

**THE DEVELOPMENT OF SPECTRA KNEE CPM
MOVING TRAIN WALK**

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MOVING TRAIN WALK**

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**THESIS SUBMITTED IN PARTIAL FULFILLMENT FOR THE DEGREE
OF BACHELOR OF ELECTRONIC ENGINEERING TECHNOLOGY
(MEDICAL ELECTRONICS) WITH HONOURS**

**DEPARTMENT OF ELECTRICAL ENGINEERING
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2017

DECLARATION

I hereby declare that the work in the thesis is my own except for quotations and summaries which been duly acknowledged.

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Date : 25 May 2017

ACKNOWLEDGMENT

First of all, I would like to express my deepest gratitude to my supervisor Dr. Hj Zunuwanas Bin Mohamad. He is the one who give me chance to work with him and for the guidance during my final year project. I really appreciated the knowledge and encouragement given in order to finish up this project.

Beside that, a special thanks to my beloved family for giving me strength and encouragement with no ends. In addition, my appreciation to my friends who are willing to be the test subjects for data collection and thanks for helping me a lot in my student life.

Lastly, I would also like to thank all those who supported me in any aspect during the completion of the project.

ABSTRACT

Total Knee Arthroplasty (TKA) or Total knee replacement (TKR) is a widely used operation that has radically improved the quality of life of millions of people suffering from symptomatic Knee Osteoarthritis during the last decades. Total Knee Arthroplasty (TKA) is an operation that replacing an artificial knee due to the degeneration by osteoarthritis. Although TKA is common for the management of arthritis but it can cause knee stiffness. Thence, Continuous passive motion (CPM) is a rehabilitation device that used to prevent stiffness of joints and allow recovering patient full functionality after surgery. The purpose of this project is to innovate the existing Knee CPM Device to more easy to carry, comfortable and convenience to use, more affordable, and even can operate in DC power supply. Besides, this project also examine the usability of the device. After that, a DC brushed motor is use to repeatedly moves the joint through a specified range of motion (ROM) with controllable speed and the duration by using an Arduino MEGA 2560. In other than that, there are some selected volunteer from public were involved in the usability test. During the usability test, the collected data from all subjects was used to evaluate the achievement of this innovative product. In addition, those collected data will be analyse by using Statistical Package for Social Sciences (SPSS) software. From the results, there are more than 80% of subjects are agree about this device are comfortable and easy to use. In conclusion, this device has proved comfortable and easy to use.

ABSTRAK

Total Knee Arthroplasty (TKA) atau *Total Knee Replacement (TKR)* adalah operasi yang digunakan secara meluas untuk meningkatkan kualiti kehidupan ramai orang yang mengalami gejala lutut *Osteoarthritis* dalam dekad yang lalu. TKA merupakan satu operasi yang menggantikan lutut tiruan disebabkan oleh degenerasi dengan *Osteoarthritis*. Walaupun TKA adalah cara penyelesaian yang biasa diguna untuk pengurusan artritis tetapi ia boleh menyebabkan *stiffness*. Selain itu, *Continuous passive motion (CPM)* merupakan alat pemulihan yang digunakan untuk mengatasi *stiffness* dan membaik pulih pergerakan pesakit selepas pembedahan. Tujuan projek ini adalah untuk membuat pembaharuan CPM lutut Peranti yang sedia ada untuk lebih mudah untuk menjalankan, selesa dan mudah diguna, lebih murah, dan juga boleh beroperasi mengguna bekalan kuasa DC. Di samping itu, projek ini juga mengkaji kebolegunaan alat ini. Seterusnya, *DC brushed motor* digunakan untuk berulang kali bergerak lutut serta pemulihan *Range of Motion (ROM)* dengan kelajuan terkawal dan dalam tempoh dengan ditentukan menggunakan *Arduino MEGA*. Lain daripada itu, beberapa orang awam telah dipilih sebagai subjek untuk menjalankan *usability test*. Semasa *usability test*, data yang dikumpul dari subjek akan digunakan untuk menilai pencapaian produk inovatif ini. Sementara itu, data yang dikumpul akan dianalisis dengan menggunakan *Statistical Package for Social Sciences (SPSS)*. Berdasarkan keputusan, lebih daripada 80% subjeks bersetuju bahawa alat ini adalah selesa dan mudah untuk digunakan. Kesimpulannya, alat ini telah dibuktikan selesa dan mudah untuk digunakan.

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LIST OF SYMBOLS

%	Percent
°	Degree
T	Torque
ω	Angular Velocity
F	Force
R	Radius of the Armature
N·m	Newton Metre
V	Applied Voltage
E _b	Back Electromotive Force
I _a	Armature Current
R _a	Armature Resistance
π	PI
N	Revolution per Minute
L	Screw Lead (in.)
P	Axial Load, (lb)

LIST OF ABBREVIATIONS

TKA	Total Knee Arthroplasty
TKR	Total Knee Replacement
OA	Knee Osteoarthritis
ADLs	Activities of Daily Living
ROM	Range of Motion
CPM	Continuous Passive Motion
AC	Alternating Current
DC	Direct Current
RPM	Revolutions per Minute
ACL	Anterior Cruciate Ligament
SPSS	Statistical Package for the Social Sciences
PWM	Pulse Width Modulation
IDE	Integrated Development Environment
LCD	Liquid Crystal Display

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND OF STUDY

The previous studies have shown that 15% of the world population suffers from osteoarthritis which includes 39 million people in the European countries and more than 20 million of Americans. The number of patients affected is on the rise and by 2020 this figure would have probably multiplied.[1] In Malaysia, 9.3% of adult Malaysians have knee pain and more than half of them have clinical evidence of Osteoarthritis. The prevalence ranges from 1.1% to 5.6% in the various ethnic groups in Malaysia.[1] [2]

After that, according to V. S. Nikolaou (2014), Total Knee Arthroplasty (TKA) or Total knee replacement (TKR) is a widely used operation that has radically improved the quality of life of millions of people suffering from symptomatic Knee Osteoarthritis during the last decades.[3] TKA is an operation that replacing an artificial knee due to the degeneration by osteoarthritis.[4] Besides, TKA is one of the most common procedures that performed during hospital stay, and according to the national registries, there is a continuously increasing number of operations performed worldwide each year due to population grows.[1] [5]

The target of TKA is to re-establish the joint to an ache-free, steady and flexible state. An early mobilization quickly turned into an urgent piece of rehabilitation protocols after TKA, in propelling traditional practices, which kept up immobilization in extension to retain wound recuperating. Therefore, to avoid the

constraints and falls after TKA, the recuperation of knee flexion is important for a patient after TKA in their daily activities.[6] Since the movement of a patient after TKA are restricted, they may face problem to perform some activities of daily living (ADLs) like walking, climbing and crouching.[7] In our daily activities, a person may need minimum 65 ° of knee flexion to walk, 85 ° for stair climbing, 95 ° for sitting and standing, and 115 ° to squat and lift an object. [8][9][10]

In other than that, although TKA is common for the management of osteoarthritis but can cause knee stiffness.[11][12] Stiffness can be characterized as restricted range of motion (ROM) that influences a patient motion and cause pain to the patient. In addition, knee stiffness also affect patient ability to perform certain activities including standing up from a seated position for the patient.[13] At the same time, stiffness is a most complicated in terms of pathogenesis and treatment because it is one of the most troublesome complications to cure. Consequently, it speaks to a disappointing issue for both surgeon and patient.[14]

Continuous passive motion (CPM) was utilized as a part of the rehabilitation of patients after knee surgery as far back as Salter and colleagues presented it on early 1980s.[15] It is a technique of passively and repeatedly moves the joint through a specified ROM to gently flex and extend the knee joint by a mechanical device. In previous studies, the CPM device is actually widely used after TKA because it might prevent the stiffening of joints and allow recovering patient full functionality after surgery. [16] Likewise, it also capable to incorporate pain relief, upkeep of range of motion, enhanced injury recuperating, and speedier recuperation.[17] Afterward, due to the movement of a patient after TKA is restricted, the CPM device is a better choice to offering the regular exercise to the knee because it does not required the effort from the patient.

Based on the characteristics of CPM device, it can adjust the set up an appropriate time, range of angle, and speed by the physiotherapists in the beginning of therapy to avoid cause pain to patient. Next, it can assist the duty of physiotherapist and accomplish such routine physical movements without the assistance of physiotherapist. When the patient has learned how to operate the CPM device, they

can do the therapy in home by using the CPM device. Therefore, the development of a CPM device was not solely offered benefit for the patient but it also brings convenience for the physiotherapists.

1.2 PROBLEM STATEMENT

The use of CPM device is usually advised by doctor and it will perform all the exercises that physiotherapist prescribes. Therefore, physiotherapists will use the knee CPM device on patient to restore their movement. After I studied the existing device there are some problems identified. First, knee CPM device is a large and heavy machine.[16] It will cause the user difficult to carry it. Second, the existing device is only operating in AC power supply. Thus, the user has to looking for an AC power supply before the treatment start and it can cause inconvenience for user. Third, an existing device on market is expensive.[18] It remains unaffordable for many because it can cost more than thousand dollar in current market.

1.3 OBJECTIVE

1. To design a knee CPM device that can reduce the pain and discomfort when operate.
2. To innovate a portable knee CPM device that easier to carry and uses.
3. To analyse the usability of knee CPM device.

1.4 SCOPE OF STUDY

The scope of this study is to examine the ease of use and comfortable of knee CPM device. Furthermore, to identify the usability of this product as well as develop a cost effective CPM device.

1.5 STUDY POPULATION

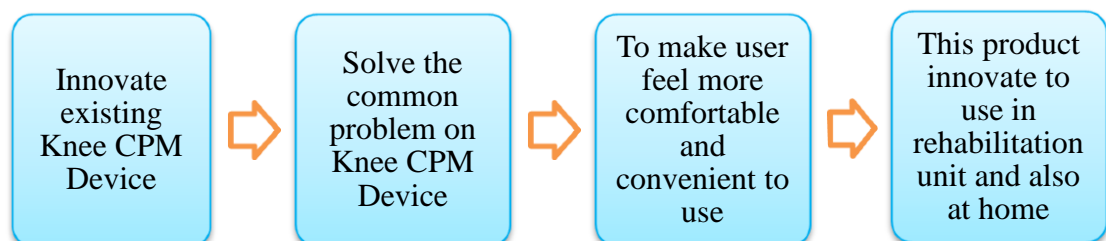
The target population for this research are included the specialist from hospital and the students from Politeknik Sultan Salahuddin Abdul Aziz Shah, Shah Alam, Selangor.

1.6 SAMPLE SIZE AND SAMPLING TECHNIQUE

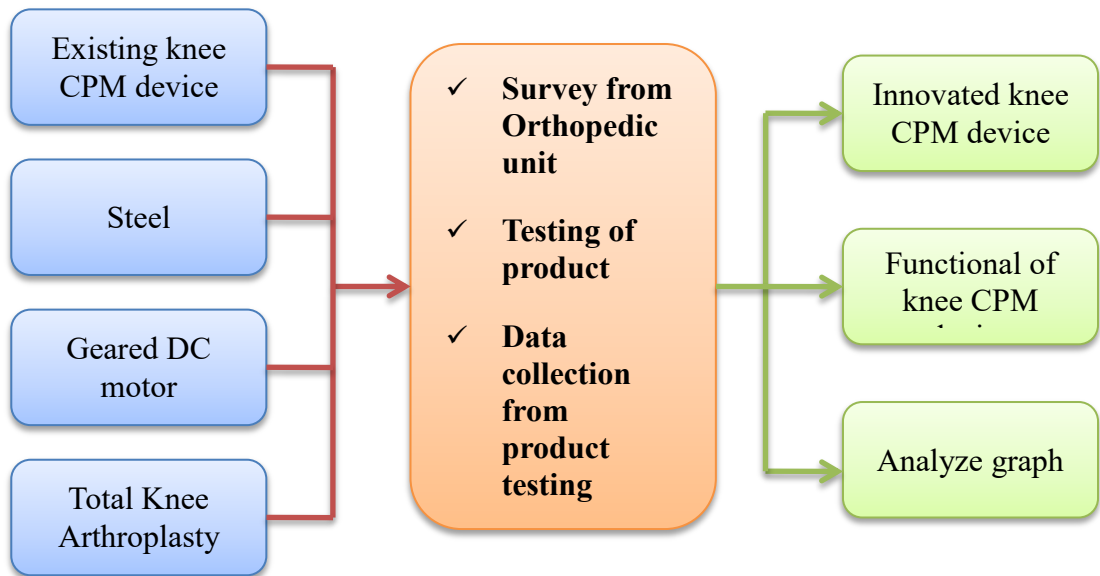
A simple random sampling procedure was used for selecting the participants in this study. In this study, there are 10 of survey questionnaire was distributed to the hospital staff at the general hospital in November 2016. In addition, to conduct the usability test, there are 30 subjects were selected from public and the examination was done in the questionnaire method. Those data will be analyse to determine the usability of the developed device.

1.7 SIGNIFICANCE OF THE STUDY

This purpose of this study is to innovating the existing knee CPM device to provide an effective method to help the TKA patient's recovery their motion of legs after surgery. Likewise, this innovation also can solve the current problem of the Knee CPM device. Besides, the existing knee CPM device may cause pain during therapy and it only can operate in AC power supply. Therefore, I will focus on to looking for a solution to solve the problem above by develop a new product to benefit the society.



1.8 THEORETICAL OF THE STUDY



CHAPTER 2

LITERATURE REVIEW

2.1 CONTINUOUS PASSIVE MOTION (CPM)

2.1.1 Introduction of CPM Device

Continuous Passive Motion (CPM) is widely utilized in rehabilitation of joints following injury or surgery on articular tissues, including cartilage, tendons, and ligaments. CPM will repeatedly move the joint without active muscle contraction. In addition, it often achieve by a mechanical stretching devices that move the influenced joint through a specify arc of motion for an extended period of time. After that, CPM assure that passive motion can be performed in the scapular plane and through a secure arc of motion without pressurize the repair.

While passive motion therapy can be performed by a trained therapist, CPM devices able to permit expanded length of treatment, which can be performed in a controlled, predefined way. Besides, CPM is purpose to prophylaxis and cure of joint contractures of the extremities, with the objective to keep up or re-establish Range of Motion (ROM) to the joint. At present, CPM devices are available for various joints such as the knee, ankle, hip, elbow, shoulder, finger and jaw. [18] The existing CPM devices manufacturer includes the Artromot, Jace System, Chattanooga, Kinetec, QAL Medical and others.

2.1.2 Knee CPM Device

A Knee CPM device (see Figure 2.1) is representing to the employ of a motorized device that applied to a patient's lower extremity, and constantly moves the patient's knee through a pre-set ROM. This device is ordinarily utilized on postoperative period and it has been theorized that early passive ROM may avoid the structure of adhesions that lead to joint stiffness.[18] CPM machines for rehabilitation in the clinic or home are used post operatively to prevent joint stiffness after Total Knee Replacement, Anterior Cruciate Ligament (ACL) repair, Femur Fractures, closed manipulation of the knee or shoulder.[16]

After that, employ of CPM after TKR as a major aspect of postoperative rehabilitation is essentially supported for its potential advantages on early acquire of knee ROM. A systematic review demonstrated that the applied of CPM following TKR has short-term impacts on recuperation of knee flexion ROM and functional mobility, no matter of the extensive variations in CPM protocols. Moreover, speedy progress of CPM application essentially predicts short-term flexion and post-TKR long-term actual results.[19] Furthermore, a CPM machine has other applications like pain relief, prevent muscle breakdown, enhance the recovery process, regain ROM in the shorter period of time, and reduce the risk of blood clotting.[20]

Nevertheless, despite the fact that was only for a brief time frame, CPM treatment pathologically limited the stiffness in the joints contrasted with the immobilization strategy. The pathological CPM treatment repeats flexion and extension practices manually in order to advance the flow of the blood and expand the rehabilitation procedure in a brief time frame. This process will minimize hemiarthrosis and periarticular edema around the joints after trauma and surgical operation of the knee. Due to this reason, utilizing the CPM technique can diminishes the quantity of times visiting hospitals and consequently keeps on ascending in its usage.[21]

Likewise, CPM is proposed to rehabilitation on articular cartilage and ligaments, as well as reducing length of stay in hospital, enhance ROM, and lead to fewer circulatory complications. With the utilization of CPM, the patient ought to intend to accomplish no less than 0 to 90 degrees ROM upon hospital discharge and 0 to 120 degrees upon realization of postoperative rehab.[22]

In addition, there are one of the mechanisms in CPM which is the movement of synovial fluid to allow for better dispersion of nutrients into damaged cartilage, and diffusion of other materials out; such as blood and metabolic waste products. Another mechanism is the precaution of fibrous scar tissue development in the joint, which tends to limit the ROM for a joint. Therefore, CPM device are a machine that created for benefit the patient after surgery or operation. In general, CPM can possibly provide a good result to patients as well as would be convenient on both surgeons and the healthcare system.[23]



Figure 2.1: Knee CPM Device

2.2 TOTAL KNEE ARTHROPLASTY (TKA)

2.2.1 Introduction of Total Knee Arthroplasty (TKA)

Total Knee Arthroplasty (TKA) or Total Knee Replacement (TKR) is a commonly used surgical procedure that has significantly enhanced the quality of life of huge number of individuals experiencing from symptomatic knee OA

at the most recent decades. The previous research has shown that TKA is one of the widely used techniques performed during hospital stay. According to the national registries, there are endlessly increasing number of operations performed worldwide each year. It has been evaluated that, by 2030, the interest for essential TKA is anticipated to increment to 3.4 million surgeries performed every year in the United States alone. In fact, studies have demonstrated that TKA is one of the worthiest surgical techniques for patients and surgeons.[24]

According to previous study, TKA is an Orthopaedic surgery which removing diseased or destroyed part of the bone and replacing it with an artificial part (see Figure 2.2). [25] Degeneration due to osteoarthritis is one of the main causes to performing TKA operation. The procedure of TKA involves replacement parts will consist of a metal cap placed on the end of the femur and a plastic cap placed on the top of the shin bone. These components or prostheses will produce a smooth gliding surface when contact. At times, a plastic insert utilized to supplant kneecap.[4]

The main target of TKA is to alleviate suffering and regain the ROM in the patient knee. Recovery of knee flexion ROM is a key indicator and crucial outcome of a satisfactory TKA. [19] Therefore, a proper rehabilitation after a TKA is essential to the recovery. Physical therapist will help patient regain much of knee ROM through Rehabilitation therapy. So the physiotherapists will tailor ROM exercises, progressive muscle-strengthening exercises, body awareness and balance training, and activity-specific training to patient specific needs.[26]



Figure 2.2: (Left) Osteoarthritis Knee (Right) Knee after Surgery

The basic concepts of physical therapy management following TKA are the same regardless of the severity of the underlying disorder, the type of knee prosthesis, or the surgical approach.[27] These basic concepts are:

- a. Return to normal biomechanics.
- b. Improvement in range of motion.
- c. Recovery of muscle balance.
- d. Alleviation of pain.
- e. Improvement in function and quality of life.

There are four basic steps to a TKA procedure:

- a. **Prepare the bone.** The damaged cartilage surfaces at the ends of the femur and tibia are removed along with a small amount of underlying bone.
- b. **Position the metal implants.** The removed cartilage and bone is replaced with metal components that recreate the surface of the joint. These metal parts may be cemented or “press-fit” into the bone.
- c. **Resurface the patella.** The under surface of the patella (kneecap) is cut and resurfaced with a plastic button. Some surgeons do not resurface the patella, depending upon the case.

- d. **Insert a spacer.** A medical-grade plastic spacer is inserted between the metal components to create a smooth gliding surface.

The complication rate following TKA is low. Serious complications, such as a knee joint infection, occur in fewer than 2% of patients. Major medical complications such as heart attack or stroke occur even less frequently. Chronic illnesses may increase the potential for complications. Although uncommon, when these complications occur, they can prolong or limit full recovery.[28]

There are five common complications following TKA procedure:

- a. **Infection.** Infection may occur in the wound or deep around the prosthesis. It may happen while in the hospital or after you go home. It may even occur years later. Minor infections in the wound area are generally treated with antibiotics. Major or deep infections may require more surgery and removal of the prosthesis. Any infection in your body can spread to your joint replacement.
- b. **Stiffness.** Sometimes the knee becomes stiff after surgery due to scar tissue forming inside the knee. If this happens the knee may require a manipulation under a second general anaesthetic to help regain movement.
- c. **Blood clots.** Blood clots in the leg veins are one of the most common complications of knee replacement surgery. These clots can be life-threatening if they break free and travel to your lungs. Your orthopaedic surgeon will outline a prevention program, which may include periodic elevation of your legs, lower leg exercises to increase circulation, support stockings, and medication to thin your blood.
- d. **Swelling.** This is a very common problem after a knee replacement, particularly affecting the ankle and foot, and may last for up to three

months or so after the operation. The ankle swelling usually settles as your walking ability improves. Swelling of the knee itself is also common over the first few months after surgery.

- e. **Pain.** A small number of patients continue to have pain after a knee replacement. This complication is rare, however, and the vast majority

2.2.2 Stiffness after the Total Knee Arthroplasty Surgery

A previous study has shown that stiffness after TKA is a common complication that happening in around 1% of patients.[29] Stiffness can be defined as restricted of ROM that affects a patient's ability to perform activities of daily living (ADL).[30] The reasons of stiffness occur may include infection, poor situating or over-measuring of the components, failure to balance the soft tissues and remove osteophytes, complex regional pain syndrome and loosening. In most cases, those problems will resolve with the structured physiotherapy.[29]

In general, a CPM device was used to avert joint stiffness. There is the probability for patient who's receiving the knee arthroplasty surgery to remain immobile for various reasons including pain and swelling.[13] Besides, protracted immobilization has numerous can result in side effect on the health of synovial joints, incorporating a reduction in the quality of ligament insertion points and an increase the need of energy to perform the movement. Moreover, immobilization may influences oxygen saturation, growth of deep vein thrombosis and muscle weakness, all of which are vital clinical implications.

In theoretical, CPM devices can neutralize the absence of joint development by providing a method that able to passively move the joint. There are some research was describe these devices may stimulate tendon and ligament recuperating in a non-invasive method that does not create any complications.[31]

From the previous studies, define of the normal knee ROM is from 0° to 140°, while a ROM from 0° to 110° after TKA can be defined as a satisfied outcome. No consensus is present in literature about the precise definition of stiffness. Stiffness has been defined in various papers, but basically those studies have defined the knee ROM was below 90°. [32]

2.2.3 Relationship between Continuous Passive Motion Device and Total Knee Arthroplasty

In the previous finding, the use of CPM device was started from the late of 1980 and begin to play an important role in the rehabilitation therapy for the patients undergoing TKA procedure.[33] At the same time, there are several potential beneficial effect of the CPM device has indicated in the earlier studies. The proposed advantages include restoring of knee ROM, decrease the length of hospital stay, prevent stiffness, reducing swelling, alleviating pain and improved wound healing.[34][35]

After the total knee replacement surgery, restricted knee ROM will occur and recover knee movement will become the primary indicators of a successful TKA. Due to the active movement might disrupt the repair process and cause pain to perform; the passive movement are a better option in the early rehabilitation process. Therefore, CPM device is a wise decision to apply in the early therapy because it can provide the controllable passive ROM exercise and reduce the burden of the patient.

At the beginning on the postoperative day, the ROM was set-up based on the protocol and then increased every day based on the tolerance of the patient. Usually the range of ROM will increased by no more than 5 ° to 10 ° in everyday day until it reach the expected outcome. The expected result of CPM therapy was a quickly regain minimum 90° of knee ROM to able the patient recover their ADL function during the first three months after surgery.[36] [37]

2.3 RANGE OF MOTION

2.3.1 Understanding Range of Motion

Range of motion (ROM) is a term commonly used to refer to the movement of a joint from full flexion to full extension (see Figure 2.3). It is also known as joint movement, full flexion and full extension. According to Q. Mourcou, exercise physiologist and physiotherapist's measure ROM in a joint with an instrument called a goniometer that measures joint range of motion in degrees from the starting position (see Figure 2.4). To measure the ROM at a joint, the center of the goniometer is positioned at the axis of rotation of a joint, and the arms of the goniometer are aligned with the long axis of the bones of the adjacent segments or to an external reference. The degree between the end point will represent the entire ROM.

In general, flexion and extension are the movements that occur in the sagittal plane. Flexion is the bending of a particular joint so that the bones that form that joint are pulled closer together. During flexion, the angle between the bones of limb at a joint is decreased. Flexion typically occurs when muscles contract and the bones thus move the nearby joint into a curved or bent position. After that, the extension is refers to the straightening of a joint. Typically, normal extension of a joint is limited to 180 degrees or less (see Figure 2.5). In other words, that joint can basically be opened until it is straight. In simple term, flexion works to shorten a joint angle while extension works to increases it. [38]

According to research of D. Renata, there are three primary types of exercises specific to ROM which is passive, active-assistive and active exercise. The passive ROM exercise is typically practiced on a joint that is inactive. The physiotherapists may use this exercise on a client who is paralyzed or unable to mobilize a specific joint. This type of exercise can help prevent stiffness from occurring. During this exercise the patient does not

perform any movement, while the physiotherapist stretch the patient's soft tissues.

Next, the active-assistive ROM exercise is more dynamic, intended for the client to perform movement around the joint, with some manual assistance from the physiotherapists or from a strap or band. These exercises can often feel painful, and the muscles can feel weak. Therefore, increasing ROM with these exercises ought to be a steady headway. And then, the active ROM exercise is highly independent, performed solely by the client. The physical therapist's role might be basically to give verbal prompts. [39]

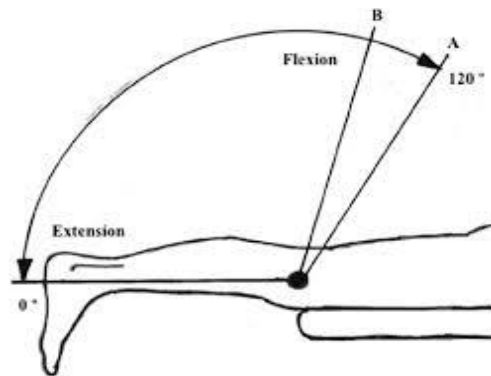


Figure 2.3: Knee Flexion and Extension



Figure 2.4: Measure ROM using Goniometer

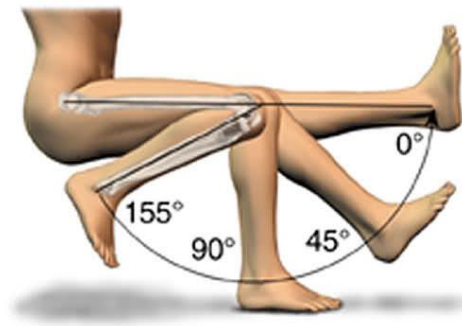


Figure 2.5: Knee ROM

2.3.2 How Injuries and Diseases Can Affect Range of Motion

Injuries to the soft tissues surrounding a joint often reduce range of motion due to swelling and tissue damage. Based on the research of A. Tendon and I. Active, regaining range of motion in a joint is one of the first phases of injury rehabilitation, and physiotherapists often prescribe specific ROM exercises for each joint.[40]

For example, decreased knee flexion or extension ROM has been reported following ACL reconstructions, TKA, arthrofibrosis of the knee, and other musculoskeletal injuries involving the knee joint. Loss of knee flexion has been shown to bring altered gait pattern affecting the ankle and hip, limited functional squatting, and difficulty negotiating stairs and sitting. The loss of knee extension can cause altered gait pattern influencing the ankle and hip, powerlessness to achieve the closed packed position of the knee, and difficulty running and jumping.[41]

2.4 BRUSHED DC GEARED MOTOR

Theoretically, a direct current (DC) geared motor is consisting of a DC electric motor and a gearbox. When a load demands high torque at low speed, use of a large DC motor capable of developing the torque would not be ideal and system efficiency would be low. In present, there are widely use of the DC geared motor because of it

greater efficiency and economical prices. In addition, it also becomes an important part of several electrical and electronic applications. These geared motors have reduction gear trains capable of providing high torque at relatively low shaft speed or revolutions per minute (RPM). The various applications of DC geared motors included industrial equipment, actuators, medical tools, robotics and manipulators.[42]

Besides, the output speed of the motor is reduced through a series of large gears rotation to resulting in increased the torque. The low RPM speed is useful because it can create a high amount of force which can be used to lift and move the heavy objects. The DC geared motor consists of a few simple components: stationary stator composed of field coils (wound field) or two hemispherical permanent magnets; an internal rotating armature consisting of two or more coils connected to a segmented commutator which is contacted by brushes connected to the DC power supply (see Figure 2.6).

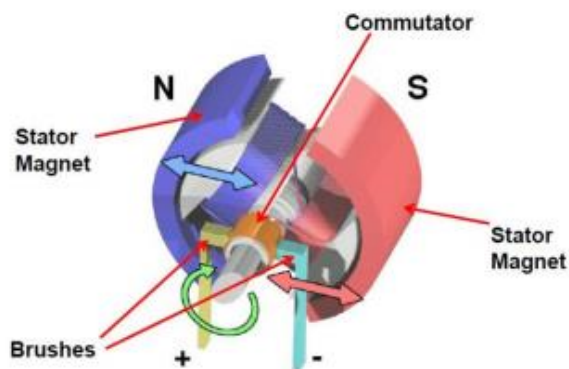


Figure 2.6: The Component Inside the Brushed DC Gear Motor

DC Brushed motors have some advantages over other designs:

- a. They are simple and inexpensive.
- b. They don't require complex drive electronics.
- c. Their speed is a direct, linear function of the armature voltage.

- d. Because of their simplicity and low cost – typically half the cost of brushless DC motors of the same size – design cycles are shortened.

However, they're not without some notable drawbacks:

- a. The brushes tend to wear out because of continuous friction. The brushes and springs need replacing from time to time.
- b. The commutator needs periodic cleaning or replacement.
- c. Arcing is ever present and causes EMI that can interfere with nearby electronics.
- d. The rotor's inertia may be an issue, and the commutator makes the motor larger than its brushless counterpart.
- e. Heat generated by coil rotation is always an issue.

2.4.1 Equation of the DC Motor

- a) Torque Equation of DC Motor

$$\text{Torque } (T) = F \times r \text{ (N.m)}$$

F = Force

r = Radius of the armature

$N \cdot m$ = Newton metre

- b) Armature current

$$I_a = V - E_b / R_a$$

- V = Applied voltage
- E_b = Back e.m.f.
- I_a = Armature current
- R_a = Armature resistance

c) Voltage Equation of DC Motor

$$V = E_b + I_a R_a$$

- V = Applied voltage
- E_b = Back electromotive force (Back e.m.f.)
- I_a = Armature current
- R_a = Armature resistance

d) Power Equation

$$VI_a = E_b I_a + I_a^2 R_a$$

- VI_a = Armature input (electric power supplied to armature)
- $E_b I_a$ = Armature output (power developed by armature)
- $I_a R_a$ = Armature Cu loss (electric power wasted in armature)

e) Angular velocity (ω) and Revolution per minute (RPM)

$$\text{Angular velocity } (\omega) = 2\pi N / 60$$

$$\text{Revolution per minute (RPM)} = \omega / (2\pi / 60)$$

- 2π = 2 radians or 360 degrees
- N = Revolution per Minute (RPM)
- 60 = 60 second or 1 minute

2.5 BALL SCREW

The ball screw (see Figure 2.7) is an instrument which is utilized to transform rotational movement to translational movement. There are three fundamental parts inside the Ball Screw which is shaft, nut and balls in string between them (see Figure 2.8).[43] The ball screw is generally utilized in machine instrument and other industries. The main advantage of ball screw is high positioning accuracy, more efficient and requiring less torque. Generally speaking, ball screws are better for applications that require smooth motion, efficiency, accuracy, precision, and prolonged continuous or high-speed movement. Therefore, Ball screws should be the suitable choice to use in linear-actuation applications.



Figure 2.7: Ball Screw



Figure 2.8: Inside Ball Screw

2.5.1 Basic and Equation of Ball Screw

Ball screws are force and motion-transfer devices in the group of energy transmission screws. They work like conventional power screws yet the rolling friction of bearing balls replaces sliding friction. The screw has an exactness ground or milled helical groove acting as the inner race. The nut has inner sections that act as the external race. Circuits of accuracy steel balls recirculate in the grooves between the screw and nut. Either the screw or nut turns while the alternate move in a linear direction. This converts torque to thrust. A simple calculation determines the torque required to drive a ball screw:

$$T = LP/5.65$$

T = torque (lb-in.)

L = screw lead (in.)

P = axial load, (lb)

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

The methodology applied for this project is discussed throughout this section. Before deciding the device specification, several studies based on literature review were carried out and the multiple survey questionnaires have distributed to the few general hospital staff. The objective to distribute questionnaire is to gathering the necessary information that can help me to design an optimal device that based on the market needs. After that, there are some engineering aspects are needed to consider which include:[44][45]

- a. Adjustability based on various patient sizes.
- b. Comfort, particularly for long uninterrupted application.
- c. Use in a variety of settings: in bed while sleeping, while ambulating during the day, at home or in hospital.
- d. Durability and light weight.
- e. Cost effective.
- f. Full anatomic range of motion capability and multi axis motion capability.

- g. Minimum loading of joints.
- h. Precise and changeable range of motion (ROM) control.
- i. Speed control.
- j. Safe and reliable operation.
- k. Simple and straightforward operation.
- l. Protection for unstable joints.

Besides, before the start of build and assembly process, there are few design are proposed and compare to decide which one is the best. Furthermore, after the mechanical part has finished assembling, the circuit and the programming are the essential part to provide the adjustability of the speed, range and duration. In other than that, there are a usability test are conducted in this study to evaluate the performance of the device. Lastly, those data will be analyse by the Microsoft Excel and SPSS software.

3.2 PLANNING

3.2.1 Data Collection

In this study, data collection is an important aspect to ensure the successful project outcomes. At the beginning, the interview and distribute questionnaire (Pre-survey) to the physiotherapist, doctor and nurse were performed in the November 2016. After that, the data that collected from the questionnaire will be evaluated to determine the design of the device. In addition, those data also help to reveal the problem on the existing device. Therefore, the first questionnaire was important to ensure the appropriate

design and innovate to solve the existing problem. Likewise, the Microsoft Excel was used to analyse the collected data.

Beside that, when the device had finished assembly, there are the second questionnaire (see Appendix A) will be distribute to the subjects that involved in the usability test (see Figure 3.1). The purpose of the second questionnaire is to gather the review and recommendation from the subjects to evaluate the success of the project. Besides, those data will be analysed by the Microsoft Excel and SPSS software.

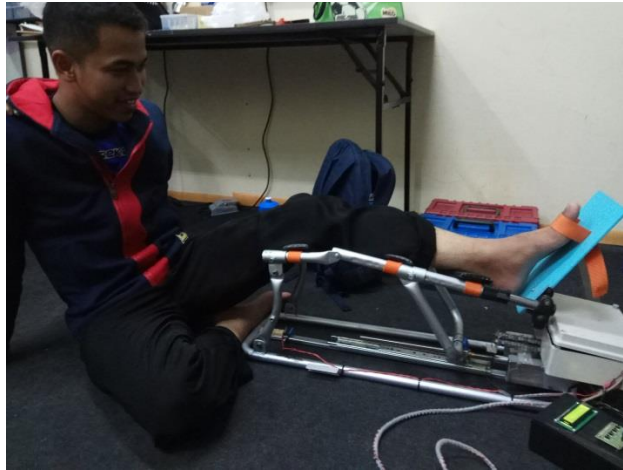


Figure 3.1: Usability Test

3.2.2 Requirement of Hardware and Software

i. Hardware Requirement

Table 3.1: Hardware Requirement

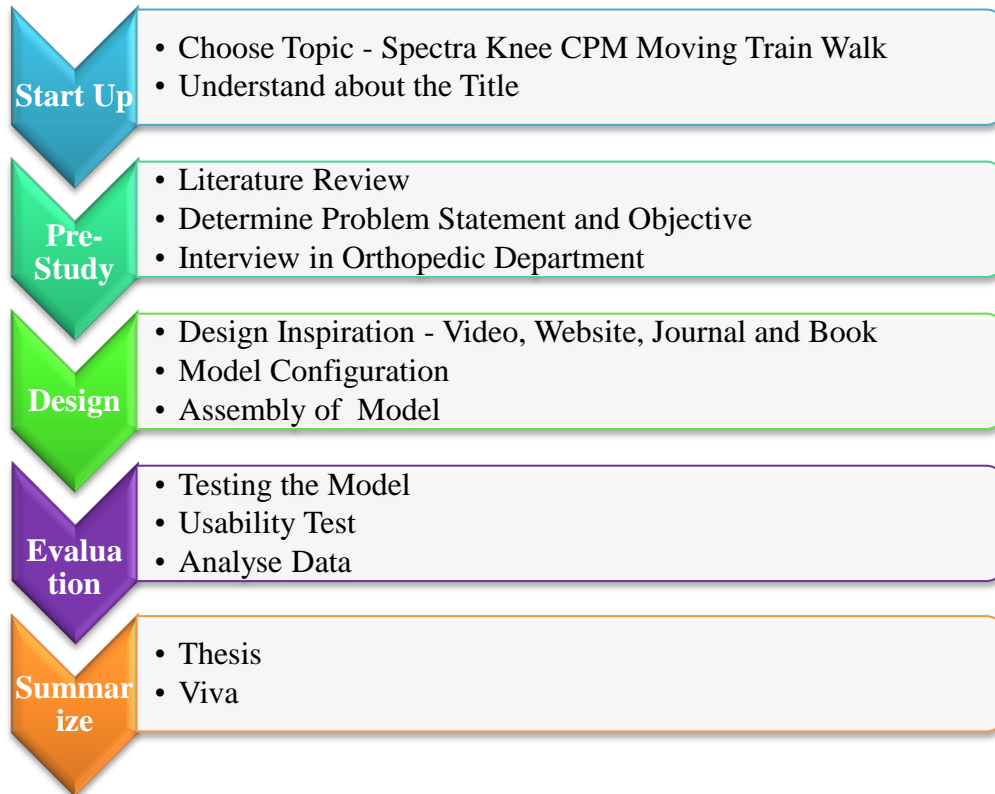
HARDWARE LIST	
12v DC Geared Motor	Ball Screw
Metal Pipe (Steel)	12V Rechargeable Battery
Casing Box	Transformer AC 220V
Rectifier	Limit Switch
Toggle Switch	Pipe Rubber Cap
Electronic Components	Real Bearing
MS flat bar	Real Bearing
16x2 LCD Display	5 Way Barrier Terminal Block
Switch Board	Acrylic
Arduino MEGA 2560	Motor Driver L298N

ii. Software Requirement

Table 3.2: Software Requirement

SOFTWARE LIST	
Microsoft Excel	Statistical Package for the Social Sciences (SPSS)
Proteus ISIS	Arduino Integrated Development Environment (Arduino IDE)

3.2.3 Informed Consent Process



3.2.4 Ethics of Study

Initially, the purpose of the study was explained to the participants verbally. The participants were then given the questionnaire form, which also explained the purpose of the study. Confidentiality and anonymity were assured and they were informed that they were not obliged to participate and that they could withdraw from the study at any time without any negative consequences. Participants were informed that the findings of the study would be used in the event of publication and no names will be used.

3.3 IMPLEMENTING

3.3.1 Brushed DC Geared Motor

In this study, a 12V 100 RPM Brushed DC Geared Motor (see Figure 3.2) is implemented in the CPM device. The reason of choosing Brushed DC Geared Motor is because it cost effective, easy to control, high torque and able to rotating in clockwise or anticlockwise. After that, a gear motor is a specific type of electrical motor that is designed to produce high torque while maintaining a low horsepower, or low speed, motor output. Gear motors are commonly used in commercial applications where a piece of equipment needs to be able to exert a high amount of force in order to move a very heavy object. The example of common commercial applications of a gear motor include hospital beds, garage door openers, cranes and many other applications.

Generally, the speed of DC geared motors can be adjusted within wide boundaries through corresponding to the applied voltage. Therefore, this characteristic can provide an easy controllability and high performance. At present, utilizing digital control, a pulse width modulation (PWM) signal is used to generate an average voltage. The motor winding acts as a low pass filter so a PWM waveform of sufficient frequency will generate a stable current in the motor winding. The frequency of the PWM signal is an important consideration. Low frequency will result in a noisy motor at low speeds and sluggish response to the changes in duty cycle. Very high frequency tends to decrease overall efficiency of the system due to switching losses in the drive circuit power transistors. In order to control precise motor speed, it is essential to apply an L298N H-bridge module (see Figure 3.3).



Figure 3.2: 12V 100 RPM Brushed DC Geared Motor

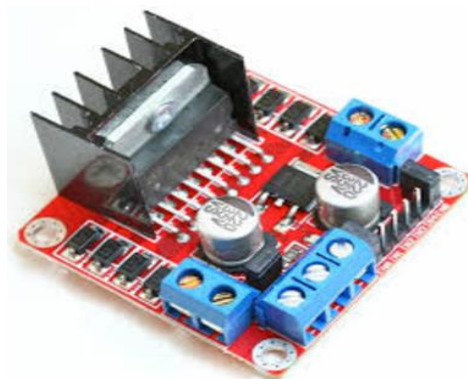


Figure 3.3: L298N H-bridge Module

3.3.2 Ball Screw

The ball screw is a mechanism which converts rotary input to linear motion. Ball screws are widely used in linear-actuation applications because of their high positioning accuracy, smooth operation, more efficiency, requiring less torque and long cycle times.[43] Ball screws are force and motion-transfer devices in the family of power-transmission screws. They operate like conventional power screws but the rolling friction of bearing balls replaces sliding friction. Ball screws consist of a screw, nut, flange, wiper, and balls that operate similarly to bearing components (see Figure 3.4).

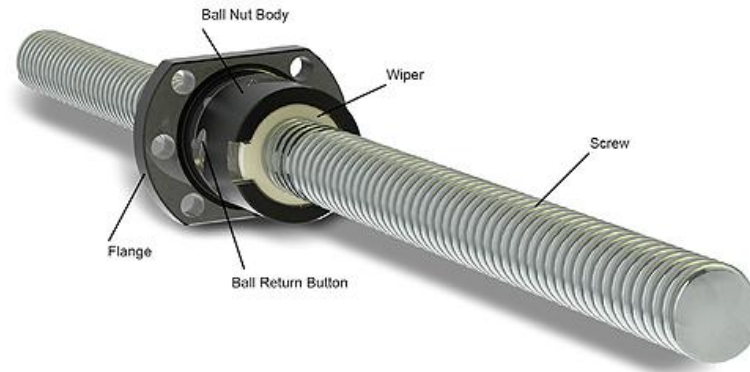


Figure 3.4: Physical Properties of Ball Screw

After that, ball screw uses ball bearings to eliminate the friction between the nut and screw and lead screws do not. The screw and nut on a ball screw have matching helical grooves that allow ball bearings to re-circulate in those races, and are typically semi-circular in shape to accept the spherical ball bearing. Therefore, the rolling nature of ball screws eliminates the sliding friction associated with lead screws.

Besides, the screw has an accuracy ground or rolled helical groove acting as the inner race. The nut has internal grooves that act as the external race. Circuits of precision steel balls recirculate in the grooves between the screw and nut. Either the screw or nut turns while the other moves in a linear direction. This converts torque to thrust. There is a simple calculation can determine the torque required to drive a ball screw:

$$T = L P / 5.65$$

T = torque (lb-in.)

L = screw lead (in.)

P = axial load, (lb).

3.3.3 Arduino MEGA 2560

Arduino is an open-source electronics prototyping platform based on flexible, easy-to use hardware and software. It's intended for artists, designers, hobbyists, and anyone interested in creating interactive objects or environments. Arduino can sense the environment by receiving input from a variety of sensors and can affect its surroundings by controlling lights, motors, and other actuators. The microcontroller on the board is programmed using the Arduino programming language and the Arduino Development Environment. Arduino projects can be stand-alone, or they can communicate with software running on a computer.

In addition to Arduino's simplicity, it is also inexpensive, cross-platform and open source. The Arduino Mega 2560 is a microcontroller board based on the ATmega 2560 (datasheet). It has 54 digital input/output pins (of which 14 can be used as PWM outputs), 16 analog inputs, 4 UARTs (hardware serial ports), a 16 MHz crystal oscillator, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller; simply connect it to a computer with a USB cable or power it with an AC-to-DC adapter or battery to get started (see Figure 3.5 and 3.6). Furthermore, the plans for the modules are published under a Creative Commons license, so experienced hobbyists and professionals can make their own version of the Arduino, extending it and improving it.

Here are the specifications:

Microcontroller	ATmega2560
Operating Voltage	5V
Input Voltage (recommended)	7-12V
Input Voltage (limits)	6-20V
Digital I/O Pins	54 (of which 14 provide PWM output)
Analog Input Pins	16
DC Current per I/O Pin	40 mA

DC Current for 3.3V Pin	50 mA
Flash Memory	256 KB of which 8 KB used by bootloader
SRAM	8 KB
EEPROM	4 KB
Clock Speed	16 MHz
Size	101.52mm x 53.3mm (Length x Width)
Weight	37g

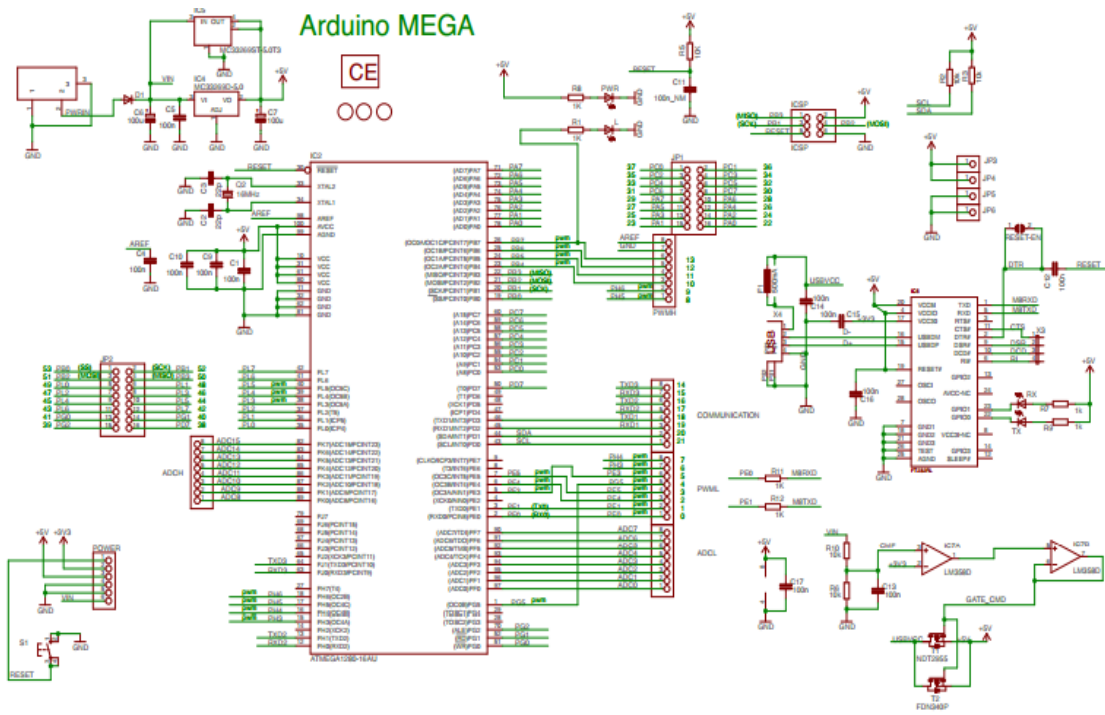


Figure 3.5: Arduino MEGA 2560 Schematic Diagram



Figure 3.6: Arduino MEGA 2560 Board

3.3.4 Arduino IDE

The Arduino project provides the Arduino integrated development environment (IDE) (see Figure 3.7), which is a cross-platform application written in the programming language Java. It originated from the IDE for the languages Processing and Wiring. It was created for people with no profound knowledge of electronics. It includes a code editor with features such as syntax highlighting, brace matching, cutting/pasting text, searching/replacing text and automatic indentation, and provides simple one-click mechanism to compile and upload programs to an Arduino board. It also contains a message area, a text console, a toolbar with buttons for common functions and a series of menus.

A program written with the IDE for Arduino is called a “sketch”. Sketches are saved on the development computer as files with the file extension `.ino`. Arduino Software (IDE) prior to 1.0 saved sketches with the extension `.pde`. The Arduino IDE supports the languages C and C++ using special rules to organize code. The Arduino IDE supplies a software library called Wiring from the Wiring project, which provides many common input and output procedures. A typical Arduino C/C++ sketch consist of two functions that are compiled and linked with a program stub `main()` into an executable cyclic executive program:

- a) `setup()`: this function is called once when a sketch starts after power-up or reset. It is used to initialize variables, pin modes, start using libraries, etc.
- b) `loop()`: after `setup()` is called, this function is called repeatedly until the board powers off. It actively controls the Arduino board and allows the program to change or respond.

After compiling and linking with the GNU toolchain, also included with the IDE distribution, the Arduino IDE employs the program `avrdude` to

convert the executable code into a text file in hexadecimal coding that is loaded into the Arduino board by a loader program in the board's firmware.

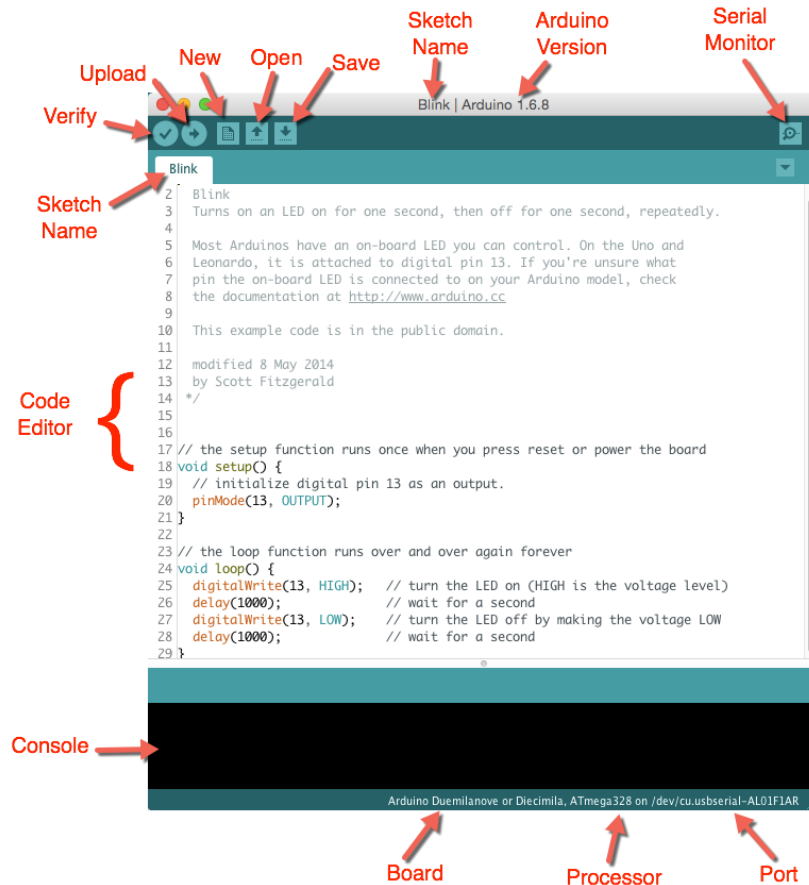


Figure 3.7: Arduino IDE Interface

3.4 DATA ANALYSIS

3.4.1 Statistical Analysis Plan

In this project, the Microsoft Excel and SPSS were used to analyse the collected data to draw a conclusion. To gathering the useful data and information, there are the pre-survey and post-survey was conducted. In pre-survey, the subject was targeted to the physiotherapist, doctor and the hospital nurse. The objective of the pre-survey is to analyse the market need and gather the important information to innovate the CPM device. After that, to make sure

the information was reliable, an interview in general hospital was conducted as well as distribute questionnaire. Those subjects from the general hospital are knowledgeable in CPM device and also the therapy session. In addition, they are providing the useful information can ensure the successful of this study.

Besides, in post-survey, there is the usability test and endorsement was implemented. In the usability test, there are 30 subject from Politeknik Sultan Salahuddin Abdul Aziz Shah was involved. The reason to conduct the usability test on student is to ensure the safety of patient before the pilot study was implemented on the patient. Furthermore, a questionnaire was distributed to the student and the detailed explanation for them is essential to make sure they are eligible to answer the question on the questionnaire.

For endorsement, an interview with the biomedical engineer was required to determine the safety of the device. Therefore, to receive the endorsement, the device was brought to the biomedical engineer to allow them to test the model. Next, the endorsement was important to the model because it can enhance the confidence for the others and allow this study to move on to the next phase.

3.4.2 Microsoft Excel

Microsoft Excel is a spread sheet program that used to store and retrieve numerical data in a grid format of columns and rows. It is the ideal for entering, calculating and analysing data for the research and business. Besides, Excel has offers far more important tools for calculating, arrange, and analyse data. The Excel program can turn a spread sheet of data into a pie chart, bar diagram or a variety of other visual diagrams.

After that, even there are a lot of specialist software packages are available today, Microsoft Excel still play an important role in statistical analysis. The convenience and cost are two important reasons to maintain the widely use of the Excel. Moreover, Excel is particularly for those who are new

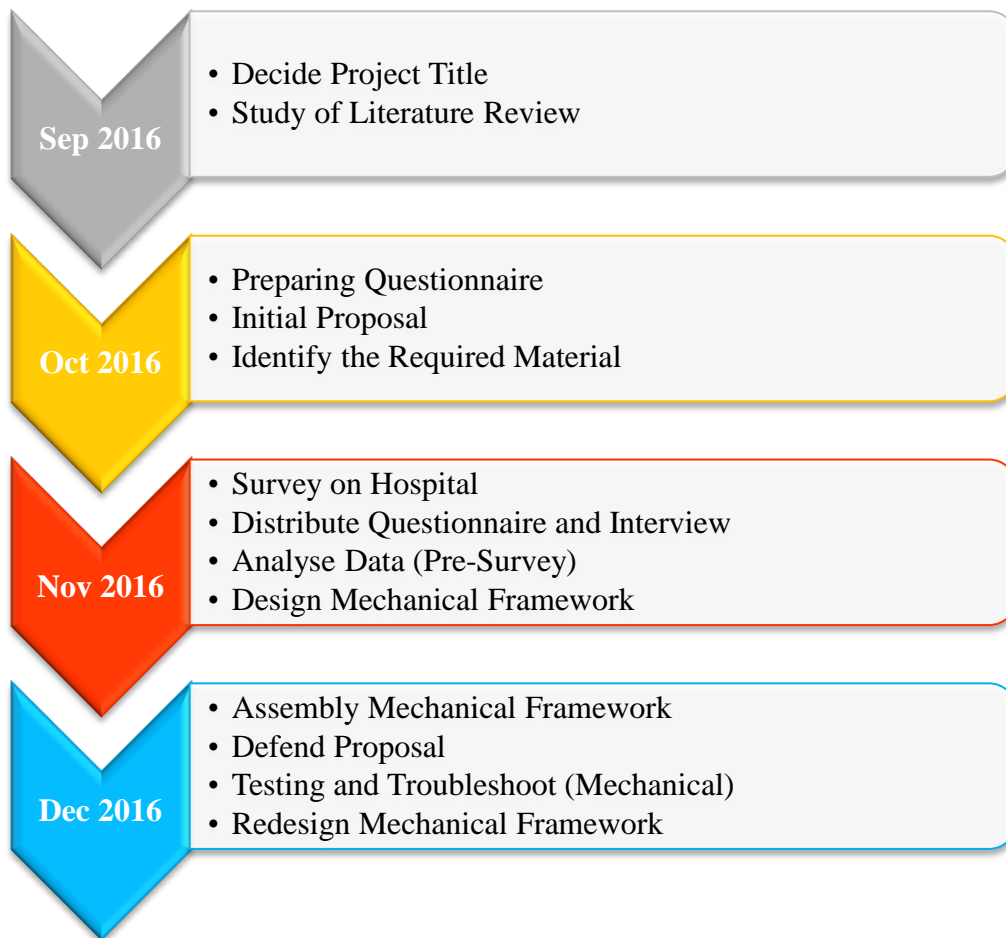
to data analysis and allow them to getting grips with the analysis techniques. Therefore, in this study, the Excel was used in analyse the pre-survey data and generating graphical for the data analysis.

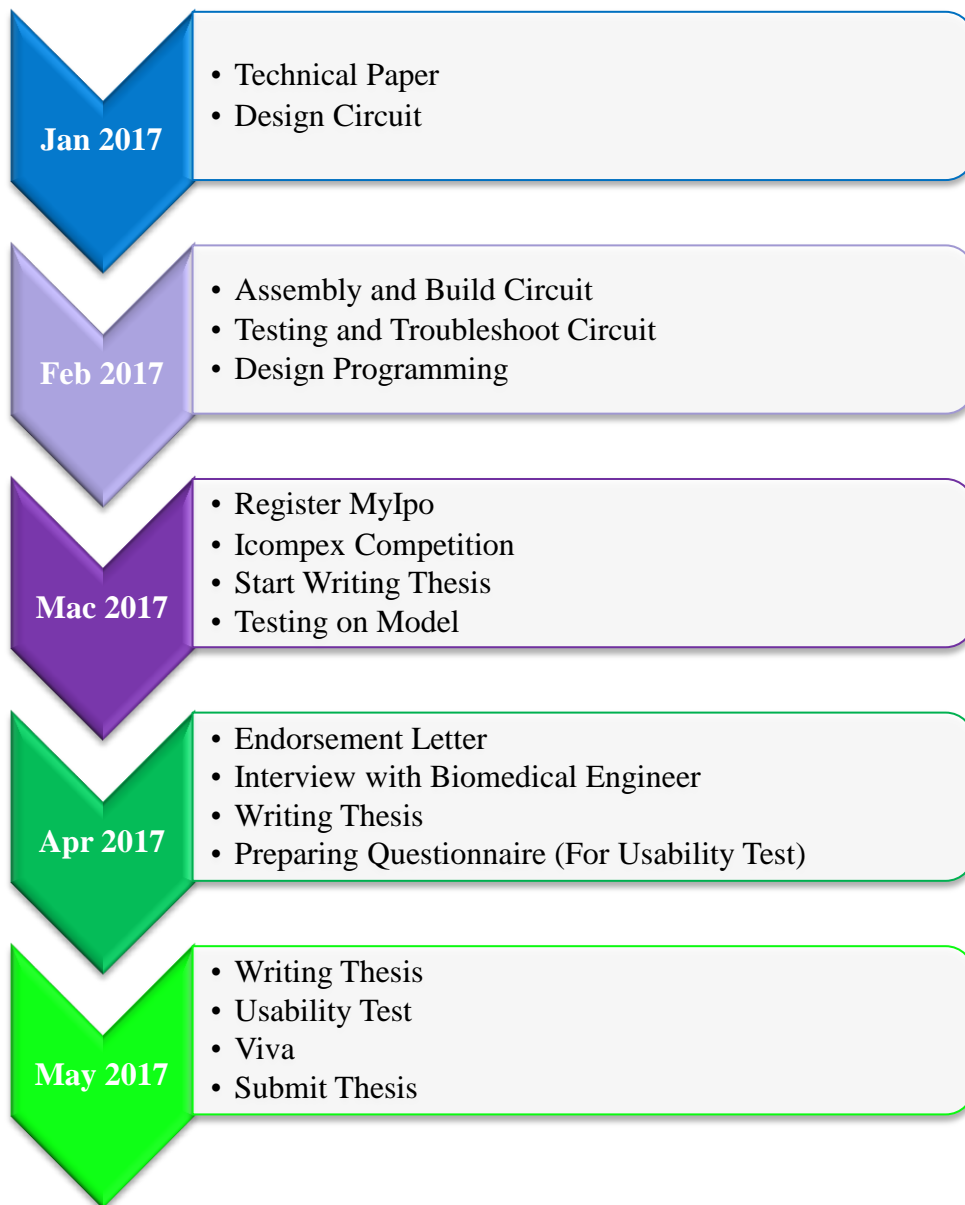
3.4.3 Statistical Package for the Social Science (SPSS)

SPSS is a Windows based program that can be used to perform data entry and analysis and to create tables and graphs. SPSS is capable of handling large amounts of data and can perform all of the analyses covered in the text and much more. SPSS is commonly used in the Social Sciences and it updated often. And then, SPSS can take data from almost any type of file (including Excel) and use them to generate tabulated reports, charts, and plots of distributions and trends, descriptive statistics, and complex statistical analysis.

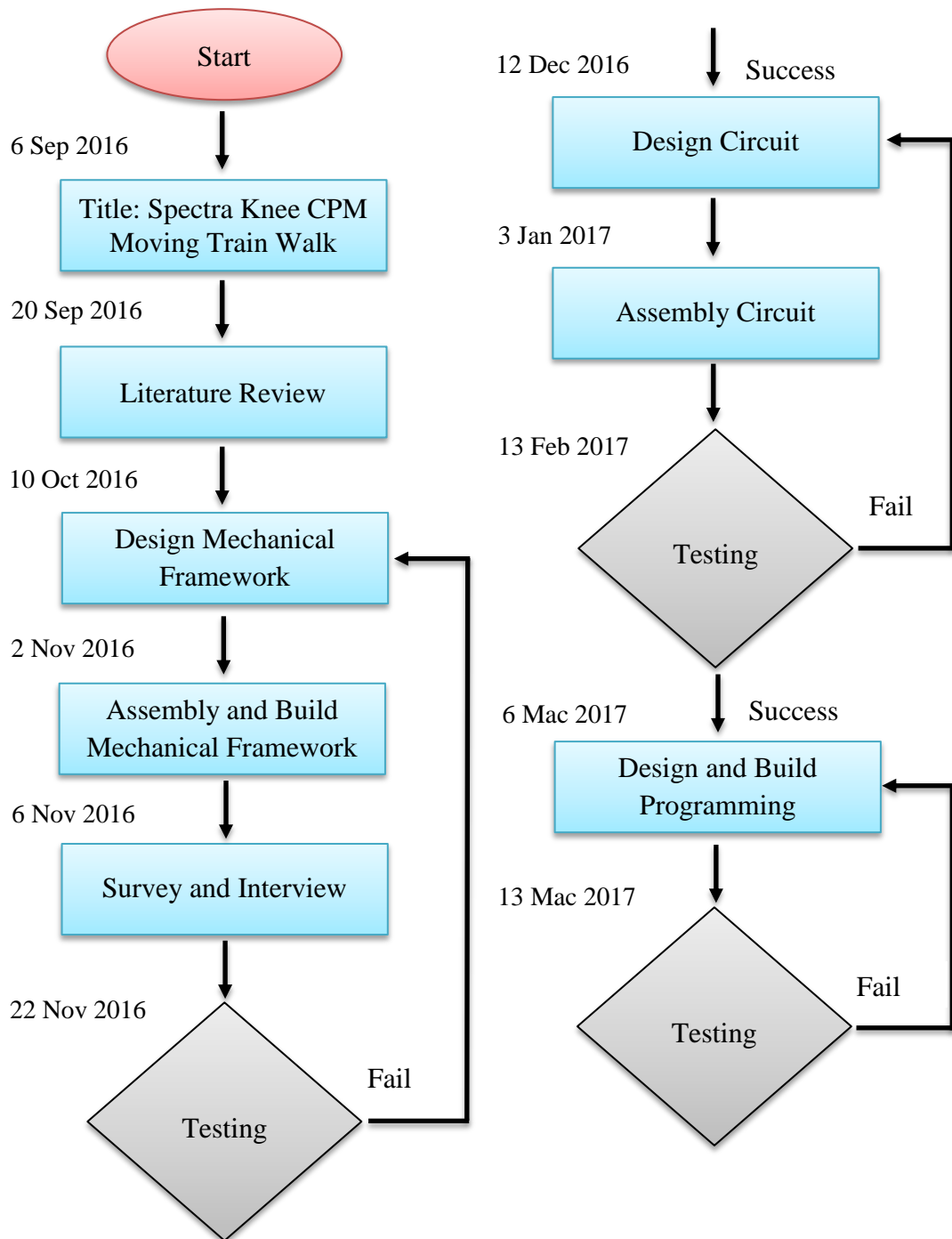
SPSS has scores of statistical and mathematical functions, scores statistical procedures, and a very flexible data handling capability. It can read data in almost any format (e.g., numeric, alphanumeric, binary, dollar, date and time formats). In addition, SPSS can read files created using spread sheet or data base software. In this study, the SPSS was used in analyse the data from post-survey because of it excellent data manipulation utilities.

3.5 TIMELINE OF STUDY



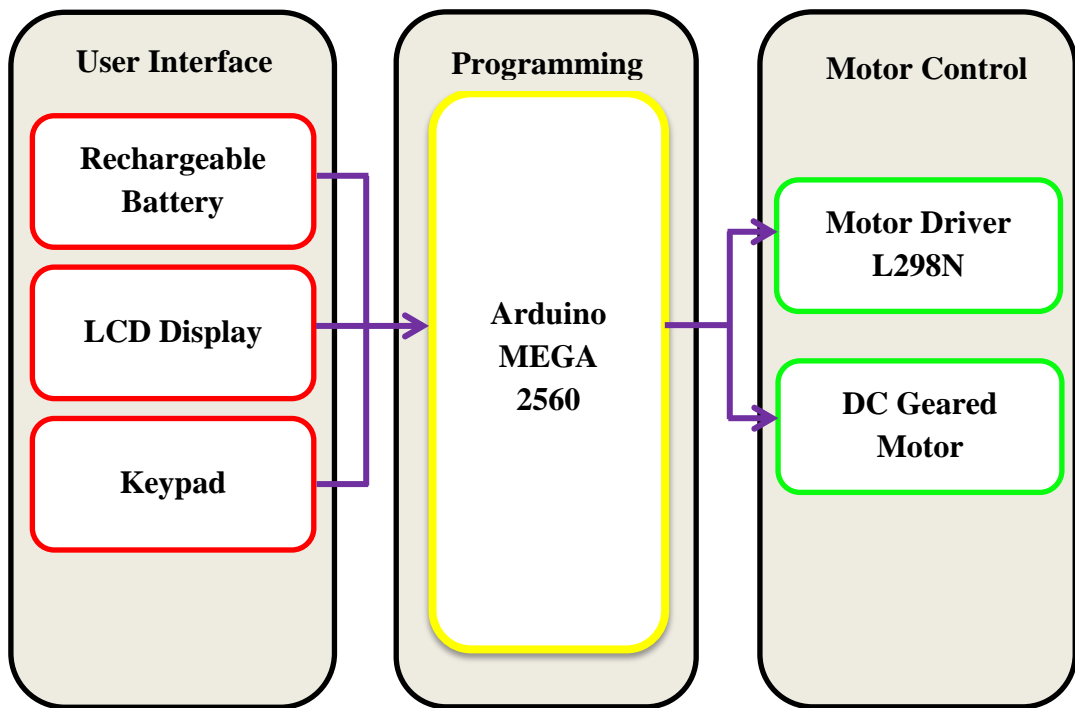


3.6 FLOWCHART OF METHODOLOGY





3.7 BLOCK DIAGRAM



3.8 GANTT CHART

YEAR	SEM 1 2016/2017														SEM 2 2016/2017														
MONTH	SEPT				OCT				NOV				DEC		FE B	MARCH				APRIL				MAY					
WEEK	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
RESEARCH PROPOSAL																													
• Title Declaration	✓	✓	✓																										
• Finalize Research Proposal				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
LITERATURE REVIEW																													
• CPM				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
• TKR				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
• Stiffness				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
• DC Geared Motor				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
• Ball Screw				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
DESIGN / TESTING / SIMULATION																													
• Schematic Design	✓	✓	✓	✓																									
• Identify Component					✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
• Purchase Component														✓	✓	✓	✓												
• Design Application																✓	✓	✓											
• Construct Circuit																		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
• Writing Coding																			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
• Testing Project																				✓	✓	✓	✓	✓	✓	✓	✓	✓	
SURVEY AND TEST																													
• Survey (Pre and Post)									✓	✓											✓	✓	✓	✓	✓	✓	✓	✓	
• Usability Test																						✓	✓	✓	✓	✓	✓	✓	
• Analyse Data																										✓	✓	✓	
PUBLICATION																													
• Journal /Conference/Proceeding																			✓										
• Review Paper															✓														
THESIS WRITING																													
• CHAPTER 1 – Introduction			✓	✓	✓																								
• CHAPTER 2 – Literature Review					✓	✓	✓	✓	✓	✓	✓	✓	✓	✓															
• CHAPTER 3 – Methodology															✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
• CHAPTER 4 – Data analysis																				✓	✓	✓	✓	✓	✓	✓	✓	✓	
• CHAPTER 5 – Conclusion																										✓	✓	✓	
• Submit Final Draft																											✓	✓	
• Submit Thesis																												✓	
ASSESSMENT																													
• VTVA																											✓	✓	
• Thesis																												✓	

CHAPTER 4

RESULT AND DISCUSSION

4.1 INTRODUCTION

This chapter discussed about the results obtained from the device. The result of collected data (questionnaire) is explained based on graphical presentation (graph and table) acquired from the experiment conducted. Those results were taken from students in Politeknik Sultan Salahuddin Abdul Aziz Shah as the test subjects. For analyse the result, the Microsoft Excel and SPSS software was used to generated graph and analyse result will be discuss in this chapter.

4.2 SPECTRA KNEE CPM MOVING TRAIN WALK

The figure 4.1 below has shown the structure of Spectra Knee CPM Moving Train Walk. This device provided 9 degree selections which are 10 °, 20 °, 30 °, 40 °, 50 °, 60 °, 70 °, 80 ° and 90 °. After that, this device also has 10 speed selections, which can set the number of speed from 10% until maximum 100%. In addition, there are 4 timers available which from 1 hour until 4 hours.

Besides, before start implement a treatment, the 12V DC rechargeable battery should be insert and switch on the power on the remote. Next, The LCD display will light up in the control panel. And then, there are three parameters are needed to set up. When all the parameters are complete set up, there are last steps which press the 'Enter' button twice to begin the treatment.

This Knee CPM Device has two main parts, which are control panel and the leg placement framework. The control panel contained 4 buttons which is increase button, decrease button, select button, enter button and LCD displays.

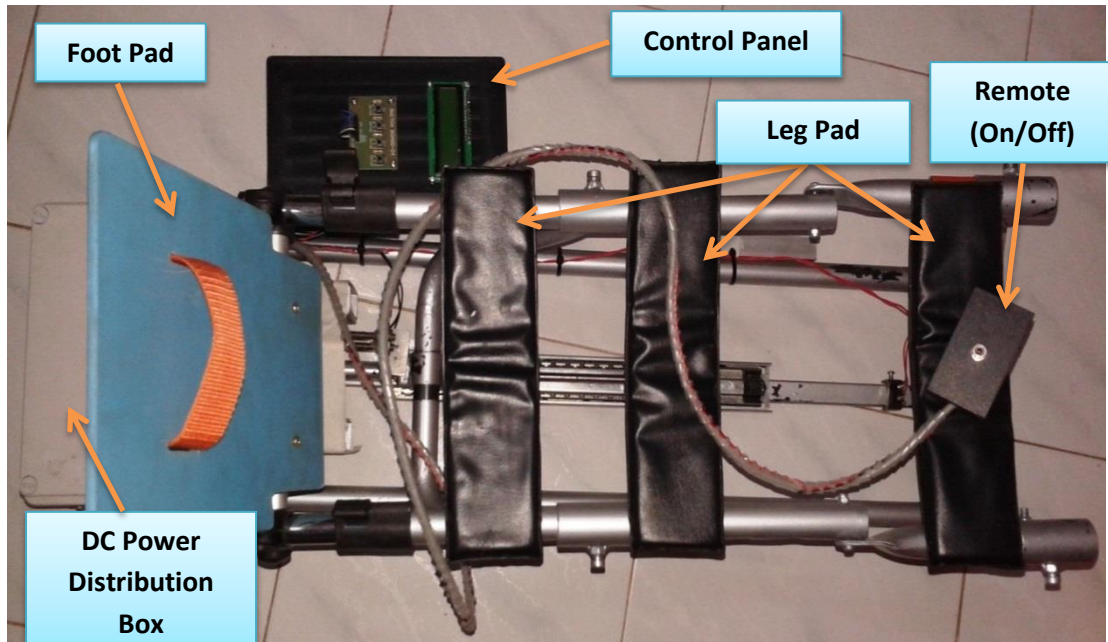


Figure 4.1: Knee CPM Device (Top view)

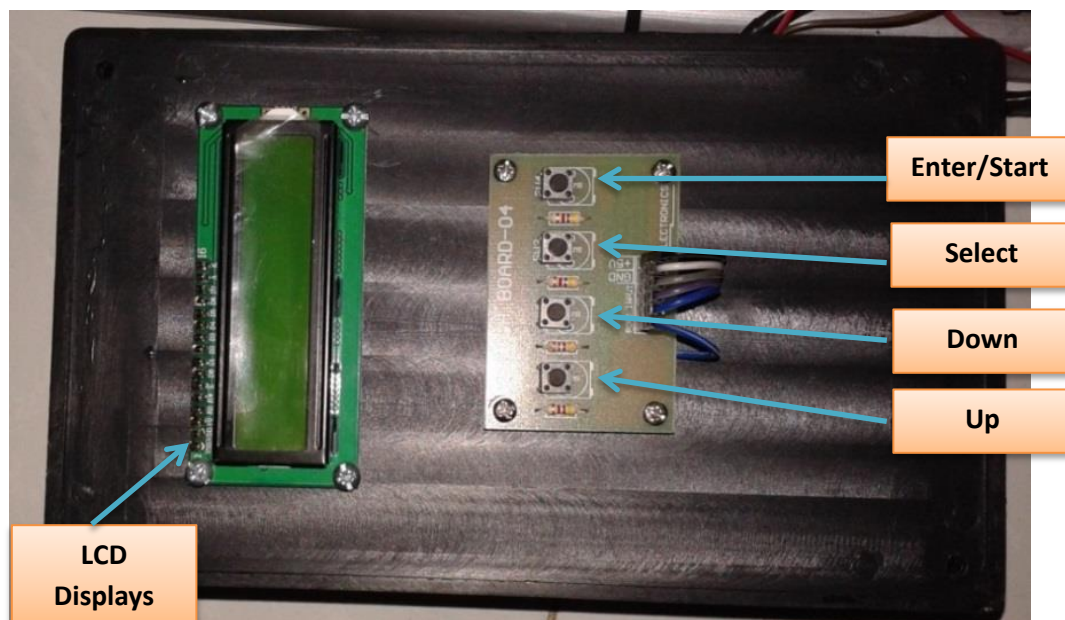


Figure 4.2: Knee CPM Device - Control Panel (Top view)

4.3 PRE-SURVEY

During this pre-survey, 10 subjects were involved and a questionnaire was distributed to them. There are total 10 questions in the questionnaire and all questions had answered by the subjects. Therefore, those answer will be analyse in the diagrams below.

Table 4.1: Data of Pre-survey

Question	Yes	No
Do you know what is CPM Machine?	10	0
CPM Machine is suitable for knee replacement surgery patient?	10	0
Feel comfortable when using CPM Machine?	6	4
CPM Machine can speed up recovery?	10	0
CPM Machine can eliminate the problem of stiffness?	10	0
CPM Machine is inconvenient when use?	6	4
Satisfied with the result after using CPM Machine?	10	0
CPM Machine is useful?	10	0
Purchase/rent the CPM Machine for rehabilitation?	5	5
Recommend the CPM Machine to the other patient?	10	0

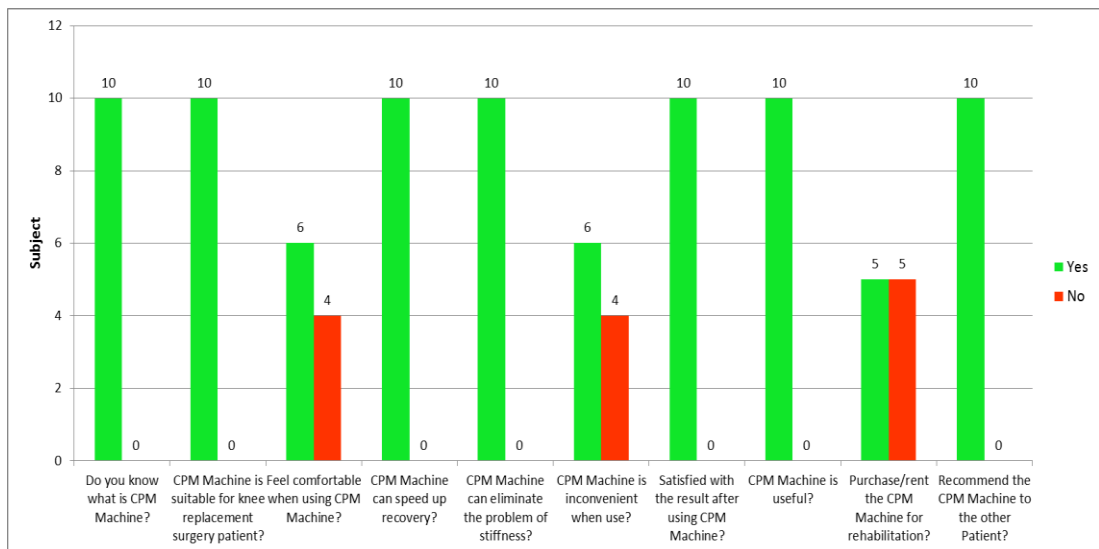


Figure 4.3: Graph of the Pre-survey

From the figure 4.3:

- 1) In first question, there are 10 subjects are agree they knew what is CPM machine.
- 2) In second question, there are 10 subjects were agree CPM machine is suitable for knee replacement surgery patient.
- 3) In third question, there are 6 subjects were agree the CPM machine is comfortable to use and 4 subjects are disagree with it.
- 4) In Fourth question, there are 10 subjects were agree CPM machine can speed up recovery.
- 5) In fifth question, there are 10 subjects were agree CPM machine can eliminate the problem of stiffness.
- 6) In sixth question, there are 6 subjects were agree CPM machine is inconvenient to use and 4 subjects are disagree with it.
- 7) In seventh question, there are 10 subjects were satisfied with the result after using CPM Machine.
- 8) In eighth question, there are 6 subjects were agree CPM machine is useful.
- 9) In ninth question, there are 5 subjects will purchase / rent the CPM machine for rehabilitation and 5 subjects are disagree with it.
- 10) In tenth question, there are 10 subjects will recommend the CPM machine to the other Patient.

4.4 USABILITY TEST

For the usability testing of the device, there are 30 subjects were selected to conduct this test. There will be distribute questionnaires and they will answer the question based on the assessment. This usability test have consists of 5 main parts which are Effectiveness, Comfortableness, Speed, Range and Time, Design and Final Satisfaction Review. Those data was collected through the usability test, which the subject have tested the Spectra Knee CPM device and answered questionnaire.

4.4.1 Effectiveness

There are 4 questions was consisted in this part, the table 4.2 is the question for the Effectiveness test.

Table 4.2: Data of Effectiveness

	Question	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	Do you like to use this product?	0	2	3	10	15
2	Most people can learn how to use this product quickly.	0	1	1	3	25
3	Do you find some additional function to integrate this product?	0	2	4	6	18
4	Do you think this product can effective enhance recovery for Total Knee Arthroplasty (TKA) patient?	0	1	2	6	21

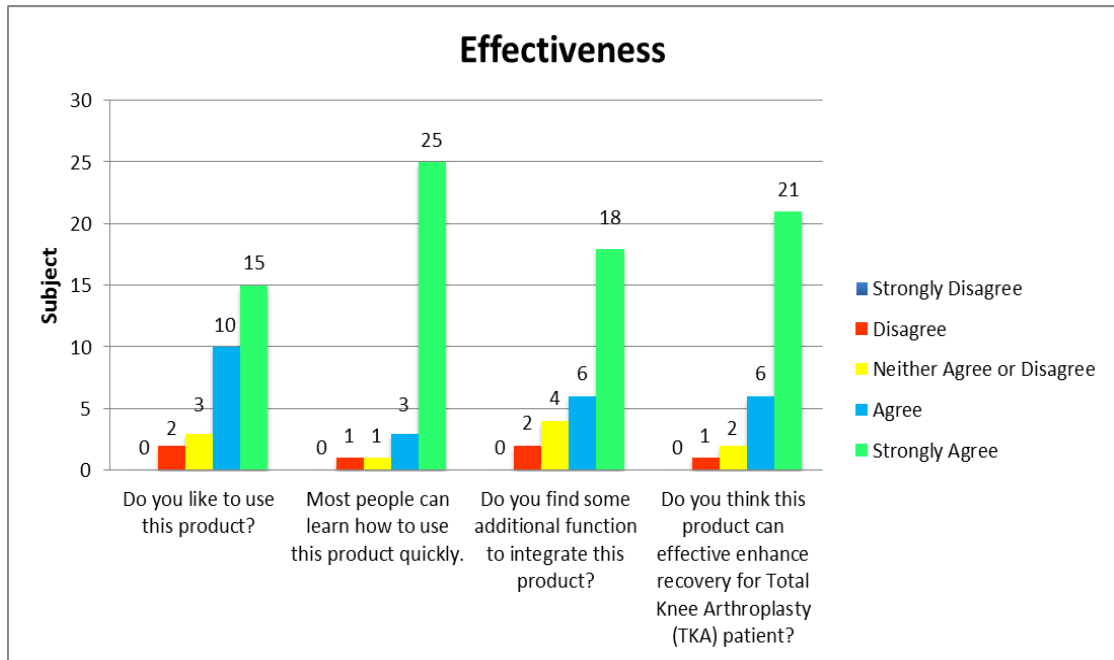


Figure 4.4: Graph of Effectiveness

From the figure 4.4:

- 1) In the first question, 15 subjects are strongly agree that their like to use this device, 10 subjects are agree with that, 3 subjects are neither agree or disagree and 2 subjects is disagree with it.
- 2) In the second question, 25 subjects were strongly agree that they can learn how to use the device quickly, 3 subjects are agree with that, 1 subject are neither agree or disagree and only 1 subject was disagree with it.
- 3) In the third question, 18 subjects were strongly agree that they can find some additional function to integrate this device, 6 subjects are agree with that, 4 subjects are neither agree or disagree and 2 subjects was disagree with it.
- 4) In the Fourth question, 21 subjects were strongly agree about this product can effective enhance fast recovery for Total Knee Arthroplasty (TKA) patient, 6 subjects are agree with that, 2 subjects are neither agree or disagree and only 1 subject was disagree with it.

4.4.2 Comfortableness

There are 4 questions was consisted in this part, the table 4.3 is the question for the Effectiveness test.

Table 4.3: Data of Comfortableness

	Question	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	Are you feeling comfortable when putting leg on this product?	1	2	4	10	13
2	Does this product easy to use and user friendly?	0	1	1	4	24
3	Do you think this product is stable while operating?	0	2	2	10	16
4	Does this product easy to stop / pause when operating?	0	1	2	9	18

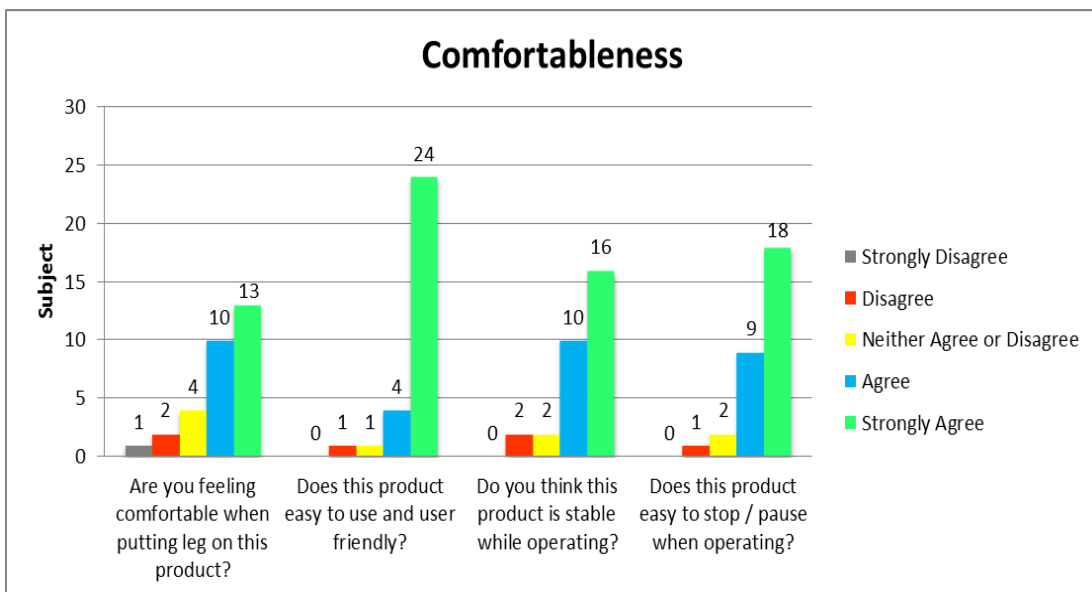


Figure 4.5: Graph of Comfortableness

From the figure 4.5:

- 1) In the first question, 13 subjects are strongly agree feeling comfortable when putting leg on this device, 10 subjects are agree with that, 4 subjects are neither agree or disagree, 2 subjects are disagree and only 1 subject was strongly disagree with it.
- 2) In the second question, 24 subjects were strongly agree this device are easy to use and user friendly, 4 subjects are agree with that, 1 subject are neither agree or disagree and only 1 subject was disagree with it.
- 3) In the third question, 16 subjects were strongly agree this device is stable while operating, 10 subjects are agree with that, 2 subjects are neither agree or disagree and 2 subjects was disagree with it.
- 4) In the Fourth question, 18 subjects were strongly agree this device are easy to stop / pause when operating, 9 subjects are agree with that, 2 subjects are neither agree or disagree and only 1subject was disagree with it.

4.4.3 Speed, Range and Time

There are 4 questions was consisted in this part, the table 4.4 is the question for the Speed, Range and Time test.

Table 4.4: Data of Speed, Range and Time

	Question	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	Do the speed, range and time are easy to adjust?	0	1	3	12	14
2	Do you think the speed, range and time display clearly when adjust?	0	0	1	2	27

3	Does the speed or range comfortable?	0	2	1	5	22
4	Does the current speed and range operation suitable for the TKA patient?	0	0	0	3	27

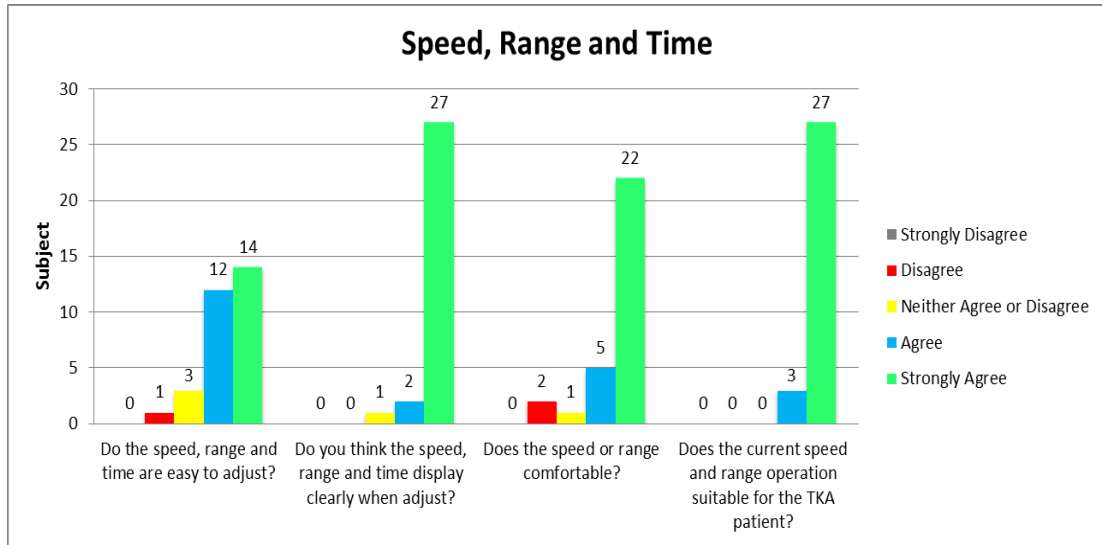


Figure 4.6: Graph of Speed, Range and Time

From the figure 4.6:

- 1) In the first question, 14 subjects are strongly agree the speed, range and time are easy to adjust, 12 subjects are agree with that, 3 subjects are neither agree or disagree and only 1 subject was disagree with it.
- 2) In the second question, 27 subjects were strongly agree the speed, range and time display clearly when adjust, 2 subjects are agree with that and only 1 subject was neither agree or disagree with it.
- 3) In the third question, 22 subjects were strongly agree about the speed or range are comfortable, 5 subjects are agree with that, 1 subject are neither agree or disagree and 2 subjects was disagree with it.

- 4) In the Fourth question, 27 subjects were strongly agree the current speed and range operation suitable for the TKA patient and 3 subjects are agree with it.

4.4.4 Design

There are 4 questions was consisted in this part, the table 4.5 is the question for the Speed, Range and Time test.

Table 4.5: Data of Design

		Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	Does this design look great?	2	2	4	10	12
2	Does this product suitable to be used at home?	0	1	2	9	18
3	Does this product easy to lift and carry?	0	2	4	8	16
4	The movement of this product is smooth and stable?	0	1	1	6	22

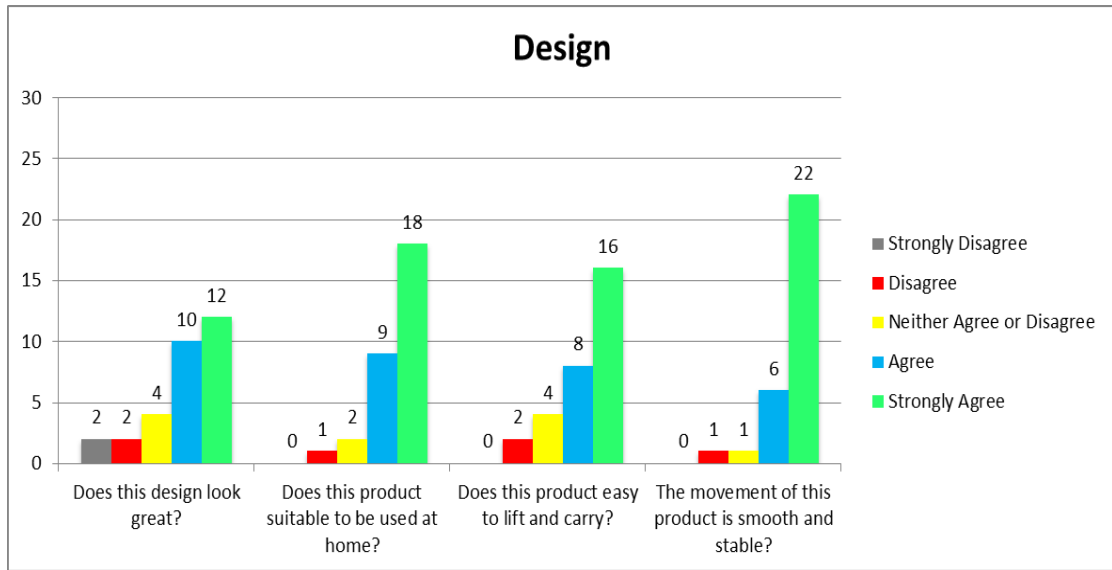


Figure 4.7: Graph of Design

From the figure 4.7:

- 1) In the first question, 12 subjects are strongly agree the design of device look great, 10 subjects are agree with that, 4 subjects are neither agree or disagree, 2 subjects are disagree and 2 subjects was strongly disagree with it.
- 2) In the second question, 18 subjects were strongly agree this device are suitable to use at home, 9 subjects are agree with that, 2 subject are neither agree or disagree and only 1 subject was disagree with it.
- 3) In the third question, 16 subjects were strongly agree the device is easy to lift and carry, 8 subjects are agree with that, 4 subjects are neither agree or disagree and 2 subjects was disagree with it.
- 4) In the Fourth question, 22 subjects were strongly agree the movement of this device is smooth and stable, 6 subjects are agree with that, 1 subjects are neither agree or disagree and only 1subject was disagree with it.

4.4.5 Final Satisfaction Review

There are 4 questions was consisted in this part, the table 4.6 is the question for the Final Satisfaction Review.

Table 4.6: Data of Final Satisfaction Review

		Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	Is this product easy to use?	0	1	2	6	21
2	Do you think this product was important for those their need?	0	2	2	3	23
3	Do you have confident on using this product?	0	1	3	9	17
4	I would like to recommend this product to those people whose need?	0	1	0	5	24

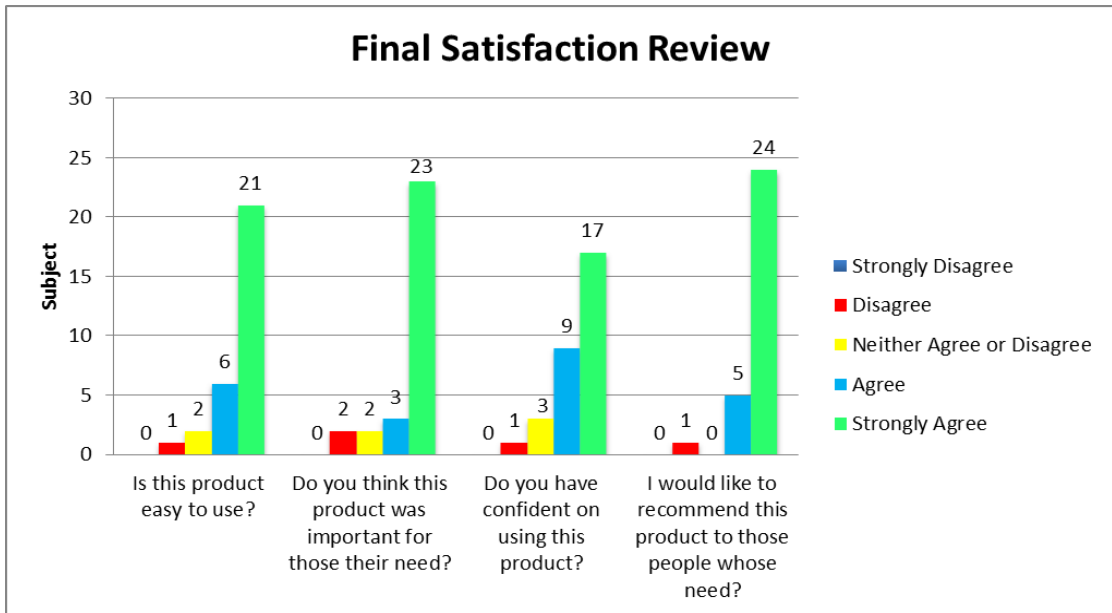


Figure 4.8: Graph of Final Satisfaction Review

From the figure 4.8:

- 1) In the first question, 21 subjects are strongly agree the device easy to use, 6 subjects are agree with that, 2 subjects are neither agree or disagree and only 1 subject was disagree with it.
- 2) In the second question, 18 subjects were strongly agree this device was important for those their need, 9 subjects are agree with that, 2 subject are neither agree or disagree and only 1 subject was disagree with it.
- 3) In the third question, 17 subjects were strongly agree about they have confident on using this product, 9 subjects are agree with that, 3 subjects are neither agree or disagree and only 1 subjects was disagree with it.
- 4) In the Fourth question, 24 subjects were strongly agree to recommend this device to those people whose need, 5 subjects are agree with that and only 1subject was disagree with it.

4.5 SUMMARY FOR USABILITY TEST

From the developed device, there are total 5 parts which is Effectiveness, Comfortableness, Speed, Range and Time, Design and Final Satisfaction Review were tested with difference subjects. The results obtained from this project will summarize in below:

- 1) In the effectiveness of the device, there are total 65.8% was strongly agree and 20.8% was agree with the device effectiveness.
- 2) In the comfortableness of the device, there are total 59.2% was strongly agree and 27.5% was agree with the device comfortableness.
- 3) In the speed, range and time of the device, there are total 75% was strongly agree and 18.3% was agree with the device speed, range and time.
- 4) In the design of the device, there are total 59.7% was strongly agree and 27.5% was agree with the device design.
- 5) In the Final Satisfaction Review, there are total 70.8% was strongly satisfied and 19.2% was satisfied with the device.

4.6 TECHNICAL TEST

After the usability test, a technical test had conducted to this device. The purpose of this test is to testing the consumption of time with the difference angle of the movement in differences speed. The table 4.7 below have shown that the result of time consumption between difference of angle in difference Speed.

Table 4.7: Consumption of Time (In One Cycle) Between Differences Angle with Difference Speed

Angle	Speed				
	20%	40%	60%	80%	100%
10	16 sec	12 sec	7 sec	4 sec	2 sec
20	21 sec	16 sec	10 sec	6 sec	4 sec
30	27 sec	21 sec	14 sec	9 sec	6 sec
40	34 sec	26 sec	18 sec	12 sec	8 sec
50	42 sec	32 sec	23 sec	15 sec	10 sec
60	51 sec	39 sec	28 sec	18 sec	13 sec
70	62 sec	45 sec	33 sec	22 sec	16 sec
80	74 sec	53 sec	38 sec	26 sec	19 sec
90	88 sec	64 sec	44 sec	30 sec	22 sec

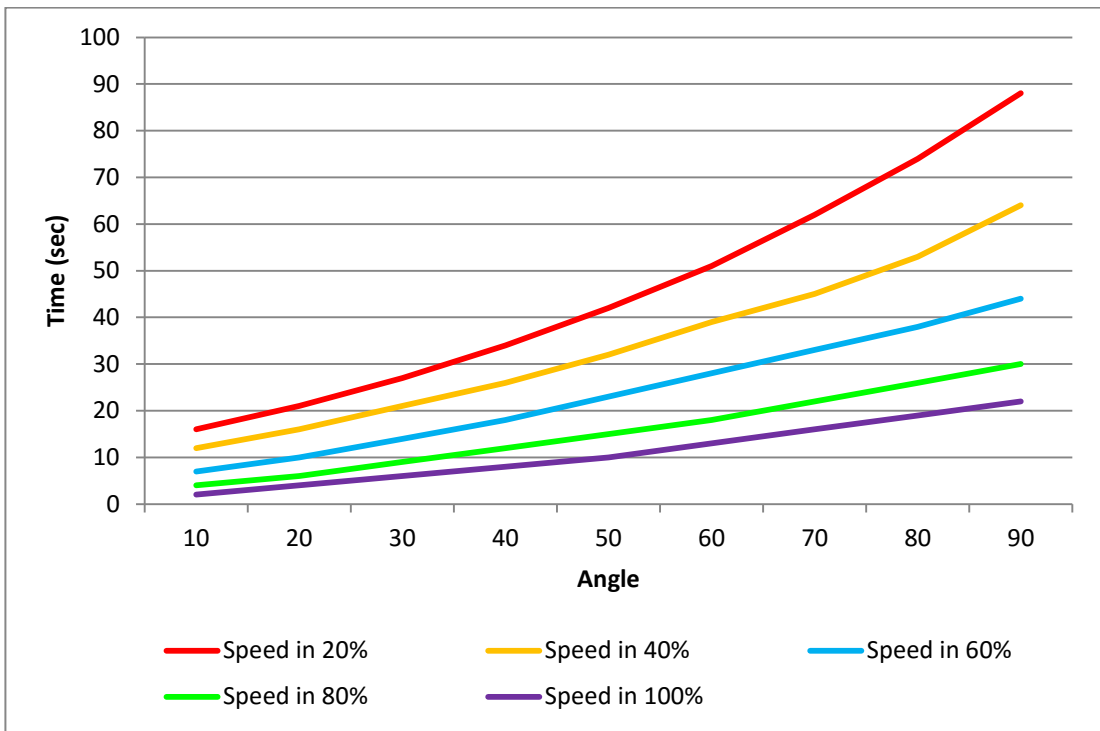


Figure 4.9: Graph of Technical Test

CHAPTER 5

CONCLUSION AND RECOMMENDATION

5.1 CONCLUSION

In this project, a Spectra Knee CPM device for Total Knee Arthroplasty (TKA) patient is developed. This device contains two main sections, which include a control panel and the mechanical framework. After that, there are two survey (Pre and Post) was conducted in the general hospital and the endorsement letter from Radicare was received.

Afterwards, there are a usability test was conducted on 30 subjects to measure the Effectiveness, Comfortableness, Speed, Range and Time, Design and Final Satisfaction Review of the device. During the usability test, the developed device was tested in willingly by the 30 subjects and the data was collected by distributed questionnaire to the subject. Once the testing was finished, the data will be analysis by using Microsoft Excel and SPSS.

After the result had analysed, this developed device has been recognize by most of the subjects in effectively, comfortable and easier to use. In addition, those subjects were satisfied with this developed device. In conclusion, the developed device have achieved the first objective which to design a knee CPM device that can reduce the pain and discomfort when operate and the second objective to innovate a portable knee CPM device that easier to carry and uses.

5.2 RECOMMENDATION

In order to develop a rehabilitation device, the opinion from the physiotherapist and doctor are essential to ensure the device is suitable to apply on the patient. Therefore, the survey and interview was conducted in the Hospital Kuala Lumpur and Hospital Sultanah Nur Zahirah with the medical specialist. In addition, an interview with biomedical engineer was also important to ensure the safety of the developed device.

From the recommendation from the specialist, the uses of DC rechargeable battery are not suitable to operate this device in a long time and uninterrupted therapy. After that, they also propose the existing design is difficult to boost the confidence for the others. Besides, there is some recommendation from the biomedical engineer which is the noise that produced by the device should be minimised. Lastly, those problems above will be solved in the future study.

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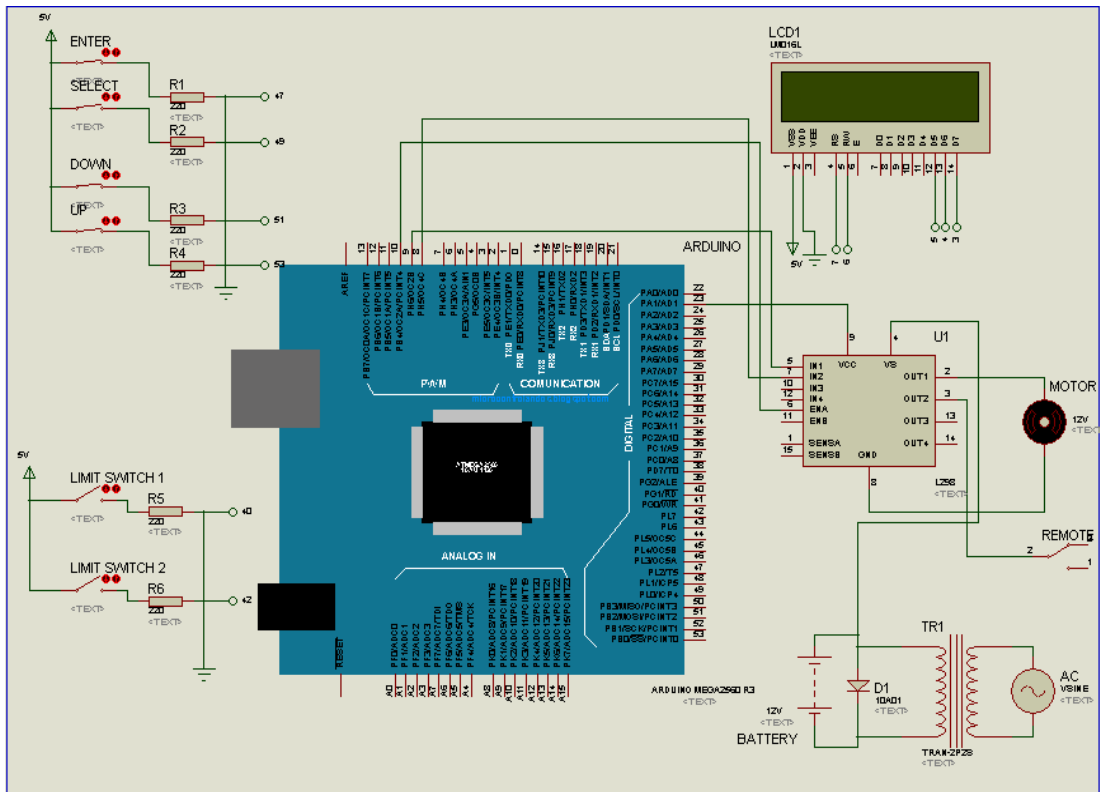
APPENDIX A: QUESTIONNAIRE (USABILITY TEST)

<i>This survey was divided into 2 sections which is Section A and B.</i>						
SECTION A						
Please circle an answer only with each of these statements below						
No	Item	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
<u>Effectiveness</u>						
1	a) Do you like to use this product?	1	2	3	4	5
	b) Most people can learn how to use this product quickly.	1	2	3	4	5
	c) Do you find some additional function to integrate this product?	1	2	3	4	5
	d) Do you think this product can effectively enhance fast recovery for Total Knee Arthroplasty (TKA) patient?	1	2	3	4	5
No	Item	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
<u>Comfortableness</u>						
2	a) Are you feeling comfortable when putting leg on this product?	1	2	3	4	5
	b) Does this product easy to use and user friendly?	1	2	3	4	5
	c) Do you think this product is stable while operating?	1	2	3	4	5

		1	2	3	4	5
No	Item	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
<u>Speed, range and time</u>						
3	a) Do the speed, range and time are easy to adjust?	1	2	3	4	5
	b) Do you think the speed, range and time display clearly when adjust?	1	2	3	4	5
	c) Does the speed or range comfortable?	1	2	3	4	5
	d) Does the current speed and range operation suitable for the TKA patient?	1	2	3	4	5
No	Item	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
<u>Design</u>						
4	a) Does this design look great?	1	2	3	4	5
	b) Does this product suitable to be used at home?	1	2	3	4	5

c)	Does this product easy to lift and carry?	1	2	3	4	5
d)	The movement of this product is smooth and stable?	1	2	3	4	5
SECTION B						
Please cycle an answer only with each of these statements below						
No	Item	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	Is this product easy to use?	1	2	3	4	5
2	Do you think this product was important for those their need?	1	2	3	4	5
3	Do you have confident on using this product?	1	2	3	4	5
4	I would like to recommend this product to those people whose need?	1	2	3	4	5
Recommendation / Comments: <hr/> <hr/>						
<i>THANK YOU AND HAVE A NICE DAY</i>						

APPENDIX B: SCHEMATIC DIAGRAM



APPENDIX C: ENDORSEMENT LETTER (RADICARE)



6th April 2017

TO WHOM IT MAY CONCERN

Letter of Acknowledgement for "The Development of Spectra Knee CPM Moving Train Walk"

Hereby, with a sense of gratitude and appreciation for the innovations that has been made on the Spectra Knee CPM Device. The innovator detail as below:


Name of innovator : WANG WEE KEE
NRIC : 930716065143
Innovation's name : The Development of Spectra Knee CPM Moving Train Walk

2. This innovation also demonstrated the ability to provide benefits to the consumer and society. Furthermore, this innovation is suitable to market for the use by Knee Arthroplasty and Anterior Cruciate Ligament (ACL) reconstruction patient. With the use of battery to operate machine, electrical safety risk to the consumer is eliminated.

3. We hope for more innovation to improve the quality of therapy in rehabilitation field.

Thank you

Sincerely,


NORAINI ISMAIL
Technical Manager, Eastern Zone
Biomedical Engineering Maintenance Services

APPENDIX D: COLLABORATION WITH HOSPITAL



Politeknik Sultan Salahuddin Abdul Aziz Shah
Persiaran Usahawan, Seksyen U1,
40150 Shah Alam,
Selangor Darul Ehsan.

Tel : 603-51634000 Fax : 603-55691903 Laman Web : www.psa.edu.my



Rujukan Kami:PSA/JKE/06/04/004 JLD 5 (4)

Tarikh:

Kepada,
Hospital Sultanah Nur Zahirah
Jalan Sultan Mahmud, 20400 Kuala Terengganu,
Terengganu Darul Iman

Tuan,

KEBENARAN UNTUK MELAKSANAKAN PROJEK TAHUN AKHIR DILUAR

Dengan segala hormatnya adalah disahkan bahawa pelajar-pelajar berikut merupakan pelajar Jabatan Kejuruteraan Elektrik, Politeknik Sultan Salahuddin Abdul Aziz Shah bagi Program Ijazah Sarjana Muda Teknologi Kejuruteraan Elektronik (Elektronik Perubatan), semester enam.

BIL	NAMA	NO.MATRIK
1.	Wang Wee Kee	08BEU15F3023
2.		
3.		

Pelajar-pelajar tersebut dikehendaki menyiapkan kajian dan projek berkaitan dengan kursus seperti yang dinyatakan di bawah:

TAJUK PROJEK: The Development of Spectra Knee CPM Moving Train Walk

2. Sehubungan itu, kerjasama tuan adalah dipohon untuk membenarkan pelajar-pelajar tersebut mendapatkan maklumat yang berkaitan daripada organisasi tuan. Sekiranya terdapat sebarang pertanyaan, tuan boleh menghubungi **Dr. Hj. Zunuwanas Bin Mohamad** di talian 013-3896812
3. Segala kerjasama dari pihak tuan didahului dengan ucapan ribuan terima kasih. Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"
Saya yang menurut perintah,

(NORAZLINA BT JAAFAR)
Ketua Program
Diploma Kejuruteraan Elektronik (Perhubungan)