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October 15, 2002

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

Subject: Functional Specification for a Wireless EMG System

Dear Dr. Rawicz:

The document enclosed with this letter, *Functional Specifications of a Wireless EMG System*, lists the functional specifications of our ENSC 340 Project. We are developing a wireless solution to solve many problems that are associated with standard EMG acquisition techniques.

We are providing this document as a comprehensive list of specifications that our product will meet. The specification provides details of functional specifications for both the prototype development (that will be completed within the timeframe of the course) and a final product version.

Wireless Medical Devices was formed in June of 2002 by four highly skilled and motivated Engineering Science students: Eric Chow, Aaron Ridinger, David Press, and Andrew Pruszynski. We look forward to hearing your comments on our functional specification. Please feel free to contact me by phone @ (604) 782-7488 or email @ wireless-medicaldevices@sfu.ca.

Sincerely,

Jedrzej (Andrew) Pruszynski
Chief Executive Officer
Wireless Medical Devices

Enclosure: Functional Specification for a Wireless EMG System

WIRELESS MEDICAL DEVICES

Functional Specification for a Wireless EMG System

Project Team: Eric Chow
Dave Press
Andrew Pruszynski
Aaron Ridinger

Submitted To: Dr. Andrew Rawicz
Mr. Steve Whitmore

Revision Number: 1.2

Revision Date: October 15, 2002

Executive Summary

An Electromyograph is a recording of muscle activity used for rehabilitation, injury prevention and performance enhancement. Unfortunately, current systems rely on the use of restrictive wires and equipment that result in inaccurate and inconvenient diagnosis. Applying wireless communications principles to Electromyography (EMG) will lead directly to better diagnosis, research and rehabilitation. These advances have far-reaching implications for corporations, insurance agencies, athletes and patients.

Corporations will increase productivity as they reduce injuries occurring in the workplace. Insurance agencies will substantially cut their payment to the injured as the recovery time is minimized. Athletes will have completely unimpeded measurements of their muscle activity and thus increase performance and suffer fewer injuries. Lastly, and most importantly, the injured patient will get better analysis and diagnosis leading to faster rehabilitation.

The development of the Wireless EMG System (iEMG) will occur in two stages. By the end of the first stage WMD will present a prototype, called the iEMG, that will prove our concept of wirelessly acquiring muscle activity data. By December 2002, the iEMG will:

- Transmit wireless data from 8 EMG pads to a PC mounted receiver
- Record and display the data via a simple software package
- Demonstrate the miniaturization of the EMG pads and transmitter

After the second stage the iEMG will:

- Be reliable and user friendly
- Be capable of transmitting other biological signals such as ECG and EEG
- Have a more extensive software package

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List of Figures and Tables

Acronyms

CSA	Canadian Standards Association
EMG	Electromyograph
ESD	Electrostatic Discharge
FCC	Federal Communications Commission
FDA	Food and Drug Administration
GUI	Graphical User Interface
iEMG	Independent Electromyograph
ISM	Industrial, Scientific, and Medical
MTBF	Mean Time Before Failure
PC	Personal Computer
TGE	Transmitter and Ground Electrode
UL	Underwriters Laboratories
WMD	Wireless Medical Devices

1 – Introduction

WMD will use proven EMG sensors and established wireless communications techniques to develop the iEMG. Our product will be more portable, easier to use, and more accurate than the current available systems. By eliminating all wires, iEMG can be quickly and easily setup in any environment. The lack of wires greatly reduces the restriction on the subject's movement which, in turn, leads to more accurate diagnoses.

1.1 – Scope

This document lists the necessary functional specifications of the iEMG system. A rigorous set of requirements is given for the prototype device, as well as an overview of the specifications that will be needed for future production. The final product requirements may change slightly as the prototype nears completion. The functional specifications outlined in this document are used to drive the design process.

1.2 – Intended Audience

All members of the WMD team will use the functional specifications. The engineers will use the document as a guide when making design decisions. Marketing personnel will use it to assess the product position in the market. Managers will gauge the project's progress based on these specifications. Lawyers will use this document to protect the intellectual property developed by WMD.

1.3 – Targets

Throughout the document, the following precedes each requirement:

[R*x* – *y*]

x is the requirement number, used for ease of reference in future documents.
y is one of the following:

- P – The requirement applies to the prototype only
- F – The requirement applies to the final production only
- B – The requirement applies to both prototype and final production

2 – System Overview

Figure 2.1 gives an overview of the Wireless EMG system. The EMG pads are placed on the subject's body to measure muscle activity. Each pad sends information to a TGE Module that is also placed on the subject. The TGE modules wirelessly transmit the EMG data to the Receiver Station. A PC installed with appropriate software collects the data from the Receiver and can display it to the screen in real-time and save the data for future use.

A reciever can simultaneoulsy receive data from up to four TGE Modules. Each TGE Module is connected to two EMG pads. In the final production module, one or more EMG pads may be replaced by an ECG or EEG pad.

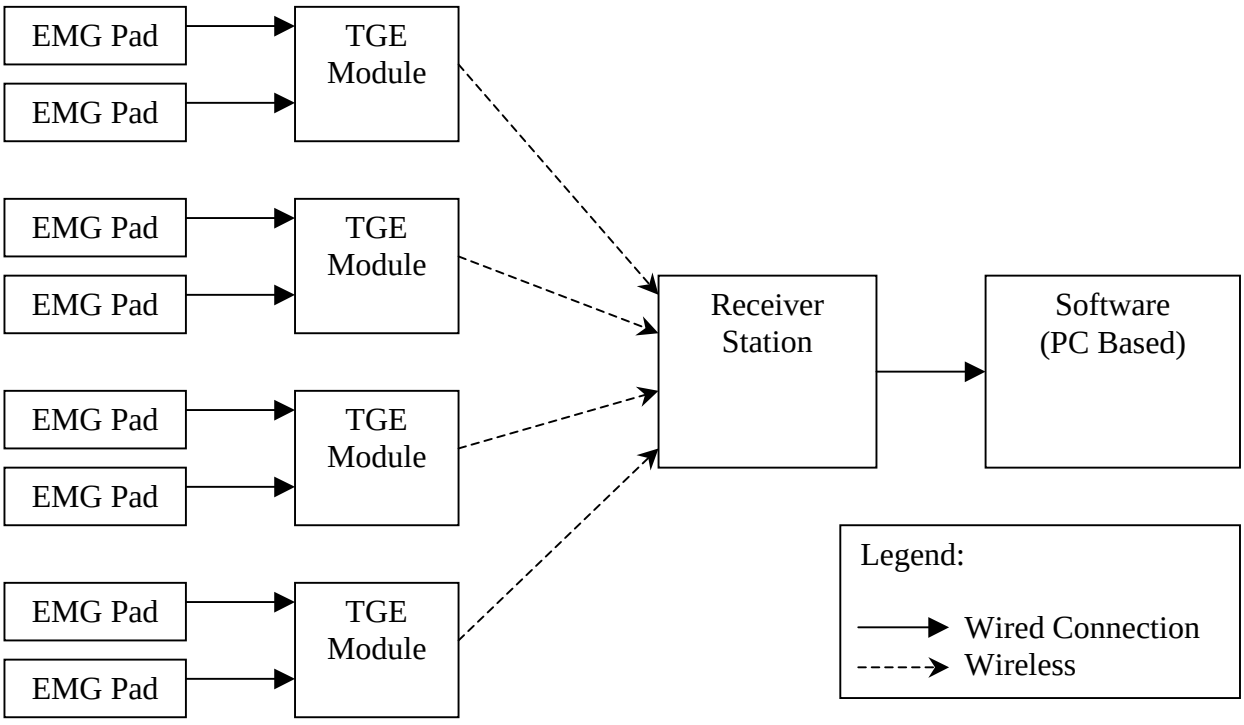


Figure 2.1: System Block Diagram

The requirements are organized according to the applicable system component (as described in Figure 2.1).

Figure 2.2 shows how the EMG pads and TGE Module can be placed on the subject's body to measure muscle activity.

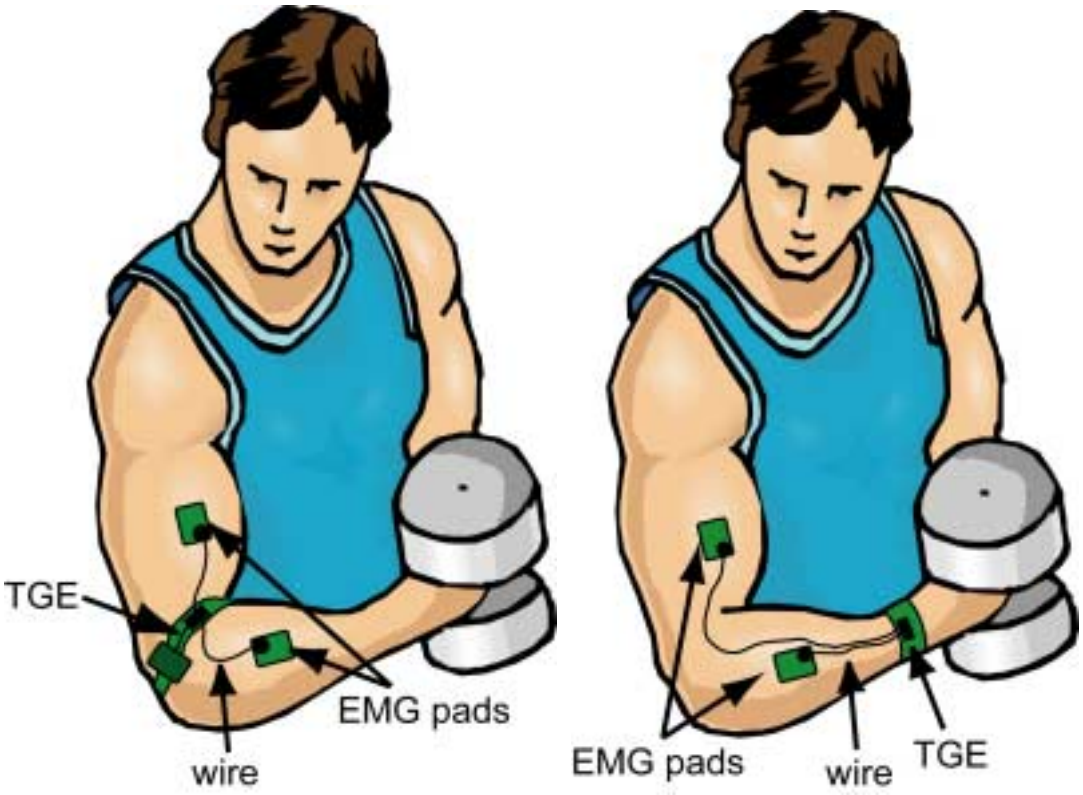
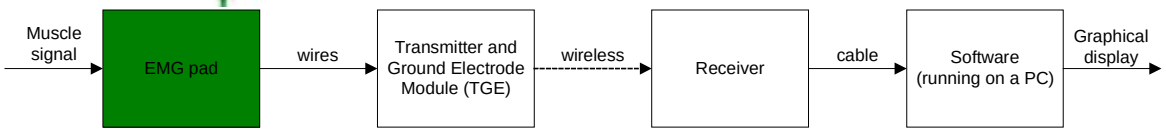


Figure 2.2: EMG Pads and TGE Module shown around the wrist and elbow



3 – EMG Pad Requirements

The EMG Pad collects the muscle activity signal and sends it to the TGE.

3.1 – General Requirements

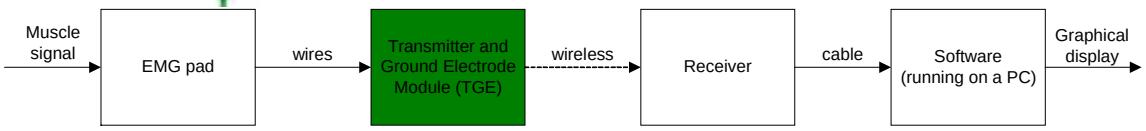
[R1-B] The EMG pads will operate from –20 to 50 degrees Celsius, 0-90% humidity, and regular atmospheric pressures.
[R2-F] The EMG pads will be water resistant against splashes and rain.
[R3-B] Each EMG pad will draw its power from a TGE module.
[R4-B] The heat dissipation of each EMG pad will be low enough that the subject cannot discern a temperature difference between her skin and the pad.

3.2 – Physical Requirements

[R5-B] The physical dimensions of each EMG pad will be identical to existing EMG equipment (1cm wide by 1.5cm long by 0.5cm tall).
[R6-B] Each EMG pad will be attached to the patient's skin using a 5cm square adhesive pad.
[R7-B] The device components will be enclosed to prevent damage due to handling such as electrostatic discharge.
[R8-B] The EMG pad will weigh less then 20g.

3.3 – Performance Requirements

[R9-B] Each EMG pad will be sensitive to EMG signals ranging from 200µV to 20mV in peak-to-peak amplitude.
[R10-B] The EMG pad will amplify the received signal to a maximum peak-to-peak level of 5V.
[R11-B] The gain of the EMG amplifier will be easily adjustable while the system is in operation.
[R12-B] The EMG amplifier will use common-mode noise rejection to clean the signal.
[R13-B] The EMG amplifier will have a pass-band of 20-500 Hz.
[R14-B] The EMG amplifier will use the ground electrode, located on the TGE, as a ground reference.



4 – TGE Module Requirements

The TGE module consists of a power supply, a ground electrode, a wireless transmitter, and an antenna. Figure 4.1 shows a block diagram of the TGE.

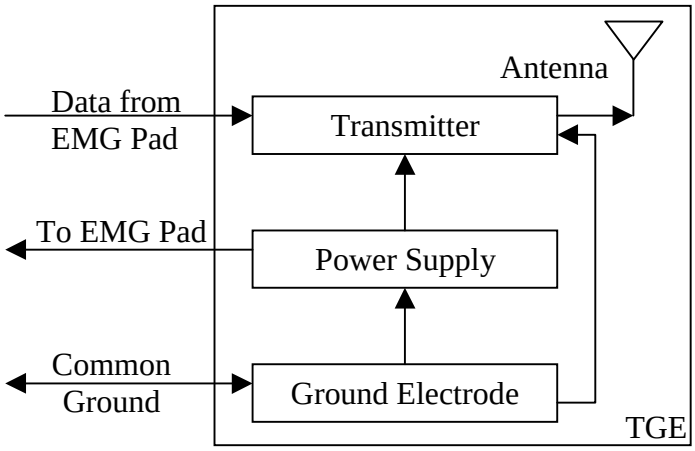


Figure 4.1: Block diagram of TGE Module

4.1 – General Requirements

[R15-B] The TGE will operate from –20 to 50 degrees Celsius, 0-90% humidity, and regular atmospheric pressures.

[R16-F] The TGE will be water resistant against splashes and rain.

[R17-B] The heat dissipation of the TGE will be low enough that the subject cannot discern a temperature difference between her skin and the TGE.

[R18-B] A small power supply, located on the TGE, will run the TGE and the two connected EMG pads for 6 hours of continuous use.

4.2 – Physical Requirements

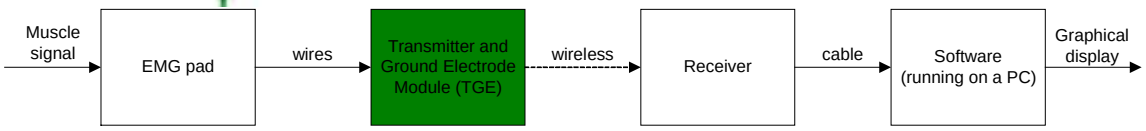
[R19-B] The physical dimensions of the electronic components of the TGE will be 3cm wide by 5cm long by 0.5cm tall.

[R20-B] The device components will be enclosed to prevent damage due to handling such as electrostatic discharge.

[R21-B] The total weight of the TGE, including batteries, will be less than 50 g.

[R22-B] The TGE will connect to two EMG pads via two wire bundles, each 1 meter long.

[R23-F] The wire bundles will be spring-retractable so that the excess length is not restrictive to the subject.



[R24-F] The wire bundles have small detachable plugs at the pad end, which will allow the EMG pads to be replaced by ECG and EEG pads.

[R25-B] The ground electrode will be a 1cm wide conductive elastic strap, adjustable in circumference from 15cm to 45cm, that can be worn around the wrist, elbow, shoulder, ankle, knee, or thigh.

[R26-B] The transmitter and power supply will be attached to the ground strap.

[R27-P] The transmitter antenna will be a free-dangling 10cm length of flexible shielded wire.

[R28-F] The transmitter and power supply will be enclosed in a protective yet flexible package that will conform to the subject's body. This package will protect against physical damage and ESD.

[R29-F] The transmitter antenna will be an integrated surface-mount device, inside the enclosure.

[R30-B] The TGE module will have a small toggle power switch.

4.3 – Performance Requirements

[R31-B] Each transmitter will sample signals from two EMG amplifiers.

[R32-B] The EMG signals will be converted to 12-bit digital data.

[R33-B] The TGE must be able to sample EMG, ECG and EEG signals without losing any data.

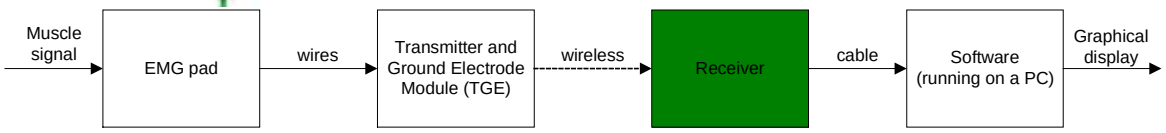
[R34-B] The transmitters will broadcast in the 915Mhz ISM frequency band.

[R35-B] Up to four transmitters may be operated simultaneously.

[R36-B] The transmitters will operate up to 100 m away from the receiver station outdoors, and 50 m indoors.

[R37-B] The power output by the antenna of each transmitter will be less than 1W, in compliance with FCC rule 47CFR15.

[R38-B] The TGE must be able to recover from any hardware or firmware errors by cycling the power switch.



5 – Receiver Station Requirements

The Receiver Station receives data from the TGE and transfers it to the PC for analysis.

5.1 – General Requirements

[R39-B] The Receiver Station will operate from –20 to 50 degrees Celsius, 0-90% humidity, and regular atmospheric pressures.

[R40-B] The Receiver Station will draw its power from the PC, and will consume low enough power to not significantly decrease the battery life of a laptop PC.

[R41-B] The Receiver Station housing will not heat more than 20 degrees Celsius above the ambient air temperature.

5.2 – Physical Requirements

[R42-B] The physical size will be comparable to other external PC devices such as a 3.5” floppy disk drive (approximately 10 cm wide by 20 cm long by 10 cm high), to ensure portability.

[R43-F] All components, including antennae, will be enclosed within a rigid case to protect them from physical damage and ESD.

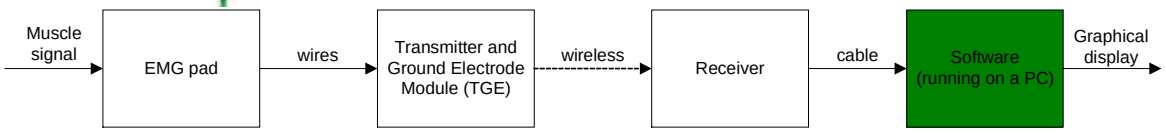
[R44-B] The receiver will be connected to a desktop PC by means of a cable and a PCI card.

[R45-F] The receiver may be connected to a laptop PC by means of a cable and a PCMCIA card.

5.3 – Performance Requirements

[R46-B] The Receiver Station will receive data broadcast from up to four TGE modules (eight EMG signals) simultaneously, and send this data to the PC.

[R47-B] The receiver station will have a reset button that restarts all hardware to recover from any possible errors.



6 – Software Requirements

The software is a simple interface that will save and display the muscle activity data transmitted from the EMGs.
Figure 6.1 is a flow chart of typical program operation.

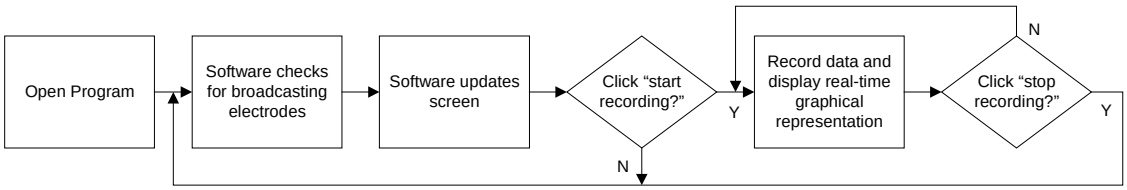


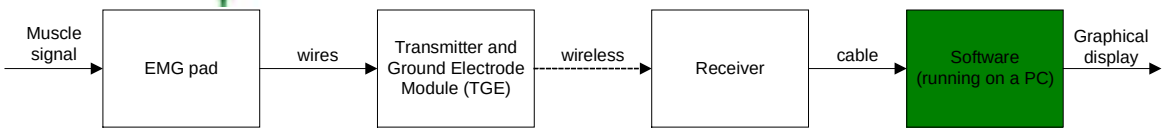
Figure 6.1: Program Flowchart

6.1 – PC Requirements

[R48-B] The software should run on a Pentium II 400 MHZ processor with 64 MB of RAM or greater.
[R49-P] The software will be compatible with Windows 98/NT.
[R50-F] The software should be compatible with Windows 95/98/Me/NT/2000/XP.

6.2 – GUI Requirements

[R51-F] The GUI will have an appearance similar to existing windows programs.
[R52-B] Before recording data, the software will automatically check for broadcasting EMG pads, and graphically illustrate which pads are broadcasting.
[R53-B] The software will display EMG data from all active pads on the screen in real-time.
[R54-F] The user will be able to label each EMG channel to distinguish which muscle each pad is measuring.
[R55-B] There will be an obvious 'Start Recording' button on the screen to click that will prompt the user for a path and file name to save data before starting to record the data.
[R56-B] The software will record and store the data from each active EMG pad and display graphical results in real time.
[R57-B] The software will write the data to an ASCII text file, which can later be analyzed using existing software, such as EMG analysis packages or Matlab.
[R58-F] The software will be able to display and analyze previously saved data.
[R59-B] The software will alert the user when the signal from the transmitters is getting too weak or noisy to provide reliable data.



[R60-B] The software will be able to detect if an EMG pad has fallen off, has become unplugged, or has stopped working due to battery failure.

[R61-B] There will be an obvious 'Stop Recording' button on the screen.

[R62-B] The software will indicate when the receiver is not plugged in or connected properly.

[R63-F] An extensive help menu will be available, which will be similar to Microsoft Windows Help menus. It will troubleshoot problems, and give a general overview of system capabilities.

7 – Documentation

The primary users of this product will already be experienced in the use of EMG apparatus. The documentation will focus on the system's abilities and limitations, and how to setup the equipment.

[R64-F] A user manual will be available in English and French.
[R65-F] The user manual will instruct the user in installation and set up of the device and proper use of the wireless EMG device.
[R66-F] The user manual will include a troubleshooting guide.
[R67-F] A specification sheet will be provided to the user.
[R68-F] A manufacturer's warranty card will be included with the system.
[R69-F] Company contact information will be provided.

8 – Reliability and Serviceability

[R70-F] The MTBF of the system, excluding the wire retractor and wire plugs, should be greater than 100000 hours due to the absence of mechanical parts.

[R71-F] The wire retractor and plugs should last through 5000 cycles.

[R72-F] The wire retractor and plugs will be easily and inexpensively replaceable by the end user.

[R73-B] Each adhesive pad will only be used once to attach an electrode to the skin.

[R74-F] The PC software will be easily upgrade-able by the user.

[R75-F] The hardware and firmware should operate for at least 100 hours without crashing.

[R76-B] If a hardware malfunction occurs, it should be recoverable by cycling the appropriate power switches or reset buttons.

[R77-F] The software should operate for at least 100 hours (when it is the only program running on the PC) without crashing.

[R78-F] If the software crashes, the user should easily be able to reopen the program, reload the data that has been last saved, and continue recording current data.

[R79-P] The entire system must be able to run at least 1 hour continuously without failing, just long enough to complete a demonstration.

[R80-F] If the hardware malfunctions during the warrantee period, the unit must be sent to the manufacturer, who will immediately send a replacement.

9 – Regulatory and Safety Requirements

The Wireless EMG system will comply with the following:

[R81-F] Title 47, chapter 1 (Federal Communications Commission), section 18 of the Code of Federal Regulations regarding ISM device requirements.

[R82-F] Title 47, chapter 1 (Federal Communications Commission), section 15 of the Code of Federal Regulations regarding Radio Frequency devices.

[R83-F] International Electrotechnical Commission Sub-Committee 62D (IEC/SC62D): Electromedical Equipment standards for patient monitoring equipment.

[R84-F] The regulations set forth for medical devices in the Canadian Food and Drugs Act - Medical Devices Regulations (SOR/98-282).

[R85-F] The standards set forth for medical devices by the U.S. Food and Drug Administration Center for Devices and Radiological Health.

[R86-F] ANSI/IEEE Std 602-1986 Standard for Electric Systems in Health Care Facilities.

[R87-F] CSA and UL requirements for medical devices.

[R88-B] The packaging of all system components will protect the user from electrical shock and physical injury.

10 – Conclusion

This document contains the functional specifications for both the prototype and final version of a complete wireless EMG system, called the iEMG. The prototype is specified to prove the concept of wirelessly acquiring muscle activity data in an efficient and convenient way without jeopardizing the quality of data. The prototype will meet these requirements by December 2002. Functional specifications for the final product incorporate the prototype specifications with the addition of regulatory and safety requirements, aesthetics, and additional user friendly features. Final product specifications will be met as part of future device development.

11 – References

[1] Dr. Andrew Rawicz, School of Engineering Science, Simon Fraser University

[2] U.S. Food and Drug Administration - Center for Devices and Radiological Health (http://www.fda.gov/cdrh/devadvice/313.html)

[3] Department of Justice Canada (http://laws.justice.gc.ca/en/F-27/SOR-98-282/)

[4] FCC Wireless Telecommunications Bureau – Rules and Regulations (http://wireless.fcc.gov/rules.html)

[5] Canadian Standards Association (http://www.csa.ca/standards/Default.asp?language=English)

[6] DelSys Inc. Electromyography (www.delsys.com)

[7] KinMyo Electromyography (www.kine.is)

[8] Perez, Reinaldo. *Design of Medical Electronic Devices.* Academic Press: San Diego, 2002.