January 22, 2007

Dr. Lakshman One
School of Engineering Science
Simon Fraser University
Burnaby, BC V5A 1S6

Re: ENSC 305/440 Functional Specification for a Laparoscopic Surgery Training System

Dear Dr. One,

The attached document entails the functional specification for the Laparoscopic Surgery Training System for the final Capstone project via ENSC 440.

The project is currently entering its design and building stage, where sensors are now being installed to provide feedback in order to evaluate the user's performance. Currently, the system consists of an enclosure, cameras, and a connection to a main computer to run the training software.

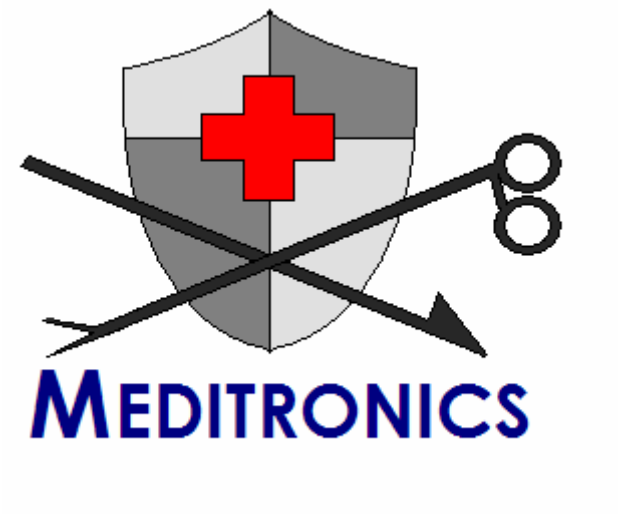
The functional specification will list off the functions that must be completed by the April deadline, the functions that will be attempted if enough time remains, and functions that would be beneficial for future developments at production levels.

MediTronics is a group of three fifth-year engineering students: Alexander Hahn, Mark Jung, and Han-Lim. If there are any questions in regards to the functional specification, please contact us by e-mail at ensc440-group3@sfu.ca or by phone at (604) 828-1276.

Sincerely,

Alexander Hahn
CEO and Software Developer
MediTronics

Enclosure: *Functional Specification for a Laparoscopic Surgery Training System*



Functional Specification for

Laparoscopic Surgery Training System

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Executive Summary

Minimally Invasive Surgery (MIS) has become a popular form of surgery as of late and required a specific method of surgery called ***Laparoscopic surgery***. The training system we are building is designed to help those medical students whose goal is to be able to perform laparoscopic surgery and allow MIS to become more mainstream and more reliable to people considering MIS as an option for themselves. The training system's goal is to elevate the experience level, proficiency, and competence of the members involved in the field of laparoscopic surgery.

The functions of the training system can be split into three ordered phases: crucial functions that must be completed, functions that would like to be completed, and functions that won't be attempted but should be considered for future developments. The following list describes each phase and the features belonging to that phase:

1) Phase #1: Crucial/Mandatory Functions
2) Phase #2: Functions that will be attempted, given enough time
3) Phase #3: Functions that should be reviewed for future considerations

Phase #1 is our base target that we believe will be accomplished by April 2007, taking into account the worst possible scenario. In the event that Phase #1 is completed early, Phase #2 will be attempted to its fullest possible extent. Phase #3 is more of a guideline for future development, if the training system were to go into production.

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1 Introduction

The laparoscopic training system is designed to help surgeons learn how to perform the laparoscopic surgery tasks quicker, and more accurately by providing the trainee's with video playback (to see where they need improvement), as well as computer assigned grade to the trainee to indicate their progress for a certain tasks. The tasks will include cutting, suturing, gripping, and object movement; however, gripping will be incorporated with cutting and object movement and monitored throughout those two tasks.

The proposed system is a basic concept model that can be developed into a more successful production level version, given more time and research. The proof of concept version, called *Phase 1*, is our main focus and is targeted for completion by April of 2007. This deadline assumes the worst possible case for development time and so, we are expecting to complete *Phase 1* sooner than that, assuming not everything goes wrong. In the event that *Phase 1* is completed ahead of schedule, more functions will be added onto the proof of concept model to increase the system's robustness and value. These extra functions will be considered as part of *Phase 2*. The final functional phase, called *Phase 3*, is a phase we will not reach by April 2007, but is intended to be pursued for the development model.

This document is based heavily on the proposal and progress report material for the training system [1] [2]. It will provide a general list of functions that is required, and then a more detailed breakdown of these functions into its physical, system, and user interface component functions. These functional specifications are meant to be used as a base for the design and building of the training system, so this document will contain as much detail as possible; however, as with any project requiring ongoing research and development, more functional specifications will need to be added.

1.1 Acronyms and Symbols

MIS	Minimally Invasive Surgery
FSR	Force Sensing Resistor
FAQ	Frequently Asked Questions
{#}	Numbered Functional Requirement
(Phase #)	Phase that the Functional Requirement belongs to

2 General Requirements

Many aspects of the training system need to be looked at to get a complete list of functional specifications, such as physical requirements, system requirements and user interface requirements. In order to examine each of these requirements and their respective detailed functionalities, we need to look at a general overview of the system and look at what main functions our system needs to perform as a whole [2].

2.1 Mandatory Functions

The mandatory functions are imperative and must exist in our proof of concept design as well as the production level design. These are the functions we will have completed for *Phase 1*, which should be done by April 2007 at latest. The following is a list of the mandatory functions:

1) Evaluation of the user's ability to move an object with one laparoscopic tool from a starting point to a destination, while measuring the gripping force on the object.

2) Evaluation of user's ability to suture (stitch) two pieces of sponges together

3) Evaluation of user's ability to cut a circle from a sponge model while monitoring gripping force.

2.2 Optional Functions

The optional functions are also an important set, but due to time constraints, these functions will only be attempted if the mandatory functions of phase 1 are completed early. The following optional functions are part of *Phase 2*:

1) Evaluation of user's ability to move one object from a starting point to a destination point while being passed first by one laparoscopic tool to the other. Gripping force will also be continuously monitored.

2) Evaluation of user's ability to cut a randomly given enclosed figure of a sponge model while monitoring gripping force.

2.3 Production Level Functions

The production level functions are merely just proposal ideas for when the proof of concept model is expanded and carried on into production. These functions will require a lot more time and research to implement, but would definitely have some beneficial use. The following is a list for *Phase 3*, the production level functions [2]:

1) Evaluating the quality of the user's suturing ability by measuring the tension of the sponge prior to and after suturing then determining if the suture is too loose or too tight.

2) Evaluation of user's ability to move many different objects one at a time from a starting point to a destination point while being passed first by one laparoscopic tool to the other. Gripping force will also be continuously monitored.

3) Store the user's test results in a database then provide statistical analysis on the user's long term progress.

3 Physical Requirements

The training system is meant to emulate a real life surgical experience as much as possible, so the size constraint of the enclosed system must adhere to that of a body cavity. The system will also be connected to a computer to monitor the user's actions and compute their progress. From these basic requirements, we can create a list of functions that they system must perform physically:

{1} System enclosure should be about the size of a human cavity, but small enough to allow proper movement of two laparoscopic tools. *(Phase 1)*

{2} System enclosure must not allow visibility inside the box, but must have a door to allow access to the inside, to place objects in the box. *(Phase 1)*

{3} Enclosure requires three port holes for the laparoscopic camera and the two tools. *(Phase 1)*

{4} Two cameras must be placed in any two top opposing corners in order to monitor the user's actions. *(Phase 1)*

{5} Enclosure requires proper lighting for the two monitoring cameras to capture images/videos accurately. *(Phase 1)*

{6} System must be placed near a computer in order to connect the monitoring cameras for evaluation. *(Phase 1)*

{7} The laparoscopic camera will require its own power supply as well as a converter box to connect to the computer. *(Phase 1)*

{8} To avoid wire possible wire tangling, a wireless module will be placed in the enclosure to communicate with the computer. *(Phase 2)*

{9} A computer able to run the windows 2000 OS or higher is required for the system to connect to. *(Phase 1)*

{10} All wireless modules and electronic components will be built with a circuit board and housed in a rigid enclosure. *(Phase 2)*

{11} System should work under normal physical conditions of a medical learning centre. *(Phase 1)*

{12} All electrical circuits, wiring, and heat modules will be placed in areas that will receive the least possible amount of human contact. *(Phase 1)*

{13} System must be built with strong and durable materials to withstand long term use and to allow strong anchoring for monitoring cameras. If the monitoring cameras move enough, they must be recalibrated. *(Phase 1)*

The following figure shows a possible design for the enclosure box, called *SurgiBox*.

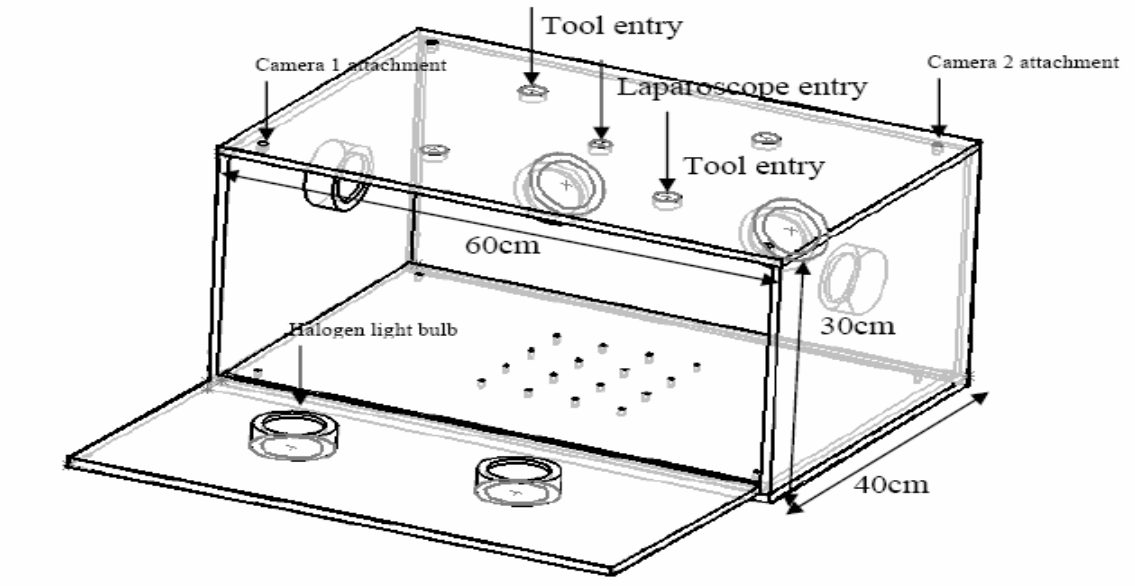

Figure 1: SurgiBox enclosure [3]

4 System Requirements

4.1 General

The training system in general contains an enclosed surgery training box system called the *SurgiBox* and a desktop computer connected to the *SurgiBox* to monitor all activities inside the box, as well as provide the training program for the user to follow. For this system to work properly there has to be a seamless integration of the *SurgiBox* and the desktop computer.

{14} A desktop computer, or laptop, running windows 2000 or higher with a serial connection is necessary for data evaluation. *(Phase 1)*

{15} A data connection must exist between the enclosed box system and the desktop computer. *(Phase 1)*

{16} The data connection must be able to transmit small amounts of data at timed intervals and handle stacking of data. *(Phase 1)*

{17} The same, or separate, data connection must connect the monitoring cameras in the corner to the desktop computer. *(Phase 1)*

{18} A dedicated connection must exist between the laparoscopic camera and the desktop computer. *(Phase 1)*

{19} All hardware sensors require an analog to digital converter/encoder to quantify data being sent to the computer. *(Phase 1)*

{20} All data connections, except for the dedicated laparoscopic camera, should be wireless to minimize wire tangling. *(Phase 2)*

4.2 Sensors

The *Phase 1* functions included moving one object, cutting a circle from a model, suturing two pieces of sponges together, and monitoring gripping force during some of these tasks. In order to measure gripping forces, we need sensors to detect when as well as how much force is applied to materials. We also need sensors to detect when an object is being moved and how accurately it is being moved from once location to another.

{21} FSRs are required to detect and measure force readings on the grippers of the laparoscopic gripping tools [2]. *(Phase 1)*

{22} Contact sensors are required for detecting contact on the moving object to determine when the grippers touch the object and to detect where the object lands after being moved. *(Phase 1)*

{23} A tension gauging sensor is required to be implemented onto the suturing models to determine if the suturing is too loose or too tight. *(Phase 3)*

4.3 Video

The cutting and stitching tasks requires the computer to use image processing techniques to evaluate the trainee's work. In order to use image processing, an image or video of the trainee's work is necessary, so two video cameras are required to monitor activity in the enclosed system. The laparoscopic camera is required for the trainee to view what is inside the enclosed box, but this camera will be discussed in the user interface section.

{24} The monitoring video cameras must have a resolution of 330 TV lines or higher. *(Phase 1)*

{25} The monitoring video cameras must be small enough as to be placed in any top two opposing corners of the box while not obstructing the trainee's performance. *(Phase 1)*

{26} The monitoring video cameras must be able to connect to the desktop computer either directly, or through a converter box. *(Phase 1)*

5 User Interface Requirements

5.1 Physical Interface

The physical interface entails any tool or device the user gets to physically handle to interact with the training system.

Figure 2: Laparoscopic surgery tool with a color band [3]

{27} The system will require two laparoscopic rod tools, shown in Figure 2, to be used by the user with one in each hand. *(Phase 1)*

{28} The enclosed system will have a door on the side for access to objects and models inside the box. *(Phase 1)*

{29} The computer will have the training program running for the user to interact with, so the computer must have a keyboard, mouse, and monitor. *(Phase 1)*

5.2 Software Interface

The software program deals with everything from retrieving data from the *SurgiBox,* all the way to calculating the user's test scores.

{30} The software program must allow the laparoscopic camera video to be displayed onto the monitor during training, in order for the trainee to view inside the box. *(Phase 1)*

{31} The software program must have three training simulations to choose from: Moving, Suturing, and Cutting. *(Phase 1)*

{32} Each training simulation must have a start and stop button in order to time the user. No pause option will be given, since no pauses are allowed in a real MIS surgery. *(Phase 1)*

{33} The software program needs to calculate and display the user's grade after a training program has been completed. *(Phase 1)*

{34} The grading scheme for Cutting will depend on length of time taken, how accurately the cut is, and how hard the user gripped onto the tissue throughout the procedure. *(Phase 1)*

{35} The grading scheme for Moving will depend on length of time taken, how accurately the object was moved to the destination location, and how hard the user gripped onto the object throughout the procedure. *(Phase 1)*

{36} The grading scheme for Suturing will depend on length of time taken and how close the suturing pulls the pieces of sponge together. *(Phase 1)*

{37} The grading scheme for Suturing will also depend on how loose or tight the suturing is. *(Phase 3)*

{38} The software program must be able to superimpose a circle over a model sponge organ to indicate the cutting area. *(Phase 1)*

{39} The program must be able to superimpose a randomly enclosed loop over a model sponge organ to indicate the cutting area - see Figure 4 below. *(Phase 2)*

{40} The software program must be able to be able to detect when an object is passed from one tool to another. *(Phase 2)*

{41} The software program must be able to detect which object gets moved, and to which destination – see Figure 3 below. *(Phase 3)*

{42} The software program must be able to store the user's training results for that session. *(Phase 3)*

{43} The software program must have a database to store a username, password, and test results for trainees. *(Phase 3)*

{44} The software program must be able to load the results of the trainee's previous simulations by username. *(Phase 3)*

{45} The software program must be able to show statistical progress over a certain period of time for the trainee. *(Phase 3)*

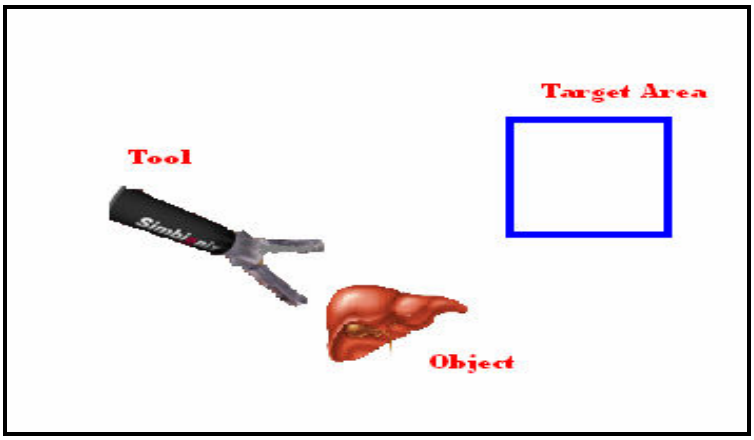

Figure 3: Object movement into a destination location

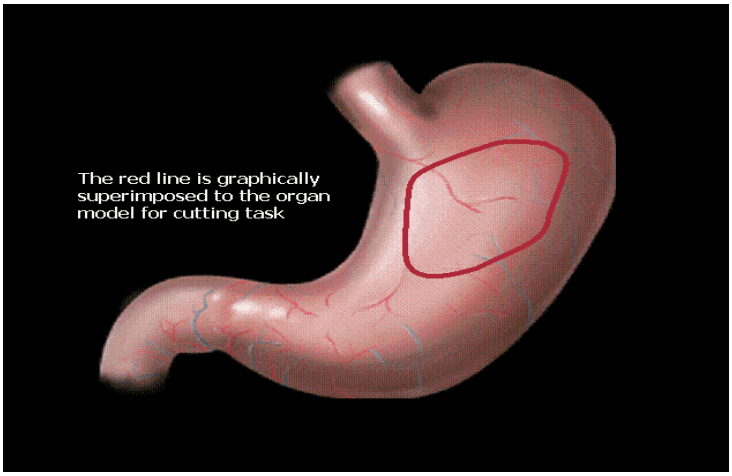

Figure 4: Randomly shaped loop superimposed onto a model organ

(Slight Modification from [4])

6 Reliability and Safety Requirements

6.1 Reliability and Serviceability

The training system is intended to be used by professionals as a learning tool for frequent use and for long periods of time. As such, reliability and serviceability become a huge factor in the design of the system. The key areas of concern for reliability and serviceability lie in the hardware circuits, and the trainee evaluation software on the desktop computer.

{46} The system should have a standby/idle time of at least 100 hours straight, without any failure. *(Phase 3)*

{47} The system should work in active mode for a reasonable length of time, at least 24 hours straight, without any failure. *(Phase 3)*

{48} In the event of a failure, system should be able to reboot. *(Phase 3)*

{49} The electrical circuit enclosure(s) must be accessible to qualified servicemen. *(Phase 3)*

{50} The mechanical parts need to be easily replaceable in case of damage. *(Phase 3)*

{51} The software and firmware should be upgradeable by the end user by means of a patch or a new program upgrade installation. *(Phase 3)*

{52} The mechanical and/or electrical parts should not be accessible or serviceable by the end user. *(Phase 3)*

6.2 Safety and Regulations

The training system is intended to be used by surgeon trainees at a medical training facility, university, or clinic, and as such, some safety regulations and precautions need to be considered.

{53} System uses external power sources, so approved electrical regulations must be followed. *(Phase 3)*

{54} System has a lot of wires connected to tools that should be covered properly to avoid any human contact. *(Phase 1)*

{55} Warning labels need to be placed in areas containing electrical circuits, power modules, or heating modules. *(Phase 3)*

As with any systems using electrical circuits, the circuit enclosures should remain closed except for when repairs are needed, which should be done by qualified professionals. Electrical components should also be kept away from any liquid sources.

7 Documentation and User Training

The training system is meant to be used by qualified medically trained individuals seeking to train in laparoscopic surgery; however, due to the complex nature of the system, documentation is mandatory for the use of the system

{56} A user manual must be provided, describing to the user the purpose and description of the physical parts and interface system. *(Phase 3)*

{57} The user manual must be written in several different languages: English, French, Spanish, German, Swedish, Japanese, Korean, etc. *(Phase 3)*

{58} The user manual must be written in an understandable format for non-technical users, but should assume the user to have a medical background. *(Phase 3)*

{59} The user manual should have a section for novice users and advanced users to understand the basic functions, as well as the more advanced functions of the system. *(Phase 3)*

{60} The user manual must include a safety guide for proper use. *(Phase 3)*

{61} The user manual requires a section for trouble shooting tips. *(Phase 3)*

{62} The user manual should have all contact information to the company including phone number, address, e-mail, and website. *(Phase 3)*

{63} The website should contain the user manual, other documentation material, and a FAQ section regarding the training system. *(Phase 3)*

{64} The proof of concept model and the enhanced concept model must be used under the developers' supervision. *(Phase 3)*

{65} The training for the final product version will be provided in the user manual, the accompanying CD, and also on the website. *(Phase 3)*

8 Conclusion

This document lists a heavy set of functional requirements ranging from the proof of concept model all the way up to the production model. These requirements will be used as the foundation for the design and are subject to change or addition as the project develops further. All the functions shown in this document are broken down into three *Phases*. *Phase 1* will be completed by April 2007 and *Phase 2* will be attempted as a set of add-on features if *Phase 1* is completed and fully tested ahead of schedule. *Phase 3* requirements are intended to be implemented for the final production level development. When all phases are completed, the final product version will be available at medical training facilities for MIS trainees to use and enhance their skill set.

9 Referenced Material

[1] Proposal for Laparoscopic Surgery Training System. MediTronics.

[2] Progress Report. MediTronics.

[3] SurgiBox: A Computerized Physical Laparoscopic Surgery Training System. Herman Lo.

[4] Image of Stomach. http://www.sciencebob.com/lab/bodyzone/stomach.gif.