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System for Reducing the Risk of Mortality due to Ischemic Heart Disease among the Elderly **Project Period:** 1 February 2017 – 30 June 2017

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#### Abstract:

The world's population is currently experiencing a trend towards ageing. People now live longer than ever before and it is expected that by 2050 one out of every five people will be at least 60-years-old. Respectively, of all age groups senior citizens experience the highest mortality rates. Among the global leading causes of death, the foremost is Ischemic Heart Disease. The focus of the current Thesis is to develop a system – hereafter referred to as Vixi - that would aid in reducing the risk of death due to the aforementioned ailment. In order to do so, research is conducted into the nature of Ischemic Heart Disease, specifically the exact conditions that can lead to a fatal outcome, along with their pathology, as well as the technologies that can detect them. From the discovered diagnostic tools, the noninvasive ones are extracted so as to be applied within the service - these are preferred because the Vixi is intended for continuous daily monitoring.

The Vixi system is based on the utilization of the following two devices: the smartwatch and the wearable ECG. The data gathered via their various sensors serves as input for Vixi's main algorithm. The aforementioned algorithm is designed by the author; it can interpret sensor and user input in order to determine at any given moment whether its user is experiencing an ischemia-induced cardiac event that can lead to a fatal outcome. Additionally, within the current report a proposal for the accompanying system architecture is also provided.

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## **List of Abbreviations**

- ACS Acute Coronary Syndrome
- AMI Acute Myocardial Infarction
- ATL Arrhythmia Time Limit
- AV Atrioventricular
- **BDS** BeiDou Navigation Satellite System
- **BTS** Base Transceiver Station
- **CPR** Cardiopulmonary Resuscitation
- CVD Cardiovascular Disease
- ECG Electrocardiogram
- **EENA** European Emergency Number Association
- FDMA Frequency Division Multiple Access
- **GLONASS** Global Navigation Satellite System
- **GNSS** Global Navigation Satellite Systems
- GPS Global Positioning System
- HCL Higher Count Limit
- HHL Higher Heart Limit
- IHD Ischemic Heart Disease
- LCL Lower Count Limit
- LFT Lower Fall Threshold
- LHL Lower Heart Limit
- LOS Line-of-sight
- MI Myocardial Infarction
- MS Mobile Station
- NB Node B
- NLOS Non-line-of-sight
- NSTEMI Non-ST-segment elevation myocardial infarction

- **PEA** Pulseless Electrical Activity
- PPG Photoelectric Photoplethysmogram
- **RFID** Radio Frequency Identification
- **RHR** Resting Heart Rate
- **RSS** Received Signal Strength
- **RSSI** Received Signal Strength Indicator
- RTT Round Trip Time
- $\mathbf{SA}-\mathbf{Sinoatrial}$
- $\mathbf{SCD}$  Sudden Cardiac Death
- STEMI ST-segment elevation myocardial infarction
- TA Timing Advance
- TDMA Time Division Multiple Access
- **UFT** Upper Fall Threshold
- UML Unified Modeling Language
- UMTS Universal Mobile Telecommunications System
- UWB Ultra Wideband
- $\mathbf{VF}$  Ventricular Fibrillation
- VT Ventricular Tachycardia
- WCDMA Wideband Code Division Multiple Access

#### **1** INTRODUCTION

The current chapter is dedicated to providing an overall impression of the topic area of this Master Thesis, as well as to present the reasoning behind the specifics of the problem formulation that will be presented in the subsequent chapter.

#### 1.1 BACKGROUND

We are now in the midst of an ageing global society. The population ageing trend is due to two complementary phenomena: the first being a decline in fertility rates and the second – reduced mortality[1]. As of 2015, the number of people aged 60 and over was 901 million[2]. Additionally, it has been estimated that by the year 2030 that number will rise to the astounding 1.4 billion[2]. People now live longer and healthier than ever before; so much so, that the elderly population itself is also growing older: in 2015 there were 125 million people worldwide that were at least 80-years-old (what a United Nations report terms "oldestold")[2]. By 2050 that number is expected to rise more than three-fold and reach 434 million[2]. To put this in perspective, it is expected that by 2050 twenty percent of the global population will be at least 60-years-old.

As stated above, older people are becoming a significant part of the populace worldwide. This demographic trend shines a light on life as a senior citizen, which comes with its own challenges and difficulties. Perhaps the most severe consequence of the globally increasing life expectancy is that it also naturally leads to changes in the age-specific mortality rates. The average age at death has increased significantly over the last century, with demographic studies confirming this being carried out in a number of countries, such as Canada[3], France[3], Japan[3], the USA[3], Australia[4] and Finland[5]. Considering the results of these studies, it can be seen that in the past decade, in a number of developed countries with increased life expectancies, people that have died were mostly senior citizens – as the authors of a 2001 report put it: "Today, death…is largely reserved for the elderly"[6]. That is why the focus of the current Master Thesis will be on providing a system, which would be able to potentially prolong and improve the lives of elderly people by helping to avoid life-threatening events.

#### 1.2 MOTIVATION

Given the purpose of the current Thesis that has been stated above, what has to be addressed first is what ailments constitute the primary causes of death among senior citizens. According to the latest data from the World Health Organization, the leading top five causes of death globally, ranked from highest to lowest, are as follows: ischemic heart disease, stroke, lower respiratory infections, chronic obstructive pulmonary disease, as well as trachea, bronchus and lung cancers[7]. Of the aforementioned conditions, ischemic heart disease is the topmost leading cause of death[8]. As such it can be considered to be the primary concern for senior citizens and, therefore, it will also be the focus of the current Master Thesis.

If this matter were to be evaluated strictly based on the concept of risk, then attention should be turned to what exactly constitutes risk. Although the concept of "risk" can be somewhat fluid (ex. objective vs. perceived risk[9]), there is an overall agreement as to what constitutes risk. In more general terms, risk has been accepted to have two dimensions - probability and consequences. That is to say, the risk of a specific event/action/etc. is tied to the uncertainty of said event/action/etc. ever occurring, as well the severity of its consequences[10]. A certain event can have a very high probability of occurring but the severity of its consequences - very low and vice versa[10]. Given the context of the current Thesis, where the focus is on ischemic heart disease-related death, it can be acknowledged that the risks that are to be reduced have a very high severity of their consequences. The same cannot be said for the element of uncertainty – cardiovascular disease for the elderly can include a wide variety of conditions, each one carrying its own level of uncertainty for every individual person.

Having gone through the comprising elements of the concept of risk, it can be concluded that in order to reduce a given risk, it would be necessary to reduce, either the correlating probability, the severity of the accompanying consequences, or perhaps both. Specifically for this Thesis, reducing the uncertainty of the risk would be expressed in the act of prevention – individuals would be monitored in order to look out for any warning signs of a life-threatening event. The alternative possibility is to reduce the severity of the consequences, after such a critical event has taken place – in the given context that would entail ensuring that the senior citizen in question promptly receives the necessary help as soon as possible. This is a service function that could prove to be essential, since 40% of individuals, aged 60 and over, live on their own[1]. This means that if they are physically or mentally incapacitated, they might not be able to get the help that they need, in the expedient manner that is necessary. Throughout the length of the current Thesis the goal will be to mitigate, both the likelihood of a life-threatening event, as well as the harshness of its aftermath.

## 2 PROBLEM FORMULATION

The current chapter will be dedicated to the establishing of a clear and concise research question. Additionally, accompanying objectives will be provided, so as to guide the completion of this Master Thesis towards answering the abovementioned research question. The final section of the chapter is focused on formulating the delimitations that will be implemented in order to further narrow down the focus of the current Master Thesis.

#### 2.1 RESEARCH QUESTION

In this section the main research question, which would be answered by the conclusion of the Thesis, is to be presented. It is the following:

How can a system be designed so that it would reduce the risk of death for elderly individuals caused by ischemic heart disease?

Additionally, a number of sub-questions will be utilized in order to get a more detailed perspective into the main research question:

- 1. What conditions constitute ischemic heart disease? Which of them can lead to a fatal outcome?
- 2. What physiological or environmental parameters should be monitored in order to detect the onset of the established conditions?
- 3. What devices should be utilized in order to measure the aforementioned parameters?
- 4. How should the system respond when an established condition has been detected?
- 5. How can the proposed solution be made to suit the needs of the target population segment?

#### 2.2 OBJECTIVES

The subsequent section of this chapter is dedicated to formulating the objectives that have to be fulfilled along the course of the current Master Thesis and they are the following:

- 1. Find the top causes of death among the elderly, including their pathology and symptoms.
- 2. Get in contact with professionals in the field of medicine or medically-relevant areas so as to discuss and affirm the discoveries, regarding the physiological aspects of the system.
- 3. Conduct research into the existing relevant algorithms and technologies that are currently on the market.
- 4. Determine what devices would be necessary so as to fulfill the functionalities of the system.
- 5. Get in contact with potential representatives of the target customer segment so as to gain insight into their needs and interests regarding the service.
- 6. Produce a valid Requirements Specification.
- 7. Devise an algorithm for detecting critical ischemic heart disease-related conditions.
- 8. Provide a design of the necessary device applications.
- 9. Devise protocols for testing the designed system.

#### 2.3 DELIMITATIONS

The purpose of this section of the chapter is to establish the delimitations, necessary for the completion of the Thesis. Although the research question formulated at the beginning of the present chapter, is delimitation in itself, considering further delimitations can be useful towards the additional clarification of the direction that will be taken within this Master Thesis. The delimitations set here are as follows:

- 1. Due to the overwhelming task of accounting for local specifics worldwide, the service proposed in the current Thesis will be aimed at individuals from the Western world (in the sense of similar socioeconomic backgrounds) those that live within European continent, the United States of America and Canada.
- 2. Within the limits of this Master Thesis the smartphone operating system to be taken into consideration will be Android, given that it has the largest market share[11]. It ought to be noted that in some Western countries, the market share of iOS-based smartphones is comparable to that of Android[12][13].
- 3. Due to the previous delimitation, only Android Wear smartwatches will be taken into consideration, given their compatibility with Android and iOS-based smartphones[14].
- 4. Due to time constraints the wearable ECG component will not be implemented as a proof of concept.

## 3 METHODOLOGY

Research methodology can generally be divided into two main categories: qualitative research and quantitative research. Additionally, research can be defined as primary or secondary. Due to the fact that all of the aforementioned research types are to be utilized towards the completion of the current Thesis, a brief overview of the differentiating methodologies will be provided in the following sub-sections.

#### 3.1 QUALITATIVE AND QUANTITATIVE RESEARCH

In general, research can be, either quantitative, or qualitative[15]. Qualitative research is used for examining an individual's (or a group's) behavioral, cultural and societal nature[16]. The results of qualitative research do not have numerical equivalents; rather they are more abstract and immeasurable[16]. Qualitative research can take various forms – especially during today's digital age – including: interviews, focus groups, online chats, text messages, emails and so on[16]. What should be noted is that, although qualitative research can involve the personalized thoughts and opinions of interviewees (focus group participants, etc.), the research itself must be objective and not subjected to the bias of the researcher[16]. Qualitative research is complementary to quantitative research.

Quantitative research presents information in a numerical manner[17]. Quantitative data, as well as qualitative, are gathered in order to solve a problem but in the case of the former it is "quantifiable", i.e. it can be expressed through numbers and processed via mathematical methods[17]. Although the two seem mutually exclusive, there are such situations where qualitative information can be gathered in a quantitative manner[17]. An example would be surveys – although the gathered data relies on personal opinions and beliefs, it can be processed via various data analysis tools[17]. A part of this toolset is the element of statistics – statistics are mathematically-based methods of data analysis[17].

#### 3.2 PRIMARY AND SECONDARY RESEARCH

Primary research consists of a researcher collecting information firsthand[15]. It refers to the type of research, where information is gathered directly from the real world by the author/researcher him/herself[18]. Surveys are an example of primary research and they are among the most often implemented[15]. They can be especially versatile in nature, thus making them suitable for the variety of target audience[15]. Other instances of primary research can include interviews, observations and analysis[18].

There are various interpretations of the term "secondary research". In general, secondary research is collected by third-party persons and for goals different than those of the one performing the research[15]. Secondary research involves utilizing information that has already been published by another searcher[19]. It is not one's own original work but rather the application of someone else's research so as to contribute to one's own.

Both the primary and secondary research methods have been utilized towards the fulfillment of the current Thesis. Secondary research was heavily relied upon during the pre-study phase, as well as for the completion of the Ischemic Heart Disease<sup>1</sup> and State of The Art chapters.

<sup>&</sup>lt;sup>1</sup> Cross-references are market in blue.

Primary research has also been conducted within the confines of the Thesis. It has mainly been conducted within the form of a survey and an interview. The aforementioned primary research methods are introduced and discussed in sections 6.2 and 6.3 of the Analysis chapter.

#### 4 ISCHEMIC HEART DISEASE

As it was mentioned in the Introduction chapter, the leading cause of death worldwide is ischemic heart disease, which is a facet of cardiovascular disease. The current chapter is dedicated to providing answers to the first two sub-questions in section 2.1 of the Problem Formulation chapter, which are the following:

What conditions constitute ischemic heart disease? Which of them can lead to a fatal outcome?

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What physiological or environmental parameters should be monitored in order to detect the onset of the established conditions?

Additionally, in order to provide context for the diseases being reviewed, the first section of the current chapter will be dedicated to an introduction to the biological workings behind the human cardiovascular system.

#### 4.1 OVERVIEW OF THE HUMAN VASCULAR SYSTEM

A simplified diagram of the human vascular system (often noted as "circulatory system") can be seen on Figure 1. It is made up of the following: the heart, blood, blood vessels, neurohumoral influences, as well as the lymphatic system[20][21]. The blood that circulates throughout the body consists of formed elements within a liquid, called plasma (which is mostly water)[21]. Blood and its formed elements serve three main purposes: (1) to transport oxygen, carbon dioxide, nutrients, etc, (2) to regulate temperature, pH, etc, and (3) to protect against disease, loss of blood (clotting), etc[21]. The elements within the blood are platelets (that play a major role in clotting), white blood cells (which are used in immune responses) and red blood cells[21]. The latter constitute the majority of all blood cells (~99%) and serve as a transportation tool to deliver oxygen to the rest of the body[21].

Blood travels via blood vessels, which include arterial systems, venous systems and microcirculatory systems[20]. Blood vessels branch out throughout the human body - starting from larger ones, such as arteries/veins down to the smallest blood vessels, known as capillaries - and all of them effectively form a closed loop[21]. The previously-mentioned closed loop can also be viewed as two complementary loops: (1) the pulmonary circulation and (2) the systemic circulation[21]. The former serves to transport deoxygenated blood from the right heart (via the two main pulmonary arteries) to the lungs, where it becomes enriched with oxygen and is then transported to the left heart(via the pulmonary vein)[21]. The latter's purpose is to transport oxygenated blood from the left heart to the rest of the body (via the aorta) and to transport deoxygenated blood to the right heart via the superior and inferior vena cava[20][21].



FIGURE 1: VASCULAR SYSTEM[22]

The heart is what keeps the circulation in motion – it pumps oxygenated blood through the arteries and receives carbon dioxide-rich blood from the veins[21]. A diagram of the human heart can be found in Figure 2, where it can be seen that it consists of four chambers, the upper two being the atria and the lower two - the ventricles[23]. The atria collect blood, while the ventricles pump it out[23]. The right atrium and the right ventricle (collectively known as the right heart) serve to collect the deoxygenated blood from the body and then pump it to the lungs[23]. The left atrium and the left ventricle are utilized so as to collect the oxygenated blood from the lungs and to send it out to the rest of the body[23]. In order to maintain the directionality of the blood flow, as well as to prevent leakage, the heart contains four valves: the atrioventricular (AV) valves (tricuspid and mitral) that regulate the flow between the atria and ventricles, and the semilunar valves (pulmonary and aortic) that control the flow between the ventricles and the major arteries[23]. Although the heart is full of de-oxygenated and oxygenated blood, it doesn't receive its oxygen and necessary nutrients directly but rather through the so-called coronary artery circuit[24]. It consists of three main arteries (left coronary artery, right coronary artery and the conus artery), the extramural coronary system

(the accompanying blood vessels, situated on the surface of the myocardium<sup>2</sup>) and the intramural coronary system (the blood vessels within the myocardium)[24].



FIGURE 2: ANATOMY OF THE HUMAN HEART[25]

As it has already been mentioned, the heart serves as a pump of sorts, which maintains circulation throughout the human body. In order to collect and pump blood, the four chambers of the heart contract sequentially in an established order and that activity is controlled by the cardiac conduction system[26]. This system consists of altered cardiac muscle cells; some of them are the so-called pacemaker cells – they generate electrical activity. The rest are conductive cells, which serve to spread the created electrical impulses to the rest of the designated areas within the heart[26]. These electrical impulses disperse throughout the heart in a specific order[26]:

1) A spontaneous depolarization wave starts up from the sinoatrial node  ${}^{3}(SA)$ , which is located around the top of the right atrium;

<sup>&</sup>lt;sup>2</sup> Myocardium – constitutes most of the heart wall; contains cardiac muscle[59].

<sup>&</sup>lt;sup>3</sup> The SA node is the natural pacemaker of the human heart, it dictates the normal sinus rhythm [26].

- 2) The depolarization wave spreads throughout both atria, causing them to contract;
- 3) The wave reaches the AV node, which lays at the bottom of the right atrium;
- 4) The AV node relays the depolarization wave with a delay on to the right and left ventricles, causing them to contract;

#### 4.2 ISCHEMIC HEART DISEASE

As is the case with the rest of the human body, cardiac tissue requires oxygen, as well. Ischemia defines the restriction of blood flow to tissues that leads to a deficiency in the oxygen and energy substrates being delivered [27]. Therefore, ischemic heart disease (IHD) refers to the restriction of blood flow to the heart, which means restriction of the blood flow within the coronary artery circuit (due to the blood delivery system being specifically dedicated to the heart itself). The condition that results in the abovementioned restrictions is called "atherosclerosis" - it is a progressive disease that includes the build-up of lipids and fibrous components[24][28]. These lipids and fibers can accumulate into plaques that protrude on the inside of blood vessels, effectively narrowing the corresponding lumens <sup>4</sup> of said blood vessels, which in turn limits the amount of blood that can flow through them[24]. Additionally, atherosclerosis can lead to the creation of blood clots (thrombi), which can travel to smaller arteries and completely occlude them[24]. Keeping in mind the significance that atherosclerosis has on the development of IHD, it would be therefore beneficial to be able to detect its presence in an individual. However, diagnosing atherosclerosis can be challenging – currently the preferred method is catheterization, which is highly invasive and is only performed in a medical environment[28]. Risk factors for atherosclerosis and IHD in general seem to be a combination of genetic predisposition and environmental conditions[24][28]. However, significant risk factors seem to be smoking (cause of 36% of IHD[24]), obesity (cause of 20% of IHD[24]), gender (bellow the age of 60, men develop atherosclerosis twice as often as women[28]), sedentary lifestyle[24] and age[24]. In general, IHD can be divided into two main conditions: (1) stable angina and (2) the so-called acute coronary syndrome (ACS)[29]. ACS is considered the more significant of the two and it includes the following three conditions: (1) unstable angina, (2) ST-elevation myocardial infarction (STEMI), and (3) Non-ST-elevation myocardial infarction (NSTEMI)[29].

#### 4.2.1 ANGINA

The most common symptom of IHD is angina pectoris, which can also be referred to as stable angina[24][30]. It can demonstrate as chest pain, pressure or a squeezing sensation in the chest area; the discomfort can also travel to the back, shoulder, arm, neck or jaw[30]. However, women may also experience nausea, vomiting, shortness of breath, sharp chest pain or abdominal pain[31]. Angina pectoris typically manifests itself during physical exertions, cold weather and during emotional or stressful episodes[24][30], but it is notable that angina pectoris flare-ups usually do not last longer than 5 minutes and can be treated with rest or medicine (such as nitroglycerin)[30]. Additionally, it usually occurs at higher heart rates[32]. Angina pectoris, by itself, is purely a symptom of IHD and does not indicate damage to the heart. However, its own existence signifies the presence of IHD, which puts the individual experiencing it at higher risk of suffering from other, more hazardous, instances of IHD[30].

<sup>&</sup>lt;sup>4</sup> Lumen – the interior section of a membrane-covered entity[161]; not to be confused with the SI unit for Luminous Flux[162].

Another type of angina is the unstable angina, which is also known as one of the acute coronary syndromes[33][34]. It can develop as a consequence of angina pectoris (meaning that individuals with angina pectoris should be vigilant for a change in symptoms) or on its own[33]. Unstable angina presents as a sudden and unexpected pain, usually occurring during rest[33] – as opposed to angina pectoris, which is triggered by physical exertion or intense emotion. Because unstable angina occurs suddenly, usually during rest and not due to exertion or stress, heart rate can be a distinguishing indicator. When an individual is experiencing angina symptoms, if their heart rate is low, then that would strongly indicate that they are in fact experiencing unstable angina, rather than angina pectoris[32]. Additional symptoms can be sweating, nausea, vomiting, elevated anxiety[24]. Instances of unstable angina last more than 15 minutes and cannot be treated with rest and medication[33][35]. Unstable angina requires immediate medical attention, since it often precedes conditions such as myocardial infarction or sudden cardiac death (SCD)[33][35]. Unstable angina can be diagnosed via coronary angiography, computerized tomography coronary angiography, stress testing (through exercise or pharmacologically-induced) or via electrocardiogram (ECG)[24][36]. Of the abovementioed methods, coronary angiography<sup>5</sup> is fairly invasive and computerized tomography coronary angiography <sup>6</sup> is less so but still requires highly specialized equipment[36]. Stress testing can lead to a cardiac incident and as such should only be conducted under medical supervision[24][36]. ECG is often the first test performed when cardiovascular disease is suspected; it can be performed relatively quickly and it is noninvasive[37]. Angina can be reflected in an ECG with a deviation of the ST-segment – individuals with unstable angina symptoms (chest pain, etc.) and ST-segment elevation are in immediate danger since that would indicate that they are experiencing a STEMI[24]. In such cases individuals should undergo revascularization as soon as possible - time span from the onset of pain until the procedure should be no more than 90 minutes[24].

#### 4.2.2 ACUTE MYOCARDIAL INFARCTION

Acute myocardial infarction (AMI) is another acute coronary syndrome[34]. AMI generally has two forms: with (STEMI) or without ST-segment elevation (NSTEMI)[38]. AMIs occur when cardiac ischemia has lead to oxygen deprivation severe enough to cause necrosis of the cardiac tissue[38]. Most AMIs are caused by atherosclerosis, however, other (much rarer) causes can include coronary artery dissection, anemia, hypotension, cocaine use[38]. AMIs are most often accompanied by unstable angina that typically presents as chest pain[38]. However it has been observed that up to 20% of those, affected by AMI, do not experience chest pain but rather they are asymptomatic – these are generally women, elderly, diabetics or postoperative patients[38].

Diagnosing AMIs generally requires the following components: clinical history, ECG, physical examination, chest radiograph and cardiac markers[38]. ECG-based diagnosis will be on focus within the current section, due to the fact that it is the primary initial diagnostic tool utilized when an AMI is suspected. As it has already been mentioned, AMI has two forms:

<sup>&</sup>lt;sup>5</sup> Coronary angiography is a procedure where (via cardiac catheterization and with the help of X-ray imaging) a specialized contrast dye is inserted into the coronary arteries. After that another X-ray is taken, where coronary blockages will be made visible[37][163]. Traditionally it is still used in cases where there is a strong suspicion of coronary blockage because said blockages can be removed during the procedure itself[164].

<sup>&</sup>lt;sup>6</sup> Computerized tomography angiography is a procedure, similar to 5 but less invasive since no catheter is used, rather it relies on a more powerful X-ray machine[164].

STEMI and NSTEMI. The former is named after its most significant ECG indicator and that is elevation within the ST-segment[39]. Meanwhile, individuals with a suspected NSTEMI often manifest with ST-segment depression, T-wave inversion, flat T-waves or with no significant tracings at all[39]. To be more specific, it is considered that a MI is occurring when there is new ST-elevation above 0.1 mV at the J-point in two contiguous leads  $^{7}$ , i.e. all leads but V2 and V3, where the cutoff points are 0.20 mV for men over 40-years-old and 0.15 mV for women[40]. Also, new ST depressions  $\geq 0.05$  mV in two contiguous leads and/or Twave inversion  $\ge 0.1$  mV in two contiguous leads with an R/S ratio above 1[40]. Another MI indicator is the presence of new pathologic Q waves – pre-existing pathological Q waves are to be excluded as a diagnostic method since they are indicators of a prior MI[40]. Reinfarction <sup>8</sup> can be diagnosed in the presence of ST elevation  $\geq 0.1$  mV or of new pathologic Q waves in two contiguous leads, especially when accompanied by symptoms that last for more than 20 minutes[40]. Pathologic Q waves are those that last longer than 0.04 seconds or that have an amplitude at least a third of that of the accompanying R wave[41]. The reason why AMI symptoms are looked for in *any* two contiguous leads is that, depending on which section of the coronary artery system is affected, various sections of the myocardium could be damaged. Different ECG leads present different views of the heart; therefore specific sections of the heart (and their possible damage) are visible via specific ECG leads[42].

Identifying the presence of an AMI based on pulse is not as precise a method as when using an ECG. What is known is that the higher the resting heart rate (RHR), the more likely that an incident MI or total death will occur[43]. Bradyarrhythmia is a known complication for 25%-30% of AMI cases[44]. It generally manifests within the first 6 hours of the MI, ranging from sinus bradycardia (40% of bradyarrhythmias) to AV blocks[44]. Traditionally, bradyarrhythmia is considered to constitute a heart rate, lower than 60 bpm[44][45]. Bradyarrhythmias often lead to dizziness and even to a syncope $^9$ - specifically, they are the cause of 3% - 10% of all syncope cases [46]. It ought to be noted that for some people usually young adults and professional athletes - an RHR below 60 bpm can be a regular rhythm, not an arrhythmia[47]s. Additionally, ischemic damage to parts of the cardiac conductive system can lead to electrical re-entry, causing tachyarrhythmias[44]. These include ventricular tachycardia (VT) and ventricular fibrillation (VF)[44]. The former can be nonsustained (less than 30 seconds) - occurs in 67% of AMIs within the first 12 hours - and sustained (longer than 30 seconds)[44]. Nonsustained VT does not correlate with increased mortality but sustained VT does[44]. In the presence of sustained VT, one's heart rate is above 100 bpm. VT's ECG tracings can be somewhat distinctive - wide complexes (with a QRS complex longer than 0.12 second or an RS interval longer than 0.1 seconds in at least one precordial lead), with no preceding P waves[48][49]. Sustained VT leads to reduced perfusion and can have similar symptoms to those of bradyarrhythmia: dizziness, palpitations and loss of consciousness. If left untreated, sustained VT can turn into VF[50]. VF is a type of arrhythmia where rapid and irregular electrical impulses spread throughout the heart, causing the myocardium to quiver rather than actually pump blood. VF can be treated via cardiopulmonary resuscitation (CPR) and by shocking the heart with electricity with a defibrillator[51]. The outward symptoms preceding VF coincide with those of VT,

<sup>&</sup>lt;sup>7</sup> Contiguous leads are leads that belong together in one of the following groupings: anterior leads (V1-V6), inferior leads (II, III, aVF), lateral leads (I, aVL)[40].

<sup>&</sup>lt;sup>8</sup> Reinfarction is the occurrence of a second MI within 28 days of the initial one[40].

<sup>&</sup>lt;sup>9</sup> Syncope – loss of consciousness, fainting[47].

accompanied with a lack of pulse[50]. Both VT and VF typically occur in individuals, who have a preexisting cardiac condition, whether due to IHD, congenital disease, etc[50][51].

Although, as it has already been mentioned, there are multiple symptoms for the acute coronary syndromes, chest pain is still a frequently observed one among adults and the elderly[52]. However, the elderly are still at a higher risk of experiencing the so-called "silent" myocardial infarction – one, where there are no apparent outside symptoms, rather it is detected by medical professionals (most often via an ECG, where it tends to present as a new pathological Q wave)[40][53]. Additionally, individuals with pre-existing CVD are also more likely to experience silent MIs[53]. Age is not the only risk factor for silent MIs: it has been established that individuals with diabetes mellitus are more likely to suffer from a silent MI – especially among diabetics with a history of coronary artery disease or peripheral artery disease[54].

#### 4.2.3 SUDDEN CARDIAC DEATH

Another factor that ought to be noted that individuals with IHD are more likely to experience SCD – it has been estimated that in developed countries IHD is the underlying cause for SCD in 70%-80% of the incidences[55]. SCD defines a death that is sudden, unexpected, due to CVD and develops within 1 hour of a significant change in clinical presentation[55]. Elderly people are especially at risk of SCD and it is most often related to, either IHD, or congestive heart failure[55]. A study has found that men who have a RHR above 75 bpm are four times as likely to die from SCD and that men whose HR has increased less than 89 bpm during physical exercise are six times more likely to die from SCD[56]. In the first year after an AMI, a heart rate above 70 bpm leads to a 47% increase in the risk of mortality[57]. It has been estimated that two-thirds of all instances of SCD are due to ventricular arrhythmias, specifically VT and VF[58]. Both of the aforementioned arrhythmias were touched upon in the previous section. Additionally, with the increasing of age, the incidence rate of initially presenting pulseless electrical activity (PEA) also increases[55]. PEA refers to the condition where although the individual presents with regular ECG complexes, they are actually in the middle of a cardiac arrest where circulation has halted[59].

# 4.3 OVERVIEW OF ISCHEMIC HEART DISEASE AND ACCOMPANYING SYMPTOMS

In conclusion of the current chapter the following table (Table 1) is presented. It contains a condensed overview of the conditions that have been examined so far, with a focus on their presenting symptoms.

Condition	Underlying Causes	Symptoms	Detection via Pulse	Detection via ECG
Angina Pectoris	IHD; Physical stress; Emotional stress; Cold weather;	Chest pain/ pressure/ squeezing - usually lasting no more than 5 minutes; Possible symptoms in women: nausea, vomiting/ shortness of breath/ sharp chest pain/ abdominal pain - usually lasting no more than 5 minutes;	Symptoms occur at higher heart rates;	No discernible signs;
Unstable Angina	IHD; Sudden onset of symptoms;	Chest pain, occurring unexpectedly during rest and lasting more than 10- 15 minutes; Sweating; Nausea/vomiting; Elevated anxiety;	Symptoms occur at lower heart rates;	ST – elevation at J point: $\geq 0.1$ mV in any two contiguous leads, other than V2 and V3; ST – elevation at J point in leads V2 and V3: $\geq 0.2$ mV for men and $\geq 0.15$ mV for women;
AMI	IHD;	Unstable angina symptoms; Dizziness; Palpitations; Syncope;	Bradyarrhythmia (<60 bpm); Tachyarrhythmias (>100 bpm); Lack of pulse;	ST – elevation at J point: $\geq 0.1$ mV in any two contiguous leads, other than V2 and V3; ST – elevation at J point in leads V2 and V3: $\geq 0.2$ mV for men and $\geq 0.15$ mV for women; New ST depressions $\geq 0.05$ mV in 2 contiguous leads and/or T inversion in 2 contiguous leads, where R/S>1; New Q waves that are: $\geq 40$ ms or $\geq 1/3$ of R wave Reinfarction: ST elevation $\geq 0.1$ mV or new Q waves; QRS complexes longer than 120 ms with no preceding P waves; RS interval longer than 100 ms in a precordial lead;
SCD	IHD; Congestive heart failure;	PEA; VT; VF;	Tachyarrhythmias (>100 bpm); No pulse but regular ECG complexes; No pulse and irregular ECG complexes;	Regular ECG complexes but no pulse; QRS complexes longer than 120 ms with no preceding P waves; RS interval longer than 100 ms in a precordial lead;

#### TABLE 1: OVERVIEW OF ISCHEMIC HEART DISEASE

In conclusion to the current chapter it ought to be noted that, although an individual's heart rate is the most easily accessible, it also does not provide distinguishingly pathological information. Data extracted solely from heart rate measurements, are not sufficient in order to yield a reliable diagnosis as to one's health status. Meanwhile, ECG readings provide much more insight into a person's cardiac activity and as such are considered a necessary component of Vixi – especially during the first year after an IHD incident, when people are exposed to a higher risk of morbidity.

### 5 STATE OF THE ART

The current chapter will be dedicated to fulfilling the following objective from section 2.2 of the Problem Formulation chapter:

Conduct research into the existing relevant algorithms and technologies that are currently on the market.

#### 5.1 POSITIONING METHODS

An essential component to the service being developed is accurate positioning – this is necessary in order to provide users in need with assistance as soon as possible. Positioning technologies are generally divided into three groups: (1) satellite-based, (2) terrestrial-radio-based, and (3) standalone[60]. Of the abovementioned groups, the most preferred are the satellite-based positioning systems, which is why the following brief section is dedicated to them.

#### 5.1.1 GLOBAL NAVIGATION SATELLITE SYSTEMS

In recent years satellite-based positioning systems, the so-called Global Navigation Satellite Systems (GNSS), such as the American Global Positioning System (GPS), the Russian Global Navigation Satellite System (GLONASS), the Chinese BeiDou Navigation Satellite System (BDS) or the European Union's Galileo, have gained popularity. Of these systems, BDS is currently servicing primarily the Asian-Pacific region[61] and Galileo will not be fully functional until 2020[62]. GLONASS and GPS have somewhat similar accuracies (the former being ~ 5-10 m[63][64] and the latter being up to 4.9 m [65]) and both have global coverage. Additionally, both have augmented versions deployed for smartphones, which allow for faster start-up times by making use of the additional network connectivity. Although one does not have much advantage over the other, it has been discovered that the combination of the two, with a combined (55) satellites, can provide a more complete global coverage[66][67][68] and - with more satellites being visible to users' devices – provide an improved accuracy of up to 2m.

While GPS and GLONASS are fairly accurate, these positioning systems both have a significant flaw: they require line-of-sight (LOS). This can be a hindrance in two main situations: (1) when the device is within urban canyons, or (2) when the device is located indoors. This can be a problem, given that there has been a trend of population transference towards urban areas in recent years and the fact that these senior citizens mostly live within cities. The second situation is especially detrimental since, as stated previously in Problem Formulation chapter, a large portion of elderly people live on their own and the purpose of this service is to provide them with help when they are unobserved (which is more likely to be indoors at home, rather than outside in a public place). Although the effect of non-line-of-sight (NLOS) signals can be diminished by using dual-polarization antennas, most smartphones are equipped with linearly polarized antennas, which cannot discriminate between NLOS and direct signals[69].

In order to manage the problems with this kind of situations, many positioning services are actually hybrid systems that combine GNSSs with systems that can work better with NLOS

signals. These other positioning methods can be utilized when LOS signals cannot be attained and these will be explored in the following section.

#### 5.1.2 NLOS POSITIONING METHODS

#### **Cell ID Positioning**

Cell ID positioning is a network-based positioning method, meaning that the mobile Station (MS) segment does not need to have any special hardware of software components, rather the burden of additional resources falls on the network infrastructure[70]. In order to understand how this positioning method is executed, a brief overview of cellular technology is necessary.

Cellular technology is based on the principle of dividing geographical coverage into individual areas, called "cells" (Figure 3). This rather simple idea solves a number of problems, including: (1) the limits of the RF spectrum, (2) the high power requirements for the UE segment, as well as for the network transceivers, (3) the limited capacities tied to using small numbers of network transceivers in order to cover larger geographical areas.



FIGURE 3: BASIC CELLULAR NETWORK CONFIGURATION[71]

Whenever an individual wants to make use of the connectivity features of their MS (such as a mobile phone or a smartphone), then their MS would send to and receive the data in question from the Base Transceiver Station (BTS) that is servicing the cell, in which the individual is located. The Cell ID positioning method entails approximating a user's location to that of the cell that they are in and that is achieved by identifying the BTS that is servicing them[72, p. 49]. This localization method hails from the time of the second generation cellular network but is still very much in use today - a testament to this is a 2014 report from the European Emergency Number Association (EENA), titled "Caller Location in Support of Emergency Services"[73]. In it they include a small sample data on the success rate of network providers

providing the location of their customers that make emergency calls. With Cell ID they have a success rate of up to 97.4%, while GPS positioning had its highest success rate at 24.6% [73, p. 16]. Meanwhile, within Europe, of the 27 of the 30 countries listed in the report, still rely on Cell ID positioning[73, pp. 18–19]. An advantage to this method is that it is actually more accurate within urban environments[72, p. 49]. This is due to the fact that in cities, where population density is higher, individual cell geographical coverage tends to be smaller in order to compensate for the higher amounts of traffic. In this way, a network can accommodate, both picocells <sup>10</sup>, as well as macrocells <sup>11</sup> [60]. Due to the somewhat limited accuracy of this method – especially given the imposed requirements for USA's E911 (50 m for 67% of calls[73]) and EU's112 (30 m for 67% of calls[73]) – there have been a multitude of proposed additional methods and algorithms to improve it.

#### Cell ID based positioning methods

One such method is the Cell ID Timing Advance (TA). The TA parameter is tied to the nature of GSM network, which utilizes Frequency Division Multiple Access (FDMA) alongside Time Division Multiple Access (TDMA)[74]. There is a necessity for the synchronicity between the MS and the BTS and there are mechanisms for achieving it, both frequency- and time-wise[74]. Specifically, in order to properly maintain time synchronization, there has to be a negation to the various time delays between the MS and the BTS. These delays stem from the fact that an MS is mobile and at any point in time can be at various positions within its cell, at differing distances from its servicing BTS[75, Sec. 5.3]. To counteract the aforementioned lagging problem, the start time of data sent from the MS is moved forward ("advanced") and this is done proportionally to the distance from the BTS[75, Sec. 5.3]. Applying the TA parameter in the context of positioning, it enables the placing of an MS within a specific annulus that has the corresponding BTS at its center[74]. Cell ID and Cell ID+TA may only provide ambiguous locations, but both of these positioning methods do not require any additions to the existing infrastructure, which is what makes them such attractive options to network providers. There are other methods that can be used alongside them in order further improve accuracy – Received Signal Strength (RSS), Angle of Arrival (AOA), Uplink Time Difference of Arrival (U-TDOA), etc[73][74]. However, these techniques require additional investments in the infrastructure[74], which means that it is up to each network provider to decide how to allocate its resources in order to appease the requirements set forth by American government and the EU[73].

The implementation of Wideband Code Division Multiple Access (WCDMA) that came with the addition of Universal Mobile Telecommunications System (UMTS) on top of the previously deployed 2G cellular network led to the possibility of utilizing another technique. The method in question is the Round Trip Time (RTT) positioning one – it requires measuring the time it takes radio waves to travel from a Node B (NB - the UMTS equivalent of BTS) to the MS and back[76]. From this time-of-flight measurement, approximations of distance between the NB and the MS, as well as of the direction of the MS, can be made[76]. Ideally the MS would be in range of more than one NB in order to get a more accurate position. However additional algorithms have been proposed in order to compensate for this deficiency in accuracy in case there is only one NB available (e.g. [76], [77]).

<sup>&</sup>lt;sup>10</sup> Picocell – a cell dedicated to a smaller physical area; picocells can have a radius of up to 200 m[165]

<sup>&</sup>lt;sup>11</sup> Macrocell – a cell utilized so as to provide coverage for areas of up to 10 km[165]

#### 5.1.3 INDOOR POSITIONING METHODS

Indoor positioning methods mainly consist of three major groups: scene analysis, triangulation and proximity(Figure 4)[78][79]. What makes these specific groups so favourable is that they can be used in a manner that would compensate for the difficulties, related to anticipating wave propagation indoors, such as floor plans, shifting positions of objects, the effects of multipath and NLOS[79]. Scene analysis involves the collection of data on specific features of scenes - this data can be in the form of radio waves, acoustics, visual data, etc.[78]. The collected data is then mapped to the physical environment and the observed specific features are used to approximate the positioning of individual devices[78]. An example of a scene analysis techniques is the so-called "location fingerprinting"[78]. Triangulation involves utilizing the characteristics of triangles in a geometric context[78]. Triangulation methods can be divided in two overall groups: (1) ones, based on angulation (that use angle measurements), and (2) those that use lateration (which utilize distance measurements)[78]. It ought to be noted that with lateration, it is not the distance that is directly measured; rather it is deduced from the measurement of other parameters - mainly the time it takes a signal to travel between an observed device and some reference points, as well as the signal phase of a received signal [78]. Proximity techniques involve the assignment of a location of a device to the location of a reference point that has detected its presence and example is positioning via radio frequency identification (RFID)[78]. The Cell ID method, discussed in the previous section, is based on the same working principle only on a larger geographical scale[78].

Existing positioning solutions from the abovementioned groups include RFID, Wi-Fi, Bluetooth and Ultra Wideband (UWB) among others[79]. Of the listed systems, Wi-Fi-based ones have been preferable and so the remainder of the current section is dedicated to them.



FIGURE 4: INDOOR POSITIONING METHODS[78]

#### Wi-Fi fingerprinting

Recently Wi-Fi has been gaining a lot of much traction in indoor positioning, which is due to the ever-increasing number of Wi-Fi devices being deployed as part of an existing network[78][80][81]. Although there are multiple Wi-Fi-based location techniques, the one that is in most use today is fingerprinting via Received Signal Strength Indicator (RSSI) [79][80][82]. A second option to fingerprinting has been triangulation; however triangulation techniques lose accuracy due to multipath and additional algorithms would have to be included in order to compensate for such errors[80][81][82]. As it has already been mentioned earlier in the current section, fingerprinting is a scene analysis method, therefore Wi-Fi fingerprinting functions along those same principles. Specifically, it consists of two phases: the offline training phase and the online positioning phase [78][81]. The offline phase involves the collection of data on RSSI location fingerprints and creating/updating a database that contains said information [78]. In the online phase Wi-Fi enabled devices extract the relevant fingerprint from the database and use them to make an approximation as to their location[78][80]. Given the comparatively smaller ranges of Wi-Fi emitters (50m-100m), this method provides a fairly accurate location estimation[79]. However, there are a number of accompanying algorithms (K-Nearest Neighbour, Neural Networks, Probabilistic, etc) that are utilized in order to further improve accuracy to up to 2m-3m[78][79]. Perhaps the most significant disadvantage to this method is the amount of effort it would be required in order to create a fingerprint database, as well as to maintain it[80][81].

#### 5.2 MEASURING AN ELECTROCARDIOGRAM AND HEART RATE

The following section provides an overview of the tools used to measure the two most commonly relied upon parameters when diagnosing cardiovascular disease – the electrocardiogram and the pulse rate. Accordingly, the current segment of the chapter will be divided into two parts: one, dedicated to the electrocardiograph (which has common origins with the modern ECG itself[83]), and the other introducing devices that can obtain a measurement of an individual's pulse rate.

#### 5.2.1 MEASURING AN ELECTROCARDIOGRAM

The first electrocardiograph was built in 1903 by Willem Einthoven[84], for which he later received a Nobel prize (Einthoven was also the one to name the notable ECG deviations as P, Q, R, S and T)[83][85]. Einthoven's electrocardiograph consisted of a string galvanometer that moved in accordance with the currents, generated by the human heart; the string was illuminated and the movement captured on a photographic plate[84]. It also weighed around 270 kg and needed 5 operators in order to function properly[83].

Nowadays, the electrocardiograph looks quite different and is much easier to operate[83]. It involves attaching electrodes to the skin of the one being examined[85]. A modern ECG can have a varying number of leads and electrodes <sup>12</sup> but the gold standard for assessing an individual's cardiac electrical activity is utilizing the 12-lead ECG[85]. Utilizing 10

<sup>&</sup>lt;sup>12</sup> There is a significant difference between a lead and an electrode. Electrodes are physical components of the ECG device; they are attached to the surface of the skin and measure the electrical changes on it[85]. Leads are not a physical manifestation of the ECG device; rather they represent the different views of the heart[41].

electrodes, the 12-lead ECG provides a more thorough view of the electrical activity in question due to the multitude of angles and planes being observed[85]. The ten electrodes are in the following configuration: 1 on each wrist, 1 on each ankle and 6 on the chest[41]. Combining the readings from these electrodes, the following 12 leads are extracted[41]:

- 1) 3 standard bipolar leads (I, II, III), which reflect the difference in electrical potential between two electrodes of opposite polarity. The electrodes utilized are the ones on both wrists and the one on the left ankle.
- 2) 3 augmented unipolar leads (aVR, aVF, aVL), which reflect the potential at one positive electrode, with regard to the two remaining leads. The electrodes used here are the same ones utilized for the standard leads.
- 3) 6 precordial unipolar leads ( $V_1$ ,  $V_2$ ,  $V_3$ ,  $V_4$ ,  $V_5$ ,  $V_6$ ) that provide a view of the cardiac electrical activity in the horizontal plane.

#### Wearable Long-term Counterparts

While the 12-lead ECG provides the most detailed and accurate information, other configurations are also feasible solutions. Some might include simply not utilizing all 10 electrodes on a standard ECG (for example using all limb electrodes, but only one precordial electrode[85]), while others might involve reshaping the ECG as a device. There are four main kinds of long-term wearable ECGs and they are the following: (1) implanted ones, (2) those that record events only, (3) ones those that continuously recording data, and (4) ones that monitor health status in real-time [85]. Implanted recorders are placed underneath the skin and can stay there for a number of years[85]. There are a number of models with varying features, which can include storing data when arrhythmias are detected or recording events triggered by the user when they start experiencing symptoms[85]. It should be noted that these types of devices are mostly used on individuals that are difficult to diagnose[85]. The second of the aforementioned types of ECG, the event recorders, are used in order to record data only at certain times, which are selected based on prompts from the user[85]. Meanwhile the third type of ECGs records data constantly but for predetermined periods of time, usually amounting to 24-to-48 hours[85]. Lastly, the fourth type of ECG device is used for real-time monitoring, meaning that data is constantly being collected but, rather than being recorded within the device itself, it is being sent to a second location where it is consequently stored[85]. Generally, these devices can have a number of leads (and therefore multiple accompanying electrodes) - such as the Holter monitor - but frequently they only have one lead (single-lead ECG). Single-lead ECGs most often make use of the standard leads (I, II, III) or modified precordial leads (MCL1, MCL6)[86].

Focusing on non-invasive devices, examples of wearable ECGs that are available on the market or about to be released are the following:

- > The QardioCore single-channel wearable ECG[87]
- The Shimmer3 ECG Unit, which utilizes four precordial leads (with a choice from V1 to V6)[88];
- ➢ iRhythm's Zio[89];
- The crowdfunded CALM.[90];

#### 5.2.2 MEASURING HEART RATE

Among the most commonly referenced vital signs are temperature, respiratory rate, urine output, heart rate and blood pressure[91]. Of the aforementioned vital signs, the ones that are directly related to the cardiovascular system are the heart rate and blood pressure. However, from research conducted in the Ischemic Heart Disease chapter is it known that although blood pressure is not an indicative symptom to the onset of an ACS, heart rate can be.

An individual's heart rate can be measured via a number of non-invasive methods. In fact it is often measured merely by using one's fingers and a watch – the most accurate measure would be taken by placing the fingers on one of the parts of the human body where the pulse could reliably be monitored, such as the side of the neck, the wrist, the inside of the elbow or the top of the foot[92]. The one executing the measurement would then count the palpable beats for a period of 60 seconds and the resulting number would be the observed pulse, expressed in beats-per-minute, i.e. bpm[92]. Although this method is considered to be reliable, it can turn into a challenging task when an individual has to be monitored for longer periods of time. To solve this problem, among others, automated devices have been developed that are capable of detecting the human heart rate.

#### Wearable Counterparts

There are various methodologies behind heart rate measuring devices but generally they are either electronically-based or optically-based; with the former being more accurate but also less affordable[93]. An electronically-based example is the focus of the previous section (5.2.1) – the ECG – it detects the electrical impulses that guide the contractions of the heart and the heart rate itself. The optically-based technology most often used is the one utilizing pulse oximetry[94].

Pulse oximetry is a technology developed as a non-invasive method for measuring the oxygen saturation levels of arterial blood[95]. It is based on utilizing the varying capabilities between oxygenated and deoxygenated blood, concerning light absorption. To be more precise, the hemoglobin within the blood reacts to infrared and red light differently, depending on how much oxygen it is bound to[95]. Pulse oximetry devices generate light and use it on the human skin; the light itself is emitted in two wavelengths – 660 nm and 940nm – which correspond to infrared and red light, respectively[94]. The devices then detect the light absorption at both wavelengths in order to estimate the arterial oxygen absorbance rate[94]. What is of interest, however, is that pulse oximetry can also be utilized so as to measure heart rate, as well. In essence, the output of a pulse oximetry device is a photoelectric photoplethysmogram (PPG)[96]. PPGs can be used so as to gain a measure of a number of bodily functionalities, among which are: an assessment of venous function, blood vessel viscosity, cardiac output and, most significantly, heart rate[96].

Because of its relatively low production cost and non-invasive nature, the PPG sensor can often be found among consumer goods that utilize heart rate for various reasons, depending on the purpose of the product. Such products have taken the form of rings[97][98], chest straps[99][100] and smartwatches[101][102], among others.

#### 5.3 FALL DETECTION

As previously mentioned in the Acute Myocardial Infarction section of the previous chapter, a direct consequence of a myocardial infarction (MI) can be dizziness and/or syncope, both of which often lead to a fall. That is why fall detection is to be included as a component of the system being developed. In order to gain a sufficient overview of the topic, the following section will shed light on existing solutions that could be of use in the further development of the service.

Before going into depth with fall detection systems, it would be beneficial to first get an overview of the mechanics behind the human gait – specifically, that of the elderly. The human gait can be considered to be the style of walking for individual people[103]. Walking in humans is a type of locomotion, described as "striding bipedalism", which involves the use interchanging use of two legs, while also constantly alternating the center of gravity over each foot[103]. The human gait is a learned skill and therefore it can differentiate from one person to another, however there is an overall consensus that there is a deterioration of locomotion skills among senior citizens[104]. In fact, falls have been such an issue for the elderly that they are actually the leading cause of death from an injury[105]. An important parameter is the so-called "long lie", which is where, after a fall, an individual remains on the ground for an hour or more[106]. The significance of the long lie is that half of those that experience it die within the following six months[106].

#### 5.3.1 EXISTING SOLUTIONS

Research on fall detection algorithms for the elderly has concluded that there are two general types of fall detection systems (Figure 5): one that includes wearable devices and that utilizes non-wearable devices[107]. Additionally, the former can be divided into devices based on an accelerometer and devices that include a multitude of sensors working in tandem, while devices from the latter may be based on visual or audio input[107].



FIGURE 5: OVERVIEW OF FALL DETECTION ALGORITHMS[107]

What is of bigger interest are the wearable-inclusive algorithms. There have been numerous propositions for fall detection systems that are based solely on accelerometer input and there is a general similarity in the algorithms that depend solely on acceleration data input: an initial

extraction of the magnitude of its acceleration vector and, consequently, of the amplitude of the differential acceleration[107]. The first thing to monitor is the acceleration vector (5.1), since it symbolizes the intensity of exertion of the body – during falls this parameter increases significantly and for longer periods of time[107]. After that the amplitude of the differential acceleration is calculated for the acceleration vector's high-value groupings (5.2) – a significant increase in the amplitude would implicate a fall[107]. After these two steps individual algorithms have had different additional steps that are often used to further improve accuracy[107].

$$SVM = \sqrt{a_{x^2} + a_{y^2} + a_{z^2}} \tag{5.1}$$

$$MADS = \frac{1}{T_0} \int_0^{T_0} |SVM'| dt$$
(5.2)

A team from Australia presented a solution that consists of placing a singular 2-axes accelometer on the hips of elderly individuals [108]. The placement of the device was such that it was aligned with the vertical and anterior-posterior axe of the human body. The Australians concluded that different fall types had different prediction accuracy, but they also found out that results improve by, not only measuring the magnitude of acceleration, but also its sign change[108]. Another study, conducted by a team in Germany, proposes the implementation of the accelerometer at head level (specifically within a hearing aid housing)[109]. The study results in the conclusion that there are three trigger thresholds for fall detection: (1) the acceleration sum-vector of the xy-plane (where x-axis denotes the frontal axis and the y-axis denotes the sagittal axis) is higher than 2g, (2) the velocity sumvector of all axes right before initial contact is higher than  $0.7 \text{ m/s}^{-1}$ , and (3) the acceleration sum-vector of all axes is higher than 6g[109]. The first threshold is related to the direction a person's head was facing - they analyze the x-axis since the eyes are usually aimed at the ground during the fall itself and the y-axis because after the fall the eyes are generally pointed to the side[109]. The z-axis (the vertical axis) was ignored in order to eliminate false alarms from running or sitting down, which cause high accelerations in that specific direction[109]. The second threshold being a velocity sum-vector from all three axes was chosen in order to minimize the incidences of false alarms that would have occurred whenever a user laid their head down on a bed. Velocity was calculated via the following integral:

$$V_0 = \int_{t_1}^{t_0} a(t) dt$$
 (5.3)

In essence, it is the same as the one in (5.2) with different annotations. In the equation above  $t_0$  is the moment of impact and  $t_1$  is 1500 ms later – the period of 1500 ms was extracted empirically, as it was observed that 1500 ms after initial impact there were no significant changes along the different axes since at that point the person's body is immobile[109]. The third parameter, the acceleration sum-vector threshold was used because it was not reached in any of the daily life simulations, only with the intentional falls. What is also significant is the fact that by utilizing the acceleration sum-vector they were able to identify dangerous falls such as those on staircases, which could be missed by the first two thresholds[109]. A few years later a team from Taipei proposed a similar solution, where they used a 6-axes accelerometer, placed at head level[110]. The parameters they utilized in their algorithm were then the sum-vector of all axes, the sum-vector of the horizontal plane, the timestamps for the falling body at rest and for its initial impact with the ground, as well as the reference velocity,

which similarly to [109] has not been measured but extracted from the acceleration measurements[110].

In 2005 a team from the Swiss Federal Institute of Technology published and article describing a fall detector within a wrist watch that they dubbed "Speedy"[111]. They chose wrist watches as target devices due to their ubiquity and unobtrusiveness and the sensors integrated were two accelerometers to measure along the three main axes[111]. Their detection algorithm included three thresholds, calculated not unlike the ones in [109]: (1) the first one they call the "norm", which is the acceleration sum-vector of all axes, (2) the second is a velocity (5.4), calculated via integration of the norm, while also compensating for the Earth's gravitational acceleration (9.8 m/s<sup>2</sup>), and (3) the third is a second velocity (5.5), calculated similarly to the previous one, only the separate axis parameters are integrated separately and the Earth's gravitational acceleration is also subtracted separately.

$$V_1 = \int \left( \sqrt{a_x^2 + a_y^2 + a_z^2} - 9.81 \right) dt$$
(5.4)

$$V_2 = \sqrt{(\int a_x dt)^2 + (\int a_y dt)^2 + (\int a_z dt)^2} - \int 9.81 dt$$
(5.5)

Calculated as in (5.1), the norm indicates the intensity of body movement, regardless of orientation, used to indicate a possible significant event. The first velocity parameter (5.4) is used to eliminate significant movements along the horizontal plane where the Earth's gravitational acceleration would be constant. The second velocity (5.5) is used so as to account for fast accelerations in the vertical plane, where velocity would be inaccurately estimated via the first velocity parameter[111]. The Swiss team demonstrated that their algorithm could handle situations such as handshakes without raising false alarms (which can be challenging due to the placement of the device on the wrist) and detect forward-facing falls 100% of the time. However, the algorithm had difficulty detecting backward-facing and sideway falls, bringing the overall success rate down to 65%[111].

Another accelometer-based fall detection system to be reviewed here was introduced by a team from Australia[112]. The proposed system consisted of 3 main elements: the PreventaFall ambulatory monitor, the MiiLink data portal and a remote data server[112]. The PreventaFall monitor contains a tri-axial accelometer that the user wears at their waist - the monitor rests in a charger overnight, in the morning the user puts it on and in the evening they let it charge again. While the monitor is active, it continuously sends data to the MiiLink where the data is stored to a Secure Data memory card. Once every day this data is transmitted to the remote server via a Local Area Network or by dial-up[112]. The novel approach to this system is that every day the user is tasked with performing a risk assessment of sorts – they perform a number of actions according to instructions and their performance is monitored by the PreventaFall and related to the MiiLink[112]. In the event of a fall a twoway audio channel is established from the PreventaFall, via the MiiLink, with the appropriate responder [112]. Additionally, there are alternatives as to who that responder could be - if after the fall the user recovers and is active the call would be to a neighbour/friend/family member, otherwise emergency services would be contacted[112]. Another element of the service relies on remote processing - as it has already been mentioned at the end of each day, the recorded data by the MiiLink is sent to e remote server[112]. These servers keep track of the longitudinal records <sup>13</sup>of every user, which are constantly updated with daily ambulatory data, as well as the data from the self-assessments and are re-examined, in order to attempt to establish any long-term patterns[112]. Lastly, the data on these remote servers is made accessible to relevant third parties, such as physicians[112].

The final purely accelerometer-based solution is one proposed as recently as 2016 by a team from Switzerland who based their algorithm on using a smartwatch[113]. With a 40 Hz sampling rate of the three axes of the onboard accelerometer (that discounts the gravity component); they again calculate the norm according to (5.1). They identified an upper threshold of 10-to-18 m/sec<sup>2</sup> and a lower threshold of 2-to-7 m/sec<sup>2</sup> [113].Incoming data is sifted through searching for values above the upper threshold. When such an event is detected they then look for a vale bellow the lower threshold within 0.5 seconds after the upper threshold has been crossed – if that has also been detected then a fall is suspected[113]. In order to confirm whether a fall has actually taken place, they analyze data in 6-second-windows, within which a count is kept of suspected fall events:  $X \le$  counter <Y, where X = 1 and  $Y = (5 \div 10)[113]$ . If the counter value is less than 1 then this would indicate that the user has possibly made some sudden movement; if the counter value equals or is larger than Y then that would point to a different type of activity, e.g. running[113].

There is a consensus that fall detection systems, which depend purely on accelerometers, can have a higher risk of false alarms (largely due to the sensitivity of the results to the chosen thresholds); however, their implementation in conjunction with other sensor can significantly reduce said risk[107]. An example of such a system is that of the French TIMS-IMAG lab, which employs the so-called "actimeter" that incorporates three different sensors: an accelerometer to measure vertical acceleration, a position tilt switch to indicate the orientation of the wearer's body and a vibration sensor to measure the surface vibrations of the body[114]. Their detection algorithm consists of two considerations: (1) whether any vibrations been detected, and if so (2) if the body in a "laying" orientation and the vertical acceleration limit has been exceeded, then the person has indeed suffered a fall[114].

Meanwhile, a team from the Shibaura Institute of Technology in Tokyo has proposed a solution that involves the use of an Android smartphone, along with an external pulse wave sensor[115]. Up until the moment of publishing their paper the team had not yet connected the two components so, in effect, they had developed two separate systems, dedicated to fall detection - one, consisting of a smartphone application, and the other - a ubiquitous pulse wave sensor that they developed themselves, that nevertheless were supposed to function in tandem[115]. The first steps in their algorithm were at the application level, where the accelerations and angular velocities are monitored. Two thresholds are set for each of the parameters: (1) the acceleration for all three axes is below  $\pm 3 \text{ m/s}^2$ , and (2) angular velocity is above  $\pm 30$  deg/s[115]. The team investigated different placements of the smartphone along the user's body, including back pocket, chest, thigh, waist[115]. Among these four placements it was observed that the thigh location produced the most inaccurate results (from 20% detection rate in the applications first iteration, to 90% in its second)[115]. If the abovementioned thresholds have been reached, then the next step would be to confirm the suspected fall by measuring the pulse wave pattern with their own developed device. They tested the pulse wave patterns of 15 people across 150 falls (including incidences where the person would stumble but not fall)[115]. It was observed that at the beginning of a fall there is

<sup>&</sup>lt;sup>13</sup> Longitudinal record – data about an individual, collected over long durations of time[166]

a drop in blood flow, after which two major patterns emerged [Figure 6]: (1) if the blood flow rate returned to its previous equilibrium then there had not been a fall, and (2) if the pulse rate remained decreased then a fall had occurred. However, as it can be seen in Figure 6 there have also been blood flow patterns that could not be attributed to either pattern.



FIGURE 6: BLOOD FLOW RATE PATTERNS[115]

Additionally, the paper [115] does not provide accurate data as to what a significant decrease in pulse rate constitutes and after how long should the pulse rate return to normal in order to be identified as a non-fall (or if it is indeed a fall).

A joint team from the USA and Vietnam proposed a fall detection algorithm that utilized data from an accelerometer and a gyroscope, housed within a sensor placed at chest level[116]. Their results achieved a sensitivity <sup>14</sup> of 96.3% and a specificity <sup>15</sup> of 96.2% - a definitive high among the rest of the solutions examined in the current section. Their algorithm starts off with calculating the acceleration sum vector according to (5.1) with data from the accelerometer, as well as the calculation of the sum vector of the angular velocity following the same calculation principle, based on data acquired from the gyroscope.

$$\omega = \sqrt{\omega_x^2 + \omega_y^2 + \omega_z^2} \tag{5.6}$$

They noted that when the device is stationary, the acceleration sum vector equals +1g and angular velocity is 0°[116]. They have also determined two different acceleration thresholds – a lower (0.30-0.35 g) and an upper (2.4 g) fall threshold – as well as an angular velocity threshold (240°). Their algorithm depended on sifting through the incoming data for a sum acceleration vector value below that of the lower fall threshold. When one is detected they then examine the following 0.5 seconds looking for acceleration above the higher fall threshold and angular velocity above the angular velocity threshold. If both of those incidents are detected within the abovementioned time period, then a fall has been detected[116].

<sup>&</sup>lt;sup>14</sup> Sensitivity – also referred to as true positive rate or recall; it is utilized in order to evaluate how many positives were correctly identified as such, e.g. how many of all falls were successfully detected[167].
<sup>15</sup> Specificity – also referred to as the true negative rate; it is utilized so as to measure how many negatives have been correctly been identified as such, i.e. how "few" false alarms have been detected[167].

#### 5.4 SMARTWATCH CAPABILITIES

Smartwatches appear to be an appropriate device to be a component within the system; therefore a brief overview of their essential features will be provided in the current section. Taking into consideration the delimitation that Android Wear-based devices are to be utilized; only smartwatches with the aforementioned operating system would be examined. The overview to be presented will be in the form of the following table (Table 2). The features to be examined across the various smartwatch models are whether they are SIM-enabled (therefore having direct contact with a cellular network, rather than via a companion smartphone); what their connectivity capabilities are; whether they have an onboard PPG sensor and what types of motion sensors they possess. The specific devices to be examined are the ones present in the official device list of Android Wear<sup>16</sup>[14].

Smartwatch model	SIM- enabled	Connectivity capabilities	PPG	Motion-related sensors
Montblanc Summit[117]	No	Bluetooth 4.1, BLE Wi-Fi 802.11 b/g/n	Yes	Accelerometer, gyroscope, e- compass, barometer
Huawei Watch 2[118]	Yes	LTE, TD- SCDMA, GSM, Bluetooth 4.1, BLE, Wi-Fi 802.11 b/g/n	Yes	Accelerometer, gyroscope, compass, barometer
Huawei Watch[119]	No	Bluetooth 4.1, BLE, Wi-Fi,	Yes	Accelerometer, gyroscope, barometer
Tag Heuer ConnectedModular 45[120]	No	Bluetooth 4.1, BLE, Wi-Fi 802.11 b/g/n	No	Accelerometer, gyroscope, tilt detection sensor
<b>ZTE Quartz</b> [121]	Yes	GSM/EDGE, HSPA, Bluetooth BLE	No	Accelerometer, gyroscope, barometer
New Balance RunIQ[122]	No	Bluetooth 4.0, Wi- Fi 802.11 b/g/n	Yes	Accelerometer, gyroscope
Casio Pro Trek Smart[123]	No	Bluetooth 4.1, BLE, Wi-Fi 802.11 b/g/n	No	Pressure (air pressure, altitude) sensor, accelerometer, gyroscope, compass
LG Watch Style[124]	No	Bluetooth 4.2, BLE, Wi-Fi 802.11 b/g/n	No	Accelerometer, gyroscope
LG Watch Sport[125]	Yes	GSM, WCDMA, UMTS, LTE,	Yes	Accelerometer, gyroscope, barometer

TABLE 2: SMARTWATCH FEATURES OVERVIEW

<sup>&</sup>lt;sup>16</sup> It should be noted that a small number of smartwatch models from the official Android Wear listing are not present; that is because they have counterparts present in Table 2 from the same manufacturer with identical relevant features. These are: Moto 360 for Women, Michael Kors Access Dylan, Fossil Q Marshal, Casio Outdoor Watch, Tag Heuer Connected[14].

		Bluetooth 4.2, BLE, Wi-Fi 802.11 b/g/n		
LG Watch Urbane 2 <sup>nd</sup> Ed. LTE[126]	Yes	GSM, HSPA, LTE, Bluetooth 4.1, BLE, Wi-Fi 802.11 b/g/n	Yes	Accelerometer, gyroscope, compass, barometer
LG Watch Urbane[127]	No	Bluetooth 4.0, Wi- Fi	Yes	Accelerometer, gyroscope, compass, barometer
<b>Polar M600</b> [128]	No	Bluetooth 4.2, Wi- Fi 802.11 b/g/n	Yes	Accelerometer, gyroscope
Michael Kors Access Bradshaw Smartwatch[129]	No	Bluetooth 4.1, Wi- Fi 802.11 b/g/n	No	Accelerometer, gyroscope
Fossil Q Wander[130]	No	Bluetooth 4.1, BLE, Wi-Fi 802.11 b/g/n	No	G-sensor, gyroscope
Fossil Q Founder[131]	No	Bluetooth 4.1, BLE, Wi-Fi 802.11 b/g/n	No	Accelerometer, gyroscope
The Mission, by Nixon[132]	No	Bluetooth 4.1, BLE, Wi-Fi 802.11n	No	Accelerometer, gyroscope, altimeter, barometer, compass
Asus Zenwatch 3[133]	No	Bluetooth 4.1, BLE, Wi-Fi b/g/n	No	Accelerometer, gyroscope
Asus Zenwatch 2[134]	No	Bluetooth 4.1, Wi- Fi b/g/n	No	Accelerometer, gyroscope
Moto 360[101]	No	Bluetooth 4.0, BLE, Wi-Fi b/g	Yes	Accelerometer, gyroscope
<b>Moto 360 Sport</b> [135]	No	Bluetooth 4.0, BLE, Wi-Fi b/g	Yes	Accelerometer, gyroscope, barometric altimeter

A few observations can be made while examining Table 2:

- 1) Concerning motion-related sensors, all of the examined watches contained at least a gyroscope and almost all had an accelerometer. The exceptions were two Fossil models that nonetheless contained a G-sensor, which still measures acceleration, only it does so with the gravitational component[136].
- 2) Of the listed 20 devices in Table 2, half of them contain an integrated optical heart rate sensor. Overall, of the 25 officially listed Android Wear devices, 11 have a PPG sensor, i.e. 44% of official Android Wear devices have an optical heart rate sensor.
- 3) All Android Wear devices have Bluetooth and Wi-Fi capabilities.
- 4) Among all of the 25 Wear devices, only 4 (16%) have incorporated SIM capability and the accompanying network access, such as GSM/LTE/etc. However, it ought to be noted that before the release of Android Wear 2.0 earlier in 2017 Wear-based smartwatches were not able to support standalone applications, rather they had to rely
on companion smartphone apps[137]. However, the aforementioned 4 devices are among the 7 (57%) smartwatches released to the market with pre-installed Android Wear 2.0 have integrated SIM. Having SIM-integration rate jump from 0% during pre-Wear 2.0 to 57% within the Wear 2.0 era, would suggest that now that Android Wear smartwatches can function independently from smartphones, independent network capabilities would become more common among future devices.

It ought to be noted that the abovementioned devices are constrained when it comes to power performance: they can typically have a battery life of up to a day-and-a-half with mixed use[101] [122][138][128].

## 6 ANALYSIS

The following chapter is dedicated to combining data from previous chapters along with newly introduced primary research (in survey- and interview-form) and analyzing them in order to establish the requirements specification that is essential for the subsequent chapter.

# 6.1 INTEGRATION OF PARAMETERS TO BE MEASURED WITHIN THE INTENDED DEVICES

The first section of the current chapter is dedicated to fulfilling an objective from section 2.2 of the Problem Formulation chapter and it is the following:

#### Determine what devices would be necessary so as to fulfill the functionalities of the system.

The Ischemic Heart Disease chapter concluded with overview of the parameters that have to be monitored in order to determine whether a stroke or an MI is occurring. The Measuring an Electrocardiogram and section of the State of The Art chapter is also dedicated to the devices that could be used to measure the two main physiological parameters – the user's ECG and their heart rate. The following section of the chapter is dedicated to establishing a connection between the parameters to be monitored and the devices that would be utilized towards that purpose.

#### 6.1.1 DETECTING ALARMING PULSE PATTERNS THROUGH A PPG

As it has been shown in Table 1 in the Ischemic Heart Disease chapter, arrhythmias commonly accompany AMIs and SCDs and when an individual is experiencing an arrhythmia it would almost always lead to an abnormal heart rate – consider the aforementioned table from the previous chapter, where it can be seen that bradycardias relate to heart rates lower than 60 bpm and that tachycardias are associated with heart rates above 100 bpm.

Consider also the brief overview of the cardiovascular system as a whole, presented in section 4.1 of the Ischemic Heart Disease chapter. It relates how the left heart pumps oxygenated blood to the rest of the body. It does so rhythmically and so the blood throughout the cardiovascular system does not flow in a smooth continuous motion but rather in waves[96]. These waves are driven by increased pressure so that they would reach the whole of the body and the force of their passing causes the larger blood vessels to expand briefly[96]. It is this rhythmic expansion of blood vessel walls due to pressure, created by the heart that is referred to as a pulse.

A brief overview of the working of PPG sensors was presented in section 5.2 of the previous chapter, where it became known that the aforementioned sensors emit light at specific wavelengths and then use photodetectors to measure the absorption rate of the blood. However, the working principle behind these sensors was discovered in 1938 and it involves the relation between blood volume and the amount of backscattered light[139]. It states that the amount of light absorbed by illuminated skin with an arterial blood vessel close to the surface depends on the contents and properties of the blood within the aforementioned vessel[139]. As it was previously mentioned, the blood within the blood vessels in question flows in waves - therefore there is a rhythmic change of the volume and properties of the

aforementioned blood. It is these changes that the PPG sensor measures and from which the heart rate is extracted.

#### 6.1.2 DIAGNOSING AN AMI THROUGH AN ECG

As it has already been mentioned in the Ischemic Heart Disease chapter, the human heart has its own conduction system, which serves to regulate the contractions of its four chambers via alternating depolarizations and repolarizations. It is exactly these changes in potential that are detected via an electrocardiograph. An ECG complex of sinus rhythm, i.e. regular heart rhythm, dictated by the SA node[59], is shown in Figure 7.



FIGURE 7: ECG COMPLEX[140]

The figure above includes the annotations of the various components and segments of the sinus ECG complex, where the vertical deflections depict voltage variations and the horizontal axis reflects time. Section 4.1 of the Ischemic Heart Disease chapter included a brief description of the usual way electrical impulses travel throughout the cardiac conduction system, starting with the spontaneous depolarization of the SA node and ending with the depolarization of both ventricles. The aforementioned vertical deflections of ECG readings reflect the depolarization and repolarization processes that take place within the various sections of the heart at any given moment - the figure bellow (Figure 8) illustrates this exact connection.



FIGURE 8: CARDIAC CONDUCTION SYSTEM WORKINGS REFLECTED ON ECG [141]

The initial component of the ECG complex is the P wave – it illustrates the depolarization of the atria[142]. In sinus rhythm the P wave always precedes the QRS complex, and is upright I leads I, II, aVF, V2-V6 – if that is not the case then it would indicate that the atrial depolarization process was not initiated by the SA node[142]. Following the P wave is the QRS complex, which depicts the depolarization of the ventricles[142]. Some of the most dangerous arrhythmias affect the ventricles directly and as such they can often be observed as anomalous deflections within the QRS complex as is the case with VT, discussed in the Ischemic Heart Disease chapter. Following the QRS complex is the T wave, which signifies the ventricular repolarization[142]. Between the two is the ST segment, which includes the last of the ventricular depolarization process and the beginning of their repolarization[142]. The point where the QRS complex concludes and the ST segment begins is called the J point[142].

As it can be seen in Figure 7, when interpreting the results of an ECG reading, it is not only its individual components that have pathological significance, but also some different time intervals, marking the duration of transitioning from one component to another. The first time period of interest is the PR interval – it represents the time it takes for the depolarization wave to get from the atria, through the AV node and into the myocardium of the ventricles[142]. Following is the QRS interval, which reflects the time it takes for the depolarization wave to spread throughout the ventricles themselves[142]. Lastly, there is the QT interval, which is a measure of how long it takes for the ventricles to experience, both depolarization, and repolarization[142].

#### 6.1.3 VIXI DEVICES AND THE USER



FIGURE 9: OVERVIEW OF DEVICES IN RELATION TO THE USER'S BODY

The figure above (Figure 9) is presented in order to provide an overall view of the Vixi devices when it comes to their relation with the user and their placement on the user's body. From the previous section of the current chapter and from the Ischemic Heart Disease chapter it has become apparent that an ECG can provide a multitude of information as to the workings of the human heart, making it an incredibly useful tool in detecting signs of IHD. From the State of The Art chapter it is also known that there are long-term wearable versions of the ECG machine on the market. Therefore it has deemed necessary that a wearable ECG will be a part of the Vixi system. Additionally, the Ischemic Heart Disease chapter has shed light on the fact that pulse rate can be used as an indicator for certain IHD conditions. From the State of The Art chapter it is known that a wearable realization of a pulse rate sensor is the smartwatch, which is a proposed component of the system. Lastly, the user's smartphone would also be a component of the Vixi system.

#### 6.2 ELDERLY SURVEY

The present section of the chapter is intended to fulfill the following objective of section 2.2 of the Problem Formulation chapter:

Get in contact with potential representatives of the target customer segment so as to gain insight into their needs and interests regarding the service.

Thus gathering information towards the answering of one of the subquestions from section 2.1 of the aforementioned chapter:

How can the proposed solution be made to suit the needs of the target population segment?

#### 6.2.1 HYPOTHESES

During the process of working on the current Thesis, a few hypotheses <sup>17</sup>emerged as to what the acceptance would be of the designated target segment towards system being developed. Given that the system is intended for commercial realization, it was acknowledged that input from elderly individuals should be taken into consideration. The hypotheses that needed to be tested were the following:

- 1) Senior citizens would not mind wearing a smartwatch, most probably due to its resemblance to the regular wristwatch that has been a staple accessory for many years.
- 2) Due to the fact (unlike the smartwatch with its wristwatch counterpart) the wearable ECG does not have a real-world analogue, elderly individuals would not be quite as willing to wear it on a daily basis.
- 3) People that have had encounters with cardiovascular diseases would be more apprehensive of the risk they pose and more willing to use the system being developed, as well as its accompanying devices.
- 4) People's attitudes towards the service could be influenced by the opinions of their personal physicians.
- 5) People would like for their personal physicians to have access to any medicallyrelevant data, gathered by the service.
- 6) In case of an emergency people would like to contact, not only emergency services, but also family members, friends, etc.
- 7) People could feel apprehensive towards unnecessarily occupying the emergency services' time and in case of a detected emergency they might not want to have them contacted, rather family members, friends, etc.

In order to confirm or discredit these hypotheses, as well as to gain insight into other matters, a survey was conducted. The details of the survey itself will be reviewed in the following section. Every question will be reviewed, along with the corresponding summarized answers from the participants and the resulting conclusions that can be drawn from them.

#### 6.2.2 CONTENTS AND RESULTS FROM THE SURVEY

The survey itself was in the form of a digital online survey. The platform used to conduct it was Google Forms[143]. The survey was divided in three sections: (1) section for choosing the language of the survey, (2) English version of the survey, and (3) Bulgarian version of the survey. When the person being surveyed starts filling out the survey the first section they see is the one that has a single question offering a language choice (1). When they make their choice, they are redirected accordingly to, either the English version of the survey (2), or the Bulgarian one (3). After they fill out the entirety of either section, the survey can be submitted. It should be noted that both versions of the survey have identical contents, therefore only the contents of the English section will be looked into in the current chapter, while the Bulgarian version of the survey will be included in the Appendix.

There were a total of 46 individuals that participated in the online survey and they responded to the following questions.

<sup>&</sup>lt;sup>17</sup> Hypothesis – an idea, which can be verified or discredited via experimentation[168]

The first question of the section is used to establish the age of the participant, where participants are allowed to choose from four age categories (Figure 10). Although people are considered "elderly" when they are at least 60-years-old, the additional age groups were included because of the supposition that those close to the target age are of a similar mindset. The age distribution among the participants can be found in Figure 11. As it can be seen, 21 out of 46 participants were at least 60-years-old, meaning that almost half of those surveyed are within the desired market segment. Among the remaining age groups there is downward trend of, both the number of participants, and the corresponding ages – the second largest group are the 55-to-60-year-olds, followed by the 50-to-55-year-olds and lastly there are the 45-to-50-year-olds.

1. How old are you? \*

0	45-50
0	50-55
0	55-60
0	60+

FIGURE 10: ESTABLISHING PARTICIANT AGE



#### FIGURE 11: PARTICIPANT AGE DISTRIBUTION

The second question is related to the  $3^{rd}$  hypothesis, presented in the previous sub-section. The question is aimed at establishing the mindset of the participant when it comes to CVD – this is an attempt to establish if people that have chosen one of the first two options show a larger concern for the dangers of CVD (Figure 14) or if they are more willing to wear the proposed devices (Figure 18, Figure 20, Figure 22). The participant's responses are shown in Figure 13, where a somewhat equal distribution among the available responses can be seen.

2. Have you or your family had a history of cardiovascular disease? \*

- Yes, I and other members of my family do.
- I am the only one of my family that does.
- 🔵 I do not, but other family members do.
- No, neither I, nor other family members do.

FIGURE 12: HISTORY OF CVD



FIGURE 13: HISTORY OF CVD – ANSWERS

The third question (Figure 14) of the survey has a two-fold significance. Firstly, it is tied to the previous question, meaning that it could reveal if there is a correlation between a participant's history of CVD (or lack thereof) and their apprehension towards the dangers of CVD. Additionally, it will serve to verify whether a higher level of concern on the part of the participant is tied to a higher probability that the participant would be willing to use the proposed devices. The results from the question can be seen in Figure 15. As it can be seen in the abovementioned figure, the majority of participants demonstrated an above-average concern towards the health risks that the current Thesis is trying to address.

How concerned are you about the dangers of a stroke or a heart attack to \* your personal health?
\*Please choose from 1 to 5.







FIGURE 15: GAUGING THE PARTICIPANT'S MINDSET – ANSWERS

The fourth question (Figure 16) was utilized in order to estimate the digital literacy of the participants, specifically when it comes to smartphones. Given the fact that the survey was disseminated digitally, it is acknowledged that a judgment of the overall computer literacy would be a skewed estimation. However, the question is targeted towards the participant's familiarity with smartphones specifically, due to the fact that the smartphone is a proposed component of the Vixi system. Additionally, smartwatch interfaces somewhat resemble those of smartphones. That is also especially relevant in the case of Android Wear, which extremely similar to its originator – the Android OS, which has been the prevalent smartphone OS leader on the global market (reaching a high of 87% in 2016[144]). Summarized results from the question can be seen on the following figure (Figure 17), where an overwhelming majority of the participants responded that they had owned a smartphone at the moment of completing the survey. Additionally, a minority of 4% has never had one but do have some experience, while a distinctive 15% of participants have never had a smartphone and have never worked with one before.

## 4. Have you ever owned a smartphone? \*

- I currently have a smartphone
- I have previously had a smartphone
- I have never owned one but I have experience with smartphones.
- I have never owned a smartphone and I have never used one before.





FIGURE 17: GAUGING THE TECHNICAL COMPETENCY OF THE PARTICIPANT- ANSWERS

The fifth question within the section (Figure 18) serves to test the participant's willingness to use a smartwatch. This is relevant to the first of the hypotheses, expressed earlier in the current chapter. In order to be as close to a real-life scenario as possible, an Android Wear smartwatch had to be depicted. There are a number of brands with Android Wear watches, therefore the one chosen for the survey image is the one to be utilized as a proof-of-concept and that is the Moto 360. Due to the unpredictable economic backgrounds and privacy concerns of the participants, these potential concerns are addressed within the premise of the question. Additionally, in the case that any other participant concerns were not addressed in the premise of the question, other than the Yes/No options the participants were presented with the possibility to supply their own unique answer ("Other"). The responses for this question are shown in Figure 19, which shows that an overwhelming majority – 91% - of the participants expressed a willingness to wear a smartwatch.

5. Given that it is affordable and that your personal data will be saved only on \* your device, would you wear a smartwatch (an example is pictured bellow) if it benefited your personal health and safety?



O Yes

🔿 Na

O Other...

FIGURE 18: VERIFYING THE PARTICIPANT'S WILLINGNES TO WEAR A SMARTWATCH



FIGURE 19: VERIFYING THE PARTICIPANT'S WILLINGNES TO WEAR A SMARTWATCH – ANSWERS

The sixth question (Figure 20) is relevant to the second hypothesis, wherein the willingness of the participant to use a wearable ECG is questioned. As in the previous question, privacy and financial concerns are addressed within the question, in order not to receive a more direct answer from the participant without it being distorted by them. Additionally, the open "Other" answer option was again also included. The wearable ECG depicted in the survey is the QardioCore, which is among the most recently developed products of this type[87]. The resulting answers to the question are shown in Figure 21, where it can be seen that 67% of

participants answered positively. A single participant could not make a definitive decision and indicated that their choice would depend on the condition of their health.

6. People that have had heart attack are at even a higher risk of experiencing \* another one. If you had a heart attack, would you use a wearable ECG (example pictured bellow) if it would detect the onset of another one? \*Keep in mind that the device would be affordable and all your data will be kept private.



Yes
No

O Other...

FIGURE 20: VERIFYING THE PARTICIPANT'S WILLINGNESS TO WEAR AN ECG (1)



FIGURE 21: VERIFYING THE PARTICIPANT'S WILLINGNESS TO WEAR AN ECG (1) - ANSWERS

The seventh question (Figure 22) in this section of the survey is almost identical to the previous one but it was modified so as to test the fourth hypothesis, where it is proposed that the participant's attitude might be influenced by their doctor's recommendation. Once more there was the option for the participants to choose "Other" as an answer, where they could elaborate further on their decision. The accompanying answers can be found in Figure 23.

7. Would you use a wearable ECG (example pictured bellow) if your doctor \* recommended that you do so?

\*Keep in mind that the device would be affordable and all your data will be kept private.



🔿 Yes

() No

O Other...

FIGURE 22: VERIFYING THE PARTICIPANT'S WILLINGNESS TO WEAR AN ECG (2)



FIGURE 23: VERIFYING THE PARTICIPANT'S WILLINGNESS TO WEAR AN ECG (2) - ANSWERS

The eighth question within the survey (Figure 24) serves to verify the fifth hypothesis, which states that the involvement of a personal physician would be desirable to potential users. The participants' responses can be seen in Figure 25, where 100% of participants responded positively.

8. If you were using a smartwatch/wearable ECG, would you like to have the \* option of your doctor being able to access the medically-relevant data gathered (such a pulse and ECG readings)?

0	Yes
$\bigcirc$	No

-	
$\cap$	Other
	oule



FIGURE 24: VERIFYING THE DESIRED INVOLVEMENT OF A PHYSICIAN

FIGURE 25: VERIFYING THE DESIRED INVOLVEMENT OF A PHYSICIAN – ANSWERS

The ninth and final question of the survey (Figure 26) is intended to test the sixth and seventh hypothesis, where it is suggested that people might like to have more than one entity contacted in case of an emergency (that is why the question has a multiple-choice answer) and that the emergency services might not even be among those entities. The participants' answers to these questions are shown in Figure 27, where it can be seen that in fact the top two choices for emergency contacts are emergency services and family members.

9. If your device (smartwatch/wearable ECG) detects that you are having a heart attack or a stroke, who would you like to have the option to be contacted?

\*More than 1 answer is allowed.

Emergency services (112)
Your General Practitioner (GP)
Family member
Friend
Neighbour
Other

#### FIGURE 26: IDENTIFYING DESIRED EMERGENCY CONTACTS



FIGURE 27: IDENTIFYING DESIRED EMERGENCY CONTACTS – ANSWERS

\*

#### 6.2.3 REVISED HYPOTHESES

After introducing the relevant hypotheses at the beginning of the current section and the consequent gathering of the necessary data from the survey participants, the next step would then be to reexamine the proposed hypotheses in the light of the newly acquired information. The following part of this section will therefore be dedicated to individually revising all of the proposed hypotheses.

### Hypothesis 1

The first hypothesis states that participants would be more willing to wear a smartwatch due to its resemblance to the regular wristwatch, which has been pervasive within Western culture for some time. The fifth question of the survey served to at least partially verify the abovementioned hypothesis. Although the underlying motivation is not apparent, from the participants' answers it became known that 91% of them are willing to wear the device – a clear indicator to the viability of such a device as being an essential component of the service. The overwhelming majority of positive answers confirms the hypothesis.

## Hypothesis 2

The second hypothesis declares that the elderly would not be as willing to use a wearable ECG, as they would a smartwatch. The fifth and sixth questions of the survey were dedicated to verifying this hypothesis. Again, although the underlying motivation is not known, the results from these questions -91% of those surveyed answered yes to a smartwatch, while 67% answered yes to the wearable ECG – show that a smartwatch would indeed be a better choice for the service when it comes to user preference. The abovementioned results confirm the validity of the hypothesis.

#### Hypothesis 3

The third hypothesis indicates that individuals that have had a history of CVD, whether personal or familial, might display a larger concern for such health conditions along with a willingness to make use of the service and the devices it requires. In order to verify or discredit this hypothesis, the results of questions 2, 3, 5, 6 and 7 must be analyzed. This will be done by segregating the participant answers into four groups that are defined by the possible answers to question 2, meaning: (1) those with no history of CVD, (2) those with personal and familial history of CVD, (3) those with strictly personal history of CVD, and (4) those with strictly familial history of CVD. The analyzed results to questions 2, 3, 5, 6 and 7 can be seen in Table  $3^{18}$ .

<sup>&</sup>lt;sup>18</sup> The percentages given for Questions 5, 6 and 7 indicate a positive response, i.e. participants that answered "Yes" to the corresponding question.

Group type	Percentage of overall participants (Question 2)	Average rate of concern (Question 3)	Willingness to wear a smartwatch (Question 5)	Willingness to use a wearable ECG (Question 6)	Willingness to use a wearable ECG with doctor's recommendation (Question 7)
No history of CVD	28%	2.6	100%	62%	69%
Familial and personal history of CVD	28%	3.5	77%	62%	77%
Personal history of CVD	11%	3.2	80%	100%	100%
Familial history of CVD	33%	3.3	100%	67%	73%

TABLE 3: RELEVANT ANSWERS ACCORDING TO GROUP TYPE

From the contents of Table 3 a few conclusions can be made:

- 1) Individuals with no history of CVD do show a lesser degree of concern, albeit not a significant one compared to the other participant groups there is an average difference of 0.7 on the scale of 1-to-5, or 14%.
- 2) The lack of history of CVD does not reduce one's willingness to wear a smartwatch 100% of participants with no CVD history agreed to it.
- 3) The lack of history of CVD does not seem to have a distinctive influence on the participants' willingness to use a wearable ECG 62% of those with none agree to wear one, which is comparable to those with strictly familial (67%) and equal to those with familial and personal history (62%). They do seem to be less influenced by a doctor's opinion.
- 4) A significant result might be the fact that all 100% of people with a strictly personal history of CVD would agree to use a wearable ECG, with or without a doctor's recommendation. However, it ought to be noted that at 11% they represent the smallest segment of participants considering the relatively small number of participants in total (46), further investigation into this group type should be carried out before such a definitive conclusion can be made.

Overall the hypothesis has mostly been discredited: individuals with a familial and/or personal history of CVD do express a larger concern for the detriments of CVD but they do not exhibit a significantly higher willingness to wear a smartwatch or an ECG.

#### Hypothesis 4

The fourth hypothesis states that the participants' opinions towards the proposed service would be influenced by the opinions of their personal physicians. In order to test this

hypothesis, the sixth question (regarding the wearable ECG) was repeated in place of the seventh question, only it was modified so as that it would include the involvement of a doctor. Comparing the results from the sixth and the seventh questions, it can be seen that the segment of participants willing to use an ECG rises from 67% to the more substantial 76%. Additionally, two of the participants chose "Other" as an answer to the seventh question – it should be noted that both of them conveyed that they would be willing to wear such a device after they got a second opinion from another doctor. Nevertheless, the overall results serve as validation for the hypothesis.

## Hypothesis 5

The fifth hypothesis proposed that elderly individuals that make use of the service would want their personal physicians to have access to their medically-relevant data. This hypothesis is verified by the eighth question of the survey with extremely positive results – with 100% of those surveyed answering yes, this is the only question on which all participants agreed fully. The unified response serves to validate this hypothesis.

## Hypothesis 6

The sixth hypothesis introduces the idea that in emergency situations individuals would want to contact more than just emergency services. This hypothesis was verified with the ninth question of the survey, which showed that most participants do want to contact emergency services (93.5%), however almost as many (82.6%) want a family member involved. Additionally, half of the participants (52.2%) indicated that they also wanted their personal physician to be contacted. The results above stated confirm the validity of the hypothesis.

#### Hypothesis 7

The seventh and last hypothesis states that elderly individuals might not feel comfortable with contacting emergency services upon the detection of an event. This was tested with the ninth question of the survey, where 93.5% of participants indicated that they wanted to make use of emergency services. This would mean that only 6.5% of participants rejected emergency services as a potential contact, thus discrediting the proposed hypothesis.

#### **Additional conclusions**

The results from the survey have also lead to some additional conclusion. To start with, the initial overview of the devices within the Vixi system (Figure 9) has to be reexamined. It is significant that even with the verification of Hypothesis 2 and with an accompanying recommendation from their personal physician a quarter of participants did not answer positively to the notion of a wearable ECG. Considering the conclusions from the Ischemic Heart Disease chapter, these results can prove to be detrimental to the overall accuracy of Vixi. Therefore, it is proposed that Vixi should be able to function in two different system configurations. The first configuration would include the user's smartwatch (to which the participants of the survey demonstrated an almost unanimous approval and willingness to wear), as well as their smartphone. This would be a more appealing option to a wider customer base but the loss of data input from the wearable ECG is also accompanied by a loss of diagnostic precision. However, there are some certain additional facts, which would allow for the improvement of the diagnostic precision of the smartwatch-based solution. To begin with, research within the Ischemic Heart Disease chapter, concluded that among the possible

symptoms for AMI are dizziness and even syncope. Although a syncope presenting in children in young adults does not necessarily signify a life threatening condition[145], when it comes to the elderly it can be an indicator to a critical cardiac event[146]. Being aware of the falls that often accompany dizziness and syncope episodes, especially among the elderly, it is proposed that fall detection should be incorporated within the service. What is more, the presence of fall detection could help distinguish between sustained arrhythmias at RHR and arrhythmias that are due to physical exertions – sports activities, for example, can require an increase of oxygen intake which would come across as a tachyarrhythmia. This will also create additional value to the service, given that falls themselves in general are a substantial cause for concern among the elderly. It is estimated that up to 35% of people above 65-yearsold and up to 42 % of those aged over 70 suffer from falls[147]. Elderly individuals that have experienced a fall often require hospitalization (more than 50% of hospitalization cases among the elderly are due to falls[147]) and are a major cause of injury-related death with death rates due to falls tending to rise with the increase of age[147]. From the Smartwatch Capabilities section of the State of The Art chapter it is known among the onboard sensors of most available smartwatches is the accelometer and that it is almost always accompanied by the presence of a gyroscope, as well. The Fall Detection section of the aforementioned chapter introduced the fact that there are a number of existing fall detection solutions that rely purely on data from accelometers or that are accelometer based. Therefore, it is proposed that fall detection would be incorporated within the smartwatch via the utilization of its onboard accelometer and gyroscope.

It ought to be noted that despite the added value to the service, fall detection contributes to the detection of cardiac events when they have already had a significant enough of an impact on the human body, i.e. when the brain has suffered from a lack of oxygen. In order to prevent events from progressing to such an extent, as well as the possible accompanying injuries, a wearable ECG should still be a part of Vixi. An ECG would also be able to detect cardiac events that do not result in syncope, or even ones that seemingly have no outward symptomatic manifestation. To iterate once more, the participants of the survey showed some unwillingness towards the ECG, indicating that a scenario where users would be willing to wear it on a daily basis for an indefinite amount of time cannot be relied upon to have credibility in real world exploitation. However, the participants' apprehension was somewhat eased by the potential recommendation of a doctor. Additionally, research conducted in the Ischemic Heart Disease chapter indicated that within the first year after an ACS incident there is a significantly higher risk of morbidity. It is therefore proposed that the wearable ECG component of the system be available for all potential users but that it should be marketed more aggressively to elderly individuals that have had an ACS episode, preferably with the involvement of medical professionals.

#### 6.3 EXPERT INTERVIEW

The current segment of the Analysis chapter will be dedicated to the fulfillment of one of the objectives, presented in section 2.2 of the Problem Formulation chapter:

## Get in contact with professionals in the field of medicine or medically-relevant areas so as to discuss and affirm the discoveries, regarding the physiological aspects of the system.

An important component of the algorithm being developed is medical research. Given the strictly engineering background of the developer it was deemed necessary that an interview

with an expert in the medical or biological field ought to be conducted. Towards the fulfillment of that goal, a number of potential experts were contacted. This included reaching out via online communication to several hospitals within the Greater Copenhagen Area (they can be found in the Appendix), as well as to the official representatives of the Danish Cardiovascular Research Academy (DaCRA). As a result of these efforts an interview was arranged - via the chairman of DaCRA - with Jens Jacobsen, an associate professor with the Department of Biomedical Sciences of the University of Copenhagen. The interview began with a brief introduction into the topic of the Thesis project, along with some details about the system being designed. This information had to be shared in order to provide context for the other party, since the topic overview was only succinctly described in the contact email for the sake of brevity. Although a number of questions had been prepared beforehand in expectation of the interview, the interview itself was in the form of a free flowing conversation. Some of the prepared questions were asked at appropriate times during the conversation, whenever they were touched upon thematically and some were asked at the end of the interview. The following section provides an overview of the topics discussed in the interview, along with the resulting information from the interview itself.

#### Leading causes of death and IHD

The premise of the current Thesis – regarding what the leading causes of death among the elderly are, about the nature of IHD, etc - relies heavily on results from secondary research. As it is necessary, only reliable sources were utilized for secondary research. However, there was a concern that the Engineering background of the author and the lack of experience in the medical sciences would lead to possible misinterpretation of the information available.

Starting with the leading causes of death among the elderly, the interviewee confirmed that they are indeed IHD and stroke. Additionally it was confirmed that the dangerous IHD conditions that generally lead to death are the ACSs, i.e. unstable angina, AMI and SCD. Another key component behind the motivation of the Thesis also received affirmation and that is the presence of the problem with the long lie among elderly individuals and the severity of its consequences.

#### **Sudden Cardiac Death**

Of all the ACSs, perhaps the most severe one is Sudden Cardiac Death. The concern of the author was that, given the nature of the condition, it would require the most immediate medical attention. A discussion with the interviewee revealed that that was the case, however, there is one significant consideration that has to be taken into account. SCD results in the cessation of blood circulation throughout the body, therefore depriving the body's organs of oxygen. Perhaps the most significant impact of that lack of oxygen is on the brain - it can take only three to four minutes of lack of oxygen before brain damage sets in. Once that happens, brain damage can be a substantial burden and a great detriment to the quality of life to an oxygen deprivation survivor. Even discounting the effects of brain damage, a SCD victim still has only a few minutes where they can successfully be resuscitated. It was concluded that, outside of a hospital, a SCD victim would have a chance of survival if, either there was someone with them who was capable of performing CPR on them until medical help was available, or if there was an automated external defibrillator nearby that another person could use on the affected party.

#### Possible actions until receiving access to medical help

During the pre-study research phase, among other information gathered regarding the leading causes of death, was also data as to the emergency medical protocols into their treatment. Among the prescribed medication in the instance of MI is aspirin. Given that aspirin can nearly be considered a household item, two possibilities came into question: 1) should individuals be instructed to take the aforementioned medicine if it is available in their home and 2) are there any other actions that individuals can take before emergency services arrive or before they reach a hospital. Regarding both of these notions, the expert related that it would be inadvisable for an individual to do anything else then to get access to professional medical help. It is a matter of expediency, once an individual becomes aware that they are experiencing an emergency situation, their primary goal ought to be to get themselves to a medical establishment.

#### Sensitivity of single-lead ECGs

As it has already been remarked upon in section 5.2.1, a number of the wearable ECGs available on the market rely on the utilization of only one lead, i.e. they are single-lead ECGs. This has lead to a concern that the symptoms to look for in suspected ACSs may not be as visible on a single-lead ECG as they are on a standard 12-lead device. The interviewee did agree that this could present as a challenge when attempting to detect dangerous patterns. More on this topic is presented in the Future Recommendations chapter because due to time constraints this matter is considered out of scope. The interviewee did suggest that even though there is a possibility that even though a wearable ECG would not provide the same detailed readings as a standard 12-lead, it would still be capable of detecting the various arrhythmias that can accompany ACSs.

#### 6.4 SCENARIOS

Scenarios are useful tools for depicting situations where a product or a service can be of use. Not only that, but they allow for utilizing simple stories in order to get into the mindset of the everyday user[148]. Scenarios provide a usability context to a product in development, so that the end result of the development process does not provide only functionality, but also an ease of use which is a desirable feature for the average potential user. That is especially valid for the algorithm being developed here, whose target population segment can have difficulty handling newer technologies – consider the results of the survey that has been carried out: close to 20% of those surveyed had never owned a smartphone and 15% overall had never even worked with one before. While taking usability into account is one benefit to utilizing scenarios in any development process, another is that they illustrate what the product being developed would consist of, in the sense that the various stakeholders with various technical competences would be able to fully comprehend it[148]. Scenarios can also be a constructive step on the way to determining what requirements have to be fulfilled[148]. Two scenarios will be presented within the current section, each one describing the regular activities of a different senior citizen as an actor over the course of a single day.

#### Scenario 1

The first scenario will follow "a day in the life" of a 65-year-old woman, named Jane who lives on her own. Jane is having a busy day because she has to get to work by 8 o'clock; therefore she gets up at half past 6 in the morning. The first thing she does is to reach over to her nightstand, where her smartwatch has been charging while she was sleeping. She puts it on and then starts her day – this includes taking a shower, getting dressed, having breakfast. By a quarter past 7 she has left her apartment, after which she gets on her bike and rides it to work, where she continues to spend most of her day. After lunch she starts to sweat and she is feeling nauseous. Jane does not get too concerned, she thinks she just has not gotten over the flu she had a few days ago so she decides to go home early. After Jane gets home she still does not feel any better, in fact she starts to feel more and more anxious. Suddenly her smartwatch starts sounding an alarm; she does not turn it off because needs help. Her daughter calls her on the phone, asking her if anything's the matter – Jane relates her symptoms, expressing her worry and anxiety. Her daughter comes by as soon as possible in order to take her to the hospital, where they discover that Jane was having unstable angina that has been developing into an AMI.

#### Scenario 2

The second scenario will focus on John, an 80-year-old retiree who lives on his own. He suffers from atherosclerosis, as well as diabetes. Lately he has been having some trouble sleeping so he is usually up by 6 o'clock and today is no different. The first thing he does is to get a shower and get dressed. While he is doing that he notices that the wearable ECG is still stuck on his chest (his doctor recommended that he wear the ECG after his MI) but he realizes he forgot to put on his smartwatch when he first got up. He corrects this mistake and keeps going with his day. He eats some breakfast, takes his medications and then decides to watch some television. While he is watching he suddenly hears the alarm on his smartwatch – he feels fine so he turns the alarm off. Later on he hears the alarm again – at this moment John starts to get concerned so he decides to call a cab and goes to the hospital, where he is diagnosed as having a silent MI.

#### Scenario 3

The third scenario to be introduced revolves around Jill, a 75-year-old woman who lives with her husband of the same age. Although she is a retiree, she likes to keep herself busy and so she works part-time. Today is another usual day for Jill: she wakes up at 7 o'clock in the morning, puts on her smartwatch, which has been charging all night, gets ready for the day and by 8 o'clock she has left for work. By early afternoon she has finished working and decides to walk home since the weather is nice. As she is walking she suddenly starts to have trouble catching her breath; a few minutes later she starts to feel dizzy and not long after that she faints. Jill does not live in a busy neighbourhood and at this time of the day there is no one in sight. A few minutes later she is suddenly aware of a siren sounding in the distance – it is an ambulance coming to pick her up and take her to a hospital, where it is discovered that she is experiencing ventricular tachycardia. While she was unconscious Vixi contacted the emergency services to notify them of Jill's critical condition, along with her current position, where she can be located.

#### 6.5 SYSTEM CONTEXT DIAGRAM

System context diagrams are useful visualizations for providing a basic overview of the various interactions between the system being developed and other entities outside its boundaries[149]. It is generally considered to be a block diagram but on a much higher level – instead of focusing on the internal workings of the system, it focuses outwards facing other external actors, systems, environments[149]. The following figure (Figure 28) includes the context diagram, depicting the system being developed – Vixi. Below the abovementioned figure brief descriptions of the interactions displayed in it can be found.



FIGURE 28: SYSTEM CONTEXT DIAGRAM

- 1) Vixi and the Elderly User elderly individuals are the target user segments of the system and in that sense interactions with the elderly user are perhaps the most fundamental ones among the systems communications with external entities. The communications taking place between the system and the user go both ways the user can request help from the system, while the system can notify the user when a significant event is being detected.
- 2) Vixi and Family/Friend the relationship between these two entities is purely oneway. When an emergency about a specific user has been detected, the family members and friends of the abovementioned user would be notified of the event.

- 3) Vixi and the Emergency Services these interactions are also unidirectional. In certain critical situations emergency services could be contacted so as to provide the most immediate medical attention.
- 4) Vixi and Hospital Staff although out-of-scope for the current project, a full-scale solution would include the possibility of hospital staff members being able to access the recorded by the system medically-relevant data, such as pulse and ECG readings. This will be elaborated on in the Future Recommendations chapter.
- 5) Vixi and the Personal Physician another segment of the full-scale solution that is mostly out-of-scope for the current project. Included is the option to notify a user's personal physician whenever an emergency is underway. What will be elaborated on in the Future Recommendations chapter is the functionality of the physicians being able to access their patients' medically-relevant data.

#### 6.6 USE CASES

Among the various benefits of utilizing scenarios during the development process is that they can be used to extract use cases[148]. Where scenarios are beneficial for providing a comprehensive overview of the functionalities of the product being developed to all stakeholders, regardless of their technical background and preexisting knowledge; use cases are the tools of more advanced stakeholders[150]. In other words, use cases are scenarios looked at through the prism of a developer's point of view. Use cases provide an overview of the interactions taking place between the product being developed and other outside entities, such as actors or other products/systems[151]. The system being developed is considered as a black box, meaning that its internal workings are not the focus of the use case, but rather the way it interacts with a given actor/system[151]. The figure below depicts a use case diagram (Figure 29). It is a visual representation of the various use cases along with the actors that are associated with them. The figure consists of a Use Case Diagram, which is one of the many tools of the Unified Modeling Language (UML). UML is a part of the current development process due to its general popularity among the developer community. Additionally, brief descriptions of the use cases seen in the figure are provided below it.



FIGURE 29: USE CASE DIAGRAM

1) Register as a User

The first use case to be discussed is the one, taking place whenever an elderly user would initially register to Vixi service. Due to the personalized nature of the Vixi service, each user would have to create his/her own individual account. This would involve choosing a username, a password, as well as some basic personal information such as their name.

Additional information would include age, preexisting medical conditions and emergency contacts.

## 2) Initial Setup

The second use case to be examined is the "Initial Setup". Given that different people have differentiating physiologies, what constitutes as "regular" vital signs - such a variation can be observed with the resting heart rate, which was noted upon in the Ischemic Heart Disease chapter – can be a very singular in nature. In order to improve the overall accuracy of the service, it would be extremely beneficial if the RHR of the individual user was accounted for. The RHR can be measured by two of the components of the system – the smartwatch and the ECG. Given the higher accuracy of the ECG, if a given user is utilizing both devices then the RHR will be extracted from it. However, if that is not the case, then the RHR will be measured directly by the smartwatch. Other possible additional input could be data on pre-existing conditions, etc.

3) Login

The third use case that can be seen in the figure above is the one, titled "Login". This use case is used to depict the process of when the various users would try to login into their account. As it has been mentioned in the summary of the first use case, upon registering with the service all users have to provide a personalized username and password. It is that username and that password in question that will be provided by the stakeholders in order to log into their own personal account. This process is intended to take place locally, on the user's smartphone, where after logging in they would have access to their logged data about their personal health.

## 4) Backup Medical Data

The "Backup Medical Data" use case is mostly connected to the ongoing functionalities of the service but also to potential emergency situations. During the everyday usage of the service, all medically-relevant data (such as pulse and ECG readings) that has been collected about the user will be stored continuously so that later it could possibly be used for diagnosing purposes. Data will be stored on the user's smartwatch, as well as backed-up on their smartphone. The users themselves would be able to review their own personal data at any time.

## 5) Continuous monitoring

The current use case constitutes the ongoing processes of the smartwatch application. It is constantly receiving input about the user's status from its own sensors, possibly from the wearable ECG as well. Via its internal algorithm that includes a number of thresholds, the application will continuously be updating its user's status by referring to them being in one of a set of predetermined states.

6) View recorded data

This "View Recorded Data" use case includes the functionalities involved with enabling the user to access the medically-relevant data, recorded about them by the Vixi application. Users will be able to view the data logs of their heart rate and ECG readings. In order to be more visually comprehensive, the abovementioned logs will be accessible through the smartphone

application. However, at any point in time the user will be able to view their current heart rate, ECG readings or status on their smartwatch.

7) Emergency Alert

The "Emergency Alert" use case has perhaps the most significant weight when it comes to it providing the most beneficial functionalities for the target user, i.e. the elderly. This use case also includes a multitude of processes within itself. When it comes to the interactions with the different actors, they are the following:

- i. User this interaction can start in two ways either when the system determines that the user requires emergency help and it notifies him/her, or when the user activates the emergency alert himself/herself. In both cases if there is a "false alarm" the user should be able to deactivate the alert before any further interactions with other actors take place.
- ii. Emergency services (112) if the user has not turned off the alert and if the system has determined that the emergency event taking place is severely critical, then emergency services would immediately be contacted. If that is not the case, then the system should notify one of the other two following actors.
- iii. Personal Physician if the user has not turned off the alert after a certain period of time then, depending on what emergency situation has been detected, their personal physician could be notified of the situation. The role of this actor in this use case could be eliminated if the user had not already indicated who their personal physician is in their account, prior to the emergency event.
- iv. Family member / Friend much like with the actor discussed above, the current one can be contacted if the alert has not been disabled by the user and depending on the emergency event that has triggered the alert. Once more, if such an actor has not been indicated in the user's account prior to the emergency event then would not play a role in the current use case.

#### 6.7 REQUIREMENTS SPECIFICATION

The current segment of the chapter is intended to fulfill the following objective from section 2.2 of the Problem Formulation chapter:

#### Produce a valid Requirements Specification.

An essential element of the development process is the requirements specification. It contains the so-called "requirements", i.e. features that the product being developed has to possess. The requirements to be featured in the following section are to be extracted from the previous sections of this chapter, including the survey disseminated among elderly individuals, the expert interview, the scenarios and use cases. To be more precise, there is a more direct connection to the latter two: one of the purposes of scenarios is to extract relevant use cases; from these use cases requirements can be discovered[148]. A requirements specification contains two types of requirements – functional and nonfunctional – and both of them will be presented in the following sections. All requirements listed in the following two sections are accompanied with brief descriptions, their origin, as well as their prioritization. It ought to be noted that the prioritization technique utilized in this chapter is the MoSCoW method. It allows for the division of requirements into four levels of "importance" and they are the

following: (1) Must (M) – requirements of the highest priority that have to be fulfilled, (2) Should (S) – requirements that have a high priority but which may not necessarily be fulfilled, (3) Could (C) – requirements of a lower priority that would be fulfilled if there are resources available, and (4) Won't (W) – requirements that would not be implemented during the current development stage but rather at a potential future point in time[152].

## 6.7.1 FUNCTIONAL REQUIREMENTS

Functional requirements describe the functionality of the developed product, that is what it can do for the user[151].

N⁰	Name	Description	Origin <sup>19</sup>	Priority
F1	Register username	The user will be able to register their own chosen username.	1)	S
F2	Register password	The user will register their own password.		S
F3	Registration notification	The user will be notified whether the registration process has been successful or not.	1)	S
F4	Login	The user will be able to login to their smartphone application.	3)	S
F5	Request for permissions	The Vixi application will ask the user for the necessary permissions upon installation time.	1)	S
F6	Measure RHR	Upon initialization of Vixi, either the ECG, or the smartwatch will be used to measure the initial RHR of the user.	2)	S
F7	Measure heart rate	The system will be able to measure the user's heart rate.	5)	М
F8	Measure ECG	Ieasure ECG The system will be able to measure the user's electrocardiogram.		W
F9	Input pre- existing conditions	The user will have the option of inputting information of pre-existing medical conditions.	2)	С
F10	Display current heart rate	The smartwatch application will be able to show the user their current heart rate.	6)	М
F11	Display heart rate logs	The smartphone application will be able to show the user logs of their previously recorded heart rates.	6)	S
F12	Display current ECG readings	The smartwatch application will be able to show the user their current ECG readings.	6)	W
F13	Display ECG readings logs	The smartphone application will be able to show the user logs of their previously recorded ECG readings.	6)	W
<b>F14</b>	Notify user of	Once a certain state has been established, the	7)	М

<sup>&</sup>lt;sup>19</sup> The numbers that can be seen in the "Origin" column refer to the heading numbers of the sections within the report being referenced.

	alert	smartwatch application will notify the user.		
F15	Turn off alert	The user will be able to turn of the alert.	7)	М
F16	Notify emergency contacts	If the user has not turned off the emergency alert their emergency contacts will be notified of the alert.	7)	S
F17	Notify emergency services	If the user has not turned off the emergency alert and their status is sufficiently severe, then emergency services will be notified.	7)	S
F18	Educate user	The system will inform the user as to the nature of symptomatic manifestations of relevant conditions that cannot be detected by the system itself.	4.2	S
F19	Activate alert	The user will be able to initiate the emergency alert on their own.	7)	М
F20	Fall detection	The smartwatch will be able to detect when the user has suffered a fall	4.3	М

## 6.7.2 NONFUNCTIONAL REQUIREMENTS

Nonfunctional requirements are somewhat complementary to the functional ones in the sense that, while functional requirements describe what functions a product/system should perform, nonfunctional requirements describe how they should be performed so that a certain quality-of-service is maintained[151].

N⁰	Name	Description	Origin	Priority
NF1	Backup data	The smartwatch application will periodically backup its logs to the smartphone application.	4)	S
NF2	Hub-and- spoke topology	The data flow between the different devices will follow the hub-and-spoke model with the smartwatch acting as the hub[153].	6.2.3	М
NF3	Smartphone platform	The smartphone application will be available for Android and iOS.	2.3	W
NF4	Smartwatch platform	The smartwatch application will be available for Android Wear and watchOS.	2.3	W
NF5	Access to GSM networks	The smartwatch will be able to establish a connection with a GSM network.	5.1	S
NF6	Pulse detection capability	The smartwatch will be able to measure the user's pulse.	6.1	М
NF7	Network fault tolerance	The smartwatch application will be able to fail gracefully if there is a signal drop or a significant signal strength reduction.	7)	С
NF8	Prioritize thresholds	Due to the power constraints on the smartwatch, it will prioritize the utilizing of	5.4	М

		thresholds above machine learning in order to spare CPU and memory resources.		
NF9	Acquire position	The smartwatch will be able to discover its user's current physical location.	6.4	S

## 7 DESIGN AND IMPLEMENTATION

The current chapter is dedicated to answering the main research question via the completion of a number of objectives as to be presented in the individual section of the chapter.

#### 7.1 SYSTEM ARCHITECTURE

The first section of the design chapter is dedicated to Vixi's system architecture. This is so as to fulfill the following objective from section 2.2 of the Problem Formulation chapter:

Determine what devices would be necessary so as to fulfill the functionalities of the system.

The Analysis chapter included a survey among potential users, an interview with an expert, day in the life scenarios that illustrate how Vixi would function, use cases to provide more detail. All these components were utilized as source material for the crafting of a requirements specification, with which the chapter was concluded. The proposed architecture within the current section is based on that exact requirements specification. What is more, whereas the specification takes on the form of a list of individual requirements for the various facets of the system, the system architecture provided in the current section aims to provide an overall view of the Vixi system as a whole.

The figure bellow (Figure 30) depicts a block diagram that includes all possible components of the Vixi system.



FIGURE 30: SYSTEM BLOCK DIAGRAM

The block diagram that can be seen in Figure 30 illustrates the three devices that would participate within Vixi. The data flow between the devices follows two point-to-point connections with a common end point – the smartwatch - which essentially constitutes a hub-and-spoke topology, thus satisfying requirement NF2 from the requirements specification. Given that the wearable ECG device can be an optional component of Vixi (as concluded in section 6.2.3 of the previous chapter), any essential processes have been moved to the smartwatch. The ECG device itself is only utilized in order to gather data about the electrical activity of the user's heart and to send its ECG readings to the smartwatch.

The user's smartphone is the second component of the system, as it can be seen in Figure 30. So as to satisfy requirement NF3 of the requirement specification, the aforementioned smartphone can have one of two operating systems – either Android, or iOS. The accompanying Vixi smartphone application will be utilized so that data from the smartwatch can be transferred to the smartphone, which will act as a backup. The information to be stored within the smartphone will be pulse rate readings from the smartwatch, the ECG readings from the wearable ECG device (if there is any) and information on detected falls (if any had taken place). Additionally, the data that has been backed up within the smartphone will be available for viewing via the smartphone application. This would also be a beneficial contribution towards improving usability, given that generally the smartphone screen sizes are larger than those of a smartwatch, meaning that the visual representation of the data would be more comprehensive.

The results from the Elderly Survey that had been conducted varied among the different questions asked. However, a notable result was the unanimous response to the question regarding the possible involvement of a personal physician within the service – 100% of users agreed that they would like their doctor to have access to their medically relevant data. Nevertheless, in order to appease potential privacy concerns due to the personal nature of the recorded information it has been decided that user data will be stored locally, on the user's devices. It is also because of this that data from the user's smartwatch is also stored within their smartphone – this serves as a backup. Therefore, the inclusion of medical professionals within the system is left for a latter development process stage, but what is known is that such an extension to the system would include the sharing of sensitive information between two entities. However this information is being delivered it would require some form of authentication and because of this the establishing of some basic credentials - such as username and password - upon the initialization of the service is proposed (F1, F2, F3 and F4). Given that smartwatches are generally designed for hands free use, it is proposed that these extensibility provisions take place within the smartphone application. The final element of the smartphone application presented in the system block diagram is the one regarding "Educational notifications". It is related to the research conclusions of the Ischemic Heart Disease chapter and the fact that users would potentially be taking advantage of the service without utilizing the wearable ECG device. Upon examination of Table 1 while excluding any ECG input it becomes apparent that the system would not be able to detect come ACSs. An example is unstable angina – it tends to manifest itself during times at rest, therefore it would not be reflected in the heart rate readings. It also does not generally lead to syncope and therefore relying on fall detection solely is unadvisable. It can also present itself with a variety of symptoms (not only the traditional chest pain), especially among women. It is then a point of concern that, due to their inability to recognize significant symptoms, users would dismiss them thus adding the risk of the unstable angina further deteriorating into an MI. Therefore push notifications with information regarding ACS symptoms are to be issued on a periodic basis. As was the case with viewing stored data, the reason the notifications are to be displayed on the users' smartphones is related to their generally larger screen sizes, making them more suitable for displaying longer forms of text.

The last component of the Vixi system is the smartwatch. Requirement NF4 of the requirements specification stated that the smartwatch application should be available for Android Wear and watchOS – a requirement that is necessary, given that the smartwatch should be able to function along with Android- and iOS-based smartphones. An advantage of using a block diagram is that it can provide a high-level view of the system being developed and that is also how it has been utilized in the current chapter. That is what makes the diagram on Figure 30 equally relevant for the Android Wear and the watchOS version of the Vixi smartwatch application. As it has already been established, of two main Vixi devices smartwatch and wearable ECG - only the former will always be present. The user's smartphone is also a component of Vixi but it ought to be considered that the user might not have their smartphone with them at all times, whereas this would not be true for their smartwatch. Therefore, all core system processes are to be concentrated within the smartwatch application itself. When it comes to sensory input, the smartwatch will continuously collect data from two of its onboard sensors and those are its PPG sensor and its accelometer. What is more, if the user is also utilizing an ECG device, then additional sensor input in the form of ECG readings will be received from the ECG device. The combined sensor input will then be processed by the application's algorithm for detecting critical events. The output of the algorithm has a two-fold purpose. Firstly, the state of the user will be updated, based on the outcome of the algorithm. Additionally, some of the data will be stored on the smartwatch, such as the heart rate and ECG readings, along with information on any detected falls.

If a critical event has been detected by Vixi then the user's state will be updated accordingly. Once such a significant state has been indicated, then the user will be notified of the event. After the user has been alerted of their situation they would be given the opportunity to turn off the alarm - as it has been dictated by requirement F15 – thus essentially manually modifying their own state. If the user does not reject the alert, then action will be taken to notify their emergency contacts. Part of the information to be shared will include the user's physical location, meaning that location services will be utilized in this situation. The aforementioned services will acquire the user's current position, which will then be sent, along with other necessary information, to their emergency contact. An existing possibility is that the user will have symptoms that are undetectable by the system (such as the previously mentioned example with unstable angina). For such situations it is proposed that the user should be able to initiate the emergency alert (F19), even when the system has not detected a significant event. This could also provide additional value to the system, given that potentially users could utilize this functionality when they are experiencing other, non-IHD-related health emergencies, such as a stroke.

#### 7.2 ALGORITHM FOR DETECTING A CRITICAL EVENT

The current section of the chapter will be dedicated to the fulfillment of the following objective, presented in the Problem Formulation chapter:

#### Devise an algorithm for detecting critical ischemic heart disease-related conditions.

The algorithm to be developed has a vital role within the Vixi service. The previous section clarified the proposed overall system architecture for Vixi. From the aforementioned architecture an overview of Vixi's comprising components was provided, as well as their relation to one another. What still has to be clarified, however, is how these components work together in order to detect dangerous ischemic heart disease conditions, i.e. how can Vixi determine whether its user is experiencing an emergency or not. This will be looked into within the following sections.

#### 7.2.1 FALL DETECTION ALGORITHM

As it has already been discussed in the System Architecture section of the current chapter, the inclusion of fall detection within the smartwatch application is a necessity in order to improve the precision of the service when detecting potentially fatal cardiac conditions. Research, conducted in the State of The Art on the matter revealed that - largely due to the significant threat that falls pose for the elderly by themselves - there are a number of solutions, dedicated to fall detection. From the aforementioned research it became apparent that the majority of them rely on acceleration data. This is extremely beneficial for the current development process since the Smartwatch Capabilities section of the State of The Art chapter related that accelometers are a common feature among smartwatches. Of the fall detection algorithms, examined in the abovementioned chapter, there are two - proposed by two different Swiss teams - that involve devices placed on the user's wrist. These two solutions are of a larger significance since fall detection algorithms rely strongly on the physics behind body motion. From a purely biological perspective, different body parts would behave differently during a fall. Additionally, they also have varying behaviour during everyday activities, meaning that it is inadvisable to depend on equivalent detection requirements for different body placements. Of the two aforementioned solutions, one uses a simple wristwatch ("Speedy"[111]) and the other (F2D) a smartwatch[113] - the wristwatch naturally has more limited capabilities, however at the time of publishing the smartwatches available also had extremely limited capabilities. The Speedy solution achieved an overall sensitivity of only 68%, while the F2D solution achieved a much higher sensitivity of 93%. What is of interest is that F2D does not rely on a different way of data processing - in fact, while Speedy calculates the norm (sum acceleration vector) from which it calculates two different velocities, F2D only calculates the norm. The team behind Speedy concluded that they had to further refine the accepted threshold values; given that from their testing phase they did not encounter any false positives, it seems as if they could have sacrificed detection sensitivity for the sake of specificity. The F2D algorithm included the extraction of the sum acceleration vector only; however the resulting values are compared to, not only one, but two separate thresholds. It is this approach that would be utilized in Vixi since not only did it achieve a higher accuracy rate, but it can be argued that it puts a lesser strain on computational resources because the continuous computations are reduced from performing three simultaneous calculations at a time to one. The complete fall detection algorithm is depicted via a flow chart in Figure 31, however in order to reduce the complexity of the flow chart, two distinct processes within it -

"Process accelerometer data" and "Suspected fall" - are illustrated separately in Figure 32 and Figure 33, respectively.





FIGURE 32: PROCESS ACCELEROMETER DATA

The initial part of the algorithm – relatively speaking since it is essentially an ongoing loop – will be called "Process accelerometer data" (Figure 32). It begins with the extraction of data at the given sample rate from the raw data stream - the sampling rate will again be 40 Hz, i.e. a sample will be taken every 25 ms. For every individual sample the accompanying acceleration sum-vector for the three main axes will be calculated. Given that standard Android accelerometers do not exclude gravitational force[136] while in F2D it is excluded, the sum vector will be calculated according to the following formula in order to compensate for the aforementioned discrepancy:

$$SVM = \sqrt{a_{x^2} + a_{y^2} + a_{z^2}} \tag{7.1}$$

The following component of the fall detection algorithm is the "Suspected fall" process, which can be seen in Figure 33. It utilizes the output of "Process accelerometer data" as its initial input. Each of the calculated acceleration sum vector values will first be compared to an upper fall threshold (UFT). If the UFT has been reached, then for a time period of 0.5 seconds SVM values (with a sampling rate of 40 Hz that equals to 20 values) will be compared to a lower fall threshold (LFT).



FIGURE 33: SUSPECTED FALL
If an SVM value has reached the LFT within the aforementioned time interval, then the possibility of a fall is registered and this output is passed along as input for the "Fall detection" algorithm (Figure 31). Afterwards, for all the following 5.5 seconds the consequent 220 SVM values are examined for fall possibilities according to the same manner explored above, while a running count of the possible fall events is being maintained. At the conclusion of these combined 6 seconds, the total count of possible falls is compared to a predetermined set of values, which will be labeled lower count limit (LCL) and higher count limit (HCL). If the counter value is simultaneously: (1) equal or higher than the LCL, and (2) lower than the HCL, then a fall will be registered and the device will notify the user that an alert is to be sent out to their emergency contacts and the user will have 30 seconds to turn of the alert.

The specific values of the UFT and LFT thresholds still have to be determined. In [113] the both thresholds had somewhat flexible values, rather than a specific one – the developers chose these in order to increase accuracy. However, these flexible values are dependent on the user's profile and information as to what constitutes a user's profile and its relation to the aforementioned thresholds is not provided. The values they provide for the UFT are (10-18) m/s<sup>2</sup> and for the LFT – (2-7) m/s<sup>2</sup>. The team behind F2D had previously introduced another paper about the same system[154]. Within it they utilize the more rigid thresholds of 7 m/s<sup>2</sup> for the LFT and 18 m/s<sup>2</sup> for the UFT[154]. Given that the fall detection algorithm still retained a 92% accuracy rate, these values will be utilized in the current algorithm. In both papers the LCL is accepted to be 1 and that is the value to be utilized here. However, in [113] they improved on the HCL, going from a value of 14[154] to a range of (5-10). In order to improve on sensitivity, the value of the higher end of the range is selected, i.e. 10 (Table 4).

### 7.2.2 SENSOR THRESHOLDS

As it has been stated in NF8 in the Nonfunctional Requirements section of the previous chapter, the proposed solution ought to rely on a more simplistic algorithm, one that would rely on thresholds where possible, rather than lean on machine learning algorithms which could prove to be too taxing on the constrained resources of the smartwatch, where the continuous monitoring and status assessment will be taking place. The main argument behind the reasoning that utilizing thresholds is a viable possibility lies in the findings of the Ischemic Heart Disease chapter, as well as the Fall Detection section of the State of The Art chapter, as well as the fall detection algorithm, discussed in the previous section. The former was concluded with Table 1, which relayed an overview of the relevant IHD conditions, their symptomatic manifestations and how to detect them - if possible - via the utilizing of an ECG or depending on heart rate. From the State of The Art chapter it is known that a number of existing algorithms rely on utilizing thresholds in order to detect a fall and based on the abovementioned solutions a proposal for Vixi will be made within the following text. The current section will conclude with an overview of the decisions made in the form of Table 4. It should be noted that the threshold values, examined in the following text, are tied to the individual sensors utilized within Vixi. That is to say that if a given sensor threshold has been reached it might not be of particular significance unless another threshold(s) – possibly for another sensor entirely - has also been reached.

### 1) Heart Rate Thresholds

From the conclusions of the Ischemic Heart Disease chapter it is known that in general the acceptable RHR limits are from 60 bpm up to 100 bpm[155]. However, it is noted that with

athletes those limits can be significantly lower, such as 40 bpm to 60 bpm[155]. These will be referred to as Lower Heart Limit (LHL) and Higher Heart Limit (HHL). In some cases, most notably with adult well-trained athletes, one's RHR can be bellow 60 bpm, even reaching as low as 40 bpm. Although senior citizens cannot be considered to be in the same physical conditions as with professional athletes, there can still be individual variations from user to user, not only from the perspective of fitness level but also based on effects from certain medications, as well[155]. That is where recommendation F6 from the requirements specification gains its significance from - it is proposed that upon the initialization of the smartwatch application, the user's RHR will be measured by the onboard PPG sensor in order to verify that it is within the generally accepted limits. If that is not the case then the LHL will be adjusted accordingly. Additionally, if the only anomalous indication encountered by Vixi at a given moment is LHL or HHL - because the arrhythmia cannot be detected via an ECG or because the user is utilizing the smartwatch only - then the system should compensate for the possibility that these fluctuations could be momentary deviations due to everyday activities. Of the ACSs, AMIs develop gradually over a matter of hours - given that there must be a compromise between specificity and sensitivity, it is proposed that upon first registering either threshold, the system should await a certain amount of time, after which it ought to notify the user of the suspected emergency and allow the user the opportunity to turn off the alert. Additionally, it ought to be taken into account that arrhythmias could be triggered by short-term exertions and not last more than a few minutes. It is therefore proposed that the system include an arrhythmia time limit (ATL) of 5 minutes. Upon first registering the presence of an arrhythmia, the system would count down until the ATL is reached. During this countdown the system would be monitoring for two types of input whether the arrhythmia has normalized, or if the fall detection algorithm has detected a fall. In the case of the former then the system ought to return to its regular monitoring activities. If it is the latter, then the alert should be enabled. If none of the aforementioned input is registered before the ATL is reached, then the user would be notified of the alert and they should be given the opportunity to disable it. Taking into consideration the case of sporting activities, the user should be able to, not only disable the alert for the moment, but also to instruct the system that for the following X-amount of time they would be performing strenuous activities and that the system should ignore heart rate input.

## 2) ECG Thresholds

Within the Ischemic Heart Disease chapter it was acknowledged that an important diagnostic tool for identifying a suspected ACS is the ECG. Of the examined IHD conditions, the only one that is undetectable via an ECG is angina pectoris. It can be argued that - since it does not indicate any actual cardiac damage but rather it is a symptom – the fact that angina pectoris is unobservable on an ECG is not detrimental to the overall service. Additionally, unstable angina is also mostly undetectable on an ECG, except in its most dangerous form, when it can lead to a STEMI. More significant ACS incidents, such as STEMI, NSTEMI and SCD can be identified more clearly via an electrocardiograph. The ECG thresholds presented in the current chapter in Table 4 have been extracted from the summary table within section 4.3 of the Ischemic Heart Disease chapter.

### 3) Accelerometer Thresholds

The accelerometer has a significant role for the examined fall detection algorithm examined in the previous section (7.2.1). The significant accelerometer values – UFT and LFT - have

already been examined in the abovementioned section and so no further discussion is required in the current one, rather they are presented in Table 4. The same reasoning applies for the additional count limits - LCL and HCL - that are a component of the fall detection algorithm; therefore they are also included in Table 4.

# 4) Threshold Overview

The following table (Table 4) provides an overview of the decisions made as to the selection of relevant thresholds that has been conducted within the current section of the Design and Implementation chapter. The table includes the following information: the sensor with which the threshold is to be measured, the designated name of the individual threshold, as well as its value, presented via the appropriate measurement units.

Sensor	Designation	Threshold
PPG	Lower Heart Limit (LHL)	Under 60 bpm or under adjusted RHR.
PPG	Higher Heart Limit (HHL)	Above 100 bpm.
Clock	Initial Time Limit (ATL)	5 minutes
ECG	ST elevation at J point (STE)	Leads V2 & V3: $\geq 0.2 \text{ mV}$ for men $\geq 0.15 \text{ mV}$ for women All other pairs of contiguous leads: $\geq 0.1 \text{ mV}$
ECG	New ST depression (NST)	Any pair of contiguous leads: $\geq 0.05 \text{ mV}$
ECG	New T inversions (TINV)	Any pair of contiguous leads, where: $R/S > 1$
ECG	New Pathologic Q Waves (NPQ)	Q waves that are: $\geq 40 \text{ ms or}$ $\geq 1/3 \text{ of } R \text{ wave}$
ECG	Wide QRS complex (WQRS)	QRS complexes longer than 120 ms with no preceding P waves
ECG	Wide RS Segment (WRS)	RS interval longer than 100 ms in a precordial lead
Accelerometer	Upper Fall Threshold (UFT)	$18 \text{ m/s}^2$
Accelerometer	Lower Fall Threshold (LFT)	$7 \text{ m/s}^2$
Accelerometer-	Lower Count Limit (LCL)	1
related	Higher Count Limit (HCL)	10

7.2.3 STATE CLASSIFICATION AND OVERALL SYSTEM ALGORITHM

In essence, the system algorithm will be based on a finite state machine. Finite state machines consist of a set of known states, including a start state and transition functions leading to the following state and so on[156]. As was the case in section 6.6, UML will also be utilized in the current one, given its widespread acceptance among developers.

To begin with, the following table (Table 5) contains the possible states of the user, as well as the corresponding response from the system.

TABLE 5: SYSTEM STATES OVERVIEW

State	System Response
Norm	Continue monitoring status
Acceptable	Await additional input
Warning	Notify user and contact emergency contacts
Critical	Notify user and contact Emergency services (112)

At any moment in time the system will keep track of the current state of the user, which as it is shown in Table 5 can be one of the following:

- 1) Norm this state would indicate that all measurable parameters are within their accompanying limits, none of the thresholds, presented in Table 4 have been reached or crossed;
- 2) Acceptable this state will be utilized in order to represent the situation, where one or more thresholds have been reached or crossed but it is not enough for the system determine whether a significant event is in fact taking place, i.e. it is suspected but Vixi cannot determinately assert that that is the case. When the system is within this state it would await for additional input so as to either return to the Norm, or to transition to one of the other two states ("Warning" and "Critical");
- Warning this state specifies the situation where the threshold(s) that have been crossed are sufficient so as to determine that the user is currently experiencing a critical event. In this state the user and their emergency contacts would be notified of the situation;
- 4) Critical this state indicates that the user is in a physical condition that requires immediate medical attention;

As it has previously been declared, a finite state machine model will be utilized so as to illustrate they way that the different states relate to each other and transition into one another. In order to provide context to the state machine diagram, the following state transition table (Table 6) is presented so as to clarify the transitions between the states and the events that trigger the aforementioned transitions.

#### TABLE 6: STATE TRANSITION TABLE

Current State	Action	N⁰	Event	Next State
Norm	Continue monitoring	1	-	Norm
	indefinitely until a	2	LHL or HHL	Acceptable
	change of state.	3	STE/NST/TINV/NPQ/WQRS/ WRS	Warning
		4	Detection of a fall	Warning
Acceptable	Wait for normalization	5	Heart rate normalization before	Norm
	of arrhythmia, the		ATL	
	detection of a fall or	6	ATL	Warning
	until ATL is reached.	7	Fall detected	Critical
Warning	Notify user of alert and	8	User input	Norm
	enable them to disable it, otherwise notify emergency contacts.	9	Fall detected with a preceding ECG threshold	Critical
Critical	Contact emergency services (112).	10	User input	Warning

The figure bellow (Figure 34) is presented so as to visually illustrate the states and the transitions between them that have been described in Table 6.



FIGURE 34: STATE MACHINE DIAGRAM

The aforementioned state transitions can follow along these action flows:

- ➤ When Vixi is in its Norm state it continuously monitors the incoming information from its sensors, including ECG readings, heart rate input, and acceleration data. If no threshold has been reached, then the state would remain the same, i.e. Norm (No1).
- ➤ If Vixi is in its Norm state and one of the heart rate thresholds has been reached, then the system would transition into the Acceptable state (№2) where it will await until one of the following things happen:
  - If the heart rate input is normalized before the ATL is reached, then the system would transition back to the Norm (N<sup>0</sup>5).
  - If the ATL is reached and the heart rate has not normalized, then Vixi transitions to the Warning state ( $N_{2}6$ ).
    - While in its Warning state, if the user disables the alert Vixi transitions to the Norm (№8).
    - If the user does not disable the alert, then emergency contacts will be notified.
  - If a fall has been detected before the ATL has been reached, then the system transitions to the Critical state (№7).
    - While in Critical, if the user disables the alert, then Vixi transitions back to Warning (№10).
- ➤ If Vixi is in its Norm state and an ECG threshold has been reached, then it transitions to Warning (№3).
  - While in Warning, emergency contacts are notified.
  - $\circ$  If Vixi also detects a fall, then it transitions into Critical (No9).
    - While in Critical, if the user disables the alert, then Vixi transitions back to Warning (№10).
- > If Vixi is in its Norm state and a fall is detected, then it transitions into the Warning state ( $N_{2}4$ ).

# 7.3 DEVICE APPLICATIONS

The final section of the current chapter will be dedicated to fulfilling the following objective, presented in the Problem Formulation chapter:

## Provide a design of the necessary device applications.

As to the devices in question, these will be the smartwatch and the smartphone. The wearable ECG device is acknowledged as a component of the system; however, since no processing will be conducted within the aforementioned device it is deemed that it does not warrant its own application at this stage of the development process - as it can be seen in Figure 30, the sole functionality of the wearable ECG device is to send its ECG readings to the smartwatch.

It should be noted that Figure 30 and its accompanying description in section 7.1 already provides an overview of Vixi as a whole. The aforementioned section gives insight into what functionalities are implemented within the system, along with their distribution across the different components of the aforementioned system. However, it has been deemed necessary that further clarification as to the workings of the two Vixi applications (smartwatch and smartphone-based) ought to be included within the limits of the Thesis. Once more, UML methods will be utilized in order to illustrate the details of the proposed design. To be precise,

the UML method to be used will be class diagrams, which are often utilized for the purpose of describing a design in finer detail[157]. As per general class diagram instructions, scaffolding code will be avoided so as to simplify the diagrams in the following sections in order to focus on more significant operations[157].

### 7.3.1 SMARTWATCH APPLICATION

The class diagram for the smartwatch application can be seen in Figure 35:



FIGURE 35: SMARTWATCH APPLICATION CLASS DIAGRAM

The figure above includes six classes that have varying connections with each other. Input data from three different sensors is processed within this application. From section 7.2 it is known that the measured values from the different sensors have to constantly be monitored and compared to predetermined thresholds. For that purpose there is a separate class for every type of sensor input (accelerometer-based, ECG-based and PPG-based), within which the necessary continuous monitoring is conducted. The three classes are generalized by a common superclass. If a threshold has been reached, the State class is notified. The state class is responsible for handling the state transitions, described in Table 6. If Vixi transitions to the Warning or Critical state, then the Alert class is utilized.

## 7.3.2 SMARTPHONE APPLICATION

The smartphone application contains limited functionality, compared to the smartwatch application. As it has been previously stated, that is because it has been concluded that the smartwatch application ought to be able to function properly without the aid of the smartphone application. The following figure (Figure 36) consists of a class diagram of the proposed smartphone application, while bellow it is a brief overview of the classes, presented within it and their relation with each other.



FIGURE 36: SMARTPHONE APPLICATION CLASS DIAGRAM

The BackupData class has a central role in the smartphone application. It is responsible for storing information that has been sent from the smartwatch; the user's registration information, as well as the educational notifications (Educate). If the user wanted to view their current or past heart rate/ECG readings, they would use either the CurrentReadings or the PastReadings class. Both of the latter are connected to a common interface (DisplayReadings). The Register class handles the initial user registration process.

The current chapter is dedicated to fulfilling the following objective that has been presented in section 2.2 of the Problem Formulation chapter:

## Devise protocols for testing the designed system.

A full implementation of Vixi was not achievable in the limited time reserved for the execution of the Thesis project; therefore system testing was not executed. However, a fully-realized project would warrant the inclusion of a testing phase. The following chapter serves to provide a brief overview of what testing procedures would have to be utilized in relation to the proposed Vixi system. The testing efforts will be divided between two major foci: (1) functionality and (2) usability.

### **Testing functionality**

Functionality testing is an essential segment of the testing phase as it is necessary in order to obtain a measure as to how well – if at all – the various functions of the system perform after having been implemented. Naturally, all of the implemented functionalities of the system would not be considered to be implemented if they do not perform their assigned tasks, however functionality performance can vary among the different devices and users.

A functionality that should be tested is the fall detection algorithm; more specifically its sensitivity and specificity rates. Given that the fall detection algorithm proposed in the current document has been acquired from an outside source, then if that algorithm is to be implemented in the final version of the service its validity would first have to be confirmed by the Vixi development team. It should be noted that the thresholds that have been chosen for that algorithm were selected based on empirical data, therefore there is the possibility that the aforementioned thresholds might need to be adjusted, depending on differences between the devices utilized in Vixi and the F2D team's equipment.

During the secondary research phase, conducted in relation to section 5.4 of the State of The Art chapter, it became apparent that various smartwatches seem to have different performance accuracies when it comes to their heart rate measuring capabilities. Therefore, it is recommended that the Vixi development team compare the accuracies of these devices firsthand. If an accuracy discrepancy does indeed exist; then by discovering it the Vixi team could use acquired results in order to recommend specific smartwatch models to their users. If it does not, then it will formally be established that Vixi would perform equally well on all tested smartwatch models<sup>20</sup>.

## **Testing usability**

Another essential aspect of the system that ought to be taken into consideration is its usability. When examining the usability of a product/system, one has to consider the various aspects of the concept, i.e. its usefulness, efficiency, effectiveness, learnability and satisfaction[158]. Naturally, all the facets of usability should be dealt with, however of more learnability is of a more particular interest as it relates to Vixi. Consider the results from the survey carried out among potential users, presented in section 6.2 of the Analysis chapter. Among all those

 $<sup>^{20}</sup>$  That is not to say all smartwatch models available on the market. A recommendation would be to first test available Android Wear models.

surveyed, 19% of them had never owned a smartphone, meaning that one out of five people does not have any reliable experience with smartphones. Even acknowledging that the overall participant base for the survey was somewhat limited in scope, this kind of data can be indicative of a trend that might be observed on a larger scale. The aforementioned lack of experience therefore could translate into difficulties with learnability, which could then prove to be detrimental to the effectiveness of the product/system. Therefore a few recommendations can be made as to the testing of the usability aspect of Vixi.

Firstly, it is recommended that the smartphone and smartwatch applications' user interfaces be designed with a specific persona in mind. That is to say, one that is presumed to have extremely limited digital skills. Secondly, the applications ought to be developed according to an Agile framework. The iterative nature of Agile would allow for the implementation of usability testing during the development process, which would then grant the opportunity for the development team to make adjustments accordingly[159]. Although more than a single usability test could seem unnecessary, it can be extremely beneficial due to the disparity of digital literacy between the development team and the intended users. Lastly, when selecting test participants, the ones with the least amount of technical skills ought to be selected.

# 9 DISCUSSION

Within the Problem Formulation chapter the main research question governing the direction of the current Thesis was introduced. Along with the research question stated above, five additional subquestions were presented so as to further expand on the main question and to provide clarification for the objectives that were to be fulfilled throughout the length of the Thesis. Within the following chapter the abovementioned subquestions will be examined individually with the purpose of exploring how they have been addressed within the previous chapters and their accompanying subsequent results.

# What conditions constitute ischemic heart disease? Which of them can lead to a fatal outcome?

The first subquestion is actually a composite of two questions. The reason that they are introduced simultaneously is because of their closely associated semantics. Indeed the two have both been addressed within the limits of the Ischemic Heart Disease chapter. Research into the matter revealed that IHD as a whole can encompass two main conditions: stable angina and ACS. It was discovered that of the two, only the latter is connected to actual tissue decay (and possibly leading to a fatal outcome). However, the former is considered to be a possible precursor to ACS, meaning that it ought to not be discounted.

In addition to the secondary research, conducted in order to answer the first subquestion, primary research was also executed. The specific nature of the necessary information - i.e. the fact that it is rooted in the medical field – along with the author's experience in the engineering field, led to the necessity of outside evaluation of the achieved results from the secondary research, performed by an expert. For this purpose that a number of institutions were contacted with a request for an interview. These efforts resulted in an interview with an expert from the Department of Biomedical Sciences of Copenhagen University. The outcome of the interview was favourable as to the aforementioned research results, which were confirmed.

The second subquestion is the following:

# What physiological or environmental parameters should be monitored in order to detect the onset of the established conditions?

It has partially been answered within the Ischemic Heart Disease chapter. After finding the answers for the first subquestion and recognizing on what the sought-after conditions are, the chapter continues on in examining them individually in more detail. This allowed for further determining how they present themselves symptomatically, as well as how they are detected and diagnosed by medical professionals. The diagnostic tools utilized by the aforementioned medical experts were discovered to be numerous; however a distinction was made between invasive and non-invasive methods. In order to further narrow down which parameters were to be utilized by the service, it was essential to consider the purpose of the system being developed, i.e. that it is intended to be used on a daily basis for prolonged periods of time. Therefore, it was decided that the focus ought to be on the non-invasive methods, specifically on measuring the user's heart rate and their electrocardiogram. These might not be as conclusive when it comes to presenting a certain diagnosis of the user's health status, however they would prove to be sufficient in the sense that they would provide a significant enough suspicion that it would warrant emergency treatment. Given that the various facets of ACS

have various presentations relating to heart rate and ECG, Table 1 was included as a conclusion of the aforementioned chapter in order to provide a brief overview of all of them. As to the achieving a more precise estimation of the user's overall health statues, it was concluded that they ought to be monitored if they had suffered a fall. This was due to the observation made that as an ACS progresses, it leads to an increasing lack of oxygen to the whole body – when the brain itself experiences a significant enough amount of oxygen deprivation, it can often result in dizziness or even a syncope. Often the former – and always the latter – would lead to a fall. Therefore it was observed that, along with any indications of heart rate and ECG anomalies, the presence of a fall would signify a stronger severity of the user's condition.

The third subquestion to be examined is the following:

#### What devices should be utilized in order to measure the aforementioned parameters?

From the answers to the previous subquestion the parameters that the system should monitor became known. The State of The Art chapter was then dedicated to discovering how these parameters could be monitored. From section 5.2 it was concluded that a user's heart rate could be measured by a PPG sensor and that their ECG could be monitored via a wearable electrocardiograph. Additionally, section 5.3 focused on examining existing algorithms for fall detection and it was observed that the common denominator between them (sensor-wise) was the accelerometer. Consequently, it was observed that a smartwatch might be a suitable device to be utilized within the service as it had been present in both sections 5.2 and 5.3 as an example of existing technologies on the market that contain PPG sensors, as well as accelerometer. Section 5.4 was then introduced in order to attempt to verify the abovementioned observation and indeed it was confirmed. Therefore, it was concluded that the devices to be utilized so as to monitor the user's heart rate and ECG would be a smartwatch and a wearable ECG.

The fourth subquestion is the following:

### How should the system respond when an established condition has been detected?

Considering the different facets of the ACS and their contrasting severity and progression rates it was observed that they would therefore warrant different responses. Section 7.2.3 of the Design and Implementation chapter proposed that the system should transition between four pre-determined states. Each state would be triggered by different events and would elicit a specific response from the system. The "Norm" would be the state the user is in when there are no abnormalities detected – here the system would not have any remarkable response, it would merely continue monitoring the user's condition. The "Acceptable" state is where an abnormality has been detected but it is not deemed significant enough as to warrant additional response. Instead the system would await further input so as to determine which state it ought to transition to next. The "Warning" state is one, where the system has detected abnormalities that are of sufficient significance to warrant a consultation with a medical professional and so the user and their appointed emergency contacts would be notified by the system. The "Critical" state is one where according to the system it is deemed necessary for the user to receive immediate medical attention and so emergency services would be notified of the user's condition.

The fifth and final subquestion to be examined is the following:

#### How can the proposed solution be made to suit the needs of the target population segment?

An essential aspect of the development process is to design a product that would fulfill its purpose but whether it would be accepted by potential users also needs to be given significant consideration. Therefore, it was deemed necessary that primary research ought to be conducted on this matter - this was done in survey form in order to reach a wider participant base. Section 6.2 of the Analysis chapter was dedicated to providing an overview of the contents of the survey in question, as well as to analyze its results by verifying or discounting previously suggested hypotheses. It was concluded that of the two necessary devices smartwatches and wearable ECGs – users were more willing to utilize the former, rather than the latter. However, they seemed to favour the wearable ECG more when input from a personal physician was involved. Additionally, there was a unanimous agreement among participants that they would like their personal physicians to have access to the medicallyrelevant data, collected by the service. Lastly, observations could be made as to the nature of the users' potential emergency contacts, the most common being emergency services, followed by family members and personal physicians. This would also serve to indicate that users would not feel apprehensive towards the capability of the system to involve emergency services on their behalf.

Aside from answering the subquestions, discussed above, a few other observations have also been made along the course of the Thesis. One of these was the benefit of introducing positioning capabilities to the system. The system is designed mainly to solve the problem of senior citizens – most probably being in their own homes - requiring emergency medical attention when they are not able to call for help on their own. However a few possible situations have to be considered. The first one being that the user might not even be in their abode when they would require medical attention – if the user is not capable of contacting anyone for help, then they would also not be able to relay their location either. Secondly, if the user was at home at the time, then their designated emergency contacts would most probably be aware of their home address but that would not be valid for the emergency services that would potentially have to be contacted. Therefore, it has been deemed necessary that the system ought to have positioning capabilities. Given that the smartwatch component of Vixi can possess the necessary functionalities, it has been determined that the inclusion of the positioning functionality would be an acceptable proposition.

Another observation is related to the already discussed results of the survey. It was noted that even with a recommendation from a personal physician, users were still apprehensive towards the wearable ECG. Therefore it was concluded that the wearable ECG would not be a suitable long-term component of the system. However, it does provide essential data, as it allows for an earlier detection of ACS – without it the system would be able to detect it at a later stage of its progression. It is therefore proposed that the smartwatch component (which includes all essential system functionalities) be presented to the users as a more long-term solution. The wearable ECG, however, ought to be intended for users that have already suffered through an ACS. Research from the Ischemic Heart Disease chapter has indicated that people that have already experienced an ACS are more likely to have another one, especially during the first year after the initial one, where the risk of mortality is significantly higher. Accordingly, it is proposed that the wearable ECG be utilized by individuals that have had an ACS for a period of up to 12 months after the initial incident.

# **10 CONCLUSION**

The previous chapter was dedicated to reviewing the various subquestions presented in section 2.1, along with examining the manner that they have been addressed throughout the course of the current Thesis. The focus of the present chapter is on the main research question, posed in 2.1 and it was the following:

# How can a system be designed so that it would reduce the risk of death for elderly individuals caused by ischemic heart disease?

Given the positive outcomes to its accompanying subquestions, along with the overall results of the Thesis, it can be concluded that the main research question has been answered in sufficient detail. Firstly, in the Introduction chapter it was proposed that it is possible to reduce the risk of a fatal outcome of an IHD incident via reducing the severity of its consequences or even the possibility of it ever occurring. From the Ischemic Heart Disease chapter it became apparent that risk factors for IHD include aspects such as smoking, lack of exercise, etc. Compensating for the aforementioned risk factors would depend more on a change of lifestyle and even if those changes are implemented, there is simply no guarantee that it would sufficient for avoiding dangerous IHD incidences. Additionally, there are some risk factors that cannot be affected, such as sex, the presence of diabetes and even age. Therefore, in order to achieve the desired outcome, the focus was shifted on to reducing the severity of the consequences of an IHD event that is already taking place. Research from the aforementioned chapter revealed that time is a common factor that greatly influences the outcomes of such situations. Consequently, it was determined that early detection of an ACS in its initial stages would be the most effective way of increasing the possibility of a positive non-fatal outcome.

Once the relevant aspects of IHD became known, it was then necessary to discover what devices should be utilized within the system so as to allow for the automated detection of the onset of an ACS. The State of The Art chapter was used towards that goal, from where it was acknowledged that it is feasible to utilize existing hardware products that are already on the market, in the form of smartwatches and wearable ECGs. Upon closer examination of their software capabilities it was also determined that concerning the software aspect of the service, it was also possible to make use of existing market solutions. Additionally, an algorithm was devised that would be utilized so as to combine the various sensor input included in the system and to interpret it in a manner that would allow to determine whether an ACS is occurring or not. What is more, potential user needs were also addressed by conducting a survey among representatives of the target age group and then applying the consequent results and conclusions from it to the overall design of the system.

In conclusion, the current Thesis has successfully answered its main research question. A design for a system that would reduce the risk of mortality due to ischemic heart disease has been proposed – one that would not rely on producing specialized equipment, but rather make use of existing devices already on the market.

# **11 FUTURE RECOMMENDATIONS**

Throughout the various stages of fulfillment of the current Thesis, a number of challenges have been encountered. Some have been resolved within the confines of the report. Others have been deemed to be too significant to be undertaken at the current stage of development; perhaps even warranting a dedicated project of their own. It is the aforementioned challenging tasks that are to be briefly introduced within the following sections, along with recommendations for future research and development.

### **11.1 WEARABLE ECG VARIABILITY**

As it has already been established, ECG input is an essential component of Vixi, especially when it comes to predicting critical cardiac events before their actual onset. Research, conducted in the Ischemic Heart Disease chapter, led to the specification of a number of ECGassociated thresholds, accompanied by the leads where they ought to be detected (Table 1). What is of significance, however, as it has also been concluded in section 4.2 of the aforementioned chapter, is that depending on the position of the ischemic damage to the heart, different leads would be able to detect it. This is of some importance, since in section 5.2.1 of the State of The Art chapter, it was also noted that existing wearable ECG devices are often single-channel. The limited number of leads, available to wearable ECGs, seems to be a constraint on their effectiveness. However, it is known that even in hospital conditions it can be common to not utilize all 12 leads of the standard ECG (5.2.1). Manufacturers also appear to have overcome this difficulty, since some of these devices are listed as providing medicalgrade monitoring (e.g. the QardioCore[87]). What is of concern, however, is that research into specific examples of the abovementioned devices revealed that manufacturers do not list the leads that they are utilizing within their solutions (among the encountered examples, there was only one exception - the Shimmer3[88]).

Android-based smartwatches were chosen as one of the other system components partly because of Android's openness towards third-party developers. In contrast, wearable ECGs and their accompanying algorithms tend to be proprietary in nature, which can be a hindrance when trying to integrate them within a third-party system. It is therefore recommended that further research be conducted into the specific nature and functionalities (such as which leads are being utilized) of the wearable ECG devices on the market. A positive outcome to such an undertaking would be to produce a list of wearable ECG devices, compatible to Vixi. Another possibility is to involve specific wearable ECG manufacturer(s) as stakeholders within the Vixi system. Such a collaboration would ensure a compatibility between the specific ECGs and the rest of the system that would increase its overall reliability.

# 11.2 INCLUDE PERSONAL PHYSICIANS AS STAKEHOLDERS WITHIN THE SYSTEM

The current recommendation is related to two of the hypotheses that were tested and verified via a survey disseminated among representatives of the target age group of the service being developed. The fifth hypothesis, presented in section 6.2.1 of the Analysis chapter, states that senior citizens would like to have their personal physicians involved in the services, in the sense that they ought to have access to the medically-relevant data that has been collected by the Vixi. This ought to be taken into consideration as it would add significant value to the

service given that there was unanimous affirmation from survey participants on this matter. However, upon the designing of this additional system functionality, a number of challenges have to be dealt with among which is protecting the user's privacy. At the current development phase of the system, all of the user's data is stored in their smartwatch and further backed up in their smartphones, i.e. it does not leave their devices. Allowing the users' personal physicians access to their medical data would mean that the data itself would have to traverse through networks in order to get to the intended endpoints. Given the sensitive nature of such information, this would warrant data encryption, along with the implementation of authentication methods. It would also require a dedicated server(s), which would create new operational costs.

### 11.3 DEVISE A HOSPITAL RECOMMENDER SYSTEM

Given the relatively free form of conversation that constituted the interview with the expert in section 6.3 of the Analysis chapter, a few unpredicted notions were touched upon. These, although out of scope of the current Thesis, could nevertheless prove to be of substantial significance for any future research. One of these topics was regarding the dilemma as to which hospital should someone go to, when they are experiencing a complex condition such as an ACS, stroke, etc. These types of ailments require specialized medical equipment and perhaps more importantly - medical professionals that possess the necessary skills for the specific medical field. It appears that there has been some debate among representatives of the medical profession as to whether a patient in such a critical situation ought to go the nearest medical establishment, or if they should spend an additional 30-60 minutes in transit, in order to get to hospital that is further away but better equipped to help them in their current situation. Apparently there is a consensus that the former can be a better alternative and there are studies that support the assertion that the nearest hospital is not necessarily the best option[160], however this does raise the question how to best deliver a recommendation about the optimal choice of a hospital in an emergency. This type of functionality would warrant its own dedicated recommender system that would have to simultaneously consider: (1) the user's location in relation to available hospitals; (2) the facilities and personnel of the hospital in relation to the specific critical condition of the user, and (3) the progression rate of the user's condition, i.e. in the situation where a better option is further away, could the user afford to waste that additional time on the road or do they require more immediate attention.

The difficulty with designing such a recommender system would be in the adequate approximation of the user's condition. More precisely, how accurate the system's estimation will be regarding how long the user would be able to spend on the road without a significant worsening of their condition or even a fatal outcome. If the system underestimates the time available, then it would probably send the user to a hospital located closer to the user. This would not cause the user additional harm but it would reduce the value of the recommender system as a whole. However, if the system overestimates the time limit, then there would be a risk of the user being directed to a hospital that is further away but which they might not be able to reach at all. In such a situation the recommender system could potentially be detrimental to its user's health and wellbeing. Therefore, further study has to be conducted into collecting relevant hospital data, classifying the aforementioned data according to relevant conditions and establishing a more precise estimation of a user's condition when it comes to the time variant.

## 11.4 UTILIZE FALL DETECTION TOOLS TO DIFFERENTIATE BETWEEN VARIOUS ACTIVITIES

From the Ischemic Heart Disease chapter it is known that arrhythmias are almost always present in the manifestation of an ACS. Tachycardia or bradycardia can both signal the onset of a critical event: irregular heart rhythms that accompany AMIs can lead to cardiac arrest or even SCD. Detecting the presence of arrhythmias is already a significant component of the system; however there is still the issue of distinguishing between dangerous arrhythmias and those triggered by exercise. Currently, the user would have to momentarily deactivate the application during sport activities in order to avoid an onslaught of alarms. Given that there is already a motion detection component within the system – in the form of fall detection - it is proposed that the abovementioned functionality be further developed. Vixi should be able to automatically detect activities that could raise the user's heart rate in order to reduce the risk of false alarms.

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