DEVELOPING A SYSTEM OF HOLDERS FOR AN ULTRASOUND KINEMATIC ANALYSIS SYSTEM

Author: Mats Boeve

Client: The Orthopaedic Research Laboratory

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University of Twente
Department of Industrial Design Engineering

UNIVERSITY OF TWENTE.

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Mats Boeve
S0212490

FACULTY OF ENGINEERING TECHNOLOGY
DEPARTMENT OF INDUSTRIAL DESIGN ENGINEERING
BACHELOR REPORT

EXAMINATION COMMITTEE
ir. E.E.G. Hekman
dr. ir. H.J.M. Geijselaers
A.M.J. Sprengers, Ph.D

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PREFACE

The enthusiasm of Prof. Verdonschot during a coincidental meeting was the initiation of this Bachelor assignment. At that time he was looking for a student industrial design engineering, who could aid in the development of a new kinematic analysis system. The development of the ultrasound based kinematic analysis system had come to the point where an interface between the ultrasound system and the subject was required. After an informative conversation, I decided to accept the challenge and start with the design of the holder system for the ultrasound based kinematic analysis system.

I am grateful to have gotten this opportunity and hope that I have delivered a valuable contribution to the work of the Orthopaedics Research Laboratory. During the project I felt supported in good and bad times and would like to offer my heartfelt thanks to the following people:

- Prof. N. Verdonschot for his enthusiasm
- Andre Sprengers for his support
- Edsko Hekman for his guidance
- Kenan Niu and Victor Sluiter for their help with testing, thinking and printing

Table of contents

Appendices:

Samenvatting

Achtergrond

Omdat de huidige technieken voor de analyse van de knie kinematica ofwel invasief ofwel radiatief zijn, is de vraag naar nieuwe, niet-invasieve en niet-radiatieve, technieken ontstaan. Een systeem op basis van ultrasound is een van de alternatieven die wordt onderzocht. Het doel van deze bachelor opdracht is het ontwikkelen van een houder die kan dienen als de interface tussen het ultrasound systeem en de patiënt. De houders moeten het mogelijk maken om op dynamische wijze de kinematica van het kniegewricht in kaart te brengen. Hiervoor moeten 30 ultrasound transducers verdeeld worden over het boven- en onderbeen van de patiënt. Dit maakt het mogelijk om de locatie van het dijbeen en scheenbeen van de patiënt te bepalen en daarmee de kinematica van de knie te reconstrueren.

Analyse fase

De eerste stap was het in kaart brengen van de stand van zaken in de ontwikkeling van het ultrasound systeem. Door het bijwonen van een kadaver test is getracht de werking en de tekortkomingen van de gebruikte materialen beter inzichtelijk te maken. De kennis van het systeem is daarna verder uitgediept door naar de theorie achter de verschillende ultrasound modes te kijken. Ook is het Visualeyez motion capture systeem geanalyseerd en is bepaald dat de prototypes met behulp van een 3D printer worden vervaardigd. Het gebruik van A-mode ultrasound en het Visualeyez motion capture systeem brengt een aantal beperkingen en eisen aan het ontwerp van de houders met zich mee. Deze zijn, samen met de eisen en wensen van de opdrachtgever, vertaald naar een programma van eisen.

Concept fase

Na de analyse fase is begonnen met verkennen van mogelijke oplossingen voor de houders, waarbij er gevarieerd is in complexiteit en versitalietit van de ideeën. De drie meest belovende ideeën zijn uitgewerkt naar basis concepten, waarbij geprobeerd is een basis principe achter de ideeën neer te zetten. Uiteindelijk is het meest kansrijke concept gekozen en een gesimplificeerd prototype van dit concept is getest. Het doel van deze test was het in kaart brengen van de haalbaarheid. Door te kijken of het überhaupt mogelijk is tijdens een dynamische beweging het bot te blijven zien met behulp van ultrasound, kon een inschatting worden gemaakt of het gekozen principe levensvatbaar is. De resultaten van deze test waren positief. Er werd echter wel besloten dat met behulp van een gestructureerde test de locaties op het been waar dit principe werkt in kaart moeten worden gebracht. De reden hiervoor was de onzekerheid omtrent de werking van het principe op karakteristiek locaties, die noodzakelijk zijn voor de reconstructie van de kinematica. Met behulp van een theoretische aanpak zijn de te testen locaties bepaald en vervolgens getest met behulp van een speciaal ontworpen houder. Dit resulteerde in de 30 locaties die het meest geschikt zijn voor het reconstrueren van de kinematica met behulp van het basis principe.

Final concept fase

Met behulp van de opgedane observaties tijdens de locatie testen is een morfologische analyse opgesteld. Deze is gebruikt om de keuze voor een aantal belangrijke onderdelen te kunnen maken. Op basis van de informatie uit de locatie testen en de morfologische analyse zijn concepten gemaakt van zes houder delen. Voor elk van deze onderdelen is een parametrisatie opgesteld zodat op maat gemaakte versies geprint kunnen worden voor alle patienten. De concepten zijn vervolgens vertaald naar Solidworks modellen, waarbij de parametrisatie als basis is gebruikt. Prototypes van de modellen zijn vervolgens geprint en geanalyseerd. Dit leidde tot enkele verbeteringen die dan ook zijn door gevoerd in de uiteindelijke versie van de concepten. Daarnaast is een speciale documentatie is geschreven waarin wordt uitgelegd hoe een patiënt opgemeten moet worden en hoe deze waardes omgezet kunnen worden naar een patiënt specifiek Solidworks model.

Conclusies

Uiteindelijk is er een concept ontwikkeld dat het mogelijk maakt om op dynamische wijze de kinematica van de knie te analyseren. Hoewel er nog geen uitspraken gedaan kunnen worden over de werking van het systeem van houders samen, deze zijn namelijk nog niet getest, kan wel worden geconcludeerd dat er is aangetoond dat het mogelijk is om met het gekozen principe het bot te volgen op de, voor de reconstructie van de kinematica, benodigde karakteristieke locaties.

Summary

Background

Because the current techniques for the analysis of knee kinematics are either invasive or radiative, the demand for new, non-invasive and non-radiative techniques has originated. A system that relies on ultrasound is one of the explored alternatives. The goal of this bachelor report is to develop a holder that is the interface between the ultrasound system and the patient. The holders must enable the dynamic reconstruction of the knee joint kinematics. Theretofore 30 ultrasound transducers must be divided in correct manner over the upper and lower leg of the patient. This enables the localisation of the femur and tibia bone of this patient and as a result the reconstruction of the knee kinematics.

Analysis Phase

The first step was to map the current situation regarding the development of the ultrasound system. By attending a cadaver testing, an attempt was made to provide insights in the operation and shortcomings of the required materials. Furthermore the knowledge regarding ultrasound has been broadened by looking into the theory behind it. Besides the Visualeyez motion capture system has been analysed and it is specified that the prototypes will be fabricated using 3D-prinitng techniques. The use of A-mode ultrasound and the Visualeyez motion capture system incorporates several requirements and limitations to the design of the holders. These, together with the requirements and wishes of the client, are translated into a statement of requirements.

Concept phase

After the analysis phase the exploration of possible solutions for the design of the holders started, complexity and versatile were varied here. The three most promising ideas are further elaborated into basic concepts, where it is tried to establish a basic principle behind the ideas. Eventually the most promising concept is chosen and a simplified prototype has been tested. The goal was to determine the feasibility of the basic idea. By determining if it is even possible to keep seeing the bone during a dynamic measurements using ultrasound, an estimation could be made whether the principle is viable. The results of this test were positive, but it was decided that structured testing was necessary to reveal where on the leg the chosen basic principle works. The reason was the uncertainty regarding the performance of the chosen principle on the characteristic locations, who are required for the reconstruction of the kinematics. The locations that would be tested were determined using a theoretical approach and then tested using an especially designed testing holder. This resulted in the 30 most appropriate locations to reconstruct the kinematics using the basic principle.

Final concept phase

Using the observations done during the location testing, a morphological analysis could be prepared. It was used to be able to make choices regarding a few key components. Based on the information obtained in the location testing and the morphological analysis, concepts could be made of the six separate holder parts. For each of them a parametrisation has been prepared to enable the fabrication of versions tailored specially for a subject. The concepts are then translated to Solidworks models, using the parametrisation as base for the models. Prototypes of the models were printed and analysed, leading to several improvements to the design, these were implemented in the final design of the concepts. Furthermore a special documentation has been written explaining how a subject must be measured and how these values can be translated into subject specific Solidworks models.

Conclusion

Eventually a concept is developed that enables the analysis of the knee kinematics in a dynamic fashion. While no conclusions can be drawn regarding the working of the system of holders, they aren't tested yet, it can be said that it is proven that, while using the chosen basic principle, it is possible to keep seeing the bone in the characteristic locations required to reconstruct the knee kinematics.

1. Introduction

This Bachelor assignment is done for the Orthopaedic Research Laboratory (ORL) as part of a project that aims to develop an ultrasound-based kinematic analysis system. The introduction is used to give some background information concerning the ORL and introduce the ultrasound project. Furthermore the Bachelor assignment's objective will be stated and finally a bookmaker is supplied to enhance the reading of this report.

The Orthopaedics Research Laboratory[1]:

The Orthopaedic Research Laboratory (ORL) is an institute that performs research to strengthen the scientific basis of Orthopaedics. This research is done in several fields such as bone and meniscus tissue, pre-clinical testing of implants and biomechanical tools. Prof. Verdonschot, who holds the chair of the ORL, was awarded an "European Research Council – Advanced Grant" entitled "Biomechanical Diagnostic, Pre-planning and Outcome Tools to improve Musculoskeletal Surgery" in 2012. The goal of this programme is to develop diagnostic and evaluation tools to quantify the degenerative status of orthopaedic patients using techniques as MRI and ultrasound. The interest of developing these tools is to provide clinicians and researchers with detailed biomechanical analysis about abnormal tissue deformations, pathological loading of the joints, abnormal stresses in both hard and soft tissues, and deviating joint kinematics. Currently the methods used are often crude and subjective, which leads to non-optimal analyses and patient care. By supplying improved tools to clinicians, patients' healthcare is enhanced.

The ultrasound based kinematic analysis system:

The development of an ultrasound-based kinematic analysis system is one of the research areas within the BioMechtools programme. The goal of this research is to create an ultrasound-based system that is able to assess knee kinematics. It can be used as a diagnostics tool for clinicians and researchers and will serve as a validation tool for biomechanical modelling. To enable this assessment a device that can be placed on the subject has to be developed. This device is the interface between a subject and the ultrasound transducers and between the Visualeyez markers and tracking cameras. The ultrasound transducers enable the localisation of the subject's femur and tibia bone relative to the outer skin. Because the position of the bones relative to the outer skin changes during movement it is necessary to obtain the relative bone positions. To enable dynamic measurements and measurements with multiple transducers, the position of the transducers relative to their environment must be known. This information is obtained using a Visualeyez system, consisting of Visualeyez markers and tracking camera's.

Assignment's objective:

The objective of this Bachelor assignment is to develop a probeholder that is the interface between subject and ultrasound transducers. This holder enables the dynamic measurement of the knee joint using ultrasound. The development includes the production and evaluation of a prototype. To achieve this several analyses are done, real world testing is attended and a concept is created, tested and evaluated. The orthopaedic research laboratory has stressed the importance of having a holder since the start of this assignment. For the ORL it is necessary to further elaborate on the ultrasound system, therefore a parametrized Solidworks model of the final results will be provided to them.

Bookmaker:

Chapter 2 provides the motivation for the development of the ultrasound analysis system and the current state of the development, as well as a description of the major issues in the design of the probeholders. The Analysis phase, chapter 3, starts with broadening the understanding of the used techniques and equipment and supplies a description of the cadaver experiment, which forms the basis for the statement of requirements. First design directions are explored in chapter 4 and resulted in a feasibility test of a basic prototype and a location testing to find suitable locations for placing the transducers. The design of the final concepts in chapter 5 starts with a morphological analysis of key features, followed by elaborated sketches of the individual holder parts. Chapter 5 furthermore treats the parametrisation of the holder parts and the Solidworks models of these parts. The report ends with the conclusions and recommendations regarding the design and the further development of the probeholders.

2. The ultrasound based kinematic analysis system

2.1 Ultrasound based kinematic analysis system: motive for development

The design of the probeholder lies within the scope of the bigger ultrasound based kinematic analysis system project. Research on this project is mainly done by ir. K. Niu in order to obtain a PhD. This chapter contains results from his works that are not published yet. The information is used with his permission and does not contain a source reference. The ultrasound system will be used mainly in diagnosis and pre and intra-operative planning of surgery of the lower extremity. Currently the assessment of knee joint kinematics is done using fluoroscopic techniques. The functionality of these techniques is long proven, but the drawbacks are known too. The methods currently available are either invasive, radiative or not accurate enough. The basics of these methods is described in this section to get an understanding of the motivation for developing an alternative to these techniques.

Skin markers:

Skin marker systems such as Vicon[2] rely on 3D motion capturing. Markers are placed on the skin and their movement is captured by cameras. The advantage of these systems is that they are both non invasive and non radiative. But studies indicate that there are significant limitations in predicting 3D kinematics of the knee joint[3]. The main cause for this is the movement of the skin relative to the bone during walking. Because the 3D motion capture system cannot deliver the desired accuracy other methods are used.

Fluoroscopy and Roentgen stereophotogrammetry:

Roentgen stereophotogrammetry (RSA) is one of these methods and is often considered as the gold standard. It makes use of implanted radio opaque markers to determine the joint kinematics. The markers are intraoperatively placed on prosthesis or bones and the motion of these markers can then be evaluated using fluoroscopic techniques. This method is often used to study the micromotion of orthopaedic implants because it is highly accurate and therefore used as indicator for loosening of prostheses[4]. But implanting these markers might require additional trauma to the patient and is therefore undesired. Furthermore the kinematic analysis requires a high dose of radiation.

As mentioned fluoroscopy is the technique used to capture the motion of the implanted markers, with this technique real-time moving images can be obtained. This is done by sending a continuous x-ray image to a screen, enabling a detailed projection of the object's movement. Software is then used to calculate the exact kinematics. Traditionally this is done using the opaque markers, but advances in technique make it possible to calculate the motion without them using 3D models. However, this is less accurate than RSA. But the high dose of radiation to which the subject is exposed, in both methods, is undesired, it can cause radiation induced burns to the skin or radiation induced cancer[5] for example. Therefore alternatives offering a truly non-invasive and non-radiative motion analysis are desired. The ultrasound based kinematic analysis system is one of these alternatives.

2.2 Ultrasound based kinematic analysis system: current situation

The drawbacks of the current kinematics analysis methods cause the desire to explore new methods and ultrasound seems a promising way of measuring the knee kinematics in a fast and non-invasive fashion. The use of A-mode ultrasound in Computer-assisted orthopaedic surgery (CAOS) has already been tested[6] and results showed that with further modifications A-mode ultrasound is an accurate and truly non-invasive method for bone registration. A more in depth look in ultrasound and the different modes of ultrasound is provided in section 3.1. The use of ultrasound enables the visualisation of the bone from the outside through the underlying tissue, eliminating the need for physical contact with the bone surface[7]. However a drawback of A-mode ultrasound is its inherent localisation error. Overcoming this can be done using a large number of registration points[6]. The bone kinematics registration will probably also depend on the locations of the transducers and error in the localization of those point. The latter is the so called 'Ultrasound Point Localization Error '(UPLE). In-silico analysis has been performed to determine two aspects of the system's accuracy: the number of ultrasound registration points and the UPLE .

A cadaver experiment was conducted on the 20th and 21st of april at the Radboud UMC in Nijmegen to provide the necessary data for the in-silicio analysis. Figure 1 provides the reconstructed knee kinematics from this cadaver testing, here the blue line gives the results from the ultrasound system and the red line the results from the ground truth. The closer these lines are to each other the better the accuracy of the ultrasound system. Section 3.3 supplies a better description of the cadaver testing, as this broadens the understanding of the used equipment and the current development state. While the cadaver experiment was done in a static way using only a single transducer setup, to perform dynamic analysis a multiple transducer kinematic analysis system is required.

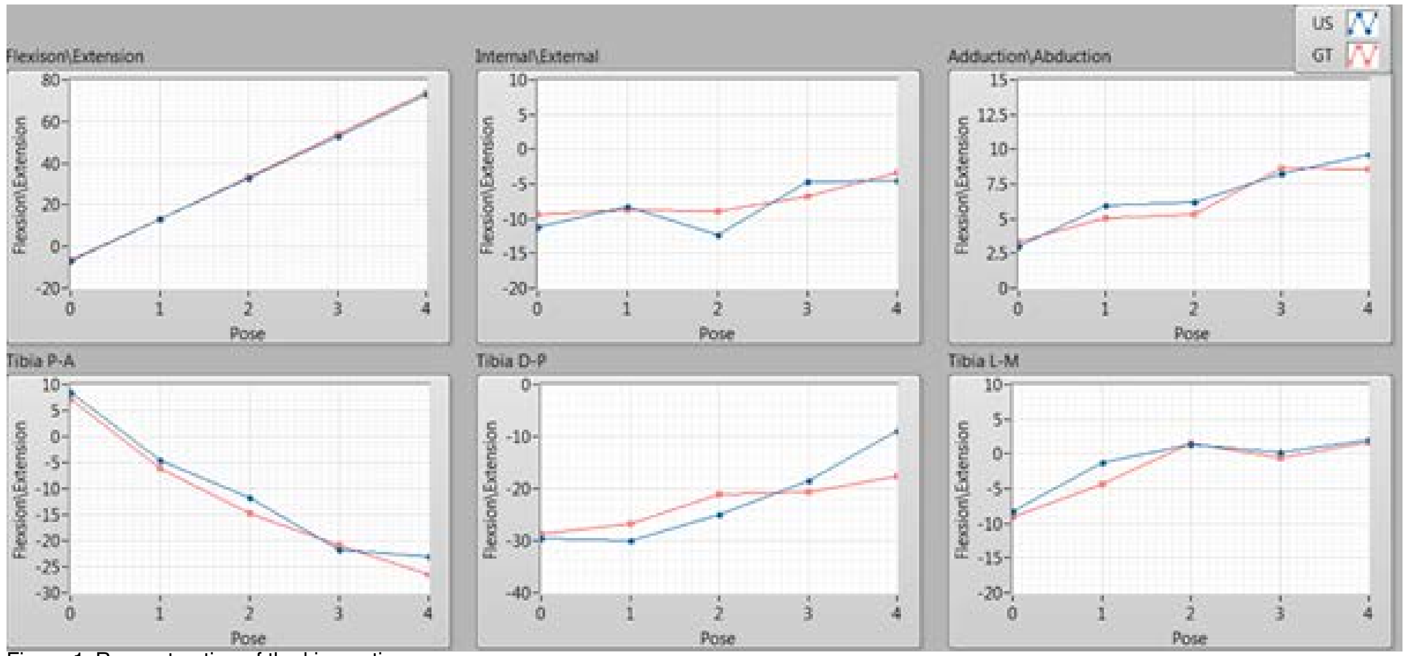


Figure 1: Reconstruction of the kinematics

2.3 Ultrasound based kinematic analysis system: design brief

This assignment is part of the progress mandatory to go from the static single transducer system to the dynamic multiple transducer setup. The probeholder, which will work as interface between the subject and analysis system, must enable dynamic measurements of the knee joint kinematics. Because the wish of the client is that a subject is able to walk around with the holder fitted to his leg, while actively measuring the movement of the knee joint. But before this happens the performance of the system needs to be proven. While the cadaver experiment already showed its feasibility, improvements on the algorithms still have to be made. But this is not a part of this Bachelor assignment, only the limitations of the system must be taken into account. For example the fact that currently there is only a single channel setup available, thus making it impossible to test with multiple transducers at the same time. This limitation makes it hard to determine the overall performance of the complete probeholder concept.

Other key aspects that must be taken into account during the design of the holder are several pre-determined decisions. The development of the probeholders first started when it was already decided that the localisation of bone will be done with A-mode ultrasound transducers. The reason is that they are cheaper and better suited to determine the bone surface in real-time because of their better accuracy[8]. Besides the available data acquisition controller can only handle 64 channels, meaning that at maximum a handful of B-mode transducer could be connected. Another important decision already made was the choice of a Visualeyez system to map the transducers locations in 3D space. The Visualeyez system is further explained in section 3.2.

Currently the bone data is acquired using a crucifix shaped part which is held by hand and can move freely. The research has already showed that 30 transducers are necessary to successfully reconstruct the kinematics. Doing this using the handheld crucifixes would be inconvenient and require approximately 15 people to do so. Therefore holders that contain the transducers are mandatory for dynamic real time measure-

ments. Furthermore during the cadaver experiment it was observed that modulation of the crucifix was necessary to find the peak that represents the bone. This raises questions about how the transducers should be placed on the subject's skin: At what angle should the transducers be placed and does this angle remain the same during movement for example? These questions will be looked at during the research and their answers will help in determining the final results, a set of holders that enable the dynamic measurements of bone kinematics.

Another important aspect is the distribution of the 30 transducers over the leg. Placing them in a dense way on a small area will not provide enough information to correctly reconstruct the movement of the femur and tibia bone. Therefore information of several characteristic locations is necessary. In figures 2 and 3 an overview of both bones and their characteristics is provided, it is easy to imagine that the tubular shaped section in the middle of both bones is unable to provide enough information to irrefutably determine the rotation and proximal or distal translation. The determination of these characteristic locations is not covered by this research, they are provided by the main researcher. The selection of locations for the probeholders though is covered by this research, as the locations where the transducers can see the bone do not necessarily correspond to the characteristic locations required for the kinematics reconstruction. Finally, the client has stressed the importance of having an actual holder, because the whole system is still in development and the main goal is to deliver a proof of principle. But during the design process the final product is also kept in mind and the goal is to establish a design that can function as basis for the eventual final product.

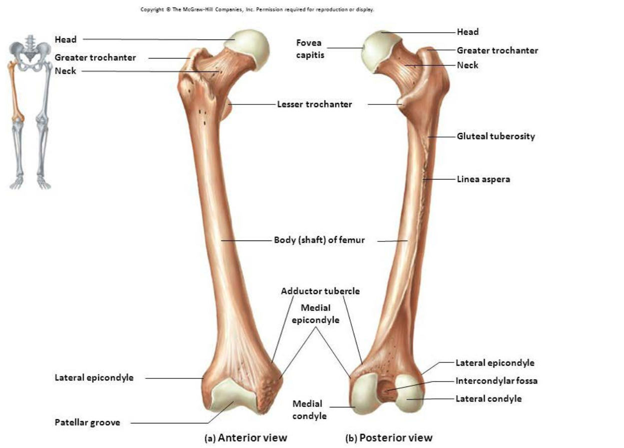


Figure 2: The femur bone (9)

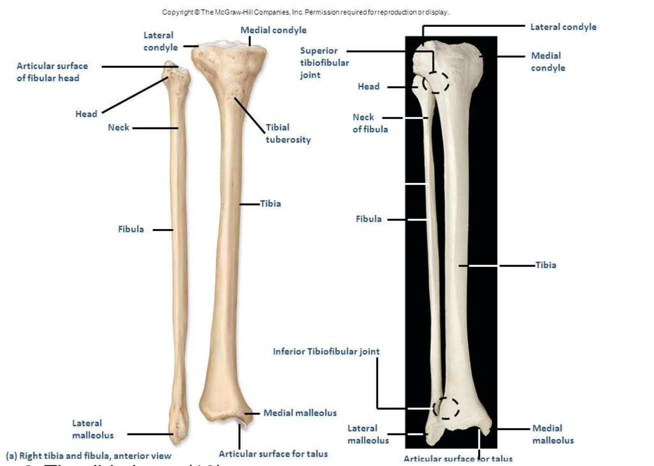


Figure 3: The tibia bone (10)

A remark must be made regarding the ultrasound beam modulation. A possible solution would be mechanically moving the transducer head and thus modulating the beam automatically, this would solve the issue. But it would require an actuator to move the transducer and a sensor to exactly determine what the movement is and where exactly the bone is seen. This solution is undesirable, the system would end up being even more complex, besides an extra error is introduced when the positon of the transducer is measured, thus decreasing the system's overall accuracy. This, combined with the choice for A-mode transducers, means that the ultrasound beam cannot be modulated during measurements. Because the available information regarding tissue movement between the skin and bone is not sufficient, the consequence of fixating a transducers must be examined too.

3. The analysis phase

3.1 Analysis: Ultrasound

Ultrasound is the main principle the kinematic analysis systems relies on. The American National Standards Institute define ultrasounds as “sound at frequencies greater than 20kHz”. Because most humans are only able to hear sound up to 20kHz, ultrasound is inaudible for humans. For medical imaging frequencies of 2mHz and higher are typically used, providing more detailed images. The basic principle behind ultrasound is the emission and reflection of pulses, when an emitted pulse reaches the boundary of two tissue structures, part of it is reflected and the rest of the pulse travels deeper in the structure until it reaches the next boundary. This is illustrated in figure 4[(11)]. The depth of the boundaries can then be calculated with the time it takes to return to the transducers, as the speed of sound in human tissue is relatively constant[(12)]. The bone is represented by the last peak found by the pulse, because bone tissue reflects nearly all of the pulse, it can be seen as a mirror for ultrasound. Still caution is necessary when examining the results, reverberation inside the tissue can cause additional peaks to appear that seem to show a deeper peak. To avoid wrong peak detection the is bone searched in a predetermined time interval.

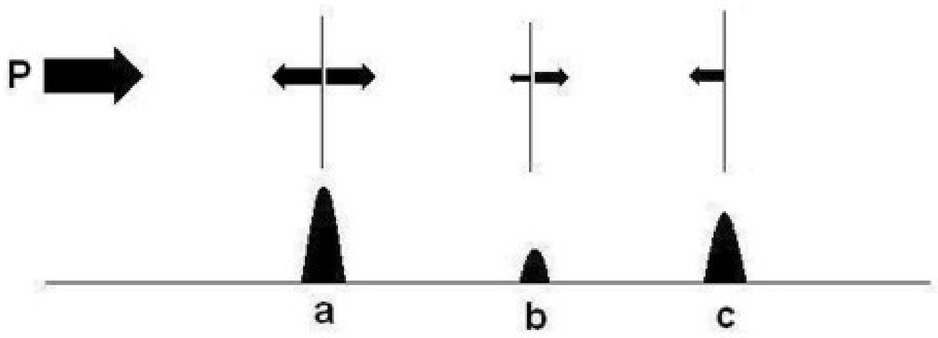


Figure 4: Basic principle of ultrasound (11)

In theory this works fine, but the practice is more complicated. In figure 4 the ultrasound pulse approaches the boundary at 90°. The law of reflection then gives that the reflected pulse also travels at 90° to the boundary, only in opposite direction. When the incident pulse approaches the boundary at a different angle, it is reflected away from the original direction, but this is only true for a smooth surface, in reality the bone surface is rough and the reflected pulse is dispersed. Figure 5 is used to illustrate this principle. So when the ultrasound pulse approaches the bone at an angle too far off from the normal incidence, too little reflection comes back to the transducer, making it hard to distinguish the bone. Therefore it is necessary to know at which angle the transducer must be placed on the skin, and how this angle varies during movement of the subject.

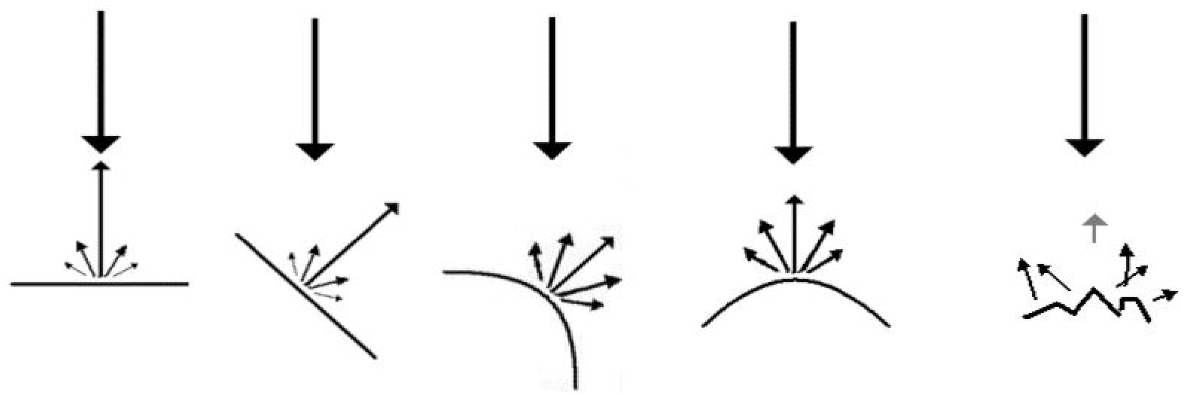


Figure 5: Reflection of the incident ultrasound pulse (11)

A-mode:

A-mode or amplitude mode ultrasound is the form used for the kinematic analysis system, here the transducer can only emit one pulse in one direction. The amount of reflected signal is represented by the amplitude, the more reflection the higher it becomes. A typical A-mode ultrasound graph is provided in figure 6, where the x-axis corresponds to the depth and the y-axis to the amplitude. The transducer used in the project are slightly focused, with a focal length of 35mm, thus the ultrasound beam converges until 35mm and diverges from there on. Appendix A provides a beam profile measurement report from the manufacturer of the transducers. Furthermore to enhance the results, gel lubrication between the skin and transducer is required because the boundaries with air reflect more signal than the boundaries with lubrication.

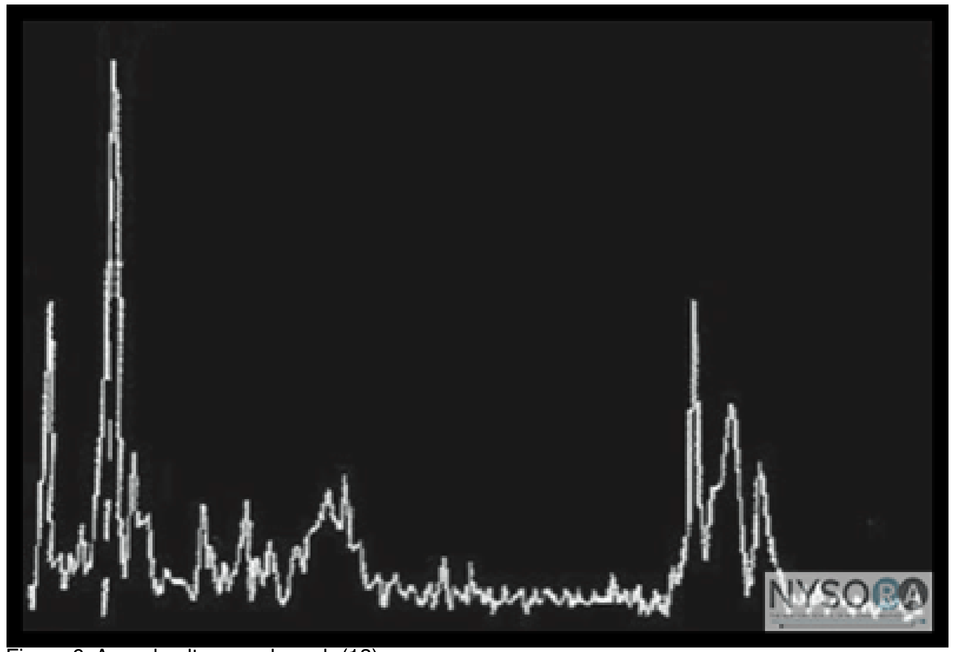


Figure 6: A-mode ultrasound graph (13)

B-mode:

B-mode or brightness mode is a more advanced type of ultrasound. With B-mode, 2D images of an object can be made. These images are made out of a large amount of B-mode lines, typically more than a 100. The image is produced using an array of small transducer elements, several types of arrays are available and are shown in figure 7[(14)]. With B-mode the amount of reflection is represented in a grey scale, the more reflection the brighter it becomes. In figure 8 a B-mode image is illustrated, in this image water is black (no reflection), muscles are grey (low reflection) and bone is white (high reflection)[(15)].

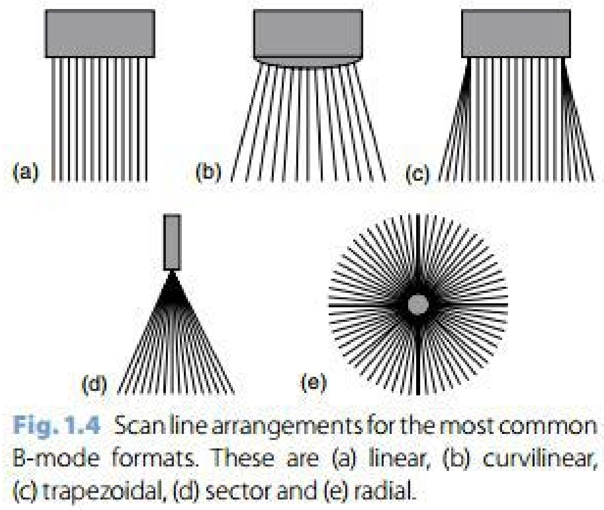


Figure 7: Most common B-mode formats (14)

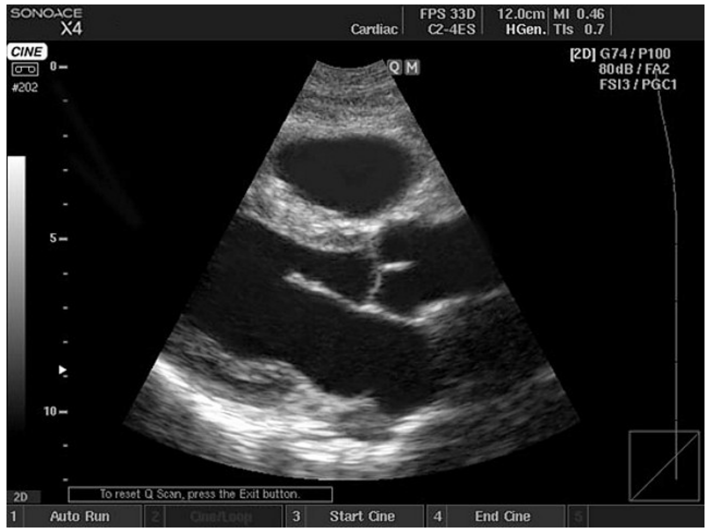


Figure 8: B-mode image (15)

M-mode:

M-mode ultrasound is used to represent movement of a structure over time. It shows the amplitude of a A-mode probe or a single transducer element from a B-mode probe over time. In M-mode the amplitude is again represented in a grey scale, similar to the one used in B-mode images. In figure 9, the M-mode graph from a single B-mode element is presented in the lower half of the figure, the x-axis represent the time and the y-axis the depth. The top half of figure 9 shows the B-mode image that is used to construct the M-mode image in the lower half. The vertical white line indicates the transducer element that is used for the M-mode image, obtaining the same information as a single A-mode transducer would provide. Because of its good temporal resolution, M-mode is useful in detecting and recording rapid movements[16]. These characteristics make M-Mode a suitable option to analyse the performance of an A-mode transducer during dynamic measurements, it can for example reveal if a transducer keeps seeing the bone while performing a walking movement.

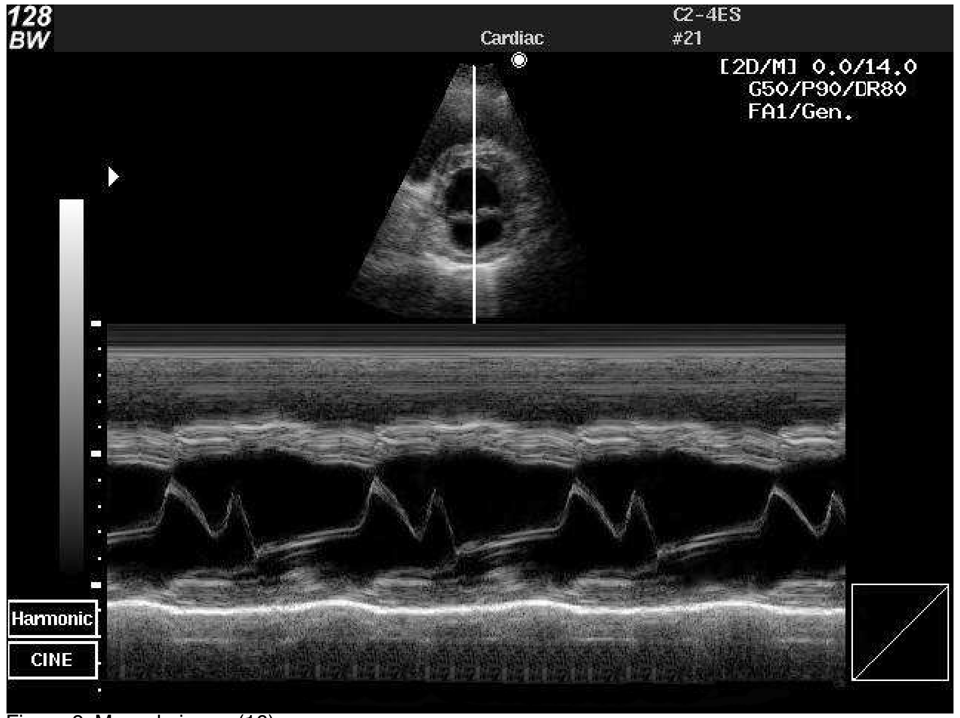


Figure 9: M-mode image(16)

3.2 Analysis: Visualeyez

The ultrasound transducers make it possible to determine the distance and position from the bone relative to the skin, but to model the full kinematic motion of the knee joint dynamically, the position of the transducers relative to their environment must be known too. If this is the case their mutual positions are known too and thus the exact locations of the bone points in 3D space. To enable this a 3D motion capture technique is used, this is the earlier mentioned Visualeyez system. The decision for this system was mainly based on its availability at the University of Twente.

To track the motion in 3D space, a setup consisting of three components is used: a sensor system, a marker system and software. The sensor system is made up of two VZ4000v trackers (figure 10), they are used to control the marker system, capture the marker positions and transmit the data to the software. The markers system contains of wireless SIT markers (figure 11), of which the University of Twenty currently has ten of these accessible. Each marker is equipped with three LEDs, that all have their own unique marker ID, enabling one marker to capture the 6 degrees of freedom of an object. Some properties of the system are that it features a sensing rate of more than 4000 data points per second, a data latency of less than 0.5 millisecond and up to 512 connected markers. Full technical specification are added in appendix B[17].


Figure 10: The VX4000v tracker (18)

Figure 11: The SIT markers (19)

While an 3D motion capture system is mandatory, its use also involves implications to the holder design. The placement of the LEDs has to be chosen carefully, as it is required that they are visible for at least one tracker at all times. But just seeing the LEDs is not enough, the way they are placed is important too, to determine the 6 DOFs of the object correctly, the LEDs cannot be aligned and must be separated at least 5cm. To identify the bone location in 3D space, the position of the transducer relative to its corresponding marker must be known. As a consequence the locations of the transducers must be either fixed, discretely adjustable or measurable. The latter would, just as with the mechanical modulation of the transducer, mean that actuators and sensor are required. This introduces again an extra error in the measurement and is therefore deemed inadequate. Another consequence is that the holder must be rigid, as deformations of the holder would lead to errors in the measurements.

3.3 Ultrasound based kinematic analysis system: the cadaver experiment

Goal:

The goal of the cadaver experiment was twofold, its main goal was to determine the number of ultrasound registration points necessary to successfully reconstruct the knee kinematics and to obtain the Ultrasound Point Localization Error. Besides, for the purpose of this research, it was used to get more acquainted with the ultrasound kinematic analysis system and to discover several clues to the design of the probeholder.

Materials:

The cadaver leg was prepared before the experiment by screwing two Visualeyez marker sets onto it, one on the tibia bone and one on the femur bone. CT scans where then taken from the cadaver leg with the Visualeyez markers attached to it, this provided the ground truth of the cadaver testing and was necessary to determine the UPLE of the ultrasound system. This is done by comparing the location of the bone found by the transducer during the experiments with the ground truth, the accuracy of the system can then be determined by measuring how far the ultrasound point is off.

Figure 12 shows a photo taken during the cadaver experiment. The complete setup used for this experiment can be seen here. To perform the measurements in a controlled manner the cadaver leg was placed on an adjustable rig, marked with #1 in figure 12. #2a and #2b are the Visualeyez markers that were fixed to the tibia and femur bone to determine the ground truth. Another Visualeyez marker and a transducers were linked to each other using a specially designed crucifix that can be seen at #3, this crucifix can be modulated manually to find the best possible bone peak. Two Visualeyez trackers were used, one placed in front of the leg (#4) and one placed to the left of the leg, to capture the location of the three Visualeyez markers. The acquired data was processed and visualised using a National Instruments data acquisition controller (#6) and Labview software (#5). Figure 13 shows the Labview GUI especially designed for this system. The two bars at the top show the A-mode graph of the ultrasound transducer, with the vertical lines representing the time frame in which the bone peak is located. The graph below them displayed a 3D model of the tibia and femur bone. During the cadaver experiment it showed a red dot representing the peak found by the software and a yellow dot representing the nearest bone location.

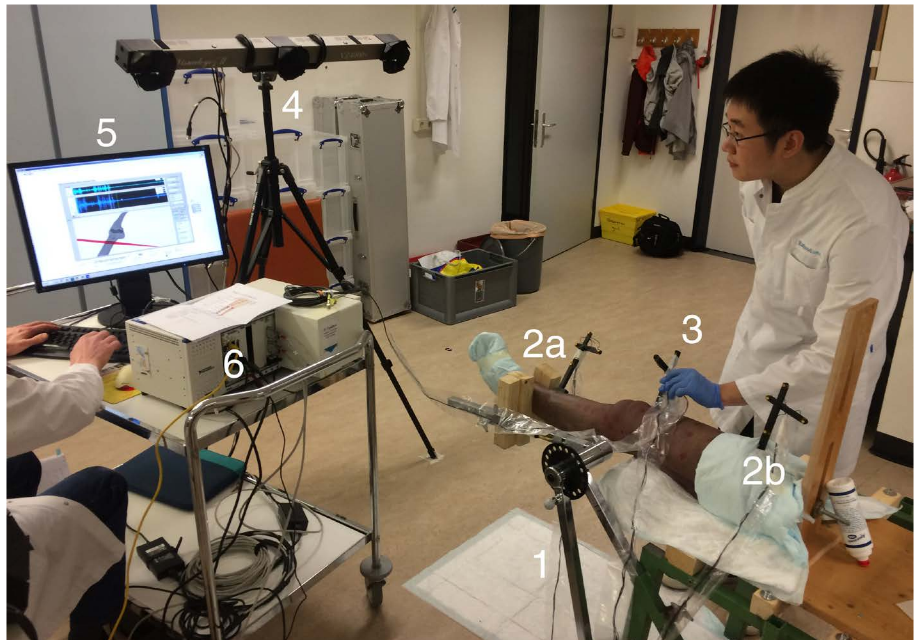


Figure 12: Cadaver experiment with the main equipment

Methods:

Beforehand 50 test locations were chosen, equally divided over both the upper and lower leg. Each of these locations were tested at five different knee angles, the adjustable rig enabled the control of the knee angle. The test locations were marked on the cadaver leg before the measurements started, so the correct locations would be used at all knee angles. Measurements were taken at 0°, 20°, 40°, 60° and 80° and the results were later combined to calculate the reconstructed knee kinematics.

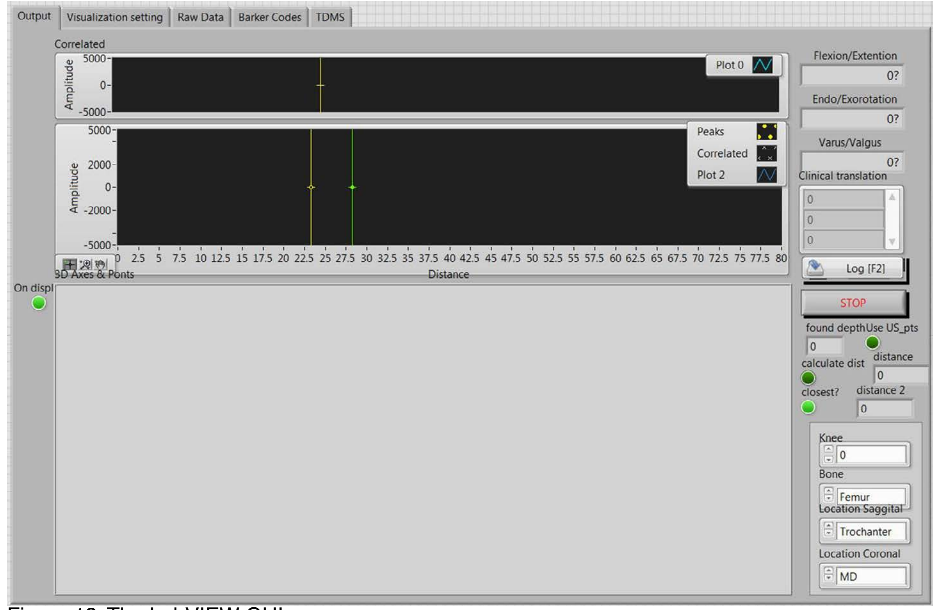


Figure 13: The LabVIEW GUI

Results:

The final results were already shown in figure 1, the interpretation is not of direct relevance to this report and therefore not treated. But besides determining the UPLE, the cadaver experiment was also used to determine the characteristic locations that are best suited to successfully reconstruct the knee kinematics. From the 50 locations tested, the 15 locations that ensured the best reconstruction were taken for both femur and tibia and the result is shown in figure 14. The characteristic areas on the femur include the greater trochanter, lateral and medial epicondyle and the adductor tubercle. On the tibia also the lateral and medial epicondyle, the tibial tuberosity and the medial malleolus are characteristic bone areas.

Discussion:

The concerns regarding the angle orientation mean that there is no certainty that these locations are actually usable, this needs to checked. Besides the fibula bone offers an extra challenge in the locations selection of the lower leg. The ultrasound system is not able to distinguish the fibula from the tibia bone, while the only available support is pre-determined knowledge of the bone depth at a particular location. But this depth is different from person to person and can change during movement. Therefore it is better to look for locations that irrefutably aim at the tibia.

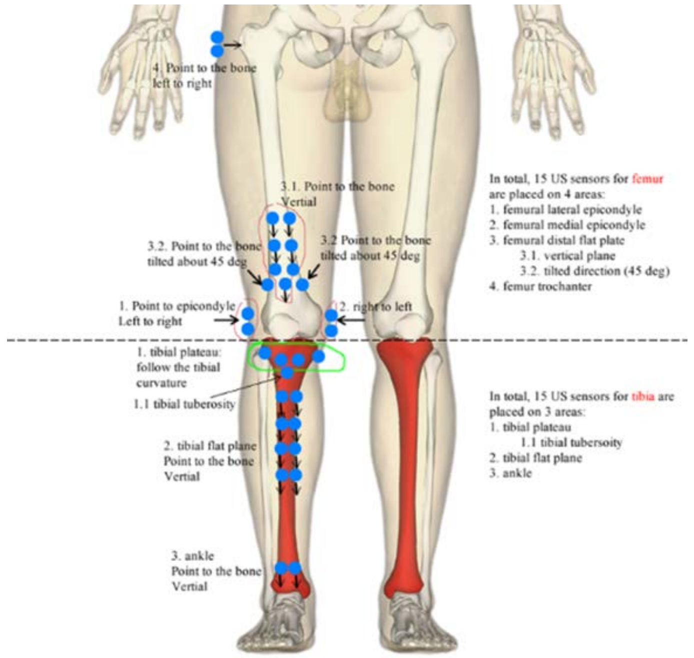


Figure 14: Locations used for reconstuction of kinematics

3.4 Analysis: Materials and 3D-printing

Material choice:

Several requirements introduce implications to the materials used in the holder. These implications and their corresponding requirements are listed in table 1. In practice the materials choice was motivated more by the production method than due to the requirements. The availability of a 3D-printer at the biomechanical engineering department of the University of Twente enables the fabrication of prototypes in a rapid and cheap way in comparison to traditional (CNC) machining techniques. The materials momentarily available for this printer are ABS and PLA, of which PLA is preferable above ABS because of its higher young's modulus and better part accuracy: it is less prone to warping. Due the relative low young's modulus of PLA the holder deformation remains a key issue: Its rigidity must be tested and evaluated. Appendix C goes into more detail regarding the materials implications and makes an comparison between several suitable materials.

Requirement	Implication
The holder must be MRI compatible	No ferromagnetic materials can be used
The TD position must be known at all times	The holder must be rigid, i.e. have a sufficient high young's modulus
The holder must be able to withstand gel lubrication	The holder must be protected against water
The holder must be lightweight	The lower the material density the better
Combination of light and rigid	The material should have a high specific modulus

Table 1: Requirements and their implications to material choice

3D printing technique:

3D printing is a relatively new technology that has become more and more popular in the past years. The technique is developing at a fast rate and its product's quality and complexity increases. The ability to print a full scale prototype in short amount of time enables faster development of products for example. Therefore 3D printing offers an appealing alternative when an adjustable holder that fits all subject is not feasible. There is no need to generate specific code for each subject, only changing the corresponding dimensions in the CAD model is enough.

The printer that is used during this project is an Ultimaker 2[20] (See figure 15), this is an open filament printer, meaning that every available filament can be used. The Ultimaker is optimized for printing ABS, PLA and CPE, but with a suitable nozzle other materials can be printed too. The printer has a maximum build volume of 223x223x205mm, which limits the size of the product, but more advanced printers on the market can print faster, bigger and better products. For prototyping the quality obtained by the Ultimaker is good enough, but a consumer ready product might need a better printer. In Appendix C a small display of future possibilities is given regarding the printing of other materials then plastics. This development might prove to be very valuable, as it enables the direct fabrication of custom aluminium holders without the use of CNC machining techniques for example.

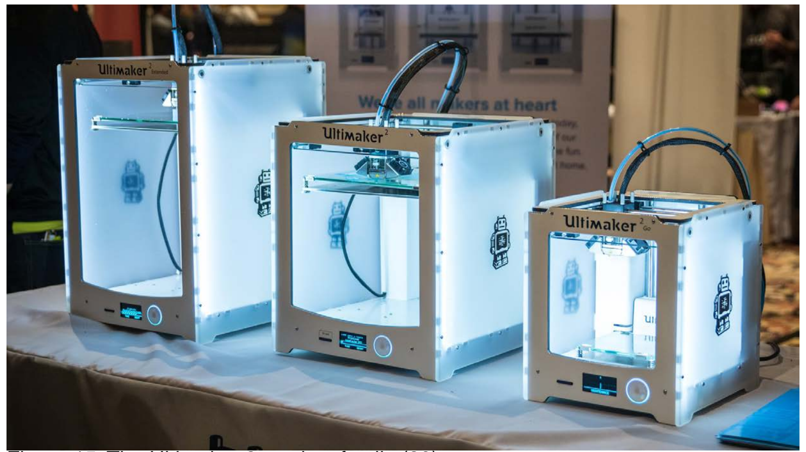


Figure 15: The Ultimaker 2 product family (20)

3.5 Statement of requirements

Most of the demands of the holder were already tackled in the problem definition and the analysis revealed many requirements that come with the selected equipment. The remaining demands and wishes were obtained during meetings with the staff involved in the ultrasound project. The statement of requirements that followed was used to start the design process. To keep track of the requirement's sources, they are divided in distinct groups.

The status of the statement of requirements was monitored continuously and updated regularly. The current version is shown below. The additional requirements are not of direct importance for this project, but they cannot be ignored when the ultrasound system reaches its finalisation phase, because this statement of requirements will form an convenient starting point for the next iteration in the holder development. Some additional information of the safety guidelines for medical devices is provided in appendix D.

General requirements:

- The design of the holder must fit in a pre-clinical testing path.
- A fitting holder must be producible for all subjects.
- The transducers should keep contact with the subjects skin at all times.
- The holder must be able to contain a total of 30 fixed transducers.
- The subject must be able to bend his knee 60 degrees starting at full extension.
- The transducers must have a total of 60% useful signal during motion.
- The holder must be MRI compatible

General wishes:

- The holder is adjustable and fits all subjects.
- The subject is able to bend his knee 90 degrees starting at full extension.
- The subject is able to walk around with the fitted holder
- The transducers have a total of 80% useful signal during motion.
- The knee itself is kept clear.

Motion tracking requirements:

- The transducer position with respect to the Visualeyez markers must be known at all times.
- Each holder part must contain at least three Visualeyez LEDs.
- The Visualeyez LEDs of one part may not be aligned.
- The minimum distance between two LEDs must be 5cm.
- Each holder part must have a battery space for the Visualeyez markers.
- Of each part at least three Visualeyez LEDs must be visible for a tracker at all times.

Transducers requirements:

- The minimum distance between bone and transducer must be 3mm.
- The medium between transducer and skin must have 1540m/s speed of sound.
- The medium between transducer and skin must have low acoustic damping.
- The holder must be able to withstand (water based) gel lubrication.

Additional requirements

- The holder must be lightweight.
- The holder must satisfy guidelines for medical devices, i.e. 93/42/EEG.

4. The concept phase

4.1 Design direction

First design exploration:

The limitations to the modulation of the ultrasound signal mean that a concept is required in which the location of the transducer is fixed. To explore the possibilities a design study is done in which complexity and shape are varied. The goal was to find suitable solutions for problems such as the fixation of the transducers and the fitting of the holder to the subjects. Several possibilities of acquiring the best locations or orientation of the transducer are selected, while balancing the size of the rigid parts and the amount of transducers per part. Using more separate holder parts means that more Visualeyez markers are needed, each of them needs to be visible to the tracker and with too many separate parts this can become problematic. On the other hand when using very large rigid parts it might be impossible to ensure that enough transducers keep seeing the bone.

The result of this study is shown below and a short description of the ideas is provided in table 2.

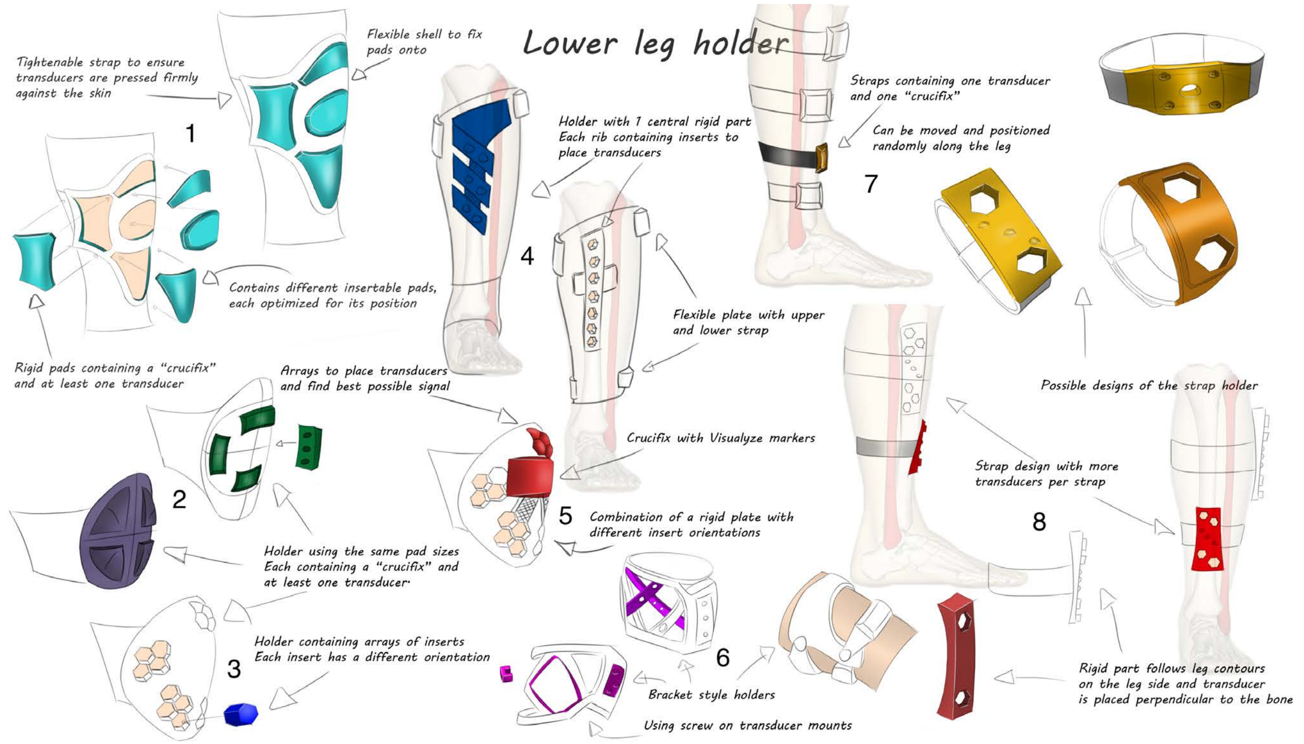


Figure 16: First design explorations

ID	Color	Markers:Transducers	Description
1	Turquoise	1:2-5	• Different shaped inserts, made specifically for one region • Each inserts must contain a marker • Flexible (heat mouldable) shell, to adapt holder to patient • Total systems contains many not interchangeable parts
2	Green	1:1-3	• Basic idea identical to #1 • Inserts are of the same size now, makes it possible to have different types of insert to find optimal signal
3	Blue	1:1	• Full flexible shell with a rigid honeycomb structure • Hexagon shaped inserts, containing one TD and marker • With an angular orientated beam, lot of possibility
4	Dark Blue	1:4-10	• Large rigid part containing several transducers on one line • Rigid part needs to follow the bone shape, or orientations must be adapted (and thus known)
5	Red	1:5-20	• Several rigid honeycomb structures paired to one central marker • A hexagon with transducer can be inserted in each position • Fit should be very precise, otherwise it won't work
6	Purple	1:1-3	• Transducers are placed in brackets with a marker • Bracket can slide back and forth over the guides to find signal • Hard to keep skin contact and movement must be measured
7	Yellow	1:1-2	• Very adjustable, small holder • Can be placed on the whole leg and rotated to find the optimal signal • Many of these holder necessary to reconstruct full kinematics
8	Red	1:2-4	• Combination of #4 and #7 • Larger rigid part and more transducer than #7, but without the shell of #4 • Holder shape needs to be optimized for the location

Table 2: description of the first design exploration

Evaluation of the first exploration:

The ideas will be discussed and evaluated in an empirical manner using the problem definition and statement of requirements as support. The descriptions in table 2 are further used to evaluate the ideas:

- Ideas #3 and #7 require at least 15 sets of Visualeyez markers, while there are only 10 sets available. Besides with such a large amount of markers, the chance of the Visualeyez tracker not seeing all the LEDs increases vastly. Therefore ideas #3 and #7 are not suitable for the holder and will not be elaborated.
- Idea #2 also requires a large amount of Visualeyez markers, the resolution that can be achieved with this system is too small. Thus idea #2 will, in addition to ideas #3 and #7, not be elaborated.
- Idea #6 is also discarded, it requires either constant monitoring of its position or predetermined positions to insert the brackets. Constant monitoring was already rejected, so that option is invalid. Besides, the shape of the brackets is very important. If the transducer loses skin contact, the signal is lost. Because of the big variation in leg shape, only small and selected parts of the leg can be used with this system. These areas probably will not cover enough characteristic locations that are needed for the kinematics reconstruction.
- Furthermore ideas #4 and #8 will combined into a holder concept. The inserts have fixed locations but the beam orientation is tuneable due the insert's shape. This discretely adjustable concept enables fine-tuning of the signal at that particular location. Increasing the chance of seeing the bone.
- In addition idea #5 will be elaborated, a full honeycomb structure with lots of possible positons. This gives lots of locations to insert a transducer, besides the orientation at each location is tuneable in the same way as with the discretely adjustable holder. Thus the chance of seeing the bone is increased much.
- Finally idea #1 will be elaborated into a concept based on a heat mouldable structure. The heat mouldable structure enables a precise and close fitting to the subject. Location specific rigid parts must ensure the precise localisation of the bones.

Discretely adjustable holder concept:

The discretely adjustable concept holder emerged from ideas #4 and #8, it consist of several rigid parts that each cover a selected region of the leg. They are kept as narrow as possible to eliminate the influence of the leg curvature. Each rigid part has several hexagon shaped inserts, these inserts are removable and contain a cavity for the transducers. Different inserts will be made with varying alignments of the transducer cavity, so the ultrasound beam gets as close as possible to perpendicular to the bone. Besides the hexagons can be inserted in six different ways, making it possible to fine-tune even more. Each rigid part contains the obligatory Visualeyez markers and therefore the distance between the parts is free. In this concept the rigid parts are all mounted to a flexible material that enables the fitting to the leg.

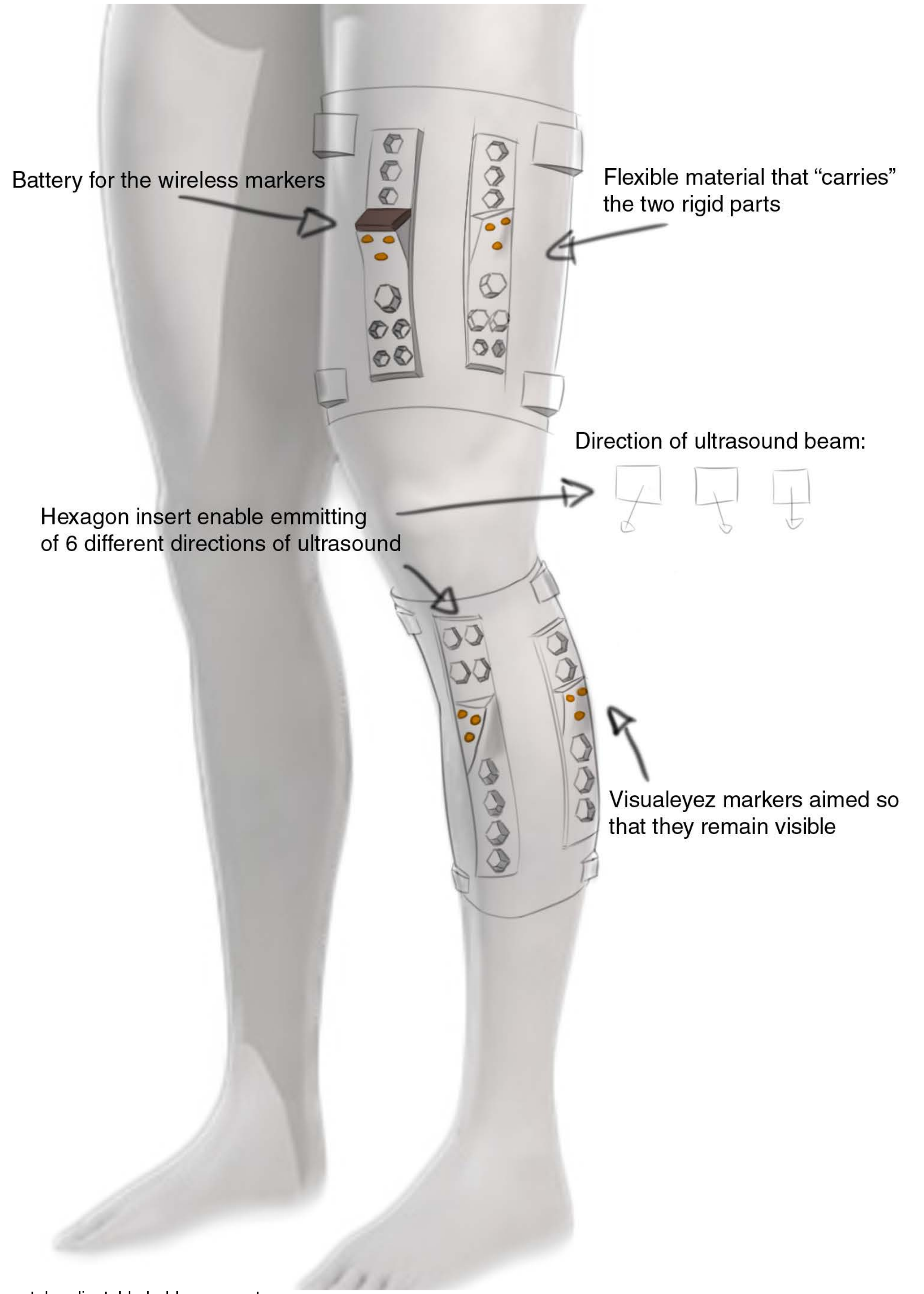


Figure 17: Discretely adjustable holder concept

Honeycomb concept holder:

The honeycomb concept is actually a more complex version of the discretely adjustable holder, it has a larger honeycomb shaped rigid section instead. While featuring the same hexagon shaped inserts, the number of locations is much higher with this honeycomb. This increases the chance of actually seeing the bone, but also makes the shape of the honeycomb part vital, as the rigid parts are larger and therefore cover a larger leg area. Again each rigid part contains a Visualeyez marker and the rigid parts are connected with a flexible material if necessary.

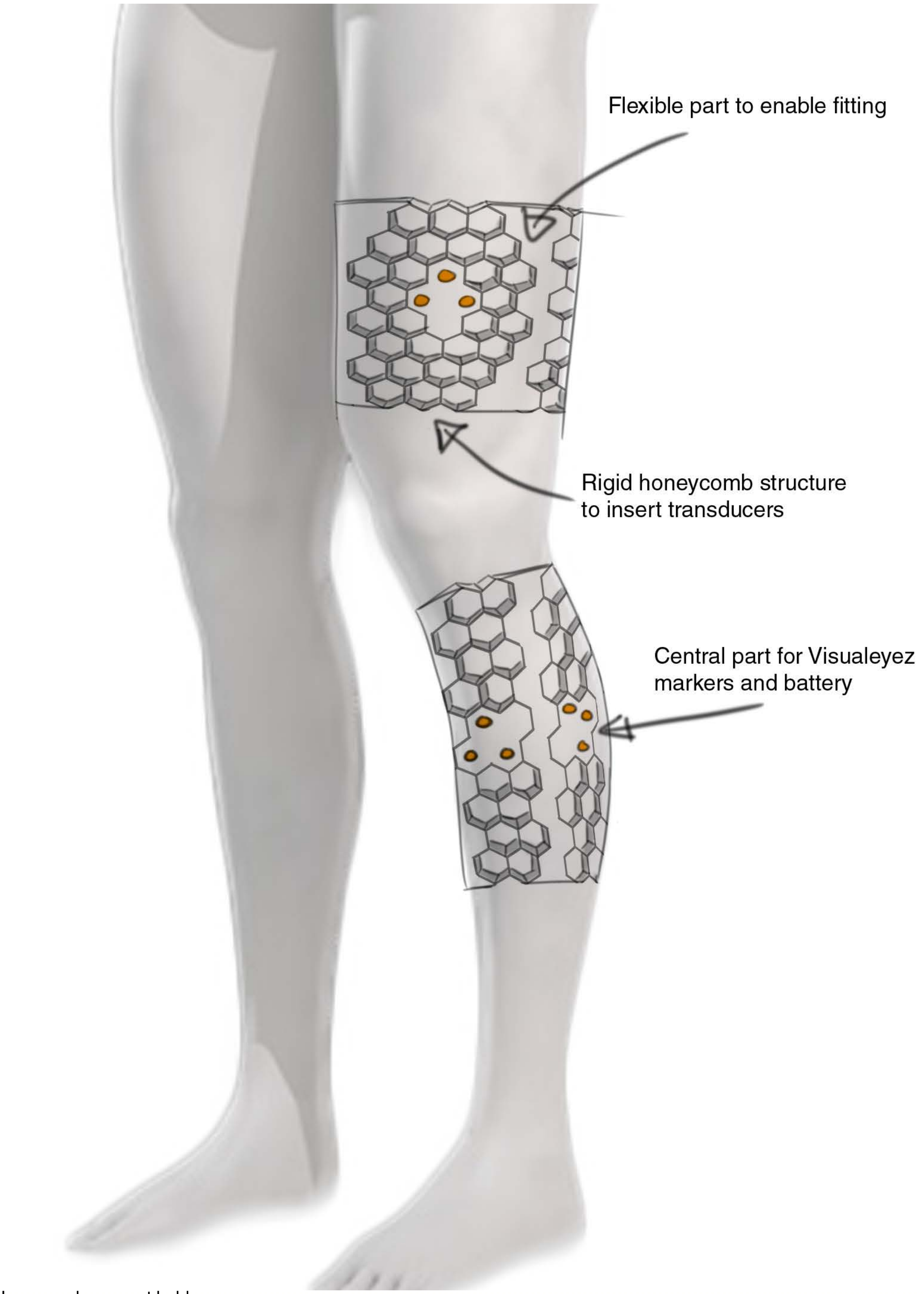


Figure 18: Honeycomb concept holder

Heat mouldable holder concept:

The third elaborated concept is based on the heat mouldable structure, where smaller rigid parts are bonded to a heat mouldable shell. Each rigid parts contains a Visualeyez marker and therefore shaping of the heat mouldable section is unrestricted. The transducer orientation is not tuneable, because the inserts are location specific meaning that the correct orientations must be predetermined. The advantage of an heat mouldable structure is that the fitting of essential locations is enhanced, for example at the epicondyles of the femur and tibia. The drawback is that the rigid parts cannot be very large, otherwise the advantage of the heat mouldable sections is negated.

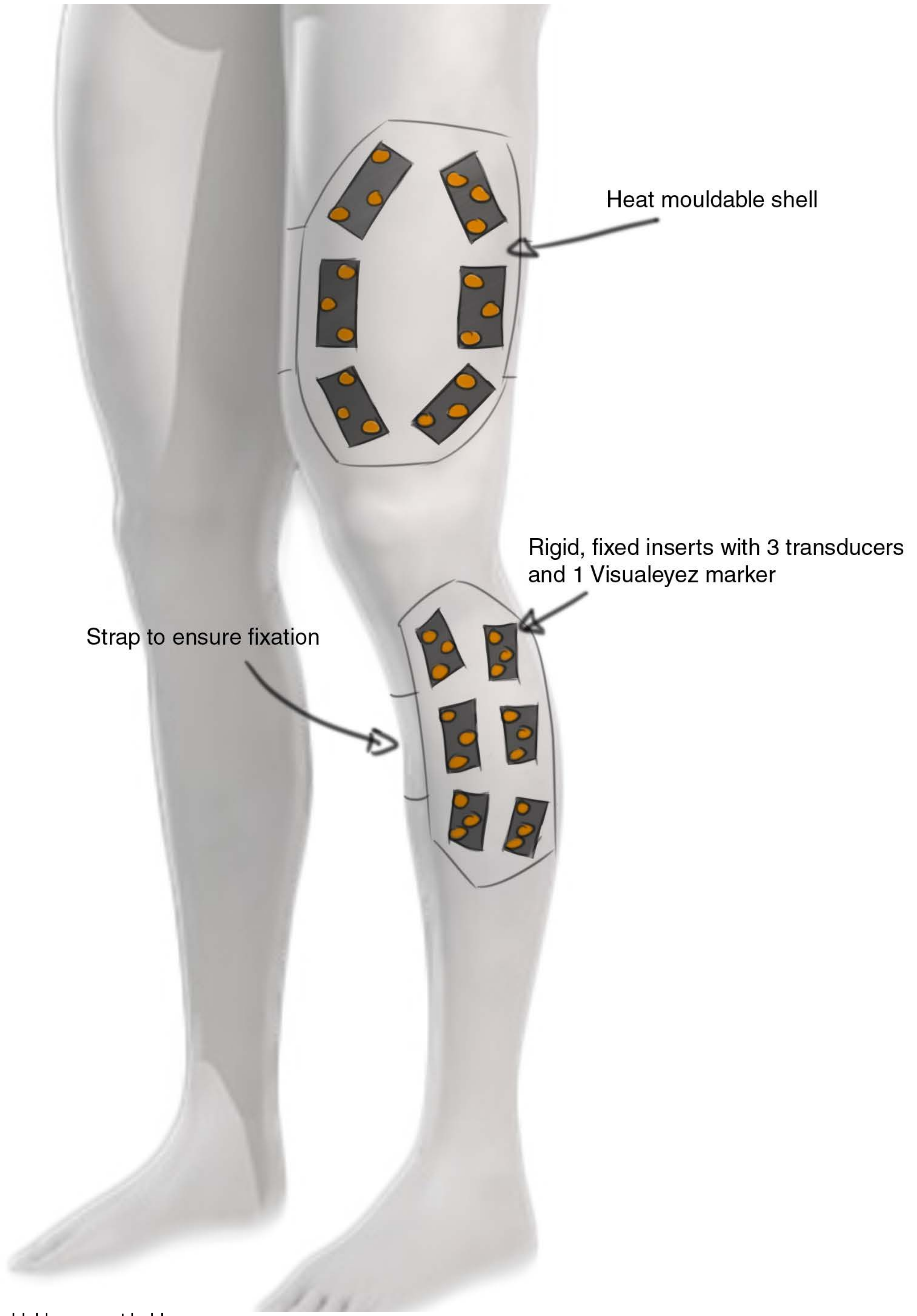


Figure 19: Heat mouldable concept holder

Design direction choice:

The three concepts are compared based on three parameters. First the complexity of the concept, the higher the complexity the harder it will be to realise a working concept. So the least complex concept is awarded three points. Second the adjustability, the higher the adjustability the greater the chance of actually seeing the bone. Finally the fitting of the holder: how hard is it to fit the rigid part to the leg? Besides that, the chance of staying in place and remain skin contact plays an important role in this parameter. Table 3 shows the scoring of the three concepts, here it can be seen that the discretely adjustable concept scores best and therefore will be elaborated. First the feasibility of this concept will be tested with a basic prototype, if this is successful a final and total concept can be made.

	Discretely adjustable	Honeycomb	Heat mouldable
Complexity	+++	+	++
Adjustability	+	+++	++
Fitting	+++	+	++
Total	7	5	6

Table 3: Comparison of the three design concepts

The concepts were not evaluated using the statement of requirements, this is done on purpose. Because the concepts are only basic ideas, they will not fulfil many of the requirements. Besides the feasibility test of the concept will first reveal if it is even possible to use the concept of a discretely adjustable holder. If the feasibility is proven, the concept can be elaborated and the design must be chosen in such a way that it fulfils the statement of requirements.

4.2 Feasibility test

Goal:

The feasibility test was done to determine if the chosen concept in chapter 4.1 is suitable to be implemented into the ultrasound based kinematic analysis system. This was done using a simplified version of the discretely adjustable concept, only able to measure on larger leg surfaces. This made it possible to determine if an ultrasound transducer is able to see, and keep seeing, the bone while it is inserted into a cavity and fixed onto a flat rigid plate.

Materials:

The specially designed simple basic holder can be seen in figure 20, it consist of a base plate that can be placed on the femoral distal flat plate and the tibial flat plate. This corresponds to the two main flat areas from figure 14 and are the two easiest accessible characteristic locations. The base plate allows the insertion of four hexagon shaped parts, they are kept in place using snap-fits (Figure 21). The fragile transducers are slid into the hexagons and kept in place using a cover cap, again using snap-fits. The hexagons are designed in such a way that the cable connected to the transducer can exit on each of the six sides, making the cable routing more convenient. Furthermore the transducers have a 1mm clearance with the bottom of the base plate, as can be seen in figure 22, this should ensure that skin contact is maintained. For the feasibility testing two types of hexagons were designed: a standard hexagon that places the transducer perpendicular to the skin and a hexagon where the transducer cavity has a three degree angle ensuring that the transducer is placed at a three degree angle of the normal incident. The base plate was strapped to the leg using fabrifoam (figure 23), a soft and grippy material that is kept in place using Velcro. The renders of the basic prototype show a multiple transducer setup, but the limitations in the software only allowed a single transducers to be used at the same time. Furthermore one Visualeyez tracker, the NI data acquisition controller and the Labview software were used, equal to the cadaver testing (#4, #5 and #6 in figure 12). Besides a Visualeyez marker set was placed onto the basic holder prototype.

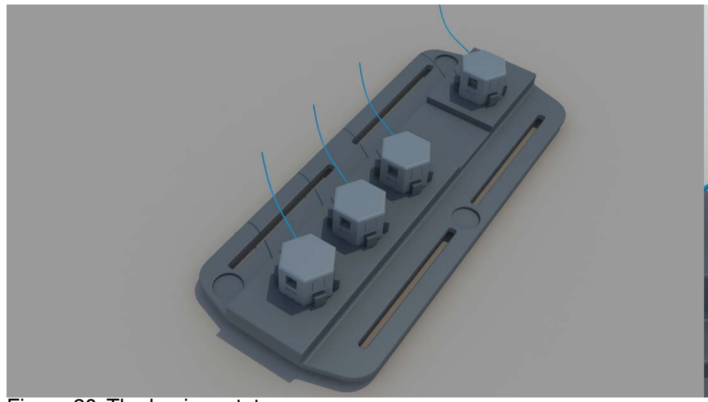


Figure 20: The basic prototype

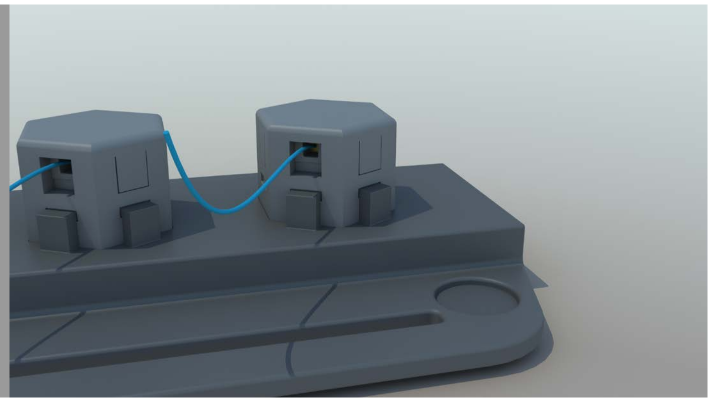


Figure 21: Close up of the basic prototype

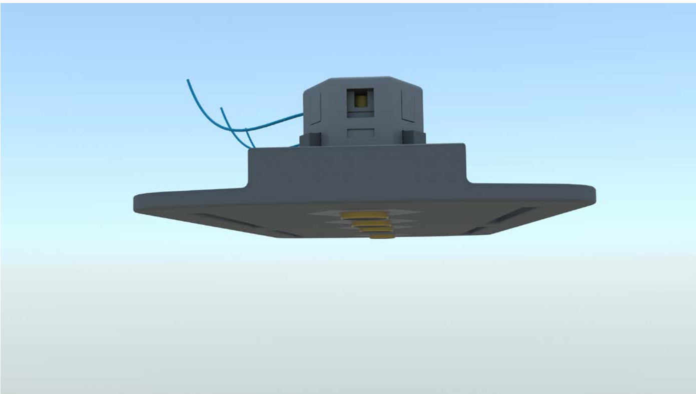


Figure 22: Underside of the basic concept

Figure 23: The fabrifoam velcro (21)


Figure 24: Lateral testing position

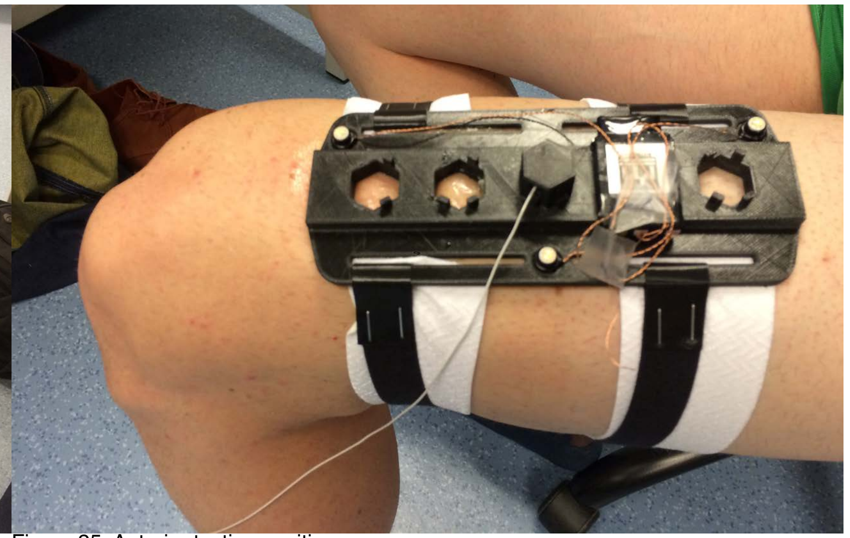


Figure 25: Anterior testing position

Method:

The testing of the basic concept was done without a predetermined protocol. The holder was strapped to the leg in 2 different ways, shown in figures 24 and 26. The hexagon that aims the ultrasound beam straight down was inserted in all locations and the leg was bent from full extension to 90 degrees of flexion. All the results were filmed and analysed later on, beceause the software was not yet adapted to make M-mode plots. Furthermore the angular hexagon was only tested on the anterior side of the leg, while the tibia couldn't be tested at all, since the holder was too wide and could not be kept in place.

Results:

The results showed the signal during several cycles of flexion and extension of the knee. The full movies are available on request and the main findings regarding the results are:

- On the anterior side the results on all four locations were comparable, there was hardly a peak at full extension but at 90° flexion the peak was very good. The pattern was the same for both straight and angular positions, only the peak amplitude was lower with the angular ones.
- On the lateral side only the most proximal position gave a good result, it even showed a clear peak from full extension to 90° of flexion.

Besides, several observations, done during the feasibility testing, yielded improvements to the basic design:

- The basic plate is already quite wide, it cannot be fit to the tibia and only on flat parts of the femur. This strengthens the decision of the chosen design direction, a bigger rigid part will be harder to fit on the leg.
- When applying force by hand the base plate warps already. This raises the concerns regarding PLA, although, only 20% part fill was used. The final concept needs higher part fill to provide definite answers to this concern.
- The snap fits are fragile and the hexagons can only be inserted from underneath, therefore it needs redesigning.
- The three degree angle of the hexagon shaped insert is chosen randomly, a more substantiated method is necessary to determine usable angle.

Discussion:

The feasibility test has showed that it is possible to retain a signal during motion while the transducer is strapped to the leg in a holder. But it also showed that the placement of the holder is crucial to the success of this process. When the skin-to-bone orientation changes during the movement, the signal is lost. Besides the feasibility testing did not reveal if this concept is usable when placed on the characteristic locations that are necessary for the correct kinematics reconstruction. Therefore a more structured testing of suitable locations is necessary. The goal of this structured testing is to find a set of locations where this holder principle can be used and who provide the necessary information to reconstruct the kinematics.

4.3 Location testing

Goal:

While the feasibility test showed that it is possible to keep seeing the bone during knee flexion and extension with the transducer fixed to a plate. More detailed information is needed regarding the locations where this is possible. Therefore the goal of the location testing is to find a set of 30 locations divided over the upper and lower leg where the transducers can be placed, whilst remaining enough signal to be useful. The set of 30 locations must also provide enough information to reconstruct the knee kinematics, in other words a sufficient number of characteristic locations must be embedded.

Selecting the test locations:

To obtain an appropriate starting point a small literature study is performed to determine the locations that will be tested. This is done to obtain the ideal location from a more theoretical approach, increasing the chance of finding suitable locations and decreasesing the chance that its based pure on luck. Because there is no theory available that describes the change in skin-to-bone orientation during movement, other theories are explored.

In 1964 Iberall found that there is virtually no skin stretch along certain lines, called 'Lines of non-extension'. He determined these lines for three human bodies in an empirical way and the results show that these lines are quite general for the human body (figure 26)[(22)]. Since then, new techniques to map the skin strain field have been developed and are used to reproduce or expand the lines of non-extensions theory (figure 27)[(23)]. A study that focussed on the elbow joint compared four subjects with varying anthropometry, results showed that their lines of non-extension form a similar and recognizable pattern (figure 28)[(24)]. Still the question remains if this could actually be useful to the ultrasound system, because the LoNEs do not proof that there is no movement between skin and bone on these lines. Although it would already be beneficial if there is less chance of a changing skin-to-bone orientation at locations where there is little or no skin deformation. Therefore the testing locations will be chosen so that they approximately coincide with the LoNEs, hoping they enhance the results. But there is no guarantee they'll be placed on the actual LoNEs, therefore no relations between the change in skin-to-bone orientation and the lines of non-extension can be deducted from the testing procedure.

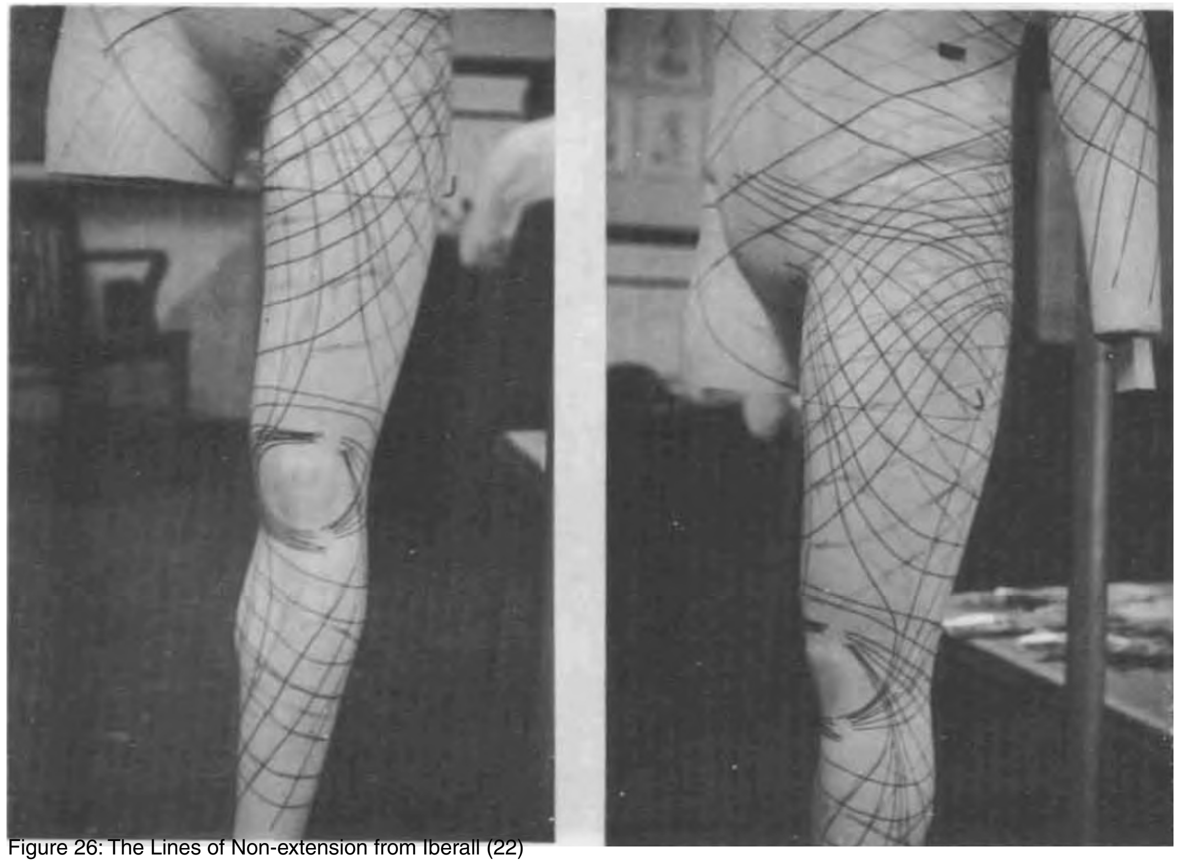


Figure 26: The Lines of Non-extension from Iberall (22)

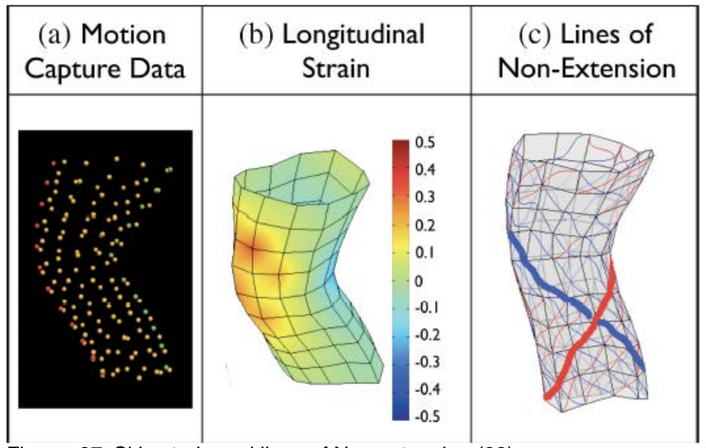


Figure 27: Skin strain and lines of Non-extension (23)

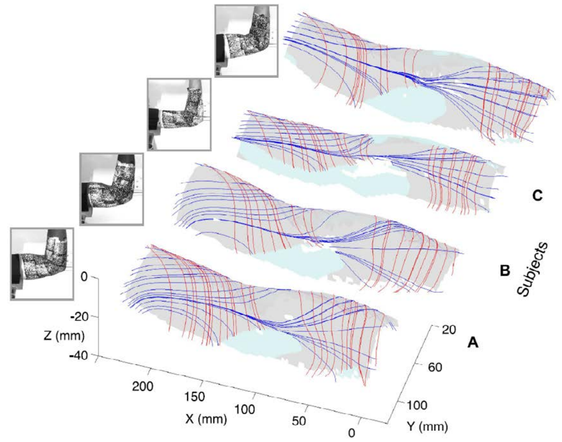


Figure 28: Lines of Non-extensions on the elbow joint (24)

As can be seen in figure 26, there are many lines of non-extensions. Placing the transducers randomly on these lines will unlikely give the desired results. Thus another approach is used to expand the location selection: The Visible Human Project[(25)(26)] in which a human corpse is sliced in 1mm pieces and images of each pierce are made. Each image providing a clear view of bone, muscle and skin tissue (figure 29).

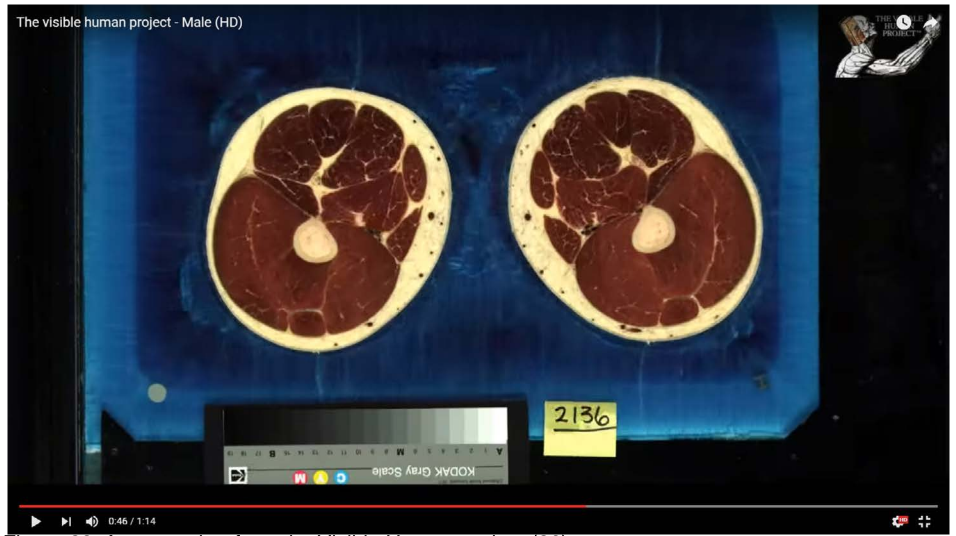


Figure 29: A screenshot from the Visible Human project (26)

To cover the complete leg, it is divided in nine regions. In this section these regions are called the test locations and are, from top to bottom: The trochanter, proximal femur, mid femur, distal femur, patella sides, proximal tibia, mid tibia, distal tibia and the ankle. The points on these locations where the transducer will be placed are named "positions" during the location testing, to enable a distinction with the locations. The shape of the bone remains fairly constant over the height of these locations. The position selection is done using the following procedure:

1. Marking interesting areas:
   - Flat areas on the bone
   - Areas where skin and bone have approximately the same curvature
2. Allocate testing points for each area:
   - Small flat area: 1 point perpendicular to mid-point of the area
   - Large flat area: 2 points perpendicular to end of the area
   - Small curved area: 2 points perpendicular to the tangent of the area
   - Large curved area: 3 points perpendicular to the tangent of the area
3. Measure the angle between a beam perpendicular to the skin and the line perpendicular to the corresponding area. (figure 30).

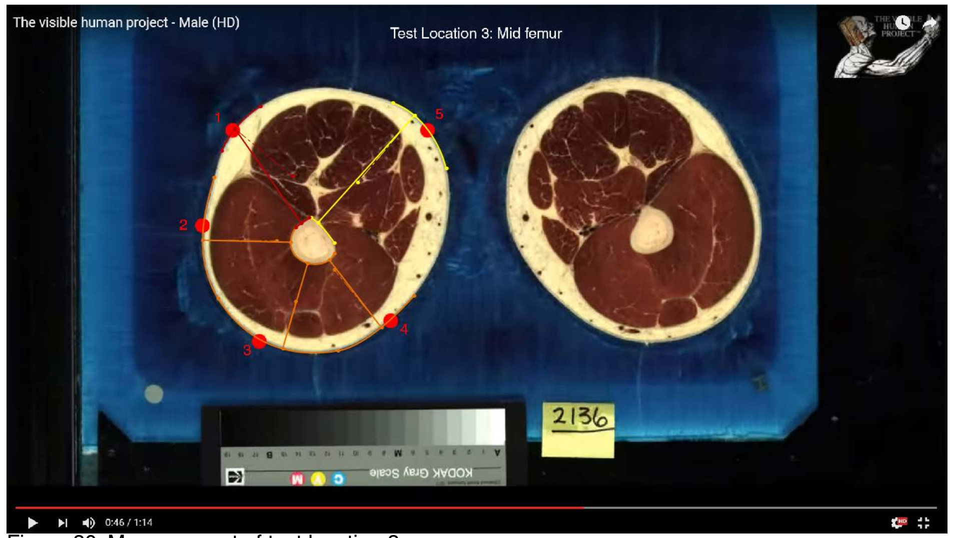


Figure 30: Measurement of test location 3

This last step is done using Solidworks and provided the information necessary to determine the approximate range in which the skin-to-bone orientation varies, but only the medial and lateral angles can measured in this way. The measurements showed that the angles varied roughly between -20° and +20°, therefore the decision is made that it must be possible to aim the transducer 10° and 20° in proximal, distal, medial and lateral directions, as well as straight down (0°). Finally the lines of non-extensions and the positions from the Visible human project are combined, the result is a total of 73 position divided over the 9 locations. In figure 31 one of the five visualisations is shown, the others are provided in appendix E.

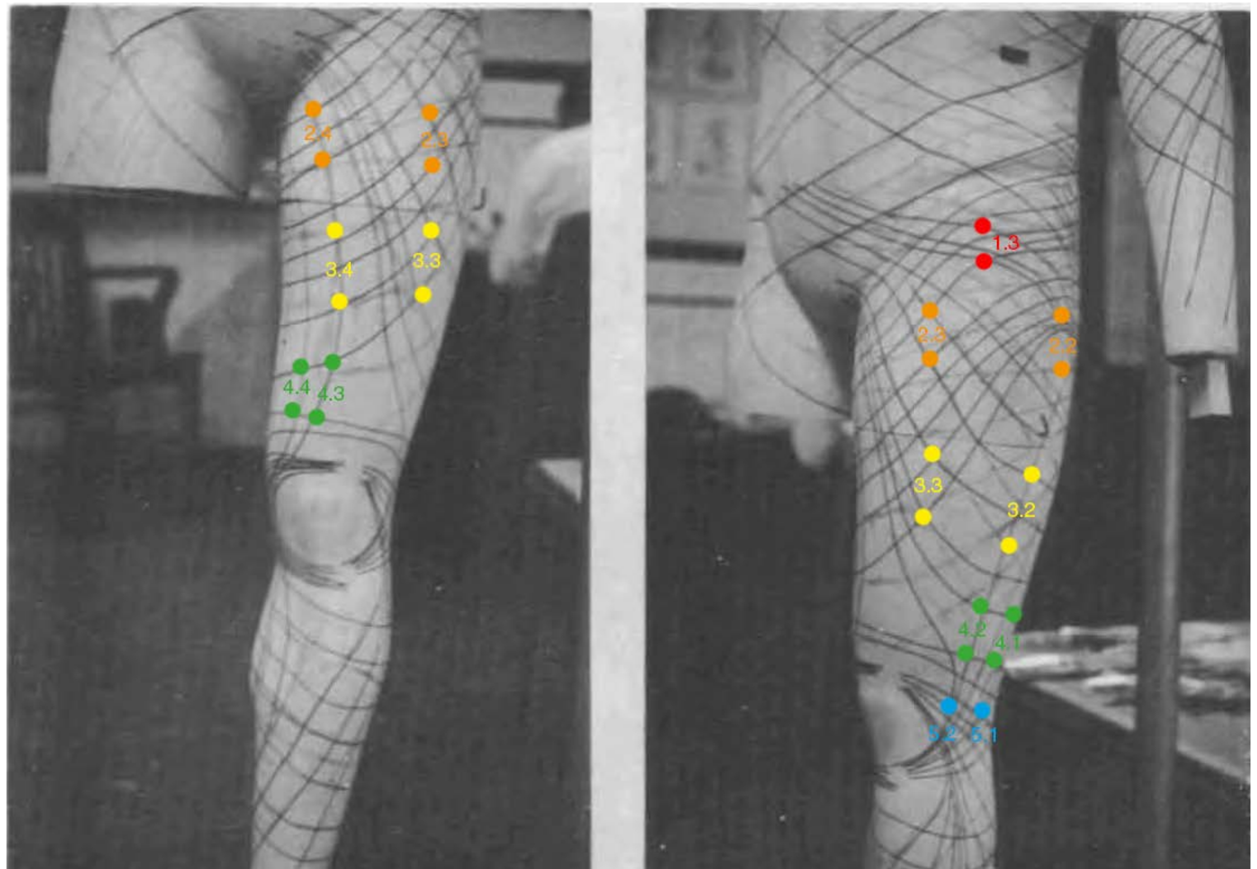


Figure 31: Selected locations on the anterior side of the femur

In figure 31 each colour represent one of the nine test locations, they are numbered from top to bottom, besides each positions also has its own unique number. When the same position is tested at two different heights within the locations, the proximal placed one becomes the A position and the distal one the B position. For example point 3 from figure 30 corresponds to point 3.3 in figure 31, where the upper is 3.3A and the lower 3.3B

Materials:

Because of the limitations in the basic prototype, a new holder is designed. Only one hexagon, and thus transducer, can be mounted to it, furthermore it has space for the Visualeyez battery and LEDs. The parts containing the Visualeyez system are raised, to prevent them from touching the skin and thus should avoid undesired movements of the holder during the measurement. Still a sufficient flat section remained to prevent the holder following the local skin movement, since a larger holder containing more transducers is also unable to adapt to local skin movement. The snap-fits have been changed too, they have been updated using BASF guidelines for snap-fits[28]. Insertion of the hexagons from the top is now possible, so the holder can remain in place when a different orientation is desired.

Also the hexagons are now made in such a way that they enable the testing of the desired orientations. To achieve this five types of hexagons are necessary: two for the 10° and 20° proximal and distal orientations, two for the 10° and 20° medial and lateral orientations and one for the 0° orientation, as a result nine different angles can be tested for each position. The Fabrifoam Velcro straps are again used to keep the holder in place, to enable this two narrow Velcro straps are sewn to the cut-outs in the holder. A Fabrifoam strap is then knitted to each of the Velcros and the Fabrifoam straps are knitted to each other using another Velcro. Doing it this ways enables an even tightening of the holder to the leg. Rendered images of the location testing holder are provided in figures 32, 33 and 34.

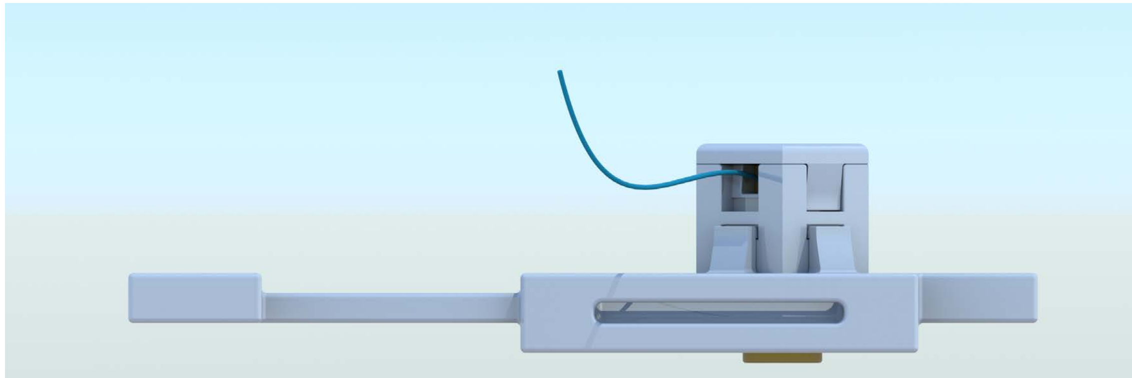


Figure 32: The location testing holder

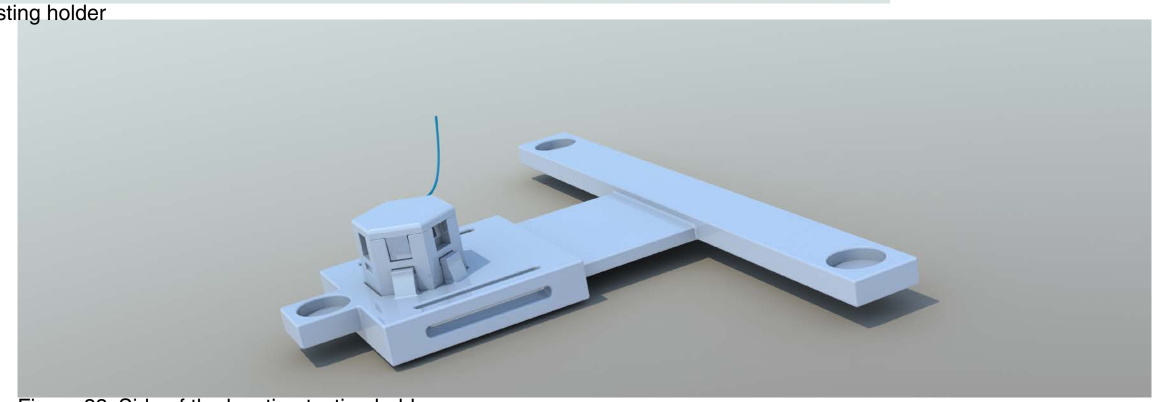


Figure 33: Side of the location testing holder

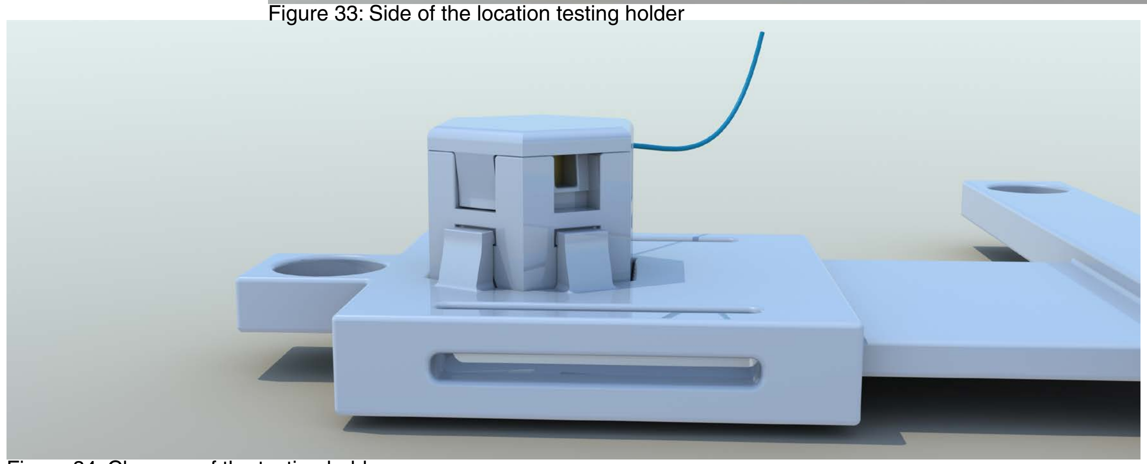


Figure 34: Close-up of the testing holder

Other materials that were used during the location testing were similar to the equipment used in the cadaver testing, this included a Visualeyez tracker, the NI data acquisutiin controller and Labview. Only the LabVIEW user interface was adapted by Victor Sluiter and the new version can be seen in figure 35. The visualisation of the bone point was replaced with a M-mode graph which provides the results of the last 30 seconds. Furthermore when the software finds a peak above an arbitrary threshold in the search region, it marks this point with a red cross in the M-mode. Finally, it also provides at what percentage of the 30 second interval it has found such a peak. During the testing a screenshot of this interface is made from every tested position and orientation.

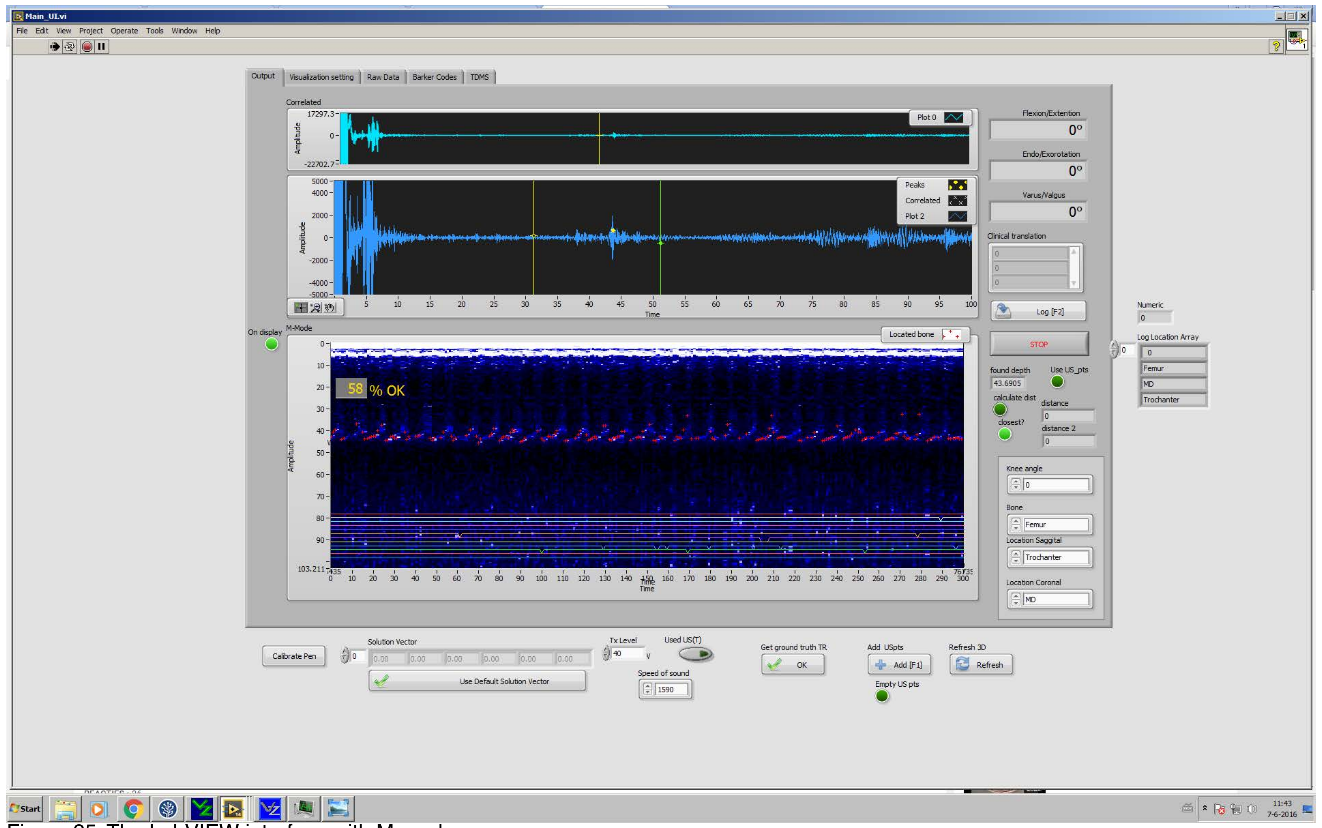


Figure 35: The LabVIEW interface with M-mode

Method:

To assess the dynamic capabilities of each location, a repetitive movement that is best described as 'marching in place' was performed. The movement starts at full extension and figure 36 shows the smallest angle that can be achieved while doing this movement. Although it must be pointed out that the angle at which the picture is taken doesn't show the angle of the motion correctly, ixt is likely that this angle is bigger than measured here. The movement was performed for every position as long as necessary to obtain a convenient M-mode plot and a screenshot was then made and saved to be analysed later.

Because of time constraint it was not possible to test all the 72 positions for all nine available orientations. Therefore it was decided that only eight key positions would be tested completely and that the locations #2 and #8 would not be tested at all. The reason to skip these locations is their similarity with respectively location #3 and #7, the results for these locations will be extrapolated from the results of locations #3 and #7.

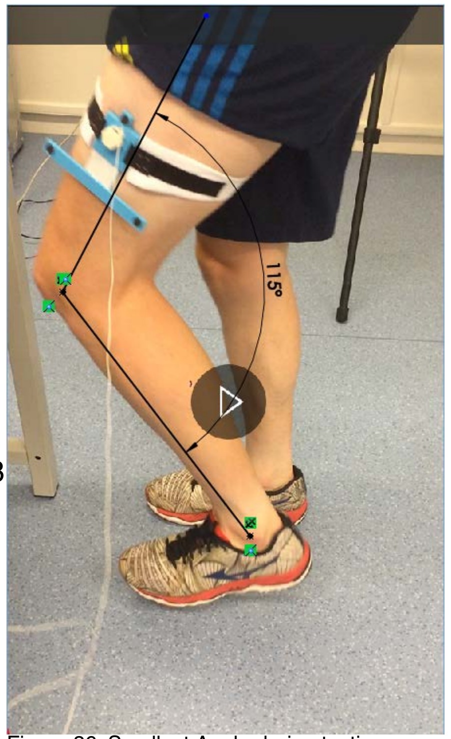


Figure 36: Smallest Angle during testing

The protocol that was followed to obtain the results of one position was as follows:

1. Insert the transducer in the correct hexagon carefully and close it with a cover.
2. Locate the desired position on the leg and keep this in mind.
3. Make sure that the correct length of Fabrifoam straps are connected to the Velcros.
4. Insert the hexagon into the base plate, making sure that it aims in the desired direction and that the arm containing the LEDs does not obstruct the motion.
5. Apply a small amount of gel lubrication to the transducer.
6. Take the holder and place it on the desired position located in point 2.
7. Press the holder onto the point by hand and make sure it lies flat on the skin, but be careful that it is not moved too much as this means that the transducer is placed in the wrong position. Besides moving it may cause the gel lubrication to fall behind.
8. Close the Fabrifoam straps with the third Velcro, making sure that both Fabrifoam straps are tightened evenly.
9. Check if the signal is still the same as before, if not start over from point 5 on.
10. Start with 'marching in place' and continue until a clean M-mode graph is visible.
11. Make a screenshot of the M-mode graph and save it.

Not all steps are necessary for every measurement. Step 1 is only necessary when the orientation of the transducer is changed and step 4 should also only be performed when there is either switched to another orientation or when the base plate is turned 180°. The order in which the positions were measured was as follows:

1. First all the positions were tested with the 0° hexagon, starting with the most proximal locations and the lowest number, i.e. 1.1A was tested first, then 1.2A, 1.3A and 1.1B was done as fourth.

2. When all the 0° positions were tested, the predetermined eight key positions were tested. Starting with the 10° distal and proximal orientation, which were both measured on one position before moving to the next position. This was done because it only required the hexagon to be turned 180° in the base plate. After that the eight key positions were measured for 10° lateral and medial, then the 20° distal and proximal orientations were tested and finally the 20° lateral and medial orientations were done.

To enhance this, an excel sheet was made to ensure that the correct order was followed and no positions were forgotten. Besides that, the tag that was given to the screenshots was added to the row of that particular position, to keep all the data sorted. This excel sheet was later on expanded to analyse the results of the testing. A part of the empty excel sheet is provided in figure 37, the rest can be found in Appendix F.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Location	Location	Number of TD positions	Number of testing heights	Total number of postions	Testing Position	Corresponding Tag from	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Total score
2										Test	0°		
3	Trochanter	1	3	2	6								
4						1.1A	1	LoNE A					
5						1.2A	2	LoNE A					
6						1.3A	3		LoNE B				
7						1.1B	4	LoNE A					
8						1.2B	5	LoNE A					
9						1.3B	6		LoNE B				
10													
11	Proximal Femur	2	5	2	10								
12						2.1A	Not tested		LoNE C				
13						2.2A	Not tested	LoNE B					
14						2.3A	Not tested	LoNE B					
15						2.4A	Not tested	LoNE B	LoNE C				
16						2.5A	Not tested		LoNE C				
17						2.1B	Not tested		LoNE C				
18						2.2B	Not tested	LoNE B					
19						2.3B	Not tested	LoNE B					
20						2.4B	Not tested	LoNE B	LoNE C				
21						2.5B	Not tested		LoNE C				
22													
23	Mid Femur	3	5	2	10								
24						3.1A	7		LoNE C				
25						3.2A	8	LoNE B					
26						3.3A	9	LoNE B					
27						3.4A	10	LoNE B	LoNE C				
28						3.5A	11		LoNE C				
29						3.1B	12		LoNE C				
30						3.2B	13	LoNE B					
31						3.3B	14	LoNE B					
32						3.4B	15	LoNE B	LoNE C				
33						3.5B	16		LoNE C				
34													
35	Distal Femur	4	5	2	10								
36						4.1A	17	LoNE B	LoNE C				
37						4.2A	18	LoNE B					

Figure 37: Excel sheet for the location testing

Testing results:

The acquired data from the location testing was evaluated and scored to grade the quality of each position, the scoring is explained in table 4. Grading is done the same way for the eight fully tested locations, only the results of the angular orientations are then compared to the straight orientation. They are only considered an added value if they provide better results. The fully graded results are provided in appendix G.

Parameter	Explanation	Points
Peak detection	• No= 0-50% detection	0
	• Half=50-75% detection	2
	• Yes=75-100% detection	4
M-Mode quality	• Nothing to see that could be bone	0
	• Some lighter points visible	1
	• Segmented distinguishable white/light blue line	2
	• Distinguishable continuous light blue line	3
	• Distinguishable continuous white line	4
Total score	• Red= Bad points, should not be used	0-4
	• Yellow= Acceptable points, use only when necessary	5-6
	• Green= Good points, preferable positions	7-8

Table 4: Scoring of the test results

To clarify the scoring of the M-modes quality, three examples are provided in figure 38,39 and 40. In figure 38 a continuous white line is visible, therefore it scores 4 points. In figure 39 the result is segmented, some white and light blue points are distinguishable, therefore it scores 2 points. In figure 40 nothing can be seen that could be bone, thus scoring 0 points

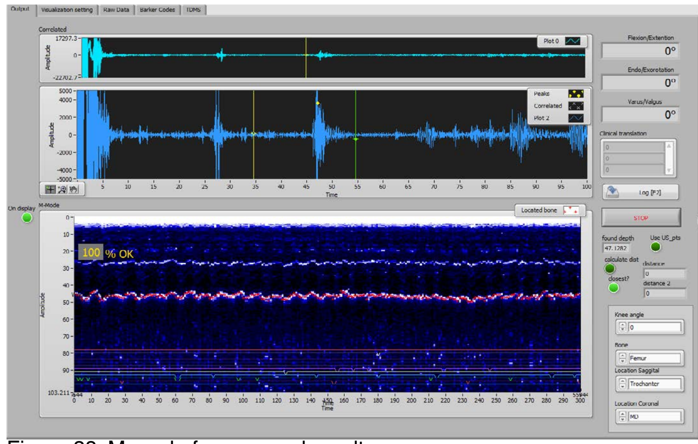


Figure 38: M-mode from a good result

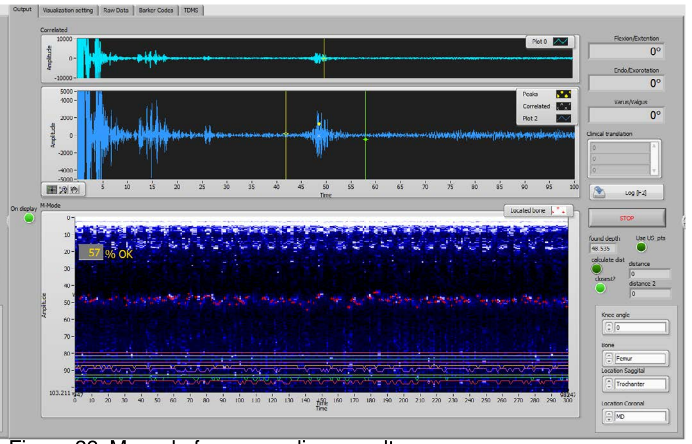


Figure 39: M-mode from a medium result

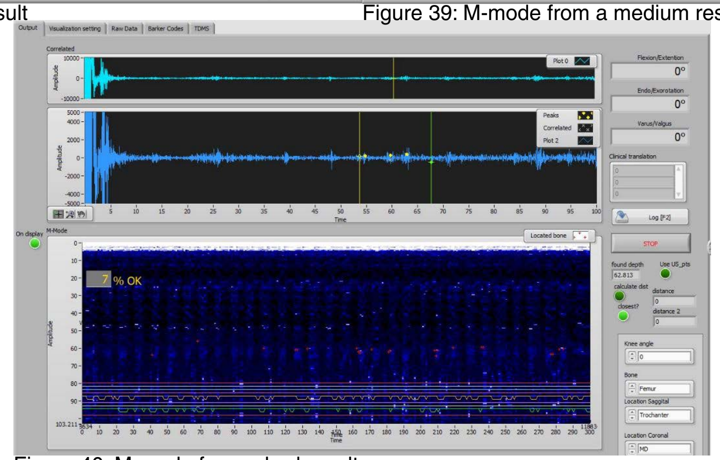


Figure 40: M-mode from a bad result

Based on the acquired results and observations during the testing the following conclusions can be drawn:

- The posterior side of the leg is not suitable to place transducers:
  - On the femur it is hard to find the bone
  - Near the knee the holder obstructs movement
  - On the tibia there is too big of a chance of hitting the fibula
- The lateral side of the lower leg is also not suitable
  - Again due to a big of a chance of hitting the fibula
  - Positions with low skin-to-bone distance have some difficulties:
  - Noise and bone signal are indistinguishable because they have approximately the same depth
- At most locations there is a bit room to move around
  - It is possible to move the holder to optimize the signal quality
  - This means there is some clearance with a bigger holder

Location selection:

Finally the best locations are selected, figure 41 provides an overview of all the results with the zero degree orientation. The locations where the left column is marked green are selected. A short description of the consideration is given below and a visualisation of the selection locations is shown in figure 42.

- Femur selected positions:
  - The positions scoring 7 or 8 points, with exception of 2.2A and 2.3A because they would not provide additional useful information for the kinematics reconstruction
  - The positions scoring 5 or 6 points on the trochanter and the patella sides, which are the epicondyles. These points are necessary for the kinematics reconstruction
  - On the patella sides a 10° distal orientation scores better than zero degrees. Using this must be considered
- Tibia selected positions:
  - At the proximal tibia locations four points on the medial side are selected and two points on the lateral side. One point on the lateral side has a bad score, including this point is a risk but it can enhance the kinematics reconstruction greatly.
  - Lots of positions scoring 7 or 8 points on mid and distal tibia. Selecting them all would not benefit the kinematics reconstruction, therefore only 5 are selected
  - The positions scoring 7 or 8 points on the ankle are selected too, they are important for the kinematics reconstruction

Trochanter		
1.1A	6	8
1.2A	2	4
1.3A	3	3
1.1B	6	8
1.2B	1	3
1.3B	2	2

Proximal Femur		
2.1A	3	5
2.2A	7	9
2.3A	7	9
2.4A	5	7
2.5A	3	5
2.1B	3	5
2.2B	7	9
2.3B	7	9
2.4B	3	5
2.5B	3	5
Results extrapolated		

Mid Femur		
3.1A	5	5
3.2A	8	10
3.3A	8	10
3.4A	6	8
3.5A	3	5
3.1B	1	3
3.2B	8	10
3.3B	7	9
3.4B	4	6
3.5B	1	1

Distal Femur		
4.1A	1	3
4.2A	7	7
4.3A	4	4
4.4A	4	6
4.5A	0	2
4.1B	0	2
4.2B	1	3
4.3b	7	7
4.4B	7	9
4.5B	1	3

Patella Sides		
5.1	5	7
5.2	8	10
5.3	6	8
5.4	6	8

Proximal Tibia		
6.1A	1	1
6.2A	7	7
6.3A	6	8
6.4A	7	9
6.5A	6	8
6.6A	7	7
6.1B	1	1
6.2B	1	1
6.3B	6	8
6.4B	7	9
6.5B	8	10
6.6B	7	7

Mid Tibia:		
7.1A	6	8
7.2A	7	7
7.3A	8	8
7.4A	1	1
7.1B	8	10
7.2B	7	7
7.3B	8	8
7.4B	1	1

Distal Tibia		
8.1A	7	7
8.2A	7	7
8.3A	7	7
8.4A	1	1
8.1B	7	9
8.2B	7	7
8.3B	7	7
8.4B	1	1
Results extrapolated		

Ankle		
9.1	7	9
9.2	8	10
9.3	7	9
9.4	8	10
9.5	6	8

Figure 41: Overview of the final location testing results

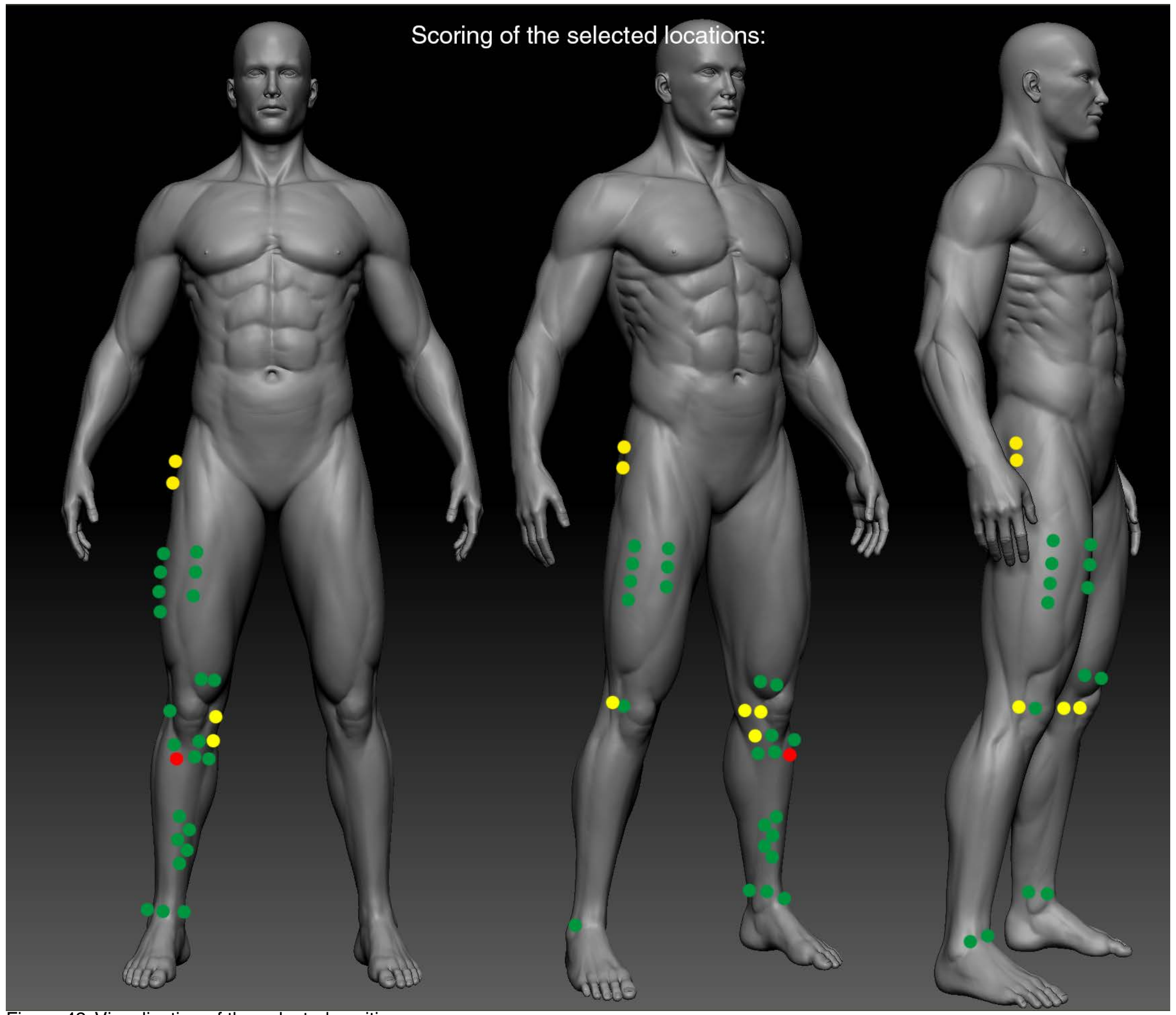


Figure 42: Visualisation of the selected positions

4.4 Conclusions after analysis and concept phase

The implications following the choice for Visualeyez and A-mode ultrasound, combined with the systems demands, has led to a statement of requirements regarding the holder design. Suitable materials and the 3D printing technique have been explored and the conclusion that currently PLA is the best material could be drawn. Furthermore several design directions were explored and three of them were elaborated. These elaborations were evaluated and eventually a concept based on discretely adjustable inserts was selected. A basic prototype of this concept was tested on its feasibility and it was decided that, after concluding that the concept was feasible, further testing was necessary. This testing should reveal the ideal locations to place the transducer while using the basic principle and if it is possible to place them on the required characteristic locations. A small literature study performed as starting point and a specific holder was designed to enhance the results. The testing resulted in a set of locations that are able to keep seeing the bone and reconstruct the knee kinematics while using the in section 4.1 chosen basic principle.

5. The final concept phase

5.1 Morphological analysis

The concept chosen in section 4.1 supplies a rough idea what the holder should look like, but it only offers the basic idea behind the concept. With the information obtained in the feasibility and locations tests a full concept can be established. To do so several decisions still have to be made, this is done by means of a morphological analysis. The holder is broken down in five key aspects and those aspects were evaluated with the complete design team. As a results the complete configuration of the holder is known and a final concept can be made.

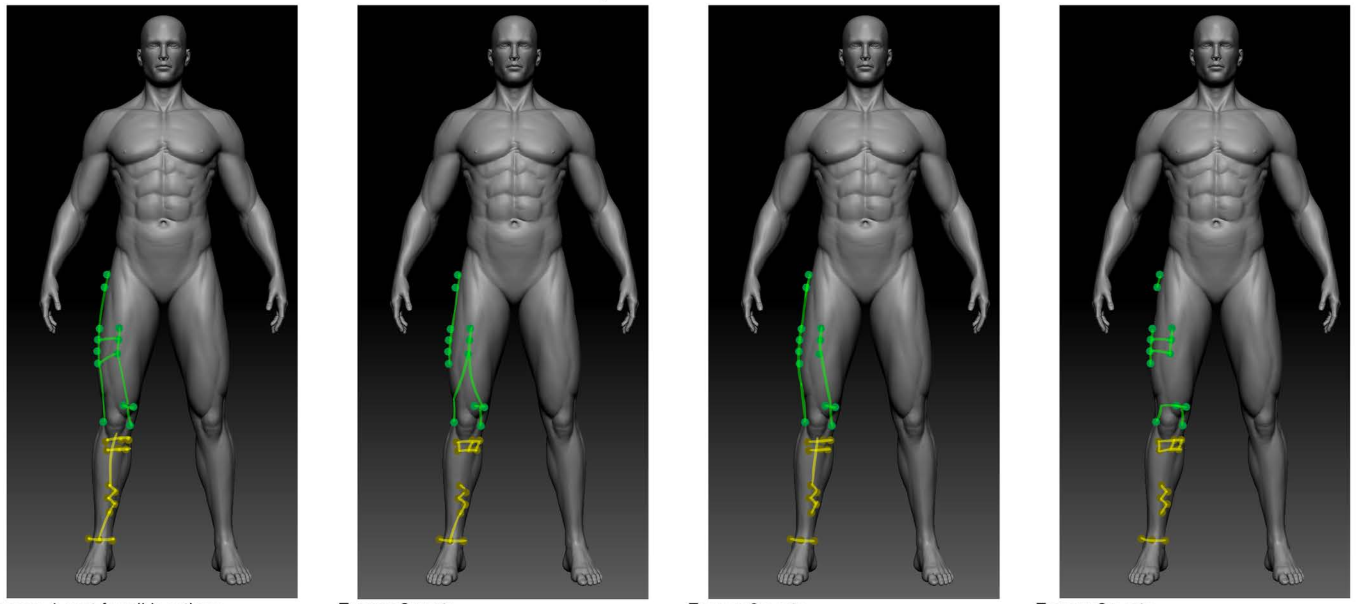
Layout of the holder:

A key aspect of the full holder system is the size of the individual holder parts, the number of transducer positions and Visualeyez markers per part needs to be carefully balanced to achieve an optimal setting. More transducer positions in one holder part means that the chance of it actually fitting and working decreases. But on the other hand too many holder parts can lead to long and inconvenient preparation of the system before it can be used to measure on a subject. Figure 43 shows four different layouts of the holders, they feature increasing number of parts from left to right, while covering the 30 transducer positions selected in section 4.3. A division is made between the femur and tibia parts, because the bones move relative to each other during the measurements. To keep 'seeing' both bones the holder must be able to follow this motion, therefore the motion must also be measured when one holder covers both bones at the same time. This was already rejected in an earlier stage, so the parts can only cover either the femur or the tibia bone.

The four options in figure 43 vary from two to six different holder parts, an option with more than six parts was not included because the change of the parts interfering with each other was expected to be too big. The evaluation led to the choice of layout D, this layout connects the transducer locations in the most convenient way and the number of Visualeyez markers, 6, should not be a problem.

Layout of the holders

Layout A · Layout B · Layout C · layout D



Layout A	Layout B	Layout C	layout D
Femur: 1 part for all locations	Femur: 2 parts Condyles+anterior Trochanter+side	Femur: 2 parts Trochanter+Lateral+Lateral part of knee Anterior+Medial part of knee	Femur: 3 parts Trochanter Knee Lateral and anterior
Tibia: 1 part for all locations	Tibia: 2 parts Ankle+shin Knee	Tibia: 2 parts Knee+shin Ankle	Tibia: 3 parts Ankle Knee Shin

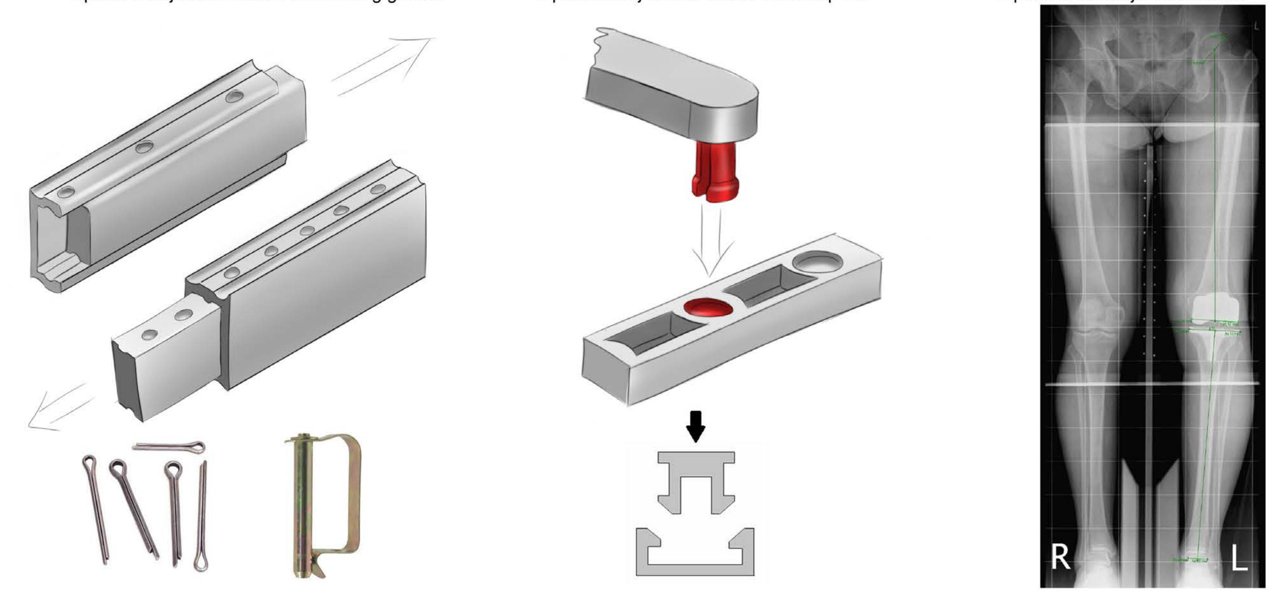
Figure 43: Possible holder layouts

Adjustability of the holder:

The option of a fully adjustable holder was already rejected because it requires a mechatronic system, but a discretely adjustable holder would still be a possibility, meaning that one holder can fit several subjects. The alternative is a full custom holder, specifically engineered for one person. Figure 44 shows two ways of making a holder part adjustable, i.e. option 1 and option 2, the adjustable features will be placed on locations where the dimension change from subject to subject, for example the width at the ankle or the epicondyles. It is decided that the full custom holder, i.e. option 3, is the best choice in the current situation, the working of the complete system still needs to be proven and a holder build to exact specifications of the subject would enhance this. The discrete adjustment step might cause one or more transducers to just miss the bone because it lies in between two steps. Besides an adjustable structure would increase the complexity of the holder design.

Adjustability of the holder

Option 1: Adjustable holder with sliding guides | Option 2: Adjustable holder with snap fits | Option 3: Not adjustable holder



Holder parts can slide back and forth.
Position is locked with linchpins or locking pens
Advantages: adjustability and reusability
Disadvantage: discrete adjustments and more complex

Holder can be snapped in place.
Advantages: adjustability and ease of use
Disadvantages: Breakable, discrete adjusments and most complex of the three

Holder will be custom made based on the dimensions of the subject
Advantages: best possible fit, simplest design
Disadvantages: changes require a new holder

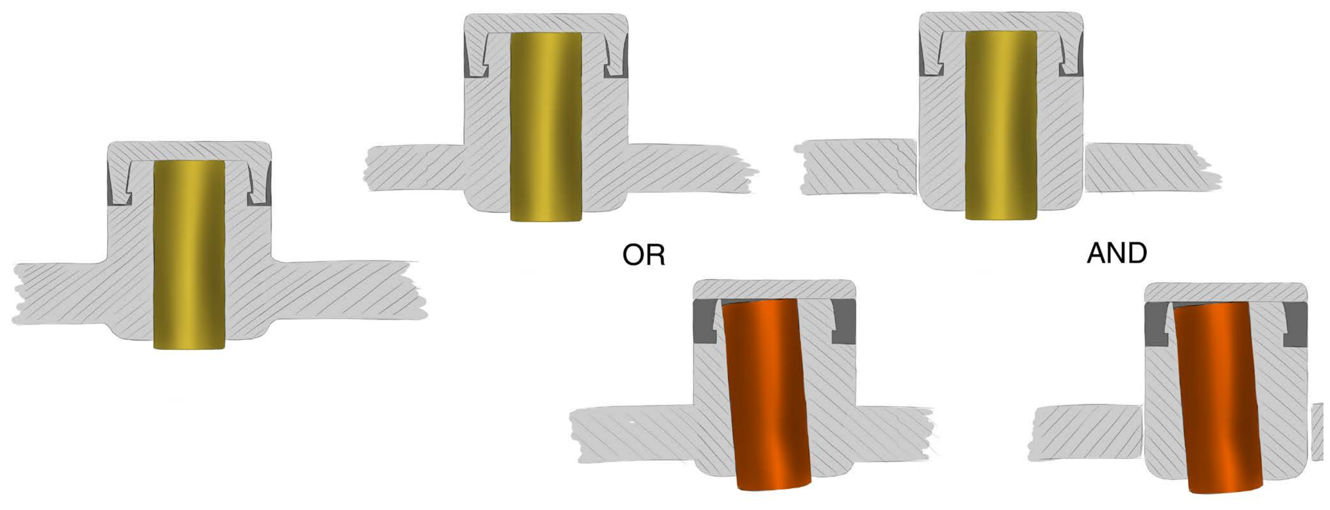
Figure 44: Holder adjustability options

Transducer orientations:

The third choice that needs to be made involves the transducer orientations. The location testing revealed that aiming the ultrasound beam straight down generally gives the best results. Figure 45 shows the three possibilities regarding the transducer orientations, in option 1 and option 2 the space to insert the transducer becomes part of the holder itself, this reduces the complexity of the holder and the number of parts, besides the stiffness is increased. The disadvantage is that the holder must be adapted when the bone isn't found. Option 3 still has the possibility to change the insert able part containing the transducer, this also is the chosen option. Again because it enhances the chance of 'seeing' the bone, when a certain location has no signal, other orientations can be tried to find the best possible signal. This offers more freedom and thus better performance and is therefore preferred above a reduction in parts and a small increase in stiffness.

Possible transducer orientatiens

Option 1: Trandsducers fixed at zero degrees | Option 2: Transducers fixed at zero and 10 degrees | Option 3: Transducers interchangeable



Make all transducers fixed and zero degrees. Selected locations all find the signal with zero

Again make all transducers fixed but aim them 10 degrees distal for all condyles of the femur.

Use changeable transducers, giving 1 or 2 options for each location. (for example zero and distal)

Advantages: Transducers go directly in the holder, no searching and finetuning.
Disadvantages: When nothing is found, you need another holder

Advantages: Ability to finetune
Disadvantages: More parts, finetuning can take a lot of time

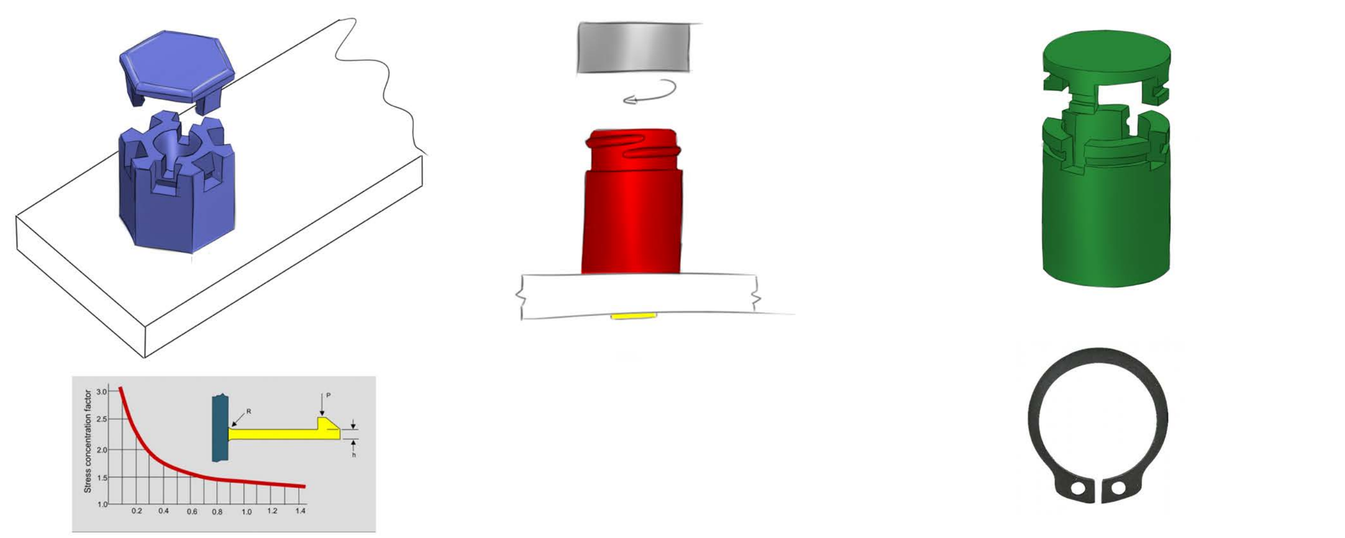
Figure 45: Transducer orientation options

Fixation of the transducers:

The snap fits used in the feasibility and location test holders were an easy and practical solution, but they proved to be fragile, even after redesigning them, therefore other options are explored too. Figure 46 provides the explored possibilities: snap-fits, screw-thread and retaining rings. The screw-threads can only be used on round shapes, due the choice for adjustable and insertable transducer containers a round shape is not possible. Besides threads need to be smoothened after printing, otherwise it will be hard to screw them onto each other. The limited availability of space makes it hard to design the snap-fits in a correct way, therefore retaining rings seem to be the only suitable option here. The downside of this fixation is the need of a special tool to secure and remove the rings.

Fixation of the transducers

Option 1: Snap fits | Option 2: Screw-thread | Option 3: Retaining rings



Advantages: easy to use and manufactre
Disadvantages: break easily, difficult to design with the current concept

Advantages: easy to use, reusable and secure
Disadvantages: Hard to 3D print, needs postprocessing and can only be used with round shape

Advantages: Secure fixation, easiest to manufactre and reusable
Disadvantages: Need special tool and takes most time

Figure 46: Options for transducer fixation

Connection shape:

The last choice that must be made is how different plates of one part are connected to each other. Connecting the holder flat on the skin means that it follows the movement of the skin, this can cause the part containing the transducer to be raised, eventually losing the contact with the skin. Although not all parts are influenced by this, a solution that decreases the skin contact area is still preferred. A possibility would be connecting the transducer containing plates with circular shaped bows, option 2. But for the bows to be raised from the skin, they need to be placed on top of the plates. Either this is a weak thin solution or a bulky one that limits the possibilities to design the plates. The third option is made of two straight perpendicular beams, they can be integrated in the side of the plate. Their width does not influence the dimension of the plates containing the transducers, besides if the stiffness is not adequate they can be easily reinforced with steel pins. Furthermore the straight beams offer good locations to place the LEDs from the Visualeyez system and thus are chosen.

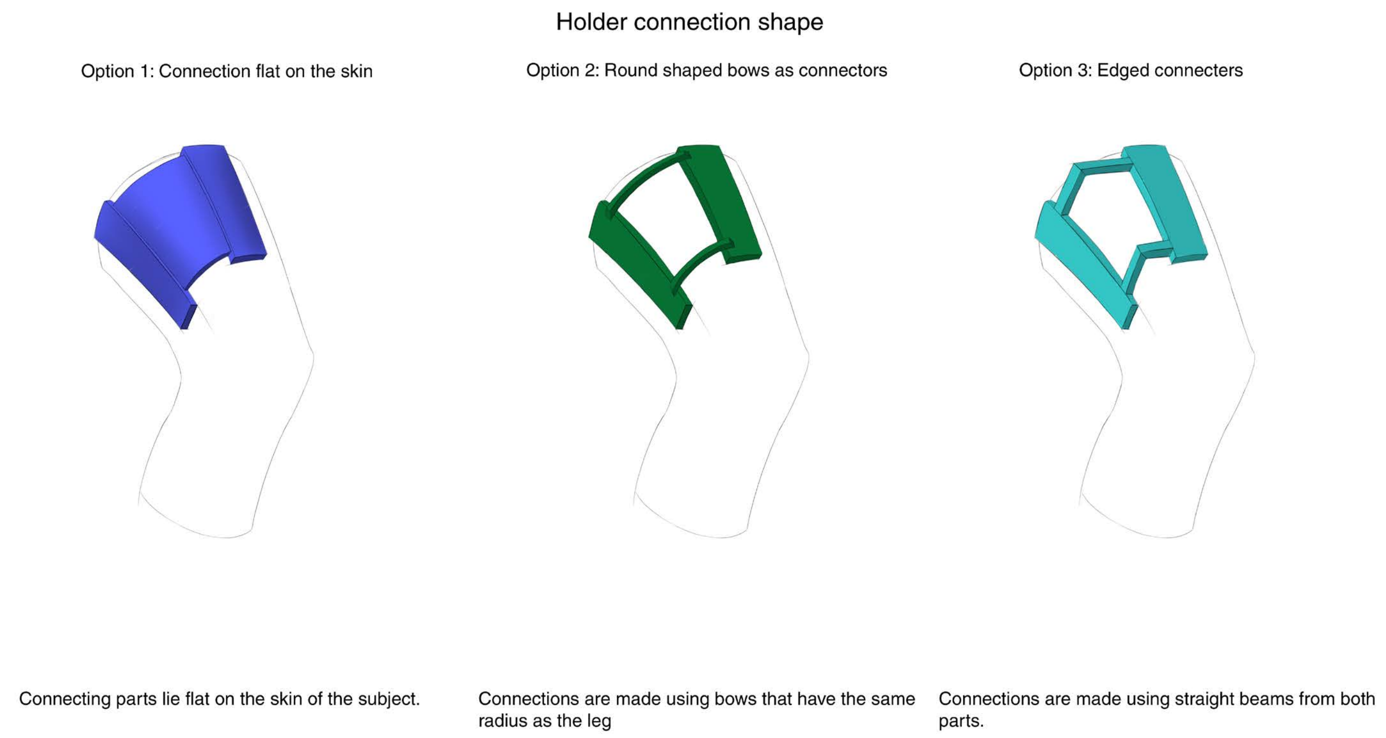


Figure 47: Connection shapes of transducer parts

5.2 Concepts of holder parts

With the results from the morphological analysis in the previous section, a full concept can be developed. Because layout D is chosen, this will results in six different holder parts: one that is suitable to use on the trochanter, one for the middle of the femur bone, one that covers the femur epicondyles and the musculus vastus medialis, one that covers the tibia epicondyles, one to be used on the subject's shins (middle of the tibia bone) and one that is suitable for use on the ankle. These six holders together cover all of the 30 selected locations in section 4.3, the image of the lower extremities in each of the parts concept designs displays the locations that are covered by that particular part. The exact locations of the points covered by a particular part can be looked up in figure 42 or Appendix G. Furthermore all the parts are designed in compliance with the statement of requirements and a left and right leg version will be made if this is applicable.

Part 1: Trochanter

The trochanter part is the simplest part, containing only two transducers and suitable for use on both the left and right leg. The locations that are covered by this part are 1.1A and 1.1B. Since there is some room to move the holder part around the trochanter, the most important aspect is the distance between the two transducers itself, therefore this distance should be adaptable in the Solidworks model. The shape is optimized in such a way that the amount of skin contact is at a minimum, reducing the influence skin movement and muscle bulging have on the performance of the holder. This feature will also be used on the other holder parts. There is a special area where the battery of the Visualeyez system can be pressed in and an arm that contains two of the three LEDs is added underneath this area. Rigidity of this arm is not of a problem because the arm is not in contact with the subject's skin. The third LED will be placed on the cap covering the transducer container and the whole part can be strapped to the subject using a single fabrifoam strap.

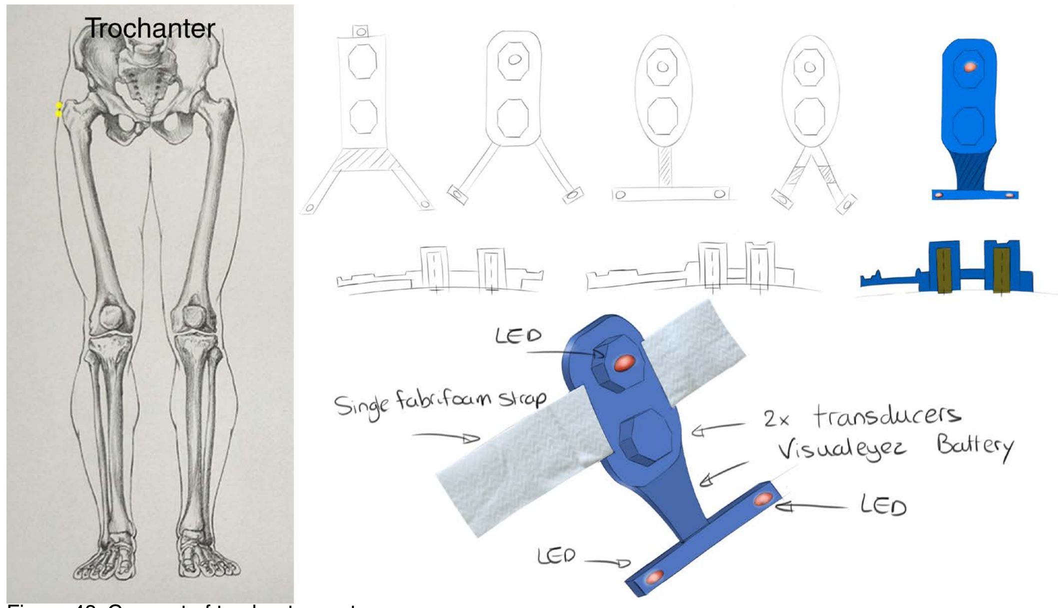


Figure 48: Concept of trochanter part

Part 2: Mid femur

The part covers the locations on the middle of the femur bone and consists of seven transducers. The locations that this part covers are 3.2A, 3.2B, 3.3A, 3.3B, 2.2B, 2.3B and 4.2A. Although the points 2.2B and 2.3B are moved slightly downwards and point 4.2A is moved slightly upwards to decrease the size of the holder. This was possible because all the points over these two lines gave similar results and therefore it is assumed that a location in between the points also gives comparable results. This means that three transducers are placed on the anterior side of the upper leg and four transducers are placed on the lateral side of the upper leg. The two plates containing the transducers are connected using the perpendicular beams, which also contain the storage for the Visualeyez battery and two LEDs. The other LED will again be placed on the cover of a transducer container and the whole part can be strapped to the leg using a single fabrifoam strap. When strapped to the leg correctly, rigidity should not be a problem since the fabrifoam is able to stretch a bit, diminishing the force that pushes against the holder. Whether this part will be suitable for both left and right leg depends on its parametrisation and still needs to be confirmed.

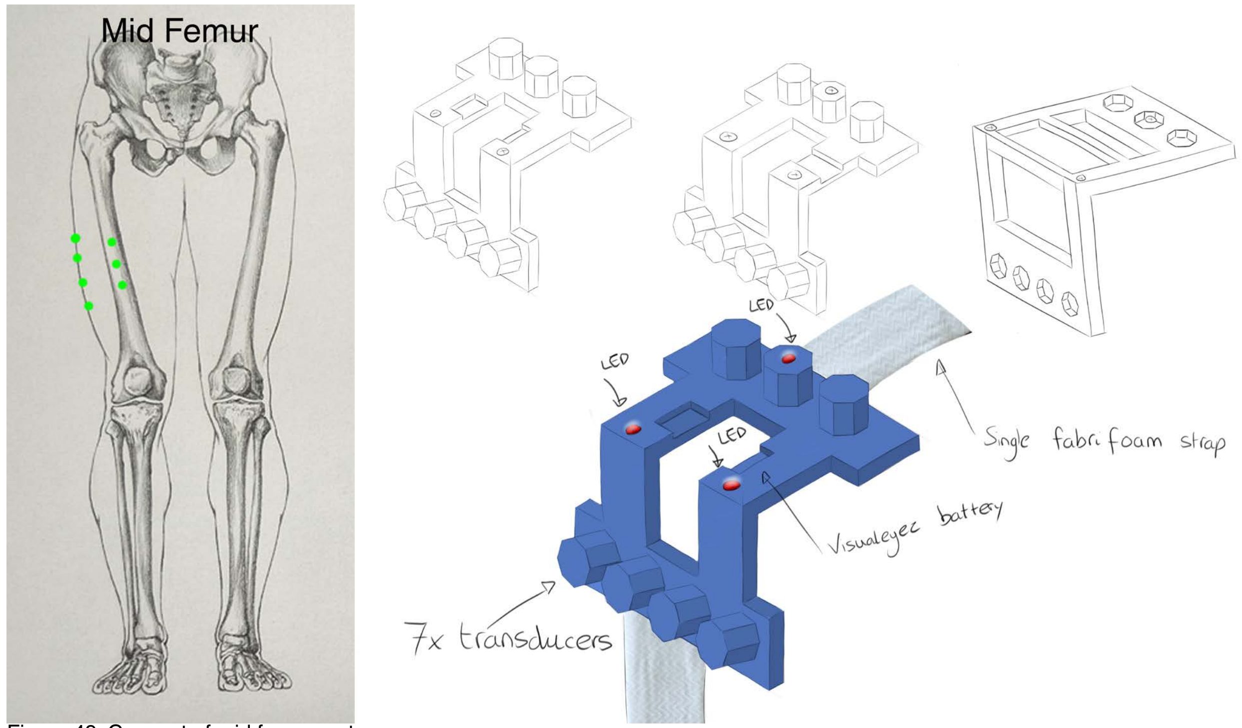


Figure 49: Concept of mid femur part

Part 3: Femur epicondyles

The femur epicondyles part covers six positions, two on each side of the knee and two on the musculus vastus medialis. They correspond to the points 4.3B, 4.4B and 5.1 until 5.4, the points of location 5 all lie on the medial and lateral epicondyles of the femur bone and therefore these should be detected first. The Visualeyez battery can be pressed in the side of the arm connecting the epicondyles plate and the m. vastus medialis plate. All three LEDs are placed on the frontal plates so they are visible for a front facing camera, just as with the mid femur plate. Whether the plate is able to remain skin contact during the entire motion is still unclear, splitting the part in two would be a (undesired) solution if the skin contact proves to be insufficient. The bulging of the m. vastus medialis can also become problematic, when it pushes against the upper plate causing the part to bent, splitting the part in two would then again be a possibility. Also a left and right leg specific version of this part is necessary.

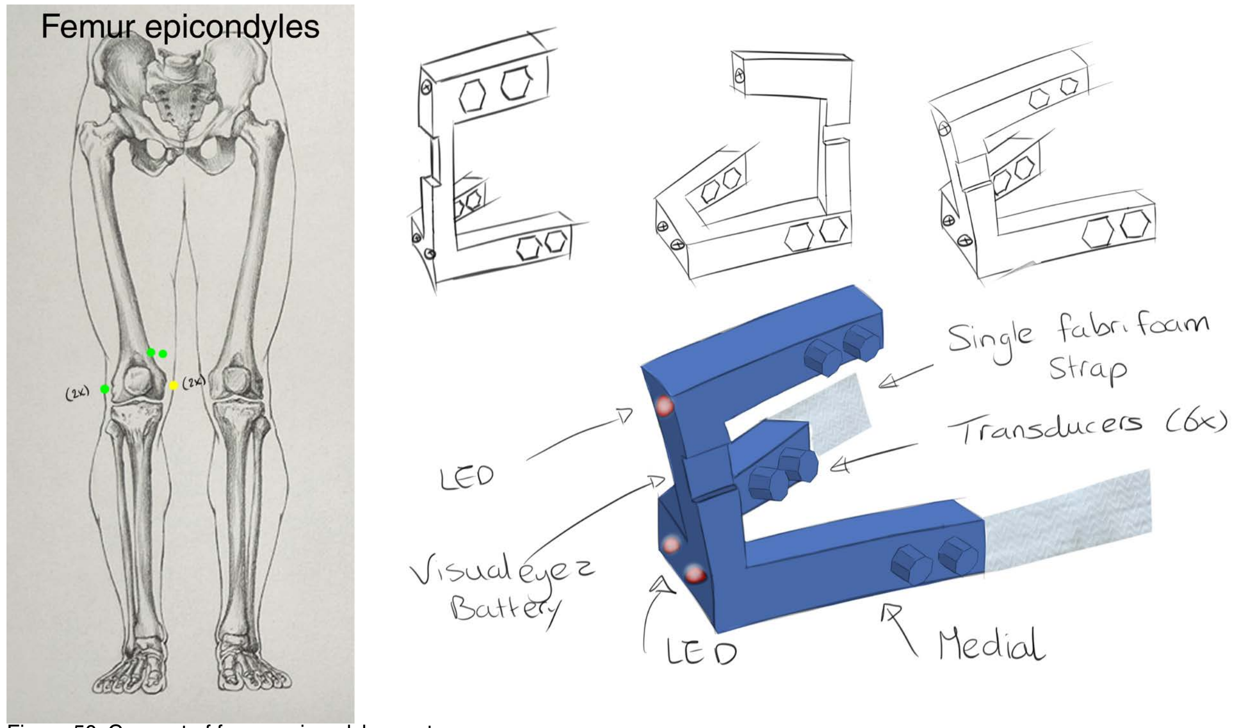


Figure 50: Concept of femur epicondyles part

Part 4: Tibia epicondyles

The tibia epicondyles part covers six transducer positions, two on the lateral side of the lower leg and four on the medial side of the lower leg. The positions this part covers are 6.2A, 6.2B, 6.4A, 6.4B, 6.5A and 6.5B, these are the medial and lateral epicondyles as wel as the region near the superior tibiofibular joint. The lateral and medial plates are connected by a cut-out section, this is done to decrease the chance of the kneecap hitting the part. The Visualeyez battery can be pressed in between the lateral plate and an arm containing two LEDs. The LEDs are mounted in such a way that they face forward and will be seen by a front facing camera, the third LED is mounted in the section that connects both plates. Rigidity of this part should not be an problem, as the fabrifoam strap enables the part to compensate for a bit of movement. Furthermore a specific left and right leg version is mandatory, because the arm containing the battery and LEDs would obstruct the leg motion when pointing upwards.

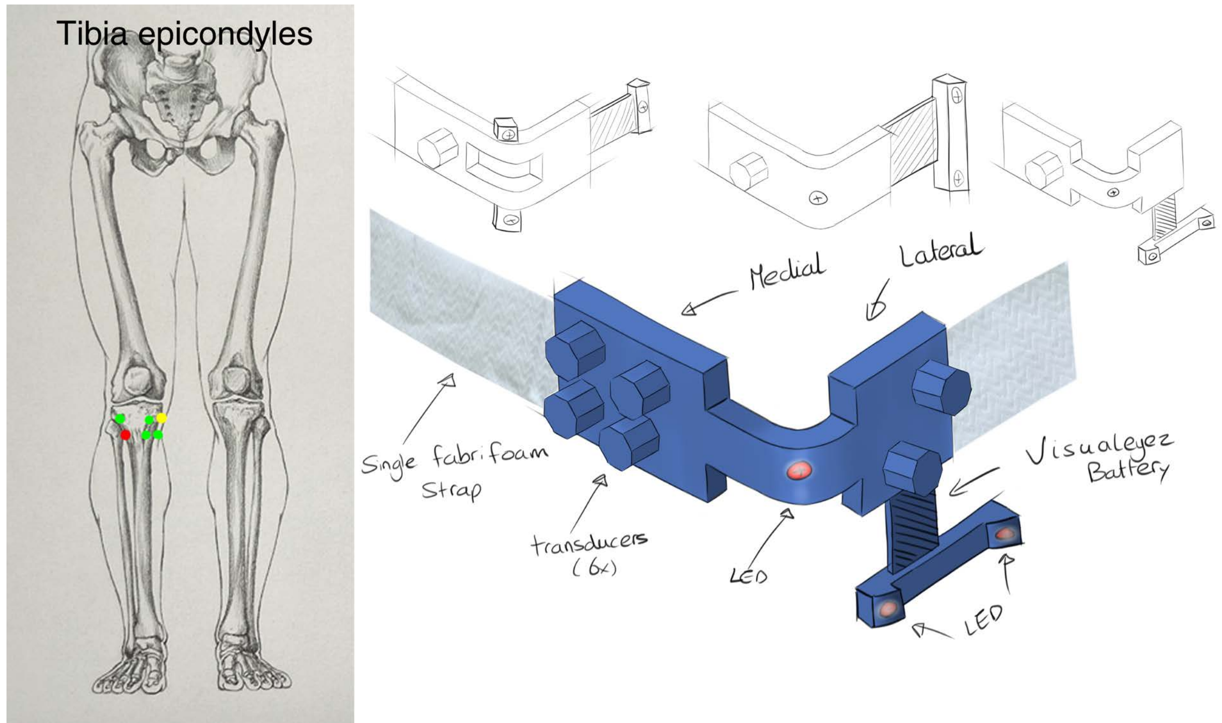


Figure 51: Concept of tibia epicondyles part

Part 5: Mid tibia

The mid tibia part contains five transducers and an arm where the Visualeyez battery can be pressed in. It covers the positions 7.1B, 7.2A, 7.2B, 8.1B and 8.2A, all these positions lie on the shins. Two of the LEDs are positioned on the covers of the transducer containers and are aimed at an angle, so they are visible by the front facing camera. The third transducer is placed next to the battery, again under an angle to be seen by the front facing camera. The part will be strapped to the leg using two fabrifoam straps, ensuring an equal fixation to the leg. Due the stretch in the straps the rigidiy of this part is not a problem and the way the part is built enables it to be used on both the left and right leg in the same configuration.

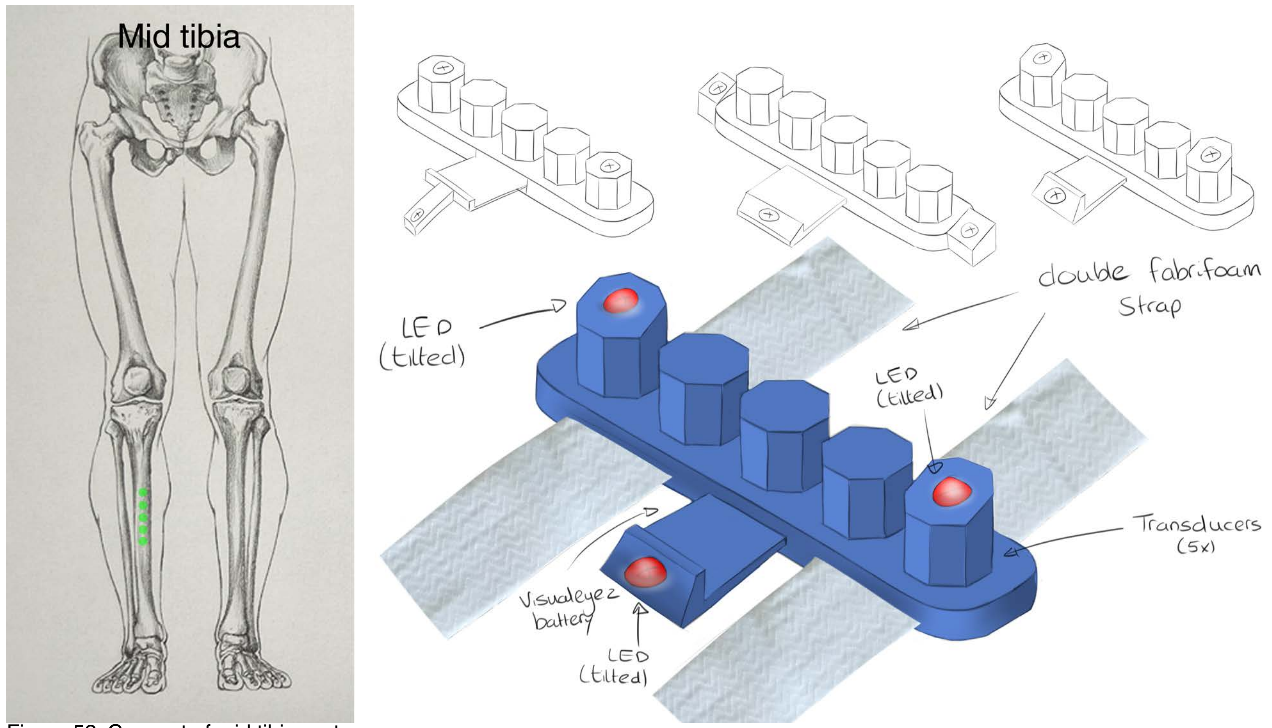


Figure 52: Concept of mid tibia part

Part 6: Ankle

The sixth part is the part that covers the four locations near the ankle, namely positions 9.1 until 9.4: One position on the anterior side, one on the lateral side and two on the medial side. A space to clamp the battery is placed on top of this and an arm is used for two LEDs. The third LED is placed on the cover of the anterior transducer container, which means that all transducer face forward. Because of the arm with the battery and LEDs the part can only be used on on leg side, thus a left and right leg specific part is necessary. It is strapped to the leg using a single fabrifoam strap. Rigidity again should not be an problem, there are no muscles with large bulging in that area. But a bit caution has to be applied when determining the positions of the transducers, as there are superficial tendons in that particular leg area that could be irritated easily.

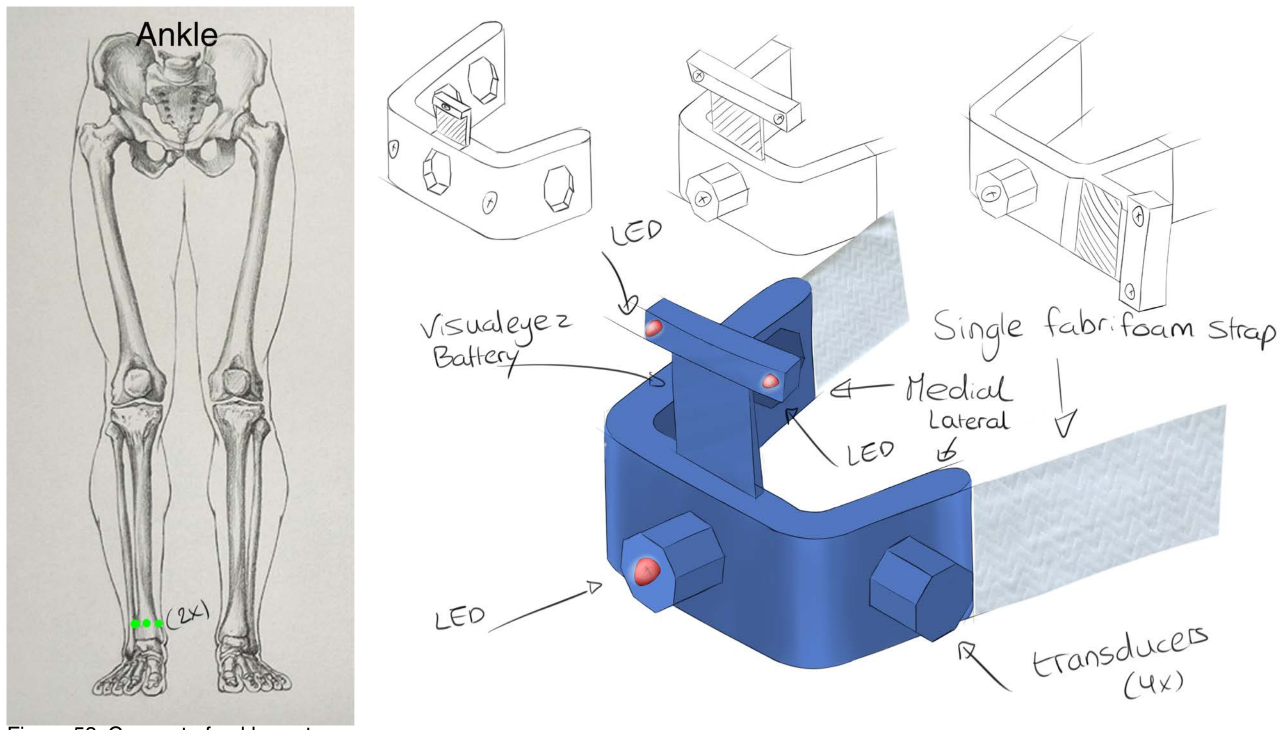


Figure 53: Concept of ankle part

5.3 Parametrisation of the holder parts

A parametrisation of the holder parts is necessary to ensure that a fitting holder can be made for all subjects. Therefore a way of measuring the dimension of the subject is defined and the resulting dimensions can be used as input in the Design table of that particular Solidworks part. The Design table enables the creation of different configurations of the parts, by adding a new configuration the specific holder for a particular subject can be made and the configuration can then be send as STL file directly to a 3D printer. A documentation has been written explaining these steps, because the process of measuring a subject and inserting this into the correct values in Solidworks is not self-explanatory. The full instructions how to parametrize a subject can be found in chapter 2 of Appendix H, chapter 3 describes how to add a configuration, create the necessary STL file and offers a short troubleshooting. While the documentation describes how a subject must be measured, it does not describe the exact locations of the transducers, it assumes that the person who performs the measurements is aware of the transducers' positions, if this is not the case it is advised to read this report. The complete documentation and corresponding Solidworks files are handed over to the design team that continues the development, this also includes a large database of rendered images of all the parts. This chapter only describes the basic principles behind the parametrisation, they are split in the three used approaches.

Trochanter and Mid tibia:

The dimensions of these two parts are roughly identical for all subjects. For the trochanter the size and shape of the greater trochanter is determining this. It requires some experience to determine where on the greater trochanter the ideal locations to place the transducers are, but because the trochanter part can be moved around to find the optimal location, only the distance between the transducers must be determined in advance. When it is determined, it can be inserted in the Design table of the Solidworks model and a fitting holder for that subject is created. The same holds for the Mid tibia part, here the maximum available length and width for the holder are the relevant parameters. The length is determined by the subject, when it has long legs the transducers can be placed further apart but for a short legged person the placement of the transducers must be as dense as possible. The width of the part is determined by the width of the tibia bone in the middle of the lower leg, it ensures that all transducer lie above the bone. The values for length and width are standard set to respectively the minimum and maximum value and should only be changed when problems occur with the current settings.

Mid femur:

The mid femur part consists of an anterior and lateral plate, each with multiple transducers. To ensure that all these transducers keep perpendicular to the femur bone a parametrisation based on four dimensions is used. Therefore the approximate position of the femur bone must be located and marked on the skin on both the anterior and lateral side. Then the distance between these points in the median and frontal plane needs to measured, this is shown in figure 54, on the left the distance in the frontal plane is measured, called the width, and on the right the distance in the median plane is measured, called the depth. This terminology is used in the other parametrisation in the same way.

Figure 54: Measuring the width and the depth

The width and depth are measured on a proximal and distal location that lie 10cm apart. The Solidworks model is built around these measurements, in figure 55 the two sketches that determine the part's dimensions are shown, the dimensions of the sketches are linked to the design table in figure 57, here the measurements of each subject can be stored. Figure 56 shows how the anterior plate is created from these sketches using the dimensions in the design table from the choosen configuration. The vertical dotted line is the line that connects the two widths of the mid femur plate. The actual length of the plate is then determined by the amount of transducers and the distance between the transducers, these values can be changed in the design table although this is not recommended. These parameters are included in the design table to expand the versatility of the part, in case new theories or another approach is tested. The lateral plate is created in similar fashion and the connection between these two plates is made using the locations of the plates themselves.

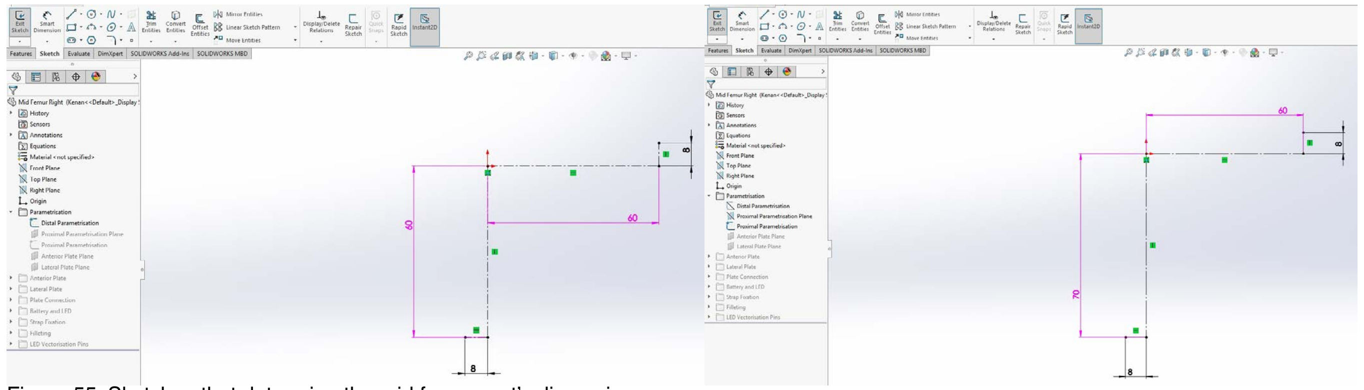


Figure 55: Sketches that determine the mid femur part's dimensions

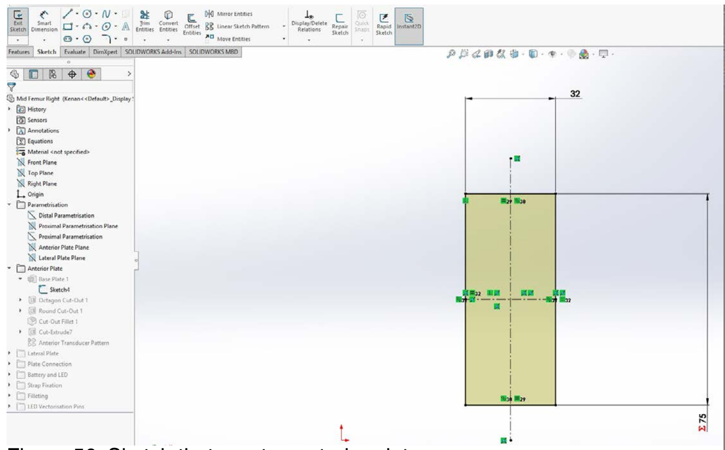


Figure 56: Sketch that creates anterior plate

Design Table for: Mid Femur Left

	Distal Width@Distal Parametrisation	Distal Depth@Distal Parametrisation	Proximal Width@Proximal Parametrisation	Proximal Depth@Proximal Parametrisation	Anterior Transducer Distance@Anterior Transducer Pattern	Number of Anterior Transducers@Anterior Transducer Pattern	Lateral Transducer Distance@Lateral Transducer Pattern	Number of Lateral Transucers@Lateral Transducer Pattern	$STATE@Pins	$STATE@Pin Points
Vectorisation	60	60	60	70	25	3	25	4	U	U
Kenan	60	60	60	70	25	3	25	4	S	S
Test	60	50	60	70	30	3	30	5	S	S

Figure 57: Mid femur design table

Femur epicondyles, Tibia epicondyles and Ankle:

The remaining three parts are parametrised using a mid-point as reference point. This point is the midpoint of the leg in the frontal plane, figure 58 shows this point for the femur epicondyles part and is located at the same height as the femur epocondyles. For the tibia epicondyles part this is at the same height as the tibial epicondyles and for the ankle this is just above the medial malleolus. The locations of the transducers need to be marked on the skin and their width and depth relative to this midpoint must to be measured. These measurements are linked to the sketch in figure 59, again via the Solidworks design table (figure 60) and can be recognized by their pink colour. This sketch plots the (virtual) line connecting the transducers and creates the base plate for the holder part at the correct distance from this line. Also keeping a 10mm clearance between the frontal holder section and the knee. Both the holders that cover the epicondyles determine a few extra measurements to complete the parametrisation. The documentation in Appendix H explains this completely. The top view of the left and right ankle holder in figure 61 demonstrates the results of two different parametrisations.

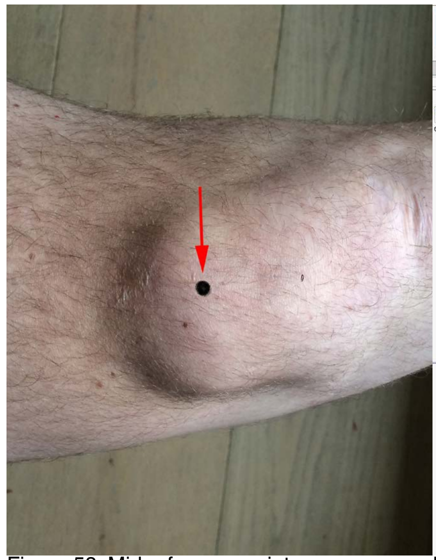


Figure 58: Mid reference point

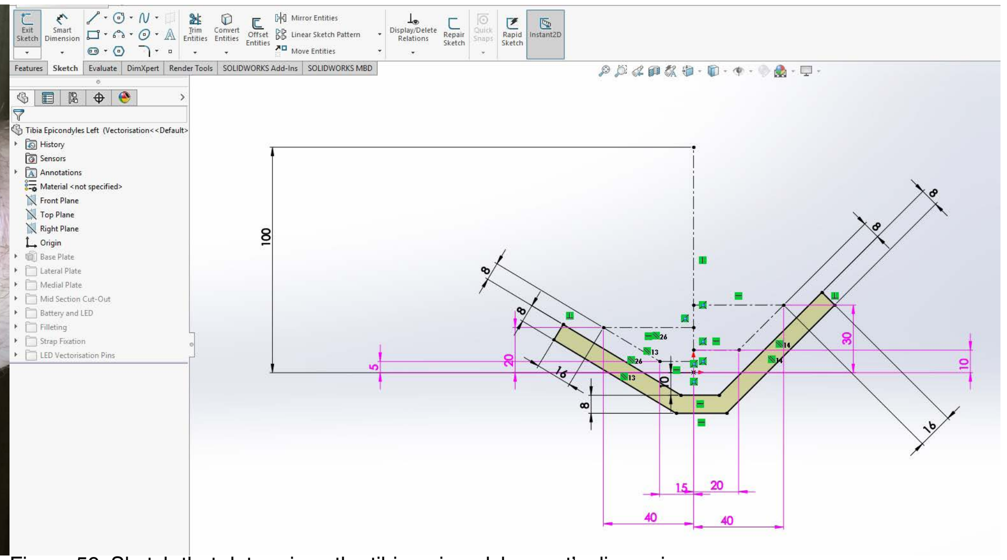


Figure 59: Sketch that determines the tibia epicondyles part's dimensions

Design Table for: Tibia Epicondyles Left

	Medial Anterior Width@Sketch2	Medial Anterior Depth@Sketch2	Medial Posterior Width@Sketch2	Medial Posterior Depth@Sketch2	Lateral Anterior Width@Sketch2	Lateral Anterior Depth@Sketch2	Lateral Posterior Width@Sketch2	Lateral Posterior Depth@Sketch2	Lateral Height@Transducer Pattern Sketch	LED Distance@Sketch21	$STATE@Pins	$STATE@Pin Points
Vectorisation	20	10	40	30	15	5	40	20	15	60	U	U
Kenan	20	10	40	30	15	5	40	20	15	60	S	S
Test	20	10	35	25	25	10	35	25	20	60	S	S

Figure 60: Tibia epicondyles design table

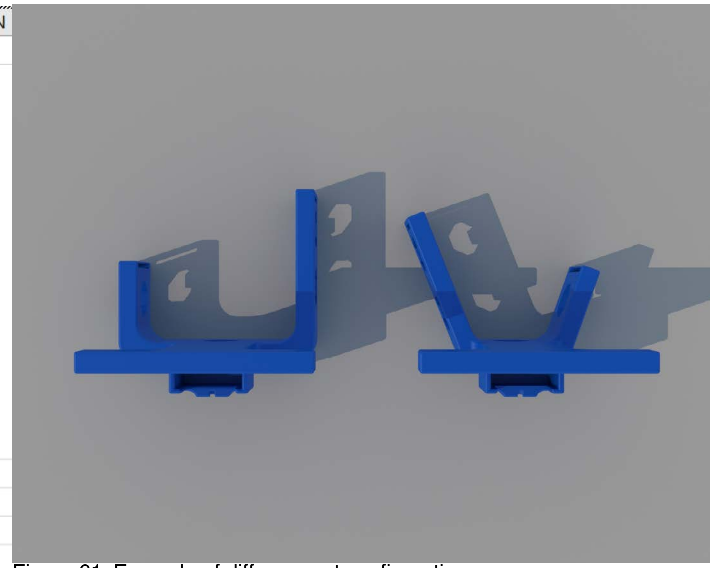


Figure 61: Example of differen part configurations

5.4 Solidworks models V1

A first version of Solidworks models is built around the parametrisation using the features chosen in the morphological analysis. The parts are dimensioned in such a way that they cover the least possible area on the leg. This both improves rigidity, smaller parts will deform less when equal force is applied, and the performance of the parts, skin movement has less influence on the smaller area. Where applicable strength and stiffness are maximized without compromising other features of the part. It would seem appropriate to calculate the necessary thickness of the parts to ensure a sufficient rigidity. But the since the amount of force applied to the part by the muscle is unknown and the stiffnes of the part is dependent on the way it is printed, determining the correct thickness is not possible without making large assumptions. Besides there are only two parts unable to move freely when an muscle pushes against it.

Transducer containers and covers:

The transducer containers have a cavity for the ultrasound transducer and enable aiming of the ultrasound beam in different directions. Therefore two version of the containers are designed, a straight version that aims the beam perpendicular to the skin and an angled version that enables aiming the beam with a 10° angle in distal, proximal, medial and lateral direction. Because the hexagon shaped containers from the location testing holder were only able to aim either proximal and distal or medial and lateral, a octagon shape is used instead. This enables aiming in all four directions with one container, besides the rounder shape is better compatible with the round retaining rings. Figure 60 shows both the straight and angular version of the containers, together with the three versions of the covers that lock the transducer in place. The straight containers have no marking on them while the angled containers have markings on them to help the user with the placement. The cover, container and plates have a groove for the retaining rings. The required ring is a stainless steel DIN471 with a nominal dimension of 19mm.

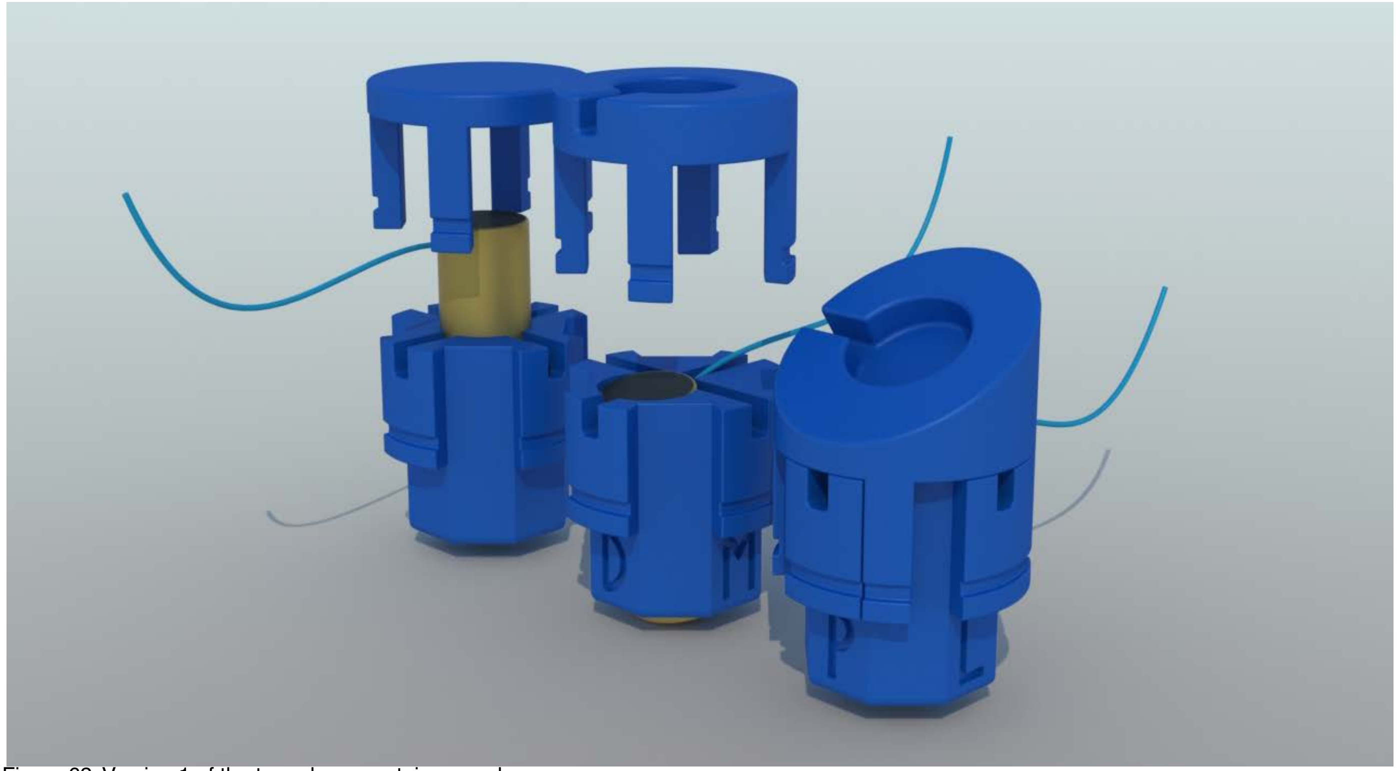


Figure 62: Version 1 of the transducer containers and covers

Parts:

Figure 63 shows the side view of the trochanter holder with the transducer containers inserted. The effect of raising the plate can be seen here, as well as the maximisation of the plate thickness to 8mm taking the transducer cable and retaining ring groove into account. Figure 64 gives the isometric view of the trochanter part, here also the locations for the LEDs and Visualeyez battery are visible, as well as the cut-out that enables the fabrifoam strap to be mounted to the parts and thus the parts to be strapped to the subject's leg.

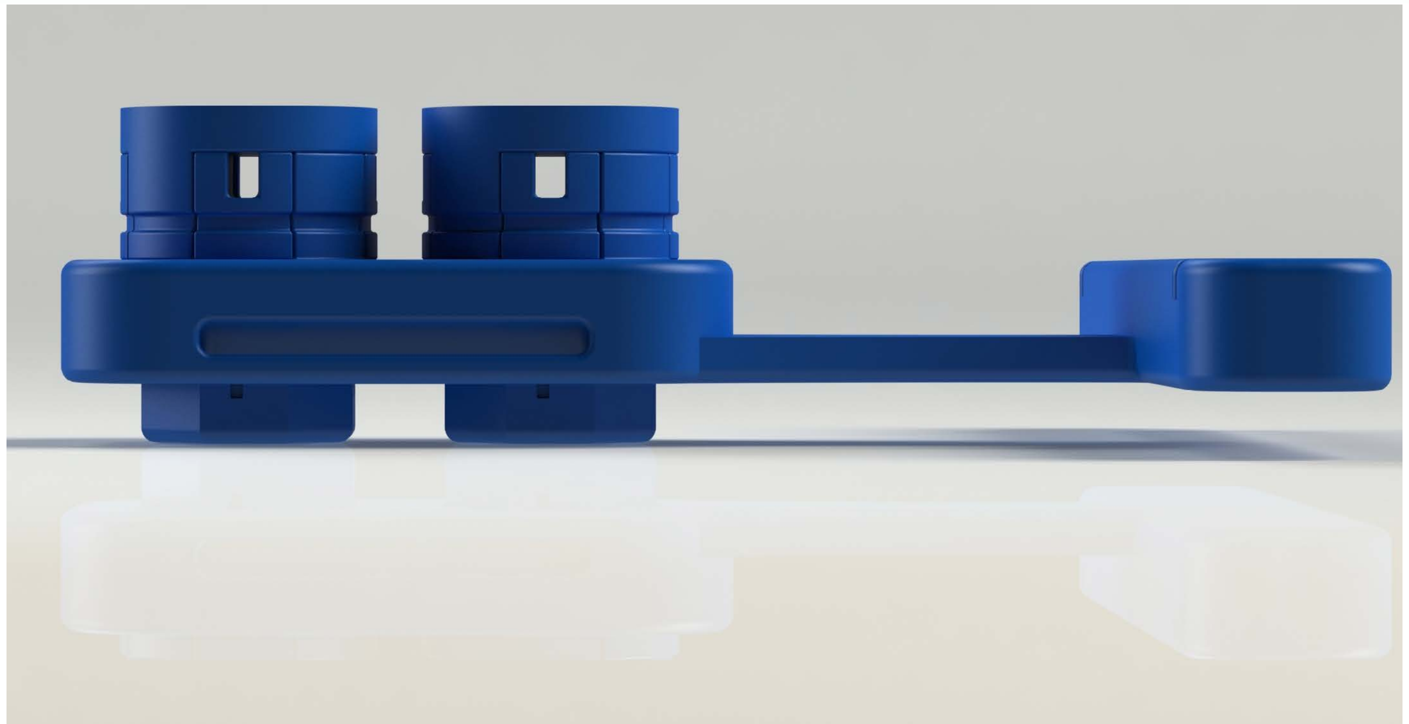


Figure 63: Side view of assembled trochanter part

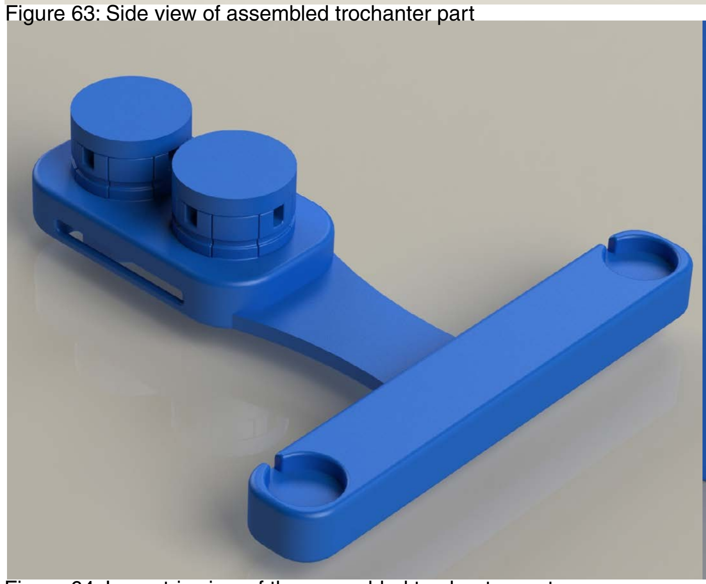


Figure 64: Isometric view of the assembled trochanter part

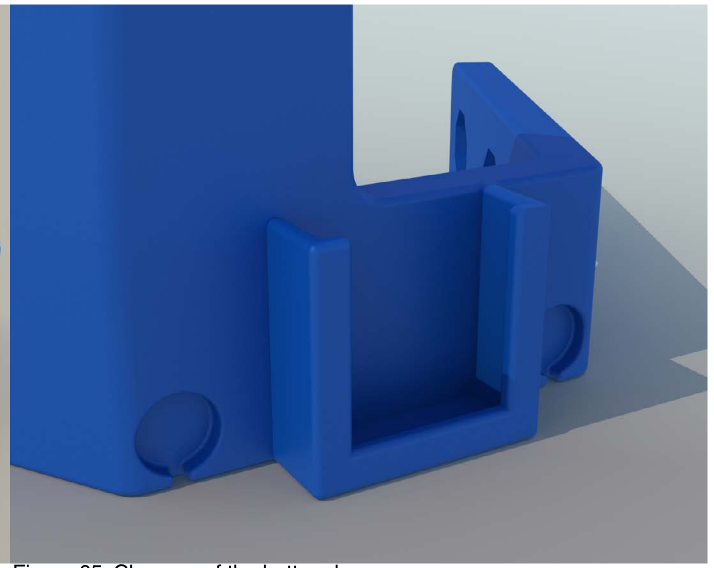


Figure 65: Close up of the battery box

The other parts are built in similar fashion, using the same thickness and width for the plates and the same cut-outs for the fabrifoam straps and LEDs. The only difference is that a battery box was added to the other parts, figure 64, instead of pressing the Visualeyez battery into place it can now be slid into the box. This ensures that the battery will stay in place during motion. Besides it eliminates the need of a cut section in the parts, which is benificial for the part's stiffness and strenght. The downside is that, with exeption of the trochanter part, all the parts will feature both a left and right leg specific version. Rendered images of all the parts can be found in Appendix I

5.5 Solidworks models V2

The Solidworks models from the holder parts were first discussed with the design team. The results of this evaluation were several improvements to the design. The main improvement was the change from a stainless steel retaining ring to a plastic retaining ring. This is done because there is no certainty that the stainless steel retaining rings are non-ferromagnetic. While austenitic stainless steels are non-ferromagnetic and therefore suitable for an MRI scanner, the reality is that when austenitic stainless steels are machined or worked they can become magnetic[28]. Besides the currently available stainless steel retaining rings are made from a magnetic type of stainless steel, therefore it is opted to use a plastic retaining ring instead. The downside of this choice is that another type of retaining ring is required, as the plastic version is not available as DIN471. Another important change is that the container covers containing LEDs are discarded, it is expected that they cannot be positioned accurate enough each time. This would introduce another error and therefore decrease the performance of the system, as a result special spots to place the LEDs will be added to the parts when applicable.

The above improvements were implemented first and prototypes were printed to evaluate the concepts further. The prototypes revealed a few other issues with the design, the cut-out for the fabrifoam strap for example was only strong enough when printed as long lines over the full width. The design of the strap cut-out was therefore changed on all the models, to ensure that the way the part is printed is not of influence. Furthermore the tolerance on the new covers was increased, due the quality of the 3D printed parts the fit was not always as desired and caused the covers to break. All the parts will be explained briefly in the following section, as well as the changes with respect to version 1.

Transducer containers and covers:

Because of the switch from stainless steel retaining rings to plastic ones, the design of the transducer containers is completely changed. The limitations in the available dimensions of the chosen DIN6799 retaining rings made it impossible to position them on the topside of the parts. This meant that the fixation of the container cover must be done in another way too, the cover was also fixed by the retaining ring in the first version. The solution is a cover that must be twisted clockwise to be locked in place and prevent the transducer from being pushed upwards, this is shown in the right image of figure 66. Another change from version 1 can be seen in the top view of figure 66: the cable guides are now offset, so the cable can still exit on all four points of the container without interfering with the cover. A third change is that the lateral and medial marking is replaced with left and right, this can be seen in the top left image of figure 66. This ensures that the marking is always correct, independent of the part or position of the transducer.

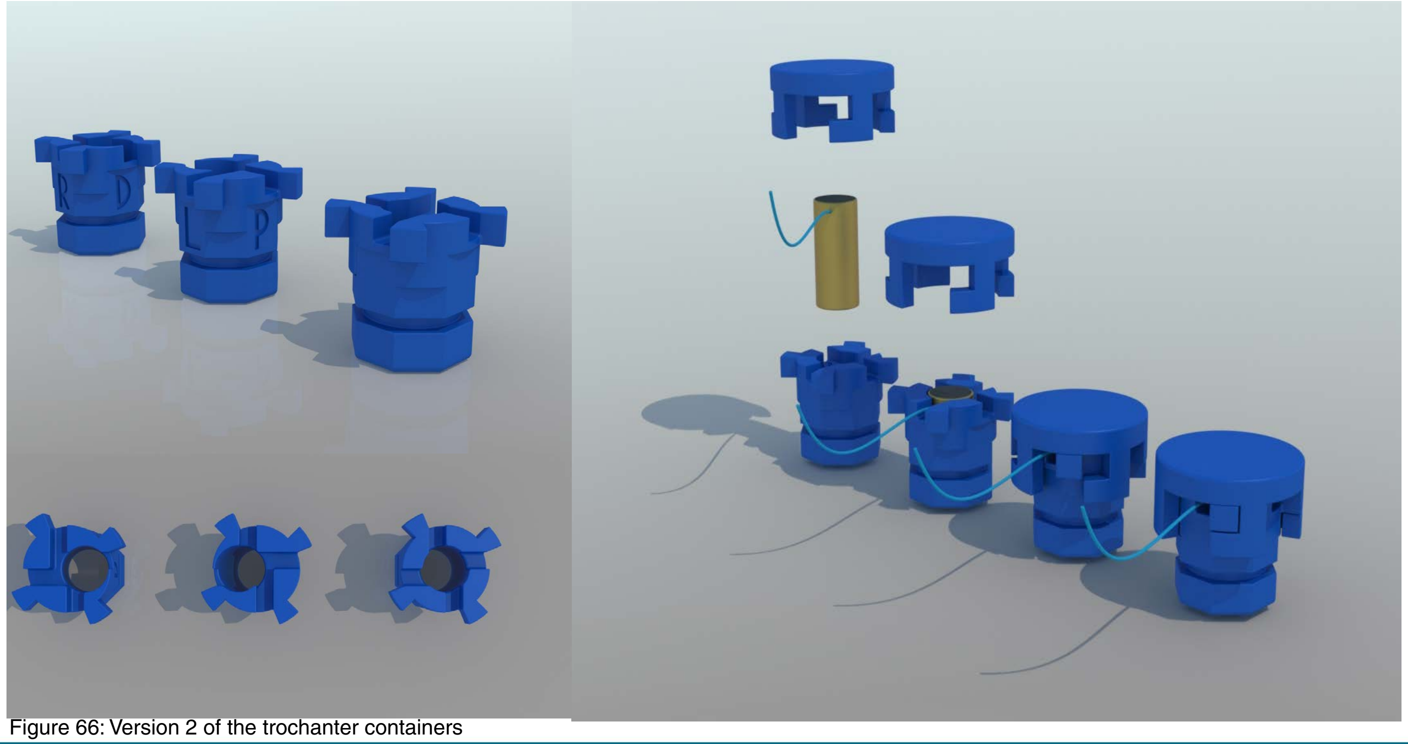


Figure 66: Version 2 of the trochanter containers

Trochanter part:

A LED spot was added at the top of the trochanter part where the third LED can be inserted and the fabrifoam strap cut-out was updated to the new version. A marking was also added to each of the transducer positions, this marking corresponds to the marking of the transducer containers and is added to all parts, it can be seen in figure 67 left to the hole for the transducer container. The section view of figure 68 shows the cut-out for the fabrifoam strap, by raising the bottom part it is ensured that the strap and the retaining ring do not touch. The plate's width is also increased to 32mm to make sure the container cover and the fabrifoam strap do not touch. Figure 69 describes the proceedings of combining all the parts into a complete assembly of the part, they are:

1. Slide the transducers in the shaft of the transducer containers, in such a way the cable is not obstructing (#2).
2. Slide the container cover on top of the container, without damaging the cable and turn it clockwise to lock in place (#3 and #4).
3. Slide the container and cover into the plate in the correct orientation, the shape of the plate prevents the cover from turning and thus coming loose (#5).
4. Slide the retaining rings on the groove on the underside of the plate (#6).
5. The part can now be strapped to the subject using fabrifoam.

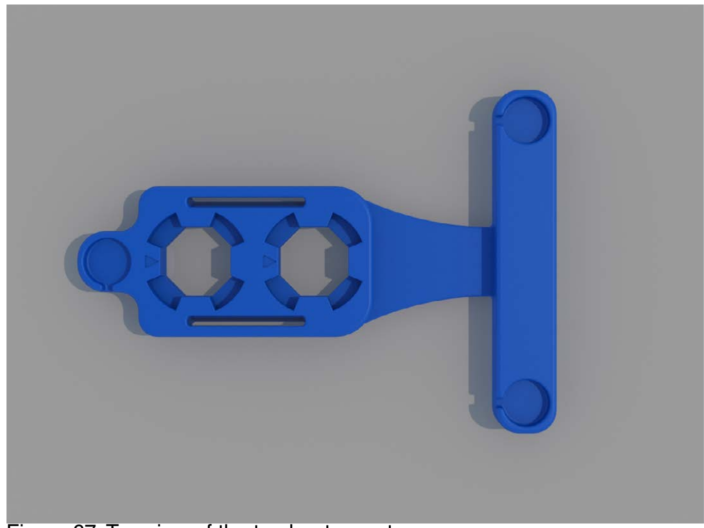


Figure 67: Top view of the trochanter part

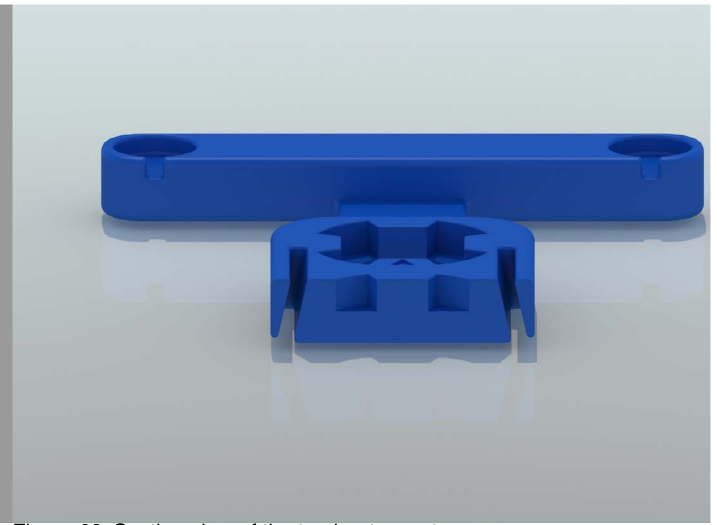


Figure 68: Section view of the trochanter part

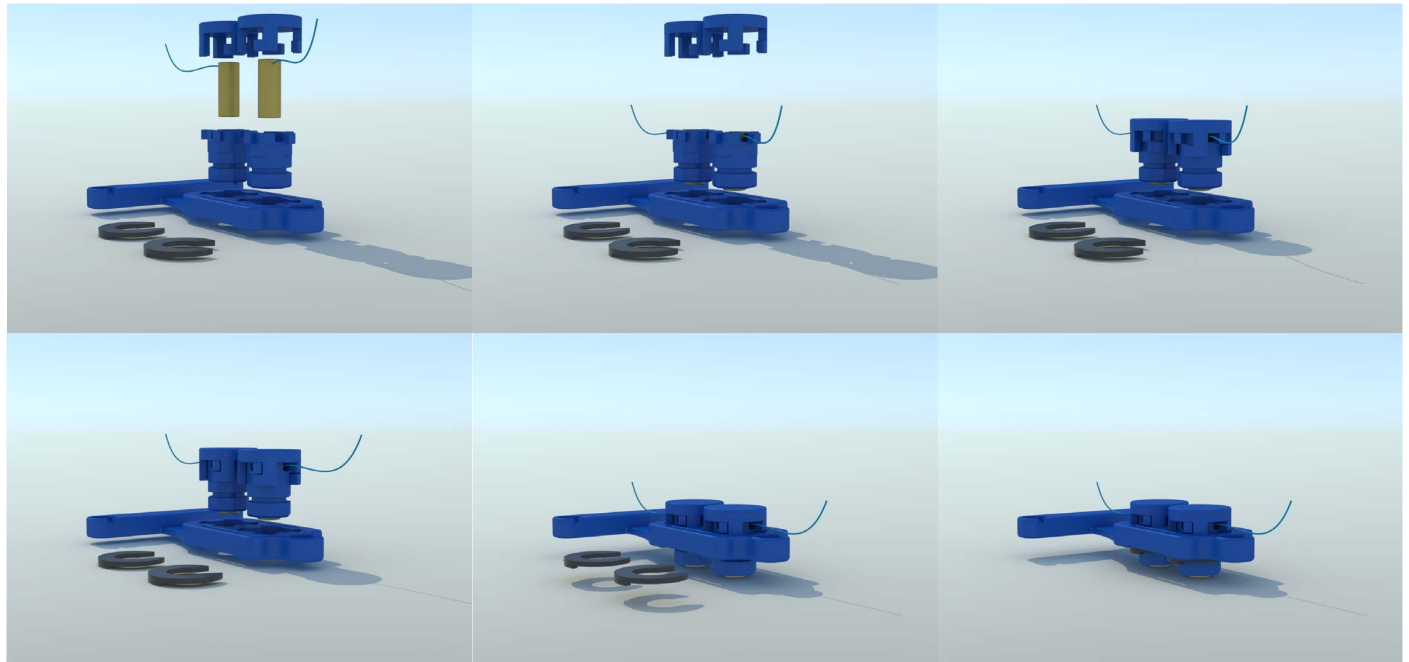


Figure 69: Step by step guide of holder installation

Mid Femur part:

The mid femur part was also updated with an extra LED spot, this spot is added on the medial side of the anterior plate. By placing it here it never becomes obstructed by a container or by the subject itself. The width of both the anterior and lateral plate was also increased to 32mm to prevent the container cover and the fabrifoam strap touching each other. Finally the new strap-cut outs and orientation marking were implemented. Figure 70 shows the assembled right leg part and the sole left leg part.

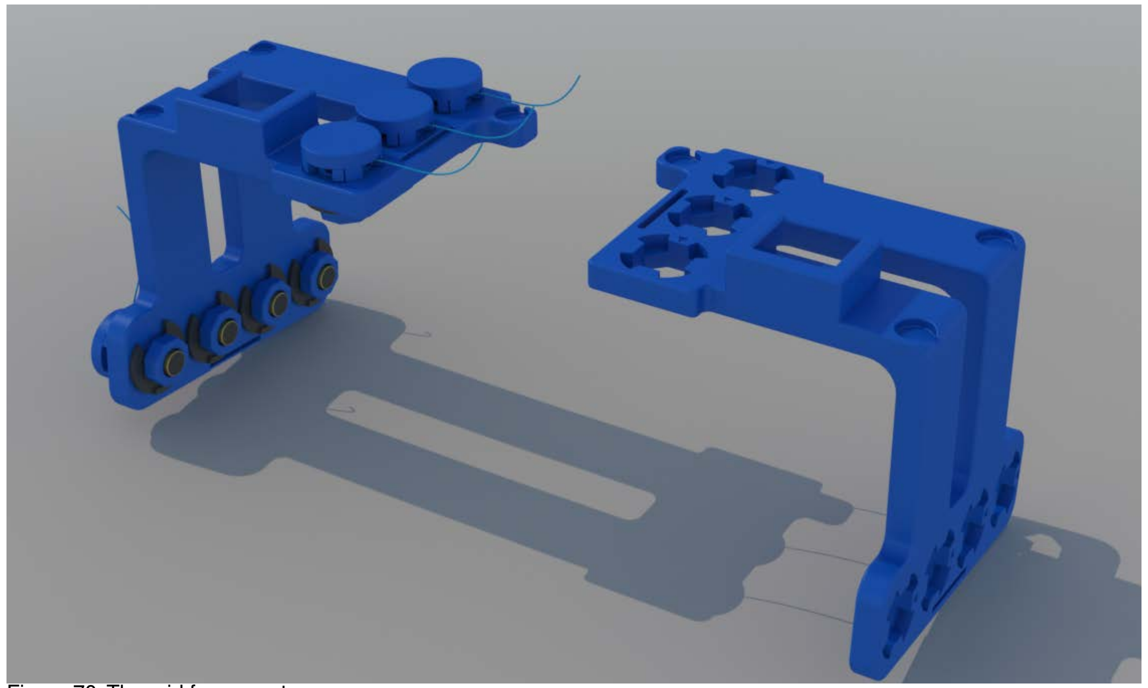


Figure 70: The mid femur parts

Femur epicondyles part:

The femur epicondyles part was only updated with the improved strap cut-outs and the orientation marking. Besides it now also features a cut-out for a fabrifoam strap on the musculus vastus medialis plate. Because the part already had three spots for the LEDs, an extra spot was not added. Figure 71 shows the left leg part on the right and the assembly of the right leg part on the left.

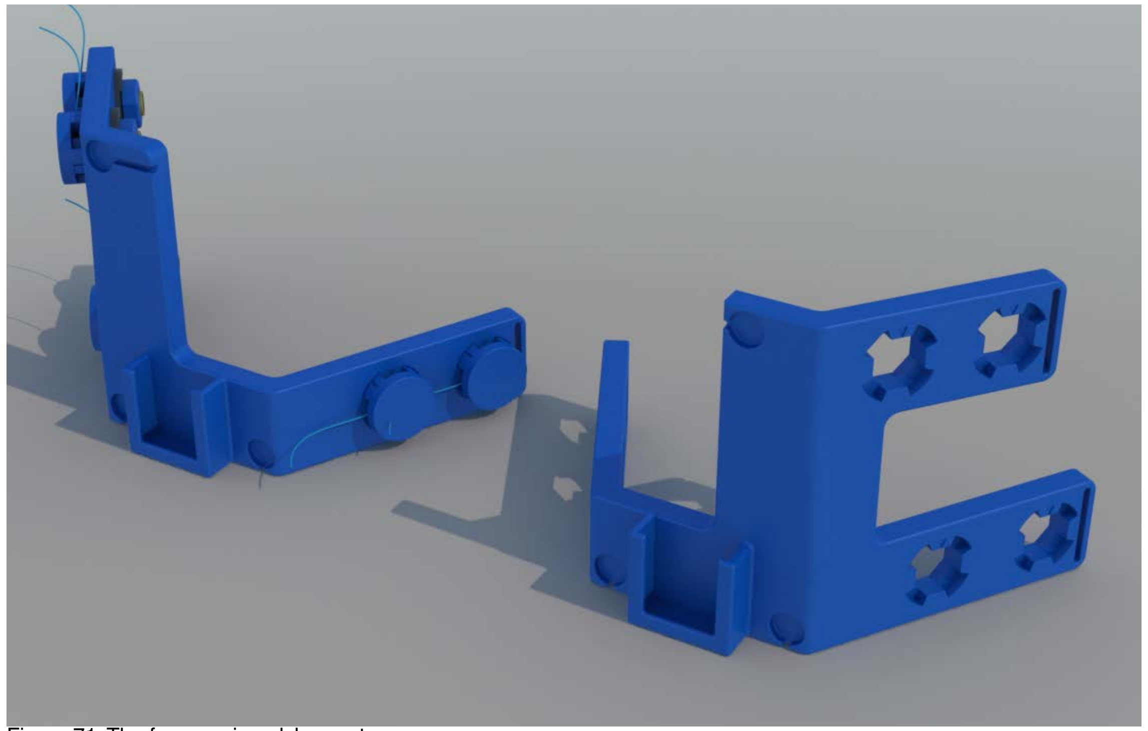


Figure 71: The femur epicondyles parts

Tibia epicondyles part:

The tibia epicondyles part has changed quite a lot. The arm with the Visualeyez battery has become shorter and the round front shape has been replaced with a straight frontal facing plate. The straight plate can better be printed, is wider which is better for the strenght of the part and the flat section is better suitable for the LED. The cut at the top has stayed because this still helps with the clearance from the knee. Furthermore the improved strap cut-out is implemented and since there were already three spots for the LEDs on the part these haven't changed. Figure 72 shows the assembly of the right leg part and the left leg part alone.

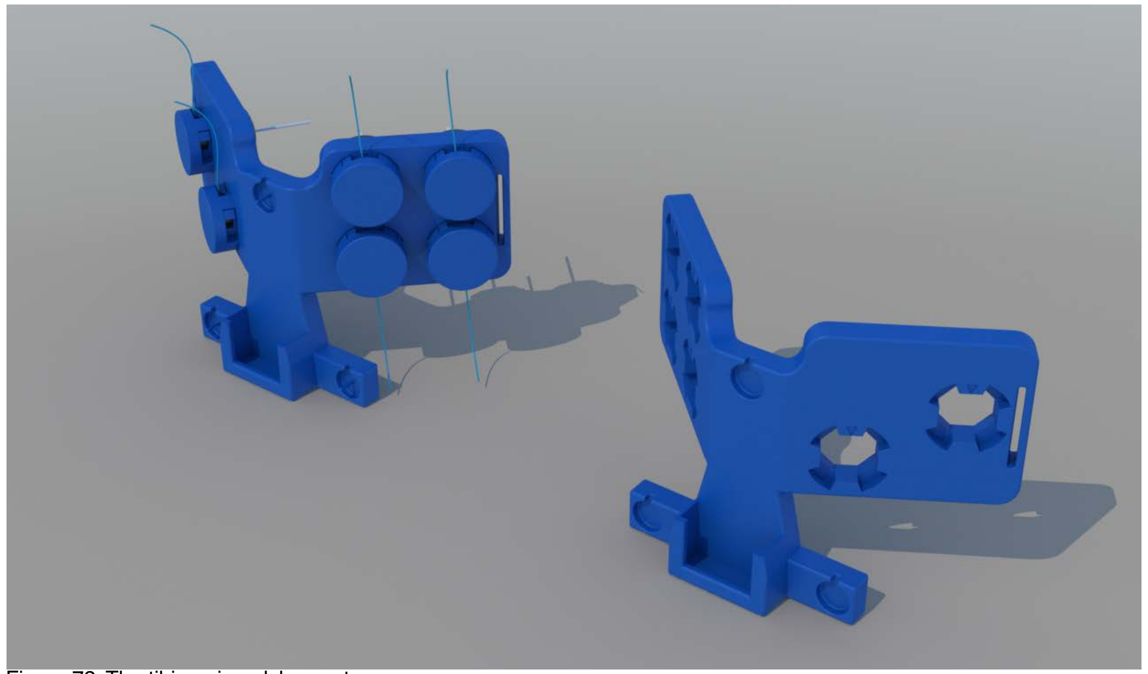


Figure 72: The tibia epicondyles parts

Mid tibia part:

Because version 1 of the mid tibia part relied on two angled container covers for the LEDs, two angled spots have been added at the top and bottom of the part as a replacement. All three LEDs are angled at 45° to enable them to be seen by a front facing camera. Furthermore the strap cut-out was updated, to prevent the strap and the container covers touching each other the plate was also widened with 2mm. The assembled right leg version and the bare left leg version are pictured in figure 73.

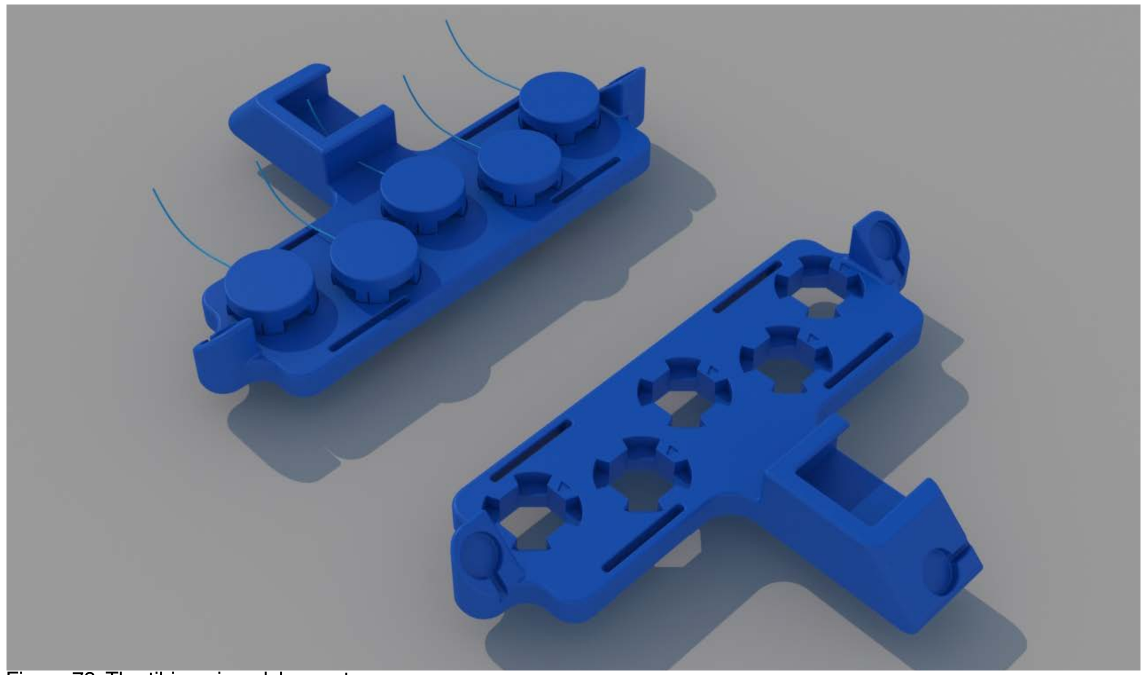


Figure 73: The tibia epicondyles parts

Ankle part:

A LED spot has been added to the ankle part on the battery box, this is done here because it would become invisible when placed underneath the part. Placing it next to the transducer location wasn't an option either, as can be seen in the right part in figure 74. Furthermore the cut-out for the strap has been updated and the markings for the orientations are added.

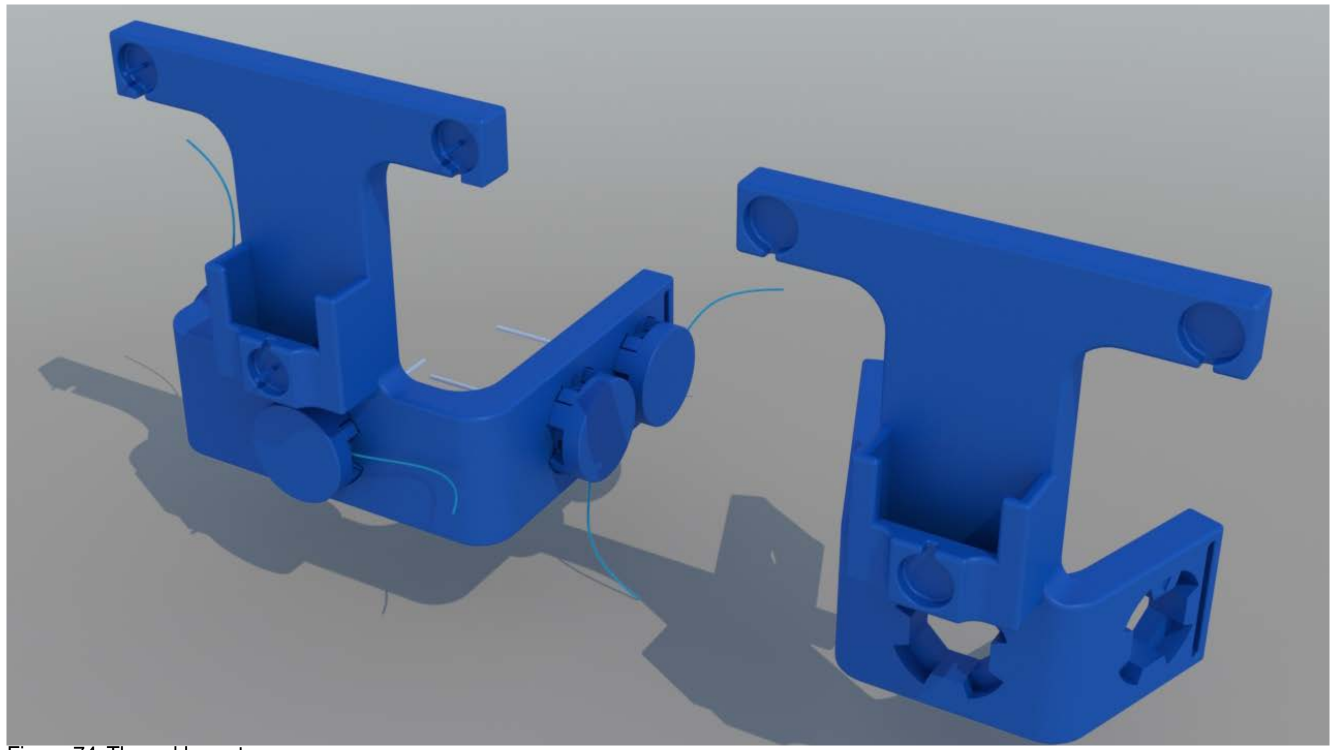


Figure 74: The ankle parts

Vector STLs:

To know the exact position in 3D space where a transducers sees the bone, the direction of the ultrasound beam and the location of the transducer with respect to the Visualeyez system must be know. Therefore the holder parts needs to be vectorised using computer software. To enable this part vectorisation, pins that represent the location of the LEDs have been added to each part. This configuration is called vectorisation and its dimension can be changed in the design table. Making it possible to create a part with the same dimensions as the printed part. Furthermore a configuration with a virtual beam is added to the transducer model, this enables the vectorisation of the beam's direction. When combined in an assembly it posseses all the dimensions necessary to determine the location where the bone is seen. Such an assembly, with the LED pins and the virtual beam, can be seen in figure 75, while figure 76 shows the resulting STL file for vectorisation. The documentation describes how these STL files can be obtained from the assemblies of the individual parts.

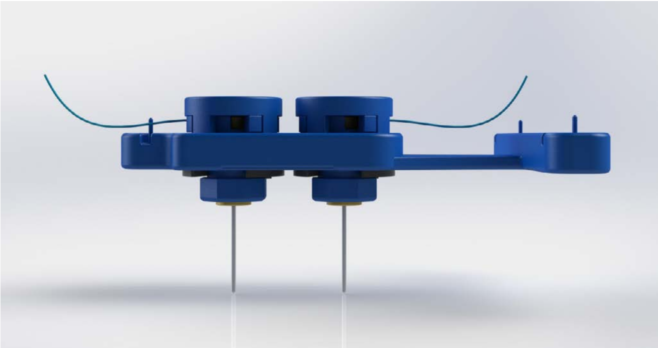


Figure 75: Side view of trochanter assembly for vectorisation

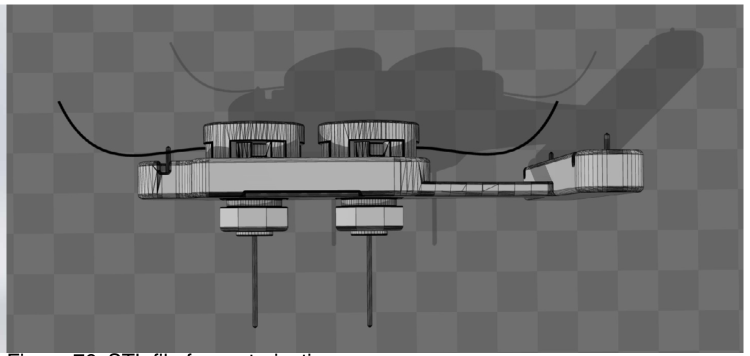


Figure 76: STL file for vectorisation

Discussion:

While the holder parts are printed already, they have not been tested yet. The long delivery times of both the Fabrifoam, which had to be order in the USA, and the retaining rings made that the actual testing of the holder parts was not performed within the scope of this bachelor assignment. Therefore no conclusions can be drawn regarding the actual working of the concepts, although the printed parts seem to fit quite well. The doubts whether the transducer will actually keep seeing the bone still exist for some parts, especially the femur epicondyles part, but only real-world testing will offer answers to this. It must be expressed that the user of the created system of holder parts must be aware that the fitting of the parts largely depends on the allocation of transducer positions and corresponding measurements of a particular subject.

While no real conclusions can be given regarding the working of the individual holder parts, a comparison with the requirements can still be made. Since the holders are not tested yet, it cannot be said if the holders are in compliance with performance related requirements, it is not known if the transducers keep contact with the subject's skin at all times for example. When comparing with the general requirements, it can be said that the holders are in compliance with the statement of requirements. A fitting holder can be created for all subjects, the system of holders is able to contain a total of 30 transducers, the system is MRI compatible and fits in a pre-clinical testing path. Furthermore it can be said that, with one exception, the holders are in compliance with the requirements regarding the motion tracking and the transducers. The only requirement that is not necessary in compliance is the requirement that the transducer position with respect to the Visualeyez markers must be known at all times. While it is expected that there won't be any problems with the rigidity of the parts, this must be tested to be certain.

6 Conclusions

The goal of this bachelor report was to develop a set of holders that can be used as the interface between a subject and the ultrasound kinematic analysis system. In chapter 2 the reason for developing such a system and the current state is explained. In the analysis phase, chapter 3, the understanding of the used equipment and techniques is broadened, besides the statement of requirements for the holder is formulated based on implications following the choice for A-mode ultrasound and Visualeyez, as well as demands and wishes from the client. Several design directions are explored in chapter 4 and the feasibility of the chosen basic concept was proven in empirical manner. But questions remained whether the concept would work on the essential characteristic locations, therefore it was decided that addition testing was required. The best placement of the transducers, using the chosen concept, was then obtained by means of both theoretical and experimental studies. This information, together with observations done during the testing, was the basis for the morphological analysis' choices. The possibilities were discussed and the decisions were made in consultation with the complete design team, as a result the eventual layout of the analysis system's parts, the determination of the system's adjustability and types of fixation were known. After this concepts of the holder parts were made combining the results from the morphological analysis and the statement of requirements. A parametrisation of each part was designed to ensure that a fitting holder can be made for all subjects and served as the underlying base of the Solidworks parts as well. A documentation was furthermore written to explain the procedure of measuring a subject and to show how a subject specific holder part can be created and prepared for 3D printing. The first versions of the Solidworks models were evaluated and prototypes were printed, based on this information several improvements were made to the designs. This resulted in the final version of the Solidworks models. Prototypes of the second version were also printed, but have not been tested on a subject yet. This is necessary to verify the working of the complete holder parts, as now only the basic principle is verified completely. When tried, the holder parts seem to fit quite well, but this is of course no guarantee that they will deliver the desired results.

But the printed prototypes already revealed a few weaknesses in the design. Mainly that the transducer containers and covers are fragile, when they are forced into place they will simply break. This of course was not desired, but it also isn't a problem, there is no high cost or effort involved in printing extra containers and covers, therefore they can be seen as disposables and used as such. The main reason for this to happens seems to be the quality of the printed parts, the printing process causes excess material to get stuck on the parts (figure 75 and 76). This needs to be removed manually. If this is not done properly the tolerances on the different parts are to small and forcing them in place will cause the cover or container to break.

All in all it can be concluded that a working principle has been developed, tested and proven for the ultrasound kinematic analysis systems' holders. A mapping of the most suitable locations for the reconstruction of the knee kinematics has been established for this working principle and a set of holders that can be tailor-made for all subjects has been designed. This system of holders is handed over to the client, accompanied with a documentation and all relevant Solidworks models. They should form a convenient basis for the elaboration of the ultrasound system's development, but have to be tested first.

Figure 75: Printed part where quality problem is shown

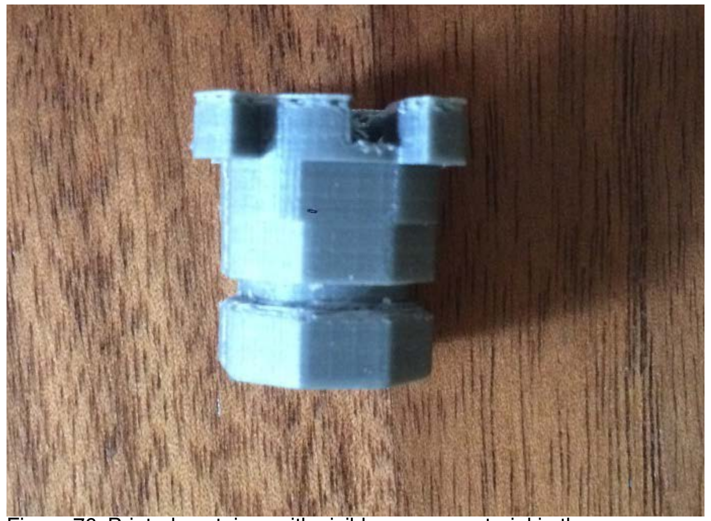


Figure 76: Printed container with visible excess material in the groove

7 Recommendations

The first step that must be undertaken now is to test the working of the actual holder parts. It would be beneficial if this is done using the same movement as during the location testing, because the results could be compared then. Since the results of each locations are available from the location testing a comparison with the corresponding location in the system of holders can be made and a conclusion regarding the performance can be drawn. If necessary the parametrisation of the holder parts must be updated and changes to the design of the parts should be made. Especially the femur and tibia epicondyles parts deserve attention during the testing, as they are the parts with the highest chance of not working correctly. If it shows that the combination between the femur epicondyles and m. vastus medialis is not performing well, the holder can be split into two parts.

While proving that the system of holders works is the initial and main objective of the testing, it can also be used to reveal whether the rigidity of the holder parts is demanding further attention. While it is expected that rigidity will not be a major problem, some tweaking to the holders might be necessary to eliminate all deformations in the parts when measuring. Since it is unexpected that problems regarding stiffness and strength of the holder parts can't be solved using polymers, further research into the production of the holders from other materials is not necessary. Still it might be interesting to look into the used polymer, currently PLA is used for the 3D printing process, but another polymer that would offer a higher stiffness or better part accuracy would be beneficial.

The part accuracy is another main issue that needs to be addressed, the current quality of the printed parts is not superb and causes limitations to the design of the holders. By changing the material or the printer, a better part accuracy could be achieved, this can greatly enhance the durability of especially the transducer containers and covers. Now they are used as dispensable, but it would be better if they can be used for several tests on multiple holders. this would reduce the cost, is better for the environment and reduces the production time for a set of holders. Besides improving the quality also means that less post processing is required.

Because the location testing is only performed on one subject, it would be useful to expand it with more subjects. The reliability and performance of the ultrasound analysis system can be enhanced greatly by proving that the selected areas are suitable for measurements with ultrasound in general. Besides if expanded testing reveals that other locations are more suitable, they can be implemented in the current system. This would again improve the overall performance of the system, and thus the chance that the development will be successful in the end.

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Appendix A: Transducer beam profile measurement

IMASONIC

BEAM PROFILE MEASUREMENTS

Measurement done with automated system in Through transmit on a Onda hydrophone

MEASUREMENT CONDITIONS

- Negative pulse generator - Olympus 5072PR IM n°3298
- Generator parameter : Energy 1 – PRF 1kHz – Damping 50 Ohms
- Cable : coaxial RG58 – 1m length

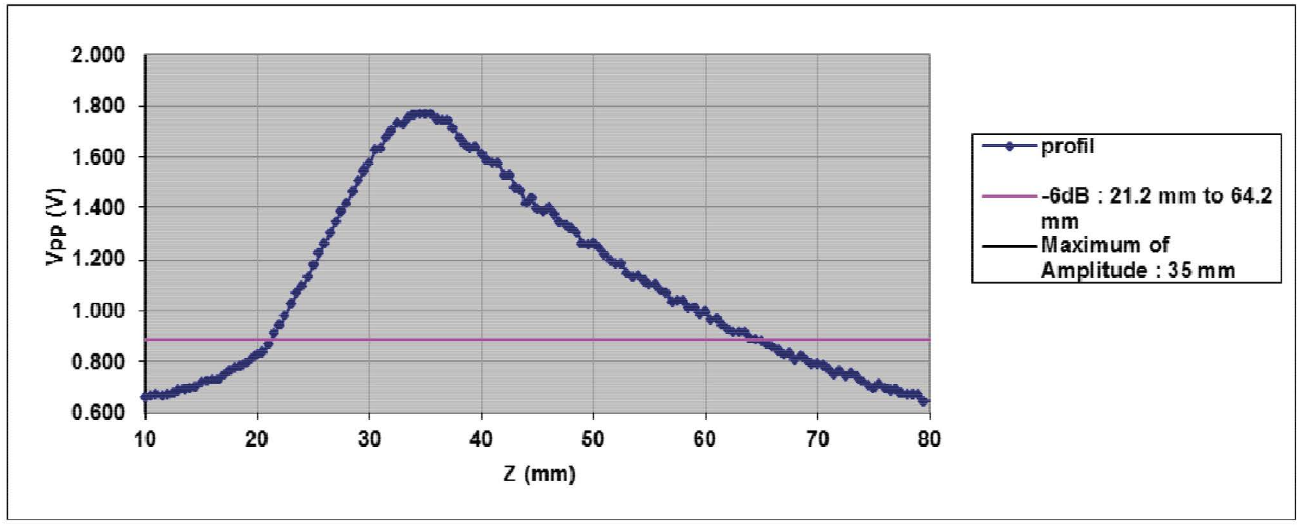
PROFIL BEAM REPORT

- Ref. Transducer : **12239 1016**
- Focal distance : **35 mm**
- Depth of field at -6 dB : **43 mm**

- Focal beam at 35 mm (-3 dB) : **0.95 x 0.88 (mm)**
- Focal beam at 35 mm (-6 dB) : **1.49 x 1.41 (mm)**
- Focal beam at 35 mm (-12 dB) : **3.28 x 3.23 (mm)**

- Focal beam at 45 mm (-3 dB) : **1.33 x 1.37 (mm)**
- Focal beam at 45 mm (-6 dB) : **1.96 x 1.91 (mm)**
- Focal beam at 45 mm (-12 dB) : **3.47 x 3.56 (mm)**

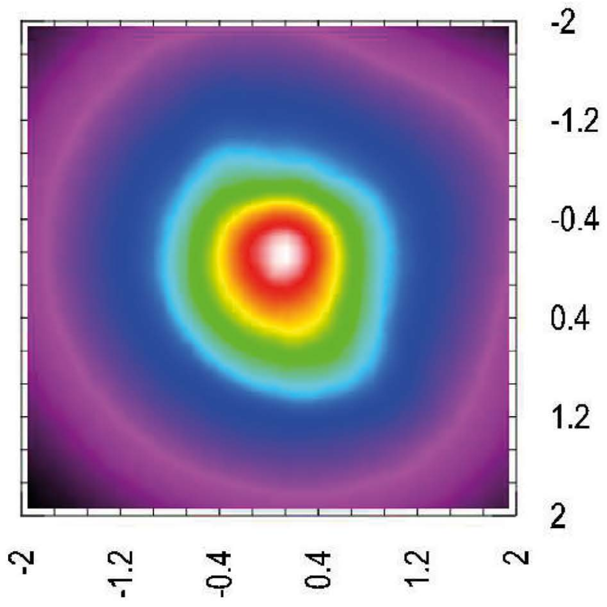
Amplitude versus distance measurement along beam axis

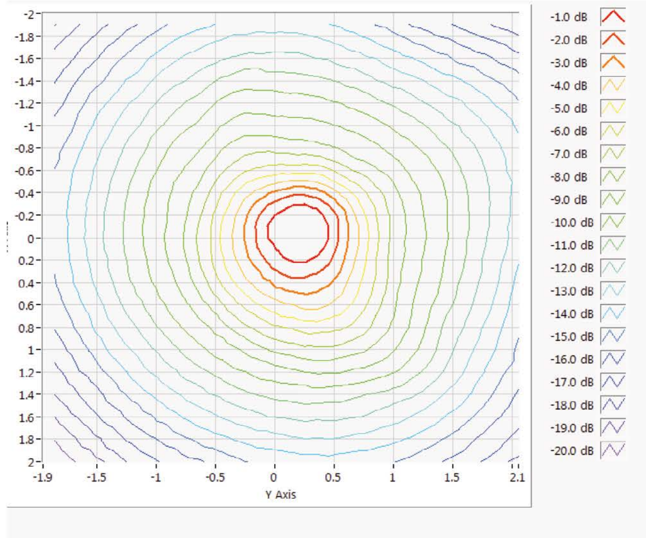


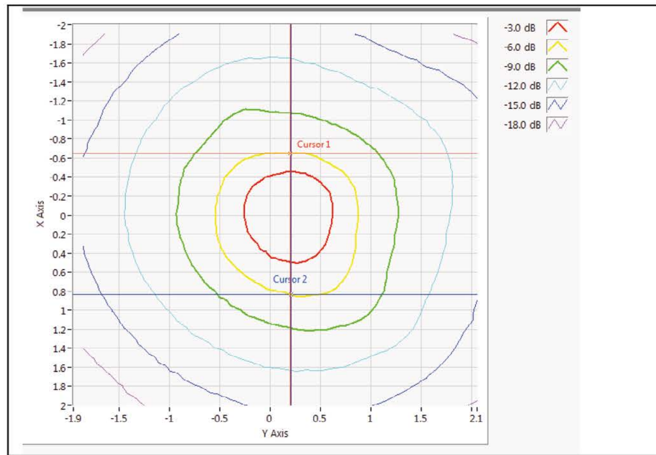
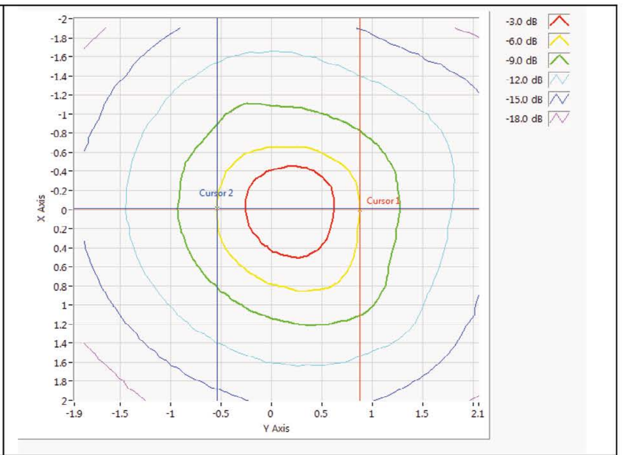
	-3dB	-6dB
Lower limit (mm)	25.9	21.2
Higher limit (mm)	50.2	64.2
Depth of field (mm)	24.4	43.0

Maximum of amplitude (focal distance) = 35 mm

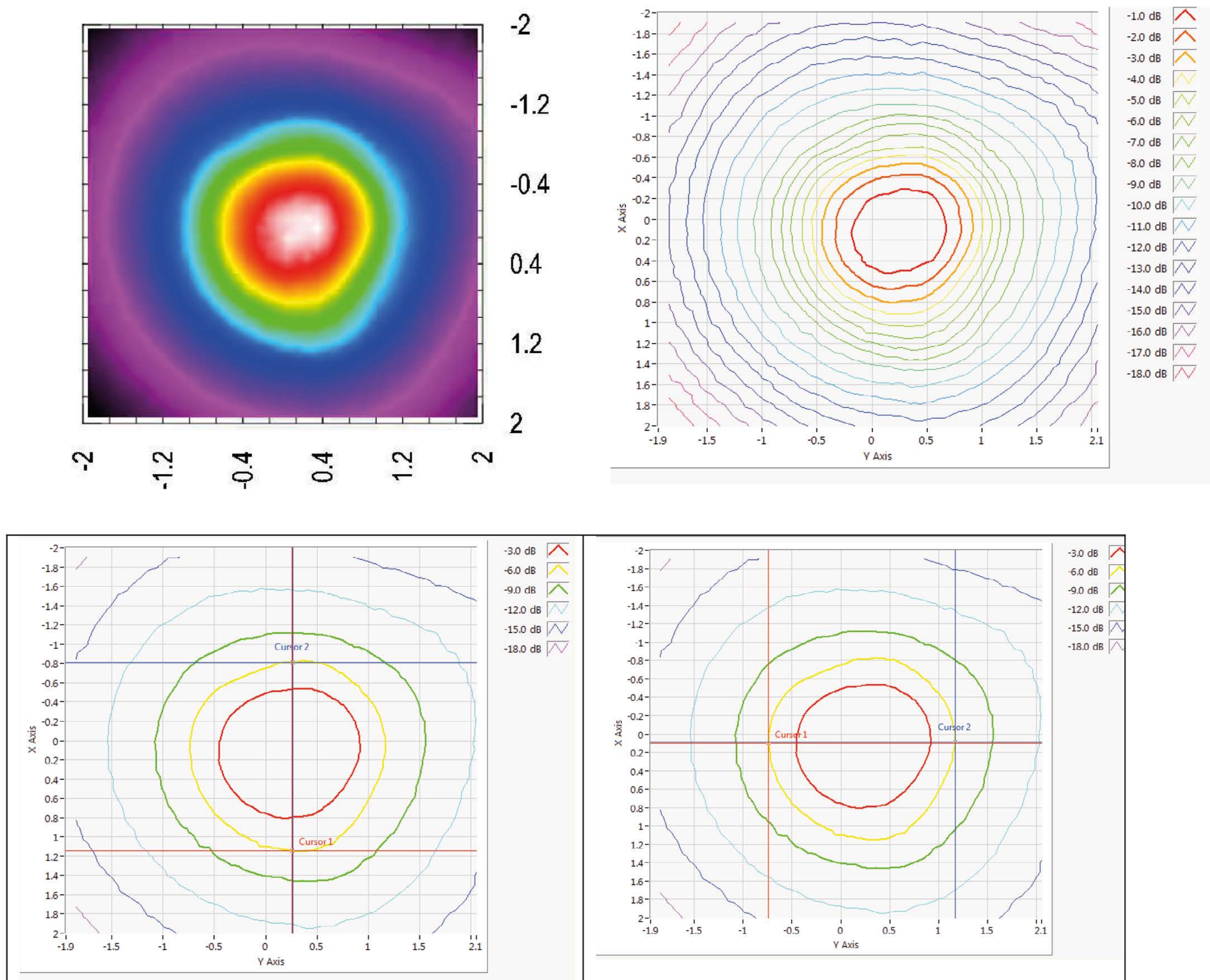
Acoustic beam C scan (radial scan) at the maximum of amplitude = 35 mm





	
WX1 (-6dB) =1.49 mm	WY1(-6dB) = 1.41 mm

Acoustic beam C scan (radial scan) at 45 mm



WX2 (-6dB) =1.96 mm	WY2(-6dB) = 1.91 mm

Appendix B: Visualeyez specifications

Phoenix Technologies Incorporated

High Performance Real-Time 3D Motion Capture System For Professionals

VZ4000v TRACKER MODELS

Robust and autonomous, VZ4000v trackers offer the highest accuracy and capture up to 4850 times per second.

	L-Series	E-Series	H-Series	H2-Series
Sensing Volume	~ 190 cubic meters of useful space, over 7.0 meters radius (at min. exposure)			
Minimum Sensing Distance	0.5 meter			
Tactile Feedback Function	No	Yes	Yes	Yes
Position Resolution	0.015 mm at 1.2m distance			
Number of Markers	512 max (no 'swapping' problem)			
Calibration	Not required for an individual tracker (factory calibrated) Automatic and continuous for multiple trackers with VZAutocal software			
Accuracy (3D combined, nominal)	0.9mm RMS (Calibration data range: 0.6~2.2m distance, ±30° yaw, ±30° pitch)	0.5~0.7mm RMS (Calibration data range: 0.6~2.2m distance, ±30° yaw, ±30° pitch)	<0.5mm RMS (Calibration data range: 0.6~2.2m distance, ±30° yaw, ±30° pitch)	<0.2mm RMS (Small Capture volume. Custom calibration range)
Operation Angle	90° (±45°) in both pitch and yaw (107° diagonally)			
Sensing Rate	4850 real-time 3D data points per second (single sampling, 'vbr' series) 4167 real-time 3D data points per second (double sampling)			
Data Latency	< 0.0005s at maximum sample rate			
Computer Communication	Serial RS232/RS422 (921.6kbps) real-time protocol			
Mounting Orientation	Any (no 'blinding' problem)			
Tracker Bar Weight	3 Kg			
Tracker Bar Length	110 cm			

www.ptiphoenix.com | info@ptiphoenix.com | +1-604-321-3238 (Canada) or +886-2-2698-9070 (Asia)

Phoenix Technologies Incorporated

High Performance Real-Time 3D Motion Capture Systems For Professionals

SI3T Markers

Revolutionary wireless marker with uniquely identified active LED targets

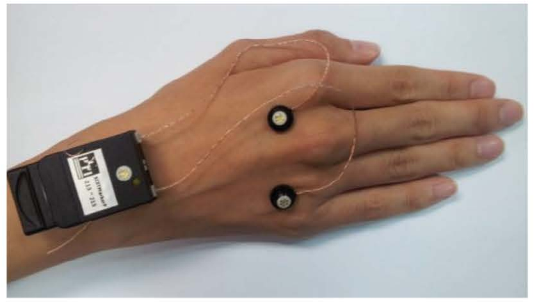
An SIT Marker can support up to 3 LEDs through its two side-connectors.

All three LEDs will have their own distinct marker IDs.

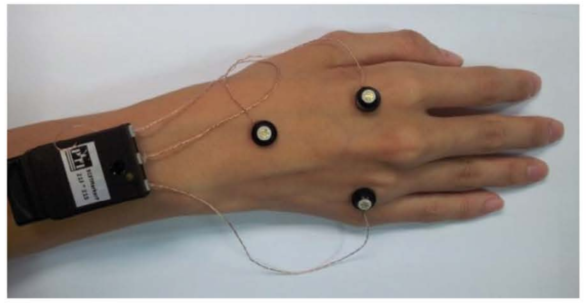
This self-identified marker is convenient for capturing the 6DOF information of an object, when placed on a rigid body.

It can also be cost-effectively used as **three independent markers.** Self-contained, it comes with its own rechargeable battery and **needs no electronic setup.**

This marker exists also with tactile feedback function – Please inquire



SI3T marker with 2 targets on extension wires, one target on marker itself



The target on the marker can be removed, so that all 3 targets are on extension wires

Appendix C: Materials and 3D printing

Materials comparison:

The statement of requirements introduces implications to the materials used in the holder. These implications and their corresponding requirements are listed in table 1. The effects these implications have on the material choice are analysed in this section

Requirement	Implication
The holder must be MRI compatible	No ferromagnetic materials can be used
The TD position must be known at all times	The holder must be rigid, i.e. have a sufficient high young's modulus
The holder must be able to withstand gel lubrication	The holder must be protected against water
The holder must be lightweight	The lower the material density the better
Combination of light and rigid	The material should have a high specific modulus

Table 1: Requirements and their implications to material choice

Non-ferromagnetic materials:

A MRI-scanner uses powerful magnetic fields, radio waves and computers to create detailed images of organs and tissues. The rapidly changing magnetic fields will attract iron-containing materials, or ferromagnetic objects. This can cause injury to the subject. Besides the ferrous objects can distort the MRI image, making it difficult to read the results. Therefore the use of non-ferromagnetic materials is obligatory.

Non-ferrous metals on the other hand are metals that do not contain iron in amounts large enough to become ferromagnetic. A list of possibly interesting non-ferrous metals is supplied in table 2. Most non-metals are also non-ferromagnetic, meaning they would be suitable for the holder. But to be sure the material's magnetic properties still needs to be checked when it will be used.

Aluminium	Lead	Copper
Brass	Magnesium	Gold
Titanium	Tin	Platinum
Tungsten	Zinc	Silver

Table 2: Non-ferrous metals

Sources:

- http://www.radiologyinfo.org/en/info.cfm?pg=safety-mr
- https://en.wikipedia.org/wiki/Ferromagnetism
- https://en.wikipedia.org/wiki/Non-ferrous_metal

Young's modulus, density and specific modulus:

The requirement that the position of the transducer with respect to the Visualeyez markers must be known at all times, means that the holder must be rigid. Deformations of the holder would lead to inaccurate measurements and decrease the performance of the ultrasound system. Thus a material with sufficiently high young's modulus is required. Furthermore the lighter the holder, the easier it is to put it on and walk around with. Because a sufficiently high stiffness is a strict requirement, this must be met first. If this is satisfied, a material with a higher specific modulus, or stiffness-to-weight ratio, would be better.

A short list of possible interesting materials with their young's modulus and density is provided in table 3. Other materials such as wood, ceramics or precious metals are not suitable for various reasons and therefore not included. The polymers ABS and PLA are commonly used for 3D printing, the benefits of this technique makes them interesting. A short comparison between the materials can be found after table 3.

Material	Young's modulus (GPA)	Density (g/cm³)
Acrylonitrile butadiene styrene (ABS)	1.4-3.1	1.06
Polylactic acid (PLA)	3.5	1.3
Aramid fibre reinforced plastic (AFRP)	50-75	1.43-1.46
Carbon fibre reinforced plastic (CFRP)	30-365	1.6-2.0
Aluminium	69	2.70
Aluminium-alloys	50-250	2.25-3.6
Titanium	110.3	4.506
Titanium-alloys	80-245	2.8-4.8

Table 3: Suitable materials and their properties

Comparison:

- Composites: Stiff and light, wide variation of available materials with different properties. Furthermore the mentioned composites are non-ferromagnetic, but a clear coat might be necessary to avoid loosened fibres hurting the subject. Besides production is labour intensive and requires a mould for each composite part. For a one size fits all holder this will not be a problem but a patient specific holder requires engineering and a new mould every time.
- Aluminium and Titanium (alloys): The pure materials are less good than their alloys. I In general they have lower specific modules than the composites, but are still light and stiff. An advantage is that they can be produced in various ways, like moulding and machining. As CNC machining custom holders is a faster and cheaper option compared to a composite holder. A drawback of aluminium is its sensitivity to corrosion, so a coating is required. Titanium is on the other hand is expensive and harder to shape.
- Polymers: They are lighter than the composites and metals, but by far not as stiff. Furthermore they are corrosion resistant and MRI compatible. They are currently the most used material for 3D printing and also are the cheapest of the lot.

Another parameter that could influence the material choice is the price. Figure 15 provides an graph from CES where the price is plotted against the specific modulus of the selected materials.

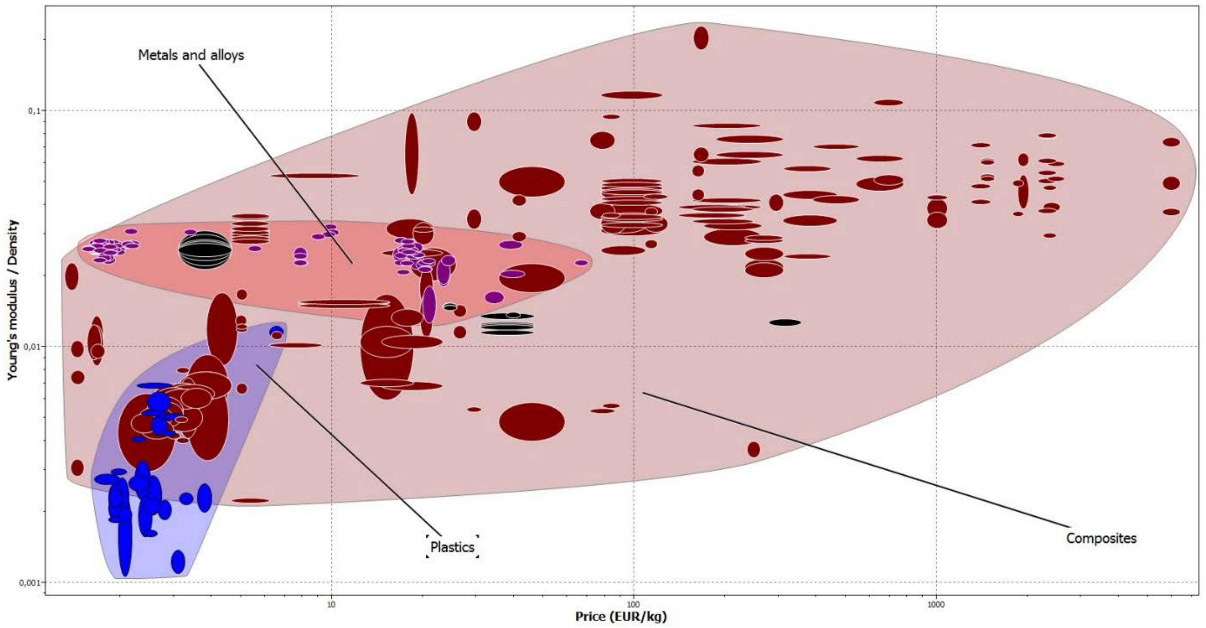


Figure 15: CES plot of specific modulus against price

Sources:

- http://www.protoparadigm.com/news-updates/the-difference-between-abs-and-pla-for-3d-printing/
- https://en.wikipedia.org/wiki/Specific_modulus
- http://www.toraycfa.com/pdfs/M60JDataSheet.pdf
- http://www.dupont.com/content/dam/dupont/products-and-services/fabrics-fibers-and-nonwovens/fibers/documents/DPT_Kevlar_Technical_Guide_Revised.pdf
- https://en.wikipedia.org/wiki/Young%27s_modulus

3D printing possibilities:

The development in printable materials makes 3D printing even more attractive. Before it was only possible to print polymers such PLA and ABS, but recent development made printing metals and composites possible. The technique that is used to print metals, such as aluminium and titanium, is called Selective Laser Melting (SLM). Metal powder is used as base material, it is melted with a solid-state laser and builds the product in layers with a thickness between 20 and 100 μm. The more complicated the part, the bigger the advantage of this method compared to traditional machining. The technique also allows the production of hybrid products, where two different metals are used. Although this is only possible when the materials can be thermically bonded. Printing carbon fibre reinforced plastic requires a special printer, such as the Mark Two from Markforged. This printer has two print heads, one builds Nylon parts the other prints continuous fibres to reinforce those parts. This MarkForged carbon fibre has better strength-to-weight ratio than machined 6061 aluminium alloy and is up to 30 times stiffer than ABS. This recent development means that a holder made from CFRP would not require a special mould, decreasing the costs and production time. When these printers become more commonly available, the material choice must be revisited.

Sources:

- https://markforged.com/materials/
- http://www.mundo-3d.nl/metaalprinten/3d_metaal_printen/
- http://www.3ders.org/articles/20150520-new-markforged-material-testing-results-reveals-even-stronger-material-specs.html

Appendix D: Medical guideline

The ultrasound kinematic analysis system must satisfy the guidelines for medical devices. Below a list and hyperlink to the relevant guidelines is provided.

- Guidelines for quality management of medical devices are described in NEN-EN-ISO 13485, the norm is internationally recognized. A certified quality system guarantees con-sistent quality and is helpful for the position of the device in the market.
- retrieved from: https://www.nen.nl/NEN-Shop/Nieuws-Medische-hulpmiddelen/Kwaliteits-en-risico-management-Medische-Hulpmiddelen.htm

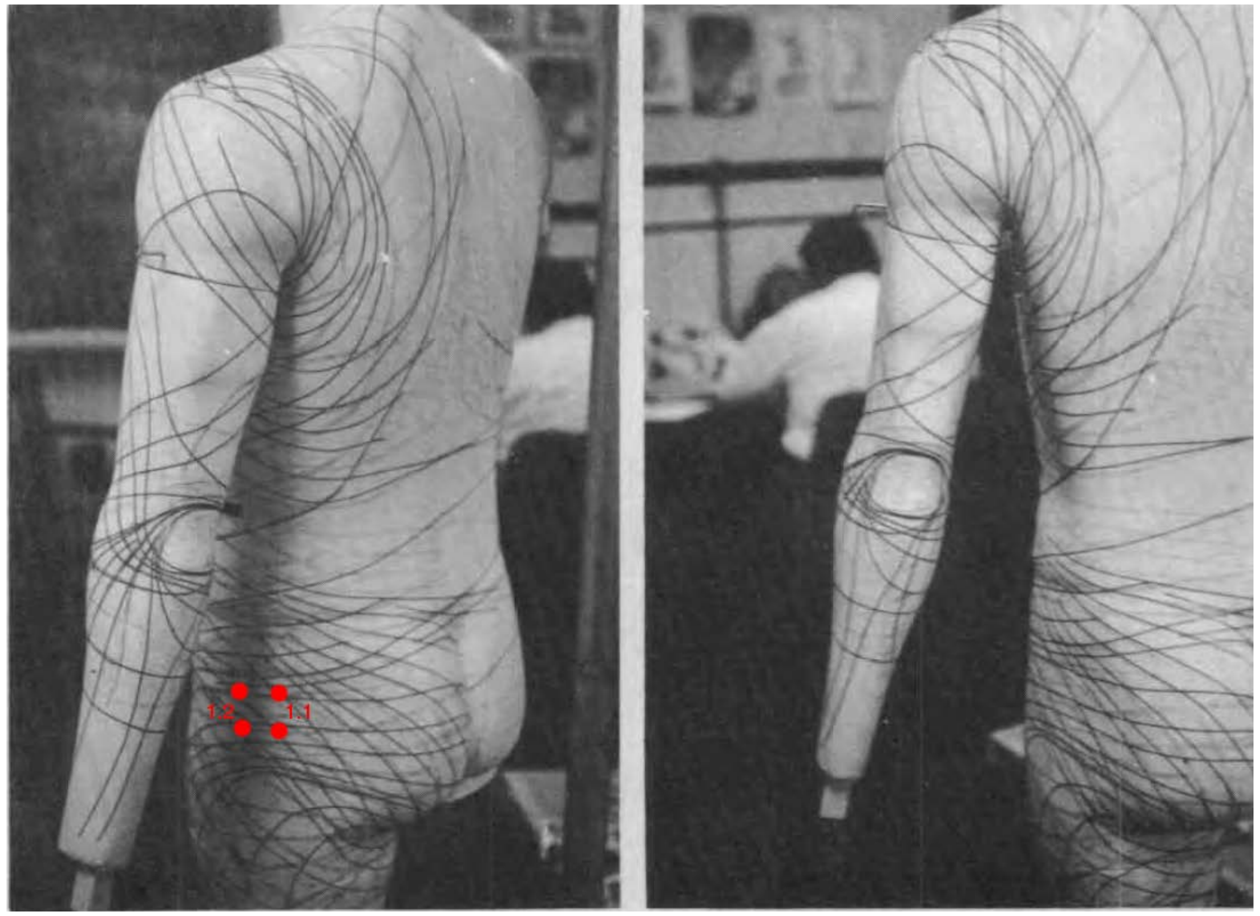
- Guideline 93/42/EEG is the guideline for medical devices. It covers everything that is used on humans to detect illness or handicaps, to treat, enlighten or prevent disease. The guideline does not cover custom made devices or devices that are used for clinical trials.
- retrieved from: https://www.nen.nl/NEN-Shop/Wetgeving-medische-hulpmiddelen/Richtlijn-medische-hulpmiddelen-9342EEG-1.htm

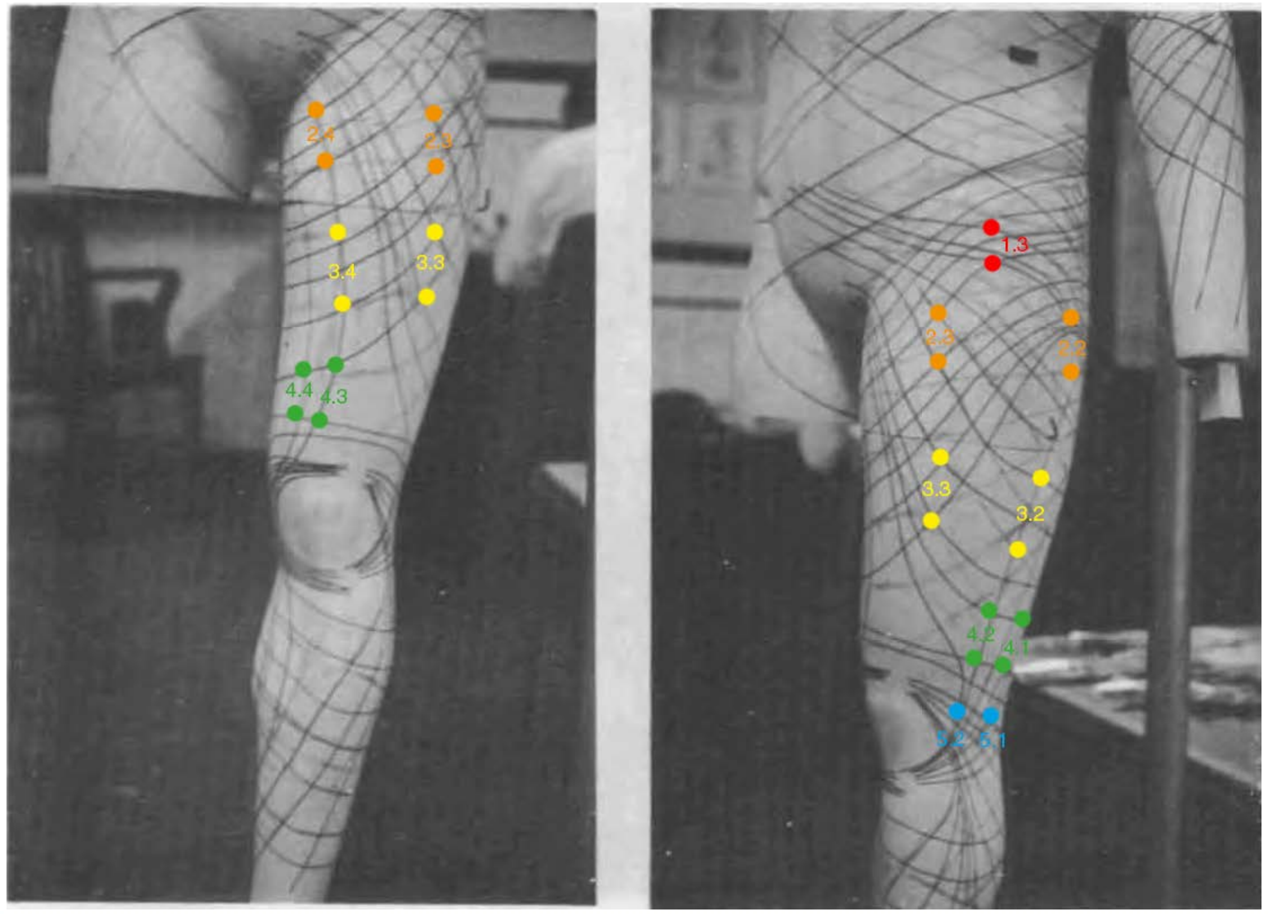
- The systems is low risk and will only stay in contact with the subject for a limited amount of time. Therefore it falls within the Class I division for devices with a measurement func-tion
- retrieved from: https://www.nen.nl/NEN-Shop/Wetgeving-medische-hulpmiddelen/Classificatie-medische-hulpmiddelen.htm

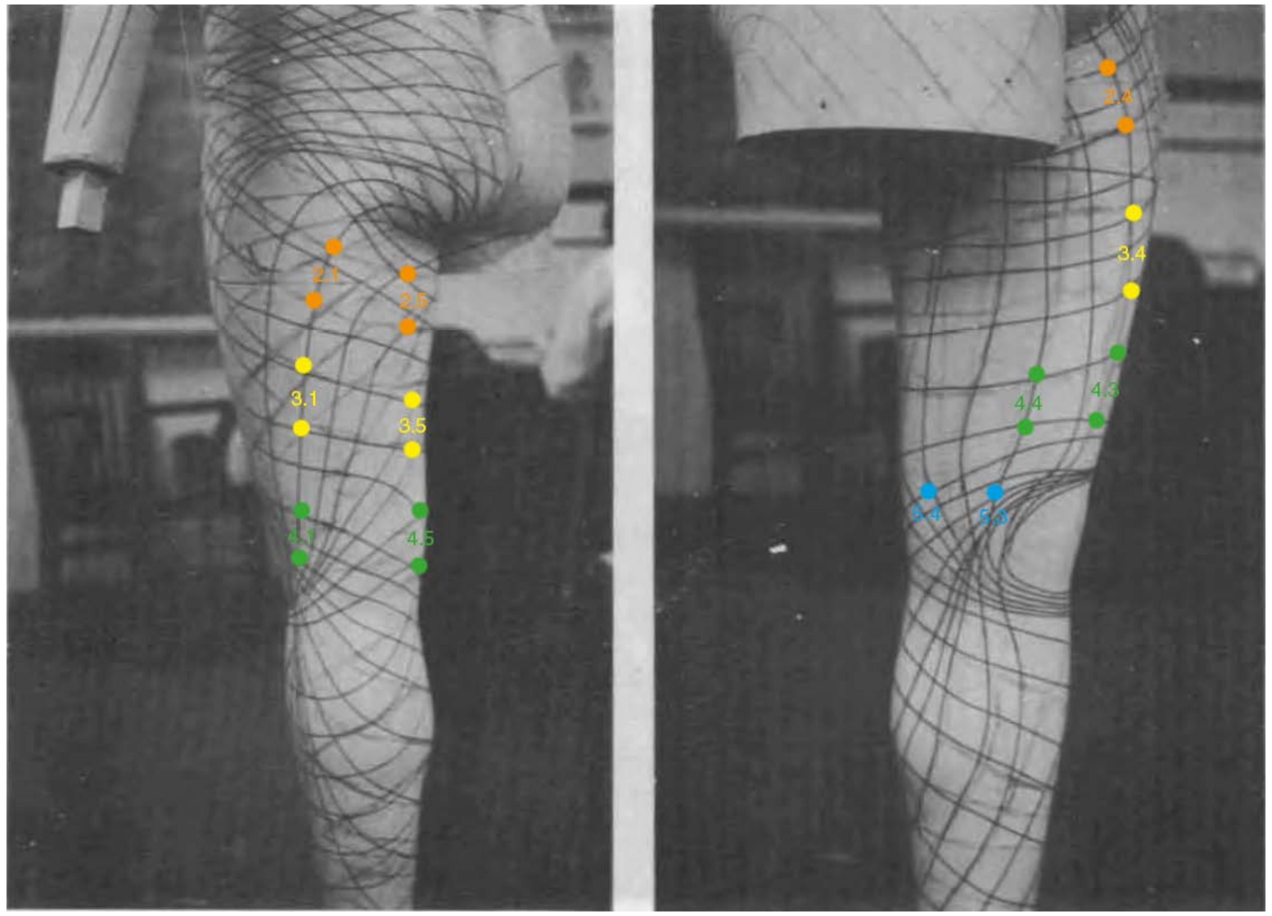
Guideline 93/42/EEG:

- The device must satisfy the essential requirements from appendix I.
- The classification of the device is done according to the rules from appendix IX.
- For clinical research the rules in appendix VIII have to be followed.
- The clinical research must be done according to appendix X.

Appendix E: Selected test locations







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3.4
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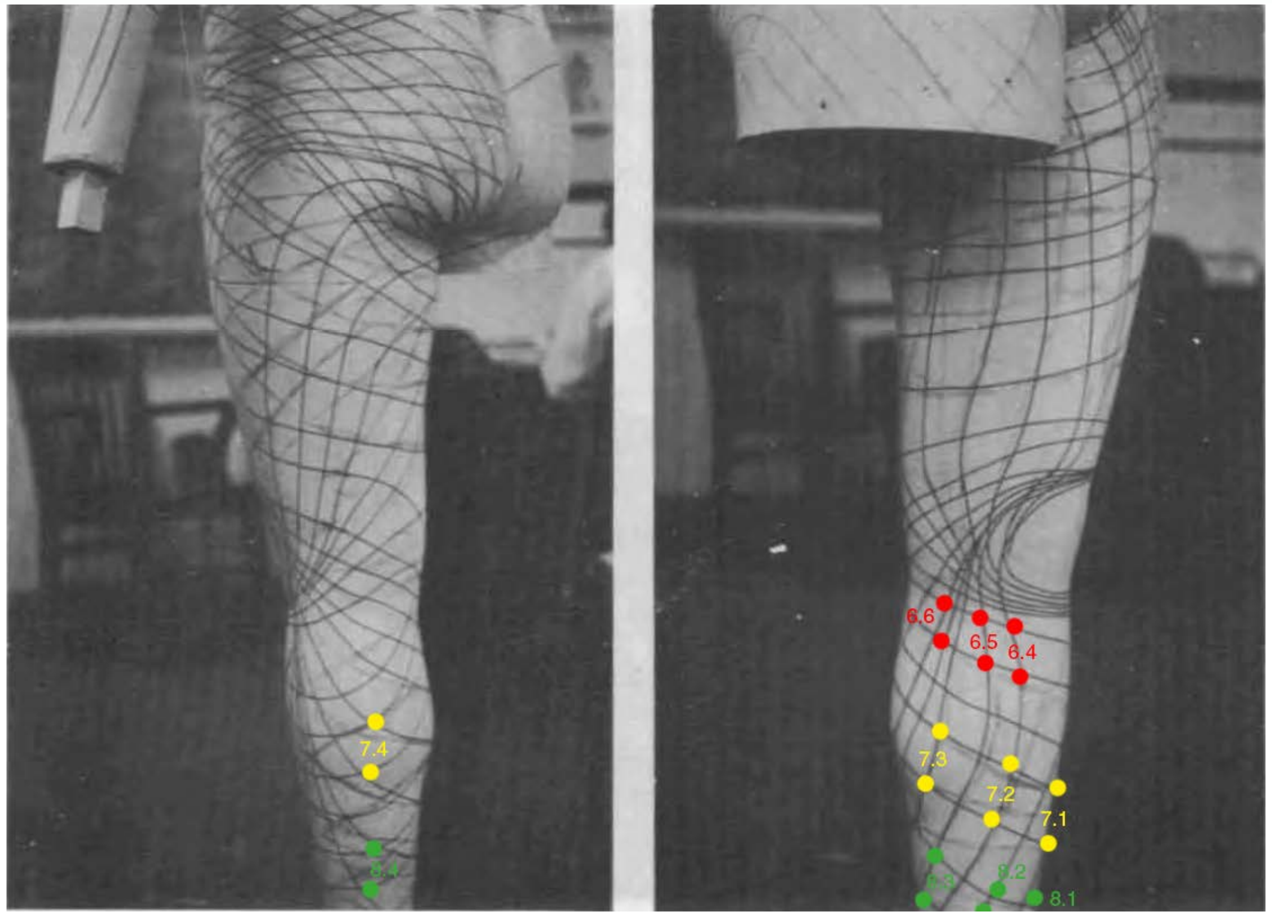
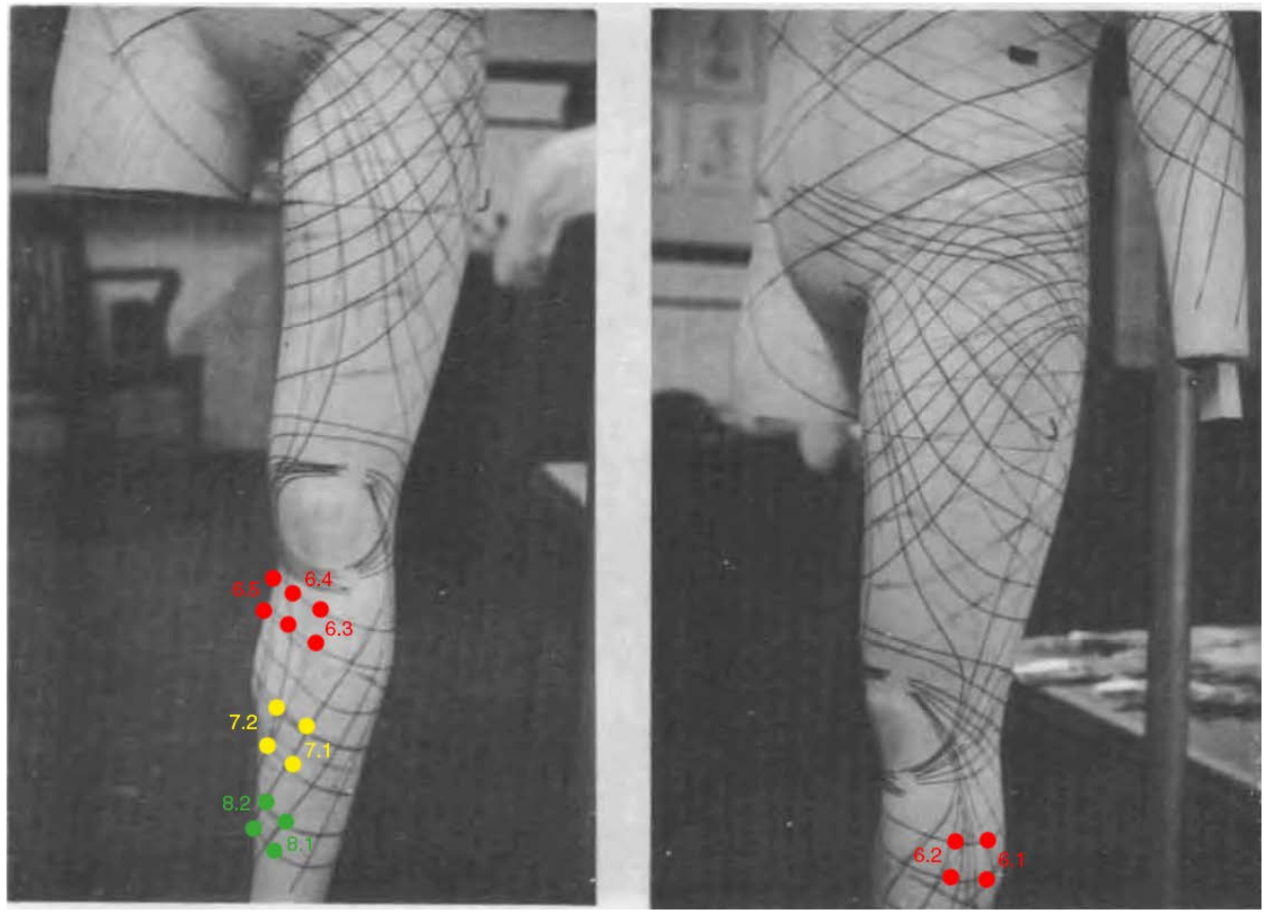
4.3



6.6
6.5
6.4
7.4
7.3
7.2
7.1
8.2
8.1



6.5
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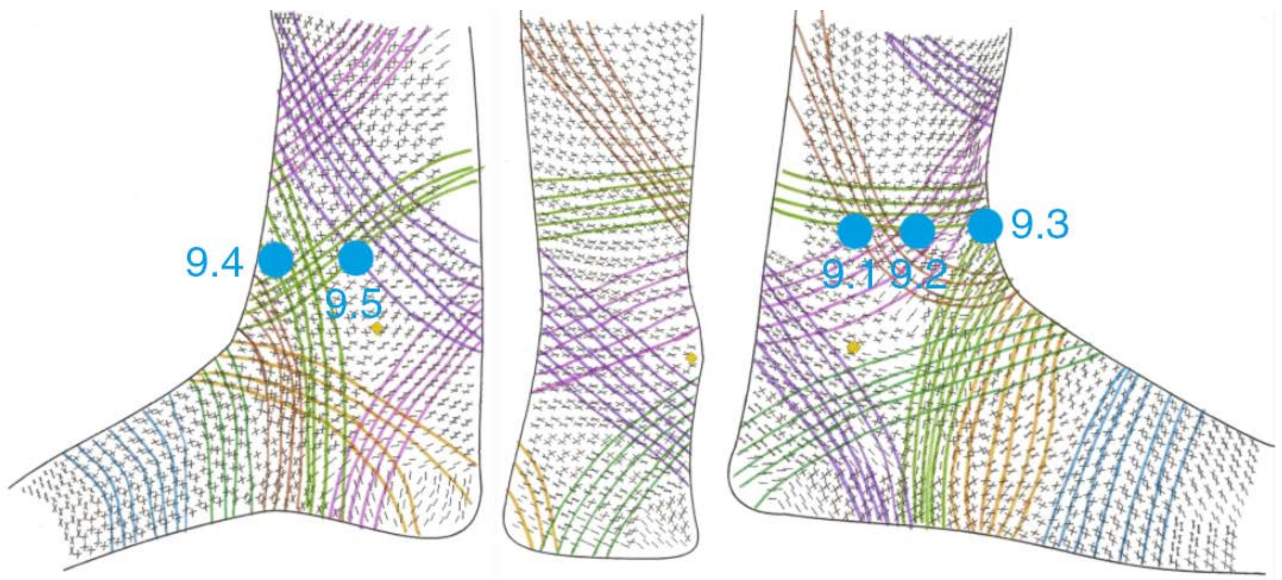
7.1
8.2
8.1
6.2



9.4
9.5
9.1
9.2
9.3

Appendix F: Protocol for location testing

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Location	Location	Number of TD positions	Number of testing heights	Total number of postions	Testing Position	Corresponding Tag from	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Total score
2										Test	0°		
3	Trochanter	1	3	2	6								
4						1.1A	1	LoNE A					
5						1.2A	2	LoNE A					
6						1.3A	3		LoNE B				
7						1.1B	4	LoNE A					
8						1.2B	5	LoNE A					
9						1.3B	6		LoNE B				
10													
11	Proximal Femur	2	5	2	10								
12						2.1A	Not tested		LoNE C				
13						2.2A	Not tested	LoNE B					
14						2.3A	Not tested	LoNE B					
15						2.4A	Not tested	LoNE B	LoNE C				
16						2.5A	Not tested		LoNE C				
17						2.1B	Not tested		LoNE C				
18						2.2B	Not tested	LoNE B					
19						2.3B	Not tested	LoNE B					
20						2.4B	Not tested	LoNE B	LoNE C				
21						2.5B	Not tested		LoNE C				
22													
23	Mid Femur	3	5	2	10								
24						3.1A	7		LoNE C				
25						3.2A	8	LoNE B					
26						3.3A	9	LoNE B					
27						3.4A	10	LoNE B	LoNE C				
28						3.5A	11		LoNE C				
29						3.1B	12		LoNE C				
30						3.2B	13	LoNE B					
31						3.3B	14	LoNE B					
32						3.4B	15	LoNE B	LoNE C				
33						3.5B	16		LoNE C				
34													
35	Distal Femur	4	5	2	10								
36						4.1A	17	LoNE B	LoNE C				
37						4.2A	18	LoNE B					

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Location	Location	Number of TD positions	Number of testing heights	Total number of postions	Testing Position	Corresponding Tag from	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Total score
2										Test	0°		
53	Proximal Tibia	6	6	2	12								
54						6.1A	Not tested	LoNE D					
55						6.2A	31	LoNE D					
56						6.3A	32	LoNE D					
57						6.4A	33	LoNE D	LoNE E				
58						6.5A	34	LoNE D	LoNE E				
59						6.6A	35		LoNE E				
60						6.1B	Not tested	LoNE D					
61						6.2B	Not tested	LoNE D					
62						6.3B	37	LoNE D					
63						6.4B	38	LoNE D	LoNE E				
64						6.5B	39	LoNE D	LoNE E				
65						6.6B	40		LoNE E				
66													
67	Mid Tibia:	7	4	2	8								
68						7.1A	41	LoNE D	LoNE E				
69						7.2A	42	LoNE D	LoNE E				
70						7.3A	43		LoNE E				
71						7.4A	Not tested		LoNE E				
72						7.1B	44	LoNE D	LoNE E				
73						7.2B	45	LoNE D	LoNE E				
74						7.3B	46		LoNE E				
75						7.4B	Not tested		LoNE E				
76													
77	Distal Tibia	8	4	2	8								
78						8.1A	Not tested	LoNE D	LoNE E				
79						8.2A	Not tested	LoNE D	LoNE E				
80						8.3A	Not tested		LoNE E				
81						8.4A	Not tested		LoNE E				
82						8.1B	Not tested	LoNE D	LoNE E				
83						8.2B	Not tested	LoNE D	LoNE E				
84						8.3B	Not tested		LoNE E				
85						8.4B	Not tested		LoNE E				
86													
87	Ankle	9	5	1	5								
88						9.1	47	LoNE F					
89						9.2	48	LoNE F					
90						9.3	49	LoNE F					

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Location	Location number	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file												
2								Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?
3							Test Angle:		0°			10° Distal			10° Proximal		
4	Trochanter	1															
5			1.1	1	LoNE A												
6																	
7	Mid Femur	3															
8			3.1	7		LoNE C											
9			3.2	8	LoNE B												
10			3.3	9	LoNE B												
11																	
12	Distal Femur	4															
13			4.3	19	LoNE B	LoNE C											
14			4.4	20	LoNE B	LoNE C											
15																	
16	Patella Sides	5															
17			5.1	27	LoNE B												
18			5.4	30		LoNE C											
19																	

Appendix G: Location testing results

Location	Location number	Number of TD positions	Number of testing heights	Total number of postions	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Total score
									Test Angle:	0°		
Trochanter	1	3	2	6								
					1.1A	1	LoNE A			Yes	2	6
					1.2A	2	LoNE A			No	2	2
					1.3A	3		LoNE B		No	3	3
					1.1B	4	LoNE A			Half	4	6
					1.2B	5	LoNE A			No	1	1
					1.3B	6		LoNE B		No	2	2
Proximal Femur	2	5	2	10								
					2.1A	Not tested		LoNE C				
					2.2A	Not tested	LoNE B					
					2.3A	Not tested	LoNE B					
					2.4A	Not tested	LoNE B	LoNE C				
					2.5A	Not tested		LoNE C				
					2.1B	Not tested		LoNE C				
					2.2B	Not tested	LoNE B					
					2.3B	Not tested	LoNE B					
					2.4B	Not tested	LoNE B	LoNE C				
					2.5B	Not tested		LoNE C				
Mid Femur	3	5	2	10								
					3.1A	7		LoNE C		Half	3	5
					3.2A	8	LoNE B			Yes	4	8
					3.3A	9	LoNE B			Yes	4	8
					3.4A	10	LoNE B	LoNE C		Yes	2	6
					3.5A	11		LoNE C		Half	1	3
					3.1B	12		LoNE C		No	1	1
					3.2B	13	LoNE B			Yes	4	8
					3.3B	14	LoNE B			Yes	3	7
					3.4B	15	LoNE B	LoNE C		Half	2	4
					3.5B	16		LoNE C		No	1	1

Location	Location number	Number of TD positions	Number of testing heights	Total number of postions	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Total score
									Test Angle:	0°		
Distal Femur	4	5	2	10								
					4.1A	17	LoNE B	LoNE C		No	1	1
					4.2A	18	LoNE B			Yes	3	7
					4.3A	19	LoNE B	LoNE C		Half	2	4
					4.4A	20	LoNE B	LoNE C		Half	2	4
					4.5A	21		LoNE C		No	0	0
					4.1B	22	LoNE B	LoNE C		No	0	0
					4.2B	23	LoNE B			No	1	1
					4.3b	24	LoNE B	LoNE C		Yes	3	7
					4.4B	25	LoNE B	LoNE C		Yes	3	7
					4.5B	26		LoNE C		No	1	1
Patella Sides	5	4	1	4								
					5.1	27	LoNE B			Yes	1	5
					5.2	28	LoNE B			Yes	4	8
					5.3	29		LoNE C		Yes	xx	xx
					5.4	30		LoNE C		Yes	2	6
Proximal Tibia	6	6	2	12								
					6.1A	Not tested	LoNE D			xx	xx	1
					6.2A	31	LoNE D			Yes	3	7
					6.3A	32	LoNE D			Yes	2	6
					6.4A	33	LoNE D	LoNE E		Yes	3	7
					6.5A	34	LoNE D	LoNE E		Yes	2	6
					6.6A	35		LoNE E		Yes	3	7
					6.1B	Not tested	LoNE D			xx	xx	1
					6.2B	Not tested	LoNE D			xx	xx	1
					6.3B	37	LoNE D			Yes	2	6
					6.4B	38	LoNE D	LoNE E		Yes	3	7
					6.5B	39	LoNE D	LoNE E		Yes	4	8
					6.6B	40		LoNE E		Yes	3	7

Location	Location number	Number of TD positions	Number of testing heights	Total number of postions	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?
									Test Angle:	0°	
Mid Tibia:	7	4	2	8							
					7.1A	41	LoNE D	LoNE E		Yes	2
					7.2A	42	LoNE D	LoNE E		Yes	3
					7.3A	43		LoNE E		Yes	4
					7.4A	Not tested		LoNE E		xx	xx
					7.1B	44	LoNE D	LoNE E		Yes	4
					7.2B	45	LoNE D	LoNE E		Yes	3
					7.3B	46		LoNE E		Yes	4
					7.4B	Not tested		LoNE E		xx	xx
Distal Tibia	8	4	2	8							
					8.1A	Not tested	LoNE D	LoNE E			
					8.2A	Not tested	LoNE D	LoNE E			
					8.3A	Not tested		LoNE E			
					8.4A	Not tested		LoNE E			
					8.1B	Not tested	LoNE D	LoNE E			
					8.2B	Not tested	LoNE D	LoNE E			
					8.3B	Not tested		LoNE E			
					8.4B	Not tested		LoNE E			
Ankle	9	5	1	5							
					9.1	47	LoNE F			Yes	3
					9.2	48	LoNE F			Yes	4
					9.3	49	LoNE F			Yes	3
					9.4	50	LoNE F			Yes	4
					9.5	51	LoNE F			Yes	2

Location	Location number	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score
						Test Angle:	0°			10° Distal			10° Proximal		
Trochanter	1														
		1.1	1	LoNE A			yes	2	6	half	2	4	half	2	4
Mid Femur	3														
		3.1	7		LoNE C		half	3	5	half	2	4	no	1	1
		3.2	8	LoNE B			yes	4	8	no	1	1	no	1	1
		3.3	9	LoNE B			yes	4	8	yes	3	7	no	1	1
Distal Femur	4														
		4.3	19	LoNE B	LoNE C		half	2	4	half	2	4	no	1	1
		4.4	20	LoNE B	LoNE C		half	2	4	yes	3	7	no	1	1
Patella Sides	5														
		5.1	27	LoNE B			yes	1	5	yes	3	7	no	2	3
		5.4	30		LoNE C		yes	2	6	yes	4	8	yes	2	6

Location	Location number	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file			Is the signal "Stable"?								
							Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score
						Test Angle:	10° Lateral			10° Medial			20° Distal		
Trochanter	1														
		1.1	1	LoNE A			no	1	1	no	1	1	half	3	5
Mid Femur	3														
		3.1	7		LoNE C		yes	3	7	yes	3	7	no	1	1
		3.2	8	LoNE B			yes	4	8	no	1	1	no	1	1
		3.3	9	LoNE B			yes	3	7	half	2	4	no	2	2
Distal Femur	4														
		4.3	19	LoNE B	LoNE C		yes	3	7	no	1	1	half	2	4
		4.4	20	LoNE B	LoNE C		yes	3	7	no	1	1	no	1	1
Patella Sides	5														
		5.1	27	LoNE B			yes	4	8	yes	3	7	yes	4	8
		5.4	30		LoNE C		half	2	4	no	1	1	yes	3	7

Location	Location number	Testing Position	Corresponding Tag from Kenan	Corresponding LoNE file			Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score	Can we get a detected peak?	Is the peak distinguishable?	Score
						Test Angle:	20° Proximal			20° Lateral			20° Medial		
Trochanter	1														
		1.1	1	LoNE A			yes	3	7	yes	2	6	no	1	1
Mid Femur	3														
		3.1	7		LoNE C		no	1	1	no	1	1	yes	4	8
		3.2	8	LoNE B			no	1	1	no	1	1	no	1	1
		3.3	9	LoNE B			no	1	1	no	1	1	no	1	1
Distal Femur	4														
		4.3	19	LoNE B	LoNE C		no	1	1	yes	3	7	no	1	1
		4.4	20	LoNE B	LoNE C		no	1	1	half	2	4	no	1	1
Patella Sides	5														
		5.1	27	LoNE B			no	1	1	yes	1	5	yes	1	5
		5.4	30		LoNE C		no	1	1	half	2	4	yes	3	7

Appendix H: Documentation

User guide for the Ultrasound Analysis system's holders

To enhance the use of the holders for the ultrasound analysis system this user guide has been written. It explains the contents of the included files and folders, the parametrization of each holder, thus how a subject must be measured, and some basic information regarding the Solidworks models and how they can be adapted. In this documentation it is assumed that the user has knowledge of the transducer's locations and is familiar with the holder parts. Therefore the exact locations of the transducers is not specified, these can be looked up in the complete bachelor report.

Table of contents:

1. Final Concept Holders V2.0:

The folder Final Concept Holder V2.0 contains all the files regarding the final version of the concept holders. Figure 1 shows the contents of this folder. First the Assemblies subfolder contains assemblies of all the holder parts, both the left and right versions, and the assembly of the transducer container, container cover and transducer. These files can be used to create new vector STLs when holders are made for a new subject. Second the Renders subfolders contains rendered images of all separate holder parts, the right leg assemblies, both the left and right leg parts next to each other, and of the transducer containers. They should give an idea of what the holders look like. Furthermore the STLs subfolder contains all the STLs that are required to print the holder parts for Kenan his right leg and the Vector STLs subfolder contains the STL files of the holder parts' assemblies. The assemblies contain pins representing the LEDs and transducer beam, they can be used to vectorise the part. Finally the separate holder parts can be found in the main folder. They can be adapted when holders for a new subject are required.

Naam	Gewijzigd op	Type	Grootte
Assemblies	21-7-2016 00:31	Bestandsmap	
Renders	21-7-2016 00:13	Bestandsmap	
STLs	20-7-2016 18:20	Bestandsmap	
Vector STLs	20-7-2016 18:11	Bestandsmap	
Ankle Left	21-7-2016 00:27	SOLIDWORKS Part...	4.021 kB
Ankle Right	21-7-2016 00:16	SOLIDWORKS Part...	3.534 kB
Femur Epicondyles Left	21-7-2016 00:19	SOLIDWORKS Part...	3.679 kB
Femur Epicondyles Right	21-7-2016 00:28	SOLIDWORKS Part...	2.663 kB
Mid Femur Left	21-7-2016 00:21	SOLIDWORKS Part...	3.211 kB
Mid Femur Right	21-7-2016 00:22	SOLIDWORKS Part...	3.263 kB
Mid Tibia Left	21-7-2016 00:23	SOLIDWORKS Part...	2.928 kB
Mid Tibia Right	21-7-2016 00:29	SOLIDWORKS Part...	1.951 kB
Tibia Epicondyles Left	21-7-2016 00:29	SOLIDWORKS Part...	2.697 kB
Tibia Epicondyles Right	21-7-2016 00:29	SOLIDWORKS Part...	1.877 kB
Transducer Container Cover	19-7-2016 16:30	SOLIDWORKS Part...	864 kB
Transducer Container	21-7-2016 00:26	SOLIDWORKS Part...	2.190 kB
Transducer	20-7-2016 14:07	SOLIDWORKS Part...	181 kB
Trochanter	21-7-2016 00:26	SOLIDWORKS Part...	2.685 kB

Figure 1: Final Concept Holders V2.0 folder contents.

2. Parametrization:

All the holder parts are built in such a way that they can be adapted to fit other subjects. This is with some limitations, for example very skinny legs can be problematic. This is caused by the fact that the centre of the transducers needs to be minimal 25mm apart, if they are closer to each other the retaining rings will touch each other. This section describes how a subject must be measured and to which parameter the measurement relates in the design table. While the femur epicondyles, tibia epicondyles and ankle parametrisation are similar, only the femur epicondyles is described completely. The description of tibia epicondyles and ankle will only mention where and how the parametrisation deviates from the femur epicondyles. Furthermore all the Solidworks models are dimensioned in millimetres and measurements should therefore also be taken in millimetres. A description how to access and change the Design table is given in sections 3.2 and 3.3.

2.1 Trochanter:

The trochanter holder is the only part that fits both left and right leg. There is only one measurement necessary and two more parameters can be controlled in the design table to increase the usability of this holder. A description of this is given below:

- First locate the greater trochanter and mark the two position where the transducers should be placed.
- Then measure their relative distance, as can be seen in figure 1, and write down.
- In the design table this corresponds to the number in column C of figure 2: TD distance(@ Transducer Pattern).
- Column A provides the name of the configuration.
- In column B the distance between the LED centres on the arm can be controlled, the standard value of this parameter is 60mm.
- In column D the number of transducers can be controlled, this number can be increased to make the holder suitable for other positions on the leg. Standard it is set to 2.
- Column E and F are set to either S or U, their working is further explained in section 3.3. and the other holders won't mention them.

	A	B	C	D	E	F	G	H	I
1	Design Table for: Trochanter								
2		LED arm width@Sketch8	TD distance@Transducer Pattern	Number of Transducers@Transducer Pattern	$STATE@Pins	$STATE@Pin Point			
3	Vectorisation	60	25	2	U	U			
4	Kenan	60	25	2	S	S			
5	Test	80	50	3	S	S			
6									

Figure 2: Measurement of trochanter and Trochanter design table

2.2 Mid Femur:

The mid femur holder comes in a left and right leg specific version. In essence the holder is mirrored, but the parametrisation has remained the same for both parts. This is also the case for the other holders. The mid femur holder can be parametrised using four measurements, additionally four other parameters can be controlled in the Design table. A description of this is given below:

Measuring the subject:

- Determine the location of the femur bone on the mid-section of the upper leg.
- Select and mark a point on the anterior side of the leg above the femur bone which is not influenced by kneecap movement. This is approximately 10cm above the kneecap
- On the same height mark a point on the lateral side of the leg above the femur bone. As can be seen on the first image of figure 3.
- Then mark a second point on the anterior side, located 10cm proximal to the first point, again above the femur bone. As shown in the second image of figure 3.
- The last point on the lateral side is marked the same way as the second point. The final result is shown on the third image of figure 3.

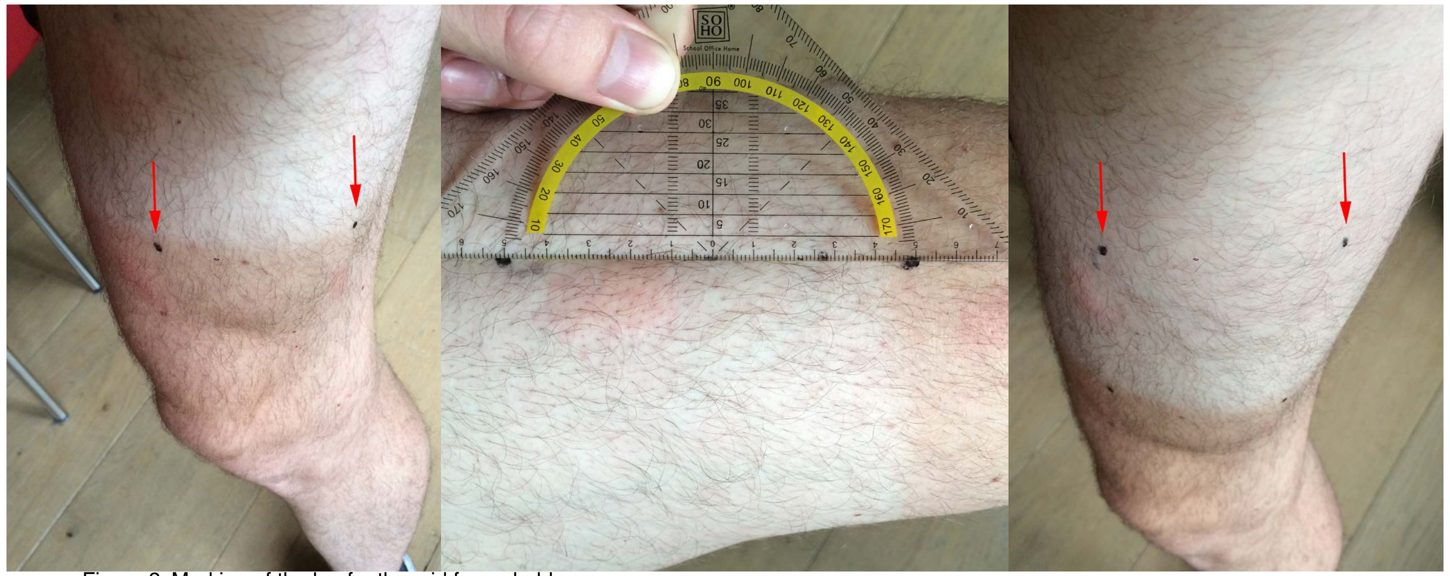


Figure 3: Marking of the leg for the mid femur holder.

- When the leg is marked correctly the relevant distances can be measured.
- The first image of figure 4 shows how to measure the distal width (column B in figure 5).
- The second image of figure 4 shows how to measure the distal depth (column C in figure 5).
- Repeat these two measurement for the proximal two points. These are all the dimensions necessary to parametrize the mid femur holder.

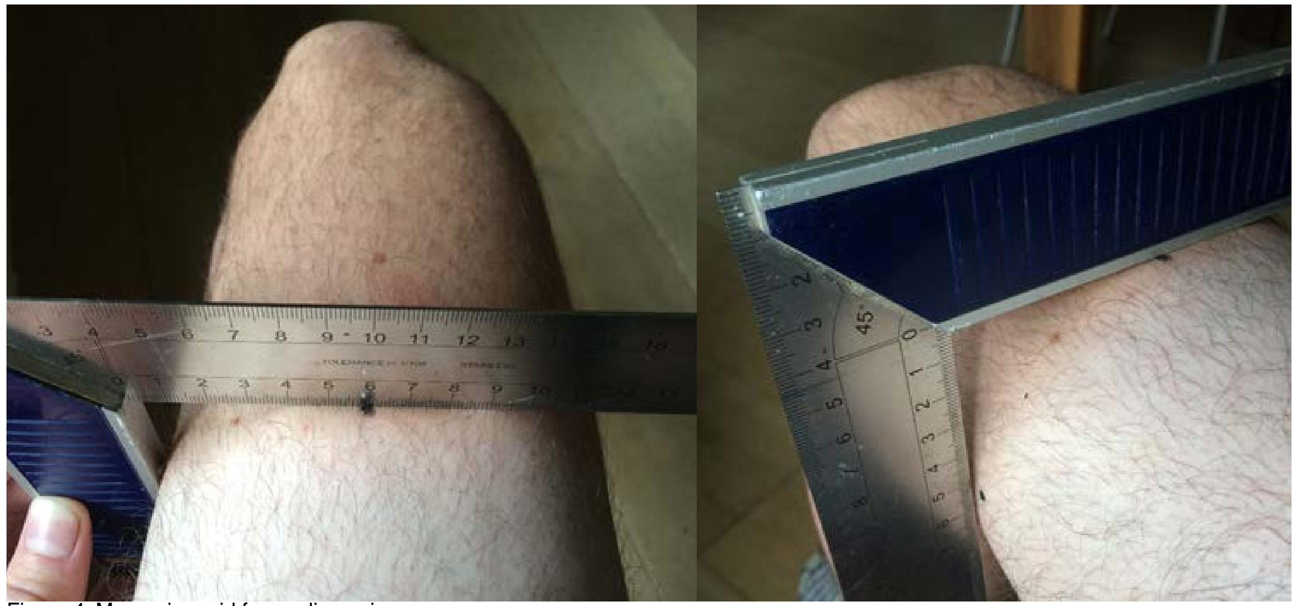


Figure 4: Measuring mid femur dimensions

Mid femur design table (figure 5):

- The collected measurement can be inserted in the columns B,C,D and E
- With columns F and G the distance between the transducers and the number of transducer of the anterior plate can be controlled. Standard these values are set to 25mm and 3 transducers
- Columns H and I control the same parameters only for the lateral transducers. These values are standard set to 25mm and 4 transducers.

	A	B	C	D	E	F	G	H	I	J	K
1	Design Table for: Mid Femur Left										
2		Distal Width@Distal Parametrisation	Distal Depth@Distal Parametrisation	Proximal Width@Proximal Parametrisation	Proximal Depth@Proximal Parametrisation	Anterior Transducer Distance@Anterior Transducer Pattern	Number of Anterior Transducers@Anterior Transducer Pattern	Lateral Transducer Distance@Lateral Transducer Pattern	Number of Lateral Transucers@Lateral Transducer Pattern	$STATE@Pins	$STATE@Pin Points
3	Vectorisation	60	60	60	70	25	3	25	4	U	U
4	Kenan	60	60	60	70	25	3	25	4	S	S
5	Test	60	50	60	70	30	3	30	5	S	S

Figure 5: Mid femur design table

2.3 Femur epicondyles:

Because the parametrisation of the femur epicondyles also explains the basics of the tibia epicondyles and ankle, it is split in 2 parts. First the basic parametrisation that also holds for the tibia epicondyles and the ankle is explained, then the additional measurements to complete the femur epicondyles holder are treated.

Basic parametrisation:

- Start with locating the height where the transducers should come, so locate the epicondyles or the medial malleolus in case of the ankle holder.
- Mark the mid-point of the anterior leg side, see the first picture in figure 6.
- Locate and mark the locations where the transducers should be placed on the lateral and medial side. Two points on both sides, as can be seen in the second and third picture in figure 6.


Figure 6: Determining transducer locations

- Then measure the width of the anterior and posterior point on the medial side
- Measure the depth of the anterior and posterior point on the medial side
- Repeat these two measurements for the lateral side.
- This results in eight dimensions which are the basic values for the femur epicondyles, tibia epicondyles and ankle holders.
- An example of these measurements is shown in figure 7.

Figure 7: Measuring the dimensions of the femur epicondyles

Besides the basic measurements five extra dimensions are required to build the femur epicondyles holder. They can be obtained as follows:

- Locate the widest part of the Musculus Vastus Medialis. Again mark the mid-point of the anterior leg side at this height (first picture in figure 8).
- Mark the two locations where the transducers should be placed on the M. Vastus Medialis.
- Measure their width and depth, as shown in the middle and right picture in figure 8.

Figure 8: Measuring the dimension of the Musculus Vastus Medialis

Design Table for: Femur Epicondyles Right

	Medial Anterior Width@Sketch1	Medial Anterior Depth@Sketch1	Medial Posterior Width@Sketch1	Medial Posterior Depth@Sketch1	Lateral Anterior Width@Sketch1	Lateral Anterior Depth@Sketch1	Lateral Posterior Width@Sketch1	Lateral Posterior Depth@Sketch1	M. Vastus Medialis Height@M. Vastus Medialis Height	M. Vastus Medialis Width 1@Sketch10	M. Vastus Medialis Depth 1@Sketch10	M. Vastus Medialis Width 2@Sketch10	M. Vastus Medialis Depth 2@Sketch10	$STATE@Pins	$STATE@Pin Points
Vectorisation	40	20	60	50	40	20	55	50	70	30	5	50	30	U	U
Kenan	40	20	60	50	40	20	55	50	70	30	5	50	30	S	S
Test	35	25	55	60	35	25	50	60	80	25	10	60	40	S	S

Figure 9: Femur epicondyles design table

Femur epicondyles Design table (figure 9):

- The columns B until I corresponds to the basis parametrisation measurements. They are named similar to the measurements, so the Medial Anterior Width is the distance from the mid-point to the anterior point on the medial side in the frontal plane.
- The columns J until N corresponds to the extra measurements for the femur epicondyles holder. Where point 1 is the most lateral and point 2 the most medial.

2.4 Tibia epicondyles:

The basic measurements for the tibia epicondyles are equal to those of the femur epicondyles. There is only one additional measurement required to paramterize the tibia epicondyles holder. The height of the two lateral transducers is different, therefore this distance needs to be measured.

- Mark the two lateral positions already in the correct height for the basic measurements.
- Do the basic measurements as described for the femur epicondyles
- Finally measure the height distance between the two lateral points, as shown in figure 10

Tibia epicondyles design table (figure 11):

- The columns B until I again correspond to the basis measurements.
- Column J is the difference in height between the two lateral points.
- With column K the distance between the LED centres on the arm can be controlled, this value is standard set to 60mm

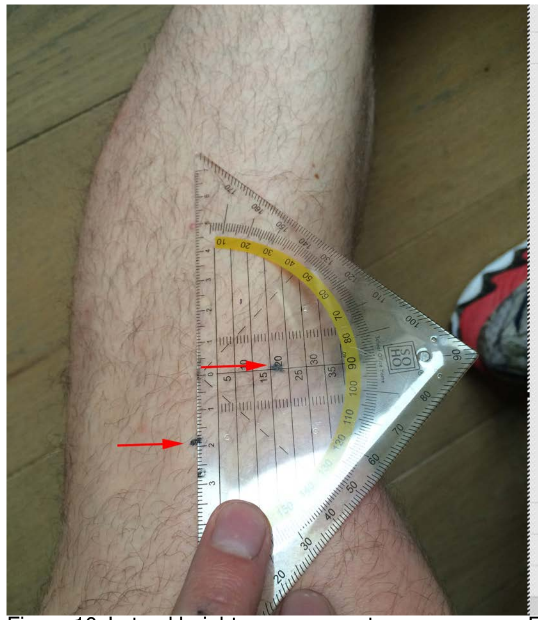


Figure 10: Lateral height measurement

Design Table for: Tibia Epicondyles Left

	Medial Anterior Width@Sketch2	Medial Anterior Depth@Sketch2	Medial Posterior Width@Sketch2	Medial Posterior Depth@Sketch2	Lateral Anterior Width@Sketch2	Lateral Anterior Depth@Sketch2	Lateral Posterior Width@Sketch2	Lateral Posterior Depth@Sketch2	Lateral Height@Transducer Pattern Sketch	LED Distance@Sketch21	$STATE@Pins	$STATE@Pin Points
Vectorisation	20	10	40	30	15	5	40	20	15	60	U	U
Kenan	20	10	40	30	15	5	40	20	15	60	S	S
Test	20	10	35	25	25	10	35	25	20	60	S	S

Figure 11: Tibia epicondyles design table

2.5 Mid Tibia:

The mid tibia holders do not require any measurements. But there are some parameters that can be controlled in the design table.

Mid tibia design table (figure 12):

- Column B controls the distance between the transducer in horizontal direction, increasing this value can enhance the fitting. But caution must be applied as the width of the tibia bone determines the maximum distance the transducer centres can be apart. The standard value is 10mm so the transducers outer edges are 26mm apart.
- Column C controls the distance between the transducer in vertical direction. Increasing this value has the same effect as for the horizontal direction. Here caution has to be applied so that the mid tibia holder doesn't touch the tibia epicondyles or ankle holder. The standard value is 25mm.

	A	B	C	D	E	F
1	Design Table for: Mid Tibia Right					
2		Horizontal Transucer Distance@Transducer Pattern Sketch	Vertical Transducer Distance@Transducer Pattern Sketch	$STATE@Mount Pins	$STATE@Battery Pins	$STATE@Pin Points
3	Vectorisation	10	25	U	U	U
4	Kenan	10	25	S	S	S
5	Test	20	40	S	S	S
6						

Figure 12: Mid tibia design table

2.6 Ankle:

The parametrisation of the ankle also uses the basic measurements from the femur epicondyles. But because it only has one transducer on the lateral side, the lateral posterior measurements are not required. Furthermore there is one extra variable that can be controlled via the design table.

Ankle design table (figure 13):

- Columns A until G are the basis measurements,
- Column H controls the distance between the LED centres of the LED arm.

	A	B	C	D	E	F	G	H	I	J	K
1	Design Table for: Ankle Left										
2		Medial Anterior Width@Sketch7	Medial Anterior Depth@Sketch7	Medial Posterior Width@Sketch7	Medial Posterior Depth@Sketch7	Lateral Anterior Width@Sketch7	Lateral Anterior Depth@Sketch7	LED Distance@Sketch16	$STATE@Arm Pins	$STATE@Battery Pin	$STATE@Pin Points
3	Vectorisation	25	15	25	40	25	10	60	U	U	U
4	Kenan	25	15	25	40	25	10	60	S	S	S
5	Test	15	10	25	35	15	12	60	S	S	S
6											

Figure 13: Ankle design table

3. Solidworks Models:

When a subject is measured using the method described in the previous chapter, it is then possible to create special configurations in Solidworks for this subject. This section describes the way the parts are built briefly and explains how a new configuration can be added and selected, as well as how the necessary STL files are created.

3.1 Setup of the Solidworks models:

The Solidworks parts are all built in similar fashion, all the features are placed in relevant folders. Thus all the features regarding the LED spots are placed in the LED folder. This makes it easier to find a feature when the model needs to be changed. Figure 14 shows the Solidworks environment of the Right Tibia Epicondyles part. On the left the FeatureManager Design Tree is visible, it shows all the folders with the model its features. A close-up of the FeatureManager Design Tree is shown in figure 15. When a new configuration causes errors they are also shown in the FeatureManager Design Tree. If the models are used as intended, it is not necessary to use the FeatureManager Design Tree.

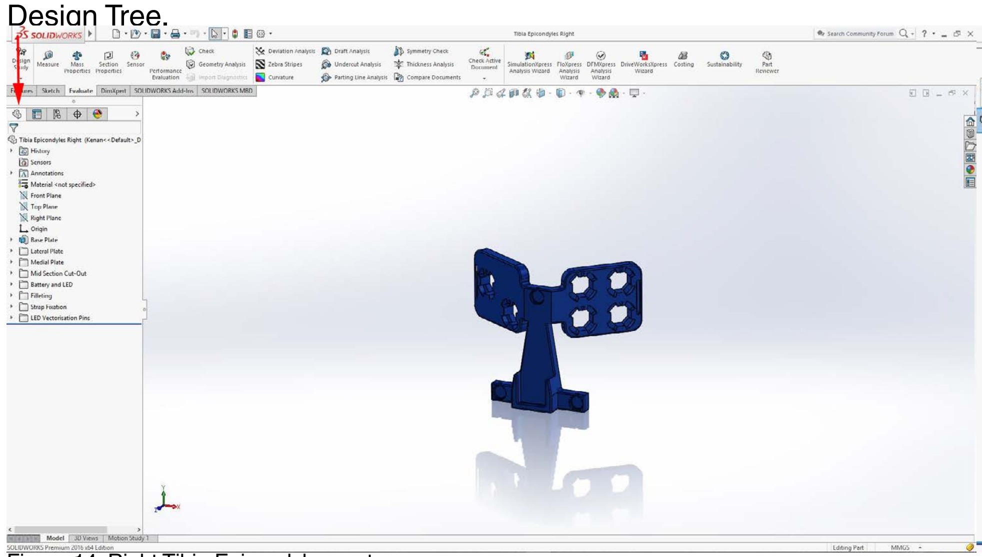


Figure 14: Right Tibia Epicondyles part

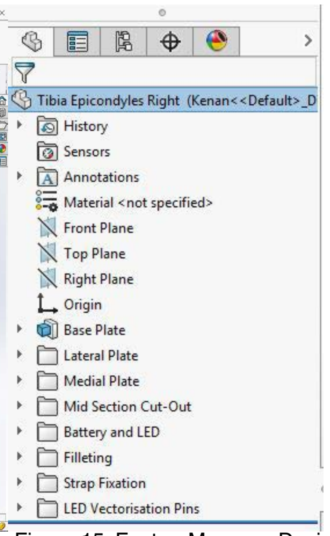


Figure 15: FeatureManager Design Tree

3.2 Selecting another configuration:

All the parts have different configurations that can be selected. For the holder parts this means that it is the same part but with other dimensions, thus the specific part for one subject. In the transducer containers case it means that a straight and angular configuration can be selected. Finally for the transducer part it means that it can be selected with and without a fictional beam representing the ultrasound wave. The configuration with beam can be used for the Vector STLs. To see and select the configurations the ConfigurationManager tab must be selected first (left picture of figure 16). Then right-click on the desired configuration and select Show configuration (mid picture of figure 16). The loaded configuration is then marked green, see right picture of figure 16

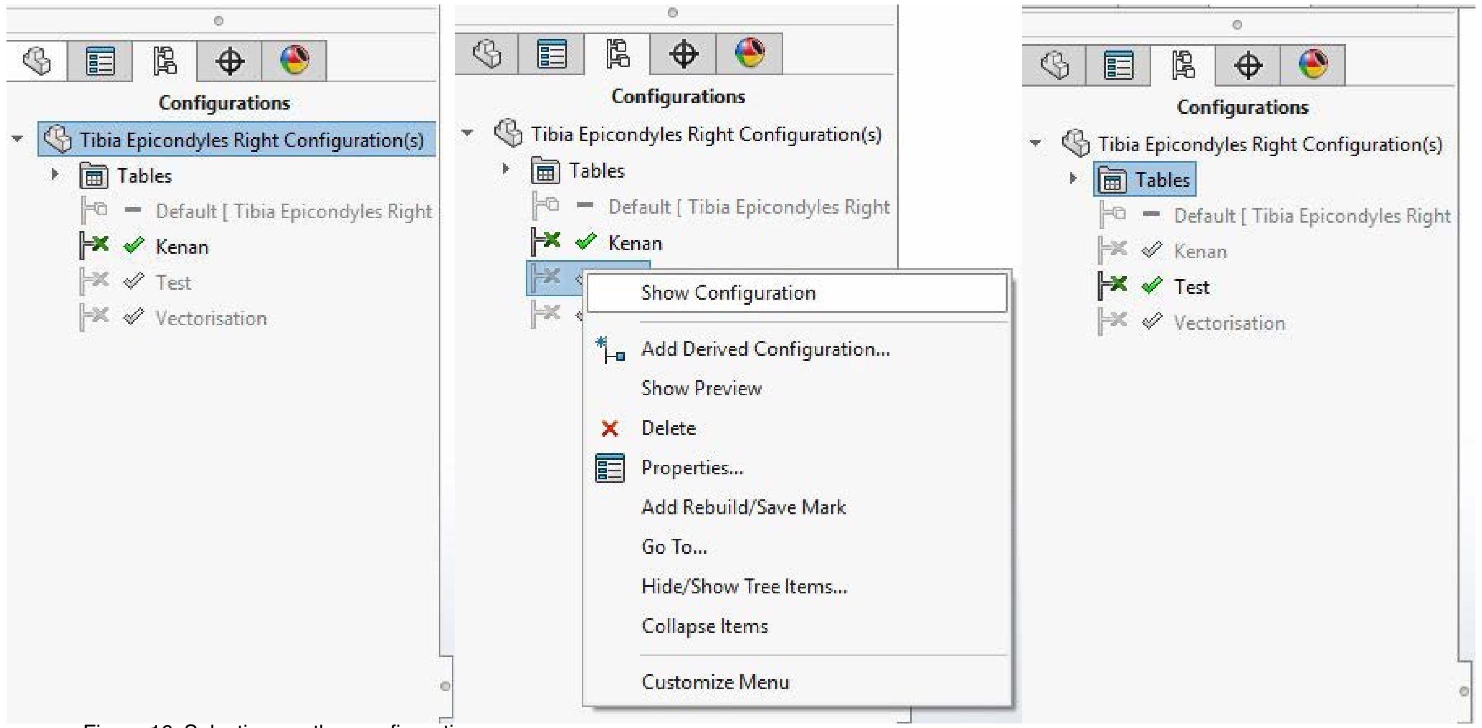


Figure 16: Selecting another configuration

3.3 Inserting a new configuration:

When a subject is measured as described in the previous chapter, the dimensions can be inserted as a new configuration into the holder parts. To do this again open the ConfigurationManager tab of the part, expand the Tables folder and right click Design Table (Figure 17). Then select Edit Table and the design table opens, this is shown in figure 18.

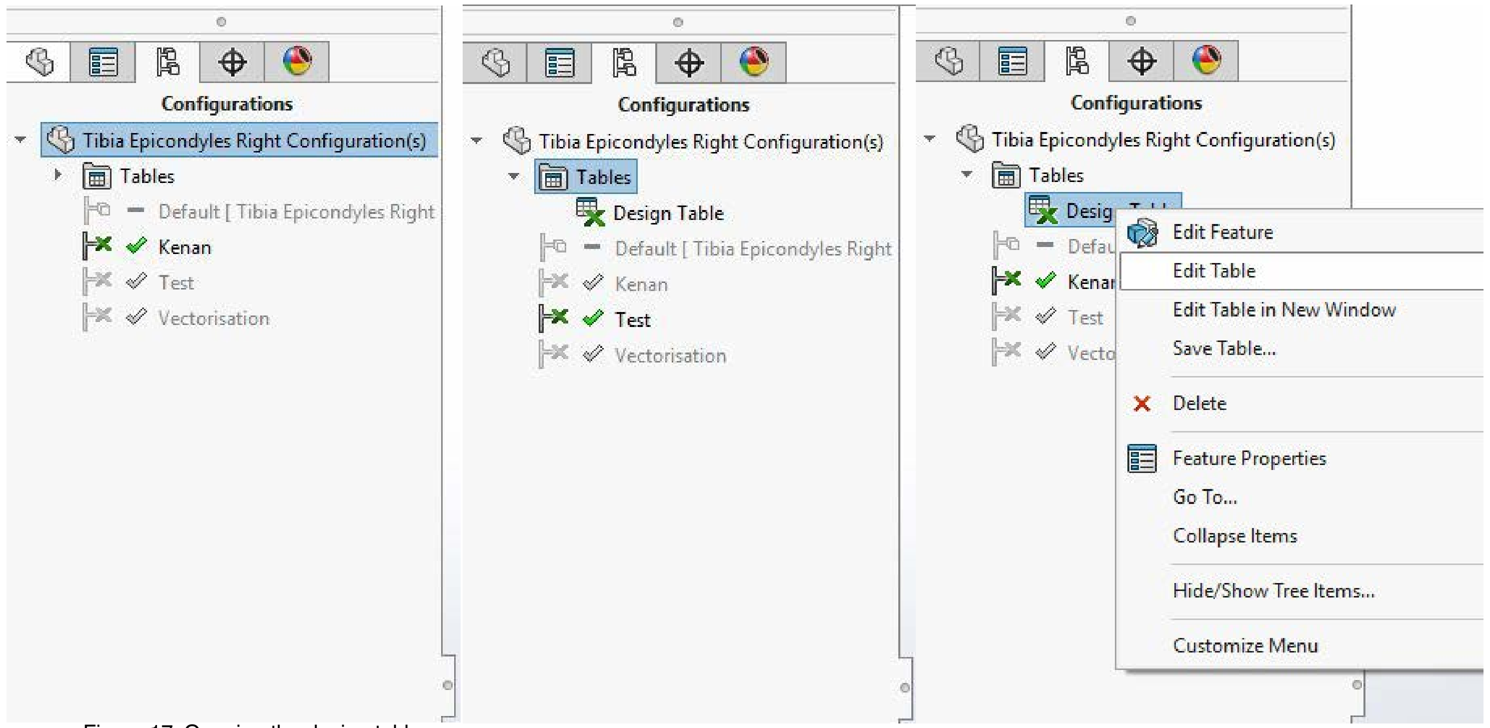


Figure 17: Opening the design table

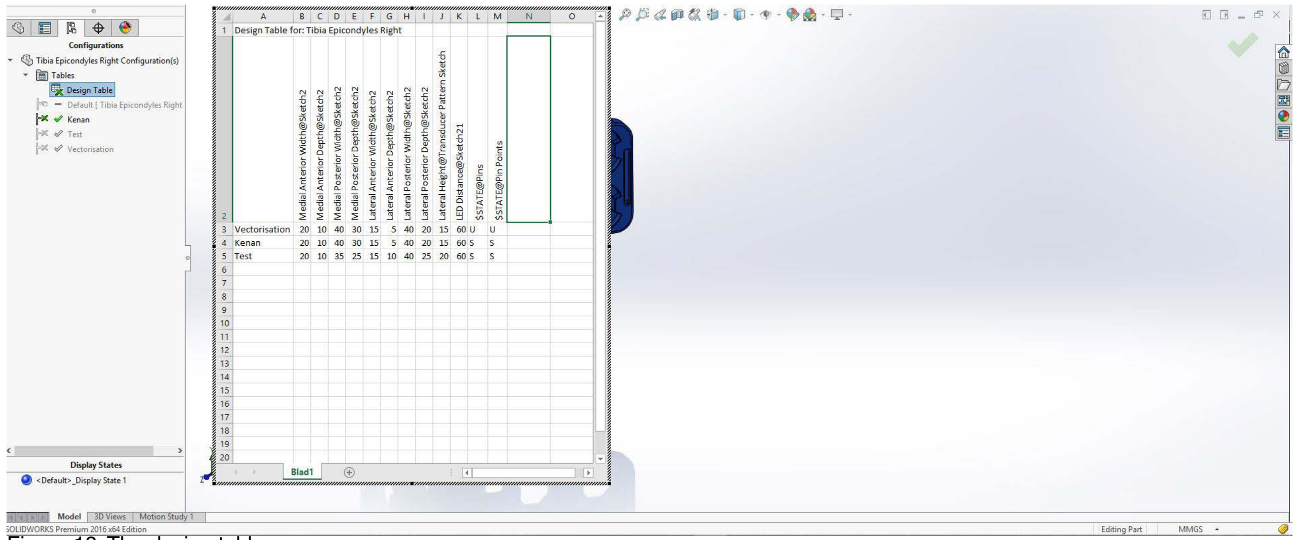


Figure 18: The design table

The first column of the design table contains the configuration names and the first row contains all the adjustable parameters. Adding a new configuration can be done by inserting a name and the values of this configuration onto a new row. An example is given in figure 19. When the new configuration is added, click on the green checkmark on the right. The design table is updated and closed and a message appears that a new configuration is generated (figure 20). When the new configuration is loaded and an error message appears, the feature causing the error is marked red or orange in the FeatureManager Design Tree. The troubleshooting paragraph in this chapter explains some commons errors and how they can be solved.

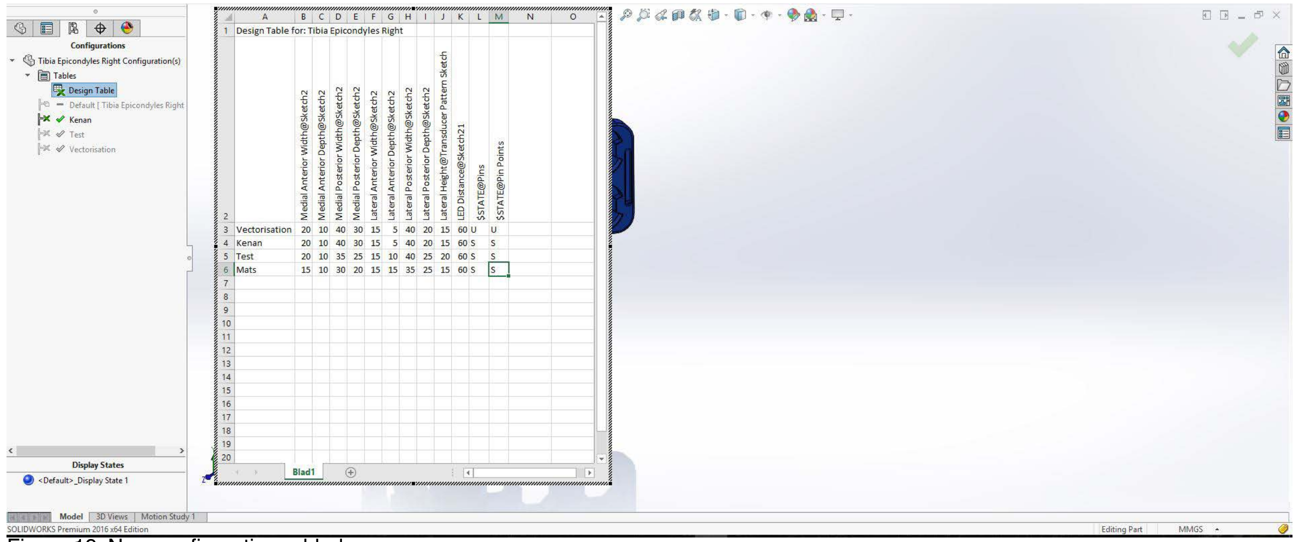


Figure 19: New configuration added.

As can be seen in the above figure the last two, or in some models three, parameters have a character as value instead of a number, they insert the pins in the model that represent the LEDs. When they are set to U (unsupressed) the pins are displayed in the model, when set to S (supressed) they are not displayed. The unsupressed version can be used in the assembly to obtain the STL for vectorisation and the suppressed version can be used to create the STL for the 3D printer, hence the suppressed version is the actual part.

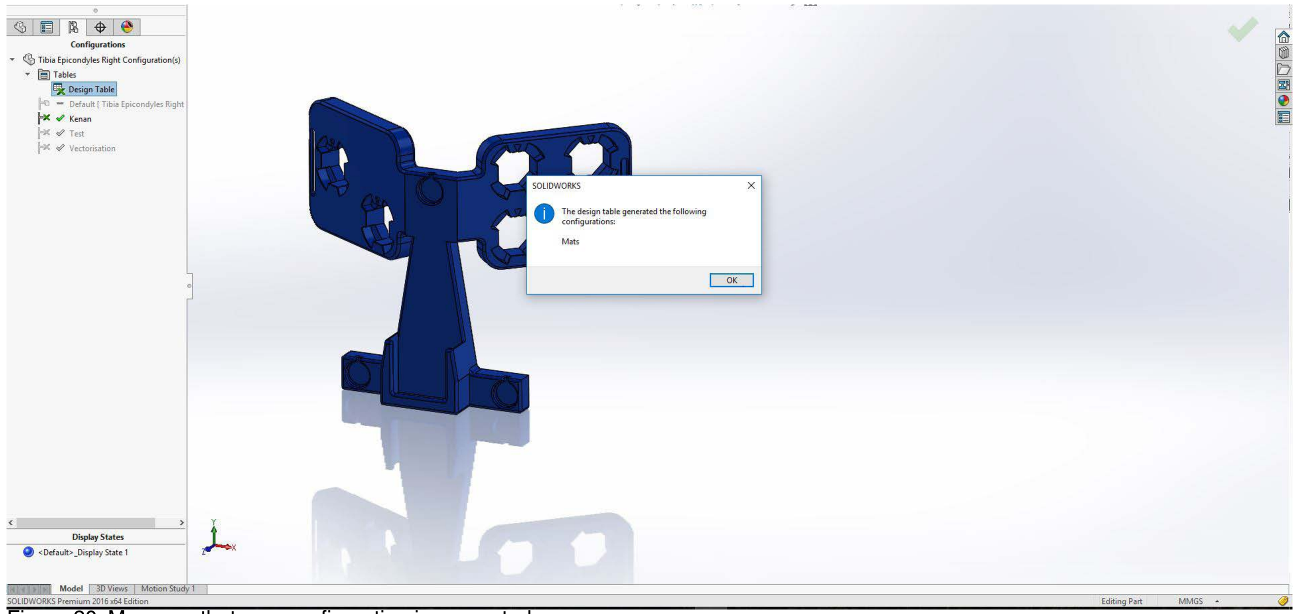


Figure 20: Message that new configuration is generated

3.4 Creating a STL file for 3D printing:

When the subject is measured and the corresponding configurations are added and checked if they are correct, the models are ready to be printed. Therefore open the Solidworks part and load the desired configuration. This should be the configuration without the pins representing the LEDs. Then go to File > Save As and select STL as file format (figure 21). Name the file as desired and save on the desired location. The generated STL file can then be send directly to a 3D printer.

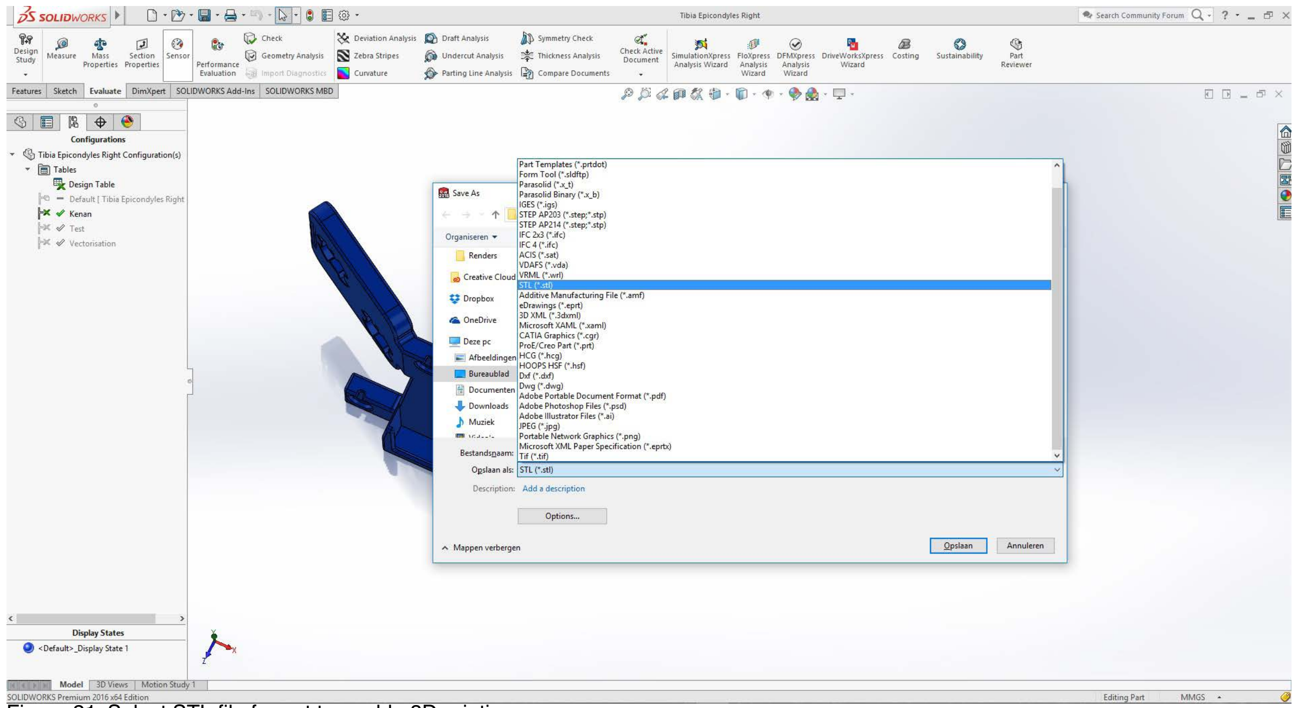


Figure 21: Select STL file format to enable 3D printing

3.5 Creating a STL file for vectorisation:

The STL file for vectorisation can be generated from the assembly of the holder part. The assembly opens with the FeatureManager Design Tree, which now shows all the parts in the assembly. The assemblies are set up in such a way that the transducers are already in the configuration with the virtual beam. Only the correct configuration of the holder part still has to be selected. This can be done via the FeatureManager Design Tree or directly in the model. Therefore right click on the model and click on the drop-down menu at the top (figure 22). Select the desired configuration and confirm by clicking on the green checkmark. The configuration of the holder is then loaded. Make sure that this is the vectorisation configuration, thus with the pins representing the LEDs.

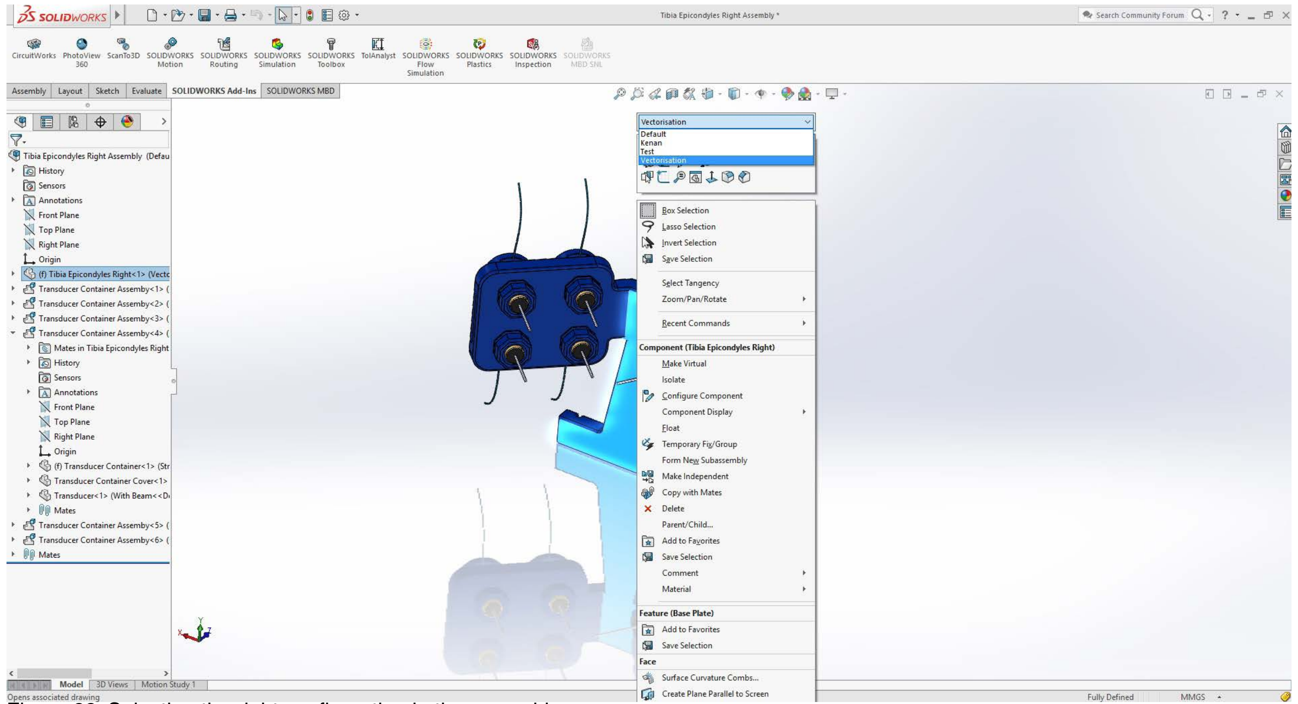


Figure 22: Selecting the right configuration in the assembly

The configuration of the transducer containers, straight or angular, can be selected in similar fashion for each container in the assembly. The transducers can also be selected without the beam, but the configuration with beam is necessary for the vectorisation. When the correct configurations of both the holder part and the containers are selected the assembly can be saved as a part. To do this go to File > Save As and select part as file type (figure 23). Then open the part file that was just created and save as STL in the way described previously. It is necessary to save the assembly as part file first, otherwise seperate STL files are created for each part in the assembly.

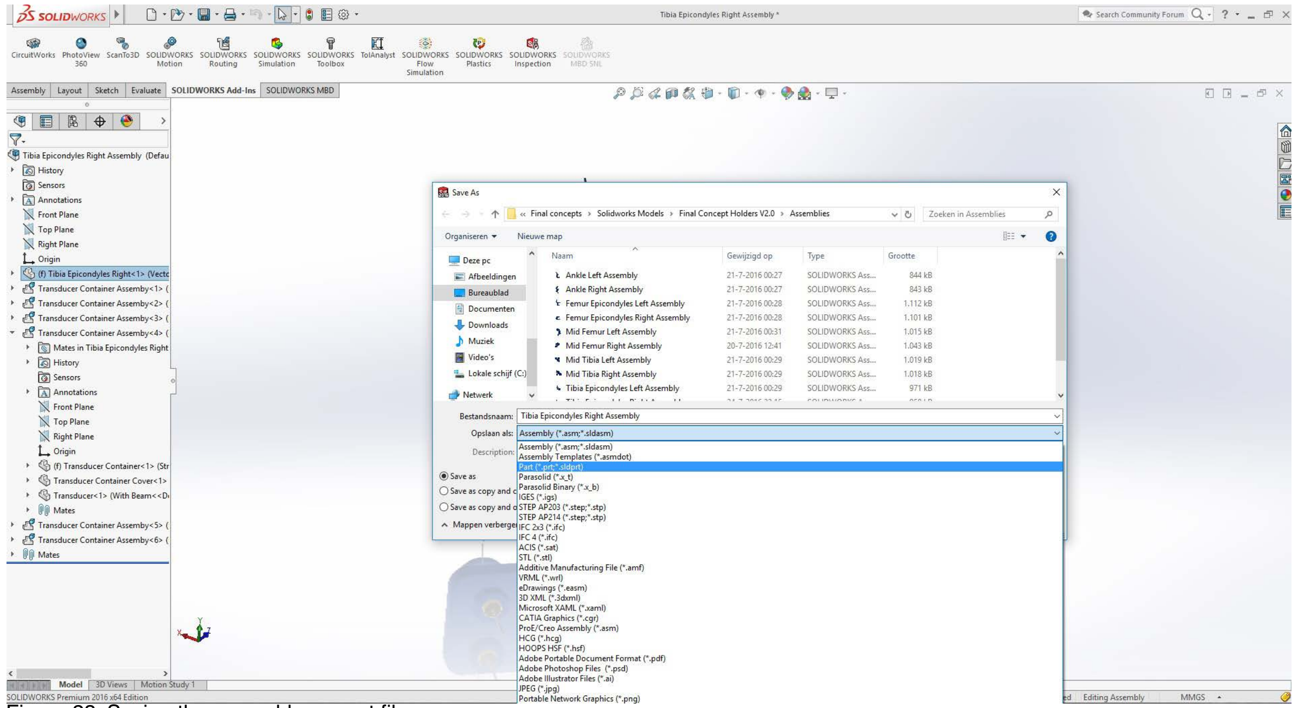


Figure 23: Saving the assembly as part file

3.6 Troubleshooting

When a new configuration is added, it is possible that this causes the model to rebuild with errors. Two of the most common errors are an invalid geometry and a filleting rebuild error. A fast fix is described here for those who are not familiar with Solidworks. Those who are familiar can try to solve the errors by editing the corresponding features.

Invalid Geometry:
The invalid geometry will most often not return an error message when the configuration is loaded. Therefore all new configurations must be inspected manually preventing an invalid holder geometry. When it occurs the features creating the inserts for the transducer containers overlap each other. Making it impossible to insert both the transducer containers, as there is too little clearance between the two inserts. An example is shown in figure 24, where both rows intersect each other. The solution is to increase the distance between the transducer positions, most often the depth and width of the posterior transducers. This may cause the affecting transducers to lose their signal during motion.

Figure 24: Invalid geometry example

Filleting rebuild error:
Filleting errors occur when a new configuration changes the model in such a way that an edge is changed or dissapeared. This results in Solidworks being unable to fillet the particular edge as desired and produces an error subsequently. But these fillets only make the model smoother and thus less likely to irritate the user, they have no effect on the function or the positioning of the holders. Therefore the fillet with an error can be suppressed. This can be done by expanding the folder with an error in the FeatureManager Design Tree and then right click the feature and select suppress (Figure 25). The error should then disappear.

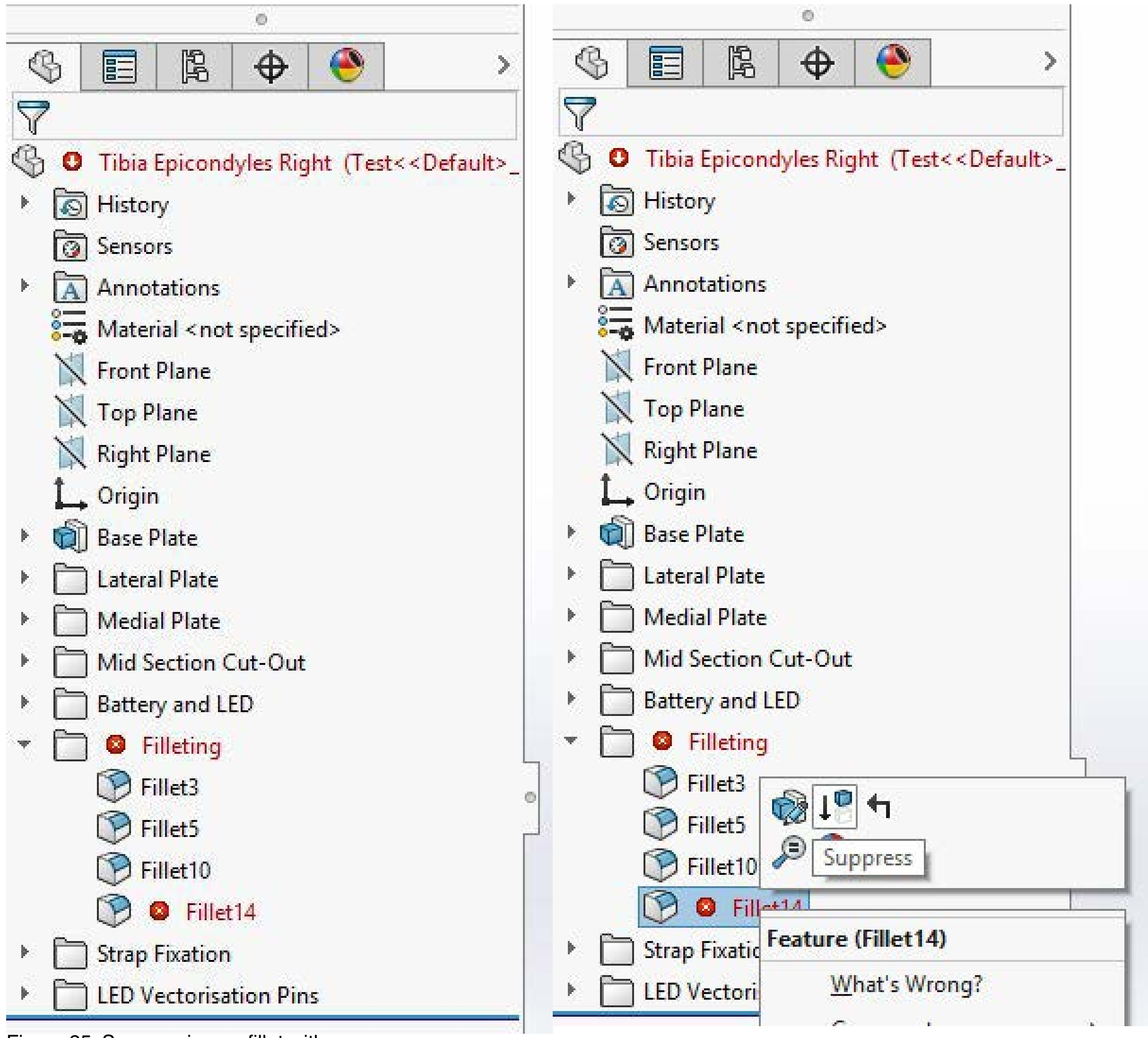


Figure 25: Suppressing an fillet with an error

4. Location testing holders:

To perform the location testing a special holder was designed. To enable repeating this protocol the original Solidworks models and STL files are included. They can be found in the Location Testing Holder V1.0 folder, as well as the data from the original testing and some rendered images of the holder. To enhance the testing, a new holder was also designed. This holder is designed to work with stainless steel retaining rings instead of snap-fits. Besides the hexagon shape of the inserts is replaced with an octagon shape, enabling the use of only one insert to aim lateral, medial, proximal and distal. The updated version can be found in the Location Testing Holder V2.0 folder. Both folders will be explained briefly in the following section.

4.1 Location Testing Holder V1.0:

The contents of the folder are shown in figure 26. First the Renders subfolders only contains some rendered images of the location holder to get a visual idea of what it looks like. Second the STLs subfolder contains the necessary STL files to 3D print all the parts. These files work correctly and should not be changed. Furthermore the subfolder Data from Original Testing contains information regarding the original testing such as pictures of the testing, final results, screenshots of the obtained M-files, an excel file with the testing protocol, the tested locations and a movie of the followed testing procedure. Finally the Location Testing Holder V1.0 folder contains the individual Solidworks parts and assemblies. With exception of the Hexagon Adjustable LT part, none of the parts and assemblies have different configurations.

Naam	Gewijzigd op	Type	Grootte
Data from Original Testing	24-7-2016 16:34	Bestandsmap	
Renders	15-7-2016 13:55	Bestandsmap	
STLs	15-7-2016 13:55	Bestandsmap	
Base Plate	25-5-2016 23:54	SOLIDWORKS Part...	671 kB
Hexagon Adjustable LT	24-7-2016 17:13	SOLIDWORKS Part...	6.262 kB
Hexagon Assembly LT	24-7-2016 17:02	SOLIDWORKS Ass...	287 kB
Hexagon Cover LT	25-5-2016 23:54	SOLIDWORKS Part...	285 kB
Location Testing Holder Assembly	24-7-2016 17:05	SOLIDWORKS Ass...	561 kB
Transducer	20-7-2016 14:07	SOLIDWORKS Part...	181 kB

Figure 26: Contents of the Location Testing Holder V1.0 folder

The Hexagon Adjustable LT part is the hexagon shaped part that contains the transducer and is inserted in the base plate. The enable 'aiming' of the transducer in different directions five different configurations of the Hexagons are made. These enable the transducer to be aimed in nine different ways: straight down and 10 and 20 degrees in lateral, medial, proximal and distal direction. The different configurations can be accessed in the ConfigurationManager tab of the part or changed in the assemblies in the same way as described previously. When loading the PD20 and LM20 configurations an error occurs, this is due an edge disappearing in the model as a result of the steep transducer shaft angle. This is not a problem and the model can be used with the occurring error. Furthermore all these configurations work with the same cover, to keep the transducer in place, and base plate.

4.2 Location Testing Holder V2.0:

In this folder the improved location testing holder can be found. Figure 27 shows its contents, who are similar to the Location Testing Holder V1.0 folder. The subfolder Renders again contains rendered images of the location testing holder and the transducers containers. The STLs folder contains the STL files necessary to print the base plate, transducer containers and container covers, as well as an STL of the complete assembly with pins to represent the LEDs and the transducer beam. This can be used to vectorise the model. The folder further only exist of the parts and assemblies of the location testing holder.

Naam	Gewijzigd op	Type	Grootte
Renders	18-7-2016 18:46	Bestandsmap	
STLs	15-7-2016 12:16	Bestandsmap	
Base Plate	15-7-2016 12:10	SOLIDWORKS Part...	868 kB
Location Testing Assembly	24-7-2016 17:50	SOLIDWORKS Ass...	884 kB
Transducer Container Cover	24-7-2016 17:26	SOLIDWORKS Part...	417 kB
Transducer Container	24-7-2016 17:24	SOLIDWORKS Part...	1.767 kB
Transducer	15-7-2016 11:32	SOLIDWORKS Part...	132 kB

Figure 27: Contents of Location Testing Holder V2.0 folder

Compared to V1.0 the snap fits are replaced with retaining rings and the model was adapted accordingly. The required retaining ring is a DIN471 with a nominal dimension of 19mm. Furthermore the shape was changed from hexagon to octagon, meaning only three different insert configurations are required. One insert is now capable of aiming lateral, medial, proximal and distal. So only a straight, angular 10 and angular 20 configuration are available, where 10 and 20 are the angle of the transducer shaft. The base plate, the Location Testing Holder part, is also improved. The top LED space is now raised to prevent shadows blocking the view and causing the Visualeyez tracker to miss the LED. Furthermore the LED spots have gotten cable guides to prevent damage to the cable. An exploded view of the complete assembly is shown in figure 3 and figure 4 shows the complete assembly.

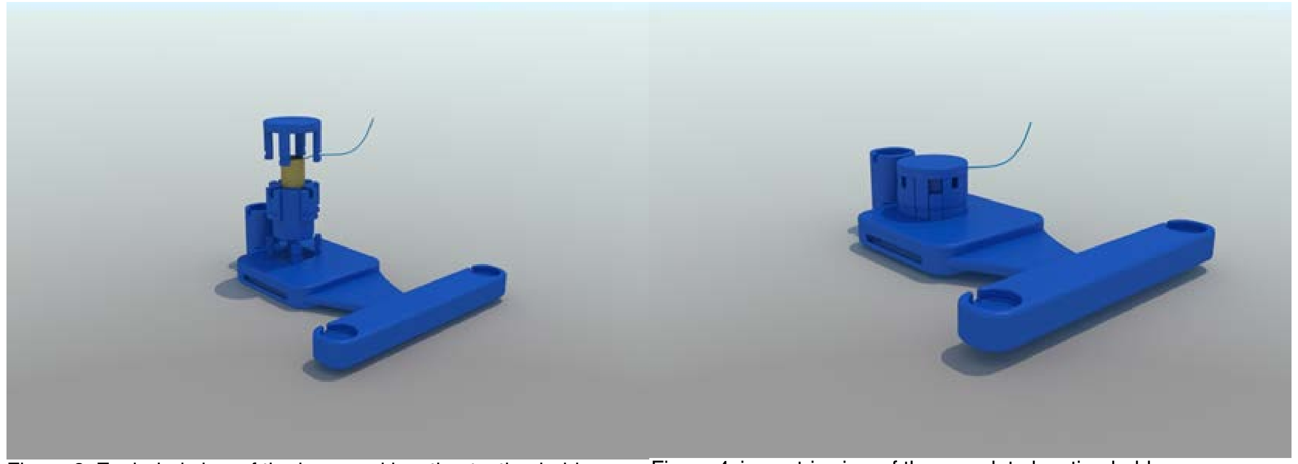
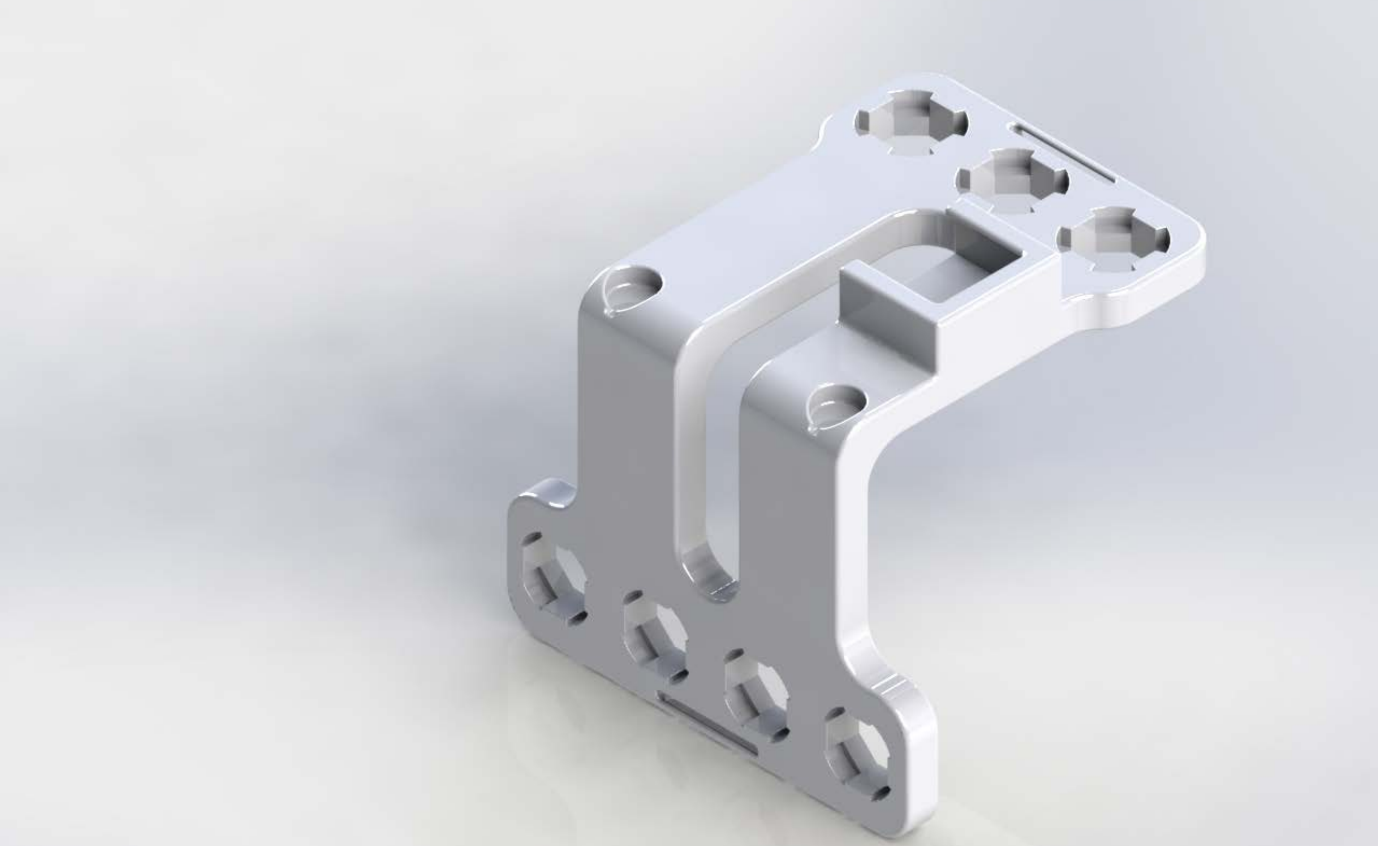


Figure 3: Exploded view of the improved location testing holder   Figure 4: isometric view of the complete location holder

Appendix I: Renders Solidworks models V1

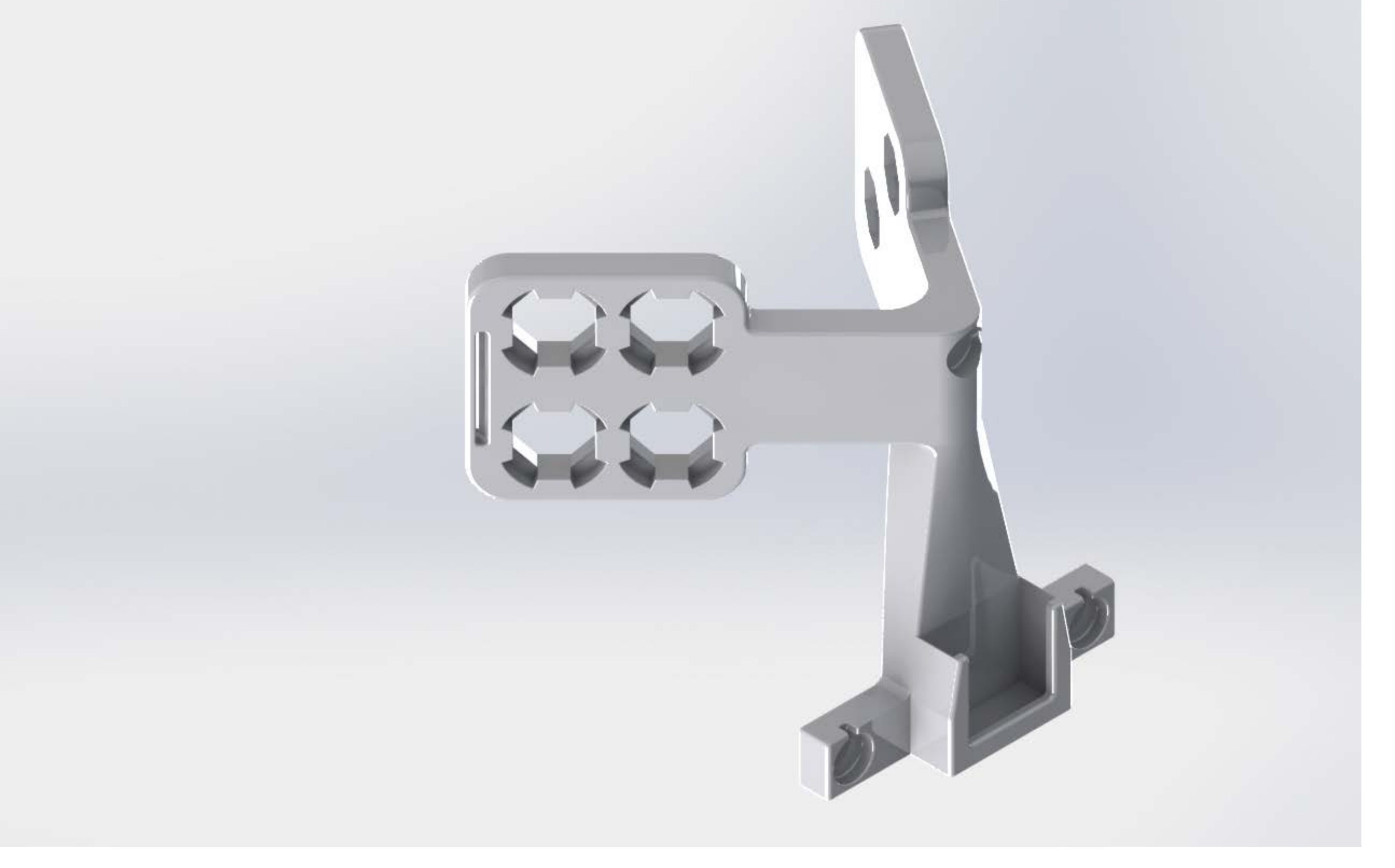
Trochanter part:

Mid femur part:

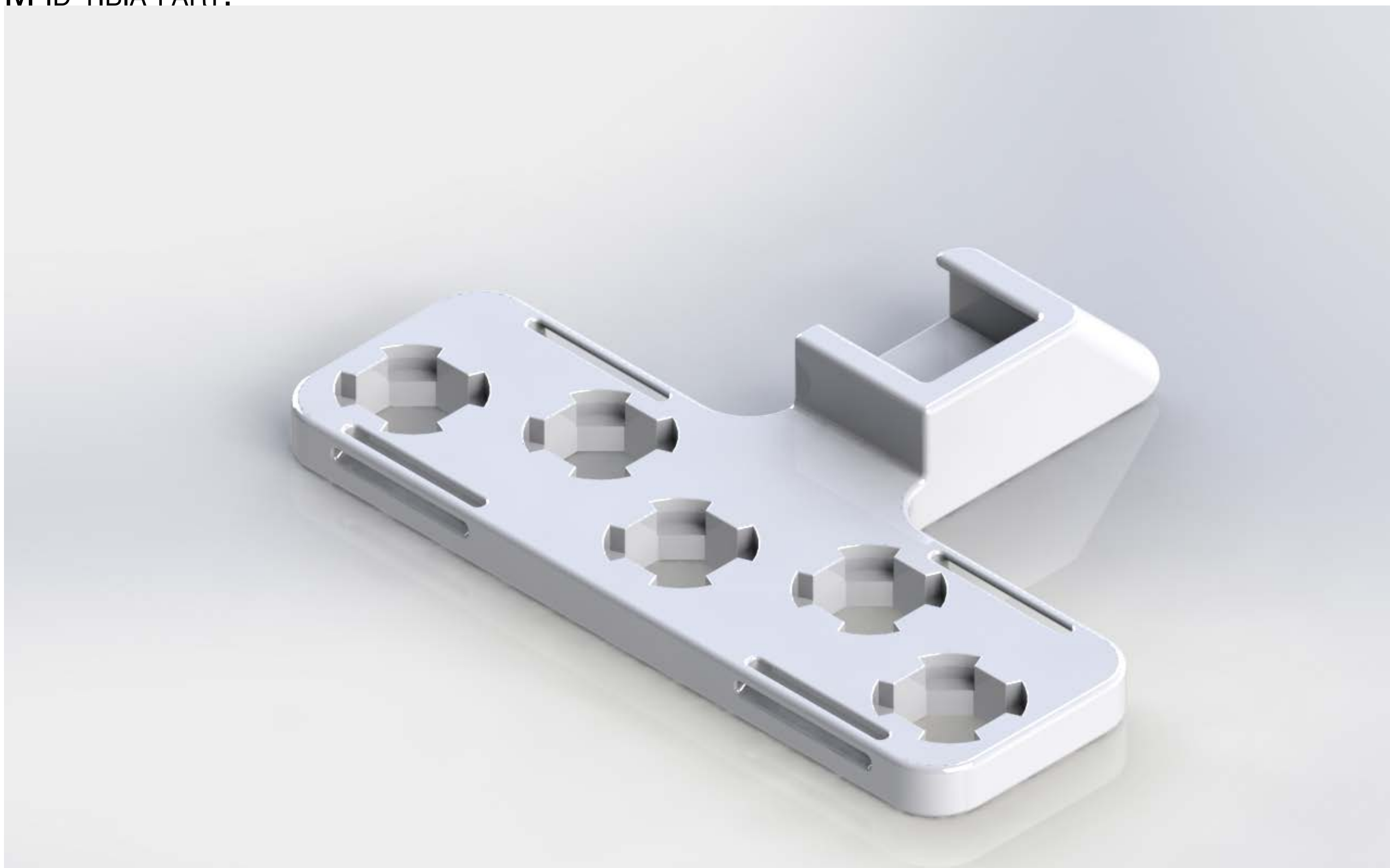


Femur epicondyles part:

Tibia epicondyles part:



MID TIBIA PART:



ANKLE PART: