Reliable Software Development in a Vital Signs Monitoring System

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Resumo

A área da saúde encontra-se em constante evolução e, actualmente, vários sistemas informáticos são usados para ajudar os médicos no seu trabalho. Um exemplo concreto é área de monitorização de sinais vitais onde produtos recentes a usar tecnologias tais como sensores de baixo custo, comunicações sem fios, aparelhos móveis e aplicações Web, estão a ser comercializadas e em constante melhoramento.

Este documento apresenta um estudo sobre tecnologias usadas para construir sistemas de monitorização. O objectivo é desenvolver um sistema fiável com a capacidade de detectar um possível desastre ou morte de um utilizador. Um protótipo funcional, composto por uma parte de monitorização e outra de controlo, é descrito. A parte de monitorização é o assunto desta tese.

A análise e design do software é o assunto com maior destaque, mas atendendo às características interdisciplinares do projecto, vão ser exploradas outras áreas como Electrónica e Medicina. O objectivo é perceber que futuros melhoramentos e extensões o sistema de monitorização pode ter.

Abstract

Health Care is in constant evolution and, currently, diverse computer systems are being largely used to help Physicians doing their work. A concrete example is the vital signs monitoring area where recent products using the latest technologies as low-cost sensors, wireless communications, mobile devices and web-based applications, are being commercialized and constantly improved.

This document presents a study about the technologies used to build monitoring systems. The objective is to develop a reliable system able to detect a possible death or disaster. A functional prototype, composed by a monitoring and a control part, is described. The monitoring part is the subject of this thesis.

Software analysis and design has the biggest focus, but attending to the project's interdisciplinary characteristics, other fields of study, such as Electronics and Medicine, are explored. The objective is the understanding of future improvements and extensions that the monitoring system might have.

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Chapter 1

Introduction

Health is the most important aspect of a person, live long and healthy is certainly the deepest wish of each human being.

Observing the causes of death in the whole world in 2004, 12% were caused by Heart Attacks[1]. It is the leading cause of death in the developed countries, and it's only under AIDS and respiratory infections in the developing countries. A quick overview in the United States facts shows that every year about 500 000 people died in a total of 1.5 million heart attacks and almost 14 million Americans have an history of heart attack or angina. Another important fact to look at is that about 50% of death occur outside of the hospital within one hour of the heart attack. Let us imagine a disaster scene where someone having an heart attack is alone, for example on his/her own house, it is almost inevitable the death or the irreversible damage of that person. What if a warning was sent to an entity each time a situation like that happened? Definitely many lives would be saved.

A control system with these characteristics can be integrally done with the current technologies, but there are many concerns to worry about before developing it. How much will it cost? What is the battery's life time of each component and how can we improve it? Is it comfortable to wear? These are some questions that need careful study about.

It is not hard to notice that Software failures are not welcome in a continuous monitoring system. It is not admissible to receive false warnings frequently about someone's health. So it is crucial to ensure a reliable and well structured software solution to the monitoring system components. These needs make Software Quality the main study subject on my work.

1.1 Background

Monitoring health aspects is a common practice all over the world inside the hospitals facilities. Patients with serious cases of illness are usually wired to monitoring machines all around their hospital beds. The cardiovascular system, due to its importance in the patients rehabilitation, is commonly monitored with the ECG, blood oxygenation and blood pressure. So, wired and big devices make part of every health institution to track the patients and help physicians doing their job.

In the beginning of the 21st century, attending to the crescent wireless communications usage and protocols definitions, some companies and research groups, interested in health care area, redesigned medical equipments eliminating the old fashioned wires. Also around the 2000's, watches using chest straps for monitoring an individual sport activity were becoming famous. Polar[2] and Garmin[3] are the the two strongest companies investing on it.

A very recent technology seems to be the new generation of monitoring systems, where sensors are embedded directly on a washable and comfort shirt communicating wirelessly with external devices via known protocols as Bluetooth [5]. A recent Portuguese company is starting to commercialize this product.[4]

Concluding, the current low cost and easy to implement wireless technologies are allowing mobile health monitoring. In another words, what a few years ago were only available in medical facilities using wired and big machines, is now turning into small and comfort devices communicating wirelessly with other devices capable of process the data.

1.2 Proposed Problem

Sports monitoring, as it is implemented currently, tracks a person heart signal, respiratory rate and temperature, for example, during his/her training. That permits to calculate interesting body parameters, like the calories wasted, and others, and with further analysis the training can be better adjusted to the personal needs of the given person.

Health monitoring has its main goal as monitoring a patient during a certain period of time, usually a few days, in his/her daily life recording the vital information and analyzing it to find possible heart related diseases. It is also commonly done in some medical facilities a tracking of the heart signal in different effort conditions like resting, walking and running. The information is analyzed in real-time by a physician to detect possible problems.

Alcor, Life Extension Foundation, is a non-profit American company located in Scottsdale, Arizona, that works in the biotechnology area. Alcor staff is very interested in a monitoring system with a different characteristic from the presented above. They want to monitor continuously, 24 hours per day, their clients. The main objective is to warn Alcor if a serious problem occurs with a certain client, like having a heart failure.

1.3 Approach

The problem proposed is multidisciplinary involving three main fields of study that will need a careful study about, Electronics, Software and Medicine.

In the Electronics side it is necessary to understand which sensors can measure the vital signs of a person and how can they be used for the effect. Due to the mobility requirements, it is necessary to understand how wireless communications work and how they can be used to connect a sensor with a near external device. In this stage a comparison between short range Wireless Technologies will be made.

The Software part is fundamental to control the whole process of receiving and process the vital signs data, sending warnings to the Alcor staff, controling how Alcor will access the information and how they are warned. A Physical and Software Architecture design will be made. A System Model will be also achieved to be the target of integrity and functionality tests. This part ends with the development of a Functional Prototype of the whole monitoring system.

To improve the whole system a study about the heart related diseases and possible situations of risk, that might predict a heart failure, will be made. The goal is to understand how can be implemented that feature in the monitoring system.

This work was proposed to me and Rui Freitas, also doing a Master Thesis, and we are working with the Alcor staff on the project. We were personally in Alcor's facilities in Scottsdale, Arizona, during a few months, understanding exactly what kind of system they aim to have. Our goal was to obtain a rigorous Requirements Analysis which is a very important stage in the role of the project. Lately, and after the understanding of Alcor requirements, we decided to make a generic system able to work with other companies or even without any company.

The Project is divided in two parts, the Mobile one, responsible for monitoring and detecting abnormal values, and the Control one manages alerts and received data, warning Alcor or other Entities if necessary. I am responsible for the Mobile Part and Rui Freitas for the Control Part [6].

1.4 Objectives

In this section the main objectives of my work will be enumerated, attending to its chronological order.

The main goal of my work is to develop a functional prototype of a continuous monitoring system able to detect a possible heart failure and to send an alert to the Control system.

For that purpose the following items are considered:

- Create a proof of principle using a first chosen sensor present in the market. This prototype is very helpful to improve the Software Requirements Analysis Stage. To select the sensor to use it is considered the price, battery life, comfort and what kind of vital signs it measures.
- Analyze the different existing communication protocols between the sensor and the device that will receive the data in terms of power consumption, connectivity range and security.
- Collect information about the cardiovascular system in order to understand which symptoms can predict cardiac problems and how can these symptoms be detected and analyzed by the monitoring system.
- Describe a software analysis and design to develop a consistent software platform for the monitoring system. For this purpose, it is done a requirements analysis stage, a software architecture is defined and a model to be tested is achieved. The model verification leads to the development of a functional prototype for a continuous vital signs monitoring system.

This thesis focus on these topics, but other subjects are also explored.

1.5 Document Overview

To understand how the problem proposed can be done articles and studies about similar wireless monitoring projects were searched. It was also necessary to study which technologies are necessary and useful for the purpose, as well as products that might be used as components of the monitoring system aimed. Chapter 2 presents the different studies, companies and technologies in the vital signs monitoring field that might support this study.

When a vital signs monitoring system is being developed is strictly necessary to understand what are the vital signs of a human being. After that, a question shows up: How can the vital signs be measured? Chapter 3 presents the vital signs and answers the question, listing the different existing sensors that can be used for measuring the vital signs of a person. Also in this Chapter, an overview and a comparison of the existing wireless technologies that can be used in this project are presented. Finishing Chapter 3, heart related diseases and cardiac problems detection are the subjects explored. The goal is to improve the system in the future with these analysis features.

In Chapter 4 the whole Software design stage is detailed. From the Requirements Analysis that will lead to a System Architecture, going through the Abstract Model and its Unit Tests and ending in the Functional Prototype, the whole stage is described and the main conclusions are referred.

Chapter 5 presents the final conclusions of the entire study done. Future work and improvements in the several fields of study and in the monitoring system are explained.

Chapter 2

State of the Art

In the current days, several kind of sensors surround ourselves, in our office, in our car, even in our home various sensors are working for our safety and well-being. The constant evolution in the Electronics Engineering area permitted the construction of small size and low cost sensors to use in several purposes. The health care is one example, where vital signs are monitored, for example, in case of illness or illness detection, pre/post surgery and also in sports performance evaluation.

The Vital Signs Monitoring is currently a field of study in many Universities in the Biomedical, Electronic and Software Engineering areas. There are also several companies commercializing solutions for this purpose.

This Chapter presents different researches and technologies, made in the last years, in the monitoring area, as well as, companies working in this field. Three wireless short-range protocols, that can be used in monitoring systems, are also presented.

2.1 Research Projects

Philip Rios, [7] researcher in the University of California and member of the "Calit2" group, refers that "Adapting wireless and sensor technologies for use in medical research is now a prime area of investigation within Calit2" [8]. Rios is the leader of a software team developing a health monitoring system. Their purpose is to build a phone application that receives a person vital signs activity from a sensor via Bluetooth, then the user can track his own vital signs. This information is periodically sent to a central repository using the 3G wireless technology and it is accessible via Internet. This data can then be analyzed with detail, for example, by a physician to check if there is any problem with the user.

Another research project in the vital signs monitoring area is "SMART - An Integrated Wireless System for Monitoring Unattended Patients" [9]. This project involved researchers from various Universities. Their propose is to monitor patients in an overcrowded Emergency Department or disaster scene. The SMART System monitors the patient's heart rate, ECG, SpO2 and geo-position. This information, as well as the caregivers location, is received wirelessly in a central server that processes and analyzes it, and then, if necessary, alert messages are created and forward to the caregivers PDA, depending on their location. This system can be very useful in an Emergency Department with a large number of patients where after the triage in the waiting area one of them can become progressively worst and no one is warned about that situation.

AID-N [10] is another project that has the same purpose as the SMART project, the monitoring and scalability of patients in a disaster scenario. Both are very similar, the main difference is that the patients' data are processed and analyzed right in the device that contains the sensors, the miTag [11], and not in the central system.

Going out of the systems designed to disaster scenes, a proof of concept was done in the American University of Sharjah of a wearable monitoring system that stores the heart rate, pulse oximetry and blood glucose level of a patient during a certain period of time. The "Wireless Stand-alone Portable Patient Monitoring and Logging System" [12] allows a physician to analyze a patient's health situation during a certain period of time during his normal life. This project seems very useful in patients that have a need of constant medical care. The article's authors refer that they were working on the data being received in the Physicians office in real time and in an SMS system that periodically send a message with the monitoring data to the Physician and warns immediately in case of an abnormal reading.

In the sensor side, a very interesting research project was done in India. The "Smart Vest" [5] is a washable shirt that contains monitors the following physiological signals: electrocardiogram, photoplethysmogram, body temperature, blood pressure, galvanic skin response and heart rate and is able to transmit them wirelessly. It also contains a GPS module.

In the 3rd International Conference in Pervasive Computing, "Pervasive 2005", was presented an architectural design of a health monitoring system. The "Body Sensor Network" [13] continuously monitor the ECG signal, the temperature, blood pressure and oxygenation. The data is received and analyzed in a PDA.

2.2 Heath and Sports Companies

"Cardionet" [14] develops products for health purposes. They provide a monitoring system during a certain period of time to their clients. The objective is the detection of heart diseases like arrhythmia.

Welch Allyn produces several types of medical devices. This company has a patient monitor system, the Micropaq Wearable Monitor [15], that continuously monitors ECG, blood oxygenation and pulse bar. It is a wireless device designed with the purpose of tracking ambulatory patients in an hospital.

Alive Technologies [16] develops monitor systems that communicate via Bluetooth with a mobile phone, computer or a central monitoring centre. The data is stored and can be analyzed with medical or sports purposes.

Biodevices, a Portuguese Company that is a spin-off from the University of Aveiro, is commercializing the Vital Jacket [17], a comfortable and washable t-shirt able to monitor a user up to 5 days. The ECG and heart rate measured can be sent in real time to a PDA or laptop, or they can be recorded for later analysis. This interesting product shows that chest straps will no longer be needed.

Around the vital signs monitoring area, there are several companies using this technology to sports performance analysis or/and for health purposes. Well known companies like Garmin and Polar produce chest straps that record the user's heart rate, position (GPS), velocity and others and transmit them to a watch. Then, the user can track his own information during his sports activities.

2.3 For Developers

For developers Mobimotion [18] and Zephyr Technologies [19] provide chest's strap monitors with SDK's. By request, Java and .NET API's can be obtained also. Zephyr Technologies develop also products for fire fighters and sports.

Plux [20], a recent Portuguese company develop monitoring sensors according to the client needs and they also develop products for sports performance monitoring and older persons health tracking. Plux provides an SDK to work with their sensors.

With the crescent using of mobile monitoring systems, the main Information Technology companies, such as IBM, Cisco, Intel and others, are certificating products to permit interoperability between future technologies working with monitoring data and devices. This was how Continua Health Alliance borned, currently with more than 200 member companies. [21]

2.4 Communication Protocols

A vital signs monitoring system needs to use short-range wireless communications to connect the vital signs sensor with a device capable of receiving the vital information, user's mobility and comfort can't be restricted. The recent wireless short range protocols in focus, commonly used and appropriated for the purpose are described next.

2.4.1 Bluetooth

The first specification of Bluetooth[22] was created in 1999, and the design goals were a low power and low cost system. In the preceding years this technology was used in several devices as mobile phones for file sharing, hands-free handsets and external control. For example, a large number of laptops nowadays integrate a Bluetooth cell for communication with mobile devices or other laptops, syncing and file sharing is then permitted. This technology was responsible for the cables replacement in Mobile Phones, Computers and some Computer Peripherals.

This protocol is in conformity with the IEEE 802.15.1 Standard [23] and it was designed for a different number of operations between different types of devices. The fact that Bluetooth protocol is not specific for a certain purpose caused a larger number of stack layers than other low range protocols. As a consequence of this aspect a connection establishment takes some seconds (usually more than 3 seconds) to be made and the connection is heavier. This requires higher energy costs and latency in comparison with other specific and stack lighter protocols. Bluetooth is a technology made for rechargeable devices with regular charging.

In terms of security, Bluetooth provides a 128 bit data encryption, a user authentication method using a Personal Identification Number (PIN) and a Bluetooth address to ensure the data is sent to the right device. [24, 25, 26, 27]

Very recently, the Bluetooth staff presented the Bluetooth low energy Technology that is a new protocol definition, with significant improvements in the energy costs, compatible with the old Bluetooth specification. [28]

2.4.2 Zigbee

The 802.15.4 Working Group of IEEE [29] developed a protocol for lightweight wireless networks. So the main concern of this standard is the energy costs.

This IEEE Working Group is formed by the members of ZigBee Alliance [30] that specified the ZigBee protocol in 2004. The necessity of ZigBee appeared for sensor networks, specially for Home Automation (Domotics), medical monitoring and PC peripherals. These technologies require low cost and long battery life sensors and transceivers.

ZigBee design goals are simplicity, low energy costs, networking capabilities (supporting different network topologies), reliability, security and low cost. The lighter stack protocol reduces latency since a connection between two ZigBee enabled devices is established in 30ms and the switch from sleeping mode to active is done in 15ms. These connection times are ideal for a light switch or a controller device where a fast response is required.

The Wireless Sensor Networks (WSNs) are the target technology of this protocol due to its low cost, low power and network capabilities. Home Automation, health monitoring and control devices are suitable applications to use ZigBee and benefit from its characteristics.

In terms of security, AES with 128-bit keys cryptography algorithm is implemented in the protocol, to avoid data corruption by other devices. In the Application Layer other security algorithms can be implemented. [31, 32, 33, 34]

2.4.3 ANT

In 2004, Dynastream Innovations created ANT Wireless [35]. ANT was designed for WSNs, so ultra low power, small size components, networking capabilities and low cost are the main goals of this protocol.

ANT is a proprietary wireless protocol with its main applications in sport, health, home and industrial control. This protocol doesn't use any standard in order to be extremely optimized for its main purposes, low power consumption and simplicity. It can operate for about three years using a coin cell battery due to its optimizations in power requirements.

In terms of security, AES 128-bit will be implemented in a next version of the protocol. If needed, encryption has to be implemented in the host, in the Application Layer. Although, an 8-byte network key is created to access control.

Chapter 3

Vital Signs Monitoring

In this Chapter are presented the vital signs and other important health parameters considered. Different existing sensors for measuring vital signs are also listed. A comparison of the wireless protocols presented in section 2.4 is also made. Finishing this Chapter, cardiac problems detection is the subject explored. The objective is to improve the system in the future with these analysis features.

The main goal of this project is to monitor the vital signs of a person. For that purpose the first thing needed is a sensor platform able to receive the signals from a person and send them to a certain device to be stored.

There is several kind of health monitoring sensors already being used in hospitals and health facilities all over the world. For example, when we do an ECG or measure our blood pressure.

3.1 Vital Signs

Health monitoring has the objective of measure the different kind of vital signs to analyze them next. The four standard vital signs are the following[36]:

- Heart rate, the number of times the heart beats in a minute.

- Blood Pressure, the forces applied by the blood in the walls of the arteries.

- Respiration Rate, the number of times an inspiration-expiration cycle occurs in a minute.

- Body Temperature.

The Electrocardiogram (ECG), a representation of the electrical activity of the heart, and SpO2, the measurement of the amount of Oxygen carried by the red blood cells, are usually measured by physicians to evaluate the state of the cardiovascular system of a patient. So, it is important to take them in consideration.

3.2 Sensors

Different kinds of sensors were created in the last years in the Electronics field. These sensors are all over the place for human's security and comfort. In our cars we have temperature, proximity and velocity sensors. In our homes sensors are in crescent using, domotics has the home automation goal. Even in the videogames area where Wii has been a huge success, taking part of motion sensors.

To measure the vital signs referred above the types of sensors used are the following:

- Electrodes. They are able to measure electric activity, so ECG and heart rate are measured using them.

- Temperature sensors. Electronic heat sensitive components are used to measure temperature, as certain diodes and resistors.

- Optical sensors. Composed by light emitting diodes and a light detector. The analysis of light reflection on blood permits the measurement of Oxygen concentration, SpO2, for example. These sensors can be also used for heart rate measurement. For these purposes they are usually attached to fingers.

- Pressure sensors. As the name suggests blood pressure can be measured with this sensors, avoiding the need of a physician with a stethoscope and a vertical mercury glass column. This kind of sensors can be used, for example, to measure respiration rates when connected to a chest strap.

Electronics Engineering is an area in constant evolution and studies in the last years about new materials and assemble techniques have made this kind of sensors more precise, smaller and cheaper. It can be found on the market low cost chest straps, wireless medical devices, home blood pressure monitors and the recent vital signs monitoring shirts, with sensors embedded on the textile. [37, 38, 39]

3.3 Communication Protocols

Sensor devices can't storage large amounts of data. It is necessary to transmit the data to an external device to be stored and processed. Comfort reasons in the project proposed implies the use of a wireless communication between the sensor and the external device.

Wireless communications usage has been growing in the last years. It is not hard to notice a crescent number of wireless Internet stations in public facilities, in our homes and in commercial services, mobile phones sharing files between them and with computers, GPS technologies and others.

A Communication Protocol defines the characteristics and rules that communicating devices have to obey to transfer information. Data structure, error detection, wave frequencies and authentication are examples of what a protocol describes.

The necessity of different kinds of networks for different purposes obliged the creation of different wireless communication protocols during the last years. In this section an overview of the principal protocols that the monitoring system can work with is made.

A Continuous Monitoring System needs a protocol with the following characteristics:

- **Security**: the data transmitted over the air needs to be encrypted. It can not be allowed a "man in the middle" able to intersect and read the vital signs information of a user.
- **Communication Range**: the protocol for a monitoring system doesn't need to have a long range of operation but it should be allowed some meters of distance between the sensor and the device. The situation of non-proximity between the user and his mobile device must be considered and it shall have the best tolerance possible.
- **Power consumption**: for user comfort the battery life of the sensor and the device has to be the best. For that purpose a low power protocol is highly needed.

Attending to these requirements I will consider and compare the following three wireless protocols described previously in Chapter 2: Bluetooth, Zigbee and ANT. Protocols like Wi-Fi, mainly used for Internet networks, Ultra Wide Band, a short range protocol used, for example, for file sharing between cameras and other media devices without using a PC, or Infrared (IR), a short range protocol that requires a line of sight communication, will not be considered since they are not appropriated for a monitoring system.

A monitoring system, because of its short range characteristics, uses a Wireless Personal Area Network (WPAN) for data transmission between devices. The

WPANs are used to connect devices that are in the same workspace, with a short distance (a few meters) between them. WPANs are commonly used for transferring data from personal computers to mobile devices or even for mobile to mobile data transfers. [40]

WPANs use Electromagnetic Radiation to transfer data and they are in the Radio Frequency range of the Electromagnetic Spectrum using wave frequencies around the 2.4 GHz.

The Institute of Electrical and Electronics Engineering, usually referred as IEEE [41], defines communication standards named 802 followed by a different number for each kind of network, for example Wi-Fi is commonly referred as 802.11. WPAN working group is the 802.15 where Bluetooth [23] and ZigBee [29] are integrated.

Putting the protocols presented in Chapter 2 in parallel, Table 3.1 shows a comparison of some important characteristics for the monitoring system proposed. [42, 43, 44]

Observing the table, the energy costs are the most relevant aspect where the differences between Bluetooth and the other two protocols are stronger. This shows that Bluetooth has energy costs much higher than ANT and Zigbee, however as referred in section 2.4.1, the new Bluetooth low energy Technology [28] seems to be a strong response to enhance this characteristic.

Protocol	**ANT**	**ZigBee**	**Bluetooth**
Standard	Proprietary	IEEE 802.11.4	IEEE 802.11.1
Application	WPANs and WSNs	WPANs and WSNs	WPANs
Data Rate	1 Mbit/sec	250 Kbits/sec	1 Mbit/sec
Network Topology	Peer to Peer, Star, Mesh	Peer to Peer, Star, Mesh	Ad-hoc, small networks
Security	Needs to be implemented	AES 128	128 bit data encryption
BOM Costs (Comparing with ANT)	-	60% greater	90% greater
Battery Life (using a coin cell battery)	3 years	6 months (theoretically)	7 days (theoretically)
Range	1 to 30 meters	1 to 100 meters	1 to 10 meters
Protocol stack size (Comparing with ANT)	-	10x larger	100x larger

Figure 3.1: Communication Protocols comparison

3.4 Cardiac Problems Detection

The monitoring system proposed in this thesis has the main goal of sending warnings each time a user is in risk of death, because of a heart related problem. This section presents some possible ways of predicting this kind of problems.

In the major part of cardiac arrest situations, known *Arrhythmias* precede the heart stop. An Arrhythmia is a heart beat rhythm problem and during one the heart beat can be too slow, too fast or have an irregular rhythm. To detect an Arrhythmia is necessary to analyze the ECG trace.

There are four heart symptoms that lead a person to a cardiac arrest [45]. Their names and ECG traces are the following: [46]

- Ventricular Tachycardia (VT) Monomorphic or Polymorphic. Usually the heart rate is between 100 and 250 bpm. There is also an unusual variation called Torsade de Pointes with heart rate values between 200 and 250 bpm.

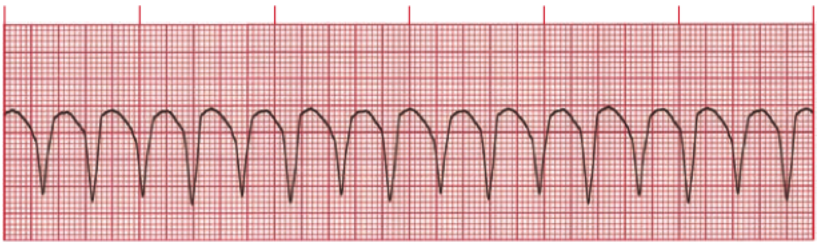

Figure 3.2: ECG trace of Ventricular Tachycardia Monomorphic.

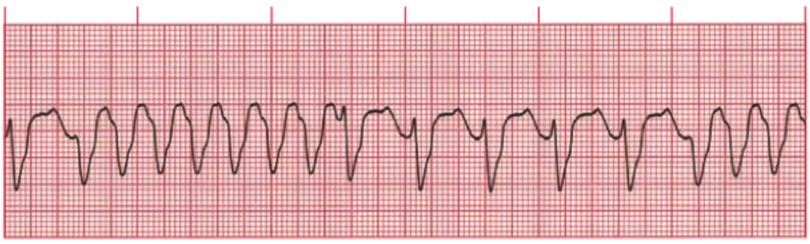

Figure 3.3: ECG trace of Ventricular Tachycardia Polymorphic.

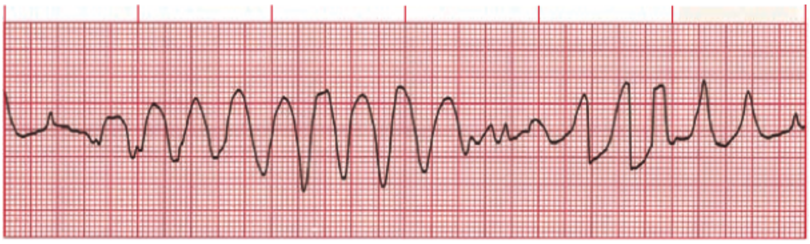

Figure 3.4: ECG trace of Torsade de Pointes.

- Ventricular Fibrillation (VF). The heart rate can not be determined, occurs a chaotic electrical activity.

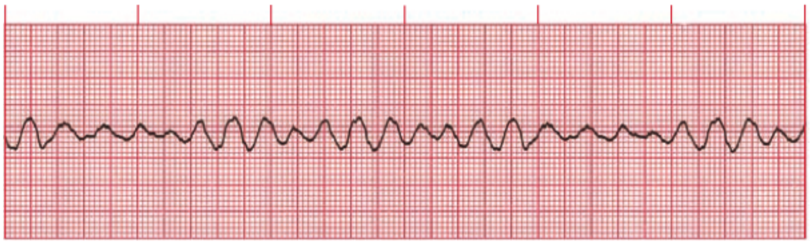

Figure 3.5: ECG trace of Ventricular Fibrillation.

- Pulseless Electrical Activity (PEA). The electrical activity is identifiable but no pulse is detected.

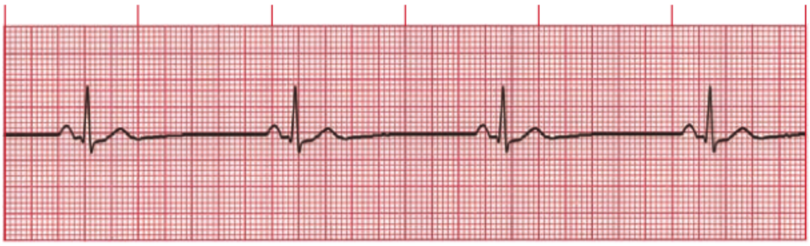

Figure 3.6: ECG trace of Pulseless Electrical Activity.

- Asystole. The ventricular electrical activity is void.

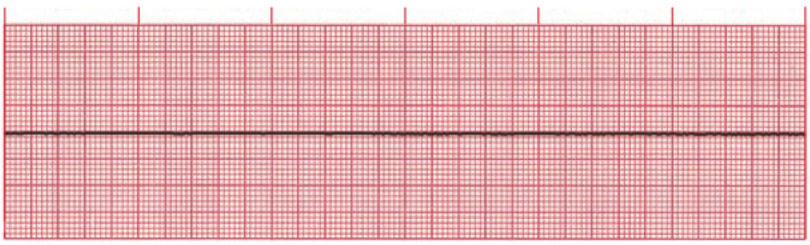

Figure 3.7: ECG trace of Asystole

There are a large number of heart related diseases not mentioned. The above presented are important because they can predict or indicate a serious heart failure which is the main goal of the monitoring system proposed on this thesis. Just as an example, Bradycardia and Tachycardia, defined as having heart rate values under 60 bpm and above 100 bpm, respectively, with no physical activity, are easy to detect analyzing the heart rate of a person during a few days.

Chapter 4

Software Analysis and Design

In this Chapter, the software analysis and design process are described and the main results presented. It starts with the Requirements Analysis stage, where the techniques used are described and the system requirements are identified. Since this stage is done by me and Rui Freitas [6], section 4.1 is common in our theses. Then, a System Architecture is achieved, with and ends with the construction of a prototype based on a reliable model.

4.1 Requirements Analysis

The Requirements Analysis has a fundamental role in the whole system development. This is the stage where the Client and the Developer cooperate to reach an agreement about which characteristics the final product will have. In the end of the Requirements Analysis the developer should obtain the System Architecture, its functionalities and properties.

4.1.1 Problem Description

Alcor, Life Extension Foundation, is an American company working on the biotechnology area. Alcor staff is very interested in a Continuous Monitoring System able to warn them every time one of their costumers had a heart failure, causing a serious danger of death. Alcor contacted me and Rui Freitas to create a system with these properties.

The basic goal is to send a warning to our client when a given person have a heart stop.

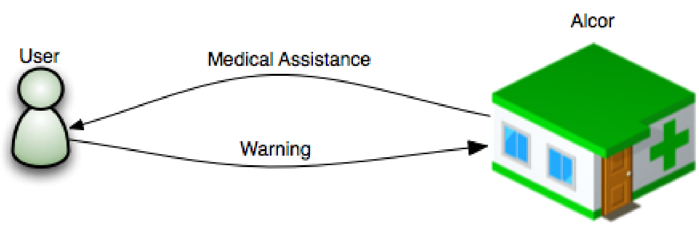

Figure 4.1: The first system scheme.

4.1.2 Introspection

To create a short overview of the problem we used an elicitation technique called Introspection. Using Introspection the analyst defines the system requirements based on what he believes the client needs are. This technique is considered to be a good starting point for other types of techniques. [47]

Based on what we knew from the Problem Description we identified the basic components of the system. Those components would be, then, a sensor receiving the heart information and transmitting it to a device capable of sending a message to Alcor. Storing the heart information of a end-user could be very useful, so the data should be stored for analysis.

4.1.3 Domain Analysis

The first technique used for the Requirements Analysis was the Domain Analysis. This technique consists in the search for documents and similar projects [47]. During the Domain Analysis we found different kinds of monitoring systems. This was important to discover which sensors could we use and to analyze the existent architectures.

About the Software development, Zephyr Open Framework [48] caught our attention. This project, led by Brad Zdanivsky, runs on a pc and works with the sensors from Zephyr Technology [49] company. The costumer connects the sensor via Bluetooth with the computer using the Zephyr Open Framework. The data from the sensor starts being transmitted over the air from the sensor to the computer each time the both connect. The costumer is able to see it in real time and store it for further analysis.

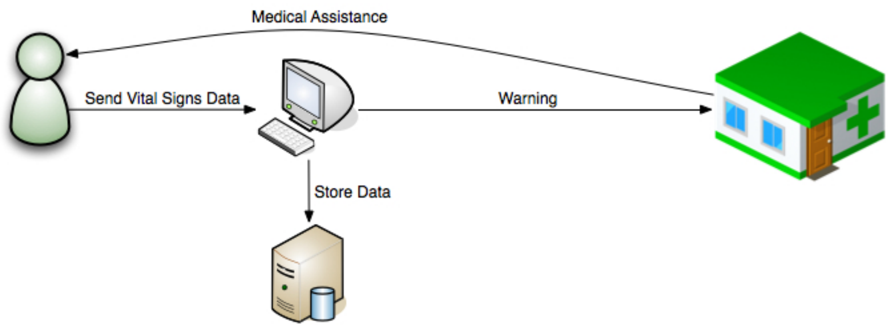

Figure 4.2: The second system scheme.

4.1.4 Prototyping

Using the framework provided by Zephyr Open, a first basic prototype was built. This is a technique known as Prototyping and consists in the creation of a rudimentary system, usually known as Proof of Principle, that implements the basic functionalities of the system. This is a good technique to receive feedback from the client and for the developer to understand if the analysis made is being the best

[47]. This feedback is very important to improve the problem description and to find some details in the client wishes.

This prototype only did the monitoring and showed the results in real time, updated every second, in the computer. We decided to add a new feature that send an email if a specific value of the heart rate was observed during the monitoring. To observe the system working we couldn't use values like "0", which is a result received from a non-beating heart. Instead, we used an achievable value, like "100", that is easy to get putting the monitoring person practicing some exercise. This demonstrated that it is possible to send a warning, in this case via email, if a certain value is reached, either if it is "0" or "100".

Figure 4.3: The Proof of Principle.

While presenting the Proof of Principle to the company we received some useful feedback, that allowed us to get a better problem specification. Our client suggestions were the following:

- It would be better to receive the data from the sensor in a Mobile Phone. In terms of user comfort this would be the best option;
- Before sending an alert the user should have a short period of time to cancel it. This is useful to avoid false alerts.

4.1.5 Final Problem Description

After the completion of the stages described above a final problem description was achieved. We divided the problem in two different parts: **Monitoring** and

Control. I am responsible for the first one and Rui Freitas for the second one.

The Monitoring part will run on a Mobile Phone or a Personal Computer and is responsible for receive the data from a vital signs sensor and send alerts to the association each time the sensor reports an abnormal reading. Before sending the alert to the association it is important to warn the client during a small period of time. If the client didn't cancel the warning then the alert should be sent to the association. The client is able to observe the data received from the sensor in real time and store it in the control system.

The Control part will manage the alerts and the vital signs information received from the client. This permits the further analysis of the data in better detail, which can also permit the detection of diseases or possible disasters. A history record is also kept for each user. One of the objectives is to put the Vital Signs Information accessible to each user, or in certain cases to the Association, to consult and observe.

4.2 System Architecture

The part of this project integrated in my thesis is the Mobile one. So, from now on, it will be the main subject.

Physically, the Mobile Part is composed by a heart rate sensor transmitting the data wirelessly and a device capable of receiving it, a mobile phone, a desktop, a laptop or a PDA, for example.

The Device that receives the vital signs information from the sensor has to analyze and show it in real time. When a problem is detected it sends a warning to the Association responsible for the given user. These warnings are sent to the Control Part to keep a record for each user. The sensor data can be also sent to the Control Part to keep a user's vital signs information record and to make a deeper analysis, for example, to detect heart related diseases.

4.2.1 Entities and Attributes

The first entity identified is the one responsible for receiving the data from the sensor, it will be called ***SensorInfo***. This entity will transform the data stream coming from the sensor in common data types, like Integers or Strings, storing them in its attributes. Basically it will parse the messages coming from the sensor. The *SensorInfo* can also analyze each message received from the sensor during the whole connection time.

The *SensorInfo* attributes are the different sensor measurements transmitted, like the Heart Rate value, the velocity, etc.. The number of informations received from the sensor may change, for example using a sensor capable of measure the respiration rate or the oxygen concentration in blood. So it is important to separate that attributes from the rest of the system, letting *SensorInfo* to take care of them.

The Sensor sends information with a certain time interval, so the system has to store these informations each time they are received and keep a record of the latest tracked values. This requirement identifies the entity ***Central*** that will store the data along with the connection time.

The *Central* entity needs to store the several *SensorInfos* sequentially created with the sensor information. So, a set containing *SensorInfos* is an attribute of this entity. *Central* will also control if the user wants to send warnings and data to the Control Part, for the effect two boolean attributes, *SendData* and *SendWarnings*, will define these properties.

4.2.2 Operations

Identified the two main entities and their attributes it is time to make an overview of the most important operations presented in the system.

SensorInfo entity needs an operation responsible for receiving the data from the sensor and store it in its attributes *HeartRate*, *Velocity*, etc.. This operation will be a constructor of the entity, usually with the same name. Operations to analyze the vital signs received make also part of the *Receiver*, for example to check if the Heart Rate is in abnormal values, very important to detect a possible warning. For this purpose, and because of the abstraction level of the current stage, it will be defined just one operation called *IsWarning*.

The *Central* entity has the main functionalities of storing the several *SensorInfos* received. For that purpose an operation called *StoreSensorInfo* is created. Send warnings and data to the Control Part is also a responsibility of *Central*, so two operations, called *SendWarning* and *SendData*, are here identified. To notice that the data sent to the Control Part needs to be transformed to be in conformity with the data stored there. This leads to the operation *DataTransform* that will receive the data as it is defined in the Mobile Part and will return the data as it is defined in the Control Part.

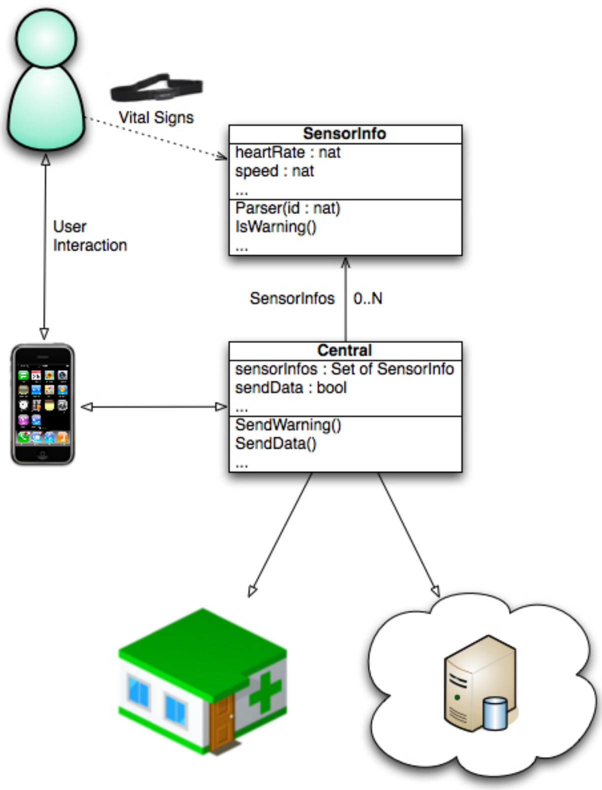

Figure 4.4: Schema presenting the Physical and Software Architecture.

4.3 VDM Model

In the Software Development process Modeling assumes the middle point between the Problem Specification and the Software Implementation. What distinguish a Model from an Implementation is the abstraction level on which the problem is described and built. After building the System Architecture, structure animation and test are the next step to take, i.e., a system model needs to be built and tested. Details must not be considered during this stage, abstraction is very important to obtain a rigorous and robust model.

The goal is to check the system base architecture consistency and search possible structural problems that only could be detected lately with high fixing costs. In the end of this process is expected the model verification and validation using analytical and/or testing methods. This will give the developer confidence to proceed with the system implementation. [50]

4.3.1 The Language

The importance of modeling software problems opened a window to the appearance of specific Modeling Languages. In this work VDM++ will be used to build the system model. VDM++ is an extension of the Vienna Development Method Specification Language (VDM-SL) that adds Object modeling capabilities. [51]

In a very short and fast description, to make a bridge between the System Architecture and the Model implementation language, I will enumerate the main nomenclature differences:

- The *entities* will be VDM++ *classes*;
- The *attributes* will be the *instance variables*, also referred by some authors as the Object State;

- The *operations* have the same name, but VDM++ makes a distinction between operations and functions. The operations can modify the instance variables of the class. The functions can not access instance variables, i.e, they just receive the inputs and return an output.

4.3.2 Mobile System Model

This section will present the model structure. Classes, instance variables and some main operations are described.

The system modeled has two classes: *SensorInfo* and *Central*. Their instance variables and main operations are already described in Section 4.2.

- SensorInfo

The Sensor Info class stores the user's heart rate and velocity. The date adds a temporal dimension to the information received from the sensor.

```
class SensorInfo

instance variables

heartRate : nat;
velocity  : nat;
date      : nat;
```

This class has operations to read the instance variables and a Constructor that receives their values as arguments. *IsWarning* returns "true" if the heart rate is equal to zero, it is the way used in the model to detect and send alerts to the Control Part. These are the operations signatures of the constructor and IsWarning that shows the inputs and the outputs.

```
operations

public SensorInfo: nat * nat * nat ==> SensorInfo
public IsWarning: () ==> bool
```

- Central

Central saves the several *SensorInfos* received in a set, and controls if the user wants to send data and warnings to the Control Part.

```
class Central

instance variables

sensorInfos      : set of SensorInfo;
sendData         : bool;
sendWarnings     : bool;
```

The operations of this class start with the constructor that creates the set of SensorInfo, as an empty set, and the boolean variables as false. There are also two operations to set the boolean instance variables values.

```
operations

public Central: () ==> Central
public SetSendData: bool ==> ()
public SetSendWarnings: bool ==> ()
```

The several SensorInfo's received are stored using the *StoreSensorInfo* operation. This operation also analyze the vital signs information and sends a warning to the Control Part if the *heartRate* value is equal to zero. So, it is necessary to receive a *Client* as a parameter and use its operation *SendAlert* to send an alert to the Control Part. Before sending the alert this operation checks the *sendWarnings* variable. *StoreSensorInfo's* pre-condition has to guarantee that the set *SensorInfos* don't contain the SensorInfo received as argument. The opposite is the post-condition.

```
public StoreSensorInfo: Client * SensorInfo ==> ()
pre si not in set sensorInfos
post si in set sensorInfos;
```

It is also necessary to send the several vital signs information to the Control Part. For that purpose is necessary to receive a *Client* and use its *AddSetOfData* operation to store the information. This operation cannot be used if the user doesn't want to send the vital signs information to the Control Part. That is the pre-condition required.

```
public SendSetData: Client ==> ()
pre sendData;
```

The class *Data*, from the Control Part, is responsible for storing the vital signs information. So, it is necessary to transform the data from the Mobile Part in data compatible with the Control Part. This led to the definition of a function that receives a *SensorInfo* set and returns a *Data* set. This function is used by *SendSetData* to transform the vital signs information. The post-condition guarantees that the number of elements in the input and output sets is the same.

```
functions

SensorInfosToData: set of SensorInfo -> set of Data
post card(setsi) = card(RESULT);
```

This is an overview of the most important aspects of the Mobile Part model. This model fits in the Control Part model because it uses operations and classes from the Control Part.

VDM++ provides a syntax, type and integrity checker that analyzes the code produced. If these properties are verified then the testing stage can be started.

4.4 Testing

In the software development process testing is the stage where the model, or the implementation, behavior is analyzed. Unit tests are commonly used to evaluate the behavior of individual operations under certain test cases. This is a method to verify, and consequently validate, the code produced by software developers.

In VDM++ unit tests can be done using the VDMUnit [50] framework. This technology will be used to observe the model's behavior in defined test cases.

In the model developed, there are three main properties that must be guaranteed. Each one will be submitted to unit tests to check if they are not being violated.

- The first test was made to check if the system was not permitting to add the same *SensorInfo* to the set of *SensorInfos* in the Central class. For that purpose I used the operation responsible to store SensorInfos twice with the same argument. As expected the test failed. Then I substituted the repeated SensorInfo and the test ran correctly.

- The second test consisted in checking if the system was respecting the boolean *sendData*. For the purpose, it was observed if the operation responsible for sending data to the Control Part, *SendSetData*, ran with the variable's value "false". It was verified that *SendSetData's* pre-condition was violated. Once again the test was repeated with *sendData* equal to "true" and no problems were detected.

- The third test was similar with the second one but for the *sendWarnings* variable. Basically it was tested if a warning is sent to the Control Part when the boolean variable has the "false" value. Once again this property was preserved.

The main tests were done successfully. This means that with the test cases used all the main properties of the model developed were preserved , i.e., the model implemented is verified. Now that the testing stage is done successfully, the prototype implementation will be started.

4.5 Prototype

VDMTools have a feature that transforms the VDM++ code into Java or C++ code. To develop the prototype, Java will be used. This VDMTools feature is only available in the complete version of the program, the free Lite version doesn't have these capabilities. Although, the translation to Java, in small problems, is quite fast and simple, since VDM++ sintax and code structure are very similar:

- Instance variables are referred with the same name;
- Operations and functions will be the class methods.

Java limitations start defining properties. Pre, post-conditions and invariants are not available in this language unless we use other tools as JML [52] or JASS [53]. Unfortunately JML and JASS are not compiled along with the rest of the java code and they can only be used for testing. The properties have, then, to be written using the common Java's *if-clauses*. However, a recent technology called Modern Jass [54] implements a *Design by Contract* tool to the language, permitting the usage of pre and post-conditions, invariants, non-null variables, etc.. Unlike other solutions, the code produced can be compiled with the rest of the Java's implementation. [55]

In terms of data types used the main difference is the *Set* type used in the VDM++ model. Switching to Java it will turn into *ArrayLists*. This choice was made based on the indexing characteristic of the type, that introduces the order notion, and on the methods provided by this class that are equivalent to the *Set's* operations previously used in the VDM++ model.

The Mobile Part prototype will consist in a system running on a desktop or laptop communicating with the sensor. Since the Control Part will run in the same conditions, the Mobile Part will be able to use its methods to send alerts and data. By its turn the Control part will store the data received by the Mobile Part and manage clients and associations.

To receive information from the sensor is necessary to establish a connection between the device and the sensor and parse the received data. The prototype works with the HxM [56] sensor from Zephyr Technologies. This company provides a Software Development Kit to integrate the sensor with several programming languages. Zephyr Open [48] is also an Open Source project that communicates with Zephyr's sensors and can be used to receive the data from the sensor.

Chapter 5

Conclusions

Health Monitoring Systems are being taken to a different dimension in the current days. The old wired, large and heavy hospital machines are turning into wearable devices using our mobile phone to track our health.

During this work I made an overview of the current technologies that are permitting such advance in health monitoring. In this final section I explain what are my opinions about the fields studied and what are the best options to build a comfortable continuous monitoring solution.

Analyzing the current vital signs sensors there are really comfortable chest straps that don't interfere with our daily life. However, the recent monitoring shirts that embed the sensors on the shirt textile are the next step of monitoring health. They may be expensive right now, but analyzing other technologies in the last years, I am certain that it will be a matter of time to have low cost monitoring shirts on the market.

To transmit the data from sensors to devices, different short-range wireless protocols were studied. The big contrast I observed was that Bluetooth has much higher energy costs than other protocols as Zigbee and ANT. There is a problem here hard to solve: Bluetooth is not the best option in terms of energy costs, but most of mobile devices are only Bluetooth capable. A solution could be adding a mobile device capable of receiving data using the other protocols. But in terms of costs and comfort this is clearly not a good solution. In good time, and probably concerned about the low energy costs of other protocols, the Bluetooth company designed the Bluetooth low energy technology. This technology is very recent (2009) and came to fill the Bluetooth energy saving gap.

As the monitoring system projected has the main purpose of detecting a possible danger of death, I studied and identified the possible ways of predict such event. This is possible analyzing the ECG trace of the user. Only with the heart rate, the task of predicting a possible death is very remote. Although, the cost differences between the heart rate sensors and the ECG capable ones are not very high.

Last, but not least, a software analysis and design was made to build a reliable monitoring solution that sends data and alerts to a Control system. From this stage I would like to highlight the importance of a careful Requirements Analysis, and a consequent System specification and architecture, in a software development process. As well as the construction of an abstract and rigorous model, its verification and validation using analytical or testing methods, before starting the concrete software implementation.

5.1 Future Work

The work on this project will continue in the future. There are many enhancements to the monitoring system to achieve, but I would like to highlight the following ones:

- Analyze the existing monitoring shirts, to futurely work with my software solution;

- Explore the new Bluetooth low energy Technology and/or monitoring solutions using Zigbee or ANT;
- Develop a software solution for diverse Mobile Operating Systems;
- Work with ECG trace capable sensors and develop algorithms to predict heart arrests based on the ECG information. This information can also be used to detect heart related diseases.

The continuous vital signs monitoring is a currently field of research and expansion. I am certain that in the next years new amazing technologies, and improvements of the existing ones, will take this field to a stage where everyone will have a permanent control of the health status. The objective is improving humans security, independence and life quality.

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