April 24, 2006

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

Re: ENSC 440 Post Mortem for Edema Measurement System

Dear Dr. Rawicz:

The attached document, *Post Mortem for Edema Measurement System (EMS)*, describes the accomplishments Vedo Medico achieved during the design and implementation of the EMS device. Vedo Medico's prototype, Edema Measurement System, was successfully designed to provide medical professionals with an easy to use device to accurately measure the amount of swelling of limbs in patients.

The purpose of this document is to give details about the product's current state, deviations from the original design and future development considerations. The final budget, timeline, difficulties encountered and individual reflections are also outlined in this document.

Vedo Medico consists of five talented fourth year Systems engineering students: Ali Khan, Sepehr Mogharei, Arthur Papian-Gorji, Babak Shafiei, and Branko Zdravkovic. Please feel free to contact us with any questions or concerns regarding our project. We can be reached by telephone at 778-885-6059, or by email at vedo-medico-ensc440@sfu.ca.

Sincerely,

Babak Shafiei

Babak Shafiei
VP Operations
Vedo Medico

Enclosed: *Post Mortem for Edema Measurement System (EMS)*

Vedo Medico

Post Mortem:
Edema Measurement System

Project team: Ali Khan
Sepehr Mogharei
Arthur Papian-Gorji
Babak Shafiei
Branko Zdravkovic

Contact person: Babak Shafiei
vedo-medico-ensc440@sfu.ca

Submitted to: Dr. Andrew Rawicz
Steve Whitmore

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Executive Summary

If you can't prevent a disease, the next best thing you can do to protect your health is to detect the symptoms of a disease early. Build-up of excess fluids in body tissues (edema) is one of the major signs of heart failure. This early sign of heart failure can easily be detected by monitoring the amount of swelling in a patient's leg. Constant monitoring of the swelling of various limbs can provide medical professionals with key information for proper diagnosis. Vedo Medico's Edema Measurement System (EMS) working prototype provides a non-invasive and accurate measurement of edema in the patient's limbs.

Throughout the past 13 weeks, Vedo Medico's team of talented engineers has been busy designing and implementing the EMS device. The end result was the working prototype of the EMS device, which meet preliminary design and functional specifications.

Several software and hardware problems were encountered during the development and integration phases of the EMS device. The proposed solutions for these problems and final design decisions will be discussed below. Moreover, individual reflections regarding the project, deviations from original design, timeline and budget, and future plans for the Edema Measurement System will be outlined.

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GLOSSARY

AC	Alternating Current
CU	Control Unit
DataFlash	Memory chip included in AVR Butterfly for storing data.
Edema	Swelling caused by excess fluids in body tissue.
EMS	Edema Measurement System
ES	Enclosure System
PC	Personal Computer
SW	Software

1 Introduction

1.1 Scope

This document outlines the technical issues encountered during the development process of the Edema Measurement System. The post-mortem also explains deviations from the original design and outlines future plans for the device.

This document also compares the projected development cost and timeline to the actual cost and timeline. Individual personal reflections regarding the overall project are discussed at the end of the document.

1.2 Intended Audience

The ideas presented in this document are intended for project managers to be able to evaluate the progress made with the proof-of-concept model of the EMS device. Project manager could use the information presented to determine the success of the design and plan accordingly for the future improvements presented.

2 Current State

2.1 Software

2.1.1 Host Software

The Host Software is responsible for storing patient information and measurements, storing the medical centre's information (i.e. departments, doctors, etc.), analyzing data and providing a means for synchronizing information with the Embedded Software. The current Host Software is fully functional and meets all the design specifications.

2.1.1.1 Handshaking

The handshaking procedure we implemented relied on sending 'ready' and 'acknowledge' bits between the PC and Embedded Software on the EMS. Obviously, this was not the best solution since both, the microcontroller and RS-232 port on the PC are capable of performing hardware handshaking protocols. Although our solution might be prone to handshaking errors in some applications that require more robust error detection techniques, it functioned well enough in the simple testing environment we set-up. We are not sure that this would be the case if the EMS device is to be used more extensively in the future so implementation of some other, improved handshaking procedures might be necessary.

2.1.1.2 Communication

The EMS device and PC communicated through the exchange of data frames with predefined formats. Each set of data was separated from the previous one by using <CR> special characters. The data received on a PC side had to be sent in proper order and in case of any error in data frame, communication module had no mechanisms to recognize the error and to discard the data. After initial handshaking procedures, PC side and EMS side should have capability to detect erroneous characters inside the data frames and to request resending of data.

2.1.1.3 Data Analysis

The software module for patient data analysis currently contains only few functions that are used to display the values of the measurements for a patient in the form of a chart. The purpose of our device is to make a measurement procedure easier and to allow the obtained data to be more readable. This is the main reason why we need to include more data analysis features into our product. Measurements and patient information stored on the Host Software's database needs to be accessible from other PC applications such as MS Word and MS Excel in order to make our EMS device more attractive to its users.

2.1.2 Embedded Software

The embedded software is responsible for the measurement, communication procedure and displaying relevant information on the EMS Control Unit's LCD.

2.1.2.1 Measurement

After consulting health professionals in the field, they advised us that their main concern is to be able to tell how the swelling has progressed (i.e. did it grow, shrink, or unchanged). Subsequent to several design considerations, and through extensive experimental analysis we decided to implement our own measurement unit, 1 Vedo. 1 Vedo is roughly 50 ml and in comparison with existing circumference measurement techniques provides a higher amount of accuracy; during testing, 1 cm change in circumference resulted in 1.6 Vedo units of change.

2.1.2.2 Communication

The communication procedure on the EMS is responsible for syncing the data between the host software (database) and the Control Unit. Currently, patient information and measurement values are stored on the EMS device and are synced with the host software via RS-232. Using the serial connection, new patient names can be sent to the EMS device and existing patient names and measurements are sent to the host software.

2.1.2.3 User Interface

Upon thorough analysis of the proposed menu, Vedo Medico's design engineers decided to simplify the user interface on the Control Unit, in order to provide a simple and user-friendly user interface. Figure 2.1, shows the new simplifies embedded software user-interface of EMS.

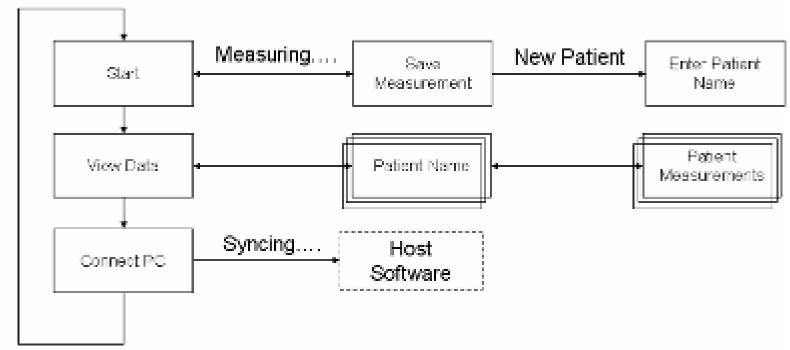

Figure 2.1 – New Embedded Software User Interface

To further improve the Control Unit's user interface the embedded software was designed to allow the input of patient names using the existing joystick and also provide more detailed information regarding the patient measurements (i.e. date, time and value of the measurement). Moreover, the user is notified by sound when an action, such as taking a measurement, is complete.

2.2 Hardware

EMS consists of an enclosed bladder that will be used as a tool in order to measure the volume. The sole purpose of this bladder is to be wrapped around the patient's leg, while the measurement is being taken by the EMS control unit. Microcontrollers in the CU control the air pump and valve in order to get an accurate and reliable data from the patient's limb, in units of volume. Proof-of-concept model of the EMS enclosed bladder and control unit are shown in Figure 2.2.

Figure 2.2 – EMS Proof-of-Concept enclosure and control unit

3 Design Challenges

3.1 Software Challenges

3.1.1 Host Software

3.1.1.1 Modular Design

During the course of our project, we experienced many difficulties when designing a software modules on host (PC) side as well as modules for communication between EMS control unit and personal computer. Every change of EMS measurement procedures and formats of data that were sent to PC, had to be reflected in end user application. This dynamics in EMS development dictated the design of application through smaller software modules that could be easily modified, recompiled, and reintegrated into the system. Constrained with short deadlines, sometimes we succeeded and sometimes not to accomplish what we planned in earlier stages of product design.

3.1.1.2 Communication

A key feature of the Host Software was to be able to communicate with the embedded software to send/retrieve patient information. A problem which we encountered was that the data that was being received contained faulty data at times. The problem was solved by lowering the communication Baud Rate to 9600. A more elegant solution was to implement parity checking and other redundancy checks to ensure problem synchronization of data; however, due to time constraints a more simplified solutions had to be chosen.

3.1.1.3 Synchronization

If few problems arose when we decided to implement and support adding of new users from the Embedded Software. A separate database on the EMS side had to be created in order to support this new requirement. Suddenly, we discovered that we needed to synchronize the changes between Embedded Software and a Host Software's database in more efficient way. We decided to send a list of all patient information on the Host Software to the Embedded Software, and the Embedded Software would send all the information it has in its database (i.e. all patient information and measurements) to the Host Software. We chose this solution only for the proof-of-concept model and under the assumption that the number of patients and measurement would be small. We are fully aware that this procedure has to be improved as soon as the number of patients in the two databases increases. One solution would be to send only a list of new patients, which are required to be measured, to the EMS side and retrieve the set of measured values for the same patients on the PC side when measurements are completed.

3.1.2 Embedded Software

3.1.2.1 Program Memory

Through out the development cycle several embedded software challenges were encountered. The initial challenge that we faced was the limited program memory on the Microcontroller. This problem was first encountered as a result of erroneous program execution. Upon further analysis it became clear that the embedded software code needed to be optimized. The result of the optimization process was the removal of unnecessary code and greater amount of assembly language programming.

3.1.2.2 Use of DataFlash

Another software problem encountered was the use of the DataFlash on the Microcontroller. We intended to use this 4MBit memory chip to store patient information and measurement. However, the driver that was written to control the DataFlash at times did not operate as expected. Due to the limited debugging time, it was decided to store the patient information and measurement on the 512 Byte EEPROM of the microcontroller. The draw back was the limited space, however, we were able to successfully store and retrieve data from the EEPROM. Using the DataFlash, we had the possibility of storing a total 100+ patients and 1000+ measurements; however, the current EEPROM limited the maximum number of patients to 10 and the maximum number of measurements to 30.

3.2 Hardware Challenges

3.2.1 Pressure Sensor

We faced several obstacles related to the use of the pressure sensor. Initially, we had to choose the pressure sensor with the appropriate range (0-5 psi). Selection for sensors in this range was limited since most pressure sensors are not as sensitive as our project required. However, because of the high sensitivity, the pressure readings contained noise which had to be filtered out. We implemented this filter using a digital finite impulse response low-pass filter. Also, while the pump was on or when air was being exhausted out of the bladder, the pressure readings would be offset. To overcome this problem we had to modify our measurement procedure to read air pressures only when they have stabilized.

3.2.2 Enclosure Unit Construction

Building the enclosure unit from scratch was a time-consuming endeavor, but the end result was worth the effort. Initially we had planned on using an air bladder purchased for blood pressure measurement around the thigh, but this option did not allow us to choose the ideal size of the bladder. Our next choice of using the foodsaver packing bags was the best choice for us, as it allowed us to build a custom bladder which also turned out to be quite robust. Another challenge was the hardware used to latch the enclosure closed around the leg. The magnets we used just barely hold the enclosure shut against the internal pressure, since they rely heavily on proper alignment. Alignment of the edges was a problem because of the flexible garbage bucket container used as the enclosure frame.

4 Future Plans

4.1.1.1 Increased Data Storage

One of the most important future improvements for the EMS device is to make the 4MBit DataFlash memory unit operational again. This allows for a substantial increase in the amount of information that can be stored on the device. The increase in storage will allow for greater mobility of the product, since the users wouldn't have to sync the device to the host software as often.

4.1.1.2 Measurement Procedure

The current construction of the enclosure introduces error in the measurement. The main cause is due to the fact that when the air bladder is under pressure, the bladder pushes some of the air above and below the area under examination, giving a false measurement reading. To fix this problem, the enclosure needs to be redesigned to ensure the bladder has maximum contact with the patient's limb. Moreover, to guarantee the enclosure is always placed at the same position on the patient's limb, a resting mechanism needs to be attached to the enclosure system. This mechanism could rest against the patient's thigh.

4.1.1.3 Software Testing

Testing in the product development is very important in order to discover all weaknesses of the design. Due to the limited amount of time we had for our project, we couldn't test all software modules for potential errors. In future development, it will be necessary to define the test cases that can predict all critical system behaviors and handle the software exceptions that could arise from those situations. Black box and white box test cases should be designed. For the first type of testing, the critical user inputs (with memory and data limits reached) will be given to the software modules and the final outcome will be observed for errors. For the second type, the errors that arose after the integration of software modules will be caught and corrected. The testing phase usually takes about 70-80% of software development time and we couldn't properly implement it during the given time frames.

5 Timeline and Budget

Table 5.1 shows a comparative analysis of Vedo Medico's project timeline and any reasons or comments for the delays experienced during the development of the EMS device.

Table 5.1 Comparative Analysis of Vedo Medico's timeline

Task	*Original Date*	*Actual Date*	*Comments*
Project Proposal	January 23rd	January 23rd	Emailed proposal to Dr. Rawicz and Steve Whitmore and TAs, after choosing our best idea among 7 other possible products that team had on the design table since 8 months before the start of the course
Research	February 15th	February 10th	With the help of our Profs, TAs and our consulting physicians we were able to make quick decisions, and speed up our research
Functional specs	February 20th	February 20th	Team agreed on the functionality of the device on time
Design specs	March 6th	March 9th	Delays on ordering sample strain gages, and uncertainty regarding final design.
Enclosure assembly	March 6th	February 19th	Ordered blood pressure cuffs for prototypes arrived sooner than expected. Started testing air flow and air seal tests
Progress Meeting	March 8th	March 8th	During the meeting with the professor and TAs, we received feedback and key suggestions regarding possible design approaches.
Preliminary Hardware	March 10th	March 15th	First sample of electronic components arrived with some delay. Started to install and familiarized with AVR Studio, winAVR, B@rry++ terminal
Embedded Software/ Host Software	April 10th	April 10th	Although we encountered numerous software problems from incorrectly programming the flash memory to USART Serial communication we managed to isolate problems individually and solve by divide and conquer method Thanks to the great experience in programming of our team members, the Host and Embedded Software were ready to launch and was waiting the completion of communication protocol on the AVR
Integration	April 12th	April 16th	Integration was more sophisticated that expected. Numerous circuit failures led to the change of AVR Butterfly, change of serial cable for communication, and re-soldering of some parts of the circuitry
Presentation	April 18th	April 19th	Host and Embedded SW communication problems, forced us to postpone the preparations for Demo to a later time
Fully Operational Prototype	April 15th	April 19th /20th	

The company's first timeline review took place on March 5th. It was then decided that the team was not on schedule, and the team was approximately behind by 1.5 week compared to our proposed timeline in the month of January. Due to uncertainty of the original design, and multiple design concepts, we were unable to commit all of our energy fully one specific design. After talking to the experts both from the school and professionals in the hospital, a specific design was approved by team members. Past experience of our team members in microcontroller selection and ordering of the main components helped us recover some of the lost time during the semester.

We took a lot of time in doing research for selecting the proper pressure sensor, which at first caused a little delay in preliminary hardware development. But that research proved to be necessary, since the pressure sensors met all of our requirements when the first wave of testing was done in lab 1. Therefore we moved quickly from the stage of proof-of-concept into hardware development for the first prototype. At that time we were on target for completing the major system blocks of with proposed functions.

Second review of our timeline still showed that we were behind by at least a week at the beginning of month of April. The embedded software development was rescheduled due to the shut down and loss of one of microcontroller's JTAG debuggers. Hardware components of the first prototype showed good results after testing separate components of the project. The team struggled with keeping up with the deadlines during the month of April, due to the software failures during the integration stage of the subcomponents. Debugging time was needed for testing the communication between the Host and Embedded Software and the use of memory on the EMS device to store patient information.

Table 5.2 presents the comparative cost analysis of our planned budget for the EMS device. We managed to stay under budget for both R&D and part selection. We were able to receive funding of $300.00 from EUSS, on behalf of the Senate Undergraduate Awards Adjudication Committee, which helped us a lot in purchasing of most of our equipment.

Table 5.2 Comparative Cost Analysis for Vedo Meco's EMS prototype

	Projected Cost	*Actual Cost*
Microcontroller/Debugger Software	$40.00	$65.00
Sensors	$150.00	$62.75
Actuator (Pump/Valve)	$80.00	$134.72
Serial Interface	$50.00	N/A
Power Supply / Battery	$100.00	N/A
Enclosure System	$20.00	$82.75
Prototype Board	$30.00	N/A
Electronic components	$15.00	$52.94
Shipping and Handling	$25.00	$14.00
Total	$510.00	$412.16

We also managed to provide some of our needed parts from our personal inventory of components obtained from other engineering science project courses, which helped us keep the costs as low as possible. Due to lack of experience, and some miscalculations we purchased some hardware components that were never used in our project. These include 'a 2 way switch valve', an 'extra pump', and some 'electronic parts'.

We managed to offset some of the unforeseen expenses by getting free samples from some of our suppliers and we would like to thank FreeScale, and Fairchild Semiconductors for their generous offers. It was concluded that team should include a 20% to 25% contingency fund for future projected plans. This amount was about 10% in our proposed budget.

6 Personal Reflections

6.1 Ali Khan

Completing this project course has been an exceedingly rewarding experience for me. One of the most beneficial aspects of the course has been the amount that I learned from my team members, especially regarding hardware prototyping and design. This project was also an interesting and optimistic study of team dynamics.

My perception of the team's organizational structure and dynamics evolved considerably over the course of the semester. During the early documentation and design phases we organized ourselves from the bottom up with no specified leader. This proved to be inefficient in getting work done ahead of time since there was no leader to divide up the tasks appropriately and motivate others. However, once the design documentation was completed and work began on the technical aspects of implementation, the dynamics of the group changed greatly. Those with specialized expertise in a certain area (hardware, firmware and software) became the technical leads for their respective field. In this way, sub-teams of 2-3 people each were formed (some of us were part of multiple sub-teams). Although we did not explicitly organize ourselves in this way, our individual experience and interests allowed the team to settle in this structure.

I can honestly say that my experience with this course has been extremely positive. Our team got along very well, making the long hours in the lab as enjoyable as possible. I feel that without this course I would not be getting the most out of my undergraduate studies; it has been an excellent culmination of the past five years in engineering school.

6.2 Sepehr Mogharei

This project was one of my most successful team projects at SFU. Learning by experience through hands on development was not only fun but rewarding. My talented team members complimented my skill-set very well, and allowed me to do what I really wanted to do: hardware design. I credit the team for getting started early, months before the semester to brainstorm and invent the ideal product, within our time and budget limits.

I learned a great deal of design and project management during this period, while trying to keep up with deadlines and team goals. Designing a project using concepts that engineers don't come across in a daily basis was one of our major challenges. This was due to the fact that most of the designing happened based on a theory on paper with little or no idea of how it would turn out in reality. We overcame this challenge by working together and researching various ideas and ways to get around every problem.

Upon constructing the hardware, I learned how to strategize in order to stay in line with the original concept, regardless of what constraints I came across. I am overwhelmed with the amount of dedication and commitment that my team members put in to this project and I congratulate them on our achievement. I don't believe we build a product that would save the man kind, however we did build a devoted circle of friends that will be remembered for years to come.

6.3 Arthur Papian-Gorji

About a year ago my mind was set and filled with ambitions around designing a product and registering a company in the field of biomedical engineering. In an earlier course 'ENSC 201', I learned about the basics of managing a company composed of fellow engineers and business partners. I also learned about the marketing aspect of bringing a product to the public. With these goals in mind I decided to gather a group of my best friends, each with unique talents, to help me reach these goals. When we teamed up together, I knew since day one that I could never go wrong with my team, and I could count on them.

I learned many skills from teamwork, managerial, and leadership skills to many technical skills. Although we disagreed on many design issues, we never disagreed on the fact that we were all improving our design on a day to day basis; therefore we learned how to have respect for each other's suggestions and opinions. I learned a great deal on how different people in a team are and how to approach each person differently, and make sure that they kept their harmony with the bigger body which was the company itself. As the VP of finance I also learned that many great ideas won't take off if they are not profitable within the framework of a company's budget and target market.

I gained a lot of knowledge and experience in research and development of a prototype, and how to integrate all the different parts into a more complex system. I had the opportunity to learn microcontroller programming using a higher level language such as C, and how to create a simple communication protocol between devices. This was also a great opportunity for me to finally work on a biomedical system, something that I was hoping to be able to spend some time on, and get the feeling of how rewarding it would be to create a solution for the well-being of the public. I could never thank my team enough, because they made me feel prouder by not just being one of their teammates but also by being their friend. Thank you all, and God bless!

6.4 Babak Shafiei

Before taking on ENSC 440, I believed that this course was going to be a miserable experience with many sleepless nights to be endured. After completing the course, I would have to say that my initial perception of the course was not even close to what I experienced. Working on the design and implementation of the Edema Measurement System for the past three months has been a wonderful experience. Even though I was working full time while registered for the course, it never felt like the work load was overwhelming. The group dynamics was great, filled with a friendly and fun good environment.

On the technical side of things, sadly enough, it's not far from the truth that most of the knowledge that was needed for getting different components of the device to work was either from online material or consulting fellow classmates and engineers. It felt like many of the previous courses taken were not that beneficial; thus, increasing the time needed to learn the new skills necessary for the getting the prototype to work. I was involved in designing the user interface on the embedded software and also helping fellow team members troubleshoot various problems during the development process (i.e. communication, voltage regulation, microprocessor programming, etc…).

Through out the project I learned that sometimes it faster to solve a problem by trial and error than trying to take on a different approach. I learned how pressure sensors work and the importance of choosing the correct sensor to meet the desired accuracy. In addition, I learned that many problems arise when trying to integrate different components and when trying to establish proper communication between devices.

Overall, the experience was valuable and enjoyable. I would like to thank my group for their hard work and dedication. With out them none of this would have been possible. Thank you guys.

6.5 Branko Zdravkovic

This exciting project was an opportunity for me to gain new skills and expand my knowledge on pressure sensors, hardware design, and programming. Sometimes, I learned new things from my own research but more often the learning was a result of sharing the experience and ideas with other team members. Whenever I was not directly involved in some part of a product development, I asked other team members for clarifications and discussed their results and findings.

Now I know how sensitive the pressure sensors are, how to calibrate them, what are the problems I can encounter when programming the microcontroller with limited memory capacity and port features, how to communicate between different devices through RS-232 and what the possible problems are, how to use reverse engineering to add parts from other devices into the new product, how to design a database and GUI etc. Maybe the most valuable experience I gained was the integration of all parts that we developed into the final product. This step in product development requires that each team member knows how the product works and what its weaknesses are. It is important to start with the integration early in the development phase in order to learn how other parts of the product function and how your part is going to fit inside the overall system. This way, the amount of problems that can be encountered during the integration phase is reduced and some extra time is available for the final device testing.

7 Conclusion

The product design cycle for the Edema Measurement System has proven to be a valuable experience for all members of the Vedo Medico Team. The project not only allowed us to collaborate together as a team, but also take on an analytical approach towards identifying and solving problems encountered. EMS was an outstanding accomplishment from an outstanding team.

8 References

[1] "Functional Specification for EMS", Vedo Medico. February 2006.

[2] "Design Specification for EMS", Vedo Medico. March 2006.

