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**COLLEGE OF ENGINEERING**

**DEPARTMENT OF COMPUTER ENGINEERING**

**BSC. BIOMEDICAL ENGINEERING**

**PROJECT:**

# AUTOMATED NEONATAL EXCHANGE TRANSFUSION (ANET) SYSTEM

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**JUNE 2020**

# DECLARATION

We hereby declare that this project is our own original work towards the partial fulfilment of the requirement for the award of an undergraduate Bachelor of Science degree (BSc.) in Biomedical Engineering. We also declare that, to the very best of our knowledge, this report contains no material that has been previously published by another person, neither does it contain any material which has been accepted for the award of any other degree of the university, except where due acknowledgment has been made in the text.

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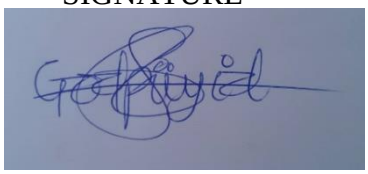
| (5962616) |  | 26/06/2020 |
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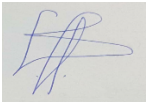
| (2279214) |  | 27/06/2020 |

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Foremost, our deepest gratitude goes to God, in whose undeserved favour we walk, growing in knowledge and in strength from day to day. His Holy Name be blessed, for without Him this work wouldn't be birthed.

Our sincere appreciation goes to our supervisor, Mr. Prince Odame for His encouragement, guidance and input throughout the project. We are also grateful to Dr. Mrs. Adoma Odame for her immense support and advice in this great project. May the good Lord bless and keep you.

To all staff of HopeXchange Medical Centre, who helped us in collecting most of the data and materials we needed, and in running our tests, we say "ayekoo". May you walk in fullness of life to the glory of God's name.

An "immeasurable thank you" to our parents for their contributions, corrections, prayers, and a lot more. May you all enjoy divine health and long life.

Never forgetting Zaks Electronics for his advice and provision of electronic components for the implementation of this project.

May God richly bless you all.

# DEDICATION

This project is dedicated to Dr. Mrs Adoma Odame and also to our families.

# ABSTRACT

In times past, a lot of babies died from life-threatening blood disorders such as haemolytic disease of the newborn and neonatal hyperbilirubinaemia. Many others developed lifelong encephalopathies. It was not until the early years of the twentieth century that a medical intervention called exchange transfusion came into the scene. It made so much of an enormous influence in the history of neonatology.

Not long after that, phototherapy and intravenous immunoglobin transfusion, among others, were introduced. Nevertheless, they were not able to deal with all situations of life-threatening blood abnormalities; exchange transfusion was therefore not totally be wiped out. The exchange transfusion procedure however is not so simple. It is very tedious and stressful, lasting for about two hours. And in our part of the world where we lack most of these sophisticated equipment to reduce the need for carrying out the procedure, exchange transfusion is very common. This project addresses the problem of stress, by seeking to automate the procedure.

The automation employs a syringe pump design to control the pumping of blood in and out of the baby, and a valve control design to control the direction of blood flow. The device was designed and built to 95% completion, with some few analysis run on it. Our inability to complete the project implementation was due to the outbreak of the coronavirus pandemic. Hence, access to shops and other places of interest were restricted. We hope to be able to get some form of sponsorship to make this project a dream come true.

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# CHAPTER ONE

# INTRODUCTION

This chapter gives a brief introduction on the project; projecting its background and essence, scope and objectives, and its significance to the advancement of the health sector in our nation, Ghana.

## 1.1 BACKGROUND

Neonatal hyperbilirubinaemia is a leading cause of lifelong neurodevelopmental impairment[1]. An estimate of over 50% of term infants and 80% of preterm infants develop jaundice, usually between two to four days after birth. It is extremely common because most new-borns develop close to significantly high levels of serum bilirubin (SBR) during their first week of life. These high levels of bilirubin in new-borns is due to the immature nature of their internal body organs such as the liver, to perform their functions in reducing levels of bilirubin in the blood. After a few days, this condition may disappear on its own.[2] But for many babies, it does not. The effects of hyperbilirubinaemia are detrimental to a baby's health; namely, encephalopathies.

Quite a number of therapeutic modalities have evolved throughout the years and decades. Exchange transfusion was the first life-saving medical intervention for this situation.[3] However, in the contemporary western world, exchange transfusion is rarely performed due to more sophisticated interventions such as phototherapy and intravenous immunoglobin transfusion. Nevertheless, kernicterus (an adverse effect of hyperbilirubinaemia that affects the brain) still occurs even in these highly-resourced settings in spite of evidence-based guidelines. There are quite a few population-based studies (from the United Kingdom, Canada, the United States of America, etc.) on the incidence of extreme neonatal hyperbilirubinaemia and kernicterus.[1]

Notwithstanding, in our country, Ghana, most of our hospitals are less-endowed when it comes to modern hospital equipment. Currently, the only alternative apart from exchange transfusion is phototherapy; which is not effective for severe hyperbilirubinaemia. Currently, no public hospital in Ghana has a highly intense phototherapy unit; the kind that can treat severe hyperbilirubinaemia. Exchange transfusion has therefore been the frequent last resort for babies with

hyperbilirubinaemia in our part of the world. This calls for a look into that life-saving procedure for ways of ensuring its efficiency and efficacy.

## 1.2 PROBLEM STATEMENT

In Ghana and other parts of the African continent, and the world at large, neonatal exchange transfusion is usually carried out by a physician and an assisting nurse(s). The procedure last for an average of two hours, during which the physician will have to pump blood in and out of the baby's body. This must be done very slowly and steadily in cycles to avoid iron overload, which can cause damage to the heart, liver and other organs in the baby's body. All these make the whole procedure tedious and very stressful, such that some doctors may not even want to perform it. Meanwhile, it is an effective life-saving procedure for babies with life-threatening blood abnormalities. This calls for an intervention in automating the procedure.

## 1.3 MAIN OBJECTIVE

The key objective of this project is to design and build a device that automates the neonatal exchange transfusion procedure.

## 1.4 SPECIFIC OBJECTIVES

The specific objectives of this project are as follows:

i) To relieve paediatricians of the stress they go through during the exchange transfusion procedure.

ii) To alleviate the errors and accompanying problems that could result from the stress on the paediatrician.

iii) To produce a low-cost neonatal exchange transfusion device with reference to the one-catheter-push-pull method.

iv) To reduce the average time taken to carry out the procedure.

## 1.5 SCOPE OF THE PROJECT

This project involves the use of motors to control the movement of blood through valves to and from designated locations in the exchange transfusion set-up. This will almost eliminate any human intervention in the procedure.

## 1.6 SIGNIFICANCE OF THE PROJECT

The significance of this project cannot be overemphasized. The automation of the neonatal exchange transfusion comes as a relief to many doctors and health workers. Moreover, the final product of this project will not be affected by power fluctuations, since its main power source is from powerful batteries. Furthermore, its cost as compared to many other medical devices is very low, and can be purchased by the average hospital in Ghana.

# CHAPTER TWO

# LITERATURE REVIEW

This chapter talks about exchange transfusion in detail; explaining its etymology and history, essence, procedures and different techniques, the likely complications that accompany it, and finally wraps up with a review on a few examples of some previous projects on exchange transfusion.

## 2.1 EXCHANGE TRANSFUSION

Exchange transfusion is life-saving medical procedure that is carried out to counteract the effects of life-threatening blood abnormalities.[4] These include jaundice, sickle-cell disease, severe malaria, acute cerebrovascular event (stroke), polycythaemia, acute chest syndrome (with respiratory failure), haemolytic disease of the new-born, multi-organ failure, mesenteric girdle syndrome, etc. In this procedure, aliquots of the patient's blood, which is designated as being 'bad blood', are removed and replaced with aliquots of the donor's blood, designated as 'good'. This is what calls for its name – exchange transfusion, blood is removed and replaced; an exchange. Because of this, exchange transfusion is also called substitution transfusion or replacement transfusion. In simple blood transfusions, blood is imply added, but not removed; there is no exchange of blood. It is called a blood transfusion process because, there is some mixing/fusion of the 'old' blood and the 'new' blood. Exchange transfusion is always allogenic, i.e. the new blood which is clean is always from a donor.

## 2.2 HISTORY OF EXCHANGE TRANSFUSION

From before the ancient Byzantium, there was no successful medical intervention for babies with blood abnormalities. Babies with life-threatening disorders or abnormalities in their blood usually died or developed irreversible serious illnesses. It was not until the twentieth century exchange transfusion came into the scene. A physician from Toronto's Hospital for Sick Children, Dr. Alfred P. Hart, in 1925 was the first to perform an exchange transfusion to treat haemolytic disease of the new-born.[5] The technique, exchange transfusion, was originally developed and named by Alexander Weiner, even though it was hinted by a Canadian surgeon, Dr. Bruce Robertson in 1921.

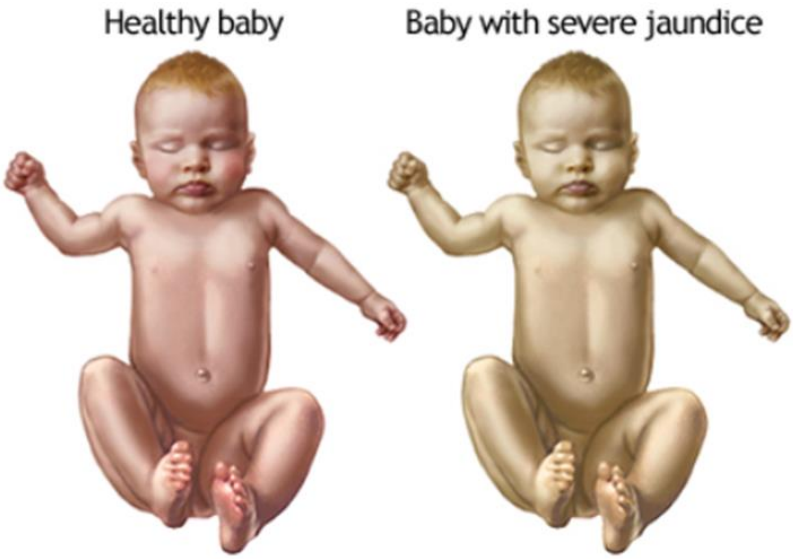
It was used in the treatment of severe burns in children. Blood was withdrawn from the femoral vein, external jugular vein, longitudinal sinus, or radial artery of the young child and replaced with fresh donor blood by way of a cut-down at the ankle. This procedure and a few other modifications of it were technically difficult, had significant complications and went unnoticed and unused, until 1946. These were supplanted by a method introduced by Dr Louis K. Diamond. He used the umbilical vein only to perform the exchange transfusion.[6] His method was relatively simple and safe was rapidly adopted around the world.[7] It made an enormous historical influence in neonatology. Exchange transfusion became so much common. In later years, the introduction of phototherapy and other medications have reduced the need for exchange transfusion. When phototherapy is initiated early, it is usually effective at controlling hyperbilirubinaemia in infants.[6][8] The use of ante-natal anti-Rh D antibody prophylaxis and screening for iso-sensitization has reduced the occurrence of haemolytic disease of the new-born, hence a reduction in the need for an exchange transfusion.[8][7]

## 2.3 ITS ESSENCE

Exchange transfusion can be done in both children and adults. But it is most commonly performed in children especially neonates/new-borns. When done in neonates, it is called neonatal exchange transfusion. Neonatal exchange transfusion is usually the last resort for the treatment of hyperbilirubinaemia (which causes jaundice) and haemolytic disease of the new-born.[9] With hyperbilirubinaemia, when other therapeutic modalities such as early and intensive use of phototherapy have proved ineffective (either by failure or insufficiency), then the doctor can perform an exchange transfusion with the consent of the parents of the baby. When performing neonatal exchange transfusion, the aim depends on the problem. So, for hyperbilirubinaemia, it is to reduce the serum bilirubin (SBR) level and to lower the risk of brain damage. For haemolytic disease of the new-born, it is to remove the infant's affected red blood cells and the circulating maternal antibodies to reduce destruction of the baby's red blood cells. The doctor may also aim for the correction of anaemia and the treatment of any potential for heart failure whilst maintaining a normal amount of blood.[9]

Hyperbilirubinaemia refers to a medical condition in which there is a build-up of so much bilirubin in the blood, resulting in a yellow discoloration of the skin and eyes; a state called jaundice. Figure

1 below shows a healthy baby and the same baby with jaundice. Bilirubin is a natural bi-product from the breakdown of red blood cells. The liver plays the role of converting unconjugated bilirubin to conjugated bilirubin. Unconjugated bilirubin is simply bilirubin that is 'free', it is not bonded or bound. It is very dangerous when in high amounts; it becomes very toxic. For new-borns, their liver is immature and does not play this role properly. Hence there is a little build-up of bilirubin in the blood. A few days after birth, the liver may now function well. But if it doesn't or due to other conditions, there will be a great build-up of bilirubin in the blood, which will result in jaundice. Severe hyperbilirubinaemia can cause serious brain damage, deafness and death, a medical condition called kernicterus. Phototherapy, as shown in figure 3 below, is usually the first treatment method applied, but when it is ineffective, then an exchange transfusion must be




performed to save the life of the baby. Hyperbilirubinaemia is very common, affecting 60% of term neonates and 80% of preterm neonates.

*Figure 1: Healthy baby vs Baby with severe jaundice*

Haemolytic disease of the new-born (HDN) refers to the medical condition where there is the premature breakdown of the new-born's red blood cells because of incompatibility of the blood types of the mother and the baby. The mother's antibodies attack the baby's red blood cells and they are broken down and destroyed (a process called haemolysis). HDN causes enlargement of organs and hyperbilirubinaemia. Hyperbilirubinaemia occurs in this case too; because the

breakdown of red blood cells produces bilirubin; hence, rapid breakdown will ultimately lead to hyperbilirubinaemia. Intravenous immunoglobin (IVIG) as shown in figure 2 below may be

administered to reduce the breakdown of red blood cells.[7] But an exchange transfusion will be needed to save the life of the baby if it proves ineffective.[9]

*Figure 2: Intravenous Immunoglobin injection (**left**)*

*Figure 3: Phototherapy unit (**right**)*

## 2.4 BLOOD VOLUME CALCULATIONS

For any neonatal exchange transfusion, we calculate the blood volume to be exchanged using an estimate of the baby's circulating blood volume. For term babies, the estimate is between 70-90ml/kg, and for preterm babies, the estimate is between 85-110ml/kg. On the average, 80ml/kg is used for terms and 100ml/kg is used for preterms.[10] Depending on the severity of the situation that calls for exchange transfusion, there are basically two main approaches that either is employed, although the latter is mostly preferred.

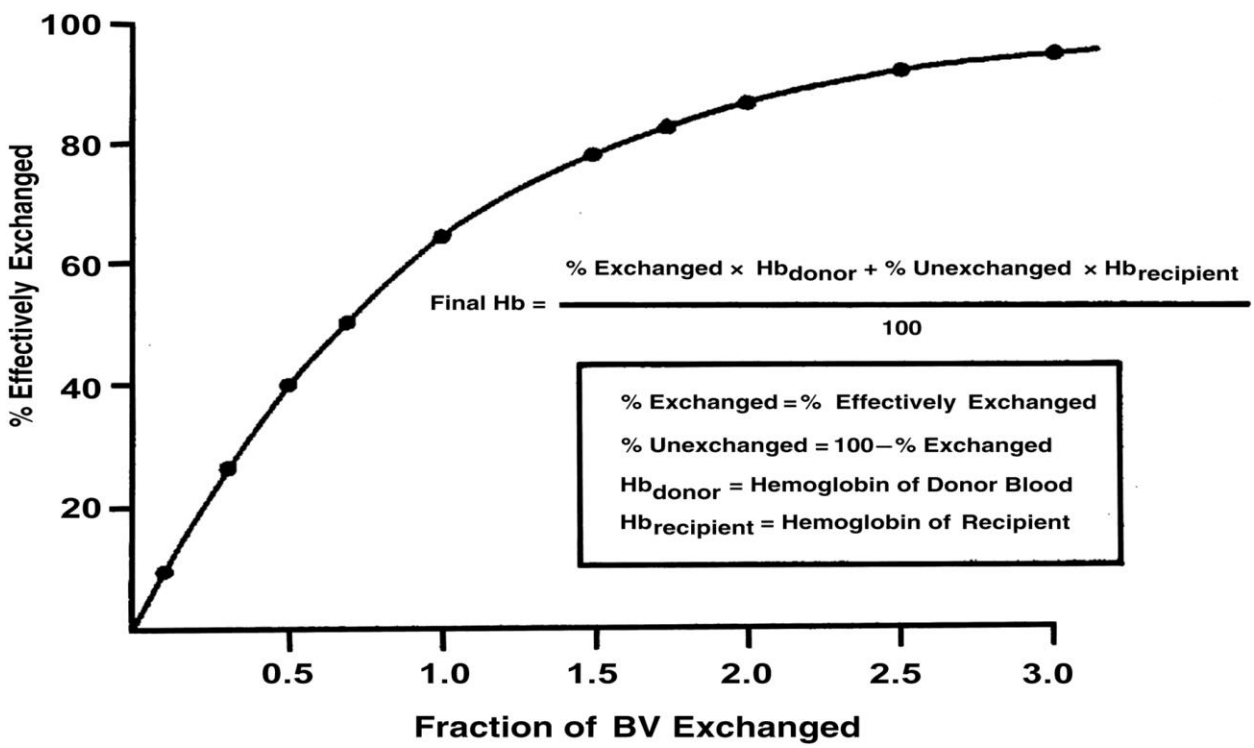
- **Single Volume Exchange Transfusion**

Here, the estimated volume is equal to one times the circulating blood volume of the baby. For example, performing single volume transfusion on a term would require just 80ml/kg of blood volume. This approach replaces about 60-65% of the baby's blood volume or red blood cells.

- **Double Volume Exchange Transfusion**

In simple terms, it is performing the single volume exchange transfusion twice. The estimated volume is equal to two times the circulating blood volume of the baby. For example, performing double volume exchange transfusion on a term would require 160ml/kg (80ml/kg ×2) of the blood volume. It replaces about 85-88% of the baby's blood volume or red blood cells.

The latter is the most commonly used and it is mainly used for the management of hyperbilirubinaemia and haemolytic disease of the new-born. One might have expected the double volume exchange transfusion to be twice as efficient as the single volume exchange transfusion. But it is not actually so. The efficiency increases by an average of just 25% (i.e. from 80 to 85). The more the number of circulating blood volume exchange, the lesser the percentage increase in efficiency. It is recorded that an exchange of about 500ml, performed by Dr. Diamond, achieved an efficiency of 90%. Not so much of an advantage over the double volume exchange. It is almost impossible to exchange 100% of the baby's blood circulating volume. This is because the baby's blood mixes with the incoming blood during circulation. Comparing the efficiency to the number of circulating blood volumes, the double volume exchange transfusion is ideal; minimizing waste by saving time, energy and resources while keeping a good efficiency. The graph in figure 4 below shows a plot of percentage of effectively exchanged blood versus the fraction of circulating blood volume exchanged. It describes what has just been explained above. The curve is asymptotic to



the 100 percentage on the ordinate. It can also be seen that, the higher the amount of circulating blood volume exchanged, the lesser the increase in efficiency/effectiveness.

*Figure 4: Graph showing efficiency of amount of blood volume exchanged.*

## 2.5 EXCHANGE TRANSFUSION TECHNIQUES

There are different methods or techniques of performing exchange transfusion. These include the one catheter push-pull technique and the two-catheter push-pull technique.

### 2.5.1 TWO CATHETER PUSH-PULL TECHNIQUE

This method is also called the Isovolumetric Method.[9] Here, equal volumes of blood are withdrawn and infused simultaneously using two blood lines. Figure 5 below shows the set-up using the umbilical vein and umbilical artery whilst figure 6 shows the set-up using a peripheral vein and a peripheral artery.

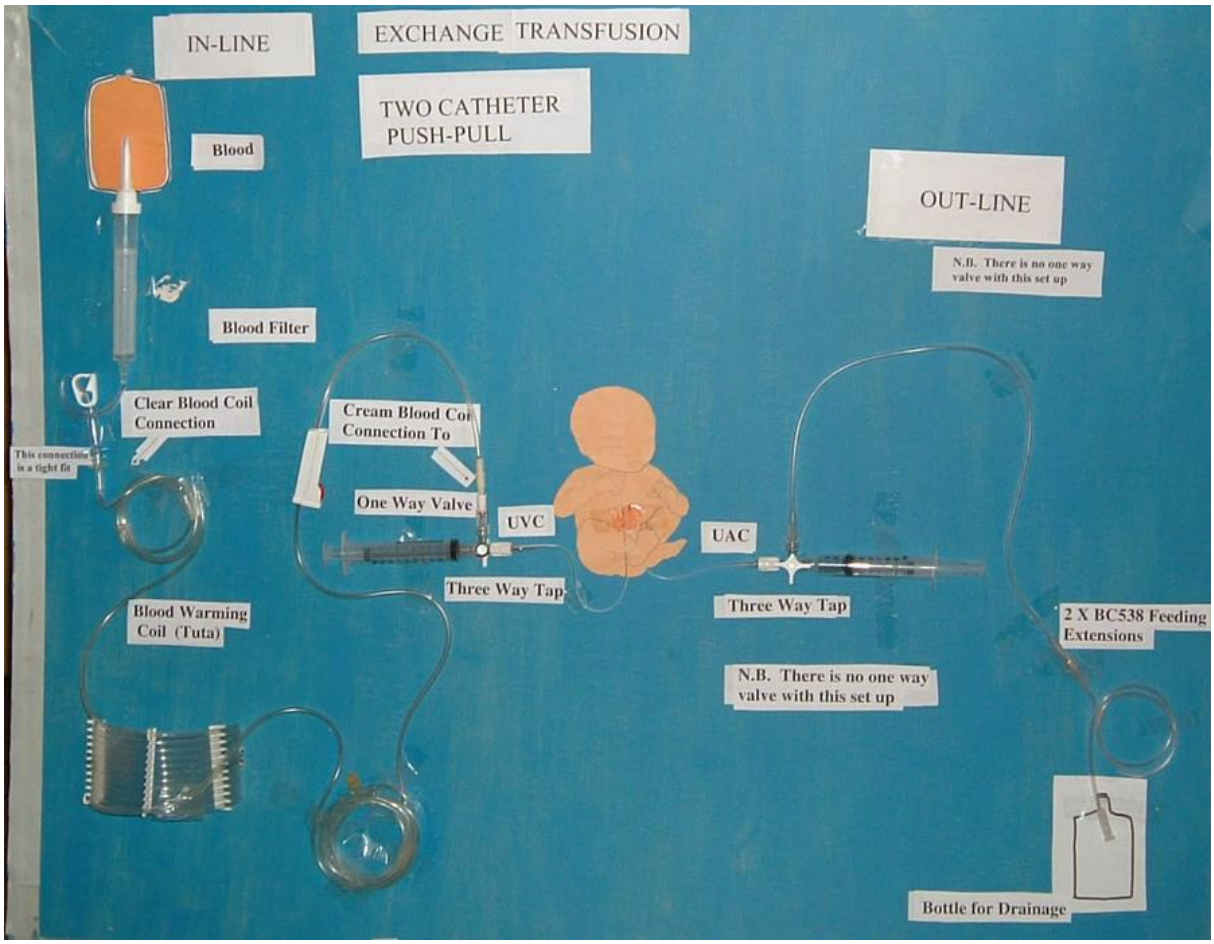


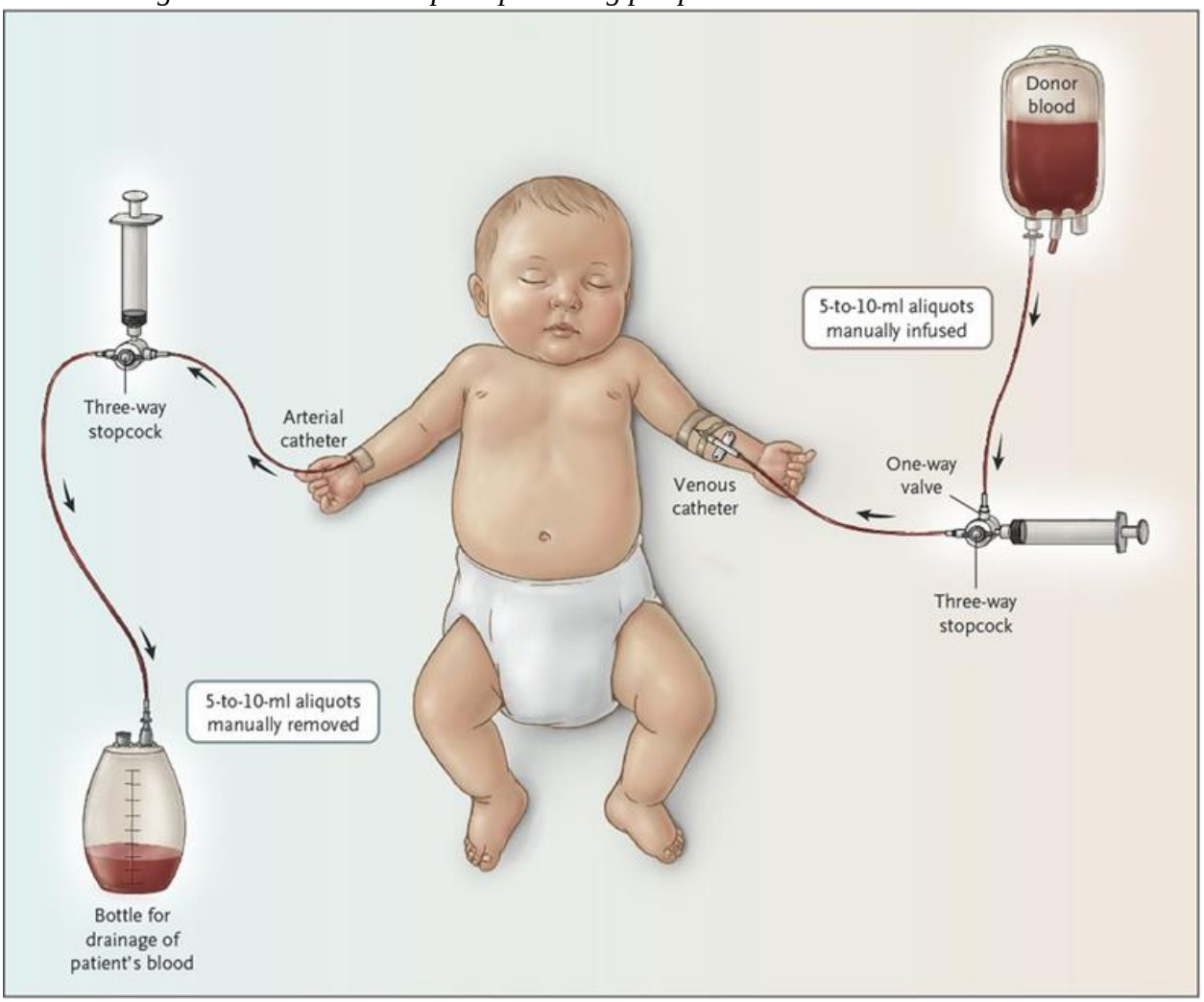

*Figure 5: Two catheter push-pull technique*

These lines can either be arterial and/or venous, being peripheral or central. It should be noted that arterial lines are only for withdrawal of infant blood, and not for donor blood.[10] This is because arterial blood pressure is much higher than venous blood pressure. The table below shows the different line pairs that can be used for performing exchange transfusion using the two-catheter push-pull technique:

*Table 1: Two catheter push-pull blood line pairs for exchange transfusion*

| **BLOOD INLET** | **BLOOD OUTLET** |
|---|---|
| Peripheral vein | Umbilical vein |
| Peripheral vein | Umbilical artery |
| Peripheral vein | Peripheral artery |
| Umbilical vein | Peripheral artery |

*Figure 6: Two catheter push-pull using peripheral arterial and venous lines*




Exchange transfusions are most readily performed via the umbilical vein, i.e. using the one catheter push-pull method catheter (yet to be discussed in this text). Moreover, our project does not employ the isovolumetric technique; hence, we wouldn't dwell much on it. We are automating the one catheter push-pull method. It is the method used by our supervising doctor in Ghana here, and as already stated, it is widely used in our part of the world and the whole world at large.

### 2.5.2 ONE CATHETER PUSH-PULL TECHNIQUE

This technique employs the use of an umbilical venous catheter. It is the method that was introduced by Dr. Louis Diamond in 1946 and is known as the classical one-way technique. He

demonstrated that the most effective therapy would be the removal of as much of the baby's blood as possible and its replacement with Rhesus-negative blood. Hence, access to a large and readily accessible blood vessel is required, of which the vein in the umbilical cord dominantly presents itself. This technique is quite simple and easy as compared to other techniques; a reason why it is widely preferred. Here, small aliquots of blood are exchanged in a number of cycles until the estimated circulating blood volume is reached. The volume of blood that is exchanged as an aliquot, is dependent on the baby's weight. This is because, per the weight of the baby, if greater than a certain amount of blood is withdrawn, the baby may pass out, or develop some organ failures. Hence, the criterion below is used to choose the volume of blood to be exchanged in a cycle. The physician may not go by this to the letter due to the baby's situation; he/she may use smaller volumes than these or greater.

- For a baby's whose weight is lesser than 1500g (1.5kg), we administer 5ml of blood per cycle until the estimated circulating blood volume is reached.
- For a baby's whose weight is between 1500g – 2500g (1.5kg – 2.5kg), we administer 10ml of blood per cycle until the estimated circulating blood volume is reached.
- For a baby's whose weight is between 2500g – 3500g (2.5kg – 3.5kg), we administer 15ml of blood per cycle until the estimated circulating blood volume is reached.
- For a baby's whose weight is greater than 3500g (3.5kg), we administer 20ml of blood per cycle until the estimated circulating blood volume is reached.[10]

With this technique, the umbilical vein is catheterized and then the catheter is connected to two three-way taps or stopcocks that are connected in series. The end of the series connection is then connected to a syringe. Figure 7 below is a diagrammatic representation of the simple connection of the one catheter push-pull technique.

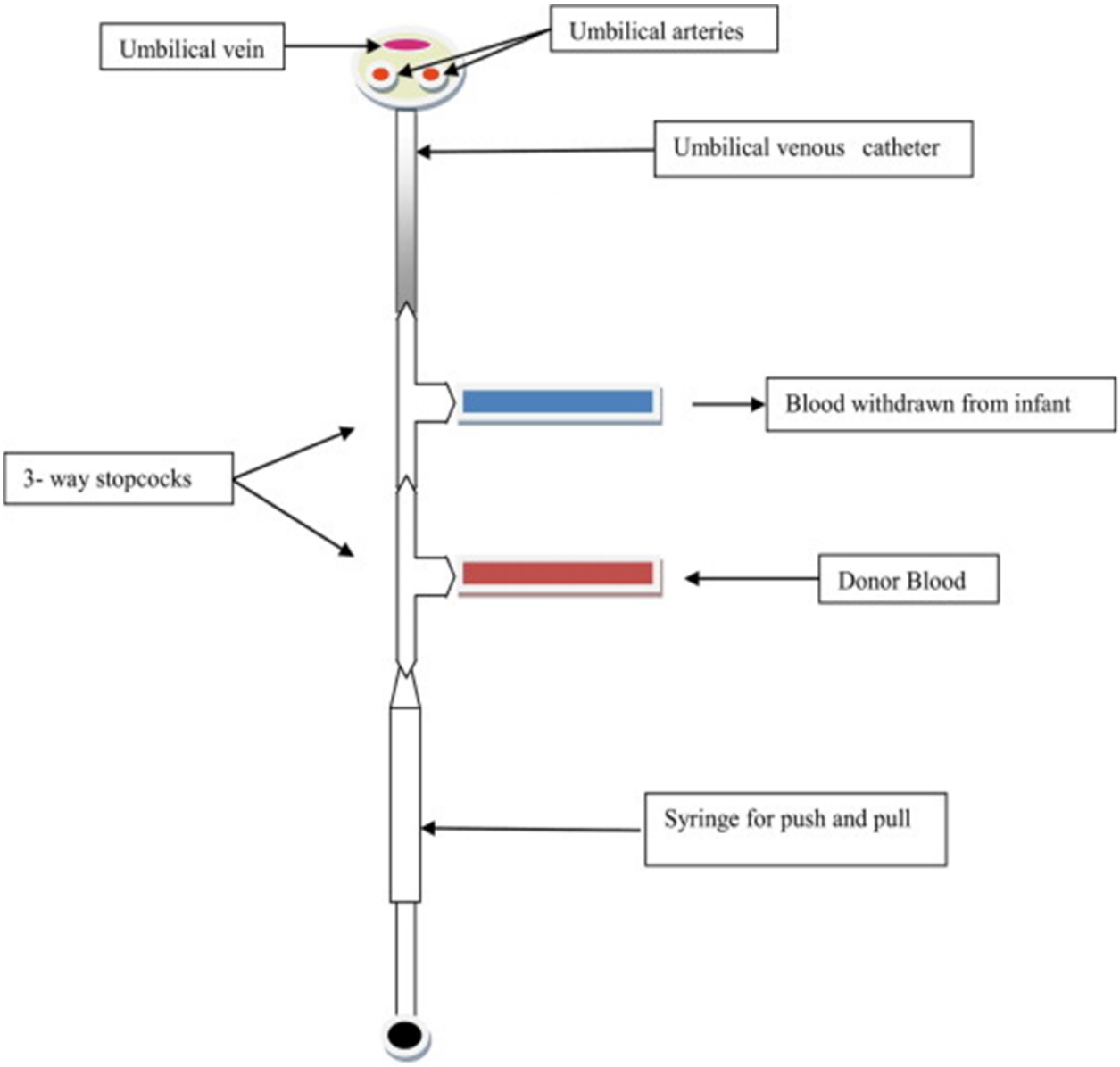



*Figure 7: Diagrammatic representation of connections in one catheter push-pull technique*

Using the one catheter push-pull method, a cycle refers to the complete sequence of actions that are used to perform an exchange of a single calculated aliquot of blood volume.

A complete cycle comprises:

- Slowly withdrawing a predetermined quantity of blood from the baby
- Discarding the blood withdrawn from the baby
- Withdrawing the same quantity of blood (taken from the baby) from the donor blood bag
- Slowly infusing the donor's blood into the baby

With withdrawal of blood from the baby, it is done slowly over 2 minutes, and slightly faster when infusing blood to the baby. The average time for which a cycle lasts is about 4-5 minutes. The complete set-up for the one catheter push-pull technique is shown in figure 8 below.

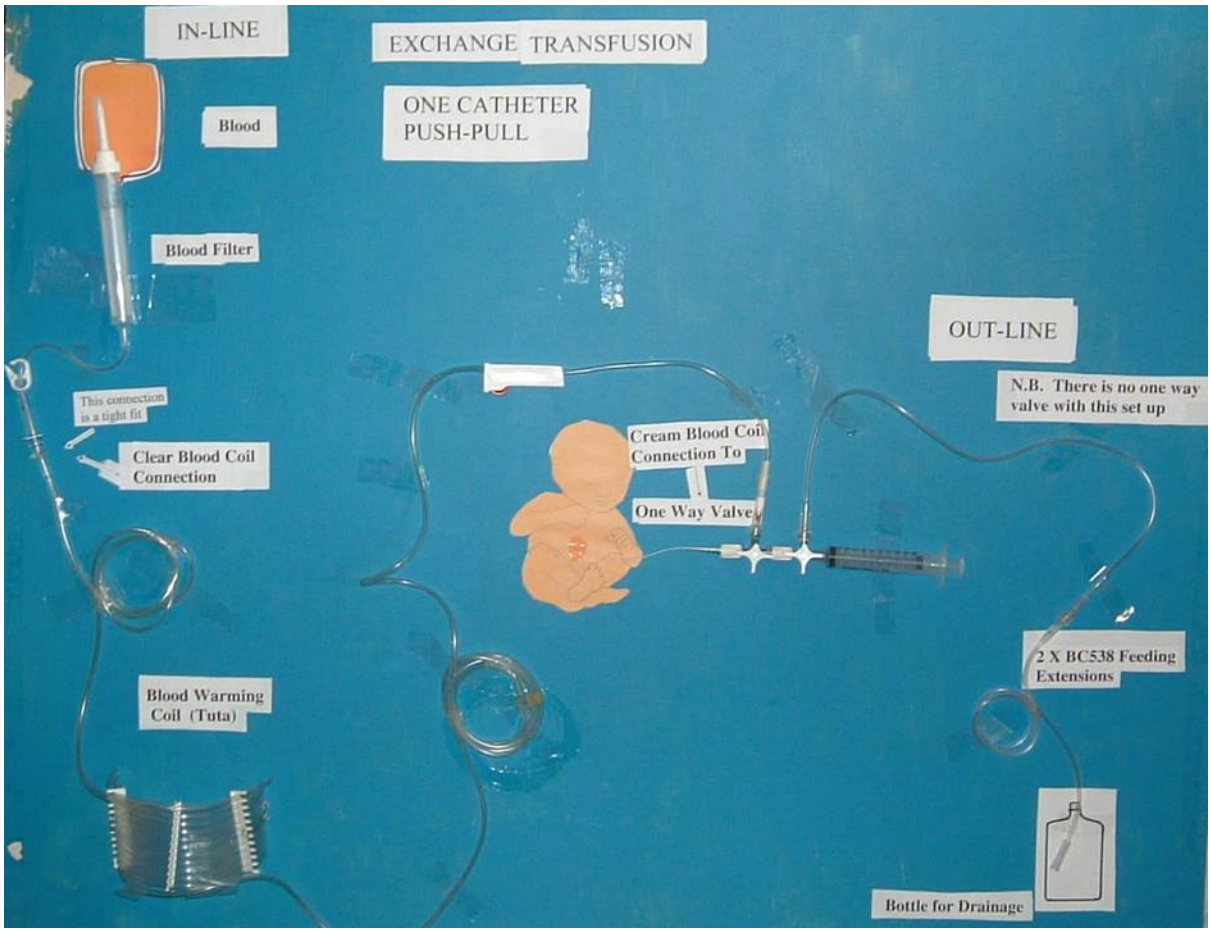



*Figure 8: One catheter push-pull technique*

The basic steps for making the set-up above is as follows:

1. Fix the umbilical venous catheter into the baby's umbilical vein as shown in figure 9 below.
2. Connect two three-way taps in series as shown in figure 8 above.
3. Attach the two three-way taps to the umbilical venous catheter as shown in figure 8 above and figure 9 below.
4. Connect the blood discarding line to the side port of the three-way tap closest to the baby (the collection bag should be below bed level as shown in figure 8 above.)
5. Connect a 10 or 20ml syringe to the port of the three-way tap furthest from the baby as shown in figure 8 above.
6. Connect the donor blood line to the side port of the three-way tap furthest from the baby (the donor blood bag should be above bed level as shown in figure 10 below.)

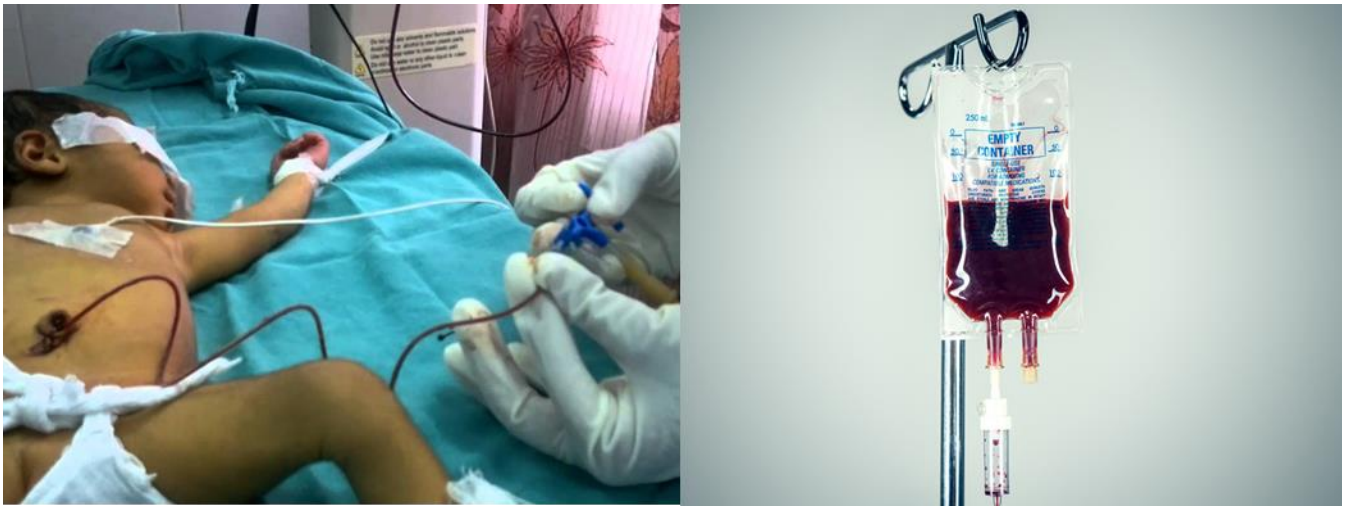



*Figure 9: Two three-way tap being put in series / umbilical catheterization can also be seen (**left**)*

*Figure 10: Donor's blood hanged at a height to enhance flow by gravitational pull (**right**)*

During the procedure, blood volumes 'in' and 'out' are always recorded after every cycle. Also, vital signs of the baby must be recorded at 15-minute intervals from the baseline. These include

- The heart rate
- The heart rhythm
- The blood pressure
- The temperature
- The respiratory rate
- The oxygen saturation
- The respiratory effort
- The infants colour, tone, and behavior. Etc.[9]

Summing up all that has been said above, now consider the following noting that exchange transfusion is to be performed on the baby:

1. A baby that is preterm, whose weight is about a kilogram of mass.

Since the baby is preterm, the parameter for average amount of blood to be exchanged is about 200ml/kg of the baby's weight. To obtain the total volume that of blood to be exchanged, we multiply this parameter by the baby's weight.

$$i.e. \quad \frac{200ml}{kg} \times 1.0kg$$

$$\underline{\underline{= 200ml}}$$

This implies that a total volume of about 200ml is to be exchanged. Also, since the baby's weight is less than 1.5kg, it implies that aliquots of blood with a volume of 5ml should be exchanged per cycle.

To find the number of cycles that will be carried out in order to exchange a total blood volume, we divide the total blood volume by the volume per cycle.

$$i.e. \quad \frac{200ml}{5ml}$$

$$\underline{\underline{= 40\ cycles}}$$

As already stated, the procedure is carried out very slowly in about 4-5 minutes per cycle. So looking at this case, the total time for the exchange transfusion on the baby being considered will be the time used per cycle multiplied by the total number of cycles.

$$i.e. \quad 40\ cycles\ \times 4\frac{mins}{cycle}$$

$$= 160mins$$

$$\underline{\underline{= 2\ hrs\ 40\ mins}}$$

2. A baby that is term, whose weight is about two kilograms of mass.

Since the baby is term, the parameter for average amount of blood to be exchanged is about 160ml/kg of the baby's weight. To obtain the total volume that of blood to be exchanged, we multiply this parameter by the baby's weight.

$$i.e. \quad \frac{160ml}{kg} \times 2.0kg$$

$$\underline{\underline{= 320ml}}$$

This implies that a total volume of about 320ml is to be exchanged. Also, since the baby's weight is above 1.5kg, it implies that aliquots of blood with a volume of 10ml should be exchanged per cycle. To find the number of cycles that will be carried out in order to exchange a total blood volume, we divide the total blood volume by the volume per cycle.

$$i.e. \quad \frac{320ml}{10ml}$$

$$\underline{\underline{= 32\ cycles}}$$

Looking at this case, the total time for the exchange transfusion on the baby being considered will be the time used per cycle multiplied by the total number of cycles.

$$i.e. \quad 32\ cycles\ \times 4\frac{mins}{cycle}$$

$$= 128 mins$$

$$\underline{\underline{= 2\ hrs\ 8\ mins}}$$

Furthermore, in a cycle the doctor draws out blood from the baby and quickly discards it; then he draws blood from the donor blood bag quickly, and slowly infuses it into the baby. In this process, it can be seen that the doctor performs about four pumping actions using the syringe of which two are very quick and the other two are very slow. Performing these pumping actions in addition to controlling the valves to direct the blood flow path, for not less than 2 hours is no small activity. This makes the nature of the procedure very tedious and stressful.

Moreover, as stress and tiredness comes into the scene, then the accuracy of the procedure is set on the edge. This is because as the doctor gets tired, he will not be able to pump blood in and out of the baby steadily. He will tend to pump the blood too fast sometimes and too slowly at other times. This is quite dangerous to the health of the baby and could cause quite a number of complications. Also, in times of stress and tiredness, errors are easily committed.

Again, Consider the time that is being spent on one baby, over two hours, this in a way reduces productivity; since a lot of other babies or patients could be attended to. Hence our project seeks to automate the procedure to alleviate most if not all of these problems.

## 2.6 COMPLICATIONS OF EXCHANGE TRANSFUSION

Exchange transfusion, even though effective and considered to be a very safe procedure, is not without a few complications. Its mortality rates range between 0.5% and 3.3%, hence, current recommendations for carrying out an exchange transfusion are based on the balance between he risks of encephalopathy and the complications related to the procedure. However, most of these complications can be avoided if the procedure is carried out very slowly, with the right hygiene and care. Often the best management of these complications is to slow down or pause the exchange.[9] Table 2 below outlines some of these complications.

*Table 2: Complications that could occur during exchange transfusion (**left**) vs those that can occur after the procedure (**right**)*

| **DURING PROCEDURE** | **AFTER PROCEDURE** |
|---|---|
| Air Embolus | Infection |
| Volume Imbalance | Thrombocytopenia |
| Hyperkalaemia | Hypoglycaemia |
| Arrhythmias | Blood transmitted infections |
| Respiratory Distresses | Hypocalcemia |
| Anaemia/Polycythaemia | Anaemia/Polycythaemia |
| Acidosis | Hypernatraemia |

## 2.7 PREVIOUS PROJECTS ON EXCHANGE TRANSFUSION

Ever since its inception in the twentieth century, quite a number of people have done some work on exchange transfusion. Several methods for its automation have been proposed; however, most of them have not been commonly used throughout the world because of technical difficulties. A few of them are discussed below:

[1] Huseyin Altunhan, Ali Annagur, Nuriye Tarakci, Murat Konak, Sabahattin Ertugrul, and Rahmi Ors, "Fully automated simultaneous umbilical arteriovenous blood exchange transfusion in both term and late preterm infants with neonatal hyperbilirubinemia", June-2015.

In this study, the efficacy and safety of two different catheterization techniques of exchange transfusion used in the therapy of newborn jaundice were compared: fully automated two-way exchange transfusion technique and the classical one-way exchange transfusion. The study included babies at gestational age greater than thirty-four weeks. In total, one hundred and seven exchange transfusions were performed on eighty-six babies. Totally, the umbilical vein (UV) group included fifty-four babies having undergone sixty-nine exchange transfusions and the

UV/UA group included thirty-two babies having undergone thirty-eight exchange transfusions. With respect to the results, the declines in bilirubin levels right after exchange transfusion and eight hours after exchange transfusion were higher in the fully automated UV/UA technique than in the classical UV technique. Furthermore, the duration of intensive phototherapy following exchange transfusion was shorter in the UV/UA method than in the UV method. There was no difference between the two methods in terms of exchange transfusion associated complications. They concluded by saying that, in neonatal hyperbilirubinemia, exchange transfusion with fully automated UV/UA technique is more efficient than the classical exchange transfusion technique, causing no additional side-effects. It is also more physiological than the classical technique, since it minimizes the fluctuations in the blood volume and intravascular pressure during exchange transfusion.

[2] Steven L. Goldman, M.D., Ho Chung Tu, M.D., "Automated method for exchange transfusion: A new modification", 1983.

In this study, the team modified a volumetric infusion pump to accommodate two syringes, one of which withdraws blood from the baby and the other infuses blood to the baby. Here, both syringe plungers are attached to the same driving element of the pump so that changes in volumes in the syringes are opposite and of an identical magnitude. They evaluated their new modification on fifteen infants and compared it with the classical one-way technique and they had similar results as in the first presented above.

We as a team believe that the wrong comparison was made in these studies. They compared an automated method to a manual method. Our project seeks to automate the manual classical one-way method, which we believe will enhance its good properties.

# CHAPTER THREE

# METHODOLOGY

This chapter discusses the specific procedure and techniques, tools and materials used to design the automated neonatal exchange transfusion device.

## 3.1 DATA COLLECTION

For this project, both primary and secondary data were collected. For the primary data, the method of collection used was interviews. Some interviewees were engaged in face-to-face conversations whilst others were spoken to on phone. Interviews were used because of the sensitivity of the research topic and the detailed information that was needed. The approach was friendly and informal, and was kept free-flowing with regard to the topic. Secondary data on the other hand was obtained using the internet. We conducted searches using 'keywords' that helped us gather the needed materials for the study. Our searches yielded a lot of articles and journals of which the following selection criteria were used to include/exclude some articles:

i. The article/journal was addressing exchange transfusion.
ii. The article/journal was published quite recently, except for a few with relevant information.
iii. The journal/article was not too complicated to be downloaded or viewed.

Our problem was spear-headed by Dr. Adoma and our supervisor.

## 3.2 DATA ANALYSIS

Data that was gathered for this project was analyzed using qualitative methods of data analysis and applying inductive reasoning. The concepts in various texts read were examined based on their relationships. The first step to this was a brainstorming session, which helped in the arrival of suggested solution. It was suggested that, because exchange transfusion is a crucial process, the best way out is to automate the process. We arrived at a conclusion that, although it took a long time to complete the process (In a space of about two hours), we could not alter the time so much

since dosage and blood rate delivery is relevant. Our decision was to automate the exchange transfusion process at the cheapest cost possible and reducing the time no matter how small it is.

## 3.3 HARDWARE DESIGN

Our design intends to automate the process by eliminating the main manual actions in exchange transfusion. This involves eliminating the manual pumping action of the syringe and the control of the valves, and replacing them with automated ones.

### 3.3.1 MATERIALS AND CHOICE OF SELECTION

Materials used in this project are discussed. Some exist already, others were designed and 3D-printed, some were bought, etc.

#### *3.3.1.1 Medical Catheters*

The exchange transfusion procedure requires the use of three catheters. A catheter is basically a hollow tube through which blood flows as propelled from a source to a destination. Figure 8 in the chapter 2 shows the set-up with the valve connections. The medical catheters are usually made of silicone because of its resistance to chemical attack and temperature insensitivity. Figure 11 below shows some silicone catheters.

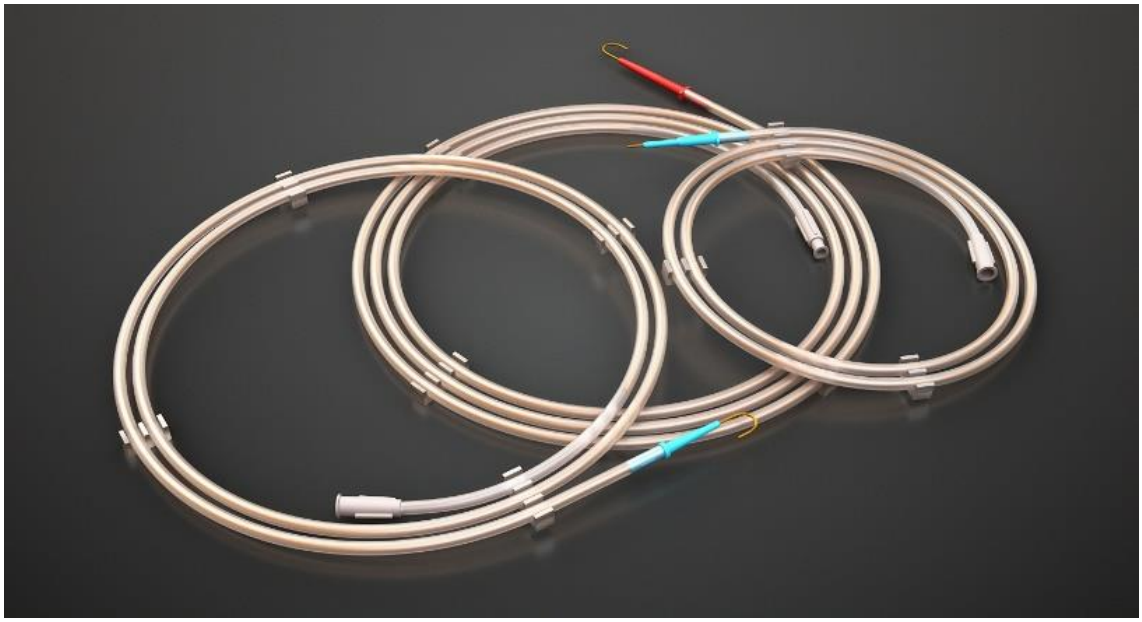


*Figure 11: Medical Catheters*

*3.3.1.2 Valves/Stopcocks*

Two three-way valves are used in the procedure. The valves are connected in series. The valves are used in controlling the direction of blood flow. They allow the movement or flow of blood in three different directions. Most of our automation focuses here since every cycle will require about 4 manual turns of the valves to achieve the required flow.

*Figure 12: Three-way valves*

*3.3.1.3 Syringe*

A 20ml syringe is used in this case because that is the maximum volume of blood that will be withdrawn or input depending on the weight of the body as explained earlier.

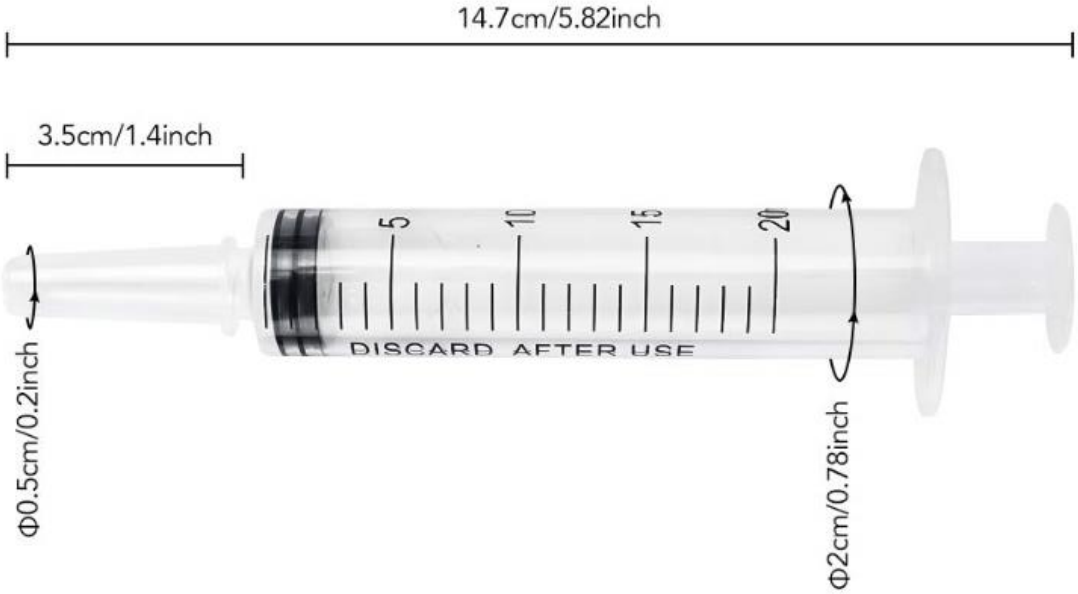



*Figure 13: 20ml catheter tip syringe*

### 3.3.2 SYRINGE PUMP DESIGN

Our syringe pump will control the forward and backward pumping actions of the syringe. Below are the materials and the choice of selection of the various materials in our syringe pump.

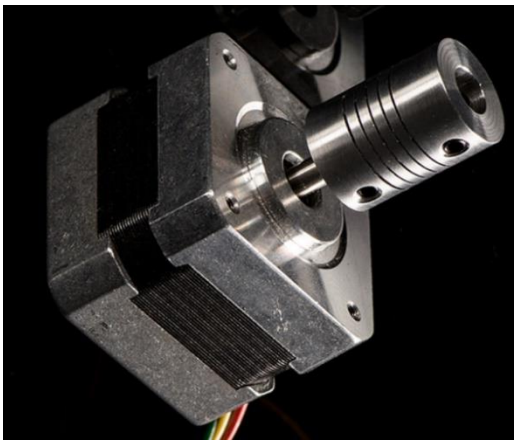
**Stepper Motors**

Stepper motors are DC motors that rotate in precise increments or “steps”. They are very useful when you need to position something very accurately. Unlike ordinary DC motors, stepper motors are controlled by applying pulses of DC electricity to their internal coils. Each pulse advances the motor by one step or by a fraction of a step (micro stepping). Because stepper motors move in discrete steps, it is not required for smooth rotation. However, with the use of gearing and micro stepping, we can achieve smoothness and great accuracy. Micro stepping is the ability to rotate or move the shaft of the motor into positions between the steps.

NEMA 17 bipolar stepper motor was chosen for this project based on several reasons. NEMA 17 is a hybrid stepping motor with a 1.8° step angle. This means that it can have 200 steps per revolution and for every step, it will rotate at an angle of 1.8 degrees. This will give us a great deal of accuracy as we will be dealing with specific blood volumes and specific rates of delivery. The bipolar stepper motor would be mounted at the back of our syringe control model which will control the syringe with the help of the other components.

The 28BYJ-48 unipolar stepper motor however, has a 5.625-degree step angle; this means for every revolution, we can have 64 steps of the internal motor shaft. That is why the NEMA 17 bipolar is used in the syringe pumping action. The unipolar was however employed to operate on the valves which will be discussed later in this section. Below are the specifications of the NEMA 17 bipolar motor.

- Size: 42.3mm square x 48mm, not including the shaft
- Weight:350g
- Shaft diameter:5mm
- Steps per revolution: 200
- Voltage rating: 4V



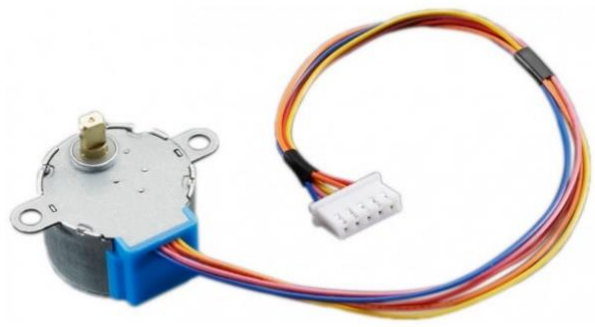


*Figure 14: NEMA 17 stepper motor with shaft coupler inserted (**left**)*

*Figure 15: Unipolar stepper motor (**right**)*

Stepper motors are employed to help pump the syringe. The stepper motor steps or rotates to cause a forward linear motion (of the attached rod) and like wisely rotates the other way round to cause a backwards linear motion. The particular angular motion and its related linear motion depends on the set up. In this case our threaded rod, yet to be discussed.

**Threaded rod**

The threaded rod is connected to the shaft of the stepper motor through to the end of the syringe pump. Because of the pitches or threads, when an angular moment is applied by the stepper, it causes the rod to rotate. The threaded rod cut through medially through a pusher block. Because of this attachment, as the rod rotates, it causes the pusher block to propel forward in a linear motion.

Below are the specifications of the threaded rod used.

- Material: Stainless Steel
- Diameter: 8mm
- Length: 250mm
- Minimum Curvature : 0.2471 1/mm
- Maximum curvature : 0.2518 1/mm

*Figure 16: Threaded Rod*

**The nut**

The nut is fixed in the pusher block and the threaded rod is passed through it. It helps in the conversion of the rotational motion produced by the motor, to linear motion.

*Figure 17: Nut*

**Guide Rod**

Also made of stainless steel, the guide rods provide support for the syringe control system and helps prevent rotations of the pusher block as it moves.

**Length**: 250mm

**Diameter**: 8mm

*Figure 18: Guide Rod*

**Base**

The base of the syringe pump supports the whole model and also gives stability when the operation in ongoing. Below are the dimensions of our base:

Length (total) = 400mm

Width = 35mm

Height (total) = 45mm

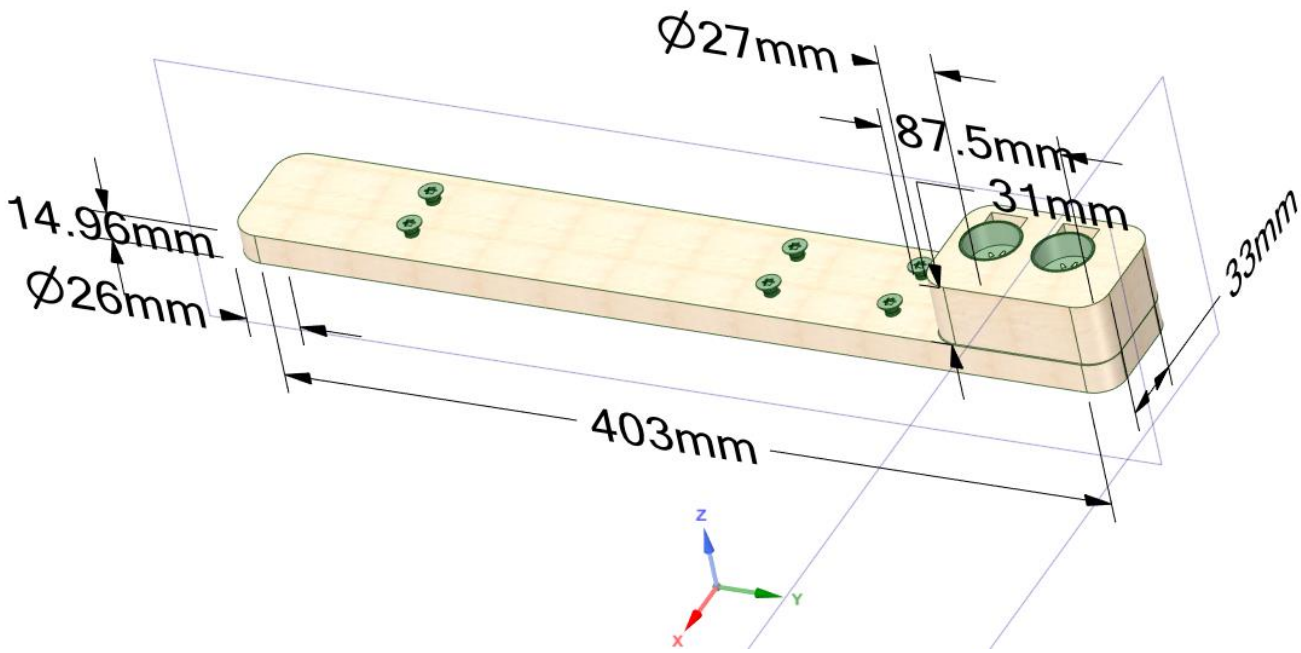



*Figure 19: Base*

3D-PRINTED MATERIALS

The whole model was created in using ANSYS Spaceclaim. Apart from the rods and the syringe, the other parts of the model were 3d printed. The 3d material used is Polylactic Acid. Below are the properties of PLA and how it affects our model positively.

- It has high strength.
- It is less difficult to use and has a very low printing temperature.
- It is relatively less expensive compared to other materials
- It has minimal shrinkage after printing: this will ensure that our measurements are not compromised.

**Motor Block**

This block houses and stabilizes the NEMA 17 motor. It prevents it from moving when being powered to rotate. Its dimensions were made to fit the size of the NEMA 17 motor.

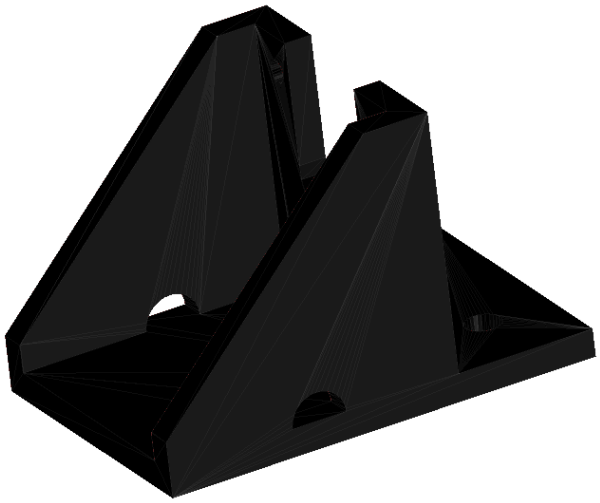


*Figure 20: Motor block*

**Pusher Block**

Below are the specifications of the pusher block, which propels to push and pull the plunger of the syringe to cause pumping and sucking. The R9mm holds the plunger top of the syringe. The two 11mm diameter holes holds the guide rods and the threaded rods passes through the 14mm diameter hole.

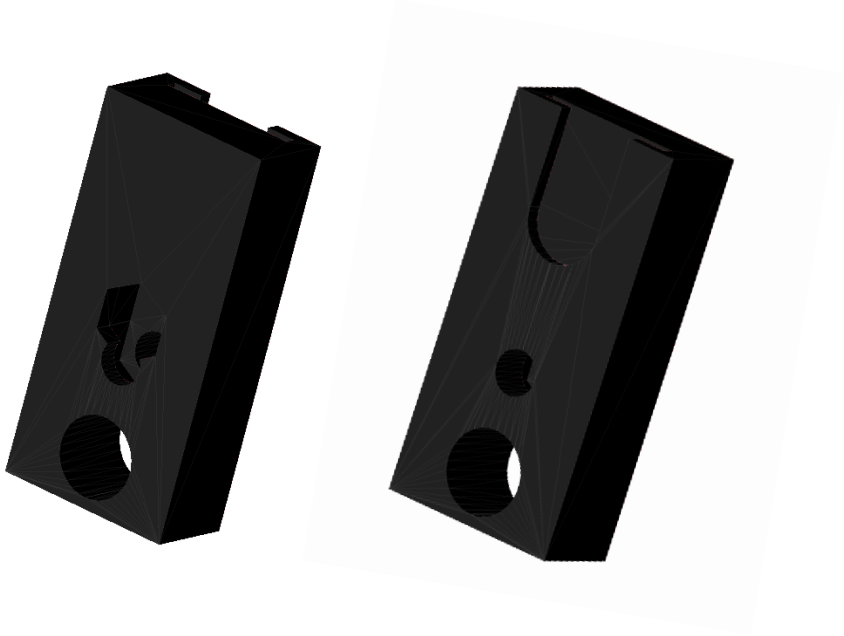


*Figure 21: Pusher block*

**Support blocks**

The support block holds the syringe in position as the movement takes place. The barrel of the syringe lies in the R12.5mm cavity, the threaded rod goes through the 25mm diameter hole in the middle and the small 7mm diameter holes holds the guide rods to prevent moment or rotation.

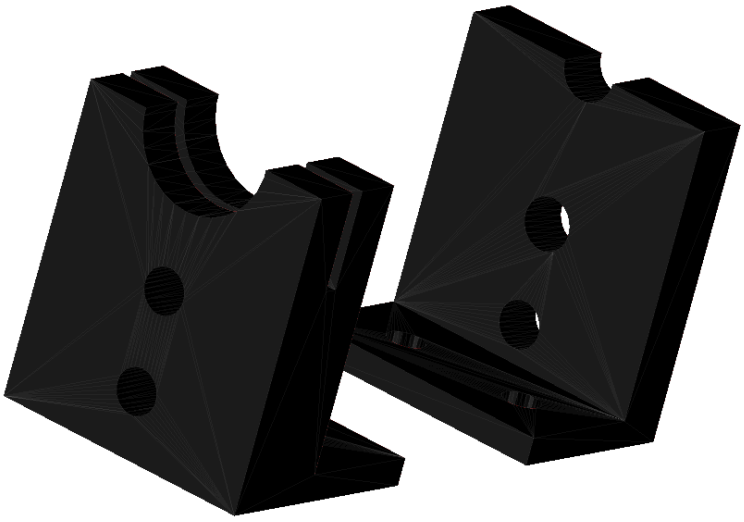


*Figure 22: Support blocks for syringe*

**Procedure of Syringe Control**

The stepper motor rotates clockwise. Its rotation causes the threaded rod to rotate in the same direction because of its attachment to the shaft of the motor.

The pusher block which is attached to the rod propels forward in a linear motion. The linear motion is achieved with the help of the guide rods as it prevents the pusher block from on its sides.

As the plunger block moves forward, it pushes the plunger of the syringe which causes a pumping action.

To cause a sucking action, the motor rotates counterclockwise which causes the threaded rod to rotate in that wise. Because the mini connector holds the syringe top tightly fitted with a screw, as the pusher block moves backward, it pulls the plunger of the syringe along which causes a sucking action.

The continuous rotations of the stepper motor and its direction causes us to suck and pump blood in and out of the baby.

### 3.3.3 VALVES CONTROL

The valve control allows the flow of blood in one direction, and inhibits the flow in another. Since we will be drawing blood from the baby and pumping fresh blood from the baby with just one syringe, there is a need for a valve control to prevent blood mixes.

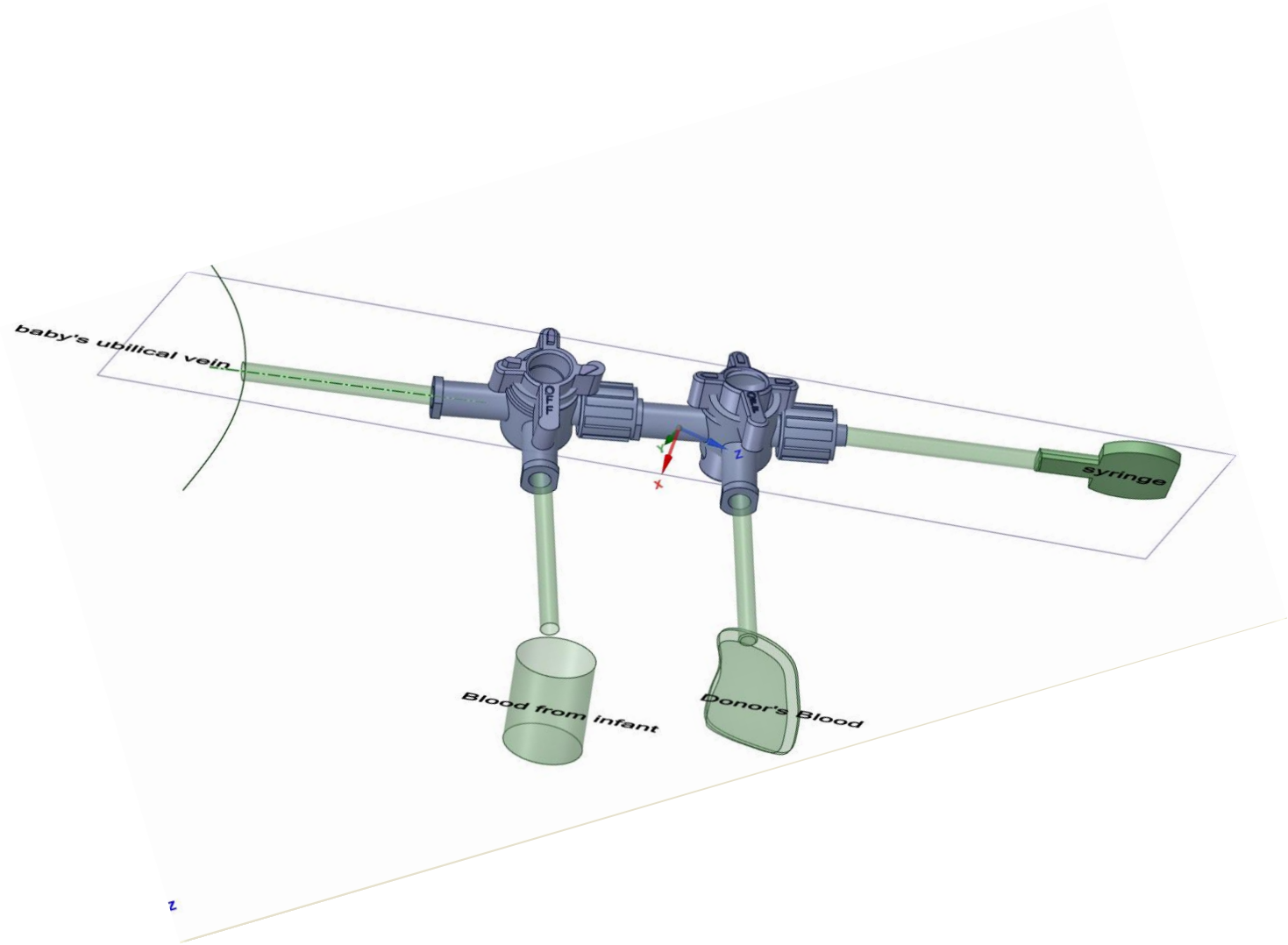



*Figure 23: Draw and pump Valve Configuration*

Below are pictures of 2 three-way valves in series and the different valve operations with respect to what type of blood and its direction its flowing to or from. The following design was modelled in ANSYS geometry.

In this set-up, the 2 valves are open on each ends through to the umbilical vein of the baby. The other ports are blocked. Because of this configuration, we can draw and pump blood from the baby without interfering with the dirty blood (blood from infant) or donor's blood.

This configuration is used when we want to draw blood from the baby and when we want to pump fresh or donor's blood to the baby.

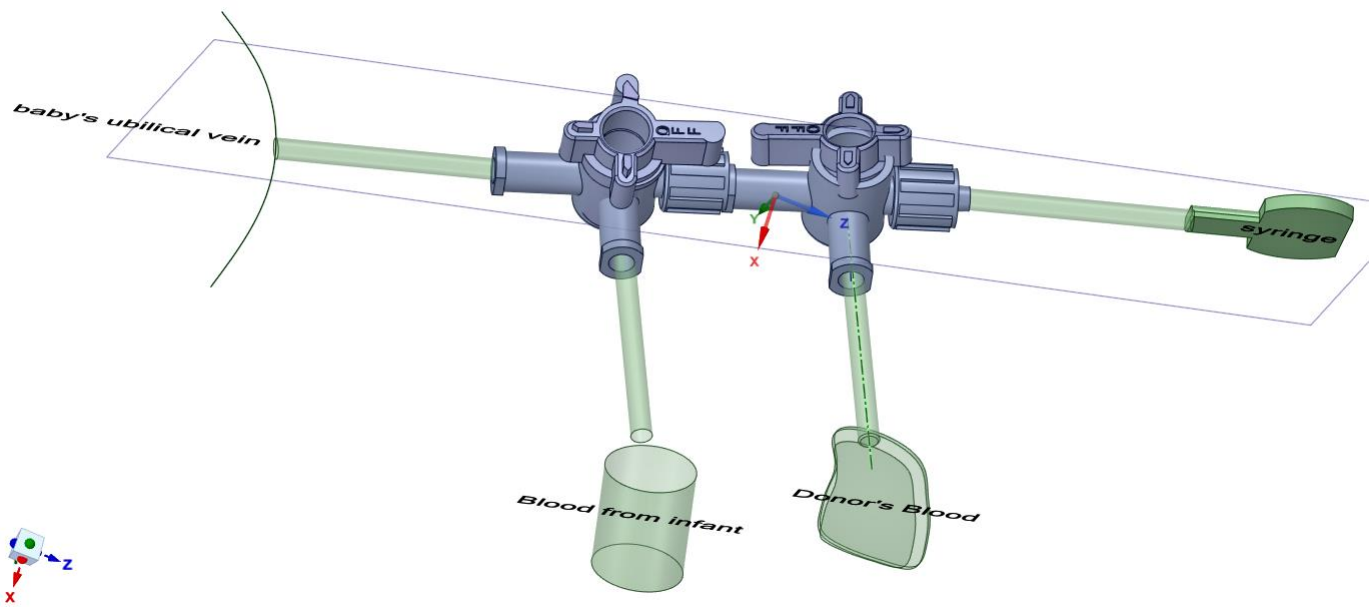



*Figure 24: Draw donor's blood valve configuration*

In this configuration, the ports that lead to the baby are blocked. Also, the port to the drainage (blood from infant) is also blocked. The only open port is the one that leads to the donor's blood. This setup has one function: To allow us to draw blood from the donor's bag.

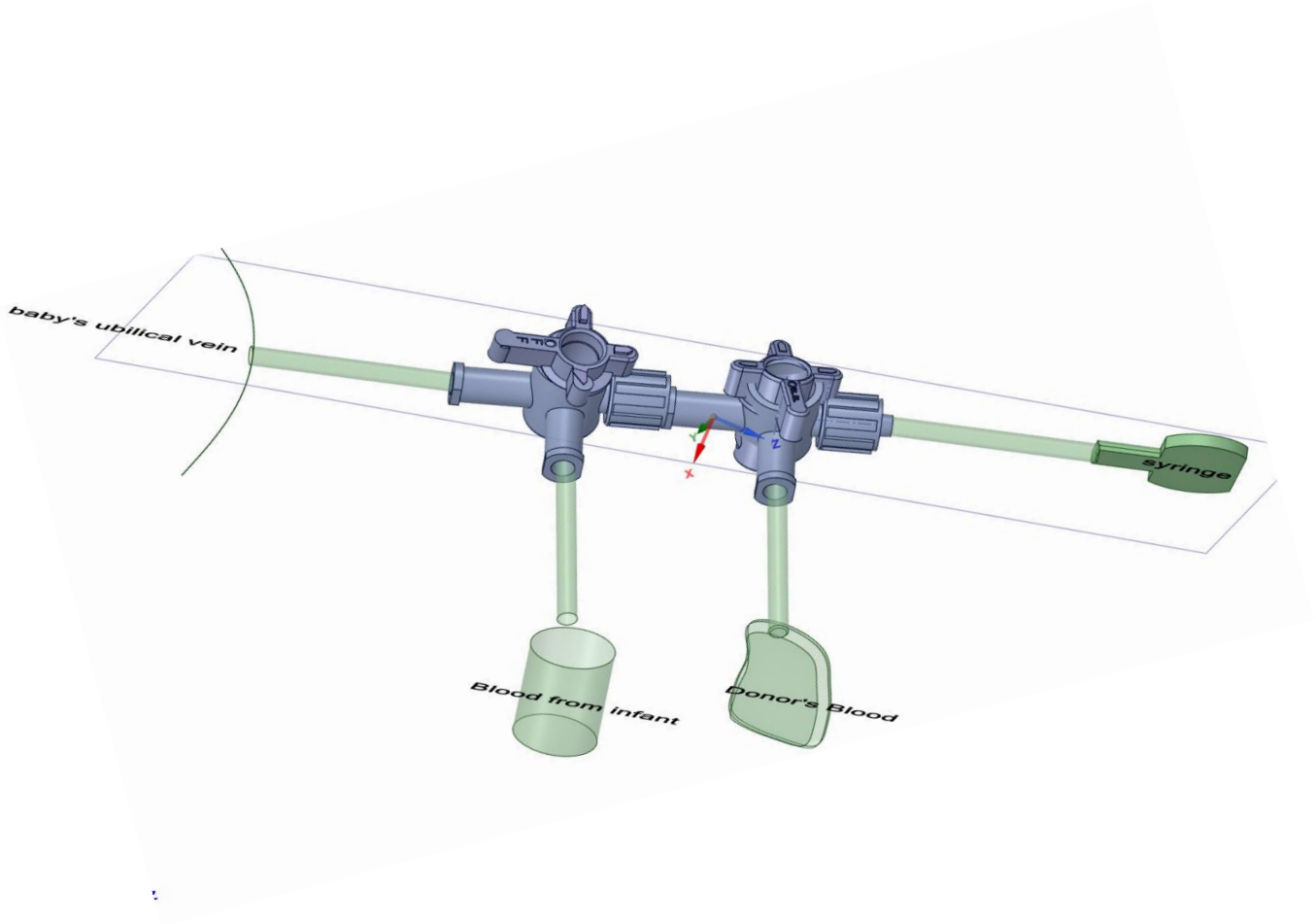



*Figure 25: Pump to drainage bag valve configuration*

In the 3rd configuration, the port that leads to the donor's blood is blocked. The port that also leads to the baby is also blocked. The only open ports are that to the drainage bag (blood from infant). The set-up will allow for us to pump blood from the syringe to the drainage bag.

The described configuration summarizes the different controls of the valves and how they affect blood flow. The pseudo code below will describe how the process was automated with the help of a microprocessor.

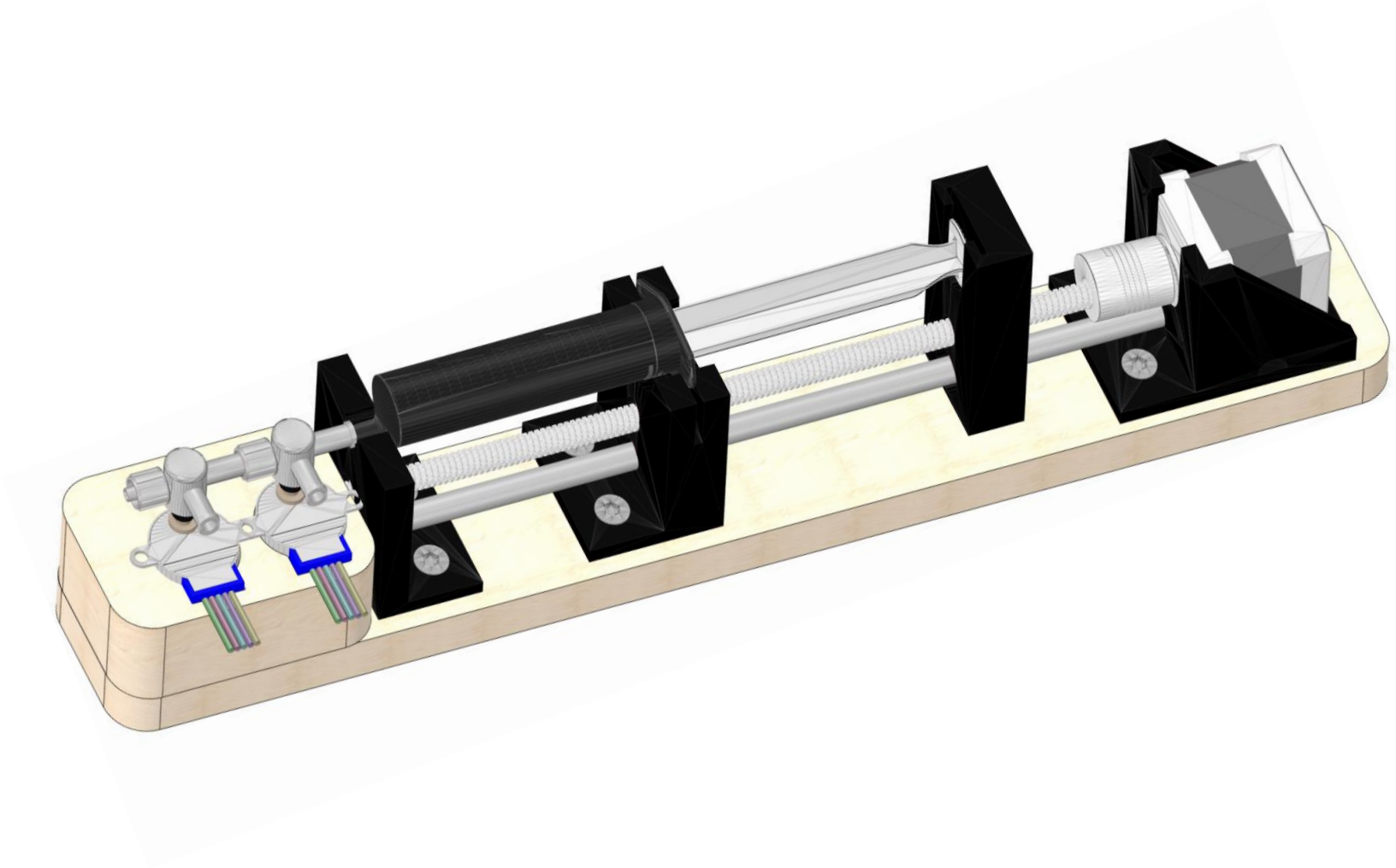


*Figure 26: ANSYS Spaceclaim model of syringe pump design*

## 3.4 ELECTRONIC COMPONENTS

Though the stepper motors are also electronic components, they have already been discussed earlier and hence wouldn't be discussed here again.

**The Arduino Mega**

It is a microcontroller board based on the ATmega2560. It has a total of 54 digital input/output pins [14 of which can be used as PWM outputs], 16 analog input pins, 4 UART ports, a 16 MHz crystal oscillator, a USB connection, a power jack, an ICSP header, and a reset button. It can be simply connected it to a computer with a USB cable or powered with an AC-to-DC adapter or battery. The Arduino Mega 2560 R3 also adds SDA and SCL pins next to the AREF. In addition, there are two new pins placed near the RESET pin. One is the IOREF that allow the shields to adapt to the voltage provided from the board. The other is a not connected and is reserved for future purposes.

We employed the Arduino Mega in our project because of it large number of pins and make. We needed a single microcontroller that could control the whole system of components in our design at once. Figure 26 below shows the Arduino Mega.

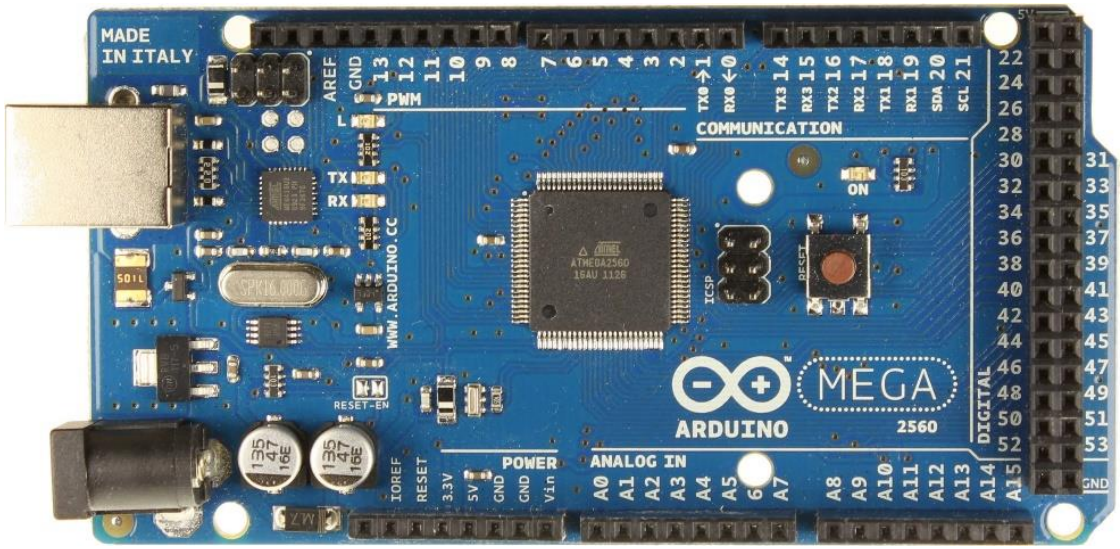



*Figure 27: The Arduino Mega Development Board*

**The Liquid Crystal Display**

The 16x2 LCD displays 16 characters per line and there are 2 of such lines, i.e. 16 columns and 2 rows. Each character in this component is displayed in 5x7 pixel matrix. The 16x2 intelligent alphanumeric dot matrix display has the ability to display 224 different characters and symbols. It has 16 pins of which 8 are data pins; hence it can operate in both 8-bit mode and 4-bit mode. The other pins are command pins.

We employed the LCD in our design to enable the user interact with the device by visualizing data and information for the purpose of knowing what is going on at any point in time. It was integrated with an $I^2C$ backpack to simplify the pin connection to the Arduino board. Figure 27 below shows the 16x2 LCD, and figure 28 shows the $I^2C$ backpack connected to the back of the LCD.

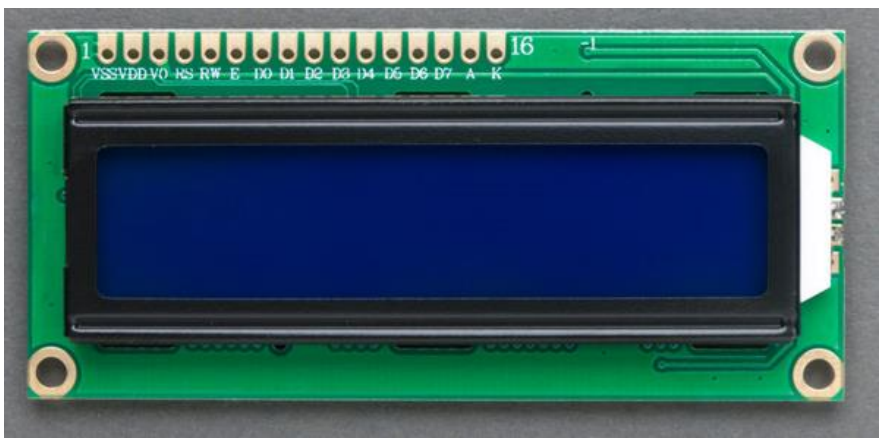



*Figure 28: The 16x2 LCD Screen*

*Figure 29: The back of the LCD showing the $I^2C$ backpack*

**The Keypad**

The 4x4 keypad has 8 pins of which 4 are row-pins (R1, R2, R3, R4) and the other 4 are column-pins (C1, C2, C3, C4). It is used for inputting data while a program is running. We employed it to enable the user to be able to control the device.

*Figure 30: The keypad*

**The Buzzer**

The piezoelectric buzzer has two pins: a positive and a negative. It can be powered by a 6V dc. It can also be connected to the microcontroller, from which it will receive commands for beeping. We employed the buzzer in our project because our device would be required to sound alarms in different kinds of situations when the need arises.

*Figure 31: The buzzer*

**THE BLOCK DIAGRAM**

The electronic components discussed above are connected together in a particular manner. This block diagram in figure 31 below shows the connections. On the left is the only input i.e. the keypad. On the right are the outputs i.e. the motors, LCD and buzzer. In the middle is the microcontroller board which links up and controls the whole system. Below the microcontroller is the power supply system, consisting of AC/DC power adapter and a switch. The power supply system powers up the microcontroller and the three stepper motors.

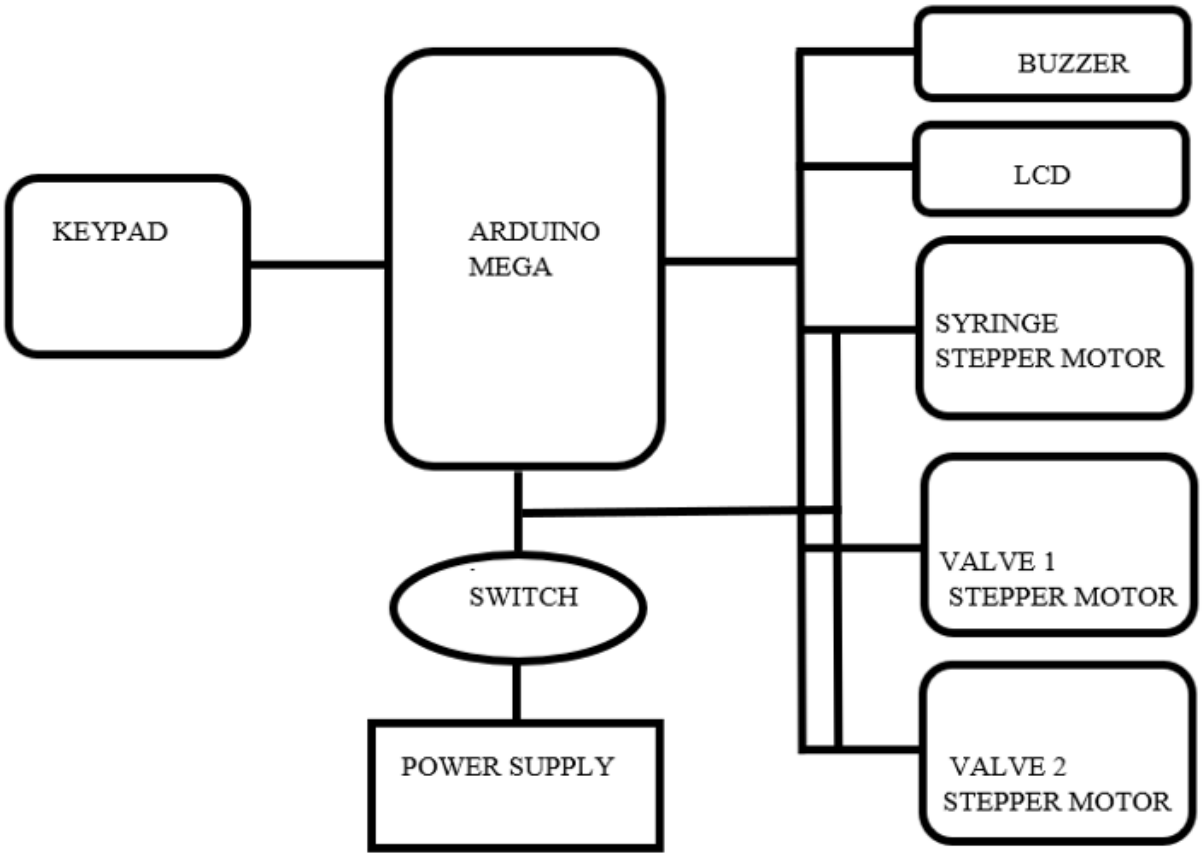



*Figure 32: Block diagram of electronic component connection component*

Figure 32, figure 33, figure 34, and figure 35 below shown the pin connection of some of the components, i.e. the LCD, keypad, unipolar stepper motor and the NEMA 17 stepper motor, to the Arduino mega board using the fritzing software.

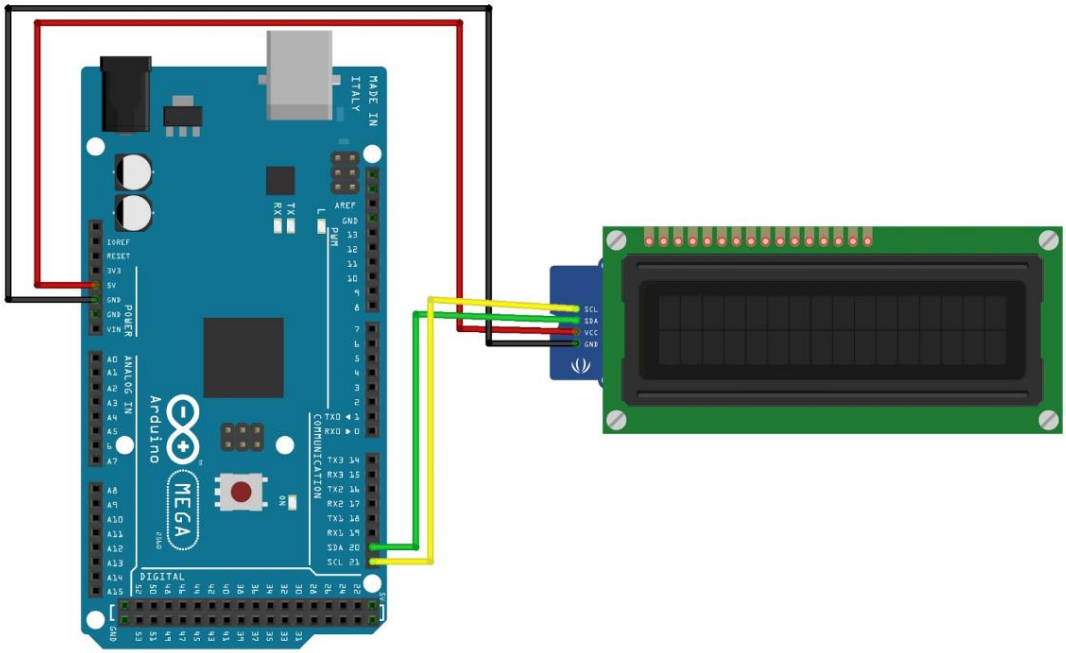



*Figure 33: Pin connection of LCD to Arduino Mega*

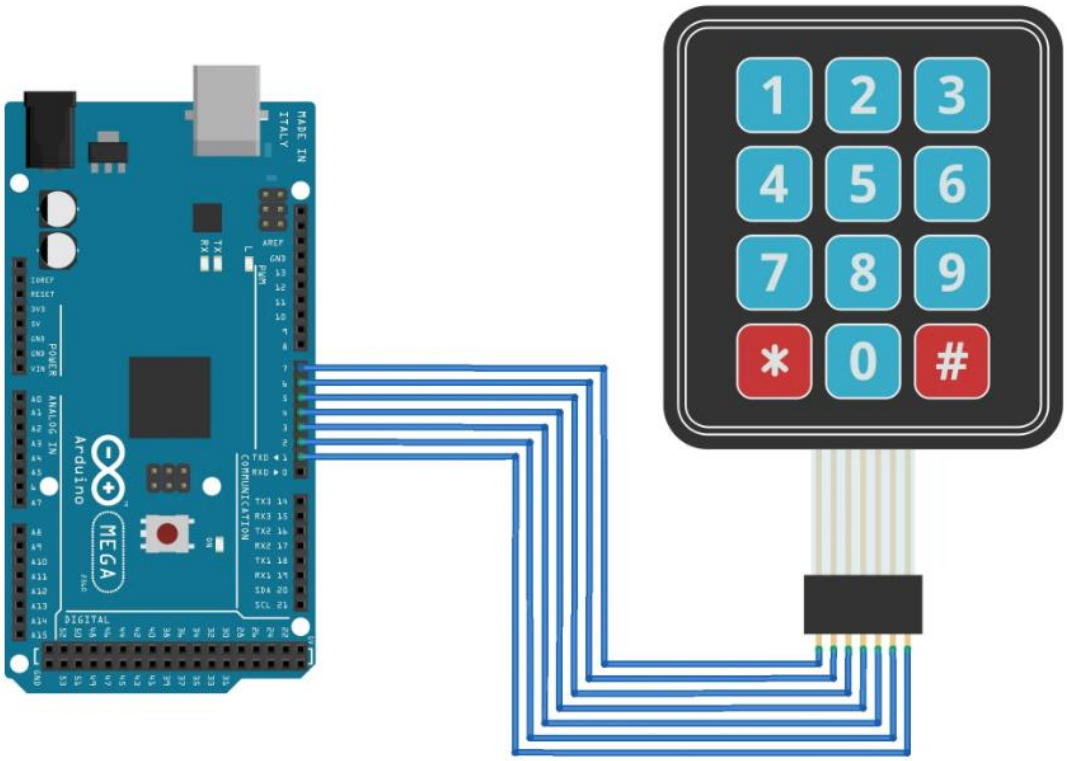



*Figure 34: Pin connection of Keypad to Arduino Mega*

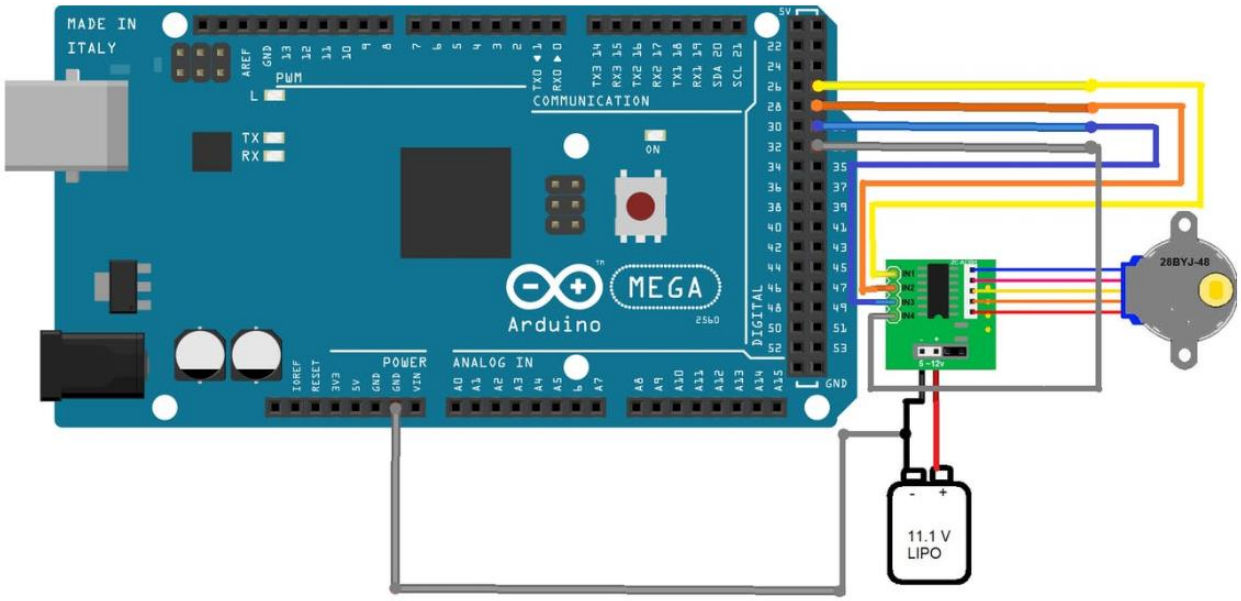



*Figure 35: Pin connection of Unipolar Stepper Motor to Arduino Mega*

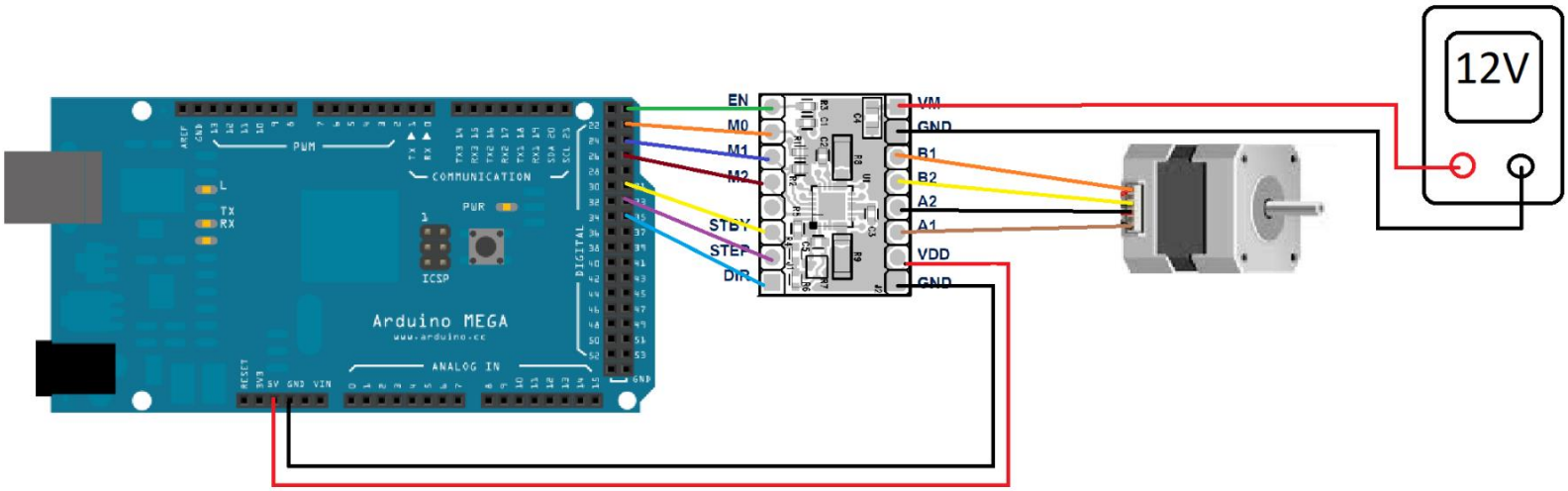



*Figure 36: Pin connection of NEMA 17 Stepper Motor to Arduino Mega*

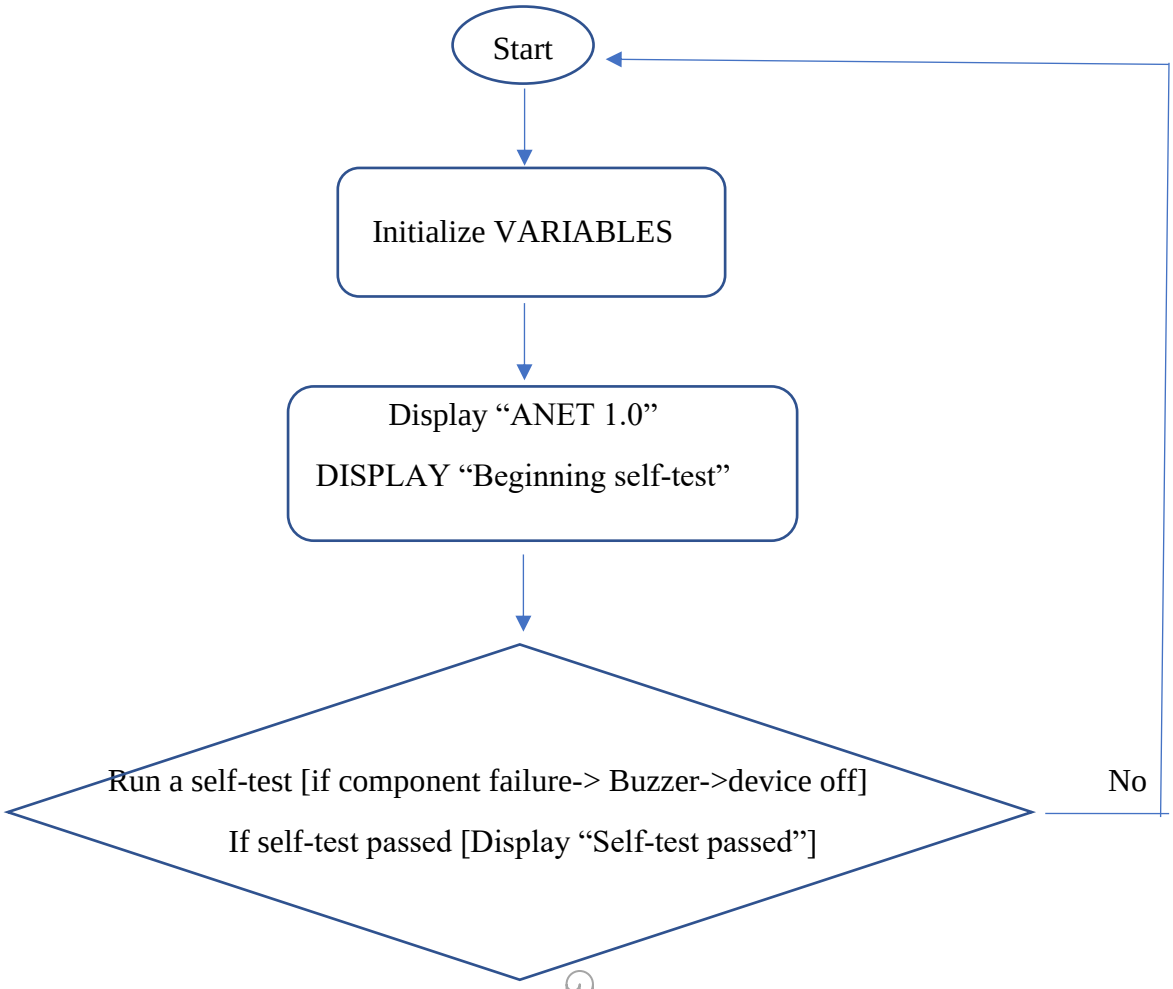
Note that these figures are not the exact pin connections we used in our design; however, they may help you to understand and have a picture view of how the pin connections were carried out.

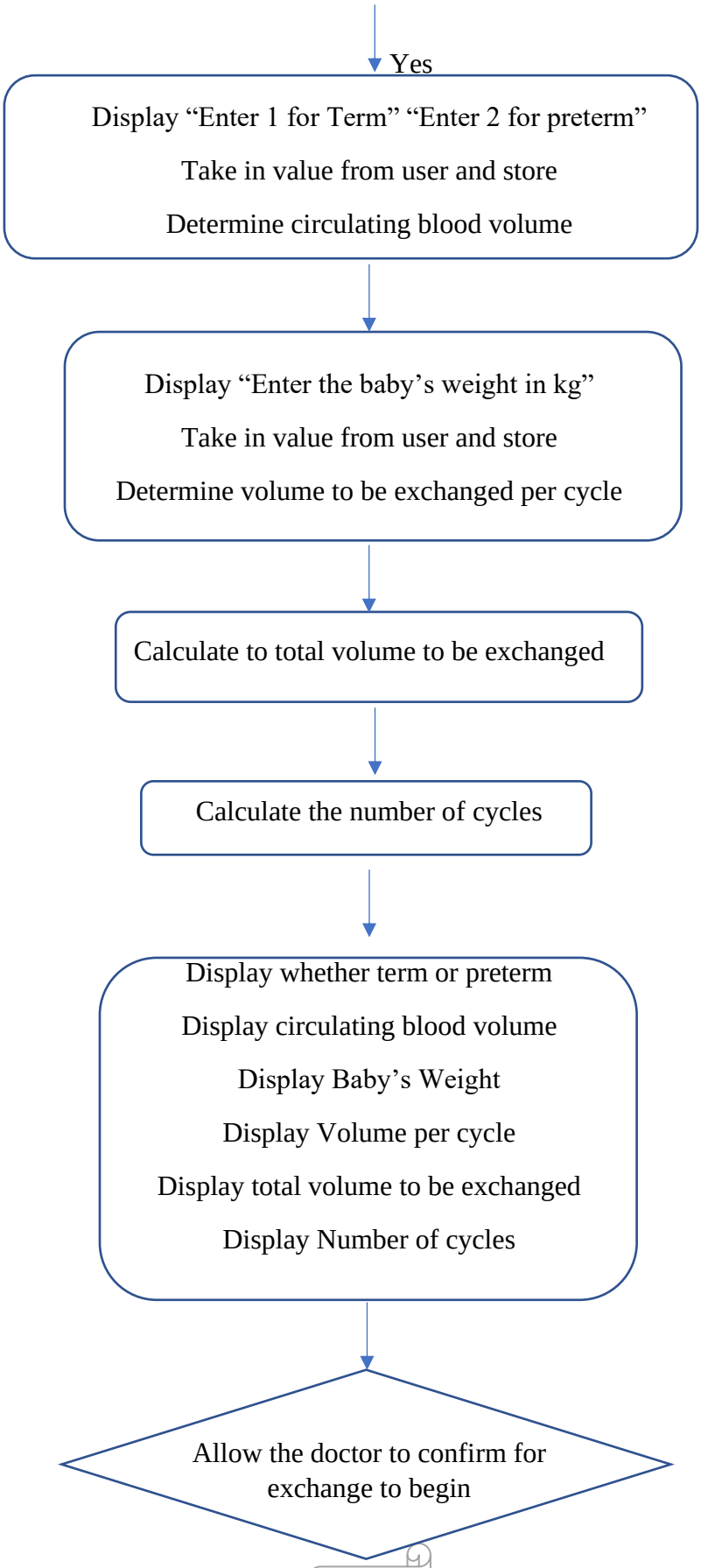
## 3.5 THE SOFTWARE DESIGN

The heart of any embedded system is the firmware on which it runs. Without the software/firmware, the hardware is virtually dumb. The core of this project was in the software design.

Basically, the software tells what, when and how something is to be done. The software runs on the microcontroller. We first prepared a pseudo-code on how we intend operating it, based on the help of the internet and our supervising doctor, then we proceeded to writing the real code for the device.

Our software design mimics the one-catheter push-pull method of exchange transfusion. The flowchart below shows a draft of our software design i.e. the pseudo-code. The main code for the project is in the appendix of this report.




Yes
Display “Enter 1 for Term” “Enter 2 for preterm”
Take in value from user and store
Determine circulating blood volume
Display “Enter the baby’s weight in kg”
Take in value from user and store
Determine volume to be exchanged per cycle
Calculate to total volume to be exchanged
Calculate the number of cycles
Display whether term or preterm
Display circulating blood volume
Display Baby’s Weight
Display Volume per cycle
Display total volume to be exchanged
Display Number of cycles
Allow the doctor to confirm for exchange to begin

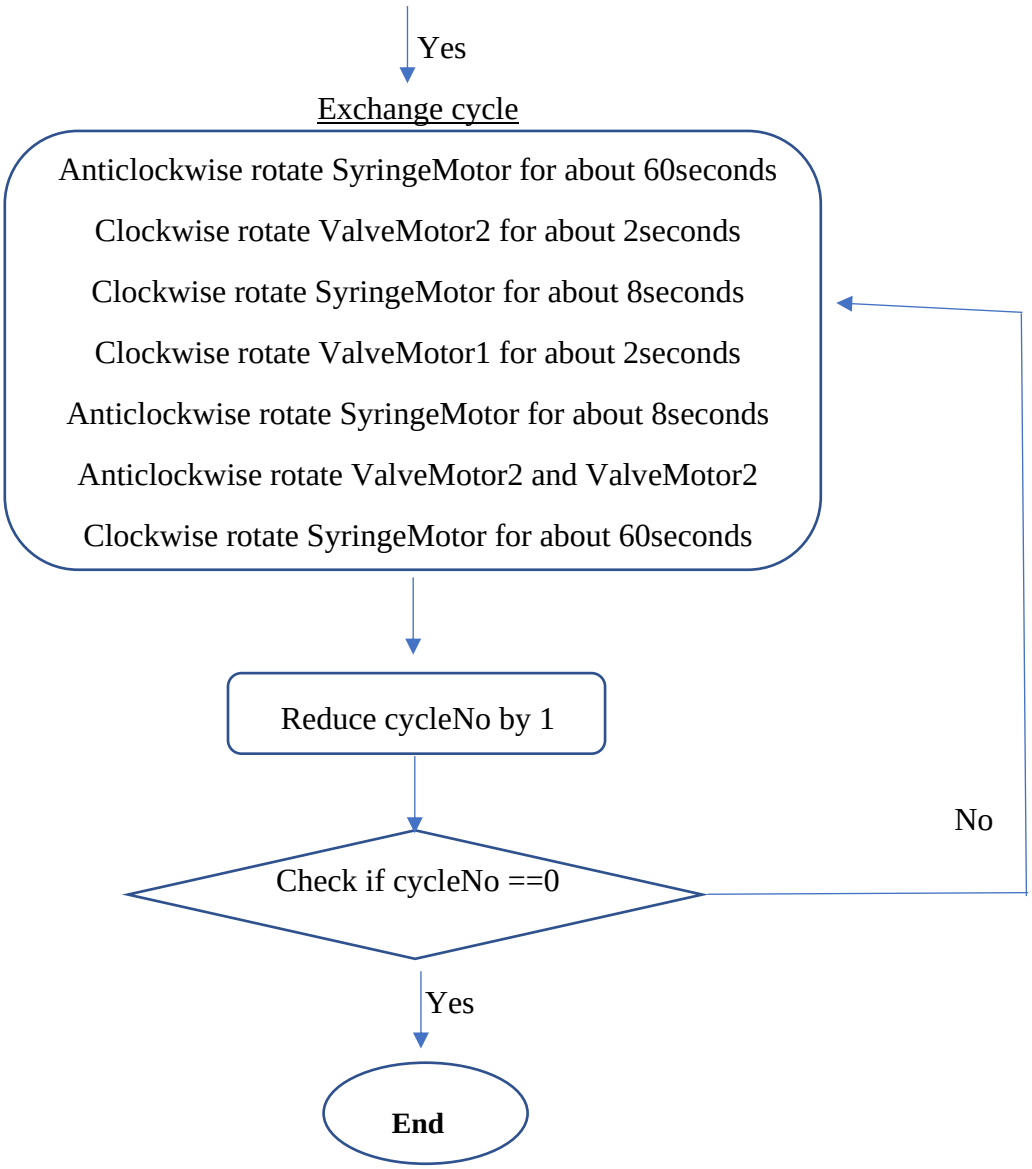



*Figure 37: Firmware Flowchart*

# CHAPTER FOUR

# RESULTS AND DISCUSSION

This chapter discusses the simulations and stress analysis that were carried out on our design model and the built device. Results are presented here, and discussed.

## 4.1 RESULTS

Analysis was run in Ansys Mechanical Model to determine the principal stresses of the model and the point of failure or deformation. Separate analysis of various device parts was run in order to achieve accurate results. The analysis was run on the base and the threaded rod. We looked out for maximum stresses at which the device is likely to fail or deform.

### 4.1.1 ANALYSIS OF THE BASE

The base carries the weight of all the other components and bears the stress from the screws. Analysis was made in this regard. It was isolated and the following material properties were assigned.

**Plywood**

Plywood, 5 ply beech, parallel to face sheet

Sample materials data from Granta Design. Additional data and information available through the Granta website.

Granta provides no warranty for the accuracy of the data.

| | |
|---|---|
| Density | 748 kg/m³ |

**Structural**

Isotropic Elasticity

| | |
|---|---|
| Derive from | Young's Modulus and Poisson's Ratio |
| Young's Modulus | 6.32e+09 Pa |
| Poisson's Ratio | 0.245 |
| Bulk Modulus | 4.1307e+09 Pa |
| Shear Modulus | 2.5382e+09 Pa |
| Isotropic Secant Coefficient of Thermal Expansion | 6.93e-06 1/°C |
| Tensile Ultimate Strength | 5.61e+07 Pa |
| Tensile Yield Strength | 3.81e+07 Pa |

**Thermal**

| | |
|---|---|
| Isotropic Thermal Conductivity | 0.324 W/m·°C |
| Specific Heat Constant Pressure | 1680 J/kg·°C |

**Electric**

| | |
|---|---|
| Isotropic Resistivity | 1.1e+06 ohm·m |

*Figure 38: Material properties of the base model*

Forces applied to the base included the weight of all the components that rest on it which is estimated to be 350grams. Bearing stress was also computed for the holes of the screws.

Below, indicate the variegated forces and supports applied to our base model.

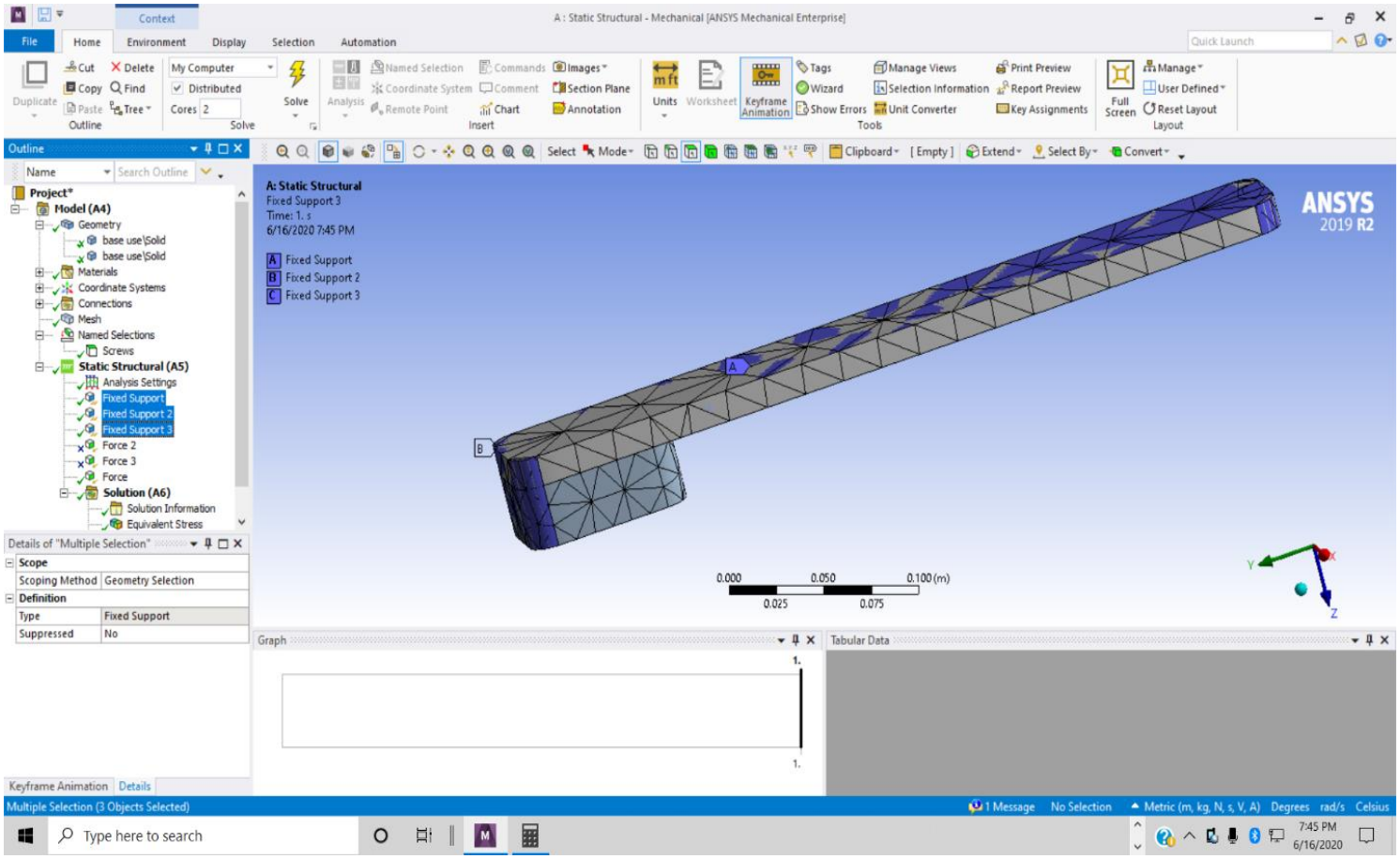



*Figure 39: Fixed supports on the base model*

The supports were fixed to restrict motion in those directions. There were three supports in total of which all was locked in all degrees of freedom.

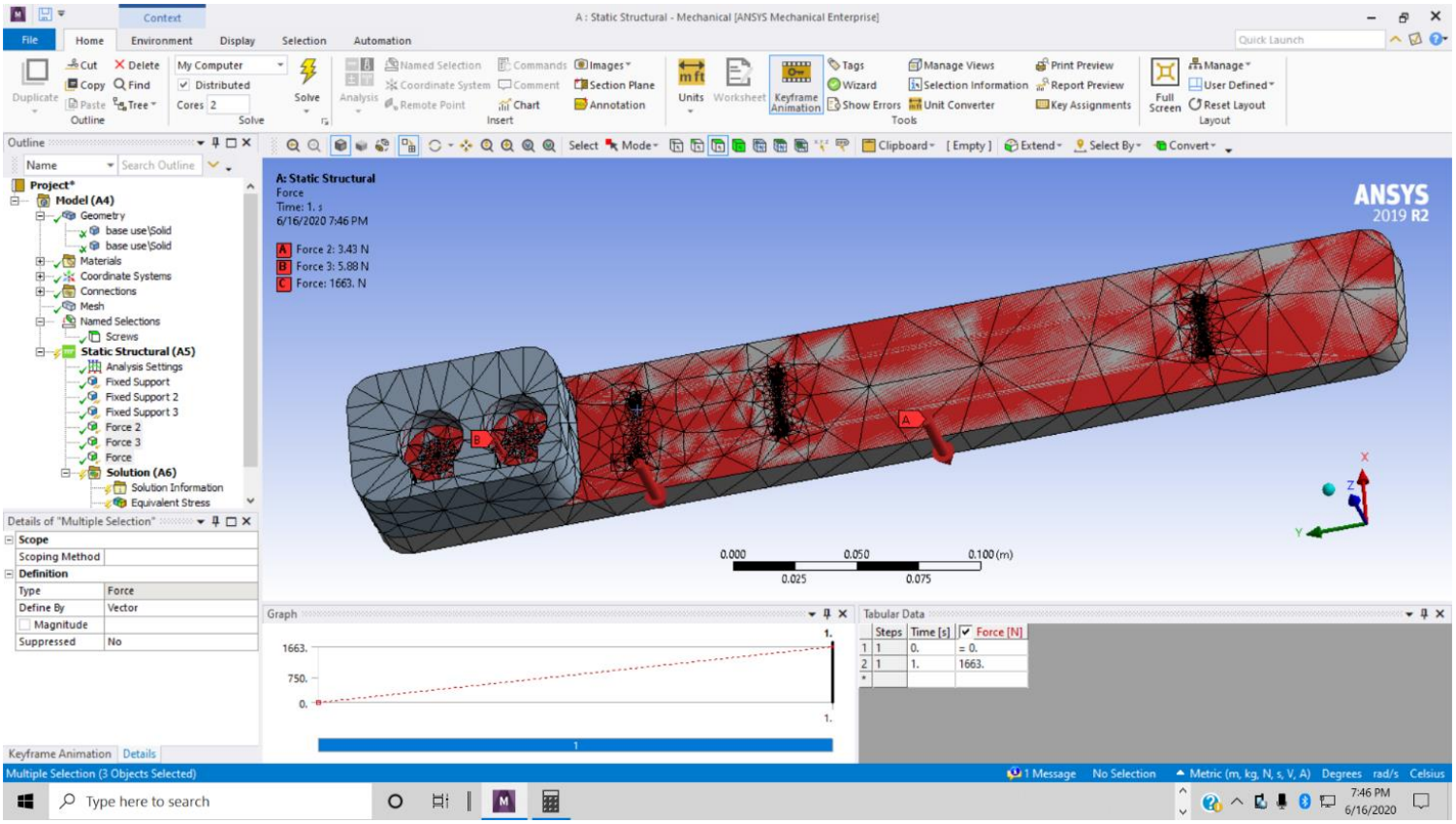



*Figure 40: Forces acting our base model*

The magnitude of the force at the main surface was 3.43N. The second force was 5.88N and the bearing force as a result of the screws was 1663N.

The resulted output from our simulation included equivalent von misses stress and total deformation of the model. Below are the results of the simulation.

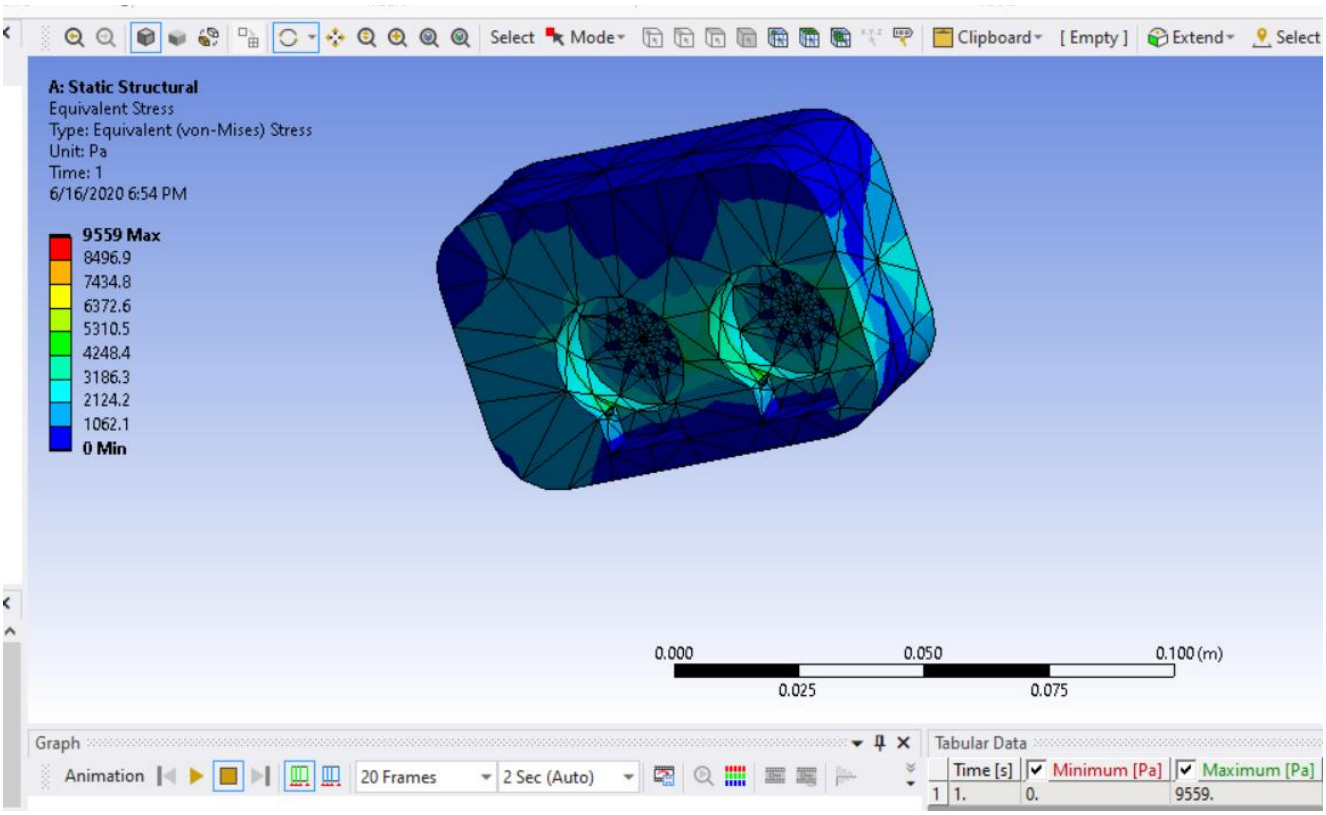



*Figure 41: Equivalent (Von-Mises) Stress of base-top model*

The maximum stress was 9559Pa and it occurred at the edges of the holes where the motors sit.

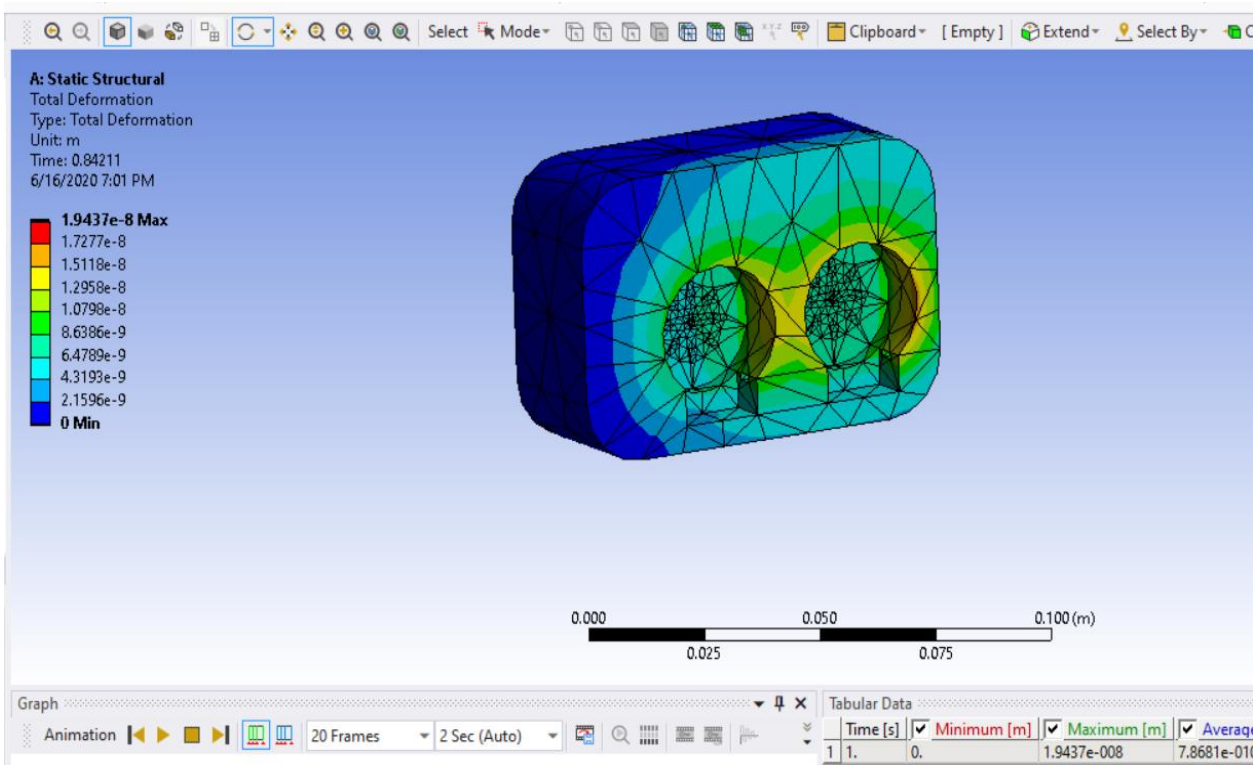



*Figure 42: Total deformation of base-top model*

The maximum deformation occurred at the edges as expected and it had a value of $1.944 \times 10^{-5}$mm with an average deformation of $7.86 * 10^{-7}$mm.

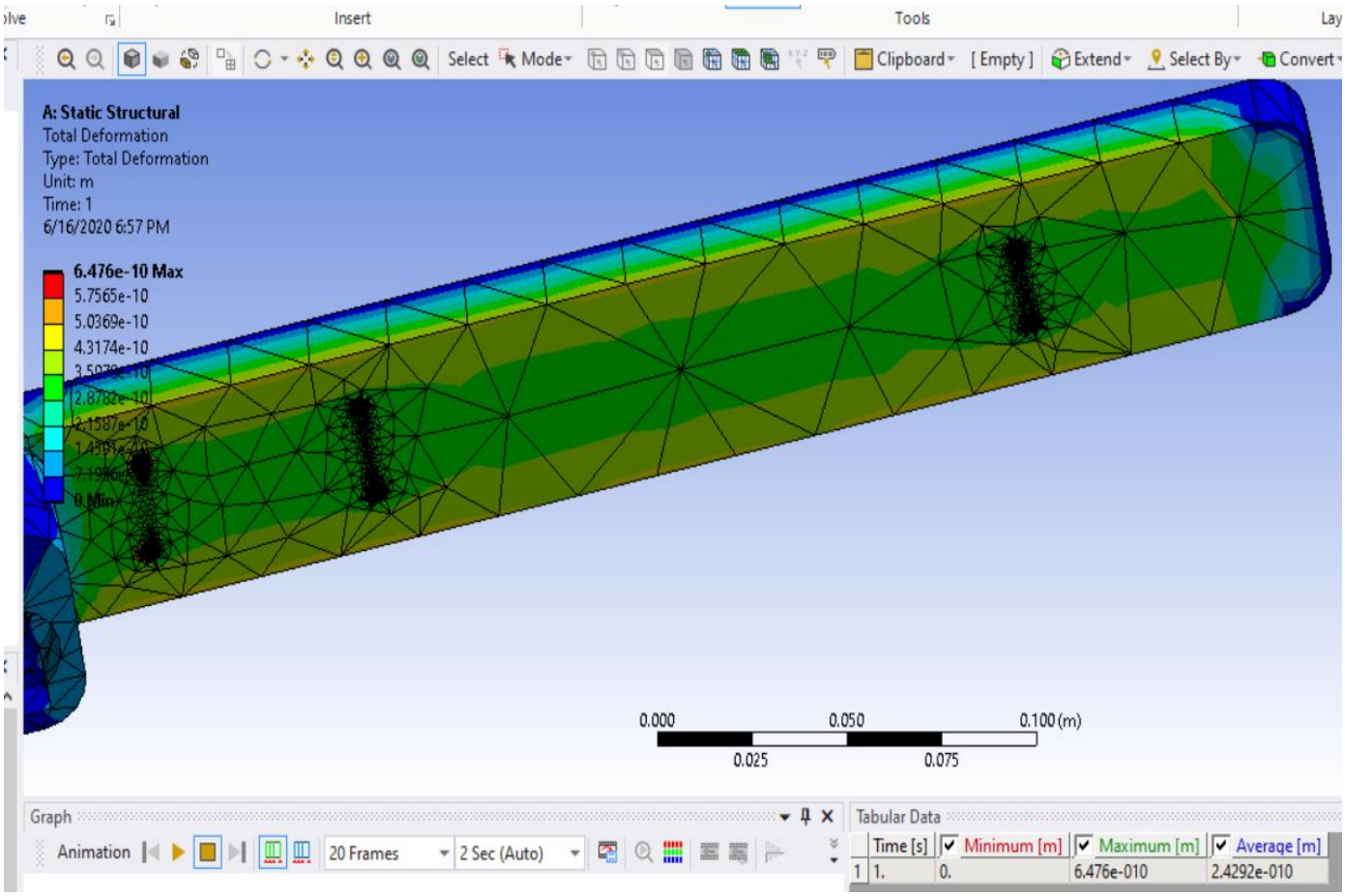



*Figure 43: Total deformation of base face as a result of component's load*

Figure 42 above shows the total deformation of the base as a result of the weight of components that rest on it.

Maximum deformation occurred at the edges at a value of $6.476 * 10^{-7}$mm with the average deformation at $2.43 * 10^{-7}$mm.

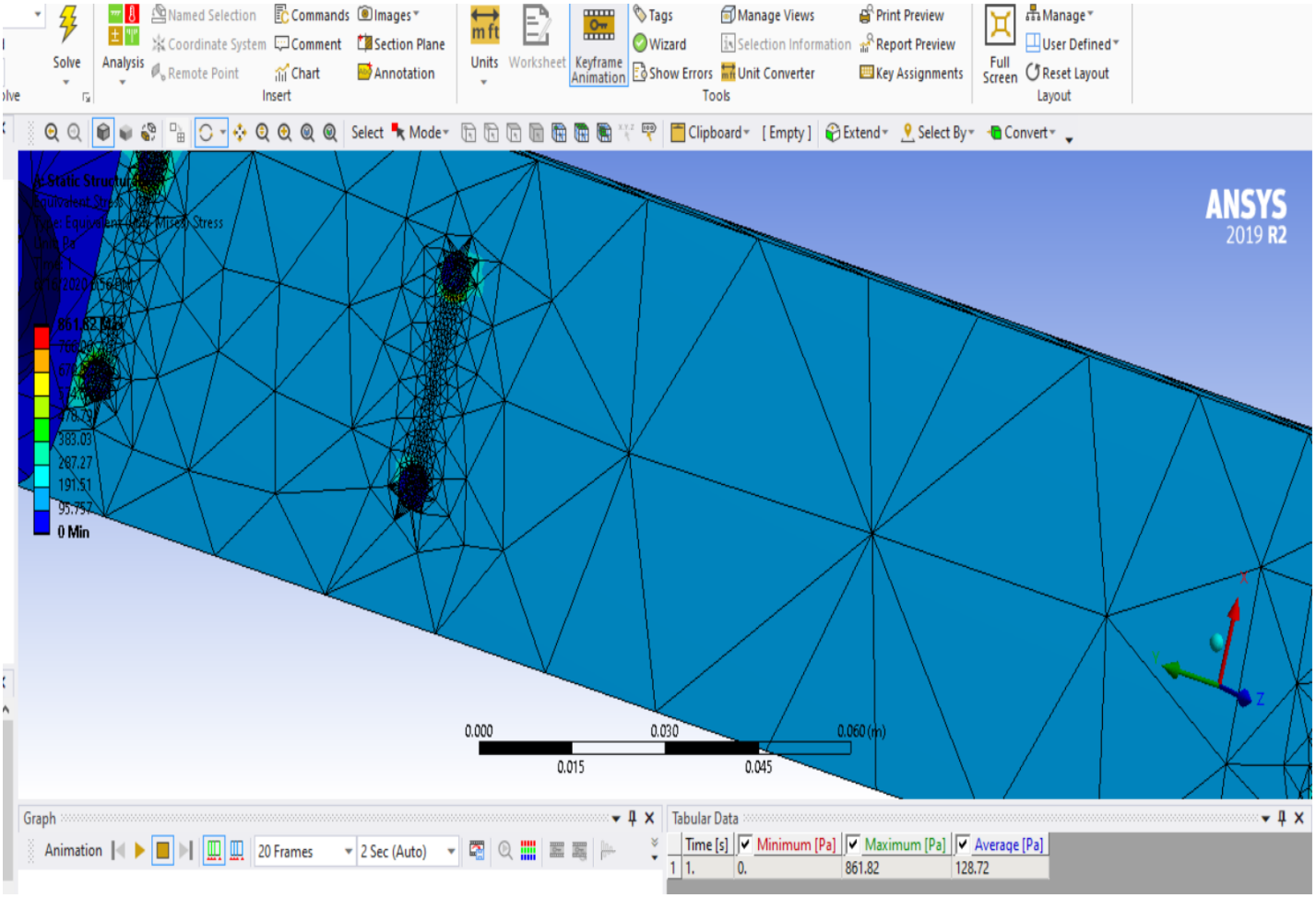



*Figure 44: Equivalent (Von-mises) stress of base as a result of component's load*

All the large stresses occurred at the hole or near the holes and had a maximum stress value at 861Pa. The main face rather had a stress mostly occurring at 95Pa. The average stress recorded was 128.72Pa.

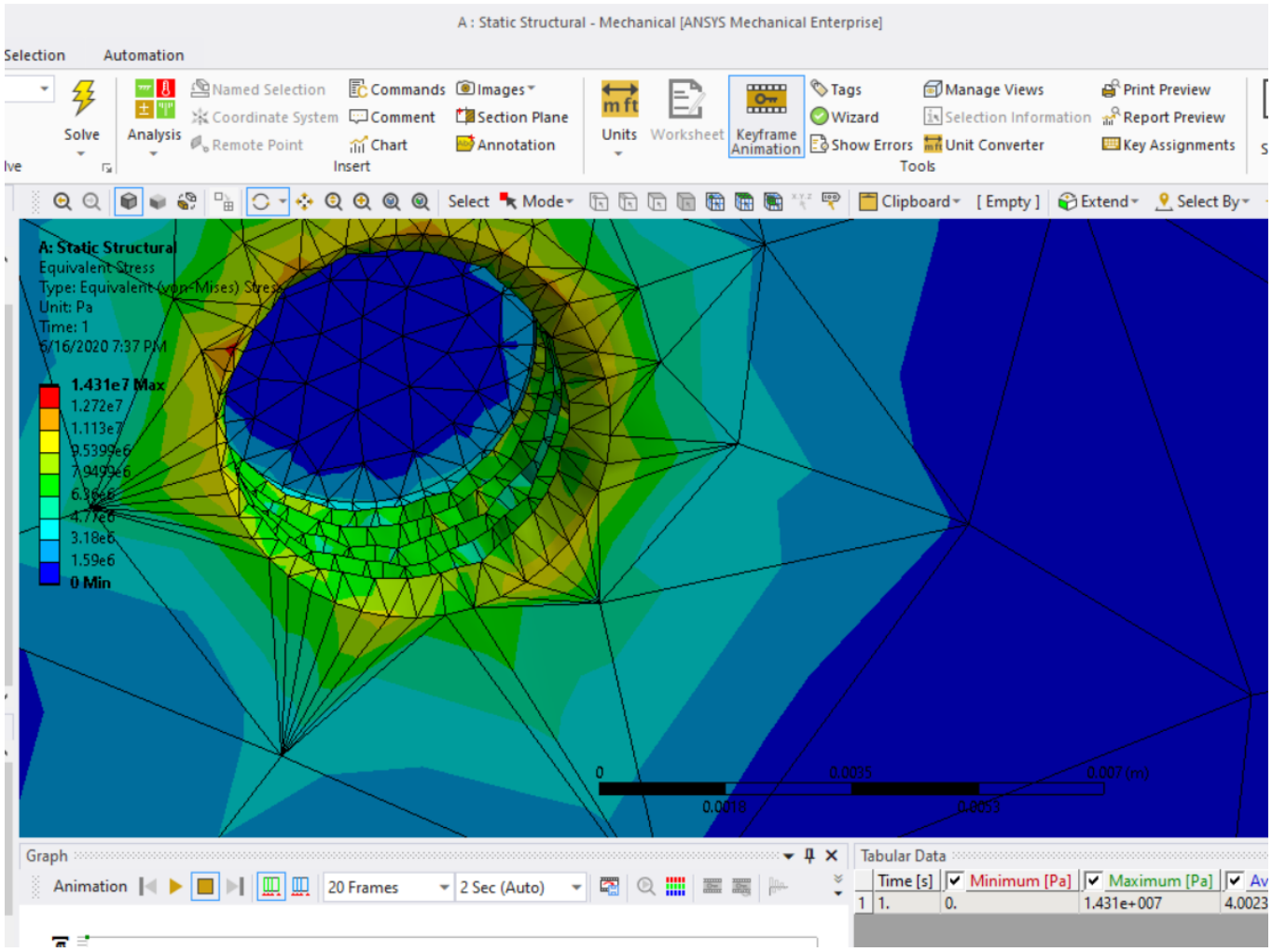



*Figure 45: Equivalent (von-mises) stress of base model as a result of bearing load*

The bearing stress as a result of the screws was maximum at 14MPa and the average at 4MPa.

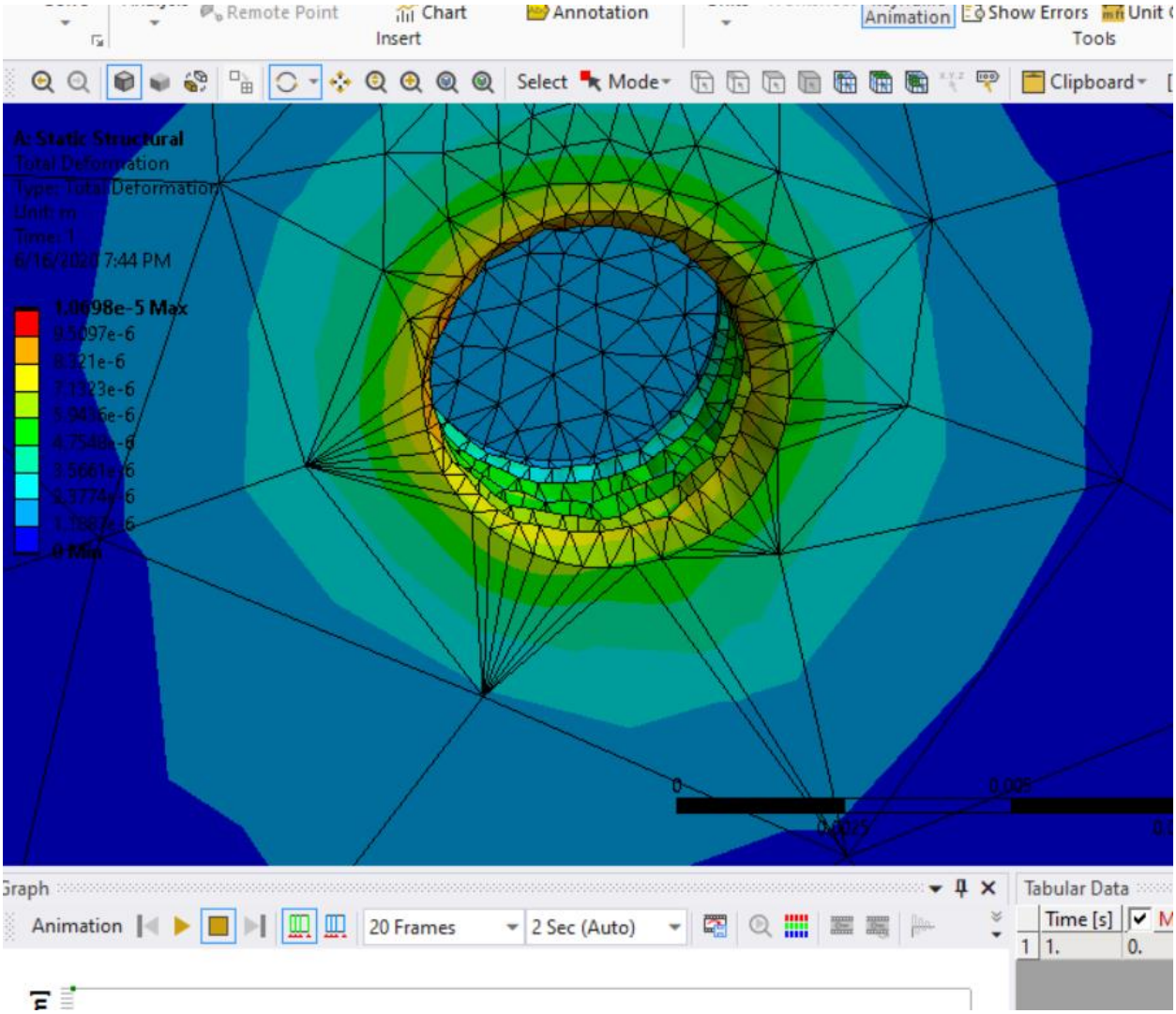



*Figure 46: Total deformation of base model as a result of bearing load*

The maximum deformation was $1.07*10^{-2}$mm.

### 4.1.2 ANALYSIS OF THE THREADED ROD AND NUT

The threaded rod is almost doing the majority of the work. It converts the rotary motion of the stepper motor into linear motion. It receives a torque from the stepper motor and converts it to linear motion with the help of the nut to move the pusher block.

The analysis made accounted for the stresses and deformation as a result of the moment generated by the torque and the friction between the nut and itself. Below, are the results of evaluation of the simulation.

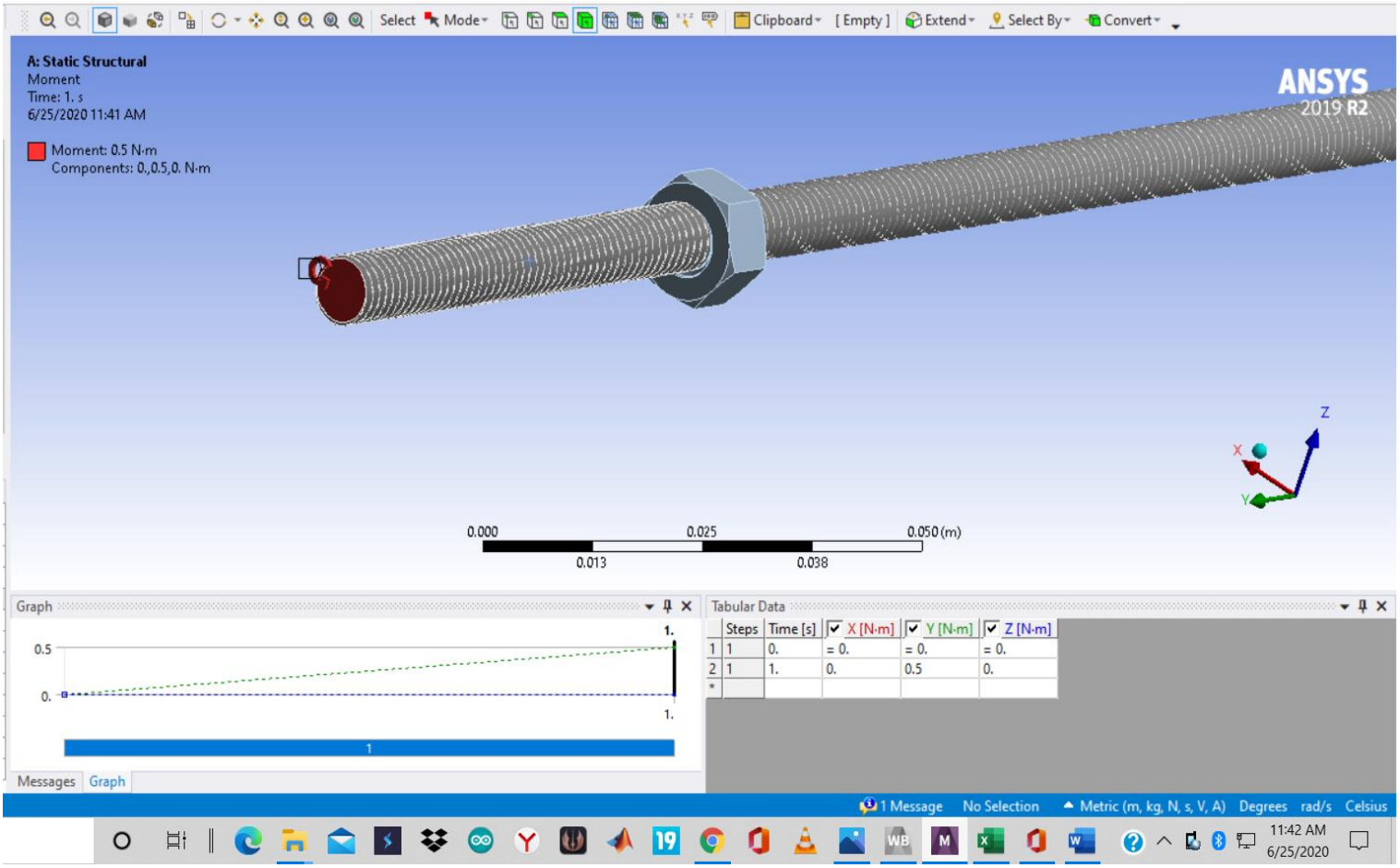



*Figure 47: Torque applied to threaded rod*

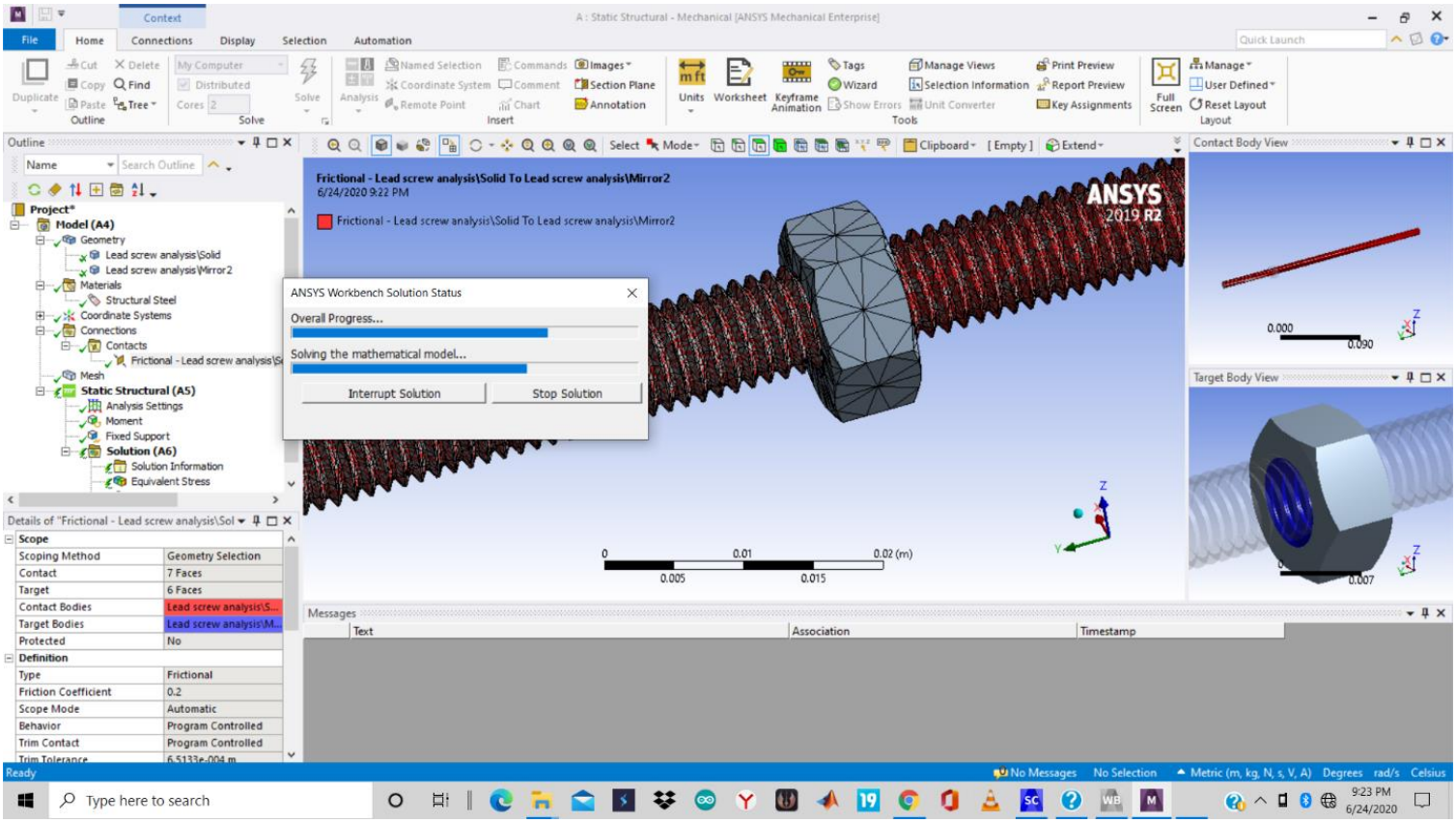



*Figure 48: frictional contact with 0.2 coefficient of friction*

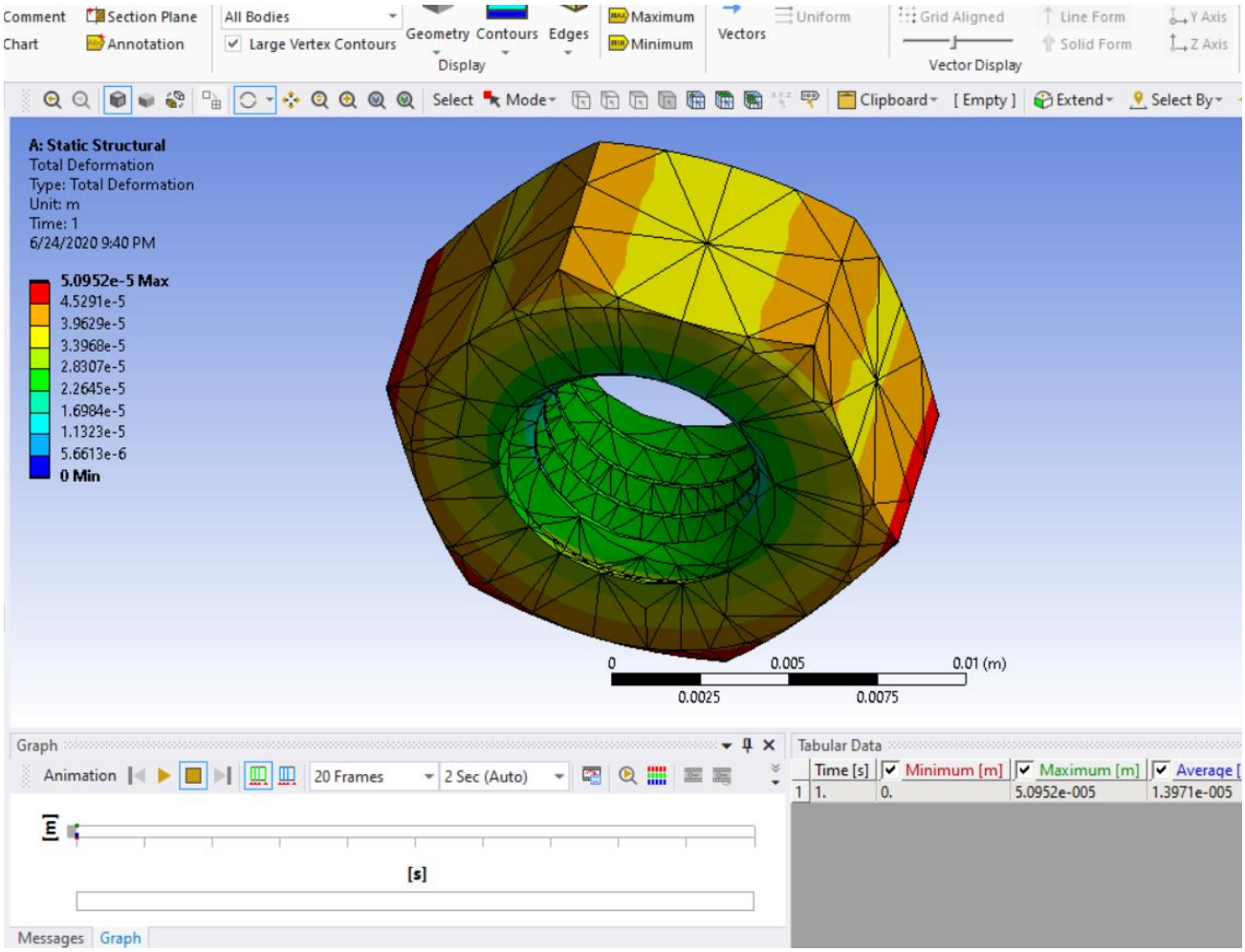



*Figure 49: Total deformation of the nut*

The nut had a total deformation of $5.0*10^{-2}$mm occurring largely at the edge point of fixation. The average occurring deformation was at $1.4*10^{-2}$mm.

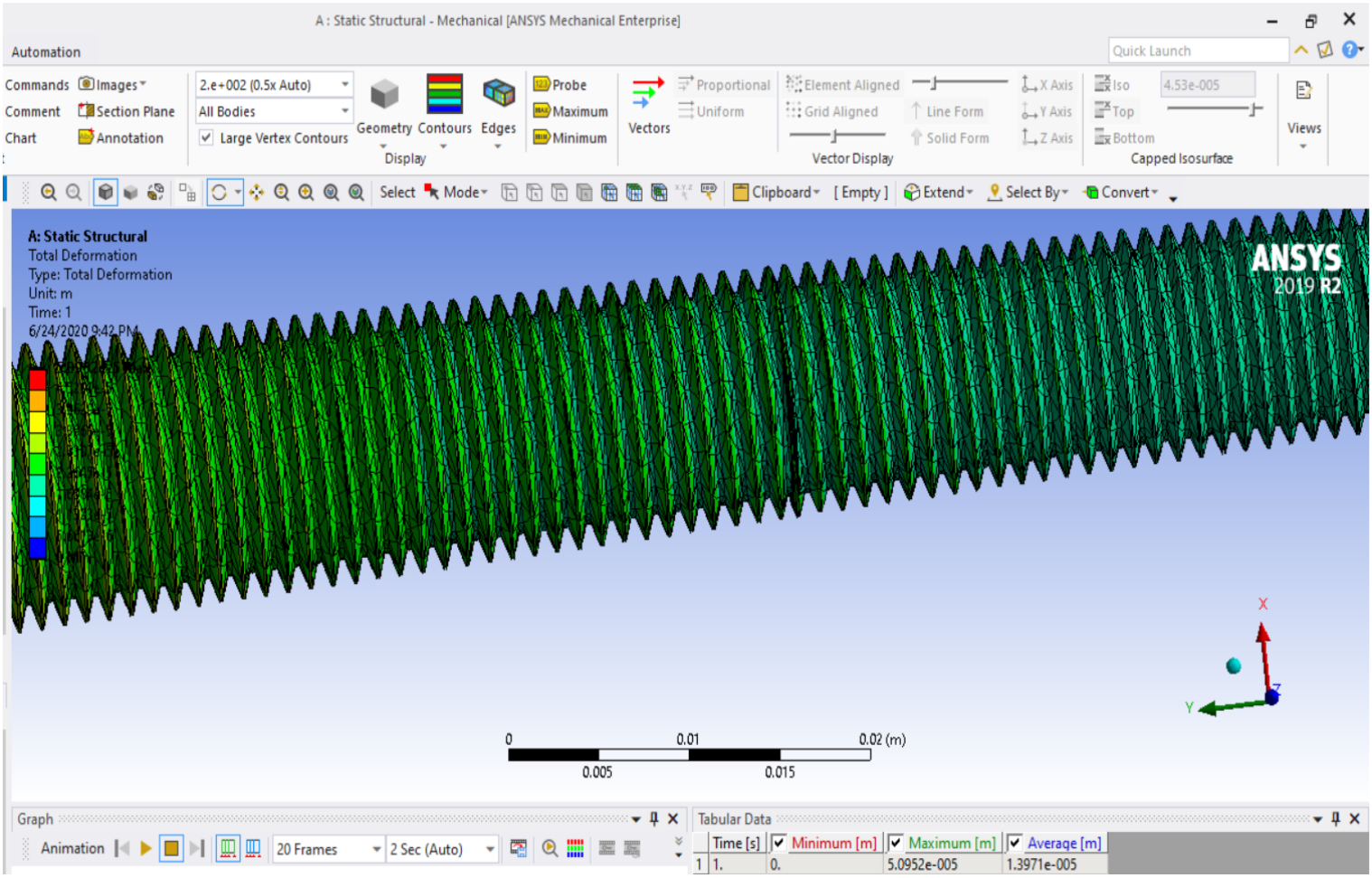



*Figure 50: Total deformation of threaded rod*

The maximum deformation occurred in the y-plane as a wobbling effect. It was at $5.09*10^{-2}$mm with an average of $1.4*10^{-2}$mm.

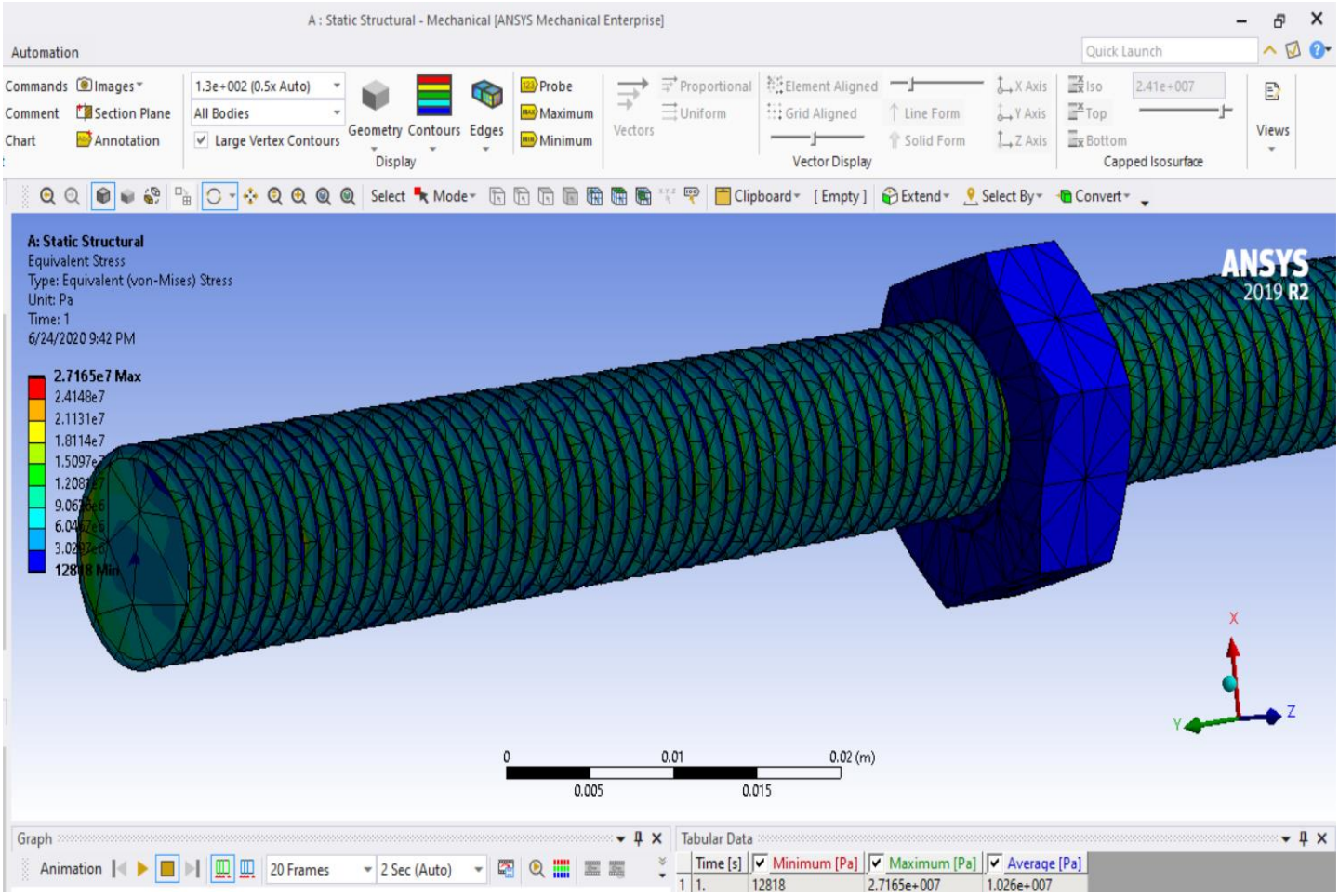



*Figure 51: Equivalent (Von-mises) stress of threaded rod and nut*

The minimum stress of the model occurred at 12.8KPa and the maximum at 27MPa. As we can see the minimum occurred mostly at the nut whilst the maximum occurred at the point of application of the torque and in between the pitches where the translation takes place.

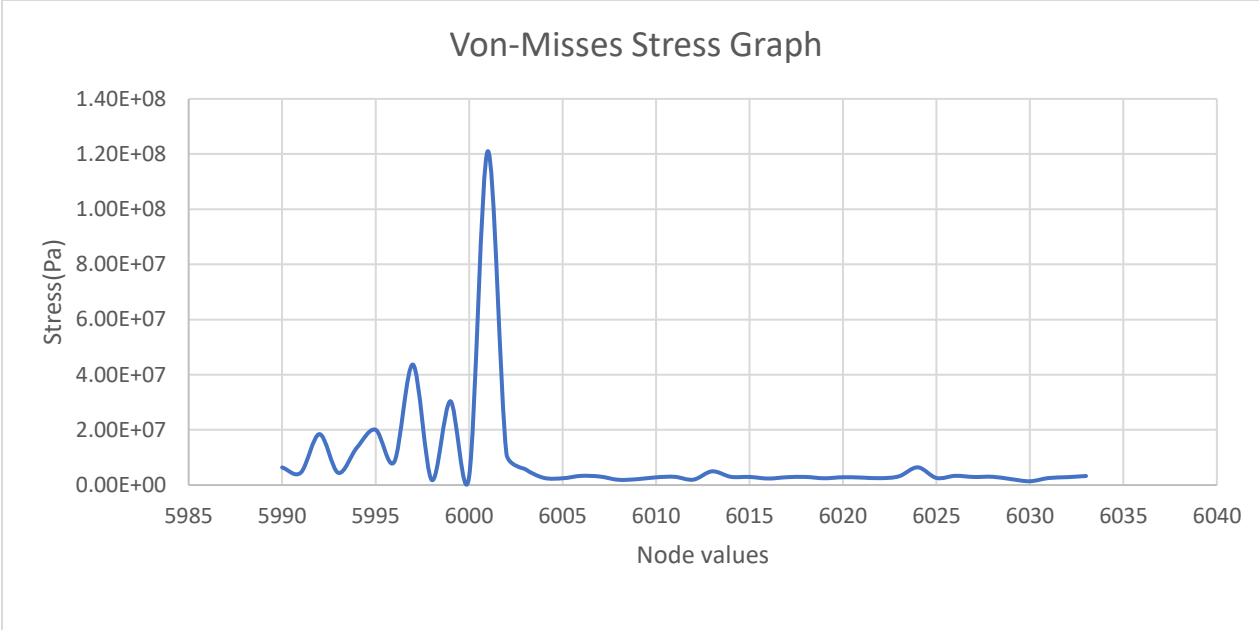



*Figure 52: Plot of nodal elements against stress values*

Further analysis was made on the factor of safety and below are the results.

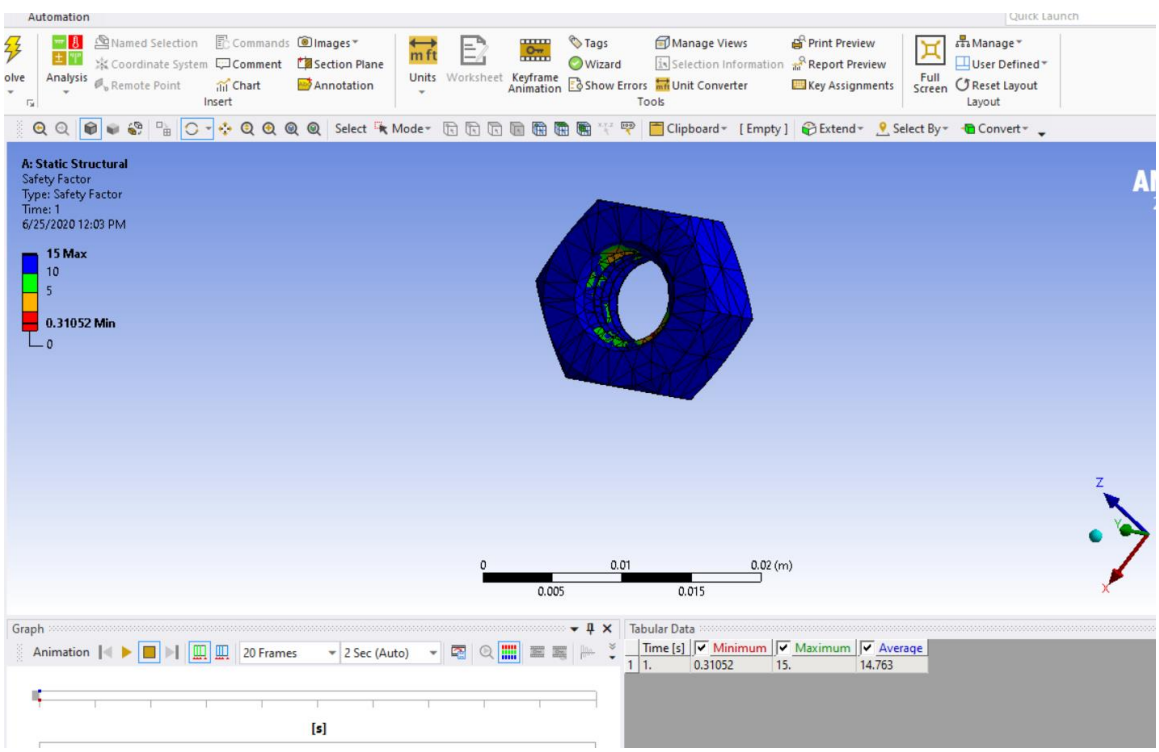



*Figure 53: Factor of safety of nut*

The maximum factor of safety generated from the simulation was 15 and the least was 0.3. The average occurred at 14.7.

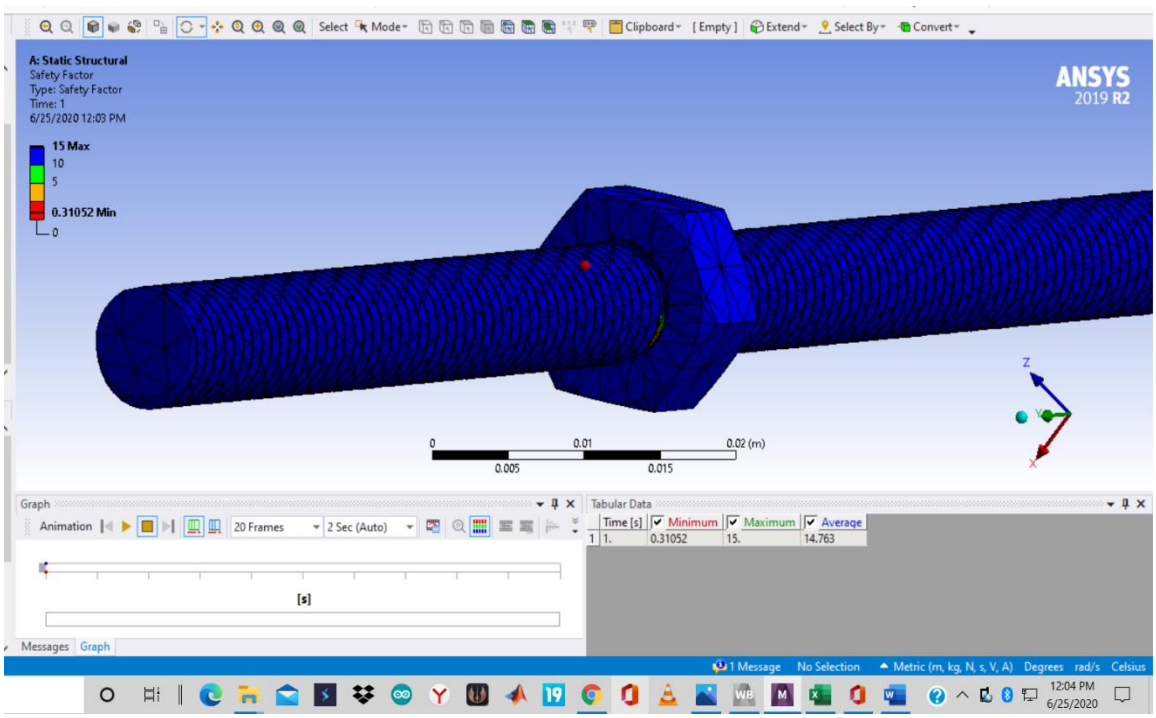



*Figure 54: Factor of safety of threaded rod*

## 4.2 RESULTS FROM BUILT UP MODEL (TESTING)

After building our model, these were the results when it was run.

The device was able to perform multiply cycles of exchange (water was used in place of blood). All the various processes were performed well. It drew out water, pumped and discarded without boluses and at an accurate speed over a period of time. However, after serval cycles had been run, the bipolar stepper motor started to heat up; Performance of the motor reduced and this caused linear translation to slow down.

Besides, there was wobbling effect from the threaded rod which caused left and right moments of our pusher block. Regardless of this, all operations were carried out in that phase.

Vibrations from the stepper motor caused the device to be unstable as the base which received the vibrations moved unsteadily.

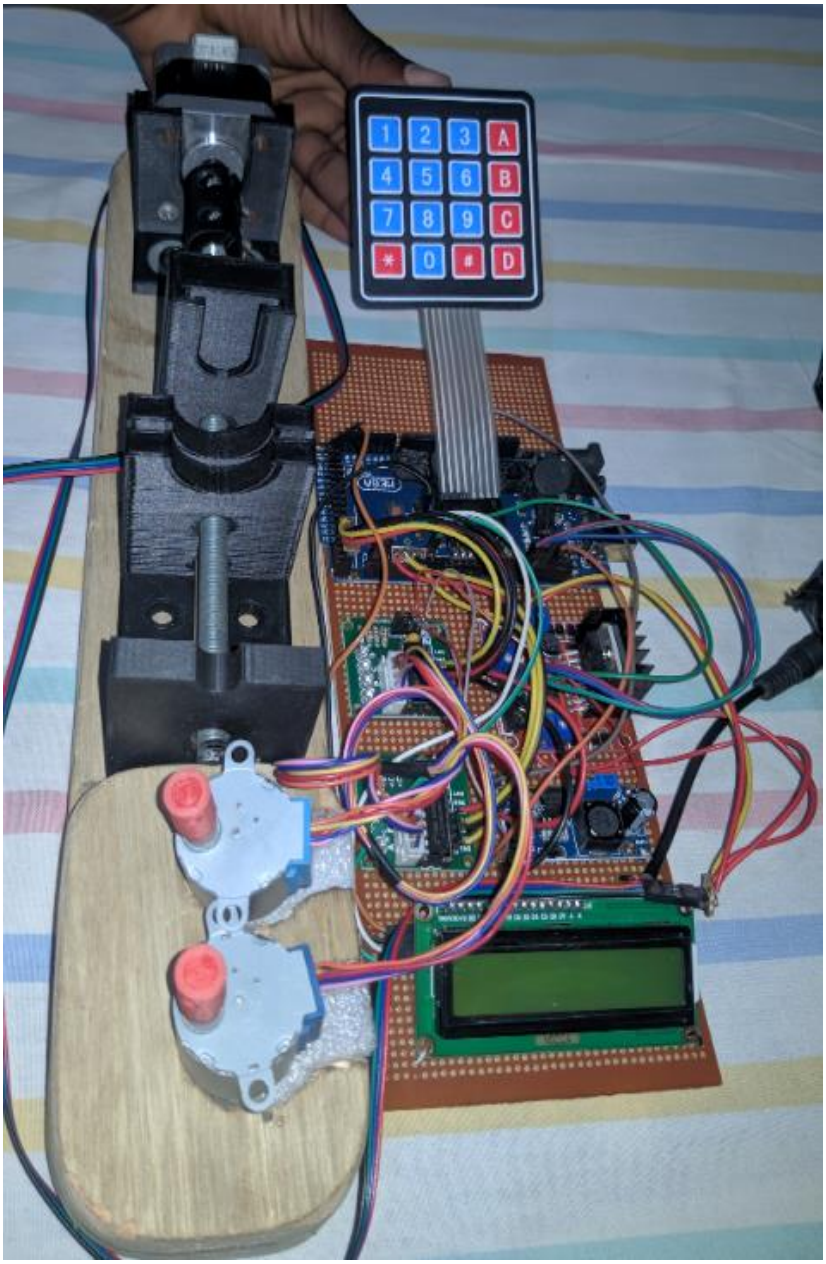



*Figure 55: Built Model of Our Device in Portrait*

After running serval tests over and over again at different time intervals, the 3D printed coupler fractured.

There is also noise after a period of time when the nema 17 stepper motor starts to heat up.

In total, the device's performance was **over** 60%.

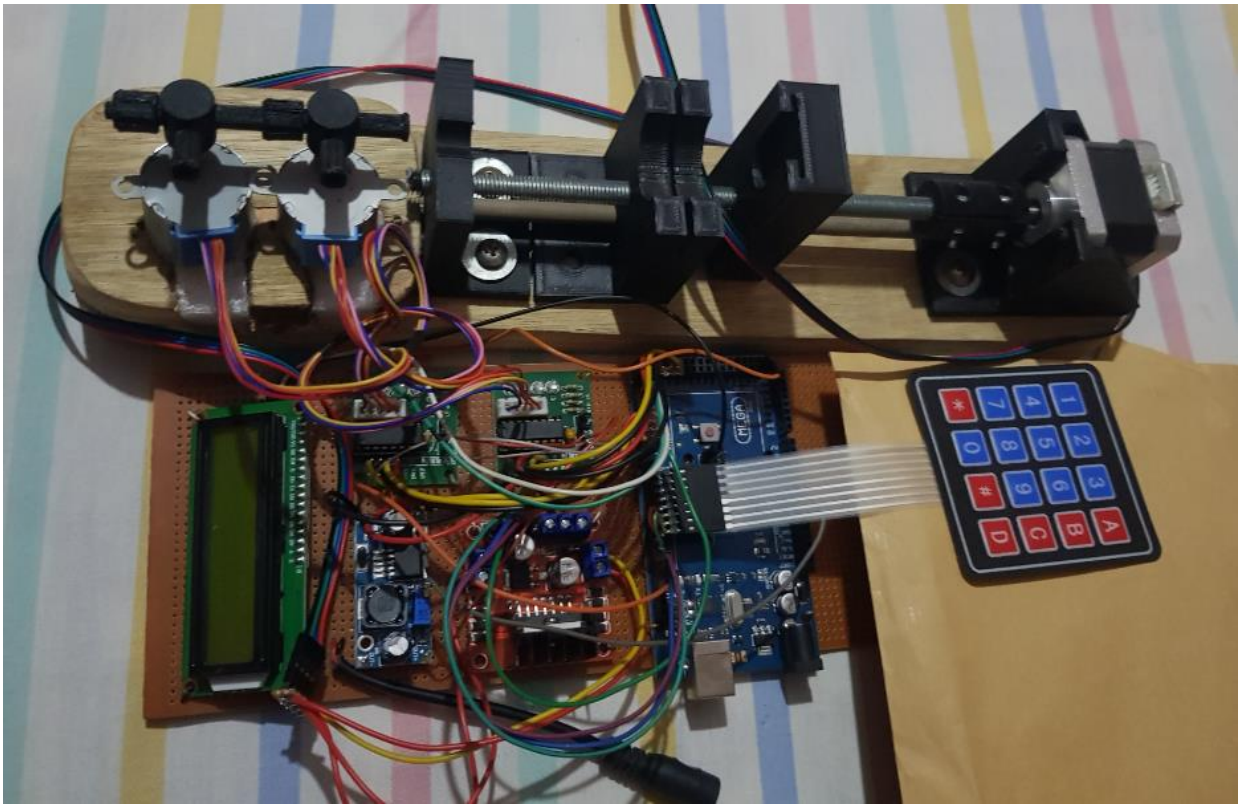



*Figure 56: Built model of our device in landscape*

## 4.3 DISCUSSION

Discussions of the results obtained from the simulation and their implications will be done in this session. The field variable of interest in our analysis is stress. Discussions are therefore made about the stress values and parameters that affect our region of interest. Further discussions on the built model will also be done.

### 4.3.1 STRESS CONCENTRATION

**Base analysis review:**

The top raised level part of the base only had two lightweight unipolar stepper motors rest within it. As a result, the stresses recorded were low and incapable of causing deformation. The maximum stress was 9KPa which yielded a maximum deformation of $1.944*10^{-5}$mm which is almost negligible. Aside the region of the hole where stresses were quite concentrated, the external body rather had very low stresses to 0 as it had little or no impact. This indicates that our choice of material and body density is good enough for the work load.

The main surface of the base where most components rested also had good results with respect to stress concentration. Almost the whole body recorded low stresses of 95Pa with a maximum stress of 861Pa occurring at the holes. Once again, the deformation was almost negligible at the surface where most components rested. The bearing stress at the holes where the screws fix the components to the base were large in magnitude and had a relatively much significant deformation over a long period of time.

We could conclude that the base model designed is suitable for the role it performs. However, the base model would not last over very long periods as the device will start to fail under the bearing stress of the screws.

**Nut**

The stress concentration of the nut occurred mostly at the point of contact with the threaded rod. The nut is attached to the pusher block and the threaded rod inserts into the pusher block through the nut. The friction between the threaded rod and the nut was the cause of the maximum stresses occurring at the point or surfaces of contact. The deformation of the nut as a result of the stresses was also very minute and almost negligible. However, over a long period of time, friction and wear

will become significant. The contact between the pusher block and the nut in safe and has a very low coefficient of friction.

We could conclude that the nut is of good efficiency as it smoothly translates the pusher block in the required linear motion. It is however advisable to change or lubricate the nut so as to reduce friction and wear over a long period of time.

**Threaded Rod**

The threaded rod had relatively large stresses with the maximum occurring at 27Mpa. This is because of the work it does to convert the rotary motion into linear motion. The maximum stresses occurred at the point of application of the torque and in between the pitches where the translation takes place. The average stress was around 10MPa yielding a deformation of $1.4*10^{-2}$mm. The deformation was rather a rotational movement along the y plane. This clearly states that there are slight wobbling effects that occur during rotation of the threaded rod.

Also, with time, the threaded rod will begin to have friction and wear effects occurring at points that make contact with the nut upon translation. Most of the stresses that caused deflection occurred at the first ½ of the length of the rod. This shows that the wobbling will happen in the region of motion of the threaded rod.

However, no significant deformation or stresses were present to deter the rod from performing a good job. Over a good period of time, the threaded rod is able to function well yielding good results.

4.3.2 FACTOR OF SAFETY

Safety factor stress tool was added to the analysis in order to generate appropriate values for the factor of safety of our device. From the results of the analysis, the least factor of safety to consider is 0.310. This factor of safety is as a result of the computational analysis of the stresses on the nut

as a result of friction. Other values from closer nodes computed an average factor of safety of 5-10. The maximum factor of safety was 15. This is because of the stresses generated as a result of the torque input. It is important to note that the results of the factor of safety are not the actual values but rather, limits to a scale of measurement which can be adjusted. Therefore, the least and maximum values do not correspond to the actual value of the factor of safety but a relative value to that scale. Factor of safety will be calculated from the formula

F.S = Ultimate stress/Allowable stress. The results only give us the scale to a correspondent stress of an element or node so as to make it easy to adjust our allowable stress against the ultimate.

## 4.4 DISCUSSION ON BUILT MODEL

From the results of the built model, we could determine that the use of the threaded rod is not the best of decision because of its wobbling effect. This was associated to its high friction, heat production and ability to bend easily. Further research led us to lead screws which has an overall better efficiency. It has less friction, wastes less energy, produces less heat, they are hard and doesn't easily bend. They also do not produce squeaky sounds like the threaded rod.

We ordered for the lead screw for testing. However, due to the Covid-19 pandemic, our order didn't arrive and we were not able to test it.

Also, further research explained the heating effect of the nema 17 stepper motor. It was associated with the choice of motor driver that was used as it couldn't drive the motor with enough current. It was also realized that, most of the base unsteady movements were as a result of the inefficiency of the stepper motor. As the stepper motor driver's performance runs down, the motor tries to generate enough power to perform its assigned work. This causes a dragging effect and increased vibration that amounts to the instability of the device.

In order to correct this, we ordered for a recommended motor driver for the nema 17. However, none of the new components ordered were received due to the covid-19 pandemic.

## 4.5 COST ANALYSIS

Most medical devices are generally very expensive. This is largely due to their sophisticated set of functions for use on patients. Table 3 below shows this argument.

*Table 3: Average prices of medical devices around the world*

| **Medical Device Type** | **Name of Medical Device** | **Price (USD)** |
|---|---|---|
| Class I devices | 1.Stethoscope | $35.00 – $500.00 |
| | 2.Bandage | $10.00 – $25.00 |
| | 3.Scalpel | $33.00 |
| | 4.Forceps | $4.00 - $22.00 |
| Class II devices | 1.Computed/Computerized Tomography (CT) Scan | $270.00 - $5,000.00 |
| | 2.Infusion Pump | $200.00 - $500.00 |
| | 3.Powered Wheelchairs | $1,400.00 - $8,000.00 |
| | 4.Pregnancy Test Kit | $8.00 - $ 20.00 |
| | 5.Catheter | $82 - $199 |
| Class III devices | 1.Pacemaker | $5,000 - $10,000 |
| | 2.Deep-brain Stimulator | $20000 - $30000 |
| | 3.Defibrillators | $700.00 - $4,000.00 |
| | 4. High frequency ventilators | $19,000.00 |

We however, decided to employ cheap but quality materials in our design to make our device of a much lower cost than most medical devices. Table 4 below shows the cost of production of our device. These are real values and not anticipated costs. This amount of money was actually spent on the production of our device.

*Table 4: Simple breakdown of device cost of production*

| | |
|---|---|
| Cost of 3D printing | GHS 120.00 |
| Cost of electronic components | GHS 470.00 |
| Cost of mechanical components | GHS 15.50 |
| Workmanship and proposed profit | GHS 370.00 |
| Total | GHS 975.50 = USD 170.00 |

Hence, compared to most medical devices that have higher functions like the class III devices or even the infusion pump, it can be seen that our device will be relatively cheaper. Also, when produced in bulk, it is anticipated that the cost of production will even be much lower, and hence a much lower price than the current cost.

# CHAPTER FIVE

# CONCLUSION AND RECOMMENDATIONS

## 5.1 CONCLUSION

The main aim of this project was to design and build a low-cost and effective device for automating exchange transfusion. The automation of the neonatal exchange transfusion comes as a relief to any doctors and health workers. Our implementation of our proposed solution was 95% complete; with the built prototype. This was due to the outbreak of the coronavirus pandemic, which caused the seizure of most human activities around the world and in Ghana also. Borders of countries were closed, cities were locked down, schools were closed down and all were advised to stay at home. Hence, we couldn't continue with our building of the device. We could buy components we needed also. We intend to continue with this project and make it a reality. The final product of this project will not be affected by power fluctuations, since it will have a backup power source from powerful batteries. Its cost as compared to many other medical devices is very low, and can be purchased by the average hospital in Ghana. This can be seen in the cost analysis done in the previous chapter.

## 5.2 RECOMMENDATIONS

During the exchange transfusion, complications such as the presence of air bubbles and the formation of boluses may occur when there is an unsteady flow rate. Our device promises a steady automated flow rate. However, it is recommended that future work be done by adding a means for air and bubble detection so as to prevent further complications.

Future improvements could implement the use of lead screws in place of the threaded rod, as it likely yields a greater efficiency.

Further improvements could be made on the valve design. It is recommended that a tighter and blood impermeable material like acrylic is used in place of the PLA material. This will help prevent blood leaks and contamination.

# REFERENCES


[1] J. Alkén, S. Håkansson, C. Ekéus, P. Gustafson, and M. Norman, “Rates of Extreme Neonatal Hyperbilirubinemia and Kernicterus in Children and Adherence to National Guidelines for Screening , Diagnosis , and Treatment in Sweden,” vol. 2, no. 3, pp. 1–11, 2019, doi: 10.1001/jamanetworkopen.2019.0858.

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