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DESIGN OF INSTRUMENT FOR KNEE JOINT KINEMATICS MEASUREMENT

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ABSTRACT

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This thesis describes the process of design and modeling of instrument for knee joint kinematics measurement that can work for both in-vivo and in-vitro subjects. It is designed to be compatible with imaging machine in a sagittal plane. Due to the invasiveness of the imaging machine, the instrument is designed to be able to function independently. The flexibility of this instrument allows to measure anthropometrically different subject.

Among the sixth degree of freedom of a knee, three rotational and one translational degree of freedom can be measured for both type of subject. The translational, proximal-distal, motion is stimulated by external force directly applied along its axis. These angular and linear displacements are measured by magnetic sensors and high precision potentiometers respectively.

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LIST OF ABBREVIATIONS

ACL	Anterior Cruciate Ligament
DFIS	Dual Fluoroscopic Imaging System
EMG	Electromyography
FCL	Fibular Collateral Ligament
KKS	Kansas Knee Simulator
PCL	Posterior Cruciate Ligament
TCL	Tibial Collateral Ligament
VIS	Video Imaging System
UFS	Universal Force Sensor
Kg	Kilogram
m	meter
Ls	lump sum
Pcs	pieces

1 INTRODUCTION

Knee joint is the biggest and complex joint in human body. It is located at the middle of the leg as depicted in Figure 1. The joint comprises of bones, ligaments, muscles and capsule. Each element of the joint plays a unique and vital role for proper function of the leg. Bones provide structural support for the body while muscles produce movement. Ligaments, on the other hand, control the extent of movement. The function of capsule is to produce synovial fluid that works as lubrication for the knee to ease the movement. The harmony of these elements allows flexion and extension movement between the upper and lower leg. In addition, slight rotational and lateral movements are possible [1, 2].

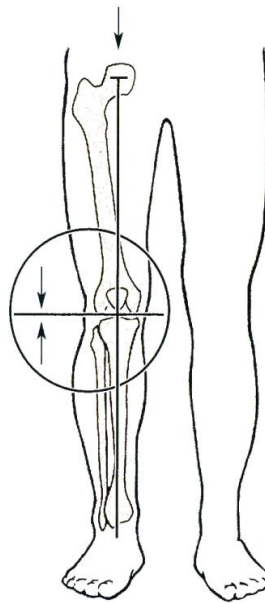


Figure 1: Location of knee joint in human body [1]

Due to configuration, condyle type, of bone surfaces at knee, the movement allowed is unique. Besides the first functional role of knee joint which is allowing movement, it provides stability. But, this configuration of the bone causes the joint to be mechanically weak; as a result stability is achieved by other elements of the joint such as muscles and their tendon, ligaments and menisci. During stabilization, it should be able to absorb the force created by

the weight of the body and the counter reaction force of the ground during different activities [1, 3].

Biomechanics is the study of mechanics on biological system like human body. It can be studied in two ways, either by qualitatively or quantitatively. Studying the movement in non numeric terms is qualitative approach. This is a method where measurement does not involve but is done by close observation. Analysis and evaluation of the movement follows after the observation. This method gives important information however it produces subjective result. Quantitative approach, on the other hand, uses numeric value to describe the movement of the body. This approach needs measuring instrument to provide numeric values for analysis and evaluation [4, 5].

Instruments used to measure human movement have been developing. This development allows to study detail characteristics of movement that cannot be discerned by observation. As the knee joint has six degree of freedom, studying the kinematics and kinetics need to be supported by measuring instrument to collect accurate data. The analysis and evaluation of this data provide information that is useful for finding solution for disorder, injuries and disease related to the joint in a better and efficient way [4]. In addition, these data are used to validate computational model which represent individual patients. The clinical applicability and usability of modeling is increasing, because it is used to explore different treatment options [6].

The objective of this research is to design an instrument that can be used clinically to measure kinematics of knee joint. The research has two limitations: firstly, the designed instrument does not able to measure all the motion of the knee. And secondly, the fixture used to hold the tibia produce inertia force which affects the magnitude of motion.

This thesis is organized in such a way that the research objective is met. Section one covers the introduction of the research. In section two: brief description of knee anatomy and its mechanics that is kinematic and kinetic behavior of the joint is discussed. It shows the

theoretical background of the thesis work. In section three: measurement instruments that are used to date are presented and discussed. These instruments may be applied for in-vivo or in-vitro subject. At the end of the section the summary of these the instruments are presented in the form of comparison using main criteria like accuracy and functionality. In the fourth section: the engineering design procedure followed to meet the objective and the design requirement is presented. In the fifth and sixth section, detail of the instrument design options and their evaluation, and measuring means are discussed respectively. A brief model of the instrument is presented in picture in section seven. In the last two sections, section eight and nine, manufacturing cost estimation and conclusion is presented respectively.

2 BIOMECHANICS OF KNEE JOINT

The union of bones of the body forms joints. These articulations enable body to move. In human body, there are three different types of joints. These are: synarthrosis, ampiarthrosis and diarthrosis. Synarthrosis joint did not allow any mobility but ampiarthrosis allows slight movement whereas diarthrosis permits free movement. Knee joint is the biggest and complex diarthrosis or synovial joint [1, 2]. It is primarily a hinge joint combined with gliding, rolling, and rotation [2]. Because of the anatomy of knee, the kinematic produced is unique. Studying this motion needs an application of principle of mechanics. Area of study where the principles of mechanics are applied to biological system is called biomechanics [4]. In the following subsection the anatomy of the knee joint and its biomechanical characteristics will be discussed.

2.1 Anatomy of Knee

Anatomical components of knee joints are bones, ligaments, muscles and cartilages. Bones that form this joint are femur, tibia and patella. Femur is the longest bone in human body which is located at the upper leg and it is slant medially at the knee, which means the anatomical axis and mechanical axis of femur forms an angle. The mechanical axis of a femur aligned from the center of knee to hip joints. On the other hand, the lower bone of the leg,

tibia, is almost vertical. Patella or knee cap is located at the middle protecting the anterior of the joint [1, 2]. Figure 2 shows arrangement of bones of knee joint.

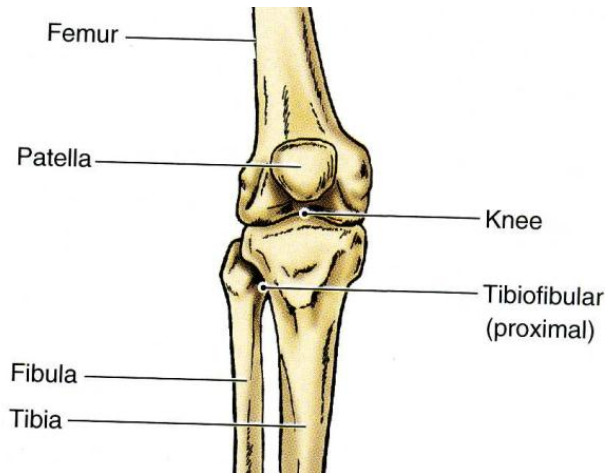


Figure 2: Structure of knee joint [1]

The articular surfaces at the junction of the joint have condyle features. The femoral and tibial condyles articulate each other forming the joint. Each bone has three condyle areas these are lateral, medial condyles and intercondylar. Anteriorly, the femoral condyles unite with patellar surface at a fossa of femur to articulate with the patella. The union between femur and tibia is tibiafemoral or femorotibial joint and between femur and patella is patellofemoral or femoropatellar joint [1, 3].

These bones are connected by ligaments. Internal ligament of the knee joint are anterior and posterior cruciate ligament. These ligaments, crisscrossing each other, are located at the center of the joint while joining femur with tibia. The anterior cruciate is attached to anterior of tibia to posterior of femur and posterior cruciate is attached to posterior of tibia to anterior of femur [4]. Anterior cruciate ligament (ACL) slacks in flexion and taut in extension preventing the joint from hyperextension of the joint. The stronger of the two ligaments, posterior cruciate ligament (PCL), tighten during flexion and protect the joint from hyperflexion [1].

In addition to the internal ligaments there are also external ligaments connecting femur and tibia called tibial collateral ligament (TCL) and fibular collateral ligament (FCL). TCL is located at the medial side of knee joint. It extends from the medial epicondyle of the femur passing downwards and slightly forwards to attach to the medial condyle of the tibia. FCL is located at the lateral side of knee joint and extends from lateral epicondyle of the femur and pass down to attach to the head of fibula. These ligaments control the varus and valgus rotation [2, 3].

Patella is also connected with femur and tibia with a ligament called patellar ligament. It is a continuation of quadriceps tendon passing from the apex of patella to the tibial tuberosity. This ligament stabilizes the knee anteriorly. Posteriorly, the joint stabilized by an oblique ligament attached from lateral posterior femur to medial posterior tibia which is called popliteal ligament [2].

Between femur and tibia there are fibrocartilage called menisci [1]. A meniscus lies on the surface of a tibia and acts like load distributor [7]. A meniscus has two parts called medial and lateral meniscus. They are connected with each other by transverse ligament [2]. The location and the arrangement of these ligaments are shown in Figure 3 [6].

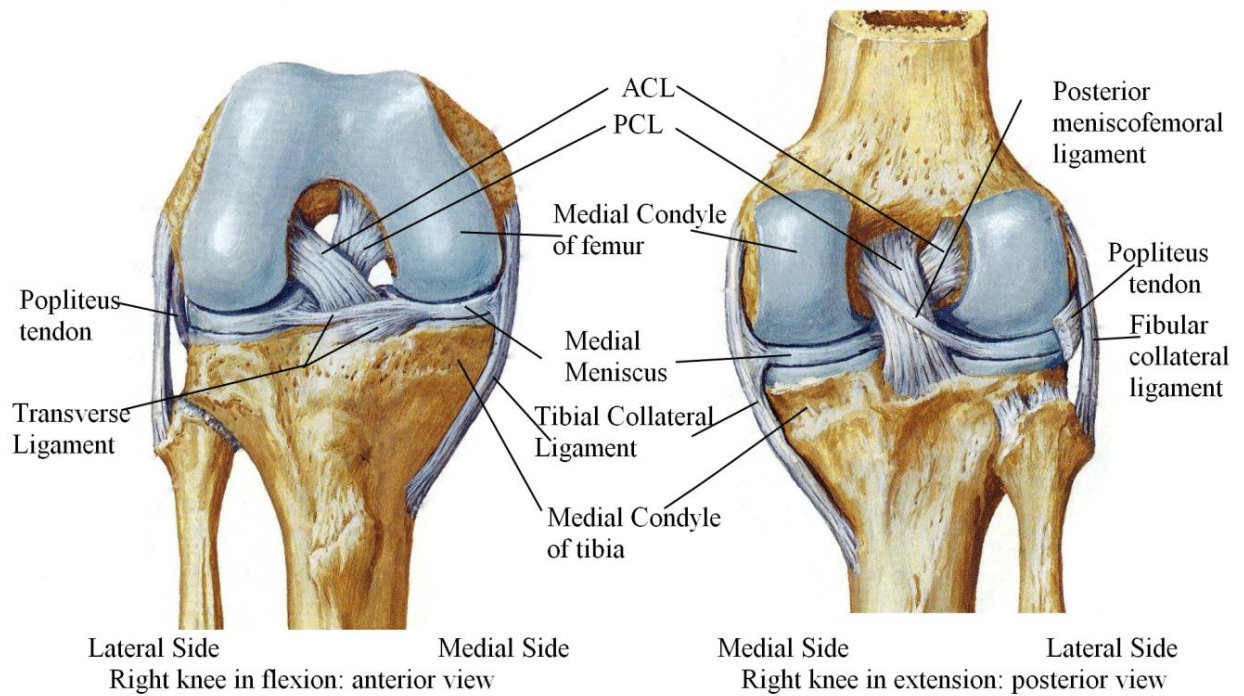


Figure 3: Arrangement of ligaments of knee (edited)[6]

Bones are pulled by muscles to produce movement. Muscles are connected with bones by tendon. The biggest, four headed, muscle in front of thigh responsible for extension movement is quadriceps. These are rectus femoris, vastus intermedius, vastus medialis and vastus lateralis muscles. Hamstring muscle is located at the back of knee and responsible for flexion motion. It refers to three muscles these are semitendinosus, semimembranosus and biceps femoris. These muscles and their relative locations are depicted in Figure 4 [8]. On the other hand, the tibial internal-external rotational motion is controlled by popliteus muscle [1]. Popliteus muscle is located at the back of the joint. The tendon of this muscle is shown in Figure 3 above. The activity of these or any other muscle of biological system is controlled by its nerves system.



Figure 4: Muscles at knee joint (edited)[8]

2.2 Knee Kinematics

In engineering mechanics, the area of study is divided into two, namely statics and dynamics. Statics is concerned when the state of the body is at rest or moving with constant velocity. Dynamics, on the other hand, deals with the accelerated motion of a body. Further, dynamics is classified into kinematics and kinetics.

Kinematics is the area of study of motion of a system without considering its cause. Kinematics of a motion is expressed by three parameters. These parameters are displacement, velocity and acceleration where each has a mathematical relation to each other irrespective of the type of path. The path of the motion can be linear or circular, or a combination of the two. The number of independent parameters that are needed to define its position with respect to a selected frame of reference in space at any instance of time is equal to the degree of freedom (DOF) of a system [5, 9].

In mechanism of a system, two or more bodies are involved for the purpose of transferring motion from the source to the output. These bodies are connected by joints where relative mobility exists. Defining this relative mobility is performed by the principle of kinematics of a mechanism [9]. With this respect, lower extreme of human body can be considered as having two bodies linked by the knee joint. The upper leg (thigh) and the lower leg (shank) are the two bodies and they have a relative mobility between them.

Knee joint, as a mechanism, has six degrees of freedom: three rotations and three translations. These motions occur about and along three axes: the tibial shaft axis, the epicondylar axis, and the anteroposterior axis. Each of these axes is perpendicular to each other. The three rotational motions are internal-external, extension-flexion and abduction-adduction (varus-valgus), and the three translational motions are distraction-compression (proximal-distal), anterior-posterior drawer and medial-lateral shift. These axes and motions are depicted in Figure 5 [10, 11].

The basic shapes of the bones at the joint essentially only allow movement in one plane that is flexion and extension. Internal and external rotation or twisting motion between the femur and tibia occurs when the intercondylar eminence of the tibia act as a pivot while lodging in the intercondylar notch of the femur. Because of the anatomical axis of femur, the force applied to the tibia can be resolved into vertical and horizontal component. The horizontal component will tend to tilt the joint widening the medial joint interspace creating a rotation called varus and valgus which is the third type of rotation that occurs in knee joint [4]. The translational motion, on the other hand, occurs mostly because of the sliding behavior of the joint. In addition, the space between the two bones and the shock absorbing characteristics of menisci allows such movement [5].

These movements are governed by knee ligaments. Due to the anatomy of knee, specifically collateral ligaments, the abduction-adduction motion is limited to approximately 5° whereas internal-external rotation and flexion-extension are much greater at approximately 35° and 150° , respectively. With respect to translation motion, 2.3 mm medial tibial shift, 1.5 mm

lateral tibial shift, 3.6 mm posterior drawer, and 1.3 mm displacement from the neutral position occurs during different instance of walking [11].

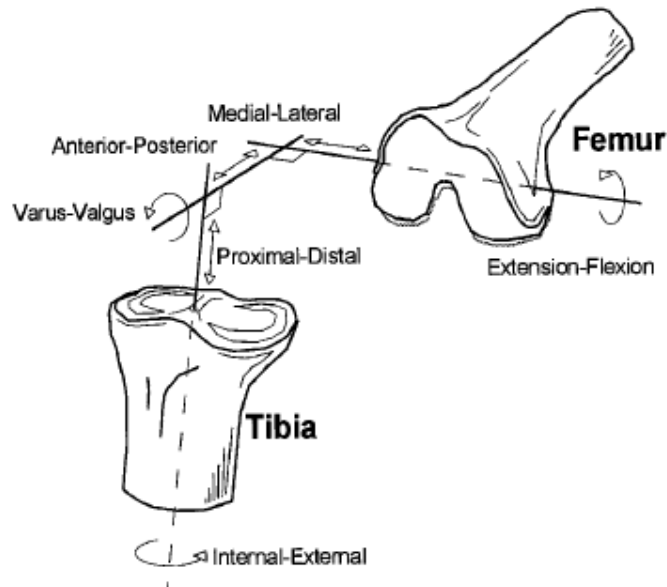


Figure 5: Motion of knee and respective axes [10]

2.3 Knee Kinetics

Unlike kinematics, kinetics is a study of the motion of the system with regard to its causes, namely force, torque, momentum, and energy. The second law of Newton state that a body continues in a state of rest or uniform motion unless acted upon by a net external force. Kinetics of motion is all about studying this force over a period of time or a displacement gained because instantaneous force does not give enough information. Observing a force with respect to elapsed time is known as mechanical impulse and observing it with respect to the distance through which it acts is the work done or is kinetic energy [5].

In case of kinematic chain, bodies linked by joints, it is important to know forces are transmitted from one body to the other or from input to output. Newton third law is an important tool for this analysis which says for every action there is equal and opposite reaction

force. It is through this transfer of force and energy from one link to the other movement of a mechanism possible.

In biomechanics, the sources of forces to generate a motion are muscles. Muscles are molecular machines that convert chemical energy into forces. As a result of the existence of muscle, the motion in a knee is not only in the direction of the external force but also occurs naturally in other translational and rotational directions. External forces can be gravitational and friction force, as well as any force applied to the leg. For example: an impact reaction force of a floor because of jumping can be considered as an external force [5, 10].

Knee joint forces acts on both femorotibial and femoropatellar part of the joint. Femorotibial joint force during level walking can reach five times body weight but usually between two and four times body weight. In similar circumstances, femoropatellar joint force is in the order of half body weight. In the case of ascending and descending ramps and stairs, femoropatellar joint forces increase significantly to between one-and-half and two times body weight. In contrast, this has little influence on femorotibial forces [3].

To produce force, muscles work in three ways: as accelerator, as decelerator and as stabilizer. To act as an accelerator, it always contracts concentrically or shortens during force production whereas when it acts as decelerator and as stabilizer, it contracts eccentrically or lengthens during force production and act isometrically or without significant change in length; respectively. In concentric contraction, the muscular force and the contraction distance are the same directions as a result positive work being done to increase the mechanical energy. Activities like lifting and uphill walking are done by this way of contraction. On the other hand, activities like sitting down and letting an object down slowly is performed by eccentric muscular contraction where the force and the motion occur are in opposite direction. This work is done to decrease the mechanical energy. In the third type of contraction that is isometric contraction because there is no change in the length of muscle no mechanical work is done [5, 12]. Figure 6 shows the accelerating and stabilizing component of knee muscles [4].

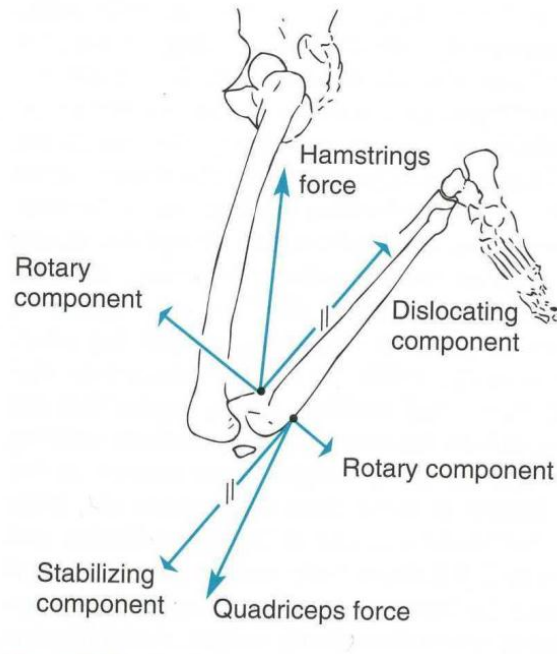


Figure 6: Effect of quadriceps when hamstrings are acting to flex the knee [4]

3 KNEE MOTION MEASURING INSTRUMENTS

Motion measurement has been an important method to quantify, study, and solve movement related disorders. To solve these problems related data should be collected. Until the mid-nineteenth century visual observation has been the sole tool to provide these data [13]. Over the years, different methods and instruments were developed to measure the dynamics of the movement in *in-vivo* and *in-vitro*. Studying these instruments has different advantages. For example, it will give an opportunity to have an overall idea of existing up to date measurement system, and it provides an insight for the design at hand.

Among a wide variety of instrument and systems only some of them are discussed below. For simplicity of discussion these instruments are grouped by their frequent application. This means some instrument can be customized easily to work for both the gait analysis and cadaveric subject measurement; and so grouping is done according to its frequent application. Accordingly, video imaging system, fluoroscopic imaging system, optoelectronic tracking

systems are grouped in instruments for gait analysis, and knee simulator and robotic testing system are grouped in cadaveric measurement systems as they are functioned for cadaveric or prosthetic test. The last group is laboratory customized instrument. Under this group, instruments that are designed by laboratories to perform a specific objective of their own are categorized. Instruments under this category cannot be generalized and used for other objective; for the sake of clarity examples are given. At the end of this section a brief comparison between instruments is presented.

3.1 Systems and Instruments for Gait analysis

Over the past years instrumented gait analysis has emerged as a powerful tool in research. It has advanced in understanding the normal gait by identifying and quantifying the biomechanics [14]. Physicians and physical therapists diagnose health problems which manifest in gait analysis. In addition, the same procedure is implemented for pre-rehabilitation planning and after rehabilitation evaluation to look into the difference between those states [15]. With this respect, instruments used to quantify the biomechanics of human movement are discussed below. These instruments are applicable to analysis the knee joint movement.

3.1.1 Video Imaging System

Motion can be studied using sequential images whereby each image shows the progressive change in the motion. One way of getting these images is video imaging system (VIS). Before the development of videography technology, cinematography was used to capture the image. Due to its relatively low cost and immediate result in color, videography replaces cinematography in most applications of motion study. In addition, in videography, the setting of the picture, for example brightness, contrast and focus, can easily be adjusted before data collection begins [4, 16].

Data collection using VIS is performed in such a way that reflective marker will be placed on the subject, as in the case of human on the skin. The markers will be identified by video

cameras which capture the motion. This can be done in one or more cameras with a frequency range of 60-250HZ depending on the accuracy needed [17, 18]. The analysis of the data is then performed. The common assumption in the analysis is to model human limbs as rigid segments linked together by joints as shown in Figure 7 [17, 19]. At the point of marker, data like joint angle, displacement, velocity, and acceleration will be analyzed. Computer can be applied to digitize and analyze so as to reduce error [18]. Recently, it is possible to track skin markers and digitize automatically, for example Vicon and ProReflex motion capture system are commercially available [17].

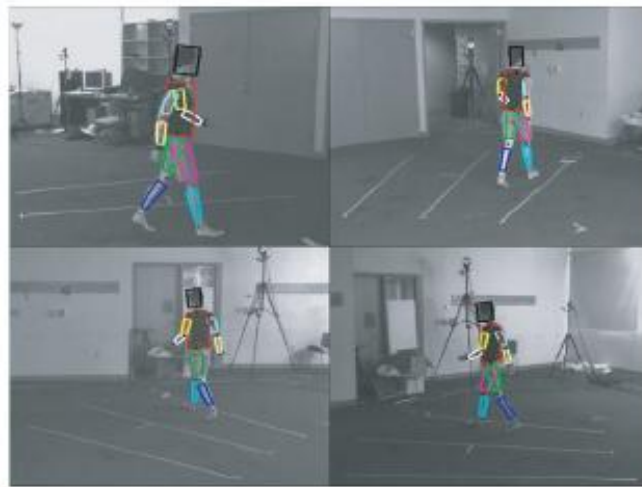


Figure 7: 3D body model as obtained by Vicon system [17]

The accuracy of VIS is not only influenced by the quality of the image and the number of camera used but also the skin movement. The accuracy is affected by the skin movement because the markers are placed on the surface of the skin. In locomation the skin moves relative to the bones which create an error to get the exact movement of the bones [11, 20, 21]. Among commercial available VIS, the accuracy of Vicon system is reported to be 2 mm during translation and 0.5° during rotation [22, 23].

3.1.2 Optoelectronic Tracking System

A number of motion tracking technologies have been developed to capture the motion of human in order to collect data related to motion including optoelectronic, magnetic, and sonic & ultrasonic tracking systems. Among these optoelectronic system is the most common which works based on the emission and detection of infrared or visible light [24]. This is made possible by different markers, either by active or passive markers. Cameras are used to detect the markers. If the marker is active the camera will be passive or vice versa [25]. Unlike video imaging system in optoelectronic tracking system, the tracking and video recording is only for the markers which do not include the body [4].

The cameras detecting the markers record the coordinate's location of the marker placed on the subject's body. The digitization of the location of the marker is performed by computer microprocessor automatically. Operator is needed only when an overlap occurs between markers during the movement of the subject [4].

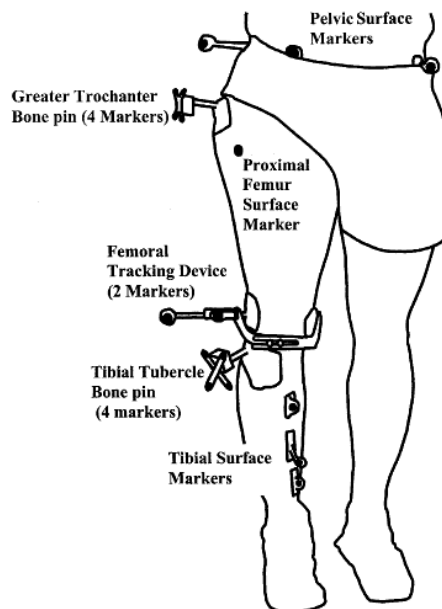


Figure 8: Placement of bone and surface mounted markers [26]

The markers will be mounted in two ways: either on the surface of the skin or on the bone by the help of bone pin as illustrated in Figure 10 above [26]. If the markers are on the surface of the skin the accuracy will be affected by the skin and soft tissue movement but in the case of the second method, using bone pin, the accuracy is improved. However, due to pin vibration, bending of pin and pin loosening; there are challenges in implementing this method [26, 27, 28]. In the case of surface marker the average accuracy is reported to be around 2-3⁰ in rotation during walking [26]. Study using optoelectronic system on cadaveric subject shows that the uncertainty is less than 1⁰ in rotation and between 1.5 and 2 mm in translation [29].

3.1.3 Dual Fluoroscopic Imaging System

Dual fluoroscopic imaging system (DFIS) has been used to investigate the motion of knee joint. DFIS can be used to investigate motion of *in vivo*, *in vitro* and prosthesis subject [30, 31]. Fluoroscopic imaging is preferred than the traditional x-ray because of its relative accessibility, easiness to operate, and low radiation dosage [32]. This system comprises commercially available C-arm fluoroscope, treadmill, placed on a platform, which creates movement of the subject under investigation, [30, 32] and two laser positioning devices are attached to the fluoroscopes to help align the subject with in view of fluoroscopes. In general, the range of a knee motion during treadmill gait is greater than fluoroscope image intensifier diameter. Therefore, to increase the accuracy of the system and the range of imaging two fluoroscopes are used where they are set to be 10cm apart and 120⁰ to 130⁰ between the planes of fluoroscopic intensifiers as illustrated in Figure 9 below [32, 33, 34]. The system creates a series of images in DICOM file format [35]. These images are then exported to computer to correct the distortion, model and analysis [33].



Figure 9: DFIS set up [32]

In DFIS, the relative movement of the bones, femur and tibia in case of knee joint, can be analyzed which minimize the error created by skin movement in other measurement systems. Using fluoroscope intensifier diameter of 350mm and image scanning capacity of 30 frames per second, the dynamic accuracy of DFIS has been reported at 0.24 mm for translations and 0.16° for rotations. This is substantially higher compared with a single plane fluoroscope which is 2.0 mm and 1.5° [34, 36].

Knee joint analysis using DFIS is time consuming and laborious which makes the method expensive and impractical to apply in routine clinical practice [33]. The other challenge of fluoroscopic imaging is the limitation of the types of dynamic task that can be captured. This is because the immobility of the fluoroscope and the size of the intensifier. For example the knee joint motion during walking is restricted to the stance of treadmill gait. In addition, it is challenging to have quality image at high speed such as that associated with running. Ackland et.al presents hypothetical suggestion for these challenges. Image quality can be improved at

high speed by integrating fluoroscope with high speed camera. The immobility of fluoroscope is overcome by introducing mobilizing system. Figure 10 illustrates the hypothetical setup of DFIS [34].

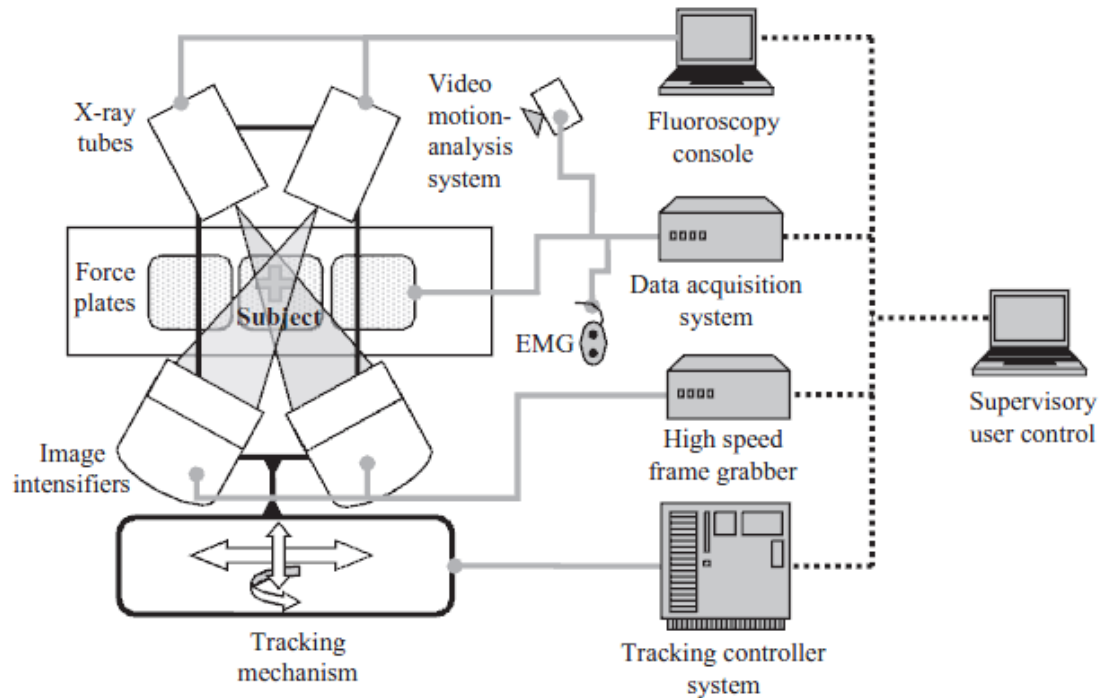


Figure 10: Schematics of a hypothetical mobile DFIS for high speed measurement [34]

3.1.4 Goniometer

Goniometer is a simple instrument used for measuring range of joint motion. The basic manual goniometer has two rods, one of which is attached to 0-180⁰ axis protractor. During measurement, the center of the protractor will be placed at the joint and the movable rod with the respective bone. Then the static position of the bones will be measured. Now days, digitized data can easily be collected from the device. Accuracy of goniometer depends on its placement on the subject with respect to the joint [4].

Electrogoniometer, technologically advanced form of goniometer, is able to measure the joint angle and angular velocity. It comprise of optical fibers which measure the motion, fixed and

telescopic end-blocks. The mechanical signal is converted into a digital signal by a datalog acquisition unit which is connected to a display unit. Electrogoniometer is depicted in Figure 11. The advantage of electrogoniometer over conventional goniometer is that it does not have a specific center of rotation. This eliminates the uncertainty of the measurement occurred due to the error in locating the center of rotation [4, 37, 38].

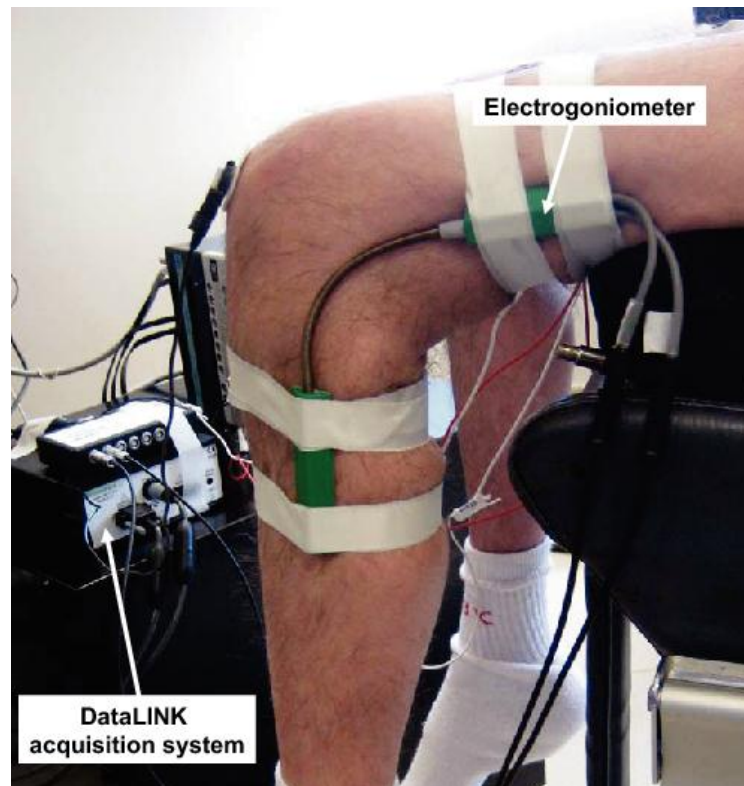


Figure 11: Electrogoniometer setup [39]

3.2 Instruments for Cadaveric Subject

Cadaver is a dead human body. It has been used for science based medicine. Medical institutes use cadaver for different kind medical training and for research to improve the method of diagnosis. This improves the quality of healthcare provided by these institutes [40]. Knee joint cadaver is also used for different kind of research. In order to perform these

researches related instruments are developed and customized. Two of these instruments are discussed below.

3.2.1 Knee Simulator

A knee simulator is a machine that reproduces the forces, moments, and motion of both patella-femoral and tibia-femoral joints on either cadaver specimen or a complete set of prostheses [41, 42]. There are different types of knee simulators; each can be characterized and distinguished by the range of motion, control scheme, load capability, simulation speed, and ability to dynamically simulate activities. These machines can generally be classified as quasi static and dynamic simulators [42]. On these machines different experiments have been performed. Some of these are:- evaluation of the retaining role of ACL during walking and stair ascent, the influence of Q angle on knee kinematics during squat, the effect of PCL resection on knee kinematics during squat, and comparison of joint kinematics of implanted mobile prosthetics and fixed implants to original intact cadaver knees [43].

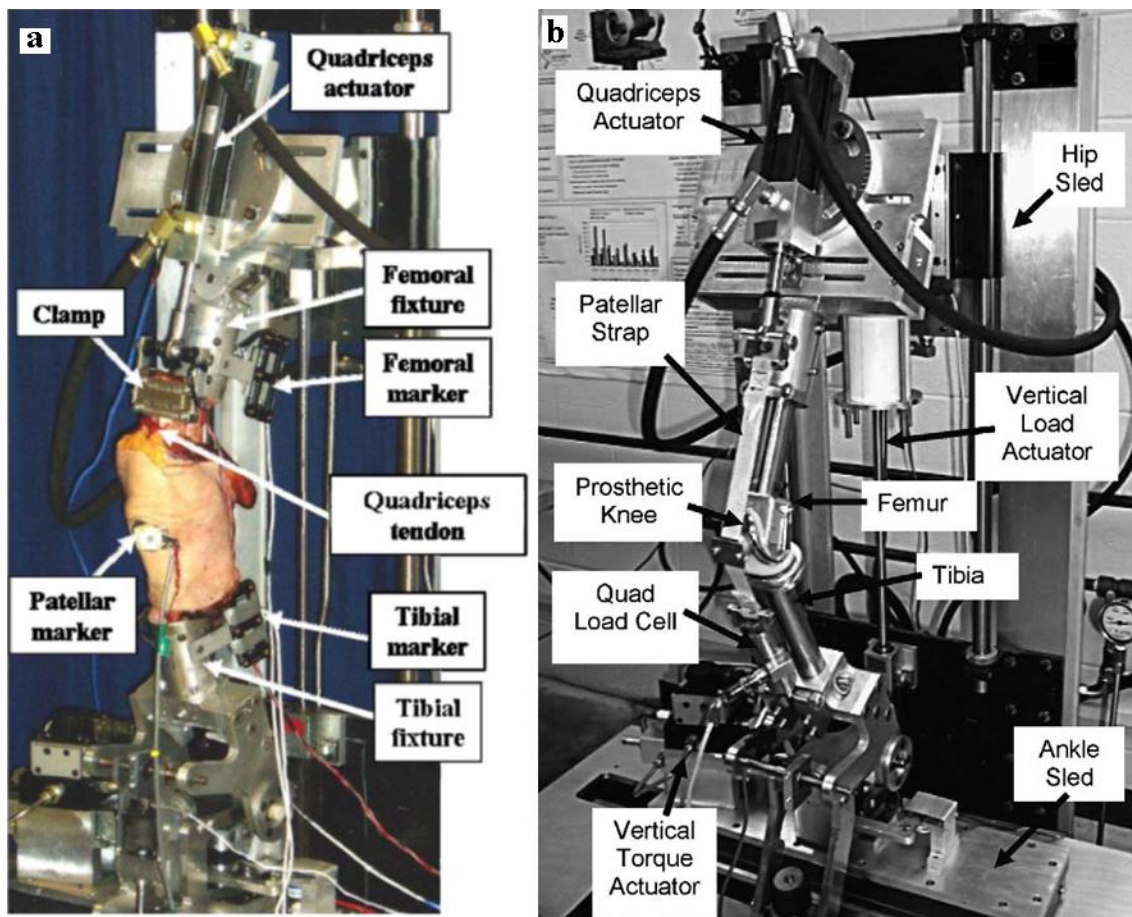


Figure 12: a) KKS setup with natural knee [41] b) KKS setup with prosthetic knee [42]

Kansas Knee Simulator (KKS) is one of these machines. It is designed by Kansas University was modeled after the Purdue Knee Simulator: Mark II. KKS has five-axis dynamics simulator consists of three translation loads and two rotation torques. Each axes is actuated by hydraulic cylinder with servo valve control hence the position and the force can easily be measured. Femur and tibia are attached to the hip and ankle sleds respectively, and they are able to flex independently to allow unconstrained kinematics. The hip sled has two DOF and the ankle sled has four DOF where three of which can be controlled. The experimental setup of the simulator is depicted in Figure 12 above [41, 42, 43, 44].

3.2.2 Robotic Testing System

A combination of robotic technology, Universal Force Sensor (UFS), multi-axial force and position control has been used to investigate kinematics of joints. The system is capable of recording 6-DOF motion and then reproducing identical path motion with an accuracy of less than 0.2mm and 0.2° . It can operate in position control, force control, or hybrid mode. [45, 46] In position control, the robot reproduces joint position and path to obtain the in-situ force in the joint. In case of force control, desired external force is applied to the joint and the resulting movement of the manipulator is determined by comparing this force with the force measured by UFS [46]. The main component of this testing system and setup is depicted in Figure 13 [47]. The advantage of robotic testing system is:- it can learn complex motion of a joint specimen in response to specific experimental condition and then reproduce this motion after the specimen is altered [45, 48].

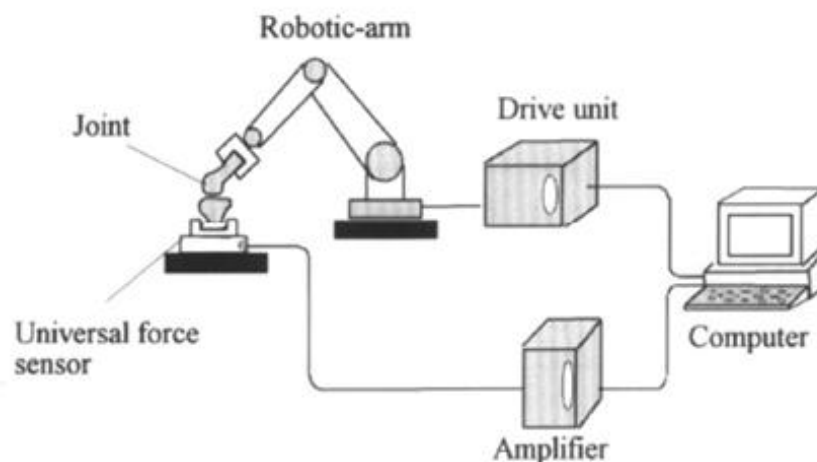


Figure 13: Schematics of robotic testing system [47]

Predicting the effect of anterior cruciate ligament reconstruction on knee joint kinematics is one case study that was investigated by the robotic system as shown in Figure 14. In this testing setup, the femur is mounted and rigidly fixed in customized clamp that enables 6 DOF relative to the manipulator base. The tibia, on the other hand, is mounted to the load cell and

rigidly fixed to the end effector. The quadriceps and biceps muscles are sutured to ropes. Pulley system is employed on the ropes to apply the necessary load which is used to stimulate flexion and extension of the knee. The coordinate systems of femur and tibia are set in such a way that their coordinate axis coincide at full extension. The position and the orientation of tibia are determined by the relative movement of these two coordinate systems; in effect the kinematics of the knee is obtained [49].

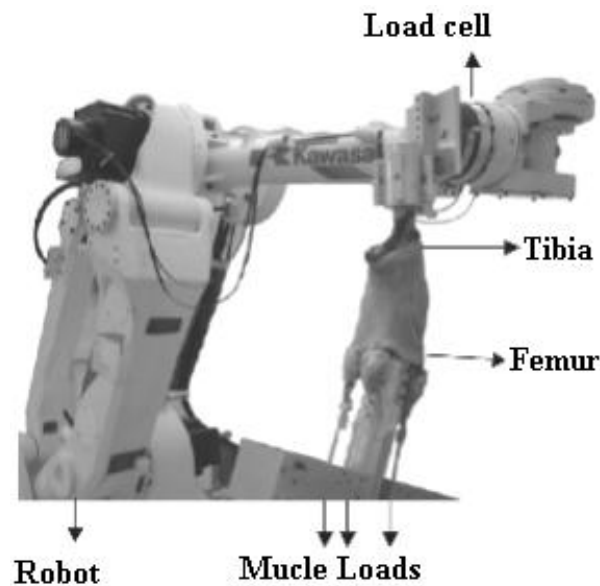


Figure 14: The robotic testing system with the specimen [49]

3.3 Laboratory Customized Testing Device

The performance of knee joint has been studied from many different points of view. The total mechanical power output generated during the dynamics of the joint [50], patellofemoral kinematics [44], and effect of patella tendon adhesion on tibia [51], contribution of reflective muscle contraction on the stiffness of the knee joint [52] can be mentioned as a very few example of the studies.

Because of the objective differences in the studies, laboratories are intended to design customized equipment that makes them perform the study. The setup and method of these

equipment are different. In addition, the subject under investigation also varies accordingly to be either in vivo or in vitro. In the following paragraphs, two of these laboratory equipment are briefly discussed below; one from the in vitro and the other from in vivo subject.

The first laboratory equipment to be discussed is used to study the effect of measure patella tendon adhesion to the anterior tibia on knee mechanics. Patella tendon adhesion is an effect the influence the knee biomechanics by increasing patellar contact force. It is prevalently caused by complication after ACL reconstruction.

During knee kinematics, patellar tendon adhesion varies. This effect was studied in orthopedic research laboratory of Columbia University. The research was on cadaveric knee in an open kinetic testing configuration. Designed knee testing machine is depicted in Figure 15. The setup is as follows: tibia moves along the curve while femur is fixed and muscle forces are stimulated by the loads that are suspended on the rope. The position and the orientation of each bone are measured with the help of two triads rigidly attached to each bone and three dimensional coordinate measuring machine [51].

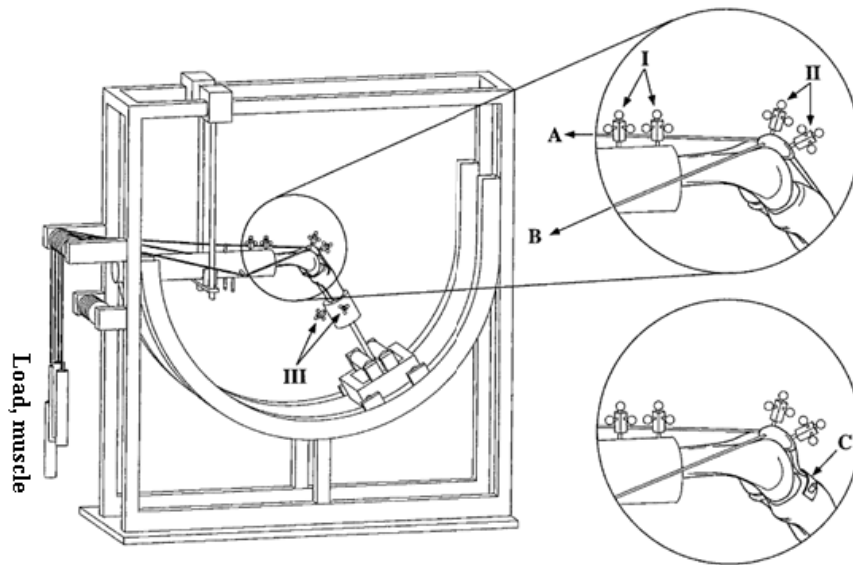


Figure 15: Knee joint testing machine. A, a combination of the rectus femoris, vastus intermedius, and vastus medialis longus muscles (267N); B, vastus medialis oblique muscle (89N). The vastus lateralis muscle is hidden behind the femur (178N). Precision triads are rigidly attached to the femur (I), the patella (II), and the tibia (III). C is metal plate compressing the patellar tendon to the tibia. [51]

The second equipment to be discussed is used to study the contribution of reflective muscle contraction on the stiffness of the knee joint on *in vivo* subject. The knee joint stiffness is one of the major factors for the stability of the joint.

The subject under investigation sits on a chair as shown in the Figure 16. Straps are used to minimize the movement of other part or joint of the subject. The motor axis of rotation is aligned with the axis of right knee joint adduction/abduction axis of rotation. The fully extended right knee joint is preloaded in abduction direction to ensure initial stretch of the medial aspect of the joint's periarticular (e.g., skin, ligament, and joint capsule) tissues. The torque-angle relationship of the joint and muscle activity is then measured in relaxed state and co-contracted state. The difference in the stiffness is then analyzed [52].

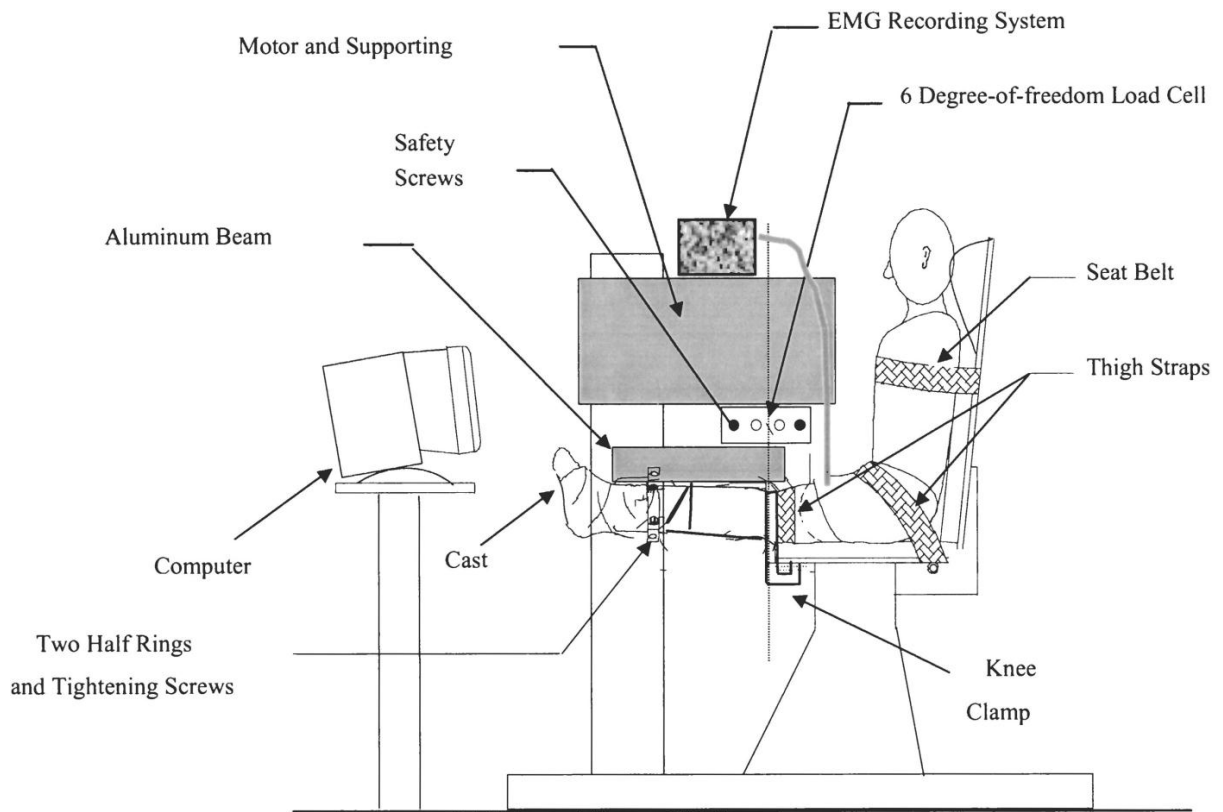


Figure 16: Experimental setup for neuromuscular reflexes contribution to knee stiffness [52]

3.4 Measurement Device/Method Comparison

Measurement instruments discussed thus far are compared according to functionality, accuracy and price. This comparison is presented in Table 1. These three criteria are the main requirement in selecting a measuring instrument for knee joint analysis. The first criterion is functionality. Functionality is about as to how the instrument is used or the type of subject used in the system whether it is in-vivo or in-vitro. Accordingly, the general functionality of the instruments discussed in this thesis is summarized and presented. Accuracy, the second criterion, is the most important criterion for any measurement instrument. The fact that no measurement is exact, accuracy shows the closeness of the measurement to the actual or exact value. The more accurate the device is the better. This criterion can be used to rank the instruments from one another. The third criterion to compare is the cost which includes only

the price of the device not the running cost. For example, a survey on running cost of VIS for average gait laboratory requires 70 Therapist hours, 120 technician hours and 25 clerical hours per month [18], which is significantly expensive. To compare the price of these systems, price estimation is performed. Price estimation of each system is done by estimating the price of their components. Some of the major components of each system are listed in the Table 1. Bear in mind that this price estimation is only for the sake of comparison and so it is very rough because the price of each and every component varies with their specification. In addition, only the major components are included in the estimation.

Table 1: Functional, accuracy and cost comparison of devices that are reviewed in this thesis

N	Measuring device/system	Functionality	Accuracy	Some component of the setup	Estimated Price (€)
1	Video Imaging System (VIS)	- if tracker is not automatic it needs long time to analysis - used for in-vivo and in-vitro	2mm, 0.5 ⁰	- reflective marker and receivers - photo and video cameras - computer and software - tripods, calibration kit	~95,000
2	Dual Fluoroscopic Imaging System	- able to measure relative motion between femur and tibia - used for in-vivo and in-vitro	0.24mm, 0.16 ⁰	- 2 c-arm fluoroscopic x-ray - treadmill and laser - computer and software	~200,000
3	Optoelectronic	- used on skin and bone marker - used for in-vivo and in-vitro	1.5-2mm, 1 ⁰		> VIS [53]
4	Electro-goniometer	- angle measurement	<3 ⁰	- computer - electro-goniometer	~€10000
5	Knee simulator	- for cadaver and prosthetic subject		- steel structure and piston - control elements	~€35000
6	Robotic Technology	- for cadaver subject	<0.2mm, 0.2 ⁰	- robot and UFS - computer	~€60000

4 DESIGN OF INSTRUMENT

In this section of a thesis, discussion about the scientific design methodology particularly design of medical device and the instrument to be design is presented. As any instrument device, to meet the objective, this instrument will have two main features. The first feature is the mechanism or the mechanical part and the second one is the measurement device and method. For example: a caliper has these two features. In the first feature, mechanical feature, of a caliper: the outer, inside jaw, depth probe and retainer are involved, and these are part of the product. The first three are used to locate the two ends to be measured, and the retainer is used to block unnecessary movement after pointing the end points and before reading is performed. All these are designed in a unique geometry to meet the objective and interlinked by a sliding mechanism. As for the second feature, the scale on caliper is a measurement device or system. The method of reading may vary depending on the design to be digital or analogue.

Accordingly, clinical knee joint measurement device has the mechanical feature and the measurement method. The mechanical feature has a function of controlling the motion of the knee so as to facilitate the measurement as well as to support the structure and fix the subject under investigation. The measurement system is used to measure the required variable. To accomplish this task a scientific design approach is used.

4.1 Design Method

Design can be define as an engineering activity necessary to provide a product or process to meet specified need or to solve a problem. Design activity uses laws and insights of science. It influences almost all area of life. Design method, however, is a pattern of behavior or a course of action for the design of technical system. The complete design course of action, from start to finish, is often outlined as depicted in Figure 17 [54, 55, 56].

Generally, identification of need starts the process of design which constitutes a creative act. It is usually triggered by random circumstance, a feeling of uneasiness or a sensing of something is not right. The source of creative idea can be from anywhere for example customer request or need, request of proposal, assignment from supervisor, and so on. From the need, a specific definition of problem and product specification must be stated to concretize the need. Having clear, unambiguous and defined problem is the first step to the design solution. In order to do this important information should be gathered. This information helps not only to define the problem but also set a requirement or criteria for successful design solution.

Concept design follows the problem definition as part of synthesis task. Various possible solutions that meet the requirement must be proposed. These possible solutions are then analyzed and optimized to assess whether the system performance is satisfactory or better. Analyzing and optimizing phase needs the construction of abstract models of the system that will admit some form of mathematical analysis. Competing options are compared so that the most competitive idea can be selected. Evaluation, the next and most important stage of design procedure, is the final proof of successful design. It involves the manufacturing and testing of prototype to check if the design satisfies the requirement. Design process is an iterative process. At any given steps of the process, returning to the earlier phase of the procedure is needed [55, 56].

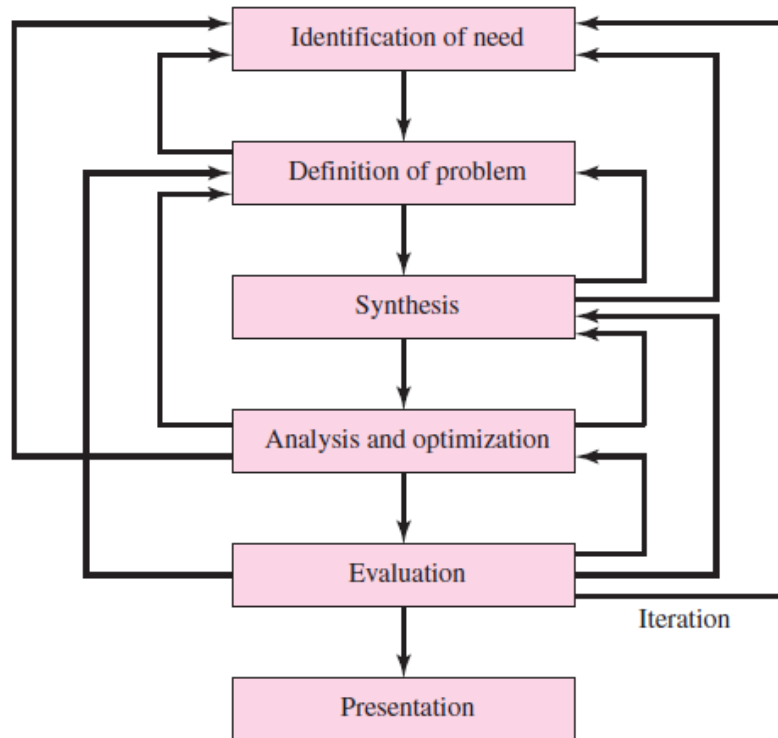


Figure 17: The design process illustrating some of the iterative steps [54]

James P. O’Leary, one of the authors of handbook of biomedical engineering and design, presents a process to design of medical device. This approach is based on concurrent engineering. Concurrent engineering is a design approach involving a team that is capable of understanding all aspect of the problem faced. The team may consist of medical experts, biomechanical experts, design experts, manufacturing experts and so on. The success of the design is dependent on the composition of the team. The team should work as a unit throughout the design process [57]. In this thesis, since it is an individual work, concurrent design approach is not followed. So, the professional gap in the biological system is filled by research.

4.2 Design need

To study the kinematics of knee joint appropriate, data collection is important. Different methods have been applied to collect data in the study of motion. Some of these methods are discussed in the literature part of this thesis. These methods are available in current market, though they are expensive not only in terms of money value but also time and space. It means that, experimental setup need larger space and data analysis is time consuming. In addition, they can be implemented for only cadaveric subject or the degree of freedom they can measure is very limited.

An instrument that can improve the drawbacks of the existing knee kinematics measurement methods is needed. An instrument with simple experimental setup, works for both in-vivo and in-vitro subjects, allows movement in more degree of freedom and measure them, and uses simplified way of collecting and analyzing data is needed.

4.3 Design Requirement

Base on the need and the literature review with a brief discussion with Kuopio University personnel the following specification or requirements are developed. These requirements are the evaluation of the designed product. The description and the requirements of the design are presented in Table 2.

Table 2: Design requirement

No.	Requirement	Description of requirement
1	Material	- Engineering material suitable for clinical purpose
2	Geometry	- Preferable suitable for in vivo and cadaver studies - Attachment of femoral and tibial parts secure, possible to be separate parts. - Adjustable to fit for range of test subject's
3	Operating condition	- Normal room temperature
4	Range of motion	- Rotation: <ul style="list-style-type: none"> o Extension-flexion: 0-120 degrees o - Varus-valgus: $-5\pm$ degrees o - Internal-external: -10 ± 10 degrees - Translations: <ul style="list-style-type: none"> o distraction-compression: -10 ± 10mm - Speed of motion is based on walking <ul style="list-style-type: none"> o 1.4m/s
5	Forces	- Distraction-compression with normal life force from zero to five of the body weight (BW) - Moment for flexion-extension: to be able to produce desired flexion-extension rotations for the cadaveric subject.
6	Compatibility	- Compatible with imaging machine in Kuopio hospital

7	Measurement method	- Directly or indirectly
8	Manufacturability	- Preferable standard parts should be used
9	Component life	- Minimum 10 years from the date manufactured - Standard component can be replaced from spare part
10	Safety	- Safety regulations for medical devices should be followed strictly
11	Ergonomics	- Medical instrument ergonomics should be strictly followed. - No harm to the test subject under any circumstances
12	Aesthetics	- Normal engineering design, outlook is not an issue

4.3.1 Design Input

Based on the requirement and the anatomy of human body the following inputs are important in designing the instrument. These are: degree of freedom, anthropometric data and angiographic (imaging) machine.

Degree of freedom of knee

As it was discussed previously, knee has six degree of freedom. Mechanism to be design should not constraint any one of them but controls them so that it can easily be measured. Among the possible movement of the joint, flexion and extension movement is the dominant.

Two angular movements, varus-valgus and internal-external angular movements, are small as compared to the flexion-extension which is up to $120\text{-}150^{\circ}$ depending on the orientation of femur.

According to Matsumoto, et al, the hip position influences the flexion angle. The maximum flexion is measured at flexed hip position because quadriceps muscles loosen. At 0° hip extension position the knee flexion is found to be $121.5^{\circ} \pm 14.2^{\circ}$ [58]. Because our requirement is 120° flexion of knee, flexed hip position is used in the design. This is because at 0° hip position there is a chance the flexed angle be lower than 120° .

Anthropometric data

Anthropometry is a science that deals with measurement of physical characteristics of a body [59]. For this report, the dimensional characteristic is fundamental to design the instrument for a range of specimen. In Figure 18, the posture of a seated man is shown with dimension symbols. The ranges of values of these symbols are listed in Table 2 [60]. Among these values, the highlighted values are the values used in the design.

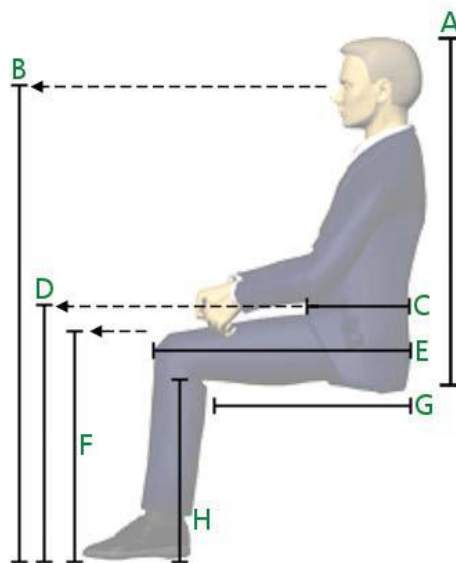


Figure 18: Common seated posture [60]

Table 3 Common anthropometric measurement for seated position [60]

Symbol	Female 5th – 95th%		Male 5th – 95th%		Overall range 5th – 95th%	
	Inch	cm ¹	Inch	cm	Inch	cm
A	31.3 – 35.8	79.5 – 90.9	33.6 – 38.3	85.3 – 97.3	31.3 – 38.3	79.5 – 97.3
B	42.6 – 48.8	108.2 – 124.0	46.3 – 52.6	117.6 – 133.6	42.6 – 52.6	108.2 – 133.6
C	7.3 – 10.7	18.5 – 27.2	7.8 – 11.4	19.8 – 29.0	7.3 – 11.4	18.3 – 29.0
D	21.0 – 24.5	53.3 – 62.2	23.0 – 26.8	58.4 – 68.1	21.0 – 26.8	53.3 – 68.1
E	21.3 – 25.2	54.1 – 64.0	22.4 – 26.3	57.0 – 66.8	21.3 – 26.3	54.1 – 66.8
F	19.8 – 23.2	50.3 – 58.9	21.4 – 25.0	54.4 – 63.5	19.8 – 25.0	50.3 – 63.5
G	16.9 – 23.2	43.0 – 58.9	17.7 – 21.1	45.0 – 53.6	16.9 – 21.1	43.0 – 53.6
H	15.0 – 18.1	38.1 – 46.0	16.7 – 19.9	42.4 – 50.6	15.0 -19.9	38.1 – 50.6

According to Table 3, Knee height varies from 502.92 to 635.0mm having a difference of 132.08mm and sitting depth varies from 429.26 to 535.94 with a difference of 106.68mm. The sitting height which is used to design a rest Table of an in-vivo subject varies from 795.02 to 972.82mm.

In addition to these anthropometric data, the diameters of the bones are also important to design the fixture of cadaver subject. Research in the mid-Anatolian population group who died during the twentieth century shows that midshaft antero-posterior diameter of the right femur is about 27 ± 3 mm and transverse diameter 26.4 ± 2.4 mm [61]. As for the tibia, research on infantry recruits shows mediolateral diameter of a tibia is 23.8 ± 2.1 mm at 13.7mm and 25.7mm at 8.7mm above the ankle joint. Anteroposterior diameter, on the other hand, is 28.1 ± 2.7 mm at 13.7mm and 25.4 ± 2 mm at 8.7mm above the ankle [62]. The shapes of both bones are depicted on Figure 19.

¹ Unit conversion is done by thesis author

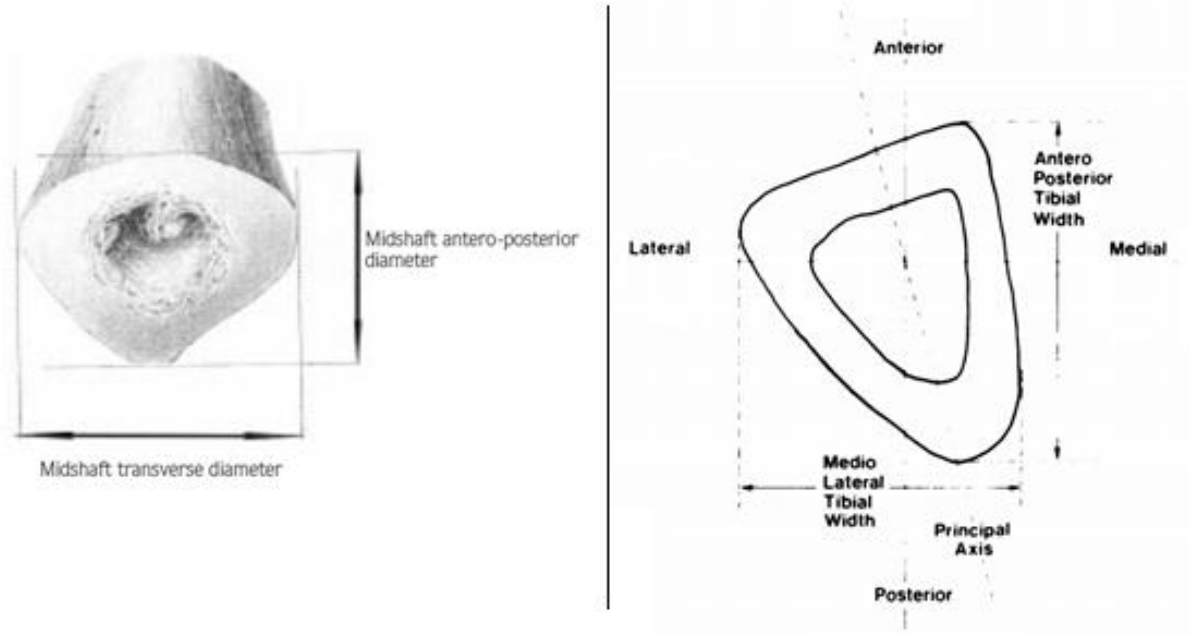


Figure 19: Cross section of femur (right) and tibia (left) [62]

Biplane imaging machine

As can be seen from the requirement Table (Table 2), one of the requirements of the design is the compatibility to selected imaging machine. Among high quality imaging equipment existed in Kuopio hospital, biplane system depicted in Figure 20 is one of them. This machine is selected for this design because of its flexibility. For knee, the more significant plane is sagittal plane because it shows the relative bone movement on the major motion of a knee that is flexion and extension. Using this machine imaging in sagittal plane is possible.



Figure 20: Biplane imaging machine [63]

5 MECHANISM AND STRUCTURE DESIGN

This part of the report includes the conceptualization and the evaluation of the design. Different options of the design are presented and compared to find a suitable solution.

The major part of this design is the mechanism and the structure of the instrument. It comprises of the mechanism, fixture and frame. Using the requirements and design input, the design of mechanism is performed by categorizing the whole system into groups of same function. These functions are flexion-extension, valgus-varus and internal rotation mechanisms. Whereas, fixture is a means to connect or inter-relate the subject with the mechanism and frame is the overall structure of the instrument.

5.1 Flexion-extension mechanism

Flexion-extension is the major movement of the knee. This motion occurs on the sagittal plane². In order to attain this movement the following two mechanisms can be implemented by neglecting the other movements. The evaluation and the description of the mechanisms are as follows:

Option 1: This option is based on a four bar mechanism where the source of the motion can be varied. The means of creating a flexion motion can be either by direct synchronization of motor with the driving link or indirectly by connecting the mid of driving link with a linear lead screw where the screw is driven by a motor. Figure 21 below illustrate this mechanism.

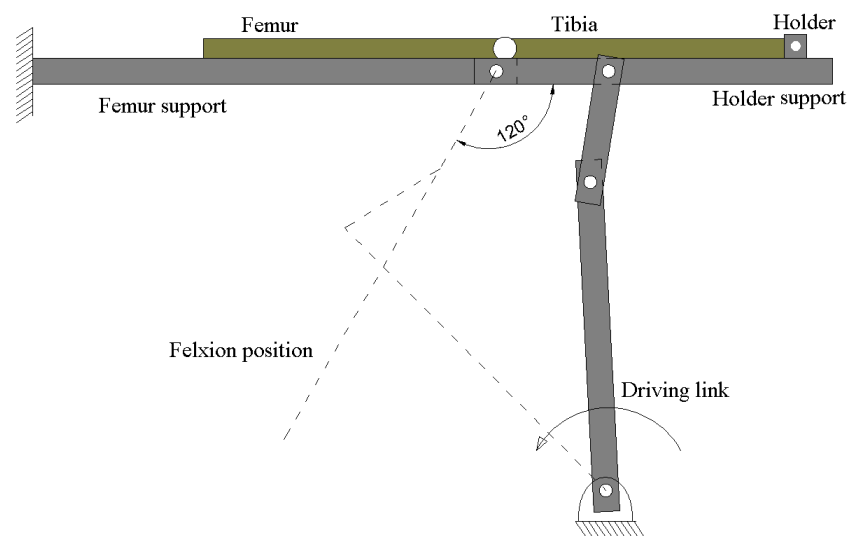


Figure 21: Sketch of four bar mechanism for flexion

Option 2: This option is based on the path of the tibia end or ankle in the flexion-extension motion. In this case, the design focuses on the driving system along the path or guide. The drive can be either by a gear system or a pulley system. In case of gear system, the guide is a

² see appendix 1

fixed curved rack and the pinion travel across the rack. In case of pulley system, the tip of the tibia will be pulled by a pulley on a curved smooth guide. In both cases motor will be used as a source of power. Figure 22 below illustrate this mechanism.

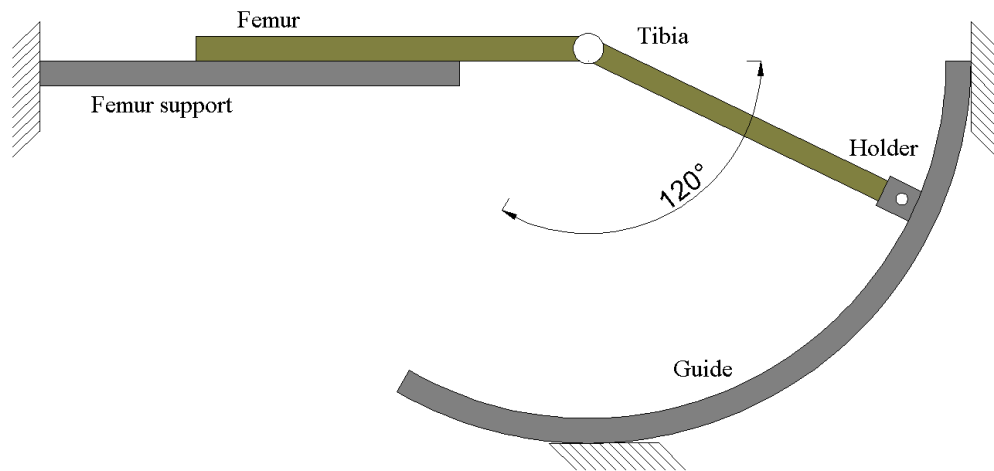


Figure 22: Sketch of flexion mechanism using tibia end point path

The two options can be compared according to cost, driving capacity, compatibility with imaging machine and simplicity for manufacturing. Each of these criteria is valued as 2, 4, 3, and 3 respectively. Driving system is a major factor for cadaver subject because for in-vivo the muscle of a subject is a source of force but for cadaver these forces are inactive. Pulley driving system is poor to accurately drive flexion and extension. As for compatibility, in a four bar mechanism the ‘holder support’ bar is a brier for a sagittal view of the imaging machine and valued to be less as depicted in Table 4.

Table 4: Design evaluation of flexion mechanism

Comparison criteria		Cost	Driving capacity	Imaging machine compatibility	Simplicity	Total value
Criteria value		2	4	3	3	
	Driving means					
Option 1	Direct	4	4	1	3	36
	Indirect	2	4	1	2	26
Option 2	Pulley system	4	2	4	3	37
	Gear system	2	4	4	1	35

According to the result of Table 4, because its relative total value is higher option 2 with pulley system is selected. Selection of component like guide, motor, and wheel is done in a later section.

5.2 Valgus-varus mechanism

Another rotational motion that occurs on the coronal plane³ is valgus and varus. To design this mechanism, two data are important. These are the radius of rotation and the angular displacement. Assuming, for the sake of simplification, the lower leg is pivoted at a single point with the radius of its length. The maximum anthropometric data of the lower leg length is given to be 635mm in Table 3 which is the radius of rotation. As for the angular displacement, the design requirement of this rotation is $\pm 5^{\circ}$ which gives angular displacement of 10° . The distance of the path of valgus-varus rotation is then the length of the cord of the arc which is calculated to be 111mm. The length the cord of the arc is the minimum width of the instrument. Notice that, this path is an arc which means the change of location of a certain point between the end points is in two directions. The design should allow these two direction of motion as it is depicted in Figure 23.

³ see appendix 1

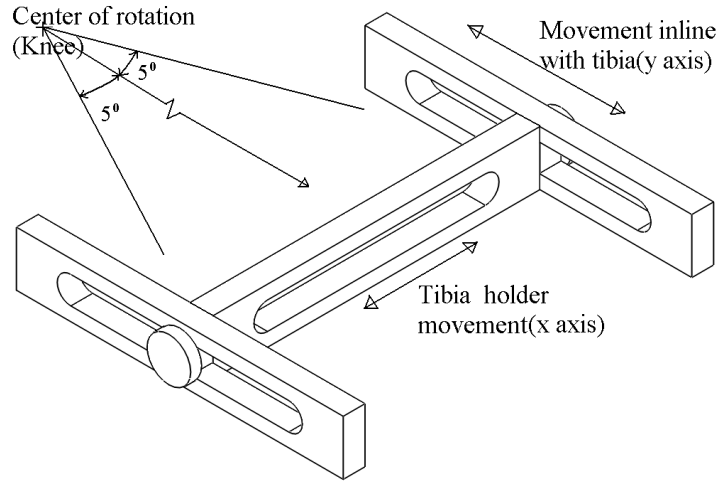


Figure 23: Sketch of valgus varus rotation motion using a slot mechanism

In this design work, external force for producing valgus-varus is not considered, so the driving force for this motion is the natural movement of a knee. This means: the force that is created to have flexion-extension motion will induce valgus-varus motion. What is needed here is: a guide that can give the path of the natural motion without creating any constraint. In order to achieve this purpose sliding mechanism will be applied. Two ways of achieving sliding motion is described and evaluated below.

Option 1: Sliding in slot: Rectangular or circular pin can be used to slide in between the inner surface of the stretched hole to produce a sliding motion. Figure 23 above illustrate this mechanism.

Option 2: Linear guide: This is linear motion guiding system with low friction having two components: guide rail and block or guide roller. Figure 24 illustrate linear guide system. Two linear guide systems, perpendicular to each other and one on top of the other, will produce an equivalent motion with 'Option 1'.

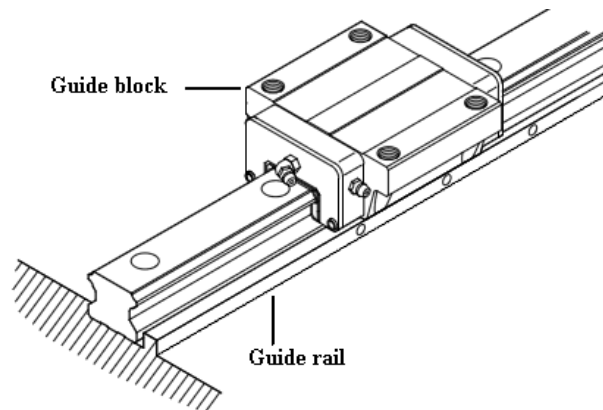


Figure 24: Linear guide system (edited) [64]

Linear guides are standard products whereas sliding using slot hole are not. In addition, in a linear guide system integrated measurement system is available. For the purpose of spare parting as well as meeting the accuracy requirement of the design, linear guide system is implemented in the design. Selection of this standard component is discussed in a later section.

5.3 Internal rotation mechanism

Internal rotation of the lower leg is the other rotational motion of the knee. The rotation axis is the same as the axis of a bone. Precision bearing is used to form this mechanism. As it is illustrated in Figure 25, the shaft is press fitted in a bearing, which is in the housing, to be bolted with the flange. Since the load on a bearing is axial, angular bearing is selected. The selection of this bearing is discussed in section 5.7. The flange is then connected to the fixture that holds the tibia. The whole assembly is then bolted with the plate so as to fix it with the linear guide. The design of the fixtures for in-vivo and in-vitro are discussed in section 5.5.

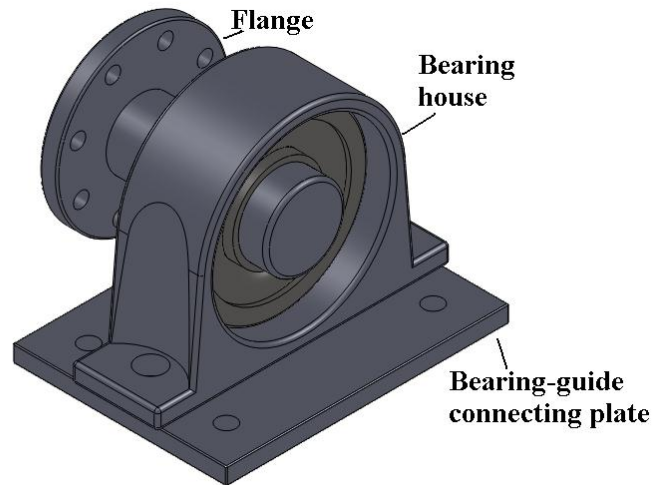


Figure 25: Sketch of internal rotation motion mechanism

5.4 External force for translational motion on cadaver subject

Translation motion measurement in proximal-distal direction is one of the instrument requirements. Force is needed to stimulate this motion. The mechanism shown in Figure 26 is used to produce the force. In the mechanism, one end is fixed with the frame and the opposite end is movable to approach the proximal-distal linear guide. Proximal-distal guide is one of the guides used for varus-valgus mechanism which is along the tibial axis. In the middle, a compressed spring is inserted to produce the force. The release of the force is produced by further compressing the spring by using a screw. The application and release of the force is done by rotating the screw manually.

The maximum magnitude of the force is given to be five times body weight. If we consider an average body mass to be 70Kg, then the load will be five times the mass. The force is mass multiplied by gravitational acceleration which is equal to 3447.5N ($70 \times 9.85 \times 5$). This is the induced load to produce the force needed.

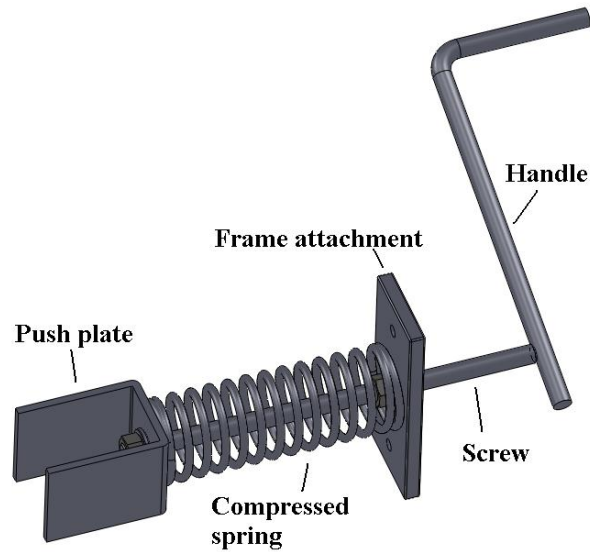


Figure 26: Sketch of mechanism for force application on proximal-distal direction

The length related to spring in the design of the spring is shown in Figure 27 [65].

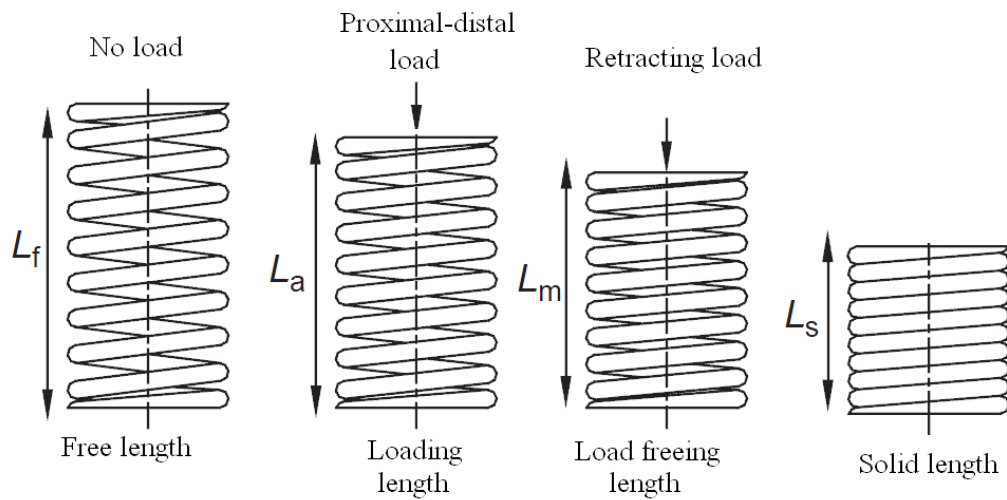


Figure 27: Various lengths associated with spring in a mechanism (edited) [65]

The design of the screw is done by the retracting load because it is the maximum load applied to it. The design is discussed in section 5.7 after the selection of spring.

5.5 Fixture design for the subject

The proper fixture design is as important as the mechanism. An instrument should be able to interact with the test subject. In this particular case, the test subject is either in-vivo or in-vitro. Both kind of subject have different fixture means. These fixtures will be assembled and disassembled at the time of experiment to change the type of subject used on the instrument. This feature gives flexibility property to the instrument. In the following sub sections the design as to how the subject is going to be placed on the instrument will be presented:

5.5.1 Fixture for In-vivo subject

An in-vivo subject should be held at the two ends that are at the ankle and on the thigh. At each point, it should be designed in such a way that it should reduce relative movement between the bone and the muscle, and it should be comfortable for the subject. Since the thigh is placed on the chair, webbing belt can be used to fix it. From anthropometric data, the height of the backrest ranges from 795 to 973mm. Because the test subject did not seat for longer time following this anthropometric data is not necessary. So, bentwood shown in Figure 28 is used for a seat and backrest. The seat of the wood is modified to have slot in 30mm distance for the purpose of tightening the thigh. The webbing belt passes through these holes to tie the thigh.

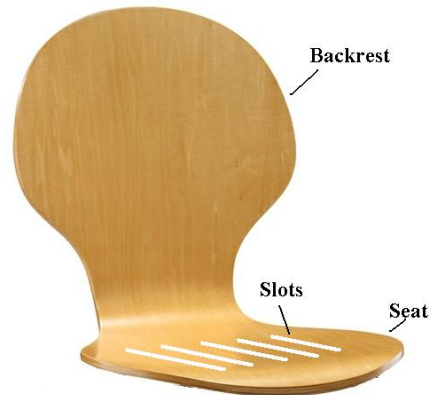


Figure 28: Bentwood for in vivo subject thigh fixture (edited) [66]

The lower leg, on the other hand, is fixed on the internal rotation mechanism. The following structure shown in Figure 29 is able to hold the tibia at the ankle and webbing belt is used to minimize relative motion between the tibia and holder. Soft spongy material is glued on the metallic surface to comfort the subject as tightening squeezes the ankle. Metallic bar is also used to create clearance length from the bottom of the foot to the ankle. Because, the rotational motion in the ankle or any movement of the foot should not affect the angle measurement. At the end of this clearance bar, flange is bolted which is used to connect the fixture to the internal rotation mechanism.

To be able to measure different subject, the tibial fixture should vary for the anthropometric range of tibia length. This range is achieved by the distal-proximal linear guide length. The selection of this linear guide is discussed in section 5.7.

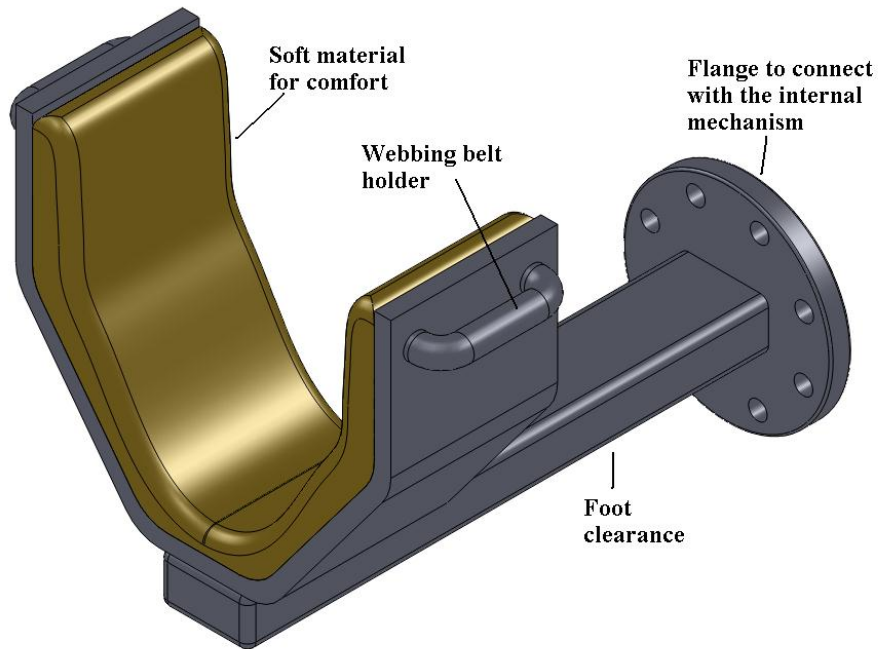


Figure 29: Ankle holder assembly for in vivo subject

5.5.2 Fixture for In-vitro subject

For the in-vitro subject both femur and tibia should be fixed on its proper place in the instrument. Here, two mechanisms are proposed for comparison purpose. The two options are depicted in Figure 30 and 31. The advantage of ‘option 1’ (Figure 30) is: the length adjustment can be done without creating twisting effect but the fixture is not in line with the bone axis. In case of ‘option 2’ (Figure 31), the axis of the fixture and bone are inline but twisting between the two ends of the fixture should be handled very carefully. Since twisting possibility can be removed, ‘option 2’ is selected for the design to follow.

Option 1:

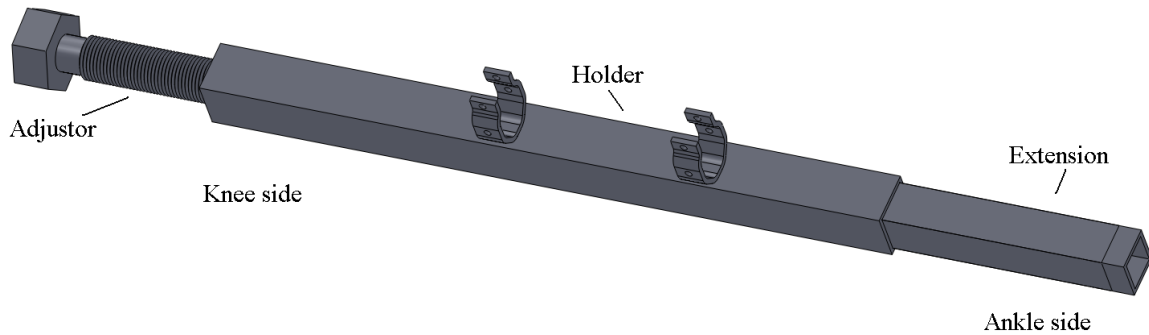


Figure 30: Tibia bone fixture

Option 2:

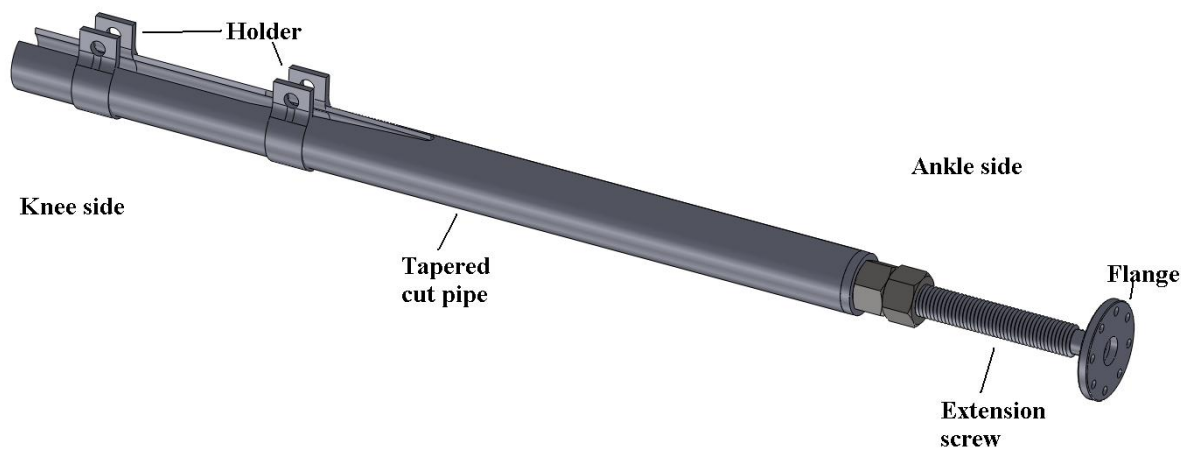


Figure 31: Tibia bone fixture

Figure 30 and 31 shows tibia bone fixture which needs length adjustment because of the anthropometric data. 'Option 2' is selected. In reference to Figure 31, at ankle side, a flange is attached to the screw which is used to connect with the internal rotation mechanism. Two nuts are used to adjust and prevent self-loosening of the extension screw. The tibia fixture without extension screw and flange is also used to fix the femur on the frame. Plate with a hole is

welded in the opposite side of the tapered cut of the pipe. This plate will connect the femur holding pipe with the frame. The purpose of tapered cut on a pipe is to allow the holder to squeeze the bone preventing the relative movement. In order to reduce the inertia of the fixture the material of the pipe is preferred to be light. For this reason, aluminum pipe is used.

As for the size of this fixture, the diameter of the pipe is determined from the bone size. The size of the bone is discussed in 'design input' section of this thesis. The average diameter of the bone is found to be 26mm. Since the shape of the bone is not circular, a taper cut on the pipe can help to hold the bone when tightening. The length of the pipe is dependent on the radius of the curved guide which is used for flexion-extension mechanism, the length of extension screw and the anthropometric data of the tibia or femur. The geometrical design of the length of the pipe and extension screw is found on Solid works, and equal to 450mm and 270mm respectively. This design is performed with the minimum length of tibia of the subject which is 150mm.

Another important element that needs a fixture is the tendons on the femur. This is to help keep the patella on its position while the tibia travels from extension to flexion position. Figure 32 illustrate two design options to implement. 'Option 1' is a pulley system with counter weight to replace the muscle and 'option 2' is a spring where both will be fixed on the frame. In case of pulley system the load is constant that is: it does not change with the motion of a knee, whereas a spring force varies with the displacement which is caused by the flexion that creates pulling effect on the tendon. Since the purpose of these load are to place the patella in its relatively stable location the variable load is not the best option.

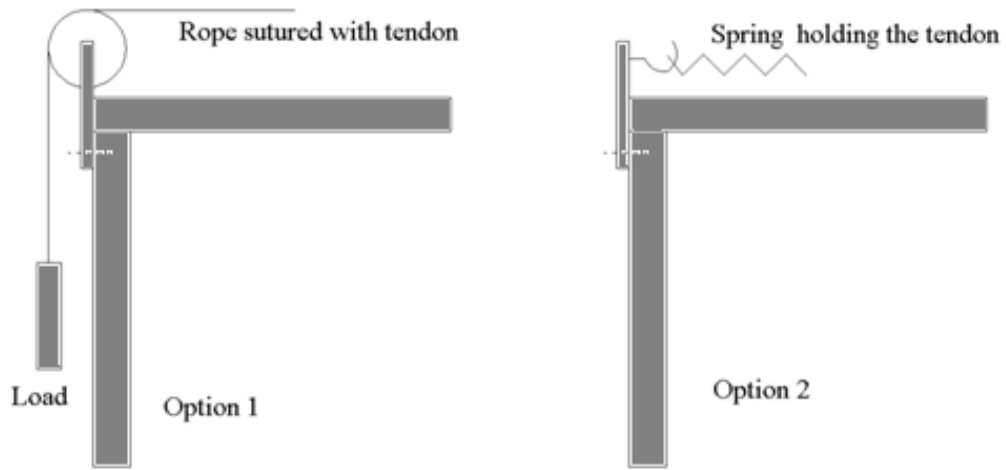


Figure 32: Sketch of tendon - instrument relation

As for the magnitude of the load, loads that are used to study the patellar tendon adhesion will be used. These loads are shown in Figure 15.

5.6 Frame

The frame of instrument is made from square section tube with dimension of 40x40x2.5mm and 25x25x2mm. Figure 33 illustrate the overall structure of the frame. Each member of the frame is connected by welding. The function of the frame is to hold all the component of the instrument to their relative locations.

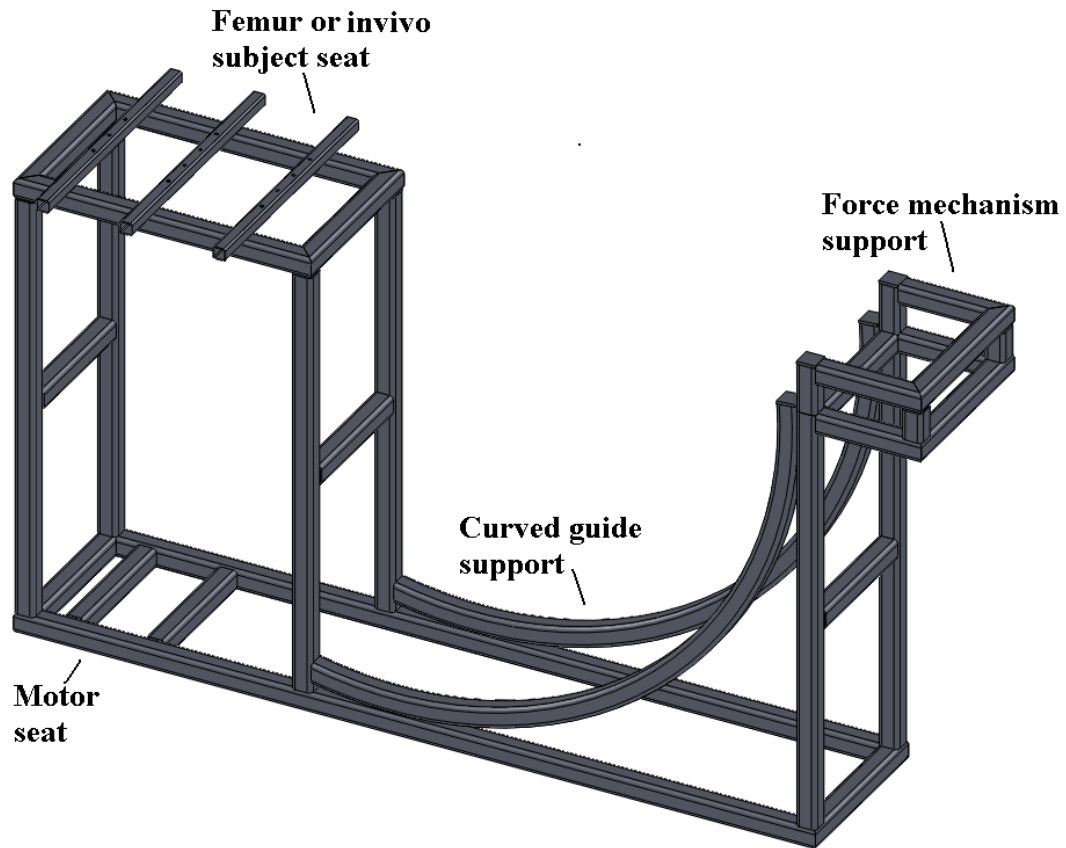
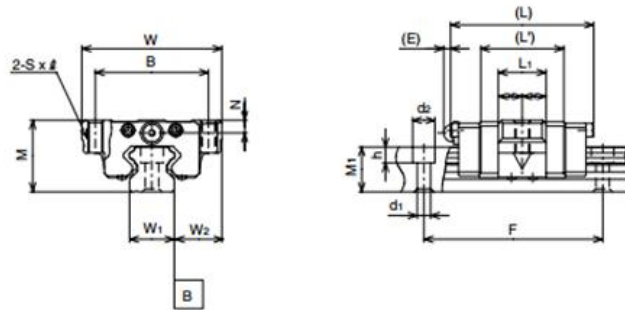


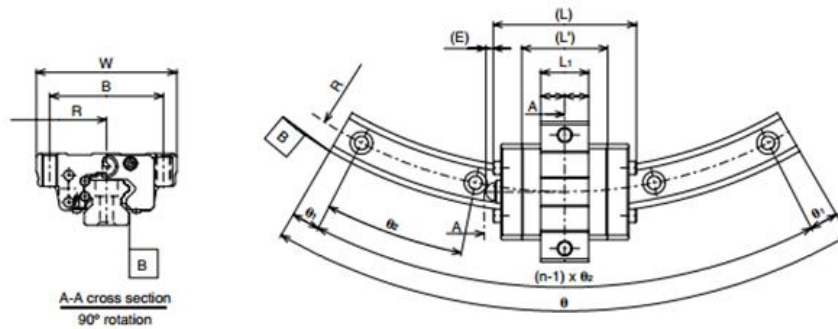
Figure 33: Sketch of frame of the instrument

5.7 Standard component design and selection

Curved guide: - For flexion-extension mechanism, two guide curve is used. The path of the motion is a curve with maximum radius of 635mm: according to anthropometry data. From THK catalogue HMG25A with LM rail radius of 750mm is chosen. Detail specification of the curved guide is depicted in Figure 34 [67].



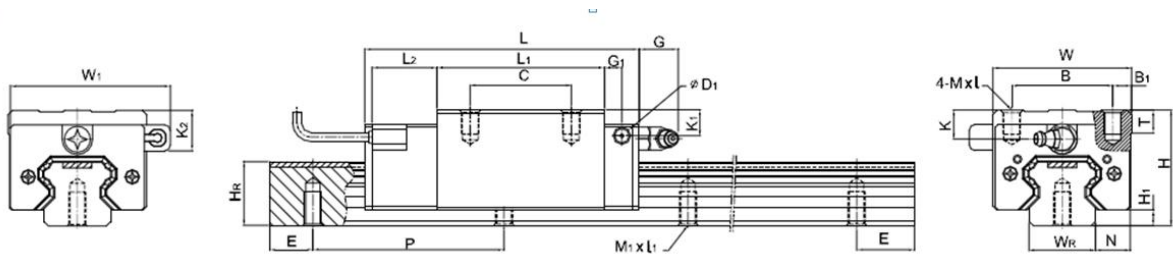
Model No.	Outer dimensions					Dimensions of LM block				Dimensions of LM rail				
	M	W	L	L'	B	S x φ	L ₁	N	E	Straight rail			Height	Mounting hole
										W ₁	W ₂	F	M ₁	d ₁ x d ₂ x h
HMG15A	24	47	48	28.8	38	M5 x 11	16	4.3	5.5	15	16	60	15	4.5 x 7.5 x 5.3
HMG25A	36	70	62.2	42.2	57	M8 x 16	25.6	6	12	23	23.5	60	22	7 x 11 x 9



Model No.	Dimensions of LM rail					Basic dynamic load rating (C)	Basic static load rating (C ₀)	
	Curved rail						Resultant load (C) kN	Straight section (C _{0s}) kN
	R	n	θ°	θ ₁ °	θ ₂ °			
HMG15A	150	3	60	7	23	2.56	4.23	0.44
	300	5	60	6	12			
	400	7	60	3	9			
HMG25A	500	9	60	2	7	9.41	10.8	6.7
	750	12	60	2.5	5			
	1000	15	60	2	4			

Figure 34: Specification of curved guide from THK catalogue [67]

Linear guide: - For valgus-varus and distal-proximal mechanism, a linear guide with built in sensor is chosen from HIWIN G99TE15-1104 catalogue. PGHH30HA is selected. Detail specification is depicted in Figure 35 [64].



Model No.	Dimensions of Assembly (mm)			Dimensions of Block (mm)														Dimensions of Rail (mm)					Basic Dynamic Load Rating	Basic Static Load Rating	Weight				
	H	H ₁	N	W	W ₁	B	B ₁	C	L	L ₁	L ₂	G	G ₁	D ₁	K	K ₁	K ₂	M ₁ x l ₁	T	W _r	H _r	M ₁ x l ₁			P	E	C _d (kN)	C _s (kN)	Block (kg)
PGHH20CA	30	4.6	12	44	52	32	6	36	90.5	50.5																17.75	27.76	0.38	2.05
PGHH20HA								50	105.2	65.2																21.18	35.9	0.39	
PGHH25CA	40	5.5	12.5	48	55.4	35	6.5	35	95	58																26.48	36.49	0.51	3.05
PGHH25HA								50	116	78.6	22.5	12	6	5	10	9	14	M6x8	8	23	22	M6x12	60	20		32.75	49.44	0.69	
PGHH30CA	45	6	16	60	67	40	10	40	110	70																38.74	52.19	0.88	4.31
PGHH30HA								60	133	93	23	12	6	5	9.5	13.8	19	M8x10	8.5	28	26	M8x15	80	20		47.27	69.16	1.16	

Figure 35: Specification of linear guide from HIWIN catalogue [64]

Motor: - It is used for creating flexion-extension motion of the subject. The torque produced by the motor to create this motion should be able to overcome the muscle load attached to the femur tendon and the force due to the stiffness of the joint by neglecting the other forces like frictional force. The magnitude of these force amounted to be 544N. Out of 544N, 534N is a contribution of the load used to keep the patella to its natural place. This load is equivalent to the sum of the load used to study the patella adhesion force [51]. The other 10N is contributed from the stiffness of a cadaveric subject. According to Zheng, et al, the stiffness of cadaveric subject is approximately 2N/mm and 1.6N/mm for male and female subjects respectively [68]. Assuming a displacement of 5mm on the knee generates a resistance force of 10N. In addition to this force, the speed of the motor should be reduced by a gear because the instrument should work at a speed of less than 1.4m/s.

Pulley diameter is selected to be 65mm by iteration

$$\omega = V/r \dots\dots\dots(1)$$

Where ω is Angular speed, V is the speed, r is the radius

Substituting the values:-

$$\begin{aligned} &= (1.4\text{m/s})/0.035\text{m}=43.1\text{rad/s} \\ &= 382\text{rev/min} \end{aligned}$$

$$\tau = Fxr \dots\dots\dots(2)$$

Where τ is the torque, F is force, r is radius

Substituting the values:-

$$\begin{aligned} &= 544\text{N} \times 0.035\text{m} \\ &= 19.1\text{Nm} \end{aligned}$$

In order to achieve this angular speed, reduction gear is applied. The minimum reduction ratio is selected from ELECON catalogue which is equal to five (5) [69]. This results an input motor speed of 1910rev/min. With these criteria variable speed electric motor with model number 0014FNFB32A having power of 0.75KW and speed of 1800rpm is selected [70]. This selection changes the walking speed from 1.4m/s to 1.32m/s.

Spring: - In external force producing mechanism spring has been used. To select standard spring the criteria of selection is important. According to the design there are two active deflection that are used before the solid length these are loading length that produce proximal-distal load which amounts to 3.5KN and load freeing length. See figure 27. At load freeing length the proximal-distal guide block will be free from load. For the sake of using standard product, selection of spring is done using these criteria because there is no geometric restriction.

From DIN standard, spring with material SS 1774-05 (DIN17223-C) is selected [65]. The specification is illustrated in Figure 36 below.

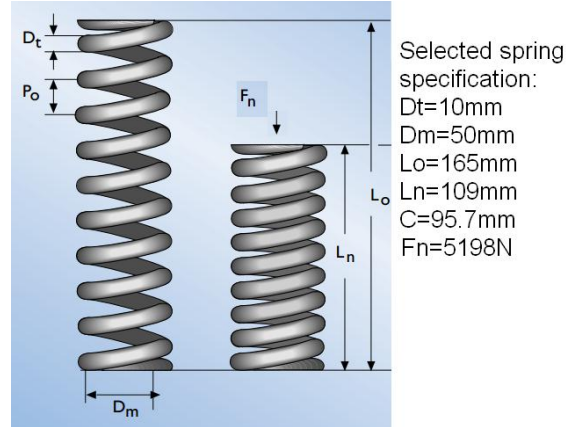


Figure 36: Specification of selected spring [65]

To produce 3.5KN the spring should be compress by deflection of $3500/95.7=36.6\text{mm}$. This is 72.4mm far from the minimum working length (L_n). This length can be used as the load freeing length. This implies that the load carried by the screw is 5.2KN [71].

Screw: - In the instrument there are two screws. The first one is used for the extension in the cadaveric subject and the other is used for the proximal-distal force producing mechanism. The size of extension screw cannot be larger than the internal diameter of the pipe which is 26mm. Whereas, the size of the screw and nut used in force producing mechanism cannot be larger than the inside diameter of the spring which is 40mm. The magnitude of the load that both screws should have to carry is 5.2KN.

The diameter of both screws is chosen to be equal to M12x1.25. The stress on the bolt is then equal to the force divided by the stress area of the tread which is 92.1mm^2 [71]. The magnitude of the stress is 56.5MPa. Selection of the material is done by comparing this value with the yield strength. The material of extension screw is selected to be Aluminum. This is to reduce the inertia created by the mass of the fixture on the knee. The material for the force mechanism is selected to be structural steel to reduce cost. The yield strength of both materials is greater than 56.5MPa [72].

Bearing:- Angular contact bearing used in the internal rotation mechanism. At the time of testing the rotational motions the load on the bearing is very small, but when testing the proximal-distal movement there is an axial static load of 5.2KN and the radial load is very small. This means, the ratio of these loads is greater than 1.9. According to FAG catalogue for a single bearing support, if the ratio of axial static load (F_{oa}) and radial load (F_{or}) is greater than 1.9, the equivalent static load (P_o) is given by:

$$P_o = 0.5F_{or} + 0.26F_{oa} \dots\dots\dots(3)$$

$$= 0.26 \times 5.2 \text{KN} = 1.35 \text{KN}$$

Assuming the instrument works continuously one hour a day and three days a week for ten years as per the requirement, the life time of bearing (L) is equal to 5.83×10^6 h. The speed of the rotation (n) is also assumed to be 10rev/min.

The basic dynamic load rating of the bearing is then:

$$C = \left(\frac{L \times n}{166666} \right)^{1/p} \times P_o, \text{ where } p \text{ is } 3 \text{ for ball bearing} \dots\dots\dots(4)$$

$$= 20.5 \text{KN}$$

Using this criterion single row angular contact bearing with designation of 7304-B-JP is selected [73].

6 MESURING MEANS DESIGN

Mechanism designed above restricts and guide the movement. This physical movement should be converted to a signal so as to measure it. A device that converts this kind of physical phenomenon into an electrical signal is defined as a sensor. Quantifiable measurement most commonly made by sensors. Therefore, the requirement of measurement will determine the selection of the sensor. The requirement of the measurement include the following: first, the quantity, characteristic, and phenomena to be measured such as temperature, pressure and so

on, second, the environment of the sensor like thermal transient sensitivity, and the third, required accuracy or uncertainty of the measurement [74].

6.1 Sensor selection

The instrument works in room temperature with no special environmental effect. So, the selection of sensor is totally dependent on the physical quantity to be measured. The physical quantity is angular and linear displacement. Flexion and extension, and internal rotation are responsible motion to produce angular displacement. Linear displacement, on the other hand, produced by valgus-varus and proximal-distal motion. The mechanism relating to this motion are flexion-extension, internal rotation, valgus-varus and proximal-distal force application mechanism respectively.

The accuracy of the instrument is not only dependent on the accuracy of the mechanisms but also highly dependent on the sensor. So, besides the physical quantity, accuracy of the sensor is considered as equally important criteria in the selection process. Accordingly, two type of sensor is selected. These are linear displacement and angular displacement sensor. Each type of sensors is discussed below:

Linear displacement sensor: This sensor is applied to measure valgus-varus and proximal-distal movement of a knee. Linear guide selected in section 5.7 is integrated with magnetic encoder for position measurement. The sensor and the magnetic strip are protected from dust, iron chips etc. The setup of the system is illustrated in Figure 37 below. It can measure up to 30m distance with accuracy in the order of $\pm 80\mu\text{m}$ [64]. Figure 38 illustrate the specification of the sensor.

From different type of displacement sensors for example optical, laser, resistive, inductive displacement sensors magnetic sensor is chosen because it can be easily integrated as well as found as standard product.

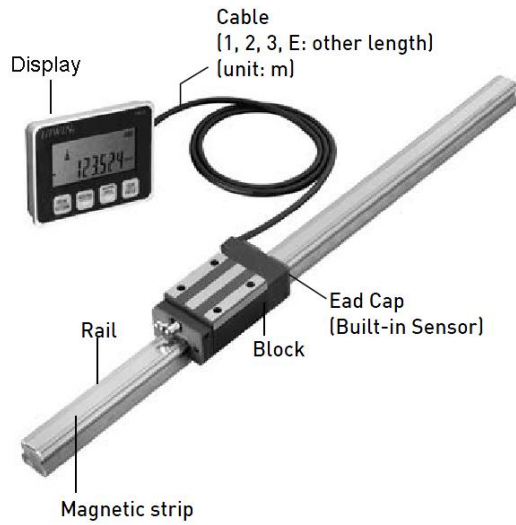


Figure 37: Setup of linear guide with sensor [64]

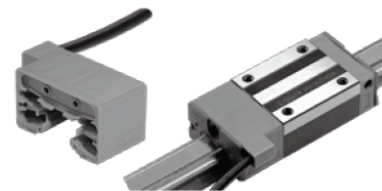
Type	
Specification	Standard
Resolution	5mm
Repeatability	$\pm 20 \mu\text{m}$
Reference signal	-
Max. speed	10m/sec
Output signal	SIN/COS 50mVp-p
Max. output frequency	2KHz
Input power	3.3VDC \pm 5%
Input current	0.1A
Operating temperature	0°C-50°C
Storage temperature	-5°C-70°C
IP class	IP67

Figure 38: Technical data for sensor [64]

Angular displacement sensor: This sensor is applied to measure flexion-extension and internal rotation movement of a knee. Potentiometer is selected due to its simplicity in setup. It can be either resistive or inductive. The hardware features on a pot's housing determine the mounting method. A typical potentiometer is shown in Figure 39.

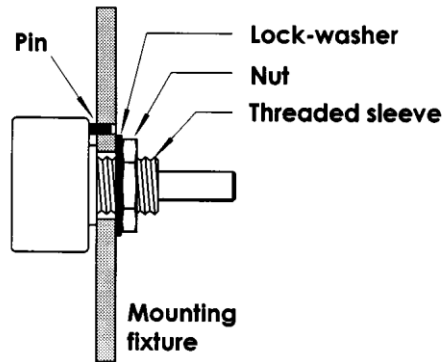


Figure 39: Rotary pot mounts [75]

High precision potentiometers with an accuracy of $\pm 0.2\%$ are selected from Bourns, Inc. [76].

7 MODEL OF INSTRUMENT

The overall model of the instrument is depicted in Figure 40 and 41. Detail drawings of the model and the parts are attached in appendix II.

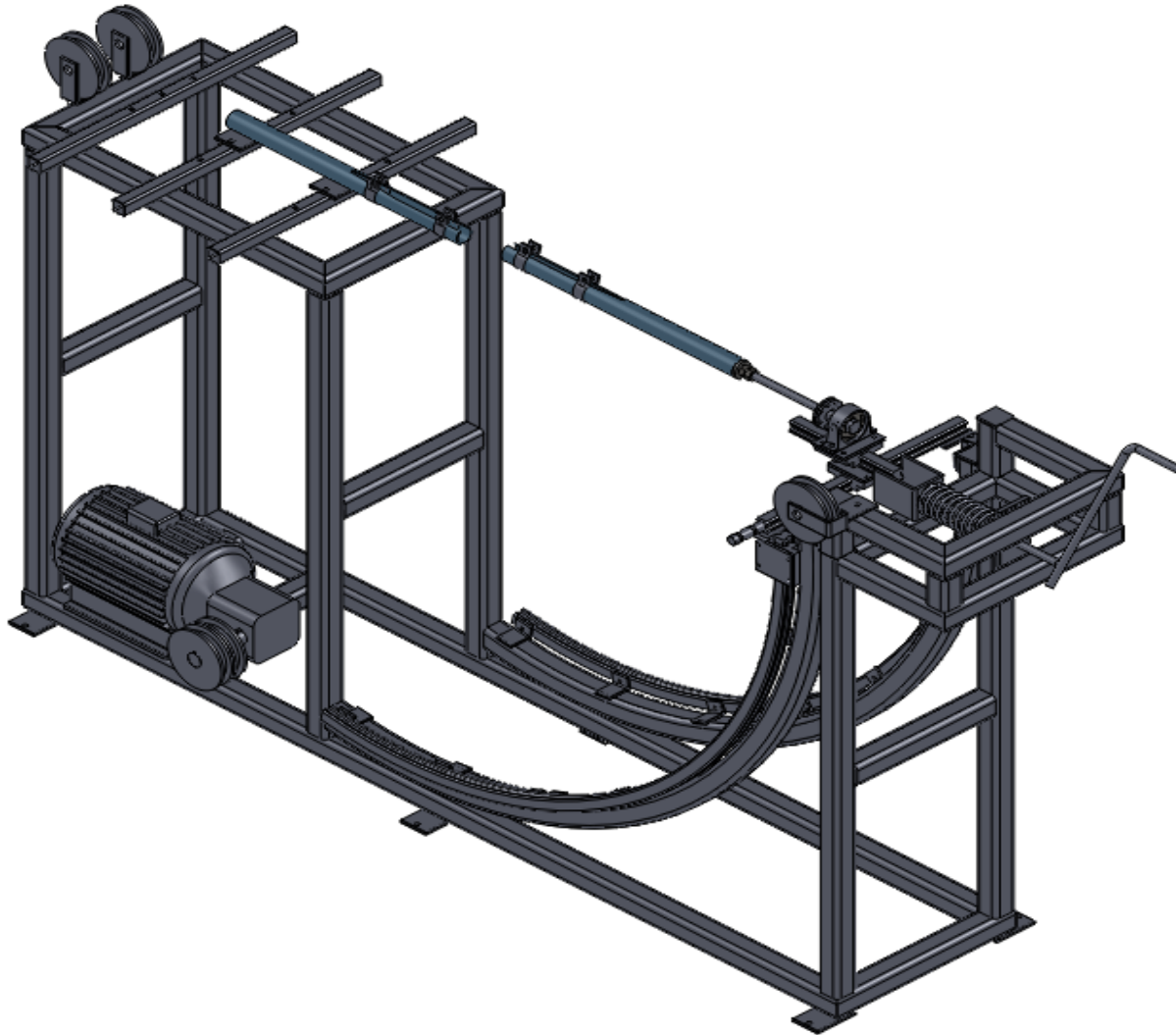


Figure 40: model of instrument for cadaveric subject

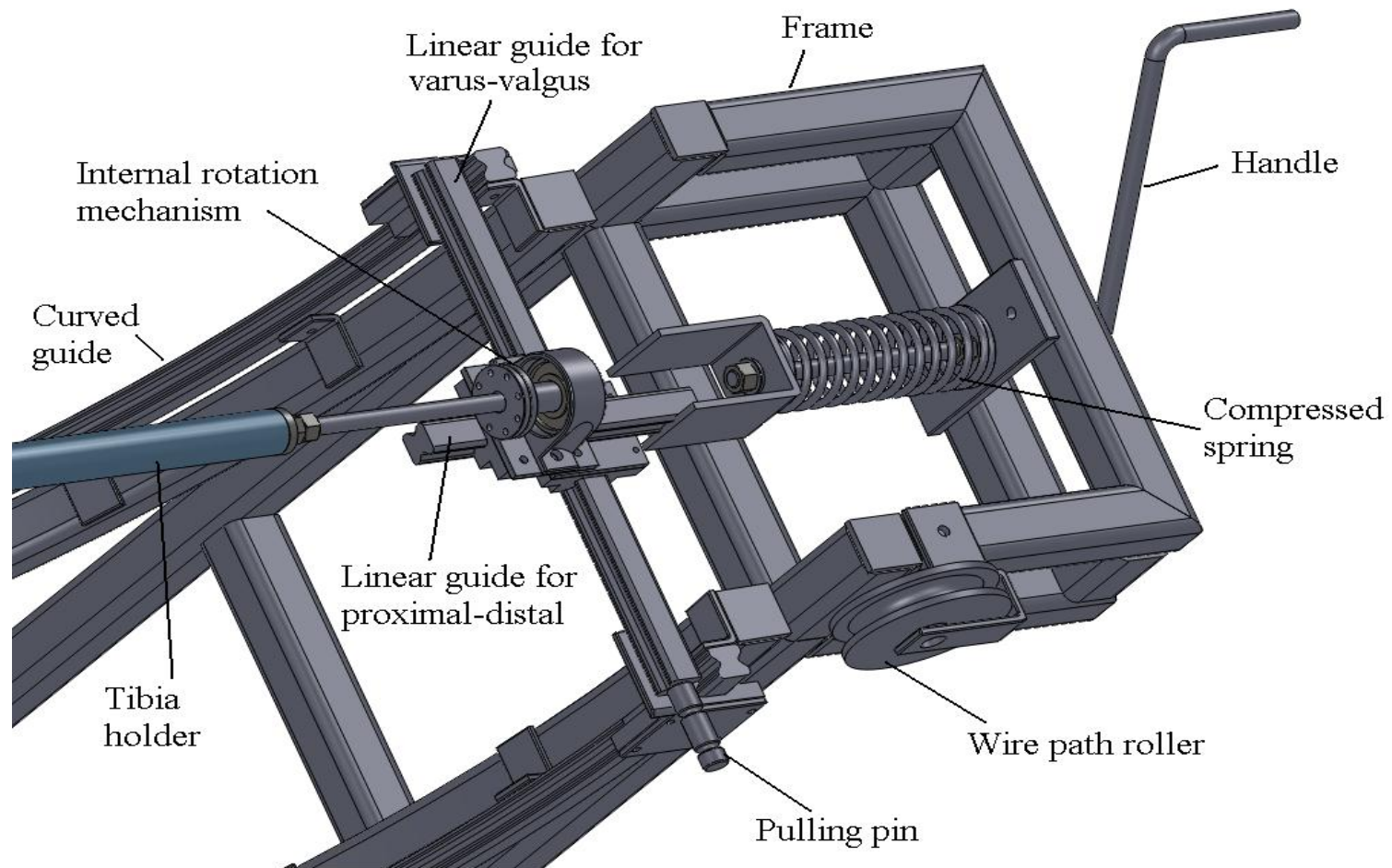


Figure 41: Instrument model details at tibial end

8 COST ESTIMATION

Cost estimation is defined as the process of forecasting the expenses that must be incurred in a product. These expenses include all expenditures involved in design and manufacturing related activity, as well as general administrative and selling costs. Cost estimation is important to determine how much must be invested, to prepare production budget, to assist financial planning, to evaluate design of the product, and so on. The total cost of a product is made up of material cost, labour cost and overhead cost. Material cost is the cost of all materials which are used to manufacture a product. Expenditure made on salaries, wages, overtime, bonuses, etc. of the employees that are involved in manufacturing the product is labour cost. Apart from material and labour cost, there are expenditures in the factory like cost of transportation, cost of depreciation, cost of special layout and design and so on are categorized as overhead cost [77]. In the following paragraphs the cost of the designed instrument is presented.

Material cost:- the direct material cost involved in manufacturing the designed instrument is amounted to be 4062.55€. The breakdown of this cost is shown in table 5.

Labour cost:- The direct labour cost is directly proportional to the time needed to manufacture and the salary of the workers involved in manufacturing the instrument. Estimating 10 working day as the total time needed to manufacture by using two persons and using the average industrial worker salary of 14€/hr. The total labour cost is amounted to be 2240€ [77, 78]

Overhead cost:- This cost depends on the expense rate of the company [77]. Assuming 60% overhead rate on material results 2437€.

Total cost:- total cost is the sum of all costs which is equal to **8740€**.

Table 5: Material cost of the instrument

No.	Description	Material	Unit	Qty	Price (€)	Cost (€)	Remark on price
1	RHS 40x40x2.5mm	Steel	Kg	141,00	0,80	112,80	[79]
2	RHS 25x25x2mm	Steel	Kg	10,00	0,80	8,00	[79]
3	Sheet metal	Steel	Kg	30,00	0,80	24,00	[79]
4	Round bar ϕ 100	Steel	Kg	20,00	0,80	16,00	[79]
5	Screw ϕ 12	Steel	m	0,50	20,00	10,00	Estimation
6	Bolts and nuts	Standard	Ls	1,00	50,00	50,00	Estimation
7	Screw ϕ 12	Aluminum	m	0,50	40,00	20,00	Estimation
8	Pipe ϕ 32x2	Aluminum	m	1,00	40,00	40,00	Estimation
9	Spring	Standard	Pcs	1,00	20,00	20,00	Estimation
10	Reduction gearbox	Standard	Pcs	1,00	400,00	400,00	[80]
11	Curved rail	Standard	m	3,00	300,00	900,00	[81]
12	Linear rail	Standard	m	0,75	225,00	168,75	[81]
13	Guide block	Standard	Pcs	2,00	100,00	200,00	[81]
14	Sensor and display	Standard	Ls	1,00	500,00	500,00	Estimation
15	Electric motor	Standard	Pcs	1,00	1 500,00	1 500,00	[67]
16	Angular bearing	Standard	Pcs	1,00	25,00	25,00	[82]
17	Bearing house	Standard	Pcs	1,00	50,00	50,00	Estimation
18	Webbing belt	Textile	m	3,00	6,00	18,00	Estimation

Total material cost	4 062,55
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9 CONCLUSION

This thesis comprises the description of different instruments or systems that are used to measure the kinematics of human motion and/or specifically the kinematics of knee joint, and the design of instrument for knee joint kinematics measurement. Engineering design process is demonstrated and applied to design the instrument.

The design requirements of the instrument are fulfilled. It is designed to measure four degree of freedom: flexion-extension, varus-valgus, internal rotation and proximal-distal. The accuracy of the measurement is in microns for linear motion and in mils for angular motions. It is also flexible to measure anthropometrically different subject. The instrument is compatible with imaging machine exist in Kuopio University. The subject to be measured can be either in-vivo or in-vitro.

The cost of the instrument is less than to the instruments discussed in section 3. The total manufacturing cost of the instrument is estimated to be 8740€. It needs an overall space of 1.6x0.5x0.9m. It also requires one operator to run the test on the subject. The data collect is done automatically and digitally which makes it simpler.

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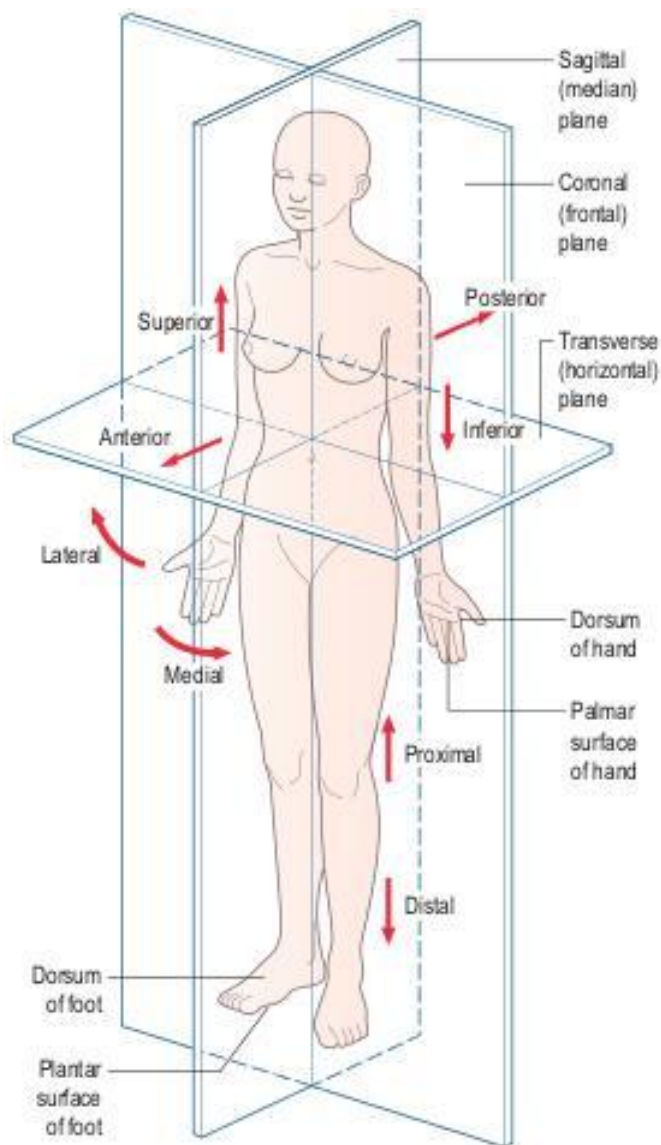
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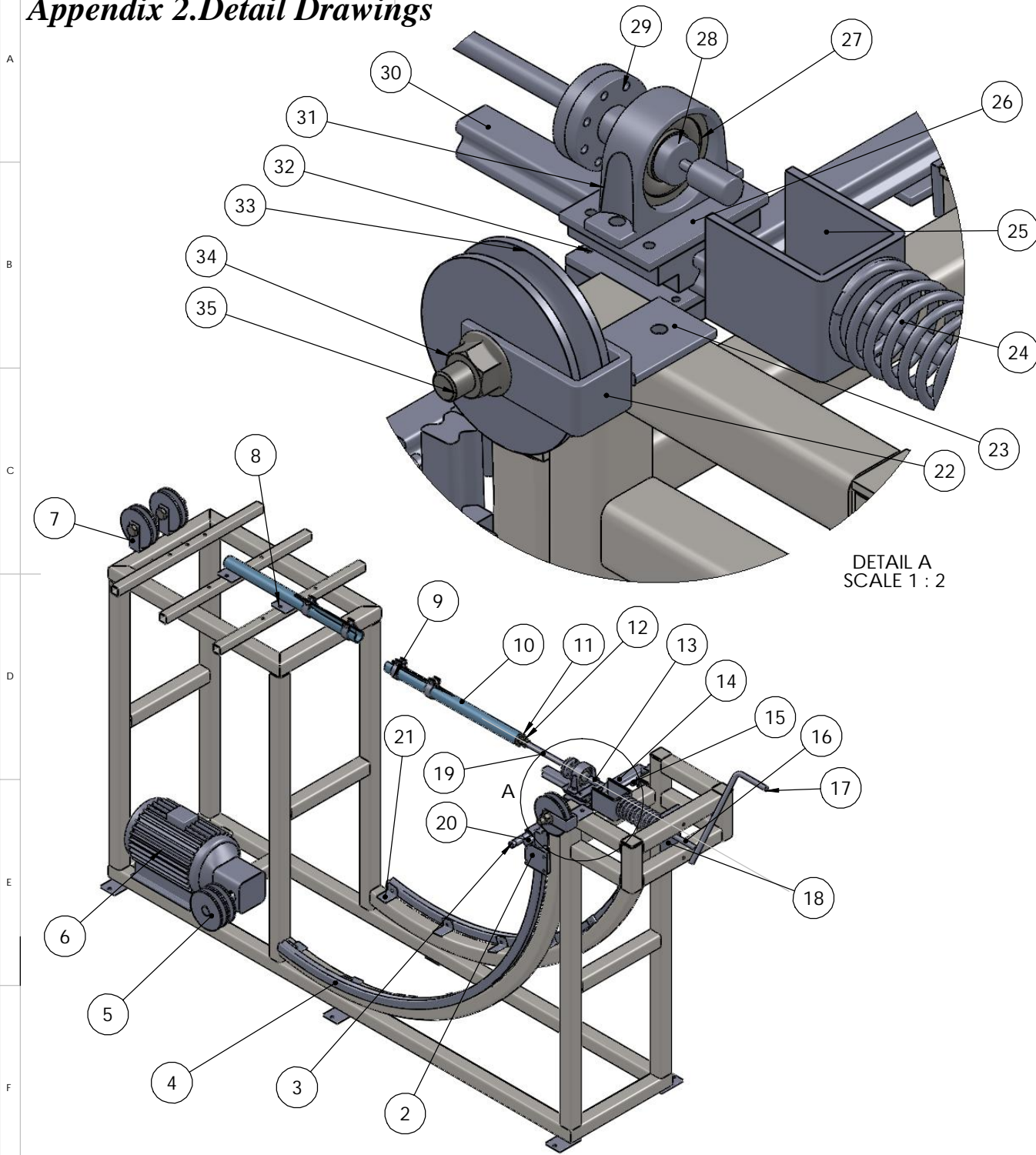
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APPENDECIES

Appendix 1. Anatomical position showing the cardinal planes and directional terminology [83]



Appendix 2.Detail Drawings



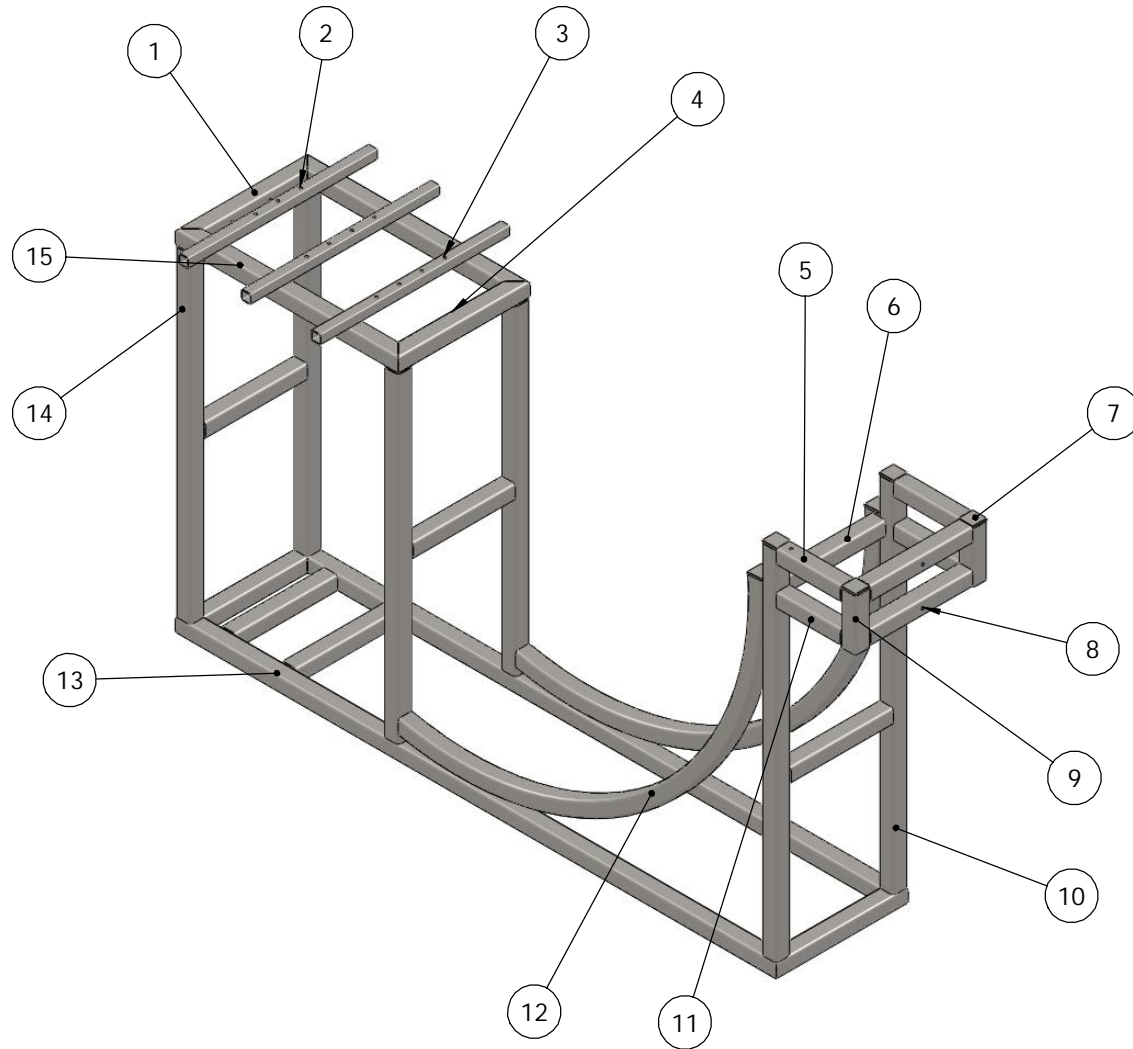
DETAIL A
SCALE 1 : 2

NO.	PART NUMBER	DESCRIPTION	QTY.
1	Structure	RHS 40x40x2.5mm	1
2	Connecting plate 4	'125x62x5mm	1
3	Pulling pin	D16x85mm	1
4	Guide_flexionextension		2
5	pulley_1	D100x25mm	2
6	Motorgearbox		1
7	pulley suport_1	'120x30x5mm	2
8	Connecting plate 5	'75x50x5mm	8
9	Tighter	'50x80x20mm	4
10	Tube	D31x450x2.5mm	2
11	Tube cup	D32x6	1
12	Hexagon nut	M12 x 1.5	4
13	Potentiometer 1		1
14	Guide_ varusvalgus		1
15	Connecting plate 3	'125x62x5mm	1
16	Screw M12x1.5 St		1
17	Handle	D12x350mm	1
18	Spring plate_1	'140x60x10mm	1
19	Screw M12x1.5 Alu		1
20	Potentiometer 2		1
21	Connecting plate 6	'65x30x5mm	16
22	pulley suport_2	'96.4x30x5mm	1
23	guide block		4
24	spring	Standard	1
25	Spring plate_2	'220x60x5mm	1
26	Connecting plate 1	'82x62x5mm	1
27	Angular contact ball bearing	7304-B-JP	1
28	shaft for bearing	D24x48mm	1
29	Flange	D50x8mm	2
30	Guide_Proximaldistal		1
31	bearing house	Standard	1
32	Connecting plate 2	'70x62x5mm	1
33	pulley_2	D100x25mm	3
34	Hexagon nut with flange	M16	3
35	Hexagon bolt	M16 x 70	3

MATERIAL:		REVISION: Unless otherwise noted: All diamension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: Assembly drawing		
Qty.	DWG NO.	A3
SCALE:		SHEET 1 OF 20

Appendix 2 continued

ITEM NO.	QTY.	DESCRIPTION	LENGTH	ANGLE
1	1	RHS 40x40x2.5mm	350	45.00
2	1	RHS 25x25x2mm	500	0.00
3	2	RHS 25x25x2mm	500	0.00
4	3	RHS 40x40x2.5mm	350	45.00
5	1	RHS 40x40x2.5mm	170	0.00
6	6	RHS 40x40x2.5mm	270	0.00
7	6	'35x35x3mm		
8	2	RHS 40x40x2.5mm	270	0.00
9	2	RHS 40x40x2.5mm	135	0.00
10	2	RHS 40x40x2.5mm	945	0.00
11	3	RHS 40x40x2.5mm	170	0.00
12	2	RHS 40x40x2.5mm	1442.34	0.00
13	2	RHS 40x40x2.5mm	1590	45.00
14	4	RHS 40x40x2.5mm	847.89	0.00
15	2	RHS 40x40x2.5mm	590	45.00

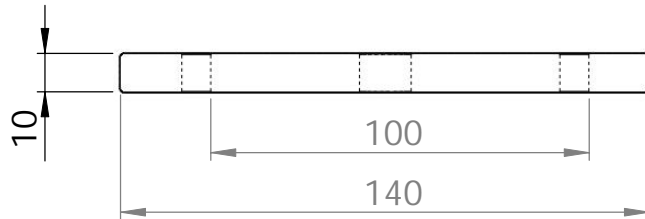


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DRAWN	DATE	
	BY	
TITLE: <i>Sturcture and cutting list</i>		
Qty. 1	DWG NO.	A3
SCALE:		SHEET 2 OF 20

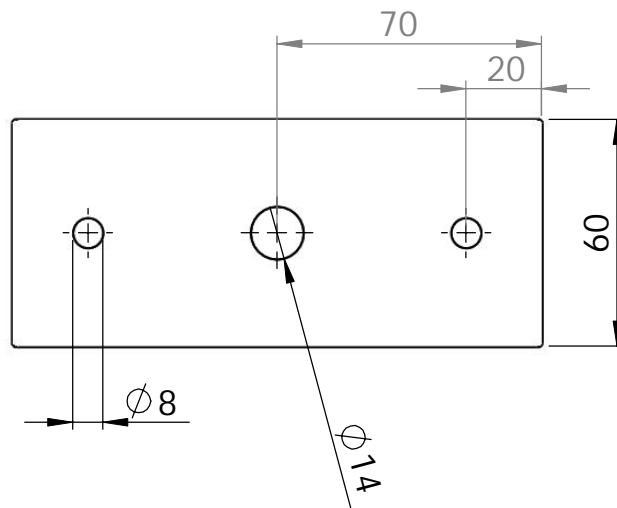
Appendix 2 continued

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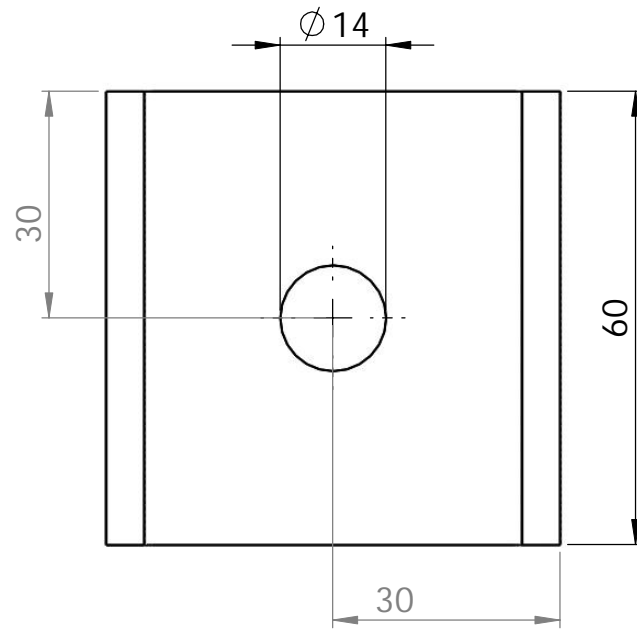
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MATERIAL:		REVISION:	
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	BY		
TITLE: <i>Plate for spring</i>			
Qty. 1	DWG NO.		A4
SCALE:1:1		SHEET 3 OF 20	

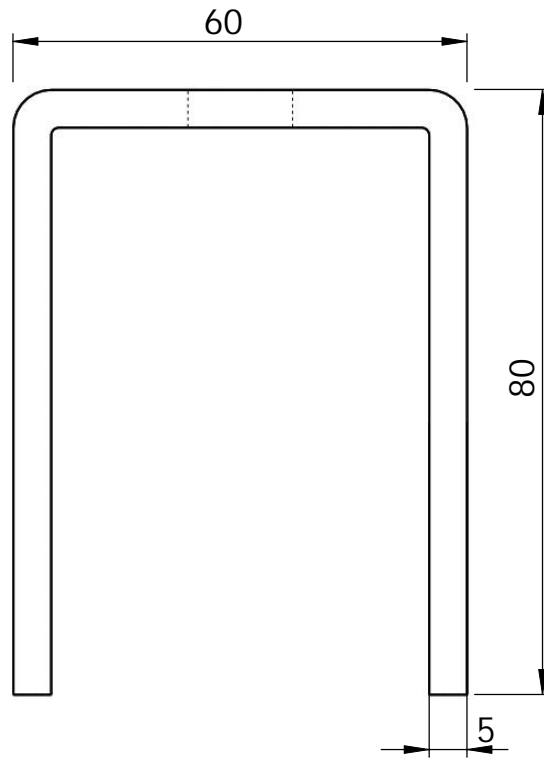
Appendix 2 continued

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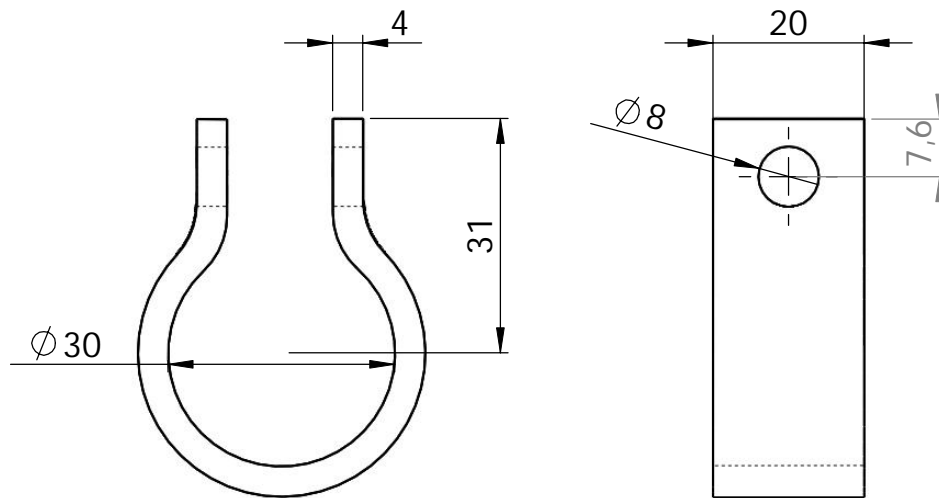
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DRAWN	DATE	Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5	
	BY		
TITLE: <i>Plate for spring</i>			
Qty. 1	DWG NO.		A4
SCALE:1:1		SHEET 4 OF 20	

Appendix 2 continued

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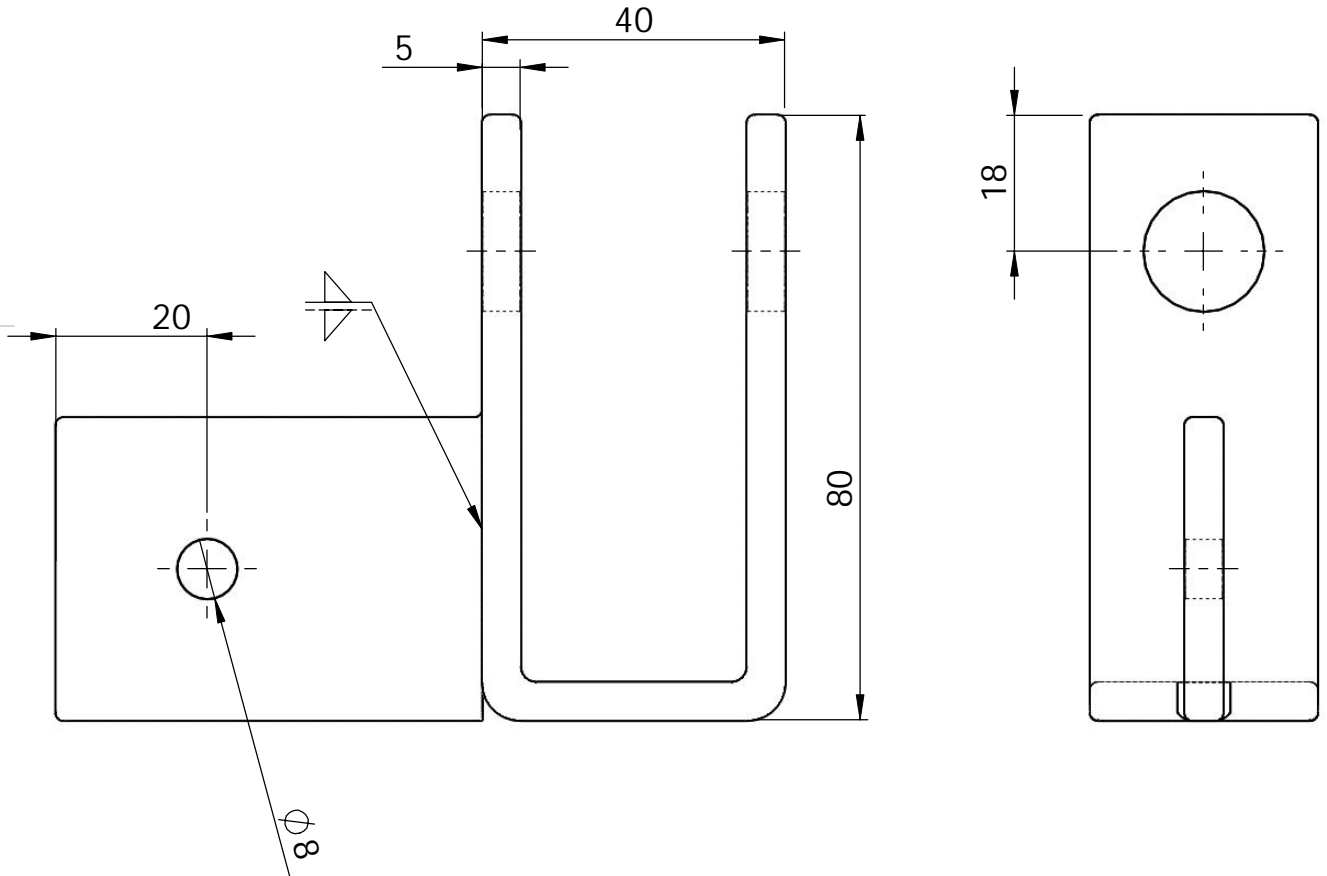
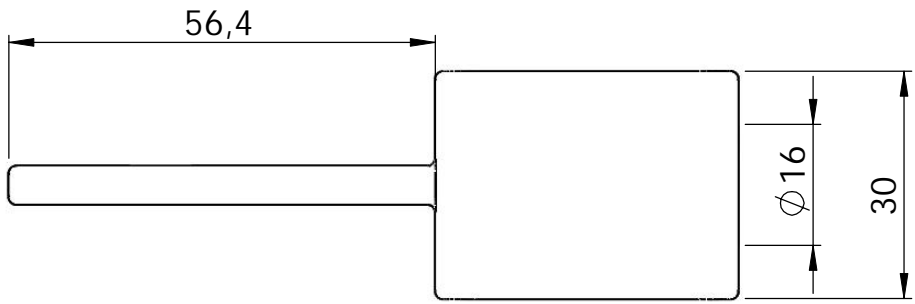
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MATERIAL:		REVISION: Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: <i>Tighter</i>		
Qty. 4	DWG NO.	A4
SCALE:1:1		SHEET 5 OF 20

Appendix 2 continued

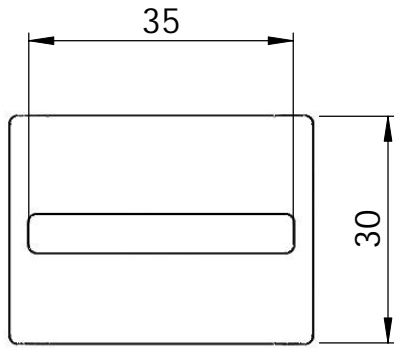
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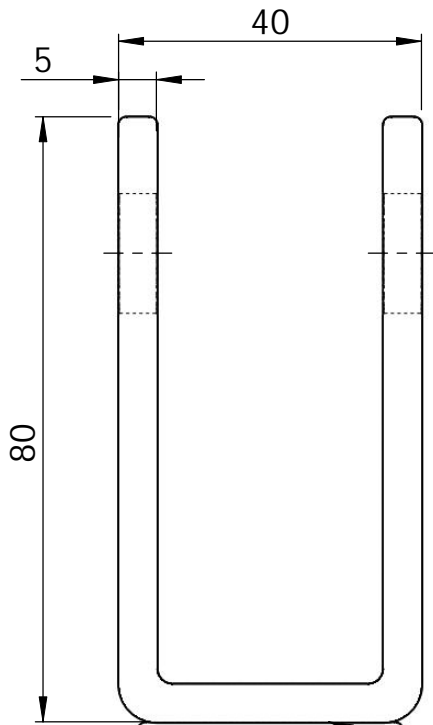
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DRAWN	DATE	
	BY	
TITLE: <i>Pulley holder</i>		
Qty. 1	DWG NO.	A4
SCALE:1:1		SHEET 6 OF 20

Appendix 2 continued

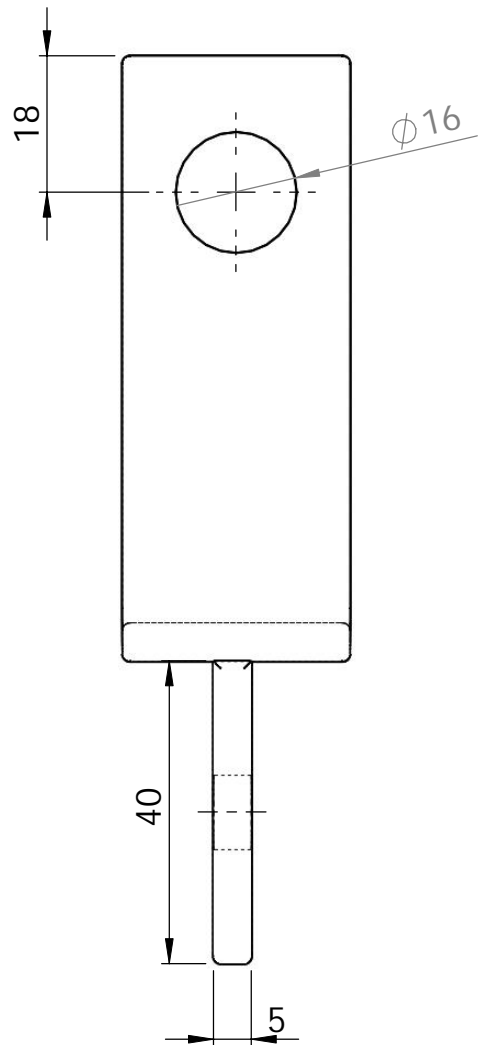
A



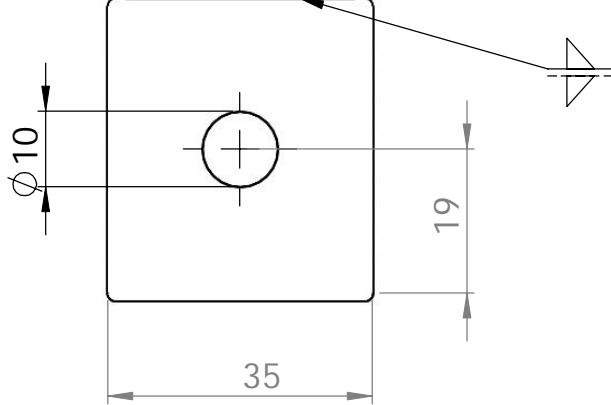
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MATERIAL:		REVISION: Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: <i>Pulley holder</i>		
Qty. 2	DWG NO.	A4
SCALE:1:1		SHEET 7 OF 20

Appendix 2 continued

A

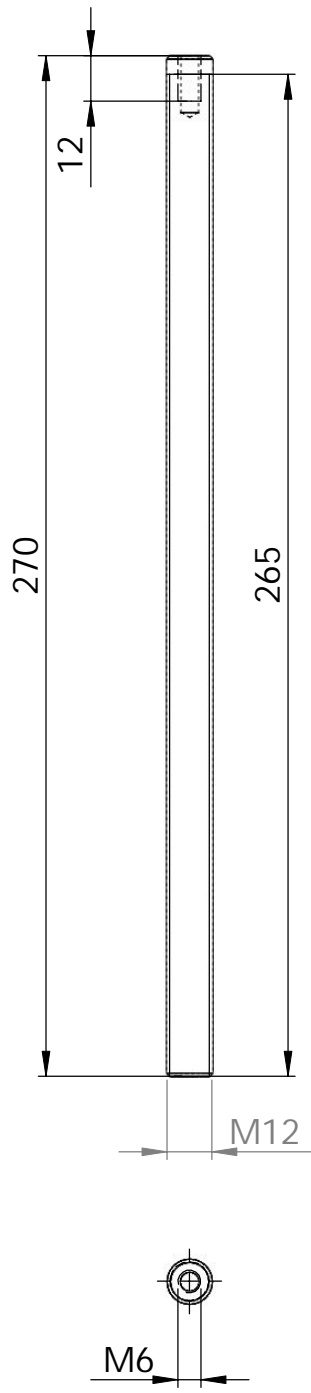
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MATERIAL: Aluminum

REVISION:

DRAWN

DATE

BY

Unless otherwise noted:
 All dimension are mm
 Tolerance are
 .xx+0.02
 angle+.5

TITLE:

Extension screw

Qty. 1

DWG NO.

A4

SCALE:1:1

SHEET 8 OF 20

Appendix 2 continued

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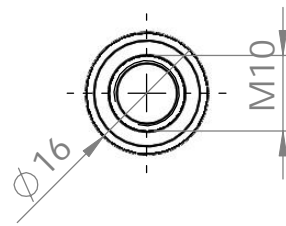
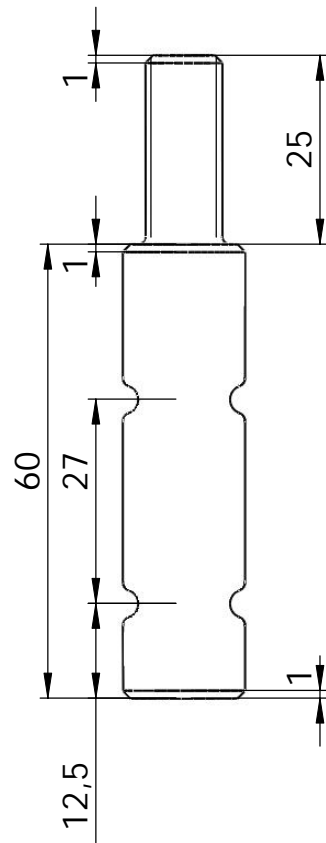
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MATERIAL:		REVISION:	
DRAWN	DATE	Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5	
	BY		
TITLE: <i>Pulling pin</i>			
Qty. 1	DWG NO.		A4
SCALE:1:1		SHEET 9 OF 20	

Appendix 2 continued

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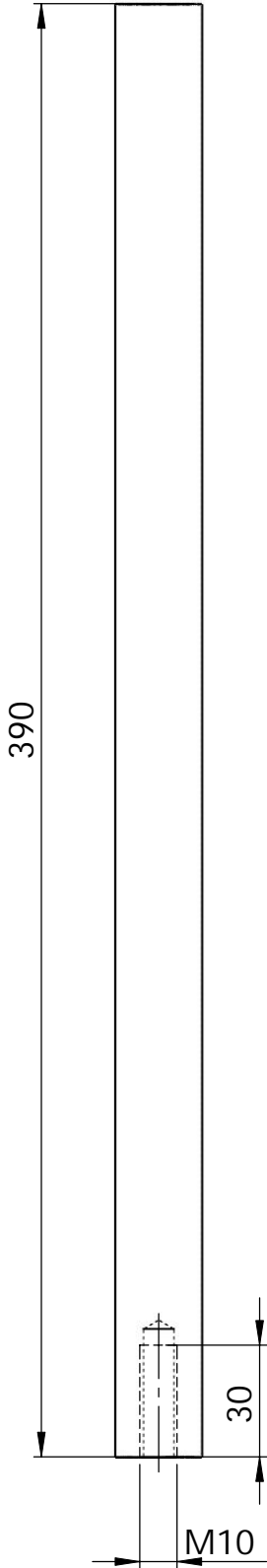
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Note: The profile is standard

MATERIAL:		REVISION: Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: <i>Varus-valgus linear guide</i>		
Qty. 1	DWG NO.	A4
SCALE:1:1		SHEET 10 OF 20

Appendix 2 continued

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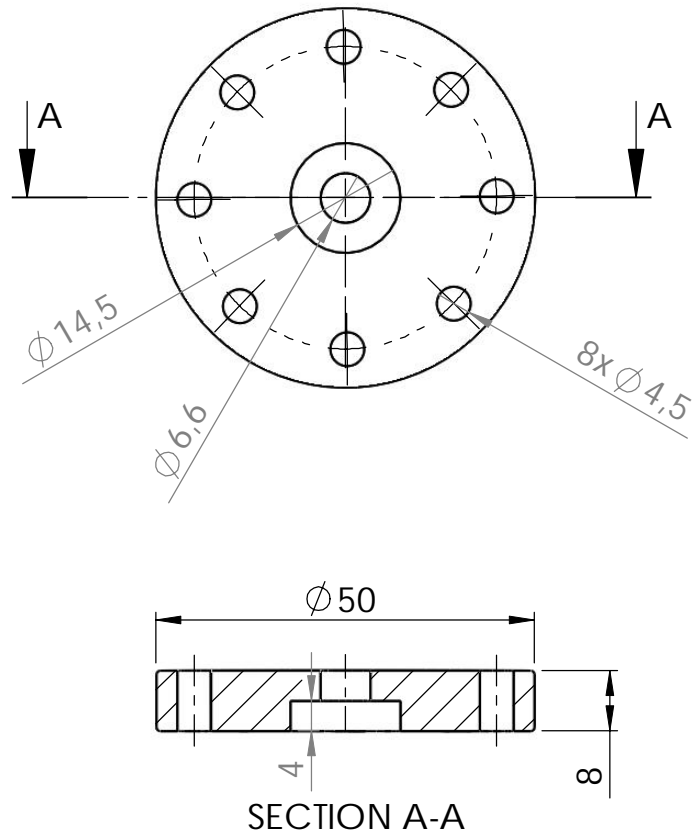
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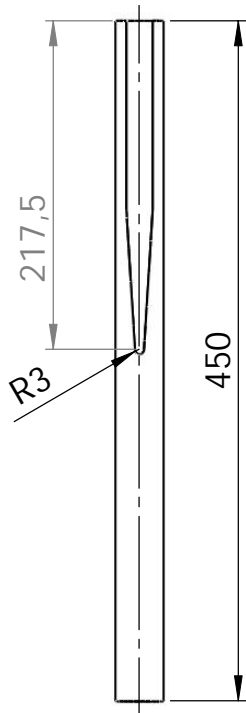
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	BY	
TITLE:		
<i>Falnge</i>		
Qty. 2	DWG NO.	
		A4
SCALE: 1:1		SHEET 11 OF 20

Appendix 2 continued

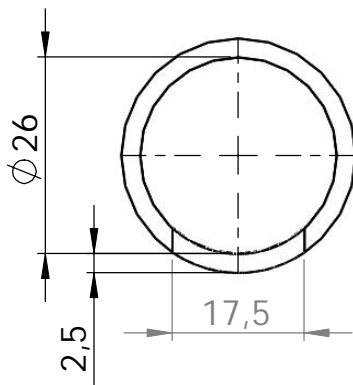
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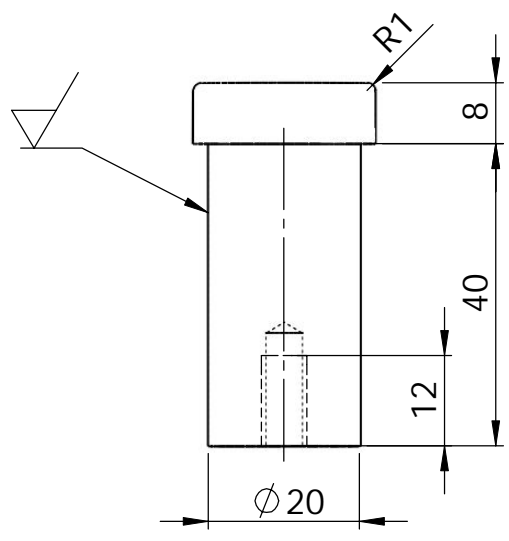
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DRAWN	DATE	Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5	
	BY		
TITLE: <i>Tube</i>			
Qty. 2	DWG NO.		A4
SCALE:1:1		SHEET 12 OF 20	

Appendix 2 continued

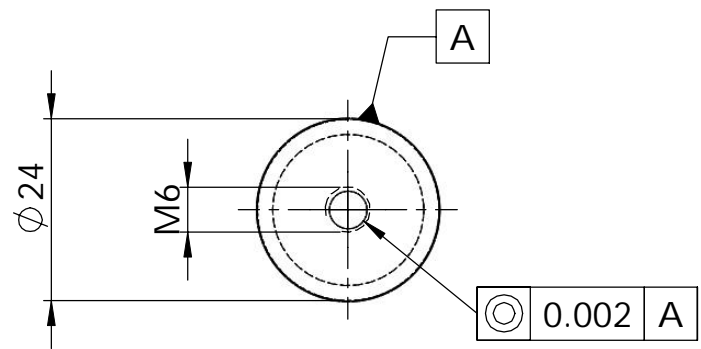
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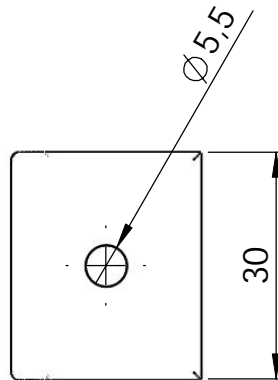
F

MATERIAL: Aluminum		REVISION: Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: <i>Shaft</i>		
Qty. 1	DWG NO.	A4
SCALE: 1:1		SHEET 13 OF 20

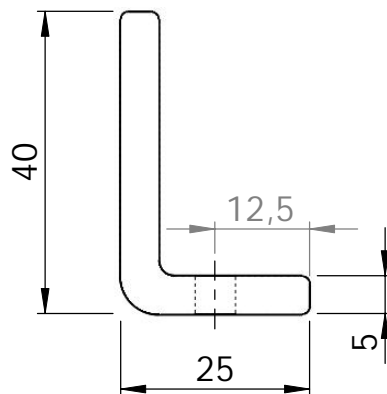
Appendix 2 continued

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Note: Location of hole depends on the guide

E

MATERIAL:		REVISION:	
DRAWN	DATE	Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5	
	BY		
TITLE: <i>Connecting plate</i>			
Qty. 16	DWG NO.		A4
SCALE:1:1		SHEET 14 OF 20	

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Appendix 2 continued

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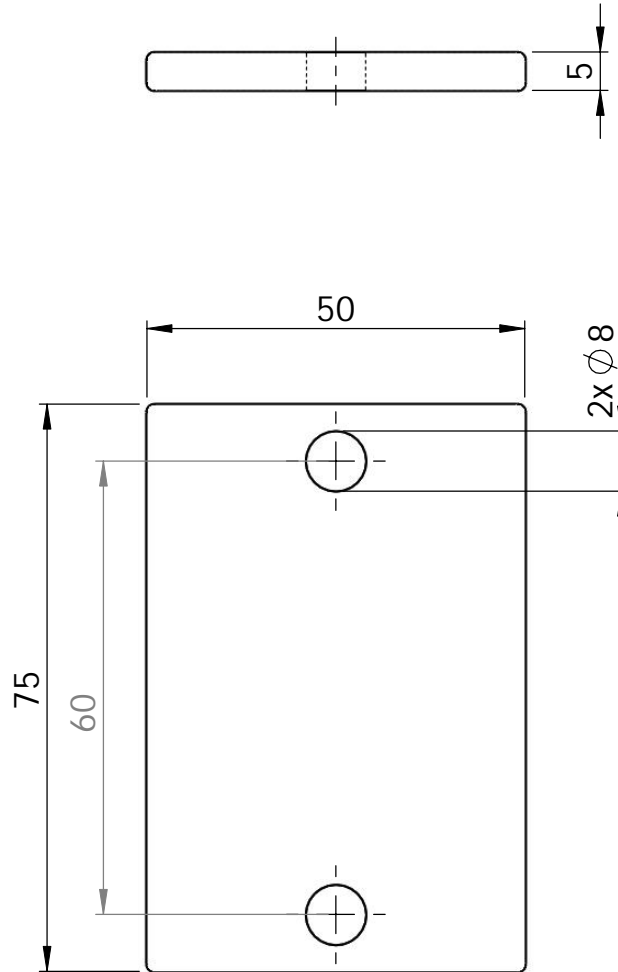
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MATERIAL:		REVISION: Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: <i>Connecting plate</i>		
Qty. 2	DWG NO.	A4
SCALE:1:1		SHEET 15 OF 20

Appendix 2 continued

A

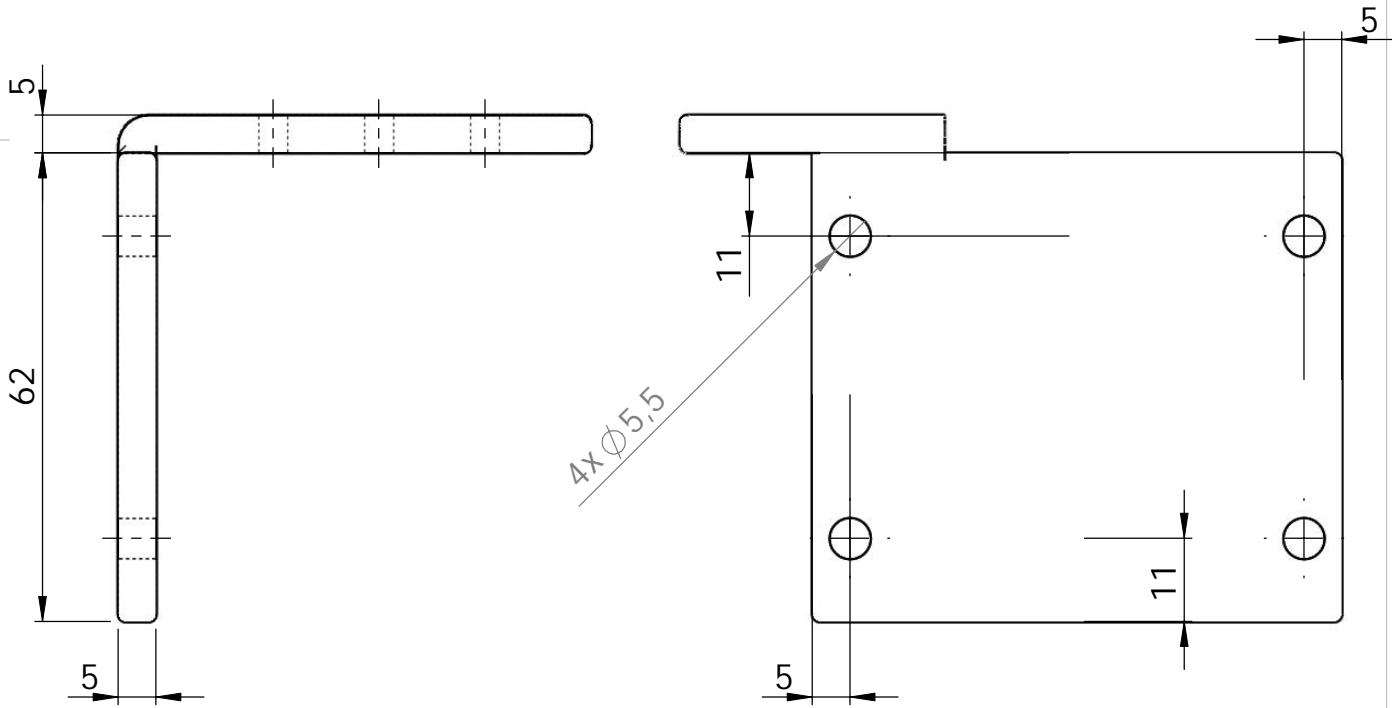
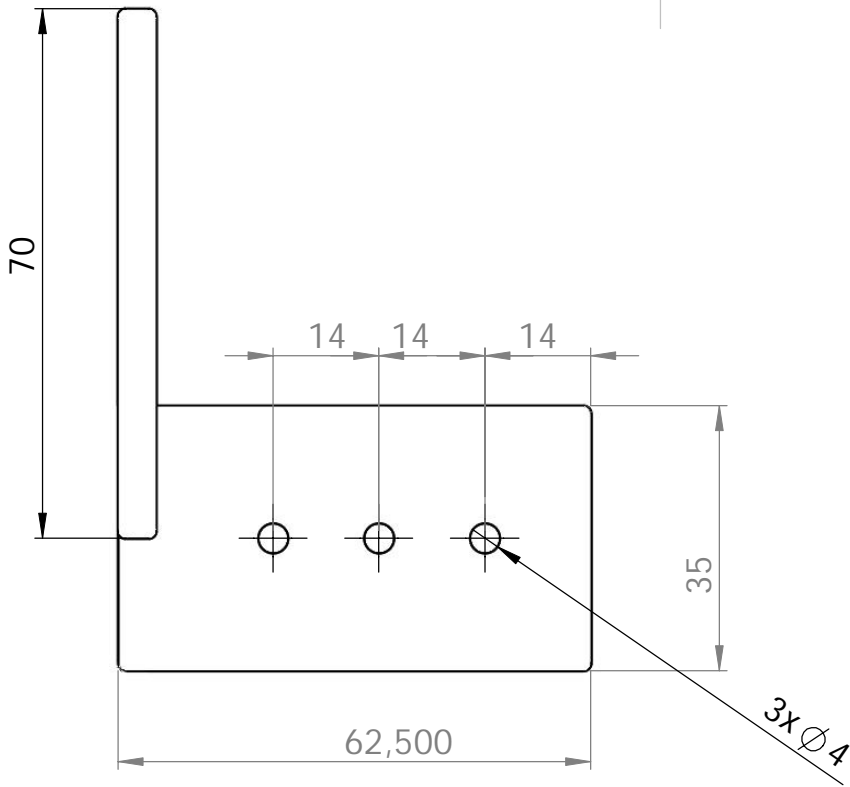
B

C

D

E

F



MATERIAL:

REVISION:

DRAWN

DATE

BY

Unless otherwise noted:
All dimension are mm
Tolerance are
.xx+0.02
angle+.5

TITLE:

Connecting plate

Qty. 1

DWG NO.

A4

SCALE:1:1

SHEET 16 OF 20

Appendix 2 continued

A

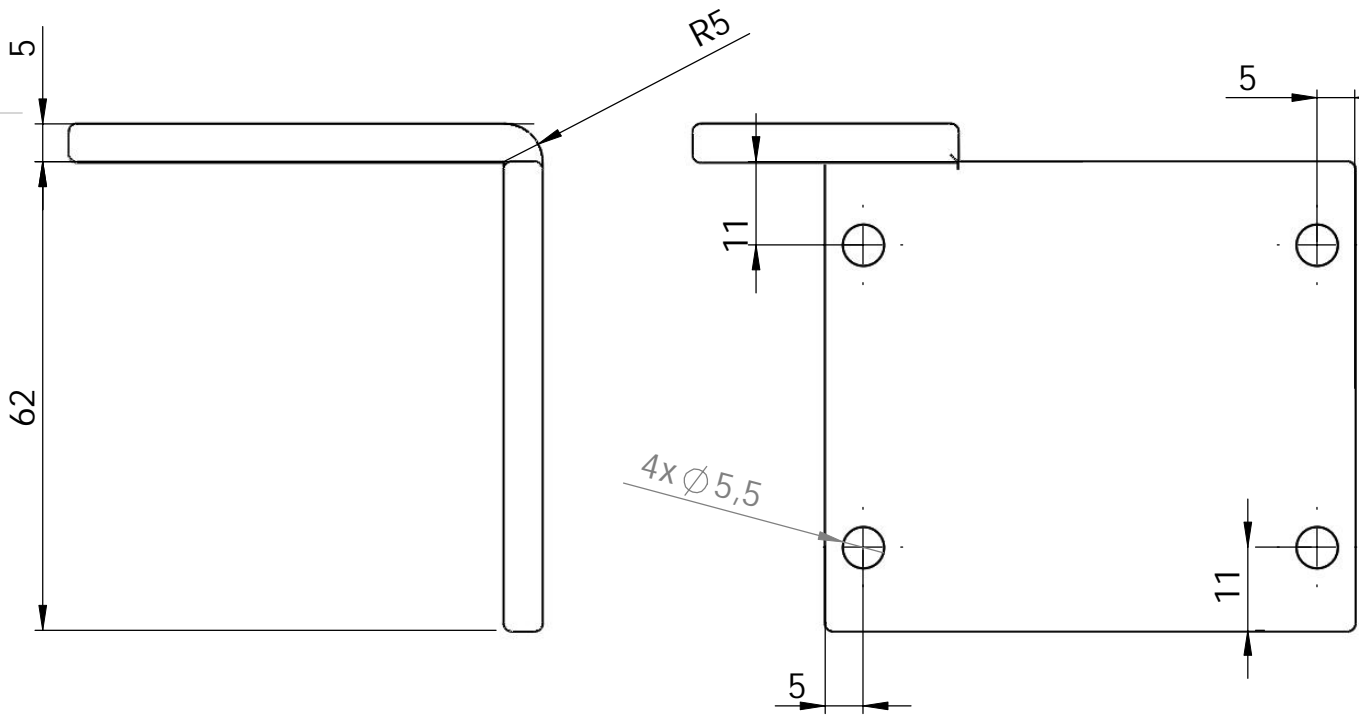
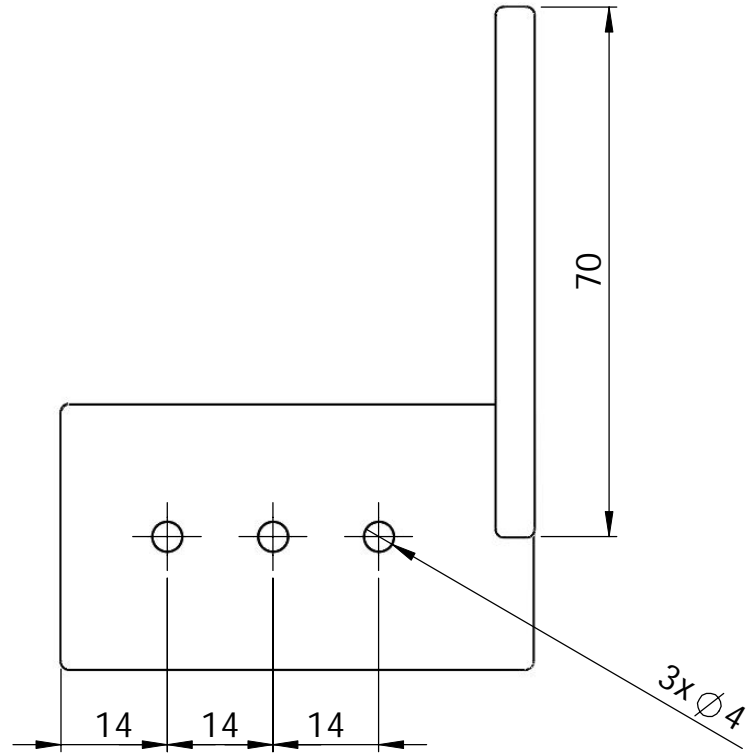
B

C

D

E

F



MATERIAL:		REVISION: Unless otherwise noted: All dimension are mm Tolerance are .xx+0.02 angle+.5
DRAWN	DATE	
	BY	
TITLE: <i>Connecting plate</i>		
Qty. 1	DWG NO.	A4
SCALE:1:1		SHEET 17 OF 20

Appendix 2 continued

A

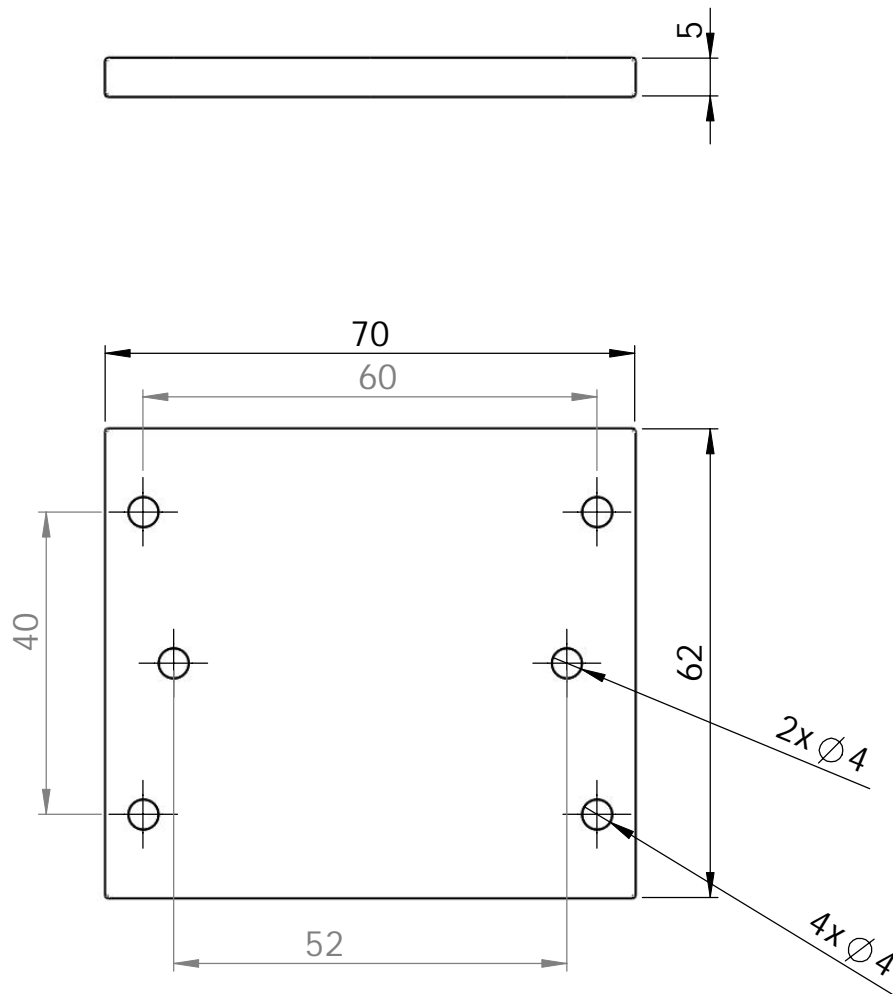
B

C

D

E

F



MATERIAL:

REVISION:

DRAWN

DATE

BY

Unless otherwise noted:
All dimension are mm
Tolerance are
.xx+0.02
angle+.5

TITLE:

Connecting plate

Qty. 1

DWG NO.

A4

SCALE:1:1

SHEET 18 OF 20

Appendix 2 continued

A

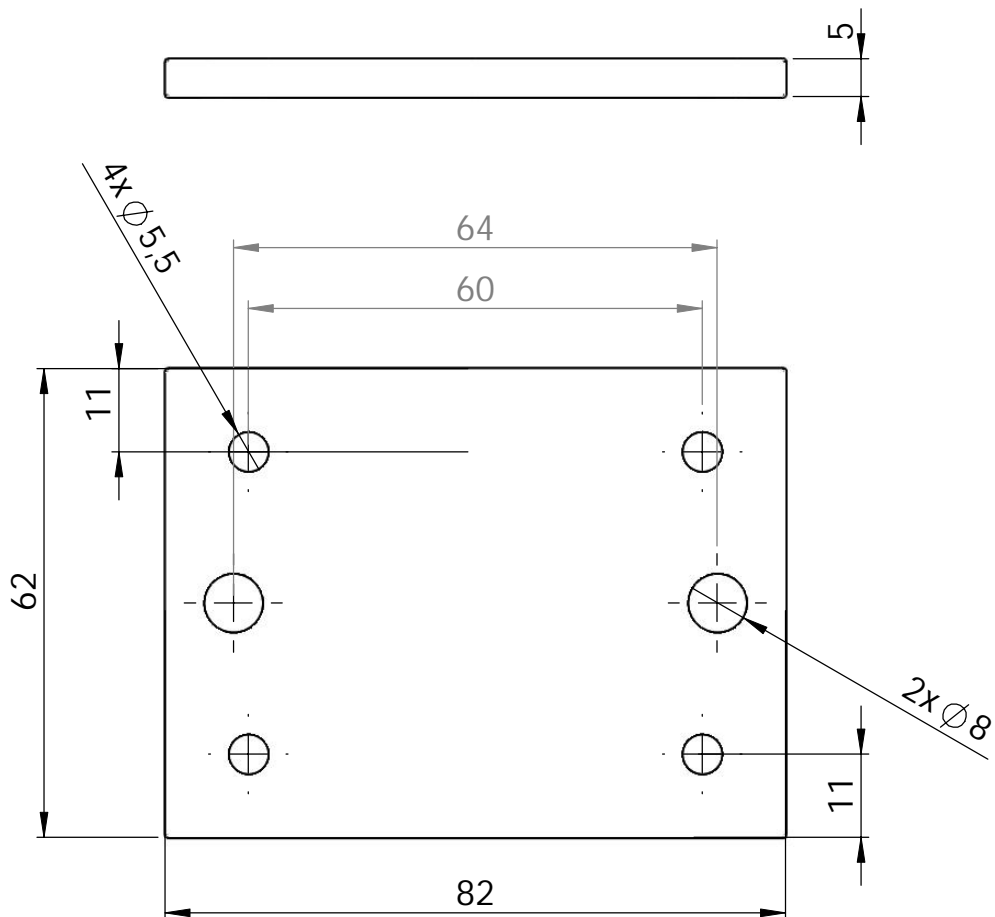
B

C

D

E

F



MATERIAL:

REVISION:

DRAWN

DATE

BY

Unless otherwise noted:
All dimension are mm
Tolerance are
.xx+0.02
angle+.5

TITLE:

Connecting plate

Qty. 1

DWG NO.

A4

SCALE:1:1

SHEET 19 OF 20

Appendix 2 continued

A

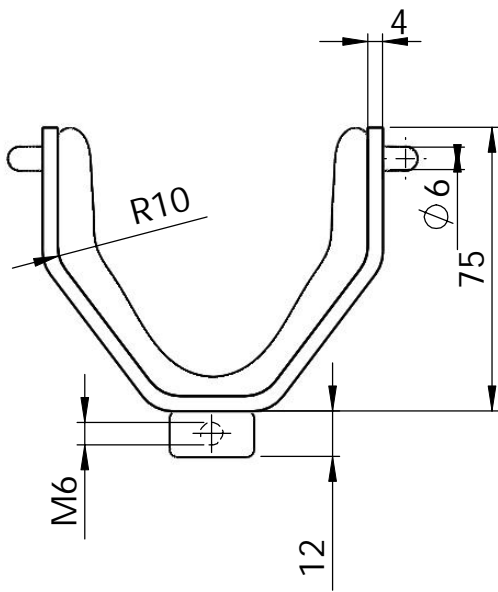
B

C

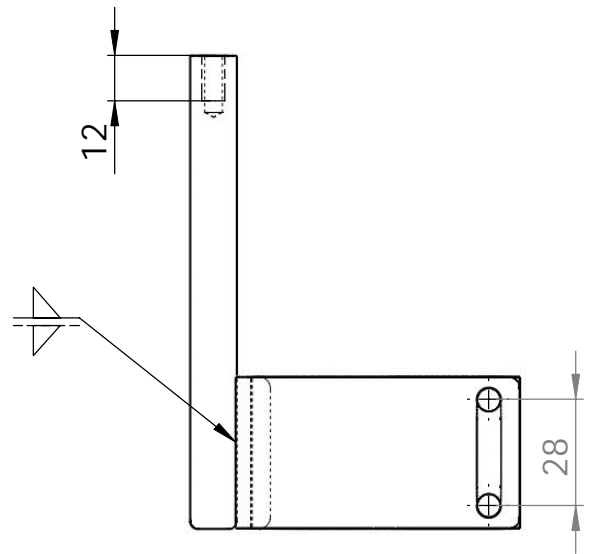
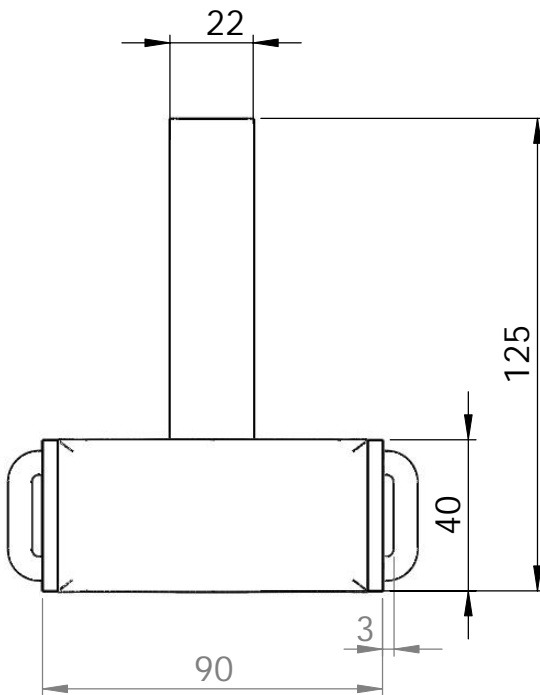
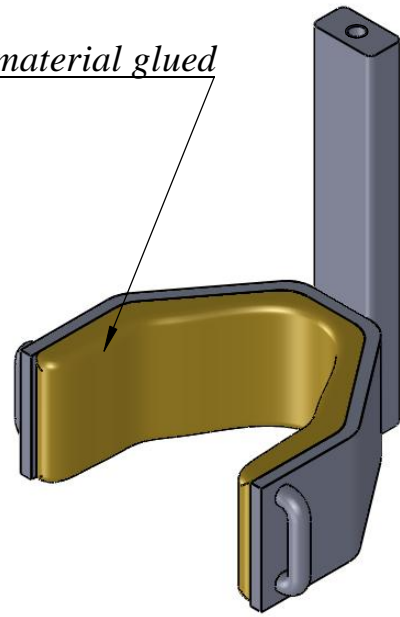
D

E

F



Soft material glued



MATERIAL:

REVISION:

DRAWN

DATE

BY

Unless otherwise noted:
All dimension are mm
Tolerance are
.xx+0.02
angle+.5

TITLE:

Ankle holder

Qty. 1

DWG NO.

A4

SCALE:1:1

SHEET 20 OF 20