CHALMERS

FOOT VOLUMETRY

- Testing and Evaluating a Possible Method to Determine the Function of the Calf Muscle Pump

Master of Science Thesis

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Göteborg, Sweden, 2011

Report No. EX024/2011

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Cover:
The Canteen Unit; a part of the Foot Volumetry Prototype
which is further described in Chapter 5.

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ABSTRACT

Varicose veins and blood thrombosis are two widespread and generally harmless illnesses. They can however be very dangerous to the afflicted persons depending on the severity of the respective conditions and how well the other functions of the body are operating. For instance, varicose veins mostly occur in the superficial veins of the leg but in severe cases the patient's deep veins could be affected. If that is the case it is crucial that the calf muscle pump is working appropriately to aid the veins to transport blood away from the lower extremities.

The Department of Clinical Physiology at Östra Sjukhuset in Göteborg has a technically outdated and non user-friendly device which is not currently in use for examination of patients. The device is based on a theory of foot volumetry which can evaluate the functionality of the patient's calf muscle pumps by registering the volume change in the feet during and after physical activity in the lower extremities. The volume change is approximated to be equal to the amount of blood being transported away from the feet to the heart due to the activity of the muscles in the legs.

During this Master Thesis the already existing device as well as other possible methods which also utilize the theory of foot volumetry has been taken into consideration. One especially promising concept, very similar to the outdated device, was further developed and realized with input from experts within various involved areas such as; cognitive ergonomics, material science, software programming and medical science. The complete prototype, in the report called the "the Foot Volumetry Prototype", consists of a software ("the Foot Volumetry Module") with a graphical user interface (GUI) and a physical prototype ("the Canteen Unit").

The Foot Volumetry Prototype was the subject of a number of tests with the ambition of trying to determine the functionality of the system as a whole. Two additional tests were conducted, one to determine the most sufficient physical activity for the examination and the other to try to approximate the relation between shoe size and foot volume which is needed for the diagnosis.

The evaluation of the test results are considered as the heart of the Master Thesis where the negative and the positive aspects concerning the design, function or material of the Foot Volumetry Prototype are weighed and discussed. This evaluation generates a number of recommendations meant to improve the performance of the next version of the Foot Volumetry Prototype. Examples of such recommendations are to change the material in and dimensions of some of the components as well as to perform observations of the staff members while they are using the whole system.

All in all, the Foot Volumetry Prototype leaves some things to wish for in terms of design and overall material selections. The prototype does however apply the theory of foot volumetry in a non-complicated and fairly reliable manner considering the delimitations of its development in this Master Thesis.

ABBREVIATIONS

CCD – Charge-Coupling Device

DVT – Deep Vein Thrombosis

GUI – Graphical User Interface

HTA – Hierarchical Task Analysis

RTSC – Real Time Surface Compensation

NOMENCLATURE

Calf muscle pump – a combined expression for the calf muscles and the veins in the lower leg

Embolus (plural: Emboli) – a blood clot that has broken off from its original place

Fibrin – a fibrous protein in the blood which is active in blood coagulation

Foot volumetry – a method for measuring the volume change of the foot

Greater saphenous vein – the largest superficial vein in the leg

Hypercoagulability – blood clotting faster than usual

Invasive – inside the body

Non-invasive – outside the body

Oedema – swelling in body parts due to fluid accumulation

PeriVasc© – software by Ekman Biomedical Data AB which is used at the department of Clinical Physiology at Östra Sjukhuset, Göteborg

Platelets – fragments of cells in the blood that are active in blood coagulation

Pulmonary embolism – when an embolus has formed a blockage of the main artery of the lung or in one of its branches

Reflux – regression of blood in veins

Teleangiectasis – or spider veins; a term for visible enlargement of blood vessels

Thrombosis – blood clot

Varicose veins – veins that have become enlarged and convoluted

Varicose ulcers – open wounds which could emerge in severe cases of varicose veins

Östra Sjukhuset – a division of Sahlgrenska University Hospital, located in Göteborg

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1 INTRODUCTION

In this chapter, a description of the background to the Master Thesis, followed by the purpose, objectives and delimitations are presented.

1.1 BACKGROUND

Varicose veins, varicose ulcers and deep vein thrombosis (DVT) are common health problems among the population in industrial countries (Norgren L. , 1992). There are a number of ways to diagnose these conditions today but none of them can fully cover all the aspects necessary to define how severe the conditions are. The Department of Clinical Physiology at Östra Sjukhuset, Göteborg, already uses several methods to diagnose varicose veins and varicose ulcers, but has expressed a need for a specific measuring device which would evaluate the functionality of the patient's calf muscle pumps. This would be done by measuring how the blood volume changes in the feet during and after physical activities in the lower extremities.

A prototype for measuring blood volume change using foot volumetry already existed at the Department at Östra Sjukhuset, but it was not in use due to the device being technically out-of-date, non user-friendly and not optimally designed in terms of hygienic aspects. However, the theory the device was realizing could very well be implemented in a newer and more user-friendly design.

1.2 PURPOSE

The purpose of this Master Thesis was to evaluate one of the possible methods of realizing the theory of foot volumetry, a diagnosis method for varicose veins, varicose ulcers and deep vein thrombosis.

1.3 OBJECTIVES

The objectives for this Master Thesis were to develop and build a prototype of an especially promising concept, to perform tests for estimating the functionality of the prototype and finally to evaluate and leave recommendations for future improvements of the prototype.

1.4 DELIMITATIONS

No deeper studies of the medical conditions of varicose veins or deep vein thrombosis were done, since the knowledge of why these two could occur and the most common ways of diagnosing and treating the conditions are considered to be detailed enough for this Master Thesis. Furthermore, no studies or considerations were done concerning Telangiectasia ("spider veins") and since it is the methods of diagnosis that is of interest and not the different devices existing on the market, little or no benchmarking was done.

Even though the prototype can be used to measure both left and right foot separately the tests, except the fifth test concerning approximation of foot volume, have only been executed with the participant's right foot.

During the development of the Foot Volumetry Prototype several different aspects came through as important to consider. It has however been impossible within the time frames of this Master Thesis to consider and develop all of these aspects at the level they probably should have been taken into account. An example of such an aspect is the approximation of the relation between shoe size and foot volume which in this report intentionally have been kept at a very crude level.

It would have been preferable to test the prototype with the already utilized software as a whole in the contemplated environment at Östra Sjukhuset, but due to shortage of time this was not feasible.

A complete redesign of the prototype post-evaluation was not a part of the Master Thesis but is rather described as a number of recommended improvements in the report.

2 MEDICAL AND MEASUREMENT BACKGROUND

This chapter describes the different diagnosis- and treatment methods used for varicose veins, varicose ulcers and deep vein thrombosis. It also explains in detail the different measurement methods of interest to this Master Thesis.

2.1 MEDICAL BACKGROUND

The blood pressure in the artery is built up in the heart and it normally varies between 80-120 [mmHg] depending on where in the cycle of relaxation and contraction the heart is (Casey & Benson, 2005). The blood pressure in the veins is however only about 30 [mmHg] and this is not enough for the blood to return to the heart by itself, especially not in the legs since gravity tends to pull mass downwards.

The calf muscle pump is a combined expression for the calf muscles and the veins in the lower leg and its function is to assist the blood to return to the heart (O'Donovan, Bajd, Grace, O'Keeffe, & Lyons, 2006). Inside the veins there are valves preventing the blood from pouring backwards when the calf muscles are relaxed (Figure 1). When the muscles are contracted the walls of the veins are squeezed together forcing the valves to open and the blood to pour upwards (O'Donovan, Bourke, O'Keeffe, & ÓLaighin, 2009). Once the muscle is relaxed again the valve is closed and the blood is trapped above this valve until the next muscle contraction. Malfunction or insufficiency in the calf muscle pump can result in pooling of blood in the veins. This could in turn lead to varicose veins or deep vein thrombosis (DVT) (O'Donovan, Bourke, O'Keeffe, & ÓLaighin, 2009). These conditions, their diagnosis and respective treatments are described briefly in the following sub-chapters.

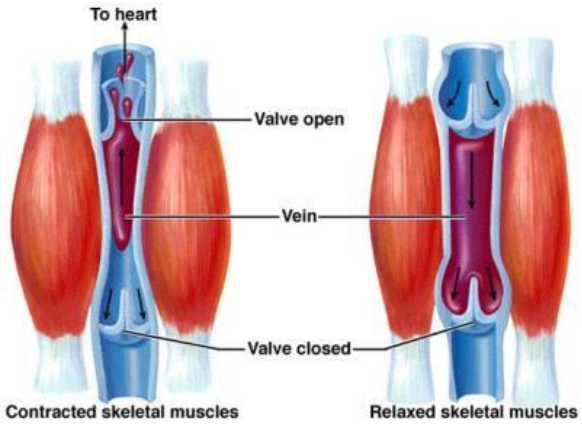

Figure 1: Description of the function of the calf muscle pump (Owen, 2010).

2.1.1 The Condition of Varicose Veins

A varicose vein is a vein that for different reasons has become enlarged both in length and in width. To be able to fit it has had to expand into a "curled up" manner, resulting in the pattern which is visible in Figure 2. Varicose veins are mostly developed from an exposed vein in the lower extremities. (Thurin, 2011)

Varicose veins are not considered to be an illness but rather a condition with different levels of severity. There are seven different levels in the classification of varicose veins, from "Class 0" to "Class 6", whereas the lowest classification stands for patients without varicose veins and the highest score are for patients with highly developed varicose veins and with varicose ulcer(s).

Figure 2: Varicose veins are often found on the lower extremities (Hampshire Vein Clinic, 2007).

This classification, called CEAP (Clinical severity, Etiology or cause, Anatomy, Pathophysiology), is widely known and used in the area of diagnosing varicose veins. (Vascular Domain, 2011) (Kistner, Eklof, & Masuda, 1996)

There are few known causes to why varicose veins transpire and it is discussed if one of these reasons is the cause of the other or vice versa. One of the possible causes of varicose veins is identified as a dysfunctionality of the valves in the veins. The valves in the veins are designed to prevent the blood from going backwards, refluxing, on its way back to the heart. Since the gravity pulls the deoxygenated blood downwards and the pressure is relatively low, this result in a high demand for fully functioning valves. The valves in the veins can be dysfunctional for different reasons; blood clots, genetics etc. This leads to the vein being forced to enlarge and with time this cycle of changing in size will lead to the vein losing its elasticity, leaving it permanently enlarged. (Derrickson & Tortora, 2006)

Another discovered cause is that the veins could, due to for instance heritage, have less elasticity which might cause a vein to permanently expand which in turns lead to that the valves are not secured tightly enough to prevent blood to flow down instead of up. This results in a vicious circle since the extra amount of blood flowing down expands the vein even more. (Thurin, 2011)

2.1.2 Diagnosis of Varicose Veins

The condition of varicose veins can be diagnosed by utilizing different methods with various levels of advancement. Some of the methods are; visual examination, ultrasound, venography, Trendelenburg test and plethysmography. All but venography are non-invasive diagnosis methods and these are recommendable from a patient comfort and resource allocation point-of-view. It is however hard to receive the same accuracy with a non-invasive diagnosis method as with an invasive, especially when trying to diagnose the internal veins (Webster, 2009).

2.1.2.1 Visual Examination

The patient is the subject of an examination of his or her possible superficial varicose veins by an experienced physician in a well lit examination room. The examination should be complemented with a full medical history of the patient covering the family history, symptoms and any possible allergies, etc. Visual examination is a very good and highly recommendable method for diagnosing a patient, it is however not preferable for this to be anything else but an introductory examination and should be complemented by other diagnosing methods in order to decide the severeness and classification of the patient's condition. (Campbell, 2006) (Bergan, 2007)

2.1.2.2 Trendelenburg Test

The Trendelenburg test is a form of visual examination (Chapter 2.1.2.1) where the patient's greater saphenous vein is compressed. This will hinder the blood from being transported away from the leg and the superficial veins are observed while they are filled up with blood. The compression of the greater saphenous vein is then released and the superficial veins are carefully observed by the physician for any possible further filling of blood in the veins. There are four different scenarios of how the blood and

veins can behave and the possible fulfilment of these will lead the physician in his or her diagnosis of the patient. The Trendelenburg test has been in use since the late 19'th century and is a well-known diagnosis method among vascular physicians today. (Gloviczki & Yao, 2001)

2.1.2.3 Ultrasound

One diagnosis method used today at the Department of Clinical Physiology at Östra Sjukhuset is called ultrasound. An educated and trained ultrasound technician examines the patient's superficial veins (mostly on the lower extremities) with an ultrasound device while the patient is standing up. The physician then subjectively evaluates the blood flow in the current vein. There are a few problems with this method; for one it requires that the person performing the diagnosis method is highly skilled and experienced in angiology and secondly, another important issue is that the diagnosis does not provide any kind of unbiased result which could be used for a later diagnosis of the patient's veins. (Thurin, 2011) (Campbell, 2006) (Bergan, 2007)

2.1.2.4 Venography

Venography is similar to the ultrasound method in the way that it provides a visualization of the condition of the patient's veins. This method produces a very detailed image of the patient's veins and it is especially useful for the non superficial veins located between the patient's muscle masses. It is however the older version of the two and it requires preparations of the patient which are more extensive than those for ultrasound. The patient has to be continuously injected with a contrast medium into his or her veins which will allow for the veins to be visually enhanced during the radiation. See Figure 3 for an example of a venography result. (Kistner, Eklof, & Masuda, 1996) (Bergan & Yao, 1985)

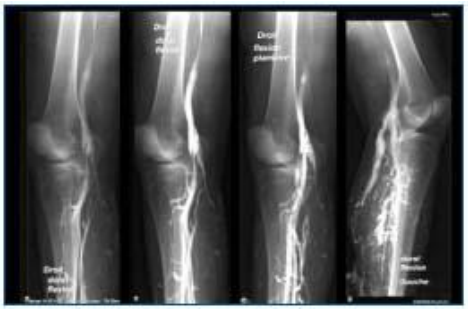

Figure 3: Venography of a patient with varicose veins (Milleret, 2009).

2.1.2.5 Measuring Feet Volume

Another possible diagnosis technique is to measure the changes in feet volume and draw conclusions about the venous flow and reflux from these results. Since the method used in the existing device falls within this technique, the different methods will be explained in detail in Chapter 2.2.

2.1.3 Treatments for Varicose Veins

There are several different treatment methods for varicose veins which either remove the incompetent vein, ligate the damaged vein or restore the veins' functionality. The majority of the patients with this condition do not need any medical treatment but can rather ease the symptom related issues with relatively simple methods. (Bergan & Yao, 1985) (Norgren L. , 1992) (Gloviczki & Yao, 2001)

2.1.4 The Condition of Deep Vein Thrombosis

Thrombosis is another word for blood clot, i.e. blood coagulating at a broken wall of a blood vessel (Figure 4). Blood coagulation is a complex process but could briefly be described as fibrin and platelets forming a net over a broken blood vessel wall to stop the bleeding and starting to repair the vessel. (Furie & Furie, 2005)

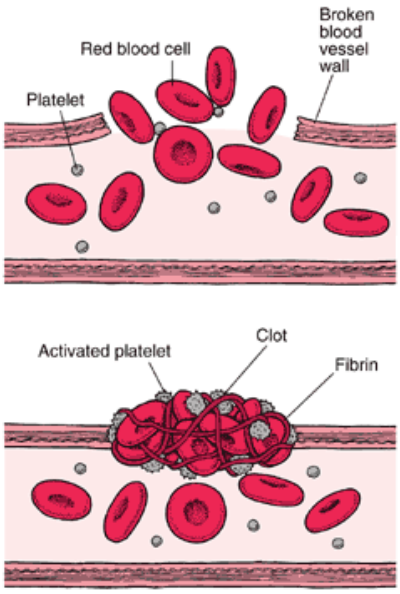

Figure 4: Formation and the active elements of blood thrombosis (Wedro, 2009).

Blood clots are not dangerous in themselves; a blood clot located in a small vessel or in the superficial veins can cause local, but not life-threatening, damage. It is the blood clots that occur in the vessels closely connected to important organs such as the heart, the lungs or the brain that are most dangerous since they can clog important blood supplies to these organs if they become emboli, that is if they detach from their original place. (Wedro, 2009)

Deep vein thrombosis (DVT) is the condition of blood clots forming in the deep veins in the lower extremities and it induces the risk of pulmonary embolism; a blockage of the main artery in the lungs by an embolus. DVT could occur due to many factors such as; immobility (due to hospitalisation, long-term travel, obesity or pregnancy), hypercoagulability (because of medication, smoking or cancer) or trauma to the leg (such as fractures, bruises or complication of an invasive procedure of the vein). (Rosendaal, 1999) (Wedro, 2009)

2.1.5 Diagnosis of Deep Vein Thrombosis

Most of the methods used for diagnosing DVT are similar to the ones used for diagnosing varicose veins. Ultrasound is the standard method used today and is described more thoroughly in Chapter 2.1.2.3. The ultrasound technician can determine if a clot exists, the size and the location of the same. The problem with ultrasound is that it is quite difficult to see the veins in the lower leg. Other methods of diagnosis are venography (Chapter 2.1.2.4) which was used before but has been more or less replaced with non-invasive methods, D-dimer test which is a blood test described below in Chapter 2.1.5.1, and measurement of foot volume change which is explained in Chapter 2.1.2.5 and could be very useful for determine DVT in the calf. Asking the patient for his or her symptoms is of course also a good guidance to determine if the patient suffers from DVT. (Lensing, Prandoni, Prins, & Büller, 1999) (Wedro, 2009)

2.1.5.1 D-dimer test

D-dimer is a blood test used as a diagnosis method for DVT. When a blood clot is partly dissolved a substance called D-dimer is produced in the blood. The test has two outcomes; either it is positive and D-dimer is found in the blood or it is negative and there are no blood clots present. This test is however a bit uncertain since other factors than DVT can show a positive result. Blood clots could be present at other locations than in the deep veins or the test could be positive due to pregnancy, a fall or a surgery, just to mention some examples (Lensing, Prandoni, Prins, & Büller, 1999) (Wedro, 2009). Therefore the D-dimer test should not be used on its own but rather combined with other methods of diagnosis.

2.1.6 Treatment Methods for Deep Vein Thrombosis

There are a number of different treatments available for deep vein thrombosis. It is possible to use medical blood thinners to try to dissolve embolus and to prevent further blood clotting. One could also use caval filters in order to stop emboli or, in very severe cases, different kinds of surgery. (Lensing, Prandoni, Prins, & Büller, 1999) (Wedro, 2009)

2.2 Measuring Foot Volume

As mentioned in Chapter 2.1 measuring the blood volume change in feet is a way to diagnose varicose veins, varicose ulcers and DVT. One way do this is to measure the change in circumference at the ankle and then apply mathematical equations to calculate the blood volume change (Perrin & Geux, 2000). The Leg-o-meter is a device used for this procedure. It consists of a tape measure attached to a stand which in turn is attached to a platform on which the patient stands (Bérard, Kurz, Zuccarelli, Ducros, & Abenheim, 1998). The measurements are made in combination with an evaluation by a physician to ensure that the enlarged circumference is due to oedema and not, for instance, obesity (Bérard, Kurz, Zuccarelli, & Abenhaim, 2002). The first measurement is used as the baseline for new measurements at later times to have something to compare with if the oedema gets worse.

According to MDr Anders Thurin the circumference can also be measured in a similar way by using an electrical tape placed around the foot, consisting of a material which changes in electrical resistance when being stretched. The change in resistance is translatable to the change in circumference. The advantage of using this method, instead of a Leg-O-Meter, is that it is possible to record the rate of derivative of the ankle. It should be noted that Anders Thurin expressed concern about how reliable this method is since the patient would be standing on a part of the tape during the examination. (Thurin, 2011)

One huge problem with measuring the circumference is that very few mathematical models take the volume of the foot in consideration. Another problem is that the methods are only used to measure the volume at one specific time, making it difficult to evaluate the occurrence of varicose veins without a physician's evaluation. Circumference measurements could therefore be considered as not as good as volumetric measurement methods when diagnosing varicose veins. (Perrin & Geux, 2000)

2.2.1 Plethysmography

Though there are many different versions of plethysmography, only two of these are used for measuring volume changes in feet; air plethysmography and impedance plethysmography. (Raju & Villavicencio, 1997) (Norgren L. , 2004)

2.2.1.1 Air Plethysmography

Air plethysmography could be used to evaluate venous outflow, venous reflux and the functionality of the calf muscle pump. In all of these cases the patient is first positioned lying down with his or her lower leg placed in a 35 [cm] long air chamber with the pressure of 6 [mmHg]. When the venous outflow is evaluated the patient has a tourniquet that is inflated to the pressure of 80 [mmHg] attached around the thigh, causing the blood to remain in the leg and enhancing the volume of the leg. The tourniquet is then quickly deflated and the volume of the leg is rapidly decreased when the pressure on the veins is released and the blood can pass through again. This volume change is noticed as a variation in the pressure of the air chamber and is indicating the venous outflow of the leg. (Christopoulos & Nicolaides, 1997)

During evaluation of the venous reflux the patient's leg is raised to an angle of 45° to empty the veins of blood. The patient is then asked to stand up, supporting him- or herself on the leg that is not placed in the air chamber. The change in volume that can be observed is due to the reflux of the blood and is just as before noticed as a change in pressure in the air chamber. (Christopoulos & Nicolaides, 1997)

The calf muscle pump can also be evaluated through the usage of air plethysmography. Similar actions as in the evaluation of the venous reflux are taken, but after the veins are emptied the patient is asked not only to stand up but also to do one heel-raising movement. The volume change indicates the ejection capacity of the calf muscle pump. It is also possible to evaluate the overall performance of the calf muscle pump. The patient is then asked to do ten heel-raisings in a row and the overall performance is measured as the residual volume fraction. (Christopoulos & Nicolaides, 1997)

When using air plethysmography, all of the above described measurements are usually done in succession of each other (Christopoulos & Nicolaides, 1997).

2.2.1.2 Impedance Plethysmography

Impedance plethysmography is mostly used for diagnosing acute deep vein thrombosis (DVT) but could also be used to determine venous outflow in the case of varicose veins. The method is based on the fact that blood is a good conductor of electricity, i.e. the more blood that is present the lower the resistance will be. By recording the changes in resistance the blood volume change is indirectly measured. (Wheeler & Anderson Jr., 1997)

An impedance plethysmograph consists of two circumference electrodes that emit a constant, high-frequency current and two electrodes inside of these that detect changes in voltage. A pneumatic thigh cuff is inflated to 50 [mmHg] in order to stop the venous outflow. When the venous pressure has reached the same value as the tourniquet, the tourniquet is deflated and the change in blood volume as well as the rate of venous outflow can be measured. (Wheeler & Anderson Jr., 1997)

2.2.2 Foot Volumetry

Foot volumetry is a measurement method that is rather unrefined. The method is constantly measuring the foot volume change; mainly due to the muscle movement in the lower extremities, i.e. the calf muscle pump, but also due to blood outflow and reflux (Thulesius & Thurin, 1997). An existing prototype constructed for foot volumetry was examined in order to get a deeper understanding of the subject, for notes from this observation see Appendix A.

2.2.2.1 The Existing Prototype

The existing prototype, constructed in the mid 1970's, consists of three main parts; a printer, a control unit and a measurement prototype (Figure 5).

The measurement process is executed as described and showed in Appendix A. The measurement device consists of two identical sides, one for each foot. Each side has two sensors for measuring the water level; one for turning off the water supply and one for the actual measurement (Thurin, 2011). The first sensor is a magnetic sensor; when the water is at the right level a small plate attached to a float interrupts the magnetic field of the sensor and a signal is sent to close the magnetic valves of the water supply. The second sensor is an optic sensor and is much more sensitive to small variations in the water level. A small transparent but shaded plate is attached to another float and placed between a light source and a phototransistor, causing the phototransistor to emit voltage depending on the level of shadowiness, i.e. the water level changes are measured as a change in voltage from the phototransistor.

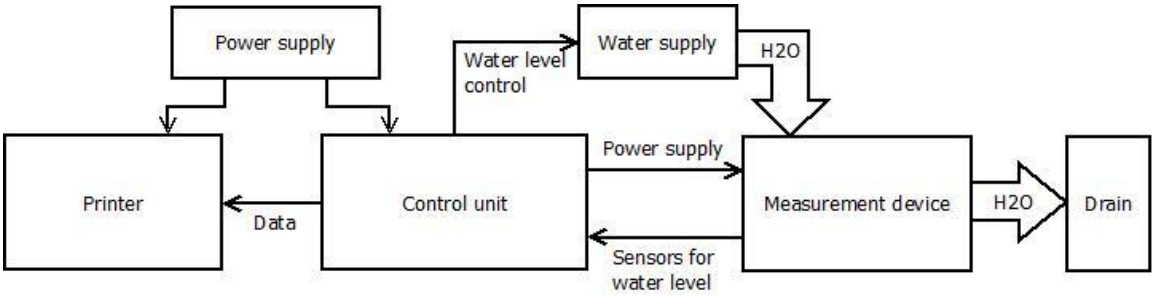

Figure 5: Main parts of the existing prototype.

The patient is placed with his or her feet in the measurement device and water is poured into the device by pressing a small red button on the control unit. The patient is then asked to bend his or her knees ten times to activate the calf muscle pump. The water level is measured during the whole exercise and the measurement device is designed to put out big waves in the water, making it possible to measure small changes of blood volume in the patient's foot.

When there are no longer any or only very small changes in the measured values the test is finished and the patient steps out of the measurement device. The device is now emptied by manually opening a valve and letting the water out and then closing the valve again. The prototype needs to be thoroughly cleaned before it is used for another patient.

During the entire process the measurement data is printed out on paper by the printer with one colour of ink for each foot. The graphs shown are the changes in voltage emitted from the phototransistor. Both the printer and the measurement device have to be calibrated before the measurements can begin. The printer is calibrated through two knobs on the control unit which makes it possible to place the zero line, i.e. the line of reference, at the desired place on the printout. Calibration of the measurement is done by removing and adding five millilitres with a permanently mounted syringe in order to know how much this corresponds to in the graph.

One of the problems with this setup is that the electrical circuits, being outdated, take really long time to warm up which means that the prototype must be left switched on at all times. Another problem is that the water supply yields another system which is connected to a tap or similar in the wall, making the prototype hard to move or use elsewhere.

The measurement device is made out of stainless steel and is welded together in a complex form, making it very hard to clean and distillate – something that is very important since it should be used by many patients and these patients could have varicose ulcers or other infectious conditions.

Overall the prototype is non user-friendly and technically old-school.

3 METHODS

Below follow descriptions of the different methods that were used in the Master Thesis.

3.1 LITERATURE STUDIES

A first step in the project was to find out more about the primary issue which was to be addressed, in this case the condition of varicose veins and blood thrombosis; what they are, why they occur, how they are diagnosed and how they are treated. In order to provide a general overview and understanding of the issues as a whole, literature studies were performed in areas preferably defined as "curios" for this Master Thesis. However, focus was laid on the subjects relating to the different methods for diagnosing varicose veins, deep vein thrombosis and varicose ulcers in order to acquire inspiration in the concept generation phase.

3.2 INFORMATION RETRIEVAL

During the work with the Master Thesis several interviews were conducted with various people with different expertise within areas of interest to the project. Moreover, a few observations were done with the Biomedical Analyzers (BMA) at the Department of Clinical Physiology at Östra Sjukhuset in order to get an general understanding to how the different diagnosis methods for venous insufficiency are utilized at the department today.

3.2.1 Interviews

The interviews were rather conversations with people of interest at several different times. People interviewed, and why, are; Anders Thurin (for medical science and his role as the Master Thesis tutor), Lars-Ola Bligård (for his expertise in cognitive- and physical ergonomics), Mikael Ekman (as the creator of PeriVasc©and for his knowledge in the programming language LabVIEW), Anders Mejlvang (the salesperson for the sensors and for his expertise in optical sensors) and Per-Anders Svensson (as the constructor of the Canteen Unit and his overall knowledge of material and construction).

3.2.2 Observations

During the observations of the biomedical analysers at work a few questions were asked. The different aspects taken into consideration were patient preparations, human machine interface (HMI), graphical user interface (GUI) and physical- as well as cognitive ergonomics. The BMAs provided input of the examination and individual concerns regarding the different tasks related to the examination throughout the whole observation.

3.2.3 Hierarchical Task Analysis

A hierarchical task analysis (HTA) was performed in order to get a better understanding of how to use and work with the prototype. HTA is a tool which helps to break down the process in main tasks, which in their turn are broken down into sub-tasks and so on (Bohgard, et al., 2009). The HTA was based partly on the observations performed, but also on what is consider being the best order to perform the tasks.

3.3 PRODUCT DEVELOPMENT METHODS

All the following product development methods mentioned are explained and argued for in various literatures about new product development. Although details about the execution of the methods might vary, they are all principally the same. The specific perspective of the methods in this project is accordingly to the book by Karl Ulrich and Steven Eppinger (Ulrich & Eppinger, 2008) and the subsequent descriptions of the different methods are mostly derived from this book. However, bear in mind that since this is a development of a prototype for testing and not a complete product, methods regarding design for assembly/manufacturing, platform development and similar were not considered. To further point out that the objective of this project is not to develop a fully functioning, on-the-market product, a conscious choice has been taken to use the word "prototype" rather than "product".

3.3.1 Prototype Specification

The prototype specification is categorised into different appropriate sections and specified as a "requirement" or "desire", the latter on a scale from one to five where five is considered as a desire which is very important to fulfil. The specification is not, once it is first defined, a fixed document but should rather be seen as an evolving manuscript to keep track of the different requirements and desires of a product.

3.3.2 Concept Generation and Selection

The concept generation and selection phase involves several very different methods such as function structure, brainstorming, morphological matrices and elimination matrices. Initially they are performed in the order in which they were just presented, but in product development most processes are iterated.

3.3.2.1 Function Structure

The function structure is formulated as a road map of the functions and the relationship between them. The point of the structure is to force the developer into identifying, dividing and organising the functions defined by the prototype specification which simplifies the development work a lot since each function now can be treated by themselves. It is very important that the functions in the function structure are defined in such a way that they are "solution free". In other words one should avoid expressions such as "wipe off water" and rather use "remove water", since it does not limit the next coming method, the brainstorming.

3.3.2.2 Brainstorming

In the brainstorming phase the participants are, during a predetermined time interval, allowed to think completely freely and statements such as "this cannot be constructed" are banned during this exercise. It is encouraged to think "outside the box" rather than to limit oneself to the "realistic world", since this is how groundbreaking ideas are formed. The brainstorming session is repeated for each of the functions previously identified in the function structure. After each session the participants will present their ideas to each other, this presentation shall always be completely free from negative criticism.

3.3.2.3 Morphological Matrices

After the brainstorming session the different ideas are structured within each of the functions they represent a solution for. The functions are mapped up and the different solutions are linked together (one solution per function), creating a concept. How the concepts are created with the morphological matrices should involve some sort of random selection of the solutions to maintain the creativity in the generation. This phase in the development should generate a large number of concepts.

3.3.2.4 Elimination Matrices

To limit the amount of concepts down to one or two main concepts for detailed design, a number of elimination matrices are conducted. The advantage with using these predetermined matrices is to maintain the objectiveness during the elimination process as much as possible. It is however worth mentioning that even though the elimination matrices help to avoid the personal involvement in the elimination stages, they are still based on a subjective rating scale.

3.3.3 Detailed Design

During the detailed design phase the chosen concept(s) are further developed to prepare for the construction section. At first a prototype architecture is formulated in order to create an overview of the system as a whole, this is changed over time as the design is further developed. The prototype architecture is almost like a function structure but rather than solution free functions it is organised by its physical parts and their internal relationships.

3.4 DEVELOPMENT OF THE FOOT VOLUMETRY MODULE FOR PERIVASC©

The Department of Clinical Physiology at Östra Sjukhuset requested that the software module developed in this Master Thesis should be able to be implemented in a software called PeriVasc©, developed by Ekman Biomedical Data AB (Ekman, 2011), used at the department today. Before programming the Foot Volumetry Module, as the module is called, block diagrams and flowcharts were created in order to understand the input and output of the module as well as making a solid basis to start programming from, just as the normal procedure for programming states. These charts are based on knowledge about the PeriVasc© software, results from the observations done and personal experience and thoughts.

The Foot Volumetry Module has been programmed from scratch in LabVIEW with some advising and help from the developer of PeriVasc©. The graphical user interface (GUI) is a result of the other GUIs used in PeriVasc© and discussions with people well familiar within the subject of cognitive ergonomics. The GUI has been written as a part of the Foot Volumetry Module but the layout is basically a further development of an already existing GUI.

3.5 PROTOTYPE TESTING AND EVALUATION

The tests were formulated before their execution in respect to which areas were considered as most important to evaluate in terms of functionality of the system as a whole. The tests were conducted with the software accompanying the sensor, IDL1700-20 Tool V2.40. Complete descriptions of how and why the tests were conducted can be found in Chapter 6.

3.5.1 Calculation of Measurement Accuracy

In order to estimate the accuracy of the measurement results a rough calculation has been done. In measurements with maximum ten results, the accuracy of the distance to the water level can be calculated according to

$$Measurement\ Accuracy = \frac{X_{max} - X_{min}}{2}$$

and is then applied to the mean [um/ml] as the percentage of the mean [ml]. (University of Karlstad, 2008)

4 CONCEPT GENERATION

In this section the process of the concept generation used in this master Thesis is presented, from the prototype specification to the chosen concept.

4.1 PROTOTYPE SPECIFICATION

A number of observations of the existing diagnosing methods were performed prior to the formulation of the prototype specification. The results from these helped to define the necessary requirements, especially the demands and desires which fall under the usability and user-friendliness category. An example of such a requirement is that the patient data, retrieved during the examination, has to be able to be saved and printed on a local printer. Another example is that there was no need for the device to be very portable since it would mostly be kept in the same examination room the entire time. General opinions from the biomedical analyzers were to keep the design simple and easy to use since the existing examination devices were perceived as more complicated than necessary. See Appendix A for the complete notes from the different observations.

The prototype specification lists the different demands identified from the observations and the general work during the Master Thesis. It has been divided into four different categories to provide an overview of the specification as a whole; "Functionality and Measurement Reliability", "Usability and User-friendliness", "Legal and Environmental" and "Software Module". A lot of the demands fell within the category concerning usability and user-friendliness, a reason for this was that it was rather easy to identify many of the requirements and desires when observing and conversing with the biomedical analyzers while they were using the existing diagnosis devices at the department. A very important requirement stated in the prototype specification is that the prototype should be able to measure changes as small as 0.50 [ml/100ml foot]. The complete prototype specification can be seen in Appendix B.

Since this is a development of a prototype, it was hard but crucial to limit the demands concerning the technical functionality of the device. It would have been impossible to develop a working prototype within a feasible time interval if extensive delimitations had not been utilized. However, note that the objectives for this Master Thesis are not only to develop but also to test and evaluate a prototype in terms of functionality and usability. In other words the requirements and desires identified while testing the prototype is discussed and stated in Chapter 7 which specifies the evaluation of the test results.

4.2 FUNCTION STRUCTURE

The function structure is formulated as an aid prior to the brainstorming session to break down the main functions into smaller sub-functions, which can be treated by themselves, and their respective relations. A difficulty in creating a function structure is to keep the balance between a "general solution-free function" without losing the important factors from the main functions. In this case there was also the condition of an already existing device that solves the main problem which could have influence the function structure to become less solution free. The initial function structure (Figure 6) shows the basic sub-functions and their internal relationship.

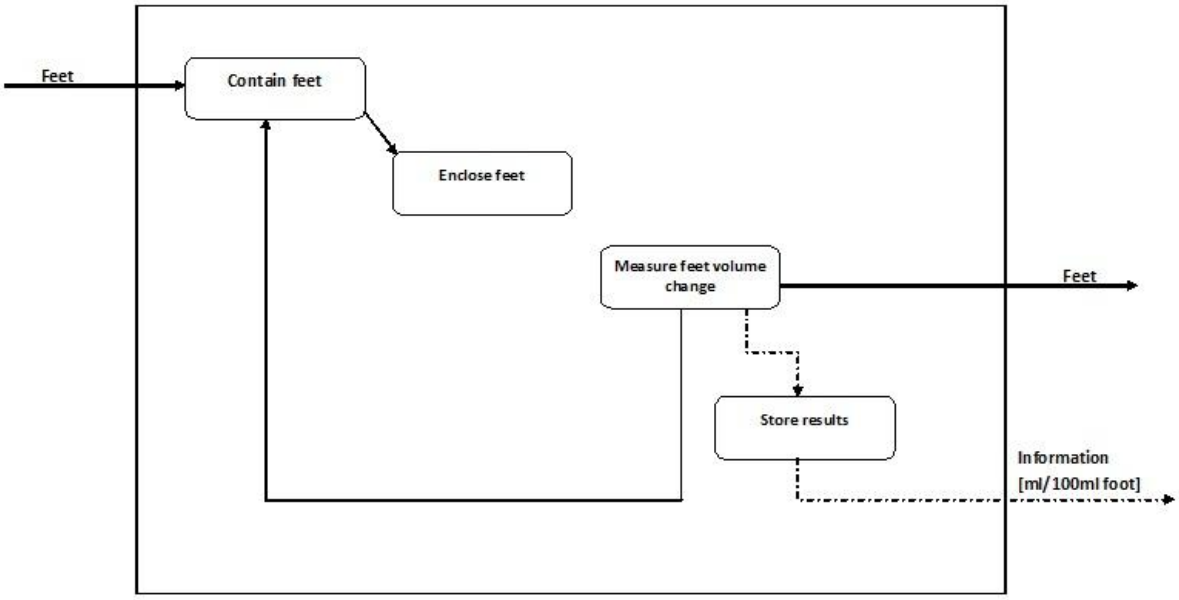

Figure 6: The hypothetical function flow of the prototype.

The prototype should perform the following tasks: "Contain feet", "Enclose feet", "Measure feet volume change", "Clean feet container" and "Store Results". The latter turned out to be formulated rather unfortunate since it was not crucial at that stage to formulate the solution to store the data from the measurement, but rather to "present" the information retrieved. This problem was however not discovered until after the brainstorming sessions were conducted. One factor, the "User interface/feedback", was added later in the brainstorming session.

The relationships between the sub-functions are presented as arrows linking the functions together. Between the first three functions it is only the feet which are of mutual interest (note that it is at this very basic level only). Later on the data is sent to the "Store results" function which transforms it into the desired unit, [ml/100 ml foot].

4.3 MORPHOLOGICAL MATRICES

At this stage the different solutions generated from the brainstorming sessions are assembled to form several different concepts. Two of the concepts were deliberately constructed to represent the existing device and the existing device with a hypothetical update to modern technology. The rest of the concepts had a huge variety in execution, design and new thinking. Some concepts built on existing techniques used within other areas such as the sphygmomanometer and others were indeed "weird" ideas which kept up the spirit and creativity of the process. All the 22 different concepts can be seen in Appendix C.

4.4 Elimination Matrices

As an aid to ensure that the most suitable concept is chosen, one can apply elimination matrices commonly used in product development. These elimination matrices guide the user to objectively review the concepts function by function and compare how well the different concepts respectively fulfil the prototype specification. Two Pugh matrices and one Kesselring matrix were conducted and these can be found in Appendix D. The matrices do not only eliminate concepts but also points to concepts which might be suitable to combine with each other.

4.4.1 Results from the Pugh Matrices

After the first round of the Pugh matrix, with the existing device as reference, half of the concepts could be eliminated due to them not fulfilling several of the functions defined in the prototype specification. One of the eliminated concepts was the existing device, proving once again that it is very much outdated in consideration of modern technology. The concept with the highest score was chosen as a reference for the next Pugh matrix and another five concepts could be eliminated. The reference consisted of a solution completely different to the original one in the existing device.

4.4.2 Results from the Kesselring Matrix

In the Kesselring matrix one defines the different importance of the functions in the prototype specification by weighing them in relation to each other. This is done so that concepts that fulfils less important functions satisfactory, but barely manage to carry out the few most crucial functions, may be eliminated. The result from this matrix is presented in the following chapter (Chapter 4.5).

4.5 The Selected Concept

The concept which got the highest ranking was the concept named “The Kayak Theorem”, see Figure 7. The basic idea is the same as the old device to practice the concept of Arkimedes principle, although the fluid is not yet defined at this stage. The patient’s feet will be placed in a foot bath covered with some kind of soft material serving as a flexible coat. A sensor which can measure distances will be mounted to the foot bath tub and it will, after the analogue signal has been translated into a digital

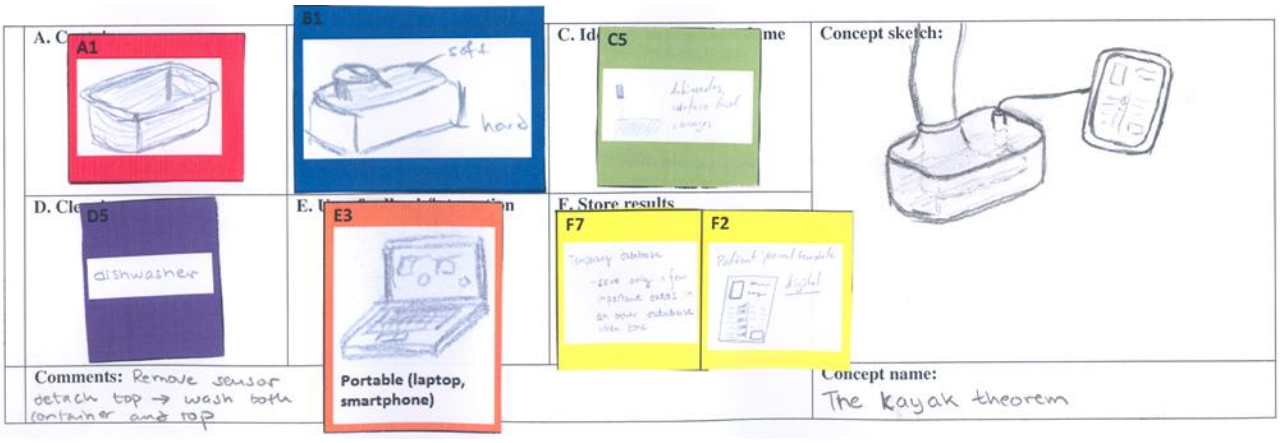

Figure 7: The concept with the best score, "The Kayak Theorem".

signal, be sent to some kind of portable device (such as a laptop or a small stationary computer) which handles the necessary calculations to transform the change in distance into a volume change. The cleaning solution chosen for this concept is “dishwasher” which is a clear benefit since according to Anders Thurin (Thurin, 2011) this is how the Department of Clinical Physiology clean most of their other medical containers.

4.5.1 Initial Prototype Architecture

The initial prototype architecture was formalized as an overview to provide an easier partition of the development of the different functions. Even though all functions were more or less dependent of each other it was considered to be a good idea to not start off with developing one function further and let the rest of the functions adapt to it. This since it could very well lead to the whole developing phase taking too much time and problems in the future could arise when the entire prototype is already built due to too much compromising of the other functions.

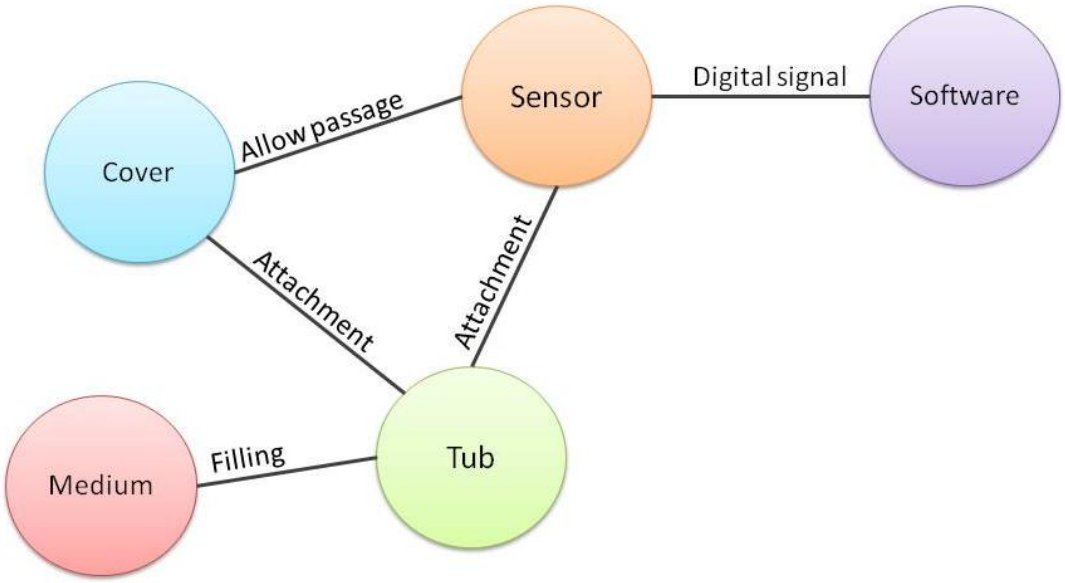

Figure 8: The initial prototype architecture of "The Kayak Theorem".

The initial prototype architecture, displayed in Figure 8, presents the five main areas of the concept: “Cover”, “Medium”, “Tub”, “Sensor” and “Software”. It also points out the relationship between the different areas which can vary between a relationship involving communications, such as between the sensor and the software, or a simple physical attachment.

These five foundations were developed further and their complete design and physical realization can be found in the upcoming chapter (Chapter 5) describing the prototype.

5 DESCRIPTION OF THE FOOT VOLUMETRY PROTOTYPE

In this chapter a detailed description of the finished prototype is given. First the complete prototype will be described together with how it is supposed to be used step by step. Then, each module shown in the prototype architecture is explained by themselves in further detail with their respective technical specifications.

5.1 OVERVIEW OF THE FOOT VOLUMETRY PROTOTYPE

The end result from the detailed design phase is somewhat different from the concept described in Chapter 4.5 since during this phase of the Master Thesis it was discovered that some functions were not as important to fulfill as was first believed. Some functions could simply not be realized within the very limited project budget. The ground principles were however still the same with the main focus on the performance and reliability of the measuring and data management areas.

Figure 9: The Canteen Unit filled with water.

As can be seen in Figure 9, the prototype consists of a canteen with a pipe attached to it. Mounted on the top of the pipe is an optic sensor with a laser technique which measure distances by reflecting a ray of laser on a float inside the pipe. The different distances measured by the sensor are sent to the module built into PeriVasc©. Each separate part will be explained further in the upcoming sub-chapters.

In order to facilitate the understanding of how the Foot Volumetry Prototype, in this chapter called "the prototype", is built up by its internal components the physical construction with the canteen as the base is from now on called "the Canteen Unit" and the prototype part communicating with the sensor is called "the Foot Volumetry Module".

5.1.1 How to Use the Foot Volumetry Prototype

Before using the prototype some preparations have to be performed. These preparations are stated in the first bulleted list in Appendix E. As described in the previous chapter, Chapter 5.1, the prototype consists of a number of different parts. In order to use the prototype, these parts should be assembled before usage. When the parts are correctly put together, the PeriVasc© software is started and the measurements can begin. The human machine interface (HMI) between PeriVasc© and the Foot Volumetry Module is shown in the flowchart in Appendix E. A further description of the Foot Volumetry Module and its usage can be found in Chapter 5.2.8.

When all measurements are managed, the prototype needs to be dismantled before it is cleaned. This process is described in the second bulleted list in Appendix E which also states how to clean the prototype properly.

5.2 PROTOTYPE ARCHITECTURE

The prototype architecture, see Figure 10, is the development of the initial prototype architecture presented in Chapter 4.5.1. The largest change in the architecture is that "Cover" was removed completely during the detailed development since it was estimated as being an unnecessary feature. The different unspecified "parts" stated in the initial architecture has now been defined completely with name and how they are to be attached to and/or how they communicate with the surrounding parts. None of the parts are permanently mounted but can easily be disassembled and replaced.

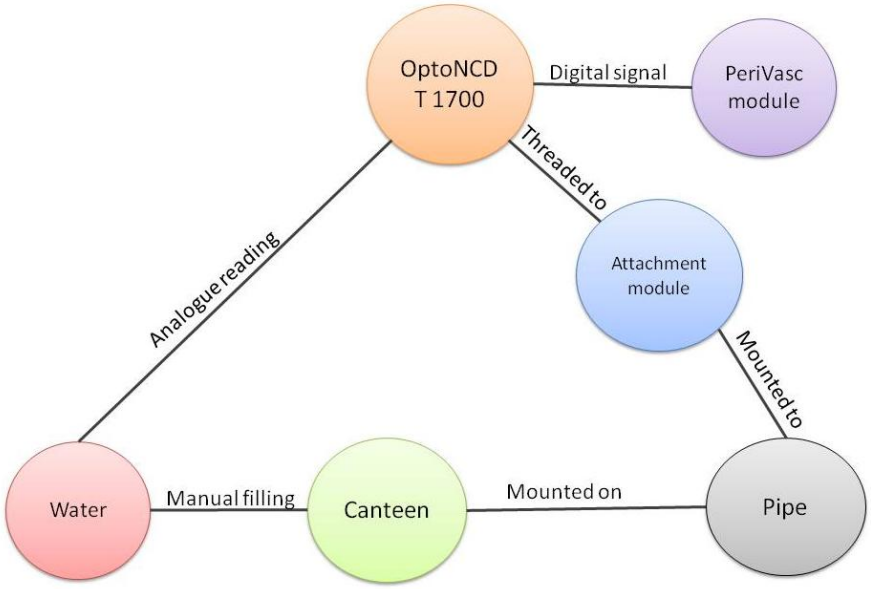

Figure 10: Overview of the physical components and their internal relations.

Each of the parts as well as their relations between each other will be explained in the following subchapters and relevant drawings of the parts can be found in Appendix F.

5.2.1 The Canteen

The choice of a canteen as the container was made fairly early in the development. The advantages of a canteen outweighed the disadvantages when comparing, for instance, with constructing a container from scratch. The canteen has soft edges which make the cleaning process more efficient and since it is a kitchen utensil for institutional kitchens such as restaurants it is known for withstanding the high temperatures, up to 80°C (Miele Professional, 2010), which an advanced dishwasher can reach. However, the canteens all come in standardized sizes which ended up with the choice between a canteen size which was at the limit to too small and a canteen size which would demand more advanced construction design in order to ensure a high measurement accuracy.

The canteen is made out of polycarbonate, a transparent polymer known for its high strength but low resistance to scratches (Boldizar, Klason, Kubát, & Rigdahl, 2001). The inner measurements limit the use of the prototype to people with a shoe size maximum 42 (European standard).

5.2.2 Water as the Enclosing Medium

The concept “The Kayak Theorem” utilized an undetermined fluid as a medium. Due to its many advantages, especially the extremely easy access to it in the examination room, it was determined that water would enclose the foot. It was discussed whether the water should be mixed with some kind of disinfectant agent to avoid patients in risk of developing varicose ulcers to obtain bacteria in any possible open wounds. However, it was discarded due to the low risk of this problem and the possible discomfort this could mean to the patient as well as the extra work, of dosing the appropriate amount of agent, this would mean for the examiner during each examination.

5.2.3 The Pipe

In the top right or left corner of the canteen the pipe is attached to the wall via a customized shim, see Chapter 5.2.4, which enables the pipe to be mounted at different heights.

The reason for even utilizing a pipe rather than to just measure the water level in the whole canteen is to isolate the measurement area from the worst disturbances caused by the water movement. During the examination the patient performs different physical activities, leading to disturbances in the water which in turn could lead to inefficient and incorrect measurement results. The pipe also turned out as a good mounting option for the sensor by an upper lid which will be further described in Chapter 5.2.7.

The pipe is made out of glass since it is good to have a see-through material to visualize the reading and how the float (Chapter 5.2.5) is changing its position in height.

During the testing phase (Chapter 6) of the Master Thesis, several experiments with different sizes of openings in the bottom of the pipe were conducted. This is made possible by an open lower lid into which a number of different customized round plates, with different sizes of holes, can be placed. The reason for this was to try to identify the optimal size of the opening to keep a steady subdued system without creating a too large slowness of the system as a whole. The upper- and lower lids are made out of polyoxymethylene (POM) commercially known as “acetal” which is a strong opaque material. (Boldizar, Klason, Kubát, & Rigdahl, 2001)

5.2.4 The Shim Construction

The shim construction temporarily mounts the pipe to the canteen. It was necessary to distance the pipe from the slightly inwardly angled canteen walls, thereof the name "shim construction".

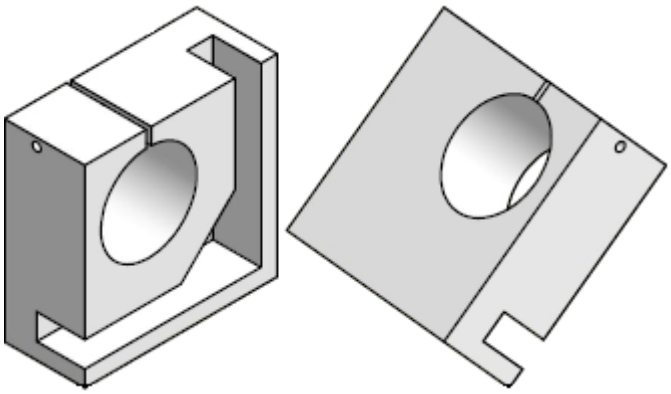

Figure 11: The customized shim construction.

The shim is positioned to the canteen walls by the customized track which can be seen in the left picture in Figure 11. The pipe in turn is mounted through the shim and then squeezed in place by a dislocation and a star knob. The shim is, as well as the two pipe lids (upper and lower), see Chapter 5.2.3, made out of the material acetal.

5.2.5 The Float

The sensor cannot provide an appropriate reading directly on the water surface but has to have an alternative surface to project on. A float in a dark matt material, see Figure 12, was designed in consultation with Anders Mejlvang, the salesperson of the sensor, (Mejlvang, 2011) and Per-Anders Svensson, a Medical Engineer at Östra Sjukhuset (Svensson, 2011). A reliable reception of the incoming signal requires a matt surface. This was achieved through abrasive blasting with glass. Another function with the float is to dampen any potential wave peaks from the water which could lead to incorrect readings of the water level.

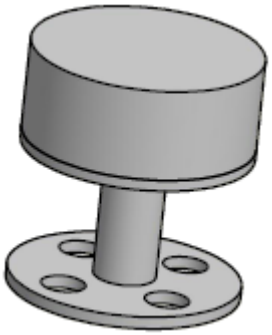

Figure 12: The float which will reflect the laser.

The float is placed inside the pipe and should be able to withstand the high temperatures it could be exposed to during the cleaning process (Miele Professional, 2010). It was also crucial that the float had to consist of a material with a density lower than that of water or be designed to float even despite a higher density (with, as in this case, a hollow inside). After consultations with Per-Anders Svensson (Svensson, 2011) the float was constructed in polyvinyl chloride (PVC).

5.2.6 The Sensor, OptoNCDT1700

The prototype is based on measuring a change of the water level. This could be done in many different ways but since one of the demands of the prototype, stated in Appendix B, was to use a non contact measuring method, a laser sensor measuring distance was chosen.

Due to a number of complications the sensor first chosen, Micro-Epsilon optoNCDT1401 ILD1401-50, could not be used. The sensor used and attached to the prototype is a Micro-Epsilon optoNCDT1700 ILD1700-20 (Figure 13). The measurements are based on laser triangulation, i.e. the sensor uses Pythagoras theorem in order to calculate the distance to the object in question. A laser diode is emitting light that is reflected at a surface and the reflected light then travels through a filter design to eliminate any light with different wavelength than the laser has. The laser is then detected by an array of charge-coupled devices (CCD) using real time surface compensation (RTSC) (Micro-Epsilon, 2010). Briefly speaking, the CCD array converts the light to voltage (Janesick, 2001) and the RTSC enables measurement against most surfaces (Micro-Epsilon, 2010).

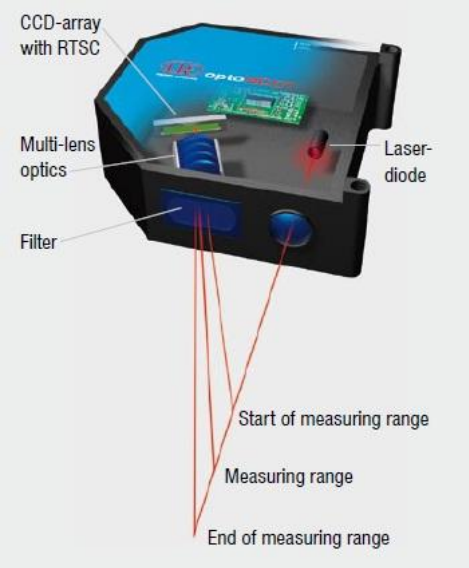

Figure 13: OptoNCDT1700 ILD1700-20 sensor and its parts (Micro-Epsilon, 2010).

When choosing a sensor the range, linearity and resolution are of great importance. The ILD1700-20 has the linearity and resolution of the right dimensions but unfortunate the range of the sensor is a bit too narrow and the distance to the midrange is too short, leading to some small complications such as the surface of the float needing to be placed closer to the sensor. The resolution is higher than of the sensor first meant to be used, which means that smaller changes can be detected but the signal representing the range is more noisy. The specifications of the sensor can be studied in Table 1. The sensor has a power supply at 24 [V DC] and 150 [mA], and the output of interest is during the tests a digital RS422 signal and during the real setup an analogue voltage of 0-10 [V DC].

Table 1: Specifications of optoNCDT1700 ILD1700-20 (Micro-Epsilon, 2010).

Measuring range				**Linearity**	**Resolution**
Total range [mm]	*Start of range [mm]*	*Midrange [mm]*	*End of range [mm]*	*[µm]*	*[µm]*
20	40	50	60	16	1.5
Power supply		**Output**		**Protection**	**Measuring rate**
[V DC]	*[mA]*	*Analogue*	*Digital*	*class*	*[Hz]*
11- 30	max 150	0-10 [V DC]	RS 422	IP 67	2500 / 1250 / 625 / 312.5

5.2.7 The Sensor Attachment

The sensor will be assembled between two bent aluminium plates by thoroughgoing screw joints via the already existing holes in the sensor, see Figure 14. These aluminium plates will be attached to the upper lid of the pipe which will be mounted on top of the pipe without any permanent attachment. It can then be easily detached from the prototype after the examination. A full visualization of the construction of the sensor attachment can be seen in Figure 14.

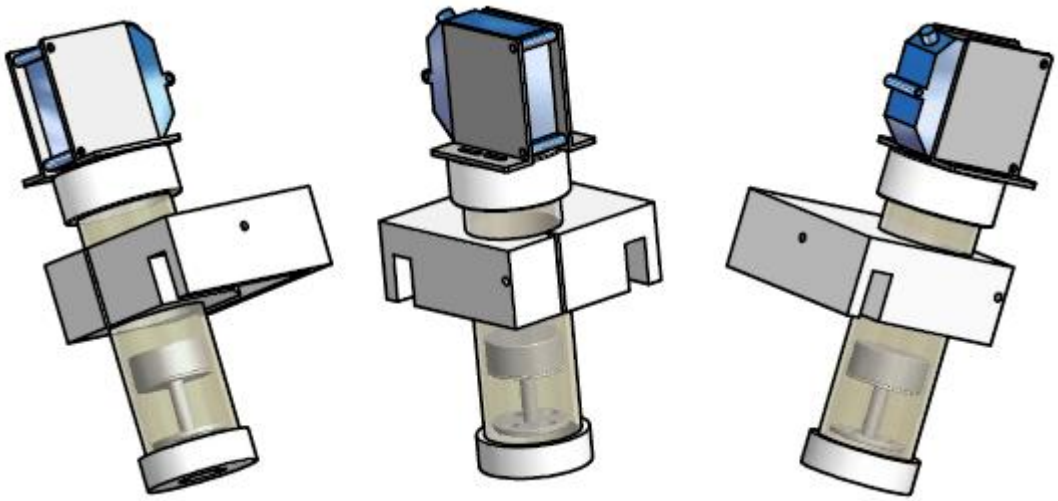

Figure 14: The complete sensor attachment including; the sensor, the aluminium plates, the upper lid, the lower lid, the pipe, the shim construction and the float.

5.2.8 The Foot Volumetry Module in PeriVasc©

PeriVasc© is a software that is currently used at Östra Sjukhuset when measuring toe and ankle pressure as well as measuring venous flow, see Appendix A. As can be seen in Appendix B, it is a highly rated desire to implement the software module for measuring foot volume changes into PeriVasc© and this desire has therefore been executed to the most possible degree. Both PeriVasc© and the Foot Volumetry Module (later referred to as "the module") are programmed in LabVIEW.

5.2.8.1 Module Architecture Basis

An hierarchical task analysis (HTA), see Appendix G, has been used as the base of the module architecture with the intention of getting an easier view of how to design and frame a good structure both in the module code itself but also for the graphical user interface (GUI). A number of charts have been made; a block diagram of the communication between PeriVasc© and the module as well as a flowchart for getting a solid basis to start from when programming the module, see Appendix H. A flowchart for an overall understanding of the human machine interaction in PeriVasc© to make the GUI more understandable and easier to use has also been made, see Appendix E.

5.2.8.2 Using PeriVasc© and the Foot Volumetry Module

The recording of the signal from the measurements are done in PeriVasc© as well as loading the patient data, such as identification number, name etc, from the patient's medical chart. An example the main graphical user interfaces (GUI) in PeriVasc© can be seen in Appendix I. The signal recordings are done in the same way as when doing blood flow measurements or measuring toe and ankle pressure; the measurements are shown continuously and the user gives a command to start recording and another to stop recording. The segment of interest can then be chosen by moving cursors around. Calibration of the prototype, which should be done before the measurements begin, is accomplished by adding 10 [ml] of water with a syringe. The baseline and the maximal point are then marked in PeriVasc© with two probes.

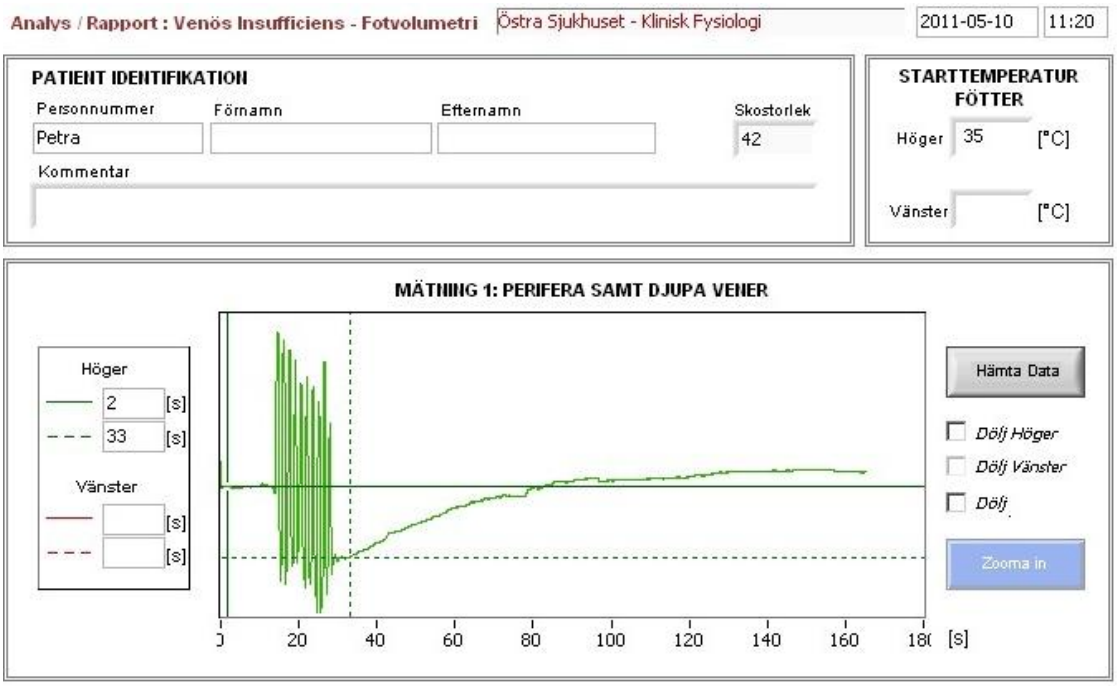

Figure 15: Part of the GUI showing the patient identification data and the graph of the right foot during a simulation.

The collected data is transferred into the module when the user presses the button "Hämta data" (Figure 15). Before this button is activated the user must enter the temperature of the patient's feet at the start of the measurement as well as the patient's shoe size. The temperature is of interest since blood flows best at a temperature of 28°C (Thurin, 2011) and the shoe size is a part of approximating the total volume of the patient's feet.

An example of how the full GUI could appear to the user can be studied in Appendix I. Due to the module being implemented at a Swedish hospital, the GUI is in Swedish. In the GUI the user can move cursors around and should place them at the baseline and at the minimum point in order to get proper values, see the line cutting the middle of the amplitude axis respectively the dotted lines in Figure 15. The cursors and the graph can be hidden if the user chooses to.

The calculated values are presented at the bottom of the GUI, as shown in Figure 16. The reason for presenting the values for the right foot (“Höger fot”) to the left and the values for the left foot (“Vänster fot”) to the right is that it is a medical standard to place the sides on the form in the same way as the patient is seen from the front by the examiner (Thurin, 2011). The values of interest are the time it takes for half of the blood volume to return (“T50”), the time it takes to regain 90% of the blood volume (“T90”), the total change in volume (“Volymdifferens”) and the maximum slope of the reflux (“Max Återflöde”). There are also three buttons at the bottom enabling saving the examination data (“Spara”), printing it (“Skriv ut”) and last but not least closing the module in a safe way (“Klar”).

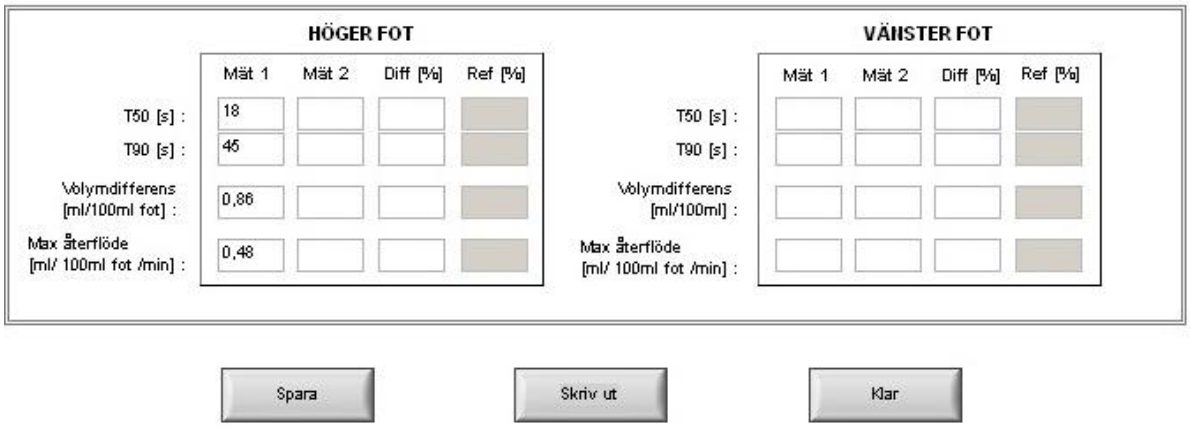

Figure 16: Part of the GUI showing calculated data for the right foot and three control buttons during a simulation.

The graphical user interface (GUI) of the module has been edited to facilitate a further development of the same. Buttons for zooming, boxes for presenting additional calculations and values as well as the possibility to present alternative measurements of the foot blood volume change are already presented at appropriate positions.

6 TESTING THE FOOT VOLUMETRY PROTOTYPE

This chapter describes which tests were conducted, why and how they were executed, as well as the results from each test.

The distance to the water surface is measured in micrometer and a transformation factor, [µm/ml], between this unit and milliliters is calculated in Test 1-3 and later on used in Test 4.

In Test 1-4 the water level was filled up to the areas of the canteen with straight walls to ensure linearity of the water level changes and not have to consider the impact of the results which the angled walls would produce. Moreover, for all of the tests which involved measurements of the water level changes it was ensured that the measurements were made within the optimal measurement range for the sensor.

The prototype had already been constructed when the problems with the original sensor begun and the borrowed sensor caused one large problem. The difference in measuring range and interval of the old sensor, see Chapter 5.2.6, called for an alternation of the design. An extra float had to be placed on top of the already existing float in order to reach the much smaller measurement range of the borrowed sensor.

Prior for each of the measurements involving the sensor, a disruption in the registered signal of a maximum amplitude of 1.25 [µm] was considered as acceptable.

6.1 TEST 1: SYSTEM RELIABILITY

The first test formulated concerned the reliability of the system as a whole and whether the measurement results from the prototype could be considered as reliable and consistent.

6.1.1 Execution of the Test

Five different volumes of water were added to the canteen (2, 5, 10, 20 and 50 [ml]) using a number of different syringes of various sizes and the changes of the water level were registered as changes in distance by the included software for the sensor. No lower lid was attached to the pipe during this test, hence the opening had a diameter of 54 [mm]. Each volume was added five times each so the mean values could be calculated for each amount of volume.

6.1.2 Measurement Results

The results from the first test are displayed in Table 2 as the mean [µm] and the mean [µm/ml] for each added water volume. The mean for all volumes is 23.01±5.07 [µm/ml].

Table 2: The measurement results from the first test.

	Test 1: Overall functionality						
	Water Level Change [µm]					Mean	
	Try 1	*Try 2*	*Try 3*	*Try 4*	*Try 5*	*[µm]*	*[µm/ml]*
2 [ml]	17,45	24,93	26,17	26,42	23,68	23,73	11,87
5 [ml]	117,16	143,33	95,97	119,65	145,82	124,39	24,88
10 [ml]	240,54	248,02	239,30	267,96	216,86	242,54	24,25
20 [ml]	512,24	557,11	489,91	562,10	525,95	529,46	26,47
50 [ml]	1367,23	1372,21	1403,37	1375,95	1377,20	1379,19	27,58
						Mean [µm/ml]	**25,80**

6.2 TEST 2: SYSTEM INERTIA

The second test was executed to determine the most sufficient size of the pipe opening. This was evaluated in terms of the reliability of the mean value and the time it took until the system was stable again after the water had been inserted.

6.2.1 Execution of the Test

Six different sizes of the pipe opening were tested (Ø 54, 30, 20, 15, 10 and 5 [mm]) with a fixed volume of water of 10 [ml] being added. It was concluded from the measurement results in the system reliability test, see Chapter 6.1.2, that 10 [ml] seemed to generate the most stable results.

For each size of the pipe opening 10 [ml] was added five times and just as in the first test, see Chapter 6.1, the amplitude from the changes of the distance to the water level was displayed in the sensor software. Moreover, the time from water insertion to system stability was estimated via the same software for each try.

6.2.2 Measurement Results

The results from the system inertia test are displayed in Table 3. The upper table displays the changes in [µm] and the mean value in [µm] per [ml] for each of the different pipe openings. The lower table states the time-to-stability results for each of the pipe openings.

The two pipe openings which enable the mean micrometer per milliliter closest to the mean obtained in Test 1, 23.01 [µm/ml], are Ø 30 [mm] (25.12±5.75 [µm/ml]) and Ø 5 [mm] (20.51± 8.22[µm/ml]) and the fastest time-to-stability are Ø 10 [mm] and Ø 54 [mm]. Since the same amount of water was added during the whole test the mean micrometer per milliliter should reasonably be the same between the different pipe openings but, as can be seen in Table 3, this is not the case.

Table 3: The measurement results from the second test.

	Test 2: Possible Inertia in the System						
	Water Level Change [µm]					Mean	
	Try 1	*Try 2*	*Try 3*	*Try 4*	*Try 5*	*[µm]*	*[µm/ml]*
Pipe opening Ø 54 [mm]	205,65	341,50	165,76	402,57	461,14	315,32	31,53
Pipe opening Ø 30 [mm]	191,44	229,33	251,76	306,60	276,69	251,16	25,12
Pipe opening Ø 20 [mm]	290,40	220,60	257,99	250,51	265,47	256,99	25,70
Pipe opening Ø 15 [mm]	292,89	299,12	280,43	235,56	211,88	263,98	26,40
Pipe opening Ø 10 [mm]	351,47	285,41	295,38	228,08	251,76	282,42	28,24
Pipe opening Ø 5 [mm]	103,45	149,56	267,96	249,27	255,50	205,15	20,51
	Time to become stable [s]					Mean [s]	Rating
Pipe opening Ø 54 [mm]	1,40	1,62	0,63	3,80	1,66	1,82	Good
Pipe opening Ø 30 [mm]	9,90	1,31	3,80	4,20	3,20	4,48	Bad
Pipe opening Ø 20 [mm]	97,60	7,30	11,40	4,60	4,00	24,98	Bad
Pipe opening Ø 15 [mm]	7,60	14,20	3,60	0,90	0,90	5,44	Bad
Pipe opening Ø 10 [mm]	1,42	0,93	0,78	1,00	1,10	1,05	Good
Pipe opening Ø 5 [mm]	5,60	5,10	6,20	7,70	18,20	8,56	Bad

6.3 TEST 3: SYSTEM RELIABILITY

Test 3 was conducted to determine which pipe opening would be most appropriate for the system and to confirm the future calibration volume.

In order to further evaluate the functionality of the two different sizes of the pipe opening, the first test was repeated for each of the two selected sizes, Ø 10 [mm] and Ø 30 [mm]. The Ø 10 [mm] was chosen due to it being the size which had the lowest time-to-stability of all the pipe openings in Test 2. The selection of the second pipe opening was however not as obvious.

The second choice should at first glance have been the Ø 54 [mm] since it was the second fastest pipe opening, but when observing the upper table in Table 4 it is clear that the readings from the Ø 30 [mm] opening is more stable than those from the Ø 54 [mm] opening, hence the reason for choosing the opening which had the third lowest time-to-stability. Moreover, the mean micrometer per milliliter of the Ø 30 [mm] is closer to the mean obtained in Test 1, than for the Ø 54 [mm] opening.

6.3.1 Execution of the Test

The third test was executed in the same manner as the first test, see Chapter 6.1, however now with the double amount of tries (from five to ten). The reason for this was that after the first two tests it was discussed whether it should have been better to apply a higher number of tries to secure a more reliable test result. The test was repeated for each of the two different sizes of the diameter of the pipe hole, Ø 10 [mm] and Ø 30 [mm].

6.3.2 Measurement Results

The measurement results from the third test can be seen in Table 4. The mean micrometer per milliliter for the Ø 10 [mm] pipe opening is 26.42±13.00 [µm/ml] and for Ø 30 [mm] it is 24.82±8.63 [µm/ml]. As in Test 2 these values should be non diverting.

Table 4: Upper table shows distance changes with Ø 10 [mm] and lower Ø 30 [mm].

Test 3: Overall functionality												
	Water Level Change [µm]										Mean	
Pipe opening Ø 10 [mm]	Try 1	Try 2	Try 3	Try 4	Try 5	Try 6	Try 7	Try 8	Try 9	Try 10	[µm]	[µm/ml]
2 [ml]	24,93	26,17	73,53	63,56	36,14	68,55	39,88	64,81	68,55	78,52	54,46	27,23
5 [ml]	171,99	145,82	150,81	135,85	117,16	169,50	125,88	108,53	103,45	183,21	141,22	28,24
10 [ml]	307,80	312,83	191,94	284,16	300,37	277,93	269,21	309,09	279,18	294,13	282,66	28,27
20 [ml]	615,69	448,68	456,16	518,48	624,41	477,35	418,77	447,43	461,14	687,22	515,53	25,78
50 [ml]	950,69	947,21	1395,45	1272,52	1099,27	1115,47	1094,28	1066,86	1358,50	978,37	1127,86	22,56
											Mean [µm/ml]	26,42

	Water Level Change [µm]										Mean	
Pipe opening Ø 30 [mm]	Try 1	Try 2	Try 3	Try 4	Try 5	Try 6	Try 7	Try 8	Try 9	Try 10	[µm]	[µm/ml]
2 [ml]	37,39	37,39	42,38	24,93	43,62	41,13	47,36	31,16	37,39	52,35	39,51	19,76
5 [ml]	92,23	157,04	137,10	133,60	112,17	120,89	127,13	124,63	138,34	88,49	123,16	24,63
10 [ml]	270,45	255,50	332,77	285,41	218,11	246,77	239,30	276,59	267,96	240,82	263,37	26,34
20 [ml]	570,82	504,77	497,29	483,58	474,85	434,97	514,74	530,94	517,23	706,67	523,59	26,18
50 [ml]	1332,33	1509,31	1135,41	1435,78	1349,78	1321,11	1359,75	1384,68	1354,77	1427,05	1361,00	27,22
											Mean [µm/ml]	24,82

6.4 TEST 4: PATIENT MOVEMENT

There are mainly three different movements that the participant can apply with this prototype; knee-bending, muscles flexing or heel-raising, the latter can be performed with the participant either standing up or sitting down. This test was conducted with the aim of trying to determine which of these movements that could be best suited for this prototype and the diagnosis form in general. The criteria for evaluation were disturbances of the water, the experience from the participant, the registered volume change and whether any water was spilled outside the canteen during and after the movement.

6.4.1 Execution of the Test

The pipe opening was determined to Ø 10 [mm] due to that this diameter in Test 3 generated the mean transformation unit ([µm/ml]) closest to the same variable in the first test when disregarding the very unstable results from the 2 [ml] addition of water. This is further discussed in the evaluation in Chapter 7.4.

The participant, with a shoe size of 36 (European standard), placed the bare right foot in the canteen and the bare left foot next to the canteen and performed five different movements: heel-raising with both feet, heel-raising with one foot, knee-bending with both feet, flexion of the calf muscles and heel-raising with one foot while sitting down on a chair. All of the movements were conducted in two sets of five tries, each with ten repetitions and the order in which the sets were performed was completely random.

For each of the movements the distance to the water surface was registered in the software accompanying the sensor. The person supervising the test also noted any disturbances of the water as well as any input from the participant concerning the experience of the movements.

6.4.2 Measurement Results

The results from the fourth test can be organized into three different categories: raw data, notes from the test observer and the graphs from the accompanying software to the sensor for each of the movements. The raw data is visualized in Table 5 as the distance change in micrometers and the calculated means in milliliters of these values for each of the movements described in Chapter 6.4.1. The notes from the test observer are summarized in this chapter and the graphs can be found in Appendix J.

Table 5: Raw data for each movement from the fourth test.

	Test 4: Patient movement											
	Water Level Change [µm]										Mean	
Movements (number of repetitions: 10)	*Try 1*	*Try 2*	*Try 3*	*Try 4*	*Try 5*	*Try 6*	*Try 7*	*Try 8*	*Try 9*	*Try 10*	*[µm]*	*[ml]*
Knee bending	296,6	377,7	243,0	310,3	498,5	494,8	371,4	390,6	344,0	430,0	375,7	14,2
Heel raising (one foot)	-94,2	-8,8	29,9	120,9	237,8	200,6	96,0	17,5	68,6	149,6	81,8	3,1
Heel raising (two feet)	196,9	235,6	197,0	215,6	159,5	219,4	-11,0	363,9	563,3	124,6	226,5	8,6
Heel raising (with one foot, sitting down)	174,5	216,9	324,1	343,9	178,2	376,4	220,6	-72,3	259,3	183,2	220,5	8,3
Flex calf muscle	363,1	290,4	196,9	153,3	99,7	464,7	215,6	335,3	143,3	203,2	246,6	9,3

6.4.2.1 Knee-Bending

The knee-bending movement did not generate a lot of disturbances in the water but it was physically demanding and the participant had to concentrate on the execution of the movement as well as counting up to the ten repetitions. The participant perceived that she activated the muscles in her thighs during the exercise.

6.4.2.2 Heel-Raising with One Foot

Heel-raising with one foot resulted in large disturbances of the water and the participant felt unnatural to only raise one heel. The participant also perceived that it was hard to execute the movement while applying the body load to the right foot and that she needed to hold onto something for support while raising the heel. During the movement the participant perceived that she barely activated the calf muscles but rather just bent her left knee to compensate for the heel-raising of the right foot.

6.4.2.3 Heel-Raising with Both Feet

The participant felt that she had to hold on to something while performing heel-raising with both feet due to difficulties in maintaining the balance during the movement. The participant also perceived it hard to perform the movement in only a vertical direction and felt that she might have leaned forward during some of the repetitions, but she could feel that her calf muscles were clearly activated during the movement. Moreover, the activity resulted in very large disturbances of the water and, in some repetitions, water was spilled outside the canteen.

6.4.2.4 Heel-Raising with one Foot while Seated

During the fourth movement the participant performed heel-raising with one foot while seated, this resulted in very small disturbances of the water. The participant also perceived it comfortable to sit down while performing the movements and that the calf muscles felt activated. Worth mentioning is that the participant had to rise up after each try (with ten repetitions) to help the blood transport back to the foot.

6.4.2.5 Flexion of the Calf Muscles

While standing, the participant flexed the calf muscles of the right leg. The movement barely generated any disturbances in the water. The participant perceived it slightly difficult in the beginning to mentally locate which muscle to flex (the participant is right-handed).

6.5 TEST 5: FOOT VOLUME APPROXIMATION

The fifth test was conducted to acquire an approximate estimation of the relation between shoe size and foot volume. The knowledge was to be saved as an imbedded table in the Foot Volumetry Module where the examiner will enter the patient's shoe size and the approximated foot volume will be utilized in the calculation of the variable [ml/100ml foot].

6.5.1 Execution of the Test

The canteen was placed in a larger bin and then filled with as much water as was possible. Each participant slowly lowered their foot into the water filled canteen. The excess water spilled over to the larger bin and was directly weighed and registered in gram, [g]. Both of the participants' feet were measured three times each and mean values were calculated for each shoe size. The water temperature was kept at the level of the body temperature, approximately 35-37^{o} C, which bring about a water density of 0.993 [g/ml] (Mörtstedt & Hellsten, 1999).

6.5.2 Measurement Results

The measurement results from the fifth test are presented in Table 6. Figure 17 presents the linearization of the raw data from the test and Table 7 shows the foot volume in milliliters for each of the shoe sizes approximated from this linearization.

Table 6: Result from Test 5, foot volume approximation.

		Test 5: Foot Volume Approximation					
		Volume Change [g]			*Mean [g]*	*Foot Volume [ml]*	Transformation factor *[ml/ 100 ml foot]*
	Shoe size	*Try 1*	*Try 2*	*Try 3*			
Right foot	*36*	1040	1026	1017	1028	1101	11,01
	38	1499	1423	1417	1446	1550	15,50
	41	1456	1570	1586	1537	1648	16,48
	46	1939	1953	1930	1941	2080	20,80
Left foot	*36*	1045	1039	1015	1033	1107	11,07
	38	1525	1521	1504	1517	1626	16,26
	41	1517	1503	1493	1504	1612	16,12
	46	1876	1845	1830	1850	1983	19,83

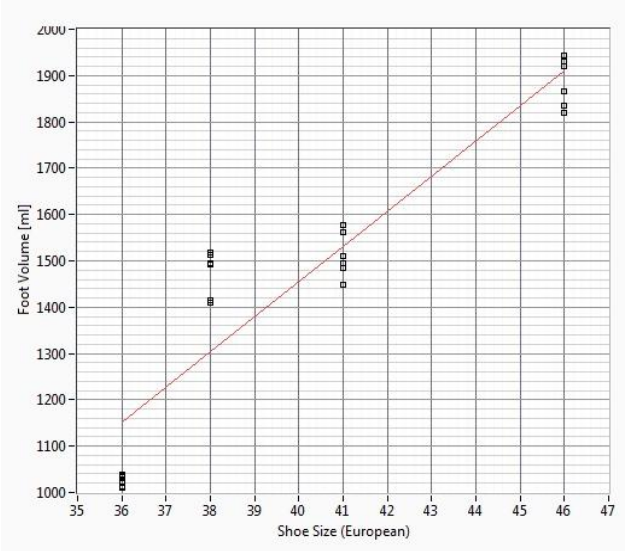

Figure 17: Linearization of the measurement results from Test 5.

Table 7: Approximated Foot Volume from the linearization.

Shoe size	Approx. Foot Volume [ml]
36	1144
37	1218
38	1295
39	1369
40	1446
41	1521
42	1594
43	1669

7 EVALUATION OF THE FOOT VOLUMETRY PROTOTYPE

Due to that the evaluation process of the prototype is a huge part of this Master Thesis this chapter is divided into subchapters, where each subchapter treats different areas of the prototype.

7.1 APPRAISING THE CANTEEN UNIT

The overall experience of the Canteen Unit construction is satisfactory. We perceive that the Canteen Unit is easy to use and understand, its function is pleasing and the design was functional in damping the disturbances from the water without affecting the measurement results too much. The Canteen Unit has a limited number of parts and does not weigh much which makes it easy to move around. It is also possible to completely dismantle, something that is very good from an environmental point-of-view. There are however some things that could be approved.

Some of the material used in the construction could be questioned. The budget for this project was limited and therefore the materials were selected from what existed at the Department of Medical Engineering at Östra Sjukhuset at the time, rather than from what were the most suitable. The material used for the shim construction and the pipe lids, acetal, is too soft and tends to wear out fast, something that became obvious during our tests. The pipe became hard to squeeze tightly since the screw thread in the shim construction was worn out and the lower lid got too loose to stay fixed to the bottom of the pipe. A solution to this problem is to choose a slightly harder but still flexible material or to redesign the parts in question; we think that since acetal seems to wear out fast another choice in material is the right way to go. Another reason for choosing a different material is that acetal is not dishwasher safe. Both the shim construction and the lower lid are in contact with water and need to be properly cleaned. Acetal is, however, a good material for the upper lid since it is easy to shape and the upper lid almost never gets in contact with water (Svensson, 2011).

The sensor attachment is another example of where it is recommended to choose another material. A part of the sensor attachment is currently made out of aluminium but in the original drawings this function was included into the upper lid. The change of sensor was the cause of the sensor attachment not being designed in this way; aluminium plate was selected since it is much easier to make new plates that fits different sensors than to make an entirely new upper lid. The downside with this idea was, as we found out during our testing, that if leakage current occurs in the sensor the current is not isolated but transferred to the aluminium plates in the attachment. Touching a live aluminium plate may lead to damage of the patient, especially since he or she has placed his or her feet into water which is a conductor for current. The damage occurred is of course depending on the size of the current and whether it is alternating current (AC) or direct current (DC). This is discussed further in Chapter 7.2. In a future version of the Canteen Unit, it is recommended that the aluminium plates are integrated in the upper lid with the purpose of isolating it further to avoid any risks of the patient getting in contact with potential leaking current.

The pipe, being made out of glass, is very fragile. An advantage of using glass instead of a polymer is that the pipe can maintain its stability even with very thin walls. This is a big preference since the pipe takes up more space if it has thicker walls due to the outer diameter has to be larger. Another positive aspect of glass is that it is harder to scratch than common polymers. Despite this, we argue for that the material is replaced with a polymer which is stronger and tougher than glass. A strong reason for this is that a pipe made out of a polymer does not shatter into as sharp pieces as a glass pipe could.

The canteen was chosen for a number of reasons. Being dishwasher-proof the hygienic aspects are augmented. Its general shape is pleasing; it is hygienic due to no sharp corners, the surrounding edge at the top acts as natural handles and less water is needed since it has declined walls. The canteen is made out of polycarbonate which is a strong but not brittle material and its price was within our limited budget. On the other hand there are some big issues with it as well. The shape of the canteen might be pleasing but its dimensions are not suitable for our purpose. The canteen is too short, limiting how big the patient's feet can be to approximately a European shoe size 42 and too shallow, causing water to splash out of the canteen during big movements. The need of a deeper and longer container is clear, but unfortunately utensil canteens are only made with certain dimensions. A lid of some sort could be useful for preventing splashing and also to dampen disturbances at the water surface but does not deal with the problem of the canteen being too short. Moreover, the declined walls disable the possibility of linearity throughout the whole height of the canteen – the water level has to be at a specific height in order to get linearity. These arguments are however considered acceptable since this is an early prototype, but it should be stated that a custom-made container for the water and as a base for the whole unit is to be preferred.

Some features that are to the Canteen Unit's advantages also become some of its disadvantages. The shim construction is good since it is easy to attach to the canteen and it allows the height of the pipe to be adjusted by turning a star knob, but because it is made in a material that is too soft it is no use once the screw thread is worn out. One should keep in mind to not tighten the star knob too much since this could break the pipe, the shim construction or the star knob itself. The thickness of the shim construction makes the pipe wobble less but also leads to it being in water. This could affect the sanitary of the canteen, since it needs to be cleaned more thoroughly, and the measurement results since the area of open water gets smaller causing a certain change in water level correspond to a bigger change in millilitres. Despite these arguments we think that the design idea of the shim construction is good if it is made thinner and, as argued before, in another material.

The pipe of the Canteen Unit is long enough to put out most disturbances but not short enough to enable full movement for patients with big feet. A shortage by a few centimetres of the pipe is preferred since it is our belief that it will enable full movement from the patient and it will still be long enough to put out any disturbances. The pipe would also benefit from having a smaller diameter given that it would make more room for the patient in the canteen. This is however hard to implement since the inner diameter is depending on the sensor's triangulation width.

The float has turned out to be the part of the Canteen Unit that we are most satisfied with. The design of it is very good; since it is made out of a construction with a hollow inside, it is heavy enough to add inertia to the system but too light to sink. The lower part of the float adds to the inertia as well as dampens the movement of the water. Given that one problem was that the float was not in range when the sensor was changed, a thought is to enable switching the upper part of the float to a higher or lower one when changing sensors. Unfortunately the material of the float cannot be cleaned in an industrial dishwasher due to the high temperatures. We therefore recommend that during the redesign of the float the material is exchanged in favour of a material which can withstand these temperatures.

7.2 Assessment of the Sensor

As pointed out in Chapter 5.2.6, we had to change the sensor due to a number of complications with the first sensor, the ILD1401-50. The sensor used, the ILD1700-20, was borrowed and could to a large degree therefore not be tampered with, leading us to being unable to add patient safety to this particular sensor setup. As argued earlier in this discussion, this sensor became live due to leakage current at a point during our tests and should have been better isolated by the design of its attachment to the canteen. Another way of increasing the patient safety is to put an isolation component between the transformer and the sensor to cut off any potential leakage currents. This was taken into account in the setup with the ILD1401-50; the sensor was supplied by two 9 [V] batteries in series and therefore the risk of high currents in contact with the patient was avoided. A solution like this is however only temporary, since batteries discharge fast, and for future setups we recommend that an isolation component is used.

The ILD1700-20 has a higher resolution than the ILD1401-50, something that is considered to be both positive and negative. The positive aspect is that since the resolution is higher, small variations in the water level height can be noticed more easily making it possible to measure smaller changes in the blood volume in the feet. On the other hand this is also the negative feature of this sensor; since smaller variations can be detected by the sensor the signal could be more affected by disturbances. In our case, the resolution of the ILD1401-50 would, with all probability, be enough to register the changes of interest.

Another difference between the ILD1401-50 and the ILD1700-20 is that the measurement range is diverting. It is not so much the fact that it is shorter – a range of 20 [mm] is enough to measure the blood volume change and the movements done in this prototype – the distance to the midrange is shorter. The design of the Canteen Unit is made with the first sensor in mind and therefore also for its specifications, leading to the float being out of range for the borrowed sensor. This was solved temporary with an extension on top of the float during our tests (Chapter 6), but reasonably the whole prototype would work better with the sensor it is designed for.

Despite all the arguments above, and with some small adjustments to the design, the ILD1700-20 was satisfying. Using a sensor based on laser measurement is clearly the right way to go in this case due to it being a non-contact method with a high resolution that is not too expensive.

7.3 EVALUATING THE FOOT VOLUMETRY MODULE IN PERIVASC©

When discussing the Foot Volumetry Module one should bear in mind that this, as well as the rest of the prototype, is in the first stadium of development. The module has more or less been done from scratch and therefore only functions that are relevant for this Master Thesis have been developed. The graphical user interface (GUI) is however prepared for future developments such as showing graphs containing both left and right foot as well as showing graphs for measurement with the peripheral veins stopped.

Some approximations had to be done in order to create a well functioning addition to the PeriVasc© software. To get tolerable values of the unit showing the volume difference and the maximum reflux, [ml/100 ml foot], a rather fair estimation of the patient's foot volume has been done. The calibration of the system was concluded after Test 3 (see Chapter 6.3) and consists of the user adding 10 [ml] of water from a syringe prior to each examination. It is important that the water is not added rapidly since this may cause the water level in the pipe to rise higher than what corresponds to 10 [ml]. Both these issues are discussed further in Chapter 7.4.

The slope of the maximum reflux is determined by taking the maximum value in the calculations of the inclination of very small sections of the curve and comparing these to each other. This might very well lead to that a small but rapid increase, caused by for instance disturbances, is seen as the maximum reflux rather than the actual graph's inclination. To avoid this from happening it is important to apply a filter and make sure that the user places the cursors at the correct points. In the Foot Volumetry Module, the signal recorded from the sensor is filtered with a low-pass Butterworth filter in order to remove the disturbances that were discovered during the testing. The disturbances are mainly due to small movements from the patient but can also occur as a result of outside factors such as someone walking by causing vibrations in the floor or electronic noise from the sensor, its cable or the transformer from 230 [V AC] to 24 [V DC]. The filter implemented into the Foot Volumetry Module is only tested on simulated graphs and imported real graphs from other recordings. Therefore the cut-off frequency may have to be adjusted and an additional Notch filter, for removing 50 [Hz] noises, may have to be implemented due to that the analogue output signal might be affected by this particular frequency.

The module has been tested on simulated and on real, but not real-time, values with satisfying results. The GUI has not yet been tested with the actual users but, as stated in Chapter 5.2.8.2, it has been developed according to findings during observations, discussions with people with great knowledge in cognitive ergonomics, HMI or medical instruments as well as, what is to us, common sense. One thing that we would like to implement in the GUI is that the patient data should be loaded automatically into the form rather than when the user presses the "Hämta data"-button. It would have been preferred that this data is presented as soon as the module is opened. Another thought is to add a box for the patient identification number in the upper right corner to facilitate finding the print-out of this in a stack of paper. It is strongly recommended to do observations of the module in action in order to, amongst other things, determine what else should be changed in the GUI.

7.4 DISCUSSION ABOUT THE TEST RESULTS

The overall conclusion of the tests, presented in Chapter 6, is that the prototype behaved as predicted but the test results still yield a lot to discuss. In order to create the best possible function and stability in the prototype we decided to try out different sizes of the lower pipe opening, different amounts of added water and different movements from the patients.

The results from Test 1, see Chapter 6.1.2, show that the prototype is relatively stable both when it comes to tries with the same volume and between the different volumes. As can be seen in Table 2, the only diverting volume is 2 [ml]; the mean volume is noticeably decreased due to the poor result in this part of the test. If the 2 [ml] results are excluded, the mean ends up at 25.80±5.17 [µm/ml], a value that is much more reasonable comparing to the mean of each volume in Table 2. During this test we had some problems with the sensor recognising a change this small and therefore we argue that there is no harm in ignoring the results from the 2 [ml] tries. An explanation for this could be that the system has some sort of inertia that is not always noticeable or that the measurements are affected by disturbances from the surroundings. However, in later tests we did not have this problem and furthermore; in Test 4 we could detect very small changes, down to 1.13 [ml] (or 29.9 [µm]). Since the participant in this test had a foot volume of approximately 1100 [ml] (achieved from Test 5) this change corresponds to 0.10 [ml/100 ml foot], which not only meets our requirement of the system but also our desire. This proofs to us that our measurements are good enough to be used in the purpose of foot volumetry.

During the performance of Test 1, it was early concluded that the best way to change the water level is to add water to the canteen rather than to remove water. When removing water, one has to put the syringe into the water which causes a small rise of the water level and therefore the corresponding measurement graph shows more than the volume removed. The disadvantage of adding water is, as we also found out during this first, test that the height of the float can increase differently depending on how fast and in which direction one adds the water. The results of Test 1 vary slightly between the different volumes added. Due to the usage of syringes with different scales the exactness of one millilitre decreases as the total volume increases, since the scales of the larger syringes in our tests were less precise. Adding water by a syringe is never the less a good way of calibrating the system; it is precise when the volume is not too big and it is hygienic and is therefore recommended to be used in the future as well. A fixed position for the syringe, in order to facilitate the calibration, might be something to include in a future design.

Test 2, in Chapter 6.2, concluded what diameter the lower lid of the pipe should have based on stability between the different tries and the time it took for the system to get stable after the water addition. We decided to choose two different diameters to compare in another test with different volumes added in order to secure that the best diameter had been chosen and to decide which volume the calibration of the system should have. The choice of Ø 10 [mm] was easy; this pipe opening has both the fastest and the most consistent measurement results (see Table 3). The second diameter to be

further investigated was harder to decide. The time to become stable suggested a pipe opening of Ø 54 [mm] but the values of the volume change was so inconsistent that we went for the slower but more consistent diameter of 30 [mm]. During this test we also realized that it was favourable to do more than five tries for each test, something that was executed during Test 3 and Test 4 and is strongly recommended for testing in the future.

As pointed out above the calibration volume was concluded in Test 3, described in Chapter 6.3, and should consist of 10 [ml] of water since this particular volume had the most consistent values for both pipe opening diameters. The Ø 10 [mm] opening was chosen based on the results from this test; the mean volume change is the closest to the one derived in Test 1 (when excluding the measurement results from the 2 [ml] tries) and has the most consistent values between the different tries.

A problem that occurred in Test 1-3 was that the mean micrometer per millilitre was not consistent between the different volumes nor the different pipe openings. These means should reasonably not divert; one millilitre of water is always one millilitre of water and should correspond to the same rise in water level, regardless of whether the pipe opening diameter changes or not. What this problem is caused by is hard to tell, but it suggests that the system is not as reliable as it was first thought to be.

The results from Test 4, described in Chapter 6.4.2, were however a bit surprising; all but one of the patient movements turned out to show better results than we expected. As showed in Table 5 the most efficient movement to remove blood is to do knee-bending, mainly because the thigh muscles are activated as well as the calf muscles. All of the movements performed can be used for evaluation of the calf muscle pump except for the heel-raisings done with one foot while standing up. The participant found that it was an unnatural movement and that it was hard to put the body weight at the right place, something that is reflected in Table 5 – this movement generated the worst values and consistencies between the tries.

All movements have their pros and cons. The knee-bending movement gave a very nice graph and good values in terms of blood transported away from the foot. On the other hand, this movement turned out to be very physically demanding from the patient's point-of-view and is therefore not recommended, or even plausible, for patients that are not physically fit due to, for instance, age or medical conditions. The fact that the thigh muscles are activated as well makes it hard to evaluate only the calf muscle pump, yet it makes it possible to evaluate the muscle pump in the entire leg. The other movements only concern the calf muscles and if the goal is to diagnose the function of this particular muscle pump then these are more appropriate to do. As mentioned above, heel-raisings while standing with one foot yields poor results and is hard to perform and should therefore be considered as a plausible movement.

Heel-raisings while standing up but using both feet are a better movement. It is an easy movement to do and to make sure that the patient activates the correct muscles, but it causes disturbances of the water in the canteen that affects the stability of the system. The risk of water splashing out of the canteen is also bigger since it is such a violent movement in comparison with the others. During all the movements mentioned above the participant in our tests at some points needed something to hold on to, which is recommended to be provided to the patient as a support without him or her asking for it.

If the patient does heel-raisings while sitting down, the movement becomes much more gentile. The measurement is not as affected by disturbances caused through waves and the calf muscles are the ones being activated. It is also a very nice movement for patients that for different reasons have problems with doing certain movements while standing. One negative aspect of this movement, and for the other heel-raising movements, is that the water level height changes dramatically due to the volume change that occurs when lifting part of the foot out of the water. Another downside is that since the patient is seated it takes a long time before blood has returned fully to the foot. During our tests this problem was solved by the participant standing up after the heel-raisings, causing another problem since the foot volume beneath the water surface increased due to higher weight being put on the foot as well as blood coming back. The most surprising results came from the movement of just flexing the calf muscles while standing up. The results were similar to the heel-raising movement, see Table 5, but without the wave creation of these movement and the huge change in foot volume beneath the water during the movement.

All and all, we think that flexing the calf muscles is the best movement to perform during diagnosis with our prototype. If this is not possible, the next best thing is to ask the patient to do heel-raisings while seated. If the physicist is more interested in the function of the entire leg muscle pump the knee-bending movement is the right one to choose. All of these movements are possible to perform even if both feet are in water, making it feasible to record both feet at the same time given that a replica of the prototype is made.

The results from Test 4 could have been more reliable if the repetitions were executed in the same rate, preferably one repetition per every other second, and with equally long pauses between the different tries. The pauses may be based on either a constant time or a time calculated by the amount of blood transported away. Unfortunately we did not realize this before half of the tries were already done and due to limited time set aside for testing we did not have the opportunity to redo the tests.

The approximation of the foot volume, used in the unit [ml/100 ml foot], is very uncertain. The foot volume is based on the shoe size of the patient and on a linearity we calculated of this that we could conclude in Test 5 in Chapter 6.5.2. What was not considered during this linearization was that in this test the participant also put a part of his or her calf into the water as well and the relationship between the shoe size and the volume of the calf is hard to define. The reasons for us to still choose such an approximation are, to start with, that our tutor, MDr Anders Thurin, described the currently used unit as odd and not accurate. Secondly, it is rather the trend of the graph

than the calculated values that is looked upon when using foot volumetry as a method of diagnosis. Finally, to determine the actual volume of the patient's feet is a task that takes a large amount of time and effort, and therefore would trespass into more important parts of this Master Thesis. It is however recommended that a more exact method is used in the future in order to get a more accurate result when presenting the calculations done in the graphical user interface.

Due to lack of time we did not have the opportunity to test the full prototype in action nor to do observations of the usability of the prototype. In order to evaluate the prototype further we recommend that all tests should be performed again using the sensor the prototype is designed for. We think that since we acquired good results from the tests done using the borrowed sensor the results from tests using the first sensor could be even better.

8 CONCLUSIONS AND RECOMMENDATIONS

This chapter starts off with a few conclusions about the finished prototype and later summarizes the main recommendations which are discussed earlier in the evaluation chapter.

8.1 CONCLUSIONS ABOUT THE FOOT VOLUMETRY PROTOTYPE

We can conclude that even though the Foot Volumetry Prototype holds several factors in need of improvement, it is still a successful result of this Master Thesis. The overall function is accomplished to a satisfactory level and it fulfills its tasks without any larger misadventures which could not be at least temporarily managed. It is without any doubt a very good idea to use an optical sensor based on laser measurements and the Foot Volumetry Prototype will work without any larger problems with the sensor (optoNCDT1401 ILD1401-50) it was primarily designed for. The system also reaches the requirement and desire set to enable fine measurements; the system is able to detect changes down to 0.10 [ml/ 100 ml foot].

A redesign with our recommendations should result in a simple but still accurate device for measuring foot volume changes.

8.2 RECOMMENDATIONS FOR FUTURE IMPROVEMENTS

There are several factors of the Foot Volumetry Prototype which need to be looked into further. Below we highlight the factors that are considered as most sufficient to ensure a successful redesign of the next prototype.

The shim construction and the lower lid should be reconstructed in another material which has to be soft enough to squeeze the pipe but hard enough to not wear out as easily as today. Another suggestion is, of course, to redesign the shim construction and the lower lid to be less sensitive for material variations. Furthermore, the shim construction should be made thinner to avoid future contact with the water surface during the measurements.

It is advisable to somehow isolate the surface of the sensor from the examiner and the patient due to experiences with leaking current from the sensor cable attachment. As a suggestion, this can be done by alternating the design of the upper lid to also include the attachment of the sensor. Another highly recommended safety precaution is to mount an isolation component between the power supply and the sensor.

The glass pipe should be redone in a material which still is translucent but less brittle, suggestively a hard, but not too stiff, and transparent polymer. It should also be shortened by a few centimetres and the inner diameter should be small enough to enable more space for the patient’s foot but still large enough to not affect the sensor reading.

The container should be redesigned with more suitable dimensions to be able to measure a larger variety of foot sizes. It is recommendable to keep polycarbonate as the material.

Preferably, the Foot Volumetry Module should be modified to enable patient identification data to be automatically loaded into the graphical user interface, instead of the user having to press the button “Hämta data” to obtain the patient identification data in addition to the measurement results from PeriVasc©. Moreover, it is recommended that a copy of the patient identification number is placed in the top right corner of the graphical user interface, since it makes it easier for the medical staff to find the correct printed documentation of the patient information.

The filter implemented in the Foot Volumetry Module should be looked over and possibly adjusted since it has only been tested with simulated graphs and real graphs which have been imported to the module.

To add water with a syringe prior to examination has proven to be a good calibration solution but it might be a good idea to implement some kind of fixed support for the syringe to enable a more stable calibration.

It is favourable to perform more than five tries during the tests since this yields a more consistent result, the more tries the more reliable result.

The movements done by the patients in order to use the prototype for diagnosis should be either flexing the calf muscles while standing or doing heel-raisings while seated. The repetitions should be executed at the same rate, one repetition per every other second, and the pauses between the tries should be equally long.

The approximated relation between shoe size and foot volume, estimated in Test 5 and currently used in the Foot Volumetry Module should be exchanged for a more precise evaluation.

All of the test should be performed again after these recommendations have been taken in consideration. It is also very important to perform observations of the end-users while they run the whole system, to be able to evaluate the graphical user interface and the overall cognitive and physical ergonomics of the Foot Volumetry Prototype.

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9.1 FIGURES

9.2 TABLES

APPENDICES

APPENDIX A – OBSERVATIONS

OBSERVATION 1 – FOOT VOLUMETRY IN THE EXISTING DEVICE

In order to get a better idea of how to develop our prototype we decided to take a closer look at the existing device. According to Anders Turin, this device was in use between the early 1970's and the mid 1990's.

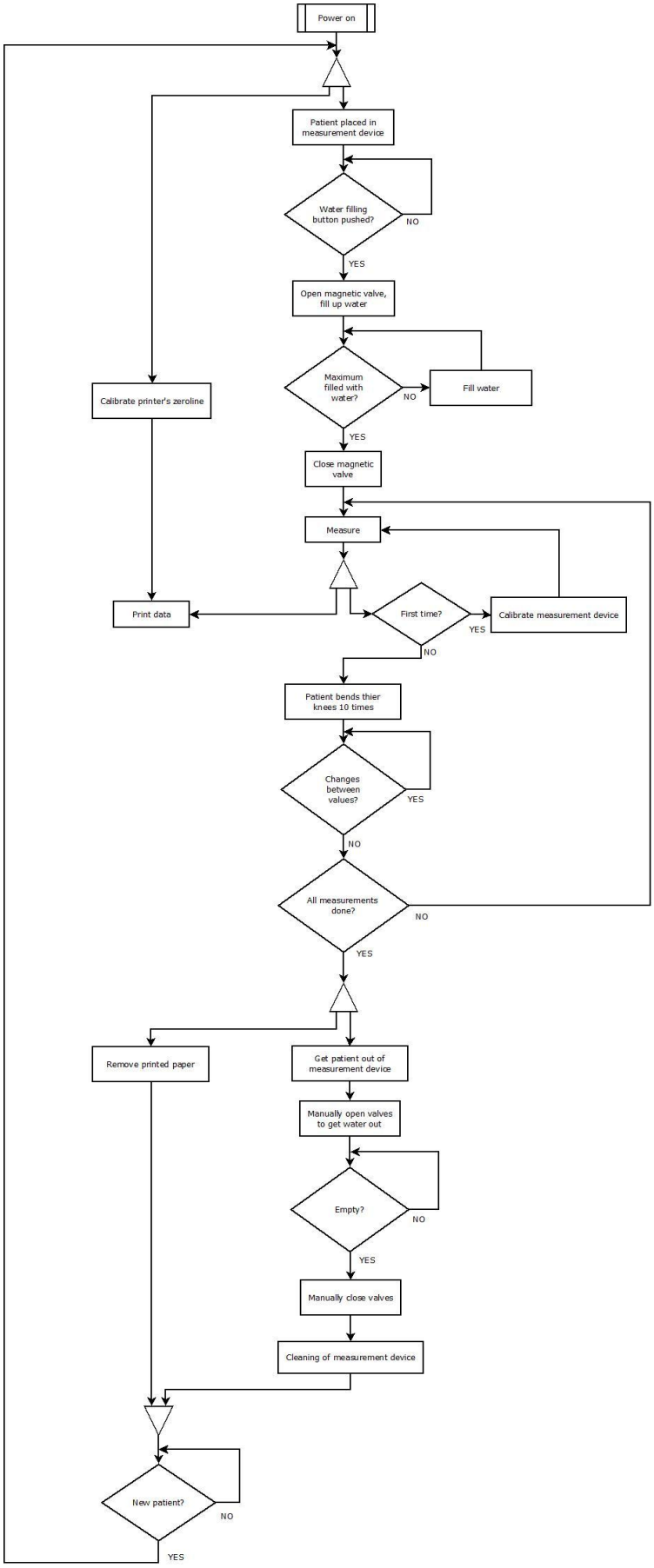
Most important to us was to evaluate if the device could be used not only when bending ones knees but also when doing heel-raisings and to see how much turbulence in the water the movement caused. It was also important to see if and how much the change in volume was before and after the movement. We only evaluated the measurement device i.e. the device was not connected to the control unit nor the printer during our tests.

The first problem with the device occurred when we filled it with water. We did not realise that the float indicating the level of water was counting on the foot being inside the tub when starting, which in turn led to water spilling over when the foot was placed in the tub. This is something that has to be obvious when we create our device. The second problem was that it was really hard to do knee bends and activating the calves and not the thighs.

The measurement seems to be good, even though we did not connect the control unit. We could see with the naked eye that the small plate between the diode and the phototransistor had moved one or two millimetres compared to before the heel-raisings. Of course the float that the plate is attached to moved during the toe-raisings, but it was due to that less of the leg is below the water surface when the heel is raised rather than the movement causing waves. The float were not very sensitive to big disturbances; it took very little time for the plate to stabilize itself post-movement, but it had a small time delay.

Since the plate is not directly attached to the float but to a lever the deviation of the plate is bigger than the one at the float. To be able to know how much the deviation corresponds to calibration is done by being able to adjust the water level with five millilitres.

We have been told that the existing device was very hard to clean and this was proven to us now since we could see a calcareous layer covering the floats.



Flow chart illustrating the usage of the existing device

OBSERVATION 2 – ULTRASOUND TO MEASURE VENOUS INSUFFICIENCY

Venous insufficiency can be measured in a number of ways. We were able to participate during an examination of varicose veins using ultrasound as the instrument of diagnosis.

The patient had, to us, no obvious varicose veins but she expressed some of the symptoms connected to the condition. She was asked to lie down on an examination couch that was later tilted in different angles. One of the two examiners used the transducer of the ultrasound to follow different veins on the leg and the other controlled the displayed image. The image was shown both on a computer screen on the apparatus and on an additional screen so that the transducer-holding examiner should be able to clearly see where to move the transducer next. The two examiners had to play quite well together since the examiner at the computer had to follow the movements of the transducer on the screen in order to receive relevant data. Both the patient's superficial and deep veins were examined. The examiner moved the transducer along the veins; first on the front of the leg and then on the rear of the leg.

The ultrasound apparatus is adjustable in height, making it possible for the user to sit or stand during the examination which is very good from an ergonomically point-of-view. Many of the Biomedical Analysers (BMA) have been involved in deciding how the user interface on the touch-screen should look and the examiners we observed were very pleased with the appearance. One problem that we observed was that the device has three different inputs; touch-screen, buttons on the device and keyboard and mouse connected to the device. To us this seems like too many different ways of interacting with the machine. The individual interactions were however all good; the buttons, for example, were divided into groups based of function

There were opportunities to freeze the image during the exam, making it possible to save interesting images but, as far as we could understand, these images are not included in the patient's medical chart. They are only used for the diagnosis during the examination. In the patient's medical chart a form was stored which is a digital form that is found online. The examiners spoke very well about this form and really liked the functions of it. Even so, during the examination they did use a paper and pen to write on a printed version of this form in order to remember everything. To write everything down on a computer directly was too time-consuming and circumstantial to the examiners to do during the examination. When the digital form was finished it was printed and sent to a physician for evaluation.

OBSERVATION 3 – PRESSURE IN TOES AND ANKLES

We got the opportunity to participate during an examination of pressure in toes and ankles in order to observe, analyze and be inspired by existing devices used for these kinds of measurements.

First, the temperatures of the patient's toes were measured and, since they were too cold, they were placed in a lukewarm bath in order to obtain a temperature of approximately 28°C. This specific temperature is used in order to facilitate the blood streaming and also so that one can compare between different measurements (patients or occasions). A plastic sheet was put in the tub before the water was added in order to facilitate cleaning. If the patient has ulcers on the feet the bath is avoided and the temperature is instead raised by using a heating pad and, if necessary, a hair dryer.

The patient was then asked to lay down on an examination couch and sensors were attached to him; a blood pressure cuff at the right arm (for comparison) and around each toe, a Doppler-sensor to measure the pulse on the right wrist and one photo-sensor on each toe to measure the pulse. These sensors are connected to an analogue control unit which is receiving signals from the sensors and also providing the cuffs with air. The signals from the sensors are presented on a computer screen, which unfortunately was placed badly; next to the control unit box and with the mouse and keyboard placed in front of the same control box i.e. to the side of the screen, which is not exactly optimal from an ergonomic point-of-view. The computer was also disconnected from the network, since the software seemed to mind this, and the examiner had to enter the patient's personal information into the computer by hand.

The sensor signals (from now on called the measurements) are shown on a real-time chart in PeriVasc© and the examiner has the possibility to record interesting time intervals in order to compare two measurements with each other. The chart shows the pressure of the different cuffs.

The examiner used a foot pedal to inflate the cuffs and then a manual valve to be able to control the deflation off the cuffs. The cuffs were inflated in order to stop the inflow of blood to the arm and to the toes and then they were deflated slowly until the flow was back in the limbs again. During this measurement the signals were recorded. No ergonomically or user interaction problems, besides the placement of the screen mentioned above, were observed so far.

When the examiner has done the test for toe pressure it was time to measure the ankle pressure of the patient. At this point we were told by the examiner that it was difficult to measure this particular pressure by using the device; mainly because the Doppler-sensor tend to move if the cuff inflates to quickly (which it does) but also because the Doppler-sensor attached to the measurement device already is in use at the right arm. Instead of using the device meant for this the examiner used a separate Doppler device and a manual driven blood pressure cuff.

Clearly this is a big fault with the device; it is too problematic to be used for half of the tasks that it is supposed to be able to handle.

Another observation worth to mention is that even though some of the measurements were shown in a digital chart the examiner still wrote the pressure values down on a paper and then printed the charts. This combined with similar actions that were done during our second observation, where we studied a examination of venous insufficiency by ultrasound, makes us draw the conclusion that the hospital world is not that digitalized after all – almost every referral is sent on paper and not via email or in any other digital communication form.

We also observed some difficulties related to the software. First, there is no feedback when the operator presses save, i.e. he or she has no knowing of if the document has been saved or not. Secondly, sometimes pop-up windows with a statement of a problem occur but these windows do not state which action should be taken to prevent or solve the problem.

OBSERVATION 4 – MEASUREMENT OF VENOUS FLOW

The device used during Observation 3 – "Pressure in Toes and Ankles" can also be used in order to measure the venous flow in a patient's legs. We were invited to observe one of those examinations.

What struck us most was that there were a lot of small preparations to do before the measurements could begin. In fact, the preparations took almost as long time as the examination itself did. The device had to be prepared for different measurement, i.e. some wires and tubes had to be replaced and/or added. This was done while the patient was present but most of these preparations, like changing wires, starting the program etc, can be done in advance. Many of these preparations where done quickly and smoothly, mainly because of good feedback from the measurement device. The analogue indicators in the device are mainly used only for calibration; the rest is taken care of by PeriVasc©.

As in the other observations the examiner had papers about the patient and some papers to fill in during the examination, there is no obvious place to put these papers. During the examination these papers was lying in front of and sometimes on top of the keyboard making it difficult for the examiner to use the keyboard. The table where the measurement device and the computer are placed cannot be moved up or down, which is a big disadvantage from an ergonomically point-of-view. The table is on wheels but is very big and really hard to move around which would not be such a huge problem if it was not for the fact that the wires and tubes used for the blood pressure cuffs are very short. As it is now the patient almost had to have the screen touching his arm for the wires and tubes to reach. The wires are marked with red and green, indicating left and right. We would have preferred that it was clearer what is left and right than just using two colours which is very hard to differ between if you are colour-blind.

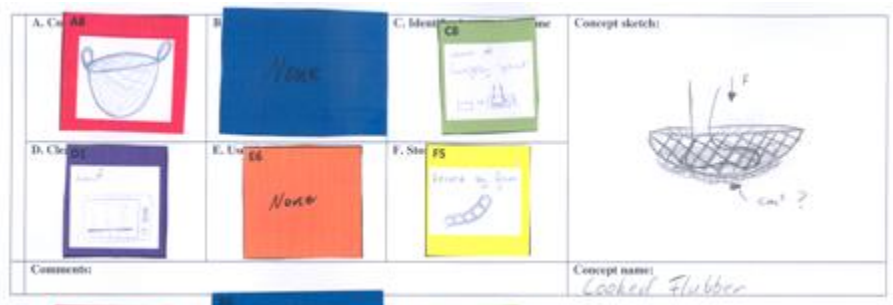
The patient was asked to lie down on an examination couch with his feet placed in two holders at the wall. His knees were bent at approximately 60 degrees. The patient in question was a normally built man but despite that the couch seemed to be too short and too narrow for him to be able to lie down comfortably. The circumference of the patient's calves were measured in order to yield a reference number, then an elastic mercury tape was placed on the calf at the same place as the measurement where taken, one around each leg. The mercury tape, which changes in resistance when stretched, was calibrated quite easily. A blood pressure cuff was placed around each thigh and inflated in order to stop the venous flow but not the artery flow. When the leg was full of blood the pressure was released and then the blood quickly returned from the legs. The mercury tape then registered the changes in circumference in the calves.

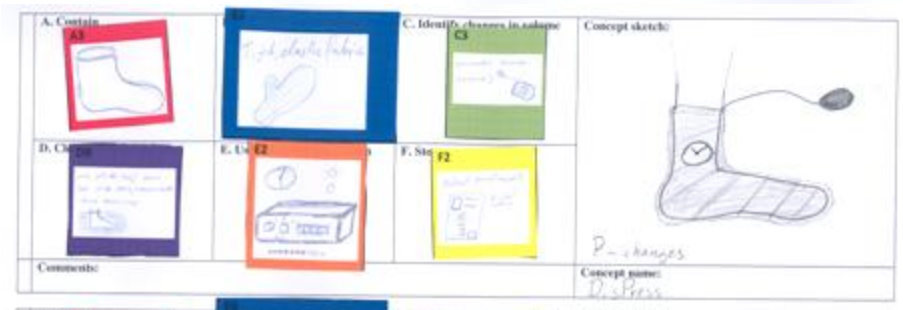
The variations of the elastic mercury tape where presented in a real-time chart in PeriVasc©. As in the measurements of toe and ankle pressure the examiner recorded the measurements. Similar software problems as in those examinations were observed, with the addition that the examiner had to repetitively select the same setting in between every mark made in the GUI instead of just selecting the setting once.

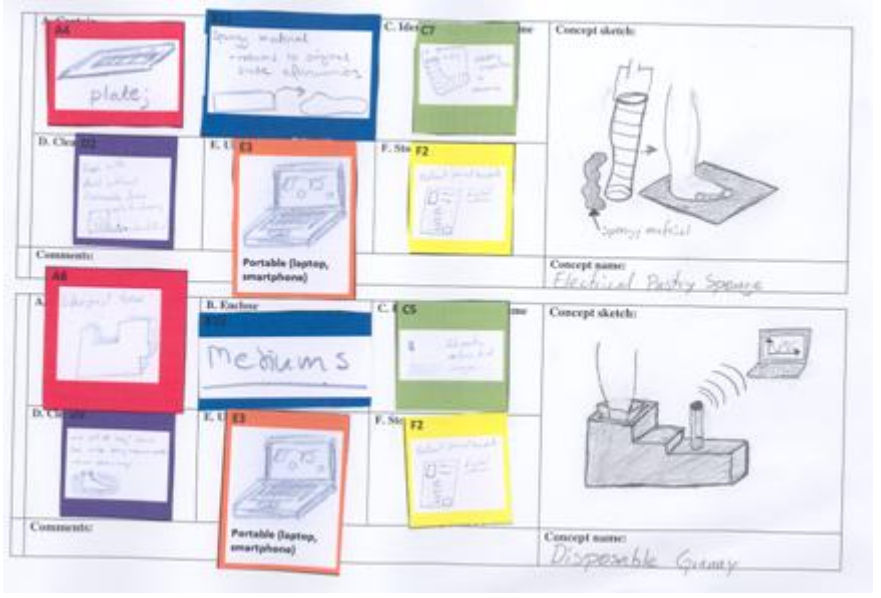
The measurement of venous flow seemed to be much easier to perform using the measurement device, but the examiner had to use a self-made guideline while doing the setup. She explained to us that it was because she did not do it very often, but we think that it is important that the setup is so obvious to do that no guidelines should be needed.

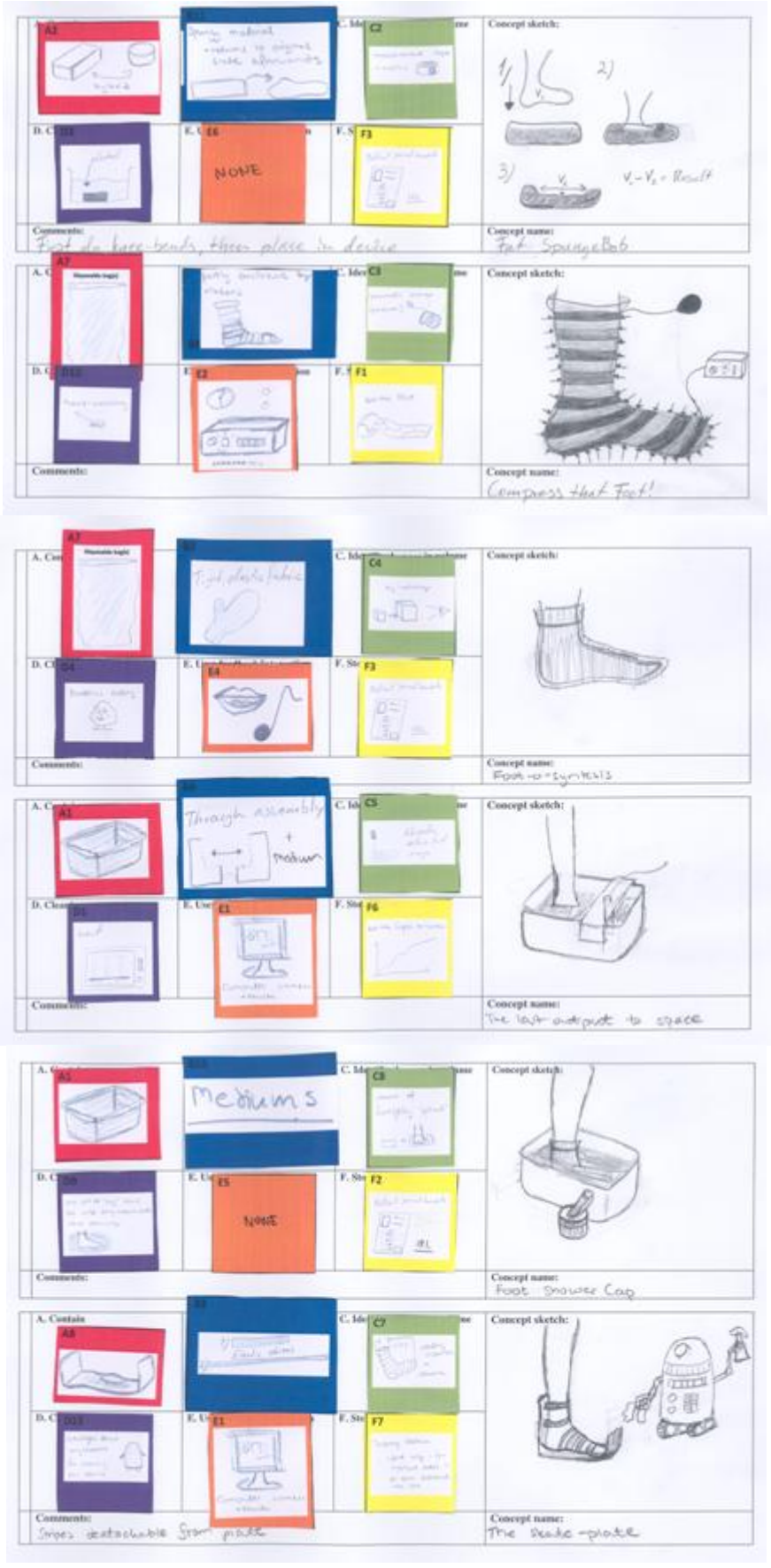
Requirements	Guideline	Validation	Classification
Functionality and Measurement Reliability			
Enable fine measurements	0.50 [ml/100ml foot]	Assessment, Functional testing	**R**
Enable fine measurements	0.10 [ml/100ml foot]	Assessment, Functional testing	**D-4**
Minimize the effect of measurement errors		Assessment, Functional testing	**R**
Minimize the noise in the signal		Assessment, Functional testing	**R**
Enable continuous measurements	Several measurement points	Assessment, Functional testing	**R**
Limited time for examination using the prototype	Maximum time 45 min	Assessment, Functional testing	**R**
Limited time for examination using the prototype	Maximum time 15min	Assessment, Functional testing	**D-2**
Enable necessary patient movement	Heel-raising and knee-bending	Assessment, Functional testing	**R**
Usability and User-Friendliness			
Enable cleaning between usage	The prototype should be able to be cleaned in an industry dishwasher	Assessment, Observation	**R**
Enable cleaning between usage	The prototype can be cleaned without having to be disassembled	Assessment, Observation	**D-3**
User interface comprehensible	Users should be guided in the use of the prototype	Assessment, Observation	**R**
Provide decent portability	Maximum weight 6[kg]	Assessment	**R**
Provide portability at a high level	Maximum weight 1[kg]	Assessment	**D-2**
Be safe for patient and user	No sharp edges in the construction	Assessment, Observation	**R**
Be safe for patient and user	Non-slippery surfaces	Assessment, Observation	**D-4**
Limited time for set-up of the prototype	Maximum time 15min	Assessment, Observation	**R**
Limited time for set-up of the prototype	Maximum time 5 min	Assessment, Observation	**D-2**
Should fit most feet sizes	35-42 (European shoe size)	Design, Observation	**D-3**
Apply cognitive and physical ergonomics for filling of medium	User should understand how to safely use the device instantly	Design, Observation	**R**
Apply cognitive and physical ergonomics for drainage of medium	User should understand how to safely use the device instantly	Design, Observation	**R**
Operated by a single user	The device should be able to be operated by a single user	Design, Observation	**R**
The construction should be considered as robust	Handle everyday management, water resistant	Design, Functional testing	**R**
Legal and Environmental			
Prevent patient/user contact with electricity	Enable electrical isolation through material selection and construction design	Design, Functional testing	**R**
Consists of non human toxic material	To 100%	Assessment	**R**
Consists of environmentally friendly material	To >70%	Assessment	**R**
Consists of environmentally friendly material	To >90%	Assessment	**D-4**
Recyclable	To >70%	Assessment	**R**
Recyclable	To >90%	Assessment	**D-2**
Should withstand corrosion	To 100%	Assessment	**R**
Software Module			
Graphical user interface comprehensible	Users should be guided through the use of the software	Observation	**R**
Communicative graphical user interface	Provide user with direct feedback	Observation	**R**
Enable necessary calculations	T50 (time for reflux to reach 50% of original value), T90 (time for reflux to reach 90% of original value), maximum reflux and volume differential	Design, Functional testing	**R**
Enable input of necessary patient data	Patient ID, shoe size, feet temperature,	Design, Functional testing	**R**
Present the measurement results for the user	Enable the results to be transformed on a patient chart	Design, Functional testing	**R**
Save the measurement results	Enable the results to be saved in a digital patient chart	Design	**R**
Print the measurement results	Enable the patient chart to be printed on a local printer	Design	**R**
Compatible with the PeriVasc software	Build in software module in PeriVasc	Design	**R**

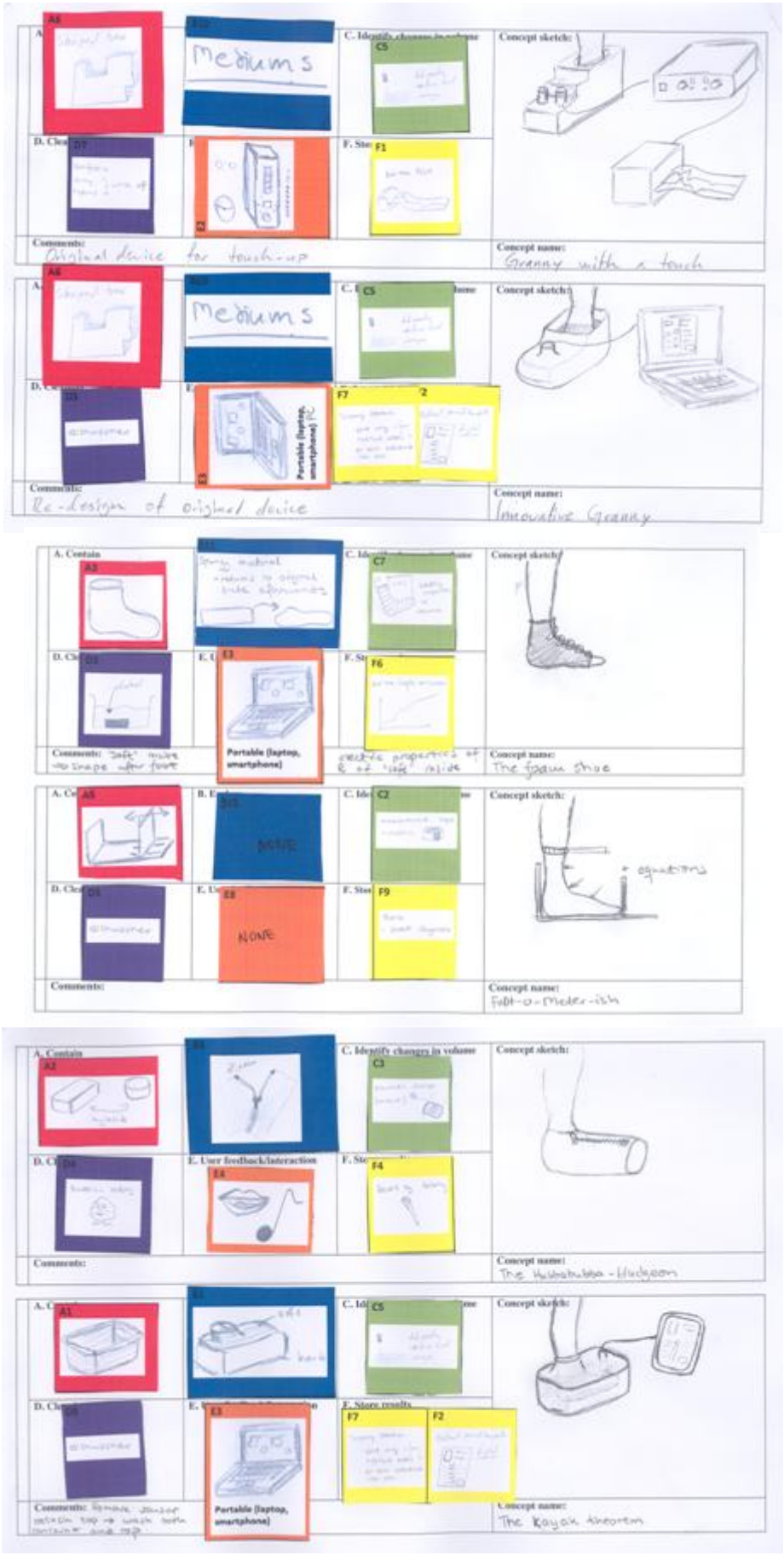
APPENDIX C - MORPHOLOGICAL MATRICES

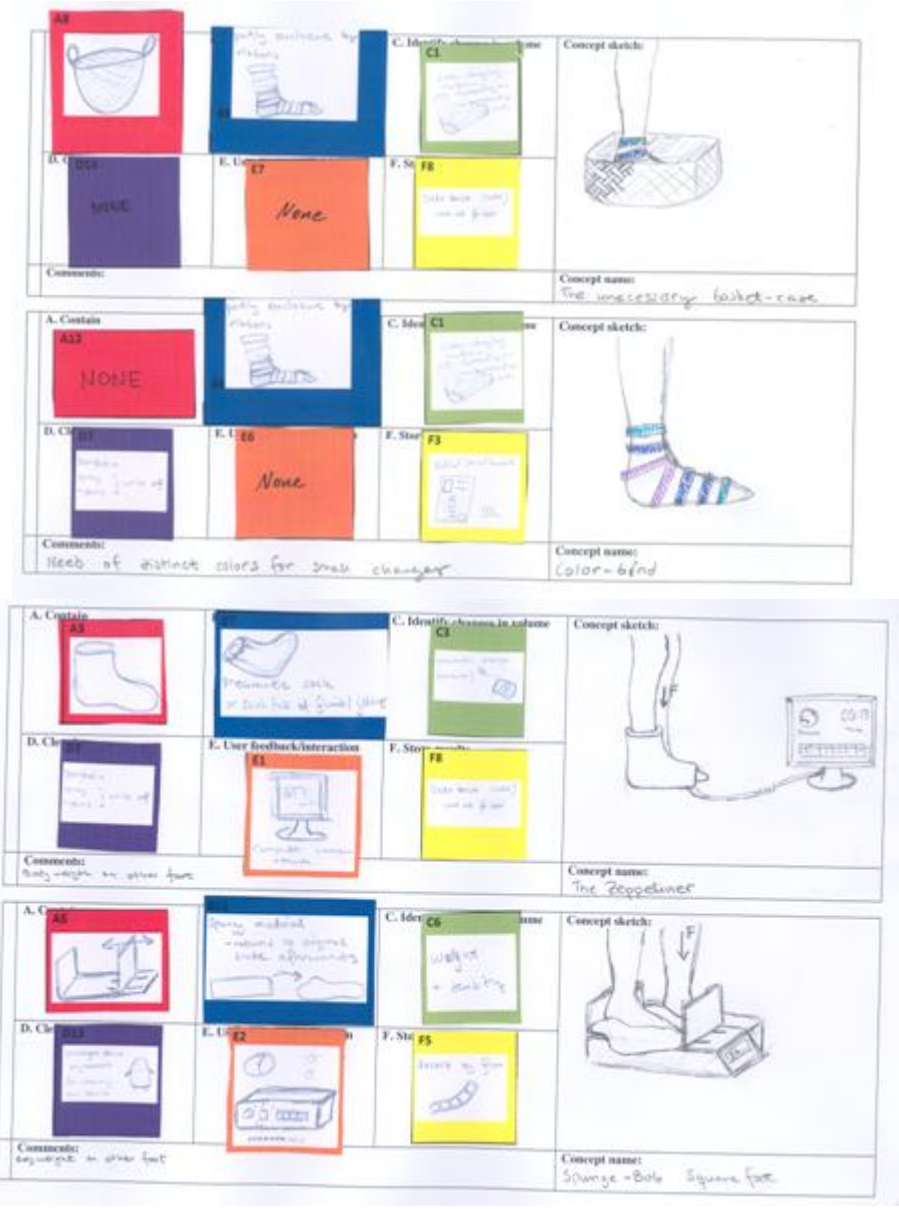







Concept sketch:
NONE
Concept name:
Fat SpringeBob
Concept sketch:
Concept name:
Compress Heat Foot!
Concept sketch:
Concept name:
Concept sketch:
Concept name:
Concept sketch:
Concept name:
The last output to space
Concept sketch:
Mediums
NONE
Concept name:
Foot Shower Cap
Concept sketch:
Concept name:
The Scale-plate


Mediums
Concept sketch:
Concept name:
Granny with a touch
Comments:
Original device for touch-up
Mediums
Concept sketch:
Concept name:
Innovative Granny
Comments:
Re-design of original device
Portable (laptop, smartphone) PC
Concept sketch:
Concept name:
The foam shoe
Portable (laptop, smartphone)
Concept sketch:
Concept name:
Felt-o-meter-ish
NONE
Concept sketch:
Concept name:
The Wheelchair - Hickam
Concept sketch:
Concept name:
The Kayak theorem
Portable (laptop, smartphone)


A2
C1
Concept sketch:
D1
MINE
E7
None
F8
Comments:
Concept name:
The unnecessary basket-case
A. Contain
A12
NONE
C1
Concept sketch:
E6
None
F3
Comments:
Need of distinct colors for trash changer
Concept name:
Color-blind
A. Contain
A3
C3
Concept sketch:
F
E. User feedback/interaction
E1
F8
Comments:
Concept name:
The Repellner
A5
C6
Concept sketch:
F
D13
E2
F5
Comments:
Concept name:
Sponge-Bob Square Pant

PUGH MATRIX TAKE 1

Selection Criterias	Granny with a Touch (Reference)	Innovative Granny	The Zeppeliner	Sponge-Bob Square Foot	DisPress	Talkative Voltage	The Foam Shoe	Foot-o-Meter-ish	Electrical Pastry Sponge	Disposable Granny	Foot-o-Synthesis
Enable fine measurements	0	0	0	-	0	-	-	-	-	0	-
Minimize the effect of measurement errors	0	0	-	-	-	-	-	-	0	0	-
Minimize the noise in the signal	0	0	+	0	0	-	0	+	+	+	+
Limited time for examination using the prototype	0	0	+	+	+	+	+	0	-	-	+
Enable cleaning between usage	0	+	+	-	+	-	-	+	-	+	-
User interface comprehensible	0	+	+	-	0	-	+	+	+	+	+
Provide decent portability	0	+	+	-	+	+	+	+	+	0	+
Be safe for patient and user	0	0	+	+	+	0	0	+	0	0	0
Present the measurement results	0	+	+	-	-	-	+	-	+	+	+
Limited time for set-up of the prototype	0	+	+	+	+	+	+	+	+	+	+
Consists of non-toxic material	0	0	0	0	0	-	0	+	-	0	-
Consists of environmentally friendly material	0	+	+	-	+	-	-	+	-	-	-
Recyclable	0	+	+	-	0	-	+	+	+	+	+
Sum +	0	7	10	3	6	3	6	9	6	6	7
Sum 0	13	6	2	2	5	1	3	1	2	5	1
Sum –	0	0	1	8	2	9	4	3	5	2	5
Net Score	**0**	**7**	**9**	**-5**	**4**	**-6**	**2**	**6**	**1**	**4**	**2**
Rank	**13**	**3**	**1**	**20**	**7**	**21**	**10**	**5**	**12**	**7**	**10**
Continue?	**No**	**Yes**	**Yes**	**No**	**Yes**	**No**	**Yes**	**Yes**	**No**	**Yes**	**Yes**

The Last Output to Space	Hubbabubba-Bludgeon	The Kayak Theorem	Fat Sponge-Bob	Compress that Foot!	Foot Shower Cap	The Skate Plate	The Unnecessary Basket Case	Color-Bind	Cooked Flubber	Rainbow Assessment
0	-	0	-	+	-	-	-	-	-	-
-	-	0	-	-	-	0	-	-	-	-
+	0	+	+	-	+	+	+	+	+	-
0	+	0	-	-	0	0	0	0	-	-
+	-	+	-	-	+	-	-	+	-	0
+	-	+	0	0	+	+	-	+	-	+
+	+	+	+	0	+	+	+	+	+	0
0	0	+	0	0	+	0	0	+	-	0
+	-	+	+	0	+	+	0	+	-	+
+	+	+	+	+	+	+	+	+	+	+
0	0	0	-	0	0	-	-	-	-	-
+	+	0	-	0	-	-	-	-	-	-
+	0	+	0	0	+	-	0	0	0	-
8	4	8	4	2	8	5	3	7	3	3
4	4	5	3	7	2	3	4	2	1	3
1	5	0	6	4	3	5	6	4	9	7
7	**-1**	**8**	**-2**	**-2**	**5**	**0**	**-3**	**3**	**-6**	**-4**
3	**15**	**2**	**16**	**16**	**6**	**13**	**18**	**9**	**21**	**19**
Yes	**No**	**Yes**	**No**	**No**	**Yes**	**No**	**No**	**Yes**	**No**	**No**

PUGH MATRIX TAKE 2

	Pugh Matrix Take 2										
Selection Criterias	**Innovative Granny**	**The Zeppeliner (reference)**	**DisPress**	**The Foam Shoe**	**Foot-o-Meter-ish**	**Disposable Granny**	**Foot-o-Synthesis**	**The Last Output to Space**	**The Kayak Theorem**	**Foot Shower Cap**	**Color-Bind**
Enable fine measurements	0	0	0	-	-	0	-	0	0	-	-
Minimize the effect of measurement errors	+	0	0	-	-	+	-	0	+	-	-
Minimize the noise in the signal	0	0	-	-	+	0	+	0	0	+	+
Limited time for examination using the prototype	-	0	0	0	0	-	0	-	-	-	-
Enable cleaning between usage	0	0	+	-	+	+	-	0	+	+	0
User interface comprehensible	0	0	-	+	+	0	-	0	0	+	-
Provide decent portability	-	0	-	0	+	-	+	-	-	-	+
Be safe for patient and user	0	0	0	0	+	0	+	0	0	0	0
Present the measurement results	+	0	+	+	-	+	+	+	+	0	-
Limited time for set-up of the prototype	0	0	0	0	+	0	+	0	0	0	0
Consists of non-toxic material	0	0	0	-	0	0	-	0	0	0	-
Consists of environmentally friendly material	0	0	-	-	+	-	-	+	0	+	-
Recyclable	+	0	0	0	0	+	+	+	+	+	-
Enable continuous measurements	0	0	0	0	-	0	-	0	0	-	0
Sum +	3	0	2	2	7	4	6	3	4	5	2
Sum 0	8	13	7	5	3	6	1	8	7	4	3
Sum –	2	0	4	6	3	3	6	2	2	4	8
Net Score	**1**	**0**	**-2**	**-4**	**4**	**1**	**0**	**1**	**2**	**1**	**-6**
Rank	**3**	**7**	**9**	**10**	**1**	**3**	**7**	**3**	**2**	**3**	**11**
Continue?	**Yes**	**No**	**No**	**No**	**Yes**	**Yes**	**No**	**Yes**	**Yes**	**Yes**	**No**

KESSELRING MATRIX

		Kesselring Matrix											
		Foot-o-Meter-ish (reference)		Innovative Granny		Disposable Granny		The Last Output to Space		Foot Shower Cap		The Kayak Theorem	
Selection Criteria	**Weight**	*Rating*	*Weighted Score*	*Rating*	*Weighted Score*	*Rating*	*Weighted Score*	*Rating*	*Weighted Score*	*Rating*	*Weighted Score*	*Rating*	*Weighted Score*
Enable fine measurements	15%	3	0,45	5	0,75	5	0,75	5	0,75	3	0,45	5	0,75
Minimize the effect of measurement errors	10%	3	0,3	4	0,4	4	0,4	3	0,3	2	0,2	4	0,4
Minimize the noise in the signal	10%	3	0,3	3	0,3	3	0,3	3	0,3	3	0,3	3	0,3
Limited time for examination using the prototype	2%	3	0,06	2	0,04	2	0,04	2	0,04	3	0,06	2	0,04
Enable cleaning between usage	10%	3	0,3	2	0,2	4	0,4	4	0,4	5	0,5	5	0,5
User interface comprehensible	9%	3	0,27	5	0,45	5	0,45	5	0,45	5	0,45	5	0,45
Provide decent portability	1%	3	0,03	2	0,02	2	0,02	2	0,02	3	0,03	2	0,02
Be safe for patient and user	7%	3	0,21	2	0,14	2	0,14	2	0,14	3	0,21	3	0,21
Present the measurement results	7%	3	0,21	5	0,35	5	0,35	5	0,35	4	0,28	5	0,35
Limited time for set-up of the prototype	2%	3	0,06	3	0,06	3	0,06	3	0,06	2	0,04	3	0,06
Consists of non-toxic material	7%	3	0,21	3	0,21	3	0,21	3	0,21	3	0,21	3	0,21
Consists of environmentally friendly material	5%	3	0,15	3	0,15	2	0,1	3	0,15	2	0,1	3	0,15
Recyclable	5%	3	0,15	3	0,15	3	0,15	3	0,15	3	0,15	3	0,15
Enable continuous measurements	10%	3	0,3	5	0,5	5	0,5	5	0,5	1	0,1	5	0,5
Sum	**100%**												
	Total Score	3		3,72		3,87		3,82		3,08		4,09	
	Rank	6		4		2		3		5		1	
	Continue?	No		No		No		No		No		Develop	

Relative Performance	Rating
Much worse than reference	**1**
Worse than reference	**2**
Same as reference	**3**
Better than reference	**4**
Much better than reference	**5**

APPENDIX E – PROTOTYPE USAGE DESCRIPTION

The following description has been written as the prototype, sensor and communication setup is meant to be used in the examination room. This setup was unfortunately not evaluated within this Master Thesis. Therefore the description might not be utterly accurate for future users.

The user description is divided into three different sections; preparation of the prototype before measurements, human machine interface (HMI) and dismantle of the prototype after measurements. The preparation and dismantle is described as bulleted lists while the HMI is presented as a flowchart, wherefore the HMI is placed last.

PREPARING THE PROTOTYPE FOR MEASUREMENTS

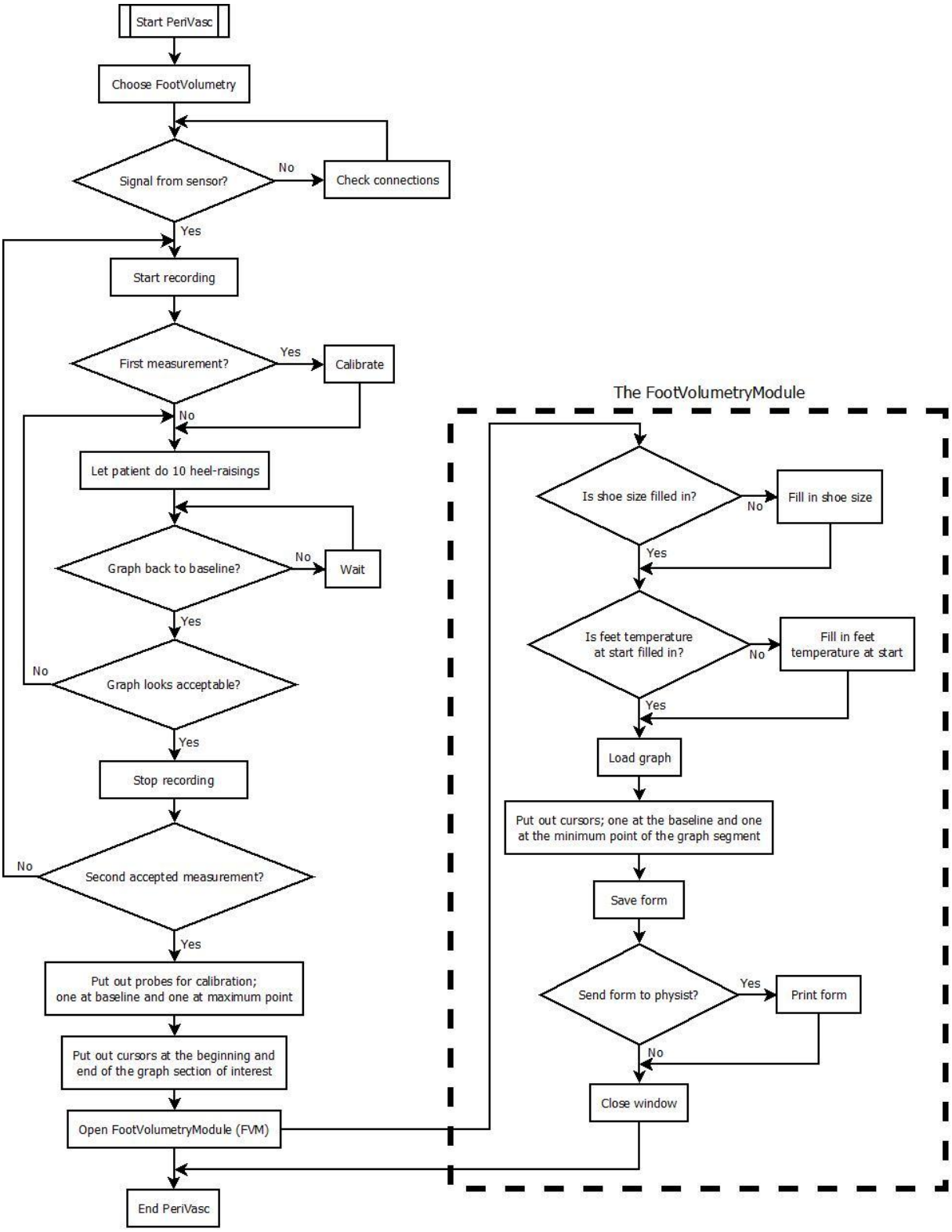
- Assemble the pipe and the shim construction.
- Assemble the lower lid of the pipe with the round aluminium plate inside facing upwards at the bottom of the pipe.
- Attach the shim construction to the canteen.
- Fill half of the canteen with water.
- Put the float into the pipe.
- Unpack the sensor (which already should be attached to the upper lid through the bent aluminium plate) and its cables from the padded box.
- Assemble the upper lid and pipe.
- Connect the cable to the sensor.
- Connect the output part of the cable to the computer via the A/D-converter.
- Connect the power supply part of the cable to the power supply.
- When the patient's foot is placed in the canteen, continue to fill water until the water level is approximately 0.5 [cm] above the line that marks the start of the straight part of the canteen.
- Adjust the pipe height so that the sensor light called "State" turns from red or green to orange – the float is now in midrange of the sensor's measurement range. Keep in mind to not tighten the star knob too hard.

The prototype is now ready to use.

DISMANTLING THE PROTOTYPE AFTER MEASUREMENTS

- Disconnect the power cable from the power supply.
- Disconnect the output cable from the A/D-converter.
- Disconnect the cable from the sensor.
- Disassemble the upper lid from the pipe.
- Place the sensor, still attached to the upper lid, and its cables in the padded box.
- Remove the shim construction from the canteen.
- Remove the lower lid from the pipe and take out the round aluminium plate.
- Remove the float from the pipe.
- Empty the canteen of water.
- Disassemble the pipe and the shim construction.
- Place the canteen and the pipe in the dishwasher.
- Wipe off the remaining parts with disinfectant agent.

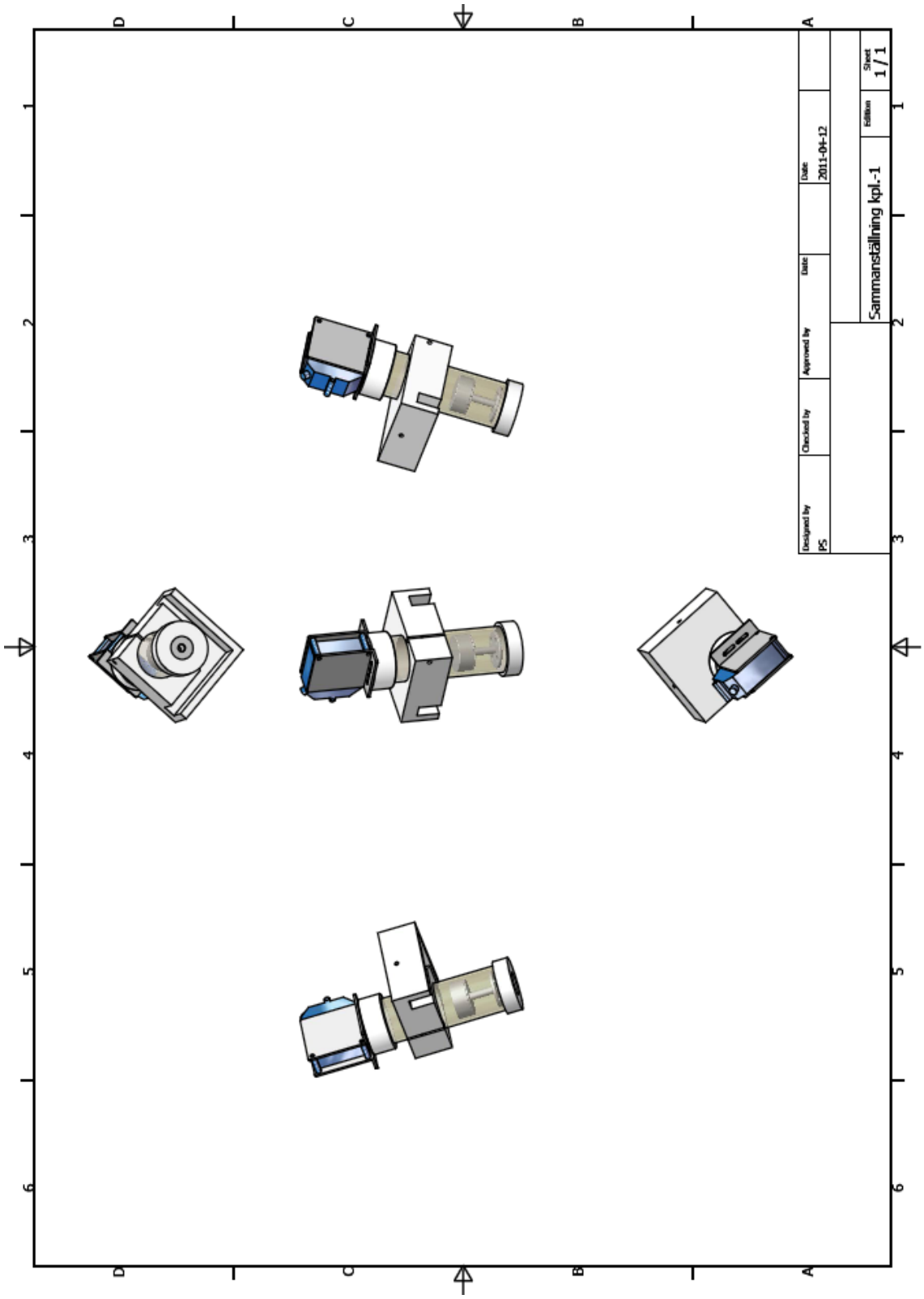
HUMAN MACHINE INTERFACE



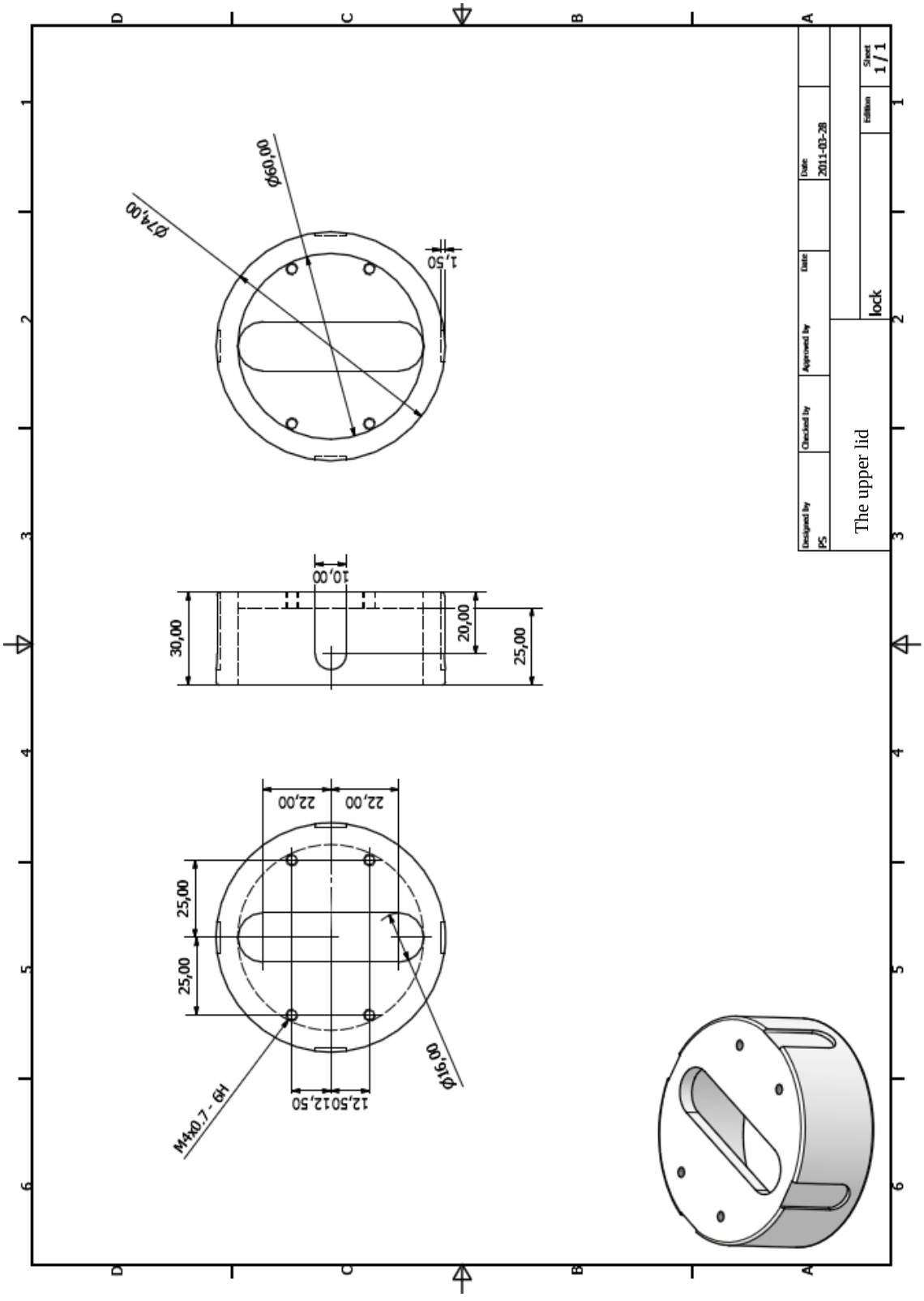
Flowchart of the Human Machine Interaction of the prototype

APPENDIX F – SKETCHES OF THE CANTEEN UNIT

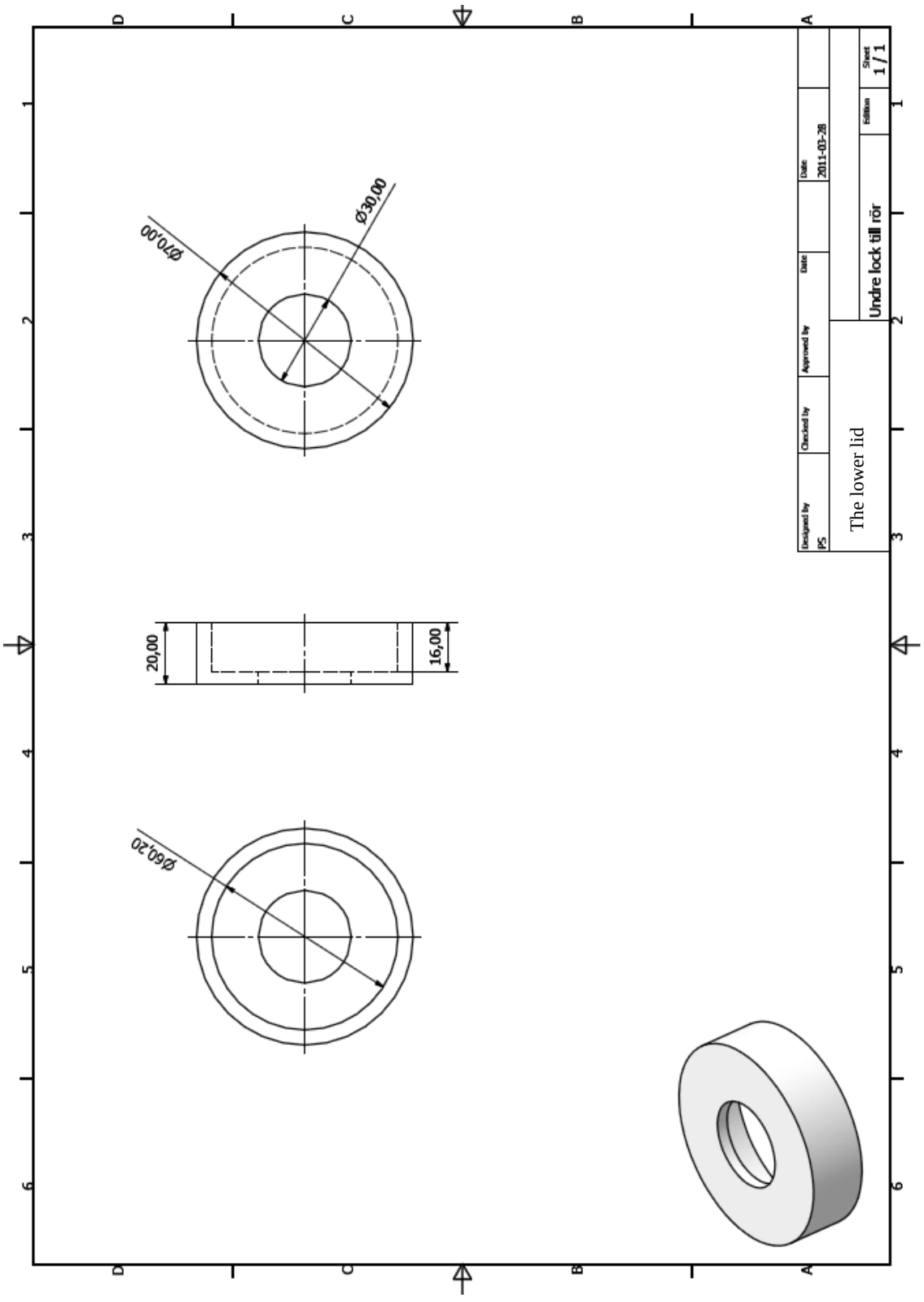
Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset



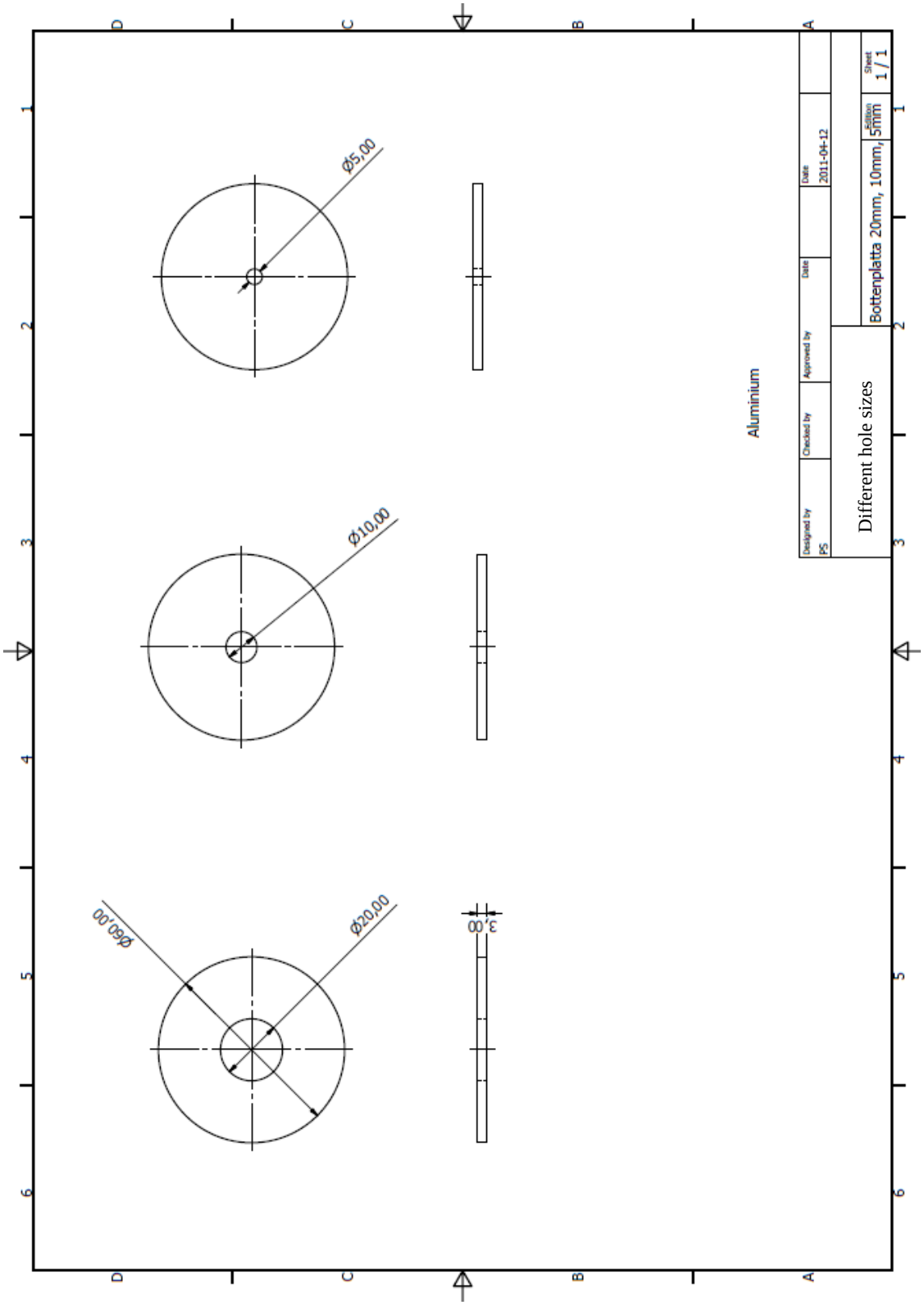
Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset



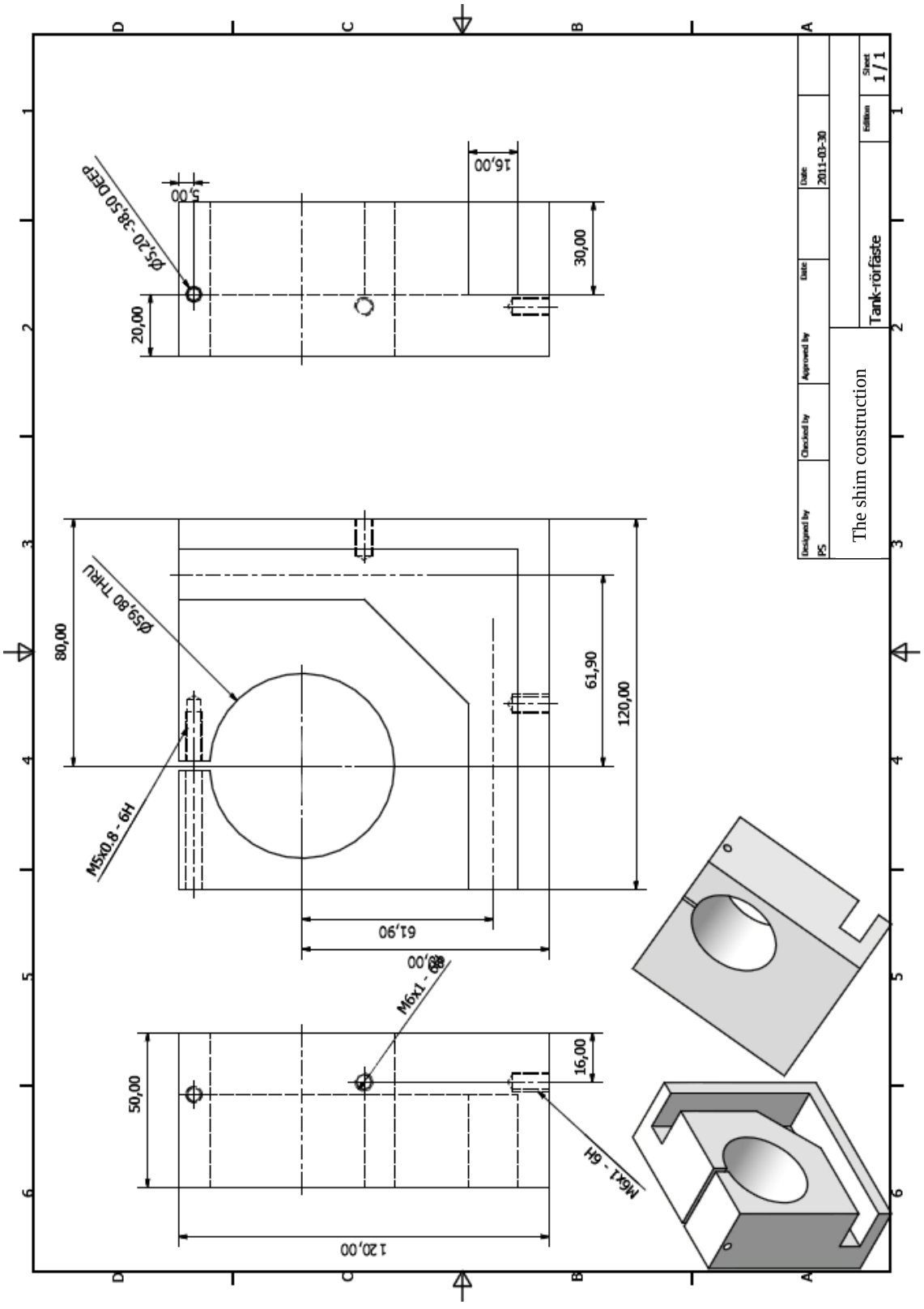
Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset



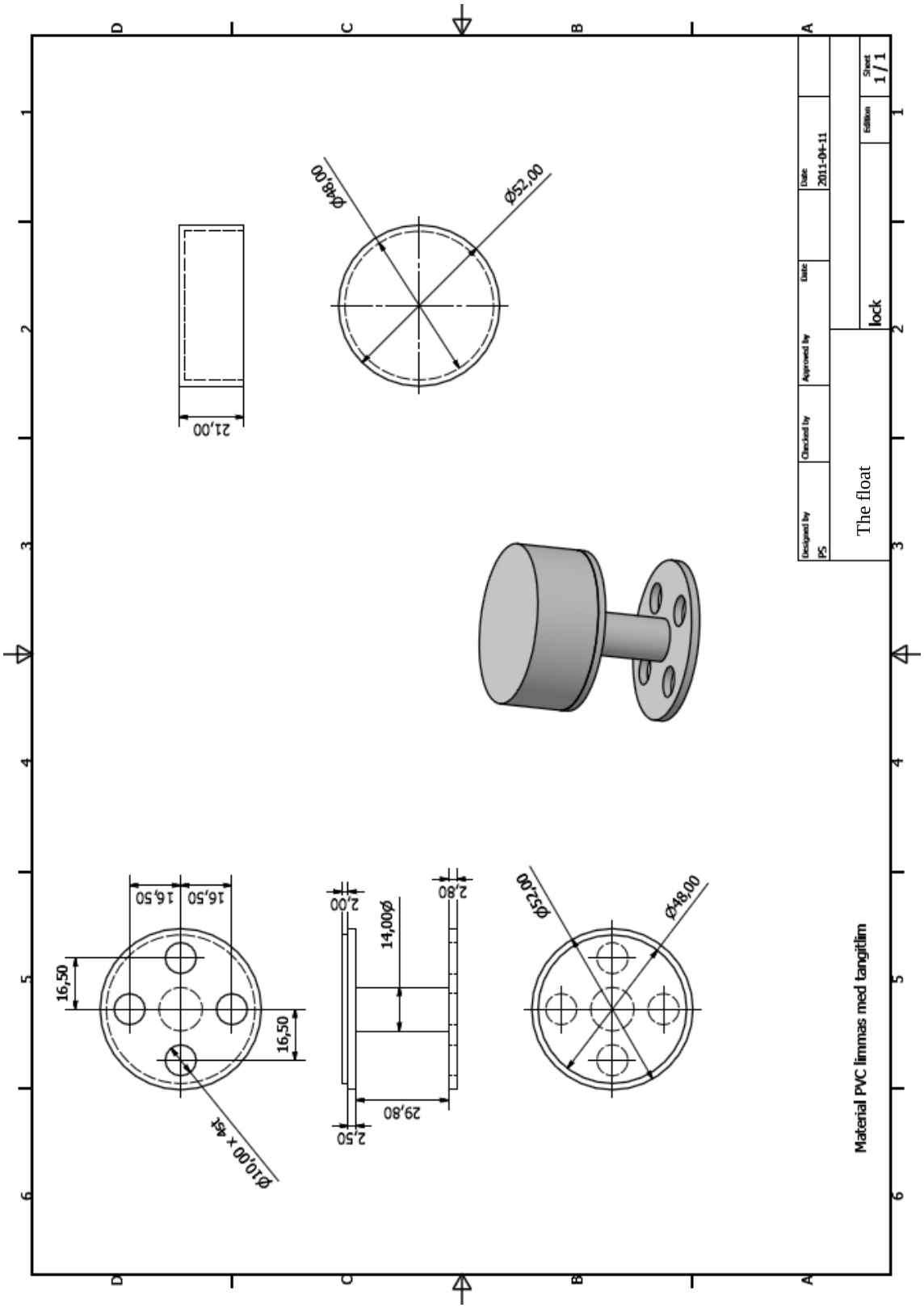
Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset



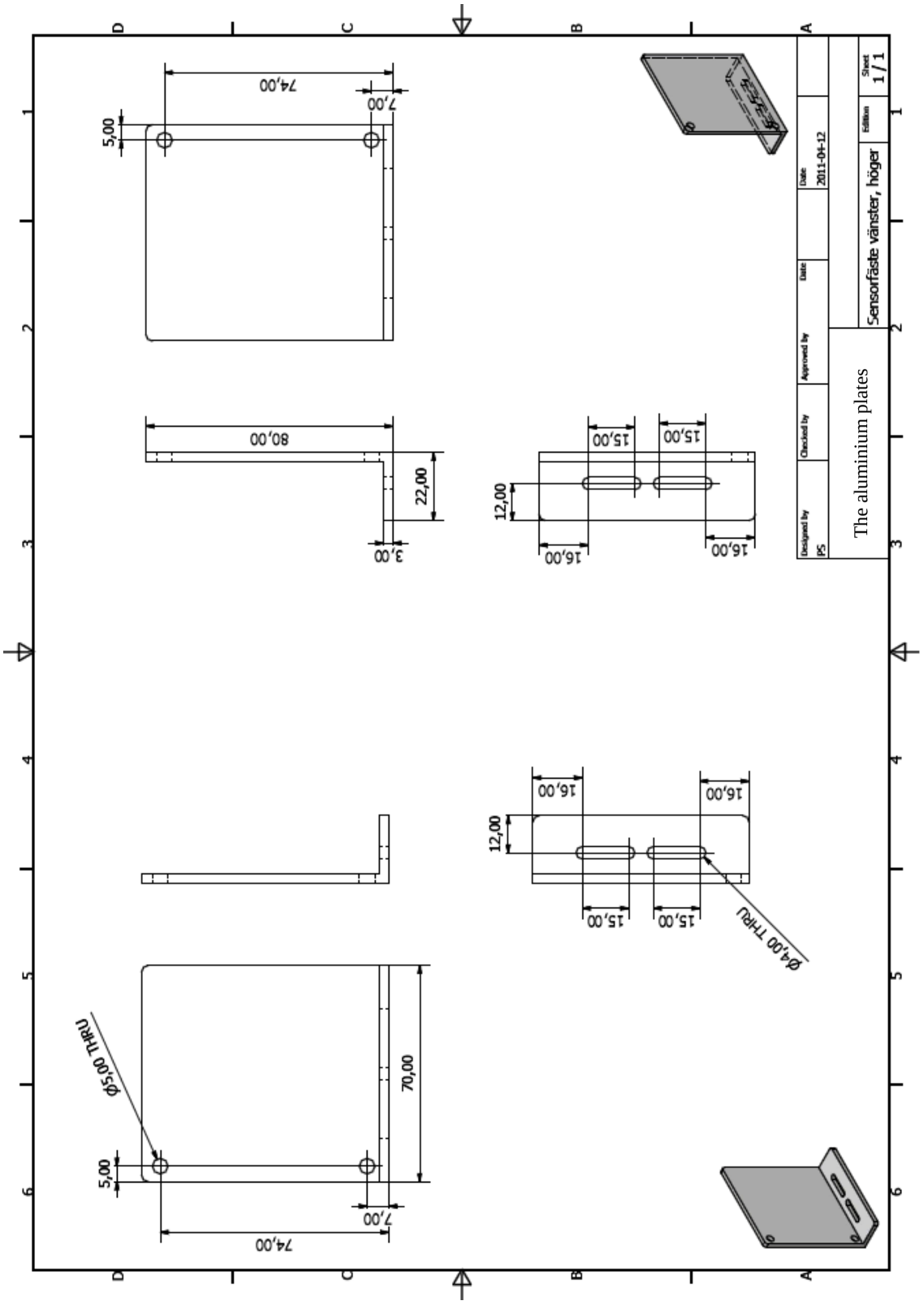
Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset



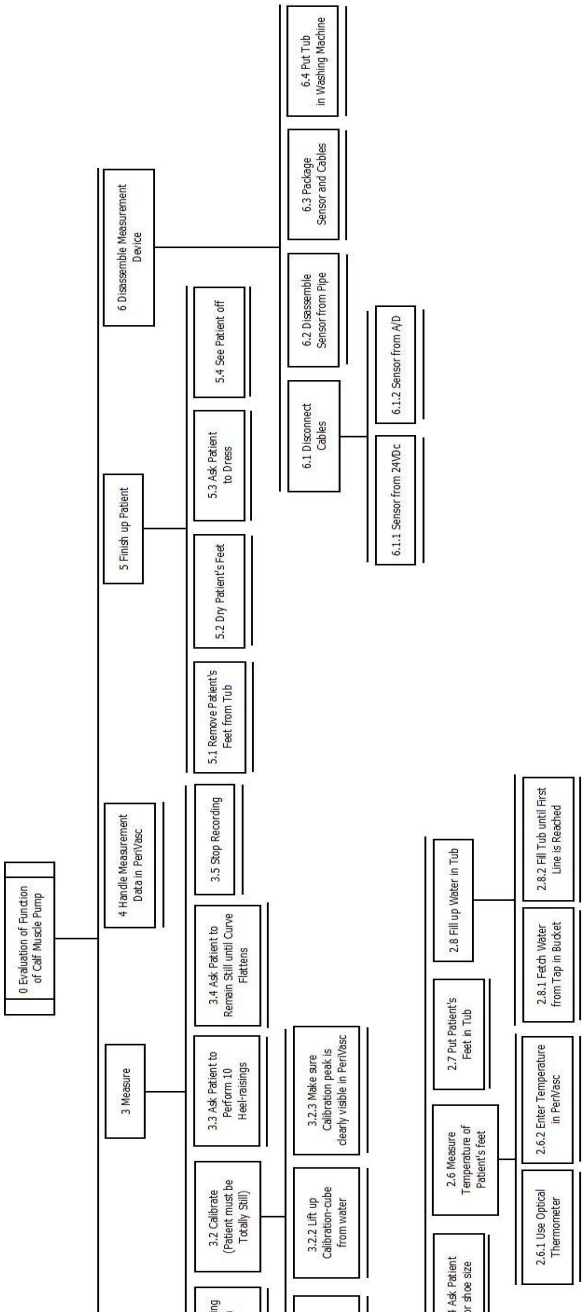
Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset



Courtesy of Per-Anders Svensson, Medical Engineer at Östra Sjukhuset

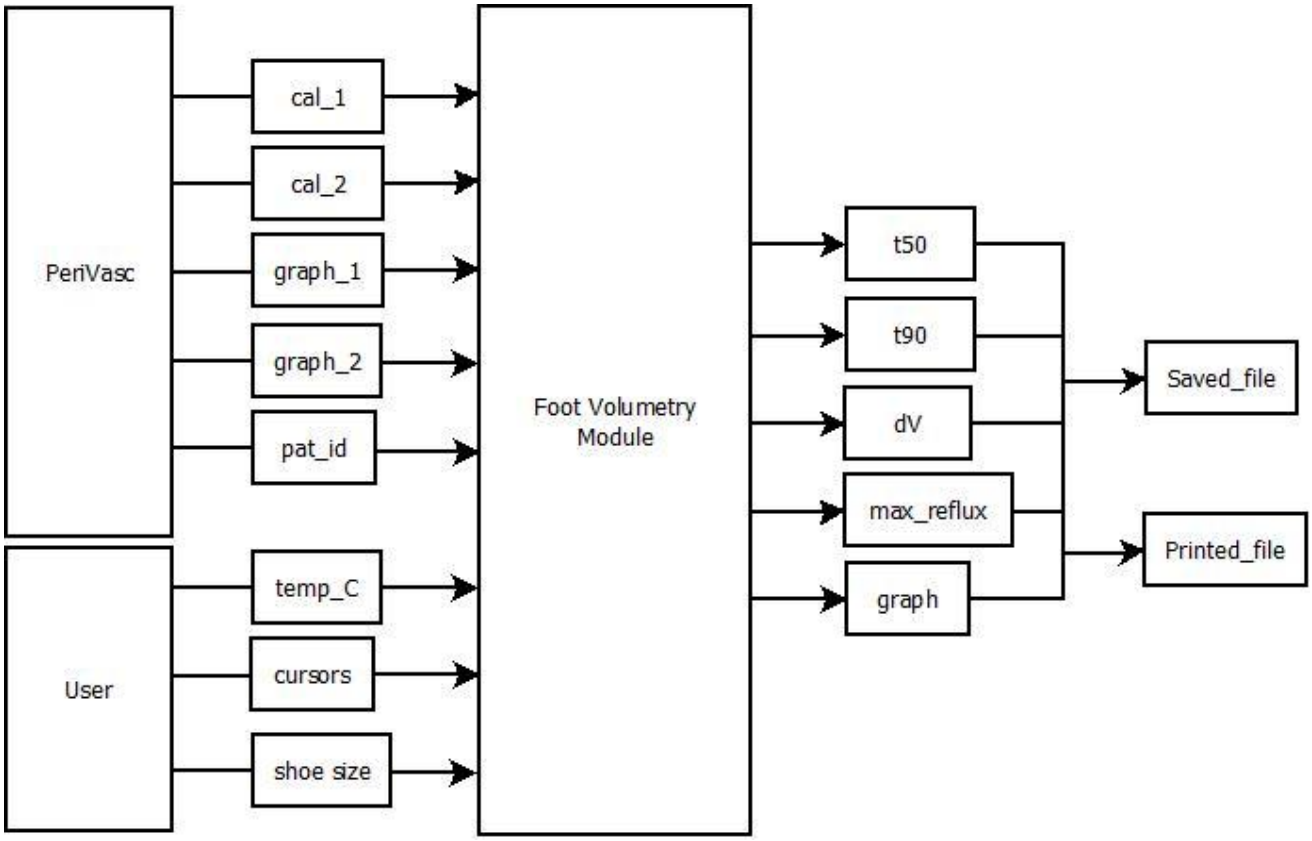


APPENDIX G – HIERARCHICAL TASK ANALYSIS

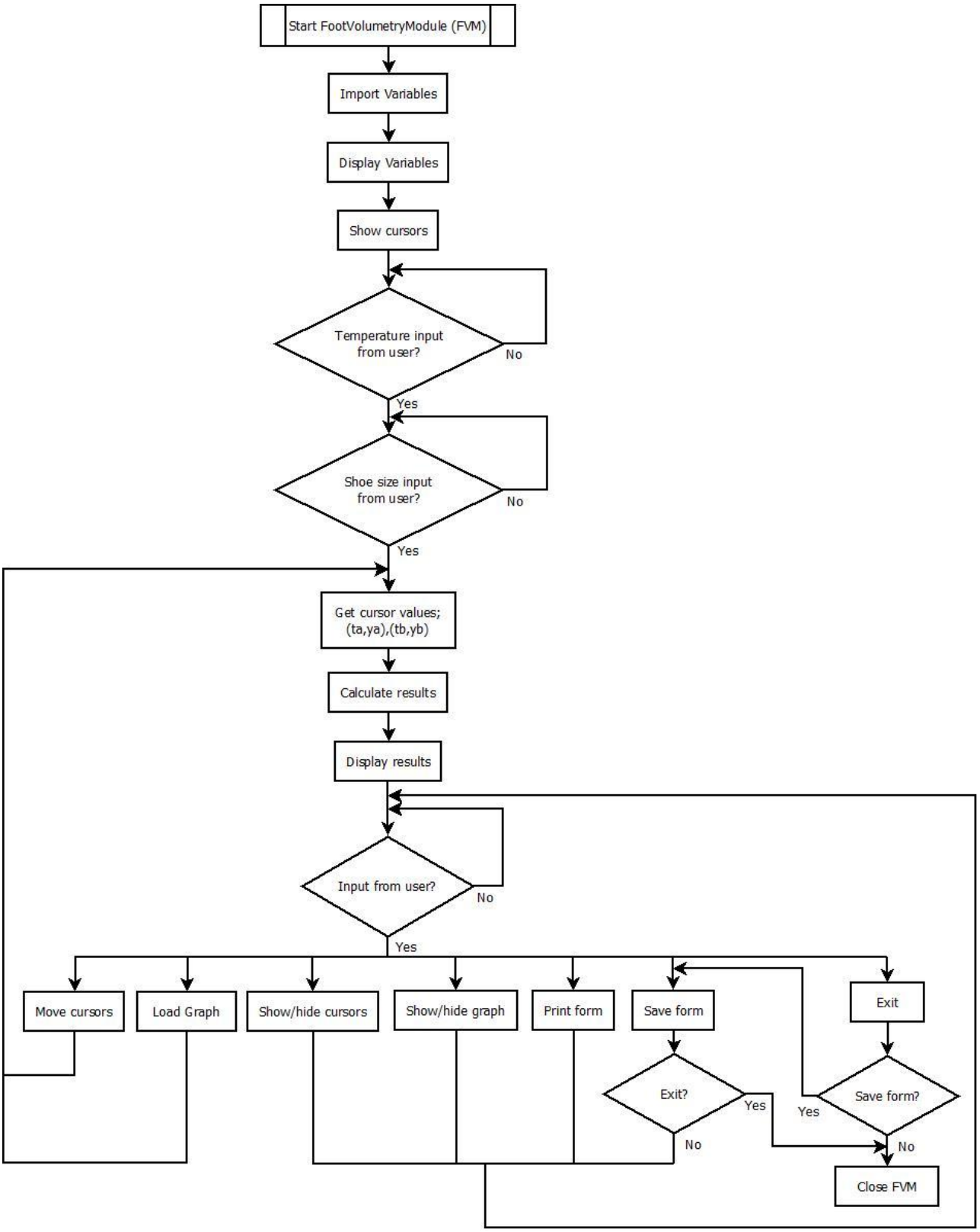


The hierarchical task analysis has been used as a basis for the graphical user interface. It differs somewhat from the prototype user description since this estimation of how the prototype is meant to be used was made in an early stage of the Master Thesis.

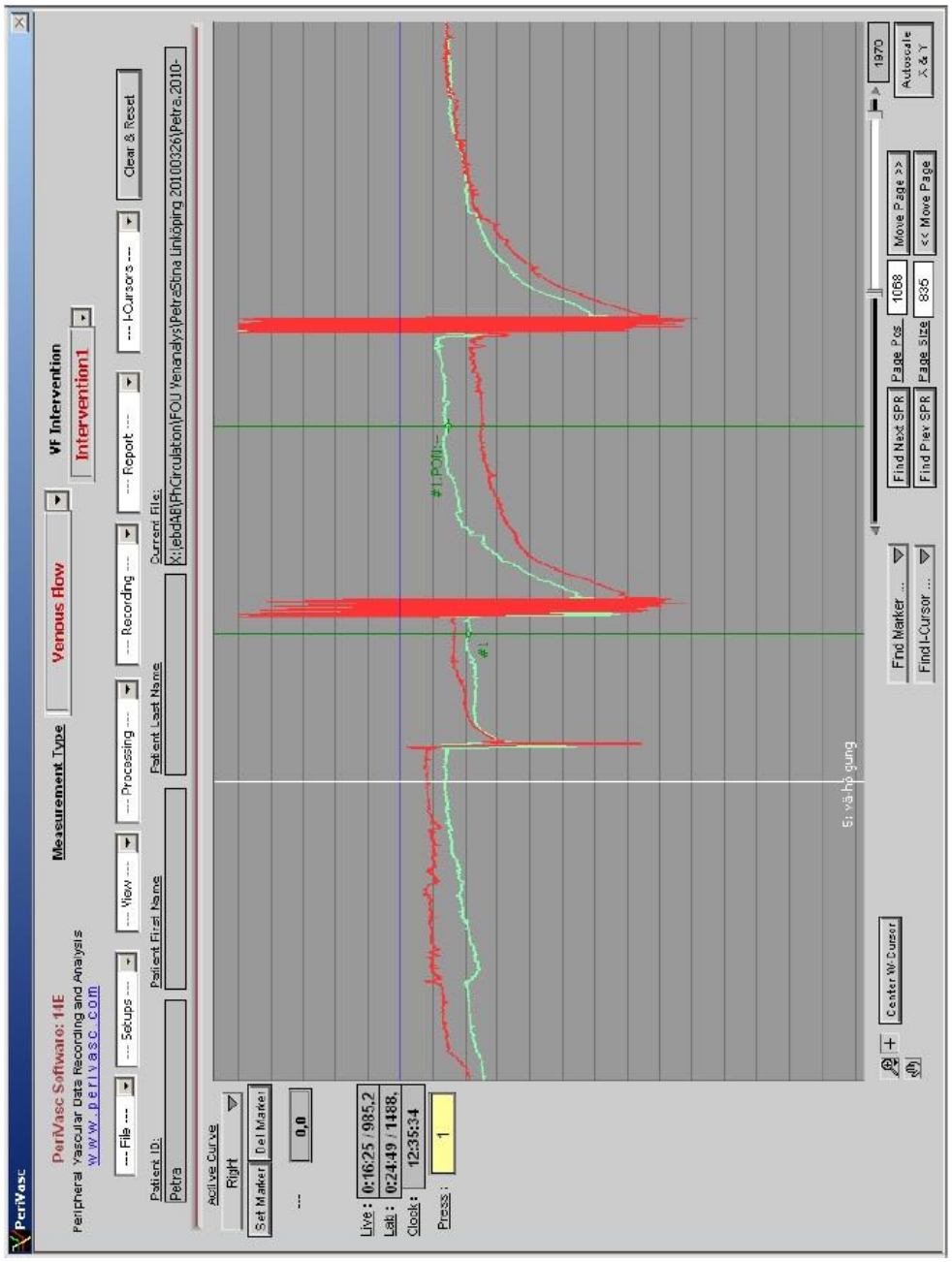
APPENDIX H – ARCHITECTURE OF THE FOOT VOLUMETRY MODULE IN PERIVASC©



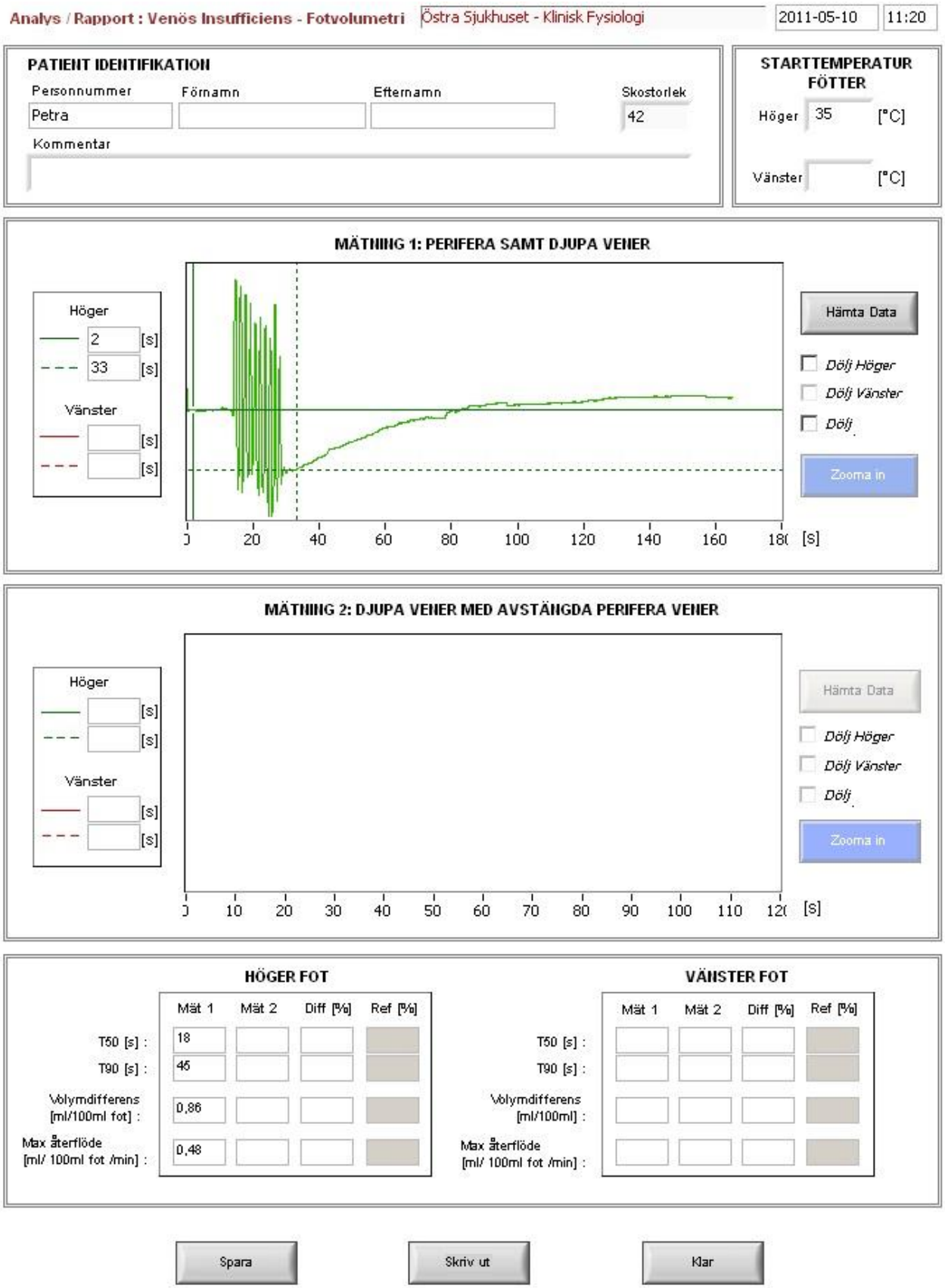
Block diagram of the interaction between PeriVasc© and the Foot Volumetry Module



Flow chart displaying the programming architecture of the Foot Volumetry Module

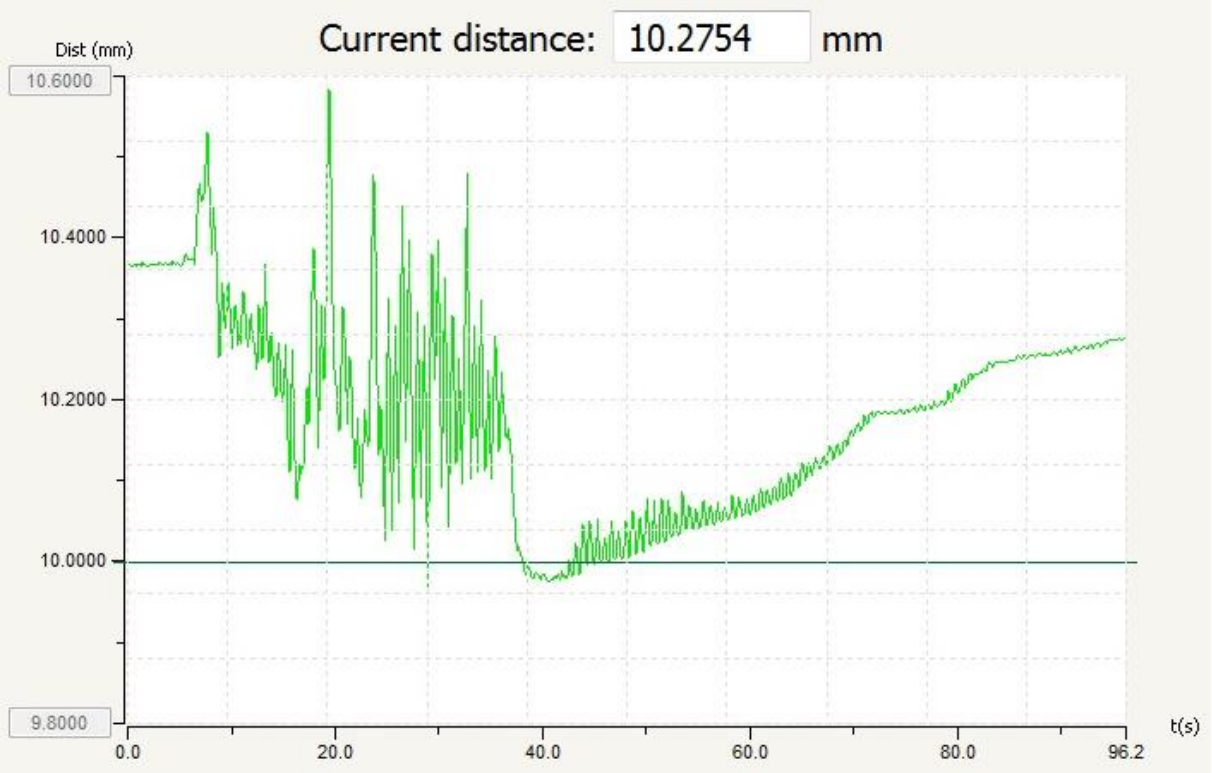


One of many graphical user interfaces of the PeriVasc© software, courtesy of Ekman Biomedical Data AB



The graphical user interface of the Foot Volumetry Module

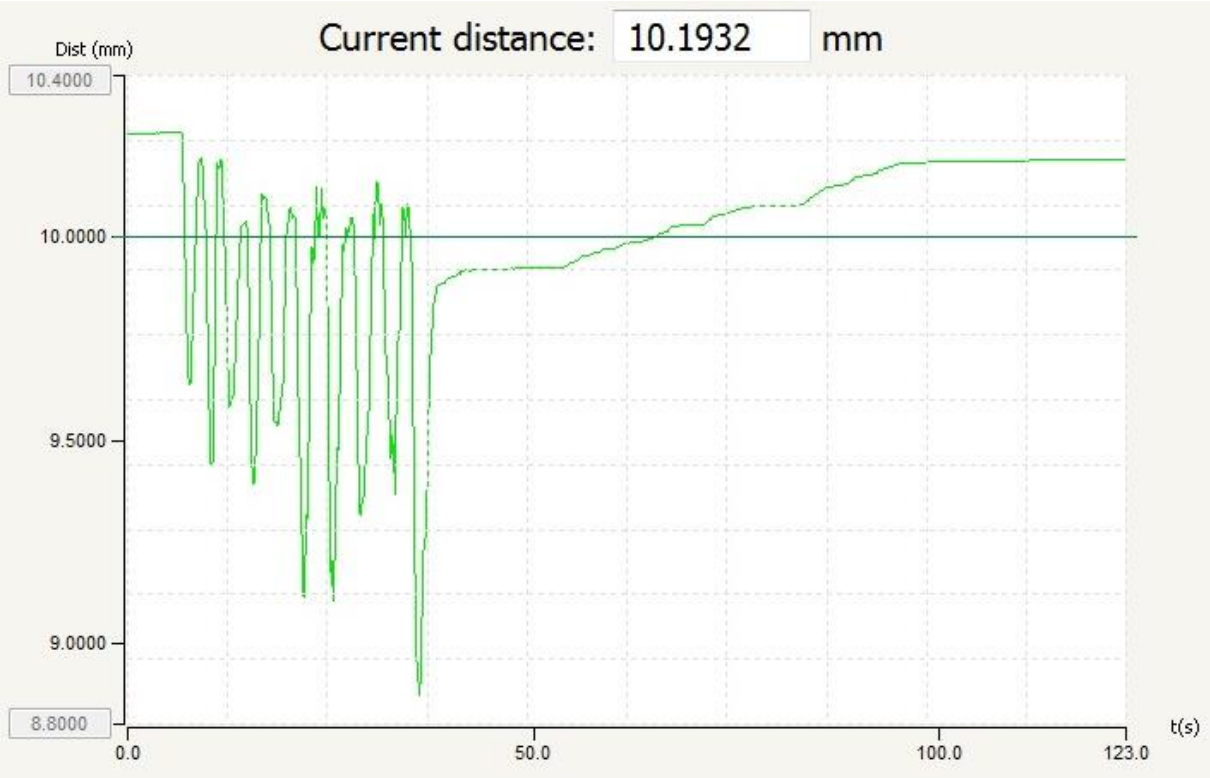
APPENDIX J – MEASUREMENT OF PHYSICAL ACTIVITY IN TEST 4



Healthy person performing ten knee-bendings

Healthy person performing ten heel-raisings with both feet

Healthy person performing ten heel-raisings with one foot while seated



Healthy person performing ten flexions of the calf muscles