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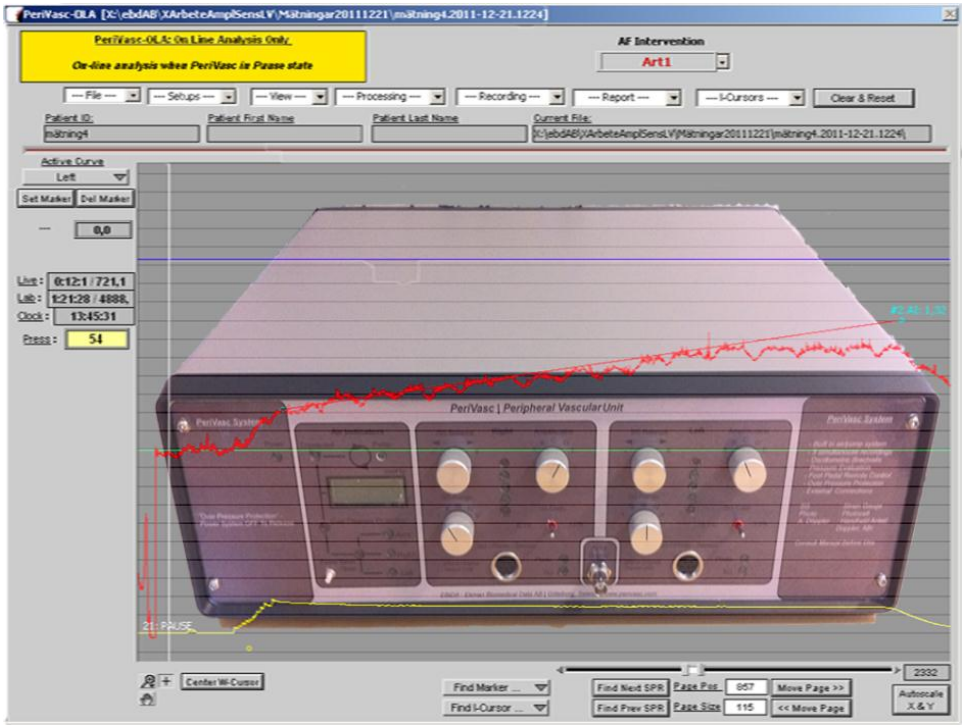

Development and Construction of a Plethysmographic Measurement Device, Including Sensor and Software for Testing

Master of Science Thesis

MARIA BERLIN

ZAKARIA MAGHDER

Department of Signals and Systems

Division of Biomedical Engineering

CHALMERS UNIVERSITY OF TECHNOLOGY

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Technical report no. EX028/2012
Department of Signals and Systems
Chalmers University of Technology
SE-412 96 Göteborg
Sweden
Telephone +46 (0)31-7721000

Cover:
Final version of the Plethysmographic Measurement Device with PeriVasc© software.

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We are very fortunate and thankful for having this opportunity to conduct a project of this extent. We have acquired a huge amount of knowledge within the field of biomedical engineering and electronics construction throughout this master thesis.

We are very thankful for having the opportunity to do our Master Thesis at Ekman Biomedical Data AB (EBIDA), and having Mikael Ekman as our supervisor and mentor throughout this thesis work. He has given us valuable input, support and guidance throughout this thesis project.

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Last but not least we would like to thank our friends and families for the support and input that they have provided us with.

Abstract

Peripheral blood pressure is an important vital sign to measure for patients with diabetes or cardiac diseases. The measurements can be performed by using non-invasive plethysmographic measurements devices in combination with pressure applied with the help of cuffs.

The purpose of this project was to develop a measurement device that can handle two types of plethysmographic measurements; strain gage and Photo-plethysmography. The following parts should be constructed and taken into consideration in order to achieve this;

- An IR-based photo-cell sensor should be constructed.
- Development of amplifiers for the IR-based photo-cell sensor.
- Construction of circuits for obtaining signals during measurements using strain gage.
- Development of an amplifier for strain-gage.
- Base line level shifting through hardware.
- Front panel LED indicators with hysteresis for user friendliness.
- A simple LabVIEW GUI (graphical user interface), to be used for testing and verifying of the amplifiers.
- Low current consumption
- Photoplethysmography (PPG) and strain gage sensitivity
- Sensor and circuit for pressure measurements.

The project was carried out on the count for Ekman Biomedical Data AB (EBIDA) in Gothenburg Sweden during a period of 6 months and consisted of construction, evaluation and verification of a prototype for future manufacturing. The extent of this project was only within the field of biomedical instrumentation hence no medical or physiological aspects where taken into consideration or explored to a greater extent.

A photo-cell sensor prototype was created and worked as good as a commercially available one, but had a lower current consumption. The prototype was constructed using new technology that is better suited for this application. A theoretical analysis of the positioning of the IR-LED and phototransistor was conducted and the result gives a good base for further research and analysis of different components and placement. Also the strain gage measurement unit works properly and the modified Wheatstone quarter bridge has a good sensitivity. This gives a good resolution when performing blood flow measurements. The calculated values for cut-off frequencies for the filters, and gain, of the amplifiers, showed great results for the signals obtained from the strain gage sensor and the photo-cell sensor.

Measurements where done in a near clinical manor with the supervision of a professional in order to verify that the system worked properly and that the signals obtained were correct. A side from this, a comparison study between the photo-cell sensor prototype and a commercially available photo-cell sensor was carried out. This to verify that the prototype works as expected. An electrical calibration was also created to simulate 0.1% and 1% strain. In addition a variable balancing unit was developed to enable usage of a wide range of different strain gage sensors.

These results confirm that the solutions carried out works properly and that the next step would be production of a PCB layout for production of a final circuit board for a new device intended for use in research and clinical applications.

Abbreviations

PHI – PeriVasc Hardware Interface

DAQ – Data Acquisition card

PPG - Photoplethysmography

SG – Strain Gage

OpAmp – Operational Amplifiers

TTL - Transistor-transistor logic

CMOS - Complementary metal–oxide–semiconductor

USB – Universal Serial Bus

PAD – Peripheral Arterial Disease

TBI – Toe Brachial Index

ABI – Ankle Brachial Index

bpm – Beats per minute

Nomenclature

PeriVasc© - Peripheral Vascular Data Recording and Analysis, Software from Ekman Biomedical Data AB

Brachial - Forearm

Invasive – Measurements performed by penetrating the skin

Non-invasive – Measurement without penetrating the skin

Gangrene – Condition that arises when a large mass of human tissue dies (necrosis)

TABLE OF CONTENT

1 INTRODUCTION

Arteries and veins are the two systems that the blood circulation of the human body comprises of. The systems could be affected by different types of diseases that are divided into different subcategories. This project focuses on PAD (Peripheral Arterial Diseases). Peripheral vascular diseases affect the veins and arteries of the extremities of people with either diabetes or vascular diseases. Measurements of the peripheral arterial blood flow of a patient could be used to determine the capacity of the arteries. This when using a cuff for applying enough pressure for venous occlusion to occur.

A plethysmographic technique is used in biomedical applications to quantify peripheral circulation, this in term of blood pressure in fingers, ankles and toes. This method can also be used in terms of arterial and venous blood flow in forearms or calf's. In general, the peripheral blood pressure measurement is used in clinical applications and blood flow estimations are used in research applications. Two typical sensors used are photo-cell (blood pressure) and strain gage (blood flow).

1.1 PURPOSE

The purpose of this master thesis is to construct a plethysmographic device enabling Photoplethysmography (PPG) and strain gage measurements. The device should have better sensitivity than commercially available devices and be easier to use. The purpose is also to construct a prototype photo-cell sensor circuit, by considering the choice of components, placement and the optics of the human skin, to create a sensor that results in better readings and less current consumption compared with the commercially available sensors used today.

1.2 OBJECTIVES

The objectives of this project are to develop amplifier and filter configurations for two types of measurement systems of the peripheral blood pressure, namely strain gage and photoplethysmography and also develop a prototype of a photo-cell sensor circuit for the photoplethysmograph configuration of the construction. Software used for testing and verification during the development of the prototype should also be developed.

The main objective of the project is to develop a prototype of a measurement unit that can handle the two types of measurements mentioned above and make sure that it fulfils the verification requirements and performs equivalent or even surpass commercially available units.

1.3 DELIMITATIONS

This report will discuss and present constructions, solutions and configurations of measurement apparatus aimed for use within the field of peripheral arterial disease identification. This project is not conducted specifically within the field of medicine; hence the medical aspects will only be described and discussed briefly in order to justify some of the requirements put on the measurement apparatus.

The strain gage sensors has been limited to those used in medical applications which range from those used on toes up to those used around the chest.

In this project the system will be tested and verified, but the final testing and validation is not part of this project.

2 MEDICAL BACKGROUND

Here an introduction to the cardiovascular system will be given as well as an overview of Peripheral arterial diseases. Symptoms, diagnoses and treatments, will be presented as well as methods for measuring the blood pressure. The methods of diagnosis for peripheral arterial diseases may also be used when conducting diagnosis of peripheral venous diseases. Only peripheral arterial diseases will be described in this chapter.

2.1 CARDIOVASCULAR SYSTEM

Oxygen and nutrients are transported to body organs by the cardiovascular system, and waste products from metabolism are transported away from tissue and cells. The centre of the cardiovascular system is the heart (Zaret, Moser, & Cohen, 1992). Also hormones are transported to cells, nutrients from the gastrointestinal tract and hormones from endocrine glands (Tortora & Derrickson, 2010).

The human heart consists of four chambers. By contractions and relaxation blood is pumped through the body. This rhythmic pattern is called the cardiac cycle. The different phases are called diastole and systole. Diastole is when the hearts ventricles are relaxed and systole when they are contracted, it is during systole that blood is pumped out from the heart. The phase diastole takes 2/3 of the cardiac cycle and the systole phase is 1/3 (Zaret, Moser, & Cohen, 1992) (Tortora & Derrickson, 2010).

As the blood is circulating in the body it exerts a pressure on the walls of the vessels, this is called the blood pressure (Zaret, Moser, & Cohen, 1992). The blood pressure is most often given as two values; Systolic and diastole pressure, where the systole pressure is from the contraction of the heart muscle and diastole from its relaxation. Blood pressure is measured in millimetre mercury (mm Hg) and is the force per unit area on a blood vessel by the blood in it (Zaret, Moser, & Cohen, 1992). In a young adult at rest the blood pressure is around 110 mm Hg during systole and around 70 mm Hg during diastole (Tortora & Derrickson, 2010). To some extend the blood pressure depends on the volume of blood in the body; a normal volume for an adult is approximately 5 litres. If a mall loss of blood occurs the pressure can be compensated by homeostatic mechanisms, but if the loss is greater than 10% the pressure starts to drop (Tortora & Derrickson, 2010). The driving force of the blood is the differences in blood pressure, also called the pressure gradient (Zaret, Moser, & Cohen, 1992).

Blood is the only tissue that is considered a fluid. At first sight it appears homogenous, but both fluid and cellular components can be seen when put under microscope. The components of blood are; plasma (55%), red blood cells (45%), white blood cells and platelets (<1%) (Marieb & Hoehn, 2010). The blood makes up approximately 8% of the human body weight (Marieb & Hoehn, 2010). The bloods most important functions are; transportation, regulation and protection (Tortora & Derrickson, 2010).

Blood helps regulating the pH of body fluids. The water that makes up a large part of the blood plasma helps regulate the body temperature by its heat-absorbing and coolant properties, but also by its variable rate of flow through the skin. The water content of cells is also regulated by the blood, but here it is the osmotic pressure that is of interest (Tortora & Derrickson, 2010).

By clotting the blood protects against excessive loss of blood from the cardiovascular system in case of an injury. The white blood cells protect against diseases by producing antibodies (Tortora & Derrickson, 2010).

2.2 PERIPHERAL ARTERIAL DISEASE

In the 18th century it was recognized that pain and dysfunction of extremities could be caused by insufficient blood supply to the lower extremities (Dieter, Dieter, & Dieter, 2009). Peripheral arterial disease (PAD) affects the veins in the arms as well as in the legs. The vessels are narrowed and the blood flow to the outer extremities limited (Zaret, Moser, & Cohen, 1992). The main risk factors for developing PAD are smoking and diabetes (Creager, 2000). An elevated total cholesterol has also shown to increase the risk for PAD, but not to the same extend as smoking and diabetes (Creager, 2000).

Here a description of symptoms, diagnosis and treatments for peripheral arterial disease will be described.

2.2.1 Symptoms

The most classic symptom is leg pains, when walking (Zaret, Moser, & Cohen, 1992). These pains are called intermittent claudication and are caused by ischemia in the working muscles of the leg. Most often these pains stop when resting. If the veins are badly narrowed, pain might also occur when resting. The legs might look normal even if the veins are badly narrowed, but the toes might look pale, discoloured or bluish. The feet might feel cold when touched and the pulse weak or absent (Zaret, Moser, & Cohen, 1992).

In severe cases the tissue might begin to die as a result of lack of blood. This leads to ulcers in the lower extremities and in really severe cases gangrene that might result in the necessity of amputation of toes or feet, although these severe complications are uncommon (Zaret, Moser, & Cohen, 1992).

2.2.2 Diagnose

To evaluate the amount of blood that reaches the feet, a measurement of blood pressure in the ankles, or lower parts of the leg, might be used. These measurements are performed using a cuff. To conduct measurements both before and after exercise, gives additional information about the patient (Zaret, Moser, & Cohen, 1992).

To examine the blood flow in the arteries a Doppler ultrasonography might be used and to identify obstructions a magnetic resonance imaging (MRI) or angiography might be useful. These methods are expensive and some of them are invasive (Zaret, Moser, & Cohen, 1992).

2.2.3 Ankle-Brachial Index and Toe-Brachial Index

It was suggested in the 1950 that blood pressure measurements in the ankles could be used to diagnose PAD (Dieter, Dieter, & Dieter, 2009). Ankle-Brachial index (ABI) was developed. ABI is a simple blood pressure measurement where the ratio between the systolic blood pressure at the ankle and the brachial (forearm) artery. A low value of ABI is a sign of PAD in the lower extremities. A value less than 0.9 are considered low (Dieter, Dieter, & Dieter, 2009). If a patient with an ABI over 1.30 has leg pains, additional test of Toe-Brachial Index (TBI) as well as pulse-volume recordings should be performed (Dieter, Dieter, & Dieter, 2009). Such high value of ABI is caused by calcified vessels that cannot compress completely leading to a so called false ABI value and a measurement of TBI is therefore conducted. Measurement of TBI is a standard procedure that is also used on other indications than abnormally high ABI.

2.3 MEASUREMENT OF SYSTEM BLOOD PRESSURE

The measurement of blood pressure is a standard clinical measurement and is used to determine the function of the cardiovascular system (Webster) (Zaret, Moser, & Cohen, 1992).

There are several different methods for measuring blood pressure and they are divided into two subgroups; direct (invasive) and indirect (non-invasive) (Webster). The system blood pressure is an important parameter when calculating ABI and TBI. There are many ways to measure this; the most commonly non-invasive method used is the auscultator method, but an upcoming technique is the oscillometric method which can be conducted by using a cuff only, this enables automatized measurements.

2.3.1 Auscultation Technique

This is measured using the sphygmomanometer commonly recognized as a cuff. The cuff is placed just above the elbow and the cuff is inflated until a pressure that significantly exceeds the systolic blood pressure, which is approximately 120 mm Hg (Miller, 2010). Since this pressure is higher than the one inside the brachial artery, just below the surface, it collapses. After placing a stethoscope just under the cuff the pressure is slowly reduced. When the external pressure, from the cuff, is just below the systolic blood pressure the brachial artery will start to open. When the blood starts to flow the sound from the turbulence caused by the blood can be heard with the stethoscope, this sound is often referred to as the Korotkoff sound. When the pressure in the cuff falls below the diastolic pressure the sounds fades away. The pressure is measured with a manometer that is connected to the cuff. The pressure read when the Korotkoff sound appears is the systolic pressure and when the sound fades away is the diastolic pressure (Miller, 2010) (Webster).

2.3.2 Oscillometric method

A cuff is placed in the same manner as when using the auscultation technique and the pressure is raised and then slowly decreased in the same way, but instead of using a stethoscope to listen for the Korotkoff sound the oscillometric method measurers the amplitude of the oscillations that are present in the pressure signal from the cuff (Webster). These oscillations originate from the expansion of the arterial wall that happens every time that blood is forced through the artery. In the systolic pressure region, the amplitude of the oscillations on the cuff signal increases. The oscillations reach their maximum when the pressure in the cuff is equal to the pressure in the artery. After this point the strength of the cuff-pressure signal decreases proportionally to the rate that the cuff-pressure drops. With this method there is no obvious way to find the diastolic pressure since expansion of the arterial wall continues to happen below the diastolic pressure. The diastolic pressure is therefore estimated by the oscillometric monitors using an algorithm (Webster).

2.4 MEASUREMENT OF PERIPHERAL BLOOD PRESSURE

Measurements of the peripheral blood pressure are usually performed non-invasive with the help of plethysmographic devices in combination with a cuff to apply pressure to obtain venous occlusion. The most commonly used plethysmographic measurements applied for this purpose are Photoplethysmography (PPG).

2.4.1 Photo-cell Sensor

PPG is a measurement method used for measuring the blood volume with the help of a photo-cell sensor and is a non-invasive application that is very easy to implement and commonly used when performing these types of measurements. The PPG-method can be configured to measure the peripheral blood pressure in fingers and toes by using an inflatable cuff to control the arterial blood flow, and hence obtain information about the systolic blood pressure in the area of interest.

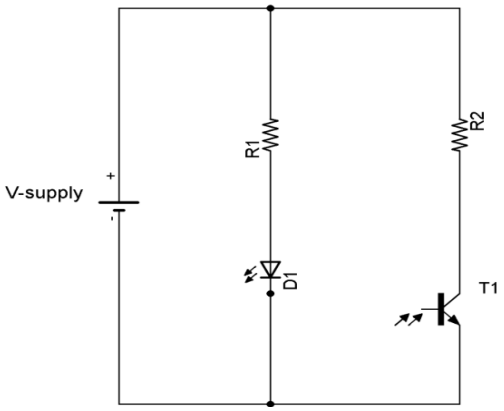

Figure 1: Schematic showing how the diode and transistors are connected in order to form a photo-cell sensor.

The photo-cell sensor consists of an infrared light emitting diode (IR-LED) as transmitter and either a photo-diode or a photo-transistor as receiver (Webster). The principle of this method is that IR-light reflected on the red blood cells and depending on the placement of the LED and receiver the reflection or absorption of the light can be measured.

The photo-cell sensor can be implemented in two main configurations; Transmission Mode whereas the finger or toe is placed between the IR-LED and the receiver, and Reflection Mode where the IR-LED and the receiver are placed adjacent on the surface of the toe or finger (Allen, 2007).

As mentioned above the photo-sensor consists of two components, the receiver is chosen to match the transmitter in order to obtain high performance. The transmitter will transmit infrared or near infrared light whereas the receiver will convert the reflected light energy, from the tissue exposed to the light, into electric current (Allen, 2007). An example of the configuration can be seen in Figure 1. The typical shape of pulses obtained by a PPG can be seen in Figure 2.

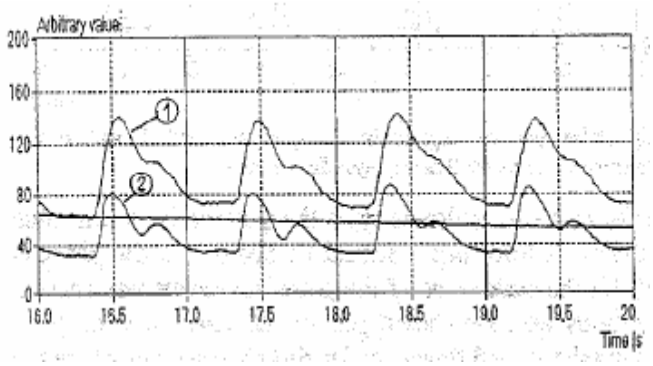

Figure 2: Typical shape of pulses when measuring with a photo-cell sensor. (source: (Wei))

2.4.2 Optics of the human skin

In measurements with a photo-cell it is important to consider the optics of the human skin. The human skin consists of different layers called Stratum corneum, epidermis and dermis. All this layers are of different thickness and have somewhat different properties. Their thicknesses are; corneum 10 µm, epidermis 100 µm and the dermis 3 µm (Andersson & Parrish, 1981)

The penetration depth of the light is dependent on the wavelength of the light. This means that it is possible to control how far the light can penetrate the skin by changing the wavelength.

The refraction index is somewhat dependent on the wavelength and in (Ding, Lu, Wooden, Kragel, & Hu, 2006) these values have been found by experiment. Also used is their result which shows that the refractive value is not dependent on the thickness of the stratum corneum and its theoretical thickness is therefore added to the thickness of the epidermis. How the light reflects or penetrates is also affected by the properties of the skin and also depends on the wavelength (Andersson & Parrish, 1981). By experiments with many different skin samples (Ding, Lu, Wooden, Kragel, & Hu, 2006) concludes that the difference in refractive index, depending on the amount of melanin in the skin, is very small.

2.5 MEASUREMENT OF ARTERIAL BLOOD FLOW

Measurements of blood flow and plethysmographic measurements can all be performed noninvasively with the Strain gage.

2.5.1 Strain Gage

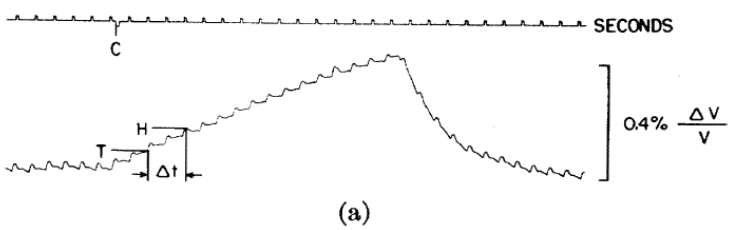

Figure 3: Signals from blood flow measurements done with strain gage. (Source: (Hokanson, Summer, & Strandness, 1972))

The strain gage is used to measure the (volume-) expansion of a limb such as forearms or calves due to the arterial blood flow when preventing the venous blood flow from returning to the heart. This is done by using a cuff that is inflated to the appropriate amount of pressure to achieve venous occlusion. When conducting this type of measurement the strain gage is connected around the forearm like a rubber bracelet around the forearm and connecting the cuff across the upper arm covering the bicep and triceps of the arm on which the measurement is to be done. Figure 3 shows what the signals recorded during blood flow measurements look like.

A strain gage is a device that in medical applications consists of a rubber tube filled with a semiconducting alloy for conducting current.

The strain gage has similarities with a potentiometer (a variable resistance) except that the resistance is dependent on the geometry rather than the value set by a user. The resistance of a strain gage varies in proportionality to the strain that the device is exposed to.

This type of strain gage is used to detect small variations and displacements in the orders of millimetres, these changes are indicated by the change of resistance across the device. The change in resistance is a function of the changes in the dimensions; length and cross sectional area of the strain gage, and is also dependent of the conductivity of the semiconducting alloy used. This relation is usually referred to as the gage factor G (Webster).

2.6 PERIVASC©

Peripheral Vascular Data Recording and Analysis (PeriVasc©) is a program used for analysing and recording of Peripheral Vascular Investigation. It is created by Ekman Biomedical Data AB (EBIDA). PeriVasc© can be used in both research and during peripheral vascular investigation. Some typical applications in research are arterial inflow and/or quantification of peripheral resistance in limbs. And for clinical use some applications are measurements of peripheral pressure, calculation of ABI and TBI and as a support during investigation of venous insufficiency (Ekman, PeriVasc).

3 ELECTRICAL BACKGROUND

In this chapter a slight overview of some electrical configurations and applications will be presented and described with illustrations.

3.1 WHEATSTONE BRIDGE CONFIGURATIONS

A Wheatstone bridge is a configuration that is used to measure deviations in resistance in a sensor. There are three common configurations of a Wheatstone bridge and they are;

- Quarter Bridge
- Half Bridge
- Full Bridge

The names of these configurations depend on how many sensors the bridge has e.g. in a quarter bridge only one of the four resistive elements is a sensor, hence the name *Quarter Bridge.* An example of this configuration is visible in Figure 4.

3.1.1 Quarter Bridge

As mentioned briefly in the introductory text about Wheatstone bridges, a quarter bridge configuration of a Wheatstone bridge is when only one of the elements in the bridge is a sensor. The configuration will detect deviations in voltage since the two arms of the bridge are simple voltage dividers where the element R_x in the right arm of the bridge is the sensor and will experience deviations in geometry due to loads or strains. As a result of the sensor experiencing changes in geometry it will experience change in resistance, which will lead to changes in voltage in the voltage divider. By measuring the differential between the two voltage dividers (arms) of the bridge it is possible to calculate the compression or strain that the sensor is experiencing.

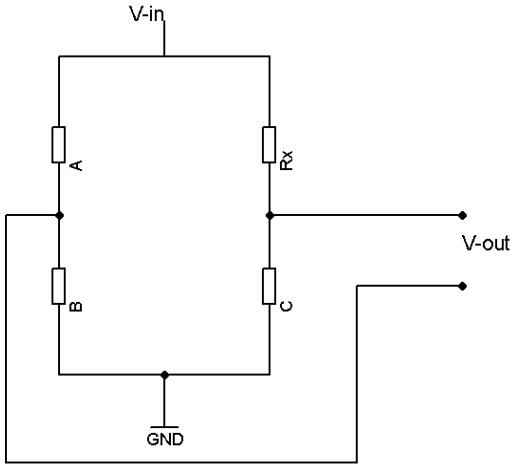

Figure 4: Quarter Bridge where the element Rx is the sensor

3.1.2 Half Bridge

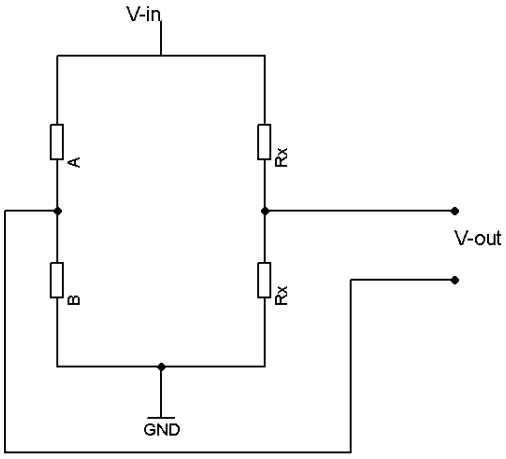

Figure 5: Schematic image of a half bridge. Where Rx is the sensor element, as seen there are two sensor elements.

In a half bridge configuration both resistive elements in one of the bridge arms are sensors, as shown in Figure 5, and are used to measure two types of changes that usually are correlated. E.g. tension and compression of a construction beam due to loads that it is exposed to.

This configuration could also be used to eliminate the temperature coefficient when performing measurement on biological signals, hence one of the sensors assumes the role as a dummy (National Instruments, 2011).

3.1.3 Full Bridge

The full bridge configuration is used for increased sensitivity resistive when performing measurements. All the elements in the full bridge configuration are sensors as shown in Figure 6 (National Instruments, 2011).

3.1.4 Shunt calibration

Shunt calibration is a method that is used in bridge circuits for simulating a certain fluctuation. This could for example be simulation of a certain percentage of strain applied on the object to which the sensor or sensors in the bridge circuit are connected to (National Instruments, 2011).

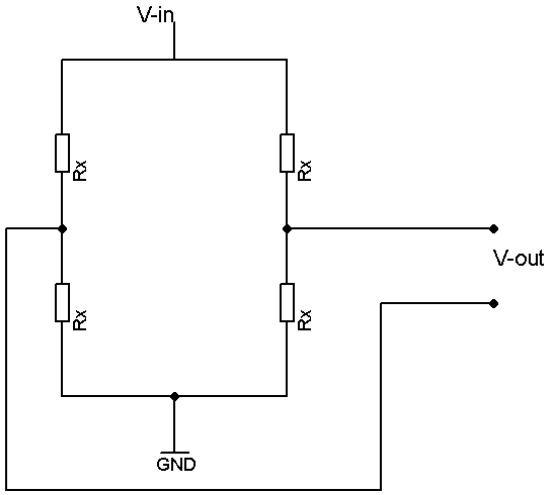

Figure 6: Schematic image of a full bridge configuration. Here Rx are sensor elements and as seen all elements are sensors.

3.2 OPERATIONAL AMPLIFIER APPLICATIONS

Amplification is a key element in order to distinguish signals that are obtained when performing a certain type of measurement of low scale voltages. The amplification is made by connecting resistors to an operational amplifier (op-amp) in a preferred manner in order to achieve the desired amplification. There already exist several amplifier connections or applications that are used for different purposes and result in different type of amplifications. Some of the alternatives that are most commonly known are listed below with a brief description.
All the characteristics and performances of the op-amp applications described below are done with the assumption that the op-amps are ideal.

- Differential Amplifier
- Instrumentation Amplifier
- Non-inverting Amplifier
- Isolation Amplifier
- Voltage Follower
- Comparator

3.2.1 Isolation Amplifier

An "Isolation Amplifier" is a device that is used to protect the signals acquired during measurements from noise that can arise as result of a potential difference between the measurement ground and the signal ground.

The isolation amplifier consists of two parts that are separated by an isolation barrier which leads to the parts being connected in a non-galvanic manner (Dorf & Svoboda, 2004) (Webster).

3.2.2 Non-Inverting Amplifier

The main purpose of non-inverting amplifiers is that they are to assume the role of buffers, hence the non-inverting amplifier is also known as buffer-amplifiers.

The non-inverting amplifier does not invert the input voltage and provides an amplification that is decided by the resistors in the voltage divider in the feedback loop from the output to the negative input on the op-amp according to equation (1). The configuration can be seen in Figure 7 (Storr, 2011) (Dorf & Svoboda, 2004).

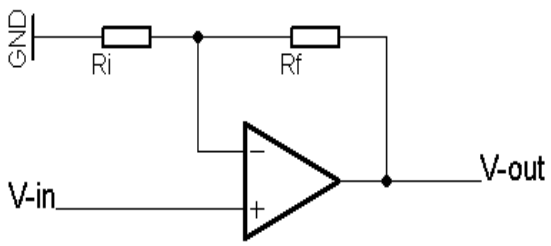

Figure 7: The amplification in a non-inverting amplifier is determined by the quotient of R_f and R_i

$$Gain = 1 + \frac{R_f}{R_i} \qquad (1)$$

3.2.3 Differential Amplifier

The differential amplifier, as the name implies, is a configuration which is used to measure and amplify the difference in voltage between two nodes. One possible configuration is shown in Figure 8.

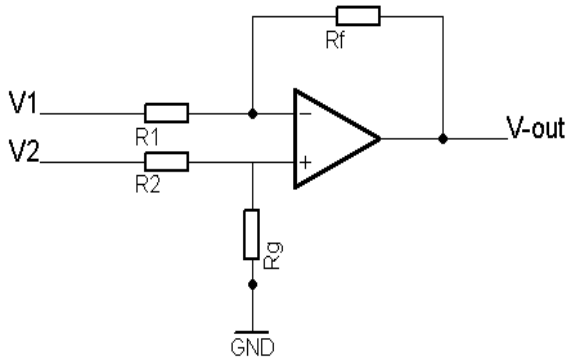

Figure 8: Schematic image of a differential amplifier were the voltage difference between the two signals is amplified.

When implementing the differential amplifier it is important to consider some aspects that need to be fulfilled in order to obtain good quality results from the intended measurements. It is of great importance to have high impedances for the differential amplifier to avoid loading of the input stage.

Except the risk for nonlinear behaviour there are also advantages in using a differential amplifier since it is more cost effective than other configurations that are intended for the same use.

3.2.4 Instrumentation Amplifier

A choice that is more accurate than the differential amplifier but more expensive is an Instrumentation Amplifier (Webster) (Dorf & Svoboda, 2004). The purpose of the instrumentation amplifier is the same as for the differential amplifier. Even though the purpose is the same the circuit constructions are different and also the characteristics of the constructions differ. The instrumentation amplifier is more accurate than the differential amplifier (Webster).

3.2.5 Voltage Follower

The gain that is provided by a voltage follower is 1 e.g. the voltage at the output of the amplifier has the same amplitude as the voltage at the positive input of the amplifier. The voltage follower is a configuration of the non-inverting amplifier, where the voltage divider is replaced by a feedback from the output to the inverting input as seen in Figure 9. The configuration is also known as a unit gain buffer (Storr, 2011).

The configuration is mostly used as isolation between two different stages since it works as a buffer and maintains the voltage amplitude from the previous stage. The ability to work as an isolation and buffer, besides maintaining the voltage amplitude, is because of the ability to not load the previous stage. This is because no current flows into the voltage follower. The configuration rather works as a current supply for the stage that is cascaded to it (Storr, 2011).

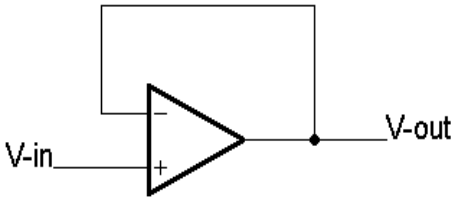

Figure 9: Voltage follower.

3.2.6 Comparator

As the name implies the comparator compares two input signals,V_a and V_b, and produces a logic output of either a high or a low voltage to indicate which one of the input voltages has the highest value. As shown in Figure 10, the comparator has a non-inverting and an inverting input similar to the op-amp, and is in fact an application of the op-amp that makes use of the differential input to enable comparison (Hambley A. R., 2000).

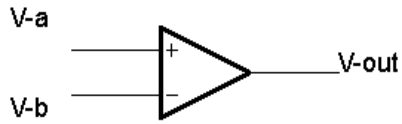

Figure 10: Comparator circuit.

The comparison is performed by checking whether the voltage at the non-inverting input is greater than the voltage at the inverting input. If this is the case, the output will indicate a positive voltage (high) and vice versa. The two voltage levels at which the output switches to indicate either high or low is called the threshold voltages (Hambley A. R., 2000).

In reality the signals that are passed to the comparator are not noise free. In cases when the noise is rather high the comparator will display uncertainty switching between high and low as a result of the noise. This is compensated by implementing hysteresis.

The hysteresis enables the comparators to with stand noise that has a peak to peak value which is lower than the hysteresis zone (Hambley A. R., 2000). The hysteresis zone is specific for each type of comparators, hence the best suited comparator is chosen with the hysteresis in consideration.

3.3 FILTERING

Filtering is a crucial part when performing signal processing. Filters can be divided into two subgenres, Ideal and Real-Filters. Whereas the ideal filter is used to describe how a filter should work mathematically but is physically not realizable.

The whole purpose of using a filter is to remove information that is not of interest for the intended application as the signal usually consists of various frequencies, "For convenience, suppose that both the input and output of this filter are voltages. This ideal filter separates its input into two parts. One part is passed, unchanged to the output; the other part is eliminated. In others words the output of an ideal filter is an exact copy of part of the filter input." (Dorf & Svoboda, 2004)

Unfortunately the reality is that a filter does not work exactly like in the ideal case, some of the unwanted information gets passed through the filter. The attribute that tells what signals that are allowed to pass or to be rejected is called the cut-off frequency.

Except being differentiated as either ideal or real the filters are also divided into passive and active types. The reason for the passive filters being referred to as passive is that they are implemented only with the help of passive components such as capacitors, resistors and inductors (Dorf & Svoboda, 2004).

The active filter configurations are implemented with the help of the passive components mentioned above and with operational amplifiers which are active components. Hence the name active filters.

The filter configurations that will be presented in this section are the following:

- Passive Low pass Filter
- Passive High pass Filter
- Active Low pass Filter
- Active High pass Filter
- Active Band pass Filter
- Active Band stop Filter

3.3.1 First Order Passive Filters

The filter cut-off frequency for a first order passive filter, regardless of being either a high pass or a low pass configuration, is determined by equation 2.

$$f_c = \frac{1}{2\pi RC} \quad (2)$$

Whereas the resistance R is given in Ω[Ohm] and the capacitance C is given in F[Farad].

One disadvantage with using passive filters is that they do not allow and support cascading without a buffer in between the filter and the stage connected to it. Also it cannot withstand any loading effects. Another disadvantage of using passive filters is that the output signal has lower amplitude than the input signal. The amplitude of the output from a passive filter can never exceed the amplitude of the input signal nor be the same.

3.3.1.1 First Order Passive Low Pass Filter

The reason to why this type of filter is called a passive filter is that the only types of components that are used to implement it are passive. The purpose of the low pass filter is, as the name hints, to allow signals with frequencies lower than the cut-off frequency, which is given by the combination of the passive elements according to equation 2, to pass through the filter and rejects signals that have a higher frequency.

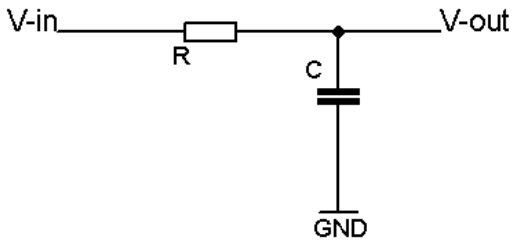

Figure 11: Passive Low Pass Filter.

In Figure 11 a passive low pass filter implemented with the use of a capacitor and a resistor is displayed. A low pass filter could also be implemented with help of using an inductance instead of a capacitance but the configuration of the circuit would not look the same since the capacitor and inductor does not have the same characteristics in performance (Phillips, Riskin, & Parr, 2003).

3.3.1.2 First Order Passive High Pass Filter

In the contrary to the low pass filter a high pass filter will reject signals with frequencies that are lower than the preferred cut-off frequency and allow signals with higher frequencies than the cut-off frequency. But since it is not an ideal filter some of the signals that are lower than and close to the cut-off frequency will pass through the filter. (Phillips, Riskin, & Parr, 2003)

Figure 12 shows and example of how a passive high pass filter could be implemented with the help of a capacitor and a resistor.

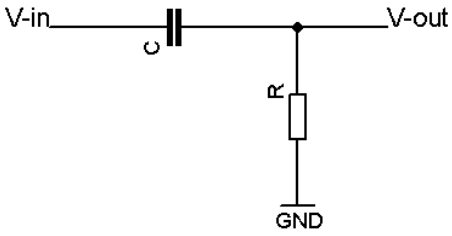

Figure 12: Passive High Pass Filter

3.3.2 First Order Active Filters

As previously described the active configurations have the active component op-amp as a part of the filter and not only the passive elements.

The cut-off frequency for First Order active filters is given by the same relation as for the passive filters, given in equation 2.

Except filtering the active filters can provide an amplification of the signal. In others words, the signal passed through an active filter will be filtered and experience amplification. This depends on how the in-signal resistor and the feedback resistor values are chosen.

Also the ability of providing a gain for the signal will prevent attenuation.

Unlike a passive configuration an active filter configuration does allow cascading without loading the previous stage, which may arise as a result of the cascading when using passive filters.

3.3.2.1 First Order Active Low pass Filter

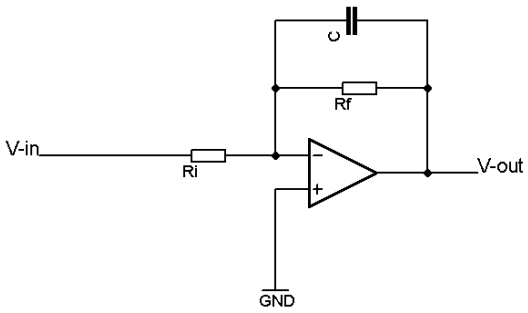

Figure 13: Inverting Active Low Pass Filter

An active low pass filter could be considered as a configuration of an integrator, where a resistor is connected in parallel to the capacitor in the feedback loop (Dorf & Svoboda, 2004).

The cut-off frequency for an active low pass filter according to Figure 13 is dependent of the resistor in the feedback loop for amplification and the capacitor value that is connected in parallel to the feedback resistor.

The calculation of the cut-off frequency is given by equation 3, which actually is the same as equation 2 presented in the section about passive filters (Storr, 2011).

$$f_c = \frac{1}{2\pi R_f C} \qquad (3)$$

Basically the filter properties of the active low pass filter are the same as the properties for the passive low pass filter. Though there are some advantages as listed above (Dorf & Svoboda, 2004).

3.3.2.2 First Order Active High pass Filter

The first order active high pass filter has the same frequency characteristics as the first order passive high pass filter. The main difference is that the first order active high pass filter will provide a gain and also enable cascading without changing the frequency properties of the filter or loading the previous stage (Storr, 2011).

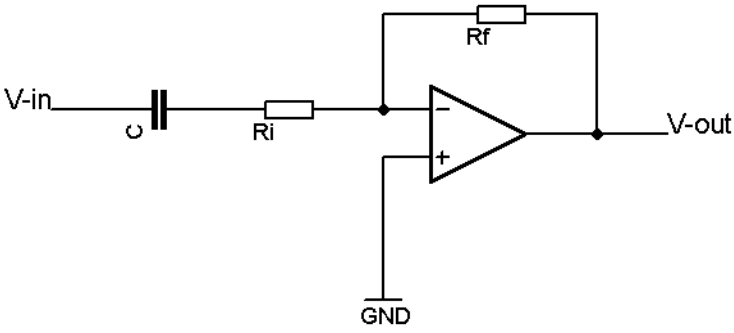

Figure 14: Inverting Active High Pass Filter

Unlike the active low pass filter the active high pass filter could be considered a configuration of a differentiator that has a resistors connected in series with the capacitor at the op-amp inverting input as seen in Figure 14.

The cut-off frequency of the filter in Figure 14 is dependent on the values of the capacitor and the resistor that are connected in series at the inverting input of the op-amp. The cut-off frequency is calculated in the same manner as presented in the previous sections about filters, except that it in this case is dependent on, as mentioned previously, the input capacitor and resistor as seen in equation 4.

$$f_c = \frac{1}{2\pi R_i C} \qquad (4)$$

3.3.2.3 First Order Active Band pass Filter

The band pass filter is a filter configuration which purpose is to only allow signals that are within a certain frequency range to pass and rejects everything below or above that range. The active band pass filter provides the same type of behaviour and also provides an amplification of the output-signal.

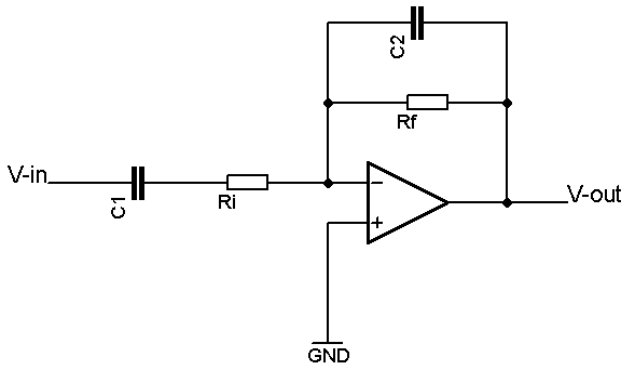

Figure 15: Inverting Active Band Pass Filter

The application can be setup up in various manners. The one described here is an Inverting First Order Active Band Pass Filter as seen in Figure 15.

The maximum gain is determined by using equation 5. The cut off frequencies are determined by using equations 3 and 4 given previously for the active low and high pass filters. Whereas equation 3 is used to calculate the higher cut off frequency for the low pass part of the filter and equation 4 is used to calculate the lower cut off frequency for the high pass part (Storr, 2011).

$$Gain = -\frac{R_f}{R_i} \qquad (5)$$

3.4 LOGIC

The output of a logic gate is either high (1) or low (0) and these values are represented by a variable voltage. There are different kinds of logic gates and the values for high and low differs between them, here two types are described the Transistor-transistor logic (TTL) and Complementary metal–oxide–semiconductor (CMOS) (Kuphaldt, 2012).

3.4.1 Transistor-transistor logic gate

These gates are powered by a nominal supply of 5 (+- 0.25) Volt and in an ideal world a high would be 5 Volt and a low 0 Volt. But this is not real for most cases and a high is represented by a voltage in the range 2-5 Volt and a low by 0-0.8 Volt for the gate input and for the output a high is between 2.7-5 Volt and a low 0-0.5 Volt. The range between a high and a low are known as the uncertain range and can be interpreted either as a high or as a low. There are no manufacture that guarantees how there logic gate performs in this range (Kuphaldt, 2012).

The ranges for a high and low differs between the output and input, this to ensure that an output from one gate is transmitted as an acceptable value for the receiving gate. The difference in accepted input and output values are called the noise margin.

3.4.2 Complementary metal–oxide–semiconductor

For a CMOS gate the values for high and low differs from the TTL gate. For a CMOS that operates on a power supply of 5 Volt the input acceptable input value for a high is 3.5-5 Volt and 0-1.5 Volt for a low. For the output these values are 4.95-5 Volts for high and 0-0.05 Volt for low. The difference in acceptable input and output values are greater than for the TTL gate and this yields a greater noise margin (Kuphaldt, 2012).

The power supply for a CMOS gate is not restricted to 5 Volt, as for the TTL, and it can operate on various supply voltages up to 18 Volt.

Values given are the theoretical values and other values might be accepted as high or low. For the CMOS gate the output values are optimistic and are only true in the case with minimum loading. Due to internal channel resistance these values might not be maintained (Kuphaldt, 2012).

3.4.3 Logic Not-AND gate

The logic Not-AND gate or NAND for short is a logic AND gate with an inverting output gate. A truth table for this gate is seen in Table 1. In circuit schematic this gate is represented by the symbol shown in Figure 16 (Hambley A. R., 2005).

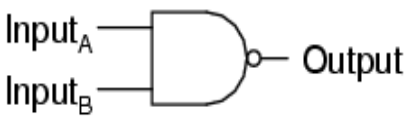

Figure 16: Schematic symbol for the logic NAND gate

Table 1: Truth table for the logic NAND gate

A	B	Output
0	0	1
0	1	1
1	0	1
1	1	0

4 METHODS

In this chapter the different methods used during the course of this Master Thesis are presented and described.

4.1 LITERATURE STUDIES

First a litterateur study was performed to better understand the problem at hand. Symptoms diagnose and treatments for diseases of interest as well as information about how measurements of blood pressure in fingers and toes are performed today. Focus was put on how to perform measurements used for diagnosing and the theory behind the methods to better understand the features of a product for such applications.

4.2 INFORMATION RETRIEVAL

Information about the system and the requirements were collected through three steps; Stakeholder identification, requirement elicitation, requirement specification and requirement prioritization. These different stages will be described in greater detail in paragraphs that follows.

4.2.1 Stakeholder identification

A stakeholder is a person or a company whose needs are important for the project and the product to be developed (Berenbach, Kazmeier, Paulish, & Rudorfer, 2009). The first step is therefore to identify the stakeholders. It is important to know who the stakeholders are and there relations. This is used to better understand the importance of their requirements. Examples of stakeholders are; the installer, tech support and of course the user (Davis, 2005).

Since the project is done on a small company many of the different stakeholders are "contained" in a single person. This stakeholder possesses, through experience, a good understanding of other stakeholders and particularly their needs.

4.2.2 Requirement elicitation

Elicitation is a definition used for the interaction with stakeholders when trying to capture their needs (Berenbach, Kazmeier, Paulish, & Rudorfer, 2009). To prepare for the elicitation literature studies as described above were used. Many different techniques for requirement elicitation exists, in this project unstructured interviews were used.

An unstructured interview is when questions are more exploratory and much more like a conversation. The questions are more open and the interviewee can answer in a few words or as completely as wished. The interviewer as well as the interviewee can steer the direction of an unstructured interview (Sharp, Rogers, & Preece, 2009).

An unstructured interview with the main stakeholder was held. Interviews were used to get a better understanding of how and where the product would be used as well as who the end user would be.

After the meeting requirements were identified and analysed. Analysis is the art of refining the needs of the stakeholder into formal product specification (Davis, 2005). Follow up meetings were held to ensure that all requirements and needs of the stakeholders were found, but also to ensure that there were no misunderstandings and to ensure that the customer's wishes were found.

4.2.3 Requirement prioritization

After identifying all requirements they were analysed to identify their importance, relations and dependencies of other requirements. From the interview requirements were defined and rated in aspect of their importance. When a list of requirements was agreed upon the design work started.

4.2.4 Requirement document

The requirement document contains the final list of requirements, some has been cancelled out due to that they have been found impossible to implement due to their low importance and conflict with requirements more important for the final product.

A requirement document was created and this document contains; input, output, function and environment (Davis, 2005). It describes all input that the system should be able to handle, in this case fabrication of sensors and their different properties. All outputs from the system are also documented here. This means the specification of properties for the signals that are delivered from the system to the PeriVasc© Hardware Interface card (PHI-card). The requirement document also contains information about how signals should be processed by the system and all functions that the system should have. A description of the environment that the system should be used in as well as information about other products; hardware as well as software, which the system is intended to function with.

This document was used to ensure that the system built were what the costumer expects (Davis, 2005).

4.3 PROBLEM IDENTIFICATION

From the use of the requirement documentation the problem at hand was identified and from that a problem description was derived.

4.4 CHOOSING COMPONENTS

Before each choice of component data sheets were studied and compared. The goal was to select the best suited component for each purpose. For our application the emphasis were to find components with small supply currents as well as low noise.

4.5 TEST AND VERIFICATION

Each part of the system has been tested alone as well as together with different parts of the system. Sensors as well as a potentiometer and a signal generator have been used to simulate signals of many different amplitudes, frequencies and patterns.

5 PROBLEM DESCRIPTION

This chapter will present the tasks that where to be done in order to achieve the final result as well as problems that had to be taken into consideration when developing a device intended for medical use.

5.1 PROBLEM DESCRIPTION

The task at hand was to develop a system with amplifiers and filters for measuring of blood flow and blood pressure with a photo-cell and a strain gage. All requirements found during elicitation can be found in the Requirement specification document in Appendix A. The requirement document also contains the requirements for the photo-cell prototype as well as for the software used during development and testing of the system. Also requirements for calibration and sensitivity when performing strain gages measurements are documented. A graphical overview of the system components and there relations can be seen in Figure 17.

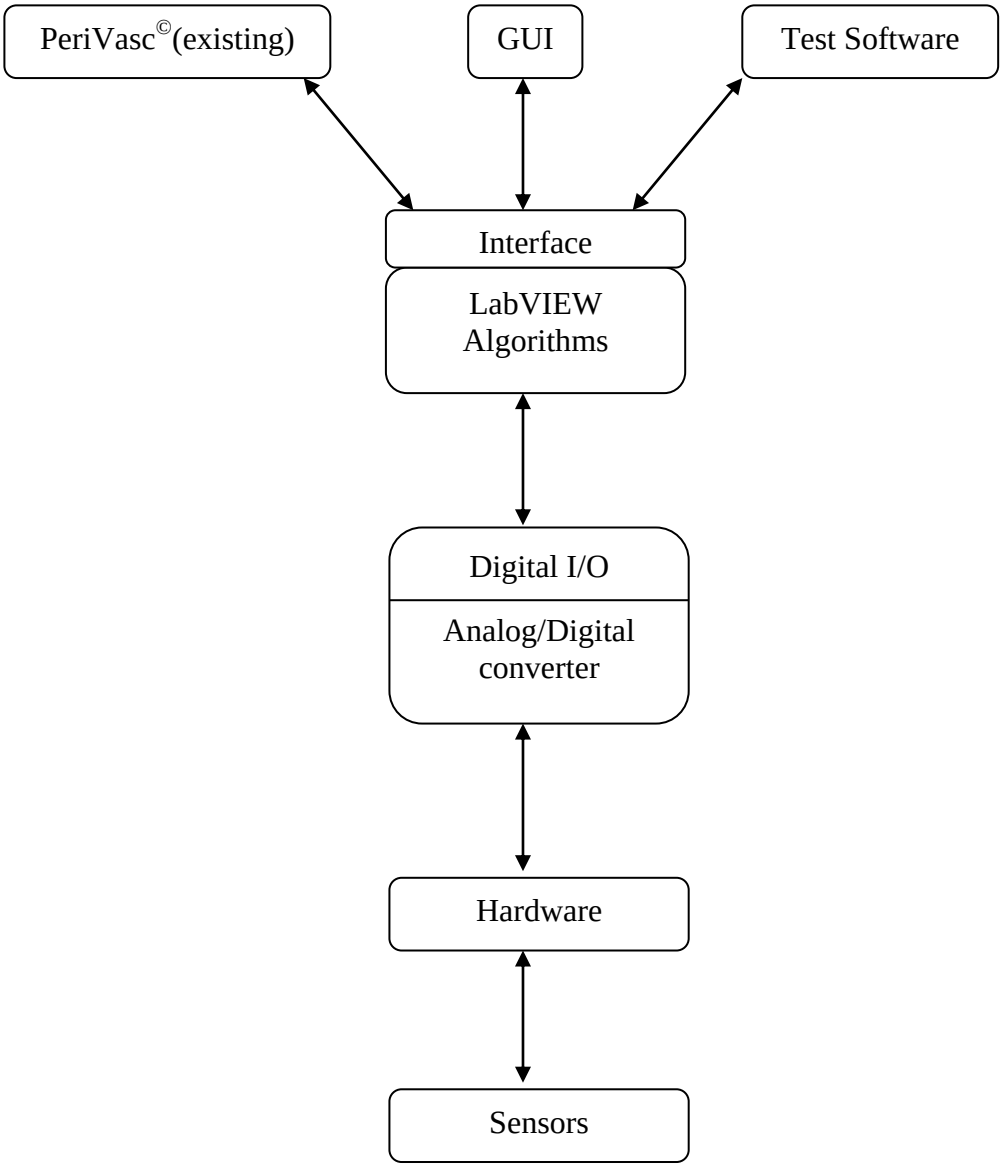

Figure 17: Graphical overview of the components in this project and their relations.

This work concerns:

1) Component selection to be used for an IR-based photo-cell.
2) Development of amplifiers for the IR-based photo-cell detector.
3) Circuit construction for obtaining signals during measurements using strain gage.
4) Development of an amplifier for strain-gage.
5) Voltage base line level shifting through hardware.
6) Front panel indicators for user friendliness.
7) A simple LabVIEW GUI (graphical user interface), to be used for testing and verifying of the amplifiers.

The system should be powered by a USB-cable connected to a computer. The amplifiers should have an interface allowing an external control when it comes to sensor selection, filter selection, amplification, base-line shift and amplifier balance (to prevent the signal from going out of range). When suitable, any amplifier algorithm, control handling etc. should be placed in the LabVIEW software in order to reduce the hardware construction. Further a design, component selection and construction should aim for a cost-effective production in the context of not choosing the most expensive components. Finally, the performance of the work will be evaluated using the LabVIEW GUI and an appropriate test set-up.

6 DESIGN AND IMPLEMENTATION

This chapter will present all the solutions implemented in order to solve the problems that where described in the previous chapter. Also problems that have been encountered during the development process will be presented with solutions used to overcome these obstacles.

6.1 POWER SUPPLY INVESTIGATION AND MODIFICATION

The PHI-card developed by EBIDA (Ekman Biomedical Data AB) in combination with a DAQ (data acquisition) card from NI (National Instruments) was used for the voltage supply of the system and data acquisition. The NI DAQ-card can deliver a supply voltage of 5 Volts DC, but this is inadequate to supply the Op-amps that are used in the system with the necessary voltages of ±15 Volts.

The PHI-card has a DC-DC converter that converts the 5 Volts to 15 Volts and also a 10 Volts DC supply.

As mentioned in the method chapter all components were chosen with the supply current in mind. The amount of current that the system can use are also shared with the PHI card which gives less than 500mA for the system. To minimize the amount of current used all component values were chosen so that as little current as possible is drawn. To gain a few extra mille amperes for the system some components on the PHI card was exchange to others with the same functionality but with less need for supply current.

To ensure that the current restriction never was breached a multimeter was connected on the USB cable during the course of the project. This to make it easy to see how much more current the system needed when new components were added. To further ensure that too much current never was used, current usage was calculated for each branch in the circuit.

6.1.1 Description of the power supply problem

A stable power supply is of great importance when performing medical measurements since the signals delivered from a sensor measuring bioelectrical signals are of low voltages and not constant, deviations in the signals are constantly occurring. Another reason for investigating the power supply signal is that USB is not guaranteed to give a steady 5V supply voltage since it has a standard deviation of ±0.25V.

Since the desired voltage supply should be a pure DC-supply with appropriate amplitude it is of great importance that this signal does not have any other characteristics than being a DC-supply and should not contain any type of noise that could affect the signal obtained during measurements and give inconclusive or misleading results.

The 5 volts supply voltage had a square wave ripple that became clearly visible when passing the signal through a high pass filter that removed the DC-content of the signal. This problem had to be investigated and solved in order to acquire good signals and supply the sensors with a stable DC voltage.

6.1.2 Investigation Measurements and Troubleshooting

The phenomenon of the reoccurring square wave signal was in particular distinct when performing measurements with the photo-cell. At instances when the photo-cell was not connected to the test subject the signal tended to assume the form of a symmetric square wave with a frequency of approximately 2Hz.

The approach of investigating this phenomenon was divided into the following steps:

- Investigate the frequency content
- Check for Aliasing phenomenon with the Nyquist - Shannon criteria
- Change supply and measurement unit

6.1.3 Investigation of frequency content

The frequency content of the signal was investigated by sampling the signal and reviewing it by using a simple LabVIEW program that displayed graphs with the power spectrum of the signals.

When obtaining the power spectrum, the frequency content of the supply voltage was investigated. It was important to understand what the frequency of the signal was and what type of characteristics it had.

6.1.4 Check for Aliasing phenomenon with the Nyquist-Shannon Theorem

After investigating the frequency content of the square wave signal, the next step was to investigate if the square wave formed signals were merely a result of aliasing. Aliasing is the phenomenon that occurs if the sampling frequency is lower than twice the frequency of the signal being sampled. The power supply signal from the USB port on the computer used is rather noisy and has characteristics of a square wave which can be viewed in Figure 18.

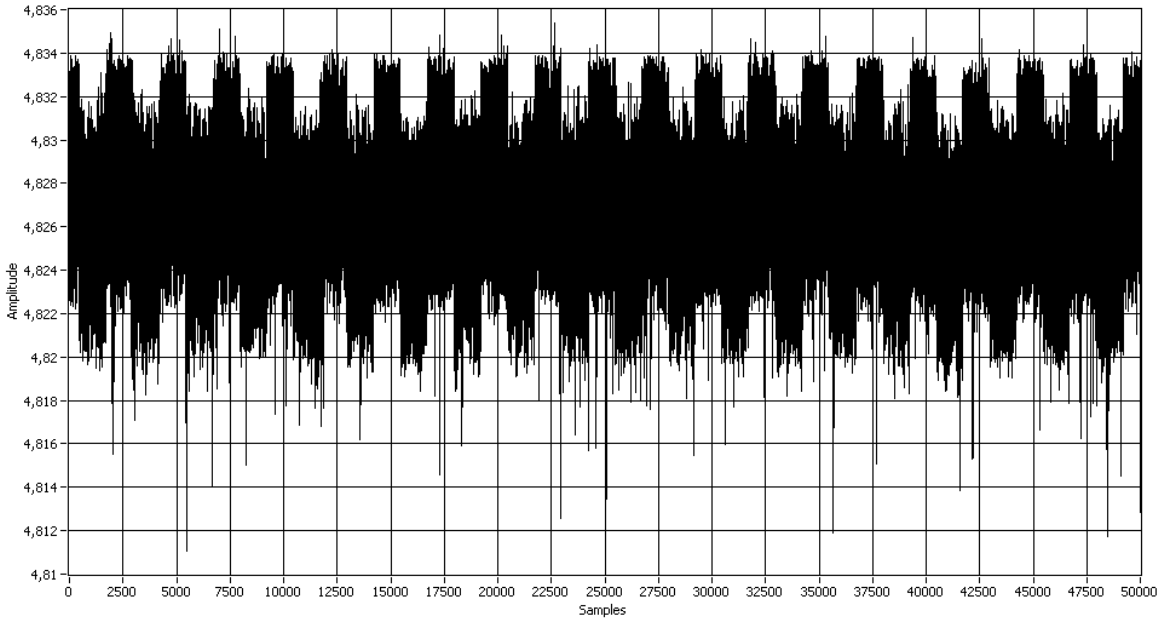

Figure 18: The USB supply voltage when using computer 1. The Peak to Peak level of the noise is approximately 34mV

The Nyquist-Shannon criterion is implemented when investigating if a signal has been subjected to aliasing. The Nyquist-Shannon criterion states the following:

"The sampling frequency should be at least twice the highest frequency contained in the signal." (Phillips, Riskin, & Parr, 2003).

One way to handle this problem is to use either a reconstruction filter (anti-aliasing filter) which actually is a low pass filter. Or one could use a band pass filter if the signal is not centred at zero and is band limited.

It was concluded that the signal was not a result of aliasing by applying a low pass filter. Since the band pass filter should remove this phenomenon in case it was a result of aliasing. The next step was to see if this was a result of the supply voltage.

6.1.5 Change of supply and measurement unit

The next step was to confirm whether it was (the DC-DC converter or) the USB drive that had this influence on the total supply. This was investigated by switching computer for supply and investigate the 5 Volts supply voltage of the new computer and see whether the square wave was still present or not, if it was still present then this problem could be either due to the DC-DC converter on the PHI-card, if not then this problem is due to the USB drive of the computer that is used as a supply and measurement unit.

The results of the measurements performed on the 5 Volts – supply voltage for two different computers can be seen in Figure 19 and Figure 20, when the sampling frequency was 5kHz:

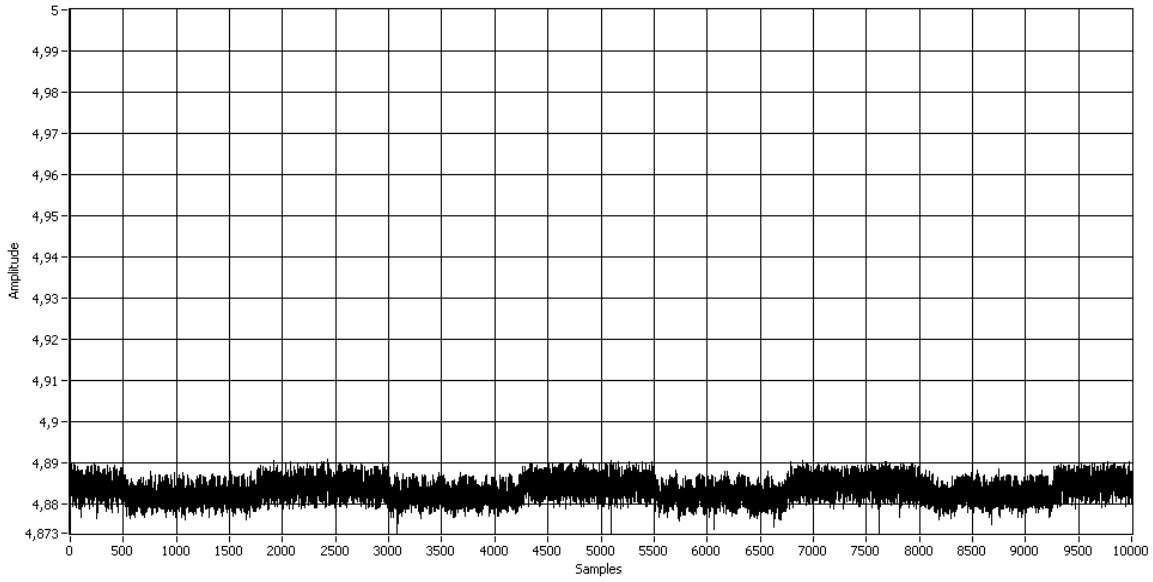

Figure 19: Voltage signal from the USB-drive of computer 1

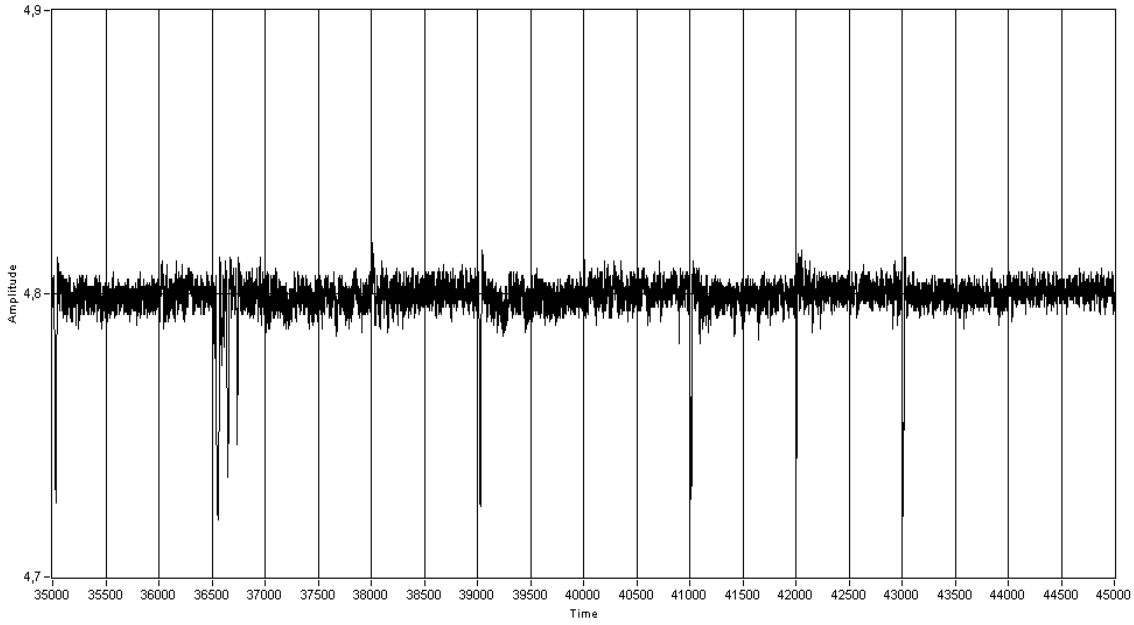

Figure 20: Voltage signal from the USB-drive of computer 2

When analysing the spectrum from the USB drives for the two different computers it is clearly visible that the 5 Volts signal in Figure 19 possesses the shape of a square wave, while the 5 Volts signal in Figure 20 has the shape of a very noisy DC-signal with some spikes.

The conclusions that can be drawn when comparing the two signals are the following: That the DC-DC converter had nothing to do with the characteristics of the 5V supply signal, and that the signal characteristics varied depending on the computer used as supply and measurement unit.

6.1.6 Cause of Problem

The problem that was encountered was that the characteristics of the voltage supply to the sensors were dependant of the supply source which in this case is the USB-port of a computer. The USB-port of a computer is intended to give a DC-voltage with amplitude of +5 Volts with a 25% margin. This does also affect the ±15 Volts DC-voltage supplies that are provided by the PHI-card since they are merely an amplification of the 5 Volts supply from the USB-port.

The computer used as power supply when testing the system was the same as the measuring unit. Hence the supply characteristics vary as a result of the switching frequencies of the DC-DC converter in the computer that is used as power supply.

6.1.7 Solution

The solution that was implemented was to use the 10V supply provided by The PHI-card and use a voltage divider in order to obtain the proper amount of voltage needed to supply the sensors.

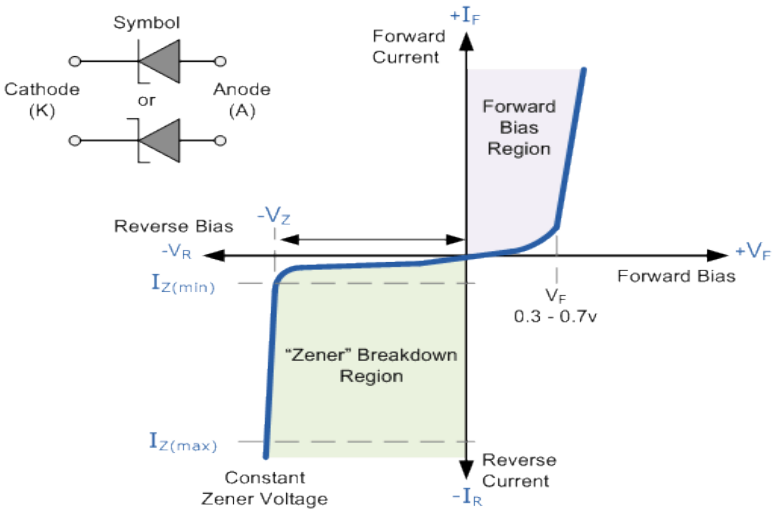

Figure 21: Characteristics of a zener diode. (Source: (Storr, 2011))

The reason why the 10 Volts supply was chosen is that it is generated by using the 15 Volts supply that is produced by the DC-DC converter and then scaled down to 10 Volts with the help of a resistor connected in parallel with a zener diode creating a voltage regulator that ensures that the voltage will be stable at 10 Volts.

This is because the zener diode is intended to work in the breakdown region and is constructed to have a really sharp and distinct knee. This means that it is intended to keep a constant voltage almost independent of the current through the zener diode in the breakdown region. But this effect known as the zener effect is limited due to the maximum power that the zener diode can withstand (Storr, 2011). The voltage-current characteristics of a zener diode is shown in Figure 21.

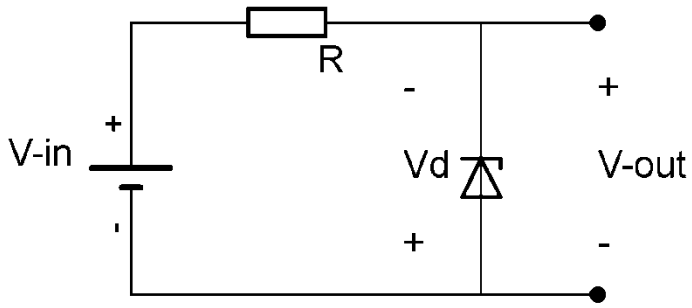

Figure 22: A schematic image of a voltage regulator. The voltage can be regulated by using components with different characteristics.

As mentioned briefly in the previous section, the voltage regulator consists of a resistor that is connected in series with a zener diode that is reverse biased. The circuit can be seen in Figure 22.

The purpose of the resistor R in the circuit is to regulate the current supply to the diode in order to keep a safe value (Hambley A. R., 2000). This is of great importance so that the diode does not exceed its power limit and get overheated. The voltage across the reverse biased zener diode is negative hence the voltage out, V_{out}, is expressed as:

$$V_{out} = -V_d = V_z \qquad (6)$$

Kirchhoff's voltage law is implemented when determining the diode current and the diode voltage so that the desired value of the diode voltage could be obtained. According to Kirchhoff's law the sum of the voltages in the circuit can be expressed as:

$$V_{in} + Ri_d + V_d = 0 \qquad (7)$$

Where i_d is the current through the reverse biased zener diode. By locating two points it is possible to construct the load line to determine the operating voltage V_d and the diode current i_d by solving the relation derived from implementing Kirchhoff's voltage law since this is the equation for a straight line (Hambley A. R., 2000). This is shown in Figure 23.

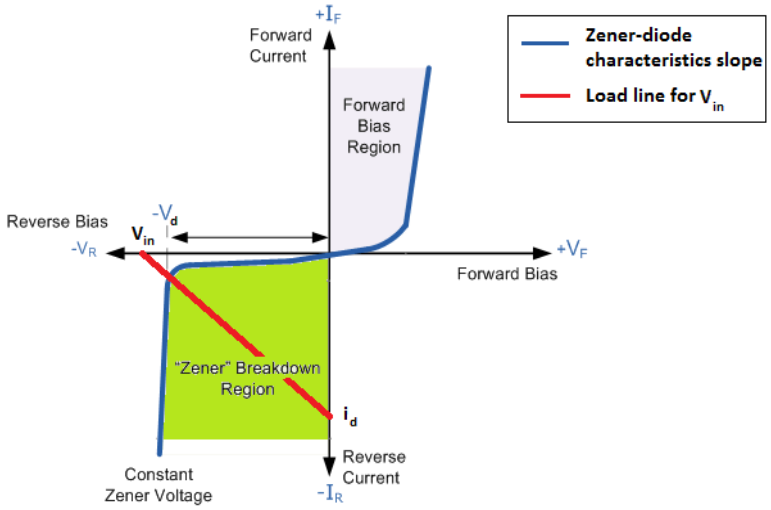

Figure 23: Load characteristics of a voltage regulator. (Source: (Hambley A. R., 2000)

Now that a stable voltage supply has been created, the next step was to modify the voltage amplitude in order to fit the purpose of supplying the sensors and keep it stable at that voltage level and at the same time supply all the stages cascaded to the sensors with the required amount of current. This was solved by cascading a voltage divider with a voltage follower. The voltage divider will decrease the amplitude of the voltage to the appropriate level that is required for the sensors. A principal schematic of the circuit can be seen in Figure 24.

As mentioned above the voltage divider will decrease the voltage to appropriate amplitude, but it is of great importance that the resistors in the voltage divider circuit have low noise, since that would actually obstruct the whole purpose of having a stable and nearly noise free DC- voltage supply to the sensors.

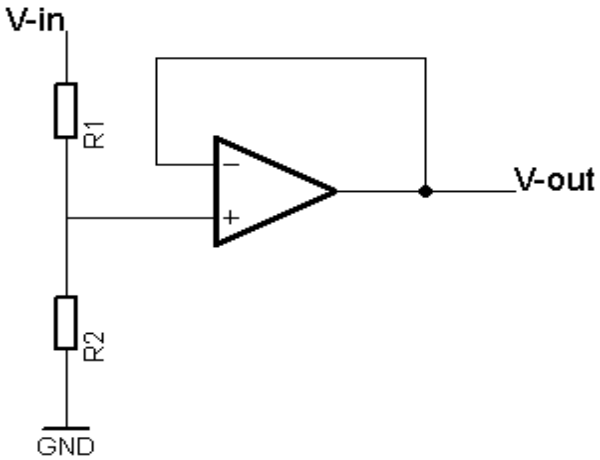

Figure 24: Voltage follower cascaded to a voltage divider

The second part of the solution is the voltage follower which ensures that the voltage will not go out of range and handles the current supply to the stages connected to the new supply voltage created by the voltage divider. In other words, this stage acts as a buffer between the divider and the stages that are cascaded.

6.2 PHOTO-CELL SENSOR

During the project three versions of a photo-cell sensor prototype were designed and built. The requirements for the final version of the photo-cell sensor were formulated partly from the experience of the prototypes. In this chapter the design and construction of the different versions of the photo-cell sensor prototype are described.

As mentioned in the filter section of the theory chapter, filtering is of great importance when dealing with signal processing in order to suppress the information that has a frequency content that is not of any interest for the measurements being conducted.

6.2.1 Photo-cell Sensor Version One

Figure 25: The first set-up for the photo-cell sensor prototype.

This was the first prototype created. It is very simple and mostly used to test the theory of light transmission from diode to phototransistor through reflection on the red blood cells. It was mostly created to simulate the small signals, much less than 0.3 Volts, common for photo sensors since these are too small to simulate through the DAQ-card. The diode and a phototransistor were placed next to each other on an experiment board seen in Figure 25 according to the schematic shown in Figure 1. This setup gave good readings, but disturbances were introduced since the diode was not shielded and light could pass directly between them. Disturbances were also picked up from the fluorescents light in the room. Also the readings were very sensitive to movements. Version 2 was then constructed to avoid some of these problems.

6.2.2 Photo-cell Sensor Version Two

To shield the diode and the phototransistor from the sources of disturbances noted, using version 1, something that could contain the components where sought. Preferably this material would be circular so that the commercial availably tape for attaching the sensor on the skin could be used.

Figure 26: The second version of the photo-cell sensor prototype

To make it easier to use the test sensor a simple sensor prototype was build using a case plug. The case plug was modified to better fit on the fingertip and the diode and phototransistor was placed inside. To minimize the direct transfer of light between the diode and phototransistor both of them were placed in some black shrinking tube. The empty space between the components was filled with glue to stabilize the components. This prototype is shown in Figure 26**.**

The same type of diode and phototransistor as those in version 1 were used. The cables used were ordinary lab cables.

This prototype made the testing of the amplifiers much easier and since the signals were better than expected a new prototype was made and it was agreed upon that this was the diode and phototransistor to use.

6.2.3 Photo-cell Sensor Version Three

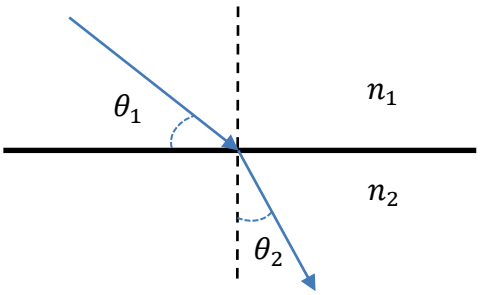

Figure 27: Representation of refraction of light.

To gain better measurements the theory of the optics of the human skin, described in chapter 2.4.2, was used together with Snell's law (equation 8). This to calculate the distance between the diode and the phototransistor that, in theory, would result in the greatest amount of reflected light (John & Raymond, 2006). Also information about the diodes view angle was derived from the datasheet used for this. It is of great importance that the IR-led and the photo transistor are not placed adjacent. The photo transistor were placed a few millimetres lower than the IR-diode, this to avoid that the photo-transistor picks up light from the transmission rather than the reflection of the light from the tissue.

$$n_1 \cdot \sin\theta_1 = n_2 \cdot \sin\theta_2 \qquad (8)$$

n_1 and $n_2$in equation 8 are the refraction constants of the materials. The indecent angle and the refraction angel are θ_1 and θ_2 respectevly. This is shown in Figure 27.

Also the aesthetics of the prototype was improved. The rings on the case plug were removed to obtain a smooth surface, and the case plug was covered with black shrinking tube, also a new cable was used and a real contact replaced the lab cables, a visual representation of this is given in Figure 28. As well as the previous version this one also lacks a protection film between the components and the skin.

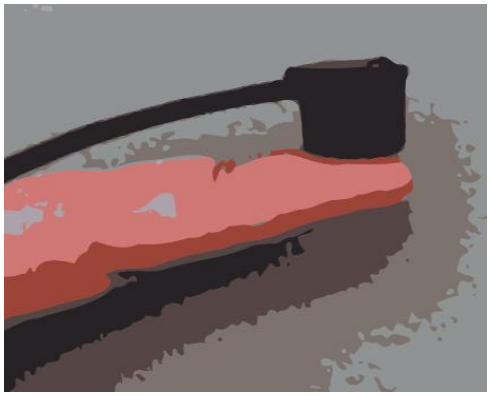

Figure 28: Version three of the photo-cell sensor prototype placed on the finger of a test subject.

6.2.4 Decoupling Stage (First Order Passive High pass Filter)

A passive high pass filter was implemented at the PPG-unit for ensuring that the signal obtained did not contain any low frequent noise. This to give the signal a baseline close to the DC-level of zero volts by removing any static DC-signal that may be part of the signal that is obtained during the measurements. This is of great importance for facilitating the amplification procedures that are to follow.

The signal obtained by the transistor during measurements is not static and has the characteristics of ripple over riding a static DC-level. Hence it is important to remove the static DC offset of the signal in order to ensure that the only part of the signal that is passed through to the amplifier stages and the filters is the part of the signal that is alternating. This is because of that the capacitor in the high pass filter allowing signals with a frequency higher than the cut-off frequency to pass through it as if it was a simple wire and suppress the signals that has lower frequency content than the cut-off frequency. The result of this can be seen by comparing Figure 29 and Figure 30.

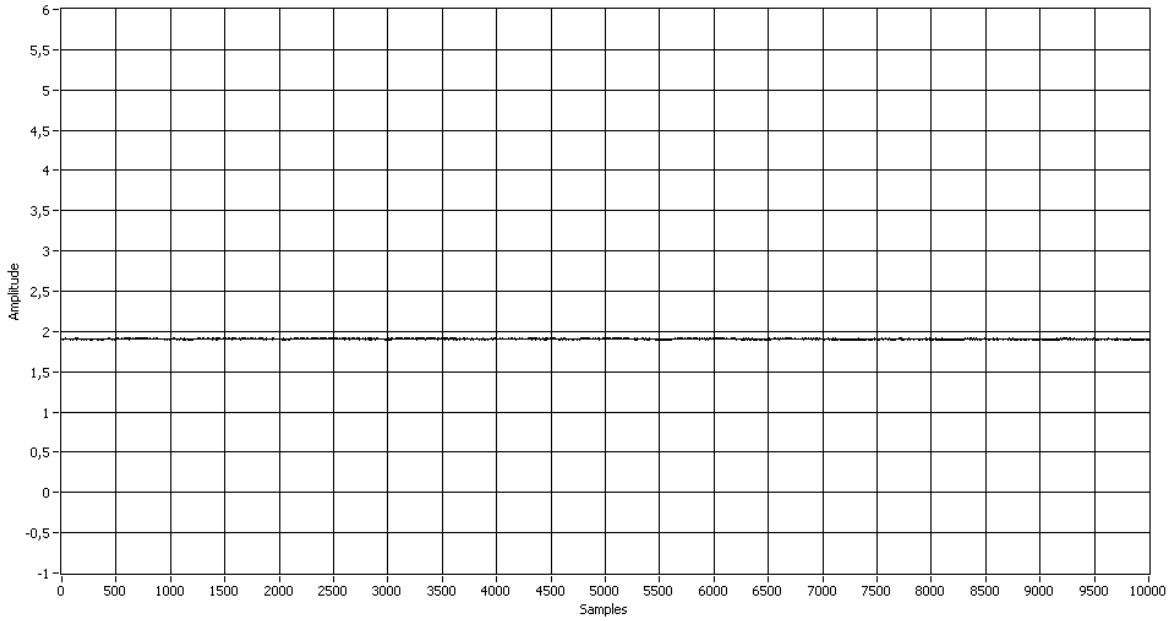

Figure 29: Signal prior to Decoupling stage (Passive high pass filter), The signal is over riding a static DC voltage with an amplitude of 2V.

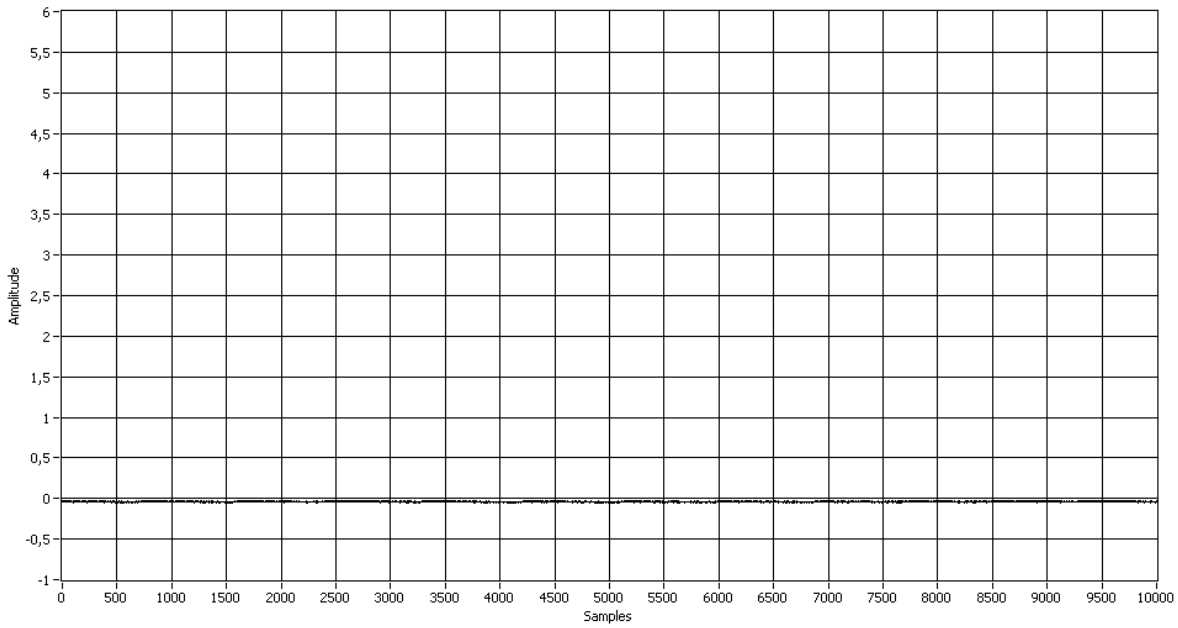

Figure 30: Signal post Decoupling stage (Passive high pass filter). Here the static DC signal is removed and only the AC-component remains.

6.2.5 Non-Inverting Amplifier

The signal is in its raw form since only the DC-content of the signal has been removed. The next step is to amplify the signal. The first amplification (pre amplification) is done with the help of a non-inverting amplifier since it is not possible to apply all the amplification in one single amplifier stage. A schematic of the non-inverting amplifier configuration that was used can be seen in Figure 7 in chapter 3 Electrical background. The effect of the pre amplification can be seen in Figure 31 and can be compared to Figure 30 that shows the signal prior to amplification.

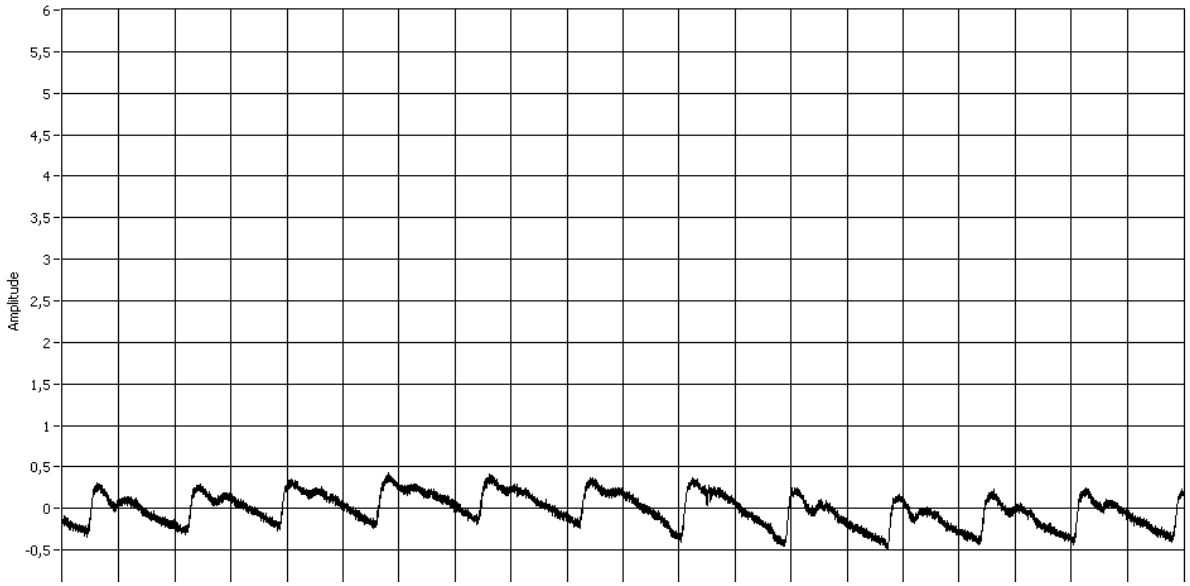

Figure 31: The signal post pre amplification.

6.2.6 First Order Active Band pass Filter

The purpose of the active band pass filter was to enhance the important characteristics of the signal by removing signal contents that is not of interest and could possibly be noise from the surroundings. The active band pass filter will also provide a gain to the signal amplitude. The schematic of the first order active band pass filter used can be seen Figure 15.

The principles are the same as those described in the theory section about filters, except that the filter should be able to have variable cut-off frequencies, because of the requirements for a user interface when using the device for research purposes. Hence changes have been done so that the filter could fulfil this requirement without changing the gain provided by the filter. This was solved by letting the values of the capacitors be variable and keeping the resistances constant. Since the gain is dependant of the relation between the in-signal resistor and feedback resistor as seen in equation 1 in the theory section about active filters. The result of the active band pass filter can be seen in Figure 31 and in Figure 32**.**

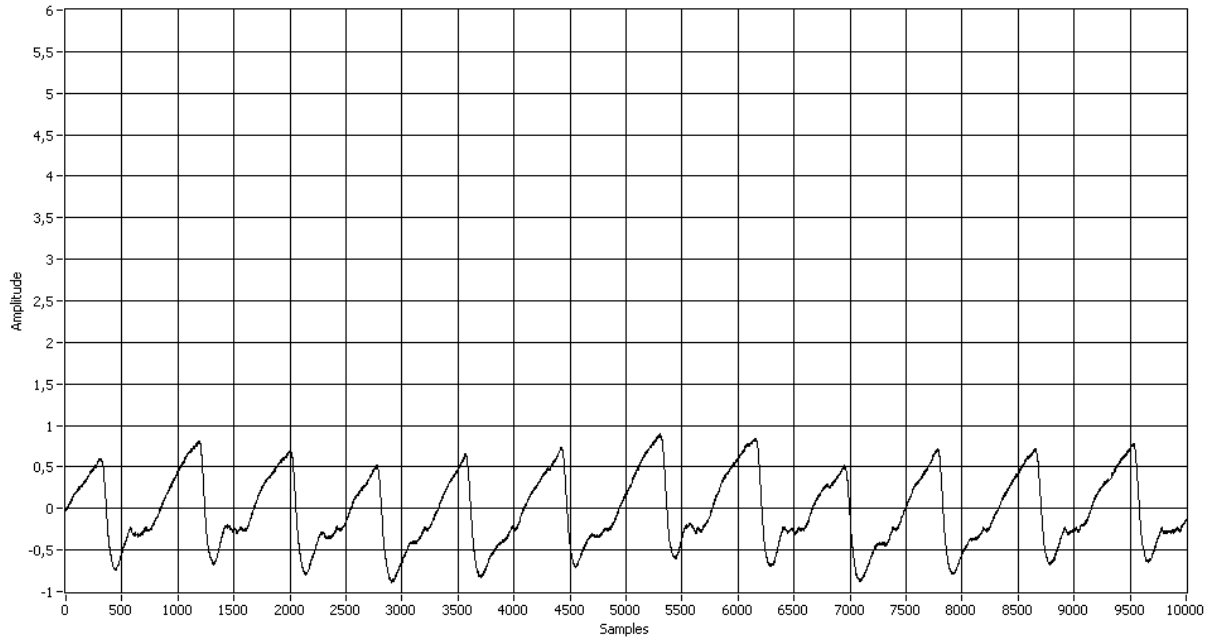

Figure 32: Post inverting band pass filtering

When observing the curve prior to filtering it is clearly affected by noise that compromises the signal. The only information that can be extracted from the signal is a very crude representation of the heartbeats.

It is very difficult to see the opening and closing of the arteries and dicrotic notch. The dicrotic notch indicates when the arteries close (Webster). This information is of great importance when carrying out actual blood pressure measurements and is clearly visible in the filtered signal. The rise of the signal indicates the opening of arteries as blood flows from the heart and the notch when the signal amplitude starts decreasing indicates closing of the arteries.

The cut-off frequencies of the active band pass filter where chosen so that the frequency of the heart rate would be within the pass band. The heart rate for humans varies depending on physical fitness and health of the person. The variance of the heart rate can be seen in Table 2.

Table 2: Heart Rate Chart - Babies to Adults (Source: (Heart.com, 2009))

Age	Beats Per Minute (BPM)
Babies to Age 1	100 - 160
Children ages 1-10	60 - 140
Children age 10+ and adults	60 - 100
Athletes	40 - 60

The lower cut-off frequency suppresses the lower frequency contents. This leads to the signal having a more distinct slope when rising and enables detection of every single pulse. The higher cut-off frequency of the filter ensures that noise from surrounding light to be suppressed. Since the photo-cell sensor consists of light sensitive devices, miss leading information could occur due to for example light from the surroundings such as a light bulb or a luminous lamp.

According to Webster (Webster) the bandwidth requirement for the pass band is DC to 20 Hz when assuming a heart rate of 120 bpm which corresponds to a heart frequency of 2 Hz according to the following relation

$$\left(\frac{Heart\ Rate[bpm]}{60} = Heart\ frequency\right) \quad (9)$$

This means that the higher cut-off frequency for a pass band intended for this application is 10 times the heart frequency.

In combination with Table 2 the following requirement was derived; since the highest heart rate when being at rest is 160 bpm, which corresponds to a heart frequency of approximately 2.67 Hz $\left(\frac{Maximum\ Heart\ Rate[bpm]}{60} = \frac{160}{60} \approx 2.67Hz\right)$. This means that the higher cut-off frequency should be at least ten times the maximum heart rate frequency (26.7 Hz), in this case the majority of heart rates could be detected.

6.2.7 Final amplification and Level shifting

A function specific for the PPG measurement is to be able to move the baseline of the obtained signal to enable visualisation of measurements from different fingers in order to compare and see if there are any differences between the two measurements that are carried out simultaneously.

This stage of the measurement should also provide the required amplification needed to make the signal visible and clear for readings, but the signals will have different amplitudes due to that signals will vary from person to person. Hence the amplification should be variable so that the person performing the measurements can adjust the amplification to an appropriate level that enables reading of the signals obtained when performing measurements with the PPG-sensor.

Figure 33 shows the basic idea of the construction of the level shifting stage created by using an Op-amp circuit.

Since the op-amp has differential inputs, an inverting and a non-inverting input, the signal that is amplified is actually the difference between the voltages at the two inputs expressed in equation 10.

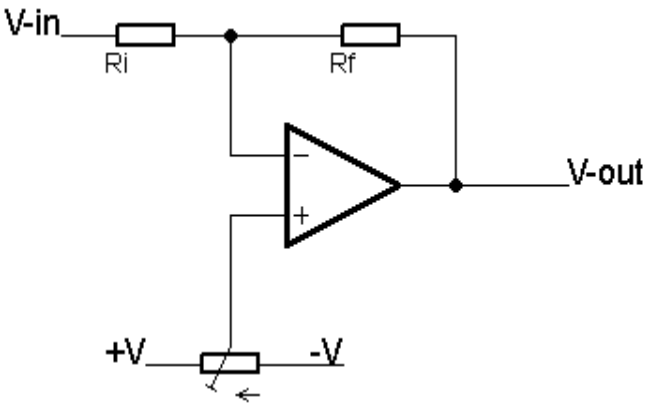

Figure 33: Levelshift circuit where the signal that is to be shifted is V_{in}

$$V_{out} = -\frac{R_f}{R_i}V_{in} + DC_{shift} \qquad (10)$$

Where v_{i1} is the non-inverting input and $v_{i2}$is the inverting input and v_{id} is the differential that will be amplified (Hambley A. R., 2000).

By applying the differential property of the op-amp that is expressed in equation 10 it is then possible to shift the base line of the signal, which is of interest, by applying a reference voltage at the non-inverting input of the amplifier as shown in Figure 33.

The idea was that the reference signal should be set by the user, so a potentiometer was used in order for this to be fulfilled. The potentiometer has a positive reference voltage connected to one of the pins and a negative reference voltage at the other pin. So the reference voltage will be set by linearly dependant of the resistance cross the potentiometer. In other words, the reference voltage at the non-inverting input of the op-amp will vary when the resistance is varied by trimming. This will result in a change of the baseline for the signal V_{out} as shown in Figure 34.

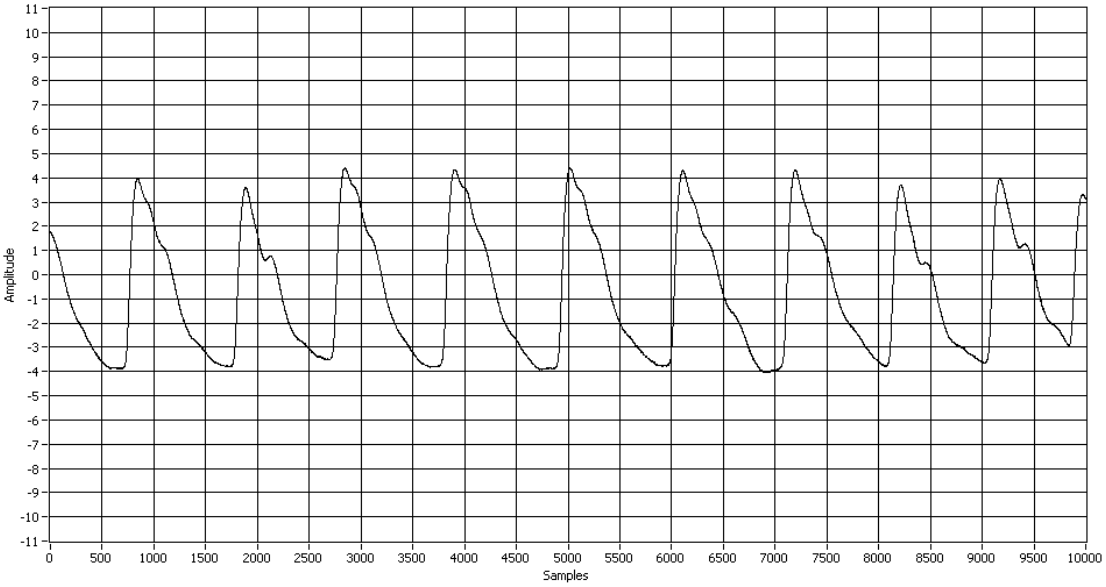

Figure 34: Result of amplification due to level shifting, the signal is also shifted by the user so that the base line is at -4 Volts instead of 0 Volt.

The level shifting stage should also provide a final amplification of the signal from the PPG-measurements. Therefore a feedback resistor and an in signal resistor is part of the circuit. But the amplification of the signal should be variable since the signals from the measurements would vary for every test. This was solved by enabling switching of the feedback resistor to cover a certain span of amplification.

6.3 Strain gage with Bridge Circuit, Amplification and Filtering

The task that was to be solved was how to obtain the signal that the strain gage would produce due to changes in its geometry in terms of elongation. Also an electrical calibration of the device should be constructed, that should mimic a certain percentage of elongation of the strain gage.

All the steps that were taken in order to succeed with the application and achieve reasonable results will be presented and described in this chapter.

An appropriate measurement configuration must be constructed in order to obtain the signals provided by the sensor.

As explained in the theory section it is possible to use bridge circuit configurations to apprehend the requested signals that are generated due to changes in the sensor, but this is not enough. There is also a need for amplification and appropriate filtering since the variations are small and the noise is rather great.

6.3.1 Four-terminal sensing connection

There are several types of bridge circuits and configurations of these; the type of bridge circuit that was chosen to be used to obtain the information about the elongation from the strain gage device is a Wheatstone quarter bridge.

The main reason for this is that the quarter bridge is sufficient for this purpose since the other configurations of the Wheatstone bridge are mostly preferred when dealing with temperature dependence or other types of "disturbances" that may affect the outcome of the measurements.

The theoretical circuit model of the Wheatstone quarter bridge can be seen in Figure 4, where the Rx element in the circuit represents the sensor that is used for measuring the expansion of the limb that is of interest for the measurement.

Figure 4 of the quarter bridge is merely the theoretical and most basic model of the configuration of a Wheatstone bridge as previously mentioned. There are additional improvements that can be done in order to acquire the signals in their raw form.

The modification that was done to acquire a good quality measurement was a so called Four-terminal sensing connection, as shown in Figure 35. This method eliminates the influence from the leading wires that are connected to the electrodes on the strain gage. The wires have an internal resistance and inductance. Since it is the voltage drop over the strain gage due to changes of the geometry that are to be measured, it is of great importance that there is no undesired voltage drop due to impedances in the leading wires.

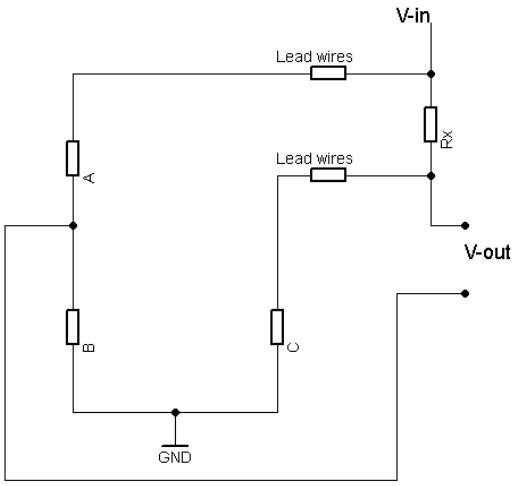

Figure 35: Circuit of Four-terminal sensing connection implementation using a Wheatstone quarter bridge

6.3.2 Amplification

When detecting the changes of the voltage drop across the strain gage an instrumentation amplifier was used to amplify the voltage obtained as a result of the voltage drop across the strain gage. The reason for this is that the instrumentation amplifier is easier to handle and is more accurate than a differential amplifier (for more information about differences between the two amplifier configurations see chapter 3.2 Operational amplifier applications).

The amplification of the signal was carried out in three different steps. The first stage of amplification was provided by the instrumentation amplifier, which is a pre amplification stage. The second stage of amplification was due to the active low pass filter and then a final amplification that had an adjustable gain that could be set by the user.

The amplifications where divided into appropriate magnitudes for each step since the final amplification step was supposed to be used for the signals obtained by both the strain gage measurements and the measurements conducted with the photoplethysmography.

The total magnitude of the amplification was decided in consideration for fulfilling certain calibration requirements. The requirement was that 0.5 mm of elongation should correspond to a 1 Volt increase of the signal output.

The magnitude of the gain for each amplifier stage was then decided and constructed in order to fulfil this requirement and the requirement posed for the photoplethysmography unit. The amplification provided by the active filter and the final stage where constructed to fit for both the strain gage measurements and the photoplethysmography and are the only stages that the two measurement systems have in common.

Hence there was only one amplifier stage that could be constructed for the sole purpose to fit the strain gage, this was the initial amplification provided by the instrumentation amplifier stage. This required an instrumentation amplifier that could cover a great range of amplification so the pre amplification could be guaranteed to be high prior to filtering and the final amplification. The amplifier should not have a single ended supply in order to cover a voltage output range of both positive and negative voltages.

The amplification for an instrumentation amplifier varies depending on the construction hence the equation for the amplification varies from model to model. The equation for calculating the gain for the instrumentation amplifier used in this construction is presented in equation 11.

$$V_o = \left(1 + \frac{100k\Omega}{R_G}\right) V_C \qquad (11)$$

Where R_G is the resistance used to obtain the gain that is preferred. The value of R_G is chosen according to a table that suggests different values of the resistance for achieving the desired gain (Analog Devices, 1999). This relation is provided from the datasheet for the instrumentation amplifier used.

6.3.3 Filtering

An active low pass filter was chosen when filtering the signal obtained by the strain gage measurements.

The filter chosen was a first order active low pass filter that provides the additional gain required.

The reason for using a low pass filter is that the variations that are of interest are of very low frequencies hence only the low frequency parts of the signal will pass and the high frequency content that might be result of fluctuations and impurities in the signal get suppressed. This is clearly visible when comparing Figure 36 and Figure 37.

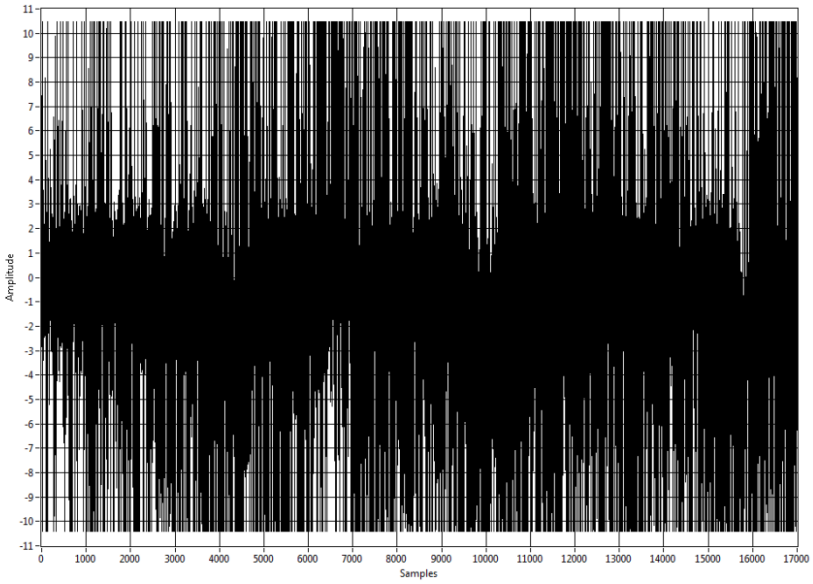

Figure 36: Signal before low pass filter.

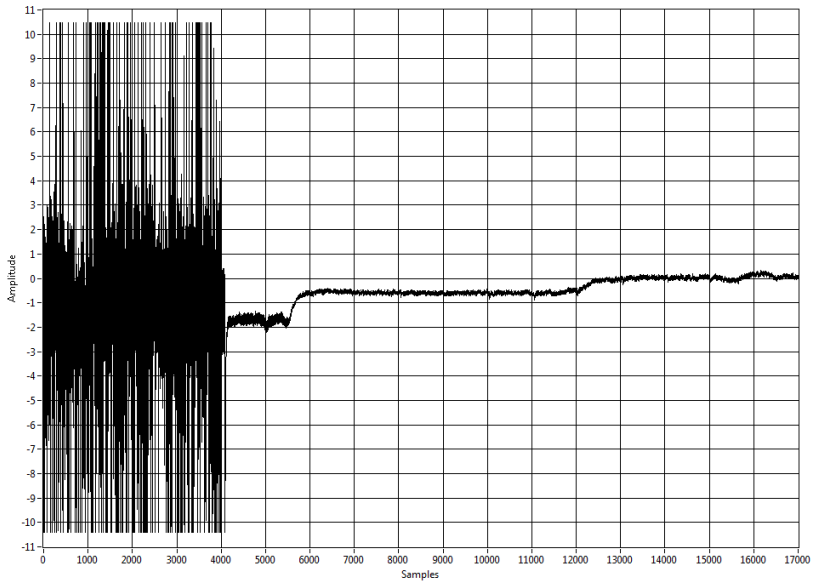

Figure 37: Here it is clearly visible that the high frequent noise is removed when the low pas filter is used.

6.3.4 Balancing

Usually devices that are used to perform these types of measurements are constructed to suit a certain span of strain gages. The strain gages usually come in different sizes depending on the application as well as manufacturer. These are used for the forearms, calf's, thighs and chest. Each of the strain gages have a certain inner resistance that is taken into consideration for the bridge circuit since all the other elements in the bridge are chosen to fit the strain gage used for the measurement. Hence balancing is used to put the bridge back into a state of equilibrium that leads to the output voltage to be zero. The balancing is usually done by replacing one of the elements in the bridge arm on the opposite side of the bridge arm where the strain gage is placed with a potentiometer.

The potentiometer will have a varying span of resistance suitable for the bridge circuit and can hence be used to set the bridge back into state of equilibrium or out of balance depending on what is to be measured. Since the device should be independent to any type of strain gage it is of great importance that the balancing of the bridge circuit could be performed for a varying span of strain gages provided from different producers. This led to yet another modification of the bridge circuit where wide range of resistance values should be covered. Hence a potentiometer that could cover the whole span of resistances independent of producer should be used and should be connected in consideration to make the balancing rather easy to conduct.

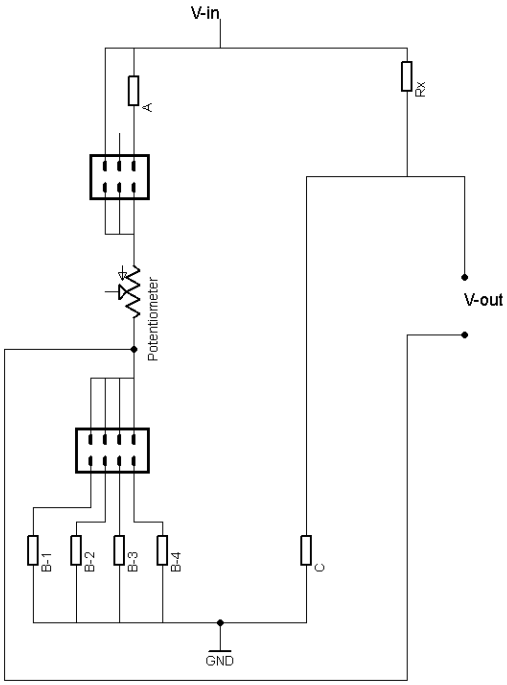

Figure 38: Schematic image of the bridge balancing circuit.

The additional modification made to achieve this goal was to counter balance the bridge by adding resistors in series and in parallel on the same side of the bridge as where the balancing potentiometer is connected. A visualisation of this can be seen in Figure 38. With this configuration it is possible to cover a great range of strain gages with various resistances depending on the values of the other elements in the bridge circuit. The counter balancing is done by connecting or disconnection any of the resistors *B-1* to *B-4* in combination with choosing to have resistor A in series with the potentiometer. The resistances *A* and *B-1* until *B-4* are used to set the range in which the potentiometer should operate in order to use it for balancing. The ranges can be seen in Table 3**.**

Table 3: The table lists the different ranges used to be able to handle a wide range of strain gages.

Range	Resistance values [Ohm]
1	0-2.6
2	2.4-3.6
3	3.3-5.6
4	5.3-11.7
5	11-28.2

6.3.5 Calibration

As mentioned previously in the theory section about the strain gage, the whole purpose of having a calibration is to simulate a certain amount of strain in order to compare this to the signals obtained during measurements and then back tracing it to how much strain the output amplitude corresponds to.

The task was to simulate two types of strains; the two strains were 1% and 0.1% elongation of the strain gage. The strain gage types used for these types of measurements are in the form of an elastic rubber tube with a galvanic solution that conducts a certain current as previously mentioned, where the resistance of the strain gage depends on the geometry of the tube. Since the resistance of a material actually depends on the geometry and resistivity of the material as seen in equation 12.

$$R_x = \rho \frac{l_0}{A_0} \tag{12}$$

Where A_0 is the cross-sectional area, l_0 is the length and ρ is the resistivity of the material, which is equal to the invers of the conductivity, and R_x is the resulting resistance of the material. This could be rewritten as the following

$$R_x \sim \frac{l_0}{A_0} \tag{13}$$

Where the resistivity is not taken into consideration and the only parameters that are of interest are the ones that are dependent of the geometry. The resistance of the strain gage in neutral mode is referred to as R_x in this section and R_1 is the resulting resistance when the strain gage has been elongated and is expressed in the following way

$$R_1 \sim \frac{l_1}{A_1} \tag{14}$$

Elongation will result in a length increase but the cross-sectional area of the strain gage will hence decrease. The change of the geometric parameters will result in a change of resistance. The change of the geometry can be expressed through the following relationships.

$$l_1 = k \cdot l_0 \tag{15}$$

$$A_1 = \frac{A_0}{k} \tag{16}$$

Where k is the calibration constant, either 1% or 0.1% depending on what type of elongation that is to be simulated and l_1 and A_1 are the length and cross-sectional area of the strain gage post elongation.

The resistance that should be connected in parallel in order to simulate the referred percentage of elongation should fulfil the following requirement

$$R_1 \sim \frac{C \cdot l_0 \cdot k}{A_0/k} = R_x \cdot k^2 \qquad (17)$$

The total resistance of the lower right arm of the bridge should correspond to $\frac{C}{k^2}$ when connecting the shunt calibration resistance.

Figure 39 shows how the shunt calibration should be performed and where the resistance should be parallel connected to obtain the proper simulated elongation.

The shunt calibration will result in a unit step change in the measurement similar to a unit step-signal and will last for as long as it is connected. The purpose of this is to be able to express the elongations that occur during measurements in terms of the calibration to know how many percent of elongation that the strain gage have experienced due to the measurement.

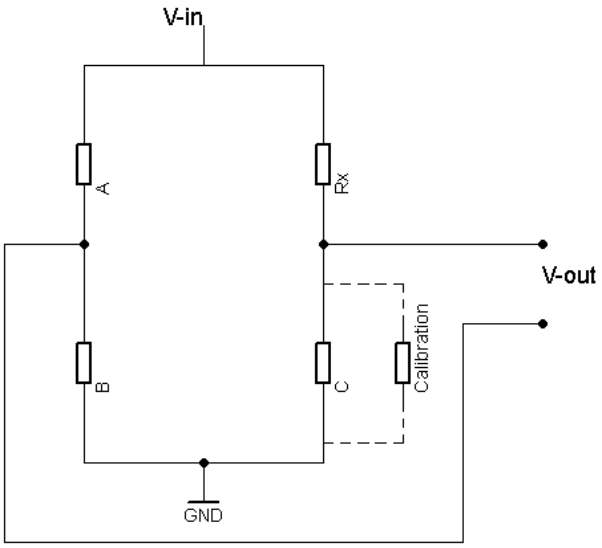

Figure 39: Circuit showing how the shunt calibration should be performed

6.4 PRESSURE SENSOR AND AMPLIFICATION

It is of great importance to know the pressure applied in the cuff or cuffs placed on the test subject. Usually the pressure is measured mechanically with the help of a manometer (Figure 40), but there are other ways to measure pressure which are not mechanical. In this case an electrical solution for measurement of the applied pressure was chosen (Figure 41). This device consists of a Wheatstone full bridge configuration, where all the elements in the bridge are active; the schematics of such a configuration can be seen in Figure 6.

Figure 40: A manometer used to measure pressure.

The signals obtained during the measurements of the pressure have small amplitude and are in need of amplification so that a certain amount of pressure in the unit of mmHg corresponds to a certain amount of volts. Then a rescaling of the voltage signal to back to pressure is done in Perivasc©. The calibration of the voltage output due to pressure was done by applying a known amount of pressure and regulating the gain of the amplifier to correspond to a desired voltage level. This was done with the help of a manometer to know how much pressure that was applied and a tank to keep the pressure at a steady level.

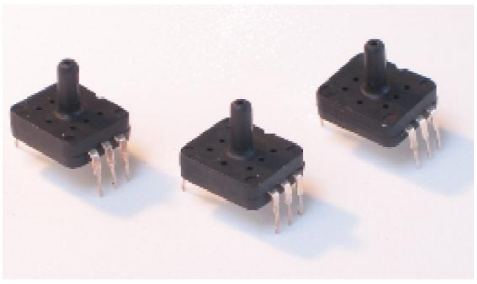

Figure 41: Analog pressure sensor (SPD015G from Smartec), consisting of a wheatstone full bridge.

The signals where obtained and amplified with the help of an instrumentation amplifier, the same type as the one used for the strain gage measurement and the gain was decided with the help of equation 10.

The pressure signal is recorded simultaneously with Perivasc© as either photopletysmographic or strain-gage measurements are done. This can be seen in Figure 56, and is represented by the yellow curve.

6.5 FRONT PANEL

From the front panel it should be possible to do some adjustment to the system. Such as changing cut-off frequencies on filters, change the amplification as well as adjustments for different strain gages. It should also be possible to shift signals and to see if they are in measuring range by only looking at the front panel since it might not always be possible to see the computer screen while setting up a patient for measuring.

Since the design of the front panel was not a part of this project only the functions that are possible to have on a front panel are briefly described without any consideration for the aesthetics and appeal for user friendliness and commercial purpose.

The things that are possible to add to a front panel are listed and shortly described here.

- **Switch between strain gage and photo-cell** sensor **-** The system itself should be able to sense if the sensor connected is a Strain gage or a photo-cell sensor and the user therefore does not need to do anything but plug in the sensor that they want to use.
- **Cut-off frequencies -** This function will mainly be used in research applications. From the front panel it could be possible to change the cut-off frequency of the active band pass filter and the active low pass filter depending on the measurement system that is in use.
- **Amplification -** It will be possible to change the amplification of the signal obtained during measurements. There is the possibility to have five different levels of amplification where level two is supposed to be used on people that are considered to be healthy when performing measurements with the photo-cell sensor and level three when performing measurements with the strain gage.
- **Baseline shift -** It is possible to shift the signal from both channels along the y-axis with a nob. For the photo-cell signals this can be done with only one control, meanwhile for the strain gage two controls are needed. This since the system is constructed to handle strain gages of many different lengths and different lengths yields different resistance values.
- **Bridge balancing –** The same nob as used for baseline shifting of the PPG-signal is used for balancing when performing measurements with the strain gage. The function of the nob is dependant of the switch used when selecting the type of measurement that is to be conducted. The nob is used in combination with a "counter balancing" switch to ensure that the user is within the right range.
- **Calibration –** The calibration could be done by using a toggle switch for choice of that type of strain that should be simulated prior to signal recordings.

The last thing that could be implanted on a front panel are five light emitting diodes that can be used as guideline for the user when balancing the bridge during strain gage measurements or shifting the baseline during PPG measurements, these will be described in greater detail in the following chapter.

6.5.1 Range Indication With Help of Light Emitting Diodes

There is a possibility to add five light diodes to the front panel, illustration can be seen in Figure 42, to help the user balance the bridge circuit for the strain gage sensor. These diodes are also used to indicate if the signal from the photo-cell sensor is in the range where measurements may be performed.

Figure 42: Illustration of the diodes that could be placed on the front panel as a help for the user. These could be in any colours which here are symbolised with black and grey. The diodes are numbered 1-5 from left to right.

Only one diode at a time should be lit and they all represent a certain voltage level of the signal, but all the user needs to know is whether to turn the knob clockwise or counter clockwise to get the signal in the range. When doing measurements with the strain gage the diode in the middle symbolise that the bridge circuit is in balance. Whereas the outer ones symbolises that the signal is outside of the acceptable range for measurements. It is possible to perform measurements when any of the three middle lights are lit, but the one in the middle yields the best measurements. If the outer most diode to the left is lit the knob controlling the balancing should be turned clockwise and if it is the outer right one the knob should be turned counter clockwise. If it is impossible to balance the bridge circuit it is possible, by another control, to compensate for the specific resistance that the strain gage causes.

By using these indicators the user does not need to know that it is a bridge circuit that has to be balanced but simply encouraged to perform measurements when one of the three diodes in the middle is lit and then preferably the one in the middle.

6.5.1.1 Construction

Since there are four limits that are examined four comparators are needed. In Table 4 the logic values at each diode, as they result from each comparator output, for specific signal amplitude is given. For each comparator an appropriate comparison value was chosen. To ensure that only one diode at a time can be lit the logic shown in Table 5 was used and in Figure 43 a schematic image of the resulting schema can be seen.

Table 4: The logic values at each comparator output when one of the five diodes should be lit. The four comparators are labelled a to d.

Signal (s)	**(Diode 1)** **s < a**	**(Diode 2)** **a < s < b**	**(Diode 3)** **b < s < c**	**(Diode 4)** **c < s < d**	**(Diode 5)** **s > d**
< Lower outer limit (a)	0	1	1	1	1
< Lower inner limit (b)	0	0	1	1	1
> Higher inner limit (c)	0	0	0	1	1
> Higher outer limit (d)	0	0	0	0	1

Table 5: Logic needed for lighting the right diode given a signal. This table uses the information given in Table 4.

Comparator values when a diode should be lit	**Logic**
Diode 1 => a=0	a
Diode 2 => b=0 a=1	(b nand b) nand a
Diode 3 => c=0 d=0	(c nand c) nand b
Diode 4 => c=1 d=0	(d nand d) nand c
Diode 5 => d=1	d nand d

As described earlier four limits were chosen to be represented with five LED's (light emitting diodes). To control the signal voltage a comparator is needed for each limit. A truth table was created for the different cases (Table 4). From this table conclusions about the logic needed to light each diode when the signal is in that specific range is given. These conclusions are seen in Figure 43. In both these tables it is assumed that a diode is lit when the logic results in low (0) logic signal. The reason for this is not to load the logic circuits, which might then not be able to hold the right logic levels for their output signals, as this would be the case if the diodes were lit on ones. The diodes are instead powered by current supplied by V-ref, which is shown in Figure 43. The logic gate chosen for this application is a CMOS logic gate with an open drain output. All outputs, from comparators and logic gates (that are followed by another logic gate), are connected to a resistor with an appropriate value, this is called a pull-up resistance and are describe further in the theory chapter 3.4 Logic.

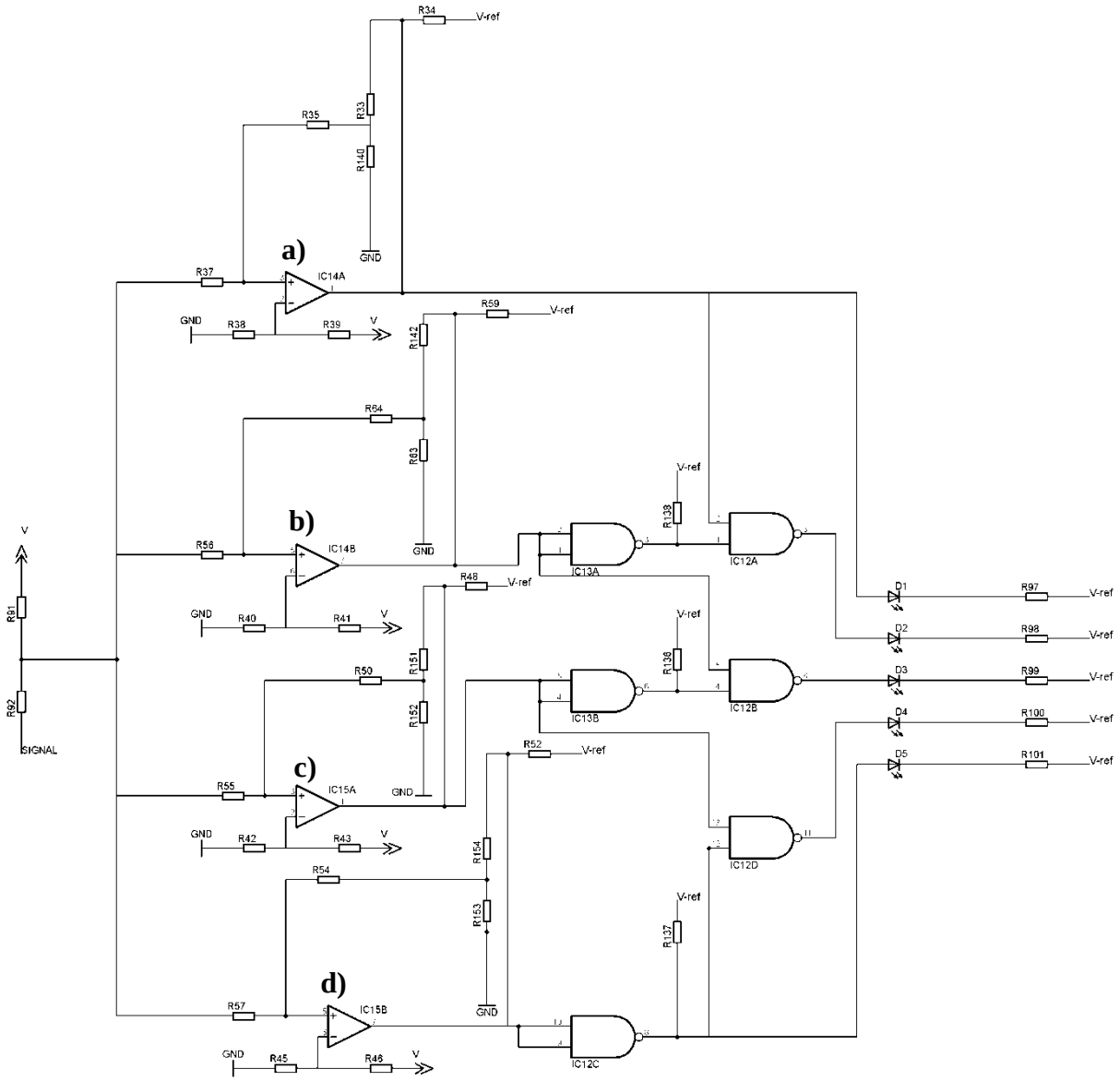

Figure 43: Schematic image of the comparators and logic circuit used for controlling the diodes. Here complete with signal scaling and pull-up resistors as well as hysteresis.

6.5.1.2 Input- and reference signals

The comparators can work with signals that are +-0.3 Volts smaller or greater than the supply voltages. To minimize the current it was chosen to use only positive voltages as supply, this means that all signals must be greater than zero for the comparator to work. The input signal is therefore shifted using two resistances, of the same value, in series to +15 Volts , as seen in Figure 43, and the input signal to the comparators are taken from the middle of these. This shifts the signal from a range that includes negative values to one that only includes positive values. The appropriate reference signals for the limits were measured and the right resistances to create these calculated. For the outer limits, with the hysteresis in mind, great care was taken so that the diodes are lit before the signal reaches the outer limits.

6.5.1.3 Noise sensitivity

To make the comparator diode circuit less sensitive to noise a positive feedback is implemented to draw advantages from the comparators hysteresis. Without this it would be possible for more than one front panel diode to be lit due to the overlapping of the intervals for high and low when the signal is equal to one of the limits. The diodes are then turned on and of faster than what the human eye can perceive, and it then appears as two diodes are lit.

Another important aspect to why it is important to have hysteresis is to limit the current consumption. More than one LED indicator could be lit if the signal is noisy and hysteresis is not implemented.

For the comparators used in this implementation the hysteresis is chosen to be approximately 200mV, which is small enough to not affect the performance and great enough to ensure that only one diode can be lit at a time. This is adjusted by configuring the values of the resistances in the feedback of the comparators.

6.6 SOFTWARE FOR TESTING DURING DEVELOPMENT

The software constructed for use during the development and test phase of this project were programmed in LabVIEW, which is a graphical programming environment (National Instruments, 2011). The test software and its functions are described below.

6.6.1 Communication and isolation

The communication between the program on the PC and the system is done using a PHI-card from EBIDA. This card is connected to the computer using an USB cable. The PHI-card allows communication in two directions as well as supplying the system with power. Through the USB 2.0 port used 500mA can be drawn and 5 Volts is distributed (USB Implementers Forum, Inc., 2000). More detailed information about the DAQ-card (DAQ 6009) can be found in the user guide (National Instruments, 2008).

Since the systems power supply is the USB port on a PC the patient safety isolation can be solved with the use of a special USB isolation device that is placed between the USB port and the electronics that is to be isolated.

6.6.2 Software features and functions

The test software has evolved during the course of this project and more functions have been added when a new need appeared. Here the final version and its features will be described. Since the software is programmed in LabVIEW it is easy to add and remove features as the need changes as well as to change the appearance of the graphical interface. This due to the simplicity to communicate with the hardware are the main reasons why LabVIEW was chosen as the programming language. The user interface as displayed in Figure 44 and Figure 45.

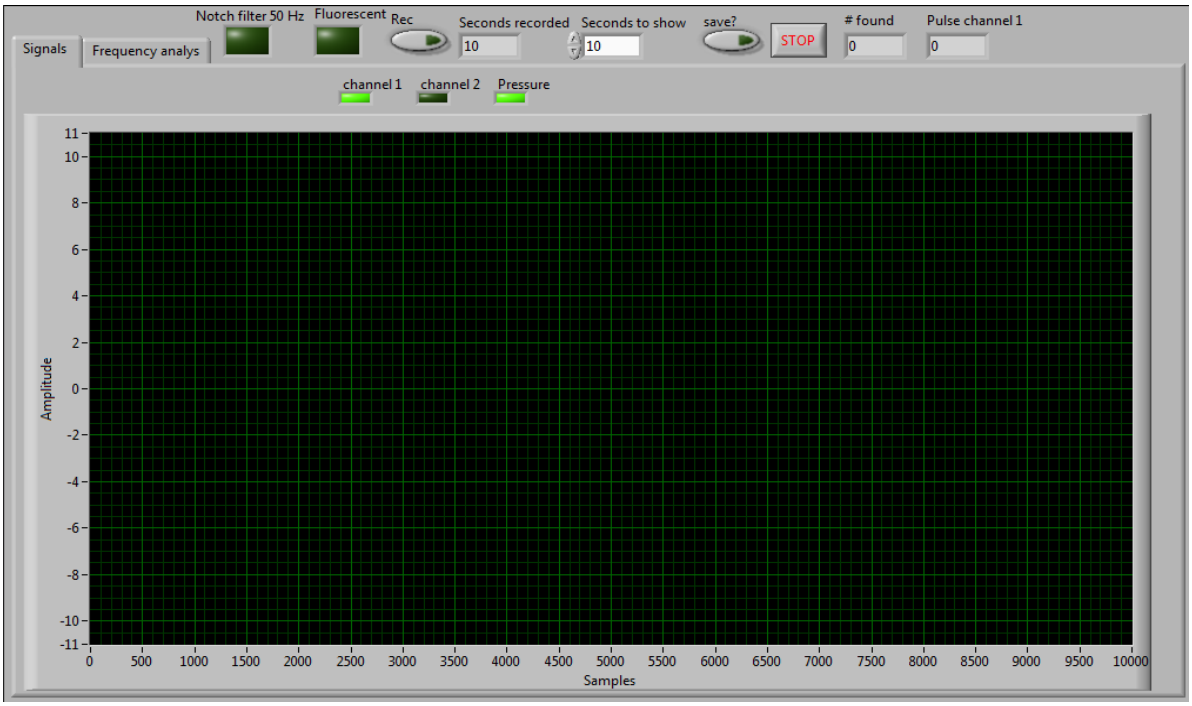

Figure 44: The user interface of the test software showing the window used for signal analysis.

Readings are made from the PHI-card by a sampling frequency of 1 kHz which is the same as thousand samples per seconds. The signals are processed and displayed concurrently.

The software reads three signals from the DAQ-card, one pressures signal, one “left” signal and one “right” signal. These are then presented in the same graph. This even thou the system test setup cannot handle more than the pressure sensor and one more sensor attached at the same time. The third signal was mostly used to compare signals before and after filters etc. By measuring with the left and right signal on either side of for example a filter and plotting them in one graph it is easy to compare them and to analyse the difference.

For the graph it is possible to adjust how many seconds to display and to zoom in and out to get a better view of the signal to noise ratio. These are functions that are default for a graph in LabVIEW but what is not default is the possibility to add data each second when more is read and therefore a function for that has been designed. The number of seconds recorded is also shown. The default value for number of seconds to display is set to ten and the graph is updated once every second. Each new set of readings are added to the end of the set. And data are saved even if not displayed so that the user can analyse it at the end of the measurement.

The software also presents the possibility to save one or more of the signals to file to be used for analysis in different software’s or together with other signals. The signals are saved in such format that can be analysed in any program that can handle a spread sheet file, for example LabVIEW or MATLAB. A small program was also constructed in LabVIEW for this purpose alone, and was used to analyse the information from the measurements on the test subjects.

Also the number of peaks detected is shown as well as the number of beats per minute that they represent. This is only an average number and has been used only as a help to count the number of pulsations in the signal.

There are two filters in the software that can be activated through the graphical interface. These are represented by big green squares and are labelled “Notch filter 50Hz” and “Fluorescent”. These squares are a darker shade of green when not active and a lighter green when active. This was mainly used in the beginning of the project before the hardware filters were implemented and at that time they were more flexible. Since implementing filters in the software is straight forward this function were used to test cut of frequencies as well as to be able to preformed tests without implementing hardware filters.

There is also a possibility to study the frequency content of one signal at a time by choosing the tab “frequency analyse”, and it is easy to switch between the different signals by using the radio buttons called “Signal 1”, “Signal 2” and “Pressure”. This graph can be used to analyse if the hardware filters performed as expected and was also used before constructing the hardware filters to test the different cut-off frequencies in the software as shown in Figure 45.

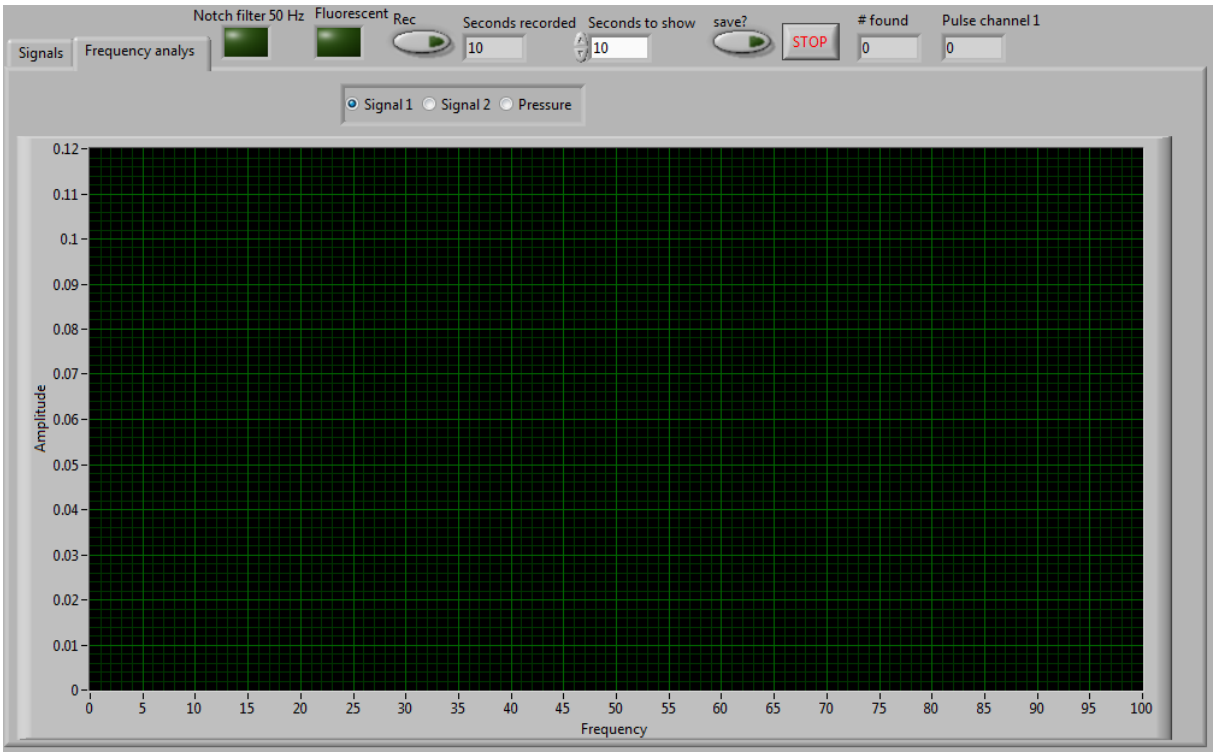

Figure 45: The test software showing the window used for analyse of frequency content.

6.6.3 Software usability

The focus for the graphical user interface was on functions and features instead of the aesthetic. The simplest graphical components were chosen and default colours were used. As seen in Figure 44 and Figure 45 all graphical components that are used to manipulate the signal or the visible content in the graph has a descriptive name so that it should be easy for the user to understand what their function is. When more signals are made visible in the graph they are in different colours and this is also the default colours.

The graphical interface is very compact and signals are shown in the same graph. The software was used on a laptop computer with a small screen and it was desirable that all functions are visible without scrolling and therefore a tab system was implemented. Another positive characteristic of a tab system is that most users are accustomed to it from other software applications.

7 VERIFICATION

The verification procedures that where performed to investigate whether the configurations that were chosen are appropriate or not for the intended use will be described in this chapter. The verifications where done under the supervision and guidance of a professional within the field to ensure that they were done as close to the clinical approach as possible.

7.1. PHOTOPLETHYSMOGRAPHY UNIT

First the signal amplitude for the photo-cell sensor prototype was verified using the test software designed during this project. After that, verification was performed using PeriVasc©, the software that the system will be used together with when used for diagnostic purposes in health care facilities. The photo-cell sensor prototype was also compared with a sensor that is commercial available and that is currently in use at different hospitals. This to be able to evaluate how the prototype performs compared with a sensor used today. All these different stages of verification will be described in greater detail in the paragraphs to follow.

7.1.1 Signal amplitude

At first, tests were performed to ensure that the prototype fulfils the requirements of signal amplitude for a person considered healthy. All measurements where preformed with what is supposed to be the default amplification that is supposed to be used with patient that are considered healthy. Measurements were done on a small test group and all measurements were conducted following this procedure;

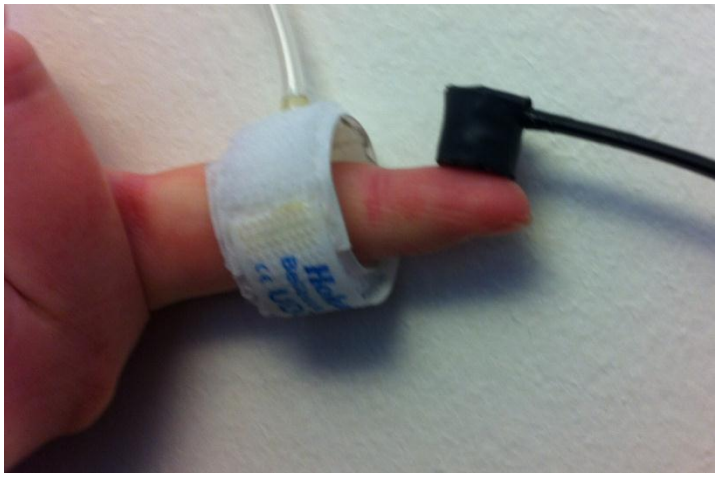

Figure 46: Placement of cuff and photo-cell sensor on finger.

Before the measurements can start the temperature of the test subject's hands are checked. If they appear cold the test person is asked to put the hands under hot water to raise the temperature. This since the measurements is sensitive to low temperature and that might result in very weak signals or none at all. After that they are placed on a chair and the photo sensor is placed on the left hands index finger (as seen in Figure 46). The test person is told to sit as still as possible during the measurement since the sensor is sensitive to any movement. A measurement is recorded for approximately three minutes and is saved in a file for further analysis. Amplitude is noted as well as the time interval with typical pulses (Figure 48).

The results from these measurements were then analysed and compared to get information about the average signal amplitude. A range interval for the amplitude was decided upon together with the main stakeholder. The reason for doing this is that it should be possible to change the amplification of the signal from the front panel of the system. The number of different amplification steps was agreed upon so that they are a reasonable number so that the system still is user friendly as well as still able to handle the smallest signals, but it is not just the weak signals that the system should be able to handle. Since the strength of the pulsations differs from person to person the system must not go out of range if measuring on a person with stronger pulsations than average.

After analysing the results from these measurements the different levels of amplification was agreed on as well as the default amplification, used on people considered healthy.

The amplitude of the signal from the test group was derived from the knowledge about the measurement range for the hardware used for acquiring signals from the system. When the amplification is set on default the amplitude should be high enough for the signal to be analysed but not so high that the signal is out of range.

7.1.2 Photo-cell Sensor

To verify the PPG-system, measurements were performed on test subjects with the developed photo-cell (Version 3) as well as a commercial available sensor. Both sensors were used together with the system designed and measurements with both sensors were done on each test subject and on the same finger. Results from some of these measurements will be presented here. To get better readings measurements were also performed on the circulatory system when the test subject was provoked. All measurements were performed using the program PeriVasc©.

In Figure 47 a measurement of blood pressure in the left index finger with the developed photo-cell (Version 3) is shown and in Figure 48 the same measurement on the same person and finger but with a commercially available sensor is shown.

Also during these measurements the cuff on the finger were connected to the pressure sensor as well as to a manometer so that it also could be evaluated. This measurement follows the procedure described earlier.

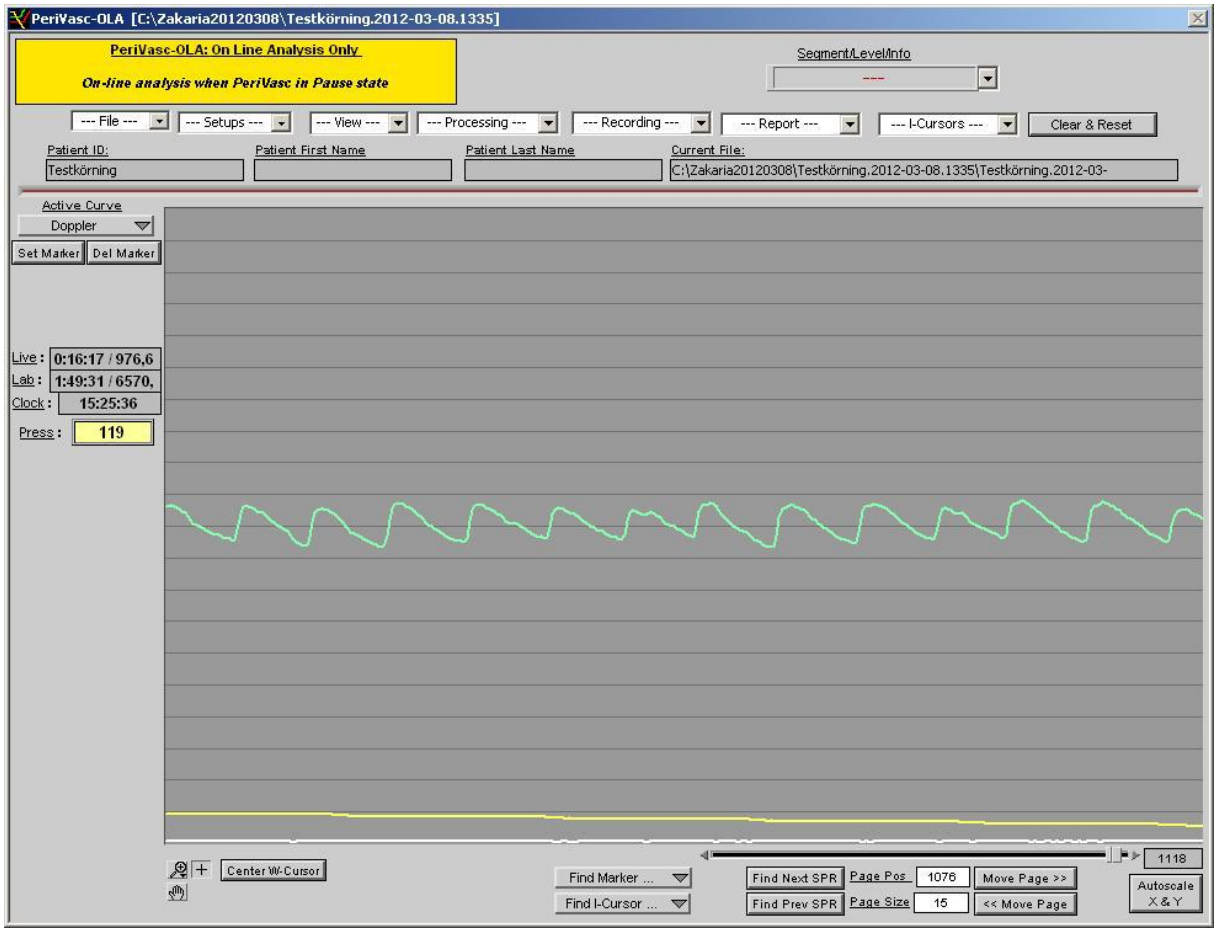

Figure 47: Readings from the prototype. The bottom curve is the cuff pressure and the one above is the signal from the photo-cell. Those curves that are left blank are not used for this evaluation. The pressure in the cuff when the pulses start to appear are 119 mmHg.

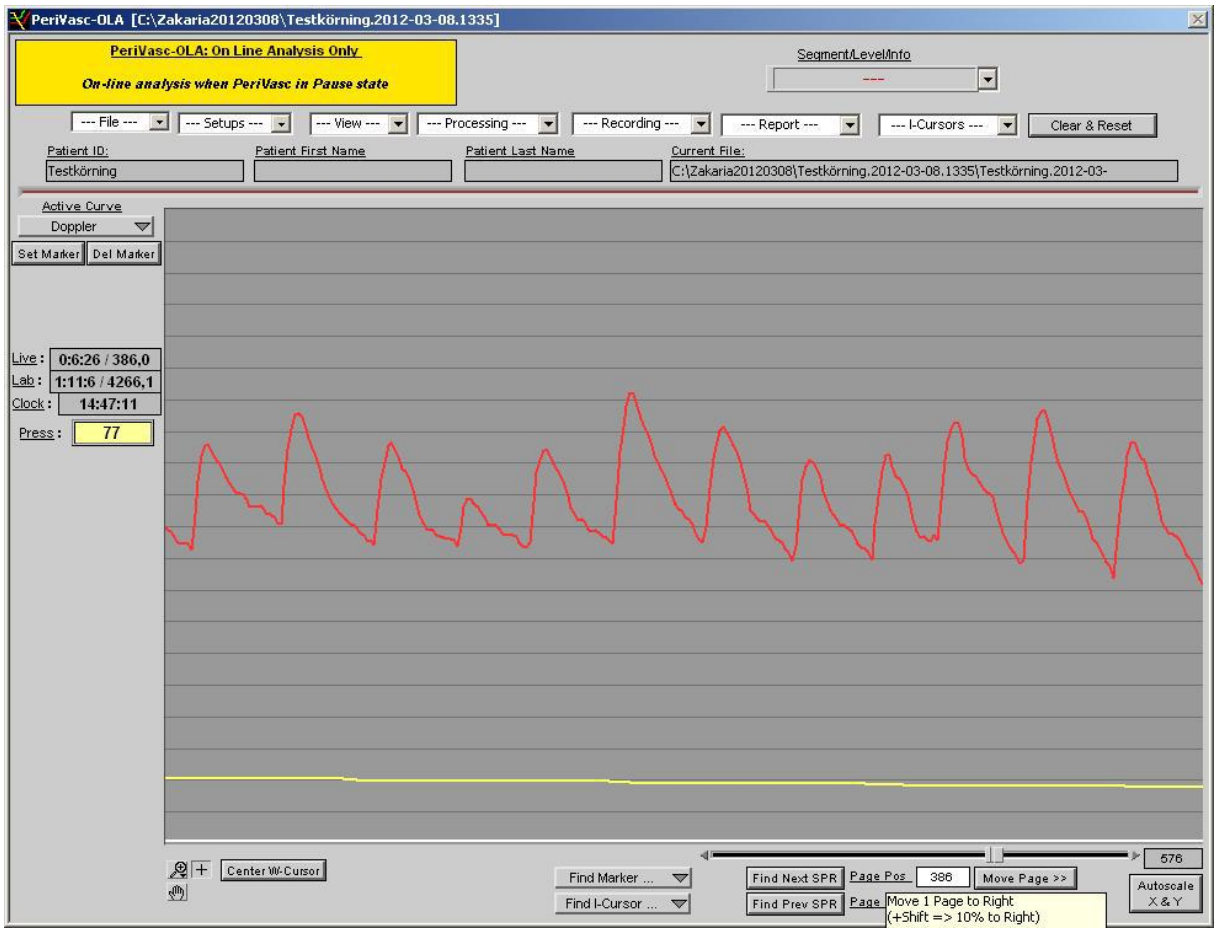

Figure 48: Measurement of blood pressure in index finger using a commercially available sensor.

It was soon established that the commercially available sensor was more sensitive to disturbances from the environmental such as light and movements. It was also established that the prototype could detect weaker pulsations. It is not possible to compare the signal amplitude in Figure 47 and Figure 48 since the program is auto scaling the window to make the signals easier to view. The amplitude was analysed and compared while the program was running but as said cannot be compared in the images as they are here.

As mentioned earlier, measurements were also performed after provocation of the test subject's circulatory system. This was to get stronger and more distinct signals for analysis and easier comparison. The provocation was accomplished by;

- Holding the test persons hand in a position higher than the heart and pressing on the finger to stop blood from entering
- Inflate the cuff placed on the finger
- The arm lowered
- Attach the sensor
- Slowly decreasing the pressure in the cuff

Since the finger was drained of blood before measurements the pulses, when starting to appear, are stronger.

The result from these measurements can be seen in Figure 49 and Figure 50. When comparing these images with those from measurements with no provocation it is easy to see how much more distinct the pulsations appear after provocation.

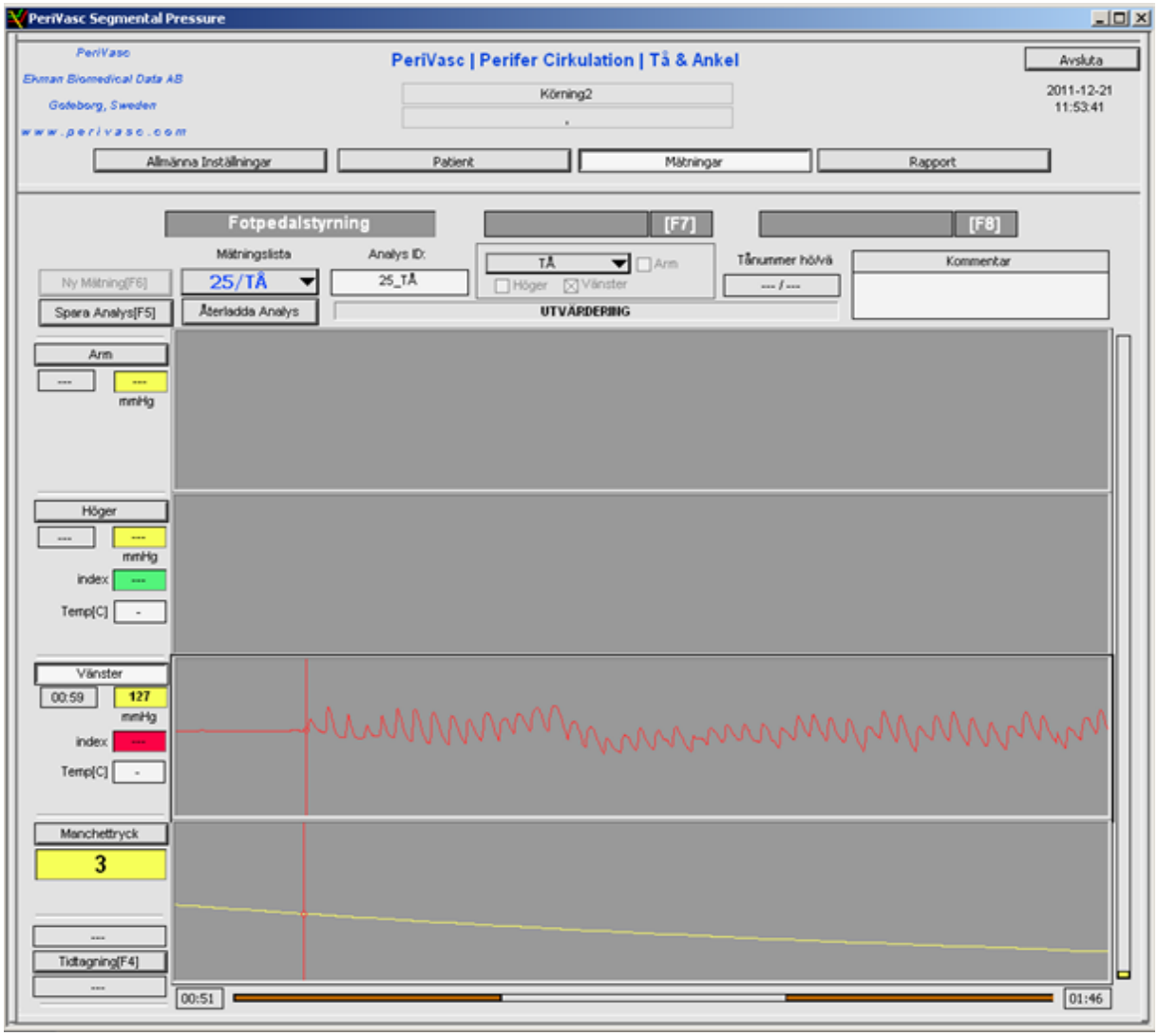

Figure 49: measurements with photo-cell sensor prototype after provocation.

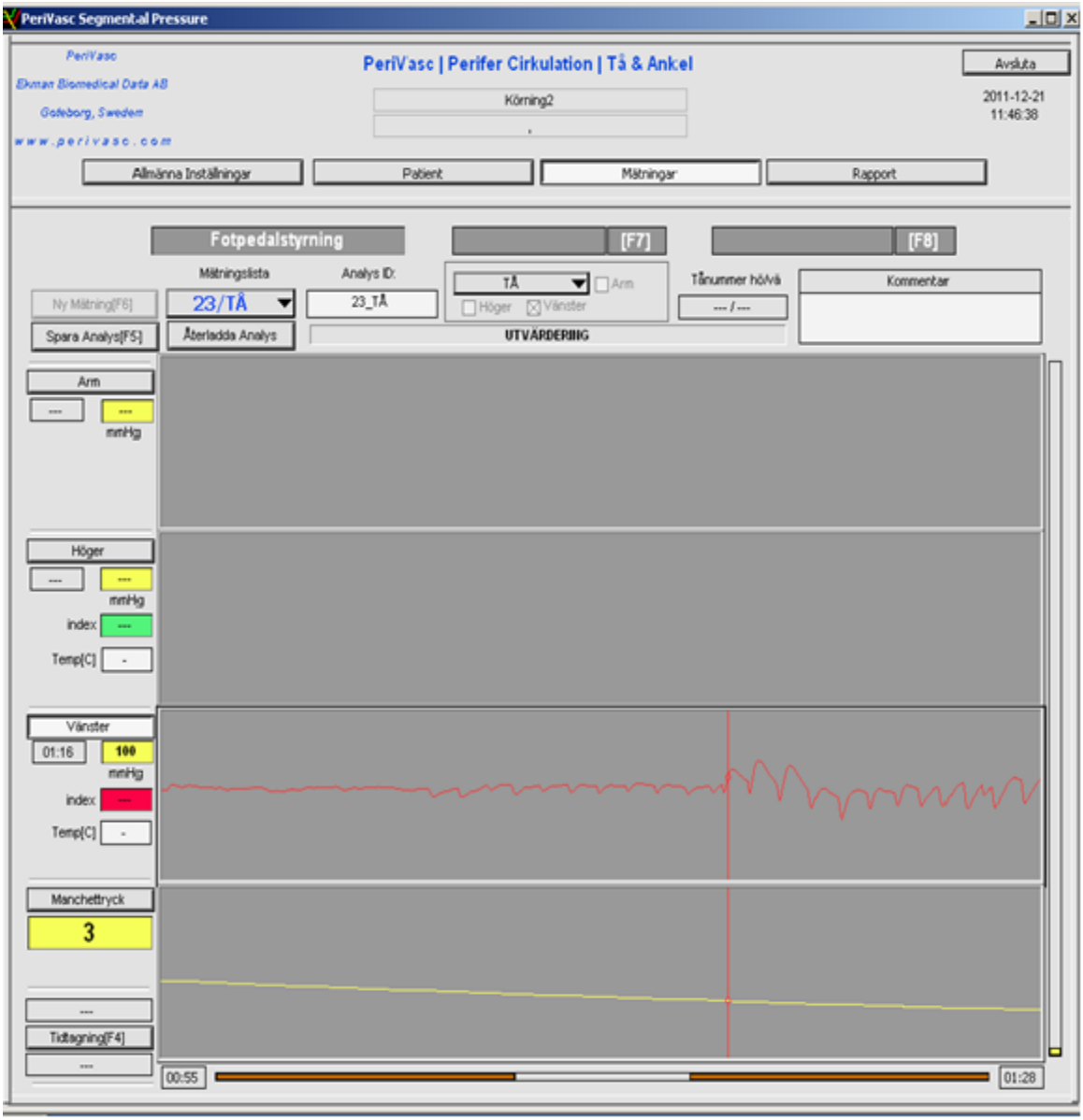

Figure 50: Measurement with a commercially available photo-cell sensor after provocation of the circulatory system of the test subject.

The signals from the prototype is less affected by noise than the sensor used for comparison. Also in Figure 50 the pulses are compressed and mirrored.

Some of the difference in appearance might be due to that the system is configured and optimized to the signals from the prototype, but still the signals are of the same frequencies so that cannot be the cause.

From the tests with and without provocation it was concluded that the prototype performance can match other sensors well and in most cases even performed better.

The same type of procedure as described previously was done when performing measurements with the final version of the system, and the results can be viewed in Figure 51. The system blood pressure of the test subject was measured to 120 mmHg. The measurement was done while the arm of the test subject was raised, this results in a drop of the blood pressure by 1.3*the height distance from the heart.

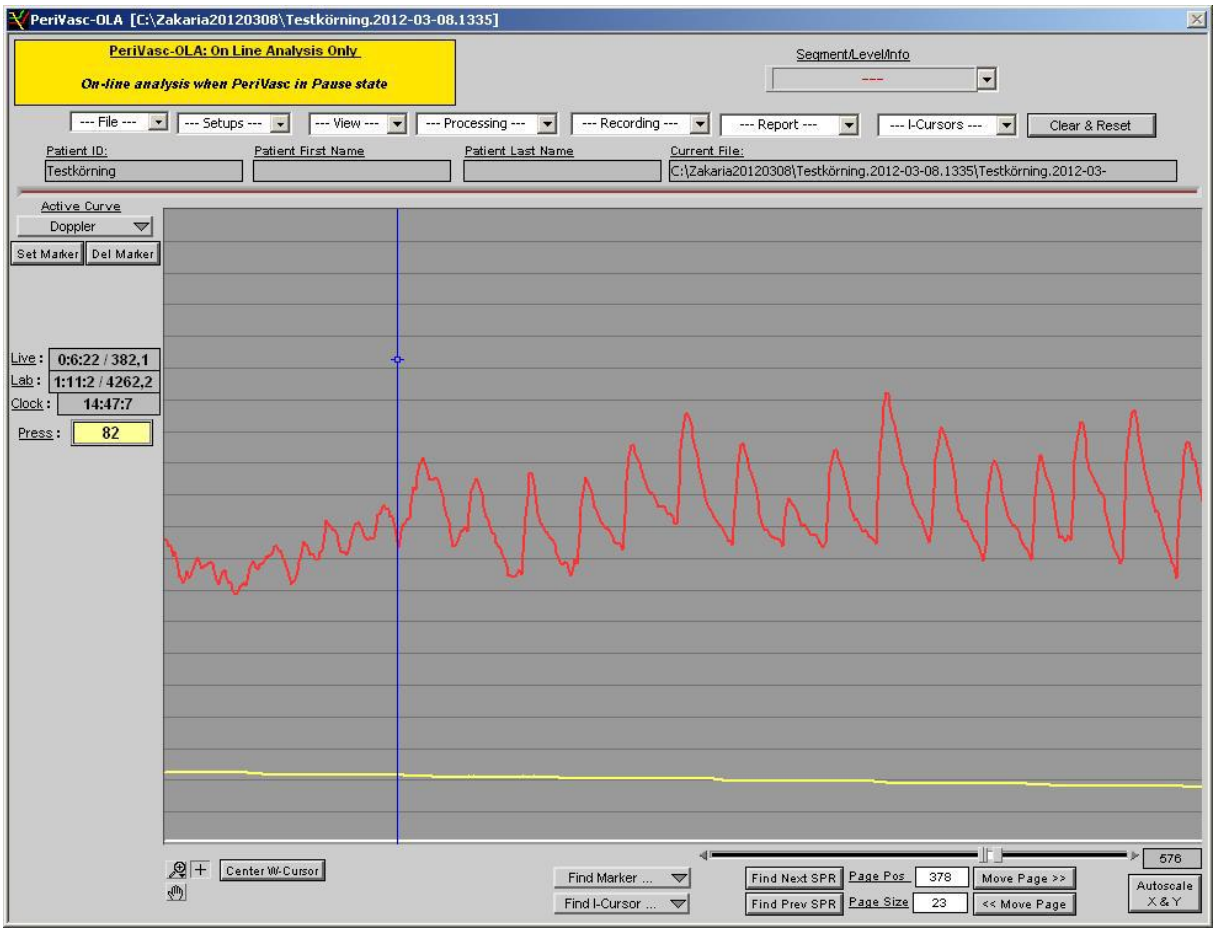

Figure 51: Measurement with a commercially sensor on the final measurement device.

7.2. STRAIN GAGE UNIT

Verification of the strain gage solution that was implemented will be presented in this section. The verification consists of mechanical calibration requirement, electrical calibration and pletysmographic measurements conducted according to clinical regulations, using the signal processing software PeriVasc© which is intended to be used together with the final product.

7.2.1 Calibration

The strain gage measurement system has two types of calibration, mechanical and electrical. The electrical calibration is a built in configuration described in 6.3.5 Calibration and the mechanical calibration are done externally by applying a certain amount of strain on the device, also described in the same chapter. The first verification to be done was the mechanical calibration by a millimetre screw. Each turn corresponds to a strain of 0.5 millimetres. The mechanical calibration is done according to the following procedure.

- The strain gage is connected to the millimetre screw calibration device
- Turned six turns clockwise for simulating tension with a short pause after each turn to see the deflection of each turn distinctively.
- The millimetre screw is now turned six times counter clockwise back to the starting point. If the calibration is successful the signal should now be at the same level as when the calibration first started.

The verification of the mechanical calibration performed according to the procedure previously described can be seen in Figure 52.

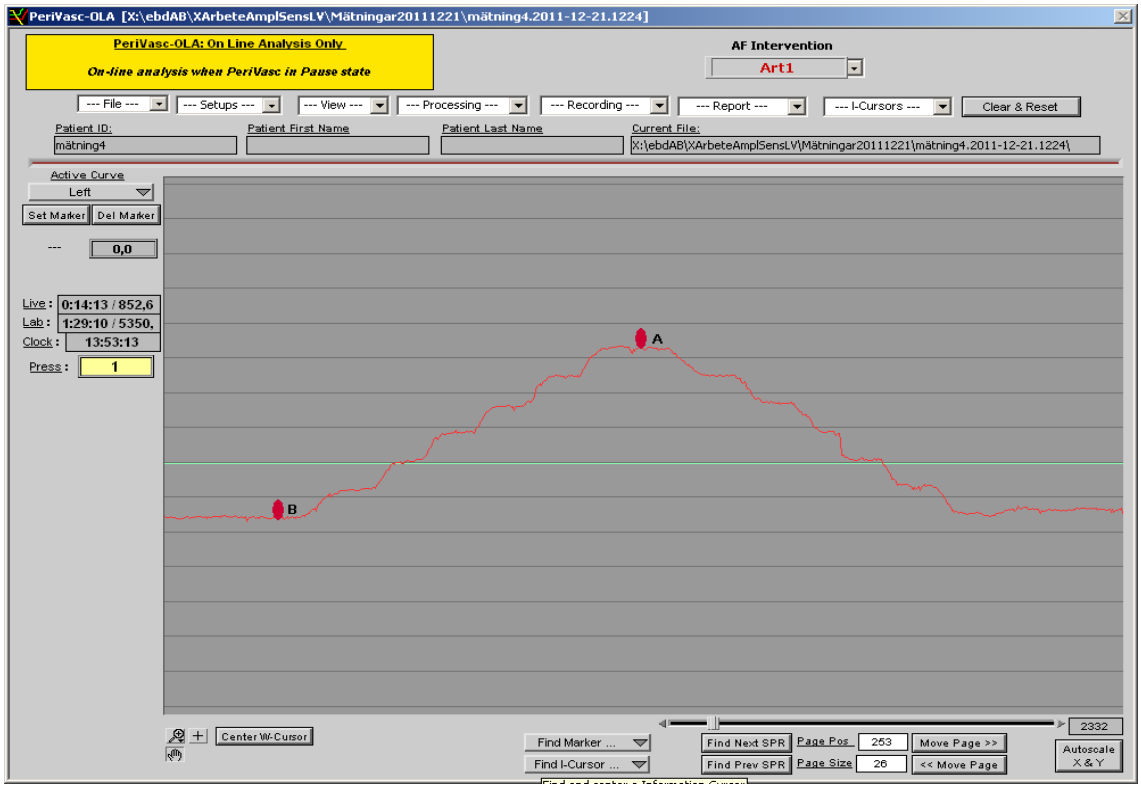

Figure 52: Calibration of strain gage using a millimetre screw, the screw is turned 6 times in one direction and then 6 turns in the other, in order to return to the baseline.

The system responds well to the mechanical calibration. The signal baseline post calibration is the same as prior to the calibration, this can be observed in Figure 52. Each turn of the millimetre screw can be seen distinctly, but there are also some fluctuations due to sensitivity due to the choice of parameters in the bridge circuit.

The system has a built in electrical calibration as mentioned previously. This feature should also be verified to fulfil the requirements of simulating 1% and 0.1% of strain according to Appendix A - Requirement specification Document. Due to the calibration, the signal baseline should shift to another static value if the calibration works as expected. The resulting curve is shown in Figure 53. Here the strain corresponds to a 1 % increase of strain as presented in the calibration section 6.3.5 Calibration.

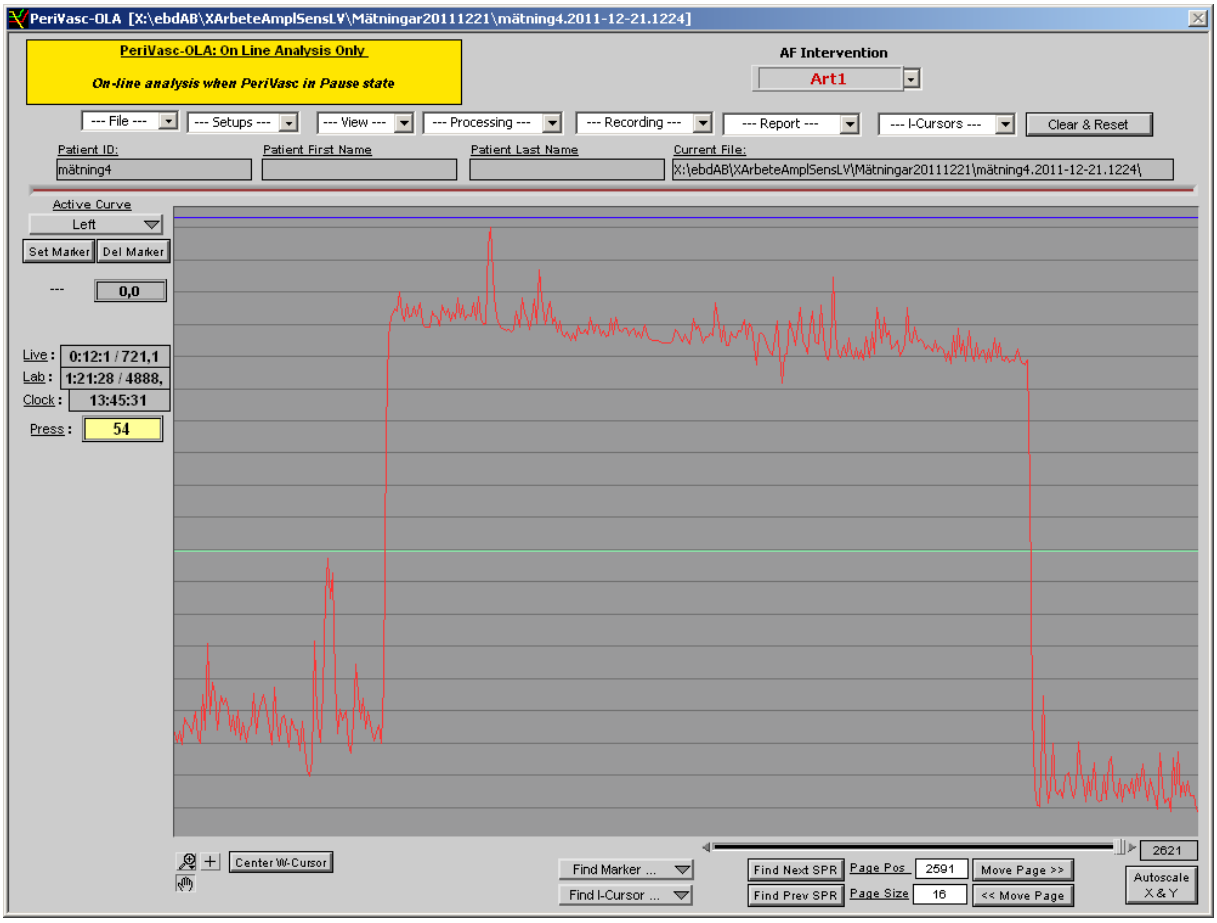

Figure 53: The electric calibration curve that corresponds to a strain of a 1 % increase of the original length of the strain gage.

The calibration is similar to a step response, the amplitude of the recorded signal changes to another static value during the calibration. All the components in the construction are connected via signal cables and are not soldered in to a circuit board; hence there are fluctuations in the signal due to noise afflicted by the signal cables since they tend to act as antennas. The calibration works according to the requirements and preforms as expected even though noise is present. This can be compared to the signals shown in Figure 54 where the electrical calibration is performed using the final system.

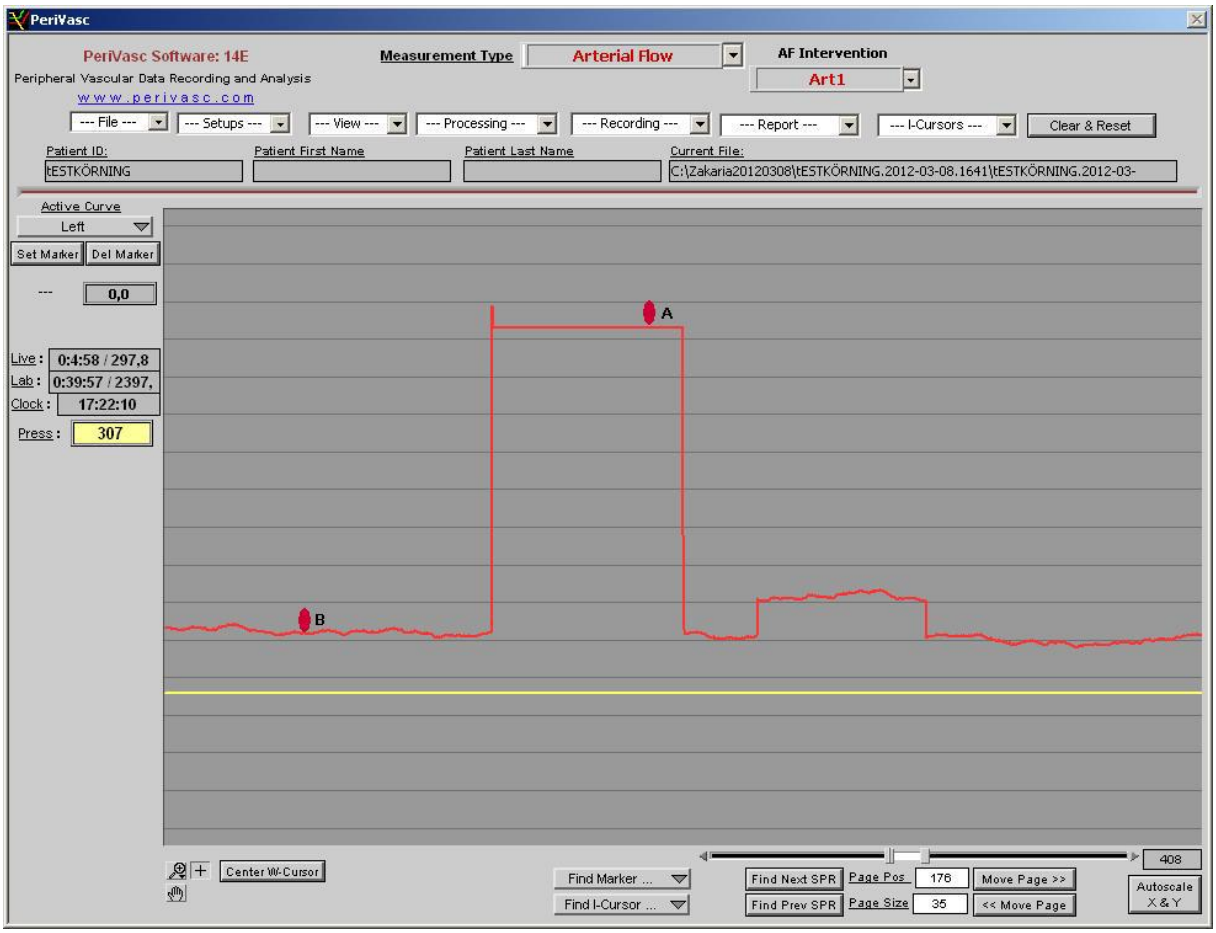

Figure 54: Here the higher peak corresponds to 1% strain (or increase of length) and the lower peak corresponds to a strain of 0.1%

7.2.2 Strain gage measurements according to clinical standards and verification of the pressure sensor

The purpose for performing the calibrations described previously is that values from these are used by the software during measurements to calculate certain parameters e.g. how much expansion the limb being tested has experienced and also to calculate the blood flow and volumetric change when performing the plethysmographic measurements. The next verification of the system was investigated in order to see whether the system gave good accuracy when performing plethysmographic measurements according to clinical regulations. The measurements where done on a forearm, where a strain gage was attached to the upper forearm of test subject as shown in Figure 55.

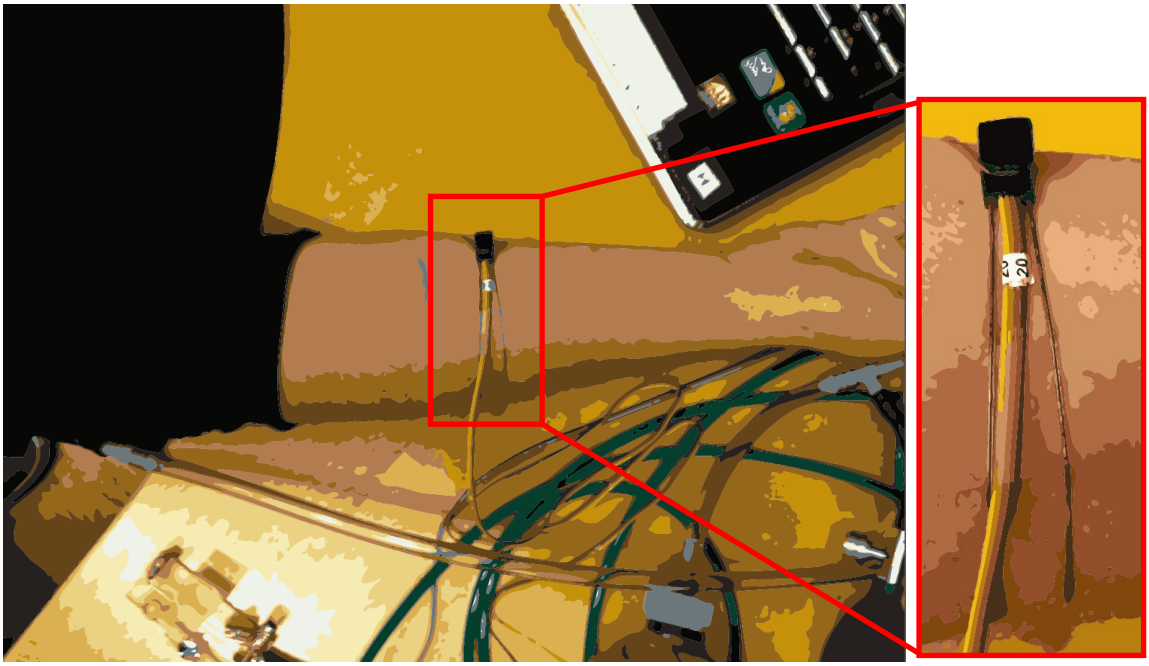

Figure 55: Strain gage sensor mounted on a test person's forearm

The plethysmographic measurements performed are called *Venous Occlusion Plethysmography* and where performed according to the following steps:

- First the perimeter of the right forearm was measured in order to have a base line to compare the expansion to.
- Then the sensor was attached on the test subject's forearm. Also a cuff was placed on the upper arm covering the bicep and triceps of the arm on which the measurements are to be performed, and the bridge was balanced with the help of the potentiometer.
- The cuff was then inflated until a pressure above 50 mmHg was reached in order to achieve venous occlusion and prevent blood from leaving the forearm. This will lead to only arterial flow to enter the limb. (Longhurst, Capone, & Mason, 1974)

The result from a measurement like this can be seen in Figure 56 and in Figure 57. The red curve displays the signal obtained from the strain gage and the yellow curve indicates the pressure in the inflatable cuff. It is clearly visible that the signal amplitude starts to rise as the perimeter of the forearm expands due to the arterial inflow.

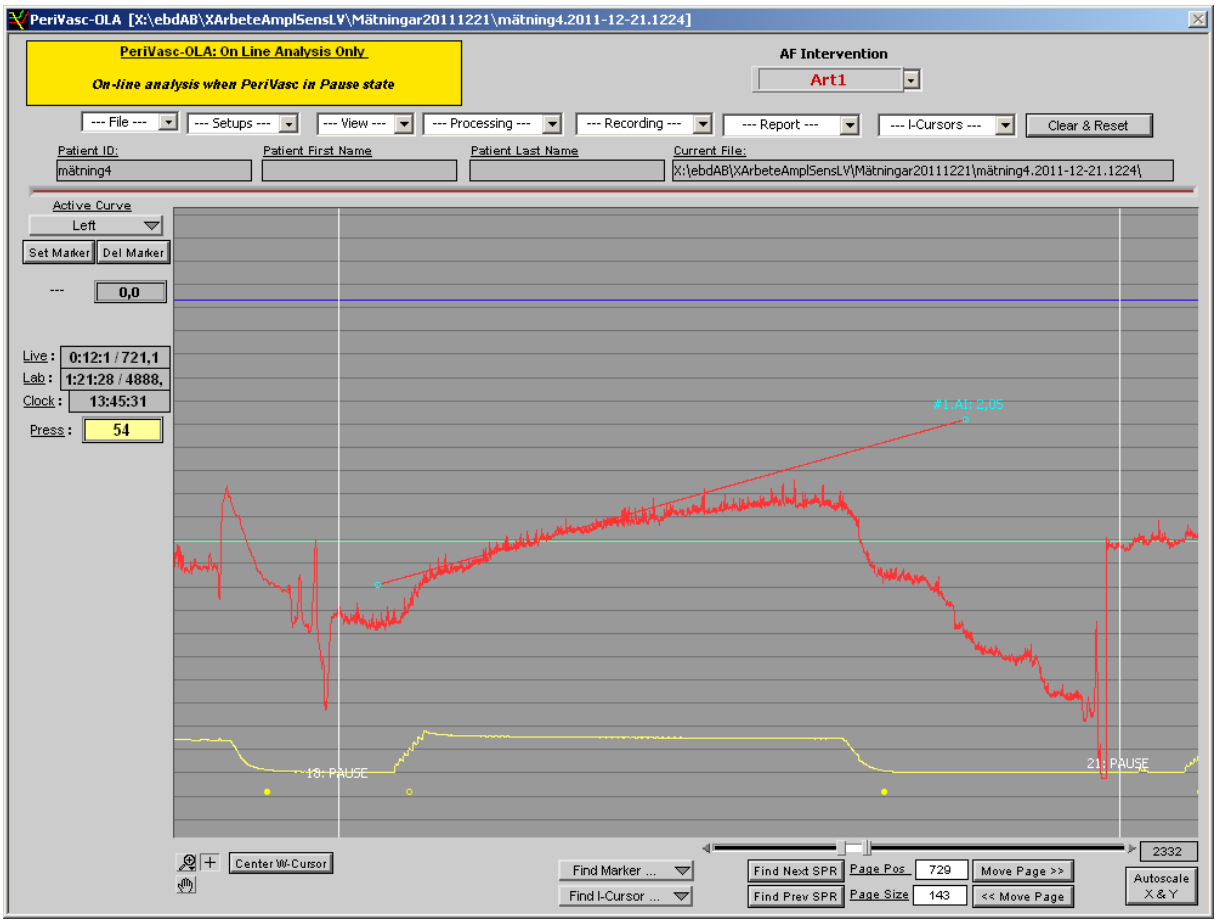

Figure 56: The result from a normal measurement on a forearm with the perimeter of 30.9 centimetres. The red curve is the signal from the strain gage and the yellow is from the blood pressure sensor. This person has a flow of 2.05[(ml/minute)/100 ml tissue] during rest.

The measurement displayed in Figure 56 shows how the expansion of the forearm increases as the arterial inflow continues while the venous out flow is occluded. By calculating the tangential of the steepest slope of the curve it is possible to get an indication of the maximum blood flow. The tangential is a straight line with a certain slope that can be seen in Figure 56. The slope of the tangential is expressed as (Webster)

$$F = \frac{\partial V}{\partial t} \qquad (17)$$

where F is the flow and V the volume.

All of the pressure applied by the cuff was not released at once but in three steps, this is distinguished in Figure 56 as the amplitude of the signal decreases and stops at three different levels. This measurement was done without any kind of provocation to obtain the maximum volume change. The second measurement was done with the help of a provocation. To provocate the body the cuff was inflated until a pressure of 54 mmHg was reached, this pressure was then maintained for a few minutes and then slowly lowered. The result is shown in Figure 57.

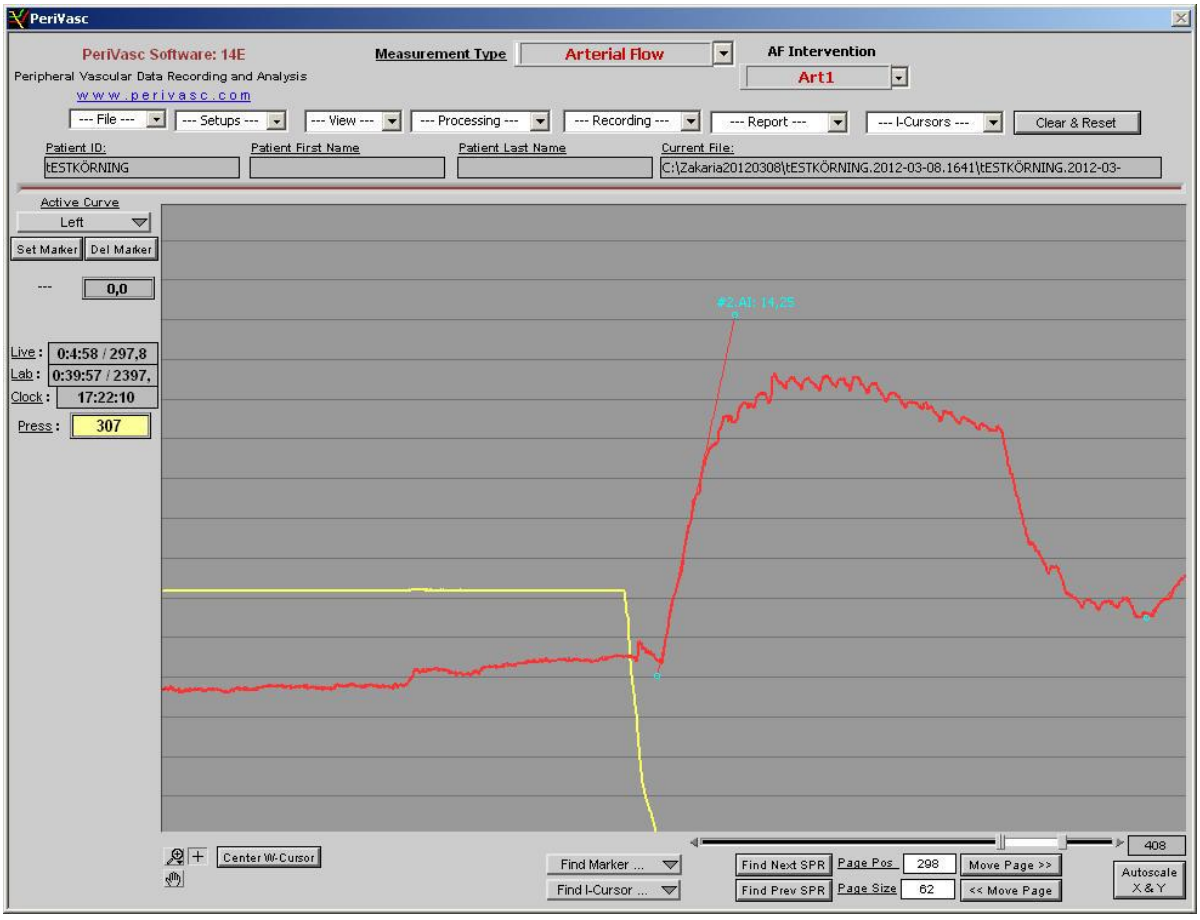

Figure 57: Result from a measurement (on the same arm and person as above) using provocation to get a more distinct curve. To provocate the body the cuff was inflated until a pressure of 54 mmHg was reached, this pressure was then maintained for a few minutes and then slowly lowered. The flow is here calculated to 14.25[(ml/minute)/100 ml tissue].

In the second measurement the flow is quite higher than in the first measurement at start and then reached a static state. This is because of that over time the flow tends to achieve a state of equilibrium and hence the volume change tends to assume a more static shape. This is due to venous and arterial flow equalize. This type of non-invasive blood flow and plethysmographic measurement is common, during more extensive tests provocations such as exercise and insertion of some kind of drug to enhance the blood flow (Longhurst, Capone, & Mason, 1974)

These measurements do also confirm that the pressure sensor works accordingly and shows a value of 54 mmHg in the software which was confirmed by simultaneously using a manometer during these measurements. The measurements would not start if the pressure does not exceed 54 mmHg since this is a built in function in PeriVasc©.

7.3 FRONT PANEL VERIFICATION AND TESTING

The testing and verification of most of the features described in this chapter has been described in earlier chapters so here the verification of the logic behind the diodes will be described.

First the limits were verified by using a potentiometer to simulate the signal. All possible signal values were simulated and it was verified that only one diode at a time was lit.

All measurements of hysteresis and reference signals were first performed with only two comparators and from the measurements when all four comparators are used it was noted that the reference signals tend to move. This due to loading of the voltage division. For this specific application it is not extremely important that the limits are exactly on spot and all reference values were therefore measured rather than calculated. From these measurements the voltage division resistance values for reference signals were calculated.

Tests were performed with a potentiometer to simulate the input signal. The voltage levels of the main input signal and the comparators input signals were measured. Each limit was passed over several times, both up and down and a mean value for each; on the in signal side was noted. From this the hysteresis for each limit could be calculated. It was found that the hysteresis was at close to the same level for all four comparators. The small differences that were noticed are most likely from loading.

8 DISCUSSION

Discussion regarding the results from the verification, design and implementation will be presented in this chapter. Also suggestions for future improvements and limitations that have influenced the choice of solutions will also be presented and discussed.

The main task of this project was to develop constructions that are used together with two types of sensors, strain gage and photo-cell, that are used when performing pletyhsmography, blood flow or peripheral blood pressure measurements. Also a prototype for a photo-cell sensor intended to be used for these types of measurements was to be constructed.

Even though these types of measurements are used to a great extent within the medical field it was hard to find useful information such as what amplitudes these signals usually have or within what frequency span they occur. Hence a lot of the time at the beginning of this project was spent to apprehend information considered relevant for these systems which itself proved to be a tough task even though the problem description was clear and distinct.

The only information that was provided at the beginning of the project was the specifications and requirements for the final product such as variable amplification or variable cut off frequencies for the filters. This information was used as a framework for the project, but the detailed information about what the cut off frequencies should be or how much the signals should be amplified was not specified at all. The information about these values were obtained partially by iterative testing and investigations. The development of these systems including software and verification will be discussed to a greater extent in the sections to follow including future improvements and modifications.

8.1 IMPLEMENTATION

As mentioned previously the signals from the strain gage sensor where obtained with the help of a Wheatstone quarter bridge that had been modified with four lead wire configuration to remove the influence from the lead wire resistances in the strain gage device. This idea was not thought of initially but first after that the resistance from the lead wires made the balancing unbearably difficult when changing strain gage sensors.

Another problem that made the balancing a challenging task was that one of the requirements for the strain gage unit to be compatible with a wide range of strain gages. This led to that the specificity of the strain gage was sacrificed for a higher sensitivity, also the sensitivity should be preserved so that it is constant regardless of strain gage. Hence the solution of implementing “counter balancing”.

Even if the quarter bridge solution with the lead wires worked wonders yet the question remains whether the solution is the best one for this purpose and why not use another bridge configuration. Yet the answer remains that this is a sufficient solution possible since there is no need of a half bridge since the temperature is taken into account during measurements. Additional limitations arose due to the current supply restriction due to the limited current supply from the PHI-card.

At first a differential amplifier was used to carry out the amplification of the apprehended voltage difference obtained by applying the bridge circuit. But this configuration was quickly replaced by an instrumentation amplifier due to its abilities to be more accurate and stable and provide more gain.

The whole photoplethysmography sensor unit was developed from scratch. This includes the photo-cell, filters and amplifications. The whole construction was performed iteratively. The most difficult part was to develop a sensor that worked properly and to only obtain the proper signals. It was quite time consuming to figure out the proper amplification and whether a passive high pass filter was adequate to remove the DC-content in the signal obtained when performing the measurements or not. The next step was to identify what cut off frequency the high pass filter should have. Since the part of the signal that is not of interest is the static DC content of the signal. It was then clear that the cut off frequency should be as low as possible, perhaps lower than 0.5 Hz to be as close to the DC frequency as possible, yet suppressing the DC-content. The gain provided by the amplifier was selected by testing three different levels of gain on five different test subjects and placing the sensor on either the index or the middle finger.

The PPG and the Strain gage units had different amplifier and filter stages that where specially constructed for each individually as discussed previously, but they did also have some stages that where in common. These are the active band pass filter that could be modified into an active low pass filter when performing measurements with the strain gage and also the final amplification stage. The active filters chosen were first order filters since this seemed adequate. If the filters were of higher order the cut off would be more abrupt which might compromise the signals. The cut off frequencies where chosen only on estimates based on heart rate frequencies.

This is actually a reason for some uncertainties since tests have not been done on people with higher heart rate than what is considered being the heart rate at rest. The only way to verify that the cut off frequencies of the active filters are good enough is to perform measurements with the help of provocations. These could unfortunately only be done with the help of drugs since movements would affect the signals obtained by the sensors due to that the signals are of such small amplitude. It is also possible to use exercise as a form of provocation, but this would contribute to motion artefacts that may arise when breathing.

When it comes to the software designed for testing one can discuss the choice of programming language. The language used when creating the signal processing tool was LabVIEW. One could ask whether another language would be better suited for the application. The answer remains no, since LabVIEW made it easy to communicate with the hardware. It also made it easy to change and adapt the software depending on the needs at any given moment. For instance if the case would be to test a special function of the system then changes in the software could be done smoothly in order to adapt the signal processing tool just for this application. When the need for a certain function in the software would arise it was easy to implement the function by simply adding to the source code, this in contrary to using any other language where the hardware communication would have been more complex.

Perhaps the user friendliness and aesthetic could be improved since not much effort was used here. For this project the functions of the software was always more important than the design. Also the graphical interface has been adjusted to suit the size of the screen on the computer used during testing.

8.2 VERIFICATION

The strain gage unit of the system was verified in several ways. First a millimetre screw was used for mechanical calibration, where one turn corresponds to half a millimetre. This was done to see whether the system had a good sensitivity ratio or not and how well it corresponded to the strain simulated with the millimetre screw. Another form of verification was to use the electrical calibration to simulate a certain percentage of strain which also corresponded well. The uncertainty of the strain gage verification is when the system was used on a test subject. This is because only one type of measurement was done, namely venous occlusion plethysmography to measure the arterial blood flow in the forearm.

Even though this type of measurement confirmed that the system worked as expected and showed promising results with good sensitivity, it would be good to make a comparison study where different forms of measurements with different systems and other procedures. For instance measurements when provocations with the help of either exercise or drugs for increasing the heart rate would be used. Also measurements of other limbs than the forearm e.g. calf's or thighs.

Unfortunately all these tests where not done during the course of this project since it was not a part of the work load except verifying that the system actually gave reasonable response. Further testing will be carried out by EBIDA in a clinical environment before introducing the final product on the market.

The tests performed during this project have shown that the photo-cell prototype performs well when it comes to signal strength and ability to detect signals. The photo-cell prototype was compared with a commercially available sensor in terms of signal to noise ratio and signal strength performance. The tests were conducted on the developed measurements system and showed that the photo-cell prototype actually surpassed the available sensor in these terms. Yet these tests are inconclusive since the system is optimized for the prototype and not for the other sensor. Since the restrictions for the amount of current that the system can use are strong, it was never possible to give the commercially sensor as much current it was specified for. Also it was discovered that it consisted of an integrated circuit that contains an emitter and reflector known as a "Reflex-sensor", which is not really optimal for this application since it is not its main application.

The main purpose of the comparison study was only focused on the performance of the sensors rather than interested in how they worked together with the system as a whole. Therefore the main interest was to investigate compatibility and sensor performance when the photo-cell sensor or the "reflex-sensor" was connected to the system, and during these tests the photo-cell sensor prototype performed satisfactory.

The sensor has only been tested on fingers when its real application also includes toes. Therefore a more extensive verification would be suitable to ensure that the sensor is good enough for both applications. This is of great importance since generally the skin on fingertips is thinner than the skin on toes.

8.3 FUTURE WORK

Since all the supply to the prototype system was done through the PHI-card there was a strict current limitation in order to not surpass the total current limit of 500mA from the USB driver. There were a lot of current optimizations done to not exceed the limit that may have compromised the performance of the sensors used. A suggestion for future improvements would be a revision of the PHI-card in terms of current consumption and reconstruction to optimize it and make it consume less current. Another solution could be integration of the PHI-card on to the prototype instead of having two different circuit boards. This would most probably save space and would make the production more cost efficient.

Another suggestion is to make a more extensive comparison of how to measure voltage differences when performing measurements with the Strain gage device in order to have the best sensitivity without the loss of specificity. In this case one should decide whether the current supply would still be the USB-drive of a computer or to change the supply source to something else that is less current restrictive. Some of the measurement techniques would be a constant current method or a Kelvin bridge, and compare these in terms of sensitivity and specificity.

The final version of the photo-cell sensor has not been built during the course of this project. A great deal of thought was put into the possible materials and shape that would fulfil the requirements and the conclusion were that something has to be specially made for this purpose. During the previous versions some requirements that the final product must fulfil was constructed and they are listed in appendix A. The design of the prototypes gave a lot of insight and ideas and it should also be mentioned that version 3 preformed satisfactory in the sense of the signals obtained. A lot of effort was put into finding cables and enclose material that could work for the final version, but this was a lot harder than expected and took too much time from other things so it was therefore decided that some requirements for how to design this version should be formulated and that we should leave it like that.

One improvement of the system could be to implement a possibility to control the system from the software, but the number of output are very limited and are all already used for different applications by parts of the device which are not in the scope of this project. It could be possible by implementing a microprocessor. By adding a microprocessor several things could be controlled with only use of one or two output channels. This could give the system more functionality that could be useful in research. But in the hospital environment there is always the possibility that one cannot see the screen when setting up the system on a patient and configuring it, so the possibility to do so from the hardware's front panel is vital and should still remain. But implementing a microprocessor solution was not part of this project.

To add more functionalities and/or channels more current then what a computer can deliver through one USB port is needed. For a future product other alternatives could be investigated to solve this, some possible solutions are: multiple USB ports or the use of another type of power supply, which require other solutions for isolation and patient security to be implemented. One disadvantage with using a power supply that is not from an USB port is the patient security and stricter regulations put on the system since it is harder and more expensive to implement the isolation stage needed to guarantee patient security.

The more controls that you add to a systems front panel the more there are for the user to learn about to be able to use the system and therefore the number of controls should be kept few. Some of the controls that are on the front panel of the system can probably be removed and atomized, but atomizing requires more components which in their turn requires more current and as long as the system is only powered by an USB-port they are hard to implement.

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9.1 FIGURES

9.2 TABLES

APPENDICES

APPENDIX A - REQUIREMENT SPECIFICATION DOCUMENT

This document contains all requirements for the system built. The requirements are sorted into the following categories; System, PPG signal processing unit, Photo-cell sensor, Strain gage signal processing unit, test and development software and LED-indicators.

System

Communication between the hardware and the software should be implemented with a PHI-card from EBIDA.

The system should be compatible with the software PeriVasc© from EBIDA.

The system should have two channels for sensors; each channel should be able to handle either a strain gage or a photo-cell sensor.

The system should have a pressure sensor that can measure blood pressure between 0 mmHg and 250 mmHg.

The system in combination with the PHI-card should not exceed a current consumption of 500mA.

The system should only use USB as power supply.

The final filtering and amplification should be common for strain gage and PPG.

PPG signal processing unit

Remove static gain present in the signal obtained during measurements with photo-cell sensor.

The amplifier should provide an appropriate gain for the signal obtained by using the photo-cell sensor.

Filter the signal from high and low frequent noise and have smooth cut-off to not supress signal contents that may be of importance.

The cut-off frequencies should be variable.

It should be possible to shift the signal baseline, this to ease reading when using more than one channel for measurements.

It should be possible to change between 5 different levels of gain.

Photo-cell Sensor

Should consist of an IR-led and a phototransistor that are two separate components.

When choosing components the following aspects should be considered; current consumption, compatibility, size.

Shape and size of the sensor should be considered.

Choice of materials should be considered in the aspect of clinical standards for disinfection.

Strain gage signal processing unit

The system should be able to handle strain gages from different manufactures.

There should be an electrical calibration for the strain gage, one that corresponds to a strain of 1% and one 0.1%.

The bridge circuit should be possible to balance for a wide range of strain gages.

Filter the signal from high frequent noise and have smooth cut-off to not supress signal contents that may be of importance.

The cut-off frequencies should be variable.

It should be possible to change the gain of the signal.

Test and development software

Input from hardware: signals from channel 1, channel 2 and pressure signal.

There should be an option to add software notch filters for 50 Hz as well as for 100Hz.

It should be possible to choice which signals are visible on the screen and if multiple signals are chosen these should be view in the same graph and be of different colours.

It should be possible to do a frequency analyse of each signals.

It should be possible to adjust the number of seconds shown in the graph, default is 1 second.

It should be possible to record the signal, but also to run measurements without recording.

There should be a possibility to save reading for post analysis.

LED indicators

The front panel should have the possibility to have 5 light diodes.

The diodes should be lit independently depending on the value of the signal.

The limits are: ±2.5V and ±9.5V.

It should be possible to use these diodes as help when balancing the bridge circuit for strain gages.