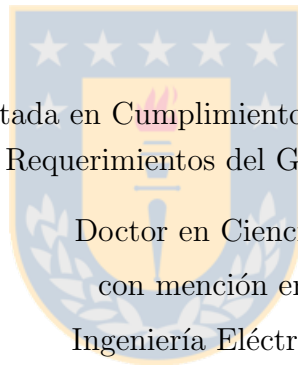


Biomedical Signal Processing for Diagnosis Support

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Biomedical Signal Processing for Diagnosis Support

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Abstract

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Esteban J. Pino, Sc.D.

Universidad de Concepción, 2009

As medical knowledge advances and life expectancy increases, the ratio of medical care providers to patients is reduced. It is expected that in the near future, “at risk” population will be too large to be adequately treated in hospitals and clinics. Moreover, the aging population will expect better life quality and will demand for self care at home or other familiar environments.

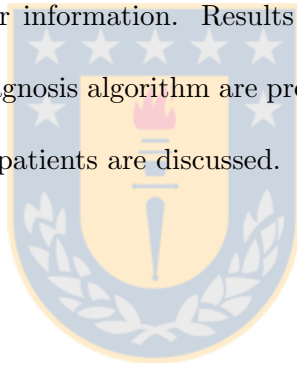
Patient monitoring in non-standard sites will become increasingly relevant. In emergency response sites, hazardous environments, nursing homes or individually at home, pervasive patient monitoring will provide a higher level of safety without impairing normal activities and life quality.

This thesis presents some necessary elements for an untethered monitoring system. Data acquisition sensors, infrastructure for data transmission, algorithms for data processing and analysis, alarm generation and location system are presented and discussed. Originally intended for disaster situations, the components, specifications and required performance of this system are easily conditioned to other environments.

This work was developed during the design, implementation and testing of such a system, and presents detailed descriptions and results from a pilot study in the Emergency

Department of the Brigham and Women's Hospital in Boston, Massachusetts, USA. Results show the feasibility of implementing a pervasive monitoring system, its perceived utility and key issues that need to be addressed.

This thesis presents diagnostic support algorithms that use acquired data from ECG and SpO₂ sensors to provide on-line information on the medical status of the patient. A quantitative criterion to select a physiologic signal processing algorithm in noisy environments is proposed. The alarming system is able to indicate dangerous conditions, trying to minimize false positives (false alerts) and avoiding false negatives (failure to alert when needed), by combining sensor information. Results from real and simulated patients on the accuracy of a multiple diagnosis algorithm are presented and the problems encountered while monitoring untethered patients are discussed.



Resumen

Procesamiento de Señales Biomédicas para Apoyo Diagnóstico

Esteban J. Pino, Sc.D.

Universidad de Concepción, 2009

A medida que avanza el conocimiento médico y las expectativas de vida aumentan, el personal médico se ve cada vez más exigido. Se espera que en el futuro cercano la población “en riesgo” aumente de tal manera que no será posible entregar una atención adecuada en hospitales y clínicas. Además, la población de adultos mayores va a esperar una mejor calidad de vida y va a demandar la opción de autocuidado en su propio hogar o en otros lugares de su elección.

El monitoreo de pacientes en ambientes no estándar se volverá cada vez más relevante. Lugares de atención improvisados para respuesta a emergencias, ambientes peligrosos, hogares de ancianos o casas particulares son los principales candidatos. Mediante monitoreo remoto, es posible proveer un mayor nivel de seguridad sin interferir en las actividades normales ni perjudicar la calidad de vida de los sujetos.

Esta tesis presenta los elementos necesarios para un sistema de monitoreo inalámbrico. Se presentan y se discuten los sensores para adquisición de datos, infraestructura para transmitirlos, algoritmos de procesamiento y análisis, generación de alarmas y sistemas de localización. Originalmente pensado para situaciones de desastre, los componentes, especificaciones y el desempeño requerido para este sistema son fácilmente adaptables a otros

ambientes.

Este trabajo fue desarrollado durante el diseño, implementación y prueba de uno de estos sistemas. Se presentan descripciones detalladas y resultados de un estudio piloto en el Departamento de Emergencias del Brigham and Women's Hospital en Boston, Massachusetts, USA. Los resultados muestran la factibilidad de implementar un sistema de monitoreo permanente, su utilidad y los problemas clave que deben ser abordados.

Esta tesis presenta algoritmos de apoyo diagnóstico que utilizan datos de ECG y SpO₂ para proveer información en tiempo real de la condición médica del paciente. Se propone un criterio cuantitativo para seleccionar algoritmos de procesamiento de señales fisiológicas en ambientes ruidosos. Mediante la combinación de la información de los sensores, el sistema de alarmas es capaz de indicar condiciones peligrosas. El algoritmo utilizado intenta minimizar los falsos positivos (falsas alarmas) y evitar los falsos negativos (falla en alertar cuando se requiera). Se presentan resultados de un algoritmo de diagnóstico múltiple obtenidos en pacientes reales y simulados. Finalmente, se discuten los problemas encontrados al monitorear pacientes en libertad de movimiento.

A mis padres...



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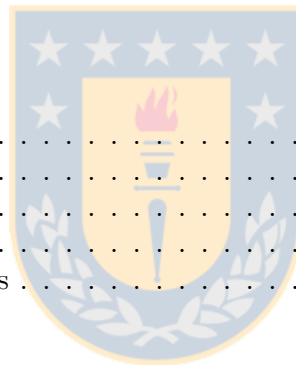
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Acronyms

ABC Activity Based Computing

AM Alert Module

AOA Angle Of Arrival

BPC Body Position Changes

BSN Body Sensor Networks



BWH Brigham and Women's Hospital

CIMIT Center for Integration of Medicine and Innovative Technology

ECG Electrocardiogram

ED Emergency Department

EKG Electrocardiogram

ESI Emergency Severity Index

FIR Finite Impulse Response

FN False Negative

FP False Positive

GPS Global Positioning System

HR Heart Rate

HRSD Heart Rate Standard Deviation

HST Health Sciences and Technology

IPS Indoor Positioning System

IRB Internal Review Board

LM Logistics Module

MIT Massachusetts Institute of Technology

NIH National Institute of Health

NLM National Library of Medicine

PDA Personal Digital Assistant

RF Radio Frequency

RFID Radio Frequency Identification

RR Interval between two R points in an ECG

RSS Received Signal Strength



RTOA Roundtrip Time of Arrival

SMART Scalable Medical Alert and Response Technology

SNR Signal to Noise Ratio

TDOA Time Difference of Arrival

TN True Negative

TP True Positive

UDP User Datagram Protocol

US Ultrasound

Wi-Fi IEEE 802.11 wireless standard



Chapter 1

Introduction



1.1 Current Issues

Common knowledge defines “at-risk” patients as people more likely to suffer some event that may critically affect their health. There can be many causes, such as disease or aging for cardiac or bronchopulmonary patients, dangerous job environments such as mining, firefighting or diving and mass casualty events such as natural disasters, terrorist attacks or wars. Whether at home, in waiting rooms, at work or at improvised emergency sites, most of the time “at-risk” people lie unattended until an emergency condition occurs. Thus, their care changes back and forth from proper intensive medical care after a critical episode to self care in a non-medical setting.

Continuous monitoring of unattended patients is desirable in many settings, even after an initial triage to assess urgency. One such setting is an overcrowded emergency department (ED), where there is always the concern that a patient in the waiting area may deteriorate suddenly without being noticed. Similarly, at a disaster site, where patients far outnumber caregivers, some monitoring of post-triage patients could be useful. At home or in nursing houses, a system that monitors at-risk patients may provide an extra level of safety, specially at night or during otherwise normal activities. In these situations, it is desirable to have a system to monitor patient status and location, and to alert one or more caregivers of significant events in an efficient way.

Building a continuous monitoring system for an overcrowded emergency room or disaster site has many challenges:

- Selecting vital signs and location sensors that are low-cost, low-power, accurate and able to communicate with other components.

- Selecting a light-weight, low-cost platform that incorporates wireless communications, can be integrated with the sensors, and has a long battery life.
- Devising a packaging of the sensors and platform that is acceptable to patients and convenient to handle.
- Guaranteeing that the wireless system can support the concurrent monitoring of a large number of patients.
- Analyzing the data from the sensors and presenting alerts and data to appropriate caregivers in a way that does not overload them.
- Integrating these components into a workable system that can be quickly deployed at a disaster site, that is familiar to disaster personnel, and that will scale to monitor large numbers of patients.

This thesis focuses on the different aspects required to implement such a monitoring system. It was developed as part of the SMART (Scalable Medical Alert and Response Technology) project, in Boston, Massachusetts (USA) from 2004 to 2006. The SMART system was implemented in the Emergency Department of the Brigham and Women's Hospital and tested on real patients from June 2006 to October 2007.

1.2 Hypothesis

The working hypothesis is:

It is feasible to continually monitor untethered patient's vital signs, and give providers appropriate warnings of critical values.

1.3 Goals

1.3.1 Main Goal

The main goal of this work is to develop signal processing algorithms for wireless ambulatory patient monitoring systems, such as the SMART system. These algorithms must be portable to similar environments.

1.3.2 Specific Goals

- To continually monitor untethered patients, the algorithms have to:
 - Continuously monitor simple physiologic signals such as 1-lead ECG and SpO₂.
 - Be robust in presence of noisy signals, as is expected from a real setting.
 - Communicate clinical patient information to a decision module (server or client-based).
- To give providers appropriate warnings, the algorithms must:
 - Rely on other available measurements to cross-check data when possible.
 - Be reliable, aiming for low false positives and no false negatives.
 - Determine intermediate conditions to propose changes in case prioritization (triage).
- Finally, we want to integrate these algorithms into a pervasive monitoring system that provides a means to monitor and locate multiple patients.

Chapter 2

Methods



2.1 Hardware

The hardware consists mainly of off-the-shelf equipment. Patients are equipped with an HP iPaq 5500 PDA, connected to a custom-made 1 lead, 3 electrodes ECG acquisition card, with a sampling rate of 200 Hz and an 8 bit ADC. An Ipod model 3212, a commercial SpO₂ sensor from Nonin Medical, Inc. [1], is used for oxygen saturation monitoring and HR validation. The ECG and SpO₂ data come through the serial ports in an iPaq backpack and are transmitted wirelessly (802.11b) to a server. The backpack also provides an additional battery pack, extending the maximum monitoring time to about 4 hours. A similar but sensorless PDA is used to remotely monitor patients and manage alarms.

Patients are tracked with an Indoor Positioning System (IPS) from Sonitor ® [2]. The pen-like tags transmit an ultrasound pulse to networked detectors, which relay the information to SMART Central where the final position is computed. Three of such detectors are wired to the router while the remaining 12 are connected to ASUS WL-330gE wireless access points.

SMART Central is the main server and operator station. It is a standard AMD Athlon 64, 1 GHz, 1 GB RAM desktop computer. It is wired to an 802.11b/g wireless router, which manages the internal network used by the mobile PDAs, the location system and the occasional laptop PC used for debugging or backup. The coverage area was originally the ED waiting room, but was later expanded to an overflow area (main lobby) using two commercial Linksys WRE54G wireless range extenders. For compatibility reasons, the wireless network is run in 802.11b mode.

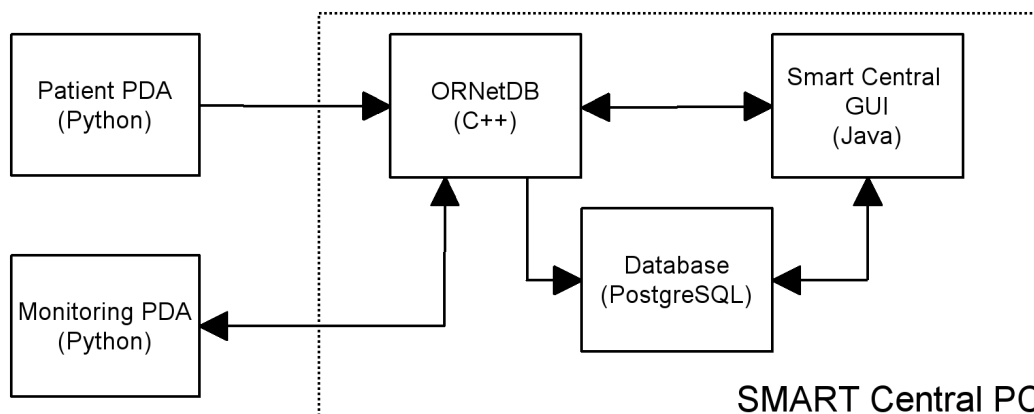


Figure 2.1: SMART software components.

2.2 Software

Software for the SMART project is written in Python, C++ and Java, according to the requirements and platforms where the different components are located. ORNetDB [3], the underlying connecting software that gets the data from the remote sensors, processes, logs and feeds data to its clients, is written in C++. It was originally developed at MIT, as an Operating Room Network interface, and works as a streaming database. This software allows input of queries into the database to subscribe to real-time data, addition of intermediate processing nodes, combination of multiple inputs, and logging of the data into a standard SQL database. A PostgreSQL [4] database is used for data logging. Both ORNetDB and PostgreSQL database run in SMART Central.

There are 2 different Python programs that run on the PDAs. The patient version has configuration screens to set-up the PDA and optional live ECG and SpO₂ display for debugging purposes. The caregiver software has a patient roster and patient-specific screens with live ECG tracings. It also provides a way to respond to alarms generated by SMART

Central. Both versions communicate wirelessly with ORNetDB for data transfer.

SMART Central's "visible" software is written in Java, and provides a GUI for the Smart Operator, a paramedic in charge of monitoring the system and alerting a triage nurse when necessary.

2.2.1 Signal Processing

The actual ECG processing is done in 2 steps. In ORNetDB, beat detection is performed as soon as the data enter the streaming database. Then, the raw ECG signal, the beat positions and the SpO₂-derived HR are further processed in SMART Central to compute the ECG HR and suggest a diagnosis. This scheme is selected to facilitate patient-specific alarm threshold modifications by the operator directly in SMART Central. All sensor data and computed values are saved into the PostgreSQL database.

Location data are also processed in SMART Central. An algorithm selects the most likely location for the tags based on signal strength and detector tuning.

2.3 Test Data

PhysioNet [5] data are used to evaluate ECG beat algorithm accuracy. The MIT-BIH Arrhythmia Database contains clean recordings from real patients presenting a variety of arrhythmias. It is normally used as the standard for algorithm evaluation [6] because it has accurate beat annotations. The annotated beat positions are compared to the detected beats to compute sensitivity and positive predictability. Using recorded noise also available from [5], 6 different SNR sets of data were generated to extensively test the algorithms



Figure 2.2: Patient simulator wearing PDA and ECG electrodes.

under varying noise conditions.

For the diagnosis algorithm, test data are obtained from healthy volunteers using the actual hardware developed for SMART. However, in order to get abnormal rhythms for training and testing, a simulator is used. The abnormal data are recorded at the STRATUS Center, part of the Department of Emergency Medicine at Brigham and Women's Hospital. This center is equipped with a Laerdal SimManTM [7] computer-controlled patient simulation system. The "patient" is an adult-sized mannequin that breathes, has pulse, blood pressure and heart, lungs and bowel sounds among other features. To obtain data, a SMART patient PDA is connected to the mannequin (Fig. 2.2) running a simulation of various heart conditions. Two sets of records are obtained: one for training purposes and another for testing after the final algorithms are implemented. SpO₂ data are not available from the simulator.

The healthy volunteer sessions add up to 3194 min of ECG data and 3276 min of SpO₂ data from 38 individuals. The STRATUS data are 15.4 min long: 5.7 min for

the training session and 9.7 min for the testing session. The rhythms on the STRATUS training session data are split into individual files and then combined into longer records, to simulate different patient state transitions. The abnormal rhythms simulated are tachycardia, bradycardia, ventricular tachycardia, ventricular fibrillation, second degree block and asystole.

2.4 Pilot Study

The pilot study was conducted between June 19, 2006 and October 1, 2007, in the Waiting Area of the Emergency Department (ED) at the Brigham and Women's Hospital in Boston. We conducted our pilot study there because it provides a controlled environment with ambulatory patients in whom the expected rate of real events is higher than normal. The assumption is that in an ED waiting room there is a higher proportion of "at-risk" patients. Only patients presenting cardiovascular or respiratory complaints with intermediate severity statuses, based on triage, are eligible for the study.

Chapter 3

Previous Work



3.1 Background

Biomedical signals have unique characteristics that require special processing. This is mainly due to the fact that generally, only indirect measurements are made, such as electrical potentials on the skin to monitor electrical activity of the heart, or light absorption of the finger to estimate blood light absorption to then estimate blood oxygen content. On the positive side, a large number of processing algorithms are available. To select and tune the best option, it is necessary to evaluate both the signal and the noise on a case by case basis.

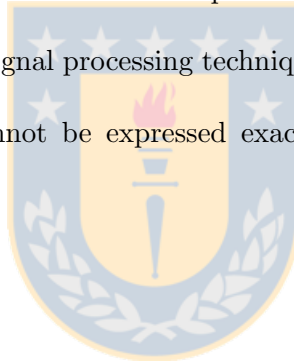
The algorithms to be developed must process two kinds of biomedical signals. Bioelectric (for ECG) and Biooptical (for SpO₂). Bioelectric signals are generated in the body during muscular contractions and nervous activity. In both cases, there is a cell membrane potential that fluctuates, producing a chain reaction that propagates this potential through the muscle or nerve cell. In muscle cells, it produces contraction, and in nerve cells, neurotransmitter release for signal relaying. Non-invasive sensors detect potential changes induced by the electric field. Bioelectric signals are probably the most sensed of biomedical signals. It allows ECG (heart), EEG (brain) and EMG (muscles) measurements. Biooptical signals are measured, directly or indirectly, from transmitted or scattered light. Blood oxygenation is estimated measuring light absorption at two different frequencies. Information on fetus status can be acquired from fluorescence characteristics of the amniotic fluid.

The anticipated noise characteristics, common to both bioelectric and biooptical signals to be acquired for this thesis, arise from the ambulatory nature of the monitoring. Since it is impractical to provide a noise controlled environment, the signal processing

algorithms must be able to deal with disturbances from:

- Noisy signals from low cost, portable and/or disposable sensors.
- Motion artifacts, from sensor displacements while the patient moves freely.
- Muscular artifacts in ECG signals.
- Loss of signal when a patient walks out of wireless coverage or a sensor falls off.

Both ECG and SpO₂ are stochastic signals (cannot be described mathematically). However, they can be considered as “almost periodic” or stationary stochastic processes, enabling the use of periodic signal processing techniques such as Short-Time Fourier Transform. Stochastic signals cannot be expressed exactly. They are described in terms of distribution probabilities.



3.1.1 ECG

The electrocardiogram (ECG or EKG) is the surface recording of the electrical activity generated by the heart. Einthoven, in 1903, enhanced the technology and introduced concepts still in use today. The EKG acronym comes from Einthoven native language: cardio in Dutch is spelled with a “K”. The basic ECG recording configuration is shown in Figure 3.1 [8]. Later, Wilson proposed a different configuration that evolved into the current augmented leads, as shown in Figure 3.2 [8]. Finally, leads V₁ through V₆ were introduced (Figure 3.3 [8]), completing the current 12 lead standard ECG. This configuration is redundant and non-optimal, but became a standard due to the massive amount of recorded data.

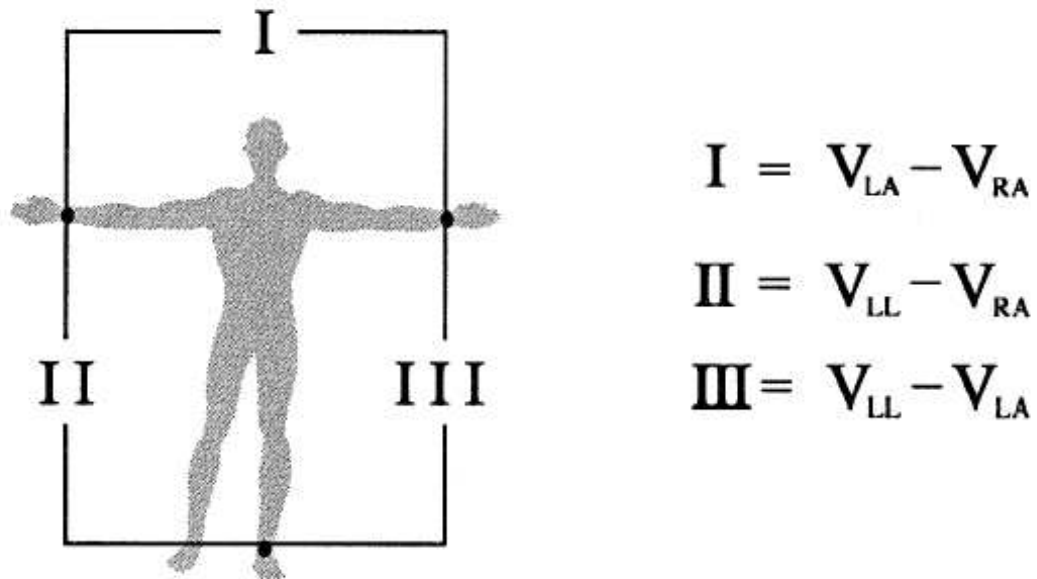


Figure 3.1: ECG basic configuration.

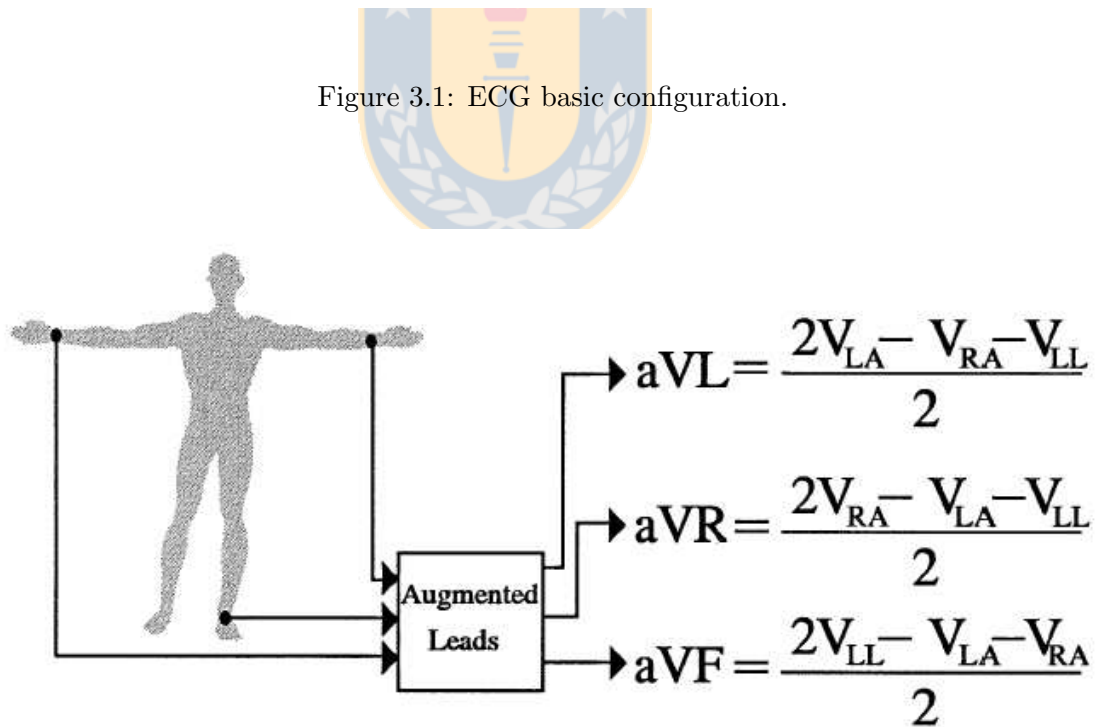


Figure 3.2: ECG augmented leads aVL, aVR, aVF.

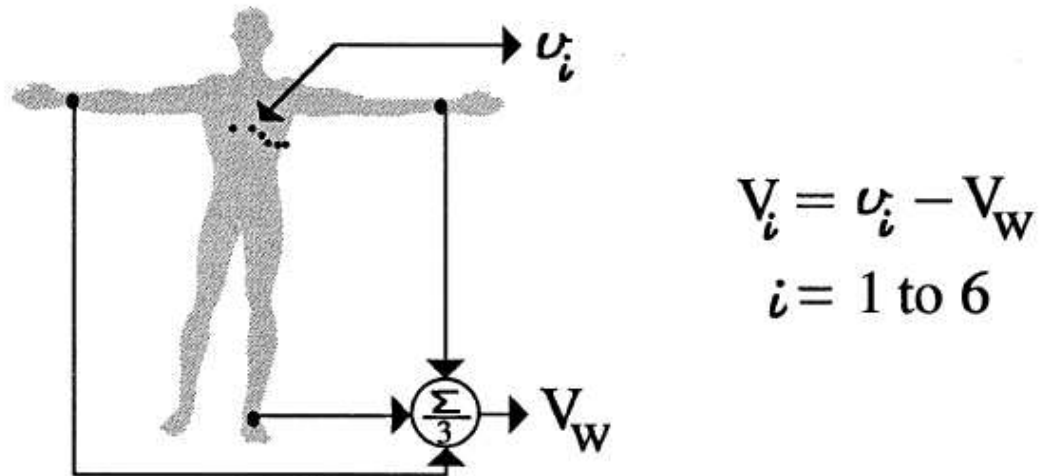


Figure 3.3: ECG chest leads V_1 , V_2 , V_3 , V_4 , V_5 and V_6 .

ECG signals are low amplitude (± 2 mV), and have a wide frequency range, from 0.05 Hz to 150 Hz. Figure 3.4 [8] shows a typical ECG wave, and Figure 3.5 [8] show computer-based measurements, typically requested by cardiologists.

Ambulatory monitoring has to be able to detect deviations from the normal ECG shape in presence of varying amounts of noise. Typical ECG processing algorithms include Filtering (band pass filters, notch filters), QRS complex detection, Heart rate variability processing and Baseline correction.

3.1.2 SpO₂

Oximetry is the measurement of oxygen saturation, or the relative amount of oxygen carried by Hemoglobin in the blood. Fortunately, Oxyhemoglobin (HbO₂) and reduced Deoxyhemoglobin (Hb) have different light absorbance profiles (Figure 3.6 [8]). This is due to the fact that, when Hb is combined with O₂, a conformational change takes place,

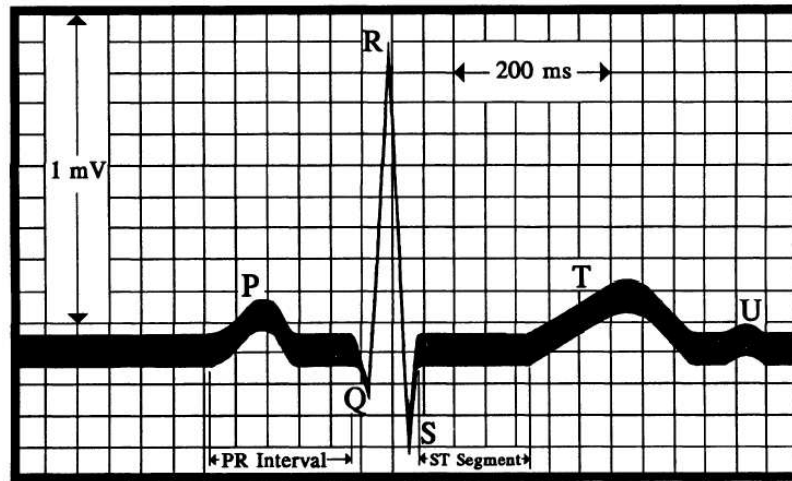


Figure 3.4: Typical ECG wave, recorded from lead II.

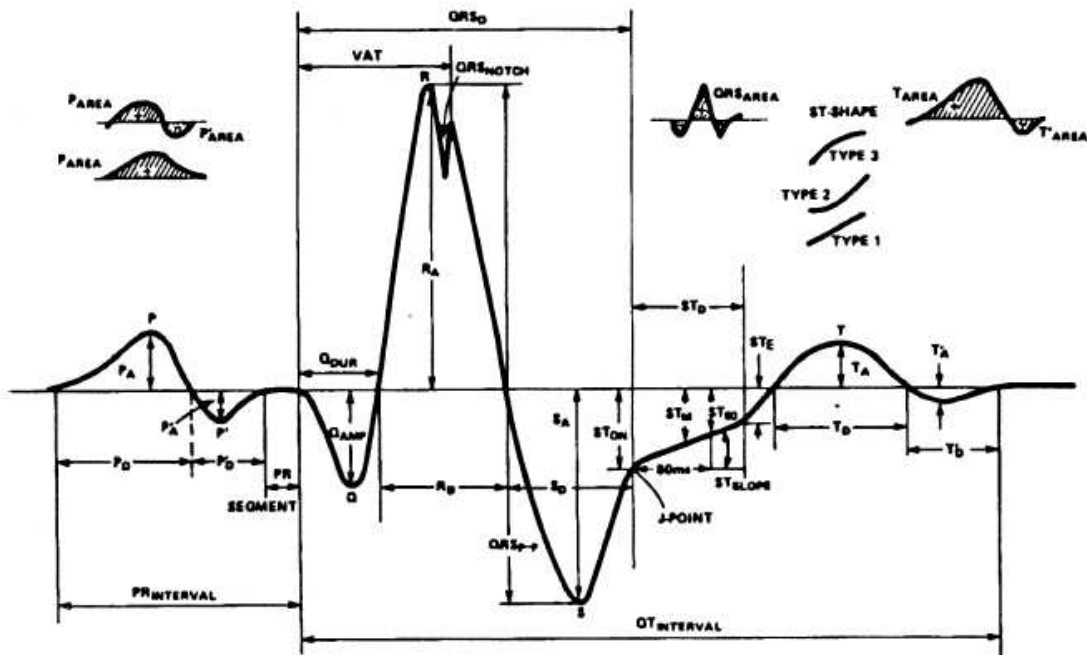


Figure 3.5: ECG measurements: durations, amplitudes and areas.

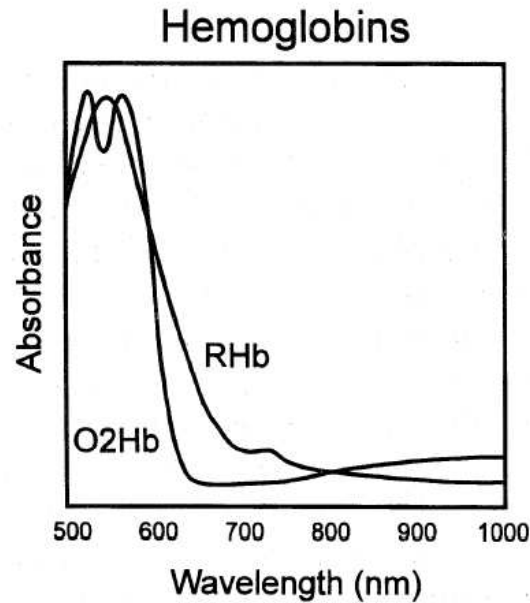


Figure 3.6: Oxyhemoglobin (HbO₂) and deoxyhemoglobin (Hb) absorbance at different wavelengths.

producing a significant color change. This is the reason why oxygenated (arterial) blood is bright red and deoxygenated (venous) blood is dark red. Arterial (SaO₂) or venous (SvO₂) oxygen saturation measurements are based on light transmission or reflection directly from tissue or blood. Typical wavelengths are 660 nm red light, where there is a significant difference in HbO₂ and Hb absorbance, and 805 nm infrared light, at the isobestic wavelength, where HbO₂ and Hb absorbance is similar. Sometimes, instead of the isobestic, a higher wavelength is used (>805 nm), where the absorbance of Hb is slightly smaller than that of HbO₂.

Pulse oximetry (SpO₂) is a method to estimate arterial oximetry (SaO₂) non-invasively. It was first suggested by Aoyagi et al. and Yoshiya et al. [9]. It relies on the detection of a time-variant photoplethysmographic signal, caused by changes in arterial blood volume at each cardiac contraction. A typical arrangement consists of two LEDs of

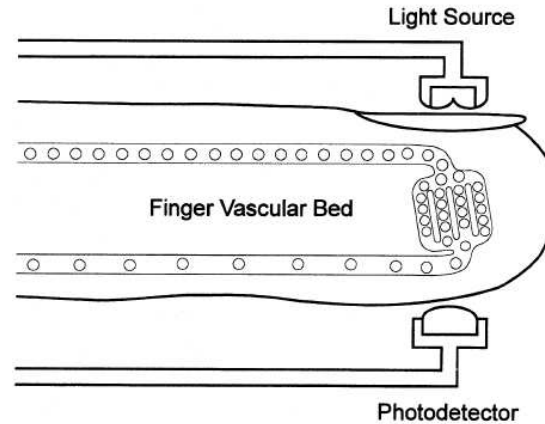


Figure 3.7: Typical pulse oximeter configuration.

different wavelengths placed at one side of a finger or ear lobe, and a sensitive photodetector on the other side, as shown in Figure 3.7 [8].

SpO_2 is derived by analyzing only the time-variant changes in absorbance caused by the pulsating arterial blood at the same red and infrared wavelengths used in conventional invasive type oximeters. A normalization process is commonly performed by which the pulsatile (AC) component at each wavelength, which results from the expansion and relaxation of the arterial bed, is divided by the corresponding nonpulsatile (DC) component of the photoplethysmogram, which is composed of the light absorbed by the bloodless tissue and the nonpulsatile portion of the blood compartment. This effective scaling process results in a normalized red/infrared ratio which is dependent on SaO_2 but is largely independent of the incident light intensity, skin pigmentation, skin thickness, and tissue vasculature.

Pulse oximetry is noninvasive, inexpensive, simple to apply, and can produce remarkably accurate saturation estimates at saturation levels above 70%. This is sufficient

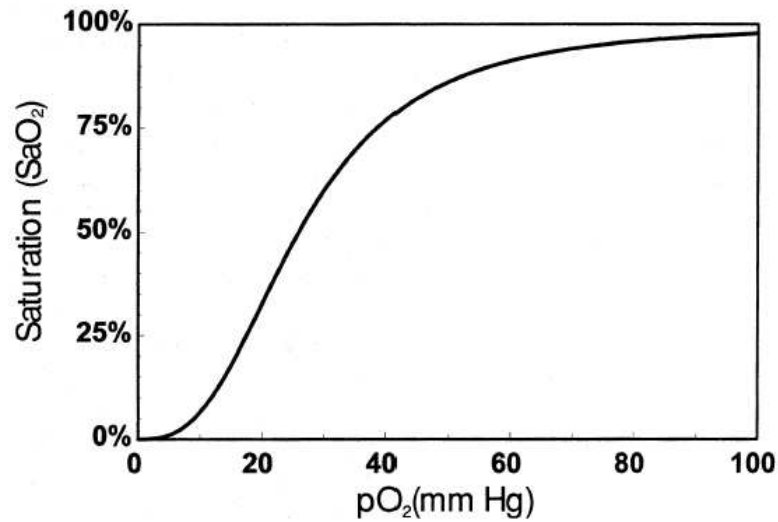


Figure 3.8: Hemoglobin oxygen saturation (SaO_2) versus partial oxygen pressure (PO_2).

since SaO_2 under 80% correspond to a partial oxygen pressure (PO_2) of about 40 mmHg, which can lead to hypoxia (Figure 3.8 [8]). It has the added benefit that the AC component of the signal can be used as a heart rate measurement. Pulse oximetry has, therefore, become widespread in patient monitoring, and has been adopted as a standard for anesthesia, neonatal care, and post-operative recovery.

The main problem during SpO_2 signal acquisition is the introduction of artifacts. Even small movements, such as shivering, can cause deformation in the area or sensor displacement relative to the skin. These changes alter the signal path and produce noise. Different algorithms have been developed to deal with noise, although a common solution is to simply freeze the last valid reading until a new reliable measurement can be made.

3.2 Patient Monitoring

3.2.1 ECG Analysis

Previous work on ECG processing related to the difficulties in ambulatory analysis is presented. These papers are a reference to the current state of knowledge on ECG analysis. Articles on baseline wander removal, ECG delineation, noise reduction, arrhythmia and ischemia detection and different processing algorithms were selected.

One of the most cited articles on Real-Time ECG processing is [10]. In 1985, Pan and Tompkins published a detailed procedure for an algorithm based on digital filters and adaptive thresholds for QRS detection. They reported accuracy on the MIT-BIH arrhythmia database, before it became one of the standard databases for beat evaluation.

In [11], the authors present a method to design a low-pass differentiator (LPD) filter, assuming *a priori* knowledge of both signal and noise spectra. Several examples of digital filters suitable for QRS complex and P-T wave processing in ECG are presented.

[12] proposes an algorithm to detect ECG characteristic points using Wavelet Transforms. QRS complexes can be distinguished from P and T waves in presence of noise, baseline drift and artifacts. Tests performed on the MIT-BIH database achieve over 99.8% detection rate. The algorithm relies on the analysis of the signal at different scales provided by a generalized linear phase quadratic spline wavelet.

[13] uses the Fourier transform to detect changes in QRS complex that indicate life-threatening ventricular arrhythmias in each heartbeat. QRS complex is detected and extracted before calculating the frequency components. The rhythms are then discriminated by a neural network as ventricular or supraventricular and fibrillation or tachycardia. Tests

using surface and intracardiac electrograms achieve a specificity of over 98%.

In [14], the authors present a study of beat to beat variability in presence of noise, while most of the studies involve signal acquisition at rest. They use a simple cardiac action potential model including variations due to respiration. QRS variability due to respiration is reduced by means of loop alignment but becomes deteriorated at high noise levels. The authors introduce a relationship between vectorcardiogram (VCG) loop morphology and noise level. The measurement of noise level and loop planarity may be used to predict loop alignment reliability.

In [15], the authors present an algorithm to correct baseline drift from ECG recordings. It is implemented as a two step procedure for selective filtering with minimal distortion of cardiac complexes. The procedure was successfully tested on 100 simulated and 210 real ECG signals. Unfortunately, the algorithm is computationally intensive, requiring forward/backward filtering, frequency estimation and least-squares line fitting for each 20 s of data.

[16] presents a server-based ECG processor for remote clinical diagnosis support. The purpose is to have a centralized server with advanced signal processing algorithms to submit locally acquired ECG data. The implemented application provides 5 different ECG processing techniques. The data are submitted to a MATLAB web server and requires only a Web browser on the client side.

A complete review of available methods for heart beat classification is presented in [6]. Algorithms are compared in terms of accuracy and speed. A special note on the need to report results on standard databases is made.

[17] provides an enhanced method for baseline wander removal. The proposed method is simple and fast and preserves the ST segment of the original signal. The algorithm considers QRS complex and skeletal muscle signal removal in a first stage and then baseline wander removal in a second stage. Although the method is tuned for neonatal ECG signals, references are provided that may help adapt it to adult signals. Baseline wander and skeletal muscle artifacts are bound to be present in ambulatory ECG monitoring.

[18] provides a detailed discussion of the current methods used for ECG data analysis. Fourier Transform, Autocorrelation, Delay Times, Approximate Entropy, Singular Values Decomposition and Discrete Wavelet Transform were applied to 2 sets of records in order to differentiate healthy from coronary artery disease subjects. Their results show the characteristics of each method and their ability to detect nonlinear signal dynamics. An appendix is included with mathematical formulation for each method.

In [19], the authors study two methods to analyze and detect body position changes (BPC) from ECG signals. They report that BPC are often misclassified as ischemia, particularly during ambulatory monitoring. The methods compared are rotation angles from VCG loop alignment and scalar representation of Karhunen-Loève coefficients. Results show that both methods lower false ischemic alarms when used in parallel with classical noise detection, achieving up to $P_D \simeq 90\%$ chance of detection. However, a previous algorithm from the same authors [20] used on the same data set has a false detection of less than 2%, turning the BPC detection less necessary. In that paper, the authors present filtered RMS difference series as a means to detect changes in the ST segments and ST-T complex, when compared to an average pattern. The detector has a sensitivity of 85%, comparable

to more complicated algorithms. A post-processing stage based on cross-correlation allows improvement of the performance to 90%. They present a comparison with 3 detectors from other authors.

In [21] the authors develop and evaluate a single-lead ECG delineation algorithm based on Wavelet Transform (WT). The algorithm is able to detect and identify peaks, onsets and ends of individual QRS, P and T waves. The sensitivity was evaluated using annotated databases such as MIT-BIH Arrhythmia, QT, European ST-T and CSE¹. The results show sensitivities of over 99.66% and positive predictability of 99.56%. Mean and standard deviation of errors in delineation (onsets, peaks and ends) was found not to exceed one sampling interval and outperformed results from other algorithms.

In [22], the authors propose to improve QRS complex recognition by using an expert system that combines different algorithms. Their implementation consists of combining Higher Order Statistics and a Hermite characterization in a Support Vector Machine. The combined effort produces an improved classifier, tested on 12 different types of arrhythmias and normal sinus rhythm from the MIT-BIH Arrhythmia Database.

[23] presents a method to characterize atrial arrhythmias. It is based on the time-frequency distribution of an ECG signal that had its ventricular activity cancelled by signal processing. If a valid atrial signal is detected, the method classifies the signal according to its time-frequency distribution.

¹More information on these ECG databases is available in [5]

3.2.2 SpO₂ Analysis

The main problem in SpO₂ processing are motion artifacts produced from unexpected deformations of the sensed region.

[24] proposes a Noise-Resistant pulse oximetry algorithm by generating a synthetic reference signal used to reconstruct noise and artifact affected regions. The reference signal is constructed based on information from clean signal sections and is used as a base for a linear subspace where the reconstructed signal will reside. The authors propose that this method can be adapted to filter other signals that exhibit a repeating, slow varying kernel function, such as blood pressure and ECG.

A complete mathematical formulation of equations involved in SpO₂ measurements is presented in [25]. Starting from Beer-Lambert law, the authors present theoretical and in practice a method to estimate pulse oximetry in presence of motion artifacts. Their method requires an extra illumination led used as a reference to equalize the remaining two channels.

Based on the mathematical foundations of pulse oximetry, [26] proposes an approximation that enables the prediction of oxygen saturation levels under 70%. Currently, calibration methods for SpO₂ estimation perform poorly at low saturations. This paper develops the exact solution and then relies on a parameter estimation to adjust SpO₂ to measured SaO₂. Experimental results produce better approximations compared to traditional empirical calibration techniques when monitoring fetal sheep.

The available SpO₂ sensor already incorporates the latest commercial algorithms for data processing. The importance of the SpO₂ sensor for this work is primarily as an

alternate data source. Data integration has been proposed in [27, 28, 29] to estimate data quality and/or to reduce the number of alarms. Basically, it is possible to confirm or reject a finding in one data source by cross-validating with other sources. In our case, ECG will be the primary source and SpO₂ the secondary, since it has a slower time response.

3.2.3 Location Systems

In recent years, Indoor Positioning Systems (IPS) have become more readily available commercially. Many health care institutions see the potential benefit of deploying such technology [30, 31, 32]. Their role in medical settings is twofold: tracking patients and tracking equipment.

IPS solutions fall into two categories: systems designed “from the ground up”, and systems that leverage an existing wireless network [33]. A system designed from the ground up can be tailored to meet specific requirements, but is usually associated with a higher cost. Using an existing network may be less expensive to deploy but may require use of devices to process location system signals that were not meant for this, and hence offer suboptimal performance.

While indoor positioning systems have been in use for several years, applications and requirements in the medical field often are different from those of deployments in other settings, for example, in large warehouses where the focus is more on inventory control. A system that provides a good solution for other applications does not guarantee success in a medical setting [34] as this setting often requires tracking of continuously moving items and persons. As a consequence, several healthcare specific IPS systems have been proposed.

CodeBlue [35], a system designed from the ground up, consists of a sensor network

for vital sign monitoring, a personal digital assistant (PDA) based triage application, and MoteTrack, a radio frequency (RF) location system. The location is determined by the infrastructure, by comparing the current radio frequency signature to reference signatures, collected off-line during system installation.

MASCAL [36] uses a positioning system based on the existing IEEE 802.11 wireless network standard (Wi-Fi). The system is reported to have short battery life due to the Wi-Fi transmitter requirements. MASCAL coverage includes the emergency department parking lot, the emergency room, radiology, surgical pre-operative and recovery departments, the operating Room, and three large medical wards. MASCAL also integrates data with TACMEDCS [37], a US Navy triage system.

The AID-N system [38] comprises a wireless vital signs monitoring system and location tracking for use at disaster scenes, in local hospitals, and during telemedicine encounters. For outdoor locations, the conventional global positioning system (GPS) is used. For indoor locations, MoteTrack-based location beacons must be installed.

The WIISARD system [39], includes an intelligent triage tag for medical response. These tags have bi-directional communication, can display triage status via light emitting diodes (LEDs), and have sensors to determine patient status. In this system, information about the general tag location is deemed enough, as long as each tag announces itself to care providers in the vicinity. Location is remotely estimated from signal strength using the wireless data network.

While the above systems differ in whether the indoor positioning system was designed from the ground up or not, i.e., how they leverage existing networks, they all use

radio frequency technology for indoor positioning.

3.2.4 Integrated Systems

Vital sign monitoring via portable devices is currently available. A special section on M-Health [40] introduces the current developments in the area. Related to this work, there is one commercial system offered by Welch Allyn®, the Micropaq® Monitor [41] that monitors patient electrocardiogram (ECG) signals and is used in certain hospital wards. Both SMART and two other research systems for vital sign monitoring were developed for disaster environments (WIISARD [39, 42, 43] and AID-N [44, 38, 45]). These two systems were implemented during the same time-frame as the SMART system. There are three systems developed for military applications (Artemis [46], BMIST-J [47] and TACMEDCS [48]), as well as two systems for physiological monitoring developed by researchers: Telcordia® T2 [49] and a system developed at National Taiwan University [50]. Also related to our efforts is ER-One [51], a collection of specifications for disaster response. With the exception of the Welch Allyn® commercial system, evaluation of these systems in a significant number of real patients has been limited. A framework for comparing these systems and SMART should include the following issues:

1. Which vital signs are monitored?
2. Are the patient's vital signs monitored continuously?
3. Can the system monitor the location of people and equipment?
4. Is there a tunable alarm system? Can it alert individual caregivers?

5. Is there a mobile caregiver component?
6. Is the system open to modification to accommodate local needs?

Commercial systems

The Welch Allyn® Acuity® LT Central Monitoring Station [41] is a commercial system that wirelessly collects data from sensors on a patient. This system monitors pulse oximetry (SpO₂) and ECG signals and its alarms are based on thresholds. SMART could have been based on this system, but this would have precluded local adaptation of the patient monitoring component, the alarm system, and the monitoring station. Our system extends these capabilities by providing an open platform for modifying the system and by adding a mobile component for the caregiver. SMART's location system allows patients, providers, and equipment to be continuously monitored.

Disaster management systems

The goal of disaster management systems is to improve the management of mass casualty incidents by introducing more accurate victim tracking and enhancing situational awareness. This is largely achieved by replacing systems based on paper and interpersonal verbal communications with electronic components. Two main paper components are replaced: records filled by first responders and paper triage tags. Verbal communications include reports from first responders to incident commanders and transportation specialists and vice-versa.

WIISARD (Wireless Internet Information System for Medical Response in Disasters) [39, 42, 43], was developed at the University of California at San Diego. At a

disaster site, responders start by deploying a wireless bubble of communications infrastructure. There are several levels of caregivers and the caregivers receive appropriate computing devices for their roles. The first responder assesses each victim and logs the victim into the WIISARD system. The responder then gives the victim an electronic tag. This tag helps responders know where the victim is: at the site, in transport, or at a hospital. The nurses in charge of coordinating transport of victims to hospitals have laptops or tablet computers that allow them to see where the victims are. The disaster command and control centers have software that allows the site commanders to see the activities of the victims, responders, and coordinators. Some of the tags given to victims monitor the patient's SpO_2 level. In addition to SpO_2 measurement and location monitoring, SMART extends the vital signs monitoring by collecting and analyzing ECG signals to generate and direct alarms to individual providers. Like WIISARD, SMART is designed to accept inputs from indoor or outdoor location subsystems.

The Advanced Health and Disaster Aid Network (AID-N)[44, 38, 45] is another research project focused on improving disaster response. It was developed at the Johns Hopkins University Applied Physics Laboratory. Like WIISARD, it is focused on managing a mass casualty incident and provides support for first responders, monitoring victims, and incident commanders. The first responders carry tablet PCs to record patient information. They give each patient an electronic tag and download patient information to that tag. In addition to the electronic tag, the first responder may give the victim an SpO_2 sensor and/or a blood pressure sensor. These Mote[52]-based sensors, developed by the Code Blue Project[53] at Harvard University and Boston University, independently report

their readings to the first responder's tablet PC, which then uploads the information to a central database when the network is available. The incident commander can monitor the status of the response via accessing the central database. AID-N uses a location subsystem based on Motes and a research-based mesh network is used to provide the communications infrastructure. SMART substitutes commercially available network gear for the research-based mesh network for more reliable collection of data. It also extends AID-N by collecting and analyzing ECG data. One conceptual difference between SMART and other disaster response systems such as WIISARD and AID-N is that the former was conceptualized so that it could potentially become part of regular ED operations that could extend to field work when necessary. The rationale was that, in disaster situations, scaling up a familiar system would be preferable to implementing a new system. So while the other systems' evaluations were based primarily on disaster drills with actors and computer simulations, ours was based on at-risk patients in a real ED, since the expectation is that the system can be utilized on a continuous basis inside an ED and be extended to a disaster site and transport units when necessary. The utilization of the same system inside and outside the hospital increases the potential for seamless integration of care and decreases time spent on patient hand-off, which is critical in overloaded EDs.

Military systems

ARTEMIS [46] (Automated Remote Triage and Emergency Management Information System) is an application developed for the military. This system focuses on providing remote triage capabilities in order to help upper level resource management and coordination of efforts. It includes a commercial SpO₂ sensor. Patients can be triaged into one of

five possible NATO severity categories by a fuzzy logic algorithm driven by physiological measurements and responder evaluations. An outdoor positioning system keeps track of the patients' locations and can guide the provider to the patient. A mesh network with dynamic routing tables provides connectivity among units and the central server. ARTEMIS relies heavily on self-assessment by the soldier or on an external caregiver to change the triage level. Only a very serious condition such as a severe SpO₂ or heart rate change and no response from the subject would trigger a critical alarm. SMART builds on this approach by monitoring ECG, in addition to SpO₂. SMART does not rely on self-assessment by the soldier/patient and, while SMART currently does not change triage levels automatically, it provides information to caregivers so that they can adjust triage levels.

BMIST-J [47] Battlefield Medical Information System Tactical - Joint is a medical information system implemented and currently in use by the military. The mobile PDA units, used exclusively by caregivers, can be pre-loaded with medical records for all the soldiers in the field. Data can be stored on the PDAs until the data can be uploaded to a central server. It contains information about allergies, medications, and treatment and is compatible with other systems such as the one used by the Veterans Health Administration, so there is a seamless transition between care centers. SMART expands on this approach by providing on-line monitoring of the soldiers/patients vital signs and by providing a geo-positioning system.

TACMEDCS (Tactical Medical Coordination System) [48] was developed by the Naval Aerospace Medical Research Laboratory. The main components of the system are a PDA carried by the medical corpsman and an RFID tag that is given to the patient.

The corpsman collects information about the patient, loads it onto the patient's RFID tag, and uploads it, when possible, to a central database. SMART extends this approach by continuously monitoring the patient's ECG and SpO₂.

Vital signs monitoring systems

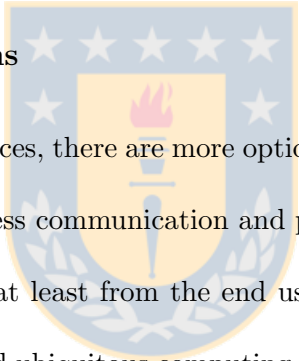
Telcordia® Technologies of Piscataway N.J. has a prototype system, T2 [49], for analyzing streams of data from “Bio-Sensors”. In this system, a patient has an ECG sensor and an accelerometer – the latter used to ignore false high heart rates derived from ECG data that correlate with high rates of acceleration. The ECG sensor uses a BioRadio® from CleveMed [54] to communicate readings to a PC. The accelerometer is on a Mote from Crossbow® [52]. The Mote uses Bluetooth to communicate to a Pocket PC PDA which uses 802.11 to forward the data to a PC. SMART extends this approach by adding location and integrating data from other vital signs such as SpO₂, as well as providing a targeted alarm system.

National Taiwan University [50] has been developing a wireless PDA-based tele-monitoring system. This system monitors heart rate, SpO₂, and ECG signals. The designers' rationale is that portable units alleviate the problems of large and unwieldy monitoring systems and the need for caregivers to be in constant proximity to patients, which is helpful in cases of radioactive agents and airborne pathogens, such as SARS. SMART expands on this approach by providing location tracking information and decision support to distribute targeted alarms.

In addition to the physiological monitoring systems above, the ER One Project [51] provides a set of recommendations for implementing an “all-risks-ready” ED. SMART

complies with many of the relevant recommendations from this project: The SMART caregiver has a PDA to wirelessly access information stored at the SMART Central computer. The PDA has dashboard displays of the roster of patients and per-patient access to vital signs, current location and other data. Vital signs data from the patients are automatically logged at the SMART Central computer, as are the continuously tracked location of patients, caregivers, and equipment. The SMART Central software runs on a laptop and so is portable to disaster sites. SMART Central monitors the network's connections with Patients' and Caregivers' PDAs and sends alerts when a connection is lost.

3.2.5 Pervasive Systems



As technology advances, there are more options available for pervasive monitoring. Sensor miniaturization, wireless communication and processing power allow more efficient, reliable and simple systems, at least from the end user perspective. In healthcare, one of the main driving forces behind ubiquitous computing is the increasing need to move patient care from the hospital to non-standard settings such as homes, nursing homes, improvised waiting areas, hazardous locations or the battlefield. For at-risk patients, such as those with chronic diseases or the increasingly aging population, being able to live in a familiar and comfortable environment improves their life quality and frees hospital resources. In disaster situations or during seasonal or regional disease outbreaks, response teams move from the hospitals to improvised settings to care for multiple casualties with varying urgency levels. Firefighters, hazmat teams and soldiers need real-time, ubiquitous monitoring to detect life threatening events. Existing solutions from industry, academia and the military share the same goal of developing unobtrusive, reliable and pervasive monitoring systems.

Powerful, disposable computers, wireless technologies, sensors and energy storage have made possible the development of Body Sensor Networks [55]. These networks are ubiquitous, allowing oversight of the humans wherever they may go. Personalized health care is a natural extension of these Body Sensor Networks (BSN). Future challenges are user acceptance (both from patients and practitioners), ease of use, and avoiding data flooding with little information.

Pervasive healthcare is a multidisciplinary field involving hardware, software, sensors, embedded systems, human-computer interfaces, wireless communications and distributed systems among others [56]. In healthcare, this multidisciplinary nature is further extended to cope with medical aspects: physiologic sensors, location systems, resource management, and intelligent systems. However, it is still an emerging field [57]. There is need for more clinical evidence of solution feasibility and user acceptance. Most of the literature present research projects but few show real-world implementation and results.

In [58], the authors provide a thorough analysis of 69 articles published from 2002 to 2006 in pervasive computing. There is a clear need of better implementation reports to evaluate actual acceptance and problems. Privacy concerns are a priority both by patients and caregivers and need to be addressed properly for a wide acceptance of pervasive monitoring.

In hospitals

[59] presents an activity recognition system for the smart hospital. Similarly, [60] proposes activity aware computing in hospitals. Pervasive healthcare systems must be prepared for highly mobile caregivers. This last study shows the variety of tasks that are

performed during a typical shift. A proposed solution involves a mobile activity monitor that is configured to alert based on patient actions or status.

[61] explores Activity-Based Computing (ABC) in hospitals, based on pervasive computing, supporting the naturally collaborative nature of hospital work.

[62] discusses a localization system that combines two sources of information (RFID and Wi-Fi) to obtain a reliable location in a hospital.

At home

For elderly care, [63] shows a pervasive computing system that allows continuous patient monitoring in non-standard settings. Simple information such as motion during daily activities at home can be used as an index of mental ability. Also for at-home elderly care (aging-in-place), [64] proposes computer vision as a pervasive healthcare system based on posture recognition.

[65] shows an implementation of a home unit with an accelerometer sensor to detect falls in the elderly and people with disabilities. It provides a means to extend “at home” care and is based on a ZigBee mesh network. [66] also shows ECG monitoring at home, using secure ZigBee networks.

As an attempt to move from hospital-based care to home-care, [67] adapted the ISO/IEEE 11073 (X73) bedside monitoring standard to wearable multi-sensor monitoring systems for home healthcare.

Chapter 4

Diagnosis Algorithms



4.1 Introduction

This chapter presents the signal processing algorithms required for SMART, from the PDA to SMART Central. The goal is to issue an alarm and a proposed diagnosis when an abnormality is detected. The algorithm has to be computationally simple so that it can be run either centrally for multiple patients or from a PDA. Other real-time PDA-based systems with high accuracy in rhythm classification have been reported [68], although they did not test on real patients. In the literature, there are many heart beat classifiers [6] with varying degrees of accuracy and speed. However, arrhythmia classification algorithms are scarce. Most of them address only a subset of possible abnormalities in the ECG signal [69, 70, 71], are beat based [72] or are too complex to implement in a real-time multiple patient setting [6]. More importantly, none of them try to classify on untethered patients. Monitoring ambulatory patients has always been difficult [73, 74, 75]. Muscle noise, electrode motion artifacts and baseline wander are the main noise inducing factors. Even simple body position changes can lead to changes in the ECG recording [19]. Our approach does not trust beat morphology, which can be distorted by noise, but rather we infer diagnosis from an integrated data approach. The proposed algorithm has two steps. First, it detects the beat positions from the ECG signal. Then, based on those beat positions, ECG statistical properties and information from the SpO₂ sensor, the algorithm determines a probable diagnosis. Similar data integration has been proposed in [27, 28, 29] to estimate data quality and/or to reduce the number of alarms.

Beat algorithms were evaluated using Physionet's MIT-BIH databases [5] with varying degrees of noise. A selection method was proposed based on specific goals. The

ECG-derived heart rate (HR) was further processed using a non-linear filter to reduce false measurements. Finally, a decision tree was implemented using data from both sensors as well as processed data. This diagnosis algorithm was tested and evaluated on a commercial patient simulator and on healthy volunteers. The complete system was tested on real patients.

4.2 Implementation

4.2.1 Requirements

The requirements for scalability and eventual use of PDA hardware for signal processing limited our choice of algorithms to simple and fast ones. After a first selection among known methods [6], we selected time-based algorithms with easily available source code. The options were CSAIL's Peak [76], Physionet's SQRS (P. SQRS) and Physionet's WQRS (P. WQRS) [5] algorithms. P. SQRS and P. WQRS were ported to our own environment and modified to comply with SMART's requirements. Only the adapted SQRS (aSQRS) algorithm was considered in the final selection because it clearly outperformed WQRS in our setting. Peak algorithm was already implemented in ORNetDB. The modifications introduced were:

1. Adaptability to work with streaming data (only a short time window is allowed);
2. Sampling frequency independence;
3. Gain independence;
4. Noise tolerance.

The sampling frequency and gain independence were introduced to allow SMART to use any hardware for ECG acquisition. These modifications proved to be good features because our custom-made boards had different gains.

4.2.2 Base Algorithm Descriptions

Peak algorithm

The Peak detector algorithm is applied directly to the ECG data. It uses a 167 ms window, divided in three 55.6 ms segments. This limits the maximum detectable beat frequency to 360 BPM. It scans the whole range looking for the maximum value. If the maximum value is on the central segment and is higher than a threshold, the position is marked as a beat and its amplitude is saved as the new threshold. At each new possible beat, the threshold is updated, using a linear decay between the previous beat amplitude and the current window maximum, at a variable rate of

$$\frac{\text{last beat ampl.} - \text{current peak ampl.}}{2} \cdot \frac{72}{60} \quad (4.1)$$

The threshold may only decrease unless it is set by a new beat detection. Fig. 4.1 shows an example, in which an extra beat is detected due to a high P wave and a rising baseline.

P. SQRS algorithm

P. SQRS algorithm uses a Finite Impulse Response (FIR) filter as an approximation to the slope of an ECG signal [77]. Using a variable threshold, it detects and identifies QRS complexes from artifacts. The C code was extracted from PhysioNet [5] web site and adapted to handle data streams.

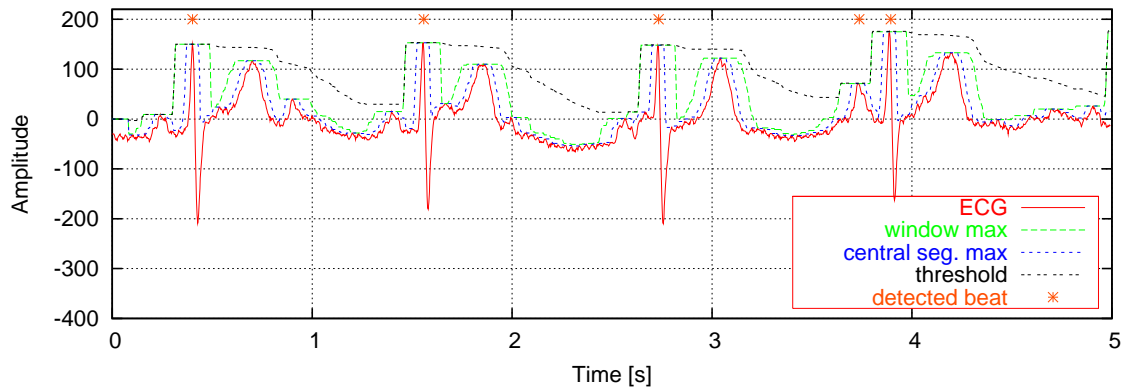


Figure 4.1: Peak algorithm. A beat is detected if the window maximum is also the segment maximum and both are greater than a threshold.

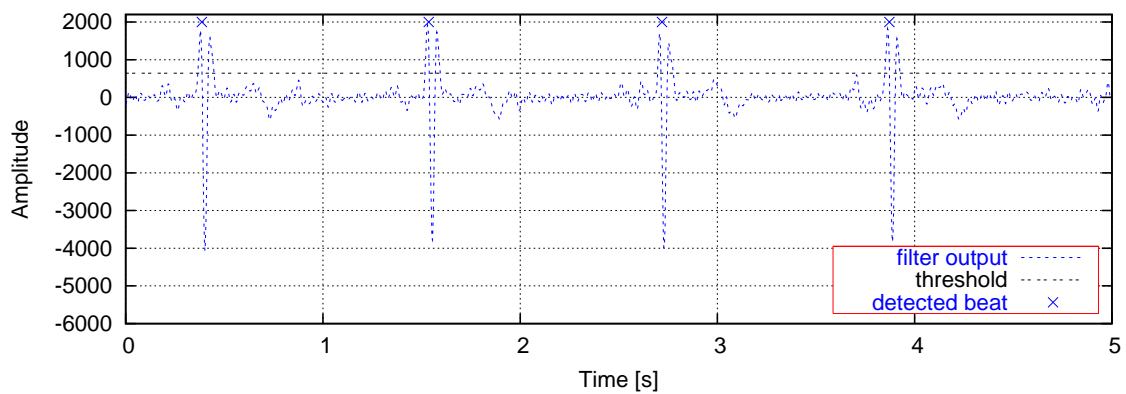


Figure 4.2: P. SQRS algorithm. A beat is detected when the filtered signal crosses a threshold 2 to 4 times. When there are more than 4 crossings the position is marked as an artifact.

A convolution filter is applied to a vector containing the last 10 values acquired from the ECG signal, to enhance its slope. If the filtered signal is greater than a threshold, the time is saved and the algorithm enters a decision phase. Two to four of these detections within 160 ms of each other indicate that a normal beat was identified. More than 4 detections within 200 ms of each other indicate an artifact. After a decision has been made, the algorithm is reset. Once every 2 seconds, if there is no detection, the threshold is reduced by $1/16^{th}$. If there are more than 4 detections, the threshold is increased by $1/16^{th}$. Every time a normal beat is detected, the threshold is recalculated, asymptotically converging to $1/4$ of the maximum filter output obtained so far. Fig. 4.2 shows the SQRS filter output for the same ECG signal used in Fig. 4.1.

P. WQRS algorithm

The original WQRS algorithm was obtained from PhysioNet [5] and adapted to handle data streams. It is based on the Length Transform [78] of the ECG.

The Length Transform of a function with n variables is defined in the interval $[t, t + q]$ as

$$L(n, q, t) = \int_t^{t+q} ds \quad (4.2)$$

where ds is an infinitesimal element along the function. For a discrete, one channel signal, the Length Transform of a signal $x[n]$ using a window q can be calculated by:

$$L_i = \sum_{k=i}^{i+q-1} \sqrt{1 + (x_k - x_{k-1})^2} \quad (4.3)$$

Our implementation considers a window length of 130 ms, in order to maximize the detection of QRS complexes. After the transformation, the output is compared to a

Table 4.1: Beat positions for figures 4.1, 4.2 and 4.3.

Reference beats [s]	0.43	1.58	2.76	–	3.91
Peak alg. beats [s]	0.40	1.56	2.73	3.74	3.89
SQRS alg. beats [s]	0.39	1.54	2.72	–	3.87
WQRS alg. beats [s]	0.43	1.58	2.76	–	3.92
WQRS J-points [s]	0.53	1.69	2.87	–	4.02

threshold and then further tested for a rising slope of the Length Transform. This algorithm has the added ability to mark the end of the QRS complex, also known as J–point. Fig. 4.3 shows the Length Transform of the ECG signal from Fig. 4.1, and the detected onset and offset of the QRS complex.

Beat detection

Table 4.1 and Fig. 4.4 show the detected beat positions reported by the algorithms for the original ECG signal from Fig. 4.1. The reference beat positions are obtained from the annotation file associated to the clean record. Note that there is a small shift in beat positions. However, they are all within 150 ms of the reference, and thus considered matching beats. The only unmatched beat in our example was detected by the Peak algorithm at 3.74 s.

4.2.3 Beat Detection Accuracy

The algorithms were evaluated for beat detection accuracy under varying noise conditions. Using PhysioNet’s MIT-BIH Arrhythmia Database and the Noise Stress Test tools, noise was added to each one of the 48 half-hour ECG recordings in 6 discrete levels: 24 dB, 18 dB, 12 dB, 6 dB, 0 dB and –6 dB SNR. The noise signal used is a record

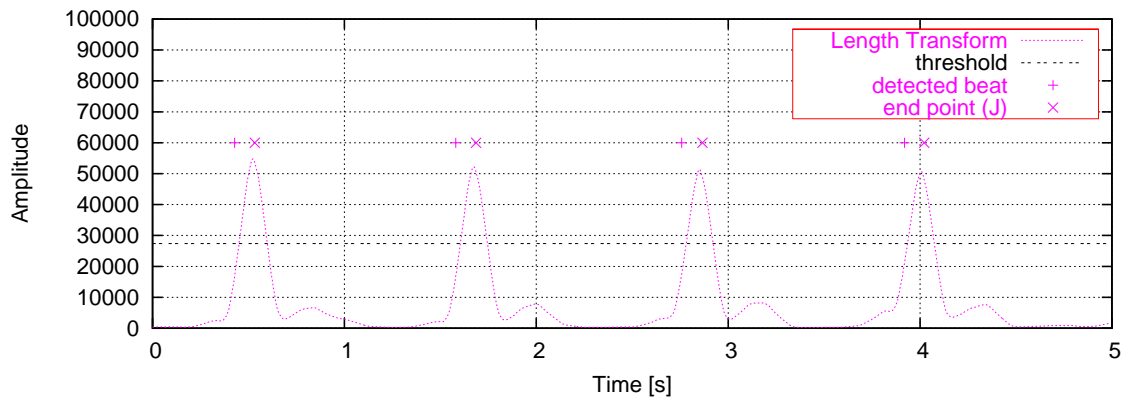


Figure 4.3: P. WQRS algorithm. A beat is detected if the Length Transform of the signal is higher than a threshold.

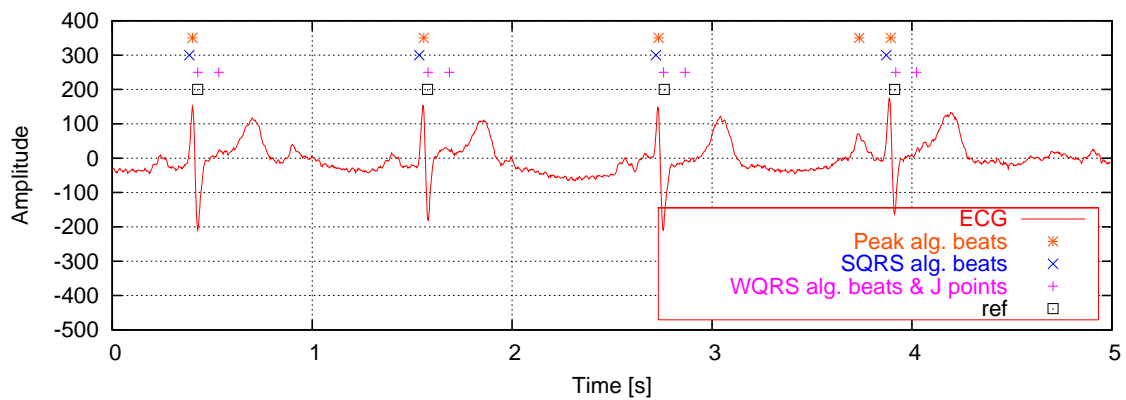


Figure 4.4: Algorithm beat detection comparison.

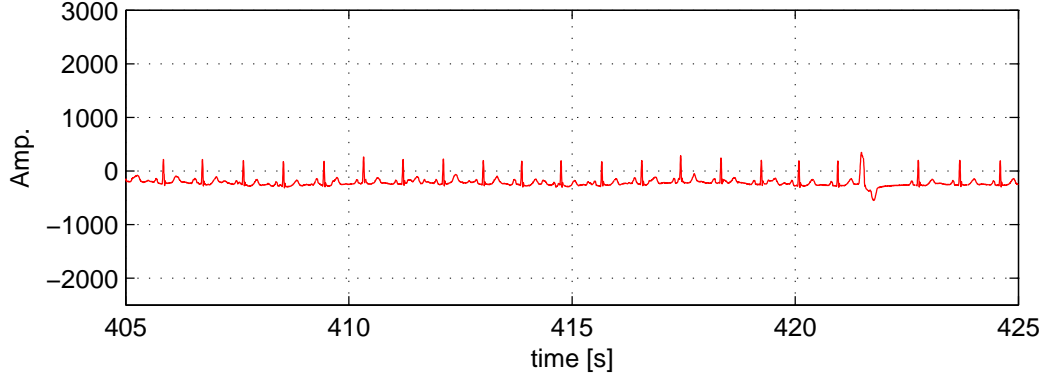


Figure 4.5: ECG sample with 24 dB SNR. Noise ends at 420 s.

combining baseline wander, muscle noise and electrode motion artifacts. As suggested in [5], it is added in alternating 2-minute segments, after an initial 5 minutes of clean signal. Examples for 24 dB, 6 dB and -6 dB SNR are shown in Figures 4.5, 4.6 and 4.7.

Beat detection accuracy was evaluated using the standard Sensitivity (Se) and Positive Predictability ($+P$) indices [6],

$$Se = \frac{TP}{TP + FN}, \quad +P = \frac{TP}{TP + FP} \quad (4.4)$$

where, TP : number of true positive detections, FN : number of false negatives or missed beats and FP : number of false positives or false beats.

Table 4.2 shows the Se and $+P$ indexes for the different noise conditions. It is clear that no single algorithm is best. Depending on the noise level, maximum Se and $+P$ is obtained on different algorithms and no single algorithm has both the best Se and $+P$ for a given noise level. The purpose of the beat detection algorithm in SMART is to obtain an accurate HR series from the raw ECG, from which to derive alarms and diagnoses. As reported in our previous work [79], the probability of computing an error in HR as a function

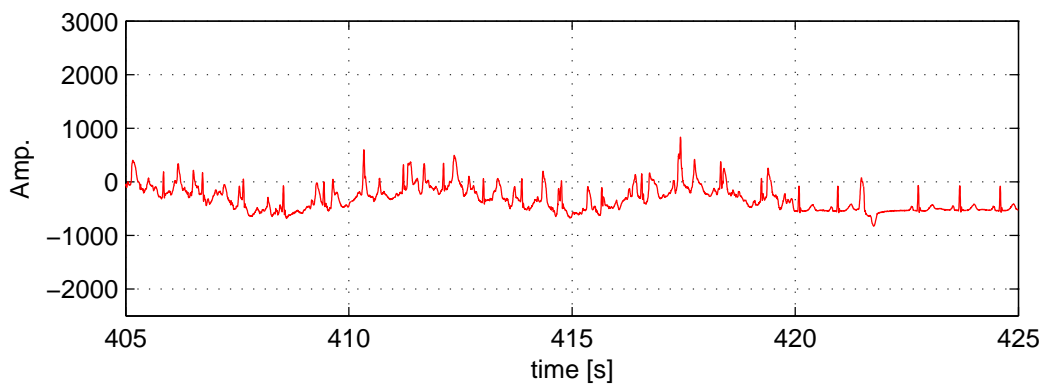


Figure 4.6: ECG sample with 6 dB SNR. Noise ends at 420 s.

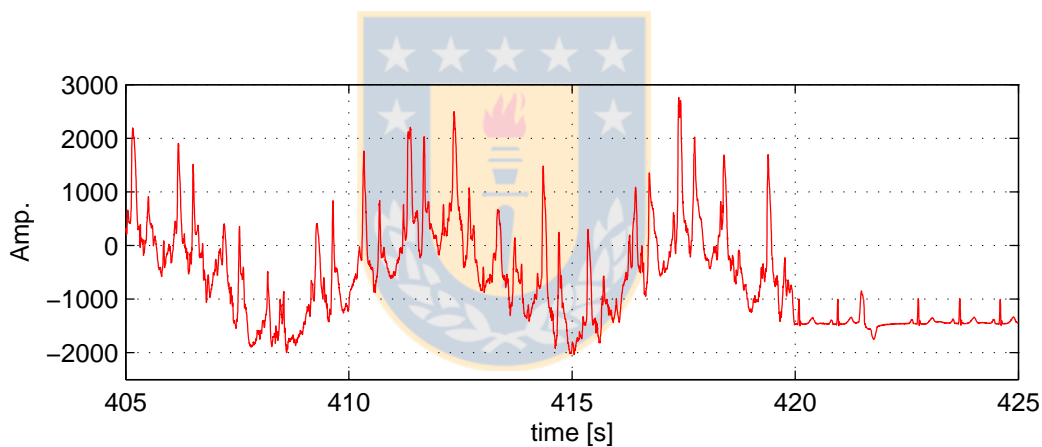


Figure 4.7: ECG sample with -6 dB SNR. Noise ends at 420 s.

Table 4.2: Algorithm Se and $+P$ [%] by noise level. Boldface indicates maximum Se and $+P$.

Noise (SNR)	24 dB	18 dB	12 dB	6 dB	0 dB	-6 dB
Peak Se	91.91	91.54	88.93	78.12	68.84	64.40
$+P$	93.85	92.89	86.60	76.53	69.16	65.74
P. SQRS Se	98.62	97.39	92.41	81.92	67.92	56.33
$+P$	98.96	96.77	87.52	77.16	73.46	78.97
P. WQRS Se	99.78	99.77	99.48	99.08	98.78	92.18
$+P$	98.60	97.15	81.66	68.44	59.42	53.40
aSQRS Se	96.63	96.34	95.00	90.71	83.31	72.30
$+P$	98.31	97.92	94.04	82.32	74.56	67.87

of missed beats (FN) and false beats (FP) results in

$$P(\text{incorrect HR}) = \frac{FN + FP}{TP + FN + FP} \quad (4.5)$$

which can be rearranged to

$$P(\text{incorrect HR}) = \frac{1}{1 + \frac{FN + FP}{TP}}. \quad (4.6)$$

Equation set (4.4) can be rewritten as

$$\frac{FN}{TP} = \frac{1 - Se}{Se}, \quad \frac{FP}{TP} = \frac{1 - (+P)}{+P} \quad (4.7)$$

From (4.4) and (4.5), the probability of having an incorrect beat-to-beat HR is

$$P(\text{incorrect HR}) = 1 - \frac{+P \cdot Se}{+P - (+P) \cdot Se + Se}. \quad (4.8)$$

Using (4.8) it is possible to evaluate and select the algorithm whose Se and $+P$ allow for the minimum probability of HR error. Fig. 4.8 is updated from [79] using equation 4.8 and Table 4.2. The aSQRS algorithm has a reasonably low probability of error in the clean range (24 to 16 dB) and the lowest from 16 dB to -6 dB SNR. aSQRS algorithm is best for beat detection under SMART's conditions.

4.2.4 Heart Rate Derivation

Besides selecting the best beat detection algorithm to minimize the probability of deriving a wrong HR, some post-processing is made to further improve HR computation. As important as the actual HR value, HR variability can be used to screen for several medical conditions [80, 81, 82]. Some tests were made to determine the best approach for HR filtering. The methodology was introduced in [79], but is repeated here for completeness with updated results.

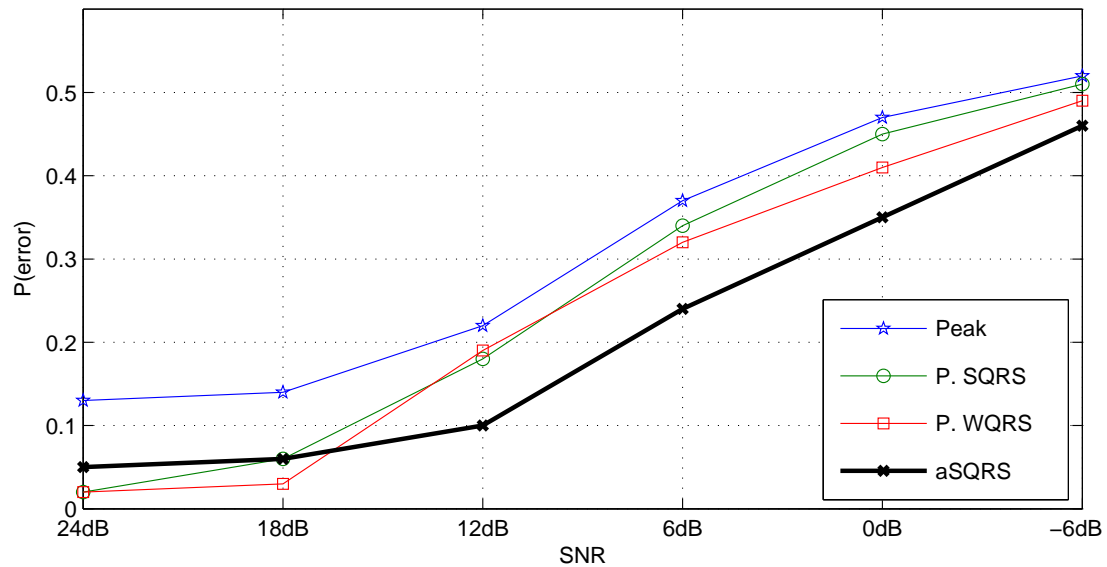


Figure 4.8: Heart Rate error probability.

The instantaneous HR is computed for consecutive normal QRS beats detected. We evaluated 3 different non-linear filter options for HR series processing: no filtering, a median filter and an outlier rejection filter. To compare the different options, we compute the standard deviation of the heart rate series. A filter that preserves HR variability would not alter significantly its standard deviation. We computed the Heart Rate Standard Deviation (HRSD) for all the records used in the noise sensitivity study. The reference HRSD is computed using the database's annotated beat positions. The no filter option is computed directly from the reported beat positions. For the median filter, we chose order 5, which is the minimum order possible to reject wrong HR values after either a single missed beat (1 wrong HR) or a single false beat (2 wrong HR). For the outlier rejection filter, we chose to reject new HR values that were over 10 BPM apart from the last one.

The results are shown in tables 4.3, 4.4 and 4.5. Without filtering, our proposed

Table 4.3: Std. Dev. of Heart Rate with no filter

SNR	ref.	P. SQRS	P. WQRS	aSQRS
24 dB	19.1	26.1	30.2	26.0
18 dB	19.1	30.2	33.3	26.9
12 dB	19.1	42.3	54.0	33.2
6 dB	19.1	51.2	64.1	46.7
0 dB	19.1	52.4	70.7	52.1
-6 dB	19.1	47.1	72.4	52.9

Table 4.4: Std. Dev. of median filtered Heart Rate

SNR	ref.	P. SQRS	P. WQRS	aSQRS
24 dB	19.1	18.1	24.3	18.7
18 dB	19.1	18.9	25.0	18.7
12 dB	19.1	25.6	39.2	20.2
6 dB	19.1	30.4	53.3	26.4
0 dB	19.1	30.8	64.2	29.5
-6 dB	19.1	27.7	66.6	26.7

algorithm aSQRS is closest to the reference HRSD. As the noise level increases, so does the HRSD due to the increasing number of incorrectly detected beats. With a median filter, HRSD is much closer to the reference, even at high noise levels. aSQRS is the best overall algorithm. Finally, since the outlier rejection filter has lower HRSD than the reference, it over-filters and hides natural HR variability. Our final choice is to implement an order-5 median filter after beat detection with aSQRS to derive the HR series.

4.2.5 Implemented Algorithm: aSQRS

All of the base algorithms in 4.2.2 were implemented for the SMART project. However, the ported versions of WQRS and Peak algorithm were rejected and aSQRS was selected due to its overall performance. The selection method was discussed in section 4.2.3 and 4.2.4. Only the aSQRS, the actual implemented algorithm, is described here.

Table 4.5: Std. Dev. of Heart Rate with outlier rejection

SNR	ref.	P. SQRS	P. WQRS	aSQRS
24 dB	19.1	16.1	17.2	16.5
18 dB	19.1	16.0	17.1	16.5
12 dB	19.1	16.2	18.7	16.4
6 dB	19.1	16.5	21.8	17.0
0 dB	19.1	16.0	28.6	17.2
-6 dB	19.1	15.7	41.6	16.7

The aSQRS algorithm was built from P. SQRS. It uses a Finite Impulse Response (FIR) filter as an approximation of an ECG signal's slope [77]. Using a variable threshold, it detects and identifies QRS complexes from artifacts. The C code was extracted from PhysioNet [5] web site and adapted to handle data streams without information about the signal properties, such as sampling frequency or gain and to improve its performance on signals with changing noise conditions.

Just like with the original P. SQRS algorithm, the filter mask is [1 4 6 4 1 -1 -4 -6 -4 -1] and its maximum gain is at $0.086 \cdot F_s$ or 31 Hz for a signal sampled at 360 Hz (Fig. 4.9). It attenuates frequencies under $0.002 \cdot F_s$ and over $0.349 \cdot F_s$ and has a notch between $0.196 \cdot F_s$ and $0.205 \cdot F_s$. This convolution filter is applied to a vector containing the last 10 values acquired from the ECG signal. If the filtered signal is greater than a threshold, the time is saved and the algorithm enters a decision phase. Two to four of these detections within a time period of 160 ms indicate that a normal beat was identified. More than 4 detections within a time period of 200 ms indicate an artifact. After a decision has been made, the counter is reset. The threshold is reduced by $1/16^{th}$ once every 2 s if there is no detection. If there are more than 4 detections, the threshold is increased by $1/16^{th}$. Every time a normal beat is detected, the threshold is recalculated, asymptotically converging to

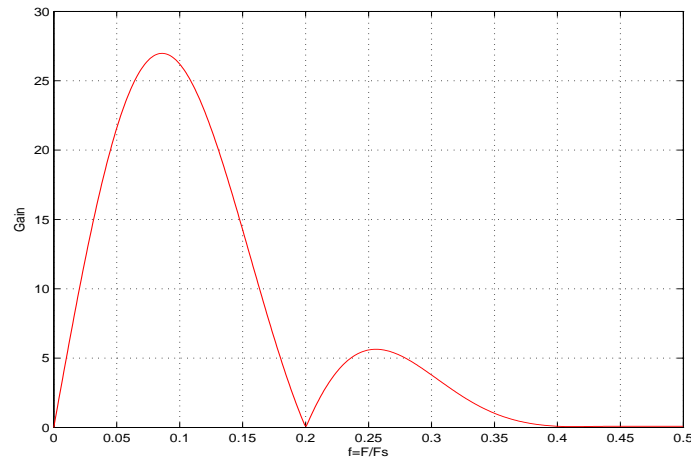


Figure 4.9: aQRS filter response.

1/4 of the maximum filter output obtained so far. Fig. 4.2 shows the SQRS filter output for a typical ECG sample.

For SMART, some extra features were added. To avoid training on noisy signals, automatic retraining when changing patients and also after a remote reboot of the PDA was incorporated. Specifically, aSQRS includes a 1 s inactivity period and then it stores the maximum filter output value for 2 s. This 3 s training period is entered after detecting a period of at least 15 s without data.

To compensate for noisy conditions, aSQRS considers a decaying maximum filter output value. This is the main reason for the differences between P. SQRS and aSQRS in Fig. 4.8. A “no-beat” output was also added to allow for a quick alarm on asystole. This output is issued after 3 s (<20 BPM) of inactivity. Finally, the sampling frequency is continuously updated based on the incoming data and is used to unpack and timestamp the individual ECG samples.

The beat detection algorithm was implemented and successfully run on the PDA;

however, this solution was not deployed and all processing was done at the main server.

4.2.6 Rhythm Diagnosis

The original constraint of having a fast algorithm made necessary the development of a simple decision system for diagnosis. A decision tree based on statistical properties of the data was implemented. Fig. 4.10 shows the flow diagram of the decision tree. The inputs are the ECG signal, the output from aSQRS and the SpO₂ HR. The diagnosis outputs are: Mismatch, Asystole, Ventricular Fibrillation (VFib), Ventricular Tachycardia (VTach), Irregular Beats, Leads off, Noisy signal, Tachycardia, Bradycardia and Normal sinus rhythm. The statistical properties and thresholds selected were based on expert advice, previous work on diagnostic detection techniques [71, 83, 84, 72], as well as trial and error with our healthy volunteers, STRATUS test set and Physionet data.

The final decision tree uses the following measurements and information: aSQRS beat classification (normal, artifact or no-beat), ECG signal max and min values, skewness of the ECG signal, QRS width, standard deviation of beat-to-beat (RR) series, computed HR and previous diagnosis. If available, SpO₂ sensor information is also used for validation. Fig. 4.10 shows the decision tests and thresholds: NOBEAT is detected by aSQRS when there is a period of 3 s without beats. SpO₂ HR is NORMAL when the sensor-reported HR is over 20 and under 150 BPM. SAT is detected when the ECG signal is saturated (i.e. the maximum and minimum values are observed in a 0.5 s window). NOSKEW is when ECG data in a 2 s window have a skewness under 0.75 with a hysteresis of ± 0.25 (0.5 – 1.0). QRS WIDTH is computed by looking at the vicinity of the detected QRS and measuring the time between mean crossings. ARFCT are artifacts detected by the aSQRS algorithm.

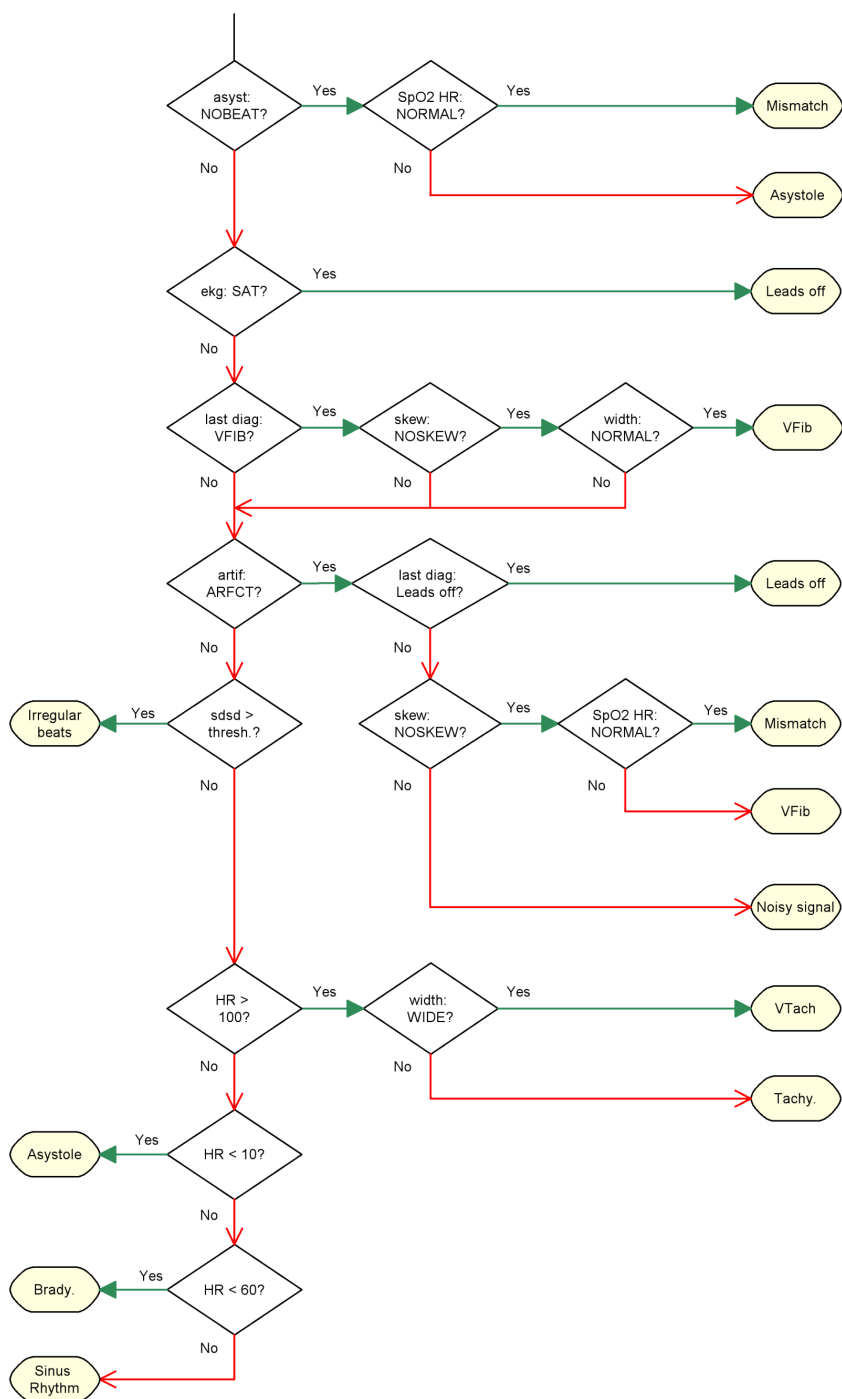


Figure 4.10: Diagnosis algorithm decision tree.

Table 4.6: Diagnostic accuracy, Stratus validation data.

	Se	Sp	+P	-P	Accuracy
Asystole	1	0.99	0.94	1	0.99
Bradycardia	0.71	0.99	0.90	0.96	0.96
Irregular Beats	0.94	0.95	0.76	0.99	0.95
Normal	0.89	0.99	0.97	0.96	0.96
Tachycardia	0.96	0.99	0.91	0.99	0.98
Vent. Fib.	0.90	1	0.96	0.99	0.98
Vent. Tachy.	0.91	1	1	0.99	0.99

SDSD [85, 86] is the standard deviation of successive differences in RR intervals, and is used to detect an irregular heart rate if over 0.4. Finally, if the computed HR is over 100 BPM, the diagnosis is tachycardia. If under 60 BPM, bradycardia. These last two thresholds are patient specific and can be changed by the SMART operator. At this point, if no diagnosis has been selected, it is classified as normal sinus rhythm.

The diagnosis algorithm is based primarily on the ECG data because the SpO₂ sensor component has a fairly slow response, making it less sensitive to artifacts, but lacks morphology details of the ECG patient signal. On the other hand, due to the ambulatory nature of the target, it is unwise to trust the selected diagnosis on a beat-to-beat basis. Artifacts are prone to be mistaken for all sorts of arrhythmias [73], which would lead to false diagnoses. To minimize those errors, we implemented a voting mechanism: the reported diagnosis is the one that is the most frequently occurring in a 15 s. window. During our early tests, this voting mechanism proved to be a valuable addition to the system.

4.3 Results

Our reportable results come from simulated and real patient experiences. After training on the original data from Stratus Center and healthy volunteers, we obtained a second simulated record for validation. The test set was prepared by STRATUS center personnel as a single-blinded experiment. The protocol required that all medical conditions were present and each episode lasted at least 1 minute. The simulator produced 561 s of data. We recorded the ECG from the patient simulator with the exact same hardware used on real patients and ran the diagnostic algorithm. Only the medical conditions were tested: Asystole, Bradycardia, Normal Sinus Rhythm, Tachycardia, Irregular Beats, Ventricular Fibrillation and Ventricular Tachycardia. The SpO₂ sensor data were not available for collection. The results were adjusted to avoid bias introduced by the diagnosis delay (15 s) and are shown in Table 4.6. To compute Sensitivity (Se), Specificity (Sp), Positive Predictability (+P), Negative Predictability (−P) and Accuracy, eq. 4.4, 4.9 and 4.10 were used, based on True Positive (TP), True Negative (TN), False Positive (FP) and False Negative (FN) diagnoses. Low Bradycardia Se and low Irregular Beats +P were due to misclassifications. The transition to Bradycardia generated a short interval of Irregular Rhythm due to the sudden change in HR.

$$Sp = \frac{TN}{TN + FP}, \quad -P = \frac{TN}{TN + FN} \quad (4.9)$$

$$\text{Accuracy} = \frac{TP + TN}{TP + FN + FP + TN} \quad (4.10)$$

Later, the printed ECG was shown to two independent experts and their annota-

Table 4.7: Accuracy comparison with 2 experts, Stratus validation data.

	Algorithm	Expert 1	Expert 2
Asystole	0.99	0.98	0.98
Bradycardia	0.96	1	1
Irregular Beats	0.95	1	0.99
Normal	0.96	0.98	0.98
Tachycardia	0.98	0.98	0.98
Vent. Fib.	0.98	0.97	0.97
Vent. Tachy.	0.99	0.99	0.99

Table 4.8: Reported diagnosis alarms for real patients.

Alarm	Total	TP	+P
Asystole	79	0	0
Ventricular Fibrillation	46	0	0
Ventricular Tachycardia	0	0	-
Tachycardia (ECG)	124	61	0.49
Bradycardia (ECG)	18	12	0.67
Irregular rhythm	116	43	0.37
Mismatch	59	59	1
Noisy	59	47	0.8
Leads Off	56	49	0.88

tions compared with the diagnosis algorithm. As shown on Table 4.7, all 3 sources agreed on the rhythms. The small differences were due to timing discrepancies regarding rhythm durations.

During the implementation phase in the waiting room, important results were obtained. In a 10-month period, 145 real patients were monitored, recording a total of 6815 min and generating 557 diagnostic alarms, averaging about 1 diagnostic alarm every 12.2 min. Alarms were generated for every diagnosis other than Normal sinus rhythm. After manually reviewing the alarms, Table 4.8 was generated. Only $+P$ index can be calculated, because we do not know the non-detected events.

The results clearly show that real patients in ambulatory settings are very dif-

ferent compared to stationary, simulated patients. The low $+P$ indexes are mainly due to misclassified artifacts. The diagnosis algorithm usually failed when the patient moved for more than 8 s (half the voting window length), which was quite common. Asystole and Ventricular Fibrillation alarms were due mostly to the adaptive aSQRS algorithm threshold becoming too high due to a run of movement artifacts. False Bradycardias were a lesser form of the same problem, while false Tachycardias were due to a series of artifacts mistaken for beats. Irregular rhythms were also sometimes misclassified due to artifacts. We believe that a solution to these problems involves improving the Noise detection rate. Even with a $+P$ of 0.8, it was evident that there were too many False Negatives. The best result was obtained by the Mismatch diagnosis, which issued when the ECG is shaped like an Asystole or Ventricular Fibrillation but the SpO₂ HR data are within normal range. Mismatch alarms were soon considered a new kind of Noise alarm by the SMART Operator and handled as technical alarms like Noisy and Leads Off.

An attempt was made to reduce false alarms by integrating information from the location system. The location tags work by emitting an ultrasound pulse every time the subject moves. However, the sensors were too sensitive for our purpose and would constantly indicate a noise condition when worn.

An additional 575 other SpO₂ and technical alarms were generated by the system, and are shown in Table 4.9. These alarms have better $+P$ because they are easier to detect. The SpO₂ sensor has a much slower response, making its alarms more stable. Technical alarms such as a SpO₂ sensor off the finger or no wireless communication to the PDA are very clearly defined, and thus either true or false.

Table 4.9: Other alarms reported for real patients.

Alarm	Total	TP	+P
High HR (SpO ₂ sensor)	79	75	0.95
Low HR (SpO ₂ sensor)	21	15	0.71
Low SpO ₂	44	35	0.8
No Signal	0	0	–
SpO ₂ sensor off	86	85	0.99
Lost communication	329	309	0.94
Battery Low	16	15	0.94

As discussed in [87], the number of false alarms was considerable and probably would be annoying to caregivers if the system were to operate unattended. However, in these conditions, the SMART Operator was able to detect 3 real events (Bradycardia and two Irregular Beats) based on medical alarms that were indeed deemed important by the medical personnel. A fourth patient benefited from the system by having an ECG recorded during her waiting time that showed pacemaker activity every time her HR dropped from 60 BPM.

4.4 Discussion

This chapter presents all the signal processing work developed for monitoring un-tethered patients. First, from our preliminary work in [79], a quantitative method was proposed to select a beat detection algorithm based on minimizing the probability of error for beat-derived HR. This approach seeks to ensure an optimal algorithm selection in terms of the intended goal, which in this case was an accurate HR. The selected algorithm was implemented and modified to quickly detect beat-level conditions, such as noise or asystole. In order to achieve independence from the hardware used for its capture and to accommo-

date patient-to-patient variability, an adaptive threshold was also introduced. A non-linear filter was selected for HR series processing to reject miscalculated rates. Finally, a multiple diagnosis algorithm based on ECG and SpO₂ sensor data provided a decision support tool to alert and reprioritize multiple patients in the waiting room of the Brigham and Women's Hospital ED.

Our analysis suggests that the programmed algorithm performed reasonably well in detecting several medical conditions in a controlled environment. The possible outputs included Asystole, Bradycardia, Normal Sinus Rhythm, Tachycardia, Irregular Beats, Ventricular Fibrillation, Ventricular Tachycardia, Mismatch, Noisy signal and Leads off, which were diagnosed based on a decision tree that integrates SpO₂ HR, raw ECG data and the output of a beat detection algorithm. The input integration allowed improvements in the detection rate by avoiding diagnoses that were noise-induced. Our design was biased to avoid missing important medical conditions and to ensure a short response time, although this greater sensitivity resulted in a considerable number of false alarms. Tests on actual patients confirmed observations in [73] and showed that movement artifacts were the main cause of misdiagnoses and false alarms. Our use of voting windows was an important addition, although it increased response time. We believe that a better noise detection system is an absolute requirement to improve detection rates and accuracy.

Overall, SMART was provided with a multiple diagnosis support tool for supervised monitoring and alerting. The system managed to detect and speed admission for 3 out of 145 patients who were initially triaged as less critical. The diagnosis algorithm allowed the SMART operator to oversee a number of patients with minimal effort. A beneficial

side effect of such a system is its data logging, which could allow faster evaluation once the patient is seen by a physician.



Chapter 5

Tracking System



5.1 Introduction

Available Indoor Positioning Systems (IPS) products, typically sold as installations of a tailored hardware and software packages, are often based on the one type of technology that the vendor supports [88]. This could be a problem for the prospective buyer, as access to data and experiences gained from large deployments of different technologies are still limited. In the absence of publicly available information, the buyer must rely on the vendor of IPSs for information on requirements and performance. However, vendors will be biased towards proposing their own technology as the solution to a wide range of situations and requirements.

This chapter describes the implementation of the ultrasound based indoor positioning sub-system, discusses which considerations went into technology choices, and provides details about the design and implementation together with a summary of our experience with it.

5.2 Case Description

In response to problems associated with disaster management, unveiled by events in recent history, and opportunities afforded by improvements in technology, the Scalable Medical Alert and Response Technology Project (SMART) [79, 89, 87] aims at evaluating technologies for wirelessly monitoring vital signs and locations of otherwise unattended patients. SMART acquires patient vital signs data from sensors and wirelessly communicates those data to a central server, tracks the location of patients, providers, and equipment, and autonomously monitors the patient's vital signs data, and communicates significant events

to appropriate providers.

The design criteria of SMART were to create and evaluate hardware and software platforms to enable extensions and modifications, and to use inexpensive commodity components so as to allow scaling and wider use.

While the design of SMART aims at mobile deployment, both indoor and outdoor, it initially was implemented in the Brigham and Women's Hospital (BWH) emergency department (ED). The tracking system in SMART Central also is capable of receiving location data from outdoor geo-positioning systems, though this was not implemented at the study site. Accordingly, the location system described here is the indoor locationing sub-system of this project.

Patient vital signs were obtained from an electrocardiograph (ECG) sensor and a pulse oximeter (SpO_2) connected to a personal digital assistant that transmits the data via wireless 802.11b communication. The patient carries these monitoring devices and an indoor positioning tag in a waist pack. These tags, from Sonitor Technologies [90], use ultrasound-based technology for positioning.

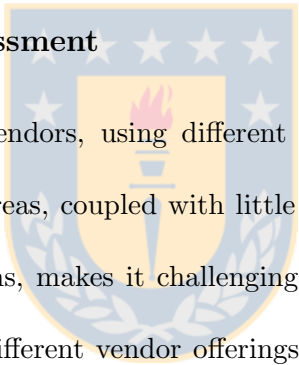
The heart of the SMART system is a server, referred to as SMART Central, which contains (1) a streaming data manager that receives and processes SpO_2 , ECG, and location data streams; (2) a decision support module that analyzes these streaming data to generate alarms; and (3) a logistics support manager, a rule-based system, to dispatch alarms to providers or to other systems.

SMART also incorporates PDAs for caregivers that allow them to view the roster of patients, review the data for a patient, and to receive and respond to alarms. SMART

was deployed in the BWH ED from June 2006 to December 2007 as part of an evaluation study [87]. Following approval from the Institutional Review Board at BWH, the system was tested on 151 patients of whom six patients were excluded. During the study period, events were reported relating to three patients in the waiting room that required a re-triage and immediate admission to the ED. SMART was also later tested as part of city-wide disaster management drill in Boston [91].

5.3 Methods

5.3.1 Technology Assessment



The multitude of vendors, using different technologies and having overlapping self-proclaimed application areas, coupled with little real-world unbiased, comparative information on different systems, makes it challenging to align operational requirements of a planned system with the different vendor offerings. However, understanding the physical properties of positioning systems technologies can aid in this task. Examples of such operational requirement dimensions are positioning resolution and accuracy, range, scalability, integration into existing work-flow and systems, privacy concerns, expandability, and system maintenance.

Any positioning system comprises a mobile unit and a referential infrastructure. The mobile unit is physically attached to the object being positioned. The infrastructure provides the referential location framework within which the mobile systems are positioned.

We can subdivide between two types of positioning systems: when the mobile unit is the transmitter, and its position is determined by the infrastructure with respect to

itself [92], the system is called a “remote positioning” system [93]. On the other hand, if mobile unit receives transmitted information from the fixed infrastructure and computes its own position, this is called “self positioning”. Global Positioning Systems (GPS) receivers and the Cricket system [94] are examples of the latter.

Remote positioning or infrastructure–centric systems, usually require less complex mobile units, lowering both their cost and size, as well as extending their battery life. Self positioning or user–centric systems have the advantage of being easily scalable. They also are in line with privacy concerns, since the computed position can be kept confidential. However, the higher computational requirements imply a more expensive unit, larger size and lower battery life. As our system is a monitoring system, it was natural to choose a remote positioning type of system.

Regardless of self positioning or remote, a positioning system relies on the properties of a signal sent from a transmitter to a receiver. The three main properties used are Angle of Arrival (AOA), Received Signal Strength (RSS) and Time of Arrival (TOA) [88]. Systems that apply radio frequency (RF) signals prefer to use signal strength related measures like RSS, while ultrasound (US) based systems use time related methods such as Roundtrip Time of Arrival (RTOA) and Time Difference of Arrival (TDOA).

Our operational requirements for the ED installation were: location resolution approximately 15 feet (about 4.5 meters) or room-level, less than 50 objects to be tracked, no need for self-positioning, and a strict rule of no interference with medical equipment. As the system was not integrated with other clinical information systems during this implementation, there were no requirements regarding existing infrastructure beyond non-interference.

However, since we were integrating the positioning system with our own electronic infrastructure on a largely open source platform, getting access to implementation documentation such as transmission protocols and help with decoding these from the vendor was a necessity.

Given these requirements, our choice of a positioning system can be discussed using the dimensions of transmission speed, signal reflectivity, and signal range. At the time of the BWH system implementation, the systems available were either radio frequency (RF) or ultrasound (US) systems. For RF, these dimensions can roughly be considered to be high speed, low reflectivity, and high range, while for US they can be considered to be low speed, high reflectivity, and low range. High transmission speed implies lower transmission times for a fixed message, resulting in a higher number of mobile units that can be serviced by the same infrastructure, or more information transmitted to and from each unit. High signal reflectivity means that signals can travel around obstacles or can be confined by suitable barriers. This can be exploited when room level position resolution is sought as a smaller investment in infrastructure is necessary. Typically, a room can be covered by one receiver. However, there needs to be transmission of signal waves out of any reflecting enclosure containing the transmitter. While this opening for ultrasound can be of the order of the wavelength used (mm), we found that in practice tags were not detected when placed into a shirt, pant or coat pocket. High signal range means that transmitters and receivers can be spaced further apart. However, if this range is higher than it needs to be, complications occur as more of the infrastructure needs to process signals from a given mobile unit. On the other hand, low signal range, in general, requires a larger investment in a fixed infrastructure for a given level of coverage.



Figure 5.1: Ultrasound tag.



Figure 5.2: Detector with wireless adapter.

As we had few objects to track, and these objects did not move often, transmission speed was not a limiting factor when considering US. The sizes of the rooms we had to cover did not exceed US range. However, given RF wave low reflectivity and high range, the investment in infrastructure to achieve our targeted resolution using RF was deemed higher than in the US case. Essentially, just one US detector per room was needed to achieve room-level resolution. Also, only five of our US detectors actually needed specialized tuning to perform adequately. Extensive tuning is often essential to the functioning of radio frequency systems in order to be able to correctly triangulate positions. The ultrasound frequencies used by the system did not conflict with any medical equipment.

5.3.2 Implementation Overview

Our IPS hardware consisted of 20 Sonitor Technologies tags (Figure 5.1), 15 Sonitor Technologies detectors (Figure 5.2), 12 ASUS wireless 802.11 b/g access points, a standard 802.11 b/g wireless router, and a standard PC with two monitors. Approximate total cost was US\$ 7,500, with detectors and tags making up US\$ 5,500 of this.

The tags were battery powered by a primary lithium thionyl chloride AA cell, penlike with dimensions $4.6 \times 0.7 \times 1$ inches ($117 \times 18 \times 27$ mm) and weighing 1 oz. (28g) in total. Each contained an motion sensor and an ultrasound transmitter. The transmission frequency range of tag – detector transmission is 35 to 45 kHz with a nominal programmable range up to 50 feet (15 meters) and maximum range of 100 feet (30 meters). The directivity of the tag, i.e., the width of the cone in front of the tag containing the majority of its transmitted signal, is 80 degrees. The programmable transmission rate (see below) was set to five seconds.

The detectors were wall mountable by double sided tape, rectangular with dimensions $6.9 \times 3 \times 1.8$ inches ($175 \times 76 \times 47$ mm) weighing 8.8 oz. (250 g). Detectors were powered by an external 7-9 VDC, 1000mA power supply. The detectors have their own network interfaces that can be connected to the local area network via IEEE 802.3 Ethernet or IEEE 802.11 wireless access points. In our installation, three detectors close to the router were connected directly while the other detectors were connected wirelessly using ASUS wireless 802.11b/g access points. Ultrasonic properties of detectors were identical to those of the tags. A more detailed description of the tags, detectors and their communication can be found in Holm et. al. [95].

The server processed position information, implemented a historical database and a tag location display. The server was connected to the router via Ethernet.

A schematic overview of the IPS software system we implemented can be seen in Figure 5.3. Its design loosely follows a model-view-controller design pattern with the goal to de-couple the collection, distribution and presentation of positioning information.

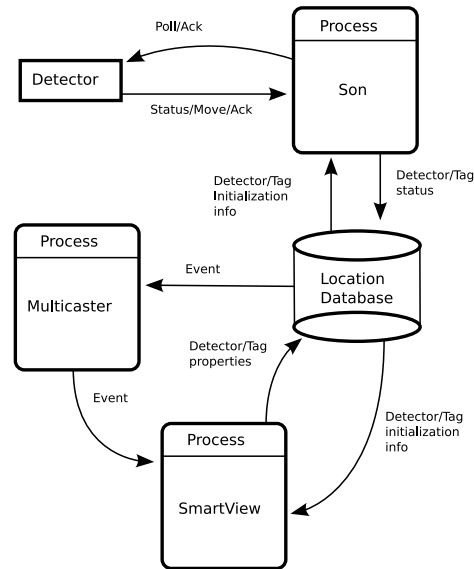


Figure 5.3: Schematic overview of the IPS system.

Sonitor Technologies tags transmit two types of messages using ultrasound: moving or sleepy. If the tag is moving as detected by a built-in motion sensor, the tag transmits this fact every predetermined number of seconds. If the tag has not been moving for a predetermined number of seconds, it transmits “sleepy”. If the tag has been sleepy long enough, it goes into powersave mode and does not transmit anything until it moves again. In addition to its status, the tag transmits its identifier, and a bit indicating its battery status.

A detector receives and decodes messages from tags. It in turn sends a User Datagram Protocol (UDP) datagram to a central server. This message includes the identity of the tag and its status, the identity of the detector, the received signal strength, and a number reflecting confidence that the information received from the tag is accurate and in fact came from a tag and was not an artifact.

In our system architecture, the positioning computation is done in a process called **Son**. For each tag, this process keeps a first-in-first-out (FIFO) list or pipe of detector “sightings” as determined from the UDP datagrams received. After a predetermined time has past since the last sighting of a tag, all the information in the FIFO pipe is used to compute the location of the tag. This waiting time is typically much less than the time between messages sent by a particular tag and is used to give all detectors that received a message from a tag a chance to report it. Sightings older than a predetermined number of milliseconds are deleted from the list to clear the pipe of sightings belonging to previous messages sent by the tag. The confidence number is used to discard unreliable sightings. For each detector a scaling factor is applied to the signal strength reported to tune the area of coverage for this detector. The **Son** process then assigns the tag to the area covered by the detector with the largest scaled amplitude reported.

Once a location is assigned to a tag, it is recorded in a central database. A trigger function in the database sends a UDP datagram about any change in a tag to a process that multicasts this datagram. This is done to avoid the need for polling the database for updates. The main client application of the IPS system receiving these multicast messages is **SmartView**, a process displaying a map with the location, status and annotations of the different tags that are being tracked.

The data base system used was PostgreSQL version 8 using trigger functions written in Perl, the **Son** process was written in C, while the **SmartView** and **Multicaster** were Java applications.

5.3.3 Physical Layout and Detector Placement

The monitored area was the waiting area of the emergency department, together with surrounding rooms accessible to waiting patients. A screenshot of the SmartView map can be seen in Figure 5.4. The monitored area is within the bold line on the map and has an area of about 4500 square feet (418 square meters). The small circles are the detectors, rectangles with letter P and a number are assigned patient tag locations, while rectangles with letter C and a number are care provider tags. In Figure 5.4 patient designated P1 is located in the north eastern part of the waiting room, patient designated P2 is located in the “Family Room”, a room that offers more privacy than the main waiting area, patient designated P3 is located in the middle of three triage rooms, patient designated P4 is located near the door into in a large hallway extending to the left beyond the edges of the map, containing a waiting room overflow area and a food vendor area, while care provider C1 is in the ED proper near the door to the waiting area.

A typical patient movement pattern is as follows. The patient enters from outdoor through the foyer (100) on the map, crosses the main waiting area (101) in order to approach the registration desk (108). After registration, the patient then sits down in the main waiting area until called into one of the three small triage rooms on the left of the waiting area (hallway of the three triage rooms is designated 109). After triage, the patient again sits down in the waiting area until called into the ED. While waiting the patient can go to the restrooms (102 and 103), or walk through the foyer (100) and enter a large hallway on the left containing among others a waiting overflow area and a food vendor.

The only area that required sub-room resolution was the main waiting area due to

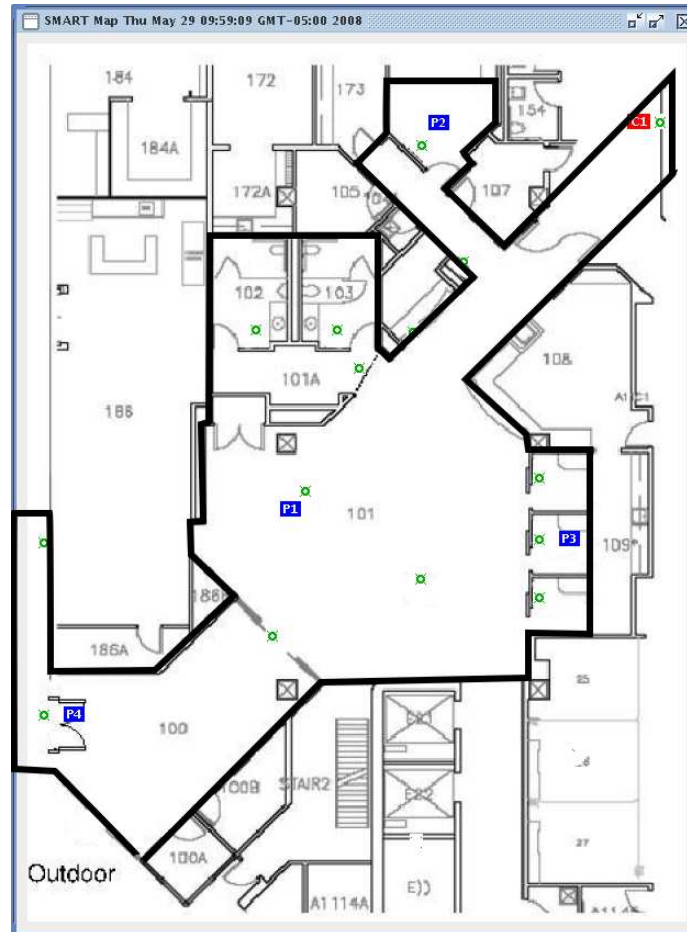


Figure 5.4: The SmartView map of the monitored area outlined by a bold line. Patient tags have a P followed by a number, while care provider tags have a C followed by a number. Detectors are small circles with short decoration lines in each corner.

size. It was subdivided into three regions, north west, south east and registration. As the coverage area of a detector ideally can be modeled as a half-plane in front of the detector, the sub-division of the main waiting area was achieved by placing two detectors back-to-back a little south east of the midpoint between the two detectors flanking the number 101 in the map. This allowed the separation of north east and south west. To achieve the last subdivision around the registration desk (108) a detector facing the desk was placed across the walkway going into the ED proper. In general, the directionality of the detectors was exploited in order to distinguish neighboring areas where there are no physical barriers, such as between the waiting area and the hallway outside the restrooms (101A). The detector was placed above the entrance to the hallway facing away from the waiting area. The same approach was taken to monitor the hallway leading to the family room (location of P2 on the map), again the detector was placed near the boundary looking into the hallway. The signal strength of the tag sighting was multiplied by a factor of 0.5 for the detectors monitoring the restroom hallway, the family room hallway, and the three triage rooms. This allowed the correct location of tags in the main waiting area that were close to these detectors. All detectors were placed at around 7 feet above the floor in order to ensure that they remained unobstructed.

5.3.4 Tag Placement and State Implementation

The high reflectivity of ultrasound requires the tag transponder to have free air access, i.e., it cannot be enveloped in any sound dampening media. For our implementation, this meant that care had to be taken in placing the tags in a manner that made them hard to obstruct. For care providers wearing a white coat, attaching the pen-like tag to the breast

pocket was the preferred mode. The patients tags were attached inside a pouch containing the vital signs processing elements such that the transducer end of the tag was protruding out of a hole in the pouch. An alternative to this was attaching the tag to a lanyard around the neck.

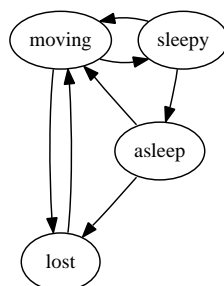


Figure 5.5: The diagram of patient location tag states.

As the tags had fixed transmission intervals, and two message types, moving and sleepy, we could use this information to implement four “tag states” as seen in Figure 5.5. The three first states correspond to the tag modes outlined above, the fourth state is “lost” and is entered when either of the two following conditions are met. The first is when the tag is in the moving state, and we do not receive messages when we expect them, the tag is assigned the lost state. The second is when the tag has been asleep too long. The time a tag has been asleep can be used to define fine-grained asleep sub-states.

Initially, we thought that the sleepy state would let us detect when patients were sitting down, but the motion sensor was too sensitive for this. It registered regular movement such as breathing or slight shifting of position while sitting. This meant that if a tag registered asleep, the patient had taken off the pouch containing the tag, and if the tag registered lost, the tag had either been obstructed or the patient had moved outside the

monitored region.

In addition to the states based on physical circumstance presented above, tags could be assigned a parallel “alarm” status. This status was used to change the appearance of the tag icon on the central display to make it easy to identify.

5.4 Discussion

Due to the particulars of the study, mainly the lack of opportunities to track patients with an alternative to the ultrasound IPS system, no gold standard could be established for the entirety of the data collection period. However, several small-scale checks were performed, mainly by assigning a tag each to a small number of volunteers, and instructing the volunteers to follow a predetermined schedule of positions within the monitored area to visit. These schedules were then compared to the data collected. The tracking capabilities of the system were deemed fully adequate.

Considering the collection of detectors as nodes in a graph, we computed the movement paths of the patients monitored. The average path length was four, and as expected the majority of time spent was in the waiting room containing three nodes (zones). The maximal recorded path length was 21.

As the system was a temporary installation, in order to not interfere with the normal operations of the ED, it had to be minimally invasive. Information security considerations also disallowed the use of existing communication infrastructure for the pilot study. This meant that we had to install a separate, wireless communications infrastructure for detector – server communication. This together with other seemingly easy engineering

problems like access to power at detector sites, combined to influence the operation of the system in a negative way.

The major problem encountered was that each detector initially supplied power to its ASUS wireless ethernet access points. The power supplies and internal detector hardware were not designed with this in mind, and the detectors started to malfunction at irregular intervals. Once the detector hardware and the power supplies were updated, the reliability of the detectors improved significantly.

A limiting factor of the ultrasound system we implemented was the time between each tag transmission that was chosen. If a tag moved too quickly from one location to a non-neighboring location, the transition through intermediate areas could be lost due to the long time before next transmission. However, as study subjects were patients presenting with chest pain and hence slow moving when not sedentary, observed path gaps were not attributed to this.

We believe that the problems with detector failures and path gaps were related to our particular implementation of the system and not inherent to ultrasound based positioning technology itself.

Our conclusion is that due to ultrasound's physical properties with respect to radio frequency waves, ultrasound should be seen as a complement to radio frequency in location systems, particularly for certain indoor applications.

Overall, the IPS performance was adequate to our needs. It allowed us to determine patient location with room-level accuracy and thus promptly finding the source of an alarm at any given time.

Chapter 6

System Integration



6.1 Introduction

This chapter describes the design of SMART system as a whole and the experience with the initial evaluation of it with 145 post-triage patients in the waiting area at Brigham and Women's Hospital's Emergency Department in Boston, MA. Because of Internal Review Board (IRB) limitations, full integration with ED protocols was not attempted. The system was able to track patients and present ECG and SpO₂ data to an operator, as well as alarm on critical conditions.

6.2 Design Objectives

In designing SMART, the primary considerations were the following:

- Open platform hardware and software for ease of modification.
- Inexpensive commodity components whenever possible.
- Robust geo-positioning to track patients, caregivers, and equipment, so that the SMART system can alert an appropriate caregiver. Appropriateness can be defined by geographical location, qualification, or availability, depending on the situation. The geo-positioning can also help locate both the patient and the nearest, relevant available piece of equipment. The system should be flexible enough to integrate a variety of commercially available location systems for both indoor and outdoor use.
- Sufficient wireless network capacity for reliably delivering data from the Patient PDAs to a central computer, data from the location detectors, alerts from the central com-

puter to the Caregiver PDAs, and other data requests/responses between the Caregiver PDAs and the central computer.

6.3 System Description

The SMART system consists of a patient monitoring device, a geo-positioning subsystem, a wireless networking subsystem, decision support and logistic support subsystems (SMART Central), and a caregiver module. The system also has a logging subsystem. Figure 6.1 shows the main components of the SMART System architecture: A geo-positioning system based on active tags and detectors provides location information for patient and caregiver PDAs. Patient data such as ECG signals, SpO₂ readings, and location information flow into SMART Central. The Streaming Data Manager inside SMART Central receives all the streams of data from the patients and caregivers, processes them and makes them available to other modules for further analysis.

6.3.1 Patient Monitoring Device

The patient monitoring device is a waist pack containing a PDA and a sensor box, as shown in Fig. 6.2. It weighs about one kilogram. The sensor box (Fig. 6.3) collects oxygenation level and a single-lead ECG (Lead II). The SpO₂ sensor is available from Nonin ® [1] and the ECG sensor was developed at MIT. The PDA is an HP iPAQ ® running Linux ®. The PDA forwards data collected from the sensors to SMART Central. Communications between the Patient PDAs and SMART Central are not encrypted since they contain no identifiers such as name, Social Security Number, date of birth, etc. The

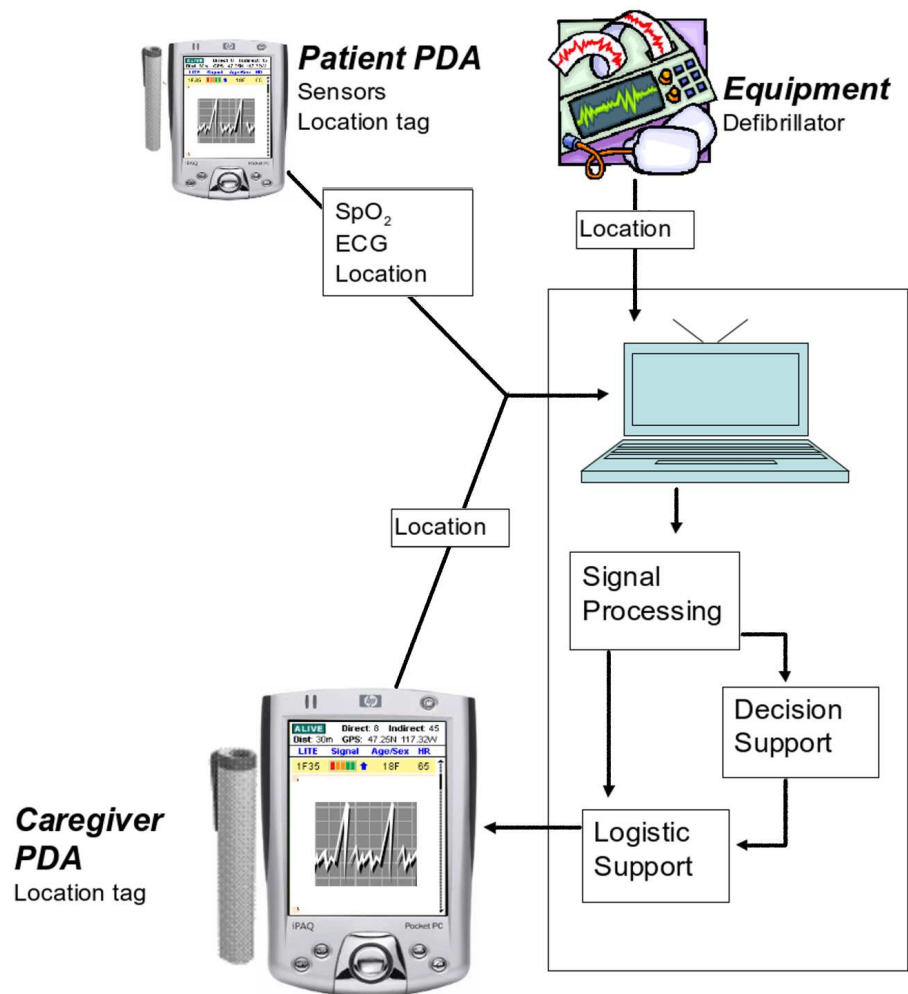


Figure 6.1: SMART components: Caregiver PDAs, location sensors and patient PDAs with ECG and SpO_2 sensors are wirelessly connected to SMART Central where all data are processed.

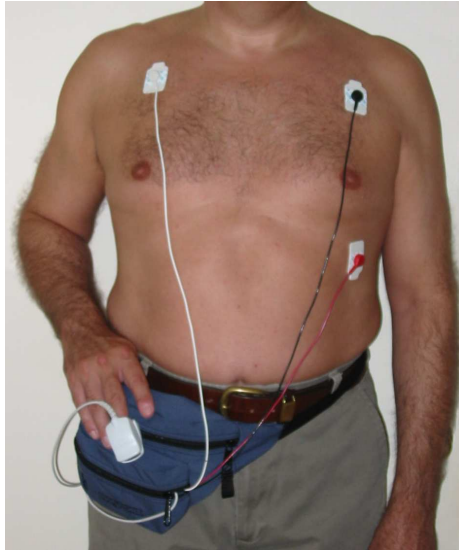


Figure 6.2: Patient wearing SMART monitoring gear: SpO₂ and ECG sensors, and a waist pack with sensor box and HP iPAQ ®.

PDA stores no patient identifying data and only limited raw data so it cannot compromise patient confidentiality by being stolen.

6.3.2 Geo-Positioning System

For this pilot study, we deployed the Indoor Positioning System (IPS) from Sonitor ® [90] for geo-positioning. This ultrasound-based system consists of active tags worn by patients and caregivers and detectors on the walls. SMART Central collects messages from the detectors and computes the location of the patient or caregiver.

6.3.3 Wireless Communication

Standard wireless networking technology (802.11b) is used to connect the Patient PDAs and the Caregiver PDAs to a wireless router. Wireless bridges are used to connect the location detectors and two remote areas to SMART Central. To decrease the possibility of



Figure 6.3: Inside the patient waist pack: SpO₂ and ECG sensors, sensor box and HP iPAQ ®.

wireless messages interfering with each other, SMART Central is connected directly (wired) to the wireless router.

The standard available bandwidth from an 802.11b network (11 Mbps) covers the communications needs, which are estimated at about 0.5Mbps for 10 patients (10 ECG messages per second + 3 SpO₂ messages per second + < 1 location message per second + < 1 battery message per second where a message has a maximum of 400 bytes * 8 bits/byte). The traffic for a Caregiver PDA is significantly less than that for a patient and there are only two Caregiver PDAs in the basic system evaluated here.

6.3.4 SMART Central

The heart of the system is SMART Central, which runs on a commodity PC, using the Linux ® Operating System. SMART Central contains a Streaming Data Manager, and two decision support components: a patient-specific Decision Support Module and a Logistics Support Manager. The Streaming Data Manager receives the real-time patient

data, processes it, and forwards it to the Decision Support Module. The Decision Support Module then analyzes the data and triggers alarms. The Logistic Support Manager matches alarms to the environment to dispatch relevant information to the appropriate caregiver. All data and alarms are logged for later review and analysis.

The Streaming Data Manager receives the SpO₂, ECG, and location data streams. The SpO₂ data stream provides both the patient's oxygenation level and the patient's heart rate. The ECG sensor provides waveform data. The location data stream shows the tag id, status and signal strength of each tag transmission received by the location system detectors. The SDM provides access to raw data and derived measurements via a simple query mechanism. This module also incorporates a computation module for detecting heart beats from the ECG waveform data using a modified version of the SQRS algorithm [77, 79], a real-time algorithm for QRS detection. The algorithm is able to report QRS complexes and QRS-like artifacts, and warns about no beats detected in the last 3 seconds.

SMART Central's Decision Support Module subscribes to the Streaming Data Manager's data streams for the ECG waveform, the detected heart beat positions (times), the SpO₂ sensor information, and location information. In the Decision Support Module, the data are combined and new higher level data are generated. A robust heart rate is obtained by using a median filter to mask missed or extra beats detected by the Streaming Data Manager. The Decision Support Module monitors and generates alarms about a patient's cardiac status by evaluating the SpO₂, ECG and heart rate data streams. Details about the implementation of the diagnosis support algorithm can be found in Chapter 4.

The Decision Support Module analyzes streams of data to detect alarm conditions

Table 6.1: Rules for generating Oximeter Medical Alarms.

<i>Alarm</i>	<i>Condition that triggers the alarm</i>
High HR	Heart rate from oximeter sensor above patient-specific threshold (default threshold is 100 BPM)
Low HR	Heart rate from oximeter sensor below patient-specific threshold (default threshold is 60 BPM)
Low SpO ₂	Oxygen saturation below patient-specific threshold (default threshold is 90%)

Table 6.2: Rules for generating ECG Medical Alarms.

<i>Alarm</i>	<i>Condition that triggers the alarm</i>
Asystole	No beat detected in 3 seconds
Ventricular Fibrillation	ECG shows artifacts, abnormal skewness, wide waves or no waves, lacks QRS complexes, and the SpO ₂ heart rate is missing or below 20 BPM or above 150 BPM
Ventricular Tachycardia	ECG has wide QRS complexes and heartrate is over 100 BPM
Tachycardia	ECG heart rate above patient-specific threshold (default threshold is 100 BPM)
Bradycardia	ECG heart rate below patient-specific threshold (default threshold is 60 BPM)
Irregular	ECG QRS complexes are irregularly spaced

and uses a rule set to generate alarms. Alarms are divided into two categories: technical and medical. Technical alarms are caused by electrodes that have fallen off, loose lead wires, etc. The rules for detecting alarms are described in Tables 6.1, 6.2 and 6.3.

The Decision Support Module also combines location data from different location detectors to compute the position of the patient. A large room typically has several detectors, and the location within the room is based on the amplitude of the signals from each detector.

The Logistic Support Manager is responsible for dispatching alarms to the appropriate personnel or system for notification. Unlike the Decision Support Module, which deals

Table 6.3: Rules for generating Technical Alarms

<i>Alarm</i>	<i>Condition that triggers the alarm</i>
Mismatch	ECG diagnosis inconsistent with SpO ₂ heart rate: (a) if ECG indicates asystole and oximeter heart rate is between 20 BPM and 150 BPM, or (b) if ECG indicates ventricular fibrillation and oximeter heart rate is between 20 BPM and 150 BPM
Noisy	Artifacts and normal skewness in ECG signal
Leads Off	ECG lead is off (signal is saturated)
Nosignal	No ECG data received
Technical SpO ₂	Oximeter sensor removed from finger
AWOL (away without leave)	No communication between PDA and SMART Central
Battery	Low battery (below 20%)

with patient-specific data that are independent of the environment, the Logistic Support Manager is highly environment-dependent, and incorporates workflow rules. These rules indicate that the alarm should be sent to the nearest available and appropriate caregiver. The rules also describe an escalation procedure in case a caregiver does not respond to an alarm. Currently, if a caregiver “responds” to an alarm, re-notification of most alarms is suppressed for ten minutes. The exceptions are AWOL (Away WithOut Leave) and battery. The Logistic Support Manager matches alerts to the appropriate caregiver and sends the alert information to that Caregiver PDA. A summary of outstanding alerts is also available on the SMART Central display.

6.3.5 Caregiver Module

There are two main caregiver interface modules in SMART: the user interface associated with SMART Central, and the interface for the Caregiver PDA.

SMART Central provides a basic monitoring interface. This interface displays the list of registered patients with their current vital signs and their most recent alarm. It

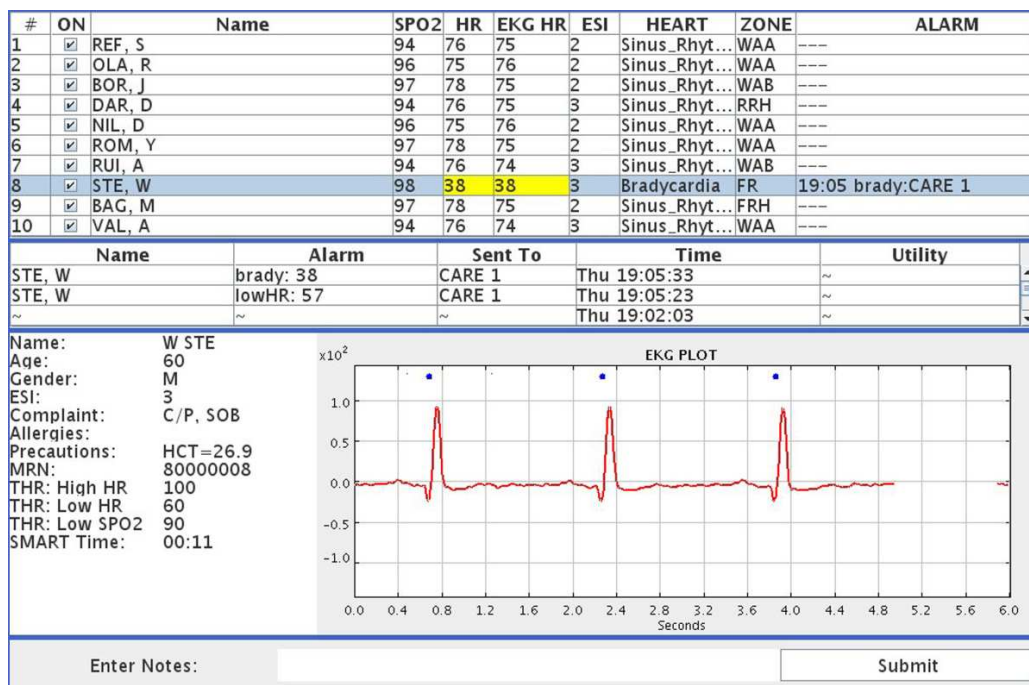


Figure 6.4: User interface for SMART Central. Yellow highlighting indicates abnormal values relative to patient-specific threshold settings.

also displays a list of recent alarms and a map of the locations of patients and caregivers.

When a patient is selected from the list, additional detail about that patient can be shown, including the patient's vital signs readings, other demographic and medical data, and the live ECG waveform, as seen in Figure 6.4. "HR" indicates heart rates calculated by the SpO₂ sensor. SMART Central uses a second screen to display location information.

The Caregiver PDA interface has three distinct modes. The first shows the roster of patients. When a caregiver clicks on a patient in the roster, the second mode shows the detailed vital signs, as depicted in Figure 6.5. When an alert arrives, the Caregiver PDA buzzes audibly and vibrates and enters the third mode for handling alarm conditions. In this mode, the window (see Figure 6.6) displays the identity of the patient with the problem, his or her location, and the type of alert (e.g., bradycardia). Then the caregiver



Figure 6.5: Caregiver's view of a patient.

can indicate to SMART Central that he will respond to that problem, by tapping on the “Respond” button. Other responses include indicating that the caregiver is busy, via the “Unavailable” button, forwarding the alarm to another caregiver via the “Forward” button, and delaying a response for a short time via the “Defer” button. These latter responses result in forwarding the alarm to another provider.

The Caregiver PDA locks up when unattended (lack of input) and requires a password to regain access. It stores no data locally and un-refreshed data ages and disappears, so a stolen Caregiver PDA will not reveal any confidential information. Wireless communications between SMART Central and the Caregiver PDAs are encrypted via SSL.

SMART Central also deals with the situation when the caregiver does not respond at all. In this case, the re-alerting behavior is governed by the LSM rule set: typically



Figure 6.6: Caregiver's view of an alarm. Clicking on "Respond" indicates that the caregiver will handle the alarm.

another caregiver will be alerted promptly.

6.3.6 Data Management

SMART Central has web pages for entering patient demographic information and caregiver registration. Smart Central logs all raw data received from patients in a database. It also logs derived data: calculated ECG heart rate, locations computed from detector data, alarms sent, responses to alarms, and buttons clicked on Caregiver PDAs.

The information is displayed via two monitors as shown in Figure 6.7. The first screen always presents the main user interface, with patient status and alarm information (Fig. 6.4). The second screen is set in a vertical orientation to show the map with current tag positions, and is also used for data input when registering a new patient.

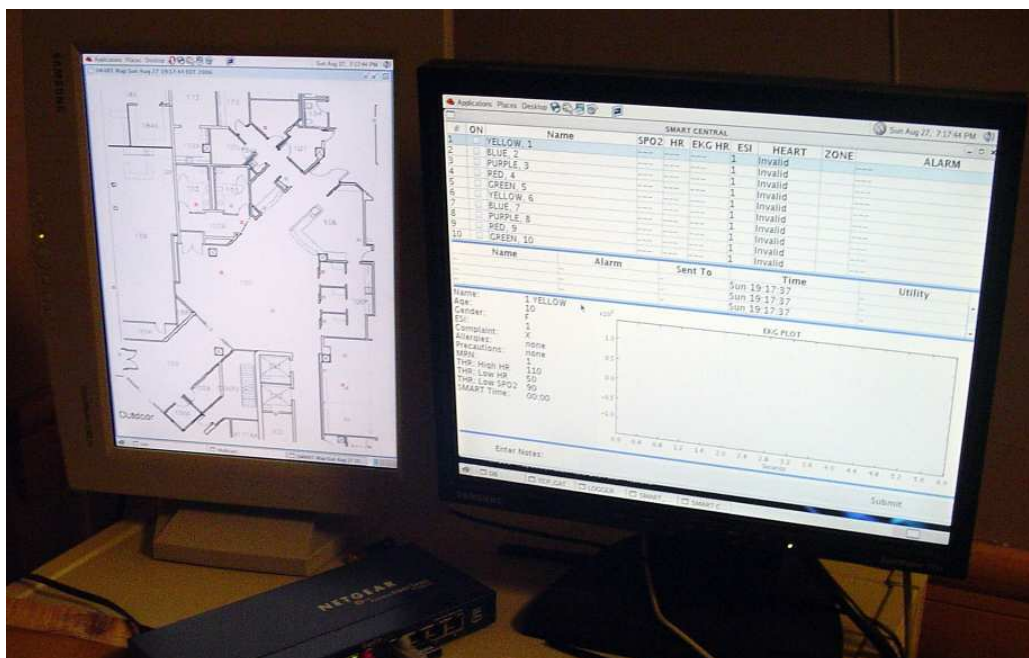


Figure 6.7: SMART Central with dual monitor. Vertical monitor shows the area map and tag positions. Horizontal monitor has the main user interface.

6.4 Results

6.4.1 Pilot Study

The pilot study reported here began on June 19, 2006, in the Waiting Area of the ED at the Brigham and Women's Hospital in Boston and ended on March 30, 2007. We conducted our pilot study there because it provided a controlled environment with ambulatory patients in whom the expected rate of real events was higher than normal. Only patients with intermediate severity statuses, based on triage, were eligible for the study.

6.4.2 Workflow

This study was approved by the IRB of the Brigham and Women's Hospital, which required that an individual with ACLS training (a paramedic who we will refer to as "SMART Operator") would monitor the SMART Central station at all times. This prevented us from testing the direct response of other caregivers to alarms, since they knew of the SMART Operator's role in filtering out false alarms and communicating directly with a triage nurse. While away from SMART Central, the SMART Operator carried the caregiver device and hence we could verify its functionality. The fact that no patients were being monitored in the waiting area of the ED before our study began did not preclude the IRB from demanding human mediation in SMART, because, once patients are monitored, the hospital is responsible for adequately responding to detected abnormalities. Caregivers knew that they would be alerted only if the SMART Operator deemed the alarm significant.

The ED workflow was as follows: Initially a triage nurse interviewed the patient and assigned an Emergency Severity Index (ESI) [96, 97]. Those deemed most severe (Category 1) were immediately admitted to the ED, while others went back to the waiting area. This process did not change at all with SMART. The SMART Operator had access to the ED census and chief complaints via the EDTrack system, the electronic patient tracking system in the ED. Patients eligible for the SMART study included those triaged in ESI categories 2-5 and presenting with cardiovascular or respiratory complaints. When the SMART Operator noticed that an eligible patient had been triaged, he approached the patient for consent. He provided a description of the study and answered any questions about it. He explained, among other things, that participation in the study would not

change the patient's waiting time. After obtaining consent, he gave the patient a SMART waist pack and placed the ECG electrodes and the SpO₂ sensor on the patient. Heart rates were measured redundantly by the oximeter and the analysis of ECG waveform.

Each waist pack had a unique number. The SMART Operator then enabled alarms for that waist pack at SMART Central and entered the demographic information. The process of enlisting an eligible patient and outfitting him with the SMART waist pack took about two minutes. At the end of the monitoring session, when a bed was available and the patient was admitted to the ED, the SMART Operator collected the waist pack and survey information from the patient. When the SMART Operator noticed that a patient was having a problem, he located a triage nurse to evaluate the situation. Although the capability existed, as explained above, in this study, other ED personnel did not carry PDAs.

6.4.3 Patient Population

During the study period, the SMART Operator approached a convenience sample of 189 eligible patients, of which 151 patients consented to participate. Six were then excluded: one withdrew; two were admitted into the ED before having a chance to receive the device, and three withdrew after starting to wear the waist pack (reasons: "got tired", "wait was too long", "device was irritating"). The 145 included patients wore the waist pack between 5 minutes and 3 hours, with an average of 47 minutes each. Ninety-four (65%) of the participants were surveyed. Respondent ages ranged from 18 to 87 years (average 49.5, 12 omitted their age). There were 38 males and 49 females (7 omitted their gender). 65% of the patients felt safer wearing the monitoring system. 93% of the patients responded

that they “would wear” or “probably would wear” the monitoring system again.

6.4.4 Location

The pen-sized location tags were attached to lanyards around the patients’ necks, since in this position the transmitter did not get covered by clothing. In analyzing the logged location data, we computed the “track” of each patient. The track is the succession of zones that the patient entered and the time spent in each zone. The average track had four zones. The main waiting area contained three zones, and these are where patients spent most of their time, as expected, but there was significant patient movement. The maximum number of zones in a track was 21. Some of the tracks showed “discontinuities,” indicating that the location system had “missed” the patient as he or she moved from zone to zone. The discontinuities were limited to skipping one zone at a time.

6.4.5 Decision Support, and Logistics Modules

Between June 19th, 2006 and August 15th, 2006, several changes were made to the SMART alarm subsystem. Table 6.4 shows the alarms the SMART system detected between August 15th, 2006, and March 30th, 2007. Unclear indicates that the alarm condition may or may not have been true, e.g., when a signal showing tachycardia is noisy, it can be difficult to see tachycardia. In other situations involving readings vs. thresholds, the reported number was near the threshold, but not over it, indicating either a race or a software bug in the reporting mechanism. The classification of each alarm was based on a majority vote of a panel of three judges. The judges, a subset of the authors, were a paramedic, a computer scientist and an electrical engineer. There were no reports of patient problems that would

Table 6.4: Alarms detected between August 15th, 2006 and March 30th, 2007

Alarm	Total	TP	FP	Unclear	Comment
High HR (SpO ₂ sensor)	79	75	1	3	Reported HR value did not exceed threshold
Low HR (SpO ₂ sensor)	21	15	3	3	Reported HR value did not exceed threshold
Low SpO ₂	44	35	5	4	Reported SpO ₂ value did not exceed threshold
Asystole	79	0	79	0	No SpO ₂ sensor present + noise or no signal
Ventricular Fibrillation	46	0	46	0	No SpO ₂ sensor present + noise
Ventricular Tachycardia	0	0	0	0	
Tachycardia (ECG)	124	61	31	32	Noise often mistaken for tachycardia
Bradycardia (ECG)	18	12	5	1	Reported HR value did not exceed threshold
Irregular rhythm	116	43	34	39	Noise often mistaken for irregular
Mismatch	59	59	0	0	
Noisy	59	47	12	0	
Leads Off	56	49	2	5	Noise sometimes mistaken for leads off
No Signal	0	0	0	0	
SpO ₂ sensor off	86	85	1	0	
AWOL	329	309	16	4	Battery message from PDA lost
Battery	16	15	1	0	

lead us to believe that there were any false negatives.

6.4.6 Reportable Episodes

During this initial period, most of the patients showed no abnormalities. SMART did provide sufficient ongoing monitoring so that some patients were re-triaged: The first case was a 30 year old female with chest pain, triaged in category 3. SMART Central reported a series of irregular rhythms alternating mainly with tachycardia. These alarms led the SMART Operator to notice that the patient was having a series of premature

ventricular contractions (bigeminy). He notified the triage nurse, and the patient got a 12-lead ECG and was admitted to the ED.

The second case involved a 70 year old female who had passed out while sitting in a hot car. The SMART System detected bradycardia. The SMART Operator asked the ED staff to review her situation. She was admitted to the ED and then to the hospital for further monitoring.

The third case concerned a 64 year old male who was sent from his primary care physician's office because of a pulse rate of 120 BPM without symptoms, a past history of hyperthyroidism, and "irregular heartbeat." The SMART Operator noticed that his SpO₂ heart rate and his ECG heart rate differed significantly. Suspecting atrial fibrillation, he notified the ED staff. The patient was admitted to the ED and the 12-lead ECG showed junctional tachycardia.

6.5 Discussion

With respect to the SMART system design objectives, almost all of the SMART components are affordable, off-the-shelf, portable, easy to deploy, and untethered. The only exception is the ECG waveform board, which we designed and built ourselves, because we could not find a commercially available board that met our needs. The patient monitoring device provided with the SMART system meets our design objectives. One shortcoming is that the battery life is about three hours. This was sufficient for our tests, but in a future deployment we would reconfigure the Patient PDA to extend the battery life. The geolocation subsystem in SMART was able to track patients adequately. We did not track

caregivers or equipment, because of limited integration with the ED operations. The geo-positioning subsystem is flexible because, in addition to the integration with the Sonitor [®] IPS reported in this thesis, further developments were able to integrate SMART with two other geo-positioning subsystems, Cricket [98] and the Global Positioning System (GPS).

The Caregiver PDA is intended to be used for receiving alerts when a caregiver is attending to patients. While the Caregiver PDA operated as intended during tests on healthy volunteers, it was not used by ED personnel and only minimally by the SMART Operator during the pilot study. The SMART Operator reported that he preferred watching ECG signals on the large display of the SMART Central workstation.

With respect to the networking components, the throughput of the wireless system was never a problem, perhaps because the number of patients monitored simultaneously was never greater than four. The lower-than-expected volume of patients presenting concurrently with cardiovascular or respiratory problems prevented us from addressing questions of scaling. This kept us from understanding how many patients a single SMART Operator could monitor well. Pushing data wirelessly to Caregiver PDAs was shown to be feasible in some demonstration situations, but was not used in the pilot study.

The SMART Decision Support and Logistics Modules received and analyzed the data and generated, for the most part, appropriate alerts. Recognizing that some medical conditions, such as atrial fibrillation, would cause almost continuous alarms, we allowed alerts related to irregular heart rates to be disabled by the SMART Operator. We also delayed alerts for technical SpO₂ problems, because these are usually caused by the patient moving the sensor from one finger to another. The literature contains many articles, e.g.,

[99, 100], concerning the problems caused by too many alarms in the Intensive Care Unit, and the ED is a similar environment – but SMART was deployed in the waiting area of the ED. This is an area without audible alerts, and we chose to keep it that way. In three cases, alarms were deemed serious enough to request reprioritization of patients. In all three cases the medical staff accepted the reprioritization.

The data management and logging subsystems performed well enough to allow us to replay and analyze the data recorded from the patients. Registration of caregivers is not supported at this time, due to lack of integration with ED operations.

An important limitation of the current study is that we were not able to measure the system utilization by ED personnel, given that they knew that a paramedic would be responsible for monitoring all study subjects. Although we received positive feedback from some of the nurses, a systematic study on the impact of the system on the ED workflow is needed.

6.5.1 Lessons Learned

The deployment of an experimental system for monitoring previously unmonitored patients within a high-functioning organization, such as an urban ED, requires an intermediary, in our case, the SMART Operator. This requirement originates from two main concerns:

1. Hospital liability: a failure to detect an event in monitored patients in the ED waiting area could lead to a lawsuit (even if the risk for not detecting an event in this system was the same as if the patients had not been monitored, as in the current standard of

care),

2. Relatively high number of false positives: false alarms might unnecessarily distract ED personnel from their existing cases, which would indirectly pose an additional risk to the patients already admitted to the ED

Selection of a location system was challenging, inasmuch as the technology is changing rapidly in this area. Although the location system we chose provided sufficiently accurate data about the location of patients, it proved more time-consuming than expected to manage: we had to regularly survey whether its various components were working and make arrangements to replace failed components.

Both redundancy in the vital signs monitoring and the provision of single lead ECG tracing proved useful. The redundancy allowed us to detect “suspected atrial fibrillation” in one patient and the single-lead ECG tracing allowed the SMART Operator to detect bigeminy in another.

Before beginning the pilot study of the SMART system in the ED waiting area at BWH, we used the SMART system on healthy volunteers and recordings from synthetic patients. These tests were quite useful in testing the whole system. One side effect, however, derived from the fact that the “volunteers” were either technically or medically savvy. As a result, they tended to request features (such as much lighter waist packs) that turned out to be irrelevant to actual patients. Although the volume of eligible patients was low, it was not due to “refusals”; in fact, the patients were more accepting of the system than expected and perceived the monitoring to be useful.

Chapter 7

General Discussion



7.1 Overall Review

This thesis presents all the necessary steps to develop a pervasive patient monitoring and alarming system. This includes the following capabilities:

1. Sensor data acquisition
2. Data transmission
3. Data analysis
4. Diagnosis suggestion based on data aggregation
5. Alarm generation
6. Patient location
7. Caregiver notification
8. Historical data review



Overall, the system performed well, on par with similar projects. The contributions of this work are: detailed review of modules required to implement a monitoring and tracking system, actual results from the implementation of such a system with multiple untethered patients in a real environment, usability reports from real patients, and a multi-diagnosis capable algorithm designed for noisy environments.

7.2 Components Discussion

We developed a quantitative method to select a beat detection algorithm based on minimizing HR error. Then we showed that a non-linear filter is the best alternative to

clean motion-induced HR errors.

A known algorithm was adapted to work as a module to the SMART project and extra capabilities were added such as hardware independence, patient independence and critical condition detection.

A diagnosis algorithm was developed based on data integration from ECG, SpO₂ and HR data, discarding illogical states by cross-validating the available sources. The algorithm was implemented as a decision tree based on physiological knowledge. It performed reasonably well in detecting Asystole, Bradycardia, Normal Sinus Rhythm, Tachycardia, Irregular Beats, Ventricular Fibrillation, Ventricular Tachycardia, Mismatch, Noisy signal and Leads off. The classification criteria were biased to avoid missing important medical conditions and to ensure a short response time, which contributed to a higher number of false alarms.

A voting window was proposed to deal with the high incidence of movement artifacts detected on actual patients. We believe that a better noise detection system is an absolute requirement to improve detection rates and accuracy, considering that results from simulated patients and from stationary healthy volunteers were much better. In our experiments, simulated patients had positive predictability indexes ranging from 0.76 to 1 while real patients presented indexes ranging from 0 to 0.67 for the same subset of medical alarms (Asystole, Ventricular Fibrillation, Ventricular Tachycardia, Tachycardia, Bradycardia and Irregular rhythm).

An IPS based on ultrasound technology was used. This system provides room-level resolution for tag positioning. The tags may be easily attached to patients, caregivers

and equipment. It was a minimally invasive system that did not interfere with normal operation of the Emergency Department. Moreover, it can be easily deployed in a variety of environments, requiring only a general location information of the detector positions. For increased accuracy, the detectors can be tuned.

A limiting factor of the positioning system was the time between each tag transmission. Ultrasound messages take longer to transmit and interfere with each other. The system could send a “moving” message every 3 seconds.

Overall, the IPS performance was adequate. It allowed us to determine patient location in defined areas and thus promptly find the source of an alarm at any given time.

Wireless PDAs were used to collect the data from the sensors and transmit to SMART central and also as a means to alert mobile caregivers. Unfortunately, IRB restrictions precluded us from thoroughly testing this notification system.

Besides the decision support analysis performed at the main computer, a Logistics Module was implemented, in charge of notifying caregivers and handling their “busy” – “unavailable” – “responding” status.

The data management and logging subsystems performed well. They allowed us to replay and analyze data recorded from the patients. We also detected a potential benefit of recording physiological data while the patient is waiting. At the time a caregiver begins to evaluate a patient, he could have between 5 minutes to 3 hours of recorded data to support his initial diagnosis.

7.3 Conclusion

We were able to implement an untethered patient monitoring system using off-the-shelf equipment. It can be deployed in a variety of environments, such as emergency response sites, nursing homes or private homes with just minimal modifications. It has the potential to improve quality of care to a vast amount of currently unmonitored “at risk” individuals. The adaptability to different environments allows the caregivers to become familiar with it in a standard setting, facilitating its later use in disaster situations.

The work presented in this thesis was tested on a real environment, for 16 months, in a study involving at risk patients on the waiting area of the Brigham and Women’s Hospital’s Emergency Department, a teaching affiliate of Harvard Medical School in Boston, Massachusetts, USA. In 3 out of 145 patients, the system generated alarms that were deemed serious enough by the SMART operator to request reprioritization of patients. In all three cases the medical staff agreed to reprioritize the subjects.

Despite the low accuracy of the diagnosis algorithm for real patients, the system allowed the SMART operator to oversee a considerable number of patients with minimal effort and monitor key physiological variables to ensure a rapid response in case of a critical condition. Even though there was a large number of false alarms, the alarm rate was only 1 every 12 minutes of monitored data. Redundancy of inputs such as ECG and SpO₂ HR is greatly responsible for improving medical condition detection.

The system and the algorithms described in this thesis show that it is feasible to continually monitor untethered patient’s vital signs, give providers appropriate warnings of critical values and thus improve patient care.

7.4 Future Work

Future research objectives that originate from this thesis are:

1. Refining the algorithms to reduce the number of false positives via sensor integration as a means to improve noise signal detection
2. Increase the integration of a SMART-like system with an Emergency Department and test caregiver usability
3. Detect scalability issues when monitoring large numbers (over 20) of patients



Chapter 8

Publications



8.1 ISI Paper

- D. W. Curtis, E. J. Pino, J. M. Bailey, E. I. Shih, J. Waterman, S. A. Vinterbo, T. O. Stair, J. V. Guttag, R. A. Greenes, and L. Ohno-Machado, “SMART - An Integrated Wireless System for Monitoring Unattended Patients,” *J Am Med Inform Assoc*, vol. 15, no. 1, pp. 44–53, 2008.

8.2 Conferences

- E. Pino, L. Ohno-Machado, E. Wiechmann, and D. Curtis, “Real-Time ECG Algorithms for Ambulatory Patient Monitoring.” *AMIA Annu Symp Proc*, pp. 604–608, 2005.
- J. Waterman, D. Curtis, M. Goraczko, E. Shih, P. Sarin, E. Pino, L. Ohno-Machado, R. Greenes, J. Guttag, and T. Stair, “Demonstration of SMART (Scalable Medical Alert Response Technology),” *AMIA Annu Symp Proc*, pp. 1182–1183, 2005.
- D. Curtis, J. Bailey, E. Pino, E. Shih, R. Greenes, J. Guttag, T. Stair, and L. Ohno-Machado, “Is redundancy in vital signs monitoring useful?” *AMIA Annu Symp Proc*, 2007, poster session.

8.3 Submissions

- E. Pino, D. Curtis, E. Wiechmann, and L. Ohno-Machado, “A Real-Time ECG Classification System for Ambulatory Patients,” submitted to *IEEE Transactions on Biomedical Engineering*, 2008.

- D. W. Curtis, J. Baileye, E. J. Pino, T. Stair, S. Vinterbo, J. Waterman, E. I. Shih, J. V. Guttag, R. A. Greenes, and L. Ohno-Machado, “Using ambient intelligence for physiological monitoring,” submitted to *Journal of Ambient Intelligence and Smart Environments (JAISE)*, 2008.
- E. Pino, D. Curtis, M. Thomas Stair, and P. Lucila Ohno-Machado, MD, *SMART: Mobile Patient Monitoring in an Emergency Department*. Book chapter proposal submitted to *Pervasive and Smart Technologies for Healthcare: Ubiquitous Methodologies and Tools*, 2008.



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