both relatively frequent and highly significant in terms of morbidity and mortality, the means to provide right ventricular mechanical support is now considered an essential capability in medical centers where LVAD therapy is performed. Today, some RVADs like SynCardia (SynCardia Systems, Tucson, AZ, USA) serve as BTT while some others like Impella RP (AbioMed, Danvers, MA,

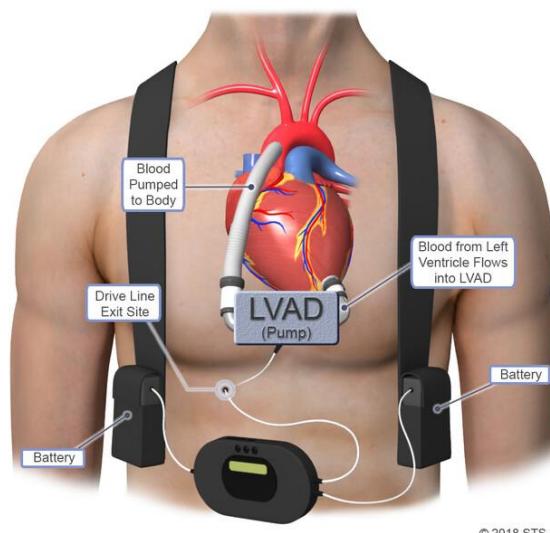


Figure 1-18 LVAD

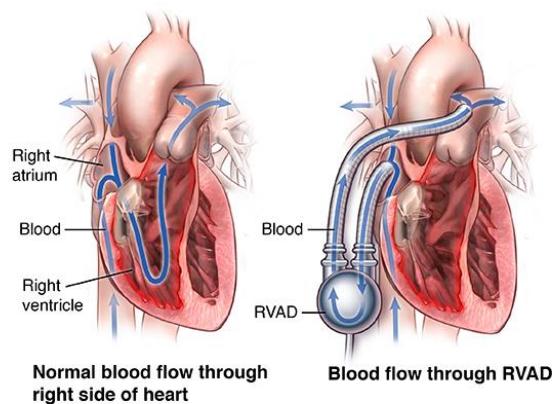


Figure 1-19 RVAD

USA), TandemHeart (CardiacAssist, Pittsburgh, PA, USA), and CentriMag RVAD (Thoratec) serve as peri-operative bridges to mechanical support.

1.5.3.2.3 BiVAD

While the majority of patients retain sufficient RV function throughout the course of LVAD therapy to avoid the need for ancillary support, nearly 48% of LVAD recipients experience sufficient levels of postoperative RV dysfunction to warrant the use of a biventricular assist device. BiVAD is especially helpful for patients with total heart failure because it supports both sides of the failing heart by balancing left and right pump flows and, in rare cases, inducing myocardial recovery. The first generation pulsatile BiVADs have saved many lives, but are limited by their bulkiness, the necessity of a large external pneumatic driver that inhibits patient mobility, infection at the driveline site, and thrombus formation. Some first generation BiVADs include AbioMed BVS5000 (AbioMed), Berlin Heart EXCOR (Berlin Heart), and Medos HIA-VAD (Stolberg, Germany).

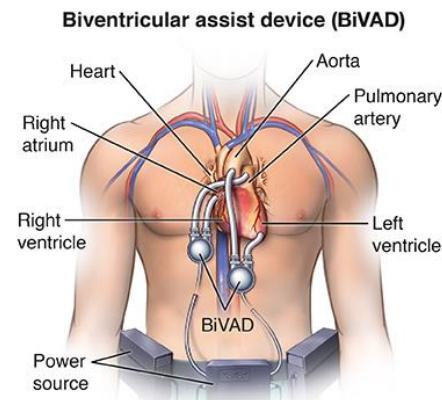


Figure 1-20 BiVAD

1.5.3.2.4 Total Artificial Heart

Total artificial hearts (TAHs) are designed to entirely replace native heart function over extended periods to treat end-stage CHF. The first human TAH implantation was performed in 1969 by Denton Cooley using the Liotta artificial heart as a bridge to cardiac transplantation. The patient was supported on this pneumatic device for three days during which time hemolysis and deteriorating renal function prompted surgeons to replace the pump with a donor heart that failed 36 h later. It was not until 1982 when the Jarvik-7 TAH (Jarvik Heart, New York, NY, USA) was able to support a patient for 112 days that these devices were generally considered a viable means to support patients for BTT. CardioWest (SynCardia), which the Jarvik 7 later became, and Abiocor (AbioMed) are examples of TAHs that have been used clinically.

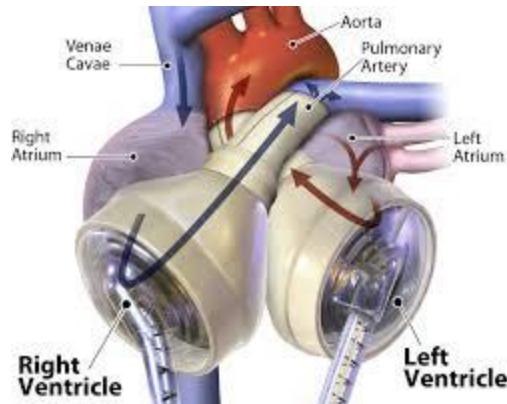


Figure 1-21 Total Artificial Heart

1.5.3.3 Second Generation: Continuous Axial Flow Pumps

Because first generation pulsatile pumps were limited by their large size, high noise emission, and durability issues leading to frequent malfunction and morbidity, research to develop smaller and more reliable devices were initiated and continued through the 1990s. As a result of this work, Thoratec introduced a new VAD in 2001 called HeartMate II that was just one-seventh the size and one-quarter the weight of the original HeartMate XVE. This radical design change was achieved by integrating a valveless axial pump with a variable magnetic field

designed to rapidly spin a single impeller that produces continuous outflow directed in parallel to the axis of rotation (Figure 4-3 B). HeartMate II received FDA approval for BTT in 2008 and for destination therapy in 2010. To date, over 26,600 patients have received HeartMate II LVAD demonstrating 85% survival at one year. Other axial flow pumps developed during this same time period included Hemopump (Medtronic), DeBakey VAD (Micromed), HeartAssist-5 (Reliant Heart, Houston, TX, USA), Jarvik 2000 (Jarvik Heart), Impella (Abiomed), and Incor (Berlin Heart). These second generation LVADs were able to provide patients with a better quality of life, mobility, and restoration of heart function compared to the first generation positive displacement VADs, but still relied on extracorporeal power sources and required patients to undergo constant anticoagulation therapy for the duration of the implant due to the risk of thromboembolic events.

1.5.3.4 Third Generation: Continuous Centrifugal Pumps

The third generation LVADs are continuous flow centrifugal pumps designed with magnetic and/or hydrodynamic levitation of the impeller with non-contact bearings and its outflow directed perpendicular to the axis of rotation. These radial rotary pumps feature further reduced device size, noise emission, infection rate, and prothrombotic sites for better patient outcomes and lifestyles. Now that nearly 99% of LVADs placed are continuous flow LVADs (CF-LVADs) today, third generation centrifugal pumps such as HeartWare HVAD (HeartWare), HeartMate III (Thoratec), CentriMag (Thoratec), Incor (Berlin Heart), Levacor (World Heart, Salt Lake City, UT, USA), and DuraHeart (Terumo Heart, Ann Arbor, MI, USA) play big roles. HeartWare HVAD and HeartMate III received FDA approval for long-term mechanical circulatory support in 2017 and 2018, respectively, and CentriMag was approved to support one or both sides of the heart for up to 30 days in patients. Some other milestones in VAD development history are summarized in the timeline shown in [Figure 2](#), while some of the most popularly used first-, second-, and third-generation VADs are illustrated in [Figure 3](#). Despite significant improvements in device function and durability, however, complications like right heart failure, infection, thrombosis, hemolysis, and neurologic events still persist.

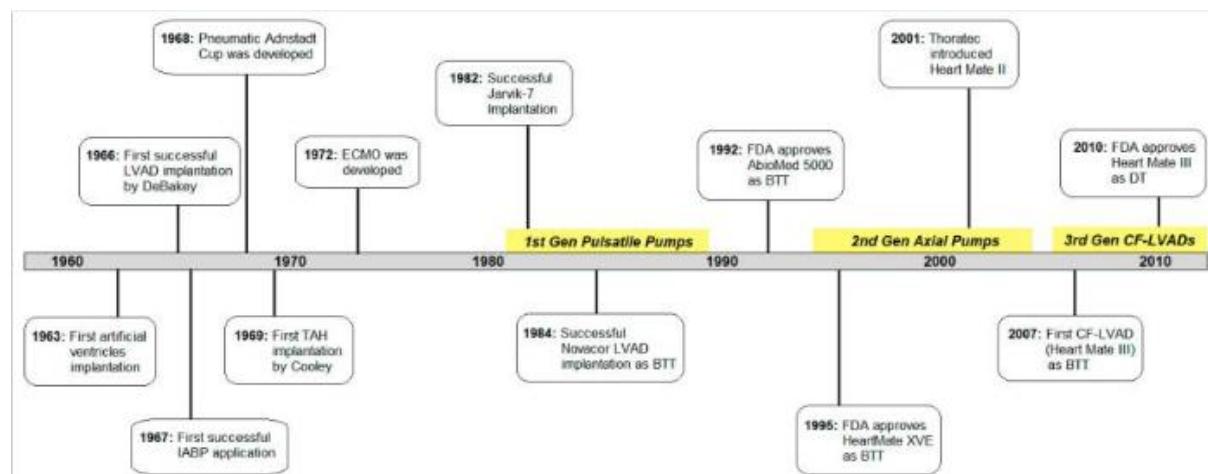


Figure 1-22 Timeline of important milestones of cardiac assist device (CAD) development history

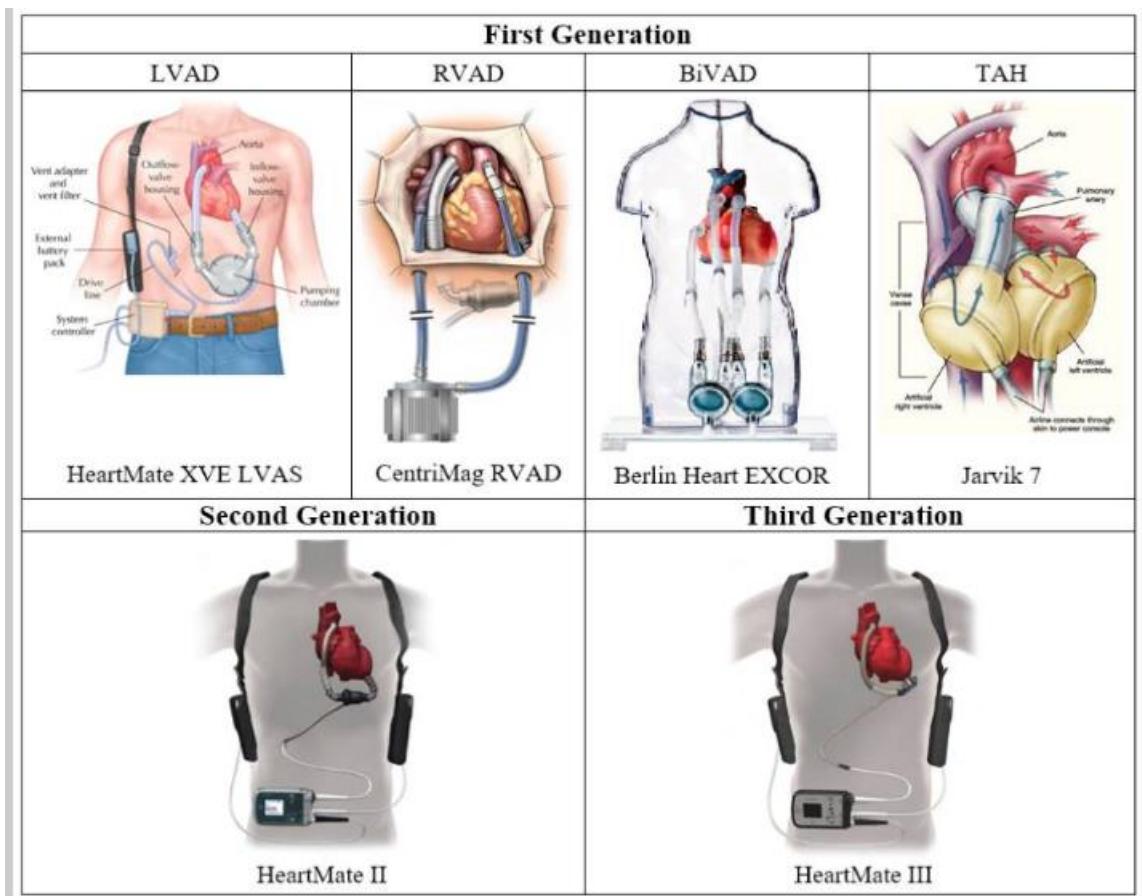


Figure 1-23 Examples of first, second, and third generation cardiac assist devices.

1.5.4 CADs in Clinical Settings Today

After five-plus decades of dedicated research aimed at developing blood pump technologies to support the failing heart, a cadre of devices capable of delivering different levels of support at different levels of invasiveness are now available to treat different varieties and severities of cardiac malfunction. These range from acute catheter-based interventions used for partial univentricular support to long-term implantable pumps designed to restore normal perfusion levels in both systemic and pulmonary circulations. Although guidance on patient selection for mechanical support is limited, the criteria usually include a combination of factors such as patient age, body size, cardiac malfunction type, disease stage, and candidacy for organ transplantation. For example, patients who require immediate VAD replacement due to the severity of their symptoms and/or are expected to have longer than normal wait times on the transplant list due to their body size and blood type are generally considered to be candidates for BTT devices. Alternatively, patients who require circulatory support but for some reason cannot be—or do not wish to be—listed for cardiac transplantation surgery are treated as destination therapy candidates.

1.5.4.1 Short-term Circulatory Support

1.5.4.1.1 Extracorporeal membrane oxygenation

Is a form of cardiopulmonary bypass that is used as a bridge to recovery, transplantation, or mechanical circulatory support. It provides blood oxygenation and circulation with a mechanical pump stationed outside the body. ECMO is generally used in an emergent setting and continued until symptoms are improved, but the typical time course is hours to days because long-term ECMO support increases the likelihood of thrombotic complications. Even though ECMO has been in clinical use as a class II/III device for over 30 years, the decision to use it remains a risk vs. benefit situation because complication rates are high as occurrences of bleeding and infection reach up to 40% and 31%, respectively. Patients with neurologic injuries, hemorrhage, immunosuppression, and/or advanced age are generally thought to be poor candidates for ECMO treatment.

1.5.4.1.2 AbioMed's Impella catheter

Is an intravascular micro axial blood pump that provides partial circulatory support from a few hours to one month maximum. Left ventricular Impella catheters come in three different models: Impella 2.5, Impella CP, and Impella 5.0, which produce flow rates up to 2.5 L/min, 3.5 L/min, and 5.0 L/min, respectively. All three are designed to circulate blood by placing their inlet in the LV and outlet in the ascending aorta. Similarly, there is Impella RP designed for partial right sided circulatory support, which provides up to 4.0 L/min of blood flow to the pulmonary circulation. Just last year in 2018, Impella Ventricular Support System received approval for expanded FDA indications for cardiomyopathy and percutaneous coronary intervention procedures after demonstrating its safety and effectiveness on over 50,000 patients treated from 2008 to 2017. One major caveat with these devices is that their proper function is highly dependent on the correct position of the catheters, which makes post-implant management of these catheter-based pumps critically important. All

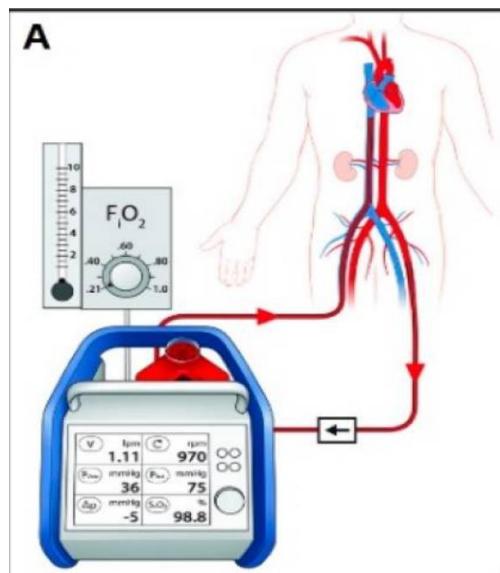


Figure 1-24 Extracorporeal membrane oxygenation

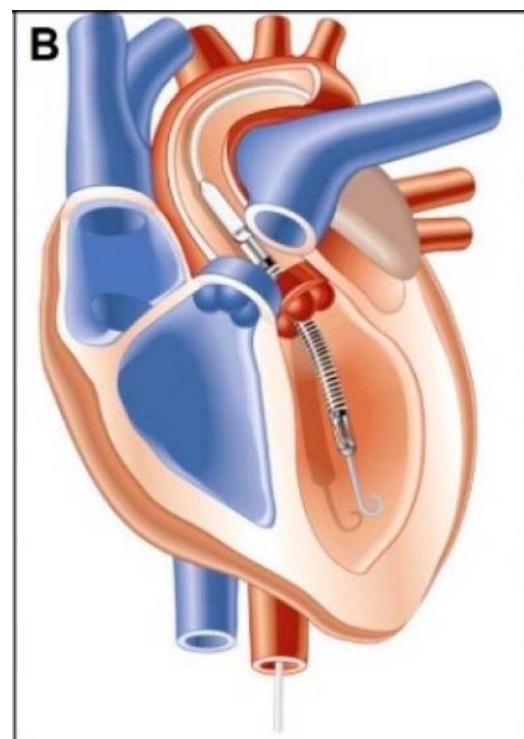


Figure 1-25 AbioMed's Impella catheter

models come with an Automated Impella Controller (AIC) that monitors and controls the overall system.

1.5.4.1.3 Pneumatic intra-aortic balloon pumps (IABP)

Which are internal counter pulsation devices placed inside the descending aorta, has been one of the most common mechanical support systems for the failing heart ever since it was classified as a class III device in 1979. The balloon is inflated during ventricular diastole to increase diastolic pressure, coronary blood flow, and systemic perfusion, and rapidly deflated during systole to induce reduced cardiac afterload and enhanced cardiac output. The IABP is actually one of the earliest CADs developed, with the first preliminary studies done as early as 1961 by Kanitrowitz and Moulopoulos and the first successful clinical application reported in 1967. Most IABPs in clinical use today are predominantly Arrow IABP series, now acquired by Teleflex Medical. Because proper actuation timing is crucial for counter pulsation therapy, Teleflex Arrow IAB Catheters come with their own AutoCAT2 control unit that has both Autopilot Mode, which automatically selects appropriate settings using arterial pressure waveforms as the guideline, and Operator Mode in which all settings are user-controlled. The catheter balloons also come in different sizes for different sized patients.

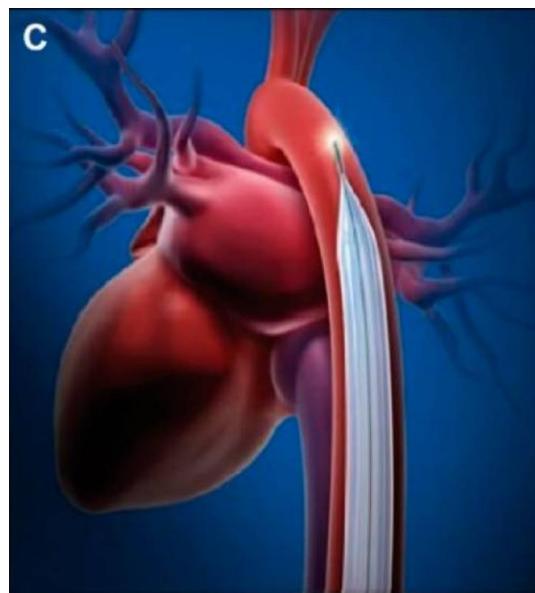


Figure 1-26 Pneumatic intra-aortic balloon pumps (IABP)

1.5.4.1.4 Thoractec's CentriMag acute circulatory support system

A temporary external VAD that can support right, left, or both ventricles, was the first and only magnetically levitated blood pump cleared by FDA in 2008. It is a continuous flow centrifugal pump without bearings or seals that operates at speeds up to 5500 rpm, delivering up to 9.9 L/min blood flow for a maximum recommended support duration of 6 h. This short-term solution for acute heart failure features a magnetically levitated pump impeller that operates within a contact-free environment to help minimize blood-related complications. The CentriMag system comes with a pump, a motor, a console with dual display monitor, a back-up console battery with a 5-hour recharge time, and a power conditioning unit that is air transport operable with AC power and able to accommodate up to four CentriMag consoles simultaneously.

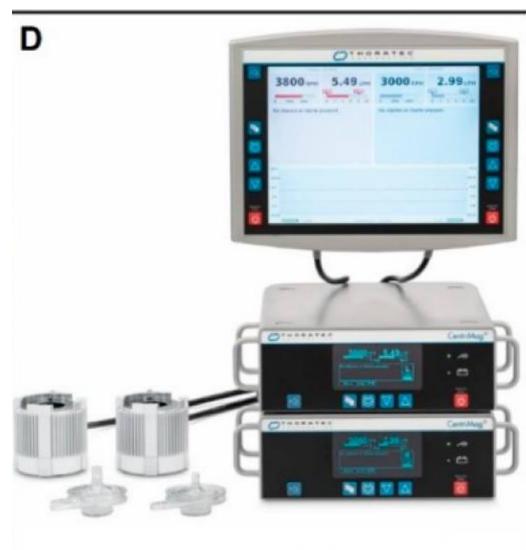


Figure 1-27 Thoractec's CentriMag acute circulatory support system

1.5.4.2 CADs for Extended Use

Although the Heartmate II axial flow pump remains the world's most widely used and extensively studied VAD to date with over 26,000 patients implanted for periods up to 10 years and beyond, third-generation centrifugal pumps like the HeartMate III (Thoratec) and HeartWare HVAD (HeartWare) are currently poised to become the device of choice as either BTT or DT for end-stage CHF patients. HeartMate III was built upon the HeartMate II platform but with key improvements that include a modular driveline, mobile power unit interface, no surgical pocket, less power consumption, and most importantly, a unique magnetically levitated core system called Full MagLev technology. This proprietary maglev system reduces overall blood trauma and maximizes hemocompatibility by maintaining large and consistent gaps within the pump housing and features an optional pulse mode as a means to minimize stasis and provide pulsatile flow to perfused organs. This design allows for significantly less shear stress (hemolysis) and blood-contacting surface area (thrombosis) since the size of the flow path that allows red blood cells to pass without rotor-housing contact is more than 20 times larger than that of its predecessor. In addition to the pump itself, the HeartMate III system comes equipped with an external controller that powers and checks the pump and driveline, a percutaneous driveline, and an external battery pack. Refined implantation techniques together with improvements in mechanical reliability, pumping efficiency, and battery life have increased 2-year survival rates from 76.2% to 82.8% while also contributing to surgical ease and patient quality-of-life.



Figure 1-28 heart mate

Heart Ware HVAD is a small CF-LVAD with a displacement volume of 50 mL and an output capacity of 10 L/min. It is characterized by a unique wide-blade impeller and a hybrid magnetic-hydrodynamic suspension technology that ensure no mechanical contact within the pump and a dual-motor system that is designed for increased efficiency and reliability. It comes with a rotary pump that operates at speeds ranging from 1800 to 4000 rpm, a percutaneous driveline, an external microprocessor-based controller, a monitor that displays and logs downloadable waveform data, lithium-ion batteries that allow patient mobility for about 4 to 6 h, AC/DC power adapters, and a battery charger. Its small device size and cannula allow minimal invasiveness and therefore faster postoperative recovery and better clinical outcomes.



Figure 1-29 heart ware

SynCardia CardioWest TAH (SynCardia) is the world's first and only commercially approved total artificial heart that is currently in use today. The mechanics of the device are fairly simple. It delivers pulsatile flow up to 9 L/min by filling two artificial ventricles that are sutured to the patient's aorta and pulmonary artery and ejects blood through unidirectional valves via a pneumatically driven diaphragm. According to INTERMACS reports, SynCardia TAH recipients experienced significantly fewer neurologic and thromboembolic events compared to BiVAD recipients. It has notably increased patients support time and currently has an overall one-year survival rate of 67.6%.



Figure 1-30 synCardiac CardioWest TAH

1.5.4.3 Pediatric Pumps

Conventional continuous flow VADs were designed specifically to treat adult patients, who comprise the vast majority of the end-stage CHF population and so tend to be too large for use in pediatric patients weighing less than 25 kg (55 lbs.). Berlin Heart EXCOR Pediatric is a pulsatile paracorporeal VAD designed for left and/or right ventricular support of young patients from newborns to adolescents. It is composed of a cannula that comes in different tip types and sizes, a blood pump that also varies in sizes from 10 to 60 cc, and a driving unit that provides alternating pneumatic pressures. The system can be powered by either the stationary IKUS driving unit or a portable battery unit that lasts for roughly 6 h. To monitor patients, the IKUS unit is integrated with laptop software that is programmed to log and store data as well as alarm both visually and audibly when waveform readings are abnormal. Besides Berlin Heart EXCOR, other pediatric pumps or miniature adult pumps include the Jarvik 2000 (Jarvik Heart) that come in different sizes for children and infants, PediaFlow (PediaFlow Consortium, Pittsburgh, PA, USA) that supports infants and young children weighing 2–25 kg, the miniature MVAD HeartWare (HeartWare), and CircuLite (CircuLite Inc., Saddle Brook, NJ, USA).

1.5.5 Clinical Complications of Current VADs

In spite of the increasing number of VAD options currently available to patients due to revolutionary advances in cardiac support technologies, numerous challenges still persist. Ventricular arrhythmia, right heart failure, infection, pump thrombosis, and bleeding are still areas of concern, as are issues of long-term patient management and a lack of clear guidelines regarding patient eligibility criteria for VAD therapy. Difficulties in gauging the likelihood of therapeutic benefit for any given individual HF patient is thought to be the biggest reason behind the recent plateauing of VAD use. Optimization of the treatment process and refinements in patient selection criteria are therefore needed to promote further improvements in survival rate and patient quality of life, especially in the setting of long-term circulatory support.

Indeed, given that heart failure has now risen to pandemic proportions across the globe while the availability of donor hearts remains woefully inadequate to meet the rising demand, continued expansion of mechanical circulatory support for use as long-term BTT or DT is considered a clinical necessity. But despite decades of development most VAD therapies are limited to short-term BTT applications due to three longstanding complications. One is bacterial infection from percutaneous drivelines, which is the most frequent LVAD-associated problem. Another is thromboembolic events associated with blood-contacting surfaces, which includes both pump thrombus formation and blood clotting in the circulatory system. And the third is bleeding, mainly at the surgical site during the early postoperative period and gastrointestinal bleeding that usually begins three months after continuous flow LVAD implantation.

1.5.5.1 Driveline Infections

Device malfunction, bleeding, thrombosis, and inadequate aftercare all contribute to VAD failure in the clinical setting, but percutaneous driveline infection (DLI) is one of the most

common cause of mortality with these devices, accounting for 47% of all unplanned readmissions for LVAD patients. This risk factor has proven difficult to avoid in these pumps as drivelines that provide power, control, and communication are percutaneously sutured to remain secure, and this driveline exit site creates a conduit for bacterial entry that often leads to DLI. The prevalence and seriousness of DLI, which often leads to erythema, hyperthermia, purulent drainage, and significantly lower survival rate, increased as LVAD therapy expanded from short-term to long-term use. Although approximately 70% of infected patients require rehospitalization in the first year, there currently is no comprehensive guideline for DLI treatment besides general precautions like minimal exit-site movement, long-term suppressive antibiotics, and antimicrobial therapy. Ongoing efforts to decrease DLI incidents include optimization of driveline implantation techniques and minimization of pump profile and operational invasiveness, which has resulted in smaller and more efficient devices such as the entirely intra-pericardial HVAD (HeartWare) and completely intra-thoracic HeartMate III (Thoratec). However, in all cases a tunneled percutaneous driveline is still required for power delivery from sources outside the body.

1.5.5.2 Pump Thrombosis

Another significant cause of LVAD complications is thromboembolism associated with blood-contacting surfaces. Pump thrombosis, where blood clots form at the blood-device interface, is a multifactorial process caused by misuse of anticoagulants, abnormal angulation of cannulas, and surface mediation of blood-contacting devices. Thrombosis can occur in any component of the LVAD in contact with the bloodstream and may result in turbulent flow, elevation in device power consumption and, in extreme cases, inability to unload the LV. The annual incidence of pump thrombosis in LVAD patients exceeds 10%, of which nearly one third lead to serious complications including aortic insufficiency, hemolysis, neurologic events, and cardiogenic shock. From the time of confirmed pump thrombosis, there is a two-fold increase in mortality at 30, 90, and 180 days, where mortality reaches 48.2% if no LVAD exchange or cardiac transplantation is performed within that given time. This potential complication, common to all blood-contacting devices, requires VAD recipients to undergo costly—and potentially dangerous—anticoagulation therapy for the duration of the implant period. In order to minimize the rate of chronic pump thrombosis, innumerable changes in VAD designs have been made over the years. Modern LVAD surface area has been scaled down, impeller profiles have been adjusted, implantation invasiveness has been minimized, and less reactive surface materials have been chosen. Nonetheless, the risk persists and long-term antithrombotic therapies including anticoagulant drugs, antiplatelet agents, and routine surveillance are still required by patients receiving VAD therapy.



Figure 1-31 Driveline Infections



Figure 1-32 Pump Thrombosis

1.5.5.3 Gastrointestinal Bleeding

The reported incidence of gastrointestinal bleeding (GIB) after continuous flow LVAD implantation is alarmingly high, as much as 61% by one account. There are several factors leading to GIB syndrome, but with third-generation continuous flow pumps the low pulsatility flow profile combined with increased oxidative and shear stresses seem to cause hematological abnormalities such as platelet dysfunction and von Willebrand factor (vWF) degradation. And chronic anticoagulative treatments like warfarin and antiplatelet agents like aspirin administered to prevent clot formation at blood contacting surfaces only worsen the risk of bleeding. GIB can be initially diagnosed and evaluated with endoscopy, but the most appropriate method of treatment after diagnosis is not always clear due to difficulties identifying the causes that underlie this complicated syndrome. Currently, a multidisciplinary approach that considers the location and severity of bleeding and thrombosis simultaneously is being used to manage GIB, but better insights into the etiology and treatment of GIB are still being sought to improve outcomes.



Figure 1-33 Gastrointestinal Bleeding

1.5.6 Innovations for Effective Long-Term Cardiac Support

The rate of DLI, thromboembolic incidents, and bleeding problems must be curtailed if long-term cardiac support is to become a viable treatment option for end-stage CHF patients. Toward that end, there have been numerous attempts to eliminate these predominant failure modes and develop an untethered, non-blood-contacting VAD as a destination therapy.

1.5.6.1 Alternative Powering Methods for Untethered Cardiac Support

To provide long-term CAD patients better quality-of-life, various powering methods have been proposed to minimize or eliminate extracorporeal power requirements that limit patient autonomy and contribute to patient stress over potential power delivery failures (e.g., driveline fracture and battery exhaustion) and DLI risk. One of the most interesting attempts was a nuclear-powered device from the 1980s that used Plutonium-238 as a power source. The potential was in the nuclear radioisotope Plutonium that offered the highest possible energy density and long half-life without requiring any energy storage. However, the critical problems of heat dissipation and safety concerns regarding nuclear element leakage eventually led to termination of the project.

Another attempt to develop a permanently implanted circulatory support system was based on a small, lightweight spring decoupled C-core solenoid that was first introduced in the early 1980s. This solenoid drive system was used to actuate a pair of preloaded beam springs that directly coupled to a dual pusher-plate blood pump, producing high starting forces and constant pump pressures through repeated ejection strokes. With this technology operating in combination with external plug-ins that included portable and rechargeable lithium-ion, nickel metal hybrid, or lead acid gel batteries, a level of patient mobility similar to that afforded by battery-powered devices available today was achieved. However, this drive system was limited not only by requiring patients to carry around external hardware like charging stations, battery

packs, and emergency back-up systems in a backpack, but also by the anxiety produced by having to charge batteries every few hours. When findings from device malfunction cases were reviewed, researchers found that there were significant numbers of hospital visits due to device alarm of unknown origin and/or actual malfunctions resulting in controller exchange or battery change. Although not all cases represented serious clinical complications, device alarms and malfunction notices caused severe levels of anxiety and considerably reduced patient quality of life. Much worse, in some cases, patients actually died from battery exhaustion because of unexpected events that drained the batteries before they could be recharged. Therefore, alternative power sources for untethered pump operation have been sought to create totally implantable devices that are safe, reliable, and relatively maintenance-free.

1.5.6.1.1 Transcutaneous energy transmission System (TET)

Technology that transfers power across intact skin makes devices completely implantable and therefore free of the risk of DLI. At a time when over 20 million Americans are estimated to have some type of implanted medical device, the TET system sounds extremely appealing. The idea of an inductive coupling of two coils that transfers electromagnetic energy at radio frequencies across a closed chest wall was first described by Schuder and colleagues in 1961. Because VADs tend to demand a higher range of power (up to about 25 W) compared to other implants like pacemakers or implantable cardiac defibrillators, transmission efficiency and the total amount of transferrable power are key performance criteria. Different methods of transmitting energy across skin such as ultrasonic energy transfer and acoustic energy transfer have been previously developed, but because inductive coupling TET outperforms the others by more than double in terms of efficiency, the latter has been used in devices like AbioCor TAH (AbioMed), which was FDA approved as a permanent TAH for humanitarian uses in 2006, and the LionHeart LVAD (Arrow International, Reading, PA, USA), which received FDA approval for Phase I human clinical trials in 2001.

The inductive electromagnetic TET system used in these devices has proven to be a promising wireless powering method that sufficiently meets the power transmission requirement of up to 25 W. When studied with 14 AbioCor TAH patients, 30-day survival rate was 71% with no device-related infections reported, which clearly demonstrated the value of the TET system regarding the elimination of DLI risks. However, this tether-free system is significantly limited by its power transmission range since the transmit and receive coils must remain very close together (within a few millimeters). This proximity restriction requires the receive coil to be implanted just under the skin and the external transmit coil to be secured in a single position on the skin surface with an adhesive dressing. The two coils can be distant for a very brief period of time (about 30 min), allowing activities like a brief shower. Another limitation is its lower energy efficiency compared to conventional extracorporeal drivelines as the TET system

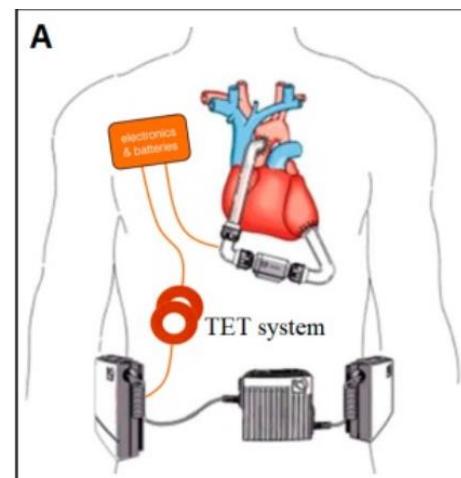


Figure 1-34 Transcutaneous energy transmission System (TET)

consumes approximately 20% of the generated power during operation. Other drawbacks like fatal component failure, bleeding, and pain due to the large cumulative volume of all implanted parts also play a big role in preventing TET technology from being the main VAD powering method today.

1.5.6.1.2 Muscle-powered VADs

The use of electrically stimulated skeletal muscle as an endogenous power source to drive circulatory support systems is another alternative that is currently under study. An internal muscle energy converter that operates by converting the contractile energy of a muscle into a hydraulic power source would greatly simplify cardiac implants by eliminating electromechanical components and avoiding the need to transmit energy across the skin. A device powered by contractile energy and controlled via a pacemaker-like device implanted beneath the skin could, in principle, provide a safe, tether-free means to support the failing heart over extended periods of time.

The concept of muscle-powered cardiac support is not new. The use of untrained skeletal muscle to aid the failing heart dates way back. In 1935, Beck and Tichy employed static muscle grafts to revascularize the myocardium. And in 1958, Kantrowitz isolated diaphragm muscles in dogs to form pouches for use as 'myocardial substitutes'. But in 1969 the concept of muscle-powered cardiac assist was given new life when Salmons and Jarvis demonstrated that myofiber properties can be changed from glycolytic fast type to oxidative slow-phenotype via muscle impulse activity training. This key discovery opened a whole new realm of possibilities involving conditioning skeletal muscle to provide fatigue-resistant long-term circulatory support.

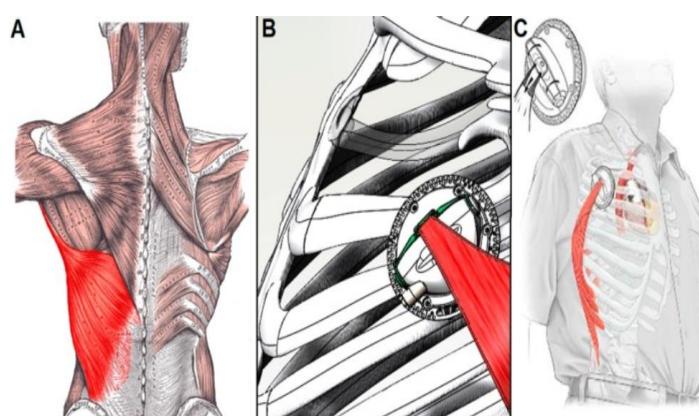


Figure 1-35 Muscle-powered VADs could use the latissimus dorsi (A) as its power source and convert this endogenous muscular power into hydraulic energy via a completely implantable muscle energy converter (B) that can potentially power pulsatile VADs for long-term(c)

The recent development of a functional muscle energy converter (MEC), which operates by converting endogenous muscle energy into hydraulic power, may ultimately provide CAD developers with the means to harness the body's own energy to assist the failing heart over the long term. Among the several large skeletal muscles that might conceivably be used for this purpose, the MEC targets the latissimus dorsi muscle (LDM) due to its large size, surgical accessibility, proximity to the thoracic cavity, and steady-state work capacity sufficient for long-term cardiac support. Trained LDM controlled by a programmable pacemaker-like cardiomyostimulator that coordinates muscle activity with the cardiac cycle has been shown to produce mechanical power at levels sufficient for pulsatile VAD actuation. As the current MEC has been optimized to operate at

contractile force and velocity levels that correspond to peak power generation in fully-conditioned human adult LDM, its potential as a means to power a completely self-contained VAD for long-term use is promising.

1.5.6.2 Non-Blood-Contacting Cardiac Assist Devices

Despite innumerable CAD designs and material modifications made over the decades in an attempt to eliminate chronic pump thrombosis, the situation still persists while the precise dosage and frequency of long-term antithrombotic therapies remain ambiguous. Consequently, several groups are currently working to avoid this problem by designing non-blood contacting devices. These devices are intrinsically pulsatile and can be programmed to deliver energy to the bloodstream during cardiac systole (*copulsation*) or diastole (*counterpulsation*). Copulsation enhances cardiac output by increasing pulse and arterial pressure during systole, while counterpulsation boosts heart function by reducing aortic pressures as the heart fills thereby providing lower cardiac afterload for the failing heart. These techniques have been shown to significantly increase aortic peak pressure, cardiac output, and regional and coronary blood flow. But, above all, the most critical advantage these technologies offers is that they can be applied without touching the blood stream.

1.5.6.2.1 *Copulsation Direct Cardiac Compression Sleeve*

A normal heart with a ventricular ejection volume of about 71.5 mL per beat ($CO = 5 \text{ L/min}$ and $HR = 70 \text{ bpm}$) has a ventricular ejection fraction (EF) of 60%. While a healthy heart's EF ranges from 55% to 70%, anything less than that is considered mild (<54%) to severe (<35%) heart failure. One way to boost the EF of a defective heart is by applying pulsatile pressure to the epicardial surface in synchrony with the natural ventricular contraction.

Copulsative biventricular compression devices have been around for decades. The Anstadt Assistor Cup became the first successful direct cardiac compression sleeve (DCCS) in 1991 and Dr. DeBakey's pneumatic LV compression cup was first implanted in 1996. As these preliminary ventricular DCCSs showed successful increases in arterial pressure and cardiac output, more pneumatic and electric sleeves were developed including the "cuff-like" Heart Booster (AbioMed) that covers and compresses the heart with parallel compression tubes, Mannequin (Chase Medical, Richardson, TX, USA) that restores round-shaped ventricles to its original oval-shape, and Heart Blanket (Leeds University, UK) that gives underperforming hearts an extra boost by contracting ventricles with piezoelectric bands in synchrony with pacemaker stimulations.

Recently, researchers have turned to emerging soft robotic technologies to improve the long-term functionality of DCCSs. In 2017 for example, a silicone molded sleeve (Figure 4-14 A) that employs McKibben pneumatic artificial muscles (PAMs) placed helically and circumferentially to both compress and twist the heart without contacting blood gathered a lot of attention. This soft robotic sleeve made of two biomimetic layers of contractile elements that shorten when pressurized during ventricular systole was able to restore cardiac output to 88% of normal when tested on porcine hearts. CorInnova's minimally invasive soft robotic DCCS (Figure 4-14 B) is a collapsible self-deploying device that wraps around the ventricles with custom fit thin-filmed pneumatic chambers. They were able to increase cardiac output by

up to 50% in large animal acute heart failure studies. Unlike these pneumatic devices that are tethered to an external air supply, a muscle-powered DCCS (Figure 4-14 C) that uses the geometric advantage produced by an array of thin-walled tubes is currently under development. This sleeve comprises hydraulically driven tubing arrays that contract and expand circumferentially when filled and emptied. As fluid enters the array of thin-walled polymer tubes connected side-to-side it transforms each tube from a flat (deflated) to a circular (inflated) cross-section to effectively compress the epicardial surface in synchrony with ventricular ejection, ultimately leading to enclosed ventricular blood volume changes as high as 60%. This hydraulic DCCS device combined with the MEC technology introduced above could, in principle, allow for the development of a completely untethered, muscle-powered, non-blood-contacting VAD for long-term cardiac support.

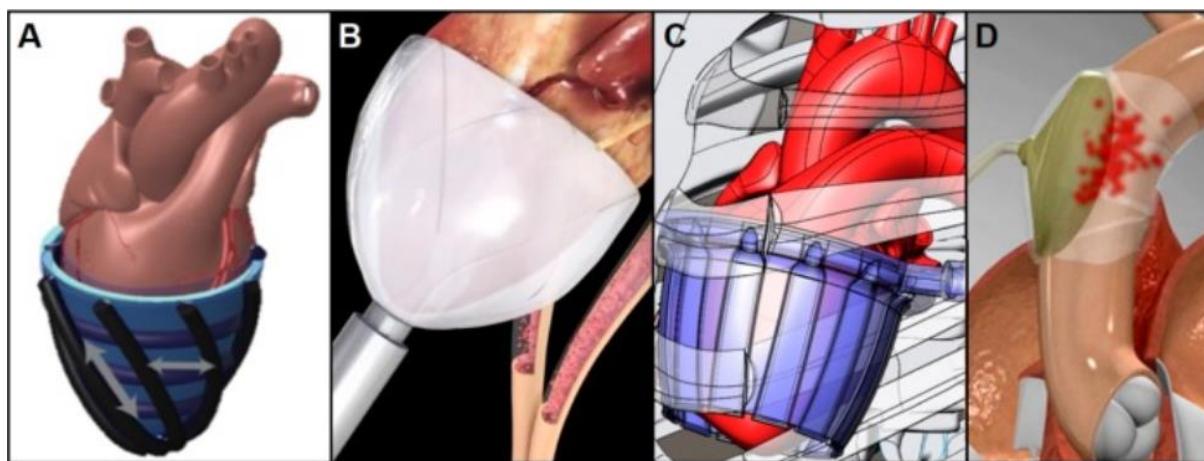


Figure 1-36 Biomimetic (A), minimally invasive (B), and muscle-powered (C) soft robotic direct cardiac compressive sleeves (DCCS) use copulsation and extra-aortic balloon pumps (EABP) (D) use counterpulsation techniques to enhance cardiac function without directly interacting with the blood stream.

1.5.6.2.2 Counterpulsation Extra-Aortic Balloon Pump

Another form of circulatory support for CHF patients that provides effective cardiac unloading and patient stabilization is displacement of blood from the aorta during the diastolic phase of the cardiac cycle. This technique is most often performed clinically using an IABP that is implanted and inflated inside of the descending aorta as previously described. This mechanical support augments diastolic pressure and coronary circulation via balloon inflation and reduces the resistance to systolic output via the presystolic deflation of the balloon. The biggest factor that prevents this technology from becoming a viable method of long-term support is the fact that it is often associated with thromboembolism with extended use due to its direct interaction with the blood stream. Therefore, an extra-aortic balloon pump (EABP) (Figure 4-14 D) that wraps and compresses the external surface of the ascending aorta like the C-pulse device (Sunshine Heart Inc., Eden Prairie, MN) may offer clinicians an alternative solution. The C-pulse counterpulsation EABP was clinically tested and shown to significantly increase aortic peak diastolic pressure, cardiac output, and regional and coronary blood flow without touching the blood. In the context of long-term cardiac support, it is worth mentioning that, like the soft robotic DCCS, this device also has the potential to be driven by muscle-powered actuation, which would allow for durations of use far beyond what is now possible with pneumatic actuation.

1.5.6.2.3 Passive Periventricular Restraint

Passive periventricular restraint, which involves wrapping the entire epicardial surface with a sleeve-like prosthetic to provide circumferential diastolic support to the failing heart, is an approach that evolved from a surgical procedure known as cardiomyoplasty (CMP) in which the ventricles were wrapped with the latissimus dorsi (LD) muscle flap and stimulated to contract in synchrony with the systolic portion of the cardiac cycle. While CMP was effective in reducing wall stress, myocardial oxygen consumption and adverse ventricular remodeling, these benefits were found to persist in some patients even after the muscle flap stopped contracting, which suggested that these same effects might be produced via passive ventricular restraint alone. Toward that end, several passive prosthetic devices were developed to produce the same effects without resorting to the surgical complexities and post-surgical complications involved with LD flap isolation and subsequent transplantation into the chest. Corcap (Acorn Cardiovascular, Saint Paul, MN, USA) and Paracor HeartNet were two such devices that were designed to act more like the passive LD flap insofar as pressure was applied uniformly across the ventricular free walls. The Acorn sleeve was a flexible, polyethylene-terephthalate mesh that was placed around the heart through a median sternotomy to provide end-diastolic support and reduced wall stress. The Paracor device was formed from Nitinol wire mesh encased in silicone that exerted continuous elastic force on the heart throughout the cardiac cycle and could be deployed over the ventricles via an introducer sheath positioned over the cardiac apex through a mini-thoracotomy. Both devices were tested in limited clinical trials but, despite showing positive LV remodeling in a subset of patients with dilated cardiomyopathy, neither produced significant improvements in patient survival or quality of life and were subsequently taken off the market.

1.5.6.3 CADs in Summary

Category	Product	Type of Support	Duration of Support	Advantages	Limitations
Early Methods of Cardiac Support	ECMO	BiVAD	Short-term	Extracorporeal artificial heart-lung bypass for acute support	Upper body hypoxia, LV dilatation, thrombosis
	IABP	Descending Aorta	Short-term	Increases myocardial oxygen perfusion and cardiac output	Thrombosis, aortic rupture, arterial flow obstruction
1st Generation —Pulsatile Flow	HeartMate XVE	LVAD	Long-term	Improved enough to receive FDA approval for DT in 2003	Bulky and Heavy

Category	Product	Type of Support	Duration of Support	Advantages	Limitations
and CE mark in 2004					
	Berlin Heart EXCOR	BiVAD	BTT	Pediatric uses with various pump sizes	Not completely implanted
	Novacor LVAS	LVAD	BTT	Longer durability and higher reliability at the time	Still large and bulky with three extracorporeal hardware
	HeartMate I	LVAD	BTT/BTR	Introduced textured blood contacting surface to reduce thrombosis	Large size and complications like bleeding and driveline infection
	Thoratec PVAD	Uni or BiVAD	Short-term	Weeks to months support for patient's home discharge post-cardiotomy	Common side effects from pneumatic driveline
	ABioMed BVS 5000	Uni or BiVAD	Short-term	Resuscitate critically ill patients for acute stabilization	Risks of bleeding, coagulopathy, and end-organ damage
	Jarvik 7	TAH	Long-term	World's first permanent total artificial heart; more used as a BTT now	Thrombotic deposition and cerebral embolic events
	AbioCor TAH	TAH	Long-term	Uses TET technology without aid of wires	Discomfort with TET system, bulkiness, clotting at device surfaces

Category	Product	Type of Support	Duration of Support	Advantages	Limitations
	ABioMed Impella RP	IVC-to-PA	Short-term	First and only FDA approved percutaneous heart pump for RV support	Thrombotic vascular complications and hemolysis
	Tandem Heart	LA-to-FA	Short-term	Significantly reduces preload and augments cardiac output	Risks of cannula migration, thromboembolism, and cardiac tamponade
	HeartMate II	LVAD	Long-term	FDA approval for DT, Improved survival rate and patient quality of life, Most commonly installed LVAD in 2000s	Bleeding, cardiac arrhythmia, infection, sepsis
2nd Generation	Heart Assist 5	LVAD	Long-term	Small size and weight, CE mark approved remote monitoring system in 2012	Bleeding, thrombosis, infections
	Jarvik 2000	LVAD	Long-term	Pediatric uses, FDA approval for trial using as a DT in 2012	Class 2 device recall for a potential external cable damage in 2018
	ABioMed Impella	FA-to-LV	Short-term	Minimally invasive, Varying sizes	Hemolysis, aortic valve injury, infection
3rd Generation	HeartWare HVAD	LVAD	Long-term	Small size, magnetically levitated	Risks of infection, bleeding,

Category	Product	Type of Support	Duration of Support	Advantages	Limitations
Continuous Centrifugal Flow				rotor, FDA approval for DT in 2017	arrhythmia, stroke
	HeartMate III	LVAD	Long-term	Magnetically levitated rotor, FDA approval for DT in 2018	Risks of infection, bleeding, arrhythmia, stroke
	DuraHeart	LVAD	Long-term	Favorable clinical outcomes as BTT in Japan and Europe	Hemolysis, thromboembolism, bleeding
	HeartWare MVAD	LVAD	Long-term	Miniature size for pediatric uses	Risks of infection, bleeding, and thrombosis
	CentriMag	Uni-VAD	Short-term	Magnetically suspended rotor for acute therapy, Minimal shear force on RBCs and hemolysis	Bleeding, infection, respiratory failure, hemolysis, neurologic dysfunction
	CorInnova	Ventricular Epicardium	Potentially Long-term	Minimally invasive, Non-blood-contacting, soft material	Studies done on large animals only
Non-blood-contacting VADs	Biomimetic DCCS	Ventricular Epicardium	Potentially Long-term	Soft material, Non-blood-contacting, compression and torsion applications	Still under development
	Muscled-powered DCCS	Ventricular Epicardium	Potentially Long-term	Tether-free, Non-blood-contacting, Biocompatible soft material	Still under development

Category	Product	Type of Support	Duration of Support	Advantages	Limitations
	C-pulse Device	Ascending Aorta	Short-term	Non-blood-contacting	No longer commercially available

1.5.6.4 Patient Management for Long-Term Treatment

Since 2001 when the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial became the landmark study that established the benefits of implantable, pulsatile, and permanent VAD therapy in patients with late stage CHF, survival rates have improved to nearly 80% one-year after primary implantation due to a combination of refinements in patient selection strategy, surgical techniques, and peri-operative management. Even though the survival rate has gone up, late-stage CHF patients still suffer from physical and psychological distress stemming from the lack of mobility and freedom. As the 2018 ENDURANCE supplemental trial concluded, the ideal form of destination therapy should provide effective and comfortable long-term mechanical support with an emphasis not only on prolonging survival, but also reducing morbidity and improving overall quality-of-life. Considering that there are currently no practice guidelines for patient management, there is an urgent need for a more systematic and organized protocols for these patients. As the PREVENT trial highlights, more seamless, real-time communication between patients and caregivers is needed. Devices like CardioMEMS (St. Jude Medical, St. Paul, MN, USA) and HeartAssist-5 (ReliantHeart Inc., Houston, TX, USA) that have sensor and remote monitoring capabilities via cell phone or other portable devices were developed to meet this critical need. Overall, VADs with long-term reliability and low complication rates in combination with proper postoperative and follow-on care will together establish what may be considered a true destination therapy.

Since its inception in the early 1960s, a remarkable amount of research and development has been performed in an effort to improve and expand the field of cardiac assist devices. As a result, a wide array of cardiac assist technologies is available to clinicians today, each with their unique set of strengths and weaknesses, but all designed with one common goal in mind: to provide safe, reliable circulatory support however and whenever it is needed.

Of course, these challenges grow larger as rising levels and durations of support are required and it is important to continue to seek solutions that will free these patients from persistent physical risks and psychological distress. Toward that end, reducing device-related complications and eliminating the loss of freedom imposed by percutaneous tethers will be key factors in developing CADs that are truly suitable for long-term or permanent use. In addition, replacing current patient management practices with physician–patient interface systems that are more systematic, convenient, and effective will likely play a big role in improving the lives of CHF patients who must rely on life-sustaining devices for years on end. Fortunately, there is reason to expect that many of these improvements will be implemented in the not-too-distant future as steps to meet these challenges are currently being taken by several groups working to

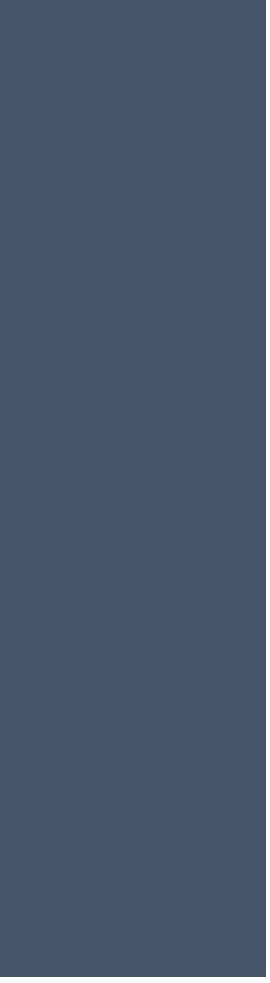
develop effective destination therapies with longer patient survival times and improved quality-of-life.

One of the most important problems that make the cardiovascular device fails when we install it in the human body is that the devices didn't be tested before we use it , some people make simulation for them using CFD but it's very hard operation and the results may be theoretical in some cases, another people make tests in human body but it's very dangerous and may lead to death.

In our project, we make a device that simulates the left ventricle of the heart so we can test the assist devices that is connected to this part of the human body.

The device consists of pulsatile blood pump (positive displacement piston pump) that simulates the heart, setup consists of resistance (valves) and compliance chamber that simulates the aorta.

We apply a code that controls the pump to make it give the flow rate and performance of the heart in the human body, so we can test different devices in a safe way.



2 Pulsatile

Pump

2.1 Introduction

A pulsatile blood pump is a medical device designed to mimic the natural pulsating action of the human heart, facilitating blood flow in patients with cardiovascular conditions or during surgical procedures. Unlike continuous flow pumps, which provide a steady stream of blood, pulsatile blood pumps generate rhythmic pulses that closely resemble the natural heartbeat. This action is crucial in maintaining physiological blood flow patterns and ensuring adequate perfusion of vital organs.



Figure 2-1 HARVARD Pump

The design and function of pulsatile blood pumps are based on principles of hemodynamics and cardiac physiology. These devices are often used in mechanical circulatory support systems, such as ventricular assist devices (VADs) and extracorporeal membrane oxygenation (ECMO) circuits. Pulsatile blood pumps can be employed in various clinical scenarios, including during heart surgeries, in patients awaiting heart transplants, and for those with severe heart failure.

Advancements in pulsatile blood pump technology have focused on improving biocompatibility, durability, and efficiency, thereby enhancing patient outcomes and quality of life. The integration of sophisticated sensors and control systems allows for precise regulation of pump activity, adapting to the patient's physiological needs in real time. This dynamic adaptability makes pulsatile blood pumps a critical component in modern cardiac care, offering hope and extended life expectancy for patients with severe cardiovascular ailments.

Pulsatile blood pumps are engineered to replicate the natural hemodynamic conditions of the heart, which consist of systolic (contraction) and diastolic (relaxation) phases. The pulsatile nature of these pumps ensures that the mechanical action aligns closely with the body's physiological requirements, thereby improving tissue perfusion and reducing the risk of complications associated with continuous flow devices.

The success of pulsatile blood pumps hinges on their ability to simulate the natural pulsations of the heart, ensuring that blood flow is synchronized with the body's metabolic demands. This synchronization not only aids in the efficient delivery of oxygen and nutrients but also helps in maintaining the health of the vascular system, reducing the risks associated with prolonged mechanical support. Additionally, research and development in this field continue to explore ways to enhance the miniaturization and integration of these devices with advanced monitoring systems, thereby increasing their usability and effectiveness. As technology evolves, pulsatile blood pumps are expected to become even more refined, providing life-saving support with fewer complications and greater comfort for patients worldwide.

2.2 Applications of Pulsatile Blood Pumps

2.2.1 Cardiac Surgery

During complex cardiac surgeries, such as coronary artery bypass grafting (CABG) or valve replacements, pulsatile blood pumps can temporarily take over the heart's function, maintaining blood circulation and oxygen delivery to tissues. This temporary support is crucial in reducing surgical risks and enhancing postoperative recovery.

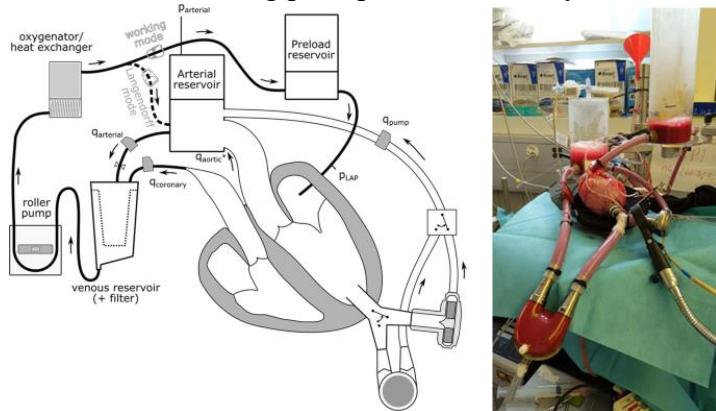


Figure 2-2 Pulsatile Pump in Cardiac Surgery

2.2.2 Heart Failure Management

For patients with advanced heart failure, pulsatile ventricular assist devices (VADs) can provide long-term circulatory support. These devices help maintain cardiac output and improve quality of life while patients await heart transplantation or as a destination therapy for those who are not transplant candidates.

2.2.3 Extracorporeal Membrane Oxygenation (ECMO)

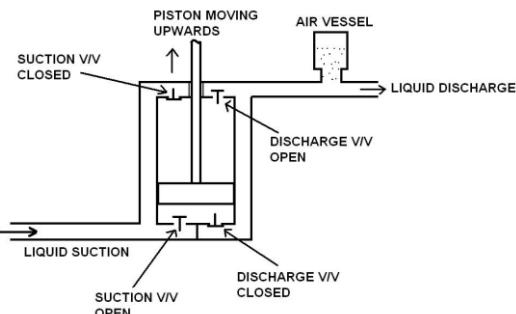
In ECMO therapy, pulsatile pumps are used to support patients with severe respiratory or cardiac failure. By providing both circulatory and respiratory support, ECMO can be a lifesaving intervention in critical care settings, allowing time for recovery or bridge to further treatments.



Figure 2-3 Extracorporeal Membrane Oxygenation (ECMO)

2.3 Piston Pump

A reciprocating piston pump is a type of positive displacement pump that uses a piston or plunger to move fluids through a cylinder, creating a reciprocating motion. This pump is characterized by its ability to deliver a consistent and controlled flow rate, making it suitable for a wide range of applications in industries such as oil and gas, chemical processing, water treatment, and manufacturing.



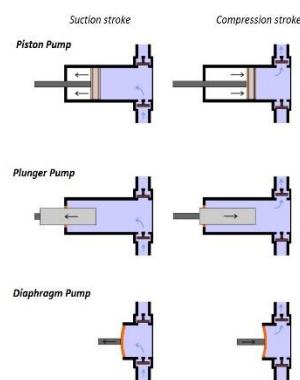
2.3.1 Components of a Reciprocating Piston Pump

- **Cylinder:** The cylinder is the chamber in which the piston moves back and forth. It is typically made of metal and must be durable enough to withstand high pressures and corrosive fluids.
- **Piston or Plunger:** The piston is the moving component that creates the pumping action. In some designs, a plunger is used instead, which is a solid rod that moves through the cylinder.
- **Piston Rod:** The piston rod connects the piston to the driving mechanism, transmitting the reciprocating motion.
- **Drive Mechanism:** This can be a crankshaft, camshaft, or other mechanical linkages that convert rotational motion into reciprocating motion. It is usually powered by an electric motor, internal combustion engine, or other power sources.
- **Valves:** Reciprocating piston pumps have inlet and outlet valves that control the flow of fluid into and out of the cylinder. These valves are typically check valves, which allow flow in only one direction.
- **Seals and Packing:** These components prevent leakage of fluid around the piston and piston rod, ensuring the efficiency and reliability of the pump.

2.3.2 Operating Principle

The operation of a reciprocating piston pump can be divided into two main phases: the suction phase and the discharge phase.

- I. **Suction Phase:** During the suction phase, the piston moves away from the cylinder head, increasing the volume inside the cylinder and creating a vacuum. This vacuum causes the inlet valve to open, allowing fluid to be drawn into the cylinder from the inlet pipe.
- II. **Discharge Phase:** In the discharge phase, the piston moves towards the cylinder head, decreasing the volume inside the



cylinder and increasing the pressure. This pressure forces the inlet valve to close and the outlet valve to open, allowing fluid to be expelled from the cylinder into the discharge pipe.

The cycle then repeats, with the continuous reciprocating motion of the piston providing a steady flow of fluid.

2.3.3 Types of Reciprocating Piston Pumps

- **Single-Acting Piston Pump:** In a single-acting pump, fluid is drawn in and expelled during one stroke of the piston. Each cycle consists of one suction phase and one discharge phase.

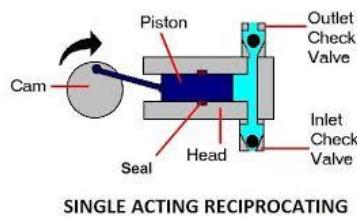


Figure 2-4 Single-Acting Piston Pump

- **Double-Acting Piston Pump:** A double-acting pump has fluid intake and discharge occurring on both sides of the piston. This design allows for a more continuous flow and higher efficiency, as each stroke of the piston performs both suction and discharge simultaneously.

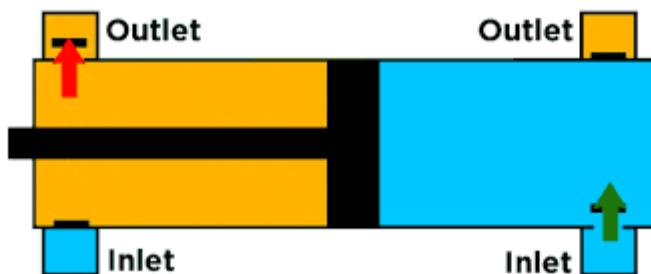


Figure 2-5 Double-Acting Piston Pump

- **Duplex and Triplex Pumps:** These pumps use multiple cylinders (two in duplex, three in triplex) to smooth out the flow and increase capacity. They are commonly used in applications requiring high pressure and flow rates.

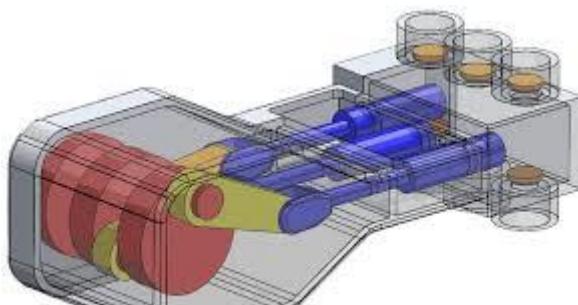


Figure 2-6 Duplex and Triplex Pumps

2.3.4 Piston Pump Calculations

Calculations for piston pumps are crucial for determining the pump's performance and ensuring it meets the application's requirements. Key parameters include flow rate, pump speed, displacement, and power requirements. Here, we will explore these calculations in detail.

2.3.4.1 Key Parameters and Formulas

2.3.4.1.1 Flow Rate (Q)

The flow rate of a piston pump is the volume of fluid it can move per unit of time. It is usually measured in liters per minute (L/min) or gallons per minute (GPM).

$$Q = \frac{V_d \times N \times E}{1000}$$

- Q = Flow rate (L/min)
- V_d = Displacement per stroke (cm^3)
- N = Pump speed (strokes per minute)
- E = Volumetric efficiency (usually between 0.85 to 0.95 for well-maintained pumps)

2.3.4.1.2 Displacement per Stroke (V_d)

$$V_d = A \times L$$

- A = Cross-sectional area of the piston (cm^2)
- L = Length of the stroke (cm)

2.3.4.1.3 Cross-Sectional Area (A)

$$A = \pi \times \left(\frac{D}{2}\right)^2$$

- D = Diameter of the piston (cm)

2.3.4.1.4 Pump Speed (N)

Pump speed is the number of strokes per minute. It can be determined based on the required flow rate and displacement per stroke.

2.3.4.1.5 Power Requirements (P)

$$P = \frac{Q \times \Delta p}{600}$$

- P = Power (kW)
- Q = Flow rate (L/min)
- Δp = Differential pressure across the pump (bar)

The factor 600 is used to convert units appropriately.

2.3.4.1.6 Efficiency (η)

$$\eta_{overall} = \eta_{volumetric} \times \eta_{mechanical}$$

Volumetric efficiency accounts for losses due to leakage, while mechanical efficiency accounts for losses due to friction and other mechanical factors.

2.3.5 Advantages

- **High Pressure Capability:** Reciprocating piston pumps can generate very high pressures, making them suitable for applications requiring significant force.
- **Consistent Flow Rate:** These pumps provide a steady and controlled flow rate, essential for precise dosing and metering applications.
- **Versatility:** They can handle a wide range of fluids, including viscous, abrasive, and corrosive substances.
- **Durability:** The robust design and construction of reciprocating piston pumps ensure long service life and reliable operation under harsh conditions.

2.3.6 Disadvantages

- **Complexity and Maintenance:** The mechanical components and seals require regular maintenance, and the complexity of the design can make repairs challenging.
- **Pulsation:** The reciprocating motion can cause pulsating flow, which may require additional dampening systems to smooth out.
- **Size and Weight:** These pumps can be large and heavy, making them less suitable for applications with space or weight constraints.

2.3.7 Applications

2.3.7.1 Oil and Gas Industry

In the oil and gas industry, reciprocating piston pumps are used for drilling mud, injecting chemicals, and transporting oil and gas through pipelines. Their ability to handle high pressures and abrasive fluids makes them ideal for these demanding applications.

2.3.7.2 Chemical Processing

Chemical plants use these pumps to handle a variety of fluids, including corrosive and viscous substances. The precise control over flow rates and the ability to withstand harsh chemicals make reciprocating piston pumps essential in this sector.

2.3.7.3 Water Treatment

In water treatment facilities, these pumps are used for dosing chemicals, transferring slurries, and handling sludge. Their robust construction and reliability ensure consistent operation in these critical processes.

2.3.7.4 Manufacturing

Manufacturing industries utilize reciprocating piston pumps for hydraulic systems, cooling systems, and lubricating machinery. The pumps' efficiency and ability to deliver precise volumes of fluid are crucial for maintaining production quality and machinery performance.

2.3.7.5 Pulsatile Blood Pump

One of the most important applications of piston pump, that we apply the working principle and calculations of the piston pump to simulate the heart as a pump to be able to use it with the patients. In our project, we make a pulsatile piston pump that simulates the left ventricle of the heart to use this pump in testing the performance of different cardiac assist devices.

2.4 Apply Piston Pump Principles on Pulsatile Blood Pump

2.4.1 Pump Design

2.4.1.1 Piston Design

The piston-based pulsatile flow pump system was designed to meet several application needs. Those were to:

- Generate high volume flow rates like those in the human aorta.
- Allow for custom input of and replicate physiologic waveforms.
- Generate very small inlet disturbances so as to enable experiments on transition from laminar to turbulent flow.
- Be capable of pumping fluids with high viscosities (e.G., 4 cp) against large impedances depending on tubing length.



Figure 2-7 Piston Design

Piston Dimensions

$$CO = SV * HR \dots [1]$$

Assuming that: CO = 15 L/min, HR = 3:200 bpm

From equation [1] SV = 5:180 mL

$$V[\text{mm/sec}] = \left(\frac{\text{Stroke Volume}[ml]}{\text{Volume/step}[ml]} * 0.025 \right) / \left(\frac{60}{\text{Heart Rate}[bpm]} * 1/2 \right) \dots [2]$$

Assuming that: Volume /step(mL) = 0.0704 mL, HR = 60 bpm,

From equation [2] V = 59.18 mm/s

$$Q = AV \dots [3]$$

From equation [3] A = $1.4 * 10^{-3} \text{ m}^2$

$$D = 4.3 \text{ cm}$$

Assuming that: Q = 5 L/min

We will choose standard dimensions

$$D = 2 \text{ in}, d = 5/8 \text{ in}$$

Groove: It is calculated by Apple Rubber

2.4.1.1.1 Genetic Algorithm

Our Goal

To minimize the diameter for the worst case(exercise) to cover all conditions (Rest& heart failure) to give the best cardiac performance.

Variables

- Length (L)

Objective Function

- Diameter function of (Vol Flow & HR & L)

Constraints

1. Stroke Volume
2. Heart Rate
3. Systole
4. Flow

Design variables

- L: length

Objective function

$$d^2 = \frac{\text{vol_flow}}{\frac{\pi}{4} \times L \times \text{bpm}}$$

Constraints

- $\text{vol_flow}=20 \text{ L/min}$
- $\text{BPM}=120$
- $t = \frac{60}{\text{BPM}} \times 0.4$
- $V_{max} \leq 0.4 \text{ m/s}$
- $L \geq 0$

Code

```

function f=diameter(x)
L1=x(1)
flow=20;
bpm=120;
f=sqrt(flow*10^(-3)/((pi/4).*L1*bpm));

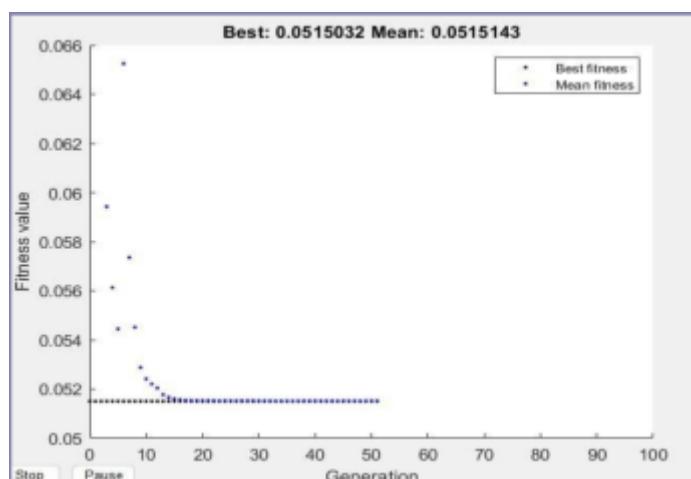
```

```
clc;clear;
flow=20;
bpm=120;
t=(60/bpm)*0.4;
A=[1/t];b=[0.4];
c=[0];
fun=@diameter;
options = optimoptions('ga','ConstraintTolerance',1e-7,'PlotFcn', @gaplotbestf);
x=ga(fun,1,A,b,[],[],c,[],[],options)
d=1000*sqrt(flow*10^(-3)/((pi/4).*x.*bpm))
```

Results

```
x =
0.0800

d =
51.5032
```



2.4.1.1.2 Material

There are numerous choices that must be made during the process of selecting parts from.

Decision must be made after taking the goal of the pulsatile blood pump project into account, as many choices could be swayed in one direction or the other by a small adjustment in overall goals.

4023-AL	2618-AL
<p>It will offer reduced noise at start-up, increased wear resistance, and durability.</p>	<p>The application will benefit from the increased strength and detonation resistance of the 2618 alloy</p>
<p>4032 alloy helps the piston to survive more heat cycles</p>	<p>the 2618 alloy a greater resistance to the shock loads of detonation.</p>

2.4.1.1.3 O Ring

Parker Size	AS568A Size	Nominal (inches)			Actual (inches)			Basic Volume (Cu. in.)
		ID	OD	W	ID	±	W	
2-129	-129	1 9/16	1 3/4	3/32	1.548	.015	.103	.003 .0432
2-130	-130	1 5/8	1 13/16	3/32	1.612	.015	.103	.003 .0449
2-131	-131	1 11/16	1 7/8	3/32	1.674	.015	.103	.003 .0465
2-132	-132	1 3/4	1 15/16	3/32	1.737	.015	.103	.003 .0482
2-133	-133	1 13/16	2	3/32	1.799	.015	.103	.003 .0498
2-134	-134	1 7/8	2 1/16	3/32	1.862	.015	.103	.003 .0514
2-135	-135	1 15/16	2 1/8	3/32	1.925	.017	.103	.003 .0531

O Ring, Parker #2-133



2.4.1.2 Cylinder Design

- ⇒ The minimum piston to cylinder clearance is 0.07 mm
- ⇒ Piston diameter of Ø50.8 mm.
- ⇒ Cylinder diameter of Ø50.87 mm
- ⇒ Length of cylinder: 100 mm
- ⇒ Maximum volume: 203.24 ml



Design	transparent
Diameter	3mm to 600 mm any size
Color	Transparent
Length of Pipe	up to 2 meter ready others customised
Usage/Application	Chemical
Packaging Type	loose or wooden packing
Shape	cylinder
Hollow Section	Circular, Square
Thickness (mm)	0.3-50mm
Quantity Per Pack	as per your order and size
Finishing	Glossy finish
Position	hollow
Hardness	tuff
Density	standard
Country of Origin	Made in India
Material	PMMA

2.4.2 Mechanical Design

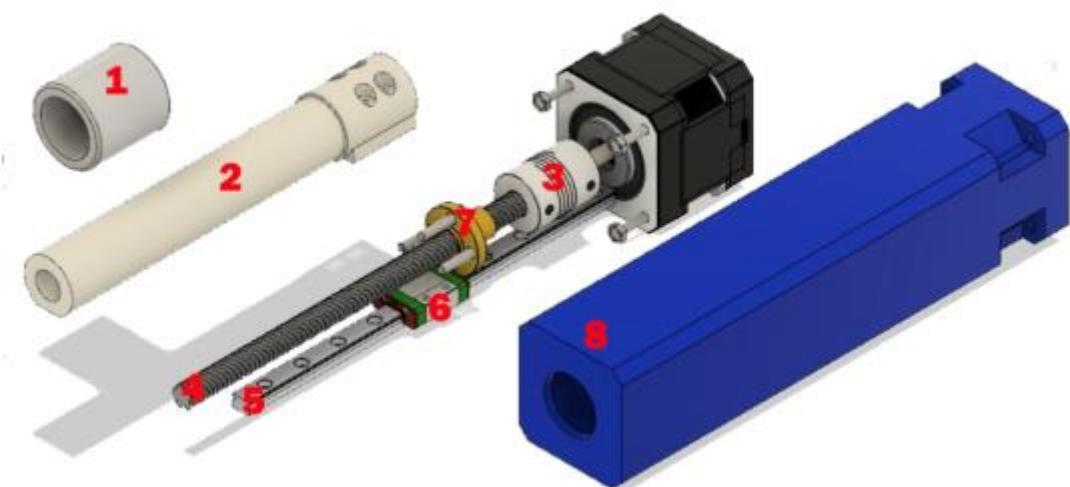


Figure 2-8 Mechanical Design of Piston Pump

Item number	Name Item	Dimension
1	Linear ball	40mm
2	Cylinder	150mm
3	Flexible coupling	500mm
4	ball screw	150 mm
5	MANR	150MM, 9 mm
6	MGN bearing	500mm, 9 mm
7	NUT	--
8	PISTON COVER	300 MM

2.4.2.1 Power Screw Calculations

Number of starts on your lead screw:

This defines the number of thread systems on your lead screw. A single start lead screw has a lead equal to its pitch, a double start lead screw has a lead twice its pitch, a 4 start lead screw has a lead 4 times its pitch, etc. Pitch is simply the distance between threads in mm. The number of starts on a lead screw can be found by looking at the end and counting the starts.

The difference between lead and pitch

In ball and lead screws there are often multiple threads, or multiple starts, running up the screw. These are referred to as multi-start screws. If the screw is a multi-start screw the lead and pitch are not the same.

- **Lead** is the distance the nut travels with one revolution of the screw.
- **Pitch** is the distance between two lands on the screw thread

-For single start screw, the lead = pitch.

-For double start, the lead = 2 times the pitch.

-For four starts, the lead = 4 times the pitch.

Critical Speeds and Lead Screws

There are a variety of factors that must be considered before screw selection is determined in any type of application. One factor that should not be overlooked when it comes to selecting lead screws is critical speed. Lead screws, like any object in our environment, have a natural frequency. When an object is excited at its natural frequency it will vibrate excessively. Critical speed is the rotational speed in revolutions per minute (rpm's) that matches the screw's natural frequency, thus causing excessive vibration.

At what point in the screw selection process should critical speed be determined? Critical speed is typically considered after the load, speed, length, and end fixity are identified. Here is a quick overview of these factors:

- **Load:** Choices include dynamic, static, reaction forces, and any other external forces that may have an impact on the screw itself.
- **Speed:** The travel rate, or linear speed of the lead nut. The travel rate is the rpm of the screw multiplied by the lead of the screw.
- **Length:** This is the unsupported length of the screw itself (distance between bearing supports).
- **End Fixity:** This refers to how each end of the screws is supported. Each end of a screw can have a different type of end fixity. The following are some common types of end fixity:
 - ⇒ Free – no bearing support, the end of the screw is “floating” in space.
 - ⇒ Simple - single bearing support
 - ⇒ Fixed - multiple and spaced bearings

In addition to the above factors, critical speed is also impacted by shaft straightness and assembly alignment. Therefore, it is recommended that the maximum speed of the screw does not exceed 80% of the calculated critical speed.

(It is also worth noting that the resonance of the screw will occur no matter the screw orientation or system design. So it doesn't matter if you're dealing with a vertical or horizontal orientation or even if the system is designed so that the nut is driven and the screw translates - resonance will occur).

Where:

"N" is the critical speed in (rpm)

"d" refers to the root diameter of the screw (inches)

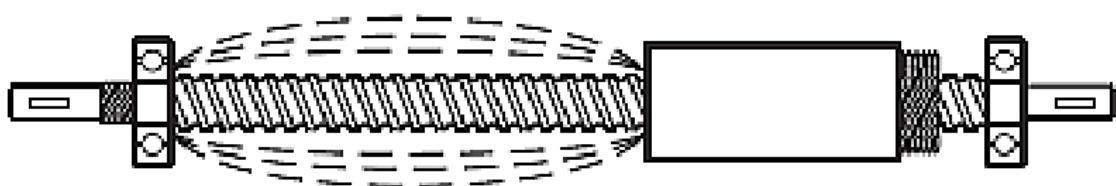
"L" is the length between bearing supports (inches)

"Cs" is the end condition factor.

A common question that we often get asked here at Helix Linear is what should be done if a selected screw fails to meet critical speed criteria. If this is the case, there are several options that can be considered.

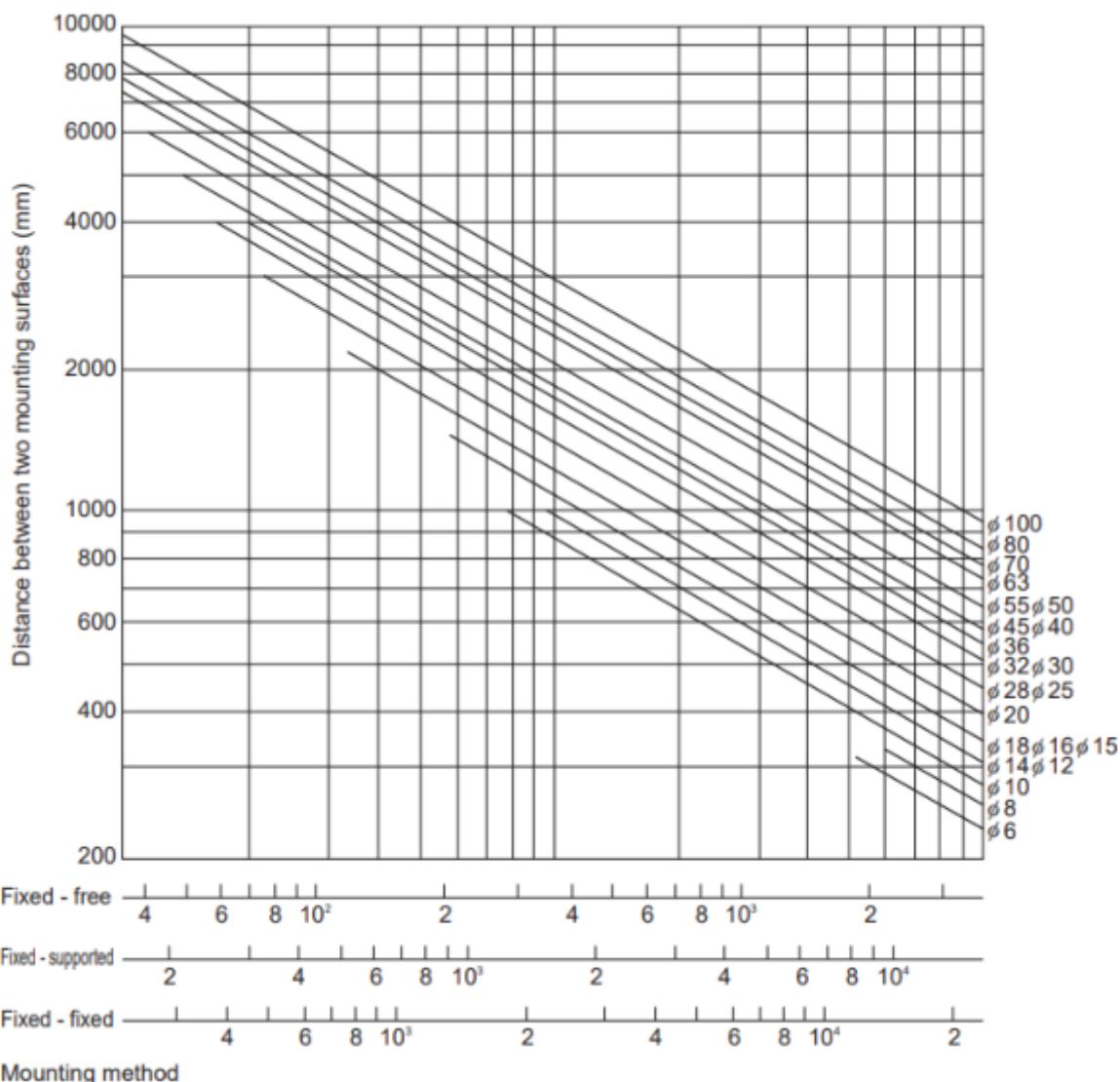
- Increase the screw lead: This will allow the same translation speed of the nut with reduced rpm.
- Modify the end fixity: Increasing the rigidity of the system. For example, going from simple to fixed support(s) increases the critical speed.
- Increase the screw diameter.

When it comes to selecting lead screws for your application, do not neglect critical speed when making your determination. It is very important to operate your lead screw below its critical speed for optimum system performance and life.



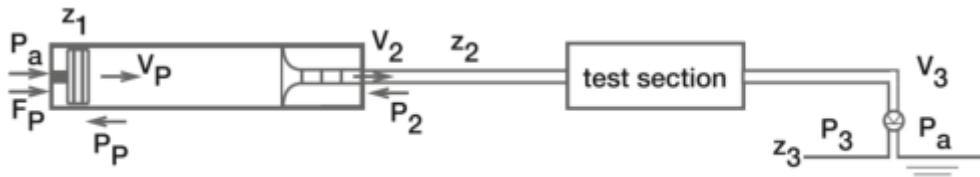
Critical Speed Ball and Lead Screw

Root diameter of screw (mm) d =	8.00
Unsupported length of screw (mm) L =	150.00
Factor for support bearings f =	3.4
Calculated Results	
Critical speed (rpm) n =	13600.00



2.4.3 Force Analysis

A force analysis of a piston-based flow loop, depicted in the Fig. was performed to obtain force and energy balance equations, which were used to determine the total piston force output required.



$$F_p = (m_p) V_p + L \cdot V_p^2 \cdot A^2 + \rho Q (V_2 - V_p) - P_a \cdot A_p + F_f + A_2 [P_3 + \left(\frac{fL}{d} + K_v \right) \cdot V_2^2 \cdot \frac{\rho}{2} - \rho g (z_2 - z_3)]$$

m_p : mass of the piston.

m_c : mass of the fluid.

P_a : the atmospheric pressure.

A_p : the area of the piston.

F_p : the force applied on the piston.

P_p : the pressure applied on the piston.

F_f : the friction force.

V_p : the acceleration of the piston.

V_2 and V_3 : the velocities at locations 2 and 3 respectively.

g : the acceleration due to gravity

P_2 and P_3 : the pressures at locations 2 and 3

z_2 and z_3 : the height at locations (L) 2 and 3,

h_L : the head loss of the system.

f : the friction coefficient.

L : the total length of tubing .

D : the inner diameter of tubing.

K_v : the head loss coefficient.

Givens :

$$M_p = 1381.13 \text{ g} \quad M_c = P * S V = 1060 \text{ g} \quad V_p = 1.16 \text{ m/s}^2$$

$$P = 1060 \text{ kg/m}^2 \quad A_p = 2.026 * 10^{-6} \text{ m}^2 \quad A_2 = 188.69 * 10^{-6} \text{ m}^2$$

$$V_p = 0.16 \text{ m/s} \quad P_a = 1.013 \text{ bar} \quad Z_2 = 0$$

$$Z_3 = -2 \text{ m} \quad V_2 = 10.24 V_p = A_p / A_2 \times V_p$$

$$R = 1430 \text{ dyne.sec/cm}^5$$

$$F_{inertia} = L \times V^{\circ} P \times A^2 = 0.031152 \text{ N (can be neglected)}$$

$$F_f = 5.032 + 25.92 = 30.952 \text{ pounds}$$

$$\Delta P = 1430 * \text{stroke volume} = 14300 \text{ N/m}^2$$

$$F_p = 146.002 \text{ N}$$

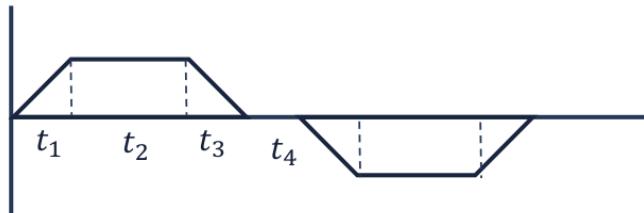
2.4.4 Acceleration

Given

$$\text{Volume} = 7.7 \text{ L/min}$$

$$\% \text{Systole} = 0.4$$

$$\text{BPM} = 60$$



Solution

$$\text{Stroke} = \frac{\text{volume}}{\text{area}}$$

$$\text{Area} = \frac{\pi}{4} (2 * 2.54 * 10^{-2})^2$$

$$\text{Stroke} = S1 + S2 + S3$$

$$\text{Time systole} = \frac{60}{\text{BPM}} \times (\% \text{systole})$$

$$\text{Time diastole} = \frac{60}{\text{BPM}} \times (1 - \% \text{systole})$$

$$\text{Stroke} = 50 \text{ mm}$$

$$\text{Time systole} = 400 \text{ ms}$$

$$\text{Time diastole} = 600 \text{ ms}$$

$$t4 = a * t_{systole} = \frac{1}{8} \times t_{systole}$$

$$t2 = b * t4 = 1.5 * t4 \quad t1 = c * t3 = 1 * t3$$

$$tsystole = t4 + t3 + t2 + t1$$

Systole

$$S1 = S3$$

$$\text{Stroke} = 2 * S1 + S2$$

$$\text{Stroke} = \frac{1}{2} V_{max} t_1 * 2 + V_{max} t_2$$

$$V_{max} = 0.235 \text{ m/s}$$

$$a = \frac{V_{max}}{\text{time}} = 1.709 \frac{\text{m}}{\text{s}^2}$$

Diastole

$$S1' = S3'$$

$$\text{Stroke} = \frac{1}{2} V_{max'} t_1' * 2 + V_{max'} t_2'$$

$$V_{max'} = 0.1568 \text{ m/s}$$

$$a = \frac{V_{max'}}{\text{time}} = 0.7605 \frac{\text{m}}{\text{s}^2}$$

$$\text{Max acceleration} = 1.7 \text{ m/s}^2$$

2.4.5 Torque

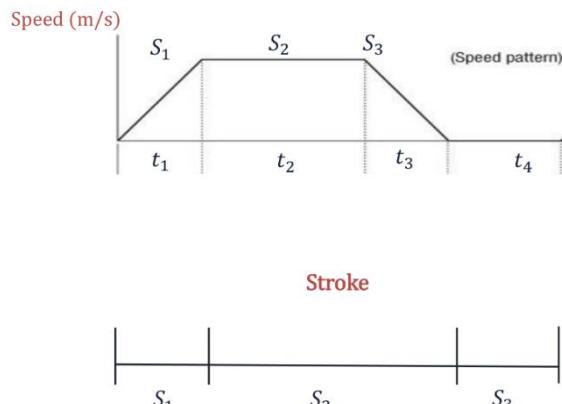
- Linear piston speed

$$F_p = 146.002 \text{ N}$$

Given: BPM=120, %Systole= 0.4, stroke= 50mm

$$V_{max} = 0.3 \text{ m/s}$$

$$a = 20 \text{ m/s}^2$$



- Torque calculations

$$T_{motor} = j \times \omega^\circ + T_{load}$$

$$j = j_{motor} + j_{power\ screw} \times (m \times R^2) = \frac{0.409}{1000} + 0.5 \times (4 \times 10^{-3})^2 = 0.45 \text{ kg.cm}^2$$

$$\omega^\circ = 15700 \text{ rad/s}^2$$

$$j_{power\ screw} = m \times R^2 = 0.5 \times (4 \times 10^{-3})^2$$

$$j_{motor} = 0.409 \text{ Kg.cm}^2$$

$$T = F_{axial} \times \frac{d}{2} \times \left(\frac{\mu_s + \cos(\theta) \times \tan(\alpha)}{\cos(\theta) - \mu_s \tan(\alpha)} \right)$$

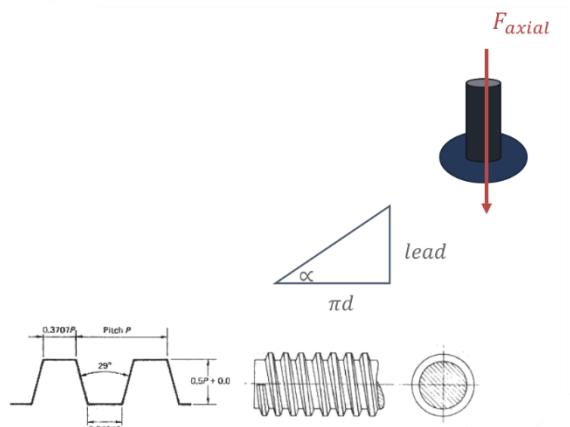
μ_s : friction coefficient

$\mu_s = 0.01$ (given for ball screw)

$$F_{axial} = 200 \text{ N}$$

$$\text{lead angle } \alpha = \tan^{-1} \times \frac{\text{lead}}{\pi d} = 17.66^\circ$$

$$\theta = 29^\circ$$



2.4.6 Specifications

Specification	Value
Torque _ Rms (N.M)	0.36
Torque _ Max (N.M)	0.966
Power _ Max (Watt)	226.08
Maximum Needed Speed (Rpm)	2250

2.4.7 Motor Selection

2.4.7.1 Selected Motor



Model parameter	Small inertia , flange size of 60mm		Small inertia , flange size of 80mm	
Servo motor	SMC60S-0020-30M□K-3LSU SMS60S-0020-30K□K-3LSU		SMC60S-0040-30M□K-3LSU SMS60S-0040-30K□K-3LSU	SMC80S-0075-30M□K-3LSU SMS80S-0075-30K□K-3LSU
Available driver	CD413-AA-000 FD413-LA-000 FD413-CA-000 FD413-EA-000		CD423-AA-000 FD423-LA-000 FD423-CA-000 FD423-EA-000	
DC link voltage: VDC	300		300	300
Performance	Rated power Pn (W) Rated torque Tn (N.m) Rated speed nN (rpm) Rated current In (A)	200 0.64 3000 1.4	400 1.27 3000 2.4	750 2.39 3000 3.8
Maximum torque	Tm (N.m)	1.92	3.81	7.17
Maximum current	Im (A)	4.2	7.2	11.4
Standstill torque	Ts (N.m)	0.7	1.4	2.63
Standstill current	Is (A)	1.5	2.6	4.2
Resistance Line - Line	RL (Ω)	11.2	5.8	2.1
Inductance Line - Line	LL (mH)	20.9	11.5	10.5
Electrical time constant	τe (ms)	1.87	1.98	5
Mechanical time constant	τm (ms)	1.8	1.29	0.9
Reverse voltage constant	Ke (V/krpm)	29	1.85 (with brake)	0.9 (with brake)
Torque constant	kt (N.m/A)	0.48	34	40
Rotor moment of inertia	Jm (kg·cm²)	0.218 (with brake)	0.562	0.662
Brake holding torque	T (Nm)	1.5	0.405	1.087
Pole pair number	3		0.409 (with brake)	1.099 (with brake)
Maximum voltage rising du/dt (kv/us)	8		1.5	3.2
Insulation class	F		3	3
Maximum radial force	Fr (N)	180	8	8
Maximum axial force	Fa (N)	90	F	F
Weight	G (Kg)	1.2	180	335
		1.6 (with brake)	90	167.5
Length of motor	L (mm)	91±1.5	2.1 (with brake)	167.5
		121±1.5 (with brake)	117±1.5	3.8
Position feedback device	SMC series-16 bit single-turn magnetoelectric encoder; SMS series-Multi-turn absolute encoder			
Cooling method	Totally enclosed, non-ventilated			
Protection level	IP65, shaft sealing IP54 (Note: Add oil seal IP54 at the shaft end and do not add oil seal IP50)			
Temperature	-20~40°C (non-freezing)			
Humidity	Below 90% RH (no condensation)			
Ambient environment	Away from active gas, combustible gas, oil drops and dust			
Altitude	Maximum altitude 4000m, rated power at 1000m or below. Above 1000m, decreasing 1.5% per every 100m rise			

Specification	Value
Torque _ Rms (N.M)	0.36
Torque _ Max (N.M)	0.966
Power _ Max (Watt)	226.08
Maximum Needed Speed (Rpm)	2250

Selected motor	
Rated Power (w)	400
Rated torque (N.m)	1.27
Rated speed (rpm)	3000
Maximum torque (N.m)	3.81



2.4.8 SOLIDWORKS Design

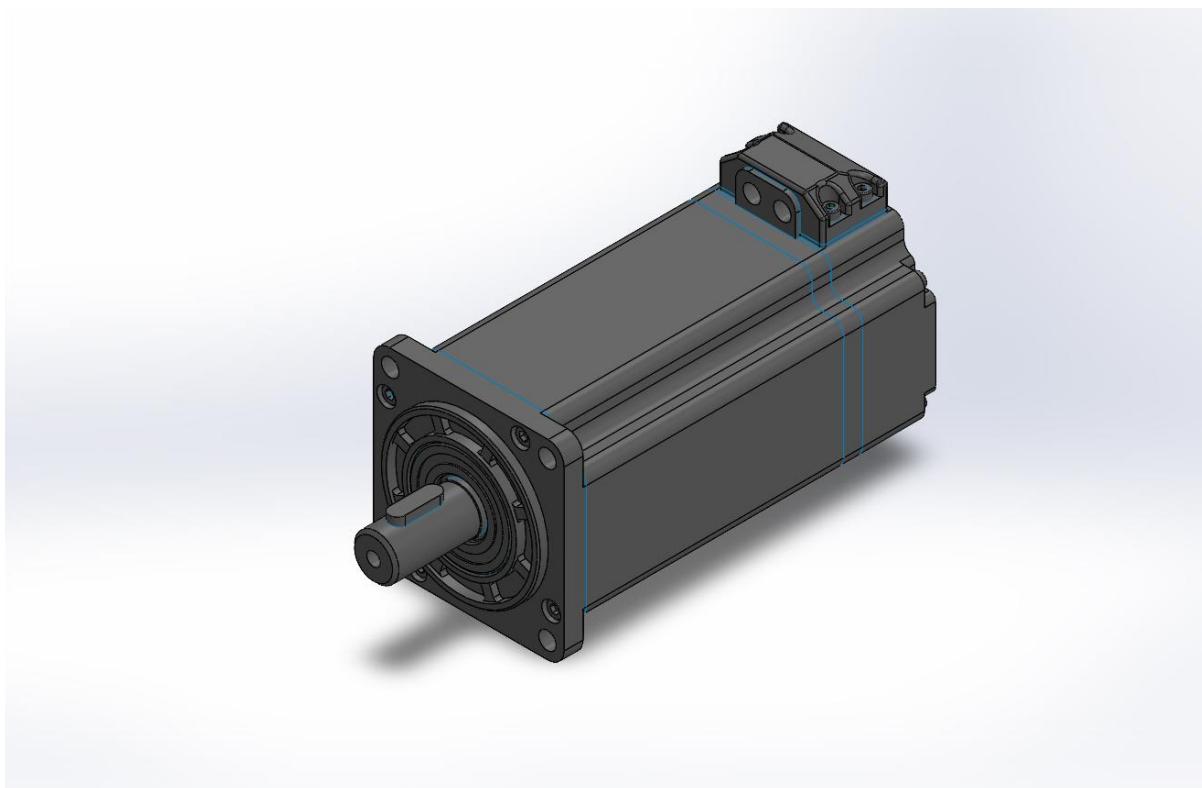


Figure 2-9 servo motor

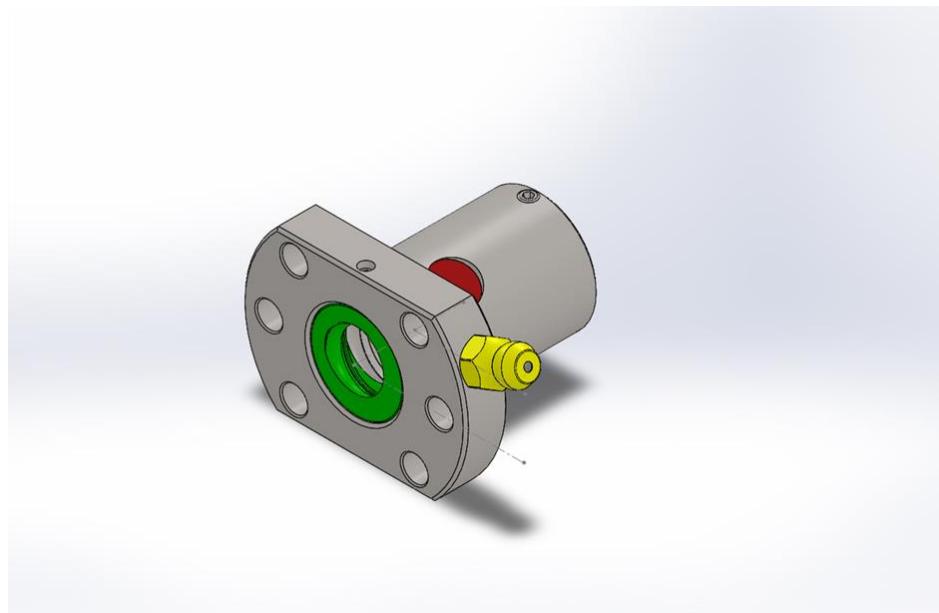


Figure 2-10 power screw washer



Figure 2-11 ball screw assembly

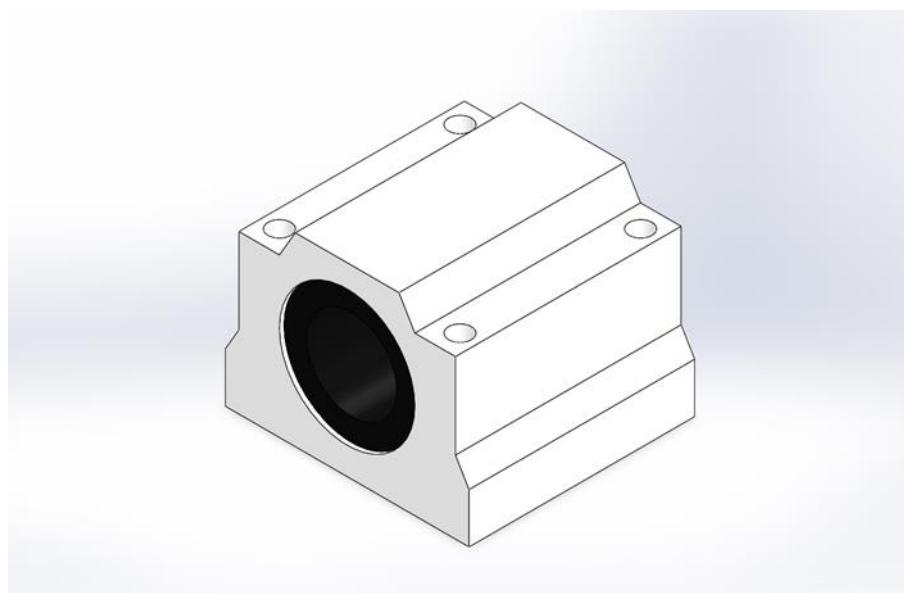


Figure 2-12 linear guide bearing

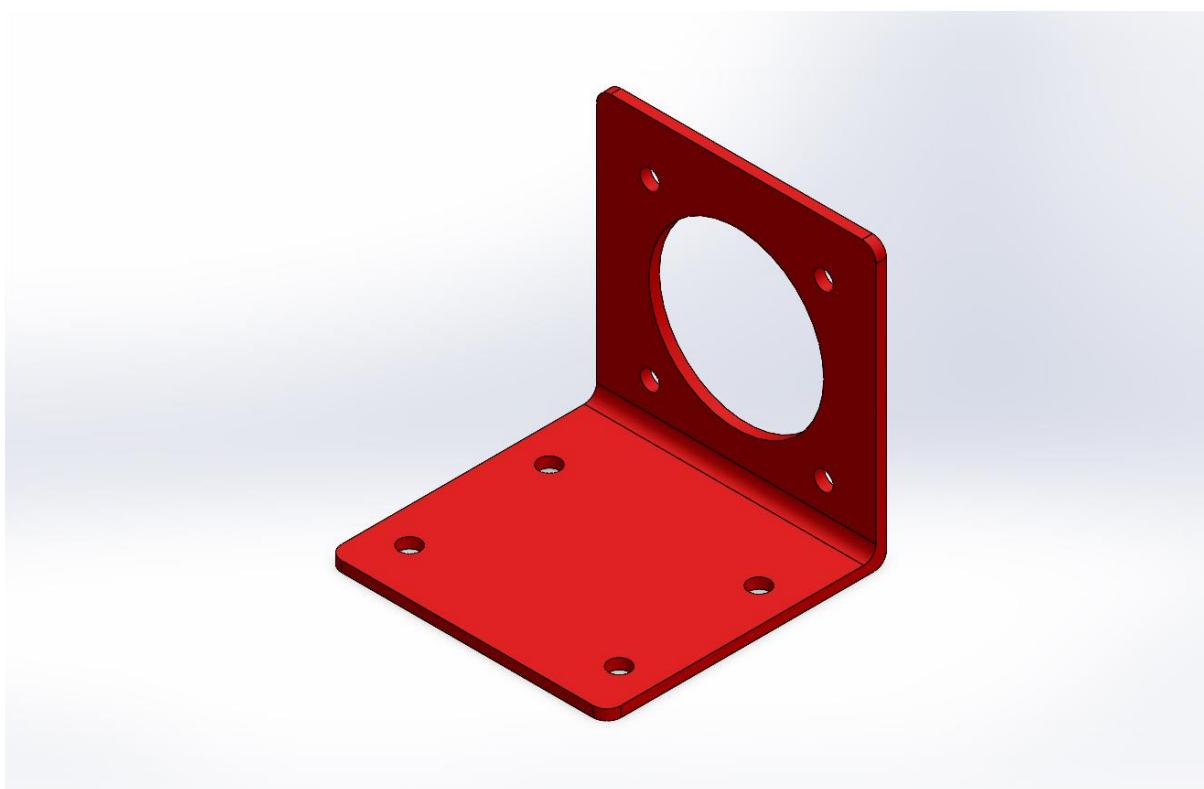


Figure 2-13 Motor fixation

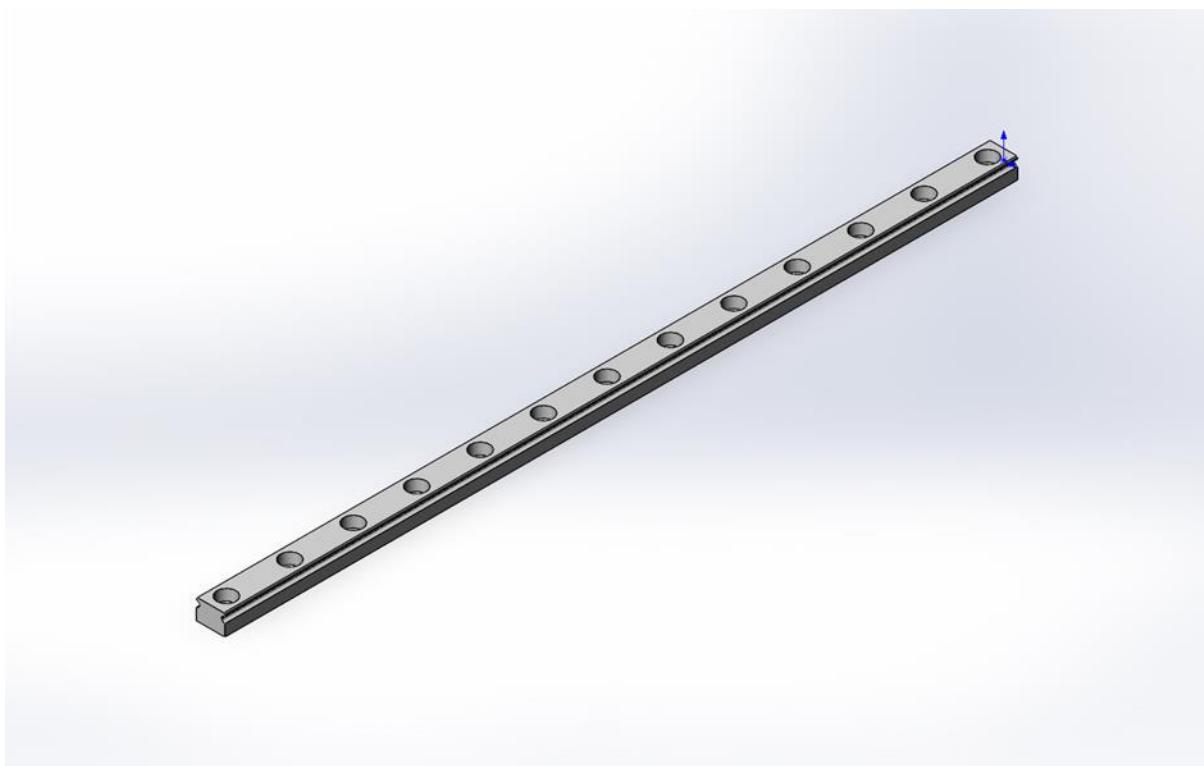


Figure 2-14 Linear bearing rail

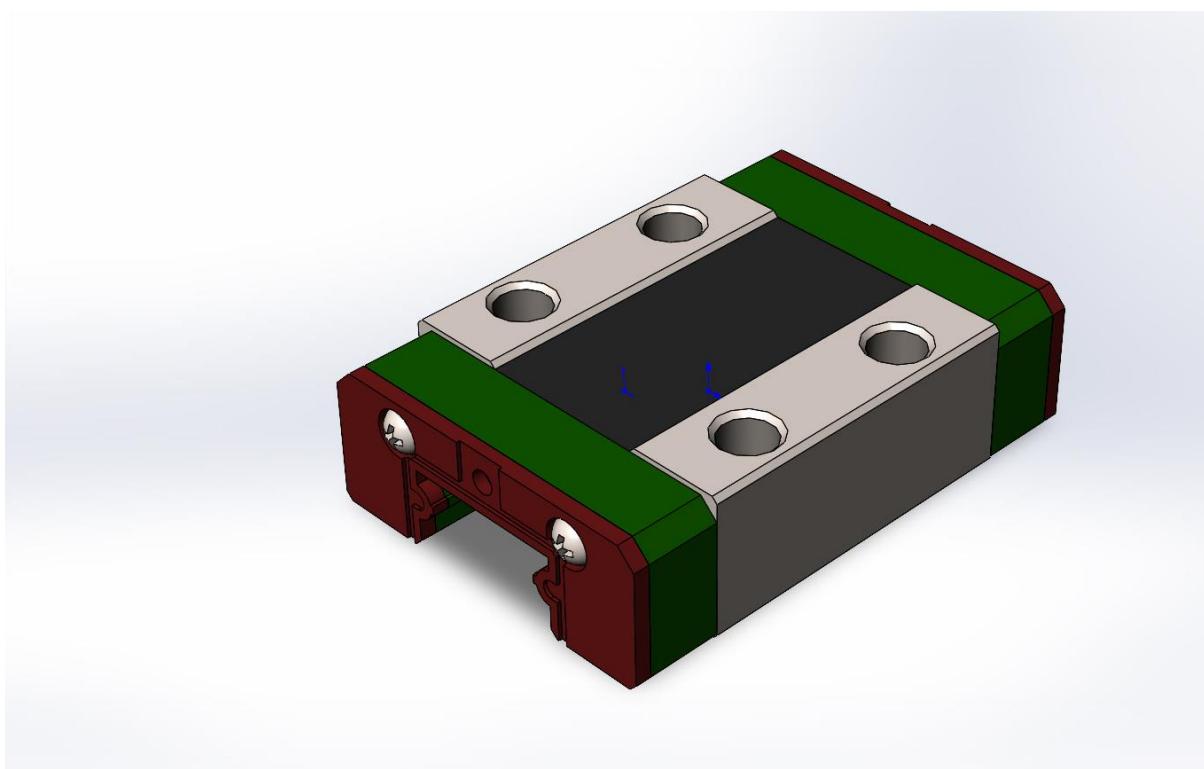


Figure 2-15 Linear bearing

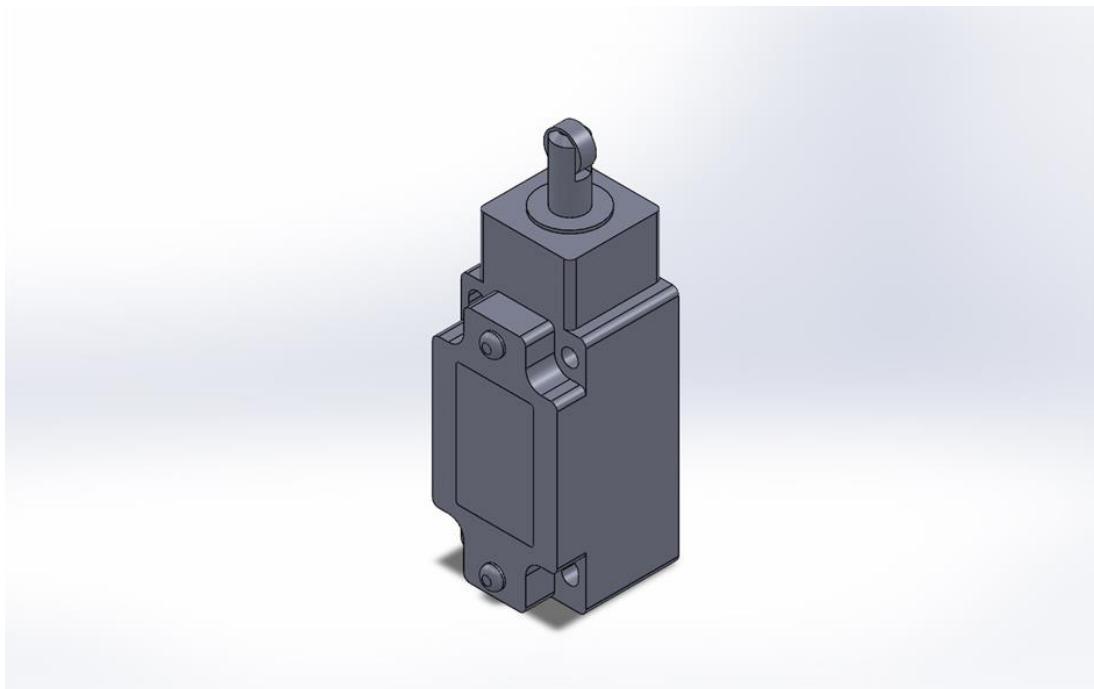


Figure 2-16 Limit switch

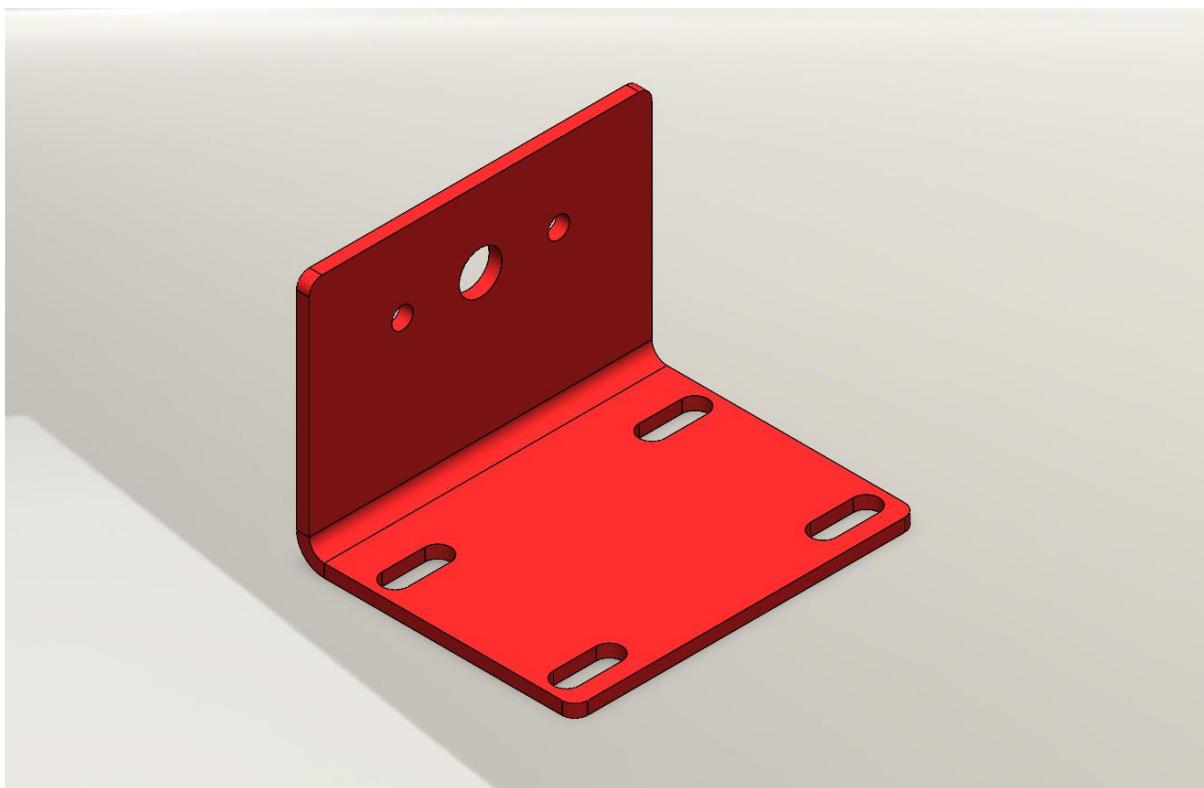


Figure 2-17 Small bearing fixation

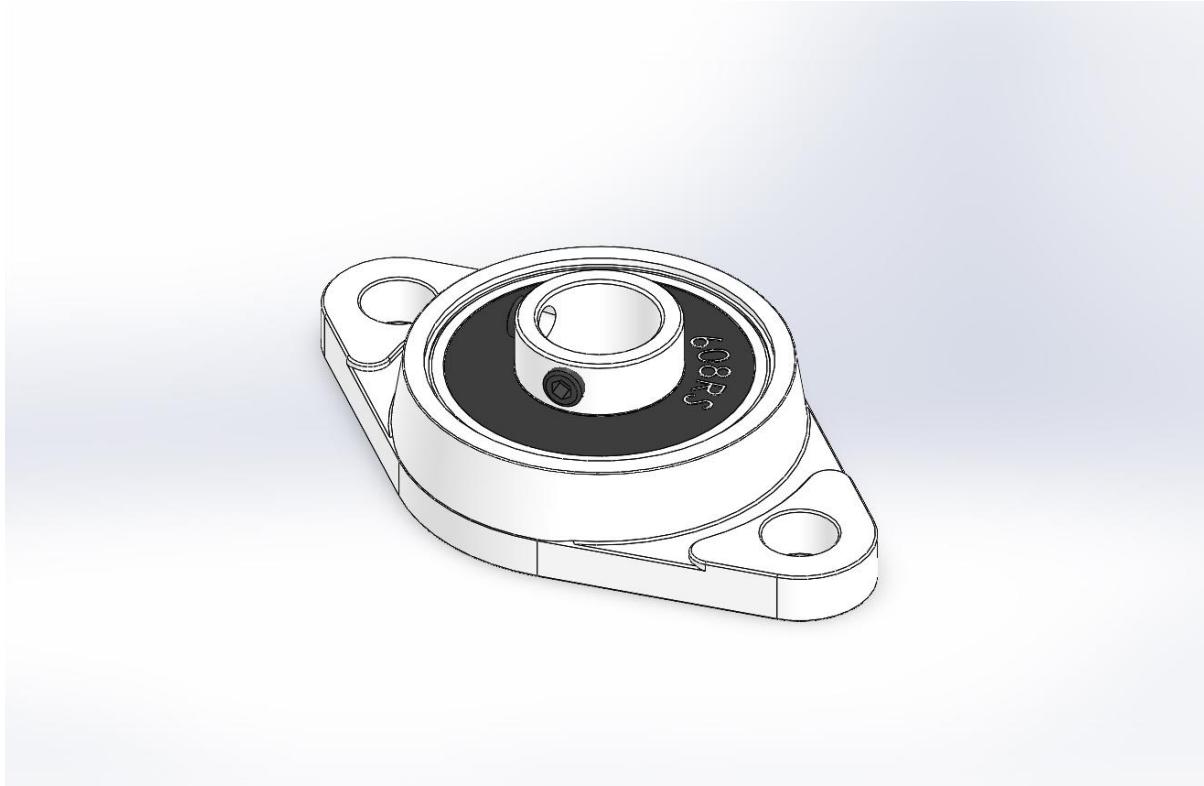


Figure 2-18 Small bearing

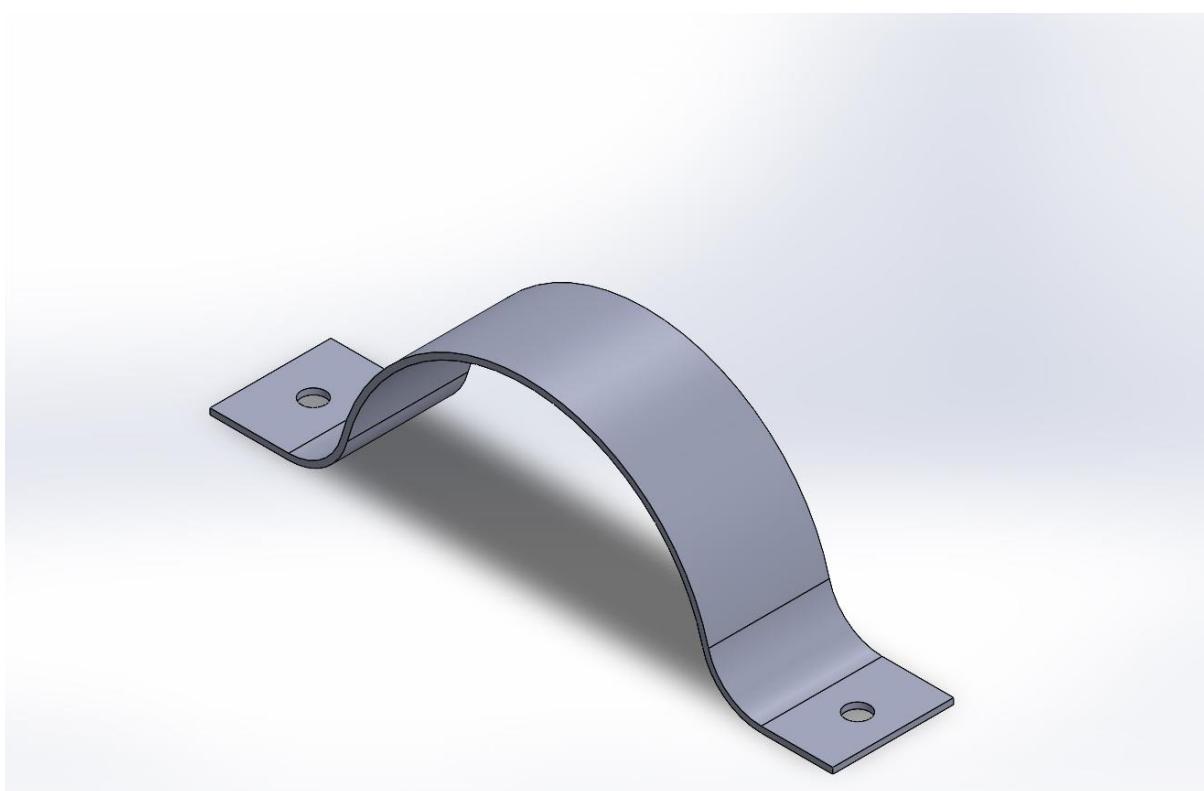


Figure 2-19 Cylinder fixation

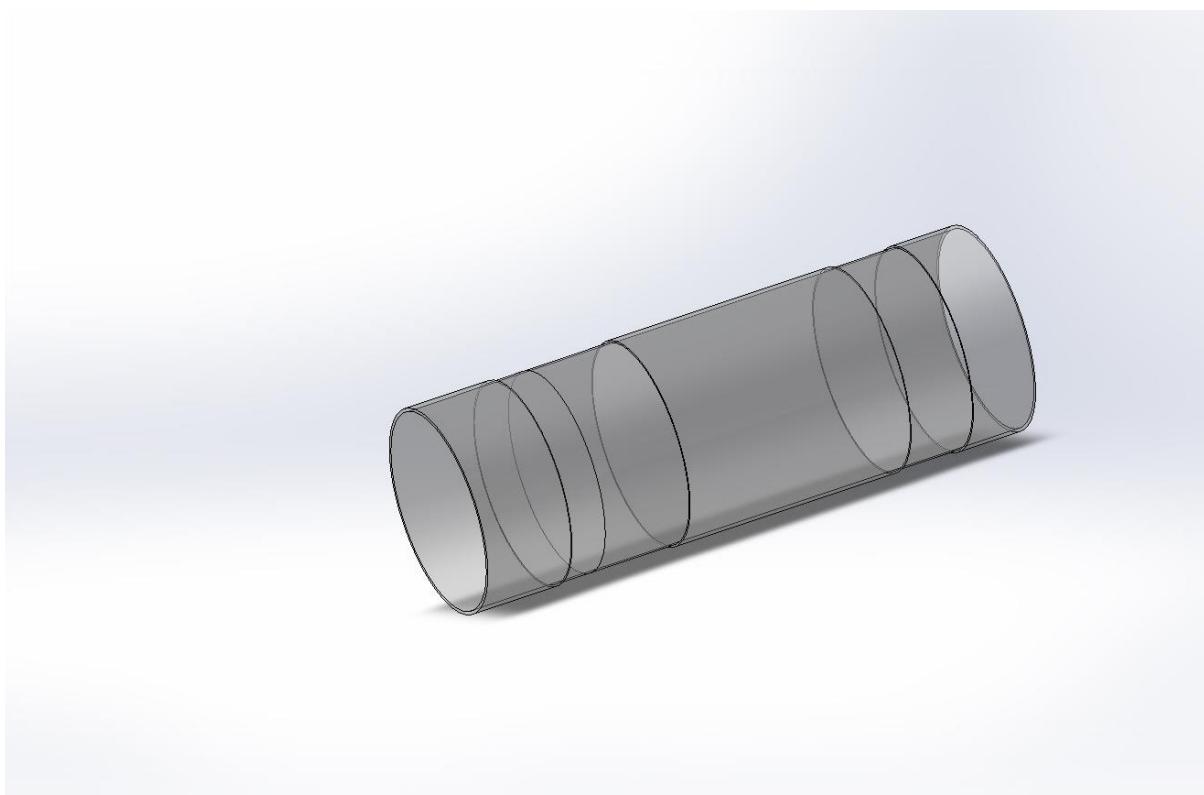


Figure 2-20 Cylinder acrylic

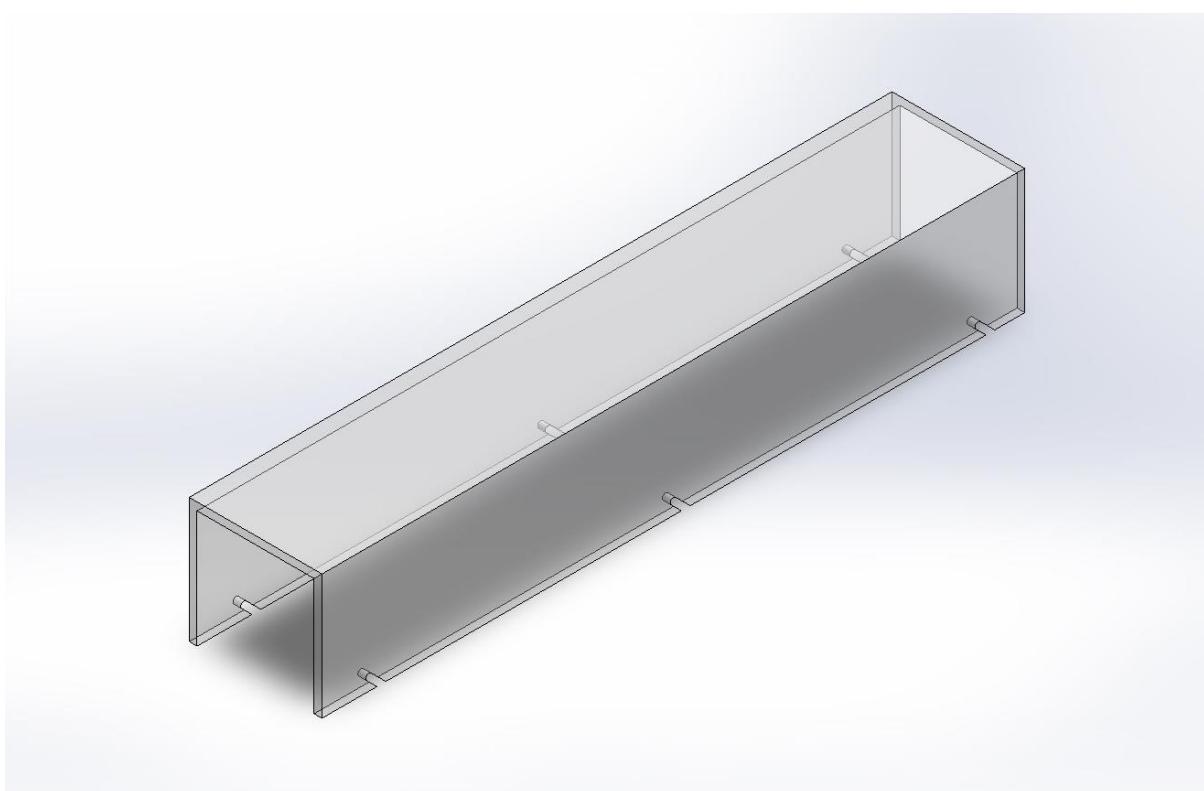


Figure 2-21 cover

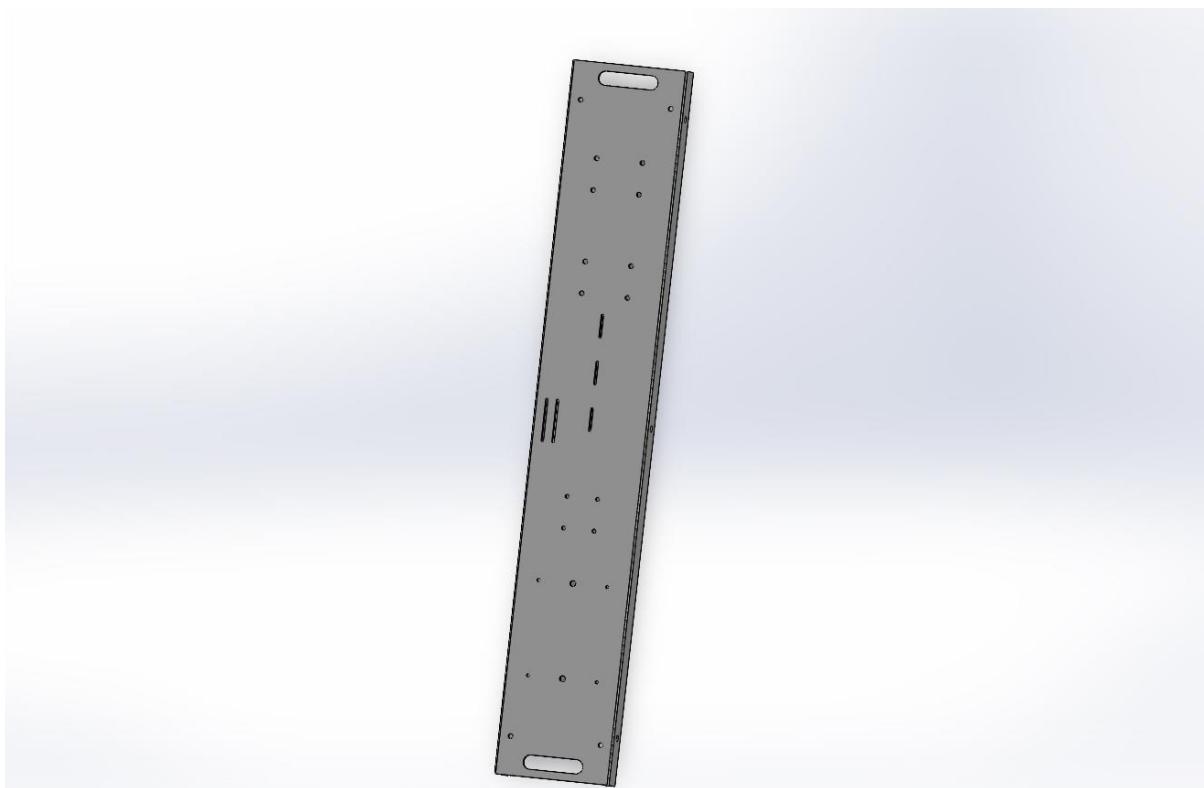


Figure 2-22 Base

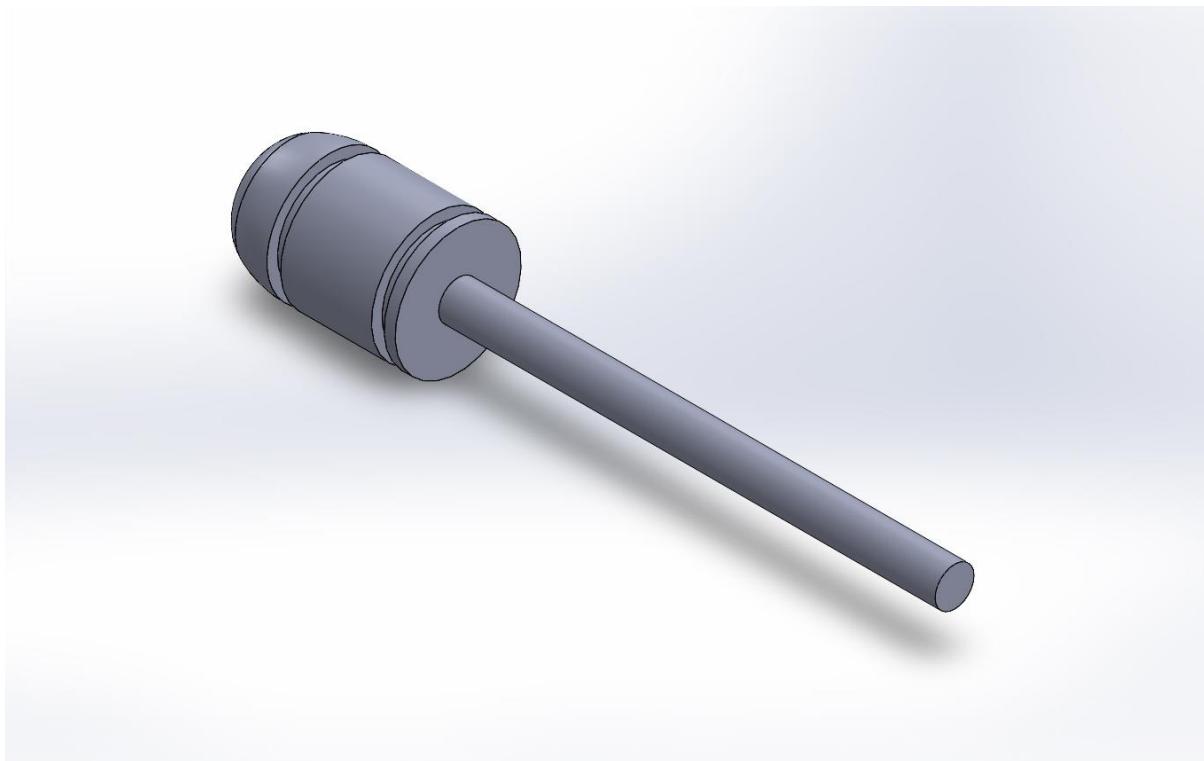


Figure 2-23 Piston

2.4.9 Valve Selection

To select the right valve that is suitable for our pump, it should be able to open at the pressure that the pump and its motor provide to the piston and should be close to the value that the aortic and mitral valve in human body open at it, so let's compare between the two values and show the selection process:

2.4.9.1 In The Human Body

Your mitral valve opens to send blood from your left atrium to your left ventricle. When your left ventricle is full it squeezes, which closes your mitral valve and opens your aortic valve. Your heart sends blood through your aortic valve to your aorta, where it flows to the rest of your body.

The opening pressures of the aortic and mitral valves in the left ventricle of the heart are critical for proper cardiac function. These pressures ensure that blood flows efficiently from the left atrium to the left ventricle and then from the left ventricle to the aorta.

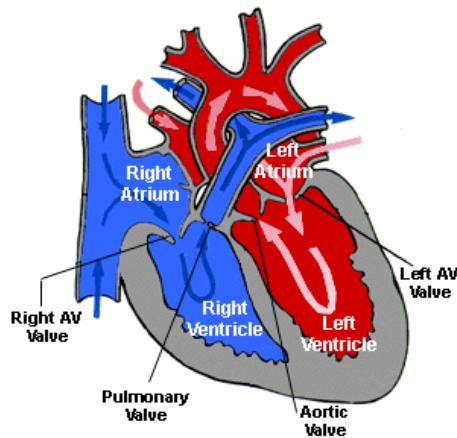


Figure 2-24 Blood flow in the left side of heart

2.4.9.1.1 Mitral Valve Opening Pressure

The mitral valve opens when the pressure in the left atrium exceeds the pressure in the left ventricle. This typically occurs when the left ventricular pressure is between 0 and 10 mmHg, and the left atrial pressure is slightly higher, around 8 to 12 mmHg during the end of the atrial contraction (atrial systole).

- **Typical mitral valve opening pressure:** Approximately 8-12 mmHg.
- **Pressure in bar:** Approximately 0.01067- 0.016 bar.

2.4.9.1.2 Aortic Valve Opening Pressure

The aortic valve opens when the pressure in the left ventricle exceeds the pressure in the aorta. This occurs when the left ventricular pressure rises above the aortic diastolic pressure during ventricular systole. The aortic diastolic pressure is usually around 70-80 mmHg.

- **Typical aortic valve opening pressure:** Approximately 70-80 mmHg (aortic diastolic pressure).
- **Pressure in bar:** Approximately 0.0933- 0.1067 bar.

2.4.9.2 Valve Selection Process

We make our selection according to the pressure of 0.1 bar of the aortic valve to simulate the heart performance.

1) Plastic PP mini vacuum check valve



Figure 2-25 Plastic PP mini vacuum check valve

Valve core is designed to be used in Compact or mini-sized vacuum systems where space is limited.

We didn't use it because we can't fix it in our head.

2) PVC valve ball wafer check valve 2-8 inch



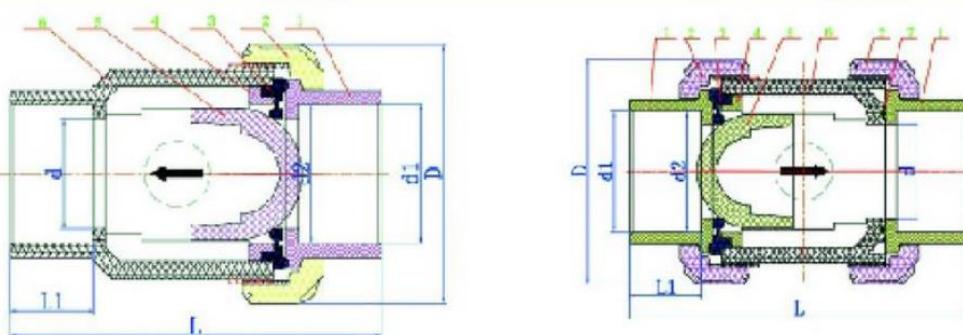
Figure 2-26 PVC valve ball wafer check valve 2-8 inch

This type has large dimensions that isn't suitable in our head.

3) DIN UPVC Industrial Water Treatment Ball PVC Check Valve Single Union Check Valve OEM Glue Industrial Grade Hydraulic General GS



Figure 2-27 DIN UPVC Industrial Water Treatment Ball PVC Check Valve



序号	名称	材质	数量	单位	序号	名称	材质	数量	单位
01	平承口	UPVC/CPVC/PPH	1	PCS	04	垫片	UPVC/CPVC/PPH	1	PCS
02	螺帽	UPVC/CPVC/PPH	1	PCS	05	球	UPVC/CPVC/PPH	1	PCS
03	密封垫	EPDM/VITON	1	PCS	06	本体	UPVC/CPVC/PPH	1	PCS

序号	名称	材质	数量	单位	序号	名称	材质	数量	单位
01	平承口	UPVC/CPVC/PPH	1	PCS	05	球	UPVC/CPVC/PPH	1	PCS
02	螺帽	UPVC/CPVC/PPH	1	PCS	06	本体	UPVC/CPVC/PPH	1	PCS
03	密封垫	EPDM/VITON	1	PCS	07	弹簧	SUS304	1	PCS
04	垫片	UPVC/CPVC/PPH	1	PCS					

规格(SIZE)	d	d1					d2					D	L	L1
		ANSI	DIN	JIS	CNS	PPH	ANSI	DIN	JIS	CNS	PPH			
1/2"(15)	15	21.40	20.25	22.30	22.40	19.30	21.25	20.05	21.85	21.90	19.00	54.00	91.00	23.00
3/4"(20)	20	26.75	25.25	26.30	26.40	24.10	26.58	25.05	25.85	25.90	23.80	63.00	106.50	26.00
1"(25)	25	33.52	32.25	32.33	34.50	31.00	33.28	32.05	31.85	33.90	30.70	73.50	125.00	29.00
1-1/4"(32)	32	42.28	40.25	38.43	42.50	39.00	42.05	40.05	37.85	41.90	38.60	84.50	141.00	33.00
1-1/2"(40)	40	48.40	50.25	48.46	48.60	49.00	48.12	50.05	47.75	47.90	48.60	98.00	150.50	35.50
2"(50)	50	60.45	63.25	60.56	60.60	61.90	60.18	63.05	59.75	59.90	61.40	119.00	169.50	38.50
2-1/2"(65)	63	73.30	75.25	76.60	76.70	73.60	72.85	75.05	75.87	75.90	72.30	150.00	245.00	64.50
3"(80)	75	89.25	90.35	89.60	89.70	88.30	88.70	90.05	88.83	88.90	86.90	169.00	270.00	70.00
4"(100)	90	114.60	110.35	114.70	115.00	108.00	114.10	110.05	113.98	113.80	106.40			

We refused it because it was very long.

-
- 4) Taike China Manufacturer Cast Iron Cast Steel Stainless Steel WCB Wafer Non Return Check Valve Price.



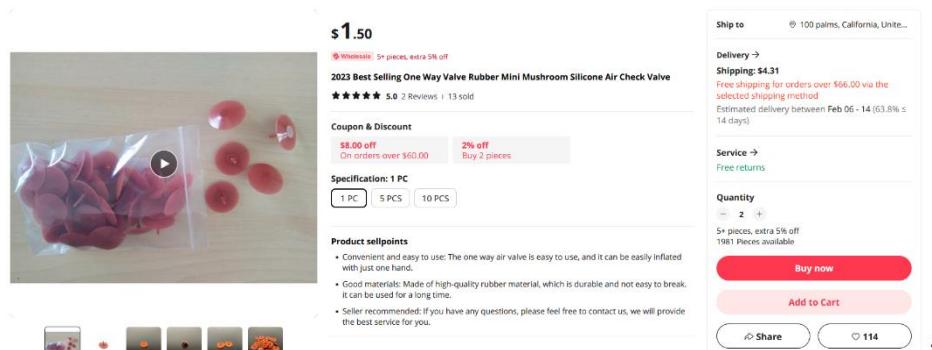
Figure 2-28 Taike China Manufacturer Cast Iron Cast Steel Stainless Steel WCB Wafer Non-Return Check Valve Price.

This is a wafer check valve, but it has a disadvantage for us that it has high cracking pressure.

- 5) 2023 Best-Selling One-Way Valve Rubber Mini Mushroom Silicone Air Check Valve



Figure 2-29 2023 Best-Selling One-Way Valve Rubber Mini Mushroom Silicone Air Check Valve



\$1.50

Wholesales 5 pieces, extra 5% off

2023 Best Selling One Way Valve Rubber Mini Mushroom Silicone Air Check Valve

★★★★★ 5.0 2 Reviews | 13 sold

Coupon & Discount

\$8.00 off On orders over \$60.00 2% off Buy 2 pieces

Specification: 1 PC

1 PC 5 PCS 10 PCS

Product sellpoints

- Convenient and easy to use: The one way air valve is easy to use, and it can be easily inflated with one hand.
- Good material: Made of high-quality rubber material, which is durable and not easy to break. It can be used for a long time.
- Seller recommended: If you have any questions, please feel free to contact us, we will provide the best service for you.

Ship to 100 palms, California, United States

Delivery →

Shipping: \$4.21

Free shipping for orders over \$66.00 via the selected shipping method.

Estimated delivery between Feb 06 - 14 (63.8% ≤ 14 days)

Service →

Free returns

Quantity 2

5 pieces, extra 5% off 1981 Pieces available

Buy now Add to Cart

Share 114

Specifications

Is Smart Device	no	NC or NO	Normally Closed
Port Size	25.60mm	Media	Water
Temperature of Media	High Temperature	Standard or Nonstandard	Standard
Model Number	UV2560	Power	HYDRAULIC
Pressure	Low Pressure	Material	Rubber
Structure	check	Origin	Mainland China
Certification	RoHS	Item	2023 Best Selling One Way Valve Rubber Mini Mushroom Silicone Air Check Valve
Color	Red	Opening Pressure	0-3Kpa
Sealing Size	25.60mm	Body	Silicone
Structure	Umbrella	Model	UV2560
Umbrella Valve Back Pressure	<=300Kpa	Origin	China Back Valve
Brand	Back Valve	Type	Check Valve Manufacturer
Custom Rubber Valve	Existing, No need new mould	Mini Valve Color	Red In stock, Customized Color Accepted

6) Car Intake System Repair Fuel FVMQ Umbrella Valve



Figure 2-30 Car Intake System Repair Fuel FVMQ Umbrella Valve

Is Smart Device	no	NC or NO	Normally Closed
Port Size	15.50mm	Media	GAS
Temperature of Media	High Temperature	Standard or Nonstandard	Standard
Model Number	UV1550	Power	HYDRAULIC
Pressure	Low Pressure	Material	SILICONE
Structure	check	Origin	Mainland China
Name	2 PCS Car Intake System Repair Fuel FVMQ Umbrella Valve	Opening Pressure	0-5Kpa
Back Pressure	<=300Kpa	Material	FVMQ

7) FVMQ Fuel Peugeot Rubber Umbrella Sealing Check Valve For Power Supply



Figure 2-31 FVMQ Fuel Peugeot Rubber Umbrella Sealing Check Valve For Power Supply

8) Plastic One-Way Non-Return Water One-way Valve Water Stop Valve Inline Fluids Check Valves for Fuel Gas Liquid



Figure 2-32 Plastic One-Way Non-Return Water One-way Valve Water Stop Valve Inline Fluids Check Valves for Fuel Gas Liquid

9) Duckbill Valve Breast Pump Backflow Protection Breast Silicone Baby Feeding Nipple Manual/Electric Breast Pump Accessories



10) BSPP Female Male Thread Brass In-Line Spring Check Valve One Way Water Pump Valve



Figure 2-33 BSPP Female Male Thread Brass In-Line Spring Check Valve One Way Water Pump Valve

Thread size	Thread Diameter (mm)		Error (mm)
	Male	Female	
1/8"	9.5	8.8	0.2
1/4"	12.5	11.5	0.3
3/8"	16.2	15.3	0.3
1/2"	20.3	19.5	0.3
3/4"	25.7	24	0.5
1"	32.5	30.5	0.5
1-1/4"	41.3	39.5	0.5
1-1/2"	47.8	46.3	0.5
2"	59.6	56.6	0.5

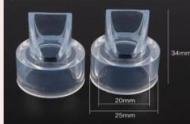
11) UPVC Pipe Check Valve Fish Tank Garden Irrigation Aquarium Tube Watering Adapter Fittings PVC Pipe Accessories



Figure 2-34 UPVC Pipe Check Valve Fish Tank Garden Irrigation Aquarium Tube Watering Adapter Fittings PVC Pipe Accessories

2.4.9.3 Valve Order

Type		Size & number	Price
10 pcs umbrella valve		10 pcs	8.5
one way plastic valve no.6		(2 pcs)	3.72
one way plastic valve no.5		(4 pcs)	3.45

Type		Size & number	Price
duckbill valve		(4 pcs)	6.02
Brass In-Line Spring Check		(2 pcs)	26.66
UPVC Pipe Check Valve (white)		20mm & 4 pcs	6.04
UPVC Pipe Check Valve (white)		25mm & 4 pcs	6.96

Type		Size & number	WITH SHIPPING	Price
UPVC Pipe Check Valve (white)		32mm & 4 pcs		8.56
UPVC Pipe Check Valve (white)		40mm & 4 pcs		12.72
UPVC Pipe Check Valve (white)		50mm & 4 pcs		18.08
total			116.01 USD = 426.1 AED	104.16 USD

This order took about 3 months to arrive to Egypt.

2.4.10 Head Design

The old design didn't represent the shape of the heart, and using it was very difficult because the priming of the pump was difficult.



Figure 2-35 Old Head

In our design, we represented the angle between the aortic valve and the mitral valve that was 150° to be sure that the flow of water will be as that in the human body.

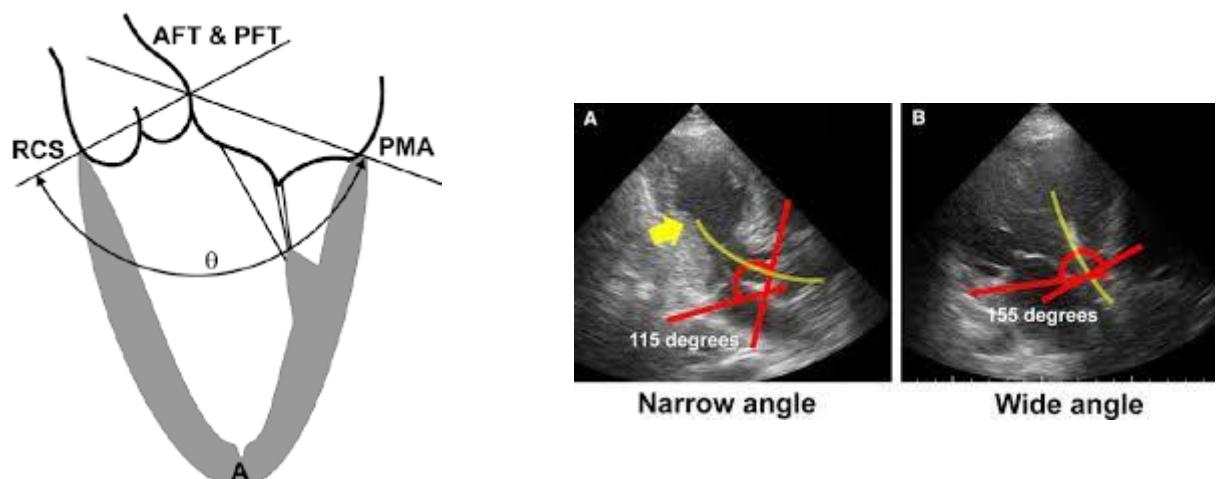


Figure 2-36 Angle between aortic and mitral valve



Figure 2-38 New Head



Figure 2-37 New Head

- Inner diameter = 62 mm.

We also make a seat for the valve according to the dimensions of the valve that we chose.



Figure 2-39 UPVC Pipe Check Valve Fish Tank Garden Irrigation Aquarium Tube Watering Adapter Fittings PVC Pipe

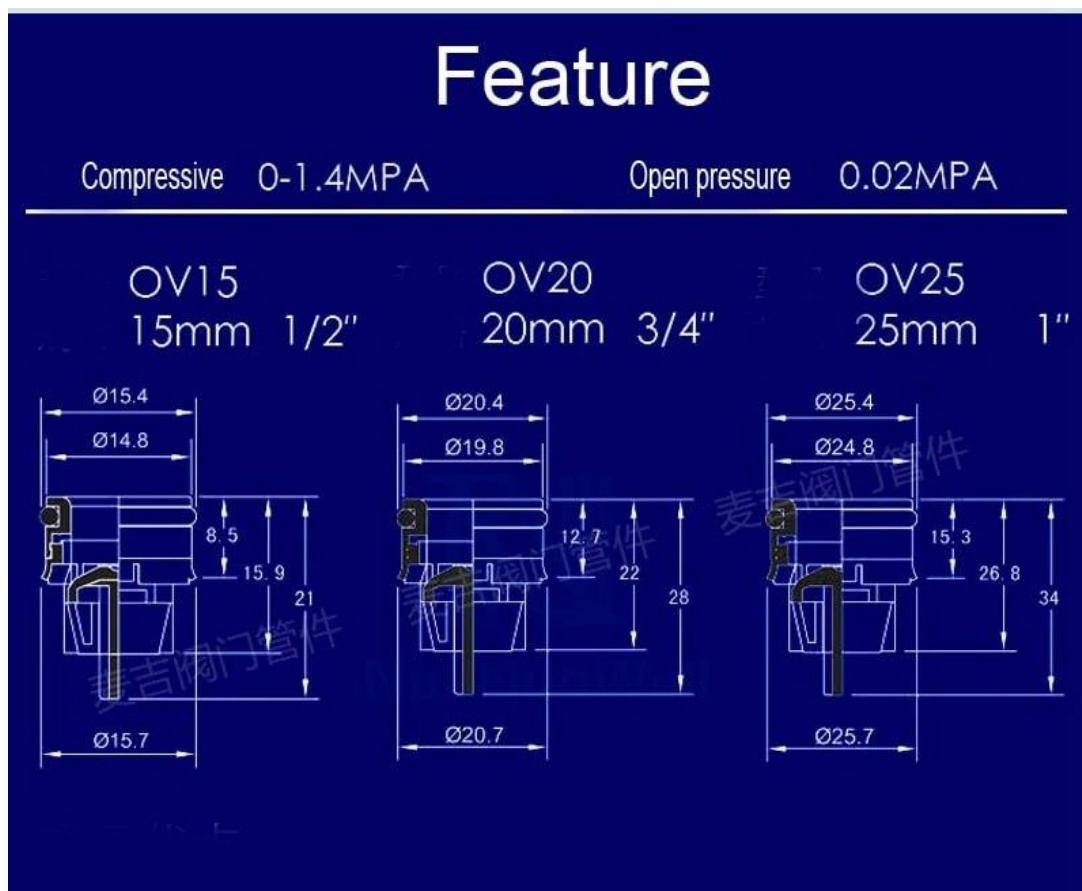


Figure 2-40 Selected valve dimensions

2.4.11 Head design in SolidWorks

2.4.11.1 Head

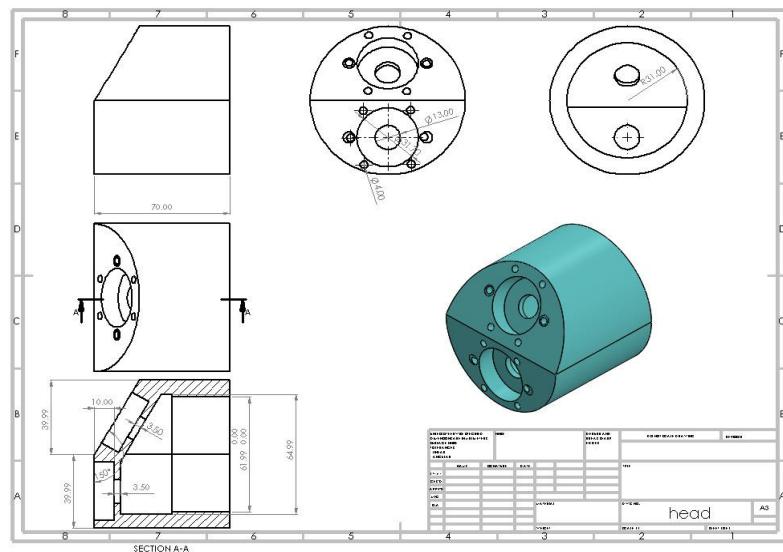


Figure 2-41 Head data sheet

2.4.11.2 Hose Flat Surface

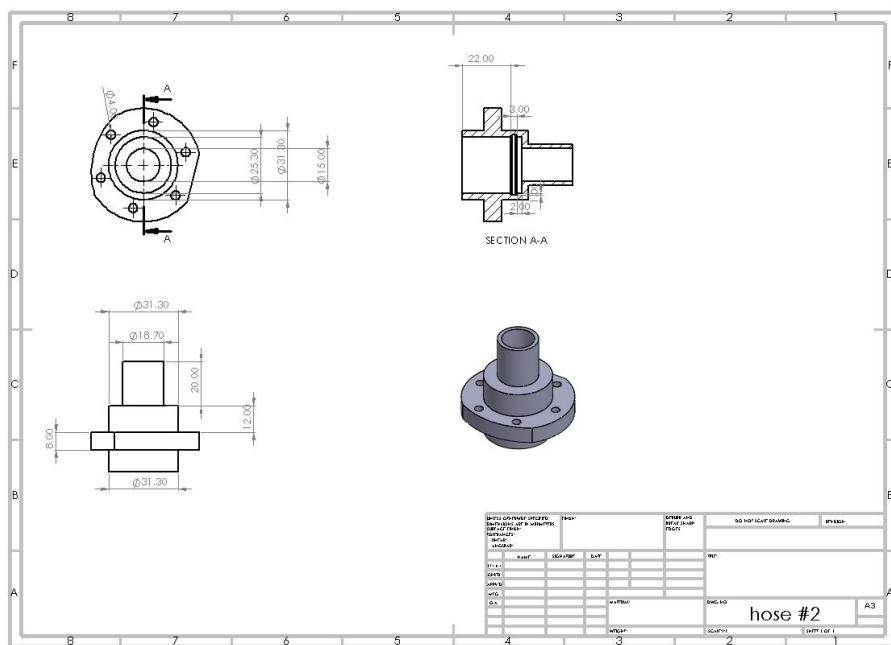


Figure 2-42 Hose Flat Surface data sheet

2.4.11.3 Hose Inclined Surface

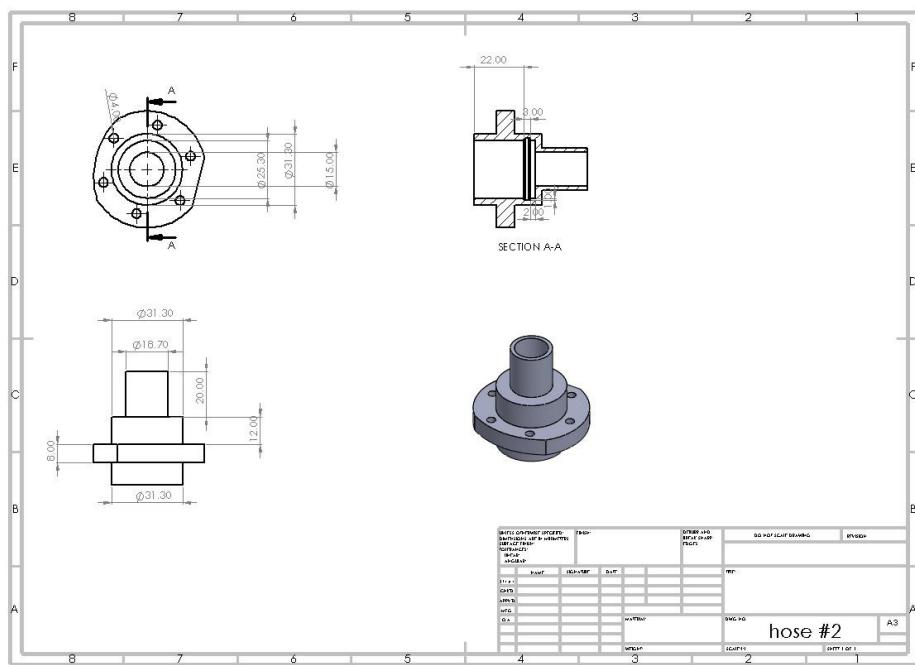
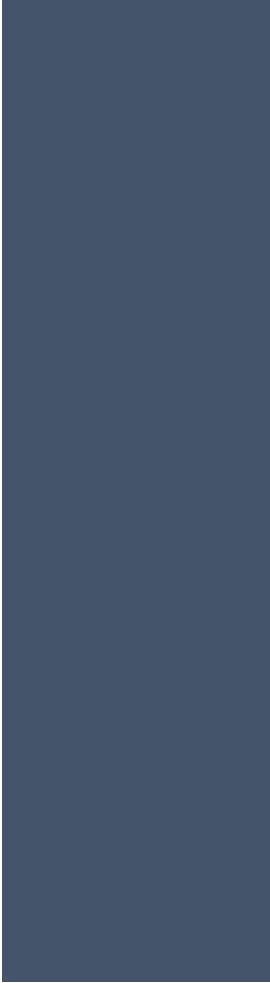


Figure 2-43 Hose Inclined Surface data sheet



3 Control

3.1 Introduction

Control systems are an integral part of modern engineering, enabling precise regulation and manipulation of various processes and systems. From industrial automation to household appliances, control systems ensure that machines and devices operate efficiently, safely, and reliably. This chapter delves into the fundamental principles of control systems, exploring both theoretical concepts and practical applications.

At its core, a control system is designed to maintain the desired output of a system by automatically adjusting its inputs based on feedback. This dynamic interaction between inputs, outputs, and feedback forms the basis of control theory, which encompasses a wide range of techniques and methodologies for achieving desired system behavior. Control systems can be categorized into two main types: open-loop and closed-loop (feedback) systems. Open-loop systems operate without feedback, relying solely on predefined inputs to achieve the desired output, while closed-loop systems continuously monitor the output and adjust inputs accordingly to maintain the target state.

The importance of control systems cannot be overstated, as they are vital in numerous applications across various industries. In manufacturing, control systems regulate machinery and processes to ensure high-quality production and minimize waste. In aerospace, they are used for flight control and navigation, ensuring the safety and stability of aircraft. In everyday life, control systems govern the operation of heating, ventilation, and air conditioning (HVAC) systems, automobiles, and even household appliances like washing machines and refrigerators.

We are using two types of control to make our physiological heart waveform. We use **PLC&HMI** to control our piston pump by controlling stroke length and velocity. The second type of control is Arduino. We use it to take our reading of pressure and flow rates to make a heartbeat waveform. We have three pressure sensors and one flow rate sensor.

This chapter will cover the essential components and functions of our control system, including sensors, actuators, controllers, and feedback mechanisms. We will also show the challenges we faced to make another control system to be able to control the pump in two different ways. We also will provide the way that we used the Arduino to take the reading from the different system

3.2 PLC & HMI Control

This type of control is used to control the piston movement to represent the heart and give flow as that of the blood inside the human body. We will discuss what the PLC&HMI is, and how we use them in our project and the result from them.

3.2.1 Programmable Logic Controller (PLC)

A programmable logic controller (PLC) or programmable controller is an industrial computer that has been ruggedized and adapted for the control of manufacturing processes, such as assembly lines, machines, robotic devices, or any activity that requires high reliability, ease of programming, and process fault diagnosis. PLCs can range from small modular devices with tens of inputs and outputs (I/O), in a housing integral with the processor, to large rack-mounted modular devices with thousands of I/O, which are often networked to other PLC and SCADA systems. They can be designed for many arrangements of digital and analog I/O, extended temperature ranges, immunity to electrical noise, and resistance to vibration and impact. PLCs were first developed in the automobile manufacturing industry to provide flexible, rugged and easily programmable controllers to replace hard-wired relay logic systems. Dick Morley, who invented the first PLC, the Modicon 084, for General Motors in 1968, is considered the father of PLC. A PLC is an example of a hard real-time system since output results must be produced in response to input conditions within a limited time, otherwise unintended operation may result. Programs to control machine operation are typically stored in battery-backed-up or non-volatile memory. The PLC originated in the late 1960s in the automotive industry in the US and was designed to replace relay logic systems. Before, control logic for manufacturing was mainly composed of relays, cam timers, drum sequencers, and dedicated closed-loop controllers. The hard-wired nature of these components made it difficult for design engineers to alter the automation process. They were soon applied to control logic in industrial processes. The PLC provided several advantages over earlier automation systems. It tolerated the industrial environment better than the former systems and was more reliable, compact, and required less maintenance than relay systems. It was easily extensible with additional I/O modules. The most basic function of a programmable controller is to emulate the functions of electromechanical relays. Discrete inputs are given a unique address, and a PLC instruction can test if the input state is on or off. Just as a series of relay contacts perform a logical AND function, not allowing current to pass unless all the contacts are closed, so a series of "examine if on" instructions will energize its output storage bit if all the input bits are on. Similarly, a parallel set of instructions will perform a logical OR. In an electromechanical relay wiring diagram, a group of contacts controlling one coil is called a "rung" of a "ladder diagram", and this concept is also used to describe PLC logic. Some models of PLC limit the number of series and parallel instructions in one "rung" of logic. The output of each rung sets or clears a storage bit, which may be associated with a physical output address, or which may be an "internal coil" with no physical connection. Such internal coils can be used, for example, as a common element in multiple separate rungs. Unlike physical relays, there is usually no limit to the number of times an input, output, or internal coil can be referenced in a PLC program.

The types of PLC may be classified according to some parameters. However, you must be reminded that some overlaps may apply thus creating a combination of PLC types per manufacturer.

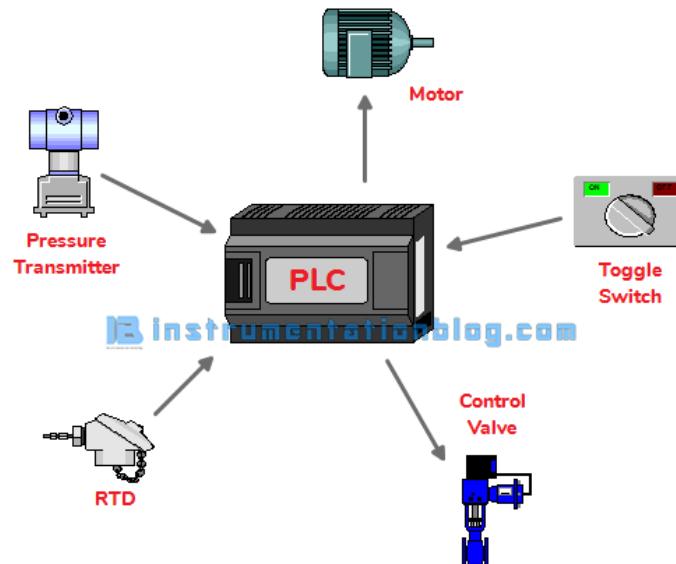
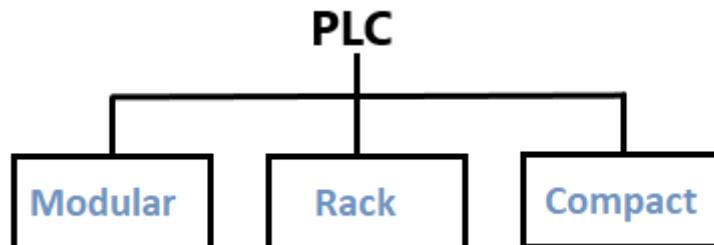


Figure 3-1 Programmable Logic Controller (PLC)

3.2.1.1 Types of PLC



3.2.1.1.1 Fixed /integrated/compact PLC

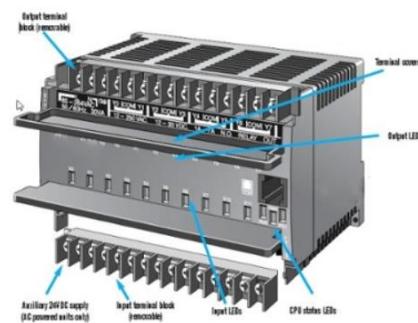


Figure 3-2 Fixed/Integrated/Compact PLC

Fixed I/O" actually stands for Fixed "Input/Output". When you buy Compact PLCs, you will notice that the input section and the output sections of the PLC are integrated into the microcontroller itself. the number of inputs and outputs may not be expanded in this type of PL

3.2.1.2 Modular PLC

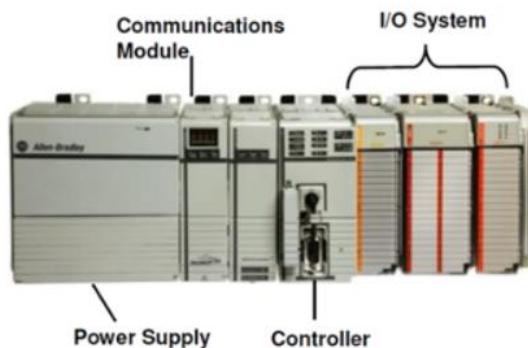


Figure 3-3 Modular PLC

The modular PLC is a type that allows multiple expansions of the PLC system through the use of modules, hence the term “modular”. Modules give the programmable logic controller additional features like an increased number of I/O units, and they are usually easier to use because each component is independent of the others. The power supply, communications module, Input/Output module are all separate to the actual microcontroller, so you have to manually connect them to each other to create your PLC control system. A type of modular PLC is the rack-mounted or rack-mounted PLC. In a rack mount PLC, the communications module of the PLC resides in the rack itself, so all connections are centralized.

What are the advantages of using Modular PLC?

The modular PLC is the most desirable type of PLC especially for large industrial systems with a lot of devices to take input from or control. Here are some of the advantages that the Modular PLC has over the Fixed PLC:

- **Scalability**

The modular PLC, because you can always add modules over and over again, provides greater scalability not only for your PLC control system but also to the company that uses the controller.

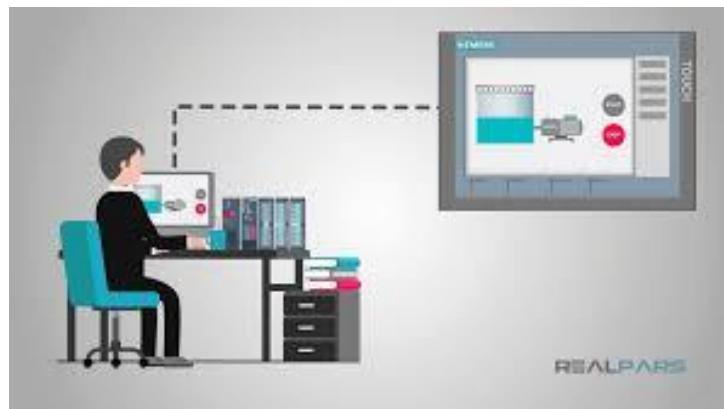
By using the Modular PLC, the processes become more centralized as the modules are only added to 1 programmable logic controller. Because of the Modular PLC’s design, the company would be able to expand its assembly lines, for example, by adding more similar output devices that perform similar tasks to be controlled by the same controller. This would not be possible with the Fixed I/O PLC. With the Fixed I/O PLC, you would be limited only to the capacity of that single device that performs the control and input scans in your control system.

- **Less Downtime**

As stated in the last point, you may have realized that the Modular PLC is easier to repair because the modules have separate systems. This means less downtime for the assembly lines being controlled by the PLC because troubleshooting will take less time than that of the Fixed

I/O. Because modules can be bought separately, a MAJOR advantage of this is you can absolutely use a backup set of modules to immediately replace a broken module once that happens. With the Fixed PLC, because it would be more difficult to troubleshoot the PLC system, more time would be required for the system to work again. Also, if the PLC happens to require some servicing by the manufacturer (which takes a lot of time again), you would have to replace the PLC altogether to get your system working again.

3.2.2 Human Machine Interface (HMI)



HMI products were originally designed to meet the need for easily operational machinery while producing optimal outputs. Predecessors of the HMI include the Batch Interface (1945-1968), Command-Line User Interface (1969-Present), and the Graphical User Interface (1981-Present). A Human-Machine Interface (HMI) is a user interface or dashboard that connects a person to a machine, system, or device. While the term can technically be applied to any screen that allows a user to interact with a device, HMI is most commonly used in the context of an industrial process. HMIs are similar in some ways to Graphical User Interfaces (GUI) but they are not synonymous; GUIs are often leveraged within HMIs for visualization capabilities.

In industrial settings, HMIs can be used to:

- Visually display data
- Track production time, trends, and tags
- Oversee KPIs
- Monitor machine inputs and outputs

Similar to how you would interact with your air-conditioning system to check and control the temperature in your house, a plant-floor operator might use an HMI to check and control the temperature of an industrial water tank, or to see if a certain pump in the facility is currently running. Basic HMI examples include built-in screens on machines, computer monitors, and tablets, but regardless of their format or which term you use to refer to them, their purpose is to provide insight into mechanical performance and progress.

Who Uses HMI?

HMI technology is used by almost all industrial organizations, as well as a wide range of other companies, to interact with their machines and optimize their industrial processes.

Industries using HMI include:

- ⇒ Energy
- ⇒ Food and beverage
- ⇒ Manufacturing
- ⇒ Oil and gas
- ⇒ Power
- ⇒ Recycling
- ⇒ Transportation
- ⇒ Water and wastewater

The most common roles that interact with HMIs are operators, system integrators, and engineers, particularly control system engineers. HMIs are essential resources for these professionals, who use them to review and monitor processes, diagnose problems, and visualize data.

Common Uses of HMI

HMs communicate with Programmable Logic Controllers (PLCs) and input/output sensors to get and display information for users to view. HMI screens can be used for a single function, like monitoring and tracking, or for performing more sophisticated operations, like switching machines off or increasing production speed, depending on how they are implemented. HMIs are used to optimize an industrial process by digitizing and centralizing data for a viewer. By leveraging HMI, operators can see important information displayed in graphs, charts, or digital dashboards, view and manage alarms, and connect with SCADA, ERP, and MES systems, all through one console. Previously, operators would need to walk the floor constantly to review mechanical progress and record it on a piece of paper or a whiteboard. By allowing PLCs to communicate real-time information straight to an HMI display, HMI technology eliminates the need for this outdated practice and thereby reduces many costly problems caused by lack of information or human error.

What is the Difference Between HMI and SCADA?

Supervisory Control and Data Acquisition (SCADA) and HMI are closely related, and often referred to in the same context since they are both part of a larger industrial control system, but they each offer different functionality and opportunities. While HMIs are focused on visually conveying information to help the user supervise an industrial process, SCADA systems have a greater capacity for data collection and control-system operation. Unlike SCADA systems, HMIs do not collect and record information or connect to databases.

High-Performance HMIs

Operators and users are increasingly moving toward high-performance HMI, a method of HMI design that helps ensure fast, effective interaction. By only drawing attention to the most necessary or critical indicators on the interface, this design technique helps the viewer to see and respond to problems more efficiently, as well as make better-informed decisions. Indicators on high-performance HMIs are simple, clean, and purposely cleared of any extraneous graphics

or controls. Other design elements, like color, size, and placement, are used with discretion to optimize the user experience. Learn more about designing high-performance HMIs here.

Touch Screens and Mobile Devices

Touch screens and mobile devices are two HMI examples of technological advances that have emerged with the advent of smartphones. Instead of buttons and switches, modernized HMIs allow operators to tap or touch the physical screen to access controls. Touch screens are especially important when used with mobile HMI, which is either deployed through web-based HMI/SCADA or via an application. Mobile HMI offers a variety of advantages to operators, including instant access to HMI information and remote monitoring.

Remote Monitoring

Mobile-friendly remote monitoring allows greater flexibility and accessibility for operators and managers alike. With this feature, an offsite control system engineer can, for example, confirm the temperature of a warehouse on a portable device, eliminating the need for onsite supervision after working hours. Soon, checking in on a process on your factory floor while being miles away from the facility won't seem like anything out of the ordinary.

3.2.2.1 HMI System Diagram

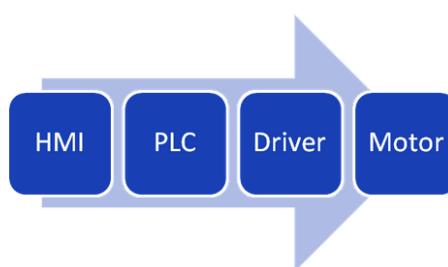


Figure 3-4 HMI system diagram

3.2.2.2 Advantages of an HMI

The greatest advantage of an HMI is the user-friendliness of the graphical interface. The graphical interface contains color coding that allows for easy identification (for example: red for trouble), as well as pictures and icons that allow for fast recognition, easing the problems of language barriers.

3.2.2.2.1 Advantages of an HMI over a PLC alone

A PLC on its own cannot provide any real-time feedback, and cannot set off alarms nor modify the system without reprogramming the PLC. The key advantage to an HMI is its functionality; an HMI can be used for simple tasks such as a coffee brewing controller, or as the sophisticated control unit of a nuclear plant. With new HMI designs emerging in the field, we are now seeing HMIs that offer remote access, allowing operators access to the terminal from a distance. Another advantage of an HMI is its customizability. The user can personalize the user interface for maximum ease of use

3.2.2.3 Key Benefits of Investing in an Advanced HMI for a Factory



There are many advanced level HMIs on the market currently that allow for monitoring and control of factory machinery. The main benefit, in terms of investing in an advanced level Human Machine Interface with multiple capabilities such as the ability to monitor machines remotely and to output dashboards with KPIs, is the simplification of factory processes and operations. The other main benefit is the ability to see key, real-time data at one's fingertips. These attributes of the modern-day, advanced level HMI, contribute greatly to the reduction of complexity of the factory environment. Furthermore, factory owners can quickly respond to changing or challenging conditions using the Human-Machine Interface. Consequently, efficiency is improved since downtime is reduced. This allows the factory owner to have intelligent systems that reduce cost and waste and ultimately improve processes and profitability.

3.2.3 Arduino program:



Figure 3-5 Arduino

Arduino is an Italian open-source hardware and software company, project, and user community that designs and manufactures single-board microcontrollers and microcontroller kits for building digital devices. Its hardware products are licensed under a CC BY-SA license, while the software is licensed under the GNU Lesser General Public License (LGPL) or the GNU General Public License (GPL), permitting the manufacture of Arduino boards and software distribution by anyone. Arduino boards are available commercially from the official website or through authorized distributors. Arduino board designs use a variety of microprocessors and controllers. The boards are equipped with sets of digital and analog input/output (I/O) pins that may be interfaced to various expansion boards ('shields') or breadboards (for prototyping) and other circuits. The boards feature serial communications interfaces, including Universal Serial Bus (USB) on some models, which are also used for

loading programs. The microcontrollers can be programmed using the C and C++ programming languages (Embedded C), using a standard API which is also known as the Arduino Programming Language, inspired by the Processing language and used with a modified version of the Processing IDE. In addition to using traditional compiler toolchains, the Arduino project provides an integrated development environment (IDE) and a command line tool developed in Go. The Arduino project began in 2005 as a tool for students at the Interaction Design Institute in Ivrea, Italy, aiming to provide a low-cost and easy way for novices and professionals to create devices that interact with their environment using sensors and actuators. Common examples of such devices intended for beginner hobbyists include simple robots, thermostats, and motion detectors. A sketch is a program written with the Arduino IDE. Sketches are saved on the development computer as text files with the file extension {ino}. Arduino Software (IDE) pre-1.0 saved sketches with the extension {pde}.

A minimal Arduino C/C++ program consists of only two functions:

Setup: This function is called once when a sketch starts after power-up or reset. It is used to initialize variables, input and output pin modes, and other libraries needed in the sketch. It is analogous to the function main.

Loop: After the setup function exits (ends), This function is executed repeatedly in the main program. It controls the board until the board is powered off or is reset. It is analogous to the function while.

3.2.3.1 Overview of the Arduino UNO Components

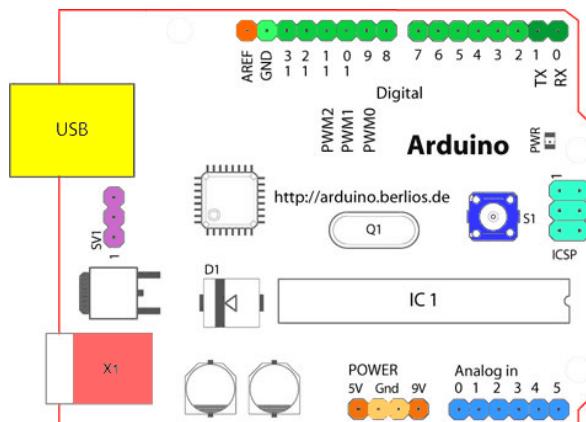


Figure 3-6 Arduino Components

Digital Pins:

In addition to the specific functions listed below, the digital pins on an Arduino board can be used for general-purpose input and output via the pin Mode(), digital Read(), and digital Write() commands. Each pin has an internal pull-up resistor which can be turned on and off using digital Write (value of HIGH or LOW, respectively) when the pin is configured as an input. The maximum current per pin is 40 mA.

Analog Pins

In addition to the specific functions listed below, the analog input pins support 10-bit analog-to-digital conversion (ADC) using the analog Read function. Most of the analog inputs can also be used as digital pins: analog input 0 as digital pin 14 through analog input 5 as digital pin 19. Analog inputs 6 and 7 (present on the Mini and BT) cannot be used as digital pins.

Power Pins

- VIN (sometimes labelled "9V"). The input voltage to the Arduino board when it's using an external power source (as opposed to 5 volts from the USB connection or other regulated power source). You can supply voltage through this pin, or, if supplying voltage via the power jack, access it through this pin. Note that different boards accept different input voltage ranges, please see the documentation for your board.
- 5V. The regulated power supply used to power the microcontroller and other components on the board. This can come either from VIN via an on-board regulator or be supplied by USB or another regulated 5V supply.
- GND. Ground pins.

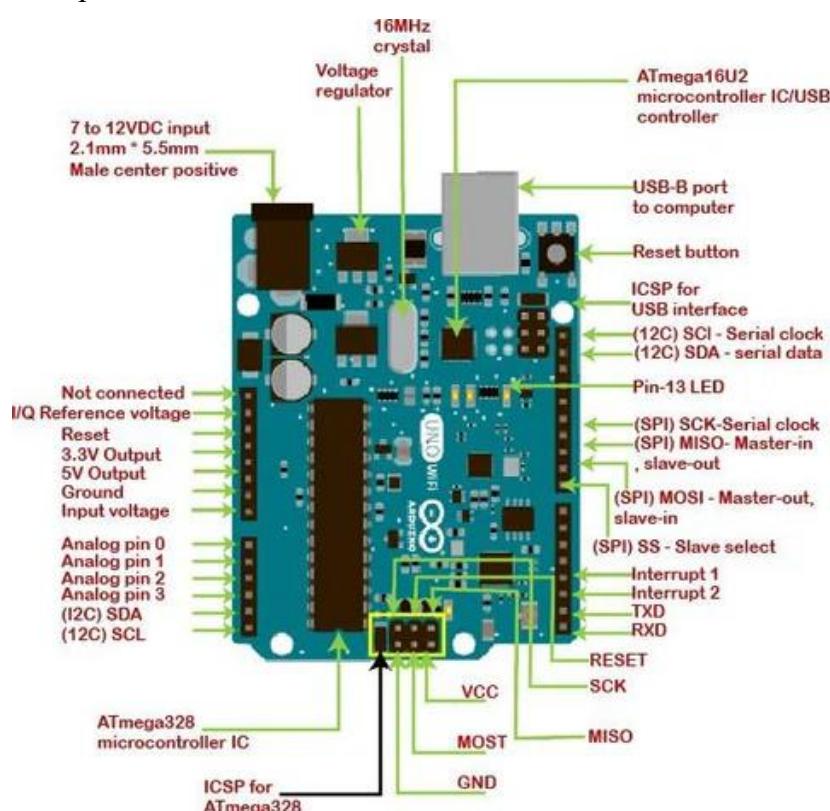


Figure 3-7 Arduino Pins

3.2.3.2 Advantages

- Not much knowledge is required to get started.
- Fairly low cost, depending on the shields you need.
- Lots of sketches and shields available.
- No external programmer or power supply is needed.

3.2.3.3 Disadvantages

- No understanding of the AVR microcontroller.
- Sketches and shields can be difficult to modify.
- No debugger included for checking scripts.

3.2.4 Our Control System in Details

Now, we will talk about our pump specifications. We will start with PLC&HMI control. We used a servo motor from **Kinco** company. We have two limit switches and one proximity limit to control pump movement. We will explain firstly pump movement theory. As we know our pump simulates the left ventricle of the heart biology so we should know what we control or operate so we will talk about it.

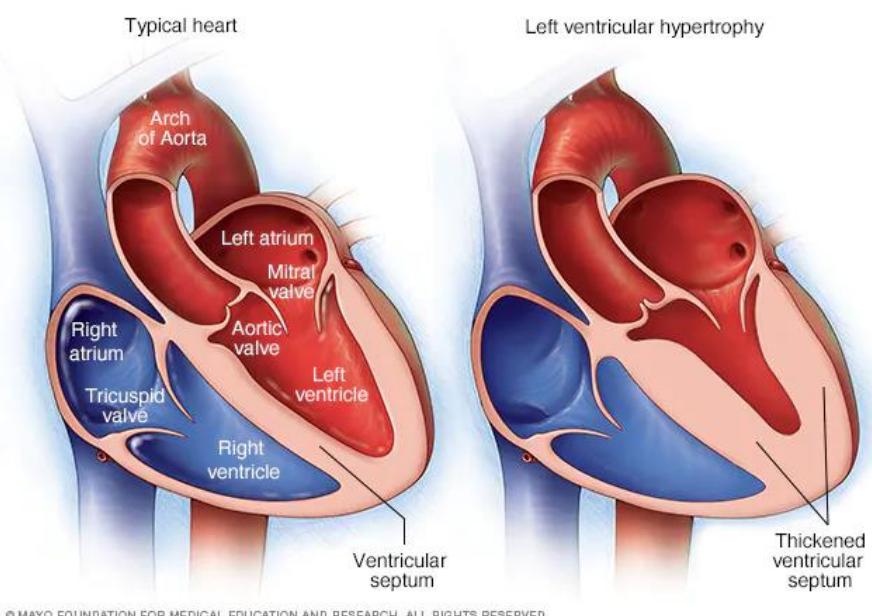


Figure 3-8 Blood flow in the left ventricle in the heart

The left ventricle is an integral part of the cardiovascular system. Left ventricular contraction forces oxygenated blood through the aortic valve to be distributed to the entire body. With such an important role, decreased function caused by injury or maladaptive change can induce disease symptoms. The primary function of the left ventricle is to provide sufficient cardiac output to maintain blood flow to other organ systems. Cardiac output results from systolic contraction of the left ventricle, which can be influenced by preload, afterload, and contractility. From this, we can deduce the biology relation of the blood.

$$CO = HR \times SV$$

$$SV = EDV - ESV$$

$$\text{EJECTION FRACTION} = SV / EDV$$

Cardiac output (CO) is the amount of blood pumped out of the heart in a given time.

Heart rate (HR) is the number of heartbeats in a given time, often recorded as beats per minute (bpm).

Stroke volume (SV) is blood ejected in a single ventricular contraction.

Left ventricular ejection fraction (LVEF) is the volume of blood pumped out of the heart during systole relative to the volume in the left ventricle at the end of diastole.

From the previous, we should control the speed and Length of stroke of our pump to make the correct waveform of the heart. before we talk about the process, we will talk about the components of control and how we operate the pump.

Components

- Servo motor
- Two limit switches
- Proximity sensor
- Ball power screw

How do we control these components?

- PLC (coding)
- HMI
- Connections

Through these components, we can explain our system and how we can run our pump. We will explain each of them in details to show our work on it. We will talk about types, coding, and shape.

3.2.4.1 Servo Motor



Figure 3-9 Kinco Servo Motor

A Servo motor is an electric motor used in a servomechanism, which means to automate a mechanical movement with a closed-loop control circuit, unlike the stepper motor, which follows an open-loop control mechanism. A servomechanism comprises a servo amplifier (servo driver), encoder, controller, and servo motor. Servomechanisms can be found in various industrial applications, including CNC machine tools, antenna rotators, and robotics. We

bought a servo motor from **Kinco** company to drive our system. It has a code of [SMC60S-0040-30MAK-3DSU]. It has a power of 400w and 3000 rpm angular velocity.

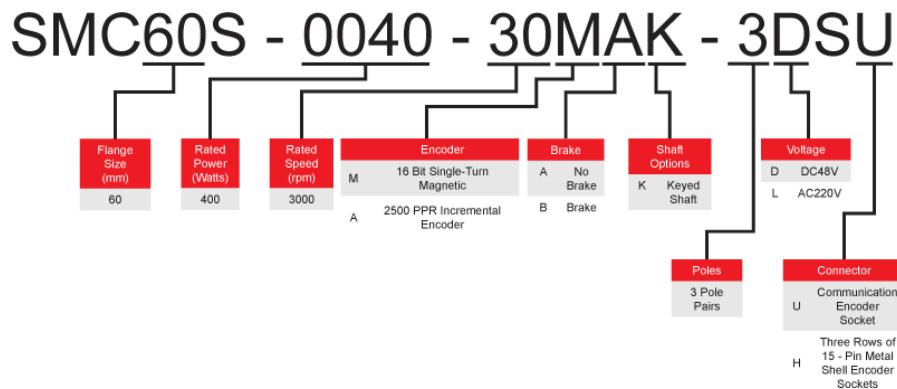


Figure 3-10 Specifications

The most important thing about this motor is that it has a magnetic encoder installed on its shaft to control the system's speed and movement.

What is an encoder?



Figure 3-11 Encoder

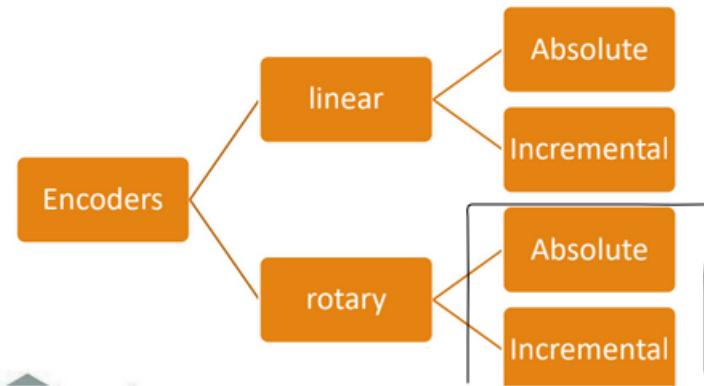
An encoder used for a servo motor is a device that measures the speed, angle of rotation, and distance traveled by an element of the machine. It also gives information on the location of the machine and its controller. The controller transmits the generated signals to the motor driver, which magnifies and transforms the signals for the motor. The motor responds to the servo driver signal and produces output to manage the speed and torque to achieve the desired location.

Importance of Encoders in Servo Motors

Mechanical servomechanisms require feedback on their positions to enable the control of speed and commutation and to take into account any interruptions in the operation of the motor or load. An encoder inside the servo motor is able to be substituted with a potentiometer, resolver, or Hall-effect transducer. But these alternatives show less robustness, responsiveness, and reliability in most cases.

Types of Encoders

There are two types of encoders based on the measurement mechanism, incremental and absolute.



A. Incremental Encoder

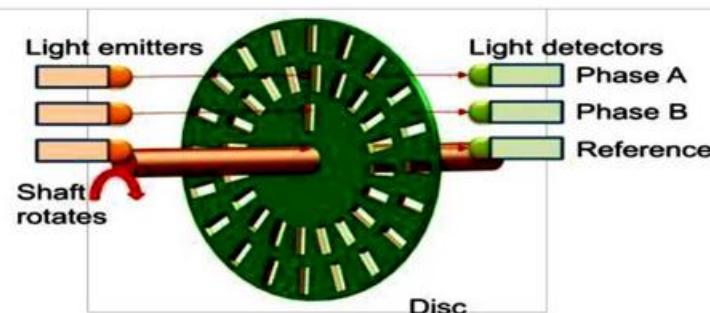


Figure 3-12 Incremental Encoder

Incremental encoders comprise electromechanical devices that monitor incremental advancements from an undetermined home position when the system is first started. They must be reset before starting operation if they shut down or fail to function. Incremental encoders have a reference point for monitoring the measurement, and they always refer to the same point to measure the change in motion; this means that they need to move to record changes in an angular direction. These encoders can be highly flexible and utilized in various motion control applications, where rehoming upon startup isn't an issue.

B. Absolute Encoder

Absolute encoders monitor position by using a specific part of code unique to each rotation location. The absolute encoders usually provide precise information about the position without needing to go home.

Absolute vs Incremental

The main choice is between the absolute and incremental types of the encoder. Incremental encoders are designed primarily to measure speed as they do not precisely indicate the positions. Absolute transducers allow speed and angular displacement monitoring permitting

the user to know precisely where the motor moved in response to the execution of the command.

C. Magnetic Encoders

Magnetic encoders depend upon magnetic flux fluctuations to determine the position and movement. The magnetic rotary encoder comprises a magnetized disc with a few magnetic poles around the circle. The sensor is located near the disk, the disk turns, and the sensor detects variations in the magnetic field when the poles on the disk's surface move towards the sensor. The magnetic field that changes can be used to produce an output signal with a sinusoidal pattern that is then converted into the form of a square pulse that an electronic control circuit can analyze. The sensors used in these encoders may use magneto-resistive devices that can directly detect changes in the magnetic field or utilize the Hall effect, a method of detecting changes in voltage.

From the previous information we could know the importance of a servo motor with a magnetic absolute encoder.

3.2.4.2 Limit switches



Figure 3-13 Limit Switches

A limit switch is an electromechanical device operated by a physical force applied to it by an object. Limit switches are used to detect the presence or absence of an object. They are electromechanical devices consisting of an actuator mechanically linked to an electrical switch. When an object contacts the actuator, the switch will operate causing an electrical connection to make or break.

3.2.4.2.1 Configurations of limit switches

Limit switches are available in several switch configurations: Normally Open, Normally Closed, or one of each

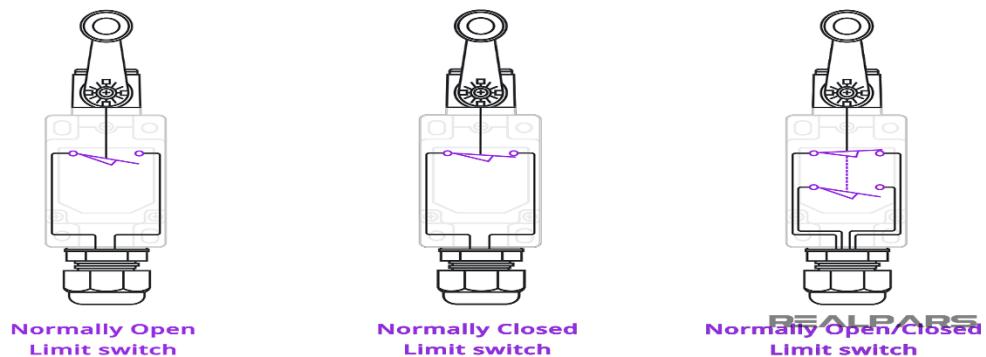


Figure 3-14 Limit Switches Configuration

Limit switches in our system act like safety devices and homing mode to protect the pump from failure.

3.2.4.3 Proximity sensor

A proximity sensor is a sensor able to detect the presence of nearby objects without any physical contact. There are various types of proximity sensors out there in the market, but one can say this device often performs its object presence detection task by emitting an electromagnetic field or a beam of electromagnetic radiation infrared, for instance), and looking for changes in the field or return signal.



Figure 3-15 Proximity Sensor

3.2.4.3.1 Benefits of the proximity sensor

- **Contactless sensing:** Contactless proximity sensing allows for detection without touching the object, ensuring the object stays well-conditioned.
- **Unaffected by surface conditions:** Proximity sensors are nearly unaffected by the surface colors of objects since it mainly detect physical changes.
- **Suitability for a wide range of applications**
- **High-speed response rate**

In our system, we use the inductive proximity sensor. It is capable of both static (position) and dynamic (vibration) measurements and is primarily used for vibration and position measurement applications on fluid-film bearing machines, as well as Key-phasor and speed measurement applications.

Working Principle

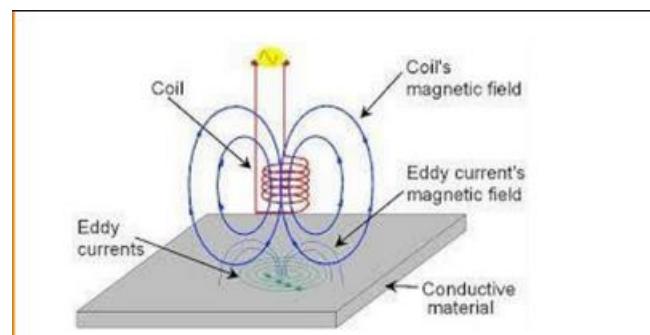


Figure 3-17 Inductive Proximity Sensor Working principle

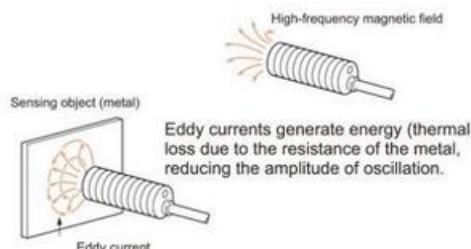


Figure 3-16 Inductive Proximity Sensor Working principle

- An alternating current is supplied to the coil, generating an electromagnetic detection field.
- When a metal object comes close to the magnetic field, eddy currents build, and result in coil inductance changes.
- When coil inductance changes, the circuit that has been continuously monitored, will trigger the sensor's output switch.

The goal of using a proximity sensor that we should make a reference position of our piston to make systole and diastole strokes.

3.2.4.4 Power Screw



Figure 3-18 Power Screw

It is used to convert rotary motion into linear motion.

Advantages

- Large load-carrying capacity.
- Compact construction.
- Simple to design.
- Fabrication is easily done on a lathe machine.
- It can be designed with a self-locking property.

Disadvantages

- High friction causes rapid wear of thread.

Power screw specifications

- Pitch = 4 mm
- Lead = $I * P$
- I=1 single thread
- The length of power screw is 225 mm

From this piston moves 4mm with one rotation of the motor shaft. So, we control the length of the stroke by controlling the number of revolutions.

$$1 \text{ rev} = 4\text{mm length}$$

Pitch is simply the distance between threads in mm. The number of starts on a lead screw can be found by looking at the end and counting the starts.

3.2.5 Control Code

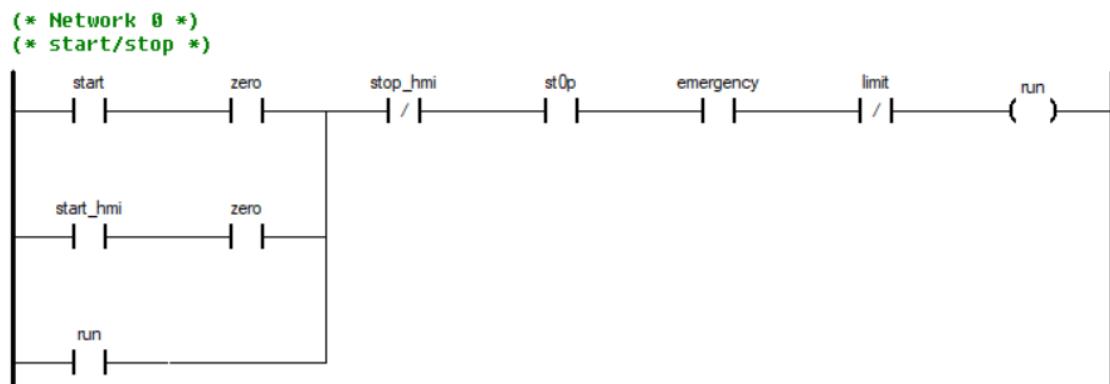
We have finished our control units and function of each unit so we will write about our ways and equations of control pulsatile blood pump. Systole of the heart is represented by discharge of the pump. Diastole of the pump is represented by suction of the pump.

We have two types of control. our first type that we have a **MATLAB** code as mentioned before. We take from it a heart waveform and insert a table in our system and the pump will move according to this table to draw the waveform experimentally. The PLC code is consists of networks. Each network represents an order in the code is converted by servo driver to pulses to drive the servo motor.

3.2.5.1 Our Software

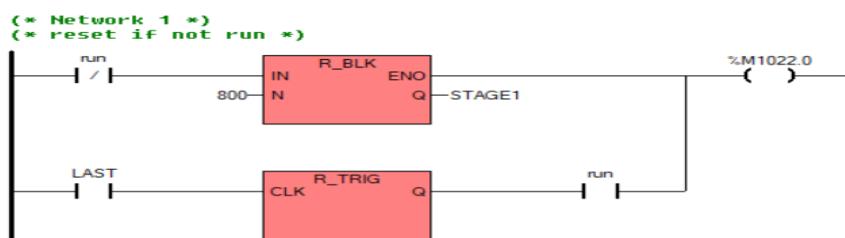
We get it from kinco website to make our code.

First network of the code:



This diagram consists of some orders in series to insert the buttons that control all process of the pump in our system. To go deeply into our process.

- **Start:** it is responsible for starting the operation.
- **Zero:** the place of the limit when metal hits it.
- **Stop_HMI:** it is used to stop the process of the pump.
- **Emergency:** when something wrong we use this button to stop the process of pump immediately.
- **Limit:** it is a safety limit if the piston want to move more than the length we want , it will stop the pump. Every button of them is named by an address to link it with the HMI.

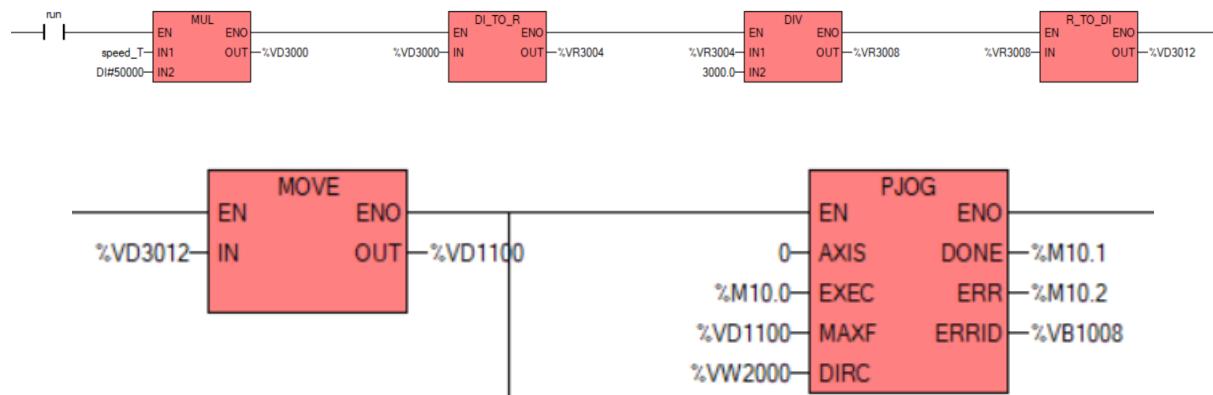


This network or line of code is responsible for resetting the servo driver if it sends wrong pulses to the motor.

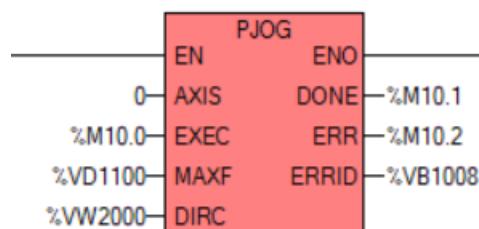
Before we continue to explain the code, we should show you the parameters we inserted in it. We insert the speed of systole and diastole by RPM for the system. The system converts it to pulses by servo driver and sends it to the encoder of the motor.

3.2.5.2 Equation

Pulses for speed = [RPM * 50000/3000]



3.2.5.3 PJOG block

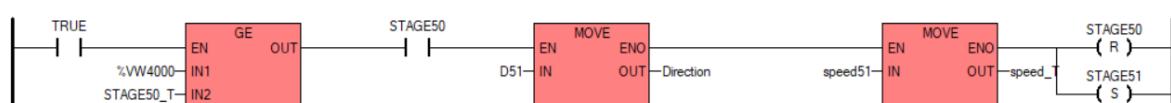


It is responsible for controlling the position of the pump and speed.

Axis: it is responsible for controlling the direction of the pump.

MAXF: it is responsible for controlling the speed of the pump that comes from pulses.

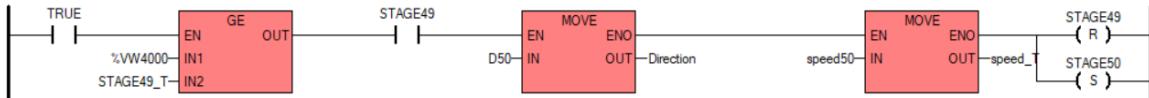
The table consists of 50 rows. We get it from graph of time versus flow rate from MATLAB plot.



GE block: it is a comparison function, it compares the value of the time that we entered. If the value of reference [VW4000] greater than or equal to value that we inserted on the table, the program will make the order, and will move by time and velocity of that time in the cycle.

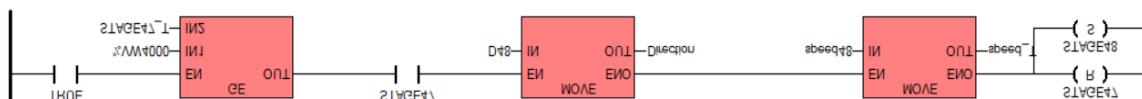
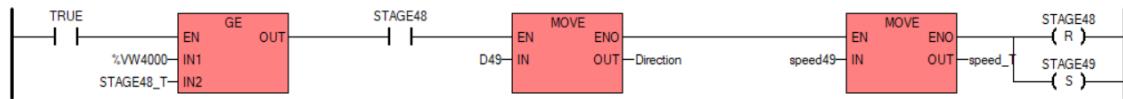
From that we could know that the waveform of the heart is a cycle. We could determine it by specific time and velocity.

(* Network 6 *)

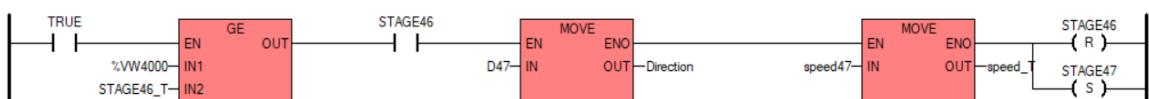


The PLC did the process of comparison again to get the specific velocity at specific time. It compared the value of [stage49_T] & [VW4000] if it accepted, it would execute the order and sent it for the pump.

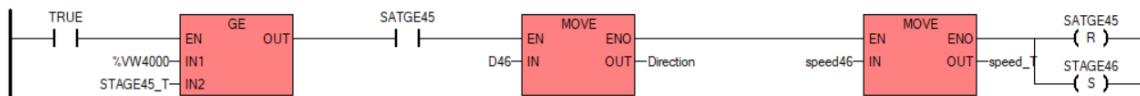
(* Network 7 *)



(* Network 8 *)

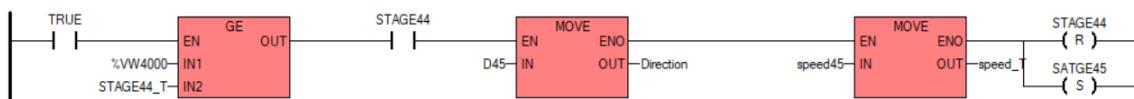


(* Network 10 *)

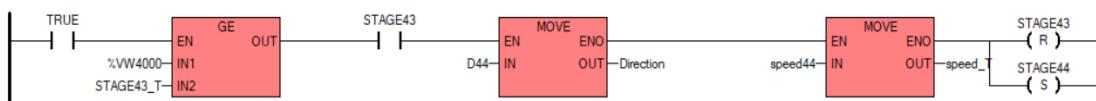


3.2.5.4 Orders of PLC

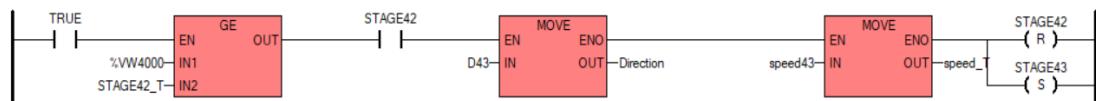
(* Network 11 *)



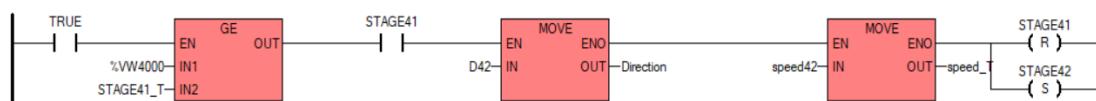
(* Network 12 *)



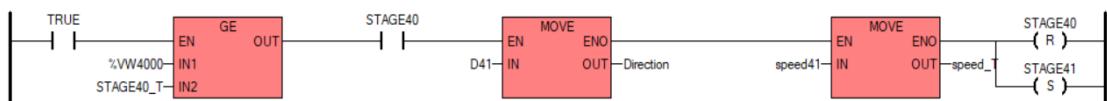
(* Network 13 *)



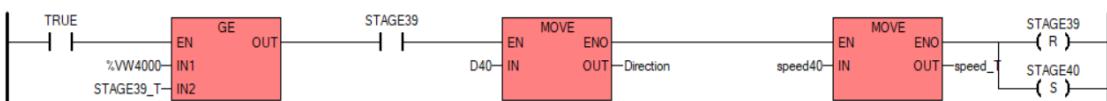
(* Network 14 *)



(* Network 15 *)



(* Network 16 *)



Note: as shown on the previous page plc repeats the process for each network. There are 50 networks like them to make the pump work to draw the physiological heart waveform.

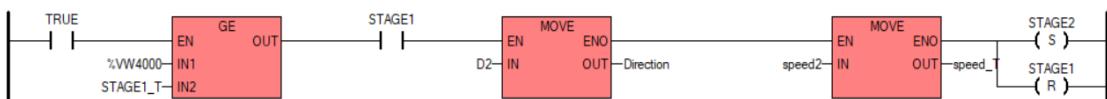


Figure 3-20 The last network

(* Network 61 *)



Figure 3-19 Emergency Button

%SM0.0: it means that this network is activated any time we run the PLC.

This network in figure4 means that emergency is always ready for using by us in case of failure of the system.

We knew the plc process, but we wanted to control it by easy way. We choose Human Machine Interface [HMI] to control the PLC by pressing buttons. We will explain it in the coming pages.

To make the orders we should define every wire to send our pulses for the servo motor.

3.2.5.5 Wires connections



I0.0: this wire is responsible for sending pulses when we want to start the process

I0.1: this wire is responsible for sending pulses when we want to stop the process

I0.2: this wire is responsible for sending pulses when we want to stop the process by emergency.

I0.3: this wire is responsible for sending pulses when the piston reaches home position.

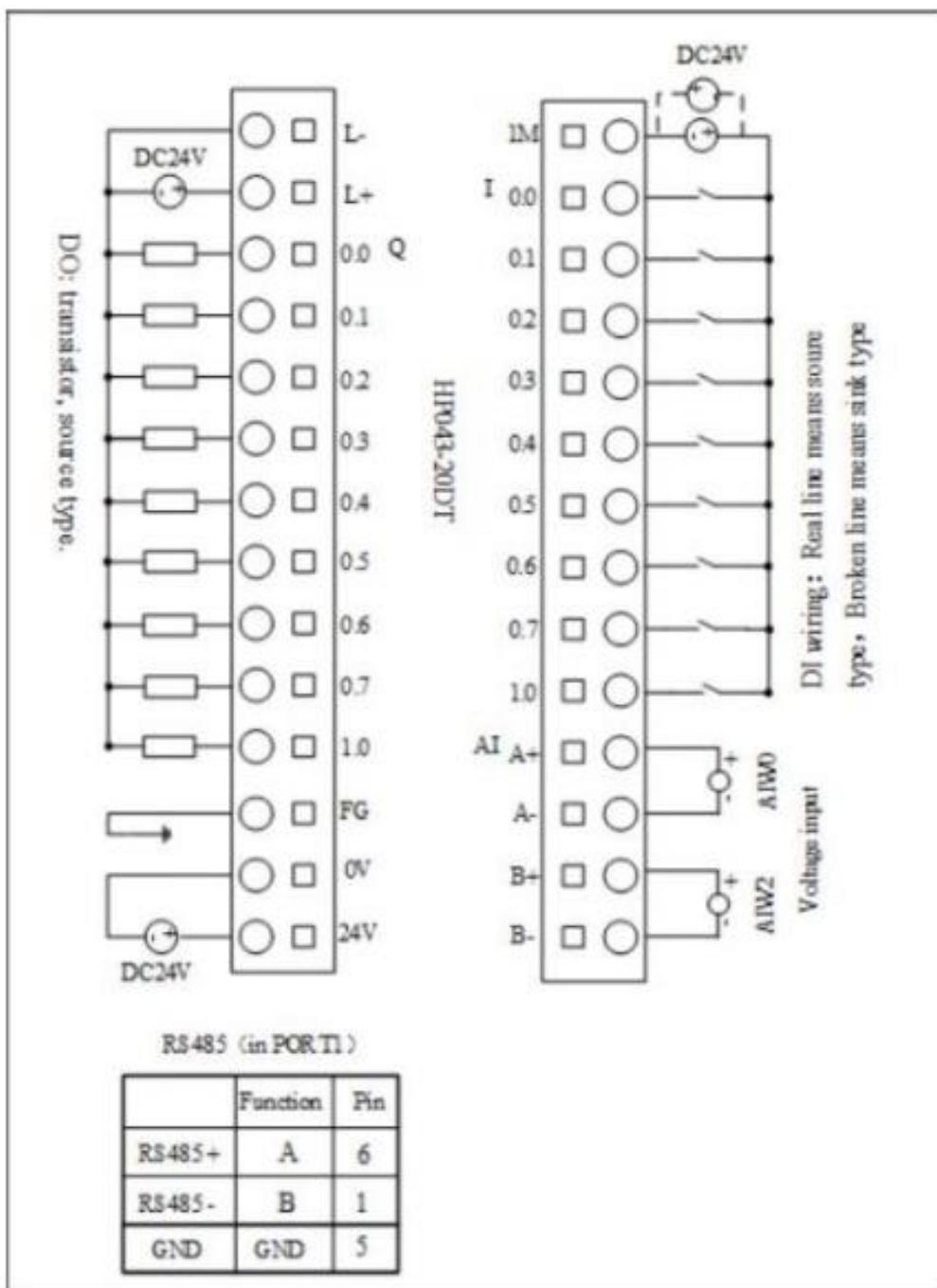
I0.4: this wire is responsible for sending pulses when the piston hit limit switches.

Q0.0: it is responsible for sending pulses for the encoder.

Q0.1: to determine the direction of rotation.

Q0.2: to enable servo driver.

3.2.5.5.1 Wiring diagram



3.2.5.6 HMI



Figure 3-21 Screen

We used HMI from Kinco company to control the PLC code. The Kinco MK series all-in-one HMI-PLC retains the high-cost performance of the Kinco HP series of all-in-one machines but adopts a high-performance CPU and the new D-Tools software technology platform for programming the HMI, to support more rich picture components and functions of the new software. In addition, combined with the Kinco M-IoT technology platform it provides remote download, pass through PLC communication over the network, VNC remote monitoring, equipment management and other advanced remote operation and maintenance functions. This will provide more value for our users.

Feature:

- Performance Upgrade
- Extended function
- High speed pulse counter
- High speed pulse output
- Serial communication ports

M-IOT Function

Built-in Internet of Things functions, support program upload and download, pass through PLC communication through network, VNC remote monitoring, equipment management and other rich remote operation and maintenance functions, easy to use and powerful, to facilitate the application needs of customers in various applications.

Performance Upgrade

The HMI part adopts an industrial CPU, 700MHz main frequency, 128MB Flash + 64MB DDR2 large capacity storage and supports the new generation of touch screen D-Tools programming software, to further improve the performance of the product.

HMI software

We used this software for making our screen.



Figure 3-22 HMI software

HMI Process

We opened the software then we chose the type of screen and PLC.

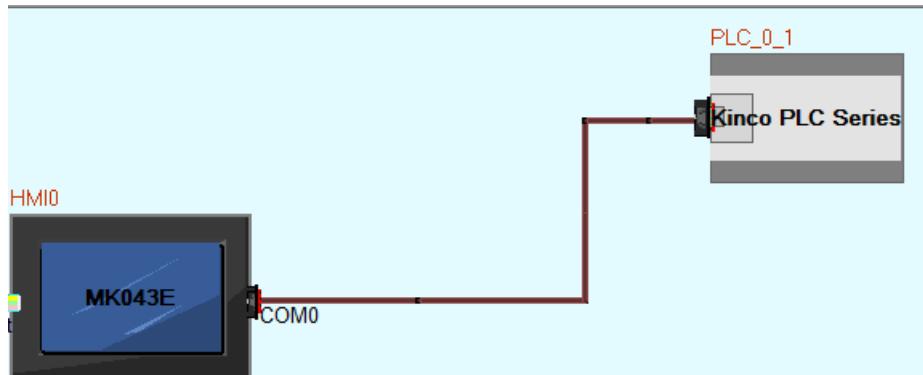
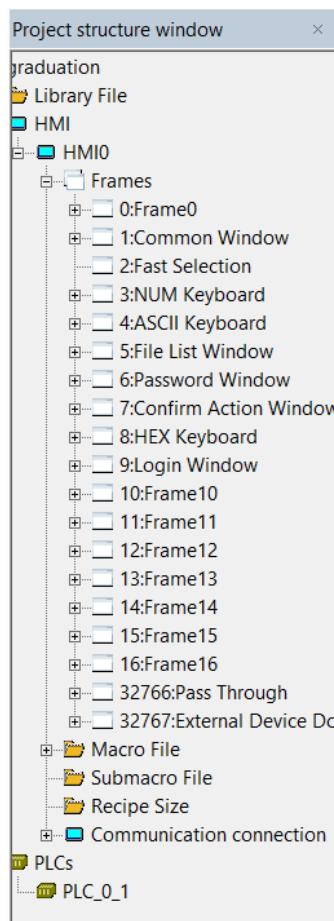


Figure 3-23 HMI&PLC Types

The process consists of frames each frame is responsible for screen contains buttons to control the process. Everything is easy and well organized for everyone to be able to use and operate our pump (servo motor). We should choose the correct types and connection for the software to make the process stable without any type of fault.

Frames



We followed these steps for making our HMI.



Figure 3-26 Frame 0



Figure 3-25 Buttons Frame

 A screenshot of the M-IoT HMI+PLC interface. At the top, it says 'M-IoT HMI+PLC'. Below that is a table with the following data:

Time	Direction	Speed	#
0	Positive	0	1
0	Positive	0	2
0	Positive	0	3
0	Positive	0	4
0	Positive	0	5
0	Positive	0	6
0	Positive	0	7
0	Positive	0	8
0	Positive	0	9

 The interface also includes a small house icon with the text '-main-' and a large orange arrow icon at the bottom.

Figure 3-24 First table

We have this table that has 51 cell, we fill it with results from the code that is 51 points as result. We got the values of cells of the table from MATLAB plot [RPM(y-axis), Time(x-axis)]. We used this type of control [table type] when we want the pump to draw a physiological heart waveform with a given data.

3.2.6 Our New Control System

We used this type of control, when we wanted to operate any case of a human according to know heart rate and cardiac output.

From previous equations of the heart.

$$CO = SV * HR$$

We want to make a relationship between biomedical and hydraulic parameters.

Cardiac output: flowrate that the pump drew during suction or push during discharge.

Systole: it is equal to the discharge stroke made by the piston pump.

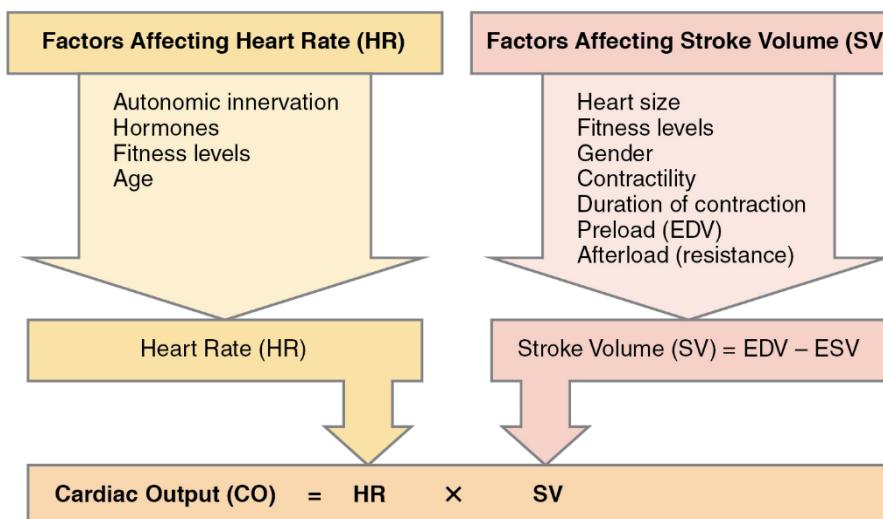


Diastole: it is equal to the suction stroke made by the piston pump.

Stroke volume (SV): it is equal to the area of piston multiplied by the length of stroke.

Heart Rate (HR): it affects us in the SV and RPM of the motor in each case.

3.2.6.1 Equations



$$CO = SV \times HR \dots (1)$$

%CO [lit/min], HR[beat/min] , SV[lit/beat]

$$SV = A_p \times L \dots (2)$$

$$A_p = \frac{\pi}{4} \times D_p^2 \dots (3)$$

% A_p (mm²)

$$length = \frac{CO \times 10^6}{A_p \times HR} \dots (4)$$

%Length (mm)

$$SV = \frac{CO \times 10^6}{HR} \dots (5)$$

%SV(mm³)

$$n = \frac{SV}{A_p \times p} \dots (6)$$

%n: number of revs

$$T = \frac{60}{HR} \dots (7)$$

%T: time of one cycle in sec

$$T_s = T \times percent\ systole \dots (8)$$

% T_s : time for systole

$$T_d = T \times [1 - percent\ systole] \dots (9)$$

% T_d : time for diastole

$$RPM_{systole} = \frac{n}{2} \times \frac{1}{\frac{1}{HR} \times \frac{T_s}{T}} \dots (10)$$

%speed of systole

$$RPM_{diastole} = \frac{n}{2} \times \frac{1}{\frac{1}{HR} \times \frac{T_d}{T}} \dots (10)$$

%speed of diastole

3.2.6.2 Plc code

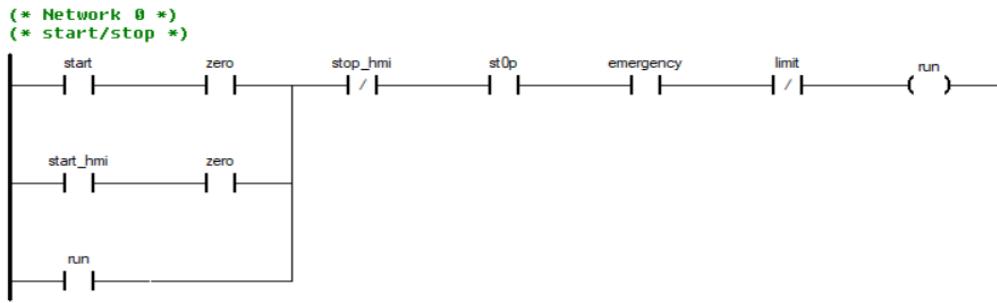
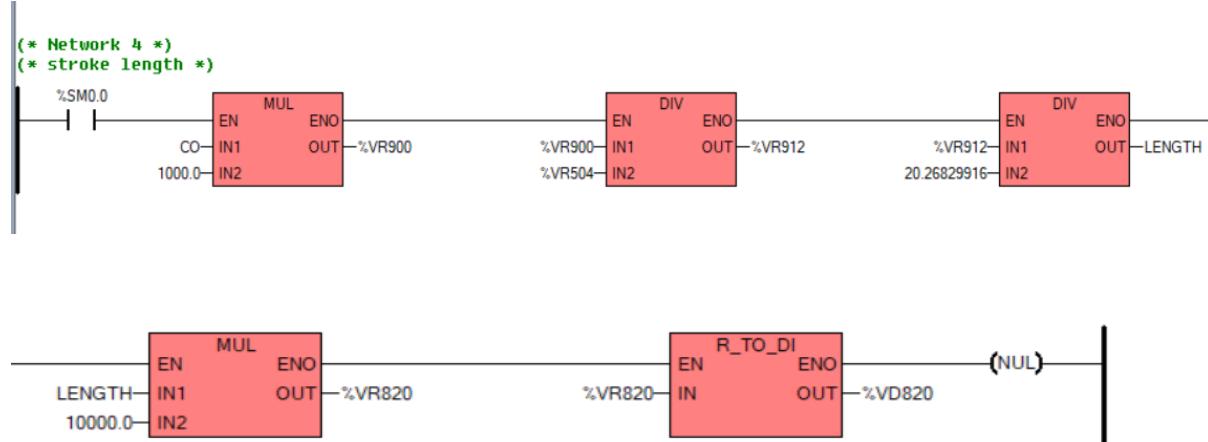
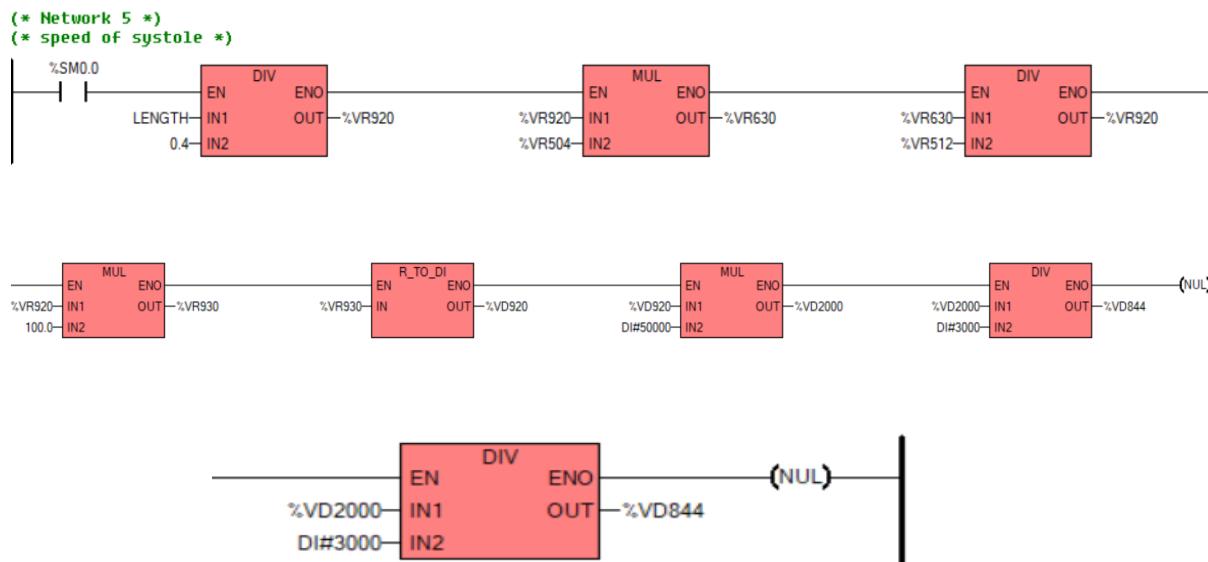


Figure 3-27 Buttons definitions

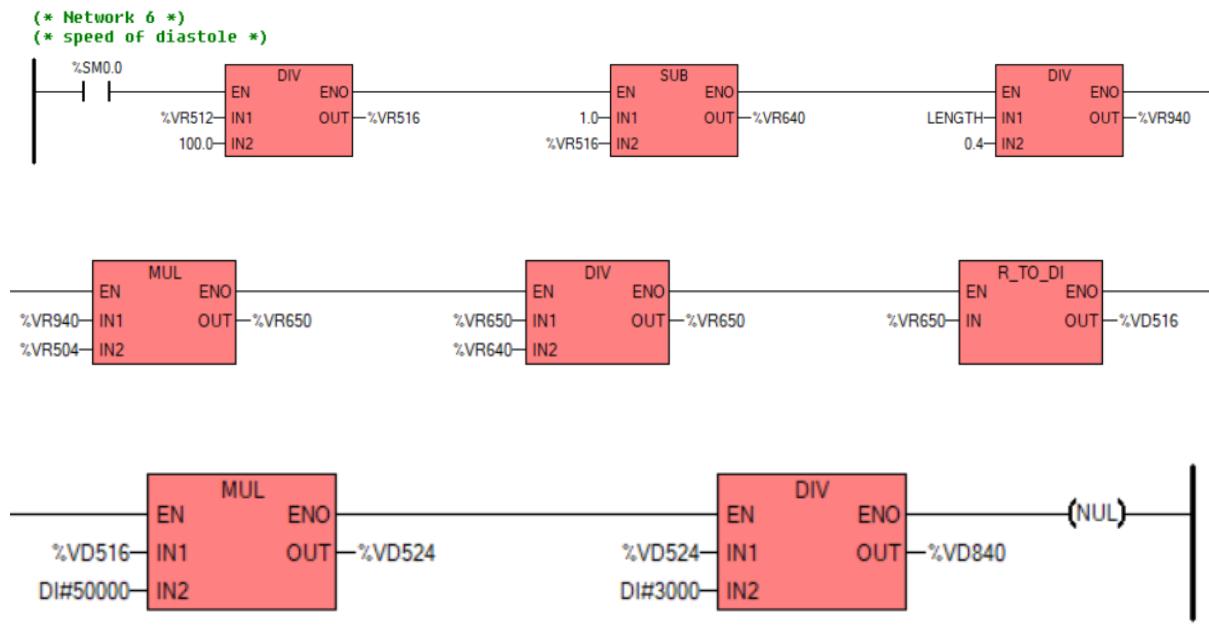
3.2.6.3 Stroke length equation on PLC



3.2.6.4 Speed of systole equation



3.2.6.5 Speed of diastole



3.2.6.6 Network of moving order

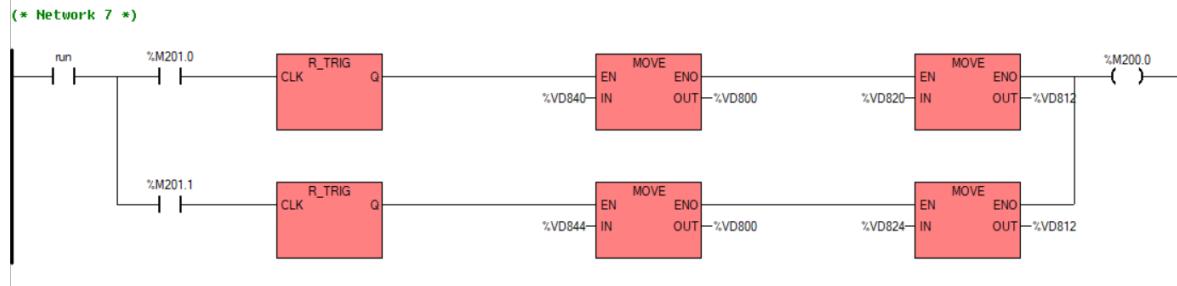
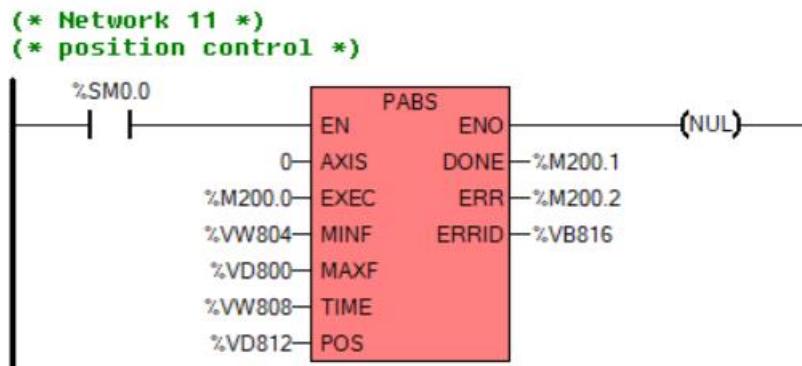


Figure 3-28 Moving coding network

This network took the results of equations and store them in variables to send it to the position control [PABS block]. PABS block is responsible for sending pulses for the servo driver and then to the magnetic encoder.



3.2.6.7 HMI Screen

Steps like first control code.

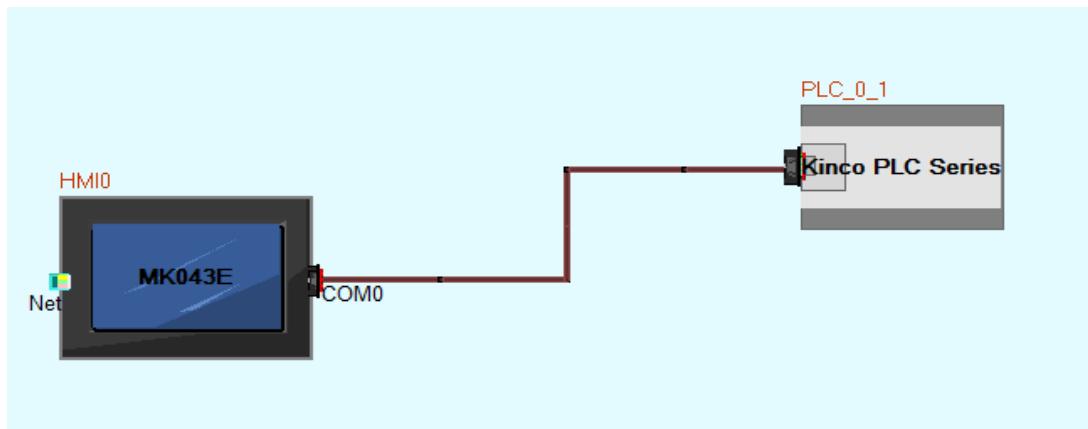


Figure 3-31 First step



Figure 3-30 Our Logo

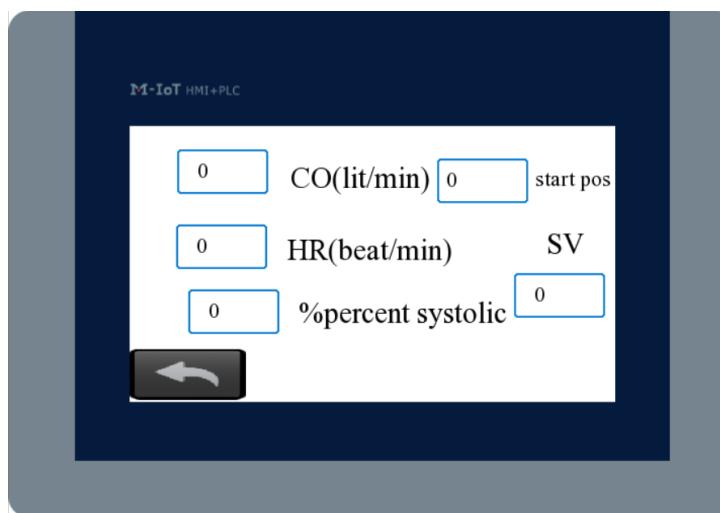


Figure 3-29 HMI parameters screen

The blue button is responsible for moving between frames.

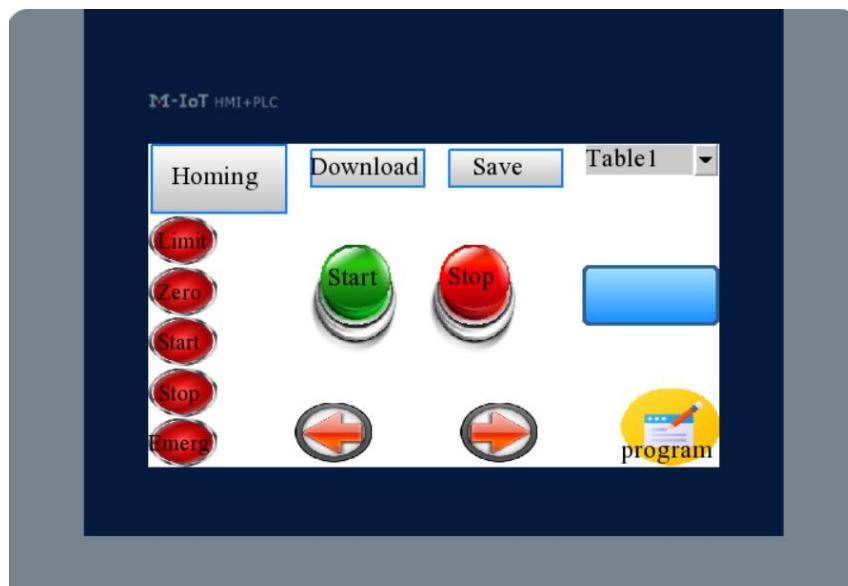


Figure 3-32 Transition screen

3.2.7 Arduino Code for Results

After running the piston pump, we wanted to validate our results experimentally. We have used flow sensors and pressure sensors to take the specifications of water that passed through it.

3.2.7.1 Flow sensor



Figure 3-33 Flow sensor

It is called Magnetic-inductive flow meter SM6120.

- Precise measurement of flow, consumption and medium temperature
- High accuracy, repeatability and measurement dynamics
- With switching output, analogue output and pulse output
- Clearly readable colour display with red/green colour change
- No inlet and output pipe lengths required

Measuring/setting range

Measuring range	0.05...35 l/min
Display range	-42...42 l/min
Resolution	0.02 l/min
Set point SP	0.25...35 l/min
Reset point rP	0...34.8 l/min
Analogue start point ASP	0...28 l/min
Analogue end point AEP	7...35 l/min
Low flow cut-off LFC	0.05...1.75 l/min
Frequency end point, FEP	7...35 l/min
Frequency at the end point FRP [Hz]	1...10000

Figure 3-34 Specifications

3.2.7.2 Pressure sensors



It is called OEM Pressure Transmitter Standard.

3.2.7.2.1 Applications

- Mechanical and plant engineering
- General industrial applications

3.2.7.2.2 Characteristics

- ceramic sensor
- accuracy 0.5 % FSO
- according to IEC 60770
- nominal pressure ranges from 0 ... 1 bar
- option: oil and grease free version

3.2.7.2.3 wiring diagram

Wiring diagrams				
2-wire-system (current)		3-wire-system (voltage)		
Electrical connection	ISO 4400	Micro (contact distance 9.4 mm)	M12x1 (4-pin), metal	cable colours (IEC 60757)
Supply +	1	1	1	WH (white)
Supply -	2	2	2	BN (brown)
Signal + (for 3-wire)	3	3	3	GN (green)
Shield	ground pin	ground pin	4	GNYE (green-yellow)

Mechanical connection (dimensions in mm)				
	G1/4" DIN 3852		G1/4" EN 837	
	1/4" NPT		G1/2" EN 837	

Figure 3-35 Dimensions

```

1  #define baudRate 9600 //constant integer to set the baud rate for serial monitor
2  #include <ezOutput.h> //make it easier to type inputs & outputs
3  #define eventTime_1 0
4  #define eventTime_2 30000
5  #define CALIBRATION_VALUE 512
6  //-----
7  ezOutput solenoidPin(3); //left vent
8  ezOutput solenoidPin(4); //right vent
9  ezOutput solenoidPin(2); //left atrial kick
10 //-----
11 unsigned long previousTime_1 = 0;
12 unsigned long previousTime_0 = 0;
13 //-----
14 //pressure sensor calibration
15 float calibration = 4; // distance between the sensor and the lower edge of eculyric tube
16 float calibration1 = 4;
17
18 float z = calibration*(1023/CALIBRATION_VALUE) ;
19 float y = calibration1*(1023/CALIBRATION_VALUE) ;
20
21
22 //-----
23 //-----
24 float BR1max = 0.00;
25 float BR1min = 160.00;
26 float AR1max = 0.00;
27 float AR1min = 80.00;
28 float BR2max = 0.00;
29 float BR2min = 80.00;
30

```

We have started the code by define variables. We have also defined each wire on each pin of the Arduino. We have defined max. and min. values of pressure sensors by using float.

```

32 //-----
33 int pot1;
34 int pot2;
35 int pot3;
36 //-----
37
38
39 const int pressuretransducermaxPSI = 375.031; //psi value of transducer being used
40 //Pressure sensor 1
41 const int before_resistance_1 = A0; //select the analog input pin for the pressure transducer
42 double BR1 ; //Aortic pressure
43 //-----
44 //pressure sensor 2
45 const int after_resistance_1 = A1 ;//select the analog input pin for the pressure transducer
46 float AR1; //LV pressure
47 //-----
48 // pressure sensor 3
49 const int before_resistance_2 = A2 ;//select the analog input pin for the pressure transducer
50 float BR2; //LA pressure
51 //-----
52 // pressure difference 1
53 float DP1;
54 //-----
55 const int flowmeter = A9; // A9
56 float flowrate;
57 //-----

```

```
60 void setup() {
61   Serial.begin(baudRate); //initializes serial communication at set baud rate bits per second
62
63   //Serial.println("BR1,AR1,BR2,RAP,RVP,PAP,LVLM,Q,R,Rp");
64   //Serial.println("mmhg,mmhg,mmhg,mmhg,mmhg,ml,L/min,dyne.sec/cm^5,dyne.sec/cm^5");
65   //-----
66   pinMode(2, OUTPUT);
67   pinMode(3, OUTPUT);
68   pinMode(4, OUTPUT);
69   //-----
70 }
71
72 void loop() {
73
74   solenoidPin.loop();
75   solenoidPin2.loop();
76   solenoidPin3.loop();
77
78   BR1 = (analogRead(before_resistance_1));
79   AR1 = (analogRead(after_resistance_1)); //reads value from input pin and assigns to variable 375
80   DP1 = BR1 - AR1;
81   BR2 = (analogRead(before_resistance_2));
82
83   flowrate= (analogRead(flowmeter));
84 }
```

We have defined the sensors case as they were sending us output signals to know the values of pressure and flowrates. We took the results on a serial monitor.

4 Harvard

Setup

4.1 introduction

Harvard setup is the setup that represents the cardiovascular system to be able to test the cardiovascular assist devices before putting them in the human body to ensure the best performance.

Harvard setup idea mainly comes from the **Aneurysm**, Aneurysm is abnormal swelling or bulge in the wall of the blood vessel, such as an artery.

A common place for this to occur is the **aortic/iliac bifurcation** (where aortic artery branches into the iliac arteries), why is this the most dangerous place?

Because of the aorta bifurcation that causes turbulence and vibration, this will increase the time that the blood interacts with the artery wall results that the cholesterol in the blood causes the plaque buildup and block the artery.

To treat this plaque buildup problem, we will use stent, but stent should be tested before using it because there are two main complications include:

- Stent migration.
- Stent leakage (flow around the side of the stent).

Testing the stent inside the human body is very dangerous and expensive, so we make a system that represents the performance of the human heart specially the left ventricle and aorta.

We will represent the cardiovascular system as two parts:

- Upstream conditions: which will be represented by the positive displacement pump that makes the role of the left ventricle.
- Downstream conditions: it is impossible and expensive to represent the rest of the body so we use “**lump**” important parameters together such that they behave similarly to how the system downstream of the body would.

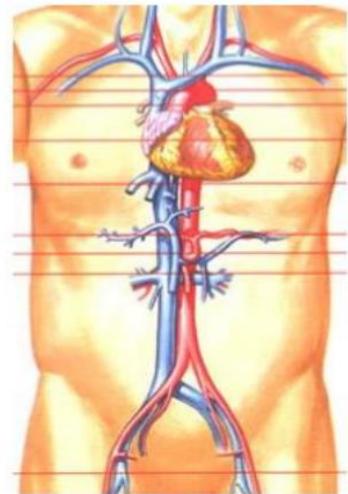
4.2 Cardiovascular system

The cardiovascular system consists of major vessels, heart and minor vessels.

- Major vessels become pipes.
- Heart becomes a pump.
- Minor vessels (smaller arteries/capillaries) are lumped into a single bundle.

There are 3 main types of blood vessels:

- Arteries: carry oxygenated blood pumped away from the heart to the organs.
- Veins: return deoxygenated blood to the heart from the body organs.
- Capillaries: tiny vessels that connect arteries and veins.



4.2.1 cardiovascular system details

The following figure shows the system that we will simplify to make it:

- ❖ Major arteries: is represented by large pipe ($D=30\text{ mm}$)
- ❖ Arterioles: is between arteries & capillaries, play a role of the flow meter & valve, because it passes a specific amount of flow by increasing or decreasing the diameter of the blood vessels.
- ❖ Capillaries diameter is very small to increase the surface area of absorption and reduce the speed of the blood then the absorption of the food from the blood is better.

Velocity in them reduces because the capillaries are parallel then area increase and according to $Q = A \times V$, $A \uparrow$ and $Q = \text{const}$, then $V \downarrow$

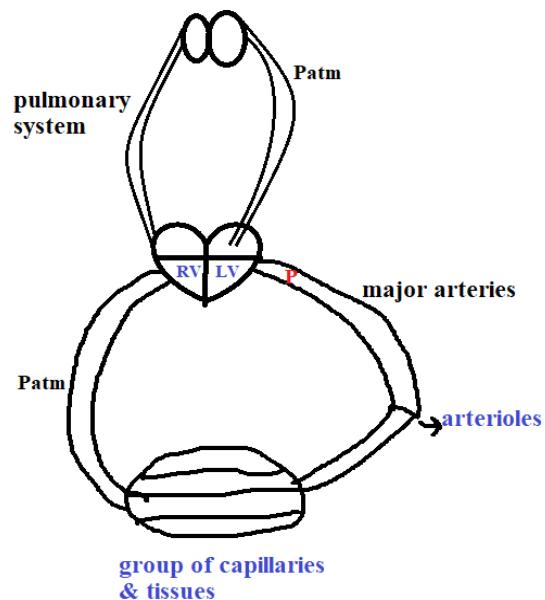


Figure 4-1 Cardiovascular System Details

4.2.2 WindKessel model

The Windkessel model is represented as a circuit containing lumped elements of resistance, capacitance, and inductance. Although these elements are more generally interpreted in an electrical system, there is a direct analogy between the governing equations of an electric circuit and those of a fluid system, where the fluid pressure, the fluid volume, and the volumetric flow rate directly parallels voltage, electrical charge, and electrical current, respectively. For example, the relationship between voltage and current related by electrical resistance as described by the equation $V = IR$, can be directly modified into $P = QR$ to describe the relationship between pressure and flow rate related by the fluid resistance.

Electrical circuit

$$\Delta V = IR, I: \text{"flow of charge"}$$

$$C = \frac{\Delta q}{\Delta v},$$

q: "charge" & v: "voltage"

Fluidic circuit

$$\Delta P = QR$$

$$C = \frac{\Delta V}{\Delta P} = \frac{V_{air}}{P_{atm}},$$

V: "air volume in the chamber"

The resistance and inductance values are associated with the **density** and **viscosity** of blood, and with the **geometry and architecture** of the vasculature which are functions of both the anatomy and the vascular tone. The capacitance value is most affected by the **physical properties** and the **vascular tone** of the large arteries.

4.2.2.1 Flow Resistance Module

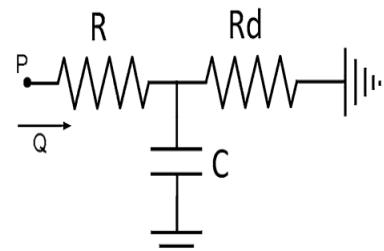
In Poiseuille's solution for laminar flow in a straight cylinder, the relationship between the pressure drop across the cylinder (ΔP) and volumetric flow rate (Q) is:

$$\Delta P = \frac{8\mu L}{\pi r^4} Q \quad (1)$$

$$R = \frac{\Delta P}{Q} \quad \therefore R = \frac{8\mu L}{\pi r^4}$$

where μ is the dynamic viscosity of the fluid, L is the length of the cylinder, and r is the radius of the cylinder.

Equation (1) is true only in laminar flow condition, where the resistance is constant and independent of flow rate. In turbulent flow, however, the additional energy loss leads to the pressure drop across the flow channel becoming proportional to the flow rate squared ($\Delta P \propto Q^2$), implying that the total effective resistance as defined by $R = DP/Q$ is proportional to the flow rate ($R \propto Q$), it is thus important to avoid turbulence and maintain laminar flow. An approximate condition for laminar flow in a circular cylinder is the satisfaction of the following equation for Reynolds number:



A basic three-element Windkessel model for component value estimation purpose.

$$Re = \frac{Vr}{\nu} = \frac{Q}{\pi\nu r} < 1200$$

where V is flow velocity, r is the radius of the flow conduit, and ν is the kinematic viscosity of the fluid.

4.2.2.2 Ways to represent the resistance in the system

4.2.2.2.1 capillary tubes

We present mathematically how such a problem can be overcome by using a large number of small channels in parallel, which simultaneously allows for high resistance and laminar flow at high flow rates.

Consider “N” number of parallel flow channels with radius “r”. We define:

A—combined cross sectional area of all channels

Q—combined volumetric flow through all channels

Q_{chan}—volumetric flow rate through each channel

Re—Reynolds number

R_{chan}—resistance of each channel

R_{total}—combined resistance of all the parallel channels.

The following two equations describe the geometry and resistances of the flow channels:

$$\frac{A}{N} = \pi r^2$$

$$R_{total} = \frac{R_{chan}}{N}$$

From the previous equations we get the following relations:

$$R_{chan} \propto \frac{1}{r^4}$$

$$A \propto \frac{Qr}{Re}$$

$$r \propto \frac{1}{\sqrt{N}}$$

$$\therefore R_{total} = \frac{1}{Ar^2}$$

$$\therefore R_{total} = \frac{Re}{Qr^3}$$

$$\frac{Q}{Re} R_{total} \propto N^{3/2}$$

This equation indicates that in order to achieve a high resistance at a high flow rate; while maintaining a low Reynolds number, a large number of parallel channels is required.

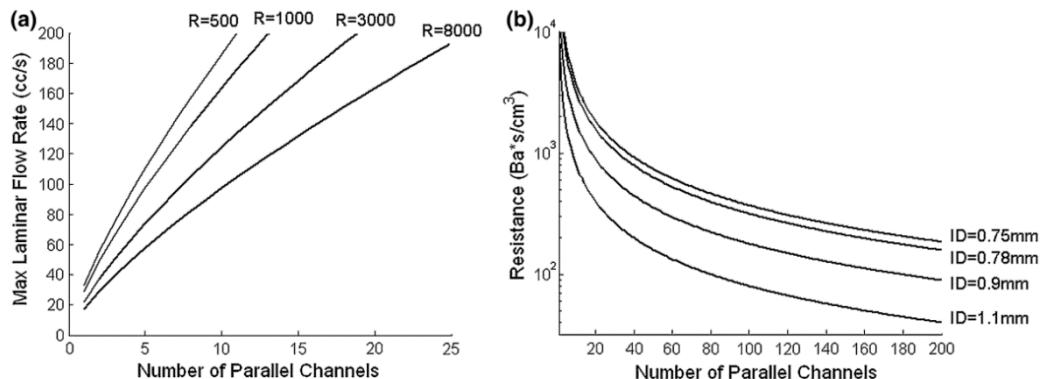


Figure 4-2 (a) Maximum laminar flow rate vs. number of parallel channels for various resistance values. (b) Resistance vs. number of parallel channels for various standard capillary tube inside diameters (ID). Calculated using: Fluid dynamic viscosity = 0.046 g/cm s.

Practical Design and Construction Methods of capillary tubes

To assemble a large number of small parallel channels in a practical and robust way, they placed thin-walled glass capillary tubes (Sutter Instrument, CA) inside a plexiglass cylinder. They applied a small amount of [silicone rubber adhesive sealant](#) (RTV 102, GE Silicones, NY) in between the capillary tubes around their middle section to adhere the tubes to one another, and to block fluid passageways through the gaps in between the tubes. We then applied a small amount of [epoxy \(5 Minute Epoxy, Devcon, MA\)](#) between the plexiglass surface and the bundle of capillary tubes to secure the capillary tubes inside the plexiglass cylinder.

The theoretical resistance of the resistance module is given by:

$$R = \frac{8\mu L}{\pi N r^4}$$

Where μ is the dynamic viscosity of the working fluid, L is the length of the capillary tubes, r is the inside radius of each individual capillary tube, and N is the total number of capillary tubes in parallel.

For a standard capillary tube length of 10 cm, Fig. b shows the relationship between the number of tubes and the resulting resistance for various standard capillary tube sizes that can be readily purchased.

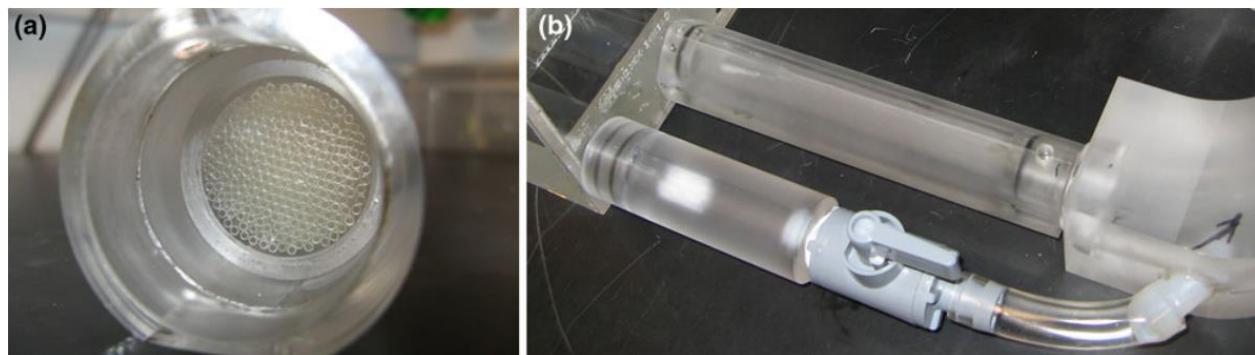


Figure 4-3 (a) Capillary tube resistance module construction. (b) Switchable resistance setup.

Using the same principle of parallel channels, Fig. b shows a method for creating a **switchable resistance module** where the resistance value can be changed during an experiment. Multiple resistance modules can be placed in parallel, with control valves that open and close to add in or remove parallel resistor(s) in order to decrease or increase the effective total resistance.

4.2.2.2.1.1 Capillary tube design

It is important to ensure that laminar flow is maintained throughout the connection tubing, and that diameter changes at the connection junctions are minimized to avoid the creation of turbulence.

TABLE 1. Estimated resistance values (and numbers of capillary tubes) resulting from various combinations of conduit diameter (maximum laminar flow rate), and capillary tube size.

Capillary tubes OD/ID ^a (mm)	1" (200 cc/s)	3/4" (150 cc/s)	5/8" (125 cc/s)	1/2" (100 cc/s)	3/8" (75 cc/s)	1/4" (50 cc/s)
2/1.56	231 (137)	410 (77)	591 (54)	923 (34)	1,641 (19)	3,693 (9)
1.5/1.1	525 (244)	934 (137)	1,345 (95)	2,101 (61)	3,735 (34)	8,404 (15)
1.2/0.9	750 (381)	1,334 (214)	1,920 (149)	3,000 (95)	5,334 (54)	12,002 (24)
1/0.78	923 (548)	1,641 (308)	2,364 (214)	3,693 (137)	6,566 (77)	14,773 (34)
1/0.75	1,080 (548)	1,920 (308)	2,765 (214)	4,321 (137)	7,681 (77)	17,282 (34)

Calculated using fluid dynamic viscosity = 0.046 g/cm s.

Fluid density = 1.1 g/mL.

Capillary tube length = 10 cm.

Circle packing density = 0.85 by area.

^aOD/ID stands for outside diameter/inside diameter.

1. The optimal capillary tube size for constructing the resistance module is determined by:
 - Identifying a resistance value that is close to the desired target value.
 - Conduit diameter that can accommodate the maximum expected flow.
2. A circle packing algorithm can then be used to determine the precise plexiglass cylinder diameter required to house the specific number of capillary tubes.

3. Upon completing the actual construction of the resistance module, we manually count the number of capillary tubes in the plexiglass cylinder, and use the resulting count, together with the measured dynamic viscosity of the working fluid and $R = \frac{8\mu L}{\pi N r^4}$ to determine the theoretical resistance of the module.

4.2.2.2.1.2 implementation process

In the market we didn't find all the sizes available, so we tried to make system of equations and MATLAB code for it that help us to specify the length of the tube instead of the diameter of it.

Equations:

$$N = \frac{A_{\text{pipe}}}{A_{\text{tube}}} \dots\dots (1)$$

Where:

- N – number of the capillary tubes
- $A_{\text{pipe}} = \pi r_{\text{pipe}}^2$
- $A_{\text{tube}} = \pi r_{\text{tube_outer}}^2$

$$MAP = \frac{2}{3} DBP + \frac{1}{3} SBP \dots\dots (2)$$

Where:

- **MAP:** mean arterial pressure
- **DBP:** diastolic blood pressure (80 mmHg)
- **SBP:** systolic blood pressure (120-130 mmHg)

$$R = \frac{MAP}{CO} \dots\dots (3)$$

Where:

- **R:** resistance in the pipe in (mmHg.min/L).
- **CO:** cardiac output (L/min).

$$SVR = R \times (133.322 \times 60 \times 1000) \dots\dots (4)$$

Where:

- **SVR:** systemic vascular resistance in (pa.s/m³).

$$L = \frac{SVR \times N \times \pi \times r_{\text{tube_inner}}^4}{8 \times \mu}$$

Where:

- **L:** tube length (m).

4.2.2.2.1.3 MATLAB code

```

1 - clc,clear
2 - SBP = 120; %systolic blood pressure
3 - DBP = 80; %diastolic blood pressure
4 - co = 5; %cardiac output (L/min)
5 - r_pipe = 0.015; %m
6 - r_tube_outer = 0.0015; %m
7 - r_tube_inner = 5*(10^-4); %m
8 - muo = 1.002*(10^-3); %pa.s viscosity of water
9 - A_pipe = pi * (r_pipe^2);
10 - A_tube = pi * (r_tube_outer^2);
11 - N = A_pipe/A_tube; %number of capillary tubes inside the pipe
12 - MAP = (2/3*DBP)+(1/3*SBP); %mean arterial pressure
13 - R = MAP/co; %mmHg.min/L
14 - SVR = R *(133.322*60*1000); % systemic vascular resistance in (pa.s/m^3)
15 - L = ((SVR*N*pi*(r_tube_inner^4))/(8*muo))*100; %cm

```

Results:

L =

36.5756

Comments

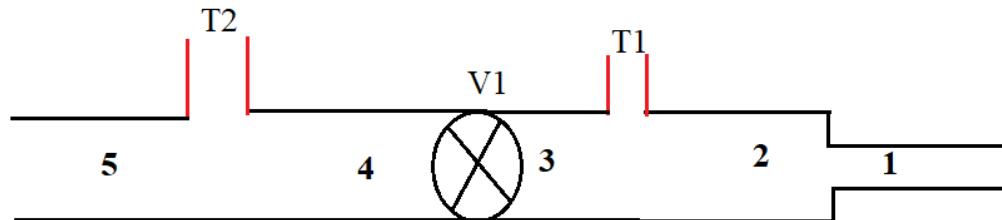
We have found that the length of the tube is very long so to make them a bundle , the collection and fixation of it will be very hard and the resistance will be a fixed resistance that won't be suitable for our system.

4.2.2.2.2 Valve resistance manual calculations

Small resistance in the upstream before the compliance chamber:

The line consists of acrylic pipes, 2 tees and one valve (Diameter 1 inch).

Flow rate is the cardiac output (Q) = 5 lit/min = $8.333 \times 10^{-5} m^3/s$



$$d_1 = 0.015 \text{ m}, d_2 = d_3 = d_4 = d_5 = 0.03 \text{ m}, \rho = 1000 \text{ kg/m}^3, \mu = 10^{-3} \frac{\text{kg}}{\text{m.s}}$$

$$L_1 = 0.055 \text{ m}, L_2 = 0.055 \text{ m}, L_3 = 0.052 \text{ m}, L_4 = 0.05 \text{ m}, L_5 = 0.08 \text{ m}$$

$$v_1 = Q/A_1 = 0.4716 \text{ m/s.} \quad v_2 = Q/A_2 = 0.1179 \text{ m/s.}$$

$$Re_1 = \frac{\rho v_1 d_1}{\mu} = 7074 \rightarrow \text{turbulent flow} \therefore f \text{ from mody chart, } \frac{\epsilon}{d_1} = \frac{0.0015}{15} = 10^{-4}$$

$$\therefore f_1 = 0.035$$

$$Re_2 = \frac{\rho v_2 d_2}{\mu} = 3537 \rightarrow \text{transition flow} \therefore f \text{ from mody chart, } \frac{\epsilon}{d_2} = \frac{0.0015}{30} = 5 \times 10^{-5}$$

$$\therefore f_2 = 0.0414$$

**c - Transition function
for both smooth and
rough pipe (Colebrook)**

$$\frac{1}{\sqrt{f}} = -2.0 * \log\left(\frac{\epsilon / D}{3.7} + \frac{2.51}{Re \sqrt{f}}\right)$$

$$h_{\text{loss in pipes}} = \frac{0.81 \times f \times l \times Q^2}{g \times d^5}$$

$$h_{\text{loss (1)}} = 1.453 \times 10^{-3}$$

$$h_{\text{loss (2)}} = 5.372 \times 10^{-5}$$

$$h_{\text{loss (3)}} = 5.079 \times 10^{-5}$$

$$h_{\text{loss (4)}} = 4.884 \times 10^{-5}$$

$$h_{\text{loss (5)}} = 7.815 \times 10^{-3}$$

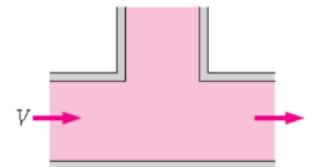
Tee resistance:

$$h_{\text{loss}} \text{ in tee} = \frac{K_L \times V_2^2}{2 \times g}$$

$$h_{\text{loss}} \text{ in tee (1)} = 1.417 \times 10^{-4}$$

$$h_{\text{loss}} \text{ in tee (1&2)} = 2.834 \times 10^{-4}$$

Tee (line flow):
 Flanged: $K_L = 0.2$
 Threaded: $K_L = 0.9$



valve resistance in different cases:

$$h_{\text{loss}} \text{ in valve} = \frac{K_v \times V_2^2}{2 \times g}$$

	K_v	h_{loss}
0°	4.1817	2.963×10^{-3}
15°	9.269	6.567×10^{-3}
30°	26.066	0.0185
45°	83.805	0.0594

How did we get Valve K_v

We used SOLIDWORKS simulation to simulate the flow inside the valve.

Results

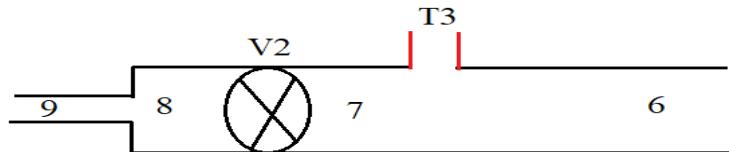
valve Angle	density(water)	viscosity(water)	Velocity(inlet)(m/sec)	pA[pa]	pB[pa]
0 degree	1000	0.001	0.1694	101375	101315
15 degree	1000	0.001	0.1694	101453	101320
30 degree	1000	0.001	0.1694	101695	101321
45 degree	1000	0.001	0.1694	102508.15	101305.7

Re	delta P [pa]	Dynamic pressure		Kv
		60	14.34818	
4235	133	14.34818	9.269468323	
4235	374	14.34818	26.0660237	
4235	1202.45	14.34818	83.80505402	

Small resistance in the downstream before the compliance chamber:

The line consists of acrylic pipes, 1 tees and one valve (Diameter_3/4 inch).

Flow rate is the cardiac output (Q) = 5 lit/min = $8.333 \times 10^{-5} m^3/s$



$$d_9 = 0.015 \text{ m}, d_6 = d_7 = d_8 = 0.019 \text{ m}, \rho = 1000 \text{ kg/m}^3, \mu = 10^{-3} \frac{\text{kg}}{\text{m.s}}$$

$$L_6 = 0.145 \text{ m}, L_7 = 0.05 \text{ m}, L_8 = 0.05 \text{ m}, L_9 = 0.08 \text{ m}$$

$$v_6 = Q/A_1 = 0.2939 \text{ m/s.}$$

$$v_9 = Q/A_2 = 0.4716 \text{ m/s.}$$

$$Re_6 = \frac{\rho v_6 d_6}{\mu} = 5584 \rightarrow \text{turbulent flow} \therefore f \text{ from mody chart, } \frac{\epsilon}{d_1} = \frac{0.0015}{19} = 7.895 \times 10^{-5}$$

$$\therefore f_6 = 0.039$$

$$Re_9 = \frac{\rho v_9 d_9}{\mu} = 7074 \rightarrow \text{turbulent flow} \therefore f \text{ from mody chart, } \frac{\epsilon}{d_2} = \frac{0.0015}{15} = 10^{-4}$$

$$\therefore f_9 = 0.035$$

$$h_{\text{loss}} \text{ in pipes} = \frac{0.81 \times f \times l \times Q^2}{g \times d^5}$$

$$h_{\text{loss}}(6) = 1.309 \times 10^{-3}$$

$$h_{\text{loss}}(7) = 4.515 \times 10^{-4}$$

$$h_{\text{loss}}(9) = 4.515 \times 10^{-4}$$

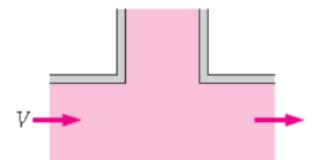
$$h_{\text{loss}}(9) = 2.114 \times 10^{-3}$$

Tee resistance:

$$h_{\text{loss}} \text{ in tee} = \frac{K_t \times V_6^2}{2 \times g}$$

$$h_{\text{loss}} \text{ in tee (3)} = 8.805 \times 10^{-4}$$

Tee (line flow):
Flanged: $K_t = 0.2$
Threaded: $K_t = 0.9$



valve resistance in different cases:

$$h_{\text{loss}} \text{ in valve} = \frac{K_v \times V_6^2}{2 \times g}$$

	K_v	h_{loss}
0°	4.1817	2.963×10^{-3}
15°	9.269	6.567×10^{-3}
30°	26.066	0.0185
45°	83.805	0.0594

4.2.3 Compliance chamber

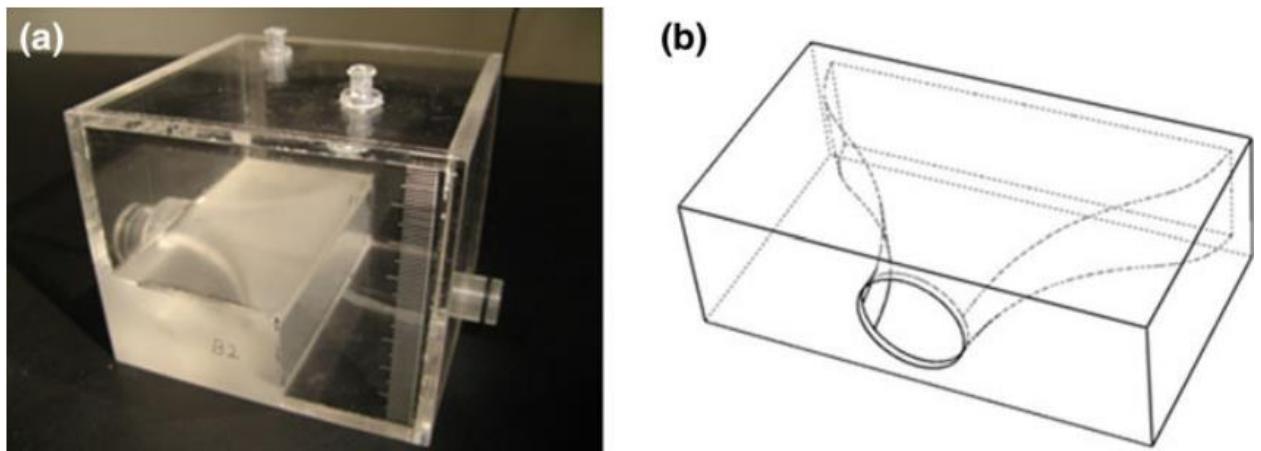


Figure 4-4 Compliance Chamber

This chamber simulates the ability of the aortic wall to expand and contract in response to changes in blood pressure. It is a measure of the elasticity and flexibility of the aorta. High compliance means the aorta can easily stretch to accommodate the blood pumped from the heart, reducing the workload on the heart and promoting efficient blood flow. Low compliance, on the other hand, indicates a stiffer aorta, which can increase the workload on the heart and may be associated with various cardiovascular conditions.

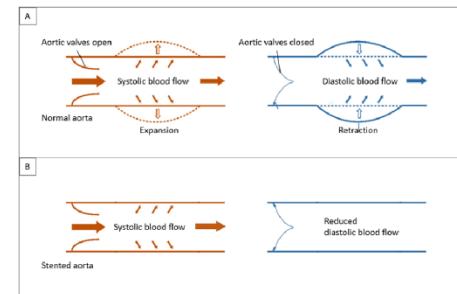


Figure 4-5 Compliance in the Aorta

Compliance is important because it affects how blood is distributed throughout the body and influences blood pressure. It is typically measured as the change in volume per unit change in pressure ($\Delta V/\Delta P$). As people age or develop certain diseases, the compliance of the aorta can decrease, leading to potential health issues like hypertension and increased risk of cardiovascular events.

This chamber is a plexiglass box that can trap a precise amount of air, which acts as a capacitance in the system, it has two holes in the upper surface:

- One is the valve to control the amount of air in the chamber so changing the capacitance value.

We measure the capacitance value based on the amount of air that we can measure it using a graduated scale on the chamber walls.

- The other hole is a pressure tap to measure the pressure of the air.

There is a smooth contour (diffuser) inside the chamber to reduce the turbulence of the flow to give the same performance as in the human body.

4.2.3.1 Calculations

$$1) \ C = \frac{\Delta V}{\Delta P}$$

$$2) \ C_a = \frac{V - \Delta V}{\Delta P} \quad \text{C}_a \text{ is the overall capacitance of air.}$$

$$3) \ \Delta P = \rho g \Delta h \quad \& \quad \Delta h = \frac{\Delta V}{A} \quad \therefore \ C_v = \frac{A}{\rho g}$$

C_v is capacitance due to varying fluid level.

$$4) \ C = \left(\frac{1}{C_a} + \frac{1}{C_v} \right)^{-1} = \frac{C_a C_v}{C_a + C_v} \sim C_a \quad \text{C the total capacitance of the chamber}$$

Note: The chamber is made in a cubic shape to be large enough to make the equation No (4) is true.

4.2.3.2 SOLIDWORKS Design

We take the dimension of the compliance chamber is $10 \times 10 \times 10 \text{ cm}$

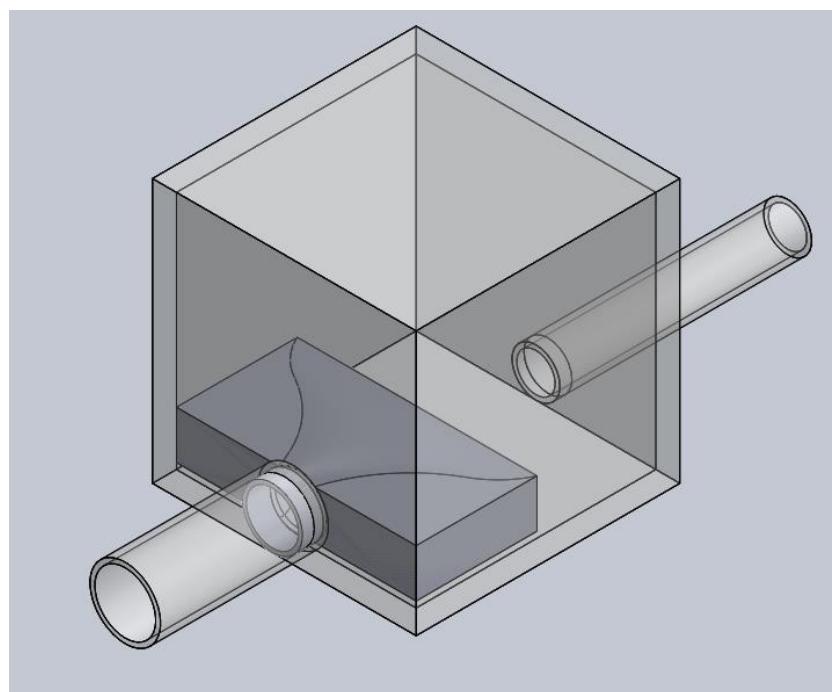


Figure 4-6 Compliance Chamber SOLIDWORKS design

4.3 Pulsatile Blood Pump Simulation in MATLAB

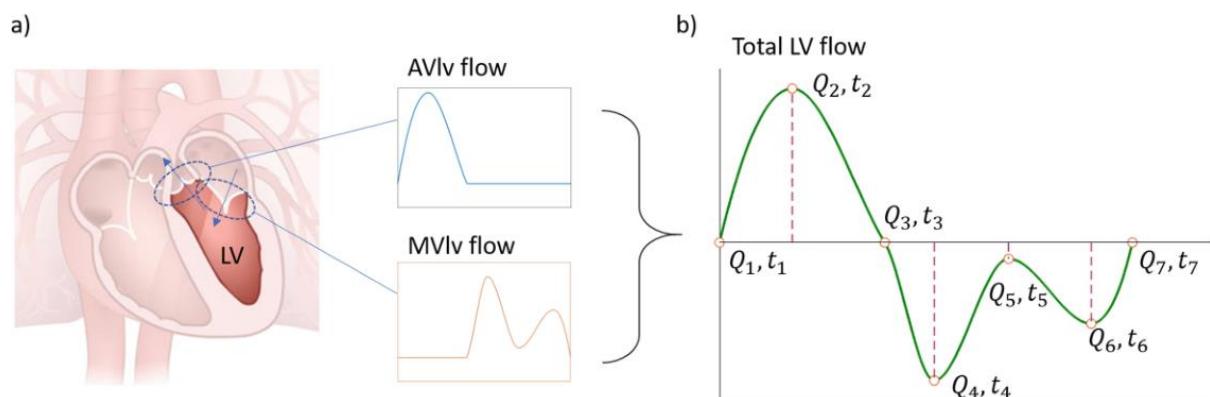
In this part we will show how we simulate a specific given case in MATLAB with its inputs flow rate and time and a SIMULINK model for the setup that we showed above.

4.3.1 Input Curve Data

Table 1. Parameter set for the LV profiles. $Q_{2,4,5,6}$ values are reported in 1/min, $t_{2,3,4,5,6}$ percentages are referred to t_7 , t_7 value is reported in s

Profile	Q_2	Q_4	Q_5	Q_6	t_2	t_3	t_4	t_5	t_6	t_7
p_0	19.4	17.2	8.6	16	16%	47%	53%	75%	92%	0.92
p_1	14.8	13.4	5.2	5.9	24%	44%	67%	81%	91%	0.66
p_2	20.6	18.4	1.4	7.6	17%	41%	58%	81%	93%	0.90

Figure 4-7 Input Data



4.3.2 MATLAB Code

```
1 -      clear;
2 -      clc;
3 -      systole=0.44;
4 -      t2=0.24;
5 -      t3=systole; %systole
6 -      t4=0.67;
7 -      t5=0.81;
8 -      t6=0.91;
9
10 -     final=51; %register count
11
12 -     t7=2;
13
14 -     t2=t2*t7;
15 -     t3=t3*t7;
16 -     t4=t4*t7;
17 -     t5=t5*t7;
18 -     t6=t6*t7;
19
20 -     Q2=14.8; Q4=13.4; Q5=5.2; Q6=5.9;
21
22 -     Q=[0 Q2 0 -Q4 -Q5 -Q6 0];
23 -     time=[0 t2 t3 t4 t5 t6 t7];
```

```

24      %
25      xq=round(linspace(0,t7,final),3); % Time(s)
26      %
27      vq=interp1(time,Q,xq,'makima');
28      figure
29      plot(time,Q,'ro',xq,vq)
30      grid on
31      xlabel ('time(s)')
32      ylabel('Flow Rate (L/min)')
33      title('flow rate')
34      V=(Q.* (10^-3) ./60). /((pi/4)*(2*2.54*10^-2)^2);%lineaar Velocity
35
36      %
37      vq2=interp1(time,V,xq,'makima');%lineaar Velocity
38      %
39      figure
40      plot(xq,vq2)
41      grid on
42      xlabel ('time(s)')
43      ylabel('Velocity (m/s)')
44      title('linear velocity')
45      %
46      vq3=vq2*60/0.004;%RPM

47      % equations
48      % slice the time %
49      x1=xq(1,1:26);
50      x2=xq(1,26:51);
51      %x3=xq(1,101:151);
52      % slice RPM (VQ3) vector %
53      y1=vq3(1,1:26);
54      y2=vq3(1,26:51);
55      % Get the equations %
56      pp1=polyfit(x1,y1,8);
57      pp2=polyfit(x2,y2,8);

58
59      z1=polyval(pp1,x1);
60      z2=polyval(pp2,x2);

61
62      % Plotting Position curve %
63      figure
64      xxx=find(xq==xq(1,23));
65      pqql=(vq3(1:xxx)./60).* (t7/(final-1)).*0.004;
66      pqq2=(vq3(xxx+1:final)./60).* (t7/(final-1)).*0.004;
67      pqq=[pqql pqq2];
68      plot(xq(1,1:final),pqq)
69      title('Position')

```

```

70 -      grid on
71
72 -      % _____ excel File _____
73 -      parameters2={'equation1';'equation2'};
74 -      figure
75 -      plot(xq,vq3,'o')
76 -      hold on
77 -      plot(x1,z1,'r','LineWidth',2)
78 -      plot(x2,z2,'c','LineWidth',2)
79 -      xlabel ('time(s)')
80 -      ylabel('RPM')
81 -      title('Curve fitting')
82
83 -      %_____ Curve Fitting Equation _____%
84 -      vpa(poly2sym(pp1),8)
85
86
87 -      time_diastole_final=xq(xxx+1:final)-xq(1,xxx);
88 -      time_systole_final=xq(1:xxx)+(t7-xq(1,xxx));
89 -      time_ms=[time_diastole_final time_systole_final] .*10^3;
90 -      parameters={'Time(ms)';'RPM';'Kinco_Rpm';'Rpm';'postion(mm)'};
91 -      rms=[vq3(xxx+1:final),vq3(1:xxx)]
92 -      rpm=round(rms);
93 -      rpm=round(rms);
94 -      figure
95 -      plot(time_ms,rpm)
96 -      grid on
97 -      xlabel ('time(ms)')
98 -      ylabel('RPM')
99 -      title('Inserting Curve to the driver')
100 -      kinco_rpm=rpm.*-1;
101 -      l=[time_ms;rpm;kinco_rpm;rms;pqq];
102 -      T=table(parameters,l)
103 -      filename='pulsatile_pump.xlsx'
104 -      writetable(T,filename)
105 -      winopen (filename)

```

4.3.3 MATLAB Code Results

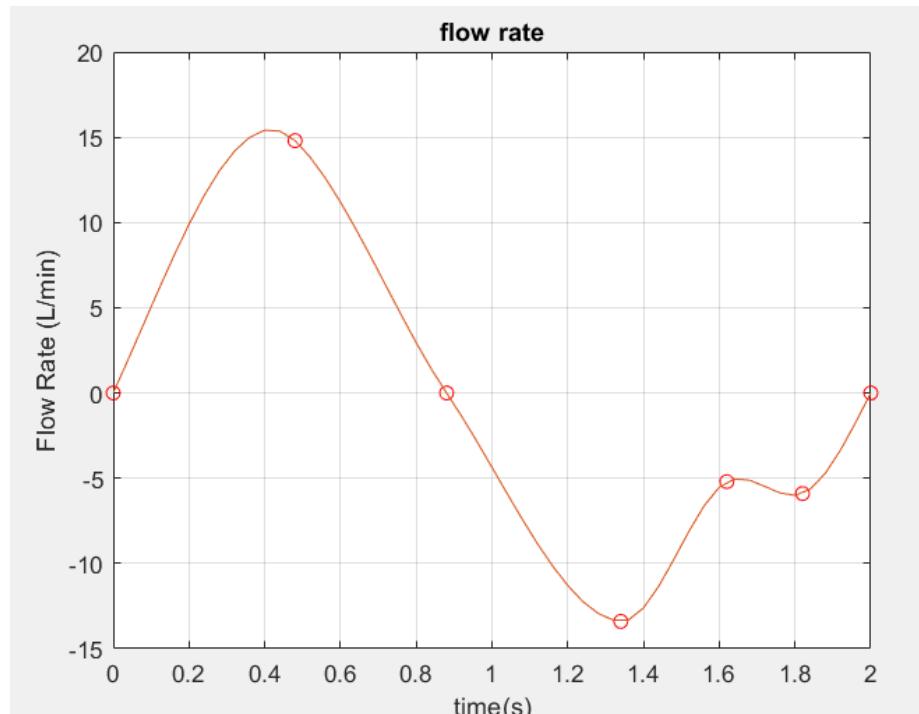


Figure 4-9 Flow Rate Output

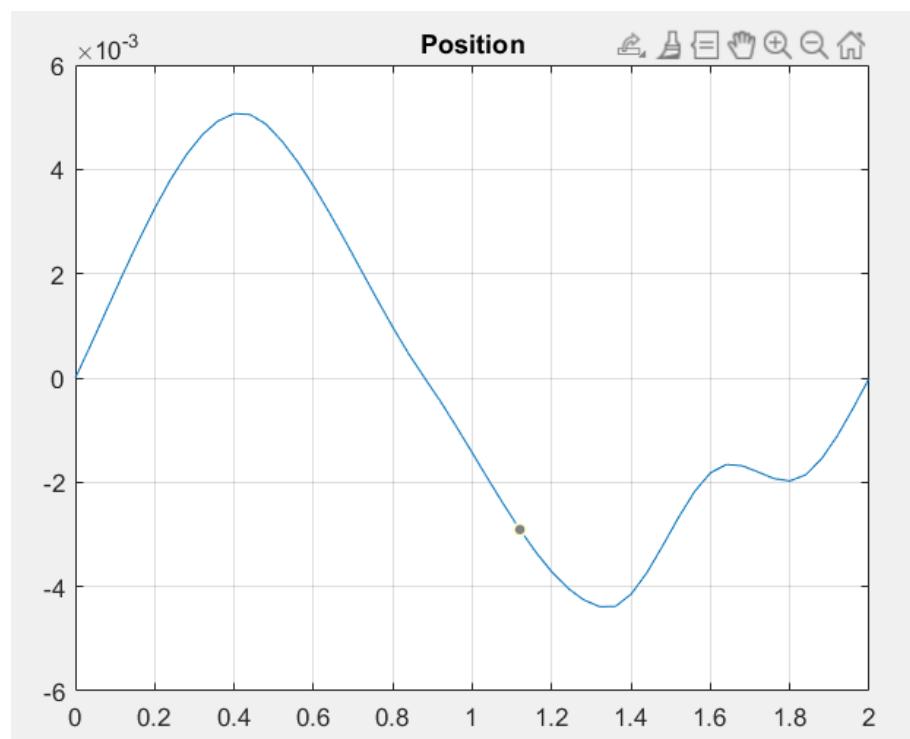


Figure 4-10 Position Output

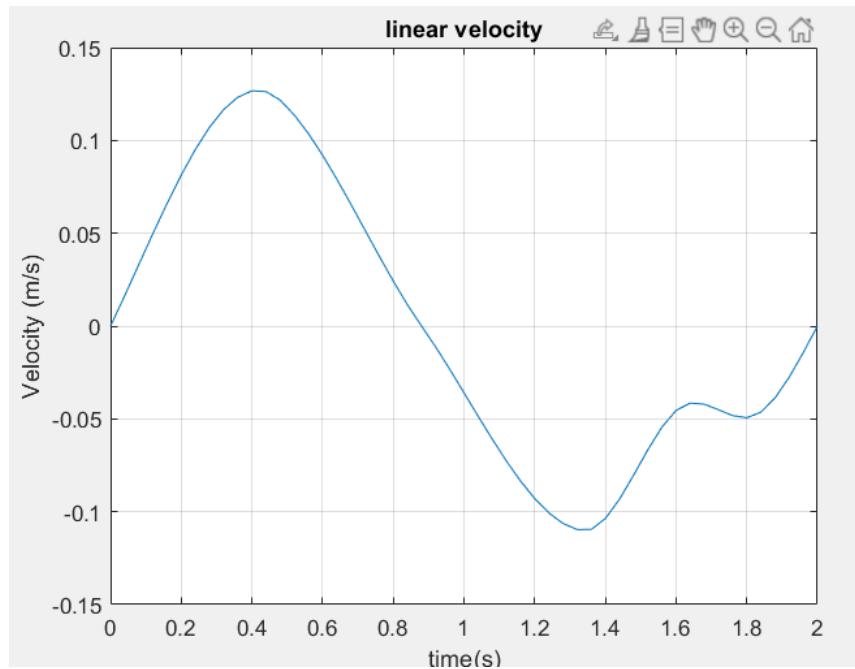


Figure 4-11 Velocity Output

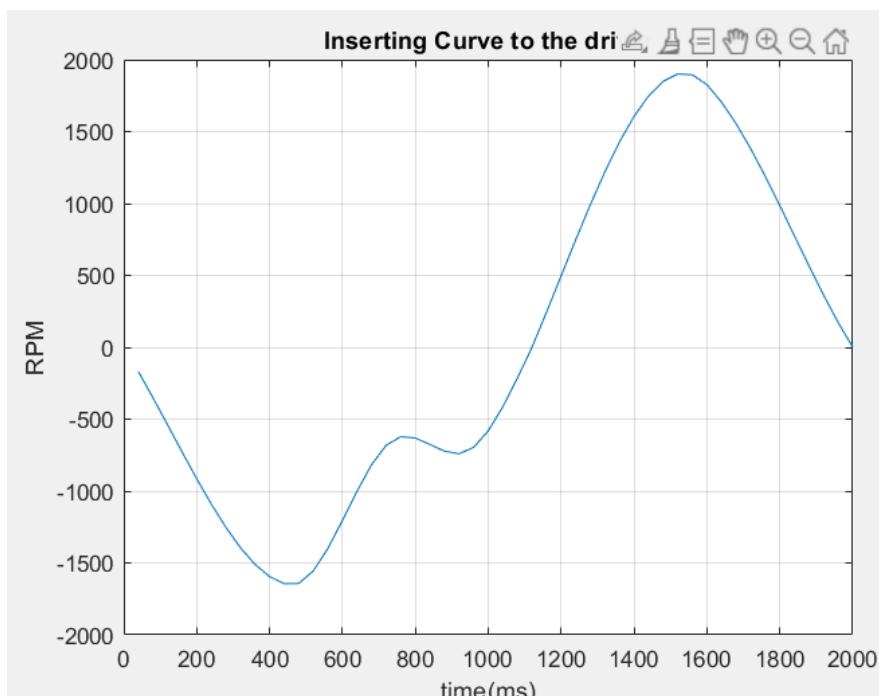


Figure 4-12 Inserting Curve to the Driver

4.3.4 MATLAB SIMULINK Module

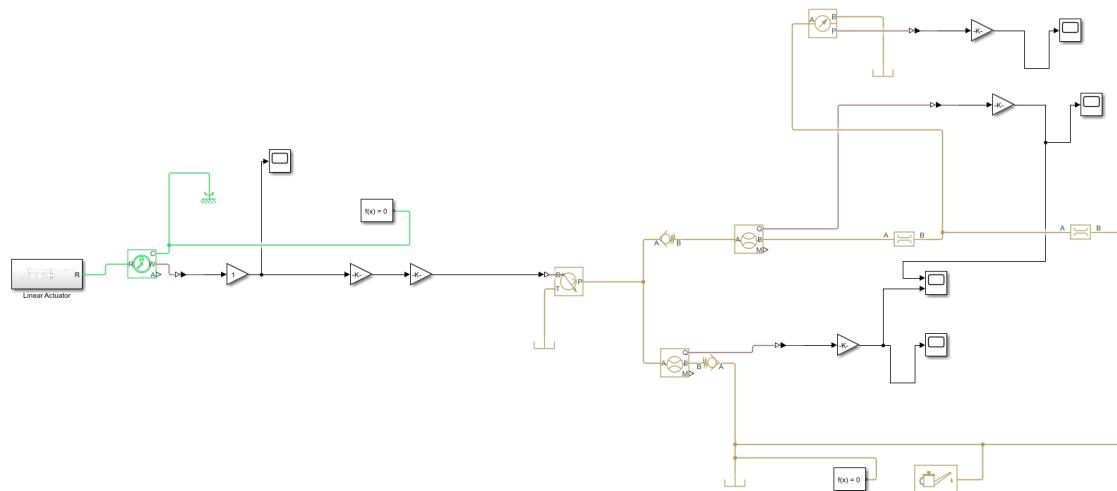


Figure 4-13 MATLAB Simulink Module

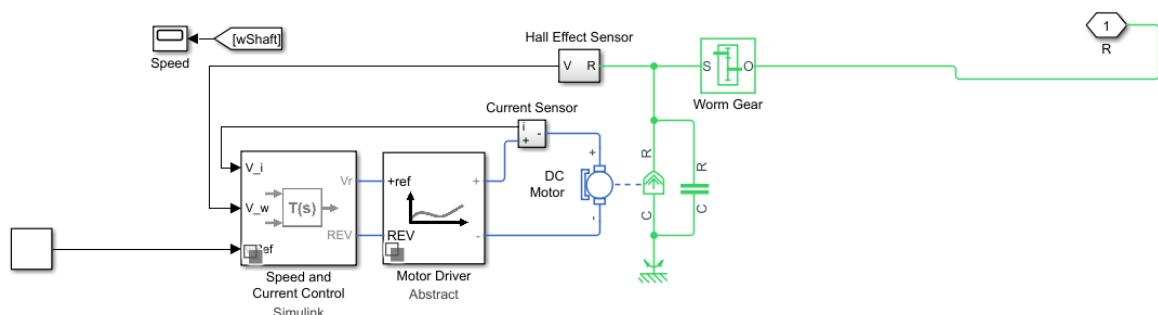


Figure 4-14 Motor SIMULINK

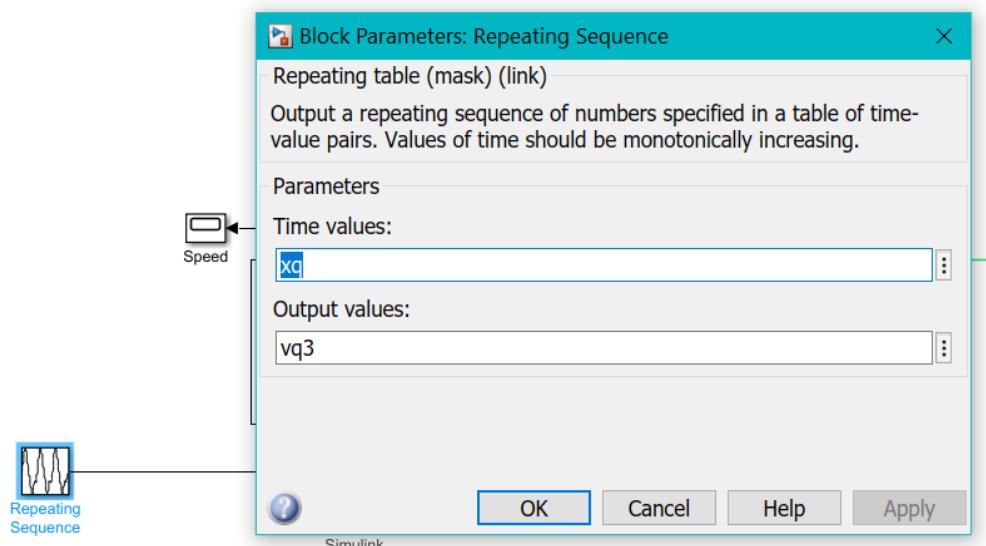


Figure 4-15 Input Data from the Code

4.3.5 MATLAB SIMULINK Results

4.3.5.1 Suction Line Flow Meter

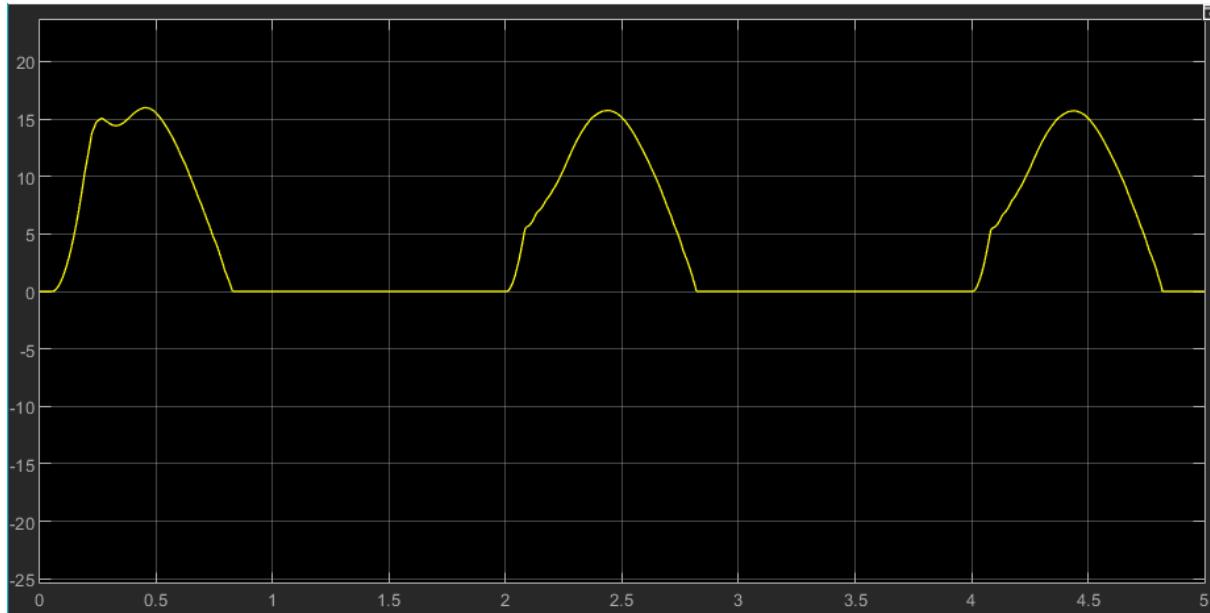


Figure 4-16 Suction Line Flow Meter

4.3.5.2 Discharge Line Flow Meter

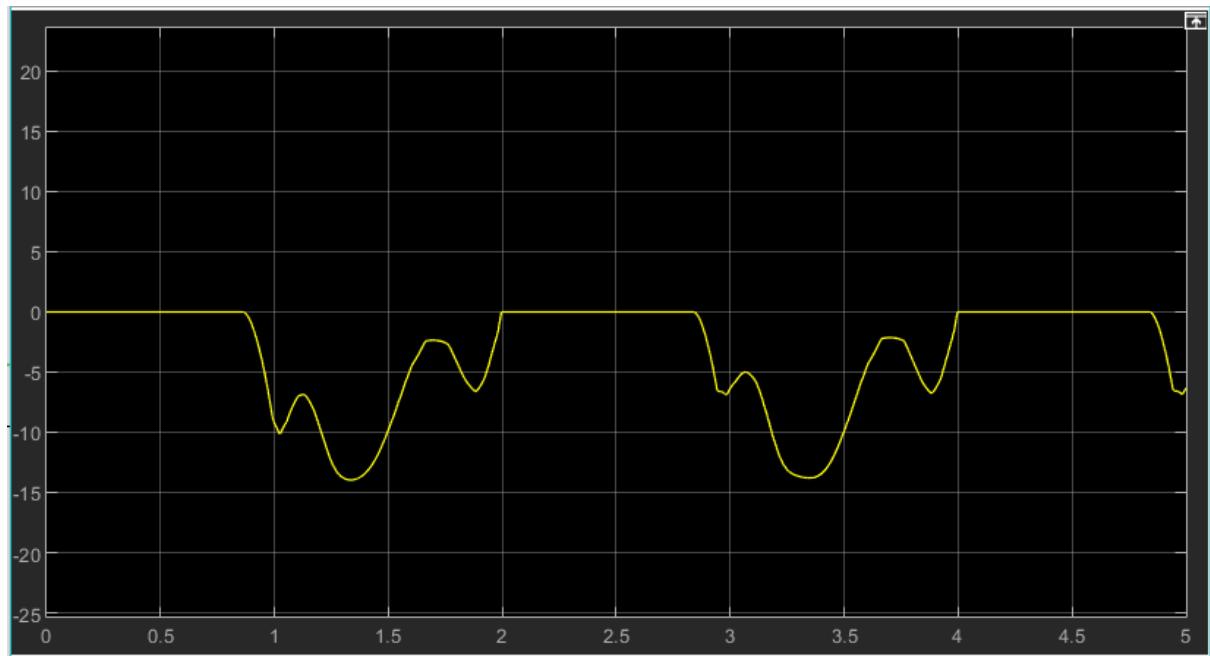


Figure 4-17 Discharge Line Flow Meter

4.3.6 The Collected Curve between Suction & Discharge Curve

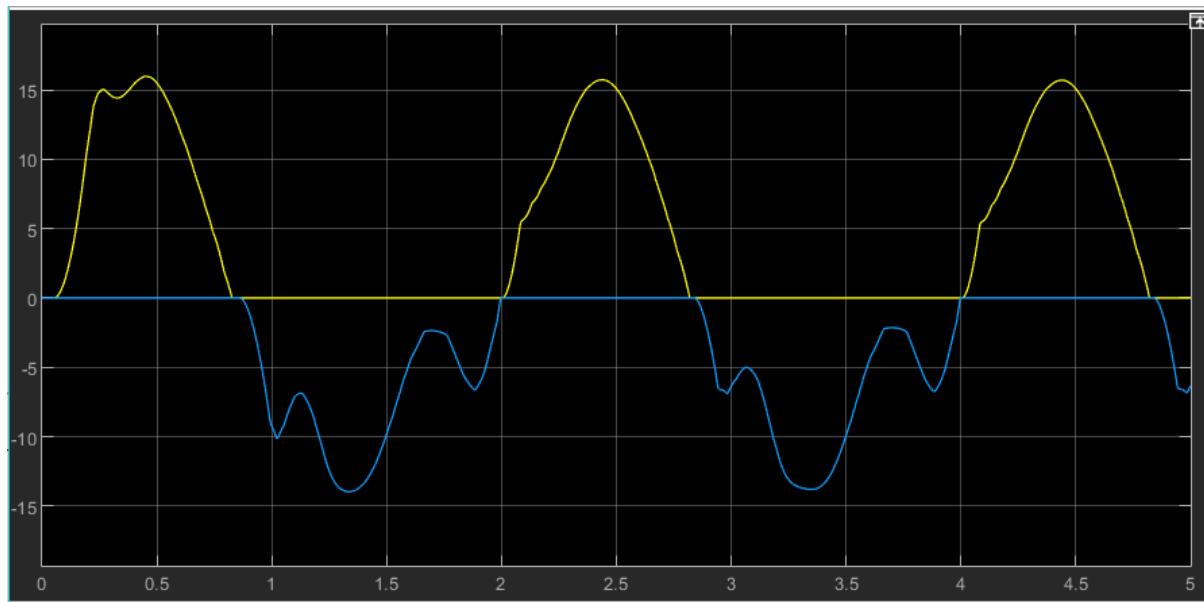


Figure 4-18 The Collected Curve between Suction & Discharge Curve

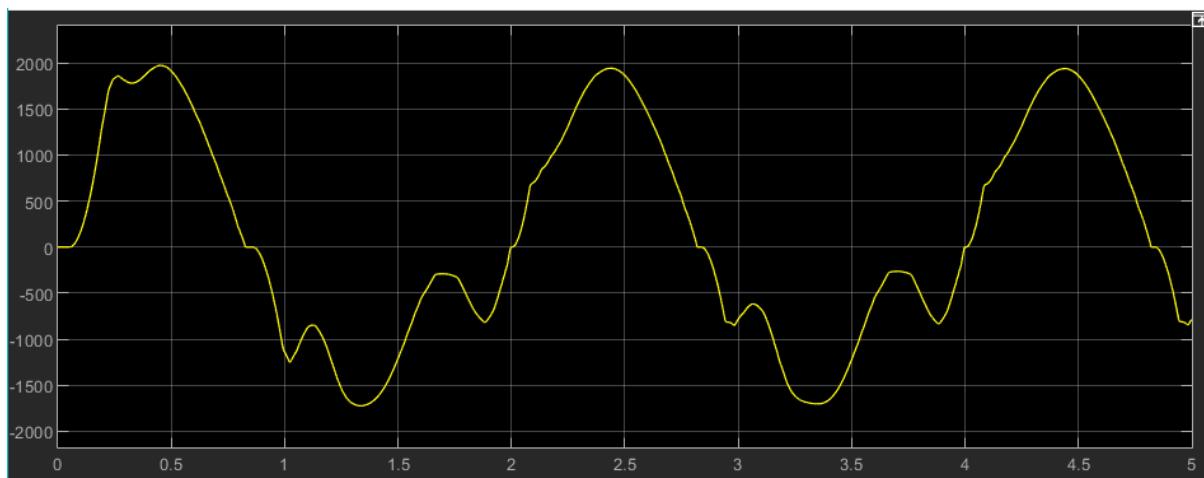


Figure 4-19 Final Curve

4.4 Results of Practical Experiment

4.4.1 Discharge Line

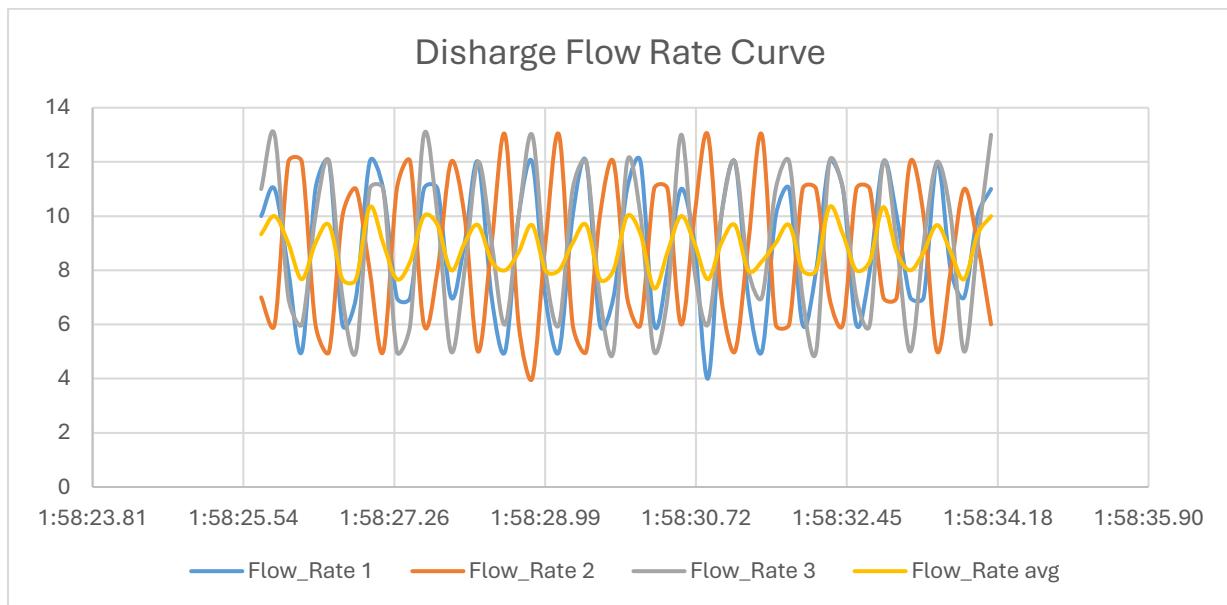


Figure 4-20 Average from Different Data Curves

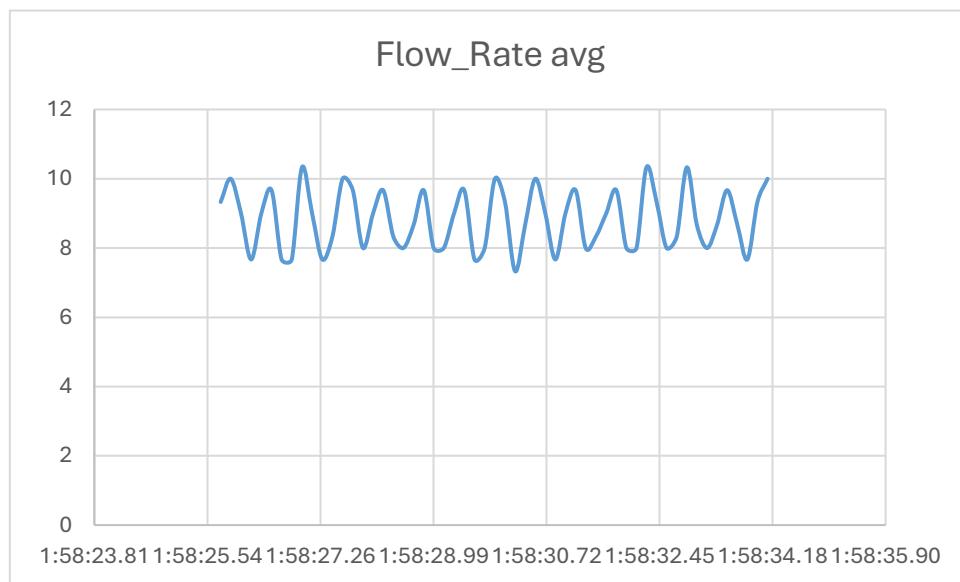


Figure 4-21 Average Data Curve

Note: This curve is wrong because the flow meter wasn't fixed and the valve spring became weak.

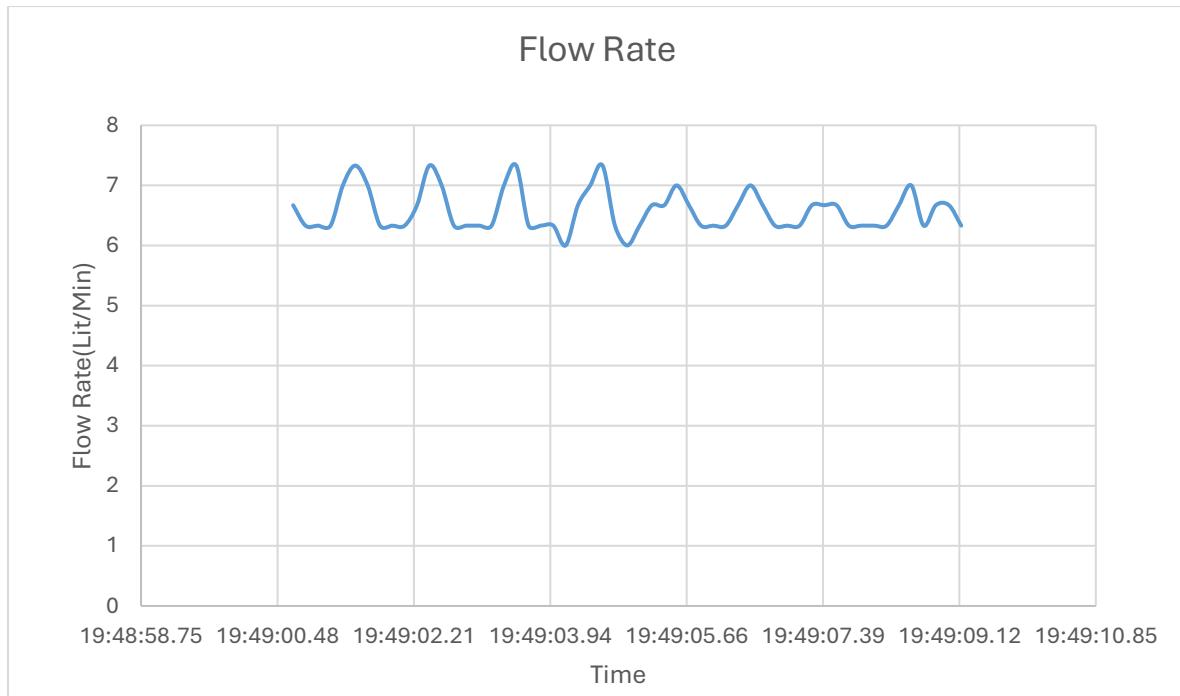


Figure 4-22 New Result After Modifications

4.5 Comparison between MATLAB Results and Practical Experiment

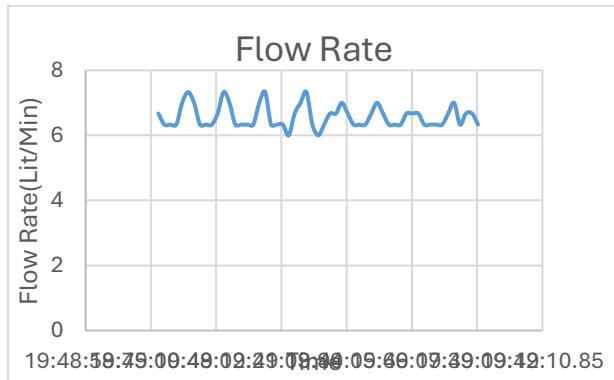


Figure 4-24 Experimental Result

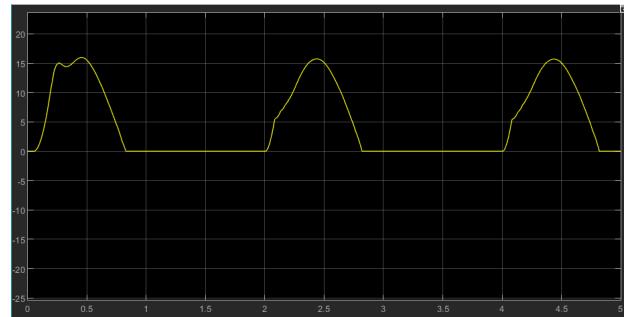


Figure 4-23 Suction Line Flow Meter

5 Trouble Shooting

5.1 Introduction

Troubleshooting is the systematic process of identifying, diagnosing, and resolving problems within a system or piece of equipment. It involves understanding the symptoms of an issue, tracing them to their root causes, and implementing effective solutions. Effective troubleshooting requires a combination of knowledge, analytical skills, and practical experience, enabling individuals to restore functionality and prevent future occurrences. By following a structured approach, troubleshooting can minimize downtime, enhance efficiency, and maintain optimal performance of various systems and machinery.

Troubleshooting a positive displacement piston pump involves systematically identifying and resolving issues that affect its performance. These pumps are critical components in many industrial and commercial applications, valued for their ability to deliver consistent flow rates regardless of pressure variations. Understanding the common problems that can arise—such as leaks, cavitation, or reduced efficiency—and knowing how to diagnose and address them can significantly enhance the reliability and lifespan of the pump. This guide provides a structured approach to identifying symptoms, tracing their causes, and implementing effective solutions, ensuring optimal pump performance and minimal downtime.



Figure 5-1 pulsatile pump trouble shooting

Troubleshooting a positive displacement piston pump is essential for maintaining the reliability and efficiency of systems that depend on these pumps, which are crucial in industries like oil and gas, chemical processing, water treatment, and manufacturing due to their ability to deliver precise flow rates and handle high-pressure applications. Common issues in these pumps include cavitation, which manifests as unusual noise, vibration, and reduced flow rate, often caused by inadequate inlet pressure or high fluid viscosity; leakage, which results in visible fluid leaks and pressure drops due to worn seals or loose connections; loss of flow or pressure, characterized by decreased flow rate or inconsistent output due to worn pistons, valves, or clogged filters; overheating, indicated by excessive heat generation and unusual smells, typically from insufficient lubrication or operational overload; and vibration and noise, which can accelerate wear and tear, usually resulting from misalignment or unbalanced components. The troubleshooting process begins with an initial assessment, observing and documenting symptoms and operating conditions, followed by a diagnosis using tools like pressure gauges and thermal cameras to gather data and identify patterns. Root cause analysis involves isolating the problem by systematically checking each component, comparing current performance metrics with manufacturer specifications. Implementing solutions includes performing necessary repairs, adjusting operating conditions, and ensuring proper lubrication and alignment. After repairs, testing and validation confirm the resolution of the issue, with performance monitored to ensure the pump operates within its designed parameters. Preventive measures involve regular maintenance schedules, training personnel on proper practices, and keeping detailed records of all troubleshooting activities and outcomes. This systematic approach ensures the pump operates efficiently, minimizing downtime and maintaining the reliability of critical processes.

5.1.1 Rust Inside the Tank

This rust in the tank causes blockage in suction and discharge line and valve that results in increasing the load on the pump motor according to increasing the pressure in the head.



Figure 5-2 Rust Inside the Tank

5.1.2 Base of The Pump

The old base was two welded pieces which caused buckling and misalignment



Figure 5-3 Old welded base

New base is one piece, made from steel and is painted with electrostatic to prolong the life of the metal and prevent rust.

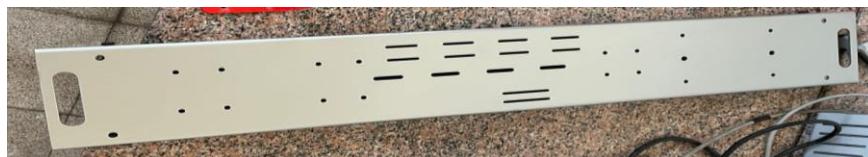


Figure 5-4 New base painted with electrostatic

5.1.3 Motor Fixation

Old fixation wasn't made according to the dimensions of the motor.



Figure 5-3 Old motor Fixation

New fixation is made according to the dimensions of the motor and the bearing to ensure good fixation.



Figure 5-4 New motor fixation

5.1.4 Damaged Ball Screw

Symptom: The ball screw is loose.

We solved this problem by buying new one.



Figure 5-6 New power screw



Figure 5-5 Cutting the power screw to fit our pump dimensions

5.1.5 Damaged Linear Bearing

We changed it.



Figure 5-7 Self-Aligning Flange Bearing (Horizontal-8mm Dia)

5.1.6 Noise

The pump was making a loud noise, we solved this problem by correcting the alignment using the dial indicator and using lithium grease.

We discovered it from the broken coupling.



Figure 5-8 Broken Coupling

Lithium Grease

Advantages of Lithium Grease

- **High Temperature Tolerance:** Lithium grease can withstand high temperatures without breaking down, making it suitable for applications where heat is a factor.
- **Water Resistance:** This grease has excellent water-resistant properties, which protect against corrosion and ensure effective lubrication even in wet conditions.
- **Versatility:** It is suitable for a wide range of applications, including automotive, industrial machinery, and household items, due to its broad compatibility with different materials and surfaces.
- **Stability:** Lithium grease has good structural stability, meaning it does not easily separate or degrade over time, ensuring consistent performance and long-lasting lubrication.
- **Load Carrying Capacity:** It provides excellent protection under heavy loads, reducing wear and tear on moving parts and extending the lifespan of machinery.
- **Oxidation Resistance:** This grease resists oxidation, which prevents it from hardening and maintains its lubricating properties over extended periods.



Figure 5-9 Lithium Grease

Disadvantages of Lithium Grease

- **Cost:** Lithium grease can be more expensive than other types of grease, which might be a consideration for large-scale or budget-sensitive applications.
- **Limited Extreme Pressure Performance:** While it handles moderate pressure well, lithium grease may not be the best choice for extreme pressure applications, where specialized EP greases might be required.
- **Environmental Concerns:** The production and disposal of lithium-based products raises environmental concerns, as lithium extraction can have significant ecological impacts.

- **Chemical Reactivity:** Lithium grease can react with certain chemicals and materials, potentially leading to compatibility issues in specific applications.
- **Not Food Safe:** It is not suitable for use in food processing equipment where food-grade lubricants are required, limiting its applications in the food industry.
- **Potential for Over-Application:** Due to its high effectiveness, there is a risk of over-application, which can attract dirt and debris, potentially causing more harm than good.

Dial indicator

A dial indicator, also known as a dial gauge or dial test indicator, is a precision instrument used to measure small linear distances, displacements, or variations in height. It is commonly used in manufacturing, machining, and mechanical applications to ensure the accuracy and alignment of parts and assemblies.



Figure 5-10 Dial indicator

Components of a Dial Indicator

1. **Dial:** The circular face with a scale, usually marked in increments (e.g., thousandths of an inch or hundredths of a millimeter), which indicates the measurement.
2. **Pointer (Needle):** The needle moves over the dial scale to indicate the measurement.
3. **Plunger (Spindle):** The rod that moves in and out of the body of the indicator when pressed against the surface being measured.
4. **Bezel:** The outer ring of the dial that can be rotated to zero the scale at any position for comparative measurements.
5. **Mounting Stem:** The cylindrical part used to mount the dial indicator onto a stand or fixture.

How to Use a Dial Indicator

A. Mount the Dial Indicator:

Attach the dial indicator to a stable base or stand. Magnetic bases are commonly used for ease of positioning. Ensure the indicator is securely mounted to prevent movement during measurement.

B. Position the Indicator:

Position the plunger so it contacts the surface or part to be measured. The plunger should be perpendicular to the surface to ensure accurate readings.

C. Zero the Indicator:

Rotate the bezel to set the pointer to zero. This establishes a reference point for comparative measurements. Some indicators have a locking mechanism to secure the bezel in place after zeroing.

D. Take the Measurement:

Move the part or surface being measured relative to the plunger, or move the plunger itself if the part is stationary. Observe the movement of the pointer on the dial. The scale will indicate the amount of displacement or variation. For multiple measurements, ensure the pointer returns to zero after each measurement to confirm consistency.

E. Record the Measurement:

Note the reading indicated by the pointer on the dial. If measuring multiple points, repeat the process and record each measurement.

5.1.7 Leakage Between Piston and Cylinder

Change the O-ring between piston and cylinder according to the dimension of the groove of it.

5.1.8 Priming Problem

By changing the head and make in it a hole to get rid off the air from it.



Figure 5-11 Pump Priming

5.1.9 Fixation Problem

We solve it by using Stainless Steel which is stronger.

5.1.10 Coupling Problem

The old coupling was small and narrow, and this can cause encoder failure.



Figure 5-12 Old Coupling

We solved this problem by using Flexible Coupling that get rid off the misalignment and reduces the vibration.



Figure 5-13 New Coupling

5.1.11 Limit Switches Connections

It was connected wrong, we fix it.



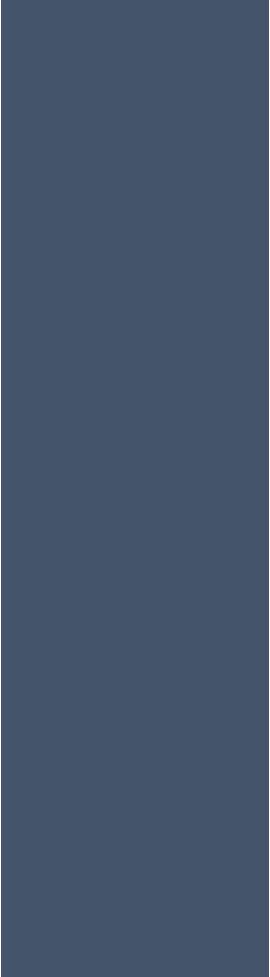
Figure 5-14 Limit Switch wrong connection

5.1.12 Limit Switches Position

We made L shape with slots to make its position changeable.



Figure 5-15 Limit Switches Fixation



6 ViVitro Super Pump

6.1 Introduction

ViVitro Labs Inc. offers industry leading cardiovascular test equipment and related laboratory testing services. Hundreds of organizations in over 42 countries for 30+ years have trusted ViVitro's expertise, accuracy, and quality for their cardiovascular device testing. As the developer of the world's first Pulse Duplicator, the ViVitro name has been synonymous with cardiovascular device testing equipment. ViVitro hardware and software products have been used by leading R&D facilities and academic labs worldwide, and its equipment and testing methods being cited in hundreds of peer reviewed publications <http://ViVitrolabs.com/company/cited-publications/>. The ViVitro Labs' Pulse Duplicator System (in particular the ViVitro Labs SuperPump) has become a worldwide standard to simulate physiological heart conditions in academic research applications.

ViVitro products are manufactured by StarFish Medical in an ISO 13485:2003 certified manufacturing facility. ViVitro Labs Inc. also holds ISO/IEC 17025 accreditation for laboratory testing services endorsed by A2LA and based on ISO 5840. This scope of accreditation includes the physical and mechanical testing of heart valve substitutes including durability and hydrodynamic testing.

ViVitro Labs is widely recognized as the authority on cardiovascular device testing. ViVitro Laboratory Services are engaged worldwide for hydrodynamic and durability testing of heart valves and other cardiovascular devices. ViVitro has been the trusted name in regulatory approvals for over 30 years and is renowned for its proven success from product development testing through to full regulatory submission.

ViVitro Labs is a member of the ISO 5840 standards committee and is actively engaged in developing regulatory requirements. Leveraging this intimate knowledge of the standard, ViVitro Labs ensures that test protocols will meet ever changing regulatory requirements. ViVitro's Laboratory Testing Services offers an ISO/IEC 17025 certified lab using ViVitro equipment, to conduct 3rd party independent testing. ViVitro's accredited testing lab is governed by a mature Quality Management System (QMS) certified to meet the ISO 5840. This gives assurance to stakeholders and regulatory bodies that results are obtained by qualified personnel using traceable calibrated equipment and up to-date test methods, all supervised by a quality assurance department.

6.2 About the Endovascular Simulator System

The ViVitro Endovascular Simulator creates physiological pulsatile flow and pressures for testing many types of cardiovascular devices and can be used for any portion of the cardiovascular system. Our vascular flow platform brings physiological pulsatility to anatomical models for research and development. The simulator can easily be reconfigured for bench top, cath lab or portable cart installation. The Endovascular Simulator addresses requirements of ISO 5840, ISO 25539, and ISO 7198 standards as they include simulated use guidelines.

The EV Simulator can be used to control a live cardiac flow in a standalone configuration. Using the ViVitro SuperPump, the Endovascular Simulator's programmable waveform system delivers physiological pulsatile flow. The system facilitates testing of a variety of endovascular medical devices and delivery systems by adding anatomical models, including abnormalities or custom patient-specific models.

The diagram below provides an illustration of the fundamental set-up:

1. SuperPump
2. Viscoelastic Impedance Adaptor (VIA)
3. Pump Head
4. Compliance Assembly
5. Peripheral Resistance Controller
6. Mounting Tray Assembly (model not included)
7. Catheter Access Port
8. Digital Camera (Fluoroscopy simulation or device monitoring)
9. SuperPump Controller
10. Computer (with ViVitest Software)
11. Flow Meter
12. I/O Module
13. Ampack Pressure Measuring System
14. Heat Exchanger (not shown)



Figure 6-1 Endovascular Simulator set-up.

6.2.1 Components

6.2.1.1 Super Pump



Figure 6-2 Super Pump

6.2.1.2 Pump Head



Figure 6-3 Pump Head

6.2.1.3 EV Simulator Tray

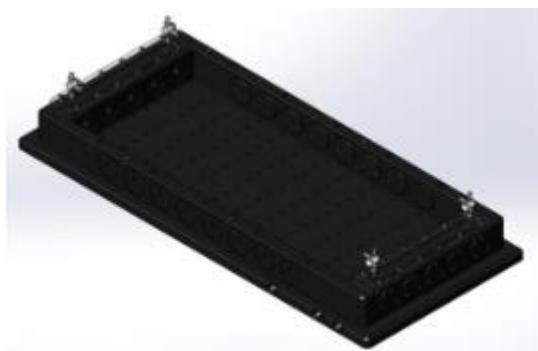


Figure 6-4 EV Simulator Tray

6.2.1.4 Compliance Assembly

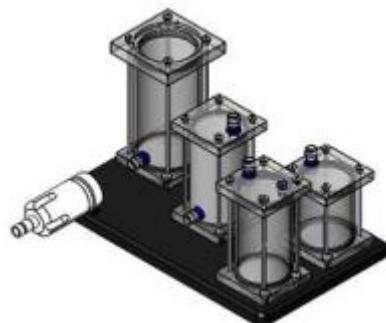


Figure 6-5 Compliance Assembly

6.2.1.5 EV Simulator Accessories

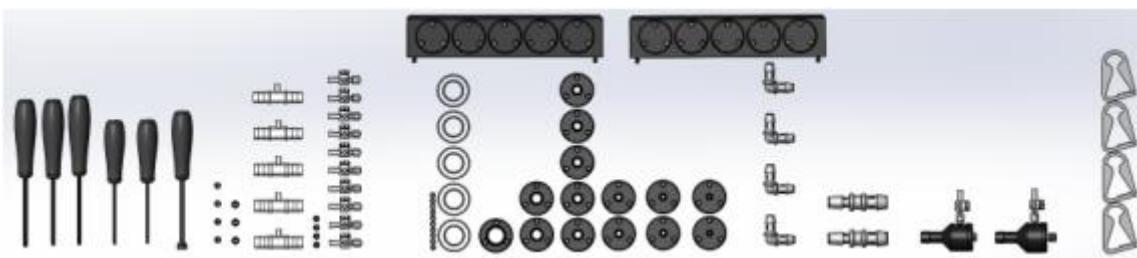


Figure 6-6 EV Simulator Accessories

6.2.1.6 Data Acquisition System



Figure 6-7 Data Acquisition System

6.2.1.7 Flow Measuring System



Figure 6-8 Flow Measuring System

6.2.2 Optional System Components

- ⇒ Viscoelastic Impedance Adapter
- ⇒ Heat Exchanger
- ⇒ Heat Bath including pump and controller box
- ⇒ Digital Manometer
- ⇒ Digital Thermometer
- ⇒ EV Simulator Camera Assembly
- ⇒ Monitor for camera assembly
- ⇒ EV Simulator Spare Parts Kit
- ⇒ ExVivo System Accessory
- ⇒ Inflator Syringe

6.2.3 System Assembly

The following steps detail the procedure for assembling the main components outlined above.

6.2.3.1 SuperPump (Pump Head & VIA)

The SuperPump arrives pre-assembled and ready for use. Place the SuperPump on a fixed surface, i.e. a table or frame suitable to accommodate the weight and dimensions of the entire system. See the SuperPump User Manual for more details on the SuperPump.

WARNING: It is recommended that the SuperPump be positioned with its longest dimension horizontal. Should the pump be vertically mounted with the pump head above the motor, the possibility of liquid contamination of the mechanical and electrical parts is likely to occur.

Install the VIA onto the head of the SuperPump. Then, install the Pump Head (with or without the VIA), as per the Pump Head.



Figure 6-9 SuperPump with Pump Head

Fill the Pump Head with distilled water, as per the Pump Head User Manual. Ensure that the ventricle in the Pump Head is filled to a neutral position when filled. It is recommended to add a biocide to this working fluid to discourage biological growth.

WARNING: Do not use saline as the working fluid. Salt crystals around the piston head can cause damage to the piston seal.

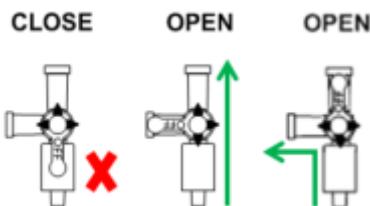


Figure 6-10 Relevant stopcock positions

6.2.3.2 EV Simulator Tray

The EV Simulator Tray comes assembled in a default configuration, with the manifolds attached. The Endovascular Simulator Tray adapts to interface with a variety of desired vascular models.

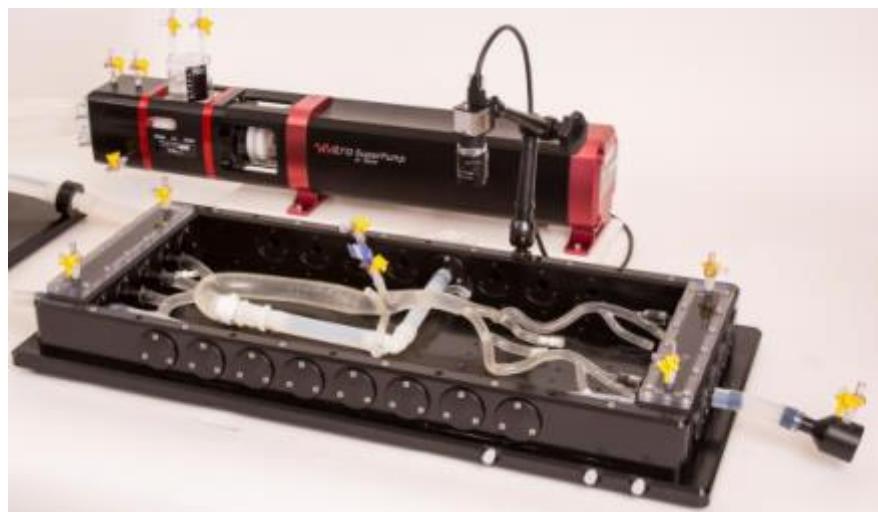


Figure 6-11 Endovascular Simulator Tray assembly (with optional vasculature and camera system shown)

The tray can be assembled as follows:

1. First determine whether the manifold end blocks will be used on the system or if the through-port end blocks will be used. If the model to be used has numerous venous outputs which are desired to manage flow (not be occluded), the manifold is recommended to simplify the flow loop setup. The through-port ends may be used when a single venous outlet is available on an end of the model or if flow outlets or inlets wish to be managed separately.



Figure 6-12 Manifold end block (left) and Through-Port end block (right)

2. If the manifolds are being used, ensure stopcocks are installed on the debubbled ports.

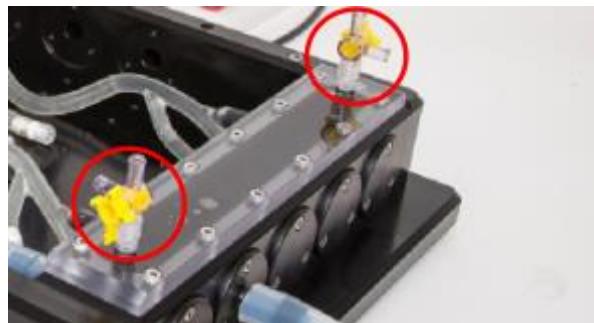


Figure 6-13 Stopcocks installed on Manifold debubbled ports.

3. Once the end blocks for each end have been chosen, set the distance between the two ends based on the length of the desired model. Note that the drain pockets on one end of the tray should be open to the inside of the tray to facilitate drainage. Fasten in place with M5 fasteners using the 4mm hex key.

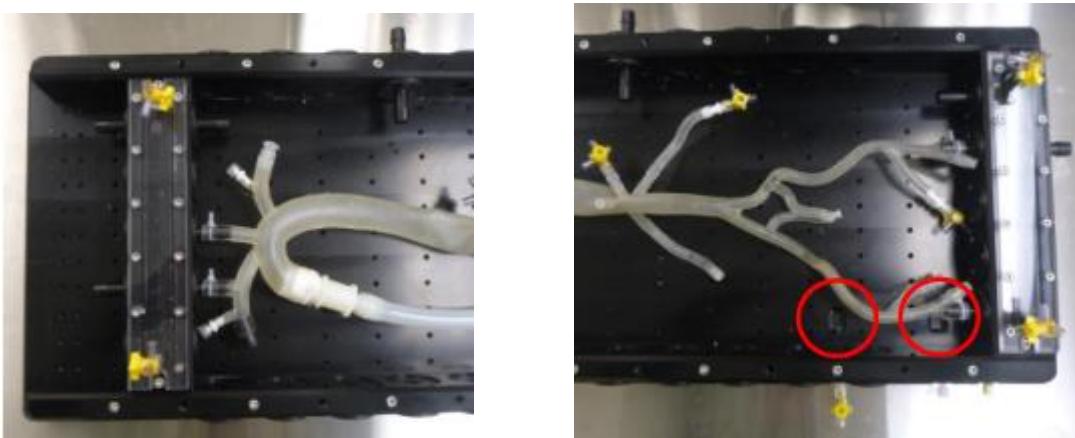


Figure 6-14 Manifold ends set to accommodate vasculature length (with drain pockets circled in red).

4. Install suitable barbs for the model connections by removing the port plugs and installing the desired barbed fitting. Fasten in place using M4 fasteners and a 3mm hex key.



Figure 6-15 Barbed fittings installed to suit model inlet/outlet sizes.

5. Typically, the inlet of the model will be plumbed to a barbed fitting on the side of the EV Simulator as shown in the image below.

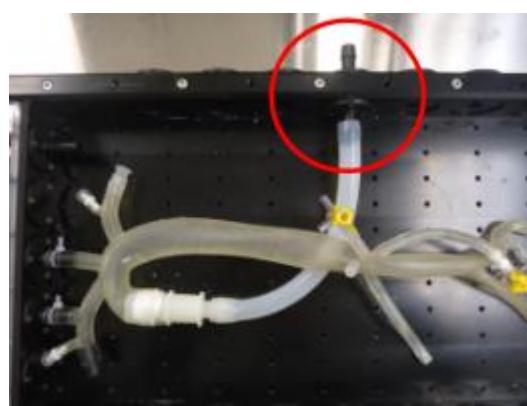


Figure 6-16 Inlet of model plumbed to a barbed fitting on side of tray.

6. If percutaneous or catheter access is desired, the Catheter Access Ports (shown below) should be connected to the system with $\frac{1}{2}$ " tubing in line with the desired vessel.

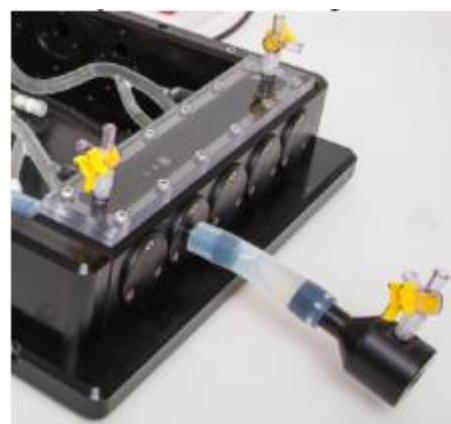


Figure 6-17 Catheter Access Port installed on Manifold end.

-
7. Position tray drain fittings over a bucket or connect drain tubing if desired.



Figure 6-18 tray drain fittings

6.2.3.3 Compliance Assembly

The EV Simulator Compliance Assembly houses the fluid reservoir, supplementary compliance chambers, and peripheral resistance elements of the system. Depending on the vasculature model used and the desired test conditions, setup requirements will vary.

1. Secure the Peripheral Resistance Controller to the compliance platform with the #10-32x1.25" SHCS fasteners provided (SDH026.1). Ensure the black spacer is in place between the controller and the platform.

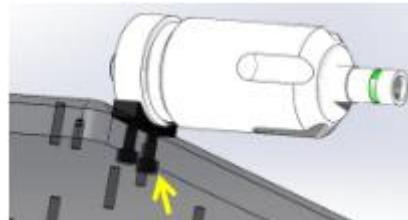


Figure 6-19 Secure the peripheral resistance controller to the platform.

2. Secure the large fluid reservoir to the platform using two red thumbscrews provided. Ensure the barbed fittings are oriented in line with the Peripheral Resistance Controller as shown. Use a short segment of $\frac{1}{2}$ " ID silicone tube to connect the outlet barb of the peripheral resistance controller with the inlet barb of the reservoir.

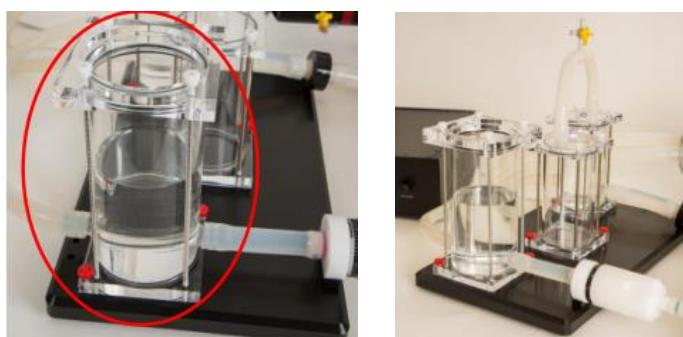


Figure 6-20 Reservoir and Peripheral Resistance Controller connected.

3. Secure remaining compliance tanks in place with the red thumbscrews provided as shown below. Note that the locations of the tanks may be varied to suit the setup configuration.

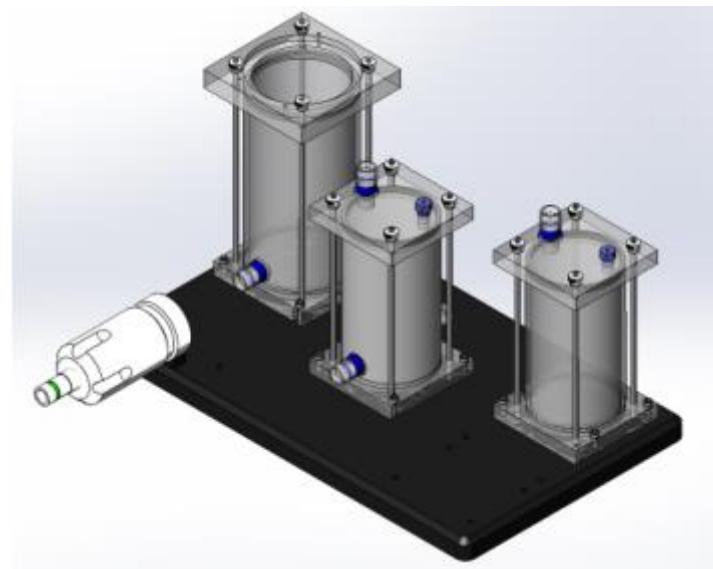


Figure 6-21 Compliance tanks installed (depending on configuration).

4. Connect the fluid throughput compliance chamber to the desired air compliance chambers with tubing and barbed luer fittings provided as shown below. Note that a barbed luer connector and stopcock are fitted in the tubing to allow adjustment of the air volume/pressure.

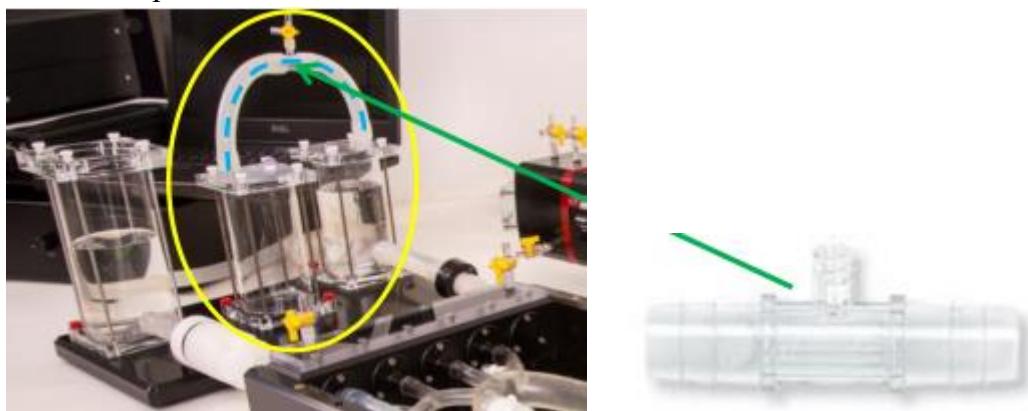


Figure 6-22 Fluid throughput chamber bridged with an additional air compliance chamber. Barbed luer connector used shown on right.

5. Connect the inlet of the fluid throughput compliance chamber to the outlet (Aortic) barb of the pump head using $\frac{1}{2}$ " silicone tubing. A clamp may be added to this tube to expedite the draining and debubbling process.

NOTE: It is ideal to keep tubing as short as possible to reduce the impact tubing has on system resistance and compliance.

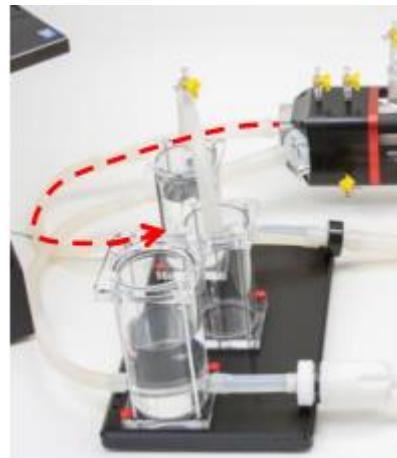


Figure 6-23 Connect fluid throughput compliance chamber with Pump Head.

6. Connect the outlet barb of the Reservoir with the inlet (Mitral) barb of the Pump Head using $\frac{1}{2}$ " silicone tubing. It is recommended to include a tee fitting and clamp in this length of tubing for draining the system. See the image below for recommended drain configuration. A clamp may also be added to this tube to expedite the draining and debubbling process.

NOTE: It is ideal to keep tubing as short as possible to reduce the impact tubing has on system resistance and compliance.

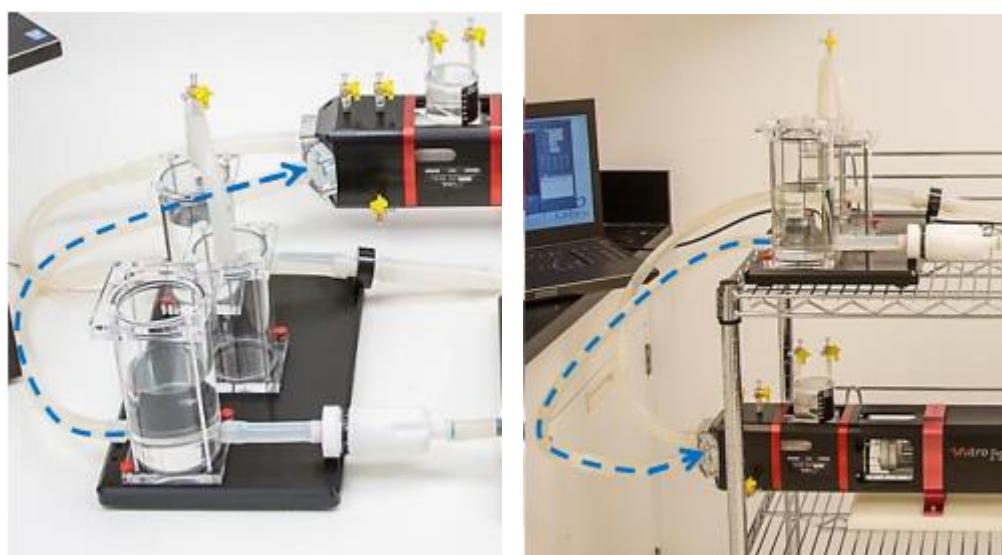


Figure 6-24 Connect reservoir to Pump Head on a flat (left) or cart working space (right).



Figure 6-25 Recommended drain configuration with clamp.

7. Connect the outlet of the Tray to the inlet of the Peripheral Resistance Controller.

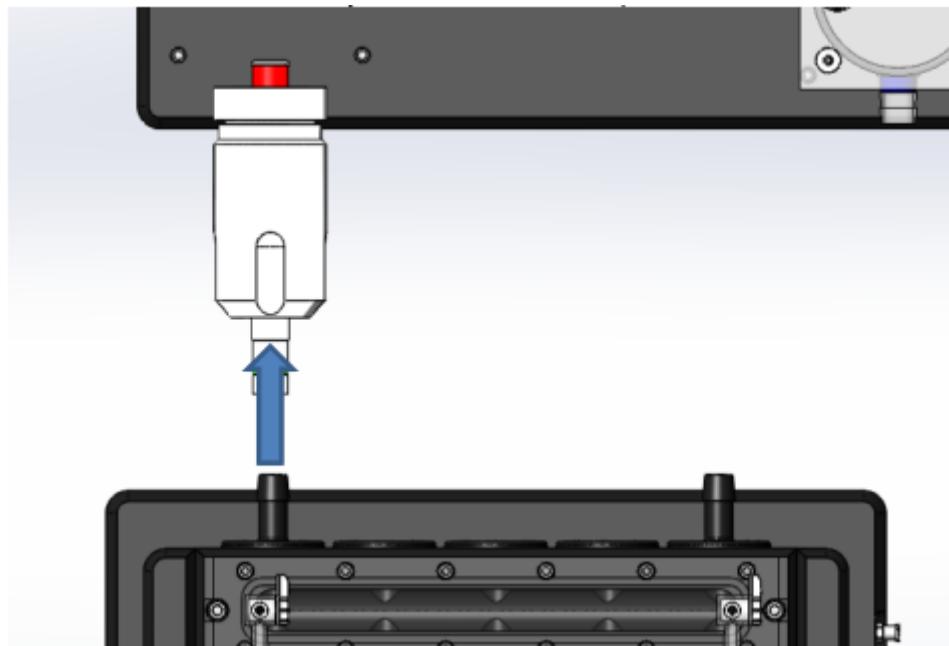


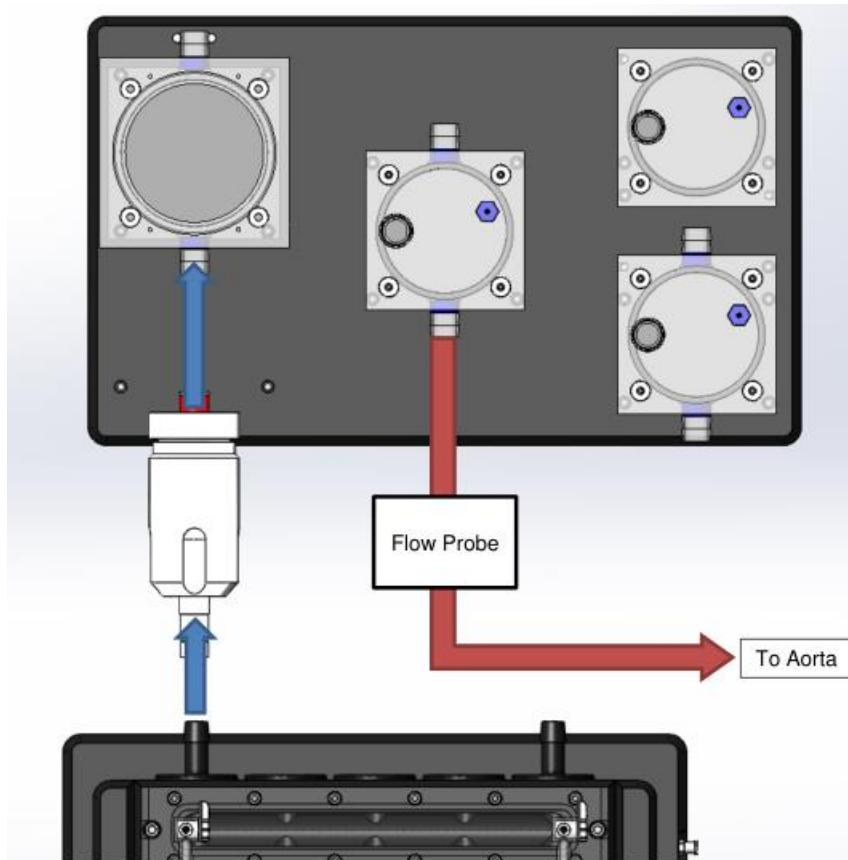
Figure 6-26 Tray return flow connected to the Peripheral Resistance Controller.

8. If two manifolds are being used, it is recommended to connect the two together with two barbed fittings and a length of tubing to combine the return flow.



Figure 6-27 Manifolds connected with a length of tubing to combine return flow.

9. Connect the outlet of the throughput compliance chamber to the inlet location of the vascular model. It is recommended to locate the flow probe in this location if the Data Acquisition System is being used.



10. With some vasculature models, it is desirable to use an additional compliance chamber which is connected to the outlet manifold of the tray to achieve more physiological conditions. The additional compliance chamber with two barbs near the base is recommended for this purpose.

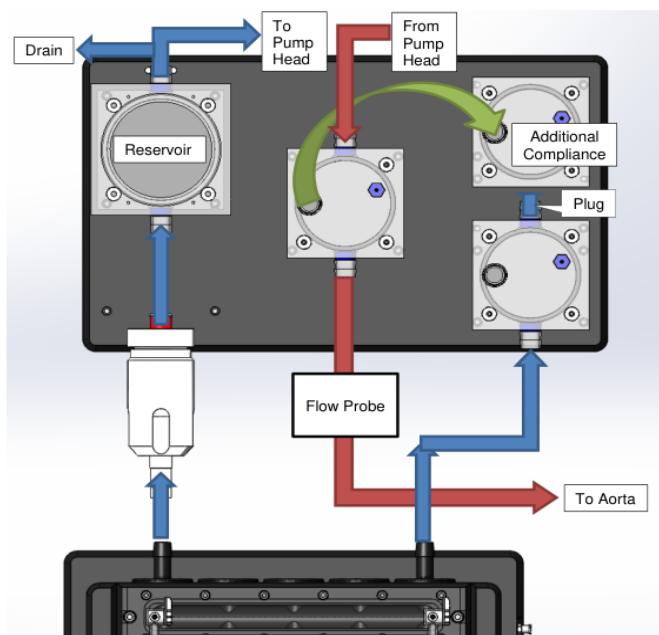
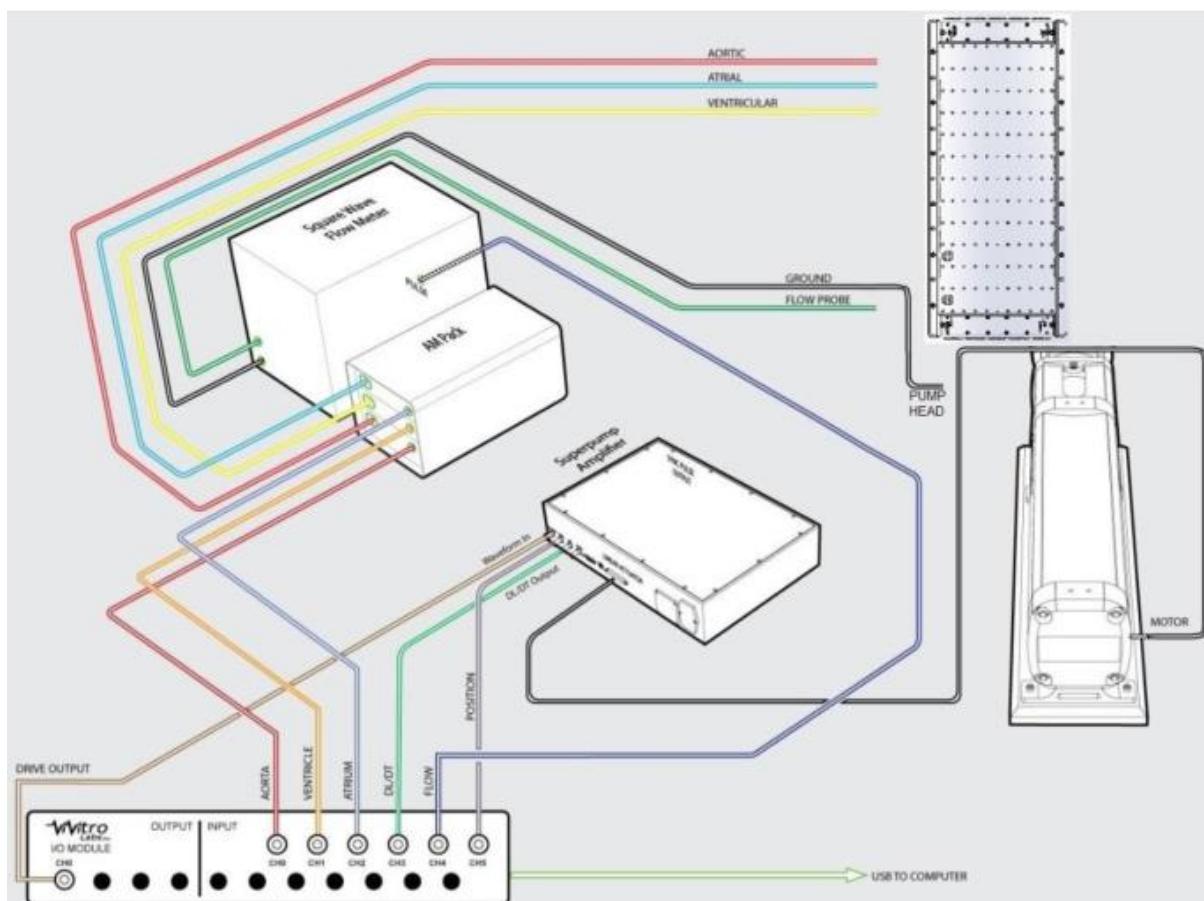


Figure 6-28 Optional compliance configuration. Note that the Manifold is used to combine the venous outputs into one common return path

6.3 Data Acquisition System

If the Data Acquisition System is being used with the EV Simulator, the following section describes the recommended setup.

6.3.1 Wiring Diagram

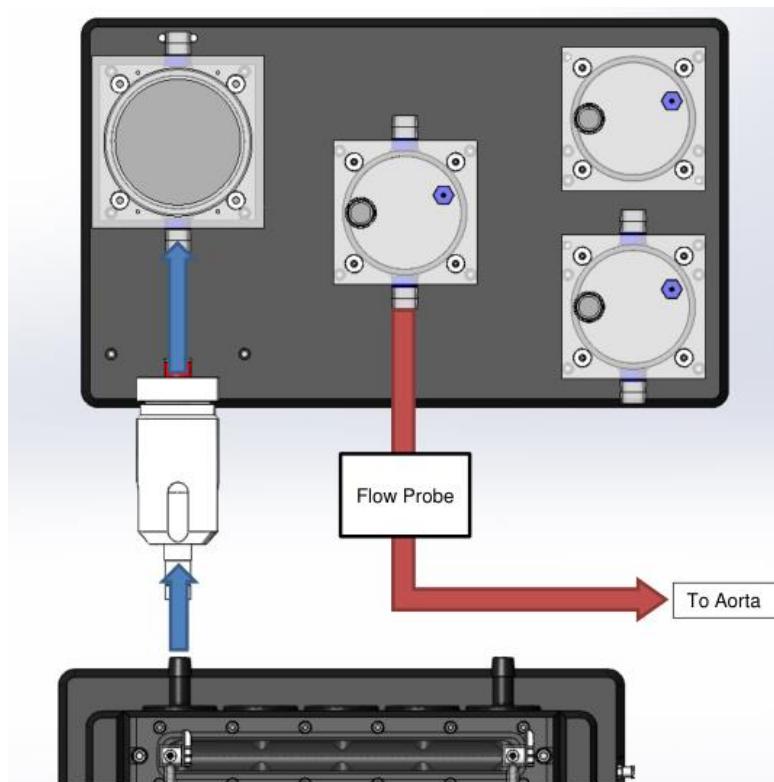


6.3.2 Flow Meter

As shown in the Compliance Assembly section above, it is recommended to place the flow probe directly before the aorta to measure the cardiac output of the system. Depending on the vascular model used and the system application, optimal flow probe locations may vary.

Note that for flow calibration, the flow probe will need to be plumbed between the pump head and the reservoir. See the calibration section for details (section 7).

In order to operate with minimal noise, the flow meter must be grounded to the test fluid. The recommended method for grounding the flow meter is to connect the ground cable clip to one of the stainless steel luer fittings of the Pump Head.



The Flow Meter must be properly grounded. It is recommended the flow meter is on its own, isolated power outlet. Connecting it to a shared power bar or outlet may result in noise in the flow signal.

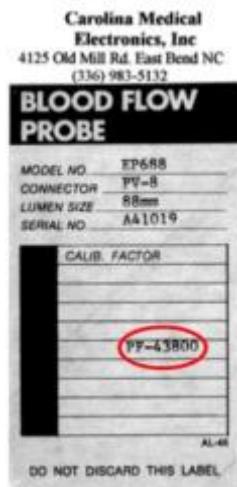


Figure 6-29 Probe factor shown on manufacturer's label.



Figure 6-30 Flow Meter with recommended settings.

6.3.3 Pressure Measuring System

The recommended locations of pressure transducers are:

- Atrial (top/blue transducer)
- Ventricular (middle transducer)
- Aortic (bottom transducer)

This is how the pressure traces will be labelled in ViVitest software.

Shown below is a suggested configuration. The desired locations of the pressure transducers may vary depending on the application of the system, and the vascular model used. Though the labels and calculations in ViVitest software are configured for the transducer locations suggested above, any transducer locations may be used to collect the desired data.

The atrial pressure transducer, if chosen to be used, can be tied into the return line from the reservoir to the Pump Head using a barbed luer connector (shown below).



Figure 6-31 Barbed luer connector.

The ventricular pressure transducer can be connected to the luer port on the side of the Pump Head shown below to read the ventricular pressure of the system.

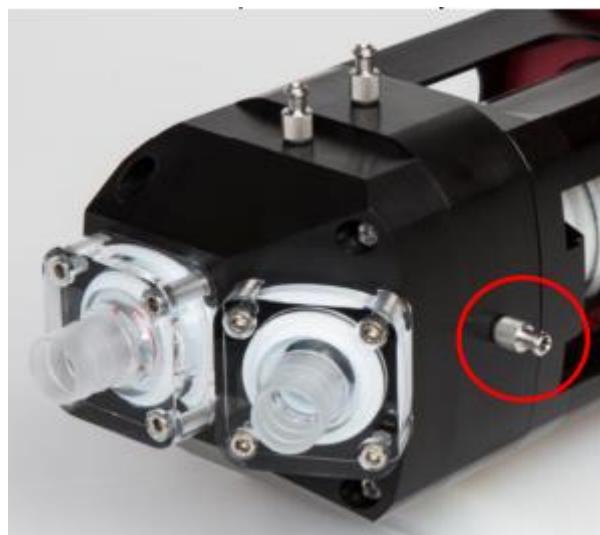


Figure 6-32 Ventricular pressure port.

The aortic pressure transducer may be connected to any luer port access point near the aorta of the vascular model. This is strongly recommended as it allows the user to tune the Mean Aortic Pressure of the system.

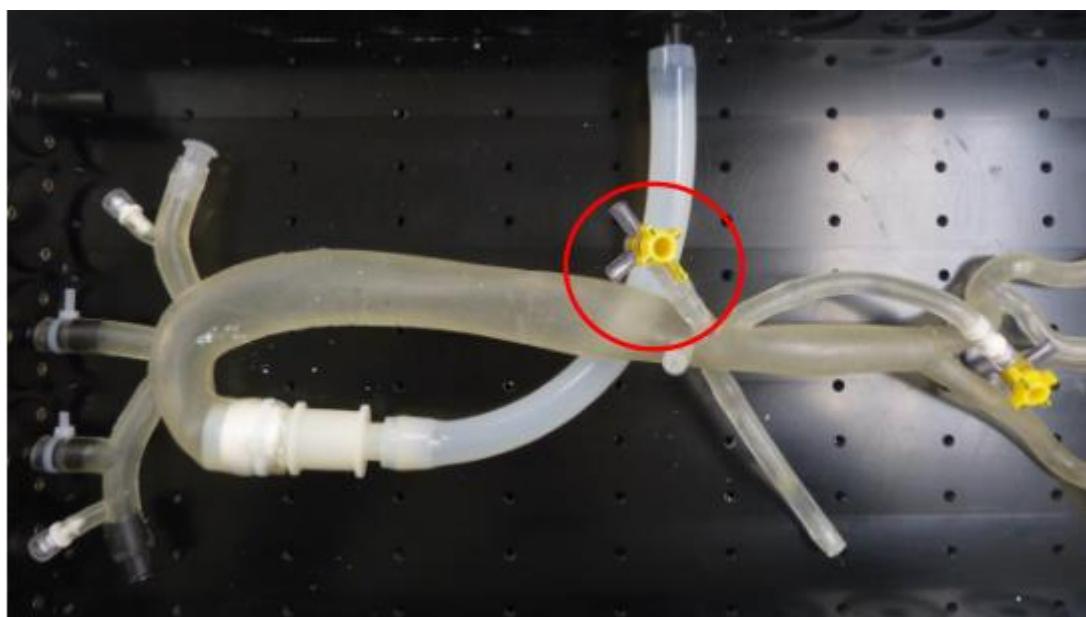


Figure 6-33 Potential Aortic pressure transducer location.

Note that the software displays the following differential pressures on the live graph.

- TRANSAORTIC = Ventricular Pressure – Aortic Pressure
- TRANSMITRAL = Atrial Pressure – Ventricular Pressure

6.3.4 Optional Components

6.3.4.1 Heat Bath

If the heat exchanger is being integrated into the system, it is recommended to locate it between the reservoir and the Pump Head. This prevents the SuperPump from pumping against additional pressure drop during the systolic phase.

Components:

- Heat Exchanger



- Heat Bath



- Connect a silicone tube from the ‘Test Fluid Outlet’ of the Heat Exchanger to the inlet of the Pump Head.
- Connect a silicone tube from the outlet of the reservoir to the ‘Test Fluid Inlet’ on the Heat Exchanger.
- Connect a silicone tube from the right inlet on the Heat Exchanger to the outlet on the Heat Bath.
- Connect a silicone tube from the left outlet on the Heat Exchanger to the inlet on the Heat Bath.
- Fill the Heat Bath with fluid.

NOTE: It is advised to add a biocide to prevent growth of bioburden.

- See the Heat Bath user manual for details on setup and operation.

NOTE: Top up Heat Bath fluid regularly. Do not run the heat bath when the system is not in use.

If the fluid drops below the minimum level, the heat bath may be damaged.

6.3.4.2 Viscoelastic Impedance Adaptor

The Viscoelastic Impedance Adaptor (or VIA) may be used with the system to simulate Ventricular compliance.



6.4 Pump Head

The ViVitro Pump Head can be used with the ViVitro SuperPump to create a circulatory, pulsatile flow loop. The Pump Head accommodates ventricular pressure monitoring through a ventricular Luer port. It may be mounted directly to the SuperPump or can be used in conjunction with the ViVitro Viscoelastic Impedance Adaptor (VIA7991) to attenuate pressure traces.

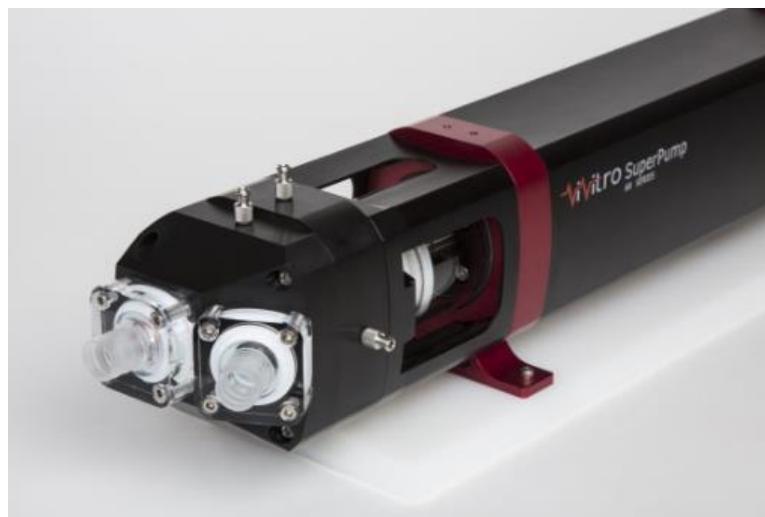


Figure 6-34 A SuperPump with a Pump Head

6.4.1 Features

The main features of the Pump Head include:

- ⇒ Silicone ventricle membrane to isolate SuperPump piston from test fluid.
- ⇒ Low closing volume spring loaded disc valves
- ⇒ 19 mm (3/4") hose connectors
- ⇒ Easy to debubble
- ⇒ East to disassemble and clean

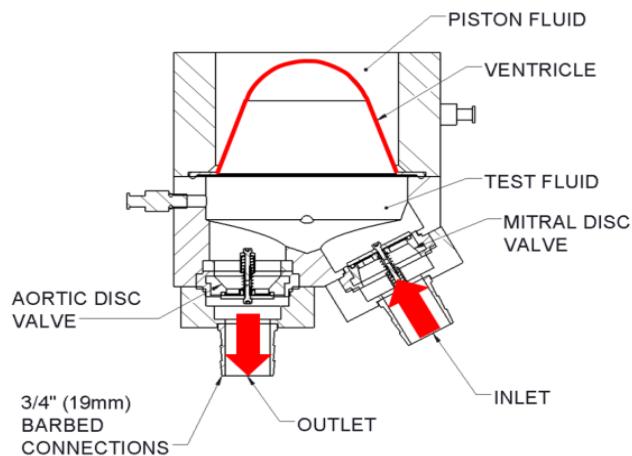
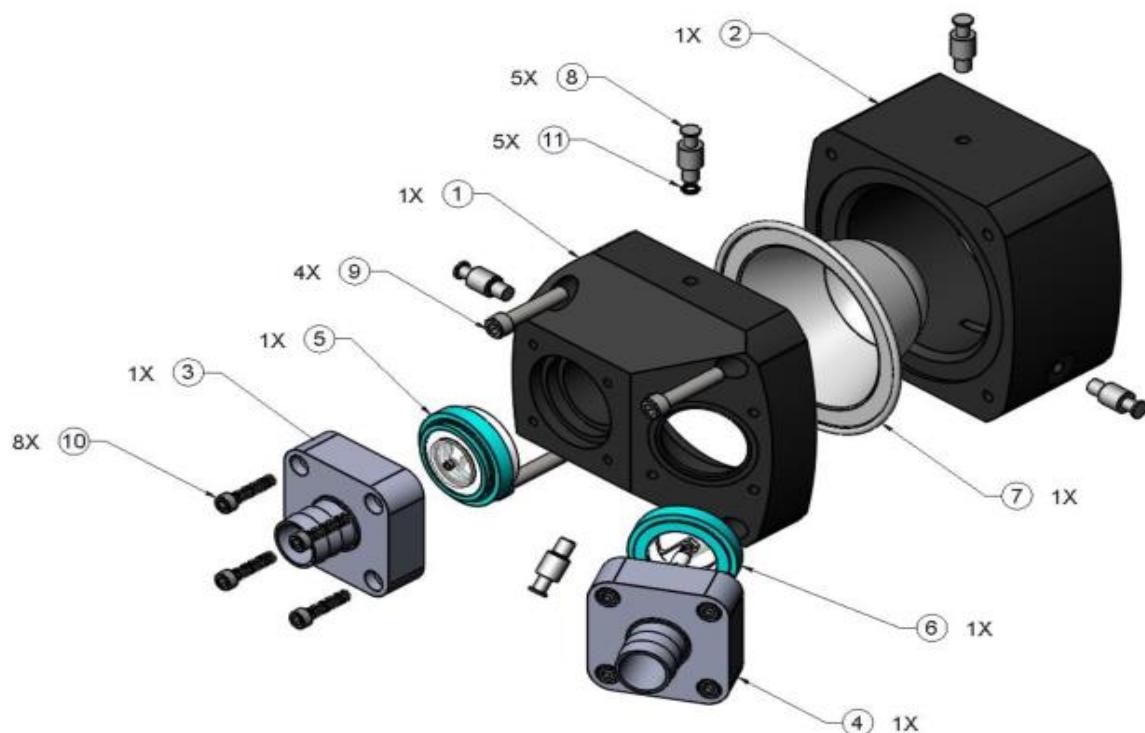
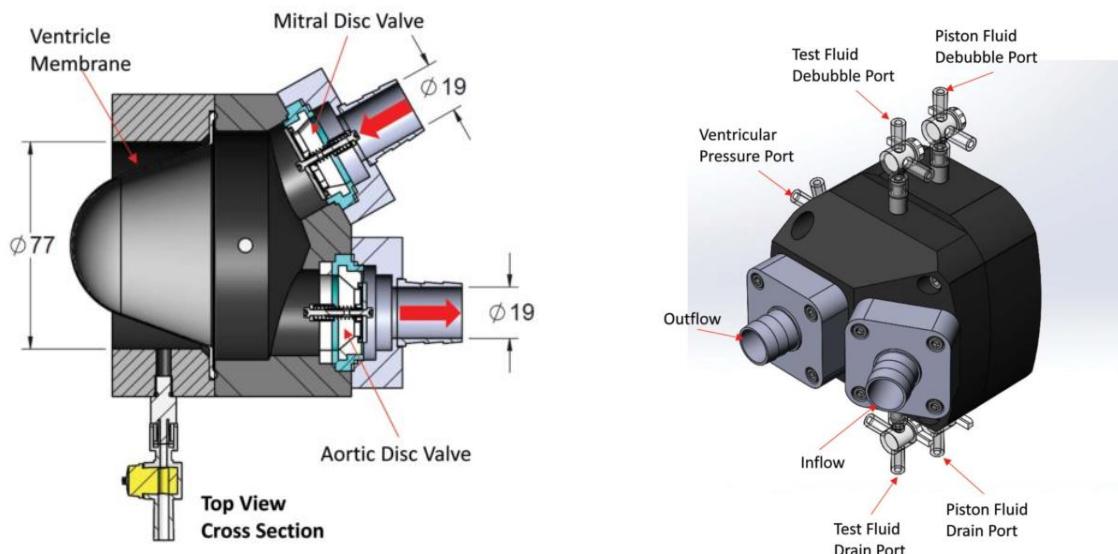


Figure 6-35 Pump Head cross section



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	12960	PH - Valve Mount	1
2	15096	PH - Ventriele Mount	1
3	21929	PH - AORTIC VALVE CLAMP ASSEMBLY	1
4	21930	PH - MITRAL VALVE CLAMP ASSEMBLY	1
5	SLDV00	AORTIC SPRING LOADED DISC VALVE	1
6	SLDV00,1	MITRAL SPRING LOADED DISK VALVE	1
7	SDE008	VENTRICLE MEMBRANE, SI, NO DRAIN	1
8	06842	Female Luer Fitting, 316 SS, 1/4"-28 Fitting	5
9	14834	1/4-20 X 1.25 SHCS SS	4
10	15207	#10-32 X 7/8" SHCS SS	8
11	HCM053	O-RING V-007-75	5



6.5 Endovascular Simulator

Can be used to approach any cardiovascular system simulations.

The EV Simulator provides functional design testing for:

- Stents
- Stent Grafts
- Coils
- Filters



Lower Leg Arterial Model

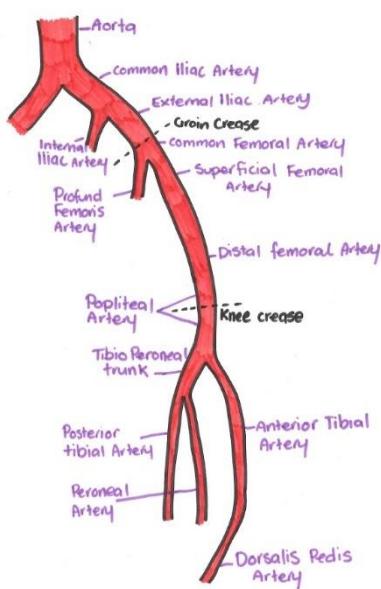
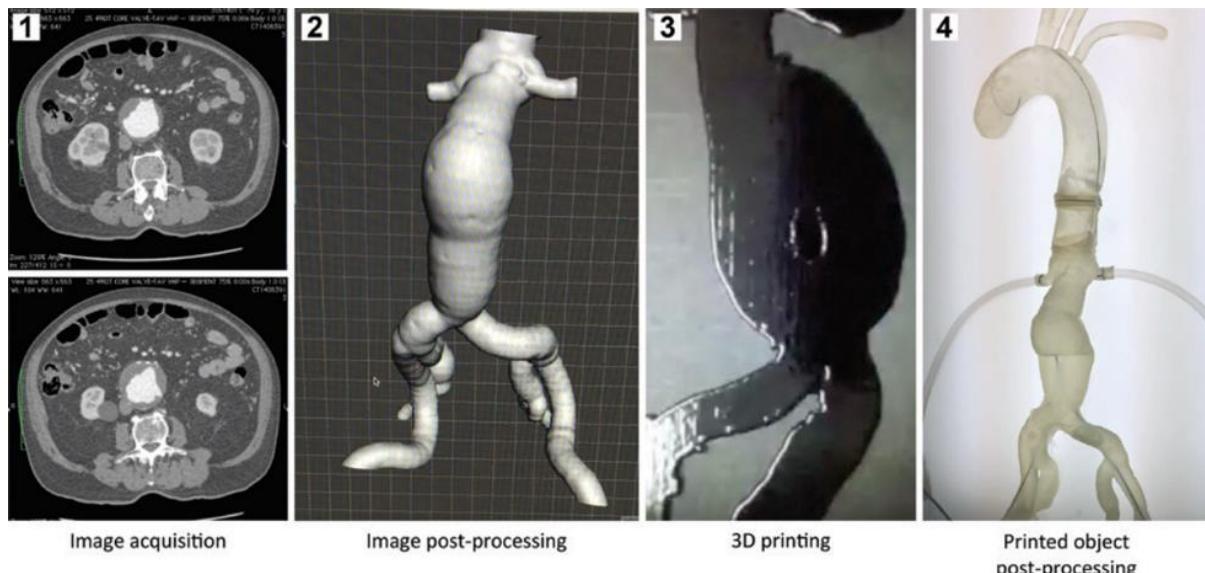


Figure 6-36 Leg Arterial

6.5.1 Endovascular Simulation

6.5.1.1 Steps



A. Image acquisition

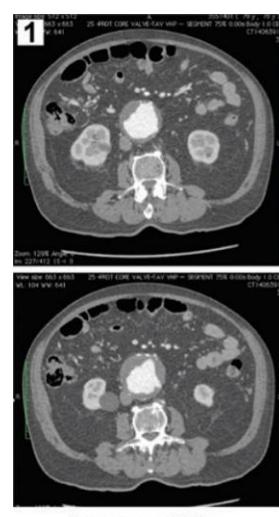
It is taken by:

- Computed angio-tomography scan (angioCT).
- Magnetic resonance imaging (MRI).

The image should be:

- a) Free of image artefacts,
- b) Have isotropic voxel resolution,
- c) High image contrast between the anatomy of interest and neighbouring tissues,
- d) Low noise.

Acquired data are saved in Digital Image and Communication in Medicine (DICOM) format.



B. Image post-processing

choose the software that we will use it to simulate the arteries.

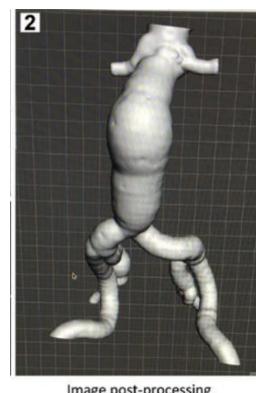


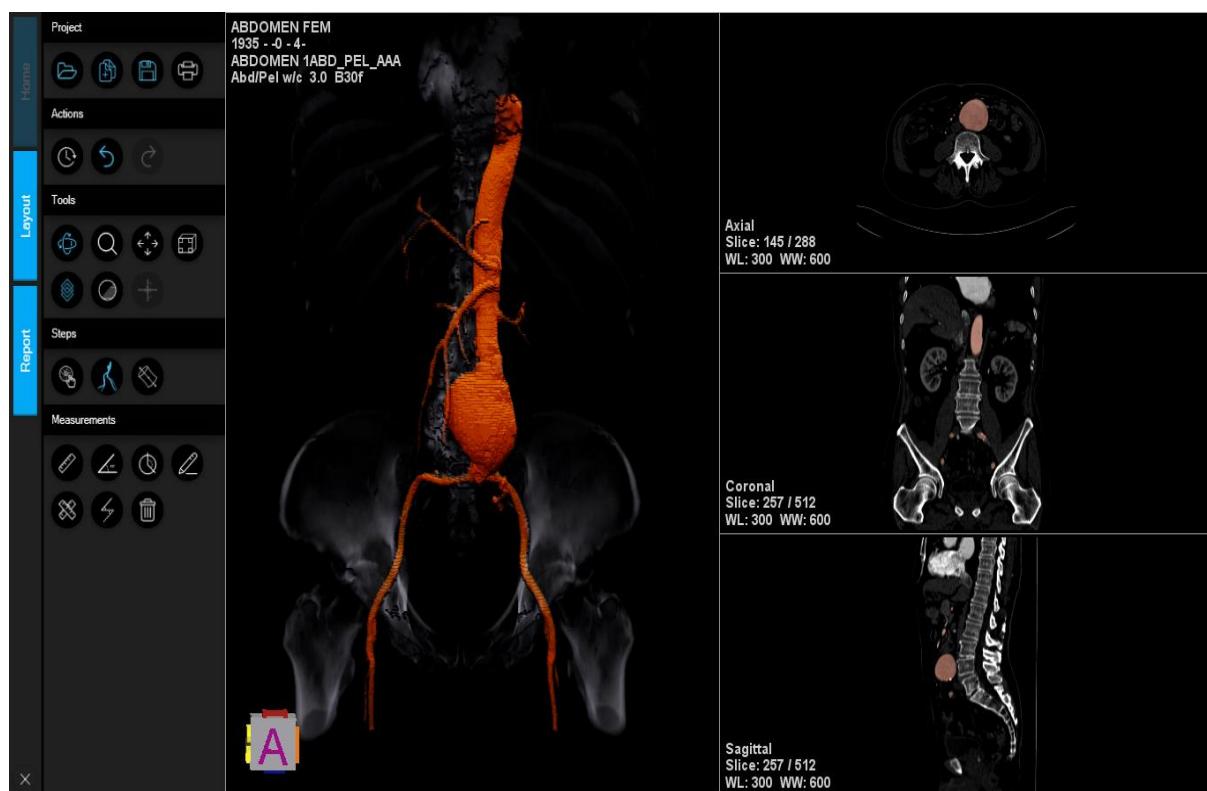
Table 1: Software programs available for image post-processing.

Software programs for DICOM file processing	References
Mimics® (Materialise NV, Leuven, Belgium)	Biglino et al. [20], Wilasrusmee et al. [21], Håkansson et al. [22], Yuan et al. [23], Mafeld et al. [18], Dong et al. [24], Koleilat et al. [25], Taher et al. [26]
OsiriX (Pixmeo SARL, Bernex, Switzerland)	Marro et al. [12], Tam et al. [27], Takao et al. [28]
Vitreo 3D Station (Vital Images, Inc., Minnetonka, MN, USA)	O'Hara et al. [29], Russ et al. [30]
iNtuition software (TeraRecon Inc., Foster City, CA, USA)	Koleilat et al. [25]
Vascular Modeling Toolkit (VMTK, Orobix, Bergamo, Italy)	Meess et al. [31]
Software programs for STL file processing	
3-matic® (Materialise NV, Leuven, Belgium)	Biglino et al. [20], Mafeld et al. [18], Koleilat et al. [25]
MeshLab (Visual Computing Lab – ISTI-CNR, Rome, Italy)	Marro et al. [12]
Blender (Blender Foundation, Amsterdam, the Netherlands)	Itagaki [13]
Google SketchUp (Trimble Inc., CA, USA)	Govsa et al. [32]
Magics (Materialise NV, Leuven, Belgium)	Yuan et al. [23]
Meshmixer software (Autodesk, San Rafael, CA, USA)	O'Hara et al. [29], Takao et al. [28], Russ et al. [30], Meess et al. [31]

C. Image post-processing steps

The first step was to generate a reconstruction of the region of interest based on the contrast inside the arterial lumen.

- The vascular reconstruction was extracted from the surrounding tissue (manually or using specific tools, such as extracting the central line in TeraRecon) and exported as a stereolithography (STL) file.
- We choose Mesh Mixer.
- These programs allow the user to smooth the surface of the vascular structure and to correct errors in the mesh.
- Wall thickness.



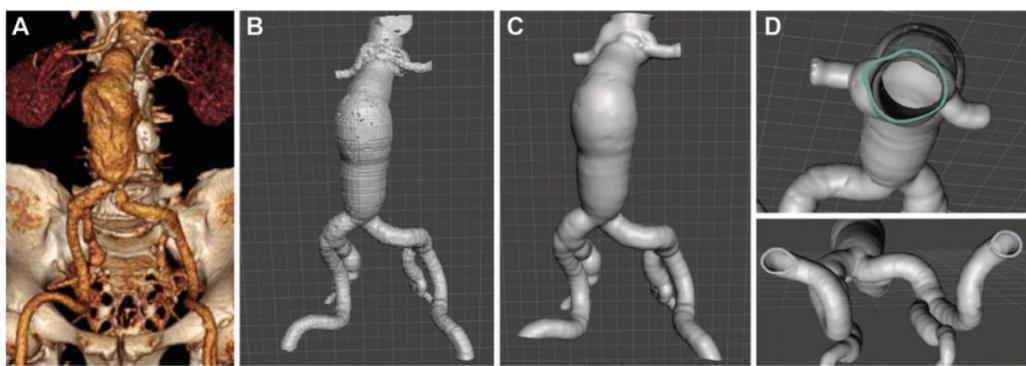


Figure 2: Image post-processing.

(A) Reconstruction of the aorta based on the contrast inside the arterial lumen – DICOM file. (B) Aorta after conversion of DICOM to STL file. (C) Surface of the aorta smoothed. (D) Wall of the aorta digitally thickened to 1.5 mm.

D. 3D Printing

Some of the following characteristics should be considered: cost , accuracy, speed and materials available.

printer and the resins is high (one 3D printer costs around US\$270,000.00, and the cost to 3D print an aneurysm is US\$1670.00). Desktop machines, in general, have smaller printing platforms, smaller accuracy and limited materials available. Therefore, they cost less (Form1+, US\$3000.00; MakerBot, US\$2118.00; Nobel, US\$2214.00) which makes their use outside study protocols feasible [19]. The com-

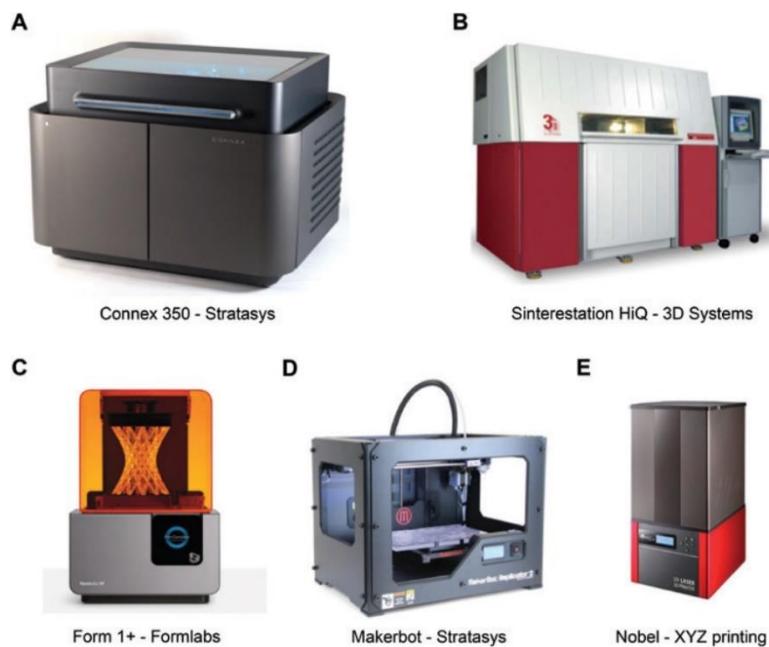
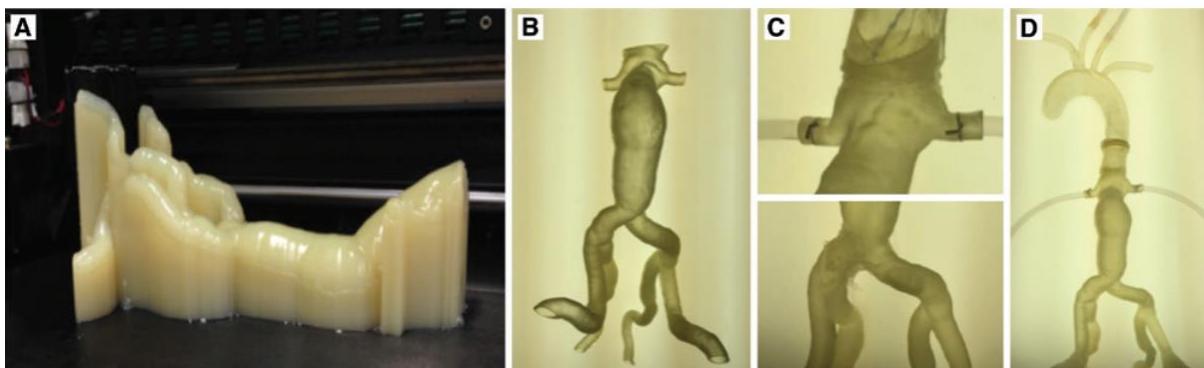


Table 2: 3D printers tested for the production of endovascular training models.

3D printer	Connex 350	Form 1+	Nobel	MakerBot	Sinterstation HiQ
Technology	Polyjet	Stereolithography	Stereolithography	Fused deposition modelling	Selective laser sintering
Printing platform (mm)	Industrial machine 340×340×200	Desktop machine 125×125×165	Desktop machine 128×128×200	Desktop machine 295×195×165	Industrial machine 381×330×457
Layer resolution (μm)	16	25–100	25	100	70
Advantages	High-resolution, large printing platform, possibility of material combination	Low cost, high resolution		Low cost	Large printing platform, good printing speed
Disadvantages	High cost, materials with insufficient transparency and/or resistance	Small printing platform		No flexible or translucent material available	No flexible or translucent material available
Materials available	Transparent, biocompatible, rigid opaque, rubber like, polypropylene like	Photopolymer resins: transparent, white, resistant, flexible, castable dental SG	Photopolymer resins: standard, castable, flexible, rigid, tough	PLA filament, ABS filament, absorbable filament	DuraForm PA, DuraForm GF, DuraForm EX, DuraForm Flex, DuraForm AF, LaserForm A6 and CastForm materials
Webpage	http://www.stratasys.com/3d-printers/production-series/connex3-systems	https://formlabs.com/3d-printers/form-1-plus/	https://www.xyzprinting.com/en-US/product/nobel-1-0	https://www.makerbot.com/replicator/	http://ntk-mt.ru/pdf/ds_sinterstation_hiq_rev.pdf

E. Post Processing

**Figure 4:** Post-processing of the aneurysms in Material 1.

(A) 3D-printed aneurysm with the support material. (B) 3D-printed aneurysm after removing the support material. (C) Areas reinforced with silicone. (D) 3D-printed aneurysm connected to the simulator.

6.5.1.2 Material

Table 3: Materials available for producing transparent vascular models for endovascular training.

Material	Typical properties of the material			Major limitation during training session ^f
	Shore	Elongation at break (%)	Tensile strength (MPa)	
TangoPlus ^a	A 26–68	170–220	0.8–1.5	Transparency and resistance
Vero Clear ^b	D 83–86	10–25	50–65	Transparency and navigability
TangoPlus and Vero Clear ^c	A 57–63	75–85	2.5–4.0	Transparency
Flexible Resin Formlabs ^d	A 80–90	90	5.95–6.5	Resistance
Flexible Resin XYZ Printing	–	–	–	Transparency and Resistance
Silicone ^e	A 30	470	5	Navigability

References

1. Ali Ostadfar-Biofluid Mechanics. Principles and Applications-Academic Press (2016).
2. Development of a Fully Controllable Real-Time Pump to Reproduce Left Ventricle Physiological Flow
Emanuele Vignali^{1,2}, Emanuele Gasparotti^{1,2}, Benigno Marco Fanni^{1,2}, Lamia Ait-Ali³, Vincenzo Positano¹, Luigi Landini², and Simona Celi¹
3. Development of a Physical Windkessel Module to Re-Create In Vivo Vascular Flow Impedance for In Vitro Experiments ETHAN O. KUNG¹ and CHARLES A. TAYLOR^{1,2} 1Department of Bioengineering, Stanford University, James H. Clark Center, 318 Campus Drive, E350B, Stanford, CA 94305, USA; and 2Department of Surgery, Stanford University, Stanford, CA, USA.
4. https://www.globalspec.com/learnmore/flow_transfer_control/pumps/piston_plunger_pumps
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11. <https://www.realspars.com/blog/limit-switch>
12. <https://www.quantumdev.com/optical-encoder-applications/servo-motors/>
13. <https://www.ncbi.nlm.nih.gov/books/NBK541098/>
14. https://www.kincoautomation.com/products/servo/Servo_Motors/SMC60S-0040/
15. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1767992/>
16. <https://pubmed.ncbi.nlm.nih.gov/3877552/>
17. <https://vivitrolabs.com/product/superpump-pulsatile-blood-pump/>