WEARABLE COMPUTING FOR PATIENTS WITH CORONARY DISEASES

Válter Rocha[1], Ricardo Seromenho[1], João Correia[1], Alessandro Mascioletti[2], Alfredo Picano[2],Gil Gonçalves[3.]

[1]Agilus I+D, {ricardo.seromenho, joao.correia, valter.rocha}@iaiti.pt
[2] LABOR, {a.mascioletti, a.picano}@labor-roma.it
[3] Informatics Engineering Department, University of Porto, gil.goncalves@fe.up.pt

Abstract: *Cardiovascular diseases are killing more and more people around the world, striking rich and poor alike. The World Health Organization identifies these diseases as challenges to population health and well being and calls it a global epidemic. These diseases can seriously affect the life of both the patient and family. In tandem with a strategy to provide information and education to individuals at risk, Information and Communication Technologies can be a valuable tool to address the challenges posed by this global epidemic.*

Keywords: *coronary diseases, HEARTRONIC project*

1. INTRODUCTION

Cardiovascular diseases (CVD) cause the death of around 4.500.000 people per year in Europe, being the first cause of deaths. The challenge of the HEARTRONIC project is to provide a real solution for continuous monitoring and real time prevention, by means of early warning, to people already diagnosed as patients with high risk. The evolution of cardiovascular condition of these patients should be taken under close and real time control but currently this is not possible: the only option to monitor patients 24 hours a day is by hospitalization, which accounts for high costs and poses serious limitations to the patients' quality of life.

The main goal is to develop a solution that allows patients to go on with a normal life, meantime increasing their expectation and improving quality of life. Information and communication technologies (ICT) have already had a significant impact on health care and the delivery of health services. From Telemedicine to electronic health records to RFID to embedded sensors, a variety of health ICTs have been shown to improve operational and administrative efficiencies, clinical outcomes, documentation and information flow in a variety of global settings, from the home to rural health centers to large urban hospitals.

The development of this system followed the Systems Engineering Process (IEEE standard, 1999). In this process, each stage of the systems life cycle is divided in three activities:

Requirements analysis; Functional analysis; and Synthesis and design. System life cycle stages range from “System definition” to “Costumer support”, including “Subsystem definition” and “Production”. The Heartronic system is currently in the final phase of the “Subsystem definition” stage, where all subsystems are integrated and system wide tests are performed.

2. MOTIVATION AND BACKGROUND

The single most important cause of death in the adult population of the industrialized world is Sudden Cardiac Death (SCD) (Richardson, ET AL., 1996) due to coronary disease. SCD is caused by electrical problems that keep the heart from pumping the right way, whereas in a heart attack a blockage in blood vessels slows or stops blood flow. SCD causes half of all heart disease deaths. Contrary to heart attack, SCD often occurs in people who appear healthy, which can make it difficult to know who is at risk. Treating someone in SCD requires “paddles” to shock the heart, as for example implantable cardioverter-defibrillator (ICD) therapy. Chronic coronary artery disease (CAD) (Richardson, ET AL., 1996) is most commonly due to obstruction of the coronary arteries by atheromatous plaque. Patients with CAD represent the majority of patients threatened by SCD. In patients convalescing from myocardial infarction, SCD may be as high as 10% in the following 2.5 years. There are a number of other heart diseases and conditions that can lead to SCD.

2.1. Heart diseases and disorders

Heart diseases can be classified in three categories: electrical, circulatory and structural (Richardson, ET AL., 1996):

- Electrical heart diseases: Characterized by abnormal heart rhythms, called arrhythmias, caused by problems with the electrical system regulating the heartbeat.
- Circulatory: High blood pressure and coronary artery disease are the main culprits in blood vessel disorders. The results, such as stroke or heart attack, can be devastating.
- Structural: Heart muscle disease (cardiomyopathy) and congenital abnormalities are two problems that can damage the heart muscle or valves.

Millions of people experience irregular heartbeats at some point in their lives but most of these episodes are harmless and are not life threatening. However, some arrhythmias are dangerous and cause sudden cardiac death. Other heart diseases can be dangerous in their own right and can increase the likelihood of arrhythmias. Preventing the causes of SCD is the best way of preventing deaths from SCD and there are a number of common risk factors that help identify potential patients. There are a number of tests that can be used to determine if someone is in a group that is at high risk for cardiac arrest, including:

- Echocardiogram: Sound waves are used to create a moving picture of the heart. This test can measure the pumping ability of the heart and identify other problems that may increase the risk of SCD.
- Electrocardiogram: Electrodes are attached to the chest to record the electrical activity of the heart in order to identify abnormal heart rhythms. Certain arrhythmias could point to an increased risk of SCD.
- Holter monitor: Walkman-size recorder that patients attach to their chest for one to two days, recording a longer sampling of their heart rhythm. Recorded data are analyzed afterwards for signs of arrhythmia.
- Event recorder: Pager-sized device that records the electrical activity of the heart. Unlike a holter monitor, it does not operate continuously and can be used over a longer period of time. Patients turn on the device whenever they feel their heart beating too quickly or chaotically.

Other tests exist but have to be performed at a hospital or clinic and involve anesthetics. This type of invasive tests is only recommended in very specific cases. Currently available computerized monitoring systems for in hospital use are mainly based on electrocardiogram (ECG) monitoring. Fig. 1 shows a typical ECG signal, with labels for significant time intervals:

- PR interval (from beginning of P to beginning of QRS).
- QRS duration (width of most representative QRS).
- QT interval (from beginning of QRS to end of T).
- QRS axis in frontal plane.

ECG monitoring enables complex diagnosis of arrhythmias, myocardial ischemia and QT interval prolongation. SCD is in most cases related with disturbances in one or more of these parameters.

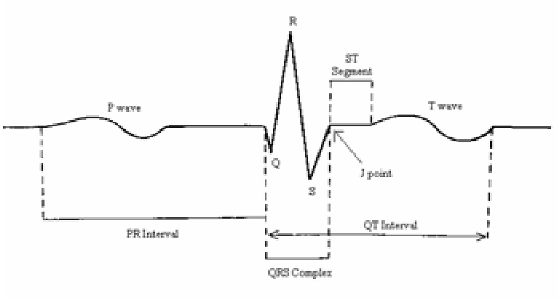


Fig 1. Typical ECG wave with main sections identified

2.2. The Heartronic project

The Heartronic project is a cooperative project involving industry and research, technological and medical partners from several European countries. The objectives of this project are not to redesign cardiology but rather to analyze medical and patients needs, to exploit existing and emergent technologies, and develop non invasive and reliable systems and safety tools that respond to doctors and patients requirements. These tools should help improving quality of life and increase life expectation in patients from groups with high risk of SCD.

The goal of Heartronic project is to develop a system that can detect, record, and analyze any heart anomaly in real time. Automatic ECG monitoring and analysis is an important part of system however, a mixed initiative approach is used to avoid over-treatment (i.e. the healthcare professional is in the control loop evaluating and validating the results of the automatic analysis). Twenty five medical conditions, not all directly related to heart diseases, have already been identified as being suitable for application of the Heartronic system. These include, for example, SCD, CAD, diabetes, hypertension, athletic heart syndrome, chronic heart failure, etc. The groups that can potentially benefit from the use of the system include (but are not limited to):

- Convalescing patients from myocardial infarction (especially in the following 6 months).
- Patients awaiting Coronary Artery Bypass Grafting and after the procedure.
- Asymptomatic patients with or without ventricular tachyarrhythmias, who have impaired left ventricular systolic function.
- Patients with known CAD or after Myocardial Infarction with syncope of unknown origin.
- Patients awaiting ICD therapy.

3. THE HEARTRONIC SYSTEMS

3.1. Concepts of Operation

The HEARTRONIC project aims to develop an innovative system for prevention and early warning of cardiovascular events, at least 2-3 hours advance, by continuous monitoring the heart conditions.

The system will be able to detect any heart anomaly in real time, warn the responsible doctor and send data all relevant data on his or hers PC, PDA or smart phone. The doctor will be able to carry out a timely diagnosis, deciding as well the most appropriate intervention to the patient. This system must be integrated in a wearable and light support like a shirt or an elastic bandage, capable to recognize cardiovascular anomalies and alert doctors and Hospitals in real time.

3.2. Architecture and Systems Components

The system architecture follows a three-tier based architecture: Client, Application and Data. Fig. 2 is a schematic description of overall architecture.

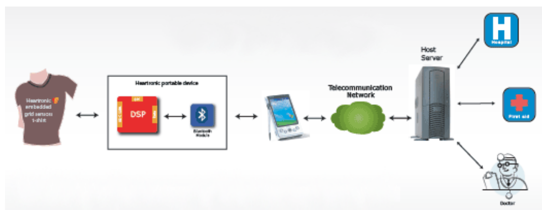


Fig 2. General system architecture

The client tier contains components such as the Heartronic t-shirt (ECG Sensor array), the Remote Unit (RU), acting as gateway, the Mobile Unit (MU), and a Personal Computer (PC). MU and PCs provide the user interface to the Heartronic application server through wireless connection. An example of a terminal is a PDA. RUs are gateways between the

Heartronic wearable processing unit (WPU) and the application tier and are responsible for integrating devices into the platform. These RUs are part of the patient equipment and they are either a PDA (or Smart Phone) with a memory card or an integrated/embedded modem for wireless connectivity.

The application (or server) tier contains the Application Server which, by handling data transfer from the client tier to the storage level, makes data access transparent to the client tier. Finally, the application server is directly connected to a database (DB) server which stores ECG patterns and additional data useful for screening, analysis and diagnosis. WPU transmits data to the RU using Bluetooth connection while the RU is able to connect to the application server using a GPRS/GSM or UMTS (if available) connection. Both RU (Client tier-Patient) and MU (Client tier-Doctor) are connected to the application server but, in particular circumstances or emergencies, the RU might be able to talk directly to MU in order to send alerts to the doctor using SMS, MMS, or triggering an emergency phone call. Furthermore, using the PC or MU, the doctor is able to view information on the patient available on the application server, in order to provide remote (mobile) diagnosis and consultation.

Heartronic t –Shirt

The Heartronic t-shirt, the ECG sensor array, is a wearable, light and comfortable device for ECG acquisition. There are several alternative methods and technologies for performing an ECG (Wung and Drew, 1999; Drew, ET AL., 1992). In order to select the method used for the Heartronic t-shirt, several prototypes were built and several problems were addressed. One of these problems is the placement of the sensors. The placement of the sensors on the body has extreme importance: they have to be placed in order to better estimate Cardiac vector and better attenuate the muscular noise interference. There are some techniques for measuring Cardiac vector components (Drew, ET AL., 1999; Drew, ET AL., 1997).

These problems can be partially resolved using a method of measurement created by Frank, and called Vectorcardiography (Frank, 1956). Fig. 3 shows the electrodes position following Frank's Leads technique. This was the technique selected for the Heartronic t-shirt, not only because from the theoretic point of view it supplies a better approximation of the heart cardiac vector, but also because from the practical standpoint it is less sensible to the electrodes position. Besides, the sensors are easy to place over a t-shirt, for example using a rubber strap (contrary to the classic 12-Lead ECG which is difficult to attach to a single strap).

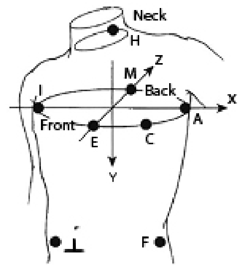


Fig 3. Orthogonal Frank's leads – X, Y, Z (8 sensors)

A drawback is that usually a physician is not interested to have an estimation of the cardiac vector, but they are interested to observe directly the ECG diagrams because they supply all the information needed (patient heart state). However, the three measured differential signals using Frank's Leads provide the projections of the heart carrier on the sagittal, frontal and transverse plane (Frank, 1956): using Dower matrix (Dower, 1968) these signals provide 12 tracks diagrams (12-Lead ECG). The WPU includes a DSP, do such mathematical transformation is not a problem. However the problem could reside in the error associated to this transformation. The DSP processor is also responsible of the first patient diagnosis using algorithms to classify ECG abnormalities (see Section 4).

After selecting the technique that will be used for ECG the next step is to guarantee that a good signal is captured, thus limiting noise amplitude. One big problem in common portable electrocardiograph is noise due to motion artifact. Two sources can generate motion artifact: the electrode metal-to-solution interface and fluctuations in skin potential due to skin stretch. The first source of artifact has been significantly reduced with modern Ag-AgCl recessed electrodes, but skin stretch remains a serious problem. Standard methods for reducing motion artifact due to skin stretch require skin abrasion, but this method has significant drawbacks: it causes patient discomfort, it results in more work for the ECG technician, and it can be ineffective for long term recordings.

The special electrode configuration suggested by Frank used for Heartronic t-shirt is less sensitive to motion artifacts and the rubber straps used to fasten the electrodes can help to prevent this kind of signal degradation. Moreover digital filters can perform another important step in this cleaning signal process: we are designing specific filters with infinite impulse response (IIR) and finite impulse response (FIR) directly embedded in the Digital Signal Processor (DSP) unit in order to eliminate this kind of artifacts, along with the noise associated with the power line capacitive effect, at the frequency of 50 Hz in Europe and 60 Hz in America.

To reduce ambient captured noise there are at least two possibilities: to screen the t-shirt using a network of electric wires covering the ECG signal wires: in this case the t-shirt could become heavier and less flexible, but the noise should be less critical; to use a network of shielded wires: in this case the t-shirt is more flexible but more sensible to noise so the filtering block should be more efficient than the first situation. We are adopting this second choice, so the Heartronic t-shirt is composed by an elastic t-shirt with three rubber straps where are attached all Frank's Leads, like it is shown in Fig. 4. The advantages of Frank's Leads configuration are obvious:

- Adaptable to patient anatomy.
- Frank's axes are parallel to anatomy body axes.
- Simplicity of electrodes placement.
- Adaptable for Heartronic t-shirt.
- Small susceptibility to interference.
- Three dimensional ST monitoring (use of Vectorcardiography in ST analysis)

Wearable Processing Unit (WPU)

Typical ECG front-end processing algorithms consist of the following phases:

- Signal acquisition and filtering (first as analog filters and then as digital filter on the DSP).
- Initialization, determines initial signal and timing thresholds, positive and negative peak determination, automatic gain control, etc.
- QRS complex detection, the reliable detection of R-peak is crucial for morphological analysis.
- Baseline correction and first diagnosis, to compensate for low-frequency ECG baseline drift.
- ST segment processing, to detect changes in the ST segment.

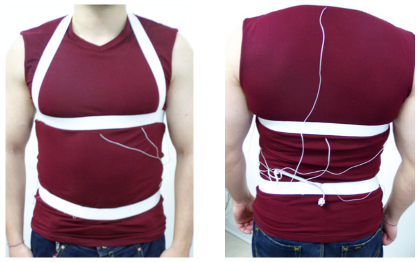
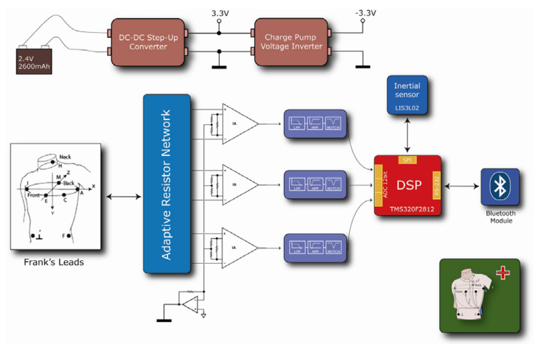


Fig 4. Heartronic T-shirt prototype

In order to detect very weak electrical signals from the heart, the WPU must have very high input impedance. A differential mode of amplification is required if the ECG is to be isolated from the large amount of 50 Hz mains interference which is always present. So, as can be seen in Fig. 5, the first stage is a differential amplifier, like instrumentation amplifier.

Fig 5. WPU detailed block diagram



The spreading electrical currents create different potentials at different points on the body, which can be sensed by electrodes on the skin surface using biological transducers made of metals and salts. This electrical potential is an alternate current (AC) signal with bandwidth of 0.05 Hz to 50 Hz, sometimes up to 100Hz. It is generally around 1-mV peak-to-peak in the presence of much larger external high frequency noise plus 50-/60-Hz interference normal-mode (mixed with the electrode signal) and common-mode voltages (common to all electrode signals). The

right leg driver is necessary because it applies an inverted version of the common-mode interference to the subject's right leg, with the aim of canceling the interference. Next to this first stage there is a sequence of analog filters, which clean the ECG signal removing noise.
The core of the WPU is a DSP that collects cleaned chest signals and acceleration data. The adaptive resistor network allows obtaining the Cardiac vector components XYZ from captured chest signals. Every component is cleaned by an analog filtering block and then is sampled by DSP ADC. The Bluetooth communication module is used by the DSP if the analysis produces an alert.

Remote Unit (RU)

The Heartronic WPU must send patient data to the application server in order to alert medical services. This data is sent from the WPU to a mobile cellular phone, used only for this purpose, and the mobile phone will send the data to the central database. Depending on the services offered by the telecommunication company, the patient information can be completed with geographic information (localization).

In case it is necessary to update some parameters on the Heartronic WPU, the central server will send the required information to the cellular phone that will deliver it to the Heartronic WPU via Bluetooth. In order to reduce the amount of information sent to the application server in order to GPRS traffic (i.e. save money and power). When some problem is detected in the ECG analysis, the information sent to the RU and from the RU to the application server is the FFT (Fast Fourier Transform) because it contains all needed information in less bytes. This is useful to enable the use of more powerful algorithms in the application Server to find out what problem the patient has and also derive the 12 ECG from the filtered signal.

Important information to be transmitted in case of a severe warning is the location of the patient, which can be derived from the phone. Presently, a rough localization through the number of the GSM or UMTS cell is available, yet very useful in case of emergency, but one should not forget that precise localization technologies are actively developed to be integrated into next generation portable phones, and will provide a very accurate localization.

Application Server

The data collected by the Heartronic t-shirt is analyzed by the WPU and, in case of alert the data will be sent to the RU, which will then send the information to the application server, by GPRS or 3G. The Server will make an analysis of the case and decide to whom the alert should be sent. The addressed person will have to make a diagnosis with all the available information (ECG, patient history and suggestions) and decide the action to take, like false alarm, call the patient or send an ambulance to pick the patient.

Database

The information collected will be stored in a central database (MS SQL Server). This database will store:

- Patient medical record: personal data, habits, clinical history, devices in use.
- Persons that interact with the system.
- Alerts: actions to take and notifications.
- Parameters for the ECG algorithm: the read raw data (VCG), the obtained ECG data, transformation matrices, parameters for the algorithm and results of the algorithm application.

4. ALGORITHM FOR CLASSIFYING ECG ABNOMALITIES

An ECG represents the electrical voltage in the heart during a contraction. Many waves, segments and intervals can be found in the ECG graphic (Drew, et al., 1999). To find irregular beats, these components have to be searched with signal analysis methods. The ECG front-end processing algorithms encompass 5 phase that were already listed in Section 3 when the WPU was described. Fig. 6 presents a detailed use case diagram of the application.

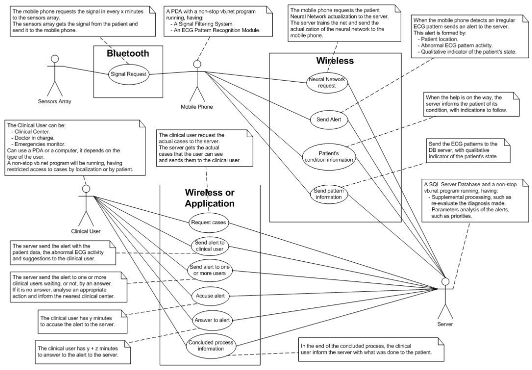


Fig 6. Use case diagram

Fig. 7 shows an example of an ECG lead I, with the marks of the ECG's components.

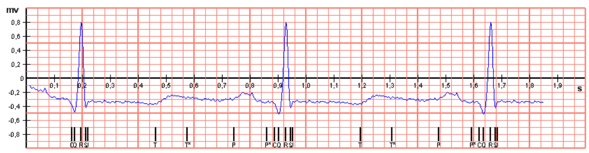


Fig 7. Visualization of an ECG's Lead I example, with components marks

As previously noted, the most commonly used clinical lead configuration is the 12-lead ECG system, which provides twelve waveforms, called leads. To provide such a 12-lead ECG, ten electrodes are placed on the patient's body and the signals from these electrodes are processed to provide the twelve leads. The Heartronic algorithms do not use 12-lead ECG. Only the Orthogonal Frank's leads - X, Y, Z (8 sensors) are needed (Frank, 1956). The 12 ECG traces can be obtained by the Frank's Leads using Vectorcardiography (Dower, 1968) - a method of measurement created by Frank. Effective filtering algorithms were developed to eliminate harmful baseline fluctuation and possible motion artifacts of the sensors used.

It was assumed that sampling rate is 512 Hz, which is a suitable choice considering that all the information of the ECG signal is contained in the range of frequencies below 100 Hz. The algorithm is composed by several blocks:

- Orthogonalisation - reduces the dimension of the signals processed in latter stages.
- Pre-processing - reduces the baseline wander, power line interference and electromyographic noise.
- Segmentation - finds the individual beats by finding the onset of P wave, the R-peak and the offset of T wave;
- Alignment - reduces changes due to respiration and body position changes.
- Matching - accounts for the remaining variation.
- Decision - takes action if the vectorcardiogram (VCG) loops and there are other anomalies.

Most of the literature concentrates on immobile patient measurements, which is a considerably easier task than the one, where the patient is monitored during its normal life.. For example, plain heart rate measurement is much less demanding than full ECG analysis. Body position changes, respiration and movement cause physical movement of the heart, which in turn is shown as changes in the measured ECG. What is more, these motion artifacts can be quite severe and may easily cause false alarm. Hence, many change detection methods are very vulnerable to these effects. Consequently, the aim of the first set of algorithms is to be insensitive to this kind of normal variation but sensitive to any abnormal changes. The sensitivity at which the arrhythmia recognition algorithms should be set is a problem. High sensitivity of the system will be connected with numerous false positive alarms (because of false ST monitoring alarms and muscle artifact simulating ventricular tachycardia). Low sensitivity may result in misdiagnosis of the potentially life threatening conditions.

Furthermore ECG monitoring does not supply sufficient information necessary to evaluate the cardiac function as a pump. It might limit preventive and diagnostic use of Heartronic especially in patients with heart failure. There are almost no published trials (Glaeser and Thomas, 1975) concerning cardiac remote monitoring so it is difficult to develop an algorithm supported by published research. The following propositions concerning Heartronic are based on our partner clinical experience and related research in the field of electrocardiography. This topic is still under development and the final algorithms will be tested in the short term.

5. CONCLUSIONS AND FUTURE WORK

The Heartronic project and its current status are presented. The goal of this project is to develop a wearable system capable of continuously monitoring and analyzing the heart condition of patients with known risk cardiovascular diseases. This system should allow patients to go on with a normal life, while increasing their expectation of life and improving quality. Currently most components of the system are developed and the first integrated tests are already planned. The algorithms for ECG monitoring and analysis are still being tested and the sensitivity at which the arrhythmia recognition should be set is still under study. Clinical trials and further testing are schedule to address this issue. Future developments of the system include changes in the WPU, with the addition of wireless communication, and the exploration of other applications were the criticality of the situation would allow the use of mesh networks and data mules to relay the data into the server.

ACKNOWLEDGMENT

The authors gratefully acknowledge the collaboration of the other partners in the Heartronic project: ACTA Service (IT), ESAPROJEKT (PL), I2M Design (E), T-Connect (I), Dunvegan (UK), AGT (I), MUG (PL), University of Oulu (FIN), S. Camillo Hospital (I).

REFERENCES

[1] IEEE standard for application and management of the systems engineering process, IEEE Std 1220-1998, Vol., Iss., 22 Jan 1999.

[2] IEEE guide for information technology - system definition - Concept of Operations (ConOps) document, IEEE Std 1362-1998, Vol., Iss., 19 Mar 1998.

[3] G. DOWER, A lead synthesizer for the Frank system to simulate the standard 12-lead ECG, Journal of Electrocardiology, 1: 101 – 116, (1968)

[4] Drew BJ, Scheinman MM, Evans GT Jr. Comparison of a vectorcardiographically derived 12-lead electrocardiogram with the conventional electrocardiogram during wide QRS complex tachycardia, and its potential application for continuous bedside monitoring. Am J Cardiol.1992;69:612–618.

[5] Drew BJ, Pelter MM, Wung SF, Adams MG, Taylor C, Evans GT Jr, Foster E. Accuracy of the EASI 12-lead electrocardiogram compared to the standard 12-lead electrocardiogram for diagnosing multiple cardiac abnormalities. J Electrocardiol 1999;32:38–47.

[6] Drew BJ, Adams MG, Pelter MM, Wung SF, Caldwell MA. Comparison of standard and derived 12-lead electrocardiograms for diagnosis of coronary angioplastyinduced myocardial ischemia. Am J Cardiol. 1997;79:639–644.Am Heart J. 2002;144:769 –781.

[7] E. FRANK, An accurate, clinically practical system for spatial vectorcardiography, circulation, 13 : 737 – 749, (1956)

[8] H. GLAESER, L. J. THOMAS. (1975). Computer monitoring in patient care. *Annual Review of Biophysics and Bioengineering*. 4. pp. 449 – 476

[9] Richardson P, McKenna W, Bristow M *et al*. Report of the 1995 World Health Organization/International Society and Federation of Cardiology Task Force on the Definition and Classification of cardiomyopathies [news]. Circulation 1996; 93: 841–2.

[10] Shu-Fen Wung, PhD, RN, and Barbara Drew, PhD, RN Comparison of 18-Lead ECG and Selected Body Surface Potential Mapping Leads in Determining Maximally Deviated ST Lead and Efficacy in Detecting Acute Myocardial Ischemia During Coronary Occlusion, Journal of Electrocardiology Vol. 32 Supplement 1999, 30-37.