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Mestrado em Engenharia Informática - Computação Móvel

Multi-sensor Framework for Heart Rate and Blood Oxygen Saturation Monitoring of Human Body

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Multi-sensor Framework for Heart Rate and Blood Oxygen Saturation Monitoring of Human Body

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Master dissertation performed under the supervision of Professors Luís Marcelino, Luís Conde Bento and Sérgio Faria all from Escola Superior de Tecnologia e Gestão of Instituto Politécnico de Leiria.

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Resumo

As doenças cardiovasculares são a causa de morte de milhões de pessoas. Mortes que, muitas vezes, poderiam ser evitadas se houvesse um aumento significativo do diagnóstico para deteção precoce de tais doenças. Este diagnóstico, por sua vez, poderia ser realizado com uma maior disponibilidade de dispositivos médicos confiáveis e de baixo custo.

Sensores tecnológicos integrados disponíveis em dispositivos móveis (wearable devices) tem sido comumente utilizados para realizar a leitura de dados fisiológicos em utilizadores (pacientes). Particularmente o sensor de oximetria de pulso, oferece um método único, não invasivo, que pode ser utilizado para auxiliar a deteção de tais doenças.

Esta avaliação da condição física do paciente em certas doenças são possíveis devido à medição não invasiva através da fotopletismografia, que permite a extração da frequência cardíaca e da saturação de oxigénio no sangue. Sendo que alguns diagnósticos de doenças requerem monitoramento simultâneo dos valores de saturação de oxigénio no sangue em vários locais do corpo, desenvolveu-se então um projeto para realizar tais leituras dos dados fisiológicos.

Esta tese (dissertação) apresenta o desenvolvimento de uma plataforma de sistemas que tem como base a utilização de múltiplos sensores de oximetria de pulso, conectados a uma aplicação desenvolvida para um dispositivo móvel através de ligação sem fios.

A finalidade desta plataforma é disponibilizar uma experiência de fácil leitura de dados de saúde que podem ser analisados para diagnosticar sintomas de doenças cardiovasculares, nomeadamente problemas circulatórios, permitindo efetuar um diagnostico precoce.

A estrutura completa, bem como aspetos da análise e implementação dos sistemas relacionados a arquitetura proposta são descritos nesta dissertação.

Palavras chave: saturação de oxigénio, *wearable sensors*, m-Health, doencas cardiovasculares

Abstract

Cardiovascular diseases have been the cause of death for millions of people. Some of these deaths could be avoided if there was a significant increase of diagnosis for the detection of such diseases. This diagnosis, in turn, could be realized with the increased availability of robust and low-cost medical diagnostic devices.

Integrated technology sensors available on wearable devices have been commonly used to read physiological data in users (patients). Particularly the pulse oximetry sensors, offers a unique, non-invasive method that can be used to detect the severity of such diseases.

This evaluation of the physical condition of the patient for certain diseases is possible due to non-invasive measurement through photoplethysmography, which allows the extraction of heart rate and oxygen saturation in the blood. Since some diseases diagnoses require simultaneous monitoring of blood oxygen saturation values at various sites in the body, a project has been developed to perform such reading of physiological data.

This thesis presents the development of a systems platform based on the use of multiple pulse oximetry sensors connected to an application developed for a mobile device though a wireless connection. The purpose of this platform is to provide an easy-to-read experience of health data that can be analyzed to diagnose cardiovascular disease symptoms, aiding in an early diagnosis.

The complete structure as well as the aspects of the analysis and implementation of the systems related to the proposed architecture are described in this dissertation.

Keywords: Oxygen saturation, wearable sensors, m-Health, cardiovascular diseases

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Acronyms

ANT+ Advanced and Adaptive Network Technology

APP Mobile Application

AW Apple Watch

BLE Bluetooth Low Energy

BPM Beats per Minute

BR Basic Rate

CES Health Ethics Committee

CFSA Cycle-by-Cycle Fourier Series Analysis

COPD Chronic Obstructive Pulmonary Disease

CVD Cardiovascular Diseases

ECG Electrocardiogram

EDA Electrodermal Activity

EDR Enhanced Data Rate

EEG Electroencephalography

FDA Food and Drug Administration

FMD Flow-Mediated Dilation

GATT Generic Attribute Profile

GHz Gigahertz

GPS Global Positioning System

GSR+ Galvanic Skin Response

HR Heart Rate

I2C Inter-Integrated Circuit

IDC International Data Corporation

IDE Integrated Development Environment

IHME Institute for Health Metrics and Evaluation

IOS iPhone Operating System

IR Infrared Radiation

LAN Local Area Network

LED Light-Emitting Diode

LIPO Lithium Polymer

OS Operating Systems

P2P Peer-to-Peer

PPG Photoplethysmography

PTT Pulse Transit Time

PWTT Pulse Wave Transit Time

RMSE Root Mean Square Error

SCL Serial Clock Line

SDA Serial Data Line

SG7 Samsung Galaxy 7

SIG Special Interest Group

SPO2 Blood Oxygen Saturation

SVD Singular Value Decomposition

TBP Toe Blood Pressure

UV Ultraviolet

UX User Experience

VLF Very-Low Frequency

WBAN Wireless Body Area Network

WBSN Wireless Body Sensor Network

WHO World Health Organization

Chapter 1

Introduction

Reports from World Health Organization (WHO) and the Institute for Health Metrics and Evaluation (IHME) show that the majority of deaths in the world are related to cardiovascular and infectious diseases [6], being in Portugal almost 35 thousand deaths per year due to Cardiovascular Diseases (CVD) [5]. Some of the CVD-related symptoms, namely those related to circulatory diseases, can be detected by using pulse oximetry devices, based on PPG sensors.

Nowadays, with easy access to technology, and with people more concerned with health and well-being, there is a greater adoption of health-related technology. Furthermore, many companies have developed sophisticated and easy-to-use electronic devices that can collect data in a less intrusive way, which can be seen in wearable devices. These are electronic devices that can be used by people in their body as a peripheral accessory or as part of fabrics used in clothing.

Besides, the fact that wearable devices are becoming popular and an important accessory, wearable electronic devices are able to collect data and transmit it through a smartphone. There are a wide range of products, of different types (e.g. smart clothing, implanted devices), that can be used in various ways such as payment methods, Global Positioning System (GPS) location, control of a smart home, health, among others, but the focus of this work is on health wearable device.

As International Data Corporation (IDC) Worldwide Quarterly Wearables Device Tracker shows [7], 94,8% of market share correspond to watches and wristbands, more accurately there is 56,9% of watches and 37,9% of wristbands.

As mentioned, one of the most common health equipment sold in the market and used by people is the wristband wearable, an electronic bracelet that has a wireless connection to a smartphone and usually has sensors like accelerometer and PPG sensor and may have a display, that shows the data collected from the sensors. Thus, this type of sensor is not only used in medical devices, but also in electronics devices used daily by people [8].

The high number of CVD-related deaths and the easy use of PPG sensors to diagnose symptoms of these diseases shows how important it is to develop new solutions to help in the diagnosis at an early stage, such as measuring multiple human body sites, which can be performed with solutions having multiple PPG sensors.

1.1 Scope and motivation

As previously mentioned, according to recent studies, a huge number of people in the world die as consequence of derivatives from cardiovascular diseases. Due to the fact that many causes of death can be diagnosed with the help of a PPG sensor, and the accessibility of having a wearable device product to help measuring it, it is evident the rising number of people, worried about living better, that are looking for a device like these.

It is important to note that the cost of clinical exams for major diseases in hospitals or specialized clinics is often more expensive than a wearable device that performs non-invasive continuous measurements and can be used at all times to collect and process reliable data, that can be analyzed further by a medical specialist.

Taking into account these considerations, some research works have been done in order to study if the differences in physiological measurements, like HR and SPO2, and their correlations with circulatory problems and cardiovascular disease. For this purpose, a framework that can measure vital signs from multiple points from the humans' body was designed, developed and tested.

1.2 Objectives

The main objective of this thesis is to propose a multi-sensor system for heart rate and blood oxygen saturation monitoring of human body. It is based on a Wireless Body Sensor Network (WBSN), designed as a wearable system architecture. It also includes the programming of the system code, as well as the development of the Mobile Application (APP) to display the results.

The solution needs to acquire and process vital signs using multiple PPG sensors to simultaneously, measures real-time heart rate and oxygen saturation at numerous sites in the human body and broadcast the data over a wireless connection to an easy-to-use system module, responsible to display and save the data acquired.

The system can be connected to two or more PPG sensors that measure the heart rate and oxygen saturation levels from multiple locations of the human body. The main goal is to investigate the possibility to diagnose early cardiovascular diseases by analyzing

data from different locations of the human body. It may be used daily by people with cardiovascular diseases, to help monitoring the progression of the disease, e.g. diabetes and blood circulation problems.

1.3 Expected outcomes and benefits

The project developed during the thesis includes a hardware prototype with two PPG sensors and the code developed for the smartphone, to receive and display the acquired data. The system runs in real time, the product is wearable, easy to use and while not in use is easy to transport.

It is possible to divide the expected results into three different parts: a commercial product, a scientific contribution and the social impact. For the business content, the project developed on the thesis is a low-cost hardware/product developed to be affordable by end users, as well as by doctors, laboratories (specialized clinics) and hospitals, so that diseases related to the cardiovascular system can be constantly monitored in a less invasive way than hospital equipment's, to reduce expenses incurred with clinical examinations.

In terms of scientific contribution, the expected results of the thesis work intent to study if the measurement of heart rate and blood oxygen level from multiple points in the human body may be helpful in an early diagnosis of circulatory diseases.

The thesis aims to increase the help and prevention over the diseases related to the cardiovascular systems. The idea of providing help to the diagnosis for the patients avoiding them to reach the hospital in an advanced stage of the disease, brings gains for the person/patient, as well as it does to the economy, once the expenses related to patients are high.

The social impact can be significant if the system shows qualitative results and if the users' adopt it, once the heart-related diseases and problems with veins are among the leading causes of death in the world.

1.4 Methodologies

Firstly, a study was carried out on the sensors field to identify the best way to used them to collect the heart rate and the saturation of oxygen in the blood.

The study was made in order to identifying the necessary boards and, to understand how the system architecture should be designed.

The research was extended to scientific publications that used the methodology of reading vital signs with Photoplethysmography sensors to analyze the health of subjects.

After identifying the adequate sensors, searches were made in academic articles, commercialized products and similar systems to understand how they could contribute to the research in term of reference, perspective and expectations. To carry out for scientific research, b-on was used to perform searches for publications within the academic and scientific community, bibliographic databases and internet engines.

The second objective was to develop the system to read the sensors and process the data, prior to be sent to a smartphone trough a wireless connection, and the smartphone application that will receive the data, save it and display it on the screen.

Due to the necessity to use a specific hardware, a board with a wireless communication to connect to a smartphone and two or more PPG sensors was developed in order to perform the experiments. Nevertheless, the objective of this thesis was not to develop the hardware.

In order to find the best solution for the systems to be developed, different prototypes were be built, being constantly evolving during the architecture's design process, to achieve the intended results.

A study was carried out on mobile applications and their characteristics, so that the development was executed following common guidelines. A questionnaire about the application interface was conducted with end-users in order for the application to be designed in the best way possible to facilitate its use, such that users could understand the data shown in a simple and precise way.

Finally, some tests were performed to show the effectiveness of the system. To ensure that the data collected and presented was reliable, a doctor was asked to perform tests with its patients.

So, in order for the mentioned objectives to be effectively achieved, it was decided to create a prototype and develop a mobile application to explore, analyze and test it with patients. In this way, it was possible to discover and comprehend the data collected through tests, to ascertain the viability and reliability of the studied methods and technology.

In order to validated work and to ensure that it was on track, weekly meetings were held with the supervisors. Having defined the functionality and objectives of the project, the meetings got spaced for the development to be carried out, as two systems were developed. After the prototype was finalized and the APP was created, the meetings were held weekly again so that necessary adjustments were made to the systems to achieve success.

1.5 Dissertation structure

The document is structured in eight chapters and the steps designated for this study, as the basic assumptions and decisions for its development, are presented in the following.

Chapter 2 presents the information collected during the research, with a focus on the area of the study, where similar and equivalent projects or the ones with some valuable features are analyzed.

In Chapter 3, the method for collecting biomedical information from the user, as well as the technologies that can be used in the development of the project, are described. Available technologies and products are detailed, in order to find the best technologies for the project.

The Chapter 4 describes the usability of sensors in heart rate monitoring, as well as advantages and disadvantages of the various mobile applications, in order to understand the solutions that are already available at the APP stores to ascertain (or verify) what this project might add.

In Chapter 5, the main functionalities of the systems are presented, through the choice of the hardware, the requirements for the system, as well as the communication between hardware and APP.

Chapter 6 details the construction of the wearable device using PPG sensors, as well as the development of the systems based on the selected features in the design phase. Regarding the software developed, there are two separate systems that work together. Its implementation was developed in two strands, one of which is the module for acquiring, processing and sending data and one module to display this data.

In Chapter 7, functional tests, acceptance and performance of the implemented system were performed to detect unknown technical or functional problems. The results of the systems are analyzed in relation to testing the validity of the system to detect cardiovascular diseases. Additionally, the results are compared with products available on the market.

Finally, in Chapter 8, the acquired data was analyzed and the results are discussed. This chapter also describes the problems faced during the project and future work.

Chapter 2

Monitoring Heart Rate and Oxygen Saturation with PPG sensors

This Chapter aims to present a brief introduction to photoplethysmography (PPG) and highlights studies carried out for the acquisition and monitoring of heart rate and blood oxygen saturation levels using multiple sensors to try to predict diseases related to the cardiovascular system.

2.1 PPG-based Sensors

Photoplethysmography (PPG) is a non-invasive method that is used to monitor and measure heart rate, blood oxygen saturation, blood pressure, among others health measurements [9] [10] [11].

To perform the HR and SPO2 measurements, the PPG method uses LED lights, a red and an Infrared Radiation (IR) lights and a photodetector in order to check any the changes that happens in the size of blood vessels immediately after the heart contracts. Subsequently, an algorithm converts these measurements and turns them into heart rate readings [9] [10] [11].

Those differences in the blood vessels that occur all along the heartbeat correspond to the systole and diastole phases [12], which can be measured with two different procedures [1] [13] [14]:

A. Transmission mode (see Fig.2.1 (a)) – where LED lights (red and IR lights) and the photodetector are parallel to each other so that the LED can transmit the lights through the veins for the PD to capture the changes, achieving a good signal. However, sites where this device can be used are restricted, as the thickness of the skin should be thin, like on a fingertip or earlobe.

B. Reflectance mode (see Fig.2.1 (b)) – the LED and the PD are on the same side, so the PD detects the changes in the blood veins reflected by LED lights. This type of PPG can be located in different parts of the body, although any movements need to be considered because the sensor may move during some activity, thus producing noise that would interfere in the measurements results. Not to mention the pressure that must always be constant or pretty much the same, so it does not affect the veins and consequently the measured results [15].

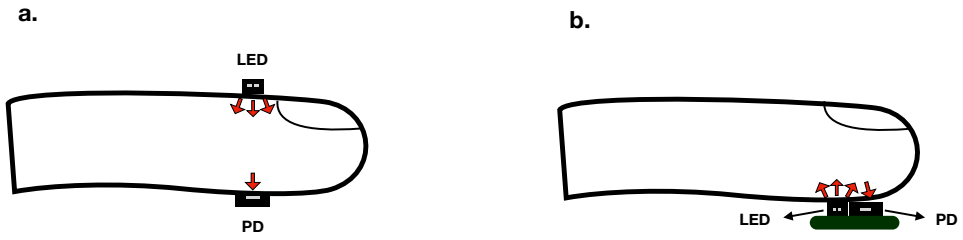


Figure 2.1: PPG techniques to detect blood variations in vessels. a. Transmission mode; b. Reflectance mode.

To ensure that the measurement results are useful and well-performed it is almost mandatory to position PPG sensors in the body where arteries are close to the skin, such as on a fingertip, earlobe, the forehead, etc. The location where the sensors are being placed is an important condition to carry out the analysis, both because of skin contact and better blood reading, and because it reduces the impact of external factors.

The PPG technique is being clinically applied to detect peripheral vascular disease by detecting low blood oxygen levels.

The PPG results may also be a sign for the physicians to perform medical exams to diagnose diseases such as anemia, congenital heart defects, interstitial lung disease, Chronic Obstructive Pulmonary Disease (COPD), pulmonary edema, pulmonary embolism, pulmonary fibrosis and also sleep apnea [16] [17] [18].

In the following sections, the concerns with photoplethysmography are described and detailed, as the results may vary and might not be so accurate when some external factors interfere.

In order to ensure that the PPG sensor works as expected, it is crucial to consider some aspects and make the necessary efforts to minimize circumstances that might contribute to measurement failures, like movement, ambient lights and other known causes. According to study [10], even the simple act of breathing might cause some noise to the PPG reading, depending on how the breath is.

After knowing the concerns that researchers have previously studied when it comes to

motion artifacts, pressure on the sensor and ambient light, it is important to understand which techniques that might help to reduce any problems that may occur.

2.1.1 Concerns with Pressure, Motion and Ambient Artifacts

The pressure exerted on the sensor by the user during the measurement is an external factor that can affect the measurements results in two different ways. If the pressure exerted on the sensor is not constant and the location is not maintained at all times, the photodetector may not be able to check the wavelengths as expected due to the invasion of the lights [15].

On the other hand, an excessive pressure applied on the sensor may constrict the veins and thereby restrict the blood circulation, which would cause the values to be incorrect.

When comparing studies A [15] and B [1], which measure the range of the contact pressure, these show that the pressure varies depending on where the sensor is located.

While study A states that the pressure on the finger (see Fig.2.2) should be light, study B reveals distinguishable changes only when the pressure is too strong.

Figure 2.2: Test using force pressure [1].

Consequently, in both cases, the absence of sufficient contact or excess pressure lead to incorrect results, so it is important to maintain a constant pressure to the PPG sensor.

After determining that PPG may yield incorrect results due to pressure issues, it must also be noted that the presence of motion artifacts may also contaminates the signal during physical movements, either voluntarily or involuntarily.

Considerable research was conducted to develop algorithms [19] to reduce motion artifacts from the PPG signal [20] [21] [22].

It is crucial to know that a simple movement can create a distance between the sensor and the skin where it is located, causing a larger motion artifact.

Studies carried out on PPG have shown that ambient light have interferes with measurement results, which is why precautions should being taken, such as turning off the lights [23], or even using a ring created for external light to be minimized [15].

Since there are different types of lights, and usually pulse oximetry is measured in clinical laboratories that normally have the same type of light, a further controlled study [24] was performed where people from the same race had their SPO2 data collected during a test with the lights off and another test with the lights on.

Even though the American Association for Respiratory Care believes and has catalogued the ambient light as an element that affects pulse oximetry readings [25], and although other researchers have found and reported interference from ambient light, Fluck's results have shown that ambient light does not affect in pulse oximetry measurements [24].

2.1.2 Addressing Issues with Black Velcro and Digital Filter

Since the body parts may vary in size, and considering that the pressure exerted on the sensor and the ambient light can produce noise in the measurements results, a black Velcro tape is a technique that is commonly used physically.

By reviewing the tests carried out by different researchers in their studies, a black Velcro tape was used to keep the pressure and contact of the PPG sensor contact with the skin steady [26] [27].

Considering those facts, in order to reduce the chances of interference that may occur from ambient light and the different pressure applied to the PPG sensor, the author proposes the use of a black Velcro tape, attaching it to the area where the sensor performs the measurements.

In addition to the physical technique to minimize the interference that occurs with motion artifacts and low or high pressure applied to the sensor, plus ambient lights, there are several types of filters that can be used to prevent such interference.

When it comes to digital filters, there is a large amount of algorithms and methods that have already been developed to detect different types of noises on the frequency that measures the signals that can be found on these studies [19] [20] [21] [22].

A comparison analysis [19] was performed with six different filtering methods used to reduce motion artifacts, and two methods – Singular Value Decomposition (SVD) and Cycle-by-Cycle Fourier Series Analysis (CFSA) - stood out because their results were better when compared to the other analyzed methods.

SVD is a well-known method, and it is also one of the most used matrices in linear algebra to reduce a complex matrix [28] and to simplify the future calculations.

CFSA is a study to understand how general functions may have the same frequen-

cy/proximity after being decomposed [29].

Low-pass filter and high-pass filter can also be used to remove noise by cutting off the frequency that passes through it. While low-pass filter attenuates signals with frequencies higher than the cutoff frequency, allowing the frequency below to pass through it, high-pass filter operates with frequencies above cutoff and attenuate signals with lower frequencies [19] [30] [31].

2.2 Multi-sensor Monitoring

Considering that cardiovascular diseases are one of the biggest causes of death in the world [3], it is clear how important it is to develop new techniques for diagnosis, as well as how crucial it is for people to carry out continuous monitoring of heart diseases. Based on this information, it is increasingly easier to find studies to try to predict disease diagnosis through new systems using PPG sensors, as can be seen in the following brief descriptions.

There are many studies in the healthcare field, and because wearable devices play a role in our lives, the researches about them have increased, along with usage.

According to the results obtained from a research conducted by IDC and Gartner, the total shipment volumes of wearable devices expected for 2017 was approximately between one hundred, nineteen million units and one hundred, third-seven million units (IDC results from 21st June 2017 and Gartner results from 24th August 2017, respectively).

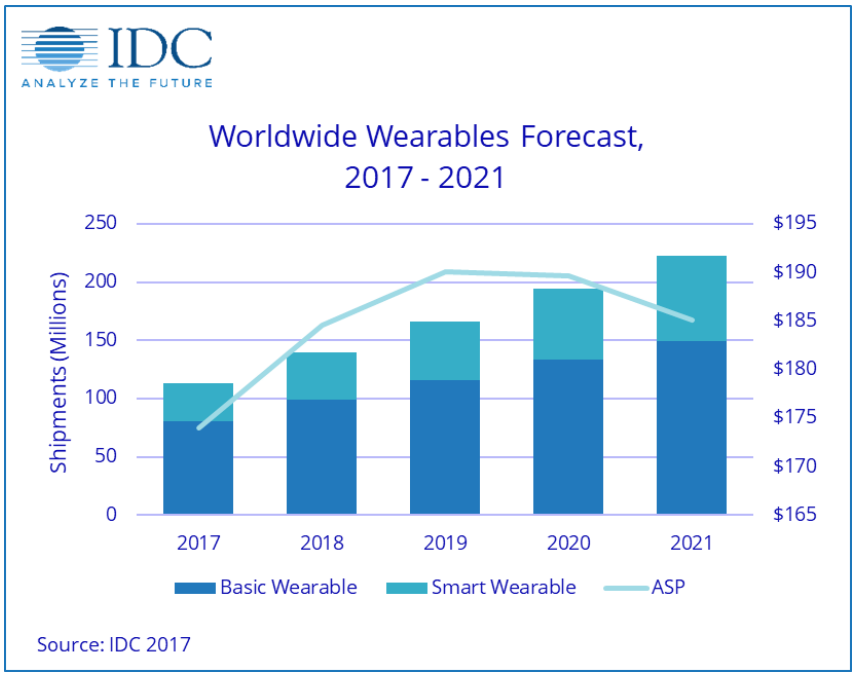


Figure 2.3: Annual worldwide wearable forecast

As shown in 2.3, specifically talking about wristbands including smart watches and

other fitness monitors, the projection for 2021 goes up to two hundred, thirteen millions to be sold worldwide [32] [7].

As briefly stated, nowadays electronic devices have been widely used in the healthcare field. Specifically, we can mention that, in recent years, heart rate and blood oxygen levels have been measured by users / patients with the use of a single device that has PPG sensors installed [33].

These are non-invasive devices that target not only at the comfort of patients, but also at their well-being, since they are a non-intrusive monitoring method that can be used in day-to-day, during any activities.

Studies have shown that wearable devices that have PPG sensors have been tested in various body sites of the human-body to ascertain the accuracy of heart rate and blood oxygen (SPO2) measurements.

Prior research, such as [34], has enabled the creation of a synchronized multi-body sensor platform that is capable of monitoring four different human vital signs in real time, using four different types of sensors, such as electroencephalography, electrocardiography, respiration and PPG. This is used to acquire health-related data of the human body, which are then assessed.

Study [35] reveals that, in all five anatomical locations tested - finger, forearm, wrist, shoulder and forehead - the heart rate was accurately measured. Unlike our study, a SPO2 measurement was not performed.

Buchs et al. [30] use multiple PPG sensors and data collected from the right and left index fingers and right and left second toes to compare the very low frequency results from non-diabetic and diabetic patients in order to check for a sympathetic dysfunction.

Study [36] has enabled the creation of a low-cost audio-based smartphone oximeter to diagnose diseases such as pneumonia. The device developed uses the audio port to establish a connection with the smartphone through a line-powered high-impedance pre-amplifier that is integrated into the sensor connector. The device created for this project made it possible to acquire the blood oxygen level using a pulse oximeter and transfer the results directly to an application developed for smartphones.

When it comes to the prevention of cardiovascular diseases, physical activity is highly recommended, as it helps to avoid obesity, reduce blood pressure and improve cholesterol levels [37] [38] [39] [40]. In this sense, studies attempted to develop algorithms that are capable of eliminating noise and increase the quality of the sensors used in order to ensure a more significant accuracy of the data acquired.

Study [41] has developed an algorithm and a system to work with the BIOPAC MP150 data acquisition system to collect PPG signals in a noisy environment, while the study [14] has developed an opto-electronic system and an algorithm to eliminate noise signals caused

by motion artifacts, as well as another algorithm to increase the quality of the PPG sensor signals to ensure accurate data during physical exercises.

Turning away from the context of using PPG sensors to measure healthcare data, another technique is also worth noting: a PPG image reading technique, known as imaging PPG (IPPG) [42], which consists of the illuminating of the site to be analyzed by PPG, plus a camera, that carries out the PPG image analysis with the system developed for this purpose.

Studies performed using PPG sensors have shown their value and purpose, as people can increasingly use such devices to analyze levels of healthcare data and monitor health remotely without the need to perform tests to check vital signs, as they that can be measured using these sensors.

Chapter 3

Background of Supporting Technologies

This chapter reviews the supporting technologies commonly used in the heart rate monitoring systems, namely the wireless communication protocols, sensor modules and popular PPG products, providing sufficient background information about the method used to acquire the patient's vital signs.

3.1 Low-range Communication Technologies

The communications between the monitoring system that acquires the user's vital signs, e.g. HR and SPO2, and the display system – a smartphone application - was chosen according to certain criteria defined in the initial project specifications:

A. **Wireless** – the communication protocol must be wireless, because the system used to display the data is a mobile app;

B. **Low power consumption** – because the wearable device works with a battery, the communication protocol needs to be optimized to maximize the device's working lifetime;

C. **Short-range communication** – the wearable device and the smartphone will be located near each other, so a short-range communication seems to fit perfectly.

Because there are many wireless communication technologies and protocols, those considered more suitable for this application will be briefly described and compared.

3.1.1 Advanced and Adaptive Network Technology (ANT+)

The Advanced and Adaptive Network Technology (ANT+) is a wireless technology designed based on ANT+ by Garmin in 2004. It was firstly used to monitor health and fitness data [43].

The ANT+ protocol is a low power consumption protocol that is based on a 2.4 Gigahertz (GHz) frequency band and it works as a broadcast, allowing for the connection of multiple devices at the same time, without being exclusively connected to a paired device. For example, ANT+ can be connected to a person's heart rate monitoring device and a bicycle's speed device, collecting in that way the user's heart's rate Beats per Minute (BPM) and the user's bike speed data.

The network connection between devices can be public, managed or private. However, the devices need to be on the same network in order to connect through an ANT+ protocol. ANT+ works as a managed network – a network type that has certain rules and behaviors, including the definition of specific profiles with standard data such as key, data type, formatting and parameters.

The critical point in ANT+ is that it requires a module to be integrated with the hardware's device, plus a software needs to be installed or even a third-party hardware needs to be connected to a smartphone to fulfill the communication between the data of user's different devices.

Currently, ANT+ is supported by a few Android devices, but it is not supported on iPhone. In order to use this protocol, each device/sensor needs to have an ANT+ connection.

3.1.2 Bluetooth

Bluetooth is a universal wireless standard that is used to establish connections between devices, allowing the paired/connected devices to exchange data over a short-range using radio frequency. It is frequently used to exchange voice files, photos and data, to stream audio, but it can also be found in keyboards and printers.

The frequency band is 2.4 GHz and the most common range covered by devices is about 10 meters around the device, according to the power class used by the devices [44] [45].

For Bluetooth 5.0, the maximum range can go up to 240m. According to Bluetooth Special Interest Group (SIG) [44], there are two different types of Bluetooth: the Bluetooth Basic Rate (BR) / Enhanced Data Rate (EDR) and BLE.

A. Bluetooth Basic Rate / Enhanced Data Rate

Also known as well as Bluetooth Classic, this technology was designed to enable a

continuous connection between two points (point-to-point), including piconet topology. Therefore, it uses a Peer-to-Peer (P2P) network topology to set up communications between devices, on a one-to-one (1:1) basis [44].

Bluetooth BR/EDR audio streaming is ideal for wireless speakers, headsets and hands-free, in-car systems.

B. Bluetooth Low Energy

In 2010, Bluetooth Low Energy was announced for the first time by the Bluetooth SIG as a Bluetooth standard, and it became to be part of the Bluetooth 4.0 specification.

Bluetooth Low Energy is also known as Bluetooth LE, BLE and Bluetooth Smart. The main reason for this designation is because it was designed to provide a significant energy/power consumption reduction, as well as cost reduction. However, the communication range needs to be, or should be, sustained exactly like the Bluetooth Classic, including the frequency band, i.e., 2.4 GHz.

BLE enables short-burst wireless connections and uses multiple network typologies, including point-to-point, broadcast and mesh.

C. Differences Between Types of Bluetooth

There are few differences that can be listed: while Bluetooth Classic has a P2P topology, Bluetooth LE has multiple network topologies like P2P (one-to-one [1:1]), broadcast (one-to-many [1:m]), and even mesh (many-to-many [m:m]) communications [46]. In contrast to Bluetooth, until it gets a connection started, BLE stays in sleep mode, which means a small battery can run applications for years [47]. There are other major differences that make BLE even more interesting to use in this project, as presented in (Tab.3.1) [44] [48].

Table 3.1: Main differences between Bluetooth LE and Bluetooth Classic.

	BLE	BR-EDR
Speed to Connect (Setup Time)	< 6 ms	100 ms
Max Connections / Devices	Unlimited	7
Power Consumption	$\sim$ 0.01x to 0.5x of reference (depending on use case)	1 (reference value)
Service Definition	GATT Profiles	Traditional Profiles
Used for	Short burst data transmission	Continuous data streaming

Since the BLE technology is marketed for smartphones, and considering all the differences that exist between Bluetooth protocols, BLE protocol has been chosen to be used in this project.

3.1.3 Wi-Fi

Wi-Fi is the most common Local Area Network (LAN) and it is used by millions of users and companies in the world to access the internet. It is used to connect devices without using any wire, which is known as wireless connection.

Technically speaking, it is a wireless radio communication protocol that uses the 2.4-GHz and 5-GHz frequencies to transmit data between computers connected to this network [49] at high communication rates.

In order to use Wi-Fi, devices must have a hardware installed to perform data transmission and reception. It is worth remembering that all smartphones and notebooks have such module installed, i.e., they are defaulted to connect via Wi-Fi.

Although Wi-Fi is a communication protocol that is commonly used, it is worth noting that it is not widely used in Wireless Body Area Network (WBAN) devices, as Wi-Fi power consumption is extremely high compared to other communication protocols and because WBAN devices require low-power technology [49].

3.1.4 Zigbee

Zigbee, like BLE and Wi-Fi, is a wireless communication protocol that uses a 2.4-GHz frequency band to transmit data through devices [50].

Because it is a small module with low-power consumption and low data rate (to reduce the energy consumption), Zigbee is commonly used for residential automation and medical products.

One characteristic of this communication protocol is that it allows data to be transferred between 10 and 100 meters. But the main characteristic is that it uses a mesh topology, allowing every device using this communication protocol to communicate with each other and to be controlled by a unique device - the controller.

Usually, Zigbee devices communicate with a controller that may have an application, and this controller/router communicates via Wi-Fi or Bluetooth with other devices, transmitting data from the device.

3.1.5 Comparison Between Wireless Communication Protocols

The different communication protocols mentioned above were selected because they are connected to the context of wireless communication and because of the various characteristics they present in the context of health-related data transmission.

By observing the features of each communication protocol, it is possible to see that they have certain features in common and others that differentiate them, as shown in Tab.3.2.

Table 3.2: Comparison of Wireless Communication Protocols.

	ANT+	BR-EDR	BLE	Wi-Fi	Zigbee
Frequency	2.4 GHz	2.4 GHz	2.4 GHz	2.4 GHz; 5GHz	868/915 MHz; 2.4 GHz
Data Rate	1 Mb/s	2-3 Mb/s	1 Mb/s	11-54 Mb/s	250 Kb/s
Range	10-100 m	10-100 m	10-100 m	50-250 m	10-100 m
Network Topology	Point-to-point, star, tree, mesh	Point-to-point	Point-to-point, broadcast, mesh	Star	Mesh
Current Consumption	15-17 mA	$<$ 40 mA	$<$ 15 mA	100-350 mA	19-35 mA
Sleep Current	3.1 uA	-	0.78 uA	-	4.18 uA
Security Protocol	AES-128 and 64-bit key	56-128 bit key	AES-128	WEP; WPA	AES-128

As can be seen from Tab.3.2, all communication protocols use the same communication frequency and work within the same range distance. Regarding the security protocol, all of them use the same type of security, except Wi-Fi.

The most singular features of the mentioned communication protocols are precisely the most important when thinking about the context of wearable devices, which are current consumption, sleep current and data rate.

When it comes to use these protocols, considering the hardware, the differences are more visible. This is because additional hardware (an extra extension) will be required to connect ANT+ and Zigbee, because the protocols mentioned are not supported by all smartphone, except for new Samsung smartphones, while Bluetooth and Wi-Fi already include these modules.

3.2 Sensor Modules

For decades, there exist sensors to measure vital signs in human bodies. However, monitoring human health is no longer only performed in hospitals and health clinics.

There is a wide range of sensor types for different purposes, from sensors to check if the user sleeps/rests well to sensors that measure temperature, body weight, blood sugar levels, and the most common ones that are used to measure heart rate and blood oxygen levels. Nevertheless, only sensors that are actually used in this project will be described.

Since our study is related to heart rate and blood oxygen levels, this section intends to introduce few photoplethysmography sensors that have been used in similar studies or that are included in consolidated products, such as the Apple Watch, Fitbit etc. The purpose of this study is to make a comparison between the available module sensors which may be used in this project.

3.2.1 MAXREFDES117

A tiny (see Fig.3.1), 12.7-mm x 12.7-mm, low power, optical heart rate monitor and pulse oximeter solution, provided by Maxim Integrated, that interfaces with any microcontroller, for instance Arduino or mbed platforms.

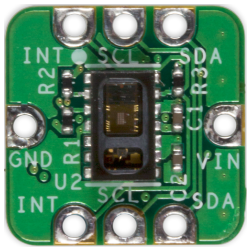


Figure 3.1: MAXREFDES117 PPG sensor board.

The MAXREFDES117 architecture (see Fig.3.2) is designed with three different sensors integrated to be used to form a wearable application that allows the user to obtain heart rate and pulse oximetry measurements.

Maxim has chosen the MAX30102 sensor to perform heart rate/SPO2 measurements and it integrates red and IR LED to carry out the blood oxygen saturation level measurement.

Since it is needed to convert the input voltage from 5.5V to 2V, a step-down converter is used as, well as a level translator that provides communication to MAX30102 from the main controller board, considering the fact that the boards may have different logic levels.

Using integrated red and IR LEDs to carry out the detection process, this module can be used on a person's fingertip, earlobe, or other fleshy extremity [51].

3.2.2 MIKROE

MikroElektronika is a company that specializes in the development of their own embedded hardware and software systems, attaching sensors and circuits from other companies.

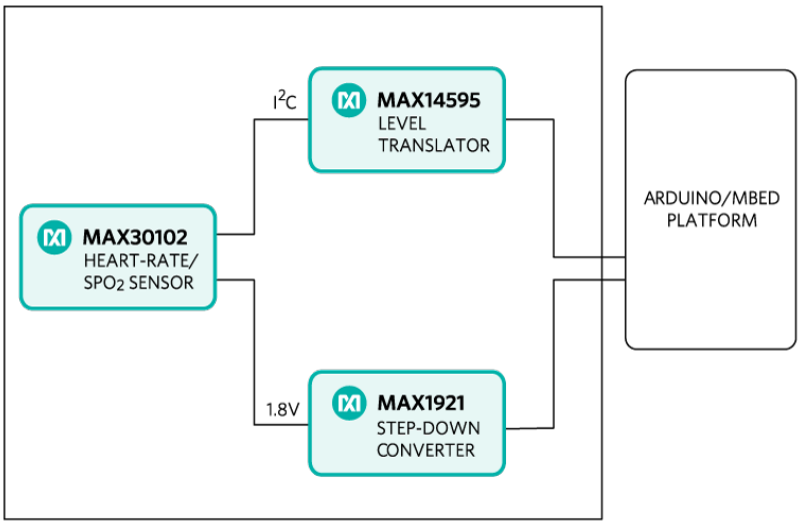


Figure 3.2: MAXREFDES117 reference design block diagram.

Healthcare products developed by MikroE use optical sensors to measure heart rate from PPG in reflectance mode, which means, photodiode and LED lights are on the same side.

Depending on which photodiode is being used, MikroE attached LED lights to the board (see Fig.3.3), as some photodiodes do not have integrated LEDs, except the sensor from Maxim Integrated.

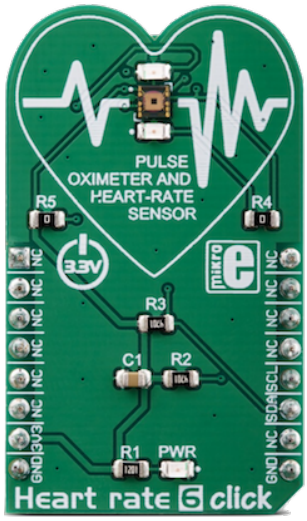


Figure 3.3: Heart rate 6 Click is an optical biosensor designed for heart rate monitoring.

MikroElektronika has been producing several similar sensor boards using different PPG sensors that are ready to use on development boards, as they need to be integrated into another board (see Fig.3.4) in order to carry out the measurements and send the data.

The boards created by MikroElektronika have the same design and size (42.9 x 25.4

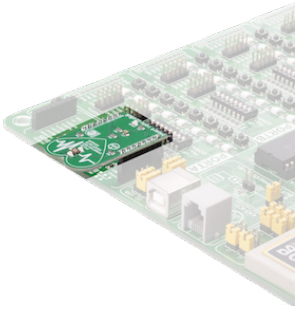


Figure 3.4: Heart rate Click attached to a main board.

mm); only the sensors and LEDs differ from each board (Tab.3.3)

Table 3.3: COMPARISON BETWEEN HEART RATE ON-BOARD SENSORS ON MIKROELEKTRONIKA BOARDS.

MikroE products	On-board sensors to measure PPG
Heart rate Click	MAX30100
Heart rate 3 Click	SFH7050; AFE4404
Heart rate 6 Click	BH1790GLC
Oximeter Click	ADPD105

As it can be seen, in each new board launched by MikroE, a different PPG sensor is added to the board. This may be considered important if the different sensor chips have characteristics suitable for different applications.

3.2.3 Shimmer3 GSR+

Shimmer3 GSR+ [2] is a skin monitoring sensor that can be used for different situations, as it works with two different data acquisition modes: one being the use of GSR+ sensors, which use electrodes to measure the Electrodermal Activity (EDA), which can be summarized as the changes that appear due to the sympathetic nervous system, induced by the change in the body's sweat; and the other one being an optical pulse sensor, which can analyze PPG data taken from the finger or earlobe, since the Shimmer3 GSR+ (see Fig.3.5) has these two types of sensors.

Shimmer comes with an integrated microSD card to storage data collected in real time and a Bluetooth Radio to perform a wireless connection with a notebook to transmit the data to the Shimmer platform, named ConsensysBasic/ConsensysPro, which carries out management from the sensor. The sensor also includes a Li-ion battery, which allows the product to collect data without being connected to a computer.

This sensor has been identified in two different studies: the first study [52] shows a

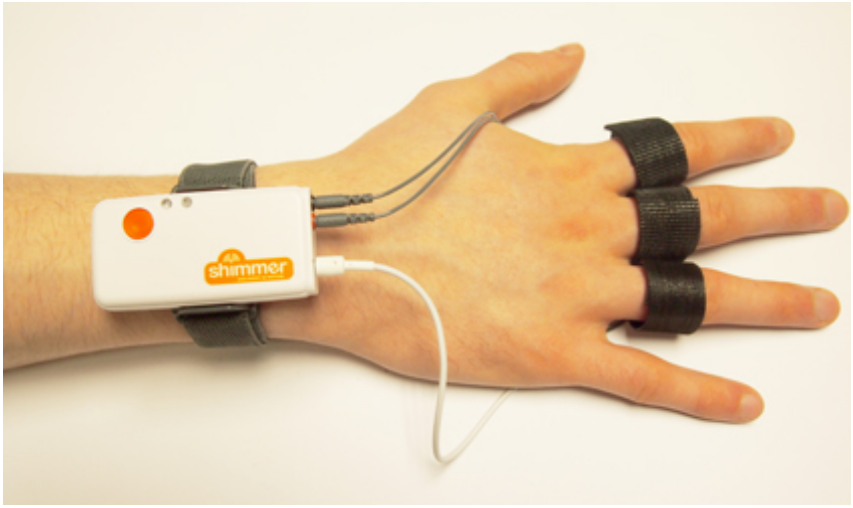


Figure 3.5: A user's hand with Shimmer3 GSR collecting vital signs as PPG [2].

comparison between all types of wearable sensors, from health monitoring systems (e.g., cardiovascular, SPO2, body temperature, etc.) to textile-based wearable sensors. On the other hand, the second study [21] uses the Shimmer3 GSR+ to obtain PPG data from human body, in order to analyze and compare the results collected using the Shimmer 3-axis accelerometer mode to the results collected with Shimmer in 3-axis gyroscope mode, so as to determine the best method to reduce motion artifacts.

Despite the comparison between GSR+ monitoring systems provided in the table, the results do not conclude which is the best sensor, as the purpose of each study that uses the sensors was different.

3.2.4 Analysis and Sensors' Comparison

Among the boards surveyed, in relation to the sensors, all the boards have PPG reading technology, while Shimmer also has electrodes to measure EDA.

Shimmer is the only one that presents a ready solution, that is, it is not possible to add or remove components. On the other hand, Maxrefdes117 and MikroE boards need to be integrated with a controller board in order to process the acquired data.

In relation to the dimensions of the boards, the smallest and the one that best fits to any part of the human body to carry out the measurements is the Maxim Maxrefdes117.

3.3 Existing PPG Products

This section presents an overview of the current state of the art in similar products to our project, showing the features implemented in solutions available in the market.

The field of health-related products is being increasingly exploited and, consequently,

gaining projection in terms of how one can obtain and analyze data in order to check a pattern for predicting a disease and/or simply for users to check their health. Regarding this fact, there are many heart rate monitors that can be found on the market, and most of them are built to record a number of biomedical data and track progress against established exercise goals.

With respect to products that have been investigated and which use photoplethysmography to measure heart rate and blood oxygen saturation levels, four HR products of greater relevance were selected. Curiously, when it comes to the best and most used heart rate monitors, all the selected products are among the top heart rate monitor list according to market share, as per [3] research.

Although the featured products are only a small sample of this fast-growing technological field, it is important to note that the four companies with the most used HR products have a large portion of the wearables market share (see Fig.3.6).

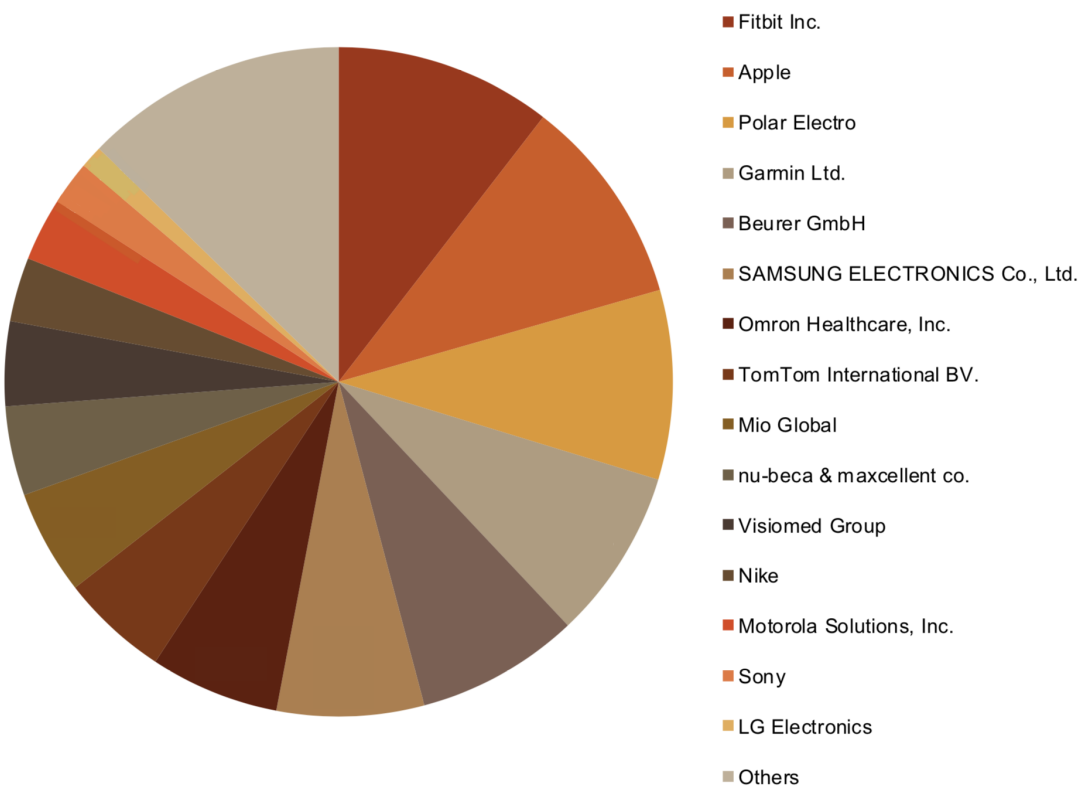


Figure 3.6: Global Heart Rate Monitors Market, Company Share Analysis, 2016 (%) [3].

The selected products where chosen according to their type, application / segment and size, in relation to the number of users plus the number of scientific researches. Not to mention the fact that the products have a wireless connection to transmit data to another device.

3.3.1 Apple Watch

After transform and revolutionizing the world of smartphones, Apple customers were expecting something different from the company. In this context, after a year and a half of Samsung's first smartwatch release, Apple released the first Apple Watch, in 2015, and it currently (2018) figures in the first position in terms of market share [8], according to IDC report.

In the first generation, Apple Watch came with several sensors inside the product, including a heart rate monitor composed of an infrared, visible-light LEDs plus photodiodes in order to measure the user's heart rate.

The latter version, known as fourth generation (see Fig.3.7), which was revealed in 2018, Apple decided to invest in sensors and health applications, so it was created a fall detection system that automatically calls the emergency number if the user does not respond to the smartwatch and indicates that everything is ok.

Figure 3.7: Apple Watch Heart Rate Application.

In addition, it was the first ECG system product that was released to the general public and approved by the United States Food and Drug Administration (FDA), and it was also supported by the non-profit organization American Heart Association. Despite having an ECG on the product itself, Apple kept the photoplethysmography sensor that is used to measure heart rate per minute and analyze the blood oxygen saturation in the wrist (see Fig.3.8), showing the effectiveness of PPG sensors.

Apple allows and encourages developers to integrate their applications with HealthKit, giving the permission for the app to read and write health data into the Health app developed by the company.

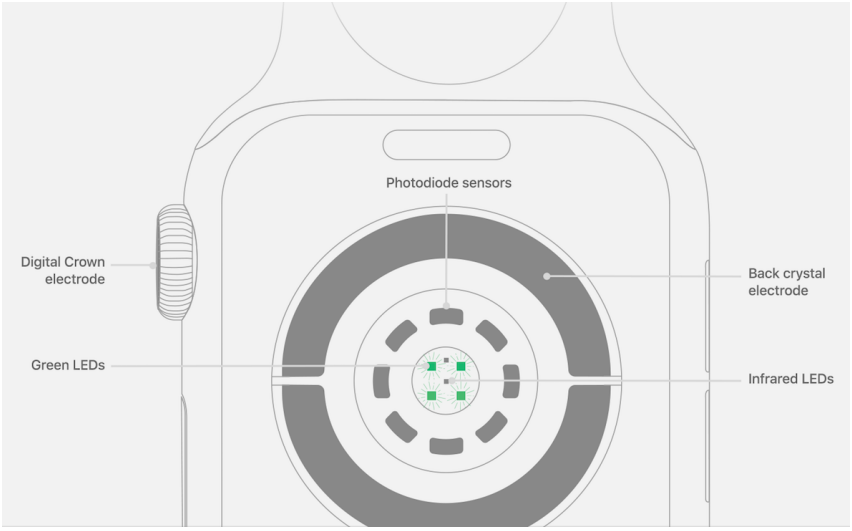


Figure 3.8: Apple Watch Series 4 back wireframe components displaying ECG and PPG sensors used to measure heart rate, where the Digital Crown electrode works with the back crystal electrode and photodiode sensors work with green LEDs and infrared LEDs. [4].

3.3.2 Fitbit Charge 3

Fitbit has been developing fitness trackers to monitor health since 2009, but it was only in 2015 that is started monitoring heart rate with photoplethysmography sensors. The first product to be placed on the market with the purpose of measuring heartbeat was Fitbit Charge HR, and the last product was revealed in October 2018 - the Fitbit Charge 3 (see Fig.3.9). It was the first device from Fitbit to measure blood oxygen saturation with a sensor.

Figure 3.9: Fitbit Charge 3 face displaying the time and the user's heartbeat.

This last updated version shows improvements in the hardware, which should display

results more accurately. Also, because they have added an SPO2 sensor, Fitbit can now analyze the user's breathing patterns to check for breathing-related health problems, including sleep stages and possible sleeping issues.

Until the fourth quarter of 2017, Fitbit was the world's leading wearables manufacturer, but they lost this position to Apple, as a result of growing Apple Watch sales. However, even after losing market leadership, Fitbit is still ranked as the second largest smartwatch brand worldwide, with sales exceeding one million smartwatches sold to this date [8].

Fitbit only works with the company's application, and this is a disadvantage because developers cannot use this wearable device in their own applications.

3.3.3 Polar OH1 Optical Heart Rate Sensor

As the first company to develop sports-related wearable devices and the pioneer of wireless heart rate monitor (1982) [53], Polar could not be left out. Not only because it has opened new paths decades ago, but also because of the new devices they are developing, Polar is still among the top 5 companies developing health products worldwide.

Polar OH1 is a 6-LED optical heart rate sensor (see Fig.3.10), running on a battery that can measure for about 12 hours, that was developed to work as a standalone sensor – it has an internal memory that can store 200 hours of heart rate training, or it can work connected through BLE to other Polar products or a smartphone (i.e., it can be connected to any fitness apps). Polar OH1 can be even connected to an Apple Watch Series 3.

Figure 3.10: Polar OH1 armband – a 6-LED optical HR sensor.

Different from other products available on the market, Polar OH1 is designed to be worn on the lower or upper arm. This allows the product to be comfortable and more accurate when compared to other wrist-worn devices during some fitness exercises [54].

The disadvantages that can be pointed out with regard to this heart rate monitor are that it only reads HR – it does not read SPO2 and does not support ANT+.

3.3.4 Garmin Vivosmart 4

Having been designing wearable heart rate monitoring devices since 2006, when Forerunner 205 and 305 were created, Garmin has been using ANT+ technology to pair devices.

Occupying the fourth position in terms of market share, Garmin released the wristband Vivosmart 4 (see Fig.3.11) in September 2018. This is a small fitness activity tracker that can measure heart rate, pulse oximetry and Body Battery^{TM} – a functionality that, by combining different measurements such as activity data, heart rate variability, stress and sleep, can tell the user when they need to rest.

Figure 3.11: Garmin Vivosmart 4 displaying heart rate in bpm.

Different from other devices that the company have developed (which only use ANT+), Garmin Vivosmart 4 uses ANT+ and Bluetooth Smart (BLE) to connect to other devices. Some negative points that have been said per reviewers [55–57] are about the touch screen and the fact that it does not have GPS or GPS sync for smartphones.

3.3.5 Analysis and Comparison of PPG Products

Apple Watch is currently the most complete product on the market, as it has several sensors that are used differently, like PPG reading, ECG and fall detection. The major problem is that it can only be connected to Apple smartphones.

The best-selling product - Fitbit - can be connected to any smartphone, and it was the first one to add blood oxygen saturation readings. The major problem is that it does not connect to third-party applications.

Unlike the others, which are designed for users to use on the wrist or chest, Polar OH1 is designed for users to wear it on the lower and upper arm. The smartphone's connection

is now similar to Garmin products, as it can connect via Bluetooth or ANT+. However, it does not support SPO2 readings.

Garmin Vivosmart 4 uses either Bluetooth or ANT+ connection, performs HR and SPO2 readings, but it has a problem with the touch screen and does not have GPS coupled or synchronized with the GPS of the smartphone.

All devices available on the market have a single point of data collection, not being possible to collect data simultaneously from multiple sites in the human body, making it impossible to determine whether there is a difference between results from different locations at the same time.

Chapter 4

Heart Rate Monitoring

As previously mentioned, currently there are devices used to acquire biomedical information from the human body, which may also serve to diagnose future diseases or health-related problems. As this work is particularly focused in the detection of diseases that can be analyzed by using PPG sensors, namely those that allow heart rate services and a pulse oximeter, this chapter aims to make a comparison of the most used applications available to assist the user with the collection of this type of data by wearable health devices.

4.1 The Use of Multiple PPG-Sensors to Measure SPO2

The purpose of having multiple sensors measuring the same psysical quantity, e.g., heart rate, pulse oximetry, Pulse Transit Time (PTT) or Pulse Wave Transit Time (PWTT), is to enable the the study the differential behaviour of the human body regarding the localization of the sensors. In some cases, large differences in the acquired values may indicate the existence of certain diseases, namely in the cardiovascular system.

In the majority of studies present in the literature [58] [59] [60] [26], the results have been obtained using Matlab (MathWorks Inc.) to process data from multiple PPG sensors (which need to be connected to a computer) to carry out different types of studies. For instance, a study to analyze the divergence of PPG results from the same individual, by measuring them repetitively in different periods of time [61], analysing the information from six sensors showed that age is a powerful factor for PTT [26].

The research proposed in our work differs from the previously mentioned ones as it performs the sensor readings and processes in real-time, not in a computer using Matlab, besides it allows to show the data in a mobile device (smartphone), using BLE, and

transmit the data, if required, using a standard smartphone.

In [61], they used two different sensors, and each of them has a different measurement technique to capture data, while our project uses the same PPG sensor on multiple sites in the body.

In relation to research [26], our project does not seek to compare results between different ages, unlike the aforementioned study that was carried out to check whether there were any differences in PTT depending on the age.

The research presented in [34] it is the most similar to our project, as it was developed to measure different parts of the human body in real time in order to send the data collected to a smartphone via BLE. But they did not use only PPG sensors, but also Electroencephalography (EEG), ECG and respiration sensors to measure four different types of body signals on a WBSN. However, all of these sensors make the patient to be tied to may paraphernalia, do not allowing its mobility as desirable.

The use of multiple PPG sensors is important to evaluate the results obtained from the sensors positioned at different areas of the human body. The results of blood oxygen saturation levels collected from them may help to diagnosis a possible disease related to cardiovascular problems.

4.2 Diseases that can be analyzed by PPG

According to the World Health Organization (WHO), the annual number of deaths caused by cardiovascular diseases may reach 22.2 million people in 2030, a 27% increase when compared to figures from 2012 [62]. After analyzing the main causes of death in Portugal [5] (see Fig.4.1), it is clear that cardiovascular diseases are the main cause and, in most cases, they may be associated with diabetes [60].

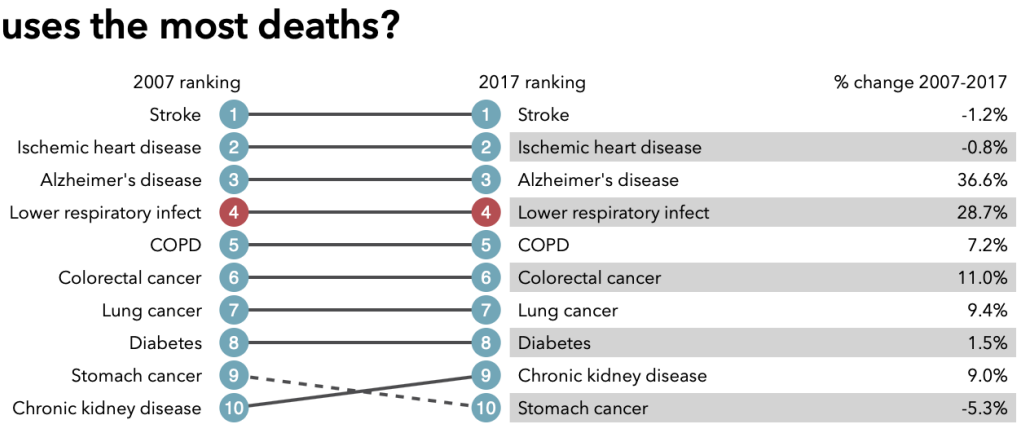


Figure 4.1: Main causes of death in Portugal 2016 [5].

Due to the increasing number of deaths related to diabetes and cardiovascular diseases, which may or may not be influenced by diabetes, several researches [59] [63] [64] [65] have been done in this field, using different types of sensors to analyze any changes in the human body that may be helpful to detect diabetes at an early stages.

As our project uses photoplethysmography, and a study was done to find projects and publications aiming to detect or monitor diabetes using PPG.

In [59] a study has been conducted using a bilateral finger PPG, where the patient's right arm had a pressure cuff attached to simulate an ischemia. As a result, it was possible to analyze the difference between the blood flow from both arms and to identify any differences in terms of Flow-Mediated Dilation (FMD) among a diabetic and non-diabetic (healthy) populations.

A comparison in [30] among the right-left correlation for diabetic and healthy people was made using PPG sensors measuring four sites in the human body, which were the two index fingers and the two second toes, in order to provide a practical and suitable evaluation of the sympathetic nervous system function.

Mediated by the sympathetic nervous system, Very-Low Frequency (VLF) spontaneous fluctuations may present some difference between right-left correlations from diabetic to non-diabetic populations. Therefore, a research [30] was conducted with the purpose of investigating whether reduced right-left correlations are related to diabetes complications.

In order to validate if a portable device using PPG created to measure Toe Blood Pressure (TBP) was performing as well as the conventional method used for that purpose - laser Doppler - a research [65] has developed a fully automatic TBP with a system to make the pulp blood, and also with methods to inflate and deflate by an occlusion cuff.

4.3 Applications for Heart Rate Monitoring

Advancements in technology, as well as the evolution of smartphones over the last few decades, have changed people's behaviour in using smartphones only to make calls and send messages, and they use them to install applications that not only keep them entertained, but also help them to stay healthy.

According to a research conducted by GSMA Intelligence Data, and extracted from a report [66] from "We Are Social and Hootsuite", the total number of mobile users is around 5.135 billion individuals, which is equivalent to 68% mobile penetration among the total population worldwide.

Along with the technology advancements, the application market has grown significantly in recent years. As a result, 78,000 new apps were added to online stores, while the

total sum of Android and IOS health apps has reached 325,000, with an estimate of approximately 3.7 billion downloads last year (2017). The current status and the estimation were taken from a mobile health report [67].

In order to monitor user's health, some companies have developed smartphones with built-in sensors, while there are some apps measuring heart rate using the camera and its flash. Nowadays, the common use of BLE has increased the number of wireless health devices made to be used with apps that are pre-installed on smartphones. The majority of applications developed to monitor human health consist of receiving signals from different types of sensors that measures a wide range of data (e.g., sensors to monitor sleep, body temperature, body weight composition, blood pressure, and the most common - heart rate).

Regarding mobile apps, it is important to emphasize the market-dominating Operating Systems (OS), which are Android and IOS, from Google (Alphabet) and Apple, respectively. On the one hand, Apple develops portable devices such as iPhone, iPad, Apple Watch, plus personal computers (in addition to providing a few services), while Google is extremely well known for their services and tools, which are commonly used by people in their everyday lives. This obviously enhances Apple's presence and position in the healthcare field. With every new Apple Watch version that is released, Apple increasingly adds sensors and different types of readings to help users monitor their health with a single device.

4.3.1 Apple Health and Google Fit

In order to gather users' health data, Apple has developed and pre-installed the Apple Health app on all its devices, so users can access and analyze data from their Apple Watch and other (third-party) devices. On the other hand, because Google has an OS that is used by different companies on smartphones and / or smartwatches, it is understandable that Android users sometimes have to install Google Fit, because it might not be installed on their device, but it can be easily found and downloaded from Google Store.

Apple Health and Google Fit can be described as applications that aim to concentrate health data from the user's devices, smartwatches and third-party apps, whether they use further health-related sensors or not.

Figure 4.2: Google Fit activity tracker.

However, because it is a growing application, Google Fit (see Fig.4.2) is somewhat more limited, and it can only record simple data such as HR, blood pressure, steps, weight and calories, either from third-party apps or from manual inserts.

Figure 4.3: Apple Health displaying the user's measurements plus medical records.

Apple Health (see Fig.4.3) is made to monitor and control the user's health, as it can save data related to vital signs such as HR, body temperature, etc.

Apple Health was also developed to save data such as body measurements, sexual health data, plus results from different types of data, i.e., blood alcohol content, inhaler usage, number of times fallen, Ultraviolet (UV) index, among many other data that can be added by applications (and third-part sensors) or manually.

When it comes to helping people to live better, both companies are compromised to study users' health by working with important medical institutions / organizations, universities and hospitals that are dedicated to improve the overall health worldwide.

4.3.2 Fitbit

Figure 4.4: Fitbit application (screenshots from Android and iOS).

Considering the number of Fitbit products sales, it is clear that the number of users that use this application is incredibly large, which leads us to believe that Fitbit application is one of the most used when it comes to health/ activity tracking. The fact that this app can be found for free in both OS stores - Play Store and Apple Store - is also an advantage.

To use the application and take full advantage of all the features offered, a compatible wearable device is required; otherwise, the user will be using the smartphone's sensors, thus limiting the full use of Fitbit app (see Fig.4.4).

Fitbit tracks the number of steps taken during the day, and it then uses the data collected to perform calculations for measuring the amount of calories burned during the day. However, features to monitor heart rate and to monitor how the user is sleeping cannot be seen without a Fitbit wearable device.

The application has a database with over 350.000 foods available, and it allows the user to enter a daily log of what they ate, in order to calculate how much energy they should be spending according to their weight target (e.g., for weight loss).

4.3.3 Polar Flow

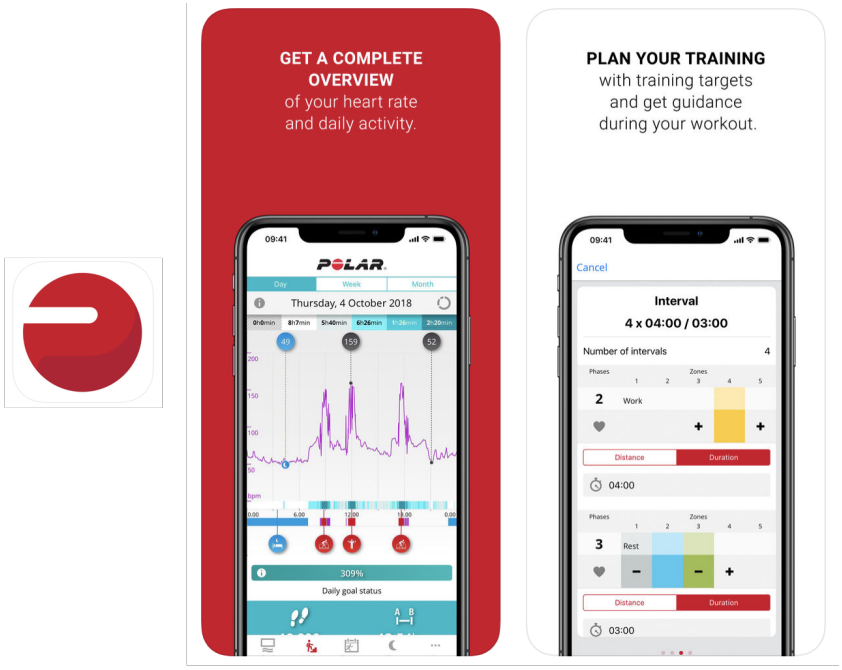


Figure 4.5: Polar Flow application.

Similarly to Fitbit, which has a large number of users, Polar products are also widely known and used on a daily basis. Commonly used for fitness tracking and continuous heart rate monitoring, it also connects to mobile applications via BLE in order to provide the user with an overview of their workouts, performance, amount of steps taken and calories burned.

Polar Flow (see Fig.4.5) allows users to analyze how they did during their training, create new workouts and set the goals they want to achieve.

It is obvious that the application works better when connected to a compatible product, but unlike the Fitbit app, even users who do not have branded products can use the Polar Flow app. That said, although the application only works with compatible devices, it does not suffer any limitation of use, that is, all the data can be entered manually, including heartbeat (maximum, minimum and average).

The app is available for free in both stores (APP Store and Play Store).

4.3.4 Withings Health Mate

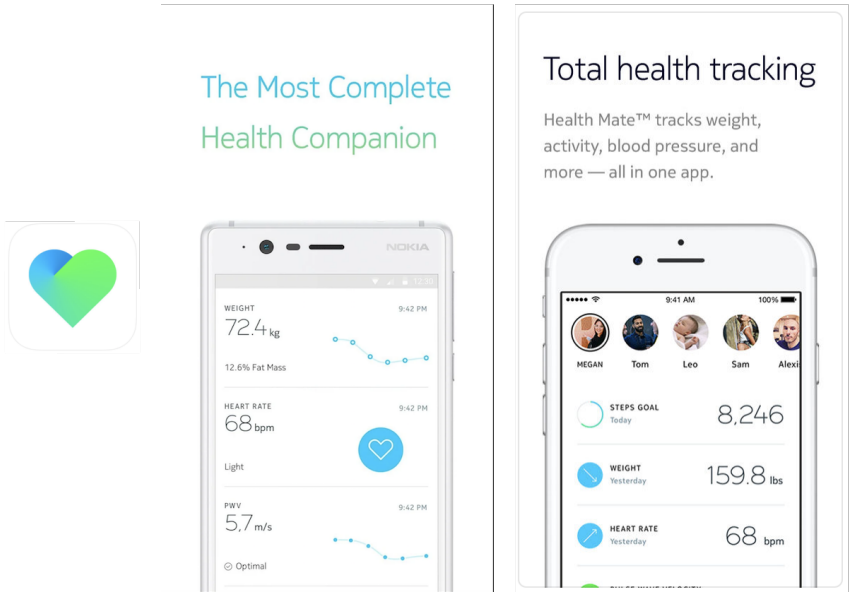


Figure 4.6: Withings Health Mate application.

Withings Health Mate (see Fig.4.6) is intended for people that are looking to monitor their physical activity, weight and sleep in just one app. Because it can connect to third-party applications such as MyFitnessPal and RunKeeper, it can receive and save data about meal calories and data about physical activities, respectively.

Regarding connections with external applications, it is possible to connect with Nest - an APP that controls thermostat temperature to confirm the ideal temperature of the house, in order to have the best sleeping conditions.

The application, as well as the others, also shows the user's vital signs, and measured data can be collected through wearable devices set by the app or manually, except for the heart rate, which can be measured through the smartphone using the camera and flash (if the user does not have a compatible wearable device).

Health Mate can be found for free in both the Play Store and APP Store.

4.3.5 Cardiogram

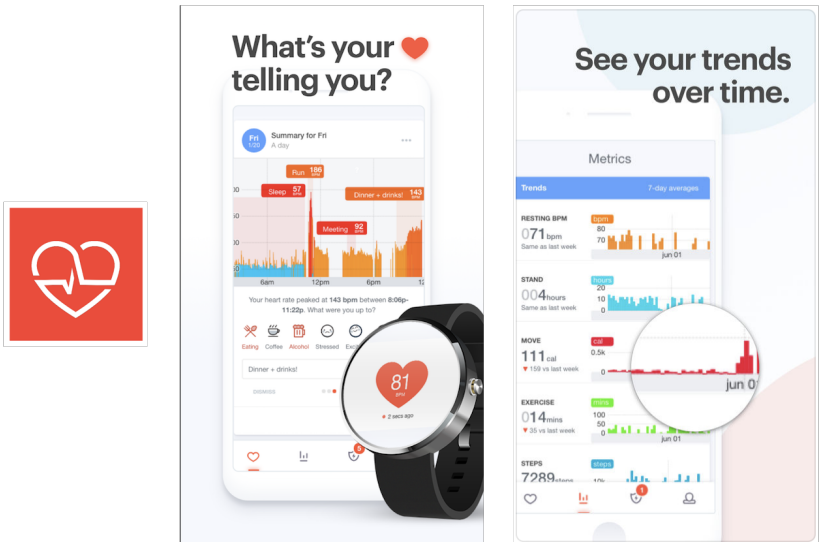


Figure 4.7: Cardiogram application.

Cardiogram (see Fig.4.7) is a very interesting application that was developed for users who want to track their health data and compare them with people of the same age or friends that are using the app as well.

In addition, it is frequently used for studies related to heart diseases. There are currently two studies - the first study is to detect chronic diseases using a smartwatch, and the second one is about the use of the smartwatch to combat heart diseases. Not to mention the pilot studies carried out with insurance companies.

Although the application only works with compatible wearable devices to perform measurements, thus limiting the use of the app without a wearable connected, it is compatible with most smartwatches that have a HR sensor, including major brands like Apple, Garmin, Polar, LG, among others.

The application has a tab/screen called "habits", that displays 3 types of habits - health and fitness, stress relief and sleep quality, where the user can subscribe to habits already practiced by other users and thus participate in the study associated with each habit.

Cardiogram is available for free in both stores (App Store and Play Store).

4.3.6 Medical Research Applications

The evolution of technology is helping hospitals, clinics and researchers to conduct researches and analyses with people who have heart problems.

Nowadays, it is getting easier for physicians to monitor patients' vital data through

applications. Therefore, more and more hospitals and physicians are using this type of procedure, as the assessment can be done in real time, anywhere.

Some applications have been developed specially for medical programs, so that physicians can analyze the patient's heartbeats remotely and continuously.

In these types of programs, the user (patient) must open the app every day and perform the respective tasks, such as answering some questions and/or performing some exercises, in order to obtain data that can be then analyzed by researchers and physicians.

Among these apps developed for the purpose of analysis and research, it is worth highlighting Samsung HeartWise and MyHeart Counts APP, which are associated with clinical teams. These applications basically record the user's activities, whether these are physical activities or sleeping records. There are daily tasks to be performed to track the user's health data, and there are also reminders so that the user does not stop performing certain tasks on schedule, such as medication, physical activity, etc.

Although these apps are available for free in any app store, they are limited to a certain target audience, as they require the user to login with a password or that the user lives in a certain region, thus limiting the use of the app geographically.

4.3.7 Out of boundaries

Apps that are frequently used to monitor physical activity such as running, swimming and bike riding will not be detailed herein, since the vast majority use standard smartwatches (sensors) and, therefore, are already covered by apps written in this chapter.

Included in the applications that will not be debated herein are apps that use the smartphone's camera and flash to measure the heartbeat, as they may not compare with existing specific sensors.

4.3.8 Analysis and Comparison of Applications

The applications mentioned above were selected for several reasons, one of them being the various features and functionalities they present in the context of health technology. Although all applications can be used by people with heart problems (as well as other health problems) by connecting the app to a wearable device, none of them have been designed to work for measuring simultaneously multiple sites of the human body.

In fact, most of the main applications developed and found in app stores work only with compatible wearable devices for which they have been created, e.g., Fitbit, Polar Flow, Withings Health Mate. However, we can also find great apps like Cardiogram that work with different wearable devices, as well as the brands cited above (and others), which

use the data collected for research studies.

Considering the scope of the project "Body distributed heart sensors" and this report, it is considered that these applications are the ones that differ the most from the others due to their specific and specialized nature.

Looking at the various functionalities that characterize the mentioned applications, it is possible to see that they have some characteristics in common and others that differentiate them, as we can see in table 4.1.

Table 4.1: Comparison between similar applications.

Features / Functionalities	Apple Health	Google Fit	Fitbit	Polar Flow	Withings Health Mate	Cardiogram
Display HR data	YES	YES	YES	YES	YES	YES
Display SpO2 data	YES	YES	YES	NO	YES	NO
Collect data from 2 or more sensors (body location)	NO	NO	NO	NO	NO	NO
Display real-time data	YES	YES	YES	YES	YES	YES
Wireless connection's device	YES	YES	YES	YES	YES	YES
Record data	YES	YES	YES	YES	YES	YES
Share/export the user's health data	YES	YES	YES	YES	YES	YES (Premium feature)

All applications allow the patient to record their biomedical data. We can also observe that there are three applications that display the user's oxygen saturation level, depending on which wearable device is being used by the user, while other three apps do not have this feature implemented.

As we can see in table 4.1, although none of the applications include all the mentioned features, there are four applications that stand out, namely Apple Health, Google Fit, Fitbit and Withings Health Mate. These include the largest number of functionalities and are the most specific for the context in question, as they are able to display blood oxygen saturation levels. However, none of them have been developed for the purpose of using sensors to measure multiple sites of the body.

The Medical research applications were not mentioned in this table because they are more focused on some aspects to their studies and do not contain most of the features listed above. In addition, some of them are restricted to a few countries and are not available in Portugal, which restricts their scope.

Chapter 5

Proposed Solution's Architecture and Development

This chapter presents the main requirements related to the project and define the entire system's architecture, from the choice of the hardware to the development of the system used in the wearable device, as well as the requirements of the mobile application and the communication between them.

Essentially, to fulfill the goal of this project there is a need to develop two distinct applications that communicate with each other using a wireless communication protocol, for the purpose of building a wearable health monitoring system. These are an application for the wearable device and a mobile application to analyze vital signs – both intended for patients whether each one with particular functionalities and goals.

The wearable device application runs on the controller that is physically connected to the sensors and acquires and processes biomedical data. As the device has limited processing and storage capabilities the processing is limited to compute the HR and SPO2.

The control of this device is performed using Bluetooth low energy, i.e., when the device is not connected to the mobile application, it remains in sleep mode, and when connected to the mobile application, the system performs the necessary readings, data processing and the data is sent via BLE by using the default profiles, services and characteristics for heart rate, pulse oximetry as can be seen in the next chapter.

The mobile application allows the user control the wearable device and to view and analyze vital signs acquired by the wearable device and allows the user to view the data history presented by the app. Connection with the wearable device is local, using a wireless protocol. Because current mobile devices have a large storage and processing power, data received from the wearable is saved on the mobile device that can then present a large period or perform a more detailed analysis.

The network capabilities of these devices enable the collected data to be shared with a healthcare provider via Wi-fi or 4G, because the data is written to a online database and / or history saved data can be shared as a spreadsheet.

5.1 Solution Architecture

5.1.1 Use Cases

According to the project's scope and main objectives, it is assumed that the main and perhaps only users of the system are patients and clinics/healthcare providers, and each user has their own specific requirements and goals to achieve by using the system.

Patients – users with heart problems and/or diabetes - will use their health monitoring system with the wearable device and their smartphone to monitor vital data on a daily basis. Therefore, if the user finds any significant changes, they can contact their healthcare providers as a preventive measure. The monitoring system is also suitable for people who do not have any health problems, because it can also be a means of helping them to have a healthy life.

To ensure that patients and healthcare providers achieve their goals, the system should be easy to use, so that anyone can use it with as few interactions as possible. The system must also display additional information to help the user utilize the system, both for the wearable device and the mobile application. In Fig.5.1 a sequence diagram is presented to describe the system behaviour considering its main functionality.

Specialized clinics/healthcare providers – In order to monitor patients, clinicians and healthcare providers may use the system to monitor possible changes that are rarely analyzed, using a non-invasive and simple system to acquire patients' health data. The fact that the system allows them to check the patient's health history is also an important factor that aims to contribute to find any abnormalities and help in a faster medical diagnosis.

The patient's vital signs can be shared with healthcare providers when the patient visits the medical clinic, showing the mobile application with the previously saved history, or by sharing the data remotely, by the data sent in a spreadsheet form.

5.1.2 Main System Requirements

To develop this project, a number of minimum requirements were considered. Functional system requirements can be divided into two categories, depending on whether we refer to the system implemented in the wearable device or the application for smartphones.

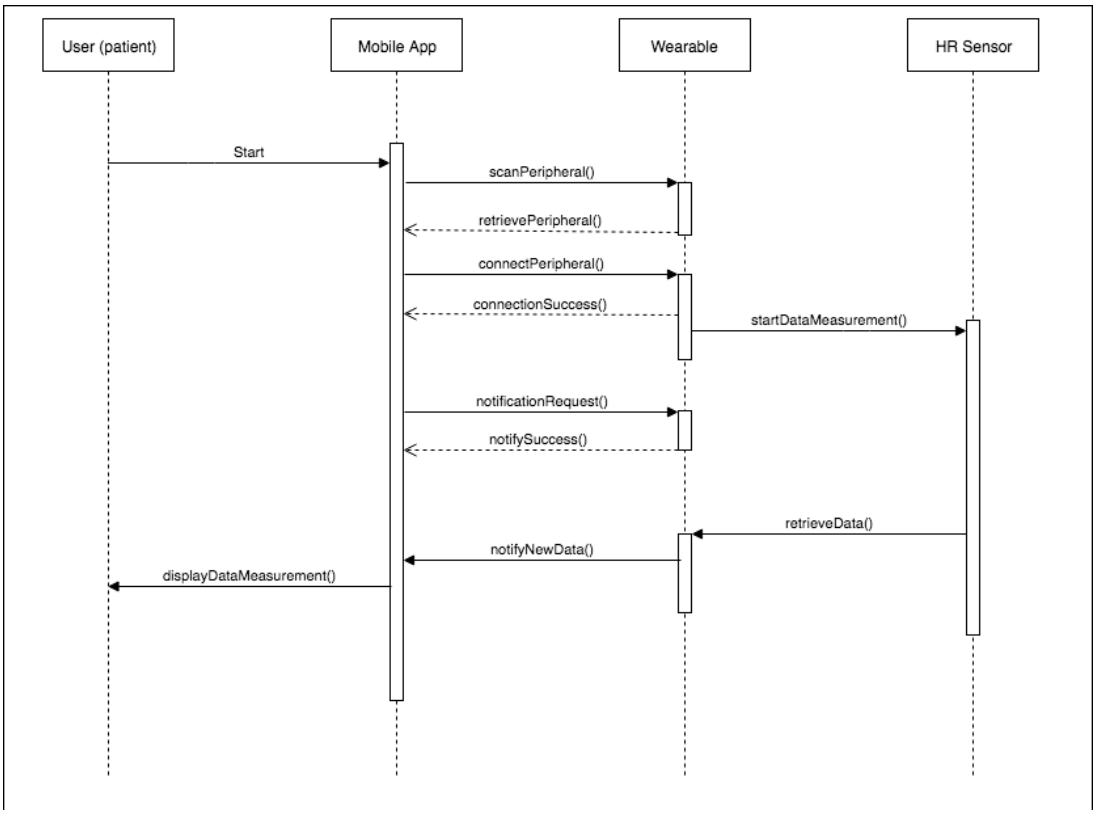


Figure 5.1: Diagram showing the sequence of the system main functionality.

To allow for a better understanding, a system block diagram is presented in Fig.5.2, in order to illustrate the entire system and the relation between the two systems.

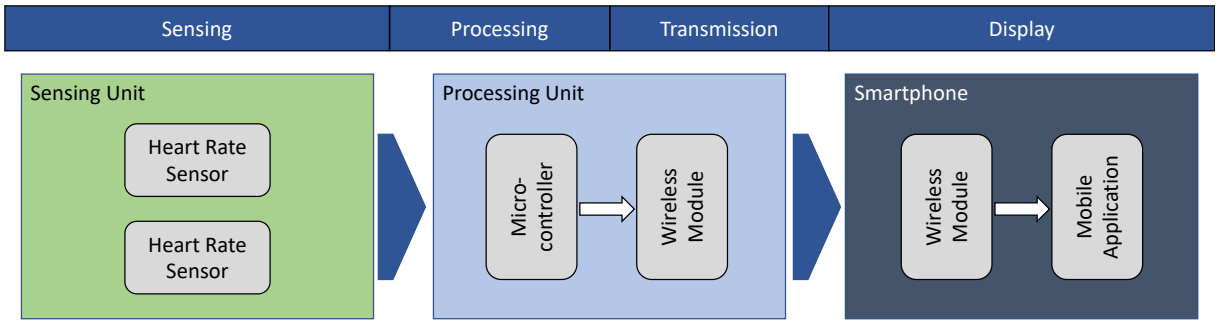


Figure 5.2: Block diagram of the entire system.

The project requirements can be divided into functional and non-functional requirements. Although some requirements were described at the outset, other were added during the development phase, after some understandings regarding the needs of the project.

A. Functional Requirements

The main functional requirements of the project are presented in the following, according to their application – wearable health system or mobile application.

Wearable health system:

- The system must be able to connect to two or more heart rate/oxygen saturation level (HR) sensors;
- The system should accurately acquire vital signs through the HR sensors;
- The system must differentiate vital data from different sensors;
- The system should measure heart rate in beats per minute (BPM);
- The system must send the data collected in real time to a mobile application through wireless connection.

Mobile application:

- The APP must be able to check that the wireless connection can be established;
- The APP should have the ability to detect nearby sensors via wireless connection;
- The APP must be able to connect to devices with heart rate services;
- The APP must read characteristics sent by sensors (wearable health system);
- The APP should show the location of the body where the sensors are placed;
- The APP must be able to display in real time the heart rate in BPM;
- The APP must be able to display in real time the percentage of oxygen saturation level values (through the oximeter);
- The APP should have the ability to determine whether data are being displayed in real time;
- The APP should be able to display the evolution of the heart rate/oxygen saturation level using a chart;
- The APP should be able to save the data;
- The APP should be able to display the wearable device's battery level.

B. Non-Functional Requirements

Regarding the main non-functional requirements of the project, the following list describes the requirements associated with the wearable health system and the mobile application:

Wearable health system:

- The wearable health system must be low-power;
- The system must have a wireless connection;

- The wearable device should work with a rechargeable battery;
- The battery should have a lifetime battery of at least 40 hours for a fully charged battery;
- The wearable device must contain some type of support to stay connected to the user's skin during measurements;
- Connections cables between the microcontroller and the sensors must be flexible;
- The system must be able to connect to a single device;
- The wearable device must be mobile, easy to use and comfortable during use.

Mobile application:

- The APP should be easy to use and user-friendly;
- The APP must be available in the app store for smartphones;
- The APP requires a wireless connection (to be defined) in order to establish a connection with the wearable health system and to work as expected, i.e., to collect and display data;
- The APP must display HR data in real time every 'x' seconds ('x' is set up on the app);
- The APP must maintain a history database;
- The chart's data should be clear and accurate;
- The app's response to any button clicks or real-time data display should be quick;
- The APP should be reliable with minimal bugs/crashes.

5.1.3 Proposed Solution Architecture

The solution's architecture was designed and created after taking into account the experience gained with the completion of the state of the art, and it was based on functional and non-functional requirements of the system mentioned previously, as well as the expected and unexpected challenges in relation to hardware and software development. As we shall see below, the architecture was structured in two different components: (i) the wearable device system and (ii) the mobile application.

Each system has different specifications and objectives, but it is the simultaneous operation of the set of applications that results in the success of the project itself, for which the communication protocol is crucial and indispensable.

Despite the fact that the purpose of the project is unique, even though the project's system will be used by a single end user, both applications that compose the system are presented individually. This is because they are completely different applications, running on different devices and with distinct functionalities, despite transmitting data between each them. Due to the fact that the applications are dissimilar, it is possible to say that each application can be executed separately, and can be connected to other applications, once the architecture and development of each application has been designed and developed under common standards, in order to be used with third party sensors and applications.

Thus, it is very important to remember that even if one of our applications work with other systems/devices, in order to achieve the objective of this project it is essential that both systems can be used simultaneously. It is also worth mentioning that the architecture designed is somewhat is different from those of found in the literature, as no applications were found with the ability to read more than one sensor in real time, except for applications developed to check wireless connection mode, completely different from the project's purpose.

As we can see in Fig.5.3, the best solution found would be to implement two independent systems comprised by the Wearable Device and the Mobile Application, that when working together allows to achieve the overall goal of the project.

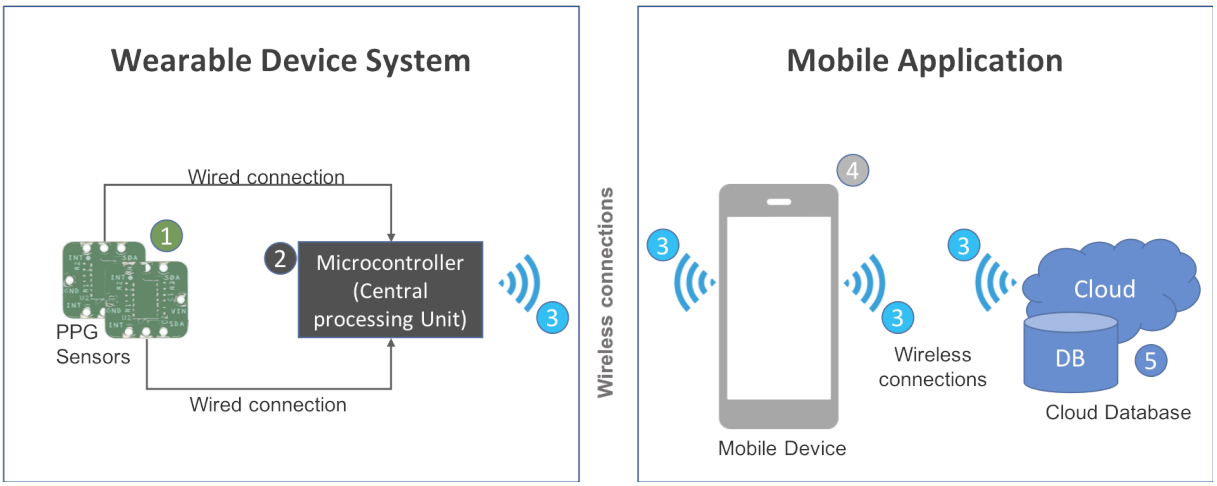


Figure 5.3: System architecture for remote patient monitoring system.

On the wearable device, the system has an architecture of a wearable device system, consisting of the following: PPG sensors to acquire health data from the user, which are then processed; a microcontroller, which is responsible for receiving and processing the data collected from the sensors, a wireless connection to the mobile application to send data; and a battery that allows the system to be used anytime and anywhere.

In order to meet the functional and non-functional requirements described above, the

system were developed based on the requirements presented.

So that the system could connect to two PPG sensors it was necessary to choose a microcontroller board that had two wire (Serial Clock Line (SCL)/Serial Data Line (SDA)) connections or a multiplexer to be used so the system could be connected with more than one sensor. Thus, it was chosen to use a microcontroller board with two wire connections since tests performed with multiplexer showed that the system would not perform correctly.

For the system to have the measured data accurate, the code was developed using noise reduction and tests were performed with other sensors to compare the results.

The developed system was designed to send vital data every four minutes so that the battery could last more. The four minutes is a standard in other devices as observed. The system used the protocol Bluetooth low energy to do the communication.

In order to be a low-power device and use low battery, the code was developed to remain the system in sleep mode if there was none connection. The board used has battery connection and USB charging mode.

The device used flexible cables to make the connection between the boards and used a 3D-printed black box to attach Velcro tapes to the user's body.

On the other side, a smartphone runs an application developed and previously installed for the project. The APP receives the data via wireless from the wearable device system and displays the measured results in a user-friendly manner. In addition, there is a cloud database that stores the user's information for possible future use.

In order to make a wireless connection between the devices, the application was developed using Bluetooth communication, and it has a filter to perform search and connection only with sensors that use Bluetooth's standard hear rate services/characteristics. The application also receives the battery level.

To display the user's vital signs, the interface was designed so that the user could know just by looking to the APP which part of the human body was being measured, with the heart rate and SPO2 results beside it in the same line. A chart was added below that line to display the heart flow.

In order to verify that the data was being displayed in real time, when the system was not receiving the real-time data from any sensor, the interface would change slightly in the display color of the data to show that the system was not receiving the data.

The application developed has a database and there is a screen to show the data recorded.

To be easy and user-friendly, a user test was performed to make the interface fit the best way, in addition to the development following the best practice guides for APP

development.

The application is available on the APP Store, and tests were performed during its evolution and development to have as few bugs/crashes as possible.

Chapter 6

Implementation

This Chapter describes the design and implementation of a wearable device prototype based on PPG sensors, as well as the software and mobile application developed to work with this hardware. As previously mentioned, the main purpose is to acquire vital signals like heart rate and SPO2 measurements from the user and send them via wireless to a mobile application.

The first section contains a description of the used technologies in order to create a better solution, according to the architecture proposed in the previous chapter. Subsequently, it is described the hardware modules used to measure the data from the PPG sensors and the software/firmware developed to process the data. The third section describes the development of the mobile application, and the fourth section presents the system usage.

6.1 Main Technology Solutions Chosen

When defining the main features of the systems – the wearable device system and the mobile application - it was necessary to determine the best technological solution for each one, in order to allow for the efficient implementation of all respective functionalities, which are referred to in the previous chapter.

In addition to the developed systems, the communication protocol used to keep them working as one is also a topic that is mentioned and detailed, as it is a significant and relevant part of the solution.

In the following, a detailed description of each system is provided, with the respective justification of the technological solution adopted for each case.

6.1.1 Wearable Device System

Regarding the wearable device system, specifically the hardware, it was intended to build a prototype that could be placed in any part of the body (with enough sensitivity to read the vital signs). Another requirement is that the product presented should be as comfortable as possible for the user, as well as low-cost and easy to operate.

To make this all possible, based on the state of the art, it was decided to use the MAXREFDES117 module, by Maxim Integrated (see Fig.6.1), for PPG sensor, because it is a sensor dedicated to the acquisition of biometric signals (i.e., heart rate and pulse oximeter). It is also small in size and it has an extremely low power consumption, with a relative lower price when compared to other sensors.

The heart rate/SPO2 sensor on MAXREFDES117 is the MAX30102 sensor, with integrated red and IR LEDs to carry out the detection process. Using integrated red and IR LEDs to do this, this module can be used on a person's fingertip, earlobe, or other fleshy extremity [51].

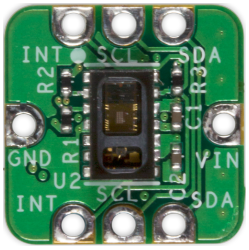


Figure 6.1: MAXREFDES117 PPG sensor chosen to be used in the project.

In addition, this sensor is commonly used by products that are being commercialized, as the case of some smartphone models such as Samsung [68], which uses the same heart rate/SPO2 sensor used by MAXREFDES117 - the MAX30102 - to perform measurements of the user's heart rate.

After conducting a few tests on prototypes with hardware, in order to find out which microcontroller would be the most suitable for the project, ESP32 (see Fig.6.2) was chosen, as it has wireless communication protocols - (i) Bluetooth and (ii) Wi-Fi - already integrated in the board. Also, it has two Inter-Integrated Circuit (I2C) communication channels, which are used to connect the microcontroller to the PPG sensors, and a dual-core system that allows tasks to be processed in parallel.

To ensure the system works as a wearable device that can carry out biometric measurements, it was decided to use a rechargeable 3.7-volt and 2000 mAh polymer lithium ion battery, allowing the device to be mobile (see Fig.6.3).

Having chosen the necessary hardware, the development of the system was started. The Integrated Development Environment (IDE) chosen was Sloeber, the Eclipse Arduino

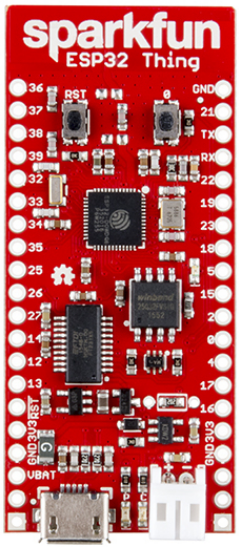


Figure 6.2: ESP32 by Sparkfun - the microcontroller used in the project.

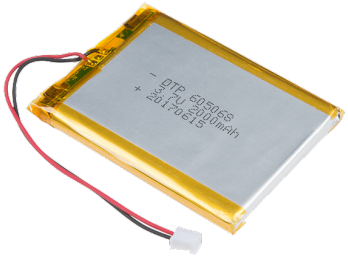


Figure 6.3: 3.7-V 2000-mAh polymer LIPO.

IDE (see Fig.6.4), a platform that is based on Eclipse, which is widely used by developers to implement board code. With more than 500 boards supported [69], this cross-platform IDE became indispensable in the development of the project, as Eclipse is one of the most consistent and most widely used IDEs.

As mentioned in the previous chapter, the FreeRTOS library was used - the use of this Kernel allows for a greater abstraction when it comes to a large number of tasks to perform, since it manages temporal tasks.

With regard to the wireless communication that was chosen, as will be presented in this chapter in a subsequent section dedicated to wireless communication, although ESP32 supports two Bluetooth modes – Classic and Low Energy - because Bluetooth Low Energy was the chosen protocol, the communication via Wi-Fi was deactivated, as it would have a high energy consumption.

Having said that, it is worth mentioning that ESP32 was used as a BLE server so that the client could connected to it, in order to perform the transaction of the data via BLE.

A subsequent section will address the global use of the system, the functionalities and

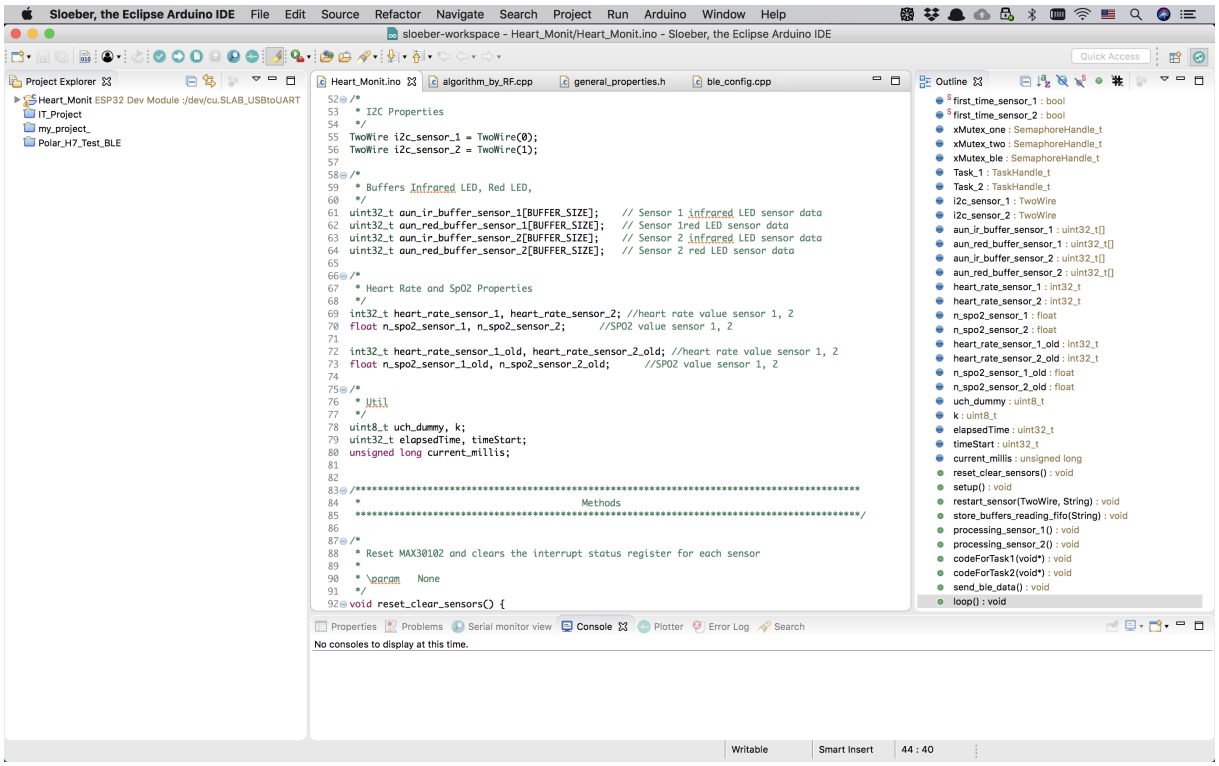


Figure 6.4: Screenshot of Sloeber, the Eclipse IDE for Arduino showing the heart monitoring project.

the process that makes the entire system work as one.

6.1.2 Mobile Application

Part of the project was to develop a mobile application for users to visualize the information collected from the biometric sensors in real time. Because this application is not the core of the project, but rather a tool to achieve the proposed objectives, by being more familiar with the development of this device and by knowing that the physician who carried out the tests has a mobile device with a IOS operational system, the author decided to develop the mobile application for this operating system, which runs on Apple iPhones.

To develop the application natively, Xcode was used (see Fig.6.5) - a program used for developers to build their apps for Apple products, such as iPhone, iPad and MacBook apps.

Developed by Apple, this IDE is an important development tool, since it is the only program that runs the apps on Apple devices even if the application has been developed on another platform using other programming languages (as several are supported).

Currently, most developers who develop native applications use Swift, an open-source

language, for a number of reasons [70], or the old but still used Objective-C [71].

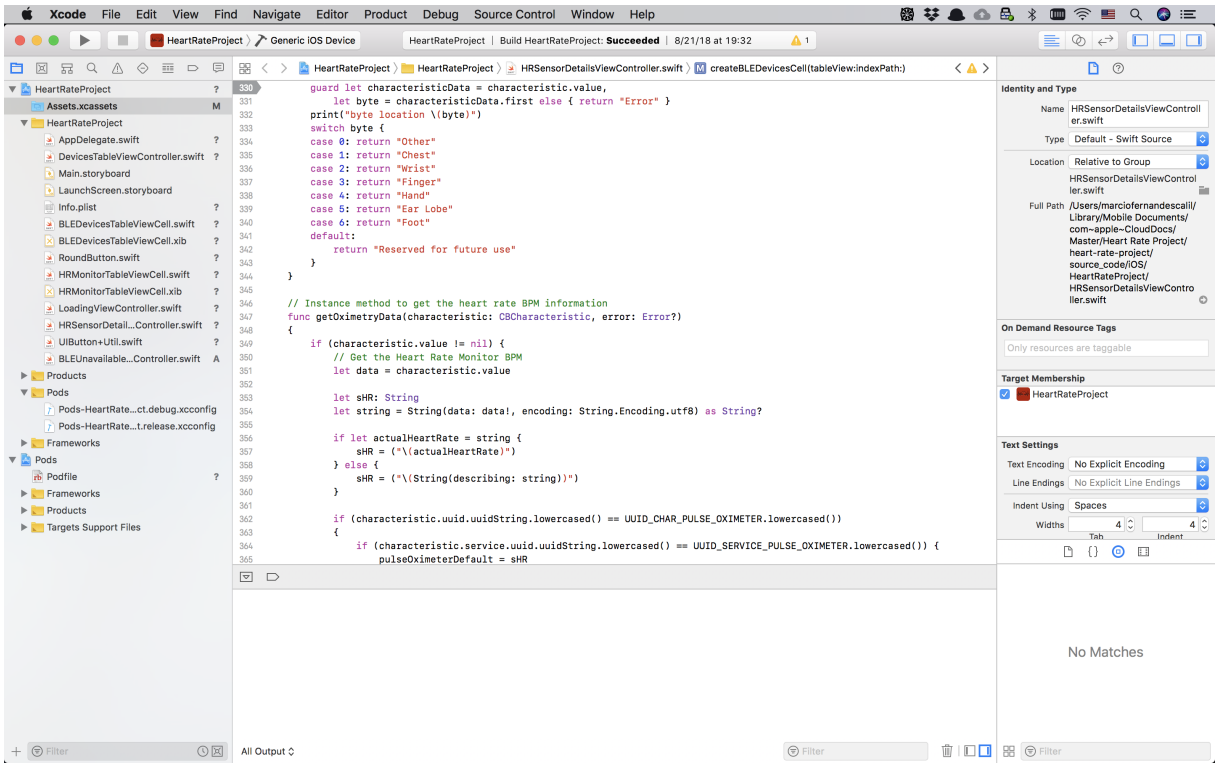


Figure 6.5: Screenshot of Xcode showing the Heart Rate Project.

The programming language chosen to develop the mobile application was Swift, which is an open-source language that is currently on version 4.0.

The application developed for this project uses the Core Bluetooth framework, which allows the user to connect their iPhone to a HR BLE device in order to communicate and receive the heart rate data measurements.

The following sub-section explains the mobile application when it comes to the development, the user interface and how the connection with BLE was implemented.

6.1.3 Wireless Communication

After analyzing the existing wireless communication technologies described in the state of the art, the technology chosen and used by the author of the project was Bluetooth Low Energy.

The choice was made for several reasons, namely:

- low power consumption – it is also able to stay in sleep mode to save even more energy;

- no need for additional hardware module – the BLE module is already integrated into the chosen hardware;
- ease of operating using a smartphone – since all smartphones have a Bluetooth module for communication.

Another interesting feature of BLE that was also analyzed is the fact that BLE has services and default characteristics to make connections with heart rate devices, pulse oximeter, battery, in addition to enabling the creation of custom characteristics when these are not found in the list. These characteristics are recognized by applications and contain data sent by Bluetooth.

A section below will describe the BLE application structure, as well as the services and characteristics used to transmit data between the two systems developed for the project.

6.2 Wearable Device

6.2.1 Wearable Device Prototypes

The first prototype was developed to understand how the system should work and to ensure that the modules and parts of the project would work together.

After following the detailed steps described in the Maxim Integrated's website [51] to see how the sensor works, the wires between Arduino Uno, Bluefruit LE UART and HR Monitor MAXREFDES117 were connected (see Fig.6.6).

In order to have all boards working properly together, some small changes were made to the pins used to connect the boards, according to Adafruit's development guide [72].

The author then updated the microcontroller with the code developed to start the measurements by reading the user's heart rate and the blood oxygen saturation level, plus send the user's vital information via a BLE connection.

After performing a few tests with the BLE module attached to Arduino Uno, the microcontroller turned out to be weak, which resulted in a lack of memory.

In regard to this fact, an Arduino Mega was used instead of Arduino Uno, and with this another major upgrade was made to the prototype. A multiplexer was added to the project along with the second Maxrefdes117, the sensor used to carry out the project's measurements.

The second prototype already had two HR sensors and could have more sensors plugged-in once an I2C Multiplexer was attached to Arduino Mega (see Fig.6.7).

The I2C multiplexer used in the prototype had the function to increase the number of sensors it identical addresses connected by I2C up to 8 devices, allowing more PPG

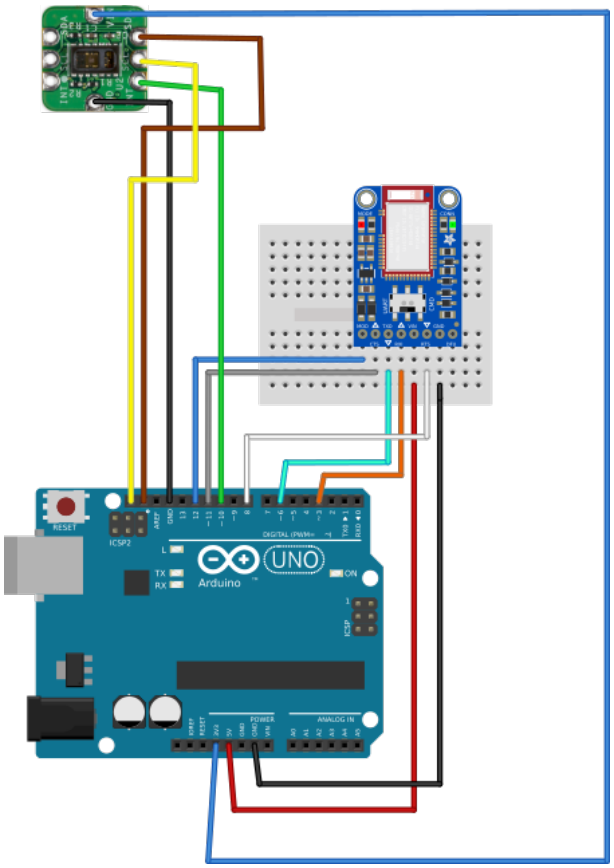


Figure 6.6: First Prototype: Arduino Uno, BLE board and Maxim heart sensor - wired connection.

sensors to be added to the prototype, considering that the Arduino Mega also had a single I2C communication channel connection. This is because the I2C port of the sensor has a unique address.

This prototype brought the project a little bit closer to the main goal, which is to measure heart rate and blood oxygen saturation levels using multiple sensors.

A new code was developed, since a new board was attached to the project, as the main function of the system was to perform the connection with the two heart rate sensors.

The problems with this prototype were two completely different issues – (i) the first one, and probably the main reason why it failed, was the way the system was working, and (ii) second, considering this is a wearable project, the size of the prototype project would be a problem, because of the large number of boards to be connected.

Due to the fact that Arduino Mega has also one I2C bus interface and its processor is not very fast, the use of the multiplexer attached to this microcontroller became an issue, as the user's vital signs were not being collected at the same time in real time.

This is because the system first reads data from the first sensor and only reads the second sensor after the multiplexer's I2C communication port is addressed, i.e., although

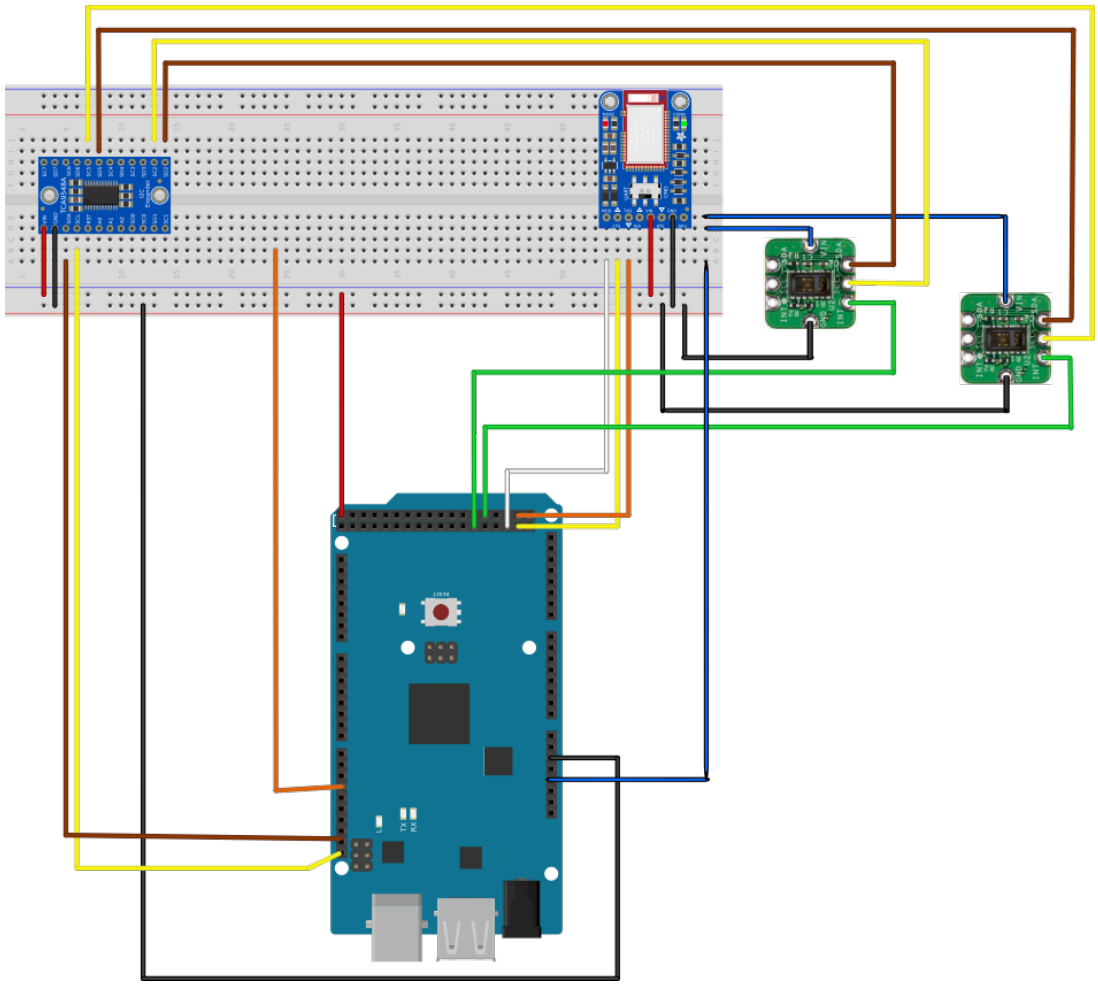


Figure 6.7: Second prototype: Arduino, BLE board, I2C multiplexer and 2 Maxim heart sensors - wired connection.

it is possible to connect up to eight sensors, the sensor need to be accessed alternatively.

Due to these delays in reading data from the two sensors, the author decided to look for another processing board with higher perform, in order to carry out the project as specified.

In our first and second prototypes, considering the fact that the used Arduino boards did not have built-in BLE, and because a lot of hardware would be needed to measure PPG from two different points in the human body, a Bluetooth Low Energy module was attached to transmit PPG data collected to the smartphone, and a multiplexer was used to provide more I2C channels in order to allow another PPG sensor to be connected.

In an attempt to improve our platform and to perform measurements in two different points of the human body in real time, we decided to switch our main hardware into an ESP32, which has dual core processor and BLE already integrated (Tab.6.1).

Table 6.1: Comparison of boards specifications used in the project - final (ESP32), second (Arduino Mega) and first (Arduino Uno) prototypes, respectively.

Specs/Boards	ESP32	Arduino Mega	Arduino Uno
Number of Cores	2	1	1
Processor	Xtensa Dual-Core 32-bit	ATmega2560	ATmega328P
Architecture	32 Bit	8 Bit	8 Bit
CPU Frequency	160 MHz	16 MHz	16 MHz
802.11 Wi-Fi	YES	NO	NO
Bluetooth LE	YES	NO	NO
SRAM	512 KB	8 KB	2 KB
Flash	16 MB	256 KB (8 KB used by bootloader)	32 KB
GPIO Pins	36	54	14
Interfaces / Busses	4 SPI, 2 I2C, 2 I2S, 2 UART, 1 CAN	1 SPI, 1 I2C, 4 UART	1 SPI, 1 I2C, 1 UART
ADC Pins	18	16	6

By looking to the comparison between the boards used during the project, it is easy to understand how superior the board used in the final prototype is (see Fig.6.8).

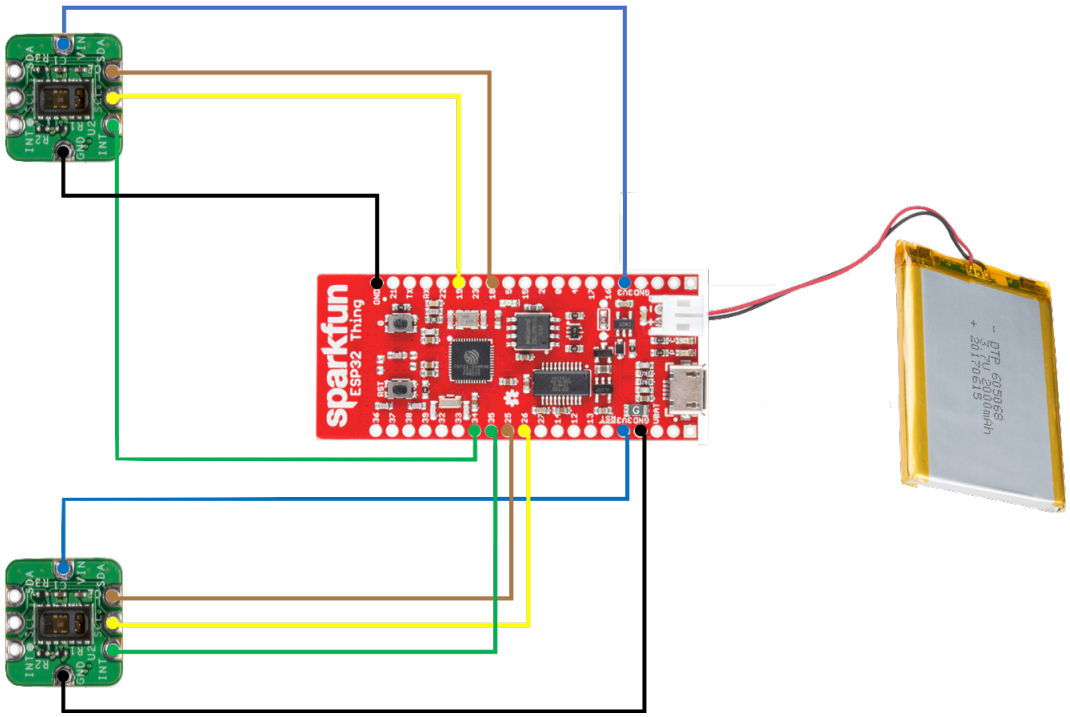


Figure 6.8: Final Prototype - ESP32 as microcontroller (built-in BLE), 2 Maxim PPG sensors plus a battery.

Because the ESP32 has two I2C bus interfaces and also a built-in BLE, two previous boards that were used - the Bluetooth Low Energy module and the multiplexer - were discarded.

6.2.2 Wearable Device System

As previously mentioned, and in order to successfully meet system requirements, the wearable device system has been developed to have low-power consumption energy, allowing the battery chosen for the design - a Li-ion battery - to last for more than 48 hours. The battery of the wearable device can be easily recharged by connecting the battery to a computer via micro-USB.

To make this possible, the code was optimized so that when there was no connection via BLE, the system saved as much power as possible, leaving the Bluetooth in sleep mode. This is because the Bluetooth connection is the one that uses the most power in the system.

Once the mobile application is connected via Bluetooth to the wearable device, the system performs the transmission of data via BLE only when all the information has been collected, establishing peaks of energy approximately every 3.6 seconds, using a low amount of energy.

Regarding the main requirement, i.e., to establish a connection with two or more PPG sensors, the use of the ESP32 microcontroller was crucial, as it allows for two sensors to be connected without the need to attach any other modules (such as a multiplexer, which was used in a previous prototypes).

The connection between the sensors and the microcontroller was made by wiring cables connected to the SDA and SCL pins, thus using the I2C communication protocol. Because I2C is used, the Wire library was added to the project to execute data reading and processing via cable.

In order for the two sensors to be read in real time, the code developed for the system uses a FreeRTOS Kernel library, which helps to create tasks and semaphores to enable the system to process the data using as much of the hardware as possible (in this case, it has two cores and can perform two different tasks in parallel to achieve the goals of the project).

FreeRTOS - Real Time Operating Systems - is a solution that has been in the market for free for several years and it is commonly used for solutions with microcontrollers (embedded systems). It was developed to use multi-threads or tasks, and implementations of semaphores, allowing the system to perform actions to allocate memory, using the hardware and the system in the best possible way.

The sensor reading code used is an optimization of the original one provided by the sensor's manufacturer.

Maxrefdes117, the PPG sensors used, perform the readings by reflectance mode, as explained earlier. Both the LED lights and the photodiode are on the same side, and while

the LED lights illuminates the skin, the light reflection is captured by the photodiode, thus detecting simple changes that might occur in the veins during blood circulation.

The PPG sensor collects and provides raw signals that are used to calculate heart rate and oxygen saturation levels. To show how the calculations are performed, a flowchart (see Fig.6.9) is provided, so that it is easier to understand how the system proceeds to obtain the final result.

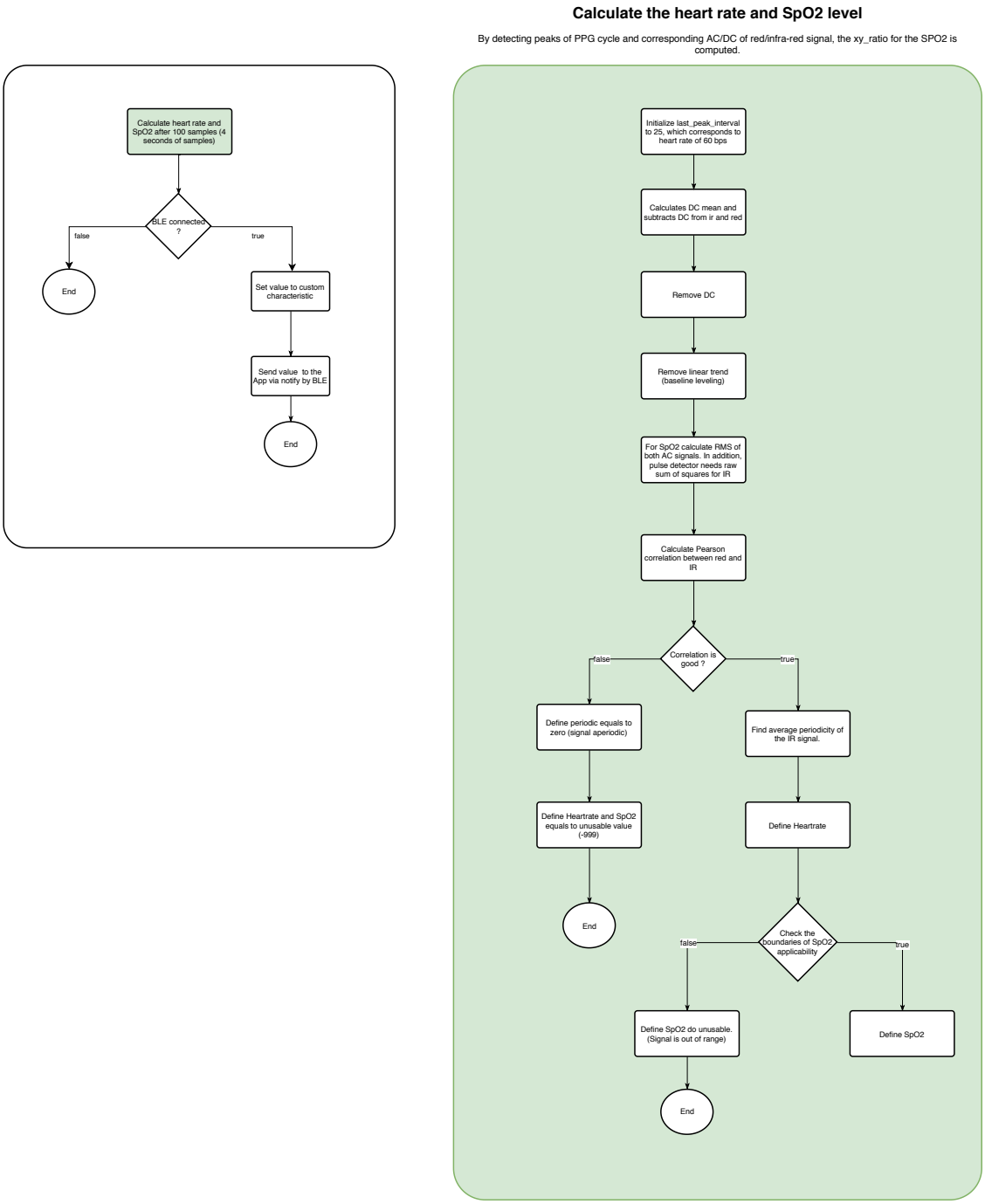


Figure 6.9: Flowchart of the algorithm to calculate the heart rate and SpO2.

Finally, a library was used for Bluetooth, which allowed for different profiles to be created, which, in turn, contained the respective services and characteristics. These profiles, services and characteristics will be explained in further detail in a dedicated sub-section about BLE.

In this sense, whenever the sensors send the user's vital data, the data are processed

by the microcontroller system and sent via BLE using default and custom settings, which have been specifically developed to behave as required according to specification.

Because the optical heart sensor requires a reasonably snug fit against the skin, a Velcro tape was used to ensure the sensor and the skin were in contact, thereby establishing a constant and efficient pressure so that the sensor could collect vital signs and measure heart rate and blood oxygen saturation (SpO2) levels.

6.3 Mobile Application

After a study carried out in the state of the art on mobile applications used to measure heart rate, a quick and basic research on the interface of the application was made. Based on this research, the programming language to be used for the development of the mobile application was chosen, and when the wearable device system was ready to do so, the development of the application initiated.

6.3.1 Development for IOS

As previously stated, the objectives of the mobile application are: (i) to receive vital signs data from the user that has been using the wearable device system, (ii) to display the user's health data, communicate by BLE, and (iii) to store the data for further analysis.

Based on the study of the state of the art and the requirements raised during the prototype construction and the architecture design stages, the application was developed to meet the system's objectives.

To structure the code, we have chosen the Model-View-Controller (MVC) as design pattern for designing our application. The model is known to be responsible for the business logic of the application, and the View presents the data to the user and handles their interactions (see Fig.6.10), while the Controller is known for doing the connection between the view and the Model.

In order to not scatter the classes and files in the same directory, it was decided that to divided them into folders (see Fig.6.11) within Xcode to make it cleaner and easier to view and to become easier to find the classes.

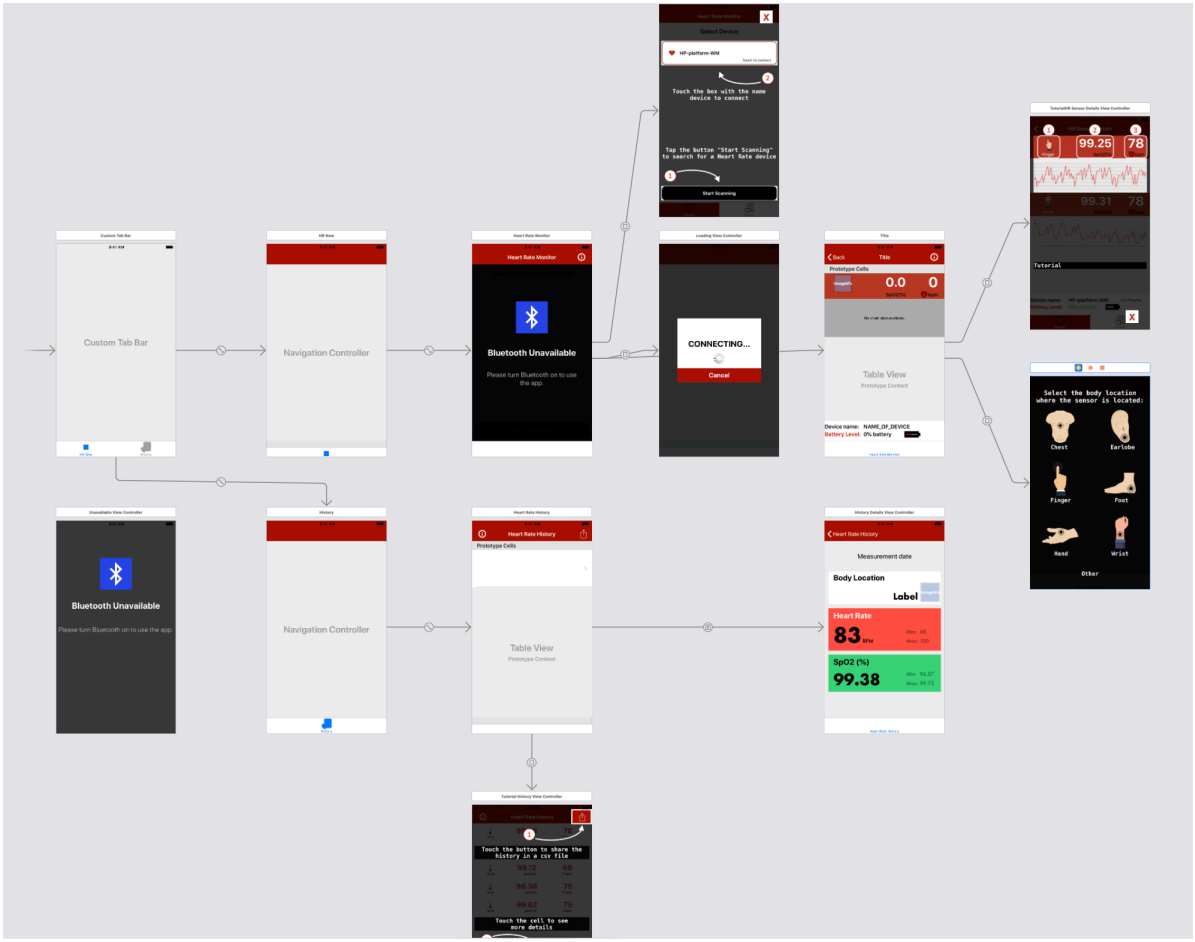
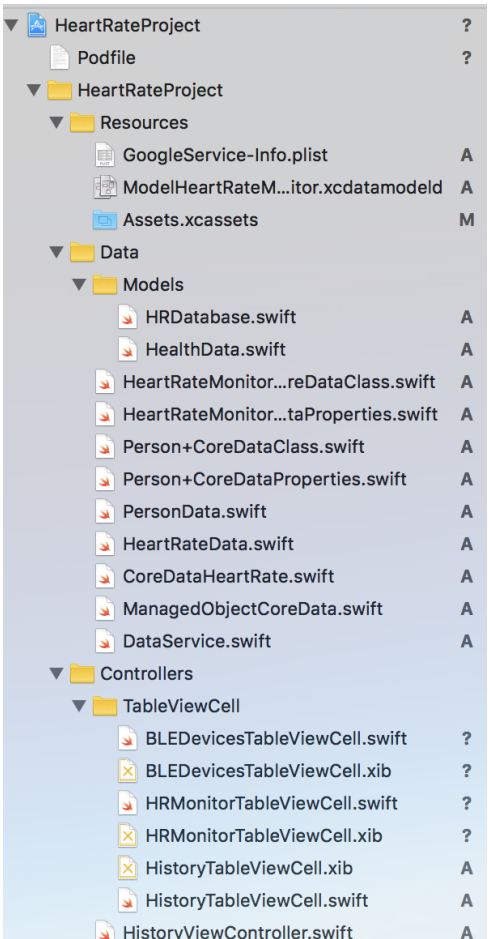


Figure 6.10: Project storyboard and its connections.



When the developed application, called My Health Pulses, is opened, there is a check to see whether the smartphone's Bluetooth is on. If it is not available, a screen (see Fig.6.12) is displayed to alert the user that the BLE must be turned on, in order to use other functionalities of the application.

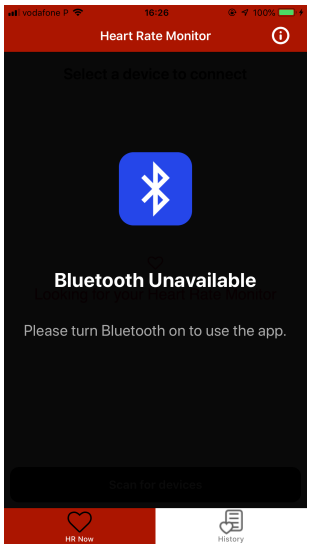


Figure 6.12: My Health Pulses app - BLE Unavailable screen.

Once the user connects the Bluetooth, or if it was already on, a list of BLE Heart Rate devices available to be connected to the user device is displayed (see Fig.6.13).

On the initial screen, a History tab is also displayed. This allows to the user to check previous data in case it has been already carried out a measurement.

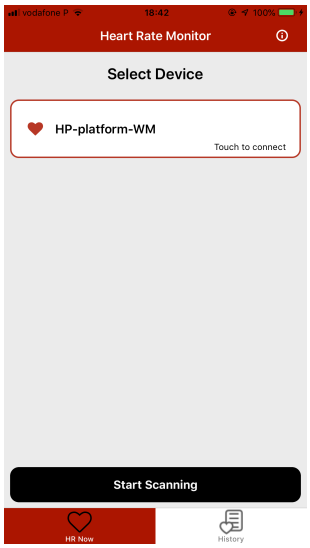


Figure 6.13: My Health Pulses app - Heart rate monitor - List of devices.

Once connected to the wearable device system, the application switches to the next screen, which is the main screen of the app, showing the data collected by the sensors in real time.

The data displayed on this screen (see Fig.6.14) is listed according to the number of sensors available on the wearable device, representing three important pieces of information, (i) body location, (ii) blood oxygen saturation level (SpO2) in % and (iii) heart rate in beats per minute (BPM). The body location is essential to help the user know which result corresponds to which sensor.

On this screen, the chart of raw values extracted from the sensors is also displayed, so that the user can observe the variation along the time of the data. This chart may be particularly useful for a specialist in healthcare. The implementation of this chart required to add a library.

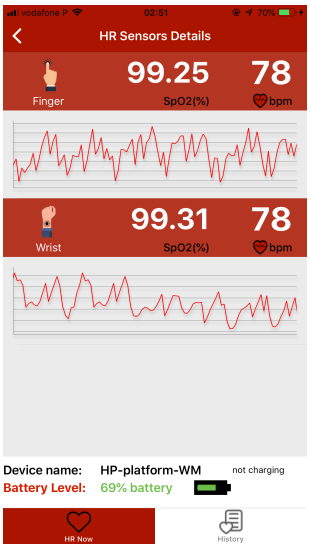


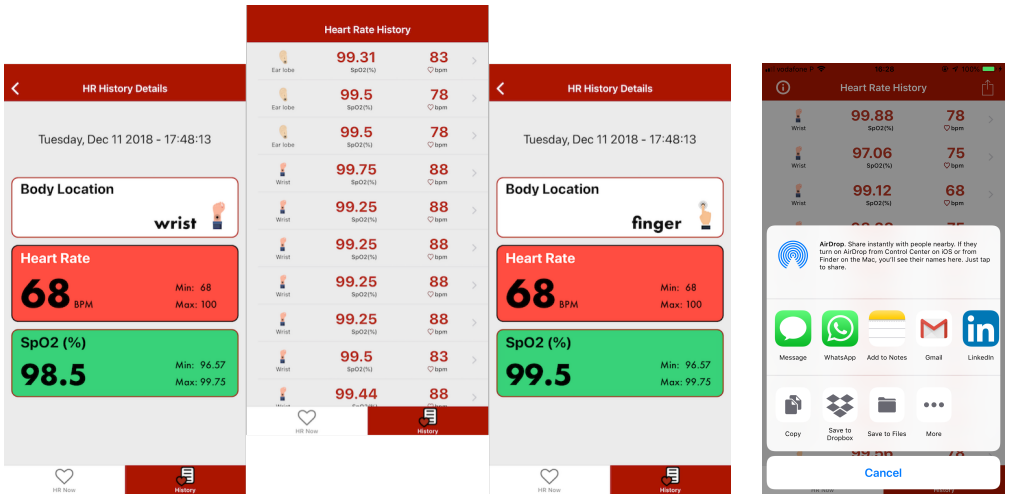
Figure 6.14: My Health Pulses app - HR sensors details - the main screen of the app.

After performing some data acquisition, the may access to the list of collected data through the History tab. The History screen displays a list sorted by date, where the most recent data appears at the top, enabling the user to see all results at once by scrolling through the screen.

The user can still export the entire list and send it by email so that they can view all the data acquired on a computer, or even send it to its physician.

Once the user selects an item from the History list, the chart can be viewed again and it is possible to check the time of a particular measurement. As soon as the user selects an item, the application will show a detail screen of the selected item (see Fig.6.15).

It is important to note that all health-related applications found and installed for testing only work with a single sensor. No applications were found working with multiple sensors at the same time, performing the reading of their data and displaying them.



(a) (b)

Figure 6.15: My Health Pulses app - (a) HR Sensors Details; (b) History's Share.

6.3.2 User Interface Application

Due to research and analysis on health-related mobile applications, especially for heart rate monitoring, as seen earlier in Chapter 4, the author decided to create a simple and user-friendly interface design.

In order carry out the design of the screen, a survey with a small number of users was performed, as mentioned in section "Proposed Solution Architecture" from the Chapter 5, where the screens in Fig.6.16 were presented and opinion users were asked about the most intuitive and appropriate one. Their opinion were considered for the chosen one.

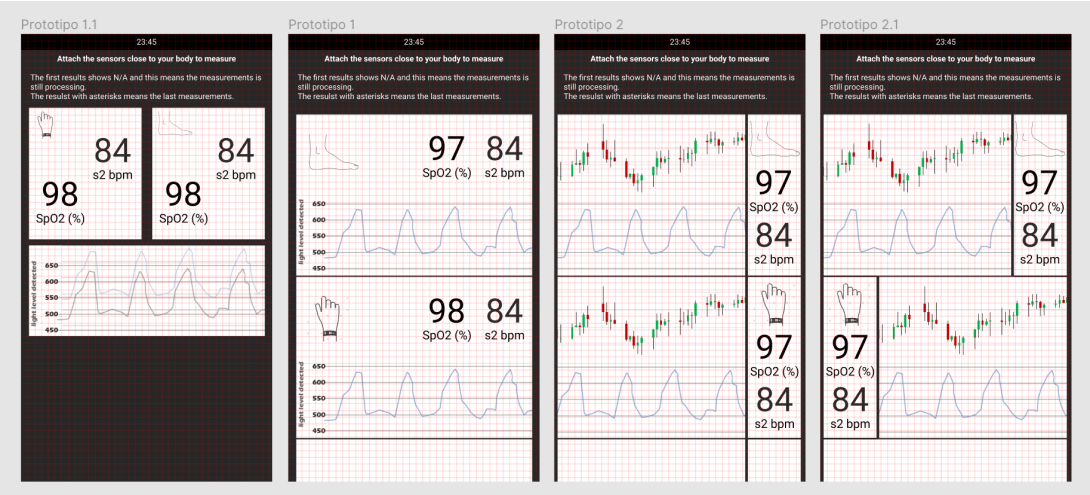


Figure 6.16: Prototype of screens shown to users so they could choose the one they prefer.

Following Apple's development guide and standards, including UI, there was a concern to use a feature called "constraints" to ensure that all objects were in the chosen location. The size and font of the buttons were also thoughtfully designed to ensure a stress-free

use.

To ensure that all iPhone sizes had the same screens and proportions (since it was not possible to test the interface in all sizes), an internal XCode tool called "preview" was used. This tool helps the developer to visualize all the possible iPhone sizes at once, so as to ensure that the interface fits on every screen (see Fig.6.17).

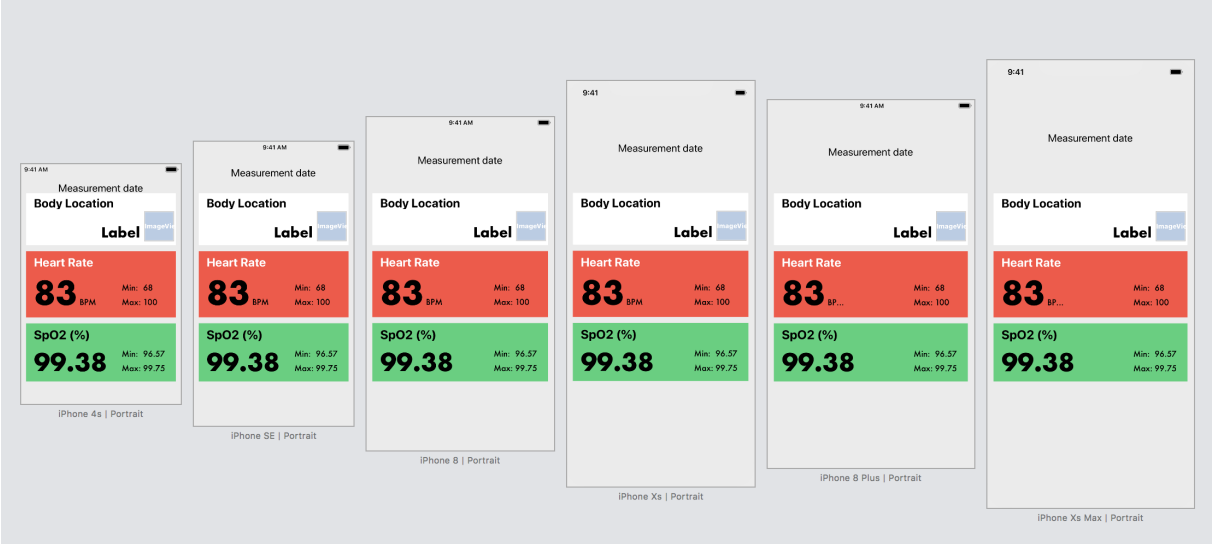


Figure 6.17: Prototype of screens shown to users.

6.3.3 Database

When it comes to storing data in the application, the implemented data model consists of two distinct tools. The first one is Core Data, a framework provided by Apple for mobile applications to manage object graphs and track data changes. However, in the course of development, thinking that a system could be created for healthcare providers to access the information remotely, Firebase was added so that the data stays in the cloud.

Although a user authentication scenario has not been implemented using login, to guarantee the security and privacy of user information, and for the user not to access data belonging to other people/devices, a unique identification key has been created. The ID is unique per device, i.e., only its data are saved, and each user is only able to see its own data on the History screen.

Although the author knows the existence of other databases that could have been used, it was decided to use Core Data and Firebase due to time and development issues, since the chosen options not only allowed the development to be faster, but also met the needs of the project, as Firebase is a real time database.

6.3.4 IOS BLE Communication

Communication via Bluetooth in IOS is performed through the Core Bluetooth Framework, a library that helps in the development of applications to communicate with this wireless protocol, as it enabled access to the necessary classes for this communication.

As we know, there are several products that communicate via BLE with apps. Therefore, it was decided to restrict the scanning by devices through the code. It was possible not only to limit the number of devices that could appear in the list, but also to specify which type of devices could appear (in this case, those with the standard heart rate service according to Bluetooth standards).

The scanning time was set during the development of the application to be 10 seconds to find a device via BLE. If the Bluetooth is not turned on, a warning screen is displayed, asking the user to turn the Bluetooth on, as the application needs it to connect to the wearable device.

In the following code, we can see the three features mentioned above. Once the BLE changes from offline to online, the startScanning method runs automatically. This function checks whether BLE is on or off (if it is off and the function is called, it is because the BLE is now on and there is no need to display the warning screen).

We can also see the dedicate search by the Heart Rate service (manager?.scanForPeripherals(withServices: [BluetoothGATT.BLEServices.heartRateService.UUID]), where the UUID for heart rate is 0x180D. However, the device can have more than one BLE service, that is, if one of the services is the heart rate service, the device will be listed. The code also shows the 10-second search per device (now() + 9).

Listing 6.1: Dedicate filter to display only heart rate devices

```
private func startScanning(){
        if !BLEAvailable {
            self.dismiss(animated: true, completion: nil)
        }
        // scan only for heart rate service
        manager?.scanForPeripherals(withServices: [BluetoothGATT.BLEServ
        DispatchQueue.main.asyncAfter(deadline: .now() + 9) { [weak self]
            guard let strongSelf = self else { return }
            if strongSelf.manager!.isScanning {
                strongSelf.manager?.stopScan()
                strongSelf.updateViewForStopScanning()
            }
```

```
        }
    }
```

The application then moves to the next screen, which will be filled with data for the next Bluetooth task, which is to check the BLE characteristics that can be obtained from the connected device by analyzing the BLE service.

As one of the services showed is the heart rate service, the characteristics from this service must necessarily be related to the heart rate, in addition to other services.

In our development, we have four different services, three of them being standards: heart rate, pulse oximeter and battery, plus a custom service – RAW Data.

Once the connection with Bluetooth is made, the application looks for the BLE services and consequently for their characteristics, so that it can then check the value of each of them. As each BLE characteristic has a unique value it can be ascertained through its own hashvalue.

Having developed the code according to BLE standards, any sensor that has an HR service should work with the mobile application developed.

6.3.5 BLE System Connection

Our project uses four BLE services, and two of them - the heart rate service and the pulse oximeter service - are used two times, since there are two sensors and each sensor needs its own service to send the heart rate and blood oxygen saturation level by the characteristics. The other two services are the Battery service and the Raw data Service.

This is because the sensor's data would be overwritten if only a single heart rate or pulse oximetry service has been created.

The Bluetooth connection between the two systems - wearable device system and mobile application - occurs when the heart rate service is exposed in the wearable device, since the mobile application searches for the UUID 0x180D corresponding to the heart rate service.

Once connected, the BLE peripheral device - the wearable device - exposes the BLE characteristics of the BLE services that have been programmed into the system. This way, the mobile application can read six different BLE characteristics of the four different BLE services exposed by the wearable device system.

The BLE structure created for the project (see Fig.6.18) comprises six distinct profiles, each one with a single BLE service. We could have separated them by sensors, making it four profiles (considering that the heart rate service and the pulse oximeter service could be in the same profile), but it was decided to separate them by services. This change

would allow us to add more profiles with new services, but it makes no difference when it comes to the code to read the sensors' data, as the mobile application searches for the required BLE characteristics.

As we can see in the list of standard BLE services, the heart rate, pulse oximeter and battery services are found briefly, while the RAW service is not found. The main reason for this is because the RAW service does not really exist, and for the RAW data of each sensor to be sent, a custom BLE service and BLE characteristic has been created for the data. The RAW characteristic is composed of an array of RAW data from the sensors.

To create a custom BLE service and BLE characteristic, it is crucial to use UUIDs that are not yet used, i.e., it is necessary to analyze default BLE services and BLE characteristics to determine which of them cannot be used.

In this case, we used the 0x18FF UUID for the RAW Service and the 0x2AFF UUID for the RAW characteristic of this service, thus enabling the data acquired by the sensors to be sent by Bluetooth successfully.

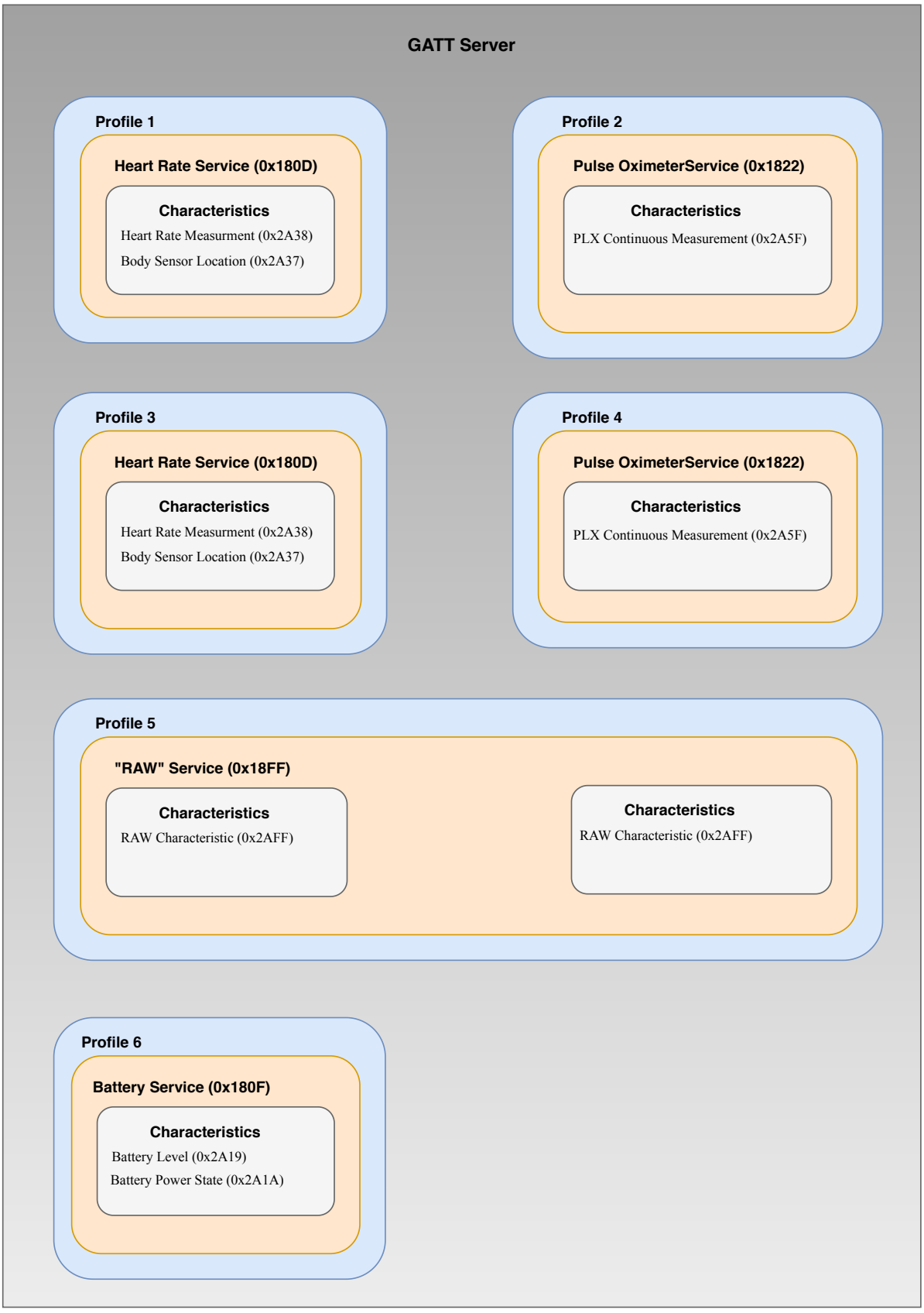


Figure 6.18: BLE structure created for the project.

6.4 Systems Operation

The correct use of the systems is described below:

1. The user/physician attaches the sensors to the user's skin in the appropriate body location to measure the blood oxygen saturation level;

2. The user/physician runs the mobile application with Bluetooth turned on;

3. The mobile application is connected to the wearable device;

4. The sensors, via the microcontroller board, send the processed data via BLE, so that the mobile application can display the results on the screen.

6.4.1 System Usage

As soon as the ESP32 is turned on, system settings (along with Bluetooth settings) are initialized.

When the BLE connection between the wearable device and the smartphone is established, the wearable device system initializes the sensors and start to the readings.

The data captured by the sensors in RAW data are processed and packed by the microcontroller before being sent to the mobile application.

The data collection process occurs due to the reflection that the LED lights cast on the skin, as the photodiode is able to capture any changes that might occur in the user's veins. The microcontroller then performs the calculations based on the heart rate and blood oxygen saturation level values.

The fact that the sensors have the same I2C address, and because it is not possible to modify it (as they comes preset from the company), another approach had to be sought out to collect the data from more than two sensors in parallel and in real time with the used microcontroller, because it has only two I2C ports.

Having the data processed by the microcontroller and sent via BLE to the smartphone, the mobile application receive the data and display it on the screen, so that the user could easily understand the measurements and variations from each measured location of the body, as can be seen in Fig.6.19.

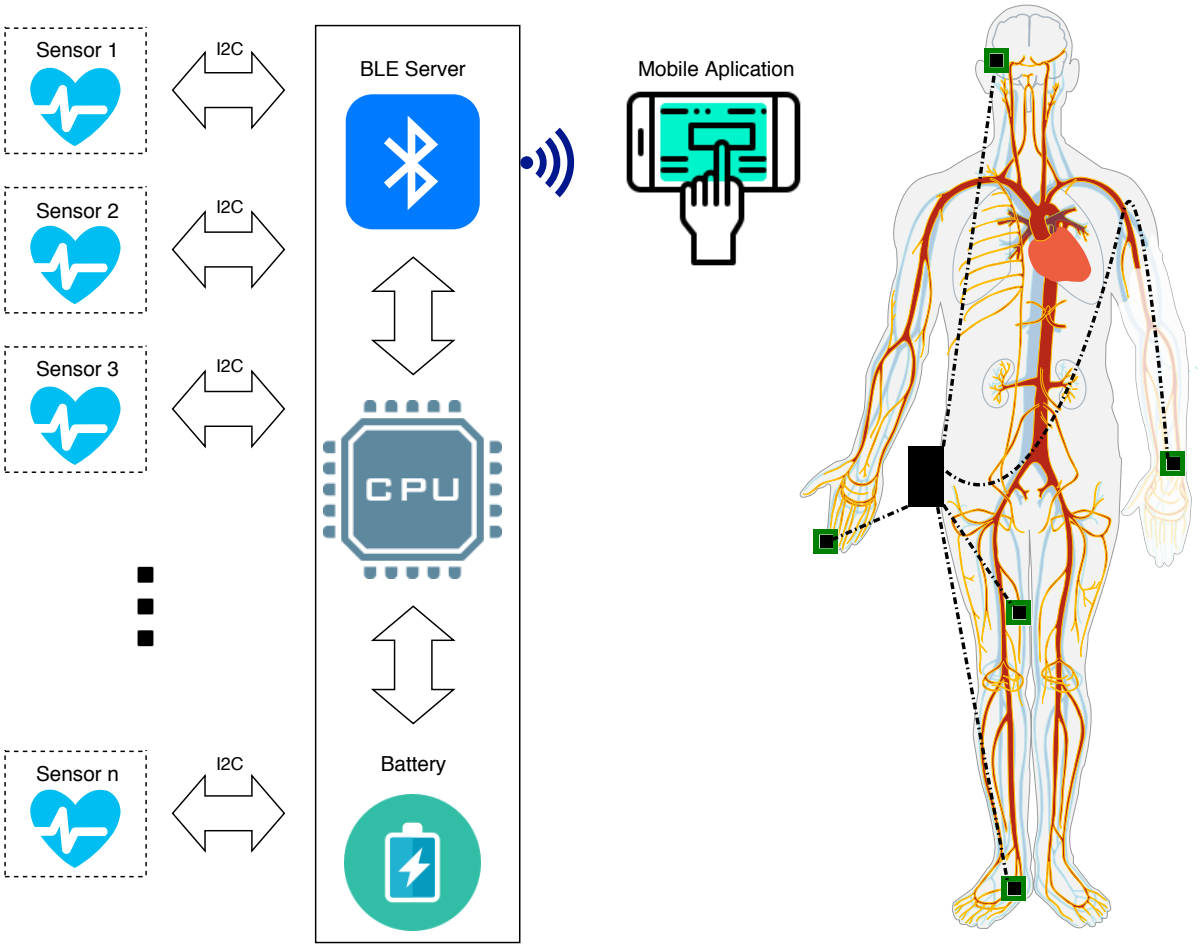


Figure 6.19: Framework Platform Systems Operation.

6.4.2 Measurement Site

During the study of the state of the art, after reviewing several researches works [14, 15, 52, 73], the most tested sites in the human body using PPG sensors were as follows:

- Finger (index fingers or thumbs);
- Earlobe;
- Toe (big toe);
- Chest;
- Forehead;
- Wrist worn;
- Cheek;

- Hand (palm / dorsal);
- Soles;

The place chosen to install the PPG sensor is very important, due to the fact that not all sites have good perfusion values to obtain data through these type of sensors, as they detect the amount of blood vessel variation using the reflection of LED lights.

Preferentially, the procedure must also occur on points where a Velcro tape can be attached, as this is used to guarantee the appropriate pressure and that there is no light interference. However, it may be attached with different manners.

As the goal of the project is to find out if different locations show a difference in terms of blood oxygen saturation levels (like for people with circulation problems, diabetes and heart-related diseases may have a lower SPO2 level in locations that are further away from the heart, such as the feet), one PPG sensor will be placed in the lower parts of the human body and another in the upper part, so that the results can be analyzed and compared.

Chapter 7

Experimental Results

As previously mentioned, this dissertation involved the development of hardware and software systems to achieve the proposed goals, i.e., monitoring the HR and SPO2 at two zones of the human body using PPG sensors in order to obtain results to compare and ascertain the possibility of anticipating certain diseases, such as diabetes and chronic obstructive pulmonary disease. Throughout these developments, several tests were carried out to ensure the systems were working as expected and to detect any related issues, in order to find out how to fix them and implement the respective solutions.

This chapter describes the experimental tests performed on patients at *Santa Casa de Misericórdia de Barretos, Brasil*, and although the main priority of this chapter is centered on the experimental tests, other tests carried out during the development stage will also be briefly discussed.

7.1 System setup

During the project development process, some tests were carried out to check both the functionalities developed - for the hardware system, namely the reading of vital data, and for the mobile application, the display of collected data.

Regarding the problems detected through these tests, most were related to the hardware used in the first prototypes, namely issues related to lack of memory of the microcontroller board and issues related to the simultaneously reading of two PPG sensors.

These problems occurred specifically when the prototypes were updated - the first time we tried to monitor two sensors, and the system failed due to lack of memory of the microcontroller. After the prototype update, with the new microcontroller, two different boards were added: a multiplexer board - to make it possible to read two or more sensors (up to eight) - and a Bluetooth Low Energy board - to perform the transfer of data to

the mobile application.

When updating the code for these new prototypes, another problem was found, concerning the method of acquiring vital data simultaneously from two sensors. As the multiplexer was being used, it was realized that the code developed for the system was first reading the data through a communication port with sensor 1 and then did the reading data through a communication port with sensor 2. Thus, the main functionality - simultaneous reading of vital data with PPG sensors in real-time - was not successfully achieved.

In order to fix the reported issues regarding the simultaneous reading of the sensors, the team decided to search for a new and more complete microcontroller board, with two communications ports for SCL and SDA, so that two sensors could be attached and the sensors could be read simultaneously. This decision also eliminated the issues regarding the number of boards and the size of the solution presented, since in the second prototype used five boards, namely a microcontroller board, a BLE board, a multiplexer and the two PPG sensors.

Due to the issues detected from these tests, the prototype was modified twice during the development process, which led to some code changes, including to the programming language used in the last prototype, as the used hardware has a native software development framework called the Espressif IoT Development Framework (ESP-IDF) that allows the system to be developed in a more performative way.

Regarding the mobile application, as the author was more familiar with the used programming environment, the Xcode framework, namely XCtest (see Fig. 7.4), was used to write unit tests during the development process, so there were no structural problems.

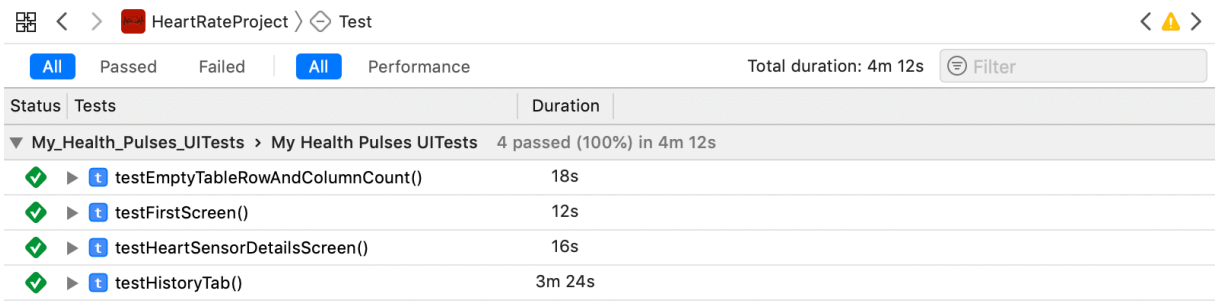


Figure 7.1: Xcode XCTest - Unit testing.

Only a few momentary difficulties occurred due to the specificity of the project, such as the Bluetooth communication between the two systems. This happened because the data sent via BLE was using the same Bluetooth characteristic for both sensors, and only

the Bluetooth profile was different, which made it difficult to read separately, because the programming language documentation did not have any tips on how to actually read them.

Another aspect that can be mentioned is that the mobile application is a simple application, i.e., as the Bluetooth connection is made between the devices, it only displays the data, so there were no significant issues during the development of the app.

With both systems properly tested and showing the expected results, the experimental tests were ready to run.

7.2 Method

To perform the experimental tests, the author asked *Santa Casa de Misericórdia de Barretos, Brasil* to perform oximetry tests on patients together with healthcare providers.

The author then remained in a room (screening room), accompanied by the hospital's healthcare providers, and after they had carried out the necessary examinations and questionnaires, the author presented the research to the subject (patient) and reported that the study was being conducted on a voluntary basis.

After questioning the subject about whether they would want to participate, a consent form was given to the patient to inform them about the terms and conditions, allowing them to agree to participate in the study. After the patient's statement, the author then placed the sensors on the subject to begin measuring vital signs.

The patient, who was already at rest, remained this way throughout the monitoring process. The subject was sitting comfortably so that the sensor placed on the finger and the sensor placed on the toe were properly secured to the patient's body.

After taking the measurements, the consent form was given to the subject so that they could keep a copy for themselves, in order to clarify any doubts and to have a reference document on hand.

The author spent two days at the hospital in the morning and afternoon periods. During these periods, seventeen tests were carried out with different populations, with ages ranging from 16 to 69 years old. The room where the tests were performed was well lit and well ventilated. Throughout the research process, the healthcare providers who assisted with their specific technical knowledge during data collection provided follow-up information.

7.2.1 Testing setup

In order to guarantee both quality and reliability, tests were conducted by a healthcare providers, accompanied by the author of this dissertation. During the test, the healthcare provider checked the results and performed common tests using equipment that was already available in the market to compare with the results presented by the system. It is important to note that the author was always present to safeguard that the system was working properly and that it did not stop reading for technical reasons.

The environment where the tests were performed was a room at a hospital, where medical instruments were available to measure the patient's heart rate and the pulse oximetry data, in order to compare with the results obtained by the proposed system.

The PPG sensors used in the study, as mentioned earlier, are those from Maxim MAXREFDES117, which can currently be found on Samsung cellphones. These sensors were placed inside a 3D-printed black box, as we can see in Fig. 7.2, specifically made for this project. This protection aims to avoid any noise caused by brightness during the collection of the patient's vital data, since it was clear from studies and tests carried in the state of the art that brightness can create noise and may change the results.

(a) (b)

Figure 7.2: Setup: (a) 3D-printed black box front; (b) 3D-printed black box back.

7.2.2 Patients characteristics

The tests conducted at *Santa Casa de Misericórdia de Barretos* were performed with seventeen participants, namely ten women and seven men, with the minimum age being sixteen and the maximum age being sixty-nine years old. The subjects age range can be observed in table 7.1

Table 7.1: AGE RANGE OF THE SUBJECTS.

	Age Range				
	16 - 25	26 - 35	36 - 45	46 - 55	66 - 75
Women	6	2	0	0	2
Men	2	3	1	1	0

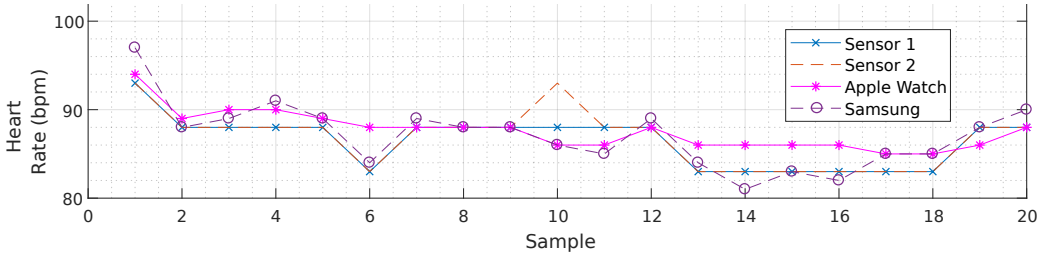
During the experimental tests, no personal data from the subjects was recorded by the application; the data was collected anonymously by the author and was not associated with the user's identity.

It was explained to the subject that the test was voluntary and that they could withdraw at any time. In addition to the explanation given by the author, the subject signed and kept a copy of a consent form so that they were aware of all the research, the explanation of the study, the procedure in question, the voluntary nature of the procedure, the confidentiality of the research, any risks and benefits, follow-up with healthcare providers and availability of the author.

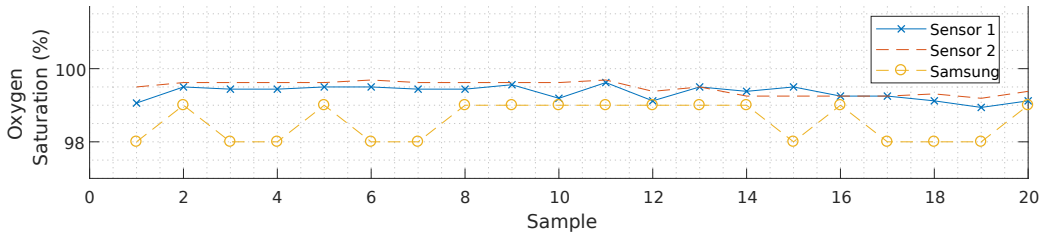
7.3 Comparison of the proposed system with other pulse oximetry readers

In order to evaluate the results presented by the developed framework, comparative tests with commercial devices were performed, namely with Samsung Galaxy 7 (SG7) and an Apple Watch (AW).

The results showed that the solution developed for this dissertation presented very similar results to those obtained by the mentioned devices, as can be observed in the figure Fig. 7.3.



(a)



(b)

Figure 7.3: Comparison of HR (a) and SPO2 (b) between framework sensors and commercial devices.

Because these early tests were performed to ascertain the reliability of the system and to ensure that the accuracy of the data collected (obtained results) were similar to the sensor

results of the Samsung Galaxy 7 and Apple Watch devices, the tests were performed on the same site of the human body, so our framework sensors were placed in one hand while the commercial sensors were placed in the opposite hand.

Analysis of the results obtained by combining all sensors revealed similar results. These first tests, besides validating the prototype, brought confidence that the developed framework could be tested under real conditions, in a hospital, with people seeking treatment and healthcare providers following the tests.

The realization of tests performed at the hospital, in a real scenario, occurred so that at least one of the framework sensors could be compared with the sensor used by the hospital itself in its daily consultations, namely, the system used by the hospital, is the Pulse Oximeter DX 2515 from Dixtal.

Figure 7.4: DX2515 Pulse Oximeter used at Santa Casa de Misericórdia de Barretos.

With the patient resting, this device was placed on the subject, just before our sensors was attached to the same participant's finger, while our second sensors was attached to the patient's toe from the same side of their body. This set-up allowed to have a more fair comparison between the sensors readings.

This comparison of sensor results leads us to the Root Mean Square Error (RMSE) values obtained, for a better understanding of the values, we present the results of all participants, separated the values of participants from the control group, and results of patients with diabetes. Thus it is possible no only to verify that there is a difference between values obtained in the lower part of the human body, but we can attest to our system, since the RMSE of patients in the control group are similar to the values obtained

by a system used in a hospital, as can be observed in 7.2.

Table 7.2: Measurement Error results

	HR	SPO2
$RMSE_{s2}^{s1}$	-	3.42 ($\sigma = 2.9382$)
$RMSE_{sh}^{s1}$	1.5904 ($\sigma = 1.3639$)	1.3808 ($\sigma = 1.3863$)
$RMSE_{sh}^{s1}cg$	-	1.1552 ($\sigma = 1.013$)
$RMSE_{sh}^{s2}$	1.5904 ($\sigma = 1.3639$)	4.0217 ($\sigma = 3.8137$)
$RMSE_{sh}^{s2}cg$	-	1.3934 ($\sigma = 1.3540$)

Where S1 is the finger sensor; S2 the toe sensor; SH the hospital's sensor and CG is Control group.

Although the study was conducted with a small sample of people with diseases that may prove the real effectiveness of the system, the study presented an added value by having results equivalent to those obtained by a system already approved for use in hospitals. Not only that, but analyzing the results, we can verify that in control group patients, who did not show symptoms of related diseases mentioned in the study, the results were equivalent, while in patients with diseases related to the present study, there was a great variation when blood oxygen levels were compared between the upper and lower limbs of the human body. This result was the expected results for this experimental tests, since the lower limbs have a greater distance from the heart and may have more obstructions in their blood vascular system, as damaged blood vessels.

During the experimental tests performed at *Santa Casa de Misericórdia de Barretos*, two subjects presented diabetes, and the tests performed with these participants showed a large difference between the blood oxygen levels between the two measured limbs.

As expected an analysis with the results of the tested sensors revealed similar values of results when the analysis was performed with people in the control group, whereas because of the large difference between the results obtained among diabetics, the values when calculated RMSE slightly differed with upper limb values compared to lower limb results (see Fig. 7.5).

Thus, because the value obtained from diabetic patients, who presented the largest variation, was not considered an error, percentage values were also calculated in relation to the difference, so that the dimension of the variation between limbs could be analyzed.

Calculating only the results of the values collected from the diabetic group, we also calculated percentage change (PC), percentage difference (PD) and percentage decrease (PDe) in relation to the difference between limb values, as can be observed in Table 7.3.

This analysis with diabetic subjects leads us to continue testing with this group, in order to eliminate all doubts regarding the achievements this system can bring.

Once proven that this subject group presents results with relevant differences in blood

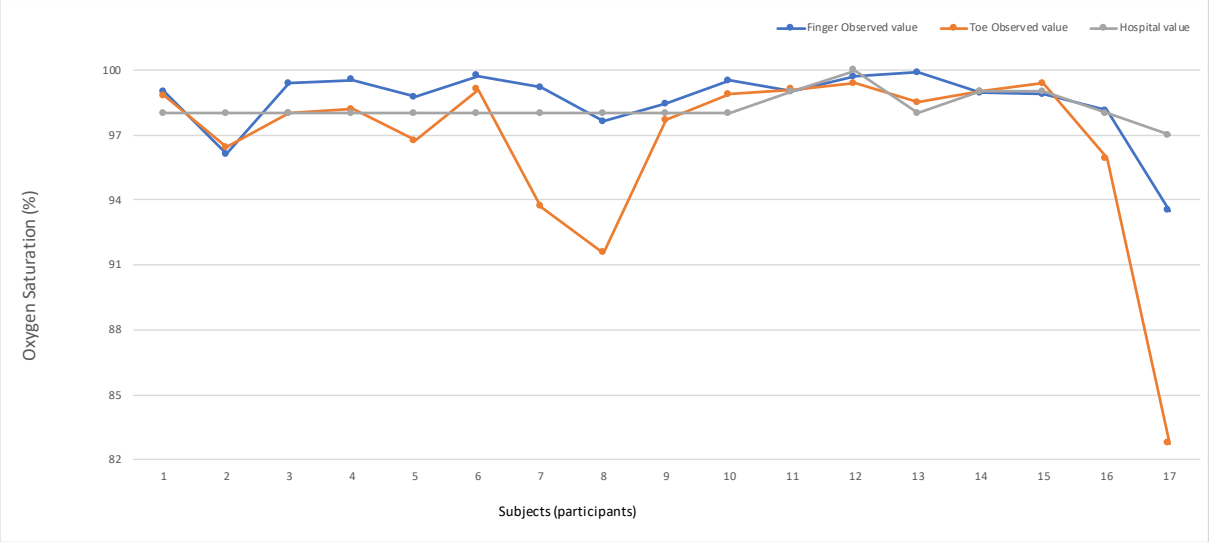


Figure 7.5: Comparison between oxygen saturation levels from all participants.

Table 7.3: PERCENTAGE OF DIFFERENT SPO2 RESULTS FROM DIABETIC POPULATION

	Subject 1	Subject 2
PC_{s2}^{s1}	-11.5 %	-6.21 %
PD_{s2}^{s1}	12.1985 %	6.406 %
$PDeC_{s2}^{s1}cg$	11.4973 % decrease	6.2077 % decrease
PC_{s2}^{sh}	-14.7 %	-6.57 %
PD_{s2}^{sh}	15.8553 %	6.7946 %
$PDeC_{s2}^{sh}cg$	14.6907 % decrease	6.5714 % decrease

oxygen levels, a system like this may anticipate possible illnesses.

One of the reasons why it was impossible to use a larger sample of subjects is related to the lack of authorization by Health Ethics Committee (CES), which has not yet been obtained although it has already been requested. Because of that it was only possible to conduct tests with a small number of subjects, since without CES approval, it is not possible to perform more extensive tests. Due to this factor, it was not possible to fully prove the effectiveness of the project as it was not possible to obtain a large volume of test data.

However, it was possible to assess the functionalities developed and the requirements implemented, so it can be said that the project fulfilled the main objectives proposed in the technological context to which this report belongs. It is therefore hoped that further testing may be performed in the future after obtaining the requested approval, which will help to prove the usefulness of the project in the clinical context.

Due to the fact that the tests are non-invasive and the PPG technology used by the project's framework to perform the tests were similar to the pulse oximeter used by the hospital itself to perform the tests in patients, the tests were authorized by medical staff

of *Santa Casa de Misericórdia de Barretos*.

7.4 Analysis of issues in relation to the tests performed

During the tests performed the system presented some issues that need to be solved to ensure a better operation and results.

In some cases, when the sensors are placed on the person at different times, with the system already started, the system may have different values in relation to the heartbeat, since the data is read at a different time (even if for seconds), since the number of samples collected may vary (i.e. sensor one with seventeen samples and sensor two with sixteen samples), which would differ by one peak from the heart rate calculation.

Another noticeable issue with the system is the graphics, since in order not to waste so much hardware battery, it was agreed that groups of raw data values would be sent. And because the data is sent every four seconds, and the data has not been processed, the system does not display a graph as constant as the heartbeat.

Chapter 8

Discussion and Future Work

The need of a system to measure vital signs as well as the increasing number of people with cardiovascular, COPD and diabetes diseases, have led/influenced to the creation of the system proposed in this work.

This system is able to measure real-time vital signs from users as well as present the results on mobile devices through BLE communication. Apart from that, those vital signs are measured, simultaneously, from multiple sites of the human body.

In the following section, a discussion of the main steps during this work as well as future work is present.

8.1 Conclusions

As previously mentioned, this work presents a system capable of measuring oxygen saturation levels, simultaneously, in multiple sites of the human body.

For this purpose, a mobile application has been developed, available (in the Health category) on the Apple App Store [74]; the design of a BLE prototype device that allow two PPG sensors to be monitored while measuring the user's heart rate and blood oxygen saturation levels; and the writing of a scientific paper explaining the project in a more simplified manner.

One of the objectives proposed for this work was the development of two systems, a hardware system, used to monitor multiple (N) sites of the human body, in order to acquire and process signals of the heart (heart rate) and blood oxygen saturation levels. Apart from that, all this information is sent to a mobile device via wireless, using standards characteristics BLE and GATT protocols.

Besides receiving the data via BLE it also enables the user to view it (the data) in real-time or from previous records, from all the N sites of the human body. This data can

be viewed in graphs or as pure values. During the implementation of this application, the User Experience (UX) have been an important concept in mind, which, for that reason, we decided to ask some users about the interface as well as follow **iOS!** (**iOS!**) best practices to develop the app, in order to have an easy and friendly user interface. The application developed also allows the sharing of results in a spreadsheet form, so that the user can send their vital signs to the physician, who can then later assess them.

Thus, the application developed within the work is novel and has innovated by displaying the results from multiple sensors in real-time. Although there are several applications aimed at monitoring patients in real-time, normally they usually use a single monitoring sensor. The performance and accuracy of the developed systems was quite impressive compared to systems used by commercially available devices and a system already approved for use at hospitals like the ones (i.e. Apple Watch, Samsung Galaxy 7, Dixtal Dx 2515) we have tested and compared results.

Despite the issues presented by the system in relation to heart rate and graphic data, only the identical data were observed during the tests.

Regarding the results obtained, in comparison to similar applications and platforms, it should be noted that the work done and described in this work fulfilled its goals, by receiving data from multiple sensors, in real-time, and displaying the vital signs information to the user.

The both systems generated as a result of this work, satisfactorily respond to the self-imposed objectives as their principle, as already shown in the results chapter and comparisons with other systems. Therefore, having obtained a functional prototype product already tested at the hospital, the project is considered successful.

Not to mention the fact that the results presented during the experimental tests, if they remain similar to those obtained after the system is tested in exhaustion, the system can be a useful part in everyday life since it will be possible to verify a difference in blood oxygen saturation levels, in the upper and lower body in diabetic patients.

To conclude, based on the literature review and the results obtained, it is evident the positive results that the project may have to evolve so that the prototype could be transformed into a product that aims not only to reduce the need to visit healthcare centers, as it would also allow their own health monitoring.

The source codes for both the firmware and the mobile application are public and can be found on GitHub [75].

8.2 Future work

For future work we would like to propose a larger study with a higher number of real users, in hospitals or other facilities that deal with the relevant types of diseases, such as diabetes, COPD and heart disease. This aspect is of utmost importance, as it will allow us to effectively assess the effectiveness of the project in the clinical context.

Also, another improvement needed is in relation to heart rate calculation and provide a way in system so that measurements can only start when the two sensors are in contact with the human body, so that no different heart rate values are displayed.

Likewise, graphics need a improvement so some filters (i.e. low / high pass filter) need to be applied so that the raw data will be better presented in the graph while it is displayed in the mobile application.

Planning ahead, we would do the improvement of the wireless communication between devices via BLE, by pairing the devices to ensure greater security and an immediate connection when the two devices are close to each other (while the BLE is on).

Also, another improvement to be made is the development of an Android app, as well as a backend so that patient data could be shown to a physician in real-time in order to perform remote consultations.

To conclude, a major improvement to the project is the addition of machine learning / artificial intelligence to identify patients in need of medical care according to their measurements.

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Appendices

Appendix A

Published paper

This appendix presents the published paper, resulted from the research work done during this dissertation.

- Marcio F. Calil, Ihor Koval, Luis Marcelino, Luis C. Bento and Sergio M. M. Faria, "Wireless Smartphone-based Monitoring of Multiple Pulse-Oximetry Sensors" 2019 11th Conference on Telecommunications (Conftele 2019), Lisbon, Portugal, 2019, pp. 39 .

Wireless Smartphone-based Monitoring of Multiple Pulse-Oximetry Sensors

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***Abstract*—Cardiovascular diseases are the cause of death of millions of people every year. With the increase availability of robust and low-cost diagnostic devices, many of these deaths could be avoided. Integrated sensor technology, particularly pulse oximetry, offers a unique, non-invasive and specific test for assessing the severity of such diseases. It provides a non-invasive measurement of photoplethysmograms, which allows the extraction of heart rate and oxygen saturation. Some diseases diagnosis requires simultaneous monitoring of pulse oximetry values in various body locations. This paper presents a system platform based on multiple PO sensors, connected to a mobile application via Bluetooth interface, developed to provide an easy experience of reading health data that can be analyzed to diagnose symptoms of cardiovascular diseases helping in early diagnosis. Implementation aspects related to the proposed architecture, taking into consideration power consumption, connectivity and App software are discussed in this paper.**

***Index Terms*—Wearable Sensors, m-Health, Pulse oximetry**

I. Introduction

In the top 10 leading causes of death in the world, provided by the World Health Organization [1], the ones causing more deaths are related to cardiovascular and infectious diseases. In Portugal, every year almost 35 thousand people die as a consequence of cardiovascular diseases (CVD) [3]. In many cases the symptoms related to CVD can be detected by pulse oximetry, which can be based on Photoplethysmography (PPG) sensors. The use of such sensors has increased, not only in medical devices, but also in consumer electronics as health wearable devices [2]. These figures show the relevance of developing new solutions based on PPG sensors to diagnose CVD, namely solutions including multiple PPG sensors, *i.e.* multi-site photoplethysmography (MPPG).

A Pulse Oximeter (PO) based on PPG sensors allows the extraction of heart rate (HR) and oxygen saturation (SpO_2) [4]. It works by shining light from two Light Emitting Diodes (LEDs) at different wavelengths, typically 660 nm (visible red) and 910 nm (near infrared), through the arterial blood of vessel and detecting the reflected light with a photodiode. Hemoglobin molecules with and without oxygen attached have different optical absorption characteristics at these wavelengths, and the oxygen saturation (SpO_2) can be obtained from the ratio of the transmitted light at the two wavelengths. The SpO_2 level measures the percentage of hemoglobin molecules that have oxygen attached, compared to those that are not bound to oxygen. A healthy individual has an oxygen saturation level above 95%.

Prior research using this type of sensors have presented different solutions for health remote monitoring. Gil et al. [5] proposed a synchronized platform that uses four-kinds of sensors, as electroencephalography, electrocardiography, respiration and PPG, to acquire vital signs in real-time to analyze the human body in multiple ways. A research [6] about pulse transit times using six PPG sensors was presented by Allen and Murray, showing how significant are the changes during the aging process. The work conducted by Erts [7] in patients diagnosed with arterial stenosis in one leg have analyzed four distinct sites with sensors placed in opposite directions. By comparing the PPG signals, it is possible to identify differences in measurements with arterial stenosis. Mikko et al. [8] presented a study on atherosclerotic diagnosis, using a synchronized platform of PPG probes attached to the index finger and to the second toe. Data collected is then post-processed in a personal computer, so real-time results cannot be generated. These research shows the importance of using multiple PPG sensors for several diseases.

In this paper, a MPPG based on a Wireless Body Sensor Network (WBSN) and its human-machine interface (HMI) is presented, this system is henceforth referred as User-Friendly Cardiovascular Data Analysis - Wireless Multi site Embedded PPG (UFDA-WMEPPG). The proposed solution is capable of acquiring vital signals using various PPG sensors to measure the oxygen saturation in various locations of the human body simultaneously in real-time, and wirelessly relay this data to a user-friendly data processing and managing module. This solution can be used daily by people with cardiovascular diseases, to help monitoring the disease evolution, *e.g.* blood circulation problems.

The remainder of the paper is organized as follows: in Chapter II, the pulse oximetry platform is described; Chapter III presents the experimental results; and, finally, in Chapter IV, final remarks are drawn.

II. Pulse Oximetry Platform

The UFDA-WMEPPG experimental setup architecture is comprised of two modules: the User-Friendly Cardiovascular

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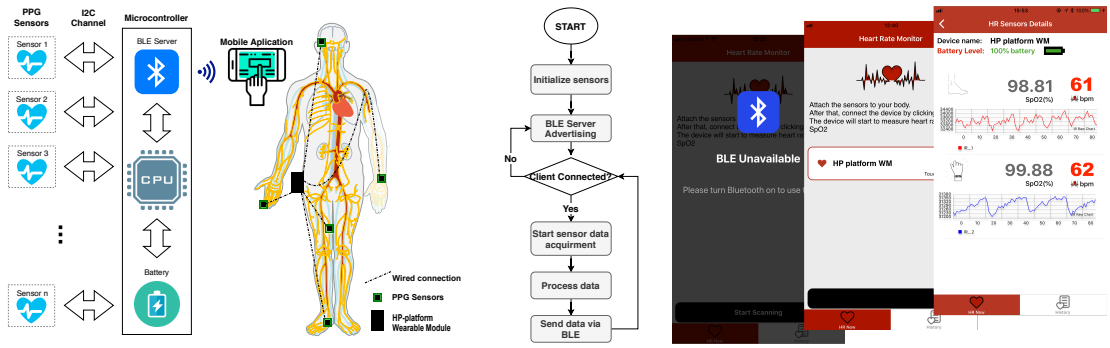

(a) (b) (c)

Fig. 1. Setup: (a) Hardware architecture; (b) Software fluxogram; (c) iOS App screens: BLE Unavailable Popup, HR Service Filtered and Monitoring data.

Data Analysis (UFDA) and the Wireless Multi-site Embedded PPG (WMEPPG). The WMEPPG module consists of a wearable device system for collection and pre-processing of vital signs data from multiple PO sensors. As shown in Fig.1 (a), the WMEPPG acquire the HR and SpO_2 data from various locations of the human body. The UFDA module consists of a mobile application (App) used to display and store the measured PPG data (see Fig.1 (c)). The App, developed in *Swift* language, runs in *iOS* smartphones, it allows connections via Bluetooth Low Energy (BLE) [12] with the WMEPPG. The App receives data from the various sensors and displays the information on the screen.

A. Wireless Multi site Embedded PPG (WMEPPG)

The WMEPPG system is composed by a microcontroller, a PPG sensor and a power management system (Fig.1(a)). The microcontroller is used to process and transmit data acquired by the sensors via BLE. The PPG sensor measures LED lights signals reflections to detect changes in the volume of blood flow in the arteries [10]. The power management allows the solution to be mobile and the level of autonomy to be long, *i.e.* in use for at least 48 hours without charging.

1) Processing Module: The processing unit was selected taking into account the following characteristics: BLE integration, low power consumption, high processing power, two or more I2C ports, affordable price and small package size. Based on these requirements, the ESP32 microcontroller was chosen [11], namely ESP32 Thing board, which allows to interface with additional components. Additionally, it includes FTDI converter for easier programming and features a LiPo charger, which is adequate for mobile applications (Fig.1(a)). The firmware was developed using Espressif IoT Development Framework (esp-idf) [11] and FreeRTOS kernel, which allows easy task scheduling between 2 independent cores (APP and PRO cores). The BLE Server was created following the BLE standard and GATT Services specifications [12], and runs in the APP core, while other processing tasks are managed by the scheduler, running mostly on the PRO core (160MHz clock).

2) Heart Rate and SpO_2 Sensor: The heart rate and the percentage of oxygen saturation are obtained from the Maxim Integrated MAX30102 sensor [9]. It is a complete low-power optical heart-rate module with integrated red and infrared LEDs. The sensor uses the Photoplethysmography method to measure optical heart rate and oxygen saturation of an individual [13]. The typical consumption is less than 5mW, while in use, and a few µW while in sleep mode. It uses I2C protocol communication (unique ID=0x77) to transmit data, and registers can be configured to define the data sampling rate. In this application, the sampling rate was defined to 100 samples/sec, averaging each 4 data samples, resulting in 25 samples/sec, each of them represented by 16 bits (ADC resolution). The internal FIFO length is 32 samples, and it was configured to generate an interruption when the FIFO has 30 samples. Sensors must be placed in the predefined location of the human body, where arteries are close to the skin, in order to correctly read the vital signs.

3) Data Acquisition: Initially, the microcontroller configures PPG sensors and set them to sleep mode. Then, creates the BLE server, which runs in the first core (APP core), then activate the MODEM-sleep mode, in order to save power while maintaining the advertisement/communications. When a connection is established and the notify is enabled, the sensors are set ON and the PPG sensors data starts being acquired. On interrupt, the sensor's FIFO is cleared and the data is buffered onto the microcontrollers' memory (Fig.1(b)). After packing the data four times (equivalent to 2.4 seconds), data is processed in the second core (PRO core). The processing algorithm uses peak detection, autocorrelation and Pearson correlation algorithms to calculate the HR [14]. Using equations 1 and 2, the SpO_2 is computed [15]. After determining both HR and SpO_2, their values are sent to the client (UFDA) *via* the BLE communication.

$$\%SpO_2 = 110 - 25 \times R \tag{1}$$

$$R = \frac{AC_{rmsRED} \ / \ DC_{RED}}{AC_{rmsIR} \ / \ DC_{IR}} \tag{2}$$

The R value is the normalized ratio of the red to infrared transmitted light intensity. The DC component is the averaged signal intensity and the AC is the varying signal component.

A known issue for autonomy (battery life) in embedded mobile devices is its power consumption, therefore an energy aware programming policy was followed, *e.g.* each device was set to sleep mode whenever it was possible. A battery

TABLE I
GATT HEART RATE SERVICE: AN EXAMPLE OF A GATT PROTOCOL WITH DEFAULT SERVICE/CHARACTERISTIC.

Characteristics Name	Attribute Value	Mode	Results/Description
Profile 1 and 3 – Heart Rate Service (0x180D)			
Heart Rate Measurement	0x2A37	Notify	Exposes heart rate and other data from a Heart Rate Sensor intended for mobile applications
Body Sensor Location	0x2A38	Read	
Profile 2 and 4 - Pulse Oximeter Service (0x1822)			
PLX Continuous Measurement	0x2A5F	Notify	Exposes processed pulse oximeter data, SPO2 value in percentage
Profile 5 - "RAW" Service (0x18FF)			
RAW Characteristic	0x2AFF	Notify	Contains raw data acquired directly from the sensor, used for graph design
Profile 6 - Battery Service (0x180F)			
Battery Level	0x2A19	Notify	Able to notify battery percentage and power state, charging/not charging
Battery Power State	0x2A1A	Notify	

monitoring system was also developed to monitor the battery level and, in the case of a low level, to notify the UFDA, alerting the user to recharge the battery. The whole hardware system consumption is less than 111mW in active mode, 150mW when connected via BLE, showing 1.1W spikes when data is transmitted wirelessly and less than 18.5mW while in sleep mode. For instance, using a LiPO battery rated for 2000mAh the system will operate for at least 48 hours.

4) Communication Architecture: The WMEPPG relies in two communication types for its operation: wired, which includes the data communication and power between the PPG sensors and the "Processing Module"; and wireless, which supports the data transfer between the WMEPPG and the UFDA modules. Although a wired connection between sensors and the "Processing Module" is less flexible and cumbersome to use, it was the adopted solution to avoid the use of batteries and communication modules in the sensor modules, thus keeping the sensor module small and light for the user. This approach allows the use of a single battery with higher capacity in the "Processing Module" and, consequently, to operate the equipment for a longer period without interruptions. In order to keep the system with a low power consumption, the microcontroller data acquisition is triggered by an interrupt signal sent by the sensor, when it starts sampling data. The communication between the WMEPPG and the UFDA mobile device is performed through a wireless protocol, specifically the BLE. In order to transfer data via BLE, it was adopted the ATT (Attribute Protocol) and GATT (Generic Attribute Profile), with 16-bit IDs for each entry, used to store Services, Characteristics and related data (Tab.I). It must be noted that using GATT the connections performed between two devices are exclusive, therefore a slave/peripheral device can only be connected to one master/central device at the same time.

B. User-Friendly Cardiovascular Data Analysis (UFDA)

The developed UFDA iOS Mobile App (available on App Store under the name "My Health Pulses") has the following main functionality requirements:

- Being able to perform data acquisition from two or more PPG sensors, simultaneously;

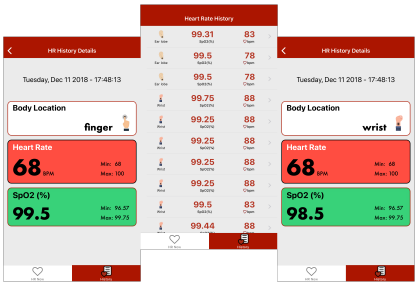

Fig. 2. App screens for monitoring sensors and history display.

- Be compliant with BLE services and characteristic standards, *i.e* Generic Attributes (GATT);
- Display the received data in real-time;
- Store the received data for historical analysis;

For easy user interaction, and to meet the previously presented requirements, the app structure is simple and the device supports BLE services. The first app screen shows a table with the available devices to connect. As soon as the app is started, a BLE validation is performed to check the availability status. Following the BLE initialization, a filter only allows devices with BLE HR Service to be presented (Fig.1(c)). A screen presenting the acquired infrared values, determined in the processing step, allows a visual evaluation of the time delay between measured peaks used in the estimation of both HR and SpO_2 values. Additionally, for better analytic assessment of the acquired data, the UFDA App includes a historical "database" and several screens presenting the table with the data readings from PPG sensors, the body sensor location, the heart rate and pulse oximeter measurements Fig.1(c)-2). The framework used to create a historical "database" - Core Data [16] enables the data to be saved and later used to track, modify and filter measurements. Each measurement value stored in the "database", can be later visualized, by choosing the "History" tab (Fig.2).

Although the UFDA App was developed mainly focused for use with the WMEPPG, it is also compatible with commercial heart rate monitors. If the connected device has a unique heart rate characteristic, the table will show only a single sensor.

III. EXPERIMENTAL RESULTS

Tests were carried out with the developed UFDA-WMEPPG prototype, including two pulse oximetry sensors. As stated in the literature, and confirmed during the tests, the sensors should not be subject to strong movements during the measurement phase or installed in body parts where the tissue does not allow the sensor to capture the reflection of the blood vessels, as it may result in wrong measurements. In order to properly install the sensors in the body, a plastic capsule was designed and 3D printed, in order to be attached to the body location by an elastic strap (see Fig.3(a)).

To validate the accuracy of the developed system, some tests were also performed with commercial devices that measure the heart rate and oxygen saturation level using a smartphone, namely the Samsung Galaxy 7 (SG7), and an Apple Watch (AW) device. The results obtained from the developed solution

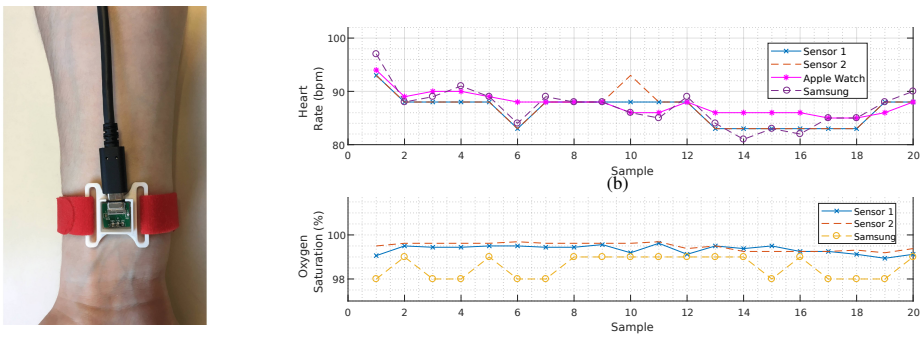

Fig. 3. Prototype and measurements: (a) Example of a PPG Sensor (wrist); (b) HR and (c) SpO_2 of Sensor 1 and 2 compared to other devices.

are very similar to those obtained from other equipment, as can be observed in Fig.3(a).

Sensors 1 and 2 of the UFDA-WMEPPG prototype were placed in 2 fingers of one hand and the AW and SG7 were sensoring two fingers of the opposite hand. An analysis of the data acquired for all 4 devices/sensors tested, revealed similar results (see Fig.3(b-c)), and therefore validated the prototype. The achieved results of the RMSE and respective standard deviation between sensors are presented in Table II:

TABLE II
MEASUREMENT ERROR RESULTS

	HR	SPO2
$RMSE^{s1}_{s2}$	1.1180 ($\sigma = 1.1180$)	0.2115 ($\sigma = 0.1658$)
$RMSE^{s1}_{sg7}$	1.7464 ($\sigma = 1.7006$)	0.9434 ($\sigma = 0.5060$)
$RMSE^{s1}_{aw}$	2.1448 ($\sigma = 1.8890$)	-

It can be observed that there is a small error between the values from different sensors, as it is desirable. However, signals were acquired at different body locations (with different skin sensitivity) and the SpO_2 values from SG7 are rounded to integer values. Also the algorithms to determine HR and SpO_2 for in each device may be different.

IV. FINAL REMARKS

This paper presents a heart rate and pulse oximetry monitoring system based on multiple PPG sensors, associated to an application developed for a mobile device. The design and development of this biomedical device and respective mobile application are detailed, namely its software and communication architectures. Its characteristics aim to provide an easy experience and to extend the battery life as long as possible, thus controlling the operation of the sensors and the processing module. All these features have been implemented by exploiting the sleep modes of the microprocessor and the sensor, as well as the interrupt signals available in the used components. Additionally, the dual-core microcontroller has been exploited to perform tasks in parallel. The Bluetooth communication protocol to connect the wearable device to a mobile device was implemented using GATT, to allow other commercially available devices display the measured data.

The App was designed to allow a simple visual interface, displaying the measured values in real-time and storing the data to subsequent analysis by the user or a health professional. The experimental tests showed that the device acquired and displayed the bio-signals similarly to other commercially available devices. The project was made available for the public on GitHub [17].

For future work, some study will be done to optimize the microcontroller firmware in terms of execution time and power consumption, as required for a mobile device. Another aspect to improve is the development of a database in the cloud, so the health professionals can monitor and analyze the data remotely sent by the patient. It is also important to perform tests to include in tests patients with diseases that require simultaneous measurements in different parts of the body, in order to validate the added value of the proposed system for health-based applications.

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Appendix B

Informed consent form for research

This appendix presents the Informed consent form for this research, a document that gives specific information about the study for the subject, a voluntary agreement to participate in research. The document presented below is part of a document of the Ethics Committee of the Polytechnic Institute of Leiria.

The document is in Portuguese because the experimental tests were performed in Brasil.

ANEXO II

CONSENTIMENTO INFORMADO, ESCLARECIDO E LIVRE PARA PARTICIPAÇÃO EM ESTUDOS DE INVESTIGAÇÃO NOS TERMOS DA NORMA N.º 015/2013 da Direção-Geral da Saúde (de acordo com a Declaração de Helsínquia e a Convenção de Oviedo)

Identificação do Investigador: Márcio Fernandes Calil

Título do estudo: Aquisição e interpretação de sinais de nível de oxigenação do sangue

Enquadramento: Instituto Politécnico de Leiria – Escola Superior de Tecnologia e Gestão

Investigador: Márcio Fernandes Calil

Professores Orientadores: Sérgio Manuel Maciel Faria, Luís Conde Bento, Luís Filipe Fernandes Silva Marcelino

Explicação do estudo: O trabalho tem por objetivo realizar um estudo cuja finalidade é entender que o facto de existir diferença de valores referentes ao nível de oxigenação do sangue em um mesmo corpo. O estudo visa ser realizado em três grupos diferentes, grupo controle, grupo de pessoas com a doença diabetes e grupo de pessoas com doenças pulmonares. A pesquisa se justifica por atualmente não existir um aparelho/dispositivo que monitore múltiplos pontos do corpo humano em tempo real, que poderá e deverá auxiliar os usuários/utilizadores a buscar o médico para realizar exames mais específicos a fim de averiguar possíveis doenças.

Procedimento(s): O(s) procedimento(s) de coleta de material, dados de batimento cardíaco e nível de oxigenação do sangue, serão realizados da seguinte forma: com os voluntários descansados, serão anexados sensores junto ao seu corpo, em diferentes partes do corpo, sendo que estes sensores são utilizados para medir o batimento cardíaco e o nível de oxigenação do sangue. O aparelho comunica-se via Bluetooth com a aplicação de smartphone, desenvolvida para este trabalho, previamente instalada no dispositivo móvel, sendo que neste caso o aplicativo será instalado apenas no dispositivo

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telefônico do autor do estudo ou do médico, que mostrará os resultados coletados de nível de oxigenação do sangue (em %) e batimento cardíaco atual, pelos sensores que foram colocados junto ao corpo do usuário/utilizador.

Para que possa ser realizado um estudo comparativo entre os níveis de quantidade oxigênio no sangue, deverá ter-se em conta a atual condição de saúde do voluntário, sendo que este pode pertencer ao grupo de controle (pessoas que não apresentam doenças relacionadas ao estudo) ou pertencer ao grupo de pessoas com doenças relacionadas ao estudo, podendo ser diabéticas e/ou com doenças pulmonares.

Os resultados coletados serão analisados de forma geral em comparação com os resultados obtidos do(s) outro(s) grupo(s) de estudo, a fim de analisar possíveis diferenças encontradas, sendo que em nenhum momento será divulgado o nome do voluntário.

Observações:

- A participação do voluntário deverá ocorrer uma única vez, já que os resultados não devem variar por já pertencerem ao grupo pré-definido.
- A duração do teste deve durar entre 1 a 3 minutos.

O local a ser realizado o teste deve ser um consultório médico, unidade de pronto atendimento (UPA) e/ou pronto socorro (PS) e todo o procedimento deve ter a presença física do investigador e possivelmente um profissional da saúde.

Desconfortos e riscos: Há a possibilidade de o participante apresentar: constrangimento, medo, vergonha e desconforto. Quebra de sigilo/quebra de anonimato.

Em relação ao constrangimento, medo, vergonha e desconforto, estes riscos podem ocorrer devido ao facto do teste a ser conduzido com os participantes necessitar ser realizado no membro inferior (pé) do participante. O que pode levar o participante a apresentar estes sintomas. O teste é feito com dois sensores de pulso oxímetro, sendo

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que um deles será colocado na mão do paciente (dedo) e o outro deve ser colocado na parte inferior do corpo humano, já que a pesquisa visa medir a diferença dos níveis de oxigenação do sangue em diferentes partes do corpo, com isto, não é possível mitigar o risco.

Em relação a quebra de sigilo/quebra de anonimato, os participantes da pesquisa não serão identificados na aplicação do questionário/testes, porém, deve-se considerar riscos mínimos com a quebra acidental do sigilo e/ou a possibilidade do desconforto. Os dados ficarão sob a guarda dos pesquisadores e serão utilizados exclusivamente para fins de divulgação nos meios académicos e científicos.

Benefícios: Esta pesquisa tem como objetivo trazer maior conhecimento sobre o tema abordado de forma a beneficiar toda a população, uma vez que existe a possibilidade do desenvolvimento de um dispositivo de baixo custo para medir o que é proposto, sem benefício direto para o participante.

Acompanhamento e assistência: O estudo pode/deve contar com a presença de um médico ou profissional de saúde que deverá explicar e esclarecer os detalhes do problema pesquisado e sanar quaisquer dúvidas apresentadas pelo voluntário. Uma vez que o sistema for validado pelo médico, poderão ser realizados testes sem a presença física do mesmo, com sua presença virtual em alguns casos, para que possam ser esclarecidos eventuais questionamentos.

Caso o participante apresente o problema que já é conhecido por si, o médico/profissional de saúde poderá explicar os exames e procedimentos que devem ser realizados. Mas caso o participante apresente o problema pesquisado, sendo que não saiba deste problema ou exames anteriores nunca tenham apresentado eventual alteração de resultado, o profissional da saúde explicará de forma clara o que se trata as alterações e quais procedimentos e exames específicos o participante deve realizar para averiguar possível doença encontrada.

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Caberá ao participante, procurar seu médico de família/confiança e solicitar os exames, ou em caso da presença física do médico, este poderá solicitar exames preventivos, a fim de descobrir o motivo da variação dos resultados.

Condições e financiamento: A participação no estudo não acarretará custos para o participante e não será disponível nenhuma compensação financeira adicional. No caso de o participante sofrer algum dano decorrente dessa pesquisa não existe qualquer compensação por danos ou seguro a ser acionado. Devido ao facto de o participante estar no centro clínico para receber atendimento médico, não há custo de deslocações para realizar o estudo, uma vez que os testes serão realizados no mesmo local.

Mencionar o caráter voluntário: A sua participação é voluntária e a recusa em participar não irá acarretar qualquer penalidade ou perda de benefícios. O participante deve ser esclarecido(a) sobre a pesquisa em qualquer aspecto que desejar. O participante é livre para recusar-se a participar do estudo, retirar seu consentimento ou interromper a participação a qualquer momento.

Em caso de denúncias ou reclamações sobre sua participação e sobre questões éticas do estudo, você poderá entrar em contato com a secretaria da Comissão de Ética em Pesquisa do Instituto Politécnico de Leiria, por e-mail: comissao.etica@ipleiria.pt, ou no endereço do Instituto Politécnico de Leiria, localizado no Campus 2 Morro do Lena 4163, Leiria, Portugal.

Confidencialidade e anonimato: O participante tem a garantia de que sua identidade será mantida em sigilo e nenhuma informação será dada a outras pessoas que não façam parte da equipe de pesquisadores/orientadores. Na divulgação dos resultados desse estudo ou em publicação resultante do mesmo, seu nome não será citado. Os dados/resultados coletados durante a pesquisa ficarão disponíveis somente até a defesa da tese de mestrado do investigador. Após a defesa da tese de mestrado, todas as informações colhidas durante os testes serão removidas.

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Disponibilidade: Em caso de dúvidas sobre a pesquisa, o participante poderá entrar em contato com o investigador/pesquisador Márcio Fernandes Calil, por telefone (11) 99898-6352 e/ou por e-mail 2162069@my.ipleiria.pt.

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Assinatura de quem pede consentimento: … … … … … … … … … ... … … … …... …

Consentimento do participante

Declaro ter lido e compreendido este documento, bem como as informações verbais que me foram fornecidas pela/s pessoa/s que acima assina/m. Foi-me garantida a possibilidade de, em qualquer altura, recusar participar no estudo "Aquisição e interpretação de sinais de nível de oxigenação do sangue" sem qualquer tipo de consequências. Desta forma, aceito participar neste estudo e permito a utilização dos dados, que de forma voluntária forneço, confiando em que apenas serão utilizados para fins científicos e publicações que delas decorram e nas garantias de confidencialidade e anonimato que me são dadas pelo/a investigador/a.

Nome: … … … … … … …

Assinatura: … … … … … … … …... … … … … ... … … … … … … … … … … …Data: …… /…… /………..

SE NÃO FOR O PRÓPRIO A ASSINAR POR IDADE OU INCAPACIDADE (se o menor tiver discernimento deve também assinar em cima, se consentir) NOME: … BI/CC N.º: .... DATA OU VALIDADE ….. /..… /…….. GRAU DE PARENTESCO OU TIPO DE REPRESENTAÇÃO: .... ASSINATURA … … … … … … … … … … … … … … … … … …

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