Monitoring core temperature, heart rate, respiratory rate and EEG through a wireless ear probe

by

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Thesis presented in partial fulfilment of the requirements for the degree of Master of Engineering (Mechanical) in the Faculty of Engineering at Stellenbosch University

Supervisor: Prof. PF. Fourie

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Declaration

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Date: 2014/12/10 ....

Abstract

Monitoring core temperature, heart rate, respiratory rate and EEG through a wireless ear probe

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Thesis: MEng (Mech)

September 2017

Vibrating a tillage tool is an effective way of reducing the draft force required to pull it through the soil. The degree of draft force reduction is dependent on the combination of operating parameters and soil conditions. It is thus necessary to optimize the vibratory implement for different conditions.

Numerical modelling is more flexible than experimental testing and analytical models, and less costly than experimental testing. The Discrete Element Method (DEM) was specifically developed for granular materials such as soils and can be used to model a vibrating tillage tool for its design and optimization. The goal was thus to evaluate the ability of DEM to model a vibratory subsoiler and to investigate the cause of the draft force reduction.

The DEM model was evaluated against data ...

Uittreksel

Diskrete Element Modellering van 'n Vibrerende Skeurploeg

("Discrete Element Modeling of a Vibratory Subsoiler")

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Tesis: MIng (Meg)

September 2017

Om 'n tand implement te vibreer is 'n effektiewe manier om die trekkrag, wat benodig word om dit deur die grond te trek, te verminder. Die graad van krag vermindering is afhanklik van die kombinasie van werks parameters en die grond toestand. Dus is dit nodig om die vibrerende implement te optimeer vir verskillende omstandighede.

Numeriese modulering is meer buigsaam en goedkoper as eksperimentele opstellings en analitiese modelle. Die Diskrete Element Metode (DEM) was spesifiek vir korrelrige materiaal, soos grond, ontwikkel en kan gebruik word vir die modellering van 'n vibrerende implement vir die ontwerp en optimering daarvan. Die doel was dus om die vermoë van DEM om 'n vibrerende skeurploeg the modelleer, te evalueer, en om die oorsaak van die krag vermindering te ondersoek.

Die DEM model was geïvalueer teen data ...

Acknowledgements

I would like to express my sincere gratitude to the following people and organisations ...

Dedications

Hierdie tesis word opgedra aan …

Contents

List of Figures

List of Tables

Nomenclature

Constants

g =	$9.81\,\mathrm{m/s^2}$

Variables

Re_{D}	Reynolds number (diameter)	[ ]
x	Coordinate	[m]
$\ddot{x}$	Acceleration	[$\mathrm{m/s^2}$]
θ	Rotation angle	[rad]
τ	Moment	[N·m]

Vectors and Tensors

$\vec{\boldsymbol{v}}$	Physical vector, see equation ...

Subscripts

a	Adiabatic
a	Coordinate

Chapter 1

Introduction

This thesis document reports on a project undertaken in die biomedical field of wearable electronics. Great advances in miniaturization of electronics and wireless communication have challenged and transformed the norm of the how we use electronics to listen to the language of our bodies: bio-signals.

The importance and usefulness of a continuous, wearable health monitor should not be underestimated. Access to accurate, long term data can lead to improved diagnosis of health issues and a better understanding of how our bodies react to drugs, exercise, emotions and the environment around us.

Traditionally, bio-signals monitoring is done with stationary equipment and with a dedicated device for each signal to be measured. It is easy to see that this is not suitable for continuous and mobile bio-signals monitoring.

This project concerns the design, development and testing of a proof of concept device that will overcome the limitations of these traditional methods. The device is to be worn on the ear and will transmit its collected data through a wireless connection to a supporting system for storage and analysis.

1.1 Aim/Research Question

To develop and test a proof of concept of a wearable device that can monitor bio-signals and transmit collected data wirelessly to a warning and storage system. Bio-signals include core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity. Is the external ear canal a feasible location for the continuous monitoring of core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity by means of a ear worn device?

In order to achieve the aim of of this project the following three objectives have to be met:

- Develop an ear worn device to measure core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity through the external ear.

- Conduct a trail to determine the functionality of this device.
- Subsequently, evaluate the feasibility of an ear worm bio-signal monitor

1.2 Motivation

Chapter 2

Literature Review

This chapter aims to describe the context within which the project is undertaken. The purpose of this literature review is to accumulate a thorough understanding of the current state of technology relevant to the project. Attention will be given to technical theory and work done by others in this field of research.

An overview will be given about the anatomy of the ear which is relevant to this study. Next, background will be given about each vital sign. Thereafter, the current technology available for monitoring vital signs will be reviewed.

2.1 Ear Anatomy

The area of the ear that is relevant to this study is the external ear. It includes the auricle, ear canal with surrounding tissue and the lateral side of the tympanum. This is the area available for the device to take the bio-signal measurement. Each part of the ear anatomy will be described, especially with regards to its ability to emit bio-signals or support the device in another way.

2.1.1 Auricle

The auricle is the visible part of the ear. It forms a C-shaped funnel that protrudes from the scull. Its structure is predominantly formed by yellow elastic cartilage covered in skin. Its complex folded shape differs from person to person, but certain structures are present in all normal auricles and have been named. As can be seen on Figure 2.1 the concha is the indented part next to the ear canal. This area is an ideal location for a wearable device. The device can be held in place by the tragus and a probe can easily extend into the ear canal.

The external ear is supplied with blood from the auricular arteries. These arteries branch from the carotid artery which supplies the rest of the brain with blood. Being made mostly of cartilage and being at an extremity of the body,

Figure 2.1: Drawing of the auricle (goo.gl/mmLnFx)

the auricle is not a suitable location for taking temperature measurements for its temperature is easily influenced by the ambient conditions.

The layer of skin covering the auricle contains blood vessels. It is possible to detect a pulse in the auricle, in fact, the ear lobe is a prime location for traditional pulse oximetry measurements. This is a possible location for a ear-worn device to make a heart rate measurement (Poh *et al.*, 2010). The ear lobe's blood vessels are, however, susceptible to vasoconstriction due to cold or hypovolaemia (WorldHealthOrganization, 2011). This will make is harder to get accurate heart rate measurements.

The auricle is used in EEG systems as a location for a reference electrode. It is far enough from the brain for it to have an extremely small electrical potential (Nunez and Srinivasan, 2006). More will be said about EEG referencing in Section **??**

2.1.2 Ear Canal

The external ear canal is the tube running from the floor of the auricle to the middle ear, ending blindly at the tympanic membrane or tympanum. Figure 2.2 depicts the structure of the ear as seen from a coronal plane section.

The ear canal in adults is approximately 25 mm long and have a diameter of 5 to 7 mm (Alvord and Farmer, 1997). The outer third of the external ear canal is surrounded by cartilage and fibrous tissue (of Encyclopædia Britannica, 2015). The inner two thirds are surrounded by the temporal bone. Thin skin from the lining of the canal and contains glands secreting ear wax. Hairs are found in the outer part of the canal. The ear canal of infants starts out relatively straight, but obtains a definite S-shape as the head develops (Alvord and Farmer, 1997). Ear canal shape varies from person to person. Therefore, an ear probe should be able to adjust to variation in ear canal shape and size.

The secluded nature of the ear canal means that it has a relative constant temperature. As with the auricle, the canal wall temperature will also be

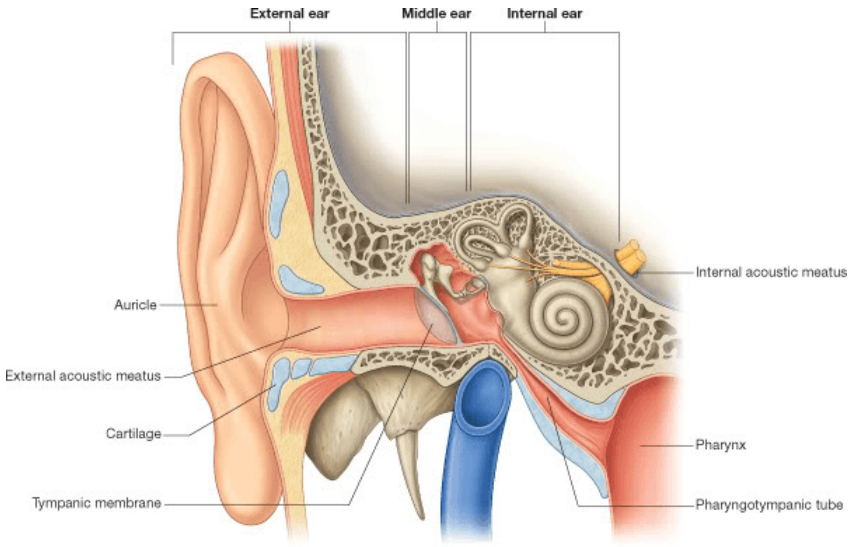

Figure 2.2: Structure of the ear (Drake et al: Gray's Anatomy for Students)

influenced by the ambient temperature, but to a much lesser extent. The wall of the ear canal is well supplied with blood. Blood vessels just beneath the thin layer of skin makes the ear canal a possible location for measuring heart rate and blood oxygen saturation. The ear canal extend toward the brain and electrical brain activity is present due to the conductive nature of the tissue. According to Nunez and Srinivasan (2006) currents from brain potentials can be focused through holes in the scull, like the ear and nose. The farther away the origin of the signal is from the electrode, the weaker the measured signal will be. Therefore, an electrode in the ear canal will detect electrical brain activity near the ear better, including the temporal lobe and brain stem.

2.1.3 Tympanum

The tympanum forms the medial boundary of the external ear canal. It is a smooth elliptical membrane with a thickness of about 0.074 mm (Alvord and Farmer, 1997). The membrane is slanted with regards to the external ear canal. The tympanum is also supplied with blood from a branch of the carotid artery, therefore sharing its supply with the brain including the hypothalamus, the thermoregulation centre of the body. It is the most medial part of the external ear, and is therefore the least susceptible to influence by the ambient temperature. This is the reason that the tympanum is one of the best locations to measure core body temperature. The location is used by physicians to measure core temperature for it is quick and minimally invasive. Variations in body temp can be sensed faster on the tympanic membrane than on other locations on the body. Contact with the tympanum can cause discomfort and harm to the patient, so non-contact infra-red thermometers are usually used.

2.2 Bio-signal Physiology

This section reviews the theory and research done about the physiological aspects of bio-signals. The origin and importance of measuring bio-signals will be discussed. This includes the typical readings expected from healthy adults, as well as the causes and implications of deviations from these healthy bio-signals.

The body constantly strives to maintain its internal environment at a stable state, suitable for its various physiological processes. Deviations from this stable state...

2.2.1 Core Temperature

Thermoregulation is the body's way of keeping its internal temperature within certain bounds to create a favourable environment for chemical reactions to take place. The temperature control centre of the body is in the hypothalamus and it regulates temperature by maintaining a fine balance between heat production and heat loss. Normal human core temperature varies between $36.5°C$ and $37.5°C$ (jones2010biomedical). Inability to maintain this balance may indicate problems in the well-being of a person. Elevated temperature (hyperthermia) due to a fever can indicate the presents of an infectious disease. Abnormally low temperature (hypothermia) can be caused by cold exposure, metabolic disorders or infection. Both hyper- and hypothermia can be life threatening. A core temperature measurement is often a key indication to start a treatment or not. Therefore, temperature measurement is part of a full clinical examination and part of the vital sings group.

The location where temperature is measured is a key factor, for temperature is not constant throughout the body. This is because heat production and heat loss are not constant throughout the body, meaning extremities are usually cooler than the core. Traditional locations for measuring temperature are the tympanic membrane, axilla, mouth, rectum, oesophagus, forehead and urinary bladder. The mean temperature of these areas varies as well. A systematic literature review done by Sund-Levander *et al.* (2002) combined the results of 20 studies to identify oral, rectal, tympanic and axillary temperature ranges in healthy humans. Table 2.3 shows the results.

Studies have also been done comparing measurements at distinct locations to pulmonary artery temperature in ill patients. A study has shown ear-based $0.07 \pm 0.41\ °C$; urinary bladder $0.03 \pm 0.23°C$; oral $0.05 \pm 0.26°C$; and axillary $-0.68 \pm 0.57°C$. The accuracy of each method varied with the level of pulmonary artery temperature. Repeated measurements with all four methods had mean standard deviation values within $\pm 0.2°C$ (Erickson and Kirklin, 1993).

A second study done by Lefrant *et al.* (2003) showed the following results: oesophageal $0.11 \pm 0.30°C$, rectal $-0.07 \pm 0.40°C$, axillary $0.27 \pm 0.45°C$, in-

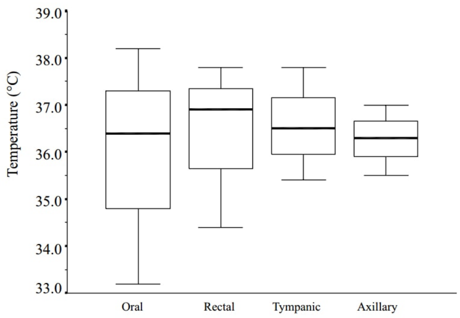

Figure 2.3: The results from 20 studies with strong or fairly strong evidence of normal oral, rectal and tympanic temperature (°C) in adult men and women are presented. Temperature is obtainable as mean value(bold lines), 1st and 3rd quartiles (unfilled bars) and range (thin lines).

guinal $0.17 \pm 0.48°C$, urinary bladder $-0.21 \pm 0.20°C$.

The location of the device in development is restricted to the ear, therefore the tympanic membrane is the preferred location to take temperature measurements. The referenced studies show that the tympanic membrane is a valid location to measure accurate core temperature.

2.2.2 Tympanum

2.2.3 Tympanum

2.2.4 Tympanum

2.2.5 Tympanum

2.2.6 Core Temperature

Thermoregulation is the body's way of keeping its internal temperature within certain bounds to create a favourable environment for chemical reactions to take place. Temperature is controlled by the hypothalamus. Core body temperature is an indication of overall health. Elevated temperature due to a fever can indicate the presents of an infectious disease. It is often the key indication to start treatment or not. Therefore, core temperature measurement is part of a full clinical examination and part of the vital sings group.

The location where temperature is measured is an important factor, for temperature is not constant throughout the body. This is because heat production and heat loss are not constant throughout the body. Extremities are usually cooler than the core. Traditional locations for measuring temperature are the tympanic membrane, axilla, mouth, rectum, oesophagus, forehead and urinary bladder. The mean temperature of these areas varies as well. A systematic literature review done by Sund-Levander *et al.* (2002) combined the results of 20 studies to identify oral, rectal, tympanic and axillary temperature ranges in healthy humans. Table 2.3 shows the results.

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According to Harrison's Principles of Internal Medicine (18th ed., normal internal body temperature is 37.0 °C.

2.2.6.1 Temperature Measurement Theory

Various methods are available for measuring core temperature. Non-electric, fluid-filled thermometers was the first to be used. The mercury-filled thermometer was used by early physicians to study the thermoregulation of the human body and crudely identify fevers. Since then, the mercury has been replaced by coloured alcohol or another heat sensitive liquid, due to toxicity of mercury.

Another type of fluid-filled thermometer is the liquid-crystal thermometer. It contains liquid crystals that changes colour when at different temperatures. The use of these two types of fluid-filled thermometers has decreased significantly due to the accuracy, speed and connivance of digital thermometers.

Electrical thermometers are now the industry standard of measuring core temperature. Medical thermometers are usually classified by the location that they use to make there measurement. For the sake of this study it is also important to obtain an understanding of how they make their measurements. Central to any thermometer lies a electrical temperature transducer/sensor. Various temperature sensors are available, but the following three are the most commonly used.

Two methods are generally available to capture the temperature of the tympanic membrane. Firstly a contact thermistor and secondly an infra-red sensor. Placing a thermistor in contact with the membrane can cause discomfort and injury to the patient. The infra-red sensor is therefore a better option for is can measure the temperature without making contact with the tympanic membrane.

2.2.6.2 Thermocouples

Thermocouples make use of the thermo-electric effect to make a temperature measurement. They consist of two dissimilar conductors connected at the one end, knows as the measuring junction. The other ends of the two wire are known as the reference junction and are connected to a voltage meter via common conductors. A voltage is generated dependant to the temperature difference between the measuring- and reference junctions.

Thermocouples do not respond to absolute temperature, therefore their accuracy depends on how well the reference temperature can be defined.

Thermocouples can be connected in series and are then called thermopiles. This amplifies the output voltages, resulting 'n a average temperature reading across many sensors (temperature averaging).

Thermopiles can be used to detect thermal radiation. All matter with temperatures above 0K radiates electromagnetic radiation. The wavelength distribution varies according to the temperature of the matter and is described by Planck's law. The temperatures relevant to this study is the core temperature of humans, which is around 37 °C. According to Planck's law, the theoretical peak density wavelength will be at 12 um (verify ad include formule). This is in the infra red range, and therefore this type of thermal radiation thermometer is called a Infra-Red thermometer.

Emissivity is the ability of an object to radiate thermal energy. Emissivity is a material-dependent property. It is quantified as a ratio of thermal energy emitted by a surface relative to the thermal energy emitted by an ideal black body at the same temperature. A black body is an idealized surface that reflects no radiation, meaning all energy radiated from the surface are due to the temperature of the surface. Thus, a black body have an emissivity of 1 and have the maximum theoretical radiation at a given temperature. The accuracy of an IR sensor depends on the ability of the target object to emit sufficient thermal radiation for the sensor to detect. Therefore, the emissivity of the target object should be close to one.

According to **source** the emissivity of skin is 0.98.

An IR thermometer generally consists out of a thermophile attached to a blackbody and shielded by an IR filter that also acts as a lens to focus IR waves [16]. This setup, shows in Figure2.4, allows for the non-contact temperature sensing of the tympanic membrane. Unlike pulse rate, breathing and electrical brain activity, the core body temperature varies slowly. It takes minutes to vary significantly. Therefore, the sampling rate of body temperature can be as slow as 0.5 Hz.

Thermocouples are widely used in medical thermometers due to their

2.2.6.3 Thermistors

Thermistors

2.2.6.4 Resistance temperature detectors

Resistance temperature detectors (RTD)

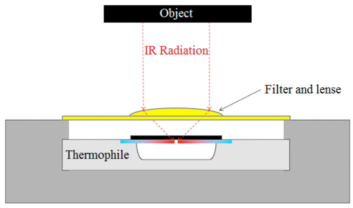

Figure 2.4: IR Thermometer diagram (V Polyzoev et al: Demystifying Thermopile IR Temp Sensors)

Another important aspect is the way in with the ele temperature measurement in set op

Other methods used by the literature

Devices used by literature

enter the test of the TMP006 subsystem word doc that is applicable here...

2.2.7 Heart Rate

The presence of a heart beat is a paramount to the sustain the vital cardiac output supplying blood to the whole body. Heart rate can be controlled or maintained through two different regulatory systems: The intrinsic conduction system and the nervous system. The intrinsic conduction system works through the rhythmic contraction and relaxation of the heart muscle tissue. The heart rhythm is regulated by the sinoatrial node. The nervous system can influence the heart rate through sympathetic and parasympathetic nerves running from the cardiovascular centres in the medulla oblongata to the heart. The heart beat rate is varied to control the blood flow and blood pressure in the body.

Heart rate is influenced by numerous physiological factors including O_2, CO_2, H^+ levels, blood pressure, stress and exercise. Pathological factors can include fever, sepsis, heart disease and anaemia. Tachycardia is abnormally high resting heart rate, generally above 100 bpm, whereas bradycardia is an lower then normal resting heart rate, usually below 60 bpm. Although these two conditions are not necessarily danger signs, it may be an indication of health problems and therefore heart rate measurement is part of any medical examination and one of the vital signs in humans.

Heart rate can be measured in a variety of ways. Electronic ways of measuring heart rate include electrocardiography (ECG), photoplethysmography (PPG), ballistocardiography(BCG), electronic stethoscopes and Doppler flowmeters.

2.2.7.1 Electrocardiography

ECG records the electrical activity of the heart over a period of time. It is the the recommended way of monitoring heart rate in most intensive care units.

A cardiologist will use a 12 lead ECG with 10 electrodes placed in a specific configuration on the chest. Various wearible devices use ECG to measure heart rate. Fitness monitors normally uses a chest strap with electrodes to detect the heart's electrical activity. Studies have been done developing wearable ECGs for clinical use.

The typical telemedicine set-up of a wearable ECG is a signal acquisition module, collecting and sending data by means of a wireless transceiver to a smart-phone, which then uploads the data to a healthcare server (Wang *et al.*, 2010) and/or (Prawiro *et al.*, 2016).

The latest in wearable ECK systems is the use of Dry Polymer-based electrodes (Wang *et al.*, 2010) or non-contact electrodes that can be place on top of clouthing (Lin *et al.*, 2013). This is an improvement above the standard conductive gels or adhesives and can be used repeatedly. But these electrods still needs to be place on the chest. An ear located ECG monitor have been developed by Winokur *et al.* (2012). This device uses an one lead set-up with on electrode place on the mastoid bone and one on the neck. This configuration relies on the conductive properties of human tissue to carry electrical charges form the heart to the location of the ear. (See also: Bluetooth Low Energy (BLE) Based Mobile Electrocardiogram Monitoring System;

2.2.7.2 Photoplethysmography

Photoplethysmography (PPG) is an optically obtained plethysmogram (volume change of an organ). PPG can be used to measure the change in volume of blood vessels close to the skin surface. When the left ventricle contracts a pressure pulse propagates through the arteries from the heart to the extremities of the body. This wave corresponds to the systolic blood pressure. Blood vessels walls contain elastic fibres that allow them to stretch. This means that the diameter of vessels will increase when the blood pressure increase, causing arteries so to stretch and contract with each heartbeat. A PPG can be used to measure this variation.

According to Lambert's law, the amount of light absorbed is proportional to the length of the path that the light has to travel in the absorbing substance. Therefore a change in blood vessel diameter will cause a change in tissue absorption. Light shined through the skin to illuminate the underlying subcutaneous tissue can either be reflected, absorbed or allowed to transmit through the tissue. Changes in the light absorption of the tissue can be detected by measuring this reflected or transmitted light. As defined by Lambert's law: changes in absorbed light is due to the changes in arterial diameter and thus, an indication of the pulse. Figure of reflective and transmittance PPG.

A photoplethysmogram of blood vessels is obtained through pulse oximetry. A pulse oximeter consiste of a light emitter and detector. It can operate in reflectance or transmittance modes as shown in Figure 2.5. Transmittance pulse oximetry measures the light that is allowed to transmit through the

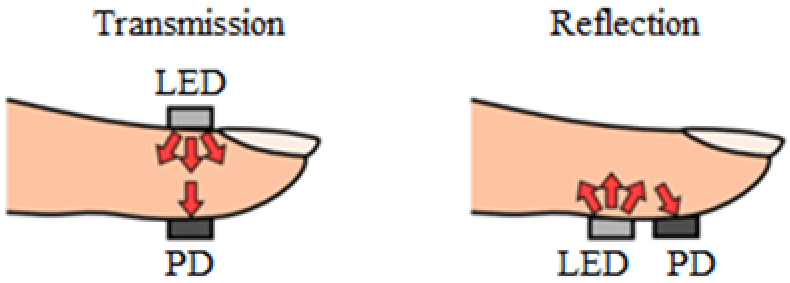

Figure 2.5: Pulse oximetry in reflective or transmittance modes

tissue. It is more common, but its placement is restricted to a thin part of the patient's body that will allow light through. Reflectance pulse oximetry has no such restrictions for it measures the light that is reflected by the tissue.

The signal read by the photo detector of the pulse oximeter consists of a AC component superimposed on a DC signal. The DC component is the constant reflection of light by the body's tissue: skin, fat, venous blood and the non-pulsating arterial blood. The AC components is the variation in reflected light due to the change in diameter of the arteries and is usually between 0.5 - 2% of the DC component (**?**). Therefore the frequency of the AC component is synchronised to the heart rate.

2.2.7.3 Ballistocardiography

Ballistocardiography (BCG), also known as a seismocardiogram, is the measurement of the mechanical effects of the beating heart. Typically accelerometers or pressure sensors will be used to measure movement or forces on the surface of the body. BCG has been researched for use in ear heart rate extraction. In a wearable device proposed by Da He *et al.* (2010), mechanical vibrations associated with heart rate are converted to electronic signals through capacitive sensing electrodes. This method works my measuring the change in capacitance between the two electrods as the distance between them changes due to heart rate vibrations. A study by Winokur *et al.* (2012) proposed measuring the head-to-foot axis recoil during the principal blood-volume shift during cardiac ejection. This is done by placing an MEMS accelerometer behind the auricle. Due to the movement dependent method of operation this technology is extremely susceptible to motion artefacts and it can only be used during which the body is stationary.

The traditional and simplest of which is placing an index and middle finger on the wrist and counting the arterial pulses felt per minute. In fact, heart rate pulse can be felt throughout the body where large arteries are close to the skin.

A variation of this technology is discussed in a article by Park *et al.* (2015). They propose using a scissor shaped hinge mechanism in the ear canal that measures the change in the canal size due to the in-ear blood pulse waves. The mechanical movement it converted to an electrical signal through a piezoelectric film sensor.

2.2.7.4 Other methods

Electronic stethoscopes uses an microphone to record heart sounds. The hears makes a distinct series of sounds during the cardiac cycle due to blood turbulence and the shutting of heart valves. The period of this sound series can be used to determine heart rate and does not require skin-contact.

A Doppler flow-meter can be used to detect the alternating blood current component in near-surface arteries. This component is synchronised to the heart rate frequency. The device can use ultrasound, microwaves of light to achieve the Doppler shift.

2.2.8 Respiratory rate

Breathing is a process critical for life. Respiration is the first step in the chain of events to get oxygen to the body's cells for metabolism to provide the body with energy. Breathing and plus it the first signs of life to check for in a medical emergency.

How is the RR controlled

Appart form the obvious face that a lack of breathing is a problem, the RR can divulge some information about a persons health. What does the RR tell us about health

Measure through baseline oscillations of BCG signal (see The Ear as a Location for Wearable Vital Signs Monitoring (Da He *et al.*, 2010))

Respiratory rate is the rate at which ventilation takes place in the lunge. One inhalation and exhalation cycle is counted a breath and respiratory rate is usually measured in breaths per minute. Healthy adults have an resting respiratory rate of between 12 and 18 breaths per minute., This can vary drastically if a the body is experiencing physical or emotional stress.

It is important to monitor breathing, for irregular breathing or difficulty to breathing may be an induction of healthy problems. Apnoea is when breathing stops completely. This is especially an danger in infants and patients in the ICU.

Traditionally, respiratory rate is measured by counting the number of timer the chest visibly rises as a person inhales. Other methods include listening to the chest with a stethoscope and counting audible breaths, fixing an accelerometer to the chest, measuring CO_2 levels in the respiratory gases and looking at variations in heart rate.

Caretakers are usually very concerned about sleep apnoea in infants, as cause a risk for infant mortality. Apnoea monitors are available to warn caretakers if breathing halts. These monitors usually measure force or acceleration caused by the breathing of the sleeping infant. The device can be worn by the infant or can by placed in the cot.

All respiratory related measurements in the reviewed products rely on movement sensors attached to the body of the infant that senses its movement. Sensors include accelerometers and the *BreathOptic*™ sensor used by Sleep-Mat. These sensors detect the chest movement produced by the infant while breathing. In some cases, like Mimo and Sleep-Mat, these sensors are sensitive enough to determine the infant's respiratory rate from this movement. In other products, such as Anglecare and Monbaby, the sensors are sensitive enough to register the movement due to breathing, but not sensitive enough the extract the rate of breathing. Alerts are sent wirelessly to the cellphone of the caretaker if the movement stops for a certain amount of time. This may indicate that the infant has stopped breathing. The problem with this method is that products like Monbaby, Anglecare and Mimo will only alert the caretakers once the infant has stopped breathing completely for 15 or 20 seconds. This may be too late to prevent an infant mortality. A product is needed that can accurately monitor the respiratory rate and warn the doctor or caretakers if the respiratory rate drops or becomes irregular. Respiratory sinus arrhythmia (RSA) is the baseline oscillation in heart rate in synchrony with the respiratory rate. It is observed as an increase in heartrate during inspiration and a decrease during expiration. According to a study done by Stratton JR et al, the variation in heart rate due to RSA is higher in younger test subjects with 74% increase in children vs. 52% increase in adults [5]. These findings support the use of RSA to determine the infant's respiratory rate. A study has been done by D da He investigating the use of ballistocardiogram heart rate measurements to detect RSA [6]. This project will attempt to detect RSA in pulse oximetry heart rate measurements. This is a unique approach in wearable monitoring devices. The advantage is that no extra sensors, like accelerometers, are needed for the measurement of respiratory rate.

2.2.9 Blood Oxygen Saturation

Haemoglobin is the oxygen transporter protein found in the red blood cells of blood. Blood gets oxygenated in the lungs and then carries O_2 to the rest of the body for aerobic respiration necessary to produce energy. The correct levels of oxygen in the blood is vital to the health of the individual.

Oxygen saturation (SO_2) refers to the fraction of oxygenated haemoglobin to total haemoglobin in the blood:

$$SO_2 = \frac{C(HbO_2)}{C(HbO_2) + C(Hb)} \times 100\%$$

Where $C(HbO_2)$ is the concentration of deoxygenated haemoglobin (deoxy-haemoglobin) and $C(Hb)$ is the concentration of oxygenated haemoglobin (oxy-haemoglobin).

Blood oxygen saturation of 95-100% is normal in healthy humans. Hypoxemia is the condition when the saturation is below 90%. This can be an indication of circulatory or ventilatory problems, anaemia or sleep apnoea. Levels below 80% can hinder organ function and can lead to organ failure, cardiac- or respiratory arrest. In the absence of oxygen, damage to the brain starts within 5 minutes with brain death ensuing within another 10 to 15 minutes.

Oxygen saturation can be measured by means of an arterial blood gas test resulting an arterial oxygen saturation reading. An alternative method is pulse oximetry. This method measures peripheral capillary oxygen saturation (Sp02). This is a clinically excepted estimation of the arterial oxygen saturation.

Various devices are available for measuring blood oxygen saturation. Elaborate...

2.2.9.1 Oxygen Saturation Measurement Theory

Blood oxygen saturation calculation through pulse oximetry relies on the different adsorption spectra of oxyhaemoglobi) and deoxyhaemoglobin. Figure 2.6 shows the absorption spectra of oxy- and deoxyhaemoglobin. It can be noted that deoxyhaemoglobin has a significantly higher absorption of red light (600 - 750 nm wavelength) while oxyhaemoglobin has a slightly higher absorption of infrared light (850 - 1000 nm wavelength). This explains the fact that oxyginated blood apperas bright red and deoxygineted blood is a darker shade of red. (find a source for the image) (What is on y-axis and what is NIR region). Literature usually uses 660 nm (red) and 940 nm (near infrared) http://www.iosrjournals.org/iosr-jeee/Papers/Vol8-issue1/D0812226.pdf?id=7592

From the Figure 2.6 it can be seen that the ratio of absorbed red light to absorbed infra-red light is unique to a certain level of blood oxygen saturation. Therefore this ration can be used to estimate blood oxygen saturation. To account for different DC absorption between patients, a modulated ratio (R) is used:

$$R = \frac{\left(\frac{AC}{DC}\right)_{\text{red}}}{\left(\frac{AC}{DC}\right)_{\text{IR}}}$$

This ensures that the O_2 saturation of only the arterial blood is calculated. The ration can be checked against an empirical determined curve. The standard formula for this curve is found in literature as $\%SpO_2 = 110 - 25R$, (http://www.ti.com/lit/an/slaa655/slaa655.pdf) but it can vary from device to device.

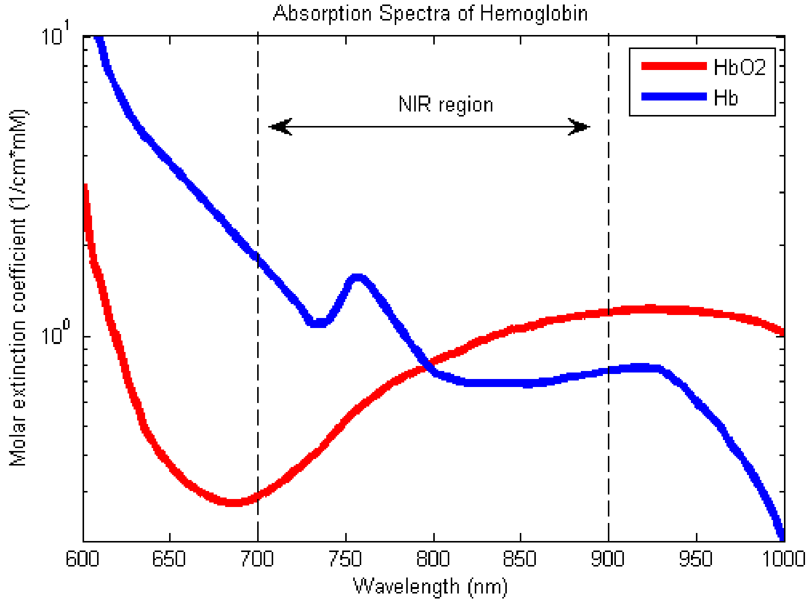

Figure 2.6: Absorption spectra of oxy- and deoxyhemoglobin

2.2.10 Respiratory Rate

2.2.11 Respiratory Rate Theory

2.2.12 EEG

2.2.13 EEG Theory

Chapter 3

Concept Design

This chapter will document the process of designing and developing the device and supporting software needed to answer the research question. The design process will combine the knowledge gained in the literature study chapter with engineering methods to find a unique solution to the stated problem. A classical engineering design approach will be taken: starting with determining the system requirements, using these requirements to set up a list of quantitative design specifications, developing concepts so meet these specifications and finally choosing the best concept through some evaluation process. After the best solutions has been identified, a detailed design phase will commence. Detailed design will consist of component selection, hardware integration and software design. In this chapter 'system' will refer to the device n development along with its supporting software.

3.1 System requirements

In order to ensure that the device can be used in a study to determine if the ear canal is a feasible location for vital sign extraction, it must satisfy the a set of high level requirements. The "system" refers to the device along with the supporting software. These requirements will act as guidelines to the rest of the design process. The system should be designed to satisfy the following requirements:

- The device must be able to measure the vital signs mentioned:
  - core body temperature
  - heart rate
  - respiratory rate
  - Blood oxygen saturation
  - EEG signals

- The devise should have an ear probe with embedded sensors to measure the mentioned vital signs from the ear canal
- Data captured should be sent to a nearby PC through a wireless connection
- It should be able for a person to wear the device without it obstructing normal movements
- The device should be mobile an no wires should extend beyond the wearer
- The device should be safe for the user to ware
- Vital sign measurement methods should not require the penetration or removal of tissue or fluid from the wearer
-
- The supportive software must:
  - store data
  - extract useful vital sign information from the data
  - detect when vital signs indicate abnormal trends via an algorithmic support platform

3.2 Quantitative Design Specifications

In order to go from system requirements to a concept, design specifications are needed. Where possible, quantitative goals will be set for different aspects of the design. These specifications will guide the selection of components for the device and the development of software to interface with the components.

3.2.1 Sensors

The most important requirements of the device is to measure the five vital signs mentioned. As seen during the literature review, there are many different methods of measuring the same physiological sign. To help in the selection of the most appropriate measuring method for each vital sign, a understanding is needed to exactly what will be required of each method this system. A "method" in this section, it refers to the set of steps or laws of physics that will be used to measure a specific vital sign. While component will refer to the physical structure that will incorporate the method to make the measurement. For example, a method can be measuring temperature by using the the physical phenomena of heat conduction, and the component that will realize this method will be a thermocouple. Specifications for the accurate monitoring of each vital sign will be discussed in the following paragraphs.

3.2.1.1 Temperature

A method is needed to monitor the core body temperature (or an acceptable approximation thereof) in the ear canal canal. The method and component to measure the temperature should meet the following goals:

- Sampling frequency: faster than 10 samples per minute
- Resolution: smaller than 0.01 °C
- Error: smaller than 0.1 °C
- Measurement range: further than 5 mm
- Overall compact shape in order to fit inside the ear canal
- Sensor diameter: smaller than 5 mm
- No contact should be made with the tympanic membrane
- Low pass filter: filter out high frequency noise
- The sensor must be able to compensate for the ambient temperature

3.2.1.2 Heart Rate

A method is needed to measure the heart rate of the patient through the ear canal. The following goals should be met to ensue a accurate heart rate monitoring:

The primary goal of the pulse oximetry sensor is to monitor the pulse rate of the patient for this on of the vital signs specified by the system requirements. SpO2 measurement is a secondary goal. The required hardware for measuring the SpO2 must be included in the device. The pulse oximeter will consist of two light emitters with wavelengths of 660 nm and 940 nm respectively. One or two photodetectors will be used to measure the light passing through the tissue. The photodetector that collects the emitted light will output a low voltage signal. This signal must be amplified to a range there it can by digitalized accurately. The sensor mush be able to compensate for the ambient lighting conditions. Further specifications are as follows:

- Sampling frequency: faster than 50 Hz
- Photodetector wavelength range: 650 to 950 nm
- Photodetector and emitters size: thinner than 2 mm
- Low pass filter: filter out high frequency noise
- High pass filter: filter out low frequency motion artefacts

3.2.1.3 Respiratory rate

3.2.1.4 Blood Oxygen Saturation

3.2.1.5 EEG

Design specifications are proposed for the EEG part of the project in order to ensure that the devise being designed by M Rabie can be integrated later on. It is important that the rest of the hardware and software being developed in this project is compatible with a basic EEG sensor. The EEG system that must be made provision for has the following specifications:

- Number of electrodes: 3
- Sampling frequency: faster than 200 Hz
- Amplifier gain: 100 - 100000
- Amplifier common-mode rejection ratio: larger than 100 dB
- Amplifier input impedance: larger than 100 MΩ
- A/D converted resolution: smaller than 0.5 μV

The design will consist of three different types of sensors to record three biosignals. All sensors will be located in the probe that enters the ear canal. The three sensors are:

- Infra-red sensor to measure tympanic membrane temperature
- Pulse oximeter to measure pulse rate
- Electroencephalogram electrodes to measure electrical brain activity

3.2.2 Dimensions

The prototype should have a probe that fits into the ear canal of the test subject to take the required measurements. The casing of the probe should be of biocompatible material. The probe shape should place the sensors in the correct positions in the ear canal to take the readings. The probe should connect with the remainder of the onboard electronics. Size requirements of the probe is as follows:

- Probe diameter: smaller than 5 mm
- Probe length: shorter than 10 mm

3.2.3 Power

The device should be battery powered. A trade-off will exist between battery size, capacity and charging time. The battery life is selected to be practical for the user. The battery pack should be removable and replaceable to allow for the minimum interruption in the monitoring of vital signs. A low power warning system should be implemented. Design specifications for the power system include:

- Battery life: 48 hours
- Charging time: 4 hours

3.2.4 Microcontroller specifications

The sensor probe will connect to an onboard microcontroller. Storage and communication modules will also be needed. The probe and processing electronics should be able to function as a stand-alone devise with a mobile power pack, onboard processing capabilities and wireless connectivity. The controller must be able to handle the processing needs of the device. The maximum amount of signal processing should be done by the onboard processor to minimize the load on the wireless network. The following are the main needs:

- Number of signals to sample: 5 (2 photodetectors and 3 EEG electrodes)
- Sampling speed: faster than 1 kHz (Sequential sampling)
- Analog to digital converter: more than 10 bit
- Onboard storage: more than 32 kB
- I/O ports: more than 10
- Communication ports: multiple UART, I2C and PWM
- Asynchronous internal clock
- Low power consumption
- Multiple power modes for power saving
- Signal processing capabilities
- High level of robustness and fault tolerance

3.2.5 Communication

The device must be able to connect to the internet through a wireless network. Collected information must be sent to a cloud hosted platform to do the final processing and run the warning system. The onboard communication module must be able to connect to the internet through a wireless local area network (WLAN) and upload data. This connection must be fast enough to stream real time data from the device. Data must be made available to the involved parties and they should be warned if alarm conditions is sensed. Requirements for the communication system includes:

- Onboard communication speed: faster than 1kB per second
- Onboard communication range: farther than 10 m
- Capable of cloud connectivity
- Cloud data storage: more the 1 month of collected data
- Cloud update speed: faster than 5 seconds

3.2.6 Pulse oximeter

3.2.7 EEG

3.2.8 Software

The software side must consist of the onboard microcontroller software, communication module firmware and the cloud base platform software. All software should be robust and include error handling and troubleshooting methods. The functionality requirements for the onboard microcontroller include:

- Structures to store a number of digitalized data points
- FFT calculation capabilities
- Digital filtering capabilities
- Extraction of pulse rate from photodetectors
- Extraction of temperature from Infra-red sensor
- Extraction of breathing rate from pulse rate by means of respiratory sinus arrhythmia
- Extraction of EEG signal from electrodes
- Sending processed data to the wireless module
- Power management algorithms

The communication module firmware should contain AT commands to connect to a WLAN and upload processed data to the cloud based platform. Specifications for the cloud based platform:

- It must have storage for the data that the device uploads
- Some final processing should be done on the data
- Detect when measured parameters are outside the pre-set limits
- Send a warning to the physician and caretakers phone
- Smartphone application with easy to use user interface for the monitoring of infant vitals

3.3 Concept Generation

Various methods available to measure different vital signs were described during the literature review stage of this project. In this step, the most suitable vital sign monitoring methods will be selected for the concept.

The next step will be to generate a number of conceptual solutions to satisfy the design specifications set in the previous section. Solutions will be in the form of components and methods selected to meet the set requirements.

Concept generation will start of with the decomposition of the system. This step involves breaking the complex system into its basic functional and physical subsystems. Individual subsystems will be handled as problems and methods of realizing these subsystems will be seen as the solutions. For example, measuring temperature is a functional subsystems and handled as a problem. Subsequently, a thermometer is a way to realise this subsystem and therefore seen as a solution to the problem.

3.3.1 Functional Decomposition

Functional decomposition is used to simplify the system, by isolating its various functions and giving attention to each one separately. This is an ideal method for generating physical concepts for the device in development, for the functional boundaries are very distinct and functions are well defined. The function of the ear vital sign monitor is so monitor the mentioned vital signs, some data processing, communication and holding the sensors in place. A detailed functional decomposition will follow. Suitable solutions will be found for each problems and the best solution will be determined by means of some evaluations method. All the selected solutions will then be combined to form the final design. (Or various combinations will be evaluated)

- Measure temperature

- Measure heart rate
- Measure breathing
- Measure Sp02
- Measure EEG
- Interfacing with peripheral components (pre-BT processing)
- Send data to PC
- Process data

3.3.1.1 Wireless Communication

3.3.2 Physical Decomposition

Physical decomposition is used to simplify the system, by breaking it into its various physical parts. This step only concerns the hardware part od the device. This will determine the size, shape and material of the device.

3.3.3 Form

3.3.4 Material

3.4 Concept Selection

3.5 Hardware Selection

Chapter 4

Hardware Design

This chapter will discuss the detailed design of the device. Attention will be given to implementation of each component selected in the consent generation stage. The interface between the various sensors and the MCU will be discussed. The communication between the device and the PC and the software running on the MCU and on the PC will be laid out.

4.1 Measure Heat Rate and Sp02

Heart rate and SpO_2 will be measured with the same sensor: A pulse oximeter.

As stated in the literature study, blood oxygen saturation can be measured through an arterial blood gas test or through pulse oximetry. Arterial blood gas test involves drawing a blood sample and doing in vitro tests on the sample. This method can be rejected, for it is in obvious violation of the system requirements. Pulse oximitry is therefore the preferred method for measuring SpO_2.

A pulse oximeter consists of two LEDs (emittors) and a photo detector. There are an few possible solutions that needs to be considered. Three set-ups are considered.

Firstly, the pulse oximeter in transmittance mode. The transmittance mode will require the emitters and detector to sit on opposite sides of a thin piece of tissue. A suitable location for this will be the ear lobule or the tragus. The cartilaginous pinna will not be ideal, for is contains less blood vessels.

Secondly, the inside of the ear canal is also considered. This set-up will consist of placing the emitters and detector on opposite walls of the ear canal. This set-up will combine reflective and transmittance modes, for light will be reflected and transmitted through the tissue around the ear canal from the ons side to the other. Figure X.

Lastly the pulse oxymeter in reflective mode. This mode allows the emitters and detector to be place next to each other. It need not be paced on a thin

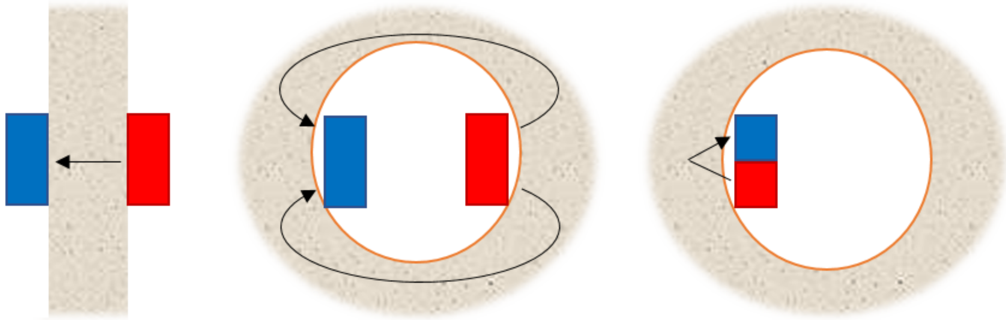

Figure 4.1: Drawing of the auricle (goo.gl/mmLnFx)

part of tissue. This means that the pulse oxymeter can be place against on side of the ear canal wall.

Figure 4.1

The pulse oxymeter in reflective mode was selecte.

Three hardware options: Custom components, NJL5501R and MAX30100

What methods and sensors was regarded. How was die MAX30100 selected at the end.

modulation ratio between red and infrared LED signals

4.1.1 Thermometer Design

Copy the Thermometer Subsystem word doc info in here, and the images.

Calibration information

Software design

The advantages of measuring the temperature of the tympanum has been discussed during the literature review. It has also been mentioned that measuring temperature through a thermistor (thermopile) in contact with the membrane can cause discomfort and harm to the wearer. Therefore an IR temperature sensor will be used to measure the tympanic temperature.

An understanding has been obtained about the general theory of IR thermosensing. This allows for the selection of a sensor to measure the tympanic temperature.

Various IR sensors are available. The main constraint for the sensor is the size. The sensor must be able to fit inside the ear canal of the wearer in order to have an unobstructed view of the tympanic membrane. This limits the options considerably. Two sensors were seriously considered: The TMP006 and the ...... The TMP006 is an non-contact IR sensor with a digital interface. (More general sensor description information from the data sheet here)

The (other sensor info) How the TMP006 choice was made at the end

4.1.2 MAX30100 flow of data

This section will explain how data flows from the MAX30100 to the user interface and how specific vital sign information is extracted.

adaptative treshold

4.1.2.1 AC and DC Extraction

As mentioned in the detailed design section, the MAX30100 converts reflected light intensity to voltage level which in turn is converted to an 16-bit? integer through an on chip ADC. This digital value is a representation of the amount of light reflected by the tissue of the ear canal. This value contains a DC and AC component. The AC component contains the pulse information. The DC components is used in calculating Sp02? and to adjust the current through the red LED on the MAX30100 (see dynamic current adjustment subsubsection) To separate the AC and DC components a IIR filter is implemented on the MCU.

Give the formula and explain what the variables are (see design word doc)

Choosing alpha close to one will create a filter with a narrow stop band close to the DC frequency. Through some trail and error an alpha value of ? was chosen. Criteria for this choice was signal form and steady DC rejection, less drift?? (Insert some graphs plotted of filtered signals with different alpha values, maby also a frequancy response graph of the filter)

4.1.2.2 Dynamic LED Current Adjustment

The MAX30100 allows for the individual adjustment of red and IR LED currents (get better description from data sheet). This ability can be used to improve the accuracy of the Sp02 calculation.

4.1.2.3 Beat Detection

The absorption spectra of oxygenated blood is highest for IR light. Therefore IR light is used to obtain the PPG.

See Pulse-Peak Detection of Wearable Sensing of In-Ear Pressure for Heart Rate Monitoring with a Piezoelectric Sensor saved article

4.1.2.4 Sp02 Calculation

After the AC component has been extracted from the signal is is possible to calculate the SpO_2. An AC root mean square is calculated of the red and IR signals over a period of 5 heart beats (why). The ratio between the red and IR RMS valus are then calculated and the $\%SpO_2$ is calculated with the standard formula from literature. The following formula describes the calculation:

$$\%SpO_2 = 110 - 25\left(\frac{RedACrms}{IRACrms}\right)$$

4.1.2.5 Measure Heat Rate and Sp02

4.1.2.6 Measure Breathing Rate

4.1.2.7 Measure EEG

Chapter 5

Experimental Procedure

5.1 Overview

This chapter will discuss the experimental set-ups used to test the functionality and performance of the developed device. The aim of the study is to determine if the developed device can indeed measure accurate vital sign data from the ear canal. This, in turn, will answer the research question. Each measured vital sign needs to be validated, in order to prove that is is indeed accurate data.

Two types of validation will be used in this study: Benchmark validation for core temperature, heart rate, respiratory rate and Sp02; and event related potential detection to validate EEG.

Healthy adult volunteers will partake in this study. These volunteers will be fitted with the developed device and with the industry standard medical device. Device and benchmark data will be collected simultaneously and compared afterwards.

This study will test the actual data measured and also the processing of this data. For example the extraction of heart rate from PPG and the extraction of breathing rate from heart rate.

Tests will involve comparing time varying signals (PPG), time invariant signals and calculated figures (Breathing rate, Sp02, Temp?)

5.2 Theory

5.3 Ethical Consent

5.4 Subjects

5.5 Benchmark Validation

Core temperature, heart rate, respiratory rate and Sp02 measurements will be tested through benchmark validation. This entails comparing the measurements made by the developed device to measurements made, in the same conditions, by a industry standard medical device. In this study, a device that conforms to the EC requirements is seen as industry standard device. This is a valid assumption, for the CE mark is sign that the device complies with the EU legislation that is applicable to the product (what does this mean?).

Three devices was selected to provide the benchmark measurements.

The vital sign measurements of the device will be compared to selected benchmarks. These benchmarks will be measurements made by various industry standard medical devices.

5.6 Method

5.6.1 Benchmark Apparatus

Benchmark devises are chosen to measure the same physiological signs as the developed device. The Nexus-10 physiological monitoring platform will be used to provide the benchmark measurements for PPG, heart rate and respiratory rate. The SureSense blablabla wil be used for the Sp02 benchmark and an ear thermometer for the core temperature benchmark.

Mind Media's Nexus-10 is a ten channel biofeedback system. It comes with a array of sensors that can acquire a range of different bio-signals. In this study the blood volume pulse, and respiration sensor will be used. The device can collect data at 128 samples per second.

SureSense blablabla is a ...

Ear thermometer...

with photoplethysmograph was used. Photoplethysmograms was compared and average heart rate readings as well. This will evaluate the feasibility of measuring a PPG from the ear canal ass well as the extracting a heart rate from this signal.

5.6.2 Comparing Data

Comparing the device PPG to the Mexus BVP

5.7 Results

Appendices

Appendix A

Discrete Element Method Theory

A.1 Ball elements

A.1.1 Ball mass and inertia parameters

Consider a volume element $\mathrm{d}V$ with respect to a static base S of an arbitrary solid body with density ρ. The mass of the body is obtained by integrating over the volume of the body,

$$m = \int_{\text{body}} \rho \, \mathrm{d}V \tag{A.1}$$

In figure A.1, a ball with radius R_i and uniform density ρ_i is depicted. The mass of the ball is after integration of equation (A.1)

$$m_i = \tfrac{4}{3}\pi\rho_i \, R_i^3. \tag{A.2}$$

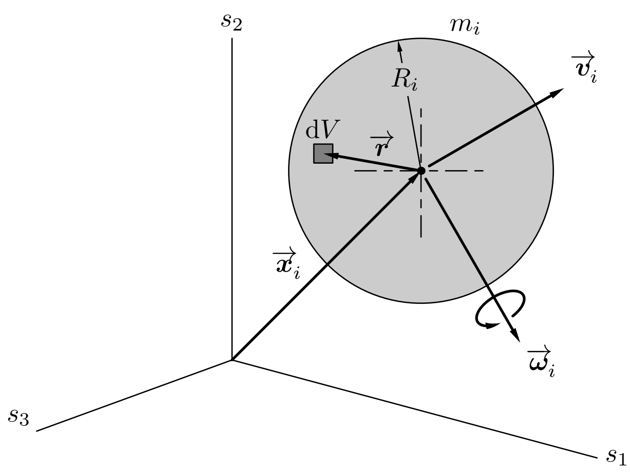

Figure A.1: Ball Element Parameters

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