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October 18, 2004

Dr. Andrew Rawicz
School of Engineering Science
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Burnaby, British Columbia
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Re: ENSC 340 Functional Specification for a Venipuncture Site Locator

Dear Dr. Rawicz:

Attached to this document is an outline of our product's functional requirements for the ENSC 340 project. We are in the process of designing a cost effective and versatile detector to locate a proper site for venipuncture.

The purpose of this document is to record the functional specifications for the venipuncture site locator device and is not intended to explore the technical aspects of the design process. The requirement analysis performed is an evaluation of the array of functionality that the system will need.

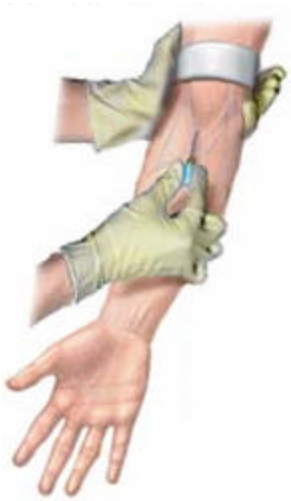
Teb Medical Inc.'s determined and diversified management consists of Balraj Mattu (CEO), Amir Goldan (CFO), Ida Khodami (COO) and Ameneh Atai (CTO). Should you have any questions or concerns regarding our functional specification or our project, please contact us via email, ensc340-vein@sfu.ca.

Sincerely,

Balraj Mattu

Balraj Mattu
Chief Executive Officer
Teb Medical Inc.

Enclosure: *ENSC 340 Functional Specification for a Venipuncture Site Locator*



Functional Specification for the Venipuncture Site Locator

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School of Engineering Science
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Date: October 18, 2004

Executive Summary

Teb Medical Inc. *(TMI)* is in the process of developing 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.

In order to deliver business functionality in as quick a manner as possible, *TMI* will work within a multiphase approach first presenting a proof-of-concept prototype which is scheduled for completion in mid-December, 2004. The prototype will contain an analog integrated circuit that transmits an infrared beam through the patient body and detects the attenuated reflected beam. It will also contain a microcontroller with a built-in A/D converter for further processing.

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1 Introduction

The purpose of this document is to record the functional requirements for the venipuncture site locator. Everything in this document is subject to change and/or refinement during the development process.

The purpose for the venipuncture site locator device is to accurately locate the appropriate vein when the operator is unable to do so.

The task of developing such a device is divided into three stages: the signal transmission stage, the signal retrieval stage, and finally the signal processing stage.

1.1 Glossary

***A/D*:** Analog to digital
***C/V*:** Current to voltage

1.2 Intended Audience

This document is intended to be a functional guideline for the designers and engineers within *TMI*. Its intention serves as ensuring that the product developed by *TMI* meets the specified requirements for appropriate marketing and production. Any objectives mentioned in this document will be protected as *TMI*'s intellectual property.

1.3 Conventions

The following notations will be used throughout this document:

[R#] A requirement

[UC#] A Use Case

Roman numerals at the end of each requirement denote which phase it is confined to. The description of each Roman numeral is shown below.

(I) A functional requirement for the device prototype only.

(II) A functional requirement for final design model only.

(III) A functional requirement for both the prototype and final design model.

2 System Overview

TMI's venipuncture site locator has three major components in its design: Transmission of incident signal, detection of the signal, and processing of the signal. Concerns for each of the stages are described below.

The presence of the environmental noise is the major source of error in the detection process, that's why *TMI* must ensure that the output signal of the transmitter isn't affected by these noise factors. Choosing the proper transmission technique to remove noise will be crucial to device operation.

In the signal retrieval stage, further filtering of noise may be necessary to ensure only useful signal information is processed. Again, the detector's sensitivity to external noise is essential to creating an accurate product.

In the signal processing stage, a device with high precision must be used to distinguish changes in the detected signal. If a vein is detected, an indicator will turn on or a beeper will start beeping on the device. Other useful information is displayed on an LCD for testing purposes only.

The functional system block diagram is shown in Figure 2.1.

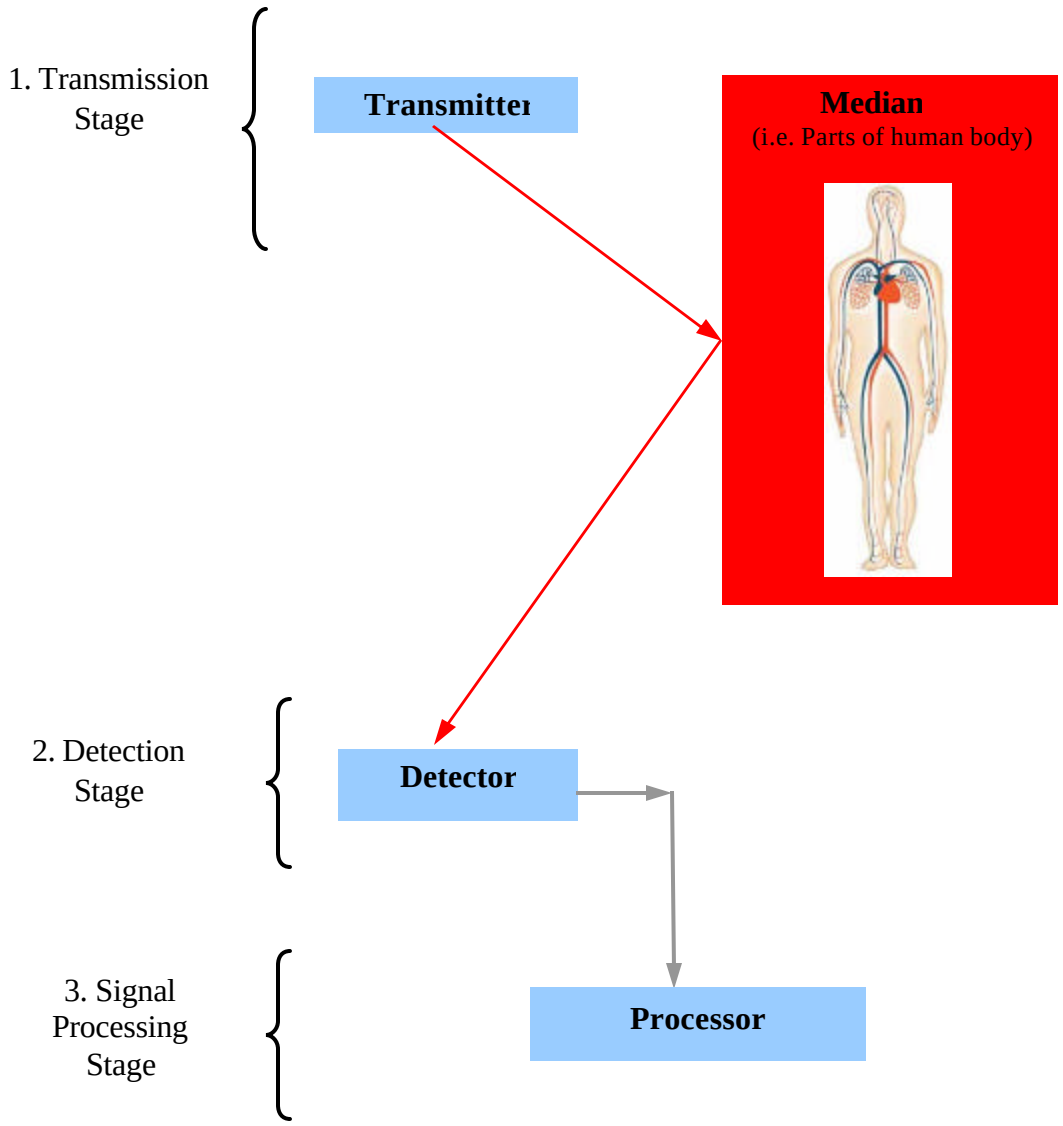

Figure 1 - The functional system block diagram.

3 Use Case Description

3.1 Actors

Operator – is a person who draws blood from the vein.

Patient – is a candidate for the blood test.

3.2 Description of Use Case

UC001 Taking a Blood Test

Pre – Condition(s): Patient is at a clinic, hospital, or office that is equipped with *TMI*'s venipuncture site locator.

Post – Condition(s): Blood is drawn from the patient's vein by the operator.

1: The use case begins when the patient enters the clinic.
1.1: Patient is seated and the puncture site is cleaned with antiseptic.
1.2: Tourniquet is bound around the upper arm to apply pressure.
1.3: Patient is instructed to open and close his/her fist a few times. This way more blood flows in the vein below the tourniquet and it distends.
1.4: The operator gently rubs the front side of the pen-shape venipuncture site locator device against the skin, below the tourniquet where she is most certain to find the vein.
1.5: Vein is located wherever the device starts beeping or the LED turns on.
1.6: The operator punctures the skin and vein simultaneously and draws blood from the vein.
1.7: The puncture site is covered to stop bleeding.

Exception(s): Any deviation from this path might result in an error.

4 General System Requirements

TMI's venipuncture site locater scans a designated body part to detect and reveal vein sites. In order for this device to operate diligently, a number of general specifications are required.

4.1 Physical Requirements

R01 The device shall be small (< 4cm^3), light (< 500 grams), and portable to allow agile scanning. **(II)**
R02 Sharp edges shall not exist on the exterior casing to avoid irritation of the patients' skin.
R03 The casing shall be composed of nontoxic material **(II)**
R04 The device shall be compatible with different skin colors, and types.
R05 The device shall be water-resistant to allow disinfection after each use. **(II)**
R06 The device shall have an alerting mechanism to confirm vein detection. **(III)**

4.2 Power Requirements

R07 The device shall be battery powered for portability **(II)**
R08 The device shall be turned off by the operator when not in use for the enhancement of power consumption efficiency **(III)**
R09 The heat dissipation of the device shall not cause inconvenience to the operator or the patient **(III)**

4.3 Performance Requirements

R10 Shall detect veins for venipuncture purposes. **(III)**
R11 The device shall not be extremely sensitive to detect capillaries. **(III)**
R12 The detection depth of the device shall not exceed 1cm to avoid detection of arteries. **(III)**
R13 The device shall be accurate within .1 mm of detection radius to ensure detection of veins. The thickness of the vein varies from .1 mm to 9 mm. [1] **(III)**
R14 The response time of the device shall be compatible with rational scanning velocity specified in the user manual. **(III)**

4.4 Environmental Requirements

R15 The device shall be capable of operating in environments containing other electronic devices. Neither the transmission signal, detection signal nor the processing unit shall interfere with other equipment in the environment. **(II)**

R16 The operation of the device shall remain consistent in various environmental conditions. i.e. the device shall operate in different altitudes (-100 – 20000ft) [2], different levels of humidity (5 - 77%) [3] and a wide range of temperatures (244 – 350K) [4]. **(II)**

5 Transmission Module Requirements

Transmission through the skin is the most basic and important factor in analyzing the underlying tissue. The transmission signal shall pierce through all layers of skin to reach the vein; however, its transmission should be limited to less than a cm in order to avoid arteries [5]. Furthermore, the transmission signal shall have a distinguishable property in the blood tissue in order to identify this median in the detection stage. The transmission requirements are listed below.

R17 The transmission signal shall be capable of penetrating through all layers of skin. **(III)**

R18 The transmission depth through body tissues shall not exceed .75 cm to avoid detection of arteries [1, 5]. **(III)**

R19 The transmission-body tissue interactions shall be minimal to avoid chemical reactions within the tissue. **(II)**

R20 The transmission stage performance shall be compatible with the detection stage. **(III)**

R21 The transmission signal shall acquire a distinguishable property in the blood tissue for posterior detection. **(III)**

R22 The transmitter shall be able to clear major noise in the environment to ensure accurate detection **(III)**

R23 The transmission signal properties (type, frequency, and intensity) shall remain constant throughout the lifetime operation of the device. **(III)**

6 Detection Module Requirements

The transmission signal is altered by the detection medium and its surrounding tissues and is detected by the detection unit. Detecting a clean (low noise) reflected signal is essential to determining variations in the transmitted signal through the skin. Since the change in the reflected signal from the skin will be very small, the detector must be chosen to appropriately match the transmission module's signal. The detection requirements are listed below.

R24 The detector shall have prior knowledge of the type (i.e. ultrasound, infrared, etc), frequency, and intensity of the transmitted signal. **(III)**

R25 The detector shall detect incoming signals at the transmission frequency only. **(III)**

R26 The detector shall have a high rejection ratio for the out-of-band signals to minimize the effect of interference. **(III)**

R27 The detector shall be able to strengthen the incoming signal and achieve a signal-to-noise ratio of greater than or equal to 12 [6] for further analog-signal processing. **(III)**

7 Processing Module Requirements

Processing the variations of the detection stage will have the most impact on the accuracy of the overall device. Not only does this stage have to be cost effective, it must be accurate as outlined in the performance specifications.

R28 Should have an onboard A/D converter for compact design **(II)**
R29 Module shall weigh less than 500 grams **(III)**
R30 Module shall be compact enough to fit in the laser casing **(II)**
R31 Module shall not be sensitive to small temperature variations **(II)**
R32 The processing unit shall be low noise **(II)**
R33 The digital processing unit will have enough memory bits to handle small variations from the signal being received **(III)**
R34 The processing unit will have a very high throughput from analog to digital stages **(III)**
R35 The processing conversion time will be high-speed **(III)**

8 System Test Plan

To ensure that *TMI*'s Venipuncture Site Locator produces very accurate and reproducible results on its patients, several phases of testing will need to be conducted. Since the result of device can only be confirmed by performing venipuncture on a patient, testing may become a very involved process. The assistance of nurses and doctors alike will be required to ensure proper precautions are taken during the tests.

Initial testing will utilize the members of *TMI* as the subjects. Since many veins can be seen through the skin on the members of *TMI*, confirmation of detection will be straightforward. After accuracy and repeatability of the device has been established, volunteer subjects with hard to find venipuncture locations must be found. A qualified venipuncture professional will then do the testing to ensure no harm can be done to the subject.

9 Standards Requirements

To ensure the product will be safe and functional to be sold in the market, numerous standards must be met. These standards ensure that the device will not physically harm its intended subject. Since this device is new to the market, there are no direct standards it will have to meet. A combination of laser and skincare safety standards will be prominent in the final design of the product. Below are certain standards that must be met nationally and internationally for the device to be sold on the global market.

9.1 Canadian Standards

• Food and Drug Acts – Medical Device Regulations: Medical Device Regulations [7].
• CAN/CSA Z386-01: Laser Safety in Health Care Facilities [8].

9.2 American Standards

• US Food and Drug Administration Center for Devices and Radiological Health: regulation on health care products [9].
• ANSI/AAMI EC11: safety and performance parameters for electrocardiographic systems [10].

9.3 International Standards

• ANSI/IEEE standards for health care [11].
• IEC 60601-1: Safety requirements, compatibility for medical electrical systems [12].
• IEC 60601-2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment [12].

10 Documentation

R37 A technical user's manual will be provided in English **(II)**
R38 The user manual shall include step-by-step use of the venipuncture Site Locator **(II)**
R39 Warranty will be included with the product package **(II)**
R40 Contacts will be available with the product package **(II)**

11 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.

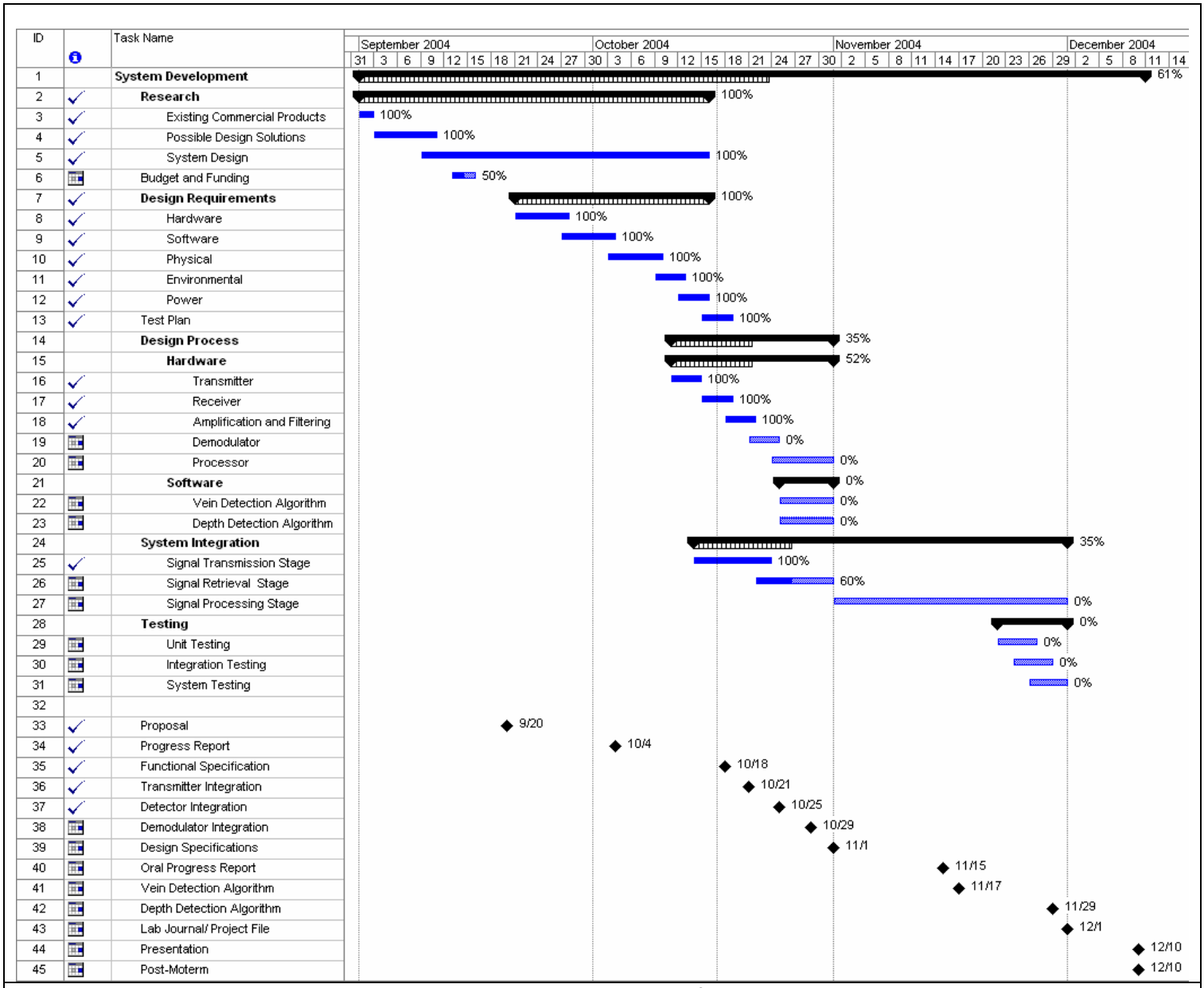

Figure 2 - Timeline and milestones for the project

12 Conclusion

This document outlines the functions, requirements and standards that must be completed for the Venipuncture Site Locator to be a beneficial tool in the medical industry. Given these specifications, we are confident that we will satisfy at minimum our prototype requirements end of December 2003.

13 References

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[2]Aircraft Owners and Pilots Association, “Airways”, (How it all works?) [online] 2004, *http://www.gaservingamerica.org/how_work/work_airways.htm*

[3] K. Terry, “Relative humidity” (Adopt a city in USA), [online] 2004, *http://vathena.arc.nasa.gov/curric/weather/adptcty/relhumid.html*

[4] F. Walter “What is the maximum and minimum distance for the Earth that is compatible with life?” (Astronomy 101), [online] 2004, *http://www.astronomycafe.net/qadir/q1209.html*

[5] L. Pokora, “Practical aspects lasers in physics and biology”, (Lasers in Medicine Surgery and Dentistry. Part III), [online] 2003, *http://www.ctl.com.pl/art/art4b.html*

[6] C. Arcoria, “Laser tissue interactions ”, (A&M University System Health Science Center), [online] 2004 , *http://www.tambcd.edu/cedental/lasetiss.htm*

[7] W. Johnstone, *Photonic Systems.* Glasgow: University of Strathclyde, 2003.

[8] Canadian Standards Association - (http://www.csa.ca)

[9] U.S. Food and Drug Administration - Center for Devices and Radiological Health (http://www.fda.gov/)

[10] AAMI Standards - (http://www.aami.org)

[11] Institute for Electrical and Electronics Engineers - (http://www.ieee.org)

[12] International Electrotechnical Commission - (http://www.iec.ch)

