NEW DESIGN OF KNEE LOCKING SYSTEM FOR KNEE SUPPORT HEALTH DEVICE

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in fulfilment of the requirement for the degree of
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DECLARATION

I declare that this project report entitled " NEW DESIGN OF KNEE LOCKING SYSTEM FOR KNEE SUPPORT HEALTH DEVICE" is the result of my own research except as cited in the references.

Signature : .....

Name : Kesavan A/L Bernabas

Date : .....

APPROVAL

I hereby declare that I have read this project report and in my opinion this report is sufficient in terms of scope and quality for the award of the degree of Bachelor of Mechanical Engineering (with Honours).

Signature	:	.....
Name of supervisor	:	Dr. Masjuri bin musa
Date	:	.....

DEDICATION

To my beloved family, friends and teachers

ABSTRACT

Knee braces are supports to be worn when you have pain in your knee. These are usually used for a period of weeks right after an injury or surgery. They keep the knee stable but still allow limited movement while it is healing. Braces are made from combinations of metal, foam, plastic, or elastic material and straps. They come in many sizes, colours, and designs. ROM knee brace is one of the types of knee braces available in the market. ROM Knee Brace is a custom adjusted ROM brace, which controls and restrict flexion and extension of the knee joint through a hinge module to allow a ROM or immobilization to the knee. It is usually worn by knee injury patients for a certain period after they underwent knee surgery. The hinge module in the ROM knee brace plays an important role in controlling and restricting the ROM of the knee. The hinge module of currently available ROM knee brace in the market needs to be adjusted manually during ROM angle adjustment process. Hence, it is important to explore alternative options for the hinge module design that may serve the same purpose in an easy way. The purpose of this project is to provide an easy handling knee brace's hinge mechanism during adjusting a desired rotational range in the extension or flexion direction which can be user-friendly and convenient to the user. An easily adjustable solenoid hinge module was developed consisting of 22 components. The design of the solenoid hinge module was developed in Solidworks 2016 software. A set of 5v solenoids is used in this design as a locking mechanism which reduces the manpower during the knob locking process. This solenoid based hinge module concept for ROM knee brace is very new and not available in the market right now. This concept makes the angle adjustment process semi-automatic and easier. There are two types of analysis conducted on the design namely stress analysis and kinematic analysis. Based on the maximum stress and total deformation result from the stress analysis, the design is capable to withstand the external force that might be applied by the user during limiting ROM of their knee. Besides that, the motion of the hinge mechanism joints also has been identified from the kinematic analysis.

ABSTRAK

Pendakap lutut adalah suatu penyokong untuk dipakai apabila anda mengalami kesakitan di lutut anda. Ini biasanya digunakan untuk tempoh beberapa minggu selepas kecederaan atau pembedahan. Pendakap lutut menyimpan lutut dengan stabil tetapi masih membenarkan pergerakan terhad semasa ia menyembuhkan. Penyokong diperbuat daripada kombinasi logam, buih, plastik, atau bahan elastik dan tali. Ia datang dalam pelbagai saiz, warna, dan reka bentuk. Pendakap lutut julat pergerakan adalah salah satu jenis pendakap lutut yang ada di pasaran. Pendakap lutut julat pergerakan adalah suatu alat yang mengawal dan menyekat kelonggaran dan perpanjangan sendi lutut melalui modul engsel untuk membolehkan pelbagai gerakan atau immobilisasi ke lutut. Ia biasanya dipakai oleh pesakit kecederaan lutut untuk tempoh tertentu selepas menjalani pembedahan lutut. Modul engsel dalam pendakap lutut julat pergerakan memainkan peranan penting dalam mengawal dan menyekat pelbagai gerakan lutut. Modul engsel yang sedia ada di pasaran perlu disesuaikan secara manual semasa proses pelarasan sudut julat pergerakan. Oleh itu, adalah penting untuk meneroka pilihan alternatif untuk reka bentuk modul engsel yang boleh menjadi tujuan yang sama dengan cara yang mudah. Tujuan projek ini adalah untuk menyediakan mekanisme engsel pendakap lutut julat pergerakan yang boleh dikendalikan dengan mudah semasa menyesuaikan julat putaran yang dikehendaki dalam arah lanjutan atau fleksi yang boleh menjadi mesra pengguna dan mudah untuk pengguna. Modul engsel solenoid yang mudah laras terdiri daripada 22 komponen dibangunkan. Reka bentuk modul engsel solenoid telah dibangunkan dalam perisian Solidworks 2016. Satu set solenoid 5v digunakan dalam reka bentuk ini sebagai mekanisme pengunci yang mengurangkan tenaga manusia semasa proses mengunci lutut. Konsep modul engsel berasaskan solenoid untuk pendakap lutut julat pergerakan ini sangat baru dan tidak terdapat di pasaran sekarang. Konsep ini menjadikan proses pelarasan sudut separa automatik dan lebih mudah. Terdapat dua jenis analisis yang dilakukan pada reka bentuk iaitu analisis tekanan dan analisis kinematik. Berdasarkan tegasan maksimum dan jumlah ubah bentuk hasil daripada analisis stres, reka bentuk ini mampu menahan daya luaran yang mungkin dikenakan oleh pengguna semasa menghadkan julat pergerakan lutut mereka. Selain itu, gerakan sendi mekanisme engsel juga telah dikenal pasti dari analisis kinematik.

ACKNOWLEDGEMENT

Throughout my journey in Universiti Teknikal Malaysia Melaka (UTeM), many people were involved both directly and indirectly helping me to build my academic career. It would have been near impossible to complete this journey without the assistance of these people. Therefore, I would like to express my deepest appreciation to all those who provided me with the possibility to complete this thesis.

A special gratitude I give to my final year project supervisor, Dr Masjuri bin Musa from the Faculty of Mechanical Engineering UTeM, whose contribution in stimulating suggestions and encouragement, helped me to coordinate my project especially in writing this thesis.

Furthermore, I have to appreciate the guidance given by other supervisors as well as the panels especially in my project presentation that has improved my presentation skills, thanks to their comment and advice.

My special thanks to all my fellow friends for their moral support, informative discussions and motivation. I am happy to thank my parents for their unconditional loving support and encouragement.

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ROM	-	Range of Motion
V	-	Voltage

CHAPTER 1

INTRODUCTION

1.1 Background

In human anatomy, the knee is the part of the lower limb that lies between the lower leg and thigh. The femur, tibia and patella make up the bones of the knee. The knee joint keeps these bones in place. The patella is a small, triangle-shaped bone that sits at the front of the knee. The knee is the largest joint in the body, and its exposed position makes it vulnerable to injury during athletic activities. There are various injuries that can occur to the knee joint, the most common injuries are Anterior Cruciate Ligament (ACL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), Meniscus tears and knee dislocation. Usually, these kinds of knee injuries need to undergo surgery. Even though there are many types of knee braces which provides some support at the side of the knee and assist knee recovery post-surgery but Range of motion (ROM) or limited motion knee brace are often prescribed to assist mobilisation during recovery following surgery.

Usually, after knee surgery, the leg needs to be completely immobilised for a few days and then the leg is gradually allowed to move in a small range (0° to 30°). This can be done with the help of ROM knee brace which is in the market and this is the reason why this type of brace is often prescribed following surgery. ROM knee brace is designed to restrict the patient's range of knee flexion and extension to the desired degree during rehabilitation. Patients are progressively given more ROM as their healing progresses.

Figure 1.1: ROM knee brace (www.amazon.com,23/10/18)

Apart from ROM knee brace, there are many other knee braces in the market. Unloader knee brace, Functional knee brace, Prophylactic knee brace and Rehabilitative knee brace are those braces which are currently in the market. These braces have their own function. Figure 1.2 shows an unloader knee brace which is for people who suffer from medial compartment knee osteoarthritis. The design of this knee brace includes adjusting dial which will unload stress from the affected joint by placing pressure on the thigh bone and at the same time, it helps reduce bone on bone rubbing with pain, inflammation and helps in providing support.

Figure 1.2: Unloader knee brace (www.mmarmedical.com,23/10/18)

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Functional knee brace which is shown in figure 1.3 is similar to unloader knee brace except it doesn't have an adjusting dial. This knee brace's design is specifically made for ligaments or meniscus injured patients. This brace will help to provide stability of the knee joint and prevent unwanted knee motion for patients.

Figure 1.3: Functional knee brace (www.breg.com,23/10/18)

Figure 1.4 shows the prophylactic knee brace. The prophylactic knee brace is especially for athletes who play contact sports such as rugby where it will be used to give protection for knee and it is a preventative measure to reduce the chance of injury. The design of this brace protects medial collateral ligament against valgus knee stresses.

Figure 1.4: Prophylactic knee brace (www.shockdoctor.com,23/10/18)

The rehabilitative knee brace is for the people who recover from knee surgery where it will protect a reconstructed or repaired ligament to prevent future or recurring injury and allow early motion of the knee joint. The image of rehabilitative knee brace is shown in figure 1.5.

Figure 1.5: Rehabilitative knee brace (www.donjoyperformance.com,23/10/18)

1.2 Problem Statement

ROM knee braces in the market currently is observed to be not user-friendly. Spring-loaded knob hinge mechanism in ROM brace seems to be difficult to adjust by the user. Therefore, it is important to come out with a new hinge design with ease of handling during adjusting the angular position of the knee and with a new type of spring-loaded knob which is resistant to unintended slippage from its selected rotation limiting position during rotation of the hinge.

1.3 Objective

The objective of this project is to provide an easy handling knee brace's hinge mechanism during adjusting a desired rotational range in the extension or flexion direction which can be user-friendly and convenient to the user.

1.4 Scope of Project

The scopes of this project are:

1. The ROM brace's adjustable hinge module will be designed by using CAD.
2. Design rigidity of hinge will be identified by using analysis software.
3. The motion of hinge mechanism joints will be identified by using kinematic analysis.

1.5 General methodology

The actions that need to be carried out to achieve the objectives in this project are listed below.

1. Literature review

   Patents, articles, or any materials regarding the project will be reviewed.

2. Survey

   A survey is one of the helpful tools to obtain information from people. So, in the early phase of this project, a survey will be conducted to obtain information from random people regarding ROM knee brace. The information will be about their requirements for ROM knee brace which will be considered as customer requirement for this project. This survey will be conducted through google form where the results will be converted into the graph at the end for the analysis process.

3. House of quality

   House of Quality is a chart utilised for analysing the connection between customer requirements and the product's engineering characteristics. Besides that, the competitor's product also will be compared with the customer requirements. For this project, HOQ will be discussed based on the information and result gathered from the survey.

4. Morphological chart

A morphological chart is in the early phase of the concept generation process. It provides a structured approach to concept generation. This chart consists of a list of product attributes and possible solutions. For each element of product attributes, there may be a number of possible solutions. Morphological chart for this project which includes attributes of the hinge mechanism and its possible solutions will be discussed.

5. Conceptual design

The conceptual design includes the sketch of concept, the components involves, how it will meet the objectives and how it will work. There are four conceptual design for the knee brace hinge mechanism will be discussed in this project.

6. Champion concept

Among the four conceptual design, one will be selected as the champion concept which will be the final concept. Weighted criteria method will be used for the concept selection process.

7. Detailed design

The champion concept of hinge mechanism will be designed by using CAD software.

8. Kinematics analysis

The kinematics analysis will be conducted at the area of the hinge mechanism of the knee brace to identify the motion of the related mechanism.

9. Design rigidity

The design rigidity of the hinge mechanism will be identified using analysis software. Materials in the hinge mechanism that displays less elastic deformation under load possess higher levels of rigidity. This analysis is very

important because to make sure the materials in the hinge mechanism can resist bending, stretching, twisting or other deformation under a load.

10. Report writing

A report on this study will be written at the end of the project.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

A comfortable and convenient ROM knee brace is needed for human being following surgery in their knee to limit the ROM of the knee which will reduce and prevent unrestricted rotation of the knee. Specifically, they are regularly prescribed when somebody has harmed one of the four major structural tendons of the knee. The function of this type of knee brace is to limit the user's range of knee flexion and extension to the desired degree because usually the users are progressively given more ROM as their healing progresses. The interconnecting hinge module in the ROM knee brace plays an important role to provide the ROM. The users need to adjust the settings in the hinge module to set a different ROM. Therefore, it is important to have a ROM knee brace with an easily adjustable hinge module which will be convenient for the user. The type of adjustable hinge module and the locking mechanism of the hinge is very important to provide convenient and easy adjustment of the ROM for the user.

This particular chapter will review studies and researches carried out in relation to the mechanism of ROM knee brace's hinge module. This could provide more understandings on the working mechanism of the hinge module. It includes section 2.1 which explains the locking mechanisms of ROM knee brace's hinge from selected patents and section 2.2 which compare and review the different types of hinge modules explained in section 2.1.

2.2 Previous studies on rom knee brace's hinge

John E. Bennett et al. (2006) designed two types of adjustable hinges for an Orthopaedic brace. The inventors identified a few problems encountered in currently available knee braces. One of the problems is that hinge settings of the knee braces are right or left handed which will limit the application of the knee braces on a limb. The second problem is the current knee braces not providing convenient adjustment of hinge settings. The inventors made certain improvements in their knee brace's design to overcome these problems.

Figure 2.1 and 2.2 shows the top view and side view of the first type of hinge. All the components in the figures labelled with numbers as a reference. This design includes few components like detent - 30, spring - 19, lower plate - 14, upper plate - 12, rivet – 26a, top cover - 20, pivot rivet – 22, spacer - 18 and washer - 26. The lower plate and upper plate connected pivotally by the hinge mechanism. The pivot rivet - 22 in the centre of the hinge connecting both upper and lower plates will allow pivot movement for them. There are washers - 26 mounted between lower plate, the upper plate and top cover to provide ease pivotal movement by reducing friction between them. The lower plate has a toothed edge while the upper plate has a curved edge. The toothed edge of the lower plate plays a vital role in the hinge mechanism where it is engageable with the detent to fix the plates in a particular angle to each other. The top cover is fixed on top of the upper plate with three rivets - 26a passing through the spacer -18 located in between the top cover and the upper plate. It has a slot in the centre line with an acceptable narrow width to keep and move the detent in between it. The detent - 30 is a locking mechanism fixed on top of the upper plate between the slot on the top cover.

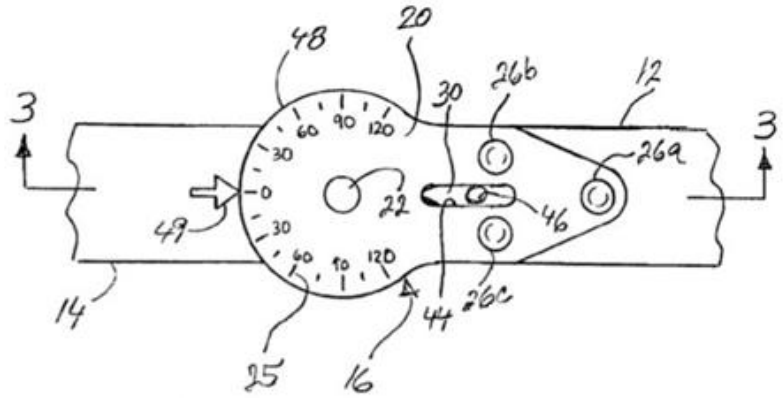


Figure 2.1: Top view of first type hinge with zero angle position (John E. Bennett et al.,2006)

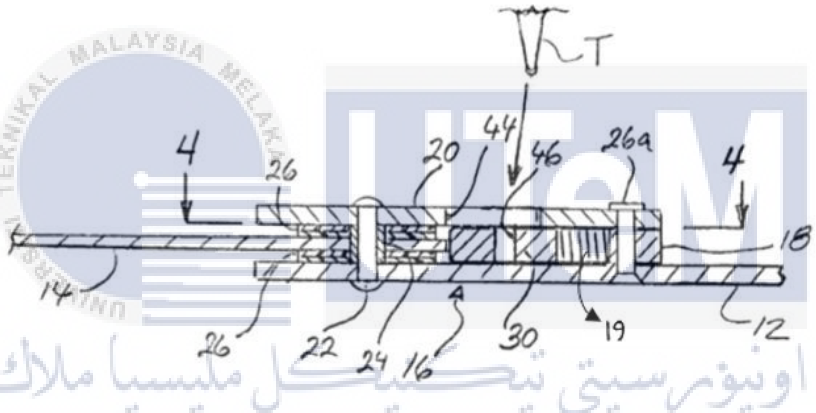


Figure 2.2: Side view of first type hinge (John E. Bennett et al.,2006)

It has an acute edge which fits between teeth of the toothed edged lower plate 14, thereby interlocking the upper and lower plates. The detent is movable on the upper plate along with the top cover's slot, into and out of engagement with a toothed edge on the lower plate. The spring - 19 is compressed between the detent and spacer - 18 which will continuously push detent towards engagement with a toothed edge. Figure 2.3 shows the engaged conditions of the detent with the toothed edge of the lower plate.

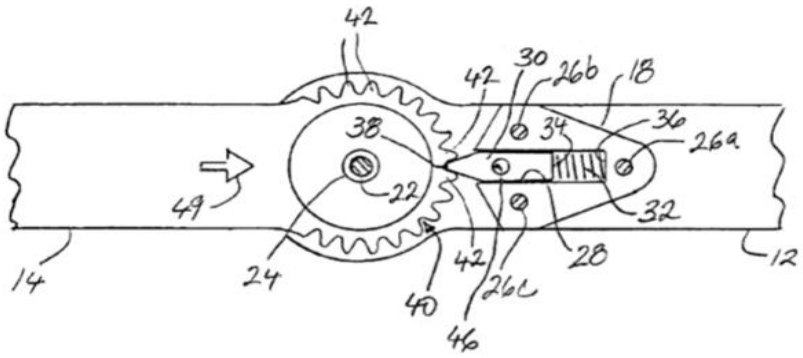


Figure 2.3: Detent engaged with the toothed edge of lower plate

(John E. Bennett et al.,2006)

The scale on the top cover is a guide to set the plates to the required angle. In order to adjust the lower plate, the detent needs to be retracted against the spring to disengage it from the engagement with the toothed edge. Once the detent disengages from the toothed edges of the lower plate, the lower plate can freely rotate 120° right or 120° left of the zero-angle position. The angular movement of 120° in both side (left & right) in this design allows this brace to be used interchangeably in both side of the leg (left & right) without any modification. This will make the brace to be both left & right handed. The detent has an aperture to receive any suitable tool during the detent adjustment. Any sharp-edged tool like a pen is needed to manually push the detent within the guideway of the slot against the force of spring in order to retract the detent. The inventor purposely came out with this type of detent adjustment to make it resistant to tampering by the patient.

Once the lower plate adjusted to a selected angle within a range of angular movement of the hinge, the detent will be released back to engage with a toothed edge. Thereby, the lower plate is fixed at that angle and concurrently it will immobilize the patient's leg at the selected angle. In addition, the inventors came out with a locking element to hold the detent out of its engaged condition. This can be done by engaging a locking screw with the threaded hole - 46 on the upper plate through the detent hole once the detent retracted from its

engagement with the toothed edge. Figure 2.4 & 2.5 shows locking screw - 11 disengage and engage with the threaded hole on the upper plate respectively.

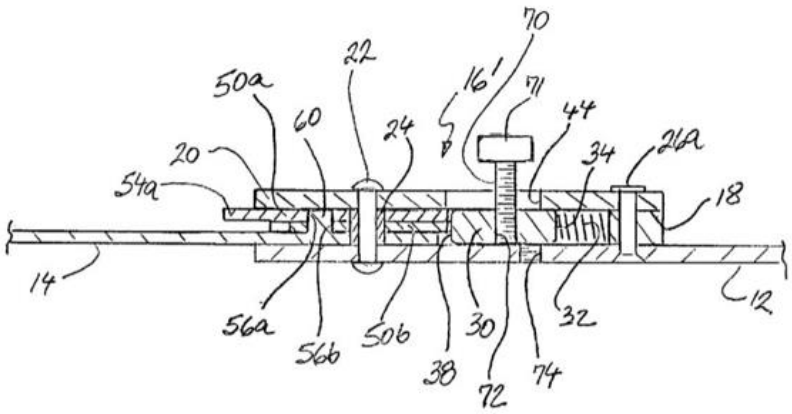


Figure 2.4: Locking screw disengage with threaded hole (John E. Bennett et al.,2006)

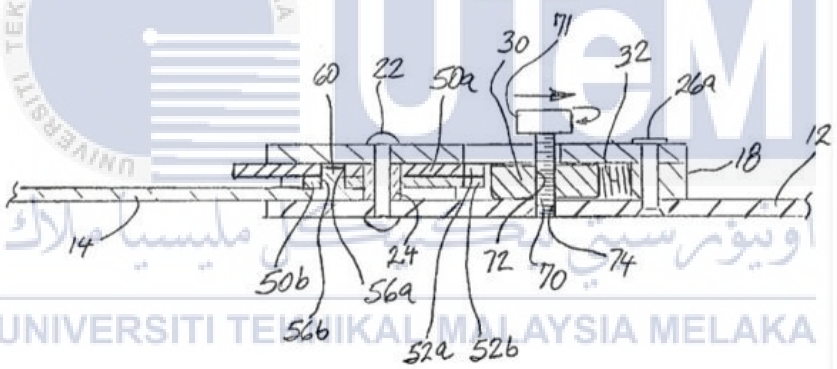


Figure 2.5: Locking screw engaged with threaded hole (John E. Bennett et al.,2006)

The inventors introduced this feature to make a full 240° rotations by the lower plate freely during the adjustment. Figure 2.6 shows the lower plate rotated 240° freely while the detent retracted from its engagement.

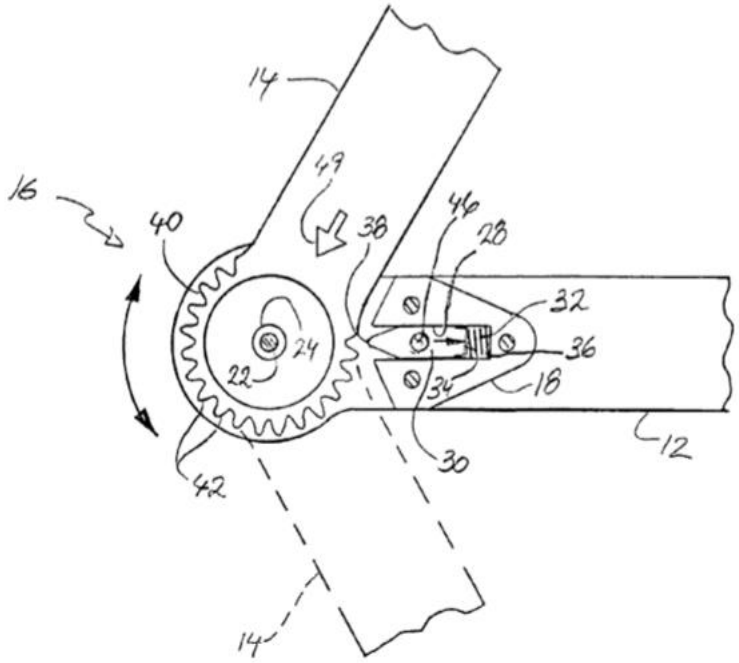


Figure 2.6: Lower plate rotated 240° freely (John E. Bennett et al.,2006)

In the second of type of hinge design, the inventors used a similar type of detent concept as the first type but they did modification in the toothed edge. In the second type of design shown in figure 2.7, the inventors introduced additional components like toothed edge wheels - 54a & 54b, curve edge lower plate - 14 and stop pin - 60. Those two wheels 54a & 54b mounted on upper plate concentrically with pivotal movement of the lower and upper plate. Both wheels have arched slots with 120 degrees of arc. There are two stops between the arched slot of the two overlapping wheels which is the end curve of both arcs. These two stops play an important role in this hinge mechanism where the angular spacing between them is the angular range of the pivotal movement of the plates. The stop pins on the lower plate will travel within the angular space of the two overlapping wheel's arched slots and it will make sure that the plate travel within the selected angular range. While the detent is disengaged, the angular spacing between the stops can be adjusted by the rotation of the wheels. Once the adjustment of the wheels to a selected angular range is done, the detent will be released back to engage with the toothed edge of the wheels. The thickness of the detent is enough to concurrently engage both toothed edges band thereby lock both wheels

at that angular range against rotation. Thereby, the lower plate can move within the angular range.

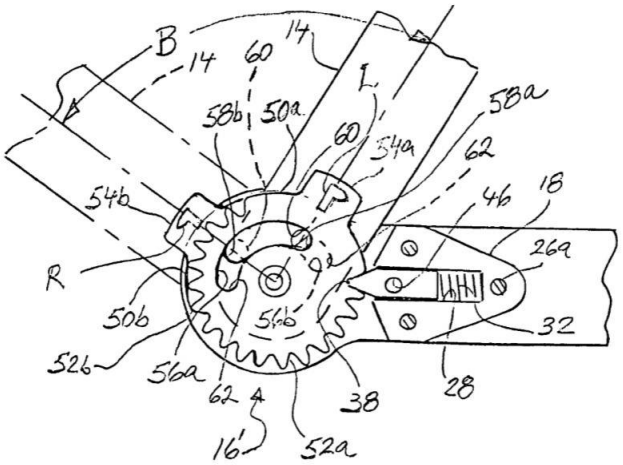


Figure 2.7: Top view of second type hinge without top cover
(John E. Bennett et al.,2006)

Figure 2.8 shows the hinge adjusted on the left side while figure 2.7 shows the hinge adjusted on the right side. This shows that this brace can be used interchangeably in both side of the leg (left & right) without any modification as the first type.

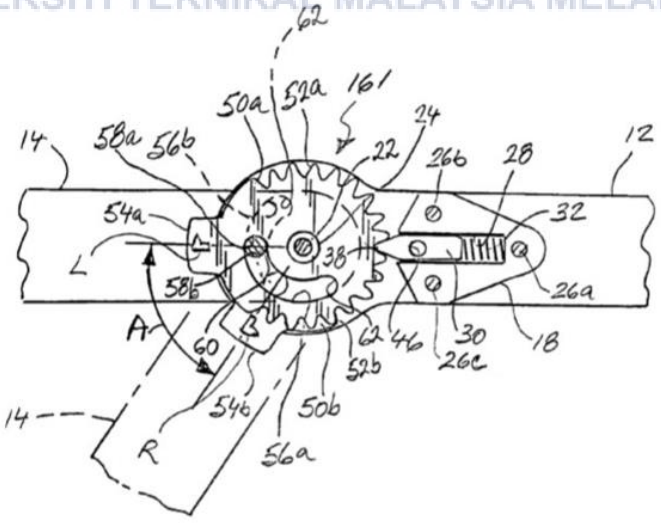


Figure 2.8: Second type hinge adjusted to a selected angular range on left side
(John E. Bennett et al.,2006)

David Cormier et al. (2005) invented a new type of knee brace hinge mechanism. They observe the existing knee brace hinge mechanism in the market is not easy to adjust, too bulky, not has many points of adjustment and not economically build. So, the inventors come out with a new type of the hinge mechanism where it can be easily adjusted by the user, compact, has many points of adjustment and economically build. Figure 2.9 and 2.10 shows exploded view and top view of hinge mechanism respectively. This hinge mechanism design is made up of few components which are labelled with numbers as a reference in the figures above. The components are flexion stop – 44, extension stop – 42, push buttons – 52 & 54, centre rivet - 56, cover plate – 74 & 72, catch plate – 68 & 70, spacers – 64 & 66, lower frame – 16 and upper frame – 18.

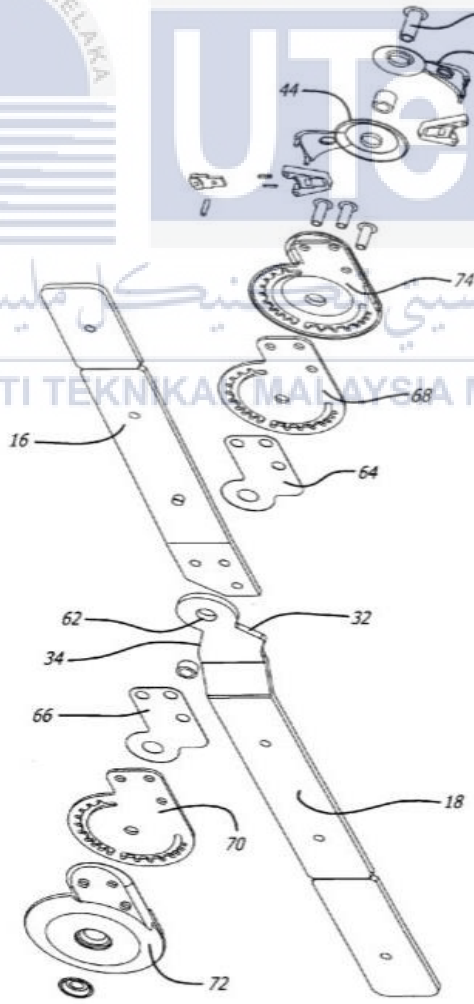


Figure 2.9: Exploded view of hinge mechanism (David Cormier et al.,2005)

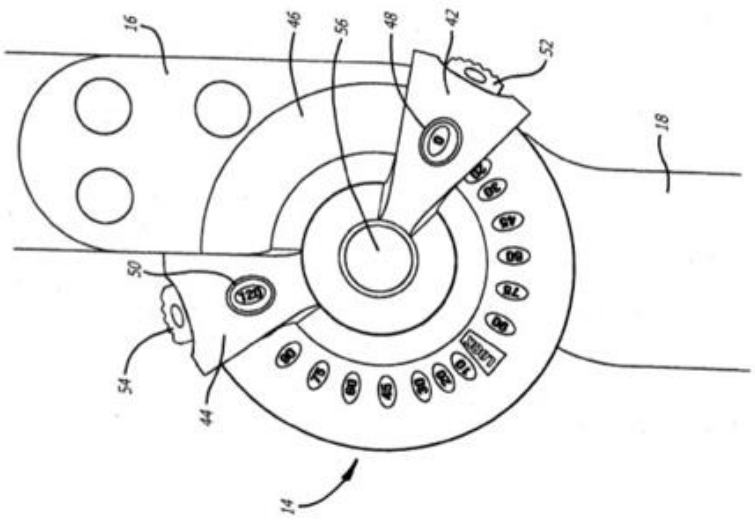


Figure 2.10: Top view of hinge mechanism (David Cormier et al.,2005)

Figure 2.11 shows the detailed view of movable stops assembly and hinge mechanism components with the back cover removed. The components of movable stop assemblies are locking pins – 82 & 86, coil springs – 96 & 98 and physical stops – 92 & 94 as shown in figure 2.11.

In this design, the two movable stops assemblies, catch plates, cover plates, spacers, lower frame and upper frame are connected pivotally at the centre of the hinge mechanism to provide flexion and extension rotation by a centre rivet -56. The function of the stops 42 and 44 are to limit the flexion and extension movement of the knee. The catch plates – 74 & 72 have a series of inwardly opening teeth to receive the locking pins of the stops. The stops having an outwardly biased locking member to selectively engage with one of the teeth of catch plates. The stop assemblies include locking pins – 82 & 86 which seats in corresponding teeth in each of the two catch plates, to provide a balanced locking position for resisting forces applied between the frames to limit flexion or extension. A pair of small coil springs – 96 & 98 are placed between the push button and the physical stops in the stop assemblies to make the locking pins outwardly bias and stay engaged with one of the catch plate teeth. The surface of the push button is knurled to avoid slippage during angular

adjustment. The two catch plates – 74 & 72 are connected to the upper frame – 18 by rivet so that it can remain static and allow the lower plate to move between selected angle. Besides that, the cover plates have a series of inwardly directed teeth to allow the locking pins engage with it which will provide extra support during the locking position. Apart from that, to facilitate the movement of the frames, there are two spacers connected between the catch plate and the frames which will act as washers.

In order to adjust the stops – 42 & 44 during the hinge angular adjustment, an inward pressure need to be provided on the push button to move it inward with the locking pin against the biased coil spring. When the locking pin moves inwardly, it will unengaged from the engagement with one of the catch plate teeth which will allow the stops to move pivotally freely. Then it can be rotated to the desired angular settings while pressing the push button. Once it moves to the desired angle, then the push button can be released to permit locking of the stop in the new angular position. This can be done when the locking pin engaged with the teeth of the catch plate at that particular angle. Once the setting of both flexion and extension stops are done, then the lower frame is only movable between that particular range of angle because the physical stop members – 92 & 94 will engage with the stop surfaces – 32 & 34 of lower plate direction respectively. Moreover, the inventors also come out with an idea to make this hinge resistant of tampering where they designed a hole at the side of the push buttons to allow the physician or technical assistant to thread wire or plastic ties through the hole to prevent re-setting or tampering with the angular settings.

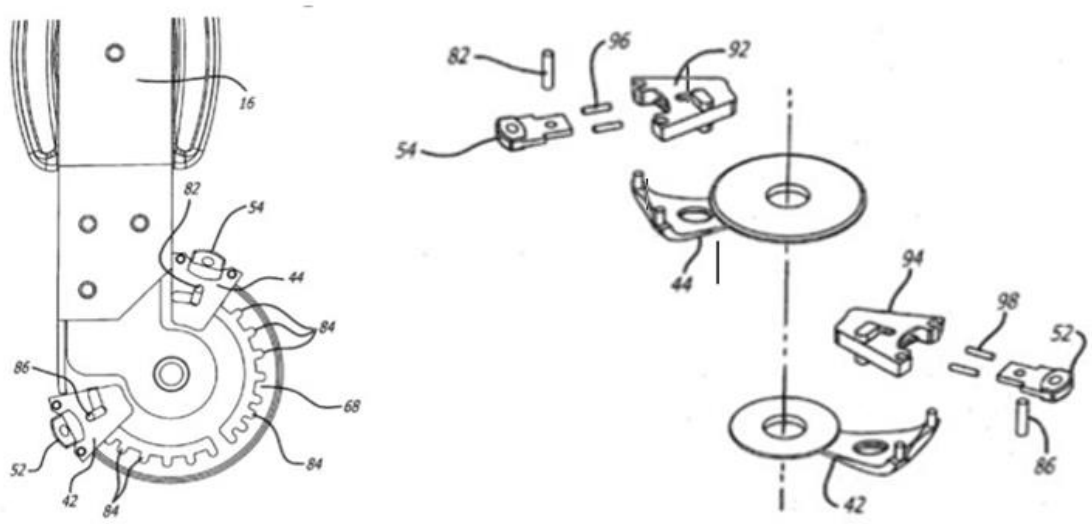


Figure 2.11: Back view of hinge mechanism with back cover removed

(David Cormier et al.,2005)

Figure 2.12 shows the hinge mechanism with the extension stop - 42 set at 0° and the extension stop - 44 set at 120°. This will grant the lower frame to move freely between the stops for 120°. It means the lower frame is restrained from movement beyond 120°.

The inventors suggest the components are preferably made of high Strength Material Such as zinc alloys, steel, titanium, other high strength metals or high strength plastic specifically the physical stops – 92 & 94 may be made of high strength zinc alloy referenced as ZA-28 to provide extra strength and compactness to prevent any mechanical failures in the hinge assembly. The inventors also claim that the overall thickness of the hinge assembly is about 1.3cm which will make the hinge compact and not too bulky.

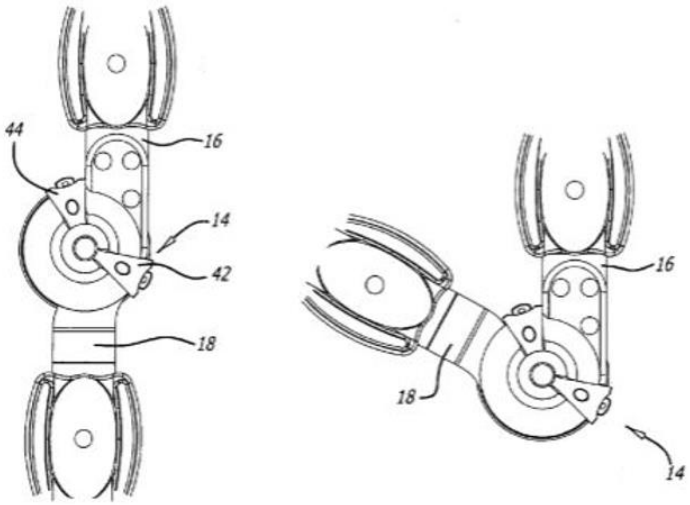


Figure 2.12: Hinge mechanism with extension at 0° and flexion at 120°
(David Cormier et al., 2005)

Jeffery T. Mason et al. (2006) invented a sideway adjustable ROM knee brace's hinge. The inventors stated that the objective of this invention is to provide a hinge for a ROM knee brace with a rotation limiting mechanism which can selectively limit the ROM. Besides that, the objective of the invention is also to provide a lock and unlock mode of operation which can selectively lock the hinge against the rotation of the upper and lower plate. Figure 2.13 shows the front view of the knee brace. The hinge module of the design comprises a rotation locking mechanism - 2, a rotation limiting mechanism - 1, lateral rotation plate – 34, medial rotation plate – 36, upper rotation arm – 14 and lower rotation arm - 16. They are connected about the pivot of the hinge with a rivet – 62. The function of the rotation limiting mechanism is to limit the ROM where it is selectively adjustable along flexion and extension direction. Then, the function of the rotation locking mechanism is to lock the hinge against the rotation of the upper plate and lower plate where it is selectively adjustable in a fixed position.

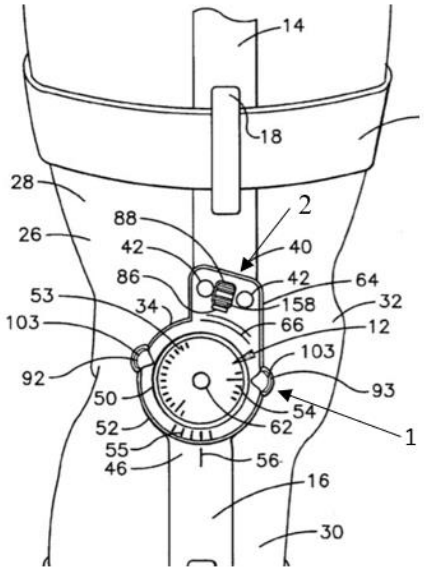


Figure 2.13: Front view of knee brace (Jeffery T. Mason et al., 2006)

Figure 2.14 shows the exploded view of the hinge. It provides a detail view of the components and how they are connected. The components of rotation limiting assembly are an adjustable knob – 103 and leaf spring – 120. The rotation locking assembly comprises actuator bar – 88, transition plate – 84 and a pair of locking pin - 76. A series of rotation limiting teeth which include teeth – 68 and receiving space – 70 are formed at the edge of the lateral and medial plate. The adjustable knob has an engagement faces – 106 & 109 which is engageable with the receiving space – 70. Besides that, the adjustable knob also has a spring cut-out -114 is formed through the adjustable knob – 94. The leaf spring will be fixed in the spring cut-out to create a biasing force which will bias the rotation limiting assembly in a radially inward direction perpendicular to the axis of hinge rotation.

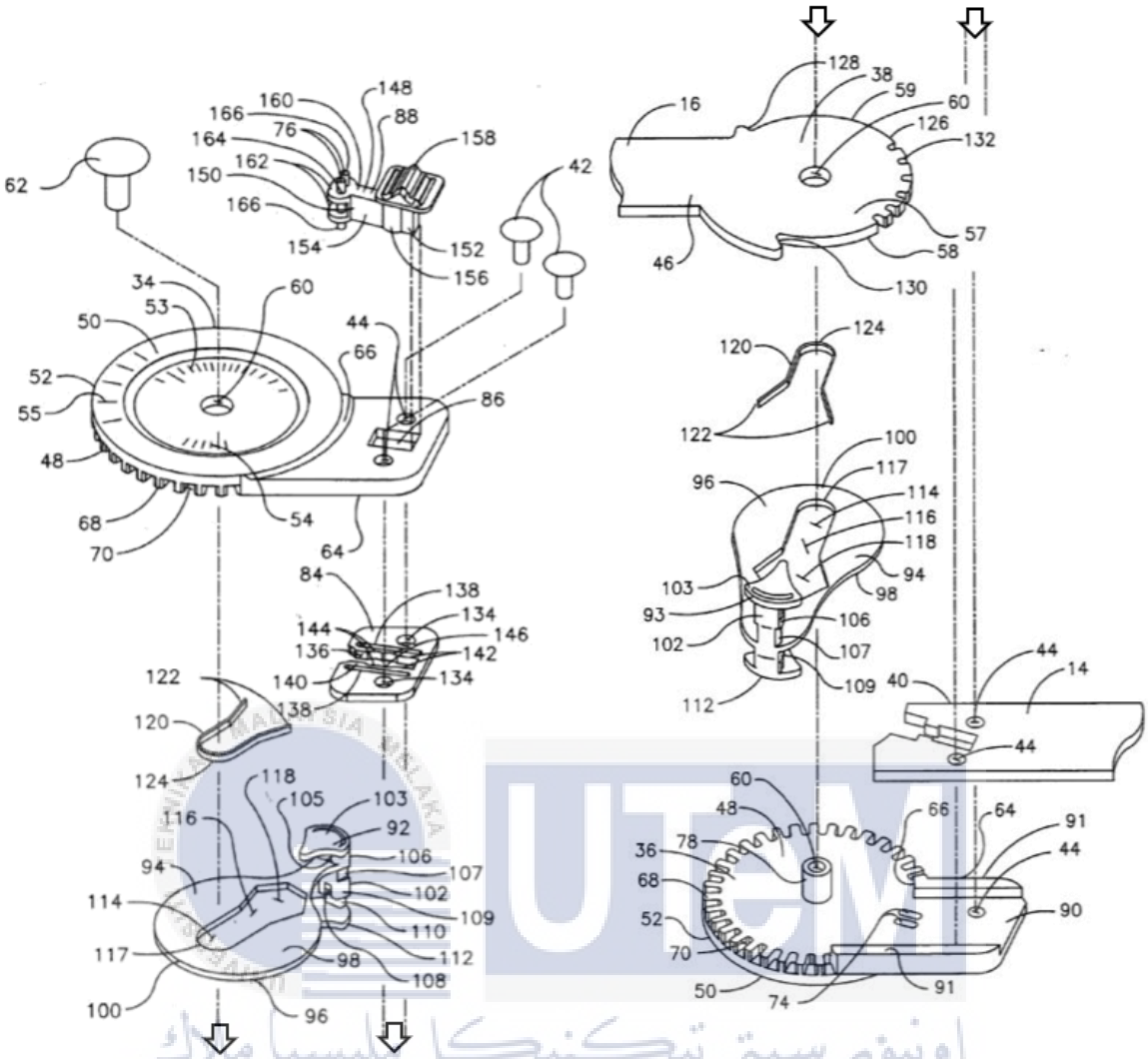


Figure 2.14: Exploded view of hinge (Jeffery T. Mason et al., 2006)

Figure 2.15 and 2.16 are the components of the rotation locking assembly. The actuator bar comprises arcuate protrusion – 156 and grip surface – 158. A pair of locking pins have been fixed vertically at the front edge of the actuator bar. The transition plate – 84 includes lock assembly cut-out – 136, expansion slots 138 and two arcuately-shaped aperture 146 & 144. The actuator bar will be fixed in between the assembly cut-out where the arcuate protrusion of the actuator can be slidably position in 146 or 144. The purpose of the expansion slot is to facilitate the expansion of lock assembly cut-out during the movement of the actuator bar along 146 and 144.

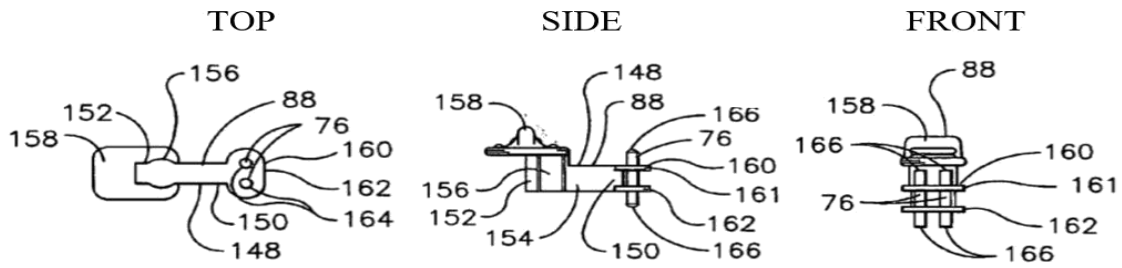


Figure 2.15: Three-dimensional view of actuator bar (Jeffery T. Mason et al., 2006)

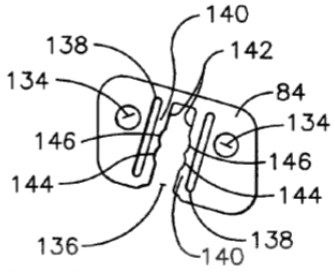


Figure 2.16: Top view of transition plate (Jeffery T. Mason et al., 2006)

Figure 2.17 shows the cross-section view of the hinge which shows how the components connected in detail. The figure shows, adjustable knobs – 103 are in engagement with the teeth of the lateral and medial plate. The radially-inward directed biasing force of the leaf spring in the rotation limiting assembly will retain the engagement. This engagement will lock the adjustable knobs at that particular position where the range of angle between the knob will limit the movement of the lower arm. The lower arm will only able to move between the selected range. During the adjustment of the ROM, the adjustable knob needs to be adjusted along flexion and extension direction to set the desired angle. In order to adjust it, a displacement force needs to be applied in sideways to the adjustable knob in radially outward direction which will withdraw it from the engagement with the teeth of the lateral and medial plate. The displacement force should exceed the biasing force of the leaf spring in order to withdraw the adjustable knob form its engagement. As long as a sufficient displacement force is maintained on the adjustable knob, the knob is free to move along flexion and extension direction. Apart from that the figure also shows the rotation locking

assembly is in unlock mode. The purpose of this assembly is to lock the lower arm against the rotation. In detail, the lock pin -76 is transition able between a locked position and an unlocked position. This can be done when the actuator is slidably adjustable along with the transition plate. When the actuator is positioned in the arcuate-shaped aperture – 144, the locking pins fixed at the edge of the actuator will engage with the notch - 132 formed at the edge of the lower arm. During this mode, the lower arm is locked against the rotation. In order to unlock it, the actuator should be position in aperture – 146 which will concurrently withdraw the engagement of the lock pins with the notch.

In addition, the inventors also suggested suitable materials for a few components of the hinge. They prefer the leaf spring is made of malleable metal, lateral and medial rotation plates are made of high strength plastic, lock pins in rotation locking assembly is made of steel or aluminium and the adjustable knob is made of high strength plastic.

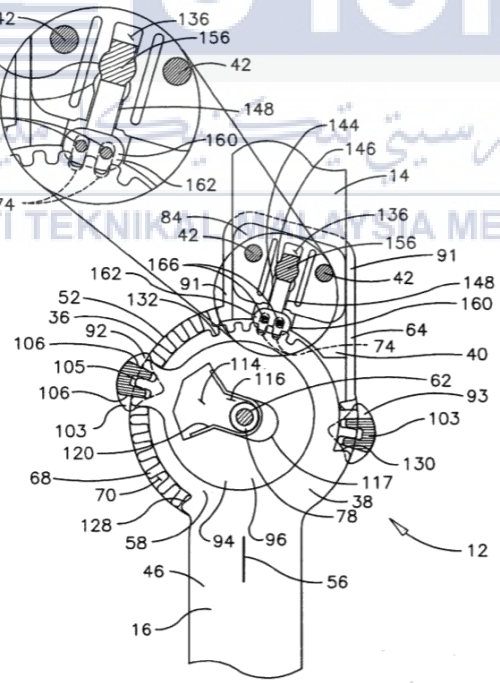


Figure 2.17: Cross section view of hinge (Jeffery T. Mason et al., 2006)

2.3 Review

There are different types of knee brace's hinge module which invented by certain inventors have been studied and discussed in section 2.1. The working mechanism and the components of the hinges are different from each other where they have both advantages and disadvantages.

The first type hinge discussed in section 2.1 which designed by John E. Bennett et al. (2006) has a movable detent fixed on the upper plate. The function of the detent is to lock the lower plate against the rotation of the upper plate. This type of hinge is not capable to limit the ROM of knee but it could only lock the rotation at a particular angle. Besides that, there is an advantage of this hinge where it can be used for both left and right leg. It's not specifically designed to be either left or right-handed. Moreover, a sharp-edged tool is required to adjust the detent. Even though the purpose of this type of detent design is to make the hinge to be a resistance of tampering by the user but it could not be convenient for the user. There might be an alternative design which can make the hinge to be the resistance of tampering by the user and at the same time can be convenient for the user. The inventors of this hinge also designed a locking element to hold the detent out of its engaged condition as discussed in the previous section. The type locking element used is a locking screw and threaded hole. This type of locking element is not convenient because it requires a specific skill to screw it.

Furthermore, the second type of hinge is the improved version of type 1. In this design, there are additional wheels with arc slots to limit the ROM. The type of hinge adjustment in this design is top way adjustment. This type of adjustment will make the user to easily adjust the ROM because it is easy to adjust the mechanism from the top angle for the user than adjusting from sideways. Even though this design could provide easy adjustment of the hinge but it has the same disadvantage with the detent as hinge type 1.

This hinge should have any protection covers as a safety feature to prevent causing any injury to the user. Not only that, the wheels in this design should be lockable so that it can be locked by the person who prescribes the ROM. This will make the hinge to be the resistance of tampering by the user where it will prevent readjustment of the ROM by the user for their comfort. In terms of limiting the ROM, this type is better than type 1.

The type of hinge adjustment in hinge type 3 which invented by David Cormier et al. (2005) is sideways adjustment. Even though this type of design could limit the ROM of knee but it is difficult for the user to adjust the mechanism to set the ROM from sideways compared to top way adjustment as type 2. It uses push-button method to adjust the ROM where it requires more radially inward force to be applied on the push button during the adjustment but the wheels in type 2 only require a minimum amount of force for the adjustment. Besides that, this type of hinge is a resistance of tampering by the user because it has lockable push button where it can be locked by the person who prescribes the ROM to prevent readjustment by the user. Another disadvantage of this hinge is it doesn't have a mechanism to lock the arms against the rotation which is required when the user needs to lock the arm of the brace at a particular angle.

The type 4 hinge which is invented by Jeffery T. Mason et al. (2006) is a sideway adjustment hinge same as hinge type 3. The users will face the same difficulties with the sideways adjustment as in hinge type 3. Both hinge type 4 and 3 are able to limit the ROM with their mechanism but the advantage of this hinge compared to the hinge type 3 is that this hinge is has a mechanism to lock the arm against the rotation. It can provide a locked and unlocked mode of the arm with transition able actuator. Apart from that, this hinge is not the resistance of tampering by the user because it doesn't have lockable knob compared to hinge type 3 which is the resistance of tampering because it has a lockable push button.

Based on this study, all these hinges have own advantages and disadvantages. It is important to come out with a new type hinge which includes all of the advantages discussed above. The new type of hinge might be easily adjustable, with safety features and resistance of tampering.

CHAPTER 3

METHODOLOGY

3.1 Introduction

This chapter describes all the methods used in this project to design ease of handling ROM knee brace's hinge. In order to discuss the sequence of the methods, the chapter will begin with an overall project flowchart. Processes taken towards the development of this study will be briefly stated in the flowchart as an overview of how the development of the knee brace's hinge takes place.

3.2 Overall flowchart

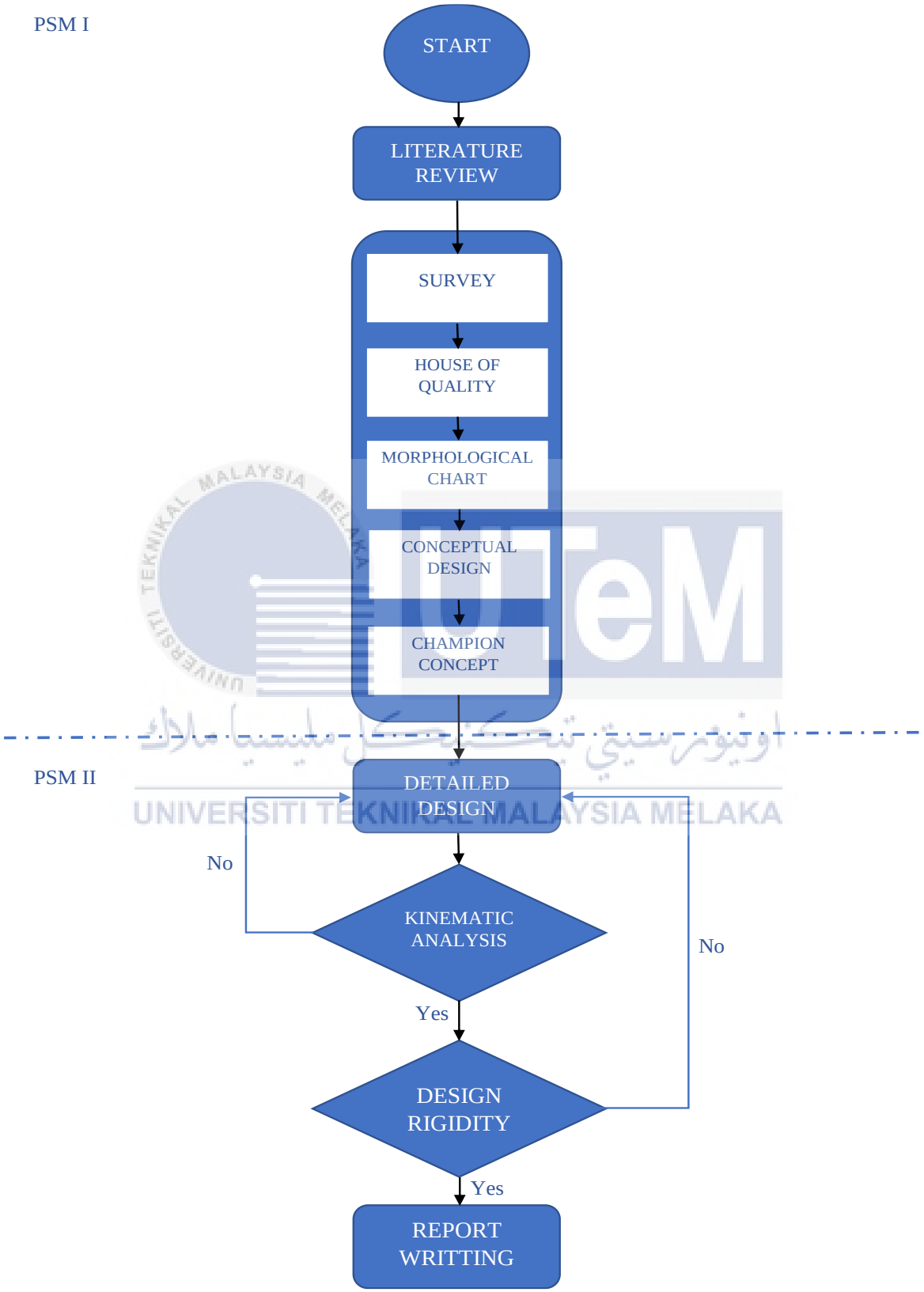


Figure 3.1: Flow chart of the methodology

3.3 Survey

Survey plays an important role in this project where it has been used as a tool to gather information from people regarding their requirements for a ROM knee brace. Survey for this project will be conducted in a government clinic. Few customer requirements for ROM knee brace have been identified and questionnaires which can analyse these customer requirements have been prepared at the beginning of this survey. Each question represents one customer requirement. Table 3.1 shows customer requirements which have been analysed in this survey with descriptions for better understandings.

Table 3.1: Customer requirements with detail descriptions

Customer Requirements	Descriptions
Resistance of tampering	Optional feature which prevent the user from readjusting the angle settings for their convenient without advice from doctor
Easily adjustable hinge	Users could easily adjust the angle of the hinge independently and don't need help from others
Smooth knob movement	The adjustable knob could move smoothly along flexion and extension direction and doesn't stuck during angle adjustment which can cause trouble to users
Safe for users	Materials used in the product could withstand force from users, prevent slippage during angle adjustment and doesn't cause any harm to user
Clear indication of angle	Users could recognise the angle quickly during angle adjustment

3.4 House of quality

This method has been used in this project to analyse the relationships between the customer requirement and the engineering characteristic which could satisfy it. Apart from that, the selected competitor's product will be compared with the customer requirements. The ratings obtained from the survey will be used in this method. At the beginning of this method, engineering characteristic of the product which could satisfy the customer requirements have been identified and listed down in Table 3.2.

Table 3.2: Customer requirements and engineering characteristic of ROM knee brace

NO	Customer Requirements	Engineering characteristics
1	Resistance of tampering	Lockable knob / Solenoid
2	Easily adjustable hinge	Angle adjustment from top ways
3	Smooth knob movement	Coil spring/ leaf spring / Solenoid
4	Safe for users	Strong materials, Knob with high grip surface and Top & Back cover
5	Clear indication of angle	Angle indicated with different colours

Table 3.2 shows the customer requirements for Rom knee brace's hinge and the engineering characteristics which could satisfy the requirements. For the first requirement in table 3.2 which is a resistance of tampering, the product should have a feature which can prevent the user from readjusting the angle setting for their convenient without doctor's advice. For example, the movable knob or solenoid with removable battery in the hinge of the knee brace might be lockable where the doctor could lock the knob to prevent readjustment of angle. Besides that, in order to satisfy the main requirement from the customer which is easily adjustable hinge, the design of the hinge might be able to adjust from top ways. If the hinge can be adjusted from the top ways, it would be convenient and

easy for the user to adjust the angle because they will only need minimum force for the adjustment. At the same time, top ways angle adjustment also could make the movement of the knob smooth. For the third requirement which is smooth knob movement, the design of the product might include coil spring, leaf spring or solenoid in the knob assembly to facilitate the knob movement. This is to make the movement of the knob to be smooth and provide convenient angle adjustment for users. This also will make the adjustment of the hinge to be easy. Moreover, to satisfy the fourth requirement which is safe for users, high strength materials like titanium and aluminium should be used in the design to prevent mechanical failure. Furthermore, the surface of the knob might be with high grip to prevent slippage when the user moves the knob during angle adjustment. In addition, the hinge might be covered with top and solenoid covers to prevent any damages to the users. Then again for the last requirement which is a clear indication of angle, the scale of angles on the hinge might be coded with different colours so that the user can recognise the angle quickly during angle adjustment.

Figure 3.2 shows the house of quality chart which will be used to analyse the relationship between the customer requirements and the engineering characteristic of the ROM knee brace hinge. The relationship is categorised into three levels, namely strong, moderate and weak. The score given for strong is 9, moderate is 3 and weak is 1. The total score for each engineering characteristic will be calculated. The value of the customer's importance represents the value of rating for each customer requirement which will be identified from the survey. In addition, the direction of improvement also will be given for each engineering characteristic based on the scores achieved. There are three types of the direction of improvement which maximise, target and minimize. Apart from that the correlations between the engineering characteristic also will be discussed. The correlations describe how the engineering characteristics relate to each other. Besides that, three

competitor’s products will be chosen and will be compared with the customer importance. The purpose of this comparison is to relate and evaluate the competitor’s product with the customer requirements and to find how their product satisfies the customer requirements.

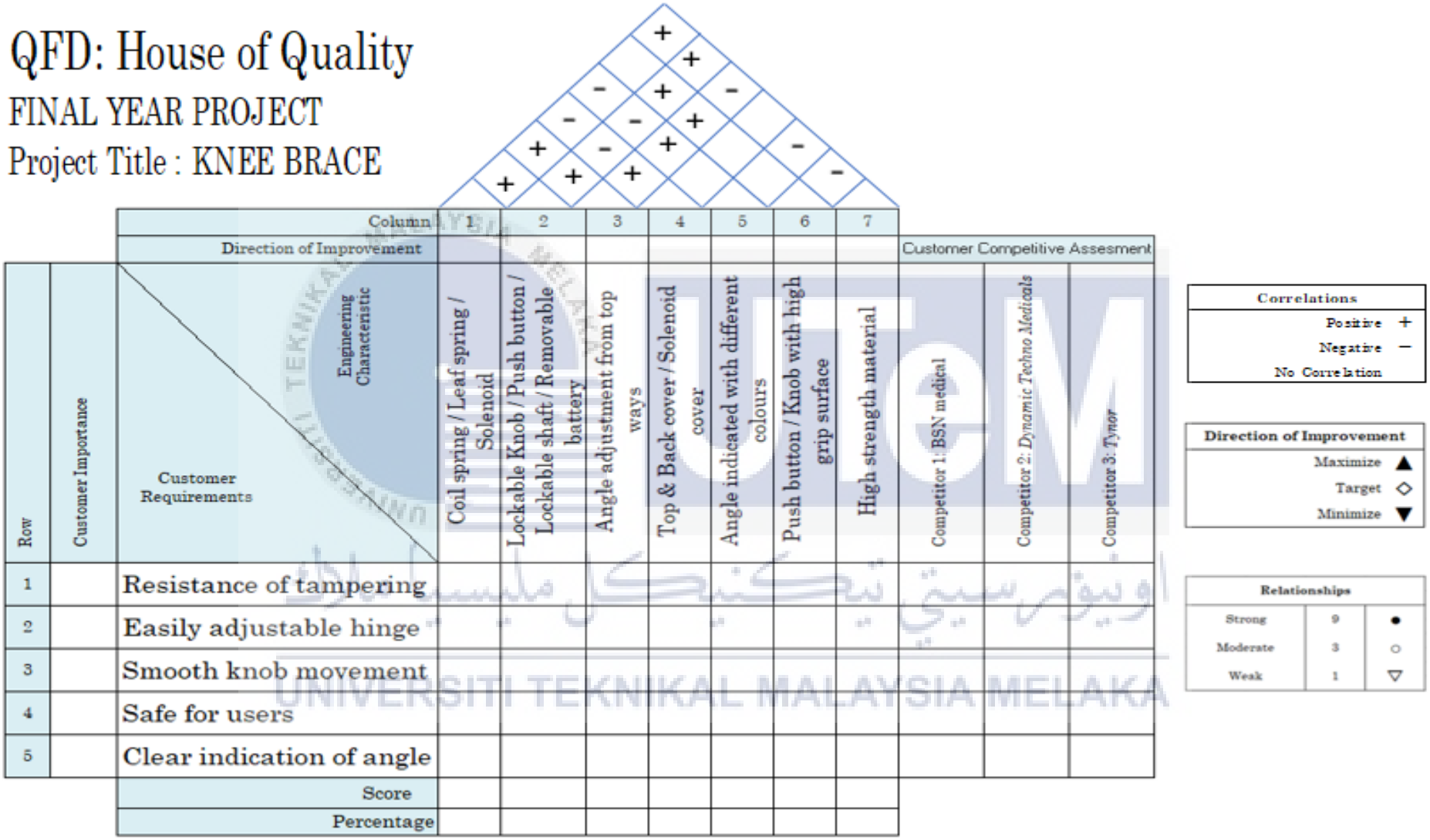


Figure 3.2: House of quality for ROM knee brace

3.4 Morphological chart

A morphological chart is a visual method to catch the necessary product functions and investigate elective means and mixes of accomplishing that functions. For every function of the product, there might be various solutions. The chart empowers these answers for being communicated and gives a structure to thinking about elective mixes. This can allow the early thought of the product design through the various combinations of solution that have not recently been recognised. The purpose of this method used in this project is to provide a structured approach to concept generation. Table 3.3 shows the morphological chart template which will be used in this project.

Table 3.3: Morphological chart for ROM knee brace's hinge

Morphological Chart Template						
Attributes/ Functions	**Solutions 1**	**Solutions 2**	**Solutions 3**	**Solutions 4**	**Solutions 5**	**Solutions 6**
EASILY ADJUSTABLE HINGE						
SMOOTH KNOB ADJUSTMENT						
HIGH STRENGTH MATERIALS FOR HINGE COVER & FRAME						
PROTECTION COVER						
HIGH GRIP PUSH BUTTON / KNOB SURFACE						
RESISTANCE OF TAMPERING						
CLEAR INDICATION OF ANGLE						
FASTENERS						

3.5 Conceptual design

Concept design is the initial sketch of the design. It shows us what problems the product will solve, how it will solve them, and what it will feel like as it is solving them. There are six conceptual designs will be discussed for this project based on a morphological chart. Table 3.4 shows the template which will be used to show the solutions for each function used in these concepts.

Table 3.4: The template of functions and solutions of concepts

CONCEPT / FUNCTIONS	CONCEPT 1	CONCEPT 2	CONCEPT 3	CONCEPT 4	CONCEPT 5	CONCEPT 6
EASILY ADJUSTABLE HINGE						
SMOOTH KNOB ADJUSTMENT						
HIGH STRENGTH MATERIALS FOR HINGE COVER & FRAME						
PROTECTION COVER						
HIGH GRIP PUSH BUTTON / KNOB SURFACE						
RESISTANCE OF TAMPERING						
CLEAR INDICATION OF ANGLE						
FASTENERS						

3.6 Champion concept

In this part, one of the concepts among the four conceptual designs which have been discussed previously will be selected as champion by using weighted criteria method. Table 3.5 shows the weighted criteria matrix table template which will be used to compare the concepts with the customer requirement. The prioritization criteria represent the customer requirements while the value in the second column represents the ratings that will be given for each of the customer requirement based on survey result. Scores will be given for each of the concept based on how it satisfies the customer requirements separately. The total scores will be calculated and will be stated in the last row. Based on the total scores, the

concept that has the highest score will become the champion concept and will be designed using CAD software.

Table 3.5: Weighted Criteria Matrix for concept selection template

Weighted Criteria Matrix																			
Prioritization Criteria	Value	Concept 1	Score		Concept 2	Score		Concept 3	Score		Concept 4	Score		Concept 5	Score		Concept 6	Score	
Resistance of tampering																			
Easily adjustable hinge																			
Smooth knob movement																			
Safe for users																			
Clear indication of angle																			
Totals score																			

CHAPTER 4

RESULT AND DISCUSSION

4.1 Introduction

This chapter will cover the result and discussion of the study on the new design of knee locking system for knee support health device. All the discussions and results related to this study are explained in the upcoming section.

4.2 Survey

The survey for this project has been conducted among patients at 'Klinik Kesihatan Puchong Batu 14' along with two doctors. The score gets for each question determine the rating for respective customer requirement from people. The responses for this survey have reached 20 and the results obtained from this survey have been converted into a bar chart. Figure 4.1 shows the results of the survey in the bar chart. The customer requirements analysed through this survey are an easily adjustable hinge, smooth knob movement, safe for users, the resistance of tampering and a clear indication of angle. The chart shows easily adjustable hinge gets the highest score (87) from customer followed by smooth knob movement (79), safe for users (70), the resistance of tampering (67) and a clear indication of angle (63). Concurrently, the scores received determines the rating or importance for each customer requirement.

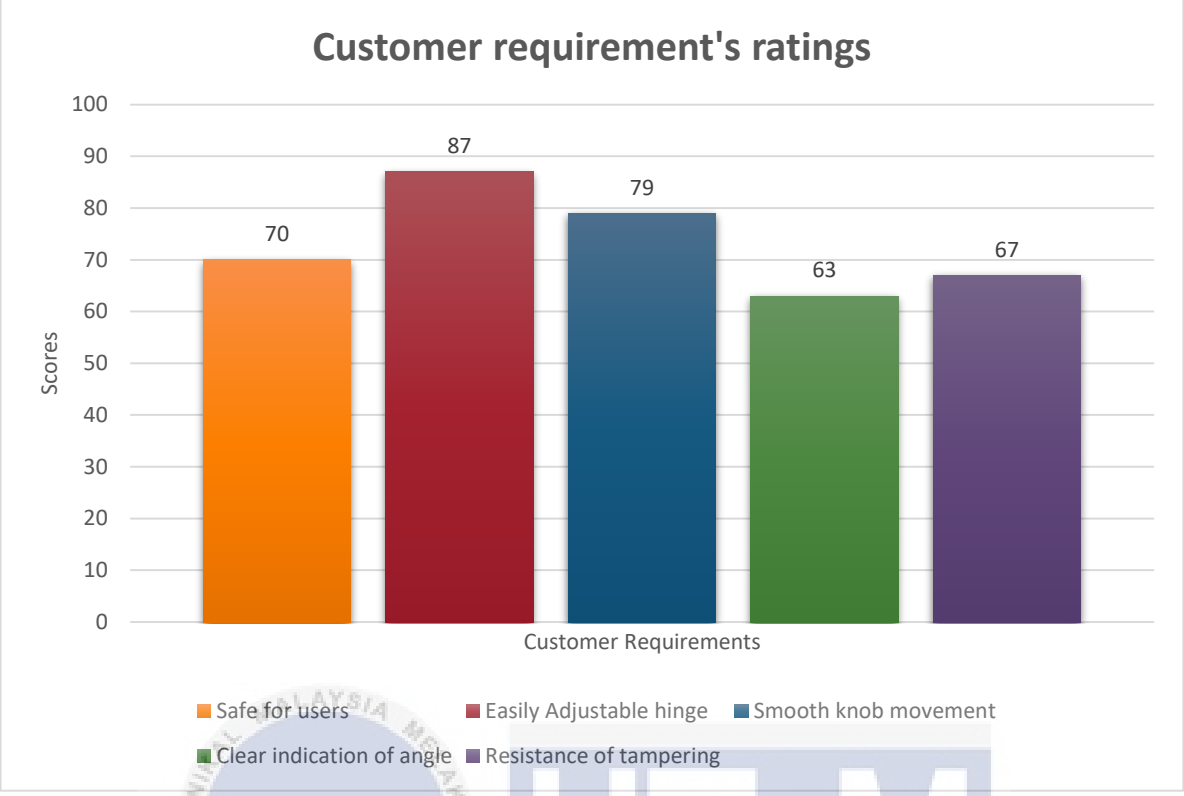


Figure 4.1: Bar chart shows the ratings for the customer requirements based on the survey result

Table 4.1: Customer requirements and their ratings

Customer Requirements	Ratings / Importance	Scores
Resistance of tampering	2	67
Easily adjustable hinge	5	87
Smooth knob movement	4	79
Safe for users	3	70
Clear indication of angle	1	63

Table 4.1 shows the ratings for each customer requirements. The ratings for each customer requirements have been given based on the score achieved from the survey as shown in figure 4.1. The ratings show how important is the customer requirements for customers. Based on this result, customers prefer a knee brace with easily adjustable hinge

the most followed by smooth knob movement and other requirements. It is important for the product to satisfy the customer requirements according to the ratings given.

4.3 House of quality

Figure 4.2 shows the house of quality chart which has been used to analyse the relationships between the customer requirements and the engineering characteristic of the ROM knee brace hinge. The relationships have been evaluated with three categories of scores which are strong - 9, moderate - 3 and weak - 1. The value of customer's importance represents the value of rating for each customer requirement identified from a survey where the first customer requirement has rating 2 followed by 5, 4, 3 and 1. The total score for each engineering characteristic is the total of multiplication of the score achieved by the engineering characteristic for each customer requirements with the respective customer importance. The percentage for each engineering characteristic also have been calculated based on the scores achieved. The score achieved by the first engineering characteristic is 108 followed by 45, 57, 33, 9, 60 and 27. This shows the first engineering characteristic which is Coil spring, Leaf spring and solenoid is very important because it has the highest score. In addition, the direction of improvement also given for each engineering characteristic. There are three types of the direction of improvement which maximise, target and minimise. The first, fourth, fifth and seventh engineering characteristic should be maximized while the sixth characteristic should be minimized based on the analysis. At the same time, the second and third engineering characteristic have reached the target. Apart from that the correlations between the engineering characteristic also have been discussed. Besides that, three competitor's products are chosen and compared with customer importance. The competitor products have been evaluated by giving the score for each customer requirements. The purpose of this comparison to find how their product satisfies

customer requirements. Figure 4.3, 4.4 and 4.5 show the products of competitors 1,2 and 3 respectively.

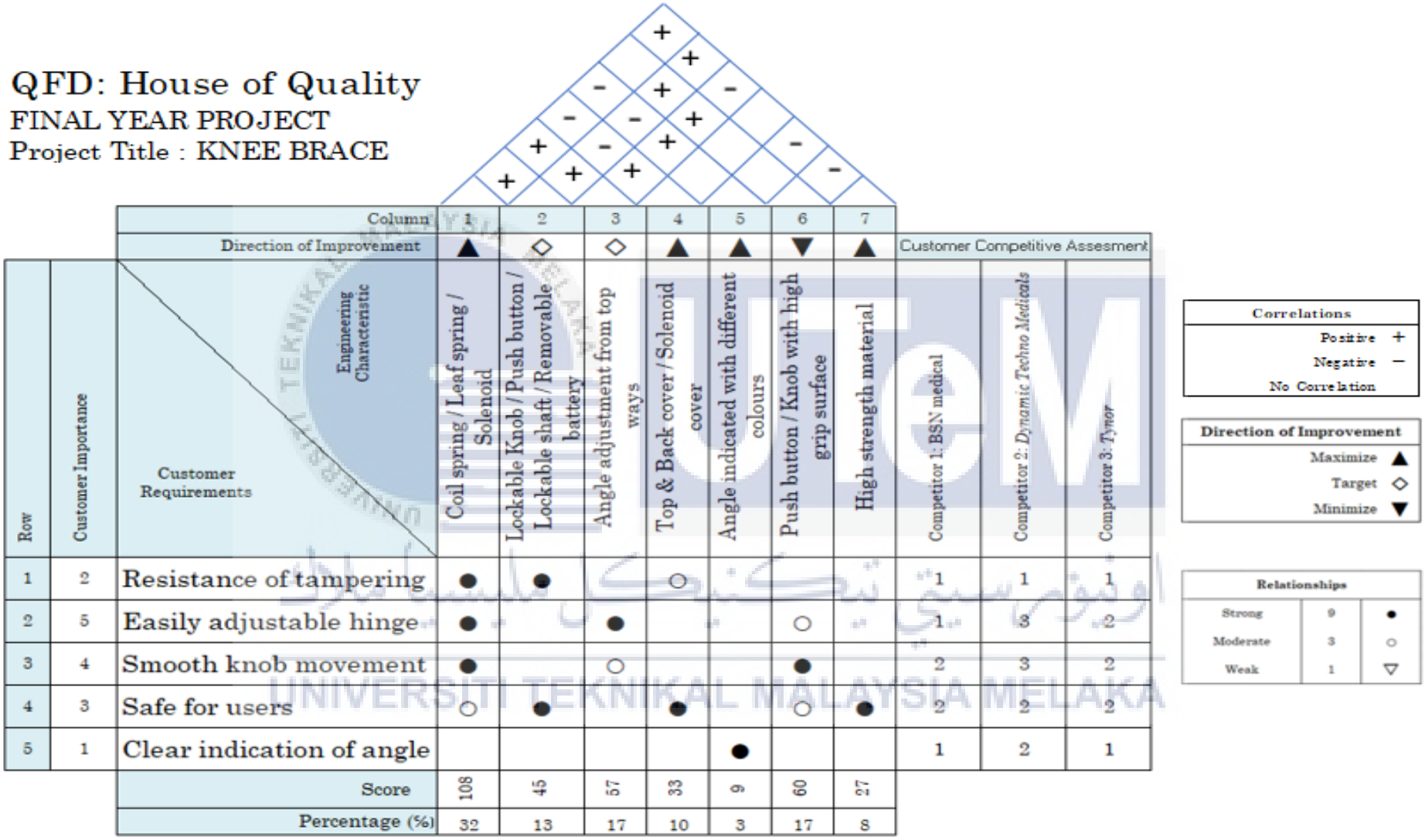


Figure 4.2: House of quality for ROM knee brace

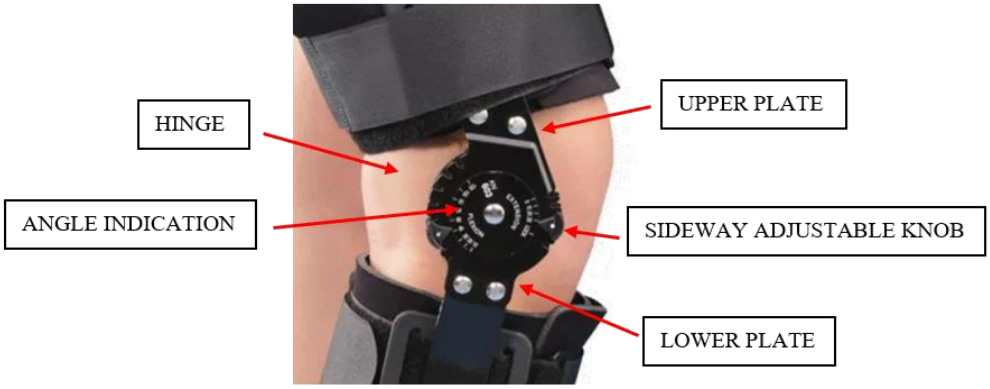


Figure 4.3: ROM knee brace's hinge of competitor 1 (http://tynorindia.com,4/12/2018)

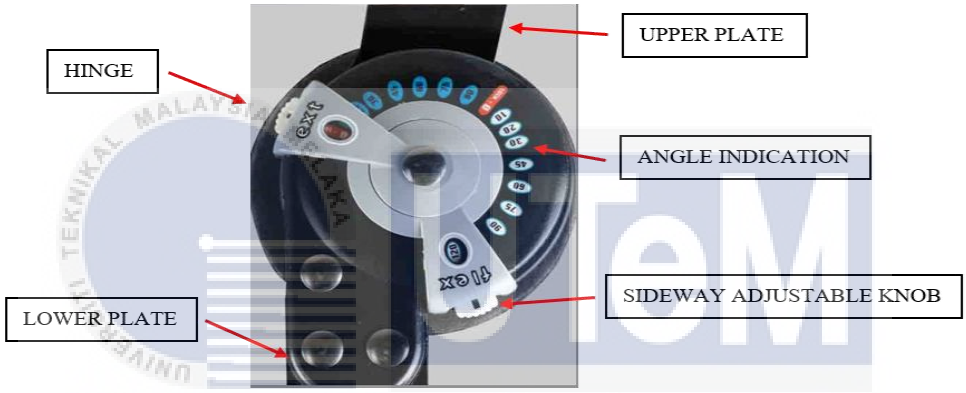


Figure 4.4: ROM knee brace's hinge of competitor 2 (www.dynamictechnomedicals.com,4/12/2018)

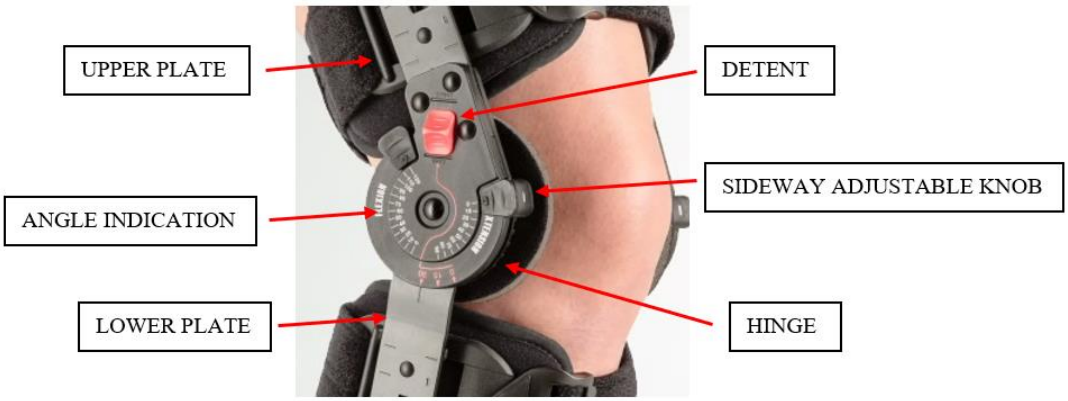


Figure 4.5: ROM knee brace's hinge of competitor 3 (www.bsnmedical.co.uk,4/12/2018)

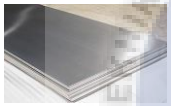
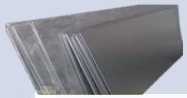
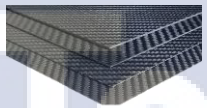
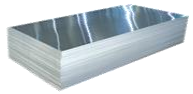
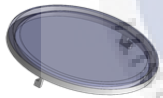
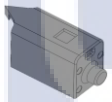
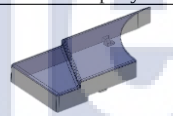
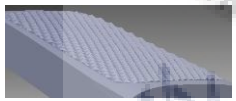
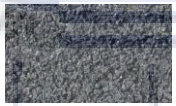
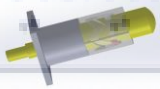
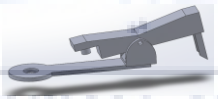
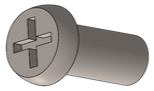
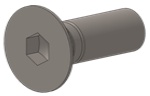
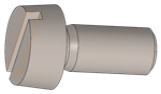
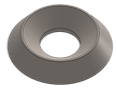
4.4 Morphological chart

Table 4.2 shows the morphological chart which includes the functions and the various possible solutions for the product. For the function easily adjustable hinge, there are two possible solutions which side way and top way angle adjustment. The hinge might be adjusted from the top way or side way to achieve that function. To achieve the second function which is smooth knob movement, the product's design might include coil spring, leaf spring, solenoid, conical spring or needle. The stiffness of these springs could facilitate the movement of the knob while solenoid can push and pull the locking shaft easily with the power from the battery which could also facilitate the knob movement too.

For the third function, the hinge components might be made of high strength materials which are stainless steel, titanium alloy, aluminium alloy, carbon fibre epoxy or polycarbonate filament. These materials have high strength properties where they can withstand the external force while polycarbonate filament can be used to 3d print where it also has high strength properties. Besides that, for the function protection cover, the hinge might have top, back, solenoid or battery cover. These covers can protect users from getting hurt. In addition, there are two solutions for the function high grip knob surface which are knurled surface and rubber surface. Both knurled and rubber surface could provide high grip.

Moreover, for the function resistance of tampering the hinge design might have either lockable knob, push button, spring-loaded button, removable battery or lockable shaft as a solution. If the hinge has solenoids which consist of solenoid shaft and removable battery, it will be the resistance of tampering when the battery is removed and the solenoid shaft in the locked position. Besides that, for the function clear indication of angle, the scale of angle on the hinge might be coded with different colours, shades of colours or grayscale colours. Lastly, for the last function, pivot screw, csk head screw, rivet, round head screw or csk washer can be used as fasteners.

Table 4.2: Morphological chart for ROM knee brace's hinge

Morphological Chart Template						
Attributes/ Functions	**Solutions 1**	**Solutions 2**	**Solutions 3**	**Solutions 4**	**Solutions 5**	**Solutions 6**
EASILY ADJUSTABLE HINGE	 Sideway adjustment	 Topway adjustment				
SMOOTH KNOB ADJUSTMENT	 Leaf spring	 Coil springs	 Conical spring	 Solenoid	 Needle	 Brake Cable
HIGH STRENGTH MATERIALS FOR HINGE COVER & FRAME	 AISI347 Stainless Steel	 Titanium	 Aluminium Alloy 6063 - T6	 Carbon fibre epoxy	 Polycarbonate filament	 Aluminium Alloy 1060
PROTECTION COVER	 Top cover	 Back cover	 Solenoid cover	 Battery cover		
HIGH GRIP PUSH BUTTON / KNOB SURFACE	 Knurled surface	 Rubber surface				
RESISTANCE OF TAMPERING	 Lockable knob	 Lockable push button	 Lockable spring-loaded button	 Removable Battery	 Solenoid shaft	
CLEAR INDICATION OF ANGLE	 Scale of angle coded with different colours	 Scale of angle coded with shades of colours	 Scale of angle coded with grayscale colours			
FASTENERS	 Pivot screw	 Rivet	 CSK Head Screw	 Round Head Screw	 Csk washer	

4.5 Conceptual design

Table 4.3 shows the functions and solutions of the concepts. The solutions for each function of the concepts are chosen based on the morphological chart. The sketch for each of the concepts is generated based on the selected solutions.

Table 4.3: The functions and solutions of concepts

CONCEPT / FUNCTIONS	CONCEPT 1	CONCEPT 2	CONCEPT 3	CONCEPT 4	CONCEPT 5	CONCEPT 6
EASILY ADJUSTABLE HINGE	SOLUTION 2	SOLUTION 2	SOLUTION 2	SOLUTION 2	SOLUTION 1	SOLUTION 1
SMOOTH KNOB ADJUSTMENT	SOLUTION 2	SOLUTION 2	SOLUTION 1	SOLUTION 1	SOLUTION 2,5,6	SOLUTION 4,5
HIGH STRENGTH MATERIALS FOR HINGE COVER & FRAME	SOLUTION 2	SOLUTION 4	SOLUTION 3	SOLUTION 1	SOLUTION 1,3,6	SOLUTION 1,3,4,5,6
PROTECTION COVER	SOLUTION 1	-	-	-	SOLUTION 1	SOLUTION 1,3,4
HIGH GRIP PUSH BUTTON / KNOB SURFACE	SOLUTION 1	-	SOLUTION 2	SOLUTION 2	SOLUTION 2	SOLUTION 2
RESISTANCE OF TAMPERING	SOLUTION 1	SOLUTION 2	-	-	-	SOLUTION 4,5
CLEAR INDICATION OF ANGLE	SOLUTION 1	SOLUTION 3	SOLUTION 3	SOLUTION 3	SOLUTION 2	SOLUTION 1
FASTENERS	SOLUTION 1	SOLUTION 1	SOLUTION 1	SOLUTION 1	SOLUTION 1,2	SOLUTION 1,2,3,4,5

4.5.1 Concept 1

Figure 4.6 shows the sketch of concept 1 which includes upper & lower frame made of titanium, knob assembly, movable support, spring-loaded detent and top cover. The ROM of this concept is from 0° to 140°. The knob assembly includes coil spring, locking pin and knob body. The knob assembly is attached to movable support where a pair of coil spring is fixed in between the knob body and the movable support. The coil springs will act bias against the knob body where it will continuously push the knob body upwards. There are round shaped apertures on the upper frame at every angle to receive the locking pin from knob assembly. During angle adjustment, the knob should be pressed to allow the movement of movable support. This is possible when the knob is being pressed, the locking pin will be released from the aperture. Then, when the locking pin is released from the aperture, the

movable support is now unlocked and able to move pivotally. In order to lock the movable support again, the knob should be released at a particular angle which will allow the locking pin to engage to the aperture at that particular angle. There is two movable support connected pivotally to the hinge to limit the ROM of the lower frame.

In addition, there is an additional feature in this concept where a sharp-edged and spring-loaded detent has been fixed on the lower frame facing the edge of the upper frame. The detent is movable along forward and reverses direction on top of the lower frame. At the same time, the upper frame which has toothed edge is ready to receive the sharp-edged detent to lock the lower frame at a certain angle. This feature usable when the user needs to lock the lower frame at a certain angle. Moreover, the materials of the upper & lower frame are titanium which can provide high strength to the hinge. The knob surface is knurled to provide high grip which can prevent slippage during angle adjustment. Apart from that, this hinge also covered with top cover to prevent any damages to the user. Lastly, the scale of angle on the hinge in this concept is coded with different colours to allow the user to recognise the angle quickly.

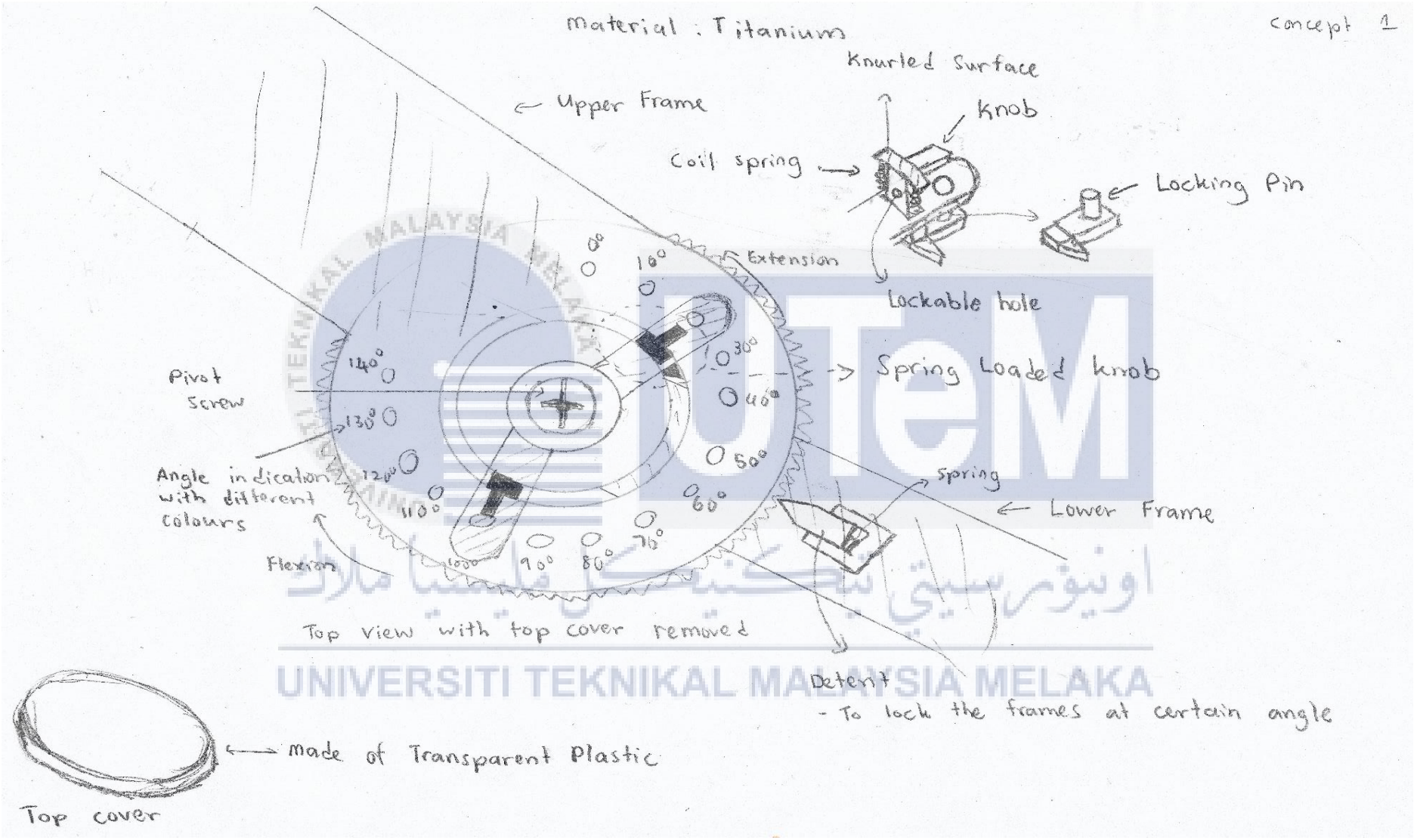


Figure 4.6: Sketch of concept 1

4.5.2 Concept 2

Figure 4.7 shows the sketch of concept 2. This concept includes movable support, push button, upper & lower frame made of carbon fibre epoxy and an indication of angle coded with grayscale colour. The range of angle in this hinge is from 0° to 160°. The push button assembly includes spring, ball and locking pin. This assembly is attached to the movable support where the movable support connected pivotally to the hinge by pivot screw. There are square shaped apertures on the upper frame at every angle to receive the locking pin from the push button. The push button with locking pin is designed to be press and release by the user. When the push button is being pressed, the locking pin in the push button will extend towards the selected aperture on the upper frame to allow the movable support locked at that position. Then the push button is capable to hold that pressed position until pressed again. During the angle adjustment, in order to unlock the movable support, the push button needs to be pressed again to unlock the locking pin. Then it could move freely along flexion and extension direction.

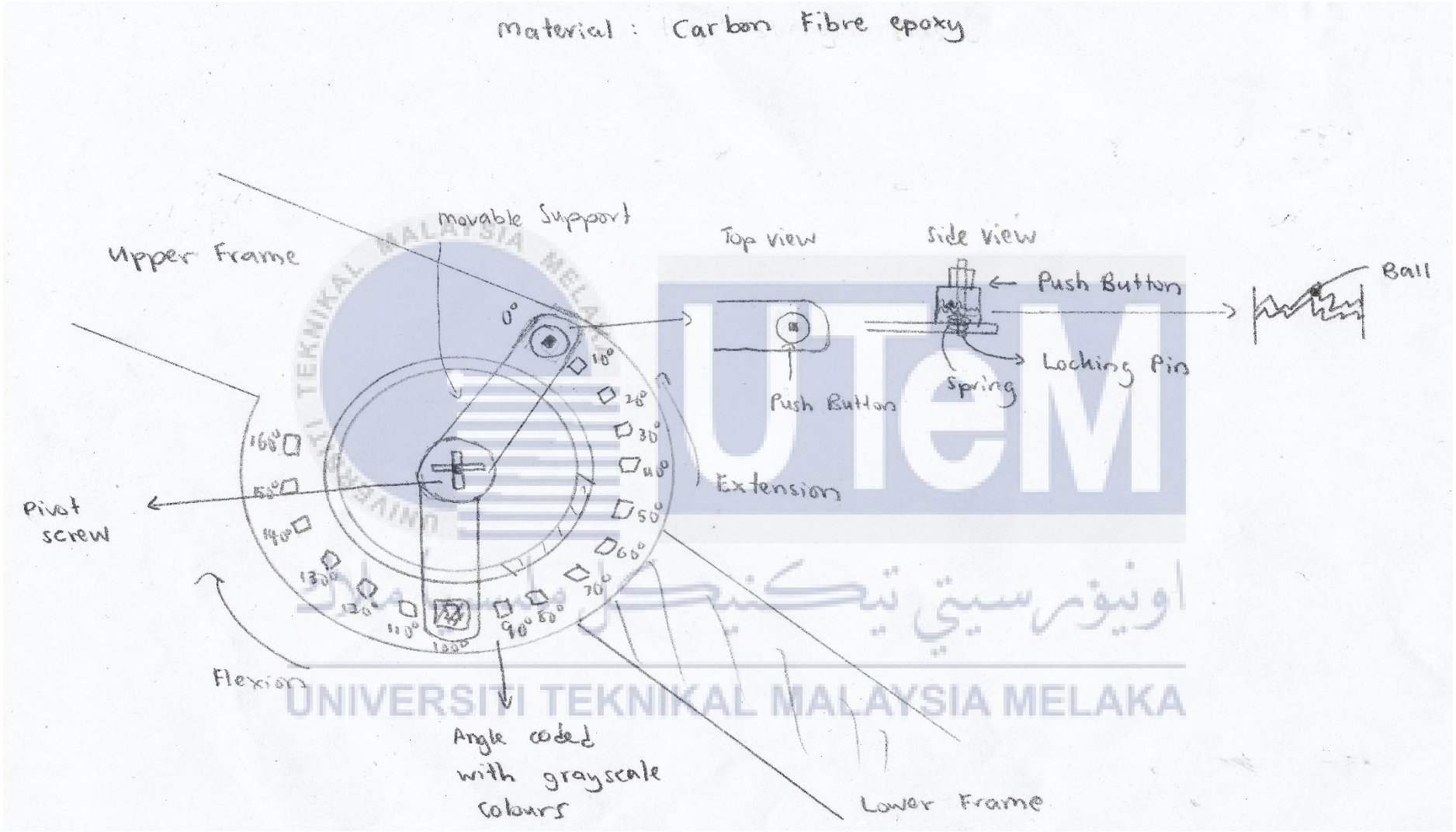


Figure 4.7: Sketch of concept 2

4.5.3 Concept 3

Figure 4.8 shows a sketch of concept 3 which includes leaf spring, locking pin, push button with rubber surface, an indication of angle coded with grayscale colours and upper & lower frame made of stainless steel. The leaf spring in this concept design could provide smooth movement during angle adjustment where it is connected pivotally to the hinge. The locking pin attached with the leaf spring to lock the leaf spring at the selected angle. The range of angle in this concept is from 0° to 150°. The purpose of the push button attached to the leaf spring is to be pressed during angle adjustment which will unlock the leaf spring and allow it to move pivotally. The surface of the push button might be made of rubber surface to prevent slippage during angle adjustment. The upper frame and lower frame are made of steel material to provide high strength. The purpose of using leaf spring in this concept is because of its flexibility where it can act as knob and moving support at the same time. The sketch in figure 4.8 shows the position of leaf spring during locked position and angle adjustment position. It shows the flexibility of the leaf spring could allow it to bend during locking and unlocking position of the locking pin.

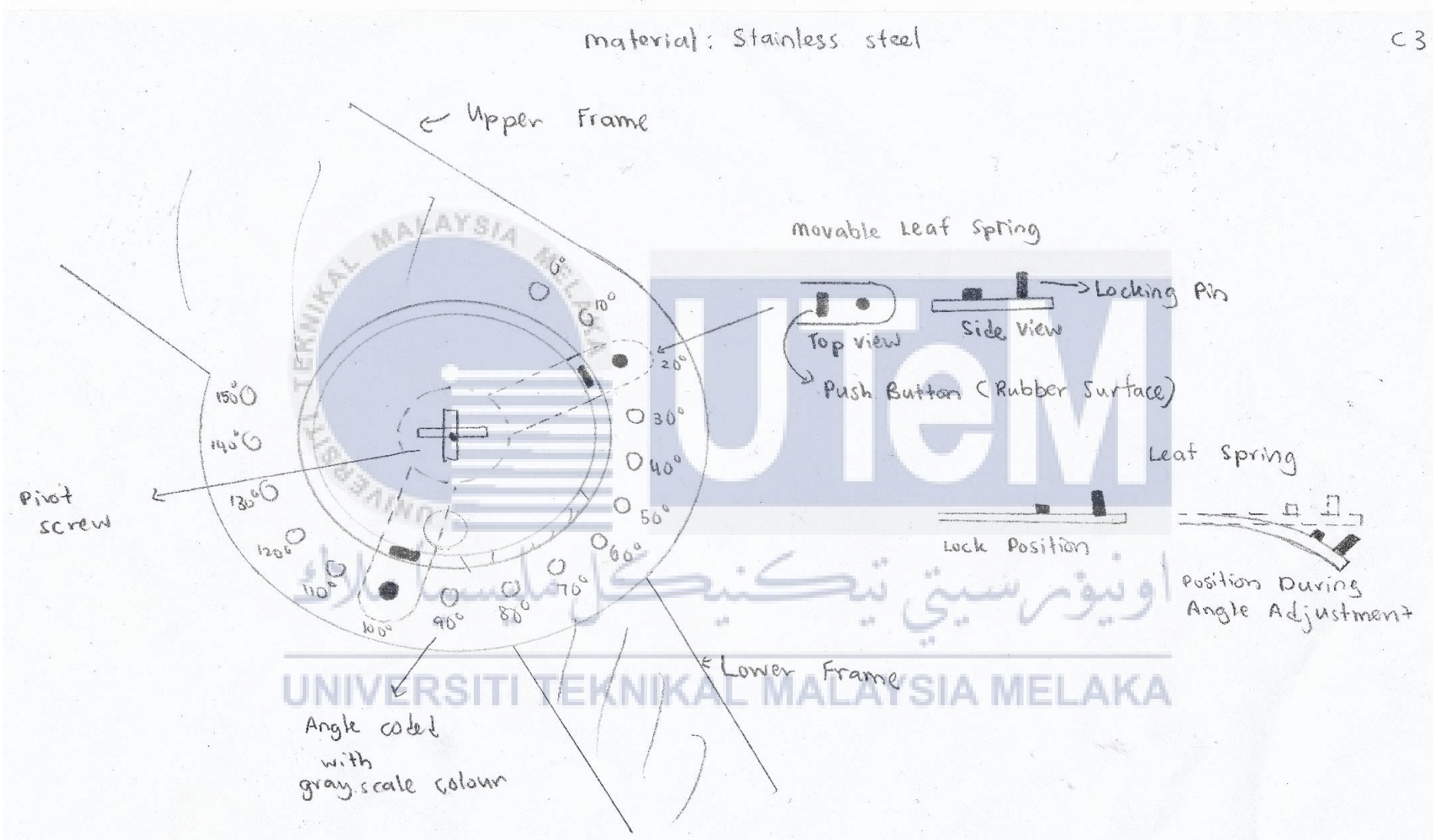


Figure 4.8: Sketch of concept 3

4.5.4 Concept 4

Figure 4.9 shows the sketch of concept 4. This concept is almost similar to the concept 3 but the upper and lower frame of this concept is made of aluminium alloy.

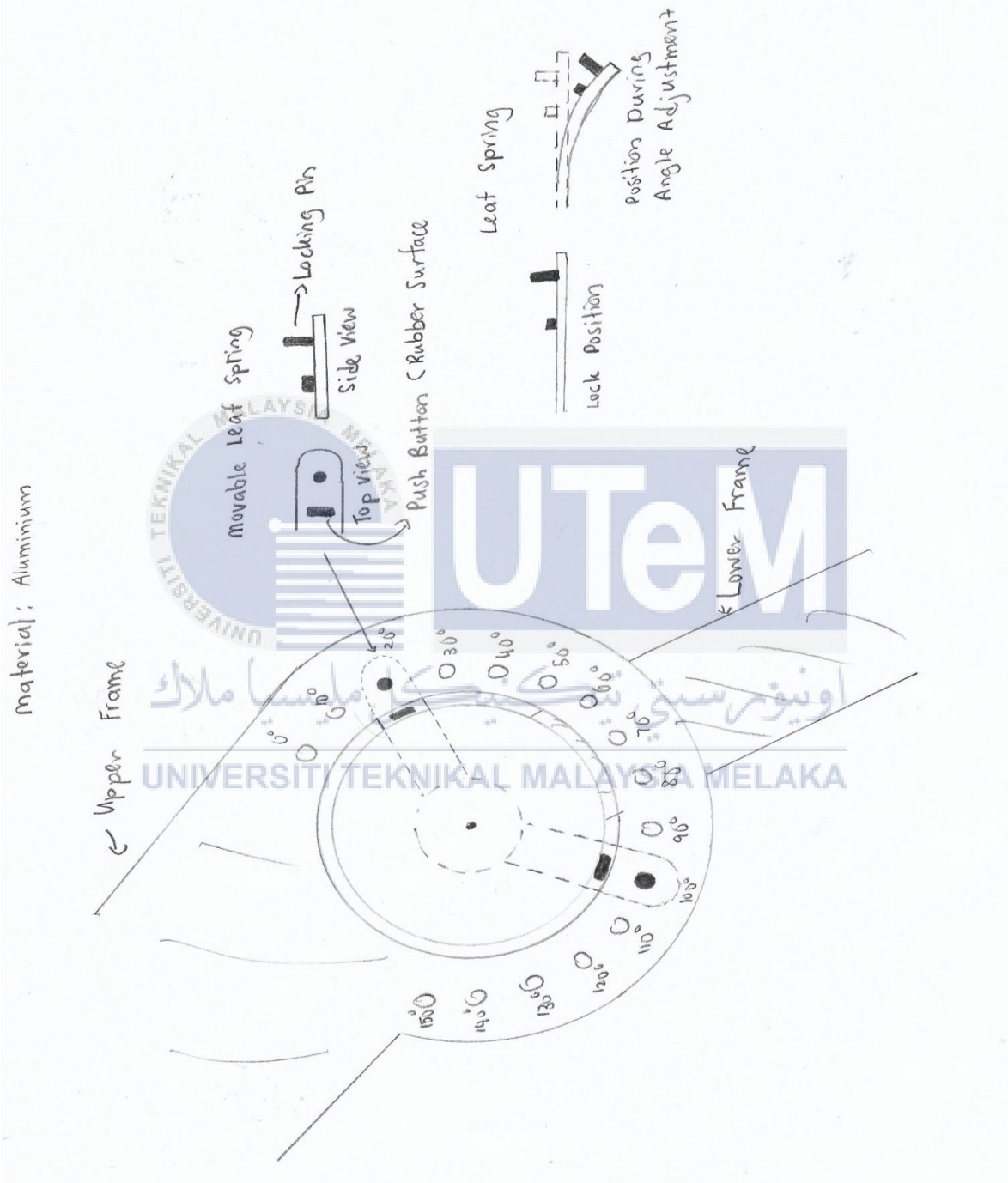


Figure 4.9: Sketch of concept 4

4.5.5 Concept 5

Figure 4.10 shows the sketch of concept 5 where the main components are a lower arm, upper arm, brake cable, locking mechanism and hinge base. The lower arm, hinge base, and needles are connected pivotally with pivot screw while the upper arm is connected with the hinge base with three rivets. The needles are playing an important role in adjusting the angle along flexion and extension direction. Each needle is connected with two brake cables on both right and left side. The needles can be adjusted along clockwise and anti-clockwise direction by adjusting the cables linearly at Flexion & Extension adjustor. In order to lock the needles at a certain angle, a locking mechanism which consists of a lock shaft and spring has been attached on the needles. In normal condition, the lock shaft will engage with the hinge base. A brake cable is attached on the end of the lock shaft to pull the lock shaft. In order to do angle adjustment, the brake cable attached on the lock shaft needs to be pulled to retract the lock shaft from the engagement with the hinge base. Once the lock shaft is retracted, the needles are free to move pivotally. When the cable is released, the spring in the locking mechanism will push the lock shaft towards engagement with the hinge base. Besides that, the angles are coded with shades of colours. This concept also includes a top cover to protect the user. The arms are made of aluminium alloy while the hinge base is made of stainless steel.

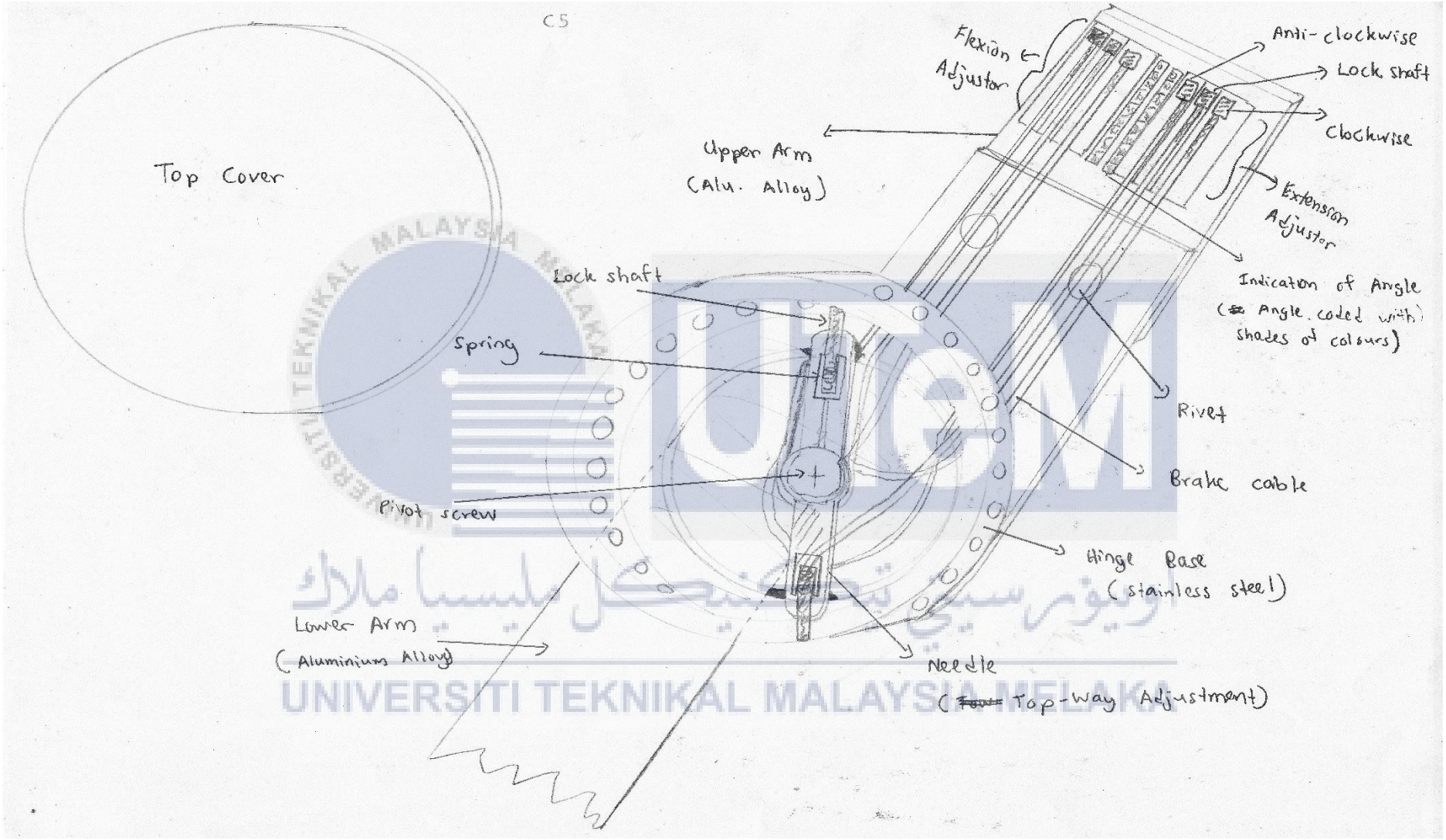


Figure 4.10: Sketch of concept 5

4.5.6 Concept 6

Figure 4.11 shows the sketch of concept 6. This concept includes upper & lower arm made of aluminium alloy 6063 –T6, hinge base made of carbon fibre epoxy, extension & flexion needles made of aluminium alloy 1060, solenoids, lithium battery, rivets, pivot screw, csk screw and round head screw. The hinge base, needles and lower arm are connected pivotally with pivot screw which will allow them to rotate pivotally. Aluminium alloy and carbon fibre epoxy have high tensile strength which could make the arm and hinge base to be stronger. There are two types of needles namely flexion and extension needle. Flexion needle will limit the rotation of the lower arm along flexion direction while extension needle will limit the rotation along extension direction. Two solenoids are attached on the needles which will be used to lock the needle at a certain angle. This is possible when there is no current supplied to the solenoid, the solenoid shaft will engage with the holes on the hinge base which will block the solenoid and the needles from rotation. In order to unlock the solenoid shaft from the engagement, the normally open switch connected with the solenoid needs to be pressed. Once the switch is pressed, the current will be supplied to the solenoid where it will retract the solenoid shaft from the engagement. When the shaft is retracted, then the needle is free to move. The current for the solenoids will be supplied by two lithium batteries which are connected in series. Besides that, there are few 3d printed covers made of polycarbonate material involves in this design to protect the users namely solenoid cover, top cover and battery cover. The angles are coded on the top cover surface and hinge base surface with different colours in order to allow the user to recognise the angle quickly during angle adjustment.

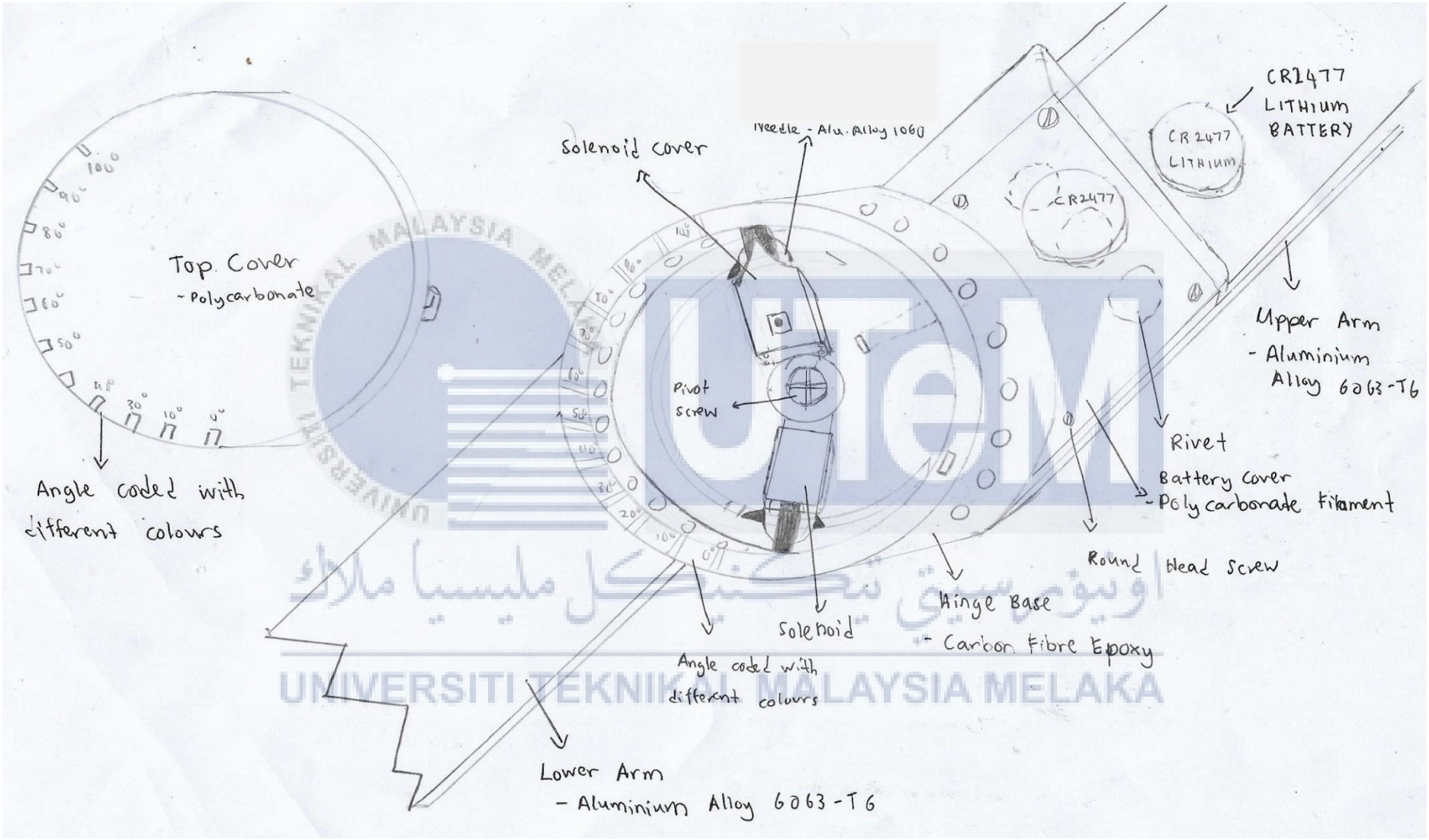


Figure 4.11: Sketch of concept 6

4.6 Champion concept

Table 4.4 shows weighted criteria matrix table which has been used to compare the concepts with the customer requirement. Scores have been given for each of the concept based on how it satisfies the customer requirements separately. The total scores have been calculated as stated in the last row. Based on the total scores, concept 6 has the highest score followed by concept 1, concept 5, concept 2, concept 3 and concept 4. Concurrently, concept 1 has become a champion concept and will be designed using CAD software.

In detail of concept 6, solution 2 which is top way adjustment is chosen for the function easily adjustable hinge. This solution is better than the solution 1 which is sideways adjustment because the top way adjustable hinge is more convenient and easily adjustable by the user compared to side way adjustable hinge. Secondly, for the function, smooth knob movement, solution 4 & 5 which are solenoid and needle have been chosen. This is because solenoid could make the locking and unlocking process easier for the user by just pressing the switch. The solenoid is fixed on the needle to limit the lower arm against the rotation. Moreover, for the function of high strength materials, solution 1,3,4,5 and 6 namely stainless steel, aluminium alloy, carbon fibre epoxy, polycarbonate and aluminium alloy respectively have been chosen. These materials have high tensile strength which will make the components stronger and withstand external loads. Besides that, in this concept knurled surface has been used for the function high grip solenoid cover surface because the knurled surface can provide high grip than rubber surface. In addition, for the function resistance of tampering, removable battery and solenoid shaft have been used because it can easily lock the needle at the certain angle compared to the lockable knob, lockable push button and spring-loaded button. In order to make the hinge resistance of tampering, the battery needs to be removed. Once the battery is removed, the solenoid shaft will stay in the engaged position with the hinge which will prevent the readjustment of the needle by the user. Apart

from that, in this concept for the function clear indication of angle, the scale of angle coded on the top cover and hinge base with different colour because the user could quickly recognise scale with different colour rather than same colour. Lastly, for the function safe for users, solution 1,2 and 3 have been chosen to protect the user.

Table 4.4: Weighted Criteria Matrix for concept selection

Weighted Criteria Matrix																			
Prioritization Criteria	Value	Concept 1	Score		Concept 2	Score		Concept 3	Score		Concept 4	Score		Concept 5	Score		Concept 6	Score	
Resistance of tampering	*2*	*Lockable knob & Top cover*	*4*	*8*	*N/A*	*0*	*0*	*N/A*	*0*	*0*	*N/A*	*0*	*0*	*N/A*	*0*	*0*	*Solenoid / Removable Battery / Top cover*	*5*	*10*
Easily adjustable hinge	*5*	*Topway angle adjusment*	*4*	*20*	*Topway angle adjusment*	*4*	*20*	*Topway angle adjusment*	*4*	*20*	*Topway angle adjusment*	*4*	*20*	*Topway angle adjusment*	*4*	*20*	*Topway angle adjusment*	*4*	*20*
Smooth knob movement	*4*	*Spring-loaded knob*	*4*	*16*	*Spring-Loaded Push button*	*4*	*16*	*Leaf spring*	*4*	*16*	*Leaf spring*	*4*	*16*	*Needle, Brake Cable*	*4*	*16*	*Needle, Solenoid*	*5*	*20*
Safe for users	*3*	*Hinge made of titanium material & Top cover*	*4*	*12*	*HInge made of carbon fibre epoxy*	*4*	*12*	*HInge made of Stainless steel*	*3*	*9*	*Hinge made of Aluminium alloy*	*2*	*6*	*Component made of Stainless steel & alu. Alloy , Top cover*	*5*	*15*	*Component made of Alu. Alloy & carbon fibre, Top cover, Solenoid cover*	*5*	*15*
Clear indication of angle	*1*	*Indication of angle with different colours*	*4*	*4*	*Indication of angle with grayscale colours*	*1*	*1*	*Indication of angle with grayscale colours*	*1*	*1*	*Indication of angle with grayscale colours*	*1*	*1*	*Indication of angle with Shades of colours*	*3*	*3*	*Indication of angle with different colours*	*5*	*5*
Totals score			60			49			46			43			54			70	

4.7 Details of design

4.7.1 Computer aided design

Figure 4.12, 4.13, 4.14 and 4.15 shows the rendered picture of solenoid hinge knee brace design which was designed by using solid works 2016 software based on concept 6 which have been discussed in the previous chapter. The concept of this design is totally new invention in the market where it uses the solenoid to limit the motion of the lower arm against the upper arm along flexion and extension direction. This type of solenoid based locking system in knee brace's hinge is totally different from the existing product in the market.

Figure 4.12: Front view of Solenoid Hinge knee brace design

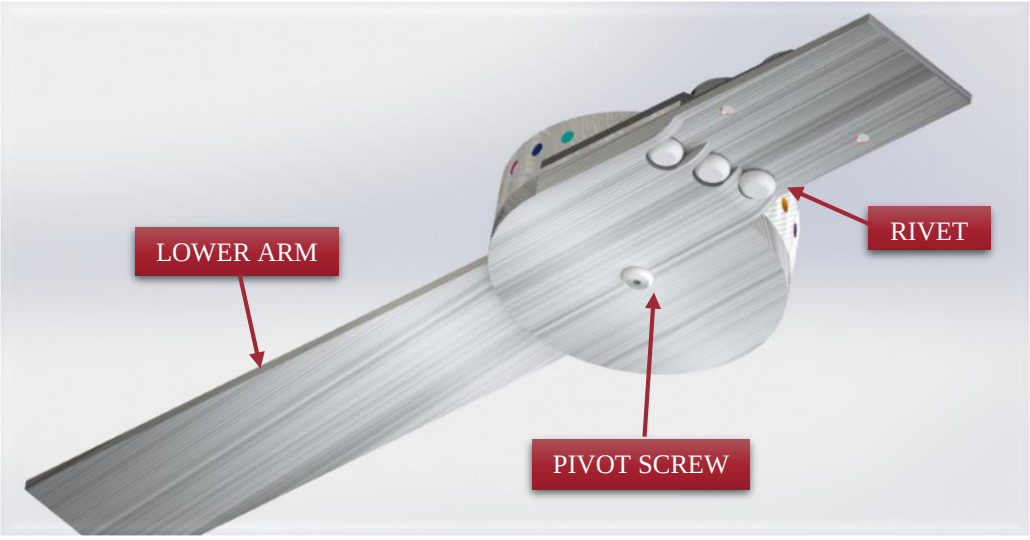


Figure 4.13: Rear view of Solenoid Hinge knee brace design

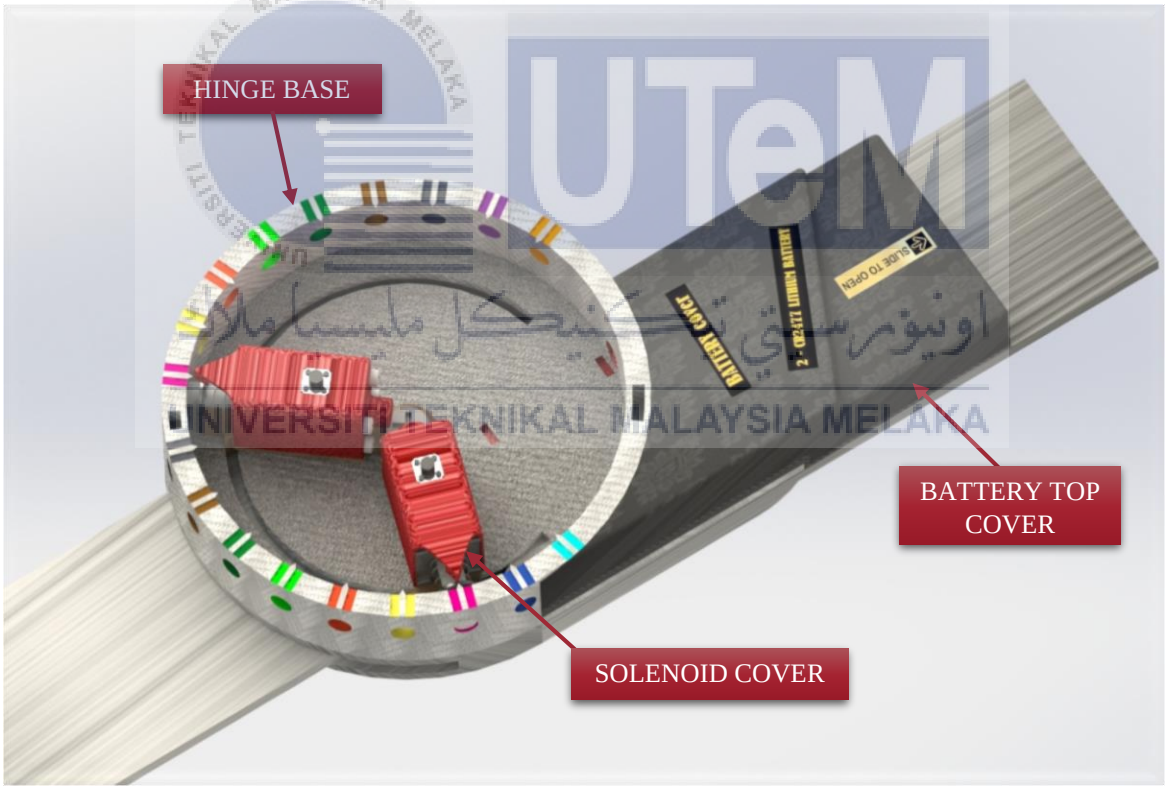


Figure 4.14: Solenoid Hinge knee brace design without top cover

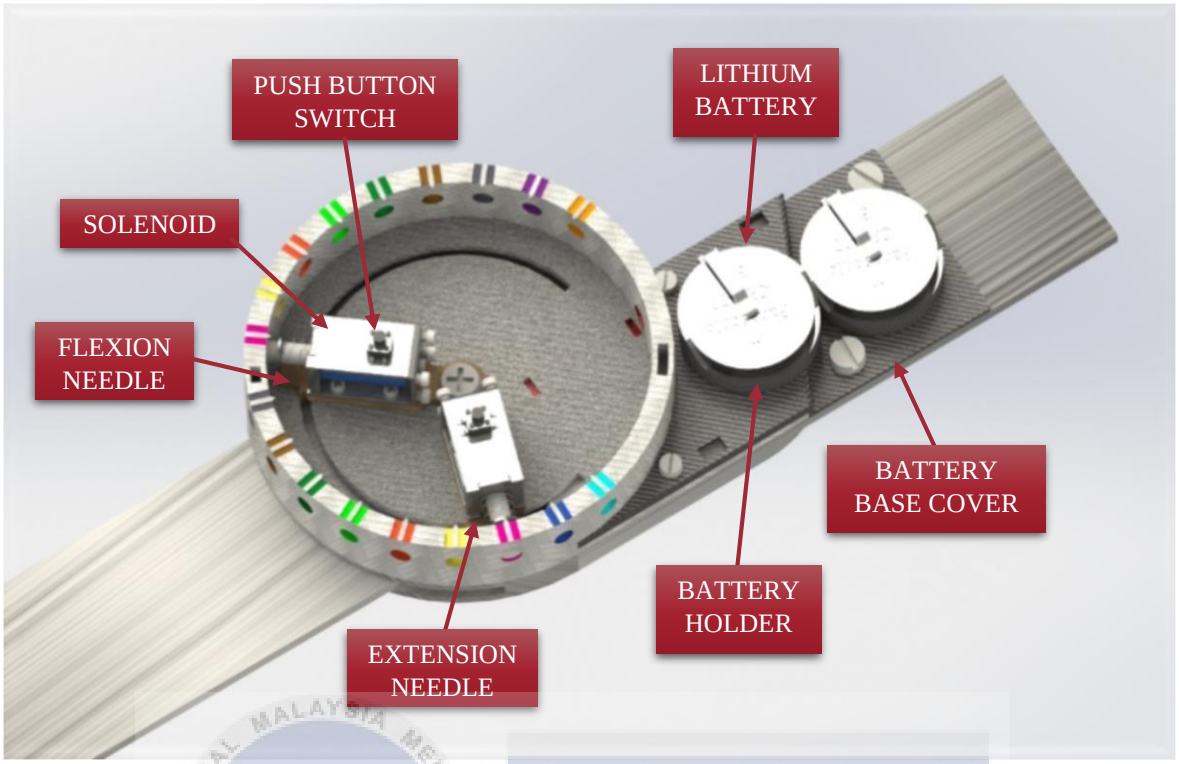


Figure 4.15: Solenoid Hinge knee brace design without top and solenoid cover

4.7.2 Design specification

4.7.2.1 Bill of materials

Figure 4.16 shows the exploded view of solenoid hinge knee brace with the components labelled according to their part number for better understanding. Table 4.5 and Table 4.6 shows the bill of materials of the fabrication parts and standard parts respectively which involves in solenoid hinge knee brace design. Solenoid hinge knee brace design is made up of 22 different components. The table includes five levels of details of each component namely part name, part name, material, supplier and quantity. For example, the part number for the upper arm is 1 which is made up of aluminium alloy 6063-T6. The part name for this part is Upper arm alu alloy. This is a customised part with the quantity one. The second example is part number 17. This part's name is M2.5 x 5 Round head screw which is made up of Stainless steel (Ferritic). The quantity of this part required in this design

assembly is 2. The supplier for this part is BENE INOX @ traceparts.com where this part can be purchased from them.

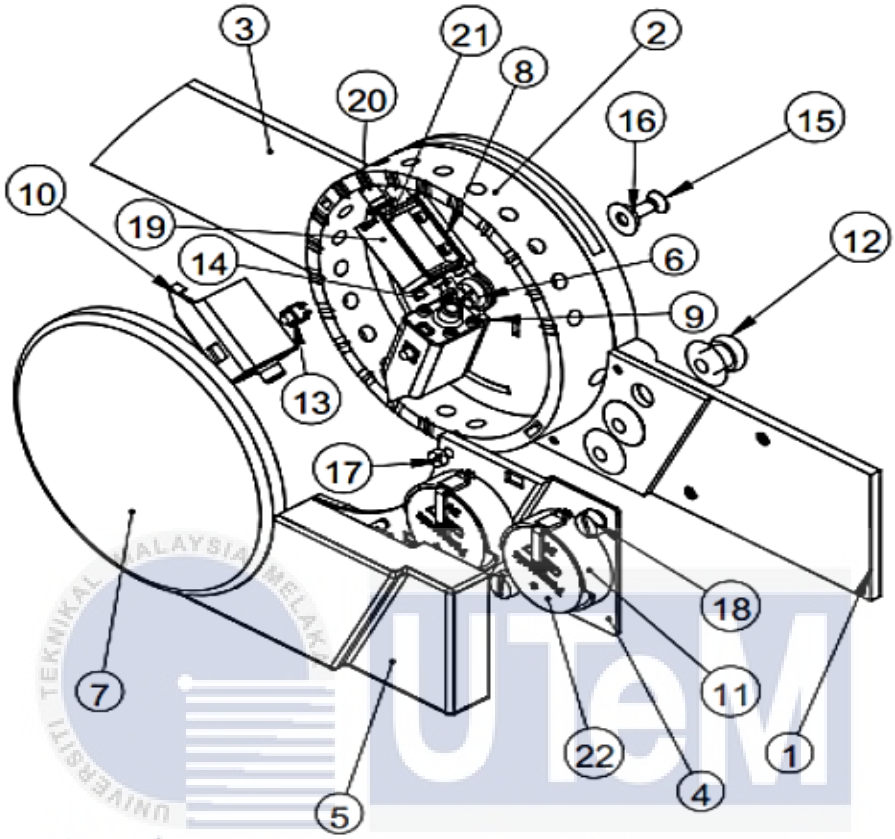


Figure 4.16: Exploded view of solenoid hinge knee brace

Table 4.5: Bill of materials of fabrication parts

PART NUMBER	PART NAME	MATERIAL	SUPLLIER	QTY
1	UPPER ARM ALU ALLOY	ALUMINIUM ALLOY 6063-T6	CUSTOMIZE	1
2	HINGE BASE	CARBON FIBRE/EPOXY COMPOSITE SHEET	CUSTOMIZE	1
3	LOWER ARM	ALUMINIUM ALLOY 6063-T6	CUSTOMIZE	1
4	BATTERY BASE COVER	CARBON FIBRE/EPOXY COMPOSITE SHEET	CUSTOMIZE	1
5	BATTERY TOP COVER	POLYCARBONATE FILAMENT	CUSTOMIZE (3D PRINT)	1
6	PIVOT SCREW	AISI 347 ANNEALED STAINLESS STEEL (SS)	CUSTOMIZE	1
7	TOP COVER	POLYCARBONATE FILAMENT	CUSTOMIZE (3D PRINT)	1
8	FLEXION NEEDLE	ALUMINIUM ALLOY 1060	CUSTOMIZE	1
9	EXTENSION NEEDLE	ALUMINIUM ALLOY 1060	CUSTOMIZE	1
10	SOLENOID COVER	POLYCARBONATE FILAMENT	CUSTOMIZE (3D PRINT)	2
20	LOCK SHAFT	AISI 347 ANNEALED STAINLESS	CUSTOMIZE	2

Table 4.6: Bill of materials of standard parts

PART NUMBER	PART NAME	MATERIAL	SUPLLIER	QTY
11	BATTERY HOLDER	PBT, NICKEL-PLATED STAINLESS SPRING STEEL	BATTERYHOLDERS.COM	2
12	RIVET	STEEL SWCH	FUKUI BYORA CO., LTD.	3
13	PUSH BUTTON SWITCH	N/A	E-SWITCH	2
14	M2 X 4 ROUND HEAD SCREW	STAINLESS STEEL (FERRITIC)	BENE INOX @ traceparts.com	18
15	M3 X 0.5 CSK HEAD SCREW	STAINLESS STEEL (FERRITIC)	UNI @ traceparts.com	1
16	M3 WASHER	STAINLESS STEEL (FERRITIC)	BENE INOX @ traceparts.com	1
17	M2.5 X 5 ROUND HEAD SCREW	STAINLESS STEEL (FERRITIC)	BENE INOX @ traceparts.com	2
18	M4 X 4 ROUND HEAD SCREW	STAINLESS STEEL (FERRITIC)	BENE INOX @ traceparts.com	2
19	SOLENOID	AISI 347 ANNEALED STAINLESS	www.adafruit.com/product/2776	2
21	SOLENOID SHAFT	AISI 347 ANNEALED STAINLESS	www.adafruit.com/product/2776	2
22	CR2477 LITHIUM BATTERY	LITHIUM MANGANESE DIOXIDE	PANASONIC	2

4.7.2.2 Angle indicator

Figure 4.17 shows the top cover while figure 4.18 shows the hinge base of solenoid hinge knee brace. The flexion and extension angles have been clearly indicated on the front surface of the top cover and hinge base with different colours for each angle. This type of angle indication will guide the user to easily recognise the angle during angle adjustment even though they couldn't see the angle clearly from a particular distance where they can easily recognise the angle by referring to the respective colour. Besides that, the user also will be able to have a look at the angle indication on the top cover closely by removing and bringing the top cover itself closer. The range of angle for flexion is from 0 degrees to 120 degrees while for the extension is from -30 degrees to 90 degrees. Table 4.7 shows the details of the colours assigned to each angle. For example, the angle 0 degrees in flexion and extension direction is indicated with pink colour while 15 degrees with yellow colour.

Figure 4.17: Top cover of Solenoid Hinge knee brace

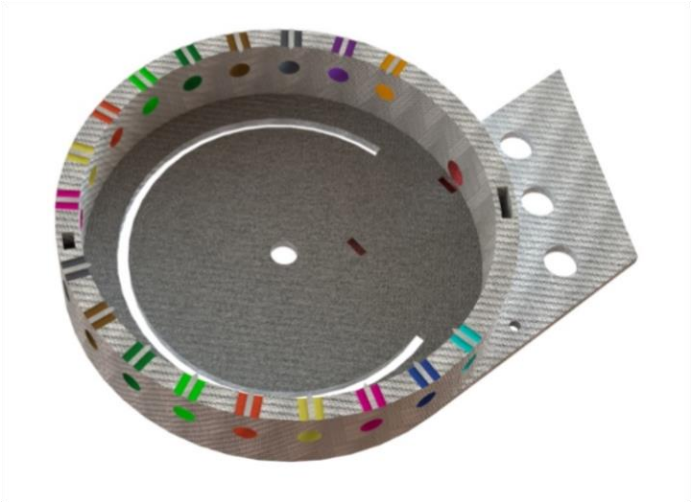


Figure 4.18: Hinge base of Solenoid Hinge knee brace

Table 4.7: Angle indicator colours

FLEXION	ANGLE INDICATION COLOURS	EXTENSION	ANGLE INDICATION COLOURS
0˚	PINK	-30˚	BLUE GREEN
15˚	YELLOW	-15˚	BLUE
30˚	RED	0˚	PINK
45˚	LIGHT GREEN	15˚	YELLOW
60˚	DARK GREEN	30˚	RED
75˚	BROWN	45˚	LIGHT GREEN
90˚	GREY	60˚	DARK GREEN
105˚	PURPLE	75˚	BROWN
120˚	ORANGE	90˚	GREY

4.7.2.3 Solenoid

The solenoid has been used in this design as a locking mechanism. The type of solenoid used in this design is a 5v push and pull solenoid – 19 as shown in figure 4.19. It is a ready stock part where it can be purchased from the supplier. Table 4.8 shows the specification of the 5v solenoid. It requires a minimum of 5 voltages and 1.1 ampere supply in order to generate a magnetic field which will push the solenoid shaft away from the coil. The total weight of the solenoid is 12.6g. There are four holes – 19.1 on the surface of the solenoid body which will be used to fix the solenoid with the flexion and extension needles

by screws. It might be also weld with the needles to provide strong support. Besides that, there are another four holes on the side surface of the solenoid body which will be used to attach the solenoid cover with the solenoid by screws.

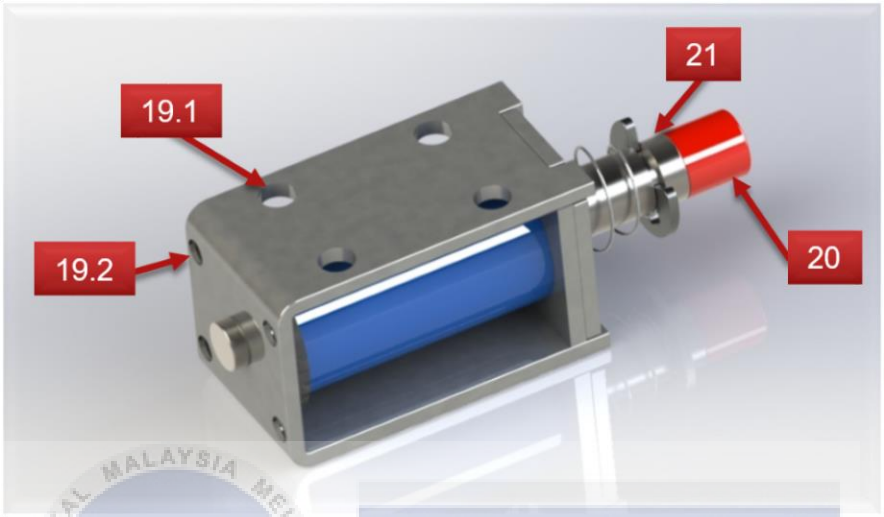


Figure 4.19: 5V Solenoid

Table 4.8: Technical specifications of 5v solenoid

Rated Voltage	5V
Current (at DC 5V)	1.1A
Weight	12.6g

Figure 4.20 shows the virtual diagram of the magnetic field created in the solenoid once the current is supplied to the copper coil which will make it energized. This magnetic field will push the solenoid shaft – 21 and the lock shaft – 20 in a linear direction. This results in the lock shaft engage with one of the angle holes of the hinge base.

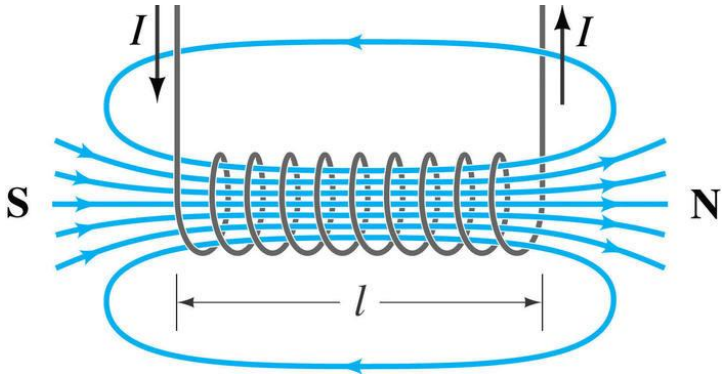


Figure 4.20: Magnetic field of solenoid (www.miniphysics.com, 17/4/2019)

4.7.2.4 Technical specifications of battery

A set of CR 2477 Lithium battery has been used in this design to supply power to the solenoid. Table 4.9 shows the specifications of the CR 2477 Lithium battery. The nominal voltage of this battery is 3V while nominal capacity is 1000 mAh where with this specification this battery would be able to provide enough power to operate the 5v solenoid. Besides that, the weight of this battery is 10.5g while the operating temperature is -30°C - +60°C. Figure 4.21 shows the image of CR 2477 Lithium battery.

Table 4.9: Technical specifications of CR 2477 lithium battery

Nominal Capacity:	1000 mAh
Nominal Voltage:	3V
Weight:	10.5g
Operating Temperature:	-30°C - +60°C

Figure 4.21: CR 2477 Lithium battery (www.amazon.com, 17/4/2019)

4.7.2.5 Hinge base

Figure 4.22 shows the hinge base of solenoid hinge knee brace. It is the core of the assembly. This part involves few geometric features which have been listed in table 4.10 The angle hole – 2.1 with a diameter of 4mm is playing an important role in this part where it will receive the solenoid's lock shaft – 20 during the angle locking process. By receiving the lock shaft, the hinge base – 2 will engage with the solenoid and the needles. This engagement will restrict the lower arm to rotate across the flexion or extension needle which will limit the ROM of the mechanism. The wires between the batteries and the solenoids will be fixed through the undercut wire path – 2.3 which prevent any disturbance during angle adjustment. Apart from that, rivet holes – 2.5 and pivot screw hole – 2.6 are provided to allow the rivet and pivot screw fix through it. The arc slot – 2.2 also provided at the centre of the hinge base which allows the extended part of the flexion and extension needle to move along it. The gap of the arc slot is good enough to allow the needles to move freely during angle adjustment. Moreover, in order to receive the locking tooth -7.1 & 7.2 of the top cover, a set of a top cover mounting slot – 2.4 is provided on the top surface of the hinge base.

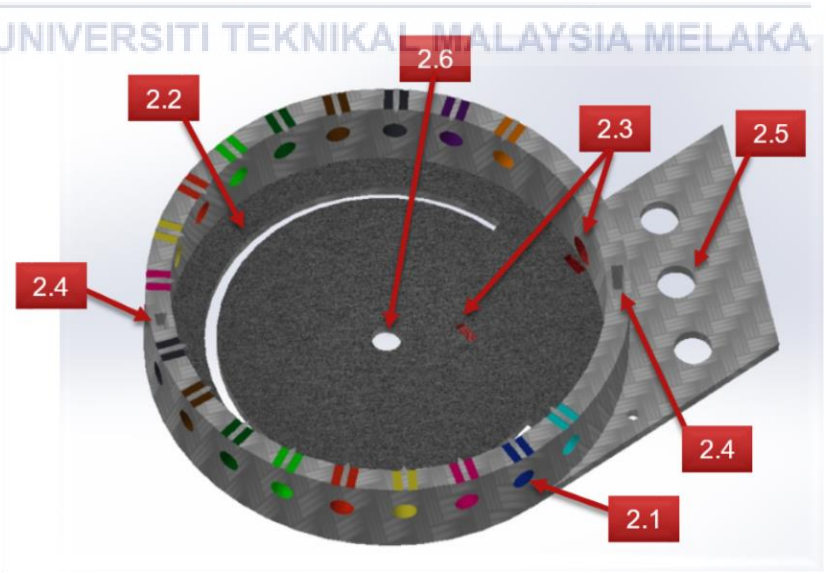


Figure 4.22: Hinge base of solenoid hinge knee brace

Table 4.10: Geometric features of hinge base

GEOMETRIC FEATURE NUMBER	GEOMETRIC FEATURE NAME
2.1	Angle hole
2.2	Arc slot
2.3	Wire path
2.4	Top cover mounting slot
2.5	Rivet holes
2.6	Pivot screw hole

4.7.2.6 Top cover

Figure 4.23 shows the front and back view of solenoid hinge new brace's top cover. This component act as a protection cover in this design where it will cover the hinge's angle adjustment mechanisms which will protect the users from any injuries during the angle adjustment process. Besides that, this cover will also make the knee brace to be a resistance of tampering where it will prevent the users from readjusting the ROM of the knee brace for their comfortableness. The design of this top cover involves locking tooth – 7.1 & 7.2 which is engageable with the mounting slot – 2.4 on the hinge base in order to lock the cover with the hinge base. Apart from that, the flexion and extension angles have been printed on the front surface of the top cover which will provide ease of angle adjustment for the wearer. The material selected for this component is polycarbonate. This material is chosen because it is light in weight and the strength is good enough for the functionality of this part. The suitable manufacturing process for this component is Fused deposition modelling 3d printing process.

Figure 4.23: Front & Back view of top cover

4.7.2.7 Upper arm

The rear view of solenoid hinge knee brace's upper arm is shown in figure 4.24 while table 4.11 shows the list of upper arm's geometric features. This part is made of Aluminium alloy 6063-T6 material and this is one of the major components. The hinge base - 2, lower arm - 3, flexion needle - 8 and extension needle - 9 in the knee brace will be assembled pivotally with the upper arm by a pivot screw – 6 through the pivot screw aperture – 1.2. Besides that, the hinge base will be fixed with the upper arm by rivets - 12 through the rivet aperture – 1.3 which will restrict the movement of hinge base against the upper arm. These connections will allow the lower arm, flexion needle and extension needle to move pivotally against the hinge base and upper arm along the flexion and extension direction for a certain range. Furthermore, there are two tapped holes – 1.4 which will be used to fasten the battery base cover with the upper arm. In addition, there is a lower arm slot in this component which will allow the lower arm to move in between in this slot. The width of this slot is designed to be bigger than the thickness of the lower arm in order to facilitate the movement of the lower arm.

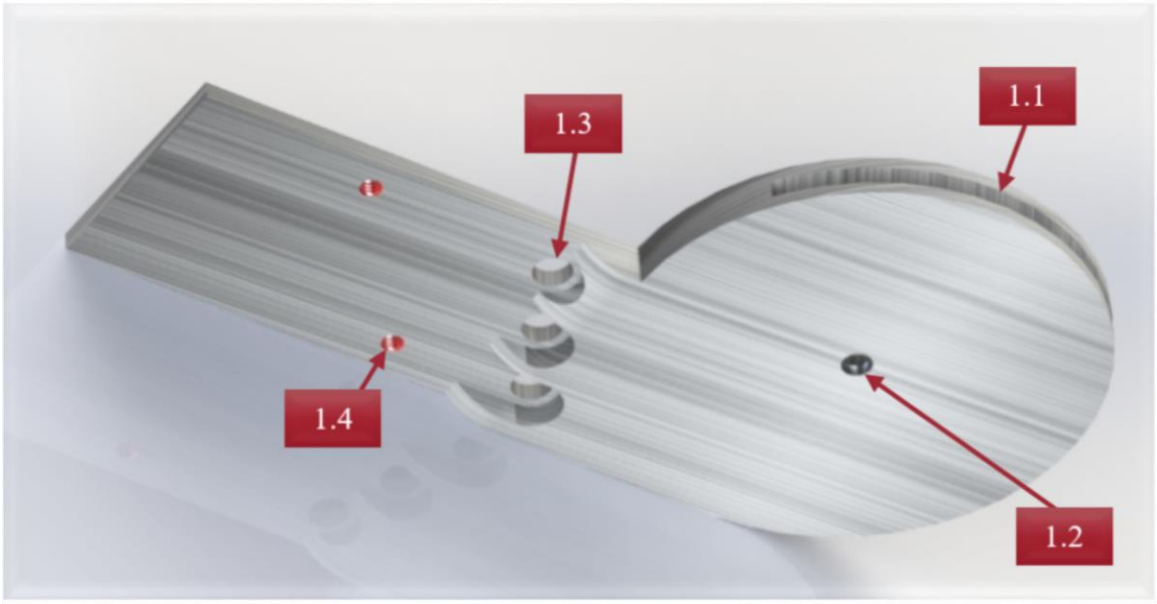


Figure 4.24: Upper arm of solenoid hinge knee brace

Table 4.11: Geometric features of upper arm

GEOMETRIC FEATURE NUMBER	GEOMETRIC FEATURE NAME
1.1	Lower arm slot
1.2	Pivot screw aperture
1.3	Rivet aperture
1.4	Battery base cover tapped hole

4.7.2.8 Lower arm

Figure 4.25 shows the lower arm of the solenoid hinge knee brace. This part plays an important role in limiting the ROM of the knee. Like upper arm, this part is also made of Aluminium alloy 6063-T6. The design of this component includes pivot screw aperture – 3.1 and stop faces – 3.2. This part will be assembled pivotally in between the lower arm slot – 1.1 of the arm by a pivot screw through the pivot screw aperture. This connection results in the lower arm to move freely along flexion and extension direction against the upper arm. Besides that, there are stop faces – 3.2 in this part where it will limit the ROM of the flexion and extension needles by engaging with the limit face – 8.1 of the needles.

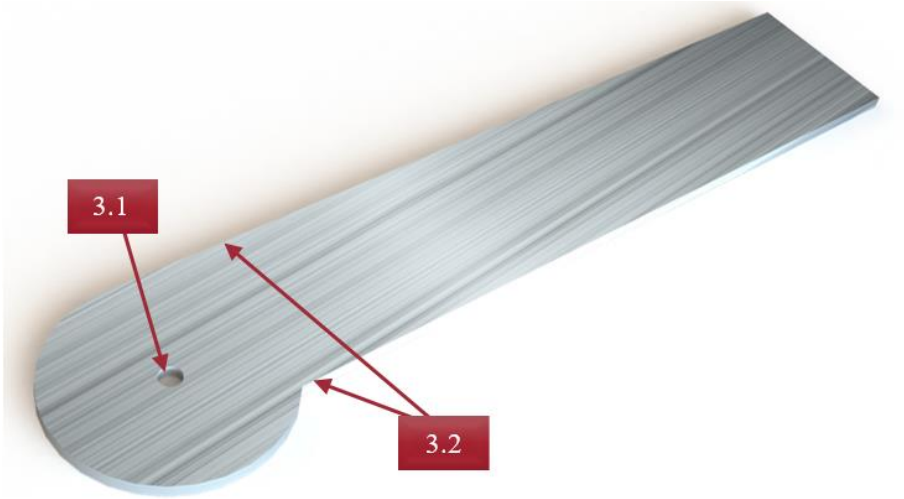


Figure 4.25: Lower arm of solenoid hinge knee brace

4.7.2.9 Solenoid cover

A set of a customised cover made of polycarbonate material has been designed and assembled in this knee brace's design to cover the solenoid. Figure 4.26 shows the rendered picture of the solenoid cover design. This component can be 3d printed by using a polycarbonate filament. The design of the solenoid cover is made up of few geometric features which have been listed in the table 4.12. The angle pointer – 10.1 in this design is to point the angle parameters located at the hinge base during the angle adjustment process. During the angle adjustment process, when the flexion and extension needles are being adjusted along flexion and extension direction, the angle pointer of the solenoid cover will be continuously pointing the angle indicated on the hinge base. Once the angle pointer of the solenoid pointed the desired angle on the hinge base, the push button switch will be released. Concurrently, the solenoid shaft will engage with one of the angle hole – 2.1 at the particular angle of the hinge base which will lock the needles at that angle. This shows, the angle pointer facilitates the angle adjustment process and makes the process easy. Moreover, there is a wire path – 10.3 in this design for a wiring purpose. It will allow the wires connecting the push button switch to pass through it. Besides that, the switch aperture – 10.2 is designed

on the top surface of the solenoid cover to place the push button switch. During the angle adjustment process, the solenoid shaft will move along forward and reverse direction. This shaft movement might hurt the user. So, an extended surface namely solenoid shaft path – 10.5 is designed to cover the shaft movement which will protect the user from any injuries. Lastly, there are four mounting apertures – 10.4 have been designed at the side surface of this cover to fasten the cover with the solenoid.

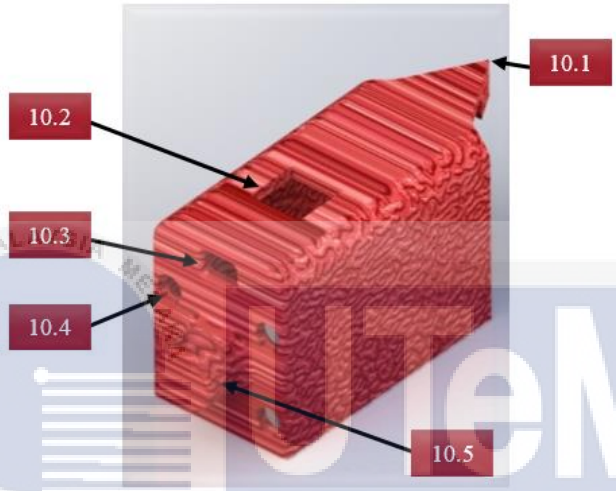


Figure 4.26: Solenoid cover

Table 4.12: Geometric features of solenoid cover

GEOMETRIC FEATURE NUMBER	GEOMETRIC FEATURE NAME
10.1	Angle pointer
10.2	Switch aperture
10.3	Wire path
10.4	Mounting aperture
10.5	Solenoid shaft path

4.7.2.10 Flexion needle

Figure 4.27 shows the flexion needle – 8 of the solenoid hinge knee brace. This part performs an important role in limiting the ROM of the knee brace. The design of this component is made up of limit face – 8.1, tapped hole – 8.2 and pivot screw aperture – 8.3

as shown in table 4.13 This component is assembled in the knee brace assembly together with the hinge base by a pivot screw through the pivot screw aperture – 8.3 similar to the upper and lower connection. This will allow the needle to move pivotally on top of the hinge base's bottom surface. The material of this component is Aluminium alloy 1060. The limit face – 8.1 will be used to stop or limit the movement of the lower arm along flexion direction. This is possible when the limit face engaged with the stop face – 3.2 of the lower arm. In addition, there are four tapped hole – 8.2 provided on the surface of the needle which will be used to fasten the solenoid on top of the needle.

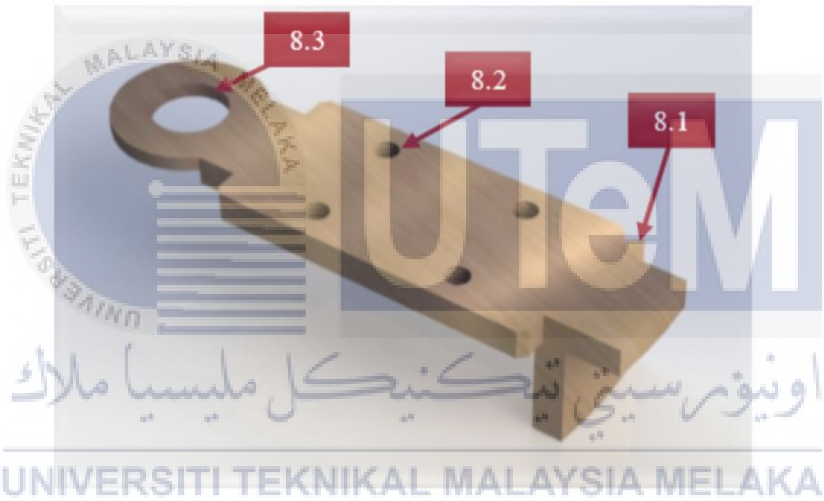


Figure 4.27: Flexion needle

Table 4.13: Geometric features of flexion needle

GEOMETRIC FEATURE NUMBER	GEOMETRIC FEATURE NAME
8.1	Limit face
8.2	Tapped hole
8.3	Pivot screw aperture

4.7.2.11 Extension needle

Figure 4.28 shows the extension needle of the solenoid hinge knee brace. Table 4.14 shows the geometric features of this component. This component is the mirror side of the flexion needle where it is designed to move and limit the ROM along extension direction which is the opposite direction of flexion. The connection of this needle with the knee brace assembly is similar to the flexion needle. Like the flexion needle, this part also made of Aluminium alloy 1060.

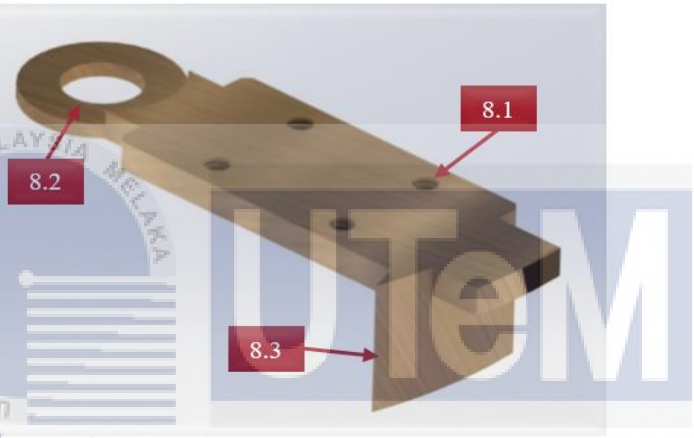


Figure 4.28: Extension needle

Table 4.14: Geometric features of flexion needle

GEOMETRIC FEATURE NUMBER	GEOMETRIC FEATURE NAME
8.1	Limit face
8.2	Tapped hole
8.3	Pivot screw aperture

4.7.2.12 Battery base cover

The rendered picture of the battery base cover's design is shown in figure 4.29. This cover is one of the components of the battery cartridge. This cover provides a platform to place the lithium battery. It is made of carbon fibre composite sheet which is strong and light in weight. It will be fixed on the hinge base and the upper arm by screws through the aperture

holes – 4.2 and 4.3. There are two mounting apertures – 4.1 provided on the base cover to receive the top cover tooth – 5.1 which will lock the top cover on the base cover.

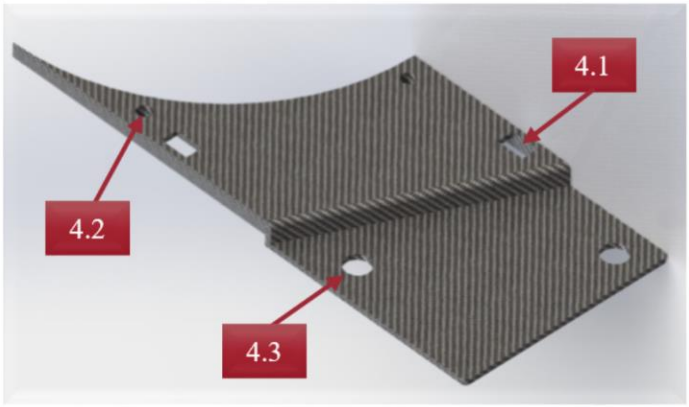


Figure 4.29: Battery base cover

4.7.2.13 Battery top cover

A battery top cover is designed to protect the batteries in the knee brace assembly as shown in figure 4.30. This cover is made of polycarbonate material where it can be printed by a 3 printer. The design of this component includes a set of the mounting tooth – 5.1. This mounting tooth will be used to lock the top cover on the battery base cover. This can be done by inserting the mounting tooth – 5.1 in the mounting apertures – 4.1 and then slide it in forwarding direction. The slide direction to open the cover is indicated on the surface of the top cover. This action will lock the battery top cover on top of the battery base cover.

Figure 4.30: Battery top cover

4.7.3 Circuit diagram

Figure 4.31 shows the circuit diagram of the solenoid module. It involves 5 voltage solenoid -19, CR 2477 lithium battery - 22 and normally open push button switch -13. Two CR 2477 Lithium battery has been used to supply power to the 5v solenoids. The required voltage and current for the solenoid is 5 V and 1.1 Ampere respectively while the lithium battery is capable to produce only 3 V and 1 Ampere. So, two CR 2477 Lithium batteries have been connected in series to increase the voltage supply into 6v in order to match the voltage requirement of the solenoid. Two normally open pushbutton switches are fixed in the circuit to disconnect the power supply from the batteries to the solenoids in normal condition. When the switches are being pressed, it will connect the circuit where power will be supply from the battery to the solenoids. The schematic diagram of the normally open pushbutton switch is shown in figure 4.32 The switch consists of pins, movable contact and stationary contact. The pin 1 and 2 are wired together while pin 3 and 4 are wired together. When the movable contact is pressed all the 4 pins are connected to each other and when the button is not pressed, the pin 1 and 2 are connected to each other and 3 and 4 are connected to each other.

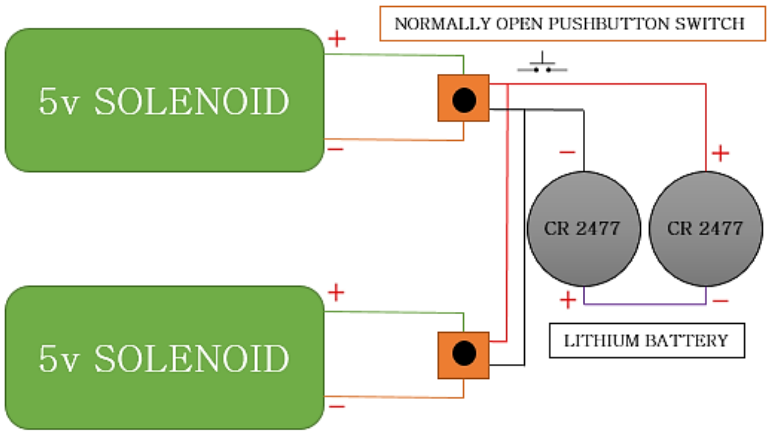


Figure 4.31: Circuit diagram of solenoid module

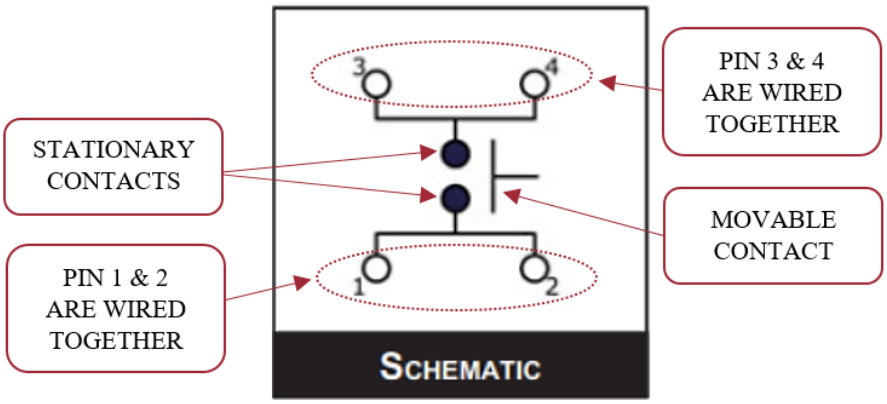


Figure 4.32: Schematic diagram of the normally open push button switch

4.7.4 Operating procedure

The image of solenoid hinge knee brace without top cover with labelled components is shown in figure 4.33. In order to operate this solenoid hinge knee brace, first of all, a set of CR 2477 Lithium battery – 22 need to be installed in the battery holder – 11. Before installing the batteries, the Battery top cover - 5 need to be open by sliding it in reverse direction as the direction is indicated on the battery top cover. Once the cover is slid in reverse direction which is away from the hinge base, then the cover is removable from the base cover - 4. Then, the batteries need to be installed at the battery holders. After this, the battery top cover needs to be inserted back on the base cover by inserting and sliding it in forwarding direction. Soon after the installation of the battery, the solenoids will be activated.

Then, for the angle adjustment process, the top cover – 7 needs to be open from the hinge base - 2. The top cover needs to be rotated along the anti-clockwise direction to unlock it from the engagement with the hinge base. Hence, the top cover can be open from the hinge base. The new ROM of the knee brace needs to be decided before the next process.

Once the ROM is decided, the colour of the angle needs to take note by referring to the colour and angle indicated on the top cover. Followed by this, the push button switch -

13 of the flexion or extension solenoids need to be pressed in order to adjust the flexion - 8 or extension - 9 needles along the respective direction. Once the push button switch is pressed, the solenoid will be activated. Consequently, the solenoid shaft - 21 and lock shaft - 20 will be retracted from the engagement with the hinge base where this will allow the solenoid – 19 and the needle to move freely along the respective direction. Then, the solenoid needs to adjust manually to the desired angle's position with the guide of solenoid cover's angle pointer - 10.1. Soon after the solenoid is adjusted, the push button of the solenoid needs to be released which will deactivate the solenoid. As a result of this action, the solenoid shaft and lock shaft will move forwardly to the original position where it will engage with one of the angle holes – 2.1 of the hinge base. Thus, the solenoid and the needle will be locked at that particular angle. Finally, the top cover needs to be closed by placing it on the hinge base and twisting it along the clockwise direction. Figure 4.34 shows the flow chart on how to operate the solenoid hinge knee brace step by step.

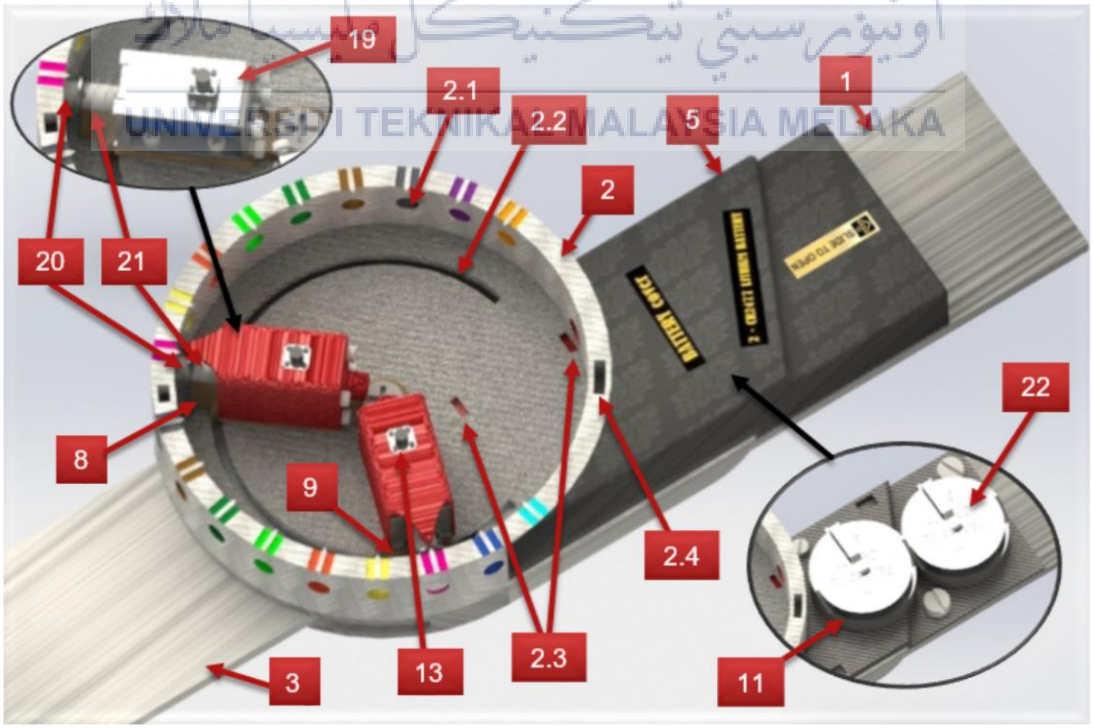


Figure 4.33: Solenoid hinge knee brace without top cover with labelled components

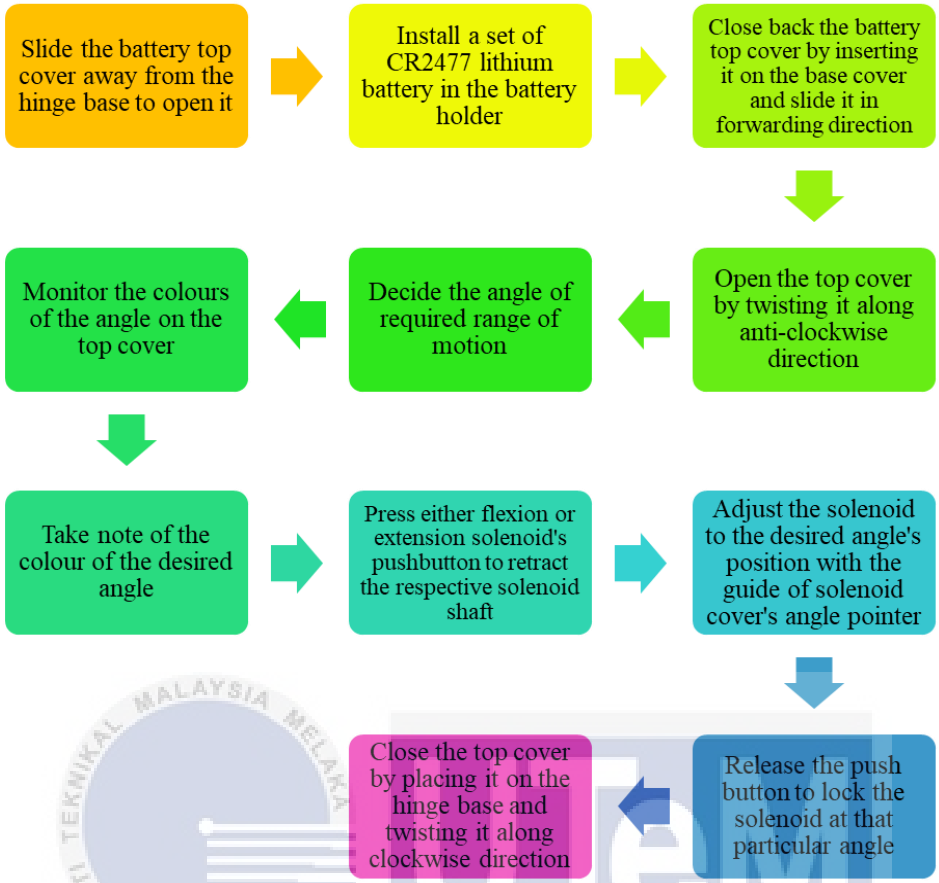


Figure 4.34: Flow chart on how to operate the solenoid hinge knee brace step by step

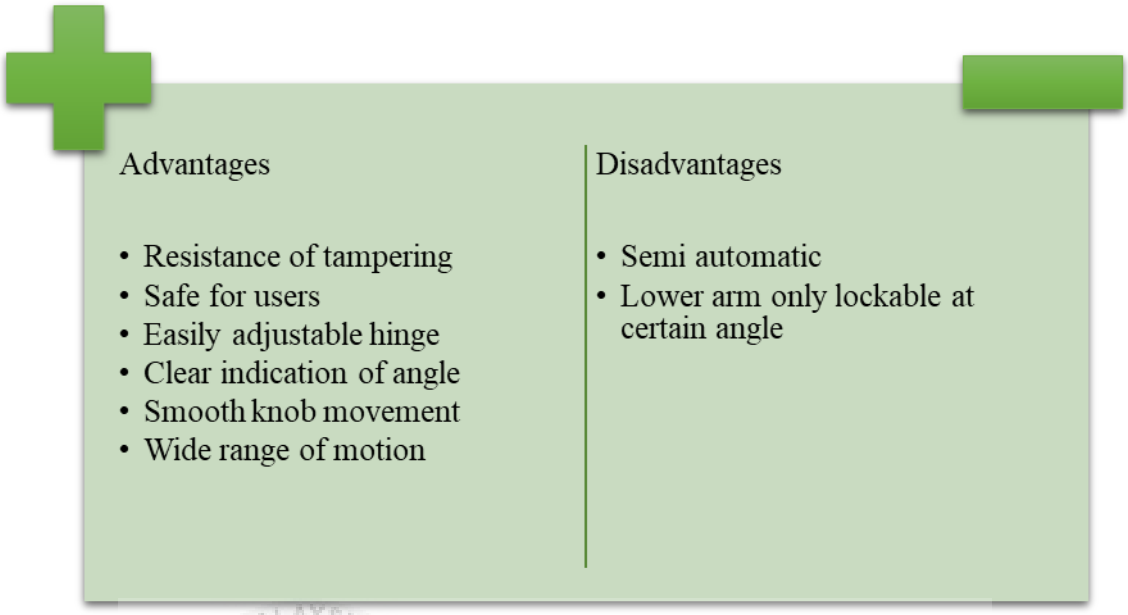
4.7.5 Advantages & disadvantages

There are a few advantages and disadvantages of solenoid hinge knee brace design which are listed in table 4.15. The first advantage is it is the resistance of tampering. This is achievable by the removable battery and the top cover. When the battery is removed from the cartridge, the solenoid is no longer adjustable. So this will prevent the wearer to readjust the previously prescribed ROM for their comfortableness. Besides that, the top cover will also prevent the wearer to readjust the ROM by closing the adjustment area. This features will lead this design to be a resistance of tampering. Secondly, this design also safe for the users because it consists of protection covers like solenoid cover, top cover and battery top cover which will protect the user from any injuries. Thirdly, the hinge of this design is easily adjustable by the user. This is possible because the user just needs to press the push button

switch and move the solenoids during the angle adjustment. Besides that, the flexion and extension angles are indicated clearly on the top cover which will allow the user to have a look at the angles in close range. This will ease the angle adjustment process. Fourthly, this design has a clear indication of angles where the angles are indicated with different colours. This will allow the user to recognise the angle easily. They also could memorise the colours of the angle instead of the values. Fifthly, this design has a very smooth knob movement. The knob which involves the needles and the solenoids are very smooth to be adjusted because they are connected pivotally by a pivot screw which can be readjusted at any time to allow them to move freely. Moreover, there is an arc slot in the hinge base to guide and facilitate the movement of the needles. The last advantage of this design is it has a wide ROM where the lower arm is free to move between -30 degrees to 120 degrees.

The first disadvantage of this design is it is semi-automatic which means the hinge is only partially automatic. The design still needs human power to control it. For example, the user needs to manually adjust the solenoids during the angle adjustment even though the locking and unlocking process automatically controlled by the solenoids. The last disadvantage is the lower arm is only lockable at certain angles. For example, the lower arm is lockable at 0˚, 15˚, 30˚, 45˚, 60˚, 75˚, 90˚, 105˚, and 120˚ but it's not lockable at -15˚ and -30˚.

Table 4.15: Advantages and disadvantages of solenoid hinge knee brace



4.7.6 Product comparison

The three types of existing hinge modules in the market which have been chosen and analysed in the house of quality previously is selected to be compared with the solenoid hinge module that is developed in this project. Table 4.16 shows the result of the comparison where the columns representing the features of the hinge modules while the rows representing the type of hinge modules. For the first feature, the type of knob adjustment in the hinge modules is sideways except for the solenoid hinge module (Type 1). Solenoid hinge module has top ways adjustable knob. Top ways adjustment is much easier for the wearer to adjust the ROM than sideways because of the direction of the force. This could make the type 1 hinge module to be easily adjustable compare to other types. Besides that, the type 2, 3 and 4 hinge module's knob makes the process of angle adjustment in the respective hinge to be manual while the knob in the hinge module type 1 makes it be semi-automatic. This is because the user needs more force to pull or push the knob in type 2, 3 and 4 hinge module but in type 1 hinge module they just need minimal force to press the push button switch to activate the solenoid. Apart from that, the ROM of all these hinge

modules are almost similar but there is a difference in the increments. The increment of angles in hinge type 3 and 4 makes them be more accurate than the other hinge modules. In terms of the safety, the type 1 hinge brace is safer for the user because it has protection covers to protect the users from any kind of injuries. Apart from that, the angle indicator of type 1 hinge module is much more easily recognisable by the user compared to the other hinge modules because the angle in hinge module type 1 is indicated with many different colours while in the other hinge module the angles are indicated either with same colour or two different colour. Last but not least, the hinge module type 1 and 3 are a resistance of tampering compared to the other hinge modules because they have a removable battery and lockable knob respectively which can be used to lock the knobs after the angle adjustment process. This feature will prevent the wearer to readjust the ROM for their comfortableness.

Table 4.16: Comparison of hinge modules

FEATURES / HINGE MODULES	TYPE OF ADJUSTMENT	TYPE OF KNOB	RANGE OF MOTION	ADJUSTMENT OF KNOB	SAFETY FEATURES	INDICATION OF ANGLE	RESISTANCE OF TAMPERING
 Type I (Newly designed solenoid hinge)	TOPWAYS ADJUSTMENT	SOLENOID KNOB	FLEXION : 0° TO 120° EXTENSION : 0° TO 30° INCREMENTS : 15°	SEMI-AUTOMATIC	PROTECTION COVERS : I) SOLENOID COVER II) TOP COVER III) BATTERY COVER	INDICATED WITH MANY DIFFERENT COLOURS	REMOVABLE BATTERY, TOP COVER
 Type II (Tynor india)	SIDEWAYS ADJUSTMENT	PULL TO RELEASE KNOB	FLEXION : 0° TO 120° EXTENSION : 0° TO 30° INCREMENTS : 15°	MANUAL	N/A	INDICATED WITH SAME COLOURS	N/A
 Type III (Dynamic techno medicals)	SIDEWAYS ADJUSTMENT	PUSH TO RELEASE KNOB	FLEXION : 0° TO 120° EXTENSION : 0° TO 30° INCREMENTS : 10°	MANUAL	N/A	INDICATED WITH TWO DIFFERENT COLOURS	LOCKABLE KNOB
 Type IV (Bsn medical)	SIDEWAYS ADJUSTMENT	PULL TO RELEASE KNOB	FLEXION : 0° TO 120° EXTENSION : 0° TO 30° INCREMENTS : 10°	MANUAL	N/A	INDICATED WITH SAME COLOURS	N/A

4.9 Design rigidity

4.9.1 Introduction

The purpose of this analysis conducted on this design is to analyse the behaviour of the components when an external load is applied. Ansys version 16 is used to conduct this analysis. This analysis is conducted on the movable components which are possibly influenced by the applied force. The involved components are the lower arm, hinge base, upper arm, flexion solenoid, extension solenoid, flexion needle and extension needle. There are two possible directions of force could apply on the knee brace in two different knee movement condition namely flexion and extension. Figure 4.35 shows the direction of flexion and extension knee movement. The torque acting on the knee brace during these movements is analysed in this analysis.

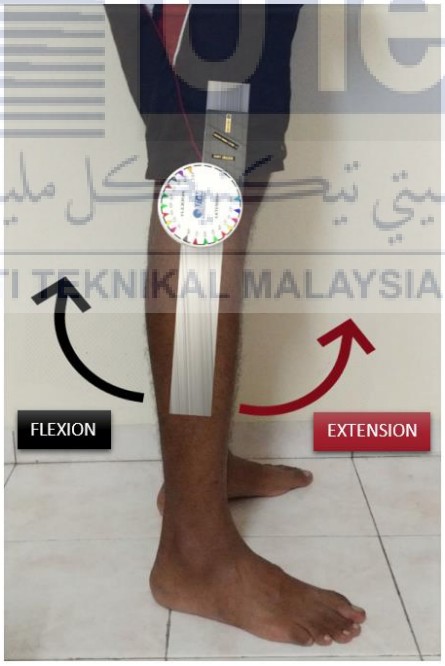


Figure 4.35: Extension and flexion movement of knee

The maximum stress and deformation result from this analysis will justify whether the components of the design are capable to withstand the external load or not. Based on the previous study, the amount of force that a knee brace needs to withstand is very minimal

because a knee brace will be just used to limit the ROM of the knee of a knee injury patient. So, the amount of torque applies on the lower arm of the knee brace along flexion and extension direction is estimated that will be not more than 10 newtons. The stress analysis on this design is conducted with a 10-newton torque along flexion and extension direction. The yield strength and ultimate tensile strength value of the component's material are needed to conduct this analysis. The yield Strength is the stress above which a material will remain permanently deformed even when the applied load is removed and the ultimate tensile strength is the maximum stress a material can withstand in tension, above which failure will occur. The strength properties of the component's materials used in this analysis are shown in table 4.17. Figure 4.36 shows the stress against strain graph.

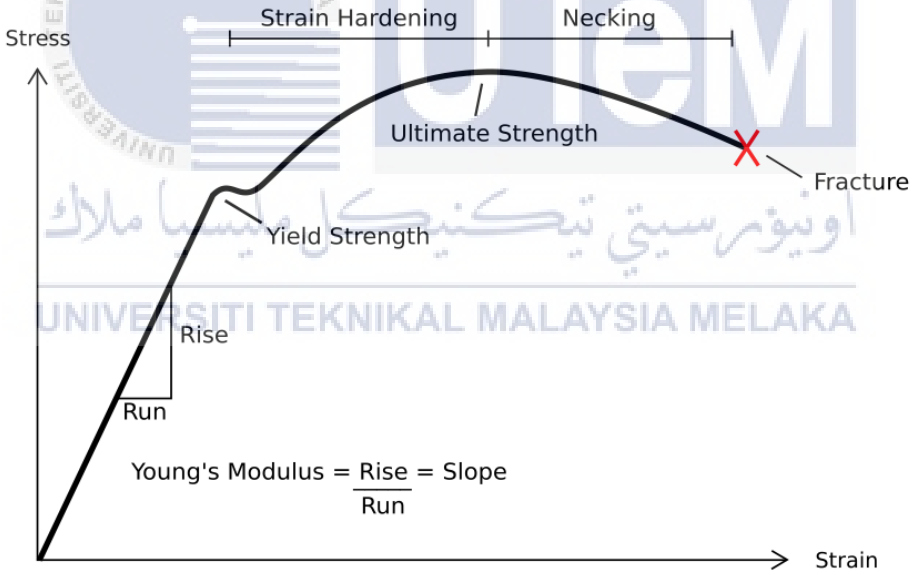


Figure 4.36: Stress against strain graph (www.instructables.com, 17/04/2019)

Table 4.17: Strength properties of materials

PART NAME	MATERIAL	YEILD STRENGTH (MPA)	ULTIMATE TENSILE STRENGTH (MPA)	SOURCE 1	SOURCE 2
UPPER ARM & LOWER ARM	ALUMINIUM ALLOY 6063-T6	215	240	SOLID WORK LIBRARY	Aalco Metals Ltd
HINGE BASE	CARBON FIBRE/EPOXY COMPOSITE SHEET	570	600	www.performance-composites.com (24/3/2019)	www.dragonplate.com (24/3/2019)
FLEXION & EXTENSION NEEDLE	ALUMINIUM 1060 ALLOY	27.57	68.94	SOLID WORK LIBRARY	www.substech.com (17/5/2019)
FLEXION & EXTENSION SOLENOID	AISI 347 ANNEALED STAINLESS STEEL	275	654.9	SOLID WORK LIBRARY	www.asm.matweb.com (24/3/2019)

4.9.1 Stress analysis in flexion direction

In order to analyse the behaviour of the components of the solenoid hinge knee brace when the torque is applied in flexion direction, the stress analysis is conducted on the design in flexion direction. Figure 4.37 illustrates a 10 N.mm torque is applied in flexion direction which is in a clockwise direction on the side surface of the lower arm which is labelled as B while another side surface of the lower arm is touching the limit face of flexion needle. The hinge base and upper arm in this analysis are considered as fixed support which is labelled as A in the figure. In this condition, the flexion needle and the lower arm are free to move against the hinge base and lower arm. Figure 4.38 shows the appearance of the geometry in the flexion movement condition after the meshing process.

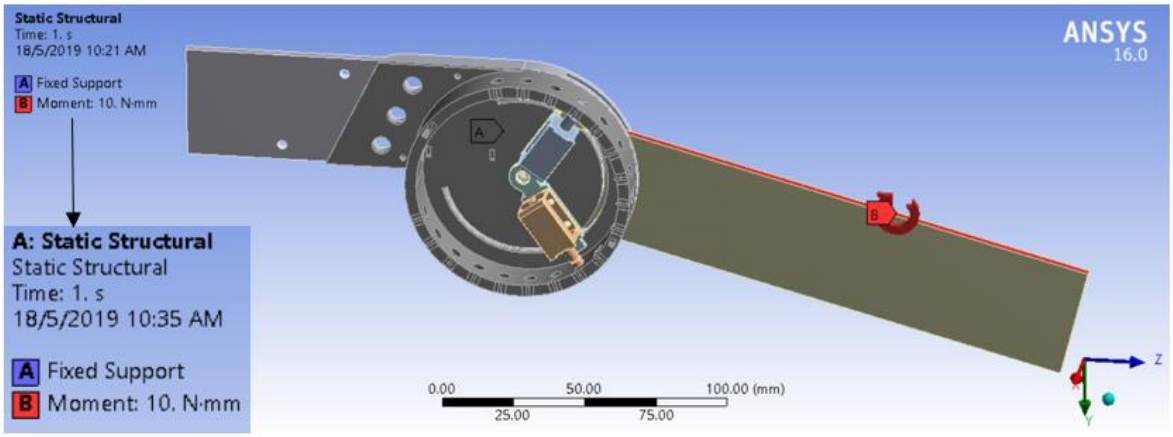


Figure 4.37: External force is applied on the components in flexion movement condition

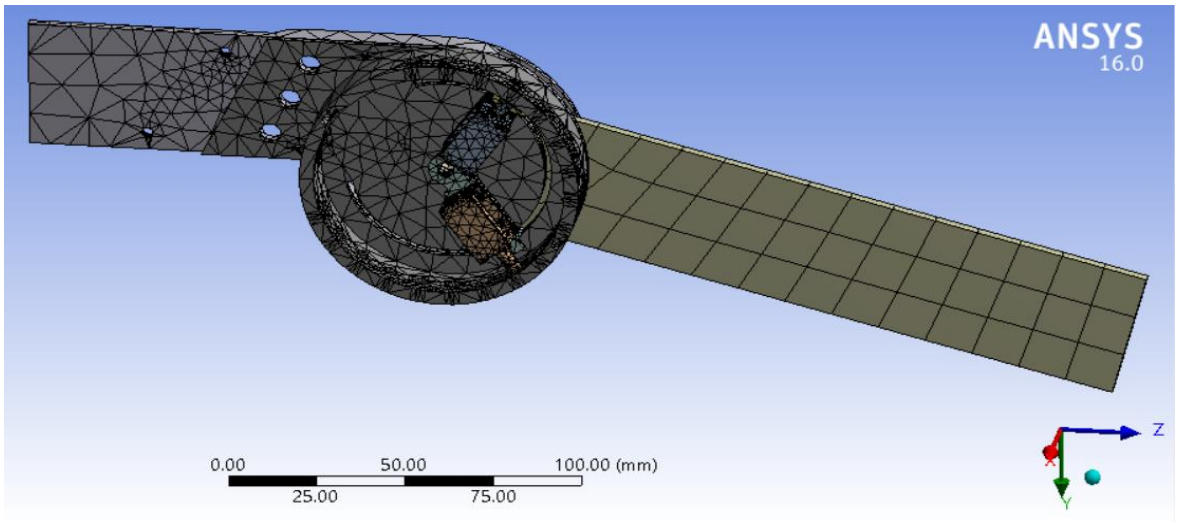


Figure 4.38: Appearance of the geometry in flexion movement condition after the meshing process

Figure 4.39 shows the equivalent stress result of the analysis. Based on the result, the maximum stress acting on the design when 10 N.mm torque is applied along flexion direction is 0.26393 MPA while the minimum stress is 5.6171e-10 MPA.

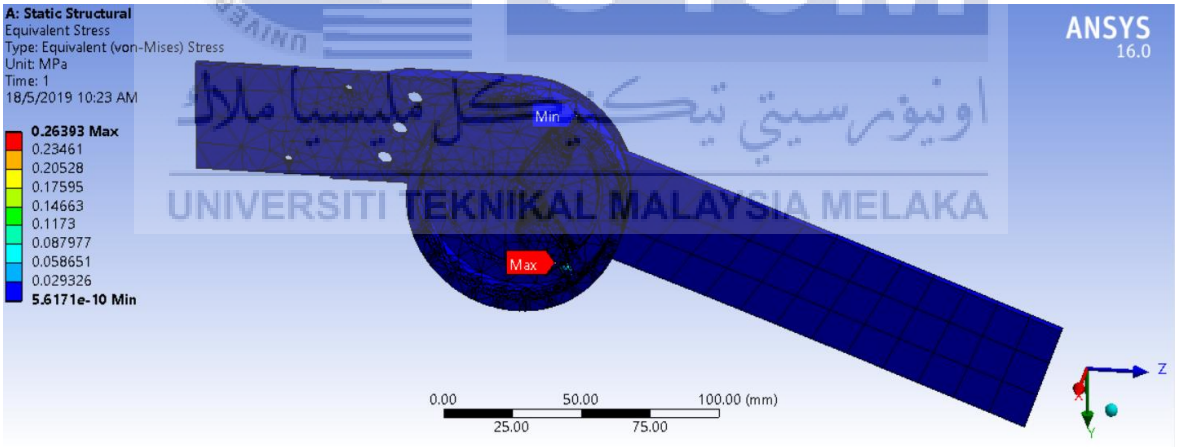


Figure 4.39: Solution of equivalent stress analysis in flexion direction

There are three different focused views from different angles of the equivalent stress analysis solution is shown in figure 4.40, 4.41 and 4.42 in order show the exact place where the maximum stress took place in the design. It shows the maximum stress is at the solenoid. To be more accurate, in the solenoid shaft. This is because when the torque is applied on the

lower arm in the clockwise direction while it is in touch with the flexion needle, the lower arm transmits the torque to the flexion needle. This causes the flexion needle to transmit the torque to the solenoid which is fixed on it. The engage condition of the solenoid shaft with the hinge base while the continuous torque transmission by the needle results the maximum stress took place on the solenoid shaft.

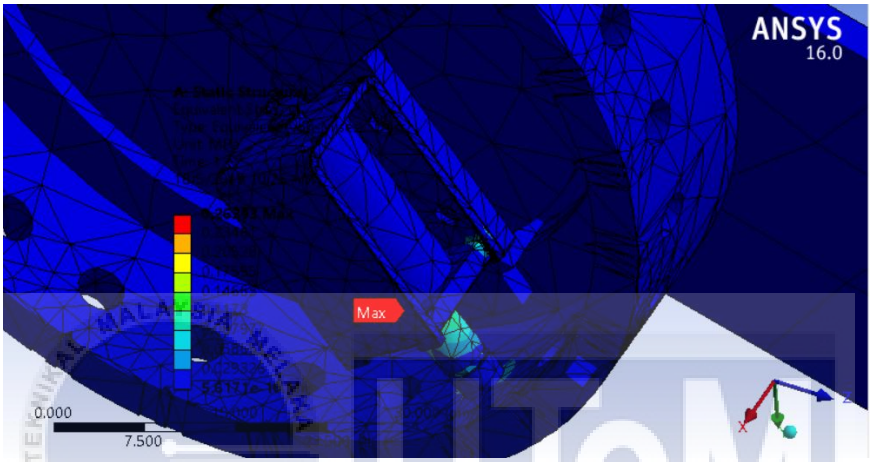


Figure 4.40: Solution of equivalent stress analysis in flexion direction from view 1

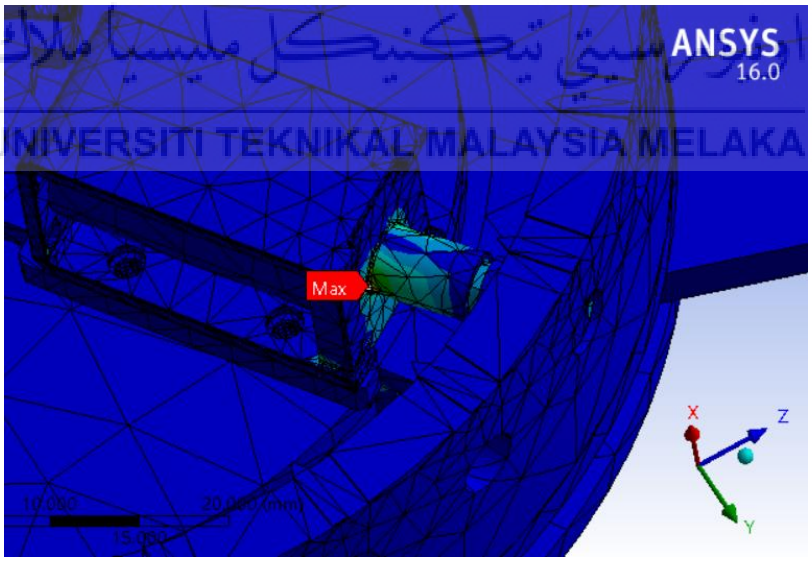


Figure 4.41: Solution of equivalent stress analysis in flexion direction from view 2

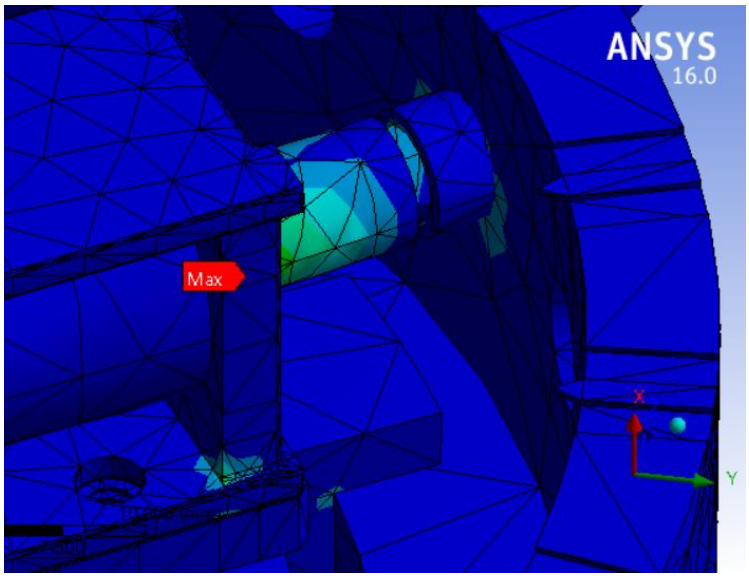


Figure 4.42: Solution of equivalent stress analysis in flexion direction from view 3

Based on the maximum stress value and the yield strength of the solenoid, the factor of safety for the design has been calculated. The yield strength of solenoid is 275 MPA while the maximum stress 0.26393 MPA. The calculation of the factor of safety is shown below.

$$Factor\ of\ safety = \frac{Yield\ stress}{Maximum\ stress} = \frac{275}{0.26393} = 1041.9$$

Figure 4.43 shows the solution of total deformation when 10-newton torque is applied in flexion direction on the lower arm. The location of maximum and minimum displacement occurred on the design are labelled in the figure. The maximum displacement is 0.00039 mm which took place the edge of the lower arm.

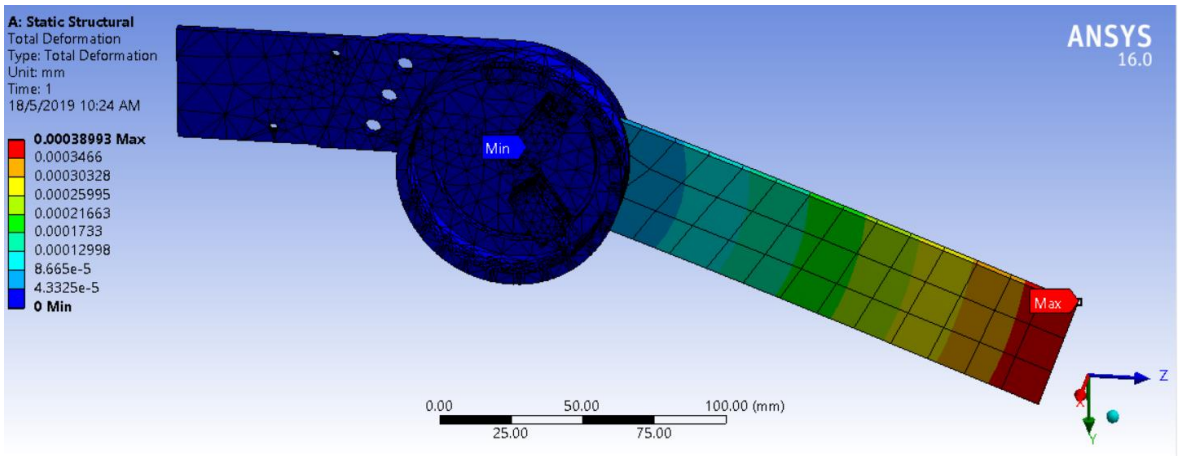


Figure 4.43: Solution of total deformation analysis in flexion direction

Table 4.18 shows the overall result of the stress analysis conducted on the solenoid hinge knee brace design in the flexion direction. The second column and third column shows the equivalent stress and the total deformation respectively. The maximum stress is 0.26393 MPA and the maximum displacement is 0.00039mm. The calculated value of factor of safety is 1041.9. These results justify that the design is capable to withstand the applied torque which is 10 newtons along flexion direction. Even though the factor of safety is too high but it cannot be optimised. This is because the maximum stress is taking place on the solenoid which is a standard part or a ready stock part. The material of the standard part cannot be modified because it is from the supplier.

Table 4.18: Overall result of stress analysis conducted on design in flexion direction

Results		
Minimum	5.6171e-010 MPa	0. mm
Maximum	0.26393 MPa	3.8993e-004 mm
Minimum Occurs On	Solid	
Maximum Occurs On	Solid	

4.9.1 Stress analysis in extension direction

The stress analysis is conducted on the solenoid hinge knee brace design along extension direction in order to understand the behaviour of the components when the external force is applied. Figure 4.44 shows a 10 N.mm torque is applied in extension direction which is in anti-clockwise on the side surface of the lower arm which is labelled as A while another side surface of the lower arm is touching the limit face of extension needle. Similar to the previous analysis in flexion direction, the hinge base and upper arm in this analysis are also considered as fixed support which is labelled as B in the figure. This condition allows the extension needle and the lower arm to freely move against the hinge base and lower arm. Figure 4.45 shows the appearance of the geometry in the extension movement condition after the meshing process.

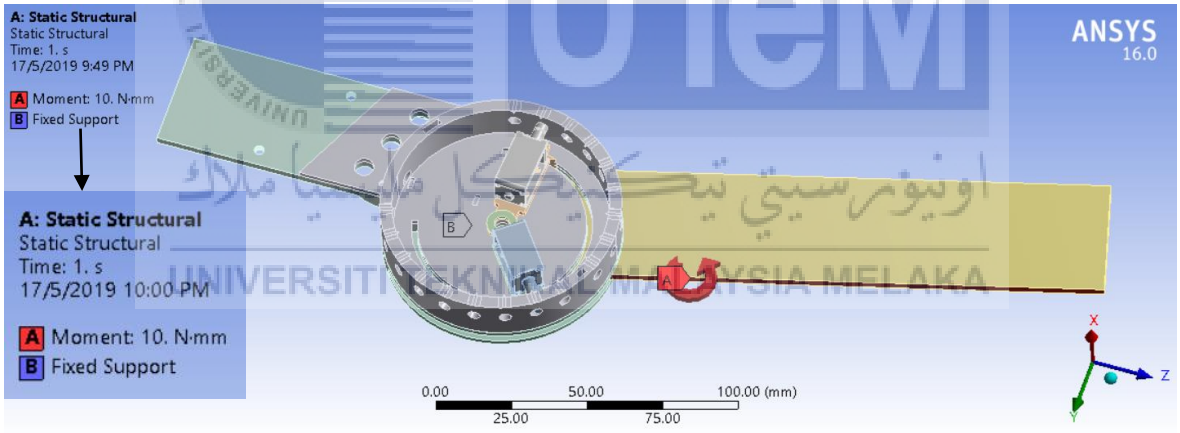


Figure 4.44: External force is applied on the components in extension movement condition

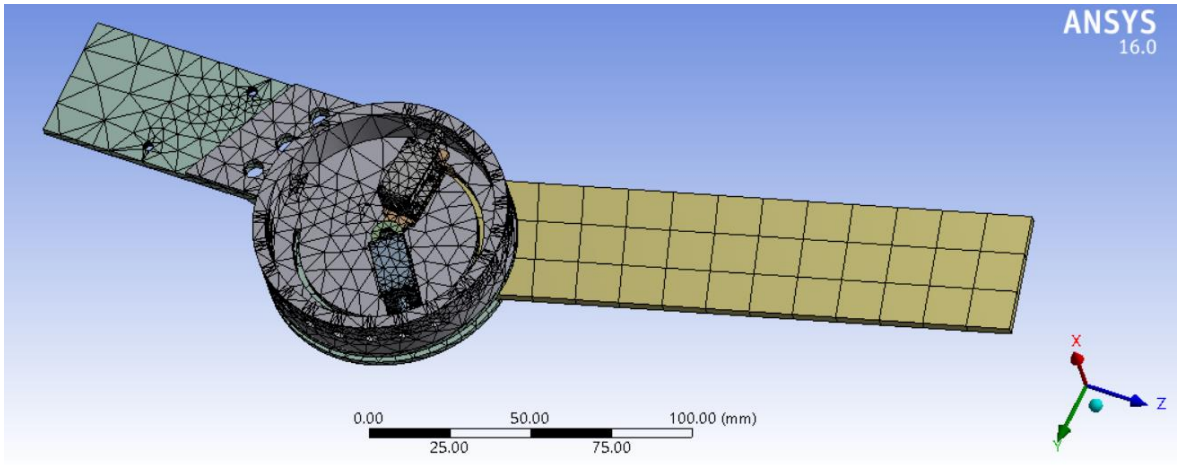


Figure 4.45: Appearance of the geometry in extension movement condition after the meshing process

Figure 4.46 illustrates the solution of equivalent stress analysis conducted on the design in extension movement condition. It shows the maximum and minimum stress on the design when 10-newton torque is applied on the lower arm along anticlockwise or extension direction. The maximum stress is 0.60461 MPA while the minimum stress is 2.6597e-9 MPA.

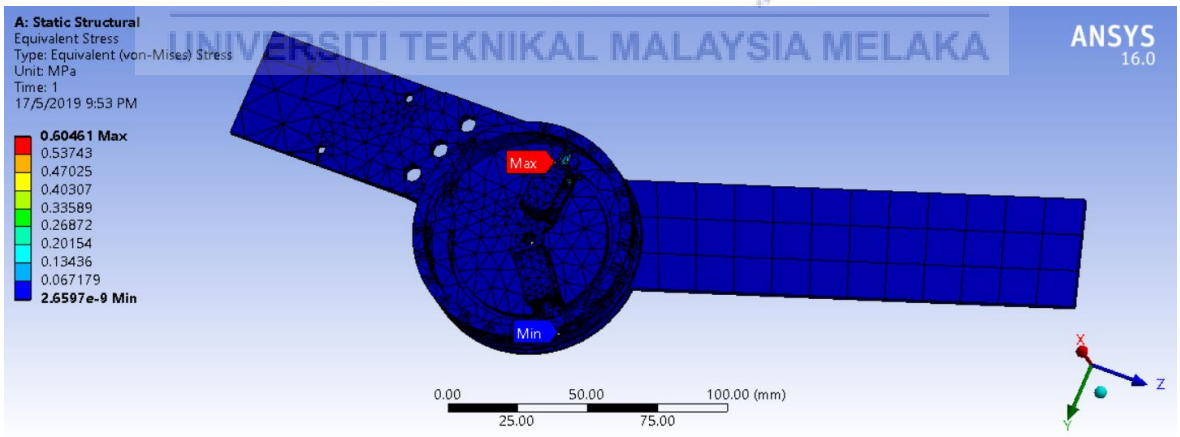


Figure 4.46: Solution of equivalent stress analysis in extension direction

Figure 4.47, 4.48 and 4.49 shows three focused views of the equivalent stress analysis solution from a different angle where the location of the maximum stress can be seen clearly. The maximum stress is taking place on the solenoid shaft. This is because when the torque is applied on the lower arm in anti-clockwise direction while it is in touch with the extension needle, the lower arm transmits the torque to the extension needle. This results in the extension needle to transmit the torque to the solenoid which is fixed on it. The engage condition of the solenoid shaft with the hinge base while the continuous torque transmission by the needle results the maximum stress took place on the solenoid shaft.

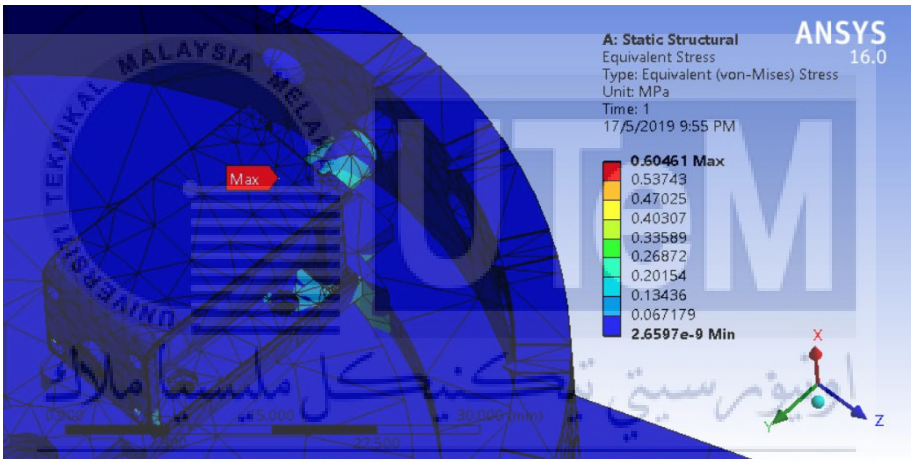


Figure 4.47: Solution of equivalent stress analysis from view 1

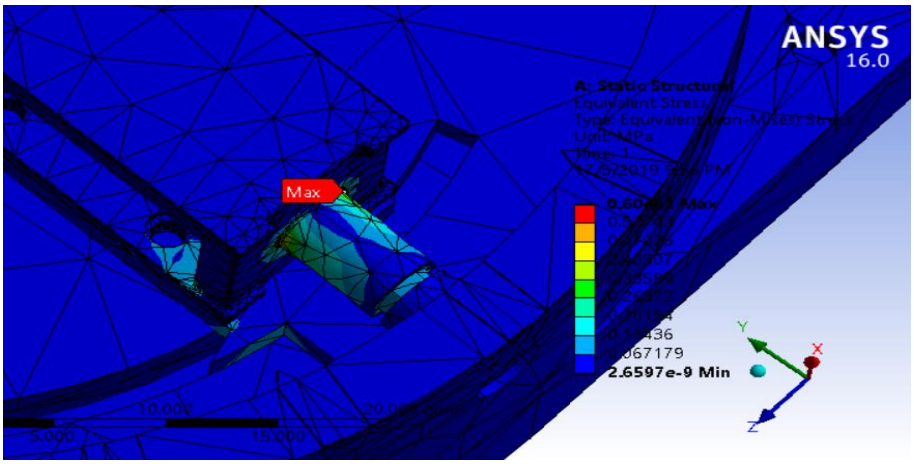


Figure 4.48: Solution of equivalent stress analysis from view 2

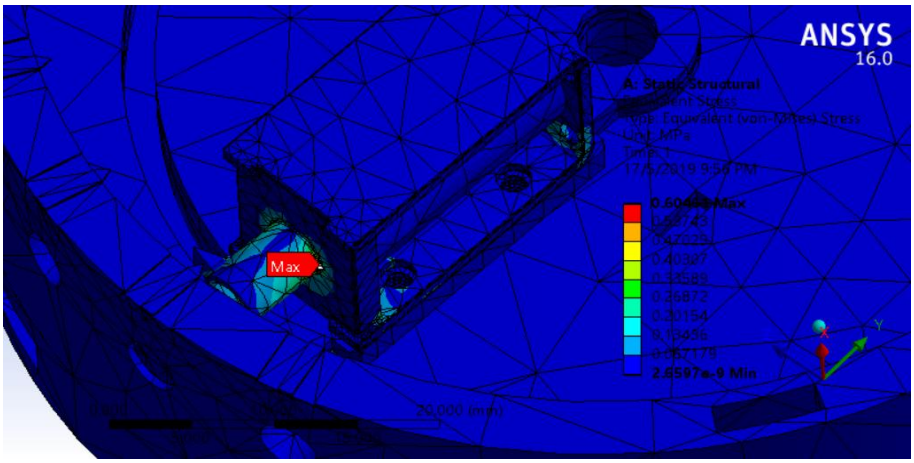


Figure 4.49: Solution of equivalent stress analysis from view 3

Based on the maximum stress value and the yield strength of the solenoid, the factor of safety for the design has been calculated. The yield strength of solenoid is 275 MPA while the maximum stress 0.60461 MPA. The calculation of the factor of safety is shown below.

$$Factor\ of\ safety = \frac{Yield\ stress}{Maximum\ stress} = \frac{275}{0.60461} = 453.5$$

Figure 4.50 illustrates the solution of total deformation when 10-newton torque is applied in extension direction on the lower arm. The location of maximum and minimum displacement are labelled in the figure. The maximum displacement is 0.0031mm which took place the edge of the lower arm.

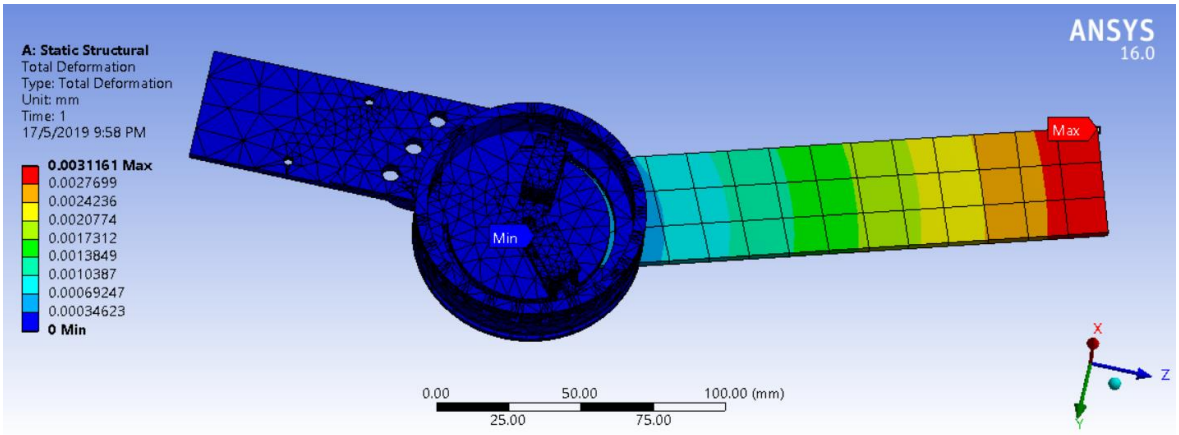


Figure 4.50: Solution of total deformation analysis in extension direction

Table 4.19 shows the overall result of the stress analysis conducted on the solenoid hinge knee brace design in the extension direction. The second column and third column shows the equivalent stress and the total deformation respectively. The maximum stress is 0.60461 MPA and the maximum displacement is 0.0031mm. The calculated value of factor of safety is 453.5. These results justify that the design is capable to withstand the applied torque which 10 newtons along extension direction. Similar to the previous analysis conducted in flexion direction, the factor of safety of this analysis also is too high but it cannot be optimised because of the location of the maximum stress in the solenoid which is a standard part.

Table 4.19: Overall result of stress analysis conducted on design in extension direction

Results		
Minimum	2.6597e-009 MPa	0. mm
Maximum	0.60461 MPa	3.1161e-003 mm
Minimum Occurs On	Solid	
Maximum Occurs On	Solid	

4.9 Kinematic analysis

4.9.1 Introduction

The purpose of this analysis conducted for this design is to analyse the movement and the exact physical positions of the hinge's components during the angle adjustment. Solid Work 2016 has been used to conduct this analysis. Figure 4.51 shows the front view of the solenoid hinge knee brace without the top cover. The major components of solenoid hinge knee brace also have been labelled in figure 4.51.

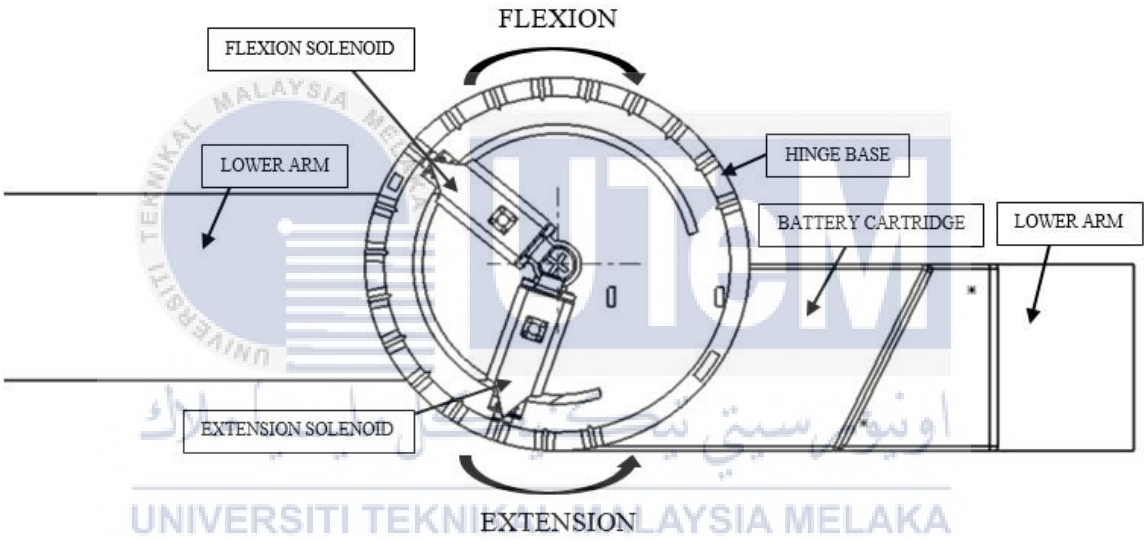


Figure 4.51: Front view of solenoid hinge knee brace without top cover

Figure 4.52 shows solenoid hinge knee brace with hidden lines visible and without solenoid. It shows the position of the needles and lower arm in detail. The needles and lower arm are connected pivotally at the centre of hinge base. The hinge base and upper arm are considered grounded in this analysis where the lower arm and needles are pivotally movable along flexion and extension direction against hinge base and lower arm. The solenoids are attached to the needles which will move together when the user adjusts the solenoids along flexion and extension direction. The lower arm is movable between the flexion and extension

needle. The extended surface of the needles will limit the movement of the lower arm when it engages with the side surface of the lower arm.

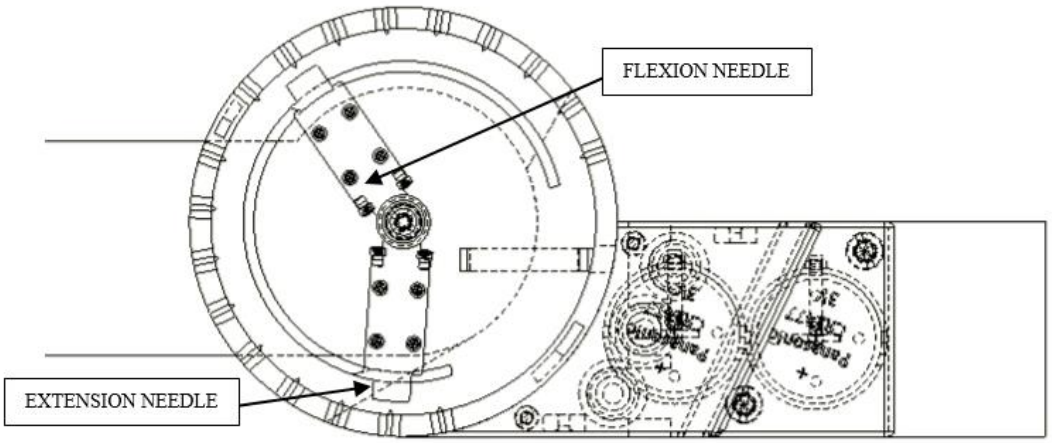


Figure 4.52: Solenoid hinge knee brace with hidden lines visible and without solenoid

4.9.2 Free body diagram

The movable components in the solenoid knee brace hinge design have been identified and the free body diagram of the component's assembly has been constructed as shown in figure 4.53. There is a total of five links in the diagram and the components of the links are listed in table 4.20. The link 1, 3 and 5 are connected at the centre of the hinge base which enables them to rotate pivotally. Link 4 which is the extension solenoid connected to the link 3. As a result of this connection, the rotation of these links is dependent on each other. They are not allowed to rotate independently. Similarly, link 2 and 1 are also dependent on each other.

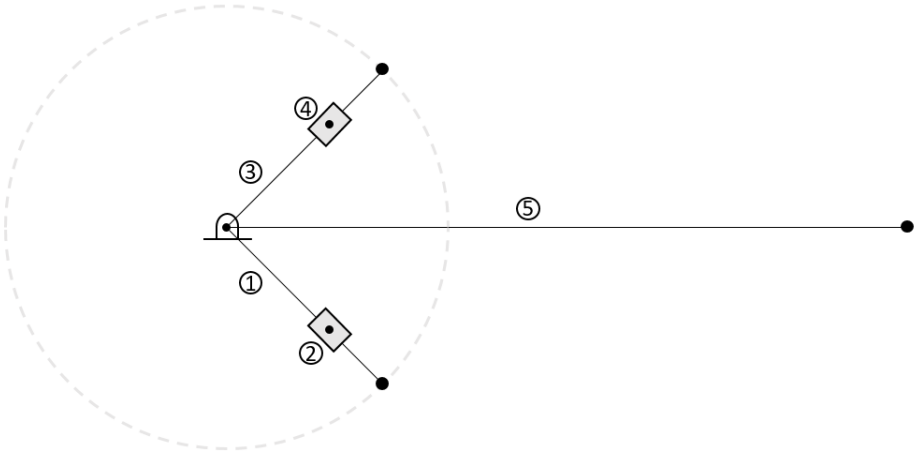


Figure 4.53: Free body diagram of Solenoid hinge knee brace

Table 4.20: Links of solenoid hinge knee brace

LINK	COMPONENT
1	Flexion needle
2	Flexion solenoid
3	Extension needle
4	Extension solenoid
5	Lower arm

4.9.3 Linear movement of solenoid locking shaft

Figure 4.54 shows the two physical position of solenoid locking shaft. Position A shows that the solenoid locking shaft is in engaged condition with the hinge base while position B shows that the locking shaft is in disengaged condition. The solenoid locking shaft is linearly movable along forward and reverses direction when the power is supplied to the solenoid by the battery. In normal condition when the power is not supplied to the solenoid, the locking shaft will be in engaged condition with one of the locking holes of the hinge base which is shown in figure 4.54 as position A. When the power is supplied to solenoid, the current will flow through the copper coil which is surrounding the locking shaft in the solenoid. This current flow will create magnetic field which will move the locking

shaft away from the engagement with the locking hole in reverse direction against the biased spring connected along the locking shaft which is shown in figure 4.54 as position B. Once the power supply is disconnected, the biased spring will push the locking shaft in forwarding direction towards the engagement with the locking hole of hinge base.

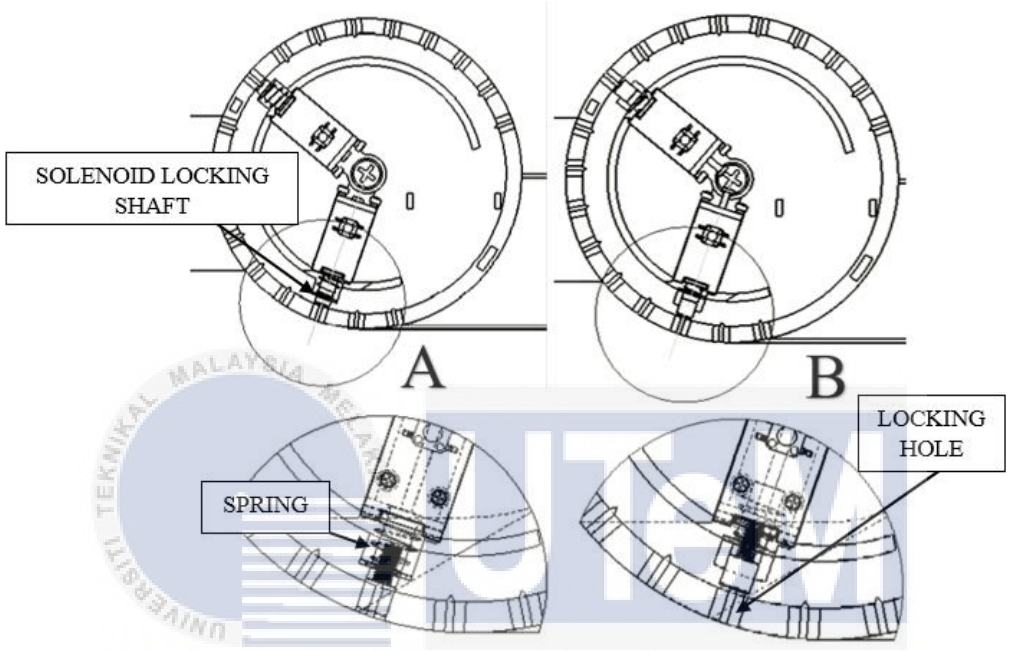
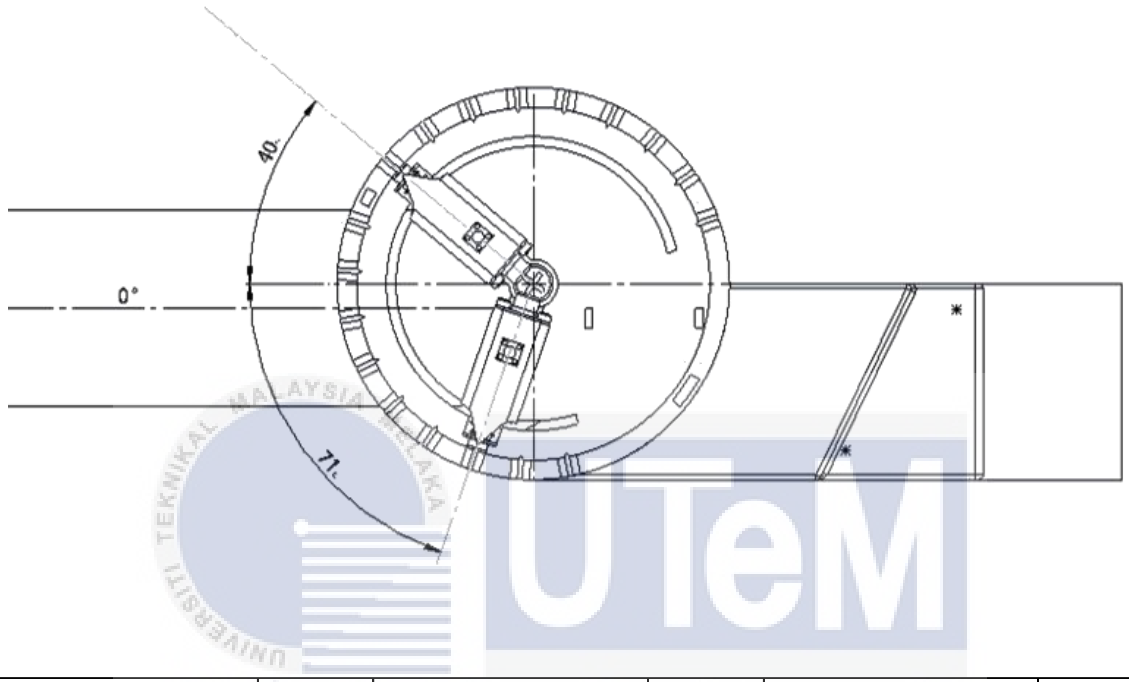


Figure 4.54: Two physical position of solenoid locking shaft

4.9.3 Locked position of lower arm

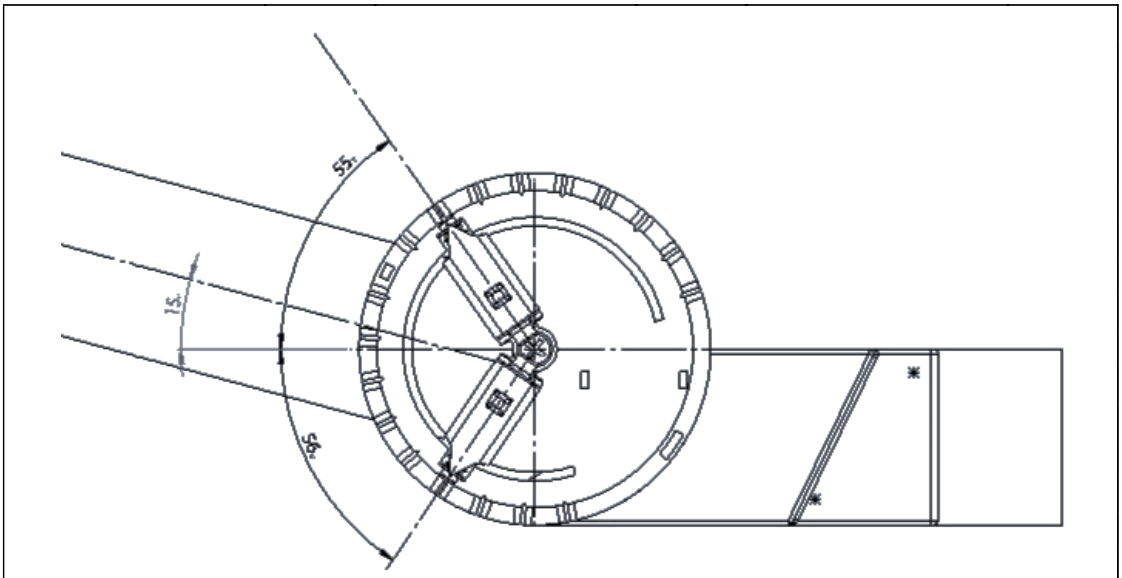
The different positions of the lower arm which can be locked at a certain angle have been analysed and identified in this analysis. The position of flexion and extension needle plays an important role in locking the lower arm at a certain angle. The results of this analysis have been tabulated in the figures 4.55, 4.56, 4.57, 4.58, 4.59, 4.60, 4.61, 4.62 and 4.63. It shows the list of the exact position of flexion and extension needles in order to lock the lower arm at a certain angle with the respective diagram. For example, in order to lock the lower arm at 0 degrees, the flexion needle needs to be fixed at angle 40 degrees while extension needle needs to be fixed at -71 degrees from the horizontal axis. When these two needles are fixed at these respective positions, the lower arm will be locked at 0 degrees where it is

restricted from moving along flexion and extension direction. Besides that, the result also shows that the angle difference is 15 degrees where the ROM can be increased by 15 degrees along with flexion and extension direction.



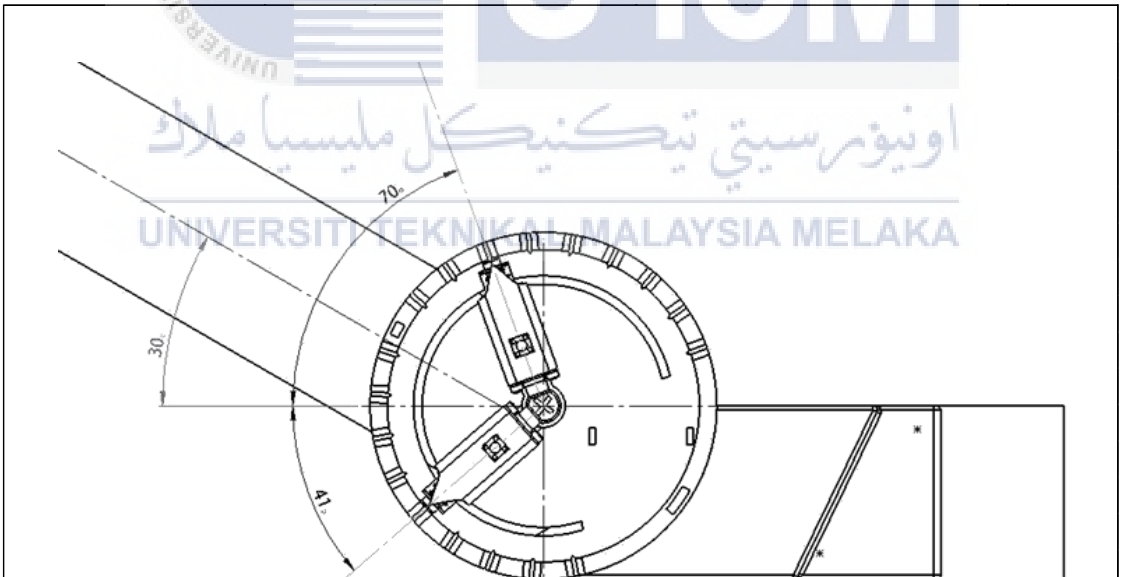
FLEXION NEEDLE POSITION	40˚	EXTENSION NEEDLE POSITION	-71˚	LOWER ARM LOCKED POSITION	0˚

Figure 4.55: Result of locked position analysis of lower arm at 0˚



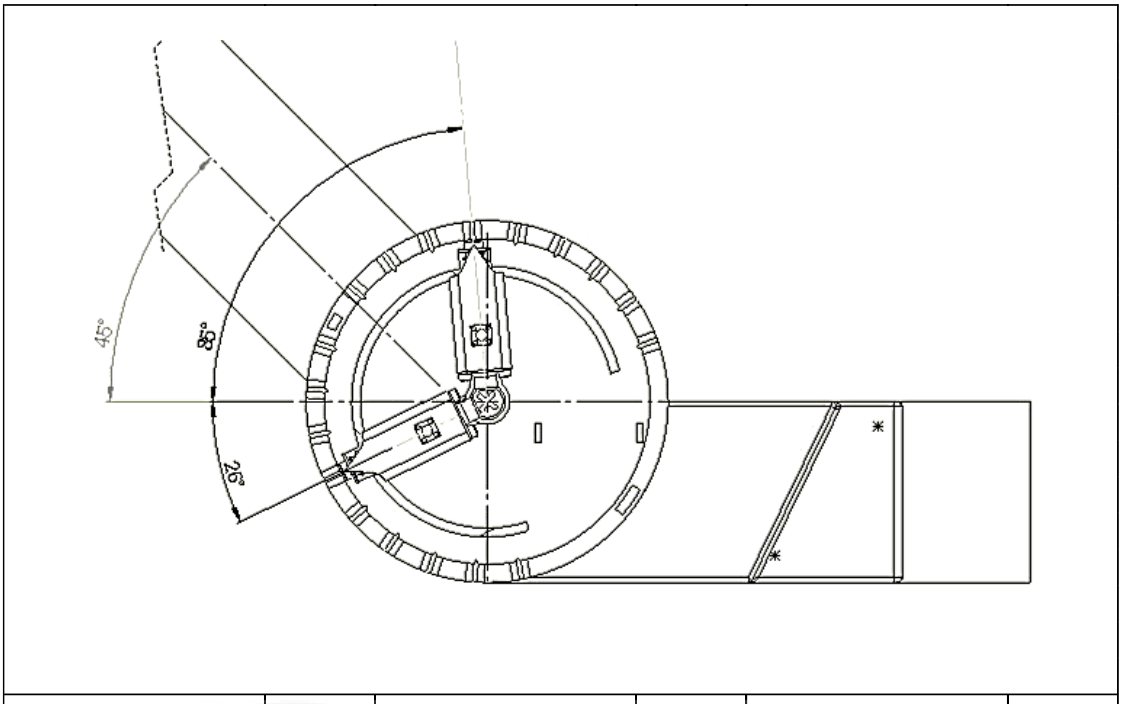
FLEXION NEEDLE POSITION	55˚	EXTENSION NEEDLE POSITION	-56˚	LOWER ARM LOCKED POSITION	15˚

Figure 4.56: Result of locked position analysis of lower arm at 15˚



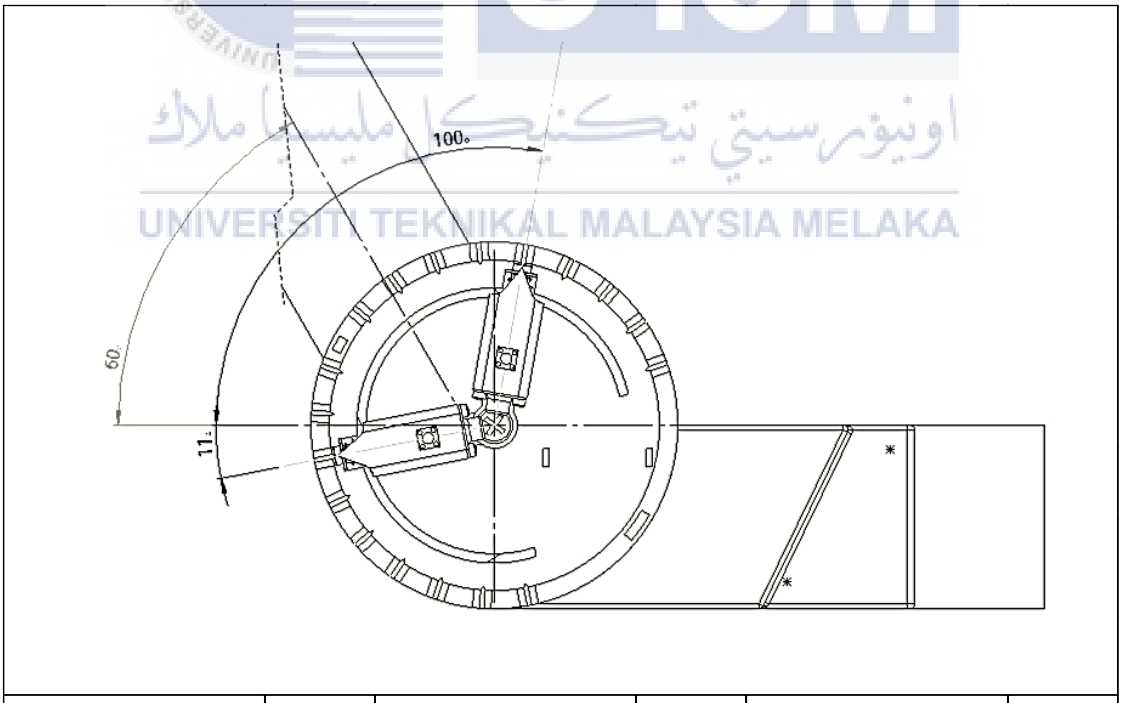
FLEXION NEEDLE POSITION	70˚	EXTENSION NEEDLE POSITION	-41˚	LOWER ARM LOCKED POSITION	30˚

Figure 4.57: Result of locked position analysis of lower arm at 30˚



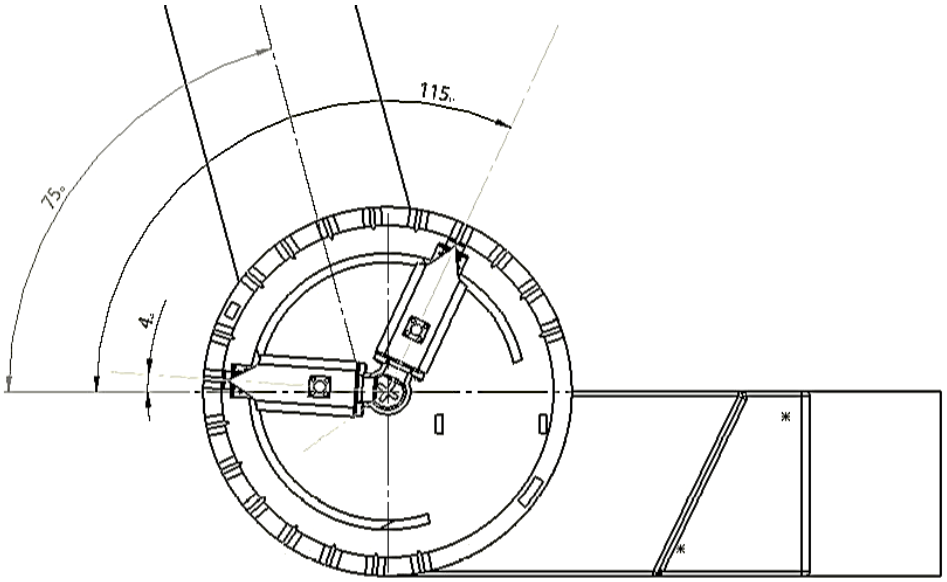
FLEXION NEEDLE POSITION	85˚	EXTENSION NEEDLE POSITION	-26˚	LOWER ARM LOCKED POSITION	45˚

Figure 4.58: Result of locked position analysis of lower arm at 45˚



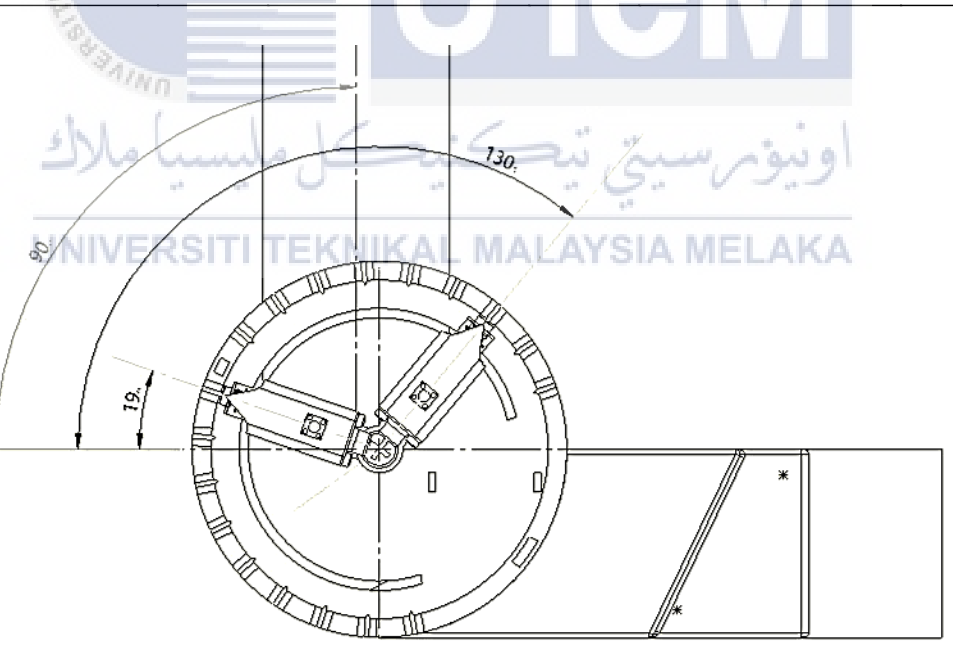
FLEXION NEEDLE POSITION	100˚	EXTENSION NEEDLE POSITION	-11˚	LOWER ARM LOCKED POSITION	60˚

Figure 4.59: Result of locked position analysis of lower arm at 60˚



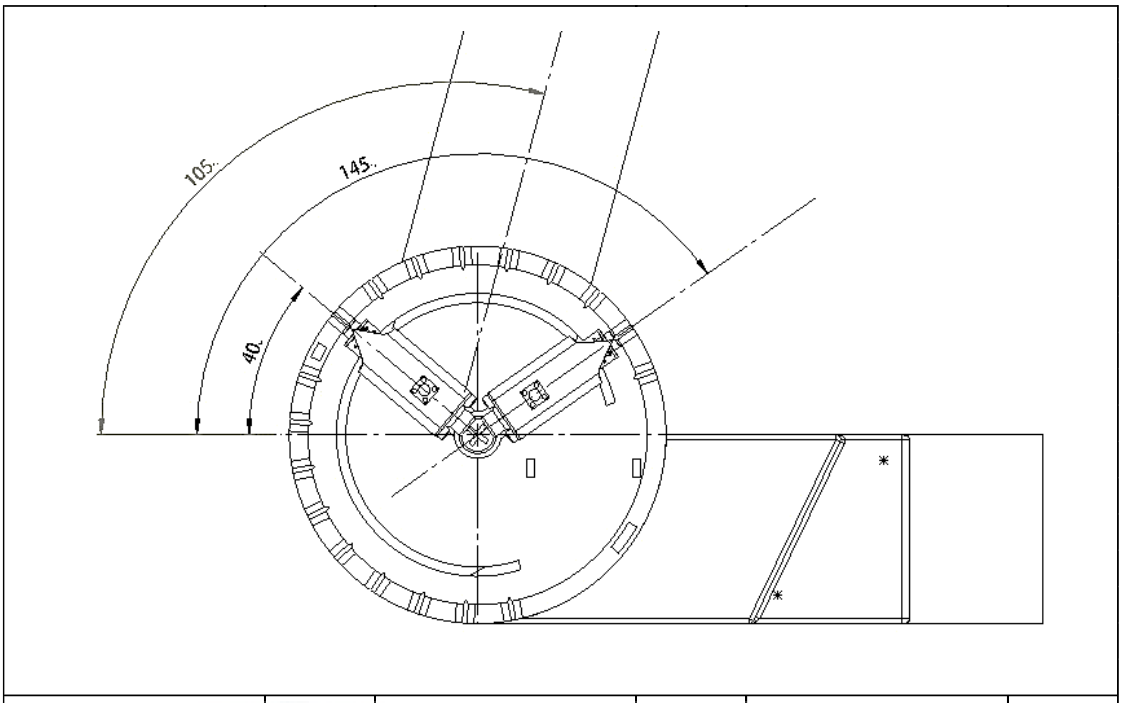
FLEXION NEEDLE POSITION	115˚	EXTENSION NEEDLE POSITION	4˚	LOWER ARM LOCKED POSITION	75˚

Figure 4.60: Result of locked position analysis of lower arm at 75˚



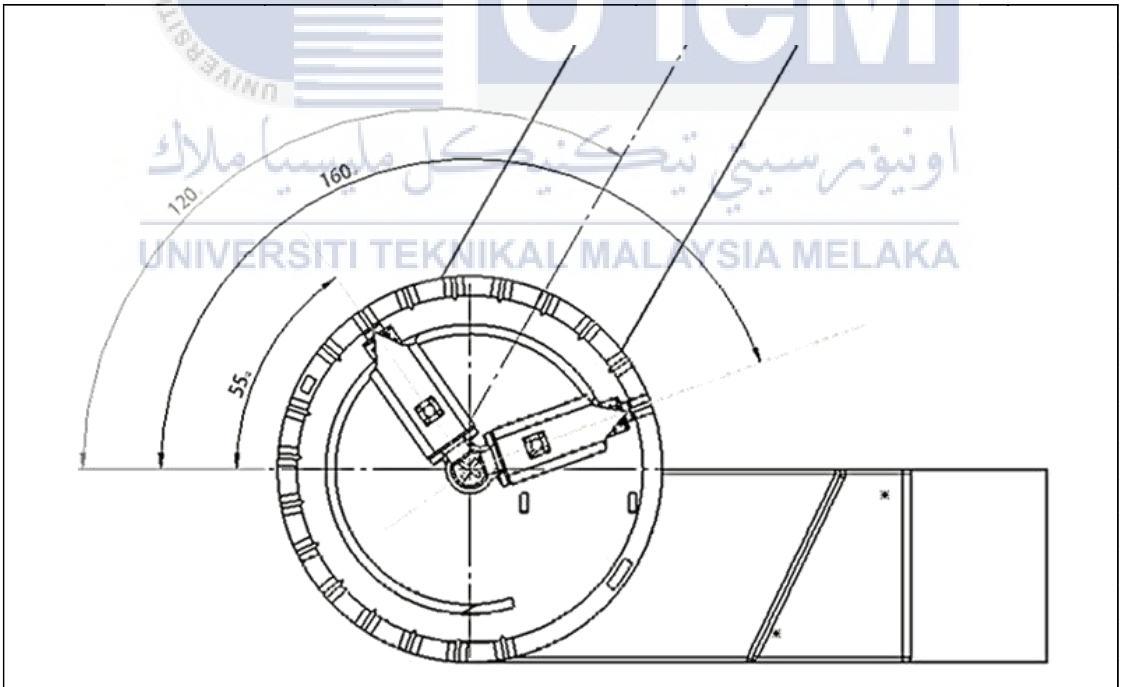
FLEXION NEEDLE POSITION	130˚	EXTENSION NEEDLE POSITION	19˚	LOWER ARM LOCKED POSITION	90˚

Figure 4.61: Result of locked position analysis of lower arm at 90˚



FLEXION NEEDLE POSITION	145˚	EXTENSION NEEDLE POSITION	40˚	LOWER ARM LOCKED POSITION	105˚

Figure 4.62: Result of locked position analysis of lower arm at 105˚



FLEXION NEEDLE POSITION	160˚	EXTENSION NEEDLE POSITION	55˚	LOWER ARM LOCKED POSITION	120˚

Figure 4.63: Result of locked position analysis of lower arm at 120˚

4.9.4 Range of motion of lower arm

Based on the analysis result as shown in figure 4.64, the maximum distance where the lower arm can travel along flexion direction is 120˚ while along the extension direction is -30˚. This can be achieved by setting the flexion needle at 160˚ and extension needle at -101˚. In this position, the lower arm is free to move from -30 degrees to 120 degrees which is the maximum ROM. This ROM can be reduced by selectively readjusting the position of the needles at different angles. The increment of the angle is 15˚.

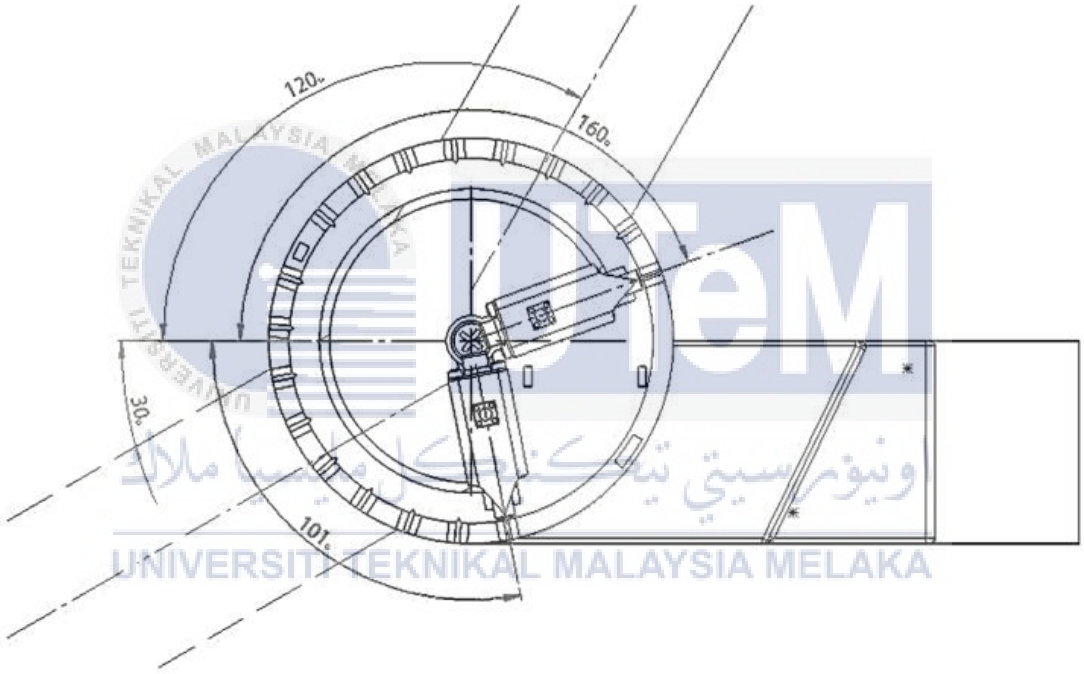


Figure 4.64: Maximum ROM of lower arm along flexion and extension direction

CHAPTER 5

CONCLUSION & RECOMMENDATION

5.1 Conclusion

The thorough research is based on an easy handling ROM knee brace's hinge module being developed. The objective of the project is to provide an easy handling knee brace's hinge mechanism during adjusting a desired rotational range in the extension or flexion direction which can be user-friendly and convenient to the user. A solenoid hinge module has been developed in this project which will provide ease of handling for the user during the angle adjustment process. The solenoid hinge module is designed using solid works 2016 software. The design of this hinge module consists of 22 components. This design is semi-automatic where it requires a power supply from batteries to activate and deactivate the solenoids. The solenoids used in this design as a locking mechanism to reduce the manpower during the ROM adjustment process. This type of solenoid based hinge module in a knee brace is very new invention in the market. This design has features like the resistance of tampering, clear indication of angle, safe for users, easily adjustable knob and smooth knob movement. These features make this design to be user-friendly, convenient and easily handleable for the user.

There are two movements involved in this knee brace when the user wears it which are flexion and extension movement. So the stress analysis has been conducted on the design of solenoid hinge knee brace in order to find the design rigidity of hinge using Ansys version 16 software in both flexion and extension movement direction. Based on the result of the analysis, the components in the design are capable to withstand the force which is 10 N.mm

torque applied on it in both flexion and extension direction. This is proven by the result of the equivalent stress analysis where the maximum stress achieved on the design in flexion movement condition is 0.26393 MPA while in the extension movement condition is 0.60461 MPA. Besides that, the total deformation in flexion movement condition is 0.00039 mm while in extension movement condition is 0.0031 mm. Furthermore, in order to analyse the motion of hinge mechanism joints, kinematic analysis has been carried out on the design using Solidworks 2016 software. Based on the analysis, the lower arm and the needles are connected pivotally with the hinge base and the upper arm. This connection allows them to rotate freely against the hinge base and upper arm. In this analysis, the exact position of the needles and the solenoids also have been identified when the lower arm is adjusted between the needles. Apart from that, the ROM of the knee brace also proven in this analysis where it is from -30˚ to 120˚ with the increment of 15˚. Besides that, this analysis also proves that the lower arm is lockable between 0˚ to 120˚ with the increment of 15˚.

In the nutshell, solenoid hinge knee brace is a newly developed hinge module for the ROM knee braces. It has easy handling knee brace hinge mechanism. It will be easily handleable, very convenient and user-friendly during adjusting a desired rotational range in the extension or flexion direction. The strength of the design also is good enough to withstand the force the might be applied by the user during limiting the ROM of their knee which is proven in the analysis. The objective of this project is achieved by this invention. Even though solenoid hinge knee brace is believed to provide ease of handling for the user but it is having room for improvement. Today's advancement in technology should be brought together and implemented in this system to further its abilities and effectiveness.

5.2 Recommendation

Over the past couple of decades, advancing technology has revolutionized the world. In future, by utilising the latest technologies, there are few improvisations could be done in

this solenoid hinge knee brace design in order to make it more efficient. One of the improvisations which could be done in this design is to make it fully automatic. This might be possible by making the angle adjustment mechanism in this design motorised. By adding motor in this design to control the solenoid and needle movement automatically, could eliminate the manual work need to be done by the user. The motor assembly could be a detachable design where it can be removed by the user if they don't prefer it. This detachable motor concept could be a cost-reducing option as the motorised knee brace could cost much higher than non-motorised. This concept design will allow the knee brace to be affordable by the patients. Furthermore, the motor could be controlled by an application in smartphones or with any simple switches. If the motor is controlled by a smartphone, then the angle adjustment process will be easy and fully automatic.

Apart from that, there is another improvisation could be made in this design in future where a detachable detent could be added in this design to lock the lower arm at every angle. This will allow the user to lock the lower arm at the desired angle without any limitation.

Furthermore, additional battery storage can be designed in this solenoid hinge knee brace in future. This will allow the user to store their back up batteries in the storage. This battery storage could be detachable so that it can be removed from the knee brace if the user doesn't prefer it.

Last but not least, a memory storing system could be added in this design in future. With this improvisation, the user could save their ROM data throughout their recovery process. The data history could be used by the person who prescribed the ROM to monitor the user's recovery progress.

REFERENCES

[1] Anon., 1996-2018. *Amazon.* [Online]
Available at: www.amazon.com,
[Accessed 23 10 2018].

[2] Anon., n.d. *Breg.* [Online]
Available at: www.breg.com
[Accessed 23 10 2018].

[3] Anon., n.d. *Bsnmedical.* [Online]
Available at: www.bsnmedical.co.uk
[Accessed 4 12 2018].

[4] Anon., n.d. *Donjoyperformance.* [Online]
Available at: www.donjoyperformance.com
[Accessed 23 10 2018].

[5] Anon., n.d. *Dynamictechnomedicals.* [Online]
Available at: www.dynamictechnomedicals.com
[Accessed 4 12 2018].

[6] Anon., n.d. *Mmarmedical.* [Online]
Available at: www.mmarmedical.com
[Accessed 23 10 2018].

[7] Anon., n.d. *Ossur.* [Online]
Available at: www.ossur.com
[Accessed 5 12 2018].

[8] Anon., n.d. *Performancehealth.* [Online]
Available at: www.performancehealth.com
[Accessed 5 12 2018].

[9] Anon., n.d. *Shockdoctor.* [Online]
Available at: www.shockdoctor.com
[Accessed 23 10 2018].

[10] Anon., n.d. *Tynorindia.* [Online]
Available at: http://tynorindia.com
[Accessed 4 12 2018].

[11] Bradley R. Mason, O. & Jeffrey T. Mason, E. b. o. C., 1997. *HNGE FOR ANORTHOPEDC BRACE HAVING ANADJUSTABLE RANGE OF ROTATON.* United States , Patent No. USOO5672152A.

[12] David Cormier, O. C. (. et al., 2005 . *ADJUSTABLE ERGONOMIC KNEE BRACE.* United States , Patent No. US 2005.0070831A1 .

[13] David Ernest Young, W., 1999 . *HINGE WITH MOVEMENT LIMITATION.* United States, Patent No. USOO5997493A.

[14] Gary R. Bledsoe, G. P. T., 1989 . *MOTION RESTRAINING KNEE BRACE.* United States, Patent No. US4817588A.

[15] Jeffery T. Manson, E. C. & Paul Oddou, O. C., 2006. *RELEASABLY LOCKING HINGE FOR AN ORTHOPEDIC BRACE HAVING ADJUSTABLE ROTATION LIMITS.* United States , Patent No. US 2006/0155230 A1 .

[16] Jeffrey H. Townsend, B. C. (. & Steven S. Knecht, B., 2009. *POST OPERATIVE KNEE BRACE WITH MULTIPLE ADJUSTMENT FEATURES.* United States, Patent No. US 20060206045A1 .

[17] John E. Bennett, R. P. V. C. (. & Willis C. Bradley, G. C. (., 2006. *ADJUSTABLE FOR ORTHOPEDIC SPLINTS.* United States, Patent No. USOO6993808B1.

[18] Max E. MOORE, L. F. (., 2007. *A RACHET HINGE FOR A KNEE OR ELBOW ORTHOSIS.* United States , Patent No. US 20070067.957A1 .

[19] William J. Popp, R. S. F. C. (. & Dennis McKaskle, E. C. (., 2006 . *ORTHOPEDIC POLYCENTRIC HINGE.* United States , Patent No. US 20060287624A1 .

APPENDICES

APPENDIX A: Solenoid hinge knee brace

APPENDIX B: Survey form

NAME:

What are the user's expectations on Range of motion (ROM) knee brace?

Range of motion (ROM) knee brace is one of the types of knee braces which used to control and restrict flexion & extension movement of the knee joint through an interconnecting hinge to allow a range of motion or immobilization to the knee. This survey is to analyse on the user's requirements for ROM knee brace's hinge.

Knee brace with adjustable hinge

Please rate the following questions based on the scales below:

1	Strongly Disagree	**2**	Disagree	**3**	Uncertain/ Not Applicable	**4**	Agree	**5**	Strongly Agree

1. **Do you expect safety features in ROM knee brace's hinge?**

1	2	3	4	5
◯	◯	◯	◯	◯

2. **Are you willing to buy a ROM knee brace with an easily adjustable hinge?**

1	2	3	4	5
◯	◯	◯	◯	◯

3. **Is it better to have a hinge knee brace with smooth knob movement?**

1	2	3	4	5
◯	◯	◯	◯	◯

Hinge's Knob

4. **Do you think a clear indication of angle on knee brace's hinge is important?**
Mark only one oval.

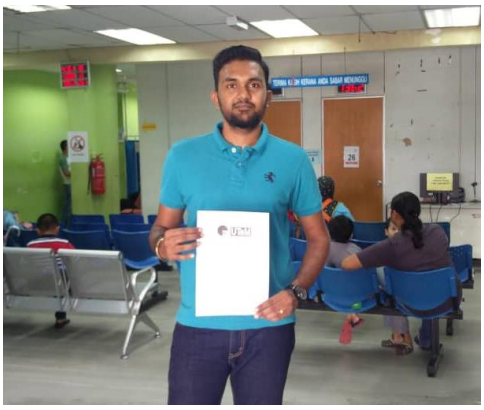
1	2	3	4	5
◯	◯	◯	◯	◯

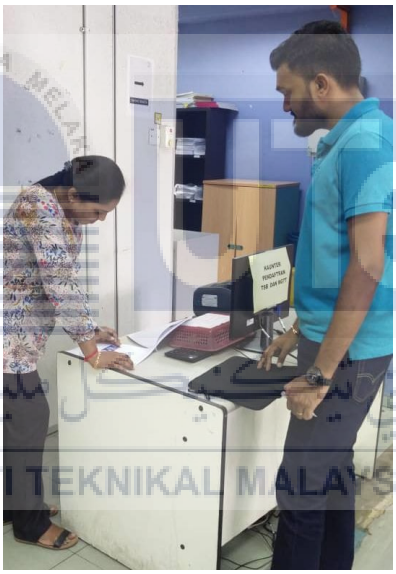
Hinge with angle indication

5. **Do you agree that hinged knee brace should be resistance of tampering?**

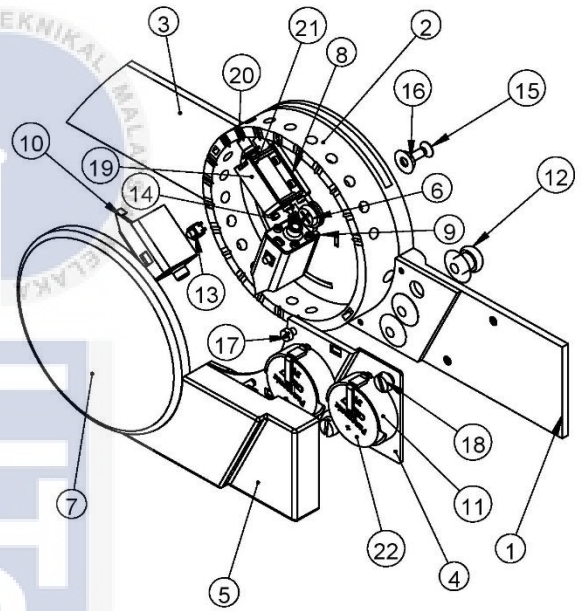
1 2 3 4 5

APPENDIX C: Survey conducted at 'Klinik Kesihatan Puchong Batu 14'



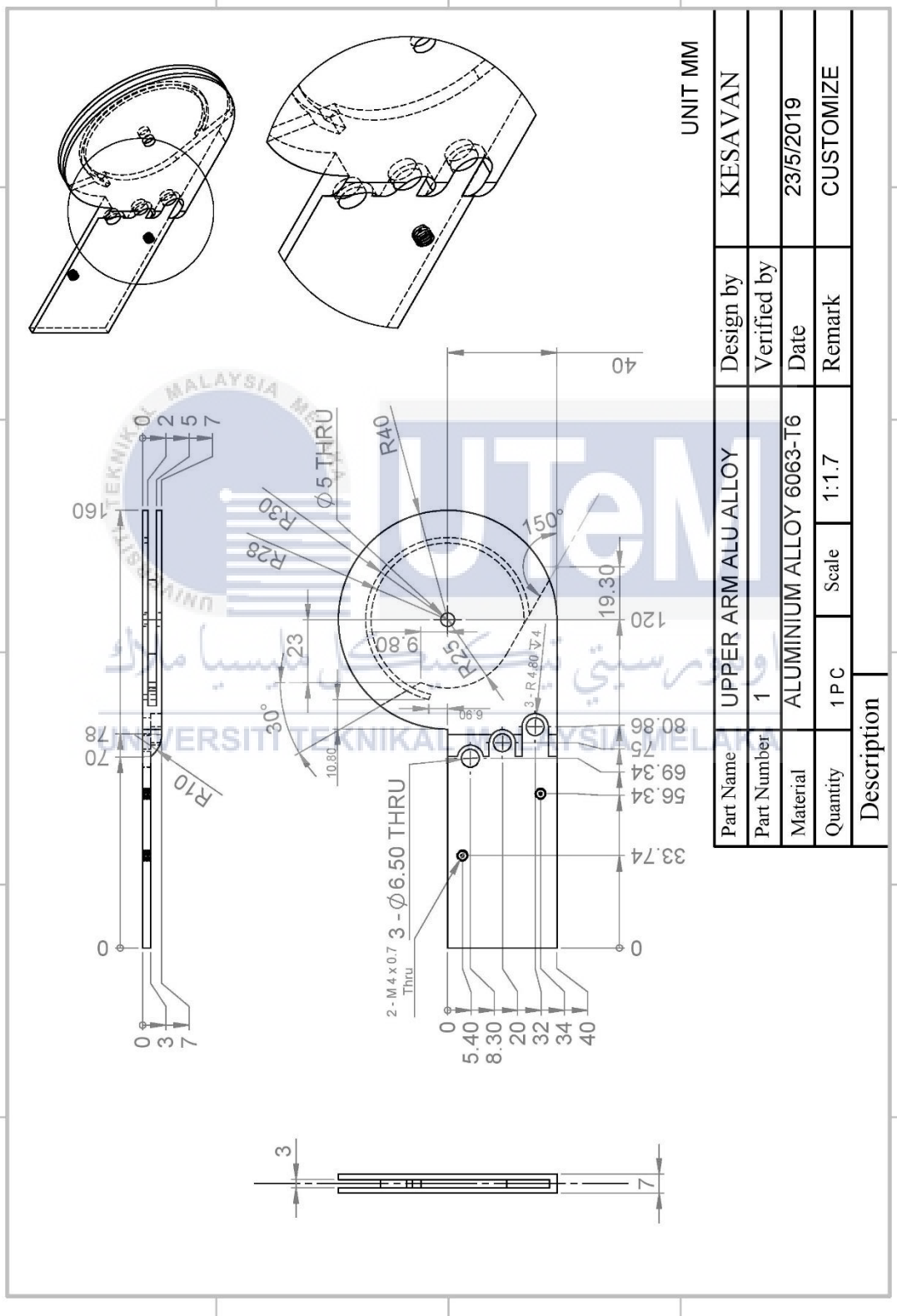


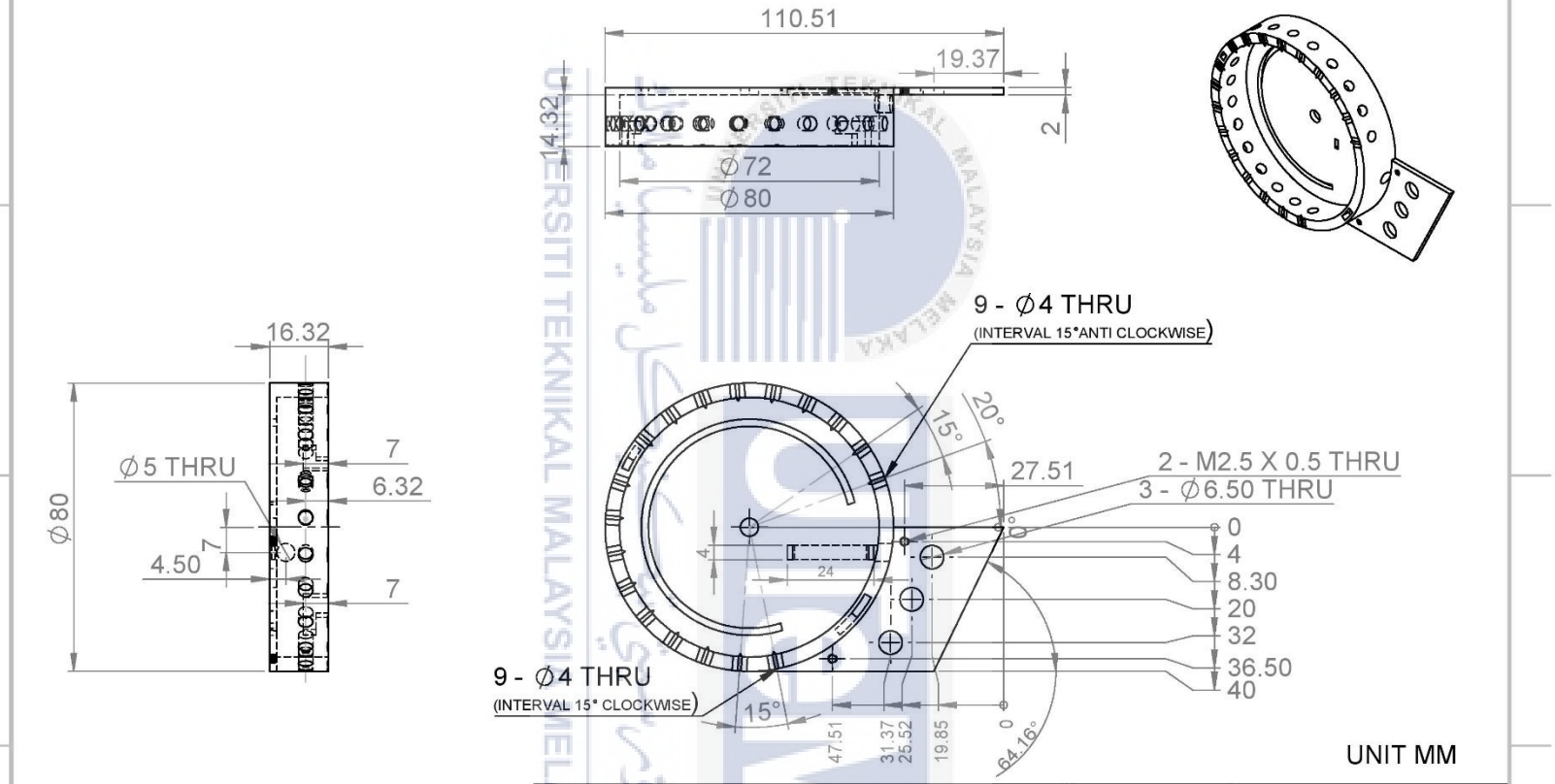
PART NUMBER	PART NAME	MATERIAL	QTY
1	UPPER ARM ALU ALLOY	ALUMINIUM ALLOY 6063-T6	1
2	HINGE BASE	CARBON FIBRE/EPOXY COMPOSITE SHEET	1
3	LOWER ARM	ALUMINIUM ALLOY 6063-T6	1
4	BATTERY BASE COVER	CARBON FIBRE/EPOXY COMPOSITE SHEET	1
5	BATTERY TOP COVER	POLYCARBONATE FILAMENT	1
6	PIVOT SCREW	AISI 347 ANNEALED STAINLESS STEEL (SS)	1
7	TOP COVER	POLYCARBONATE FILAMENT	1
8	FLEXION NEEDLE	ALUMINIUM ALLOY 1060	1
9	EXTENSION NEEDLE	ALUMINIUM ALLOY 1060	1
10	SOLENOID COVER	POLYCARBONATE FILAMENT	2
11	BATTERY HOLDER	PBT, NICKEL-PLATED STAINLESS SPRING STEEL	2
12	RIVET	STEEL SWCH	3
13	PUSH BUTTON SWITCH	N/A	2
14	M2 X 4 ROUND HEAD SCREW	STAINLESS STEEL (FERRITIC)	18
15	M3 X 0.5 CSK HEAD SCREW	STAINLESS STEEL (FERRITIC)	1
16	M3 WASHER	STAINLESS STEEL (FERRITIC)	1
17	M2.5 X 5 ROUND HEAD SCREW	STAINLESS STEEL (FERRITIC)	2
18	M4 X 4 ROUND HEAD SCREW	STAINLESS STEEL (FERRITIC)	2
19	SOLENOID	AISI 347 ANNEALED STAINLES	2
20	LOCK SHAFT	AISI 347 ANNEALED STAINLES	2
21	SOLENOID SHAFT	AISI 347 ANNEALED STAINLES	2
22	CR2477 LITHIUM BATTERY	LITHIUM MANGANESE DIOXIDE	2



		Design by	KESAVAN
		Verified by	
		Date	23/5/2019
Scale	1:2	Remark	
Description		BILL OF MATERIALS	

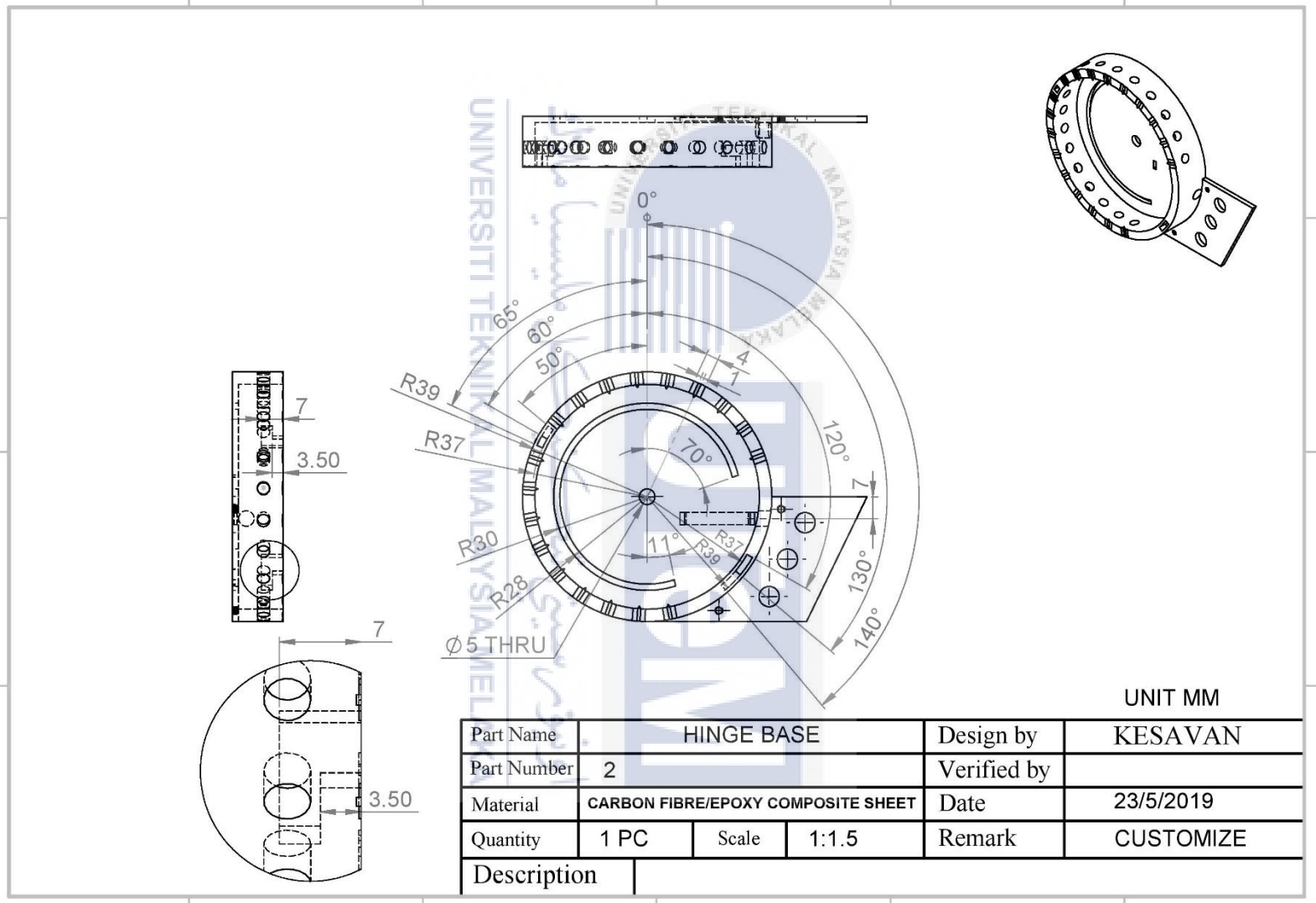
APPENDIX E: Dimensional drawing





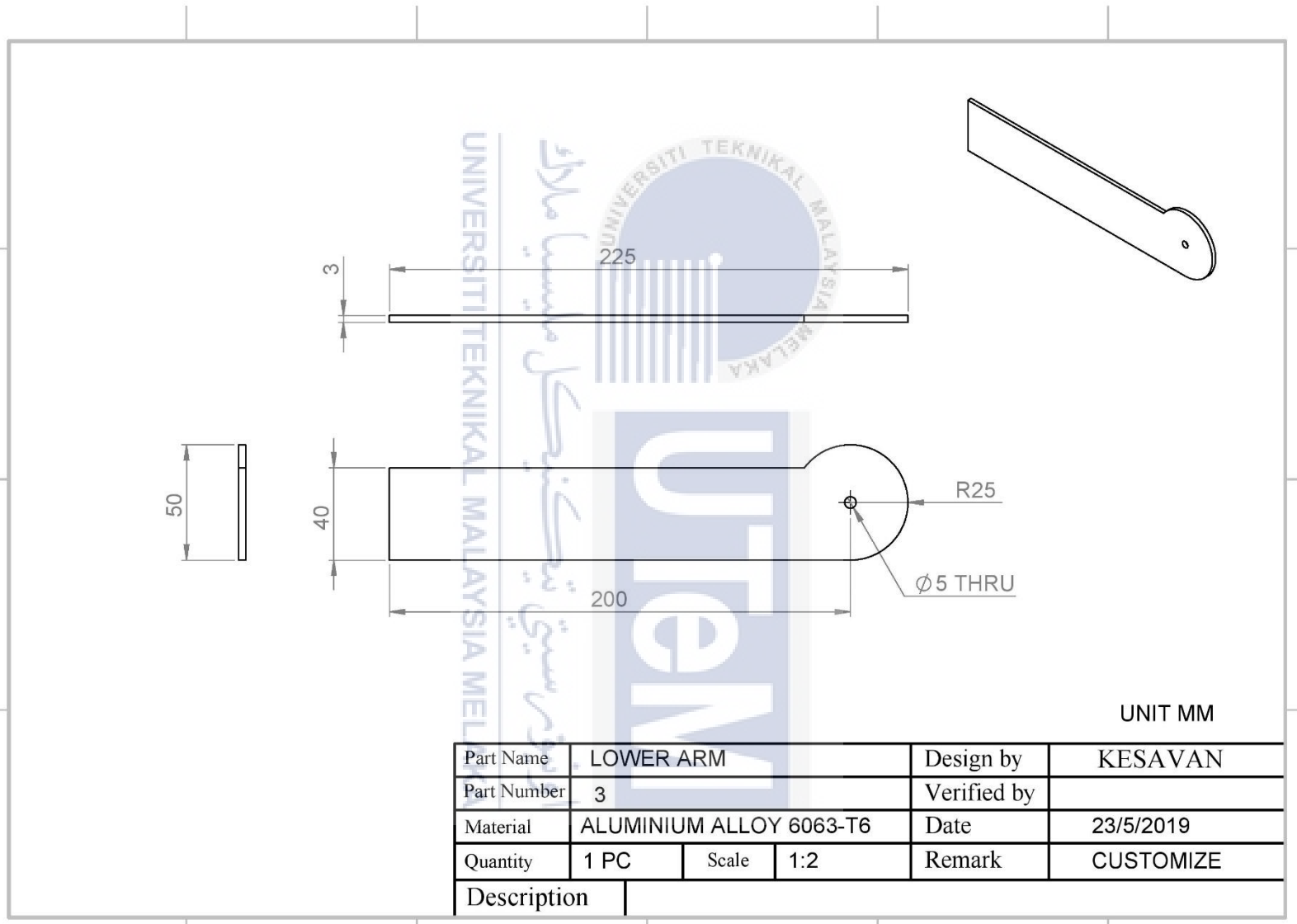
UNIT MM

Part Name	HINGE BASE			Design by	KESAVAN
Part Number	2			Verified by	
Material	CARBON FIBRE/EPOXY COMPOSITE SHEET			Date	23/5/2019
Quantity	1 PC	Scale	1:1.5	Remark	CUSTOMIZE
Description					



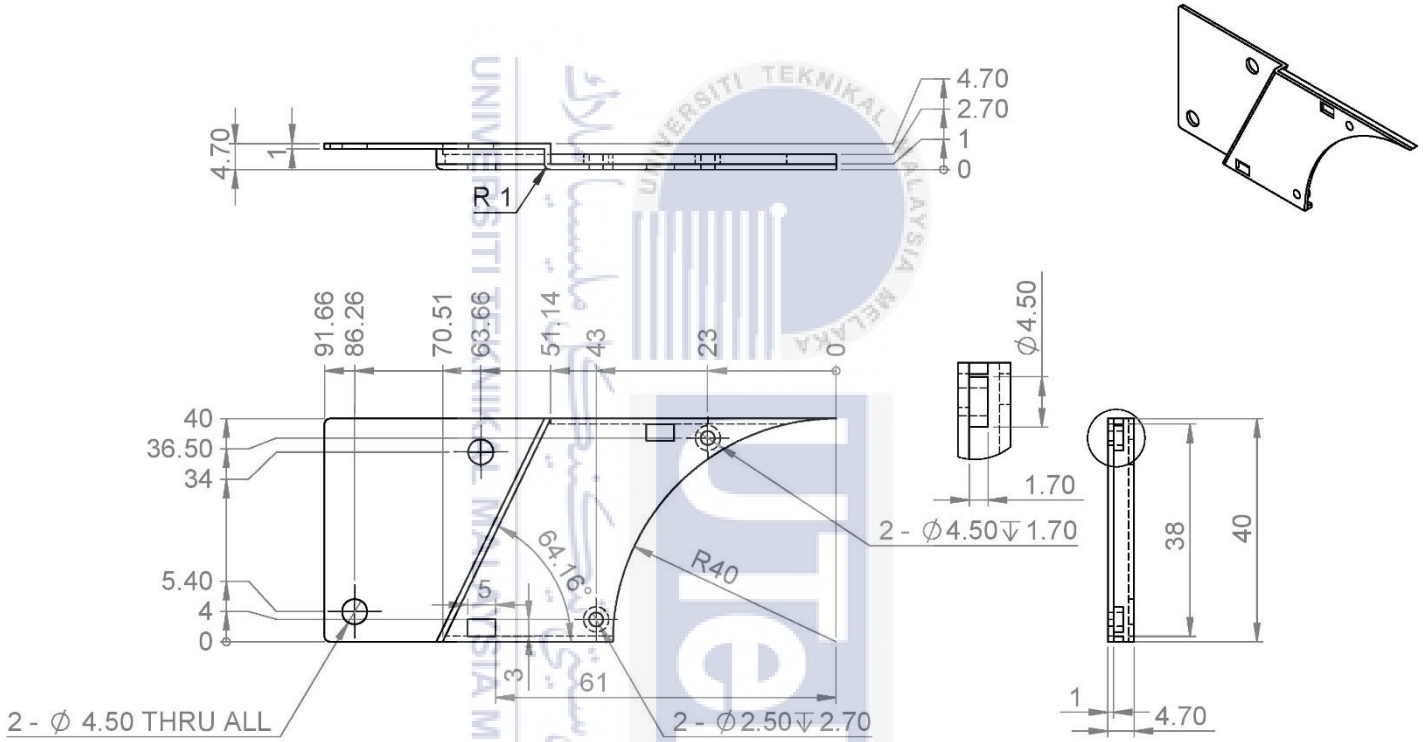
UNIT MM

Part Name	HINGE BASE			Design by	KESAVAN
Part Number	2			Verified by	
Material	CARBON FIBRE/EPOXY COMPOSITE SHEET			Date	23/5/2019
Quantity	1 PC	Scale	1:1.5	Remark	CUSTOMIZE
Description					



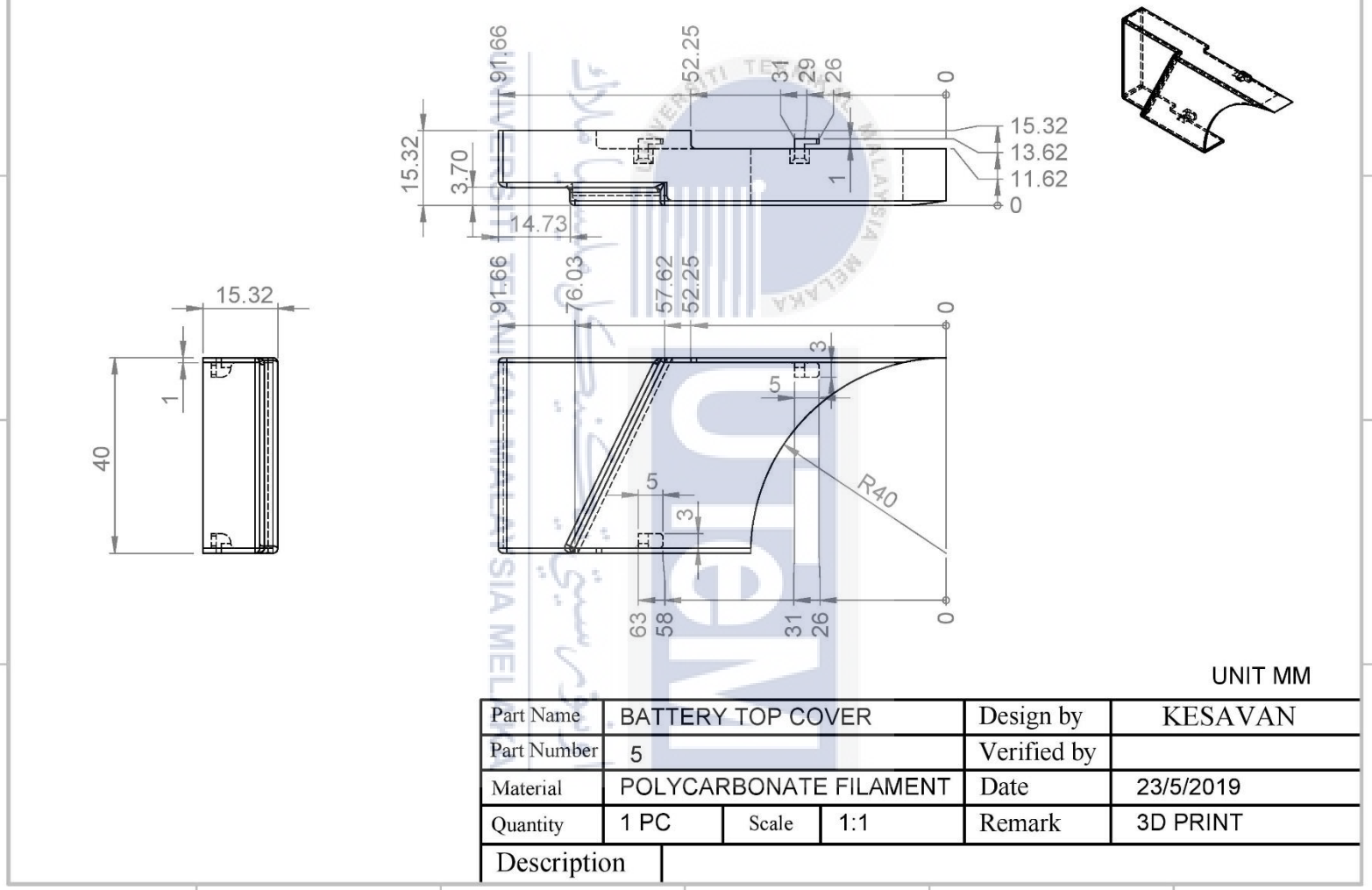
UNIT MM

Part Name	LOWER ARM			Design by	KESAVAN
Part Number	3			Verified by	
Material	ALUMINIUM ALLOY 6063-T6			Date	23/5/2019
Quantity	1 PC	Scale	1:2	Remark	CUSTOMIZE
Description					



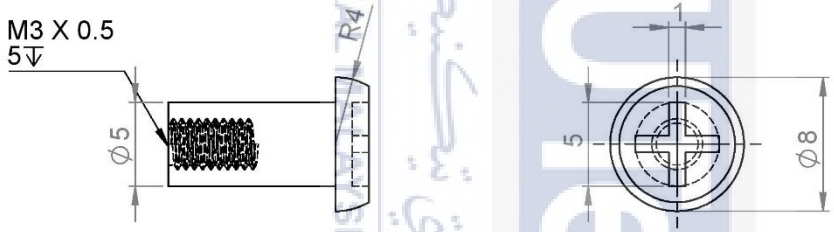
UNIT MM

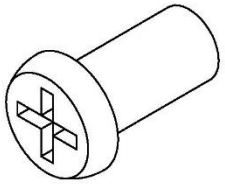
Part Name	BATTERY BASE COVER			Design by	KESAVAN
Part Number	4			Verified by	
Material	CARBON FIBRE/EPOXY COMPOSITE SHEET			Date	23/5/2019
Quantity	1 PC	Scale	1:1	Remark	CUSTOMIZE
Description					



UNIT MM

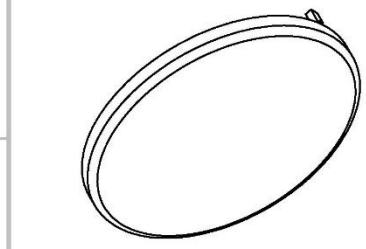
Part Name	BATTERY TOP COVER			Design by	KESAVAN
Part Number	5			Verified by	
Material	POLYCARBONATE FILAMENT			Date	23/5/2019
Quantity	1 PC	Scale	1:1	Remark	3D PRINT
Description					

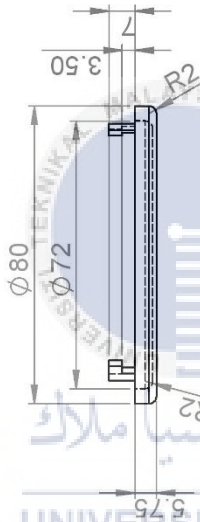


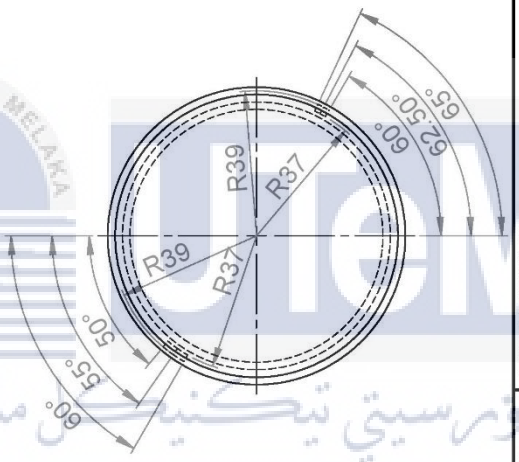


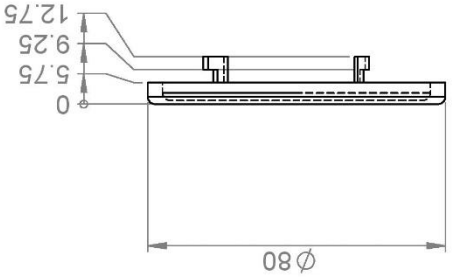
UNIT MM

Part Name	PIVOT SCREW			Design by	KESAVAN
Part Number	6			Verified by	
Material	AISI 347 ANNEALED STAINLESS STEEL (SS)			Date	23/5/2019
Quantity	1 PC	Scale	3:1	Remark	CUSTOMIZE
Description					



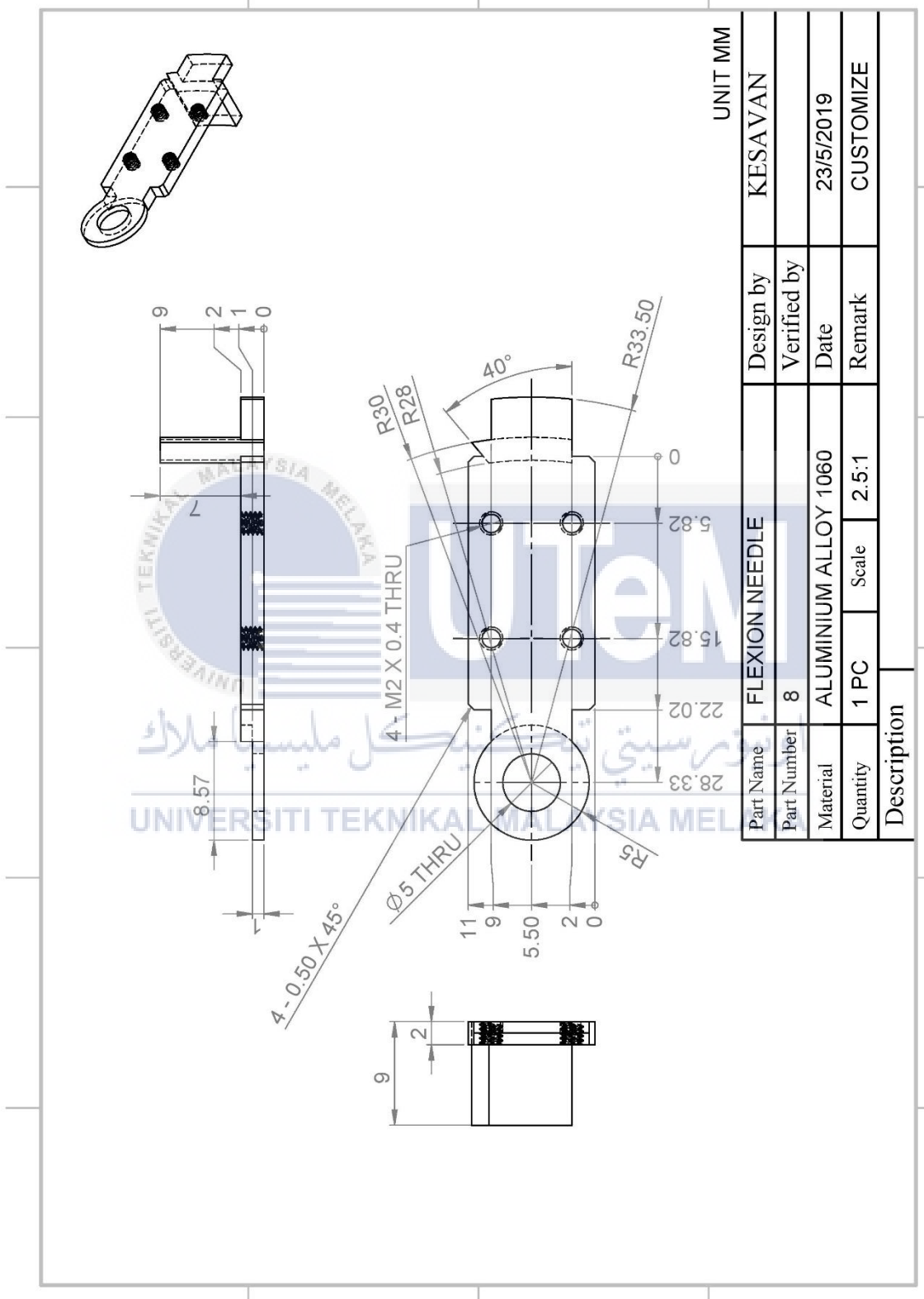


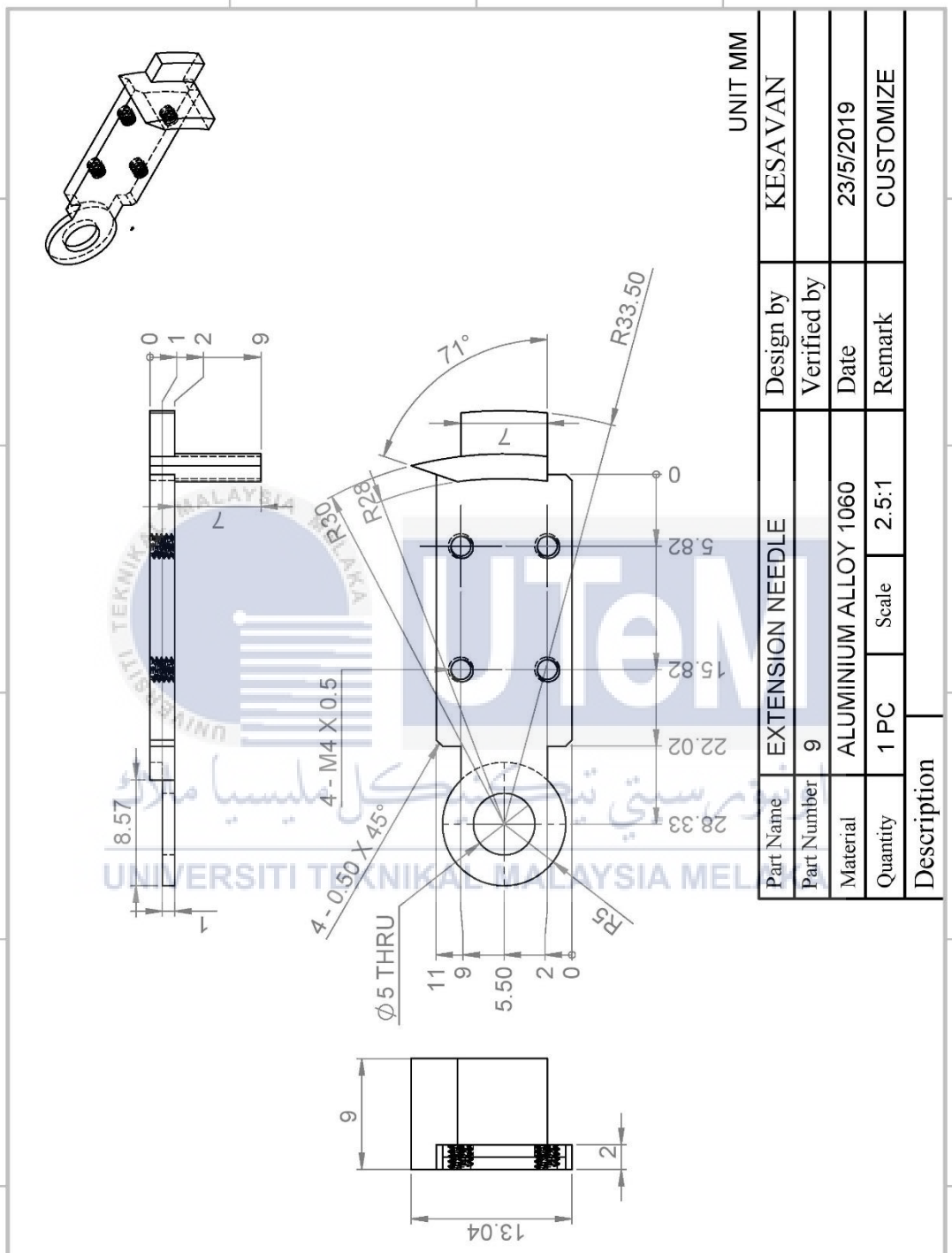


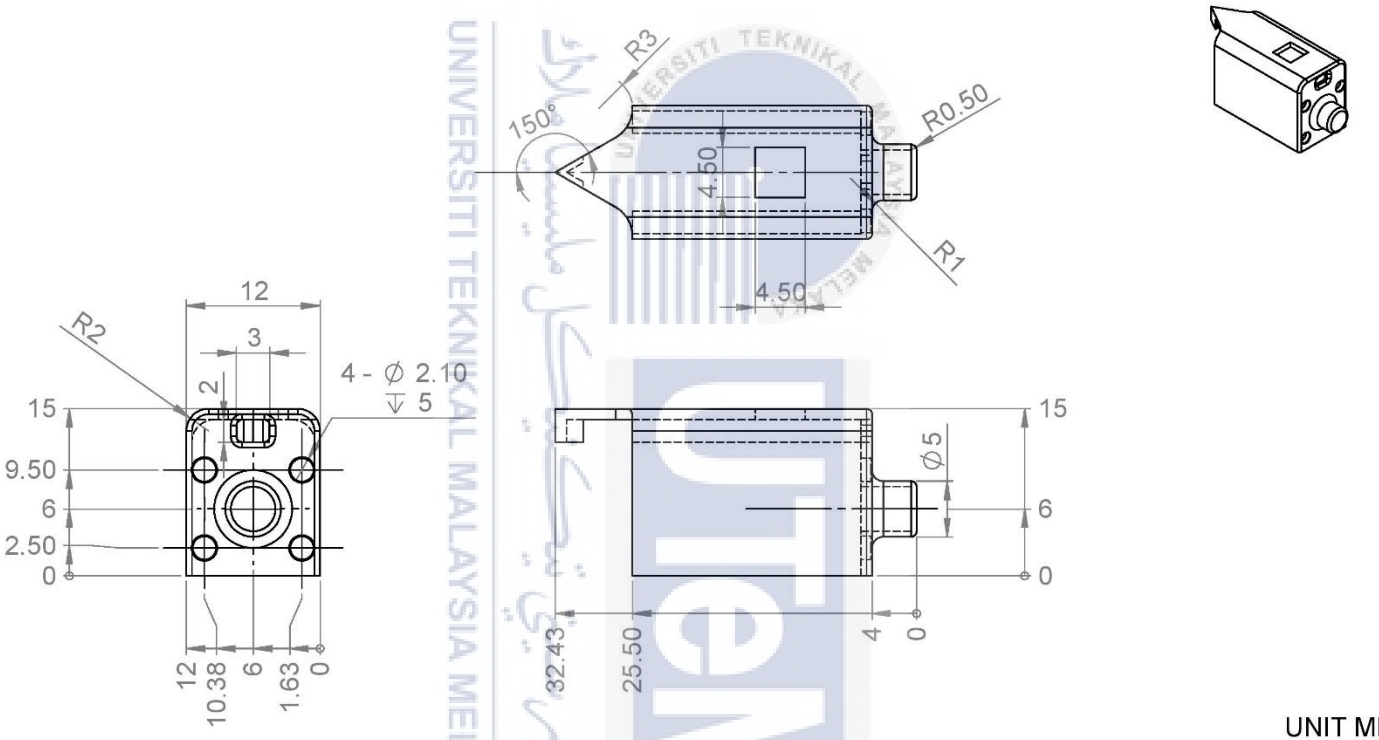


UNIT MM

Part Name	TOP COVER	Design by	KESAVAN
Part Number	7	Verified by	
Material	POLYCARBONATE FILAMENT	Date	23/5/2019
Quantity	1 PC	Scale	1:1.5
Description		Remark	3D PRINT

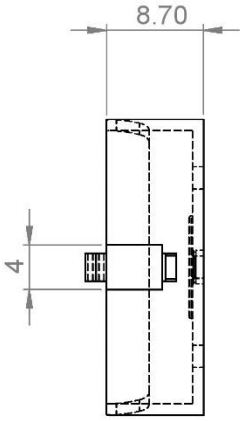


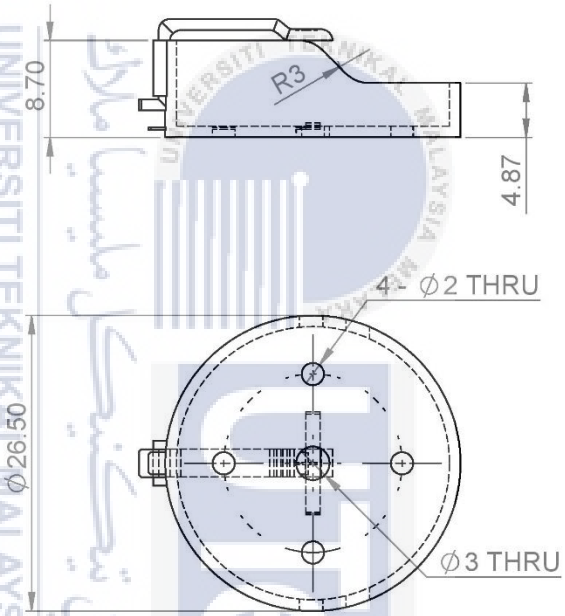


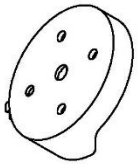


UNIT MM

Part Name	SOLENOID COVER			Design by	KESAVAN
Part Number	10			Verified by	
Material	POLYCARBONATE FILAMENT			Date	23/5/2019
Quantity	2 PCS	Scale	2:1	Remark	3D PRINT
Description					

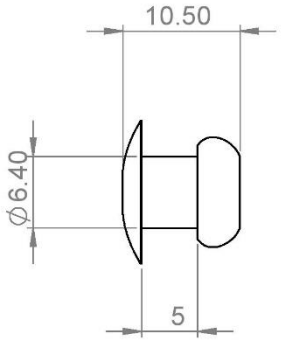


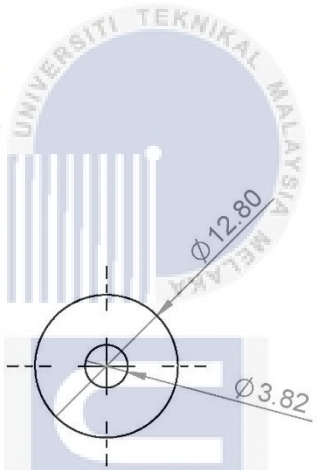


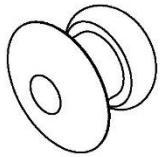


UNIT MM

Part Name	BATTERY HOLDER			Design by	KESAVAN
Part Number	11			Verified by	
Material	PBT, NICKEL-PLATED STAINLESS SPRING STEEL			Date	23/5/2019
Quantity	2 PCS	Scale	2:1	Remark	READY STOCK
Description	SPEC : CR2477 HOLDER, SUPPLIER: BATTERYHOLDERS.COM				

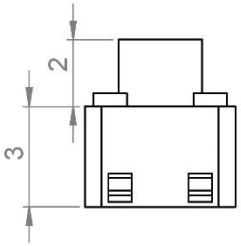


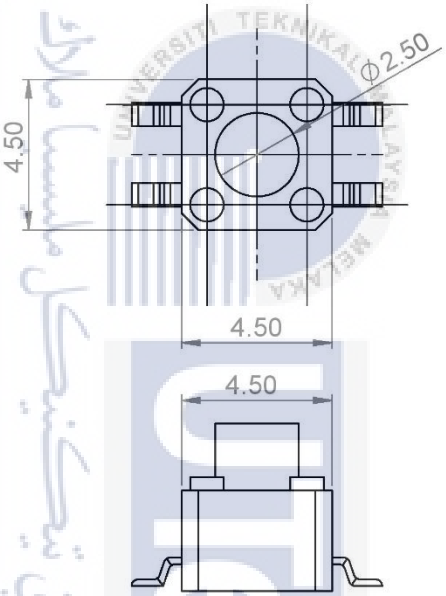


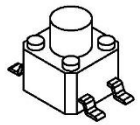


UNIT MM

Part Name	RIVET			Design by	KESAVAN
Part Number	12			Verified by	
Material	STEEL SWCH			Date	23/5/2019
Quantity	3 PCS	Scale	2:1	Remark	READY STOCK
Description	CODE : DSS84, BLIND RIVET - ROUND HEAD,SUPPLIER: FUKUI BYORA				

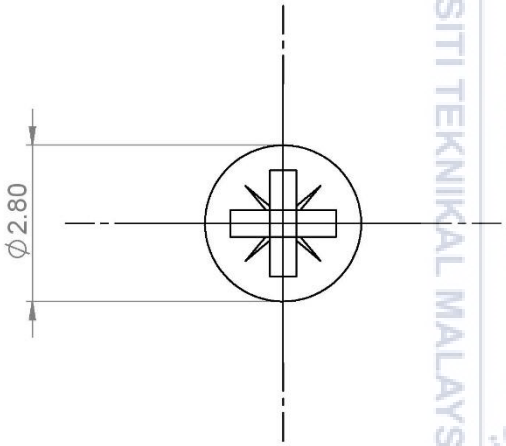


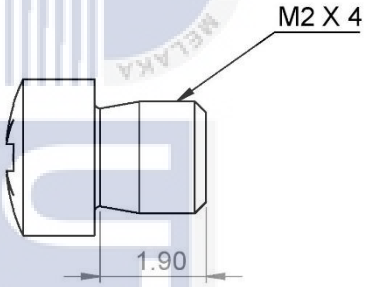


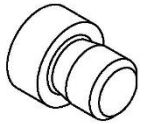


UNIT MM

Part Name	PUSH BUTTON SWITCH			Design by	KESAVAN
Part Number	13			Verified by	
Material	N/A			Date	23/5/2019
Quantity	2 PCS	Scale	6:1	Remark	READY STOCK
Description	TI3305 SerieS tact Switch (NORMALLY OPEN) SUPPLIER : E-SWITCH				

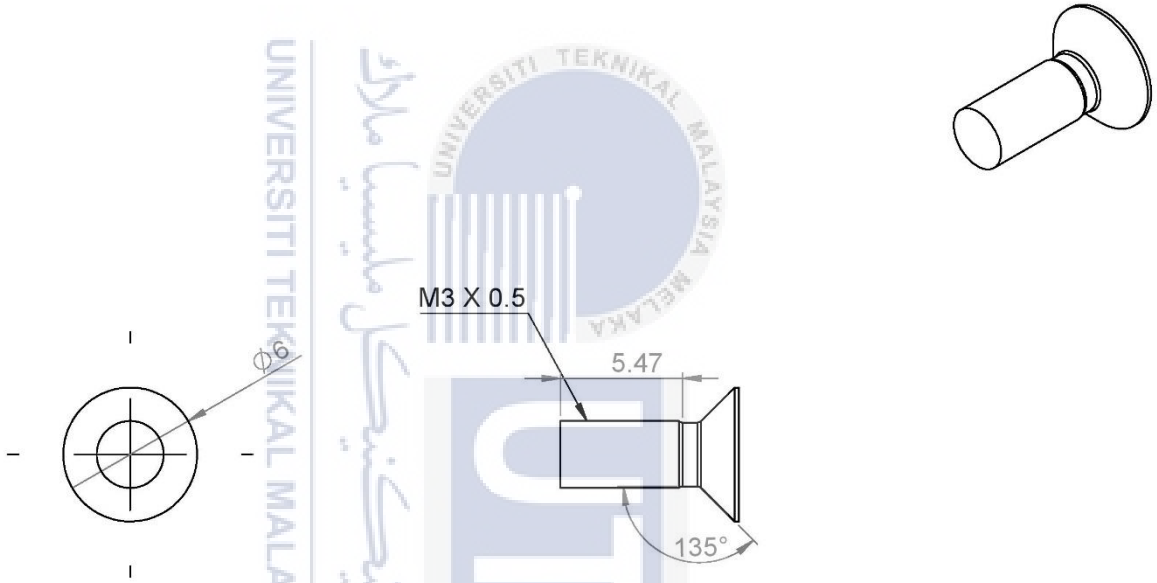






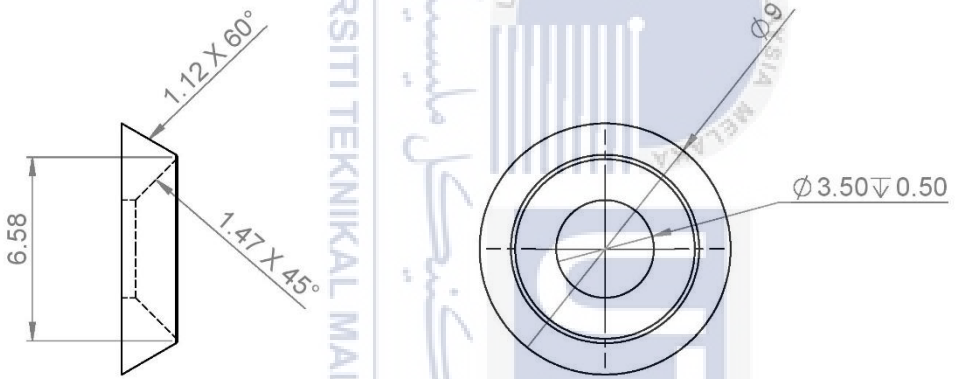
UNIT MM

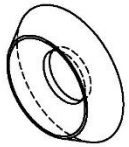
Part Name	M2 X 4 ROUND HEAD SCREW			Design by	KESAVAN
Part Number	14			Verified by	
Material	STAINLESS STEEL (FERRITIC)			Date	23/5/2019
Quantity	18 PCS	Scale	10 : 1	Remark	READY STOCK
Description	SUPPLIER : BENE INOX @ traceparts.com				



UNIT MM

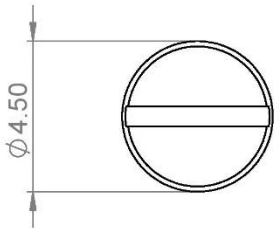
Part Name	M3 X 0.5 CSK HEAD SCREW			Design by	KESAVAN
Part Number	15			Verified by	
Material	STAINLESS STEEL (FERRITIC)			Date	23/5/2019
Quantity	1 PC	Scale	4:1	Remark	READY STOCK
Description	SUPPLIER : UNI @ traceparts.com				

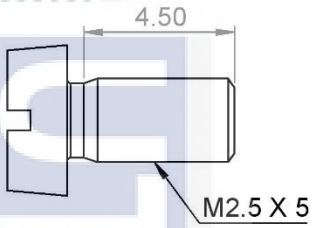


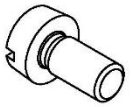


UNIT MM

Part Name	M3 WASHER			Design by	KESAVAN
Part Number	16			Verified by	
Material	STAINLESS STEEL (FERRITIC)			Date	23/5/2019
Quantity	1 PC	Scale	5:1	Remark	READY STOCK
Description	SUPPLIER : BENE INOX @ traceparts.com				

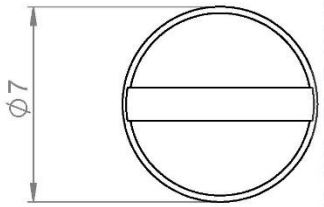


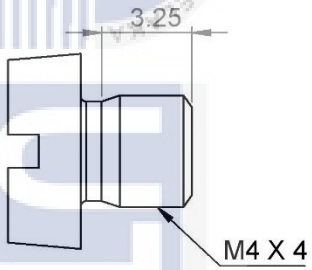




UNIT MM

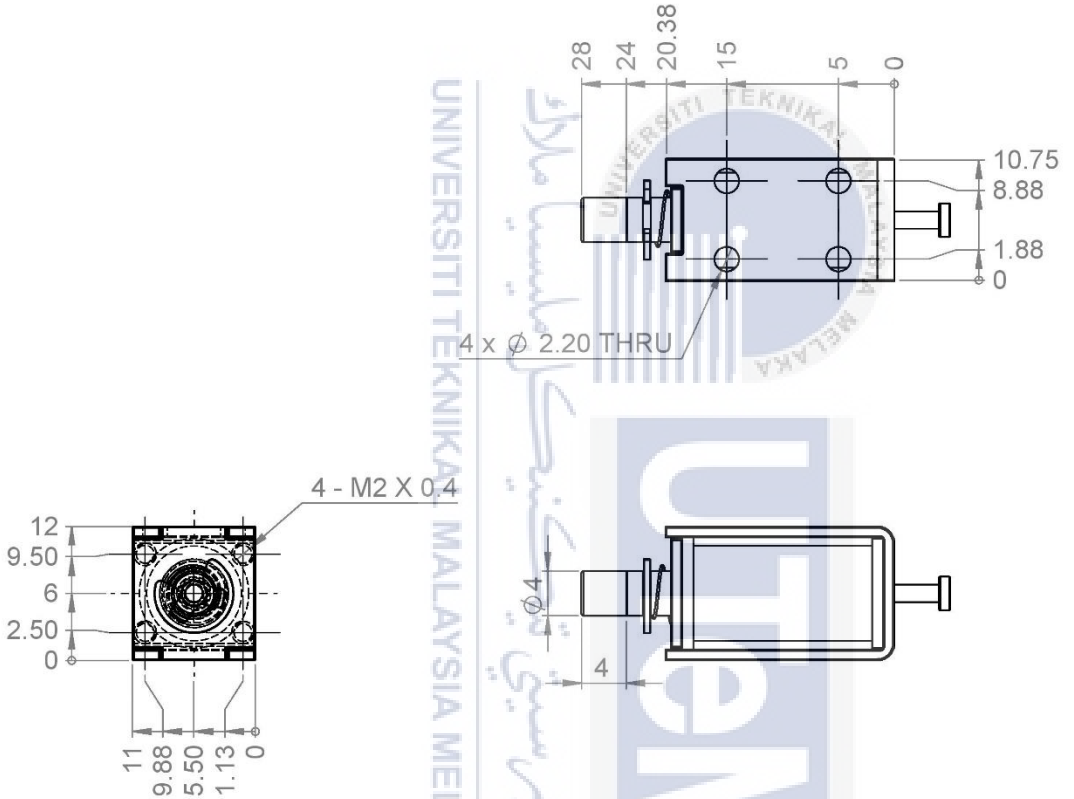
Part Name	M2.5 X 5 ROUND HEAD SCREW			Design by	KESAVAN
Part Number	17			Verified by	
Material	STAINLESS STEEL (FERRITIC)			Date	23/5/2019
Quantity	2 PCS	Scale	6:1	Remark	READY STOCK
Description	SUPPLIER : BENE INOX @ traceparts.com				





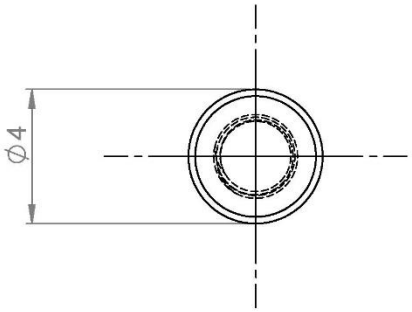
UNIT MM

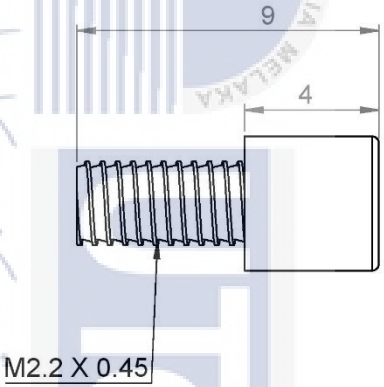
Part Name	M4 X 4 ROUND HEAD SCREW			Design by	KESAVAN
Part Number	18			Verified by	
Material	STAINLESS STEEL (FERRITIC)			Date	23/5/2019
Quantity	2 PCS	Scale	5:1	Remark	READY STOCK
Description	SUPPLIER : BENE INOX @ traceparts.com				



UNIT MM

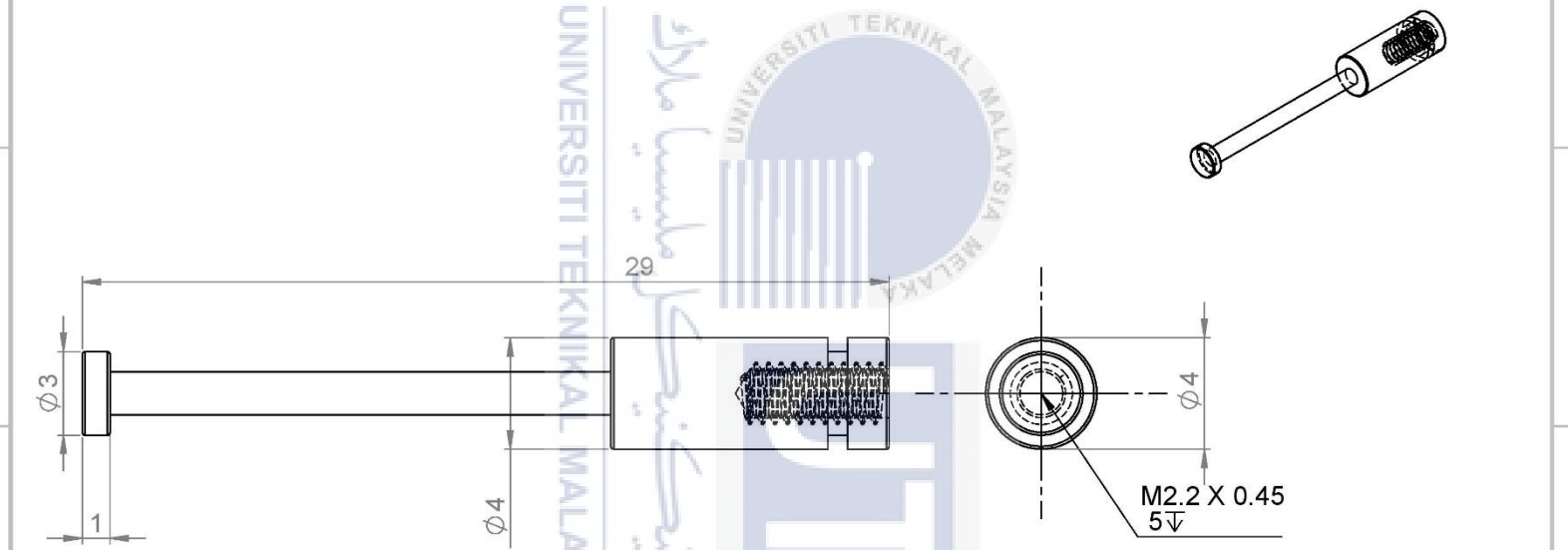
Part Name	SOLENOID			Design by	KESAVAN
Part Number	19			Verified by	
Material	AISI 347 ANNEALED STAINLES			Date	23/5/2019
Quantity	2 PCS	Scale	2:1	Remark	READY STOCK
Description	SPEC : 5V, 1.1A SUPPLIER : www.adafruit.com/product/2776				





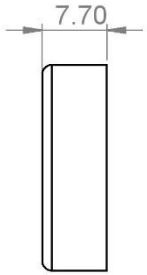
UNIT MM

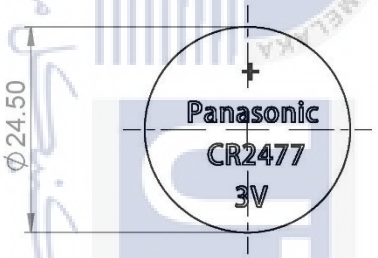
Part Name	LOCK SHAFT			Design by	KESAVAN
Part Number	20			Verified by	
Material	AISI 347 ANNEALED STAINLES			Date	23/5/2019
Quantity	2 PCS	Scale	6:1	Remark	CUSTOMIZE
Description					



UNIT MM

Part Name	SOLENOID SHAFT			Design by	KESAVAN
Part Number	21			Verified by	
Material	AISI 347 ANNEALED STAINLES			Date	23/5/2019
Quantity	2 PCS	Scale	5:1	Remark	RS MODIFIED
Description					





UNIT MM

Part Name	CR2477 LITHIUM BATTERY			Design by	KESAVAN
Part Number	22			Verified by	
Material	**LITHIUM MANGANESE DIOXIDE**			Date	23/5/2019
Quantity	2 PCS	Scale	1.5:1	Remark	READY STOCK
Description	SPEC : 3V , 1000MAH SUPPLIER : PANASONIC				