Monitoring core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity through a wireless ear probe

by

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September 2017

Declaration

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Abstract

Monitoring core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity through a wireless ear probe

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Add abstract.

Uittreksel

Monitering van kern temperatuur, hartklop, respiratoriese tempo, bloed suurstof versadiging en EEG deur middel van 'n draadlose oor probe

("Monitoring core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity through a wireless ear probe")

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Voeg uittreksel by.

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

Dedications

Hierdie tesis word opgedra aan ...

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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

$\overrightarrow{v}$	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.

This project revolves around the continuous measurement of medical signs. These are objective parameters that give an indication about physical well-being and the state of essential physiological functions. For example, infections are indicated by a rise in core temperature, pneumonia can be detected by a shortness in breath, a abnormal decrease in respiratory rate during sleep can be a warning sign for sudden infant death syndrome, a rise in heart rate can indicate physical stress and abnormal brain activity can be detected at the onset of a seizure. These signs can be detected electronically before traditionally observable symptoms appear. In many cases the deciding factor in the success of a treatment is whether the illness is detected early enough.

Because of this, 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, medical sign monitoring is done with a stationary, dedicated device for each signal to be measured. It is easy to see that this is not suitable for continuous and mobile medical sign 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 like an earphone or hearing aid. It will make multi-parameter medical sign measurements and transmit collected data through a wireless connection to a supporting system for storage and analysis. In this project, the supporting system will be on a laptop, but it can also be on the smart-phone of the wearer or on a cloud server. This supporting system can be used by a physician, caretaker or the wearer self, to monitor and track his/her health.

From here onwards, this device will be referred to as the *Ear-Monitor*. This report will discuss the project aim and objectives, relevant literature and the design, manufacturing and testing of the Ear-Monitor.

1.1 Aim/Research Question

To develop and test a proof of concept wearable device that can monitor medical signs and transmit collected data wirelessly to a warning and storage system. Medical signs include core temperature, heart rate, respiratory rate, blood oxygen saturation and electrical brain activity.

(or in the form of a Research Question:)

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 medical sign monitor

1.2 Motivation

This project arose from a need found in medical practise and expressed by the proposer/advocate of this topic. It is the need for better vital sign monitoring methods for neonates and infants in hospital nurseries and a home. High-risk patients are placed in ICUs and are thoroughly monitored, whereas lower risk patients are left in the nursery or sent home. These patients are poorly monitored while at a fragile age, increasing the risk of health issues. This insufficient health monitoring for neonates and infants is due to to the lack of a practical monitoring method. The solution to this issue is the development of a unobtrusive, wearable health monitor.

While contemplating and researching this idea, it was found that a much larger group can benefit from such a device. This lead to the project pivoting toward a more general purpose medical sign monitoring devise. This device will prove if it is practical to measure the mentioned medical signs through the

external ear canal. If this proof of concept is successful, the methods developed during this project can be used to develop specialized ear-worn devices from various applications. In practice, such a device can transmit health statistics and warnings in real time to a physician or caretaker. Applications include:

- Monitoring neonate- and infant health in nurseries and at home.
- Monitoring health of patients with chronic illnesses.
- Studying the effect of prescription drugs or other treatments.
- Monitoring vital signs and brain activity, like thalamic modulation, of patients during anaesthesia.
- Monitoring patients with a high seizure/epilepsy risk
- Monitoring the health of people working under strenuous conditions like heavy machinery operators and soldiers.
- Tracking the health and fitness of athletes.

The ear was chosen as location for the following reasons. The anatomy of the ear and the proximity of an ear-worn device to the tympanic membrane and brain, means that al the medical signs mentioned can theoretically be measured from this location. This eliminates the need for multiple devices or the need for wires connecting sensors on different parts of the body. The absence of sensors on traditional locations such as the chest or limbs and the absence of connective wires means that the ear-worn device is minimally obstructive for the wearer, especially through freeing up the hands and allowing him/her to move around. The shape of the external ear is ideal for supporting a device without the need for straps or adhesives. Furthermore, the head remains relatively still in relation to the rest of the body. This will reduce the risk of motion artefacts corrupting the signals of interest. An ear-worn device can be embedded in the already familiar shape of a earphone of hearing aid. The final motivation for using the ear as location for the health monitor is its novelty. As will be apparent in the literature review chapter of this document, there is opportunity for research to be done in the unsaturated field of ear-worn health monitors.

The five mentioned medical sign were chosen because...?

Chapter 2

Biology Literature Review

This chapter aims to describe the biological context within which the project is undertaken. An overview will be given about the anatomy of the ear which is relevant to this study. After which, background will be given about the physiology of each of the five medical signs.

2.1 Ear Anatomy

The area that is available for the Ear-Monitor to make the medical sign measurements is the external ear. It includes the auricle, ear canal with surrounding tissue and the lateral side of the tympanum. Each part of the ear anatomy will be discussed, especially with regards to its ability to emit information about medical signs or to 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, 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 and the earlobe is a popular location for traditional pulse oximetry measurements. This is a

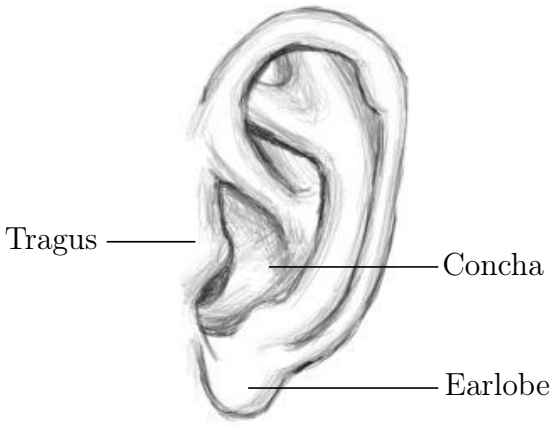

Figure 2.1: Anatomical structures of the auricle (Get source from: goo.gl/mmLnFx)

possible location for a ear-worn device to make a heart rate and SpO_2 measurement (Poh *et al.*, 2010). The earlobe's blood vessels are, however, susceptible to vasoconstriction due to cold or hypovolaemia (WorldHealthOrganization, 2011). This will reduce the blood perfusion of the subcutaneous tissue making it harder to get accurate heart rate and SpO_2 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).

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 auricle is visible and the shape and relative size of the canal can be observed.

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). This S-shape is important to keep in mind while placing a sensor to measure tympanic temperature. Ear canal size also varies from

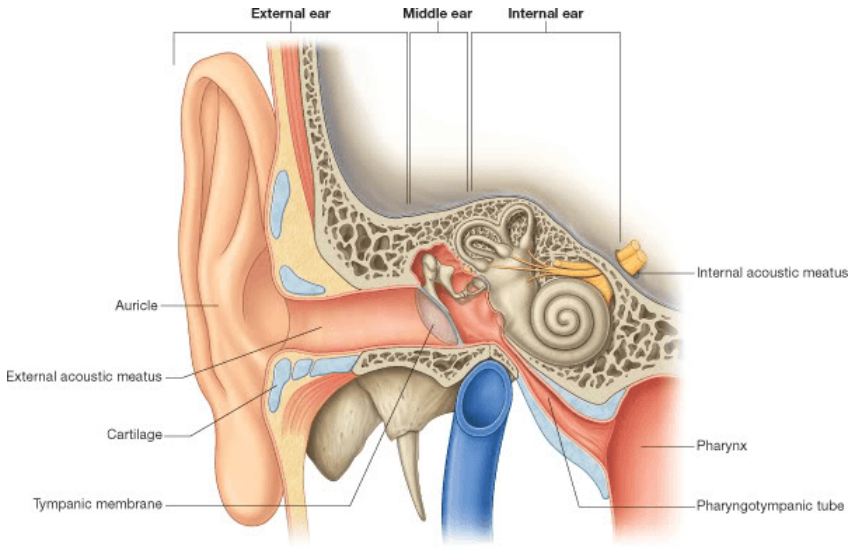

Figure 2.2: Structure of the ear (Drake et al: Gray's Anatomy for Students)

person to person. Therefore, an ear probe should be designed to fit in a variety of in ear canal shapes and sizes.

The secluded nature of the ear canal means that it has a relative constant temperature. Air trapped in the canal by a plug of high thermal resistance will reach thermal equilibrium close to the temperature of the canal wall and tympanum. This is a better location for a core temperature measurement, but will still be influenced by the ambient temperature.

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 still nature of the head will minimize movement artefacts.

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 Tympanic Membrane

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.

As with the rest of the external ear, the tympanum is 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 Medical Sign Physiology

This section reviews the theory and research done about the physiological aspects of each medical sign that the Ear-Monitor is required to measure. The importance of each of the five medical sign will be discussed, including the typical range of measurements expected from healthy adults and the causes and implications of deviations from these healthy measurements.

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 $37.5°C$ (Jones, 2010). 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 of medical signs.

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

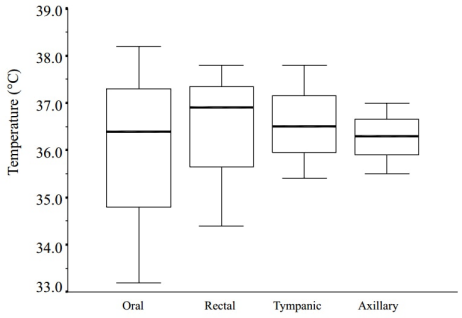

Figure 2.3: The results from 20 studies with strong or fairly strong evidence of normal oral, rectal and tympanic temperature (°C) in adult men and women are presented. Temperature is obtainable as mean value(bold lines), 1st and 3rd quartiles (unfilled bars) and range (thin lines).

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 $0.07 \pm 0.41\ ^{\circ}C$; urinary bladder $0.03 \pm 0.23^{\circ}C$; oral $0.05 \pm 0.26^{\circ}C$; and axillary $-0.68 \pm 0.57^{\circ}C$. 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 $\pm 0.2^{\circ}C$ (Erickson and Kirklin, 1993).

A second study done by Lefrant *et al.* (2003) showed the following results: oesophageal $0.11 \pm 0.30^{\circ}C$, rectal $-0.07 \pm 0.40^{\circ}C$, axillary $0.27 \pm 0.45^{\circ}C$, inguinal $0.17 \pm 0.48^{\circ}C$, urinary bladder $-0.21 \pm 0.20^{\circ}C$.

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 Heart Rate

The presence of a heart beat is paramount to 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.

The heart is the source of a group of biosignals. The firing of nodes and propagation of electrical charges through neurons and the conductive cardiac muscle gives of an electrical signals that can be detected. The contraction of the ventricles forces blood into the arteries, causing a temporary increase in blood pressure. This pressure increase propagates though the arteries as a wave, causing a temporary local increase on blood volume. Pressure- and volume changes can be detected. Blood turbulence and the opening and closing of heart valves causes the characteristic heart sound and chest movements, both indications of heart rate.

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 a lower than normal resting heart rate, usually below 60 bpm (Laskowski, 2015). 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 group of medical signs.

2.2.3 Respiratory Rate

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. Respiration ventilates the lungs with air through inhalation and exhalation. The respiratory rate of a healthy adult at rest is usually between 12 and 20 breaths per minute (Charbek, 2015). This can vary drastically if the body is experiencing physical or emotional stress. In increase in respiratory rate can be cause by a fever, pulmonary dysfunction or any one of numerous medical conditions. Respiratory rate is also part of the vital signs group of medical signs.

Respiratory rate monitoring is especially useful for diagnosing sleep apnoea. Symptoms include regular pauses in respiration or periods of shallow breathing (hypopnea) during sleep. This causes an oxygen deficiency in the body and lowers the quality of sleep. Short term symptoms include excessive daytime sleepiness, morning headaches, impaired alertness, and vision problems. If left untreated sleep apnoea can lead to high blood pressure, diabetes, depression, worsening of ADHD, stroke, heart failure, irregular heartbeats, and heart attacks (Blahd, 2016). Sufferers may be unaware of their condition and a sure-fire method of diagnosing it is my monitoring respirator rate during sleep, traditionally done during an overnight sleep study.

2.2.4 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 concentration fraction of oxygenated haemoglobin to total concentration of haemoglobin in the blood:

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

Where $C(HbO_2)$ is the concentration of deoxygenated haemoglobin (deoxyhaemoglobin) and $C(Hb)$ is the concentration of oxygenated haemoglobin (oxyhaemoglobin).

Blood oxygen saturation of 95-100% is normal in healthy humans. Hypoxaemia 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 and cardiac- or respiratory arrest. The brain in extremely susceptible to damage due to a lack of oxygen. Cerebral hypoxia is the insufficient supply of oxygen to the brain. This can cause brain damage and in severe cases, brain death.

2.2.5 Electrical Brain Activity

EEG, or electroencephalography, is the recording of the electrical activity in the brain. The neurons in the brain...

Chapter 3

Theory Literature Review

This chapter will accumulate a thorough understanding of the theory and current state of technology relevant to the measurement of each medical sign required of the Ear-Monitor. Attention will be given to the different methods available to determine each medical sign. This section will also make reference to various articles and studies done by other researchers in this field of study. The aim is to gather all the relevant information in order to make an informed selection of the methods and sensors the Ear-Monitor will use to measure each medical sign.

3.1 Core Temperature

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. Central to any digital thermometer lies a transducer that convert temperature to an electrical signal. Resistance temperature detectors, thermocouples thermistor and thermopiles will be discussed. They can be divided into contact and non-contact thermometers.

3.1.1 Contact Thermometers

These are a family of thermometers that measure their own temperature with the assumption they and the object whose temperature is of interest, are in thermal equilibrium. Therefore, they are usually placed in contact with the object. When using a contact thermometer in the ear, the sensor part of the thermometer can be placed in contact with the ear canal wall, the air inside the canal or with the tympanic membrane self.

3.1.1.1 Resistance Temperature Detector

Resistance temperature detectors (RTDs) uses the temperature-resistance relationship for metals to measure temperature. Thin wire coils or films of platinum, copper or nickel are usually preferred for they have a stable and repeatable temperature-resistance relationship over a large temperature range.

3.1.1.2 Thermocouple

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 hot junction (measuring junction). The other ends of the two wires are known as the cold junction (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. Reference temperatures are usually determined by a precise thermistor. Thermocouples are very versatile and widely used in clinical applications, but the downsides are that their output signal is low and non-linear, therefore requiring a sensitive and stable voltage measuring device (Jones, 2010).

Thermocouples can be connected in series and are then called thermopiles. This configuration sums the output voltages, resulting in temperature averaging. This method improves accuracy by reducing noise.

3.1.1.3 Thermistor

A thermistor is a type of semiconductor whose resistance varies with changes in temperature. They differ from RTDs in that they are usually made of ceramics, they have higher precision over a smaller temperature range and they can have a negative relation to temperature. Thermistors are preferred above RTDs and thermocouples for use as biomedical sensors due to their faster response time and higher sensitivity over a smaller range and. The smaller range does not matter, for the temperature range of interest in biosensors are small and well defined.

3.1.1.4 Contact Thermometer Application

In the case of RTDs and thermistors, the measuring element is placed in position and a current is sent through the sensor. By measuring the voltage across the resistive element, it is possibly to calculate the voltage and subsequently determine the temperature. In the case of the thermocouple, the hot junction can be placed in contact with the canal wall or tympanum. Typically, the hot junction will be enclosed with a soft material to protect the canal and tympanum. The canal is sealed off and time is allowed for the area to equilibrate to tympanic temperature.

Placing a thermometer in contact with the tympanic membrane will give an accurate measurement, but can cause discomfort to the wearer. There is also a risk of harming the tympanic membrane. Sensors in contact with the ear canal wall or the air inside the canal run the risk of making errors by measuring the temperature of objects that are not in thermal equilibrium with the tympanic membrane. Therefore, non-contact thermometers will be considered.

3.1.2 Non-contact Thermometers

Thermopiles can be used to detect thermal radiation without being I contact with the object. All matter with temperatures above 0 K radiates electromagnetic radiation according to the Stefan-Boltzman law. The thermal radiation, Q, per unit area is given by the equation:

$$Q = \varepsilon \sigma T^4.$$

Where ε is the emissivity, σ the Stefan-Boltzman constant and T the temperature of the object.

The wavelength distribution varies according to the temperature of the object and is described by Planck's law:

$$B_\lambda(\lambda, T) = \frac{2hc^2}{\lambda^5} \frac{1}{e^{\frac{hc}{\lambda k_B T}} - 1}.$$

Where B_λ is the spectral radiance, λ the radiation wavelength, h Planck's constant, k_B Boltzman's constant c the speed of light and T the object's temperature. Through maximizing B_λ , it is possible to find the dominant wavelength that is emitted at a certain temperature. Figure 3.1 shows a plot made of spectral radiance versus wavelength at $T = 37\ ^\circ C$, the core temperature of humans. It can be seen that the dominant wavelength is at 9.35 μm. This is in the infrared range, and therefore this type of thermal radiation thermometer is called an infrared thermometer.

In the case of measuring the temperature of the tympanic membrane, the hot junction's temperature will be determined by the radiation received from the tympanum minus the radiation radiated by the sensor self.

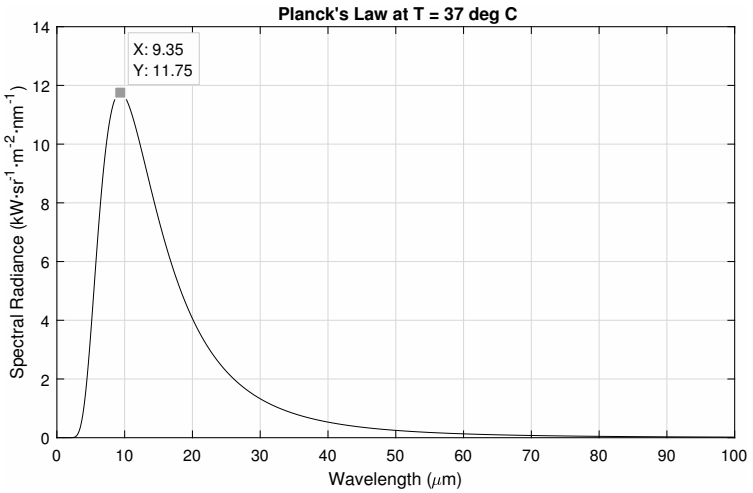

Figure 3.1: Plot showing how Planck's law can be used to determine the dominant radiation wavelength at certain temperature

When talking about thermal radiation, an important aspect is emissivity. Emissivity is the ability of an object to radiate thermal energy. 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 infrared sensor depends on the ability of the object to emit sufficient thermal radiation for the sensor to detect. Cross-referencing various emissivity tables, it was found that the emissivity of human skin is 0.98, meaning that it is an excellent emitter of thermal energy (Stumme *et al.*, 2003) (ThermoWorks) (Optotherm, 2017). The ear drum is covered with skin, making it an ideal target object for a non-contact thermometer.

An infrared thermometer generally consists out of a thermophile attached to a blackbody and shielded by an infrared filter that also acts as a lens to focus infrared waves (Karaki and Polyziev, 2014). This setup, shows in Figure 3.2, 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 period of core temperature can be as long as 10 seconds.

3.1.3 Commercial Temperature Monitoring Devices

Ear thermometers are widely used at home and in hospitals. Ear contact thermometers like Novatemp® and Starboard® claims a $\pm 0.2\ ^{\circ}C$ accuracy. Non-contact infrared ear thermometers usually have a similar rated accuracy. None of these are, however, wearable devices.

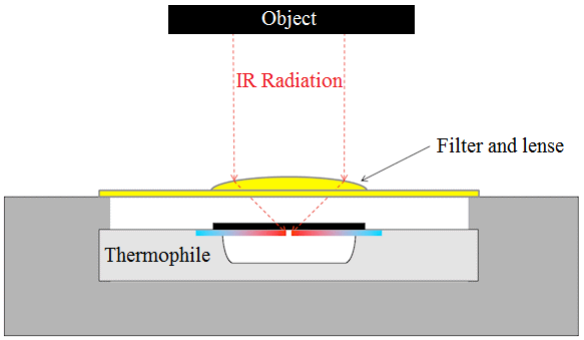

Figure 3.2: IR Thermometer diagram (V Polyzoev et al: Demystifying Thermopile IR Temp Sensors)

The *degree*°, Figure 3.3, is a continuous in-ear thermometer for children, developed by *cosinuss*°, a company specialising in wearable sensors. The bulk of the device is worn behind the ear, and there is a wire running over the auricle to the ear canal, in which a probe is placed. The device takes its temperature measurements with a sensor placed in contact with the canal wall. The manufacturer claims an accuracy of $\pm 0.1\ ^{\circ}C$. It monitors temperature continuously and sends real time data to a mobile phone.

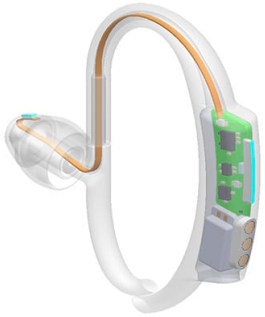

Figure 3.3: CAD model of the *degree*° from the *cosinuss*° website (include ref)

Apart from the *degree*°, there are not much literature on wearable ear thermometers. Two patents were found describing similar devices: US 6556852 B1 and US 20090221888 A1. The first of which proposes the use of an infrared sensor pointed at the tympanic membrane, and the latter not specifying the method of measuring. Hopefully, the tests planned for this study can add to this insufficient body of knowledge.

3.2 Heart Rate

The heart is a very dynamic organ whose influence can be felt throughout the body. Therfore there are many options available to monitor heart rate. Electronic monitoring methods include electrocardiography (ECG), photoplethysmography (PPG), ballistocardiography(BCG), phonocardiography and doppler flow-meters.

3.2.1 Electrocardiography

ECG is a recording of the electrical activity of the heart over a period of time. Electrical activity arise from the depolarization and repolarization of the heart muscle during the cardiac cycle. The most prominent electrical charge is the QRS complex, which corresponds to the ventricular depolarization and is visible on the electrocardiogram as a sharp peak in the millivolt range. ECG 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 wearable 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 ECG devices for clinical use.

The latest in wearable ECG electrodes is the use of dry polymer-based materials (Wang *et al.*, 2010) or non-contact electrodes that can be place on top of clothing (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 a single lead set-up with one electrode place on the mastoid bone behind the ear and a reference electrode placed on the neck. This configuration relies on the conductive properties of human tissue to carry electrical charges form the heart to the ear. They where able to used the electrocardiogram in conjunction with PPG and BCG to determine various heart intervals and track changes in mean arterial blood pressure. Figure 3.4 shows Winokur *et al.* (2012)'s device and a plot of its electrocardiogram. No heart rate information was extracted.

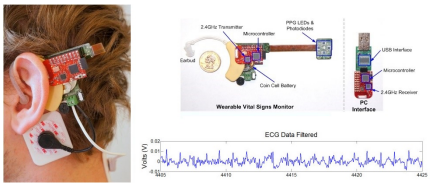

Figure 3.4: Ear-worn device developed by Winokur *et al.* (2012)

3.2.2 Photoplethysmography

PPG produces an optically obtained plethysmogram, which is a plot of volume the change of an organ over time. PPG can be used to measure the change in the 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 to stretch and contract with each cardiac cycle. PPG can be used to determine heart rate by measuring this volumetric variation.

A photoplethysmograph can non-invasively determine peripheral arterial blood volume by shining light through the skin surface, into the dermis and subcutaneous tissue and collecting the light transmitter or reflected. Light shined into the tissue can either be reflected, absorbed or allowed to transmit through. This leads to the two modes of PPG operation depicted by Figure 3.5.

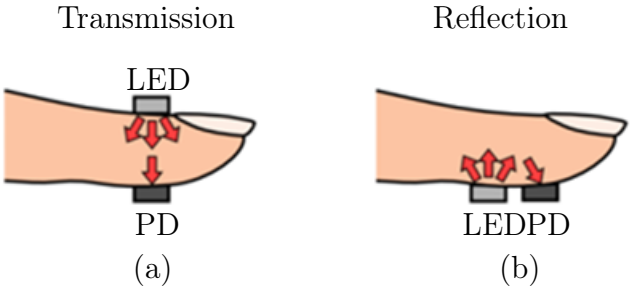

Figure 3.5: The two modes of Photoplethysmography (Tamura *et al.*, 2014)

In (a) the emitter and detector faces each other and are separated by tissue that can transmit the light, leading to a transmission mode PPG. Transmittance mode PPG is limited to locations on the body where transmitted light can be detected, like the finger, ear lobe, concha and tragus. These locations have limited blood profusion, especially at low temperatures. In (b) the emitter and detector is placed on the same plane and both faces toward the tissue. Light from the emitter is reflected by the tissue and captured by the detector, leading the reflection mode PPG. The emitter and collector needs to be optically isolated so that light cannot pass from the one to the other without going through the tissue. Reflectance mode PPG can be used at more locations, but they are more susceptible to motion artefacts (Tamura *et al.*, 2014).

According to Lambert's law, the amount of light absorbed is proportional to the length of the path that the light must travel in the absorbing substance (Encyclopædia-Britannica). Therefore, a change in blood vessel diameter will increase the distance the light must travel causing a change in light absorption.

This can be detected by measuring reflected or transmitted light. Variation in the light reflected or transmitted will be synchronised with the heart rate.

Shorter light wavelengths are mostly absorbed by the tissue, while longer wavelengths can penetrate deeper. Red and near infrared light are preferred for transmission PPG. While green light is becoming more popular for shallow reflectance PPG, due to larger light variations during the cardiac cycle and less noise than near infrared PPG (Tamura *et al.*, 2014).

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 due to the constant transmission or 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 transmitted or reflected light due to the change in diameter of the arteries and therefore, synchronised to the heart rate. The AC component is usually between 0.5 - 2% of the DC component (Tavakoli Dastjerdi, 2006). Figure 3.6 illustrates the way in which which the heart rate is visible in a photoplethysmograph. It can be seen that the blood volume increase with each heartbeat, and that this causes more light to be absorbed, thus less detected by the photodiode.

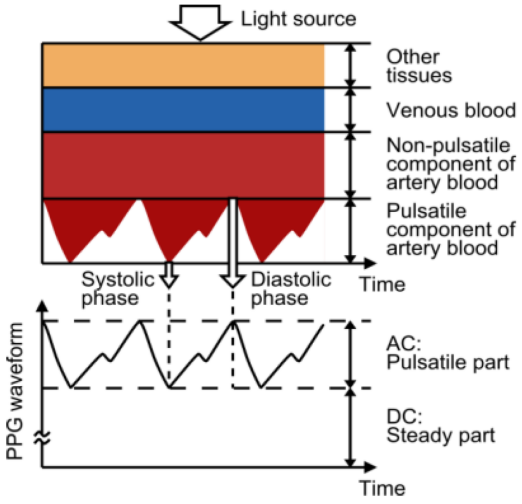

Figure 3.6: Pulse oximetry diagram (Source: tamura2014wearable)

3.2.2.1 Work done by others in Ear PPG

At this point, PPG is the most attractive option for the Ear-Monitor to measure heart rate and it is given extra attention during the literature review. A review of work done by others in the field of ear PPG revealed six devices relevant to this study.

Shin *et al.* (2009) presents a wearable music headset with an integrated transmission PPG ear clip that attaches to the ear lobe. The device includes an accelerometer to aid in the removal of motion artefacts. Evaluation was done through a study comparing the HR from the devise to that made with a conventional ECG recorder. This study revealed a heart rate error of 0.6% was found.

Poh *et al.* (2010) designed a wearable PPG with a magnetic earring sensor. The bulk of device sits in front ear canal and held in place by the auricle. A reflective PPG sensor is held against the ear lobe by placing a magnet on the opposite side. The device also includes an accelerometer to make baseline measurements for motion artefact cancellation. A study was conducted to compare the PPG signals measured by the wearable device to chest ECG signals collected by a FDA-approved commercial system. Whilst standing motionless, the study found a very high agreement between the ear PPG and the chest ECG with a mean bias of $0.62 \pm 4.51\%$ with ECG reference measurements.

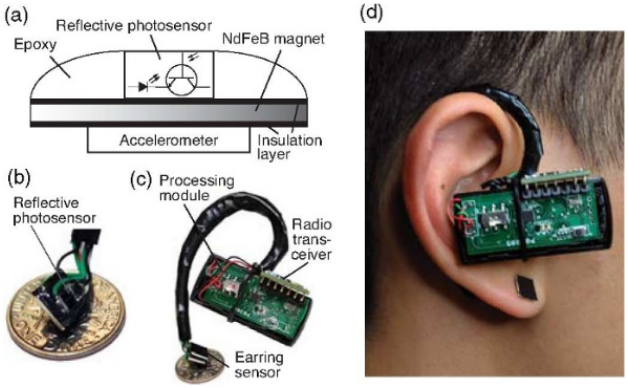

Figure 3.7: Pulse oximetry diagram (Source: tamura2014wearable)

Da He *et al.* (2010) researched an ear worn heart rate monitor containing PPG sensor in reflectance mode. Red light is shined into the tissue behind the ear and collected by a photodiode chip with an integrated transimpedance amplifier. Signals were not digitalised on the device, but recorded and processed on MATLAB. They compared their collected signal with a transition finger PPG and a chest ECG. Figure 3.8 shows this comparison.

Winokur *et al.* (2012) developed a similar device that shines 660nm and 940nm light waves through tissue at the mastoid bone and collecting the reflected light with 4 photodetectors. A PPG front end conditioned the signals and their device sent the raw heart beat information to a PC through a radio connection. This is the same device that records ECG and is used to analyse heart intervals and mean blood pressure rather than heart rate.

Buske *et al.* proposed yet another location. They modified a pair of headphones to measure a transmission PPG from the concha. During the testing

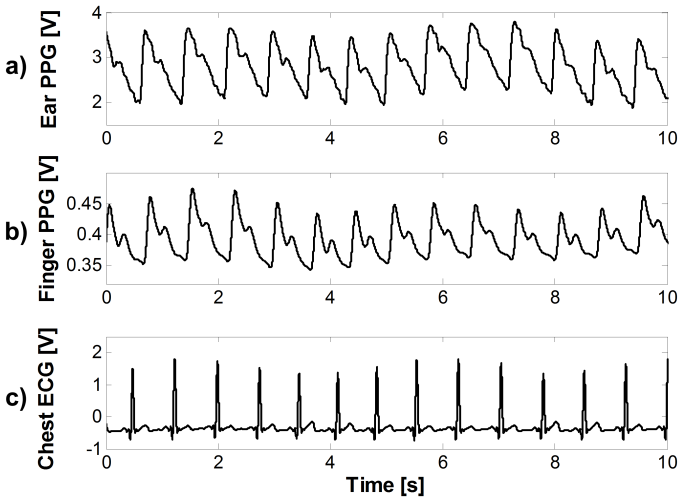

Figure 3.8: Pulse oximetry diagram (Source: tamura2014wearable)

phase, the device showed an average heart rate accuracy of around 85% when compared to an ECG.

The *cosinuss° one*®is a commercial device the monitors heart rate through the ear canal. The earpiece presses against the ear canal wall and records a PPG in reflection mode. It is marketed to athletes that want to monitor their bodies during exercise.

Figure 3.9: https://www.cosinuss.com/en/products/one

3.2.3 Ballistocardiography

BCG is the measurement of the mechanical effects of the beating heart on the body over time. 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 placed behind the ear. This method works by measuring the change in capacitance between the two electrodes 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 due to the 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.

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 is converted to an electrical signal through a piezoelectric film sensor. Figure 3.10 shows an drawing of this device from Park's 2015 article.

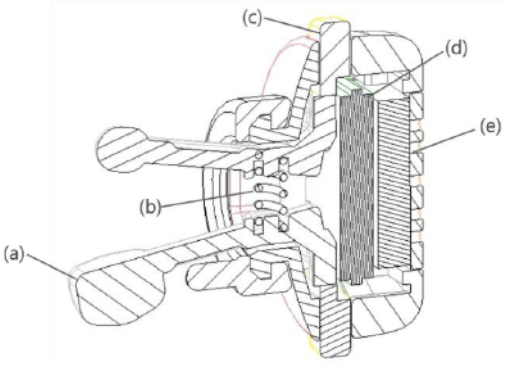

Figure 3.10: Device to measure in ear pulse waves due to the heart beat (Park *et al.*, 2015)

3.2.4 Other Heart Rate 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.

3.3 Respiratory Rate

Unlike the other medical signs, a person cannot measure his or her own respiratory rate. As soon as a person is consciously thinking about respiration, breathing usually slows. Measuring needs to happen while the person's thoughts are otherwise occupied. Therefore, a continuous measuring method are preferred. Typically, a nasal mask or chest strap will be used to measure respiration.

3.3.1 Respiratory Rate Ear Sensors

Ear located devices that extract respiration information are rare, but some literature sources are available.

Goverdovsky *et al.* (2016) tested an ear probe with two embedded microphones. The microphones could detect the sound created by turbulence in the airways for breathing rates higher than 12 breaths per minute. Figure 3.11 shows a plot of the normalised sound amplitude at two different breathing rates. Variation during breathing can be seen in both recordings.

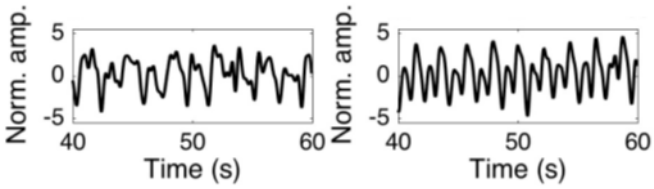

Figure 3.11: Breathing detected through microphones inside the ear canal (Goverdovsky *et al.*, 2016)

Da He *et al.* (2010) did extensive research on the ear as a location for medical sign monitoring. They extracted respiratory rate from baseline oscillations in a BCG signal recorded by capacitive electrodes placed behind the ear. Mechanical movement is converted to electrical signals by these electrodes. Therefore, the movement of the head due to respiration is seen on the BCG as baseline oscillations, Figure 3.12.

3.3.2 Respiratory related Heart Rate Characteristics

A different approach is to extract respiratory rate by looking at the heart rate. A PPG signal contains three distinct respiratory related characteristics:

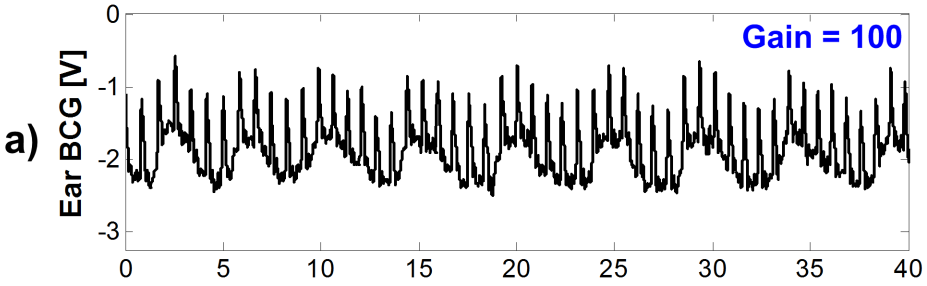

Figure 3.12: Baseline osculations in behind the ear BCG due to breathing (Da He *et al.*, 2010)

amplitude modulation (AM), respiratory-induced intensity variation (RIIV) and frequency modulation (Johansson, 2003).

Amplitude modulation is due to blood pressure changes during the respiratory cycle called Pulsus Paradoxus. RIIV is chances in the volume of the dermis and subcutaneous capillary bed. It is visible as baseline variation in the PPG signal. Frequency modulation of the heart rate synchronised to respiration rate, called respiratory sinus arrhythmia (RSA).

RSA can also be detected in ECG, but differ from the fluctuations seen in chest ECG, due to electrodes movement relative to the heart and changes in chest impedance during the respiratory cycle (Moody *et al.*, 1986). These fluctuations cannot be detected in the ear. RSA is observed as baseline oscillation in heart rate in synchrony with the respiratory rate. Heart rate increase during inspiration and a decrease during expiration (Yasuma and Hayano, 2004). According to a study done by Stratton *et al.* (2003), the variation in heart rate due to RSA is higher in younger test subjects with 74% increase in children vs. 52% increase in adults.

Research was been done to develop algorithms to utilise these characteristics to extract respiratory rate from PPG signals. Clifton *et al.* (2007) used wavelet analysis, achieved a respiratory rate accurate to within 1 breath per minute and Leonard *et al.* (2006) documented a respiratory rate error of 7.9%. Johansson (2003) developed two neural network algorithms that uses the different respiratory related characteristics of PPG signals to detect breaths. Table 3.1 shows the results of the best algorithm.

3.4 Blood Oxygen Saturation

Oxygen saturation can be measured by means of an arterial blood gas test resulting an arterial oxygen saturation reading. This requires drawing a blood sample for testing and therefore is not relevant to this study. An alternative method is pulse oximetry. This method estimates peripheral capillary oxygen

Table 3.1: Results of the respiratory rate extraction through neural networks (Johansson, 2003)

Respiratory Related Characteristics	False Positive (%)	False Negative (%)
RSA	3.7	6.9
AM	5.2	4.7
RIIV	5.2	5.9

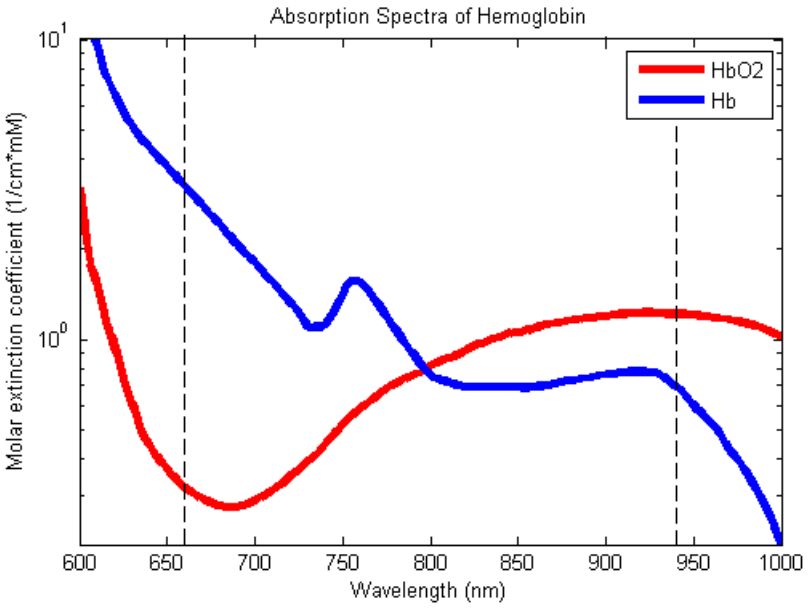

Figure 3.13: Absorption spectra of oxy- and deoxyhemoglobin

saturation, SpO_2, through the spectrophotometric analysis of PPG signals captured at two different wavelengths. This is a clinically excepted estimation of the arterial oxygen saturation.

3.4.1 Pulse Oximetry Theory

Blood oxygen saturation estimation through pulse oximetry relies on the different adsorption spectra of oxyhaemoglobin and deoxyhaemoglobin. Figure 3.13 shows the absorption spectra of oxy- and deoxyhaemoglobin.

It can be noted that deoxyhaemoglobin has a significantly higher absorption of red light while oxyhaemoglobin has a slightly higher absorption of infrared light.

According to Beers law, the amount of light absorbed by a dissolved substance is proportional to its concentration (Encyclopædia-Britannica). Therefore, oxygenated blood (with a higher concentration of oxyhaemoglobin) will

absorb more infrared light and reflect more red light. Whereas deoxygenated blood (with a higher concentration of deoxyhaemoglobin) will absorb more red light and reflect more infrared light. This explains why oxygenated blood appears bright red, while deoxygenated blood is a darker shade of red.

Red and infrared light are shined into the peripheral tissue and the light reflected or transmitted is measured for both wavelengths. Literature and commercial devices usually uses wavelengths of 660 nm (red) and 940 nm (near infrared) (Tytler and Seeley, 1986) (Chan and Underwood, 2005) (Bagha and Shaw, 2011) (Bheema lingaiah *et al.*, 2013) (Duun *et al.*, 2007). The ratio of reflected or transmitted light is unique to a certain level of blood oxygen saturation and is used to estimate blood oxygen saturation.

The Beer-Lambert law describes the absorption of a specific wavelength of light by a substance in a homogeneous solution (Bagha and Shaw, 2011).

$$A = \varepsilon cL = ln\left(\frac{I_o}{I}\right)$$

$$I = I_o e^{-\varepsilon_\lambda cL}$$

Where A is the dimensionless adsorption, ε is the wavelength dependant molar absorptivity, c is the concentration of the substance and L is the path length the light needs to travel through the substance. I_o is the intensity of the light entering the solution and I is the intensity of light passing though the solution.

When applying this law to measuring O_2 saturation, a concentration ratio can be calculated. Factoring out L, I_o, and the constants in ε, the ration can be written as:

$$R = \frac{log\left(I_{red}\right) \cdot \lambda_{red}}{log\left(I_{ir}\right) \cdot \lambda_{ir}}$$

Where I is the light intensities and λ is the wavelength (Chan and Underwood, 2005). Red and infrared light sources are alternated and intensity measurements are made for both separately.

In practice, a different modulated relationship is used to compensate for the different DC absorption between patients (König *et al.*, 1998) (Duun *et al.*, 2007) (Bheema lingaiah *et al.*, 2013) (Bagha and Shaw, 2011) (Nitzan *et al.*, 2014) (Oak and Aroul, 2015)

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

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 $\% \ SpO_2 = 110 - 25R$, (Oak and Aroul, 2015) but it can vary from device to device.

As mentioned, SpO_2 can be calculated using reflected or transmitted light. Light that is not absorbed or scattered by tissue can be either reflected, or transmitted. Thus, both reflected and transmitted light is proportional to the mount of light absorbed. Transmittance mode pulse oximeters are more common, but their use is restricted to parts of the body that will allow for light to pass through, like a fingertip or earlobe.

A big challenge to conventional pulse oximeters is noise due to movement (Barker *et al.*, 2002).

3.4.2 Work done by others in ear pulse oximetry

Standard locations for pulse oximetry includes the fingertip, earlobe, ankle and forehead. A study comparing fingertip and earlobe pulse oximetry to an arterial blood gas test found that finger pulse oximetry differed by a mean of -0,71% and earlobe pulse oximetry differed by a mean of +4.2% (Olive *et al.*, 2016). Literature and commercial wearable pulse oximeters typically utilise a finger clip to measuring SpO_2 (Watthanawisuth *et al.*, 2010) (Pujary *et al.*, 2003) (Huang *et al.*, 2014) (Khalifa *et al.*, 2014). This location is not ideal for continuous monitoring and is especially susceptible to motion artefacts. Although the fingertip location is not of interest to this study, the literature is still reviewed for similar principals can be applies to ear pulse oximetry.

Ear lobe pulse oximetry usually done through a sensor that clips to the ear lobe, which is attached to a stationary device. Wearable ear pulse oximetry, is still novel and not well covered in literature. There are some patients filled for such devices (US 20050177034 A1) (US 4086915 A) (US 3412729 A) (US 6556852 B1) and commercial devices like but little academic material is available.

A study done by (Aziz *et al.*, 2006) tested a wireless earlobe-mounted pulse oximeter on a group of subjects. Subjects were tested while sitting, walking and running. During the sitting and walking phases they recorded an SpO2 reading of above 95%, which is "as expected" according to them. But during the running phase they could not obtain any accurate reading.

During running, they could not take an SpO_2 reading, but Literature on ear PPG, only uses infrared light to determine heart rate. Theoretically, infrared light can be added in the same way to produce and red PPG and a R value can be calculated to estimate SpO_2.

Pulse oximetry patch

3.5 Electrical Brain Activity

Chapter 4

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.

4.1 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

4.2 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.

4.2.1 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.

4.2.1.1 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

4.2.1.2 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

4.2.1.3 Respiratory rate

4.2.1.4 Blood Oxygen Saturation

4.2.1.5 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

4.2.2 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

4.2.3 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

4.2.4 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

4.2.5 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

4.2.6 Pulse oximeter

4.2.7 EEG

4.2.8 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

4.3 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.

4.3.1 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

4.3.1.1 Wireless Communication

4.3.2 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.

4.3.3 Form

4.3.4 Material

4.4 Concept Selection

4.5 Hardware Selection

Chapter 5

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.

5.1 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

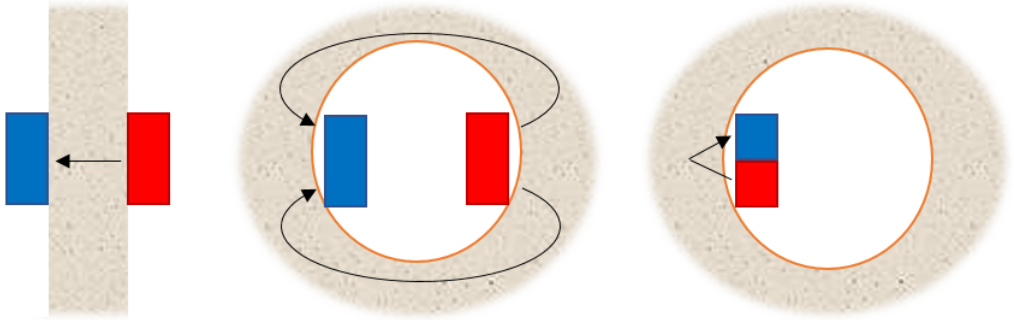

Figure 5.1: Drawing of the auricle (goo.gl/mmLnFx)

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

Figure 5.1

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

5.1.1 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

5.1.2 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

5.1.2.1 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)

5.1.2.2 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.

5.1.2.3 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

5.1.2.4 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:

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

5.1.2.5 Measure Heat Rate and Sp02

5.1.2.6 Measure Breathing Rate

5.1.2.7 Measure EEG

Chapter 6

Experimental Procedure

6.1 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?)

6.2 Theory

6.3 Ethical Consent

6.4 Subjects

6.5 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.

6.6 Method

6.6.1 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.

6.6.2 Comparing Data

Comparing the device PPG to the Mexus BVP

6.7 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)

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

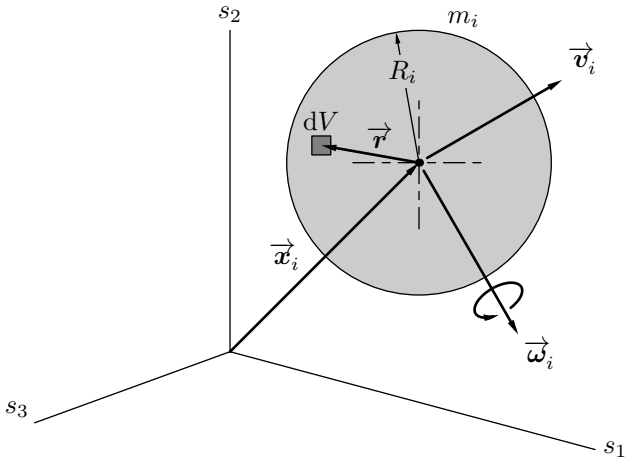

Figure A.1: Ball Element Parameters

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