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September 20, 2004

Dr. Andrew Rawicz
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Re: ENSC 340 Project Proposal for a Venipuncture Site Locator (Teeka)

Dear Dr. Rawicz:

Attached to this document is an outline of *Teb Medical Inc.*'s product, *Teeka*, for the ENSC 340 project. Our goal is to design a cost effective and practical device to locate a proper site for venipuncture.

A vital task at any medical center for nurses and doctors is administering blood tests. Although common, it can prove challenging to find a proper site for venipuncture (the process of drawing blood from a patient). *Teb Medical Inc.* intends to improve these tedious and painful circumstances.

Teb Medical Inc.'s determined and diversified management consists of Balraj Mattu (CEO), Amir Goldan (CFO), Ida Khodam (COO) and Ameneh Atai (CTO). Should you have any questions or concerns regarding our proposal or our project, please contact us via email, ensc340-vein@sfu.ca .

Sincerely,

Balraj Mattu

Balraj Mattu
Chief Executive Officer
Teb Medical Inc.

Enclosure: *ENSC 340 Project Proposal for a Venipuncture Site Locator*



Proposal for a Venipuncture Site Locator

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Date:

September 20, 2004

Executive Summary

The majority of the general population has never experienced a problem walking into a medical clinic to get a blood test. Nevertheless, some individuals with various physical conditions – obesity, cancer, and drug addictions to name a few, go through excruciating pain if a proper venipuncture (the process of drawing blood from a patient) site cannot be located by the doctor or nurse taking the test.

Teb Medical Inc.'s (TMI) goal is to research and develop an accurate, safe and inexpensive device allowing doctors and nurses to locate a venipuncture site on any patient quickly and effortlessly. The trauma some patients experience during this procedure can, therefore, be reduced or even eliminated. *TMI* plans to build a versatile laser-based device, which will carry out this task.

Since there are no similar products on the market, *TMI* intends to globally distribute this product wherever venipuncture is performed including: hospitals, clinics, offices, etc. With the projected low cost, *TMI* intends to supply these institutions with large quantities of this device.

TMI is composed of four innovative engineers who have extensive experience in hardware/software design, laser technology, and business expertise through schooling and working in industry. The projected completion time of the prototype is early December and the estimated cost is below \$300. We will obtain our financial support from various sources of funding.

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1 Introduction

Everyone is required to go through the venipuncture procedure at some in point in life.



For a number of patients, this simple routine can turn into a nightmare. This is very common in chemotherapy, obese, or *Coronary Artery Disease (CAD)* patients.

Often, the simplest things in life go unnoticed and untouched. The core of our product is based on this principle; design a simple

device for a simple problem to ease the life of many individuals. It will aid in finding veins of people, and even pets, who suffer from the previously mentioned, and many more, physical and medical conditions.

By conducting a rigorous patent search, *TMI* found no evidence of any similar products on the market or even in development. Our team believes a cost effective and efficient design of this product will be successful.

The proceeding proposal describes an overall system description, functional design considerations and project scheduling. Including ultrasound, several design solutions are discussed, and after careful analysis, an optical method is designated and described for prototype development. Furthermore, the expected financial requirements and sources of funding are highlighted, along with project, Gantt and milestone charts.

2 System Overview

In the venipuncture procedure, first a tourniquet is bound around the upper arm to apply pressure. This impedes the blood's flow, resulting in an excess before the tourniquet. Operator then locates the venipuncture site and punctures the vein. *TMI's* new invention helps the operator to locate the best possible venipuncture site. [1] The overall system block diagram is shown in figure 2.1:

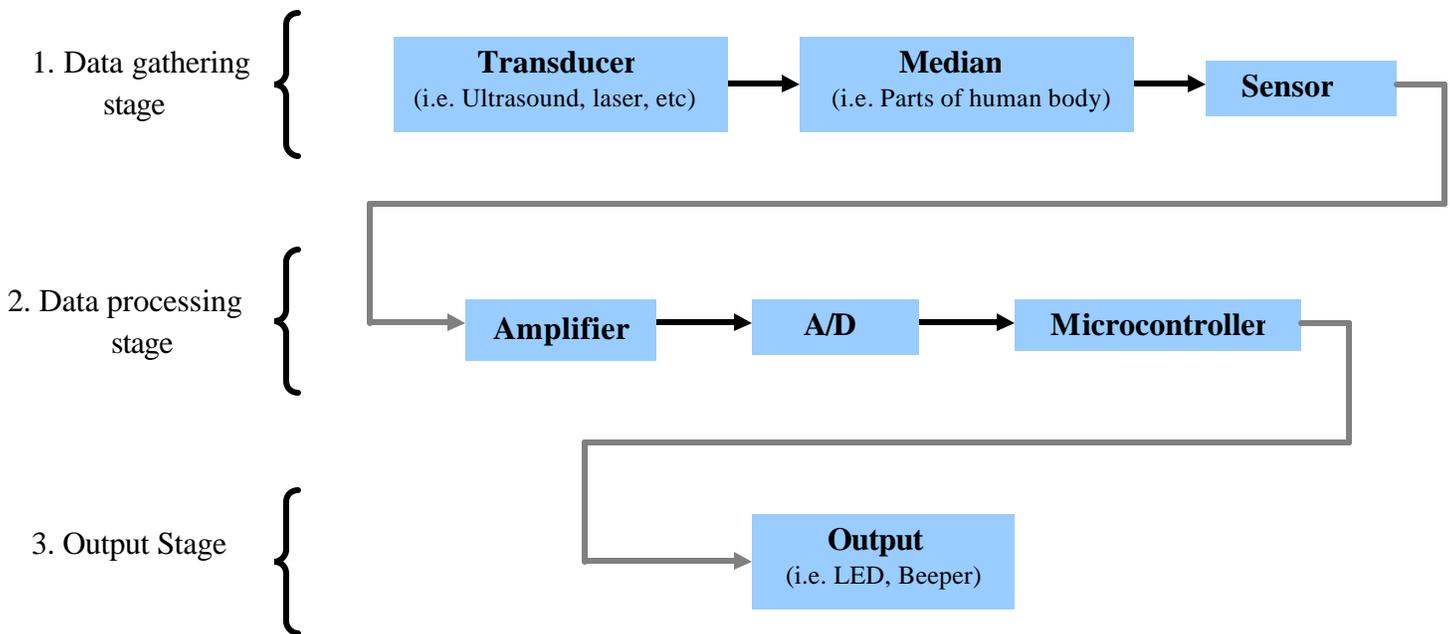


Figure 2.1 – The overall system block diagram.

The system comprises of three stages:

- data gathering stage,
- data processing stage and
- output stage.

In the first stage, a transducer emits an electromagnetic wave through a median (arm in our case) and the reflected wave is detected by a sensor. Note the output of the sensor is a low-level analog signal. In the second stage, the analog signal is amplified and converted into an n -bit digital data (n is to be specified in the design process). Finally, the output of



the microcontroller is employed to provide feedback for the operator. For example, if a venipuncture site is detected a green LED will turn on or a beeper will start beeping.

3 Possible Design Solutions

Two completely different detection mechanisms, ultrasound and laser, can be employed in the data gathering stage.

3.1 Ultrasound Detection

Ultrasound maps the reflection and attenuation of sound. Ultrasound waves require a medium to propagate. As the waves propagate through the medium, they cause disturbances consisting of alternate compression and rarefaction. [2]

The reflection of ultrasound at an interface between two tissues or media is determined by impedance mismatch for ultrasound propagation perpendicular to the interface. Note the large reflection at air/solid or air/liquid interface makes it necessary to avoid any air space between the ultrasound applicator and the patient. Applying gel to create a liquid medium coupling the applicator and the patient almost annihilates the error. [2]

The ultrasound transducer generates sound waves, which pass through the skin and also serves as a microphone to record the returning sounds—the echoes. When pressed against the skin, the transducer directs high-frequency sound waves toward the area being studied and records the returning echoes. The echoes are detected and processed by a microcontroller. [3]

Advantages of this method include:

1. The wide availability of ultrasound scanning compared to other imaging methods.
2. The harmless procedure associated with the standard diagnostic ultrasound.
3. The noninvasive nature of the procedure, which requires no penetration of the skin or any body cavity.

Although the design could be carried out with this technique, many disadvantages arise, including:

1. Poor Spatial Resolution, unless multiple transducers are utilized.
2. The associated high cost exceeds the projected funding, because many transducers are required to pinpoint a vein.
3. The need for the application of gel to the patient for accurate results.

3.2 Laser Detection

The optical solution employs a simple and economical system to locate veins in the human body. This technique applies a low power red-laser diode, a photodiode and an optical lens. The red-laser diode illuminates precise points of the human body which causes body tissue to react; the resulting reflections are collected by the optical lens and detected by the photodiode. Storing these reflections in a processor and making the appropriate calculations will lead to finding the proper venipuncture site.

Advantages of this method include:

1. Narrow laser beams (radius < 5mm) yield accurate results.[5]
2. High sensitivity of the laser is adequate to perform the desired task
3. Low cost lasers are sufficient for this application.

Some concerns with this method are:

1. Radiation-tissue interactions caused by high power lasers can result in chemical reactions in tissue cells. [5]
2. Determination of the appropriate signal strength for the intended application.

4 Proposed Design Solution

After careful analysis of both detection mechanisms, *TMI* proposes to implement a versatile and inexpensive laser based device for locating the venipuncture site.

Transmission through the skin is an important factor in order to analyze the underlying tissue. Light penetration, through all layers of skin, reaches its maximum at the red and infrared region of the electromagnetic spectrum.

After piercing these layers, the body tissue will *transmit*, *absorb*, and *reflect* the remaining photons and, through inspecting total wavelength reflectance, body tissues may be identified. Blood vessels tend to reflect 40% of near-infrared wavelengths, whereas soft tissues, exclusive of blood, reflect 65%. [6]

Light absorption, transmission and reflectance also depend on laser power. Higher power lasers easily penetrate through most body tissues, whereas, lower power lasers penetrate less.

Considering the above specifications, the preferred laser for venipuncture detection is a low power red-laser diode. Such lasers can be obtained at a very reasonable price due to their low output power and region of operation. Furthermore, red-laser diodes do not require high input current densities to operate.

An optical lens is often employed in optical systems to align the photodiode; light emissions, due to both reflection and scattering, are collected by the optical lens and redirected towards the photodiode. Since the reflections are expected to be in the near infrared region, a photodiode with high *responsivity*¹ at 600-900 nm is required. [6, 7] Typically a silicon photodiode has great responsivity at the specified bandwidth.

¹ Responsivity is a term used in optical engineering to describe the responsiveness of photo-detectors.[7]

Furthermore, a *Reflective Object Sensor* which consists of an emitting diode and a phototransistor may be employed in this circuit.

To examine a potential venipuncture site, the nurse must first designate a scanning area. Then, the area is scanned with the appropriate² wavelength. The reflections intensities are captured by the photodiode, sent to the processor, and compared against a threshold³. If the intensity detected is low enough, the nurse will be alerted with a flashing LED implying vein existence.

The optical system introduced above may need modifications. In most photodiode applications, the signal requires amplification prior to further processing. Depending on the application, the amplification may be done in one or two stages. Via one stage amplification, the signal is amplified after being detected by the photodiode; for two stage amplification a preamp may be inserted. In some photo-detectors the preamp is integrated on the photodiode chip. If noise is an issue, an *Avalanche Photo Diode (APD)* may also be utilized to obtain higher *signal to noise ratio (SNR)* and sensitivity. [7]

A foreseen obstacle includes determining the absorption spectrum; and hence, the appropriate emission wavelength. In optical applications, where the absorption of emission light is significant, the sample's absorption spectrum of the sample is acquired to precisely specify the emission wavelength. The absorption spectrum is obtained by scanning the by a range of wavelengths. Peaks on the absorption spectrum indicate the highest levels of absorption and hence the best emission wavelength values. Absorption spectra are typically achieved via placing a sample in a spectrometer. In this application, the absorption spectrum changes accordingly (with respect to the patient); furthermore, the usage of a spectrometer is impossible considering the nature of the sample. However, absorption spectra of different body tissues have already been obtained and may be suitable for this application.

² Determination of the appropriate wavelength will be discussed shortly.

³ The threshold is calculated through various tissue reflectance rates.

5 Budget and Funding

Table 5.1 outlines the estimated expenditures for to develop the prototype of the Venipuncture Locator. All costs have been inflated 10% - 20% to ensure a cost overrun.

Table 5.1 – Tentative budget

Materials	Estimated Cost
Lasers/Sensors	\$50
Microcontrollers/Comparators	\$50
Miscellaneous Components	\$20
Batteries	\$15
Prototyping/Casing	\$80
Cables & Wires	\$10
Total	\$225

As in most cases, building the prototype will cost far more than a mass produced design. *TMI* predicts the end device will cost around the \$50 range. Since our development costs are fairly low, extensive external funding is not required. *Teb Medical Inc.* is in the process of applying for the *Engineering Science Student Endowment Fund* and the *Wighton Development Fund*. If external funding is not obtainable to *TMI*, our team members are prepared to make up the costs.

6 Schedule

The following chart outlines our projected schedules for each segment of the project. The main goal of this schedule is to ensure a proper prototype and the paperwork can be completed within allotted time frames.

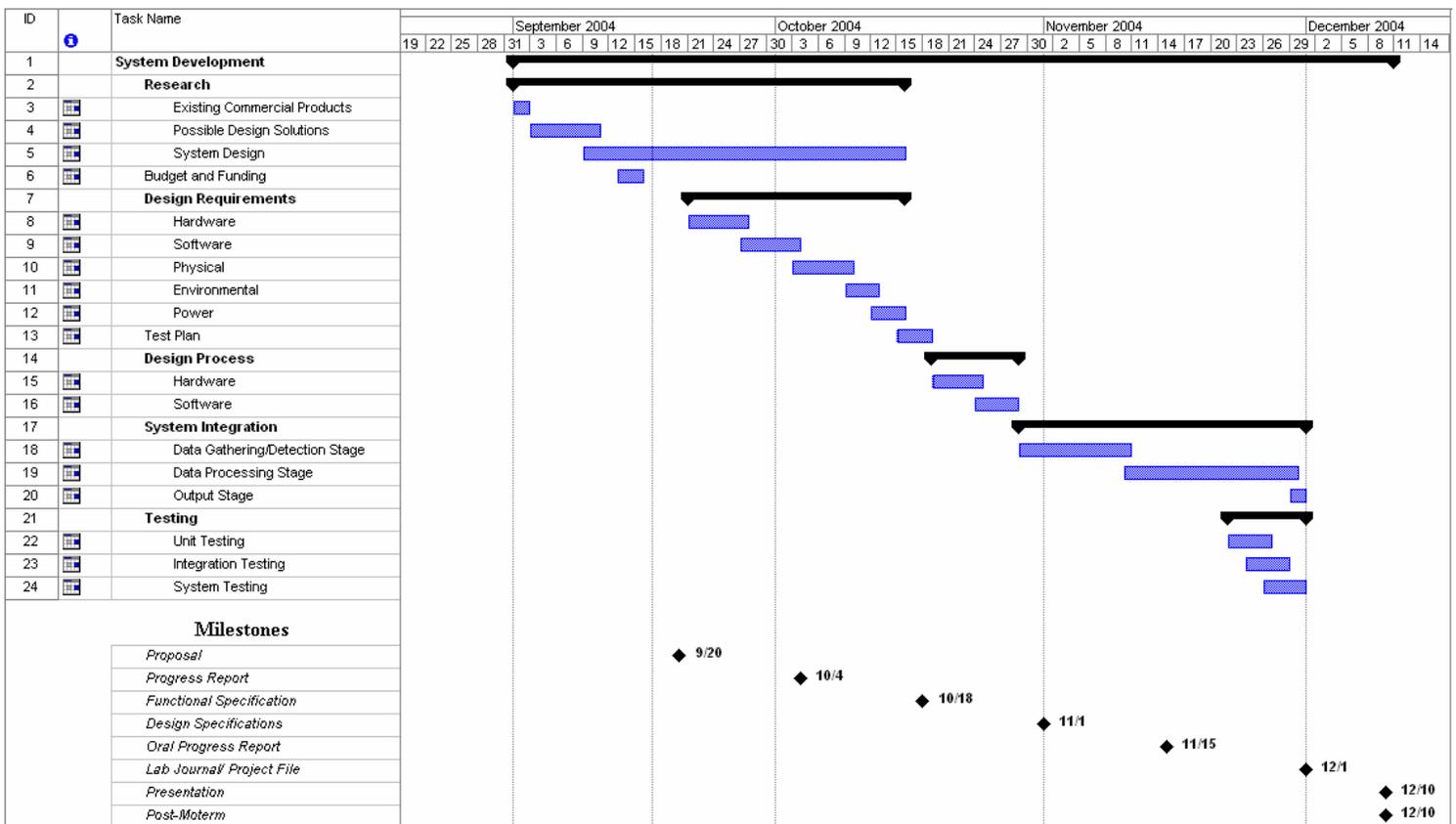


Figure 6.1 – Timeline and milestones for the project

7 Team Organization

Teb Medical Inc. is founded by four outstanding and dedicated individuals with high technical, operational, and business expertise who are responsible to carry out three major tasks:

1. **Planning:** Identify alternatives, select a course of action, and determine how these actions are going to be implemented.
2. **Directing and Motivating:** Guide and motivate other members and make sure that the plan is being carried out in a timely manner.
3. **Controlling:** Collect feedback and make appropriate changes to the plan if necessary.

Each member is also assigned a specific task. Balraj Mattu is the Chief Executive Officer (CEO) and is responsible for providing direction and framework for project communication, reporting, and procedural activity. Ida Khodam is the Chief Operation Officer (COO) and is responsible for managing the project progress against the projected schedule and resolving deviations from the project plan. Ameneh Atai is the Chief Technical Officer (CTO) and is responsible for outlining technical design specifications and selecting and purchasing product components. Amir Goldan is the Chief Financial Officer (CFO) and is responsible for balancing company's budget and applying for grants.

8 Company Profile

TMI's major asset is its four knowledgeable and innovative engineers with diverse expertise. Below is a brief biography of company directors.

Balraj Mattu – Chief Executive Officer

Balraj Mattu is in fourth year Systems Engineering pursuing the Biomedical Engineering stream at Simon Fraser University. Balraj has extensive experience in the business industry including running his own computer service company. He has been on two co-op work terms in the lumber and paper industry, specializing in hardware programming for robotic systems. Balraj's organizational and communication skills are definite assets to the company and will guide *Teb Medical Inc.* to become a successful innovator.

Ida Khodam – Chief Operation Officer

Ida Khodami is a forth year in Electronics Engineering at Simon Fraser University. In addition to her excellence in academic studies, Ida has completed two co-op terms where she was able to further augment and enrich her knowledge in the field of optical engineering. The analog electronics design is the field that interests her the most. Her design skills are beneficial to the growing success of *TMI*.

Ameneh Atai – Chief Technical Officer

Ameneh is a fifth year engineering science student at Simon Fraser University with previous year experience in optical system design at University of Stratchclyde, Glasgow. With completion of her thesis, Ameneh's strengths predominately lie in optical system and digital signal processor design. She's familiar with a variety of optical emitters, receivers, amplifiers, and fibres. She also has extensive experience in object oriented design (JAVA) and assembly language. Ameneh's technical skills and exceptional communication skills are an asset to success of *TMI*.

Amir Goldan – *Chief Financial Officer*

Amir is a fifth year engineering science student with a minor in computing science. He has extensive programming experiences and has used computers in real-time and embedded applications. He is also experienced with the analysis, design, and layout of analog integrated circuits.

9 Conclusion

TMI's goal is to avoid multiple punctures for a simple blood test when a venipuncture site is hard to locate. We believe that our product Teeka, with the proposed laser based design solution, can aid the operator to locate the best possible venipuncture site and therefore the blood test procedure can be completed in a single needle insertion.

We have interviewed family physicians, nurses, and venipuncture operators about the venipuncture site locator and they have all felt the need for our product. Also the fact that so far no such device has been patented in US and CANADA further ensures the huge market for our new invention.

TMI is all about patients and how to make their medical procedures simple and painless. With our knowledgeable team and smart design solution we believe that we can deliver the product on time and on budget.

References

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