UNIVERSITY OF TWENTE - MASTER'S THESIS

Testing different foot sole stimulation paradigms for experimental setup to study balance while standing still

Danny Sanders	Electrical Engineering	s2423723

SUPERVISORS:
DR. IR. B.J.F. VAN BEIJNUM
DR. IR. S.U. YAVUZ
DR. IR. E.H.F. VAN ASSELDONK

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Term list

CoP	Center of Pressure
PT	Perceptual Threshold
LF	Left Front
LH	Left Heel
RH	Right Heel
RF	Right Front
NI-Card	NI USB-6211
EMG	Electromyography
FA	Fast Adapting
SA	Slow Adapting
GRF	Ground Reaction Forces
MVC	Maximum voluntary contraction
TA	Tibialis Anterior
Sol	Soleus muscle

Summary

As people become older their chance of falling becomes higher and they will suffer more heavily from a fall. The increased chance of falling is caused by a decrease in e.g. muscle strength, a change in the walking pattern and a reduction of the number of mechanoreceptors in the foot. Using certain stimulation paradigms on the sole of the foot might help prevent falls.
This type of stimulation can be used to either increase the sensitivity of the mechanoreceptors in the foot sole or readjust the walking pattern of the subject, which can help prevent falls. Mechanical stimulation is currently used but due to issues with power and ease of use, alternatives are sought. One of these alternatives is electrical stimulation, but this type remains untested.
To test this a setup is created consisting of a stimulation device (Digitimer DS5) an EMG measurement device (TMSi SAGA) and a GRF measurement device (Xsens Force Shoes), which are controlled by a control device (NI-USB 6211). With these devices a set of pretests and two experiments are performed.
9 Subjects participated in a set of experiments, where first the perceptual threshold (PT) of several regions of their foot sole was measured and then using these results two experiments were performed. In the first experiment, stochastic noise paradigms were tested, with the expectation that under certain noise bands the area of the postural sway would be minimized. In the second experiment the effect of electrical pulse stimulation on several regions of the foot sole was tested. The expectation is that every stimulation area, has a different effect on the direction of stimulation caused movement.
In the first results, it seemed that the current paradigm of stochastic noise did not influence the postural sway, this part of the research needs to be re-evaluated and the paradigms need to be changed. In the second result a clear difference was shown in variability of the centre of pressure (CoP) in a subject. The variability of the CoP would be higher after the pulse for both the X and Y direction. The effect of stimulation was however not observed in every measurement and so optimization is still needed.

Contents

1 Introduction

Humans are becoming older on average, and with old age the body starts to deteriorate, eye sight and hearing become worse, muscles and bone structure become weaker and there is a decrease in the functioning of the sensory system. This causes the elderly to fall more often and suffer more serious injuries from a fall[1]. Annually approximately a third of the adults aged over 65 suffer at least one fall, of which a third results in a serious injury[2].
The increased chance of falling is not the only attributable to these causes. Other causess that also can lead to an increased chance of falling are an altered gait, related balance deficits, increased sway of the body and quicker fatigue build-up. In some cases these effects can be lessened by a healthier lifestyle or a work out regime[2], but this on its own cannot compensate for the weaker balance system.
One pivotal discovery is the effect of stochastic noise on balance position. Several research papers have shown a decrease in natural sway during and after stimulation with stochastic resonance. This effect is attributed to a higher sensitivity of the mechanoreceptors due to stochastic resonance[3] [4]. Using stochastic resonance might thus decrease the natural sway in elderly, creating a more stable balance position.
Another important discovery is that for different areas where the mechanoreceptors are stimulated there are different effects. The paper of Zehr et all. discusses the effect of ambulatory steering of the foot and shows that stimulation at different stimulation sites have different effects[5]. If these reactions can be mapped, they could be used to stabilize the walking gait of an elderly person, by correcting their walking gait using stimulation.
The current state of the art method of stimulation of mechanoreceptor is the mechanical stimulation in the form of perturbation or vibrations. This method is reported to be most lifelike, but its application is bulky, is not energy efficient and generally has a high mechanoreceptor stimulation range.
Stimulation of the mechanoreceptors is stated to have the following effects:[6]

- Mechanical stimulation induces a predictable reaction dependent on the stimulation site.
- Mechanical stimulation can improve postural stability by reducing postural sway.
- Mechanical stimulation can change automatic responses during postural instability.

An alternative for this method is electrical tactile stimulation, this method requires a smaller setup, is more energy efficient to use and has a better resolution than mechanical perturbations but is also reported to feel less natural at higher stimulation amplitudes[7]. Electrical stimulation is thus an alternative for mechanical stimulation, but it is not certain if the effects of electrical and mechanical stimulation will illicit the same effects.
Thus, one of the paradigms that will be tested is stochastic noise. It is unclear what the noise exactly influences. Zippenfennig et al. name two theories. Mechanical noise either adds power to the subliminal stimulus, increasing its transmission through the skin, or noise directly influence the mechanoreceptors, causing small changes in trans-membrane potential, which result in a higher level closer to the depolarization threshold[8]. This theory also seems to hold up for electrical noise, as some effects can be observed during electrical stimulation[3].
Our expectation is that during stimulation using stochastic noise, an electrical stimulation pulse train will affect more neurons during stimulation at a lower amplitude. This in turn will create a greater effect on the centre of pressure of a test subject. Also due to

stochastic noise, the CoP is expected to return to a balance position quicker than without stochastic noise. Outside of pulse stimulation intervals, the displacement of the CoP from the mean should be smaller.
Another subject that will be looked into during this experiment, is the effect of the location of the electrodes on the effects of electrical stimulation. The paper of Sonnenborg et al. discusses the effect of stimulation through electrodes on several places on the foot showing different responses in the EMG of the tibialis anterior and the Soleus muscle[9].
As in the paper of Strzalkowski et al. it is discussed that the distribution of the Pacinian throughout the foot is not uniform, but location dependent, some regions shows a higher distribution of Pacinian corpuscle than other regions[10].
Most similar experiments that are performed, use small, specific areas of the foot. But since the distribution of the Pacinian is uneven in the foot, using a central anode and several cathodes placed around it at equidistance could net unexpected effects. Logically, stimulating left to centre and stimulating right to centre is stimulating in different directions. It is unclear if this will illicit different effects in this case.
Two types of measurements can be used to inspect the effects of mechanical stimulation. Ground reaction forces (GRF) can be analyzed to check the direct effect of stimulation. Factors that can be looked into can be the mean deviation from the mean, maximum deviation from the mean, speed of the sway, acceleration of the sway, and area of the sway.[4]
The other type of measurement that can be looked into is the electromyography (EMG) of a subject's muscles. Stimulation of the mechanoreceptors, especially the fast adapting (FA) mechanoreceptors show muscle responses in the Tibialis Anterior (TA) and the Soleus muscle (So). Depending on the location, the effects observed can be inhibitory or excitatory. By ensemble averaging and RMS filtering these effects can be amplified.[9]
The aim of this study is to further test the use of electrical stimulation as an alternative for mechanical stimulation. Before this is possible however, a setup must be created which both provides effective electrical stimulation, as well is able to measure the effects caused by the electrical stimulation. The system must both be validated on a dummy, as well as on a living subject. The ultimate goal of this setup is to create an electrical stimulation paradigm which shows the effects as stated by Visuex and make these effects measurable. The current goal is creating the setup and testing the current paradigms on effectiveness.

2 Background

The human balance system is complicated. Several different systems, such as the vestibular, optic, and proprioceptive have functions within it. These systems have an overlap in their function and in some cases, it is even observed that functions change or adapt due to a changing environment or loss of a (part of a) system. The balance system is highly adaptable.
In the elderly population, the overall function of the balancing system starts to deteriorate, causing an increased risk of falls. One of the areas where a significant change can be observed, is in the number of mechanoreceptors and specifically in the number of Pacinian corpuluscle in the skin.[11]
As stated, different strategies exists for maintaining balance. The proprioceptive system can be associated to standing balance, or rhythmic movement. It is governed by mechanoreceptors in the muscle tissue, but the mechanoreceptors in the foot sole also seem to affect is functioning. It is theorized that the neurons of the mechanoreceptors are interwoven with the motor neurons of the muscles, which can activate muscle reactions, or help tune the muscle response to stimuli[12].

2.1 Mechanoreceptors

Mechanoreceptors are cells in the body that are used for multiple functions. Their primary function is to create a sensation of touch, but they are also important to the haptic feedback of the body. There are four types of tactile mechanoreceptor but open nerve endings can be counted among them, although these are mostly known to react to noxious stimuli.
The four main types of mechanoreceptors can be split into two groups, the SA mechanoreceptors and the FA mechanoreceptors. The SA mechanoreceptors mainly react to slow sustained actions, like indentation of the skin, continuous applied pressure or skin stretch and will react for sustained periods of time, while the FA mechanoreceptors react to quick changes, like changes in pressure or a quick touch. It can be stated that FA mechanoreceptors are able to directly influence balance, while SA mechanoreceptors tune the response threshold for muscle reactions.
The following mechanoreceptors can be identified, a quick overview will be given, with some known functions:[12]

- Pacini's corpuscle: The Pacini's corpuscle is a FA mechanoreceptor with a large perceptive field. This mechanoreceptor reacts to quick changes in pressure. It is theorized that this mechanoreceptor is innervated with the muscles controlling the ankle and that it plays a role in maintaining standing balance.

- Meissner's corpuscle: The Meissner's corpuscle is a FA mechanoreceptor with a small perceptive field. This mechanoreceptor reacts to light touch and can only be found in primates. It is related to motion detection and controlling grip.

- Merkell cell-neurite complex: The Merkel complex is a SA mechanoreceptor with a small perceptive field. This mechanoreceptor reacts to sustained changes in pressure and is mostly used for form and texture perception. There is some speculation as to how the Merkel complex is innervating the muscles, as to make it more responsive to other stimuli.

- Ruffini corpuscle: The Ruffini corpuscle is a SA mechanoreceptor with a large perceptive field. This mechanoreceptor reacts to skin stretch. Like the Merkell, this

mechanoreceptor is speculated to influence the reaction of the muscles. Both are speculated to 'tune' muscle proprioceptive and other reactions.

Each mechanoreceptor is located at a different skin depth and this seems to be related to its receptive field. In short this means that the Meissner and the Merkell can be stimulated at a lower current amplitude, while it takes a higher current to stimulate the Ruffini and the Pacinian, see figure 1.

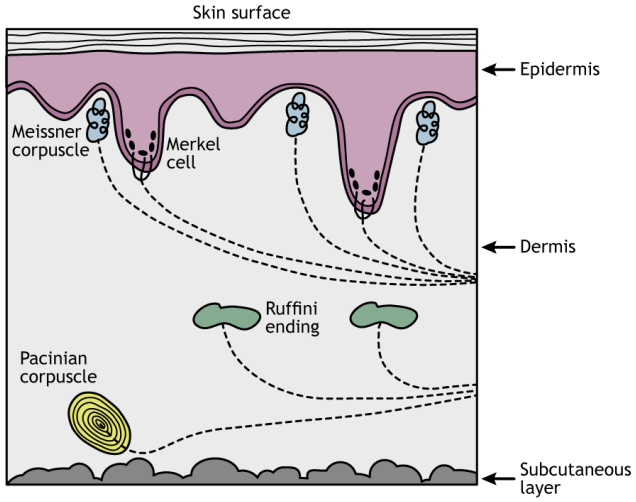

Figure 1: Schematic image of the distribution of the mechanoreceptors in the skin. 'Mechanoreceptors' by Casey Henley is licensed under a Creative Commons Attribution Non-Commercial Share-Alike (CC BY-NC-SA) 4.0 International License[13]

There are multiple theories on how the mechanoreceptors affect the postural balance, but the conditions for a reaction and the effects of stimuli that cause a reaction are still unknown.
This research will focus on the Pacini's corpuscle. This is a fast adapting mechanoreceptor which responds to changes in pressure and vibrations in the range of 20-1500 Hz, with an optimal response between 200-400 Hz[14]. Currently two main methods are used to stimulate the Pacinian and other mechanoreceptors, which are mechanical and electrical stimulation.

2.2 Neurostimulation

During mechanical stimulation, the stimulator will directly interface with the intended mechanoreceptor. This will make the mechanoreceptor create a natural action potential, which the brain will interpret as the intended stimuli. This is the most natural form of stimulation, but its application can be both bulky and not energy efficient. Creating problems that can't be overcome with current technology, without putting strain on the subject.[7]
During electrical stimulation, the mechanoreceptor is not activated directly, but its neurons are. In this way a semblance of mechanical stimulation can be achieved but it is possible that certain aspects of the natural stimulus are missing in this case. The process behind this is complex and not completely in the scope of this project, yet some background information must be provided to understand the scope of this project.
Neurons are on some basic level the data wires of the body. They sent data to and from the brain. A neuron consist of cells, which are covered by myelin sheets, except at the

nodes of Ranvier. A potential difference between the inside and outside of the neurons is maintained using certain different ion concentrations. These concentrations form what is called a Nernst potential. When the potential between the inside and the outside of the neuron changes, gates open or close accordingly letting certain ion types through, restoring the balance. When a high enough potential difference occurs, one gate letting in positive ions will open, quickly changing the potential difference from -70 to +50 mV. During this process, other gates will open, counter acting the change in potential and restoring the potential balance.
This quick increase in potential is called the action potential (AP) and is used to propagate electrical signals along neurons. This is normally done at nodes of Ranvier, where an AP at a neighboring node will create an AP in the next node. It must be noted that AP's propagate in one direction.
An AP can also be created using electrical stimulation. As the neuron is mostly isolated from the outside, the potential outside of the neuron can be lowered, creating the situation in which an AP can occur. Changing parameters in the stimulation can change the frequency at which AP's occur. More factors that influence the amount of AP's that can occur in a certain time frame are stimulation amplitude, the drop off in potential between nodes, the circumference of the neuron and the stimulation frequency.[15]

2.3 Propagation of the electrical field

The simplest way to represent an electric field is in a static, homogenous, isotropic medium. Representing the electrodes as two point current sources, one moving into the medium, the other going out of the medium.
For every stimulation, an optimal current path can be calculated. This path is the route on which the electrical current will face least resistance and this is the path electrons are most likely to follow. However, like cars on a highway, electrons will not move in a single file, but distribute themselves over an area along the path. Further away from the optimal path, less and less electrons will be encountered. This effect is visualized in figure 2.

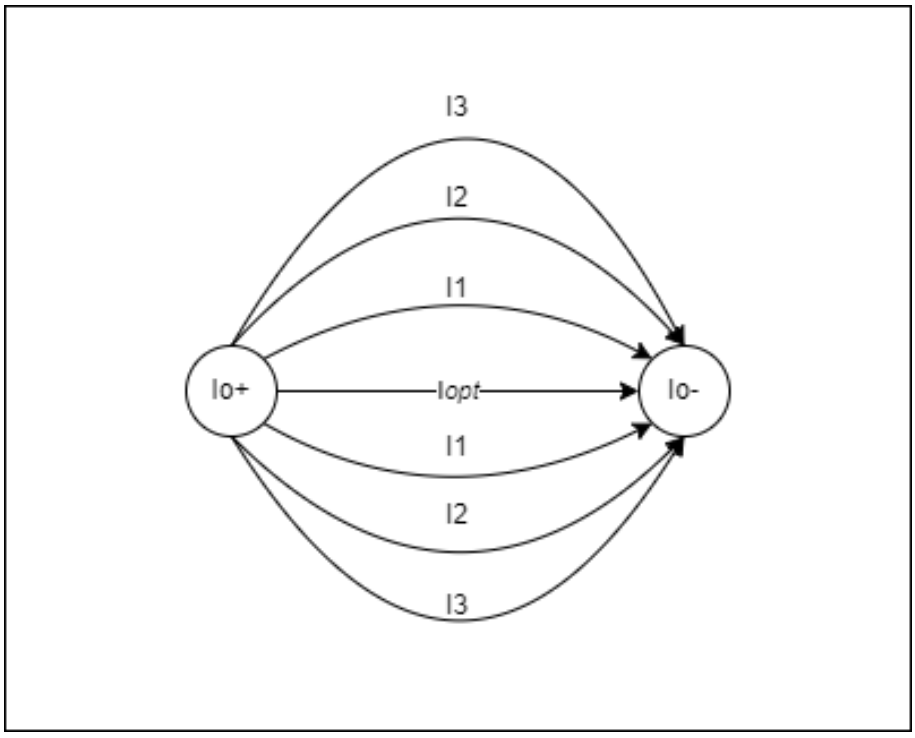

Figure 2: Schematic representation of the distribution of the electric field in a homogenous medium. With Iopt > I1 > I2 > I3.

Following Kirchhoff law, the potential along every line must be the same, to get the same potential with less current. The resistance along the path must be higher in equal measures. So for every line counts:

$$I_1 * R_1 = I_2 * R_2 = ... = I_n * R_n \tag{1}$$

This is simple enough in a homogenous, isotropic field with symmetrical axis, but the situation in which this experiment is performed is far from that. For instance, the electrodes are not point charges but have a current distribution. They will be placed on the foot sole, where part of the electrode is connected to the foot sole and part to the air, where the relative conductivity of air is significantly lower than the relative conductivity of the foot sole. The foot sole also consists of multiple layer, of which some are anisotropic[16].

Skin

The first problem that is encountered is the skin. The skin is not a homogenous media, it consists of multiple layers of different types of material, each with their own resistive and capacitive properties, some of which are also anisotropic (conduction in x direction is not the same as conduction in y direction). The build and distribution of these layers differs per person and thus the perceptual threshold is different for every person.
The layers of the skin that are significant for this project are the Stratum corneum (calluses), the Vital epidermis, the Dermis and the fat layer. Of these layers the vital epidermis and the dermis are anisotropic and the stratum corneum has a relatively high resistivity. The Pacinian can be found between the dermis and the subcutaneous fat layer and is the deepest located mechanoreceptor.
Taking into account the following conductivities and layer depth:

heightLayer	Conductivity (σ in S/m)	Layer thickness in mm
Stratum corneum (X, Y, Z)	$5 * 10^{-4}$	0.748
Vital Epidermis (Z) Vital Epidermis (X, Y)	0.15 0.95	0.213
Dermis (Z) Dermis (X, Y)	1.62 2.57	5.1
Subcutaneous fat	0.025	9.7

Table 1: The conductivity and layer depth of the several layers of the foot sole, according to Frahm et al[17].

A rule of thumb in electrical engineering is that the current will always take the route with the least resistance. Using this rule it can be stated that most current will pass through the Dermis, followed by the Vital epidermis, some will pass through the subcutaneous fat and the current will only pass through the Stratum corneum to reach the layers above it or the opposing electrode. It must be noted that the layer thickness used here, is taken from the experiment notes of[17] and may not be representative of an average human.
The problem that now occurs is that the optimal path is not straightforward to find anymore, and that the branching paths are also not symmetric. The skin adds an extra layer of complexity to the problem. This is added onto by the next problems. See figure 3.

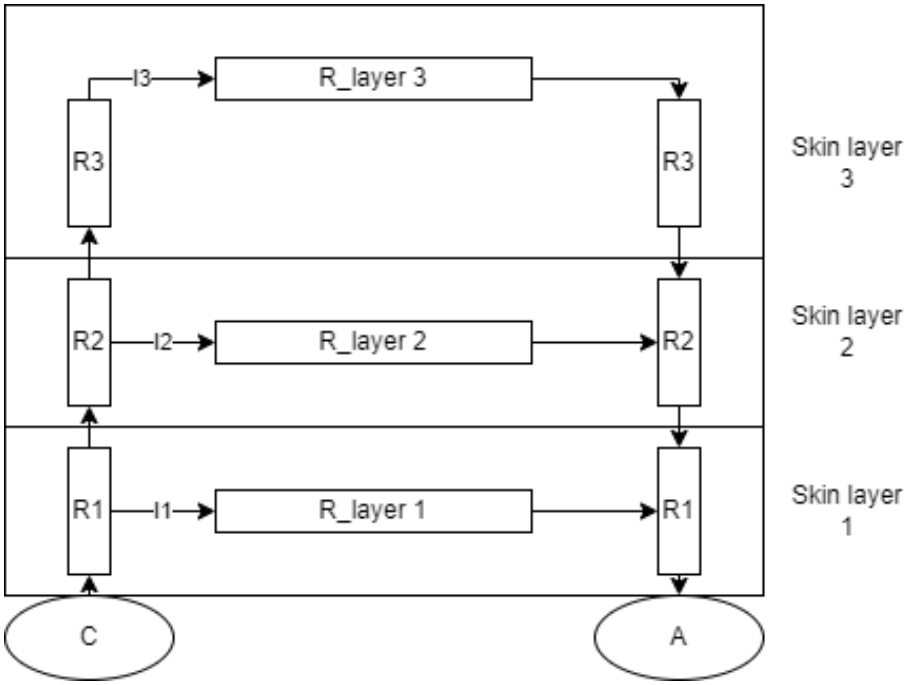

Figure 3: Schematic representation of the skin resistance.

Effects of parameters
As stated earlier, the current will not be provided by point charges, but by electrodes. Because of this some additional effects will take place. For instance, the greater the electrodes contact area with the skin is, the more spread out the current will be. The trade-off here is that with smaller electrodes it is easier to stimulate deeper neurons, with the drawback that a smaller area is stimulated.
So where a point charge stimulates a concentrated area with great depth, an electrode will stimulate a wider area with less depth. This also means that with an increase of size, an increase in stimulation amplitude is also needed to reach the same depth. See figure 4 for a schematic representation.

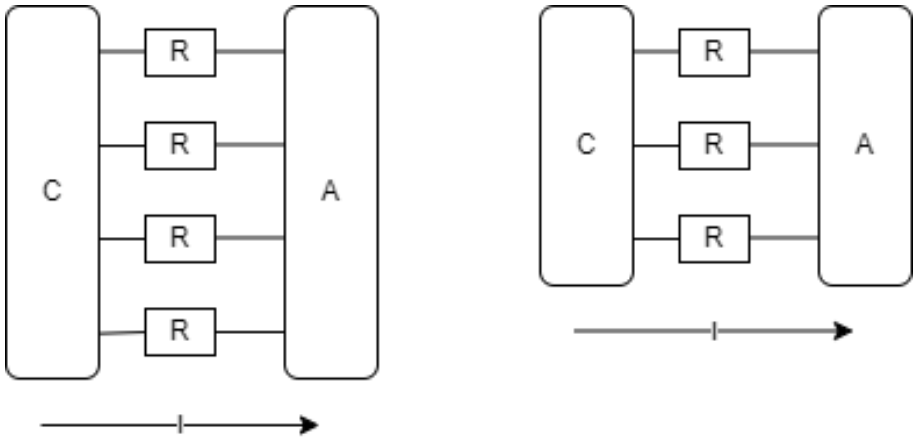

Figure 4: Schematic representation of the effect of electrode size.

Another parameter which effects the stimulation depth is the current. The current division through the skin is constant for an electrode setup, but the effective current through a certain area will change. This can create some extra penetration, although within limitations.
Two limiting factors can be named, firstly the maximum tolerance of the skin. As is logical, from some stimulation intensity on, the stimulation will start causing damage to the skin. As this is not a wanted effect, the current must be limited.
A second limiting factor is the potential/power that can be provided. Electrical equipment is limited in the amount of power it can supply, so if the active resistance between the electrodes becomes too high, the equipment cannot deliver the required potential and thus the stimulation will be limited. In this scenario, it is possible that no depolarization will take place, although the equipment delivers the right amount of current/potential.
A final parameter which effects the stimulation depth is the electrode distance. The upper layer of the skin has a high resistance and an electrical current will normally follow the path with the least resistance. So logically, when two electrodes are placed very closed together, the path with the least resistance is the shortest path, but when the electrode distance becomes larger, it becomes more beneficial to travel through the deeper, less resistive skin layers. See figure 5.

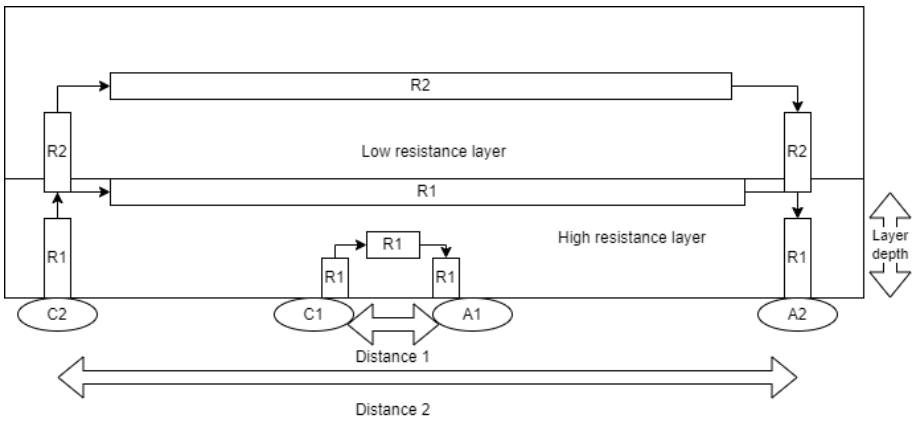

Figure 5: Schematic representation of the effect of electrode distance on stimulation depth.

Non-static stimulation
The stimulation that will be performed creates a non-static electric field. Because of this the earlier statement that the capacitive properties of the skin can no longer be ignored.

Logically, the optimal path taken by the current will change over time. The initial path taken will be in some way controlled by the capacitive properties, but in a steady state (controlled DC voltage) the path will be generally different. This will influence the effect of the pulse width, a higher capacitance means that a either a higher stimulation frequency or wider pulse width is needed to activate the neurons.

3 Materials & Method

A system using two sensors and a stimulator (TMSi SAGA, Xsens Force shoes and an Digitimer DS5) were tested in experiments. The goal of the experiments was to observe if electrical stimulation of the footsole under certain parameters showed effect and to check if these effects could be made measurable using an EMG and GRF sensor.

3.1 Measurement setup

In this section the research population and measurement setup setup will be discussed.

Research population

9 university students (5 female) with an average age of 24 +/- 2 years old, an average weight of 70 +/- 13 kg, an average height of 178 +/- 19 cm and an average shoe size of 42 +/- 4 standard European size were recruited into this study. All subjects went through the same experiments. No different groups were created for these experiments. All subjects were informed of possible risks and signed a consent form. The research protocol received a non-WMO statement under dossier number 2023-16309.

Electrical stimulation

We will use 2 different stimulators in this study. During the first and the second experiment, the foot sole will be stimulated using the Digitimer DS 5[18] which is a constant current isolated bipolar stimulator with a CE certificate. The Digitimer works in combination with the NI USB 6211[19] (NI-card). Where the NI-card provides the stimulation pattern in potential that the Digitimer converts to current, following ratios of 10 V : 10 mA, 10 V : 25 mA or 10 V : 50 mA. Stimulation will take place in the form of pulses or stochastic noise. The NI-card can be controlled using MATLAB. The second setup will be discussed in appendix D

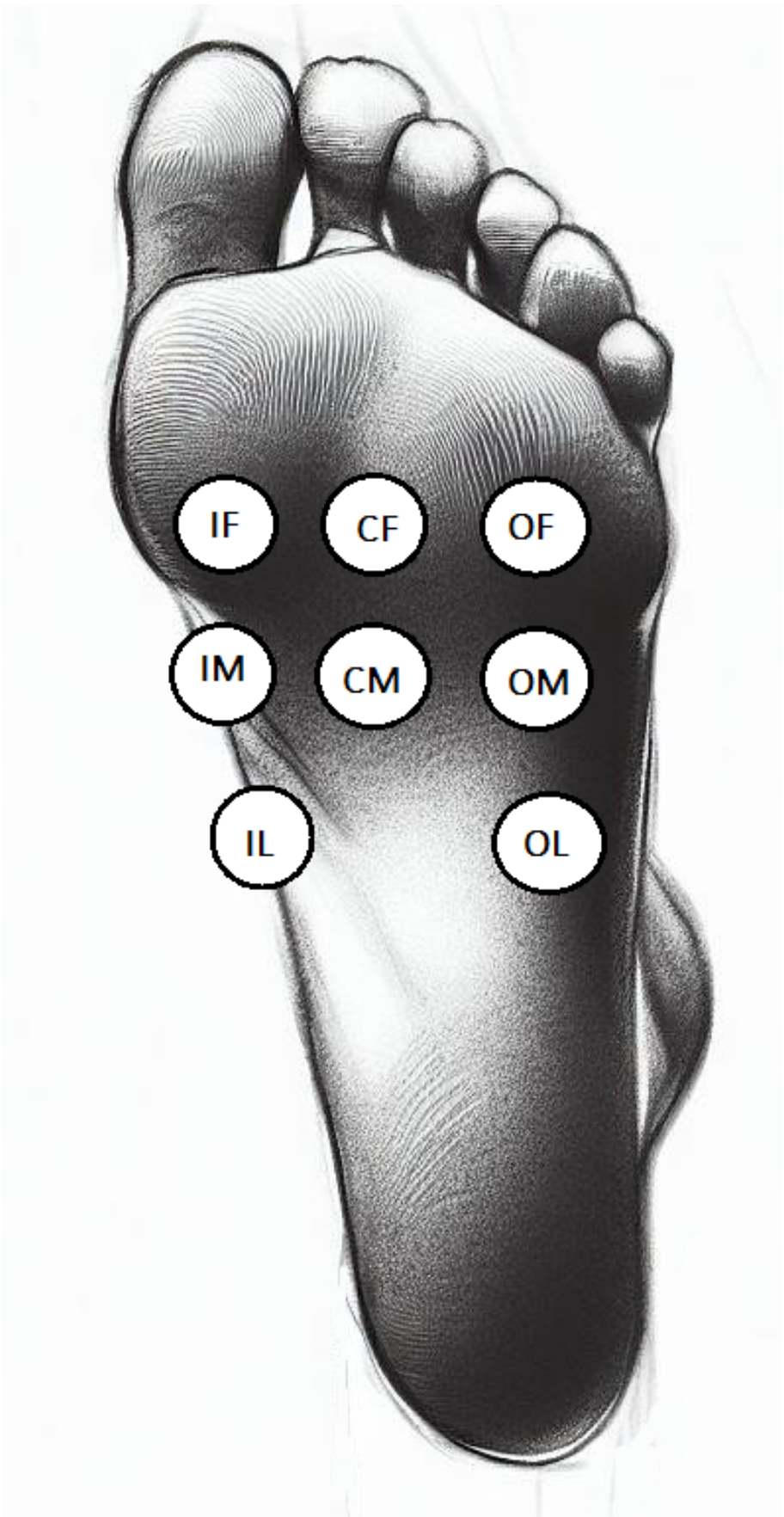

Figure 6: A schematic representation of the foot with an indication of the electrode location

The stimulation electrodes that will be used for these tests are Axelgaard Pals circular 25 mm diameter stimulation electrodes. They will be placed in a rectangular pattern, with a spacing of about 2 centimeters between electrodes. 8 electrodes will be placed following the configuration in figure 6. Electrodes are either anodes or cathodes during one experiment, but their function may vary in between experiments. The electrodes that are used and their configuration will be explained in the experimental protocols.

Measurements

The measurements will consist of two synchronized types of measurements. A non-invasive EMG measurement and a non-invasive GRF measurement will be performed, and by using these GRF measurements, a subjects centre of pressure (CoP) will be calculated. Synchronization of the devices will be done using the NI-card.

The non-invasive EMG measurement will be done using the TMSi SAGA [20]. The measurements will take place using a wired connection and a sampling frequency of 4000 Hz. Two pairs of bipolar electrodes will be placed, one at the soleus muscle and one at the tibialis anterior muscle, which are antagonistic muscles and either inhibit or excite plantar movement, [6] and a common ground electrode on the subject's ankle. The electrodes that will be used for EMG measurements are the Kendall H124SG electrodes.

The subjects center of pressure (CoP) will be measured using the Xsens Force Shoe [21]. From the force shoe measurement data set, the GRF in Z direction is taken and from that measurement the CoP is calculated. The force shoes have a sampling frequency of 100 Hz and a slave mode in which they can be triggered through either NI-card or Arduino Uno. This is done for synchronization purposes.

The setup can be visualized in the following way:

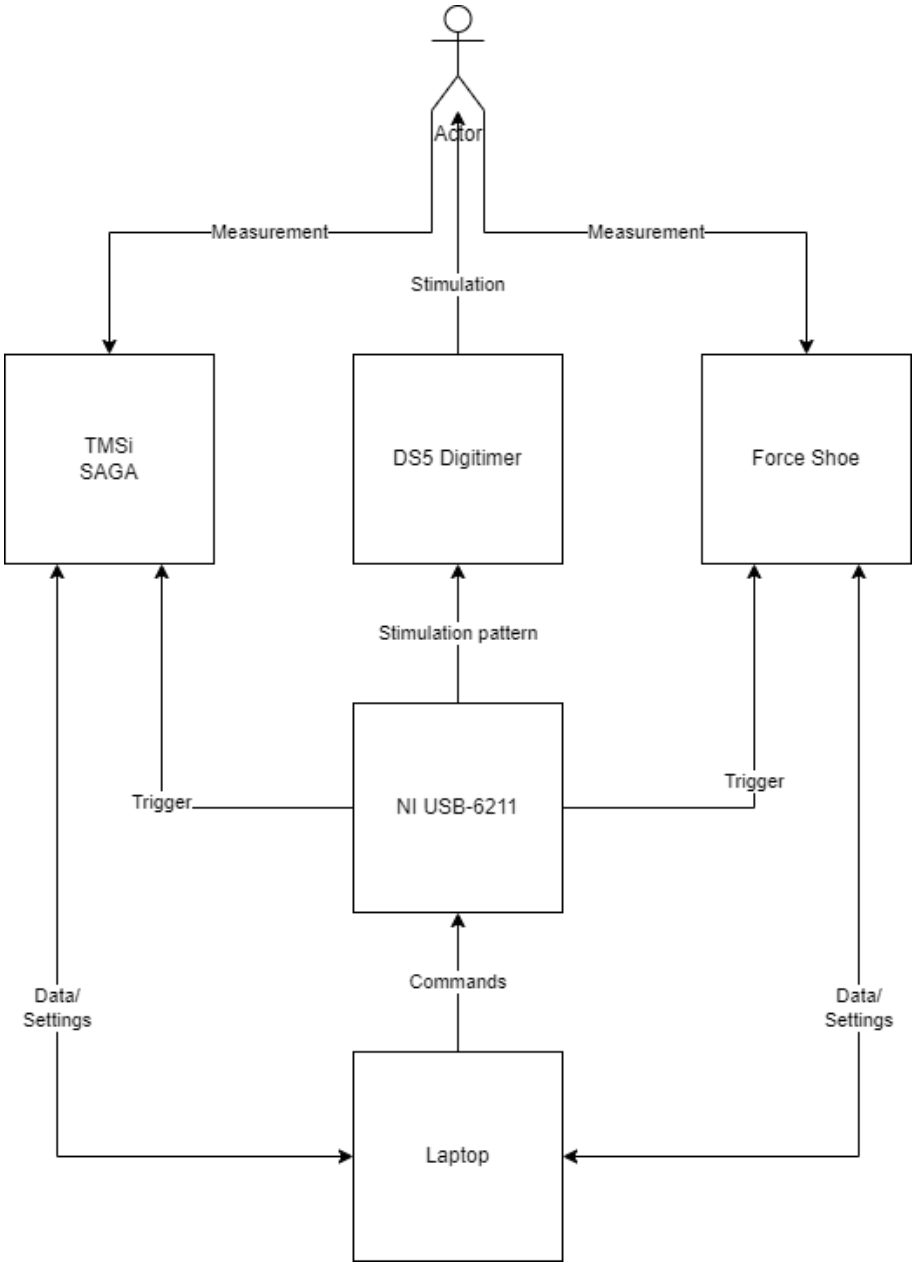

Figure 7: A schematic representation of the setup used in the first and second experiment

3.2 Force shoe test

It was unclear how the force shoe functions in a static situation. For this reason a method was developed and tested to ensure the correct function of the device.

Rationalization

As the test was done to validate the function of the device, only one participant was used. The provided documentation and earlier experiments in which the force shoe is used, are in an ambulatory situation for which a dynamic setup is used, with multiple sensors. In this setup, the force shoes will be used as a stand-alone tool to calculate the centre of pressure (CoP). To achieve these calculations, some changes and simplifications are made to the protocol used by Refai et al.[22]. From these simplifications, one calculation method was created. This method only uses the force in Z direction to calculate the CoP.

These measurements will be compared to CoP calculations gained from the ViCon at the Roessingh.
The Vicon system is a device used at the Roessingh rehabilitation facility to measure walking patterns. It consists of a force plate and camera system which can accurately measure both ground reaction forces, moments of the foot, which are both measured by a force plate and foot position, which is measured through markers. This system is seen as a golden standard.

Formula
The formula derived from Refai et al. is as follows:

$$CoP = \frac{F_{z,LF}}{F_{z,tot}} * Pos_{LF} + \frac{F_{z,LH}}{F_{z,tot}} * Pos_{LH} + \frac{F_{z,RF}}{F_{z,tot}} * Pos_{RF} + \frac{F_{z,RH}}{F_{z,tot}} * Pos_{RH} \quad (2)$$

In the formula Fz,tot indicates the sum of all measured forces in the Z-direction, Pos is the set coordinate of the sensor, and LF (Left Front), LH (Left Heel), RF (Right Front), RH (Right Heel) are abbreviations of the sensor positions. The CoP is expressed in X and Y coordinates. In this system, Y is in the walking direction. For further clarification see figure 8

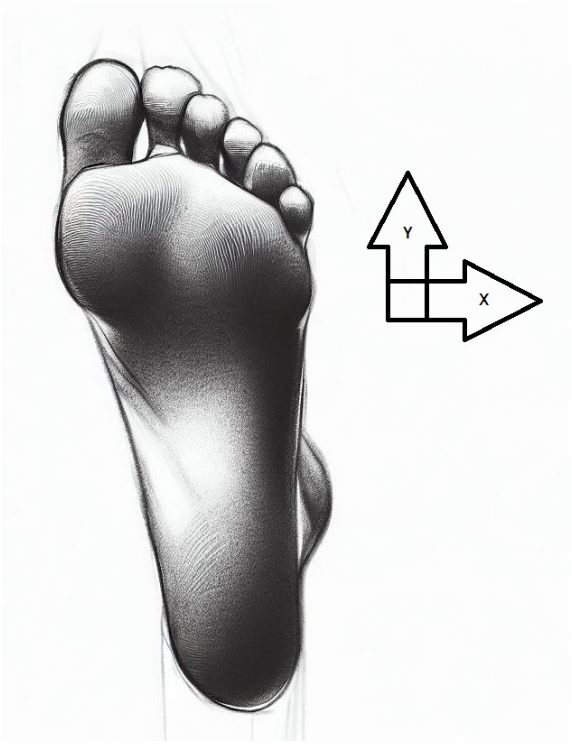

Figure 8: A schematic representation of the foot with an indication of the coordinaten systems direction

Test protocol
During the test protocol, a subject will wear the Force Shoes while standing on a force plate. Both measurements for the ViCon and Force Shoes will then be initialized. After both devices are confirmed to be measuring, the subject will start a synchronization procedure by first lifting and stamping down his/her right foot and then lifting and stamping down his/her left foot. After this one of two tasks will be performed. Either the subject will follow a path leaning forward, backward, left and right or a path leaning left front, right front, right back and left back. After this task is performed, the subject will

end the trial with a repeat of the synchronization protocol. The measurements are then stopped and the trial is completed. Each task will be repeated three times. During the test it is important that the subjects feet stay firmly planted on the ground.
The relevant data of both devices is collected using the synchronization. This is done by manually selecting 2 data points close to either of the peaks and cutting this part of the data out. The samples within the synchronization period are first visually inspected and the data will be shifted and multiplied by a constant to ensure the data matches. It is necessary to make adjustments as the force shoe data uses a defined static position to make its calculation, while the Vicon data can measure the foot position at a given time making the foot position a variable during the measurement.

3.3 Main experiment

In total two experiments and one test to determine the perceptual threshold (PT) will be performed. In this section the pre-tests performed before the experiments and the protocol of the experiments will be explained.

Initial parameters
Before the start of the actual trials, some steps are performed to optimize the signal output, and the subjects response.

1. At first the balance position of the subject is locked. This is done by having the subject stand with his/her feet at shoulder width and then measuring the distance between the feet and putting down markers. The subject then should always place his/her feet at the markers.

2. Secondly, a step will be performed to find a good placement location for the electrodes. This is done by placing the electrodes 2 cm apart and measuring the potential between electrodes during the PT test, when the potential is too low, the electrodes will be moved further apart to increase the potential.

3. The third step that is performed is the Perceptual threshold test. This test is done by stimulating between 2 electrodes with 5 pulse trains of 5 pulses with an inter pulse frequency of 200 Hz and a period of 3-6 seconds between each pulse train. At the start, the amplitude will be 4 mA (high enough that it should be felt, but low enough to be outside the neurons activation range) and will be lowered during the test. During the test, the researcher will get a visual cue when stimulation takes place, when stimulation takes place, the participant is meant to give an audio cue when the stimulation is felt. A pulse train is considered felt if the visual cue and audio cue match up. After each trail in which the subject felt all 5 pulse trains, the subject will be asked how clearly they felt the pulse trains and the amplitude will be lowered accordingly. The perceptual threshold will be determined at the point where the subject only feel 2 out of 5 pulse trains.

4. In the final step, electrodes will be placed at the soleus muscle and the tibialis anterior. To ensure correct placement (SENIAM) protocol will be followed[23] [24].

Main procedure
All experiments follow this main procedure, for which a flow chart is shown in figure 9. Before the start of the first trail, the participant will be fitted with the stimulation

and measurement electrodes following the previously explained protocols and they will put on the force shoes and lock stance, as previously explained. In between trials, the subject is asked to sit in a chair, to reduce the build-up of fatigue. During trials the subject will stand, with feet at locations marked during the optimization of their stance and eyes open. During the protocol, designated areas of their foot sole will be electrically stimulated using the parameters explained in each protocol. The foot sole will be stimulated using pulse trains of 5 pulses consisting of either 1 ms unipolar pulses or 2 ms bipolar pulses (1ms positive pulse, 1ms negative pulse)[25], with inter pulse frequencies varying between 100 and 300Hz and stimulation amplitudes between 2 and 3 times the designated PT[25] [9] [5] of the used electrode pair. Each trail will consist of 5 stimulation periods, with a randomized time interval of 4-10 seconds between each stimulation period. During the trials, EMG measurements will be done at the participants soleus and tibialis anterior muscles and their CoP is measured. Measurements will start 10 seconds before the first pulse and end 10 seconds after the last pulse. An overview is given in figure 10

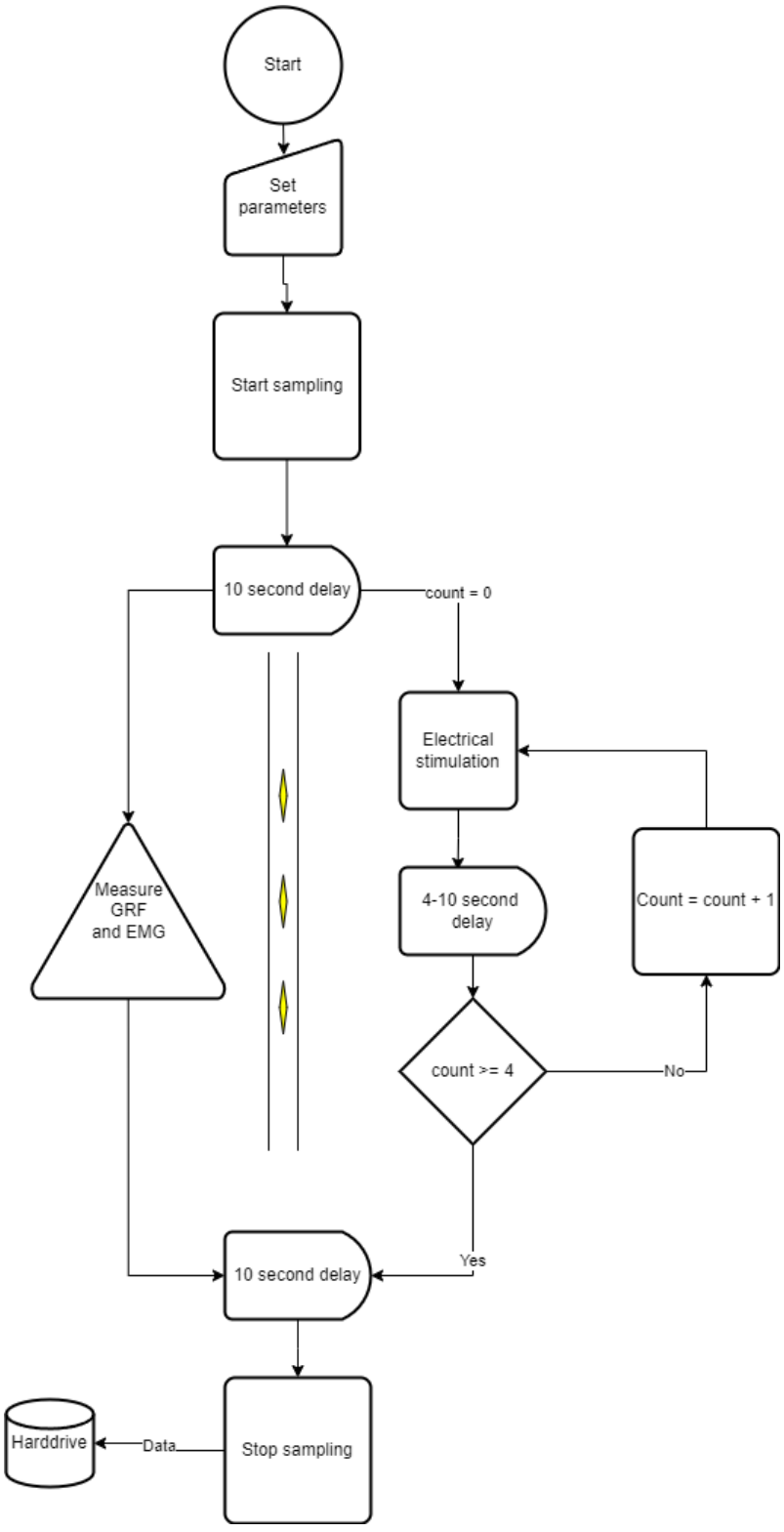

Figure 9: Flow chart of the main procedure of the experiments.

1. Frequency and noise test

For this experiment electrode pair OF and IF of figure 6 will be used. Stochastic noise is created by bandpass filtering randomly generated samples. During the whole trail, electrical stochastic noise will be added to the stimulation pattern with a stimulation am-

plitude of 0.2 times PT[26]. Each trail will consist of 5 pulse trains of 5 bipolar pulses with a pulse width of 2 ms (1 ms positive, 1 ms negative). Stimulation frequencies of 100, 200 and 300 Hz will be used and the bandwidth of stochastic noise that will be used will be 50 -500, 100 - 400 and 200 – 300 Hz. A total of twelve trials will be performed, 4 for each stimulation frequency, one noiseless test and 3 with the designated bandwidths (see figure 10. These trials will be designated as TsFf0N or TsFf0Ba-b. Where s is the subject number f is the significant number of the stimulation frequency, N indicates a noiseless stimulation and a – b indicate the two most significant numbers of the stimulation bandwidth. An explanation of the trial codes is given in appendix C.

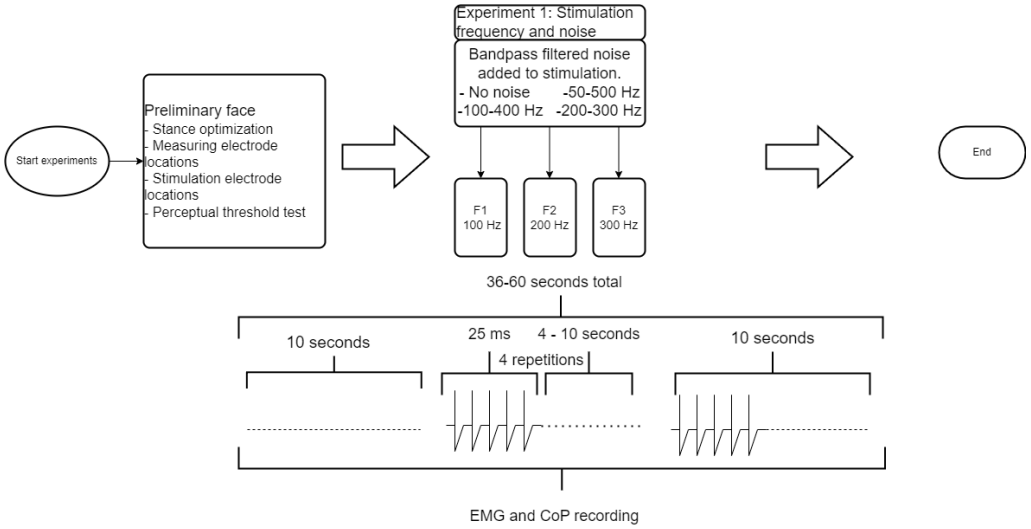

Figure 10: Flow of the first experiment, with all tests included

2. Electrode location test

For this experiment electrodes OM, OF, CF, IF and IM, will form electrodes pairs with cathode CM, (see figure 6) as anodes. During a trail, one of the cathodes will be paired with CM as anode and the area of the foot sole will be stimulated with 5 pulse trains consisting of 5 bipolar pulses with an inter pulse frequency of 200 Hz and a stimulation amplitude of 2 – 3 times PT. This protocol will be used for each electrode pair. In total 5 trials will be performed. The experiments here are designated as TsCL-AL, where s is the subject number, CL is the cathode location and AL is the anode location, cathode locations are IM (Inner Middle), IF (Inner Front), CF (Center Front), OF (Outer Front) and OM (Outer Middle), the anode location is CM (Center Middle).

3.4 Data processing

In this section the data processing will be explained and the reasoning for the chosen parameters will be explained.

Synchronization

As stated earlier, three separate devices are used in this setup. A synchronization method is used which requires further data processing using a trigger signal. This trigger signal consists of three types of pulses, see figure 11

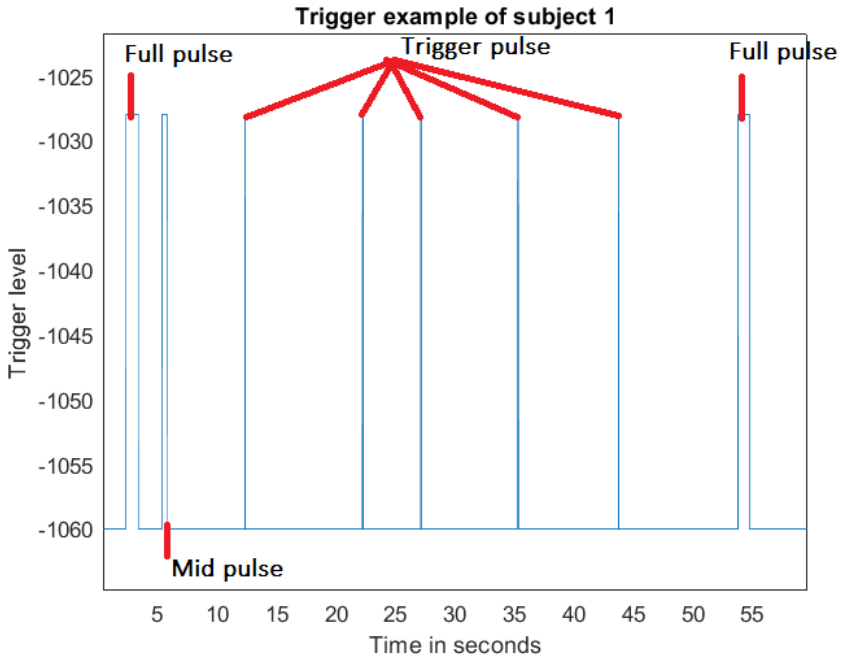

Figure 11: Example of a trigger signal

The full pulses indicate the start and end of the stimulation protocol, these occur 10 seconds before the first stimulation pulse set and 10 seconds after the final stimulation pulse. The mid pulse is used to indicate the start of force shoe measurements and trigger pulses are used to indicate when stimulation takes place.
Two cutting methods are used, the first is used to synchronize the EMG measurement and the GRF measurement. The GRF measurement starts at the same time as the mid pulse, so for synchronization all samples before the mid pulse are cut out and the time from the first sample after the cut is set to 0, synchronizing the time axis. The other method will be explained in the EMG analysis section.

Initial EMG data processing
The trigger data will be used to find the time stamps at which stimulation occurred. From these time stamp points 0.1 second before the first pulse until 0.25 seconds after the first pulse will be taken as a sample from the EMG data. Then the EMG data will be highpass filtered with a second order butterworth filter of 5 hz to remove drift and offset. The data is then ensemble averaged to filter out random behaviour and checked for a clear stimulation artefact and a reaction to the stimulation (80 – 120 ms after the pulse)[8]. This is done for both the Tibialis Anterior and the Soleus muscle.
If the data does not show clear peaking or shows other problems, it will be labeled and a note will be made about what goes wrong and a possible explanation (see appendix E. Further data analysis will be still be considered with the caveat that the data might not yield useful results.

Force shoe data pre-processing
The force shoe data will be processed using the formula derived from Refai et al.. This processed data will then be filter using a 10 Hz 2nd order low pass butterworth filter to remove system noise and smooth the data.
During testing an issue occurred with right front pressure sensor of the force shoe. Data obtained from the right front force shoe sensor was distorted, resulting in noisy data and

samples outside of the probable range. To account for this an initial test will be performed on the data. The datasets which were obtained will be visually inspected. If a relatively small amount of samples is corrupted, the data can be restored, else the subjects weight will be used to artificially create this sensor's data using the following formula:

$$F_{Z,RF} = M * 9.81 - (F_{Z,LF} + F_{Z,LH} + F_{Z,RH}) \tag{3}$$

With LF, LB, RB and RF indicating sensor positions defined earlier and M being the subjects mass.

EMG analysis
After that the EMG data will be bandpass filtered with a 2nd order butterworth filter in a range of 20 Hz to 500 Hz (active range of the EMG). This filtering is done to remove the offset and any possible drift for the lower spectrum and to remove any artefacts caused by the Nyquist frequency. A second order butterworth filter is used to minimize the time shift in the signal due to the filter. At the onset of stimulation until 50 ms after the onset of stimulation, the data samples will be replaced by zeros, to remove the stimulation artefact. A sample will be taken of the first 2 seconds of the filtered measurement, this sample is RMS filtered and the the maximum value of the sample set is collected as the normalized background noise value.
A RMS method will be applied to the filtered EMG data to better emphasize the activation of the muscles. The window length is set at 400 samples (about 0.1 seconds). This is done to better emphasis the reaction and to compensate for time shifts in the reaction. The resulting values are then divided by the normalized background noise value, as a normaliztion method. The effects of electrical stimulation in the EMG are expected to be observed between 80 and 120 ms after electrical stimulation.
The EMG (both Soleus and Tibialis Anterior) and CoP data in plantar (y) direction will then be cut in time frames of 1 second before the pulse and 2.5 seconds after the pulse and will be plotted into one plot. Only the plantar direction will be taken as that is the direction of movement controlled by the Soleus and Tibialise anterior. This plot will then be inspected on any clear movement EMG response to the pulse and any CoP responses to an EMG response. A separate analysis will be done for both experiment 1 and 2.
After this, a sample of the first 0.25 seconds after the pulse is taken per subject per trial and the maximum value of the normalized EMG in the sample is calculated. All samples are then collected and a box plot is made of the results. This is done for every trial and the results are then collected per experiment.

G.R.F. data analysis
Two types of analysis were done on the force shoe data: For the first experiment, the effects of stochastic resonance stimulation were investigated using confidence ellipses. Confidence ellipses are ellipses which contain a certain percentage of all samples and can therefore be used to get a visual indication of the overall spread of the data and the data can be quantified using the area of the ellipse. In this case a 95% confidence ellipse was used, which for a 2 degree of freedom system (2 variabels in this case) has a confidence factor of 5.991 following chi-square distribution. Two assumptions were made for this experiment:

1. The mean does not change during the experiment (Wide Sense Stationary)
2. The effect of pulse stimulation is negligible over the whole experiment

The area of the CoP displacement will be calculated and plotted per subject per trial of the first experiment. After this the samples will be gathered per trial, per stimulation frequency and per stochastic noise band and these will be boxplotted as to observe differences per trial, per stimulation frequency and per noise band.
It is expected that stimulation with stochastic noise, will make the pacinian more sensitive to changes, which will increase the reaction speed to perturbations, lowering the natural body sway. The area of the sway can be calculated using confidence ellipses, and stochastic resonance stimulation should lower the area of the sway. If the intended effect is not observed clearly, the area of the individual ellipses will be calculated and plotted in a graph, and from here on individual samples will be investigated and compared with a scatter of the significant data.
For the second experiment, the effect of pulse stimulation was investigated. Again confidence ellipses will be used but for different implications. A confidence ellipse can also show a direction or an increase in sway in one direction. The expected effect here was that after stimulation, the body would become unbalanced and a temporary shift in balance position can be observed. The expectation is that the stimulation of certain ranges of the foot will change the direction and the amplitude of the response.
The effects will be measured by taking an ensemble average of 150 samples before the pulse and 150 samples after the per trial. These ensemble averages will then be turned into confidence ellipses, where the confidence ellipse before the pulse is expected to have rounder shape than the confidence ellipse after the pulse. The expectation is that the pulses will create a deviation in the CoP. The deviation should be significant enough for to alter the confidence ellipses and change its shape.
These samples are then taken for every subject per trial. The variance will then be calculated before and after the pulse, in order to observe if there is any reaction due to the pulse. The samples will be categorized per trial and boxplotted, to observe any changes in the distribution. After this the individual confidence ellipses will be investigated for any deviating ellipses, these will then be further investigated and the calculated CoP data points will be scattered in the ellipse to see if any abnormalities can be observed.

4 Results

This chapter presents the results on the functioning of the force shoes as a GRF measurement device and functioning of the setup as a whole.

4.1 Validation and tests

In this section, the results of the tests done before the main experiment are shown and explained.

Force Shoe Validation

In figure 12 the results of the force shoe validation test are shown. The results show the CoP measurement in the X and Y plane measured by the Vicon and the force shoes using method 1. It must be noted that the Vicon data has been increased by a factor 2 in the x-direction and a factor 1.3 in the y-direction. This amplification was constant over all results. Data was also shifted to account for the measurement axis not being aligned. The other measurement can be found in appendix A.2.

It can be observed that both scatters are similar, although some small differences exist, these seem to occur at moments where there is a quick change in direction. Also the sample frequency of the ViCon is 10 times higher than the sample frequency. This shows in the scatter distribution.

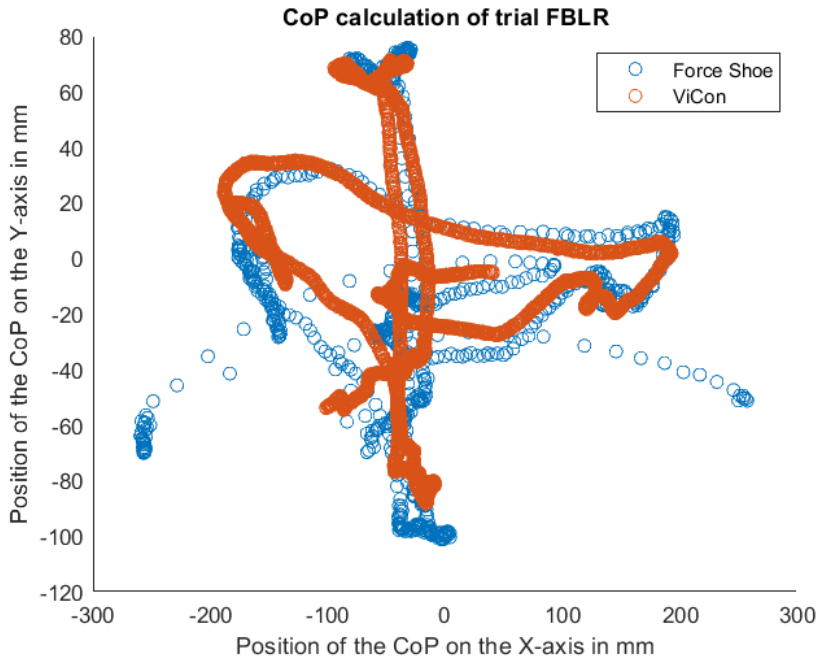

Figure 12: Plot of the CoP derived from the ground reaction forces (GRF) of the Vicon and the the force shoes, with the position of the CoP on the Y and X axis.

Preliminary test

During the preliminary test, experiment 1 and 2 were performed on a subject and the effects were analyzed to ensure correct function and find and patch possible flaws in the design. The following base data was collected using the first test (frequency = 100 Hz , no noise).

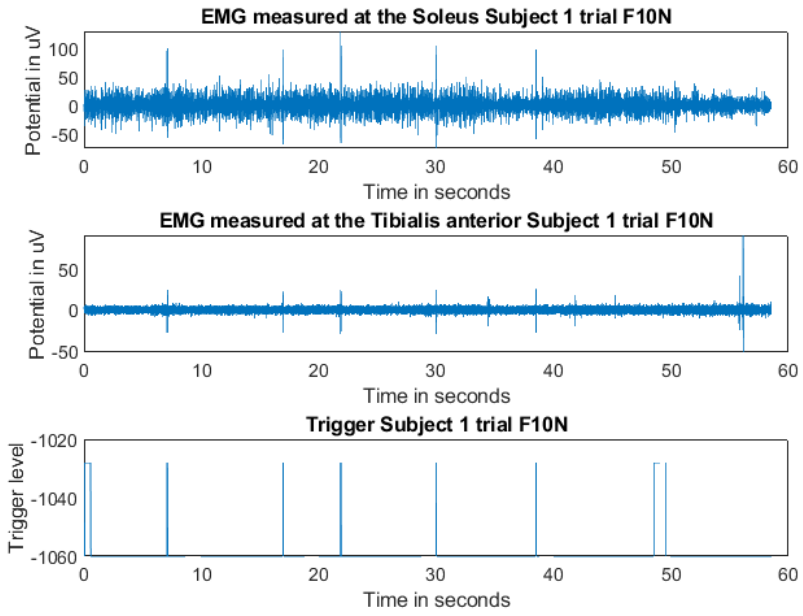

Figure 13: The EMG measured at the Soleus and Tibialis Anterior plotted against the trigger for subject 1, experiment 1 with a stimulation frequency of 100 Hz and no noise

In figure 13 the highpass filtered EMG measurements at the Soleus and Tibialis anterior and the trigger of subject 1, the stimulation frequency set to 100 hz and no noise is shown. In the top graph the EMG measurement at the Soleus is shown, in the middle graph the EMG measurement at the Tibialis anterior and in the bottom graph the trigger level. At the moment of stimulation, when the trigger level is high, a stimulation artifact can be observed in the data.

PT test

Before the experiments started, a test was performed to determine each subjects PT. The results of this test are shown in the following table:

Stimulation, Placement	mean	Range
Stochastic, LF-RF	2.88 mA	± 1.62 mA
Pulses, LF-RF	3.06 mA	± 1.44 mA
Pulses, OM-CM	2.96 mA	± 1.46 mA
Pulses, OF-CM	2.62 mA	± 1.12 mA
Pulses, CF-CM	2.94 mA	± 1.14 mA
Pulses, IF-CM	2.90 mA	± 1.40 mA
Pulses, IM-CM	2.80 mA	± 1.30 mA

Table 2: The mean perceptual thresholds found during the tests and the maximum range of these PT's. For each test stimulation type, and anode-cathode location are given. For anode-cathode abbreviations see figure 6. The complete overview is given in Appendix A.1

The mean values within table 2 are within a 0.5 mA range. Most mean PT values range within 2.8 mA and 2.9 mA. The mean measurements for pulses, LF-RF and pulses OF-CM seem to be the only measurements outside of the normal range. A complete overview of the measured PT's is given in appendix A.1.

During the PT-test, multiple subjects mentioned difficulty with perceiving the stimula-

tion due to a tingling sensation in their foot. Also, if a subject showed an overall lower PT for multiple measurements, the starting point for stimulations was lowered (from a standard 4 mA). For two subjects this starting point was increased to 5 mA.

4.2 EMG analysis

In the following graphs the EMG measured at the Soleus and Tibialis anterior is plotted against the displacement in Y- (plantar and dorsal) direction. The displacement in X-direction was left out as their should be no direct correlation between the X direction and the muscle activity in the soleus and tibialis anterior. Explanations of the trial codes can be found in appendix C.

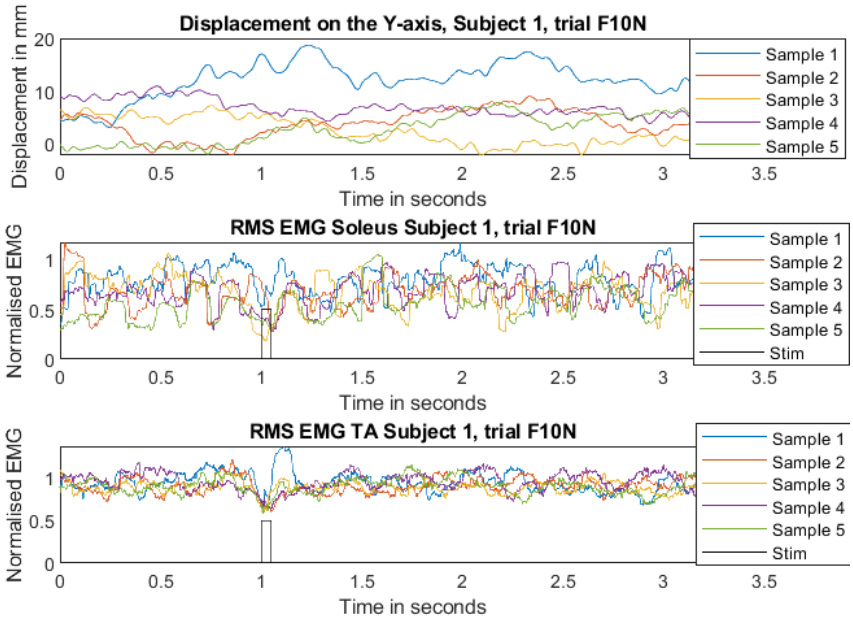

Figure 14: The EMG measured at the Soleus and Tibialis Anterior plotted against CoP in the Y-direction for subject 1 experiment 1 with a stimulation frequency of 100 Hz and no noise. The moment of the pulse is indicated by the black line in the EMG channels.

In figure 14 the plantar displacement of the CoP in the top graph and the normalized EMG measured at the Soleus and Tibialis anterior in the middle and lower graph are displayed. At the moment of the pulse the corresponding samples were made zero, which caused a clear artefact in the measurement. A root mean square method of 0.1 s was then applied to the data. Because of the zero substitution this resulted in a dip in all graphs around 1 second. After one second the first third and fifth sample of the EMG of the Tibialis Anterior show possible peaking, while the second and fourth do not. No such behaviour can be observed in the EMG of the Soleus.

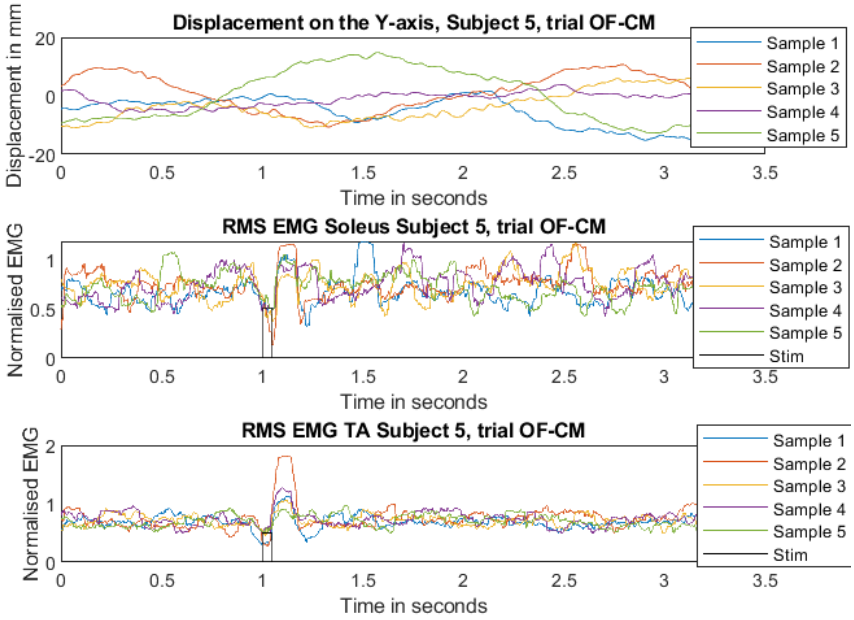

Figure 15: The EMG measured at the Soleus and Tibialis Anterior plotted against CoP in the Y-direction for subject 5, experiment 2 with a stimulation frequency of 200 Hz and electrode placement at OF-CM. The moment of the pulse is indicated by the black line in the EMG channels.

In figure 15 the plantar displacement of the CoP in the top graph and the normalized EMG measured at the Soleus and Tibialis anterior in the middle and lower graph are displayed. After one second all samples seem to show the same behaviour, a rise in potential for about 200 ms. This was designated as activation. This behaviour was observed in multiple data sets from experiment 2.
In figure 16 the maximum value of the EMG measured at the Soleus for the stochastic noise experiment is shown, normalised against the background noise. It can be observed that for most boxes the main body of the box or the 3^{rd} quartile (75% of the samples) is below 1. Some of the maximum are higher than 1.5 x background noise, and some of the outliers are as well, although only one is above 2.

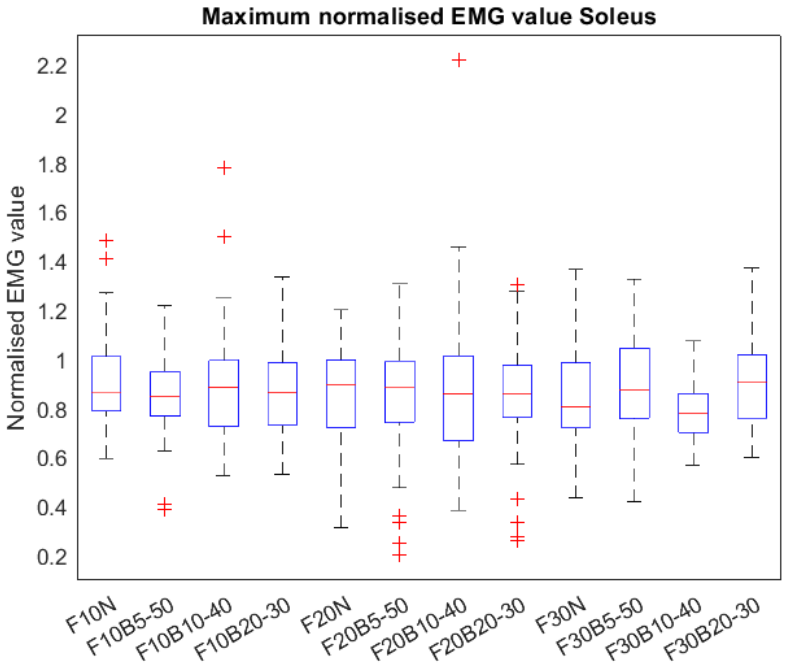

Figure 16: The maximum EMG measurement at the Soleus muscle during the first experiment, in the timeframe up to 0.25 seconds after the pulse

In figure 17 the maximum value of the EMG measured at the Tibialis anterior is shown for the stochastic noise experiment, normalised against the background noise. What is apparent from this figure is that there are many relatively high outliers going up to almost 10 times background noise level. This plot contains 45 samples per box.

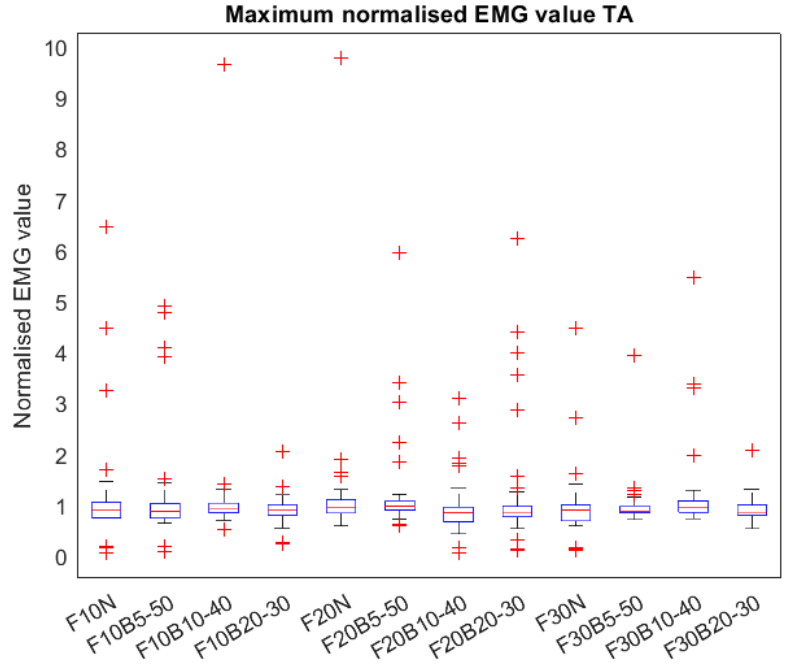

Figure 17: The maximum EMG measurement at the Tibialis anterior during the first experiment, in the timeframe up to 0.25 seconds after the pulse

In figure 18 a zoom in of the boxplots of figure 17 is shown. Again the 3^{rd} quartile of the boxplots is around 1. That counted with the high outlier values, can indicate that here

some reaction to the stimulus has occurred.

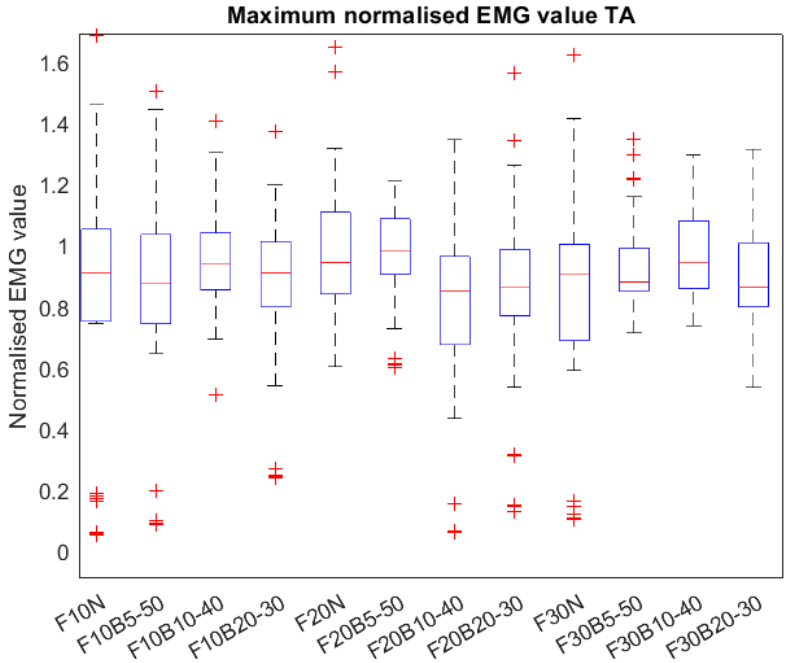

Figure 18: The maximum EMG measurement at the Tibialis anterior during the first experiment, in the timeframe up to 0.25 seconds after the pulse. The image is zoomed in on the boxes

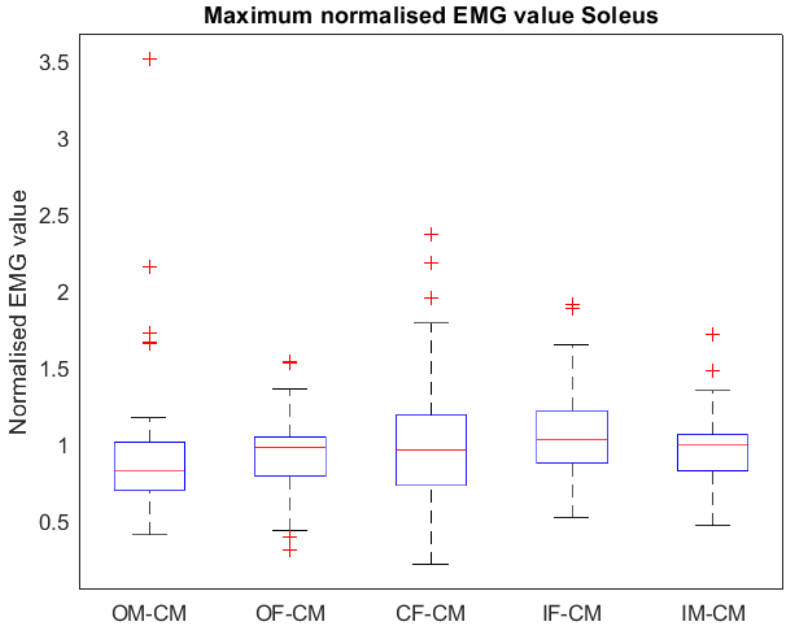

Figure 19: The maximum EMG measurement at the Soleus muscle, in the timeframe up to 0.25 seconds after the pulse

In figure 19 the maximum value of the EMG measured at the Soleus for the electrode location experiment is shown, normalised against the background noise. In the Image the median of the boxplots is around 1, so at background noise level. Only 4 samples seem to be higher then 2x background level, and these are categorized as outliers. This plot contains 45 samples per box.

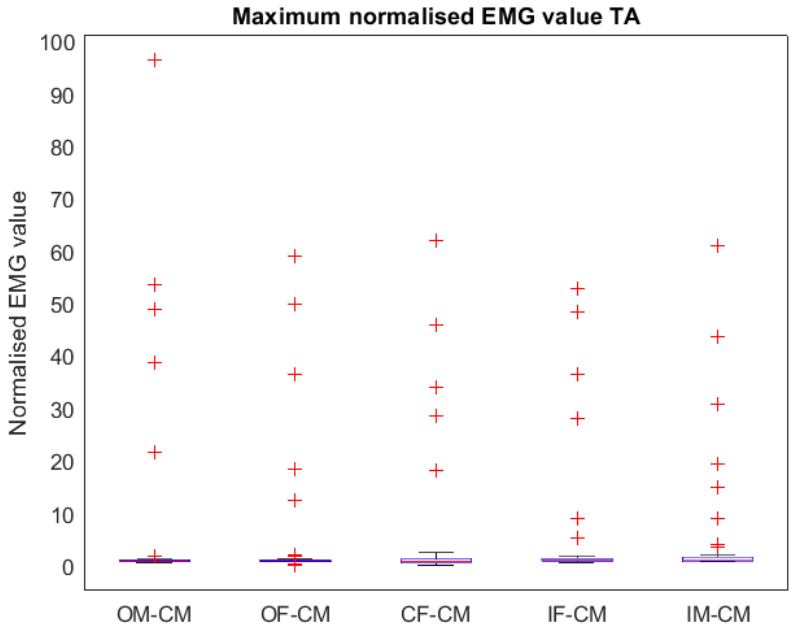

Figure 20: The maximum EMG measurement at the Tibialis Anterior, in the timeframe up to 0.25 seconds after the pulse

In figure 20 the maximum value of the EMG measured at the Tibialis anterior is shown, normalised against the background noise. What is apparent from this figure is that there are many relatively high outliers going up to almost 100 times background level. This obscured the boxplots themselves. These extreme outliers all come from subject 7.

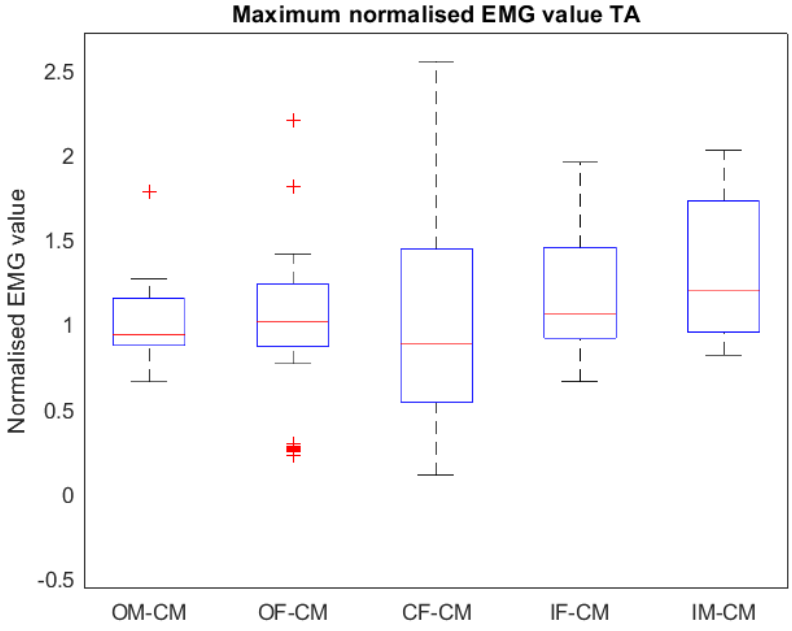

Figure 21: The maximum EMG measurement at the Tibialis anterior, in the timeframe up to 0.25 seconds after the pulse. The image is zoomed in on the boxes

In figure 21 a zoom in of the boxplots of figure 20 is shown. Again the median of the boxplots is around 1 but some of the boxes, with CF-CM in particular, show that about

25% of the non outlier samples are above 1.5 times background noise.

4.3 Stochastic noise

In the following graphs the area of the 95% confidence ellipses is calculated and plotted in various ways.

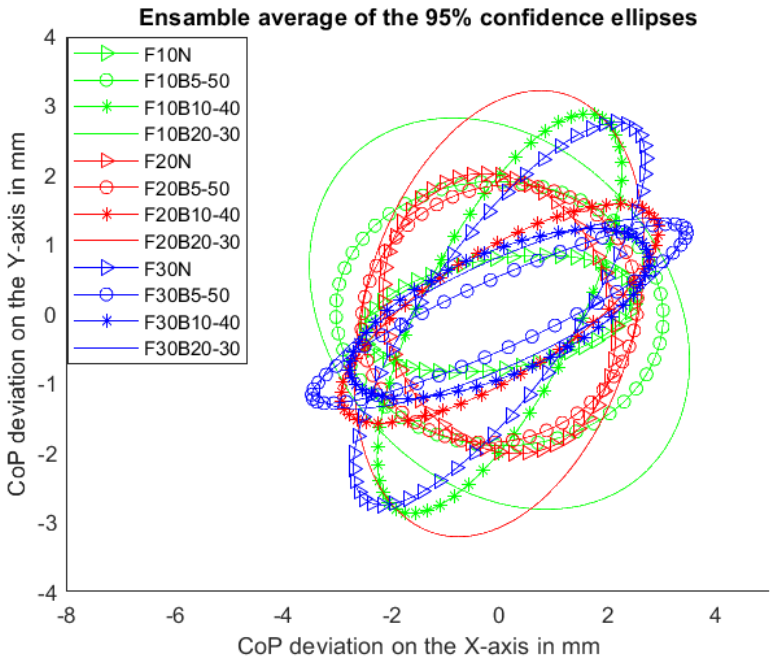

Figure 22: The ensemble averaged 95% confidence ellipses of all subjects

In figure 22 the ensemble averaged 95% confidence ellipses of the trials of all subjects is shown. In this figure it seems that the area of the ellipses shrinks with time as the green (first stimulation frequency, 100 Hz) ellipses are generally the largest and the red (seconds stimulation frequency, 200 Hz) are smaller and the blue ellipses (last stimulation frequency, 300 Hz) are generally the smallest.

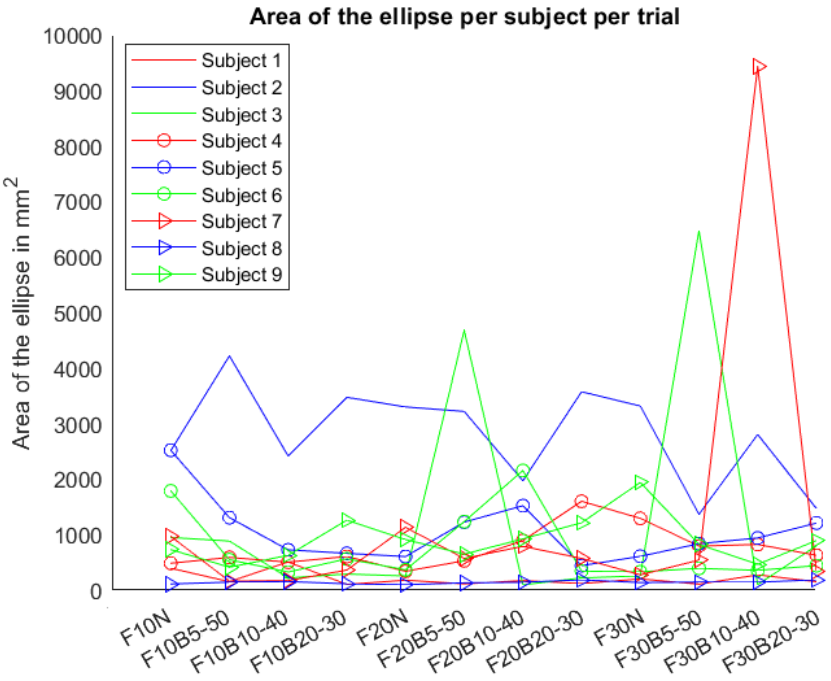

Figure 23: The areas of the ellipses plotted per subject per test

In figure 23 the area of the confidence ellipses per trial per subject are given. There are some clear distinctions per individual trials, but no direct pattern is shown in the data. Some deviating peaks can be observed, which will be further analyzed. No clear pattern for the peaks can be observed.

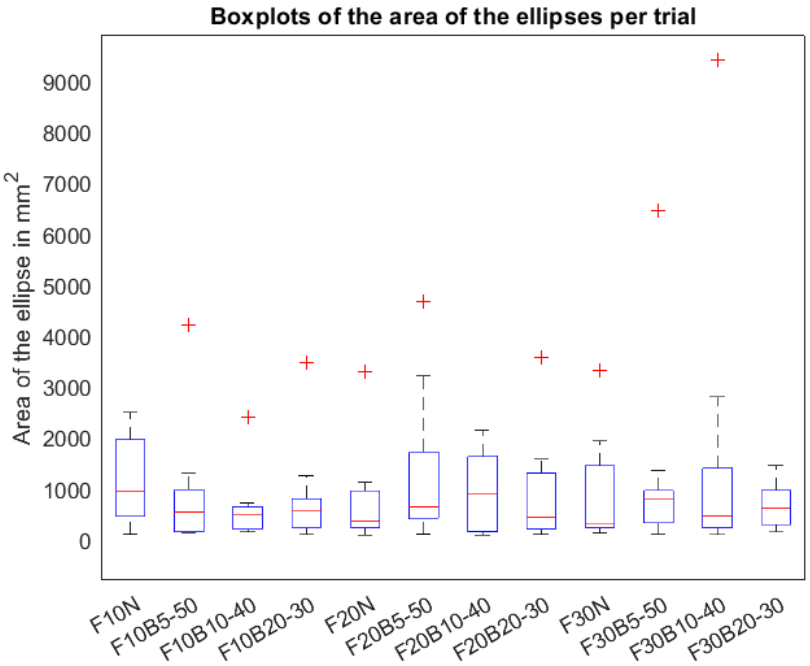

Figure 24: The areas of the confidence ellipses per trial per subject plotted in boxplot form.

In figure 24 the boxplots for every trial is plotted. There seems to be some deviation per trial and especially the first trial (F10N) seems to deviate from the rest by having a higher overall area. However, almost all boxes have at least one outlier. The boxes consist of 9

samples.

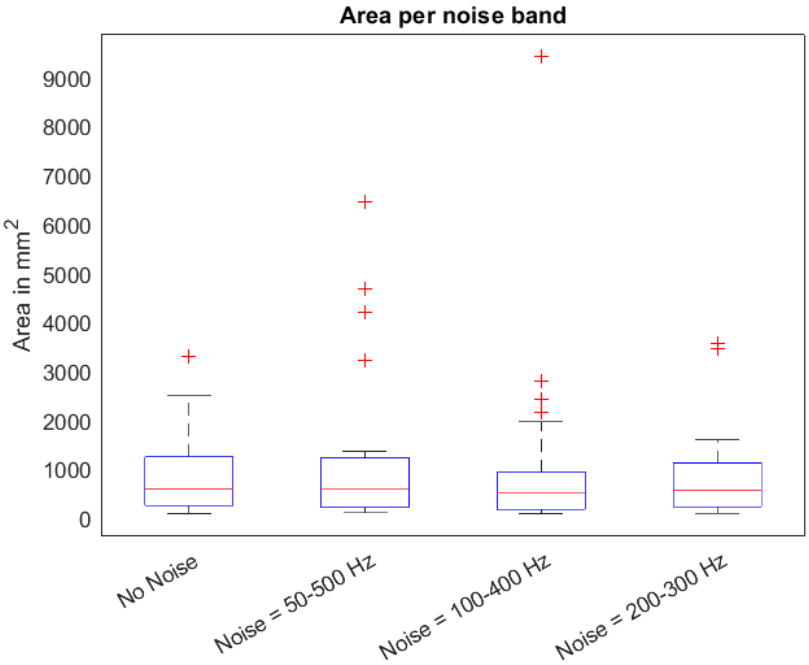

Figure 25: The 95% confidence ellipse areas in boxplot form per noise bandwidth

In figure 25 the area is plotted in boxplot form, where samples were distributed per noise bandwidth. In this case the bottom, median line and top of the boxes all align with some margin of error. Although there are some outliers, no real difference between the boxes can be observed, which can be interpreted as noise not having any effect. Each box consists of 27 samples.

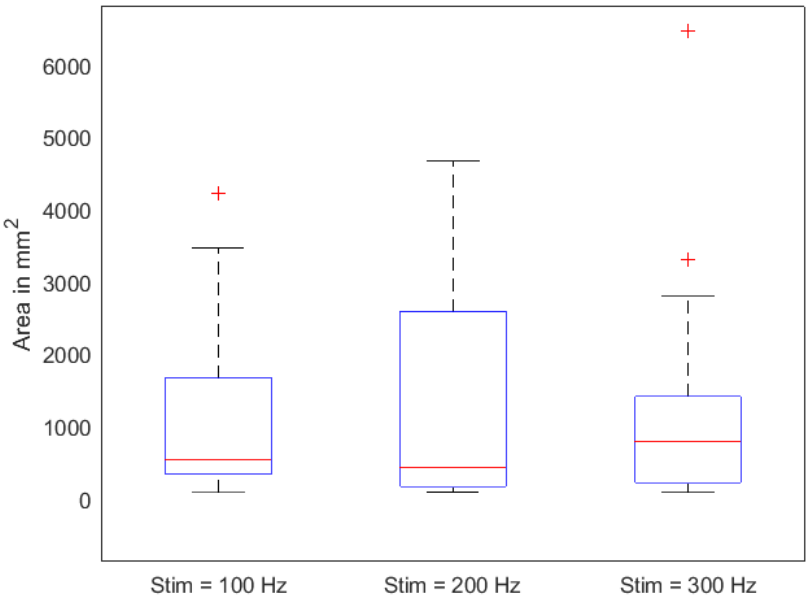

Figure 26: The 95% confidence ellipse areas in boxplot form per stimulation frequency

In figure 26 the area is plotted in boxplot form, where samples were distributed per stim-

ulation frequency. In this case the median of the 100 and 200 Hz stimulation frequency are about equal, and the median of the 300 Hz is higher than the other two. The 3rd quartile and max of the 200 Hz stimulation frequency are significantly higher. Which can indicate that activation is more likely to happen at 200 Hz. Each box consists of 36 samples.

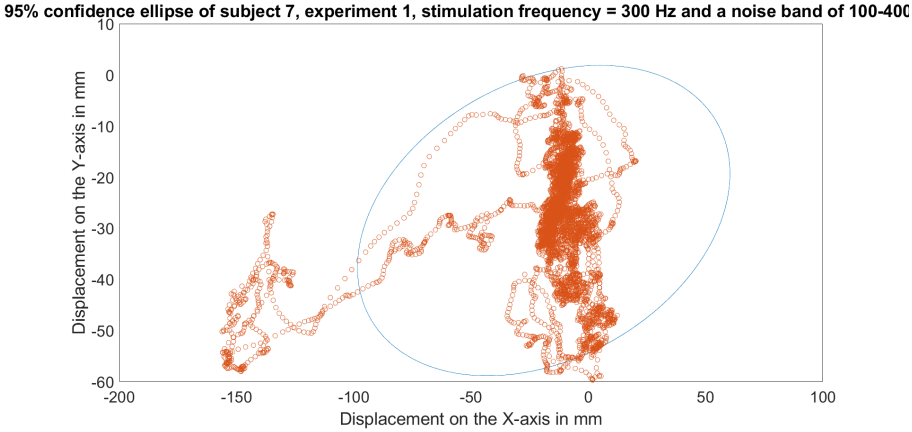

Figure 27: The 95% confidence ellipse of subject 7, with the data points scattered throughout the confidence ellipse.

In figure 27 the 95% confidence ellipses of subject 7 are shown. As can be observed, one is significantly larger than the other ellipses. This also showed in the plot of the areas in figure 23. For this ellipse the X and Y data points were scattered and seems that the data points are mostly clustered around 3 or 4 areas with some deviations throughout the measurement. Some movement artefacts can be observed. This process was also performed for the other peaks in the graph of figure 23. The plots for subject 3 showed similar behavior. The movement artefacts seem to enlarge the area of the ellipse.

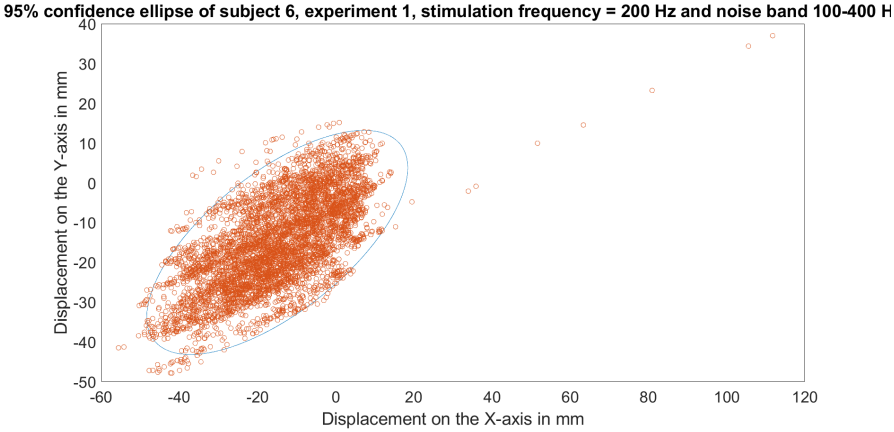

Figure 28: The 95% confidence ellipse of subject 6, with the data points scattered throughout the confidence ellipse.

In figure 28 the 95% confidence ellipses of subject 6 are plotted and the data points of trial F20B10-40 (the blue peak in figure 23) are scattered. Here it can be observed that the data is clustered in one point and no (clear) movement artefacts can be observed except for the initial 7 data points forming a line.

4.4 Effects of Pulses

In this section, results of the second experiment are shown and further clarified.

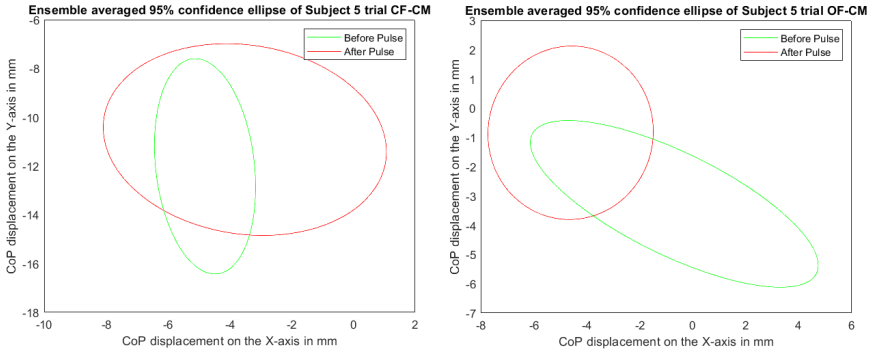

Figure 29: Ensemble averaged 95% confidence ellipses of 150 samples before and 150 samples after the pulse of trials OF-CM and CF-CM of subject 5. T

In figure 29 the confidence ellipses subject 5 trail OF-CM and subject 5 trail CF-CM are shown. Here the sample points are ensemble averaged and from the result a confidence ellipse is made. What can be observed in these is that the confidence ellipse made of 150 samples before the pulse is not necessarily smaller than the confidence ellipse made of 150 samples after the pulse.

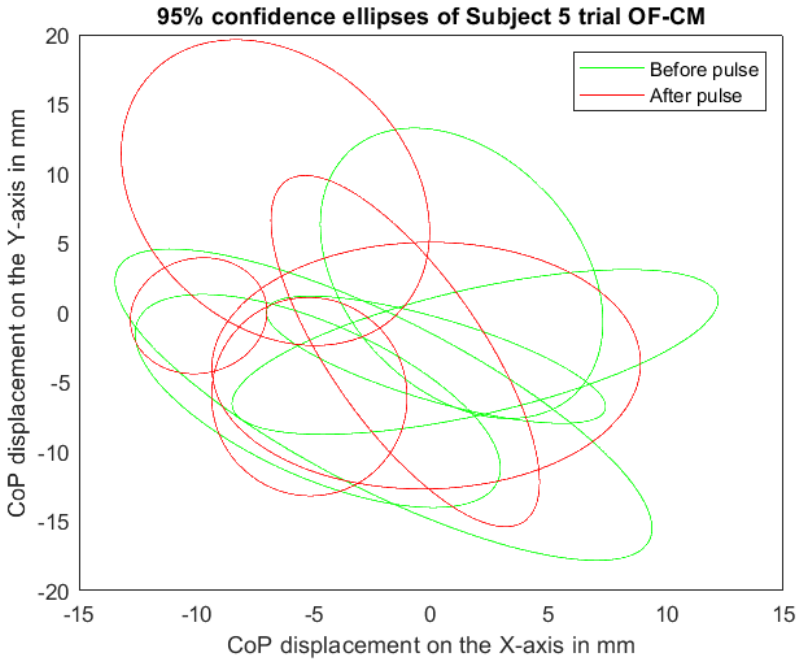

Figure 30: The individual 95% confidence ellipses of 150 samples and 150 samples after the pulse of trial OF-CM of subject 5.

In figure 30 the individual samples that make up the ensemble average of subject 5 trail OF-CM are shown. It can be shown that some of the green ellipses are clearly larger than the red ellipses. Further investigation of this was warranted to see which ellipses formed a pair and why some of the green ellipses are as large as they are.
in figure 31 the boxplots of the variance, before and after the pulse in x and y direction after stimulation between the OM and CM electrodes are shown. The boxplots after the pulse are larger than the boxes before the pulse. However, the median is the same for all

boxes. The third quartile and the maximum is higher after the pulse than before.

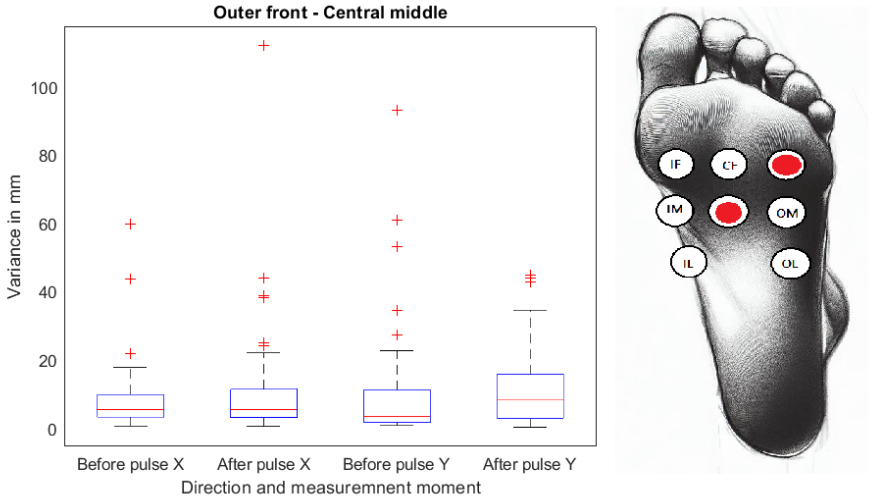

Figure 31: Boxplot of the variance in mm of the CoP for each subject 150 samples before and after the pulse in both x and y direction, with the stimulation locations next to the the plot.

Similar observations can be made for the other box plots, these can be found in appendix A.3.

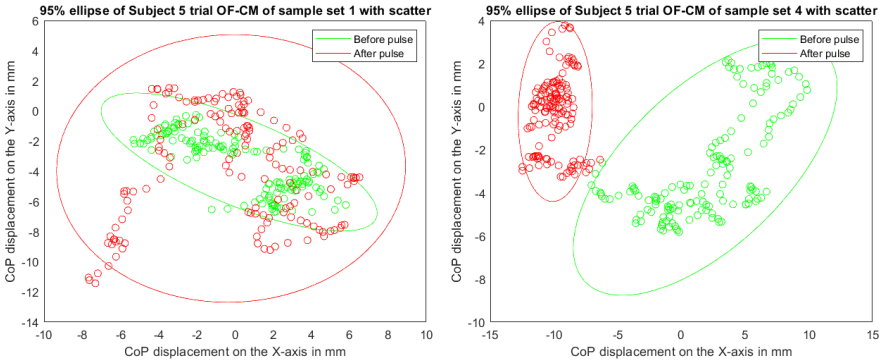

Figure 32: The 95% confidence ellipse of subject 6, with the data points scattered throughout the confidence ellipse

In figure 32 the 95% confidence ellipses of sample sets 1 and 4 are shown. In the left scatter, the green scatter plot contains less movement before the pulse and then the CoP shows more movement after the pulse. In the right figure, it is shown that there is clear movement before the pulse and less movement after the pulse.

5 Discussion

In this chapter the results and current design choices will be discussed and solutions to current problems and improvements of the design will be given.

5.1 Setup and Protocol

In this first section, problems with the setup will be discussed and solutions will be provided if possible.

Data corruption
During the experiments some of the Force Shoe data got corrupted due to a defect sensor. To deal with this the subjects weight was taken and multiplied by the gravity coefficient to get the force exerted by them in the Z-direction. By now subtracting the forces from the other sensors from this mean force, an approximation of the sensor value could be found. However, the total gravitational force during the experiment is not completely constant and some significant data is possibly lost or lessened by this method. Because of this it was also not possible to use the second force shoe data method.

Stimulator
During experimentation, the stimulator would sometimes give off a beep, indicating that it was near or over its potential/power limit. This might be why for some subjects no response was observed, as stimulator could not supply enough power to activate (sufficient) neurons. As stated earlier, it is useful to create a feedback program from the stimulator itself. For the Digitimer this is already possible. In this case the potential, and errors occurring during the experiment can be monitored and it is possible to relate these errors to failed tests.
Also the power limit is a significant problem, especially in subjects with large feet or thick calluses. If the potential measurements are also done, it is possible to calculate the potential used at stimulation. In this case the decision can be made to place electrodes closer together, or change the electrodes to an area with less calluses, if the required potential is too high.

CoP measurement
Currently, only the CoP is measured. However, there seems to be a delay between EMG measurements and reactions in CoP. Adding an extra system through which the center of mass (CoM) can be estimated might yield more insight into this. It is possible that the initial reaction is suppressed by for instance upper body movement. If this becomes measure able, a clearer solution can be drawn.

Measurement adjustments
In the current protocol, some measurements are missing or actions are not performed, which are important for comparison. The extra steps that should be taken will be listed here:

- The normalization of the EMG is currently done using background noise. This is a feasible method, but random behaviour can interfere with the measurement. It is therefore better to use maximum voluntary contraction (MVC) as a normalization basis. This should get more reliable results.
- Better care should be taken in skin preparation. In the current iteration minimal care

was taken and subjects with hairy legs or calluses showed worse results. Actions like shaving the EMG electrode site and removing calluses/cleaning the foot sole should improve function.

- Measurements are started 10 seconds before the first pulse train and end 10 seconds after the last pulse train with a random time between pulse moments of 4-10 seconds. This protocol should be adjusted, the measurement time before the first pulse and after the final should be increased to 20 seconds and the time between pulse trains should be increased to at least 15 seconds without randomisation. It might also be possible to have a trial consist of only one pulse train and doing multiple trials per parameter set.

- The subjects stance is not yet optimized and no visual reference point is used. A different stance can help further stabilize the subject, reducing natural sway and possibly amplifying the effects of stimulation. A visual reference point will also help stabilize the subject.

- Our objective during this experiment was to keep subjects engaged in conversation as to keep their focus away from the stimulation. This however seemed to result in moments were the subject would lose focus on keeping their balance and would voluntarily move, resulting in artefacts.

5.2 Validation and tests

In this section the results of the validation and tests will be discussed and possible improvements will be given.

Force shoe validation

This test that was done was to check if the measurements from the Force Shoes are similar to the measurements obtained from the ViCon. During this test it was shown that the reactions were similar, but a few caveats came up. The first of which, during the experiment the coordinate system did not line up, which caused a shift in mean balance position. This can be manually changed and does not cause much of an issue.
The second, the ViCon measures the position of the feet using markers, no such thing exists for the force shoe, the sensor position have to fitted manually causing an error. This can be shown in the test as the CoP data had to be increased by a factor of 1.3 in X direction and 2 in Y-direction and was shifted -30 mm on the X-axis. As the goal of this experiment is to make the shift in balance position measurable and not to quantify it, this is not a problem.

Preliminary test

As observed in figure 13, during the first preliminary test a clear reaction to the stimulation could be observed in the expected time frame. Some minor adjustments were made in the protocol, such as labeling electrodes, but no further major changes were necessary. As no unexpected or wrong results were collected, it was decided that experiment 1 and 2 could continue. The data of the preliminary test was kept as Subject 1.

PT test

The mean results of the PT test is shown in table 6. It was initially expected that the PT's per location would vary more, but in going over the process once more this seemed logical. The AP in the neuron is caused by a change in potential. Apparently, the current

distribution in the foot still is not affected as much as was expected.
Still a change in potential was observed but not measured. This might however be significant. For this reason it is advised to further look into the Digitimer DS5's integration in the system. It is possible to get direct feedback from this device (current, potential and errors). For further experiments this data might be useful.
Furthermore, in subjects differences in PT's could be observed during this test, while the overall mean seems homogenous. There may be several reasons for this, such as not optimal placement of the electrodes, degradation in the function of certain electrode, insufficient skin prep, difference in foot size and differences in thickness of the calluses in both subjects and in different parts of the foot. For this we would advise improvement of the protocol, such improvements could entail:

1. Better measurement of electrode distance during placement
2. Better feedback options (potential measurement)
3. Electrode locations based on foot landmarks
4. Bigger electrode sizes to increase the stimulation area

Another issue that came up was the protocol itself. As stated, subjects reported a tingling sensation in there foot, through which they indicated they found it difficult to say with certainty if they felt the stimulation. This might indicate that changes in the protocol are necessary and more time should be given to subject to recover between trials. The following advises are given:

1. More repetitions per PT could be added, to ensure that the measurement is correct
2. Reduce the total amount of measurement locations, PT-tests take longer than the experiment
3. More recovery time in between trials should be given, or an action should be taken to reduce the tingling sensation

Finally, it was reported by multiple that subjects that they found it difficult to determine if they felt anything during the stochastic noise test. This may have led to the PT of the stochastic resonance to become too high.

5.3 Experiments

In this section the results of the experiments will be discussed and improvements or future work will be suggested.

EMG analysis
From figures 14 and 15 one observation can be made. A clear reaction in the EMG does not warrant a clear reaction in the CoP. This might indicate that either the body compensates for the electrical stimulation in a different way than the ankle, or the muscles are able to compensate for themselves, suppressing the (initial) reaction.
In figures 16, 17 and 18 the maximum reaction of the normalized EMG is shown for the stochastic noise experiment. Only a few sample values seem to be higher than 1.5 for the Soleus and the non-outlier samples of the TA. However, some of the outliers for the TA

reach a normalized EMG between 2 and 10. This might be an indication of activation of the TA muscle, but this may also be due to the measurement method. In figures 19, 20 and 21 the maximum reaction of the normalized EMG is shown for the electrode location experiment. Here it can be observed that the normalized EMG value for the Soleus and TA is generally higher than the samples of the stochastic noise experiment. For the second experiment the median is around 1 while for the first experiment the third quartile is around one. The first being that although a clear stimulation artefact can be observed in the data, this does not always lead to a reaction in the EMG. Since the initial reaction seems important for observing further results, it is clear that more care must be taken to ensure it actually happens. Currently our method for inspecting the correctness of the EMG was to check for a stimulation artefact. This can however happen sporadically or be overshadowed by another reaction. For this reason it will be advised to do an extra pre-test, for which the EMG is checked for activation under the set stimulation intensity. If no or sporadic activation is observed, this indicates that either the electrodes are too far apart, or the stimulation intensity is too low. The following reasons can be given as to why stimulation is not always effective:

- Stimulator range. In some cases it is possible that the stimulator simply could not provide enough power to sufficiently stimulate the correct neurons. In this case the spike in the EMG could indicate that the neurons that were activated were not the intended neurons. In this case the electrodes need to be placed closer together, to ensure that activation can take place.

- Stance, pressure on the foot sole. In the paper of Zippenfennig et al.[27] it is stated that the Merkell and Rufinni can tune the perceptual threshold of the Pacinian. Also the foot position seems to influence the PT[28] A logical step would be that this also includes the activation threshold. In this case, putting more or less pressure on the foot sole can influence if neuron activation will take place.

- Contamination. In the experiment it can be shown that the effect of stimulation took longer than expected and in some cases this can create contamination. In this case the effect of the stimulation pulse on a still active systems might net a different result than in a system in rest.

Stochastic Resonance
In figures 22 - 28 the effects of stochastic resonance are shown. In figure 22 it seems that the area of the ellipses shrinks with time, but nothing conclusive can be stated yet.
In figure 23 the areas of the ellipses were plotted per test and subject. From here the distribution of the area seems to be uncorrelated with the tests. In figure 24 the areas are plotted in boxplot form. Here again a sort of random distribution of the areas can be observed, where for instance the median of F10N is higher than the third quartile of the other tests. This seems to suggest that the noise stimulation has some effect, but this effect does not show for the other stimulation frequencies (F20 and F30).
As a next step, the boxplots per noise band (figure 25) and stimulation frequency (figure 26) were plotted. In the case of the noise band, no clear distinction between the different noise bands seems to exists, for the stimulation frequency there is a clear distinction between the stimulation frequency at 200 Hz and the other two, although the median of the 300 Hz stimulation frequency is higher than the other two. There are three possible explanations for that. The first is that the stochastic noise stimulation is effective in (some) subjects and the effect of stochastic noise endures after stimulation. Because of this a subject is more stable after a certain trail and prolonged exposure to stochastic

noise improves the effect. The second option is habituation to the standing position. Because the subject is standing in a certain position for an amount of time, the subject starts to stabilize and finally, the effect that is observed is random and there is no correlation.
In figure 23 some peaks are observed, for these peaks the individual trials were plotted and in them the data belonging to the peaks was scattered in this plot. One such plot is shown in figure 27. In this plot it can be observed that a certain cloud of data points exists and that outside of this cloud movement artefacts exist. It seems that the movement artefacts inflate the confidence ellipse, this does not only happen in the plots of the peaks of figure 23, but also in other random data sets.
The expectation was that the data would be distributed as in figure 28, but since this is not the case, the confidence ellipses are currently designated as an unreliable form of measurement. To ensure reliability, improvements can be made to how the measurements are done.
Also a strategy must be devised on how to handle these movement artefacts. For this clear parameters must be set as to when a sample is seen as an artefact and thus is removed, or a method must be created which removes the unwanted movement from the data.
This is due to movement artefacts in the data. These movement artefacts seem to inflate the ellipse, making this type of measurement less reliable in observing the true balance position/sway. The following actions can be undertaken to in improve the measurement:

1. Improve the balance position of a subject with for instance a different standing position or a visual mark as a reference point. This should minimize the amount of movement artefacts in the data and ensure that the data set contains enough data for statistical tests.

2. A protocol can be created to deal with movement artefacts. Parameters can be set in for which samples are labeled transient/movement and these can be removed. In this case it is possible that the data will form a cloud around a different mean, in this case, steps must be undertaken to ensure that the change in mean does not influence data.

3. For the stochastic noise, an intensity of 20% PT was chosen for stimulation of the foot sole. Another stimulation method that is used, is stochastic stimulation at the ankle around 90% PT. A test could be performed to show the differences between the two methods.

4. The current test was too ambitious. For the next tests it would be best to ensure that the chosen parameters actually function well individually (pulse stimulation, stochastic resonance). So it would be best to find a methods where these parameters work well individually and then combine them.

5. It is possible that the Force Shoes cause additional instability. The rigid form of the force shoes can make for an uncomfortable stance and especially when a subject focuses on his/her stance, this might have a negative effect.

The effect of pulses
In figures 29-32 the effect of the pulses is shown. From figure 29 the ensemble averaged confidence ellipses are shown, it can be observed that the confidence ellipses after and before the pulse show different changes in sizes, sometimes they are bigger before the pulse sometimes smaller and sometimes they stay the same size.
In figure 30 the individual confidence ellipses that make up the left figure of figure 29 are

shown. The individual samples represent a smaller change than expected. This can be due to the mean of one sample set filtering each other out, while the other sets amplify each other.
From these boxplots were made for all subjects in figure 31. Here it is shown that the variance is generally higher after the pulse than before, however some outliers exist in the before the pulse boxes, which are significantly higher than the rest. This might be due to contamination of the previous pulse.
In figure 32 the corresponding data points are also scattered into one sample sets confidence ellipse. Here it is again shown that there are movement artefacts. Although movement artefacts were expected in the red ellipse, they were not in the green ellipse, or at least not to this size. This might be due to movement artefacts and contamination. Some steps that can be taken are:

1. Doing a measurement to find a minimum amount of time needed to wait until a subject is back in a resting position. Doing this will ensure that no contamination can be found in the data.

2. Ensure neuron activation takes place. It is not definite that neuron activation takes place at the moment. A pre-test can be done in which the data can be checked to see if activation actually takes place.

3. An experiment can be performed to see if stimulation during movement causes inhibition. This effect seemed to occur several times, but it could be coincidence.

6 Conclusion and recommendations

This report is concluded by addressing the research questions and by providing recommendations as to what future research could be done based on the findings of the report.

Research questions
The device functions as it should and the stimulation paradigms can be performed.
Currently we can show results in the pulse stimulation aspect of the device. It seems that the electrical stimulation is effective, but steps must be taken to further optimize the stimulation paradigms.
For the stochastic noise stimulation, no clear effect can yet be shown, this is either due to mistakes in the stimulation parameters, due to a wrongfully chosen protocol or due to a wrongfully chosen stimulation area.

Setup
It can be concluded that the first setup functions as intended and can be used to collect data. However, there are still some problems with the protocol that is connected to these devices. Not enough time was spent on optimizing signal quality, improvements can be made in how to handle subjects, preparations before experiments need to be revised and trials should be repeated / lengthened to increase the amount of useful data.
For the next step, improvements can be made to the connection of the Digitimer DS5 stimulator. From the stimulator information, such as potential and error markers could be read, which can help analyse the measurements. It could also be beneficial to measure center of mass (CoM). Currently, it seems that the body compensates for the electric pulse, but this compensation cannot be clearly seen in CoP. It is possible that the compensation is done in another part of the body and thus does not show up in the CoP data directly.

Protocol
More steps should be taken to increase signal quality. These steps include optimization of stance through standing posture and addition of a visual reference point. Skin preparation should be improved by creating a skin prep protocol for the foot sole and a skin prep protocol for the EMG electrode placement. More tests should be performed to indicate if the electrodes (both stimulation and EMG) are placed correctly.

Experiments
The experiments as intended were too ambitious. A step back should be taken and the effects of both stochastic resonance and pulse stimulation should be researched individually, so a framework can be found in which both these methods function. If effective neurostimulation is devised for both types of stimulation, these parameters can be fused together and the resulting effect of both can be observed, if there is any resulting effect.
A test should be performed to check what the maximum amount of time is for stimulation takes effect. In this experiment the minimum amount of time between pulses was set to 4 seconds, while for a subject a time to recover of about 7-9 seconds was measured. This resulted in contamination of the Force shoe data and thus measurements where no clear distinction could be made in before the pulse and after pulse characteristics.

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A Results

In this section, a part of the results will be posted, to keep the main report concise.

A.1 PT results

	S1	S2	S3	S4	S5	S6	S7	S8	S9
St res OF-IF	4 mA	2.8 mA	3.5 mA	4 mA	3.2 mA	2.2 mA	1.5 mA	2.4 mA	1.8 mA
Pulses OF-IF	3.5 mA	2.4 mA	4.5 mA	4 mA	3 mA	2.8 mA	2 mA	3.6 mA	1.7 mA
Pulses OM-CM	3 mA	2.8 mA	4 mA	3 mA	3.5 mA	2.8 mA	2.2 mA	3.8 mA	1.5 mA
Pulses OF-CM	2.8 mA	1.9 mA	3.5 mA	3.4 mA	2.8 mA	3.2 mA	1.8 mA	2.7 mA	1.5 mA
Pulses CF-CM	3.2 mA	2.7 mA	2.8 mA	3.8 mA	3.5 mA	3 mA	1.8 mA	3.7 mA	2 mA
Pulses IF-CM	3 mA	2.6 mA	4 mA	3.7 mA	2.8 mA	2.5 mA	2.2 mA	3.8 mA	1.5 mA
Pulses IM-CM	2.8 mA	3.6 mA	3.8 mA	3 mA	3.5 mA	2.5 mA	2 mA	2.5 mA	1.5 mA

	S1
OF-IF	3.5 mA
OM-IM	3.6 mA
OL-IL	2.8 mA

A.2 Force shoe validation results

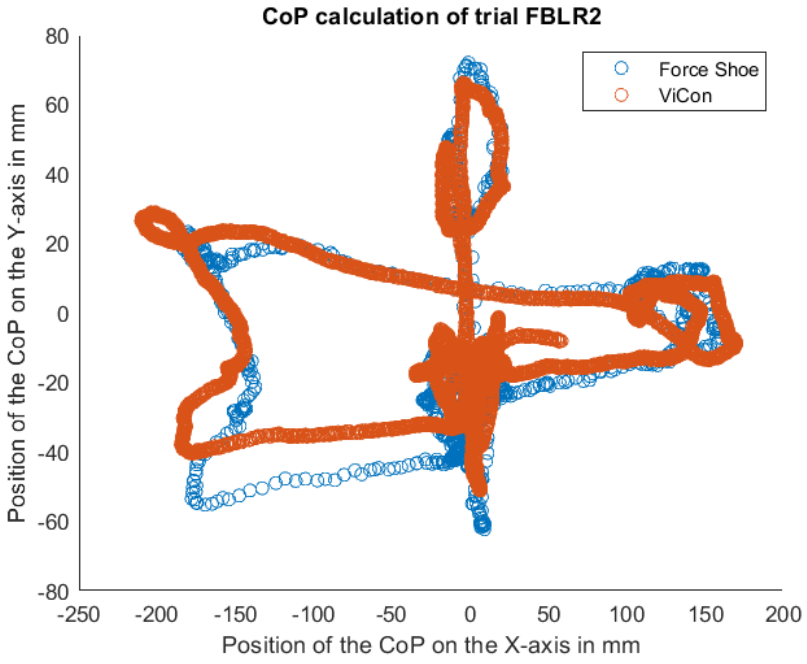

Figure 33: Results of validation test 2 of the force shoe validation

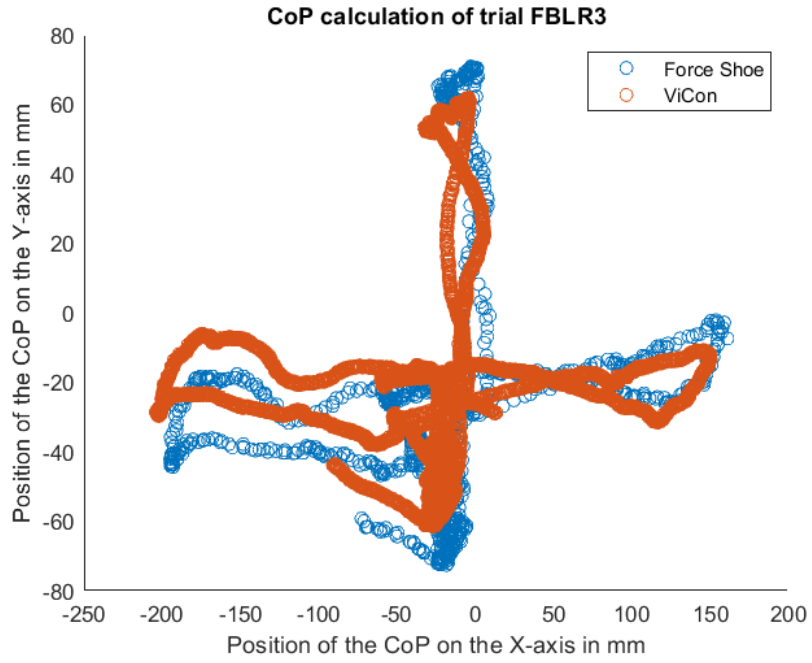

Figure 34: Results of validation test 3 of the force shoe validation

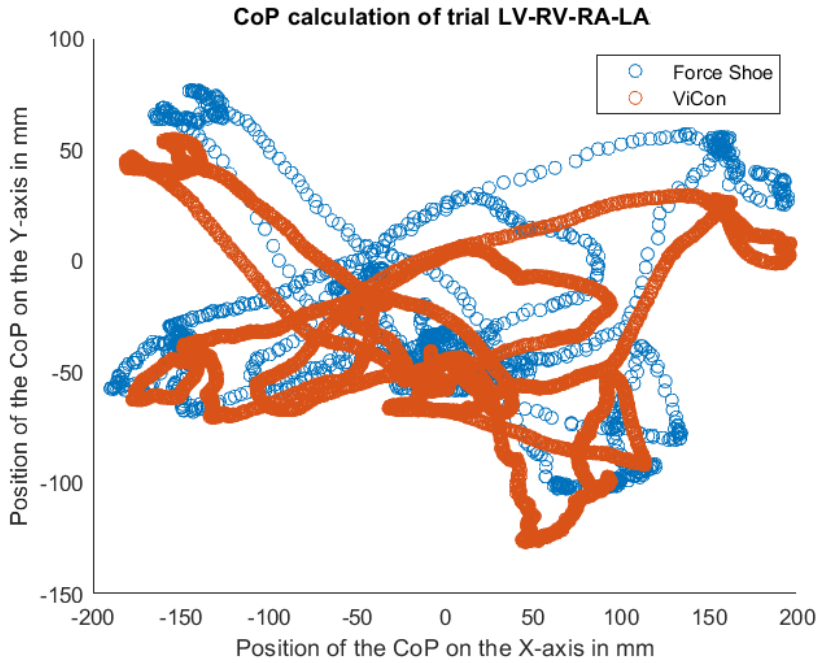

Figure 35: Results of validation test 4 of the force shoe validation

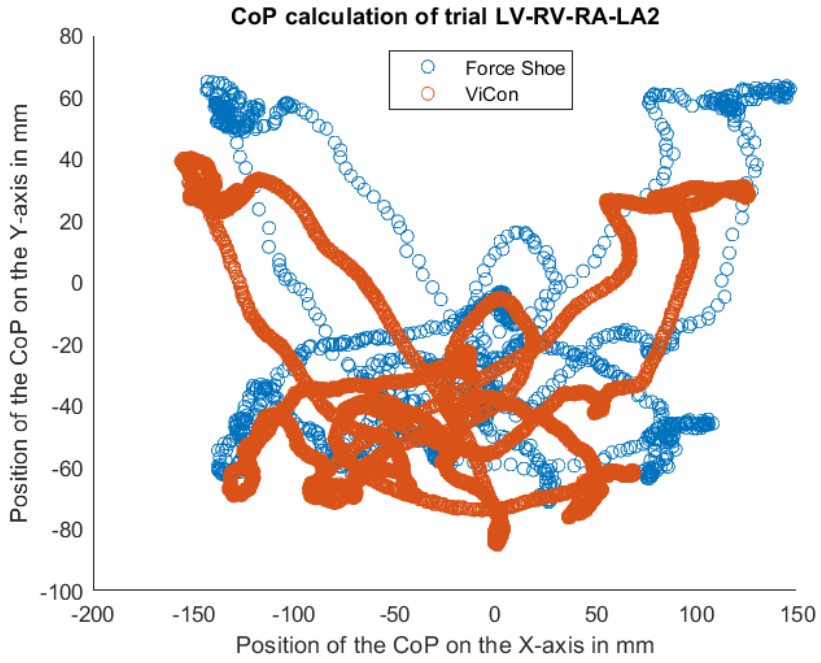

Figure 36: Results of validation test 5 of the force shoe validation

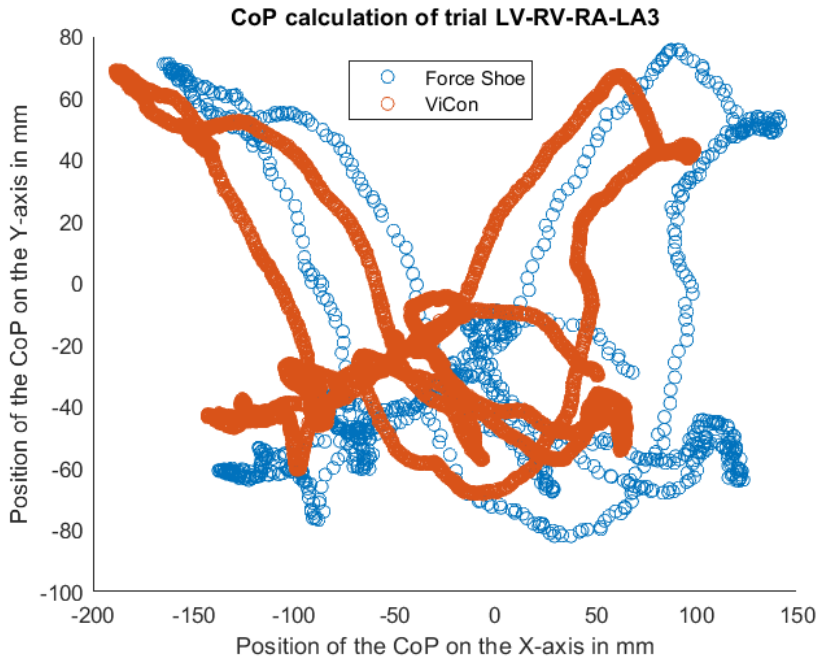

Figure 37: Results of validation test 6 of the force shoe validation

A.3 Electrode location experiment results

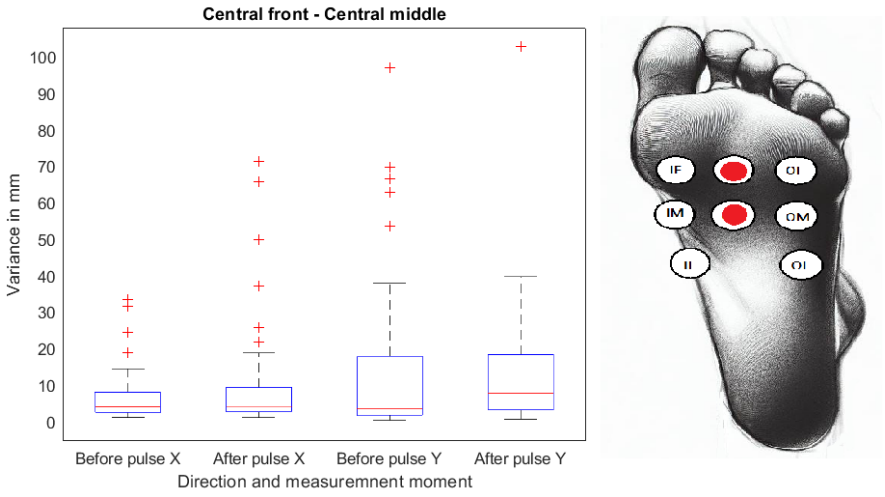

Figure 38: Boxplot of the variance in mm of the central front - central middle trial

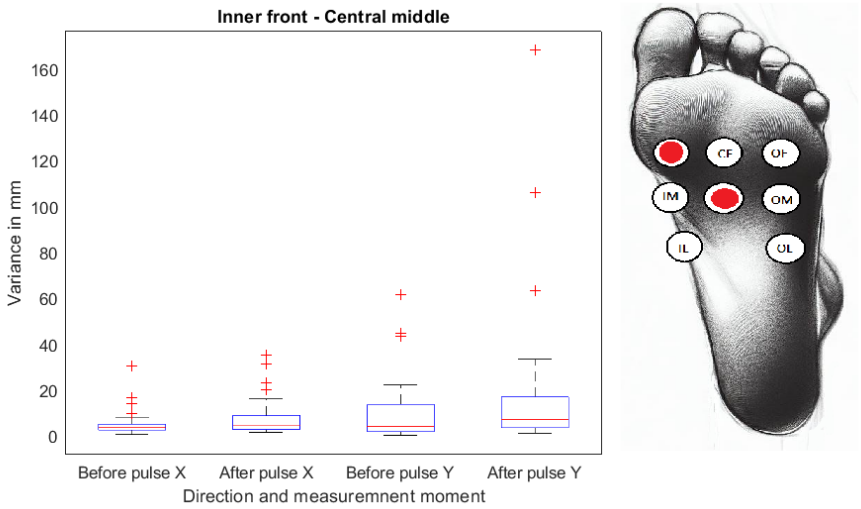

Figure 39: Boxplot of the variance in mm of the inner front - central middle trial

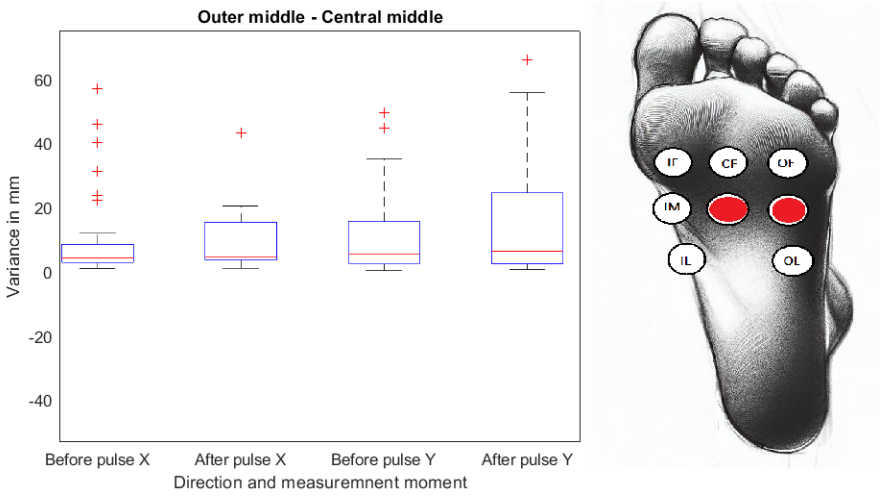

Figure 40: Boxplot of the variance in mm of the outer middle - central middle trial

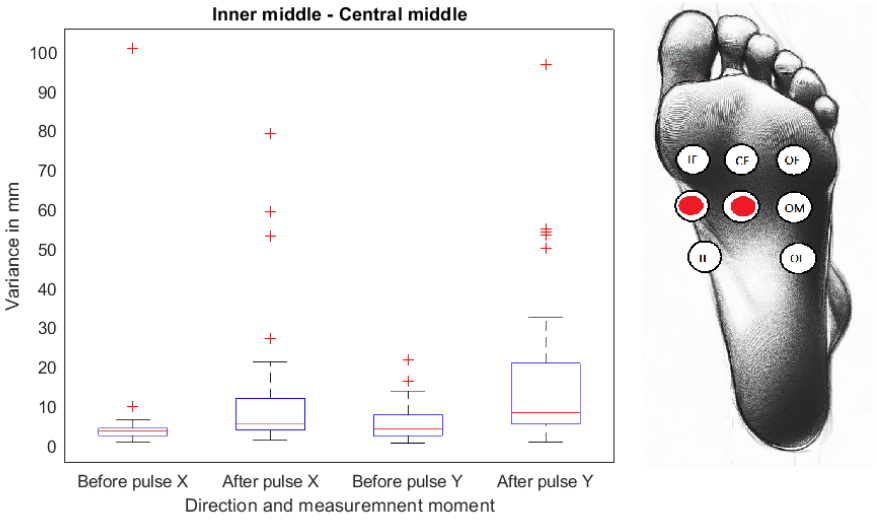

Figure 41: The 95% confidence ellipse of subject 6, with the data points scattered through the ellipse

B Validation

In this appendix the validation method and and its results will be described.

B.1 Validation method

The setup was tested before actual human subjects are used. In this test a check is done on the functioning of the signals and stimulation patterns. To test this protocol, a test subject will wear the force shoes and their EMG at the soleus and tibialis anterior will be measured. The stimulator will however be connected to a resistor and the stimulation pattern over the resistor is measured using an oscilloscope. The protocol as to be described, will be run for several of the stimulation patterns and the results will be checked for amplitude and frequency. The EMG and Force shoe data will be checked for synchronization patterns and the amount of samples.

Validation protocol

To validate setup 1 several tests were performed to find the individual functioning of components. This results in a final test, in which the whole setup is used and a measurement is done using a 9.8 K resistor and an oscilloscope to simulate stimulation. The main focus of this test is the synchronization of the individual components and the validity of the stimulation pattern. The setup consists of a NI-USB 6211 as the main controller, a TMSi SAGA as an EMG measurement device, the Xsens Force Shoes as a ground reaction forces (GRF) measurement device and the Digitimer DS 5 as a stimulator. During operation, the NI-card is connected to the trigger of the Force Shoes, the trigger of the Saga and the input of the Digitimer. During the protocol, the stimulation pattern is uploaded to the NI-card, after which the SAGA will be initialized and a measurement will start. Once started, the NI-card will give a starting pulse on the SAGA's trigger port and will start triggering the Force shoes until the end of the protocol. During the experiment, corresponding stimulation pulses will be given following a pattern at given times with an intensity of 8 mA. During the experiment, the stimulation pattern will be checked using the oscilloscope and after the experiment the time length of the data retrieved from the force shoes will be compared to the time length of the data retrieved from the saga between start and end pulse.

B.2 Validation results

At first the correct response of the stimulator was checked on a 9.8 K resistor. Here the intended stimulation pattern and the resulting stimulation pattern were compared. This resulted in the following graphs:

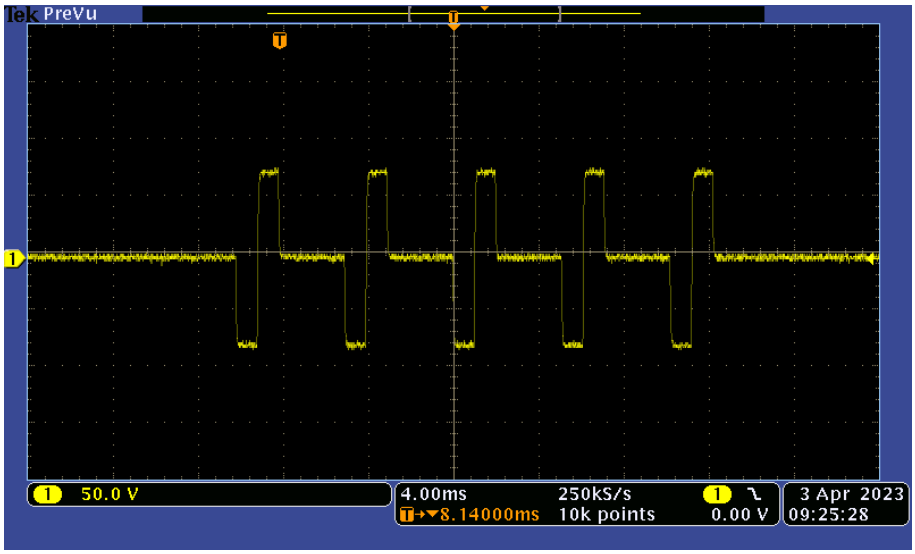

Figure 42: Oscilloscope measurement of the pulse test. Oscilliscope settings are set to a time (x) axis of 4 ms per division and a y-axis of 50 V per division

In figure 42, the parameters were set as a bipolar pulse with a pulse width of 1 ms (2 ms total), an interpulse frequency of 200 hz and an amplitude of 8 mA. In the resulting measurement the two pulses seem equal in width and together take up about half a division, so 0.5 * 4 ms which adds up to about 2 ms, which would correlate to the desired signal. The distance between pulses seems to be around 1.25 divisions, so 1.25 * 4 ms, which is 5 ms, which is 200 Hz. There is a small offset in the signal, but the signal's amplitude is about 1.6 division, so 1.6*50 which is 8 mA * 9.8 k = 80 V.

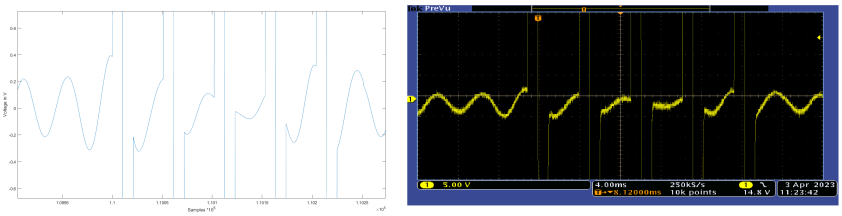

Figure 43: The intended noise signal and the measured noise signal around the stimulation point. The settings on the oscilloscope are 4 ms per division on the x-axis and 5 V per division on the y-axis

In figure 43 a comparison between the intended and the measured signal is shown. The noise in this test was created by taking a set of random values and bandpass filtering them with a second order butterworth filter between 200 and 300 Hz. In the comparison in figure 43 it can be observed that the intended signal and the noise parameters are similar in the same time frames (between pulses). Also the amplitudes, with a division of 10 V: 10 mA seem to be correct. The setting on the y-axis is 5 V per division. The peak to peak of the first noise bands is about 0.4 V, which is 0.4 mA. 0.4 mA times 9.8 is about 4 V, which is about 0.8 divisions , which seems to match the graph. At last a validation test was performed to show that the timing of the system was correct. For this test an EMG and CoP measurement was done on a subject and stimulation was substituted by a trigger signal. This resulted in the following graphs:

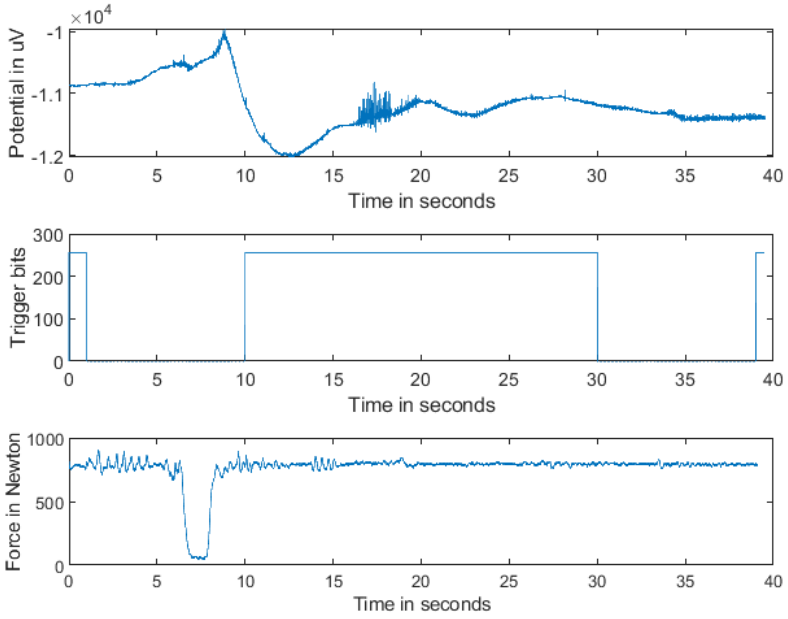

Figure 44: Unprocessed data collected in the same time frame. From top to bottom, an EMG measurement performed on the bicep, a trigger signal and a measurement of the total forces measured by the force shoes

In figure 44 the raw EMG data is shown in the top graph, the trigger data in the middle graph and the Force shoe data in the bottom graph. The significant data in this graph is the time axis, as this is a synchronization test. In the test it is shown that the time axis contain the same amount of time data.

B.3 Validation conclusion

Figures 42-44 are relevant for this test. During the tests it was shown that the stimulation device follows the intended signal and stays within the expected ranges. As no unexpected behaviour was shown during the stimulation tests, the device was considered save to go into the next testing phase. The synchronization was successful, a small shift at the end of stimulation can be observed between the Saga and the force shoes of a couple of milliseconds. This shift is likely the result of a phase shifts and different sampling frequency, through which the data does not completely overlap. The anomaly in force shoe data was due to the test subject leaning during the measurement. Overall this part of the protocol seemed to work, and thus the next step was taken.

C Experiment codes

In this appendix an overview of the used experiments codes will be given and the codes will be further elaborated upon.

Trial number	Trial code	Trial parameters
1	F10N	Stimulation Frequency = 100 Hz, Noiseband = None
2	F10B5-50	Stimulation Frequency = 100 Hz, Noiseband = 50 - 500 Hz
3	F10B10-40	Stimulation Frequency = 100 Hz, Noiseband = 100 - 400 Hz
4	F10B20-30	Stimulation Frequency = 100 Hz, Noiseband = 200 - 300 Hz
5	F20N	Stimulation Frequency = 200 Hz, Noiseband = None
6	F20B5-50	Stimulation Frequency = 200 Hz, Noiseband = 50 - 500 Hz
7	F20N	Stimulation Frequency = 200 Hz, Noiseband = 100 - 400 Hz
8	F20N	Stimulation Frequency = 200 Hz, Noiseband = 200 - 300 Hz
9	F30N	Stimulation Frequency = 300 Hz, Noiseband = None
10	F30N	Stimulation Frequency = 300 Hz, Noiseband = 50 - 500 Hz
11	F30N	Stimulation Frequency = 300 Hz, Noiseband = 100 - 400 Hz
12	F30N	Stimulation Frequency = 300 Hz, Noiseband = 200 - 300 Hz

Trial number	Trial code	Electrode locations (Cathode - Anode)
1	OM-CM	Outer Middle - Central Middle
2	OF-CM	Outer Front - Central Middle
3	CF-CM	Central Front - Central Middle
4	IF-CM	Inner Front - Central Middle
5	IM-CM	Inner Middle - Central Middle

Note: To avoid confusion, feet locations were named inner foot and outer foot instead of left or right.

D Setup 2

In this appendix, a short overview will be given on the second setup. This will be done in standard article form.

D.1 Introduction

Here the effect of "wave stimulation" will be investigated. The theory behind this form of stimulation is that during walking the pressure on the foot is constantly changing and with it the activation of the Pacinian corpuscle. It should be possible to mimic this response by using multiple stimulation electrodes pairs. Some experiments have been done on this subject already, such as Gravano et al., where mechanical stimulation on the front and back of the foot is used under body weight support to help rehabilitate patients[29]. Another such experiment is performed by Nakajima et al. where changes in walking pattern were observed after long term stimulation on specific stimulation regions[30]. These experiments focus on two stimulation sites, one at the heel and one at the front foot. More concentrated stimulation areas and different stimulation patterns may have more pronounced reactions and different speeds at which the stimulation changes electrodes, might net different results.
This will first be tested in a static situation. It is possible that following natural stimulation will increase the response of the Pancinian/muscle reactions.
Most experiments performed using electrical stimulation either use a static location, or change the stimulation site at random. However logically, feet do not move randomly and natural stimulation does not happen at random. The mechanoreceptors seem to mostly react to unexpected stimulation, but what would happen if this unexpected stimulation would follow a more natural pattern (e.g. normal step). The expectation for this experiment is that stimulating the foot sole using a pattern which follows a normal step pattern will inhibit the reaction of the effect on the CoP.
The current research is meant as a step towards this direction. During this research, a setup will be created which is able to stimulate the mechanoreceptors using electrical stimulation and measure the synchronized EMG of a subject and the GRF. This setup must be tested and validated, and if then the earlier described experiments will be performed, where it will be checked if the both the EMG and GRF measurements show a response to the electrical stimulation, and if this is the case it will be checked if there is a correlation between the EMG and GRF.

D.2 Methods and Materials

In this section the materials and methods that were used for this experiment are further explained.

Materials

During the third experiment, the foot sole will be stimulated using the AmbuStim (NociTrack) device. This is a constant current isolated bipolar stimulator, which can stimulate up to +/- 10 mA. The AmbuStim has an investigation medical device certificate (IMDD). Additionally, a bundle protocol with its use has been approved through non-NOW declaration (NL2019-5832/ NDT-EP). The AmbuStim is connected to the system with a Bluetooth connection, through which its setting can be changed using NI LabVIEW. The device can be triggered using block pulses provided by an Arduino Uno. Stimulation will take place in the form of pulses.

Validation protocol

The validation of setup 2 mostly follows the validation of setup 1. The main focus of this test is the synchronization of the individual components, the validity of the stimulation pattern and the start timing of the stimulators. The setup consists of an Arduino Uno, a TMSi SAGA as an EMG measurement device, the Xsens Force Shoes as a CoP measurement device and three NociTrack stimulators as a stimulation device. The setup is shown in figure 45

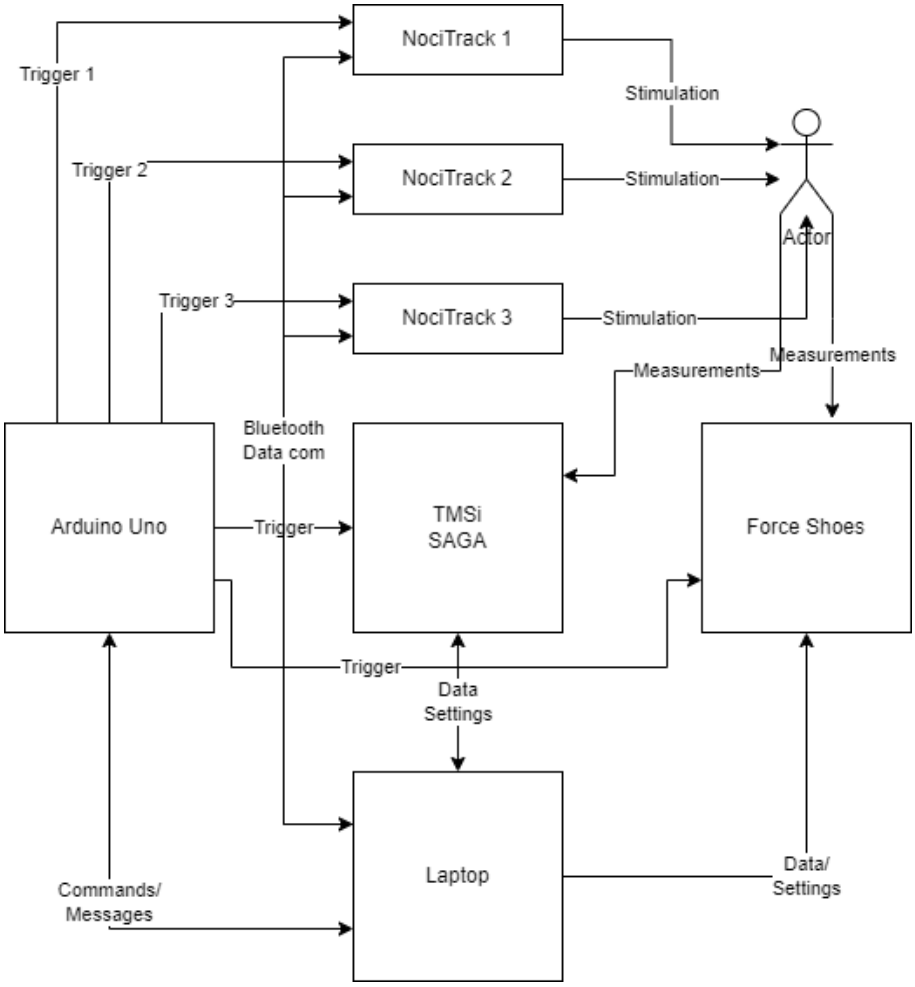

Figure 45: A schematic representation of the second setup used for experiment 3.

During operation, the Arduino is connected to the trigger of the SAGA and the trigger of the Force Shoes and the triggers of the NociTrack stimulators. To use the NociTrack stimulators, the stimulation pattern is uploaded to the NociTrack stimulators via Labview using Bluetooth, once a trigger pattern is detected on the trigger port of the NociTrack device, the device will start stimulation using the uploaded pattern. Once done, a new pattern must be uploaded.

During the protocol, a stimulation pattern must first be uploaded to the Nocitrack devices, once this is done the devices will communicate to the Arduino that a stimulation pattern is ready, and a led on the Trigger box will indicate that the process is ready to start. Once the button on the trigger box is pressed, the Arduino will start triggering the NociTrack devices in set order and with set time interval in between triggers. Once this

process is done, the Arduino will send a clear to the Labview program, and Labview will reupload the stimulation pattern and send an indication to the Arduino once this is done. The process will then be repeated for a set number of times, after which both Arduino and NociTrack devices will return to an unloaded state.

D.3 Validation results

For the validation of the setup, the described protocol was performed using several parameters. The base parameters that were set are a stimulation frequency of 100 Hz, a pulse width of 1 ms, 5 pulses per stimulation and amplitude of 3.5 mA. The time between onset of pulses trains was made variable between experiments and the pulses were performed on a 9.8 k resistor. The following time between pulse trains were used:

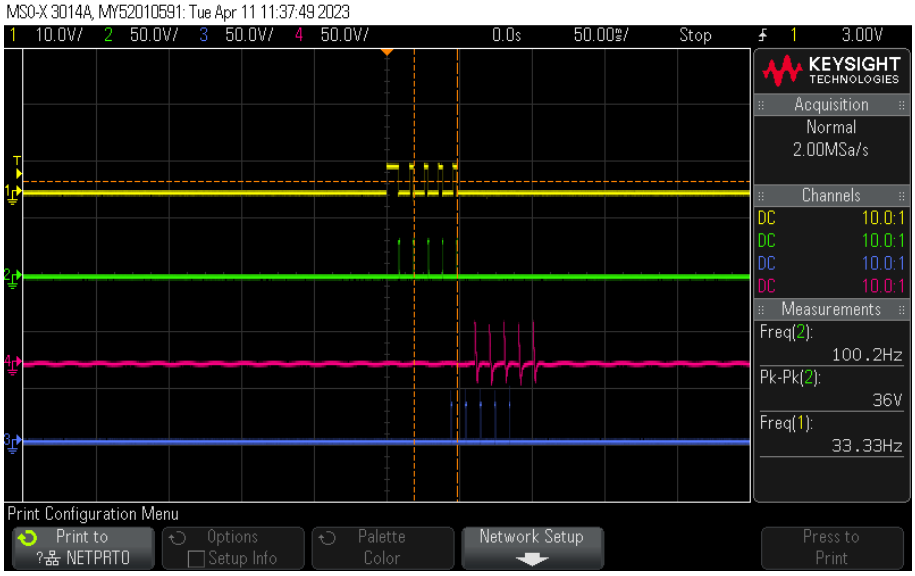

Figure 46: Oscilloscope screen with time between stimulators set to 30 ms

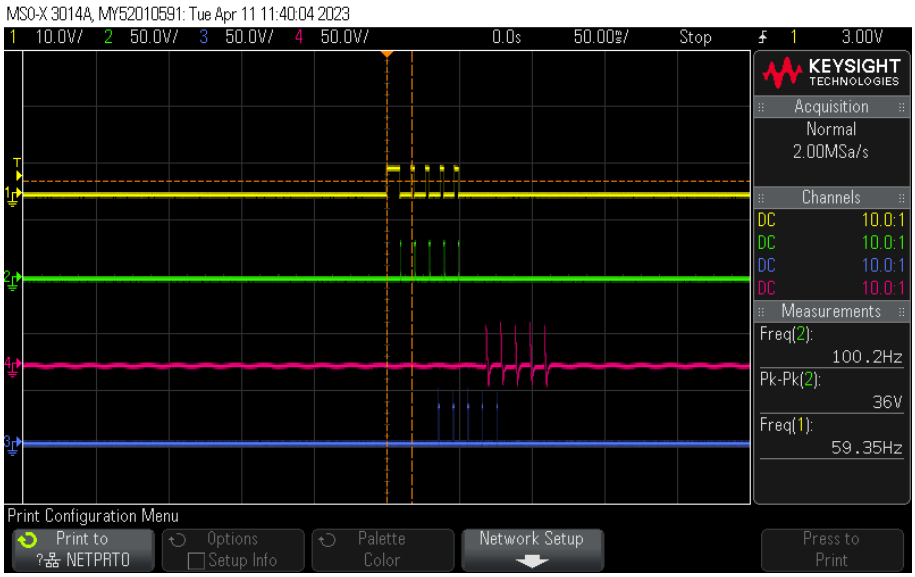

Figure 47: Oscilloscope screen with time between stimulators set to 30 ms

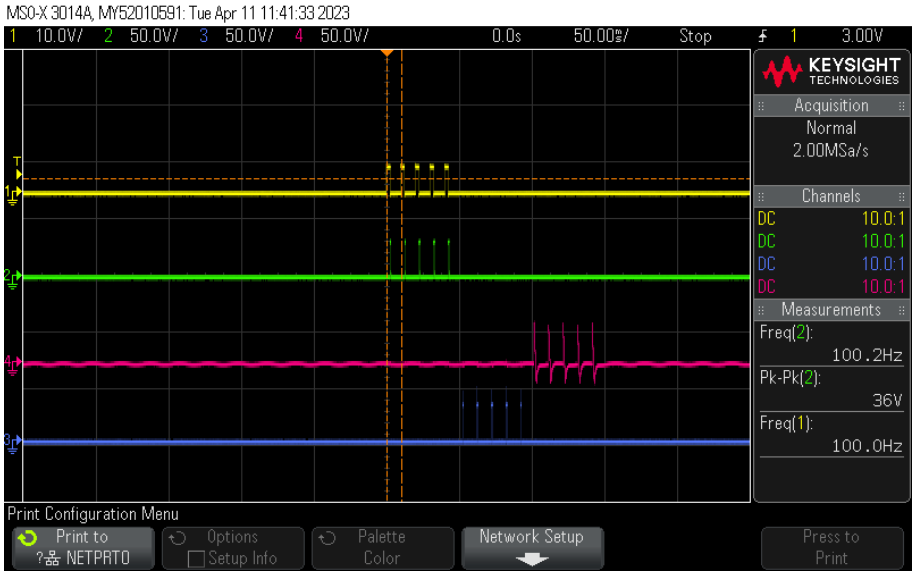

Figure 48: Oscilloscope screen with time between stimulators set to 50 ms

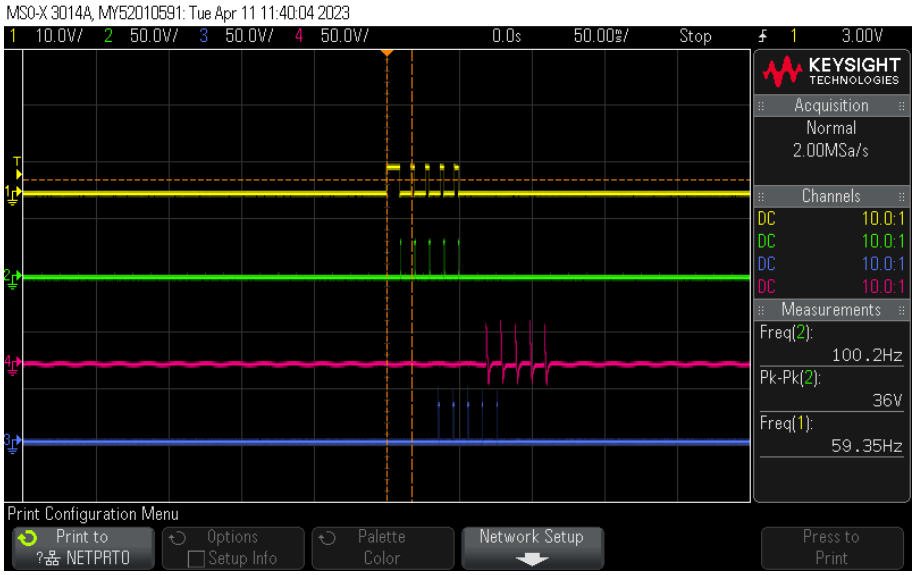

Figure 49: Oscilloscope screen with time between stimulators set to 10 ms

In figure 46 - 49 the responses of the NociTrack devices are shown for different parameters. In yellow the trigger signal from the Arduino to the first NociTrack device is shown, in green the stimulation provided by the first NociTrack device, in blue the stimulation by the second NociTrack device and in magenta, the stimulation by the last NociTrack device is shown. Figure 46 and 47 show measurements taken at an interval of of about 0.6*50 ms = 30 ms. Here it can be seen that the onset of electrical stimulation happens at different times. The time between first and second is about 30 ms in the first and about 35-40 ms in the second, and switched in between 2nd and 3rd. In figure 48 it can be seen that there is a spacing of about 50 ms between the onsets of stimulation, which is according to parameters, but in figure 49 the stimulation of the onsets of the second and third stimulator is simultaneous, although the timing between the 1st and 2nd second stimulator is about 10ms (1 pulse).

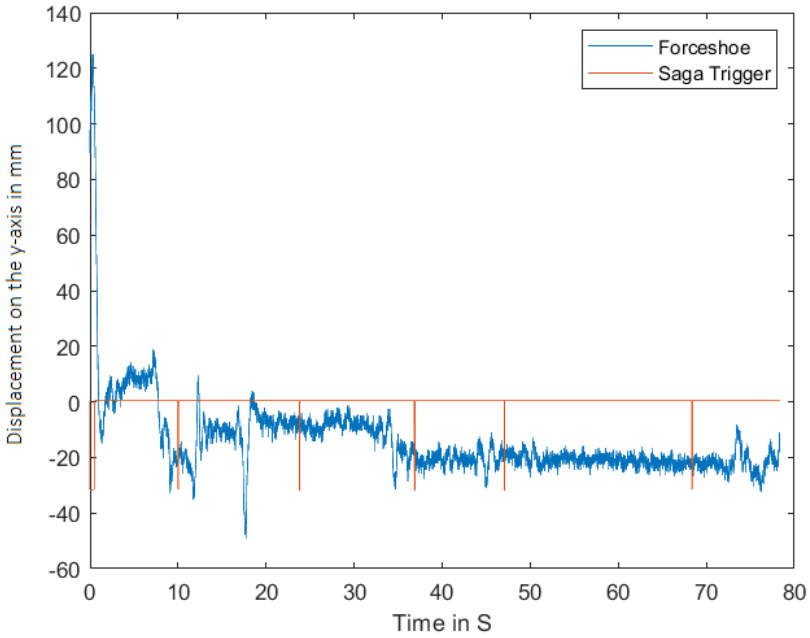

Figure 50: Force shoe data overlapped with Saga Trigger data to show a sync in the time axis

In figure 50 the trigger data from the saga is overlapped with the measured displacement on the Y-axis from the Force Shoe. No stimulation took place yet, but it can be seen that the axis sync up. It can however be seen that at times the time between pulses is longer than 10 seconds.

Wave stimulation experiment
For this experiment electrode pairs OF-IF, OM-IM, and OL-IL (figure 1) will be used. During a trail, all three electrode pairs will stimulate the area between them, with a set timing between activation of the first, second and third electrode pair. The activation time between consecutive electrodes pairs will vary from instant to 100 ms after activation of the previous electrode pair. The foot sole will be stimulated using 5 pulse trains of 5 unipolar pulses of 1ms pulse width and inter pulse frequency of 200 Hz and a amplitude of between 2 – 3 times PT. As a base test, the effect of every individual electrode pair will also be investigated. A total of 6 trials will be performed. one instant activation test and 5 tests with different activation timings. A schematic representation of the setup of experiment 3 can be found in appendix E2.

Data
In figure 51 the highpass filtered EMG measurements at the Soleus and Tibialis anterior and the trigger of subject 1 trial 70ms is shown. The upper graph shows the EMG data collected at the Soleus muscle during a time period of about 70 seconds. In the middle graph the EMG data collected at the Tibialis Anterior is shown and in the bottom graph the trigger level measured by the Saga's trigger port is shown. In the EMG data of the Soleus and Tibialis Anterior no stimulation artefact seems to occur as in the test of figure 13. Also only 4 trigger moments can be observed in the data of which one is about 1 second, which should be about 25 ms.

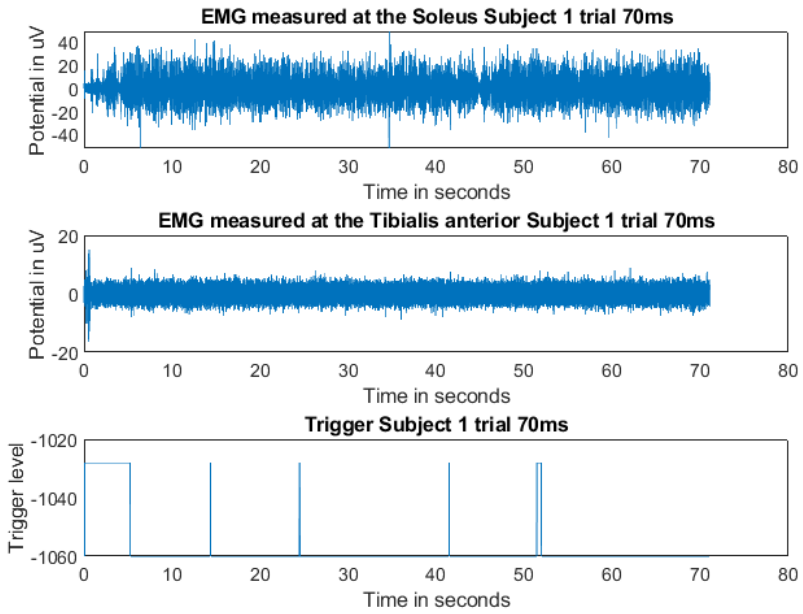

Figure 51: The EMG measured at the Soleus and Tibialis Anterior plotted against the trigger for subject 1, for experiment 3, with a time between stimulator onsets of 70 ms

D.4 Discussion

Figures 46 - 50 are relevant for this test. Some issues occurred during this measurement. There generally was no problem, but sometimes the connection to one of the stimulation devices was lost and it could take up to a minute to regain connection. This often resulted in one of the stimulation devices not giving the correct stimulation. Some of this behavior can be observed in figure 51, where the time between stimulation sets at time exceeds 10 seconds. In figures 46 – 49 the final stimulator does not show correct pulsing behavior. This behavior did not matter for the test as other devices showed a correct response. For later tests the behavior of the devices was checked and only those showing pulsing behavior were used in experiments. A small offset in the timing seemed to occur, overall this should not be an issue as the test is to observe if the changes in time intervals show effect. For later tests this behavior should however be fixed. In figure 46 it is shown that if timing between devices falls under 10 ms, correct timing cannot be guaranteed. It is therefore advisable to keep the timing above 10 ms per device. Using a device with a better time regulation than the Arduino might fix this issue. As it stands, the Arduino has a PWM module which depends on one of the ports to get a better timing. Meaning an output must be sacrificed to for correct timing. Despite the minor issues it was decided that the device functioned well enough and the experiments could be started.

Preliminary test

As observed in figure 51, during this test problems occurred with the synchronization and stimulation. For this reason it was decided to scrap this test from the main experiment. Although this test is still seen as viable, the setup needs more work and might be subjected to some limitations. The following problems need to be reviewed:

1. Wired communication: The current Uart protocol cannot be terminated. Once the protocol is turned on the initial connection (both existing or none existing) is set. The only way to change it is to terminate the run of the program, change the de-

sired COM-port and restarted the protocol. This means the program can be worked with, but it should be possible to switch COM ports or turn of COM ports during operation.

2. Wireless communication: Issues can occur with the Bluetooth connection between device and laptop. Due to this connection error, stimulation parameters can be lost and one of the devices may not stimulate. Not having all devices start at once already reduces this problem, but when devices communicate at the same time this can cause issues. The devices need to be set in such a way that only one can communicate at a time.

3. Currently an Arduino Uno is used to communicate with the NociTrack devices. This has its limitations because of the limited PWM ports and the way the PWM ports are configured. For this reason it might be better to use a different device than the Arduino Uno, so more PWM ports can be added if necessary.

4. The NociTrack device has a limited amount of power it can deliver. The Digitimer can deliver up to 50 mA and up to 140 V, for the Nocitrack this is however limited to about 80 V and 10 mA. This can still be worked with, but has limitations. In this case the maximum electrode distance used for the NociTrack device is limited and it's functionality is more affected by calluses.

The second setup does not yet function as intended. This could be due to the devices simply not being capable of the delivering the necessary stimulation. Further tests should be performed to check if the device can produce enough power to stimulate the intended neurons.
If this is possible, changes should be made in the setup. One step that should be taken is switching out the Arduino for a different microcontroller. The amount of PWM ports on the Arduino is limited, PWM ports are linked in pairs and to improve the time control, one of a pair needs to be sacrificed, leaving only three ports with good time control or 6 with poor time control.
The current issue likely stems from the bluetooth protocol that is used. Currently the device is being improved upon, and a new bluetooth protocol and trigger system are being created. It might therefore be best to focus on testing the limitations of the NociTrack device, using only one stimulator, in order to find how usable this device is for future reference.

E Observations

During the processing of the data, some observations were made. These observations are not relevant to the experiments themselves, but might be useful for future works.

E.1 Difference in stance

One observation that was made, was a difference in force distribution. Some subjects show variability in force in both feet, while other other only show variability in on foot.

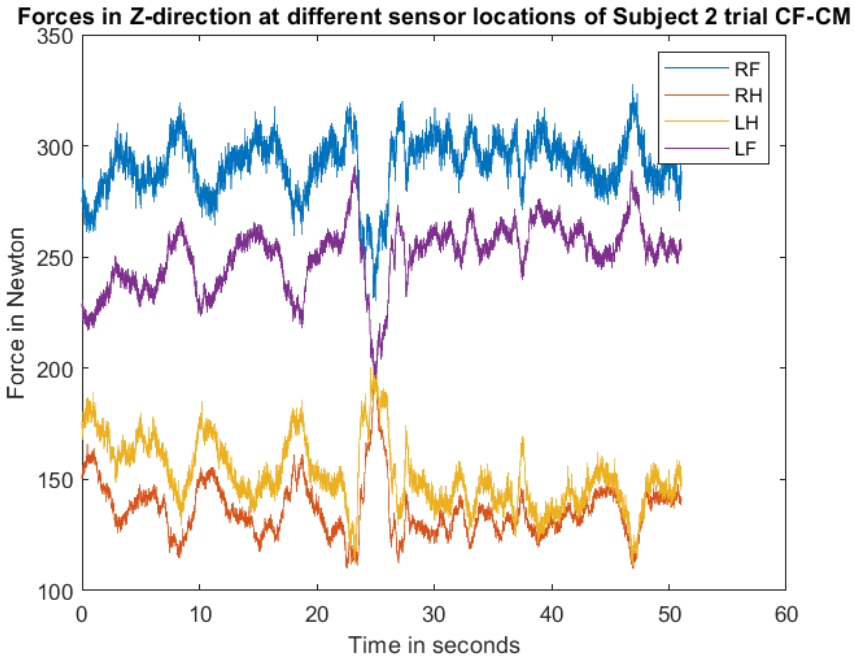

Figure 52: Raw force shoe data in which both feet show movement

In figure 52 the forces measured from the force shoe at the right front, right heel, left heel and left front are shown. It can be observed that the data gathered from the left foot shows more variance than the data gained from the right foot. The expectation was that more variance would be shown in the right foot as this is the foot that is stimulated. This type of stance was observed for subject 3, 4, 6 and 9.

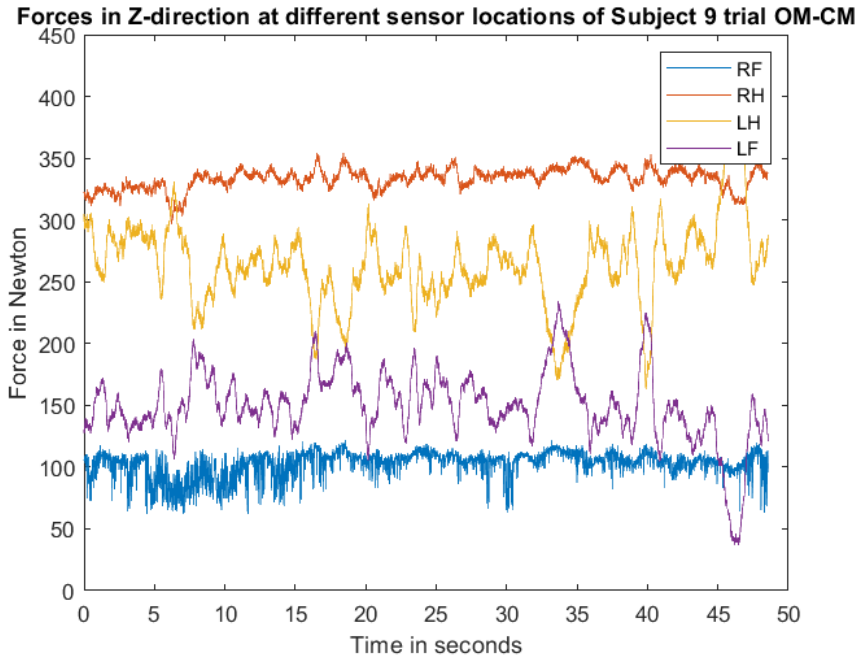

Figure 53: The GRF in Z-direction in Newton on the Y-axis. This plot contains the forces in Z-direction measured at every sensor

In figure 53, the forces in Z-direction are plotted per sensor. In this measurement, the measurements at the front of the foot seem to mirror the measurements at the back of the foot in this case. It seems that the measurements can be divided into two groups, in one group only the left foot shows change and in the other group both feet shows changes. This type of stance was observed for subject 1, 2, 5, and 7. In figure 52 the GRF data is shown, in this data plot it can be seen that the force on the right foot fluctuates less than the force on the left foot. This was expected to be the other way around as the right foot is stimulated. One possible reason for this behaviour is bracing, the subject in this case tries to compensate for the stimulation by standing more on the right foot. In other subjects, both feet show movement, where the upper part of both feet and the heel of the feet are somewhat synchronized, as shown in figure 53. This behaviour is odd and can lead to differences in CoP measurement. One reason this might happen is bracing, the subject expects the electrical stimulation and changes his stance accordingly. A test could be performed where the subject CoP is measured without electrodes, with electrodes and after that with stimulation, to see if there are significant changes in stance.

E.2 EMG abnormalities

Some other observations can be made in the EMG data. In figure 54 the EMG of subject 9 is shown. What can be observed is that after the pulse the EMG does not seem to show any significant data because the signal is almost completely sinusoidal. This effect could also be observed for subject 3. This could have been caused by wrongly placed electrodes. After placement there should be more checks in place to ensure that this does not happen.

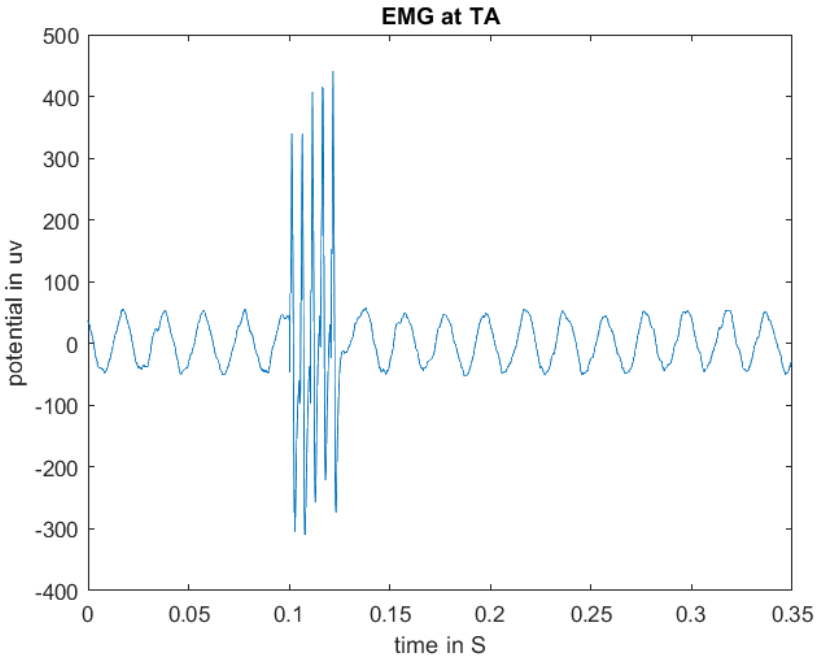

Figure 54: EMG as observed for subjects 3 and 9

In figure 55 the EMG of subject 7 is shown. What can be observed is that their are some extreme peaks in the EMG. This can be a startle effect, which is caused by the electrical stimulation amplitude being too high. If this is observed, the PT test should be redone.

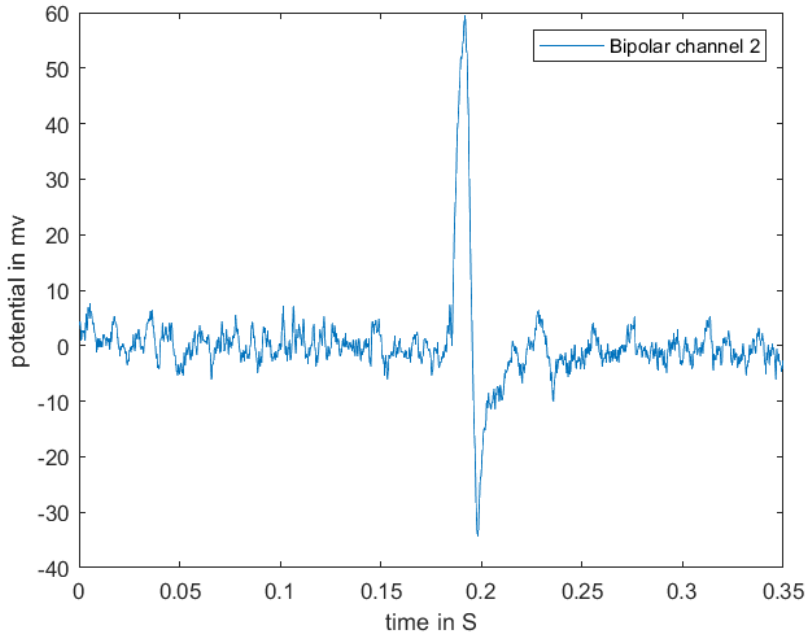

Figure 55: EMG as observed for subject 7

E.3 Contamination

In figure 56 the top graph shows the trigger moments in the form of downward peaks along a time axis. In the same time axis, the response of the four sensor of the Force Shoe are shown. Here the colors correspond to different placements of the sensors. These

include right front (RF, blue), right back or heel (RB, red), left back or heel (LB, yellow) and left front (LF, purple). It can be seen that the that the peaking in the raw force shoe data seems to start after the first pulse and ends about 7-9 seconds after the final pulse. The time between pulses is 4 – 10 seconds, which means contamination of data is possible. In this graph RF and LF seem to mirror the responses of RB and LB.

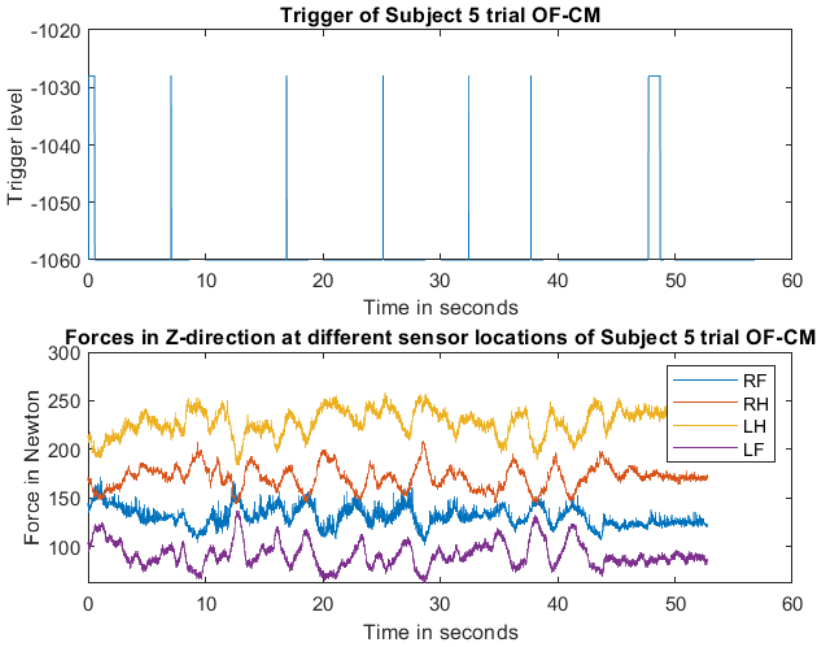

Figure 56: Raw force shoe data, with trigger pulses

F Manual

In this chapter the setups that are used will be further explained, a manual on how to setup the system is given and some explanation about the programs that are used is given. This chapter should be sufficient to get the setup working.

F.1 Connections

For the first step, the devices must be connected to each other. This is shortly explained in the following section. In figure 57 the upper part of the NI-USB 6211 is shown. This device is the control system of the setup and the control and synchronization is done through this device. 2 of its analog output ports (ao0 and ao1) and 1 of its digital output port (PFI 4) are used along with the digital and the analog ground. We will now go over which ports are connected to which devices, what the function of the connection is and which cables are used to connected to these devices.

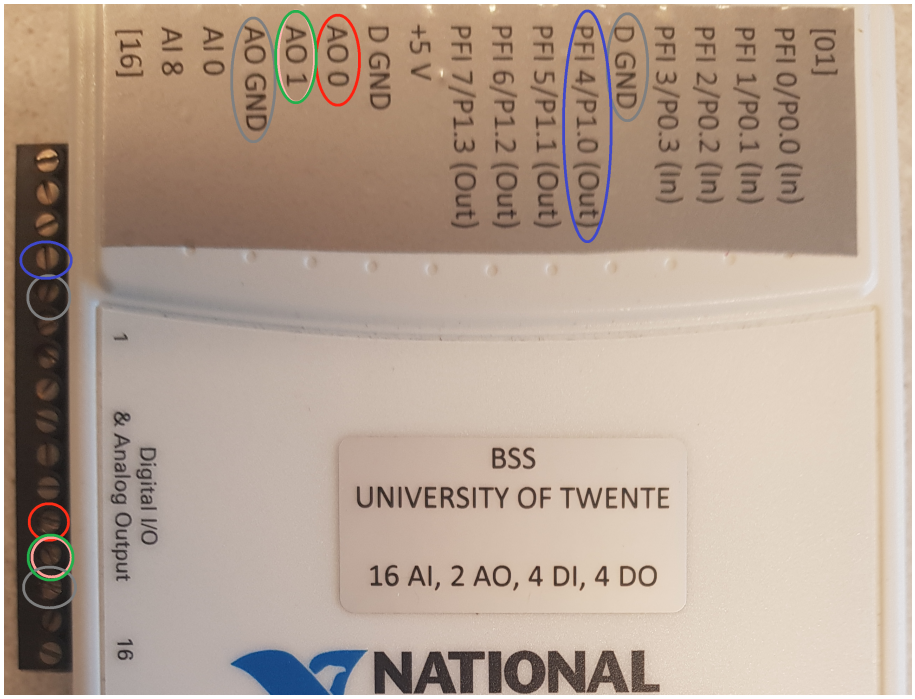

Figure 57: The NI-USB 6211 and its connections color coded

The TMSi SAGA is connected to the NI-USB 6211 using the connector in figure 61.A and figure 61.B. The red wire of cable A goes into the ao1 port of the NI-card and the black wire goes into the analog ground. This cable is then connected to cable B, which goes into the digi port of the TMSi SAGA, see figure 58.
This connection is used to time the triggering of the NI-card and for the initial synchronization. The initialization pulse on the trigger occurs at the same time the force shoes are triggered, making the measurements coincide from that point on. It also gives a pulse signal on the at the same time electrical stimulation is applied on the foot sole.

Figure 58: The digi port to which the connection to which the connection to the NI-card must be made

The Xsens Force Shoes Xbus master is connected to the to the NI-card using the connector in figure 61.D. The red wire is connected to the PFI 4 port and the black wire to the digital ground. This cable is then connected to the sync port of the of the Xbus master. See figure 59.
The Force shoes can be set in slave mode, in this mode they will only take measurements if a trigger signal is present on the sync port. By controlling when the trigger signal is present, the measurements of the TMSi SAGA and Xsens Force Shoes can be synchronized.

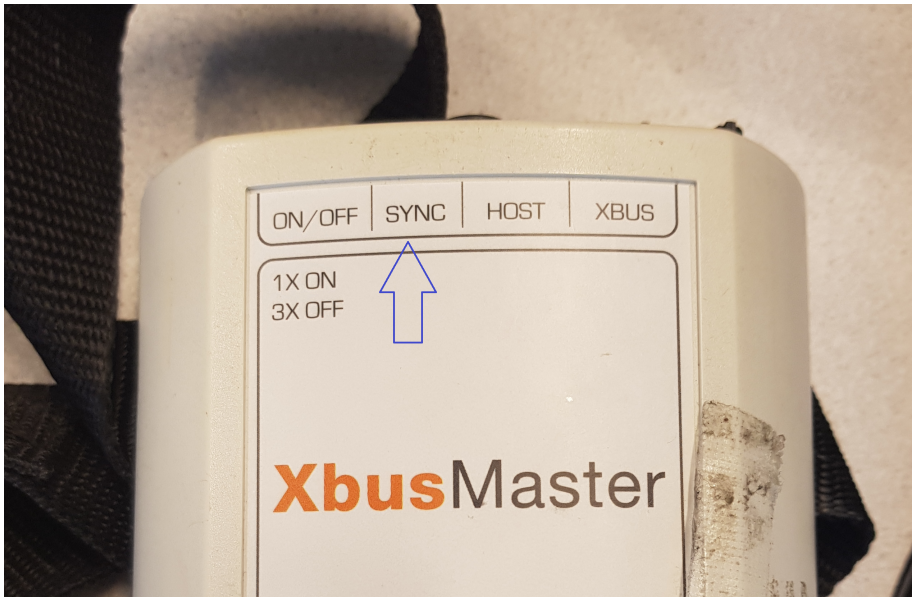

Figure 59: The GUI of the PT test

The Digitimer DS5 is connected to the NI-card using the connector in figure 61.C. The red wire is connected to ao0 port and the black wire is connected to the analog ground. The cable is then connected to the top left connector shown in figure 60.
The template of the stimulation pattern is uploaded to the NI-card which sends this tem-

plate out to the Digitimer in potential form. In the Digitimer, this potential is converted to a current, and applied to the foot sole as a stimulation pattern.

Figure 60: The GUI of the PT test

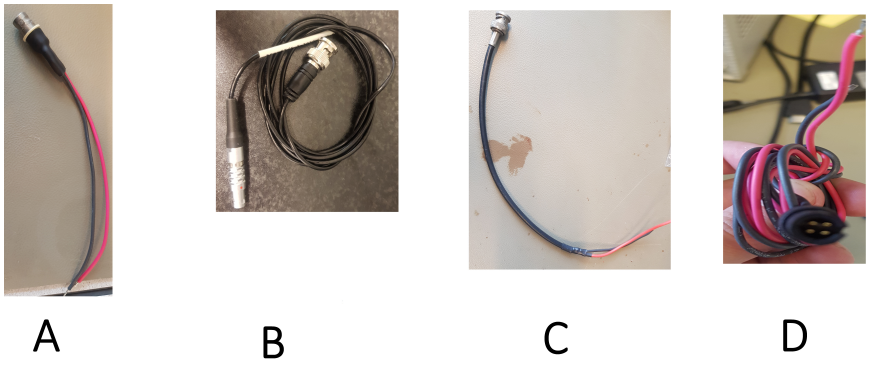

Figure 61: The connectors cables that are used

F.2 Protocol

In the protocol, two different programs are used to obtain measurements, using three different devices. These devices need to be set up before they can be used and during measurements a set of protocols must be followed to both ensure safety and correct measurements. The protocols will be described step by step.

Xsens force shoes

To use the force shoes, the program MT manager version 1.7.4.0 is needed, only this specific version can connect to the force shoe. When first starting up the program, make sure to run it as administrator. The program, will then ask for a code, this code should be provided in the map the program is in.

Also make sure that when the program is initially started, the driver for the transceiver is correctly installed, this should be availlable in the map in the usb driver map. More documentation on this should also be provided in the case.

Finally it is possible that when the system is first booted up an error will occur. This is caused by the program running on an old version of Microsoft visual studios, which has a bug. To use the program make sure that this version of visual studios is installed on the device you are using to run the program. This should be Microsoft Visual C++ 2008 Service Pack 1 and Microsoft Visual C++ 2008 Redistributable Package ATL

If the program functions correctly, starting it up, a pop up will appear with settings, the-

ses settings can be found in the map under filename MT settings and a walk through is provided in the file "READ THIS". The steps will also be provided here.

1. Open MT manager
2. Click Next in the configuration wizard window
3. In the second window check 'Calibrated Data'
4. Click Next until finish
5. Select each device using its ID (01322316/0, 01322260/3, 01322259/2, 01321169/0) see red box in figure 62
6. Click the Icon for MT/XM Settings and make sure it is same as the picture saved titled 'MT Settings', see blue box in figure 62
7. You can now record Force Data (press the red button in the yellow box in figure 62
8. Go to Tools -> Do ForceShoe Unloaded before starting experiments
9. Save an offset trial

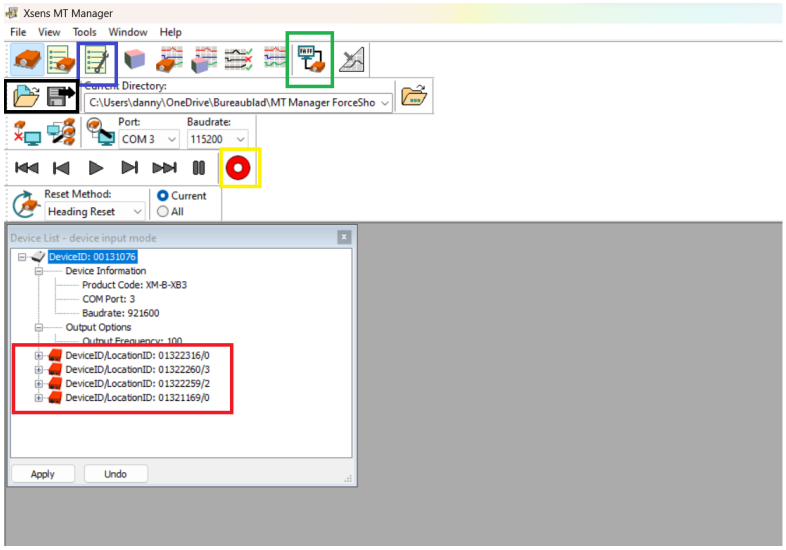

Figure 62: Settings used for the force shoes in MT manager

Once this is done, a measurement can be started by pressing the record button. However, the system must likely still be set to slave mode. To do this go to data viewer (green box in figure 62. Here a pop up menu, a check box and a send button can be seen in the top bar. In the pop up menu select "GotoConfig" to set the system into configuration mode. In this mode find "SetSyncMode - Slave" and press send with the checkbox unmarked. Lastly set the pop up menu to "GotoMeasurement" and press send. Once you are done with the measurements, return the old settings by starting the process again, but instead of selecting "SetSyncMode - Slave", select "SetSyncMode - Master".

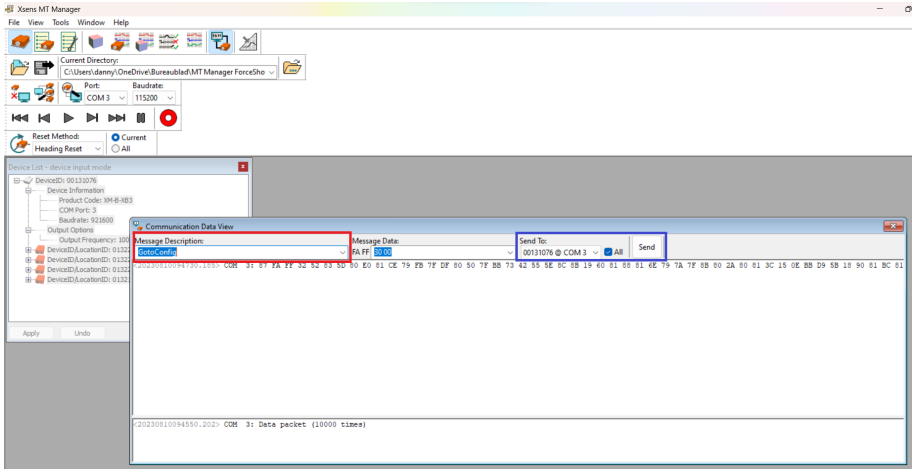

Figure 63: The dataviewer of MT manager

It is recommended to change the names of the data files in which the measurements are saved. This can be done by going to tools->options, this opens a second window. In this window, select loggings and in the text field, write the file name, for instance subject 1. This will make it easier to find the correct files later on.
To convert the files to a text file, the following steps must be taken. Open one of the files using the button in the black box in figure 62 and then press the button next to it. The MT manager file will now be converted into 4 text files containing forces and moments. These are saved per sensor (right front, right heel, left heel, left front). Each of these files must be named manually, do not use batch export!

F.3 PT Test

Before the experiments, a test is performed to find a subjects perceptual threshold in different regions of the foot sole. These values are currently written down and used as settings in later programs. The GUI of the PT test is shown in figure 64

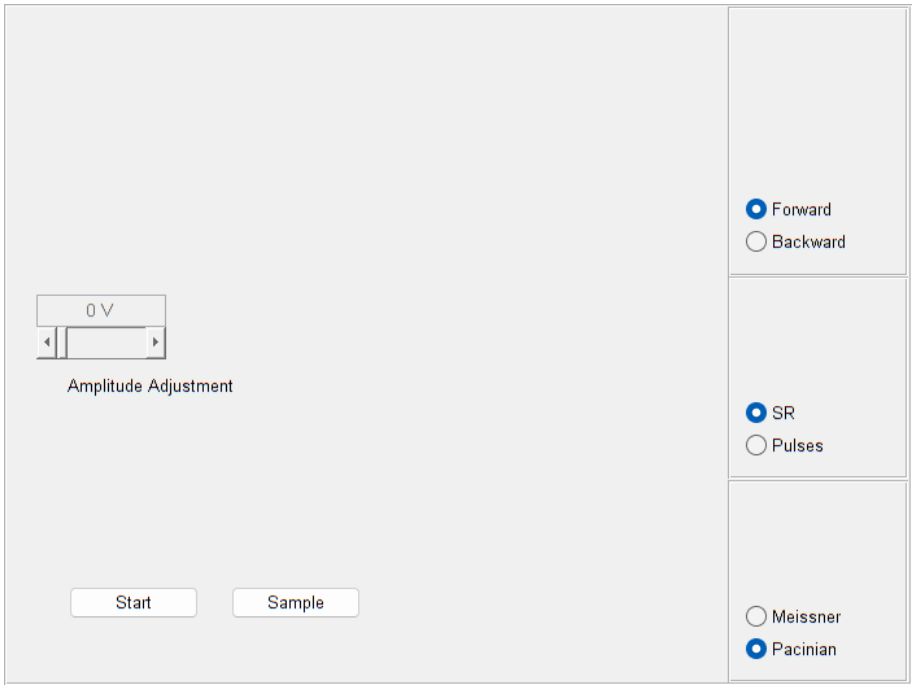

Figure 64: The GUI of the PT test

In the main field a set slider, a start button and a sample button are shown. The slider is used to set the stimulation amplitude somewhere between 0 and 10 mA, the start button will start a PT measurement and sample will give a sample stimulation of 3 x PT.
In the side bar three blocks are defined, in the current iteration the top block is not used. This block shows the ticks forward and backward. This was meant as a restriction, to ensure the slider could only be shifted in one direction. Later on it was decided that this was not necessary and so the function was removed, but not yet completely.
Under this block is the stimulation type block, here the stimulation type can be set as either a stochastic noise stimulation or a pulse stimulation. In case pulse stimulation is used, the stimulation frequency is set to that of either the Pacinian (about 200 Hz) or the Meissner (about 30 Hz). For noise the noise band is to 100 - 400 Hz for the Pacinian and 20 - 60 Hz for the Meissner.

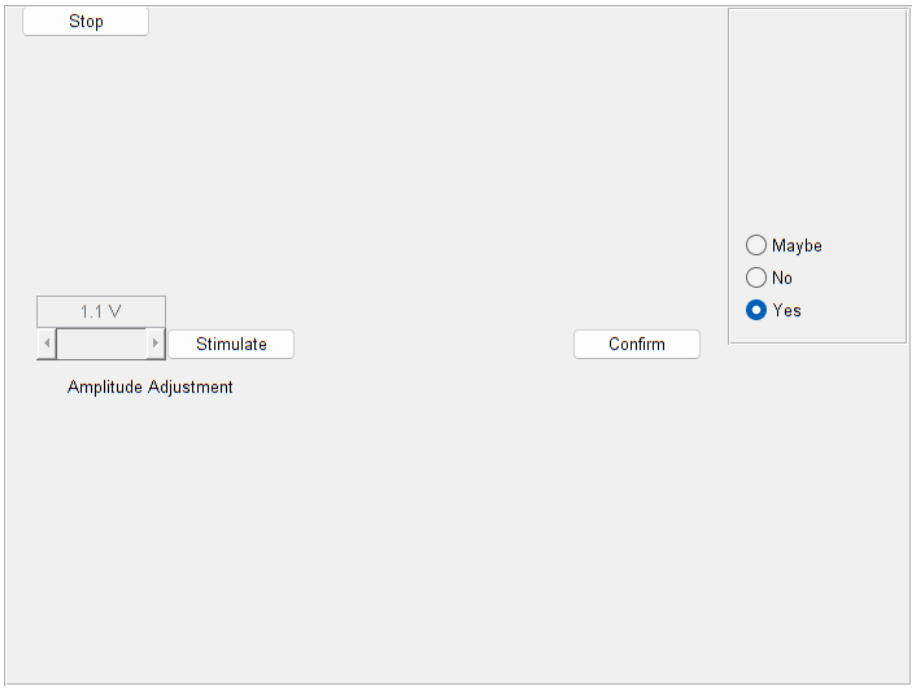

Figure 65: The second GUI of the PT test

Once the start button is pressed, initialization is done and a second GUI pops up as shown in figure 65. In this GUI the stimulation will be performed. Stimulation can be set to an current of 0 to 10 mA. When the stimulate button is pressed, 5 pulse trains of 0.5 seconds will be applied on the designated stimulation area. Once the stimulation is done, the system will ask if the pulse was felt (answer following the set protocol). This system still needs work, as the intended function was a system that would automatically plot regions and extrapolate the PT, but this still needs work.

F.4 Experiment 1

For the first experiment the following GUI is created:

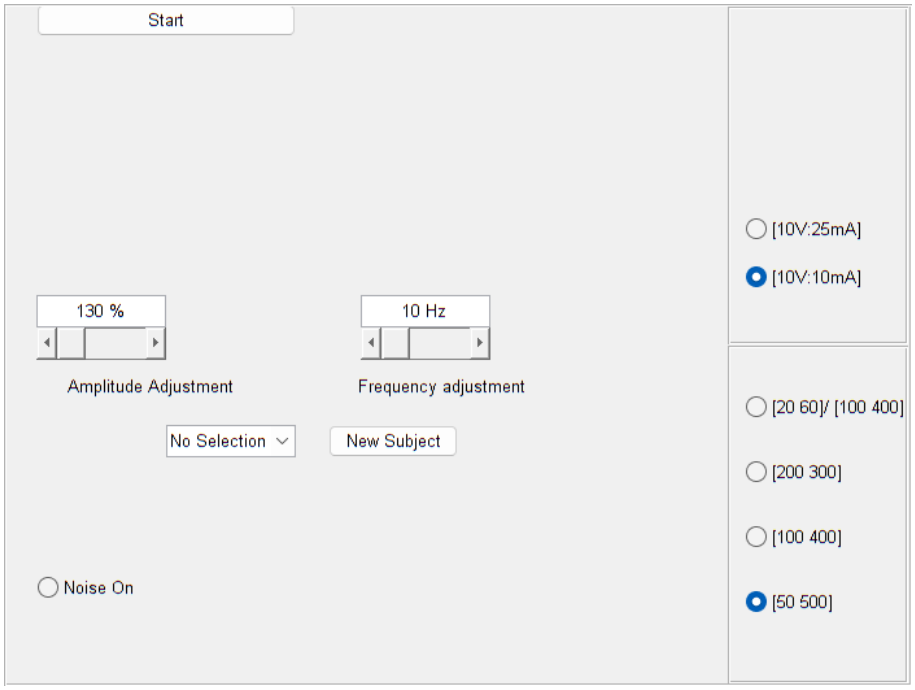

Figure 66: The GUI of the First experiment

At the start of the program, when calling the function, the pulse and stochastic resonance PT must entered into the function. In the GUI a subject can be selected (pop-up menu) or a new subject can be created (new subject button) and then selected. The amplitude adjustment slider can be used to set the amplitude of the pulses, (normally between 200 and 300 %) and the stimulation frequency can be set using the frequency slider.
Noise can be turned on and in that case noise will be created using a random function and filtering this using the selected bandpass. It must be noted that the top function does not currently work.
The top right panel will set the potential current division, in case currents higher than 10 mA will be used. There currently is no feedback from the stimulator, so it must be manually checked that the setting on the stimulator and the setting in the program match before use. A measurement will automatically be named, using the following template. T(subject)F(two most significant number of the stimulation amplitude)X(N (no stimulation)/ B(2 most significant numbers of lower frequency band - 2 most significant numbers of upper frequency band)). In case a measurement is repeated, the system will warn that a file will be overwritten.

F.5 Experiment 2

For the second experiment the following GUI is created:

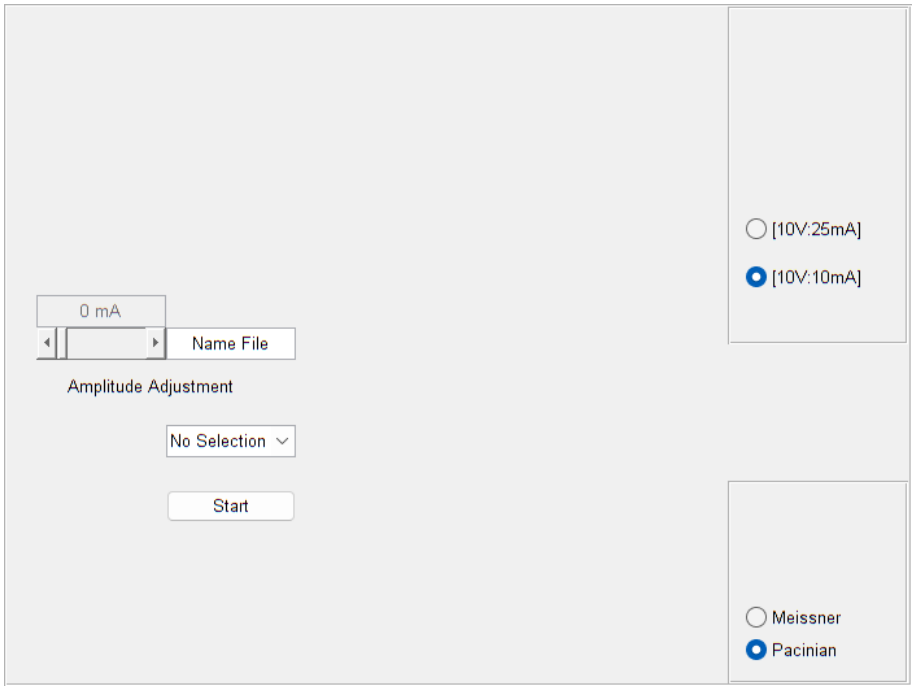

Figure 67: The GUI of the second experiment

The GUI has an amplitude adjustment slider, set between 0 - 10 mA or 0 - 25 mA depending on the setting in the top right panel. The bottom right panel can be used to the stimulation frequency to the optimal frequency for the Pacinian (200 Hz) or the Meissner (30 Hz). The pop-up menu can be used to select the subject and the text box can be used to write the trial name. In the case of this experiment the naming convention was the abbreviation of the cathode and anode position, so (CP - AP).
When the start button is pushed, measurements are started using the set parameters and the foot sole will be stimulated using 5 pulse trains of 5 bipolar pulses, with pulse width set to 2 ms (1 ms positive, 1 ms negative) and stimulation frequency either set to 200 or 30 Hz. Time between pulse trains is set to a random interval between 4 and 10 seconds.

F.6 Experiment 3

For the third experiment the following GUI is created:

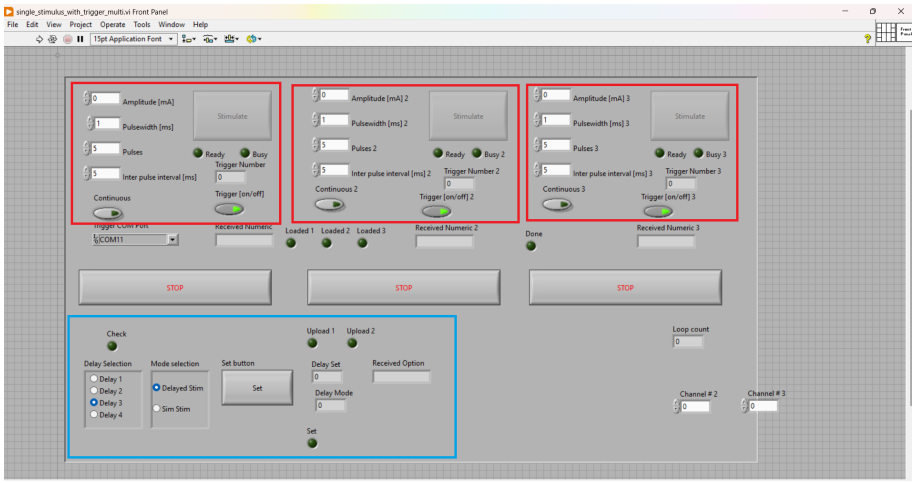

Figure 68: The GUI of the third experiment

In figure 68 the GUI of the third experiment is shown. Marked in red are the individual stimulator controls, marked in blue is the arduino settings. Outside of these marked areas is also the trigger port and the start arrow. Before the program is started, the correct trigger port must be set (trigger pop up menu), this depends on the device that is used. Once this is done the arrow in the top left can be pushed to start the program, this will open an additional screen. In this screen the connection to the devices is set up. Set...
Once this is done, the individual stimulator settings can be set, per device the stimulation amplitude, time between pulses, pulse width and number of pulses can be set. Once the right settings are made, pushing the stimulate button will send the parameters to the stimulator. Note that if the stimulate button is grayed out, no connection to a stimulation device exists. If the message is received correctly, the corresponded loaded indicator will turn on.
The blue marked area can be used to set the arduino trigger settings. These settings will change the timing of the Arduino triggering and thus how much time between stimulation device activation there is.
When all stimulators are set, all loaded indicators should be turned on and a LED on the Arduino trigger box should light up. If this LED is lit, the button on the trigger box can be pressed to start the stimulation protocol. During the protocol, each stimulator apply give 5 pulse trains of 5 unipolar pulses with a pulse width of 1 ms and a stimulation frequency of 200 Hz on the specified regions of the foot sole, where each stimulator will perform its function at a designated time. Once the protocol is done, the system will reset and await new input.

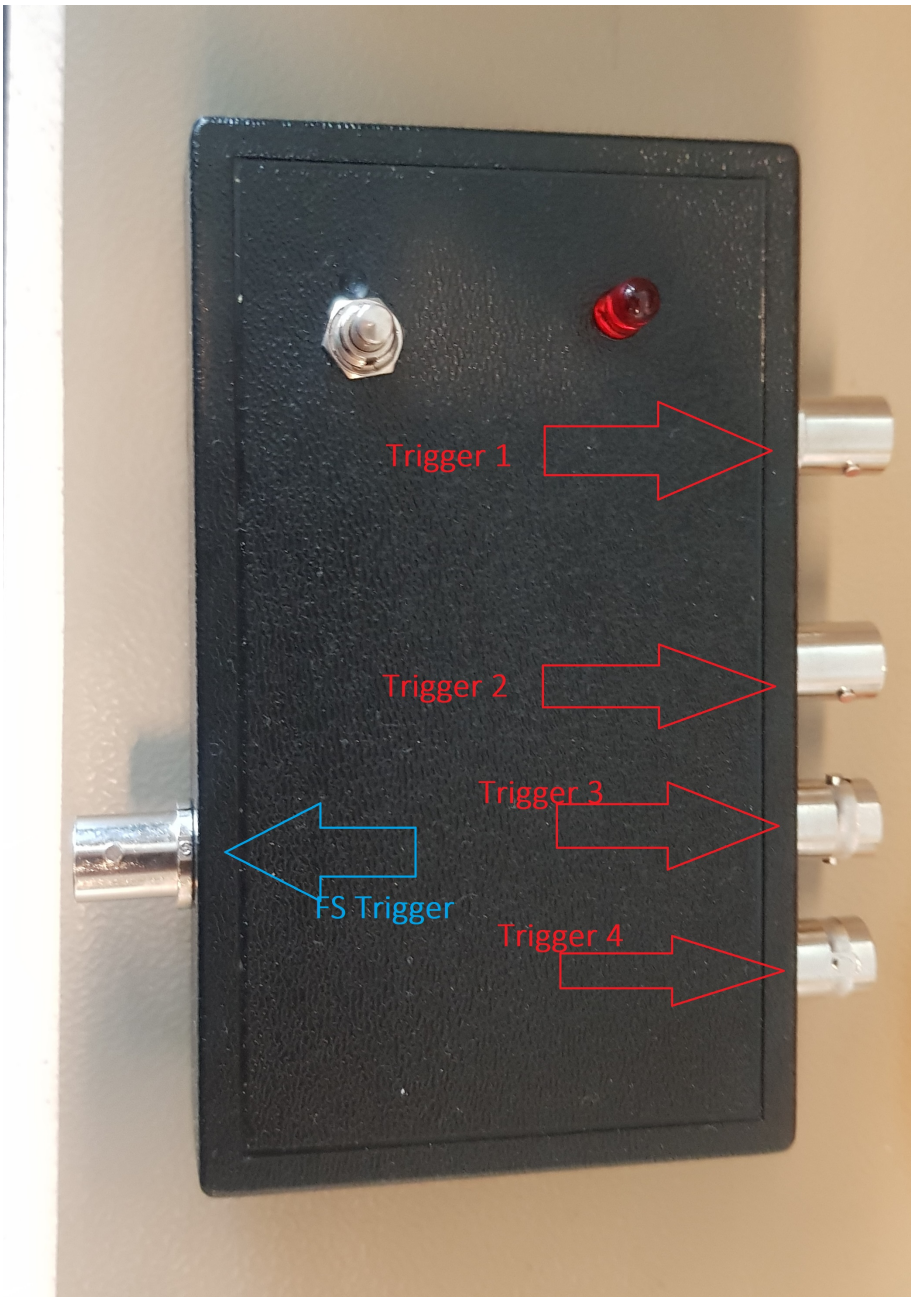

Figure 69: The Arduino trigger box

F.7 Data collection

Once the experiments are performed and data has been gathered, the data has to be processed. To read the data files two programs were created. "gatherData" and "gatherData2" are used to prep the data for use. "gatherData" is used to process the Force shoe. It must be noted that this file is file location specific and to use it the path to the map where the file is must be known. Either the map can be selected in Matlab or the path to the file can be saved. This can be done by going to the map in Matlab and typing cd in the command window, this will result in the full path to the map. In this case the naming convention "File name" + 1, 2, 3 or 4 was used. In this way the program could open all necessary files by only having the file name.

G Force shoe improvement

Currently, the force shoe CoP calculation uses a simplified method. This method can be improved upon using the following formula.

Formula
In this formula, the positions are set, static positions. In the second formula, the initial CoP positions are altered using the following formula:

$$Pos_{adj,ij} = \frac{M_{ij}}{F_{z,ij}} + Pos_{ij} \tag{4}$$

$$CoP = \frac{F_{z,LF}}{F_{z,tot}} * Pos_{adj,LF} + \frac{F_{z,LH}}{F_{z,tot}} * Pos_{adj,LH} + \frac{F_{z,RF}}{F_{z,tot}} * Pos_{adj,RF} + \frac{F_{z,RH}}{F_{z,tot}} * Pos_{adj,RH} \tag{5}$$

The Vicon adjust the GRF on a force plate to a central point. Because of this the CoP can be calculated using the following formula:

$$Pos_X = \frac{-M_Y}{F_Z}, Pos_Y = \frac{M_X}{F_Z} \tag{6}$$

Where M indicates the moments measured in the X and Y direction.

Future work
The current method should be sufficient for the current research. If however the CoM is to be calculated, the CoP method must be improved upon. Currently this method still has some issues, as it is not clear how the moment is to be used in this situation. This requires further investigation

H Information letter

Information letter

The effects of electrical stimulation on the foot sole on the balance position

Dear readers,

In this letter, we would like to inform you about the research "The effects of electrical stimulation on the foot sole on the balance position" that you are called to participate in. Your decision to accept or deny participation should be based on proper information. This letter consists of the aim of the research, details about the procedure, and possible risks.

If you decide to participate, you are free to withdraw from the study at any time, without stating any reason. Within 24 hours after the experiment, you can decide that your data may not be used for the research after all, again, without a statement of a reason. At the end of the entire research, you can be informed about the results obtained if desired.

Signing this document, you declare that you are a volunteer and will not receive remuneration. Details about the date and location of the experiment will be shared with you separately.

Aim and background

The aim of this study is to observe the effect of several different electrical stimulation methods on the foot sole. The goal is to get a clearer understanding of the effects of stochastic resonance and the mechanoreceptor hierarchy in the foot sole. These experiments can potentially be used to create methods which can help prevent falls in the elderly and methods that help with revalidating people suffering from extended bed rest, like coma patients.

In this study, we will focus on the Pacinian corpuscle, this is a mechanoreceptor that is activated by high frequency vibrations. It reacts for instance in quick changes in foot pressure, for instance during walking. In the elderly or people with certain disorders, for instance diabetics, these mechanoreceptors are reduced in numbers. This can influence the persons reflex when becoming unstable and thus increase the risk of falling.

As little is known of the intricacies of the dynamic behaviour of all mechanoreceptors, research is being done in this field to increase our knowledge. These experiments are done to try and create a baseline from which we can predict the actions of electrical stimulation on the foot sole. For instance, mechanical noise with certain bandwidths can increase sensitivity to subliminal stimuli. For electrical stimulation a similar concept seems to apply. This could mean that electrical stimulation can be used to help increase the sensitivity of the feet of the elderly and thus reduce the risk of falling among other applications.

The experiment procedure

This experiment will consist of 2 sessions with each two stages, preparations and the experiments. The duration of a session is supposed to be 2 hours.

- The first preparation stage, in this stage we will perform some simple actions to

optimize the signal quality. The first test is a test were the optimal foot placement is measured. Here you will wear special shoes called the force shoes and your feet are placed at around shoulder width and a check is performed to see if your movement during stance is below a certain limit. The second procedure that is performed is the placement of the EMG electrodes, these will be placed at the tibiallis anterior and the Soleus (shin and calf), this placement will follow the SENIAM procedure. After this, the stimulation electrodes will be placed following figure 1. Using a stimulation current of 6 mA, the resistance between electrodes will be measured and it will be checked if you will feel the stimulation. When this is done a test will be performed to find the Perceptual threshold for each electrode pair. The perceptual threshold is the lowest current for which stimulation can be felt. For this procedure, we will use descending stimulation amplitudes. During the test, your right foot will be stimulated using 5 pulse trains with a randomized time between pulse trains. During the set of trains, the researchers can see when stimulation takes place. If you feel the stimulation, you are supposed to give a verbal que. If this que is at the right time, this will be counted as a pulse felt. Perceptual threshold will be reached if only 2/5 or less pulses are felt. Stimulation will be performed at 2-3 x PT. We fill let you get familiarized with the stimulation before starting the test.

- The first testing stage will consist of two tests. In the first test we will look at the effects of stochastic resonance in combination with different stimulation frequencies. During this test you will stand while wearing special shoes called the force shoes. During the experiment your foot sole will be stimulated using predefined stimulation patterns. Stimulation will take place 5 times, at random intervals between 4 and 10 seconds. The second test will consist of different stimulation locations on the foot. During this test, one electrode will stimulate in the direction of the other, and after this polarity will be reversed. During these tests your center of pressure will be measured and an EMG measurement will be done at the soleus muscle and the tibiallis anterior muscle to measure the muscle responses.

- In the second preparation stage, the process of the first preparation stage will be repeated, for the set of electrodes significant for this test.

- In the second measurement stage, we will perform a wave test. Three stimulator will be connected to your foot soles in the form of an electrode pair. These stimulators will stimulate the foot sole in a certain pattern as to create a stimulation wave on the foot sole, meant to mimick at least part of the walking cycle. The activation timing of subsequent stimulators will change during the experiment, to observe if, faster or slower waves create a stronger response.

Possible Risks

There should be no direct risks involved in this experiment. We use electro-cutaneous non-nociceptive stimulation. As the stimulation is limited to the foot sole of the right foot, no current should be able to go over the heart. Stimulation current, although dependent on the subject, should generally be lower than 15 mA. Both electro-tactile stimulation and electrode placement are standard experimental procedures applied in the BSS group and have shown no adverse effects.

However, some people might find the electrical stimulus discomforting. Discomfort can be caused by not completely healed wound or blemishes of the skin. In this case it would

be advised to stop the trails, as pain may influence the results. The subject is always allowed to stop the experiment and the researchers can stop the process immediately. In the case of some adverse effects, the phone number of the laboratory technician and the emergency from the University of Twente are provided on the lab's wall in front of the entrance. The laboratory is also equipped with a fire extinguisher.

Finally, the subject should be mindful that the selection criteria of the experiment will be made to minimize any unexpected risk. Subjects with pregnancy, implanted stimulation devices, skin reactance against alcohol or scrub gel, etc. will be excluded from this research. Please refer to the "Subject's Consent" document to find out more about the inclusion criteria.

Data

The subject's data will be handled confidentially and will be anonymized right after the experiment to protect sensitive personal identity information. The anonymized data will be stored in certified data storage facilities (i.e., Surfdrive) that comply with Dutch and European privacy legislation. The subject's name will be in no manner connected to the data. We will never disclose the data to third parties without your permission. In the publication of this research, as a BSc or MSc thesis and possibly scientific publications, the personal information (e.g., age and height) will be given on a group level and no individual data will be disclosed. The selected research data will be archived 10 years and deleted end of this time, unless legal or contractual regulations demand another term. Thanks for your cooperation. Should you have any other questions, please do not hesitate to contact us.

Ing. D. Sanders,
Master Student
Biomedical Signals and Systems research group
Faculty of EEMCS
The University of Twente, room ZH207
tel:+31644246332
E-mail: D.sanders@student.utwente.nl

I Consent form

Subject's Consent:

Testing different paradigms of functional sensory stimulation on the foot sole for balance manipulation.

I declare that I've read and understood the information brochure about the research titled: "Testing different paradigms of functional sensory stimulation on the foot sole for balance manipulation." I have been able to ask questions and, if applicable, been answered to my satisfaction.

- I declare that I voluntarily participate in the abovementioned experiment. I'm aware that I can withdraw from this study at any time without stating any reasons.
- I permit processing my data in the above-mentioned manner. Data will be anonymized and not shared with any third parties without my consent.
- I declare that I do have the two inclusion criteria for this experiment:

☐ Age between 18-55 years old.

☐ I do understand the written and verbal instructions in English

☐ I have a shoe size between 38 and 46 (eu size)

- I declare that I do not have this exclusion criterion for this experiment:

☐ Having implanted stimulation device

☐ Pregnancy

☐ Diabetes

☐ Motor impairment, deficiency, and postural deformities

☐ Musculoskeletal pain

☐ Extensive consumption of alcohol or any psychoactive drug/stimulant within 24 hours before the experiment

☐ Wounds or freshly healed wounds on the foot sole

- I would like to be informed about the result of the study; I permit you to reach out to me at the following email address:

_____

Participant information

Age: _____ Gender: Male/Female/Other_____

_____ _____ ____/_____/_____

Name participant Signature Date

The researcher declares to have properly informed the participant about the research and, to the best of his/her ability, ensured that the participant understands what they are freely consenting.

_____ _____ ____/_____/_____

Name participant Signature Date

Figure 70