

Communication Tools With Intra-Body Sensors

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Abstract

Over the years some medical studies have tried to better understand the internal behavior of human beings. Many researchers in this domain have been striving to find relationships between intra-vaginal temperature and certain female health conditions, such as ovulation and fertile period since woman's intra-vaginal temperature is one of the body parameters most preferred in such studies. However, due to the lack of an appropriate technology, medical research devoted to studying correlations of such body parameters with certain woman's body phenomena could not obtain improve on better results. The objective of this work falls in the creation of communication tools with intra-body sensors. These sensors must be able to collect intra-body parameters such as human core temperature. To reach this main objective the construction of a new intra-body sensor for acquisition and monitoring the intra-vaginal temperature is proposed. This novel intra-body sensor provides data collection that is used to studying the relation between temperature variations and female health conditions, such as anticipation and monitoring of the ovulation period, detection of pregnancy contractions, preterm labor prevention, etc. The novel sensor and his communication tools was tested and validated on hospitalized women as well as normal healthy women. Finally a medical team has attested to the accuracy, usability and performance of this novel intra-body sensor.

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Resumo

Ao longo dos anos alguns estudos médicos tentaram aumentar o conhecimento do comportamento interno do corpo humano. Várias investigações realizadas nesta área foram investindo na busca de uma relação entre a temperatura intra-vaginal e alguns estados na saúde das mulheres, como sejam, os períodos de fertilidade e de ovulação. Este parâmetro corporal é o mais usado em estudos para detecção dos estados do corpo feminino referidos. Devido à falta de uma tecnologia capaz de recolher com exactidão este parâmetro corporal feminino, estes estudos médicos não podem garantir a exactidão dos resultados recolhidos. O objectivo deste trabalho centra-se no desenvolvimento de ferramentas de comunicação com sensores intra-corporais. Estes sensores têm de estar habilitados para recolher parâmetros intra-corporais, tais como, a temperatura interna do corpo humano. Para atingir este objectivo é proposta a construção de um novo sensor intra-corporal para aquisição e monitorização da temperatura intra-vaginal. Este novo sensor permite a recolha de dados que vão posteriormente ser usados em estudos médicos para estabelecer uma relação entre a variação da temperatura intra-vaginal e alguns estados do corpo feminino, tais como, a antecipação e monitorização do período de ovulação, detecção de contracções durante a gravidez, prevenção de parto pré-termo, etc. O novo sensor e as ferramentas de comunicação desenvolvidas foram testadas e validadas tanto em mulheres hospitalizadas como em mulheres saudáveis no seu dia-a-dia. Finalmente uma equipa médica atestou a precisão, usabilidade e performance deste novo sensor intra-corporal.

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Keywords

Body Sensor, e-Health, Temperature Monitoring, Biofeedback.

Palavras Chave

Sensores Corporais, Saúde Electrónica, Monitorização da Temperatura.

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Acronyms and Abbreviations

°C	:	degree Celsius
A/D	:	Analog to Digital Converter
ADC	:	Analog to Digital Converter
AMON	:	Alert Portable Telemedical Monitor Project
AnEx	:	Analogue External Connector Breakout Board
BASNs		Body Area Sensor Networks
BBT	:	Basal Body Temperature
CD	:	Compact Disc
cm	:	centimetres
COM	:	Serial Port Interface
CPU	:	Central Processing Unit
ECG	:	Electro Cardio Grams
EEG	:	Electroencephalography
e.g.	:	exempli gratia (for example)
e-health	:	electronic health
EMG	:	Electro Mio Grams
EOG	:	Electooculography
Gbytes	:	Giga Bytes (10 ⁹ Bytes)
GE	:	General Electrics
GHz	:	Giga Hertz (10 ⁹ Hertz)

GPRS	:	General Packet Radio Service
GUI	:	Graphical User Interface
IDE	:	Integrated Development Environment
IEEE	:	Institute of Electrical and Electronics Engineers
JAR	:	Java ARchive
Kbps	:	Kilo bits per second
LED	:	Light Emitting Diode
MA100	:	Thermometric Biomedical Chip Thermistor
mAh	:	mili-Amperes hour
MBytes	:	Mega Bytes (10^6 Bytes)
MHz	:	Mega Hertz (10^6 Hertz)
MicroSD™	:	Micro Secure Digital
min	:	minutes
nesC	:	network embedded system C
NTC	:	Negative Temperature Coefficient
OS	:	Operating System
PDA	:	Personal Digital Assistant
PC	:	Personal Computer
RAM	:	Random Access Memory
RISC	:	Reduced Instruction Set Computer
RS-232	:	Recommended Standard 232
SDK	:	Software Development Kit
sec	:	seconds
SHIMMER	:	Sensing Health with Intelligence Modularity, Mobility and Experimental Reusability
SpO2	:	Oxygen Saturation
TinyOS	:	Tiny Operating System
UHF	:	Ultra High Frequency
USB	:	Universal Serial Bus

Chapter 1

Introduction

With the advancement of electronic health (e-health), an increasing number of biomedical sensors are being implanted or be worn in a human body for the monitoring, diagnosis, and treatment of diseases [1]. Nowadays, body sensor systems are very helpful methods for medical diagnosis, monitoring and treatment. Several studies have been continuously accomplished in medical applications to achieve better results in the treatment and prevention of diseases [2-5]. In some cases of medical studies, researchers need to analyze physiological parameters that can only be taken by electronic sensors [6, 7]. These studies lead to the development of new body sensors that could help in the collection of physiological parameters and data to carry out these medical studies [8-10]. These body sensors could be classified generally in two groups according to their placements: *i*) Intra-body sensors, that are placed inside the human body and *ii*) Body sensors that are used outside the human body, most of them operate in contact with skin.

According to studies carried out over past years, there is a close relationship between certain human body states and their body temperatures (e.g. basal metabolism, muscle contraction, intake of food, and some disease's symptoms). Even during the day (24 hours) for the same individual, his body temperature varies by about 0.5 degree Celsius ($^{\circ}C$) [11].

The monitoring of the human physiological parameters could help medical staff correlating temperature readings with some of the pathologies [12]. Intra-vaginal

temperature is one of the female body physiological parameters that is the most controlled and useful for monitoring in fertility medical studies [13-16]. For every woman, the characterization of this parameter could help in establishing a pattern for the correlation of intra-vaginal temperature readings and menstrual cycle stage. This could help females to detect their ovulation and fertile period such that it would be easy to know the best time to get pregnant. In other way round, it could also help females to avoid pregnancy if they can know the occurrence of this period. Female intra-vaginal temperature could also help in the prevention and detection of the following situations: detection of pregnancy contractions, effectiveness of some gynaecological therapeutics, preterm-labor prevention, and supporting the discovery of new possible contraception methods.

1.1 Problem Definition and Objectives

All studies based on basal body temperature (BBT)¹ control used a very painful method for the females, in which their BBT have to be taken with a basal digital thermometer [17] at specific times (recommended at 6:30 AM). Every reading is then used to fill a fertility chart. With the continuous filling of this chart, females could detect their fertile period by observing the increasing of their basal temperature [13]. Besides described problems, another debatable issue in this method is the validity of the data gathered. Sometimes the measurement of the temperature, performed by each female, could not be taken in appropriate way. Most likely, the temperature readings could be wrong on inappropriate handling of the thermometer, thus resulting incorrect filling on fertility chart.

Our work helps to provide a medical study with a usable device to gather intra-vaginal temperature values during a specific time (e.g. menstrual cycle) defined by the medical staff. This medical study tries to establish a correlation between intra-vaginal temperature and some stages in female reproductive system. The

¹ Basal body temperature is the lowest temperature attained by the body during rest. In women, ovulation causes an increase of one-quarter to one-half degree Celsius in basal body temperature.

data gathered by this device will not only be used to monitor intra-vaginal temperature, but also, to develop studies that could help medical staff in a better knowledge in relationship between intra-vaginal temperature and some pregnancy issues. Therefore the motivation for this work focuses on the creation of communication tools with a biosensor that will fill the gap we realize in medical technology to collect intra-vaginal temperature. This project was conducted in collaboration with a medical team leaded by Prof. José A. F. Moutinho, Health Sciences Faculty of University of Beira Interior, Covilhã, Portugal. This proximity results is an important contribution for medical validation of accuracy, usability, efficiency, and performance of the system. Also it helps to increase available features and continuous improvement of the system to achieved better results.

In 1994 and 1996 respectively in [15] and [16] a research team propose a system to radio telemetry of vaginal temperature. This system relays in two physical modules a Patient-worn module and a Remote receiver unit. The two modules communicate each other using Ultra High Frequency (UHF) radio telemetry. The Remote receiver unit is responsible for receive the temperature measures taken by Patient-worn module using UHF and store them in memory. After, the Remote receiver unit can be attaching to a computer for retrieve the stored data for further analysis. The solution proposed in this work differs from the above-mentioned in the construction of an integrated system with a single module device that can measure and store the intra-vaginal temperature values and after sends them to a computer application with a wireless communication.

Therefore the main objective of this work was the study and development of communication tools with intra-body sensors. To reach this objective the following intermediate objectives were identified and performed:

- Detailed review of the related literature in intra-body sensors area.
- Proposal of an integrated system to perform communication with intra-body sensor.
- Construction of a new intra-body sensor to gather long-term intra-vaginal female temperature readings.

- Development of communication tools with the intra-body sensor.
- Creation of a computer application to communicate and operate the intra-body sensor.
- Test and validate the created system in medical environment and in normal day life conditions.

1.2 Main Contributions

This section is devoted to the scientific contributions of this work project to the state-of-the-arte in intra-body sensors.

The first contribution is a publication of a journal scientific paper. This paper presents a new intra-body sensor for monitoring female intra-vaginal temperature. It also presents the results achieved by this new sensor that were validated by a medical team. This paper appear in MDPI Sensors Journal [18].

The second contribution is as part of a scientific paper that describes the use of a preliminary version of the intra-body sensor for intra-vaginal temperature monitoring and the application software for control and operates this sensor. The paper was presented at 7th *Conference on Telecommunications (CONFTELE2009)* [19].

1.3 Thesis Organization

This document is organized in six chapters and the chapters are organized as follows. This chapter, the first, presents the context of the thesis, focusing the topic under studies, the definition of the problem and main objectives, the thesis organization and its main contributions.

Chapter 2 starts with the literature review on Sensor Networks and Body Sensor Networks. Next, most relevant related works of medical and non-medical systems applied to measure core and skin body temperature are exploited, showing the added value of our proposal for each case. Finally some projects on intra-body communication technologies are described.

In chapter 3 the design of a new intra-body sensor for measure intra-vaginal temperature is proposed. It exploits the hardware, procedures, methods and tools used to construct an intra-body sensor that could gather long-term intra-vaginal temperature measures in a stand-alone operation mode. This chapter also describes the firmware construction and its embedded communication details.

Chapter 4 presents the communication tools with the intra-body sensor. This chapter starts by described the details of the communication between the sensor and the computer. After the evolution Intra-vaginal Temperature Monitoring computer application is exploited.

In chapter 5 is presented the computer application validation and performance assessment of the developed system. This chapter, first, exemplifies the use of the Intra-vaginal Temperature Monitoring application. Next the result of practical tests performed by the intra-vaginal sensor in both hospitalized women and normal day life women are presented. The results of these tests are represented in line graphs and some observations are taken.

Finally, Chapter 6 concludes the dissertation with its main research findings and puts forward proposals for further research direction.

Chapter 2

Intra-body and Body Sensors

In this chapter are addressed the actual state of the main relevant areas where this work fits. After, some related works in intra-body sensors and communication with intra-body sensors are exploit.

2.1 Sensor Networks and Body Sensor Networks

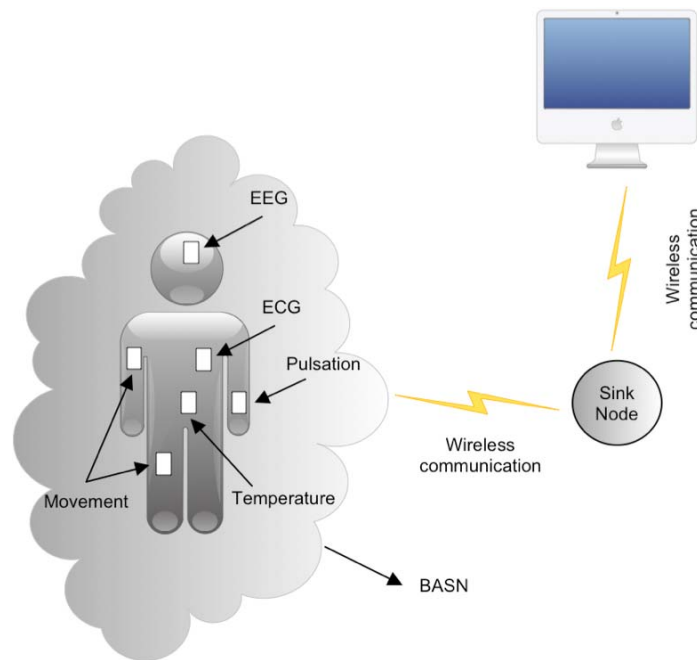
Wireless sensor networks are composed of small smart sensing nodes with a processing unit and memory, a wireless transceiver, and a limited power supply [20, 21].

Sensor networks could be applied in medical care, providing healthcare monitoring services [10]. From the nature of the in-body sensing capabilities where the sensors are placed in contact or very near the person's body, the designation evolved to body sensor networks [22].

Smart sensors scattered around a person's body can sense medical parameters such as body temperature, perform Electro Cardio Grams (ECG), Electro Mio Grams (EMG), calculate heartbeat rate, in an efficient and unobtrusive way [23].

Body area sensor networks (BASNs) are emerging technologies that promise novel uses in healthcare and other medical applications. Each BASN consists of multiple interconnected nodes on, near, or within a human body, which together provide sensing, processing, and communication capabilities [24]. Figure 1 shows a typical example of a BASN.

Figure 1. Body Area Sensor Network (BASN) example.



In this scenario body-sensors collect human body parameters and retrieve them to a sink node connected to a central computer. This computer is responsible for gather and process all the data collected by all the sensors in the BASN.

2.2 Body Sensors and Intra-body Sensors

Several devices, developed by research projects, perform monitoring of physiological parameters, such as body temperature. This section presents some of the developed projects to monitor and analyze human body and core temperature. Duofertility project [25] has been already developed as a trail commercial system for monitoring and analysing female's body temperature. This system can detect and calculate both ovulation and fertile period. Duofertility aims helping couples that want to get pregnant. It measures female's body skin temperature placing a sensor reader under her arm. This sensor is used all the time and records skin temperature measurement every 10 minutes. The sensor device under the arm only collects the skin temperature measurements. For monitoring and analysing the

collected measurements, this system uses a remote reader unit. This unit, by demand operation, retrieves all collected data from the skin sensor. After the analyses of the received data, the reader unit provides signalling with a colour code that has the potential fertile period.

Another project, ANOM [26], integrates their system with a skin temperature sensor. With the integration of this sensor, ANOM project aimed to establish a correlation between core body temperature and skin temperature. This attempt did not succeed, because they concluded that skin temperature could vary with change in environmental condition, so the correlation between core body temperature and skin temperature could not be established. This failure results in dismissal of this feature from ANOM system for medical propose.

The above-mentioned projects based their temperature studies for measuring and analysing skin body temperature. As it can be seen in [11] and [27], skin body temperature could be influenced by environmental conditions. This behaviour could lead in poor accuracy and wrong results when skin temperature measurements are used for study.

Another recent research project was conducted with the goal to avoid the excessive fatigue of American football players by monitoring their intra-body temperature [7]. The research team used a radio pill system developed to monitoring core body temperature in astronauts. This system comprises two modules, a radio pill that must be ingest by a player a couple of hours before the effort, and a wireless reader that is used to monitor the intra-body temperature in real time. If the couch wants to know the core body temperature of a player, he can use the reader to check it by pointing the temperature reader to this player. Once this operation is performed the reader show the real-time temperature for that player. That way, the technical team could proceed in accordance, if needed, switching the player to cool him down. Each radio pill only remains in the body during the digestion time (about 24 to 36 hours). After this period it is eliminated and cannot be used again.

In papers [15] and [16], the authors presented a system using UHF radio telemetry to measure the vaginal temperature and monitor the temperature. The main topics and differences of this research work were highlighted in first chapter. Our work presents a system capable to monitor and analyze the woman's intra-vaginal temperature in a continuous way. It leads in the development of a thermal sensor that can be placed in the female cervix where it can get a core body temperature. That way the system can get better accuracy in the collected temperature measures leading to more reliable results in this parameter monitoring and analyses. It is also important to mention that this sensor is reusable and very ease to sterilize and wash.

2.3 Communication With Intra-body Sensors

This section reviews the BASN communication technologies through the description of some projects in this area. As already survey in [23] and [9] next are presented some of these projects.

CodeBlue is a wireless infrastructure intended to provide common protocol and software framework in a disaster response scenario, allowing wireless monitoring and tracking of patients and first responders. The system integrates low-power wireless wearable vital sign sensors, handheld computers and location tracking tags. Protocols for resource naming and discovery, publish/subscribe multi-hop routing, authentication and encryption provisions are provided. It also offers services for credential establishment and handoff, location tracking, and in-network filtering and aggregation of sensor-produced data. A simple query interface allows emergency medical technicians to request data from groups of patients. CodeBlue is designed to scale across a wide range of network densities, and operates on a range of wireless devices, from resource-constrained motes to more powerful Personal Digital Assistant (PDA) and PC-class systems [9, 28].

LifeShirt [29] is a miniaturized, ambulatory version of an in-patient system, and is available as a commercial prescription medical device. The system consists of the LifeShirt garment with embedded sensors, data recorder, and the VivoLogic

analysis and reporting software. LifeShirt functionality includes respiratory function, ECG, accelerometer, blood pressure, blood oxygen saturation, EEG (electroencephalography), EOG (electrooculography), periodic leg movement, core body temperature, skin temperature, end tidal CO₂, and cough. The system collects and analyzes the data, and integrates subjective patient input from an on-board digital diary. A PDA continuously encrypts and stores the patient's physiologic data on a memory card. Data can be uploaded via the Internet or read from data cards.

MobiHealth [30] is an European Union project that aims to provide continuous monitoring of patients outside the hospital environment. MobiHealth targets improving the quality of life of patients by enabling new value added services in the areas of disease prevention, disease diagnosis, remote assistance, clinical research, physical state monitoring and even clinical research.

UbiMon [31] aims to provide a continuous and unobtrusive monitoring system for patient in order to capture transient events. A number of biosensors were developed such as a 3-lead ECG, 2-lead ECG strip, and SpO₂ (oxygen saturation). The system architecture is divided in the body sensor network nodes, the local processing unit, the central server, the patient database and the workstation. The sensor data is collected and transmitted to a server via WiFi/GPRS (General Packet Radio Service) network for long-term storage and analysis.

eWatch [32] is a wearable sensing, notification, and computing platform built into a wristwatch form factor. eWatch senses light, motion, audio, and temperature, providing visual, audio, and tactile notification. The eWatch system can sense if the user is in distress and then query to confirm that it is an emergency. If the user does not respond, then the eWatch could use its networked abilities to call for help. eWatch communicates wirelessly using a Bluetooth module and an infrared data port for control of devices.

Chapter 3

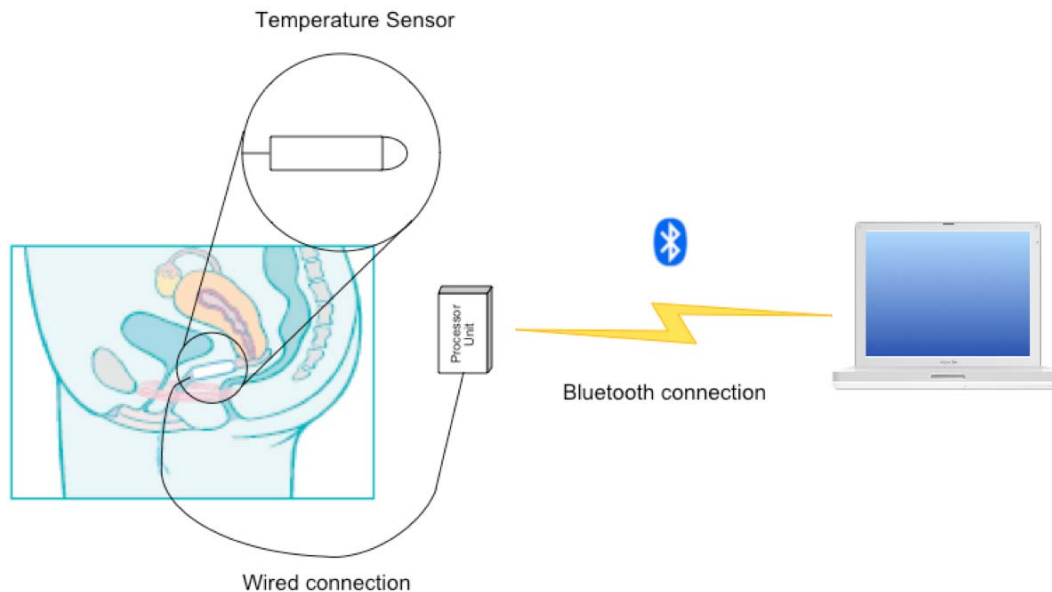
Intra-vaginal Temperature Sensor

The detection of ovulation and fertile period could help females in both to get pregnant or in opposite to avoid pregnancy. This period in females could be detected by monitoring their intra-vaginal temperature. This females body parameter could also help in the prevention and detection of the following situations: detection of pregnancy contractions, effectiveness of some gynaecological therapeutics, preterm-labor prevention, and supporting the discovery of new possible contraception methods. Thus the objective is to construct a system able to gather long-term intra-vaginal temperature measurements. This system will help medical staff to study the temperature correlation with above-mentioned situations. To reach the objective proposed the construction of an intra-body sensor is required.

The first prototype of this intra-body sensor uses the ALFATxp platform [33]. This solution was presented in [19]. ALFATxp have a considerable dimensions for an intra-body sensor. Thus make it very difficult to handle and use to reach the desired application. Furthermore ALFATxp only connects to computer with a wired connection. The limitations of the ALFATxp led to the construction of a new prototype using a different platform. This new platform is more compact and provides wireless communication modules. To achieve a usable system to gather

long-term intra-vaginal temperature measurements the architecture shown in Figure 2 is proposed.

Figure 2. System architecture



This architecture comprises of three modules, the thermal sensor device, the communication between the device and computer, and computer application for monitoring and analysing temperature measurements. This chapter focuses only on the first module. The communication module and the computer application will be described in next chapters. Following sections details the hardware used to achieve construction of the intra-body sensor to collect long-term intra-vaginal female’s temperature measurements. Next the construction details and the firmware developments of the intra-body sensor are described. And finally the used development tools are explained.

3.1 Hardware Overview

This section describes the relevant features in the hardware platform used as based for this investigation. The platform mentioned is the SHIMMER (Sensing Health

with Intelligence Modularity, Mobility and Experimental Reusability) platform (Figure 3 and Figure 4).

SHIMMER platform was chose as a processor unit for the developed intra-body system, because his excellent characteristics, described forward, to the proposed work. This platform is a wireless sensor platform designed by Intel Digital Health Group with TinyOS (Tiny Operation System) [34, 35] support. It consists of following components: an 8MHz Texas Instruments™ MSP430 CPU (Central Processing Unit), a class 2 Bluetooth® radio communication, a 2.4GHz IEEE (Institute of Electrical and Electronics Engineers) 802.15.4 Chipcon™ wireless transceiver (C2420), a 3-Axis Freescale™ accelerometer, a MicroSD™ slot for up to 2GBytes, an integrated lithium-ion battery management and some extension boards (internal and external) that increase the potential of SHIMMER platform with new features and functionalities. All these features are compacted in a very small form factor (2.0 x 4.5 cm) with no more than a thumb size [36]. Next will be described some of this components in detail.

Figure 3 and Figure 4 presents the top and bottom view of the SHIMMER platform indentifying all the components above described.

Figure 3. SHIMMER platform – top view.

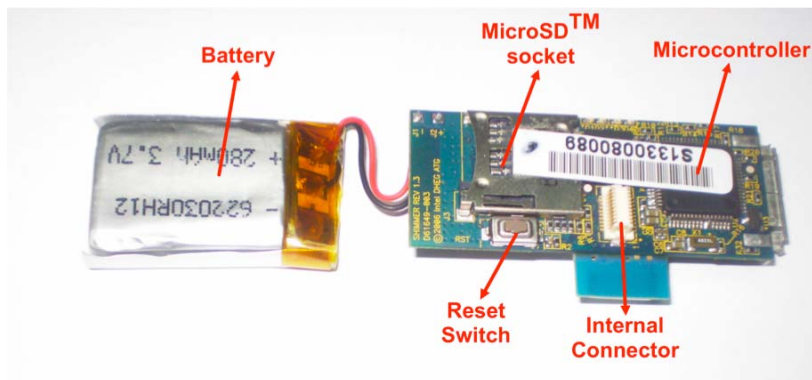
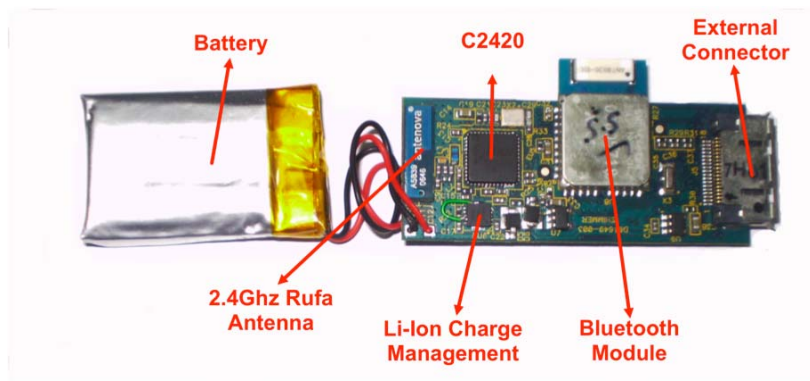


Figure 4. SHIMMER platform – bottom view.



The selection of the components described below is related to the most relevant ones for the present work. All the other ones were considered not relevant just because they were expendable for this work.

Micro-controller

SHIMMER platform uses a Texas Instruments MSP430 [37]. One of the most interesting features of this micro-controller is its low power consumption during periods of inactivity. It is based in a 16-bit RISC (Reduced Instruction Set Computer) CPU with 10KBytes of RAM (Random Access Memory), 48KBytes of flash memory and 128Bytes of information storage. The flash memory can be programmed via RS-232 (Recommended Standard 232) programming dock. This micro-controller also has 8 ADC (Analog-to-Digital Converter) channels for 12-bit A/D (Analog-to-Digital Converter) conversions. In our study this ability is extremely necessary for the integration of a new thermal sensor.

Communication

SHIMMER platform has the ability to communicate with outside world in a wirelessly way. It provides both communication radio modules 802.15.4 and Bluetooth.

Bluetooth communication was preferred to 802.15.4 instead for the reason that, nowadays, the most computers have the built-in ability to communicate with Bluetooth. We also prefer that choice because of the possibility of further development of a mobile application to operate the system. In this case the

Bluetooth option has become predominant due to the popularity of this communication module in current mobile devices. A wired solution was not considered due to the discomfort caused to women in removing the intra-body sensor every computer data recovering operation.

SHIMMER platform uses a Roving Networks RN-46 Class 2 Bluetooth [38] communication module with a 2.4GHz antenna. The range of detection is about 10 meters and has a baud rate of 921,6Kbps.

Power Management

This platform includes a Texas Instruments BQ24080 Smart Li Charger [39] for battery management. In this work was used the default rechargeable battery 250mAh lithium-ion with a voltage of 3,7Volts. With this configuration our system could work for about two days without recharging the battery. This fact and the use of rechargeable batteries were also two of the main reasons for the choice of this platform.

Information Storage

SHIMMER's flash memory is limited if the propose is to gather great amounts of data. Due to this limitation this platform has integrated a MicroSD™ card slot that can incorporate up to 2GBytes MicroSD™ card for extra memory. In our solution this feature is very useful considering the possibility of the system can work in stand-alone mode (not connected to a computer). In this case the system has to provide a memory support to gather great amounts of collected data. The possibility of integration MicroSD™ cards in the sensor system became the ideal solution.

3.2 Intra-vaginal Sensor System Design

This section describes all the hardware details that led to the design and conception of the new intra-vaginal temperature sensor capable of measuring and gathering long-term female's intra-vaginal temperature readings. This section also

includes the description of the developed firmware used to operate and control this sensor.

3.2.1 Temperature Sensor Integration

Even though SHIMMER platform has most of the required features for our design, a temperature sensor is not installed in it, so one of the challenges is to integrate a temperature sensor into SHIMMER platform in order to get constant temperature readings.

For the design of the temperature sensor, we chose the MA100 thermistor [40] , which is a NTC Type MA Biomedical Chip Thermistor developed by GE Industrial Sensing and is exclusively use for biomedical applications. Its main features fulfil the requirements of our solution. That means, its sensitivity ranges from $0^{\circ}C$ to $50^{\circ}C$, size is 0.762×9.52 mm; moreover it is created for biomedical applications. To get more accurate temperature readings, the temperature sensor must be placed inside the female cervix that is an ideal thermal source. For this purpose, the MA100 needs to be placed inside the vagina. Figure 5(a) presents MA100 the thermal sensor used in this system. However, since MA100 is very flexible, it is very difficult to place at right position inside the vagina. So for encapsulating MA100, a tampon like specialized enclosure was designed which is not only anatomically comfortable for women but also robustness and easy way to use.

Figure 5. (a) MA100 thermal sensor. (b) MA100 inside enclosure tampon resembles.

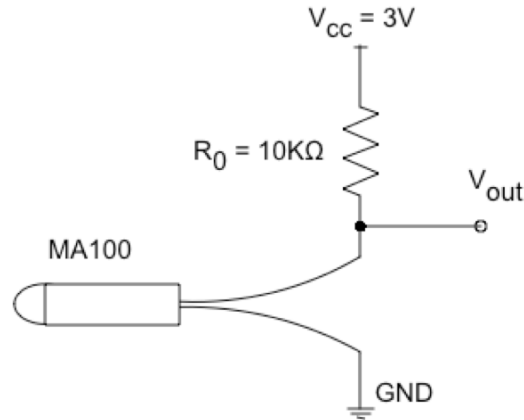


Figure 5(b) shows the MA100 with the enclosure. Placing the temperature sensor, with this configuration, is trivial for women and should not cause any problems while using it. Thus using this intra-body sensor is like using a traditional tampon. Hence, to place the enclosed MA100 inside the vagina, we follow similar procedure as in any traditional tampon. Furthermore, in order to achieve reusable intra-body sensor, we have considered that it should be easily sterilized and washable.

3.2.2 Sensor Operating Principles

The developed intra-body sensor comprises two parts: a thermal temperature sensor (MA100) with an enclosure and a processor unit (SHIMMER platform). The temperature sensor (MA100) actually is the only part of the system that is placed inside female's body. To achieve accurate temperature readings, the MA100 is placed in cervix. The processor unit (SHIMMER) is placed outside of the woman body, because of bulky size, and could be placed anywhere if the cable is long enough (~ 80 cm). For example, it may be easily placed inside pants pocket, attached to the belt. The temperature sensor (MA100) measures the voltage values and sends them to SHIMMER using a wired flexible connection. Each voltage value has a linear correspondence to one temperature value, according to the analysis of the supporting electronic circuit. This analysis gives us the real-time temperature measured by the temperature sensor. Figure 6 presents the electronic circuit developed for the integration of the MA100 thermal sensor in the system. The analysis of this circuit is translated by equation (1) where T corresponds to the temperature measurement, in degree Celsius ($^{\circ}C$). In this equation, $V_{0^{\circ}C}$ corresponds to voltage measurement (in milli-volts) at $0^{\circ}C$ temperature; V_{out} corresponds to the measured voltage at the terminals of the MA100 thermistor; and the constant value 30.04 corresponds to the variation of increasing temperature value 1 degree Celsius ($^{\circ}C$), in milli-volts.

Figure 6. Electronic circuit for thermal sensor.



$$T = \frac{V_{0^{\circ}C} [mV] - V_{out} [mV]}{30.035 [mV/^{\circ}C]} [^{\circ}C] \quad (1)$$

Equation (1) represents the theoretical value calculation. In practical experiences this equation suffers some corrections when the calibration temperature operation was performed. These corrections have been made due to the imprecision of the temperature values obtained when it was used the equation (1). This imprecision was related to the voltage loss occurred in the electronic components. Equation (2) was the final result of the temperature measures calibration process. The temperature values calculated with (2) were validated with a temperature calibrator available from Sefram Instruments & Systemes model 4821 [41].

$$T = \frac{V_{0^{\circ}C} [mV] - V_{cal} [mV]}{30.035 [mV/^{\circ}C]} - 1.66 [^{\circ}C] \quad (2)$$

Where:

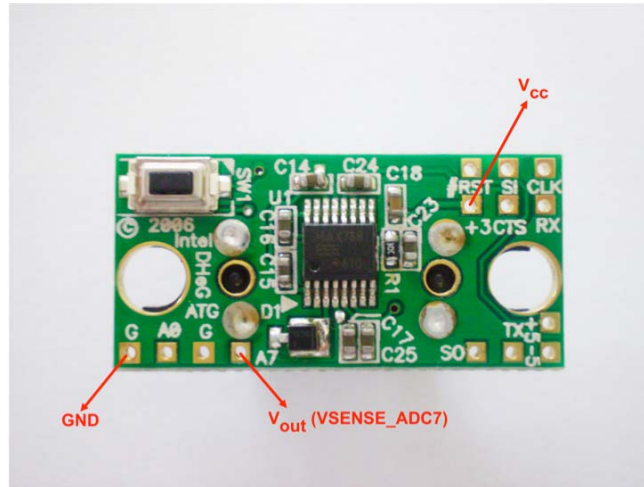
$$V_{cal} = V_{out} \times 0.7326 [mV]$$

$$V_{0^{\circ}C} = 2299.9 [mV]$$

The integration of MA100 thermal sensor in SHIMMER platform was able to use one of the available ADC (VSENSE_ADC7) channels in the SHIMMER external board (AnEx board) [36]. In Figure 7 it is shown the SHIMMER external board, used to attach additional sensors that could increase the features available on this

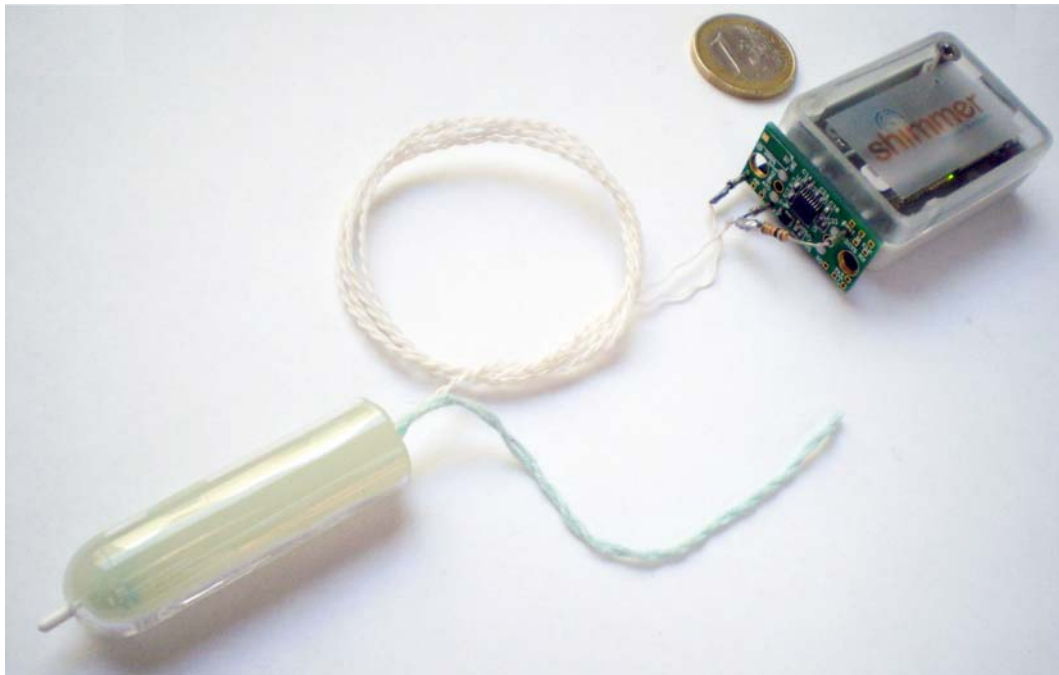
platform. It is also represented in Figure 7 the terminal points used to the implementation of the thermal sensor (MA100) and their respective description according to Figure 6.

Figure 7. SHIMMER external board (AnEx board).



In Figure 8, the developed intra-body sensor prototype to gather long-term intra-vaginal temperature measurements is presented.

Figure 8. Developed system prototype.



To gather the temperature measurements by the sensor, SHIMMER provides a MicroSD™ slot. This feature relieves the need of a constant communication to a personal computer in order to receive and store each temperature measurement. In this way, the system can work in a stand-alone mode for a long period in collecting temperature measurements. Computer communication is needed to operate SHIMMER. This communication is also used to retrieve all temperature measurements gathered in the SHIMMER's MicroSD™ card to the computer for the analysis.

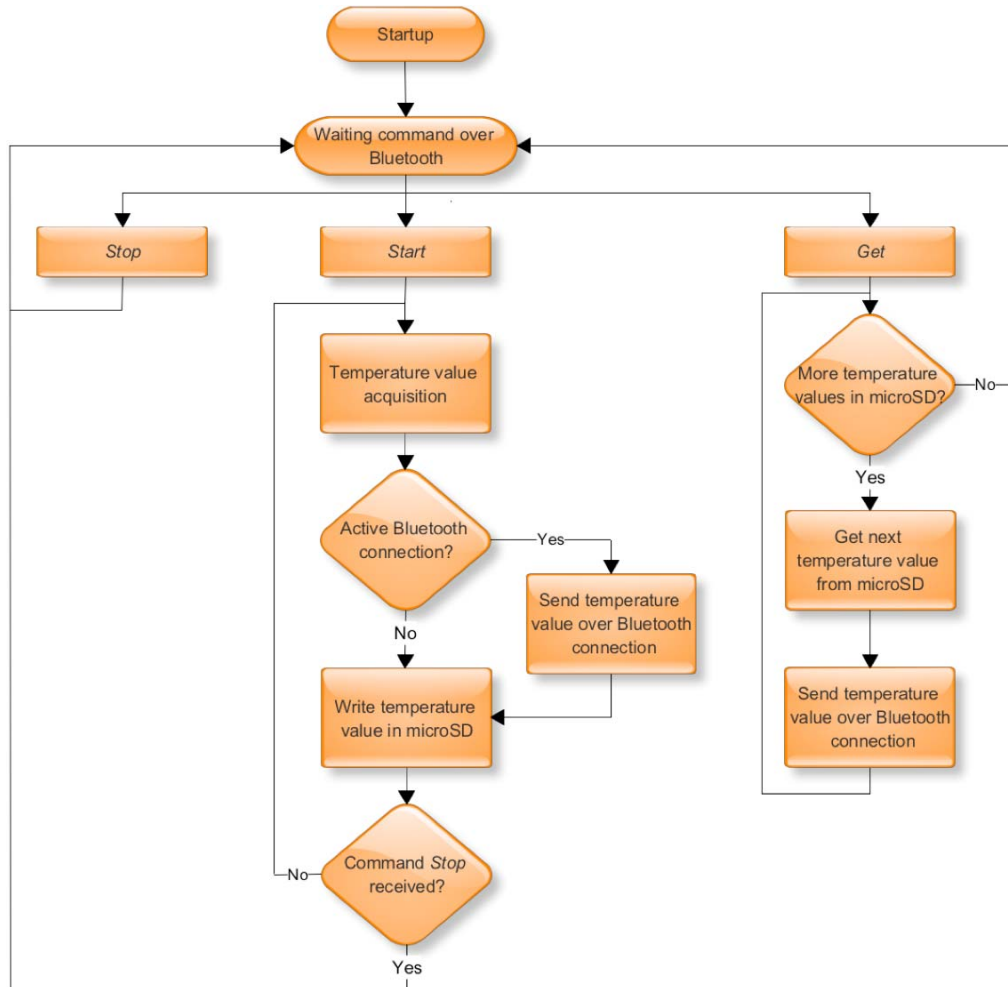
3.2.3 Firmware Development

The communication between SHIMMER and computer is performed by a Bluetooth connection. This communication will be fully explained in the next chapter. The computer sends operating commands to SHIMMER, which in turn, sends information and data to computer. SHIMMER always waits for computer commands over the Bluetooth connection. Once a command is received then it proceeds accordingly. The operating commands available in SHIMMER are the following:

- *Start*: when SHIMMER receives this command, it starts collecting temperature measurements in the MicroSD™ card. If a Bluetooth connection continues available temperature measurements are also delivered to computer for real-time monitoring and analyses. If no connection is available, temperature measurements are only written in MicroSD™ card. That way, SHIMMER prevents unnecessary use of Bluetooth connection and allows increasing the battery lifetime.
- *Stop*: this command stops the collection of new temperature measurements.
- *Get*: this command performs the transmission of all temperature measurements gathered in MicroSD™ card to the computer application for further study and analysis.

Figure 9 presents the firmware diagram implemented in SHIMMER. This firmware provides all the above-mentioned features.

Figure 9. SHIMMER firmware diagram.



The analysis of temperature measurements is performed in off-line mode. So to ensure good results, it is vitally important to know the exact time when each temperature measurement is taken. SHIMMER only has a local time clock, which starts on SHIMMER’s start up. This clock can’t give the real global time clock. To associate each measurement with the right global time clock instant, when a *start* command is send to SHIMMER, computer also sends its clock and date time (assuming computer clock is global clock synchronized). This information is then used by SHIMMER’s firmware as an offset to local time clock in order to

calculate the exact global time clock for every instant of temperature measurements.

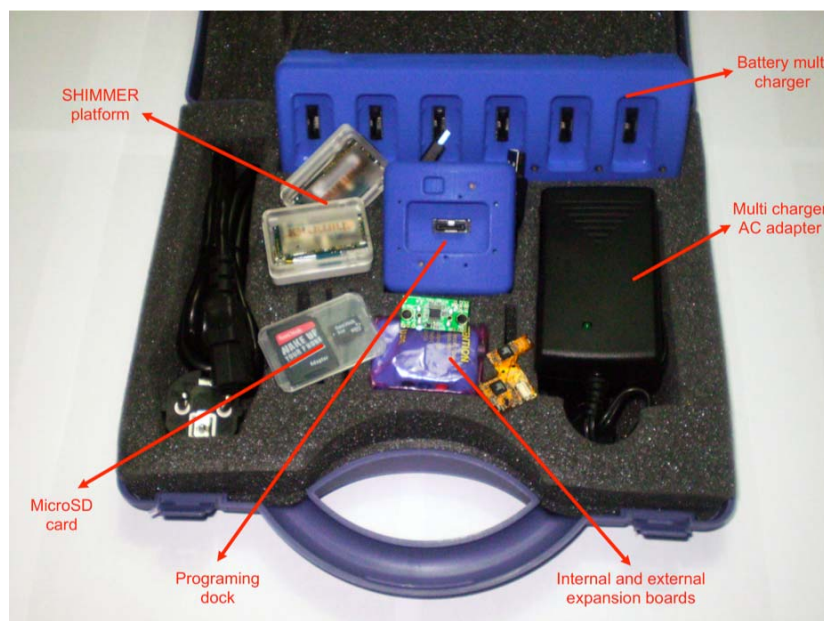
3.3 Development Tools

This section describes the developed environment used to create the firmware to control and operate the SHIMMER platform.

3.3.1 Software Development Kit

To improve the MSP430 SHIMMER processor firmware it was used a virtual machine system. This virtual machine was available from CD (Compact Disc) software included in SHIMMER SDK (Software Development Kit) kit used as part of the development of this system. This SHIMMER SDK includes two SHIMMER platforms, a dock station for SHIMMER firmware deployment, a multiple SHIMMER charger for battery recharges, all expandable boards that can be coupled to SHIMMER and a MicroSD™ card of 2GBytes. It also includes a CD software and an instruction manual [42]. In Figure 10 it is presented the SHIMMER SDK packaged.

Figure 10. SHIMMER SDK



The virtual machine used was a Linux system Ubuntu 7.10 image for VMware application. This image was ready to be used; SHIMMER developers had already done all the configurations and installation procedures. Because of the procedure to install the SHIMMER development environment is not quite simple, the use of this virtual system proved to be a good option. We just have to run it and use it, without needing additional configurations or installing procedures.

The use of this programming environment is simple, like C Linux programming. As soon as we are located in developed firmware source code directory it can be compiled with command line:

```
make shimmer
```

If we want not only to compile but also deploy the firmware to the SHIMMER platform, firstly we have to be sure to connect the programming dock to an computer USB port and make sure it was detected by the virtual machine. Then we couple the SHIMMER platform to the dock and execute the next command line:

```
make shimmer install bsl,/dev/ttyUSB?
```

where the question mark must be replaced by the correspondent USB port assigned to the programming dock. To find this information can be used:

```
ls -l /dev/ttyUSB*
```

to list all the Linux system USB ports assigned.

3.3.2 Sensor Operating System and Programming Language

SHIMMER as support for TinyOS [35, 43] operating system that is highly recommended for design implementation of firmware. In [42] it is recommended the use of TinyOS v1.x instead of TinyOS2.x. The point is that v1.x was extensively tested and developed. In this project it was also taken into account that at the time of the development of the SHIMMER's firmware TinyOS v2.x it hasn't support for Bluetooth communication yet. This limitation in TinyOS v2.x was decisive in our choice because of the reasons pointed in section 0 for the use of Bluetooth communication.

TinyOS is an operating system developed for sensor networks using. This operating system was design to support concurrency intensive operations required by that sensors with minimal hardware requirements. TinyOS is based in the programming language nesC [44, 45], his libraries and applications are written in this language.

Chapter 4

Communication Tools with Intra-Body Temperature Sensor

This chapter describes the communication between the SHIMMER platform and the computer and the developed computer application used both to operate SHIMMER platform and monitor and analyze the collected data performed by this one.

4.1 Communication Between Sensor and Computer Application

Although SHIMMER is a powerful biosensor platform, it has very limited resources in terms of computation and is very dependable from a power battery with no long lifetime. In order to ensure increase of the battery lifetime, we only gather temperature readings from SHIMMER, instead of collecting and processing them. Temperature readings are transmitted to a computer and collected by an application for further analysis and processing.

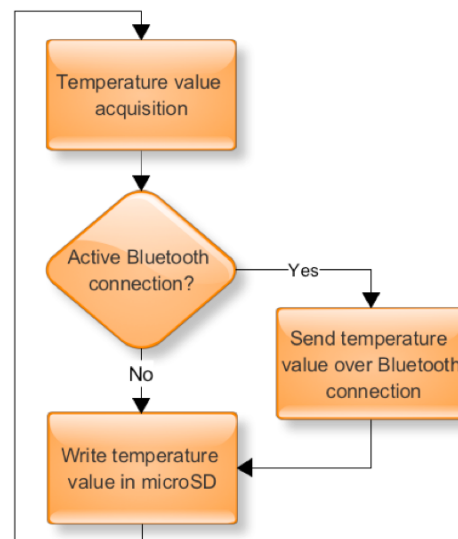
Bluetooth performs the communication between SHIMMER and computer. Wireless communications seems to be more realistic than other wired alternatives, taking into account patient's comfort and operation simplicity by medical staff, as previously mentioned.

Like any body area sensor networks (BASNs), it is unique in that it attempts to restrict the communication radius to the body's periphery. Limiting transmission

range reduces a node's power consumption, decreases interference, and helps maintain privacy.

As expected, the connection between the biosensor and computer is only available if the sensor is in Bluetooth's connection range to the computer. Because of that, we cannot have the effective monitoring of the temperature values if the sensor is out of range. Therefore, in case of communication failure between SHIMMER and the personal computer, SHIMMER only collects temperature and saves temperature readings on its local microSD card such that it can transmit them when the Bluetooth connection is active. This procedure prevents unnecessary use of power to perform the communication and increases battery's lifetime. Figure 11 shows a diagram of Bluetooth data transmission presenting the procedure performed in case of existence of an active Bluetooth connection, or not.

Figure 11. Diagram of Bluetooth data transmission, existing an active connection or not.



4.2 Intra-vaginal Temperature Monitoring Application Evolution

This section describes the creation and evolution of the Intra-vaginal Temperature Monitoring application. It starts with the functional requirements for this

application. Next, the construction of the application and the used tools are highlighted.

4.2.1 Functional Requirements

An application to collect, process, analyze and visualize the reading measures performed by the intra-vaginal sensor in a personal computer was created. To achieve intra-vaginal sensor temperature values, both real-time and off-line operation modes are available.

In *real-time* mode, measured values can be achieved when SHIMMER has a Bluetooth connection with the computer. In this case, the application software shows the real-time temperature values measured by SHIMMER. Simultaneously, all the temperature measures sent to the connected computer, via Bluetooth, are written on the MicroSD™ card of SHIMMER platform.

In *off-line* mode, the application software can collect all the long-term temperature readings and store them in the MicroSD™ card. The application software can retrieve all the stored data from the SHIMMER's MicroSD™ card. These data may be both visualized and saved in a text file for further use, if needed.

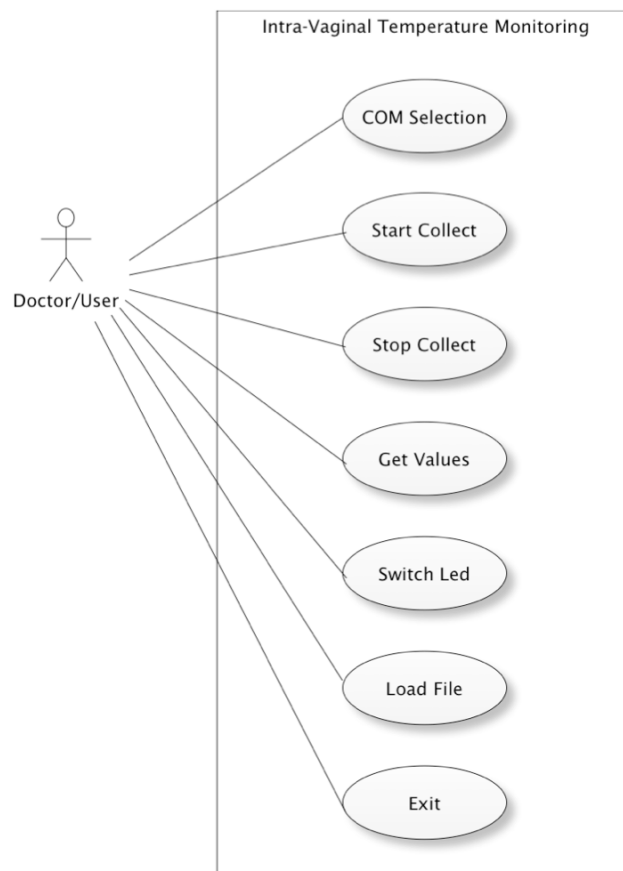
The developed application performs all the following system features:

- Define the time interval between each temperature reading (e.g., 1sec, 30sec, 1min, 5min and 10min).
- Start the acquisition of SHIMMER's temperature readings. SHIMMER start collecting the reading values and save them on the MicroSD™ card.
- Stop data acquisition.
- Collect temperature readings stored on SHIMMER's MicroSD™. Application import data from the MicroSD™ and also may save them in a text file for persistent storage.
- Verify if SHIMMER is well connected with computer. Using *Switch Led* button, the user may confirm if SHIMMER is responding to computer

commands or not. This means the user may check if SHIMMER is well recognized by Intra-vaginal application or not.

As the application interacts directly with SHIMMER, these features are only accessible if Bluetooth connection is available between computer and SHIMMER. Figure 12 describes the Use Case Diagram of Intra-vaginal Temperature Monitoring application. This Use Case represents the interaction of the user that could be the doctor with this application. This user can perform all the valid operations, previously described, implemented in this software.

Figure 12. Use Case Diagram of Intra-vaginal Temperature Monitoring application.

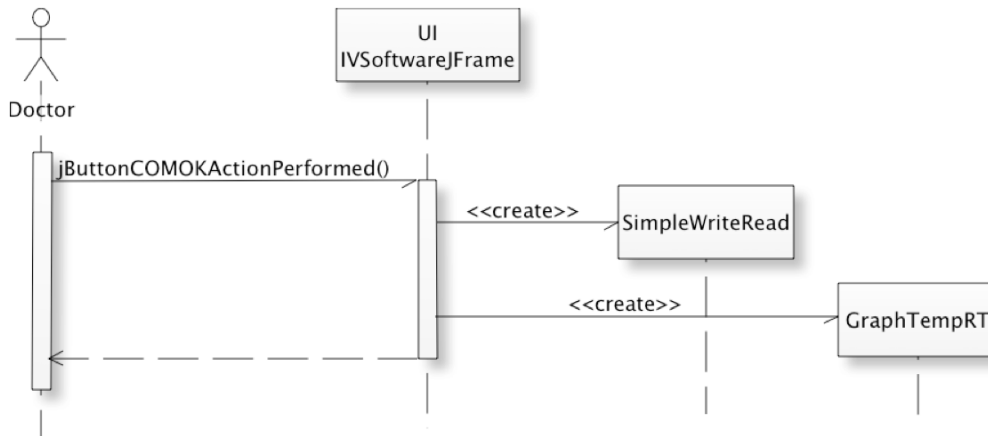


Next all the Sequence Diagrams based on the Use Case Diagram above represented are described in detail.

The serial port selection (*COM selection*) associated with the Bluetooth SHIMMER communication is performed by the user (doctor) by the selection of

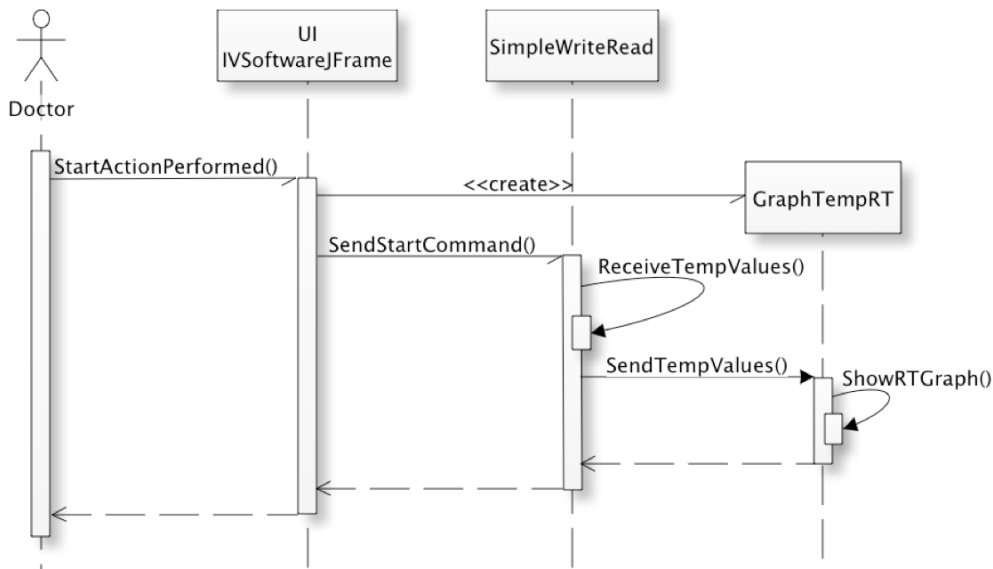
this serial port in a combo box and then clicks on OK button in the application graphical user interface (GUI). This action performs the creation of two threads. One “*SimpleWriteRead*” is responsible for the communication between the SHIMMER and the computer. The other “*GraphTempRT*” is responsible for the real-time temperatures graph representation if the intra-vaginal sensor is already collecting measures. Figure 13 presents the *COM selection* Sequence Diagram.

Figure 13. Sequence Diagram – *COM selection*.



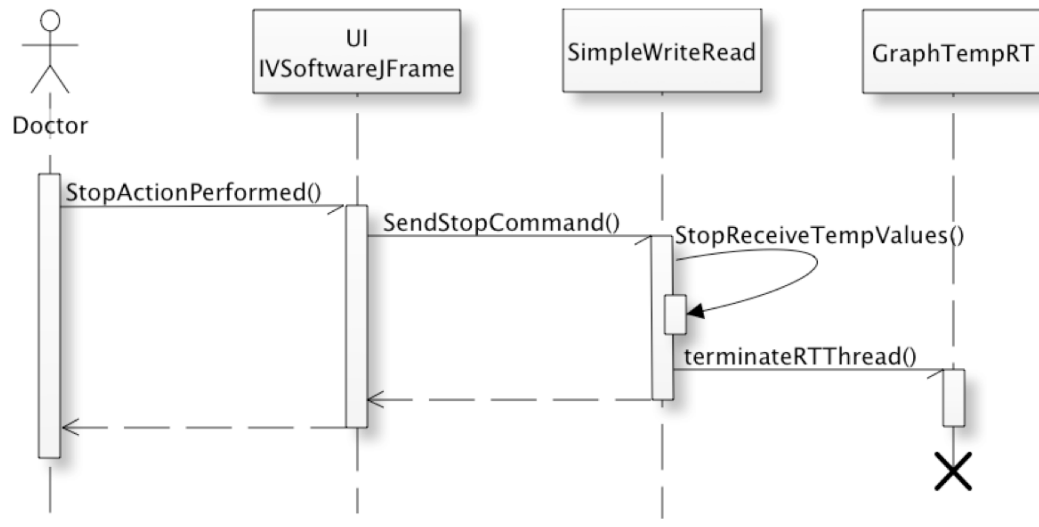
To *Start Collect* temperatures measures in the intra-vaginal sensor the user (doctor) uses the GUI button “*Start Collect*”. This action creates a “*GraphTempRT*” thread to represent the real-time graph temperatures measured by the sensor. It also sends to “*SimpleWriteRead*” thread the command to be sent to the sensor for initialize the temperature measures collection. This command is transferred between “*IVSoftwareJFrame*” thread and “*SimpleWriteRead*” thread using a pipe. And it is sent to intra-vaginal sensor by the “*SimpleWriteRead*” thread using the Bluetooth’s serial communication port. After that “*SimpleWriteRead*” thread continuously receives the temperature measures returned by the sensor over serial communication. These temperature values are then sent synchronized to “*GraphTempRT*” thread. This synchronization allows the integrity of the represented values in the graph – it only goes to the next one if the previously is already represented. In Figure 14 it is presented the *Start Collect* Sequence Diagram.

Figure 14. Sequence Diagram – *Start Collect*.



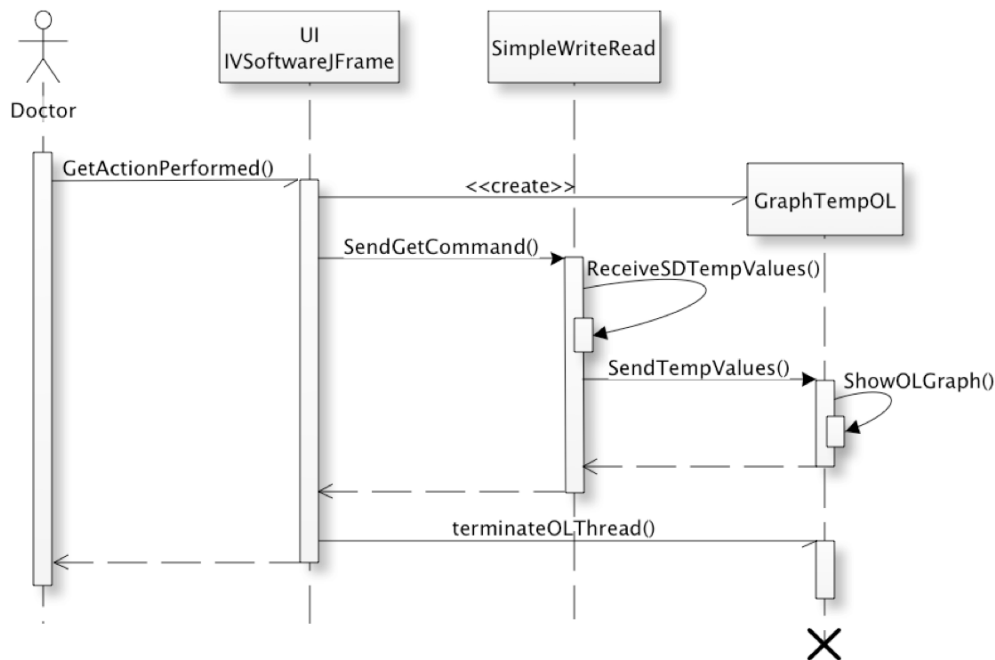
To *Stop Collect* temperature measures in the intra-vaginal sensor the user (doctor) uses the GUI button “*Stop Collect*”. This action sends to “*SimpleWriteRead*” thread the command to be sent to the sensor for stopping the acquisition of temperature measures. This command is transferred between “*IVSoftwareJFrame*” thread and “*SimpleWriteRead*” thread using a pipe. And it is sent to intra-vaginal sensor by the “*SimpleWriteRead*” thread using the Bluetooth’s serial communication port to inform the sensor to stop acquiring new measures. After that “*SimpleWriteRead*” thread terminates “*GraphTempRT*” thread because no more temperature values have to be represented. Figure 15 shows the *Stop Collect* Sequence Diagram.

Figure 15. Sequence Diagram – *Stop Collect.*



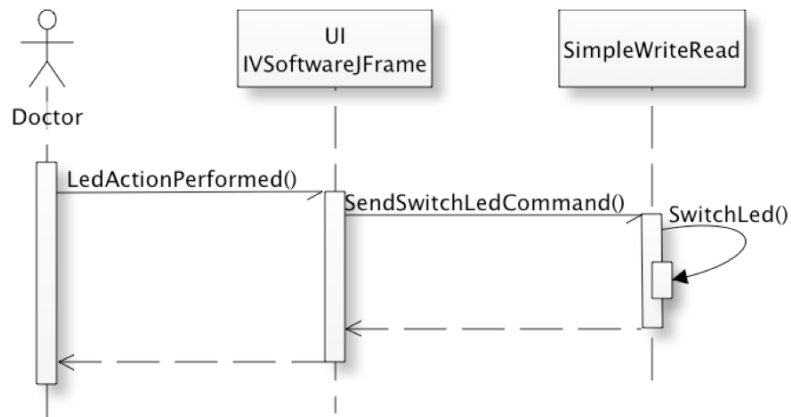
The *Get Values* Use Case allows the user (doctor) to get all the temperature measures collected by the intra-vaginal sensor in their MicroSD™ card. To perform this operation the user uses the *Get Values* button in the GUI. This procedure creates a “*GraphTempOL*” thread to be responsible for the graph representation of the temperatures values received from the sensor. Then a get command is sent to “*SimpleWriteRead*” thread over the pipe. This command is then sent to the sensor, over Bluetooth connection, to start sending the collected temperature measures in the MicroSD™. So “*SimpleWriteRead*” thread continuously receives the temperature measures returned by the sensor over the Bluetooth serial communication. This temperature values are then sent synchronized to “*GraphTempOL*” thread. This synchronization allows the integrity of the represented values in the graph, as described. Finally when all values are returned and represented in off-line graph “*IVSoftwareJFrame*” thread terminates the “*GraphTempOL*” thread. Figure 16 presents the Sequence Diagram of *Get Values* use case.

Figure 16. Sequence Diagram – *Get Values*.



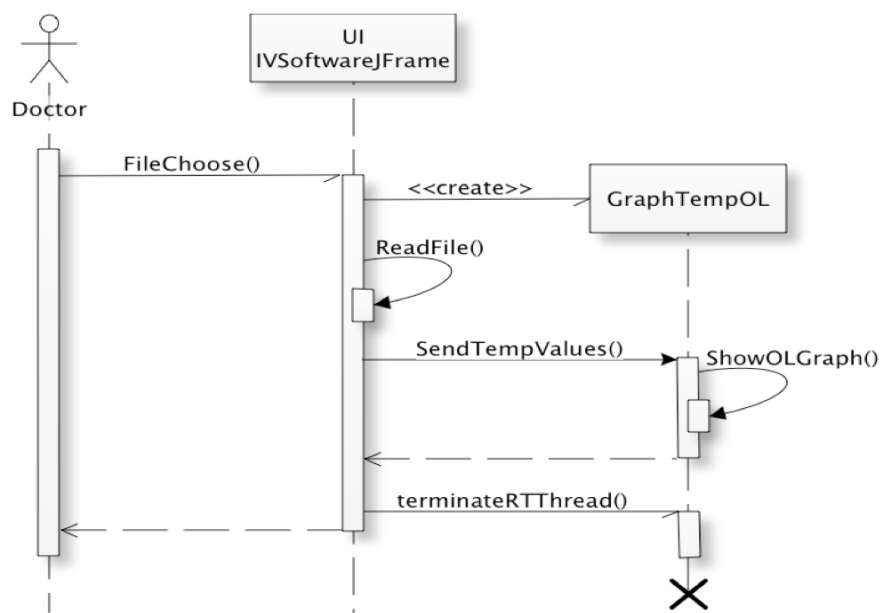
Switch Led operation is used to confirm the right Bluetooth serial connection between the computer and the intra-vaginal sensor. The action performed by this operation is the switching of a red LED in the sensor if the communication is well done. To perform this behaviour the user (doctor) uses the *Switch Led* button in the GUI. This operation sends to “*SimpleWriteRead*” thread the switch led command again over the pipe established between the two entities. As soon as “*SimpleWriteRead*” thread receives this command, it sends it over Bluetooth to the intra-vaginal sensor. If the connection is perfect the red LED in the sensor must be switched. In Figure 17 is presented the *Switch Led* Sequence Diagram.

Figure 17. Sequence Diagram – *Switch Led*.



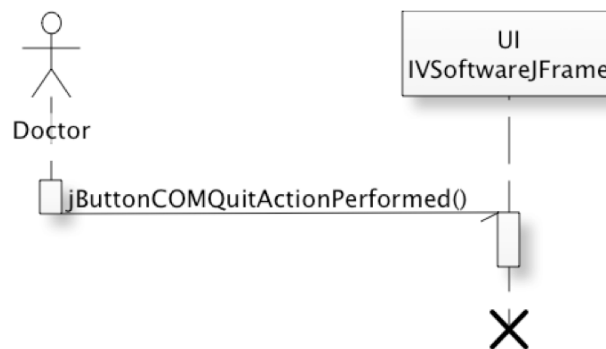
Load File feature allows the user (doctor) to load temperature values from a file. This operation is performed using the *Load File* option from *Load* menu in the GUI. When this menu option is chosen a “*GraphTempOL*” thread is created. This thread is used to represent the temperature graph of the values in the file. These values are represented in a synchronous way to ensure the integrity of the values represented in the graph. It only goes to the next one if the previously is already represented. After all the values in the file are represented the “*GraphTempOL*” thread is terminated. The Sequence Diagram of *Load File* case use is presented in Figure 18.

Figure 18. Sequence Diagram – *Load File*.



To terminate the Intra-vaginal Temperature Monitoring application the user (doctor) uses the *Exit* option from the *File* menu in the GUI. This action terminates the “*IVSoftwareJFrame*” thread and consequently the application itself. Figure 19 represents the *Exit* Sequence Diagram.

Figure 19. Sequence Diagram – *Exit*.



4.2.2 Tools and Construction

Tools

Intra-vaginal Temperature Monitoring application is programming using Java language. The NetBeans 6.5 Integrated Development Environment (IDE) from SUN Microsystems is used for the software development. To improve versatility to the application it evolution goes from Windows XP Operation System to Mac OS X Version 10.5.7.

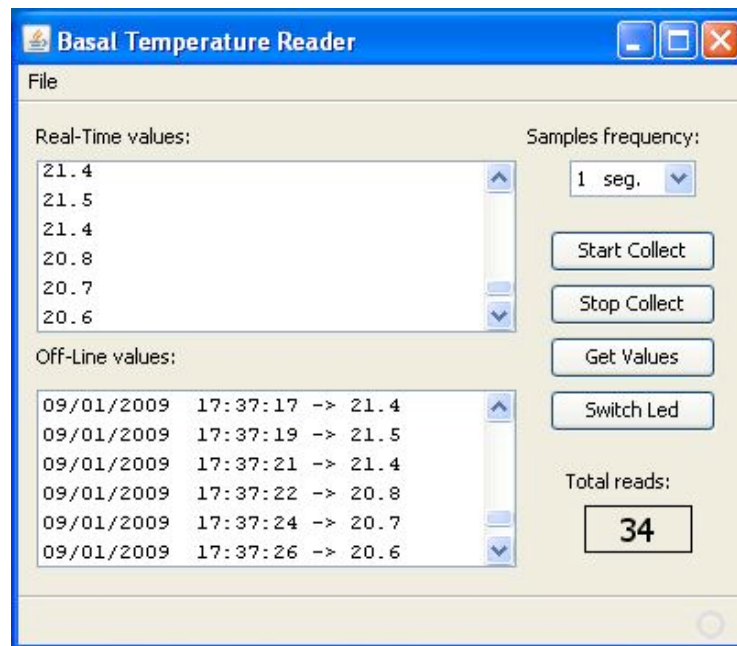
Construction

The evolution of the Intra-vaginal Temperature Monitoring application starts as a command line application that interacts with SHIMMER using the windows MS-DOS command line emulator. This application implements a simple shell that accepts strings from the user and then validates these strings as a valid implemented command and sends them to SHIMMER. The strings accepted as valid commands, in this simple application, are single letters (like a, b, c, d...). Each valid letter corresponds to one of the above-described SHIMMER operations. All the information retrieved from SHIMMER as a result of some

operations is presented in text mode of MS-DOS command window. This application communicates with SHIMMER via Bluetooth connection using a standard serial communication.

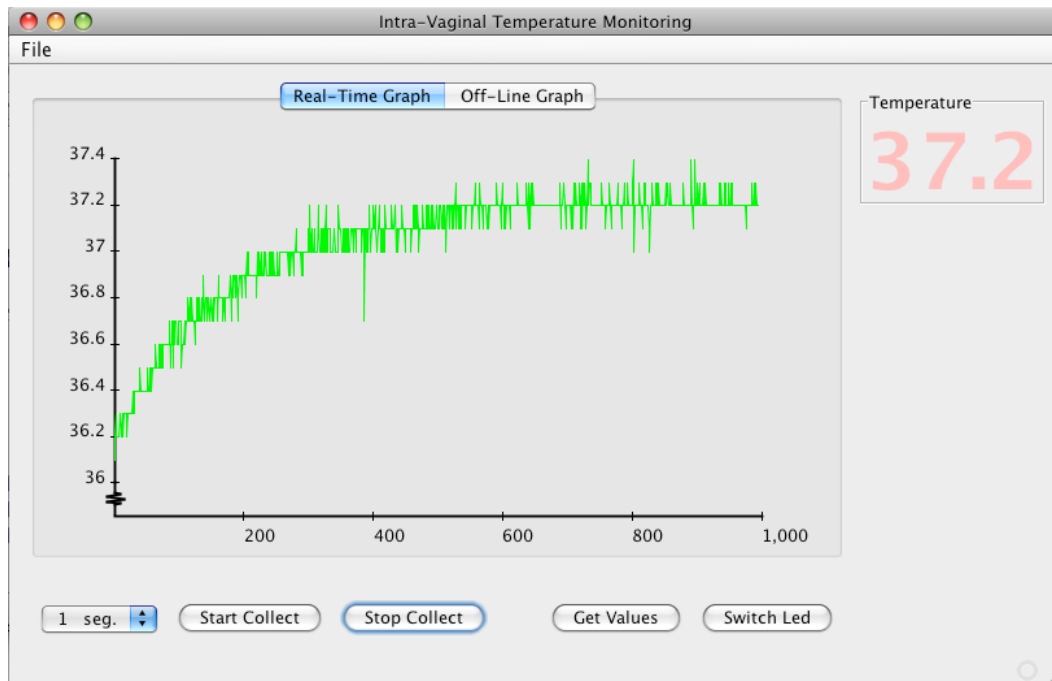
Next the first Graphical User Interface (GUI) is created. This evolution contributes to an easier interaction with SHIMMER platform. It allows the use of graphical buttons to send commands to the sensor. The information received from SHIMMER is presented in text boxes, which is easier to be read and analyzed. This application is constructed to run on Windows Operating System. Figure 20 shows the graphical interface of version v1.0 of the Intra-vaginal software application

Figure 20. Intra-vaginal Temperature Monitoring application – first GUI.



In continuous evolution of the application a new GUI is created and consequently a new application. To multiply the versatility of the Intra-vaginal Temperature Monitoring application this new one is developed to run on Mac OS X. Figure 21 shows the new GUI of this application.

Figure 21. Intra-vaginal Temperature Monitoring application.

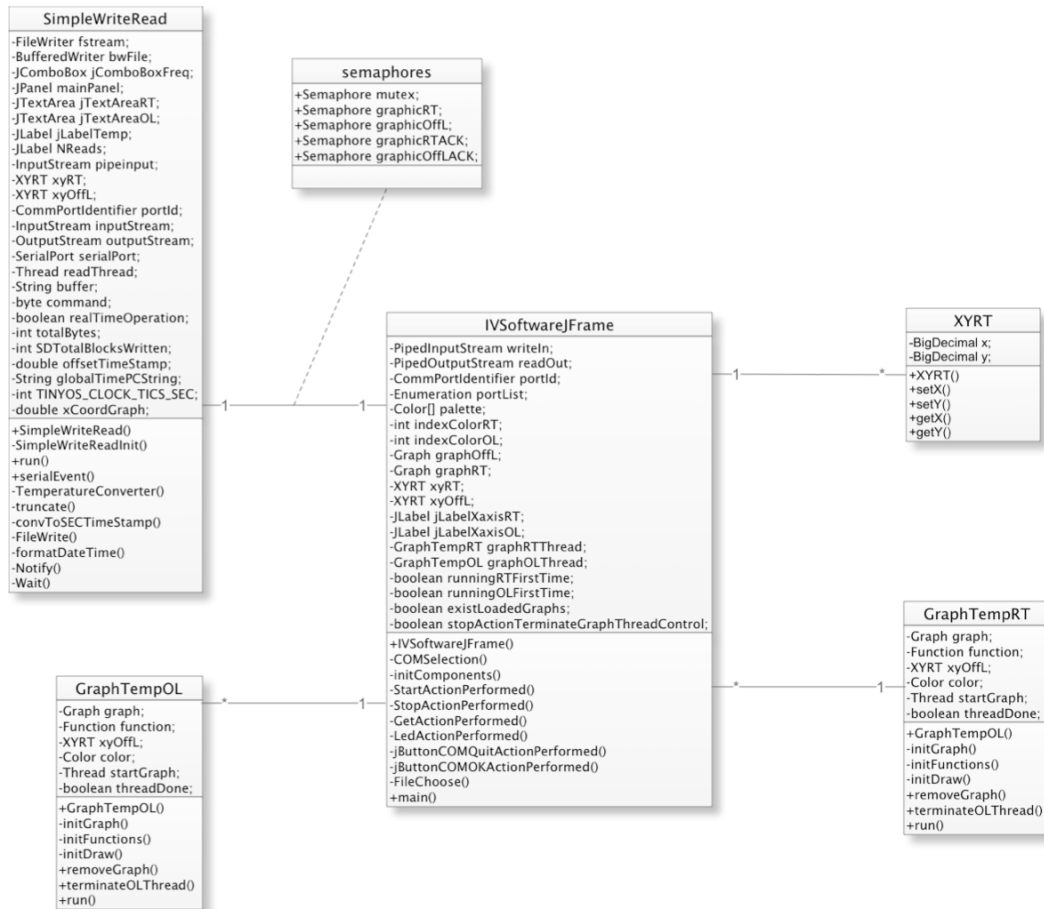


As we can see in Figure 21, temperature values, in this new version, are presented using a graphical representation. Thus, it is easy to visualize and identify values outside the normal pattern. These values can lead to sign a range of conditions on female reproductive system (e.g., pregnancy contractions, ovulation period, best fertilization period, etc.). Next, a medical research will be carried out with the execution of very important studies to be applied in different kind of gynecology issues, such as, the preterm labor prevention, detection of pregnancy contractions, anticipation and monitoring of the ovulation period (used either as a natural contraception method or, at the opposite, as an estimation of the best fertilization period), effectiveness of some gynecology therapeutics, and supporting the discovery of new possible contraception methods.

For the graphics representation it is include a graph package – QN Plot version 1.6.1 developed by Pascal S. de Kloe. This JAR package allows to render great amounts of real-time data and provides the implementation of graphs of one or more functions as Swing components [46].

In Figure 22 is presented the Class Diagram of the Intra-vaginal Temperature Monitoring application. This diagram became as the software solution to the requirements above-mentioned.

Figure 22. Class Diagram of Intra-vaginal Temperature Monitoring application.



Chapter 5

System Validation – Tests and Results

This chapter will demonstrate the use and validation of the Intra-vaginal Temperature Monitoring application. After, will be highlighted the achieved results with the developed system in performed tests and the medical validation of these results.

5.1 Intra-vaginal Application Software

The operation of the intra-vaginal sensor is performed by the Intra-vaginal Temperature Monitoring application. This application is also used to monitor, process and analyze the temperature measurements performed by the thermal sensor (MA100) installed in SHIMMER platform. This subsection describes the user interface of this application. All procedures next described assume that SHIMMER is in Bluetooth's detection area of the computer. SHIMMER can operate in real-time or off-line mode. We say real-time mode when SHIMMER is acquiring temperature measures and off-line mode when SHIMMER is in standby mode.

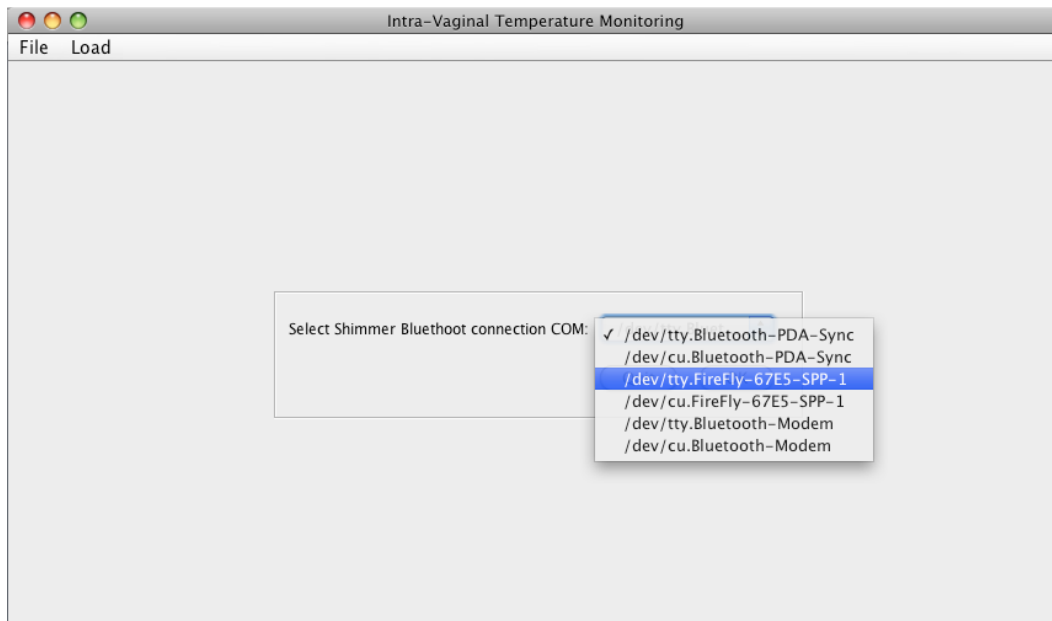
In the development of user interface for the Intra-vaginal application it was considered the simplicity of use. The interaction with this application is based on the use of mouse device by clicking on buttons and access to simple menus.

5.1.1 Requirements to Run the Application

To use the Intra-vaginal temperature monitoring application software is needed the installation of one additional packaged known as RXTX package. This packaged enable Mac OS X to communicate with serial ports using Java applications. It will install the Java communications libraries [47]. Because of the developed application communicate with SHIMMER via Bluetooth serial connection, the installation of this package must be performed.

After executing the application, it is asked to the user which COM port will be used to communicate with the SHIMMER device. The user can choose the SHIMMER associated COM port from a list with all COM ports available in the computer. To perform this selection, SHIMMER has to be, previously, Bluetooth paired with the computer that runs the intra-vaginal application. To do so, the user must access to Bluetooth devices list within range of the computer. There, SHIMMER device will be found with a name in the format “FireFly-XXXX”. To complete the paired operation it is asked to enter the passkey associated with SHIMMER. The default passkey used for SHIMMERs devices is “1234”. If SHIMMER was correctly paired the associated COM port must appear in the COM ports list presented by intra-vaginal application. In order to the application can communicate with SHIMMER device the user must select the correct COM port from the list. Typically, in Mac OS X operating systems COM ports associated with SHIMMERs devices have this format: “/dev/tty.FireFly-XXXX”. In Windows operating systems the information about which COM is associated with SHIMMER, can be obtained in “My computer properties”. In Figure 23 it is presented an intra-vaginal application screenshot, with the COM port selection interface in Mac OS X Version 10.5.7 operating system.

Figure 23. Intra-vaginal application – COM port selection.

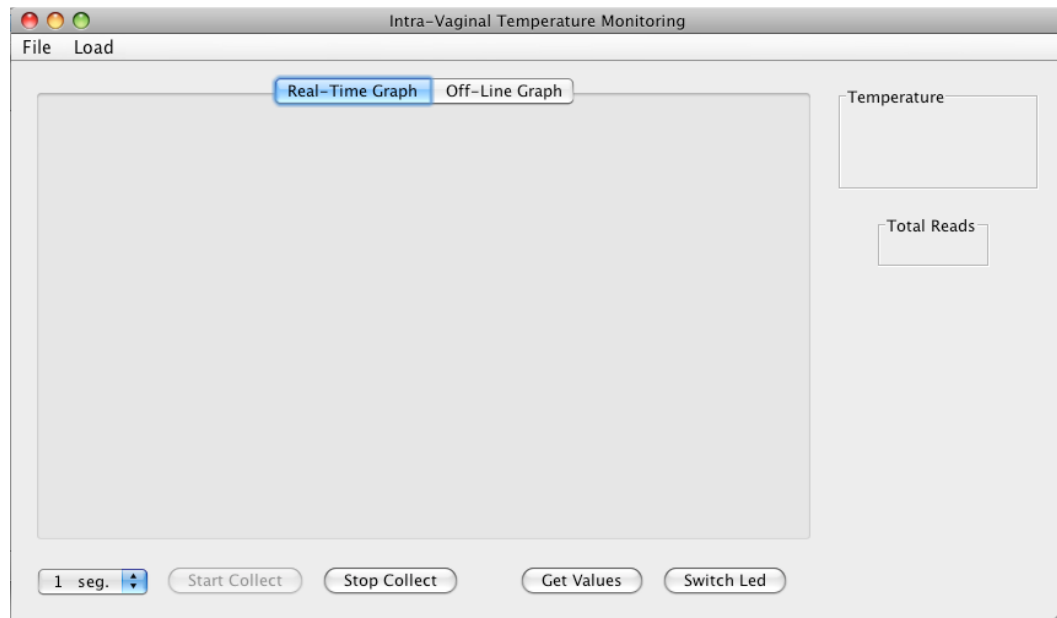


After selecting COM port the application presents the user interface to communicate with SHIMMER. To perform this communication SHIMMER must be in the detection area of Bluetooth range.

5.1.2 Application Validation

Main Interface

Figure 24 presents the developed application interface. Here the user can perform several operations in order to operate and configure the SHIMMER platform operations. This interface also provides a visualization area of graphical temperature readings performed by SHIMMER in both *real-time* and *off-line* modes.

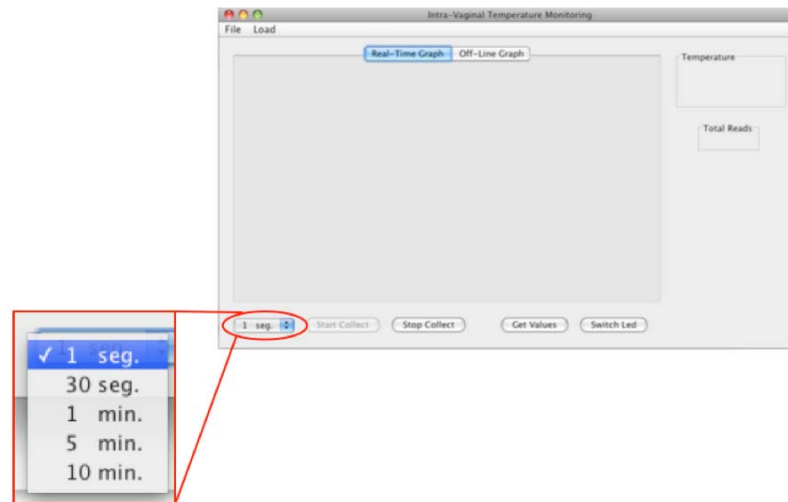
Figure 24. Intra-vaginal application – Main interface.

When interface first presented to the user, the *Start Collect* operation is disabled. This behaviour is an implemented protection in case that intra-vaginal sensor is already in collection mode. In that mode, if the user starts another collection all data previously collected will be lost. In this case a *Stop Collect* operation must be firstly performed to guarantee if sensor is in collection mode no data will be lost accidentally by performing a *Start Collect* operation inadvertently. The intra-vaginal sensor accepts *Stop Collect* operation both if sensor is in collected mode this operation stops the acquisition of data and if sensor is in standby mode this operation does nothing. After *Stop Collect* operation is performed the *Start Collect* operation is unblocked.

Definition of Frequency Interval for Measures Acquisition

The combo box presented in Figure 25 is used to define the frequency interval used by the sensor between each temperature measure. Due to the fact that *Start Collect* operation sends the selected information in this combo box to the intra-vaginal sensor, this selection must be performed before each start operation. In acquisition mode red SHIMMER's LED flashes on each new measure acquisition.

Figure 25. Combo box, for frequency interval selection, of data acquisition.



Start Collect operation

The *Start Collect* operation is used to start the acquisition of temperature measurements in the intra-vaginal sensor. This operation also sends to the sensor the current date and time of the computer and the frequency interval explained in the previous paragraph. To perform a *Start Collect* operation SHIMMER must be in a standby mode. Observing the colour LEDs in this device can be identified this mode. Green LED on and orange LED flashing indicates standby mode.

Stop Collect operation

Stop Collect operation stops the acquisition of temperature measurements. This operation performs a transition from acquisition mode to standby mode in SHIMMER.

Get Values operation

Get Values operation performs the transmission of all measures stored in the MicroSD to the Intra-vaginal application software. This operation also saves data collected to a text file placed in the same directory of the executable Intra-vaginal application file (IVSoftware.jar). This text file can be used for persistent storage

of collected data. When SHIMMER is preformed a *Get Values* operation red LED flashes quickly.

Switch Led operation

Switch Led operation is used to verify if SHIMMER is connected with Intra-vaginal application or not. If so, each time the user uses this command, red LED in SHIMMER must switch on and off. Otherwise if red LED doesn't switch, this means SHIMMER is not well recognized by the application. In this case close the application and start from the beginning. If the problem persists COM port probably selected isn't the one associated with this SHIMMER platform, or SHIMMER could not be well paired with the computer. Repeat these configurations and try again the application.

Temperature Information

The label *Temperature* is used when SHIMMER is operated in real-time mode and if it is in Bluetooth detection area of computer. This information field shows the current temperature measure, acquired by SHIMMER.

Total Reads Information

The label *Total Reads* informs the number of collected temperature measures stored in the MicroSD™. This information is updated each *Get Values* operation.

Real-Time Graph

This tab is used when a *Start Collect* operation is performed. If SHIMMER is in Bluetooth detection area this field represents a real-time graph of temperature measures collected by the sensor. The graph is updated each new measure.

Off-Line Graph

Off-line tab presents the temperature graph of all collected temperature measures stored in the MicroSD™ card. This field is filled when a *Get Values* operation is performed.

Load Menu

This option is used to load saved text files with previous temperature measures into the *Off-Line* tab field. This feature helps in analysis of collected data by the comparison with previous patterns. Various files could be loaded. A different graph colour line represents each loaded file. Figure 26 and Figure 27 illustrates the used of load option.

Figure 26. Load File menu option.

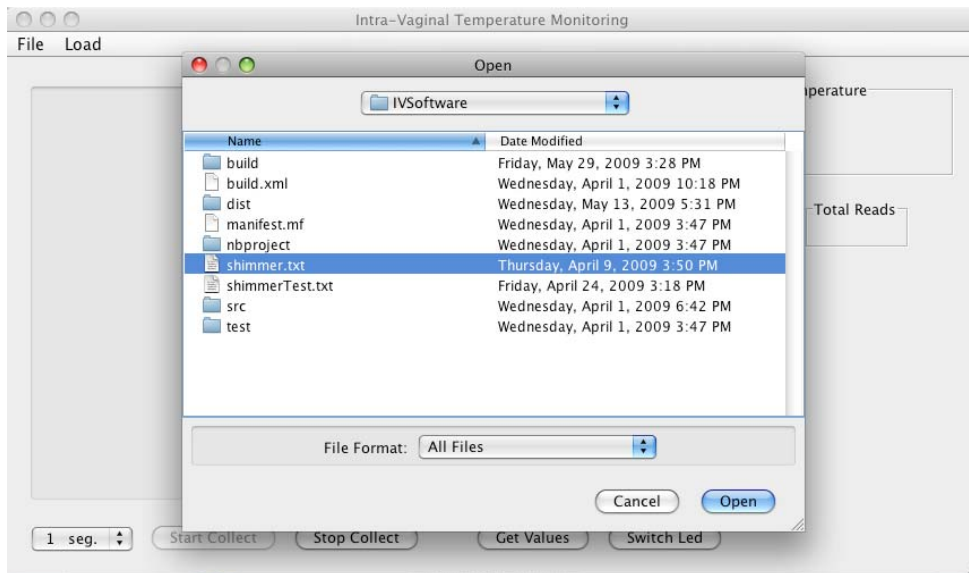
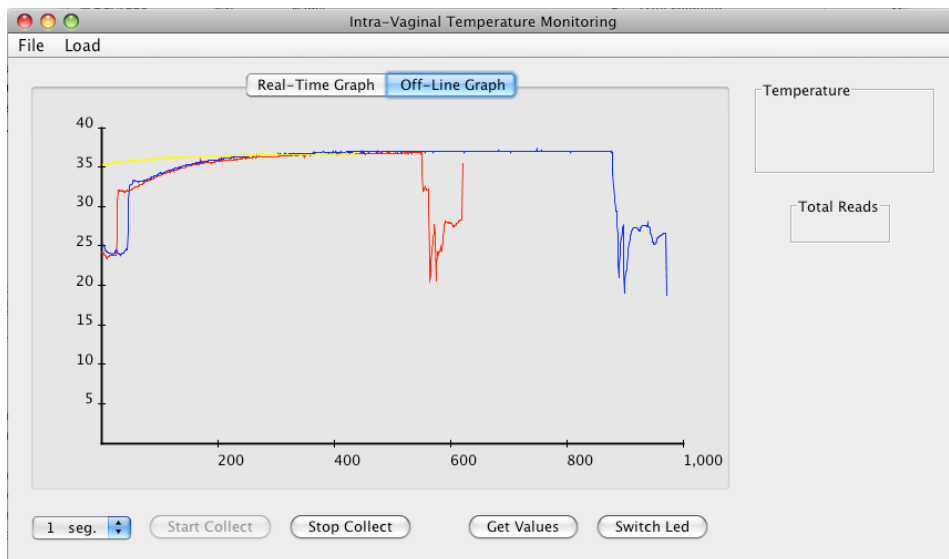


Figure 27. Load File result – This picture presents three graphs, each one corresponds to a different loaded file.



5.2 System Tests and Results Validation

In order to validate the comfort, usability and accuracy of the proposed system, the medical team performed several tests in the hospital. These tests were only possible with the great collaboration of the hospitalized women who agreed to conduct the tests. Twelve women were monitored with the intra-vaginal sensors for about sixty minutes, under medical supervision. In all the tests, an interval of one second was used for each new temperature measurement. This gave us a total of three thousand and six hundred measurements for each test. All these values were then analysed in off-line mode by the medical team. They compared it with temperature measurements performed at the same time for each woman under the arm and under the tongue. In this case, the temperature measurements were gathered in a traditional way by using trivial digital thermometers [17]. After analysing the temperature measurements acquired in both methods (traditional way and intra-vaginal sensor) for each test, the medical team concluded that the results obtained from the intra-vaginal sensor gave accurate results. Also we verified the comforts of the thermal sensor during the test. At the end, each woman was asked to report any complications in using the intra-vaginal sensor. None of them report any problem in using the intra-vaginal sensor, even some said, “It is just like using a tampon”. Thus the newly designed intra-vaginal sensor is comfortable as well as very easy to use.

Additional tests were performed for eight women in their normal day life. These tests result from the monitoring of these women in different periods of the day. Each test lasts about two to three hours. The validation of the performed tests was possible according to patterns previously established of temperature measurements for these women. These patterns were defined using the same method described above (measuring the temperature under the arm and under the tongue). Medical team confirmed the accuracy of the temperature measurements from the intra-vaginal sensor when compared to earlier patterns.

Figure 28 presents a sample of the tests performed in hospitalized and normal day life women. In Figure 28(a), the results shown in the graph correspond to three

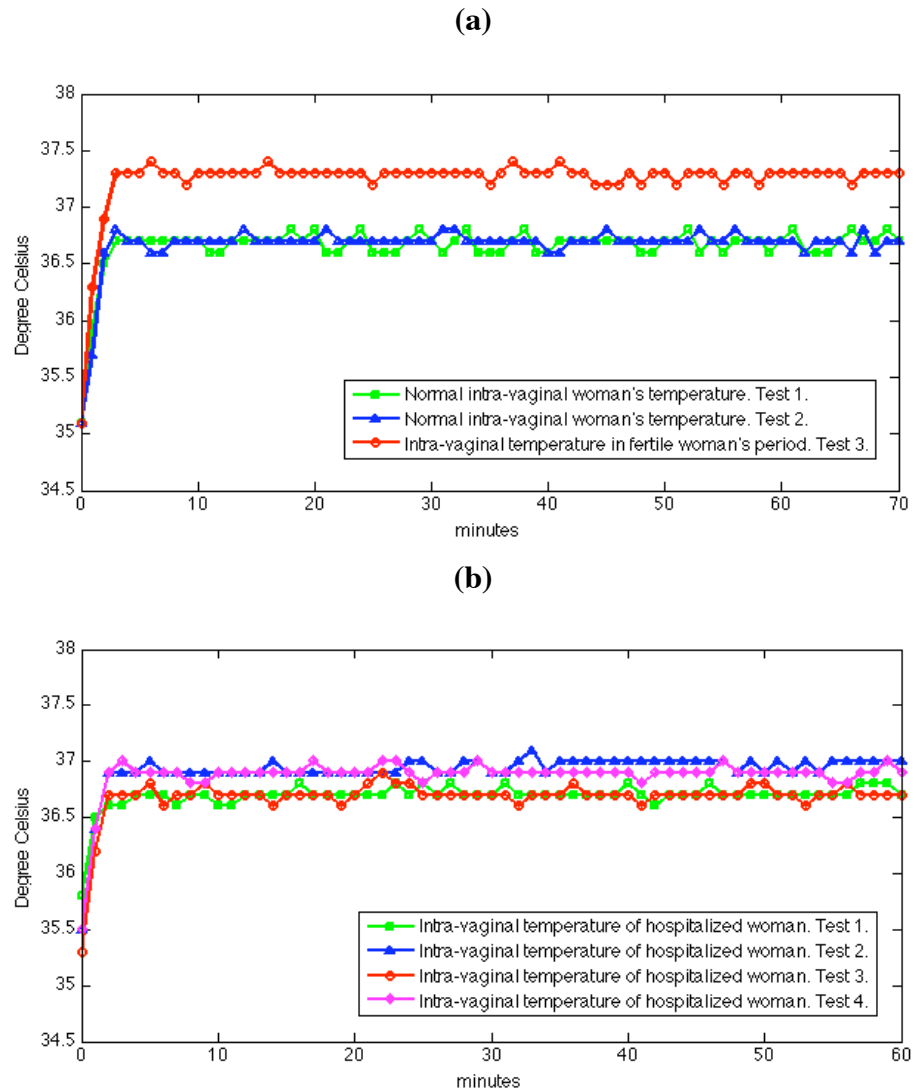
tests performed in the same woman at different days. Each graph can be divided in two parts. First part from zero minute to second minute corresponds to the warm-up of the sensor to reach inside vagina's temperature. Second part from third minute onwards represents the actual temperature inside the woman's vagina. It can be seen that two curves with squares and with triangles differ in average of about 0.5 °C from the curve with circles. This difference corresponds to the observation of normal body temperature (curve with squares and curve with triangles) and fertile period temperature (curve with circles) for this woman. As we have expected, different stages in woman's body reflect variations on intra-vaginal temperature. The correlation of these variations and the occurrence of some situations in woman's body could help medical staff in a better understanding of female's reproductive system. This understanding could be extensive help for medical procedures in many situations, such as, pregnancy issues, preterm labor prevention, and detection of pregnancy contractions. This system could even help women that want to monitor their self in detection of fertile and ovulation period (used both as a natural contraception method and, in the opposite, as an estimation of the best fertilization period). Furthermore, women could use this system only to better understand their intra-vaginal temperature regulation.

Figure 28(b) presents the result of four tests performed in the hospital. These tests correspond to four different women. To construct the graph, above-mentioned procedures can be applied into these tests too. From third minute onwards, as above, are the actual intra-vaginal temperature measurements for these four women. The conclusion of these tests is that each woman has her own intra-vaginal temperature pattern. Therefore, it is necessary to define these patterns. This system helps a health-care management system, such that it can have storage of the intra-vaginal temperature measurement, obtained from each woman, which can be applied for further use.

The great results achieved in these first tests by the medical team encourage them to continue the development of new tests in order to accomplish better results and improve the available features in the system. Medical team also wants to study the

possibility of new applications of the sensor in medical application. They intent to discover new correlations of human body phenomena with variations of core body temperature.

Figure 28. (a) Samples of performed tests in day life woman. **(b)** Samples of performed tests in hospitalized women.



Chapter 6

Conclusions

This chapter presents a synthesis of the main achievements and points to several directions for future work.

After introducing and delimiting the theme of the work, describing the objectives, and showing its main contributions, in chapter 2, the related work in intra-body sensors was presented. There was highlighted the headed value of the proposed solution.

Chapter 3 presented the construction of a new intra-body sensor essential to the main objective of this work. First, is detailed the hardware used to construct the new sensor. Next, the construction itself was exploit with the conception of a temperature sensor to measure intra-vaginal temperature. The firmware creation for the sensor was also presented where it was detailed the embedded communication solution. Finally the development tools to reach the construction of the sensor and the creation of the firmware were described.

In chapter 4 the communication between the new body sensor and the computer was exploited. There the Bluetooth communication was chosen as the best way to get the temperature measures from the intra-body sensor to the computer. Next, the development details of the computer application were presented. The evolution of this application from a text mode interaction to a graphical user interface (GUI) was detailed explained. The application was developed in an object-oriented language (Java) so all the Use Cases, Sequences and Classes Diagrams was presented.

Chapter 5, starts, with the validation of the computer application, showing an example of use. After, some tests made with the sensor in both hospitalized and normal day life women were presented. There a medical team validates the computer application and the sensor usability, comfort and accuracy in the tests performed.

The main objective of this dissertation was to present a Communication Tools With Intra-Body Sensors. This was carried out with the construction of a new intra-body sensor to collect the female's intra-vaginal temperatures, the communication between this intra-body sensor and computer and the creation of a computer application to operates the sensor and monitor the intra-vaginal temperatures. This objective was successfully accomplished.

6.1 Future Work

To conclude this document, it remains to suggest future research directions that result from this research work:

- Miniaturize the actual intra-vaginal sensor such that it (MA100 together with SHIMMER) can be easily placed inside female cervix.
- Construction of a new version of our computer application for a Personal Digital Assistant (PDA).
- Power limitations still one of the weaknesses of this system. So the use of energy scavenging techniques could be considered to improve the stand-alone characteristics aimed for this system.
- Integration of Zigbee communication to the intra-body sensor. Therefore it could be easily attached to a Body Area Sensor Network (BASN) or a Sensor Network.
- Development of a mobility solution to monitor intra-vaginal temperature in hospitalized women with the integration of the intra-body sensors in a Sensor Network.

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