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Dr. Andrew Rawicz School of Engineering Science Simon Fraser University Burnaby, BC, V5A 1S6

Re: ENSC 340 Project Palm[™] Bio-Reader Functional Specification

Dear Dr. Rawicz,

We have attached the *PalmTM Bio-Reader Functional Specification* based on the project described in the proposal we submitted previously. Our product, VitalChart, allows the display and storage of biofeedback data in the form of an EKG waveform and the respiration rate for patient monitoring in hospitals.

The functional specification describes in detail the goals we plan to achieve for this project. The functions of each component of our system, as well as overall system operational specifications, are discussed. In addition, individual components are separated according to their priorities during development, and are indicated by the difference in colour and bullet type.

Please feel free to contact us should you have any questions, comments or concerns. We can be reached by email through vitalstatis-med@sfu.ca or by phone through See-Ho Tsang, our CEO, at 604-274-1888 (home) or 604-818-7899 (cell). Thank you for your time.

Sincerely,

See-Ho Tsang

See-Ho Tsang CEO VitalStatis Medical Solutions

Enclosure: Palm TM Bio-Reader Functional Specification



Palm[™] Bio-Reader Functional Specification

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|----------------|---|
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Executive Summary

As the Canadian population ages, the state of health care is an increasingly significant issue. Most hospitals have limited beds, and are understaffed. By combining an electrocardiogram (EKG) and respiration rate monitor together on a portable handheld device, our proposed product, VitalChart, automates and simplifies patient charting in order to improve the efficiency of healthcare professionals.

Our product consists of a hardware module that clips on to the serial port of a Palm[™] m500 series personal digital assistant (PDA) as well as a software package containing a graphical user interface (GUI) and a database system. The hardware module facilitates the capture of biofeedback readings from a patient via EKG electrodes and a solid state accelerometer. The collected data is sent to the Palm[™] OS by a microcontroller using RS-232 serial communication protocol. The software package will perform the serial communication control and the necessary manipulation of the data for display and storage.

VitalChart will display the waveform created by contraction of the heart on a scale from 0 to 5 seconds in addition to the numerical heartbeats per minute. The hardware module will also calculate the number of breaths per minute and display it on the GUI.

Additions to the minimal requirements include a sophisticated scaling system that allows the user to view more, or less detail of the EKG waveform as well as retrieval of previously recorded data for viewing and editing.

The VitalChart hardware module will be contained in a light compact package that is functional as well as cosmetically attractive, and at a low cost to the customer.

In order to meet the requirements, a meticulous test plan, including the consideration of international standards, is implemented to ensure good quality and performance of our product.

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Glossary

| AAMI | The Association for the Advancement of medical instrumentation, standards body |
|---------------|---|
| AC | Alternating current, electric current that reverses in direction periodically |
| ANCI | (i.e. current from Wall Sockets) |
| ANSI | American National Standards Institute, US standards body |
| Baud rate | Measurement of speed in data transmission, equals to one bit per second |
| Biofeedback | an autonomic bodily function, such as heart rate or blood pressure |
| Bit | Fundamental unit of digital information having possible values of either 0 or 1 |
| bps | Bits per second, unit of measurement of baud rate |
| Bvte | Collection of 8 bits |
| CSA | Canadian Standards Association, standards body |
| DC | Direct current electric current that flows in one direction only (i.e. current |
| | from a battery) |
| DSP | Digital signal processing, computer manipulation of analog signals that have been converted to digital form |
| EKG | Electrocardiogram, a graphical record of the cardiac cycle |
| ESD | Electrostatic discharge, also called static electricity |
| g | Gravitational constant, equals 9.8 m/s^2 |
| GUI | Graphical user interface, the screens of the software that the user interacts with |
| IEC | International Electrotechnical Commission, international standards body |
| IEEE | Institute of Electrical and Electronics Engineers, Inc., technical association |
| KB | Kilobytes, 1024 bytes |
| Multiplex | Merging of two or more signals for transmission on the same wire |
| OS | Operating system, software to interface between application and hardware |
| РСВ | Printed circuit board, a thin board to which electronic components are fixed by solder |
| PDA | Personal digital assistant, also called handheld computers |
| Pixel | Basic unit of image composition on a display |
| Protocol | Standard procedure for regulating data transmission |
| QRS | QRS complex, name of the electrocardiogram waveform. The various |
| ~ | peaks and troughs of a waveform are named P, Q, R, S, and T |
| RS-232 | A communication interface standard, also named EIA-232 |
| Serial | Method of communication in which data is sent one bit at a time through |
| Corriging and | a single challel |
| Serial port | Gateway for Serial communication |
| Stylus | ren input device of the raim ¹ ¹ handheid computer |
| UL | Underwriter's Laboratories Inc., product safety testing and certification organization |



1. Introduction

Our product, VitalChart, is an EKG and respiratory rate monitor implemented on a Palm[™] PDA. VitalChart will capture vitals, then record, store, and allow the manipulation of the data in an easy-to-use GUI. Using VitalChart, doctors and nurses can easily measure and document a patient's EKG and breathing rate, simplifying and automating common tasks in the medical industry.

This document describes the functionality of the VitalChart system in detail and includes a test plan that will be used to verify the functions. The functional requirements of the overall system and each component — EKG unit, respiratory measuring device, hardware interface, and software program, are outlined. The system overview includes a system block diagram, Palm[™] PDA specifications, power supply specifications, environmental specifications, package specifications, and standards compliance. For each hardware component, the functionality and behaviour, physical requirements, and cost will be examined. For the software program, the requirements will outline the GUI, Palm[™] interface functions, and algorithms needed to process the EKG and respiratory rate data.

The intended completion date of VitalChart is December 13, 2002 and the expected development cost is \$1165. Upon completion, our prototype will satisfy the minimum requirements required for this project. In addition, this document includes the requirements we would like VitalChart to have, namely, the ideal requirements. Time permitting, we will attempt to satisfy as many of the ideal requirements as possible. The minimum requirements can be differentiated from the ideal requirements by the type of bullet and colour of the text used.

- **D** This type of bullet and colour indicates the specification is a minimum requirement
- > This type of bullet and colour indicates the specification is an ideal requirement



2. System Overview

VitalChart is a Palm[™]-based bio-reader. It is able to measure a patient's EKG signal and respiratory rate utilizing a hardware attachment to a Palm[™] PDA. Electrodes are attached to the patient's body and the signals are sent through the hardware to the Palm[™] PDA, where they are displayed on the screen by the software. The system can be divided into three main components: measurement hardware, interface hardware, and Palm[™]-side software. The system block diagram in Figure 1 illustrates how the components in the system interact with each other.



Figure 1: System block diagram

The EKG electrodes and respiratory rate sensor continuously measure heartbeat and respiratory signals. The data is captured by the data transmission unit, and sent periodically to the Palm[™] PDA. Once the data is acquired by the PDA, the software interprets the data and displays the EKG signal and respiratory rate on the GUI. A display of the patient's EKG signal, respiratory rate, and pulse rate are arrayed in an easily read format for quick diagnosis of the patient's condition. As a future improvement, the PDA would be able to communicate and synchronize with an external patient information database via the HotSync operation, allowing easy storage and filing of patient data.



3. Overall System Requirements

The specifications stated in this section apply to the complete system. Functional specifications pertaining to individual components of the system will be described in later sections of the document.

Performance of the overall system will be guaranteed to satisfy the following minimum requirements, and as many as possible of the ideal requirements. The system must utilize a suitable PDA and meet particular power specifications. Ideally, the system should also meet suitable environmental requirements and product standards. These requirements will be outlined in the following sections.

3.1. Handheld PDA Requirements

The handheld PDA must satisfy the following requirements to be compatible with the VitalChart software.

- □ The PDA must be a Palm[™] m500 series
- □ The PDA must be running on Palm[™] OS version 4.0 or above
- □ The PDA must have a minimum of 500KB free memory for the VitalChart software
- □ The PDA must have a working 16-pin serial connector standard in the Palm[™] m500 series
- ➤ Compatibility of VitalChart should be enhanced for operating with a variety of Palm[™] PDAs without additional hardware adapters

3.2. System Power Specifications

Communication using the serial port on the Palm[™] PDA draws extra power from the Palm[™] rechargeable battery, and the hardware attachment to the Palm[™] PDA requires an external power supply to power the circuits. Our system must meet the following power specifications to ensure safe and reliable operation.

- □ The hardware attachment must operate with full functionality on a positive to negative supply voltage difference of less than 9V DC
- □ The hardware attachment power supply must have an on/off switch to control power to the hardware attachment
- > The hardware attachment power supply should be a battery
- > The hardware attachment should operate with a voltage supply variance of $\pm 10\%$
- > The power consumption of the hardware attachment should not exceed 0.5W
- The hardware attachment should operate continuously for 30 hours on a fully charged battery

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➤ The Palm[™] PDA should operate continuously with VitalChart software for a minimum of 3 hours on a fully charged battery



3.3. Package Specifications

The hardware attachment will be housed in a small and portable package. The package will satisfy the following requirements.

- **□** The package must have a rigid structure to protect the circuitry
- □ The package must not have sharp edges
- The entire hardware package excluding the PDA should not exceed 10cm in width, 5cm in length, 1cm in height
- > The package should not exceed 1 kilogram in mass
- > The package should survive a 1 metre drop without degradation of performance
- > The package should sustain shock and vibration without damage
- > The package should insulate the circuitry from up to 15kV of ESD on the package

3.4. Environmental Specifications

An important feature of our system is its portability. Therefore, the system must be able to operate under a wide range of environmental conditions. The production version of the system will meet the following environmental specifications.

- The system should operate properly with minimal degradation in performance in both indoor and outdoor environments
- > The system should operate properly under temperature ranging from -20°C to 70°C
- The system should operate properly under relative humidity range of 0% to 98% non-condensing
- > The system should operate properly under normal atmospheric pressure
- The sensors should operate properly with minimal degradation in performance upon variation in patient's body temperature and skin secretion
- > The system should not be affected by external high frequency signals



4. Standards Compliance

The production version of VitalChart will comply with medical and operational standards to ensure safe and reliable usage of the system in the environments specified in the environmental specifications (section 3.4). The following list encompasses the minimum standards VitalChart will adhere to.

- ANSI/AAMI EC11 minimum safety and performance requirements for electrocardiographic systems with direct writing devices which are intended for use in the analysis of rhythm and of detailed morphology of complex cardiac complexes
- ANSI/AAMI EC12 minimum labeling, safety and performance requirements; test methods; and terminology for disposable electrocardiographic electrodes
- ANSI/AAMI EC13 minimum safety and performance requirements for electrocardiographic heart rate and waveform monitors
- ANSI/AAMI EC53A safety and performance requirements for disposable and reusable leadwires as well as the cables used for surface electrocardiographic monitoring in cardiac monitors
- CAN/CSA-C22.2 No. 601.2.25-94 Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographs
- CAN/CSA-C22.2 No. 601.2.27-98 Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
- IEC 60601-1-1 Medical electrical equipment Part 1-1: General requirements for safety -Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-27 (IEC 62D/459/CD) Medical electrical equipment, Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
- IEC 60601-2-51 (IEC 62D/407/CDV) Medical electrical equipment, Part 2-51: Particular requirements for the safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs
- > The VitalChart system should pass applicable IEEE standards
- > The VitalChart system should pass UL testing and regulations for similar devices



5. Electrocardiogram

This section will describe the functions and requirements of the EKG unit.

5.1. General Requirements

- **□** The EKG unit must send a signal that the hardware interface can process
- □ The output signal must be an EKG waveform
- > The EKG unit should be suitable for use in a hospital or clinic

5.2. Physical Requirements

- □ The EKG unit must have three shielded leads left, right, and ground
- □ The EKG unit must be less than 10cm in length, 10cm in width, and 5cm in height
- > The circuit should be implemented on a PCB
- > The leads should accommodate a wide variety of EKG electrode pads
- > The leads should be 1.5 metres long
- > The EKG unit should weigh less than 300 grams
- > The EKG unit should be less than 5cm in length, 5cm in width, and 1cm in height

5.3. Performance Requirements

- **□** The EKG unit must function with leads connected to the patient's left arm, right arm, and leg
- D The EKG unit must output an analog signal
- **□** The EKG unit must minimize noise in the output signal
- **□** The EKG unit must use an active ground to minimize the current through a patient
- > The EKG unit should function with the leads connected on the patient's chest

5.4. Cost Requirements

- **D** The EKG unit must cost less than \$50
- > The unit should cost less than \$25 in production volume

5.5. Test Requirements

This section outlines the tests we will perform on the EKG unit to ensure its functionality and reliability.

- □ Attach leads to a test subject and observe the EKG waveform output
- □ Ensure the various components of the QRS complex can be easily identified from the EKG waveform output

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□ Verify the EKG unit output can be read by the hardware interface



6. Respiratory Measuring Device

This section will describe the functions and requirements of the respiratory measuring device.

6.1. General Requirements

- **D** The respiratory unit must send a signal to hardware interface
- □ The calculated breathing rate must be sent to the Palm[™] PDA
- □ The device must operate properly when the patient's breathing rate is under 40 breaths per minute
- > The interface should be suitable for use in a hospital or clinic
- The device should operate properly when the patient's breathing rate is greater than 40 breaths per minute

6.2. Physical Requirements

- **□** The respiratory sensor must be installed on a disposable medical pad
- **\Box** The respiratory unit must be able to measure acceleration of less than $\pm 1g$
- □ The breathing rate of the patient must be measured in an environment with a constant acceleration of 1g
- □ The respiratory unit must not cause discomfort to the patient
- **□** The device must operate properly when the patient is stationary
- **□** The respiratory unit must be less than 10cm in length, 10cm in width, and 4cm in height
- > The circuit should be implemented on a PCB
- > The respiratory unit should weight less than 300 grams
- > The respiratory sensor should be durable and reliable
- > The respiratory unit should be less than 5cm in length, 5cm in width, and 1cm in height

6.3. Cost Requirements

- **D** The respiratory unit must cost less than \$50
- > The respiratory unit should cost less than \$30 in production volume

6.4. Test Requirements

This section outlines the tests we will perform on the respiratory unit to ensure its functionality and reliability.

- □ Attach the respiratory unit to a test subject's chest and observe the output
- □ Verify integrity of signal generated from the respiratory sensor
- **□** Ensure the respiratory unit output can be read by the hardware interface

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7. Hardware Interface

This section will describe the functions and requirements of the hardware interface.

7.1. General Requirements

- **□** The interface must read signals from the EKG unit and respiratory unit
- **□** The interface must calculate the breathing rate from the respiratory input signal
- □ The interface must send either the EKG signal or the respiratory data, one at a time to the Palm[™] PDA through the serial port
- > The interface should be suitable for use in a hospital or clinic

7.2. Physical Requirements

- □ The interface must have enough input pins to receive data from the EKG unit and the respiratory unit simultaneously
- □ The interface must have enough output pins for serial communication with the Palm[™] PDA
- □ The interface must be less than 10cm in width, 10cm in length, and 4cm in height
- > The interface should use a Palm[™] serial connector
- > The interface circuit should be implemented on a PCB
- ➤ The interface should "clip" on to the Palm[™] serial port
- > The interface should weigh less than 300 grams
- > The interface should be less than 5cm in width, 5cm in length, and 1cm in height

7.3. Performance Requirements

- □ The interface must perform 10-bit analog to digital conversion on the EKG input signals at least every 0.05 seconds
- □ The interface must perform digital signal processing on the respiratory input signals at least every 0.25 seconds
- **□** The interface must contain enough memory to buffer the processed data after sampling
- □ The interface must send data serially to the Palm[™] PDA using the RS-232 protocol
- □ The interface must send data in the packet form required by the Palm[™] PDA
- The interface should multiplex both EKG and respiratory digital signals on a single serial output
- > The interface should digitally process the EKG input signals to enhance the output signal
- The interface should apply more powerful DSP algorithms on the respiratory inputs and update the number of breaths per minute every 5 seconds



7.4. Cost Requirements

- □ The interface must cost less than \$225
- > The interface should cost less than \$150 in production volume

7.5. Test Requirements

This section outlines the tests we will perform on the hardware interface to ensure its functionality and reliability.

- □ Verify the interface will sample data from the EKG unit
- □ Verify the interface will sample data from the respiratory unit
- □ Verify the interface will process the respiratory data
- □ Verify the interface will transmit processed EKG and respiratory data to the Palm[™] PDA



8. Software Program Specification

This section will describe the functions and requirements of the software application. The application is divided into three components: graphical display, GUI, software to hardware interface. Specifications for each of the components will be described separately.

8.1. Graphical Display

The graphical display will facilitate the display of the EKG and respiratory data as transmitted from the RS-232 serial interface. The data samples will be displayed relative to a time reference generated by the Palm[™] OS software. In addition, the graphical display will be controlled via functions invoked by the GUI. This section outlines the functions and requirements for the graphical display.

8.1.1. General Requirements

- **□** The graphical display must display the number of heartbeats per minute
- □ The graphical display must display the respiration per minute
- □ The display must have a grid for the plotting of EKG data which can be turned on/off at the user's convenience
- **□** The data must be plotted against a time reference as generated by the software
- □ The graphical display must have a pause function which allows the current screen to be retained for further examination
- **D** The graphical display must be able to restart display of EKG plots after it exits pause
- □ The waveform must be displayed utilizing a screen wipe from left to right where data from the previous time is retained and new data is plotted on top of the previous screen
- The triggering function should be able to increase/decrease the time scale for which the QRS waveform data is plotted
- > The Palm[™] should not automatically turn off when measuring vital signals

8.1.2. Performance Requirements

- **□** The graphical display must convert raw EKG data into coordinate data for display in real time
- **□** The definition of real-time will be less than 1 second delay
- □ The QRS waveform must be displayed in 1x1 pixel resolution on the 160x160 pixel screen
- **□** The time scale must have a maximum of 0 to 5 second resolution
- □ The graphical display must update the heartbeat and respiratory rate displayed on screen at least every 15 seconds
- The display should be triggered such that an entire QRS complex waveform is displayed at all times
- The graphical display should update the heartbeat and respiratory rate displayed on screen at least every 5 seconds



8.2. Graphical User Interface

The Graphical User Interface is the part of the VitalChart software that communicates with the user. The style and layout of the GUI will be similar to common Palm[™] PDA applications, where the user is able to manipulate the functions built into the software via point-and-tap input from the stylus. The GUI of the VitalChart software is sub-divided into two sections: interface layout, and application menus. Their functions and requirements will be outlined in the following sections.

8.2.1. Interface Layout

This section will describe the functions and requirements of the interface layout.

8.2.1.1. General Requirements

- **□** The GUI must allow the user to interact with the software via the touch screen of the PDA
- **□** The GUI must be displayed in monochrome
- □ The GUI must allow the user to access all VitalChart software functions
- □ The toolbar must normally be hidden to maximize the EKG signal display area, and can be accessed anytime by clicking on the tab button located at top left corner of the GUI
- > The GUI should display the hardware connection status
- > The EKG graph should have time scaling capabilities
- > VitalChart software should allow the user to record either the EKG or respiratory rate
- > The breathing rate display box should flash for every breath detected
- > The heartbeat rate display box should flash for every heartbeat detected
- > The GUI should display the patient's name, ID, date, and time
- > VitalChart software should have a unified database to store patient records
- > VitalChart software should record the EKG signal and store it in a database
- > VitalChart software should create and retrieve patient's EKG records through a database
- VitalChart software should be able to transfer and backup the patient database via the HotSync operation to a desktop computer
- Upon exit or terminating of the application, VitalChart software should save the user settings and preferences for the current session and load it automatically the next time the application begins
- VitalChart software should not interrupt data sampling when user is accessing the toolbar functions

8.2.1.2. Performance Requirements

- □ The "stop" and "resume" buttons must have response times of less than 0.25 seconds
- > The "record" button should have a response time within 0.25 seconds
- > The toolbar functions should have response times within 0.25 seconds



8.2.2. Application Menus

This section will describe the functions and requirements of the application menus.

8.2.2.1. Zoom Tools Requirements

- VitalChart software should have zoom functions under the "Zoom" menu of the application toolbar
- VitalChart software should scale the time axis of the EKG signal display via functions in the "Zoom" menu
- VitalChart software should perform a "box" zoom by selecting the zoom area via stylus on the touch screen
- VitalChart software should be able to center the display on any area of the EKG signal via a "center" zoom function
- VitalChart software should exit the zoom menu when the user clicks any area outside the zoom toolbar

8.2.2.2. Database Requirements

- VitalChart software should allow the user to access the database function under the "Database" menu of the application toolbar
- VitalChart software should allow the user to create a new record for a patient
- > VitalChart software should allow the user to enter patient name and ID
- VitalChart software should allow the user to retrieve other patient records
- VitalChart software should allow the user to delete existing patient records
- VitalChart software should allow the user to append new EKG and/or respiratory rate data to a patient's record

8.2.2.3. About Pages Requirements

- VitalChart software must display the company's name, logo, and contact information in an "About" form
- □ VitalChart software must display the application name, version number, and serial number in an "About" form
- > VitalChart software should display a link to the application's user manual



8.3. Software to Hardware Interface

The EKG and respiratory rate signals are communicated to the Palm[™] through the hardware connection and the communication management portion of the VitalChart application. This section describes the functionality of the software component that interfaces to the hardware.

8.3.1. General Requirements

- VitalChart software must detect a connection when the VitalChart hardware module is attached to the connector
- □ VitalChart software must establish a connection to the peripheral using the RS-232 protocol upon connection of the correct peripheral
- VitalChart software must be able to initiate data transfer from the peripheral
- □ VitalChart software must receive data from the peripheral at fixed intervals of time
- VitalChart software must stop data acquisition and terminate the connection upon detection of disconnection of the peripheral
- □ VitalChart software must detect disconnection of the peripheral
- VitalChart software should begin an automatic hardware connection detection sequence upon the start of the application
- VitalChart software should be able to discriminate between the proper peripheral and other peripherals upon attachment of the hardware
- VitalChart software should detect abnormal termination of data transfer and indicate status of connection to the user

8.3.2. Performance Requirements

> Data acquisition rate (baud rate) of the signals should reach 19200bps

8.4. Test Requirements

The VitalChart software application should be tested for the following to ensure robustness of the software.

- □ Verify menu and button functionality
- □ Investigate human factors and usability
- **D** Examine signal and data display accuracy and quality
- **D** Ensure database functionality and integrity
- **D** Ensure software compatibility and integrity
- □ Verify proper establishment of connection upon attachment of hardware module
- □ Verify ability to initiate and terminate transmissions
- Verify integrity of data transmitted
- □ Investigate response to abnormal operations (accidental disconnection, error in data transmitted)
- □ Ensure compliance to Palm[™] design standards



9. System Test Plan

In addition to the test requirements for each sub-section, a total system test is also required and will be outlined by the following.

9.1. System Test without the Hardware Interface

- □ All buttons and menus must be operational to the requirements as outlined in section 8.2
- □ Attempts to record and display data must be deactivated to the requirements as outlined in section 8.2
- □ The VitalChart Palm[™] application must exit successfully as defined by the Palm[™] OS User Interface Guidelines

9.2. EKG System Test with the Hardware Interface Connected

- □ The user will connect the hardware module to the PalmTM PDA
- □ All buttons and menus must be operational to the requirements as outlined in section 8.2
- □ The user will test the signal integrity of the EKG system by feeding in a known signal such as a sinusoid and making comparisons between input and output
- □ The user will test the record function of the VitalChart Palm[™] application (should this function be available)
- □ The user will disconnect the hardware module from the PalmTM PDA
- □ The VitalChart Palm[™] application must exit successfully as defined by the Palm[™] OS User Interface Guidelines

9.3. Respiration Rate System Test with the Hardware Interface

- □ The user will connect the hardware module to the PalmTM PDA
- □ All buttons and menus must be operational to the requirements as outlined in section 8.2
- □ The breathing rate as displayed by the VitalChart Palm[™] application will be compared to the frequency of the input of a known signal
- □ The user will disconnect the hardware module from the PalmTM PDA
- □ The VitalChart Palm[™] application must exit successfully as defined by the Palm[™] OS User Interface Guidelines

9.4. Total System Test on a Human Subject

- □ The user will invoke the VitalChart Palm[™] application and connect the EKG leads to the human subject as defined by section 5.3 of the document
- **□** The user will connect the respiration sensor to the subject's chest
- **□** The user will connect a third party EKG system to the subject
- □ The user will observe the output of the third party EKG and the output of the VitalChart and make a comparison to the two signals
- □ The user will observe the respiration rate as shown by the VitalChart display and compare the respiration rate as observed using conventional methods



10. Conclusion

This document outlines the functions, requirements, and standards that must be completed for VitalChart to be an effective tool in the medical industry. The specifications of each component have been carefully defined where the minimum requirements for effective use are stated as well as additional features that would increase the utility of the system. This allows the VitalStatis development team to concentrate on designing the most essential functions while keeping in mind features likely to be included during future expansion of VitalChart. The flexibility of this approach will allow VitalStatis engineers to design a system that will not overly restrict future development.

The system overview states all of the general requirements of VitalChart, taking into consideration reliability, portability, and standards compliance. Each hardware component has been specified so as to meet a set of physical and functional specifications, with a focus on acquiring the desired data and then communicating that data to the Palm[™] PDA. This allows the software program functionality to focus on receiving data from the hardware, then processing and displaying it in an easy-to-use GUI.

Given these specifications, we are confident we will satisfy all of our minimum requirements and more by our completion date of December 13, 2002. To ensure that these requirements are, in fact, met, we have included test plans for each component of VitalChart, as well as a test plan to be performed once integration of the entire project is completed.

These functional specifications are a blueprint for the future development of VitalChart. By examining all relevant issues, we are positioned to produce a first-rate design specification and, ultimately, a successful prototype and product.



11. References

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