

ELECTRO CARDIO GRAPH CONVERTER



By

NC Ammar Zaheer

NC Qurat-ul-Ain Salim Khan

NC Hassaan Owais

NC Aleena Zahid

Submitted to Faculty of Computer Science, Military College of Signals, National University of Sciences and Technology, Rawalpindi in partial fulfillment for the requirements of BE Degree in Computer Software Engineering

March 2007

ABSTRACT

Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. This has been a major issue confronting a uniform e-Health environment, more so in exchange of electronic health records (EHR). Our project, a blend of research and application development converts the Electro cardiograph (ECG) output files from equipment implementing major Health care standards into a standard format. The project has been done in collaboration with Armed Forces Institute of Cardiology, National Institute of Heart Diseases (AFIC-NIHD).

Many ECG standards are being used around the globe. Our project focuses on three major standards, Health Level 7 (HL7), Digital Imaging and Communications in Medicine (DICOM) and Standard Communication Protocol for Computer-Assisted Electrocardiography (SCP-ECG). Our application reads the file from any of the three standards, extracts the waveform and encoded Meta data, translates it into an xml file and then converts it into DAT format. DAT format is the ECG file format used by MIT / Physionet for research purposes in the study of ECGs. ECGC is developed in Java.

The ECG files converted by ECGC can be used by software packages that are format specific like VT Detection System and Cardio Genic. These systems can be deployed in a real time environment.

DECLARATION

No portion of the work presented in this dissertation has been submitted in support of any other award or qualification either at this institution or elsewhere.

DEDICATION

In the name of Allah, the Most Merciful, the Most Beneficent

To our parents, without whose unflinching support and unstinting cooperation, a work of
this magnitude would not have been possible

ACKNOWLEDGMENTS

We are grateful to Almighty Allah for bestowing us with the strength and resolve to undertake and complete the project.

We gratefully recognize the continuous supervision and motivation provided to us by our Project Supervisor, Commandant (MCS-NUST), Brig Dr. MUHAMMAD AKBAR. A lot of effort and contribution has been put in by our external supervisor Brig Dr. IMRAN MAJEED (Head of Department Clinical Cardiac Electrophysiology AFIC-NIHD). Not only is he a cardiologist of international repute but also the fore runner in R and D at AFIC. Being the only electro physiologist in Pakistan, he has an obvious desire to see people exploring this field. Special thanks to all the faculty members of MCS who have taught us. We are grateful to the staff of cardiac electrophysiology department for being very tolerant and helpful with our work. We deeply treasure the unparalleled support and tolerance that we received from our friends for their useful suggestions that helped us in completion of this project. We are also deeply obliged to our families for their never ending patience and support for our mental peace and to our parents for the strength that they gave us through their prayers.

And above all, a word of thanks to the **MILITARY COLLEGE OF SIGNALS (MCS)** as it had been our foundation and has made us capable to undertake the project.

TABLE OF CONTENTS

| | |
|--|-----------|
| LIST OF FIGURES | VIII |
| LIST OF TABLES | IX |
| | |
| 1 Introduction | 1 |
| | |
| 1.1 PREFACE | 1 |
| 1.2 ECG AND ECG DEVICES | 2 |
| 1.2.1 ELECTROCARDIOGRAM (EKG,ECG): | 2 |
| 1.2.2 CLINICAL CARDIAC ELECTROPHYSIOLOGY AND ECG DEVICES: | 5 |
| 1.2.3 STANDARDS | 8 |
| 1.3 CONCEPT EVOLUTION | 9 |
| 1.4 THE PROJECT | 10 |
| 1.4.1 SCOPE | 10 |
| 1.4.2 OBJECTIVES | 10 |
| 1.5 WORK BREAKDOWN STRUCTURE | 13 |
| 1.6 RESEARCH OBJECTIVES | 15 |
| 1.6.1 PROJECT GOALS AND OBJECTIVES | 15 |
| 1.6.2 DELIVERABLES | 15 |
| | |
| 2 ECG Standards..... | 16 |
| | |
| 2.1 DIGITAL IMAGING AND COMMUNICATIONS IN MEDICINE | 16 |
| 2.2 STANDARD COMMUNICATION PROTOCOL FOR COMPUTER-ASSISTED ELECTROCARDIOGRAPHY | 20 |
| 2.3 HEALTH LEVEL 7 | 22 |
| 2.4 COMPARISON BETWEEN THE STANDARDS | 23 |
| 2.5 PROPOSED STANDARD | 24 |
| | |
| 3 Design and Implementation of ECG waveform Extraction Procedures..... | 29 |
| | |
| 3.1 STANDARD COMMUNICATIONS PROTOCOL IN COMPUTER ASSISTED ELECTROCARDIOGRAPHY (SCP-ECG) | 29 |
| 3.1.1 IMPLEMENTATION | 30 |
| 3.2 DIGITAL IMAGING AND COMMUNICATIONS IN MEDICINE (DICOM) | 32 |
| 3.2.1 IMPLEMENTATION | 34 |
| 3.3 HEALTH LEVEL 7 (HL7) | 35 |
| 3.3.1 IMPLEMENTATION | 36 |
| 3.3.2 THE OUTPUT FILE FORMAT | 36 |
| 3.4 FLOWCHART | 37 |
| | |
| 4 ECGC and Arrhythmia Detection System..... | 38 |

| | | |
|------------|--|------------|
| 4.1 | INTRODUCTION | 38 |
| 4.2 | HOW TO USE THE SOFTWARE | 38 |
| 4.3 | MAIN MENU | 39 |
| | 4.3.1 ECGC | 39 |
| | 4.3.2 HELP | 41 |
| | 4.3.3 DOCUMENTATION | 41 |
| | 4.3.4 ABOUT | 42 |
| 4.4 | HOW TO USE VTDS | 43 |
| 4.5 | MENUS AND WORKING | 43 |
| 4.6 | STANDARD SETTINGS | 43 |
| 4.7 | ILLUSTRATION OF ALL COMPONENTS OF ECG ANALYZER: | 43 |
| 4.8 | STEPS FOR GENERAL ANALYSIS: | 48 |
| | | |
| 5 | Testing and Results | 50 |
| | | |
| 5.1 | TESTING | 50 |
| 5.2 | RESULTS | 50 |
| | 5.2.1 OVERALL RESULTS | 50 |
| 5.3 | GRAPHS | 51 |
| 5.4 | COMPARISONS | 52 |
| | | |
| 6 | Conclusion and Future Work | 53 |
| | | |
| 6.1 | CONCLUSION | 53 |
| 6.2 | FUTURE WORK | 53 |
| | | |
| | Annexure A: Result Tables | 55 |
| | Annexure B: System Requirement Specification Document | 59 |
| | Annexure C: Software Development Plan Document | 69 |
| | Annexure D: Test Plan Document | 91 |
| | Annexure E: Definitions, Acronyms and Abbreviations | 105 |
| | References..... | 107 |

LIST OF FIGURES

| <i>Number</i> | <i>Caption</i> | <i>Page</i> |
|---------------|--|-------------|
| Figure 1-1: | ECG Signal Characteristics | 2 |
| Figure 1-2: | Different QRS Complexes | 3 |
| Figure 1-3: | Holter Machine | 6 |
| Figure 1-4: | MAC 5000 | 7 |
| Figure 2-1 : | Scope of DICOM | 17 |
| Figure 2-2: | Conformance Statement Document | 18 |
| Figure 2-3: | Transport Message Exchange | 20 |
| Figure 2-4: | Message Structure for ECG data exchange | 24 |
| Figure 2-5: | Internal Structure of a Data set or Module | 26 |
| Figure 2-6: | Secure Transmission of ECG message on a reliable TCP/IP connection | 27 |
| Figure 3-1: | An SCP ECG Record | 29 |
| Figure 3-2: | An SCP ECG Header Details | 30 |
| Figure 3-3: | Basic File Structure | 32 |
| Figure 3-4: | File Header | 33 |
| Figure 3-5: | Flow Chart | 37 |
| Figure 4-1: | Introduction | 38 |
| Figure 4-2: | Main Menu | 39 |
| Figure 4-3: | ECGC | 40 |
| Figure 4-4: | Help | 41 |
| Figure 4-5: | Documentation | 41 |
| Figure 4-6: | About | 42 |
| Figure 5-1: | Arrhythmia Graph | 51 |
| Figure 5-2: | Conversion Graph | 52 |

LIST OF TABLES

| <i>Number</i> | <i>Caption</i> | <i>Page</i> |
|---------------|-------------------------|-------------|
| Table 2-1: | Comparison of Standards | 23 |
| Table 5-1: | Conversion | 50 |
| Table 5-2: | Results of VTDS | 51 |

1 Introduction

1.1 Preface

The **IEEE** defines interoperability as:

The ability of two or more systems or components to exchange information and to use the information that has been exchanged

The term interoperability is used to describe the capability of different programs to exchange data via a common set of business procedures, and to read and write the same **file formats** and use the same **protocols**. The lack of interoperability strongly implies that the described product or products were not designed with **standardization** in mind. Indeed, interoperability is not taken for granted in the non-standards-based portion of the computing.

According to **ISO/IEC 2382-01**, *Information Technology Vocabulary, Fundamental Terms*, interoperability is defined as follows: "*The capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units*".

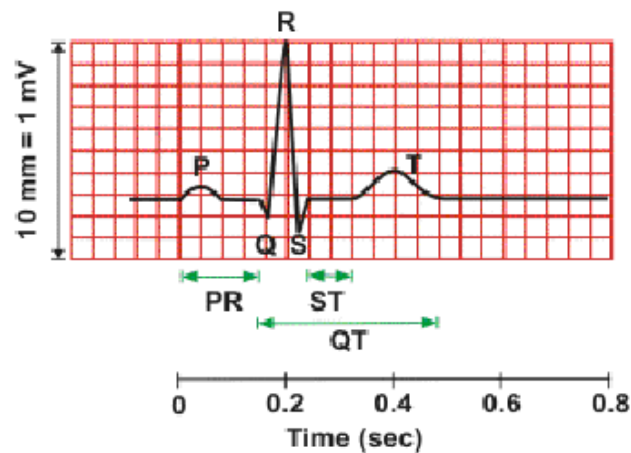
Interoperability frequently has a major impact on the organization concerned, including issues of ownership (do people want to share their data?), staff (are people prepared to undergo training?) and usability. Interoperability can have important **economic** consequences, such as **network externalities**. If competitors' products are not interoperable, the result may well be **monopoly** or **market failure**. For this reason, it may be prudent for user communities or governments to take steps to encourage interoperability in various situations.

Interoperability can be achieved in four ways: through product engineering, industry/community partnership, access to technology and IP, and implementation of standards.

1.2 ECG and ECG Devices

1.2.1 Electrocardiogram (EKG,ECG):

As the heart undergoes depolarization and re-polarization, the electrical currents that are generated spread not only within the heart, but also throughout the body. This electrical activity generated by the heart can be measured by an array of electrodes placed on the body surface. The recorded tracing is called an electrocardiogram (ECG, or EKG). The different waves that comprise the ECG represent the sequence of depolarization and re-polarization of the atria and ventricles. The ECG is recorded at a speed of 25 mm/sec, and the voltages are calibrated so that 1 mV = 10 mm in the vertical direction. Therefore, each small 1-mm square represents 0.04 sec (40 msec) in time and 0.1 mV in voltage.



P wave (0.08 - 0.10 s) QRS (0.06 - 0.10 s)
P-R interval (0.12 - 0.20 s) Q-T_c interval (≤ 0.44 s)*

Figure 1-1: ECG Signal Characteristics

The **P wave** represents the wave of depolarization that spreads from the SA node throughout the atria, and is usually 0.08 to 0.1 seconds (80-100 ms) in duration. The brief

isoelectric (zero voltage) period after the P wave represents the time in which the impulse is traveling within the AV node (where the conduction velocity is greatly retarded) and the bundle of His.

The period of time from the onset of the P wave to the beginning of the QRS complex is termed the **P-R interval**, which normally ranges from 0.12 to 0.20 seconds in duration. This interval represents the time between the onset of atrial depolarization and the onset of ventricular depolarization. If the P-R interval is >0.2 sec, there is an AV conduction block, which is also termed a first-degree heart block if the impulse is still able to be conducted into the ventricles.

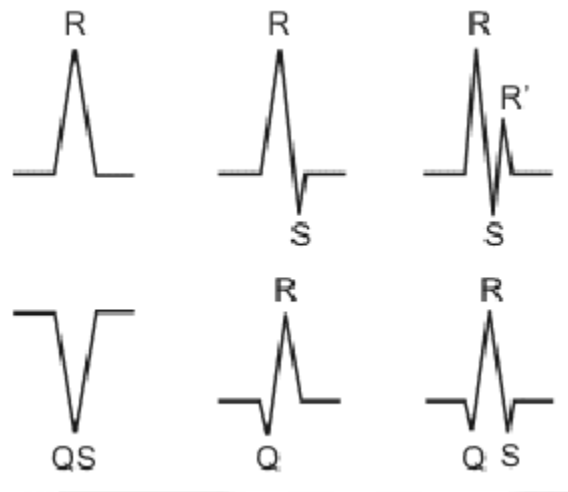


Figure 1-2: Different QRS Complexes

The **QRS complex** represents ventricular depolarization. The duration of the QRS complex is normally 0.06 to 0.1 seconds. This relatively short duration indicates that ventricular depolarization normally occurs very rapidly. If the QRS complex is prolonged (> 0.1 sec), conduction is impaired within the ventricles. This can occur with bundle branch blocks or whenever a ventricular foci (abnormal pacemaker site) becomes the pacemaker driving the ventricle.

Such an ectopic foci nearly always results in impulses being conducted over slower pathways within the heart, thereby increasing the time for depolarization and the duration of the QRS complex.

The shape of the QRS complex in the above figure is idealized. In fact, the shape changes depending on which recording electrodes are being used. The shape will also

change when there is abnormal conduction of electrical impulses within the ventricles. The figure to the right summarizes the nomenclature used to define the different components of the QRS complex.

The isoelectric period (**ST segment**) following the QRS is the time at which the entire ventricle is depolarized and roughly corresponds to the plateau phase of the ventricular action potential. The ST segment is important in the diagnosis of ventricular ischemia or hypoxia because under those conditions, the ST segment can become either depressed or elevated.

The **T wave** represents ventricular re-polarization and is longer in duration than depolarization (i.e., conduction of the re-polarization wave is slower than the wave of depolarization). Sometimes a small positive U wave may be seen following the T wave. This wave represents the last remnants of ventricular re-polarization. Inverted, or prominent U waves indicates underlying pathology or conditions affecting re-polarization.

The **Q-T interval** represents the time for both ventricular depolarization and re-polarization to occur and therefore roughly estimates the duration of an average ventricular action potential. This interval can range from 0.2 to 0.4 seconds depending upon heart rate. At high heart rates, ventricular action potentials shorten in duration, which decreases the Q-T interval. Because prolonged Q-T intervals can be diagnostic for susceptibility to certain types of tachyarrhythmias, it is important to determine if a given Q-T interval is excessively long. In practice, the Q-T interval is expressed as a "corrected Q-T (QTc)" by taking the Q-T interval and dividing it by the square root of the R-R interval (interval between ventricular depolarization). This allows an assessment of the Q-T interval that is independent of heart rate. Normal corrected Q-Tc intervals are less than 0.44 seconds.

There is no distinctly visible wave representing atrial repolarization in the ECG because it occurs during ventricular depolarization. Because the wave of atrial repolarization is relatively small in amplitude (i.e., has low voltage), it is masked by the much larger ventricular-generated QRS complex.

ECG tracings recorded simultaneous from different electrodes placed on the body produce different characteristic waveforms.

1.2.2 Clinical Cardiac Electrophysiology and ECG Devices:

Clinical cardiac electrophysiology is a branch of the medical specialty of cardiology concerned with the study and treatment of rhythm disorders of the heart. Electro-physiologists are trained in the mechanism, function, and performance of the electrical activities of the heart. Electro-physiologists work closely with other cardiologists and cardiac surgeons to assist or guide therapy for heart rhythm disturbances (arrhythmias).

An **electro-physiologic study** is a term used to describe a number of invasive (intracardiac) and non-invasive recording of spontaneous electrical activity as well as of cardiac responses to programmed electrical stimulation. These studies are performed to assess arrhythmias, elucidate symptoms, evaluate abnormal electrocardiograms, assess risk of developing arrhythmias in the future, and design treatment.

In addition to diagnostic testing of the electrical properties of the heart, electro-physiologists are trained in therapeutic methods to treat many of the rhythm disturbances of the heart. Therapeutic modalities employed in this field include anti-arrhythmic drug therapy and implantation of pacemakers and implantable cardioverter-defibrillators.

In any circumstances, the ECG Devices play the most important part in the world of Cardiac Electrophysiology. The devices taken under study during the course of the project are discussed:

- **Holter**

The Holter is a recording device that comes in two different forms: a small portable tape recorder (like a walkman), or a small digital device the shape of a pager. The patient wears the device on a belt round his waist. Four or six ECG leads from the device are taped to the chest. The device records the electrical activity of the heart for 24 to 48 hours or for up to 7 days if a digital one is used. The doctor can then analyze the electrical activity and rhythm of your heart to find out if you have any arrhythmias.

These are more sophisticated versions of the basic Holter. Whenever you have an attack of symptoms, you can activate the device to record your heart's rhythm (cardiomemo). The advantage of the cardiomemo is that it doesn't have any leads, so you can just place it on your chest when you get symptoms, without having to put any leads in position.

The Aria recorder is state-of-the-art Holter monitoring made simple. No larger than a typical pager, it uses four leads to record three channels of patient data. Worn under the shirt in a chest pouch or clipped to the patient's belt, Aria monitors can record up to 48 hours of full-fidelity ECG data without data compression.

Pathfinders unparalleled analysis speed and accuracy, is based on the ergonomics and workflow of the system, the accuracy of its automatic analysis and the level of interaction and control, that Pathfinder provides the trained operator. Together this provides for a rapid and confident result, from even the most challenging ECG recording.

Symphonet is the latest innovation in Holter Communication technology. As easy to use as it is secure, Symphonet adds a new dimension to information management in Holter analysis. In its simplest form, Symphonet allows you to securely transfer raw ECG from any remote site to a central analysis location. A PDF of the Holter report is returned via the same secure route for review at the remote site. Whether in a large Hospital, Group Practice or Clinical Research environment Symphonet helps you maximize the efficiency with which Holter ECG is analyzed and reports shared.



Figure 1-3: Holter Machine

- **GE MAC 5000**

The MAC 5000 system is the new standard in the modular automation for scientific applications. All aspects of the MAC 5000 have been designed for simplicity. The stacking module concept, the flexible interfacing, the comprehensive array of component modules, all makes the MAC 5000 the choice for complete automation.

The ability to unify all the automation into a single controller dramatically simplifies system design, programming, implementation and troubleshooting. There are no boards to install into the computer only a standard RS-232 or USB interface. Each module is configurable either via hardware switches or by software override.

The LEP philosophy makes basic operation and programming of the MAC 5000 system easy. While at the same time sophisticated commands are available that enables an application to fine tune the system for the vital performance edge.

Manual joystick control is always available. While it may seem mundane, this feature can save costs in terms of hardware integration and processing overhead. Each module supports either analog joystick or digital digipot control. In some cases both inputs are simultaneously supported.



Figure 1-4: MAC 5000

- **Signal-Averaged Electrocardiogram**

A signal-averaged electrocardiogram (SAECG) is a more detailed type of ECG. During this procedure, multiple ECG tracings are obtained over a period of approximately 20 minutes in order to capture abnormal heartbeats which may occur only intermittently. A computer captures all the electrical signals from the heart and averages them to provide the physician more detail regarding how the heart's electrical conduction system is working.

SAECG is one of several procedures used to assess the potential for arrhythmias (irregular heart rhythms) in certain medical situations.

An SAECG may be performed almost anywhere, as the equipment is very compact and portable. Thus, an SAECG can be done in physician's office, the ECG department of a hospital or clinic, in a procedure or testing area, in the Emergency Department, or even in a hospital room or bed. The equipment used includes the ECG machine, skin electrodes, and lead wires, which attach the electrodes to the ECG machine. The patient has to lie flat on a table or bed for the procedure. It will be important to lie still and not talk during the procedure, so as not to interfere with the tracing.

1.2.3 Standards

The basic interoperability between medical devices and host systems is a key requirement to ensure standardized, readily-transferable patient medical records. A prerequisite for interoperability is standardization of message formats, protocols and storage. But different manufacturers use different standards with different scopes and standardization philosophies. This raises the disparity between existing equipment.

In order to promote a multi-vendor environment, a standard format for digital ECG storage and data exchange is desirable. Currently the market has heterogeneous hardware and software platforms which are generally integrated to some extent using costly and cumbersome propriety interfaces, which will soon become obsolete as technology advances. Currently there are various standards, mostly proprietary, that are followed

around the globe. Some of the well known standards include, DICOM, HL7, SCP-ECG, MFER etc.

Digital ECG waveform processing can be reduced to 3 principal stages:

- Data acquisition, encoding, transmission and storage
- Pattern recognition and feature extraction, i.e. ECG measurement
- Diagnostic classification

Out of these three, the first stage is essential for developing a standard.

Out of the many ECG standards used around the globe, the three most widely made use of are SCP-ECG, DICOM and HL7. Our research is focused on these three standards.

1.3 Concept Evolution

The project has been evolved in a series of steps as the search started early in the fifth semester, about a year and a half back. There were many triggering events and motivating factors that led us to select this project of such great caliber. In search of such a project we went to various organizations like CARE, NIIT and various software houses but eventually we landed up in AFIC-NIHD. We were convinced that we should do our degree project in the field of biomedicine. Thus we were enthused to take up this uphill task. After rigorous meetings and interactions with DS and domain experts it was decided to carry forward the work done on the same field and develop an altogether new, interoperable and implementable system which takes the ECG signal in any format as input and provide arrhythmia detection. The main aim was to provide AFIC-NIHD with workable software to detect cardiac diseases. Each day leads us to new venues of exploration and learning and gradually the system idea became clear.

1.4 The Project

1.4.1 SCOPE

The project has a stupendous scope for the time to come .This is one of the first projects of its kind in Pakistan in the field of clinical cardiac electrophysiology to present a fully interoperable environment for arrhythmia detection using Beat to Beat Analysis and classification as well.

The project scope includes its colossal market value and great research potential. The product cannot only be installed in hospitals but it also invites new courses of undergraduate and even graduate level for research and development. The system places a new concept in the field of non-invasive treatments in general and the field of cardiology in particular.

1.4.2 Objectives

The project had many multi dimensional objectives which were achieved with the course of time by ALLAH's Grace. These objectives are delineated as follows:

1.4.2.1 Immediate Objective

- To develop a completely interoperable system that could take ECG signal of any format as an input and detect cardiac arrhythmias.
- To provide a generalized solution to the problem by taking under consideration the specific system requirements of AFIC.
- To develop a GUI based software on computer showing the ECG analysis of the input signal of any standard.
- To built user friendly architecture for both the static and dynamic data.
- To apply all the engineering skills, hardware knowledge and software expertise in the development of this system.

1.4.2.2 Future / Subsequent Objectives

The future objectives of developing the system are as follows;

- After validation and thorough experimentation this system can be installed at the hospitals.
- The software can be used to detect all types of VT with greater efficiency and accuracy.

1.4.2.3 Project Beneficiaries

The project beneficiaries include the hospital for which the system has been developed i.e. AFIC/NIHD. Apart from that this project can benefit not only those who want to take up the field of bio-medical research engineering but also the ones who are interested in Detection Systems Development. Involving many dimension of exploration this project is capable of producing new vistas of R & D in the college.

1.4.2.4 Project Title

Business Title: ECGC

Technical Title: Electrocardiography converter and arrhythmia detection system

1.4.2.5 Project Descriptions

The system contains the following vital features which are to be known by the user;

Platform: The system will be implemented on Windows XP (due to familiarity of end user) machine. It is recommended that the service be run on minimum Intel based 1.0 GHz microprocessor with minimum of 256 MB RAM since the system is real time.

Development Environment:

Software: The software main module is made in JAVA jdk 1.5.1 and MATLAB Version 7.0. Moreover, C++ has also been used for wfdb library. In addition help and guidance has been taken from JAVA, MATLAB documentation and also from the internet. The methodology followed is Spiral Model

Testing Environment: Testing was conducted after the successful completion of each module and in case of an error a bug report was being generated. The testing was conducted in accordance with IEEE standard 1058a-1998.

1.4.2.6 Project Specifications

The Project is being developed for AFIC-NIHD Electrophysiology Department; it is aimed at providing an interoperable environment for detecting cardiac arrhythmias with higher accuracy and sensitivity, thus laying a new concept in the field of non-invasive treatment and electrocardiography research. This system allows input of ECG file of any format to detect tachyarrhythmias and also shows different views of ECG storing the valuable information. These are the functionalities which are not provided in conventional ECG system.

Project Limitations / Constraints

The software was tested and analyze thoroughly and the limits and constraints of the system are as follows:

- There are dozens of standards followed around the globe, most of them quite rarely though, the system does not cater for all those standards.
- The waveform display in CI System is real time but it has to be configured with the deployed ECG System.

1.5 Work Breakdown Structure

For the successful completion of the project, the project was divided into main modules and structures. It was ensured that each task being assigned was carried out appropriately and on time.

Requirements Engineering

1. Requirements Elicitation
 - i. Interaction with Domain Expert
 - ii. Understanding basis of ECG, Standards and study related Problems

2. Developing Problem Statement
 - i. SRS Preparation

3. Solutions Evaluations
 - i. Analyze various options Available (i.e. Platform Compatibility, Language)
 - ii. Propose the best Approach to Problem Solution

4. Analysis
 - i. Feasibility Study

5. Assignment and Planning
 - i. Assignment of Tasks to the syndicate members
 - ii. Preparation of Gantt Charts
 - iii. Preparation of TimeLine Charts

Literature Review

1. ECG Systems Research Work
2. ECG Standards Research Work
3. DAT Format Research Work Study

Software Module

1. Algorithm Design

- i. Parameters Design
- ii. Working out the best Techniques
- iii. Basic Modules
 1. SCP-ECG to DAT converter
 2. DICOM to DAT converter
 3. HL7 to DAT converter
 4. GUI
- iv. Real Time ECG Display
- v. Main Menu
- vi. Converter
- vii. Miscellaneous Information
- viii. ECG Analyzer
 1. Step by Step ECG View
 2. All Parameters View
 3. Noise Factor Results
 4. Results and Graphs View

Integration and Testing

- Prepare test Cases
- Black Box Testing
- White Box Testing
- Validation
- Verification

Documentation

- Preparation of System Manual
- Preparation of Data Dictionary
- Detailed Thesis
- Research Papers and Publications
- User Manuals

Refinement

To refine certain short comings in the System

1.6 Research Objectives

1.6.1 Project Goals and Objectives

The objectives of the project were:

- (a) To develop a completely interoperable system that could take ECG signal of any format as an input and detect cardiac arrhythmias.
- (b) To provide a generalized solution to the problem by taking under consideration the specific system requirements of AFIC.
- (c) To develop a GUI based software on computer showing the ECG analysis of the input signal of any standard.

1.6.2 Deliverables

Deliverables of the project are:

- (a) EXE code of ECGC
- (b) Stored results files for reusability
- (c) Comparison Graphs

2 ECG Standards

A pre-requisite for interoperability is standardization of message formats, protocols and storage. But different manufacturers use different standards with different scopes and standardization philosophies. This raises the disparity between existing equipment.

In order to promote a multi-vendor environment, a standard format for digital ECG storage and data exchange is desirable. Currently the market has heterogeneous hardware and software platforms which are generally integrated to some extent using costly and cumbersome propriety interfaces, which will soon become obsolete as technology advances. Thus a better method to exchange data would be eagerly welcomed.

The key standards followed around the globe in the field of cardio electrophysiology are discussed.

2.1 Digital Imaging and Communications in Medicine

Digital Imaging and Communications in Medicine (DICOM) is a comprehensive set of standards for handling, storing, printing, and transmitting information in medical imaging made by ACR/NEMA organization. DICOM developed the Waveform Standard (DICOM 3.0 Supplement 30), which addressed the robust interchange of waveforms. This includes ECG, electrophysiological and hemodynamic curve data, such as pressures flow signals, independent from sampling frequency, amplitude and system sensitivity. Furthermore, audio signals such as voice comments can be entered.

This Standard embodies a number of major enhancements:-

- It is applicable to a networked environment. The previous versions were applicable in a point-to-point environment only; for operation in a networked

environment a Network Interface Unit (NIU) was required. DICOM Version 3.0 supports operation in a networked environment using industry standard networking protocols such as OSI and TCP/IP.

- It specifies how devices claiming conformance to the Standard react to commands and data being exchanged. Previous versions were confined to the transfer of data, but DICOM Version 3.0 specifies, through the concept of Service Classes, the semantics of commands and associated data.
- It specifies levels of conformance. Previous versions specified a minimum level of conformance. DICOM Version 3.0 explicitly describes how an implementer must structure a Conformance Statement to select specific options.
- It is structured as a multi-part document. This facilitates evolution of the Standard in a rapidly evolving environment by simplifying the addition of new features. ISO directives which define how to structure multi-part documents have been followed in the construction of the DICOM Standard.
- It introduces explicit Information Objects not only for images and graphics but also for studies, reports, etc.
- It specifies an established technique for uniquely identifying any Information Object. This facilitates unambiguous definitions of relationships between Information Objects as they are acted upon across the network.

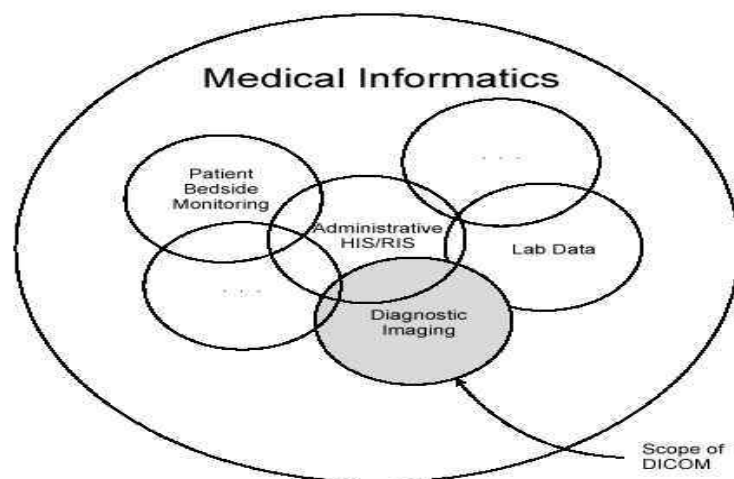


Figure 2-1: Scope of DICOM

DICOM version 3.0 consists of the following nine parts:

- **PS 3.1:** Introduction and Overview (this document)
- **PS 3.2:** Conformance
- **PS 3.3:** Information Object Definitions
- **PS 3.4:** Service Class Specifications
- **PS 3.5:** Data Structure and Encoding
- **PS 3.6:** Data Dictionary
- **PS 3.7:** Message Exchange
- **PS 3.8:** Network Communication Support for Message Exchange
- **PS 3.9:** Point-to-Point Communication Support for Message Exchange

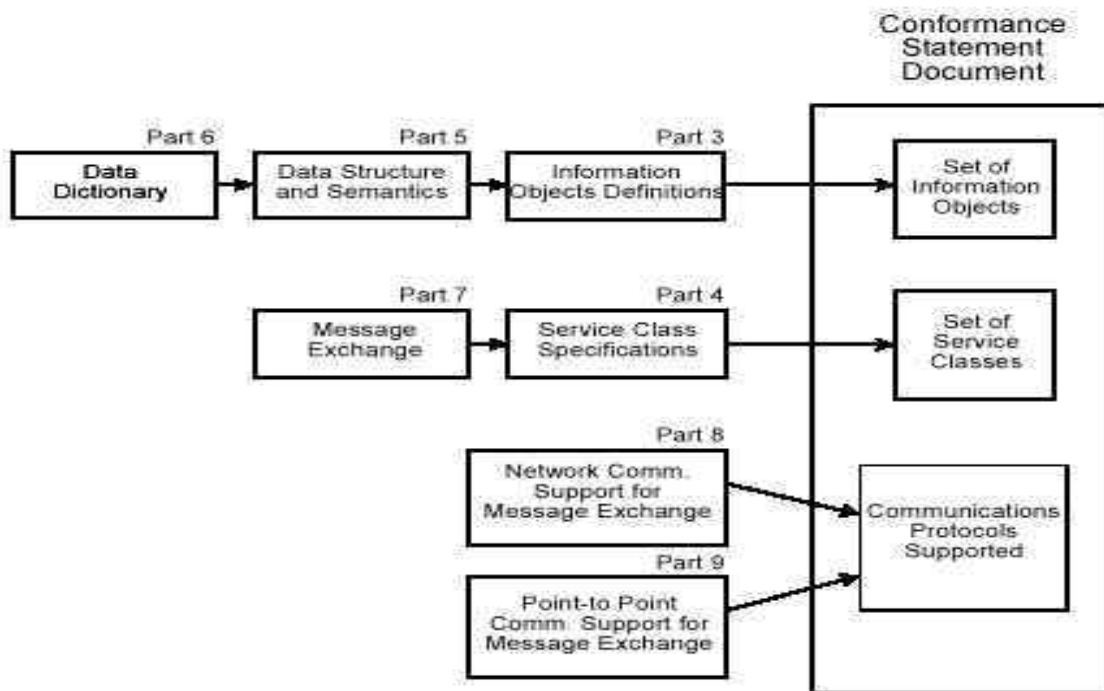


Figure 2-2: Conformance Statement Document

- **Data Storage:** In DICOM information is stored as DICOM file-sets. Each DICOM file represents a separate class of information. These files in the file set contain a collection of data elements known as the Data set. Internally these data sets are maintained in a tree structure. Each data set contains elements which comprise of a) a tag, b) a value length and c) a value field. Besides this core data, additional Meta information is stored. The waveform object carries the raw

waveform sample data only; it does not specify how the waveforms are to be displayed.

- **Data acquisition:** In order to identify a DICOM file-set and to facilitate accessing the information stored in the DICOM files of the file-set, the DICOM standard has defined the Basic Directory IOD (Information Object Definition). A DICOM file-set contains one or more DICOM files. One of the files contained in the file-set is the DICOMDIR file, which contains information about other files in the file-set. Supplement 30 has defined three waveform classes: 12-lead, Resting ECG and Exercise ECG. This waveform data is organized into channels.
- **Data Compression:** DICOM uses the deflated transfer syntax, to apply a lossless ZIP compression to all data. Transfer syntax is a part of the DICOM Presentation Context which specifies a set of encoding rules that allow Applications to unambiguously negotiate the encoding techniques, they are able to support, thereby allowing these Applications to communicate. It also provides a mechanism for supporting the use of Run Length Encoding (RLE) Compression which is a byte oriented lossless compression scheme through the encapsulated Format.
- **Transmission:** Its communication protocol is an application protocol that uses Transmission Control Protocol / Internet Protocol (TCP/IP) to communicate between systems. Its Transport Layer Secure (TLS) protocol provides a means of adding security to DICOM communication. The security added targets three main areas: a) Authentication, b) Confidentiality and c) Data Integrity. Authentication is carried out using a series of challenges and responses between the "client" and the "server". Confidentiality is achieved by encrypting the data sent over the communication channel. Data integrity is maintained by using message authentication codes for each packet sent across a DICOM Network.

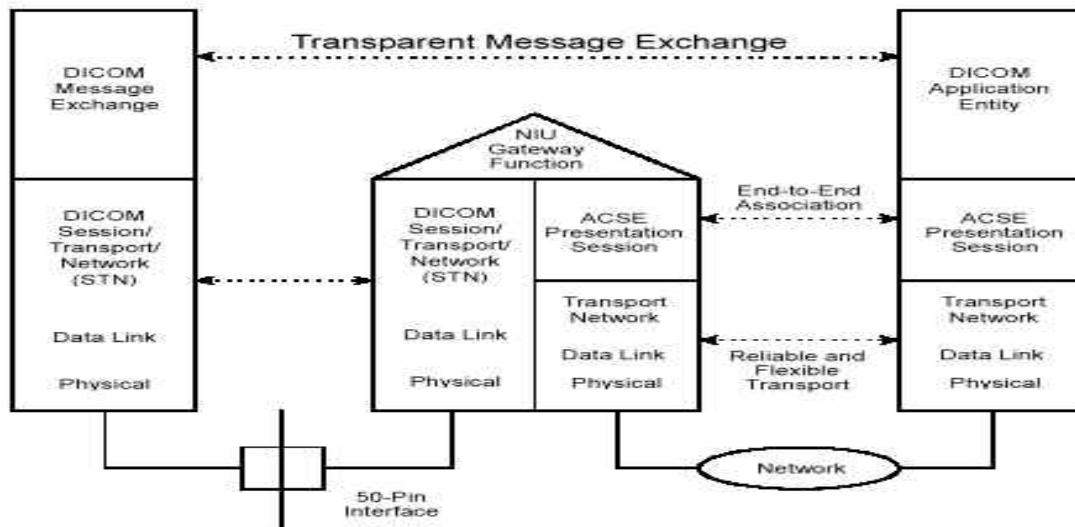


Figure 2-3: Transport Message Exchange

- **Implementation:** The implementation of DICOM waveforms is possible using an existing DICOM toolkit. It is an Open Source toolkit named “The OFFIS DICOM conformance testing tool”.

In summary, DICOM supports a good variety of waveform data and allows the integration of further types.

2.2 Standard Communication Protocol for Computer-Assisted Electrocardiography

Standard Communication Protocol for Computer-Assisted Electrocardiography (SCP-ECG) is a standard that specifies the interchange format and a messaging procedure for standardized transmission of ECGs between various computer systems and electrocardiographs. It is a project of OpenECG.

- **Data storage:** All ECG files are stored in a record format. This record is divided into different sections which in turn are divided into two parts a) ID header and b) data part. Global fields in the data structure are CRC checksum, size of record, Pointer to the record, Header, ECG data and various types of processing results.

This format allows for a rather large number of options to store and format the ECG data.

- **Data acquisition:** In SCP information is stored in a record format which has a built-in self identification mechanism. Its pointer section gives an overview of what is within the whole record with information from the header of each section. This information can determine the possible options for the information content of that section and locate and access the required information from the required data field.
- **Data Compression:** SCP employs Huffman tables for entropy dependent encoding to achieve data compression. This type of encoding allows the transmission of the original ECG data by dense bit packing. It provides a well-assessed support for lossless and lossy ECG compression and achieves compression ratios up to 20:1. It ensures that the errors in the reconstructed signal are maintained within thresholds described in the standard itself, sufficient to guarantee a correct re-interpretation of the ECG signal.
- **Transmission:** It uses an enhanced XMODEM data transport protocol. It is an error free file transfer protocol. It breaks up the original data into a series of packets that are sent to the receiver, along with additional information allowing the receiver to determine whether that packet was correctly received. It uses checksum method for error checking. It has disadvantages in terms of speed, performance and recovery functionalities. A physical link between the systems involved in the file transfer is necessary.
- **Implementation:** For the implementation of SCPECG detailed Implementation guides are available. OpenECG portal is one source for easy and free access to these guides.

2.3 Health Level 7

Health Level 7 (HL7) is currently the selected standard for the interfacing of clinical data in most institutions. For waveform data only ECG is integrated into HL7 V3. The ECG is called aECG or Annotated ECG.

- **Data Storage:** It defines very simple data structures and messages for exchanging waveform data. The data that is acquired is stored as a collection of digital information represented as sequence sets of numbers, using xml coding. Annotations are added. The waveform samples are organized into channels, and codes are used to identify concepts such as channel or measurement units.
- **Data acquisition:** It defines a kind of standard format for information exchange. Many value fields inside the segments are optional. It uses OIDs (Object Identifiers). OIDs are strings of numbers separated by dots. Each number indicates a branch in a tree of identifiers. It makes use of a self-identifying and self-delimiting encoding scheme, thus each data value can be identified, extracted and decoded individually without knowing the structure of the message.
- **Data Compression:** HL7 does not compress waveforms. Thus does not employ any compression techniques. It transmits and operates on raw ECG data.
- **Transmission:** It uses the TCP/IP protocol for information interchange. It defines the LLP (Lower Level Protocol), which allows the exchange of messages in less robust communications such as over a RS-232 connection. The LLP defines the protocol to fragment a message and methods to prevent data loss. An HL7 message is composed of different segments. For transferring waveforms, HL7 combines OBX (observation/result) segments separated into several messages.

- **Implementation:** HL7 V3 standards are developed as syntax-independent models. The current preferred implementation technology is XML.

2.4 Comparison between the Standards

| Standard/ Attribute | DICOM | SCP-ECG | HL7 |
|--------------------------------|---|---|--------------------------------------|
| Data Storage | DICOM File sets | Record format | Sequence sets of numbers (xml coded) |
| Data Acquisition | Basic Directory Information Object Definition (IOD) | Pointer section | OIDs (Object Identifiers) |
| Data Compression | Deflated transfer syntax | Huffman tables for entropy dependent encoding | Does not compress waveforms |
| Transmission | TCP/IP | XModem Transfer Protocol | TCP/IP (LLP) |
| Ease of Implementation | DICOM Toolkit | Implementation guides available online | XML |

Table 2.1: Comparison of Standards

2.5 Proposed Standard

Based on the storage, acquisition, encoding, transmission and implementation of the prominent market standards, a “general purpose” standard has been devised. Thus, in order to develop an effective data storage format for efficient data interchange, a hybrid design is required.

For data storage, a merger of the qualities of an SCP Record and a DICOM file-set is advised. The basic message can be taken as four parts:-

- a) CRC checksum field
- b) Pointer section
- c) Version number
- d) File set

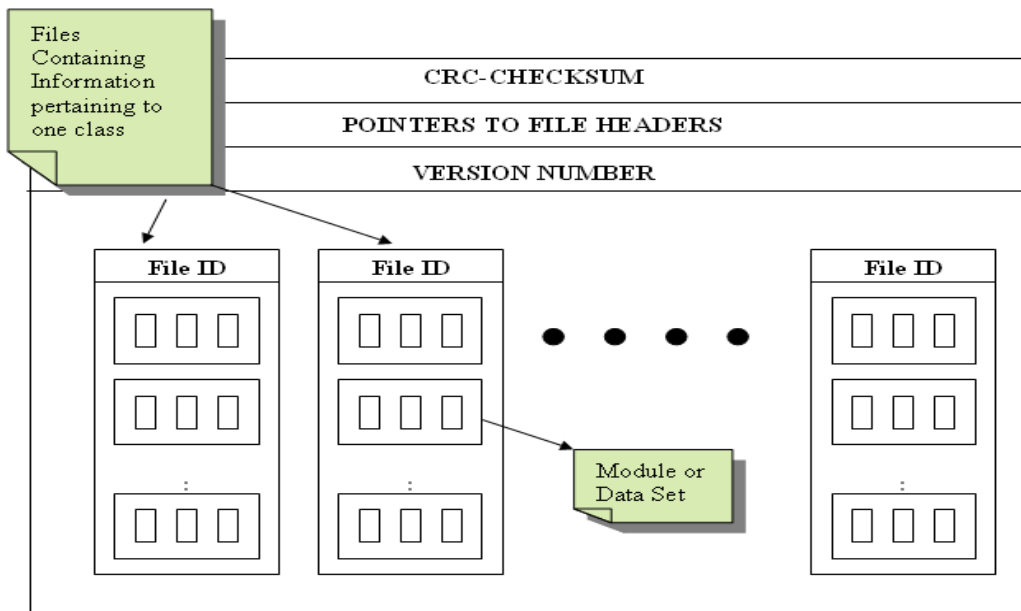


Figure 2-4: Message Structure for ECG data exchange

The checksum field is reserved as the first field of the message format. This Cyclic Redundancy Check (CRC) using the checksum bits in this field is a simple and effective error detection technique.

The second field is reserved for the pointer section. This is a useful means to identify what the contents of a transmitted message will be. The pointers will highlight the file headers of the files in the file set. This will make it easier for the manufacturer to access the information contained in these files.

The rest of the message is comprised of a file-set – as in the DICOM message. The DICOMDIR file, as in the DICOM, is replaced with the pointer section. for ease of access to the supposed table of contents of the message.

The third field is reserved for keeping the version number of the standard being implemented. This is necessary because all standards must evolve as the applications they support change. In recognition of this, the standard should include a field for its version ID in all messages. New transactions or data elements will be added to operational environments of the standard as a result of changes in the standard or due to changes in the local implementation as permitted within the standard. It is important that these changes are implemented at a site without requiring all communicating applications to upgrade simultaneously. This way, new fields can easily be added first to the sending or source system and the receiving system will ignore the new fields until it has been updated to use them.

This file-set feature of the DICOM message is used to allow for inclusion of multiple classes, i.e. one file for each class. This is beneficial when working with different ECG. The SCP format however does not allow for different types of ECG.

Each file in the file set will contain a file ID in its header section. This will be used as a reference to that file in the pointer section. The file would comprise of modules which in turn will maintain data elements in a tree structure as in the DICOM message. Each data element will comprise of an identifier value (or tag), a value length field and a value field. This hierarchical structure facilitates with the implementation.

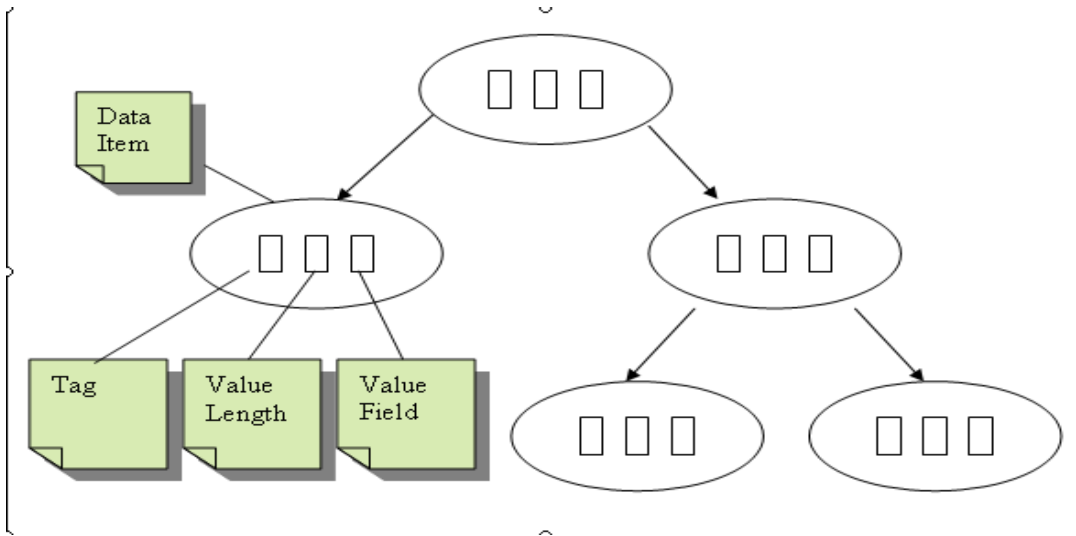


Figure 2-5: Internal Structure of a Data set or Module

For Data compression and encoding of the ECG waveform SCP-ECGs' data compression technique seems like the best option available since it provides high compression ratios and data integrity is kept intact. If Optimized Huffman tables are used, depending on the noise spectrum, they can result in only marginal compression effects and much higher compression ratios. For safe and secure transmission of data HL7's transfer protocol is selected for file transfer over a network as it uses the 7th layer (Application layer) of the OSI model using TCP/IP protocol. The application level, deals primarily with the semantics or data-content specification of the transaction set or message. It uses LLP for secure transmission over less robust connections. The TCP/IP protocol has features to help with error, flow and congestion control. It also helps ensure the data integrity, confidentiality and authenticity of the packet being interchanged.

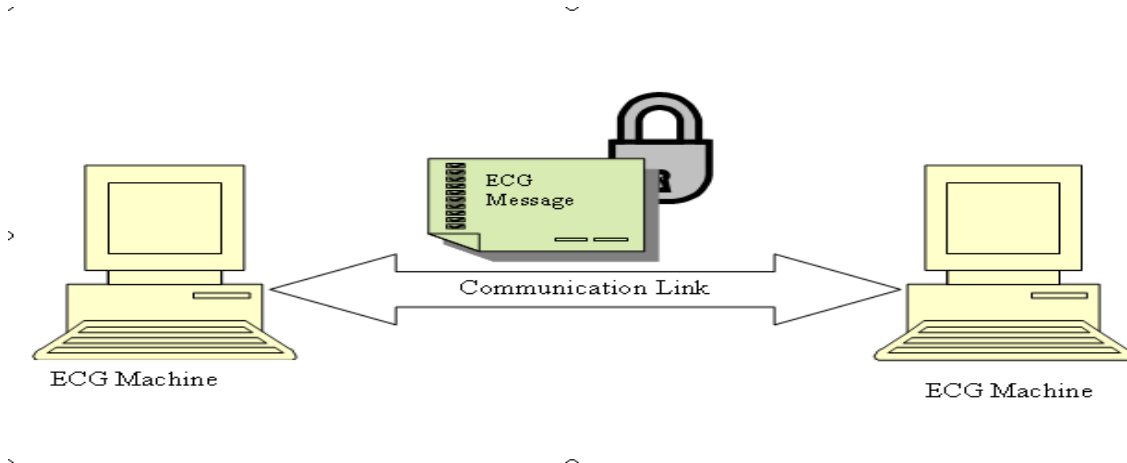


Figure 2-6: Secure Transmission of ECG message on a reliable TCP/IP connection

The existing prominent market standards have high flexibility with too many manufacturer specific implementation options and some ambiguity within the text. Many implementation details are left to the ingenuity and innovation of manufacturers, who must take into account their knowledge of the clinical environment and effective user interfaces. This gives rise to differences in understanding and results in a difference in implementation, thus decreased interoperability amongst the different manufacturers, even when using the same standard. One solution, as proposed in this paper, is the implementation of a single ECG waveform standard in medical institutes universally. This can only happen if a recognized medical body takes up the challenge to strictly implement one ECG standard worldwide. Currently manufacturers affirm their compliance with a particular standard without describing their respective level of conformance in the conformance statement.

We do realize that the main obstacle to the implementation of this standard are the market leader companies who's main aim is the protection of their own market and creation of a more extended market for their ECG management system. Secondly the conversion of the large number of existing ECG devices and ECG management systems to cover a different file format and protocol entails a high cost. It is necessary to take account of these

obstacles if we really wish to promote standardization in the ECG file format and data exchange.

3 Design and Implementation of ECG waveform Extraction Procedures

The first and foremost task, when extracting information from an ECG file, is to parse the file and mark the fields required and understand the trends followed. Then extract the lead measurement results and decode the encoding techniques used.

3.1 Standard Communications Protocol in Computer Assisted Electrocardiography (SCP-ECG)

In SCPECG data is stored in a record format. Information and its pointer section are used to identify all the fields.

| | |
|------------------|---|
| Mandatory | 2 BYTES - CHECKSUM - CRC - CCITT OVER THE ENTIRE RECORD (EXCLUDING THIS WORD) |
| Mandatory | 4 BYTES - (UNSIGNED) SIZE OF THE ENTIRE ECG RECORD (IN BYTES) |
| Mandatory | (Section 0) POINTERS TO DATA AREAS IN THE RECORD |
| Mandatory | (Section 1) HEADER INFORMATION - PATIENT DATA/ECG ACQUISITION DATA |
| Optional | (Section 2) HUFFMAN TABLES USED IN ENCODING OF ECG DATA (IF USED) |
| Optional | (Section 3) ECG LEAD DEFINITION |
| Optional | (Section 4) QRS LOCATIONS (IF REFERENCE BEATS ARE ENCODED) |
| Optional | (Section 5) ENCODED REFERENCE BEAT DATA IF REFERENCE BEATS ARE STORED |
| Optional | (Section 6) "RESIDUAL SIGNAL" AFTER REFERENCE BEAT SUBTRACTION IF REFERENCE BEATS ARE STORED, OTHERWISE ENCODED RHYTHM DATA |
| Optional | (Section 7) GLOBAL MEASUREMENTS |
| Optional | (Section 8) TEXTUAL DIAGNOSIS FROM THE "INTERPRETIVE" DEVICE |
| Optional | (Section 9) MANUFACTURER SPECIFIC DIAGNOSTIC AND OVERREADING DATA FROM THE "INTERPRETIVE" DEVICE |
| Optional | (Section 10) LEAD MEASUREMENT RESULTS |
| Optional | (Section 11) UNIVERSAL STATEMENT CODES RESULTING FROM THE INTERPRETATION |

Figure 3-1: An SCP ECG Record

Each section is divided into two parts:

- The section ID Header.
- The section Data Part.

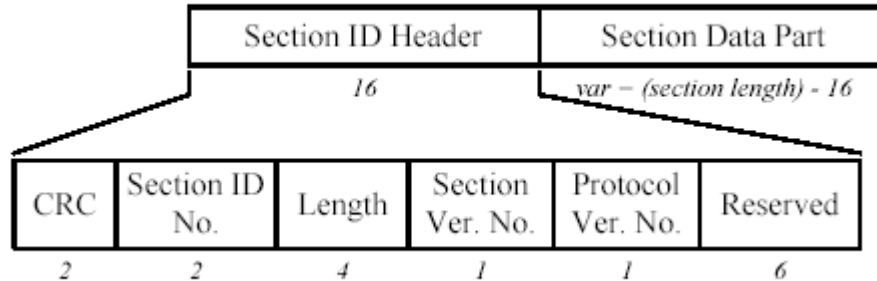


Figure 3-2: An SCP ECG Header Details

While the section Id. Header always has a length of 16 bytes, the section data part is variable. Note that the complete section length (relevant for the section length information) includes the length of the ID Header.

The SCP standard allows for a rather large number of options to store and format the ECG data. ECG data may be acquired at different sampling rates, with different quantization levels; they may be not compressed or be compressed by selectable methods and an SCP-ECG record may or may not contain analysis and over reading results. Also, the number of leads, the length of the recording interval and even the simultaneity of leads is left open to the manufacturers and other implementing bodies.

Once the fields have been identified using the information given in the header and pointer section, the next step is to mark the fields that contain the lead and encoding information. Looking at the record shows that section 2, section 3, section 4, section 6 and section 10 are required for the purpose.

3.1.1 Implementation

When extracting information from any file, input streams are opened to channel in the data into storage structure. The next step is to get the decompressed rhythm data. For that we need to extract the following two parameters from section 2:

- Number of Huffman Tables

- The Huffman Tables

And the following from section 3:

- Number of leads
- Number of samples
- Reference beat used for compression

And the following from section 4:

- Sample Number of QRS of Fiducial
- Sample Number of Residual to Start Subtracting QRS
- Sample Number of Residual of Fiducial
- Sample Number of Residual to End Subtracting QRS
- Sample Number of Residual to Start Protected Area
- Sample Number of Residual to End Protected Area

And the following from section 5:

- Sample Time Interval

And the following from section 6:

- Amplitude Value Multiplier
- Difference Data Used
- Compressed Lead Data
- Bimodal Compression Used
- Sample Time Interval for Rhythm

The above information is used along with the decimation factor to decompress the data, identify the lead information for each lead separately and save it in a text file using the input streams and the file writer object created at the start of the extraction procedure. Once the text file “temp.txt” is generated the control is shifted to the module carrying out the conversion to the “.dat” format.

3.2 Digital Imaging and Communications in Medicine (DICOM)

In DICOM information is stored as DICOM file-sets. Each DICOM file represents a separate class of information. These files in the file set contain a collection of data elements known as the Data set. Internally these data sets are maintained in a tree structure. Each data set contains elements which comprise of

- a) Tag,
- b) Value length and
- c) Value field.

To facilitate accessing the information stored in the DICOM files of the file-set, the DICOM standard has defined the Basic Directory IOD (Information Object Definition). A DICOM file-set contains one or more DICOM files. One of the files contained in the file-set is the DICOMDIR file, which contains information about other files in the file-set. Supplement 30 has defined three waveform classes: 12-lead, Resting ECG and Exercise ECG. This waveform data is organized into channels. An illustration of the basic file structure can be seen below.

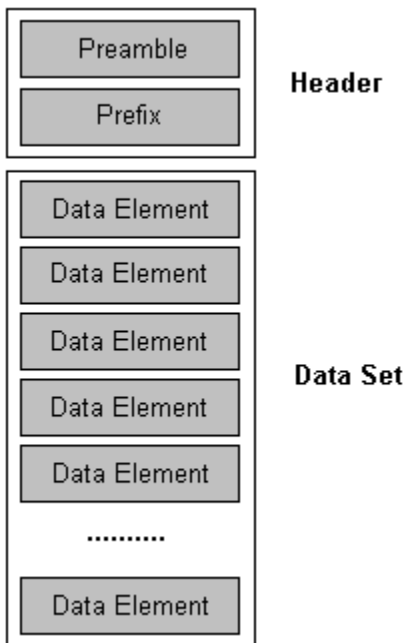


Figure 3-3: Basic File Structure

File Header

The header consists of a 128 byte File Preamble, followed by a 4 byte DICOM prefix. The header may or may not be included in the file.

| Preamble | Prefix |
|---------------------|------------------------------|
| 128 bytes = ??? ??? | 4 bytes = 'D', 'I', 'C', 'M' |

Figure 3-4: File Header

The DICOM Standard does not require any structure for the fixed size Preamble. It is not required to be structured as a DICOM Data Element with a Tag and a Length. It is intended to facilitate access to the images and other data in the DICOM file by providing compatibility with a number of commonly used computer image file formats.

- a) If the File Preamble is not used by an Application Profile or a specific implementation, all 128 bytes shall be set to 00H. This is intended to facilitate the recognition that the Preamble is used when all 128 bytes are not set as specified above.
- b) The File Preamble may for example contain information enabling a multi-media application to randomly access images stored in a DICOM Data Set. The same file can be accessed in two ways: by a multi-media application using the preamble and by a DICOM Application which ignores the preamble.

The four byte DICOM Prefix contains the character string "DICM" encoded as uppercase characters of the ISO 8859 G0 Character Repertoire. This four byte prefix is not structured as a DICOM Data Element with a Tag and a Length.

Data Set

Each File shall contain a single Data Set representing a single SOP Instance related to a single SOP Class (and corresponding IOD). A file may contain more than a single 2D image frame as specific IODs may be defined to include multiple frames.

The Transfer Syntax used to encode the Data Set shall be the one identified by the Transfer Syntax UID of the DICOM File Meta Information. A DICOM Data Set does not

include its total length. The end of the file indication provided by the DICOM File Service is the only indication of the end of the Data Set.

The last Data Element of a Data Set may be Data Element (FFFC,FFFC) if padding of a Data Set is desired when a file is written. The Value of this Data Set Trailing Padding Data Element (FFFC,FFFC) has no significance and is ignored by all DICOM implementations reading this Data Set. File-set Readers or Updaters shall be able to process this Data Set Trailing Padding (FFFC,FFFC) either in the Data Set following the Meta Information or in Data Sets nested in a Sequence.

A Data Set represents an instance of a real world Information Object. A Data Set is constructed of Data Elements. Data Elements contain the encoded Values of Attributes of that object. The specific content and semantics of these Attributes are specified in Information Object Definitions (IOD).

Data Elements

A Data Element is uniquely identified by a Data Element Tag. The Data Elements in a Data Set shall be ordered by increasing Data Element Tag Number and shall occur at most once in a Data Set. A Data Element Tag may occur again within Nested Data Sets

3.2.1 Implementation

First of all the input streams and the File writer objects are created. Then the DICOM file parsing is begun to extract out the relevant lead information. Each Item of a Data Element of Value Representation SQ is encoded as a DICOM Standard Data Element with a specific Data Element Tag of Value (FFFE, E000). The Item Tag is followed by a 4 byte Item Length field encoded in one of the following two ways:

- Explicit Length
- Undefined Length

Data Element Tags (FFFF,eeee) are reserved by this standard and shall not be used.

Each Item Value shall contain a DICOM Data Set composed of Data Elements. Within the context of each Item, these Data Elements shall be ordered by increasing Data Element Tag value and appear only once. There is no relationship between the ordering

of the Data Elements contained within an Item and the ordering of the Data Element Tag of SQ Value Representation that contains that Item. One or more Data Elements in an Item may be of Value Representation SQ, thus allowing for recursion.

Using the information above SCP Lead codes for all the leads are identified. This helps in identifying the lead information contained in each Channel (i.e. each file set) of the waveform information. The source ECG is reconstructed as a text file with information separated in channels and each channel in turn separated into waveform lead information. The leads associated with each channel are identified by the lead codes extracted from the file in the first step of the extraction procedure, and written onto “temp.txt” using the streams and the file writer created earlier.

3.3 Health Level 7 (HL7)

HL7 messages are XML documents, which look somewhat similar to HTML. Each message is a string of text with information enclosed by tags, wrapped in angle brackets. Start tags look like <tag> and end tags look like </tag>. Tags can be qualified by attributes such as <tag attribute="value">.

The HL7 tags and attributes are derived from the HL7 Reference Information Model (RIM) and the HL7 Data Types. The structure of each HL7 message is set out in an XML schema, which specifies the tags and attributes needed or allowed in the message, their order and the number of times each may occur, together with annotations describing how each tag shall be used. The RIM defines a set pre-defined Attributes for each class and these are the only ones allowed in HL7 messages. Each attribute has a specified Data Type. These Attributes and Data Types become tags in HL7 XML messages.

One common data type is the Instance Identifier, which is used to give unique identity to people, persons, organizations, things and information objects.

HL7 uses two main types of code. The first type covers the specialized codes used for structural attributes and are defined by HL7 itself. The second type covers externally defined terms and codes such as SNOMED CT (Clinical Terms).

3.3.1 Implementation

First of all a file writer and an input stream should be created to write all the information gathered during the course of execution. The HL7 file is parsed like any HTML file because of the extreme similarity between the two formats. So to handle a HL7 file, a default handler is created and an instance of the class implementing it is assigned to it. Since all the functions are designed to go through a single clause and then end, the handler ,however, makes sure it doesn't stop execution after each clause and repeats the same steps for all the clauses till the file ends and all clauses exhausted.

The handler searches for the lead information throughout the document and stores it in "temp.txt" as soon as it encounters it.

Each time a required attribute is encountered the string containing all the values of the attribute that the handler automatically generates is tokenized. All unnecessary information is removed and the waveform information related to each lead is saved on the file.

3.3.2 The Output File Format

The output file Format file two-part names: the first part is the record name and the second part (following the ".") indicates the file type. For example, a file named "chf08.hea" is a file of type .hea (see below) belonging to a record named "chf08".

The Output file consists of the following two files as part of its format:

- * **.dat** files are binary signal files. See the questions and answers below, beginning with "What is the format of the signal files?", for information about their format and how to read them.

- * **.hea** files are short text "header" files used by all of the software that reads the signal files to determine their location and format. In some cases, .hea files also contain structured comments that include information about the subjects (e.g., age, gender, medications, and diagnoses).

The output file created by ECGC is in "Format 16". In Format 16 each sample is represented by a 16-bit two's complement amplitude stored least significant byte first.

Any unused high-order bits are sign-extended from the most significant bit. Historically, the format used for MIT-BIH and AHA database distribution 9-track tapes was format 16, with the addition of a logical EOF (octal 0100000) and null-padding after the logical EOF.

3.4 Flowchart

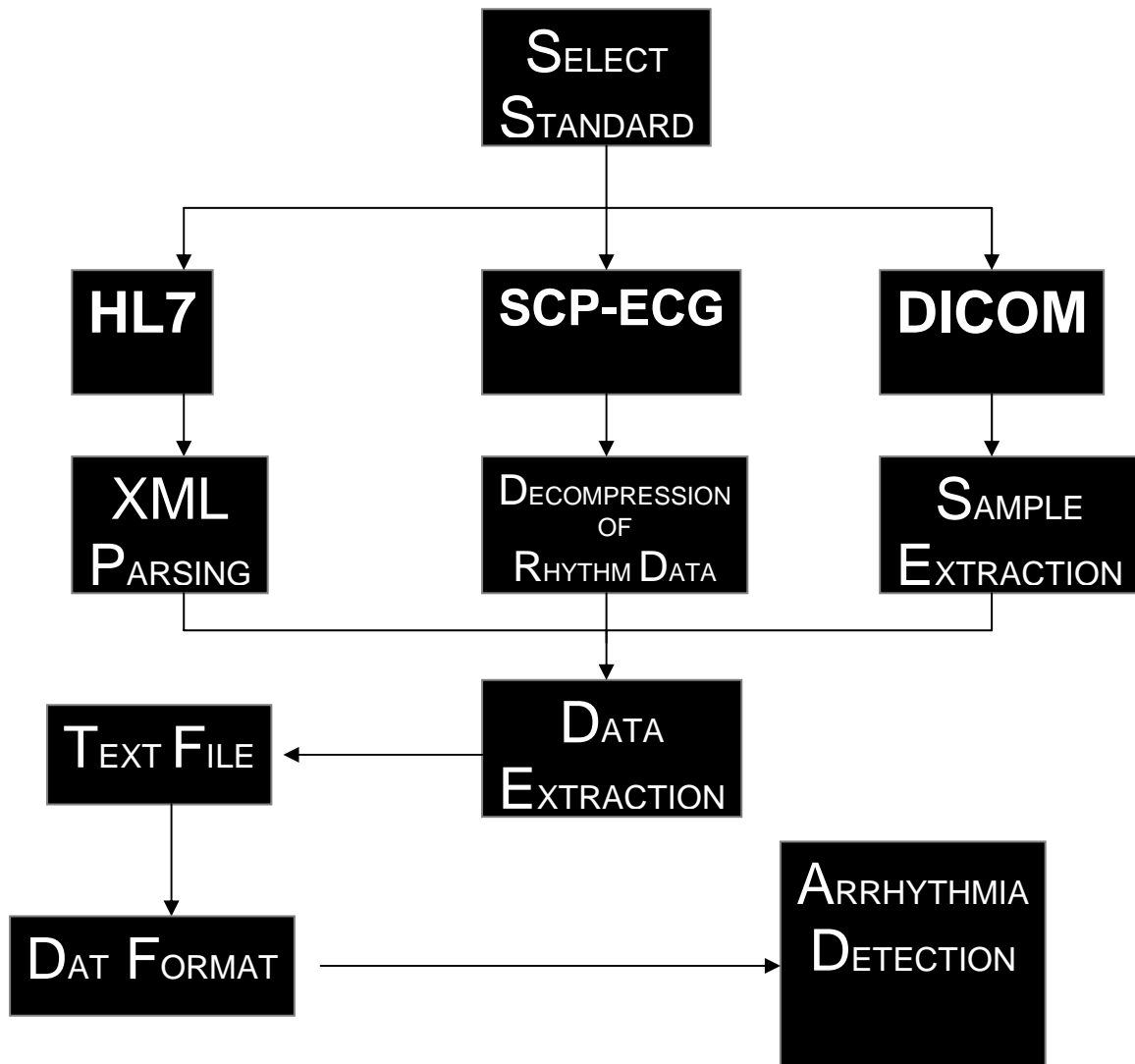


Figure 3-5: Flow Chart

4 ECGC and Arrhythmia Detection System

4.1 Introduction

ECGC aims to provide interoperability between ECG devices and arrhythmia detection softwares by converting any ECG file format into a simple DAT format. This will give doctors two main advantages

1. Use many research based softwares that operate on the DAT format.
2. Tele-consultation will be made easy as the Physicians won't have to cater for different standards in other hospitals.

ECGC comprises of a very user friendly interface, implemented keeping the end users in mind (who will be the Doctors and Nurses) and provides ease of use even to a layman. This venture is a brain child of a Cardiac Electro Physiologist and was realized by young software engineers of Military College of Signals (NUST).

4.2 How to Use the Software

The software is highly user friendly providing a quick inbuilt help button, so that the newcomer will be able to start in just a few seconds. The buttons / menus are very simple and provide tool tips for the uninitiated. The detail help on using the software is given in the user manual attached to the Documentation menu.

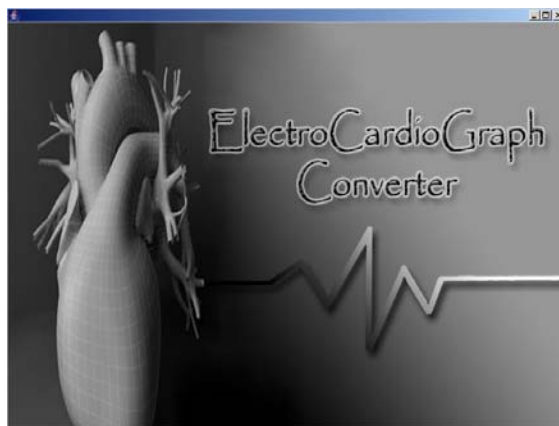


Figure 4-1: Introduction

4.3 Main Menu

The software has a main menu with four basic buttons

1. ECGC (The Main Conversion Menu)
2. Help (Get acquainted with ECGC in 6 simple steps)
3. Documentation (Contains link to detailed documentation)
4. About (Info about the authors and the Project)

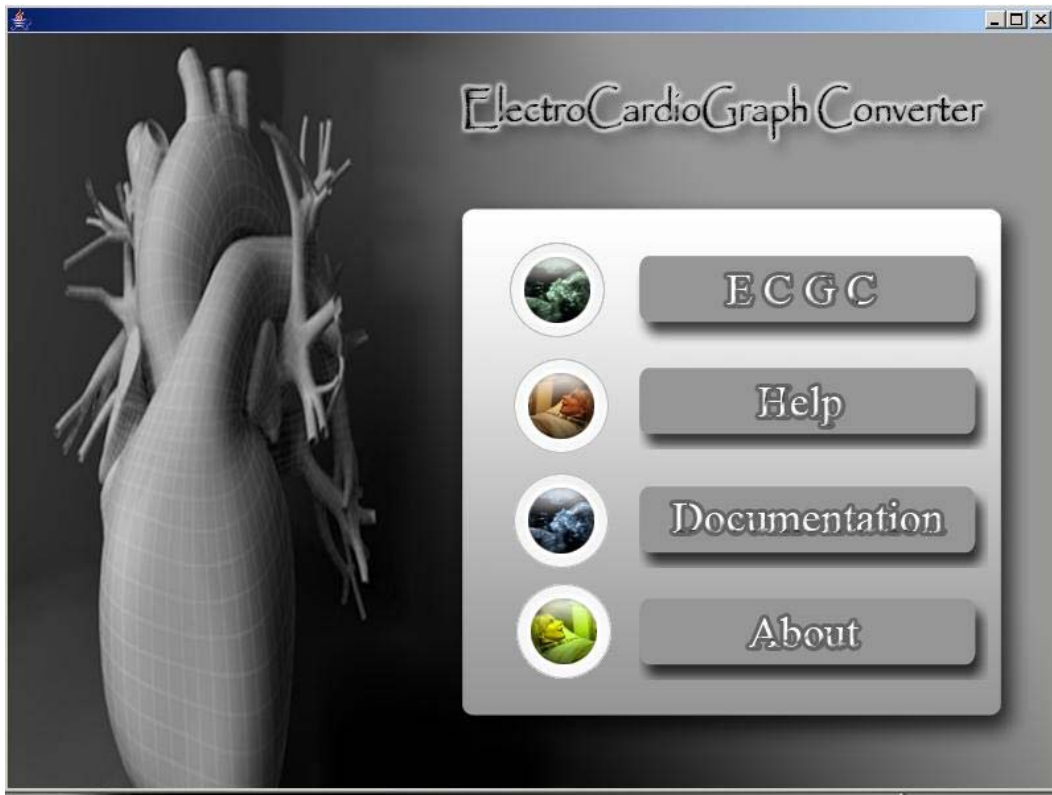


Figure 4-2: Main Menu

4.3.1 ECGC

From Main Menu click on ECGC

- **Standard**
Select the Standard of your machine from the drop down menu
- **ECG**
Select the file by either inserting its full path and file name or by pressing browse and selecting the file
In the Save as box write a new name for the file
- **Convert**
Press Convert to start the conversion. It approximately takes 5 seconds for the file to convert. A dialog box will appear indicating that the conversion is complete
- **Launch VT**
This button will start the VT Detection System, so that the files can be analyzed
- **Status Bar**
The status bar shows the status of the conversion. It also shows if any errors occur
- **Back**
Go back to the main menu



Figure 4-3: ECGC

4.3.2 Help

Click Help from Main Menu. Help is a quick guide by which a newcomer can learn to operate ECGC in 6 simple steps

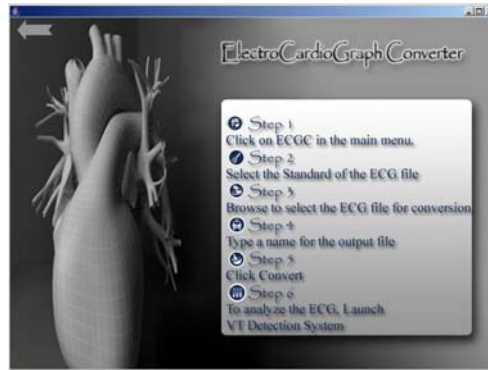


Figure 4-4: Help

4.3.3 Documentation

Click Documentation from Main Menu. It provides quick links to documents.



Figure 4-5: Documentation

- **User Manual**
Detailed document on how to use the software
- **Documentation**
Project Documentation, This Document.
- **What is ECG?**
Information about the electrocardiograph
- **ECG standards**
Information about DICOM,SCP-ECG and HL7 standards
- **Data Flow**
Shows a diagrams detailing the data flow
- **Information Flow**
Shows a diagrams detailing the data flow

4.3.4 About

Click About from Main Menu. It contain information about the Project its authors and their contacts.

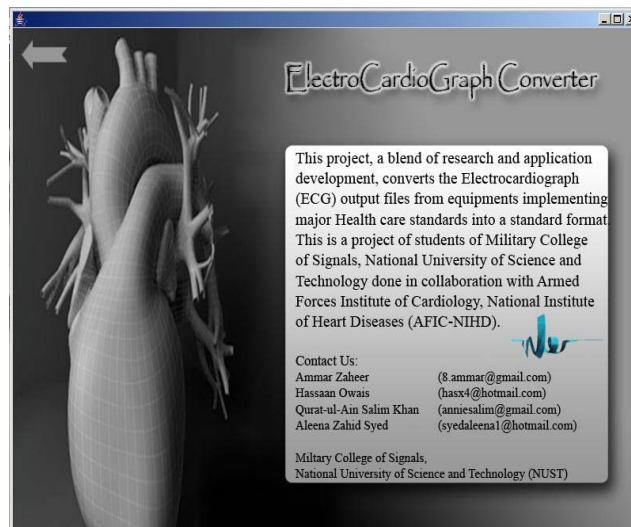


Figure 4-6:- About

4.4 How to Use VTDS

The software is highly user friendly providing inbuilt help regarding many topics. The buttons /menus provided give a comprehensive detail and functionality. The details of using the software is given in the user manual attached to the software main menu.]

4.5 Menus and Working

The software has a main menu with help about what is ECG, what is VT, what is this project, what is Wavelet Transform, Information and Data flow of this Project and the ECG ANALYZER (which performs the main analysis and detection of Ventricular Tachyarrhythmia).

4.6 Standard Settings

The contents of the package must be placed into a writeable directory. This directory also has to be added to the MATLAB path with the command "addpath". This package contains some c-programs, which have to be compiled into mex-files first. To do this, copy all c-files from the package into the MATLAB home directory. The name of the MATLAB home directory can be found by typing "matlabroot" into the command window. Then compile the files with the command "mex filename.c". The result from this command is a mexfile, which can be carried out by MATLAB. Copy these files into the the directory, where the package is located. Then you can start the analysis.

4.7 Illustration of all Components of ECG ANALYZER:

- **Directory**

The text beside shows, which is the current directory from where the data should be read. The contents of this directory are shown in the left listbox. There are only shown subdirectories and files of type *.dat, *.bda and *.CMP, because only such files can be analyzed. Therefore, otherfiles are not interesting.

- **Change directory**

The text beside shows, which will be the current directory as soon as the input will be confirmed with "Enter". If the directory does not exist, this will be told the user. Changing the directory also changes the result directory.

- **Result directory**

The text beside shows, into which directory the results will be written. This directory can differ from the directory, from where the data are read. The contents of the result directory are shown in the right listbox.

- **Change result directory**

The text beside shows, which will be the current result directory, as soon as the input will be confirmed with "Enter". If the directory does not exist, this will be told the user. Changing this directory does not change the directory, from where the data are read.

- **Standard settings**

Pressing this button results in a setting of the analyzing parameters in the following way:

Starting time of data in seconds: 0,

Ending time of data in seconds: 12,

Window length in seconds: 8,

Time interval in seconds: 1,

None of the checkboxes (noise, draw ECG, draw single steps, only one channel per file) is activated.

The algorithm does not change. The list of the data to be analyzed also does not change. The standard setting can be applied to all algorithms and yield the most relevant results. Each second the last 8 seconds of the data are analyzed. There are not drawn any plots and no noise is added. If a data file consists of more than one channel, all are analyzed.

- **Available data**

This list box shows, which subdirectories and files of type *.dat, *.CMP and *.bda are contained in the current directory. By double clicking the *.dat-, *.CMP- or *.bda files in the list, they can be moved into the list beside to be analyzed afterwards.

- **Data to be analyzed**

This list box shows data that will be analyzed when the algorithm is started. The data can be obtained by double clicking on the *.dat-, *.CMP- or *.bda- files in the left listbox. To remove files from the middle listbox, double click on them.

- **Result**

This list box shows, which result files already exist.

During the analysis such result files are added stepwise.

A result file is structured as follows:

First, there stands an "E", then the name of the original file, e.g. "cu05", then a hint to the used algorithm, e.g. "jSP" for Barros spectral algorithm described in Jekovas paper. Finally the extension ".dat". Therefore, all in all for example "Ecu05jSP.dat".

The result file is a text file with a few columns.

The first column contains the time within the data file.

The time difference between two successive rows is just the time interval. The last but one column contains the decision of the algorithm:

0: Sinus rhythm, no fibrillation (SR),

1: Ventricular fibrillation (VF),

2: Ventricular tachycardia (VT),

-1: no decision,

-2: not available.

The columns in between contain calculated parameters of the analysis. Since each algorithm calculates different parameters, they are listed in the main menu item "algorithm".

The last column contains the desired values according to the annotation file *.atr(ANO). (32 means VF; this is important for the calculation of the quality parameters sensitivity and specificity.) Double clicking the entries in the right listbox creates a graphical illustration of the calculated results and of the decision and desired value according to the attributes-file. The decision of the algorithm is illustrated by colored asterisks.

yellow: no decision, green: Sinus rhythm, do not defibrillate!

red: ventricular fibrillation, blue: ventricular tachycardia

- **Algorithm**

'Here the algorithm can be chosen. It is used to analyze the chosen data.

Details about the different algorithms can be found in the main menu item "algorithm".

- **Starting time of data in seconds**

'This entry defines the time, from which on the data is analyzed.

- **Ending time of data in seconds (-1: entire file is analyzed)**

'The chosen data is analyzed up to this entry in seconds. To analyze the entire file, the entry must be -1.

- **Window length in seconds**

Each algorithm requires a certain amount of data to yield a result. The window length defines the duration (in seconds), that is used within the data file to carry out a single calculation in the analysis. The standard value is 8 seconds.

Large window lengths cause long durations for the calculation, small window lengths cause inaccurate results.

Some algorithms cannot work with any window length.

Still the value should always be about 8 seconds.

For details look into the main menu item "algorithm"!

- **Time interval in seconds**

This number defines the "movement" of the analyzing window from one analysis to the other. To obtain an analyzing result every second, the time interval has to be 1, to obtain a result every 2 seconds, it has to be 2, and so on.

Very small time intervals result in a many calculations, very large time intervals result in small accuracies. The standard value for the time interval is 1.

- **Noise factor**

Artificial noise of a certain amount is added to the signal.

White noise (not band limited) is used, the amplitude of the noise is: noise factor * signal amplitude.

With this tool different kinds of artifacts can be somehow simulated (long electrical leads, bad contacts...).

- **Draw ECG**

A plot is drawn from every file that should be analyzed.

The number of plots is the same as the number of file that should be analyzed.

- **Draw single steps**

A plot is drawn after every single calculation of the analysis of every analyzed file.

Every plot has a time range with the size of the window length.

In case of a large time range to be analyzed, many plots are produced. Therefore, this application is recommended only in the case of small episodes to be analyzed (like for example when using the standard settings, 12 s).

- **Only 1 channel per file**

Some files contain more than one channel.

Normally, an evaluation requires just a single signal.

Using this application it is possible to analyze only one channel per file.

- **Start**

Pressing this button starts the analysis with the defined parameters.

Attention: already existing result files are possibly replaced!

- **Stop, exit**

Pressing this button stops the analysis and terminates the ECG analyzing program.

- **Processing**

The text shows, which file is processed in the moment.

"Press Start" means, that the analysis has not started yet.

- **CPR factor**

'Before the ECG signal is analyzed, an artificial CPR signal is added. The ratio from the maximal amplitude of the CPR signal to the maximal amplitude of the ECG signal is specified by the entry in this field.

- **Execute CPR filtering**

'If the signal contains CPR artifacts, it is advisable to filter these artifacts before running the actual analysis. This prefiltering is carried out with a CPR filter algorithm, which was written by Andreas Klotz from the University of Vienna.

4.8 Steps for General Analysis:

A typical analysis is carried out as follows:

1.) In the MATLAB command line type "mex -setup", enter, choose the intern C-compiler and confirm.

The C programs must be located in the MATLAB home directory, which can be found by typing "matlabroot" in the command window. The C programs have to be compiled and the compiled programs copied back to the package containing the other programs.

The directory of the package also has to be added to the MATLAB path with the command "addpath".

- 2.) Choose the data directory (in the left listbox or type directly into the edit window).
- 3.) Choose the result directory (this is either the directory, from where the data is read, or another one, that has to be typed into the edit window).
- 4.) Transfer the data that you want to analyze, from the left listbox into the middle one (by double clicking). Data files can be removed from the middle list box by double clicking.
- 5.) Choose parameters, set checkboxes, choose algorithm, and possibly use standard settings.
- 6.) Press start button.
- 7.) Double click on the result files to view the result and the computed parameters.

5 Testing and Results

5.1 Testing

Files from different Ventricular Tachyarrhythmia Databases and the three main ECG healthcare standards have been exhaustively tested to evaluate the ECGC as well as the functioning of the Detection System.

The data sets were taken from the SCP-ECG databank (35files, 1061791654.ecg to 1061791688.ecg), DICOM databank (35 files, 1173272641.dcm to 1173272675.dcm), HL7 databank (35 files, ECG-AB-001.xml to ECG-AB-034.xml), AFIC-NIHD data bank (50 files), BIH-MIT data bank (50 files), the CU data bank (50 files), the AHA data bank (files 7001 - 8210).

5.2 Results

The results of the individual Standards have been attached in Appendix A.

5.2.1 Overall Results

- **Conversion to DAT format**

| <u>Standard</u> | <u>Conversion to DAT format</u> |
|-----------------|---------------------------------|
| SCP-ECG | <i>100%</i> |
| DICOM | <i>100%</i> |
| HL7 | <i>100%</i> |

Table 5-1: Conversion

- **Result of Arrhythmia Detection System**

| Sensitivity | Specificity | Positive Predictivity | Accuracy |
|-------------|-------------|-----------------------|----------|
| 50%-60% | 92% | 72%-90% | 90%-95%* |

Table 5-2: Results of VTDS

- depending upon noise in data

5.3 Graphs

The results of each algorithm are shown in Figure 5-1 and Figure 5-2,

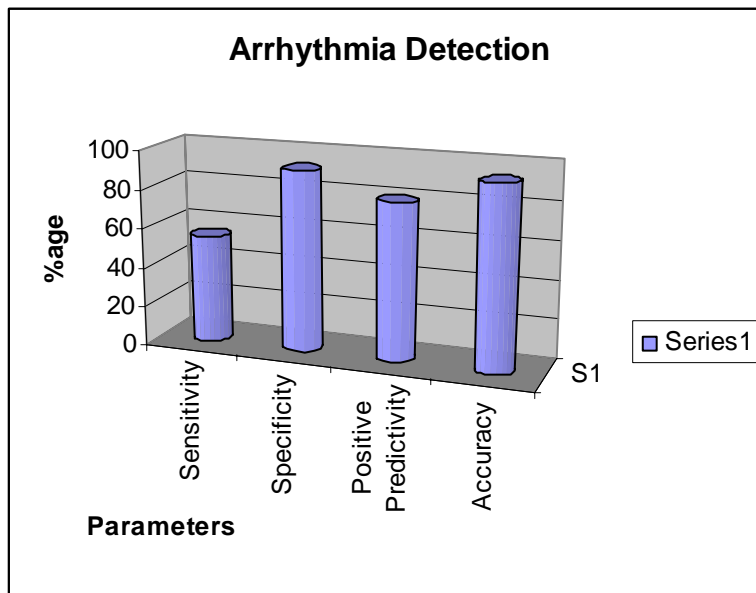


Figure 5-1: Arrhythmia Graph

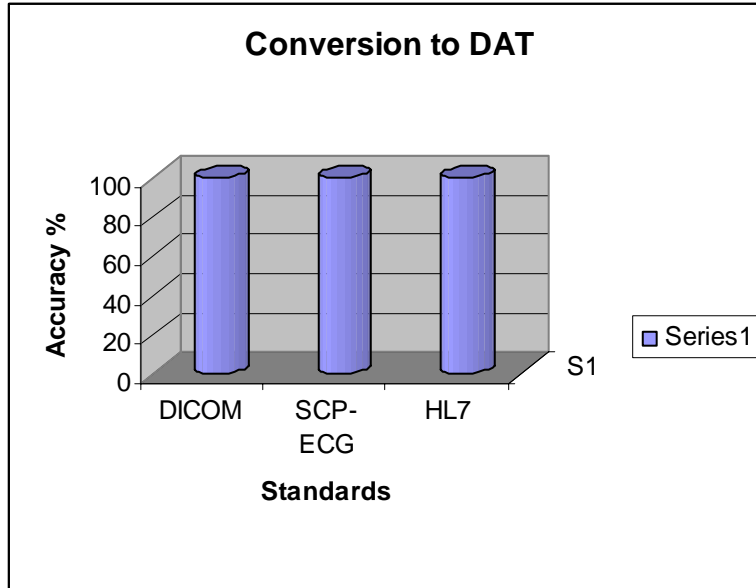


Figure 5-2: Conversion Graph

5.4 Comparisons

Comparisons show that the VT Detection System is highly reliable as compared to most of the systems available.

6 Conclusion and Future Work

6.1 Conclusion

ECGC is the first of its kind and the only system that would provide interoperability in the field of cardiac electrophysiology. The three major health care standards use around the world i.e. DICOM, SCP-ECG and HL7 files are converted to the DAT format using ECGC, which can then be fed into any arrhythmia detection system. It enhances the degree of research in the field of biomedical engineering. Its accuracy is as high as 100%. Higher level of accuracy achieved by this system is also a milestone in field of biomedical engineering. Enhanced features and user friendly interfaces offer all kinds of users a responsive system. The proposed system is highly reliable and efficient. Furthermore the detection system integrated with it i.e. VTDS is the first ever of its kind. It performs beat to beat analysis on the ECG signal. The accuracy of the system is as high as 90%.

6.2 Future Work

Presently the system caters for the three main health care standards used around the globe. This can be extended to cater for the other less well known standards as well. This would result in complete interoperability. The detection system integrated with it analyzes ventricular tachyarrhythmia only. The system can be broadened to include all kinds of arrhythmias and make other ECG facilities embedded in one software product.

Hardware module can be designed and implemented for data acquisition. Features such as web service can also be initiated in it enabling end to end communication between cardiologists from different parts of the world share data and results.

APPENDIX A
RESULT TABLES

SCP-ECG

| Data | Conversion to DAT | Sensitivity | Specificity | Positive Predictivity | Accuracy |
|-----------------|-------------------|----------------|---------------|-----------------------|-----------------|
| 1061791654.ecg | Yes | 0.973 | 1 | 1 | 0.984 |
| 1061791655.ecg | Yes | | 0.97 | 0 | 0.97 |
| 1061791656.ecg | Yes | 0.442 | 0.996 | 0.905 | 0.948 |
| 1061791657.ecg | Yes | 0.327 | 0.987 | 0.967 | 0.629 |
| 1061791658.ecg | Yes | 0.575 | 0.99 | 0.926 | 0.918 |
| 1061791659.ecg | Yes | 0.197 | 1 | 1 | 0.78 |
| 1061791660.ecg | Yes | 0.248 | 1 | 1 | 0.511 |
| 1061791661.ecg | Yes | 0.207 | 1 | 1 | 0.87 |
| 1061791662.ecg | Yes | 0.298 | 0.998 | 0.944 | 0.918 |
| 1061791663.ecg | Yes | 0.359 | 1 | 1 | 0.754 |
| 1061791664.ecg | Yes | 0.314 | 1 | 1 | 0.812 |
| 1061791665.ecg | Yes | 0.155 | 0.997 | 0.968 | 0.671 |
| 1061791666.ecg | Yes | 0.204 | 1 | 1 | 0.914 |
| 1061791667.ecg | Yes | | 0.996 | 0 | 0.996 |
| 1061791668.ecg | Yes | 0.301 | 1 | 1 | 0.856 |
| 1061791669.ecg | Yes | 0.054 | 1 | 1 | 0.788 |
| 1061791670.ecg | Yes | 0.487 | 1 | 1 | 0.96 |
| 1061791671.ecg | Yes | 0.296 | 1 | 1 | 0.958 |
| 1061791672.ecg | Yes | 0.395 | 0.99 | 0.895 | 0.991 |
| 1061791673.ecg | Yes | 0.072 | 1 | 1 | 0.511 |
| 1061791674.ecg | Yes | 0.488 | 0.995 | 0.969 | 0.864 |
| 1061791675.ecg | Yes | 0.027 | 1 | 1 | 0.786 |
| 1061791676.ecg | Yes | 0.157 | 1 | 1 | 0.828 |
| 1061791677.ecg | Yes | 0.206 | 0.998 | 0.933 | 0.89 |
| 1061791678.ecg | Yes | 0.231 | 1 | 1 | 0.94 |
| 1061791679.ecg | Yes | 0.095 | 0.97 | 0.35 | 0.84 |
| 1061791680.ecg | Yes | 0.13 | 0.998 | 0.75 | 0.958 |
| 1061791681.ecg | Yes | 0.333 | 1 | 0.4 | 0.972 |
| 1061791682.ecg | Yes | 0.115 | 1 | 1 | 0.77 |
| 1061791683.ecg | Yes | 0.054 | 1 | 1 | 0.295 |
| 1061791684.ecg | Yes | 0.0571 | 0.996 | 0.8 | 0.984 |
| 1061791685.ecg | Yes | 0.043 | 1 | 1 | 0.91 |
| 1061791686.ecg | Yes | 0.591 | 1 | 1 | 0.928 |
| 1061791687.ecg | Yes | 0.286 | 1 | 1 | 0.92 |
| 1061791688.ecg | Yes | 0.16 | 0.994 | 0.571 | 0.952 |
| AVERAGE: | 100% | 0.29403 | 0.9969 | 0.86671 | 0.862714 |

DICOM

| Data | Conversion to DAT | Sensitivity | Specificity | Positive Predictivity | Accuracy |
|-----------------|-------------------|----------------|--------------|-----------------------|----------------|
| 1173272641.dcm | Yes | 0.99 | 1 | 1 | 0.994 |
| 1173272642.dcm | Yes | 0.42 | 0.95 | 0 | 0.95 |
| 1173272643.dcm | Yes | 0.907 | 0.858 | 0.675 | 0.862 |
| 1173272644.dcm | Yes | 0.39 | 0.686 | 0.523 | 0.671 |
| 1173272645.dcm | Yes | 1 | 0.732 | 0.639 | 0.778 |
| 1173272646.dcm | Yes | 0.584 | 1 | 1 | 0.886 |
| 1173272647.dcm | Yes | 0.479 | 0.577 | 0.72 | 0.873 |
| 1173272648.dcm | Yes | 0.678 | 0.971 | 0.721 | 0.874 |
| 1173272649.dcm | Yes | 0.491 | 1 | 1 | 0.942 |
| 1173272650.dcm | Yes | 0.792 | 0.578 | 0.51 | 0.629 |
| 1173272651.dcm | Yes | 0.387 | 1 | 1 | 0.832 |
| 1173272652.dcm | Yes | 0.5 | 0.993 | 0.98 | 0.802 |
| 1173272653.dcm | Yes | 0.874 | 0.589 | 0.62 | 0.509 |
| 1173272654.dcm | Yes | | 0.92 | 0 | 0.92 |
| 1173272655.dcm | Yes | 0.65 | 1 | | 0.794 |
| 1173272656.dcm | Yes | 0.982 | 0.634 | 0.729 | 0.549 |
| 1173272657.dcm | Yes | 0.513 | 0.745 | 0.545 | 0.727 |
| 1173272658.dcm | Yes | 0.44 | 0.968 | 0 | 0.916 |
| 1173272659.dcm | Yes | 0.5 | 0.932 | 0.505 | 0.878 |
| 1173272660.dcm | Yes | 0.076 | 0.996 | 0.952 | 0.811 |
| 1173272661.dcm | Yes | 0.504 | 0.457 | 0.489 | 0.737 |
| 1173272662.dcm | Yes | 0.873 | 0.958 | 0.774 | 0.916 |
| 1173272663.dcm | Yes | 0.647 | 0.99 | 0.943 | 0.92 |
| 1173272664.dcm | Yes | 0.971 | 0.982 | 0.892 | 0.98 |
| 1173272665.dcm | Yes | 0.385 | 0.584 | 0.072 | 0.869 |
| 1173272666.dcm | Yes | 0.757 | 0.967 | 0.78 | 0.936 |
| 1173272667.dcm | Yes | 0.43 | 0.803 | 0.34 | 0.966 |
| 1173272668.dcm | Yes | 0.43 | 0.916 | 0.34 | 0.894 |
| 1173272669.dcm | Yes | 0.97 | 0.981 | 0.12 | 0.727 |
| 1173272670.dcm | Yes | 0.083 | 1 | 0.91 | 0.617 |
| 1173272671.dcm | Yes | 1 | 0.971 | 0.5 | 0.972 |
| 1173272672.dcm | Yes | 0.936 | 0.996 | 0.957 | 0.99 |
| 1173272673.dcm | Yes | 0.83 | 0.981 | 0.901 | 0.954 |
| 1173272674.dcm | Yes | 0.518 | 0.998 | 0.967 | 0.944 |
| 1173272675.dcm | Yes | 0.12 | 0.889 | 0.054 | 0.85 |
| AVERAGE: | 100% | 0.71814 | 0.865 | 0.7308 | 0.86712 |

| Data | Conversion to DAT | HL7 | | | | Accuracy |
|-----------------|----------------------|--------------|---------------|--------------------------|----------------|----------|
| | | Sensitivity | Specificity | Positive Predictivity | | |
| ECG-AB-001.xml | Yes | 0.667 | 1 | 1 | 0.804 | |
| ECG-AB-002.xml | Yes | | 0.976 | 0 | 0.976 | |
| ECG-AB-003.xml | Yes | 0.256 | 1 | 1 | 0.936 | |
| ECG-AB-004.xml | Yes | 0.158 | 0.974 | 0.878 | 0.831 | |
| ECG-AB-005.xml | Yes | 0.632 | 0.957 | 0.753 | 0.9 | |
| ECG-AB-006.xml | Yes | 0.073 | 1 | 1 | 0.747 | |
| ECG-AB-007.xml | Yes | 0.344 | 1 | 1 | 0.573 | |
| ECG-AB-008.xml | Yes | 0.171 | 0.998 | 0.933 | 0.862 | |
| ECG-AB-009.xml | Yes | 0.175 | 0.998 | 0.909 | 0.904 | |
| ECG-AB-010.xml | Yes | 0.146 | 1 | 1 | 0.773 | |
| ECG-AB-011.xml | Yes | 0.307 | 1 | 1 | 0.81 | |
| ECG-AB-012.xml | Yes | 0.021 | 0.997 | 0.8 | 0.619 | |
| ECG-AB-013.xml | Yes | 0.278 | 1 | 1 | 0.922 | |
| ECG-AB-014.xml | Yes | | 0.996 | 0 | 0.996 | |
| ECG-AB-015.xml | Yes | 0.631 | 0.995 | 0.97 | 0.92 | |
| ECG-AB-016.xml | Yes | 0.545 | 1 | 1 | 0.898 | |
| ECG-AB-017.xml | Yes | 0.462 | 1 | 1 | 0.958 | |
| ECG-AB-018.xml | Yes | 0.296 | 1 | 1 | 0.962 | |
| ECG-AB-019.xml | Yes | 0.535 | 0.986 | 0.885 | 0.908 | |
| ECG-AB-020.xml | Yes | 0.042 | 0.949 | 0.478 | 0.771 | |
| ECG-AB-021.xml | Yes | 0 | 1 | | 0.743 | |
| ECG-AB-022.xml | Yes | 0.045 | 1 | 1 | 0.79 | |
| ECG-AB-023.xml | Yes | 0.225 | 1 | 1 | 0.842 | |
| ECG-AB-024.xml | Yes | 0.426 | 1 | 1 | 0.922 | |
| ECG-AB-025.xml | Yes | 0.282 | 1 | 1 | 0.944 | |
| ECG-AB-026.xml | Yes | 0.284 | 0.991 | 0.84 | 0.886 | |
| ECG-AB-027.xml | Yes | 0 | 0.99 | 0.4 | 0.944 | |
| ECG-AB-028.xml | Yes | 0 | 0.99 | 0.2 | 0.966 | |
| ECG-AB-029.xml | Yes | 0.4 | 1 | 1 | 0.844 | |
| ECG-AB-030.xml | Yes | 0.019 | 1 | 1 | 0.769 | |
| ECG-AB-031.xml | Yes | 0.571 | 1 | 1 | 0.988 | |
| ECG-AB-032.xml | Yes | 0.383 | 1 | 1 | 0.942 | |
| ECG-AB-033.xml | Yes | 0.114 | 1 | 1 | 0.844 | |
| ECG-AB-034.xml | Yes | 0.286 | 0.991 | 0.8 | 0.912 | |
| ECG-AB-035.xml | Yes | 0.56 | 1 | 1 | 0.978 | |
| AVERAGE: | 100% | 0.382 | 0.9937 | 0.8306 | 0.87571 | |

APPENDIX B

SYSTEM REQUIREMENT SPECIFICATION DOCUMENT

Ventricular Tachyarrhythmia Detection System
System Requirement Specification

Version (1.0)

VT DETECTION SYSTEM

Project Supervisor

- Brig Dr. Muhammad Akbar
 - Commandant Military College of Signals
(National University of Sciences and Technology)

Domain Expert (Medical)

- Brig. Dr. Imran Majeed
(HoD Clinical Cardiac Electrophysiology AFIC-NIHD)

Project Team

- Ammar Zaheer (Project Leader)
- Hassaan Owais
- Qurat-ul-Ain Salim Khan
- Aleena Zahid Syed

EXECUTIVE SUMMARY

Heart is an important organ in the human body. Its functioning depends upon two major aspects. The Physiological aspect which consists of the physical structure of the heart like atria, ventricles etc and the Electrophysiological aspect which consists of the Sino-Atrial (SA) Node and the Atrio-Ventricular (AV) Node along with the conduction paths i.e., His Bundles. The pumping of the heart takes place due to the electrical signals / impulses emanated by these electrical nodes. The electrical impulses polarize and depolarize the heart muscles causing contraction and relaxations.

Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. This has been a major issue confronting a uniform e-Health environment, more so in exchange of electronic health records (EHR). Our project, a blend of research and application development converts the Electro cardiograph (ECG) output files from equipments implementing major Health care standards into a standard format. This project is done in collaboration with Armed Forces Institute of Cardiology, National Institute of Heart Diseases (AFIC-NIHD).

Many ECG standards are being used around the globe. Our project focuses on three major standards, Health Level 7 (HL7), Digital Imaging and Communications in Medicine (DICOM) and Standard Communication Protocol for Computer-Assisted Electrocardiography (SCP-ECG). Our application reads the file from any of the above mentioned standards, extracts the waveform and encoded Meta data, translates it into an xml file and then converts it into DAT format. DAT format is the ECG file format used by MIT / Physionet for research purposes in the study of ECGs.

The ECG files thus converted by ECGC can now be used by softwares that are format specific, like VT Detection System and Cardio Genic, which then can be deployed in a real time environment.

Ventricular Tachyarrhythmia (VT) is responsible for 75 to 85% of sudden deaths in heart patients. The traditional ECG is normally based on 12 leads signal acquisition

comprising of 4 limbs and 6 chest leads. The information rendered by this mechanism is usually insufficient in diagnosing / identifying VT. Another important factor that makes the ECG phenomena fall short is its time domain graphical representation but no frequency information.

The project is undertaken as a degree project hence no cost factor is involved or needs to be negotiated.

OVERVIEW

The SRS includes a brief product perspective and a summary of the functions the software will provide. User characteristics are discussed and any general constraints or assumptions and dependencies are listed. A process diagram and various state diagrams are included.

INTRODUCTION

- **CONCEPT**

Heart is one of the most important organs in the human body. Its proper functioning (i.e., healthy habits) depends upon two phenomena:-

- The Physiological structure of the heart i.e., the muscles and the physical structure of the heart
- The Electrophysiological aspect i.e., the electrical conduction system around the heart.

In order to understand the project in its entirety it is essential to understand the structure and functioning of the heart to a reasonable degree.

- **The Heart**

Structure of the Heart

Human Heart is located between lungs in the middle of the chest, behind and slightly to the left of breastbone (sternum). A double-layered membrane called the pericardium surrounds the heart like a sac. The outer layer of the

pericardium surrounds the roots of heart's major blood vessels and is attached by ligaments to the spinal column, diaphragm, and other parts of the body. The inner layer of the pericardium is attached to the heart muscle. A coating of fluid separates the two layers of membrane, letting the heart move as it beats, yet still be attached to the body.

The heart weighs between 7 and 15 ounces (200 to 425 grams) and is a little larger than the size of ones fist. By the end of a long life, a person's heart may have beaten (expanded and contracted) more than 3.5 billion times. In fact, each day, the average heart beats 100,000 times, pumping about 2,000 gallons (7,571 liters) of blood.

The heart has four chambers and few other parts as following:-

- **Atria.** The top two chambers that receive blood from the body or lungs.
- **Septum.** A wall of muscle called that separates the left and right atria and the left and right ventricles.
- **Ventricles.** The bottom two chambers. The right ventricle pumps blood to the lungs to pick up oxygen, the left ventricle is the largest and strongest chamber in the heart. The left ventricle's chamber walls are only about a half-inch thick, but they have enough force to push blood through the aortic valve and into the body.
- **Valves.** There are four valves in the heart that help to direct blood flow. As they open and close, the valves produce sounds that can be heard with a stethoscope. The heart sounds can often tell your doctor about your hearts function.

○ **The Electrical Conduction System**

Electrical impulses from the heart muscle (the myocardium) cause heart to contract. This electrical signal begins in the sinoatrial (SA) node, located at the top of the right atrium. The SA node is sometimes called the heart's "natural pacemaker." An electrical impulse from this natural pacemaker travels through the muscle fibers of the atria and ventricles, causing them to contract. Although

the SA node sends electrical impulses at a certain rate, the heart rate may still change depending on physical demands, stress, or hormonal factors.

The further propagation of the electrical impulse is through the Atrio-Ventricular (AV) node. Through which the impulse is first held for a while and then released to cause contraction of the Ventricles. The electrical impulse gets terminated at the Purkinje fibers.

- **Motivation**

The main motivation behind the project is to provide a highly interoperable environment for the cardiac electro physiologists

All Arrhythmia detection systems used in the field on cardiology are format dependent. Thus there was a need to build a system that could solve the problem of interoperability. The two main advantages are:-

- The cardio electro physiologists will be able to use many research based softwares (especially softwares from MIT's ECG research hub) that operate on the DAT format.
- Tele consultation will be made easy as The Physicians won't have to cater for different standards in other hospitals.

The project has sufficient inherent potentials to stand among one of the best projects in the field.

Definition of System

“To develop an application program that can convert major health standards ECG files into DAT format ECG files, to be use in real time situations for format specific arrhythmia detection and analysis systems like the VT detection system etc”.

Implicit Requirements of the Defined System

- **Calls for a comprehensive Research Work.** Since not much work has been done earlier on this project / methodology, so this shall serve both the ends,
 - Firstly, Clarification, Improvement and Translation of the conceptual schema of the project into technical terms through successive and progressive experimentation.
 - Secondly, providing a base / referential blueprint for the development work on the system.
- **Need for Extensive Experimentation.** The research and development involves active and progressive experimentation. This experimentation is challenging due to a number of reasons namely,
 - Concept Evolution Experimentation at various stages of design.
 - Testing on the ECG data needs active involvement of the domain expert and the paraphernalia of the stakeholder i.e., AFIC / NIHD.
 - Validation of the developed / researched concepts and mathematical modeling.
 - Final testing and deployment of the system as working model.

GENERAL OVERVIEW

SYSTEM INPUTS

- **Signals**

Files from any of the three major ECG standards used around the world can be the input to ECGC.

SCP-ECG, HL7, DICOM, AFIC-NIHD, MIT, CU and AHA database .dat files with associated header files are used to test the algorithm results.

OUTPUTS

- **Results**
 - All parameters results
 - Noise factor results

ALL FUNCTIONS

- **Signals Acquisition from Machine**
- **Noise Filtration**
- **Application of Algorithms**
- **Graphical User Interface (GUI)**
 - **Main Menu**
 - **ECG analyzer**
- **Results View**

PRODUCT FUNCTIONS

Software shall perform the following functions:

- a) Provide Complete Help for each and every aspect of the Software
- b) Provide a highly interoperable system
- c) Acquire .dat files both online and offline
- d) Analysis of ECG signal using a specific algorithms
- e) Noise factor results calculation
- f) Parameters results computation

USER CHARACTERISTICS

Following types of users shall interact with the system:

- a) System Administrator

- b) Engineers
- c) Electro physiologists.
- d) Cardiologist(s)
- e) Technicians
- f) Junior Clerks/ Data Entry Operators

Based on above type of users and their skills following precautions should be taken

1. The interfaces shall be designed keeping novice in mind.
2. Data entry masks should recognize and correct wrongly entered data.
3. Confirmation shall be asked from the user while deleting or changing a record
4. Error messages shall be used wherever required.
5. Users shall be consulted throughout design
6. Help option will be provided to all users.
7. Interfaces should be user friendly.

APPENDIX C

SOFTWARE DEVELOPMENT PLAN DOCUMENT

Ventricular Tachyarrhythmia Detection System

Software Development Plan

Version (1.0)

Preface

In this document the detailed development and management plan for Electro Cardio Graph Converter (ECGC) is described. This plan will be strictly followed over a course of six months. Any modifications applied to this plan will be incorporated in the next versions of this document.

The document includes the details of the software to be delivered; major activities, major deliverables, major milestones, required resources, and top-level schedule and budget will be followed in the sections to come.

1. Introduction

This section contains the details of the project and the software product being to be built. In this section we give a brief overview of the project.

1.1 Project Overview

ECGC aims to provide interoperability between ECG devices and softwares by converting any ECG file format into a simple DAT format.

The VT Detection System is a complete solution with tools that enables cardiologists and electro physiologists for accurate, specific and sensitive VT detection.

1.1.1 Product Functions

ECGC is software which performs the conversion of multiple file formats into a single research based. DAT format which is the required input of the VTDS. VTDS is a multipurpose software kit, which performs various important functions; it provides the capability to perform VT detection.

1.1.2 Minimum Requirements

The minimum requirement for the software to be operational requires Microsoft Windows/ Linux with MATLAB and JAVA jdk 1.5.

1.1.3 Major milestones

The major milestones of the project are

- Completion of Project Plan
- Completion of Requirement Analysis and Project Specifications phase.
- Completion of Design phase
- Implementation and Integration of components.
- Product testing, installation and approval

The details of the software to be delivered, major activities, major deliverables, major milestones, required resources, and top-level schedule and budget will be followed in the sections to come.

1.2 Project Deliverables

This section delineates the major items to be delivered to either the external customer or the in-house user. Following are the details:

1.2.1 List of Project Deliverables

List of project deliverable is as follows:

| Deliverable Name | Due Date |
|--|---------------------------------|
| 1) Project Definition and List of team Members | 22 nd Feb 2006 |
| 2) Project Plan | 2 nd March 2006 |
| 3) Requirements Description | 13 th April 2006 |
| 4) Requirement Analysis | 15 th June 2006 |
| 5) Project Specifications | 27 th September 2006 |
| 6) Testing Plan | 12 th Dec 2006 |
| 7) Detail Design Document | 2 nd March 2007 |
| 8) Fully Functional Product Model | 29 th March 2007 |
| 9) Project Report and Review | 31 st March 2007 |

Further deliverables will be provided upon request.

1.2.2 Details of the Deliverables

Following are brief details of the project deliverables

Project Definition and List of team Members

This includes definition of project and list of team members

Project Plan

This document describes how the team is to be structured and managed for the duration of the project.

Requirements Description

This document outlines the requirements of the proposed software system, upon which design and coding is based.

Requirement Analysis

A detailed analysis of user requirements based on requirements document

Project Specifications

This document will describe detailed specification for ECGC defining parameters and interface.

Testing Plan

It is a complete testing plan describing how and when the testing will be carried out.

This document describes the methodologies used in testing the system.

Detail Design Document

This document builds on the high-level design, and further details the specifics of Coding Product implementation and key algorithms as required.

Fully Functional Product Model

A fully functional product model will be demonstrated. A full source code will also be given if requested.

Project Report and Review

This will include complete project journal explaining what was achieved during the project. Also further improvements possible will also be described.

1.3 Evolution of the Software Project Management Plan

The project document is to be expected to evolve in the following manner over time. The following chart illustrates.

| Version | Primary Author(s) | Description of Version | Date Expected |
|----------------|--------------------------|--|-----------------------------|
| Draft | AHAA Soft | Initial draft created for distribution and review comments | 1 st March, 2007 |

| | | | |
|-------------|-----------|--|---------------------------------|
| Preliminary | AHAA Soft | Second draft incorporating initial review comments, distributed for final review | 9 th March, 2007 |
| Final | AHAA Soft | First complete draft, which is placed under change control | 19 th March, 2007 |
| Revision 1 | AHAA Soft | Revised draft, revised according to the change control process and maintained under change control | 31 st March 30, 2007 |

Any modifications applied to this plan will be incorporated in the next versions of this document.

6.3 1.4 Reference Materials

Refer Appendix A

6.4 1.5 Definitions and Acronyms

Refer Appendix B

2. Project Organization

This section describes the development structure of the project which includes the process model (e.g., lifecycle model), the organizational structure (e.g., chain of command or management reporting structure), and responsibilities of individuals on the project.

2.1 Process Model

2.1.1 Project Life Cycle Model

ECGC will be developed using spiral life-cycle model. The model is as follows:

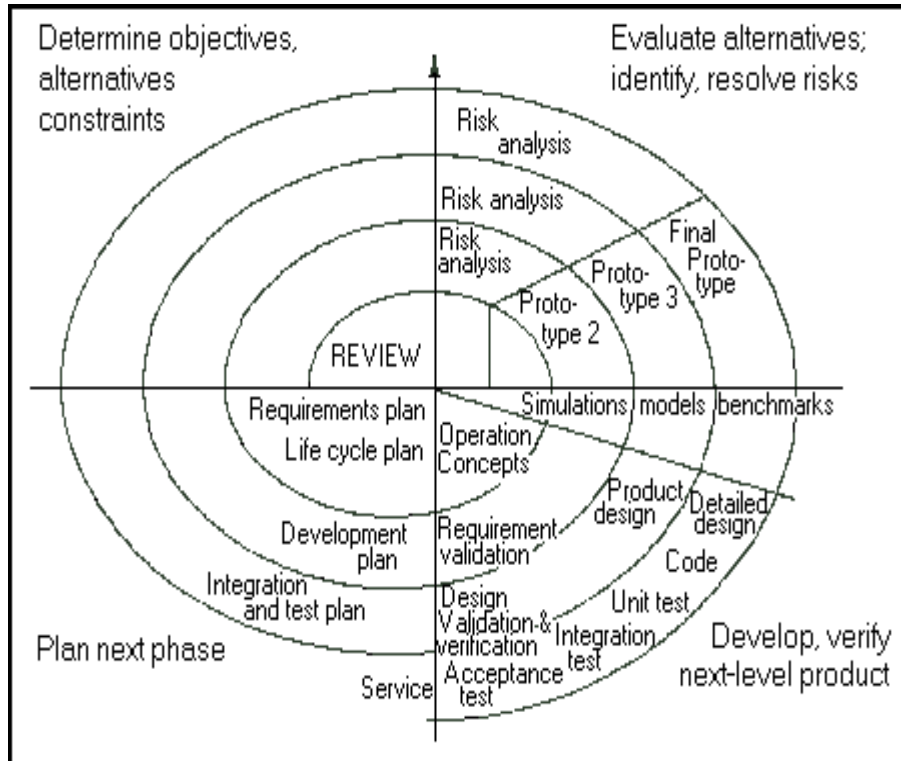


Fig. 1 Spiral Model

2.1.2 Significance

Incremental Model is best suited for ECGC as:

- The Spiral model is better from waterfall as it allows for risk management where the Waterfall places too much emphasis on project management
- The duration of the development period is 8-12 months for which this model is best suited.
- There are only four team members. So each and every member will have to participate in all the phases and deliverables
- Good for large and complex projects
- Customer Evaluation allows for any changes deemed necessary, or would allow for new technological advances to be used
- Allows customer and developer to determine and to react to risks at each

evolutionary level

- Direct consideration of risks at all levels greatly reduces problems

2.1.3 Project Work Products

| Work Product Name | Placed Under Change Control? | Deliverable to Customer? | People Who Must Sign Off on the Work Product |
|---------------------------------------|-------------------------------------|---------------------------------|---|
| EQUIREMENTS DESCRIPTION | Yes | Yes | Project Manager, CEO, Requirements Engineer |
| REQUIREMENT ANALYSIS | Yes | Yes | Project Manager, CEO, Requirements Engineer |
| PROJECT SPECIFICATIONS | Yes | Yes | Project Manager, CEO, Requirements Engineer |
| TESTING PLAN | Yes | Yes | Project Manager, Test Officer, CEO |
| DETAIL DESIGN DOCUMENT | Yes | No | Project Manager,CEO, Designer |
| Fully Functional Product Model | Yes | Yes | Project Manager, CEO |
| Project Report and Review | Yes | Yes | Project Manager,CEO |

2.2 Organizational Structure

2.2.1 Parent Organization

The personnel involved in this project are as follows:

- Ammar Zaheer (Chief Executive Officer, Designer, User Interface Prototyper)
- Hassaan Owais (Chief Technical Officer)
- Qurat-ul-Ain Salim Khan (Customer Analyst, Chief Operational Officer)
- Aleena Zahid Syed (Quality Assurance Manager, Chief Project Officer)

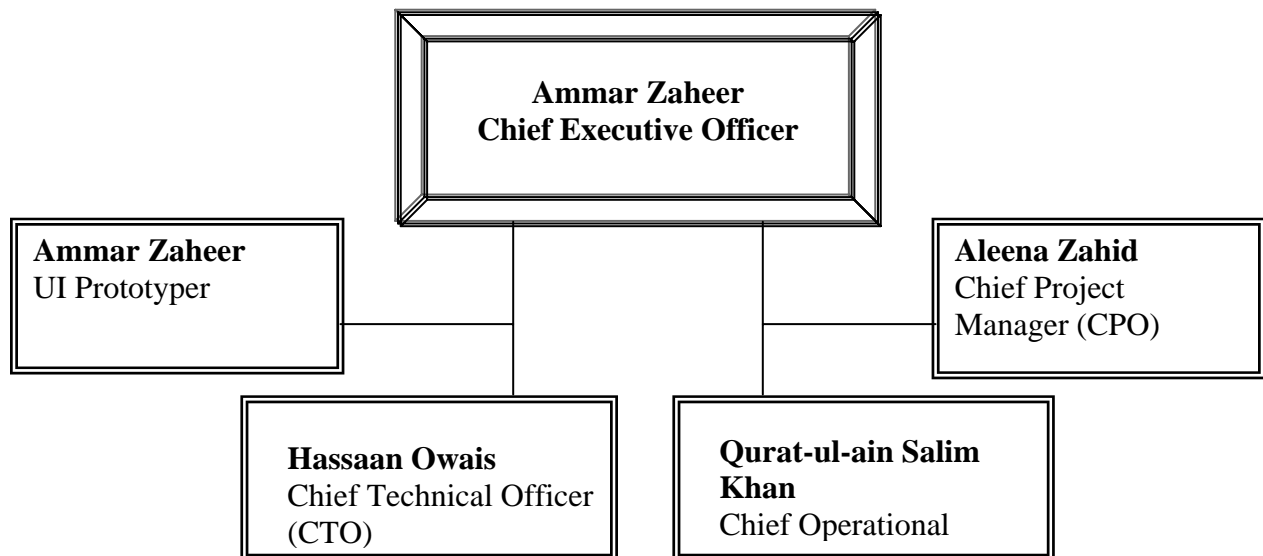


Fig. 2 Organization Chart of the Executive Staff

Each member is equipped with significant Computer Science, Mathematics and other skills acquired during education training to accomplish the project.

All are expected to contribute approximately equal amounts of work to the project on a weekly basis. This workload needs to be balanced with other subjects team members are undertaking. It is expected that a weekly workload for this project should be a minimum of approximately **20 hours/week**.

2.2.2 Customer organization (external)

AFIC-NIHD being the external customer organization has been kept in linked to the project directly by the project manager.

2.3 Organizational Boundaries and Interfaces

- Regular meetings with client will be held. The project progress will have to be approved by the client at least once a week. Explanation of different requirements will be acquired from the client.
- Any member of the team will not reveal the project documentation to any party other than the client.
- Also every member will have to attend team meetings unless he/she has a valid reason. Team members will meet at least twice a week and a detailed meeting will be held before submission of each deliverable.

Informal Communication will also be used extensively in this project due to its quick and efficient information transferal properties. The team utilizes personal communication and email communication (somewhat formal in nature given that they are archived) as much as possible. While it is difficult to always meet with the other team members required (given their varying academic timetables), personal communication is preferred over email communication for its instantaneous feedback. However, given these academic restrictions, email communication is used as the primary form of interacting with other team members. Email communication also affords a form of trace ability that other informal mechanisms fail to provide.

- The Project is directly communicating with the upper management of the organization as it is the key project at hand.
- Project Manager will be responsible for communicating with the upper management.
- Direct communication is being held and will be held with the Customer

organization externally.

- Again the Project manager will be responsible for communication with the customer organization.
- There are no subcontracting organization(s) associated with project.
- There are no other organizations that the project interacts with. Any future interactions or relationship will be delineated in the future revised versions of the document if the need arises.
- This project is completely independent of the other projects that the organization is dealing with. Currently this project and its completion remain the top priority of Vision Software Makers. All other projects have been halted for the time being to give utmost time and resources to this project currently at hand.

2.4 Project Responsibilities

The following chart illustrates the persons and their respective responsibilities concerning this project. Any changes in the given structure will be incorporated in the future versions of the document.

| <i>Responsibility</i> | <i>Persons Responsible</i> |
|--------------------------------|----------------------------|
| Overall Project Manager | Ammar Zaheer |
| Engineering Manager | Aleena Zahid |
| Quality Assurance Manager | Hassaan Owais |
| End-User Documentation Manager | Qurat-ul-Ain Salim |
| Requirements Engineer | Hassaan Owais |
| Software Architecture | Aleena Zahid |
| Technical Self-Reviews | Ammar Zaheer |

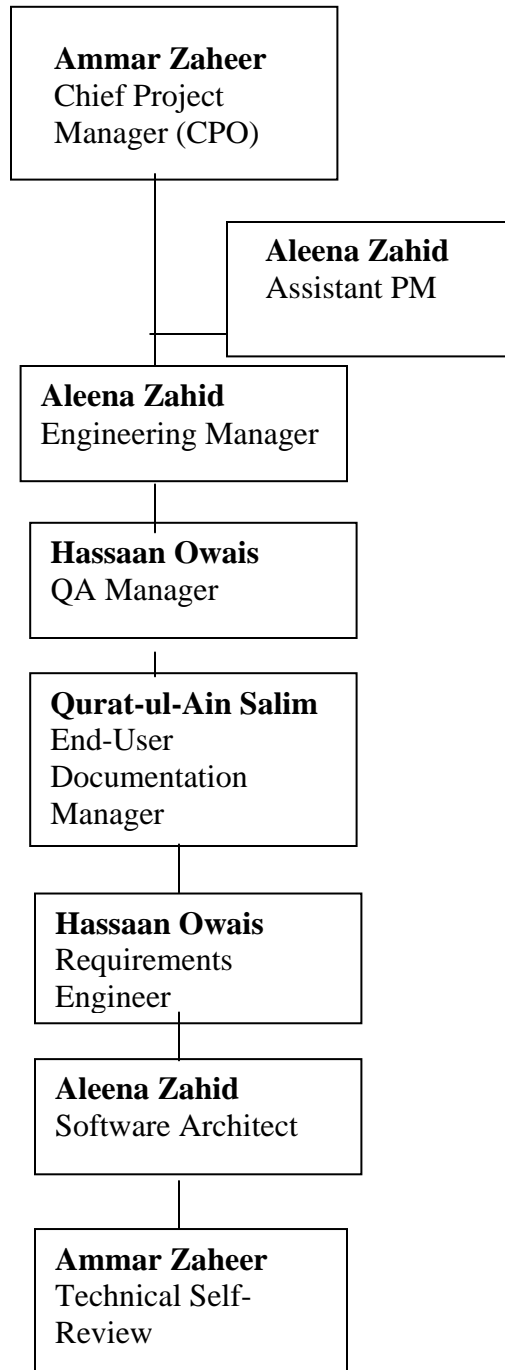


Fig. 3 Organizational Chart for Project Responsibilities

3. Managerial Process

In this section we describe policies that will be adopted to manage ECGC. This includes management objectives, priorities, project assumptions, dependencies, constraints, risk management techniques, monitoring and controlling mechanisms, and the staffing plan.

3.1 Management Objectives and Priorities

The main objective is to ensure that time constraints are strictly followed. Also the priority will be given to the quality of work.

During the earlier stages of the project more priority will be given to schedule.

Cost will not be as much a major factor in this project. Though this is a commercial project but it does not fall into the category of high budget projects, so cost management is not the primary goal. Due to work load main concern will be, to meet time constraints and to make sure work is completed on schedule.

More priority will be given to functionality as well. The main aim of the project will be to achieve the maximum possible efficient functions of the project in the minimum possible time. The project team will attempt to strike maximum possible balance between time and functional priority.

Minimum attempts will be made to acquire any third party software. The development team may decide to obtain or modify some existing software for the benefit of the project in an attempt to save time and resources. Existing software algorithms will be employed to provide sufficient tools for efficient and comprehensive development of the software with implementation of new algorithms as well.

3.2 Assumptions, Dependencies and Constraints

It is assumed that the schedule will not clash with the academic schedule of the team members. The team will be able to setup the project to test the product.

3.3 Risk Management

This area describes the major risks to the project, which the project plan has been designed to address. It also describes how risks will be tracked and monitored.

3.3.1 Major Risks

The major risks that can impinge on the project are

- Clash of project schedule with other activities of team members
- Work overload.
- Accurate conversion is required.
- Shortage of time
- Availability of hardware
- Lack of software engineering experience and unfamiliarity with tools, biomedical equipment and ECG characteristics.
- Highly Safe Detection is required

3.3.2 Risk Tracking and Monitoring

To avoid work overload the tasks will be distributed among team members in such a way that every personnel is able to give enough time. Every phase will have an informal sub schedule. Main schedule is made flexible enough to accommodate mishaps and undesirable circumstances

It will be made sure before integration phase or during the test plan definition phase that desired hardware and software is acquired. Knowledge to setup the hardware will also be acquired.

Every team member will be given time to get familiar to the tools. Help materials will be acquired for this purpose. Also necessary in time help will be requested from external supervisor.

Any risk factor, suggested by a team member or client will be included in this section for next versions. The possibility of risks emerging during the project is very high so a risk list along with the avoidance mechanism will be kept and updated accordingly.

The possibility of risks emerging after the project is very high as ECG has a lot of safety issues to be addressed which have to be incorporated for an accurate and specific VT detection. In case any risk cannot be overcome the priority will be given to the quality of the product as mentioned earlier that cost is not a factor for this project.

3.4 Progress Monitoring and Controlling Mechanism

3.4.1 Monitoring and Controlling Mechanisms

Project cost, schedule, quality, and functionality will be tracked throughout the project. In a weekly meeting the progress will be reviewed and analyzed by Project Manager and Quality Assurance Manager. Problems encountered by any team member will be discussed and resolved accordingly.

3.4.1.1 Report contents

Separate reports shall be prepared for monitoring the technical, functional, quality and cost monitoring of the project. Progress reports will also be maintained in due course of time. The status reports of the Managing committee will contain the following details:

- Status of the current phase activities
- Estimated time of completion of the current phase
- Milestone deliverables at current phase
- Schedule for the next phase activities
- User Actions

The status reports will be accompanied by Gantt Charts. Various other graphs will also be presented at the managing committee meeting to support the facts laid down in the status reports.

3.4.1.2 Report Format

A standard report format will be developed and circulated to all the members of the project team. All activities will be recorded in a standard manner in these reports. Copies of these reports will be saved electronically. At the same time hard copies of the reports will also be maintained.

3.4.1.3 Reporting structure and frequency

The reporting structure will be developed and circulated to all parties concerned. All reports will be developed on a weekly basis.

3.5 Staffing Plan

The number of personnel is fixed in the current project, considering the different approach of the project at hand. The minimum skill levels are not defined at this stage. The entire duration of the project will be headed and dealt with the same time, each individual acquiring different role during different phases.

There will be no extra personnel acquired during the course of the project besides those that are currently involved in the project.

There will be some necessary training that will be required in the later stages of the project. Necessary arrangements will be made to make available the essential training for the personnel working on the project.

| Type of Personnel's | Number of personnel | Required Skill Level / Qualification(s) |
|---------------------------------|----------------------------|--|
| Requirement Engineer (s) | 2 | Experience in Requirements Engineering |
| Software Designer (s) | 2 | Software Engineering |
| Project Manager | 1 | Software Engineering |
| Coder (s) | 3 | Excellent Coding in JAVA and MATLAB |
| QA Manager | 1 | Experience as QA Officer |

| | | |
|-------------------------|---|----------------------------|
| Test Officer (s) | 2 | Experience as Test Officer |
| Manager (s) | 1 | Management Skills |

4. Technical Process

This section describes the top-level technical processes used on the project including the technical methods, tools, and techniques; major software documents; and supporting activities such as configuration management and quality assurance.

4.1 Methods, Tools and Techniques

4.1.1 Operating Environment

The operating environment will be that of Microsoft Windows. Installation of MATLAB and JAVA jdk 1.5.0 IDE is mandatory.

4.1.2 Hardware

- ❖ Stand alone IBM PCs.
- ❖ Holter Machine
- ❖ MAC 5000
- ❖ Signal Averaging
- ❖ Misc ECG Machines

4.1.3 Software tools

- ❖ Compiler or IDE : JAVA and MATLAB
- ❖ Programming language : JAVA and MATLAB
- ❖ Coding standards : IEEE
- ❖ Documentation standards : IEEE

Remarks

Software will have object-oriented reusable structure. Documentation will be clear and explanatory. Microsoft Project software will be used to aid in management.

4.2 Software Documentation

The listed documents will be developed for the project, including are milestones, reviews, and signoffs for each document.

Documentation will consist of

- Project Plan
- Requirements Document
- User Interface Plan
- Requirement Analysis
- Specifications
- Testing Plan
- Detailed Design
- Product Review

4.3 Project Support Functions

The project is supported by following other documents. These documents describe the plans for functions that support the software development effort.

- Configuration management Plan and Documentation
- End - user documentation (USER MANUAL)

The plans for these supporting functions will be developed in due time and should be referred to as the need arises. Any other supporting documents that need to be included on the list of the above documents will be added in the later versions of this document.

5. Work Packages, Schedule, and Budget

5.1 Work Packages

The work packages defined for the software development lifecycle are as below. These including the sub-packages and tasks must be completed in order to complete the software.

1. Software Project Initiation
2. Software Concept Development
3. Software Requirements Development
4. Software Architectural Design
5. Software Development
6. Software Implementation and Integration
7. Software Testing and Configuration Management

5.2 Dependencies

5.2.1 Dependencies among work packages

All the work packages discussed above are extensively interdependent. Every package is dependent upon all the packages illustrated before it. And all the tasks within each work-package follow the same schematic.

5.2.2 Dependencies on external events

Various work Products will be dependent on the external approvals etc. Details of these dependencies will be specified in the later versions of this document.

5.3 Resource Requirements

The following resources will be needed.

Hardware Tools: Stand alone IBM PCs, Holter and other ECG Machines.

Software Tools Programming tools (MATLAB and JAVA)

Additional resources will be identified in the later versions of this document.

5.4 Budget and Resource Allocation

5.4.1 Budget Allocation

Following is the amount of Budget allocated to the Software processes.

| | | |
|----------------------------------|---|------|
| Software Requirements Management | : | 15 % |
| Software Design | : | 15 % |

| | | |
|----------------------------------|---|------|
| Software Construction | : | 10 % |
| Software Implementation | : | 7 % |
| Software Testing and Integration | : | 18 % |
| Documentation | : | 10 % |
| Software Project Management | : | 25 % |

5.5 Project Schedule

The following schedule will be followed during the development process. The schedule is based on project deliverables. The schedule given below is subject to change as the project development progresses. Pert and Gantt charts also represent this schedule.

PROJECT SCHEDULE FOR ECGC

Based on Project Deliverables, following Chart illustrates the Project Schedule.

| Deliverable Name | Due Date |
|---|---------------------------------|
| 10) Project Definition and List of team Members | 22 nd Feb 2006 |
| 11) Project Plan | 2 nd March 2006 |
| 12) Requirements Description | 13 th April 2006 |
| 13) Requirement Analysis | 15 th June 2006 |
| 14) Project Specifications | 27 th September 2006 |
| 15) Testing Plan | 12 th Dec 2006 |
| 16) Detail Design Document | 2 nd March 2007 |
| 17) Fully Functional Product Model | 29 th March 2007 |
| 18) Project Report and Review | 31 st March 2007 |

Fig. 5-Chart for ATAYOF Project Development Schedule

6. Additional Components

This section defines the additional components needed to manage this project.

- ❖ Training plans
- ❖ Facilities plans
- ❖ Installation plans
- ❖ Software Maintenance plans

Details of these areas will be provided in separate documents in due time.

APPENDIX D

TEST PLAN DOCUMENT

Ventricular Tachyarrhythmia Detection System
Test Plan Document
Version (1.0)

Document and Version Control

Document Information

| | |
|----------------------------|---|
| Document Title | Test Plan for ECGC |
| Filename | TestPlan_1.0.doc |
| Creation Date | March 10,2007 |
| Authors | Ammar Zaheer, Hassaan Owais, Qurat-ul-Ain Salim, Aleena Zahid |
| Version | 1.0 |
| Distribution List | 1. Qurat-ul-Ain Salim Aleena Zahid |
| Reviewers | 1. Ammar Zaheer 2. Hassaan Owais |
| Passing Review Date | March 20, 2007. |

Related Documents

| | |
|-------------------------|--|
| Input Documents | System Requirements Specifications (Annex A-1) |
| Output Documents | Test Case Document |

Document History

| S. No. | Document Version | Major Changes | Author/s | Creation Date | Review Date | Reviewer/s |
|--------|------------------|---------------|---|-------------------|--------------------|-------------------------------|
| 1. | 1.0 | Initial Draft | Ammar Zaheer, Aleena Zahid, Hassaan Owais, Qurat-ul-Ain Salim | March 10, 2007 | March 20, 2007. | Ammar Zaheer Hassaan Owais |

Project Information

Project Release Information

| | |
|------------------------------------|---------------------------------|
| Project Name | ECGC |
| Project Code | ECGC 07 |
| Project Release Number | 1.0 |
| Project Release Date | March 29, 2007 |
| Testing Dates | March 10, 2007 – March 20, 2007 |
| Testing Iteration Number | 1.0 |
| Project Modules Information | Software |

Project Team Information

| | |
|-----------------------------|--|
| Group Leader | Ammar Zaheer |
| Developer Name(s) | 1. Ammar Zaheer 2. Hassaan Owais 3. Qurat-ul-Ain Salim Khan 4. Aleena Zahid |
| Quality Analyst Name | Qurat-ul-Ain Salim |
| Tester Name(s) | 1. Ammar Zaheer 2. Hassaan Owais |

Introduction

Purpose of Document

This document is the master test plan for **ECGC**. It serves as an umbrella document to coordinate all test plans for this project. It defines the scope, approach, schedule, risks/mitigations, and entry/exit criteria that are required as part of project planning prior to Execution. It also contains various resources required for the successful completion of this project.

The purpose of this Software Test Plan is to test the functionality and make sure that the requirements stated in the Software Requirement Specification (SRS) are fulfilled.

Product Scope

The ECGC is intended to provide an accurate, sensitive and efficient system for cardiac electro-physiologists. The system comprises of software module/s for ECGC. It invokes a new concept in the field of bio-medical engineering in general and the paradigm of ECGC in particular.

Intended Audiences

The document is intended for test personnel to be used as the documented plan for the software/system test activities. Other stakeholders include development Project DS, Group Leader, AFIC/NIHD doctors and system developers.

Test Objectives

The tests included in this test plan are to be conducted to verify the software implementations for the ECGC. Major part of the test work includes software testing for ECGC components:

Test Case Matrix

List of all the test cases is attached.

Test Resources and Environment

The entire test will be conducted either in the college computer labs or in Electrophysiology department of AFIC (NIHD).

Hardware

The following hardware/system will be used in the testing process:

- Data Acquisition Module (Holter Machine, Signal Averaging, MAC 5000)
- Power Supply Module

Software

The following software /system will be used in the testing process:

- Data Communication
- Conversion to DAT format
- File /Patient Record Storage
- Abnormality Identification
- GUI

Testing Tools

All tests for this Phase will be conducted manually. At this time no specialized testing tools are being used. Test cases and bug tracking reports will be generated and documented on Microsoft Word and Excel sheets. Also no automated testing tools will be used.

Recommendations:

Software for bug tracking system is highly recommended for future phases of this project.

Test Personnel

| Parties | Contact Person | Role and Responsibilities |
|-------------------|--------------------------------------|--|
| DS | Brig Dr. Muhammad Akbar | <ul style="list-style-type: none"> Overall Supervision Work stream Management Review of Test Plan and Test Cases Monitor testing schedule and procedure. |
| Testing Team Lead | Ammar Zaheer (8.ammar@gmail.com) | <ul style="list-style-type: none"> QA Team Lead Development of Test Plan and Test Cases. Managing and directing testing activity To Ensure Testing activity comply with project and test plan Conduct testing |
| Test Engineer | Hassaan Owais (hasx4@hotmail.com) | <ul style="list-style-type: none"> Develop test cases and conduct testing Submit Bug Reports |

Testing Schedule

| Task | Start Date | End Date | Days |
|--|------------|----------|------|
| Document Requirement | 10-03-07 | 13-03-07 | 3 |
| Document Design | 14-03-07 | 14-03-07 | 1 |
| Setup and familiarity with test environment in the AFIC Labs | 15-03-07 | 17-02-07 | 3 |
| Create Test Cases | 18-03-07 | 19-03-07 | 2 |
| Conduct walk-through of Test Plan and Test Cases | 20-03-07 | 20-03-07 | 1 |
| Test Case Execution | 21-03-07 | 25-03-07 | 5 |
| Retest incidents and Regression Testing | 26-03-07 | 28-03-07 | 2 |
| Sign off on Test | 29-03-07 | 29-03-07 | 1 |

Risks, Dependencies and Assumptions

Since the development of the ECGC is almost completed and final, so unit and integration testing of the software is not possible. Only the feature testing for Software will be conducted.

The following is a list of risks and contingencies for this testing procedure.

- Testing is contingent to proper and smooth operation of the test environment in the AFIC Labs.
- The source code for ECGC should be available by the start date of testing i.e. 10-03-2007.
- In case of some critical or major bug, time is very limited for consultation with developers. Also there should be some pre-defined procedure to contact with developers for defect management etc.
- The test plan and test schedule are based on the current Requirements Document. Any changes to the requirements could affect the test schedule.

Defect Management (DM) Process

Defects (bugs) found during test execution will be captured and recorded by the testers in a separate database. For now, separate MS Excel sheets will be used. These reports will be shared by Development Manager, Project Manager and all concerned development team members. The following are the steps included in the bug report (a template is attached).

- Title or Summary
- Description of the Problem
- Software release version or phase etc.
- Priority

- Functional area: which software block/module is suspected to have problem
- Traces: attach any trace files/screen shots that are taken as part of the analysis.
- Currently assigned to: e.g. development manager, developer
- Status: Open or closed
- Remarks/comments
- Note: All new additions should be made with a date e.g. new traces, comments/remarks or any additions to description by the tester.

Bug Severity Levels

| S. No. | Severity | Definition |
|--------|-------------|--|
| 1. | Critical | A major part of the system cannot be used, or system / data integrity is in doubt, which causes a halt to the testing. All available resources must be used to resolve the incident, examples are: <ul style="list-style-type: none"> • Application crashes forcing the tester off the system. • Missing feature. • Output not generated. |
| 2. | Major | Must be fixed before the final sign off the testing phase. Productivity is adversely affected e.g. Error condition is created which was not the expected result of the test, for which there is no recovery for that test, although the user can select other tasks and run other tests. |
| 3. | Medium | Use of the relevant process can continue with a temporary workaround, but a fix must be scheduled before exit. Examples are: <ul style="list-style-type: none"> • Cosmetic errors. • Problems that do not cause easily noticeable faults. |
| 4. | Minor | Errors that have a little or no impact on interim use or productivity. Fixing these bugs before exit is not mandatory. |
| 5. | Enhancement | Not in specifications, but desirable according to tester. |

Debugging Priority Levels

| Priority | Definition |
|----------|---------------------|
| Critical | Resolve immediately |
| Major | Give High Attention |
| Medium | Normal Queue |
| Minor | Low Priority |

Testing Approach

Entry Criteria

- Sign-off and baseline Requirement and Design specification.
- Completion of this test plan, test matrix and test cases.
- Completion of Unit Testing by Software Developers.
- Complete Installation of hardware/infrastructure configuration at the testing environment site.
- Completion of a Sanity Check of test environment that prove the environment is stable, clean and isolated. The test environment must not have interference of development or production activities during QA period.
- Testers have been committed to testing and completed the sufficient training provided by developers.
- Availability of the system and support person(s) to support the testing environment during testing.

Exit Criteria

- All Critical & High defects have been fixed and a clear strategy has been devised on how to handle any remaining Medium priority defects.

- Completion of all Testing activities according to the planned test cases and conditions.
- All problems/incidents have been resolved, fixed, retested successfully and closed.
- Full record of all problems / incidents and evidence of satisfactory retest maintained.
- All Testing Activities have been stated at Test Report.

Test Execution Procedure

Test Execution steps are follows:

- Ensure the code and the test environment is in place.
- Execute the test cases according to the pre-defined test sequence
 - Document the actual results
 - Compare the actual results against the expected results
- Document any discrepancies/bugs in the ‘Bug Tracking Document’ according to the Incident Tracking Procedures
 - Assign Bug tracking document to applicable owner. For this purpose an email will be sent to the respective development engineer.
- A brief report showing status for test cases will be issued periodically.
- Errors and incidents will be updated periodically.
- Re-test issues that are turned back for re-test
 - Regressions tests will be conducted after consulting with development team (if necessary), which may have been affected as a result of the fixes.

Testing Types/Functions Used

Features and flow testing for Software part of **ECGC** will be tested. In general following types of testing will be conducted:

- Startup/shutdown Testing
- Feature/function Testing
- Negative Testing
- Unit Testing

- Integration Testing

Testing Types/Functions Not Used

Any other functionality except Software modules will not be tested. In general the following type of testing will not be conducted:

- Installation/Migration Testing
- System level Regression Testing

Test Deliverables

- Test Plan
- Test Cases
- Test Cases summary/status Report
- Bug Report Tracking Documents
- Final Test Summary Report

Test Cases

Module Name: Software

Module Information

| | |
|---------------------------------|---|
| Module Name | Software Module |
| Module Release Number | 1.0 |
| Module Release Date | 10-03-07 |
| Testing Dates | 12-03-07 to 20-03-07 |
| Testing Iteration Number | 1 |
| Developer Name(s) | 1. Ammar Zaheer 2. Hassaan Owais 3. Qurat-ul-Ain Salim 4. Aleena Zahid |

Functional Requirements

| | |
|--------------------------------|---|
| Module Description | The Software comprises of various modules integrated together. |
| Functional Requirements | 1. ECG Data Acquisition 2. Main Menu 3. ECGC 4. Record Saving 5. VTDS 6. Results Display |

Test Summary Report

The tests have shown the following results

- All software modules preliminary execution shows desired results
- All modules integration testing illustrate no problem

Desired results of Algorithms demonstrate improved values of parameters. The mean values of ECGC are:

○ Conversion to DAT format

| <u>Standard</u> | <u>Conversion to DAT format</u> |
|-----------------|---------------------------------|
| SCP-ECG | <i>100%</i> |
| DICOM | <i>100%</i> |
| HL7 | <i>100%</i> |

○ Result of Arrhythmia Detection System

| Sensitivity | Specificity | Positive Predictivity | Accuracy |
|-------------|-------------|-----------------------|----------|
| 50%-60% | 92% | 72%-90% | 90%-95%* |

* depending upon noise in data

- Bugs in few noisy data results notified to system developers
- Overall system tests demonstrate 93% accuracy for all components.

Appendix E

Definitions, Acronyms and Abbreviations

- **VT:** Ventricular Tachyarrhythmia
- **VF:** Ventricular Flutter.
- **ECG:** Electro Cardiograph traditionally known as EKG as well.
- **ECGC:** Electro CardioGraph Converter
- **VTDS:** Ventricular Tachyarrhythmia Detection System
- **DICOM:** Digital Imaging and Communications in Medicine
- **SCP-ECG:** Standard communications protocol for computer assisted electrocardiography
- **HL7:** Health Level 7
- **Cygwin:** Linux/Unix Emulator
- **XML:** Extended mark-up Language
- **SPEC:** Spectral Algorithm
- **UML Diagrams:** Various diagrams including Use-Case, Sequence and Data Flow that show the initially perceived outline functionality of the intended system.
- **GUI :** Graphical User Interface
- **UI :** User Interface
- **SRS:** Software Requirements Specification
- **SDP:** Software Development Plan
- **STP:** Software Test Plan
- **PC:** Personal Computer
- **PM:** Project Manager
- **CTO:** Chief Technical Officer

- **CEO:** Chief Executive Officer
- **QA:** Quality Assurance
- **WVL0:** Wavelet 0 Algorithm
- **WVL1:** Wavelet 1 Algorithm
- **WVL2:** Wavelet 2 Algorithm
- **WVL3:** Wavelet 3 Algorithm

Software Project Management Document References

The following documents were referred for scope and detail of SPM Documents.

- IEEE Std 610.12-1990, IEEE Standard Glossary of Software Engineering Terminology
- IEEE Std 730.1-1995, IEEE Guide for Software Quality Assurance Planning
- IEEE Std 828-1998, IEEE Standard for Software Configuration Management Plans
- IEEE Std 982.1-1988, IEEE Standard Dictionary of Measures to produce Reliable Software
- IEEE Std 1012-1998, IEEE Standard for Software Validation and Verification

REFERENCES

1. A. G. Ramakrishnan, Supratim Saha, “ECG Coding by Wavelet-Based Linear Prediction”, *IEEE Trans. on Biomedical Engineering*, Vol. 44, pp. 1253–1261, Dec. 1997.
2. Michael L. Hilton, “Wavelet and Wavelet Packet Compression of Electrocardiograms”, *IEEE Trans. on Biomedical Engineering*, Vol. 44, pp. 394–402, May 1997.
3. A. Djohan, T. Q. Nguyen, and W. J. Tompkins, “ECG compression using discrete symmetric wavelet transform”, *17th Int. Conf. IEEE in Medicine and Biology*, 1995.
4. S. Mallat, *A Wavelet Tour of Signal Processing*, Academic Press. 1997.
5. M. Antonini, M. Barlaud, P. Mathieu, and I. Daubechies, “Image Coding Using Wavelet Transform”, *IEEE Trans. Image Processing*, Vol. 1, pp. 205–220, Apr. 1992.
6. Brian Bradie, “Wavelet Packet-Based Compression of Single Lead ECG”, *IEEE Trans. on Biomedical Engineering*, Vol. 43, May 1996
7. Y. Zigel, A. Cohen, A. Abu-ful, A. Wagshal, A. Katz, “Analysis by Synthesis ECG
Signal Compression”, *Computers in Cardiology*, Vol. 24, 1997, pp. 279–282.
9. Enis Cetin, Hayrettin Koymen and M. Cengiz Aydn, “Multichannel ECG Data Compression by Multirate Signal Processing and Transform Domain Coding Techniques”, *IEEE Trans. on Biomedical Engineering*, Vol. 40, pp. 495–499, May 1993
10. P. Laguna, R.G. Mark, A. Goldberg, G.B. Moody, „A Database for Evaluation of Algorithms for Measurement of QT and Other Waveform Intervals in the
11. ECG”, *Computers in Cardiology*, Vol. 24, 673-676, 1997
12. PhysioNet: Research Resource for Complex Physiologic
13. Signals, <http://www.physionet.org/>
14. Association for the Advancement of Medical Instrumentation, “EC57: Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms” and “EC38 Ambulatory Electrocardiographs”, *AAMI, Arlington*, 1998
15. G. B. Moody, “WFDB Applications Guide”, *Harvard- MIT Division of Health Sciences and Technology*, 10th ed., 2001

16. R. Jané, A. Blasi, J. García, P. Laguna, “ Evaluation of an Automatic Threshold Based Detector of Waveform Limits in Holter ECG with the QT Database”, *Computers in Cardiology*, Vol. 24, 295-298, 1997
17. S. Suppappola, Y. Sun, “A Comparison of three QRS Detection Algorithms using the AHA ECG Database”, *IEEE Engineering in Medicine and Biology Society*, Vol. 13, 586-587, 1991
18. H.-K. Joeng, K.-K. Kim, S.-C. Hwang, M.-H. Lee, Barro S, Ruiz R, Cabello D and Mira J 1989 Algorithmic sequential decision-making in a frequency domain for life threatening ventricular arrhythmias and imitative artefacts: a diagnostic system *J. Biomed. Eng.* **11** 320–8
19. Chen S, Thakor N V and Mower MM 1987 Ventricular fibrillation detection by a regression test on the autocorrelation function *Med. Biol. Eng. Comput.* **25** 241–9
20. Clayton R H and Murray A 1999 Linear and non-linear analysis of the surface ECG during human ventricular fibrillation shows evidence of order in the underlying mechanism *Med. Biol. Eng. Comput.* **37** 354–8
21. Clayton R H, Murray A and Campbell R W F 1991 Changes in the surface ECG frequency spectrum during the onset of ventricular fibrillation *Proc. Computers in Cardiology 1990* (Los Alamitos, CA: IEEE Computer Society Press) pp 515–8—1993 Comparison of four techniques for recognition of ventricular fibrillation from the surface ECG *Med. Biol. Eng. Comput.* **31** 111–7
22. Denton T A, Diamond G A, Khan S S and Karagueuzan H 1992 Can the techniques of nonlinear dynamics detect chaotic behavior in electrocardiography signals *J. Electrocardiol.* **24** (Supplement) 84–90
23. *J. Electrocardiol.* **22** 253–62 Kaplan D and Cohen R 1990 Is fibrillation chaos? *Circ. Res.* **67** 886–92 Kerber R E, Becker L B, Bourland J D, Cummins R O, Hallstrom A P, Michos M B, Nichol G, Ornato J P, Thies
24. W H, White R D and Zuckerman B D 1997 Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis, algorithm performance, incorporating new waveforms, and enhancing safety *Circulation* **95** 1677–82
25. Kontodimopoulos N, Pallikarakis N, Christov I and Daskalov I 1998 In-house development of test equipment for quality control and training. Case study: a prototype ECG simulator–tester *Med. Eng. Phys.* **20** 711–21
26. Kuo S and Dillman R 1978 Computer detection of ventricular fibrillation *Proc. Computers in Cardiology 1978* (Long Beach, CA: IEEE Computer Society Press) pp 347–9 *Detection of ventricular fibrillation from surface ECG* 439

28. Murray A, Campbel R W F and Julian D G 1985 Characteristics of the ventricular fibrillation waveform *Proc.Computers in Cardiology 1985* (Washington, DC: IEEE Computer Society Press) pp 275–8
29. Thakor N V, Natarajan A and Tomaselli G F 1994 Multiway sequential hypothesis testing for tachyarrhythmia discrimination *IEEE Trans. Biomed. Eng.* **41** 480–7
30. Thakor N V, Zhu Y S and Pan K Y 1990 Ventricular tachycardia and fibrillation detection by a sequential hypothesis testing algorithm *IEEE Trans. Biomed. Eng.* **37** 837–43
31. Zhang X S, Zhu Y S, Thakor N V and Wang Z Z 1999 Detecting ventricular tachycardia and fibrillation by complexity measure *IEEE Trans. Biomed. Eng.* **46** 548–55
32. Muazma Zahid, Muhammad Akbar, Sadaf Malik, Umair Ahsan ,Zahid Sultan, Imran Majeed, “A wavelet based algorithmic approach for detecting Ventricular Tachyarrhythmia” , *Rhythm for Life-3rd International Conference at AFIC, 2006.*
33. Ammar Zaheer, Hassaan Owais, Qurat-ul-Ain Salim, Aleena Zahid “SCP-ECG: Using a different approach”, *Rhythm for Life-4rd International Conference at AFIC, 2007.*
34. Ammar Zaheer, Hassaan Owais, Qurat-ul-Ain Salim, Aleena Zahid, “A Step towards interoperability in ECG equipment”, *eHealth Asia Conference 2007, Malaysia.*
35. Ammar Zaheer, Hassaan Owais, Qurat-ul-Ain Salim, Aleena Zahid, “HL7: A logical and Lucid Strandard”, *IASTED telehealth conference 2007, Montreal..*