



School of Engineering Science – Burnaby, BC – V5A 1S6
– proximus-ensc440@sfu.ca

February 21, 2006

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

Re: ENSC 440 Functional Specifications for the Wireless Monitoring System

Dear Dr. Rawicz:

The attached document, *Functional Specification for the Wireless Monitoring System*, contains the functional requirements for the product we are building. The Wireless Patient Monitoring System we are building will significantly alleviate the inconvenience that patients experience from the wires that connect them to conventional bedside monitoring devices.

This functional specification provides a set of clear requirements for the system's functionality for both the proof-of-concept and production phases of development. Using these requirements our project manager and design engineers will be able to develop the product to optimally and reliably meet the needs of the user.

If you have any questions or concerns, please do not hesitate to contact us at proximus-ensc440@sfu.ca.

Sincerely,

A handwritten signature in black ink, appearing to read "Zues Rawji". The signature is fluid and cursive, written over a white background.

Zues Rawji
Chief Executive Officer
Proximus

Enclosure: *Functional Specification for the Wireless Patient Monitoring System*



Functional Specifications for the Wireless Monitoring System

Project Team:

Zues Rawji
Dave Liebich
Kevin Ciarnie
Salman Abdollahi
Jatinder Singh Mann
Dallan Hunt

Contact Person:

Zues Rawji
zrawji@sfu.ca

Submitted to:

Andrew Rawicz - ENSC 440
Steve Whitmore - ENSC 305
School of Engineering Science
Simon Fraser University

**Issued Date:
Version**

February 20th
1.0

Executive Summary

Proximus is currently developing an innovative solution that can be seamlessly integrated into existing hospital networks. Our *Wireless Monitoring System* (WMS) will increase the ease of monitoring patients in their hospital room, both for the patient and the healthcare workers. We aspire to make patient monitoring more transparent, resulting in increased efficiency of hospital staff and less impact on the patient. Sensors will be small and comfortable for patients.



We will achieve this transparency using reliable wireless technology which will comply with hospital regulations to ensure minimal noise and interference. Each hospital room will have a local wireless network, consisting of sensors and a data logger. A wireless solution will reduce human interaction in the monitoring process resulting in less human error as well as reduced patient risk and increased staff efficiency.



The data logger will receive and organize data which it receives from the sensors in the hospital room. The data will be displayed directly on the data logger facilitating immediate monitoring of the patient by healthcare workers. Phase one of our development will include using a laptop as the data logger for proof of concept, as well as developing the associated software, and developing the wireless sensor bank.¹



Phase two of our development will include sending data received by the data logger through an already existing hospital network to enable a second means of patient monitoring. The data logger will transmit data through the hospital network to a centralized location where the patient can be monitored from. By allowing the patient to be monitored from a centralized location and not just in the hospital room, quicker responses to the patient can be made. Phase two of our development will include modifications of the laptop software so that it may be used on the central location module. In addition, the main focus of phase two will be to remove the laptop from the system, and develop the data logger module.²



¹ <http://www.allproducts.com/manufacture98/gotom/product3.jpg>

² <https://marltoncomputers.com/catalog/images/computer.jpg>



Table of Contents

Executive Summary	iii
Table of Contents	iv
List of Figures	vi
1 Introduction	1
1.1 Scope	1
1.2 Glossary	1
1.3 Intended Audience	2
1.4 Convention	3
2 User Interaction Functional Specifications	4
2.1 The Patient	5
2.2 The Healthcare Worker	5
2.3 The Technician	5
3 System Requirements	6
3.1 System Overview	6
3.2 Wireless Sensor Bank	8
3.2.1 General Sensor Bank System Requirements	8
3.2.2 Physical	8
3.2.3 Accuracy	9
3.2.4 Resolution	9
3.2.5 Performance	9
3.2.6 Power	9
3.2.7 User Interface	10
3.2.8 Maintainability	10
3.2.9 Storage	10
3.2.10 Communication	10
3.3 Data Logger	11
3.3.1 General	11
3.3.2 Physical	11
3.3.3 Performance	11
3.3.4 Power	12
3.3.5 User Interface	12
3.3.6 Serviceability	12
3.3.7 Communication	13
3.3.8 Data Storage	13
3.4 Central Location Module	13
3.4.1 General Software Requirements	13
3.5 Wireless Communication from Sensors to Data Logger	14
3.5.1 Transmission Range and Radius	14
3.5.2 Interference Requirements	14
3.5.3 Transmission Power	14
3.5.4 Transmission Characteristics	15
4 Regulatory Requirements	15
5 Documentation Requirements	16
5.1 General	16



Functional Specifications for a Wireless Monitoring System

5.2	The Patient	16
5.3	The Healthcare Worker	16
5.4	The Technician.....	16
6	Testing Plan	16
	Phase One Test Plan.....	16
	Sensor Module Power Supply Test.....	16
	Sensor Resolution Test	16
	Laptop Software Performance Test	16
	Wireless Communication Test.....	16
	Phase Two Test Plan.....	18
	DLM Functionality and Performance Test	18
	Wireless Communication Test.....	18
	CLM Software Test.....	18
	General System Test	18
7	Conclusion	19
8	References.....	20
	Sensor Module	20
	Data Logger	20
	Communications	20
	Pictures.....	20
	Regulatory Requirements.....	20
	Miscellaneous	20



List of Figures

Figure 1: User Interaction	4
Figure 2: Phase One System Overview (Data Logging Module taken from [12])..	6
Figure 3: Phase Two System Overview (Data Logging Module Taken From [14])	7

1 Introduction

The Wireless Monitoring System (WMS) is a system which allows wireless patient monitoring while the patient is in their hospital room. The patient will be able to be monitored directly in their hospital rooms and also from a central monitoring location. The WMS is intended to improve upon already existing solutions for hospital patient monitoring by increasing the flexibility of monitoring, and at the same time reducing the invasiveness of monitoring for the patient.

Phase one will be developed as a proof of concept system with a completion date set in April 2006. Phase two will follow immediately and is expected to take 4 months.

1.1 Scope

This document describes functional requirements which must be met by the fully functional prototype of the WMS. The requirements are divided into phase one and phase two requirements. A complete set of requirements for phase one is listed in this document. However, for phase two the requirements are loosely defined as it is expected that a substantial amount of revisions and modifications will be made during the phase one development stage.

1.2 Glossary

AC	Alternating Current
BER	Bit Error Rate
CLM	Central Location Module
CSA	Canadians Standards Association
dBm	Power level in decibels per 1 milliwatt
DLM	Data Logger Module
ECG	Electrocardio graph
EMC	Electromagnetic compatibility
FAQ	Frequently asked questions
FCC	Federal Communications Comission
GUI	Graphic user interface
HRECG	High Resolution Electrocardio graph
Hz	Hertz, Cycles per second
IEC	International Electrotechnical Commission
ISM	The industrial, scientific and medical radio bands
kHz	Kilohertz (1000 Hertz)
MHz	Megahertz (1 000 000 Hertz)
mm	Millimeters (0.001 meter)
mW	Milliwatt (0.001 watt)
SBM	Sensor Bank Module
UL	Underwriter's Labratories
WMS	Wireless Monitoring System



1.3 Intended Audience

This document is intended for design engineers, project managers, and marketing personnel. Design engineers may use this document as a guideline for the development of this system. Project Managers may use this document as a guide for scheduling, budgeting, planning, and other management activities relating to the development of the WMS. Marketing personnel may use this document for promotional purposes and to attract investors.



1.4 Convention

The following convention will be used throughout this document for assigning priority to functional specifications.

R[n/priority] Functional specification description.

The functional specification number is denoted by n. The priority is given by A, B, or C and is displayed after the functional specification description. The priority number convention is as follows:

- A Functional specification is required for both the proof of concept, and the final production system.
- B Functional specification is for just the proof of concept.
- C Functional specification is for just the final production system.

2 User Interaction Functional Specifications

This section will discuss the different types of users, their interaction with each other, and finally how they will interact with our WMS. It is important to discuss the different user types for our product because for it to integrate into a hospital environment, it will have to work correctly with all of the three user groups. The following three subsections will discuss the interaction functional specifications for each user group.

The first user is the *patient*. The patient is the person who is wearing the wireless sensors and is in a hospital room where our WMS is installed.

The second group of users is the *medical staff*. The medical staff consists of all individuals whose job entails providing medical aid the patients. Since the medical staff helps patients, they will likely use our WMS since it reports information about the patients.

The last user is the *technician*. The technician is the person who installs and repairs the WMS.

Figure 1 illustrates the relationships between all the different user types.

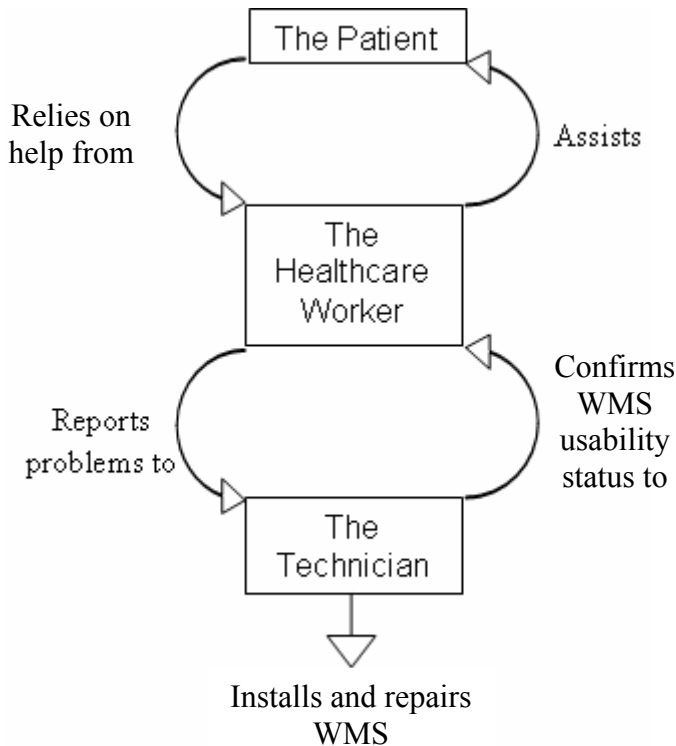


Figure 1: User Interaction



2.1 The Patient

- R[1/A]** The Patient interacts with the WMS only through sensors attached to their body.
- R[2/C]** Sensors will cause minimal discomfort for patients.
- R[3/C]** Recharging the power source for sensors will interrupt patients minimally.

2.2 The Healthcare Worker

- R[4/C]** Can add a sensor to the WMS by only turning the sensor on and attaching it appropriately to the patient.
- R[5/C]** Can remove a sensor from the WMS by only turning the sensor off and detaching it appropriately from the patient.
- R[6/C]** Can check a patient's sensor data in the hospital room easily.
- R[7/C]** Can easily identify when a sensor battery requires to be changed.
- R[8/C]** Can access WMS error(s) information easily and understand steps to solve the error(s).

2.3 The Technician

- R[9/C]** Can install the data logger easily by plugging it in and turning it on. (3)
- R[10/C]** Will not have to deal with sensors and patients together. (3)

3 System Requirements

3.1 System Overview

Phase One System Overview

Figure 2 illustrates a system diagram of phase one. Phase one consists of two modules: the sensor bank module, and the data logger module. The sensor bank module will be placed on the patient, while the data logger module will be placed by the bedside. These two modules will communicate with each other wirelessly.

The functionality of the data logger module will be temporarily implemented using a laptop. This module will have the ability to connect to multiple sensors, specified by the user. The data logger module initially sends connection requests wirelessly to the specified sensors, followed by data requests also sent wirelessly. The data logger will acknowledge any data received from the sensor bank to ensure no data is lost. Upon receiving the data transmissions from the sensor bank, the data logger module will display the readings.

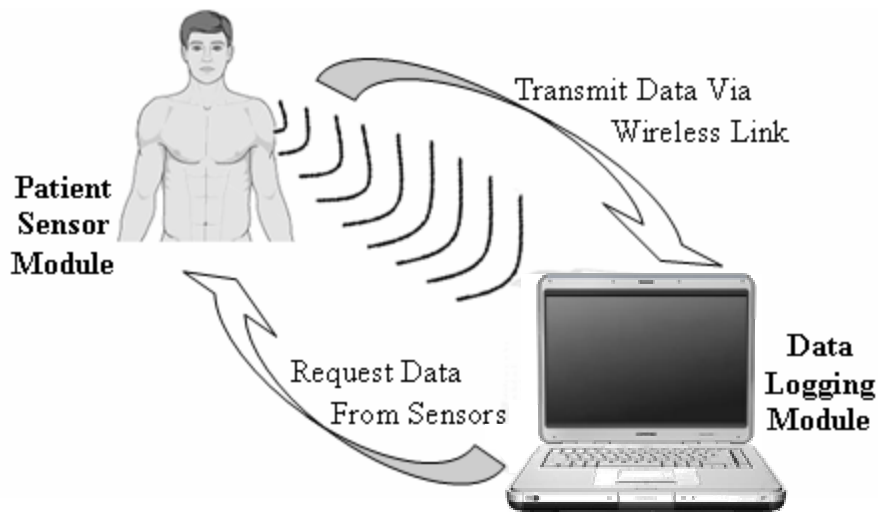


Figure 2: Phase One System Overview (Data Logging Module taken from [12])

Phase Two System Overview

Figure 3 illustrates a system diagram of phase two. Phase two incorporates the CLM into the system. In addition, the DLM will be developed instead of using the laptop as used in phase one. The communication between the CLM and the DLM will be through the already existing hospital network. This form of communication will utilize an already existing infrastructure to centralize the data from numerous patients increasing efficiency of hospital staff, and decreasing the response time to medical emergencies that occur during monitoring.

In phase two, the communication between the sensor bank and the DLM will remain wireless. However, minor modifications will be made to the wireless interface in order to increase the range, and reliability of transmission. Information received by the data logger will then be transmitted through the hospital wired network to the CLM where it will be processed, displayed, and monitored. The CLM will have the ability to receive data from multiple DLM's. When a medical emergency arises, the monitoring staff will be notified which will prompt them to contact medical staff swiftly.

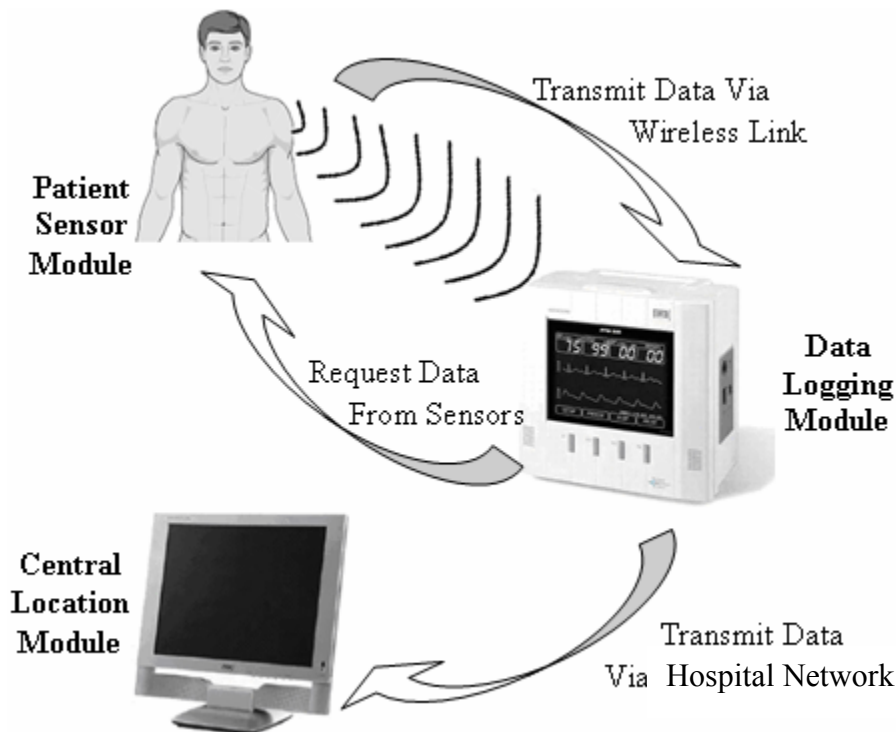


Figure 3: Phase Two System Overview (Data Logging Module Taken From [14])

3.2 Wireless Sensor Bank

The wireless sensor bank consists of multiple sensor modules that connect wirelessly to the data logger. A scheme will be implemented to ensure the retrieval of sensor data is done in a reliable manner. The functional requirements for the wireless sensor bank are as follows:

3.2.1 General Sensor Bank System Requirements

- R[11/B] Sensor bank can consist of up to 2 sensor modules on a patient to show proof of concept with multiple sensors.
- R[12/C] Number of sensor modules part of the sensor bank will be increased in order to accommodate medical needs.
- R[13/A] Each sensor will communicate independently of each other with the DLM to ensure system reliability.
- R[14/A] Sensor modules in the sensor bank will not interfere with each other.
- R[15/A] Sensor bank shall not interfere with any hospital equipment.
- R[16/C] Sensor bank on patient A will not interfere with sensor bank on patient B.
- R[17/A] The modules in the sensor bank will be robust and reliable.

3.2.2 Physical

- R[18/C] The wireless interface to the sensor shall be no bigger than a length of 30mm, width of 20mm, and a thickness of 15mm in order to be portable and comfortable for the patient.
- R[19/A] The sensors themselves shall be no bigger than the existing sensors currently being used in hospitals.
- R[20/C] The entire wireless sensor module shall be lightweight enough to not cause fatigue to a mobile patient who is wearing them for up to 24 hours.
- R[21/C] The casing encompassing the wireless sensor module will be rigid and be able to withstand compression stress.
- R[22/A] The casing shall be made of a non-toxic material, in order to not harm the users.
- R[23/C] The casing will not have any sharp edges in order to not harm the user.
- R[24/A] The wireless sensor module will be able to operate properly under normal atmospheric pressure; the majority of patient monitoring is done at this pressure level. Operation of the WMS under non normal atmospheric pressure will not be supported.

3.2.3 Accuracy

- R[25/A] The temperature sensor will have a maximum error of 2%. This is calculated by dividing the 0.6 °C uncertainty by the temperature well below the hypothermia mark, 30°C [5].
- R[26/B] The ECG sensor will have a maximum error of 10% in order to illustrate sensor accuracy for proof of concept.
- R[27/C] The ECG sensor will have a maximum error of 2% [6].
- R[28/A] Sensors will operate with minimal degradation in performance due to movements, temperature, and skin secretion.
- R[29/A] Sensors readings shall not be affected by external noise such as electro-magnetic, thermal, and acoustic noise.
- R[30/A] The sensors shall have a high sensitivity to the measured variable, but a low cross-sensitivity to the variable orthogonal to the intended measured variable. For example, sensors will be sensitive to the temperature of the patient, but not to the temperature of the room.

3.2.4 Resolution

- R[31/B] The ECG sensor will have a resolution of 3.33ms, thus being able to detect a minimum of 300Hz , which is a characteristic of standard ECG [1].
- R[32/B] The ECG sensor will have a resolution of 1ms, thus being able to detect a minimum of 1 kHz, which is a characteristic of HRECG [1].
- R[33/B] The ECG sensor will be able to detect amplitudes in the mV range in order to detect regular ECG characteristics and potential problems [2].
- R[34/C] The ECG sensor will be able to detect amplitudes that will allow for the detection of myocardial ischemia, which is important to diagnose prior to a heart attack [4].
- R[35/A] Temperature sensors will be able to detect changes of up to 0.6 °C [5].

3.2.5 Performance

- R[36/A] The electronics in the wireless sensor module will be able to withstand temperature that exists in a normal hospital environment ranging from 0-45 °C [8]. (1)

3.2.6 Power

- R[37/A] The module shall be self powered.
- R[38/C] The module shall contain a rechargeable power source.
- R[39/C] The power source will be recharged using an existing wall adapter and/or communications adapter that comply with CSA and UL



- R[40/A] When the power supply is low, the sensor module will emit an acoustic warning.
- R[41/C] Sensor module shall be able to transmit data long enough so that medical staff will only be required to replace or recharge the power source once in their shift.
- R[42/C] The sensor module shall not dissipate any detectable heat by the patient during its operation.

3.2.7 User Interface

- R[43/A] The user interface on the sensor module will only require one hand to access all the functionality of the module.
- R[44/A] The sensor module user interface will turn on a visual indicator when data is being transmitted.
- R[45/A] The user interface on the sensor module will be easy for medical staff to use.

3.2.8 Maintainability

- R[46/C] The patient will at no point need to service or repair the module.
- R[47/C] Only trained personnel will be able to service the device.
- R[48/C] Documentation will be provided in order to service this module.

3.2.9 Storage

- R[49/A] If the sensor module fails to receive a verification of the data it sent, the data will be stored in onboard memory until the DLM requests the data to be retransmitted.
- R[50/A] Data will be erased from the memory on the sensor module upon receiving verification from the DLM in order to prevent the need for large onboard storage.
- R[51/C] Once the buffer is near full on the sensor module, an acoustical buffer overflow warning will sound.

3.2.10 Communication

- R[52/A] All data transmission between the data logger and sensor bank will be done via wireless only, in order accommodate the increasing need for wireless solutions to patient monitoring in hospitals [7].
- R[53/A] Sensor module will be request driven from the data logger
- R[54/A] The sensor bank will exhibit EMC with the hospital environment and existing equipment [14].

- R[55/A]** Each sensor module will only have a maximum window to transmit its data to the DLM. This window for transmission will ensure that no timeouts occur, or that communication between the DLM and the sensor module does not hang.
- R[56/A]** Sensor module will both transmit and receive data from the DLM.
- R[57/A]** All data transmitted to the DLM will be verified using a verification scheme.

3.3 Data Logger

The functionality of the data logger is to gather all information sent to it wirelessly from the wireless sensor bank. The data logger will initiate a connection to each sensor wirelessly, and will request data from each sensor. A verification scheme will be implemented in the data logger to ensure that all packets that are transmitted from the wireless sensor bank will be received by the data logger, unmodified. The functional requirements for the data logger are as follows:

3.3.1 General

- R[58/B]** The DLM will be able to connect to a maximum of 3 wireless sensors, to show proof of concept with multiple sensors.
- R[59/C]** The number of sensor modules the DLM can connect to will be increased in order to accommodate medical needs.
- R[60/C]** The DLM will exhibit EMC with the hospital environment [18].
- R[61/B]** The DLM will implement a scheme in order to ensure that data is retrieved from each sensor in the system.

3.3.2 Physical

- R[62/A]** The data logger will weigh no more than 13kg [8].
- R[63/A]** The data logger will be no larger than 45 cm by 45 cm by 16 cm, based on the dimensions of a pre-existing solution [8].
- R[64/A]** The display will be a maximum 30.4 cm wide and 22.8 cm tall. This is the maximum size display that was found in an existing wired solution. [8].
- R[65/C]** The DLM will be capable of recharging the sensors. (3)

3.3.3 Performance

- R[66/C]** The patient's information will be processed and displayed with a maximum delay of 0.5 seconds upon receiving the information wirelessly in order to minimize the delay of patient data displayed on screen.
- R[67/A]** The information received wirelessly by the data logger will be correct



Functional Specifications for a Wireless Monitoring System

99.9% of the time. That is, the information received will be exactly what was transmitted from the wireless sensors.

- R[68/A] The data logger will operate between a temperature range of 0-45 °C [9].
- R[69/A] The data logger will operate between humidity ranges of 0 % to 90 % relative humidity. This is based on an average of humidity requirements of other wired medical monitoring devices [17,18,19,20].

3.3.4 Power

- R[70/A] The data logger will be powered by a CSA and UL approved external power adapter.
- R[71/A] The external power adapter will be powered from a standard AC power outlet.
- R[72/C] The data logger will be able to operate for 5 minutes after its power supply is interrupted (in the case of a blackout).
- R[73/C] Upon loss of power the data logger conduct a safe shut down sequence, and notify sensors of such an event.

3.3.5 User Interface

- R[74/A] The patient information on the display will be readable from a distance of 10 feet. 10 feet is the approximately the maximum diagonal length medical staff will be (at the foot of the patients bed) while providing aid to the patient.
- R[75/A] The display will show the patients ECG waveform.
- R[76/A] The display will show the patients temperature.
- R[77/A] The patient's pulse rate will be displayed.
- R[78/C] The display will display the remaining power in each sensor module's power source.
- R[79/A] The number of active sensors will be displayed.
- R[80/B] The user will be able to interact with the display using a keyboard.
- R[81/C] The user will be able to interact directly and efficiently with the display.
- R[82/C] The data logger will have a power switch.
- R[83/A] The user interface will provide an easy means for medical staff to select multiple sensors to connect to the data logger.

3.3.6 Serviceability

- R[84/C] The data logger will be installed and serviced by trained personnel.

R[85/C] The data logger's firmware will be upgraded by trained personnel.

3.3.7 Communication

R[86/A] The DLM will communicate with the sensors through a wireless link.

R[87/A] The DLM will have a wireless multipoint receiver.

R[88/A] The DLM will request data from the wireless sensors continuously.

R[89/C] Will satisfy requirements to interface with an existing hospital network.

R[90/C] The DLM will have a means to communicate with the CLM using the hospitals existing network.

R[91/C] The DLM will have a means to have its firmware upgraded locally, and to perform system diagnostics from an external device.

R[92/A] The DLM will use a verification scheme to verify the data it receives wirelessly from the sensor module.

R[93/A] If incorrect data is received, the data logger will request a retransmission from the sensor.

R[94/B] Sensors within a 10m range of the data logger can connect to it to show proof of concept of wireless data transmission from sensors.

R[95/C] Radius of reception for the data logger will be increased in order to increase patient mobility while keeping a patient in a close proximity to the DLM in the case a patient emergency occurs and the patient needs to be found.

R[96/C] If a critical situation occurs, the data logger will notify the central location module via the existing hospital network.

3.3.8 Data Storage

R[97/C] The data logger will save one hour of the most recent data. This will be a form of backup of sensor data incase of an emergency.

3.4 Central Location Module

The functionality of the CLM is to receive all incoming information from numerous DLM's via the existing hospital network. The CLM will consist of software developed by Proximus that will be installed at central locations in a hospital specified by medical staff. Upon receiving the information, the CLM will process the data and display it appropriately for medical staff to allow monitoring from a central location. The functional requirements for the CLM are as follows:

3.4.1 General Software Requirements

R[98/C] Software will receive data from multiple DLM's using the existing hospital network so that the solution will be easily implemented without requiring

- R[99/C]** Will notify monitoring staff when a patient emergency occurs so that medical staff can be contacted quickly, resulting in a swifter response time.
- R[100/C]** Software will be robust, scalable, and reliable for optimal functionality.
- R[101/C]** Software will have customizable options so that network engineers can easily adapt the software to their own network infrastructure.
- R[102/C]** Software will function with minimal processing delays so that data will be displayed in real time.
- R[103/C]** Software will be able to display data from multiple patients. This is a key requirement for having a centralized monitoring system.
- R[104/C]** Software will install on the OS currently used by hospital, that way no new platform will have to be purchased by the hospital.

3.5 Wireless Communication from Sensors to Data Logger

This section outlines the functional requirements for the wireless communication between the sensors and the data logger.

3.5.1 Transmission Range and Radius

- R[105/B]** Wireless transmission radius is 10m centered at the data logger to illustrate proof of concept for wireless data transmission from sensor modules.
- R[106/C]** Wireless transmission radius will be increased in reference to R[95].

3.5.2 Interference Requirements

- R[107/C]** Wireless transmission will not interfere with external hospital equipment.
- R[108/A]** Shall minimize co-channel interference.
- R[109A]** Shall minimize effect of multi-path.
- R[110/A]** Shall not interfere with the modules internal components (crystals, power supply).
- R[111/A]** Shall minimize crosstalk.
- R[112/A]** Wireless transmission from one sensor will not interfere with transmission from another sensor
- R[113/A]** Two Wireless Patient Monitoring Systems will not interfere with each other.

3.5.3 Transmission Power

- R[114/A]** Shall be no more than 1mW (0dBm) nominal [6].
- R[115/A]** Transmission radiation will not be harmful to the user and the surrounding

3.5.4 Transmission Characteristics

- R[116/A]** Will only operate in FCC regulated frequency band for hospitals [10].
- R[117/A]** Signal will have a bandwidth which will comply with FCC regulations.
- R[118/A]** Will be able to support multi-point transmission.
- R[119/A]** Transmissions between multiple sensors to the data logger shall occur in parallel.
- R[120/A]** All data transfer packets will have a maximum window to transfer to avoid timeouts.
- R[121/A]** Wireless transmission will have an average BER of 10^{-6} which is an acceptable BER [11].
- R[122/A]** Wireless transmission will have a maximum of 1% packet loss.
- R[123/A]** 99.9 % of all data to be processed after verification will be correct; that is it will be the same data that was transmitted by the sensor bank.

4 Regulatory Requirements

The Wireless Patient Monitoring System will comply with the following standards:

- R[124/C]** Title 47, chapter 1 (Federal Communications Commission), section 18 of the Code of Federal Regulations regarding ISM device requirements.
- R[125/C]** Title 47, chapter 1 (Federal Communications Commission), section 15 of the Code of Federal Regulations regarding Radio Frequency devices.
- R[126/C]** International Electrotechnical Commission Sub-Committee 62D (IEC/SC62D): Electromedical Equipment standards for patient monitoring equipment.
- R[127/C]** The regulations set forth for medical devices in the Canadian Food and Drugs Act - Medical Devices Regulations (SOR/98-282).
- R[128/C]** The standards set forth for medical devices by the U.S. Food and Drug Administration Center for Devices and Radiological Health.
- R[129/C]** ANSI/IEEE Std 602-1986 Standard for Electric Systems in Health Care Facilities.
- R[130/C]** CSA and UL requirements for medical devices.
- R[131/C]** The packaging of all system components will protect the user from electrical shock and physical injury.



- R[132/C]** CSA 601-1M90(R2005): Medical Electrical Equipment Part 1. General Requirements for Safety;
- R[133/C]** CSA 60601-1-2: Medical Electrical Equipment Part 1-2. General Requirements for Safety - Collateral Standard : Electromagnetic Compatibility;
- R[134/C]** CSA 60601-2-27: Medical Electrical Equipment Part 2-27. Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment.
- R[135/C]** CSA 60601-2-49: Medical Electrical Equipment Part 2-49. Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment.

5 Documentation Requirements

5.1 General

- R[136/C]** There will be three different manuals: a patient instruction, Healthcare Worker instruction, and technician instructions.
- R[137/C]** Additional information and documentation will be provided on the Proximus website and will consist of user documentation and FAQs, as seen necessary.
- R[138/C]** Users of the proof of concept device will be instructed by Proximus engineers, or use the device under the supervision of Proximus engineers.
- R[139/C]** All three versions of the documentation will be written in English, French, German, Spanish, and Japanese.

5.2 The Patient

- R[140/C]** The patient manual will be written for an audience with minimal technical expertise; it will consist of a one page leaflet document with proper sensor instrument care, and sensor placement information.

5.3 The Healthcare Worker

- R[141/C]** The Healthcare worker manual will be written for an audience with general experience with electronics device; it will provide training for complete device usage for two modules: wireless sensor and data logging modules.

5.4 The Technician

- R[142/C]** The service crew manual will be written for an audience with expertise in electronic device setup; it will provide complete training, setup, troubleshooting, and device characteristics information for all three

6 Testing Plan

The WMS will be divided into its individual subsystems and tested accordingly prior to integration. During integration, further testing will be conducted in order to ensure that proper communication and operation occurs between the three modules of the final integrated solution.

Since the testing procedures will be complex and specific to the independent type of technologies used, a brief overview for the test plan for each phase of development is described below. In addition to this testing, further tests will be conducted in order to ensure that the final solution will meet the safety standards and regulatory requirements.

Phase One Test Plan

Sensor Module Power Supply Test

The power supply on the sensor module will undergo tests to ensure that the power supply will operate safely and functionally during temperature extremes, compression stress, and in the presence of external magnetic fields.

Sensor Resolution Test

The sensor modules will receive an input signal simulating a range of expected input defined by resolution requirements. The output to the sensor module will then be analyzed to ensure that these resolution requirements are obtained.

Laptop Software Performance Test

The software on the laptop will undergo performance tests to ensure that it can process all the data received from multiple sensors, in real-time. This will ensure that the data displayed on screen is instantaneous and that processing and displaying introduces acceptable delay.

Wireless Communication Test

The wireless communication between the laptop and the sensor module will be tested by sending a stream of 1000 numbers across the wireless link, and analyzing the received transmission on the laptop. This test will verify the correctness of data transmission, and ensure that our communication requirements are met. Also, a radius of reception test will be carried out to ensure that all data will be successfully transmitted wirelessly within the required radius of reception as specified by this document.

In addition to this the same test will be conducted using multiple sensors connected to the laptop via a wireless link. This will ensure proper functionality of the software on the laptop under normal operation conditions as laid out by this document.

Furthermore, a transmission test will be carried out in the presence of external noise to ensure that correct measures are taken to minimize external interference.

Phase Two Test Plan

DLM Functionality and Performance Test

Tests will be carried out on the DLM in order to ensure proper functionality when multiple sensors are connected to it. In addition, the software on the DLM will be tested in order to analyze the performance to make sure that the processing delay on the DLM is acceptable.

Wireless Communication Test

This test will be identical to that of phase one, however the laptop will now be replaced with the DLM that will be developed in phase two. In addition, proximity tests will be modified from that of phase one to ensure that data transmission occurs in the increased radius of reception.

CLM Software Test

The software on the CLM will be tested to ensure that the modifications made to the software developed for the laptop in phase one, perform according to the requirements laid out in this document.

Furthermore, GUI tests will be conducted to ensure that the GUI developed for the final product will be user friendly.

In addition, performance tests will be conducted to ensure that data received from numerous WMS will be processed accordingly and displayed on screen.

General System Test

The test of this phase will be crucial as different medical situations will be simulated in order to ensure that the system performs as specified in this document. Patient emergencies will be simulated, and the system will undergo a *stress test* to ensure that proper functionality is obtained from the system when a patient is being monitored for extensive periods of time.

7 Conclusion

The functional specifications provided in this document specify the functionality that a properly operating WMS should have. Specifications which are intended to be implemented by April 2006, the date of delivery of the proof-of-concept system, have been laid out in a priority convention for requirements throughout. Testing overview and strategy give comprehensive testing plans to determine if our proof-of-concept device is complete. Also, since our product is used in a medical environment, complete regulatory requirements have been specified so the final product will comply with FCC, CSA, and safety regulations.

Further information regarding all aspects of the WMS can be acquired from our CEO, Zues Rawji, at zrawji@sfu.ca.

8 References

Sensor Module

- 1) <http://www.ipej.org/0202/hrecg.htm>
- 2) <http://www.fda.gov/cdrh/ode/27.pdf>
- 3) <http://www.cardiosource.com/guidelines/consensus/signal.htm>
- 4) <http://www.emedicine.com/radio/topic876.htm>
- 5) <http://www.national.com/pf/LM/LM34.html>
- 6) <http://bj.oxfordjournals.org/cgi/content/full/95/5/603>

Data Logger

- 7) http://www.draeger-medical.com/MT/internet/pdf/CareAreas/InfoMoni/mon_onenet_wireless_white_paper_en.pdf
- 8) http://www.medical.philips.com/us/products/cardiography/assets/docs/pagewriter/touch_d_atasheet.pdf
- 9) http://www.medical.philips.com/main/products/patient_monitoring/products/continuous_temperature/

Communications

- 10) http://www.cisco.com/warp/public/cc/pd/witc/ao1200ap/prodlit/wrlan_wp.pdf
- 11) <http://en.wikipedia.org/wiki/Z-wave>

Pictures

- 12) <http://www.laptop.lt/PICTURES/r3000.jpg>
- 13) <https://marltoncomputers.com/catalog/images/computer.jpg>
- 14) http://www.medi-core.co.kr/product/image/ppm300_02.jpg
- 15) <http://www.allproducts.com/manufacture98/gotom/product3.jpg>

Regulatory Requirements

- 16) http://www.aha.org/ashe/wmts/pdfs/reportmedtelemetry_wmts1998.pdf
- 17) <http://www.monitoring.welchallyn.com/pdfs/resourcelib/winslow.pdf>
- 18) http://www.ce-mag.com/archive/03/ARG/emc_standards.html

Miscellaneous

- 19) [http://us.fluke.com/usen/products/specifications.htm?cs_id=34948\(FlukeProducts\)&](http://us.fluke.com/usen/products/specifications.htm?cs_id=34948(FlukeProducts)&)
- 20) <http://www.surgivet.com/Products/Advisorspc.pdf>
- 21) <http://www.numed.co.uk/speccardiocall.html>
- 22) <http://www.clarity-medical.com/ClarityMed%20PMS320-3P.htm>
- 23) www.delsys.com
- 24) <http://www.ensc.sfu.ca/~whitmore/courses/ensc305/>