

**A CLINICAL PATIENT VITAL SIGNS PARAMETER MEASUREMENT,  
PROCESSING AND PREDICTIVE ALGORITHM USING ECG**

A Thesis Submitted For the Degree of Doctor of Philosophy

By

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## **DEDICATION PAGE**

*To the three girls in my life...Antwanette my loyal friend, partner and wife and the inspiration in my life...your strength have always been my motivation. Anneme, for your sweet kisses, kind sole and tender presence...don't grow up too fast. To Karla, daddy's little girl...your energy is inspiring and your giggle addictive, you hold my heart in your palm.*

*Thank you for the time you sacrificed for me to pursue this passion.*

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## LIST OF ABBREVIATIONS USED

ECG	Electrocardiography Electro Cardio Gram
ER	Emergency Room
CVD	Cardiovascular Disease
SSH	Saad Specialist Hospital
ICU	Intensive Care Unit
MI	Myocardial Infraction
SA Node	Sinoatrial Node of the heart and primary pacemaker
AV node	Atrioventricular Node
WPW	Wolff-Parkinson-White Syndrome
LQTS	Long QT Syndrome
Sec	Seconds
A/D	Analogue to Digital Converter
I/O	Data Input Output
OOP	Object Oriented Programming
<i>df</i>	Differentiator Value
ABS	Absolute Value
SPO2	Oxygen Saturation, as used in Medicine
LED	Light Emitting Diode
PVC	Premature Ventricular Contraction
PEA	Pulseless Electrical Activity
nm	Nano Meter
SCP-ECG	Standard Communication Protocol for Computer Assisted Electrocardiography
DNS	Domain Name Server or Service
RICU	Respiratory Intensive Care Unit
CCU	Cardiac Care Unit
AED	Automated external Defibrillator

## COMMON TERMINOLOGIES USED

**Waveform:** Movement away from isoelectric baseline

**Segment:** A line between two Segments. Ex. ST segment

**Interval:** A waveform AND a segment. Ex. PR interval

**Complex:** Several waveforms. Ex: QRS complex

**Isoelectric:** The baseline electrical level of the body

**Lead:** The signal derived from a group of electrodes

**Depolarization:** Movement of electrical charge through nerve or muscle tissue, changing its voltage

**Re polarization:** Process of a nerve or muscle cell returning to its normal electrical state

### P-Wave Characteristics

- Present in a one-to-one relationship with QRS complex
- Upright in Lead II with antegrade conduction
- Negative in Lead II indicates retrograde conduction
- Represents Atrial depolarization

### PR Segment Characteristics

- Measured from beginning of P wave to beginning of QRS complex. Duration: 0.08 to .20 seconds
- Significance: Atrial depolarization AND AV delay
- Prolonged PRI indicates AV node conduction disturbance.
- Shortened PRI indicates ectopic focus or bypass mechanism

### QRS Complex Characteristics

- Q wave represents septal depolarization. First negative deflection after P wave.
- R wave is first positive deflection after P wave.

- S wave is first negative deflection after R wave.
- Measured from beginning of first waveform deviation to the end of the last waveform deviation in a single complex
- Duration: Less than 0.10 second (use 0.12 for ease of measurement)  
Significance: Ventricular depolarization time
- Prolonged QRS: Disturbance somewhere in conduction pathway

### **ST Segment Characteristics**

- Measured from J point to beginning of T wave
- Height: isoelectric relative to PR segment
- Significance: Elevation or depression may be indicative of myocardial Damage

### **T Wave Characteristics**

- Represents ventricular re polarization
- Usually deflection is same as that of QRS complex.
- Peaked, or inverted T waves may represent abnormality



## ABSTRACT

In the modern clinical and healthcare setting, the electronic collection and analysis of patient related vital signs and parameters are a fundamental part of the relevant treatment plan and positive patient response. Modern analytical techniques combined with readily available computer software today allow for the near real time analysis of digitally acquired measurements. In the clinical context, this can directly relate to patient survival rates and treatment success.

The processing of clinical parameters, especially the Electrocardiogram (ECG) in the critical care setting has changed little in recent years and the analytical processes have mostly been managed by highly trained and experienced cardiac specialists. Warning, detection and measurement techniques are focused on the post processing of events relying heavily on averaging and analogue filtering to accurately capture waveform morphologies and deviations. This Ph.D. research investigates an alternative and the possibility to analyse, in the digital domain, bio signals with a focus on the ECG to determine if the feasibility of bit by bit or near real time analysis is indeed possible but more so if the data captured has any significance in the analysis and presentation of the wave patterns in a patient monitoring environment. The research and experiments have shown the potential for the development of logical models that address both the detection and short term predication of possible follow-on events with a focus on Myocardial Ischemic (MI) and Infraction based deviations. The research has shown that real time waveform processing compared to traditional graph based analysis, is both accurate and has the potential to be of benefit to the clinician by detecting deviations and morphologies in a real time domain. This is a significant step forward and has the potential to embed years of clinical experience into the measurement processes of clinical devices, in real terms. Also, providing expert analytical and identification input electronically at the patient bedside. The global human population is testing the healthcare systems and care capabilities with the shortage of clinical and healthcare providers in ever decreasing coverage of treatment that can be provided. The research is a moderate step in further realizing this and aiding the caregiver by providing true and relevant information and data, which assists in the clinical decision process and ultimately improving the required standard of patient care.

## ACHIEVMENTS AND PATENTS

1. A Universal Clinical Patient Vital Signs Parameter Measurement, Processing And Predictive Algorithm  
Doctoral Symposium, Ahlia University Bahrain January 2009  
- *Awarded Best Presented Paper / Best Presenter*
2. Patent Application, United States No: US 2010/0130879/A1  
May 2010: Apparatus For Processing Data Derived From A Heart Pulse Monitoring Device.
3. Patent Application, European Union (Provisional)  
No: 08015792.8 / EP08015792; May 2010: Apparatus For Processing Data Derived From A Heart Pulse Monitoring Device.

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## CHAPTER 1 INTRODUCTION

Patient monitors in emergency and intensive care areas in healthcare facilities have changed little in the past decade with respect to monitoring capability. Progress with alarm detection and interpretation has greatly improved but in essence, the functionality and parameters have slipped through the proverbial cracks; although great strides in technology have been made the emerging and putting into practice of true SMART systems have eluded the healthcare industry. The typical ER (Emergency Room) room activity has doubled in the past 10 years and thus the time a physician can spend with a patient reduced along the same ratio. Cardiac Infarction (heart attack) patients are among the most vulnerable *“For heart attack patients, even a few minutes of delay in treatment can literally mean the difference between life and death. Yet, the average wait time for a heart attack patient increased from eight minutes to 20 minutes over the study period -- a 150 percentage increase...”*(Wilper 2008). Traditionally ECG analysis was done using a graph paper containing various derivatives or traces recoded by an electrocardiogram, a method still routine today. The problem with analogue or manual methods is the human factor for currently no defined standard method exists to teach doctors in training how to interpret an ECG or assess their competence in the interpretation (University of Maryland Medical Centre, 2008). The measurements and calculations can be complex and human derived data error prone. Another problem lies with the staff required to manage the ever-increasing demand for clinical practitioners, predominantly due to the increase in patient numbers suffering from cardiovascular disease (CVD). According to the American Heart Association CVD claimed 35.3 percentage of all mortalities in 2008 or 1 out of every 2.8 deaths (Cardiovascular Disease Statistics, 2007). Following the paper graph method the next stage in the evolution of ECG processing was the introduction of electronic interpretation to recorded data collected electronically and logically analysed on the medical device. This greatly enhanced the reliability of clinical assessments and derived data as

well as having a notable effect on the efficiency of patient processing. Electronic interpretation was also introduced into real-time patient vital signs monitoring equipment typically found in ER and Intensive Care Units (ICU). Technology using predictive and dynamic assessment algorithms may during a monitoring session analyse and report abnormalities, arrhythmias and cardiac events on a continual basis alleviating pressure on clinical staff but more importantly provides for a more safe and efficient patient care. *“...cardiac monitoring of patients including noncritical care areas alerts healthcare providers about patient condition changes, which may avoid further deterioration of patient conditions and potential cardiac arrests...”* (Rosenthal, 2006 p.52)

The proverbial gap in the system lies with the fact that the analytical processing and computations are mainly executed on a post processing basis, that is, on data stored or buffered in a timeframe of 15 to 60 second window periods. The post processing limits the usefulness of the data in terms of current event indications or visual representations of the monitored segments and anomaly indicators. *“Cardiovascular system actually adjusts to a new hemodynamic state for every heart beat and that the “slow” or “per-minute” concepts of hemodynamics described are fundamentally flawed...A new and different hemodynamic state (a new pair of MAP & SI values) is thus formed for every heart beat...”* (Sramek, 1995 p.209)

The American Heart Association recently recommended continues QT measurements for patients treated on potentially pro-arrhythmic drugs; this however poses many difficulties with the technical complexities associated with advanced measurements like the QT interval (see Chapter 2 section 2.2, Helfenbein, 2006). In general the problem described lies with the difficulties in accurately identifying or detecting the onset of the ECG cycle and P-Wave and then again with the detection of the end of the cycle namely the T-Wave end point; post processing in the >15 second window is often referred to as real time but this is not accurate. The limitations of post processing (see section 1.4.1) become clear on patient monitoring devices where the ECG and other waveforms are displayed continually and where the subtle changes in patterns that occur in the now cannot be visually translated.

With the rapid advance in microprocessor technology and the consequent availability of near real time processing, complex measurements and calculation previously only possible with manual measuring methods or analysis based on recorded time delayed data (parallel processing), now becomes possible.

In the modern clinical and healthcare setting the electronic collection and analysis of patient related vital signs and measurements are a fundamental part of the treatment plan and combined with modern analytical techniques and readily available computer processing power the near real time analysis of digitized acquired signals has become reality; in the clinical context, this can directly relate to patient survival rates and more positive treatment outcomes.

The major problem researchers are faced with is the inability to integrate new processes and algorithms with existing medical devices. Equipment vendors are resistant to “tampering” by third parties and academics where software driving the devices. This is mainly due to liability and legal responsibility as well as the accountability the manufacturer has to provide safe and reliable readings and outputs from their clinical equipment. It is thus difficult to analyse and test the concept in a live patient based environment, recorded measurements are the main source for clinical test data. The medical manufacturing community has implemented standards for equipment networking like the Digital Imaging and Communication in Medicine (DICOM) standard, DICOM however focused on medical imaging only (*nema.org*). Various standards for ECG has been proposed with the most significant being the SCP-ECG standard now approved as ISO/DIS 11073-91064; the adoption of the standard though is optional and as such lacks universal appeal in the medical informatics manufacturing community (*OpenECG, 2007*). Medical Informatics and the electronic collection, storage and processing of clinical data is pushing the market to adopt and implant open standards and is as such advancing the information technology science to contribute and in many cases lead the way under the heading of Medical Informatics.

The term Medical Informatics and the associated fields of study were initially described as “...*dealing with the problems associated with information, its*

*acquisition, analysis, and dissemination in health care delivery processes..."* (Levy, 1977 p.979). The early aim and drive was mainly instigated by the need to improve clinical guidelines, formulate standardized medical terminologies and improve the communication and data sharing amongst clinical and healthcare practitioners. Although the word analysis was included in the Levy definition the true potential of computers to assist in clinical decision-making was not realized; programming techniques were optimized for the processing of data with a focus on storage and retrieval rather than the ability to dissect, analyse and ultimately interpret. Today the latter is the core area of focus in the search to streamline healthcare and to a greater extent assist to eliminate human error and or oversight (Fennigkoh, 2007).

With the progression of electronics into the digital domain the understanding of the term Medical Informatics slowly morphed to include the electronic design, real time acquisition and analysis of clinical vital signs; firmware programming and application interface development is emerging as the primary focus for biomedical engineering. The processing and the presentation of biological clinical data are overtaking the lead in the research and development arenas compared with the traditional focus on data acquisition. This merger of the computer, biomedical, clinical and engineering sciences under the umbrella of Medical Informatics is best described by the British Medical Informatics Society as *"...the name of an academic discipline developed and pursued over the past decades by a world-wide scientific community engaged in advancing and teaching knowledge about the application of information and technologies to healthcare - the place where health, information and computer sciences, psychology, epidemiology, and engineering intersect..."* (www.bmis.org)

The research presented is an intersection of biomedical and information or computer technology and as such beautifully fit the grouping of Medical Informatics. The application of the research would typically be as a toolset for the healthcare provider, the doctor or nurse caring for a patient in a critical care environment; the techniques, skillsets and knowledge required to extract the conclusions and embed the results though is from the biomedical, clinical and information sciences. Medical informatics is an emergent field of study in

the information technology world with the focus often being thrown on the management of the various data constructs required to manage modern medicine. Image processing and digitization, electronic medical record storage and remote accessibility, web integration and the “electronic” patient are some of the core subject areas. Biomedical engineering on the other hand has its main focus on the electronic and physiological interfacing of medicine where signal processing in the form of analogue acquisition, filtering and digitization, the development of electronic diagnostic measurement and analysis techniques has the upper hand. The two fields of study are however increasingly being integrated for biomedical engineering require digital storage and processing, techniques usually developed in the information technology and clinical informatics disciplines.

The aim of the research is to advance and to develop the body of knowledge and techniques concerning the organization, management and presentation of data and information in support of medical research, education and most rewarding, patient care.

## **1.1 Problem Statement**

Electronic patient monitoring and data analysis is based on the post processing or trend analysis due to the averaging of measured and monitored clinical parameters. Averaging is required due to difficulties encountered with real time ECG segmentation, a process of “cutting” the ECG waveform into its basic components or sub sections (see section 4.1). Hemodynamic and biologically generated data in the monitoring domain has little value in historical terms in the clinical environment where the destabilization of the vital signs can occur in mere seconds which in cardiology is described as sudden cardiac arrest (Jameson, 2005). The question has to be raised whether ECG analysis, segmentation and interpretation in the critical care setting are possible in the real time domain on a bit-by-bit basis thus eliminating the need for averaging and the inherent time delay caused by the averaging of data.



## **1.2 Aim and Objectives**

### **1.2.1 Aims**

The primary aim of the research is to develop an analysis and processing algorithm that can be implemented in monitoring equipment for the electronic processing of primarily the ECG waveform generated by the cardiac system. Also to find an improved segmentation process that can be deployed on real time data as to the current techniques of post processing.

A second but equally important aim of the study and development is the demonstration of alternative ECG waveform data presentations based on the developed segmentation processes and algorithm. This forms a logical step and addition to the work for the real time processing that can be demonstrated in a visual context on live patient bedside data highlighting the anomalies and waveform morphologies in the patients cardiac rhythm; the segmentation process and presentation of the real-time data is shown in section 3.2.

### **1.2.2 Objectives**

- To explore through literature review and research a deeper understanding of the cardiac physiology and current knowledge base relating to cardiac morphology processing and interpretation in both the clinical and medical informatics domain.
- The development of an autonomous and universal segmentation process and algorithm.
- To develop a digital lossless signal acquisition and storage mechanism for ECG waveforms that will form the research and input datasets.
- The electronic reproduction of the recorded waveforms and research data as to allow for the signal analysis and segmentation processed to be evaluated in an experimental format to test the hypothesis of near real time processing.
- The implementation of the algorithm in a clinical environment as to compare the electronic derived and traditional measurement techniques to assist in formulating the conclusions and proof.

### **1.3 Scope of the Research**

The content of the topic combined with the technical complexities of research built on electronic IT based clinical signal analysis defines the boundaries of this study. The study of the cardiac electric conduction system and physiology of the human heart forms the basis of understanding and is required to effectively interpret the signal analysis and conduction patterns. The study will focus on the signal morphologies of patients diagnosed with myocardial ischemia in order to produce an accurate ECG segmentation process that can be deployed on real time monitoring systems. ECG segmentation thus forms the core of the knowledge required together with a clear understanding of digital information technology techniques for the signal analysis. For the purpose of the study a clear understanding of bio signal acquisition and processing in the analogue domain is required as well as a thorough knowledge of object oriented program design. These topics are briefly mentioned in dedicated sections in both chapters 3 to 5 but in essence fall out of the bounds and primary scope of the research and study.

### **1.4 Outline of Thesis**

The study and thesis follow a logical path starting with an analysis of the cardiac system and electrical signal generation and conduction of the human heart. Chapter 1 is the introduction and thesis roadmap chapter; Chapter two examines current analytical and diagnostic techniques including a look at the anatomical and physiological functions of the cardiac system with an emphasis on the electrical conductive structures and various approaches followed and developed to understand the topic. The information is written and presented in such a way as to help familiarize the reader with the theories contained in the remainder of the thesis so as to understand the dynamic of the research. The subtle differences between heart rate and pulse rate are explored in brief in addition to supplemental vital signs and their measurement techniques. The reader is introduced to the evaluation and relationship between the critical markers found within the ECG waveform relative or rather taken into account for the research and thesis. It is important to note that

although the markers explored are known to science the combination of the data are self-derived unless otherwise indicated. The clinical markers and indicators embedded within the ECG waveform patterns is highlighted as well as the signal segmentation derivatives isolated for the construction of the algorithm and modelling phase based on the conclusions. It is important to note that the clinical aspects mentioned should not be considered as the focal point but rather the technical analysis and time sequencing that are important to the modelling and experimental work included in chapter's three to six.

The reader is drawn into the methodology of ECG analysis in the digital domain following the initial signal digitization and filtering processes.

Clinically based research is by its nature difficult as the required data to develop, test and ultimately formulate your hypothesis can be difficult to secure. The small spectrum of focus is the primary limiting factors followed closely by the ethical and moral responsibilities of the researcher to both protect the rights and privacy of the patient. The great leaps and bounds in progress experienced in the field of clinical simulation together with the refinement of clinical systemic mathematical modelling provide an additional option and tool for the researcher. Chapter three introduces the reader to the simulation environment so as to understand the algorithm design phases and the acquisition of the datasets. The methodologies followed in designing the clinical data capturing, storage and reproduction is shown as well as an introduction to the software components developed for the study.

The hardware walkthrough include the plural data verification and device predicate short study conducted as to validate the clinical datasets; the basic construct of the database and storage methodologies and the network or LAN based architecture employed in order to generate and construct the data paths and processes required to provide accurate datasets needed for the modelling phase of the research.

"The holy grail of emergency and critical care medicine lies only but a few minutes into the future..." (*Dunn Mayo, 2005*). If we can predict myocardial infraction with as little as a couple of minutes the impact on survival rates of sudden cardiac death in humans would stagger into the millions measured on a global scale.

In Chapter 4 an alternative model based on near real time nonlinear ECG analysis is presented and demonstrated to be an efficient and new taking on the prominent ECG bio-signal. The analysis is conducted in a pure digital domain or post analogue signal acquisition and processing stage; the study is only concerned with the already filtered digitized format and as such does not discuss in great detail the analogue stages or methods used in the ECG signal acquisition; it is however included so as to further paint the proverbial picture of the thesis.

Chapter five explores and shows in a comparative format the electronic autonomous analysis and classifications acquired as the results from the computations versus clinical assessments and diagnosis derived from using the more traditional methods. The latter part of the chapter includes a short study and results on the impact that the colour-coded signal injection has on the presentation of the ECG bio signal from the viewpoint of the nursing observer. As mentioned earlier the spill over of the research allows for an enhanced ECG data waveform presentation and break from the traditional mono or one-dimensional format.

Chapter six includes the conclusions drawn from the study and shows the dramatic implications the work has on the clinical implications associated with critical care monitoring and the possible paradigm shift that the live analysis and indicators have in the clinical care environment. The Chapter also includes the researcher's views and opinions on the current deficiencies still to be overcome in the clinical hardware and biomedical engineering market. The chapter ends with a look at the follow-up work that is planned for the systems developed during the study as well as possible branching of the research.

## **1.5 Methodology and Approach**

Well-designed research is based on accurate dependable data collection and analysis that allows the researcher to draw conclusions and test a proposed hypothesis. Clinical simulation forms the cornerstone and benchmark input data stream for the purposes of this research; it allows for a constant, stable

and reproducible dataset to be obtained that is required for the construction of the model and algorithms to prove the hypothesis.

Following the validation of the model, real time real world data is the next requirement to fully understand the domain of the study unlike simulation where datasets tend to be predictable, the human body is dynamic and a true test of the researcher's ideas. Clinical data, due to the nature of the human condition, has an elevated requirement of accuracy so for the purposes of this study the data collection was subjected to dual or of predicate approach. Patient data was collected using two simultaneously connected electronic critical patient monitors that as output provided digitally stored patient parameters and vital signs; the two datasets were compared in order to assure that the digitally stored data provided accurate and dependable input streams for the developed model and algorithms.

The final analysis and conclusion is achieved by comparing the electronic output of the model with graph based analogue measurements collected on traditional ECG graph paper or hardcopy.

## **1.6 Ethics and Legal aspects - Patient Confidentiality**

In essence patient confidentiality refers to the fact that patient related information should remain confidential and that no potential danger or risk exist that might harm the patient physically or emotionally by disclosing information. The evaluation datasets were collected at the SAAD Specialist Hospital (SSH), Al-Khobar Kingdom of Saudi Arabia and the hospitals charter states:

*“Expect that your health records and all communications about your care will be treated as confidential. The content of your health records are confidential and are only released to third parties such as insurance companies, government agencies, and employers of SSH has written permission to do so. Information from your health record may be released to other doctors, health facilities, or professionals concerned with your future care without your permission, unless you specifically tell us not to release information to anyone”, SSH Charter.*

To honour the Charter all patient related information and data used and compiled in the study cannot be released as part of the research publication, case studies data compilations, or any patient related identification where patient records are referenced have been encoded with a number reference system explained in Table 1. If any of the data is required for verification purposes the reference requests can be sent to hospital administration (contact details are included in the reference section).

The basic encryption used to reference patient files consist of a legitimate medical record number (MR) paired with a Random Document Reference number (DRN) used in the study; by submitting the Document Reference Number the hospital management will assess the request and respond accordingly. The example table shows the reference structure that can be used to request validation datasets:

No (Case study Number)	MR (Medical Record Number)	RDRN (Random Document Reference Number)
1	74523	RDRN 01
2	54216	RDRN 02
3	43211	RDRN 03
...	...	...

Table 1: Patient Details Encryption Sample - Synthesized Data

## 1.7 Conclusion

*“Contemporary medicine applies health science, biomedical research, and medical technology to diagnose and treat injury and disease, typically through medication, surgery, or some other form of therapy..”* (Culliford, 2002)

It is commonly understood that the purpose of medicine is to extend life or lifespan; this though is not the ultimate goal but rather to improve the quality of life. The practicing of medicine as per the definition by Culliford and thus the work presented here extends the body of knowledge and as such, if

applied add to this noble cause. The research contained in this thesis contributes to the understanding of digital clinical processing, and shows that near real time morphological monitoring in the ECG spectrum can be applied in a clinical environment to improve on the current electronic patient monitoring capability and data presentation techniques. The patient is the definitive beneficiary but the impact is aimed at the greater healthcare industry as well; the clinician is provided with accurate and timely aiding in the clinical decision process. Nursing staff benefits from and supplemental warning mechanism that can enhance the detection of patient deterioration limiting institutional and professional liability.

By examining and understanding the near real time techniques discussed in this research it is apparent that the approach is considerable different than the traditional methods that primarily focuses on pattern recognition. As mentioned further the electronic pattern based format of ECG processing is fundamentally flawed for it occurs in the post processing domain whereas hemo dynamics and the cardiac event exist in a pulse to pulse domain; post processing based on averaging over a fixed time frame has a limited reaction or response time contrary to the parameter it is measuring, in this case the cardiac ECG. By focusing on the bit-to-bit data timeframe compared to the buffer to buffer used in pattern based techniques reaction times to deviations in the cycle can be detected in what humans perceive as real time.

It is thus clear that if cardiac monitoring techniques can react at the same pace as the actual biological event the clinical caregiver has access to information and data that greatly improve the clinical diagnosis consequently the care that can be provided to the patient. Improved care directly related to the aim of practicing medicine satisfying both the quality of life as well as the extension thereof.

## CHAPTER 2 LITERATURE REVIEW

In this Chapter current analytical and diagnostic techniques are explored including a look at the anatomical and physiological functions of the cardiac system with an emphasis on the electrical conductive structures. The information contained in this chapter is written and constructed in such a way to help familiarize the reader with the concepts contained in the remainder of the thesis and to understand the dynamic of the research.

The exploration of the anatomy, physiology, related signal processing techniques and classification of the ECG is required as the theoretical background and grounding for the research and form a key block in the development of the hypothesis.

### 2.1 The Normal Electro Cardio Gram (ECG)

*“In essence the human heart is but a pump...”* Dr. Christiaan Neethling Barnard, heart transplant pioneer.

This simplified classification of the human heart by one of the world’s most renowned cardiac specialist outlines the function of the cardiac system beautifully. As with most systems in the world today the heart is driven by a complex electrical sub system responsible for the triggering or pacing, signal distribution and ultimately the stable rhythmic oscillation of the structure. In short, an ECG is a graphical recording of the electrical activity of the heart. The cardiac cells and muscles are triggered by electrical impulses that originate in the two main pacemakers namely the Sinoatrial (SA) and Atrioventricular (AV) nodes. Figure 2.1 shows the correlation between the electrical conduction path and the graphical ECG recording generated expressed in time versus voltage:



Note: The technical term for cardio electrical stimulation is depolarization and the return of the muscles to their resting state is referred to as re polarization.

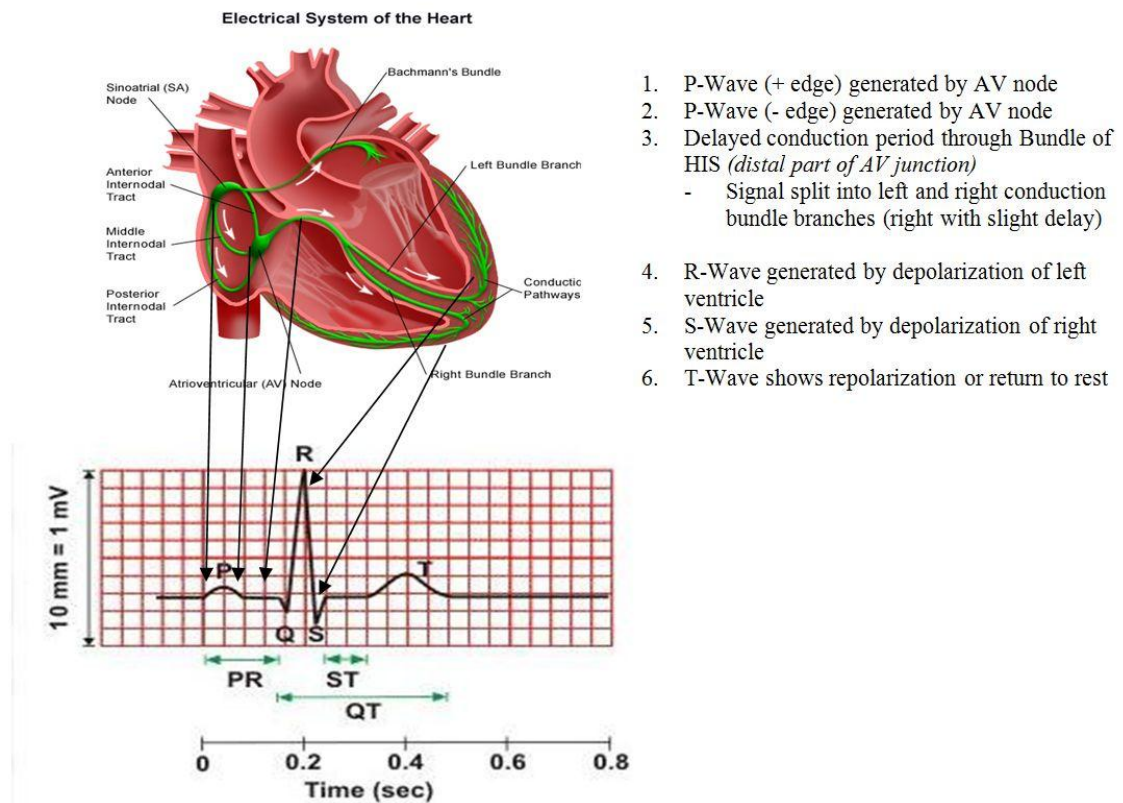


Figure 2.1 : Cardiac Electrical Conduction System (STI, 2003)

The ECG can be further described through twelve derivatives referred to as ECG Leads (the stretch between two limbs, arms or legs). Willem Einthoven derived the standard leads (I, II and III – see Figure 2.2) in the late 1800s and most of his original naming conventions are still in use today. The leads in the Einthoven triangle depict the electrical potential difference between three virtual planes measured through patient electrodes (forming a triangle) where the heart constitutes the null point. It is important to note that various clinical conditions reflect differently on the ECG leads as the leads represent a virtual conduction slice or plane in the cardiac system (Einthoven, 1912). Along with the three standard Einthoven leads nine additional derivatives were added by Dr. Frank N Wilson and his colleagues at the University of Michigan in 1933; first the three unipolar extremity or augmented unipolar limb leads (aVR, aVL and aVF on the frontal plane) and later the six unipolar chest leads (V1

through V6 on the horizontal plane). Today the collection of ECG leads is commonly referred to as the Standards twelve ECG leads.

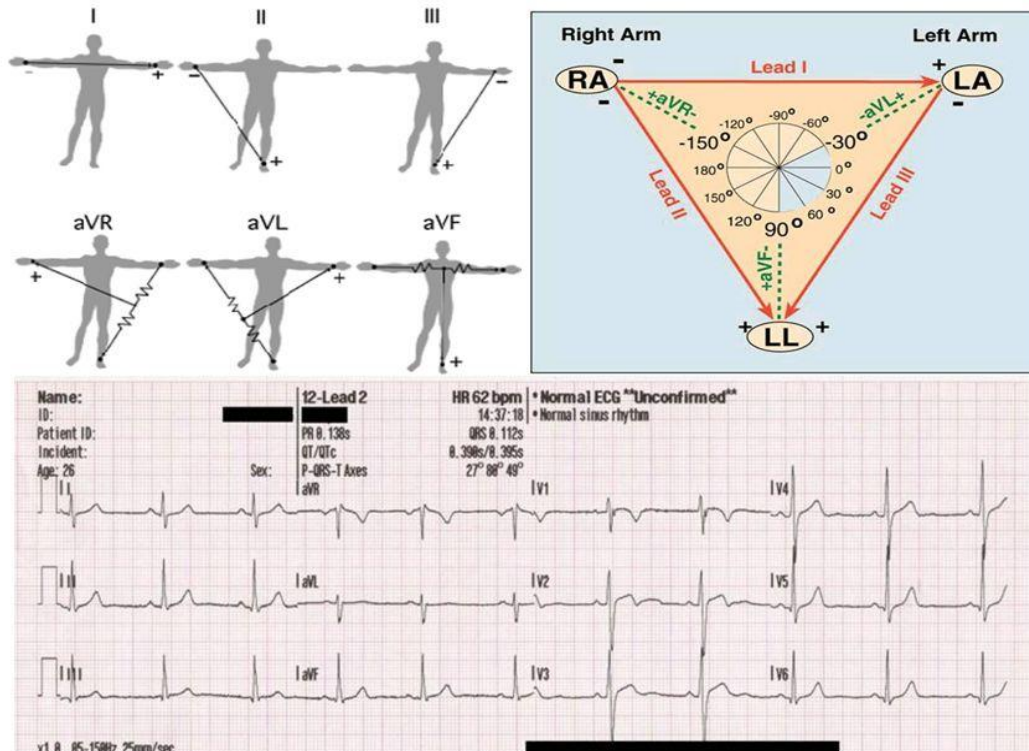


Figure 2.2 : Standard Derived, ECG Leads (Urban, 2002)

The ECG leads are derived as shown below and form an important part of the construction of any cardiac model (refer to Figure. 2.2):

**Lead I** = **LA - RA** (difference in voltage between Left Arm and Right Arm)

**Lead II** = **LL - RA** (difference in voltage between Left Leg and Right Arm)

**Lead III** = **LL - LA** (difference in voltage between Left Leg and Left Arm)

We can thus deduct that:

$$I + III = LL - RA = II$$

Equation 1: Einthoven

Kirchhoff's law states that the total potential in a closed circle is zero, this can be expressed as:

$$\textit{Lead I} + (-\textit{Lead II}) + \textit{Lead III} = 0$$

Equation 2: Revised Einthoven

The primary three unipolar leads are related so that the total of their recorded voltages should always be zero; the sum of the QRS and T-wave voltages is zero (see Figure 2.2).

$$aVR + aVL + aVF = 0$$

Equation 3: Kirchhoff

The data derived from applying the derivatives and laws enable snapshots to be taken of the various stages of the cardiac cycle (Figure 2.3). This data can be analysed and compared with international benchmarks that will allow the clinician or in this case the computer, to detect, derive and analyse deviations and / or waveform pattern morphologies.

The knowledge acquired by a clinician over many years of study and practice can be made available through technology and implemented where a skilled healthcare provider might not be present or where an arrhythmia or deviation might not be consistent, repetitive or easily distinguishable from artefacts.

**Note:** Please note that for this research the six unipolar chest leads were not be taken into account, this decision has been made in order to accommodate live ECG monitoring as pertaining to the five LEAD ECG system used as the primary and default standard in critical care continuous patient monitoring. My hypothesis covers live or rather continuous near real time monitoring so clinical data and simulations will only contain data that would under normal conditions be present and available.

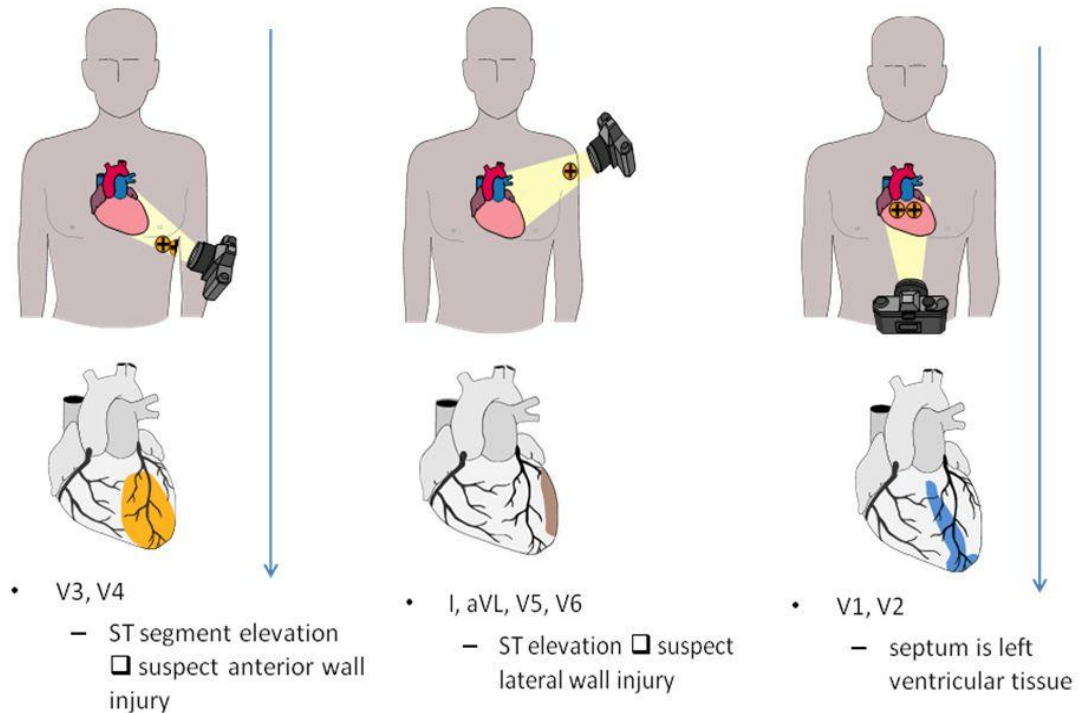


Figure 2.3 : Cardiac Abnormalities

## 2.2 The QT Interval and its QTc and QTd Derivatives

Most modern clinical patient monitors have in some form or another analytical and detection processes and these are usually based on well-understood and implemented standards and protocols (*IEC60601-2-27:2005*). Medicine though is showing huge strides in the understanding of both the physiology as well and the biological management and control system found in the human body. Emerging parameters that were classified in the past as unimportant or unattainable in the real-time or live acquisition window, can today not only be obtained but also processed. An emerging parameter or indicator as an example that shows great promise in the diagnosis of abnormal cardiac conditions is the QT interval. This interval is measured from the QRS complex to the end of the T wave; unfortunately, the clinical significance of this measurement cannot be fully used due to the level of difficulty in both identifying and the accurate measurement of the interval. A study conducted by the American Medical Association (*JAMA 2003*) showed that only 61% of respondents (clinicians) could correctly identify the QT interval and a further 36% only could in fact successfully calculate the measurement. As the world

population ages and hospitals become more crowded clinicians simply cannot pay attention to all the factors, the QT example is proof of this for the calculations and measurements are traditionally accomplished with graph paper (*Wong, 2003*).

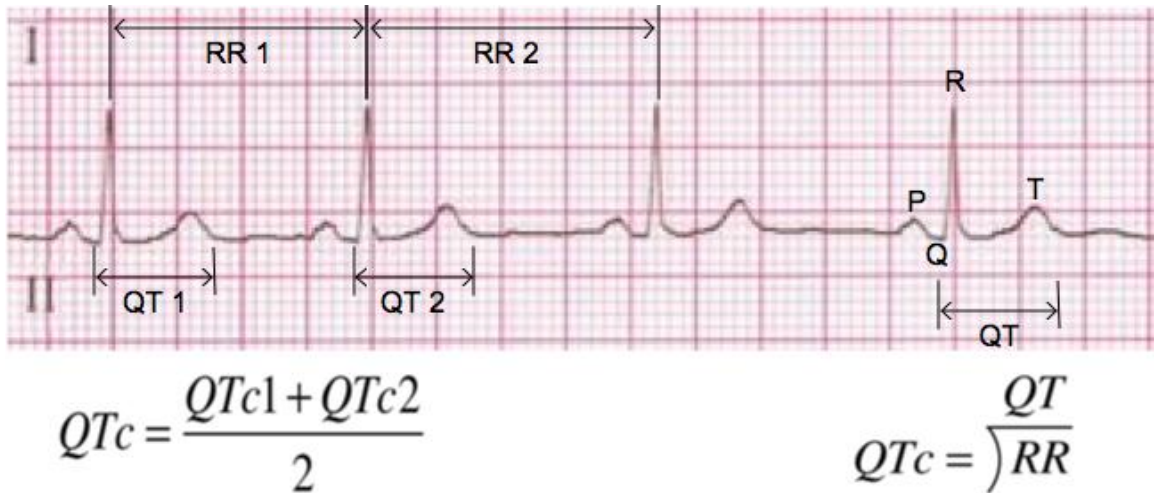


Figure 2.4 : Shows QT and QTc Intervals

The QTd or QT dispersion indicator has been proposed as an important marker for ventricular tachyarrhythmia or VT in various clinical settings including LQTS, post-myocardial infarction and congestive heart failure (*Cohen, 2002*). Subtracting the QT minimum value from the QT maximum value during a set sample interval measurement window derives QTd:

$$QTcd = QTc_{max} - QTc_{min} \quad QTd = QT_{max} - QT_{min}$$

Equation 4: QTcd, QTd Derivatives

The QTd indicator has also been found to be a potentially prominent marker for risk calculations relating to sudden cardiac death following Myocardial Infarction or MI. A reasonable conclusion can thus be drawn that the variability in the timing cycles of the cardiac systems directly relates to electrical instability in the conduction and pacemaker sub systems of the heart (ref Figure 2.2). The line can further be extended to instabilities of the de- and re-polarization cycles and Ischemic (oxygen starvation) indicators, re ST-Depression of the heart and heart muscle. These assumptions were shown to be correct in a study by Malarvili, 2002 where a sample group of 432 ECGs

were evaluated and QTd values of more than 50 ms did document an elevated risk of sudden cardiac death due to an MI. The marginal baseline or risk indicator of 50 ms QTd thus forms a possible important marker for electronic derived predictive parameters.

Indicators and electronic derivatives, if correctly applied, may significantly affect early diagnosis by non-cardiac specialists. Figure 2.4 shows a typical ECG, RR, and QT interval measurement as would be expected during normal sinus rhythm; Figure 2.4 indicates two pulses with a varying RR interval due to arterial fibrillation. The QT interval is calculated by taking the average QT intervals with the shortest and longest preceding R to R interval. It is common practice, as per Figure 2.4, to measure the QT interval from the beginning of the Q wave or QRS complex to the end of the T wave (refer to Figure 2.2), this however is not a defined measurement and has not been standardized. Standardization is made more difficult because of the QT interval variability in the heart rate with longer periods during slower heart rates and shortened period at faster rates (Sana, 2003). To bridge and compensate for this variability, the Bazette formula was derived and is applied to give the compensated QTc value. Equation 5 shows this formula and states that(Bazette,1920):

$$QTc = \frac{QT}{\sqrt{RR}}$$

Equation 5: Bazette QTc Correction

Along with the Bazette correction formula, the Fridericia cube root correction and Framingham linear regression approach is often used; empirical clinical data and proof is unfortunately not available to substantiate a claim to the more accurate approach. The Framingham formula is based on a larger population sample and has been shown to be a more stable comparative method (Hnatkova, 1999; Aytemir, 1999). Work presented in this study is based on mathematical averaging during live monitoring for comparative methodologies is less effective in near real time computations for the processing time required to compare a reading with a stored pattern which defies the real time concept. The QTc value, as discussed and shown is

calculated using the Bazette (1920) approach over a 3 – 25 averaging cycle giving the arithmetic mean:

$$QTc = (QTc1 + QTc2 + QTc3 \dots QTcn) \frac{1}{n}$$

Equation 6: QTc Averaging

Due to the lack of a standardized measuring methodology of the QT interval, a group of experts on Long QT Syndrome (LQTS) proposed the following guidelines during a sitting in August 2000 (*JAMA 2003*):

- *QT should preferably be measured manually using a limb lead (ref Figure 2.3)*
- *Measurements should be included from the Q point to the end of the T-wave on an average of 3-5 beats (RR intervals); Q-waves should be included only if merged with the T-wave.*
- *Measurements should be made during peak plasma concentration if a QT-prolonged medication is administered.*
- *QT interval measurements should compensate for heart rate (Bazette, Framingham)*
- *If arterial fibrillation is detected the measurement should be adjusted to include 10 RR cycles or beats.*

These guidelines are important as they contribute greatly to the standardization of the QT value and expected values during patient assessment and evaluation. By understanding and incorporating these principles in the computations of an algorithm the significance and clinical value of the indicators are greatly enhanced. The QT and compensated QTc values are gaining weight as early indicators and markers of possible ventricular abnormalities in pre-diagnosed patients as is typically found in an Emergency Room (ER) setting. Electronic derivatives for these values from a standard ECG monitoring session are mostly discouraged by clinicians due to the lack of standardization. It is believed that by incorporating these measurements in live patient monitoring, a validation trend can be shown and a contribution be made with a significant clinical value lowering the risk of possible clinical error and oversight.

The QT interval as a marker should be less than half of the preceding RR interval for normal patients (variable with heart rate but compensated using the QTc derivative), for normal or resting conditions, an expected value of QTc < 0.4 (400ms) is acceptable. QT prolongation is classified as QTc > 440 ms and can lead to a refractory form of ventricular tachycardia called *torsades de pointes* (Goldberger, 1999). The predictive value of QT Long (QTL) with relation to cardiac death for stroke survivors is shown in Table 1 below (K Y K Wong, 2003)

Cut off value (≥) (ms)	12 lead QTc max (area under ROC curve=0.71, SE=0.054; p=0.003)		QTc measured from lead V6 only (area under ROC curve=0.70, SE=0.057; p=0.005)		QTc measured from lead III only (area under ROC curve=0.71, SE=0.069; p=0.004)	
	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
400	100	6	100	23	75	47
410	100	19	85	39	65	62
420	100	31	70	53	55	73
430	90	40	65	64	45	86
480	35	82	10	94	5	98

Table 2: QT Cut off values for Predicting Cardiac Death (Stroke Survivors) (Wong, 2002)

As can be seen from the data in Table 2, a QTc > 430 ms shows a sensitivity of 65% for predicting cardiac death; if the QTc increase to above 480 ms predicting cardiac death improved to 94%. Although the study by Wong focused on stroke survivors, the significance of the QTc derivative cannot be ignored; the question is raised why the QTc value identifies future cardiac risk over and above conventional methods. “*Current evidence suggests that long QT dispersion or a long QTc interval is associated with acquired coronary artery disease, carotid intima-media thickness, left ventricular systolic dysfunction, left ventricular hypertrophy, and arrhythmias*” (Wong, 2003). The centre for Biologics Evaluation and Research under the FDA gives the baseline for prolongation of the QT / QTc interval as repeated demonstration of a value >450 ms (E14, Clinical evaluation of QT / QTc Interval, 2005).



The data presented in this section is incorporated into the algorithmic model derived from the study; the experimental results shown in Chapter six proved to be positive in identifying and expressing a patient's risk factor. This indicates that a shift in design methodology is due and that "smart systems" capable of not only identifying but also the classification of patients must replace the current passive based data representation where the clinical specialist has the only and final pathologic right.

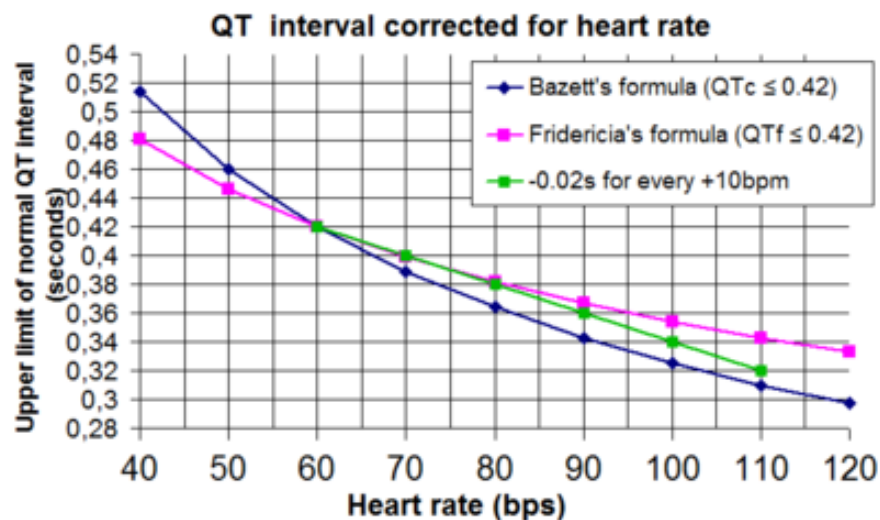


Figure 2.5: QT Interval Correction (Hosmane, 2006)

### 2.3 Myocardial Infarction (MI) Classification

*"Cardiac ischemia is a situation in which the flow of oxygen-rich blood to the heart muscle is impeded, resulting in inadequate oxygenation of the heart."* Dr. Abdou Elhendy, MD.

*"Myocardial Infarction (MI) refers to myocardial necrosis ("heart attack), which is usually caused by severe ischemia."* Dr. Ary L Goldberger MD.

According to the American Heart association up to 30% of myocardial infarctions are classified as silent and have no visible symptoms, these are formally classified as "silent" infarctions (Hnatkova, 1999).

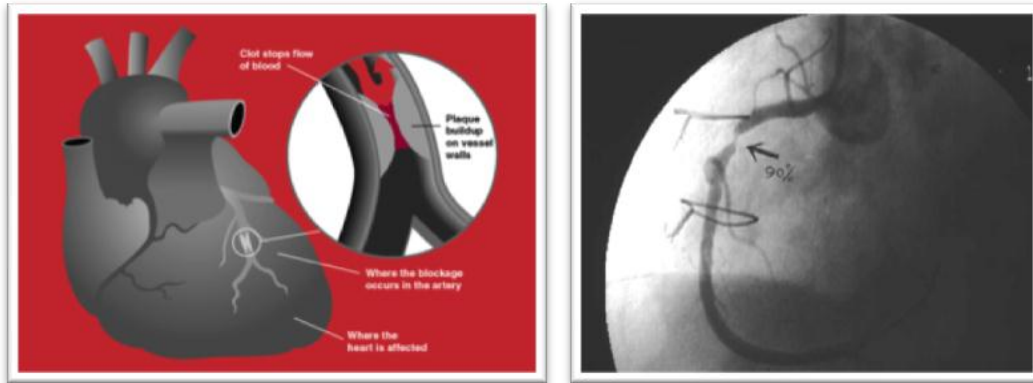
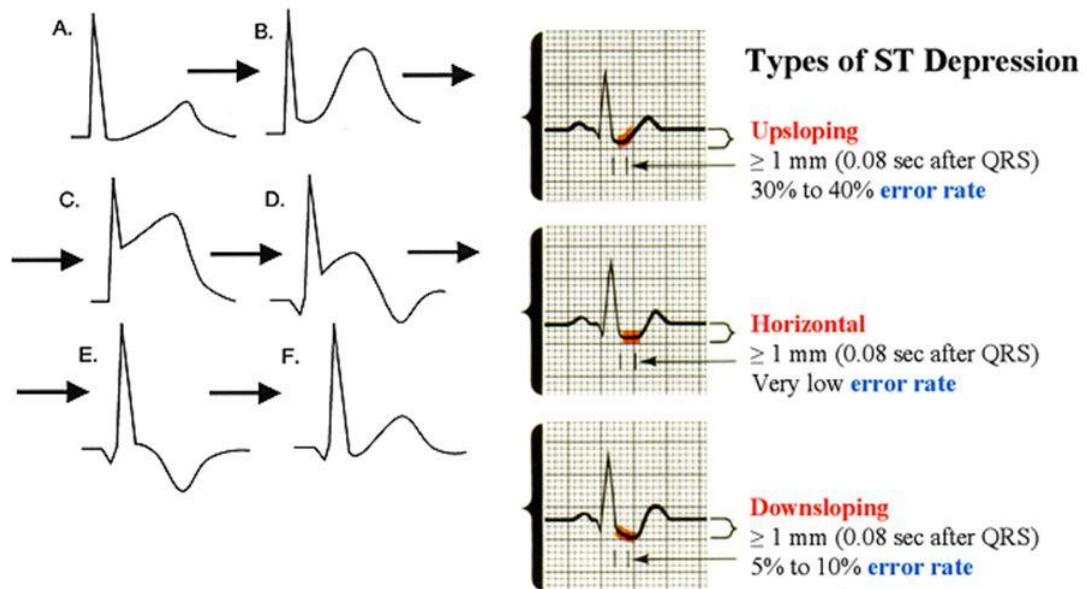


Figure 2.6 : Myocardial Infarction (Vivaili, 2006)

As can be understood from the definitions above, ischemia classifies the condition and infarction the result but as with most biological entities variations are numerous and common. Ischemia literally means, “*To hold back blood*”; as with most biological cells, myocardial cells, require oxygen and other nutrients to function. If the blood and thus “food” supply are obstructed the cardiac cells cannot re- and de polarize in a normal manner causing arrhythmias or deviations in the electrical conduction effect of the cardiac system. These electrical signals and deviations can be detected and analysed and the affected cardiac muscles deprived of oxygen and nutrients will show significant deficiencies in workload or the re- and depolarization processes. By analysing an ECG recording these problems may be detected by a clinician or competent individual; MI and MIs abnormalities are visible in the ST section of the ECG following the main QRS contractions of the ventricle with deviations shown as ST elevations and depressions. As the naming convention describe they are deviating from the normal baseline in either a positive or a negative patterns variation of the electrocardiogram (ECG):

Figure 2.7: Evolution of the Acute MI<sup>1</sup>

Studying the deviation patterns and the clinical interpretation it soon becomes apparent that common factors do exist and can thus be used as denominators in the development of detection techniques. Medical practitioners are well schooled in analysing, deriving, and then arriving at a diagnosis based on ECG abnormalities and deviations. Electronic interpretation is by no means new to cardiology and patient monitoring specialties and most modern patient monitors can detect and express ST abnormalities in the standard notation based on voltage or potential differences between two or more comparative points on the ECG wave form but there are great opportunities for improvement. The mere calculation and numerical indication of the deviation should be complimented with a clear indicator as to where the depression, elevation, or arrhythmia is occurring; the problem lies with the calculation method and processing time. Patient monitors base calculations on averaging algorithms applied to a set number of samples; in real terms a past event is being measured that in clinical terms and usefulness declines with every passing second.

<sup>1</sup> Diagram compiled from images Available  
<http://www.unm.edu/~lkravitz/EKG/stdepression.html>

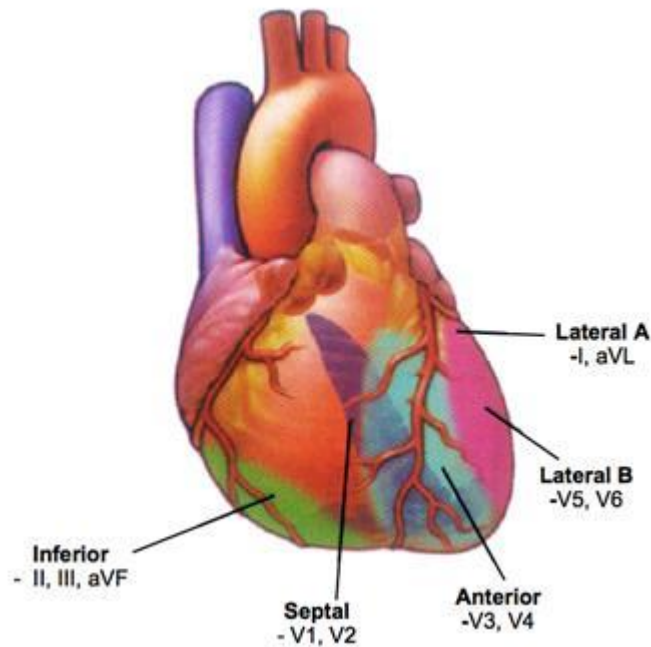


Figure 2.8 : Myocardial Infraction ECG Indicators (STI, 2003)

Detection and calculated derivatives with modern processing power is possible in real time; this has a huge advantage as critical care monitoring to a greater extent should focus on the now. The trend data and measurements of past events (< 4 hours) do come into play as an indication of the clinical state of a patient but complemented by the evaluation of current events and statistically processing trend graphs, clinical projections are indeed possible.

#### **2.4 ST Segmentation with Relation to Myocardial Infraction**

The location of the MI in the heart is a critical factor in the diagnosis of the cardiac region affected by the MI. Clinically the treatment plan is derived from accurately finding the affected areas as well as predicting and preventing possible complications. The localization of MIs is caused by the actual artery being obstructed and as such restricts the blood flow to a specific area of the heart or heart wall.

Figure 2.8 shows the main sub divisions of the heart wall as well as the ECG leads that act as markers on these regional MIs. In section 2.3 the MI process through occluded or obstructed arteries is discussed but in short the lack of blood supply and thus oxygen to the muscle result in a regional MI, the ST

segment is the main indicator in the analysis and diagnosis of myocardial infarctions. As is shown an anterior MI will be visible predominantly in leads V3 and V4 with a well-defined ST elevation together with T-wave inversion caused by occlusion in the descending artery. A septal MI will be shown by leads V1 and V2 commonly recognizable through the disappearance of the R wave, a ST segment elevation and inverted T wave; septal wall MIs are often accompanied by anterior wall MI so indicators in V3 and V4 should be considered and included in the diagnosis. A lateral wall MI, usually caused by blockage in the left circumflex artery (Cx) shows characteristic changes in the left lateral leads V5, V6, I and aVL; Premature Ventricular Contractions (PVCs) are typical together with anterior and inferior MI indicators in leads II, III and aVF. Inferior MI patients are at an elevated risk to develop sinus bradycardia or slow heart rate, sinus arrest, block and PVC rhythms. Posterior wall MI is caused by occlusion or blockage in the right and or left coronary and circumference arteries and causes changes in V1, V2 and the V3 leads. Typical changes can be seen in the tall R waves, ST segment depression and upright T waves. As a matter of interest a 12 lead ECG indicating severe or acute anterior lateral infraction is included below.

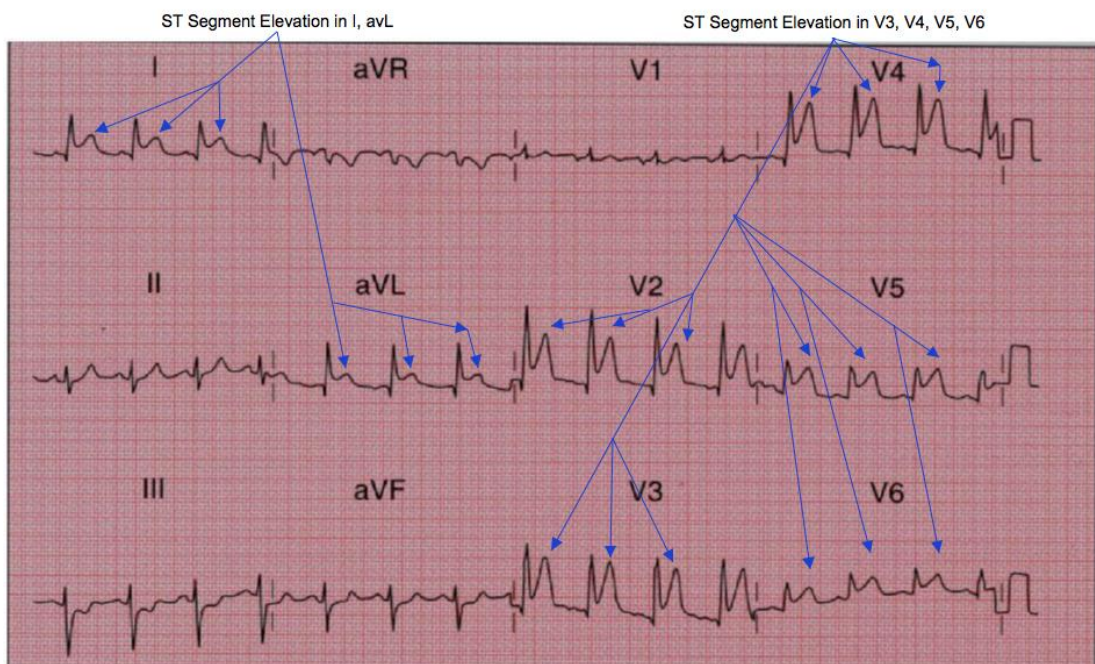


Figure 2.9 : Acute Anterior Lateral Infraction

Kjekshus first identified and illustrated the relationship and correlation between ST Segment morphologies and MI in 1972 where he showed that the ST-segment elevation occurring early after occlusion of the left descending coronary artery was closely related to coronary flow reduction at later stages. It was also proved that this correlation was especially prominent if the infraction was transmural or spanned across sections (Kleberg, 2000). ST morphologies unfortunately is not bound to coronary flow or ischemia only, clinical ST segment elevation following a MI can persist due to damage in the border zone of the MI combined with the low electrical impedance of scar tissue (Cinca, 1995). A third possible contributor to ST segment elevation is in the autonomous nervous system caused by the depletion of noradrenaline stores observed following coronary occlusion (Wilde, 1988; Schomig, 1987). Although the factors influencing the various degrees and indications of ST elevation and depressions as discussed above, the common or contributing factor point to obstruction or occlusion of the coronary artery flow. This forms an important observation and justifies the use of ST segmentation morphology as an indicator for MI related clinical conditions in non-clinical research modelling.

## **2.5 ST Vector Magnitude & Quantification of Myocardial Ischemia**

ST Vector Magnitude - The magnitude lead is the summation of the vectors of the X-Y-Z leads and is a 1-lead representation of the global electric activity of the heart; the ST-segment vector magnitude (ST-VM) is traditionally measured at 60 ms after the J point (Francis, 2002.)

This section will continue from the short introduction in section 2.2.2 into ST deviation patterns focusing on the clinical and prognostic value of ST-segment deviations and explore how the derivative ST Vector Magnitude (ST-VM) may be applied and act as an additional marker for the predictive elements in the ECG waveform. ST-segment deviations are primarily used as a diagnostic and classification tool in the identification of acute myocardial infarction or AMI (Lancet, 1994). The significance of the standard ST-segment is further

enhanced by the addition of the vector cardiogram but the main advantage of the method is that the acquisition of the vector ECG is achieved over a set time interval thus allowing data to be formed into mean vector complexes. The disadvantage for this type of study has a similar root namely timed recoding and computational delays although the outcome of near-real time analysis has not been fully validated the advantages are clear. Patient monitors with effective real time analysis may contribute in streamlining the clinical diagnostics pathway and may be implemented as a progressive patient screening utility.

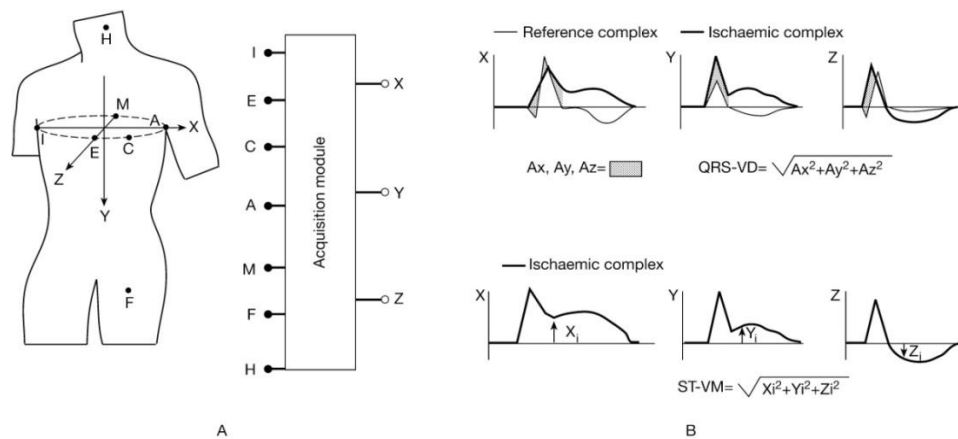


Figure 2.10 : Deriving the ST-VM (AEM, 2002)

Figure 8 (Kawahito, 2003) shows the FRANK lead placement, summation, and normalization of the data to derive the ST-VM. The analysis and implementation of the ST-VM shows the evolution of the AMI (ref Figure 2.4) but what is more important is the long term monitoring generated data on the clinical outcome of treatment. A study conducted by Francis, 2002 (Figure 2.11) with 1722 AMI patients was able to plot a scale based on baseline ST-VM verses the likelihood Ratio (AMI). By using a standard continuous patient ECG and generating a derivative of the ST-segment, it should be possible to correlate current patient deviations with long term controlled plotting.

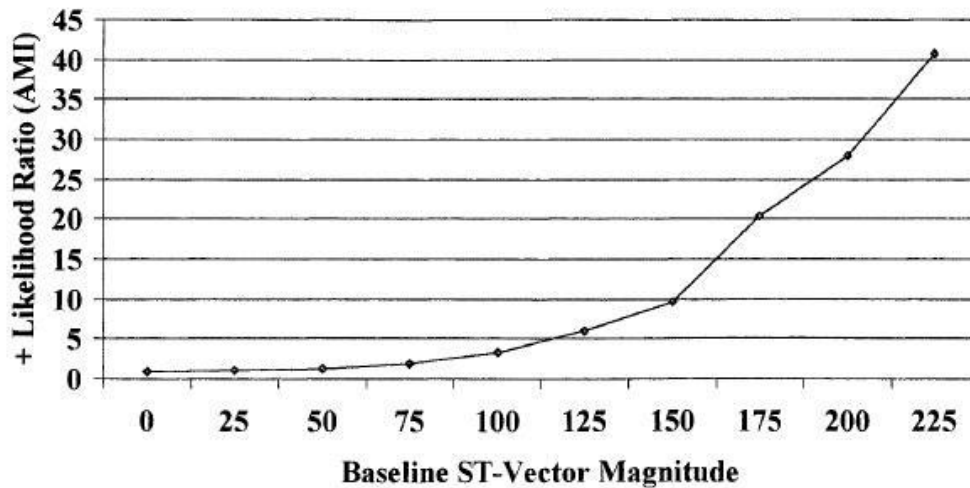


Figure 2.11: Positive Likelihood Ratio for AMI Patients (AEM, 2002)

Reports have shown the potential for ST-segment trending during ECG monitoring to indicate and even allow for early detection myocardial ischemia (Leung, 1998). The sensitivity and specificity was rated to be less than 75% overall for the detection of ST changes, a figure too low to be trusted as a medical parameter in diagnostic cardiology but as a contributing marker in a structured algorithm the potential of ST trending in the ST-VM format proves to be more valuable.

## 2.6 Medical Oxygen Saturation (SPO<sub>2</sub>)

Although SPO<sub>2</sub>, commonly referred to as “SATS” in the clinical environment does not directly form part of the cardiac systemic indicators it is a parameter that is widely associated with cardiac function. In short SPO<sub>2</sub> is an expression of the percentage oxygen in the blood compared to the maximum level expressed in percentage (%). Haemoglobin carries a maximum of four oxygen molecules from the lungs throughout the body by way of the arteries and oxygen poor or deoxygenated blood back to the heart and lungs by way the veins.

The basic and most common technique used to measure SPO<sub>2</sub> takes advantage of the difference in infrared light absorption in oxygenated and deoxygenated haemoglobin with oxygen poor haemoglobin molecules absorbing more infrared light and passing more red light than the oxygen rich



counterpart. The red light has wavelengths of 600 – 750 nm and infrared 850 – 1000 nm in the light band.

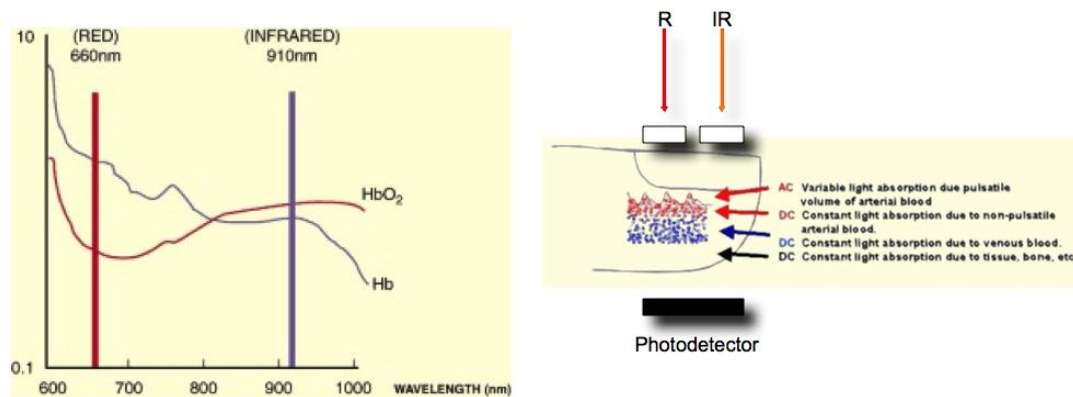


Figure 2.12 : Red and Infrared Wavelength Light Band (Townsend, 2002)

Figure 2.12 shows the light band targeted and used for saturation monitoring as well as a typical setup used for the sensor placement. The most common measurement technique makes use of two Light Emitting Diodes (LEDs) that shine through a translucent site with adequate blood flow, in adults the finger, ear lobe and toe are used and in infants the foot and palm usually suffice. A photo detector is placed opposite the LEDs and after the transmitted R and IR signals pass through the measurement is taken, the R / IR ratio is calculated. This ratio is then usually compared to an electronic lookup table based on calibration curves derived from testing done on healthy individuals. Typically an R/IR ratio of 0.5 equates to approximately 100% SPO<sub>2</sub>, a ratio of 1.0 to approximately 82% SPO<sub>2</sub>, while a ratio of 2.0 equates to 0% SPO<sub>2</sub>. Healthy individuals usually have a SPO<sub>2</sub> measurement of 97 to 99% and values below 90% causes hypoxemia and usually trigger the body to respond by increasing the heart rate in an attempt to improve the oxygen supply (Shelley, 2006).

Using the same measurement technique as is used in the SPO<sub>2</sub>, additional data can be extracted from the absorption ratios re Pulse Rate and the photo plethysmograph (Pleth), a volumetric measurement that shows the change in volume in the organ or body extremity; a finger as shown in Figure 2.12. The relation or indication of blood volume as derived from the R / IR absorption can be directly correlated to the pump action of the heart and the pressure

generated in the venous systems through the cardiac cycle. It is important to note that the heart rate measured in the ECG and the Pulse rate measured through the SPO2 are not the same indicators and must be considered as different parameters. The ECG heart rate is generated from the electrical pacemakers in the cardiac systems whereas the pulse rate derived from the SPO2 Pulse measurements indicates the mechanical action. This point is most often overlooked in the clinical monitoring environment for it is assumed that every electrical impulse in the heart should produce a contraction or mechanical action, this is not the case. Patients suffering from severe ischemia will often not have a cardiac contraction following an electrical pulse due to the sheer de-oxygenation or exhaustion of the cardiac muscles, an anomaly referred to as a Pause or Pulseless Electrical Activity (PEA).

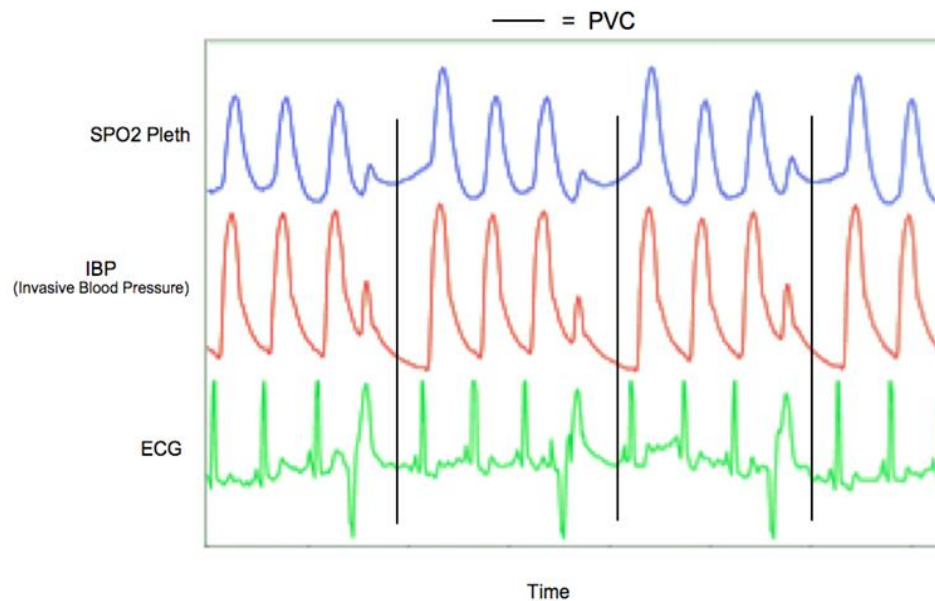


Figure 2.13 : SPO2 Pleth, IB Pressure and ECG Correlation (Townsend, 2002)

Above the correlation between the SPO2 Pleth, the IBP pressure and the ECG graphs can be seen; the Premature Ventricular Contraction (PVC) that is induced in the heart is reflected in all the measured parameters. This is a logical indicator for a “fault” in the contraction of the heart will be measurable in both the pressure generated as well as the subsequent propagation wave produces in the artery. For the purposes of this study the SPO2 and Pleth are used as a reference or verification indicator in some of the calculations if the

parameters were available to include in the process. In Chapter 6, results and findings, a case study is discussed and the predictive elements of the algorithm demonstrated using the SPO2 and Pleth in conjunction with the ECG graph and derivatives.

## **2.7 Standard Communication Protocol for Computer Assisted Electrocardiography (SCP-ECG)**

The SCP-ECG is an open standard for the storage, annotations and metadata that specifies the interchange format and messaging procedure for the communications and data retrieval for ECG based records. The protocol is an open source format developed and standardized in a joint effort between the ANSI / AAMI standard (EC71:2001) and the CEN standard (EN 1064:2005). The standardization of clinical parameter storage is an important step in the development of universal communications protocols and inter-vendor computability; although the standard is not compulsory, modern healthcare medical informatics development is to a greater extent enforcing the standard through application and integration requirements (ANSI, 1992). The SCP-ECG standard has further been approved as ISO/DIS 110073-91064 further drilling into the market as the prime standard required for clinical hardware as well as software compliance and thus international acceptance. Standardization in the modern digital healthcare has advantages not only for the patient but also the clinical service providers in the form that patient records can now be electronically duplicated and the patient, as well as clinicians, be given access to the clinical history of the patient. A second important point is the ever increasing contribution from telemedicine, a rural general practitioner can now provide, as an example, full cardiological assessments by simply forwarding digital ECGs to a specialist without the need for the patient to travel or be examined by a physician other than his local doctor.

The SCP-ECG Open ECG project thus aims to:

- *To raise the level of awareness;*
- *To organize information days, workshops, and a programming contest;*

- To consolidate expertise, assist integration and support correct implementations;
- To provide feedback to standardization bodies;
- To prepare the ground for interoperability in other ECG-related examinations.

The digital encoding of the data stream is usually accomplished by either the Huffman Entropy Encoding or by making use of inter sample corrections through first or second sample difference computing.

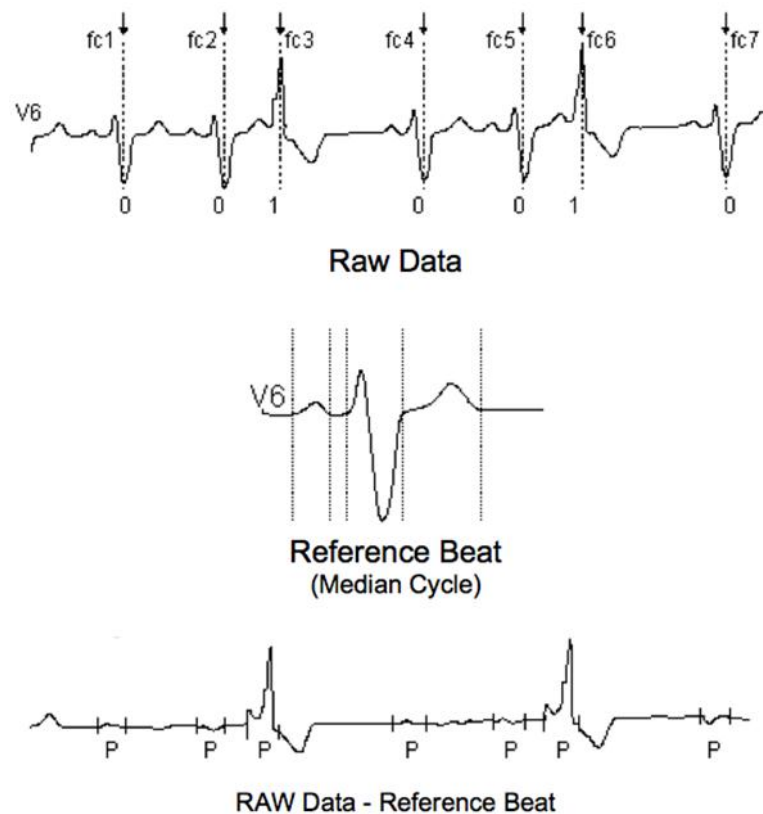


Figure 2.14 : Compressions, SCP Standard (AAMI, 1999)

Although the compression ration achieved is high, the storage method does create additional overhead that must be managed and included in the header file. If the reference beat deduction technique is used as is shown above, QRS location pointers as well as beat type metadata is required for the later reconstruction of the waveform.

The binary data steam consists of both the data samples and zero bits (representing no data) included into the steam where sample rates or

character length and type are pre-reserved in the packet and filing address. The Huffman tables allow for the transmission of the original ECG data in a losses compression format by a technique referred to as dense packing. Data is mapped to the Huffman codes according to the frequency of their reoccurrence and the signal statistics.

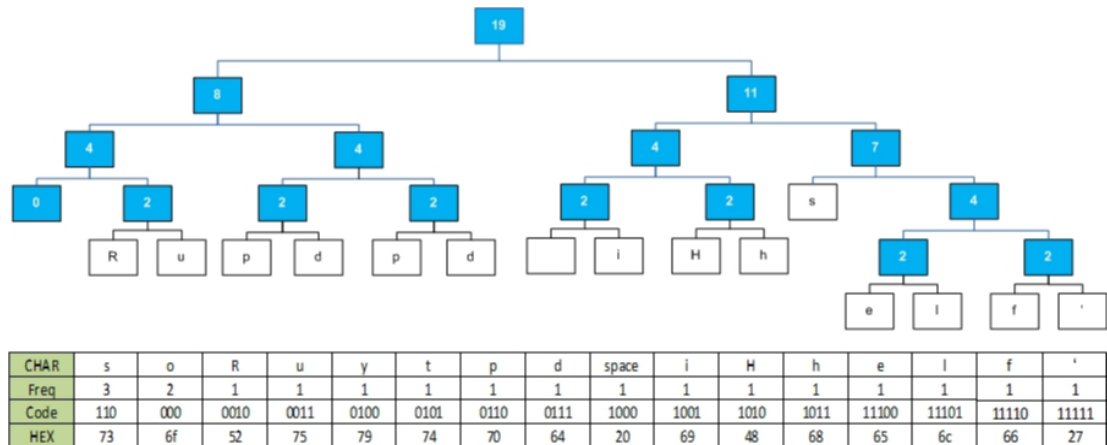


Figure 2.15 : Huffman Coding Tree

The reference beat subtraction and Huffman encoding is but only two of the techniques required in the SCP-ECG standard and although storage considerations are implemented in most if not all project types.

## 2.8 Man Machine Interaction

With the increasing man machine interaction through the graphical user interface based on personal computer interaction methodologies technologies that improve the effectiveness of communicating visually with the user is becoming the primary consideration in design requirement engineering. Tactic feedback together with colour based attention grabbing feedback or soft user interaction distinguish the functional verses outstanding design of modern machines; in the medical environment the concepts are applied and focused on decision support to the user (Lefter, 2011). In the research by Lefter speech patterns was analysed at an emergency call centre to grade the severity of the caller, this data is then used to prioritize calls and alert operators accordingly. In a live monitoring situation the same methodology can be applied to alert care givers and as such effectively assist in the

decision process based on the severity of the clinical ECG morphology as an example.

## **2.9 A Critique of the Literature**

The analysis and interpretation of bio signals, especially the cardiac cycle ECG, is rooted in the understanding of the relationships and timing intervals between the various segments that form the electro cardiogram. The data presented in this chapter form the basis of this understanding and shows how the complex calculations are used in the diagnostic processes. The clinical markers used to identify anomalies and deviations is difficult for the analogue human brain to measure and calculate, the research is focused on finding alternative method to accurately calculate and present the relationships between the ECG segments and as such assist the clinician in the interpretation of the ECG. The patient is the ultimate beneficiary.

The data and information in an overcrowded setting can be overwhelming and as such clinical human judgment errors are common as showed in section 2.2.

A study conducted by Rothschild (2005) over a period of 1000 inpatient days found 120 adverse events in 79 patients (20.2%), including 66 (55%) no preventable and 54 (45%) preventable adverse events as well as 223 serious. By automating measurable parameters like the QTd time interval during live patient monitoring, related medical errors could be minimized. The data processing methodology based on post processing and parameter averaging limits the data management and presentation possibilities. Hemodynamics is as the name suggests is a dynamic systemic system where even in as little as a fifteen second window various changes in the parameters can be noted. Current methodologies does not focus on the bit-by-bit analysis of cardiac data and as such miss the “now” window and the opportunities and data it presents. In the following chapter a model is presented that shows how real time bio signal processing in the “now” window can be accomplished.

The hypothesis of the study is thus to prove the feasibility and accuracy of near real time bit-by-bit type processing of bio signals and the signal re-injection of the processed data back into the main data stream.

### CHAPTER 3 CONCEPTUAL METHODOLOGY AND MODELLING

In this Chapter the reader is introduced to the toolsets namely simulation, the software, hardware and the communications tiers used and developed to allow for the research. The Chapter is formatted in such a way as to resemble the process used during the course of the research where much of the measurement techniques initially studied through simulation which led to the formulation of the mathematical model implemented through programming code. Based on Yanowitz (1974), the quantitative analysis of the analogue verses digital recorded datasets collected for the study form the basis for the conclusions drawn. By comparing the traditional or analogue datasets and measurements with the digitally constructed sets and measurements within the same timeframe the effectiveness of the model can be measures and tested. In essence the quantitative analysis component of the study the researcher is interested in the observations of the variables defined in the model and the expression of the change between the observations.

Following the modelling phase the data collection and analysis completes the cycle to the point where the hypothesis could be evaluated (see Figure 3.1). Chapter 2 introduced the various measurement techniques and grounded work required to understand, dissect and process ECG waveforms and structures. Datasets consisting of the studied waveform morphologies and cardiac anomalies are however difficult to capture in a real world environment and as such simulation is the preferred and selected toolset chosen to provide the data input in an isolated and controlled environment. This allows the researcher not only develop but also refine the proposed mathematically based model used to process and analyse data collected and observed through field studies (section 3.2). Clinically based research by its nature is complicated as the required data to develop, test and ultimately formulate the hypothesis can be difficult to secure or obtain. The small spectrum of focus is



the primary limiting factor (percentage of cardiac patients that display the required prognosis studied, in this case MI) followed closely by the ethical and moral responsibilities of the researcher to both protect the rights and privacy of the individual and to guard against the inclination to manage the patient as a test subject. The proposed model depends on accurate and fast ECG waveform segmentation together with a dependable storage platform where data can be accumulated for future signal and measurement reproduction, the experimentation phase of the research (section 3.1). The third component required together with the input data, storage and reproduction is the actual measurement of the datasets collected through the field study; this is achieved through the model expressed in software code and embedded into a processing application. In order to allow for precise data collection, a predicate system is used where two measurement devices collect the clinical measurements in parallel (section 3.4).

With the progress made in the field of clinical simulation as well as the refinement of clinical systemic mathematical modelling, an additional option and tool is on offer to the researcher. Clinical simulation is following in the proverbial path laid by the integration of the simulation processes and training techniques developed for the aeronautical industry. Patient simulation has matured to the point where the clinical environment can be recreated with such accuracy as to add an additional realism tier to both the training and the clinical certification of healthcare providers. *“The American Board of Internal Medicine (ABIM) will offer Interventional Cardiology Simulations, using Medical Simulation Corporation's (MSC) SimSuite(R) technology, for credit toward completion of Maintenance of Certification. This is the first time ABIM is incorporating medical simulation technology into its programs to evaluate physician competence...”* (MediLexicon, 2008) Simulation provided a well definable environment together with the prospect of realistic and true data. Much of the development and systems constructed for this research has its roots in simulation; this risk free environment is used for experimentation and forms a good introduction to conditions that can be expected in a real world

environment creating the opportunity to plan and design for the variables that the field study data collection usually adds to the pot.

Figure 3.1 represents the construct of the study where block one depicts the grounded theory required to understand the domain of the problem, block two and three build on the literary review and research performed by others with simulation providing the input data source required to develop and perfect the algorithms that collectively form the mathematical model. Block four represents the field study, experimentation and real world data collection required to test the model and hypothesis with block five pointing to the actual data analysis and conclusion.

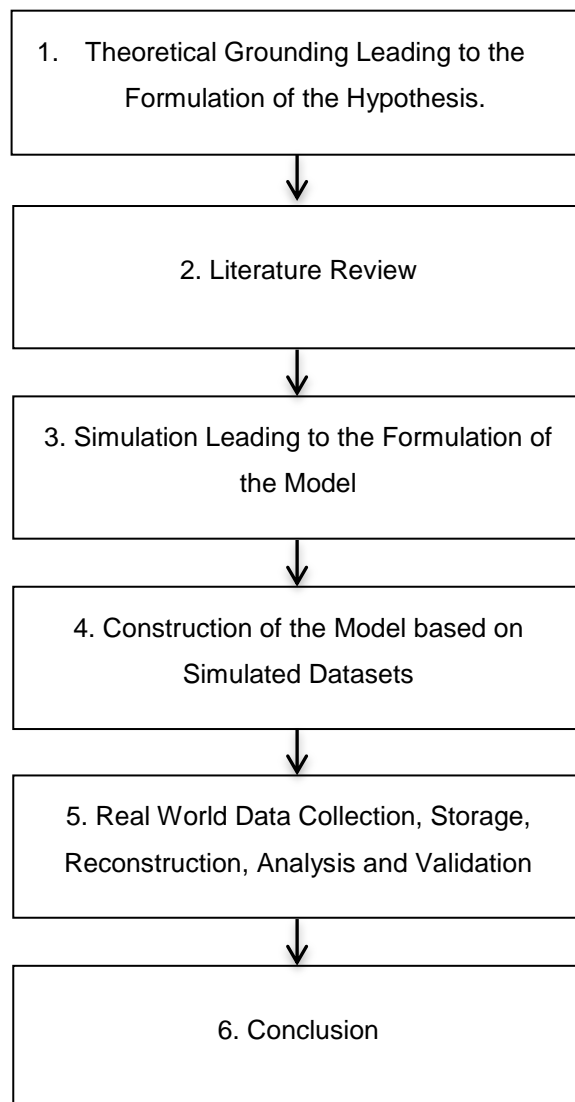


Figure 3.1 : Study Construct

It is important to note that the technical nature of the research and algorithm design renders itself prone to a pure quantitative method where a conclusion can only be drawn through the analysis of the measured (output of the model) versus input (simulated or real world data). Data, represented by clinical measurements, is used as input parameters, processed through the algorithms and the results compared with the clinical outcome of the patient whether a simulated or biological patient. The approach can best be described by:

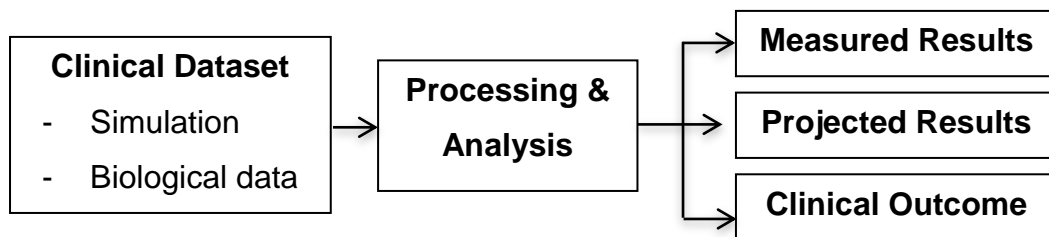


Figure 3.2 : Quantitative Structure

Considering Figure 3.2 the hypothesis can be proved if the measured results, projected results and the clinical outcome are coherent and logically telling the same proverbial story.

The remainder of the Chapter is dedicated to the research path followed to first establish a benchmark dataset through predictive value sets using simulation, the digitization and storage mechanism that assures accurate reproduction of measured and recorded data and the structures put in place to assure that the data is reliable through the deployment of the double measurement process, accomplished using two monitoring platforms.

Medical Informatics allows us today to view this overwhelming and complex range of parameters as a unified system and enable the researcher to deploy the power of modern technology and present data in a non-conventional manner to the user. This allows for improved observations to be included in the assessment, diagnosis and ultimate treatment processes; in real terms it allows for the clinician to get back to the root of practicing medicine, the patient, by allowing technology to carry some of the diagnostic and monitoring load.

In section 3.5 towards the end of the chapter the research methodologies used to develop this study are discussed; the mixed methodology approach consisting of simulation and field study is complimentary in that it allows for the base research components namely modelling and data collection to be fulfilled. The remainder of the chapter is dedicated and grouped into sections walking the reader through the research constructs introduced in Figure 3.1 forming the sub components of the conceptual model.

### 3.1 Breakdown of the Tier Structure

This section represents an overview of the research, experimental setup, data capturing, storage, retrieval and analysis is discussed so as to provide the reader with a bird's eye view of the architecture and processes designed and built to facilitate the study. The structures forming the outer perimeter of the work (Figure 3.3), is essential for the data streams required to test and apply the algorithms and measurement techniques. The core of the research has shown form the logical centre of the work with the surrounding supporting systems facilitating the process and study; Figure 3.3 shows that the process and measurement techniques is applicable to both live and stored data and can thus be applied on archived records as well as live monitoring sessions:

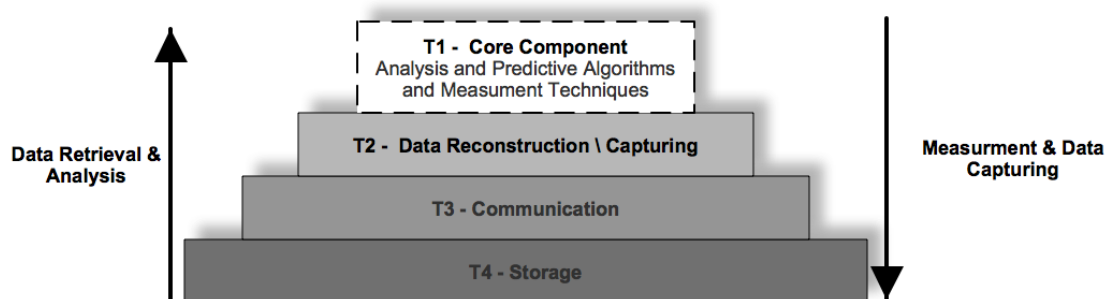


Figure 3.3 : Tier Structures Facilitating the Research

The defining factor of any research is the quality of the data and in the case of electronic digital storage, the accurate reproduction of the original or raw data collected; this is crucial especially where biological or natural data sets are used. As an example: the data used in this study is produced by biological analogue systems in the human body, any particular instance is produced

only once, if the capturing, digitization and storage is inaccurate a result and conclusion will be difficult to formulate. The analysis phase needs to reverse this process and the datasets need to be retrieved from the storage mechanisms, streamed and the analogue feed reconstructed to apply as input for the model based analysis.

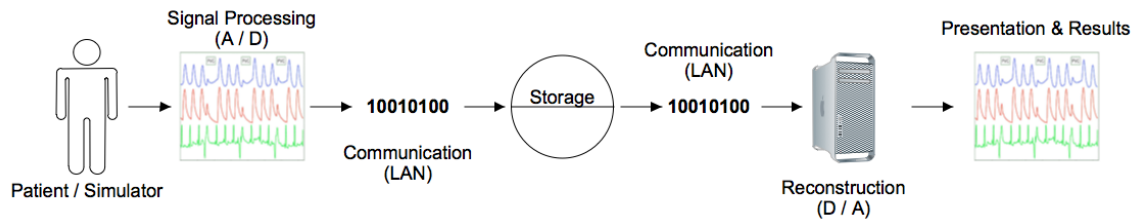


Figure 3.4 : Data Capturing and Reproduction

### 3.2 Simulation – An Introduction to the Test Environment

The research is based on a two-tone or two tier method including the design of the study and subsequent developed algorithms using extensive simulation together with the processing and collection of the clinical data through a live streaming process. It can be argued that the collection of data does not represent a method as such but the electronic recording and absolute reconstruction of the sample data for the purpose of analysis forms a substantial part of this work in conjunction with:

- Understanding the physiology and clinical implementations of the various diagnostic techniques used in cardiology as the basis and foundation for this study (grounded theory).
- The formidable undertaking to collect and analyse data without bridging the patient confidentiality and right to privacy agreement.

To successfully address the problem, data needs to be collected in two separate session blocks; first for the development of the algorithms and mathematical model (test data) and second for the proof thereof (verification data).

The data sets in both instances differ significantly; the developmental data need to be predictable, accurate and preferably pre-definable; these criteria points to simulation. By utilizing a simulated environment together with clinical simulators the data sets acquired can be used to not only develop the model in a controlled environment but in addition can further be used as a refinement, calibration and ultimately reference standard for real world implementation. For the simulated data generation a *Human Patient Simulator* or HPS from Medical Educational Technologies (METI) is used “*The HPS is the only patient simulator with the ability to provide respiratory gas exchange, anaesthesia delivery, and patient monitoring with real physiological clinical monitors*” (METI).

A primary advantage of the simulation environment is that system input is carefully controlled as well as the fact that the researcher is fully aware of the expected output parameters. Exact environments can be created and later recreated eliminating most real world environmental factors that may influence test results, in short the duplication of the experiments should render near identical results for the hypothesis to hold any water as a manner of speaking.

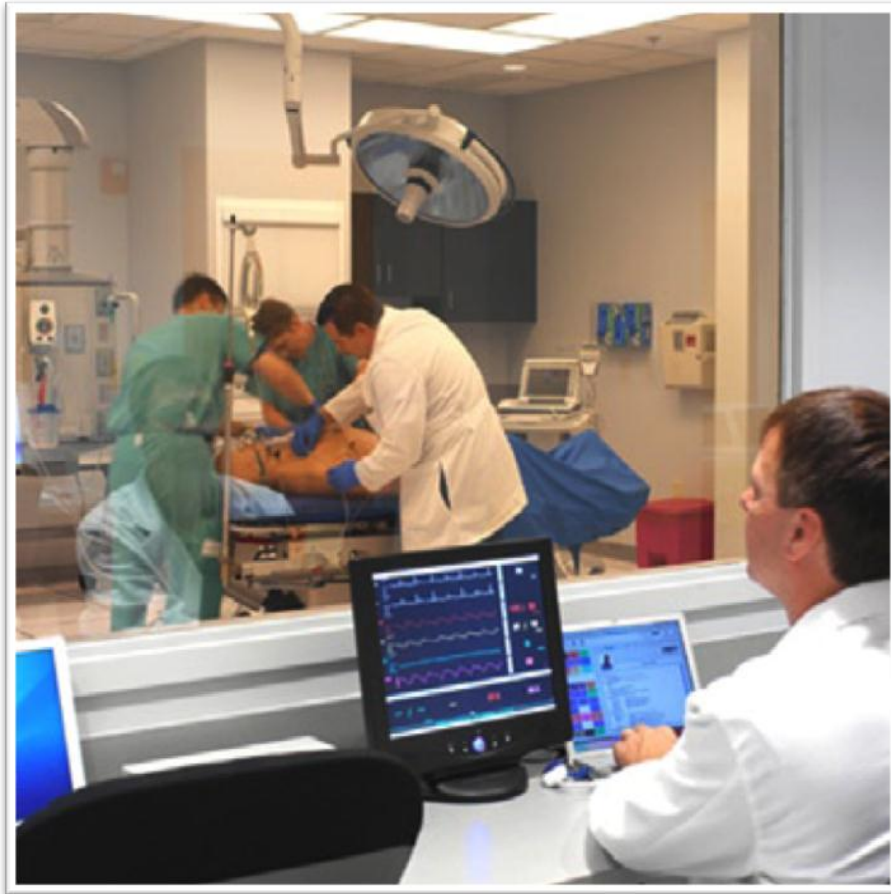


Figure 3.5 : Simulation Centre, Saad Specialist Hospital

Figure 3.5 above shows a typical simulation session with the clinical team managing a patient in a recreated critical care environment; the controller or observer is positioned behind one way glass as to not influence the scenario. Data is generated by the HPS and collected in the control room; it is important to note that the generated data corresponds to the actions of the participants and the software model driving the simulators include routines for incorporating medication administration as well as clinical conditions. These variables are built into the scenario and as such a specific situation and patient pathology can be constructed; the actions of the team contribute to the outcome and the model accepts action inputs such as chest compressions, airway management and medication; the simulators thus respond in the same manner as a human patient would.

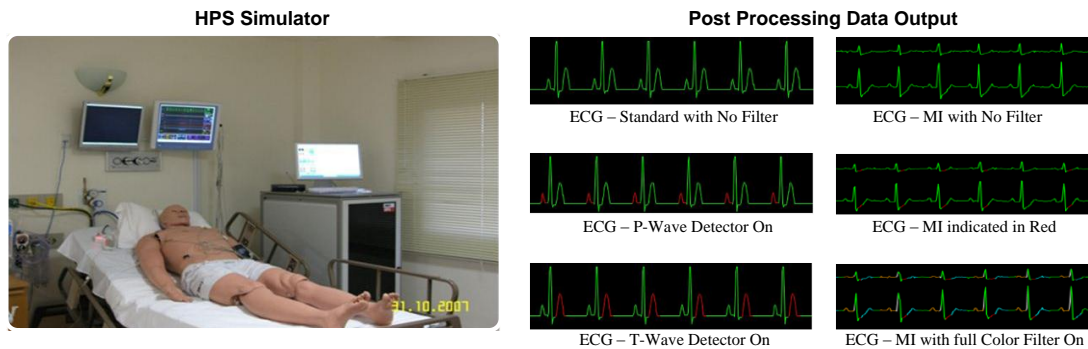
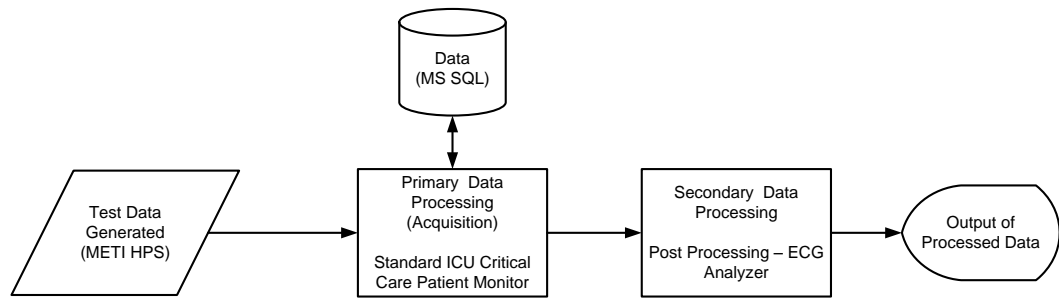


Figure 3.6 : Simulation & Data

Figure 3.6 above illustrates an abstracted view of a simulation based experiment including the processed output generated by the ECG Analyser process; the components shown above will be discussed in detail in the following sections. In essence the processing software components developed during the study forms the basis of the experimental output and would in industrial terms be seen as the outcome or product. In an academic context the product is the proof of the hypothesis or otherwise its denial; it is important to understand that although much focus is placed on the components of the experiment, they are in fact only the tools used to develop or extract knowledge and to demonstrate understanding.

Software today plays an ever-increasing role in scientific research and allows the researcher to model an abstract format of the world around us. The development of software (programming) and the ability to package the environment in mathematical terms makes possible a precise reproduction or duplication of a defined condition or state that enable output to be measured and documented based on predefined input parameters. In the next section the reader will be introduced the reader to the structures and composition of



the software developed and its part in defining the cardiac model developed through this research.

### **3.3 Software Walkthrough - An Introduction**

The software components were developed using Microsoft Visual Studio 2008 and the C# ([www.msdn.microsoft.com](http://www.msdn.microsoft.com)) language on the dot Net 3.5 platform with data storage implemented on a Microsoft SQL Express database. The implementation includes two main tiers of input data namely direct patient data acquisition, used to define and test the model and processing algorithms and a second tier where a standard patient monitor provided the primary digitization and serialization stages (Figure 3.7). The hypothesis of the study is to prove the validity of near-real time bio-signal analysis thus demanding the software processes to be efficient to the point that a near zero delay has to be maintained so as not to interfere with the vital signs presentation; the patient monitor is the main clinical long-term monitoring diagnostic toolset in the critical care environment. This poses an absorbing challenge but also provides an opportunity to examine the traditional ECG visual signal output; if real time processing can be accomplished then the output signal can effectively be improved by injecting colour coding into the presentation stream showing the detected arrhythmia or trace anomaly calculated by the algorithm.

The primary modelling interface, designed to show the measurement slice and timing intervals is built to allow dynamic adjustment to the processing model; signal analysis and calibration during live monitoring sessions is thus possible allowing the observer to interact with the model on various levels facilitating for observation and reference value adjustment. The second advantage of dynamic adjustment is that feedback loops can be introduced into the algorithm allowing the software to dynamically adapt to an individual's ECG trace. Appendix A shows the Graphical User Interface (GUI) of the toolset; it is important to note that the GUI and the ECG Analyser algorithm are logically separated as standalone software components allowing for a "black box" type integration of the ECG analyser into other systems.

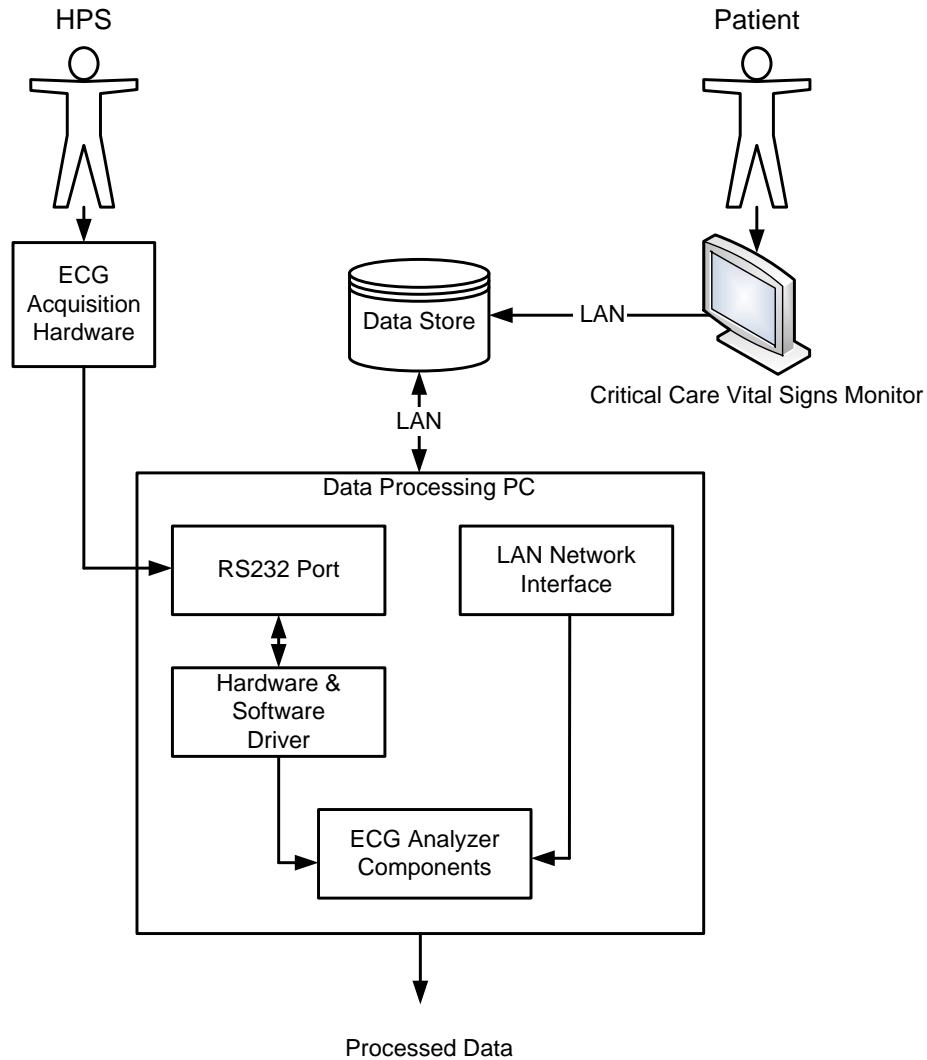


Figure 3.7 : Data Acquisition, Abstracted Software Model

As part of the study, the analysis algorithms were included and interfaced into existing commercial patient monitoring systems. The primary communication protocols on the commercial products were provided by Drager Medical, a major medical manufacturer; a predicate comparison study conducted over 3 months in 2008 served as the prequel to the clinical trials that followed in 2009. Predicate comparisons with commercial devices form an important part of the proof and add validity to the clinical and computational claims made in the study. A detailed description of the hardware systems focusing on the medical technologies used in the experiment is discussed in the following section.

### 3.4 Hardware Walkthrough and Digital Storage

#### 3.4.1 Data Capturing and Predicate Validation

As mentioned in section 3.3 the computations were developed in a simulated clinical environment followed by clinical data collection in an ICU type setting to compile realistic data sets. Data collection may include anomalies and deviations that can cause misinterpretations and as such it is important to not infuse false feeds into the experiment; data verification is important for inaccurate readings will lead to false or misguided conclusions. The calculation of deviations can be managed by conducting a short comparative study using simultaneous multi data collection methods and comparing the output reading; for this study two commercial patient monitoring systems were connected to participating patients and the data readings were collected at set intervals over a period of 90 days. Figure 3.8 shows the practical setup of the predicate study (*the predicate or reference device used was a Siemens SC 7000 Series Vital Signs Monitor*).

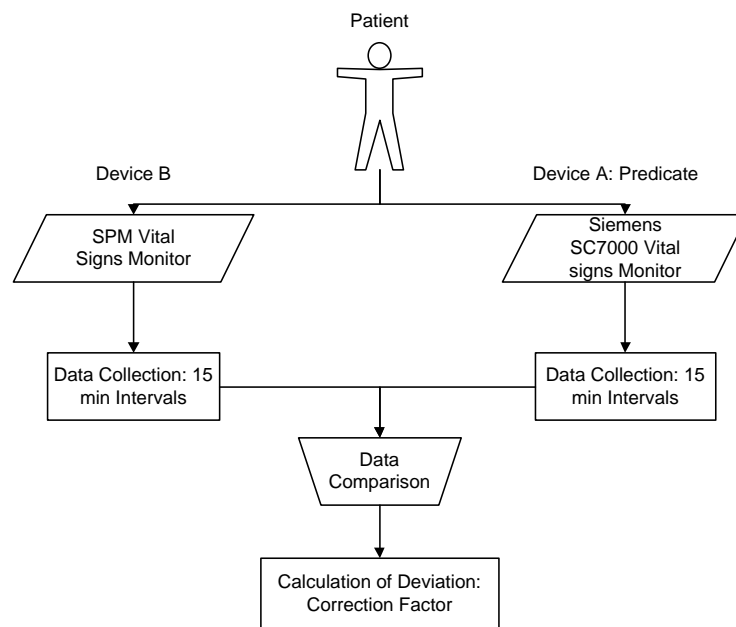


Figure 3.8 : Predicated / Reference Study

Table 2 below shows a section, ECG Heart Rate, of the comparative study; a complete set of study documentation is included in Appendix B. The predicate comparative study acts as a reference point in the interpretation and data analysis; tolerances allowed in medical equipment must be considered and

included in equations so as to assure that rogue readings do not cause the research to stray. The dual feed of data help to manage anomalies caused by the day to day activities in the critical care units to be documented and can thus be isolated and disregarded from the data sets and results. Table 2 Appendix B shows deviation caused by the physical placement of the SPO2 probe, calculated mean and averaging is used to substitute erratic readings.

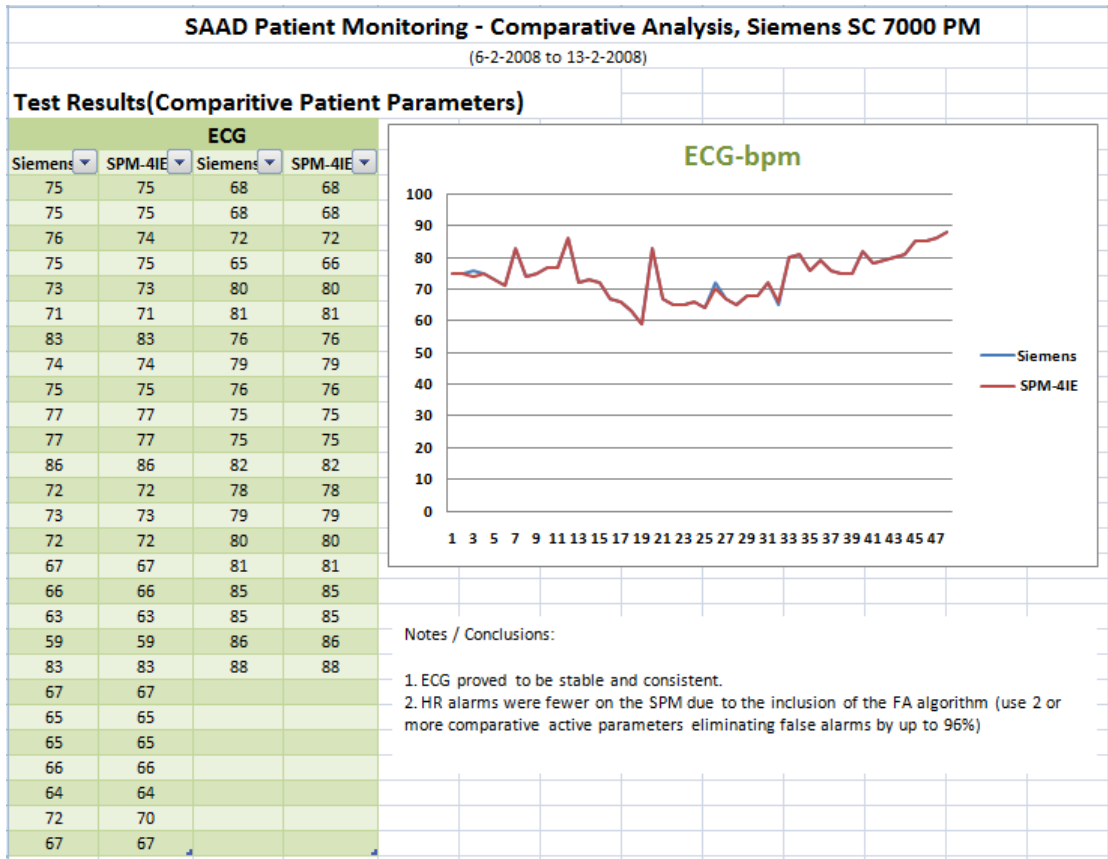


Table 3: Predicate Short Study Results Table

### 3.4.2 Electronic Storage, Database Schemas and Network Constructs

The communication tier consists of a LAN based network managed by a standard Domain Name Server (DNS) connecting the data capture, vital signs monitors, the web server and SQL based storage sub components; discussions on the communication protocols used in a standard LAN environment falls beyond the scope of this study and thesis.

The database technology is a standard relational database structure built using the Microsoft SQL Server Express edition. The serialization of the data and storage mechanism was designed to trace individual monitoring sessions grouped and packaged under the patient medical reference number as a primary key. Session numbers are dynamically allocated upon admission or discharge from the vital signs monitor and enables trending, arrhythmia and ECG deviations to be queried using the primary key (MR), the session number and a date / time key.

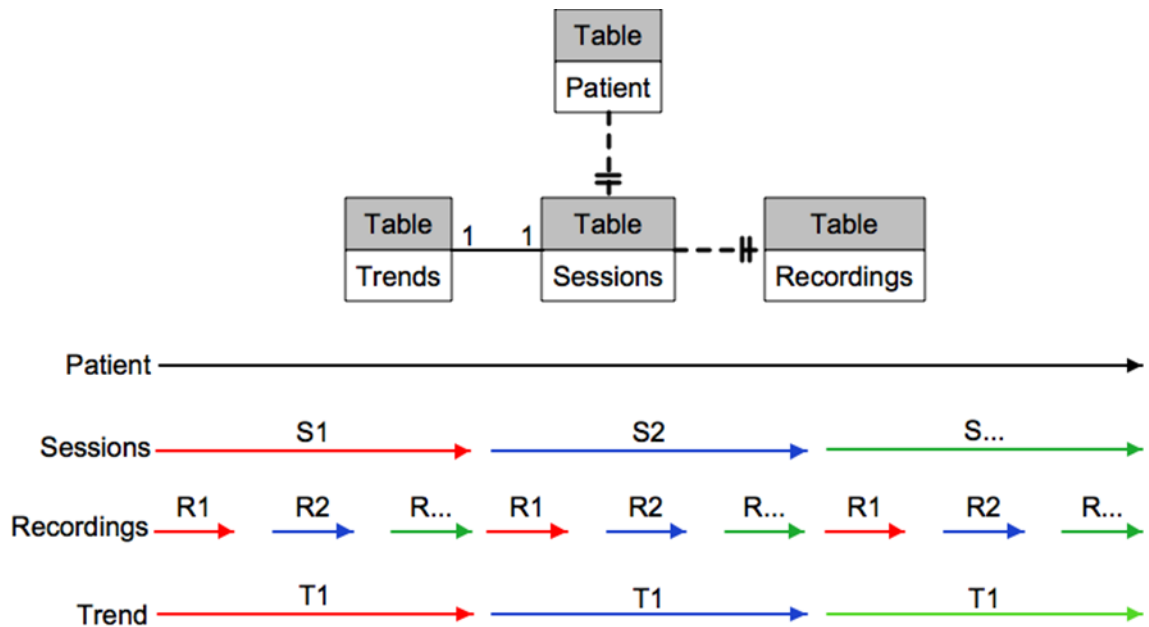


Figure 3.9 : Databases - Logical Construct

Figure 3.9 shows the logical construct of the database design; the patient forms the primary key with every patient being able to have multiple sessions. Sessions can contain multiple recordings but only one trend for the duration of the session; a trend in this context consists of a data sample taken every 60 seconds that can be presented in a graph or table format showing the time relationship of multiple parameters recorder (heart rate, SPO2, Pulse Rate...). The trend is of vital importance for the evaluation of the clinical state evaluation of the patient, the correlation as an example between heart rate and SPO2 can thus be graphically evaluated. If the SPO2 or oxygen saturation level drops the cardiac system will respond by increasing the heart rate in order to increase the blood circulation and improve the dissolved

oxygen percentage in the blood (SPO<sub>2</sub>). The data storage scheme as presented makes for accurate data extraction possible as well as enabling sectional data sessions to be analysed and verified. In the context of the study the datasets are analysed with real and post event to test the measurement computations and validate the results. Clinically the storage of digital records in conjunction with the ability to reconstruct the actual event poses great opportunities for clinical case analysis and the evaluation of the effectiveness of treatment plans, this topic is not included in the scope of this study.

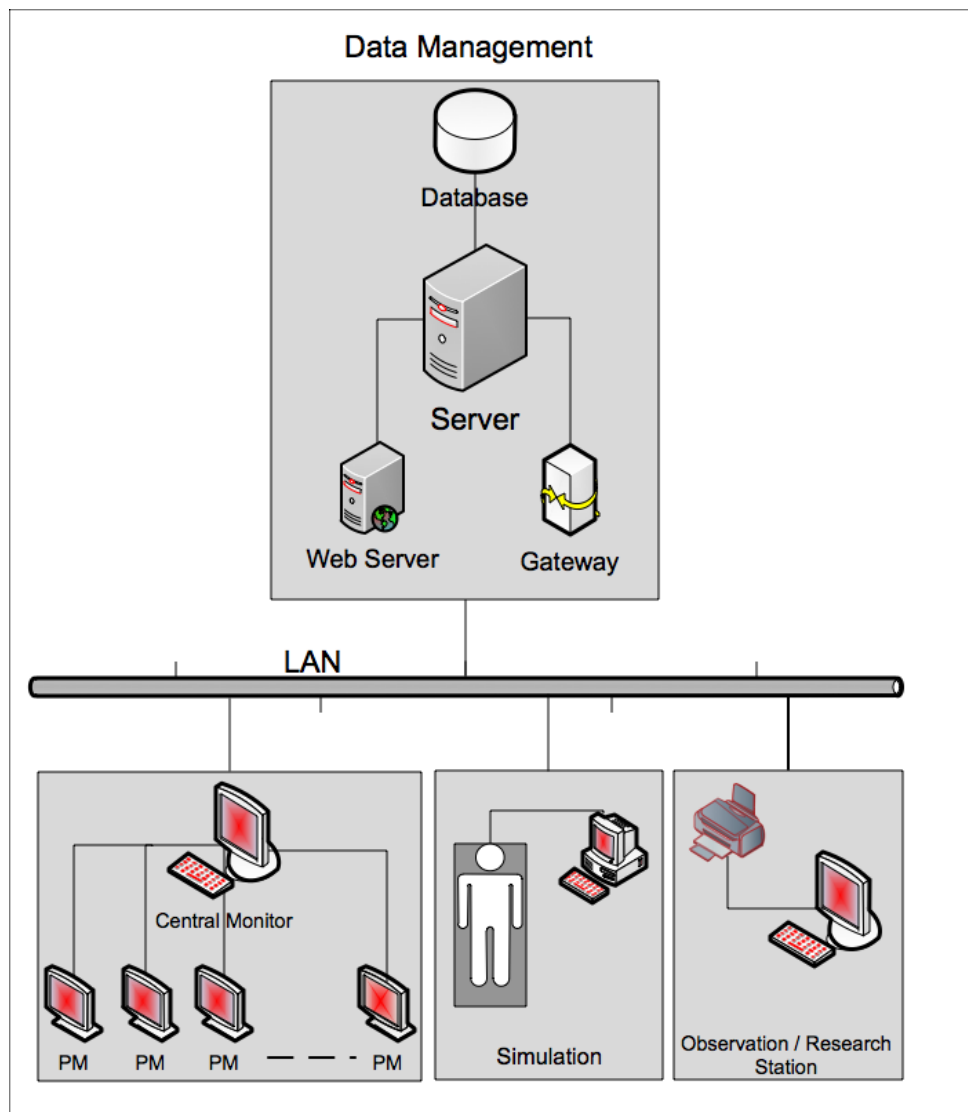


Figure 3.10 : Network Architecture

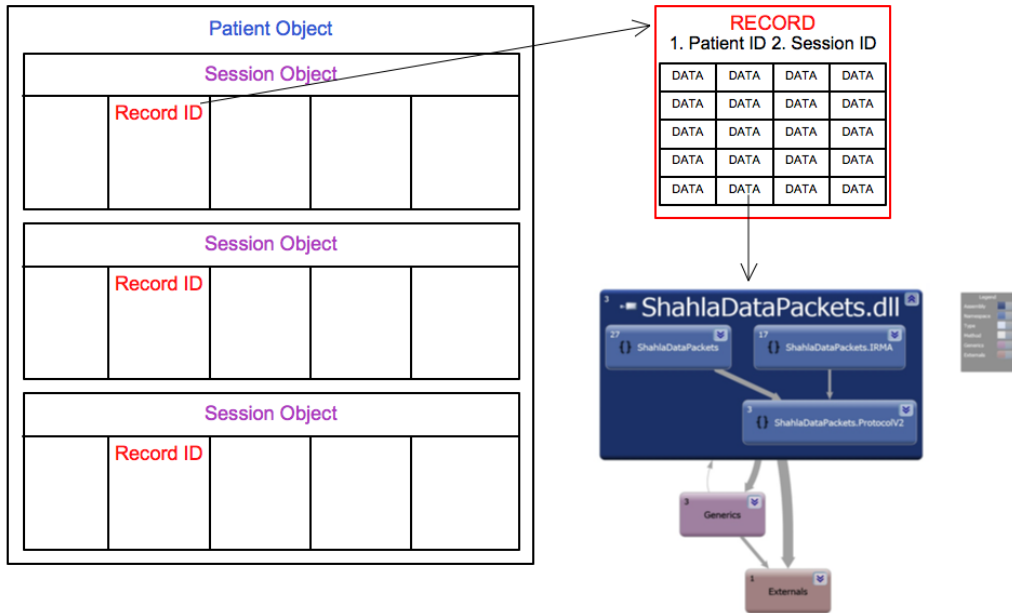


Figure 3.11 : Data Packet Storage

Figure 3.11 above is a representation of the data storage mechanism designed for this study; the efficiency of the electronic storage is not considered but rather the lossless requirements to more accurately measure and analyse the collected data. Appendix D shows a complete breakdown of the package system.

The rapper objects (AKPMDDataPackets, see Appendix D) are used for network based communication as well as storage, the network protocol wraps individual data packet object in a UDP TCP/IP communication wrappers.

This brief review of the communication and storage mechanisms is included for the purpose of completeness only but in reality falls outside the scope of the study. The communication sub systems are required for the data collection and storage and as such form a considerable part of the software developed and put in place for the study. Detailed supplemental data is included in the Appendix showing the network infrastructure and communication class relations developed.

In this Chapter, the toolsets, technologies and methods required to collect, store, reproduce and analyse the data gathered were discussed as well as the methods constructed and followed to develop the analysis model. Well-defined research requires good quality data from which information can be extracted, insights developed, conclusions drawn leading to understanding and ultimately the addition of knowledge to the global knowledge pool. In section 5.1 a short case study is presented as a walkthrough to show the methodology in action. The case study is initialized by defining the parameters and measurements required as input data to the model discussed in Chapter 4. This is followed by an analogue graph of data used as benchmark parameters to be used in the comparison tables against the digitally derived and measured values. The digitization and reconstruction of the data is shown and briefly discussed along with the comparative results.

### **3.5 Methodology**

In essence a research philosophy is a system and belief about the way in which data about a phenomenon should be gathered, analysed and used. The basic process of scientific research can be expressed as the gathering of knowledge about what we believe the world to be. This is further broken down into the basic research that tells us something that we did not know before and applied research that provides an answer to a specific problem as well as contributing to theory (Lee, 2008).

This research is broken down into two main approaches based on scientific positivist methodology namely simulation and quantitative analysis of data collected using field experiments. This section will present the two methods and explore the reasoning and utilization of the methods.



### 3.5.1 Simulation

Computer simulation as a research approach is gaining ground in popularity for it allows the researcher to define concrete input parameters but at the same time enable dynamic data input to be utilized in a controlled environment. Research methods often rely on assumptions and their testing coupled with observation based on the cause and effect nature of a system or model. Simulation allows the researcher to step away from the typical question of “what happened, how and why” and allows answering of the question “what if...” (Dooley, 2002). For the purposes of testing a mathematically calculation based model the “what if...” question allows for the input data to be defined and adjusted to cover a full range of eventualities that can occur in the natural environment of the particular research domain. In essence simulation allows for the comparison and testing of outputs with changing input parameters governed by the rules and structures included and built into the model. Simulation further is used as a substitution for experimentation using real life data; it allows for the testing of the model in a controlled environment and for the rule sets and algorithms to be refined and adjusted to cope with fluctuations usually encountered with the use of real life data as input. Simulation can thus be expressed as copying the behaviour of a system where the input can be controlled by the introduction of random variables.

The research presented in this study is especially vulnerable to input fluctuations due to the dynamic nature of bio signals produced by analogue biological structures like the electro cardiac conduction system. A further advantage of simulations in biomedical based research is that hard to find signal streams that can be tested against the model. As an example an uncommon cardiac arrhythmia can be simulated where if real world data is used as the only input the particular arrhythmia might not be available to be recorded in the research environment. A popular database of cardiac and other bio signals are available through the Harvard-MIT Division of Health Science and Technology MIT-BIH database. The database made available to researchers through the PhysioNet platform specializes in complex and

difficult to locate physiological signals stored using the SCP-ECG protocol discussed in section 2.7.

Simulation allows the researcher to consequently test the logical approximations made in the mathematical model and derived algorithms used to process the input data and further to check if these approximations are reasonable. Developing a model to be implemented through the development of a compiler application or program runs the risk of delivering unreliable output due to the programming being subject to bugs (Norman, 2000). Simulation and the mathematical modelling thus play complimentary roles; if as an example the heart rate in an ECG data stream has to be calculated the RR time interval might be used (see section 5.2.1) and expresses as:

$$\text{Heart Rate} = 60 \text{ sec} / \text{RR time interval in ms}$$

Equation 7 : Heart Rate Calculation using the RR Interval

By supplying the application a simulated data input signal with a specified heart rate the calculation is built into the model and as such the application can be tested; if an error is detected the mathematical equation can be corrected. Without simulation this type of error is difficult to detect due to the dynamic nature of physiological bio signals.

Although the example is simplistic the simulation toolset and environment used in this study (see section 3.2) was capable not only to provide the base parameters but also simulate the more advanced and difficult to pen cardiac related bio signals and waveform morphologies. Simulation as a research methodology was user to develop, test and implement the mathematical and conceptual model and measurement techniques developed to test the real time analytical model. The research however took one further step and quantified real life bio signal recordings in both analogue and digital formats and used the results in a quantitative comparison to also validate the model using real data sets.

Simulation is becoming a primary tool for modelling of ECG data, “*ECG modelling and simulation is becoming increasingly important due to its substantial ability for diagnosis of coronary diseases and anomalies...*” (Abkai, 2009). Simulation and ECG modelling based analysis has a substantial ability for diagnosis of coronary diseases and abnormalities, in the Abkai study a model was proposed for multiple dipole electrocardiography simulation. Simulation enabled the model to be developed and compared with traditional single pole approaches used in vector electrocardiography as is described in section 2.5.

The ECGSIM project is another example of a simulation based model that explores the difficulties in solving the forward and backward problem of electrocardiography to deliver a model for describing ECG pathologies and individual differences by using a double layer approach to calculate the potentials of the service by assuming a number of local measurement sources (Shahidi 1994; Ooserom, 2002, 2004). The Abkai model successfully showed through simulation the fast solution to parameterize the ECG waveform in as little as five to six cycles to describe the ECG cycle in real data in terms of QT and QRS time intervals (see section 2.2).

The research and the model presented here builds on this work and aims to shorten the analysis phase even more by using the bit by bit analysis approach model developed that allows for the added functionality of the signal injection technique that greatly enhances the visual presentation of the ECG signal in a live monitoring domain.

### **3.5.2 Field Studies and Quantitative Comparison**

Mathematical modelling is an attempt to describe a system or process using mathematical language and concepts (Byl, 2003). Section 3.5.1 discussed the purpose of simulation as was used in developing the model constructed for this study. The second part of the methodology used to test the hypothesis was to conduct field studies for the purpose of gathering data to be used as input to the model presented in the form of a computer program. Field studies are in essence non-experimental inquiries occurring in a system where independent variables cannot be manipulated or controlled (Boudreau, 2001).

Field studies in general can be sub divided into 3 phases namely the research formulation and site identification, survey and data collection and finally the research analysis and conclusion. The sequence of the research followed the same path with the first two chapters

The survey and data collection for this research was conducted at the Saad Specialist Hospital, Al-Khobar Saudi Arabia and involved the digital and analogue recording of ECG data from patients in the cardiac care unit (see Chapter 5, Results and Findings). The recorded data are pure representations bio signals of the patient at the time of the recording.

Field studies form an important part of model based research where datasets have to be tested and results validated. Simulation does not always allow for random factors and variable to be included in the input data streams due to the natural rhythms of biological sub systems, field studies fills this gap. As the definition implied the main focus is to observe and measure but to refrain from manipulation of the observed and measured data, in essence it is the collection of a pure and as a manner of speaking unpolluted natural occurring dataset. The processing of the data into quantitative values is usually presented in a visual or graph based manner. For the purpose of this study a comparison of the analogue measured and digitally recoded data was processed into a set of comparative column charts where the analogue ECG measurements were used as the benchmark for testing the mathematically calculated output from the model that was used as input with the digitized recorded data forming the final phase of the field study.

### **3.5.3 Quantitative Analysis**

In essence quantitative analysis is an attempt to replicate reality mathematically and to define and study natural phenomena (Straub, 2004). The research methodology was originally developed in the natural sciences but is now used and accepted in all social sciences in the form of survey methods, laboratory experiments, and for numerical methods including mathematical modelling. It is suggested by many researches that quantitative,

in combination with qualitative methods, a process referred to triangulation should be included in what is described as good research (Mingers, 2001).

The research presented here steps away from pure quantitative methods and combines the approach with what is described as positivist philosophy where problem solving and the testing of theories such as seen in design research; where the outcome is more often than not an improved process, a prototype or model (Vaishnavi, 2004). Quantitative Positivist Research or QPR employs deduction at the heart of the method where the researcher tests for internal consistency, distinguishes between the logical basics of a theory and the testable predictions, compares against existing theory to show the advancement of knowledge and finally the negative testing in order to falsify the theory. "Verification can be found for almost any theory if one can pick and choose what to look at" (Cook, 1979).

In the following chapter the concepts introduced will be utilized and moulded into a model intended to test the hypothesis introduced in Chapter one, the journey into the real time clinical signal analysis continues...

## CHAPTER 4      MODELLING

ECG signals are the most obvious and observable measurable data produced by the human heart and cardiac system and as such are a well-understood and studied facet of human physiology. The analysis and interpretation of this bio signal forms a major part of the human disease map and seen in context with reference to the pathology and statistical prevalence of cardiac disease, forms the most significant measurable clinical diagnostic toolset. Automated ECG signal analysis is prominent and a substantial topic of study in biomedical engineering with numerous dimensions and proposed best-in-class algorithms based on different techniques. If myocardial infraction can be predicted with as little as a couple of minutes the impact on the survival rate of sudden cardiac death in humans would be measured in millions on an annual and global scale.

In this Chapter a substitute or alternative model based on near real time non-linear ECG analysis is presented and validated to be an efficient and new take on this prominent bio-signal. The model was developed using the methodologies discussed in the previous section where simulation was used as the initial input during the development stage followed by real time patient data as validation. The analysis is conducted in a purely digital domain or post signal acquisition and processing stage; the study is only concerned with the already filtered digitized format and as such does not discuss in great detail the analogue stages but for completeness an introduction is included.

## 4.1 ECG Segmentation

The study of ECG segmentation is a core component for understanding that cardiology and forms the basis of pattern deviation recognition as well as being mathematical kick off point for cardiac analysis. As discussed in section 2.1 and shown in Figure 2.1 the ECG waveform is logically subdivided into 6 sub sections each of which represents a specific physiological trigger that relates directly to phases in the cardiac conduction cycle. Using the segment start and stop point limits the timing intervals can be derived enabling for the detection of deviations from normal in the wave morphologies. In the following subsections the significance of each segment is shown and conclusions drawn to form the basic markers for the hypothesis.

### 4.1.1 PR Interval

The PR interval begins with the onset of the P-Wave (section 3.2) and ends with the QRS complex representing the time interval for the electrical impulse to travel from the SA Node to the ventricles of the heart; normal values can be accepted as 0.12 to .020 seconds. Values less than 0.12 sec are termed short PR intervals and values longer than 0.20 sec may lead to a diagnosis or classification of a first degree blockage (John, 2006). Various cardiac abnormalities are associated and can be diagnosed where the PR Interval is used as the main indicator; examples include the Wolff-Parkinson-White syndrome (WPW) and the Wenckebach phenomenon, all well-defined and understood conditions.

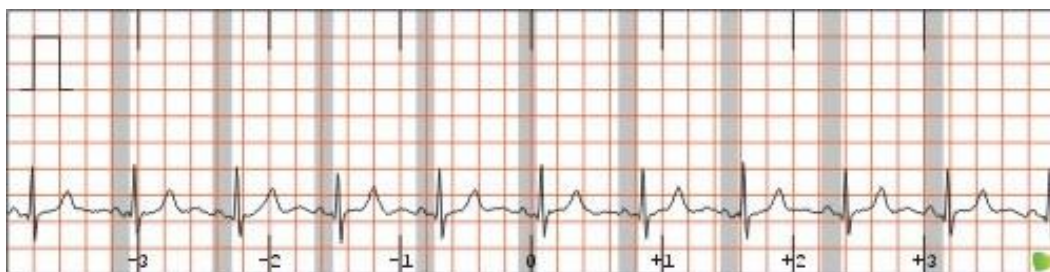


Figure 4.1 : PR Interval (Shaded)

The PR interval can thus be used as an indicator and marker if the obstacles to accurate measurement can be bridged. The difficulty in measuring the PR

interval electronically lies in defining the starting point of the P-Wave (*see section 3.2*). In cases with severe blockage or a drifting P-Wave along the x axes, the PR interval is technically non-existent; this should be taken into account during the modelling phases of any cardiac cycle algorithm or measurement technique development.

#### 4.1.2 The PR Segment

The PR segment can be best described as a sub section of the PR interval and exists in the timeframe between the end of the P-Wave and the onset of the QRS complex. This segment represents the duration of the conduction from the AV node, through the bundle of HIS (Figure 2.1) and into the bundle branches of the ventricular muscles. Considered as isoelectric, this segment of the ECG represents arterial systole and ventricular diastole but distortion can be observed under conditions of atrial injury.

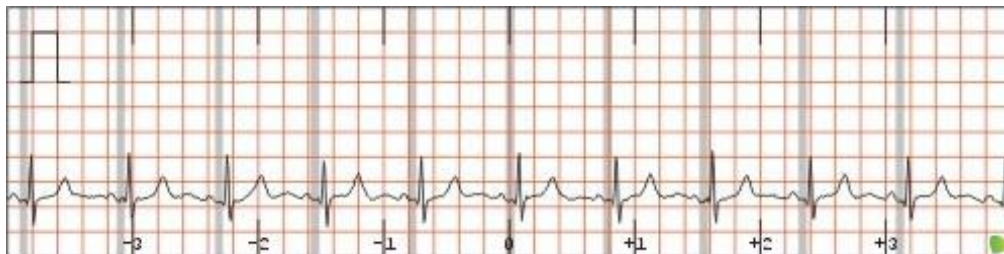


Figure 4.2 : PR Segment (Shaded)

Studies have indicated that PR segment depression can indicate disease but it is generally accepted that PR segment elevation is in general considered as clinically insignificant and seldom measured (*Yoshihiro, 2004*). For purposes of this study the PR segment is used as an indicator or reference value due to the isoelectric characteristic to calculate ST segment depression (section 3.1.3) or deviation from the virtual zero point on the y axes of the graph; a reference point as such rather than a clinical indicator.

#### 4.1.2 QRS Complex

The QRS represents the climax of the cardiac cycle and the depolarization of the ventricles, the primary pump action of the heart with duration of 0.080 to



0.120 sec formed by the combination of the Q-R and S-waves of the ECG cycle. Clinically the morphology, duration and amplitude of the QRS waves are of great importance and useful in the diagnosis of cardiac arrhythmias, conduction abnormalities, ventricular hypertrophy, myocardial infarction, electrolyte derangements, and other disease states (Thygesen, 2007). It is important to note and understand that the QRS acts as the start of the cardiac cycle where monitoring is concerned; this is due to the fact that the QRS complex has the most prominent shape and amplitude in the ECG waveform and as such can thus be easily identified electronically; the deviation from the zero point on the y axes. All other segments of the ECG waveform are usually defined, with reference to monitoring, in relation to the QRS; Figures 4.13 depicts this. During the research it was established that the QRS cannot be used as the start marker in real time analysis for the derived values and calculations would be the duration of one cardiac contraction behind. This might seem insignificant but the implications proved otherwise in the visual segmentation and deviation indicators; the QRS is the pulse indicator but for diagnostic purposes the accurate detection of the P-Wave is more significant but also more complex. The model derived from the research presented a technique that can be applied to accurately measure the P-Wave start point and as such a more defined and accurate electronic segmentation process supporting the accurate calculation of the cardiac timing intervals.

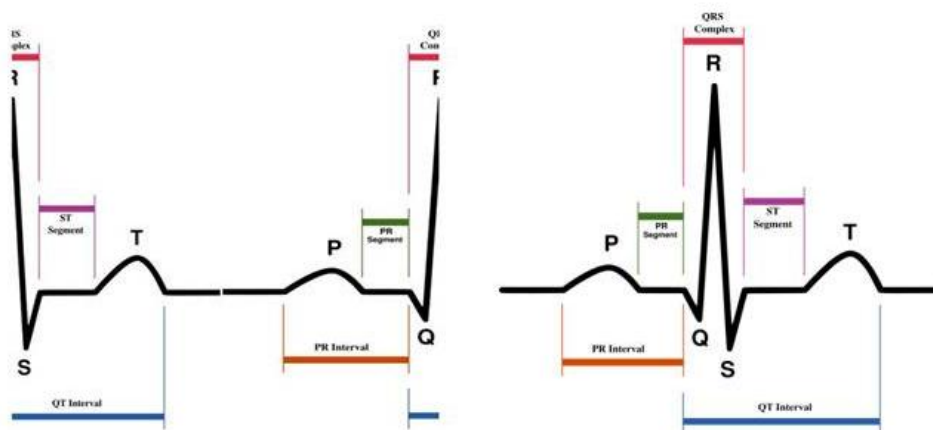


Figure 4.3 : ECG Alternative View vs. Clinical Diagnostic View

### 4.1.3 ST Segment

The ST Segment is the most important and widely used ECG segment and can be observed between the end of the S-Wave following the QRS peaks and the start of the T-Wave with duration of 0.08 to 0.12 seconds. During the ST Segment the arterial cells are relaxed and the ventricles are contracted minimizing the visibility of electrical activity; the ST segment is described as being isoelectric in the same manner as the PR segment (deviation from the logical or virtual zero point on the y axes).

Looking back at the previous section, QRS, it should now become clear why the P-Wave detection as the logical start of the cardiac cycle must be enforced in electronic real time computations. The PR section is used as the reference point to calculate the ST segment deviation, if the conventional QRS marker is used then the reference point will follow the measurement point rendering it absolute. As mentioned earlier buffered data sets and post processing was the only method deployed imposing tremendous limitations in the modelling as well as presenting, in reality, old data.

Myocardial ischemia or oxygen starvation of the ventricles is usually indicated by a depression of the ST-segment, a common indicator for CVD due to blockage in the coronary arteries (section 2.3). ST-segment elevation on the other hand indicates recent cardiac injury, ventricular aneurysms or even Pericarditis (*“Pericarditis is a swelling and irritation of the pericardium, the thin sac-like membrane that surrounds your heart” American Heart Association*).

*Note: isoelectric indicates no cardiac activity and is show as a flat section on the baseline of the ECG graph; zero positive or negative deflection.*

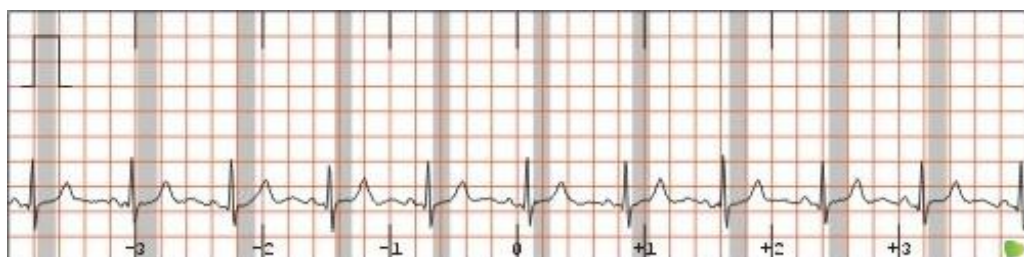


Figure 4.4 : ST Segment (Shaded)

As with other ECG segments the ST segment is difficult to accurately locate electronically especially during real time processing. The beginning of the waveform is located traditionally or with conventional techniques by traversing forwards from the QRS point within a buffered dataset. During extreme morphology of the ECG waveform the task of isolating the ST segment is complicated due to the merging or the waveform with the T-wave as well as prolonged duration of the waveform in conditions resembling extensive ST depressions. The notch following the ST segment as can be seen in Figure 4.4 is referred to as the T-Wave and represents the re-polarization of the ventricles.

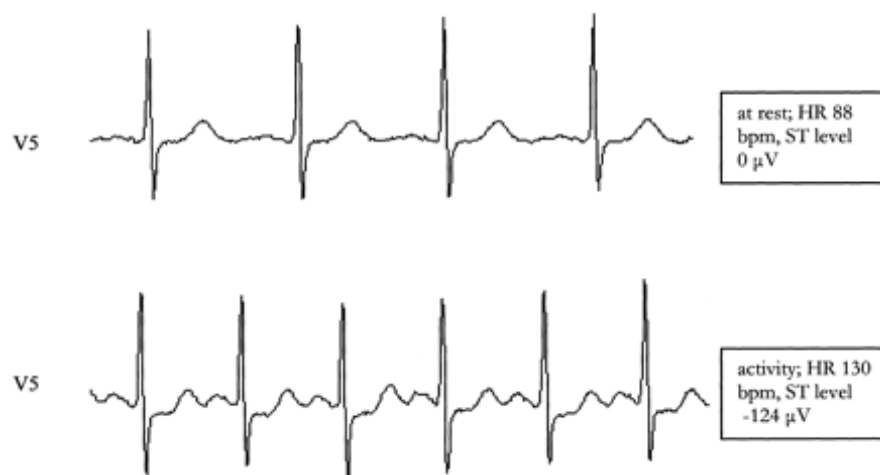


Figure 4.5 : ST Segment Depressions<sup>5</sup>

#### 4.1.5 T and U-Waves

The final component of the ECG waveform is the T-wave indicating the re-polarization of the ventricles following the QRS complex and ST segment. The T-wave morphology is complex and can vary in amplitude, can be inverted and is generally described as being asymmetric with the first half moving or forming more slowly than the second half.

*“U-waves are the only remaining enigma of the ECG, and probably not for long. The origin of the U wave is still in question...”* (Frank, 2003). Although the U-wave was originally described by Einthoven (Einthoven, 1912) the leading hypothesis subscribe the U wave to delayed re-polarization of the His–Purkinje system, the small mass of the specialized conduction system (Watanabe, 1975). For this study the effects and presence of the U-wave will

be ignored and the combination of the T- and U wave used to reference the ECG's final or end section.

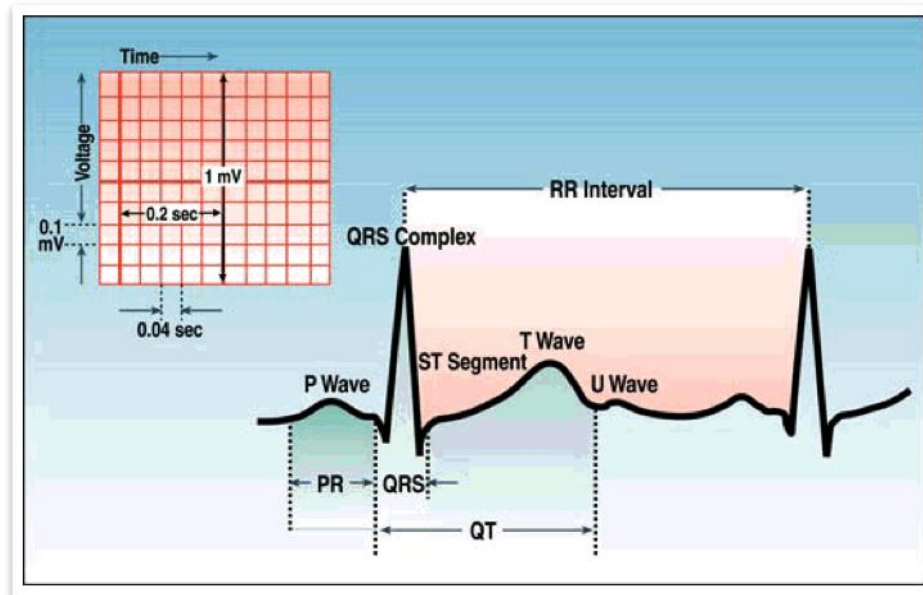


Figure 4.6 : T- and U-Wave

#### 4.2 Medial ECG Wave Derivative as Measurement Techniques

Electronic measurements techniques are typically based on a virtual reference lead also referred to as a medial lead. This virtual lead is derived by the summation of the total ECG lead derivatives being monitored and as such represents a vector of the cardiac electrical activity. In the previous sections of the Chapter, ECG waveform segmentation techniques were discussed, it is however important to show how current buffered electronic techniques are used to accomplish ECG analysis. For the remainder of the thesis the term “buffered” will refer to the short term storage or random access memory (RAM); the advantages of using RAM buffered storage is that the measured signals can be processed and as a manner of speaking be transverse in a logically windowed measurement plain. Figure 4.7 below show a logical depiction of the buffered data, transverse iteration and amplitude summation. Please note that ECG traces do tend to be processed in a synchronized manner as shown due to the time slicing or sampling of the signal, in reality

an analogue driven system like the cardiac conductive system cannot produce one hundred percentage synchronized signals.

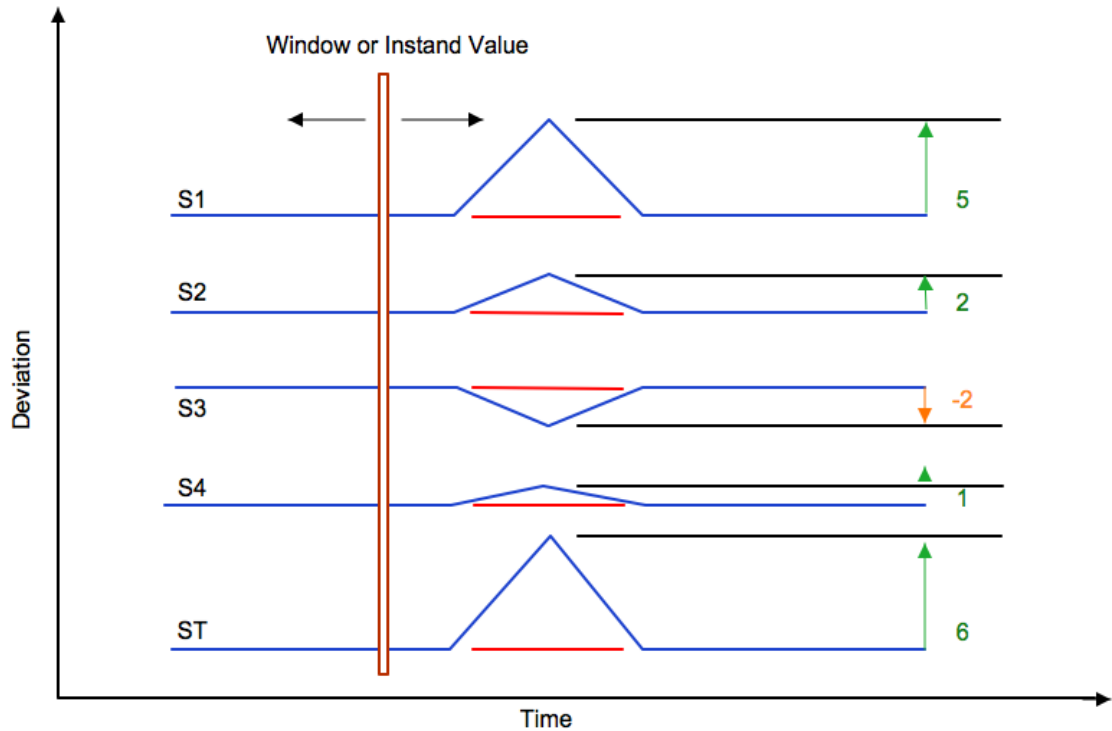


Figure 4.7 : Summations of Signals

$$S_{Total} = S1 + S2 + S3 + S4$$

$$S_{Total} = 5 + 2 + (-2) + 1$$

Equation 8: Waveform Summation

As shown in Figure 4.7 above we can calculate the summation or median logical lead:

#### Analysis Processing Walkthrough:

1. Store 1 to 15 successive QRS Cycles
2. Average and sum inter lead values, media values
3. Establish a window timespan and iterate backwards and forwards through the data using QRS peak as reference point
4. Compare deviations to zero reference line using standards segmentation time span values
5. Tag segments and calculate basic analytical indicators

The Signal Total ( $S_{Total}$ ) equates to in a positive deflection of +6 rendering a logically larger sample magnitude value and as such better computational resolution and accuracy. By applying the summation technique together with triangulation (ref section 3.3) the P-Wave and thus onset of the cardiac cycle can be calculated and the clinical measurements derived based on the time sequencing rather than the manipulated amplitude.

The summation and buffering methods do have drawbacks in the processing domain for it is bound to be buffered or “old” data. Clinically a time delay between the actual event measurement and presentation of the numeric data of less than 10000 ms does not pose any significant drawbacks but it limits and nullifies any significant data presentation within the waveform itself. In cardiology the ECG waveform and the extraction of data from it is the key tool in the diagnosis and treatment of the patient so the limitations of post processing is a key proponent of the study and the development of the algorithm and measurement techniques presented here.

**Note:**

- Real time processing or rather near real time processing, refers to data that is processed, computations and feedback, for the purpose of this study the terminology “real time data” refers to near real time data timespan (>2 ms). Processing or CPU time will mostly be ignored unless otherwise indicated.
- Post processing in the thesis refers to data and computations that are made in parallel with the data stream presentation for example the ECG wave form or graph. Results are computed over a set averaging period so live feedback cannot be re injected into the data stream.
- The ECG Analyser, as shown in Figure 4.8, processes the data stream and re injects the calculated signal values back into the stream for real time presentation in the case of the study the ECG segmentation showing waveform morphologies

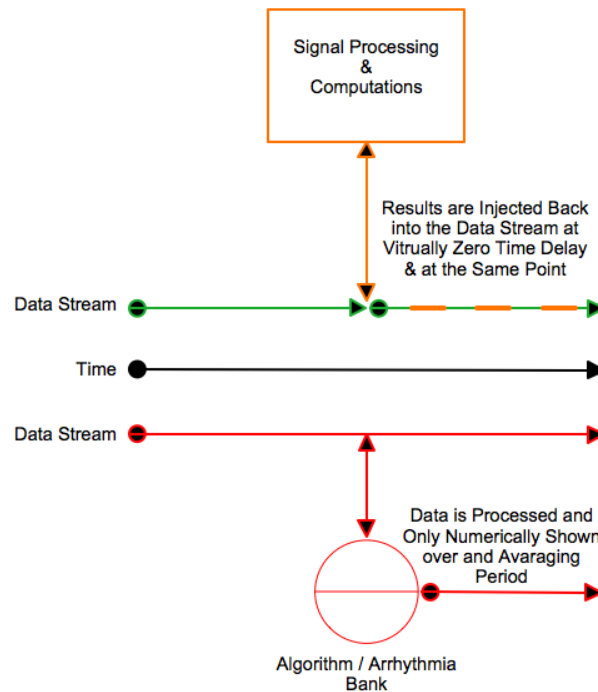


Figure 4.8 : Real Time vs. Post Processing

To demonstrate the significant shift that real time processing and signal injection has on the presentation of data a short prequel is shown below:

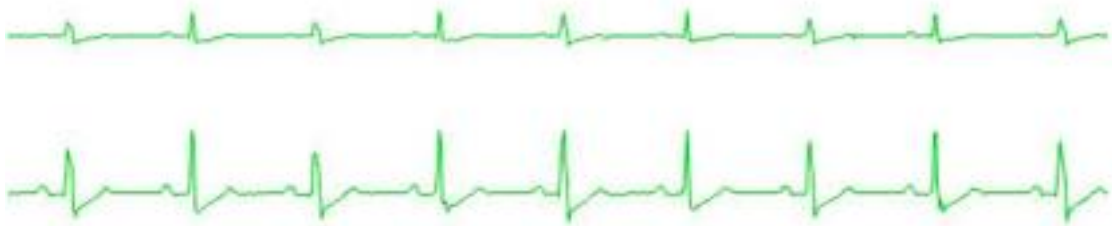


Figure 4.9 : Standard ECG

For the untrained eye the ECG presented above shows no significant morphology and as such an individual or non-critical care trained staff would not be able to classify the trace as a possible high risk. In a congested emergency room setting the inability to flag a patient with a huge negative up-sloping ST depression might be a life or death oversight, consider the same trace below but with real time processing injected into the ECG graph:

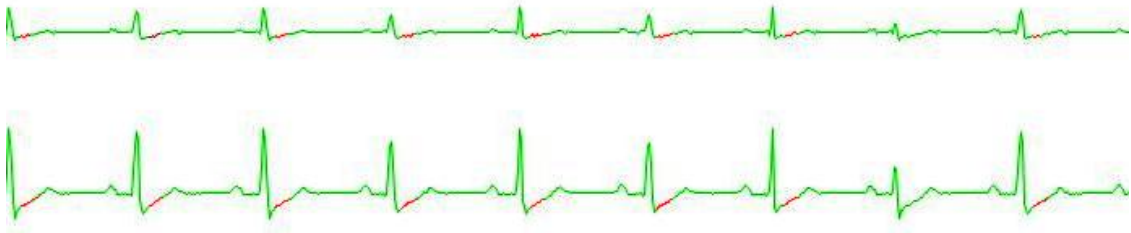


Figure 4.10 : ST Depression Highlighted in RED

Figure 4.10 shows clearly in red the deviation from the expected isoelectric ST segment pattern, even for the untrained eye the problem is clear. Staff is not required to be able to classify or even understand the morphology but only to alert the appropriate clinical staff member. Even the housekeeping staff can now be trained to actively participate in providing a more clinically patient safe care environment where the extra set of eyes may just prove to be a lifesaving tool. The example above shows the ST segment only but the same technique can be applied to most measurable waveform morphologies.

### 4.3 P-Wave and P-Wave Detection

The P-wave forms the initialization of the ECG or cardiac cycle and is the normal activation of the arterial depolarization initiated through the SA Node with duration of 0.08 to 0.1 seconds. Clinically, the significance of the P-wave is well understood and diagnostic principles related to the P-wave widely implemented.

From an electro analytical point of view the P-wave poses many problems for live detection and classification. As with the ST segment the standard method for detection is linked to traversing backward from the QRS point within a buffered dataset. This however, in a real world or live processing environment with un-buffered signal processing renders the indication of the P-wave difficult too impossible. This research addresses this problem with the development of the algorithm explained in Chapters five and six.



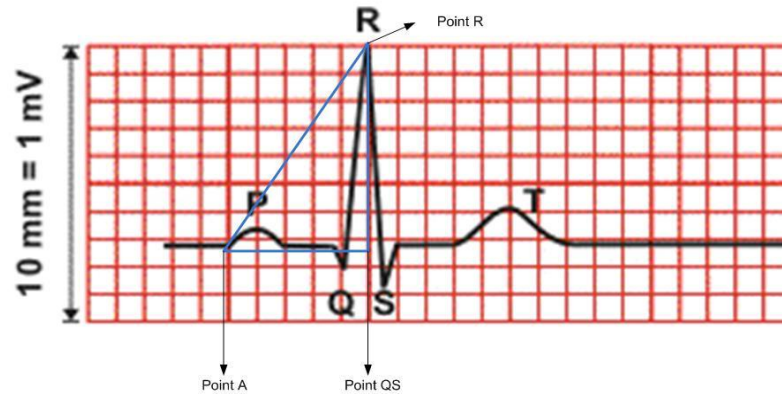


Figure 4.11 : P - Wave Triangulation

Figure 4.11 above shows a standard ECG waveform with an embedded triangle and marked points. Within a buffer, using Point R (QRS complex), and knowing the average PR and QRS time intervals a point can be calculated on the linear line where the P-wave should statistically be positioned. At this point (the distance from point QS to Point A) a measurement can be taken to determine the deviation from the zero line. If a deflection were measured the P-wave would thus be present and validated. The model presented in chapter five takes a completely different approach and processes the wave form integer values one by one in order to calculate deviation, this combined with a tagging process that runs in parallel, the exact segment point can be accurately measured or determined.

#### 4.4 Analogue Acquisition and Digitization of the ECG Signal.

The basic physiological signal acquisition circuit has changed little in the past few decades; digital semiconductors replaced the older tube based systems but in essence the technology is almost unchanged. Figure 4.12 shows the typical diagram and setup employed in most modern biological signal monitoring systems. The input buffers consist of a combination of subsystems that included the isolation circuitry as well and the preamplifiers followed by the filtering and Analogue to Digital (A/D) converters. As stated earlier this study is not concerned with this stage of the process but rather the data processing of the packet based data indicated in Figure 4.12 and shown here as the Data Input / Output (I/O).

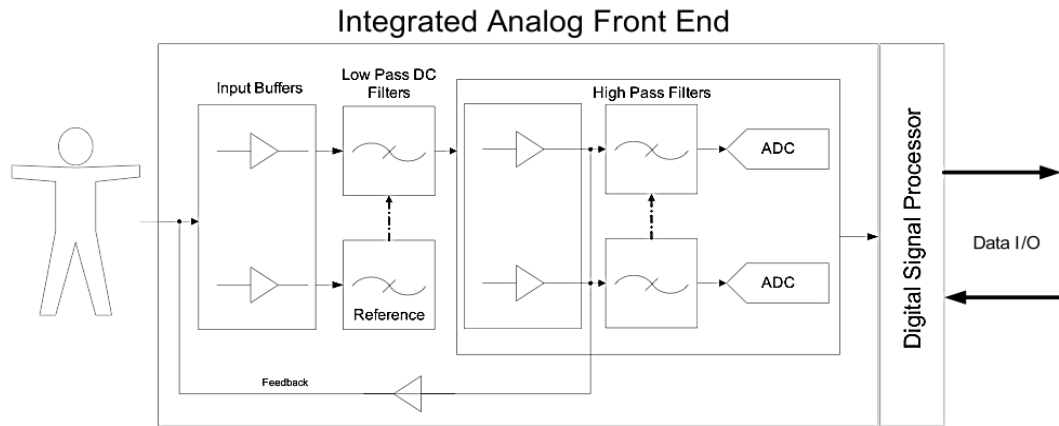


Figure 4.12 : Basic ECG Acquisition Diagram

The data offered by the system used in the experimentation is in a continuous data stream by way of serial, asynchronous communication at 115200 baud, 8 data bits, even parity bit and one stop bit subdivided into packets according to Table 3 below. In short the data includes 8 graphical waveforms synchronously, a pulse value, a respiration value and several status bytes; the data transmission is processed in blocks or packets.

The integrity of the blocks is secured by:

1. An even parity bit in each transmitted byte.
2. A checksum for each data block

The checksum value in this case is the sum of all bits in one byte, including the parity bit. To reduce the overhead for the waveform transmission the wave block uses an additional checksum algorithm to the status and value blocks.

The LEADS that are transmitted are:

1. I, Einthoven Lead
2. II, Einthoven Lead
3. III, Einthoven Lead
4. AVR, Goldberger Lead
5. AVL, Goldberger Lead

6. AVF, Goldberger Lead
7. C1, one Wilson lead that can be placed freely on the chest of the patient
8. Respiration curve

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 <b>Sync</b>	1	1	1	1	1	0	0	0
Byte 2 <b>Ctrl/Chk</b>	Bit 3 Ctrl	Bit 2 Ctrl	Bit 1 Ctrl	Bit 0 Ctrl	Bit 3 ChkSum	Bit 2 ChkSum	Bit 1 ChkSum	Bit 0 ChkSum
Byte 3 <b>Wave 1</b>	Bit 7 Wave 1	Bit 6 Wave 1	Bit 5 Wave 1	Bit 4 Wave 1	Bit 3 Wave 1	Bit 2 Wave 1	Bit 1 Wave 1	Bit 0 Wave 1
Byte 4 <b>Wave 2</b>	Bit 7 Wave 2	Bit 6 Wave 2	Bit 5 Wave 2	Bit 4 Wave 2	Bit 3 Wave 2	Bit 2 Wave 2	Bit 1 Wave 2	Bit 0 Wave 2
Byte 5 <b>Wave 3</b>	Bit 7 Wave 3	Bit 6 Wave 3	Bit 5 Wave 3	Bit 4 Wave 3	Bit 3 Wave 3	Bit 2 Wave 3	Bit 1 Wave 3	Bit 0 Wave 3
Byte 6 <b>Wave 4</b>	Bit 7 Wave 4	Bit 6 Wave 4	Bit 5 Wave 4	Bit 4 Wave 4	Bit 3 Wave 4	Bit 2 Wave 4	Bit 1 Wave 4	Bit 0 Wave 4
....								

Table 4: Waveform Data Block

“2+Ctrl” bytes are transmitted in this block; “Ctrl” is the number of wave samples in the block. The checksum is the sum of all bytes in the block including the sync character modulo 16. The wave samples are limited to a maximum number of 0xF7 (247d), so no error with sync bytes can occur.

The channels are not mapped one to one to the byte position in the block since the user can freely enable or disable all channels independently. The transmission sequence is always: I, II, III, aVR, aVL, aVF, C1 followed by Respiration; Example 1: the host requests ‘I’, ‘aVF’ and ‘C1’ to be transmitted. Wave 1 will be ‘I’, Wave 2 will be ‘aVF’ and Wave 3 thus ‘C1’, the block being 5 bytes long. Example 2, the host requests ‘C1’ and respiration waveform to be transmitted. Wave 1 will be ‘C1’, Wave 2 will be respiration waveform, the block being 4 bytes long.

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 <b>Sync</b>	1	1	1	1	1	0	Bit 1 Type	Bit 0 Type
Byte 2 <b>Ctr/Chk</b>	0	Bit 6 ChkSum	Bit 5 ChkSum	Bit 4 ChkSum	Bit 3 ChkSum	Bit 2 ChkSum	Bit 1 ChkSum	Bit 0 ChkSum
Byte 3 <b>Wave 1</b>	Bit 7 Value	Bit 6 Value	Bit 5 Value	Bit 4 Value	Bit 3 Value	Bit 2 Value	Bit 1 Value	Bit 0 Value

Table 5: Value Data Block

**Bytes transmitted in this block.**

Type == 00 -> Not Used

Type == 10 -> Respiration Value

Type == 01 -> Pulse Value

Type == 11 -> Not Used

The checksum consists of the sum of all bytes in the block including the sync character, modulo 128.

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 <b>Sync</b>	1	1	1	1	1	1	0	0
Byte 2 <b>Ctr/Chk</b>	0	Bit 6 ChkSum	Bit 5 ChkSum	Bit 4 ChkSum	Bit 3 ChkSum	Bit 2 ChkSum	Bit 1 ChkSum	Bit 0 ChkSum
Byte 3 <b>Wave 1</b>	0	RespWave	X	Chest	RA	LA	RL	LL
Byte 4 <b>Wave 2</b>	0	C1	aVF	aVL	aVR	III	II	I
Byte 5 <b>Wave 3</b>	X	Bit 1 Filter 2	Bit 0 Filter 2	EMG AMP	Bit 1 Amp	Bit 0 Amp	Bit 1 Speed	Bit 0 Speed
Byte 6 <b>Wave 4</b>	0	X	X	X	Bit 3 Status	Bit 2 Status	Bit 1 Status	Bit 0 Status
....								

Table 6: Status Data Block

Five bytes are transmitted in table 5 blocks. The 'X' indicates that the bit is unused and thus undefined; the checksum is the sum of all bytes in the block, including the sync character, modulo 128

**Note on Sampling:**

The sample rate varies from 100 to 300 Hz and as such delivers sample time slices at 3 to 10 msec intervals.

$$TimeSlice (ms) = \left( \frac{1}{\text{samplerate}} \right) * 1000$$

Equation 9: Time slice Calculation

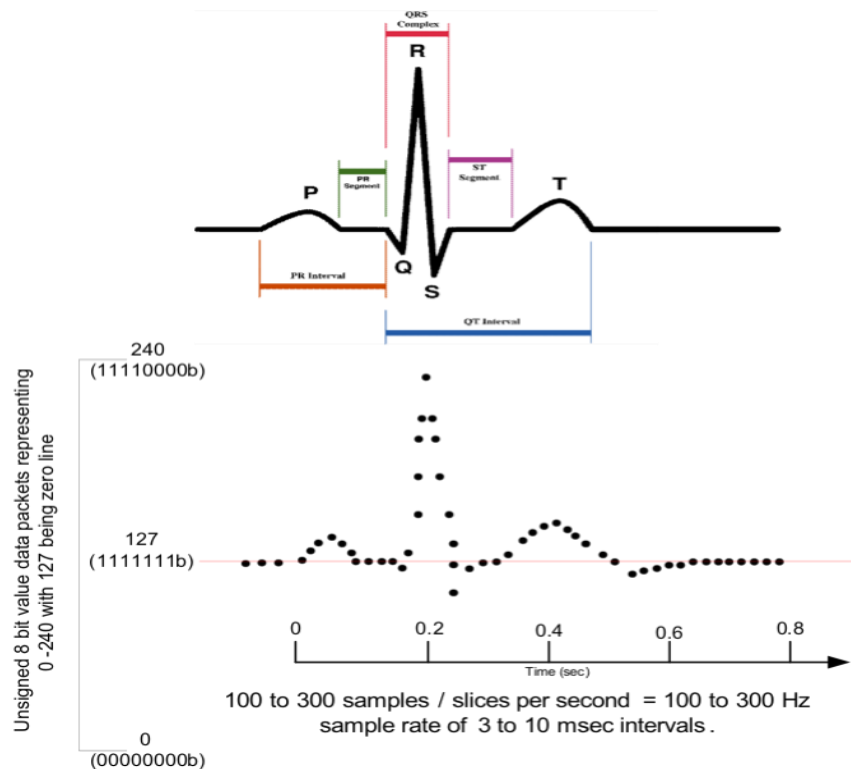


Figure 4.13 : ECG Sampling / Time Slicing

Figure 4.13 is a representation of the digitized signal over time with the amplitude expressed here in an 8-bit value where the waveform varies from 0 to 240 integers; 127 forms the logical “zero” line used as a reference in the computations. It is important to add that although the human brain interprets the packet representation as a waveform pattern the actual processing occurs on a bit by bit basis with little to no buffering in a logical synchronous format. Traditionally ECG analysis is executed on buffered data of up to 15 beat or cardiac cycles in order to establish a comparative deviational pattern; the algorithm developed for this study though involves a complete and uniquely different approach by calculating a bit-to-bit derivative value shown in section

4.2.3. The derivative value in essence eliminates any signal drift as well as the logically transformation of the signal into a pure positive and negative deflection presentation.

#### 4.5 ECG Analyser, a Walkthrough

The ECG Analyser is the software component that takes as input values the time slices, seven cardiac derivative leads in total (see section 2.1), in the format of a 10 bit array and performs the calculations to accomplish the analysis. Various software classes are passed values where the sub components of the ECG feed or data signal stream is processed and the various deviations targeted identified. Figure 4.14 shows the basic breakdown or class relation diagram of the component; please note that the ECG Analyser is the collective name used for the various algorithms and processes contained in the namespace and forms the core of the algorithm developed for this study; the data processing techniques developed addresses the feasibility of real time processing on a bit to bit basis.

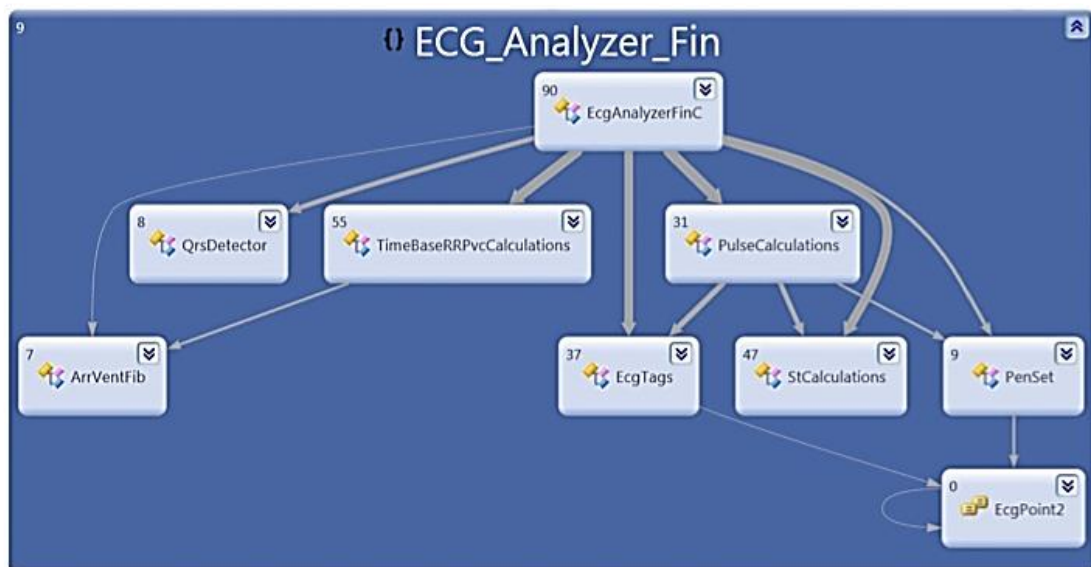


Figure 4.14 : ECG Analyser Class Relation Diagram

### 4.5.1 The ECG Analyser Component

(Class Label 90, Figure 4.14)

This class forms the basis of the component as well as the data entry point and processed output interface; a packet is passed to the components containing data of one time slice of the processed and digitized data feed. No computations are performed within this object; the data packet is distributed to the various other objects for processing. The subsequent lower order objects are hidden from the outside and data within those objects cannot directly be interacted with, read from or written to. The design is typical Object Oriented Programming (OOP) design and protects the data and processes within from any external manipulation or influences.

### 4.5.2 QRS Detector

(Class Label 8, Figure 4.14)

As the name suggest this class performs the QRS detection function that is used not as a primary QRS detector but rather as the “time keeper” within the components. The QRS peak acts as the reset trigger for the computations; logically a set time-span option would be used but by using the natural rhythm of the patient’s cardiac cycle the algorithm as a whole is dynamic and as such adapts to the individual data feed according the natural or rather physiological pacemaker of the subject data being analysed. In reality the processing cycle is not performing the computations as is the norm using the QRS as a starting point; this is an important and notable progression from the standard analysis technique where the only constantly accurate marker in the rhythm is seen as the QRS peak. The disadvantages of using the QRS as the start / stop point in the computational cycle is the limited ability to accurately detect the P-Wave, the natural starting point of the electrical cardiac cycle. Pathologies such as cardiac block where the P-Wave drift along the x-axes of the graph is thus almost impossible to detect without buffering and pattern comparisons. As a rule pattern comparisons are not an ideal measuring technique for it is an attempt to mimic the human brain and thought process which is a difficult

and inaccurate model to reproduce. The equation below is a simplified pseudo code expression of the logic applied within the QRS detector object:

```
WaveIntNew = waveIntValue;
WaveIntAvr = Math.Round (((WaveIntAvr * WaveIntAvrOld - 1) / WaveIntAvrOld)
PacketCounter = packetCounterIn;

if ((WaveIntNew > WaveIntHigh) && (WaveIntNew < maxPresetValue))
{
    WaveIntHigh = WaveIntNew;
}

if ((WaveIntHigh > QRSValueCompare)) && (packetCounter > minPresetValue))
{
    QrsDetected = true;
    WaveIntHigh = zero;
}

else
    QrsDetected = false;
```

Equation 10: QRS Detector, Pseudo Code

### 4.5.3 Pulse Calculator

(Class Label 31, Figure 4.14)

The PuleCalculator class computes the main indicator used in the analysis process namely the differential value (*DiffValue*, **df**) as well as the average integer time slice value (see note), the high and low integer values and the positive and negative values used to draw the derived waveforms according to Figure 4.15:

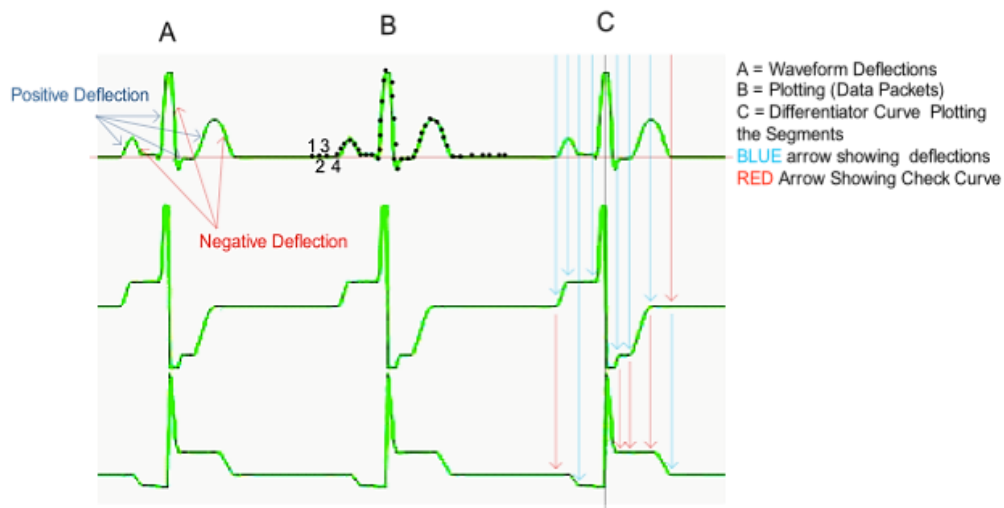


Figure 4.15 : Standard ECG and Derived Waveforms



Note: although a set scan frequency is used, section 4.4, the measured time slice is used as a check value and pulse calculation.

The waveforms above show a standard ECG graph as well as the derived graph or trace computed by subtracting the sequential data integer values and summing the positive and negative values respectively. A positive value refers to an upward curve of deflection and a negative a downward curve; no reference to the 127 null line is made in calculating the upwards and downwards slopes of the curve.

$$df = ABS[n - (n + 1)]$$

**df** = Derivative Value

ABS = Absolute Value

Equation 11: Differential Value (df) Calculation

The derivative value allows for the elimination of any drift as well as allowing for the deflection values of the integer or wave packet feeds to be more easily isolated and detected.

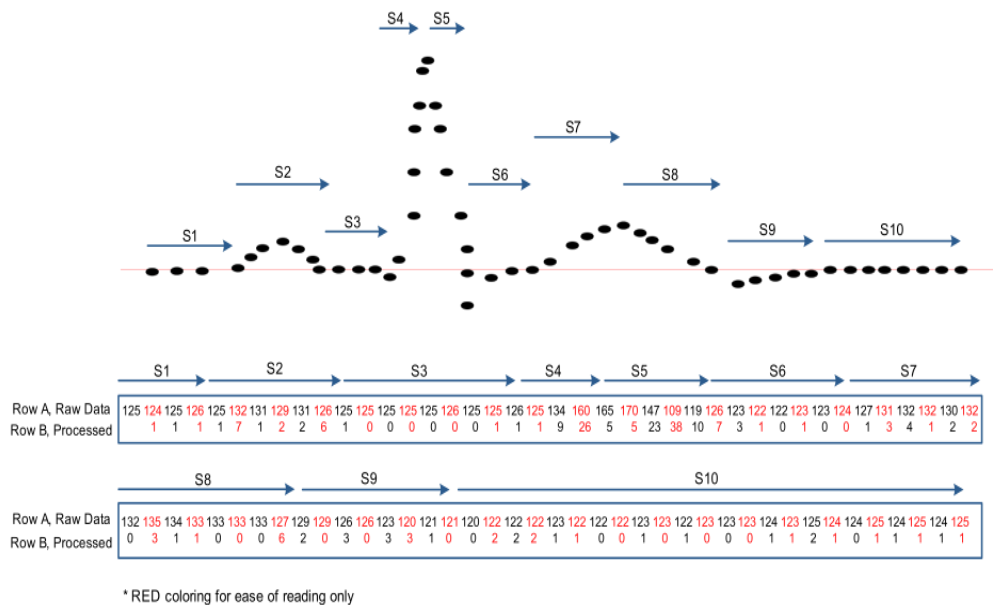


Figure 4.16 : The Differentiator in Action

Figure 4.16 shows two rows of integer data namely row “A” presenting the raw unprocessed integer waveform data as supplied directly from the acquisition output (Figure 4.16) and row “B” the processed data or differentiator output. Analysing the two data sets the advantage of the differentiator is clear, waveform deflections are easily distinguishable as the rate of change is much higher than in the standard sequential feed; zero and one values show little change where higher values indicate deflection or deviation from the x axes. The technique is effective even if baseline drift (Figure 4.17) is present in the waveform as the reference value used, namely the previous bit, is dynamic and not a pre-set static zero point thus naturally adapting and compensating for any drift offsets. The impact and value that the **df** number has on the ECG analysis process is show in the next challenge associated with ECG modelling namely ECG tagging or wave pattern segmentation (see Section 4.1).



Figure 4.17 : ECG Baseline Drift caused by a Pulmonary Embolism

#### 4.5.4 ECG Tagging

(Class Label 37, Figure 4.14)

The various identifiers or markers discussed in Chapter 4 are all required to effectively quantify the clinical parameters to be extracted from the ECG wave pattern. The timing intervals such as the PR, ST and QT (Figure 4.13) markers can only be calculated if the start / stop sections of the segments can be pinned. The challenge lies in the near real time processing of these parameters without relying on buffered and averaging information that not only results in delayed parameters but limits the possibilities and visual warnings that can be built into the output parameters (signal injection). The main components of the tagging algorithm designed for this study consist of an enumeration defining the tags combined with the beat-to-beat storage of the cyclical current tag value. Figure 4.18 shows an abstracted view of the tagging logic as well as the enumeration used to tag and store the ECG segment identifiers. The tagging or segment identification process, along with the **df** threshold check method also includes a secondary check to eliminating false positive results. For this purpose, a packet counter variable is used that keeps track of the waveform packet quantities measured from QRS to QRS cycle (RR Interval, see Figure 5.3); the packet counter resets on the RR interval or natural dynamic heart rate of the patient in contrast to the constant the sampling rates on the ECG acquisition hardware (100 – 300 samples per second, user adjustable). Considering the average timing intervals and pacemaker of the human heart (Figure 2.1), the packet counter ratio can thus be incorporated into the calculation process shown in Figure 4.18.

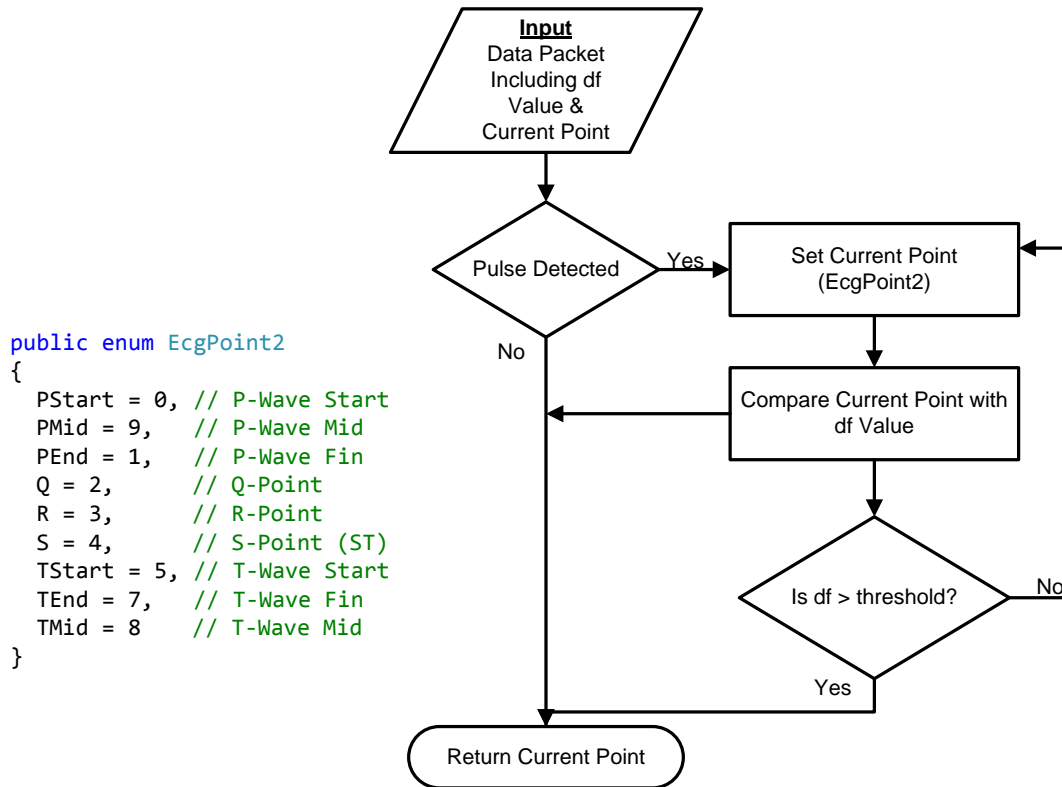


Figure 4.18 : ECG Tagging Process

Considering Figure 4.18 a table or rule set can be compiled for standard or normal heart rate timing intervals based on the sample frequency and packet magnitude:

Parameter	Duration	Sample Rate	Expected Packets
P-Wave	90 - 120 msec	100 Hz -> 10 msec	9 - 12
QRS Complex	60 - 100 msec	100 Hz -> 10 msec	60 - 100
PR Interval	120 - 200 msec	100 Hz -> 10 msec	12 - 20
T-Wave	190 - 210 msec	100 Hz -> 10 msec	20 - 22
QT Interval	320 - 480 msec	100 Hz -> 10 msec	32 - 48

Table 7: Packer Counter / Quantity Rule set

## 4.5.5 Process Summary

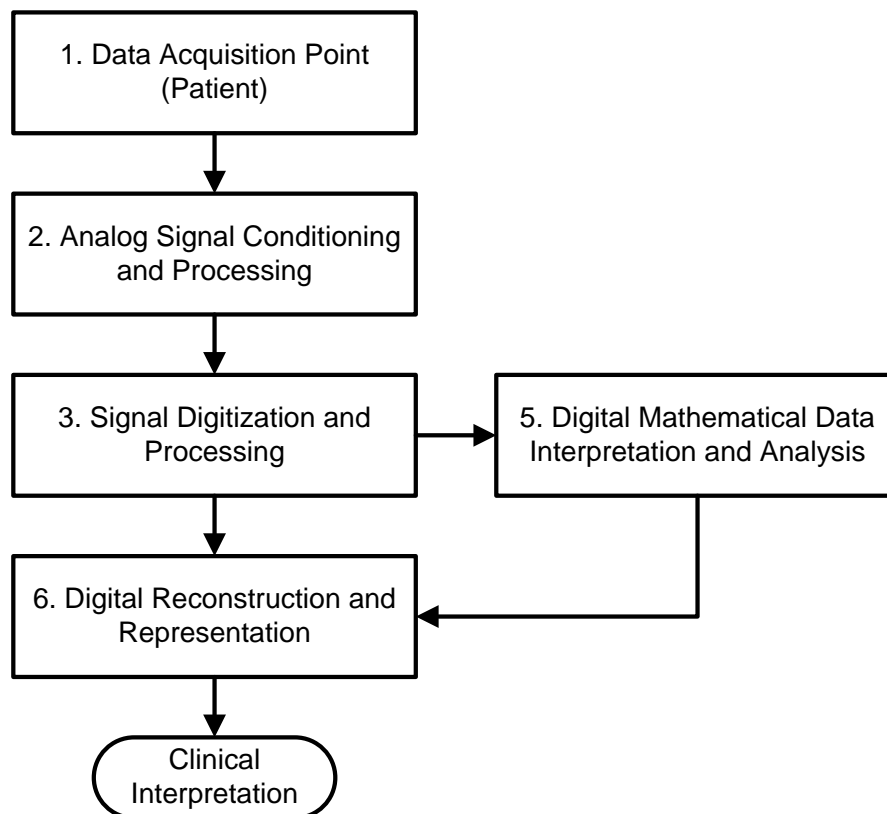


Figure 4.19 : Process Summary

Figure 4.19 shows the typical application of the ECG Analyser algorithm; block number 5 forms the core of this implementation where the mathematical timing model is implemented as well as the detection and colour output calculated. Figure 4.20 shows a logical breakdown of the object structure as well as an abstract of the basic functionality and calculations built into the shown objects. It is important to note that the core of the mapping, processing and analytical calculations is based on the *df* value and in the manner in which this indicator is used to isolate waveform morphology. The second point that classifies the approach as unique is the injection of the colour component back into the draw stream with little to no time lap; this enables the colour coding to be presented in what the user will perceive as real time showing the selected focus area or clinical deviation from normal trace values.

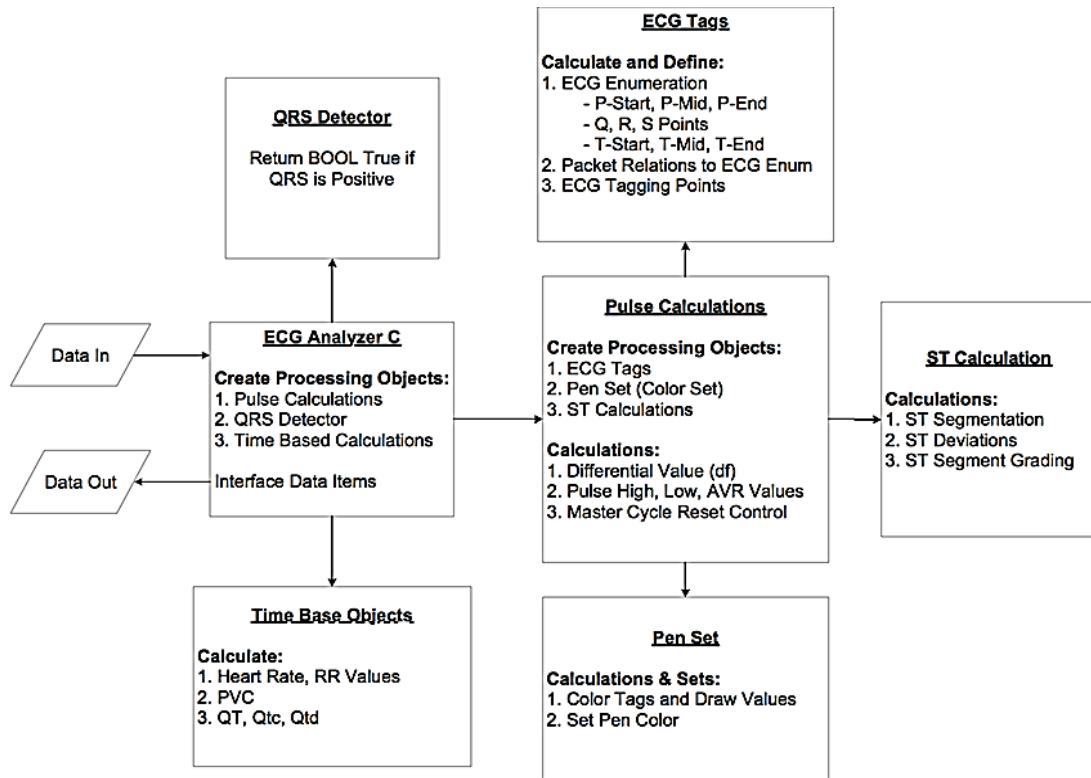


Figure 4.20 : ECG Analyser Class Layouts

## 4.6 Real-time Mapping and the Visual Elements

Building and achieving a stable near-real time analysis system can address some of the many challenges faced in the medical monitoring domain today. Technology groups in commercial environments are indeed separated by the effectiveness by which data and information can be displayed and manipulated; consider the mobile platform wars between Apple Mackintosh, Microsoft and the Google Android platforms. In the medical field the challenge is magnified due to the sheer amount of complex data that has to be presented, monitored and interpreted accurately by the ever time poor clinical caregiver.

The challenge is clear, how to present a traditional clinical parameter in such a way that the user can almost effortlessly extract and understand the unspoken data in the presentation.

The common ECG trace is by no means exempted and without effective techniques focusing on real time processing and manipulation, the hidden data within the bio-signals are often overlooked.

Please allow for a comment on real time processing to avoid confusion; all patient monitors display real-time data traces along with traditional mapping and segmentation techniques that are available. As stated earlier the processing is usually achieved with buffered data sets eliminating many indicators and visual enhancement options and possibilities. The human body's **hemodynamic** functions are as the name indicates dynamic by nature, a value calculated over as little as 5 beats in the past is dead and out-of-date data compared with the now value.

Figure 4.21 shows some of the feeds that are derived through this study made possible by using the data processing components developed and highlights some of the visual possibilities through presentation signal injection:

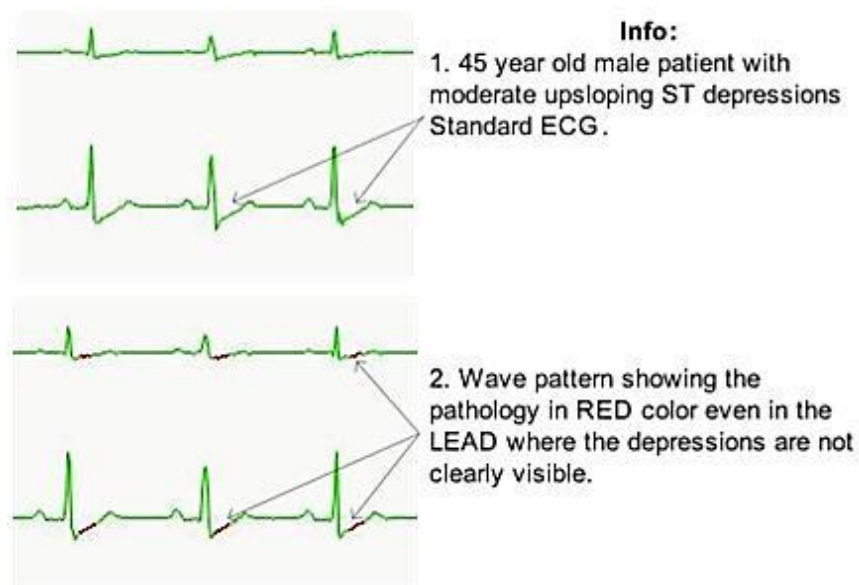


Figure 4.21 : The Algorithm in Action

As can be seen from the Figure 4.21 above, the trace where the ECG Analyser is applied to an abnormality is identifiable with no or little understanding of electro cardiac pathology by simply observing the colour indicators.

#### 4.7 SPO2 Pulse as Secondary Validator

The monitoring of real time data poses many obstacles for the data processing and analysis processes, false positive QRS detections and the

derived heart rate can cause inaccurate readings. Unstable or inconsistent alarm detection in a real world situation often leads to the desensitization in the response of clinical staff to electronic alerts; it has been estimated that ICU type false positive alarms can be as high as 86% (Clifford, 2006). To assure accurate detection of the heart rate QRS peaks, the FA algorithm developed at MIT was adapted to reference the SPO pulse rate as to the proposed IBP heart rate derivative. This is as the secondary validator and included within the processing cycle as an indicator to flag false positive detections. In addition to the SPO2 Pulse value the saturation or Pleth graph can be used to validate arrhythmia or irregular rhythms as shown in section 2.5; the attributes as mentioned and used within the analysis cycle in essence functions as feedback loops within the process to produce internal validation and assist in the stabilization of the algorithm as a whole.

The second validator is not required for the algorithm to be successful but as is the case with most critical care patient monitoring sessions, multi parameters are the norm; the algorithm automatically adapts to include a second pulse validator if the values are available.



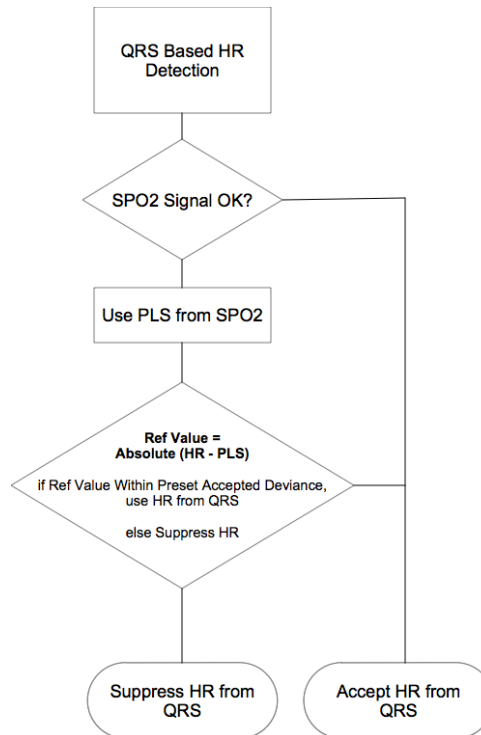


Figure 4.22 : Algorithm in Action (Modified FA)

As can be observed from the block diagram above the referenced or second pulse indicator is used to suppress false positive QRS peaks and not as an absolute indicator.



Figure 4. 23 : False Positive QRS

The false QRS values as shown will not be detected by a SPO2 components for the electrical pulse on the ECG will not manifest as a mechanical cardiac contraction as what is measured and indicated on the SPO2 Plethmograph (ref section 2.5).

### 4.8 Partial Sum as Signal Filter

The stability of the ECG waveform can be influenced by many factors including EMG or muscle contractions mainly caused by the patient moving or coughing, electrode placement, secondary equipment used like dialysis units or simply natural unstable electrical activity in the cardiac cycle. It is important for waveform or sample rejection to be built into the system and the algorithm in order to eliminate false readings and drifting averages; Figure 4.23 is an excellent example of an ECG waveform where random PVCs are shown. If the PVC values are included in the measurement the variations in the signal will cause inaccurate calculations and as such markers and ultimately arrhythmia calcification.

In order to eliminate artificial or external artefacts to be included in the calculations the partial sum of the positive and negative  $df$  value graph is calculated (middle graph shown in Figure 4.24):

$$S_k = \sum_{t=1}^k a_t$$

Where  $S_1 = a_1$ ,  $S_2 = a_1 + a_2$ ,  $S_3 = a_1 + a_2 + a_3...$

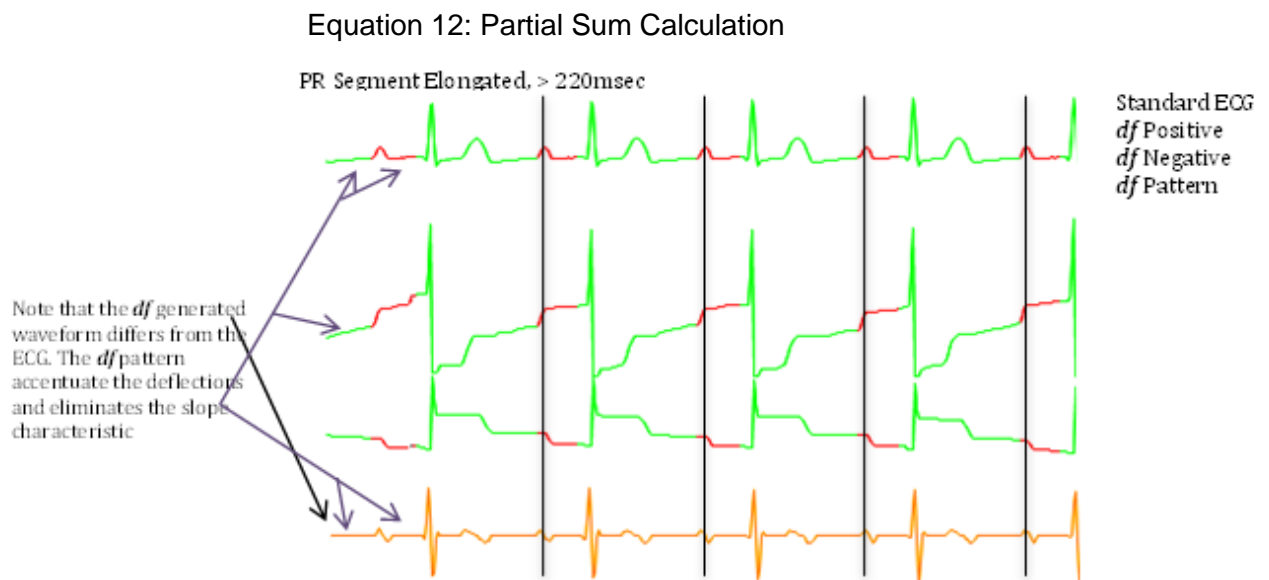


Figure 4. 24 : Partial Sum Waveform

## 4.9 The Modelling Elements and Examples

The successful segmentation and classification of the ECG waveform opens the book on several clinical possibilities; by studying the morphology of known cardiac arrhythmias it becomes apparent that patterns based on the segmentation timing intervals correlate as early warning indicators.

For the purposes of this study the more common cardiac arrhythmic myocardial ischemia forms the focal point of the experimentation and by compiling and allocating weighted values to the identifiable anomalies a predictive index can be derived that may act as an early warning system for cardiac arrest. Table 7 shows the primary indicators, their associated pathology and weighted value allocations. Please note that the weight allocations are used as part of the overall algorithm and do not necessarily reflect or indicate any clinical significance. As an example please consider the code section below:

```

public void StDepElv(int[] stStartValue)
{
    if (PrSTTemp > StDetBorder)
    {
        STDetectorCounter++;
        if (STDetectorCounter > 3)
        {
            STDetectorCounter = 3;
            StDepDetected = true;
        }
    }
    else
    {
        STDetectorCounter--;
        if (STDetectorCounter < (-1))
        {
            STDetectorCounter = -1;
            StDepDetected = false;
        }
    }
}

if (StDepDetected)
{
    if ((PrSTTemp < 8) && (PrSTTemp > 3))
    {
        _ST_Clasification = "Mild";
        _ST_Lenth = 15;
    }
    if ((PrSTTemp < 12) && (PrSTTemp > 7))
    {
        _ST_Clasification = "Moderate";
        _ST_Lenth = 19;
    }
    if (PrSTTemp > 14)
    {
        _ST_Clasification = "Severe";
        _ST_Lenth = 20;
    }
}
else
{
    _ST_Lenth = 5;
    _ST_Clasification = "None";
}
}

```

Figure 4.25 : ST Classification Sample Code

The method is passed an array of ST Segment Start Values derived from the standard 5 LEAD ECG Pattern (ref section 2.1). These values are compared with various other ECG segment points and the weighted values logically assessed as allocated in Table 7; the right side in the example shows the

classification and probability of progression for the ST segment morphology. By applying the same technique but limiting the measurement window to the P and QR segment start positions, an accurate time interval can be calculated and used to express P-Wave drift on the x- axes of the plotted ECG waveform. This indicates a clear Atrioventricular or AV Block; the accurate measurement is made possible by the accuracy of the segmentation process developed combined with the first derivative *df* value (see Section 6.1).

No	Element	Measurement Scope	Weight	Associated Pathology	Check Parameter	Output
1	ST I	+ - 2mm above/below	2	Myocardial Ischemia	<ul style="list-style-type: none"> <li>- ST Segments</li> <li>- Heart Rate (RR)</li> <li>- QT</li> <li>- QTc</li> <li>- ST Duration (ms)</li> </ul>	<ul style="list-style-type: none"> <li>- Mild</li> <li>- Moderate</li> <li>- Severe</li> </ul>
2	ST II	+ - 2mm above/below	3			
3	ST III	+ - 2mm above/below	1			
4	ST aVR	+ - 1mm above/below	0			
5	ST aVL	+ - 2mm above/below	1			
6	ST aVF	+ - 2mm above/below	1			
7	ST C	+ - 2mm above/below	2			
8	RR	500 - 1350 msec		Brady, Tachycardia		
9	QT	Normal = 1 / 2 RR	1 - 3			
10	QTc	See Table Ref	1 - 3	Long QTc Syndrome		
11	PVC	Bool - Present Yes / No	1 - 3			
12	P-Wave A	Bool - Present Yes / No	1 - 3	AV Block, 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup>		
13	P-Wave B	Drift on X Axes	1 - 3			
<b>Table Ref - Normal QTc Interval</b>						
No	QTc (msec)	Male	Female			
1	Normal	< 430	< 450			
2	Borderline	431 - 450	450 - 470			
3	Prolonged	> 450	> 470			

Table 8: Measurable Elements used in the Computations

### 4.10 Summary

The model developed is atypical of the standard understanding of the term, there is no one correct way to express and classify in computational terms a process that is without its flaws and gaps. The segmentation differentiator combination as is shown in the following chapter has been proven to be stable and accurate but currently focused to MI type processing only. This however can be expanded in further work for the techniques developed in this study can also be applied in a template format:

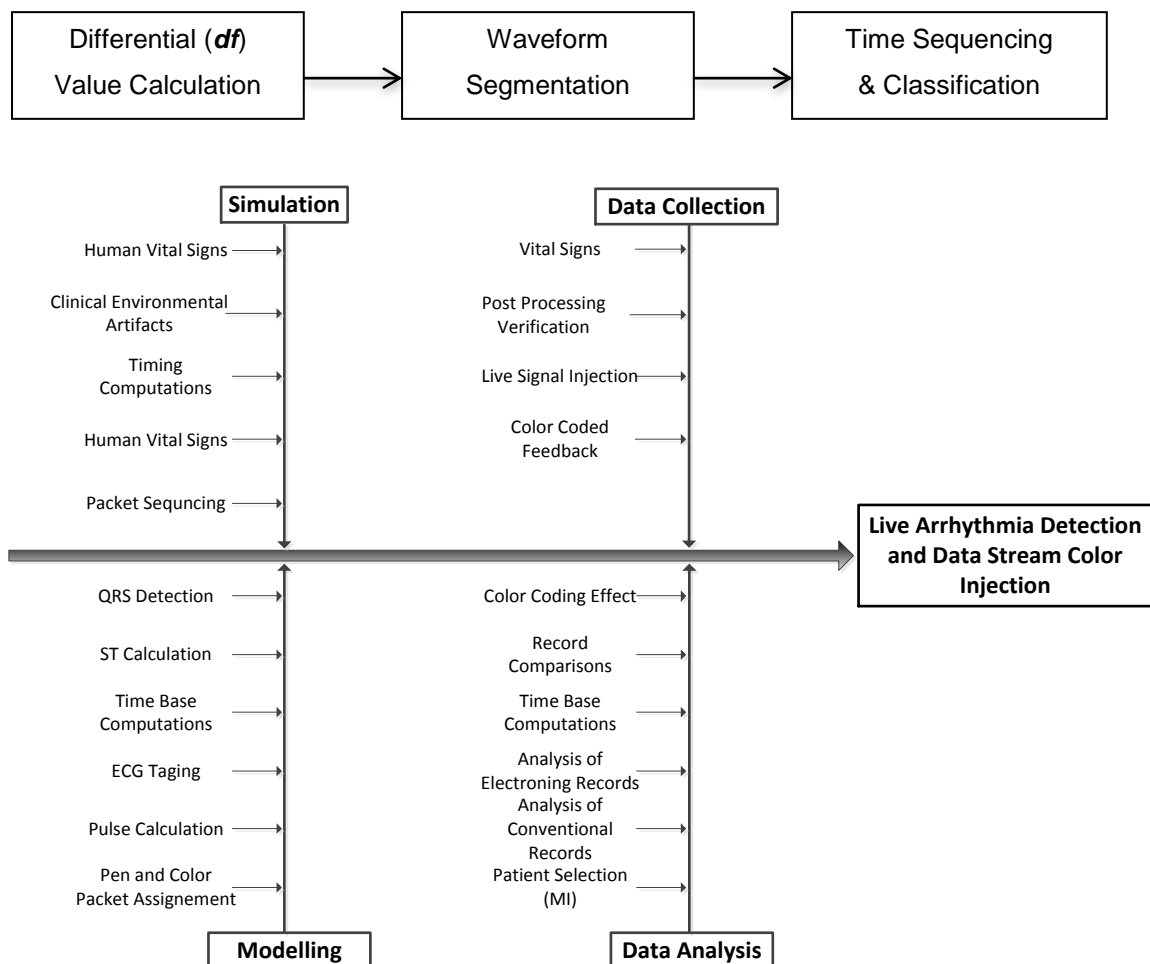


Figure 4.26 : Modelling and Data Analysis

Part of Figure 4.26 depicts the various aspects and their contributions in the development of the algorithm and its sub components, the modelling process

and sequence followed in developing the ECG Analyser. Included in the diagram is the data analysis phase presented in the following Chapter where results achieved in a clinical and experimental setting is presented and discussed.

Medical Informatics as the umbrella for the research focus on the advancement of knowledge through the application of information technology, computer science, engineering and medicine; a proverbial crossroads of the fields of study where the disciplines can complement one other. The model discussed and shown embodies this ideal as a culmination of the mentioned disciplines. An aim of the research as stated earlier is to provide the developer with a concept that can be incorporated into clinical technology development and be provided as a clinical toolset. Ultimately the field emerging as Medical Informatics assists the healthcare industry and caregiver to better the patient outcome; this can be in the format of improved recordkeeping and patient data management, inter disciplinary communication but also as shows in this study as clinical guides, measurement tools, analysers and indicators in the frontline of patient care.

The future of healthcare lies in the advancement of digital care and the further development of the digital tools used by the clinician in the direct diagnosis, assessment and treatment of the patient. In order to achieve this, the researcher is bound to prove that his hypothesis is based on sound science and that the modelling techniques employed deliver accurate and dependable results. It is thus imperative that Medical Informatics where deployed in direct patient care can never be seen as “a voodoo box” or “bag of tricks” but rather the pure application of tools and methods used in information technology, engineering and mathematics.

Today it is commonly accepted that the airline industry primarily utilizes automation in the cockpit and that the pilot is almost merely present as a safety catch; this paradigm shift is slowly being made in the practice of medicine as the clinician’s trust in technology and Medical Informatics is realized and brought to the frontline. The human mind cannot be replaced...as yet... and it is an on-going debate if technology will ever be able

to render our brains void and absolute. Medicine can be seen as one of the final frontiers where the acceptance of automated analysis has to be implemented and widely accepted; the research presented here strives to contribute to this shift by providing proof of the overall potential of Medical Informatics.

## CHAPTER 5 EXPERIMENTATION, RESULTS AND FINDINGS

In this Chapter the comparative data of the research is shown; as an introduction a short case study is discussed highlighting the data collection and measurement methods used. The aim being to demonstrate the analogue predicate measurement method compared to the real time monitoring approach. Following the case study a result table is presented with twenty-four selected patients primarily diagnosed with myocardial ischemia ranging in classification from mild to severe. For every case the calculated rating and indicators are shown, results from the algorithmic calculations as well as the clinical diagnosis and treatment outcome according to measurement techniques employed. Comments on the impact and accuracy of the live signal injection into the waveform patterns and highlighted morphologies are also presented in comparison with a traditional 12 lead ECG.

Please note that the ages of the test patients were not taken into account because the algorithm and measurement techniques were designed to be universal and self-adaptive, statistical deviations and corrective measures brought on by age related biological deterioration were nor added to any of the computational methods.

**Note:** Patient confidentiality is applied through alias names and record numbers as mentioned in section 1.4.



## 5.1 A Short Case Study and Measurements

In order to build a standardized and constant dataset for the study the data was collected and processed systematically using the following method:

1. All cases presented are from patients who suffered cardiac arrest (CODE BLUE) as hospital in-patients
2. Following the code a recovery period of one to three hours was allowed based on patient access so as to not interfere with the clinical treatment; this “rest” period allowed the patient to stabilize and biological reactions to drugs to normalize.
3. Measurements were taken in two formats
  - A standardized 12 lead ECG, specifications included in Appendix C
  - A 120 second electronic recording using a standard critical care monitor, specifications included in Appendix C
4. The electronic recording was “replayed” or reviewed using a software tool developed that included the ECG Analyser component.
5. Results were then recording, analysed and compared.

It is important to note that the ECG analyser is modelled and developed to present the same measurement results as is shown on the standard 12 lead ECG but as live data as to the post processed data traditionally used in both monitoring and standard 12 lead ECG graphs. The ECG analyser component and measurement techniques developed are meant to form part, or to be included as a software component, in a critical care patient monitoring system thus eliminating the need for the standard analogue 12 lead ECG usually deployed to accurately measure the advanced ECG related parameters as discussed in Chapter 2. Effective ECG segmentation in the real time domain lies at the heart of the research and as such the readings, measurements and calculations must be reasonably comparable to the traditional analogue measurement outcomes. The segmentation and logical sub sections of the electro cardio cycle represent the various physiological phases of the mechanical function of the heart and together with the timing derivatives such

as the QT and QTd intervals forms the basis references used in clinical diagnostic morphological deviation.

The following case study is presented to familiarize the reader with the logical approach taken to prove the accuracy and effectiveness of the digital real time model, the focus is not on the clinical content but on the measurement and results methodology deployed.

### 5.1.1 Case Study

Figure 5.1 below shows the 12 lead ECG of an 85-year-old male patient suffering from coronary artery disease admitted to the hospital emergency room on the 9<sup>th</sup> of May 2008 complaining from shortness of breath and chest pain extending to the left arm, a typical indication of myocardial infraction. The initial rhythm was classified as sinus bradycardia with moderate ST depressions.

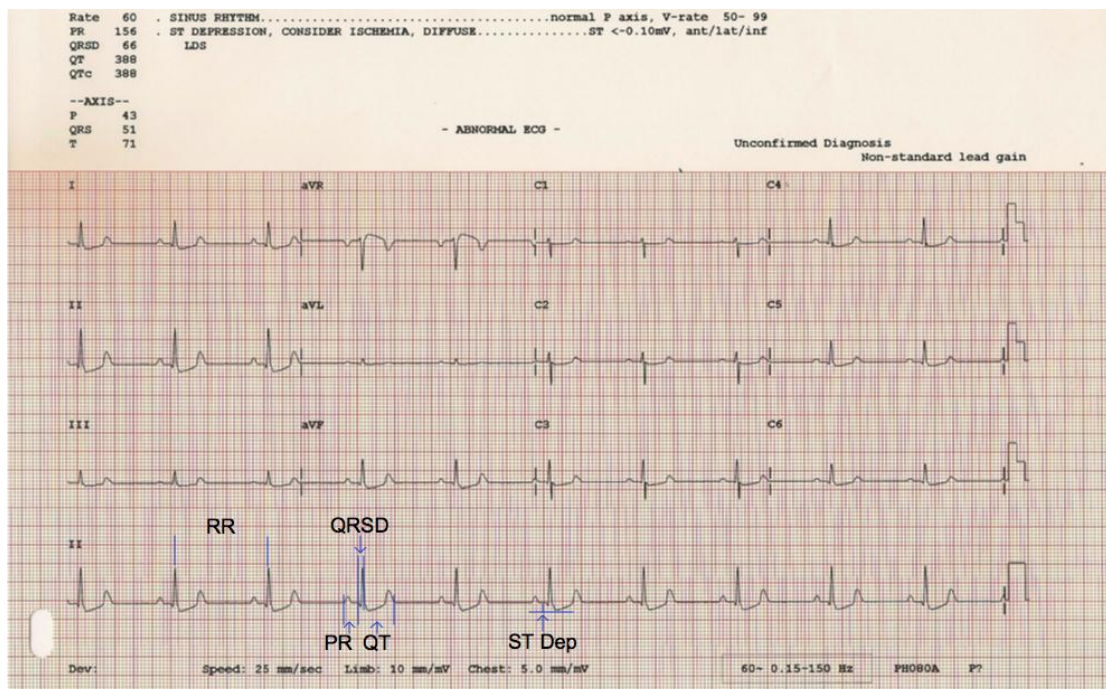


Figure 5.1 : Myocardial Infraction

Measurements taken using analogue methods on the diagnostic ECG graph as is shown in Figure 5.1 and summarized below:

- Heart Rate : 61 (ref section 5.2.1)
- ST on lead II : -0.2 mV (ref section 5.2.2)
- QT interval : 388 msec (ref section 5.2.3)
- PR Interval : 156 msec (ref section 5.2.5)
- PVC Count, if any : *Not Applicable in this case*
- QRSD Interval : 66 msec (ref section 5.2.6)

Table 9 shows the results of the 120 sec electronic recording for the patient with the same data parameters, as those measured in the 12 lead ECG graph, noted in the following format:

<b>Date of Code Blue</b>	May 9, 2008	
<b>MR# / ID</b>	24 3/31	
<b>Gender</b>	M	
<b>Year of Birth</b>	1926	
<b>Time of Arrest</b>	03:43 PM	
<b>Time of Recording</b>		
<b>Location</b>	ER	
<b>Initial Rhythm</b>	Sinus Bradycardia	
<b>Defibrillation Attempt</b>	No	
<b>Ventilation</b>	Yes	
<b>Intubation</b>	Intubation	
<b>Measurements</b>	ECG AN	12 Lead
<b>Heart Rate (bpm)</b>	59.88	61
<b>ST on Lead II (mV)</b>	N 0.21	N 0.2
<b>QT (msec)</b>	378	388
<b>QTc (msec)</b>	378	388
<b>QTc AVR (msec)</b>	--	--
<b>PR (msec)</b>	147	156
<b>PVC</b>	0	0
<b>QRSD (msec)</b>	72	66
<b>Outcome</b>	Survival	
<b>Documentation</b>	Yes	
<b>ACLS Protocol</b>	Yes	
<b>Pathology</b>	Aspiration	
<b>Code Called By</b>	RN	

Table 9: Recorded Data - Summary

As discussed in section 3.1 the defining factor of any research lays within the quality of the data, the storage of that data and the eventual reconstruction of the datasets to accurately represent the original measurements and readings.

The electronic data processing was achieved by digitization, storage and reconstruction as is shown in Figure 5.2 below:

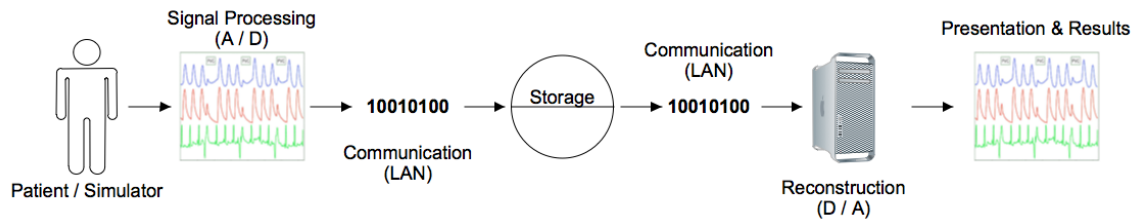


Figure 5.2 : Data Capturing and Reproduction

As can be seen in the DIFF column (Table 9) the electronic live monitoring values differ little from the manually measured parameter values and as such prove the accuracy of the real time processing; it is important to note that, with the average sampling rate of 100 Hz, a 10 msec slice constitutes one byte of data and as such is negligible in clinical terms and thus an acceptable tolerance (see section 4.4).

The clinically important parameters in the study are the data markers used to prove the hypothesis that a live monitoring and signal injection indicator is possible, accurate and in many respects superior to the current toolsets used based on buffered post processing techniques and methodologies. The results and findings especially that of the signal colour injection, have a profound effect on emergency and critical cardiac care allowing for the non-specialist to observe and identify technical cardiac deviations; an early warning indicator as. The latter concept however fell somewhat outside the bounds of the study but is wide open though for the subject to be further explored.

## 5.2 Results and Findings

In this section numerical data is presented showing the manually measured versus electronic derived values. It is important to note that the significance of the electronic method lies with the fact that the data is calculated on a byte-by-byte and beat-to-beat basis and is thus available to the user in the real

time domain. The data shows the effectiveness of the ECG segmentation and measurement techniques in comparison to the analogue measured values derived from the ECG graph in a side-by-side tabular format, values presented include (ref chapter 2):

1. Heart Rate measured in beats per minute (bpm)
2. Absolute ST value measured in mV on LEAD II
3. QT interval in msec
4. Calculated QTc measured in msec (ref Chapter 2 & 3)
5. PR Interval measured in msec
6. QRSD interval measured in msec

**Note:** Data, graphs and electronic measurement referenced are presented in Appendix C.

### 5.2.1 Heart Rate

The beat-to-beat contraction cardiac cycle or heart rate is the primary measurement or parameter used in patient monitoring and indicates a distressed condition (high rate) or an ineffective, inadequate pumping action observed as bradycardia or low heart rate (<55). Patients suffering from MIS where coronary arteries are obstructed limiting oxygen supply to the cardiac muscle usually manifest a Brady rhythm with complaints of shortage of breath. Heart rate is usually expressed in beats-per-minute but for measurement purposes the timing interval between successive QRS peaks are measured in msec and expressed as the RR rate as is shown in Figure 5.3:

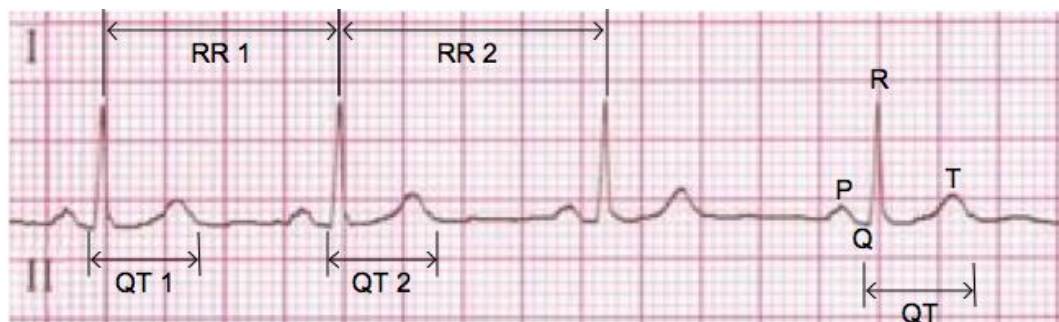


Figure 5.3 : RR Interval

The heart rate is electronically derived from the RR value measured in msec; as indicated on the Graph 1 the manual and electronic values differ little indicating that QRS detection is accurate.

The beat-to-beat calculation of the heart rate based on RR value proved to be responsive and changes in heart rate were detected in much shorter time spans. The drawback of this method though, from a clinical point of view, is that the RR rate is not consistent from beat-to-beat and without employing averaging the readout can be confusing if the heart rate is not constant or consistent over short intervals. This however has little significance because the purpose of the measurement technique is to achieve accurate beat-to-beat segmentation and secondary cardiac values difficult to measure.

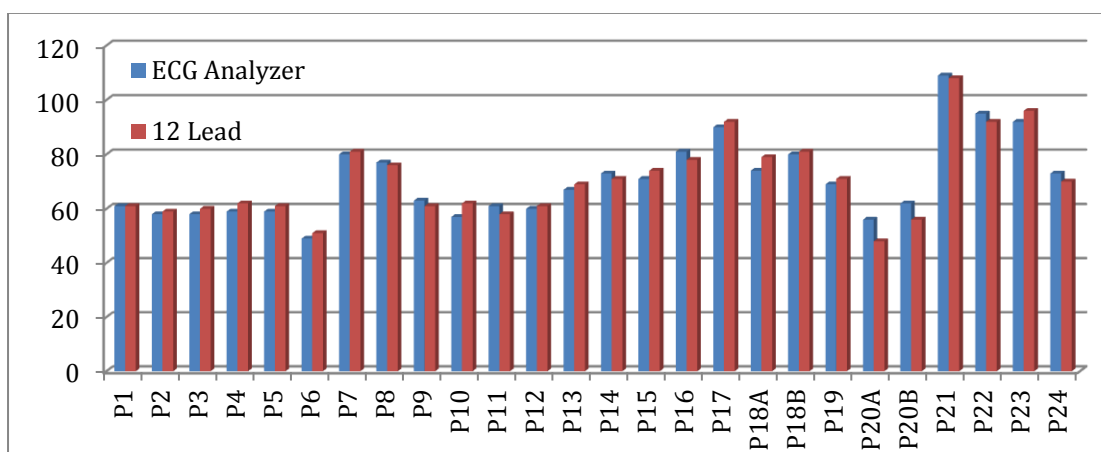


Figure 5.4 : Heart Rate, bpm per Patient

### 5.2.2 ST Segment – Absolute

ST segmentation is the definitive measurement and parameter used to diagnose myocardial ischemia usually caused by the obstruction of oxygenated blood to the heart muscles manifested as a depression in the ST segment following the QRS peak (Antman, 1999). An ST depression of at least 1mm indicated reversible ischemia with a depression of greater than 2mm usually depicting an irreversible ischemic condition (Yap, 2005). The depression shows a deviation in the repolarization or recovery phase of the

heart and ECG cycle thus limiting the effectiveness of the cardiac output as is shown in Figure 5.5 below:



Figure 5.5 : ST Segmentation Depression

For purposes of this data presentation the **absolute** ST value is plotted as to the expected negative values usually seen in MI type cases and patients. The segmentation is proved accurate as the end of the ST segment, with the onset of the T-wave, is measured to be well within expected medical tolerances of plus minus 10% compared to the graph measurement. P6, P7 and P8 show the accuracy of the electronic measurement with values of 0.05 and 0.04; the small deviation could not be measured on the ECG paper plotted graph

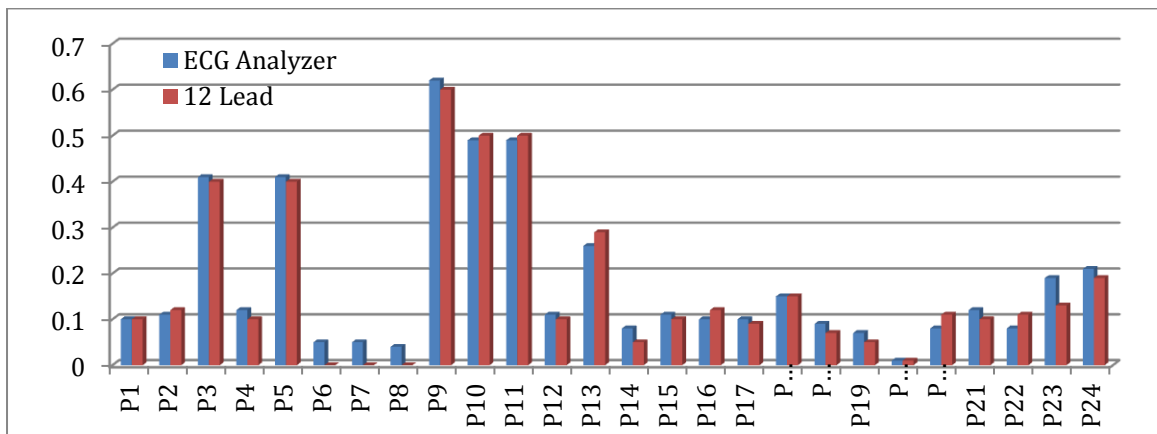


Figure 5.6 : Absolute ST Segment measured in mVolt

### 5.2.3 QT Interval

The QT interval as a base parameter is used to express various cardiac derived measurements (ref section 2.2) and as such is an important measurement to analyse. QT dispersion as a clinical marker is used to indicate post-myocardial infarction and congestive heart failure and basically shows an unstable rhythm brought on by damage that occurred in the natural pacemaker nodes and conductive system in the heart; it can also be caused by hypothyroidism or low function of the thyroid gland or acute hypercalcemia (elevated calcium level in the blood stream), (Wesson, 2009).



The accuracy of the ECG analyser measurement techniques is most prominently displayed in the QT measurement results; transition point from the end of the T wave to the resting phase on the ECG is at times difficult to accurately plot especially in post MI patients where the T wave can be inverted.

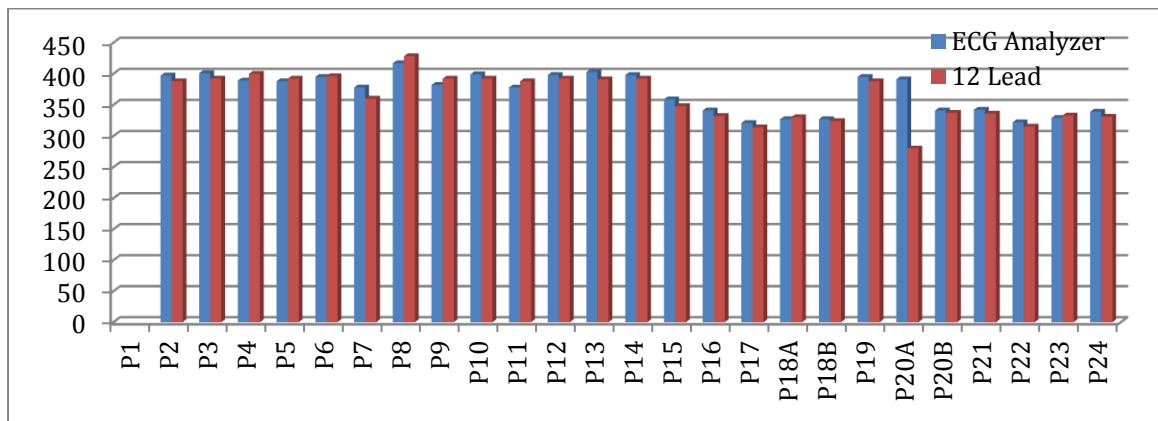


Figure 5.7 : QT Interval, measured in msec

The QT interval as presented in graph 5.7 is measured between the end of the PR interval and the end of the T-Wave. The accepted tolerance in the manual verses electronic measurement values indicate that the end of the P-wave and following PR segment, expressed as the Q-point, is correctly calculated and measured. The transition from T-wave that indicates the end of the depolarization of the ECG cycle, and the rest phase is measured accurately.

#### 5.2.4 QTc Value

The compensated QT or QTc value is gaining weight as an early indicator or warning marker for patients suffering from possible ventricular abnormalities and is especially effective in pre-diagnosed environments like the emergency room setting. Although the QTc is a calculated parameter in this research setting it is a supplemental indicator showing the accuracy of the real time measurement techniques. The QTc or corrected QT value is calculated using the Bazette formula (Bazette, 1920, ref section 2.2) and is the only non-explicitly measured value presented. The data though validates the correct

calculation and measurement of the QT and RR values, the two variables used in the Bazette formula:

$$QTc = \frac{QT}{\sqrt{RR}}$$

Table Ref - Normal QTc Interval Values			
No	QTc (msec)	Male	Female
1	Normal	< 430	< 450
2	Borderline	431 - 450	450 - 470
3	Prolonged	> 450	> 470

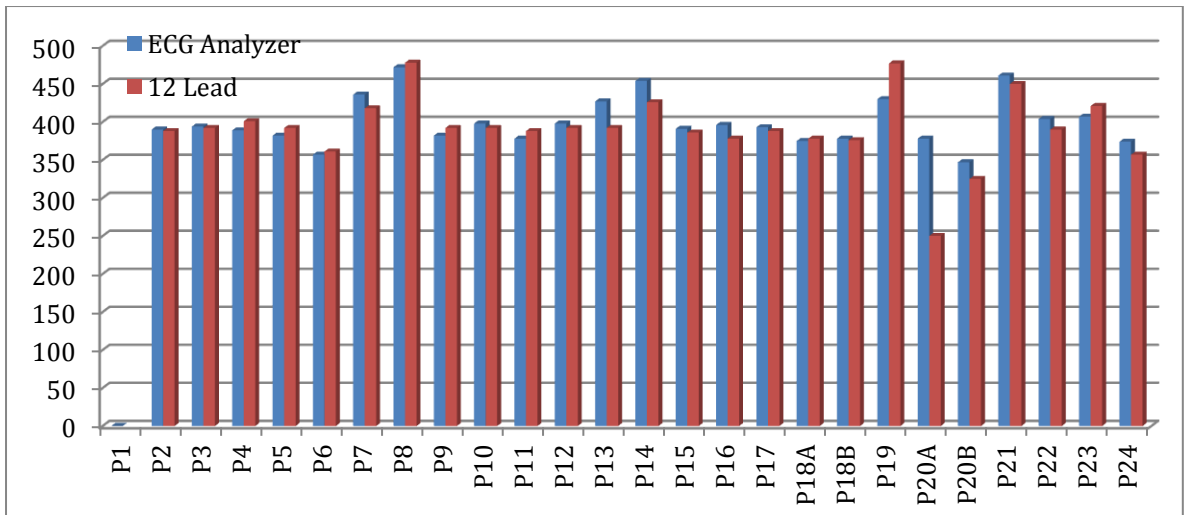


Figure 5.8 : QTc Value, measured in msec

5.2.5 PR Interval

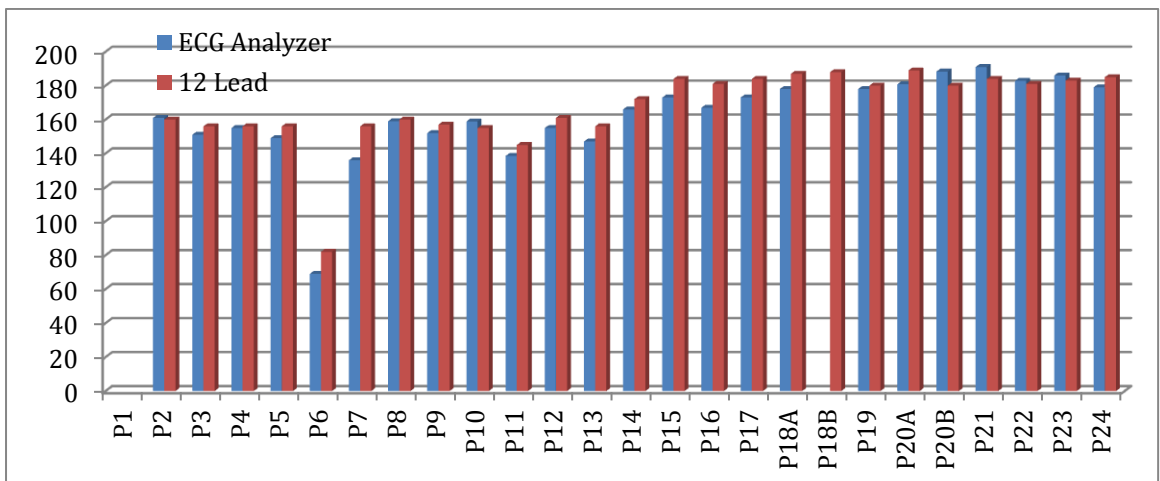


Figure 5.9 : PR Segment

The PR Interval that is measured from the onset of the P-Wave to the Q-Wave shows that the P-Wave detection is accurate and that the logical ECG waveform is segmented as per the natural pattern of the cardiac cycle (P-wave to end of T-Wave) as to the more conventional QRS point used in the post processing and analogue measurement techniques. Of the twenty-four test cases studied two patients showed P-Wave morphology; P06 showed an inverted P-wave prominent on LEAD II and LEAD III pointing to possible inferior injury and probable early acute infraction. The ECG of patient P8 manifested prolonged PR and QRS intervals pointing to right bundle branch block (RBBB) and/or Left Posterior fascicular Block (LPFB) diagnosis. A prolonged PR segment is in addition a good indicator for both pericarditis and arterial ischemia if measured relative to the baseline formed by the T-P segment (Jim, 2006).

In both cases however the segmentation was accurate indicating that dynamic auto adjustment is effective and the segmentation measurements and calculations consistent.

### 5.2.6 QRSD Interval

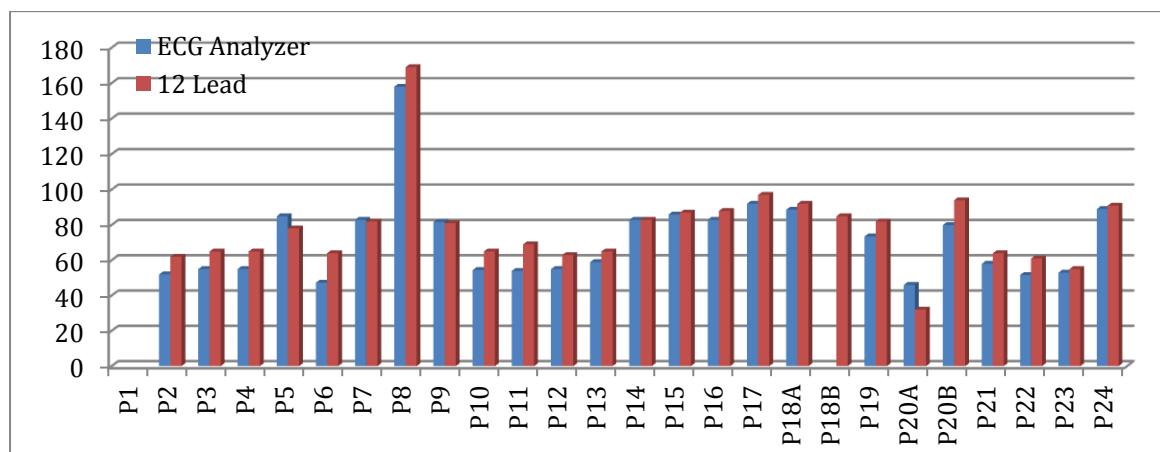


Figure 5.10 : QRSD Segment, measured in msec

The final graph shows the QRSD measurements and calculated values from the Q-Wave to the start of the ST segment representing the ventricular depolarization and intraventricular conduction time. The QRSD time interval is

a significant predictor for sudden cardiac death as an indicator for anterior myocardial infarction and as such is a vital parameter to be measured accurately (MacKenzie, 2005). On standard cardiac monitors the QRSD time is not often measured due to the sheer difficulty in accurately measuring the short time frame, QRSD in a normal cardiac rhythm is 0.4 to 0.6 msec (Yanowitz, 2010). As can be seen on the graph the QRSD measurements are considerably longer in patients diagnosed with myocardial ischemia; in the cases studied the segmentation technique proved to be accurate compared to the manual 12 LEAD measurements.

### **5.3 Observation Process**

Clinical based research in an active healthcare environment has various stakeholders or participants all contributing to the research whether active or inactive. The patient flow process followed for this research primarily depended on the cooperation between the healthcare providers namely the physicians, and nursing staff and the researcher. Patient screening and classification depended on the physician, diagnosis and prognosis, the main subject group selected for this study was myocardial ischemic patients with ECG and ST segmentation patterns typical to this condition. The main toolset in the diagnosis of cardiac conditions is the electrocardiogram and was used as the primary screening tool; ECG recordings or tests are conducted by nursing staff and results evaluated by the clinician. If a valid candidate for the study is identified the researcher would be informed and a second set of recordings made following a rest period to allow for the patient to stabilize and or adjust to medication and treatment. This second set of recording did not involve any clinical intervention from physicians with the only contributor at this stage being the nurse, responsible for recording the analogue ECG and the researcher duplicating the recording on the electronic patient monitoring platform together with the digital storage (Section 3.1 & 3.4).

## 5.4 Discussion

The human body is a dynamic analogue system with substantial inter-subject variability rendering a single formula based derivative for any specific measurement and relationship difficult to virtually impossible (Malik, 2002). The study by Dr. Malik into the relationship between the RR and QT intervals found that the two parameters are highly individual amongst test subjects. Malik showed that no mathematical formula can be found to describe the QT/RR relationship correctly and accurately in every person; a QT/RR relationship that is valid in one individual is not necessarily valid in another and that over and under correction in the QT interval and thus formula based derived QTc, to be unobtainable across subjects.

Malik's conclusion that no optimum heart rate formula permits accurate QTc comparison based measurements compliments the hypothesis of this study in that real time measurement combined with dynamic adjustable measurement techniques, to not only be accurate but clinically of more value, for the relationship measurements can be applied to the individual patient and not solely based on buffered averaged and comparative derived measurements. It is important to highlight that due to the bit-to-bit based design of the measurement techniques discussed in this study and the implementation and application of the *df* value (section 4.5.3), the algorithm dynamically responds and adjusts to the signal and as such bridges the restrictions of the formula based set implementations mentioned by Malik.

The measurement comparisons from section 5.2 clearly show that the real time electronic segmentation and measurements performs remarkably well with the manually measured graph based parameters used as benchmarks – analogue graph based measurements are not process driven but manually calculated for every individual patient or case. The accuracy of the waveform segmentation allows for the segmented data to be re-injected back into the presentation stream as is shown in Figure 5.11:

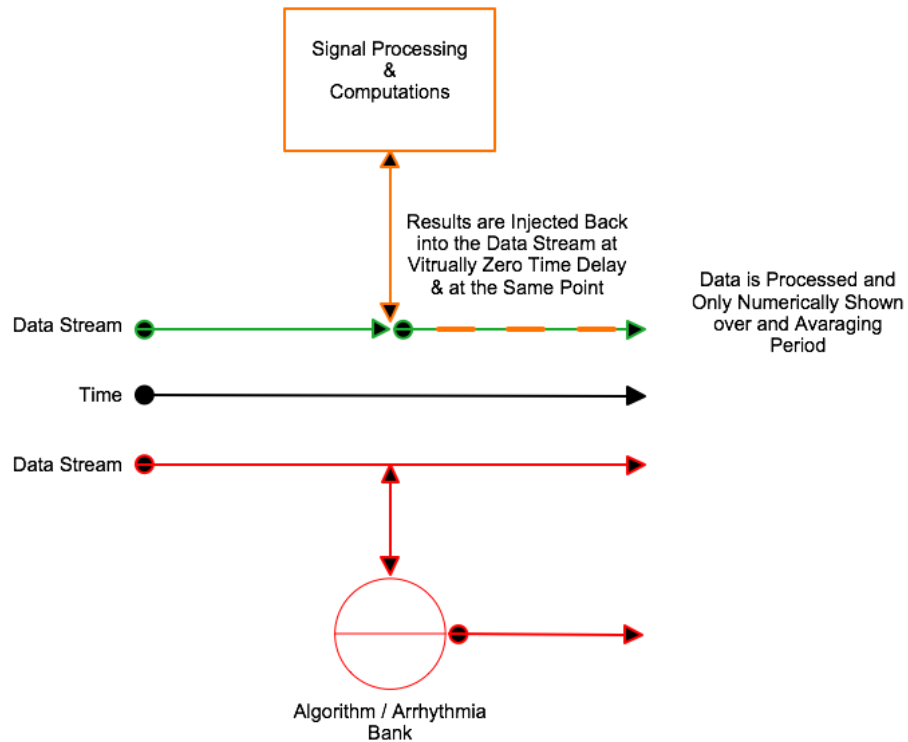


Figure 5.11 : Signal Injection

The signal injection back into the main data stream allows for the ECG segmentation to be visually presented in a unique manner hence allowing the clinician to identify difficult to detect arrhythmia morphologies especially in the presence of acute myocardial infraction as discussed in section 2.3 and 2.4. The relationship between patients with an elevated ST segment of greater than 1mm manifests a prolonged QTc interval in 100% of the test cases but the T-Wave morphologies, ST elevation and ST depression can only be visually identified in 7%, 15%, and 7% respectively with traditional methods (Kenigsberg, 2007). This is a significant finding when taken into context with the research presented here where the segmentation and signal reinjection was shown to be accurate even during clinical ST morphologies of up to an absolute value of 8mm deviation from the baseline. It is thus logical to conclude that the accuracy of the ECG segmentation technique developed and thus visual presentation through the signal injection method can greatly assist in the identification of visually complicated trace graphs. The signal injection allows for the ECG parameter waveform to visually show the segments as well as indicate morphologies in the waveform pattern. Figure

5.12 illustrate an ECG trace and associated derivatives generated by the analyser component of a detected prolonged PR segment typical of patients diagnosed with 1<sup>st</sup> degree block.

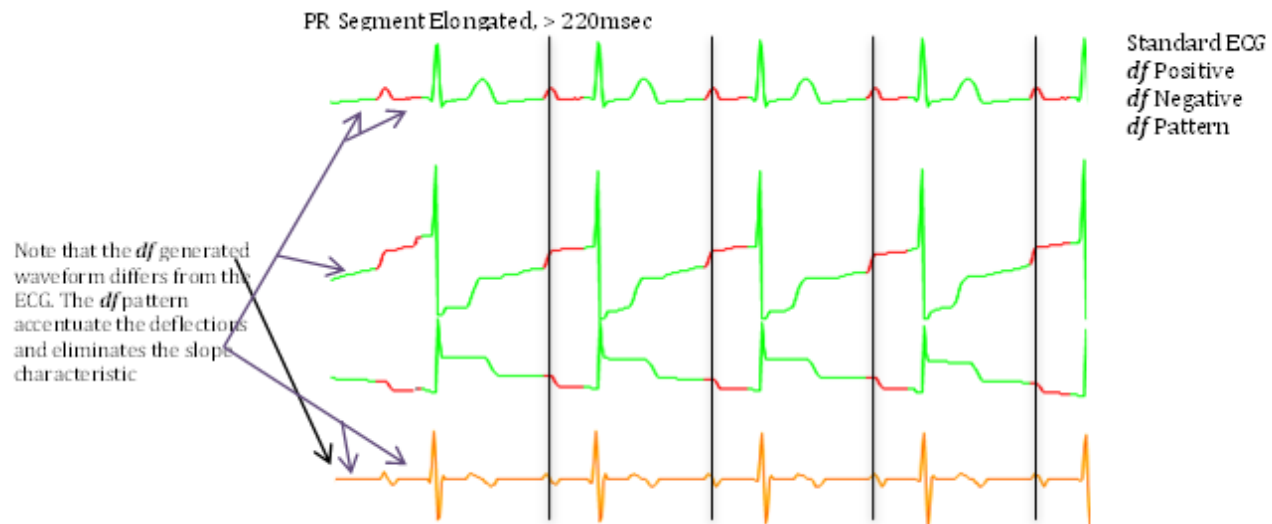


Figure 5. 12 : PR Segment Highlighting through Signal Injection

The segmentation and signal injection is dynamic and not patient and or age dependent as is typically expected and shown in section 2.2. Datasets and live recordings of 450 random patients was made as part of the study and analysed for the research validation; of the 450 cases evaluated 413 showed that segmentation and visualization techniques proved accurate, a 92% positive result.

Autonomic dysfunction as is typically seen in RR and QT interval variations can be associated with an increased risk of primary cardiac arrest among patients without clinically diagnosed heart disease (Whitsel, 2001). Results from the Whitsel study showed that the accurate measurement of an elevated heart rate, inverted T-waves, ST segment depression and Q waves combined with possible diabetes, elevated plasma glucose levels and a current smoking habit, form excellent markers or indicators for MI in non-clinically diseased hearts. The typical patient that might benefit from the inclusion of such markers in electronic measurement technologies and techniques is the patient that visits the hospital for non-cardiac, non-trauma related emergencies. With accurate segmentation on live monitors the mentioned markers can be detected and highlighted and thus brought to the attention of cardiac

specialists; these cases can typically be missed in standard ER diagnosis protocols. The traditional 12 lead ECG based on a 4 second measurements, the standard ECG device in the ER, does not provide adequate information to flag, in most cases, RR and QT variations (Whitsel, 2001). The predictive or warning flags that can be generated with the measurement techniques developed in this study can assist in addressing these shortcomings by providing the clinician with accurate and real time data.

The model proved to be effective in detecting abnormal rhythms where multiple PVC peaks or QRS pauses are present. This can be attributed to the derived waveform construct from the isolated positive and negative summed values (sections 4.2):

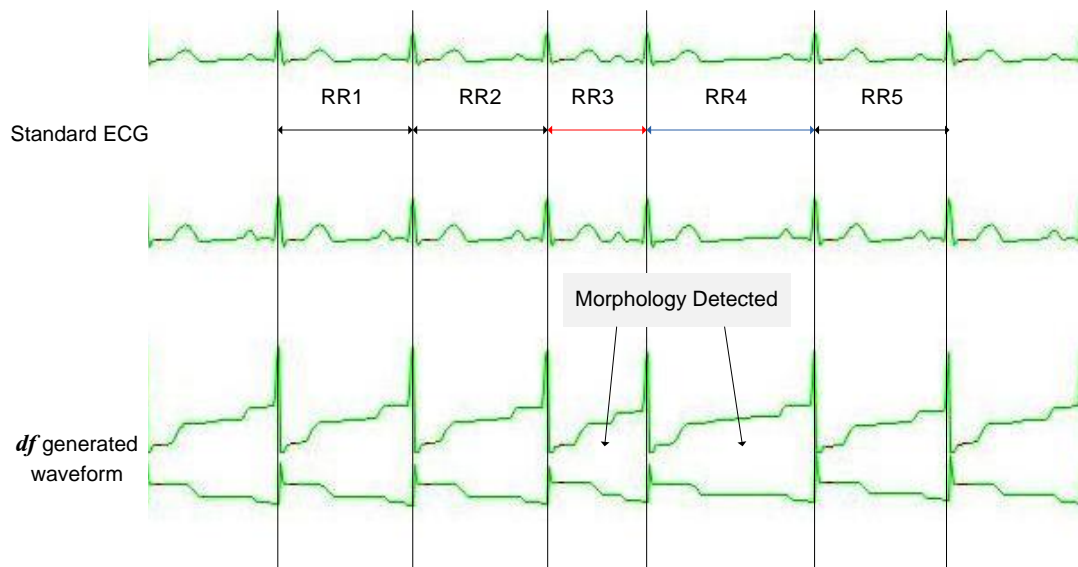


Figure 5.13 : Waveform Morphology Detection

It can thus be concluded from the case studies and presented data that the techniques developed are accurate and consistent within the study framework. The *df* calculated value and subsequent derived wave patterns show great promise as supplemental ECG data and has proved to be more clear and definitive in detecting and visually highlighting waveform morphologies compared traditionally applied methods (ref section 4.5.2).

Great strides are being made with the electronic modelling and analysis of the cardiac cycle and associated pathologies. A visual or rather virtual reality



toolkit developed at the Trinity College in collaboration with St James' Hospital approached the ECG diagnostic, presentation and segmentation or tagging, in a similar manner as is presented in this study. The focus of the Dublin study and toolkit developed was to present the cardiac activity in a volumetric based model and as a 3D output. The research has greatly contributed to especially the visualization component in a teaching capacity; the drawback as expressed by the researchers is that the 3D modelling is complex and real-time integration would be difficult (Rayan, 2004); this issue would be addressed however in future developments with the inclusion of analysis components that should add more clinical application to the system.

The work presented describe a new model for the analysis and interpretation of electrocardiography and clearly shows that the bit-by-bit analysis approach is both accurate and effective in measuring the various time intervals of the electro cardiac cycles, shows great potential as a segmentation modelling toolset and in the expression of cardiac anomalies and morphologies. The comparison between the analogue manual measurement and electronic measurements taken as output from the model validates the effectiveness of the real time approach and as such the model as it was developed.

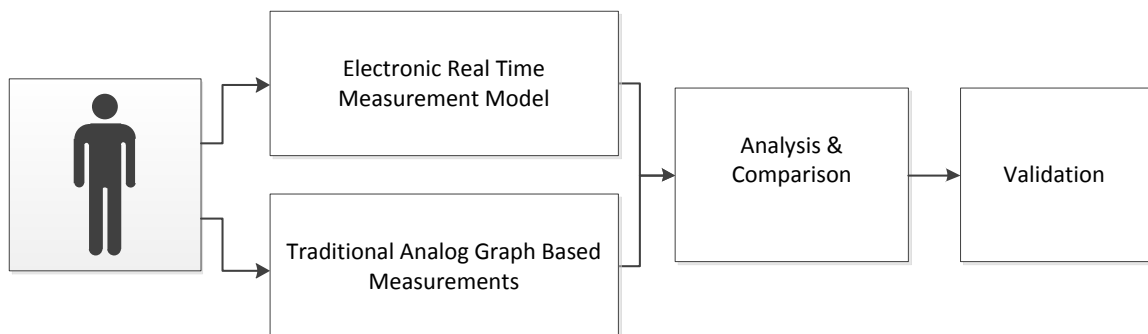


Figure 5. 14 : Model Validation

The hypothesis that real time ECG analysis, processing and anomaly detection is indeed possible was proved positive as presented in this Chapter. The research has shown that the model can be applied to real time data and has scope for application in a real world clinical application. The real time analysis model is not perfect but it is a step in the right direction of

streamlining the analysis processes and measurement methodologies as is specifically used in the critical care patient monitoring domain by excluding the dependency on short term historical averaging.

### 5.3.1 Shortcomings and Deficiencies

The major waveform morphology that negatively influences monitoring is an arterial flutter that occurs in the atria of the heart, the flutter which is associated with tachycardia is shown in the ECG strip below as the multiple positive sinus waves in between the QRS peaks. As can be seen for Figure 5.14 a clear P-Wave cannot be isolated resulting in the algorithm rejecting the data as a clear ECG start point cannot be pinned.



Figure 5.15 : Arterial Flutter

A second deficiency in the algorithm was noted for patients with a RR interval of less than 550 msec (heart rate greater than 110 beats per minute) classified as clinical tachycardia. This can be attributed due to the 100Hz time slice or 10 msec window of the data packets; the data serialization and thus short segment measurement intervals proved inadequate for accurate segmentation and thus measurements. This however does not negatively affect the study group which was focused on myocardial ischemia where heart rates of more than 95 beats per minute are rarely seen due to the oxygen starvation to the cardiac muscle caused by restricted coronary perfusion (ref section 2.3). Deficiencies rooted in hardware capabilities can however be bridged by using higher frequency scanning and sampling devices.

## 5.4 Summary

The research presented has from the onset focused on clinical application and the improvement of current monitoring techniques and methods. Real time bit-to-bit and beat-to-beat analysis has been shown not only to be possible but also to be effective, accurate and adaptive to the individual patient. In section 5.1.1 a short case study was presented comparing in Table 9 the analogue or manual graph based measurements with the real time measurements calculated using the model developed. It is clear that the results are well within tolerances and as such the electronically calculated values clinically meaningful. The advantages of using the automatic real time segmentation techniques within the model is first of all the elimination of possible human error, secondly the availability of the toolset to provide expert and specialist ECG derivatives and thirdly the elimination of time consuming manual calculations. The graph based ECG recording required additional clinical equipment and competency to actually setup and measure the ECG where if the toolset developed is embedded within standard monitoring devices the output is automatically available for clinical processing. In Chapter one, the introduction, the time critical treatment or delay is expressed by Wilber where the difference between life and death for cardiac cases is expressed in minutes. The relevance and contribution to the quality of care that the techniques and segmentation measurements present becomes clear when measured against the possible survival of the patient in an emergency or cardiac arrest treatment setting.

## **CHAPTER 6 CONCLUSION AND FUTURE WORK**

This research has investigated the ECG signal processing in the real time domain and the development of measurement and analysis algorithms based on bit-by-bit processing of ECGs in the clinical environment. The research included in the introduction is an overview of the current ECG processing methodologies focusing on the shortcomings of post-processing, buffering and averaging based techniques in live critical and emergency room patient monitoring environments.

Chapter two explored the anatomical and physiological principles describing the electro cardiac system including a study of ECG signal analysis with an emphasis on the QT interval, corrected QT measurement and typical morphologies associated with coronary artery disease. The journey continued into chapter three with an overview of modern patient simulation and the technologies and methods required for the successful measurement, digital recording, storage and reconstruction of human bio signals. The signal measurement and recording story continued with discussions on ECG hardware, predicate validation requirements, communication and data constructs in both the logical and physical domain. In Chapter three the conceptual model was presented together with the mixed methodology consisting of simulation and field study approach followed to link the solution to real time ECG segmentation.

At the heart of ECG analysis, interpretation and ultimately understanding lies signal and waveform segmentation and for the purposes of the study a digital non-linear approach was designed and presented in Chapter four of the thesis. A new take on the logical presentation of the ECG waveform in the digital domain was shown and the importance of successful P-wave detection was discussed required to correctly monitor the AV and SA node activity that form the onset of the cardiac depolarization cycle. The modelling discussion continued with a look at data packaging construct and the signal sampling or

rather slicing techniques deployed in the waveform digitization process that sits at the core of the algorithm together with the calculation of the differential (**df**) value and derived waveform values. The segmentation process continued with the detailed examination of the ECG waveform tagging methodology and the role and breakthrough contribution of the **df** value. The latter part of the chapter pulled the elements together into real time mapping, the partial sum waveform and finally a presentation of the model and measurement summary. Chapter five focused on a comparative data analysis and presentation showing the effectiveness of the processes and algorithm developed for the research to graph based analogue measurements of corresponding data samples. The Chapter concluded with a discussion on the relevance of the research, the data segmentation techniques and proverbial gap that the work presented has addressed.

In chapter one the objectives and proposed outcomes of the research were presented; the literature review in chapter two showed the current understanding of ECG analysis, segmentation and the embedded parameters within the ECG waveform like the QT and derived QDT parameters. This formed the grounded theory and basis required to understand and define the deficiencies in the current used techniques. The conceptual model and toolsets required to achieve the research objectives were presented and shown to be viable, accurate and capable to be used as a universal real time segmentation model to accurately measure and process bit-by-bit waveform datasets in the clinical measurement domain. Extensive simulation and field work introduced proved that the storage and reproduction of measurements and ECG waveforms are measurable and comparable with the traditional analogue graph based measurement technologies and techniques. The case study and subsequent detailed analysis and comparison of the manual versus the digital autonomous calculation methods concluded with the advantages that the model developed during the research are not only comparable but in many aspects superior when considering the time critical and skill set substitution capabilities of the real-time algorithm based processes. The real world impact of the research and measurement techniques are further

validated in section 6.1 where the current mind set and practice is further compared to the developed model based measurements.

### 6.1 How can the Research Impact the Real World?

The graph below shows an ECG of a 44-year-old male patient taken in the ER department, the patient complained of mild chest pain. The diagnosis was a viral illness and his ECG was considered to be within normal limits, he was allowed to go home but died later that day. A post-mortem examination revealed myocardial infarction which was probably a few hours old and that corresponded with his ER visit.

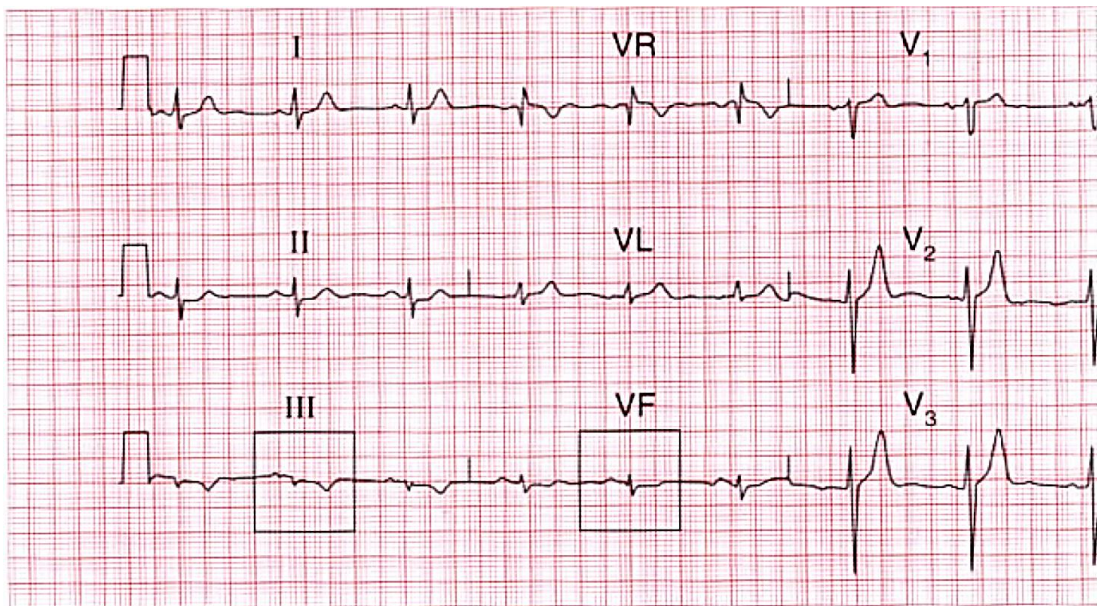


Figure 6.1 : Non Specific ST Morphology

The patient in question was not connected to a patient monitor with the argument that the 12 lead ECG was sufficient but as his case has shown, a judgment error led to his demise. If the algorithm developed during this research was deployed the signal injection feedback would have clearly highlighted the mild ST deviation and the T-Wave inversion seen on leads III, VR and VF. The highlighted morphology would have alerted the attending physician and the case would have been referred to a cardiologist before discharge. The argument that post analysis is much more conclusive is certainly relevant but the fact of the matter is that in the modern ER setting

where overcrowding and the sheer workload lead to clinical production line type treatment, technology should and must be put in place to assist the healthcare provider as to help limit medical errors; “*the average wait time for a heart attack patient increased from eight minutes to 20 minutes over the study period -- a 150 percent increase...*” (Wilper, 2008). Automated monitoring does not require the full attention of the clinician but a visual warning as shown in Figure 6.1 has the potential of attracting that split second attention that can make all the difference between life and death. With Sudden Cardiac Death being the leading cause of death in the US with 330000 confirmed cases annually (FDA, 2006), a radical paradigm shift is required in especially the emergency care environment where technology is not always fully utilized.

No claim is made that the work included here is the next proverbial “Holy Grail”, which in the medical setting simply does not exist. The focus and goal should be to encourage the establishment to reconsider traditional lines of thought and to further drive the development of “out-of-the-box” ideas and processes.

With the introduction of the Automated External Defibrillator (AED) the liability considerations led to the amendment of the Good Samaritan Law (National conference of State Legislation, State Laws on Cardiac Arrest & Defibrillators, 2008) which protects individuals from liability for damages that may occur from their use of the AED to save someone’s life at the immediate scene unless...damages are caused by gross negligence. Considering that the first AED enabled devices were launched in 1979 the establishment took the best part of three decades to fully adopt this new concept and lifesaving technology. The point being that technology, especially in a clinical setting should be more open to theories that look at problems from the other end of the proverbial map; many young designers avoid the medical technology environment due to sheer resistance from industry and fear of the personal liability law practitioner

The aim of AED technology was, and is not to replace the human mind and instinct but rather to assist in a circumstance where the required skill set is not available. The technologies developed during this research in many aspects

have the same aim, to assist and not to dictate, to be an aid and not a rule. It is our ability to evaluate data that drives the world; well informed decisions based on good information can only be based on well-structured data.

## 6.2 Contribution of this Research to Knowledge

The research presented in this study stepped away from the modern monitoring platform and asked the difficult questions about the possibility to accurately do live clinical data analysis without surrendering accuracy and precision. The colour feedback and signal injection based on the ECG segmentation algorithm developed, demonstrated the great potential the technique has in assisting the clinical process and contributes to a less error prone system. ECG tagging as a technique has been implemented in commercial systems for some time now but due to the post-processing limitations the true value of the technology could not be realized in full.

The techniques developed during the research have been adapted and implemented in commercial systems in Saudi Arabia where the research was conducted. A “black box” component that include the *df* based signal processing approach is currently being used to derive supplemental ECG data in a critical care setting as part of a wider clinical trial of the techniques with the aim of offering the technology to commercial monitoring manufactures. The impact of the system is noticeable in the reactive times of nursing staff as well as in the decline of false positive arrhythmia reports.

The system wave colour alert indicator alerts nursing staff that changes in trends have started, the waveform changes colour automatically and alerts those monitoring the screen that attention needs to be provided. These trends may settle and the patient may resume a normal output, however, if an increase of colour change occurs this is a clear indicator of a possible upcoming event and further action can be taken quickly, without being concern that it might be a false alarm. The patient thus benefits from a virtual digital cardiac specialist that in real terms is on duty, right there at the bedside



lowering the risk of undetected clinical ECG morphologies and ultimately increasing the level of patient care and positive care outcome.

A fresh perspective on ECG presentation and signal indicators is the way forward and now that real time ECG tagging has been proven to be viable and consistent the refinement of the technique and methods should be the logical next step

### **6.3 Future Work and Further Development**

Identified gaps in the processing of the various ECG morphologies do exist and future work will include improved detection in the presence of arterial flutters where the P-Wave start point is more difficult to detect due to the similarities between the flutter shape and that produced through the SA and AV nodes (P - Wave) as mentioned in section 5.3.1. The differentiator technique can be further refined into 2<sup>nd</sup> and 3<sup>rd</sup> order derivatives that in combination with the tagging methods can further define and classify cardiac abnormalities and wave pattern morphologies.

In addition to the 2<sup>nd</sup> and 3<sup>rd</sup> order derivatives the relationship between the bit count in the space between the T-End and the beginning of the P-Wave waveforms must be further studied and can be applied to accurately detect flutter wave pattern, 2<sup>nd</sup> and 3<sup>rd</sup> degree block of abnormal and pre mature P-Wave morphologies indicating anomalies in the SA and AV pacemaker nodes as described in section 2.1 and Figure 6.2 below.

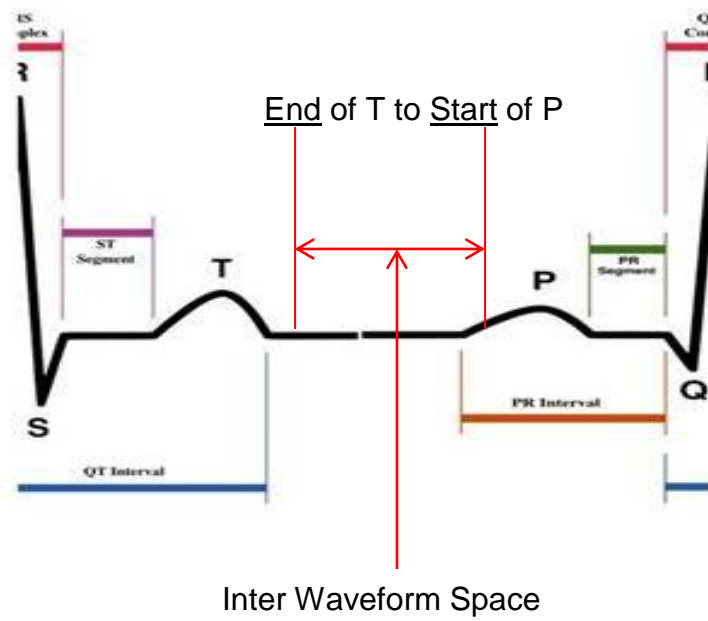


Figure 6.2 : T-Wave and P-Wave Flutter Detection

Digital waveform analysis together with real time segmentation has the potential to electronically and autonomously unlock information embedded within the ECG waveform that with traditional methods is a skill set that is only developed with years of clinical study; the positive results achieved in this study showed the potential of the work.

*“...the world is moving so fast these days that the man who says that it can't be done is generally interrupted by someone doing it...”*

*Elbert Hubbard*





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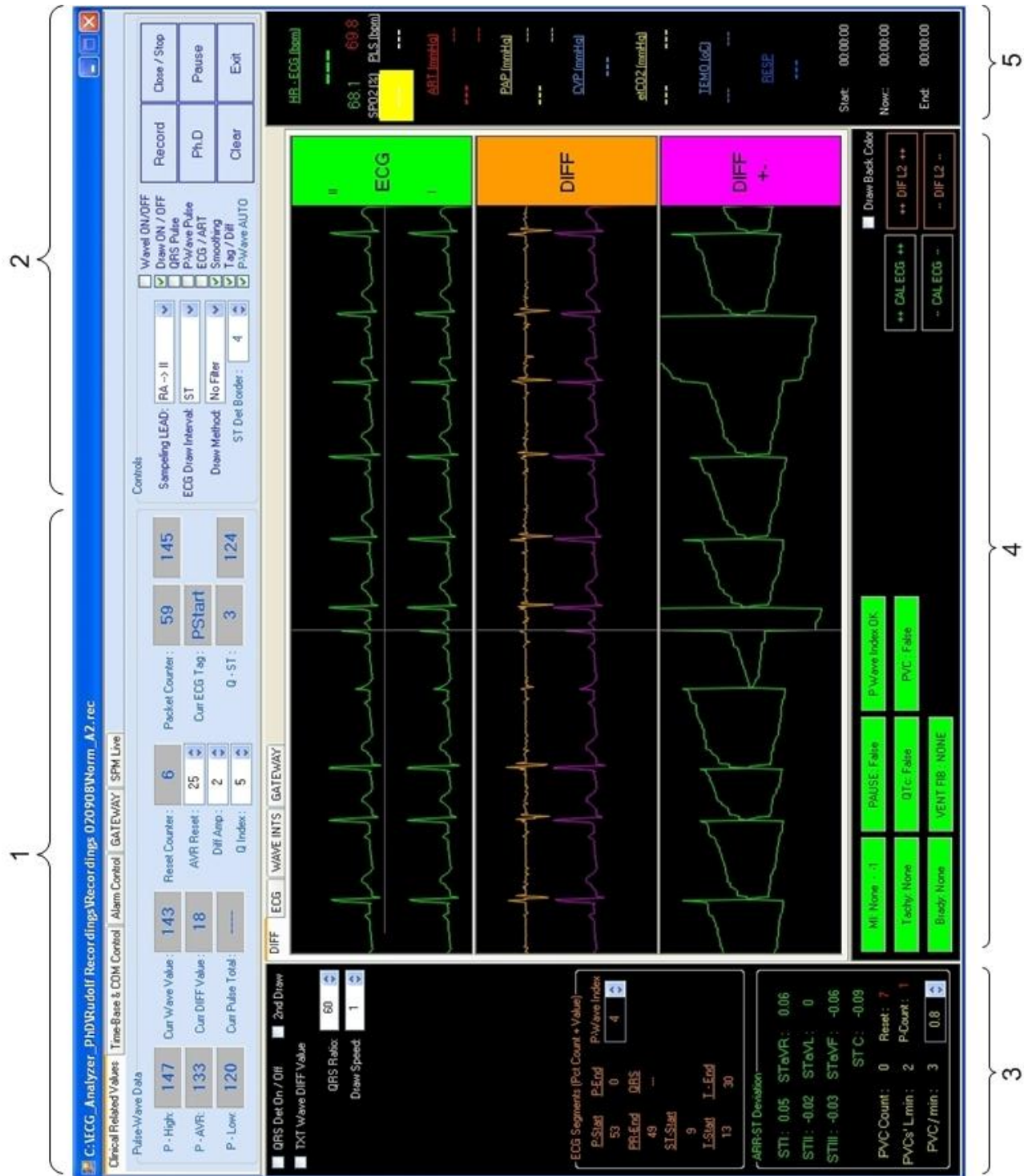
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## Appendix A – GUI Toolset



1. Data Slices and Timing Intervals
2. Object Control and General Settings
3. Arrhythmia Calculations

4. Waveform Interpretation and Control
5. Supplemental Parameter Indicators

## Appendix B – Predicate Monitor Short Study

Data collection may include anomalies and deviations that can cause misinterpretations and as such it is important to not infuse false feeds into the experiment; data verification is important for inaccurate readings will lead to false or misguided conclusions. The calculation of deviations can be managed by conducting a short comparative study using simultaneous multi data collection methods and comparing the output reading; for this study two commercial patient monitoring systems were connected to participating patients and the data readings were collected at set intervals over a period of 90 days. The table below is a specification comparison as to show that the two predicate devices used in the experimentation are comparatively equal.

No	Attributes and Parameters	SPM-2I-19	Infinity Delta XL
1	Product Code	MHX	MHX
2	Class	2	2
3	Device Description	Equivalent	Equivalent
4	Indications for Use/Intended Use	Equivalent	Equivalent
5	Warnings/Cautions/Contra-indications	Equivalent	Equivalent
6	Separate Transport Monitors Required?	No	No
7	Stand Alone Device	Yes	Yes
8	Connects to wired, wireless, and DirectNet networks?	Yes	Yes
9	Intended for Adults, Pediatric, Neonatal	Yes	Yes
10	ECG Available leads include I, II, III, aVR, aVF, aVL, V	Yes	Yes
11	ECG Accuracy	+/-2 bpm or +/-1%	+/-2 bpm or +/-1%
12	ECG Heart Rate Measuring Range	30-250 bpm	15-300 bpm
13	ECG Display Frequency Range (Filter off)	0.05-40Hz	0.05-40Hz
14	ECG Display Frequency Range (Monitoring Filter)	0.5-40Hz	0.5-40Hz
15	ECG Display Frequency Range (ESU Filter)	0.5-16Hz	0.5-16Hz
16	ECG Printer Frequency Range	0.05-125Hz	0.05-125Hz
17	QRS Detection Range Amplitude	0.5-5mV	0.5-5mV
18	QRS Detection Range Duration (Adult/Pediatric)	70-120 msec	70-120 msec
19	QRS Detection Range Duration (Neonatal)	40-120 msec	40-120 msec
20	QRS Detection Alarm Upper/Lower Limits	User selectable	User selectable
21	Pacer Detection Amplitude (Leads I, II, III)	+/-2 - +/-70 mV	+/-2 - +/-70 mV
22	Pacer Detection Width (Leads I, II, III)	0.1-2.0 msec	0.2-2.0 msec
23	Electrode Accessory Sets	3, or 5 leads	3, 5, 6 leads or 12 pod
24	ST Available Leads (not intended for Neonates)	Any 3 up to 7	Any 3 up to 12
25	ST Complex Length	892 msec	892 msec
26	ST Complex Length from Fiducial Point	-300 to +600 msec	-300 to +600 msec
27	ST Sample Rate	225 per sec	225 per sec
28	ST Frequency Response	0.05-40Hz	0.05-40Hz
29	Isoelectric Measurement Point Measuring Range	Start of ECG complex to Fiducial Point	Start of ECG complex to Fiducial Point
30	Isoelectric Measurement Point Default	QRS onset-28 msec	QRS onset-28 msec

31	ST Measurement Point Adjustment Range	Fiducial point to end of ECG complex	Fiducial point to end of ECG complex
32	ST Measurement Point Default	QRS offset +80 msec	QRS offset +80 msec
33	ST Measurement Point Interval	15 sec, 1 beat	15 sec, 1 beat
34	ST Measurement Point Resolution	+/-0.1 mm	+/-0.1 mm
35	ST Measurement Point Trends	Graphical, tabular, graph mini-trends	Graphical, tabular, graph mini-trends
36	ST Measurement Point INOP Alarm	Yes	Yes
37	ST Measurement Upper and Lower ST Alarms	+/-15, +/-0.1mm increments	+/-15, +/-0.1mm increments
38	ST Measurement Event Alarm Duration	0, 15, 30, 45, 60 sec	0, 15, 30, 45, 60 sec
39	Arrhythmia Detection for Adults/Pediatric?	Yes	Yes
40	Arrhythmia Detection for Neonatal?	No	No
41	Arrhythmia Detection ARR Mode	Off, basic, or advanced	Off, basic, or advanced
42	Arrhythmia Detection Basic ARR	Asystole, ventricular fibrillation, ventricular tachycardia and artifact	Asystole, ventricular fibrillation, ventricular tachycardia and artefact
43	Arrhythmia Detection Advanced ARR	Ventricular run, accelerated idioventricular rhythm, supra-ventricular tachycardia, couplet, bigeminy, tachycardia, bradycardia, pause, PVC/min parameter output, neonatal low heart rate alarm.	Ventricular run, accelerated idioventricular rhythm, supra-ventricular tachycardia, couplet, bigeminy, tachycardia, bradycardia, pause, PVC/min parameter output, neonatal low heart rate alarm.
44	Respiration Sensing Leads	I, II	I, II
45	Respiration Measuring Method	Impedance pneumography	Impedance pneumography
46	Respiration Auxiliary Current	</=80µA	</=10µA
47	Respiration Detection Threshold Manual Mode	0.15-40Ω	0.15-40Ω
48	Respiration Detection Threshold Automatic Mode	0.2-1.5Ω	0.2-1.5Ω
49	Respiration Measuring Range	0-99 breaths/min	0-155 breaths/min
50	Respiration Accuracy	+/-1 breath/min or 2%	+/-1 breath/min or 2%
51	Respiration Alarms	User selects upper and lower limits	User selects upper and lower limits
52	SpO <sub>2</sub> Pulse Oximetry Algorithm	Nellcor, OxiMax	Nellcor, OxiMax
53	SpO <sub>2</sub> Pulse Oximetry Connection	Direct port w/ext cable	MultiMed Pod port
54	SpO <sub>2</sub> Pulse Oximetry Displayed Parameters	Saturation and pulse	Saturation and pulse
55	SpO <sub>2</sub> Pulse Oximetry Measuring Method	Transmission Spectrophotometry	Transmission Spectrophotometry
56	SpO <sub>2</sub> Pulse Oximetry Measuring Range (SpO <sub>2</sub> )	30-100%	1-100%
57	SpO <sub>2</sub> Pulse Oximetry Measuring Range (Pulse)	30-250 bpm	30-250 bpm
58	SpO <sub>2</sub> Pulse Oximetry Accuracy (SpO <sub>2</sub> )	(90-100%) +/-1%	(70-100%) +/-2%
59		(80-89%) +/-2%	
60		(70-79%) +/-3%	
61	SpO <sub>2</sub> Pulse Oximetry Accuracy (Pulse)	+/-1%	+/-3%
62	SpO <sub>2</sub> Pulse Oximetry Alarms (SpO <sub>2</sub> and Pulse Rate)	User selects upper and lower limits	User selects upper and lower limits
63	SpO <sub>2</sub> Pulse Oximetry Alarms (Neonatal)	Life threatening desaturation	Life threatening desaturation

64	NBP Non-invasive Blood Pressure Displayed Parameters	Systolic, diastolic, mean, pulse rate	Systolic, diastolic, mean,
65	NBP Non-invasive Blood Pressure Measuring Method	Oscillometric utilizing deflation	Oscillometric utilizing deflation
66	NBP Non-invasive Blood Pressure Mode of Operation	Manual-single, continuous-5 min, and interval	Manual-single, continuous-5 min, and interval
67	NBP Non-invasive Blood Pressure Interval Times	1, 2, 2.5, 3, 5, 10, 15, 20, 25, 30, 45, 60, 120	1, 2, 2.5, 3, 5, 10, 15, 20, 25, 30, 45, 60, 120, 240
68	NBP Non-invasive Blood Pressure Heart Rate Range	30-240 bpm	30-240 bpm
69	NBP Non-invasive Blood Pressure Adult Pressure Range	Systolic: 25-280mmHg	Systolic: 30-250mmHg
70		Mean: 10-220mmHg	Mean: 20-230mmHg
71		Diastolic: 15-260mmHg	Diastolic: 10-210mmHg
72	NBP Non-invasive Blood Pressure Paediatric Pressure Range	Systolic: 25-280mmHg	Systolic: 30-170mmHg
73		Mean: 10-220mmHg	Mean: 20-150mmHg
74		Diastolic: 15-260mmHg	Diastolic: 10-130mmHg
75	NBP Non-invasive Blood Pressure Neonatal Pressure Range	Systolic: 20-155mmHg	Systolic: 30-130mmHg
76		Mean: 5-110mmHg	Mean: 20-110mmHg
77		Diastolic: 10-130mmHg	Diastolic: 10-100mmHg
78	Cuff Pressure: Default Adult Inflation Pressure	160 +/-10mmHg	160 +/-10mmHg
79	Cuff Pressure: Default Paediatric Inflation Pressure	120 +/-10mmHg	120 +/-10mmHg
80	Cuff Pressure: Default Neonatal Inflation Pressure	110 +/-10mmHg	110 +/-10mmHg
81	Cuff Pressure: Adult Inflation Pressure after measurement	Last systolic + 25mmHg +/-10mmHg	Last systolic + 25mmHg +/-10mmHg
82	Cuff Pressure: Paediatric Inflation Pressure after measurement	Last systolic + 25mmHg +/-10mmHg	Last systolic + 25mmHg +/-10mmHg
83	Cuff Pressure: Neonatal Inflation Pressure after measurement	Last systolic + 30mmHg +/-5mmHg	Last systolic + 30mmHg +/-5mmHg
84	Cuff Pressure: Maximum Adult Inflation Pressure	290 +/-5mmHg	265 +/-5mmHg
85	Cuff Pressure: Maximum Paediatric Inflation Pressure	180 +/-10mmHg	180 +/-10mmHg
86	Cuff Pressure: Maximum Neonatal Inflation Pressure	150 +/-10mmHg	142 +/-10mmHg
87	Cuff Pressure: Minimum Adult Inflation Pressure	110 +/-10mmHg	110 +/-10mmHg
88	Cuff Pressure: Minimum Paediatric Inflation Pressure	90 +/-10mmHg	90 +/-10mmHg
89	Cuff Pressure: Minimum Neonatal Inflation Pressure	70 +/-10mmHg	70 +/-10mmHg
90	Cuff Pressure Connector	Quick-release w/single airway	Quick-release w/single airway
91	Invasive Blood Pressure Maximum Number of Displays	Up to 4	Up to 8
92	Invasive Blood Pressure Measuring Method	Resistivestrain gaugetransducer	Resistivestrain gaugetransducer
93	Invasive Blood Pressure Display Resolution	1mmHg	1mmHg
94	Invasive Blood Pressure Measuring Range	-99 to 310mmHg	-50 to 400mmHg
95	Invasive Blood Pressure Frequency Range	DC-8Hz, DC-16Hz, DC-28Hz	DC-8Hz, DC-16Hz, DC-32Hz
96	Invasive Blood Pressure Zero Balance	+/-70mmHg	+/-200mmHg
97	Invasive Blood Pressure Transducer Specifications	Resistance 200-3000Ω, pressure sensitivity 5μV/V/mmHg +/-10%	Resistance 200-3000Ω, pressure sensitivity 5μV/V/mmHg +/-10%

98	Invasive Blood Pressure Accuracy	+/-1mmHg or +/-3%	+/-1mmHg or +/-3%
99	Invasive Blood Pressure IBP Alarms (Systolic)	User selects upper and lower limits	User selects upper and lower limits
100	Invasive Blood Pressure IBP Alarms (Mean)	User selects upper and lower limits	User selects upper and lower limits
101	Invasive Blood Pressure IBP Alarms (Diastolic)	User selects upper and lower limits	User selects upper and lower limits
102	Invasive Blood Pressure Accessories	Pressure transducers	Pressure transducers
103	Display Specification Type	Thin film transistor-LCD active matrix (TFT-colour LCD)	Thin film transistor-LCD active matrix (TFT-LCD)
104	Display Specification Size	482.6mm (19 in.) diagonal	264mm (10.4 in.) diagonal
105	Display Specification Channels	7 standard, 12 optional	5 standard, 6 or 8 optional
106	Display Specification Viewing Area	375x300mm	211x158mm
107	Display Specification Resolution	1280x1024 pixels	640x480 pixels
108	Display Specification Size	310mm (12.2 in) diagonal	310mm (12.2 in) diagonal
109	Display Specification Channels	7 standard, 12 optional	6 standard, 8 optional
110	Display Specification Viewing Area	246x184.5mm (9.7x7.3 in)	246x184.5mm (9.7x7.3 in)
111	Display Specification Resolution	800x600 pixels	800x600 pixels
112	Display Specification Rotary Knob	Easy menu and analogue resistive touch screen	Easy menu and fixed keys
113	Alarm Priorities (3 alarms)	High (life threatening),	High (life threatening),
114		Medium (serious), Low (advisory)	Medium (serious), Low (advisory)
115	All Following Connections? (MultiMed cables, Masimo set, Nellcor Oximax Smartpod, HemoMed pod), communication ports (2 standard), NBP input, etC)2 module, analogue output, QRS sync output, RS232, remote keypad connector, Scio Four modules?	Yes	Yes
116	Analogue Output Signals	ECG, arterial blood pressure	ECG, arterial blood pressure
117	Analogue Output Delay	</=25 msec	</=25 msec
118	Networking Method	DirectNet or wireless	DirectNet or wireless
119	Wireless Networking Encryption	None, WEP, WPA2, all standard methods	None, WEP, WPA2, all standard methods
120	Networking Access	R50N bedside recorder, printer, nurse call system, remote view MIB	R50N bedside recorder, printer, nurse call system, remote view MIB
121	Cooling	Fan + Convection	Convection
122	Size (HxWxD)	471.5x416.2x123.6mm	253x365x190mm
123	Weight	12kg (26.4 lbs)	6.2kg (13.6 lbs)
124	Data Storage	7 days	24 hours
125	Data Resolution	15 sec sampling	30 sec sampling
126	Trend Tables	1, 5, 15, 30, 60 min display format	1, 5, 15, 30, 60 min display format
127	Trend Graphs	1, 2, 4, 8, 12, 24 hour display format	1, 2, 4, 8, 12, 24 hour display format
128	Power requirements	100-250 VAC/4A	100-120 VAC/3.4A;
129			200-240VAC/1.7A
130	Power Consumption	</=180W fully loaded	</=70W fully loaded



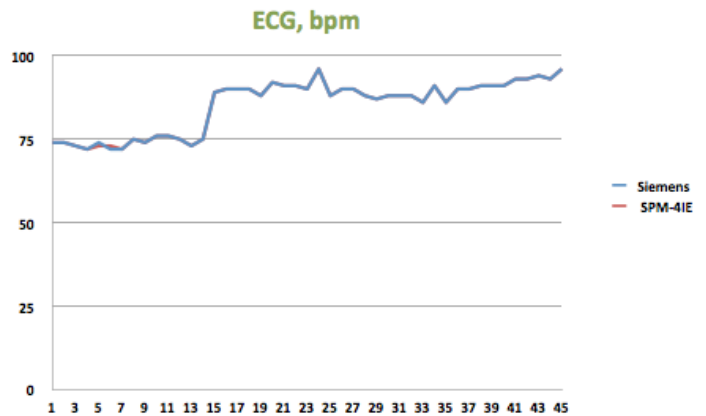
131	Patient Leakage Current	<math>\leq 10\mu\text{A}</math>	<math>\leq 10\mu\text{A}</math>
132	Protection Class	Class 1 (IEC 60601-1)	Class 1 (IEC 60601-1)
133	Frequency	50-60Hz	50-60Hz
134	Chassis Leakage Current	<math>< 300\mu\text{A}@120\text{VAC}</math>;	<math>< 300\mu\text{A}@120\text{VAC}</math>;
135		<math>< 500\mu\text{A}@220\text{VAC}</math>	<math>< 500\mu\text{A}@220\text{VAC}</math>
136	External Battery/UPS Charging Time	6.5 hours@25C	6.5 hours@25C
137	External Battery/UPS Type	Sealed Lead-acid	Sealed Lead-acid
138	External Battery/UPS Capacity	50 minutes	50 minutes
139	External Battery/UPS Size (HxWxD)	62x182x24mm	62x182x24mm
140		(2.4x7.2x9 in)	(2.4x7.2x9 in)
141	Temperature Range During Operation	10 to 40C (50 to 104F)	10 to 40C (50 to 104F)
142	Temperature Range During Storage	0 to 40C (32 to 104F)	-20 to 40C (-4 to 104F)
143	Relative Humidity During Operation	10-95% non-condensing	20-90% non-condensing
144	Relative Humidity During Storage	10-95% in packaging	10-95% in packaging
145	Atmospheric Pressure During Operation	525-795mmHg (70-106kPa)	525-795mmHg (70-106kPa)
146	Atmospheric Pressure During Storage	375-795mmHg (50-106kPa)	375-795mmHg (50-106kPa)
147	Device Meets IEC60601-1 (2 <sup>nd</sup> edition) and Applicable Particular and Collateral Standards	Yes	Yes
148	Electromagnetic Compatibility Class per IEC 60601-1-2:2007	CISPR11, Class B	CISPR11, Class B

In the next section tables of the predicate comparison readings are shown in processed form. Each table shows two readings from the same parameter in both numerical and graphical format. The readings are used in the computations and experiments to equate and compensate for possible deviations in the vital signs due to analogue drift typical in biological measurements.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

ECG			
Siemens	SPM-4IE	Siemens	SPM-4IE
74	74	88	88
74	74	87	87
73	73	88	88
72	72	88	88
74	73	88	88
72	73	86	86
72	72	91	91
75	75	86	86
74	74	90	90
76	76	90	90
76	76	91	91
75	75	91	91
73	73	91	91
75	75	93	93
89	89	93	93
90	90	94	94
90	90	93	93
90	90	96	96
88	88		
92	92		
91	91		
91	91		
90	90		
96	96		
88	88		
90	90		
90	90		



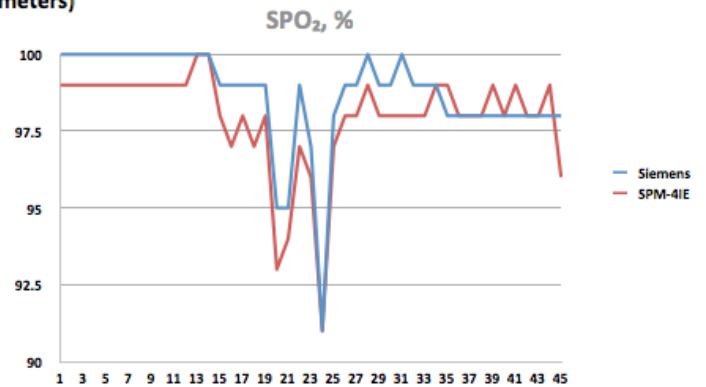
Notes / Conclusions:

1. ECG proved to be stable and consistent.
2. HR alarms were fewer on the SPM due to the inclusion of the FA algorithm (use 2 or more comparative active parameters eliminating false alarms by up to 96%)

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

SPO <sub>2</sub>			
Siemens	SPM-4IE	Siemens	SPM-4IE
100	99	100	99
100	99	99	98
100	99	99	98
100	99	100	98
100	99	99	98
100	99	99	98
100	99	99	98
100	99	98	99
100	99	98	99
100	99	98	98
100	99	98	98
100	99	98	98
100	100	98	99
100	100	98	99
99	98	98	98
99	97	98	98
99	98	98	99
99	97	98	96
99	98		
95	93		
95	94		
99	97		
97	96		
91	91		
98	97		
99	98		
99	98		



Notes:

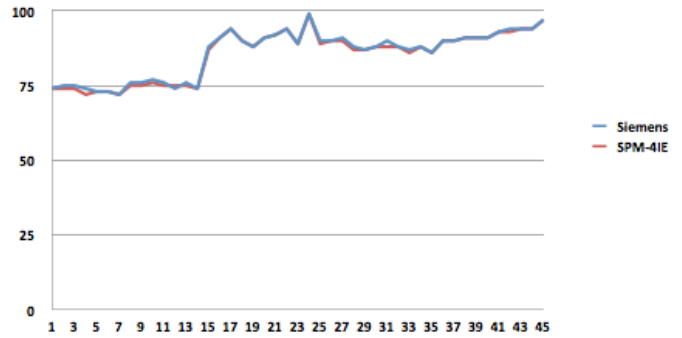
1. Stable and consistent
2. Deviations due to probe placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

PLS(Saturation)			
Siemens	SPM-4IE	Siemens	SPM-4IE
74	74	88	87
75	74	87	87
75	74	88	88
74	72	90	88
73	73	88	88
73	73	87	86
72	72	88	88
76	75	86	86
76	75	90	90
77	76	90	90
76	75	91	91
74	75	91	91
76	75	91	91
74	74	93	93
88	87	94	93
91	91	94	94
94	94	94	94
90	90	97	97
88	88		
91	91		
92	92		
94	94		
89	89		
99	99		
90	89		
90	90		
91	90		

**Pulse from SPO2, bpm**



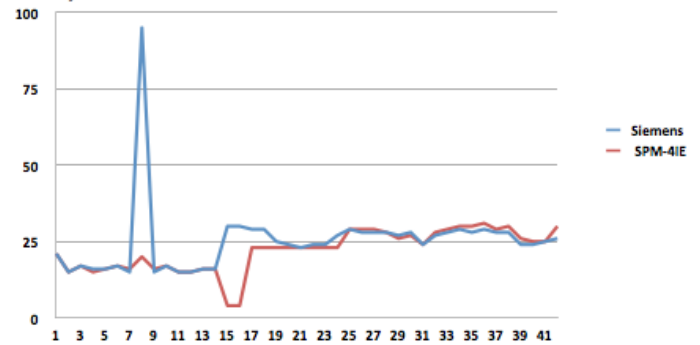
Notes:  
1. Stable and consistent

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

Respiration			
Siemens	SPM-4IE	Siemens	SPM-4IE
21	21	28	28
15	15	27	26
17	17	28	27
16	15	24	24
16	16	27	28
17	17	28	29
15	16	29	30
95	20	28	30
15	16	29	31
17	17	28	29
15	15	28	30
15	15	24	26
16	16	24	25
16	16	25	25
30	4	26	30
30	4		
29	23		
29	23		
25	23		
24	23		
23	23		
24	23		
24	23		
27	23		
29	29		
28	29		
28	29		

**RESP, breths pm**



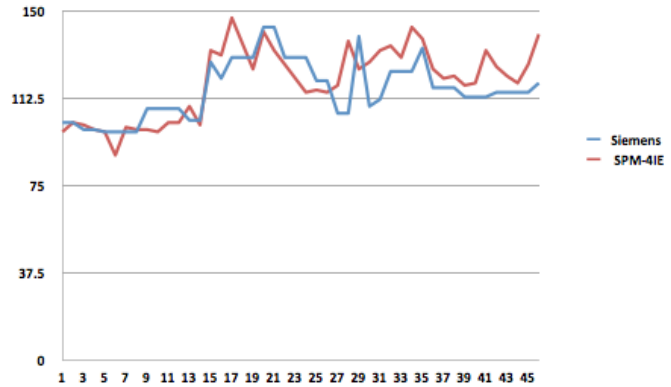
Notes:  
1. Stable and consistent  
2. Deviations due to inconsistent readings on Siemens monitor.  
3. SPM consistent with ventilator RESP settings and reading.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

NIBP(SYS)			
Siemens	SPM-4IE	Siemens	SPM-4IE
102	98	106	137
102	102	139	125
99	101	109	128
99	99	112	133
98	98	124	135
98	88	124	130
98	100	124	143
98	99	134	138
108	99	117	125
108	98	117	121
108	102	117	122
108	102	113	118
103	109	113	119
103	101	113	133
128	133	115	126
121	131	115	122
130	147	115	119
130	136	115	127
130	125	119	140
143	141		
143	133		
130	127		
130	121		
130	115		
120	116		
120	115		
106	118		

**NIBP (SYS), mmHg**



Notes:

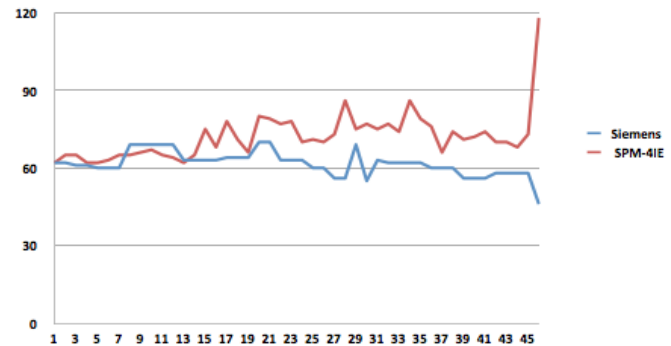
1. Stable and consistent
2. Deviations due to cuff placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

NIBP(DIA)			
Siemens	SPM-4IE	Siemens	SPM-4IE
62	62	56	86
62	65	69	75
61	65	55	77
61	62	63	75
60	62	62	77
60	63	62	74
60	65	62	86
69	65	62	79
69	66	60	76
69	67	60	66
69	65	60	74
69	64	56	71
63	62	56	72
63	65	56	74
63	75	58	70
63	68	58	70
64	78	58	68
64	71	58	73
64	66	46	118
70	80		
70	79		
63	77		
63	78		
63	70		
60	71		
60	70		
56	73		

**NIBP(DIA), mmHg**



Notes:

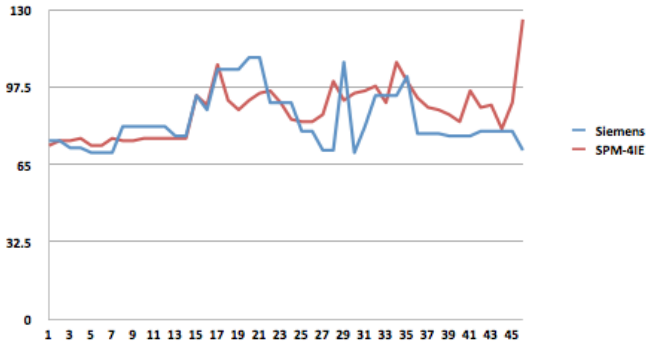
1. Stable and consistent
2. Deviations due to cuff placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

NIBP(MAP)			
Siemens	SPM-4IE	Siemens	SPM-4IE
75	73	71	100
75	75	108	92
72	75	70	95
72	76	81	96
70	73	94	98
70	73	94	91
70	76	94	108
81	75	102	100
81	75	78	93
81	76	78	89
81	76	78	88
81	76	77	86
77	76	77	83
77	76	77	96
94	94	79	89
88	90	79	90
105	107	79	80
105	92	79	91
105	88	71	126
110	92		
110	95		
91	96		
91	91		
91	84		
79	83		
79	83		
71	86		

**NIBP(MAP), mmHg**



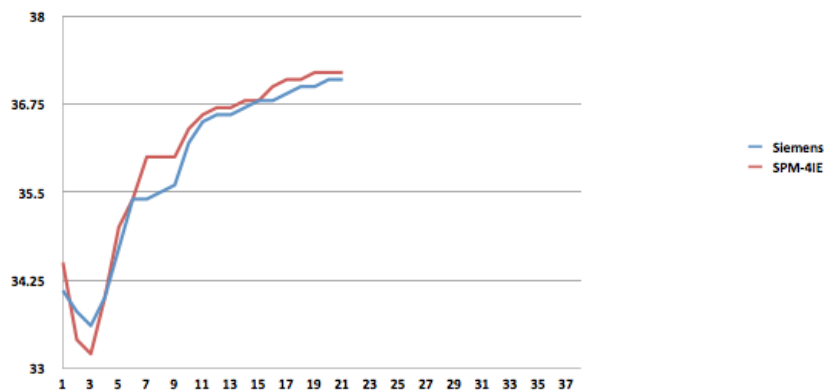
- Notes:
1. Stable and consistent
  2. Deviations due to cuff placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(28-1-2008 to 30-1-2008)

**Test Results (Comparative Patient Parameters)**

Ta	
Siemens	SPM-4IE
34.1	34.5
33.8	33.4
33.6	33.2
34	34
34.7	35
35.4	35.4
35.4	36
35.5	36
35.6	36
36.2	36.4
36.5	36.6
36.6	36.7
36.6	36.7
36.7	36.8
36.8	36.8
36.8	37
36.9	37.1
37	37.1
37	37.2
37.1	37.2
37.1	37.2

**Ta-°C**

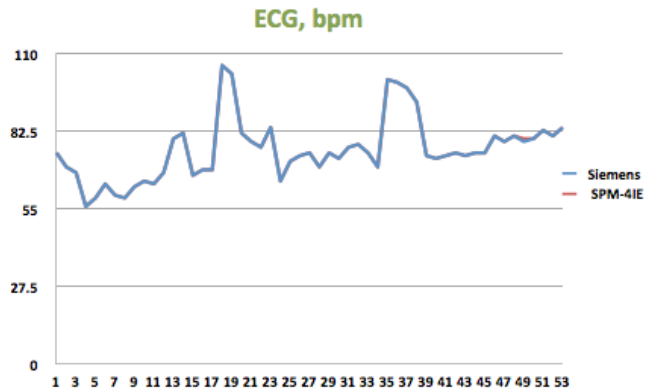


- Notes:
1. Stable and consistent
  2. Limited deviations due to probe placement (Two probes cannot be placed at same location)

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

ECG			
Siemens	SPM-4IE	Siemens	SPM-4IE
75	75	70	70
70	70	75	75
68	68	73	73
56	56	77	77
59	59	78	78
64	64	75	75
60	60	70	70
59	59	101	101
63	63	100	100
65	65	98	98
64	64	93	93
68	68	74	74
80	80	73	73
82	82	74	74
67	67	75	75
69	69	74	74
69	69	75	75
106	106	75	75
103	103	81	81
82	82	79	79
79	79	81	81
77	77	79	80
84	84	80	80
65	65	83	83
72	72	81	81
74	74	84	84



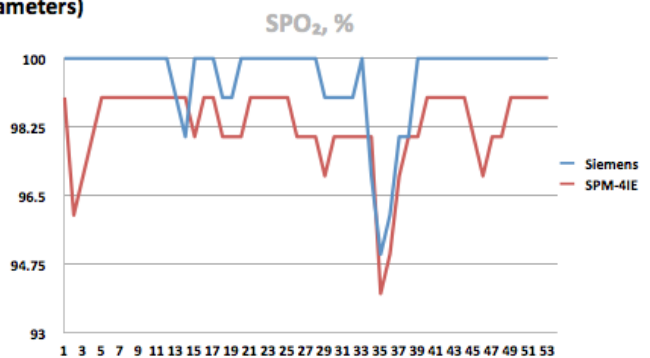
Notes / Conclusions:

1. ECG proved to be stable and consistent.
2. HR alarms were fewer on the SPM due to the inclusion of the FA algorithm (use 2 or more comparative active parameters eliminating false alarms by up to 96%)

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

SPO <sub>2</sub>			
Siemens	SPM-4IE	Siemens	SPM-4IE
100	99	100	98
100	96	99	97
100	97	99	98
100	98	99	98
100	99	99	98
100	99	100	98
100	99	97	98
100	99	95	94
100	99	96	95
100	99	98	97
100	99	98	98
100	99	100	98
99	99	100	99
98	99	100	99
100	98	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	99	100	99
100	98	100	99



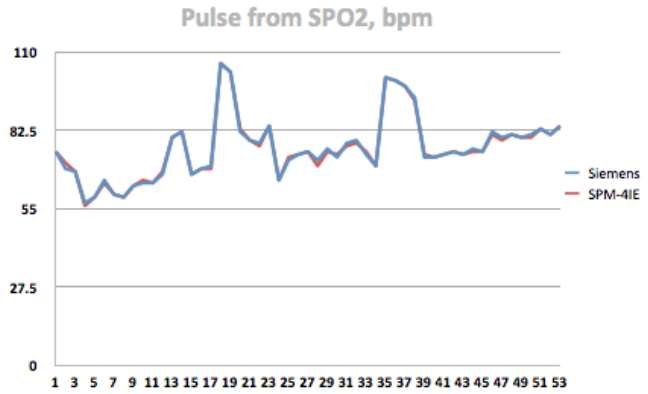
Notes:

1. Stable and consistent
2. Deviations due to probe placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

PLS(Saturation)			
Siemens	SPM-4IE	Siemens	SPM-4IE
75	75	72	70
69	71	76	75
68	68	73	74
57	56	78	77
59	59	79	78
65	64	74	75
60	60	70	70
59	59	101	101
63	63	100	100
64	65	98	98
64	64	94	93
67	68	73	74
80	80	73	73
82	82	74	74
67	67	75	75
69	69	74	74
70	69	76	75
106	106	75	75
103	103	82	81
82	83	80	79
79	79	81	81
78	77	80	80
84	84	81	80
65	65	83	83
72	73	81	81
74	74	84	84

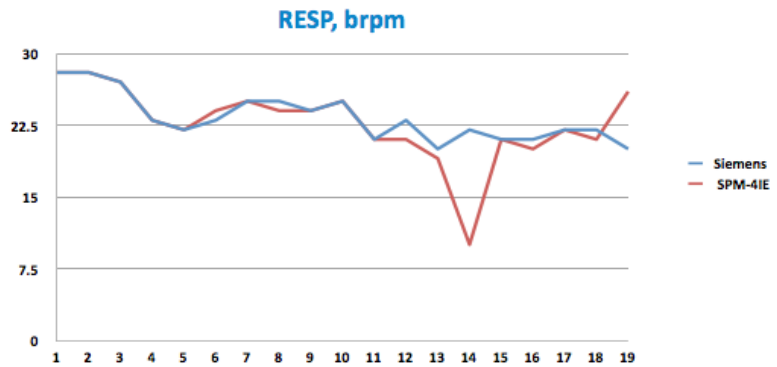


Notes:  
1. Stable and consistent

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

Respiration	
Siemens	SPM-4IE
28	28
28	28
27	27
23	23
22	22
23	24
25	25
25	24
24	24
25	25
21	21
23	21
20	19
22	10
21	21
21	20
22	22
22	21
20	26

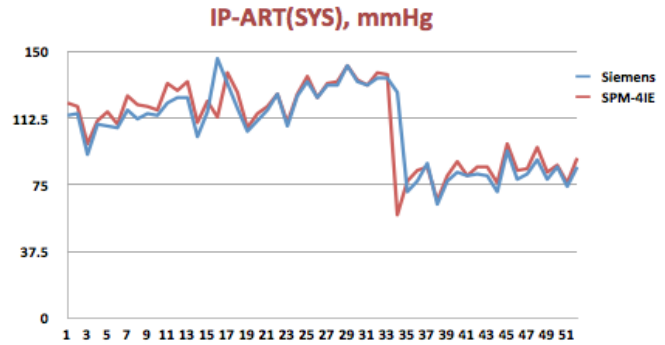


Notes:  
1. Stable and consistent  
2. Deviations due to inconsistent readings on Siemens monitor.  
3. SPM consistent with ventilator RESP settings and reading.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-ART(SYS)			
Siemens	SPM-4IE	Siemens	SPM-4IE
114	121	131	133
115	119	142	142
92	98	133	134
109	111	131	131
108	116	135	138
107	109	135	137
117	125	127	58
112	120	71	77
115	119	77	83
114	117	87	85
121	132	64	66
124	128	77	80
124	133	82	88
102	110	80	80
116	122	81	85
146	113	80	85
132	138	71	76
118	127	94	98
105	107	78	83
111	115	81	84
117	119	89	96
126	126	78	82
108	110	85	86
125	126	74	76
133	136	85	90

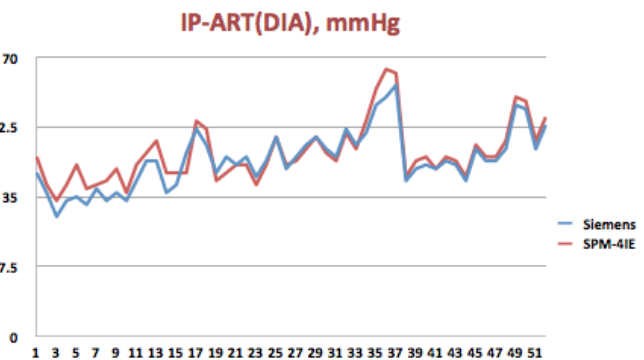


- Notes:
1. Stable and consistent
  2. Deviations within limits
  3. Siemens monitor known for lowered IBP readings.
  4. SPM transducer connected without flu

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-ART(DIA)			
Siemens	SPM-4IE	Siemens	SPM-4IE
41	45	48	47
36	38	50	50
30	34	47	46
34	38	45	44
35	43	52	51
33	37	48	47
37	38	51	54
34	39	58	62
36	42	60	67
34	36	63	66
39	43	39	40
44	46	42	44
44	49	43	45
36	41	42	42
38	41	44	45
46	41	43	44
52	54	39	40
48	52	47	48
41	39	44	45
45	41	44	45
43	43	47	49
45	43	58	60
40	38	57	59
44	43	47	49
50	50	53	55
42	43		



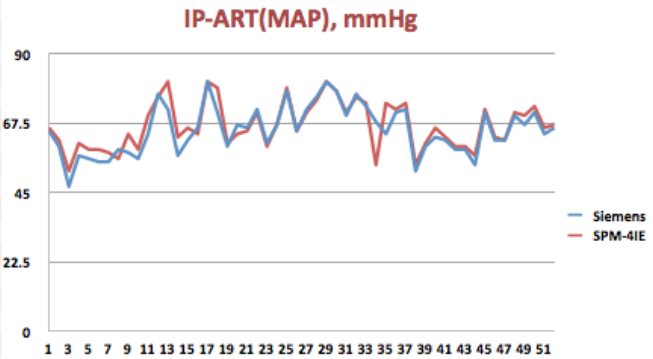
- Notes:
1. Stable and consistent
  2. Deviations within limits
  3. Siemens monitor known for lowered IBP readings.
  4. SPM transducer connected without flush line pressure.



**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-ART(MAP)			
Siemens	SPM-4IE	Siemens	SPM-4IE
65	66	76	75
60	62	81	81
47	52	78	78
57	61	70	71
56	59	77	76
55	59	73	74
55	58	68	54
59	56	64	74
58	64	71	72
56	59	72	74
64	70	52	54
77	76	60	61
72	81	63	66
57	63	62	63
62	66	59	60
66	64	59	60
81	81	54	57
71	79	71	72
60	61	62	63
67	64	62	62
66	65	70	71
72	71	67	70
61	60	71	73
67	67	64	66
78	79	66	67



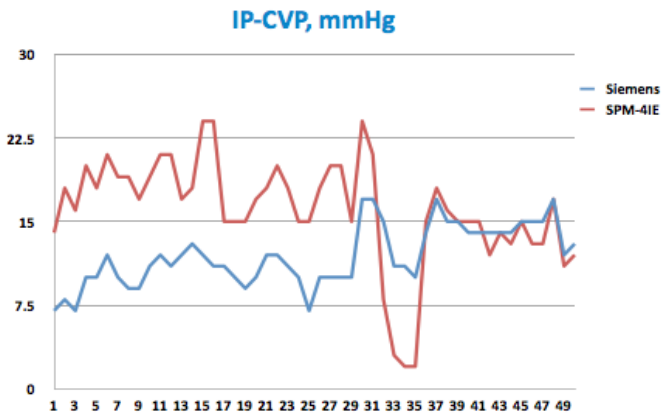
Notes:

1. Stable and consistent
2. Deviations within limits
3. Siemens monitor known for lowered IBP readings.
4. SPM transducer connected without flush line pressure.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-CVP			
Siemens	SPM-4IE	Siemens	SPM-4IE
7	14	10	20
8	18	10	15
7	16	17	24
10	20	17	21
10	18	15	8
12	21	11	3
10	19	11	2
9	19	10	2
9	17	14	15
11	19	17	18
12	21	15	16
11	21	15	15
12	17	14	15
13	18	14	15
12	24	14	12
11	24	14	14
11	15	14	13
10	15	15	15
9	15	15	13
10	17	15	13
12	18	17	17
12	20	12	11
11	18	13	12
10	15		
7	15		
10	18		



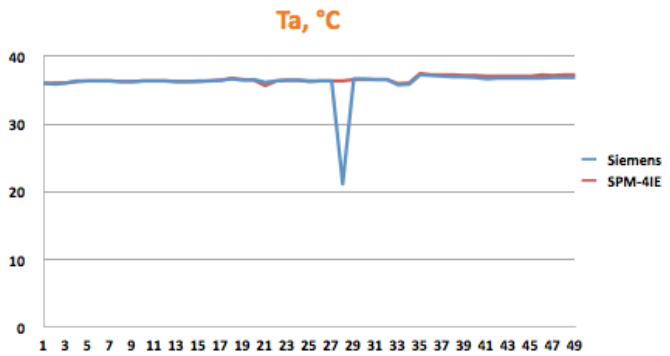
Notes:

1. Deviations noted.
2. Siemens monitor known for lowered CVP readings.
3. SPM transducer connected without flush line pressure.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(2-2-2008 to 5-2-2008)

**Test Results (Comparative Patient Parameters)**

Ta			
Siemens	SPM-4IE	Siemens	SPM-4IE
36.1	36	21.2	36.4
35.9	36.1	36.7	36.6
36.1	36.1	36.7	36.6
36.4	36.3	36.6	36.6
36.4	36.4	36.6	36.6
36.4	36.4	35.8	36
36.4	36.4	35.9	36.1
36.3	36.3	37.3	37.5
36.3	36.3	37.2	37.3
36.4	36.4	37.1	37.3
36.4	36.4	37	37.3
36.4	36.4	37	37.2
36.3	36.3	36.9	37.2
36.3	36.3	36.7	37.1
36.4	36.3	36.8	37.1
36.4	36.4	36.8	37.1
36.5	36.5	36.8	37.1
36.7	36.8	36.8	37.1
36.5	36.6	36.8	37.3
36.6	36.5	36.9	37.2
36.2	35.7	36.9	37.3
36.4	36.4	36.9	37.3
36.5	36.5		
36.5	36.5		
36.4	36.3		
36.4	36.4		



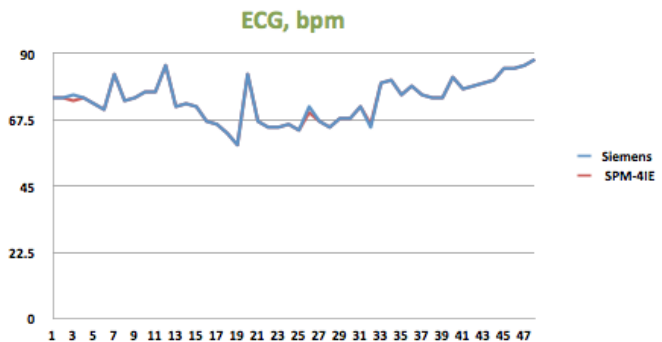
Notes:

1. Stable and consistent
2. Limited deviations due to probe placement
3. Siemens lowered reading caused by probe failure

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

ECG			
Siemens	SPM-4IE	Siemens	SPM-4IE
75	75	68	68
75	75	68	68
76	74	72	72
75	75	65	66
73	73	80	80
71	71	81	81
83	83	76	76
74	74	79	79
75	75	76	76
77	77	75	75
77	77	75	75
86	86	82	82
72	72	78	78
73	73	79	79
72	72	80	80
67	67	81	81
66	66	85	85
63	63	85	85
59	59	86	86
83	83	88	88
67	67		
65	65		
65	65		
66	66		
64	64		
72	70		
67	67		



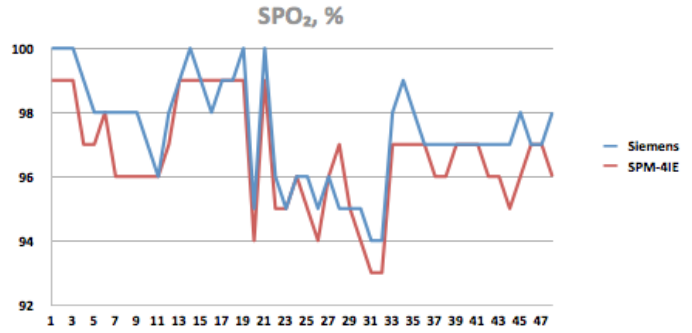
Notes / Conclusions:

1. ECG proved to be stable and consistent.
2. HR alarms were fewer on the SPM due to the inclusion of the FA algorithm (use 2 or more comparative active parameters eliminating false alarms by up to 96%)

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

SPO <sub>2</sub>			
Siemens	SPM-4IE	Siemens	SPM-4IE
100	99	95	95
100	99	95	94
100	99	94	93
99	97	94	93
98	97	98	97
98	98	99	97
98	96	98	97
98	96	97	97
98	96	97	96
97	96	97	96
96	96	97	97
98	97	97	97
99	99	97	97
100	99	97	96
99	99	97	96
98	99	97	95
99	99	98	96
99	99	97	97
100	99	97	97
95	94	98	96
100	99		
96	95		
95	95		
96	96		
96	95		
95	94		
96	96		

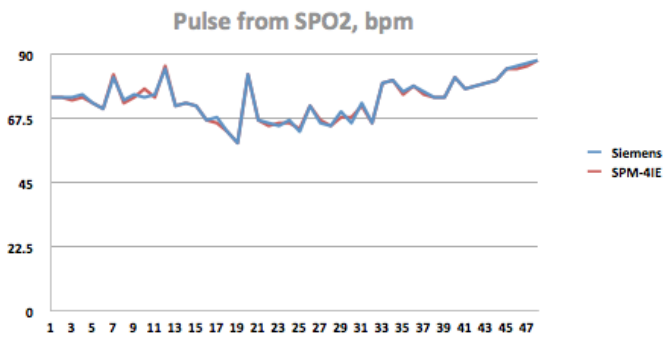


- Notes:
1. Stable and consistent
  2. Deviations due to probe placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

PLS(Saturation)			
Siemens	SPM-4IE	Siemens	SPM-4IE
75	75	70	68
75	75	66	68
75	74	73	72
76	75	66	66
73	73	80	80
71	71	81	81
82	83	77	76
74	73	79	79
76	75	77	76
75	78	75	75
76	75	75	75
85	86	82	82
72	72	78	78
73	73	79	79
72	72	80	80
67	67	81	81
68	66	85	85
63	63	86	85
59	59	87	86
83	83	88	88
67	67		
66	65		
65	66		
67	66		
63	64		
72	72		
66	67		

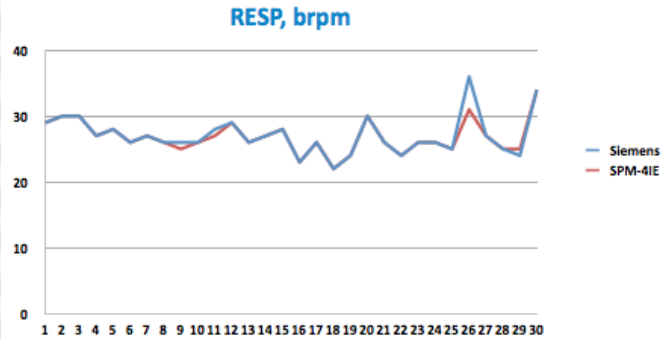


- Notes:
1. Stable and consistent

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

RESPIRATION			
Siemens	SPM-4IE	Siemens	SPM-4IE
29	29	24	25
30	30	34	34
30	30		
27	27		
28	28		
26	26		
27	27		
26	26		
26	25		
26	26		
28	27		
29	29		
26	26		
27	27		
28	28		
23	23		
26	26		
22	22		
24	24		
30	30		
26	26		
24	24		
26	26		
26	26		
25	25		
36	31		
27	27		



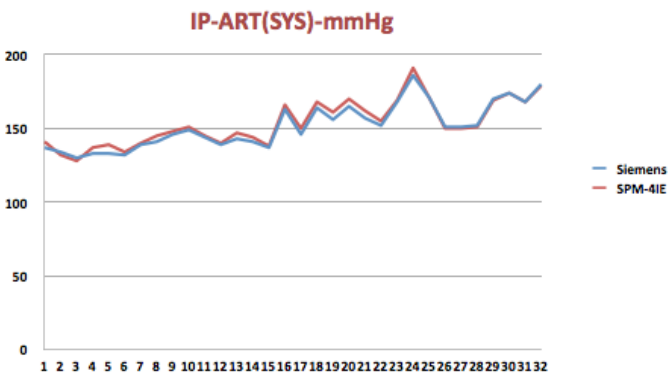
Notes:

1. Stable and consistent
2. Deviations due to inconsistent readings on Siemens monitor.
3. SPM consistent with ventilator RESP settings and reading.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-ART(SYS)			
Siemens	SPM-4IE	Siemens	SPM-4IE
137	141	170	169
134	132	174	174
130	128	168	168
133	137	180	179
133	139		
132	134		
139	140		
141	145		
146	148		
149	151		
144	145		
139	140		
143	147		
141	144		
137	138		
163	166		
146	150		
164	168		
156	161		
165	170		
157	162		
152	155		
168	169		
186	191		
171	171		
151	150		
151	150		



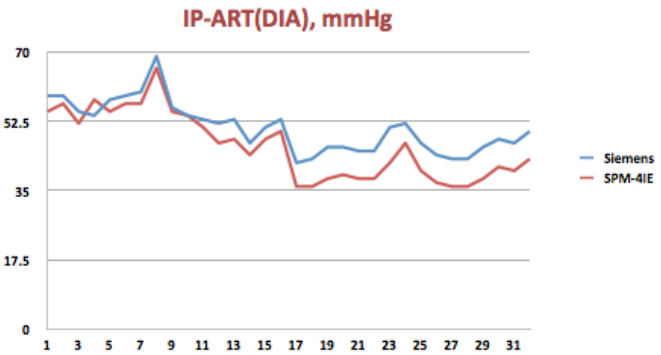
Notes:

1. Stable and consistent
2. Deviations within limits
3. Siemens monitor known for lowered IBP readings.
4. SPM transducer connected without flu

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-ART(DIA)			
Siemens	SPM-4IE	Siemens	SPM-4IE
59	55	46	38
59	57	48	41
55	52	47	40
54	58	50	43
58	55		
59	57		
60	57		
69	66		
56	55		
54	54		
53	51		
52	47		
53	48		
47	44		
51	48		
53	50		
42	36		
43	36		
46	38		
46	39		
45	38		
45	38		
51	42		
52	47		
47	40		
44	37		
43	36		

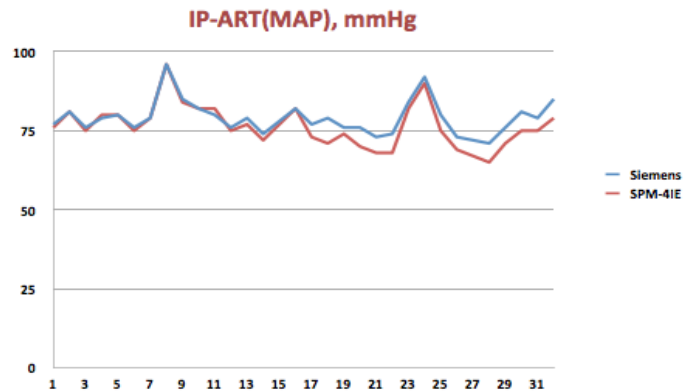


- Notes:
1. Stable and consistent
  2. Deviations within limits
  3. Siemens monitor known for lowered IBP readings.
  4. SPM transducer connected without flush line pressure.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-ART(MAP)			
Siemens	SPM-4IE	Siemens	SPM-4IE
77	76	76	71
81	81	81	75
76	75	79	75
79	80	85	79
80	80		
76	75		
79	79		
96	96		
85	84		
82	82		
80	82		
76	75		
79	77		
74	72		
78	77		
82	82		
77	73		
79	71		
76	74		
76	70		
73	68		
74	68		
84	82		
92	90		
80	75		
73	69		
72	67		

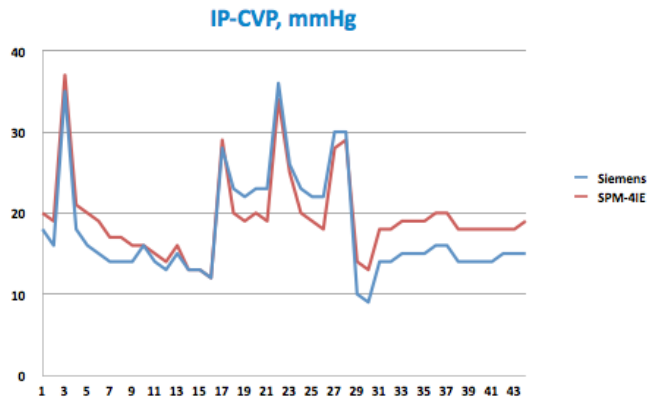


- Notes:
1. Stable and consistent
  2. Deviations within limits
  3. Siemens monitor known for lowered IBP readings.
  4. SPM transducer connected without flush line pressure.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

IP-CVP			
Siemens	SPM-4IE	Siemens	SPM-4IE
18	20	10	14
16	19	9	13
35	37	14	18
18	21	14	18
16	20	15	19
15	19	15	19
14	17	15	19
14	17	16	20
14	16	16	20
16	16	14	18
14	15	14	18
13	14	14	18
15	16	14	18
13	13	15	18
13	13	15	18
12	12	15	19
28	29		
23	20		
22	19		
23	20		
23	19		
36	34		
26	25		
23	20		
22	19		
22	18		
30	28		



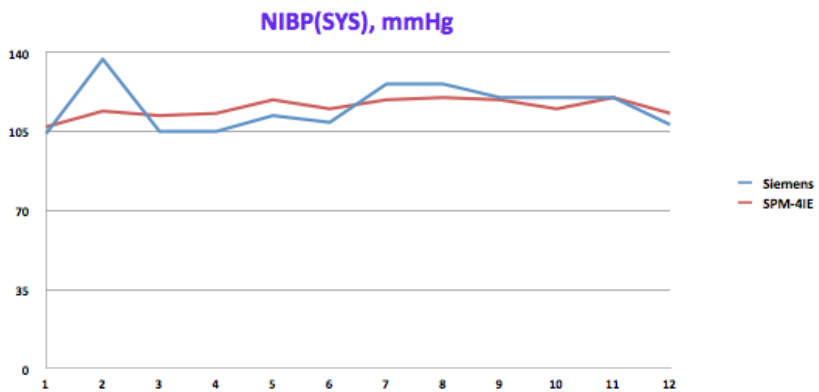
Notes:

1. Deviations noted.
2. Siemens monitor known for lowered CVP readings.
3. SPM transducer connected without flush line pressure.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

NIBP(SYS)	
Siemens	SPM-4IE
104	107
137	114
105	112
105	113
112	119
109	115
126	119
126	120
120	119
120	115
120	120
108	113



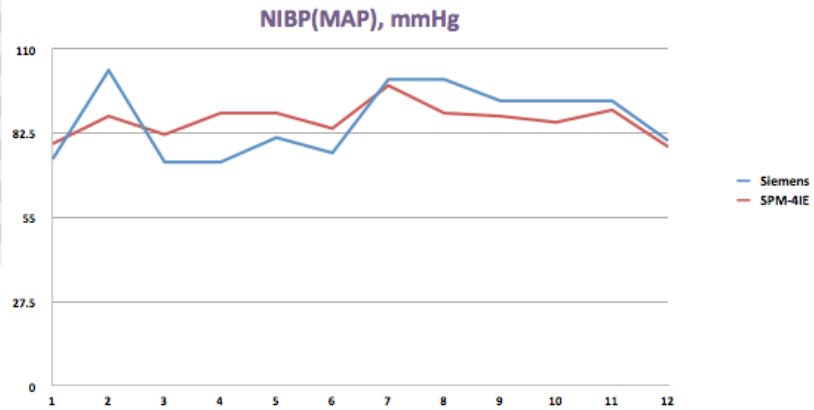
Notes:

1. Stable and consistent
2. Deviations due to cuff placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

NIBP(MAP)	
Siemens	SPM-4IE
74	79
103	88
73	82
73	89
81	89
76	84
100	98
100	89
93	88
93	86
93	90
80	78



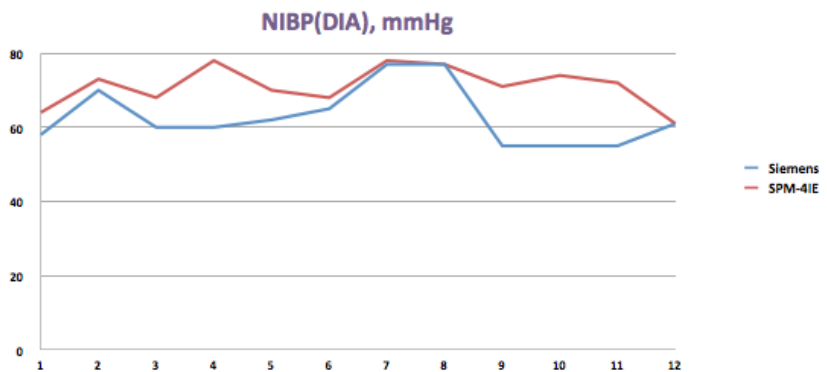
Notes:

1. Stable and consistent
2. Deviations due to cuff placement (Siemens left, SMP right hand) but within acceptable operating limits.

**SAAD Patient Monitoring - Comparative Analysis, Siemens SC 7000 PM**  
(6-2-2008 to 13-2-2008)

**Test Results (Comparative Patient Parameters)**

NIBP(DIA)	
Siemens	SPM-4IE
58	64
70	73
60	68
60	78
62	70
65	68
77	78
77	77
55	71
55	74
55	72
61	61



Notes:

1. Stable and consistent
2. Deviations due to cuff placement (Siemens left, SMP right hand) but within acceptable operating limits.

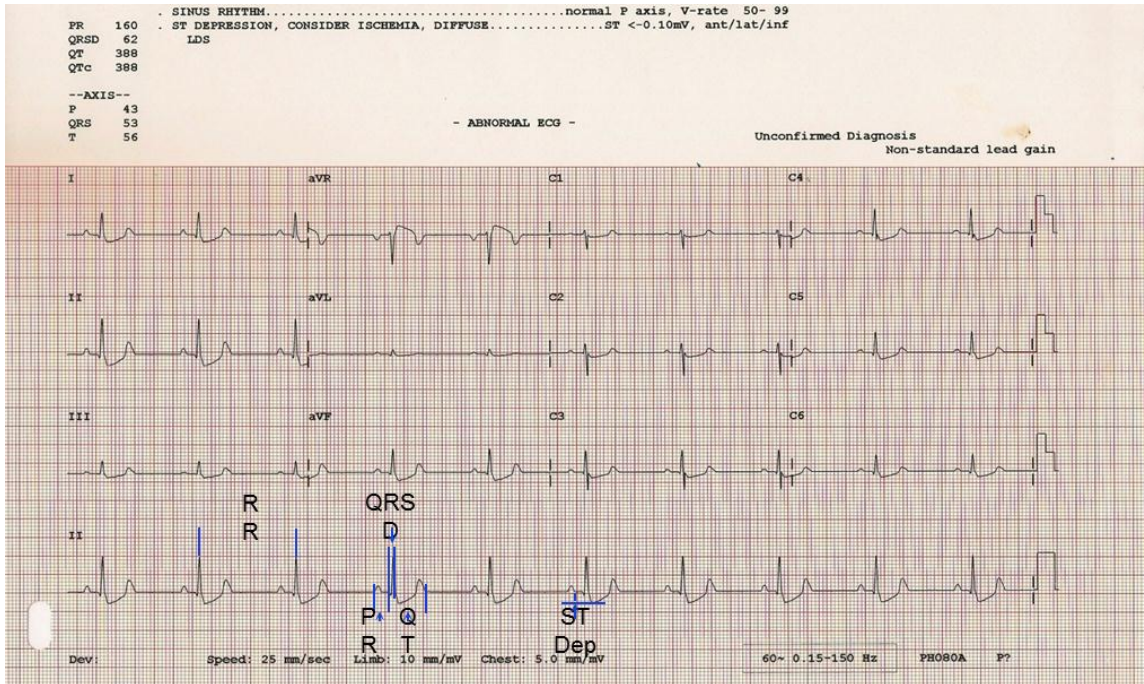
## Appendix C – Chapter 5 Reference Documentation (Experimentation, Results and Findings)

The graphs presented in this section represent the conventional analogue measurements compared to the electronically derived measurements used in the experimentation as is presented in **Chapter 5**. A diagram set is made up of an analogue graph as is produced using a standard 12 Lead ECG plotter versus the software tool showing the electronic computations as is explained in Appendix A.

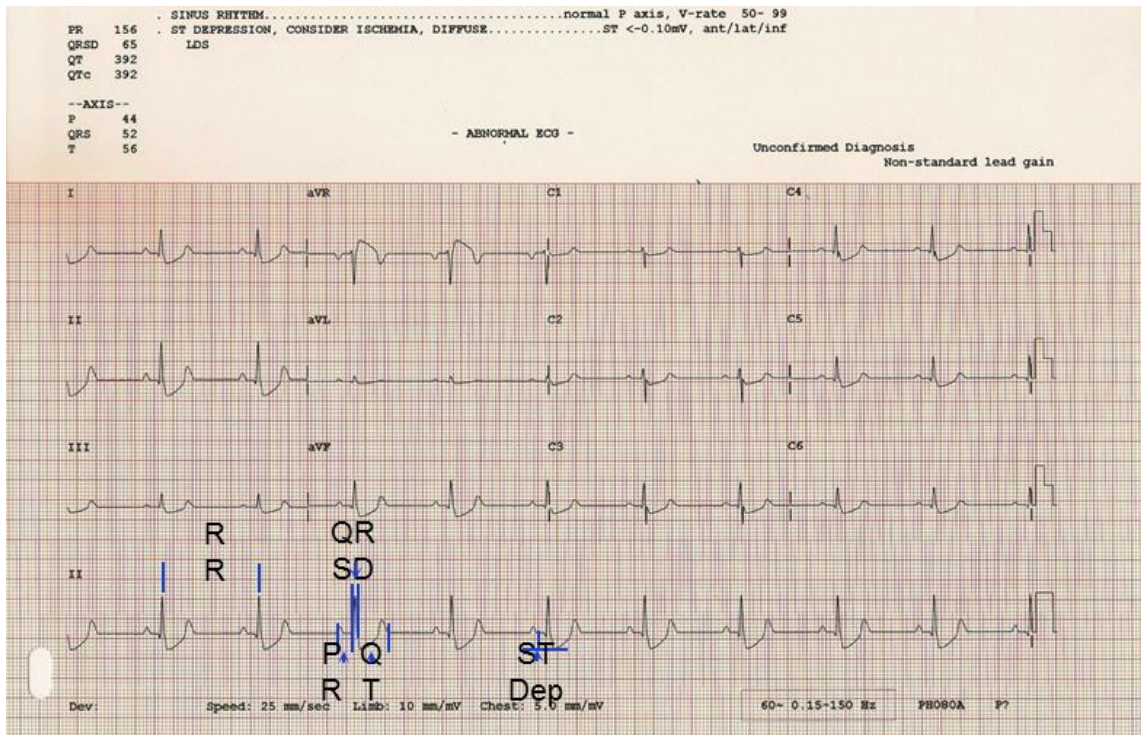
The measurement points of the various timing intervals used in the study are indicated on the graph whereas the second image in the set depicts the numerical output of the same data section.



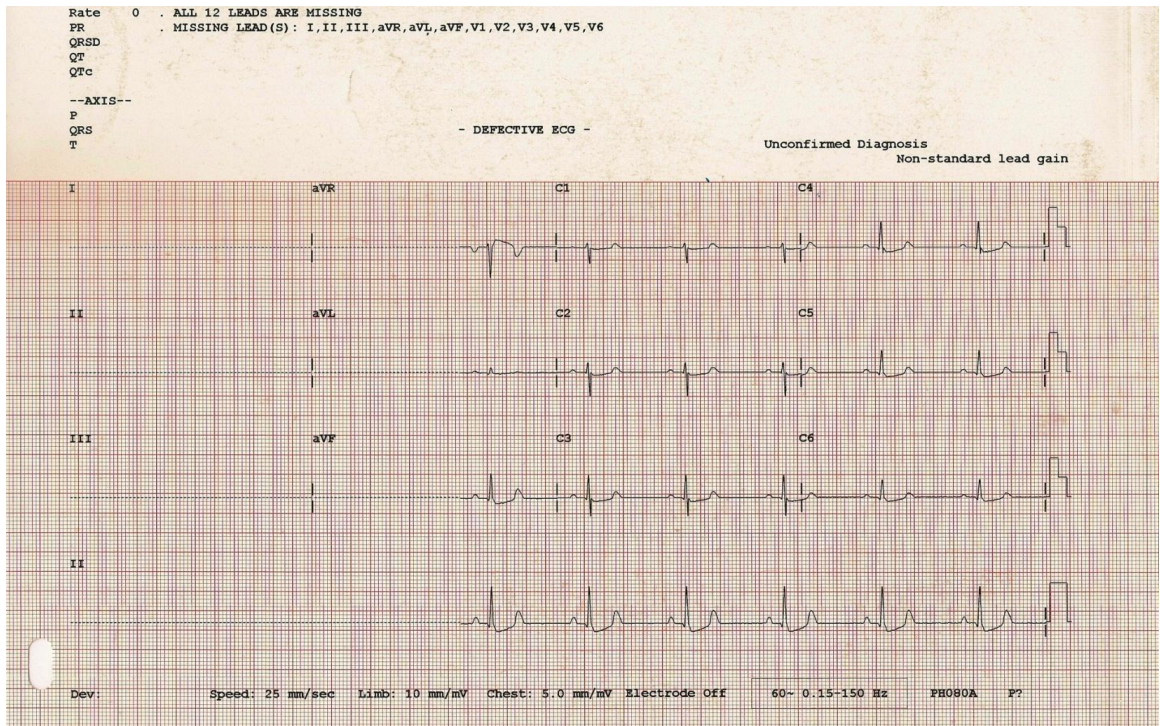
P1



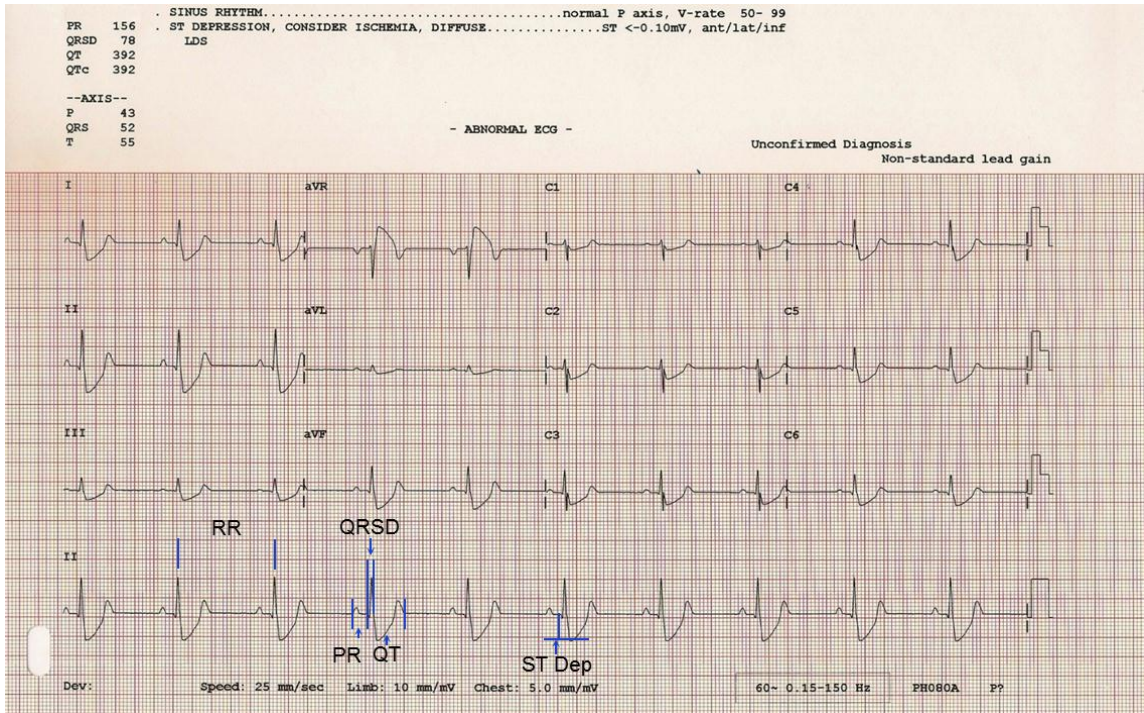
P2



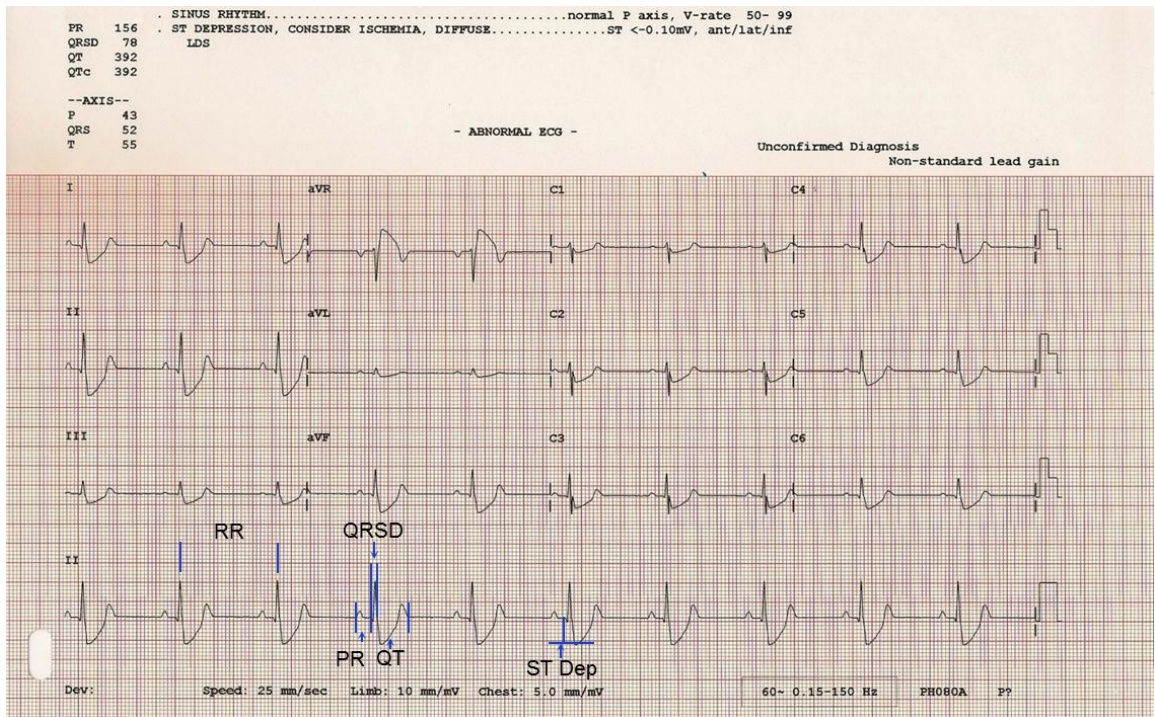
P3

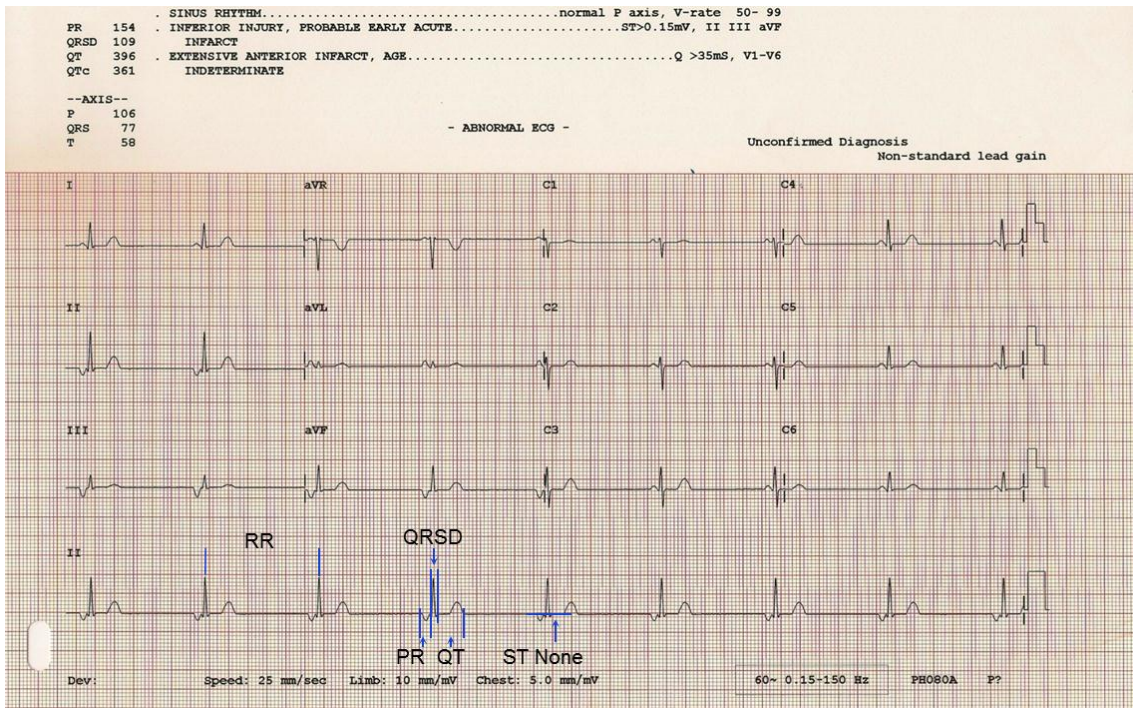


P4

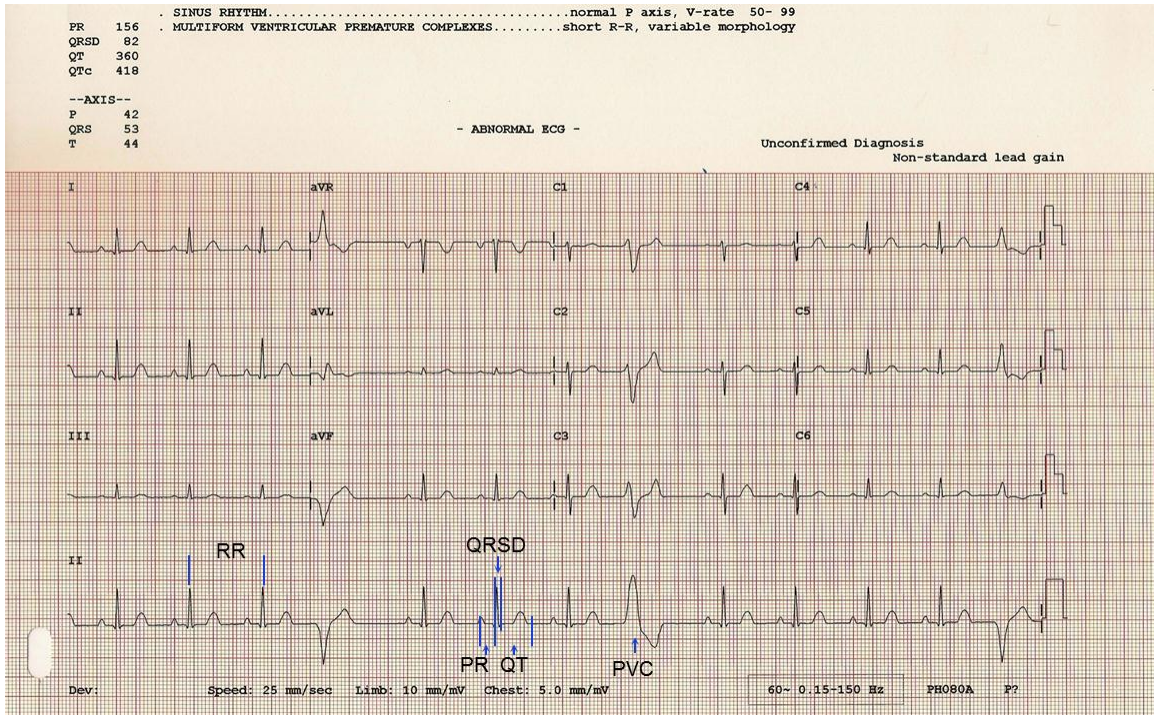


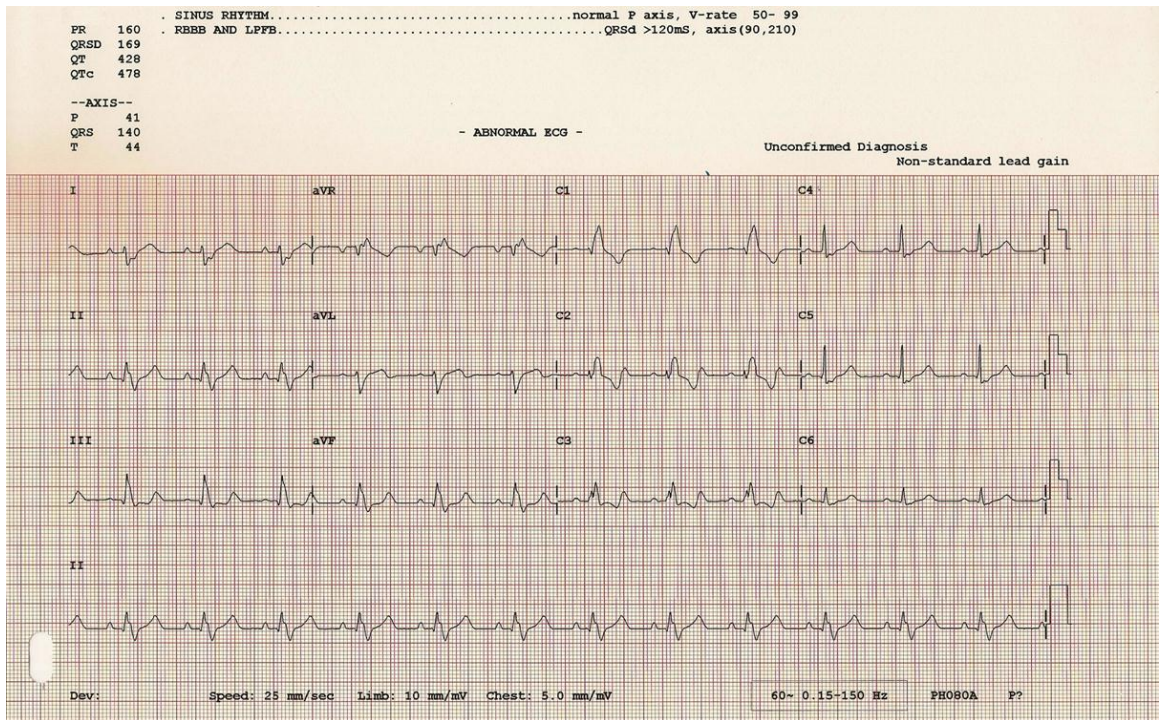
P5



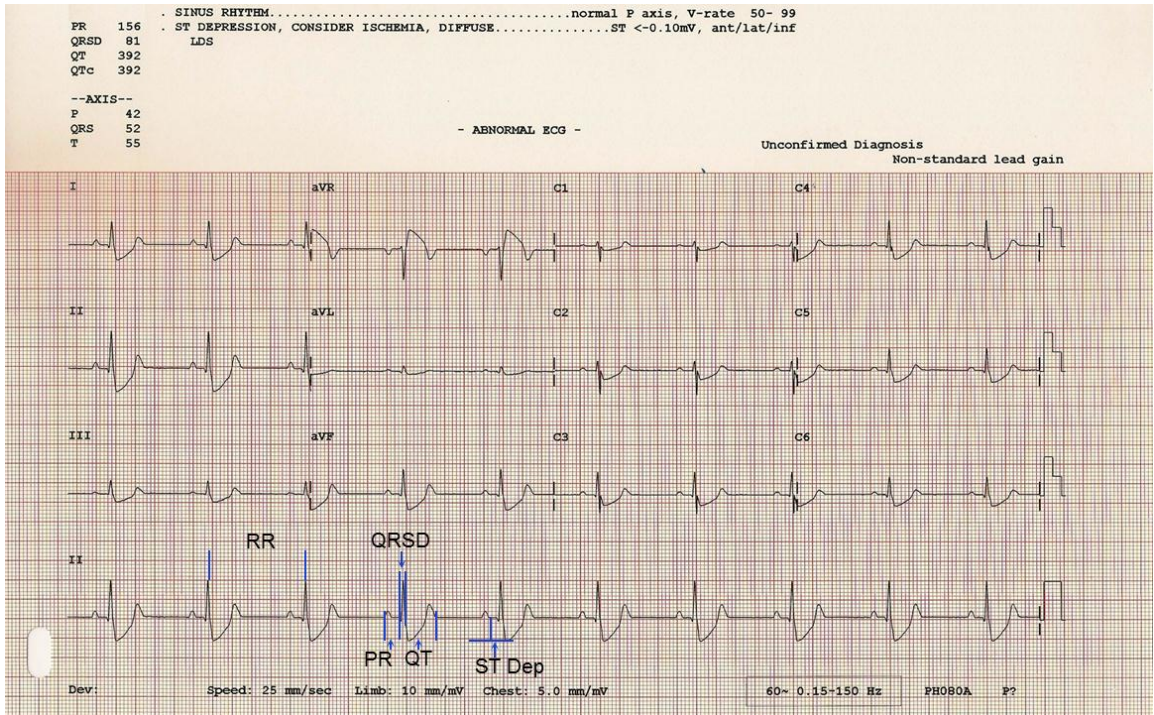


P7

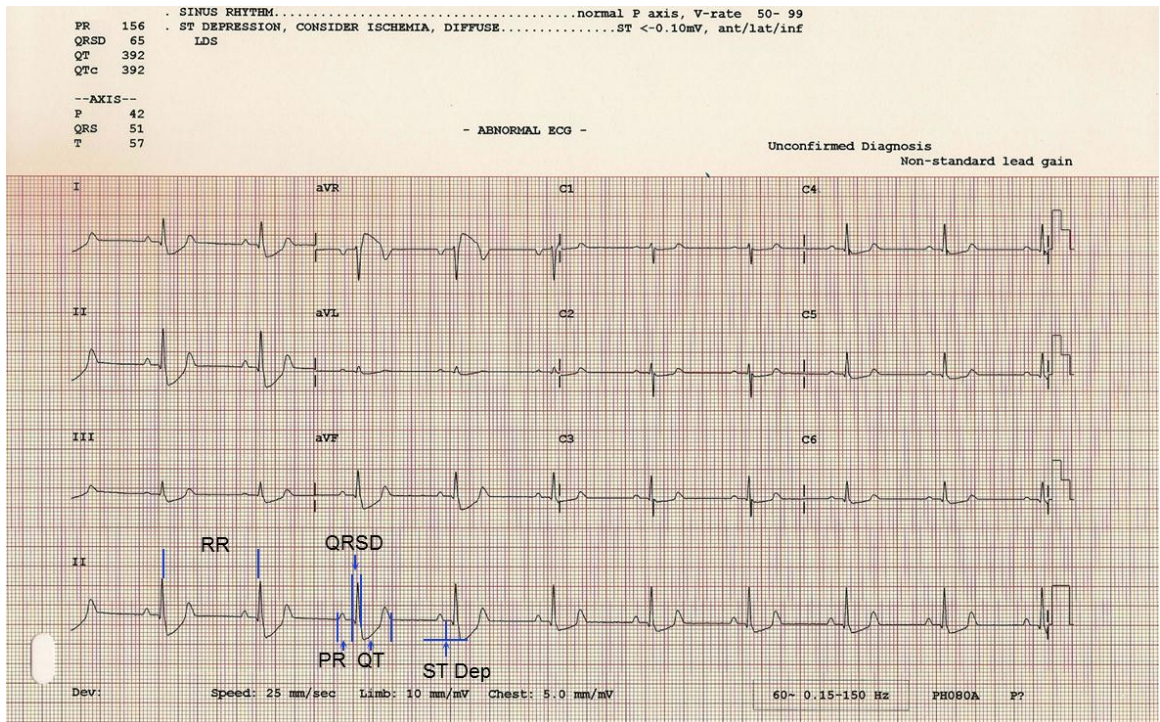




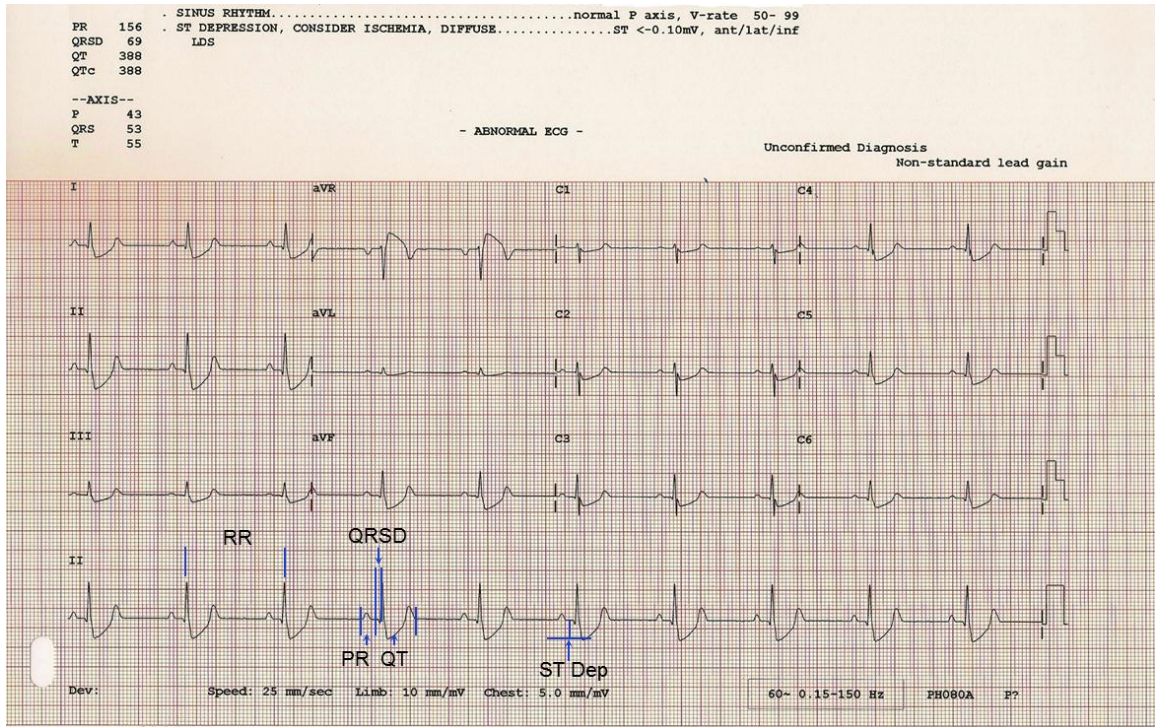




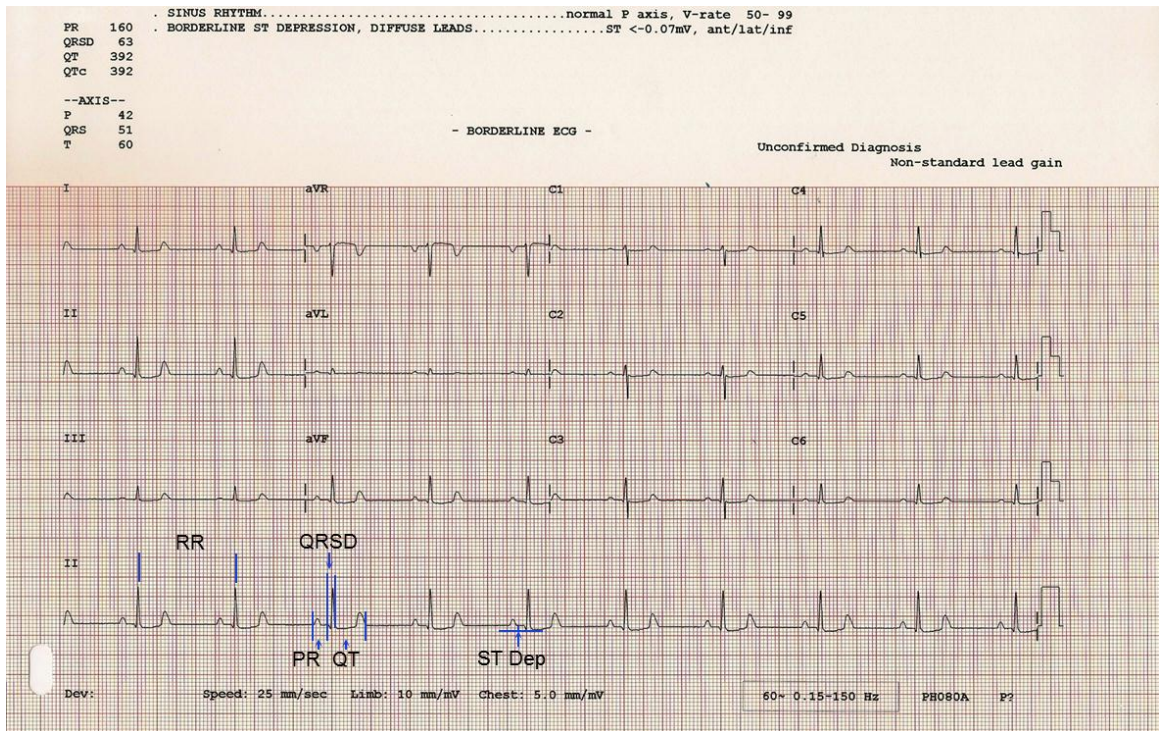
P10

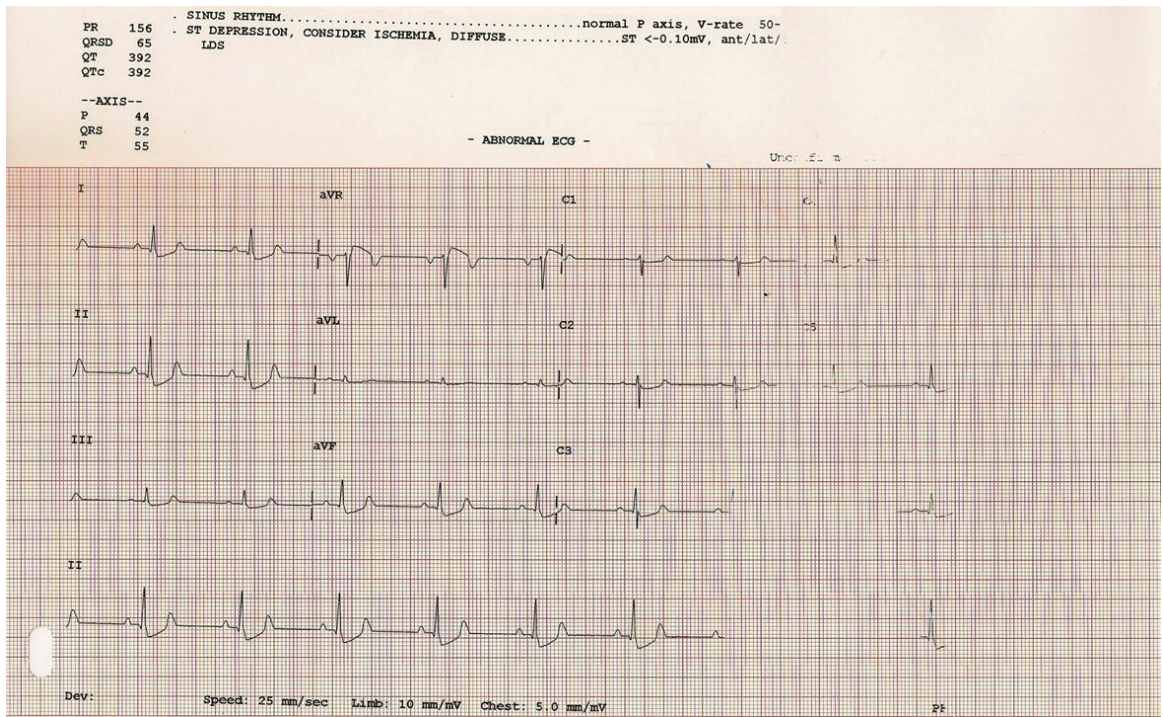


P11

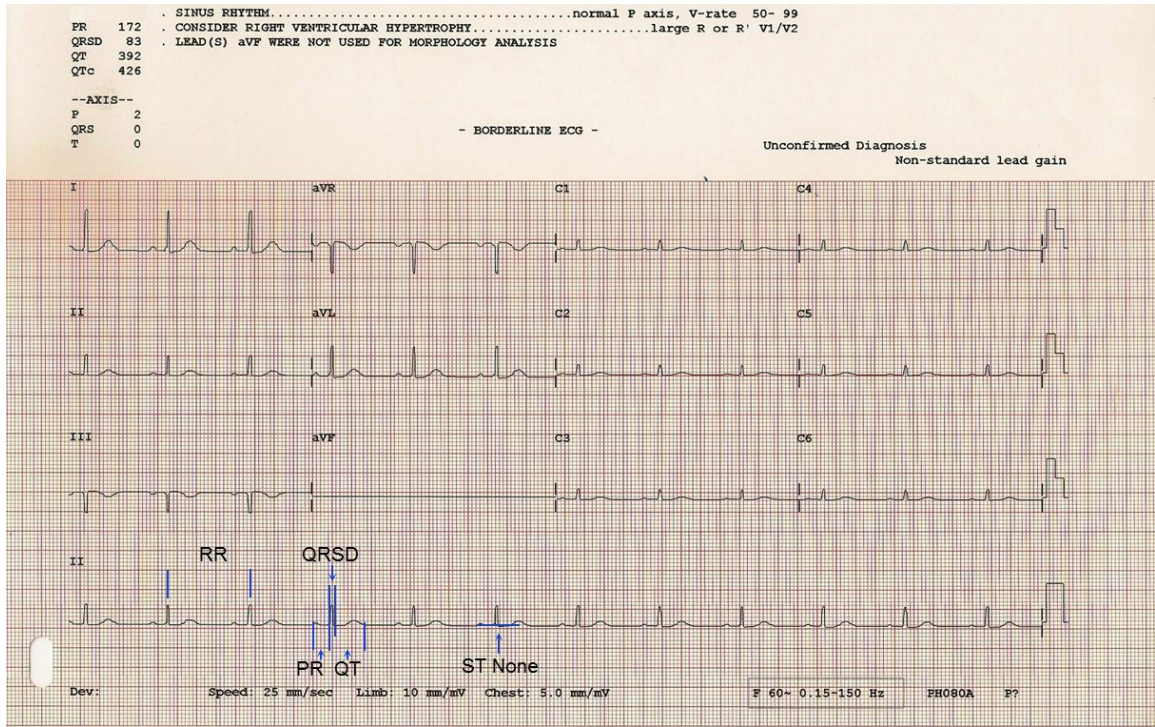


P12

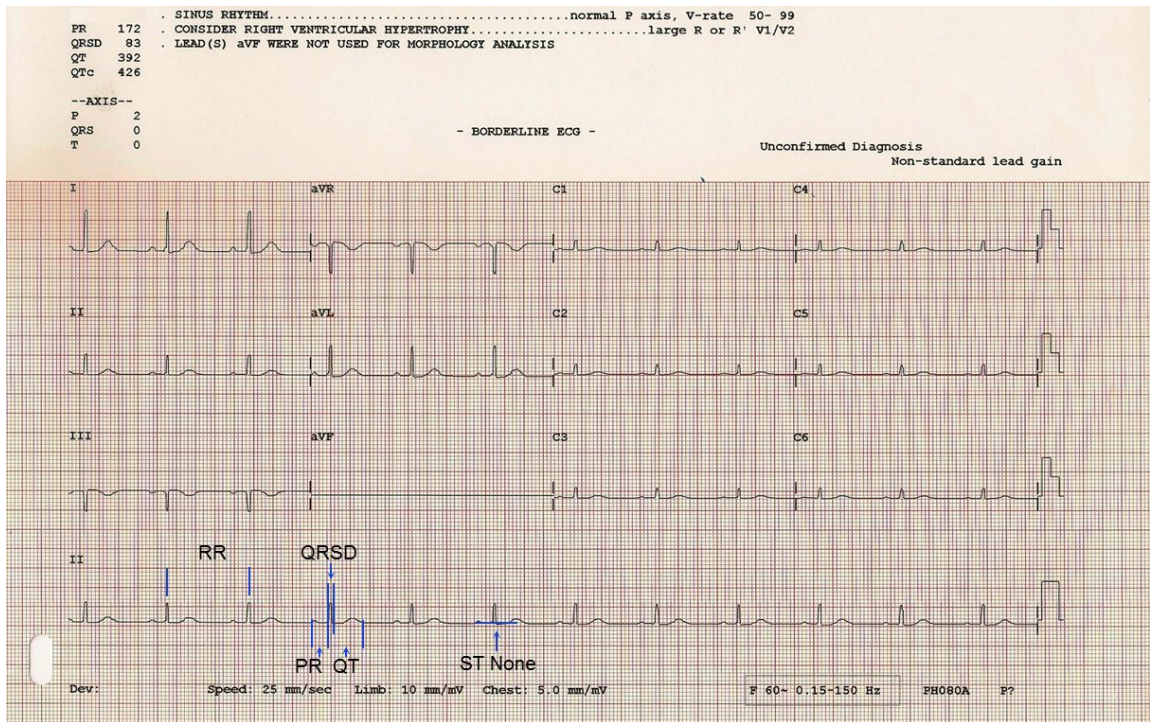


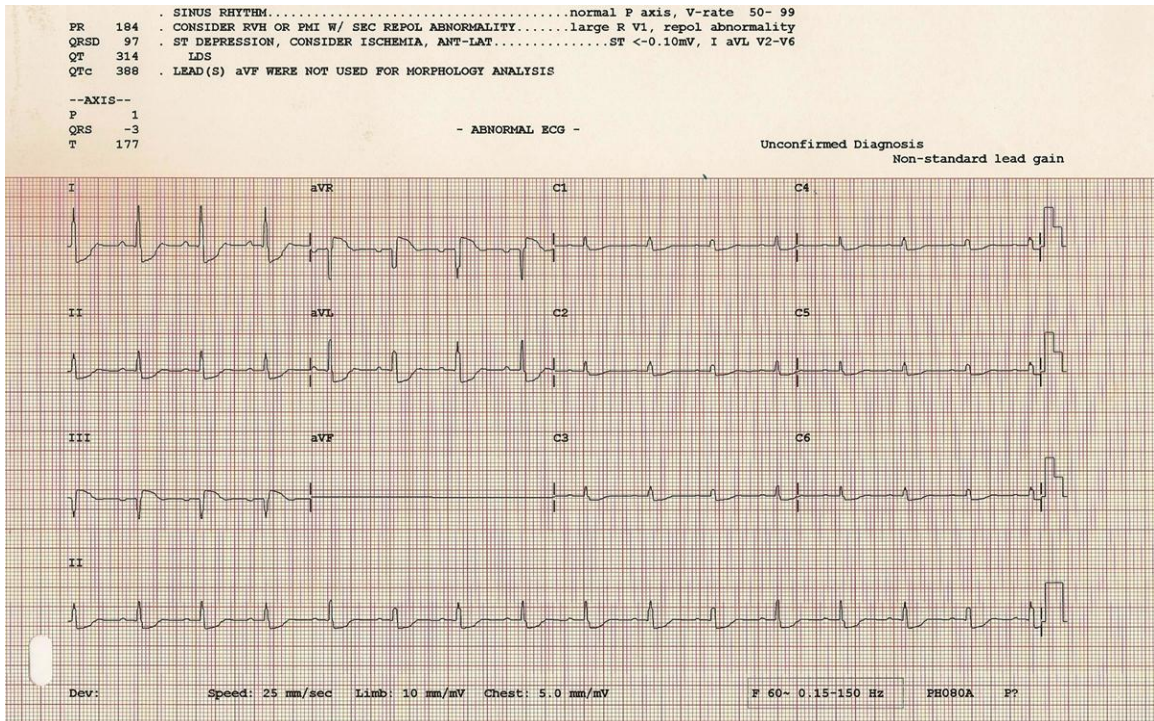
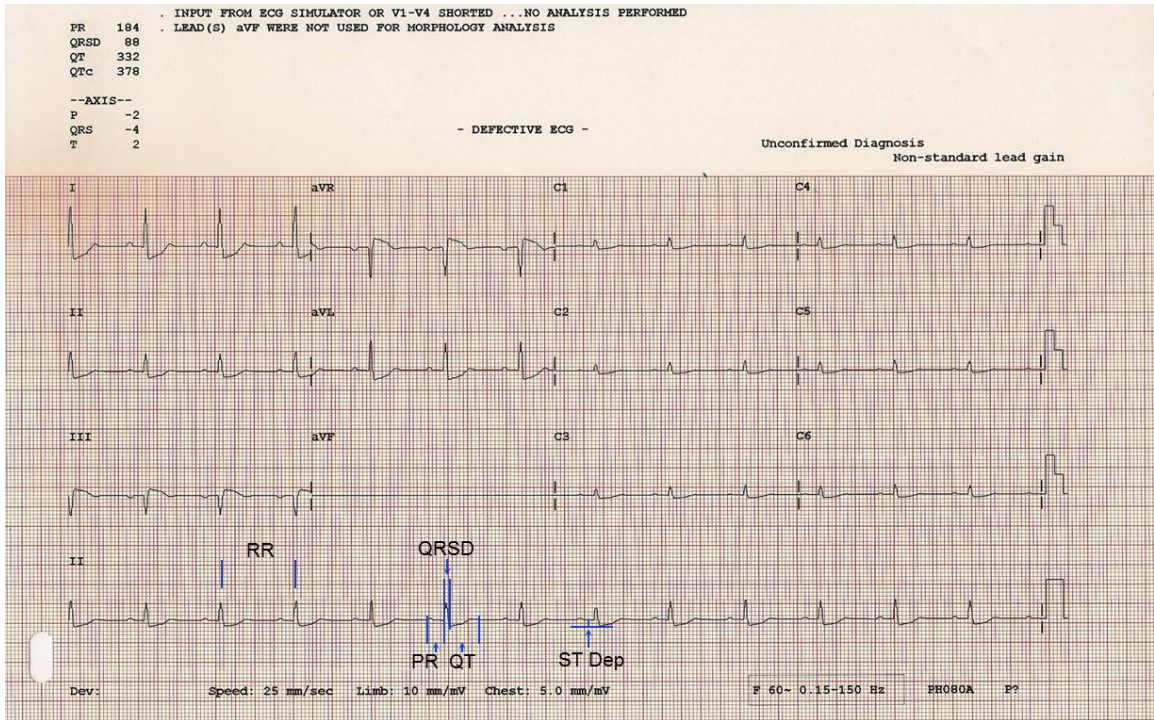


P14



P15





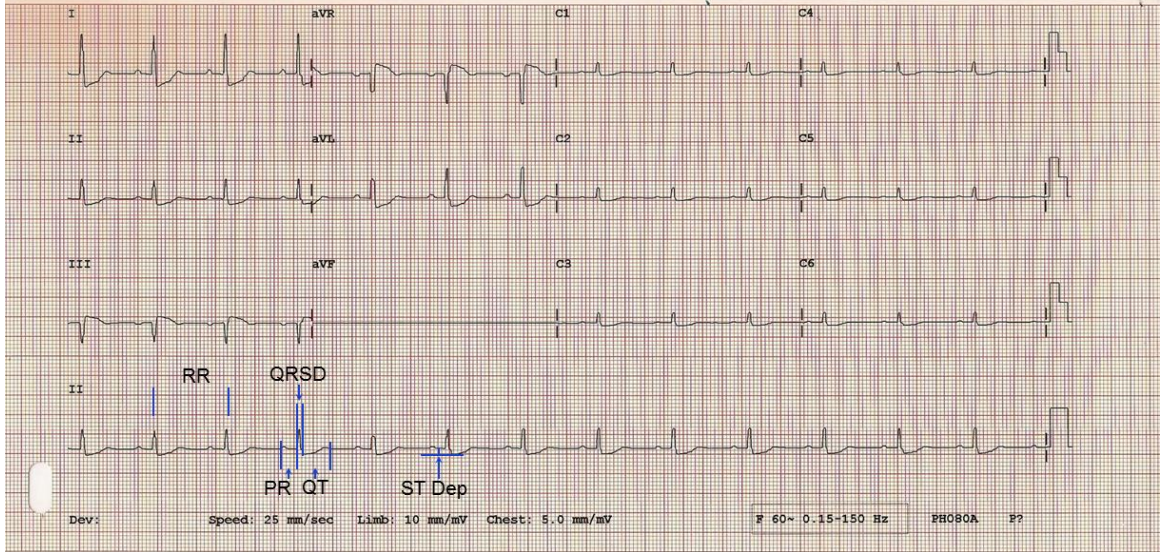


SINUS RHYTHM.....normal P axis, V-rate 50- 99  
 FR 188 . CONSIDER RVH OR PMI W/ SEC REPOL ABNORMALITY.....large R V1, repol abnormality  
 QRSD 92 . ST DEPRESSION, CONSIDER ISCHEMIA, ANT-LAT.....ST <-0.10mv, I avL V2-V6  
 QT 330 . LDS  
 QTc 378 . LEAD(S) aVF WERE NOT USED FOR MORPHOLOGY ANALYSIS

--AXIS--  
 P -1  
 QRS 0  
 T

- ABNORMAL ECG -

Unconfirmed Diagnosis  
 Non-standard lead gain

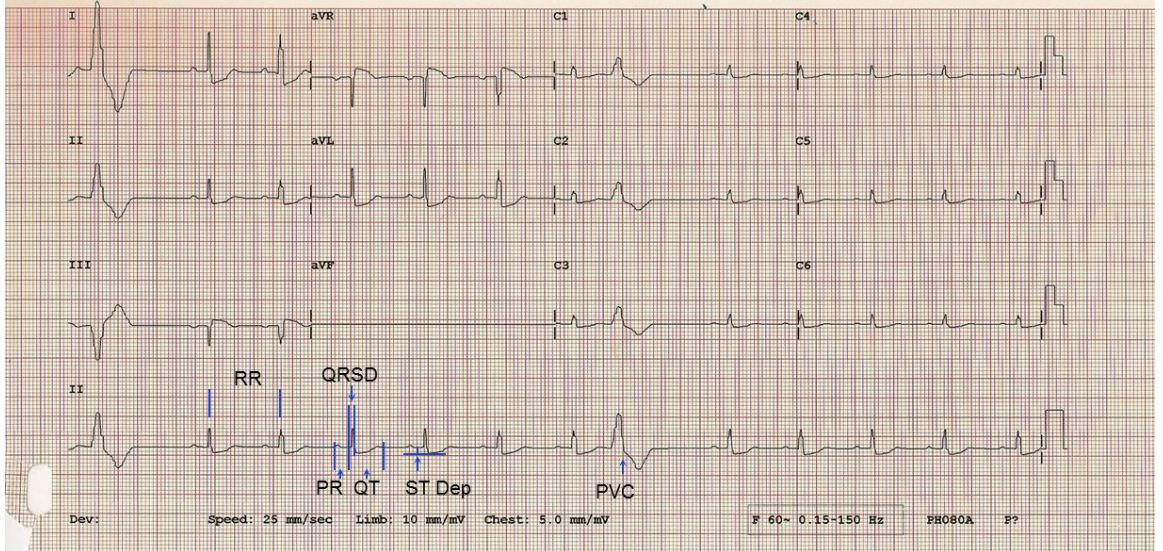


SINUS RHYTHM.....normal P axis, V-rate 50- 99  
 FR 188 . CONSIDER RVH OR PMI W/ SEC REPOL ABNORMALITY.....large R V1, repol abnormality  
 QRSD 85 . ST DEPRESSION, CONSIDER ISCHEMIA, ANT-LAT.....ST <-0.10mv, I avL V2-V6  
 QT 324 . LDS  
 QTc 376 . LEAD(S) aVF WERE NOT USED FOR MORPHOLOGY ANALYSIS

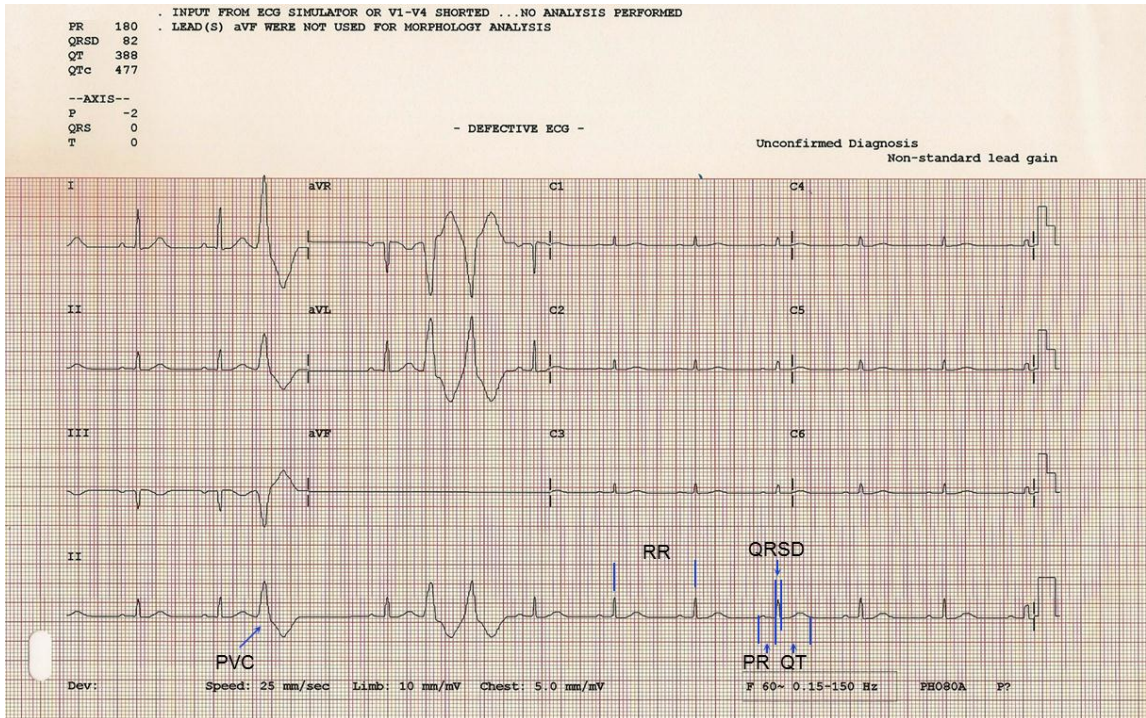
--AXIS--  
 P -1  
 QRS -2  
 T -9

- ABNORMAL ECG -

Unconfirmed Diagnosis  
 Non-standard lead gain







C:\RecordOld\Record PDH Data Main\5-05-16-32.rec

Clinical Related Values Time-Base & COM Control Alarm Control GATEWAY SPM Live

Pulse-Wave Data

P - High: 241 Curr Wave Value: 143 Reset Counter: 1 Packet Counter: 25 83  
 P - AVR: 172 Curr DIFF Value: -4 AVR Reset: 25 Cur ECG Tag: TEnd  
 P - Low: 103 Curr Pulse Total: --- Diff Amp: 2 Q - ST: 9 125  
 Q Index: 5

Controls

Sampling LEAD: RA -> II  
 ECG Draw Interval: ST  
 Draw Method: Color Selector  
 ST Det Border: 4

Wavel ON/OFF  
 QRS Pulse  
 P-Wave Pulse  
 ECG / ART  
 Smoothing  
 Tag / Diff  
 P-Wave AUTO

Record Close / Stop  
 Ph.D Pause  
 Clear Exit

QRS Det On / Off  2nd Draw  
 TXT Wave DIFF Value  
 QRS Ratio: 60  
 Draw Speed: 1

ECG Segments (Pct Count + Value)

P-Start	P-End	P-Wave Index
63	0	5
PR-End	QRS	
73	78	
ST-Start		
9		
T-Start	T-End	
13	20	

PR Interval: 178  
 QRS Interval: 73.5

ARR-ST Deviation

STI	STaVR	STII	STaVL	STIII	STaVF	STC
-0.18	0.13	-0.07	-0.13	0.09	-0.02	-0.07

PVC Count: 1 Reset: 15  
 PVCs' L min: 12 P-Count: 0  
 PVC / min: 4 0.8

MI Moderate: 0 PAUSE: False P Wave Index OK  
 Tachy: None QTC: False PVC: False  
 Brady: None VENT FIB: NONE

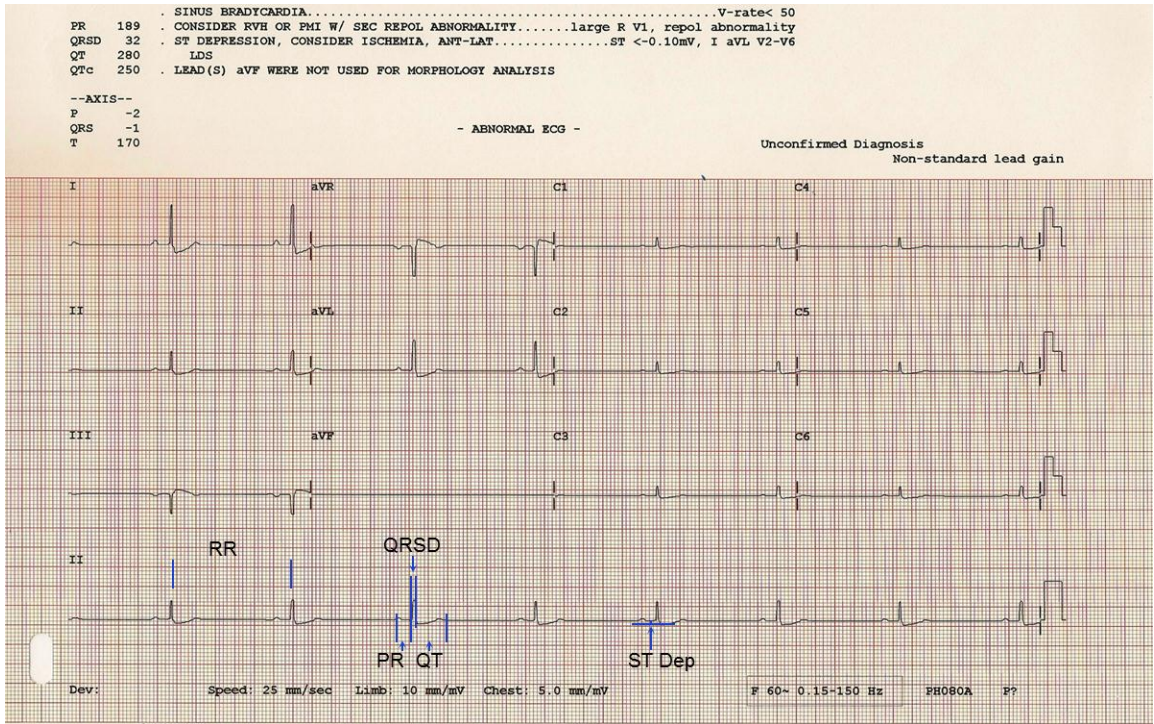
Draw ON / OFF  Draw Back Color

++ CAL ECG ++ ++ DIF L2 ++  
 - CAL ECG - - DIF L2 -

HR - ECG (bpm) 69.44 75.4  
 SPO2 (%) PLS (bpm)  
 aBT (mmHg)  
 PAP (mmHg)  
 CVP (mmHg)  
 etCO2 (mmHg)  
 TEMO (°C)  
 RESP

5/12/2009  
 Start: 5:15:18  
 Now: 5:16:30  
 End: 5:17:32

P18



C:\Record\Old\p20.rec

Clinical Related Values Time-Base & COM Control Alarm Control GATEWAY SPM Live

Pulse-Wave Data

P - High: 220 Curr Wave Value: 127 Reset Counter: 5 Packet Counter: 60 107  
 P - AVR: 156 Curr DIFF Value: 0 AVR Reset: 50 Cur ECG Tag: TEnd  
 P - Low: 93 Curr Pulse Total: --- Diff Amp: 2 Q - ST: 23 126

Controls

Sampling LEAD: RA -> II  Wave ON/OFF  
 QRS Pulse  
 ECG Draw Interval: ST  P-Wave Pulse  
 ECG / ART  
 Draw Method: Color Selector  Smoothing  
 Tag / Diff  
 ST Det Border: 4  P-Wave AUTO

Record Close / Stop  
 Ph.D Pause  
 Clear Exit

QRS Det On / Off 2nd Draw  
 TXT Wave DIFF Value  
 QRS Ratio: 60  
 Draw Speed: 1

ECG Segments (Pct Count + Value)

P-Start	P-End	P-Wave Index
89	0	5
PR-End	QRS	
101	106	
ST-Start		
9		
T-Start	T-End	
13	21	

PR Interval: 180.8  
 QRS Interval: 46.2

ARR-ST Deviation

STI	STaVR	STII	STaVL	STIII	STaVF	ST C
-0.42	0.33	-0.11	-0.31	0.23	-0.03	-0.23

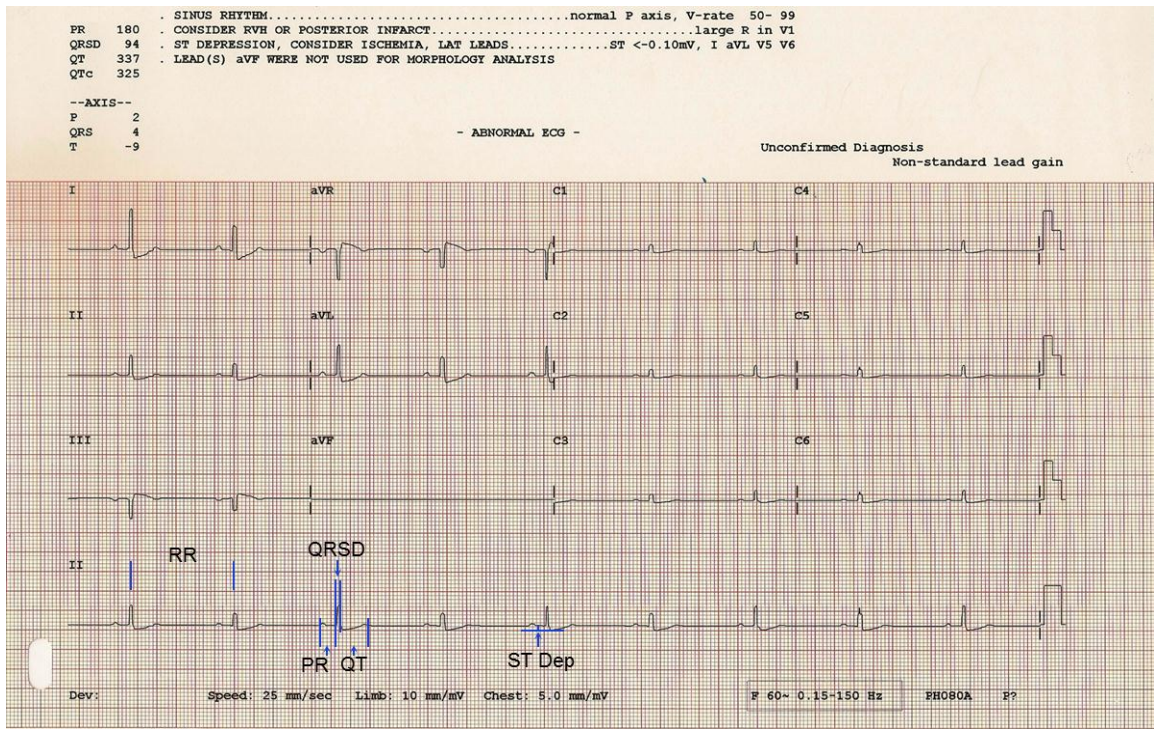
PVC Count: 0 Reset: 42  
 PVCs' L/min: 0 P-Count: 0  
 PVC/min: 27 0.8

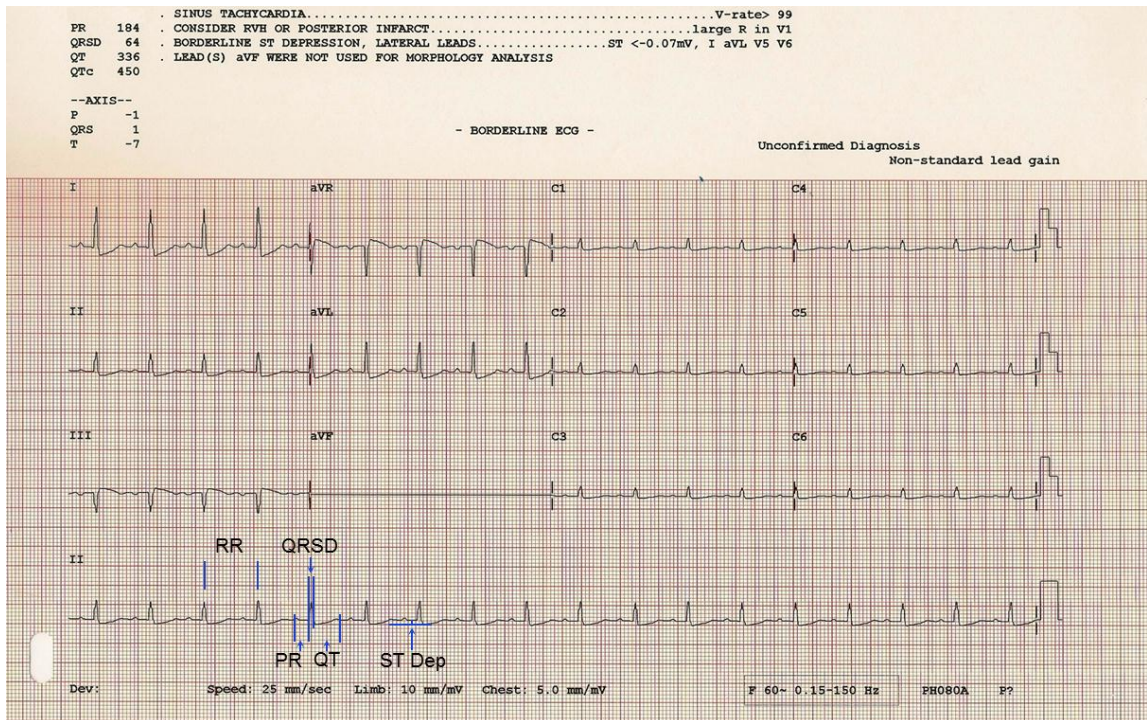
MI: None PAUSE: False P-Wave Index OK  
 Tachy: None QTc: False PVC: False  
 Brady: None VENT.FB: NONE

Draw ON / OFF Draw Back Color  
 ++ CAL ECG ++ ++ DIF L2 ++  
 - CAL ECG - - DIF L2 -

HR - ECG (bpm) 67.7  
 67.57 50.2  
 SPO2 (%) PLS (bpm)  
 ART (mmHg)  
 PAP (mmHg)  
 CVP (mmHg)  
 etCO2 (mmHg)  
 TEMO (°C)  
 RESP

6/12/2009  
 Start: 1:19:46  
 Now: 1:21:00  
 End: 1:22:00





C:\Record\Old\P21.rec

Clinical Related Values Time-Base & COM Control Alarm Control GATEWAY SPM Live

Pulse-Wave Data  
 P - High: 223 Curr Wave Value: 124 Reset Counter: 46 Packet Counter: 44 107  
 P - AVR: 158 Curr DIFF Value: 0 AVR Reset: 50 Cur ECG Tag: TEnd  
 P - Low: 93 Curr Pulse Total: --- Diff Amp: 2 Q - ST: 24 126  
 Q Index: 5

Controls  
 Sampling LEAD: RA -> II Wave ON/OFF  
 QRS Pulse  
 P-Wave Pulse  
 ECG / ART  
 Smoothing  
 Tag / Diff  
 P-Wave AUTO  
 ECG Draw Interval: ST  
 Draw Method: Color Selector  
 ST Det Border: 4

QRS Det On / Off  2nd Draw  
 TXT Wave DIFF Value  
 QRS Ratio: 60  
 Draw Speed: 1

ECG Segments (Pct Count + Value)  
 P-Start P-End P-Wave Index  
 49 0 4  
 PR-End QRS  
 49 54  
 ST-Start  
 9  
 T-Start T-End  
 13 21  
 PR Interval: 191  
 QRS Interval: 57.95

ARR-ST Deviation  
 STI: -0.46 STaVR: 0.34  
 STII: -0.12 STaVL: -0.34  
 STIII: 0.25 STaVF: -0.02  
 ST C: -0.25

PVC Count: 0 Reset: 0  
 PVCs' L.min: 18 P-Count: 1  
 PVC / min: 55 0.8

Draw ON / OFF  Draw Back Color

HR - ECG (bpm) 80.0  
 80.43 109  
 SPO2 (%) PLS (bpm) ---  
 ART (mmHg) ---  
 PAP (mmHg) ---  
 CVP (mmHg) ---  
 e(CO2) (mmHg) ---  
 TEMO (cC) ---  
 RESP ---

6/12/2009  
 Start: 1:22:01  
 Now: 1:22:40  
 End: 8:24:11

P21

