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## A Novel Electronic Laparoscopic Training Device

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A Novel Electronic Laparoscopic Training Device

Paul Allen Shields

A Thesis Submitted to the Graduate Faculty of

GRAND VALLEY STATE UNIVERSITY

In

Partial Fulfillment of the Requirements

For the Degree of

Masters of Science in Engineering with Biomedical Emphasis

Seymour & Esther Padnos School of Engineering and Computing

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## **Abstract**

Laparoscopic surgery is a modern surgical technique gaining popularity due to the advantages of smaller incisions, reduced pain, and shorter recovery times when compared with open surgical techniques. Training for laparoscopic surgery is a multiyear process in which candidate's progress through a series of surgical simulations beginning with simple dexterity and coordination building exercises and ending with actual human surgeries. Early laparoscopic surgical training is performed using simulators as high tech as virtual reality computer simulations and as low tech as mirror box trainers. Studies have clearly demonstrated that variation in surgical training devices can produce variation in training results. Virtual Reality trainers are emerging as the desired standard for training due to their increased realism and increased capture of quantitative training data. Box trainers, however, remain the consensus standard because of price and the inconsistent record of VR trainers in the literature. The Electronic Laparoscopy Trainer was developed to bring the advantages of virtual reality trainers to existing video box trainers at a drastically reduced price. In this study seven subject were trained in two groups using traditional video box trainer techniques and the Electronic Laparoscopy Trainer. Subjects that trained with the Electronic Laparoscopy Trainer in combination with traditional techniques saw 18% greater skill development over the control as measured by traditional assessment techniques. Additionally, subjects who trained using

the electronic laparoscopy trainer showed a commensurate increase in performance as measured by the electronic laparoscopy trainer over the Control Group.

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## I. Background:

Laparoscopic surgery requires an additional set of skills that differ from open surgery skills in that the procedures are performed at the end of long instruments in a three dimensional environment but viewed on a two dimensional screen away from the area of interaction. The transition from three dimensional vision of the surgical procedure to a two dimensional representation requires that surgeons learn certain basic cognitive and psychomotor skills. This has led to a specialized system of training for laparoscopic surgery. This training is typically comprised of three main modes: animal labs, virtual reality (VR) trainers and/or video box trainers, and operating room (OR) experience (1). Typically OR experience is reserved for residents who have completed multiyear training routines with animal labs and simulator experience. Animal labs are considered to be the most effective training mode before OR experience but are also the most expensive, while video box trainers are considered to be the least effective but lowest cost. Virtual reality (VR) trainers have the widest variety of effectiveness and expense and are often used to supplement or augment video box trainers (2). A large amount of research has been done to determine the relative effectiveness of each method of training particularly based on the Fundamentals of Laparoscopy (FLS) a standardized test developed in 2004, by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and endorsed by the American College of Surgeons (ACS) (3). It has been shown that deliberate practice using video box trainers improves performance on the FLS test (3)

(4). It has also been shown that FLS training results in significant increase in operation room performance (5). This has resulted in exponential increase in demand for structured laparoscopic training programs (6).

#### A. Training Programs:

Training for laparoscopic surgery typically takes place in a 4-5 year program with basic surgical techniques in the first year, box training and/or VR training in the first and/or second year, animal model training in the third year, and OR surgical training in the fourth and fifth year (3). Rapid skills development during the second year of training is essential for the surgeon to be allowed to move on to subsequent phases of training. Contact hours with the training devices are generally limited in that the devices are owned by training institutions. Although surgical residents are often excused from clinical duties to ensure attendance to training sessions, little or no time exists for extra practice. This means that the efficiency with which residents gain skills from a training device is critical. In an attempt to determine the most efficient training method many types of trainers have had specific validation of effectiveness using controlled trials including a variety of box trainers and VR trainers. Currently box trainers are the standard for training and assessment but, because of their perceived increased realism and data collection, there has been a growing call for VR trainers to play a greater role (7). A variety of specific VR trainers and box trainers have been validated against each other and broadly the distinction between video box trainers and VR trainers has been studied and well characterized.

## B. Box Trainers:

Box trainers come in a wide variety of forms including torso models, boxes with built in ports and cameras, boxes with built in ports for laparoscopes, and even homemade practice trainers (8), (9). Most box trainers include several similar features designed to simulate the surgical experience and help develop skills used in surgery. Generally all box trainers include an open cavity with a work field in which procedures take place, a cover over the cavity through which instruments and or laparoscopes can be inserted, and video screen to view the instruments and objects in the work field.

Figure 1 shows an example of a basic box trainer.



Figure 1: 3-Dmed Large Body MITS Video Box Trainer

Trainers may also include a built in camera, built in ports, or in some cases a set of mirrors to replace the video screen (8). For this paper the category of box trainers will be defined as any trainer that includes an enclosed or partially enclosed box with ports for instruments and a display that allows the user to see the workspace.

Training in a box trainer consists of a variety of tasks primarily designed to increase hand eye coordination, increase familiarity with the instruments, and for certain tasks increase familiarity with techniques used in surgery. Some basic tasks include moving objects around a peg board, cutting patterns in fabric, and tying sutures.

Though many types of box trainers exist, the Fundamentals of Laparoscopic Surgery (FLS) training box and accessory kit is generally considered the standard for skill assessment (6). An FLS box trainer with training accessories is shown in Figure 2.



Figure 2: FLS Box Trainer with Accessories (Left), FLS Box Trainer Ready to Use (Right) (8)

Performance using the box trainers is assessed by the FLS test using time to complete (TTC) tasks as well as accuracy and efficiency (3). A task is prepared for the resident and their time to completion is measured. Accuracy and efficiency are qualitatively judged by a panel of expert surgeons. Some tasks include time penalties or disqualifications based on accuracy of performance. Training for the tasks includes performing the actual tasks as prescribed in the test procedure but also includes simple psychomotor skill building exercises. Previous studies have shown that skills necessary to pass the FLS test can be developed using box trainer tasks and activities other than the specific test tasks (10). Additionally some research has shown that virtually any psychomotor skill building exercise including playing video games can improve performance on laparoscopic tasks as long as it increases the amount of psychomotor practice the subject performs (11). The nature of video box trainers, however, limits the realism of tasks that can be performed and generally does not allow quantitative performance metrics other than TTC to be measured. VR trainers allow for a wider variety of metrics to be assessed.

#### C. VR Trainers:

VR trainers are designed to teach users the same skills as video box trainers however VR trainers can increase realism and allow for a broader set of performance metrics to be assessed. In addition to TTC, total number of hand movements (THM), total path length (TPL), economy of hand movement (EOM), and total score (TSC) may be available as quantitative performance measurements in real time (12). The additional

performance metrics available from VR trainers can allow a more effective training experience, and a more reliable testing system. Desire for more quantitative methods of skills development and assessment has been demonstrated in the literature but consensus on the effectiveness of VR trainers has not yet been reached (13). Some studies have shown that training with VR simulators can shorten the learning curve and improve training effectiveness (14). Others have shown that VR trainers do not lead to improved training outcomes (15).

One major criticism of VR trainers is that they do not provide adequate physical feedback. Haptic feedback, a type of feedback that applies forces, vibrations, or motions to the user, has been implemented on some VR trainers but studies suggest that it does not provide significant added value (16).

Aside from training, there has also been some desire to move to VR simulators as a testing mechanism, however, once again consensus has not been reached. Perhaps the most significant review of available data regarding the training outcomes of VR trainers published in 2010 and drawing from 42 studies on the subject concluded that “Using the right simulator, tasks, and metrics, trainees’ and experts’ laparoscopic skills can reliably be compared. However, VR simulators cannot yet predict levels of real life surgical skills.” (17). The unproven capabilities of VR trainers combined with the relative price differential between box trainers and VR trainers seem to indicate that box trainers will remain the standard in training and assessment for

laparoscopic surgery for the time being. Even so the desire for more data driven performance assessment and skill acquisition characterization is clear.

#### D. Force Tracking:

Though all box trainers and some VR trainers incorporate physical feedback as part of the training routine there are currently not any commercially available training methods that record the forces applied by the surgeon during tasks (18). Limiting the amount of force used during surgery is thought to improve surgical outcomes, including reducing collateral damage, and reducing blood loss (19) (20). Forces applied to the training surface during training have been studied to a limited extent and basic force parameters have been characterized. Additionally it has been shown that novice surgeons and residents in training apply significantly greater forces during procedures than experts (18).

#### E. Training and Games:

Both box trainers and VR trainers have game like elements to the simulations and training routines but in the past it seems that more emphasis has been placed on skill assessment and procedure simulation than on enjoyment. A connection has been drawn between surgical ability and the outside use of video games in several papers. A 2010 review of available literature revealed that video game users acquire endoscopic and laparoscopic skills quicker and training on video games appears to improve surgical performance (21). This may indicate that making training more game like will improve the accessibility of techniques. Additionally the link between



increased practice and improved performance has been well demonstrated (3).

Making training routines more game-like may increase trainee's enjoyment and desire to train.

Laparoscopic training is still evolving and although the box trainer is the current standard, many programs incorporate VR simulators into the training routine. The FLS test, which uses a box trainer for assessment, is widely accepted as the chief means of skills assessment for promotion past second year laparoscopic training as well as for continuing assessment of laparoscopic skills. The desire to reduce the training learning curve and increase the amount of quantitative data available for skills development assessment is still strong. The Electronic Laparoscopy Trainer (ELT) aims to improve in both of these areas at a significantly reduced cost versus VR trainers. The Electronic Laparoscopy Trainer targets skill development as assessed by the current performance assessment standard, the FLS test.

#### F. Preliminary ELT development:

Preliminary development of the ELT yielded a device that is designed to fit into the current FLS box trainer. This device, pictured in Figure 3, has up to 24 touch sensitive tiles that the trainee interacts with to complete tasks. Each of the 24 tiles is independently controlled by an Atmel ATtiny series micro controller which communicates with a central Atmel ATXmega micro controller housed on the main board. Each of the tiles is capable of independently illuminating in any one of five

colors and recording touches. This allows for the surface of the ELT to become a constantly changing field of interaction.

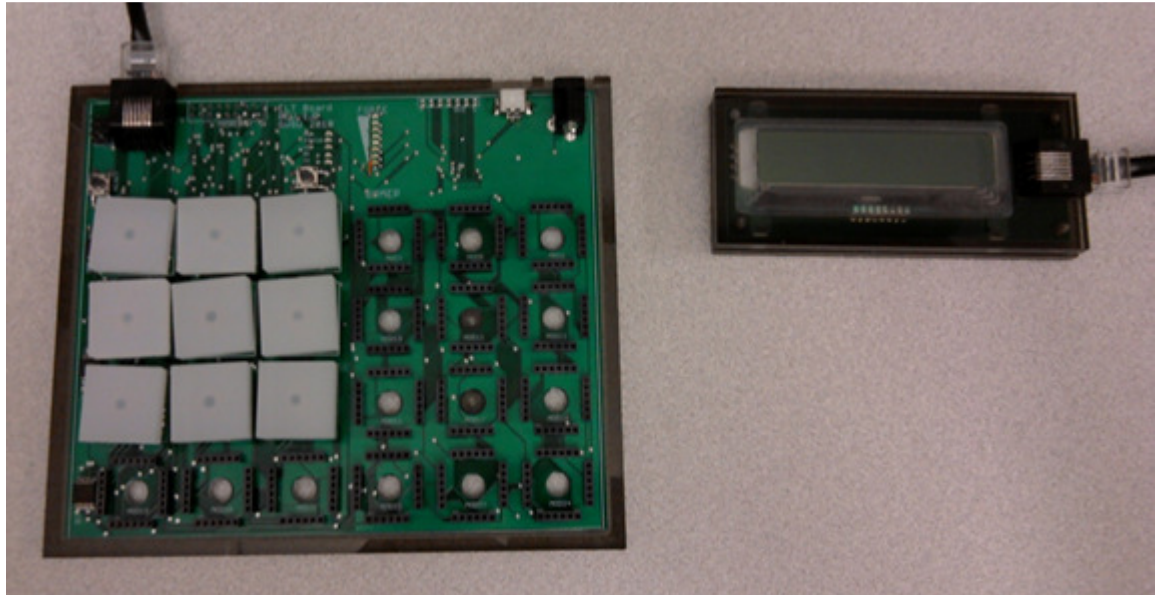


Figure 3: ELT with Nine Tiles

Like many other box trainer accessories the ELT is placed into a box trainer in the field of view. The trainee then interacts with the device as seen on the box trainer screen using standard laparoscopic instruments. Each tile that lights up can require an action by the user or relay information to the user to move the training routine forward. Information about in-routine performance including accuracy and speed can be displayed on the attached LCD screen which can be placed inside the box trainer or positioned near the trainer display screen. A record of game performance statistics can be stored on the ELT and downloaded to a computer for later analysis.

The original ELT was capable of measuring touch on any of the 24 tiles but did not record direction or magnitude of the touch force. Games were able to be set up to

require the user to use both hands but no mechanism for enforcing which hand is used for any given action is available.

The original ELT was programmed with two games: “Random Squares” in which squares are illuminated with blue light randomly and the user must touch each square as quickly as possible and “Green Hold” in which squares are illuminated with green light randomly and the player must touch and hold the illuminated square until the next square is illuminated. These games were designed to develop speed, accuracy, and reaction time. The device was capable of being programmed with dozens of game modes to increase the set of skills it trained for but additional hardware capabilities were desired to allow for more extensive skill development. The ELT is shown in Figure 4 with several tiles illuminated.

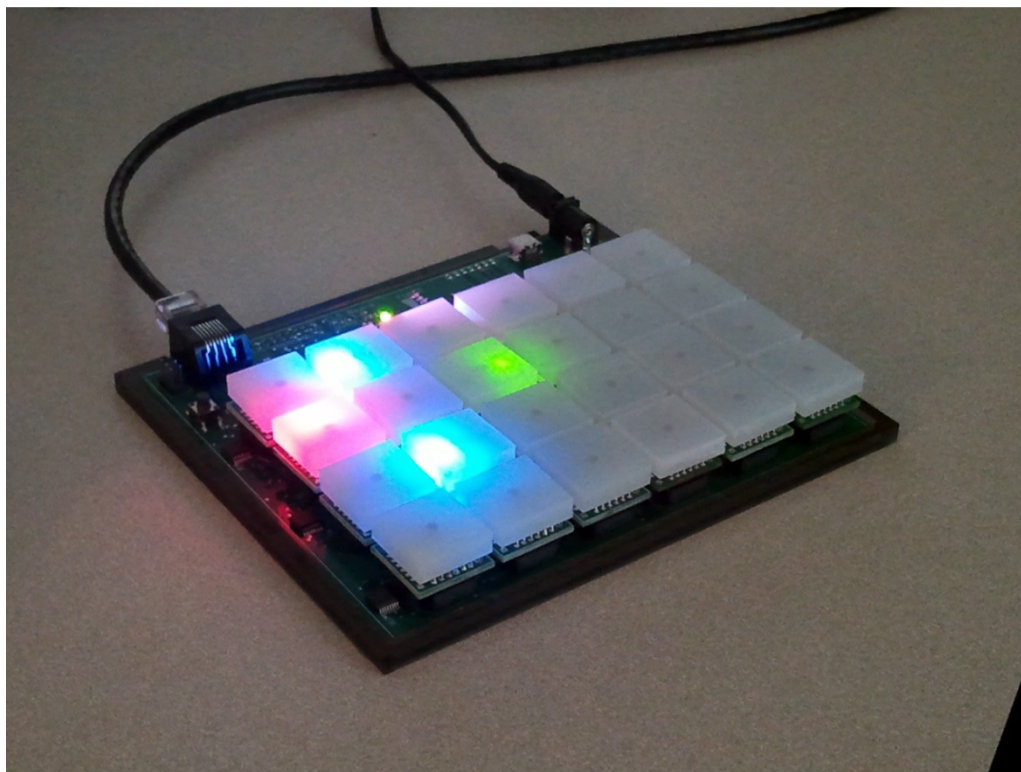


Figure 4: ELT with “Directional Pad” Illuminated

The ELT was presented to expert surgeons, educators, and residents at Grand Rapids Medical Education Partners in the fall of 2011. Initial feedback about the ELT was positive but a number of changes and additions, designed to expand the number of skills the device can train for, were proposed. The following is a list of desired changes generated from the fall 2011 meeting.

- Add force sensing
- Add handedness sensing
- Add game modes
- Increase the visibility of the green illumination on the screen

## II. Methods:

### A. Device Development and Improvement:

#### 1. Hardware:

In order to add the desired features electronic laparoscopy trainer hardware changes were necessary. Although the basic design of the device remains the same, the main board was modified and rebuilt to include force sensing capabilities. Additionally a new hand sensor module was designed and built to allow for enforcement of handedness during game play. The existing LCD display panel and the existing modules that form the surface play were not modified.

##### i) Main Board:

Building on the success of previous revisions of the electronic laparoscopy trainer hardware, a new device was created from scratch. The main board platform of the electronic laparoscopy trainer was modified to include a force sensor on each of the four corners of the main platform consisting of force sensitive resistors with rubber footings. This allows the detection of relative force magnitudes for each of the four corners of the main board. The second major change that occurred to the main board was the addition of a wireless transceiver circuit which allows the board to communicate with a newly added wireless hand sensor. The new main board with

attached modules is shown in Figure 5. Schematics and board diagrams can be seen in Appendix C.

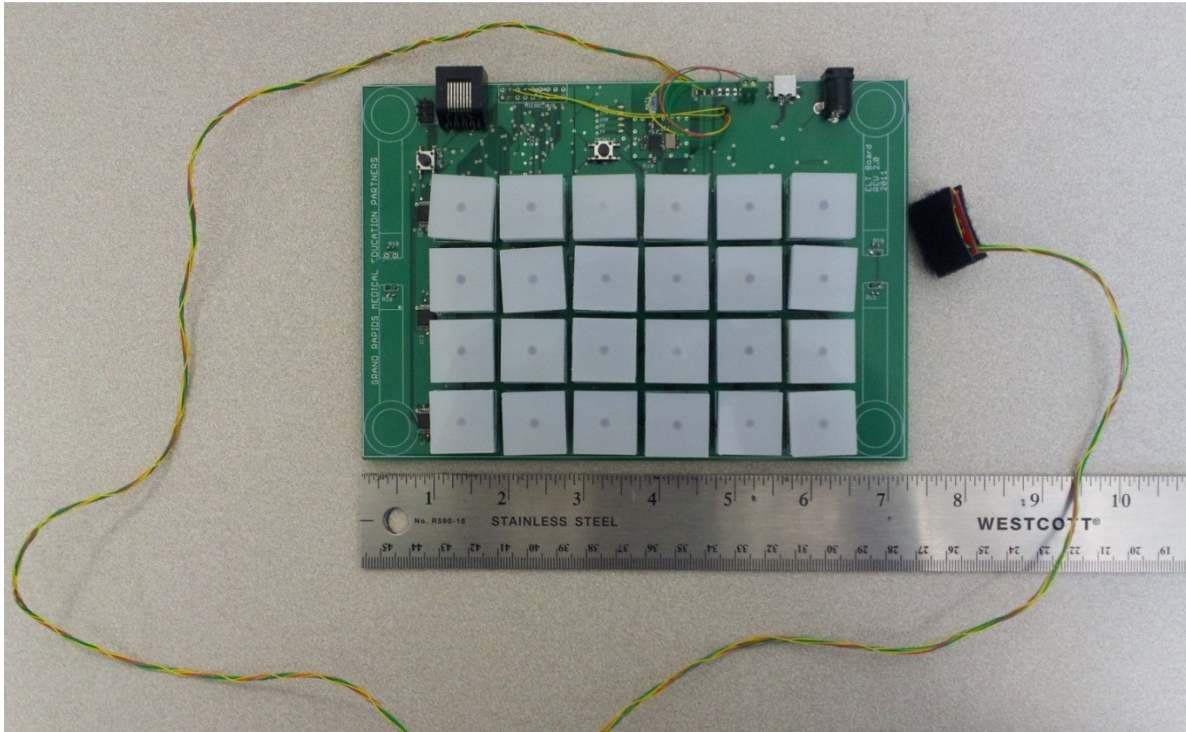


Figure 5: Main Board with Attached Modules

ii) Hand Sensor:

In order to add the ability to enforce handedness in the game modes it was necessary to add a wireless module, to be attached to one of the instruments, which would be able to detect when the hand was used to press interact with the illuminated modules. This hand sensor module consists of a wireless transceiver, chip antenna, accelerometer with hardware “Tap Detection”, and a microcontroller to communicate between the wireless chip and the accelerometer. The wireless version hand sensor

module is shown in Figure 6 attached to an instrument. Schematics and board diagrams can be seen in Appendix C.

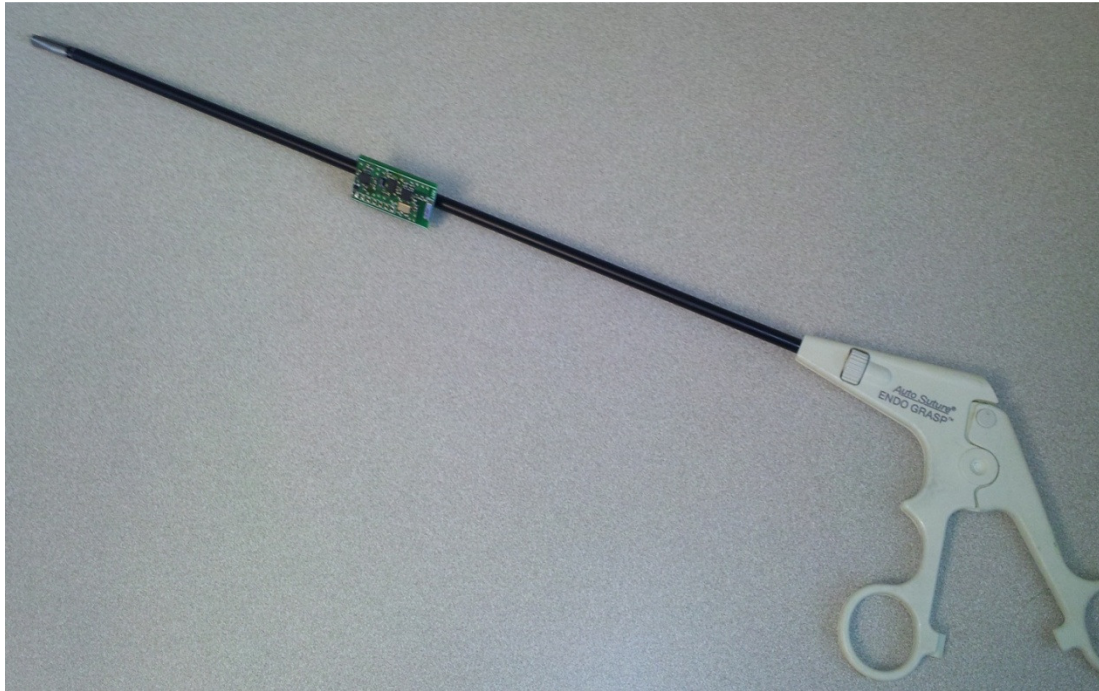


Figure 6: Wireless Hand Sensor Module

During game play, anytime a play surface module is pressed, the main board will query the hand sensor module to determine if the hand that initiated the press had the hand sensor module. If the hand sensor module reports accelerometer readings typical of a tap or press the main board assumes that the instrument with the attached hand sensor was responsible for the press. Since only two instruments are used at a time, any interaction not associated with a tap or press event from the hand sensor board can be assumed to have been initiated by the other hand. In addition to the wireless hand sensor board a wired version was also created which can be attached directly to the main board. Typically the hand sensor module is attached to the dominant hand and the software is designed to

require usage of both hands in concert during multiple games. Both the wired and wireless hand sensor modules are small enough and unobtrusive enough to have a negligible effect on instrument usage and performance. The wired hand sensor module is shown attached to an instrument in Figure 7.

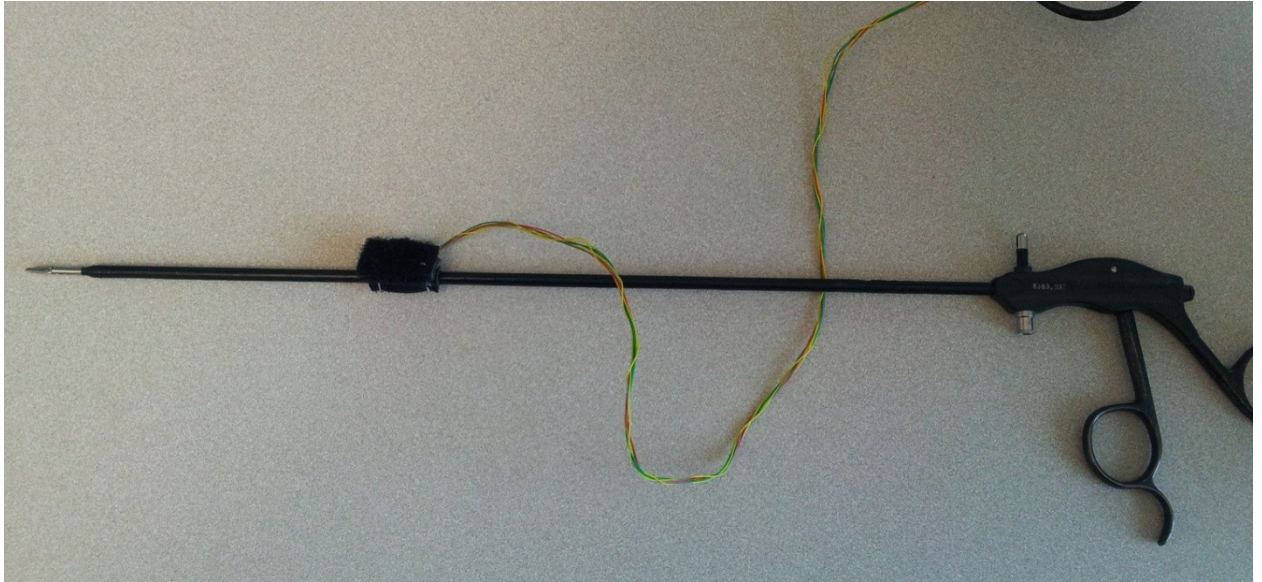


Figure 7: Wired Hand Sensor Module

## 2. Software:

In order to take advantage of the additional hardware capabilities and more effectively develop laparoscopic surgical skills as measured by the FLS test game modes were added and modified. The improved hardware capabilities of the electronic laparoscopy trainer allowed for more complex and engaging game modes. A total of five games were created with two of the games enforcing handedness and requiring bimanual movement and one of the game modes requiring the application of precision forces. The use of green light to



illuminate modules was limited to indication of errors due to the fact that it is less visible on typical laparoscopic box trainer screens.

i) Random Squares:

The “Random Squares” game is the only game that has remained unchanged from previous versions of the electronic laparoscopy trainer. In this game a series of modules are illuminated with blue light in random positions and the trainee must press the modules as fast as possible. Incorrect presses are recorded and shown on the field of play as red squares. Handedness is not enforced and so the trainee is allowed to use either hand at any time to press modules. The game is scored by calculating the total time before 50 blue modules are successfully pressed plus a one second penalty for each erroneous press. Lower scores are desired.

ii) Press and Hold:

The “Press and Hold” game is a new game in which modules are randomly illuminated with purple light and the trainee must press and hold the module for a randomly determined amount of time. The modules flash indicating that the hold time is being counted down while they are being held. If a module is mistakenly released early the hold timer restarts. Once the time has expired a new module illuminates and the player must release the old module and press the new one. Incorrect presses are recorded and shown on the field of play as green squares. The game is scored by calculating the total time to press and hold 50 modules minus

the cumulative total time that was required to hold each square and plus a one second penalty for each erroneous press. Lower scores are desired.

iii) Two Hands:

The “Two Hands” game is the first game to introduce the concept of bimanual interaction and enforces specific use of each hand using the hand sensor module. In this game a random module is illuminated using purple light. The trainee must press and hold the purple module using their dominant hand which is enforced by the hand sensor. The field of play will then illuminate a second module with blue light keeping the first module illuminated. The player must then press the blue square with their non-dominant hand while holding the purple module with their dominant hand. Attempts to press the purple module with the non-dominant hand are recorded and indicated by flashing orange backlight on the LCD display. Incorrect presses using either hand are also recorded. The game is scored using Equation 1. Lower scores are desired.

$$\text{Score} = \frac{(\sum_1^N T_{p_n} + T_{b_n} * 1.5)}{N} * 10 + H * 2 + W \quad (1)$$

Where:

$T_p$  is time to press the purple square

$T_b$  is time to press the blue square

$H$  is a count of wrong hand presses

$W$  is a count of incorrect presses

iv) Circle:

The game “Circle” also enforces bimanual interaction. In this game a random single module is illuminated with yellow orange light indicating that the trainee must press and hold the module using their dominant hand. Once the module has been successfully pressed and held the four modules immediately adjacent to the original module will illuminate one by one

and the trainee must press them in order using their non-dominant hand.

This game is scored using Equation 2. Lower scores are desired.

$$\text{Score} = \sum_{n=1}^N T_{y_n} + \left( \sum_{i=1}^4 T_{b_{n_i}} * PF_i \right) \quad (2)$$

Where:

$T_y$  is time to press the Yellow Square

$T_{b_i}$  is time to press the blue square  $i$

PF is the penalty factor (based on the number of possible positions left)

v) Force Test:

The game “Force Test” introduces the concept of precision application of forces. In this game squares are illuminated with red light which indicates to the player that they must press and hold the square using a randomly determined force range. As the player applies force the LCD screen will be illuminated with a blue backlight indicating force too low, a green backlight indicating force in acceptable range, or a red light indicating a force too high. Once the proper force has been achieved the player must hold within the force range for a randomly determined amount of time. Once the time has expired a new square will illuminate and the game will continue. The game is scored using Equation 3. Lower scores are desired.

$$\text{Score} = \sum_1^N TTC_n * PF_n - Ht \quad (3)$$

Where:

PF is the penalty factor (based on force required)

TTC is the time to complete each force hold

Ht is the hold time

## B. Study Design:

Undergraduate and graduate students with less than one hour of total laparoscopic experience were eligible for this GVSU Human Research Review Committee exempt study. Appropriate informed consent was obtained and a total of eight participants were selected to participate. The subjects underwent baseline FLS style testing and were randomly assigned to either the Control Group (n=4) or Training Group (n=4). The Training Group then trained using the ELT in six, 15-30 minute training sessions along with six, 15-30 minute FLS style training methods. The Control Group completed only six, 15-30 minute training sessions. Both groups were then assessed using a final FLS style test and a final ELT test. Figure 8 summarizes the flow of participants through the study.

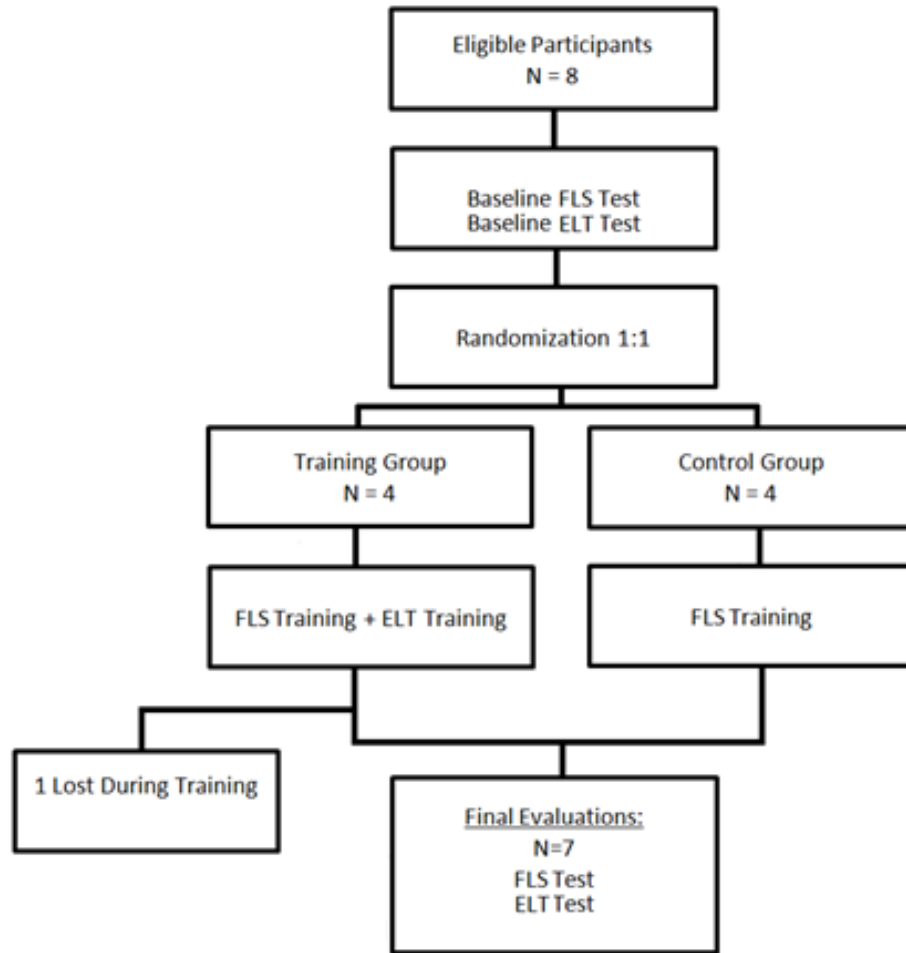


Figure 8: Participant Flow

1. Randomization:

Randomization was achieved by assigning random numbers to each participant using the Excel 2007 “rand()” function and sorting participants in order of their randomly assigned number. After randomization the two groups broke down with the differences as shown in Table 1.

Table 1: Participant Differences

Participant	Gender	Age	Handedness	Degree Being Sought	Past video game playing (1-5)*	Current Video Game playing (1-5)*
1	M	23	Right	MSE	3	1
2	M	25	Right	MSE	2	1
3	M	24	Right	MSE	4	2
4	M	38	Right	Articulated MSE	1	1
5	F	27	Left	MSE	1	1
6	M	25	Right	MSE	2	1
7	M	22	Right	Articulated MSE	4	2
8	F	22	Right	BA	2	1

\*1 indicating self reported “little or no experience” and 5 indicating “a great deal of experience”

## 2. ELT Training:

Each ELT training session consisted of playing through each of the five games listed in the software section once until a minimum of 15 minutes of training had occurred. If 15 minutes had not passed after one time through each game the participant was allowed to play through additional games until fifteen minutes had passed. A maximum of 30 minutes was allowed for each training session. Total training time for each session was recorded. Participants were allowed to use any available instruments. The ELT in the training box is shown, as it appears on the video screen, during a training session in Figure 9.



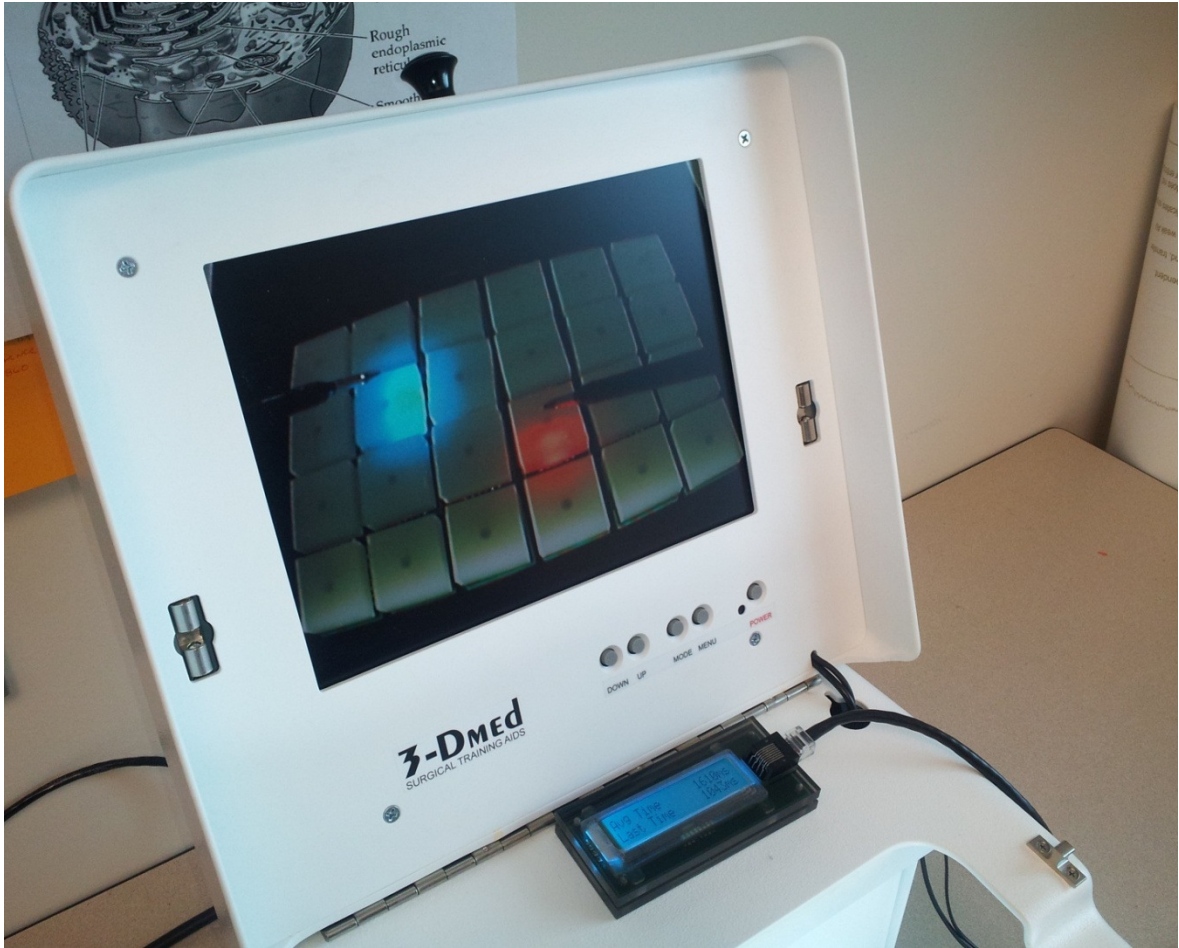


Figure 9: The ELT during training

### 3. FLS Style Training:

The Fundamentals of Laparoscopic Surgery test is a controlled proctored test that takes place using an FLS video training box, FLS provided training/testing materials, and at an approved FLS training site. Additionally only Junior and Senior surgical residents enrolled in an accredited surgical education program are eligible to take the FLS test. Therefore, an FLS style test was developed to simulate the FLS training and testing as closely as possible. As with the FLS test five tasks were developed including a peg transfer task, a gauze circle cut, placement of a ligating loop, simple suture

with extracorporeal knot, and simple suture with intracorporeal knot. The materials used in training and testing were simulated as closely as possible with the most significant exceptions being:

- i) A 3Dmed Large Body MITS video box trainer was used instead of the FLS video box trainer.
- ii) Cotton polyester blend threads were used instead of silk suture for all tasks involving suturing or ligating.
- iii) For the ligating loop task, low durometer PVC tubing was used in place of the foam appendage.
- iv) For the simple suture tasks, Penrose drains were handmade using thin pliable synthetic leather fabric.
- v) For all tasks the selection of laparoscopic instruments was limited to (shown in Figure 10):
  - a) 2 standard Wolf 8383.037 double action micro fenestrated jaw 32cm x 5mm graspers
  - b) 1 Ethicon Endosurgery Endopath lockable 30cm x 10mm rotating shaft babcock jaw grasper
  - c) 1 Stryker Endoscopy 250-010-31, 30cm x 8mm Multi-Cut curved tip scissor
  - d) 1 Coviden Autosuture Endo Grasp 5mm
  - e) 1 Coviden Autosuture Endo Dissect



Figure 10: Available Instruments

Each FLS style training or test session consisted of completing each of the five tasks once. Tasks were scored using typical FLS scoring methods with time to complete being recorded for each task and time penalties of approximately 5-10% of allowable time assessed for each mistake. As with the ELT training, FLS sessions were required to be at least 15 minutes but limited to 30 minutes.

#### 4. Performance Evaluation:

Performance on the FLS style tests and training sessions was evaluated using FLS style standards. Each test score is evaluated based on time to complete the task (TTC) plus time penalties assessed for mistakes resulting in a total time score (TTS). Performance on the ELT style training was evaluated using the scoring systems described in the Software Section.

#### 5. Statistical Analysis:

The primary outcome evaluated was the performance on the FLS style test using the TTS metric. Due to the small sample sizes, t-tests assuming equal variance and independent data were used to compare the mean times for each of the FLS style tests between the two groups at the baseline and at the final evaluation. Paired t-tests were used to compare the baseline and final performance within each group separately. Improvement from the baseline to final test was compared across the two groups using percent improvement over global baseline values for each test.

### III. Results:

#### A. Baseline testing:

Baseline testing was conducted to determine the starting skill level for each study participant. Baseline testing was conducted starting on February 20, 2012 and was finished February 22, 2012. Time scores were recorded and broken down by group; performance is shown in Table 2.

Table 2: Baseline FLS Style Test Results

		Peg Transfer	Circle Cut	Ligating Loop	Simple Suture with Extracorporeal Knot	Simple Suture with Intracorporeal Knot	FLS Total Test
Training Group	Average	177.99	578.89	344.92	373.72	430.88	1906.40
	Std. Dev.	66.00	208.77	190.47	172.35	247.44	575.80
Control Group	Average	149.17	693.43	443.01	442.81	387.43	2115.85
	Std. Dev.	41.15	116.27	439.73	119.59	149.61	794.98

The mean time scores for each of the five FLS style tests and the overall time score were compared between the two groups using the Student's t-test (assuming equal variance), the mean times for the peg transfer across the Training Group and the Control Group was not found to be significantly different ( $P = 0.49$ ). The same was found for the circle cut test ( $P = 0.37$ ), the ligating loop test ( $P = 0.72$ ), the extracorporeal suture test ( $P = 0.53$ ), the intracorporeal suture test ( $P = 0.77$ ), and the overall time ( $P = 0.70$ ).

Baseline testing was also conducted using the Electronic Laparoscopy Trainer. Participants in both the training and Control Groups were tested on the ELT. The results of the baseline testing are shown in Table 3.

Table 3: Baseline ELT Test Results

		Random Squares	Random Hold	Two Hand	Circle	Force Test	ELT totals
Training Group	Average	132.25	138.15	174.41	185.73	170.63	801.18
	Std. Dev.	3.77	12.17	25.27	55.06	54.75	14.46
Control Group	Average	96.13	145.81	116.73	180.13	138.61	677.42
	Std. Dev.	5.57	21.19	34.32	36.65	42.01	81.96

Again, the mean time score values for each of the five ELT test and total test time were compared using the Student's t-test (assuming equal variance). The mean times for each test varied more widely across the two groups and in the case of the Random Squares game the means were found to be statistically different ( $P = .03$ ). The remainder of the task-means including the total mean total times were not found to be statistically different across the two groups with  $P = 0.60$ ,  $P = 0.06$ ,  $P = 0.88$ ,  $P = 0.42$ , and  $P = 0.10$  respectively.

**B. Training Period:**

One participant in the Training Group was lost after only two training sessions during the training period due to conflicting time commitments. Training sessions took place over the course of one month starting on February 23, 2012 and continued until March 23, 2012. Typically participants were limited to two sessions of each training mode per week. Total training times for each participant are shown in Table 4.

Table 4: Training Times by Participant

Participant	Group	FLS Training Time	ELT Training Time
1	Training	121	108
2		47	
3		123	107
5		129	113
4	Control	145	
6		120	
7		119	
8		143	

All subjects completed FLS style training consisting of at least one time through each task per session. Training session performance on each task the first time through in a training session was recorded. Each subjects performance as measured by overall time score using the FLS style test throughout the training period is shown in Figure 11.

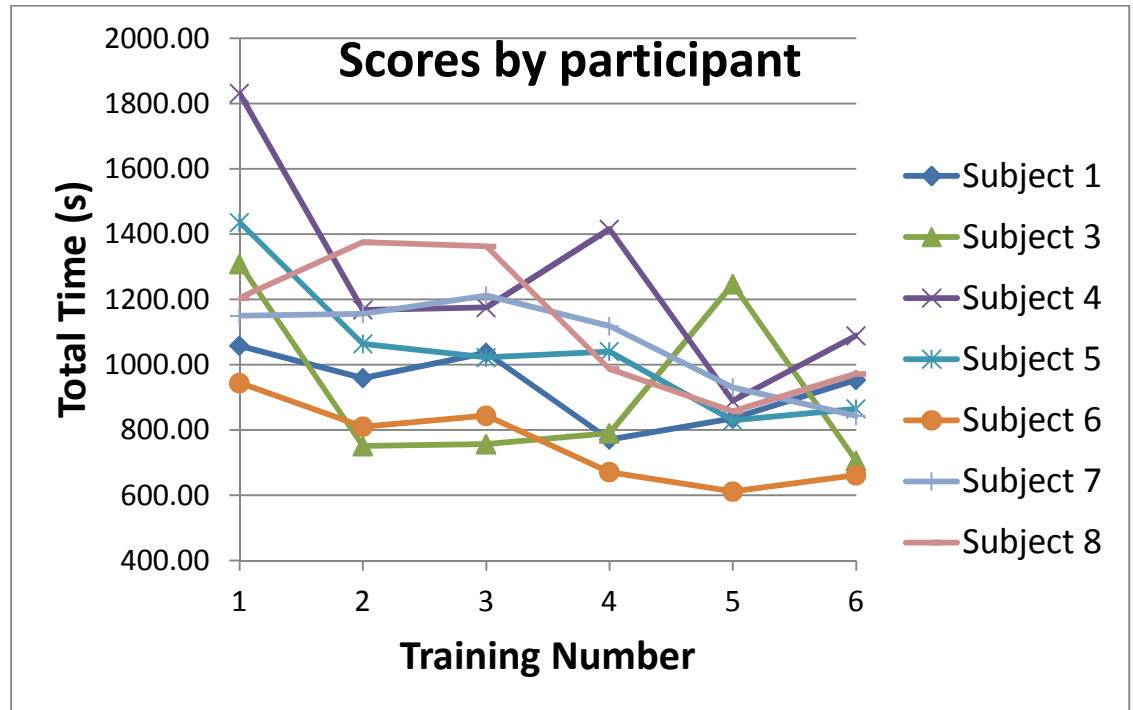




Figure 11: FLS Training Performance

In addition to the FLS style training, the Training Group also completed ELT training consisting of at least one time through each FLS game. Total scores from the first completion of each game during a training session were recorded and are shown in Figure 12.

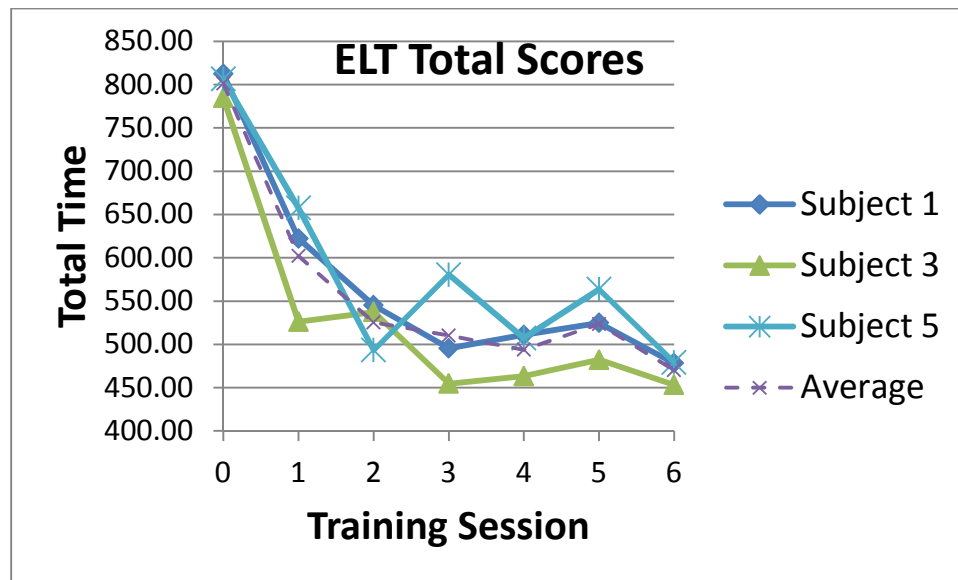


Figure 12: ELT Training Performance

### C. FLS Results:

Following the training period each group completed a final FLS style test. Paired t-tests were used to determine if the mean total time scores changed from the baseline to the final FLS style test. Table 5 shows the numerical improvement for each subject measured as difference in total time from baseline to final test. The change in mean time for both the training and Control Groups were found to be statistically significant ( $P < .05$ ).



Table 5: FLS Total Time Improvement

	Subject	Improvement (s)	P value
Training	1	1838.56	<b>P = 0.02</b>
	3	1259.81	
	5	1254.81	
	<b>Group Mean</b>	<b>1451.06</b>	
Control	4	2330.29	<b>P = 0.03</b>
	6	1191.04	
	7	1085.49	
	8	804.65	
	<b>Group Mean</b>	<b>1082.29</b>	

The change from baseline to final for each group was is reflected in lower means for all of the FLS style tasks. Time improvement were not equal among all of the tests, however, improvement from baseline to final for each individual test are shown in Table 6.

Table 6: FLS Improvement by Task (Group Average)

FLS Test Task	Training Group (s)	Training Group (%)*	Control Group (s)	Control Group (%)*
Peg Transfer	123.39	77%	83.69	52%
Circle Cut	358.78	55%	293.43	45%
Placement of Ligating Loop	350.48	85%	283.14	68%
Extracorporeal Suture	280.60	64%	256.24	59%
Intracorporeal Suture	337.81	76%	165.79	37%
Total	1451.06	69%	1082.29	51%

\*Percent improvement is over global average from the baseline test

The Training group showed greater time improvement in every single task than the Control Group resulting in an overall improvement more than six minutes

better than the Control Group. Improvement, as a percentage over the baseline test global average, was also larger for the Training Group for every task. The Training group had the largest percent gains on the peg transfer, the placement of the ligating loop and the intracorporeal suture. All three of these tasks rely heavily on bimanual dexterity, speed, and accuracy of movements.

D. ELT Results:

Following the Training period and the final FLS test each participant completed a final ELT test. Again, paired t-tests were used to determine if the mean scores changed from the baseline to final tests. Overall test results are shown in Table 7.

Table 7: Total ELT Time Improvement

	Subject	Improvement (s)	P value
Training	1	317.20	
	3	298.89	
	5	277.32	
	<b>Group Mean</b>	<b>297.80</b>	
Control	4	138.40	
	6	207.05	
	7	-32.47	
	8	-97.45	
	<b>Group Mean</b>	<b>53.88</b>	

The Training Group significantly improved their total times on the for the ELT games with  $P < .01$ . Without ELT training, however, the Control Group did not improve their mean total time for the ELT test ( $P = .50$ ). Once again the gains were not distributed equally amongst each of the games, Figure 13 through 18 show the

relative performance gains between the groups for each of the games and the overall score.

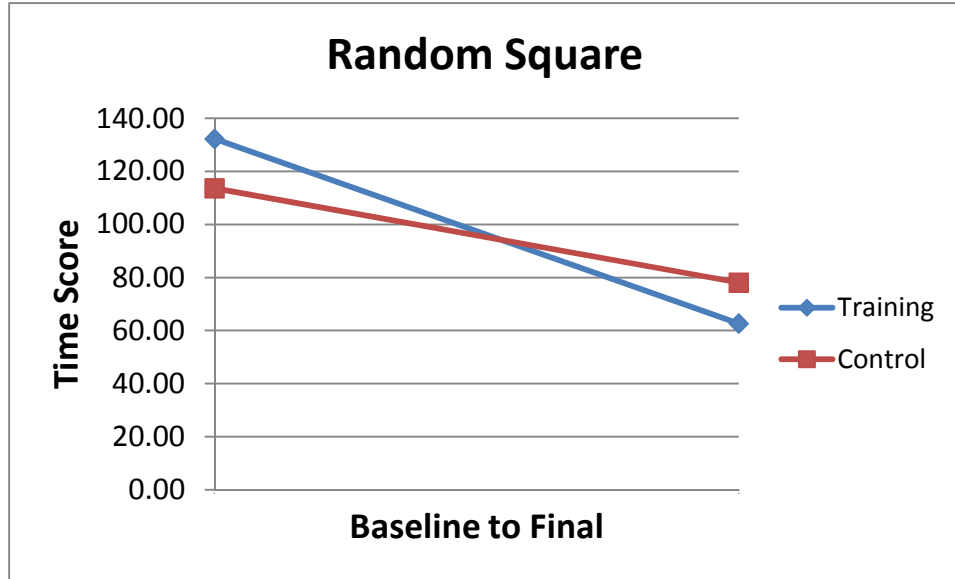


Figure 13: Random Square Score Change

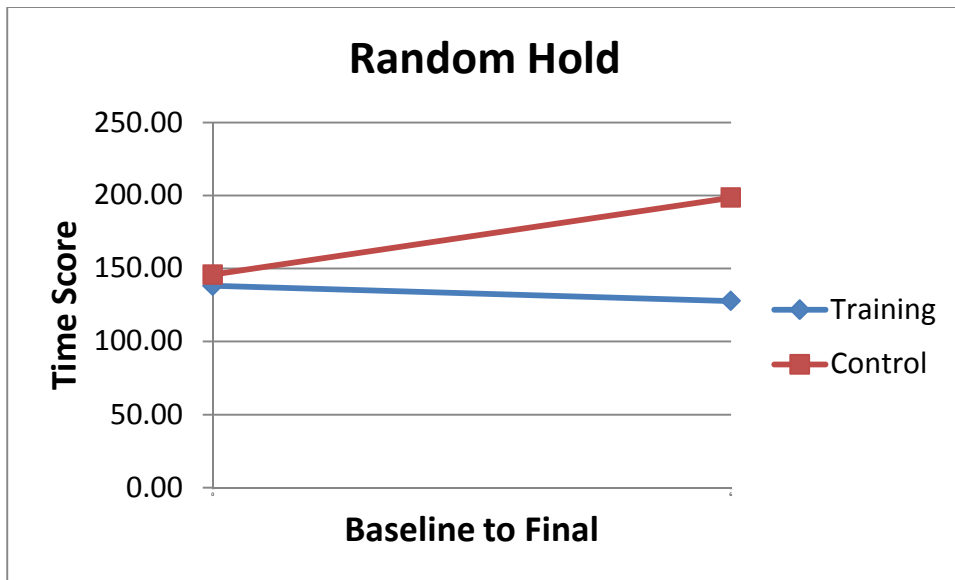


Figure 14: Random Hold Score Change



Figure 15: Two Hands Score Change

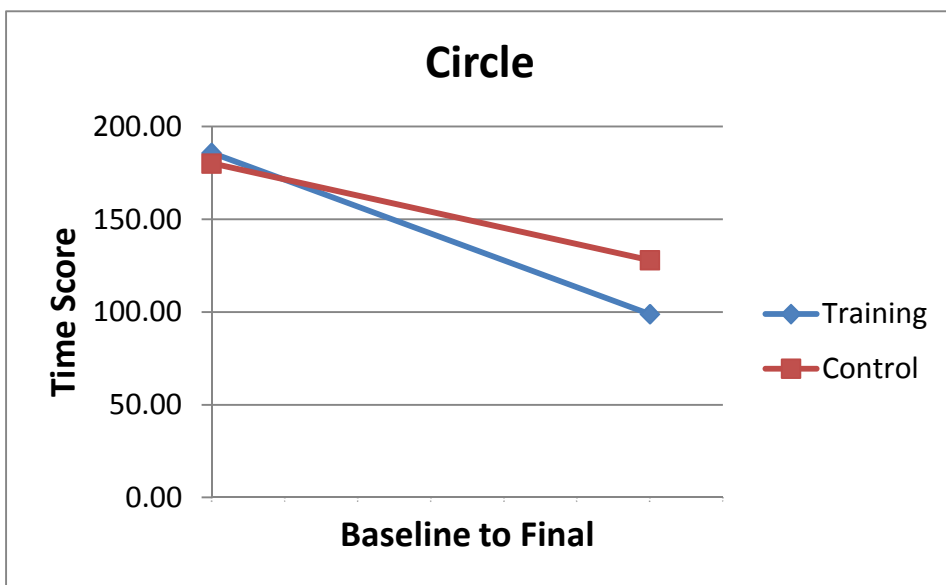


Figure 16: Circle Score Change

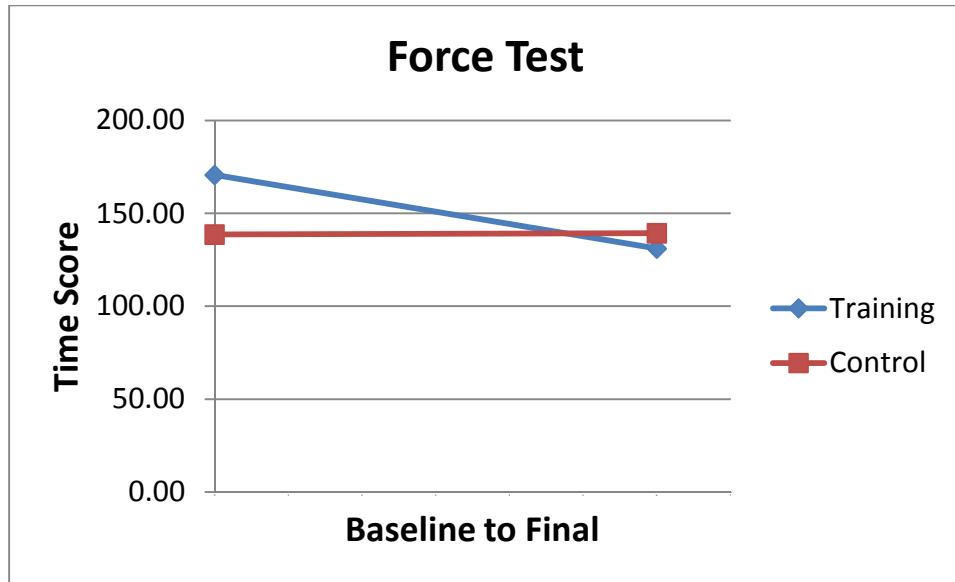


Figure 17: Force Test Score Change

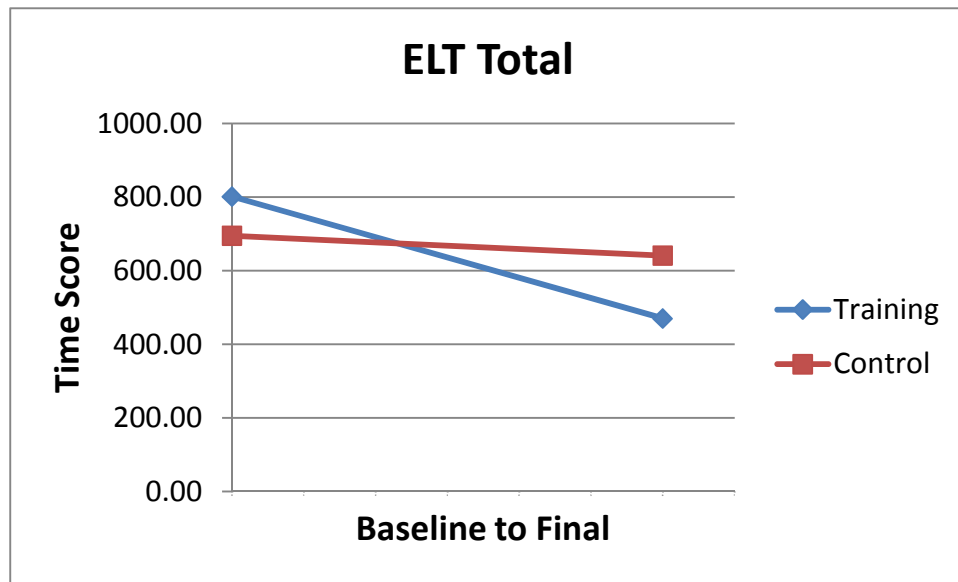


Figure 18: ELT Total Score Change

Although the Training Group exceeded the performance of the Control Group in the final test on all tasks, the Training Group showed the highest levels of improvement on Random Square, Circle, and Two Hands. This improvement along with the FLS style test improvements indicate that the Training Group's bimanual dexterity, accuracy of movement, and speed improved at a faster rate

than the Control Group. Additionally, the time improvement of 26% over baseline for the Training Group on Force Test versus no change for the Control Group indicate that the training gained more control over their application of forces using laparoscopic instruments. A complete listing of the improvements from Baseline to Final is shown in Table 8.

Table 8: ELT Improvement by Game (Group Average)

ELT Test Game	Training Group (s)	Training Group (%)*	Control Group (s)	Control Group (%)*	Difference (training - control)
Random Square	69.57	57%	35.53	29%	34.04
Random Hold	10.42	7%	-52.68	-37%	63.10
Two Hands	124.61	88%	19.55	14%	105.06
Circle	86.84	48%	52.2	29%	34.64
Force Test	39.58	26%	-0.71	0%	40.29
Total	331.01	45%	53.88	7%	277.13

\*Percent improvement is over global average from the baseline test

As with the FLS style testing, the Training Group decreased their time score (increased performance) for every game and the overall test total, faster than the Control Group. The direction of change correlates between the FLS style test and ELT test for the Training Group. The smaller performance gains for the Control Group also correlate between the two tests.



#### IV. Discussion

The Training Group improved by a larger amount than the Control Group on every single task in the FLS style testing and every single game in the ELT style testing. Additionally, the Training Group's absolute scores were better on every single ELT test at the Final than the Control Group. The Training Group also had better time scores at the final than the Control Group for the Circle Cut and Placement of Ligating Loop. The overall of improvement rates on the FLS style test and ELT test suggest that the Training Group increased their bimanual dexterity, speed, and movement accuracy at a faster rate than the Control Group. Additionally, the improvement on the Force Test game indicates that the Training Group also increased their ability to apply precision forces quickly. This ability which has been shown to be an important contributor to surgical outcomes does not appear to have been improved at all in the Control Group as measured by the ELT test. The size of the data set makes it particularly vulnerable to outlier data. Several subjects had data that appeared to be out of line with trends on one or more test. Analysis of the data with the outlier data points removed did not show a significant difference in overall results.

##### A. Study Shortcomings:

This phase of development and testing of the ELT was necessarily of limited scope. In each stage of the development and refinement of the device, data has been gathered to help direct and justify future improvements, changes, and validation of the device. This phase of development was designed to demonstrate

the devices ability to improve laparoscopic surgical abilities using a known standard.

This study is a first step to proving the device as a valid addition to existing laparoscopic training platforms. This study has a few notable shortcomings, most notably the small sample size for both the Training and Control Group, the substitution of Undergraduate and Graduate students in place of Medical Residents, and the length of the training period.

#### B. Future Recommendations:

In the future it would be desirable to repeat the study using a larger group of medical residents as the study participants. In this way a participant's desire to learn laparoscopic skills is not in question. Additionally the study length should be modified to accommodate part or all of a typical laparoscopic residency training schedule. Finally, the study could, but does not necessarily have to, be modified to use a different standard of development such as the Global Operative Assessment of Laparoscopic Skills (GOALS) system or similar.

In order to facilitate a more robust study design several device changes are proposed and are shown in order of importance:

1. General debugging to eliminate any errors or crashes during the programs and make the use of the wireless hand sensor possible.

2. Design a graphical user interface for the computer side data collection and analysis
3. Build a case for the main board and the hand sensor to make the device more durable
4. Refine or add more game modes that utilize the force measurement capabilities
5. Develop new module tops with varying geometries

## V. Conclusion:

It was successfully demonstrated that the new version of the Electronic Laparoscopy Trainer is capable of increasing the rate of laparoscopic skill development as measured by traditional skill assessments. The Electronic Laparoscopy Trainer was modified to include hardware and software capabilities that allow it to provide a complex and robust training routine. Study participants who used the device in combination with traditional laparoscopic teaching techniques developed skills, as measured by traditional assessment, an 18% larger amount than the Control Group. Additionally skills as measured using the electronic laparoscopy trainer were developed at a faster rate for the Training Group than the control. The Training Group outperformed the Control Group in tasks and games that required bimanual dexterity, speed, and accuracy of movement. Finally, the Training group improved their ability to apply precision forces quickly, a skill that is not trained for using traditional laparoscopic training techniques. In short, using the Electronic Laparoscopy Trainer in addition to traditional training, the Training Group improved a larger amount on every measure of performance than the Control Group.

## Appendix A: FLS Times

Min:					34.3			178.1			29.0			48.9			89.5	503.1
Max:					265.5			880.3			1052.4			557.2			736.1	3254.3
			Peg Transfer			Circle Cut			Ligating Loop			Extracorporeal Knot	Intracorporeal Knot			TOTAL		
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	Baseline	2/20/2012	255.53	1	265.5	650.3	23	880.3	441.1	11.5	556.1	247.9	0	247.9	736.1	0	736.1	2686.0
2	Baseline	2/20/2012	161.44	3	191.4	318.0	21	528.0	105.0	10	205.0	203.4	0	203.4	170.7	0	170.7	1298.5
3	Baseline	2/21/2012	125.41	1	135.4	478.0	3	508.0	119.2	4.5	164.2	536.4	0	536.4	512.8	0	512.8	1856.8
4	Baseline	2/20/2012	165.89	2	185.9	840.9	2	860.9	852.4	20	1052.4	557.2	0	557.2	597.9	0	597.9	3254.3
5	Baseline	2/20/2012	109.59	1	119.6	319.3	8	399.3	424.5	3	454.5	507.1	0	507.1	303.9	0	303.9	1784.3
6	Baseline	2/21/2012	155.16	2	175.2	507.3	17	677.3	201.8	1.5	216.8	345.0	0	345.0	279.9	0	279.9	1694.1
7	Baseline	2/21/2012	131.16	1	141.2	427.4	21	637.4	159.1	5.5	214.1	534.8	0	534.8	281.4	0	281.4	1808.9
8	Baseline	2/22/2012	84.47	1	94.5	468.0	13	598.0	183.8	5.5	238.8	334.3	0	334.3	390.6	0	390.6	1656.1
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	T1	2/23/2012	50.69	0	50.7	344.4	19	534.4	87.4	3.5	122.4	183.7	0	183.7	166.7	0	166.7	1057.9
2	T1	2/28/2012	53	0	53.0	179.3	17	349.3	45.9	2.9	74.9	252.4	0	252.4	89.5	0	89.5	819.1
3	T1	2/23/2012	57.44	0	57.4	242.1	2	262.1	114.1	3	144.1	443.9	0	443.9	400.9	0	400.9	1308.4
4	T1	2/23/2012	64.78	0	64.8	324.3	23	554.3	53.8	2.5	78.8	523.9	0	523.9	609.7	0	609.7	1831.5
5	T1	2/27/2012	94.54	1	104.5	508.4	6	568.4	214.3	3.5	249.3	274.3	0	274.3	239.3	0	239.3	1435.9
6	T1	2/29/2012	68.28	0	68.3	234.6	15	384.6	76.6	5	126.6	161.6	0	161.6	203.0	0	203.0	944.0
7	T1	2/28/2012	70.12	0	70.1	263.2	16	423.2	36.3	2.5	61.3	238.3	5	288.3	306.6	0	306.6	1149.5

8	T1	2/28/2012	53.03	0	53.0	431.9	9	521.9	192.4	2.5	217.4	150.8	0	150.8	261.3	0	261.3	1204.4
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	T2	2/27/2012	48	0	48.0	301.2	16	461.2	45.7	8.5	130.7	203.6	0	203.6	115.5	0	115.5	959.0
2	T2	3/13/2012	54.16	0	54.2	257.5	28	537.5	118.4	8	198.4	172.2	0	172.2	281.3	0	281.3	1243.5
3	T2	3/1/2012	62.1	0	62.1	172.4	6	232.4	24.5	2	44.5	142.4	0	142.4	269.1	0	269.1	750.6
4	T2	2/28/2012	124.34	3	154.3	246.1	5	296.1	65.1	1.5	80.1	262.2	0	262.2	375.1	0	375.1	1167.8
5	T2	2/28/2012	81.28	1	91.3	407.1	11	517.1	84.3	1	94.3	183.6	0	183.6	177.7	0	177.7	1064.0
6	T2	3/2/2012	48.38	0	48.4	180.7	11	290.7	89.1	0	89.1	114.1	0	114.1	267.6	0	267.6	809.8
7	T2	3/13/2012	52.75	0	52.8	224.3	38	604.3	58.4	0	58.4	252.9	0	252.9	187.9	0	187.9	1156.2
8	T2	3/1/2012	42.47	0	42.5	425.7	19	615.7	76.8	20	276.8	159.7	0	159.7	280.3	0	280.3	1374.9
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	T3	3/1/2012	61.66	1	71.7	347.3	4	387.3	108.0	3	138.0	234.5	0	234.5	204.9	0	204.9	1036.4
2	T3	1/0/1900	0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	
3	T3	3/5/2012	55.83	0	55.8	243.4	1	253.4	28.7	1	38.7	196.0	0	196.0	212.9	0	212.9	756.7
4	T3	1/0/1900	62.31	0	62.3	264.0	12	384.0	80.9	2	100.9	221.2	0	221.2	356.6	5	406.6	1174.9
5	T3	3/14/2012	66.03	0	66.0	301.8	8	381.8	38.4	20	238.4	122.5	0	122.5	213.5	0	213.5	1022.3
6	T3	3/7/2012	57.12	0	57.1	167.4	10	267.4	128.4	20	328.4	73.9	0	73.9	117.0	0	117.0	843.9
7	T3	1/0/1900	48.06	0	48.1	188.1	40	588.1	65.2	4	105.2	229.4	0	229.4	241.2	0	241.2	1211.8
8	T3	1/0/1900	56.13	0	56.1	412.4	23	642.4	57.8	8	137.8	337.4	5	387.4	138.4	0	138.4	1362.2
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	T4	3/5/2012	61.91	0	61.9	207.9	15	357.9	59.2	5	109.2	105.5	0	105.5	136.3	0	136.3	770.9
2	T4	1/0/1900	0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	
3	T4	3/14/2012	63.19	0	63.2	208.4	7	278.4	66.8	6	126.8	120.2	0	120.2	201.5	0	201.5	790.1
4	T4	3/16/2012	65.09	1	75.1	344.6	33	674.6	84.5	6	144.5	217.7	0	217.7	303.6	0	303.6	1415.5
5	T4	3/14/2012	51.81	0	51.8	251.8	5	301.8	150.6	20	350.6	120.8	0	120.8	215.4	0	215.4	1040.4

6	T4	3/8/2012	42.49	0	42.5	198.5	9	288.5	30.5	5	80.5	162.9	0	162.9	96.4	0	96.4	670.8
7	T4	3/19/2012	70.62	1	80.6	234.8	23	464.8	17.3	3.5	52.3	160.1	0	160.1	360.2	0	360.2	1118.1
8	T4	1/0/1900	50.34	0	50.3	290.5	16	450.5	80.7	14	220.7	146.2	0	146.2	118.8	0	118.8	986.5
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	T5	3/8/2012	48.06	0	48.1	224.2	9	314.2	30.3	4	70.3	144.2	0	144.2	258.2	0	258.2	834.9
2	T5	1/0/1900	0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	
3	T5	3/15/2012	41.49	0	41.5	200.8	3	230.8	64.1	20	264.1	478.0	0	478.0	232.4	0	232.4	1246.8
4	T5	3/19/2012	63.19	0	63.2	215.0	14	355.0	52.4	3	82.4	152.0	0	152.0	186.4	5	236.4	889.0
5	T5	1/0/1900	52.28	0	52.3	309.0	6	369.0	76.2	3	106.2	134.8	0	134.8	167.1	0	167.1	829.3
6	T5	1/0/1900	41.13	0	41.1	192.0	13	322.0	67.1	3	97.1	48.9	0	48.9	102.1	0	102.1	611.3
7	T5	3/19/2012	45.03	0	45.0	156.2	27	426.2	55.8	3.5	90.8	156.0	0	156.0	212.1	0	212.1	930.2
8	T5	1/0/1900	78.34	1	88.3	209.7	18	389.7	52.5	1	62.5	167.4	0	167.4	148.9	0	148.9	856.8
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	T6	3/14/2012	39.25	0	39.3	241.7	20	441.7	84.3	1	94.3	208.0	0	208.0	170.5	0	170.5	953.7
2	T6	1/0/1900	44.83	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	
3	T6	3/20/2012	34.31	0	34.3	239.3	12	359.3	27.8	1	37.8	86.7	0	86.7	186.9	0	186.9	704.9
4	T6	1/0/1900	49.47	0	49.5	217.9	34	557.9	45.9	6	105.9	215.9	0	215.9	159.7	0	159.7	1089.0
5	T6	3/23/2012	49.16	0	49.2	277.5	5	327.5	29.3	1.5	44.3	128.5	0	128.5	315.4	0	315.4	864.8
6	T6	3/16/2012	39.12	0	39.1	158.8	16	318.8	61.3	4	101.3	82.3	0	82.3	120.3	0	120.3	661.7
7	T6	3/20/2012	39.06	0	39.1	248.9	16	408.9	18.5	4	58.5	154.2	0	154.2	182.5	0	182.5	843.2
8	T6	3/20/2012	46.13	0	46.1	194.4	18	374.4	56.8	4	96.8	118.9	0	118.9	285.8	5	335.8	972.0
Subject	Trial Code	Date	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	Time (sec)	Errors	Total	
1	Final	3/15/2012	43.03	0	43.0	241.0	6	301.0	22.9	1	32.9	215.1	0	215.1	255.5	0	255.5	847.4
2	Final	1/0/1900	0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	0.0	0	Dropped	
3	Final	1/0/1900	56.5	1	66.5	147.4	7	217.4	31.4	3	61.4	132.4	0	132.4	119.3	0	119.3	597.0

4	Final	3/20/2012	48.09	0	48.1	215.7	10	315.7	73.0	2.5	98.0	180.4	0	180.4	281.9	0	281.9	924.0
5	Final	3/24/2012	40.83	0	40.8	192.9	0	192.9	24.0	0.5	29.0	102.2	0	102.2	164.6	0	164.6	529.5
6	Final	1/0/1900	37.12	1	47.1	128.1	5	178.1	61.9	3	91.9	84.9	0	84.9	101.1	0	101.1	503.1
7	Final	3/22/2012	39.03	0	39.0	250.6	8	330.6	19.2	5	69.2	111.0	0	111.0	173.5	0	173.5	723.4
8	Final	3/22/2012	43.97	0	44.0	322.2	16	482.2	37.3	1	47.3	113.7	0	113.7	164.3	0	164.3	851.4

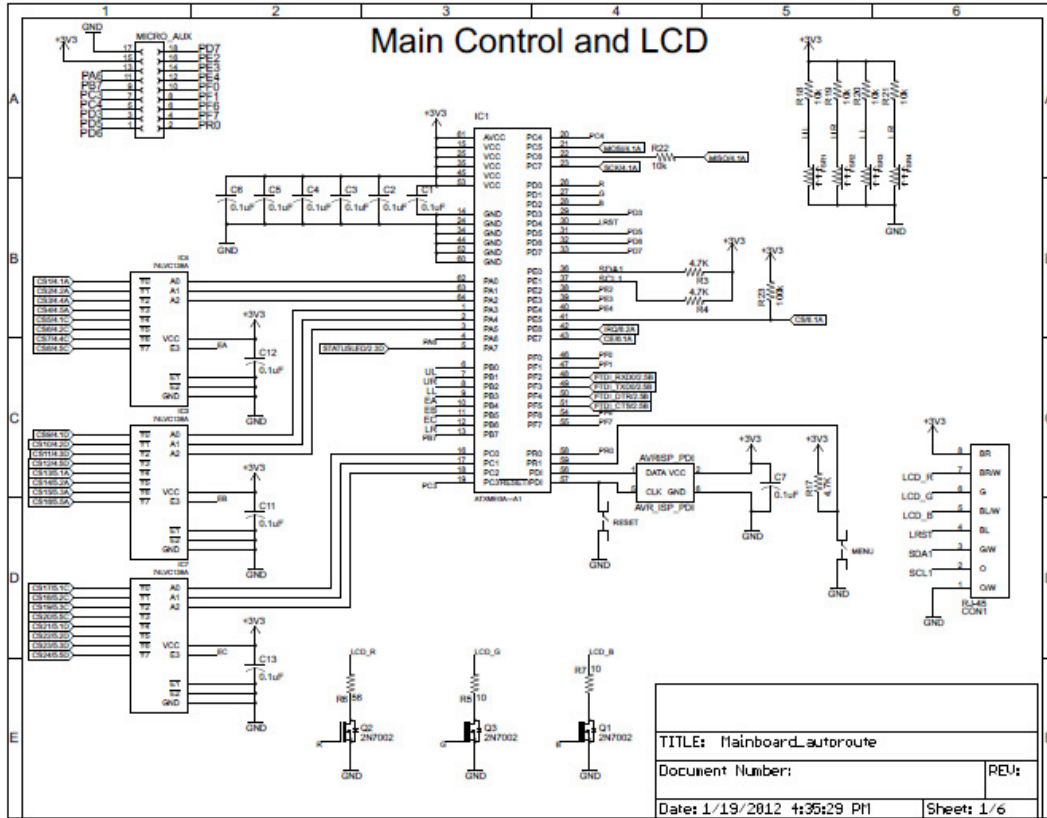


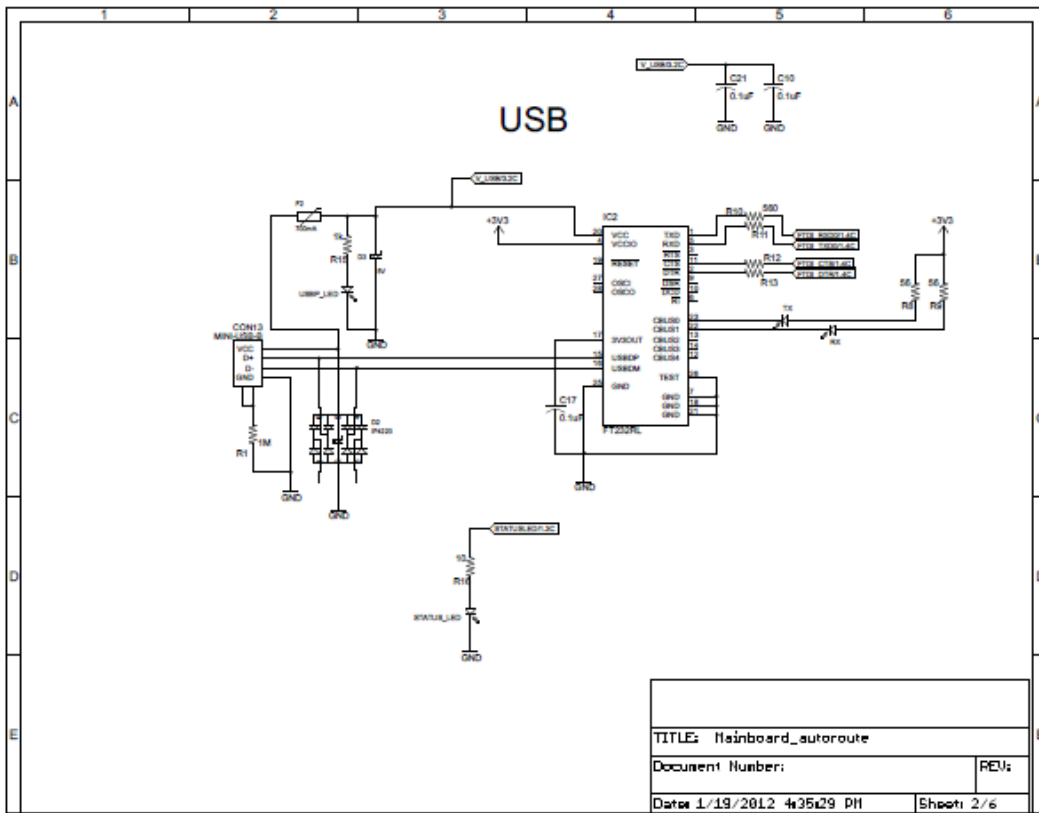
### Appendix B: ELT Times

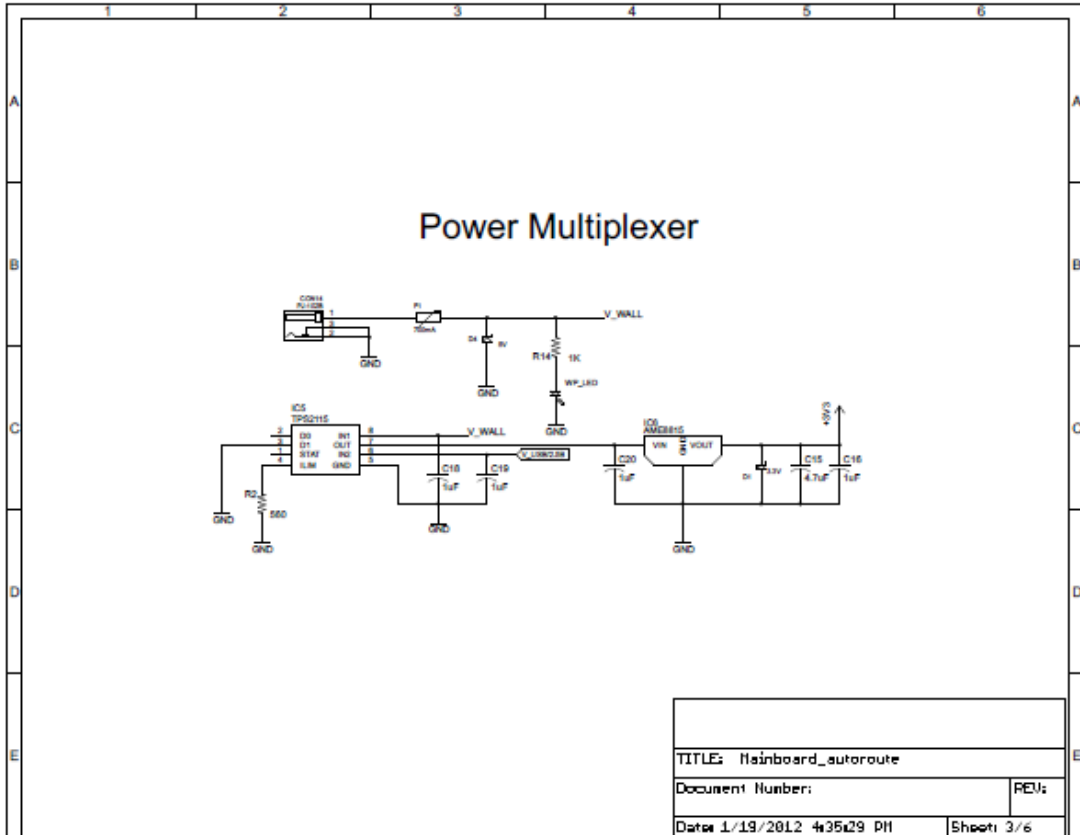
Subject	Date	Trial Code	Random Sq	Random Hold	Two Hands	Circle	Force Test	Total Score
1	2/22/2012	ELT Baseline	128.1	152.2	203.5	196.4	132.0	812.3
2	2/28/2012	ELT Baseline	84.8	131.6	158.4	126.1	233.3	734.1
3	2/22/2012	ELT Baseline	135.5	130.7	161.3	234.7	146.6	808.7
4	2/22/2012	ELT Baseline	126.6	174.1	98.8	161.1	194.4	754.9
5	2/22/2012	ELT Baseline	133.1	128.4	124.2	168.2	100.0	654.0
6	2/22/2012	ELT Baseline	109.6	150.1	82.6	156.6	113.5	612.4
7	2/24/2012	ELT Baseline	103.3	135.3	76.2	123.3	156.0	594.2
8	2/23/2012	ELT Baseline	114.9	157.9	107.8	211.3	307.4	899.2
1	2/27/2012	T1	89.7	134.5	79.4	148.8	169.8	622.2
3	2/27/2012	T1	79.3	114.6	85.7	124.4	122.2	526.2
5	2/27/2012	T1	73.7	265.9	61.2	124.1	132.6	657.5
1	3/1/2012	T2	66.6	129.8	59.1	110.9	178.6	545.1
3	3/1/2012	T2	75.2	118.7	92.9	121.4	129.1	537.3
5	2/28/2012	T2	67.8	123.4	68.6	109.9	123.8	493.4
1	3/5/2012	T3	63.8	118.4	51.7	118.2	143.3	495.4
3	3/5/2012	T3	65.5	112.9	57.5	97.4	121.2	454.6
5	3/15/2012	T3	76.5	191.3	67.2	127.1	118.4	580.4
1	3/9/2012	T4	78.6	152.9	36.8	106.9	135.7	510.9
3	3/13/2012	T4	68.9	141.8	45.9	114.2	92.6	463.3
5	3/15/2012	T4	69.3	147.5	63.5	126.4	100.5	507.2
1	3/13/2012	T5	75.7	151.3	39.6	128.6	129.7	524.9
3	3/19/2012	T5	72.0	167.8	39.9	106.2	96.2	482.2
5	3/19/2012	T5	66.7	158.1	53.0	122.5	163.3	563.6
1	3/15/2012	Final	56.0	119.9	45.9	96.0	160.3	478.2
3	3/20/2012	Final	61.8	129.4	54.5	98.1	109.4	453.1
5	3/20/2012	Final	70.3	133.8	49.0	102.6	123.5	479.2
4	3/23/2012	Final	86.7	176.1	130.5	125.9	142.2	661.5
6	3/23/2012	Final	74.9	124.3	72.5	128.3	130.9	530.9

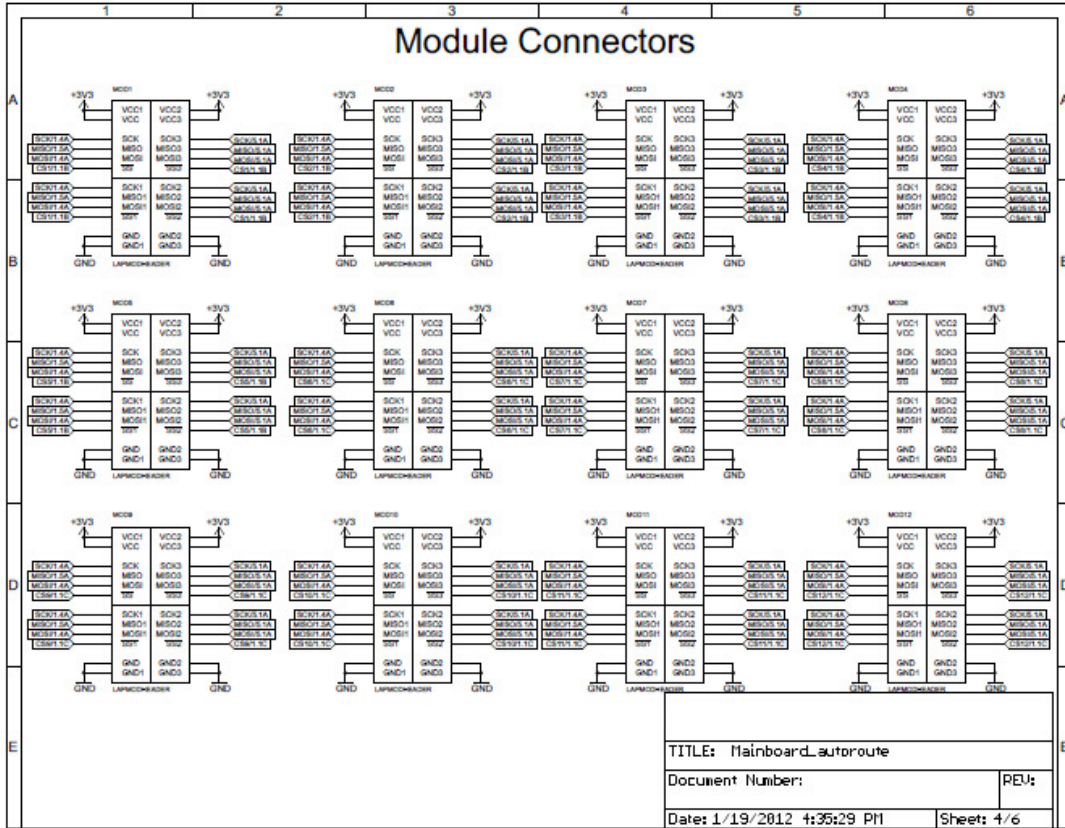
7	3/23/2012	Final	73.6	239.8	77.7	125.2	140.4	656.6
8	3/23/2012	Final	77.2	253.8	108.0	132.3	143.8	715.1
		Max	135.5	265.9	203.5	234.7	307.4	899.2
		Min	56.0	112.9	36.8	96.0	92.6	453.1

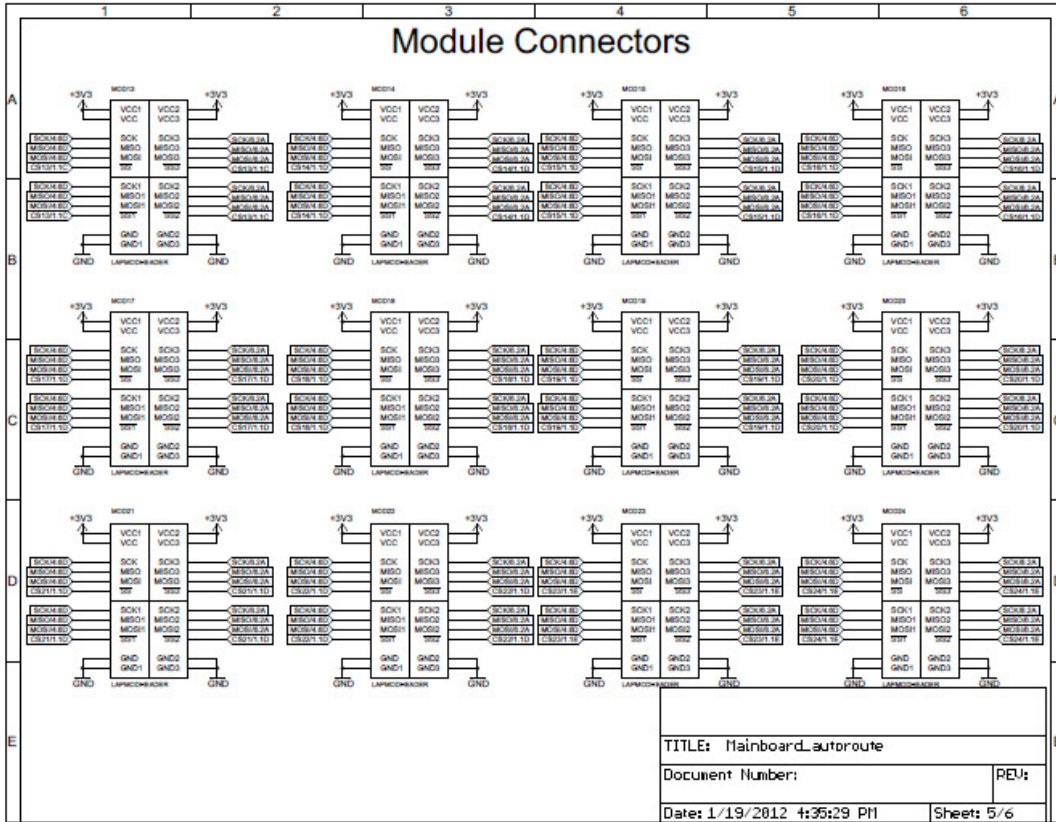
## **Appendix C: Schematics and Board Diagrams**



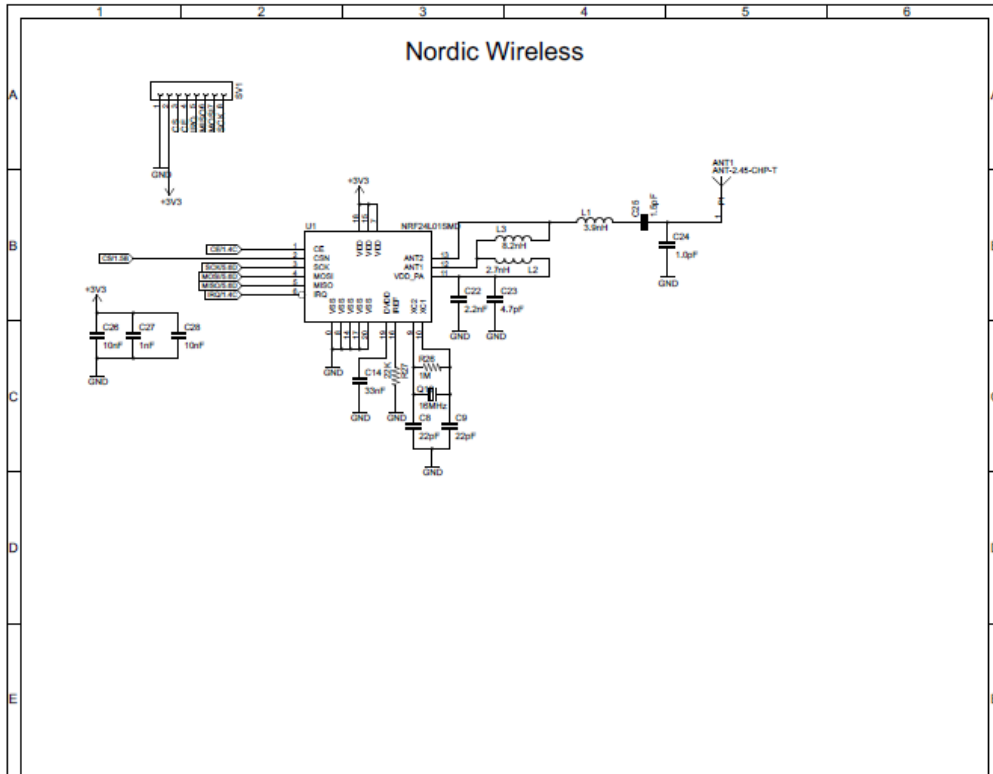


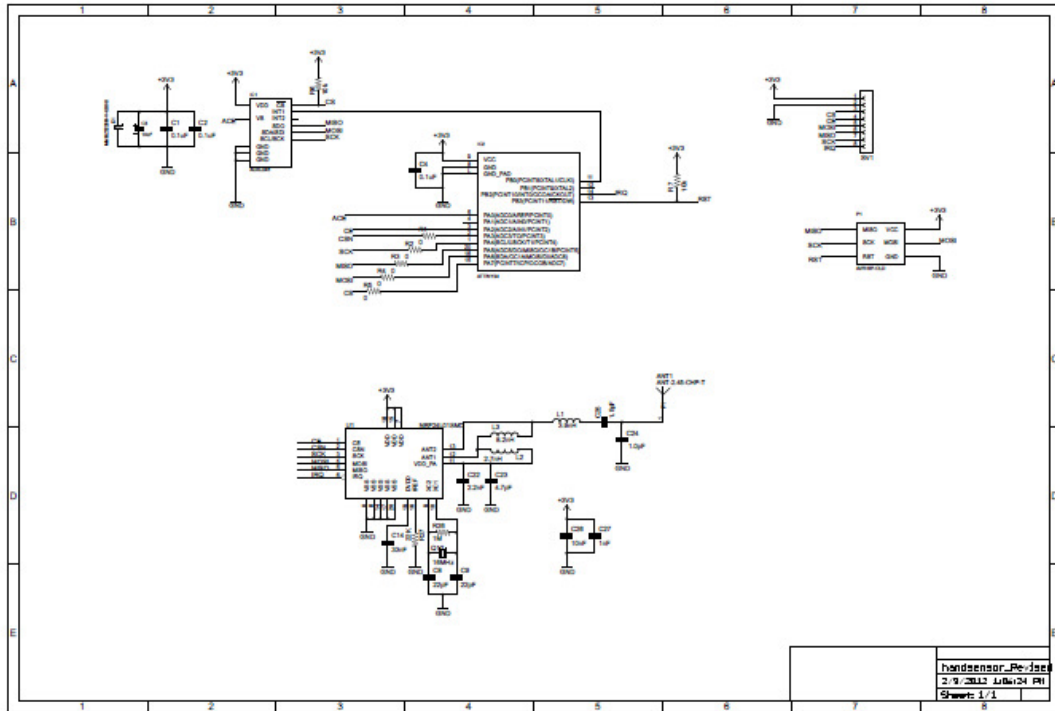


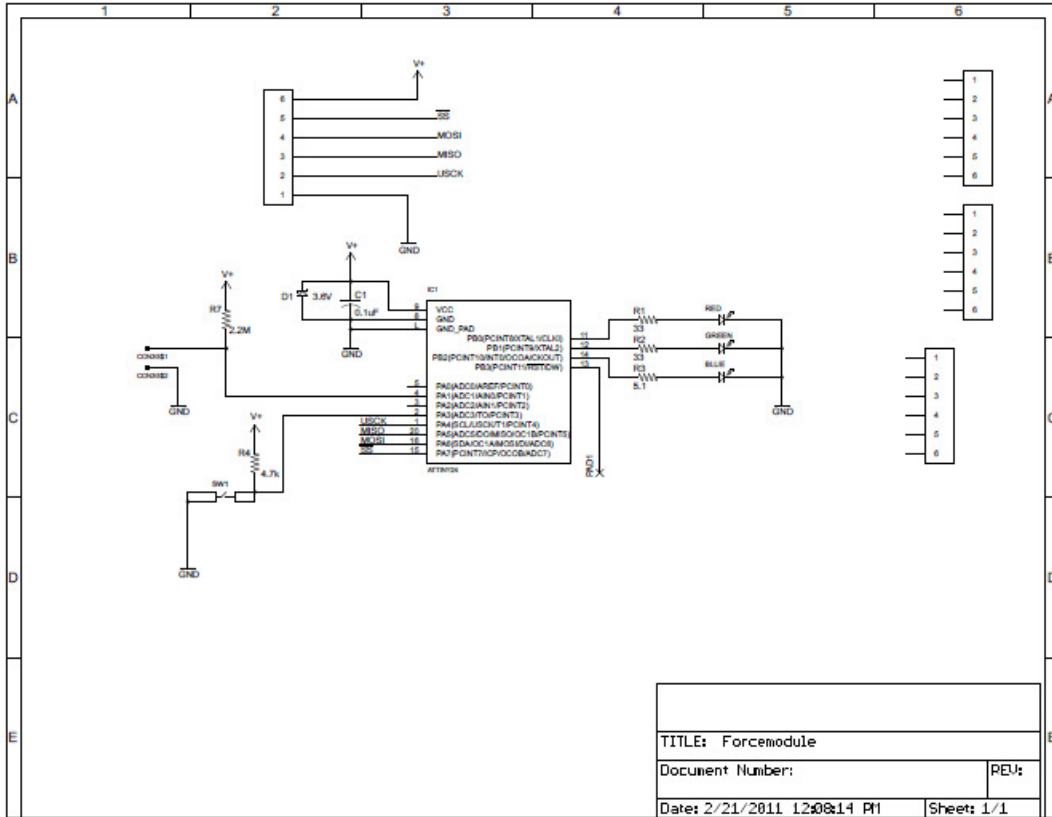


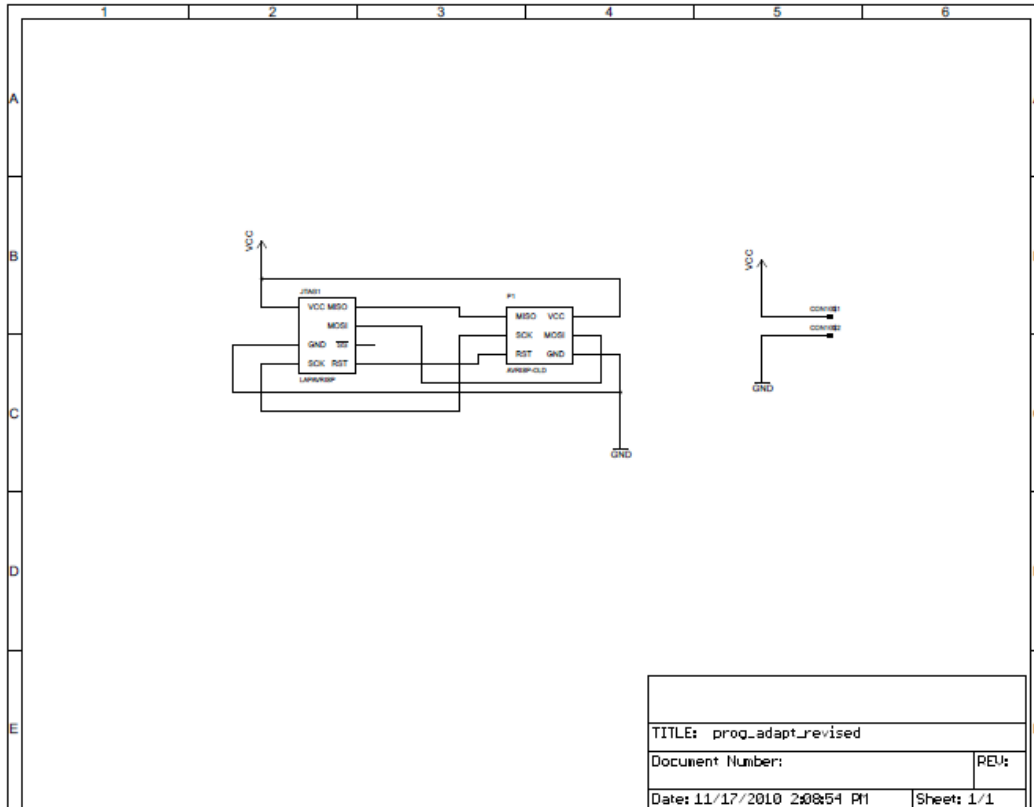


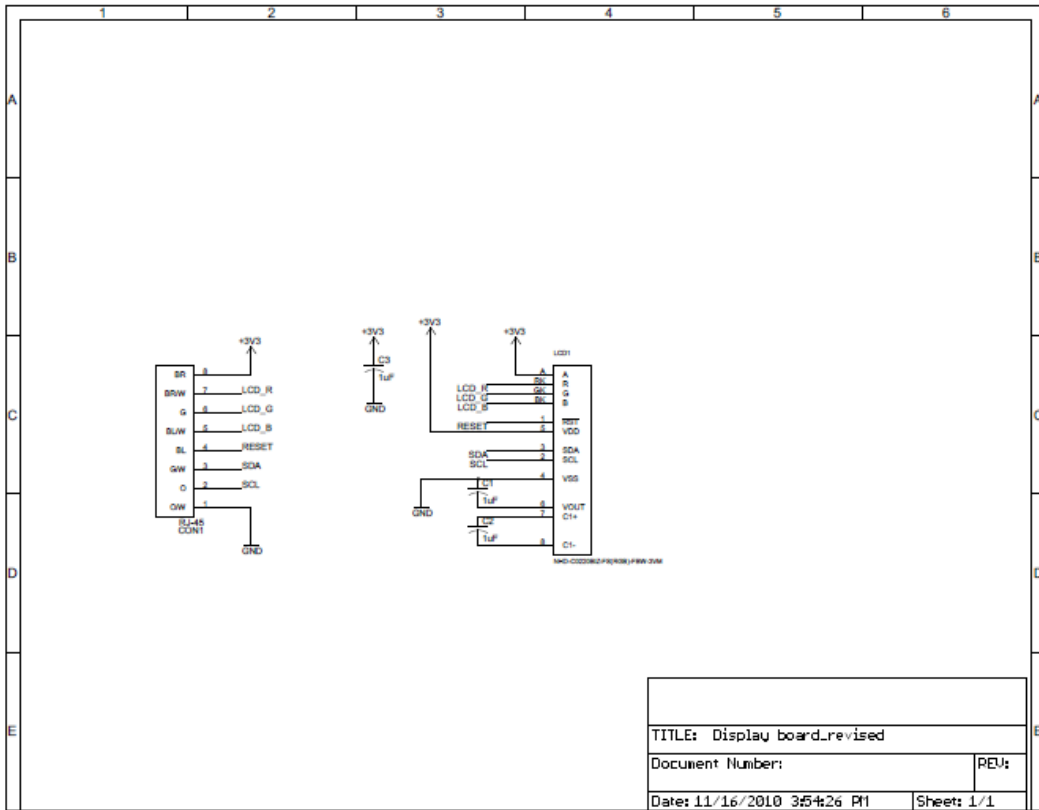


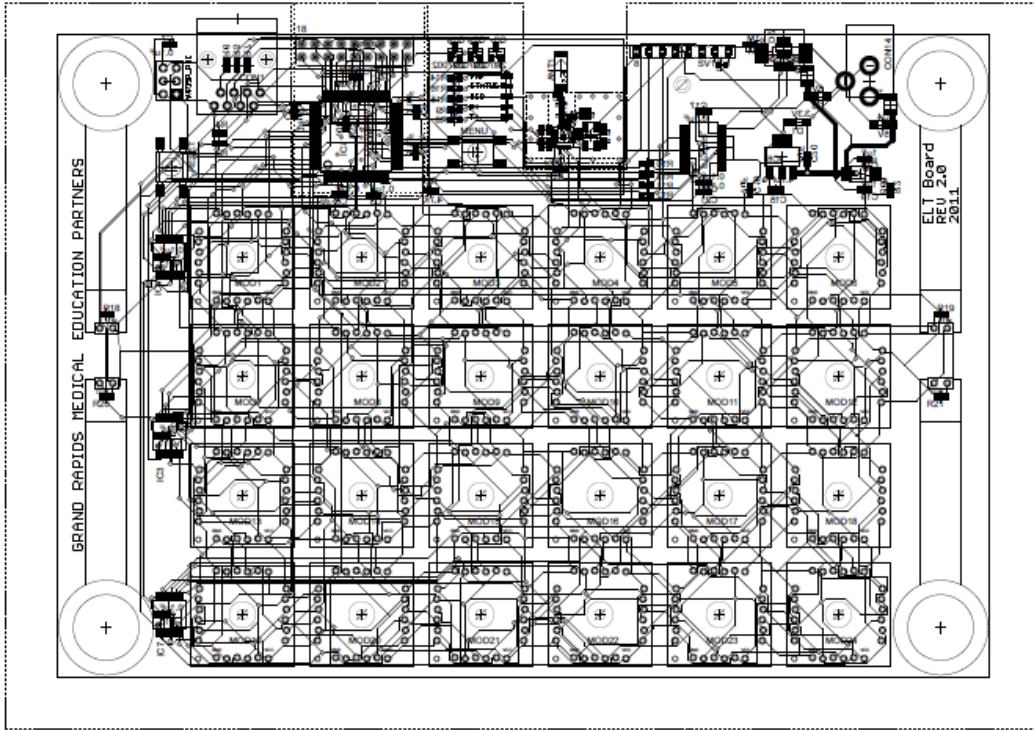


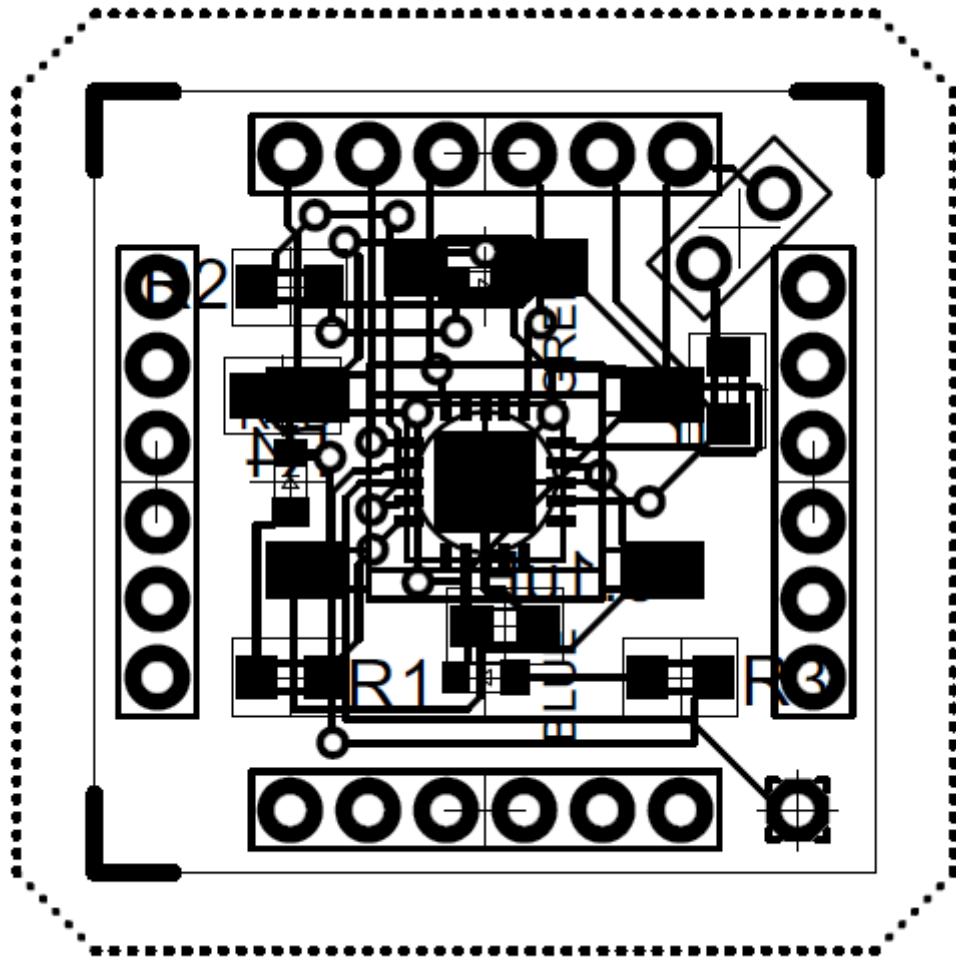


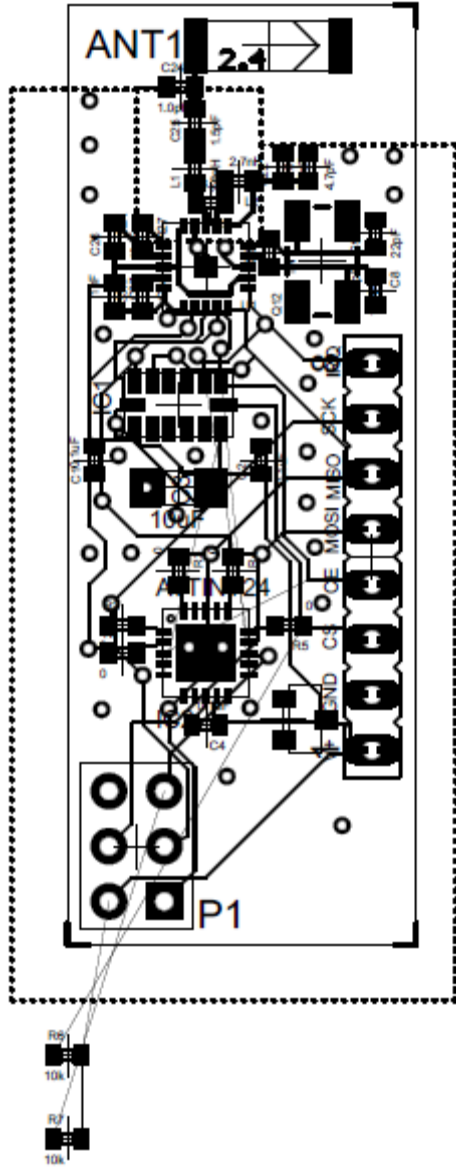




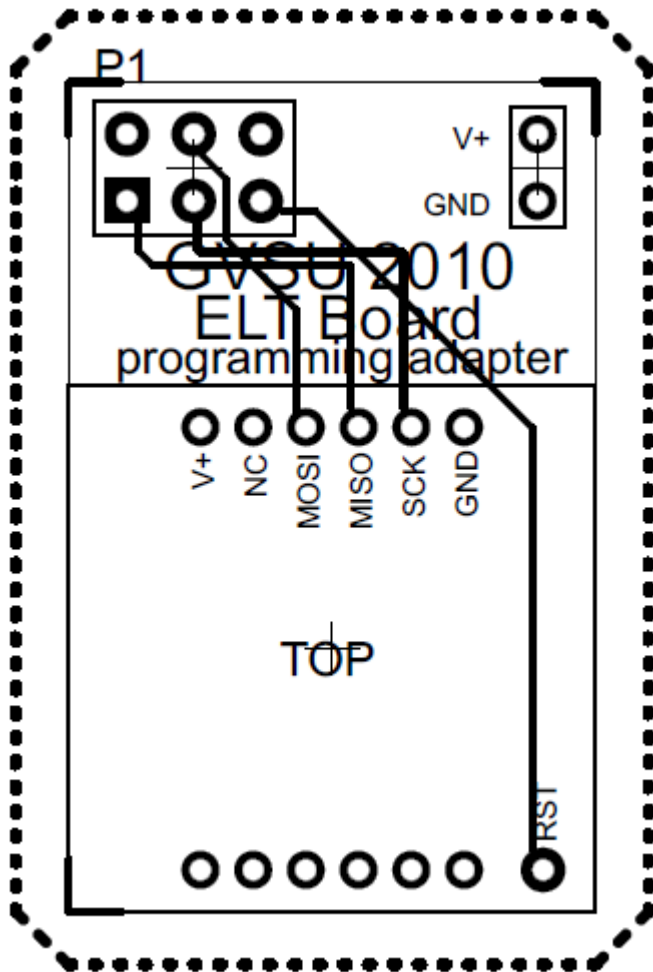


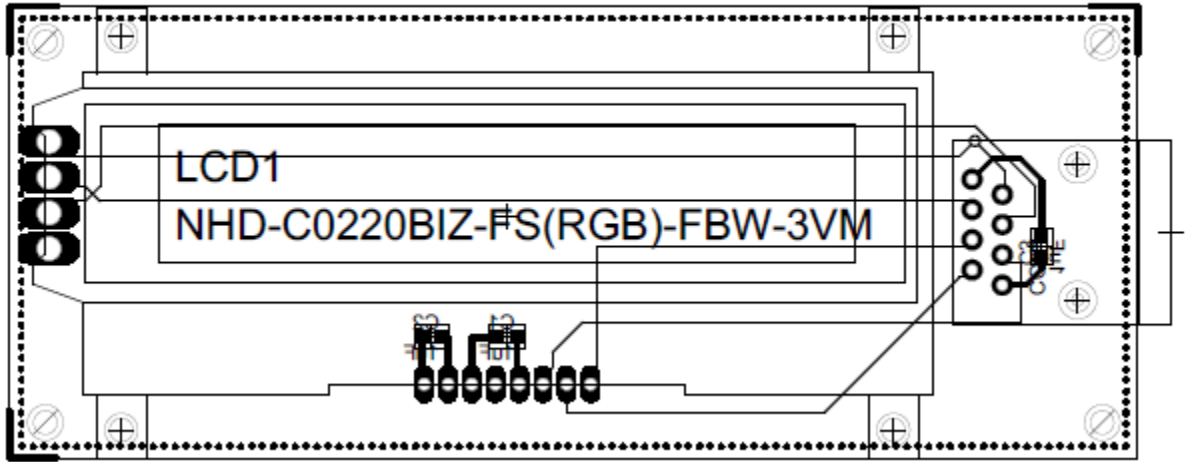












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