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Collage of Engineering

Biomedical Engineering Department

Simulation of Rotation Left Ventricle Assistant Device

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B.Sc. (Honors) in Biomedical Engineering**

Prepared by:

- 1. Islam Abdallah El-tayeb Abdalgader**
- 2. Tsabeeh Satti Mohamed Mohamed Abaddi**
- 3. Romissa Husain Hassan Yaagob**

Supervised by:

Dr. Megdi Al-Noor El-tayeb

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الايه:

(فَفَهَّمْنَاهَا سُلَيْمَانَ وَكُلًّا آتَيْنَا حُكْمًا وَعِلْمًا وَسَخَّرْنَا
مَعَ دَاوُدَ الْجِبَالَ يُسَبِّحْنَ وَالطَّيْرَ وَكُنَّا فَاعِلِينَ)

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الاهداء:

اهدي هذا العمل المتواضع الي ابي الذي لم

يبخل علي يوما بشئ

وإلي أمي التي ذودتني بالحنان والمحبه

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أقول لهم : أنتم وهبتموني الحياة والأمل والنشأة

على شغف الاطلاع والمعرفة

.....

وإلي أخوتي وأسرتي جميعا

.....

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Abstract

Left ventricular remodeling is a process of progressive alteration of ventricular size, shape and function. A left ventricular assist device (LVAD) receives blood from the left ventricle and delivers it to the aorta. The HVAD is a small continuous-flow rotary pump which working as third generation which is simulation its work in this project. Computational modeling is the first step to simulation work of HVAD by using solid work program after this step must be tested the device to ensure if the device provide 5L/min so to reach this flow, the velocity is adjusted until achieved the flow in 50000RPM. Also the parameter (pressure and temperature) are tested to ensure the device is safe to human. The final step after testing the device is manufacturing it. There are three options to manufacture, but the option which we found is turn machine. The result in computational is acceptable but result after manufacturing is not acceptable (not provide 5L/min) due to the change occurring in the dimensions of devise.

المستخلص

إعادة تاهيل البطين الايسر هي عملية تقديم بديل لحجم ووظيفه البطين.الجهاز المساعد للبطين الايسر يستقبل الدم من البطين الايسر ويوصله الي الشريان الابهر.جهاز يطلق عليه هارت وير هو مضخة صغيرة دوارة بانسياب مستمر يعمل على نفس مبدأ الجيل الثالث وهو الذي تم محاكات عمله في هذا المشروع. اول خطوة لتصميم الجهاز هي الرسم في الكمبيوتر باستخدام برنامج الصولد ويرك بعد ذلك تم اختبار الجهاز للتأكد من انه يعطي 5 لتر/دقيقه ووجد ان السرعه المطلوبه هي50000 لفة/دقيقه.تم اختبار (الضغط والحراره) للتأكد من ان هذا الجهاز آمن للانسان. الخطوه الاخيريه بعد اختبار الجهاز هي التصنيع و لتصنيعه استخدمت ماكينة الخراطة وهي احد خيارات التصنيع الثلاث .ونجد ان التحليل بالكمبيوتر اعطيت نتائج مقبولة ولكن النتائج بعد التصنيع وجد فيها بعض الاختلاف (لم تعطي النتائج المطلوبه 5لتر/دقيقه) وذلك بسببالتغير في الابعاد.

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list of Abbreviations

Abbreviations	Declaration
VADs	ventricle assist devices
RVAD	Right ventricle assist device
LVAD	Left ventricle assist device
RV	Right ventricle
LV	Left ventricle
ASD	Atrial septal disease
VSD	Ventricle septal disease
COPD	Chronic obstructive pulmonary
HF	Heart failure
Bi_VAD	Bi_ ventricle assist device
BTT	Bridge To Transplantation
PVAD	Paracorpreal ventricle assist device
IVAD	Implantable ventricle assist device
LVAS	Left ventricle assist system
DT	Destination Therapy
FDA	Food And Drug Administration
AC	Alternating current
DC	Direct current
RPM	Revolution per minute
HVAD	HeartWare ventricle assist device
CAD	Computer Aided Design
CNC	Computer numerical control
CAM	computer aided manufacturing
3D	Three Dimension

Chapter 1

Introduction

1.1 General review

Mechanical assist devices can be used in patients who fail to respond to standard medical therapy but in whom there is either transient myocardial dysfunction with likelihood of recovery (e.g. post anterior myocardial infarction treated with coronary angioplasty) or a bridge is needed to cardiac surgery, including transplantation. Ventricular assist devices (VAD). Ventricular assist devices are mechanical devices that replace or help the failing ventricles in delivering blood around the body. A left ventricular assist device (LVAD) receives blood from the left ventricle and delivers it to the aorta; a right ventricular assist device (RVAD) receives blood from the right ventricle and delivers it to the pulmonary artery. The devices can be extracorporeal (suitable for short-term support) or intracorporeal (suitable for long-term support as a bridge to transplantation or as destination therapy in patients with end-stage heart failure not candidates for transplantation).[1]

1.2 Problem statement

Patients with severe heart failure who are waiting to receive a heart transplant, or are not qualified to receive a heart transplant require a device to assist the pumping function of their heart.

1.3 General objective

To design device for people in the end-stage heart failure to supply 5 L/min.

1.4 Specific objective

To design and manufacture of a rotation left ventricular assist device (centrifugal pump).

1.5 The structure of the thesis

This thesis is divided into several parts. chapter 1 presenting an overview of the problem and objective, chapter 2 give an overview of relevant background information, with chapter 3 presenting a detailed literature survey of the most relevant previous work. chapter 4 explain the approach that is being taken in designing and computational processes, chapter 5 focus in computational model and its associated results and the discussion of those results, chapter 6 presents the conclusion and area of future work. in the end of this thesis represent the source of the information.

Chapter 2

Theoretical background

2.1 Background

The heart is a powerful muscular organ about the size of a large closed fist, weighing between 8 to 12 ounces which functions as the body's circulatory pump body by means of a coordinated contraction. The heart is located in the thoracic cavity between the lungs. [2]

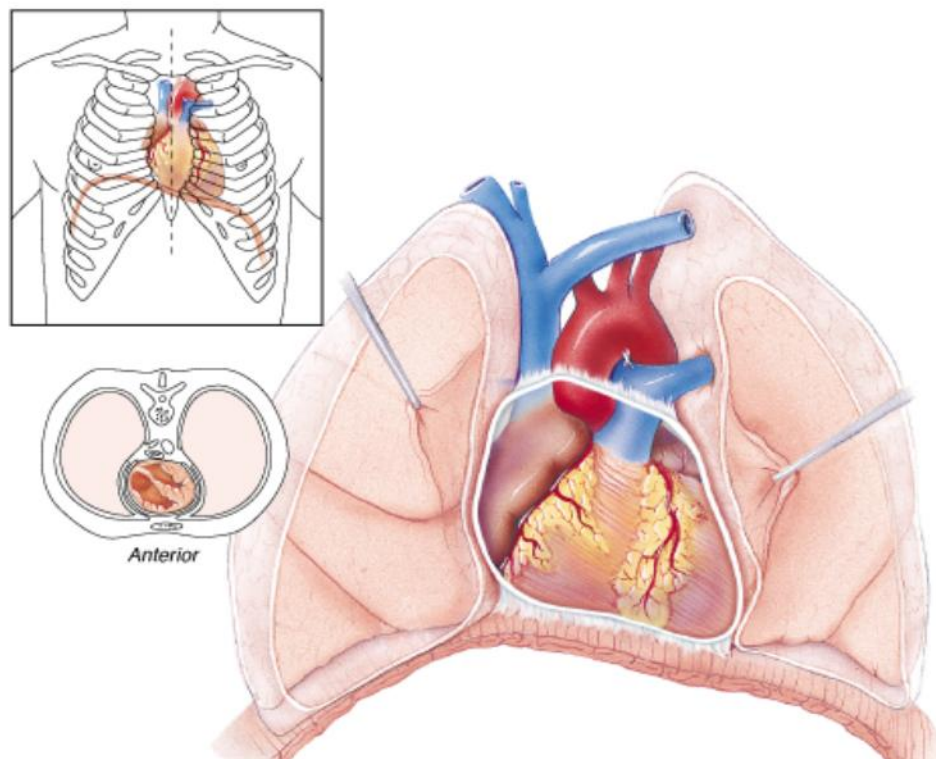


Figure2.1: the location of the heart[2]

The heart takes in deoxygenated blood through the veins and delivers it to the lungs for oxygenation before pumping it into the various arteries (which provide oxygen and nutrients to body tissues transporting the blood throughout the body). The coronary arteries are the vessels that branch off from the aorta and bring oxygenated blood to the heart. A wall called the septum divides the right and left sides of the heart. The right side pumps blood to the lungs, where the blood picks up oxygen. The

left side pumps blood to the rest of the body. The heart is made up of four hollow chambers, the upper two chambers are the right atrium and left atrium. These are called "collecting chambers" because they collect the blood as it returns to the heart. The lower two chambers are the right ventricle and left ventricle. These are called "pumping chambers" because they pump the blood out of the heart to where it needs to go. Blood flows from chamber to chamber through valves. The valves keep the blood flowing forward and prevent it from leaking backward. There are four heart valves, the tricuspid valve lets blood flow from the right atrium to the right ventricle. The pulmonary valve lets blood flow from the right ventricle to the pulmonary artery. The mitral valve lets blood flow from the left atrium to the left ventricle. The aortic valve lets blood flow from the left ventricle to the aorta.[2]

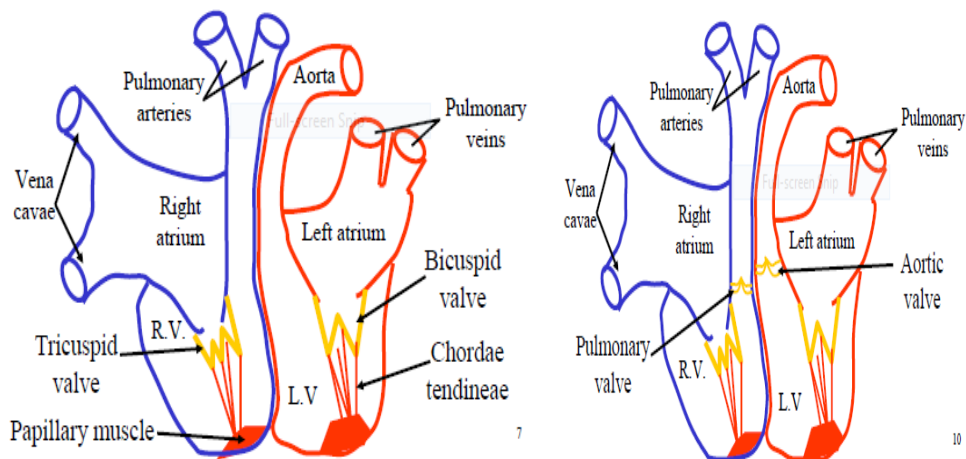


Figure2.2: the chamber and the valve of the heart[2]

2.2 Compare between the heart chambers

The heart contains four chambers, the right atrium, left atrium, right ventricle, and left ventricle. The atria are smaller than the ventricles and have thinner, less muscular walls than the ventricles. The atria act as receiving chambers for blood, so they are connected to the veins that carry blood to the heart. The ventricles are the larger,

stronger pumping chambers that send blood out of the heart. The ventricles are connected to the arteries that carry blood away from the heart. The chambers on the right side of the heart are smaller and have less myocardium in their heart wall when compared to the left side of the heart. This difference in size between the sides of the heart is related to their functions and the size of the two circulatory loops. The right side of the heart maintains pulmonary circulation to the nearby lungs while the left side of the heart pumps blood all the way to the extremities of the body in the systemic circulatory loop.[2]

2.3 Conducting System of the Heart

One heartbeat to the beginning of the next are called the cardiac cycle. The normal heart contracts rhythmically at about 70 to 90 beats per minute in the resting adult. The contraction is generated by an electrical activation, which is spread by a wave of bioelectricity that propagates in a coordinated manner throughout the heart. Under normal conditions, the sinoatrial node which this node is located in the superior lateral wall of the right atrium near the opening of the superior vena cava. It initiates an electrical impulse that propagates through the atria to the atrioventricular node through the A-V bundle. Because of this special arrangement of the conducting system from the atria into the ventricles, there is a delay of more than 0.1 second during passage of the cardiac impulse from the atria into the ventricles where a delay permits ventricular filling before the electrical impulse proceeds through the specialized His-Purkinje conduction system that spreads the electrical signal at speeds of meters per second throughout the ventricles. This allows the atria to contract ahead of ventricular contraction, thereby pumping blood into the ventricles before the strong ventricular contraction begins. Thus, the atria act as primer pumps

for the ventricles, and the ventricles in turn provide the major source of power for moving blood through the body's vascular system. This electrical impulse propagates diffusively through the heart and elevates the voltage at each cell, producing an action potential, during which a surge in intracellular calcium initiates the mechanical contraction.[2]

2.4 Blood Flow through the Heart

Deoxygenated blood returning from the body first enters the heart from the superior and inferior vena cava. The blood enters the right atrium and is pumped through the tricuspid valve into the right ventricle. From the right ventricle, the blood is pumped through the pulmonary semilunar valve into the pulmonary trunk. The pulmonary trunk carries blood to the lungs where it releases carbon dioxide and absorbs oxygen. The blood in the lungs returns to the heart through the pulmonary veins. From the pulmonary veins, blood enters the heart again in the left atrium. The left atrium contracts to pump blood through the bicuspid (mitral) valve into the left ventricle. The left ventricle pumps blood through the aortic semilunar valve into the aorta. From the aorta, blood enters into systemic circulation throughout the body tissues until it returns to the heart via the vena cava and the cycle repeats.[2]

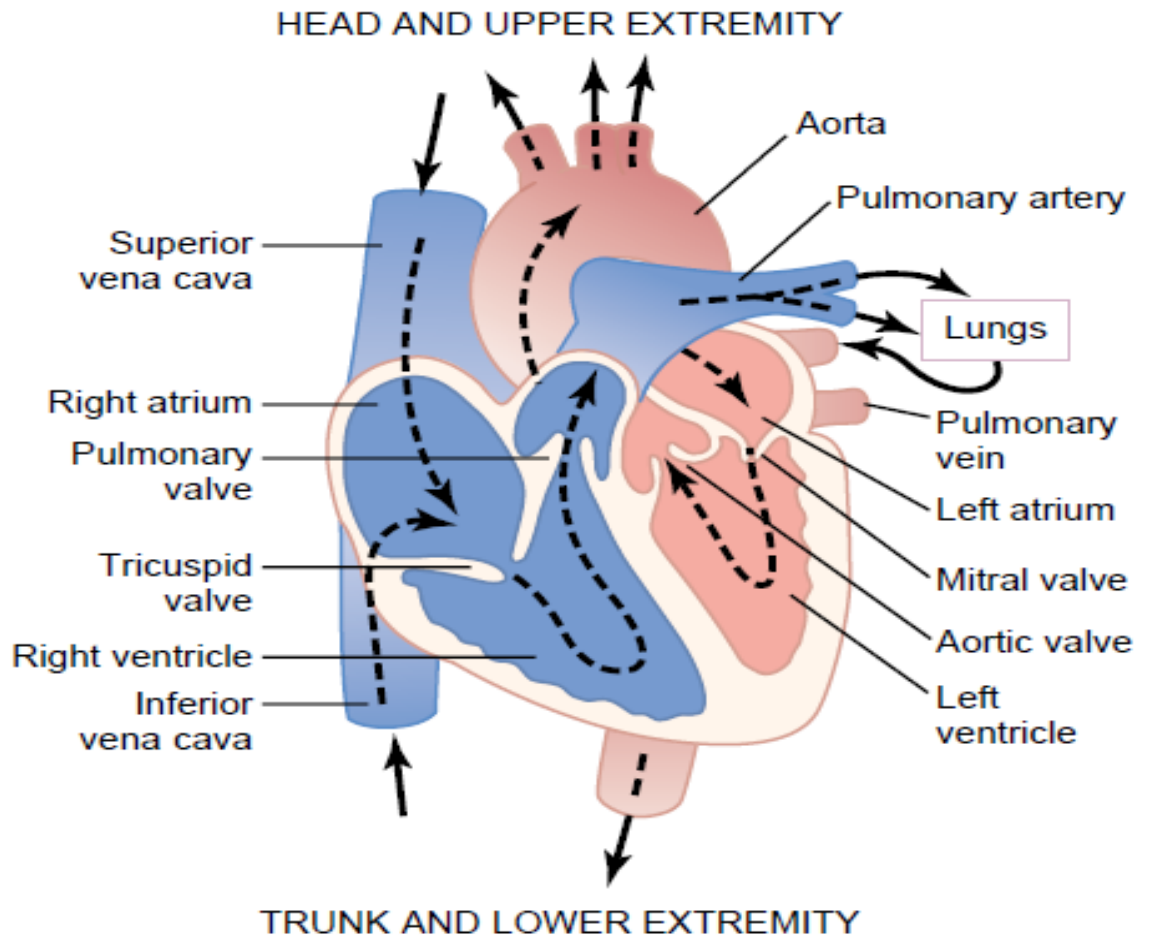


Figure2.3:the blood flow through the heart[2]

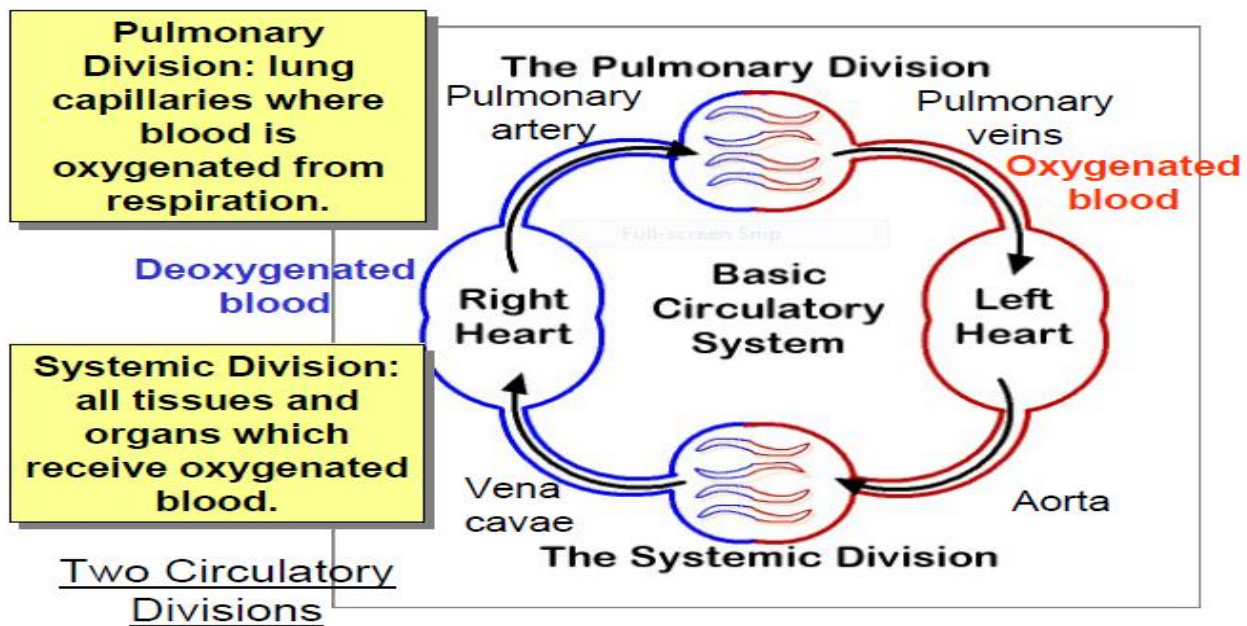


Figure2.4: pulmonary and systemic division[2]

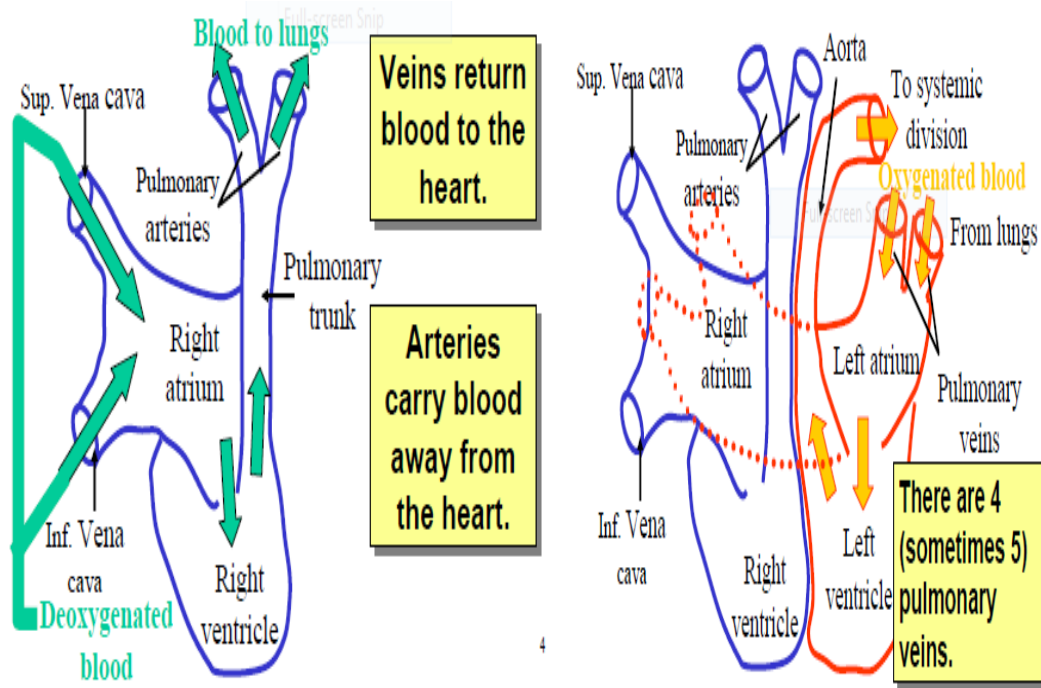


Figure2.5: the blood flow through the heart[2]

2.5 Structure of the Heart Wall

The heart wall is made of three layers: epicardium, myocardium and endocardium. The epicardium is the outermost layer of the heart wall and is just another name for the visceral layer of the pericardium. Thus, the epicardium is a thin layer of serous membrane that helps to lubricate and protect the outside of the heart. Below the epicardium is the second, thicker layer of the heart walls the myocardium. The myocardium is the muscular middle layer of the heart wall that contains the cardiac muscle tissue. Myocardium makes up the majority of the thickness and mass of the heart wall and is the part of the heart responsible for pumping blood. Below the myocardium is the thin endocardium layer. Endocardium is the simple squamous endothelium layer that lines the inside of the heart. The endocardium is very smooth and is responsible for keeping blood from sticking to the inside of the heart and forming potentially deadly blood clots. The thickness of the heart wall varies in

different parts of the heart. The atria of the heart have a very thin myocardium because they do not need to pump blood very far-only to the nearby ventricles. The ventricles, on the other hand, have a very thick myocardium to pump blood to the lungs or throughout the entire body. The right side of the heart has less myocardium in its walls than the left side because the left side has to pump blood through the entire body while the right side only has to pump to the lungs.[2]

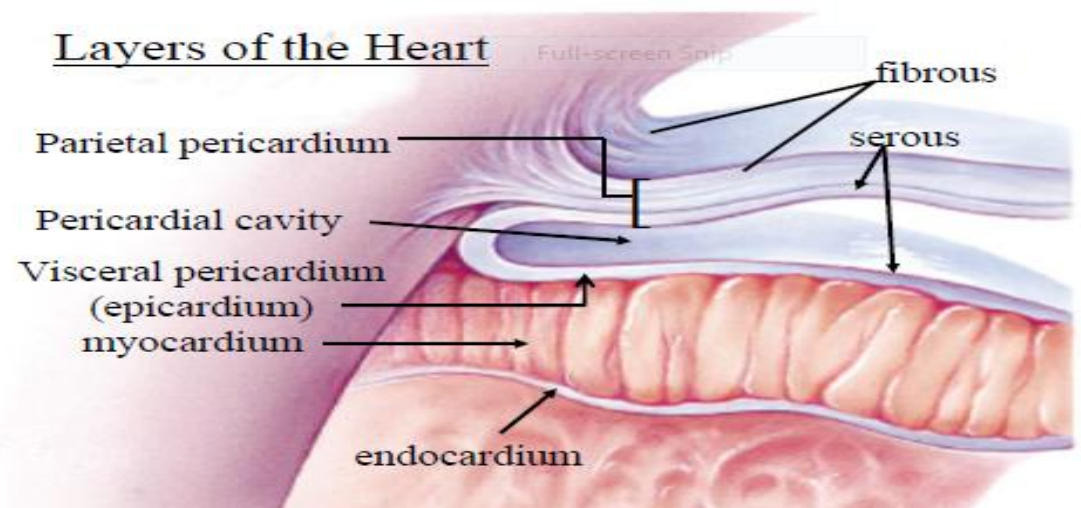


Figure2.6: the layers of the heart[2]

2.6 Physiology of the Heart(Systole and Diastole)

At any given time, the chambers of the heart may found in one of two states:

contraction, during it cardiac muscle tissue is contracting to push blood out of the chamber called systole. Relaxation, during it, the cardiac muscle cells relax to allow the chamber to fill with blood. Blood pressure increases in the major arteries during ventricular systole and decreases during ventricular diastole. This leads to the two numbers associated with blood pressure-systolic blood pressure is the higher number

and diastolic blood pressure is the lower number. For example, a blood pressure of 120/80 describes the systolic pressure (120) and the diastolic pressure (80). Figure 2.7 shows the different events during the cardiac cycle for the left side of the heart. The top three curves show the pressure changes in the aorta, left ventricle, and left atrium, respectively. The fourth curve depicts the changes in left ventricular volume, the fifth the electrocardiogram, and the sixth a phonocardiogram, which is a recording of the sounds produced by the heart-mainly by the heart valves-as it pumps. It is especially important that the reader study in detail this figure and understand the causes of all the events shown.[2]

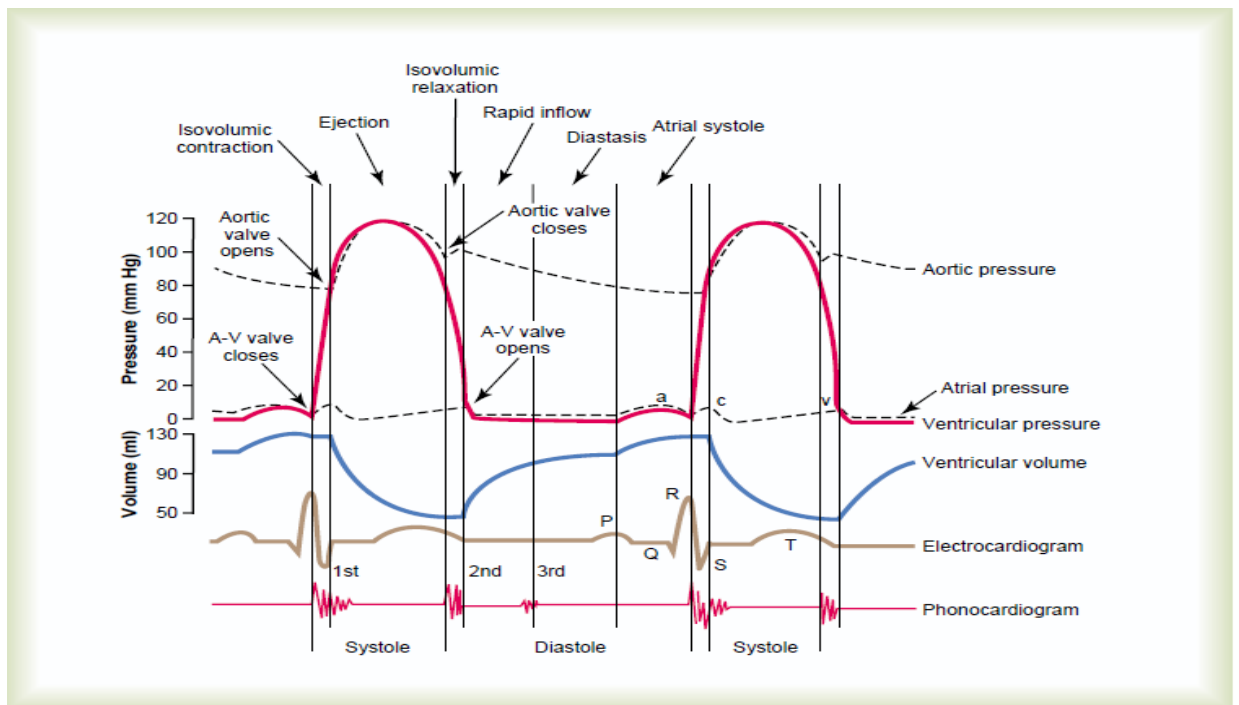


Figure 2.7: the cardiac cycle for left ventricular function (systole and diastole)[2]

The cardiac cycle for left ventricular function, showing changes in left atrial pressure, left ventricular pressure, aortic pressure, ventricular volume, the electrocardiogram, and the phonocardiogram.[2]

2.7 Cardiac Output

Cardiac output (CO) is the volume of blood being pumped by the heart in one minute. The equation used to find cardiac output is: $CO = \text{Stroke Volume} \times \text{Heart Rate}$. Stroke volume is the amount of blood pumped into the aorta during each ventricular systole, usually measured in milliliters. Heart rate is the number of heart beats per minute. The average heart can push around 5 to 5.5 liters per minute at rest. [2]

2.8 Heart Failure

Heart failure is a complex syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the heart to function as a pump to support a physiological circulation. When the heart fails, considerable changes occur to the heart and peripheral vascular system in response to the haemodynamic changes associated with heart failure. These physiological changes are compensatory and maintain cardiac output and peripheral perfusion. However, as heart failure progresses, these mechanisms are overwhelmed and become pathophysiological. The development of pathological peripheral vasoconstriction and sodium retention in heart failure by activation of the renin-angiotensin-aldosterone system are a loss of beneficial compensatory mechanisms and represent cardiac decompensation. The main causes of heart failure include Ischaemic heart disease (35–40%), Cardiomyopathy (dilated) (30–34%) and Hypertension (15–20%), also heart failure can be caused by Cardiomyopathy, hypertrophic/obstructive, Valvular heart disease (mitral, aortic, tricuspid), Congenital heart circulation (anaemia, thyrotoxicosis, haemochromatosis, Paget's disease), Right heart failure (RV infarct, pulmonary hypertension, disease (ASD, VSD), Alcohol and drugs (chemotherapy – trastuzamab,

imatinib), Hyperdynamic pulmonary embolism, cor pulmonale (COPD)), Arrhythmias (atrial fibrillation, bradycardia (complete heart block, the sick sinus syndrome)), Infections. Pathophysiological changes in heart failure, Ventricular dilatation, Myocyte hypertrophy, Increased collagen synthesis and Salt and water retention. [3]

2.9 Classification of heart failure

Class I No limitation. Normal physical exercise does not cause fatigue, dyspnoea or palpitations. Class II Mild limitation. Comfortable at rest but normal physical activity produces fatigue, dyspnoea or palpitations. Class III Marked limitation. Comfortable at rest but less gentle physical activity produces marked symptoms of heart failure. Class IV Symptoms of heart failure occur at rest and are exacerbated by any physical activity.

Chapter 3

Literature Review

3.1 Introduction

Heart failure (HF) is a growing disease that occur when the heart does not work efficiency. Patients with chronic HF, often become candidates to receive a Ventricular Assist Device (VAD). A VAD is an electromechanical circulatory device that is implanted in people whose heart is too weak to pump blood in to the body. It is also referred to as a heart pump, and partially or completely takes over the function of a failing heart. The type of ventricular assistance device applied depends on the type of heart disease, and on the pulmonary arterial-resistance, which determines the workload of the right ventricle. If a VAD is implanted in the right ventricle, so it called the Right Ventricular Assist Device (RVAD); if it is implanted in the left ventricle, it is called the Left Ventricular Assist Device (LVAD), if two devices are implanted in both ventricles, it is referred to as a Bi-Ventricular Assist Device (Bi-VAD). LVADs are most commonly used, but when pulmonary arterial resistance is high, in this case right ventricular assistance may become necessary. Long term VADs are normally used to keep patients alive with high quality of life while they wait for a heart transplantation (known as a "bridge to transplantation"). However, LVADs are sometimes used as destination therapy and sometimes as a bridge to recovery. In the last few years, VADs have improved in terms of providing quality of life to the patient among recipients. The early VADs emulated the heart by using a "pulsatile" action where blood is collected into the pump from the left ventricle then pushed it into the aorta. Pulsatile LVADs, have pusher plates which change the volume of a pumping chamber to push blood from the LV to the aorta in a

pulsatileway. Valves in the inflow and outflow ensure unidirectional flow through the pump. The flow in pulsatile VAD, similar to the normal circulation which is include the Heart Mate IP LVAS, which was approved for use in the US by the Food and Drug Administration in October 1994. These devices are commonly referred to as first generation VADs. In the first generation had many problems which lead to find other way to pump blood to the body. More recent work has concentrated on continuous flow pumps, which can be centrifugal pumps or axial flow impeller driven pumps which produce a non-pulsatile nearly continuous flow pattern. The rate of flow depends on the pressure gradient across the pump. These LVADs have the advantage of greater simplicity resulting in smaller size and greater reliability; they do not have valves because there is no possibility of backflow and therefore produce almost no noise. These devices are referred to as second generation VADs. A side effect is that the user will not have a pulse, or that the pulsatile manner is reduced. Third generation VADs suspend the impeller in the pump using either hydrodynamic or electromagnetic suspension, thus removing the need for bearings and reducing the number of moving parts to one. The typical LVAD is comprised of three primary components: a pump which receives blood through an inflow cannula and pumps blood through an outflow cannula; a wearable controller which powers the pump and permits adjustment of system operating parameters and a power source which typically allows switching between a base station powered by alternating current and a rechargeable battery pack. [1]

3.2 First generation LVADs

First generation LVADs came to clinical use in the mid-1980s. They include the Heart Mate XVE, Throated pVAD and IVAD, and Novacor LVAS. All these devices are used for bridge to heart transplantation (BTT), but only the Heart Mate XVE is approved by the Food and Drug Administration for DT in the United States. As volume displacement pumps, they have an internal reservoir chamber to collect the blood with inflow and outflow valves. The pumps function by cyclic filling and emptying of the reservoir chamber either by “pneumatic or electrical drive systems”.

[4] Unfortunately, first-generation devices have some limitations in their engineering design. The pump size is quite large, so the surgical to implant device became very difficult, which cause risk of” hematoma” and infection. The implantable device need large body, so they are not suitable for women and children. In addition,” a large-diameter percutaneous lead” is needed for removing of air. This can lead to more “trauma”, healing problems, and subsequent driveline infections. These pulsatile devices also have audible pump operation. Finally, to develop the device malfunction, requiring device exchange or causing possible death. Device failures are more common with pulsatile pumps, especially the Heart Mate XVE, because they have more moving parts and also have valves that can degenerate. [5]

3.3 The Second generation of LVAD

This generation is developed to obtain greater reliability and to reduce the size of the pump. Continuous flow LVADs or second generation can be divided into centrifugal and axial flow pumps. Axial flow pumps have many advantages than centrifugal pumps. They are more compact and weigh less than centrifugal pumps and thus less

invasive to implant. Axial flow pumps are able to generate higher flow rates at lower pressures than centrifugal pumps, and axial flow pumps consume low power which allowing it more compact and lighter power supply components than centrifugal pump as well as potentially implantable batteries. The first axial flow LVAD used the "Medtronic Hemopump", was developed by Dr. Richard Wampler and tested at the Utah Artificial Heart Institute. [6]

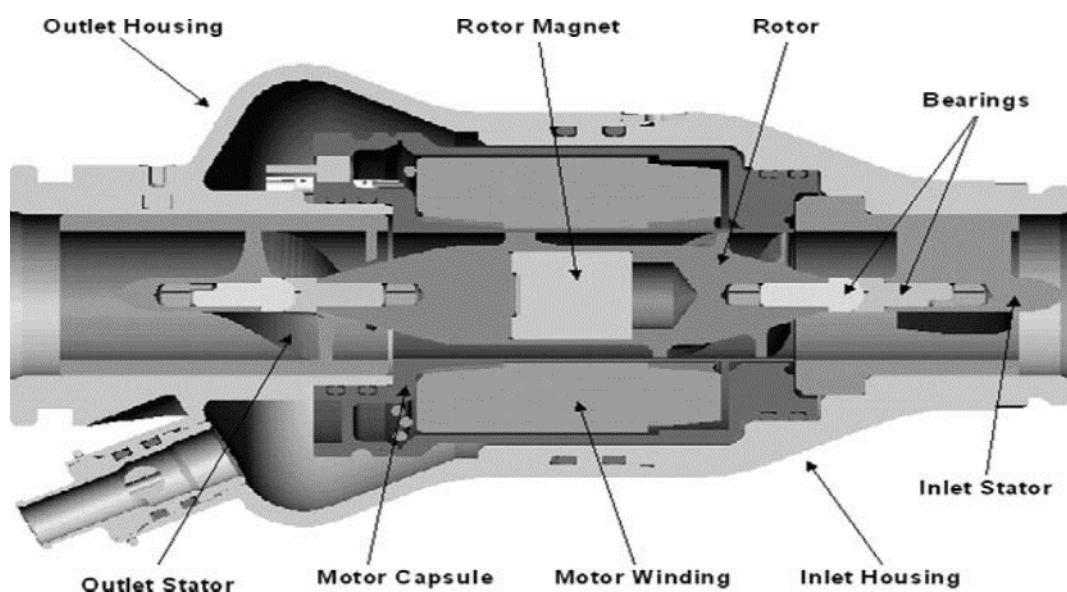


Figure 3.1: 2nd generation continuous flow rotary pump with an axial blood flow path and contact bearing design [5]

the figure above presentation of a 2nd generation continuous flow rotary pump with an axial blood flow path and contact bearing design suspending the internal rotor. Spinning of the internal rotor is achieved by magnetic coupling between the rotor magnet and external motor. Several axial flow continuous flow LVADs are currently available for treatment of adult heart failure patients in the United States. The first problem in the 2nd generation that the presence of contact bearings to suspend the

rotor represents a frictional of wear resulting in device failure and subsequent need for device exchange and also still cause thrombus formation on the device as result of constraining and disturbances of the blood flow path. An additional problem of 2nd generation rotary pumps with axial design is related to its hydrodynamic performance. During changing in pressure across the inlet and outlet orifices of the pump, this relative degree of insensitivity of the hydrodynamic performance of the pump or “steep” pressure-flow relationship can result in left ventricular collapse and “suction”. [5]

3.4 The third generation of LVAD

The limitations of the device technology of the 2nd generation of rotary pumps have led to further improvements in device design leading to a 3rd generation of devices with continuous-flow rotary technology with centrifugal configuration and noncontact bearing design. The major advancement in design of the 3rd generation of rotary pumps has been the feature of magnetic and/or hydrodynamic levitation of the impeller with elimination of contact bearings within the pump. The elimination of contact bearings has the potential to significantly improve durability which results in a greater degree of blood flow around the suspended impeller and “washing” of the impeller that provide a major benefit in terms of reducing the risk of thrombus formation within the pump and reducing the intensity of antithrombotic therapy necessary with this technology. The 3rd generation of rotary pumps with centrifugal design have a more sensitive pressure-flow than the 2nd generation of rotary pumps with axial design which can result in greater changes in flow for any given change in pressure across the inlet and outlet orifices of the pump. Further, the sensitive pressure-flow characteristics of the 3rd generation of rotary pumps with centrifugal

design increases the reliability of the estimated flow from pump power and rotor speed. In terms of its physical size, the magnetic-levitation of 3rd generation rotary pump made the pump smaller than 2nd generation rotary pump with axial design and mechanical bearing support of the rotor. The improvements of the 3rd generation of rotary pumps with centrifugal design, include mechanical wear, operation at low flow, and perceived improved potential for hemocompatibility, while still maintaining a manageable size, warrant further clinical investigation. Whether these attributes of the 3rd generation of rotary pumps with centrifugal design will result in significant improvement in clinical outcomes over that observed with the 2nd generation of rotary pumps with axial design is not known at this time. [5]

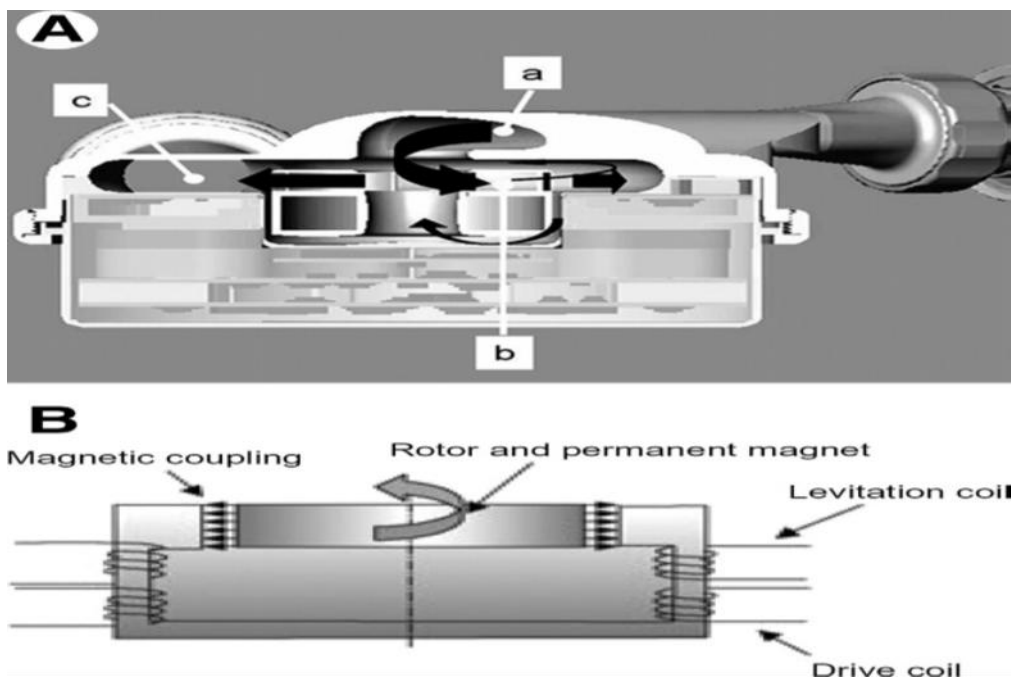


Figure 3.2: 3rd generation continuous-flow rotary pump with centrifugal design [5]
 Example of a 3rd generation continuous-flow rotary pump with centrifugal design incorporating active magnetic levitation and coupling of the internal impeller with a bearing less drive system (a) The main flow path from the inflow section; (b) blood

flow path through the impeller and the backflow paths above the shroud and between the rotor and motor; (c) outflow path. (Reprinted with permission from Farrar et al.16) (B) Schematic representation of a self-bearing or bearing less drive system in a 3rd generation continuous-flow rotary pump. In a self-bearing system, both the drive and levitation coils share the same stator core. (A) Typical pressure-flow relations of the HeartMate III, 3rd generation centrifugal pump is compared with the HeartMate II, 2nd generation axial flow pump at two different speed ranges. The pressure-flow curves are similar at high flows, but the HeartMate III has a “flutter” relationship at lower flows. [5]

3.5 Working of a centrifugal pump

A centrifugal pump works on the principle that when a certain mass of fluid is rotated by an external source, it is thrown away from the central axis of rotation and a centrifugal head is impressed which enables it to rise to a higher level. The working/operation of a centrifugal pump is explained step - wise below:

1-The delivery valve is closed and the pump is primed that is, suction pipe, casing portion the delivery pipes up to the delivery valve and completely filled with liquid (to be pumped) so that no air pocket is left.

2-Keeping the delivery valve still closed, the electric motor is started to rotate the impeller. The rotation of the impeller causes strong suction or vacuum just at the eye of the casing.

3-The speed of impeller is gradually increased till the impeller rotates at its normal speed and develops of the normal energy required for pumping the liquid.

4-After the impeller attains the normal speed, the delivery valve is opened when the liquid is continuously sucked (from pump well) up the suction pipe, it passes through the eye of casing and enters the impeller at its center or it enters the impeller vanes at their inlet tips. This liquid is impelled out by the rotating vanes and it comes out at the outlet tips of the vanes into the casing. Due to impeller action the pressure head as well as velocity heads of the liquid are increased (some of this velocity head is converted into pressure head in the casing and in the diffuser blades/vanes if they are provided).

5-From casing, the liquid passes into pipe and is lifted to the required height (and discharged in the outlet or upper end of the delivery pipe).

6-So long as motion is given to the impeller and there is supply of liquid to be lifted the process lifting the liquid to the required height remains continuous.

7-When pump is to be stopped the delivery valve should be first closed, otherwise there may be backflow from the reservoir. [7]

3.5.1 Advantages of centrifugal pump over displacement (reciprocating)pump

1-The cost of centrifugal pump is less as it has fewer part.

2-Installation and maintenance are easier and cheaper.

3-Its discharging capacity is much greater than that of a displacement pump.

4-It is compact and has smaller size and weight for the same capacity and energy transfer.

5-Its performance characteristics are superior.

6-It can be employed for lifting highly viscous liquid such as oil, blood and sugar molasses.

7-It can be operated at very high speed without any danger of separation and cavitation.

8-It can be directly coupled to any electric motor or an oil engine.

9-The torque on the power source is uniform and also output is uniform. [7]

3.5.2 Component parts of a centrifugal pump

a centrifugal pump consists of four main components impeller, casing, suction pipe and delivery pipe. [7]

3.5.2.1 The impeller:

An impeller is a wheel (or rotor) with a series of backward curved vanes (or blades) is mounted on shaft which is usually coupled to an electric motor. The liquid enters the impeller at its center and leaves at its outer periphery and it had three design. The first design is called closed impeller which its vanes are provided with metal cover plates on both sides. The shroud is mounted into shaft and front shroud is coupled to the former by the vanes. It provides better guidance for the liquid and the wear is reduced to minimum this ensure full capacity operation with high efficiency. It is employed when the liquid to be pumped is pure and relatively free from debris. Because this design is closed, the blood collides in all direction so the blood cells are destroyed so this design isn't suitable to use. [7]

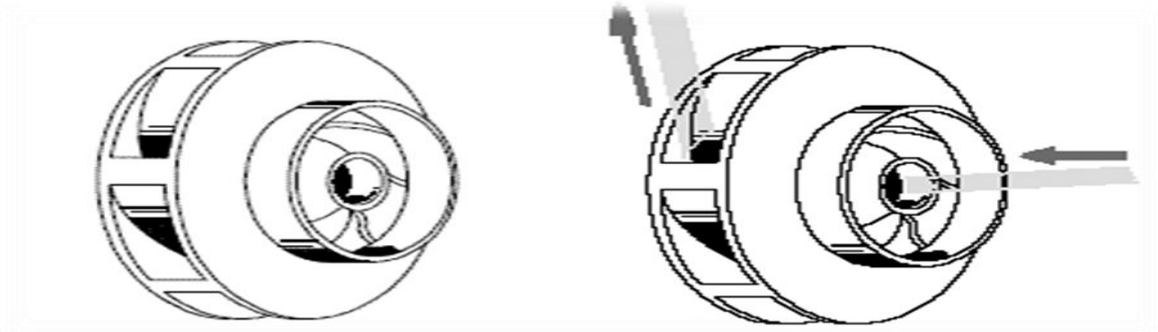


Figure3.3: closed impeller [7]

In second design no shroud or plate is provided on either side (the vanes are opened in both sides) which called open impeller. The impellers are employed for pumping liquids which contain suspended solid matter (water containing sand or grit). In this design the blood doesn't move smoothly because it hasn't diffuser guide so isn't suitable to use. [7]



Figure3.4: open impeller. [7]

The last design of impeller called semi-open impeller. A semi-open impeller has a plate only on the back side. The design is adopted to industrial pump problems which required a rugged pump to handle liquids containing fibrous materials such as sugar molasses and blood. [7]



Figure3.5: semi- open impeller [7]

3.5.2.2 The casing

The casing is an airtight chamber surrounding the pump impeller. It contains suction and discharge arrangements, supporting for bearings and facilitates to house the rotor assembly. It has provision to fix stuffing box and house packing materials which prevent external leakage. The essential purposes of the casing guiding blood to and from the impeller and partially converting the kinetic energy into pressure energy. The casing had three types the first one called (Casing with guide blades(diffuser)) whichn this type of casing the impeller is surrounded by a series of guide blades (or vanes) mounted on a ring which is known as a diffuser. The liquid leaving the impeller passes through the passage (having a gradually increasing area) between guide vanes/blades; the velocity of flow decreases and the kinetic energy is converted into pressure energy. Machines with diffuser blades have rather maximum efficiency, but are less satisfactory when a wide range of operating conditions is required. These pumps are costlier than volute pumps. [7]

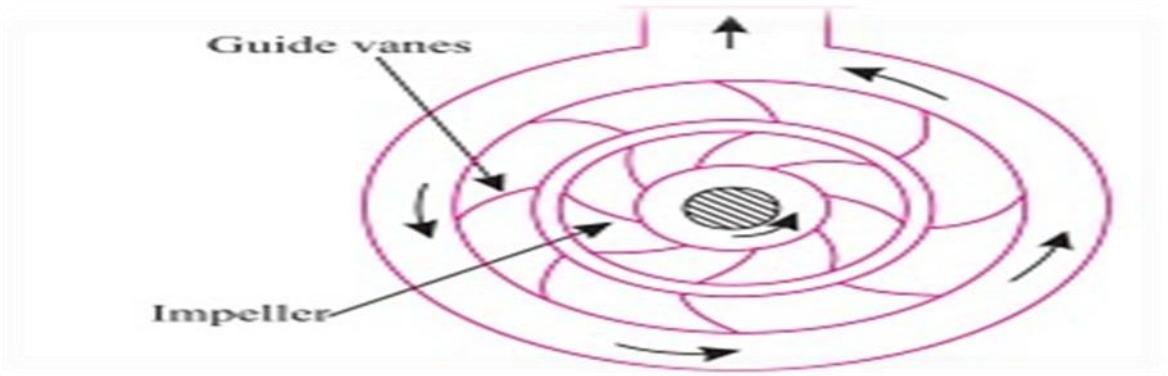


Figure3.6: Casing with guide blades(diffuser). [7]

The second called Volute casing whose area is of cross-section gradually increases towards the delivery pipe. The velocity of liquid decreases as the area increases along the path of flow, thus the increase in pressure which occurs this arrangement, converts kinetic energy into pressure energy, so by the velocity decrease of blood, the blood can be clotted. The efficiency of this casing is less than the others. larger amount of energy is lost due to formation of eddies. [7]

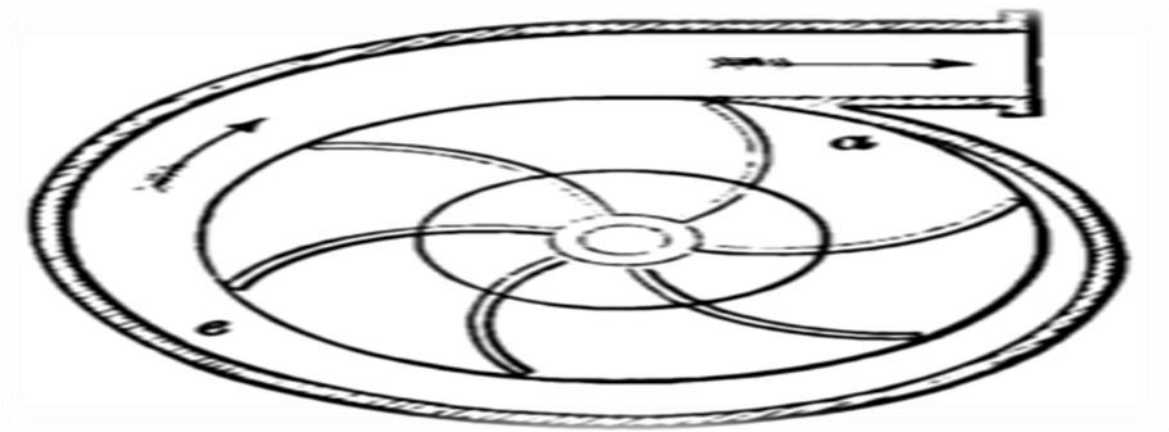


Figure3.7: volute casing. [7]

If a circular chamber is provided between the impeller and the volute chamber, the casing is known as vortex casing. The circular chamber is known as *vortex* or whirlpool chamber and such a pump is known as a volute pump with vortex chamber. The vortex chamber converts some of kinetic energy into pressure energy. In this

case, the liquid from the impeller enters into the vortex chamber and then through the volute chamber. In this arrangement the eddy loss is considerably reduced and the efficiency of conversion from kinetic energy into pressure energy is increased as compared with volute casing. Thus the efficiency of a volute pump fitted with a vortex chamber is more than that of a simple volute pump. [7]

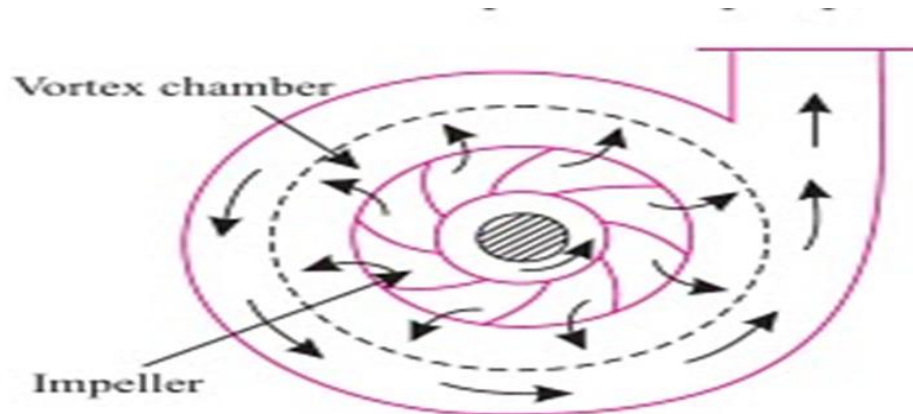


Figure3.8: vortexpump. [7]

3.5.2.3 Suction pipe design

The pipe which connects the center/eye of the impeller to sump from which liquid is to be lifted is known as *suction pipe*. In order to check the formation of air pockets, the pipe is laid air tight. To prevent the entry of solid particles or debris into the pump, the suction pipe is provided with a strainer at its lower end. The lower end of the pipe is also fitted with non-return foot valve which does not permit the liquid(blood) to drain out of the suction pipe. When the pump is not working; this also helps in permitting. The vertical height of the center line of centrifugal pump above the blood surface in the pump from which blood is to be lifted this height is called suction head/lift. [7]

3.5.2.4 Delivery pipe design

The pipe which is connected at its lower end to the outlet of the pump and it delivers liquid to the required height is known as delivery pipe. A regulating valve is provided on the delivery pipe to regulate the supply of blood. The vertical distance between the center line of the pump and the blood surface in the pump from which the blood is delivered, is known as delivery head. [7]

3.6 HVAD

The HVAD is a small continuous-flow rotary pump with centrifugal and noncontact bearing design [8]

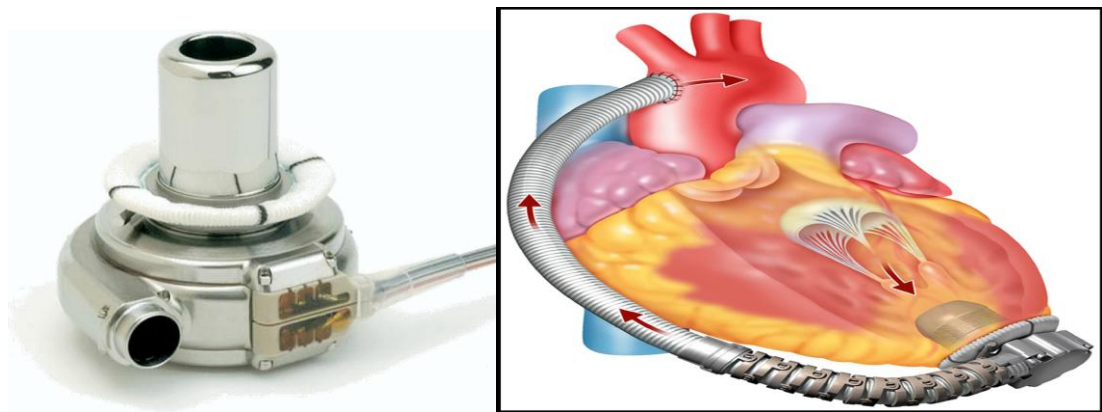


Figure3.9: HVAD (HeartWare Corp.) [5]

The HeartWare System consists of an implantable centrifugal flow pump (HVAD), an external controller, and external power sources. A wide-blade impeller with a hybrid suspension system uses passive magnetic and hydrodynamic thrust bearings to create a contact-free rotation of the impeller. The pump is surgically positioned in the pericardial space with the integrated inflow cannula in the left ventricle. [8]

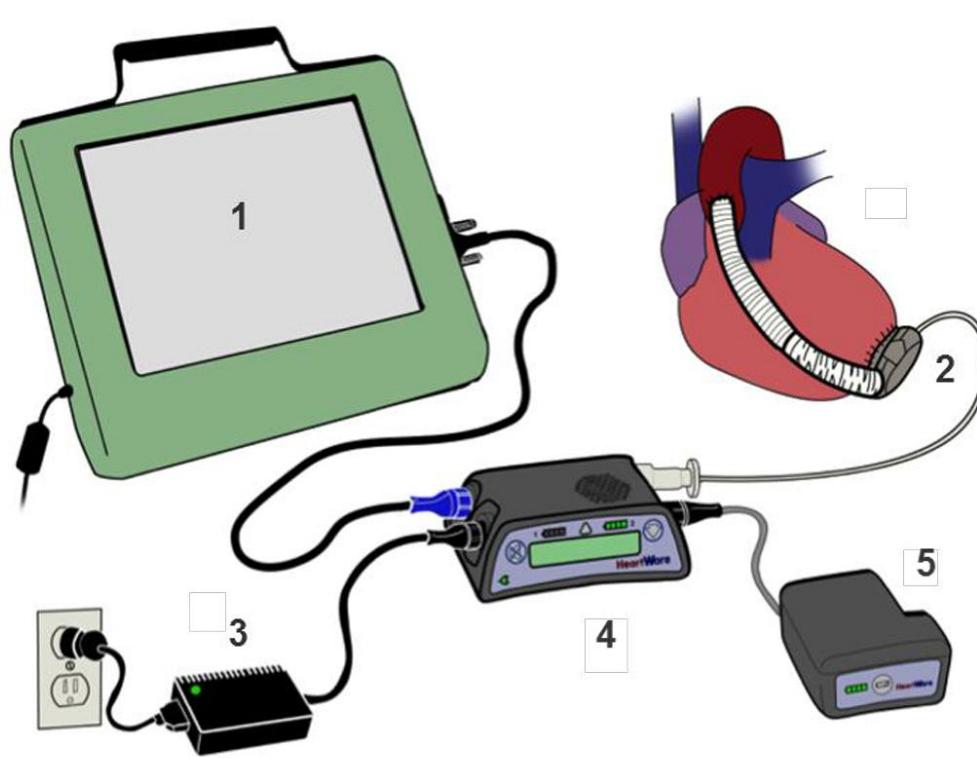


Figure 3.10: The HeartWare System consists [8]

1. Monitor
2. HVAD Pump
3. AC Adapter
4. Controller
5. Battery

Blood from the left ventricle enters the pump through the inflow cannula and exits through a 10-mm outflow graft that is attached to the ascending aorta. The maximum flow rate is 10 L/min. A short inflow cannula (25-mm long; 21-mm outer diameter) is fabricated of smooth titanium and contains a silicone O-ring to ensure a seal with the sewing ring, outflow cannula (12mm inner diameter) and adjustable speed ranging from 1,800 to 4,000 RPM. The pump is connected to external system components by a driveline that is tunneled subcutaneously and exits the patient's abdominal wall. A controller operates the pump, regulates power, monitors system performance, and displays alarm notifications. A carrying case for the controller may be worn on a belt or over the shoulder. The system can be powered by three ways: a pair of rechargeable direct current (DC) lithium-ion batteries, alternating current (AC) power from an electrical wall outlet, or a 12-V DC power source. For safety, two sources of power are always used. A monitor displays pump performance, is used to set and adjust the operating parameters, and provides a means to download data from the controller. [8]

3.6.1 Internal (implantable) Components

The HVAD pump is small (displaced volume, 50 ml; weight, 145 g) and incorporates a short inflow cannula to allow for placement at the apex of the left ventricle. The pump has three main parts: a front housing with an integrated inflow cannula, a rear housing with a magnetic center-post, and the rotating impeller. Front and rear housings are hybrid titanium-ceramic assemblies which platinum alloy impeller suspended inside it; each contains a hermetically sealed motor stator. Dual motor stators enhance system efficiency and provide power redundancy to rotate the impeller. [8]

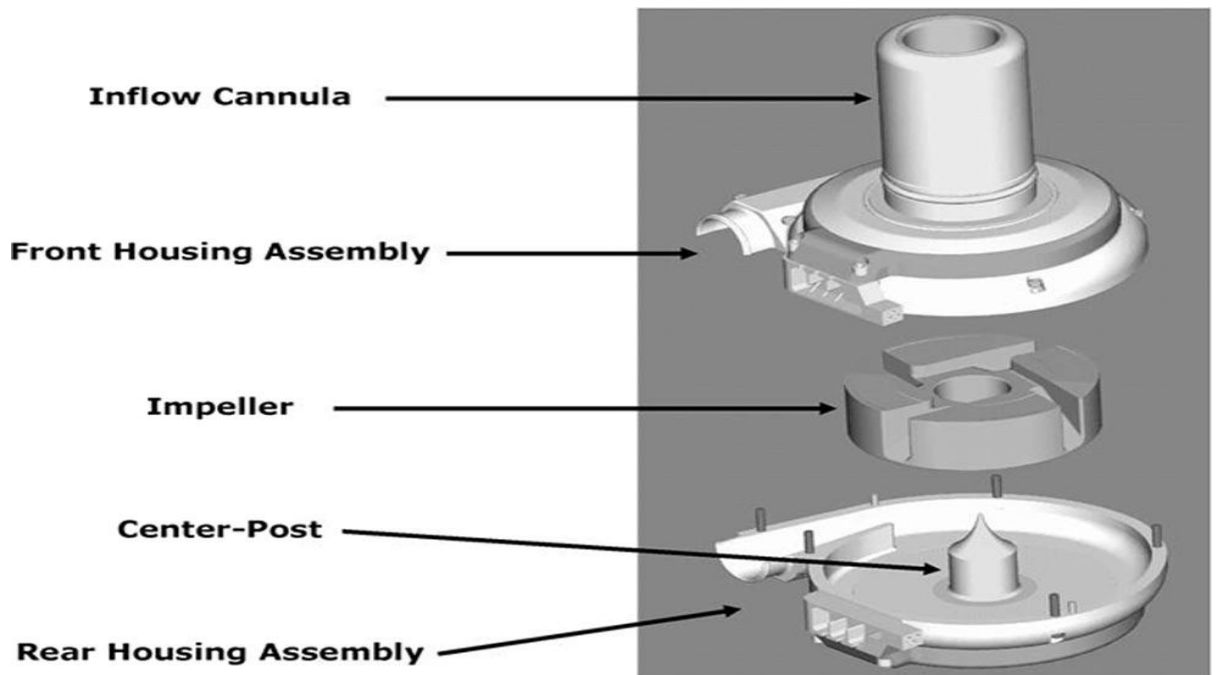


Figure3.11:the internal component of HVAD.[8]

3.6.2 External Components

The microprocessor-based controller (13.34 cm × 10.4 cm × 5.08 cm) weighs 0.362 kg and is connected to the implanted blood pump by the percutaneous driveline. The controller operates the pump, manages power sources, monitors pump function,

provides diagnostic information, and stores pump parameter data. The controller automatically identifies the AC or DC power source, and an indicator symbol illuminates to inform the operator which source is being used. Two battery power indicator lights provide estimates of the percent of total power remaining in the attached rechargeable battery packs. An internal, non-replaceable, rechargeable battery within the controller provides an audible alarm if all power is lost. A two-line liquid crystal display on the controller continuously displays the pump speed, pump flow rate, and power consumption. [8]

3.6.3 clinical evaluation

The HVAD has undergone clinical evaluation in Europe and Australia and is scheduled to begin clinical evaluation in the United States in 2008. In a multi-institutional trial in Europe and Australia, 20 patients underwent implantation other HVAD from March of 2006 through September of 2007. Mean age of the patients was 46-12 years (range 28-68 years). Median cardiopulmonary bypass time to implanted device was 67 min (range 21-140 min). Mean duration of HVAD device support was 167-143 days (range 13-425 days). Range of blood flow provided by the pump was 4.0-6.5 L/min. Three patients were successfully transplanted after 426, 349, and 157 days, respectively. One patient was weaned from pump support on postoperative day 266, two patients died on device (postoperative days 13 and 203), and 14 patients remain alive with ongoing device support. Actuarial survival at 1 year was 80%. [8]

Table 1: Evolution of rotary blood pumps, features, and clinical[9]

	Pumps	Features	Clinical usage and problems
First-generation blood pumps (1965–1990)	Hemadyne Medtronic BioPump BP-80 Spindle Pump Tea Spoon Pump Hemopump Terumo Capiox Nikkiso HPM-15 Sarns Delfin Pump Kyocera Gyro Jostra Sorin Stockert	Shaft seal Purge system Mechanical-bearing Magnetic coupling	CPB ECMO Temporary left heart support Mechanical trauma Thrombogenicity 48 h–2 weeks in-hospital use
Second-generation blood pumps (1990–2000)	MicroMed DeBakey VAD MicroMed DeBakey VAD Child Jarvik 2000 Pediatric Jarvik 2000 Thoratec HeartMate II NEDO Pump SunMecial EVAHEART Impella Recover TinyPump	Seal-less structure Contact bearings Magnetic coupling Direct drive	Implantable VAD BTT, BTR Percutaneous energy delivery 4–5-year use In- and Out-of-hospital use
Third-generation blood pumps (2000–)	Thoratec HearMate III WorldHeart HeartQuest MedTech Heart Levitronix CentriMag Berlin Heart INCOR Arrow CorAide VentraCor VentrAssist CCF PediPump University of Pittsburgh PediaFlow	Noncontact bearings Magnetic levitation Hydrodynamic levitation Magnetic coupling Direct drive	Implantable VAD BTT, BTR Permanent use Percutaneous energy delivery TETS Over 10-year use Out-of-hospital use

3.7 Options of manufacturing

There are three options to manufacture third generation LVAD (Heart wear). The first option is a Turning machine or Turning operation which is one of the most basic machining processes. That part is rotated while a single point cutting tool is moved parallel to the axis of rotation n. The tool can be straight line, curves or angles, but they are essentially linear (in the non-mathematical sense). The starting material is generally a work piece. Because this type of manufacturing uses human hand (doesn't use computer), so the production isn't precise and also need to use this device inmedical applications, this type of manufacturing isn't suitable to use.[10]



Figure3.12: turning machine [10]

Also the device can be manufactured by 3D printer which known as additive manufacturing(AM), refers to the processes used to create a three-dimensional object in which layers of material are formed under computer control to create an object. Objects can be of almost any shape or geometry and are produced using digital model data from a 3D model or another electronic data source such as solid work, can also use computer aided design(CAD) or by plain digital camera. The manual modeling process operating geometric data for 3D computer graphics, is similar to plastic arts. 3D scanning is a process of collecting digital data on the shape and appearance of a real object, creating a digital model based on it. Although this type uses computer to create the design(precise), but it isn't available and costly so it isn't suitable to use. [11]



Figure3.13: 3D printer [11]

The third option is CNC which is the automation of machine tools by means of computers executing preprogrammed sequences of machine control commands. This is in contrast to machines that are manually controlled by hand, wheels or levers. In modern CNC systems, the design of a mechanical part and its manufacturing program is highly automated. The parts of mechanical dimensions are defined using computer aided design(CAD)software or solid work and then translate into manufacturing directives by computer aided manufacturing(CAM) software. The resulting directives are transformed into the specific commands necessary for particular machine to produce the components and then loaded into the CNC machine. Since any particular component might require the use of a number of different tools, modern machines often combine multiple tools into a single cell. In other installations, a number of different machines are used with an external controller and a human or robotic operators that move the component from machine to machine. In either case, the series of steps needed to produce any part is highly automated and produces a part that closely matches the original CAD or solid work

design. CNC like systems are now used for any process that can be described as a series of movements and operations. These include laser cutting, welding, ultrasonic welding, bending and sawing. A CNC machine is a computer machine (imprecise) so we can use it in medical applications and also it is cheaper than 3D printer and available. [12]



Figure3.14: CNC machine. [12]

Chapter 4

Methodology

To design this device, followed three steps, mathematical modeling, computational modeling and testing.

4.1 Mathematical modelling

The LVAD System is designed to provide circulatory assistance to patients diagnosed with end stage, refractory heart failure. The pump size is significantly small with a displacement volume less than 70 mL which is a displacement volume of left ventricle (to prevent our device to section all blood from all chambers), and small weight. To achieve this small volume, chosen small diameter and high for the casing as represent in equation below

$$V = \pi r^2 h \dots\dots\dots (1)$$

where:

V=the displacement volume.

r=the radius of the casing.

h=the high of casing.

In cardiovascular fluid mechanics, shear stress is a particularly important concept. blood is a living fluid, and if the forces applied to the fluid are sufficient, the resulting shearing stress can cause red blood cells to be destroyed. Since the fluid element will be moving at a constant velocity, and not rotating, the shear stress on the element must be the same. Physically the shear stress at the wall may also be

represent by (force/plate area). The yield stress for blood is very small. In mathematical, this small stress (pressure= force/area(L×w)) is achieved by assume the dimensions of plate impeller is 18.16mm high(h), 20.50mm length(L) and 5mm width(w). To calculate stress, first calculate the volume of blood over the plate(=h×L×w) so equal 1.641μm³. The mass of blood (= density of blood (1067 kg/m³)/volume) is equal 1.75g. The force of blood that applied to impeller (mass× 9.81) equal 0.0171N, so the stress equal 168.41N/m² (1.2mmHg) which make low stress to the blood cells.

4.2 Computational modelling

in design used solid work which is a solid modeling computer-aided design, computer-aided engineering and computer program that run on micro soft windows. In this chapter, explained the design of all components of Heart Ware as in chapter2.

4.2.1 The design of suction pipe

This part of device use to path blood from left ventricle to the pump(impeller). As in chapter2, this pipe enters in the heart(LV) with small diameter (inner 13mm and outer 21mm) and small inflow canal(25mm).

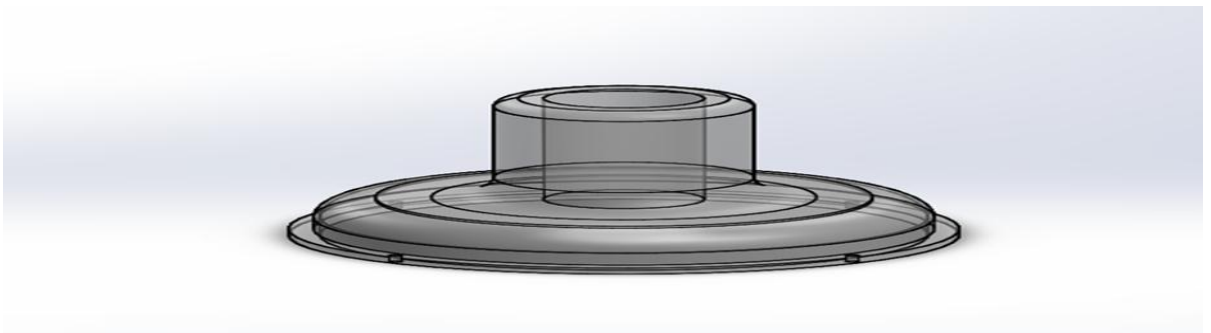


Figure4.1:The suction pipe

4.2.1.1 The dimensions of suction pipe

The top view

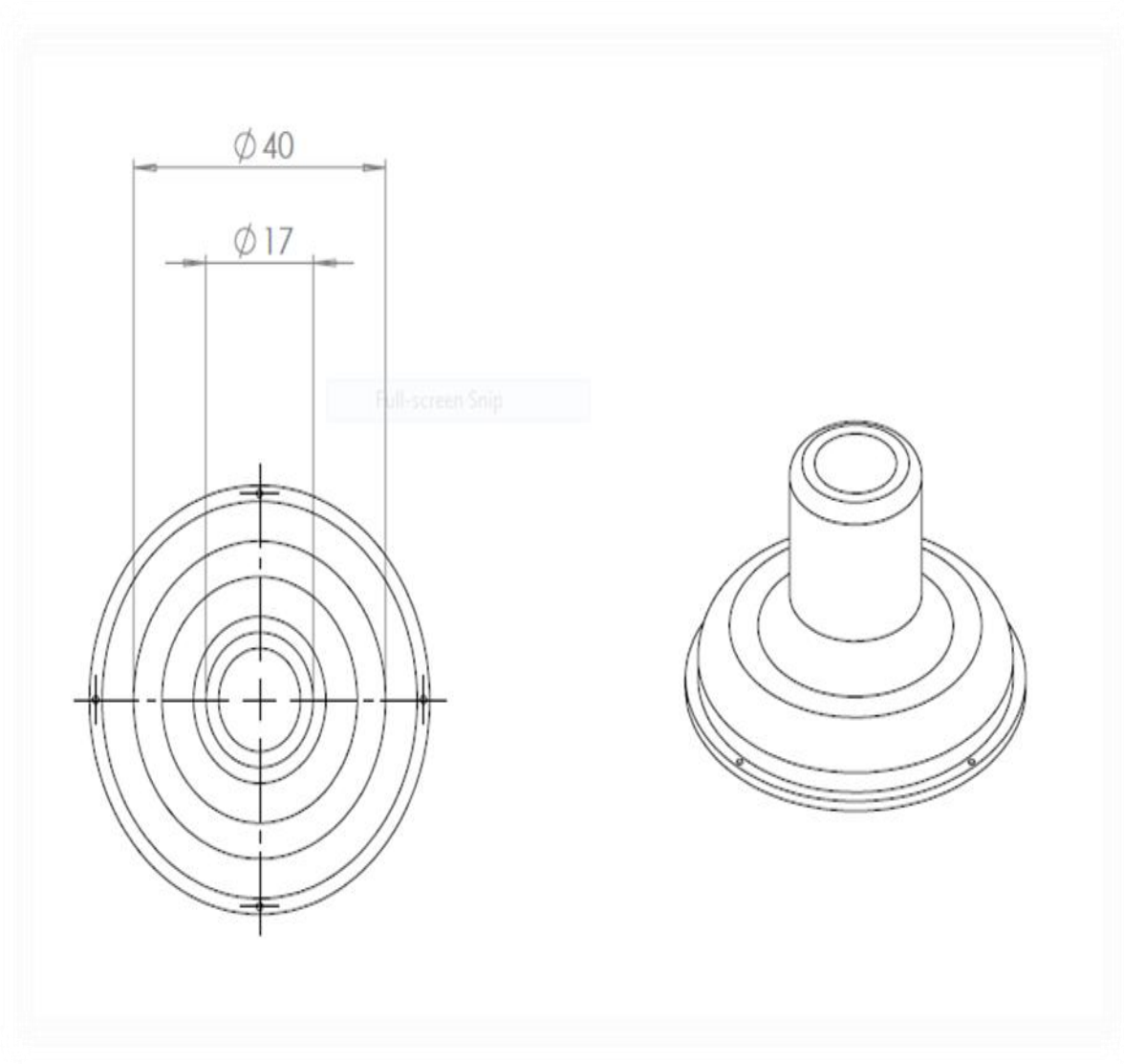


Figure4.2: The top/dimensions of suction pipe

The front view

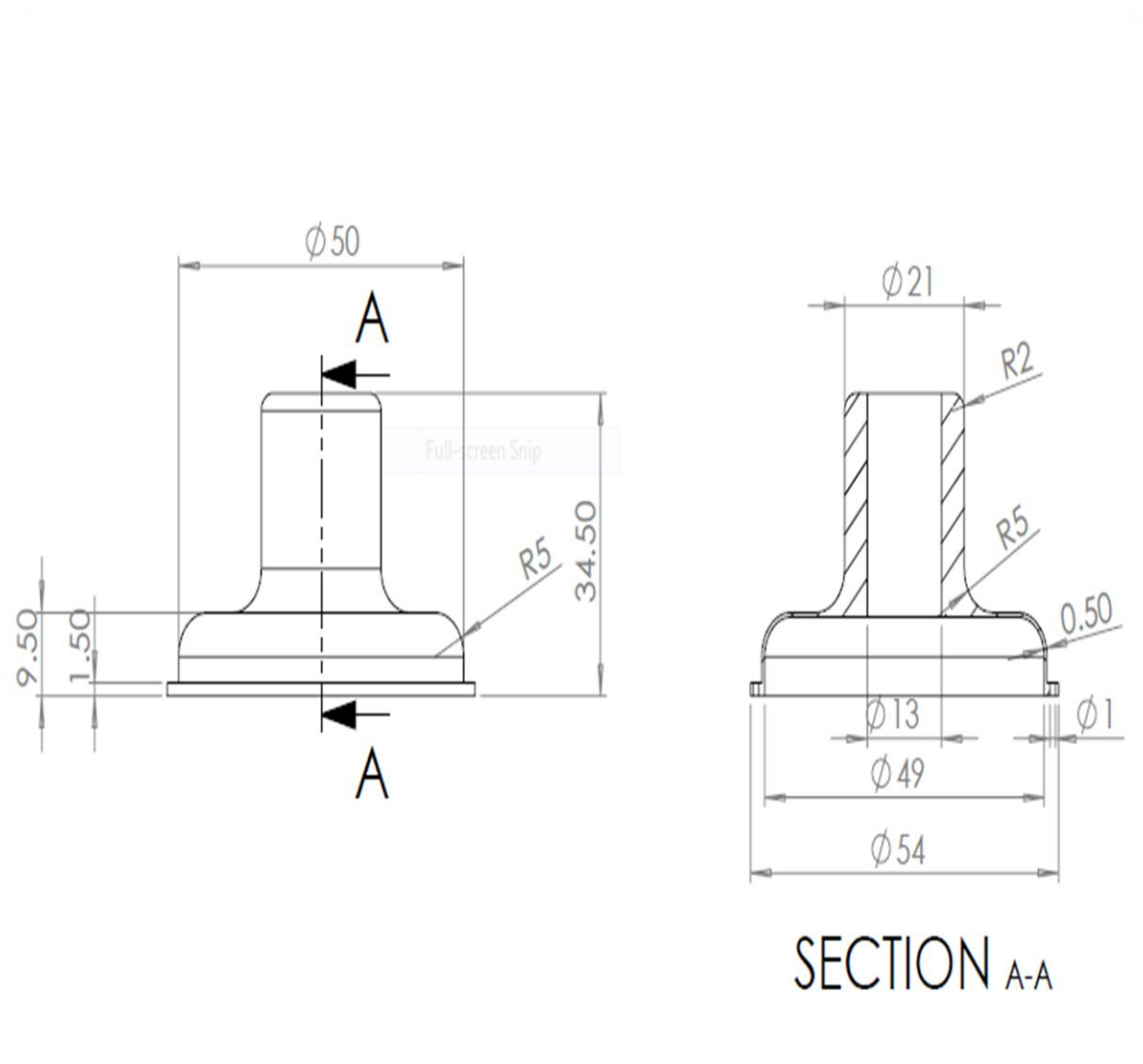


Figure4.3: The front/dimensions of suction pipe

4.2.2 The design of delivery pipe

To deliver blood from pump to aorta used this pipe with circular drift to reduce the shear stress applied to the blood with outflow graft aided.

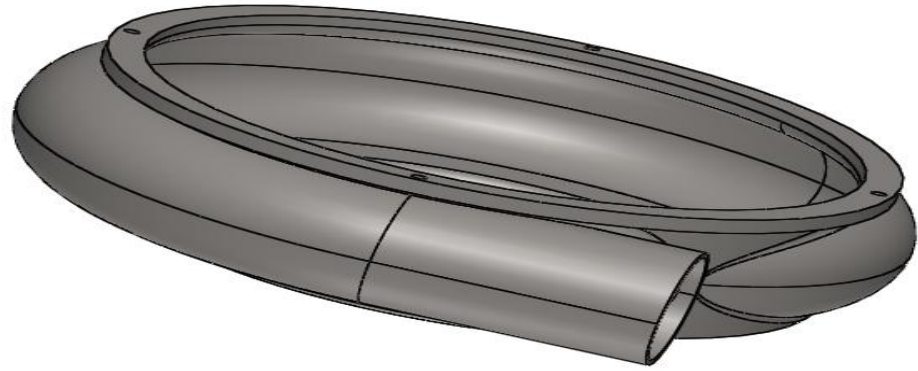


Figure4.4: The delivery pipe

4.2.2.1 The dimensions of delivery pipe

The top view

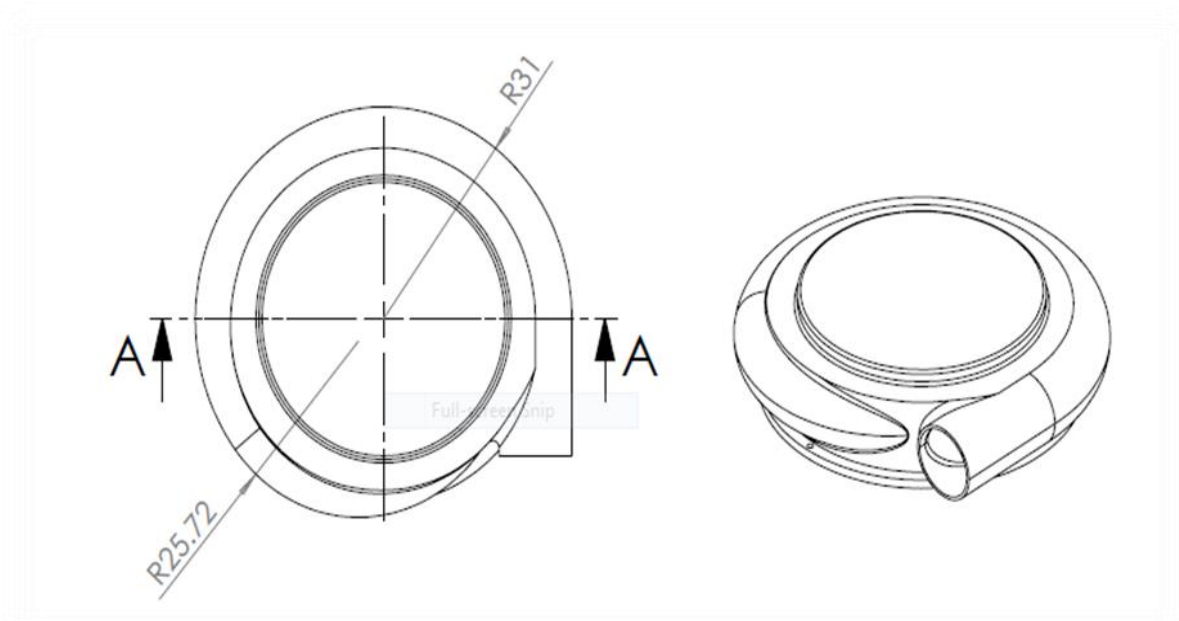


Figure4.5: the top/dimensions of delivery pipe

The front view

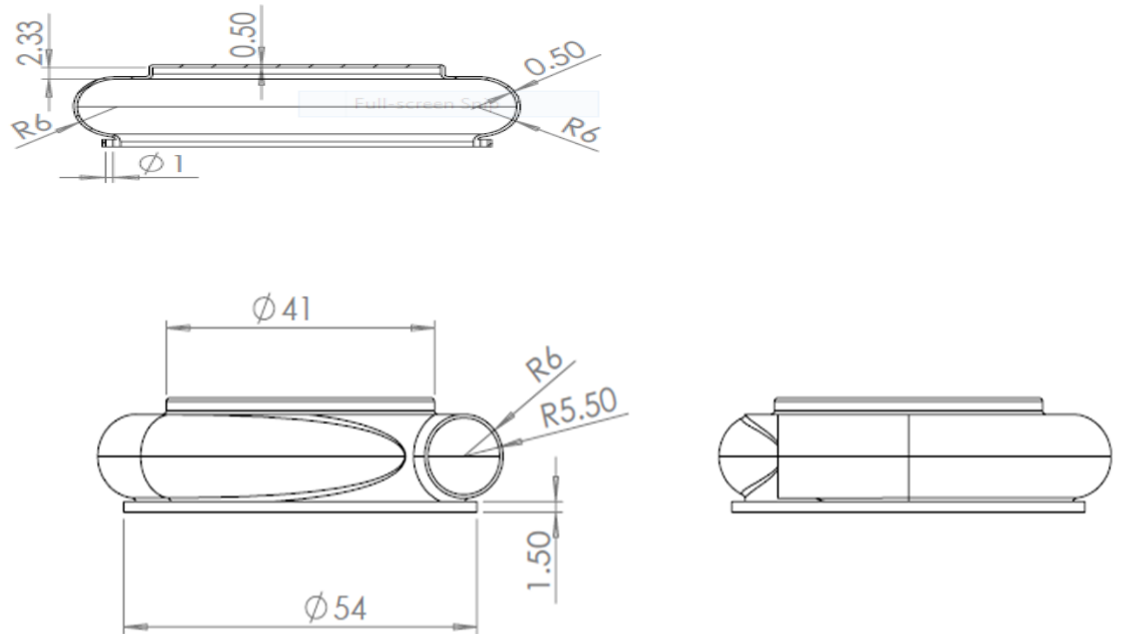


Figure4.6: The front/dimensions of delivery pipe

2.33mm use to fix impeller in the casing and prevent blood leakage under impeller, 5mm costumed in both side to allow blood path to outlet. To connect the upper casing with lower used mechanical attach (used screws).

4.2.3 The design of impeller

As in chapter 2 the function of impeller is produced negative pressure to suction blood from LV to aorta. When the blood flow from LV, it collides with solid surface (blade of impeller) so used slope shape to make blood flow easy without collides which achieve small shear stress on blood.

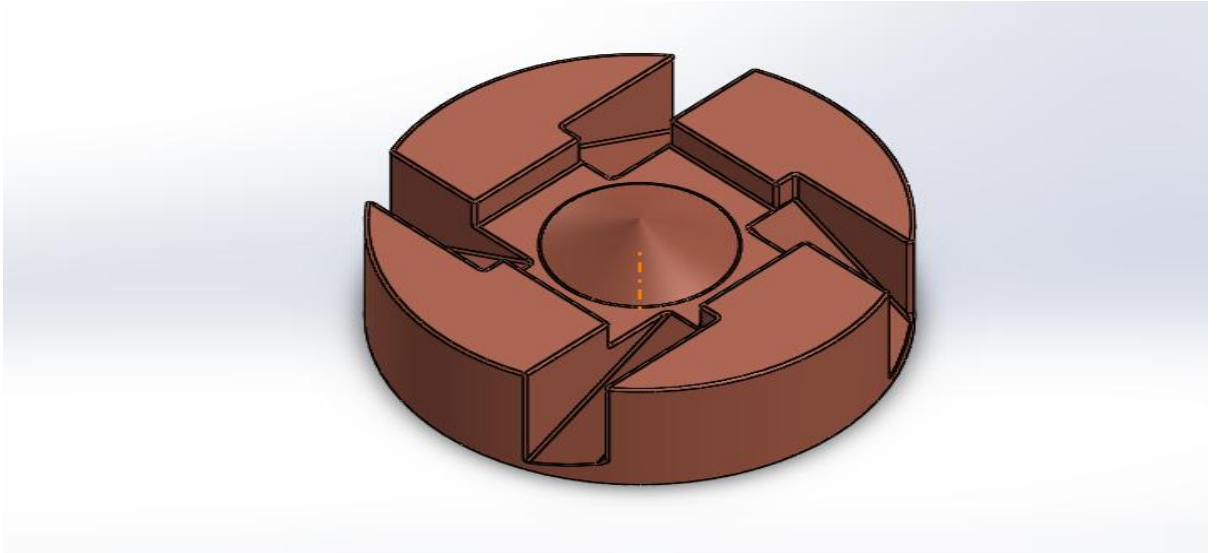


Figure4.7: The impeller

There is four blood path in impeller as sow above to provide enough energy (pushing force) for push blood to outlet.

4.2.3.1 The dimensions of impeller

the top view

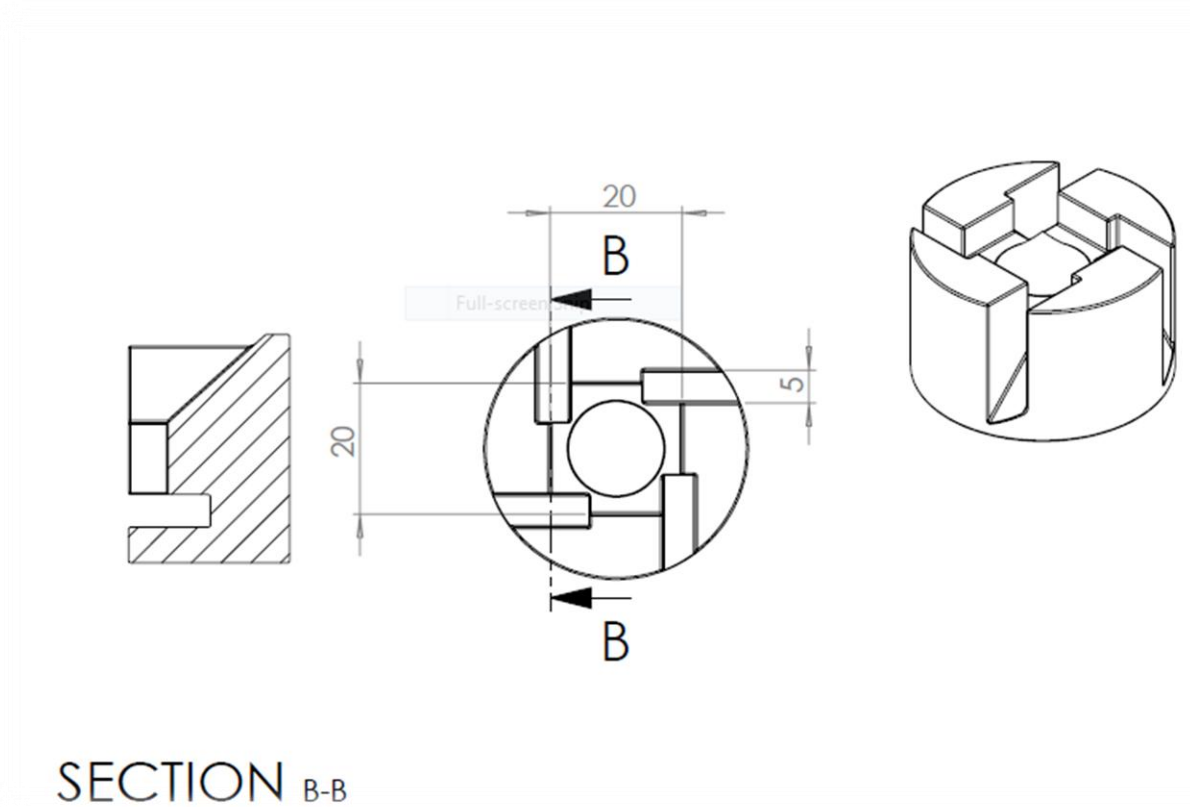


Figure4.8: The top/dimensions of impeller

The width of blades of impeller 5mm because the inner inlet diameter 13mm which divided in to four blades ($13/4=3.2\text{mm}$) but to reduce contact between blood cells, increased width to 5mm.

The front view

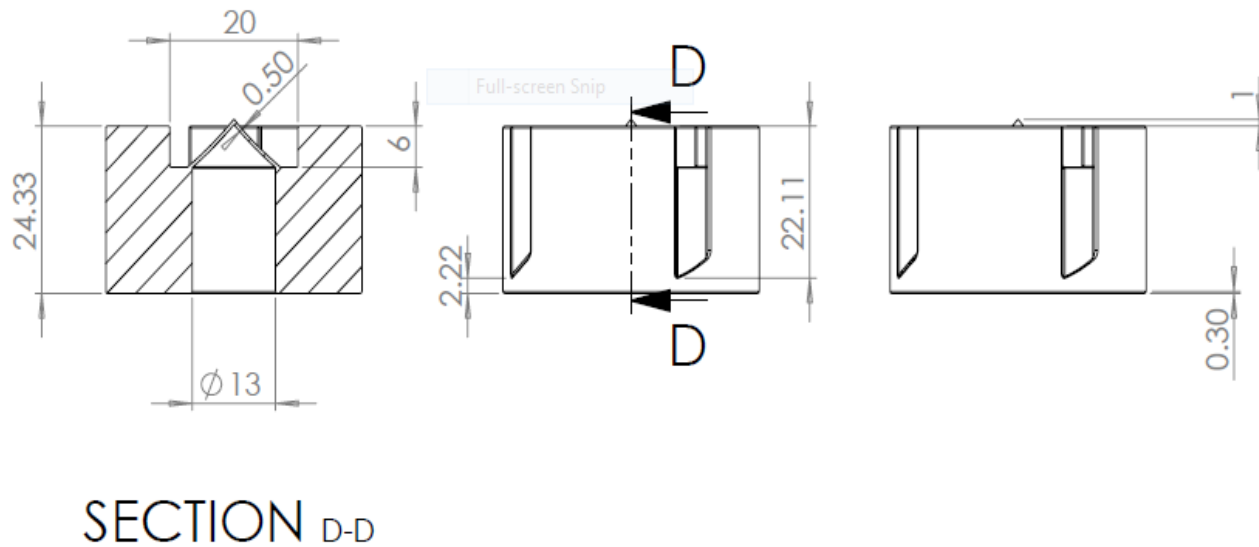


Figure4.9: The front/dimensions of impeller

The casing diameter is 50mm and there must be space to allow the blood flows the diameter of impeller 40m (decrease 10mm from casing diameter). The height of impeller is equal to height of casing to prevent blood leaking which cause and make clotting. Slope shape height (6mm) is suitable to make blood move smoothly and easy.

4.3 Manufacturing

There are three options to manufacture as in chapter2, but the option which found is turn machine. The material that are available and good to represent the project as simulation and also suitable to be manufactured by this machine is Teflon material. Teflon is solid with an extremely low coefficient of friction. It is commonly used as a non-stick coating for pans. Teflon can be used to make a variety of articles having a combination of mechanical, electrical, chemical, temperature, and friction-resisting properties unmatched by articles made of any other material. Commercial use of these and other valuable properties combined in one material has established Teflon

resins as outstanding engineering materials for use in many industrial and military applications. Teflon resins may also be compounded with fillers or reinforcing agents to modify their performance in use. The property of this material is represent in this table.

table 2 the property of Teflon material

Chemical Properties	Electrical Properties	Mechanical Properties
Chemical resistance to corrosive reagents	Low dielectric constant	Flexibility at low temperatures
No solubility and No adhesiveness	Low dissipation factor	Low coefficient of friction
Long-term weather ability and No flammability	High arc-resistance and surface resistivity and volume resistivity	Stability at high temperatures

4.3.1 Inlet part



Figure4.10: inlet part

In the figure above, the diameter of this part is different from diameter showed in computational model which is the first problem faced because the tools to manufacture device is not available such as limit of turn pens (the dimensions of this pen is too large than our device diameters) and the device is too small, so the

operator changed outer diameter from 17 to 20mm. The base of inlet also changed (inner diameter from 40 to 55mm, outer from 50 to 90mm).

4.3.2 the impeller

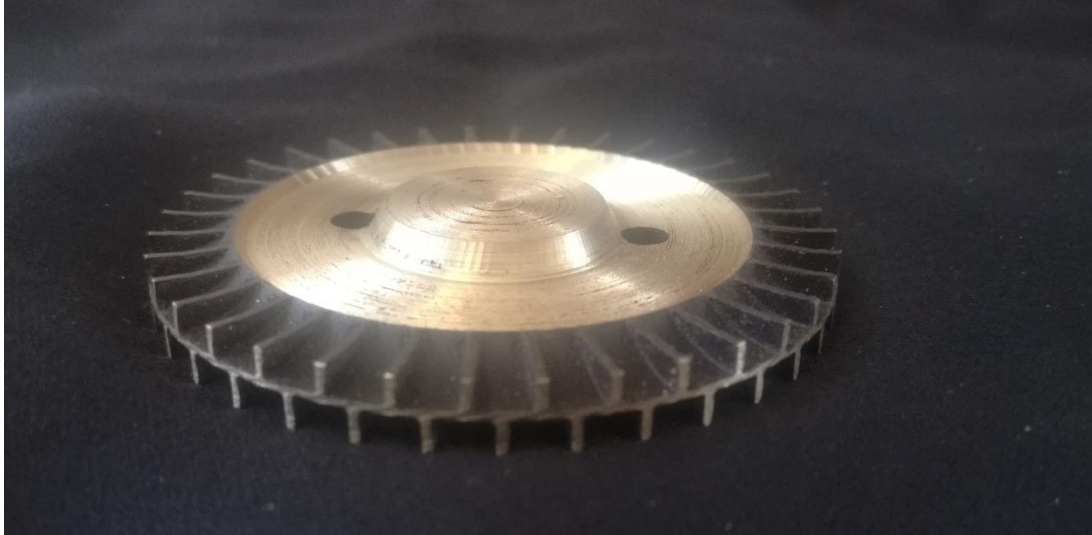


Figure4.11: the impeller

The design of impeller is complicate and the manufacturing machine is not able to design it, so it replaced by other impeller which provide similar function called semi open impeller as in chapter2. The dimension of new impeller (diameter 55mm and the space of blade is 5mm) this dimension produce greater stress due to its several number of plate than actual impeller and the blood can clash with the surface of impeller and can damage the blood cells.

4.3.3 Outlet part

the turn machine cannot manufacture irregular shape. so that the outlet is manufactured as outer part and then attached it with the center of device which cause the flow diffuser and irregular (resist the flow) as in chapter2 which is different from design in computational model. This change in dimensions (inlet, impeller and outlet) cause change in flow rate(5L/min), also the DC motor cannot use in this devicebecause it has large size, large thickness and the impeller is heavy and cannot rotate so used AC motor which has high efficiency and long shaft.

Chapter 5

Result and discussion

As in chapter 3 the flow rate of the pump is 5l/min but there is no specific velocity to get it. In solid work assumed different velocity to reach this flow rate (5l/min). First, apply 5000RPM and found the flow rate equal (0.50228l/min) as in fig (5.1)

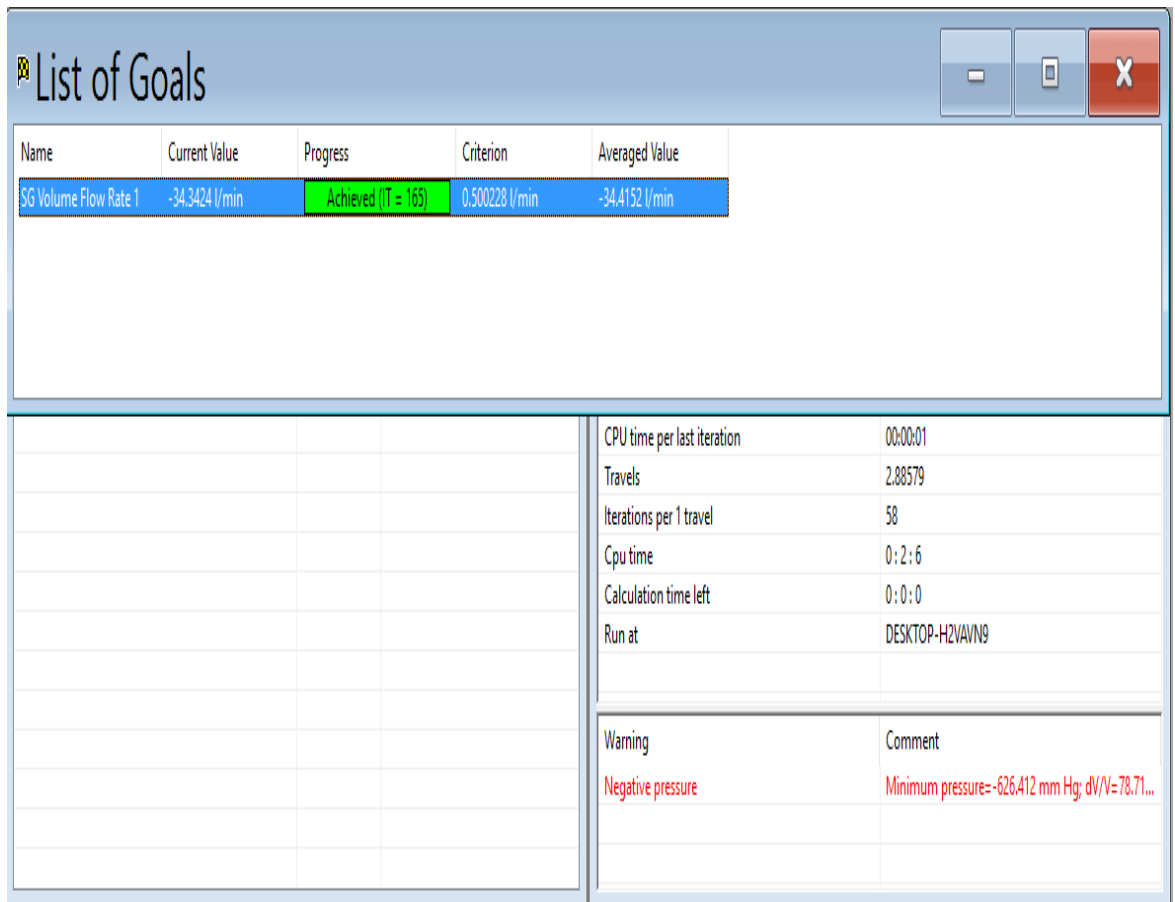


Figure5.1: the flow rate of 5000RPM

The flow rate does not equal 5l/min because the velocity is not enough according to the direct relation between velocity and flow rate ($Q=A*V$) as in chapter 3, so increased the velocity of impeller to 10000RPM and find result as in fig (5.2)

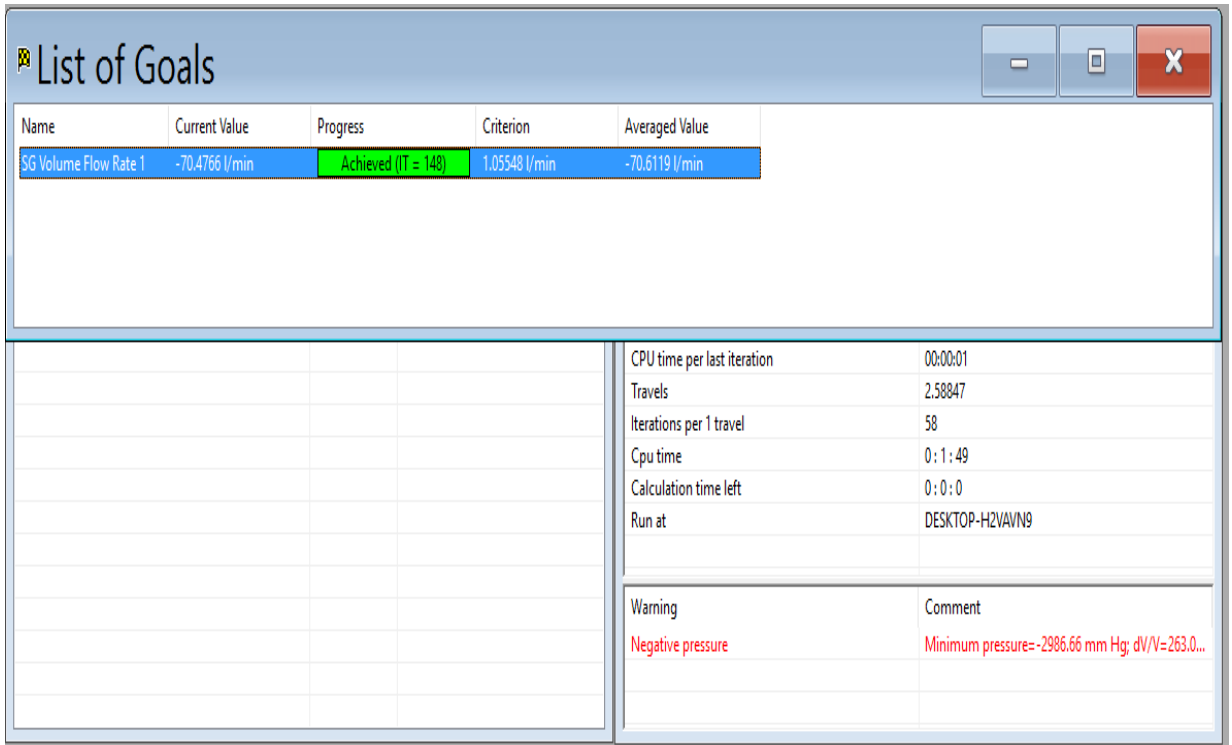


Figure5.2: the flow rate of 10000RPM

Still the flow rate not equal 5l/min(1.05L/min), so must increase the velocity of impeller more larger than above velocity to 40000RPM, the result equal 4.8L/min as infig(5.3).

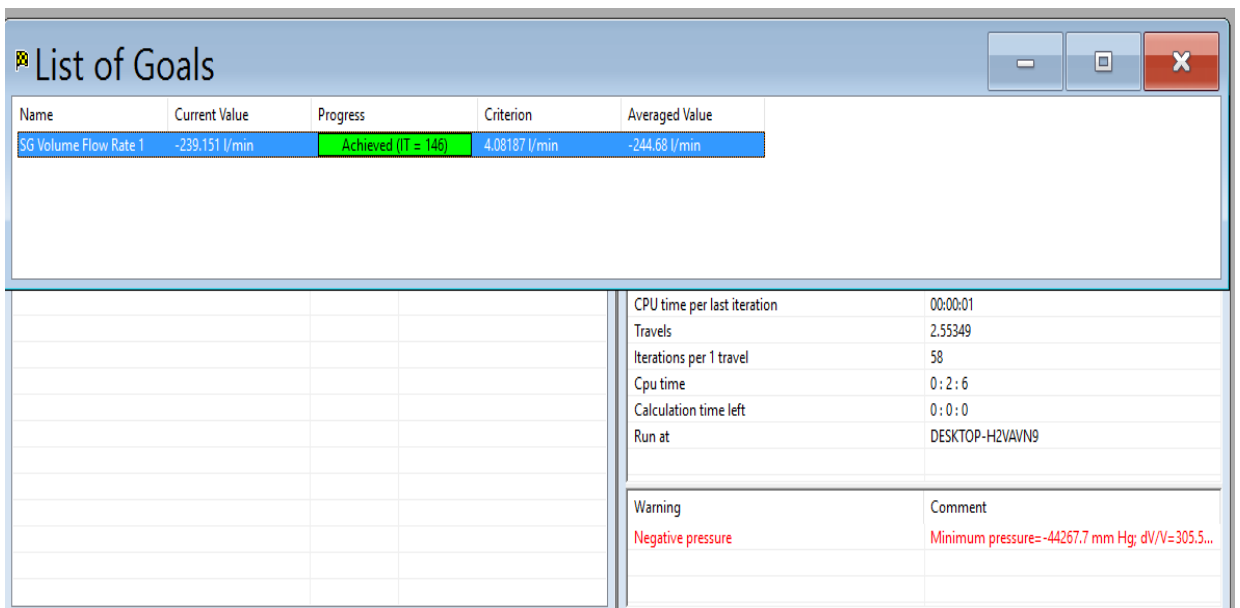


Figure5.3: the flow rate of 40000RPM

Still did not get result, the result of 5.1l/min come from applying 50000RPM as in fig (5.4) and accept this velocity of impeller to use it in our design.

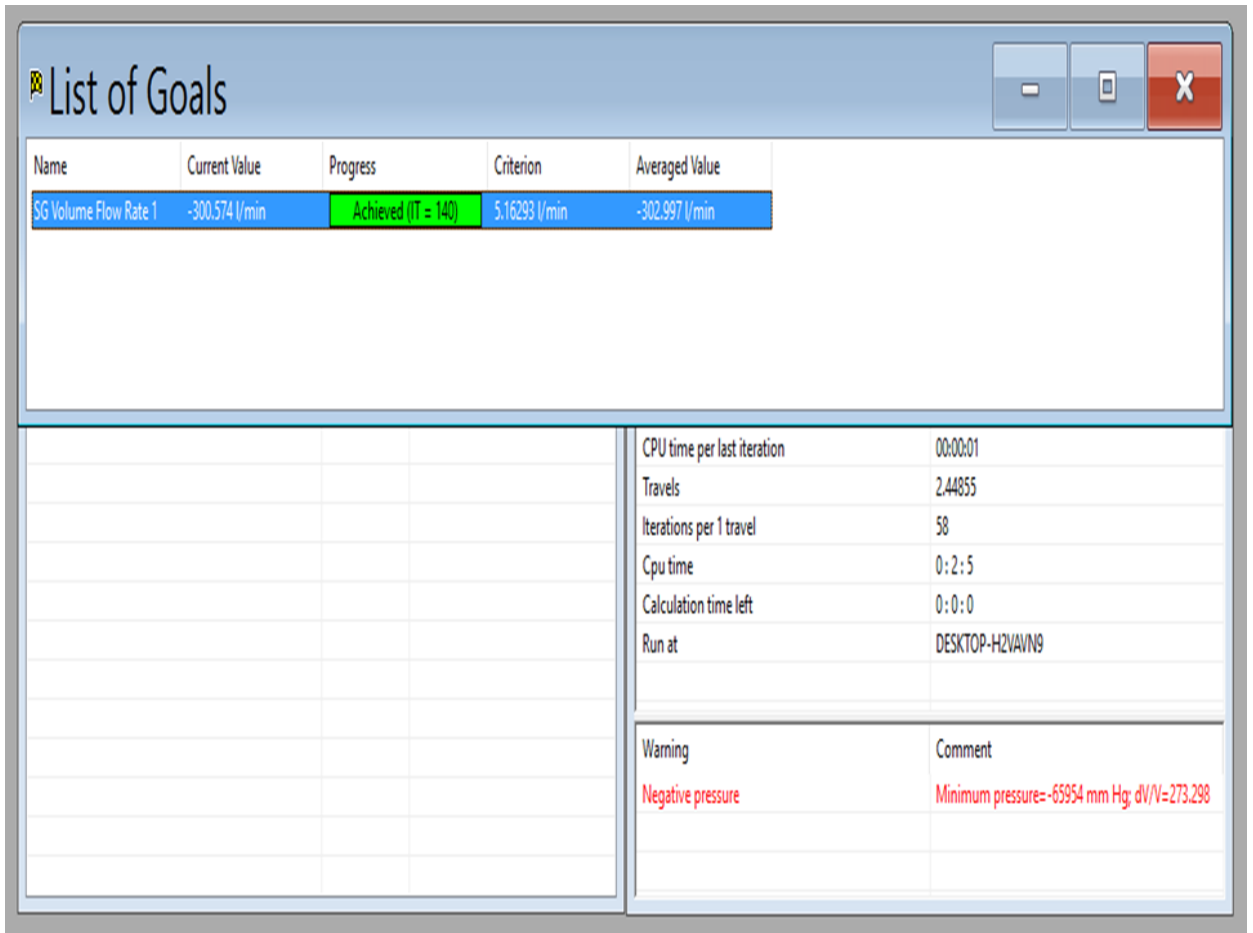


Figure5.4: the flow rate of 50000RPM

5.1 The effect of 50000RPM in pressure of the device

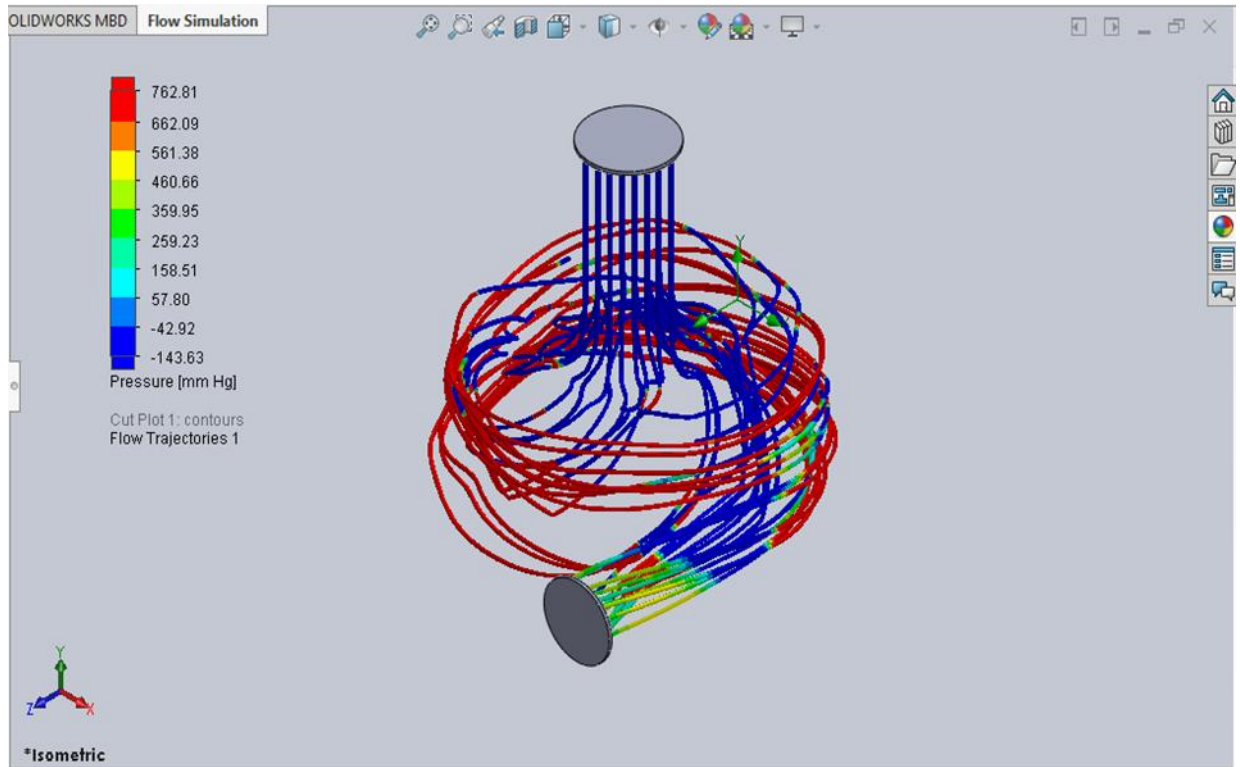


Figure5.5: the distribution of pressure

In the figure above, the pressure at input of case equal (-143.68mmHg) as in blue area in the figure, which is negative pressure to section the blood because the maximum pressure in the heart is 120mmHg so the pressure must be larger than in the heart to section it, and (-) refer to negative pressure. The pressure increase until arrived 762.81mmHg (red regions) because the area that blood flow in it become very small($P=F/A$). the pressure in the plate of impeller is approximately from -42.92 to 57.80mmHg which in the range of pressure in mathematical modelling as in chapter3. After the red region the pressure decrease as in blue area because in the design this area be large and cause low pressure. Again the pressure increase from 259.23 to 561.38mmHg in green region, because this area is decrease to 12mm which cause this high pressure. An additional potential concern of this device (the mechanism of working is 2nd generation rotary pumps is related to its hydrodynamic performance. To observe changes in pump flow at a fixed rotor speed, significant changes in pressure across the inlet and outlet orifices of the pump must occur. This relative degree of insensitivity of the hydrodynamic performance of the pump or

“steep” pressure-flow relationship can result in left ventricular collapse and “suction”.

5.2 The effect of 50000RPM in velocity of flow

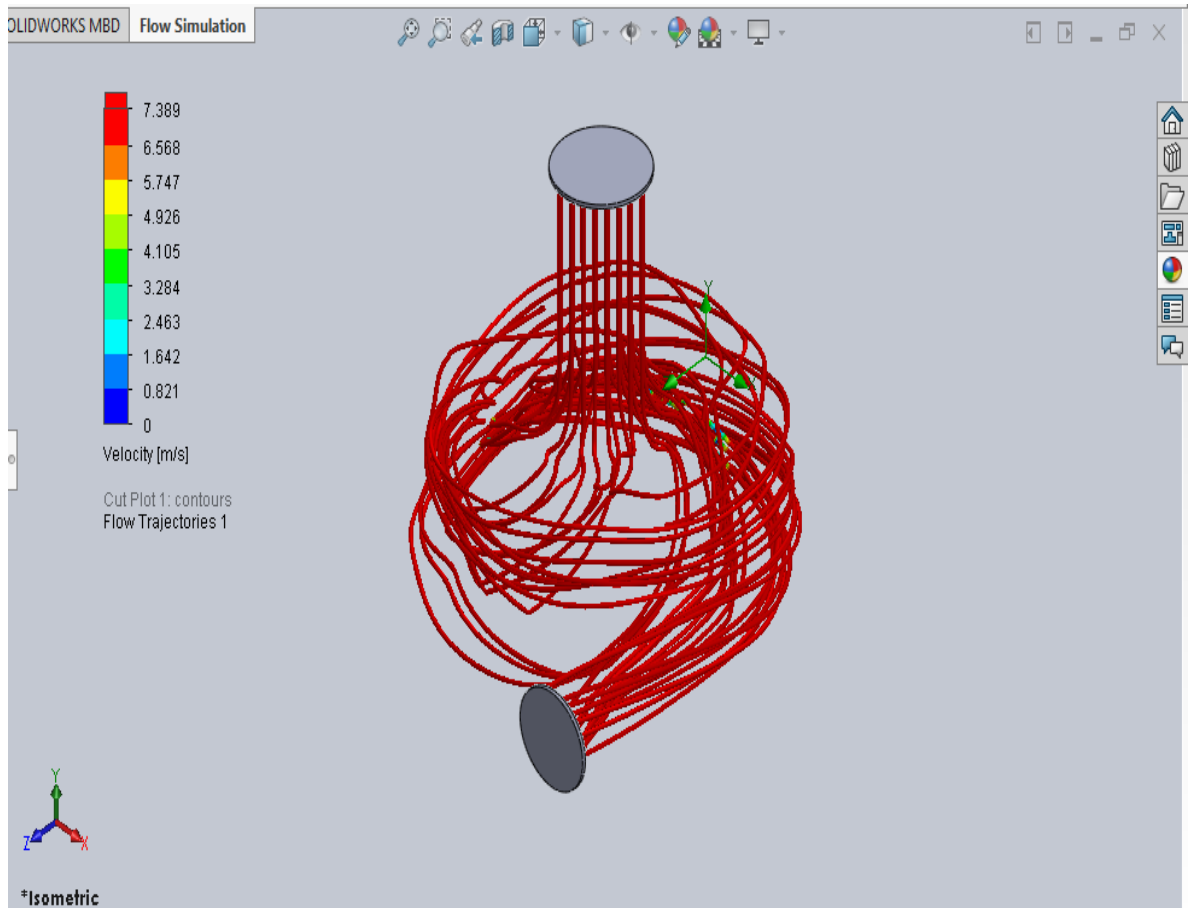


Figure5.6: the distribution of flow velocity

The maximum velocity of flow that obtain in solid work analysis is equal 7.89m/s and all area have the same distribution of velocity (all part is red) because the flow of blood is fixed (not change) that because the velocity to section blood is fixed. The velocity of flow (7.89m/s) is equal 3485.5RPM which is closely to velocity of Heart ware in scientific paper as in chapter 3.

5.3 The effect of 50000RPM in temperature

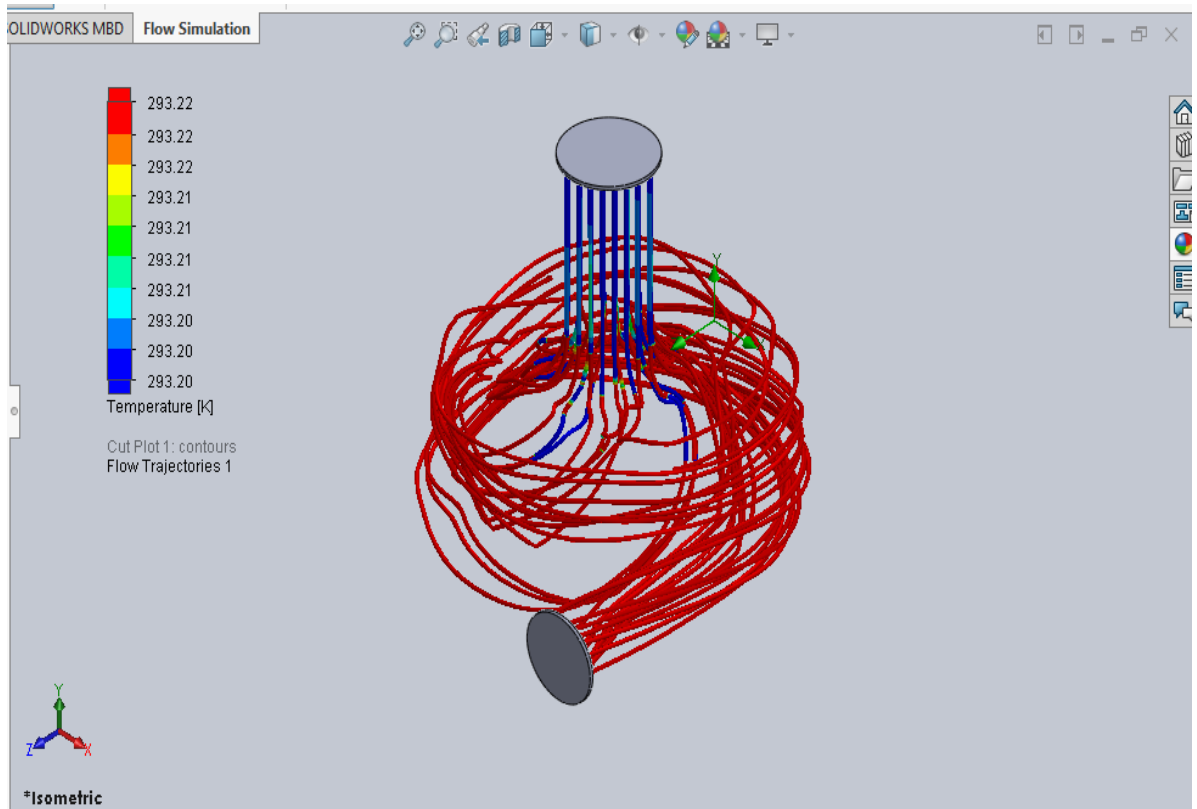


Figure5.7: the distribution of temperature in the device

In temperature analysis which is the result of friction, found the distribution of heat in the device equal 293.22k (20.22C) which mean the device do not affect to the body and nots increase the temperature of the blood.

Chapter 6

Conclusion and Recommendations

6.1 Conclusion

Cardiovascular disease, and heart failure specifically, are increasingly prevalent in today's world and the improvement of treatments will help save lives. VADs are already in use clinically but have the potential to benefit many more patients if their current shortcomings can be eliminated. Solid work is an invaluable tool in the development of VADs, enabling new designs to be tested rapidly and undesirable flow characteristics eliminated in successive versions before prototypes are manufacture. Solid work is used for predicting velocity –flow characteristics to obtain a suitable velocity that produce 5 l/min which is 50000RPM and also tested the parameter associated the velocity (pressure and temperature). the negative pressure to section blood is (-23mmHg) and other pressure in the device is different as the different in the area. The result of temperature from friction is 22C which is low than 37C. For manufacture the device,turns machine and Teflon material is used, the result after manufacture is not like actual result (5l/min) because the demission of the device is not correct.

6.2 Recommendations

After the project is completed, found that there is some lack specially in manufacture as in chapter 3, thus there is future work:

- 1- use 3D printer or CNC machine instead of turn machine.
- 2- use magnetic levitation (non-contact bearing) to rotate impeller instead of DC motor.
- 3- the material for manufacture must be change to hybrid titanium-ceramic.

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