October 4, 2010

Dr. Andrew Rawicz
School of Engineering
Science Simon Fraser University
8888 University Drive
Burnaby, British Columbia
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Re: ENSC 440 Project Functional Specification for the Remote Diagnostic System

Dear Dr. Rawicz:

Enclosed is the functional specification provided by MediCare Solutions for the Remote Diagnostic System. The system is composed by three components – the remote diagnosis software, a central server and an embedded handheld tablet. Our system is designed to allow paramedics to transmit patient information and their vital signs data electronically to the hospital in real time. The goals are to improve communication efficiency and accuracy between paramedics in an ambulance and the personnel at the hospital. Thus, it will result in shorter waiting time and better preparation at the emergency room (ER).

From prototype to production to future enhancement, this document provides a comprehensive set of functional requirements at different stages of the project's developmental cycle. This document will be used as the guideline and assessment of the project progress for the MediCare Solutions team.

MediCare Solutions consist of five members of senior engineering students with different engineering concentration: Da Zhou, Danny Chieh-Yao Cheng, Eric Chow, Jeffrey Tam, and Sean Yu-Hsiang Fang. If you have any questions or concerns about our proposal, please feel free to contact me by e-mail at cca16@sfu.ca.

Sincerely,

Danny Chieh-Yao Cheng
President and CEO
MediCare Solutions

Enclosure: *Proposal for a Remote Diagnostic System*

Functional Specification for a

Remote Diagnostic System

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Executive Summary

In an emergency, there is no time to waste and reliability needs to be top notch. When paramedics bring a critically ill patient to the hospital, it is important that the triage nurses and doctors have all the necessary information to perform a treatment. The information needs to be delivered in a timely manner and accurate to the last detail. However, if the nurse handling the call is swamped by multiple calls, critical information ends up in a queue and hence treatment is delayed. After observing the ER for an entire morning, we noticed some steps that we feel are redundant between the ER nurse and the paramedics. We feel that any information that paramedics record and are re-entered into the computer by the nurse is redundant.

At MediCare Solutions, we thrive to introduce a product that eliminates redundancy and improve how the patient information is organized in ER. It is unavoidable that our product requires minimal intervention. For example, in a life and death situation, no time should be spent on figuring out how the device works or what went wrong. After receiving feedback from an ER manager, we hope to decrease standard length of stay from two to four hours to less than two hours.

The Remote Diagnostic System was envisioned to be lightweight, durable, user friendly, and cost effective. For some hospitals, our product may just be an add-on, but for others it would be a brand new system. Regardless of the situation, recognized standards such as International Electrotechnical Commission (IEC) and Waste Electrical and Electronic Equipment (WEEE) will be followed.

The project is currently in its design stage where multiple functional requirements have been carefully thought out. In addition, a set of functional tests have been designed before a final product can be delivered for certification. In the end, the prototype is scheduled to complete by December 15, 2010.

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Glossary

ER	Emergency Room
EMS	Emergency Medical Service
GUI	Graphical User Interface
Handheld Tablet	A portable touch screen computer
Server	A computer **Server** that stores all information about patients and hospitals

1. Introduction

The Remote Diagnostic System will be an embedded system tailor-made to allow paramedics to retrieve/enter patient information to/from the hospital **Server**. The ability to be able to interact with vital sign devices on the ambulance and transmit these data to the hospital in real-time will be implemented to provide a pre-assessment of the patient by the medical personnel remotely from the hospital. Requirements for each component of the system are provided in this functional specification.

1.1 Scope

The document describes the function requirements for the prototype, the actual product as well as future enhancement features of MediCare Solutions' Remote Diagnostic System. These requirements will be fully met but revision will be made where necessary at any stage of the development cycle to ensure superior product design.

1.2 Intended Audience

The functional specification described in this document will act as a guideline for each of our MediCare Solutions members as well as any design engineer while research and implementation stages of the system. The project manager will assign each member's responsibility based on the specification, and keep track of the project progress. During the integration and testing phases, this document will provides necessary information and test plans, which test engineers can apply to ensure the quality of the final product.

1.3 Classification

All of the functional requirements described within this document will be denoted by the following convention:

[GR*-#]

where G is the classification of the section where the requirement belongs, R simply means it is a requirement, * represents "Requirement number", and # represents the priority of the functional requirement denoted by the following:

I. Proof of concept
II. Prototype Quality
III. Production Quality
IV. Enhancement

1.4 Terminology

In this document, the key words "**MUST**", "**MUST NOT**", "**REQUIRED**", "**SHOULD**", and "**MAY**" are to be interpreted as follows:

MUST and **REQUIRED** Indicate absolute mandatory requirements

MUST NOT	Indicates an absolute prohibition
SHOULD	Indicates a recommendation. There may exist valid reasons in particular circumstances to ignore a recommendation, but the full implication must be understood and carefully weighed before choosing an alternative course.
MAY	Indicates an item is optional

2. System Requirements

Applicable system requirements for the Remote Diagnostic System are presented in this section.

2.1 System Overview

The overall Remote Diagnostic System is described by the flow chart shown in Figure 1.

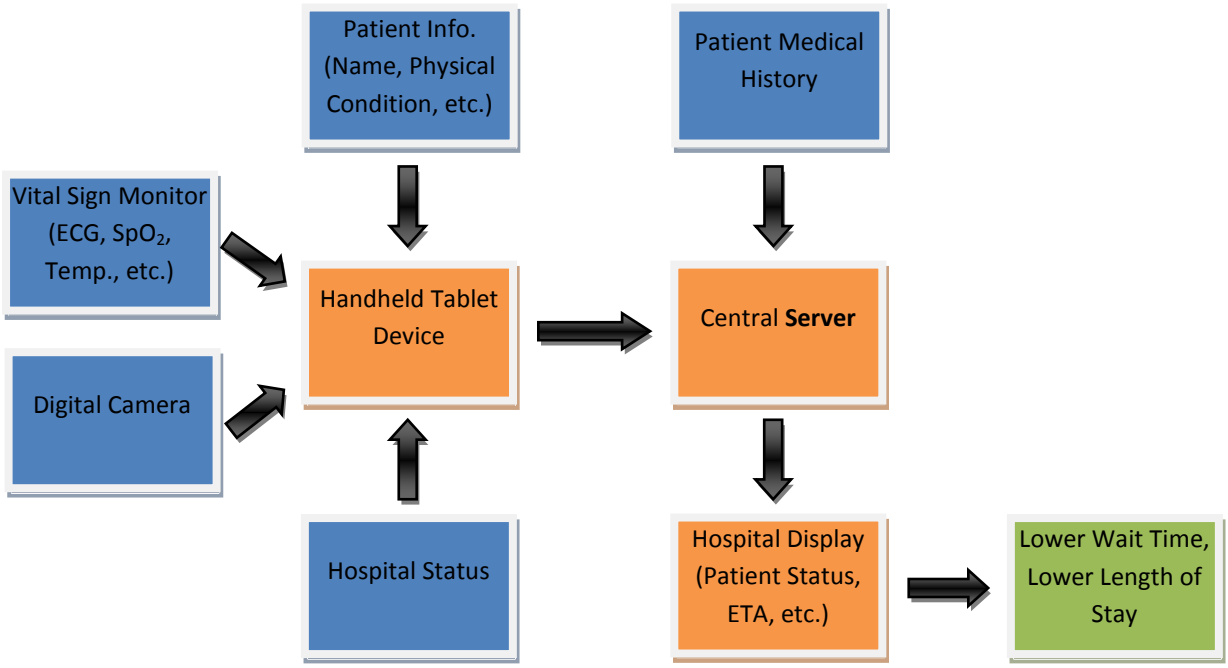

Figure 1 - System Overview Flow Chart

The idea is that all that paramedics do will be consolidated into one **handheld tablet** device. Then, all the needed information between the paramedics and hospitals will be stored and communicated through a central **server**. The intended result is reduction in redundancy between processes, lower wait time, and cost reduction due to inefficiency.

2.2 General Requirements

[GR1-I] Entire prototyping of the system with a single tablet cost MUST be less than $600.

[GR2-I] The prototype system MUST be functional.

[GR3-III] System MUST be able to support multiple handheld devices, no less than the number of ambulances in a given district.

[GR4-IV] Different systems MUST be able to integrate together

[GR5-III] System MUST be scalable.

[GR6-II] System is REQUIRED to provide a user graphical interface.

2.3 Electrical Requirements

[ELR2-I] The power supply MUST be sufficient to support continuous operation of the system.

[ELR3-III] During power outage, system MUST continue to operate for at least 30min.

2.4 Reliability and Durability

[RDR1-III] System MUST NOT crash with regular usage.
[RDR2-III] System **server**'s MTBF MUST be more than 1 month.
[RDR3-III] System **server** MUST be serviceable by trained technicians.
[RDR4-IV] Regular system maintenance interval SHOULD be half-a-year.
[RDR5-III] System **server** application data MUST be backed up on a daily basis.

2.5 Safety Security Requirements

[SSR1-II] System MUST be password protected.
[SSR2-IV] System MAY have finger scan security system.
[SSR3-III] Transmitted data must be encrypted to prevent unintended audience from accessing private information.
[SSR4-III] The electronic component of the system MUST NOT cause interference with other nearby operating system.
[SSR5-III] Transmission signal power MUST be under 36dBm.
[SSR6-III] The electronic component of the system MUST be shielded in to protect users.
[SSR7-III] In case of system failure, device MUST NOT cause a **Server** crash.
[SSR8-IV] Every time a system boots up, a self-diagnostic procedure SHOULD be performed and provide a self-check report.

2.6 Performance Requirements

[PER1 - I] Data transmission between **Server** and **handheld device** SHOULD not be delayed unless a network outage.
[PER2-I] Full data transmission SHOULD be completed within seconds.
[PER3-II] Two-way transmission between the handheld device and **Server** MUST be supported.
[PER4-I] Data transmission SHOULD occur immediately after the user confirms the validity of the data.
[PER5-IV] [PER4-I] must be fulfilled.

2.7 Usability Requirement

[UR1-II] Data transmission MUST be guaranteed assuming all components are setup and functioning properly.
[UR2-II] Data consistence MUST be guaranteed assuming normal operation of the system.
[UR3-II] System SHOULD provide error detection during data transmission and report the results upon request.
[UR4-III] System MUST provide firmware upgrade service without significant impact on system behaviour.
[UR5-III] System SHOULD provide an interface for external diagnosis.

3. Handheld Tablet

Applicable requirements for the embedded handheld tablet device are presented in this section.

3.1 General Requirement

[HGR1-II] Handheld Device MUST provide friendly user interface specific for paramedics.

[HGR2-IV] Handheld device user interface SHOULD be configurable for different users.

[HGR3-II] Handheld device SHOULD pick up the input from navigation of both touch-screen pen and finger.

[HGR4-I] Handheld device MUST be able to communicate with the **server** application located in a distance computer.

[HGR5-II] The development cost of a single handheld device SHOULD not exceed $500

[HGR6-II] Device MUST be able to establish communication with **server**.

[HGR7-I] Device MUST provide a way to take image of the wounds.

3.2 Physical Requirement

[HPR1-II] Device MUST be enclosed by dimension of num cm x num cm x num cm.

[HPR2-II] Device MUST weight from range of num lb to num lb, for an average individual to carry around.

[HPR4-III] Device SHOULD be ergonomically designed for portability.

[HPR5-III] Device SHOULD have handle for single hand carrying.

[PHR6-III] Device casing MUST NOT be conductive.

3.2 Certification Requirement

[HCR1-IV] Device MUST meet the standards laid out by the IEC.

[HCR2-IV] Device MUST meet the standards laid out by the WEEE.

3.3 Software Requirement

[HSR1-II] Device application SHOULD operate on Linux platform.

[HSR2-IV] Device application SHOULD be able to upgrade/modify with reasonably easy effort.

[HSR3-IV] Device SHOULD provide software failover, and attempt to recover to boot up condition again.

[HSR4-IV] A backup storage SHOULD be implemented to avoid loss of input data.

[HSR5-II] Device MUST save input data whenever it detects the new data entry, and prepare data transmission.

[HSR6-III] Handheld device's MTBF SHOULD be longer than 1,000 hours of continuous operation.

[HSR7-II] Handheld device MUST display all input on a friendly design interface.

[HSR8-III] Handheld device SHOULD provide self-diagnostic functionality that will perform on a daily basis.

[HSR9-IV] Handheld device SHOULD provide detection of connected external equipments.

[HSR10-II] Device MUST be able to receive measurement results from vital sign monitor.

[HSR11-III] Different operating modes SHOULD be appropriately implemented, such as sleep, hibernation.

[HSR12-II] Warning MUST prompt in case of losing connection to **server**, low battery, and system failures.

[HSR13-IV] Device SHOULD attempt to save user input data in case of losing connection to **server**, low battery, and system failures.

3.4 Performance Requirements

[HPFR1-II] Handheld device input interface responding time must be less than 100ms.

[HPFR2-III] Image processing time SHOULD be under 30s.

[HPFR3-III] Boot up time MUST not exceed 60s.

[HPFR4-III] Device reboot time consumption SHOULD be less than 2min.

[HPFR5-II] Operating Mode change time SHOULD be within 30s.

[HPFR6-III] Image taken by the device MUST have a reasonable resolution for clear display.

[HPFR7-III] When device transmit the image, the image SHOULD NOT be blurry.

3.5 Safety Requirement

[HSFR1-III] Docking station for handheld tablet MUST be available inside the ambulance to hold it stationary when unattended.

[HSFR2-III] Docking station MUST secure the handheld device from sudden changes in motion.

[HSFR3-III] Device casing MUST protect the internal structure of the device from unintentional dropping from a height no more than 1 meter, unless device lands on sharp objects.

[HSFR4-III] The electronic component of the handheld device MUST NOT cause interference with other nearby operating system.

[HSFR5-III] In normal operation and any system failures, the device MUST NOT overheat over 50°C.

[HSFR6-III] The electronic component of the system MUST be shielded in to protect users.

[HSFR7-II] Device MUST have a protective (waterproofed and shock-proofed) cover to internal equipment.

3.6 Power Management Requirement

[HPMR1-III] Device running fully on battery MUST last longer than 5 hours.

[HPMR2-III] Device MUST provide power management ability to allow device into different modes, sleep, hibernate, etc.

[HPMR3-III] Device MUST have low batter warning before battery life is less than 20%.

[HPMR4-IV] Device SHOULD have battery life estimation tools to evaluate the necessity of changing battery.

[HPMR5-I] Device MUST run on both battery and electrical cord with power supply feasible to North America outlets standard, 120V@60Hz.

3.7 Usability Requirement

[HUR1-II] During battery replacement, current device information SHOULD be stored and allow quick restore after replacing the battery

[HUR2-II] Device application SHOULD be intuitive for the users (paramedic, medical personnel) to operate.

[HUR3- I] Handheld device MUST be functional and allow user input without crashes or disruption.
[HUR4-I] Device MUST handle all user input during normal operation.
[HUR5-III] Device design MUST allow battery switch to be done easily.
[HUR6-II] Device MUST allow taking images to be done very intuitively by the user.
[HUR7-III] The size of the display MUST be large enough for clear and normal reading.
[HUR8-II] The input method MUST be able to handle quick data input.
[HUR9-I] The input method MUST be intuitive for average people to use efficiently.

3.8 Environmental Requirements

[HENR1-III] Handheld device MUST operate during all season temperatures.
[HENR2-III] Handheld device MUST operate during all season humidity.
[HENR3-III] Handheld device SHOULD operate in all normal weather condition, except possibly extreme weather.
[HENR4-III] Handheld device MUST operate under consistent motion.

3.9 Function Expansibility Requirements

[FER1-III] Handheld device SHOULD be able to connect to common ambulance equipment and allow information transmission from the equipment to the **server**.
[FER2-IV] Handheld device MUST have configuration settings to allow them to communicate with each other directly.
[FER3-IV] Handheld device MUST allow other customized user interface to be installed when required.
[FER4-IV] Handheld device SHOULD support different cameras in case of needing a higher resolution image.
[FER5-IV] Handheld device SHOULD support different video recording devices in case of needing for video recording.
[FER6-IV] Handheld device MAY support voice transmission to emergency usage.

4. Server Application

Applicable requirements for the host **server** at the hospital are presented in this section.

4.1 General Requirement

[SGR1-III] The **server**'s display MUST be installed in an openly accessed area for staff viewing.
[SGR2-III] Installation cost of the **server** system SHOULD be less than $3000.
[SGR3-III] **Server**'s Display MUST be stationary secured.
[SGR4-III] **Server**'s Display SHOULD be usable with a wall outlet of 110V/120V at 60Hz AC.

4.2 Software Requirement

[SSR1-III] **Server** applications SHOULD be compatible with current existing applications installed in emergency room.
[SSR2-III] **Server** application MUST allow installation under Windows or Linux platform or operate as a standalone system.

[SSR3-I] **Server** MUST be able to communicate with handheld device.
[SSR4-II] **Server** MUST clearly display information received from handheld tablet in an orderly manner.
[SSR5-III] **Server** MUST be able to handle multiple requests from different **handheld tablets** simultaneously.
[SSR6-II] **Server** application SHOULD NOT crash under normal operation.
[SSR7-II] **Server** application MUST be able to display live transmission from the handheld device.
[SSR8-II] **Server** application MUST keep a back up of all reports receive from the handheld devices, in case of system failure and also for reference.
[SSR9-III] **Server** application MUST generate a printable report for any selected report.
[SSR9-III] **Server** application MUST allow printer to be connected.
[SSR10-IV] **Server** application SHOULD transmit the reported information to a mobile device upon request.
[SSR11-III] **Server** application SHOULD keep a copy of the patient information in its database for future reference, if the consent is obtained from the patient.
[SSR12-II] Sever application MUST display a summary of all incoming handheld tablet connections, and provide detailed display upon request with a separate window.
[SSR13-IV] **Server** application MUST support the live video transmission from the remote handheld tablet.
[SSR14-III] **Server** MUST preserve the image received in its best quality possible.

4.3 Performance Requirements

[SPER1-I] **Server** respond time to incoming connections and data transmissions MUST be less than 1s.
[SPER2-III] **Server** MUST check for consistency between transmitted data.
[SPER3-I] Switching between different GUI interfaces SHOULD NOT exceed 500ms.
[SPER4-II] Printable report SHOULD be prepared in less than 1s.
[SPER4-IV] **Server** MUST display updated patient information in less than 1s after new information has been delivered.

4.4 Environmental Requirements

[SENR1-III] **Server** computer MUST function normally under typical indoor **server** room temperatures.
[SENR2-III] **Server**'s display MUST function normally under typical indoor temperatures.
[SENR3-III] **Server** computer and display MUST continue normal operation under typical **Server** room humidity conditions.
[SENR4-III] **Server** and **server**'s display MUST be used indoor.
[SENR5-IV] Noise and heat generated during maximum **server** activity SHOULD be under 25dB and 60°C.

4.5 Usability Requirements

[SUR1-III] Information input method MUST be intuitive.
[SUR2-II] System upgrade SHOULD be done easily by a trained technician.
[SUR3-III] Multiple login SHOULD be supported.

[SUR4-III] **Server**'s display SHOULD be installed in a height that is comfortable for average human viewing without stressing their neck.

5. User Documentation

The Remote Diagnostic System is designed for emergency paramedics to use, and a detailed user manual will be provided. A second detailed technical documentation will also be provided for maintenance and personnel usage.

[UR1-II] User documentation SHOULD include user manual, installation guide, technical support and website address which provides an online version of document.

[UR2-II] User documentation SHOULD be presented in different languages.

[UR3-II] User manual SHOULD contain a quick start guide for paramedics with little computer experience to use the device.

[UR4-III] Maintenance manual MUST be provided for any possible system error diagnosis, and provide quick method for system recovery.

6. System Test Plan

The general approach of testing the system will consist of individual module testing, integration testing, and prototype testing. The individual module testing will be carried out during the entire development process. They will be done once the module development is completed. Integration testing will ensure that difference module will work together. In the proof-of-concept design, we planned to perform the integration test on the core modules first to ensure the system could work as a whole. Afterwards, extra modules like the camera and vital sign device compatibility will be tested. The prototype testing will be carried out to simulate normal operation conditions. We planned to invite people without technical background to use the prototype device. It will be a random test to ensure that arbitrary user input will not break down the device functionality.

6.1 Individual Module Testing

The following test sets are detailed basic tests required to be performed on both the **handheld tablet** and the **server**.

1. Handheld Device GUI
    a. Turn on the handheld device power
    b. Observe the device boots up with GUI welcome page
    c. Observe a set of available function selections on the welcome page
2. Handheld Device Functionality
    a. Turn on the power of the tablet device
    b. Observe that the device boots up
    c. Observe that default application is loaded
    d. Try to input data to the device

   e. Observe that the device take input data, and save data immediately
      i. This can be checked by introducing a power off during the process,
      ii. Data should be saved to memory and loaded upon next boot up
   f. Observe that device display data correctly
   g. Turn off the device through GUI
   h. Observe a normal power off sequence is carried out
3. Touch Screen
   a. Select screen calibration in GUI
   b. Observe the location of the curser
   c. Observe the x-y coordinate display after touching the curser with both finger tip and the touch pen
   d. Make sure the curser does not appear off the track as drawing across the screen
4. Camera Module
   a. Open up camera utility
   b. Observe the camera field of view displayed on screen
   c. Take a picture with the camera
   d. Copy the camera to a standard computer
   e. Use Photoshop or other image processing application to check for the image resolution
   f. Make sure the resolution of the taken image meets the requirements
5. Connectivity Module
   a. Connect handheld device to Internet through Ethernet cable
   b. Try to ping the following hosts
      i. www.google.ca
      ii. www.yahoo.ca
   c. Make sure a ping reply within 30ms is received.
   d. Transmit a customized packet with certain checksum from **server** to handheld device and vice versa
   e. Check the checksum value of the transmitted packet, ensure that packet is transmitted correctly

   Repeat the test with wireless network configuration

6. Compatibility With Monitor Devices
   a. Connect handheld device to the vital sign monitor
   b. Use vital sign monitor to take a measurement
   c. Make sure the inputs from vital sign monitor are received and recorded by the handheld device correctly

6.2 Integration Testing

Remote Diagnostic System is separated into different modules, and each member of MediCare Solutions will be able to work on different modules in a parallel manner. Before the modules are ready for integration, each of them will be tested individually for its functional correctness. In addition, the codes

or implementation will be reviewed by other members to ensure the quality and compatibility between each module. The bottom-up approach may lengthen the time spent for implementation and integration, but it provides a greater assurance to the reliability of the product.

6.3 Prototype Testing

Upon the completion of the development and integration process, a prototype will be given to a non-technical personnel for testing. A normal operating procedure can be described with following key points:

a. **Server** application and handheld device are both powered on
b. User will remove the device from the docking station
c. The handheld device resume to a start up page upon activation
d. User start to input data to the device during which a picture of wound might be taken and saved as a part of the information required to be transmitted
e. User input can be interrupted several times during which constant device vibration might be present
f. User finished inputting data and confirmed for transmission
g. User might place the handheld device back to docking station for connecting to a vital sign monitor
h. **Server** application receives the incoming transmission and warns the user
i. Summary of the incoming information is displayed on the **server** application
j. Detailed information can also be obtained through **server** application by selection

This situation will be confirmed and simulated during the prototype testing of the device. A sanity test will also be carried out to make sure that random user input and wrong operation order will not cause system to crash. The functional specification also include requirement in several different fields, such as reliability and safety requirements. Each requirement will be tested in the prototype again to ensure the device quality. Error conditions will be simulated and manually introduced to the system, and system response will be recorded and further analyzed to provide improvement to the overall system behaviour. In case of failing to meet the requirements, the individual module will be redesigned and test cycle will be carried out again.

The error tolerance of the transmitted information will be measured and carefully determined. All final products will have to meet this requirement to ensure that there will not be any misdiagnosis due to our device. However, such an error tolerance measurement will not be available in the prototype device.

7. Conclusion

The functional specification for Remote Diagnostic System have been presented in this documentation. The requirements given with high priority (MUST, REQUIRED) are the functional specifications we are currently focusing on as part of design and implementation. Development of the proof-of-concept model meeting high priority requirement is expected to be delivered by December 15, 2010.

8. Sources and References

[1] International Electrotechnical Commission, "CISPR 11-am1 Industrial, Scientific, and Medical Equipment - Radio Frequency Disturbance Characteristics - Limits and Methods of Measurement," Mar. 2010.

[2] Canadian Standards Association International, "CSA C22.2 NO 60950-1-07-CAN/CSA Information Technology Equipment Safety Part 1," Canadian Standards Association, Mar. 2007.

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[4] Province of Alberta: Stakeholder Technology Branch, "Wireless Local Area Network (WLAN) Best Practices Guide," Oct. 2007. [Online]. Available: http://education.alberta.ca/media/822010/wirelessbestpracticesguid.pdf. [Accessed: Oct. 12, 2010].